U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K083903 - 1556 pages
COMPANY:	3M COMPANY (3M)
PRODUCT:	STETHOSCOPE, ELECTRONIC (DQD)
SUMMARY:	Product: 3M LITTMANN ELECTRONIC STETHOSCOPE, MODEL 3200
DATE REQUESTED:	Jan 21, 2016
DATE PRINTED:	Jan 21, 2016

Note: Printed

K083903

1/2

5.0 Premarket Notification (510(k)) Summary

Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

JUL 15 2009

Contact Person: Jizhong Jin
Senior Regulatory Affairs Associate
Phone Number: (651) 733-6655
FAX Number: (651) 737-5320

Date of Summary: December 22, 2008

Device Name and Classification:

Common or Usual Name: Electronic Stethoscope

Proprietary Name: 3M™ Littmann® Electronic Stethoscope Model 3200

Classification Name: Electronic Stethoscope (21 CFR § 870.1875(b))

Performance Standards: None

Predicate Device:

3M™ Littmann® Electronic Stethoscope, Model 3000
3M™ Littmann® Electronic Stethoscope, Model 4100

Description of Device:

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is a healthcare device that picks up sounds of the heart, arteries, veins, lungs and other internal organs with the use of selective frequency ranges. After amplification and filtering, the sounds are transferred to the user's ears via an active speaker and passive sound tubes.

The Model 3200 can also exchange audio data with a personal computing device (PC) using wireless Bluetooth link.

The user interface includes a 5-button keypad and an LCD display. Sound processing is carried out with the aid of a digital signal processor.
The Model 3200 does not incorporate any off-the-shelf (OTS) software.
The Model 3200 operates on one (1) AA alkaline, lithium, or NiMH battery.

Indications for Use:

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Information provided in this 510(k) submission shows that 3M™ Littmann® Electronic Stethoscope, Model 3200 is substantially equivalent to the predicate device 3M™ Littmann® Electronic Stethoscope, Model 3000, cleared under K050159 and Littmann® Electronic Stethoscope, Model 4100, cleared under K051790 in terms of intended use, indications for use, composition, physical properties and technological characteristics. There are no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2009

3M Health Care
c/o Mr. Jizhong Jin
Regulatory Affairs
3M Infection Prevention Division
3M Center, Bldg 275-05-W-06
St. Paul, MN 55144-1000

Re: K083903
Trade/Device Name: 3M™ Littmann® Electronic Stethoscope, Model 3200
Regulatory Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II (Two)
Product Code: DQD
Dated: June 16, 2009
Received: June 17, 2009

Dear Mr. Jin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083903

Device Name: 3M™ Littmann® Electronic Stethoscope Model 3200

Indications For Use: The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zac Kerman

(Division Sign-Off) 7/15/09

Division of Cardiovascular Devices

510(k) Number K083903

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 7/16/09

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K083903/A2

To: Division Director: CV/DCD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

__✓__ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: [signature]

Date: Sept. 11, 2009

hard copy of previously reviewed Emails from reply only.

NR SEP 11 2009

DMC 9/11

VEMel 9/11/09

3M Health Care Business

3M Center, Bldg. 0275-05-W-06
St. Paul, MN 55144-1000
651 733 1110

K083903/A2

FDA CDRH DMC

JUL 15 2009

Received

K-1

July 14, 2009

Dr. Charles Ho
Scientific Reviewer
Food and Drug Administration
Center for Device and Radiological Health
Office of Device Evaluation [510(k)]
Document Control Center HFZ-401
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: 2nd Supplement to Traditional 510(k) Premarket Notification for the 3M Littmann Electronic Stethoscope, Model 3200 K083903

Dear Dr. Ho,

Reference is made to our December 22, 2008 request for evaluation of traditional premarket notification for the 3M Littmann Electronic Stethoscope, Model 3200, K083903. As we discussed via email communications, attached is the 2nd supplement to the original submission that provides the answers to your questions in a chronological order.

Sincerely,

Jizhong Jin
Regulatory Affairs
3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

"Ho, Charles S." <Charles.Ho@fda.hhs.gov>
07/05/2009 06:44 PM

To <jjin1@mmm.com>
cc "Ho, Charles S." <Charles.Ho@fda.hhs.gov>
bcc
Subject K083903/S1 F/U Questions

History: This message has been replied to and forwarded.

Dear Mr. Jin:

Thanks for waiting! I have done a more thorough review of your official response, and have some f/u questions, attached. Please see if you can respond to them quickly. At present I am still keeping your file under review in your office. Please call me to discuss your draft response since I can wait only a few more days before placing the file on hold again.

Regards,

Charles

Charles Ho, Ph.D.
Scientific Reviewer
FDA/CDRH/ODE
Phone: 240-276-4077
Fax: 240-276-4002
Email: Charles.ho@fda.hhs.gov

INDICATIONS FOR USE FORM ODE REVISED_Jul052009.DOC K083903_S1f_U Q_Jul052009.doc

Jizhong Jin/US-Corporate/3M/US
07/06/2009 03:39 PM

To "Ho, Charles S." <Charles.Ho@fda.hhs.gov>
cc
bcc
Subject Re: K083903/S1 F/U Questions

Dear Dr. Ho,

Please see 3M's response attached, let me know if you have additional questions as soon as possible. Please also inform me if I should send this to the documentation room.

Regards,

Jizhong

INDICATIONS FOR USE FORM ODE REVISED_Jul052009.DOC Response to FDA July 6, 2009.doc

Jizhong Jin
International Regulatory Affairs
3M Infection Prevention Division
3M Center, Bldg 275-05-W-06
St. Paul, MN 55144-1000
Tel: 651-733-6655
Fax: 651-737-5320
e-mail: jjin1@mmm.com

"Ho, Charles S." Dear Mr. Jin: 07/05/2009 06:44:59 PM

"Ho, Charles S." <Charles.Ho@fda.hhs.gov>
07/05/2009 06:44 PM

To <jjin1@mmm.com>
cc "Ho, Charles S." <Charles.Ho@fda.hhs.gov>
Subject K083903/S1 F/U Questions

Dear Mr. Jin:

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Regards,

Charles

Charles Ho, Ph.D.
Scientific Reviewer
FDA/CDRH/ODE
Phone: 240-276-4077
Fax: 240-276-4002
Email: Charles.ho@fda.hhs.gov

[attachment "INDICATIONS FOR USE FORM ODE REVISED_Jul052009.DOC" deleted by Jizhong Jin/US-Corporate/3M/US] [attachment "K083903_S1 f_U Q_Jul052009.doc" deleted by Jizhong Jin/US-Corporate/3M/US]

Indications for Use

510(k) Number (if known): K083903

Device Name: 3M™ Littmann® Electronic Stethoscope Model 3200

Indications For Use: The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K083903/S1 f/u questions on July 5, 2009:

A. In response to our f/u Q. 1 emailed to you on May 11, 2009, you have provided a new FDA 3654 form, but it is entitled IEC 60601, not IEC 60601-1-2 for EMC testing. Please re-transmit a FDA 3654 form for the correct IEC 60601-1-2.

   3M has provided the FDA 3654 form of IEC 60601-1-2 on May 28, 2009. The IEC 60601-1-2 is listed on the second page of the form.

B. In response to our previous Q. 2, you have provided a new Indications for use form. But you have forgotten to check the prescription use entry blank. Further, the prescription use line should be located above the FDA concurrence line, as shown in the attached blank form. Please revise the Indications for Use form accordingly.

   Please see the indication for use statement attached.

C. In response to our previous Q. 5, you have provided two test reports on IEC 60601-1, which indicate that the subject device is rated IPX4 (for the chest piece only) and can be used inside a flammable anesthetic gas environment. However, the IEC test reports are summary reports since they do not contain the actual test report(s) describing how water was used to test the subject device for the IPX4 claim. Similarly, Annex G, which seems to substantiate the claim for use in a flammable gas environment, is not provided. Hence, please provide these two documents for FDA to review.

   In Appendix 13 of the 510(k) submission, Intertek IEC 60601-1 test report (Report Reference No. 809546-1, date of issue 2008-12-10) documents testing and test results for ingress of water (IPX4) and fire prevention (AP rating) for use in a flammable gas environment.

   Clause 11.6.5 of IEC 60601-1 and of this test report documents ingress of water testing per IEC 60529. Level four, or "IPX4", is protection against splashing liquids and is consistent with the level of protection provided on previous models of 3M Littmann electronic stethoscopes. Ingress of liquids exposure is used to precondition the stethoscope (as defined in IEC 60529 and Level 4) prior to testing for dielectric strength and leakage current (as defined by IEC 60601-1 Clause 11.6.5). The "Results" and "Verdict" section of the test report (Clause 11.6.5) document the results.

   Clause 11.2.1 documents the protection against fire. Specifically, the "Results" section of Clause 11.2.2.1a provides expert analysis stating that the equipment complies to IEC 60601-1 Annex G and that there are no sources of ignition in normal and single fault conditions. Annex G is also included in the same test report starting on page 115.

D. In your response to our previous Q. 9 on the PC's remote control of the subject stethoscope, we see the PC's control of the stethoscope is so thorough that it in fact turns the stethoscope into a eavesdropping device on unsuspecting persons. And this near real-

time transmission of patient sounds (and any other sound or conversation near the stethoscope) can be continuously on for as long as the battery inside the device lasts. Please explain how this remote recording and near real-time transmission feature will not conflict with laws against eavesdropping. Is there a predicate stethoscope with this feature?

General knowledge indicates that eavesdropping is defined as surreptitiously listening to a private conversation, which is commonly thought to be unethical.

The E3200 stethoscope's intended use is for medical diagnostics purpose only. Furthermore, it is classified as a Prescription Device, to be purchased only by healthcare professionals.

The primary control against wireless eavesdropping is the fact that only one Bluetooth device can be connected at a time to a E3200 stethoscope via an encrypted link. Furthermore, the stethoscope user controls which single PC is paired and connected.

The software (on the PC) will only stream audio during a recording session that is initiated by the stethoscope user with the M key. Each single record session in the PC software is limited to 60 seconds and thus is unable to record continuously. Without the 3M proprietary communication protocol, the transmission of sounds cannot not be programmed for continuous streaming. Eavesdropping would be much easier to do with a cellular phone or digital recorder.

E. In your response to our previous Q. 11, you have indicated that a test report on 3M CVE Design validation would be available on June 5. Yet up to now, we have not received this report. Please provide the test report.

   3M CVE has confirmed that the failure modes identified in the Risk Assessment Report have been successfully mitigated through the design control process by the device manufacturer.

Attachment: Indications for Use form (blank)

"Ho, Charles S." <Charles.Ho@fda.hhs.gov>
07/09/2009 06:26 PM

To <jjin1@mmm.com>
cc "Ho, Charles S." <Charles.Ho@fda.hhs.gov>
bcc
Subject RE: K083903/S1 F/U Questions

History: This message has been replied to and forwarded.

Dear Mr. Jin:

Here are my remaining issues:

- For Q. C, you have referred me to that IEC test report, which showed that the tester checked the entry indicating that the device is IPX4. But I still do not see the actual test report of sending water to the device, and afterwards checking that the device could still function as specified. Please provide the actual IPX4 test report.

  (By the way, the issue of use in a flammable gas environment is resolved. I have found Annex G as you pointed out, thank you!)

- For Q. D on the issue of recording conversation, please confirm what you said today, namely that the stethoscope will time out after 60 seconds during a BT session (due to no key press), and that operator intervention via key press(es) at the stethoscope is needed to reactivate the stethoscope to continue recording sound. Thus, I believe the actions of the operator will provide warning to patients and bystanders that the device is recording sound.

- For Q. E on the 3M CVE Design validation report, please provide a summary of the failures that were found, corrected, and retested successfully. I do not need the full report if it contains information not intended for the present submittal.

At present, the file is still under review.

Regards,

Charles

Charles Ho, Ph.D.
Scientific Reviewer
FDA/CDRH/ODE
Phone: 240-276-4077
Fax: 240-276-4002
Email: Charles.ho@fda.hhs.gov

-----Original Message-----
From: Ho, Charles S.
Sent: Thursday, July 09, 2009 6:49 PM
To: 'jjin1@mmm.com'
Cc: Ho, Charles S.
Subject: RE: K083903/S1 F/U Questions

Dear Mr. Jin:

Please call me to discuss your file. I will be at my desk for another hour, so that we can discuss before your vacation tomorrow.

Regards,

Charles

Charles Ho, Ph.D.
Scientific Reviewer
FDA/CDRH/ODE
Phone: 240-276-4077
Fax: 240-276-4002
Email: Charles.ho@fda.hhs.gov

-----Original Message-----
From: jjin1@mmm.com [mailto:jjin1@mmm.com]
Sent: Monday, July 06, 2009 4:39 PM
To: Ho, Charles S.
Subject: Re: K083903/S1 F/U Questions
Importance: High

Dear Dr. Ho,

Please see 3M's response attached, let me know if you have additional questions as soon as possible. Please also inform me if I should send this to the documentation room.

Regards,

Jizhong

(See attached file: INDICATIONS FOR USE FORM ODE REVISED_Jul052009.DOC)(See attached file: Response to FDA July 6, 2009.doc)

Jizhong Jin
International Regulatory Affairs
3M Infection Prevention Division
3M Center, Bldg 275-05-W-06
St. Paul, MN 55144-1000
Tel: 651-733-6655
Fax: 651-737-5320
e-mail: jjin1@mmm.com

"Ho, Charles S."
<Charles.Ho@fda.h
hs.gov>

07/05/2009 06:44
PM

To
<jjin1@mmm.com>

cc
"Ho, Charles S."
<Charles.Ho@fda.hhs.gov>

Subject
K083903/S1 F/U Questions

Dear Mr. Jin:

Thanks for waiting! I have done a more thorough review of your official response, and have some f/u questions, attached. Please see if you can respond to them quickly. At present I am still keeping your file under review in your office. Please call me to discuss your draft response since I can wait only a few more days before placing the file on hold again.

Regards,

Charles

Charles Ho, Ph.D.
Scientific Reviewer
FDA/CDRH/ODE
Phone: 240-276-4077
Fax: 240-276-4002
Email: Charles.ho@fda.hhs.gov

[attachment "INDICATIONS FOR USE FORM ODE REVISED_Jul052009.DOC" deleted by Jizhong Jin/US-Corporate/3M/US] [attachment "K083903_S1 f_U Q_Jul052009.doc" deleted by Jizhong Jin/US-Corporate/3M/US]

Jizhong Jin/US-Corporate/3M/US
07/13/2009 11:55 AM

To "Ho, Charles S." <Charles.Ho@fda.hhs.gov>
cc
bcc
Subject RE: K083903/S1 F/U Questions

Dear Dr. Ho,

Please see the answers below. Please let me know if you have additional questions as soon as possible.

Regards,

Jizhong Jin
International Regulatory Affairs
3M Infection Prevention Division
3M Center, Bldg 275-05-W-06
St. Paul, MN 55144-1000
Tel: 651-733-6655
Fax: 651-737-5320
e-mail: jjin1@mmm.com

"Ho, Charles S." Dear Mr. Jin: 07/09/2009 06:26:47 PM

"Ho, Charles S." <Charles.Ho@fda.hhs.gov>
07/09/2009 06:26 PM

To <jjin1@mmm.com>
cc "Ho, Charles S." <Charles.Ho@fda.hhs.gov>
Subject RE: K083903/S1 F/U Questions

Dear Mr. Jin:

Here are my remaining issues:

- For Q. C, you have referred me to that IEC test report, which showed that the tester checked the entry indicating that the device is IPX4. But I still do not see the actual test report of sending water to the device, and afterwards checking that the device could still function as specified. Please provide the actual IPX4 test report.

  The detailed test requirement for ingress of water is listed on pages 87 and 88 of the test report in Appendix 13 of the 510(k) submission, Intertek IEC 60601-1 test report (Report Reference No. 809546-1, date of issue 2008-12-10). The test protocols are listed on page 88 of the report in the result section. The more detailed information is listed in appended tables in the test report.

  (By the way, the issue of use in a flammable gas environment is resolved.

I have found Annex G as you pointed out, thank you!)

- For Q. D on the issue of recording conversation, please confirm what you said today, namely that the stethoscope will time out after 60 seconds during a BT session (due to no key press), and that operator intervention via key press(es) at the stethoscope is needed to reactivate the stethoscope to continue recording sound. Thus, I believe the actions of the operator will provide warning to patients and bystanders that the device is recording sound.

With current PC software, the maximum time for a single recording session to the PC is 60 seconds. It can only be initiated with a button press by the stethoscope with an active Bluetooth connection. Subsequent recordings by the PC require setup at the PC and another button press at the stethoscope to initiate the recording. Inactivity by the stethoscope will end the Bluetooth connection after 90 seconds.

- For Q. E on the 3M CVE Design validation report, please provide a summary of the failures that were found, corrected, and retested successfully. I do not need the full report if it contains information not intended for the present submittal.

3M CVE has confirmed that the failure modes identified in the Risk Assessment Report (IAD0007 E3100-E3200) have been successfully mitigated through the design control process by the device manufacturer.

Components	Potential Hazards	3M CVE results
10	PCB (printed circuit board) falls out during battery replacement	Did not occur
12	Battery supply missing (POGO pin)	Did not occur
15	Battery supply or loudspeaker signals missing	Did not occur
26	Wrong heart rate displayed	Did not occur
27	Device turns on under storage condition in pocket etc	Did not occur
27	Device turns off during	Did not occur

	examination. Device can still be turned on by the On switch	
38	Poor or no sound	Did not occur

At present, the file is still under review.

Regards,

Charles

Charles Ho, Ph.D.
Scientific Reviewer
FDA/CDRH/ODE
Phone: 240-276-4077
Fax: 240-276-4002
Email: Charles.ho@fda.hhs.gov

-----Original Message-----
From: Ho, Charles S.
Sent: Thursday, July 09, 2009 6:49 PM
To: 'jjin1@mmm.com'
Cc: Ho, Charles S.
Subject: RE: K083903/S1 F/U Questions

Dear Mr. Jin:

Please call me to discuss your file. I will be at my desk for another hour, so that we can discuss before your vacation tomorrow.

Regards,

Charles

Charles Ho, Ph.D.
Scientific Reviewer

FDA/CDRH/ODE
Phone: 240-276-4077
Fax: 240-276-4002
Email: Charles.ho@fda.hhs.gov

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Sent: Monday, July 06, 2009 4:39 PM
To: Ho, Charles S.
Subject: Re: K083903/S1 F/U Questions
Importance: High

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Regards,

Jizhong

(See attached file: INDICATIONS FOR USE FORM ODE REVISED_Jul052009.DOC)(See attached file: Response to FDA July 6, 2009.doc)

Jizhong Jin
International Regulatory Affairs
3M Infection Prevention Division
3M Center, Bldg 275-05-W-06
St. Paul, MN 55144-1000
Tel: 651-733-6655
Fax: 651-737-5320
e-mail: jjin1@mmm.com

"Ho, Charles S." <Charles.Ho@fda.hhs.gov> 07/05/2009 06:44 PM

To <jjin1@mmm.com>

cc "Ho, Charles S."

<Charles.Ho@fda.hhs.gov>
Subject
K083903/S1 F/U Questions

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Phone: 240-276-4077
Fax: 240-276-4002
Email: Charles.ho@fda.hhs.gov

[attachment "INDICATIONS FOR USE FORM ODE REVISED_Jul052009.DOC" deleted
by Jizhong Jin/US-Corporate/3M/US] [attachment "K083903_S1 f_U Q_Jul052009.doc" deleted by Jizhong Jin/US-Corporate/3M/US]

3M Health Care
3M Infection Prevention

3M Center, Bldg. 0275-05-W-06
St. Paul, MN 55144-1000
651 733 1110

K083903/A1

FDA CDRH DMC

APR 03 2009

Received

Received

March 27, 2009

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
CDRH/ODE
Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SUBJECT: Change to the correspondent for the 510(k) 3M™ Littmann® Electronic Stethoscope Model 3200, K083903

Dear Ms. Shulman,

This letter is to let you know that Jizhong Jin will be the official correspondent for 510(k) 3M™ Littmann® Electronic Stethoscope Model 3200, K083903.

His contact information is as follows:
Jizhong Jin
3M Infection Prevention Division
3M Center, Bldg 275-05-W-06
St. Paul, MN 55144-1000
Tel: 651-733-6655
Fax: 651-737-5320
e-mail: jjin1@mmm.com

Sincerely,

Rica Morris

Rica Morris

cc: Charles Ho, Ph.D
Jizhong Jin

K64

5

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

December 30, 2008

3M COMPANY
3M CENTER, BLDG. 275-5W-06
ST. PAUL, MINNESOTA 55133-3275
UNITED STATES
ATTN: RICA MORRIS

510k Number: K083903
Received: 12/29/2008
Product: 3M LITTMANN ELECTRONIC STETHOS

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/cdrh/mdufma/index.html for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" (http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1655.pdf. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2009

3M Health Care
c/o Mr. Jizhong Jin
Regulatory Affairs
3M Infection Prevention Division
3M Center, Bldg 275-05-W-06
St. Paul, MN 55144-1000

Re: K083903
Trade/Device Name: 3M™ Littmann® Electronic Stethoscope, Model 3200
Regulatory Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II (Two)
Product Code: DQD
Dated: June 16, 2009
Received: June 17, 2009

Dear Mr. Jin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083903

Device Name: 3M™ Littmann® Electronic Stethoscope Model 3200

Indications For Use: The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

Prescription Use ____X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 7/15/09

Division of Cardiovascular Devices

510(k) Number K083903

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

February 25, 2009

510k Number: K083903

Product: 3M LITTMANN ELECTRONIC STETHOS

3M COMPANY
3M CENTER, BLDG. 275-5W-06
ST. PAUL, MINNESOTA 55133-3275
UNITED STATES
ATTN: RICA MORRIS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

3M Health Care Business

3M Center, Building 0275-05-W-06
St. Paul, MN 55144-1000
651 733 1110

K083903

December 22, 2008

FDA CDRH DMC
Received
DEC 29 2008

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation [510(K)]
Document Control Center HFZ-401
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: Traditional 510(k) Premarket Notification for the 3M™ Littmann® Electronic Stethoscope, Model 3200

Dear Sir or Madam:

In compliance with the Federal Food, Drug and Cosmetic Act (as amended) and as required in 21 CFR § 807, Subpart E, 3M Health Care submits this subject Premarket Notification for your review. In accordance with 21 CFR §807.90(c), this document is submitted in duplicate with this original cover letter, and two additional copies of the cover letter are provided.

3M™ Littmann® Electronic Stethoscope, Model 3200 will be shown to be substantially equivalent to the 3M™ Littmann® Electronic Stethoscope Model 4100 and the Littmann® Electronic Stethoscope Model 3000.

3M considers the intent to market this device as confidential commercial information. Therefore, 3M considers the information provided under this submission to be a trade secret and confidential commercial information under 21 CFR §20.61 and requests that the Food and Drug Administration not disclose this information either in response to a Freedom of Information Request or by any other means.

(b) (4)

[redacted]

Sincerely,

Rica Morris

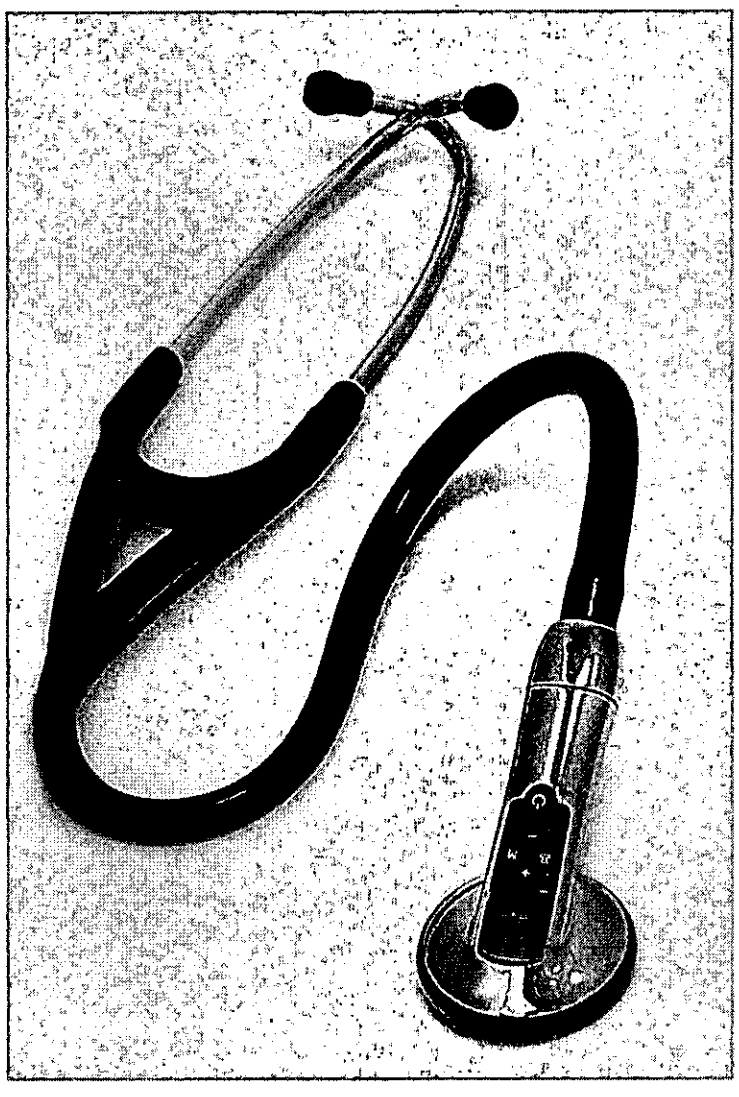
Rica Morris
3M Health Care Regulatory Affairs
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Phone (651) 733-6791
Fax: (651) 737-5320
remorris2@mmm.com

64S

510(k) Premarket Notification for

3M™ Littmann® Electronic Stethoscope, Model 3200



Submitted by
3M Health Care
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144-1000

Submission Date:
December 22, 2008

Contact:	Rica Morris
Contact's Phone:	(651) 733-6791
Contact's Fax:	(651) 737-5320
Contact's Email:	remorris2@mmm.com

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Appendix 15 Risk Management

1.0 Device User Fee Cover

Form Approved: OMB No 0910-0511 Expiration Date: January 31, 2010 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: Write the Payment Identification number on your check. (b)(4)Trade Secret Process Product

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (Include name, street address, city state, country, and post office code)	2. CONTACT NAME
3M COMPANY CORP 3M CENTER BLDG 275 5W 05 ST PAUL MN 55144-1000 US	Rice Morris
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 410417775	2.1 E-MAIL ADDRESS remorris2@mmm.com 2.2 TELEPHONE NUMBER (Include Area code) 651-733-6791 2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)Trade

22-Dec-2008

Form FDA 3601 (01/2010)

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2.0 Submission Cover Sheet (form)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission ☐ Premarket Report ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment ☐ Licensing Agreement	☐ Regular (180 day) ☐ Special ☐ Panel Track (PMA Only) ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA & HDE Supplement ☐ Other	☐ Original PDP ☐ Notice of Completion ☐ Amendment to PDP	☑ Original Submission. ☑ Traditional ☐ Special ☐ Abbreviated (Complete section I, Page 5) ☐ Additional Information ☐ Third Party	☐ Pre-510(K) Meeting ☐ Pre-IDE Meeting ☐ Pre-PMA Meeting ☐ Pre-PDP Meeting ☐ Day 100 Meeting ☐ Agreement Meeting ☐ Determination Meeting ☐ Other *(specify)*

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission ☐ Amendment ☐ Supplement	☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment	☐ Original Submission ☐ Additional Information	☐ Original Submission ☐ Additional Information	☐ 513(g) ☐ Other *(describe submission)*

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: 3M Company	Establishment Registration Number *(if known)*: 2110898		
Division Name *(if applicable)*: 3M Health Care	Phone Number *(including area code)*: (651) 733-6791		
Street Address: 3M Center, Bldg. 275-5W-06	FAX Number *(including area code)*: (651) 737-5320		
City: St Paul	State / Province: MN	ZIP/Postal Code: 55144-1000	Country: USA
Contact Name: Rice Morris			
Contact Title: Senior Regulatory Affairs Associate	Contact E-mail Address: remorris2@mmm.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*: ( )		
Street Address	FAX Number *(including area code)*: ( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

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SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site
- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Sterilization
  - [ ] Packaging
  - [ ] Other *(specify below)*
- [ ] Response to FDA correspondence.
- [ ] Change in design, component, or specification
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*
- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*
- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager
- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment
- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address
- [ ] Other Reason *(specify)*

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access
- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor
- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final
- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing
- [ ] Other Reason *(specify)*

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [x] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology
- [ ] Other Reason *(specify)*

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SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1 DQD	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K050159	1	3M™ Littmann® Electronic Stethoscope Model 3000	1	3M Health Care, 3M Center, Bldg 275-5W-06, St Paul, MN 55144-1000
2	K051790	2	3M™ Littmann® Electronic Stethoscope, Model 4100	2	3M Health Care, 3M Center, Bldg 275-5W-06, St Paul, MN 55144-1000
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Electronic Stethoscope

	Trade or Proprietary or Model Name for This Device		Model Number
1	3M Littmann Electronic Stethoscope	1	Model 3200
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: DQD

C.F.R. Section (if applicable): 21 CFR 870.1875(b)

Device Class

- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Classification Panel: Cardiovascular

Indications (from labeling)

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number (if known)

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☑ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☑ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name: 3M Company		Establishment Registration Number: 2110898	
Division Name (if applicable): 3M Health Care		Phone Number (including area code): (651) 733-6791	
Street Address: 3M Center, Bldg. 275-5W-06		FAX Number (including area code): (651) 737-5320	
City: St Paul	State / Province: MN	ZIP/Postal Code: 55144-1000	Country: USA
Contact Name: Suzanne M. Danielson	Contact Title: Director, Regulatory Affairs and Quality	Contact E-mail Address: smdanielson@mmm.com	

☑ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☑ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name: (b)(4)Trade Secret Process Product		Establishment Registration Number: (b)(4)Trade S t	
Division Name (if applicable): (b)(4)Trade Secret		Phone Number (including area code): (b)(4)Trade Secret P P d t S	
Street Address: (b)(4)Trade Secret P P d t		FAX Number (including area code): (b)(4)Trade Secret	
City: (b) (4)T d	State / Province: (b)(4)Trade Secret	ZIP/Postal Code: (b)(4)Trade S	Country: (b)(4)Trade Secret
Contact Name: (b)(4)Trade Secret	Contact Title: (b)(4)Trade Secret P P d t S	Contact E-mail Address: (b)(4)Trade Secret Process Product Specs	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name:		Establishment Registration Number:	
Division Name (if applicable):		Phone Number (including area code): ( )	
Street Address:		FAX Number (including area code): ( )	
City:	State / Province:	ZIP/Postal Code:	Country:
Contact Name:	Contact Title:	Contact E-mail Address:	

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SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "*Declaration of Conformity to a Recognized Standard*" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 10993-Part 1	ISO	Biological Evaluation of Medical Devices	2003	08/01/2003
2	ISO 14971	ISO	Medical Devices - Application of Risk Management to Medical Devices	2007	10/01/2007
3	IEC 60601-1	IEC	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005	12/15/2005
4	IEC 60601-1-2	IEC	Medical electrical equipment - Part 2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Compatibility - Requirements and tests	2007	03/30/2007
5	IEC 60601-1-6	IEC	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability	2006	12/08/2006
6	EN 301 489-1	EN	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements	V 1.6.1	09/01/2005
7	EN 301 489-17	EN	ElectroMagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific Conditions for 2.4 GHz Wideband Transmission Systems and 5 GHz High Performance RLAN Equipment	V1.2.1	08/01/2002

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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Additional Standards cited in this submission:

	Standards No.	Standards Organizations	Standards Title	Version	Date
8	EN 55022	EN	Information technology equipment. Radio disturbance characteristics. Limits and methods of measurement	2006	11-1-2006
9	EN 61000-4-2/A2	EN	Electromagnetic Compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test	2001	05/04/2001
10	EN 61000-4-3	EN	Electromagnetic Compatibility (EMC) – Testing and measurement techniques. Radiated, radio- Frequency electromagnetic field immunity test	2006	06/15/2006
11	EN 60068-2-1	EN	Environmental testing – Part 2-1: Tests – Test A: Cold	2007	05/21/2007
12	EN 60068-2-2	EN	Environmental testing – Part 2-2: Tests – Test B: Dry Heat	2007	09/25/2007
13	EN 60068-2-78	EN	Environmental testing – Part 2-78: Tests – Test Cab: Damp heat, steady state	2001	12/11/2001
14	IC RSS-210	IC	Low-power Licence-exempt Radiocommunication Devices (All Frequency Bands): Category I Equipment	Issue 7	June 2007

paygovadmin@mail.doc.twai.gov
12/22/2008 02:26 PM

To "remorris2@mmm.com" <remorris2@mmm.com>
cc
bcc
Subject Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Payment Summary

Application Name: FDA User Fees
Pay.gov Tracking ID: 24V5TFRF
Agency Tracking ID: 6040484

Account Holder Name: Lesley J. Larson
Transaction Type: Sale
Billing Address: 3M Center, Bldg. 275-5W-06
City: St. Paul
State/Province: MN
Zip/Postal Code: 551441000
Country: USA

(b)(4)Trade Secret Process-Product Specs

[redacted]

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3.0 510(k) Cover Letter

December 22, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation [510(K)]
Document Control Center HFZ-401
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: Traditional 510(k) Premarket Notification for the 3M™ Littmann® Electronic Stethoscope, Model 3200

Dear Sir or Madam:

In compliance with the Federal Food, Drug and Cosmetic Act (as amended) and as required in 21 CFR § 807, Subpart E, 3M Health Care submits this subject Premarket Notification for your review. In accordance with 21 CFR §807.90(c), this document is submitted in duplicate with this original cover letter, and two additional copies of the cover letter are provided.

3M™ Littmann® Electronic Stethoscope, Model 3200 will be shown to be substantially equivalent to the 3M™ Littmann® Electronic Stethoscope Model 4100 and the Littmann® Electronic Stethoscope Model 3000.

3M considers the intent to market this device as confidential commercial information. Therefore, 3M considers the information provided under this submission to be a trade secret and confidential commercial information under 21 CFR §20.61 and requests that the Food and Drug Administration not disclose this information either in response to a Freedom of Information Request or by any other means.

(b) (4)

[redacted]

Sincerely,

Rica Morris

Rica Morris
3M Health Care Regulatory Affairs
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Phone (651) 733-6791
Fax: (651) 737-5320
remorris2@mmm.com

4.0 Indications for Use Statement

Indications for Use Statement

510(k) Number (if known):_____

Device Name: 3M™ Littmann® Electronic Stethoscope Model 3200

Indications for Use:

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter-Use ___

5.0 Premarket Notification (510(k)) Summary

Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person:	Rica Morris Senior Regulatory Affairs Associate
Phone Number:	(651) 733-6791
FAX Number:	(651) 737-5320

Date of Summary:	December 22, 2008

Device Name and Classification:

Common or Usual Name:	Electronic Stethoscope
Proprietary Name:	3M™ Littmann® Electronic Stethoscope Model 3200
Classification Name:	Electronic Stethoscope (21 CFR § 870.1875(b))
Performance Standards:	None

Predicate Device:

3M™ Littmann® Electronic Stethoscope, Model 3000
3M™ Littmann® Electronic Stethoscope, Model 4100

Description of Device:

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is a healthcare device that picks up sounds of the heart, arteries, veins, lungs and other internal organs with the use of selective frequency ranges. After amplification and filtering, the sounds are transferred to the user's ears via an active speaker and passive sound tubes.

The Model 3200 can also exchange audio data with a personal computing device (PC) using wireless Bluetooth link.

The user interface includes a 5-button keypad and an LCD display. Sound processing is carried out with the aid of a digital signal processor.
The Model 3200 does not incorporate any off-the-shelf (OTS) software.
The Model 3200 operates on one (1) AA alkaline, lithium, or NiMH battery.

Indications for Use:

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Information provided in this 510(k) submission shows that 3M™ Littmann® Electronic Stethoscope, Model 3200 is substantially equivalent to the predicate device 3M™ Littmann® Electronic Stethoscope, Model 3000, cleared under K050159 and Littmann® Electronic Stethoscope, Model 4100, cleared under K051790 in terms of intended use, indications for use, composition, physical properties and technological characteristics. There are no new questions of safety or effectiveness.

6.0 Truthful and Accuracy Statement

Truthful and Accurate Statement

Pursuant to 21 CFR §807.87(k), I certify that, in my capacity as Senior Regulatory Affairs Associate for 3M Health Care, I believe to the best of my knowledge, that all data and information submitted in this Premarket Notification are truthful and accurate and that no material fact has been omitted.

Rica Morris

Signature

Rica Morris

Typed Name

December 22, 2008

Date

7.0 Class III Summary and Certification

Not applicable. The subject medical device is not a Class III device.

8. 0 Financial Certification or Disclosure Statement

Not applicable. This submission does not contain information from clinical studies.

9.0 Declarations of Conformity and Summary Reports

9.1 Declaration of Conformity

Not applicable. This is not an Abbreviated 510(k) submission.

9.2 Summary Reports

Not applicable. There is no recognized standard or guidance for subject medical device.

10.0 Executive Summary

10.1 The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.

The following trade name is applicable to this device:

3M™ Littmann® Electronic Stethoscope, Model 3200

The common or usual names for this type of product:

Electronic Stethoscope

The classification name for this device:

Electronic Stethoscope (21 CFR §870.1875(b))

10.2 The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

This 510(k) Premarket Notification is submitted by:

3M Health Care
3M Center
Building 275-5W-06
St. Paul, MN 55144-1000
FDA Establishment Registration No. 2110898

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is contract manufactured for 3M by:

(b)(4)Trade Secret Process-Product Specs

[redacted]

10.3 The class in which the device is classified under section 513 of the act and, if known, its appropriate classification panel.

Electronic Stethoscope, Class II (21 CFR §870.1875(b))
Product Code: DQD (Electronic Stethoscope) suggested

The appropriate classification panel is the Cardiovascular Panel.

10.4 Performance Standards - Action taken by 3M to comply with the requirements of the act under section 514 for performance standards.

There are no mandatory performance standards under section 514 of the Act to which this device is subject. Additionally, to the best of 3M's knowledge, no specific performance standards (e.g., AAMI, ISO, EN) have been developed for this product.

10.5 Concise Description of Device

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is a healthcare device that picks up sounds of the heart, arteries, veins, lungs and other internal organs with the use of selective frequency ranges. After amplification and filtering, the sounds are transferred to the user's ears via an active speaker and passive sound tubes.
The stethoscope chestpiece is designed for use with adult, pediatric, and infant patients.

Indication for Use:

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

10.6 Device Comparison Table

Table 1. Comparison of Littmann® Electronic Stethoscope, Model 3200 versus Littmann® Electronic Stethoscope, Model 3000 and Littmann® Electronic Stethoscope, Model 4100

	Model 3200 (New Device)	**Model 3000 (Predicate Device) K050159**	**Model 4100 (Predicate Device) K051790**
Intended Use	Electronic Stethoscope	Electronic Stethoscope	Electronic Stethoscope
Indication for Use	The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.	The 3M™ Littmann® Electronic Stethoscope Model 3000 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.	The 3M™ Littmann® Electronic Stethoscope Model 4100 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.
Ambient Noise Reduction	Yes	Yes	Yes
Frequency Response	Bell (20-200 Hz), Diaphragm (100-500 Hz) and "Extended Range" (50-500 Hz) modes	Bell (20-200 Hz) and Diaphragm (100-500 Hz) modes	Bell (20-200 Hz), Diaphragm (100-500 Hz) and "Extended Range" (20-1000 Hz) modes
Amplification	Up to 28 dB acoustic gain, equivalent to 24 times amplification	Up to 25 dB acoustic gain, equivalent to 18 times amplification	Up to 25 dB acoustic gain, equivalent to 18 times amplification
Maximum Sound Level	(b) (4) dB SPL Max	(b) (4) dB SPL Max	(b) (4) dB SPL Max
Power Source	One (1) (AA) alkaline, lithium, or NiMH battery	One (1) (AAA) alkaline battery	Two (2) (AAA) alkaline batteries
Low Battery Indicator	Includes a low battery indicator	Includes a low battery indicator	Includes a low battery indicator
Displays Heart Rate	Yes	No	Yes
Record and Playback Sounds	Yes	No	Yes

	Model 3200 (New Device)	Model 3000 (Predicate Device) K050159	Model 4100 (Predicate Device) K051790
Permits Data Transfer of Stored Digital Signals to/from PC	Yes, using Bluetooth® wireless link	No	Yes, using Infrared Port wireless link
Volume Control	9 Step Volume Control	8 Step Volume Control	8 Step Volume Control
ON/OFF Switch and/or Automatic Shut-off by Electronics	Yes	Yes	Yes

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is substantially equivalent to the predicate devices above in terms of indications for use, composition, physical properties and technological characteristics. Please see Section 12 of this submission for additional details related to the above comparisons.

10.7 Concise Summary of Performance Testing

This submission includes data from bench testing to evaluate the performance of The 3M™ Littmann® Electronic Stethoscope, Model 3200. Although there are no specific performance standards for this device, the device was tested for compliance with voluntary standards for general safety (IEC/EN 60601-1), environmental testing (EN 60068-2-1, etc.), and EMC (EN 60601-1-2, FCC Part 15B) testing.

Please see Section 17 and 18 for additional details.

This submission does not include animal or clinical performance testing.

11.0 Device Description

11.1 General Description

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is a healthcare device that picks up sounds of the heart, arteries, veins, lungs, and other internal organs, electronically amplifies, filters the signals to the speakers, and transfers them to the user's ears via an active speaker and passive sound tubes. The stethoscope chestpiece is designed for use with adult, pediatric, and infant patients.

The user interface for the Model 3200 includes a 5-button keypad and a liquid crystal display (LCD) display. The user has the ability to change the filter mode and increase/decrease the volume using the keypad. The LCD on the chestpiece displays the following information:

- Heart Rate
- Selected Filter Mode
- Battery Level Indicator
- Bluetooth® link Indicator
- Volume Level
- Record and Playback

The Model 3200 provides three filter frequency modes for auscultation:
Bell (20-200 Hz), Diaphragm (100-500 Hz) and "Extended Range" (50-500 Hz). This stethoscope provides amplification and includes features that permit it to record and store sounds. Stored recordings of the heart, lungs, and other body sounds can be up to twenty-nine (29) seconds in length.

The Model 3200 incorporates embedded software. The embedded software controls all of the various features found in the Model 3200 stethoscope, such as volume control, frequency mode selection, LCD display, record and playback, and Bluetooth® link pairing. In addition, the embedded software provides digital signal processing (DSP) over the entire acoustic range of the stethoscope; DSP produces the bell, diaphragm, and "extended range" frequency response modes that are used to listen to heart, lungs, and other body sounds. Furthermore, the embedded software supports the Serial Port Profile (SPP) that handles Bluetooth communication.

The Model 3200 does not incorporate any off-the-shelf (OTS) software.

The Model 3200 operates on one (1) AA alkaline, lithium, or NiMH battery. It has power management profiles to optimize battery lifetime. The battery provides approximately 50-60 hours of continuous use, depending on the frequency of Bluetooth® communications or backlighting of LCD display.

11.2 Digital communication function

The 3M™ Littmann® Electronic Stethoscope, Model 3200 has a Bluetooth® wireless link that can exchange recorded sounds with other Bluetooth® capable personal computing devices (PC).
Audio data can be sent in near real time, allowing for visual presentation, recording, and analysis by software that complies with communication protocols used by the Model 3200 stethoscope.

The Model 3200 can only communicate with one PC at a time. This requires the user to pair both devices. Through a Bluetooth® link, different signal paths can be selected by a connected PC. The Bluetooth® link also allows for the audio playback through the Model 3200 to the user.

The Model 3200 cannot pair with a second Model 3200 stethoscope.

The Model 3200 uses a Class 2 Bluetooth® link, with a maximum range of 10m.

11.3 Device Photos/Drawings

Figure 1 3M™ Littmann® Electronic Stethoscope, Model 3200

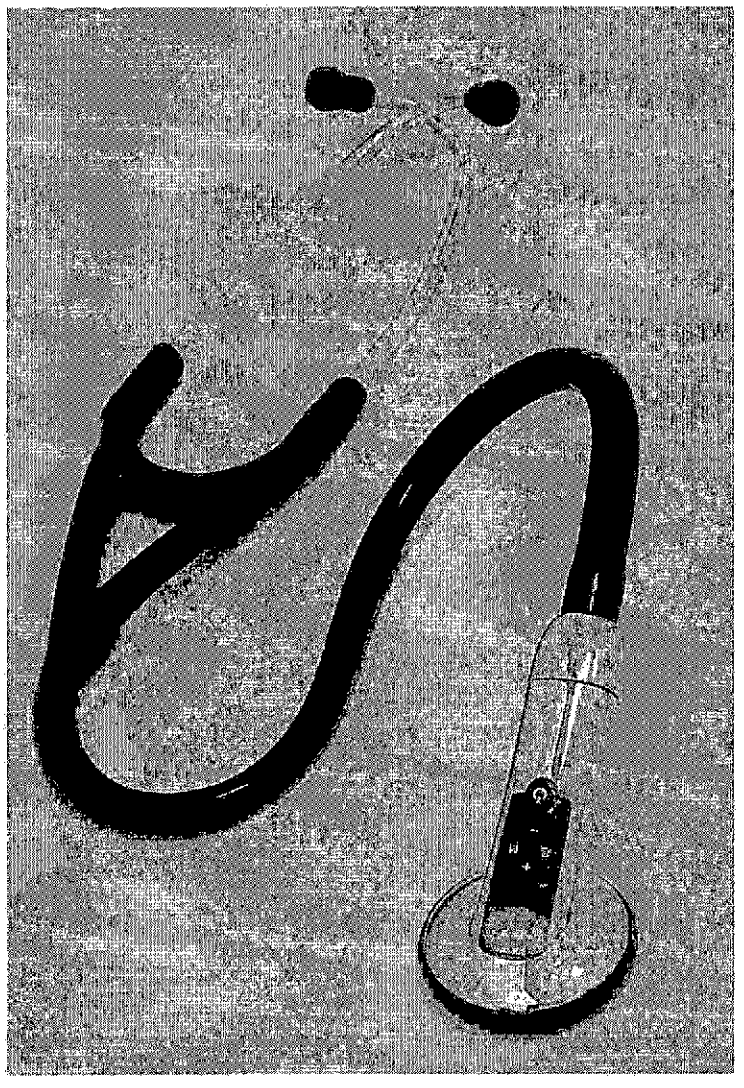

Figure 2 **Expanded View of Littmann® Electronic Stethoscope, Model 3200 Chestpiece**

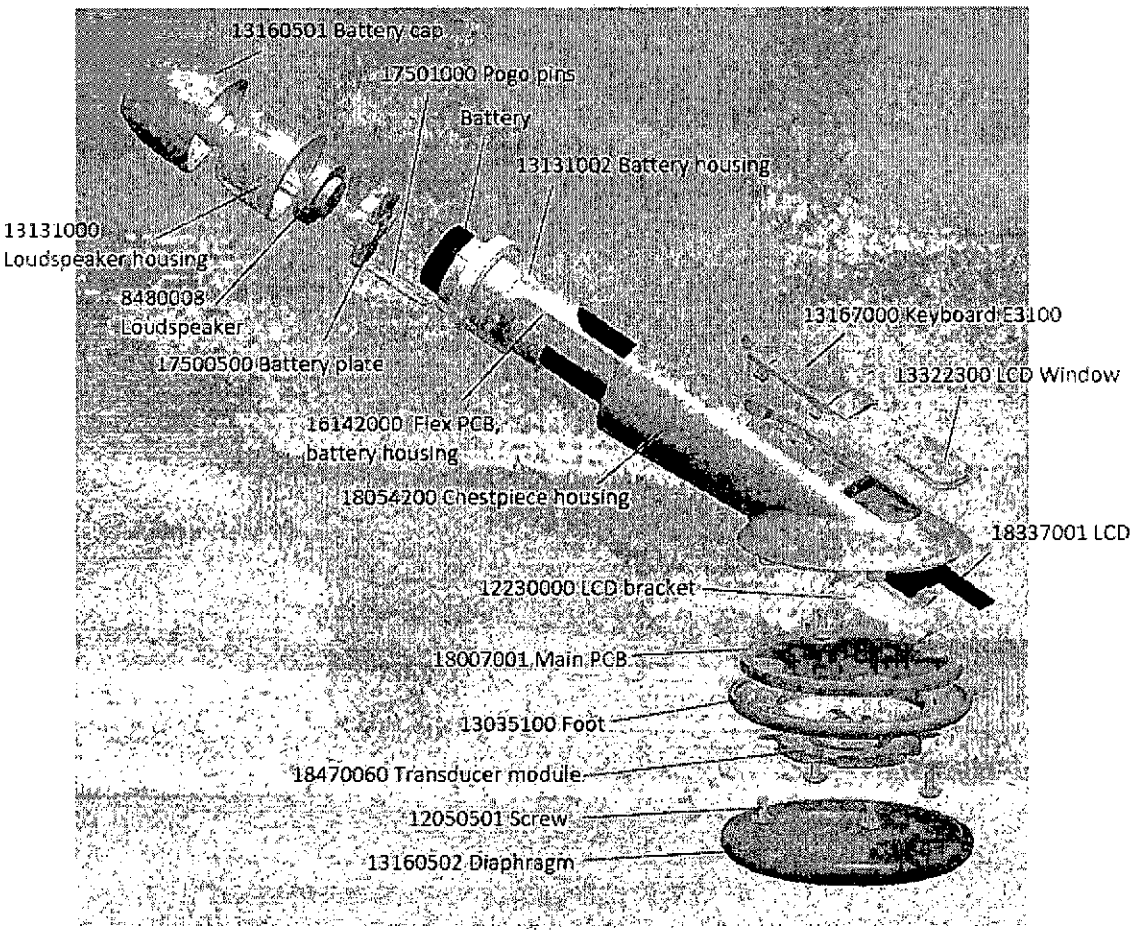

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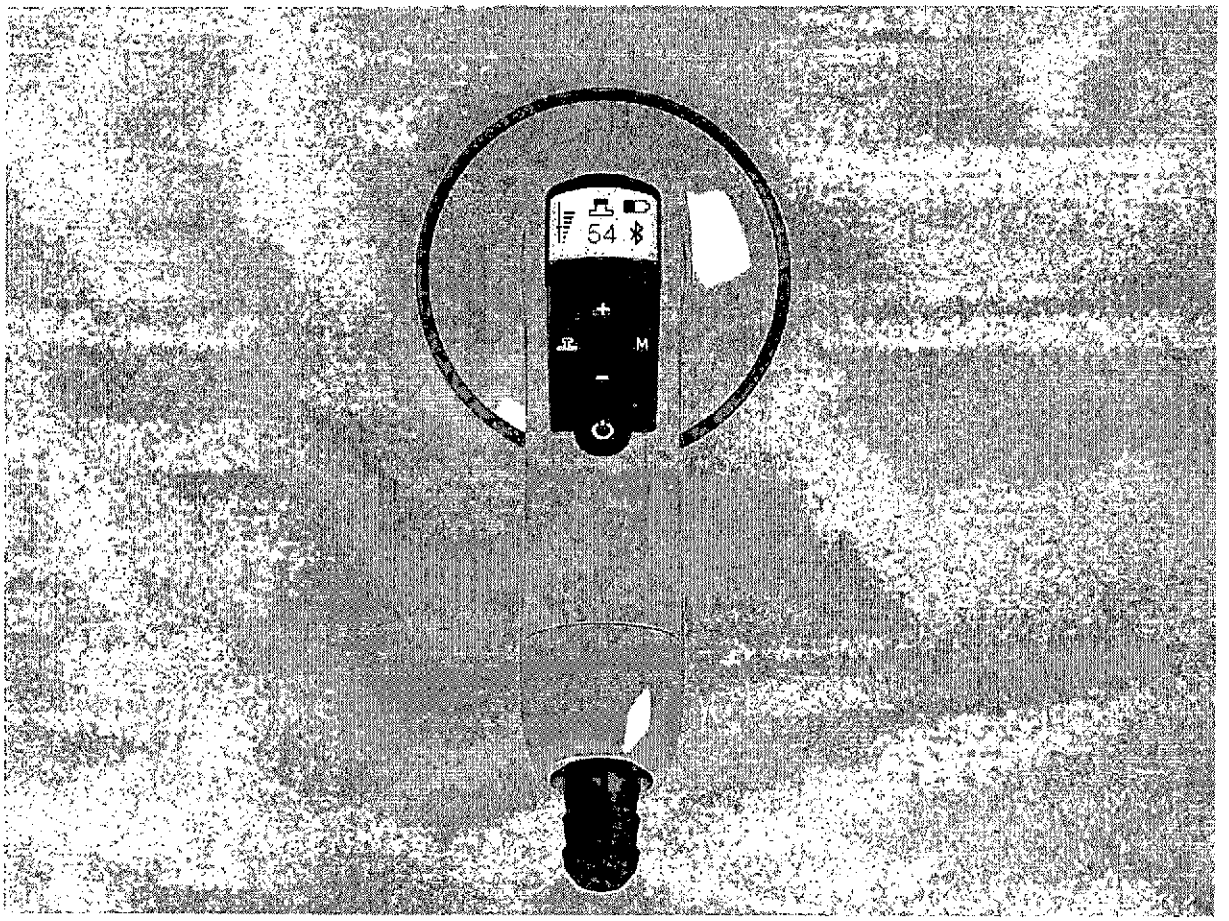
Figure 3 M3200 chestpiece showing backlit LCD and 5-button keypad



11.4 Available models

Table 2 Models

Models	Colors
3200BK	**Black**
3200NB	**Navy Blue**
3200BU	**Burgundy**

3M™ Littmann® Electronic Stethoscope, Model 3200, will be sold with various colors. Additional colors and different tube lengths may also be added.

11.5 Proposed Claims

In addition to the indications for use, the claims to be used in the promotion and advertising of the 3M™ Littmann® Electronic Stethoscope, Model 3200 are listed below.

- Up to 28 dB acoustic gain, equivalent to 24 times amplification of the best/most advanced conventional/traditional (i.e. non-electronic) Littmann® stethoscopes (0°-50°C)
- Filter circuitry provides three frequency response modes – Bell (20-200 Hz), Diaphragm (100-500 Hz), and "Extended Range" (50-500 Hz)
- Digital signal processing over entire acoustic range of stethoscope
- Electrical signal-to-noise ratio greater than 75 dB with less than 2% total harmonic distortion (THD).
- The proprietary passive ambient noise reduction (ANR) technology provides a significant reduction in distracting ambient noise without loss of body sounds under typical use conditions.
- Wireless, near real time data transfer ability; capable of transferring sound data via a Bluetooth® communications link to external devices such as PCs, etc., with appropriate software drivers.
- Multiple backup features for low battery warning to advise users of remaining battery life.
- Excellent acoustic seal and comfortable fit with 3M™ Littmann™ Snap Tight Soft-Sealing Eartips
- Limits maximum sound pressure at ear canals to 140 dB (transient) to protect user's hearing

- Meets applicable EMC requirements
- "Latex-free" – Does not contain natural rubber latex or dry natural rubber as components in the product or packaging

Proposed claims will be substantiated prior to marketing product.

11.6 Performance Specifications

Table 3 Performance Specifications

	Model 3200 (New Device)
Intended Use	Electronic Stethoscope
Indication for Use	The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.
Ambient Noise Reduction	Yes
Frequency Response	Bell (20-200 Hz), Diaphragm (100-500 Hz) and "Extended Range" (50-500 Hz) modes
Amplification	Up to 28 dB acoustic gain, equivalent to 24 times amplification
Maximum Sound Level	(b) [redacted] dB SPL Max
Power Source	One (1) (AA) alkaline, lithium, or NiMH battery
Low Battery Indicator	Includes a low battery indicator
Displays Heart Rate	Yes
Record and Playback Sounds	Yes
Exchanges Stored Digital Signals to and from external device	Yes
Volume Control	9 Step Volume Control
ON/OFF Switch Automatic Shut-off by Electronics	Yes

11.7 Risk Management

3M evaluated 3M™ Littmann® Electronic Stethoscope, Model 3200 using a process compliant with ISO 14971:2007 Risk Management for Medical Devices, and specific procedures and practices outlined by division Standard Operating Procedures. Please see Risk Management Section 21. Please see also precautionary information in the proposed Instructions for Use in Appendix 10 and biocompatibility information in Section 15.

11.8 Compositions

Table 4 identified the larger external components (including material composition) for 3M™ Littmann® Electronic Stethoscope, Model 3200.

Table 4 Compositions of Main Components

Component and Material Type	Model 3200
Ear-tip (Ribbed Style)	Silicone rubber
Diaphragm (Transducer cover)	Silicone with polyacrylate coating
Tube	Vinyl compound (PVC)
Eartube Mount	Anodized aluminum
Yoke	PVC
Chestpiece housing/battery cap	Chrome-coated zinc
LCD window	Polycarbonate/SEBS with acrylate coating
keypad	Polycarbonate with acrylic urethane coating

11.9 Manufacturing

The Model 3200 is contract manufactured for 3M by:

(b)(4)Trade Secret Process-Product Specs

[redacted]

12.0 Substantial Equivalence Discussion

12.1 Summary Statement

The Littmann® Electronic Stethoscope, Model 3200 is substantially equivalent to the Littmann® Electronic Stethoscope Model 3000 cleared under K050159 and the Littmann® Electronic Stethoscope Model 4100, cleared under K051790.

The Model 3200 proposed under this new premarket notification submission is composed of the same or similar materials, and has similar performance features, intended use and indications for use as the Model 3000 and Model 4100.

12. 2 Comparison Data

Tables 5, 6, and 7 provide comparison data for the purpose of demonstrating substantial equivalence between the Model 3200 (new device), and the Model 3000 (predicate device) and the Model 4100 (predicate device).

Table 5 identifies the larger external components (including material composition) for the Model 3200, Model 3000, and Model 4100 stethoscopes.

Table 5 Comparison of Components

Component and Material Type	Model 3200 (New Device)	Model 3000 (Predicate Device) K050159	Model 4100 (Predicate Device) K051790
Ear-tip (Ribbed Style)	Silicone rubber	Silicone rubber	Silicone rubber
Diaphragm (Transducer cover)	Silicone with polyacrylate coating	Silicone with polyurethane coating	Silicone with polyurethane coating
Tube	Vinyl compound (PVC)	Vinyl compound	Santoprene (b) [redacted] (4)T
Eartube Mount	Anodized aluminum	Anodized aluminum	Anodized Aluminum
Yoke	PVC	PVC	Nitrile
Chestpiece housing/battery cap	Chrome-coated zinc	Chrome-coated Polycarbonate/ABS	Chrome-coated zinc
LCD window	Polycarbonate/SEBS with acrylate coating	Not Applicable; No LCD window	Polycarbonate with acrylate coating
keypad	Polycarbonate with acrylic urethane coating	Silicone rubber	Polyurethane

Table 6 summarizes the similar and different performance features of the Model 3200 compared to the Model 3000 and Model 4100 predicate devices.

Table 6 Comparison of Performance Features

Performance Features	Model 3200 (New Device)	Model 3000 (Predicate Device) K050159	Model 4100 (Predicate Device) K051790
Ambient Noise Reduction	Yes	Yes	Yes
Frequency Response	Bell (20-200 Hz), Diaphragm (100-500 Hz) and "Extended Range" (50-500 Hz) modes.	Bell (20-200 Hz) and Diaphragm (100-500 Hz) modes.	Bell (20-200 Hz), Diaphragm (100-500 Hz) and "Extended Range" (20-1000 Hz) modes.
Amplification	Up to 28 dB acoustic gain, equivalent to 24 times amplification.	Up to 25 dB acoustic gain, equivalent to 18 times amplification.	Up to 25 dB acoustic gain, equivalent to 18 times amplification.
Maximum Sound Level	(b) (4) dB SPL Max	(b) (4) dB SPL Max	(b) (4) dB SPL Max
Power Source	One (1) (AA) alkaline, lithium, or NiMH battery	One (1) (AAA) alkaline battery	Two (2) (AAA) alkaline batteries
Low Battery Indicator	Includes a low battery indicator	Includes a low battery indicator	Includes a low battery indicator
Displays Heart Rate	Yes	No	Yes
Record and Playback Sounds	Yes	No	Yes
Permits Data Transfer of Stored Digital Signals to and from PC	Yes, using Bluetooth wireless link	No	Yes, using Infrared Port wireless link
Volume Control	9 Step Volume Control	8 Step Volume Control	8 Step Volume Control
ON/OFF Switch and/or Automatic Shut-off by Electronics	Yes	Yes	Yes

Table 7 presents a comparison of the intended use and indications for use of the Littmann® Model 3200, Model 3000, and Model 4100 Electronic Stethoscopes. Intended Use and Indicatons for Use are identical among these devices.

Table 7 Intended and Indications for Use Comparison

	Model 3200 (New Device)	**Model 3000 (Predicate Device) K050159**	**Model 4100 (Predicate Device) K051790**
Intended Use	Electronic Stethoscope	Electronic Stethoscope	Electronic Stethoscope
Indications for Use	The 3M™ Littmann® Electronic Stethoscope, Model 3200, is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.	The 3M™ Littmann® Electronic Stethoscope, Model 3000, is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.	The 3M™ Littmann® Electronic Stethoscope, Model 4100, is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

12.3 Conclusion

Based on the above comparison, 3M finds the 3M™ Littmann® Electronic Stethoscope, Model 3200 substantially equivalent to the 3M™ Littmann® Electronic Stethoscope, Model 3000 and the 3M™ Littmann® Electronic Stethoscope, Model 4100.

The model 3200 proposed under this premarket notification submission is composed of the same or similar materials, has same or similar performance features, same intended use and indications for use as the predicate devices. The change in wireless technology from Infrared Port to Bluetooth link does not have a significant effect on the device's performance.

13.0 Proposed Labeling

13.1 Labeling/Instructions for Use

Copies of the proposed labeling for the Model 3200 (i.e., the User Manual and primary box and master shipper carton) are included in Appendix 1 of this submission. The User Manual also includes directions for routine care and maintenance of the device.

Each primary box contains one (1) Model 3200 stethoscope, the User Manual, two (2) additional pairs of ear tips and one (1) AA battery. Three (3) primary boxes are included in each master shipper carton.

Note that as required by the latest revision of the Electromagnetic Compatibility (EMC) Standard (IEC-60601-1-2), specific results for EMC testing are included in the User Manual for the Model 3200.

Reference labeling for the predicate devices, the Model 3000 and Model 4100 stethoscopes, is included in Appendix 2.

14.0 Sterilization and Shelf Life

14.1 Sterilization

Sterilization is not applicable. Model 3200 is not labeled nor otherwise represented as sterile, nor is it intended to be sterilized by the user.

14.2 Shelf Life

There is no labeled shelf-life for the device; this requirement does not apply.

15.0 Biocompatibility

15.1 Overview

All of the larger external components of the 3M™ Littman® Electronic Stethoscope, Model 3200 are identical or substantially equivalent to those used in the currently marketed predicate devices (Littmann® Electronic Stethoscope, Model 3000 (K050159) and the Littmann® Electronic Stethoscope, Model 4100 (K051790)), as shown in Table 5.

Moreover, 3M has reviewed all components of the Model 3200 stethoscope that have potential for direct skin contact with either the user and/or patient for biocompatibility with respect to ISO10993-Part 1, *Biological Evaluation of Medical Devices* for limited (≤ 24 hour) skin contact for both patient and/or health care professional exposure. Each component with potential skin contact with either the user or patient was reviewed for possible health concerns.
A copy of 3M's biocompatibility assessment is provided in Appendix 3.

15.2 Conclusions

3M concludes that all of the components of the Model 3200 Stethoscope would have minimal potential for any adverse health concern.

16.0 Software

16.1 Overview

Because Littman® Electronic Stethoscope, Model 3200 contains embedded software, 3M reviewed the ODE/OIVD Document *"Guidance of the Content of Pre-market Submissions for Software Contained in Medical Devices"* issued May 11, 2005. This document requires the completion and submission of Section 2 (Level of Concern) by the manufacturer. Section 3 of the document outlines the documentation required in the pre-market notification submission. The documentation required by Section 3 varies depending on the level of concern established by Section 2. 3M has determined that this embedded software has a minor level of concern, as illustrated in the following paragraphs of this section.

- The device software does not qualify as Blood Establishment computer software.
- The device software is not intended to be used in combination with a drug or biologic.
- The device software is not an accessory to a medical device that has a Major Level of Concern.
- Prior to mitigation of hazards, the failure of the device software would not result in death or serious injury to either a patient or a user of the device because:

    1. The device software does not control a life-supporting or life-sustaining device.
    2. No energy is delivered to the patient. Acoustic energy is delivered to the ears of the healthcare practitioner and is controlled by the embedded software to limit sound output to not exceed [redacted] (b) (4) dB.
    3. The embedded software does not control any treatment delivery. In addition, the Model 3200 electronic stethoscope is not intended to control treatment delivery.
    4. The stethoscope does not provide diagnostic information, but is a diagnostic aid. It amplifies body sounds, which the health professional must interpret to make the diagnosis. The device is used by a trained health professional who uses the device as one part of a physical assessment. The health professional relies on a complete set of assessment tools to arrive at a diagnosis.

5. The Model 3200 electronic stethoscope does not provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary.

- The device software is not an accessory to a medical device that has a moderate level of concern.
- Prior to mitigation of hazards, the failure of the device software would not result in minor injury to either a patient or a user of the device.
- A malfunction of, or a latent design flaw in the device software would not lead to an erroneous diagnosis or to a delay in delivery of appropriate medical care that would likely lead to minor injury. The device itself is but one of the tools used by a health professional to examine and diagnose a patient, it is not a diagnostic device. The health professional arrives at a treatment decision based on their training, experience and information provided from various sources.

Because 3M determined that the Level of Concern for the Model 3200 is "Minor", 3M has provided the documentation listed in Table 8 below, in accordance with the ODE Guidance document.

During the development, the project name for the Model 3200 was "E3000 Plus"; thus many of the referenced reports refer to the Model 3200 as "E3000 Plus".

Table 8 Software Documentation Required in the Premarket Submission

Software Documentation	Requirements for "Minor" Concern	Documentation Reference(s)	
Level of Concern	Required	Minor. The rationale is included above.	N/A
Software Description	Required	E3000 Plus Software Description, Version 1.0 (MBG0851B – Software Description E3000 Plus.doc)	Appendix 4
Device Hazard Analysis	Required	IAD0007 E3100-3200 Risk Assessment Report, Version 1.00 (SSR0850a Risk assessment Report E3000+.doc)	Appendix 5
Software Requirements Specification	Required	M3100-M3200 SRS SW Software Requirement Specification, Version 2.0 (MBG0751C – SRS SW Requirement Specification for E3000 Plus.docx)	Appendix 6
Architecture Design	Not Required	Not Required	N/A

Table 8 Software Documentation Required in the Premarket Submission

Software Documentation	Requirements for "Minor" Concern	Documentation Reference(s)	
Chart			
Software Design Specification (SDS)	Not Required	Not Required	N/A
Traceability Analysis	Required	M3100-M3200 SRS SW Software Requirement Specification, Version 2.0 (MBG0751C – SRS SW Requirement Specification for E3000 Plus.docx) IAD0007 E3100-3200 Risk Assessment Report, Version 1.00 (SSR0850a Risk assessment Report E3000+.doc) E3000 Plus SAS, SW Acceptance Test Specification, Version 1.00 (MBG0802a – SAS SW Acceptance Test Specification for E3000 Plus. Doc)	Appendix 6 Appendix 5 Appendix 7
Software Development Environment Description	Not Required	Not Required	N/A
Validation, Verification and Testing (VV&T)	Required	E3000 Plus SAS, SW Acceptance Test Specification, Version 1.00 (MBG0802a – SAS SW Acceptance Test Specification for E3000 Plus. Doc) Software Validation Report, version 1.00 (MBG0849a – SVR SW Validation Report. docx)	Appendix 7 Appendix 8
Revision Level History	Required	E3000 Plus SRD SW Release Description, Version 8.00 (MBG0837A – SW Release Description E3000Plus.doc)	Appendix 9
Unresolved anomalies (bugs)	Not Required	Not Required	N/A

16.2 Conclusion

Based on the information and supporting data noted above, 3M considers the level of concern to be "Minor". According to ODE/OIVD Document *"Guidance of the Content of Pre-market Submissions for Software Contained in Medical Devices"* issued May 11, 2005, the definition of "Minor" is as follows: "the level of concern in Minor if failures or latent design flaws are unlikely to cause any injury to the patient or operator.

17.0 Electromagnetic Compatibility and Electrical Safety

The 3M™ Littmann® Electronic Stethoscope, Model 3200 was tested for compliance with EMC Standards and FCC Requirements.

In addition, because Littman® Electronic Stethoscope, Model 3200 uses RF wireless technology (Bluetooth, 802.15.1), 3M reviewed the CDRH/OSEL Document *"Radio-Frequency Wireless Technology in Medical Devices, Draft Guidance"* issued January 3, 2007. The Model 3200 has been tested to verify conformance to the Bluetooth Specifications established by Bluetooth Special Interest Group (SIG). 3M anticipates obtaining Bluetooth Qualification prior to marketing the product.

All of the testing and results are summarized in Table 9, with complete reports and certification of testing included in Appendices 9, 10, and 11.

Testing for general safety and compliance with the voluntary EMC standard was conducted by Eurofins, Germany. Eurofins is a Recognized Notified Body for EMC testing and has been accredited as Bluetooth Qualification Test Facility (BQTF) by Bluetooth Qualification Review Board.

Table 9 Electromagnetic Compatibility Testing Summary

Test	Reference Standard	Test Results	Documentation Reference(s)	
Medical electrical equipment. General requirements for basic safety and essential Performance. Collateral standard. Usability	IEC 60601-1-2:2007	Passed	E3000 Plus EMC Design verification protocol (AMI0821a Design Verification Protocol – EMC) EMC Test Report: G0M20810-2051-E-17	Appendix 10
Radio interference characteristics	EN 55022:2006 EN 301489-1 V1.6.1:2005 Subclause 8.2	Passed		
Electrostatic Discharge	EN 61000-4-2: 2006 EN 301489-1 V1.6.1:2005 Subclause 9.3	Passed		
RF-Electromagnetic Field, Immunity (80-2500 MHz)	EN 61000-4-3: 2006 EN 301489-1 V1.6.1:2005 Subclause 9.2	Passed		

Test	Reference Standard	Test Results	Documentation Reference(s)	
50 Hz Magnetic Field	EN 61000-4-8	Passed	E3000 Plus EMC Design verification protocol (AMI0821a Design Verification Protocol – EMC) EMC Test Report: G0M20810-2051-E-17	Appendix 10
RF Power Output, Conducted	47 CFR part 15.247(b) RSS-210 A8.4	Passed	FCC Test report (FCC Rules Parts 15.247, IC Radio Standards RSS-210 Issue 7): G0M20810-2051-P-15 FCC Test report (FCC Rules Parts 15/Subpart B, IC Radio Standards RSS-Gen Issue 2): G0M20810-2051-C-1	Appendix 11
20dB Bandwidth	47 CFR part 15.247(a)(1) RSS-210 A8.1	Passed		
Time of Occupancy (dwell time)	47 CFR part 15.247(a)(1) RSS-210 A8.1	Passed		
Number of Hopping Channels	47 CFR part 15.247(a)(1) RSS-210 A8.1	Passed		
Carrier Frequency Separation	47 CFR part 15.247(a)(1) RSS-210 A8.1	Passed		
Spurious Emission Radiated	47 CFR part 15.247(d) RSS-210 A8.5	Passed		
Band Edge Compliance	47 CFR part 15.247(d) RSS-210 A8.5	Passed		
Radiated Emissions	47 CFR part 15.109 RSS-Gen 7.2.3	Passed		
Bluetooth Qualification	Test Specification for the Bluetooth Wireless Technology Radio layer, Radio Frequency, System Specification 1.2/2.0/2.0+EDR	Passed	Bluetooth Test – Report Report No: G0M20810-2051-BlueT-71	Appendix 12

18.0 Performance Testing – Bench

The 3M™ Littmann® Electronic Stethoscope, Model 3200 was tested for compliance with *"Medical electrical equipment Part 1: General requirements for basic safety and essential performance"* (IEC/EN 60601-1). For the complete report, please refer to Appendix 11.

Table 10 Basic Safety Testing Summary

Test	Reference Standard	Test Results	Documentation Reference	
Medical Electrical Equipment – Part 1: General Requirements for Safety Part 1-6: Usability	IEC 60601-1:2005 IEC 60601-1-6:2006 EN60601-1:2005 (except Biocompatibility, EN10993-1, Bluetooth)	Passed	Certificate Number: SE-56568, issued by Intertek Semko AB Report No: 809546-1	Appendix 13

Devices were subjected to environmental testing as part of design verification testing, as summarized in Table 11. Each device was acoustically tested after the completion of the environmental testing to confirm acoustical performance.

Table 11 Environmental Testing Summary

Test	Reference Standard	Test Result (Pass/Fail)	Documentation Reference(s)	
Cold Storage	EN 60068-2-1:2007	Passed	E3000 Plus Design Verification protocol – mandatory requirements, Version 2.0 (TAD0821a Design Verification protocol – mandatory requirements E3000 Plus) E3000 Plus Design Verification report – Mandatory requirements, Version 1.0 (trh0839a Design Verification report – mandatory requirements E3000 Plus)	Appendix 14
Cold Operating Atmosphere	EN 60068-2-1:2007	Passed		
Dry heat storage atmosphere	EN 60068-2-2:2007	Passed		
Dry heat operating atmosphere	EN 60068-2-1:2007	Passed		
Damp heat, steady state	EN 60068-2-78:2007	Passed		
Change of Temperature	EN 60068-2-1:2007	Passed		
Damp Heat, Cyclic	EN 60068-2-1:2007	Passed		
Vibration, broad band random	EN 60068-2-1:2007	Passed		

19.0 Performance Testing -- Animal

Not applicable. This submission does not contain animal performance testing.

20.0 Performance Testing -- Clinical

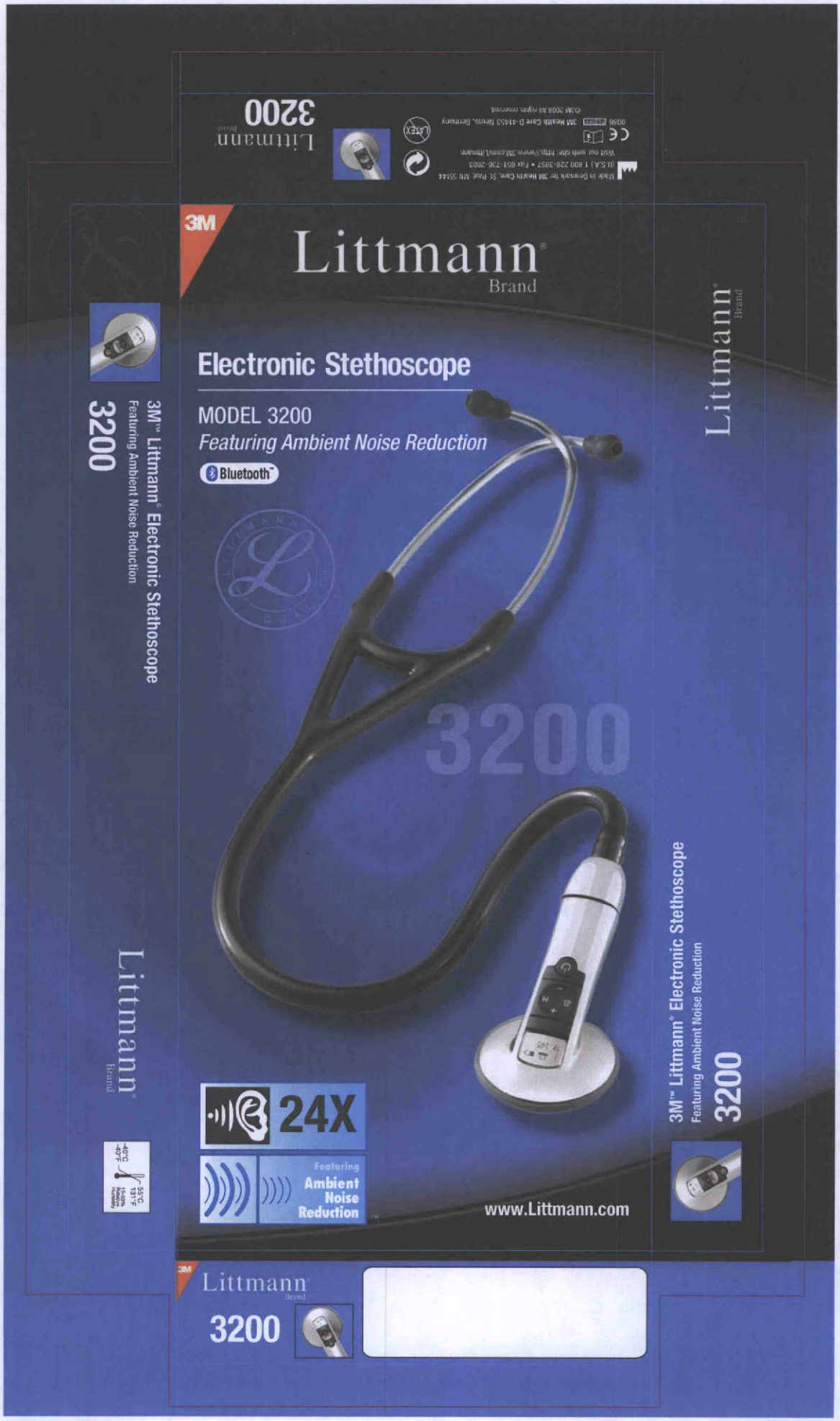
Not applicable. This submission does not contain clinical performance testing.

21.0 Risk Management

3M evaluated 3M™ Littmann® Electronic Stethoscope, Model 3200 using a process compliant with ISO 14971:2007 Risk Management for Medical Devices, and specific procedures and practices outlined by division Standard Operating Procedures.

Th e Model 3200 has completed all risk management activities as identified in the products risk management plan. All known and foreseeable risks, both in normal and fault conditions, along with the overall residual risk, are at an acceptance level. Appropriate methods for monitoring of post production information have been established in the risk management plan.

Please refer to Appendix 15 for the copy of Risk Management.


3M
Littmann
Brand
Electronic Stethoscope
MODEL 3200
Featuring Ambient Noise Reduction
Bluetooth
3200
24X
Featuring
Ambient
Noise
Reduction
www.Littmann.com
3M™ Littmann® Electronic Stethoscope
Featuring Ambient Noise Reduction
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3M™ Littmann® Electronic Stethoscope

Featuring Ambient Noise Reduction

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3M | Littmann®

REF 3200BK27
70-2007-5809-5

GB Electronic Stethoscope
FR Stéthoscope Électronique
DE Elektronisches Stethoskop
IT Stetoscopio Elettronico
ES Fonendoscopio electrónico
NL Elektronische Stethoscoop
SE Elektroniskt Stetoskop
DK elektronisk stetoskop
NO Elektronisk stetoskop
FI Elektroninen stetoskooppi
PT Estetoscópio Electrónico
GR Ηλεκτρονικό Στηθοσκόπιο

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15-93% Relative Humidity

Latex-Free

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EC REP

3M Health Care
D-41453 Neuss, Germany

(01) 5 07 07387

34-8702X-XXXX-X

Made in Denmark for **3M Health Care**, St. Paul, MN 55144-1000

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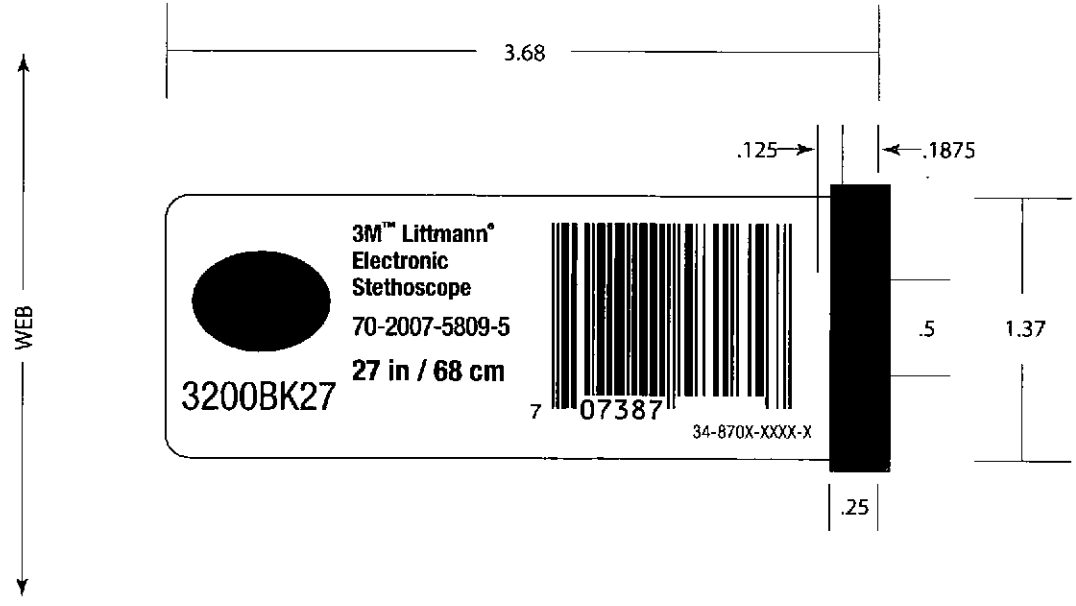
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Stethoscope
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Required Approvers: Hub team members

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E3200 User Guide – English Version

(Cover)

(Fit graphics of package front & copy to front cover)

(Inside Cover)

(Translations for user guide front copy)

(English Section)

(VERY BOLD "English" at top of each page within booklet. Consider black box with white Arial Black text)

3M™ Littmann® Electronic Stethoscope
Model 3200
With Ambient Noise Reduction

Introduction
Congratulations and thank you for choosing the 3M™ Littmann® Electronic Stethoscope Model 3200.

The Model 3200 brings you the very latest in advanced auscultation and wireless electronics technology in a highly ergonometric and easy-to-use format.

The Model 3200's combination of Ambient Noise Reduction technology, frictional noise dampening materials, electronic amplification (conventional bell / diaphragm modes plus an "extended" mode), Bluetooth data transfer, and an all-new user interface takes you to the next level of performance and ease of use.

Whether you are auscultating infant, pediatric or adult patients, in quiet or noisy environments, or picking up difficult-to-hear heart and body sounds, you'll appreciate the technology that's been built into this latest electronic stethoscope bearing the Littmann® brand.

Don't miss the sounds you need to hear!

SAFETY INFORMATION

Please read, understand, and follow all safety information contained in these instructions prior to using this electronic stethoscope. Retain these instructions for future reference.

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Explanation of Safety Related Labels and Symbols

	Indicates Type B Equipment: The equipment provides protection against electrical shock and electrical current leakage. Applied parts are considered to be the complete chestpiece with diaphragm and binaural.
	Consult instructions for use.
IPX4	Protected against splashing liquid (chestpiece only).
	This product contains electrical and electronic components and must not be disposed of using standard refuse collection. Please consult local directives for disposal of electrical and electronic equipment.
LATEX	This product and packaging does not contain natural rubber latex.
AP	Indicates Category AP Equipment. Tested for use with flammable anesthetic mixture with air.

Explanation of Signal Word Consequences

⚠ **CAUTION:**	Indicates a hazardous situation, which, if not avoided, could result in minor injury and/or property damage.
NOTICE:	Indicates a hazardous situation, which, if not avoided, may result in property damage.

⚠ CAUTION

- **To reduce the risks associated with infection** follow all cleaning and disinfecting instructions included in this manual. Establish and follow a cleaning and disinfecting schedule.
- **To reduce the risks associated with very strong electromagnetic fields** avoid using the stethoscope near strong radio frequency signals or portable and/or mobile RF devices. If you hear sudden or unexpected sounds, move away from any radio transmitting antennas.
- **To reduce the risks associated with sharp edges** make sure that the soft sealing eartips are snapped firmly into position as shown in this manual. Use only Littmann replaceable eartips.
- **To reduce the risks associated with an incorrect result** store and operate this stethoscope only as instructed in this manual. As there is no acoustic (non-amplified) mode available with this stethoscope, replace the battery within two hours of the battery life icon beginning to flash in the LCD display. Replace battery with only type AA. Also, do not immerse the stethoscope in a liquid or subject it to any sterilization processes.
- **To reduce the risk associated with an electrical shock** do not use the stethoscope on patients without the stethoscope's diaphragm cover in place

NOTICE

- **The Model E3200 Electronic Stethoscope contains a Bluetooth wireless data link.** This radio frequency data link operates at a frequency of 2.4 GHz using GFSK modulation and with a maximum transmit power of 230 microwatts (0.000230 watts). The maximum radio frequency field strength generated by the stethoscope is below three volts per meter, a level that is considered safe to use with other medical devices. However, if electromagnetic interference is encountered due to the Bluetooth wireless data link, immediately move the stethoscope away from that device and/or turn the Bluetooth feature OFF.
- **To reduce the risks associated with environmental contamination** follow applicable regulations when disposing of this stethoscope. Properly dispose of, or recycle, spent batteries.
- **No modification of this equipment is allowed.** Use only authorized 3M service personnel to repair this stethoscope. Read, understand, and follow all the safety information on the battery package.

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EMC Compliance

FCC Intentional Radiator Certification

3M Littmann Electronic Stethoscope Model 3200

FCC ID: DGFIPD3200

This equipment contains an intentional radiator approved by the FCC under the FCC ID numbers shown above. This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesirable operation.

NO MODIFICATION: Modifications to this device shall not be made without the written consent of the 3M Company. Unauthorized modifications may void the authority granted under Federal Communications Commission rules permitting the operation of this device.

Industry Canada radio frequency rules and regulations

IC: 458A-IPD3200

This Class A digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe A est conforme à la norme NMB-003 du Canada.

EMC compliance Europe

This equipment complies with the EMC requirements of the IEC 60601-1-2.

Intended Use

The 3M™ Littmann® Electronic Stethoscope Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of selective frequency ranges. It can be used on any person undergoing a physical assessment.

Operator Profile

The 3M Littmann® Electronic Stethoscope Model 3200 is designed to be used by anyone who wishes to listen to sounds as described in the Intended Use section above. This manual provides complete information on how to operate the Model 3200 so that no additional operating training is required.

Functional Description

The Model 3200 electronic stethoscope picks up sounds, such as heart and lung sounds, from a patient's body. After amplification and filtering, the sounds are sent to the user through a binaural headset. The stethoscope chestpiece is designed for use with adult, pediatric, and infant patients.

The user interface for the stethoscope includes a 5-button keypad and an LCD display. Sound processing is carried out with the aid of a digital signal processor. Stethoscope power is provided by a single AA battery in the chestpiece. A power management system is included to prolong battery life. Using its Bluetooth wireless link, the stethoscope can exchange audio data with an external device such as a personal computer (PC).

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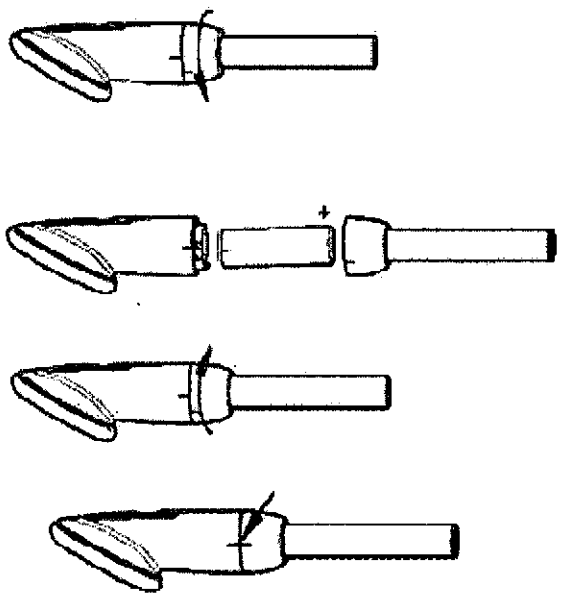
Serial Number
Each Littmann Electronic Stethoscope Model 3200 comes with a unique serial number on the chestpiece for easy identification. Please record your serial number in this manual for future reference:

_____

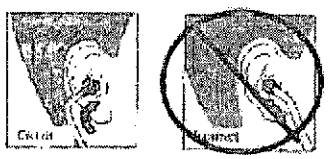
INSTRUCTION FOR USE

1. Insert Battery
Insert AA battery (provided in package) into Stethoscope.



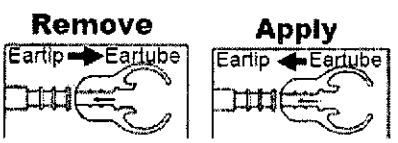
1. Hold chestpiece in one hand while slightly twisting the battery cap approximately 25° counter-clockwise. Remove battery cap.
2. Insert new battery with positive end out (plus sign will be visible in the battery compartment)
3. Remount battery cap, twisting cap approximately 25° clockwise until locked.
4. Make sure the two marks are aligned

2. Position Headset
Eartips should point in a forward direction as you insert them into your ear canals. When ear tips are properly positioned, diaphragm will face towards your body.



Your new Littmann Electronic Stethoscope is designed to give you a very comfortable, acoustically sealed fit. It comes with two sizes of eartips to assure a perfect fit. The large eartips are pre-installed. Smaller eartips are included in package. Please choose the set that is most comfortable for you.

To remove eartips, pull eartips firmly away from eartube. To apply new eartips, push eartip firmly onto eartube to secure.



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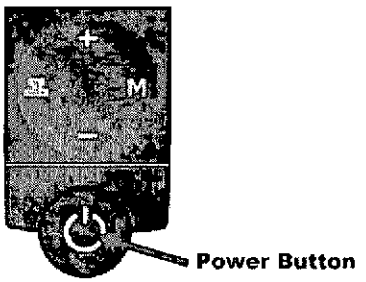
3. Adjust Headset for Comfort

To **reduce spring tension** in the headset, hold each eartube at the bend near the eartips and gradually pull apart until fully extended (180 degrees).

To **increase spring tension**, grasp the headset with one hand where the metal eartubes enter the plastic tubing, and squeeze until the plastic tubing on one eartube touches the other. Repeat as necessary.

4. Turn On / Off

This stethoscope comes equipped with an advanced power management system.



- **Manual Turn On:** Depress and release power button. LCD display will activate, indicating stethoscope is on.
- **Manual Turn Off:** Depress and **hold** power button for two seconds. LCD display will shut off, indicating stethoscope is off.
- **Auto-on with Standby Feature:** After manual turn-on, stethoscope will stay on during use, but switch to a power-saving standby mode after 10 seconds of inactivity. LCD display will display the Littmann® logo during "standby mode." When stethoscope diaphragm or any button is pressed, LCD display settings will reappear and stethoscope will be ready to use. After 30 minutes of non-use, stethoscope will leave "standby mode" and fully power down. You may customize on-time and off-time to meet your own personal needs. See **Custom Configuration** section below.
- **LCD Display Backlight:** Backlight options are available for use at low ambient light levels. By default, depressing and releasing the power button at any time ("on demand") will illuminate the LCD display for 3 seconds.

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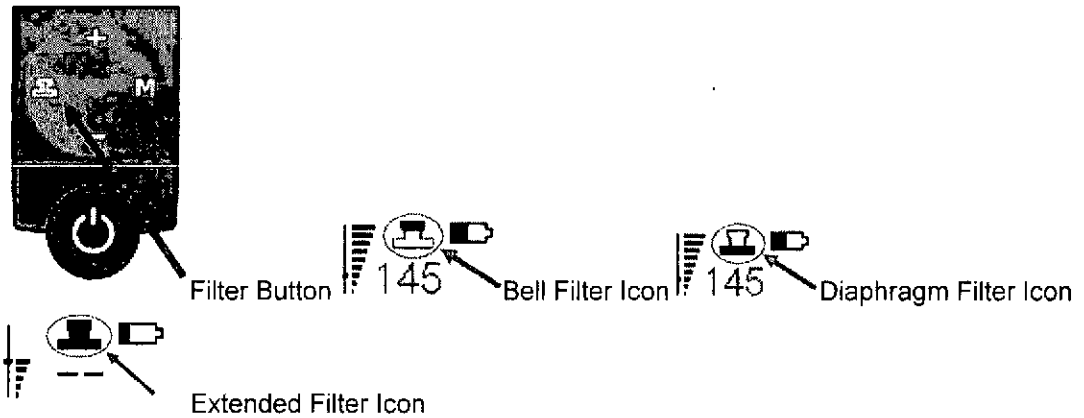
5. Select Filter

This stethoscope comes equipped with three filters: bell (low frequency), diaphragm (high frequency), and "extended" (overlap of bell and diaphragm filters). The default setting is the diaphragm filter. Instructions for changing the default filter setting are given in the **Custom Configuration** section below.

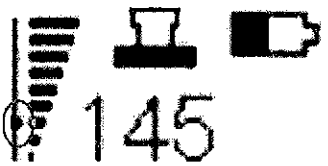
To select filter: Depress and release filter button (as shown in diagram) until desired filter mode appears on the LCD display.



6. Adjust Sound Amplification Level

The Model 3200 sound level can be amplified in 8 increments up to 24X amplification of a non-electronic (cardiology-level) stethoscope. Level 1 is equal to a non-electronic stethoscope. Level 9 is equal to 24X amplification of a non-electronic stethoscope. The greater the amplification, the more bars you will see.

A default start-up amplification level can be set using the instructions provided in the **Custom Configuration** section below. The default setting is marked by the box on the vertical bar shown in the volume icon in the LCD display. The illustration shows a default amplification setting at Level 3.



- **Increase Amplification:** Press (+) button until desired amplification level is achieved
- **Decrease Amplification:** Press (-) button until desired amplification level is achieved

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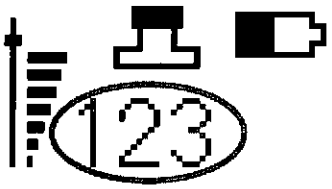
7. Monitor Patient Heart Rate

The Model 3200 detects and displays an acoustic-based heart rate when presented with consistent heart sounds (heart rate variation < 10%). It takes five seconds to compute the initial heart rate and updates are provided every two seconds. Prior to the initial reading, the display shows two dashes (--). For heart rates outside a range of 30-199 bpm, the display will also show two dashes (--).

The acoustic-based heart rate display functions best when the Model 3200 is placed near the apex of the patient's heart. If the heart rate changes from consistent to inconsistent or if there is excessive ambient noise, patient movement or lung sounds during auscultation, the heart rate display number will display two dashes (--).



8. Monitor Battery Life

Battery life is indicated by an icon in the LCD display.

The Model 3200 comes with a AA Alkaline battery. Battery will provide approximately 50-60 hours of continuous use, depending on the frequency of Bluetooth data transfers. In a typical clinical setting, this represents about three months of use.

As the battery life depletes, the icon will change as follows:

= 50 -100% battery life

= 25 – 50% battery life

= 10 – 25% battery life

= 0 – 10% battery life

The battery icon begins to blink when only a few hours of battery capacity remains.

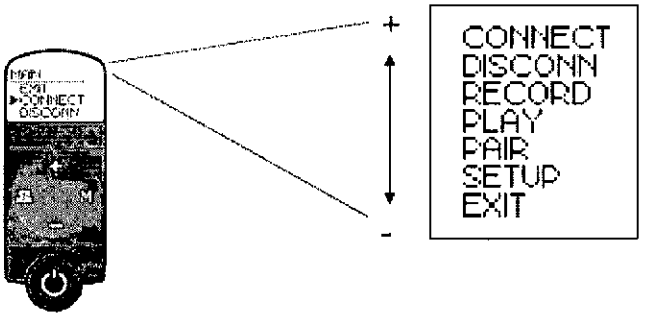
⚠**CAUTION:** When the battery is completely depleted the scope becomes inoperable. No sound will be transmitted without a functioning battery.

IMPORTANT! NiMH (rechargeable) and Lithium batteries may also be used in the Model 3200. However, battery type must be specified to ensure a reliable battery life indication (see **Custom Configuration** section below).

9. Custom Configuration

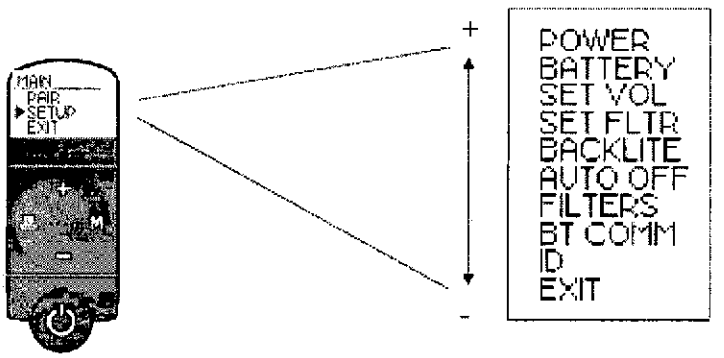
The Model 3200 stethoscope has several operational settings that can be changed using its configuration menu system. Within this menu system, the (+) and (-) buttons are used for scrolling and the (M) button is used for selecting options. The Filter button acts as an "escape" key, used for returning to the previous menu or to the operating mode of the stethoscope.

To access the Main menu: Depress and release the (M) button. The "MAIN" menu will be displayed, with the CONNECT option highlighted (NOTE: Only 3 options will be visible at a time. All options can be viewed in sequence upon scrolling with either the (+) or (-) buttons):



To leave the Main menu: Use the (M) button to select the "EXIT" option. This will return the stethoscope to its normal operating state.

To enter the Setup Menu: Use the (-) button to scroll down the list of Special Functions until "SETUP" is highlighted. Select the Setup option by pressing and releasing the (M) button. This will display the following menu:



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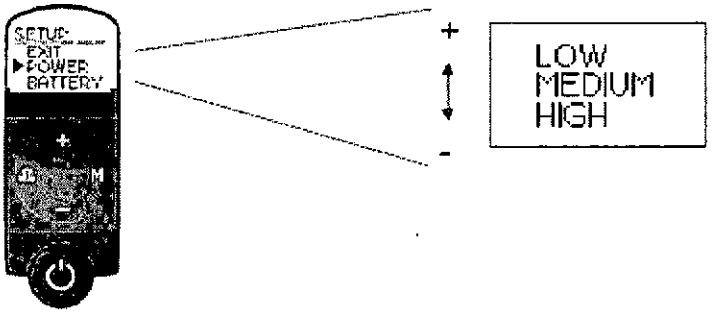
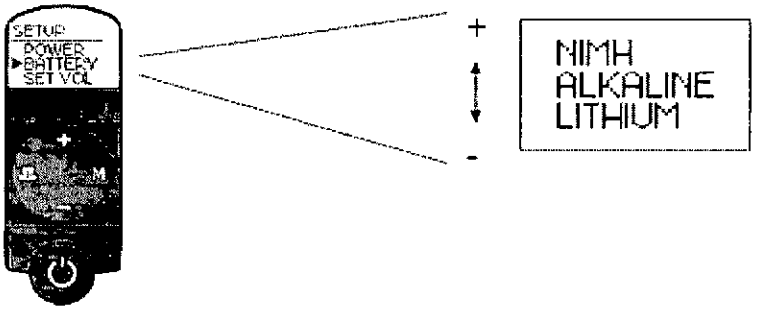
To set Power: Select the "POWER" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of power settings. Press and release the (M) button to select a setting.



The power settings provide different degrees of power consumption. In general, the longer the stethoscope remains in an active mode, the greater its power consumption. The factory default is the LOW level. (NOTE: The Auto Off power management feature is further described below)

	Auto Off enabled			Auto Off disabled		
Power Level	Low	Medium	High	Low	Medium	High
Power On Time	10 sec	20 sec	30 sec	3 min	5 min	7 min
Power Off Time	30 min	2 hr	5 hr	30 min	2 hr	5 hr
Backlight	3 sec	5 sec	5 sec	3 sec	5 sec	5 sec

To specify the battery type: Select the "BATTERY" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of battery types. The LITHIUM battery is a non-rechargeable cell especially recommended for low-temperature operation of the stethoscope. The NIMH battery is rechargeable (external charger required). Press and release the (M) button to select a setting. The factory default is the ALKALINE battery.



To specify the preset (default) volume level: Select the "SET VOL" option in the Setup menu. Press and release the (M) button to select the current volume level as default. The factory default is level 3.

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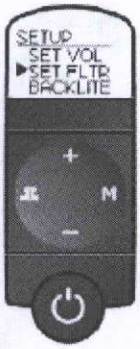
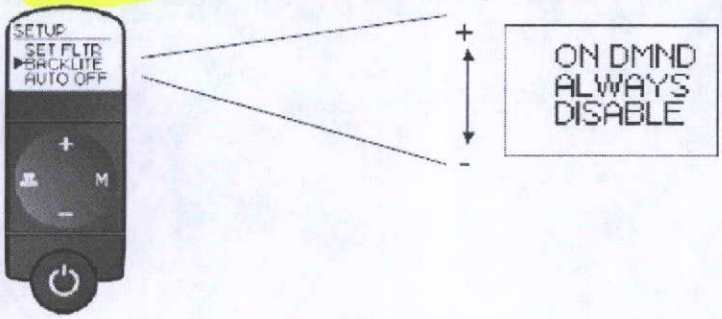
To specify the preset (default) filter setting: Select the "SET FLTR" option in the Setup menu. Press and release the (M) button to select the current filter as default. The factory default is the diaphragm filter.



To specify Backlighting duration: Select the "BACKLITE" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of options. Press and release the (M) button to select. The factory default is "ON DMND" ("On Demand" - backlight will illuminate for three seconds by depressing and releasing the power button). The "DISABLE" option disables the backlight at all times and will conserve power. The "ALWAYS" option will illuminate the backlight at all times at a reduced level while the stethoscope is powered on and not in standby mode.



To select Auto Off power management: Select the "AUTO OFF" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of options. Press and release the (M) button to select. The factory default is "ENABLE".

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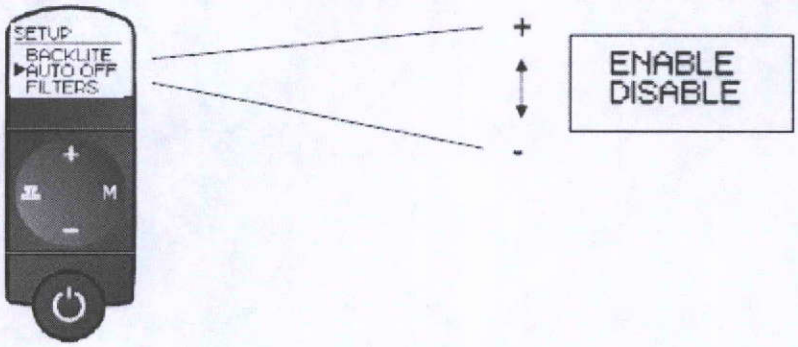
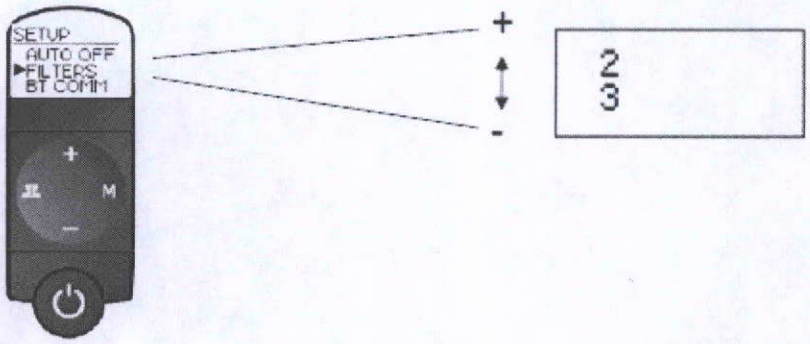
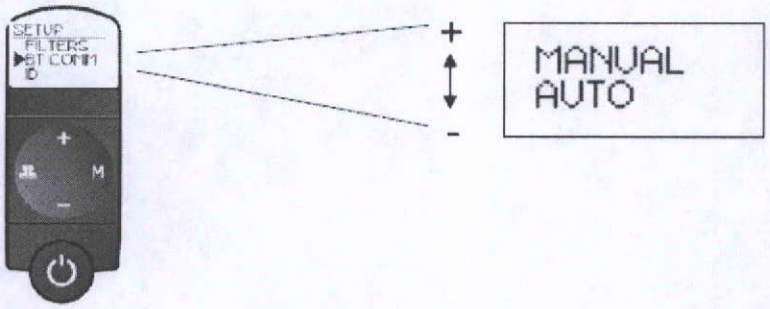


The Auto On feature powers on the stethoscope from its standby mode when contact is detected with the diaphragm. With the Auto Off feature, power is turned off when user activity is no longer detected (the stethoscope returns to its standby mode after a delay equal to the Power On time.)

To set number of frequency ranges: Select the "FILTERS" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of options. Option "2" supports toggling between two filters (bell and diaphragm) with the FILTER button. With option "3" the FILTER button cycles the stethoscope through each of three filter modes (bell, diaphragm, and extended). Press and release the (M) button to select. The factory default is three filters.



To specify Bluetooth mode: Select the "BT COMM" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of options. The MANUAL option means that the Bluetooth link can be used for data transfers but requires user activation. The AUTO option means that the Bluetooth link is powered whenever the stethoscope is in an active mode. Press and release the (M) button to select an option. The factory default is "MANUAL."



To obtain model and software version information: Select the "ID" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of reference numbers. Press "M" to return to the operating mode of the stethoscope.

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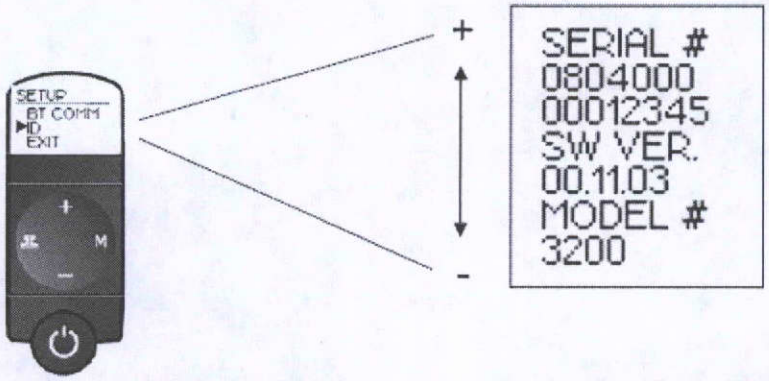


To leave the Setup menu: Use the (M) button to select the "EXIT" entry and return to the operating mode of the stethoscope.

11. Using the Bluetooth Interface

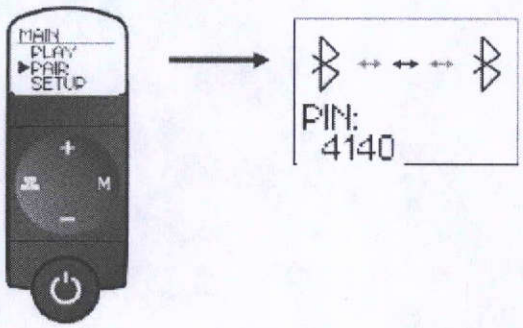
The Bluetooth interface provides a means of exchanging audio data with external devices such as a Bluetooth-enabled PC. Audio data can be sent in near real time, permitting their visual presentation, recording, and analysis by applications software complying with communication protocols used by the Model 3200 stethoscope.

IMPORTANT! The Model 3200 uses a Class 2 Bluetooth link, with a maximum range of 10m.

In order to transfer data between two Bluetooth devices, they must be "paired" electronically. This requires user operations to be performed on both devices. The Model 3200 can be paired with up to 8 devices at a time. However, it cannot pair with a second Model 3200 stethoscope.

How to pair the Model 3200 with an external device:

1. **Initiate pairing process**: Depress and release the (M) button. The "MAIN" menu will be displayed. Use the (-) button to scroll down the list of Actions until "PAIR" is highlighted. Select this option by pressing and releasing the (M) button. The LCD screen will signal that pairing is in progress with the following animated display:



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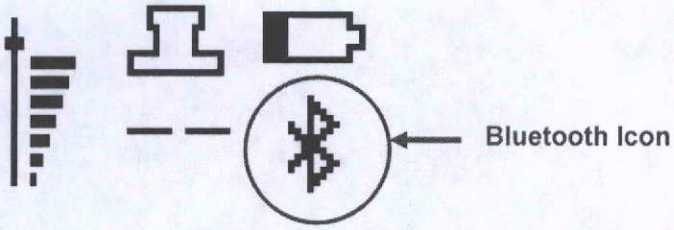
Note: The Personal Identification Number (PIN) for Bluetooth pairing is displayed in the lower left-hand corner of the LCD screen

2. **Select Model 3200 stethoscope on external Bluetooth device**: Consult application software for details, process may vary by computer platform utilized. If pairing is successful, the LCD display of the Model 3200 will show a flashing Bluetooth icon and the stethoscope will be ready for wireless operations.



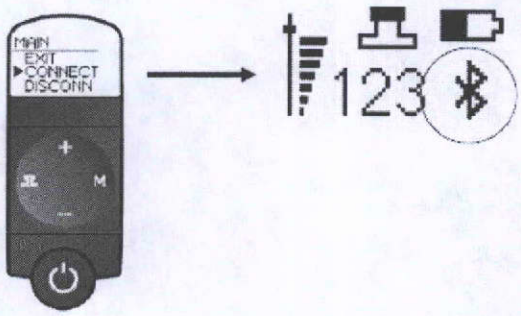
If the Bluetooth connection with the external device is subsequently lost or times out, the Bluetooth icon will disappear from the LCD display.

When connected by a Bluetooth link, external, Bluetooth-enabled devices can take control of the display and keypad of the Model 3200 stethoscope. They can also transfer audio (ex. voice prompts) to the Model 3200 headset. During audio transfers to the stethoscope, a tone will be sounded every 8 seconds.

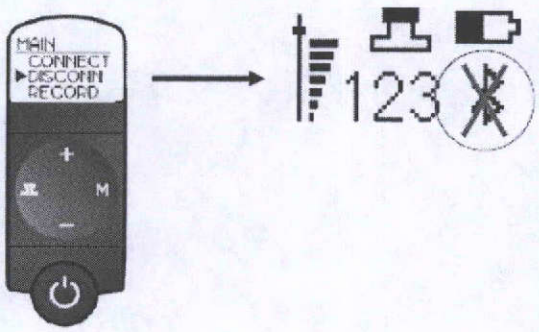
How to transfer real-time data to an external device:

1. Ensure the Model 3200 is paired with the external device.

2. Depress and release the (M) button. The "MAIN" menu will be displayed with the "CONNECT" option highlighted. Select this option by pressing and releasing the (M) button. The LCD screen will signal that the Bluetooth link is active. The stethoscope will automatically return to operational status. Consult application software for details on initiating real-time transfer, the process may vary by computer platform utilized.



A Bluetooth connection with the stethoscope will automatically be ended if no data transfers occur in a 90 second period. Alternatively, they can be manually ended using the "DISCONN" (disconnect) option of the Main menu.



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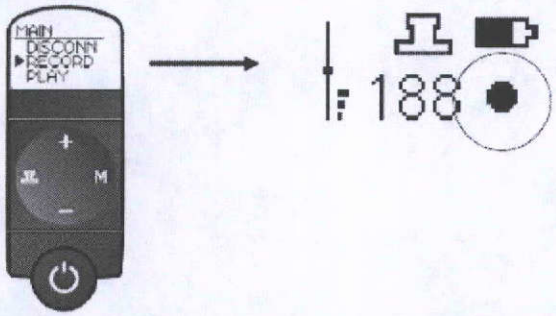
12. Using Onboard Recording

Onboard recording provides a means to acquire and play an auscultation sound track. This track can be uploaded to an external device using the Bluetooth link and the software accompanying the Model 3200 stethoscope.

How to record a sound track:

1. **Enter the recording mode:** Depress and release the (M) button. The "MAIN" menu will be displayed. Use the (-) button to scroll down the list of options until "RECORD" is highlighted.

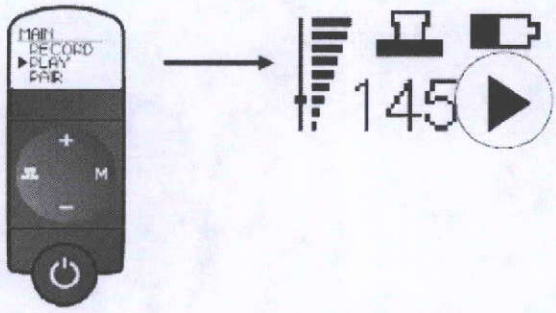
2. **Begin the recording**: Depress and release the (M) button. The stethoscope will start recording and the LCD screen will show a "recording" icon.



3. **End the recording**: Depress and release the (M) button. The stethoscope will stop recording and the recording icon will disappear from the LCD display. If the time between the beginning and ending of the recording session is greater than 29 seconds, only the last 29 seconds will be saved.

How to play back a sound track:

1. **Enter the playback mode:** Depress and release the (M) button. The "MAIN" menu will be displayed. Use the (-) button to scroll down the list of options until "PLAY" is highlighted. Select this option by pressing and releasing the (M) button. The LCD screen will show a "PLAY" icon and the sound track will "loop" continuously.



2. **End playback**: Depress and release the (M) button. The stethoscope will stop playing the sound track and will return to its previous operational mode.

Uploading a sound track to an external device:

1. **Prepare the external device to receive the sound file.** Start the Model 3200 software program on the external device.

2. **Initiate a Bluetooth connection with the Model 3200.** Use the same procedure as described above for initiating real-time data transfers to an external device.

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3. **Return to operating mode:** When transmission of the sound track is complete, the Bluetooth link to the external device can be disconnected and the Model 3200 will return to its previous operating mode.

13. Other Operating Considerations

Operating range is -22° to 104°F (-30° to 40°C), 15 to 93% relative humidity.
Storage and transport range is -40° to 131° F (-40° to 55°C), 15 to 93% relative humidity.

To extend the life of your stethoscope, avoid extreme heat, cold, solvents and oils. Remove the battery whenever the stethoscope will not be used for several months.

If you plan to use the stethoscope below 0°F (-18°C) you should use a lithium battery to insure proper function.

Failure to follow care and maintenance recommendations could result in damage to the internal components of the Littmann Electronic Stethoscope. Internal damage could cause malfunction of the product, ranging from a slight decrease in auditory response to complete failure of the product.

If you experience any problems with the electronic stethoscope, do not attempt to repair it yourself. Please notify our 3M Health Care Service Center for directions on shipping and receiving.

MAINTENANCE & WARRANTY

Cleaning
Cleaning of stethoscope should be done between each patient use.

Cleaning the Chestpiece
Under normal conditions, it is unnecessary to remove the diaphragm for cleaning. The diaphragm can easily be cleaned by using an alcohol wipe. If however, it is necessary to remove the diaphragm, carefully follow the instructions below:

- **Diaphragm Removal**: With diaphragm side up, using a thumbnail, lift the underside portion of the diaphragm out of its designated groove, and peel it off of the chestpiece. The groove that holds the diaphragm in place can be cleaned by sliding the edge of an alcohol swab around the groove. All parts of the chestpiece can be wiped down with alcohol. IMPORTANT: The stethoscope should not be immersed in any solution. Excess liquid used in the cleaning process may result in moisture getting into the internal components.

- **Diaphragm Reassembly**: Once the diaphragm is completely dry, insert the diaphragm into the groove of the rim, starting at one point, and run your finger around the diaphragm until it is seated back in the groove.

Cleaning Other Parts of the Stethoscope
Eartips, eartubes, plastic tubing and chestpiece can be wiped clean with alcohol. Eartips may be removed for a more thorough cleaning.

***NOTICE*: Do not immerse the stethoscope in any liquid or subject it to any sterilization process!**

Service & Warranty Program
Your Littmann Electronic Stethoscope comes with the finest service and warranty policy in the industry. The Littmann Electronic Stethoscope Model 3200 is warranted against any defects in material and manufacture for a period of two years. If a material or manufacturing defect is discovered during the warranty period, repairs will be made without charge upon the return of the instrument to 3M, except in cases of obvious abuse or accidental damage.

For Maintenance or Repair Services

Please include your name, physical address, e-mail address, and phone number inside with your stethoscope.

In the U.S.A., send your stethoscope directly to:

3M Health Care Service Center
3M Bldg 502-1W-01
3350 Granada Ave N
Suite 200
Oakdale, MN 55128
1-800-292-6298

NOTE: **The official document is electronic. Paper copies are uncontrolled.**

In Canada, send your stethoscope directly to:

3M Health Care Service Centre
3M Canada, Inc.
80 Enterprise Drive South
London, Ontario
Canada, N6N1C2
1-800-563-2921

Outside of the U.S.A. and Canada, contact your local 3M subsidiary for maintenance and repair information.

APPENDIX

Declaration – Electromagnetic Emissions		
The 3M Littmann® Electronic Stethoscope, Model 3200, is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 3200 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment –guidance**
RF emissions CISPR 11	Group 2	Model 3200 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	Model 3200 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Declaration – electromagnetic immunity

The 3M Littmann® Electronic Stethoscope, Model 3200, is intended for use in the electromagnetic environment specified below. The customer or the user of Model 3200 should assure that it is used in such an environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for supply lines ± 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial magnetic field or hospital environment
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycle 70 % UT (30 % dip in UT) for 25 cycle < 5% UT (>95 % dip in UT) for 5 sec	Not applicable	

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Declaration – electromagnetic immunity - continued

The 3M Littmann® Electronic Stethoscope, Model 3200, is intended for use in the electromagnetic environment specified below. The customer or the user of Model 3200 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Model 3200 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	$d = 1{,}2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1{,}2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range, [b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 3200 is used exceeds the applicable RF compliance level above, the Model 3200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 3200.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the 3M™ Littmann® Electronic Stethoscope Model 3200

The Model 3200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 3200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 3200 as recommended below, according to the maximum output of the communications equipment.

Rated maximum output power of transmitter, P [W]	**Separation distance according to frequency of transmitters, d [m]**		
	150 kHz to 80 MHz	80 Mz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Revision History

<<Document History>>

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3M | Littmann®

REF 3000GR
70-2007-5683-4

Electronic Stethoscope Gray

73 cm / 29 in

3	1 /	3 /	B.U. 3

LOT

(01) 5 07 07387 58039 6

3M, St. Paul, MN 55144-1000

38-9001-9203-0

Made in U.S.A. by 3M Healthcare

3M | Littmann®

REF 3000GR
70-2007-5683-4

Electronic Stethoscope Gray

73 cm / 29 in

3	1 /	3 /	B.U. 3

LOT

(01) 5 07 07387 58039 6

3M, St. Paul, MN 55144-1000

38-9001-9203-0

Made in U.S.A. by 3M Healthcare

722

3M™ Littmann® Electronic
Stethoscope Model 3000

3000GR Gray

70-2007-5683-4

29 in. / 73 cm

7 07387 58039 1

225

Made in Denmark for **3M Health Care**, St. Paul, MN 55144
(U.S.A.) 1 800 228-3957 • Fax 651 736-2803
Visit our web site: http://www.3M.com/Littmann

CE ⚠ Attention, see instructions for use.
0086 EC REP **3M Health Care** D-41453 Neuss, Germany

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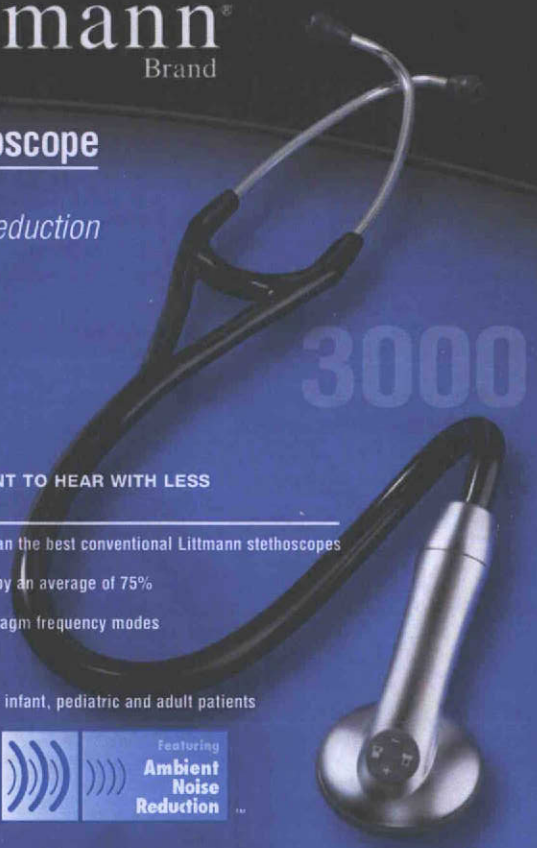
3M

Littmann® Brand

Electronic Stethoscope

MODEL 3000
with Ambient Noise Reduction



AMPLIFY THE SOUNDS YOU WANT TO HEAR WITH LESS DISTRACTING AMBIENT NOISE

- Amplification up to 18 times greater than the best conventional Littmann stethoscopes
- Reduction of unwanted ambient noise by an average of 75%
- Easy to switch between bell and diaphragm frequency modes
- Lightweight and well-balanced
- Versatile chestpiece can accommodate infant, pediatric and adult patients
- Ergonomic, single-button operation
- Uses one AAA battery

Featuring Ambient Noise Reduction™

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English

3M™ Littmann® Electronic Stethoscope Model 3000 *with Ambient Noise Reduction*

Congratulations and thank you for choosing the 3M™ Littmann® Electronic Stethoscope Model 3000 *with Ambient Noise Reduction*, the next generation stethoscope that offers the very latest in advanced auscultation technology.

This powerful, electronic stethoscope provides the superior acoustic sensitivity users have come to expect from the Littmann brand, **and more.** It includes state-of-the-art amplification and filtering systems, ideal for picking up difficult-to-hear heart and other body sounds. It features ambient noise reduction technology (patent pending) that reduces an average of 75% of distracting room noise. The versatile chestpiece can accommodate infant, pediatric and adult patients, and it is ergonomically designed for easy hand manipulation and patient comfort.

Powered by a single AAA battery, the stethoscope is conveniently controlled by a single button on top of the chestpiece. Amplification, up to 18 times greater than the best conventional scopes, and an advanced filtering system providing two frequency modes (standard bell and diaphragm) allow outstanding heart and lung auscultation.

Because of the unique design of its diaphragm, the Model 3000 can be used comfortably on all body types and sizes. The eartubes are capped with 3M™ Littmann® Snap Tight Soft-Sealing Eartips for excellent acoustic seal and comfortable fit. They, and more importantly, the patented ambient noise reduction technology internal to the chestpiece, significantly reduce distraction from unwanted room noise, greatly enhancing overall utility.

With its ergonomic design, state-of-the-art amplification and filtering systems, and ambient noise reduction technology, the Littmann Electronic Stethoscope Model 3000 is a powerful, effective tool for health care professionals. Most of all, know that the Model 3000 carries the Littmann brand name, the name known worldwide for unsurpassed quality. As a trusted leader in auscultation technology, the Littmann brand is your assurance of acoustic superiority, innovative design, and exceptional performance.

The following symbols are applicable to this device:

- ⚠ • Attention, see instructions for use.
- 🚶 • Indicates Type B Equipment: The equipment provides protection against electrical shock and electrical current leakage.
- **IPX4** • Protected against splashing liquid (chestpiece only).
- (LATEX) • This product and package do not contain natural rubber latex.

Each Littmann Electronic Stethoscope Model 3000 has a serial number beginning with the letter "R".

Indications:

This device is intended for medical diagnostic purposes only. It can be used for the amplification of faint heart, lung, and other body sounds as well as normal auscultation and selective frequency filtering. This product is not designed, sold, or intended for use except as indicated.

⚠ Caution:

Failure to follow the directions in this manual could result in damage to the device or possible injury to the user.

Failure to follow general use and maintenance recommendations could result in damage to the internal components of the Littmann Electronic Stethoscope. Internal damage could cause malfunction of the product, ranging from a slight decrease in auditory response to complete failure of the product.

- Stethoscope not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Use only AAA alkaline batteries. Carefully follow all cautions, warnings, and instructions on the battery package. When the Low Battery Indicator Tone is heard, replace the battery within two hours. There is no acoustic (non-amplified) mode available in the Littmann Electronic Stethoscope.
- The Littmann Electronic Stethoscope has been tested to be resistant to both electromagnetic fields (EMI) and electrostatic discharge (ESD). However, it may be susceptible to very strong radio frequency signals or portable and/or mobile RF devices. When using your stethoscope, if you hear sudden or unexpected sounds, you may be in close proximity to a strong radio transmitter. If this should occur, move away from the radio's transmitting antenna.
- Do not immerse the stethoscope in any liquid or subject it to any sterilization processes.
- At the end of this device's useful life, dispose or recycle in accordance with your local, state, and governmental regulations.
- Refer to appendix for information relating to electromagnetic compatibility testing.
- If you experience any problems with the Littmann Electronic Stethoscope, do not attempt to repair it yourself. Please notify the 3M Health Care Service Center at 1-800-292-6298 for directions on shipping and receiving.

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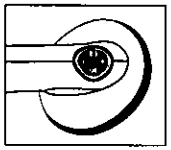
Instructions for Use:

The stethoscope is controlled by a single button on the top of the chestpiece and has four activation points identified as follows:



Button symbol	Function
	Bell filter button Single Tone
	Diaphragm filter button Double Tone
+	Increase volume button (Single tone representing volume increase each time button depressed)
—	Decrease volume button (Single tone representing volume decrease each time button depressed)

Turning on the Stethoscope

The device may be activated by pushing one of the two filter-mode button

or .

(The specific identifying filter tone will be heard upon activation)

Operation

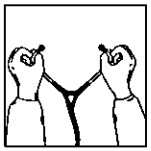
Select the frequency mode desired for auscultation by pushing either the bell or diaphragm filter symbol (this is accomplished when activating the stethoscope initially). Adjust the volume to the desired level by pushing either the plus or minus symbol. At the 4th volume level, the stethoscope is set to the approximate gain of a typical acoustic stethoscope.

You can change the preset volume level by holding down the volume button at the desired volume until you hear a double tone signal. The stethoscope will start at that volume level each time the scope is turned on until you program it differently. Changing the volume during auscultation will not affect the preset volume setting you have established.

Auscultate as you would using an acoustic stethoscope. It is important to find a comfortable grip that allows you to hold the stethoscope in a secure but relaxed manner. Use the bell and diaphragm modes to accentuate or attenuate different heart and body sounds. Low frequency sounds have a tendency to mask or obscure the high frequency sounds. Adjust volume control as necessary.

Headset Positioning

Your new Littmann Electronic Stethoscope is designed to give you a very comfortable, acoustically sealed ear fit. Notice that the eartubes are permanently set at an angle to accommodate the typical anatomy of the ear canal. The eartips should point in a forward direction as you insert them into your ear canals.



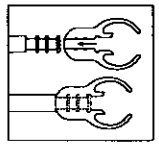
Reduce Tension

To reduce spring tension in the headset, hold each eartube at the bend near the eartip and gradually pull apart until fully extended (180 degrees).

Increase Tension

To increase spring tension, grasp the headset with one hand where the eartubes enter the plastic tubing and squeeze until the plastic tubing on one eartube touches the other. Repeat as necessary.

For maximum acoustic performance, comfortable patented Littmann Soft-Sealing Eartips are provided with your stethoscope.



The stethoscope utilizes a unique design for attaching the eartip to the eartube. The eartips are pushed on to the end of the eartube and snapped tight. To remove, pull firmly on the eartip.

Additional Littmann eartips are available. To order, contact your Littmann Stethoscope distributor or the 3M Health Care Service Center.

Turning Off the Stethoscope

The stethoscope will automatically turn itself off after 3 minutes of no button activation. You can also turn the scope off manually by depressing either filter mode button and holding it down until you hear a diminishing triple tone.

Battery Life

The battery will last for approximately 200 hours of continuous use. In a typical clinical setting, this represents about six months. When the Low Battery Indicator Tone is heard, sufficient battery power remains for approximately 2 hours of normal auscultation activities. When the battery is completely depleted the scope becomes inoperable. It is important to remember that there is no acoustic (non-amplified) mode available in the Littmann Electronic Stethoscope. When the battery is finally exhausted, the stethoscope will not operate.

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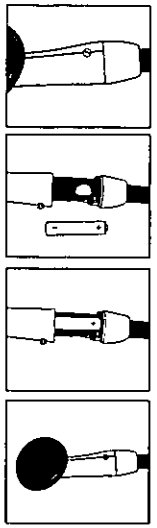
Battery Replacement



To insert or replace the battery, use a coin to loosen the screw on the underside on the neck of the chestpiece and slide open the battery compartment. Remove an old battery by pushing through the slot on the backside of the battery compartment. Insert a fresh battery with the positive end toward the eartubes (the plus sign will be visible in the battery compartment after insertion). Slide the compartment closed and tighten the locking screw.

One battery is enclosed for use with the Littmann Electronic Stethoscope.

Use AAA alkaline batteries only (IEC LR03, 1.5V). Carefully follow all instructions and warnings on the battery label and package.

Remove the battery when the stethoscope will not be used for several months.

General Use and Maintenance

Cleaning The Chestpiece

Under normal conditions, it is unnecessary to remove the diaphragm for cleaning. The diaphragm can easily be cleaned by using an alcohol wipe. If, however, it is necessary to remove the diaphragm, carefully follow the instructions below.

Diaphragm Removal

With diaphragm side up, using a thumbnail, lift the underside portion of the diaphragm out of its designated groove, and peel it off of the chestpiece. The groove that holds the diaphragm in place can be cleaned by sliding the edge of an alcohol swab around the groove. All parts of the chestpiece can be wiped down with alcohol. IMPORTANT: The stethoscope should not be immersed in any solution. Excess liquid used in the cleaning process can result in moisture getting into the internal components.

Diaphragm Reassembly

Once the diaphragm is completely dry, insert the diaphragm into the groove of the rim, starting at one point, and run your finger around the diaphragm until it is seated back in the groove.

Other Considerations

- To extend the life of your stethoscope, avoid extreme heat, cold, solvents and oils.
- Eartips, eartubes, plastic tubing and chestpiece can be wiped clean with alcohol.
- Do not immerse the stethoscope in any liquid or subject it to any sterilization process.
- Eartips can be removed for a more thorough cleaning.
- Remove the battery whenever the stethoscope will not be used for several months.
- Operating range 32° to 122°F (0 to 50°C), 15 to 95% relative humidity.

Failure to follow care and maintenance recommendations could result in damage to the internal components of the Littmann Electronic Stethoscope. Internal damage could cause malfunction of the product,

ranging from a slight decrease in auditory response to complete failure of the product.

If you experience any problems with the electronic stethoscope, do not attempt to repair it yourself. Please notify our 3M Health Care Service Center for directions on shipping and receiving.

Littmann Stethoscope Service and Warranty Program

Your Littmann Electronic Stethoscope comes with the finest service and warranty policy in the industry. The Littmann Electronic Stethoscope Model 3000 is warranted against any defects in material and manufacture for a period of two years. If a material or manufacturing defect is discovered during the warranty period, repairs will be made without charge upon the return of the instrument to 3M, except in cases of obvious abuse or accidental damage.

For maintenance or repair services in the U.S.A., send your stethoscope directly to:

3M Health Care Service Center
3M Bldg 502-1W-01
3350 Granada Ave N
Suite 200
Oakdale, MN 55128
1-800-292-6298

Include your name, address, and phone number inside with your stethoscope.

In Canada:
3M Health Care Service Centre
3M Canada Inc.
80 Enterprise Drive South
London, Ontario
Canada N6N1C2
1-800-563-2921

Outside of the U.S.A. and Canada, contact your local 3M subsidiary for maintenance and repair information.

Appendix:

Table 201

Declaration – Electromagnetic Emissions		
The 3M Littmann® Electronic Stethoscope, Model 3000, is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 3000 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	Model 3000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Model 3000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Table 202

Declaration – Electromagnetic Immunity			
The 3M Littmann® Electronic Stethoscope, Model 3000, is intended for use in the electromagnetic environment specified below. The customer or the user of Model 3000 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Electrostatic discharge (ESD IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30 %
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for supply lines ± 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycle 70 % U_T (30 % dip in U_T) for 25 cycle < 5% U_T (>95 % dip in U_T) for 5 sec	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 204

Declaration – Electromagnetic Immunity (Continued)			
The 3M Littmann® Electronic Stethoscope, Model 3000, is intended for use in the electromagnetic environment specified below. The customer or the user of Model 3000 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Model 3000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	$d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range,[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Model 3000 is used exceeds the applicable RF compliance level above, the Model 3000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 3000.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 206

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the 3M™ Littmann® Electronic Stethoscope Model 3000

The Model 3000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 3000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 3000 as recommended below, according to the maximum output of the communications equipment.

Rated maximum output power of transmitter, P [W]	Separation distance according to frequency of transmitters, d [m]		
	150 kHz to 80 MHz	80 Mz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

FOR PRINTER USE ONLY
This barcode symbol was produced using a bar width adjustment of -0.0025. If this does not meet the needs of the printing process or equipment to be used, the printer is responsible to recreate the file using the appropriate bar width adjustment while meeting 3M quality requirements.

Artwork #: 38-9018-8457-7
Date: 12/20/06
Author: S Barker
Supersedes: 38-9018-8068-2
Pkg. Spec. Reference: 34-7000-2841-1
Structure: PC

SCALE: 1 Inch
artwork prints 4 color

3M™ Littmann® Electronic Stethoscope
Model 4100 With Ambient Noise Reduction

LOT

Electronic Stethoscope Model 4100WS Black

Made in Denmark for **3M Health Care**, St. Paul, MN 55144-1000

27 in • 68 cm **1 each / Box**

38-9018-3636-1

3 Each
QTY. B.U.

4100WS

3M I.D. NO.
70-2007-4477-2

CE 0086

LOT

(01) 5 07 07387 56529 4

Artwork Number:	**38-9018-3636-1**
Date:	**8-16-04**
Author:	**R Myhre**
Supersedes:	**Not Applicable**
Pkg. Spec. Reference:	**34-7057-1116-5**
Structure:	**MC PP**

SCALE: **1 Inch**

all artwork prints black

FOR PRINTER USE ONLY
This barcode symbol was produced using a bar width adjustment of -0.008. If this does not meet the needs of the printing process or equipment to be used, the printer is responsible to recreate the file using the appropriate bar width adjustment while meeting 3M quality requirements.

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3M™ Littmann® Electronic Stethoscope Model 4100

4100 Black

70-2007-4475-6

27 in. / 68 cm

7 07387 56528 2

Artwork #:	**38-9018-3637-9**
Date:	**8-16-04**
Author:	**R Myhre**
Supersedes:	**N/A**
Pkg. Spec. Reference:	**34-7057-1082-9**
Structure:	**PC label**

SCALE: **1 Inch**

Black

FOR PRINTER USE ONLY

This barcode symbol was produced using a bar width adjustment of -0.008. If this does not meet the needs of the printing process or equipment to be used, the printer is responsible to recreate the file using the appropriate bar width adjustment while meeting 3M quality requirements.

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Made in Denmark for **3M Health Care**, St. Paul, MN 55144
(U.S.A.) 1 800 228-3957 • Fax 651 736-2803
Visit our web site: http://www.3M.com/Littmann

CE ⚠ Attention, see instructions for use.
0086 EC REP **3M Health Care** D-41453 Neuss, Germany

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38-9018-8322-3

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3M

Littmann®
Brand

Electronic Stethoscope

MODEL 4100
with Ambient Noise Reduction

4100

AMPLIFY *AND* RECORD THE SOUNDS YOU WANT TO HEAR WITH LESS DISTRACTING AMBIENT NOISE

- Amplification up to 18 times greater than the best conventional Littmann stethoscopes
- Reduction of unwanted ambient noise by an average of 75%
- Recording and playback capability
- Playback capability at normal or half-speed
- Easy to switch between frequency modes: bell, diaphragm, and extended range
- Heart rate display
- Versatile chestpiece can accommodate infant, pediatric, and adult patients
- Uses two AAA batteries

Featuring Ambient Noise Reduction

Artwork No.:	**38-9018-8322-3**
Date:	**12/20/05**
Author:	**S Barker**
Supersedes:	**38-9018-6521-2**
Pkg Spec Ref:	**34-7058-5474-2**
Structure:	**Booklet Cover**

Scale: |+++++++++| **1 Inch**
all artwork prints 4 color process

753

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(English)

3M™ Littmann® Electronic Stethoscope Model 4100

Congratulations on the purchase of your new Littmann Electronic Stethoscope Model 4100, the next generation electronic stethoscope that offers the very latest in advanced auscultation technology and now features ambient noise reduction technology (patent pending) that reduces an average of 75% of distracting room noise.

This powerful, state-of-the-art electronic stethoscope provides superior acoustics. With amplification up to 18 times greater than the best conventional stethoscopes, the Model 4100 is specially designed to pick up difficult-to-hear heart and other body sounds without amplifying sounds you don't want to hear.

Three frequency modes are available for optimal heart and lung auscultation: Bell, Diaphragm and Extended Range.

The Model 4100 offers recording, storage and playback capabilities using six separate soundtracks. Instant playback is available at normal and half speed. Additionally, the Model 4100 provides infrared data transmission of recorded sounds to another Model 4100, an IBM-compatible PC, Pocket PC, or Palm Pilot, giving you the option of sharing or storing the sounds.

Other features include digital signal processing over the entire acoustic range, built-in display for easy viewing of the heart rate, patient-friendly nonchill diaphragm with a proprietary, low friction surface, and patented 3M™ Littmann® Snap Tight Soft-Sealing Eartips for excellent acoustic seal and comfortable fit. Plus, the Model 4100 operates on just two AAA alkaline batteries.

Most of all, know that the Model 4100 carries the Littmann brand name, the name known worldwide for unsurpassed quality. As a trusted leader in auscultation technology, the Littmann brand of stethoscopes is your assurance of acoustic superiority, innovative design and exceptional performance.

The following symbols are applicable to this device:

- ⚠ • Attention, see instructions for use.
- • Indicates Type B Equipment: The equipment provides protection against electrical shock and electrical current leakage.
- IPX4 • Protected against splashing liquid (chestpiece only).
- LATEX • This product and package do not contain natural rubber latex.

Each Littmann Electronic Stethoscope Model 4100 has a serial number beginning with "SN T".

Indications

The Littmann Electronic Stethoscope Model 4100 is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung and other body sounds with selective frequency filtering. The Model 4100 can also be used for recording, playback and transmitting/receiving of heart, lung, and other body sounds. This product is not designed, sold, or intended for use except as indicated.

⚠ Caution:

- Stethoscope not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Failure to follow directions, general use, and maintenance recommendations could result in damage to the device or possible injury to the user. Damage could cause malfunction of the product, ranging from a slight decrease in auditory response to complete failure of the product.
- Half speed playback is for reference and should not be the only basis for diagnosis.
- It is the responsibility of the clinician to assure that all recordings and data transmissions correspond to the appropriate patient data.
- Transmissions of soundtracks to a computer are for storage purposes only.

- Soundtracks should not be listened to from a computer for diagnostic purposes.
- The Littmann Electronic Stethoscope Model 4100 has been tested to be resistant to both electromagnetic fields (EMI) and electrostatic discharge (ESD). However, it may be susceptible to very strong RF signals or portable and/or mobile RF devices. When using your stethoscope, if you hear sudden or unexpected sounds, you may be in close proximity to a strong radio transmitter. If this should occur, move away from the radio's transmitting antenna.
- Use only AAA alkaline batteries.
- The Model 4100 will not function if the batteries are depleted.
- Do not immerse the stethoscope in any liquid or subject it to any sterilization processes. The entire Model 4100 can be wiped clean with alcohol.
- At the end of this device's useful life, dispose or recycle in accordance with your local, state, and governmental regulations.
- If you have any problems with the Model 4100, do not attempt to repair it yourself. Refer to the Service and Warranty section of this manual.

Instructions for Use

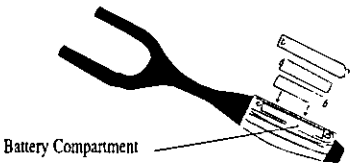
Battery

When used in a typical setting, the Littmann Electronic Stethoscope Model 4100 will operate for about one month on two AAA alkaline batteries. Using the recording options or infrared data transfer will reduce the average battery life.

When the batteries are close to depletion, the LOW BATTERY indictor, located on the display, will blink. When this occurs, the batteries should be replaced within two hours of continuous use.

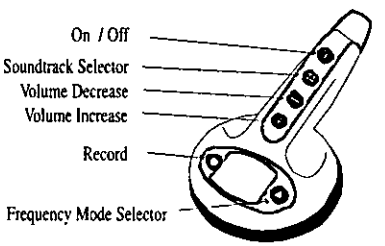
When the batteries are no longer able to power the Model 4100 stethoscope, the stethoscope will automatically turn off. All recorded sounds and settings are saved. The Model 4100 will not function if the batteries are depleted.

Insert batteries as shown

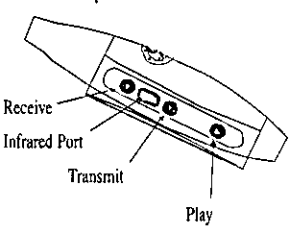


Electronic Controls

The chestpiece of the Littmann Electronic Stethoscope Model 4100 contains six buttons.



The battery compartment of the Model 4100 contains three buttons and the infrared port.



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Electronic Control Quick Reference

(Refer to Operation section for complete instructions)

On/Off Press the ON/OFF button to turn the stethoscope on. Press the ON/OFF button for approximately two seconds to turn the stethoscope off. Pressing the ON/OFF button cancels the current action, for example, to stop a playback, transmission, or reception of a soundtrack.

Soundtrack There are six soundtracks available on the Model 4100.

Selector Press the SOUNDTRACK SELECTOR button once to display soundtrack one, press again to advance to the next sound track.

Volume Decrease Press the VOLUME DECREASE button to decrease the sound level.

Volume Increase Press the VOLUME INCREASE button to increase the sound level.

Record Press the RECORD button for one second to record sound onto the selected soundtrack. Press again to stop recording.

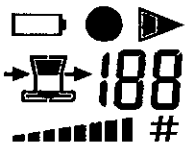
Frequency Mode Selector Press the FREQUENCY MODE SELECTOR button to select Bell, Diaphragm or Extended Range.

Receive Press the RECEIVE button to receive a soundtrack from another Model 4100 or computer.

Transmit Press the TRANSMIT button to transmit the displayed soundtrack to another Model 4100, computer or handheld device.

Play Press the PLAY button to hear the selected soundtrack. The display panel will indicate that the playback is at normal speed. Press and hold the PLAY button for two seconds to play back in half speed. The display panel will indicate that the playback is at half speed. To return to normal speed, press the PLAY button again. Stop playback by pressing the ON/OFF button.

Display Panel



The above picture demonstrates the graphics that are used on the Model 4100 display panel. As a functional test, when the Model 4100 is turned on, all the graphic indicators as shown above will be briefly displayed. After this brief test, the display will then indicate the current listening mode and the volume setting. The factory setting for listening mode is Bell mode and a volume setting of level three.

If Er is shown on the display, refer to the Error Message section.

When the display panel shows:	It means:
	Blinking means the two batteries are almost depleted.
	The sound volume has eight levels. The bar shows the current sound level, increasing from the left. The more bars visible, the higher the sound level. When one element is displayed, the sound level is similar to a typical acoustic stethoscope.
	This is also used to indicate soundtrack reception or transmission progress during data transmission.
	Bell mode.
	Diaphragm mode.
	Extended range mode. The extended range amplifies sound from a broader range of frequencies than the bell or diaphragm mode.
	Playing a recorded sound at normal speed.
	Playing a recorded sound at half speed.
	Recording a sound.
	Transmitting a recording. The arrow will blink until the infrared connection is made. After connection is made, the arrow will no longer blink.
	Receiving a recording. The arrow will blink until the infrared connection is made. After connection is made, the arrow will no longer blink.
#	The number displayed indicates the soundtrack currently selected.
u2 #	The symbol u indicates that the soundtrack is occupied by a previous recording. If u is not displayed, the soundtrack is vacant. When the u is rotating, a sound transmission is in progress. # is located below the number of the soundtrack you have selected.
- -	A number displayed is the heart rate. If two dashed lines are displayed, refer to the heart rate section
199	If the display is blinking 199, the heart rate is above 199 bpm and cannot be displayed.
Er	*Error Message.* See Error Message section of this manual.

Operation

Power On Press the ON/OFF button on the Littmann Electronic Stethoscope Model 4100. The factory or personalized setting will be in operation.

Automatic Power Off The Model 4100 automatically turns off three minutes after the last actuation of any button. Press the ON/OFF button within 10 seconds of automatic power off and the same settings will be restored. If longer than 10 seconds have transpired, the Model 4100 will power up at your personalized setting or factory setting.

Note, the stethoscope will not power off automatically during a data transmission.

Change Sound Volume Level Press the VOLUME INCREASE or VOLUME DECREASE button. The sound volume bar displays the change.

Change Frequency Mode Press the FREQUENCY MODE SELECTOR button to select one of the frequency ranges (Bell, Diaphragm or Extended). The selection is indicated on the display panel.

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Personalized Setup

The Model 4100 is factory set in bell mode and sound level 3. To personalize setup, select the desired frequency mode and volume level, and then press and hold the FREQUENCY MODE SELECTOR button for two seconds. The Model 4100 will now function with these settings on startup.

Heart Rate

The Model 4100 detects and displays an acoustic-based heart rate. It takes five seconds to compute the initial heart rate and is updated every two seconds. For heart rates below 30 bpm or before the initial reading, the display shows two dashes (--). Heart rates above 199 bpm will flash the number 199. Heart rate is not displayed during recording or playback.

The acoustic-based heart rate display functions best when the Model 4100 is placed near the apex of the patient's heart. If the heart rate changes from consistent to inconsistent or if there is excessive ambient noise, patient movement or lung sounds during auscultation, the heart rate display number will flash or display two dashes (--). The flashing heart rate will change to two dashes (--) after 10 seconds of inconsistent sounds or no heart rate detection.

Select Soundtrack

Select any one of the six soundtrack by pressing the SOUNDTRACK SELECTOR button one or more times. The selected soundtrack is displayed. A number shown by itself indicates an empty track. A number shown with the U indicates a recorded soundtrack. Recording on a soundtrack that displays the U will erase the currently stored sound.

Press the ON/OFF button to return to the heart rate display.

Recording

Press and hold the RECORD button for one second. The record symbol will flash in the display. Press the record button again to stop recording. Wait for approximately two - three seconds after an auscultation event before pressing the RECORD button to stop recording. Each soundtrack has a recording duration of eight seconds. Each recording must be at least two seconds in duration.

The recording process captures the full frequency range and stores it on the soundtrack. This allows the ability to change the frequency mode from bell, diaphragm or extended range during playback. To ensure that clear auscultation sounds are captured, do not adjust volume or frequency mode during recording.

Playback

To play back a recording, select the desired soundtrack and press the PLAY button. When the entire soundtrack has been played, there is a one second delay before the soundtrack will play again. To end playback, press the ON/OFF button.

Half Speed Playback

Press and hold the PLAY button for two seconds. To stop the continuous half speed and return to normal playback, press the PLAY button. To end playback, press the ON/OFF button.

Erase Single Soundtracks

Erase soundtracks by recording new sounds onto them. Erased soundtracks cannot be recovered.

Erase All Sound tracks (use with caution)

Press and hold the SOUNDTRACK SELECTOR button for tw seconds. This will erase all soundtracks. Erased soundtracks cannot be recovered.

Data transmission to another Littmann Electronic Stethoscope Model 4100

1. Select the soundtrack to be transmitted and the soundtrack to receive the transmission.
2. Position the two IR ports within two feet.
3. Press the RECEIVE button on the receiving Model 4100 then press the TRANSMIT button on the transmitting Model 4100. The arrow will blink until the infrared connection is made.
4. Transmission is indicated on the Model 4100 display by a rotating U.
5. Progress of the transmission is shown on the Model 4100 display with the ▬▬▬▬▬▬ symbol. To stop the transmission, press the ON/OFF button on either stethoscope.

Sending a copy of a soundtrack to a computer using Microsoft® Windows® 98/2000/XP[1] with an infrared (IR) port

1. Select the soundtrack to be transmitted.
2. Position the two IR ports within two feet.
3. Press the Model 4100 TRANSMIT button. The arrow will blink until the infrared connection is made.
4. Transmission is indicated on the Model 4100 display by a rotating U. The computer status bar will display two red lights flashing towards one another.
5. Progress of the transmission is shown on the Model 4100 display by the ▬▬▬▬▬▬ symbol.
6. WINDOWS 98 – Downloaded soundtracks are stored in: C:\My Received Files.

   WINDOWS 2000 – Downloaded soundtracks are stored in: C:\Documents and Settings\username\Desktop and appear on the desktop.
7. The soundtrack filename format is: 'Trk*.e4k' (* is the soundtrack number on the stethoscope)

   Example: soundtrack 2 = 'Trk2.e4k'

   If the default soundtrack filename already exists, a new name, "Copy of Trk*.e4k" or "Copy # of Trk*.e4k" is given, example: soundtrack 2 = "Copy of Trk2.e4k" (# is the number of duplicates from the same soundtrack)

   It is advisable to rename the soundtrack files once they are transmitted to avoid confusion. It is not necessary to maintain the file extension *.e4k.

If Er appears in the display of the stethoscope, refer to the Error Messages section of this manual to determine a possible cause.

[1] Prompts may vary between versions of Windows; and prompts are the responsibility of Microsoft. References to Windows as it pertains to use of the Littmann Electronic Stethoscope Model 4100 are for clarification only. Please consult your Microsoft user manual for specific instructions. Microsoft® and Windows® are trademarks of Microsoft Corporation.

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Receiving a copy of a soundtrack from a computer using Microsoft® Windows® 98/2000/XP[2] with an infrared (IR) port

WINDOWS 98 - From the Start menu select 'Start – Programs – Windows Explorer'. Open the folder "My Received Files" and locate the soundtrack file to be transmitted.

WINDOWS 2000 – From the desktop (or within the folder that contains the soundtrack file to be transmitted) locate the soundtrack file to be transmitted.

1. Select the Model 4100 soundtrack to receive the transmitted file.

   Caution: If the selected soundtrack contains a recording, the transmitted file will replace it. Erased soundtracks cannot be recovered.

2. Position the two IR ports within two feet.
3. Press the Model 4100 RECEIVE button. The arrow will blink until the infrared connection is made.
4. Immediately right click on the soundtrack file to be transmitted and select 'Send To – Infrared Recipient'
5. Transmission is indicated on the Model 4100 display by a rotating ⊔. The computer status bar will display two red lights flashing towards one another.
6. Progress of the transmission is shown on the Model 4100 display with the symbol.

The Model 4100 is compatible with the following handheld computer operating systems:

Pocket PC operating systems 2002, 2003; Palm™ Pilot operating systems 4 and 5.

Palm Pilot operating systems 4 and 5 must have a proper FILE MANAGER installed that is set-up to accept .e4k file extension, to work.

(UniCMD can be used for beaming and for accepting .e4k files on Palm Pilots. Remember to set-up UniCMD to accept .e4k files and use the 'Send' command to transmit from the PDA. Note that UniCMD stores the files in an application-specific format, which is not directly usable from other applications on the PDA. Example: Using UniCMD for accepting .e4k files and using FileZ for beaming the received files will not work, as the files transmitted and received will not be the same (file is modified with additional bytes).

Sending a Copy of Soundtrack to Handheld Device from Model 4100:

1. Select sound track to be transmitted.
2. Position the two infrared (IR) ports within two feet of each other.
3. Press the Model 4100 transmit button. The ⊔ will rotate until the file is transferred.
4. When handheld asks you to accept file, click on yes.
5. Progress of file transfer is shown on the Model 4100 display with the Ψ symbol.
6. The transferred file name format is Trk*.e4k, (the soundtrack number on the stethoscope).
7. Repeat steps 1 through 6 for additional track transfers.

[2] [Prompts may vary between versions of Windows and they are the responsibility of the Microsoft. References to Windows as it pertains to use of the Littmann Electronic Stethoscope Model 4100 are for clarification only. Please consult your Microsoft® users manual for specific instructions. Microsoft® and Windows® are trademarks of Microsoft Corporation]

Receiving a Copy of Soundtrack on Model 4100 from Handheld Device

1. Open up file manager program on handheld device and identify which file you want to transfer.
2. Align Model 4100 and handheld IR ports within two feet of each other.
3. Press receive button on Model 4100.
4. Send file from handheld to Model 4100.
5. Transmission of the file is indicated on the Model 4100 display by a rotating ⊔.
6. Progress of file transfer is shown on the Model 4100 display with the Ψ symbol.

Transferring Sound Track from Handheld device to PC

1. To transfer sound track to your PC from a handheld device:
   a. Align IR ports within 2 feet of each other.
   b. Open file manager program on handheld and identify which file you want to transfer.
   c. Send file from handheld to PC.
   d. Accept file on PC.

   OR

2. To transfer sound track to your PC from a handheld device you can simply dock your handheld device and let your PC handheld software (e.g. Microsoft® Active Sync) transfer files for you. Once transferred, you can use standard PC file manager to move and rename files as desired.

Transferring Sound Track from PC to Handheld Device

1. To transfer sound track from your PC to handheld device:
   a. Open file manager program on PC and identify which file you want to transfer.
   b. Align IR ports within 2 feet of each other.
   c. Send file from PC to handheld.
   d. Accept file on handheld.

   OR

2. To transfer sound track from your PC to your handheld device you can simply locate file you want to transfer, put it into correct directory on your PC and then dock your handheld device. Let your PC handheld software (e.g. Microsoft Active Sync) transfer files for you. Once transferred, you can use standard handheld file manager to move and rename files as desired.

   Note: The soundtrack filename is not transmitted to the stethoscope. If appears in the display of the stethoscope, refer to the Error Messages section of this manual to determine a possible cause.

Error Messages

If Er shows while transmitting data to another Model 4100 or a computer:

- The path of infrared light may be blocked. Position the infrared ports at each other and retry the operation.
- The infrared port may be dirty. Clean both infrared ports.
- The Model 4100 was removed before the soundtrack was completely transferred. Do not move the stethoscopes until the ⊔ is finished rotating.
- The Model 4100 may be exposed to excessive electromagnetic or radiofrequency interference (EMI/RFI). Remove the source of noise.

If none of these issues is the cause of the Er message, refer to the Littmann Stethoscope Service and Warranty section.

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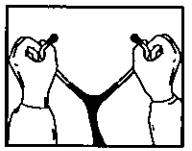
Headset Positioning

Your new Littmann Electronic Stethoscope Model 4100 is designed to give you a very comfortable, acoustically sealed ear fit. Notice that the eartubes are permanently set at an angle to accommodate the typical anatomy of the ear canal. The eartips should point in a forward direction as you insert them into your ear canals.

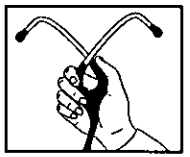
Correct

Incorrect



Reduce Tension

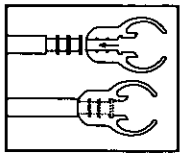
To reduce spring tension in the headset, hold each eartube at the bend near the eartip and gradually pull apart until fully extended (180 degrees).



Increase Tension

To increase spring tension, grasp the headset with one hand where the eartubes enter the plastic tubing and squeeze until the plastic tubing on one eartube touches the other. Repeat as necessary.

For maximum acoustic performance, comfortable patented Littmann Soft-Sealing Eartips are provided with your stethoscope.



The stethoscope utilizes a unique design for attaching the eartip to the eartube. The eartips are pushed on to the end of the eartube and snapped tight. To remove, pull firmly on the eartip.

Additional Littmann eartips are available. To order, contact your Littmann Stethoscope distributor or the 3M Health Care Service Center.

Cleaning of the Diaphragm:

Under normal conditions, it is unnecessary to remove the diaphragm for cleaning. The diaphragm can easily be cleaned by using an alcohol wipe. If, however, it is necessary to remove the diaphragm, carefully follow the instructions below.

Diaphragm Removal

With diaphragm side up, using a thumbnail, lift the underside portion of the diaphragm out of its designated groove, and peel it off of the chestpiece. The groove that holds the diaphragm in place can be cleaned by sliding the edge of an alcohol swab around the groove. All parts of the chestpiece can be wiped down with alcohol. IMPORTANT: The stethoscope should not be immersed in any solution. Excess liquid used in the cleaning process can result in moisture getting into the internal components.

Diaphragm Reassembly

Once the diaphragm is completely dry, insert the diaphragm into the groove of the rim, starting at one point, and run your finger around the diaphragm until it is seated back in the groove.

Other Considerations

- The entire stethoscope can be wiped clean with alcohol.
- Do not immerse the stethoscope in any liquid or subject it to any sterilization process.
- Eartips can be removed for a thorough cleaning.
- Remove the battery whenever the stethoscope is stored or will not be used for several months.
- Avoid extreme heat, cold, solvents and oils. Recommended normal storage conditions are from 32°F to 122°F (0°C to 50°C), 15 to 95% relative humidity.

Failure to follow care and maintenance recommendations could result in damage to the internal components of the Model 4100. Internal damage could cause malfunction of the product, ranging from a slight decrease in auditory response to complete failure of the product.

If you experience any problems with the Model 4100 do not attempt to repair it yourself. Please notify the 3M Health Care Service Center for directions on how to return the product for repair.

Littmann Stethoscope Service and Warranty Program

The Littmann Electronic Stethoscope Model 4100 is warranted against any defects in material and manufacture for a period of two years. If a material or manufacturing defect is discovered during the warranty period, repairs will be made without charge upon the return of the instrument to 3M, except in cases of obvious abuse or accidental damage.

For technical questions, call the 3M Health Care Tech Line at 1-800-441-1922.

For maintenance or repair services in the United States, send your stethoscope directly to:
3M Health Care Service Center
3M Building 502-1W-01
3350 Granada Ave N
Suite 200
Oakdale, MN 55128
1-800-292-6298

Enclose your name, address, phone number and reason for repair with your stethoscope.

In Canada:
3M Health Care Service Center
3M Canada Inc.
80 Enterprise Drive South
London, Ontario
Canada N6N1C2
1-519-668-3663

Outside of the United States and Canada, contact your local 3M subsidiary for maintenance and repair information.

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Appendix

Operating conditions
Temperature: 0°C - 50°C
Humidity: 0% - 95% RH
Pressure: 700 – 1060 hPa

Normal storage conditions
Temperature: 0°C - 50°C
Humidity: 0% - 95% RH
Pressure: 700 – 1060 hPa

Short-term storage (up to 96hrs)
Temperature: -20°C - 60°C
Humidity: 0% - 95% RH
Pressure: 700 – 1060 hPa

Table 201

Declaration – Electromagnetic Emissions		
The 3M Littmann® Electronic Stethoscope, Model 4100, is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 4100 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Model E4100 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Model E4100 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emmisions IEC 61000-3-3	Not applicable	

Table 202

Declaration – Electromagnetic Immunity			
The 3M Littmann® Electronic Stethoscope, Model 4100, is intended for use in the electromagnetic environment specified below. The customer or the user of Model 4100 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Electrostatic discharge (ESD IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30 %
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for supply lines ± 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycle 70 % U_T (30 % dip in U_T) for 25 cycle < 5% U_T (>95 % dip in U_T) for 5 sec	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial magnetic field or hospital environment.

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Table 204

Declaration – Electromagnetic Immunity (Continued)

The 3M Littmann® Electronic Stethoscope, Model 4100, is intended for use in the electromagnetic environment specified below. The customer or the user of Model 4100 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment –guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Model 4100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	$d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range, [b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Model 4100 is used exceeds the applicable RF compliance level above, the Model 4100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 4100.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 206

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the 3M™ Littmann® Electronic Stethoscope Model 4100

The Model 4100 is intended for use in the electromagnetic environment in which the RF disturbances are controlled. The customer or the user of the Model 4100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 4100 as recommended below, according to the maximum output of the communications equipment.

Rated maximum output power of transmitter, P [W]	Separation distance according to frequency of transmitters, d [m]		
	150 kHz to 80 MHz	80 Mz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Biocompatibility Summary of
3M™ Littmann® Electronic Stethoscope, Model 3100/3200

Introduction

All components of the 3M™ Littmann® Model 3100/3200 stethoscopes have been reviewed for biocompatibility with respect to ISO 10993-Part 1 for limited (≤24 hour) skin contact for both patient and/or health care professional. Each component with the potential for direct skin contact with either the user and/or patient was reviewed for possible health concerns. When applicable, material use in a legally marketed device was documented in this assessment.

Note: Internal components without potential contact with either user and/or patient are fabricated from standard materials used in commercial electronic devices and are not listed in this document.

The final conclusion is that all of the components of the 3M™ Littmann® Model 3100/3200 stethoscopes would have minimal potential for any adverse health concern.

Assessment completed by: Anita M. Kore, DVM, PhD, Dipl. ABVT
Lead Toxicology Specialist
Toxicology Assessment and Compliance Assurance
3M Medical Department, Saint Paul, MN

DIAGRAM 1
3M LITTMANN ELECTRONIC STETHOSCOPE, MODEL 3100/3200
(see 19300001_00_3M_color_DRAFT.pdf)

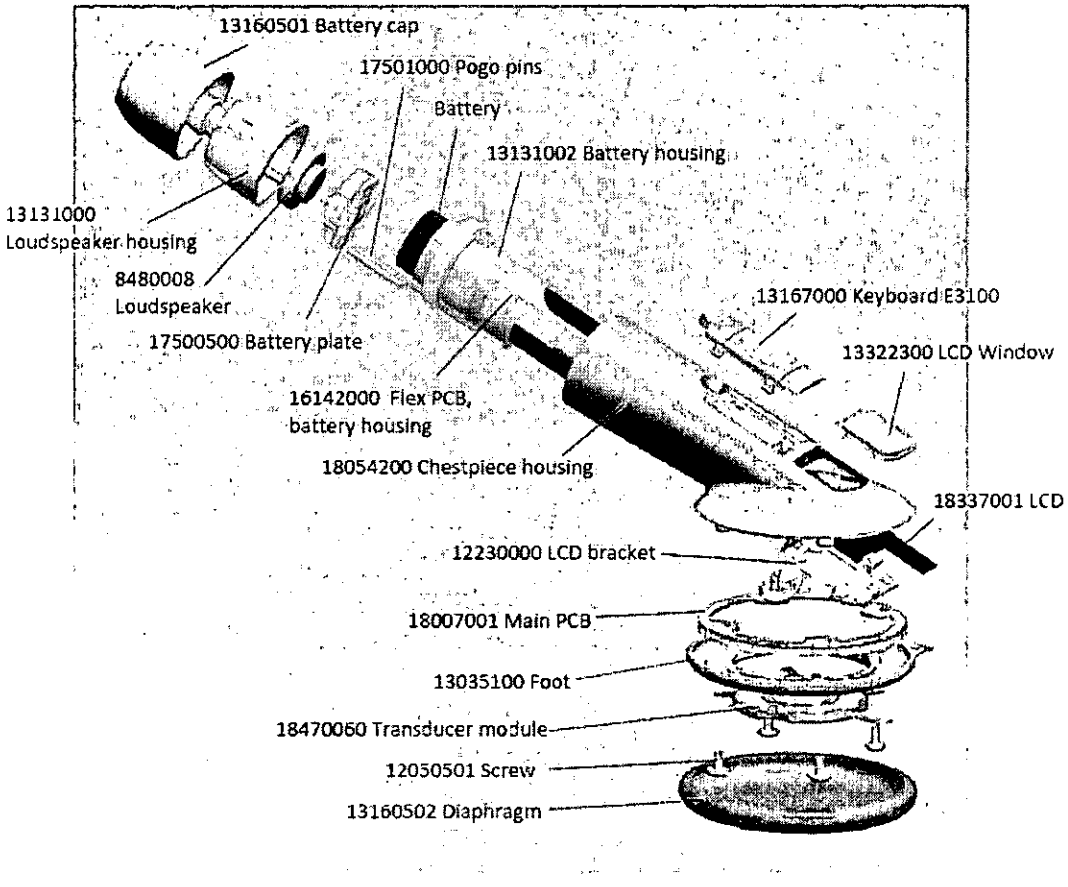

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DIAGRAM 2
MAIN ASSEMBLY (CHESTPIECE)

(See E31000 Main Assembly.pdf)

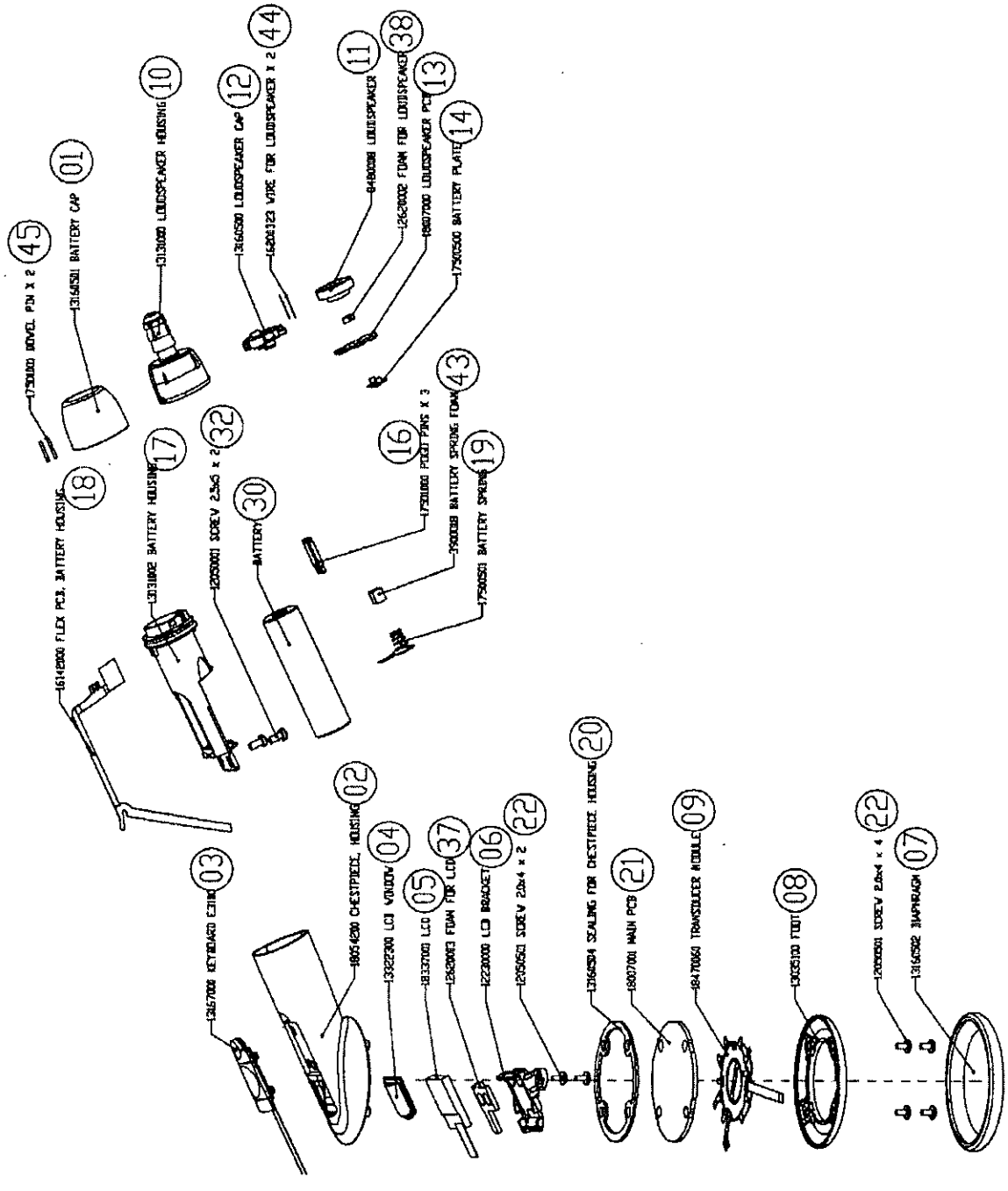

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DIAGRAM 3
TRANSDUCER MODULE

(see Transducer Module 18470060_00_A.pdf and
Transducer Assembly 18470060_00_A.png)

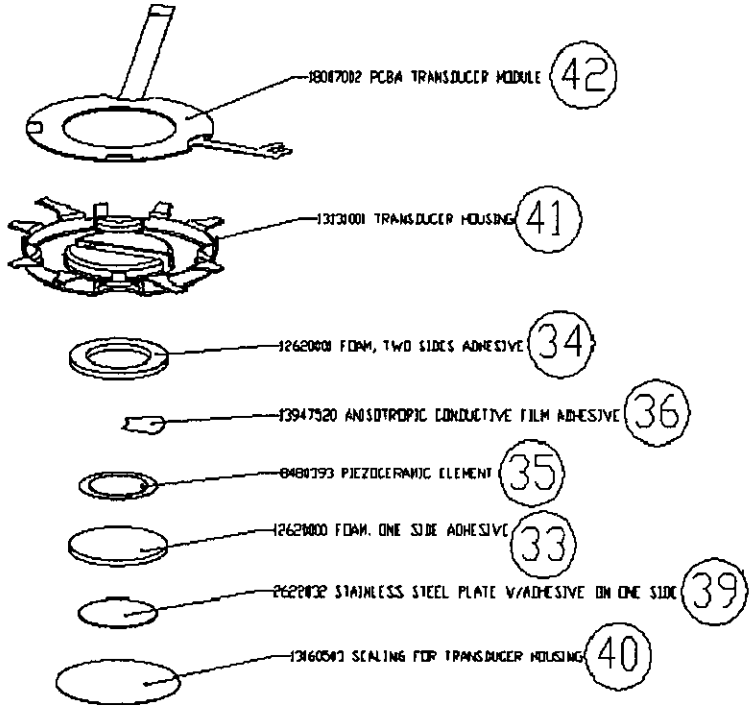

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TABLE I

COMPONENT LISTING
3M™ LITTMANN® ELECTRONIC STETHOSCOPE, MODEL 3100/3200

Part	Component Name	Material
1	Battery cap	Zinc coated with chrome
2	Chestpiece housing	Zinc coated with chrome
3	Keyboard	Polycarbonate, printed and coated with acrylic urethane
4	LCD Window	Polycarbonate/SEBS with UV-cured acrylate coating
7	Diaphragm	Polyacrylate-coated Silicone
8	Foot	Polycarbonate / ABS copolymer
14	Battery Plate	Brass with a nickel and gold coating
16	Pogo Pins	Brass, Gold Plated; Stainless steel spring
17	Battery Housing	Glass-filled Polyarylamide/SEBS
18	Battery Spring	Tin Plate
23	Sound Tube	PVC
24	Headset	Anodized aluminum tubes/stainless steel spring
25/31	Eartips	Silicone rubber
32	Screws	Stainless Steel
40	Transducer Seal	PVC film/adhesive
43	Battery Foam	Urethane foam
45	Dowel Pins	Tool steel

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Component Descriptions
3M™ LITTMANN® ELECTRONIC STETHOSCOPE, MODEL 3100/3200

Numbers above each component relate to the number designation in Table I.
(See E3000 Main Assembly 19300001_00_B.pdf, E3000 Main Assembly 19300001_00_B.wmf and Transducer Assembly 18470060_00.wmf)

#1 – Battery Cap
#2 – Chestpiece Housing
Both the battery cap and the chestpiece housing are made from zinc castings [redacted] and plated with a chrome metal coating. The chrome coating may contact the user. Chrome-plated parts are also used in currently marketed 3M Littmann Model 3000 and Model 4100 stethoscopes. No adverse heal th effects are expected from the use of this material.

#3 – Keyboard
The keyboard is made of polycarbonate [redacted], printed with an ink [redacted] and coated with an acrylic urethane [redacted]. No adverse health effects are expected from the use of this material.

#4 – LCD Window
The liquid crystal display (LCD) window is made of polycarbonate [redacted] and styrene-ethylene/butylene-styrene (SEBS) thermoplastic elastomer [redacted] and coated with an acrylate polymer [redacted]. No adverse health effects are expected from the use of this material.

#7 – Diaphragm
The diaphragm is made of silicone rubber [redacted]. It is coated with a hydroxyl-bearing polyacrylate [redacted]. The 3M Littmann logo on the diaphragm is printed with a silicone encapsulant/adhesive [redacted]. No adverse health effects are expected from the use of this material.

#8 – Foot
The foot is made of a molded polycarbonate/ acrylonitrile-butadiene-styrene copolymer [redacted]. Exposure of the user to this part is limited and would only occur when removing the diaphragm for cleaning and/or replacement, or reattachment if dislodged. No adverse health effects are expected from the use of this material.

#10 – Loudspeaker Housing
The loudspeaker housing is made of glass-filled polyarylamide [redacted]. This part has a very limited potential for exposure to the user. No adverse health effects are expected from the use of this material.

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#14 – Battery Plate
The battery plate is made of C 2680 brass with a nickel and gold coating. Exposure of the user to this part is limited and would only occur when changing the battery. No adverse health effects are expected from the use of this material.

#16 – Pogo Pins
The pins are gold plated brass with stainless steel spring inside. Exposure of the user to this part is limited and would only occur when changing the battery. No adverse health effects are expected from the use of this material.

#17 – Battery Housing
The battery housing is made of glass-filled polyarylamide [redacted] A seal made of styrene-ethylene/butylene-styrene (SEBS) thermoplastic elastomer [redacted] and [redacted] wax on polypropylene carrier mold release [redacted] is molded on the housing in a secondary operation. Exposure of the user to this part is limited and would only occur when changing the battery. No adverse health effects are expected from the use of this material.

#18 – Battery Spring
The battery spring is made of tin. Exposure of the user to this part is limited and would only occur when changing the battery. No adverse health effects are expected from the use of this material.

#23 – Sound Tube (not shown)
The sound tubing is made of polyvinyl chloride (PVC) and is the same material [redacted] stethoscopes.

24 – Headset (not shown)
The headset is comprised of anodized aluminum eartubes which contact the user and stainless steel springs which are covered by the yoke portion of the PVC sound tube. [redacted]

25 and #31 – Eartips (not shown)
The eartips are made of silicone rubber and are [redacted]. The results of the cytotoxicity test showed a minimal response (0.75/0.75) when test using L-929 mouse fibroblasts. The results of the Human Repeat Insult Patch Test (HRIPT) study indicated that the silicone rubber eartips did not induce sensitization in a 215-subject panel. Irritation results extracted from the HRIPT study showed that only five transient irritation responses during the induction phase, indicating no irritation under repeated dermal contact.

#32 – Screws 2.5x2
The screws are made from zinc-plated (Trivalent Blue), stainless steel wire (AISI 1018). No adverse health effects are expected from the use of this material.

#40 – Transducer Seal

The seal is a PVC film [redacted] intended to protect the transducer from exposure to alcohol and soap and water. Exposure to this part is minimal (only during removal of diaphragm for disinfection, cleaning or replacement. No adverse health effects are expected from the use of this material.

#43 – Battery Spring Foam

The battery spring foam is made from polyurethane [redacted] Exposure to this part is minimal. No adverse health effects are expected from the use of this material.

#45 – Dowel Pins

The dowels are made from [redacted] low alloyed tool steel. These dowels provide locking for bayonet closure of the battery compartment. Exposure of the user to these parts is limited and would only occur when changing the battery. No adverse health effects are expected from the use of this material.

Revision	Details:
1	Initial release October 9, 2008.
2	December 16, 2008. - ADD Part #44 (dowel pins); CHANGE composition of Part #14 (battery plate); MINOR CORRECTIONS to compositions of Part #16 (Pogo pins) and Part #17 (Battery housing); UPDATE Diagram 2 (Main Assembly-Chestpiece) and Table 1 (Component Listing).

(b)(4)Trade Secret Process-Product Specs

[redacted]

E3000 Plus
Software Description

Version 1.00
Page 1 of 4
File name: MBG0851B - Software Description E3000 Plus.docx

Author

17/11-08 [illegible]
Date, Name - Software Designer

Approved by

17/12-08 [illegible]
Date, Name – Quality Assurance

(b)(4)Trade Secret Process-Product Specs

[redacted]

(b)(4)Trade Secret Process-Product Specs

Version history

Version	Author	Date	Description	Reviewed by	EC number
1.00	MBG	15. dec. 2008	Document created		

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1 Purpose

The purpose with this document is to collect the software design documents and make an overview of these documents.

2 Scope

This document covers the software design of the M3100 and the M3200.

3 Design Description Documents

[1] MBG0751A MIPS estimation for signal path.xls
[2] MBG0751B SignalPath (DSP).pdf
[3] PMP0748C mmi state event action.pdf
[4] PMP0810A RTX Interface Product Requirement Specification.docx
[5] PMP0833A Service counter specification.doc
[6] PMP0845 Signal parth interface.pdf
[7] port assignments.pdf
[8] PMP0746A Bluetooth SPP protocol record specification.docx
[9] Appendix A to PMP0746A Bluetooth SPP protocol record specification.docx
[10] MBG0751C - SRS SW Requirement Specification for E3000 Plus.docx

4 Design simulation

A simulation of the design can be found in the folder 'E3000plus_simulator_Matlab', which contains a running Matlab simulation of the signal processing.

5 Software description.

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[redacted]

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[redacted]

IAD0007 E3100-E3200
Risk Assessment Report

1.00

File name: SSR0850a Risk assessment Report E3000+.doc

Author

11-12-2009
Date, "Name" – "Add department"

Approved by

12-12-2009
Date, "Name" – Quality Assurance

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[redacted]

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1 Purpose

The purpose of this document is to assess the current status of the Risk Assessment process at relevant milestones in the project to summarize the essential output of the Risk Assessments, necessary mitigations and the progress of the risk control activities implementations.

2 Scope

This document covers the current status of risk assessment of the component design involved in the development project E3000+ at PPC milestone.

2.1 Resources

Skills	Name, title	Lifecycle HAZOP	Component Design	Process
Therapy and user knowledge,				
Product knowledge				
Mech. engineering	(b)(4)Trade Secret Process-Product Specs Mechanical designer		x	
Electr. engineering	(b)(4)Trade Secret Process- Electronic designer		x	
SW engineering	Per Mølgaard PMP (b)(4)Trade Secret Process-Product Specs Software designers		x	
Process engineering	(b)(4)Trade Secret Process- Process engineer		x	
Quality agreements	(b)(4)Trade Secret Quality engineer		x	
Test and verification procedures				
Risk Assessment Team leader	(b)(4)Trade Secret Process-Product Specs		x	

2.2 Method

A FMECA assessment method was used

3 References

[1] SSR0808a Risk Management Plan E3100-E3200.doc

4 Assessments

SSR0808b Risk assessment Component Design E3000 plus.fmea

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5 Essential outputs

All identified risks rated R2, R3 or R4 and/or with a severity of S3, S4 or S5 are listed below:

Components	Function	Failure mode	Potential Hazards	Potential Causes	Effect to user, patient...	Current design control prevention	Current design control Detections	Severity	Before mitigation	Risk Control Activities			
										Recommended Risk Controls			After mitigation
									Risk Ranking	Description	Category	Status	Risk Ranking
25. PCBA Main	9. Radio Waves transmitted/ received by Antenna	1. Transmitted BT power too high	1. External devices disturbed	25.9.1.1.1. Incorrect power setting	Could affect life sustaining/ monitoring equipment	Transmitted power controlled by DSP, BT is a low power RF source	None	S4	R3	1. Functional test of output power at sub supplier	9. Q-Agreement	Completed	R1
										2. 3. party Blue tooth certification	7. Design ver.	Completed	
1. Tube	1. Mechanical interface to Loudspeaker Housing	1. Loose	1. Tube comes off	1.1.1.1.3. Release agent from manufacturing process	Cannot use device	None	1. article inspection	S2	R2	1. Instructions to supplier regarding residues	9. Q-Agreement	Completed	R1
1. Tube	1. Mechanical interface to Loudspeaker Housing	1. Loose	2. Acoustic leak	1.1.1.2.1. inner diameter too large	Sound quality reduced	None	Acoustic test	S2	R2	1. Sub supplier tolerance requirements	9. Q-Agreement	Completed	R1
1. Tube	2. Transfers sound from loudspeaker to headset	1. No sound in headset	1. Damage to loudspeaker	1.2.1.1.1. Release agent from manufacturing process	Cannot use device	None	1. article inspection	S2	R2	1. Instructions to supplier regarding residues	9. Q-Agreement	Completed	R1
5. Loudspeaker Housing	1. Interface to Tube, potentially high tension	2. Barbed tube connector cannot retain tube when pulled	1. Tube comes off	5.1.2.1.1. Diameter under dimensioned	Cannot use device	Use experience from mechanical stethoscopes	Engineering test of pull off force	S2	R2	1. Implement bigger diameter on barbed connector	3. Design mod.	Completed	R1
5 Loudspeaker Housing	3. Snap interface to Loudspeaker cap	1. Only one snap locks	1. Acoustic leak	5.3.1.1.1. Poor alignment tool	Sound quality reduced	Battery spring will push snap lock in place	None	S2	R2	1. Loudspeaker assembly DWG	8. Transfer to Process RA	Completed	
										2. Loudspeaker assembly instructions	8. Transfer to Process RA	Completed	
										3. Assembly line device testing	8. Transfer to Process RA	Completed	

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Components	Function	Failure mode	Potential Hazards	Potential Causes	Effect to user, patient...	Current design control prevention	Current design control Detections	Severity	Before mitigation	Risk Control Activities			After mitigation
										Recommended Risk Controls			
									Risk Ranking	Description	Category	Status	Risk Ranking
6. Loudspeaker assembly	1. Electrical connection between Loudspeaker and Loudspeaker PCB	1. Soldering fails	1. No sound	6.1.1.1.1. Wrong assembly order	Cannot use device	None	None	S2	R2	1. Loudspeaker assembly DWG	8. Transfer to Process RA	Completed	
										2. Loudspeaker assembly instructions	8. Transfer to Process RA	Completed	
6. Loudspeaker assembly	1. Electrical connection between Loudspeaker and Loudspeaker PCB	1. Soldering fails	1. No sound	6.1.1.1.2. Poor solder quality	Cannot use device	None	Corrosion test, Vibration test	S2	R2	1. Training of personnel	8. Transfer to Process RA	Completed	
6. Loudspeaker assembly	1. Electrical connection between Loudspeaker and Loudspeaker PCB	1. Soldering fails	1. No sound	6.1.1.1.3. Wires too rigid	Cannot use device	Material selection, flexible wire	None	S2	R2	1. Loudspeaker assembly DWG	8. Transfer to Process RA	Completed	
6. Loudspeaker assembly	2. Hards pre mounted loudspeaker	1. Poor alignment against Loudspeaker cap	1. Assembly problems later in the process resulting in leaks	6.2.1.1.1. Poor alignment tool	Sound quality reduced	None	None	S2	R2	1. Loudspeaker assembly instructions	8. Transfer to Process RA	Completed	
7. Loudspeaker cap	1. Snap interfaces to Loudspeaker PCB	1. Snap feature cannot retain the PCB	1. PCB comes out during battery replacement	7.1.1.1.1. Snap feature too weak	Cannot use device	Design improved with better defined stops. Tolerance analysis	None	S2	R2	1. Assembly instruction	8. Transfer to Process RA	Completed	
8. Loudspeaker	1. Adhesive interface to Foam for Loudspeaker	1. Poor alignment of foam	1. Assembly problems later in the process resulting in leaks	8.1.1.1.1. Poor alignment tool	Sound quality reduced	None	None	S2	R2	1. Loudspeaker assembly instructions	8. Transfer to Process RA	Completed	
										2. Assembly tooling for Loudspeaker assy	8. Transfer to Process RA	Completed	
										3. Assembly line device testing	8. Transfer to Process RA	Completed	
8. Loudspeaker	2. Adhesive interface to Loudspeaker Housing	1. Protective member was not removed before assembly	1. Acoustic leak	8.2.1.1.1. Assembly error	Sound quality reduced	None	None	S2	R2	1. Assembly instruction	8. Transfer to Process RA	Completed	
										2. Assembly line device testing	8. Transfer to Process RA	Completed	

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Components	Function	Failure mode	Potential Hazards	Potential Causes	Effect to user, patient...	Current design control prevention	Current design control Detections	Severity	Before mitigation	Risk Control Activities			
										Recommended Risk Controls			After mitigation
									Risk Ranking	Description	Category	Status	Risk Ranking
8. Loudspeaker	3. Enables solder terminals for Loudspeaker PCB	1. Solderings breaks during assembly	1. Loudspeaker signal missing	8.3.1.1.1. Assembly error	Cannot use device	Material selection, wire	None	S2	R2	1. Assembly instruction	8. Transfer to Process RA	Completed	
										2. Assembly line device testing	8. Transfer to Process RA	Completed	
8. Loudspeaker	4. Delivers acoustic output for Tube/headset	1. Loudspeaker damaged during assembly/ snipping	1. Loudspeaker out of spec's	8.4.1.1.1. Assembly error	Sound quality reduced	None	None	S2	R2	1. Assembly instruction	8. Transfer to Process RA	Completed	
										2. Tool for Loudspeaker fastening	8. Transfer to Process RA	Completed	
										3. Assembly line device testing	8. Transfer to Process RA	Completed	
10. PCB loudspeaker	2. Snap interface to Loudspeaker Cap	1. Poor fit to snap lock	1. PCB falls out during battery replacements	10.2.1.1.1. 1. Solderings squeezes PCB out of snaps	Cannot use device	Interference check	None	S2	R2	1. Design improvement of snap lock	3. Design mod.	Completed	R1
										2. 3M CVE	10. Design validation	On Hold	
12. Battery Housing	5. Bayonet interface to Loudspeaker Housing	2. Bayonet connector not fully locked	1. Battery supply missing (POGO pins)	12.5.2.1.1. 15.2.1.1.1. No tactile feedback	Cannot use device	Tolerance stack analysis	Wear test to mission	S2	R2	1. New click feature in Battery housing design and Loudspeaker Housing for improved tactile feedback	3. Design mod.	In Progress	R1
										2. 3M CVE	10. Design validation	On Hold	
12. Battery Housing	6. Sealing interface to Chest piece Housing	1. Battery housing squeezed during assembly	1. Sealing loosens	12.6.1.1.1. Assembly error	Cannot use device	Tolerance stack analysis	None	S2	R2	1. Assembly line device testing of frequency response	8. Transfer to Process RA	Completed	
										2. Assembly instruction	8. Transfer to Process RA	Completed	
12. Battery Housing	9. Holds POGO pins	1. Damaged by soldering	1. Contacts fail	12.9.1.1.1. Assembly error	Cannot use device	Material selection	None	S2	R2	1. POGO pins mounted in Battery Housing before soldering to avoid over constraining	8. Transfer to Process RA	Completed	

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Components	Function	Failure mode	Potential Hazards	Potential Causes	Effect to user, patient...	Current design control prevention	Current design control Detections	Severity	Before mitigation	Risk Control Activities			
										Recommended Risk Controls			After mitigation
									Risk Ranking	Description	Category	Status	Risk Ranking
14. Battery spring foam	1. Interface to Battery spring to reduce ringing effects from spring	1. Foam does not attenuate the ringing	1. Ringing sounds in headset	14.1.1.1.3. Missing	Sound quality reduced	None	None	S2	R2	1. Assembly instruction	8. Transfer to Process RA	Completed	
15. POGO Pin	2. Spring loaded contact interface to Loudspeaker PCB	2. POGO pins bent	1. Battery supply or loudspeaker signals missing	15.2.2.1.1. Attempt to mount bayonet connector in a wrong position	Cannot use device	Design review	None	S2	R2	1. 3M CVE	10. Design validation	On Hold	R1
16. Flex PCB Battery housing	3. Soldering interface to Battery Spring	1. Soldering fails	1. Power supply missing	16.3.1.1.1. Poor soldering process	Cannot use device	None	None	S2	R2	1. Training of personnel	8. Transfer to Process RA	Completed	
17. Chest piece Housing E3100	6. Holds device labeling	1. Difficult to laser print labeling	1. Difficult to read labeling	17.6.1.1.1. Material not suitable for laser printing	Cosmetic issue	Principle known from E4000/E4100	None	S1	R2	1. Process qualification	8. Transfer to Process RA	Completed	
17. Chest piece Housing E3100	6. Holds device labeling	1. Difficult to laser print labeling	1. Difficult to read labeling	17.6.1.1.2. Curved surfaces	Cosmetic issue	Principle known from E4000/E4100	None	S1	R2	1. Process qualification	8. Transfer to Process RA	Completed	
17. Chest piece Housing E3100	9. Smooth outer surface	1. Surface too rough	1. Handling noise	17.9.1.1.1. Poor surface quality	Sound quality reduced	Sub supplier dialog	1. article inspection	S2	R2	1. Process validation at sub supplier	9. Q-Agreement	Completed	R1
										2. Incoming inspection	9. Q-Agreement	Completed	
18. LCD Window	3. Provides acoustic and IPX4 sealing against Chest piece Housing	1. Sealing fails	1. Acoustic leak	18.3.1.1.1. Sealing damaged during assembly	Sound quality reduced	None	None	S2	R2	1. Assembly instruction	8. Transfer to Process RA	Completed	
19. Keyboard E3100	3. Enables adhesive acoustic and IPX4 sealing interface against Chest piece housing	1. Adhesive fails	1. Keyboard loosens	19.3.1.1.1. Fingers touches adhesive during assembly	Cannot use device	Extra securing snap features	None	S2	R2	1. Assembly instruction	8. Transfer to Process RA	Completed	
19. Keyboard E3100	3. Enables adhesive acoustic and IPX4 sealing interface against Chest piece housing	2. Sealing fails	1. Ambient noise enters the device	19.3.2.1.1. Adhesive sealing damaged during assembly	Sound quality reduced	None	None	S2	R2	1. Assembly instruction	8. Transfer to Process RA	Completed	

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Components	Function	Failure mode	Potential Hazards	Potential Causes	Effect to user, patient...	Current design control prevention	Current design control Detections	Severity	Before mitigation	Risk Control Activities			
										Recommended Risk Controls			After mitigation
									Risk Ranking	Description	Category	Status	Risk Ranking
19. Keyboard E3100	4. Enables electrical connector for mounting into J2 on Main PCB	2. One or more short circuits	1. Functional failure	19.4.2.1.1. Supplier process	Operational mode does not match user expectation	PSI	None	S2	R2	1. Functional test at sub supplier	9. Q-Agreement	Completed	R1
19. Keyboard E3100	4. Enables electrical connector for mounting into J2 on Main PCB	3. Broken wires	1. Functional failure	19.4.3.1.1. Handling error in assembly line	Operational mode does not match user expectation	None	None	S2	R2	1. Assembly instruction	8. Transfer to Process RA	Completed	
25. PCBA Main	5. Power supply regulation	2. High ripple on regulators	1. Noisy sound signal	25.5.2.1.1. Short circuits or wrong components	Sound quality reduced	None	None	S2	R2	1. Visual and X ray inspection at sub supplier	9. Q-Agreement	Completed	R1
										2. Assembly line device testing	8. Transfer to Process RA	Completed	
25. PCBA Main	5. Power supply regulation	3. Instability of regulators	1. Noisy sound signal	25.5.3.1.1. Missing components	Sound quality reduced	None	None	S2	R2	1. Visual and X ray inspection at sub supplier	9. Q-Agreement	Completed	R1
25. PCBA Main	9. Radio Waves transmitted/ received by Antenna	3. Wrong transmitter frequency	1. Device cannot connect	25.9.3.1.1. Frequency not calibrated	Cannot transfer data	Frequency controlled via DSP	None	S2	R2	1. Functional test and adjustment at sub supplier	9. Q-Agreement	Completed	R1
										2. 3. party Blue tooth certification	7. Design ver.	Completed	
26. Software	1. Samples amplified piezo sensor signal	2. Heart rate miscalculated	1. Wrong heart rate displayed	26.1.2.1.1. Other bio signals disturbs le from stoff pulse	Misinterpretation of vital life signs	Lower level discrimination Rythm consistency check. Trend check.	Engineering test on simulated test signals	S3	R2	1. 3M CVE	10. Design validation	On Hold	R1
27. Transducer module	2. Mechanical interface to Foot	1. Cannot be assembled	1. Transducer damaged	27.2.1.1.1. Fit too tight	Cannot use device	Tolerance stack analysis	None	S2	R2	1. Assembly line device testing	8. Transfer to Process RA	Completed	R1
27. Transducer module	3. Mechanical interface to Main PCB	1. Shortcut to conductive area on Main PCB	1. Electronic malfunction	27.3.1.1.2. Solder points between Transducer housing and PCBA for transducer close to Main PCB	Cannot use device	Tolerance stack analysis	None	S2	R2	1. Training of personnel	8. Transfer to Process RA	Completed	R1
27. Transducer module	4. Electrical FLEX1 to Main PCB	1. Connector fails	3. No sound	27.4.1.3.3. Internal transportation	Cannot use device	Edges rounded.	None	S2	R2	1. Internal handling in trays	8. Transfer to Process RA	Completed	R1

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Components	Function	Failure mode	Potential Hazards	Potential Causes	Effect to user, patient...	Current design control prevention	Current design control Detections	Severity	Before mitigation	Risk Control Activities			After mitigation
										Recommended Risk Controls			
									Risk Ranking	Description	Category	Status	Risk Ranking
				damage						2. In line final testing of device	8. Transfer to Process RA	Completed	
27. Transducer module	5. Amplification and filtering of piezo signal for Auto ON signal to Main PCBA	1. Wrong sensitivity response	1. Device turns on under storage conditions in pockets etc.	27.5.1.1.1. Too sensitive	Unexpected battery low feedback	Targeted for rumbling noise from hand and skin interface	Test on simulated data	S2	R2	1. 3M CVE		On Hold	R1
										2. In line testing of transducer module	8. Transfer to Process RA	Completed	
27. Transducer module	5. Amplification and filtering of piezo signal for Auto ON signal to Main PCBA.	1. Wrong sensitivity response	2. Device turns of during examination. Device can still be turned on by the On switch	27.5.1.2.1. Poor sensitivity	Cannot use device	Targeted for rumbling noise from hand and skin interface. Temperature compensation of piezo sensitivity	Test on simulated data	S2	R2	1. 3M CVE	10. Design validation	On Hold	R1
										2. In line testing of transducer module	8. Transfer to Process RA	Completed	
27 Transducer module	6. Amplification and filtering of piezo signal for DSP	1. Wrong frequency response	1. Distortion of sound signal	27.6.1.1.2. PCBA damaged by fixation/ soldering process	Misinterpretation of body sounds	None	None	S2	R2	1. In line final testing of device, frequency response and Auto On function	8. Transfer to Process RA	Completed	R1
27. Transducer module	6. Amplification and filtering of piezo signal for DSP	2. Low sensitivity	1. Low sound signal	27.6.2.1.1 Transducer assembly variability	Sound quality reduced	None	Corrosion test. Vibration test	S2	R2	1. Screening of transducer modules at assembly level	8. Transfer to Process RA	Completed	R1
										2. Process validation	8. Transfer to Process RA	Completed	
30. Transducer Housing	1. Adhesive mechanical interface to Transducer assy	1. Poor alignment of sensor	1. 1.Stress in piezo	30.1.1.1.1. Rough or uneven surface	Sound quality reduced	Flatness specified	1. article inspection	S2	R2	1. Transducer assy inline testing	8. Transfer to Process RA	Completed	
30. Transducer Housing	3. Solder interface of GND terminals to PCBA transducer housing	1. Poor solder quality	1. Shielding effect lost	30.3.1.1.1 Solder tags not correctly bent	Sound quality reduced	None	None	S2	R2	1. Assembly tool and instruction	8. Transfer to Process RA	Completed	
30. Transducer Housing	3. Solder interface of GND terminals to PCBA transducer housing	1. Poor solder quality	1. Shielding effect lost	30.3.1.1.2. Poor soldering process	Sound quality reduced	None	None	S2	R2	1. Training of personnel	8. Transfer to Process RA	Completed	

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Components	Function	Failure mode	Potential Hazards	Potential Causes	Effect to user, patient...	Current design control prevention	Current design control Detections	Severity	Before mitigation	Risk Control Activities			
										Recommended Risk Controls			After mitigation
									Risk Ranking	Description	Category	Status	Risk Ranking
30. Transducer Housing	4. Enables slit for mounting of Transducer assy	1. Flex damaged	1. No sound signal	30.4.1.1.1. Sharp edges on transducer housing	Cannot use device	DWG: All corners rounded No burrs allowed	None	S2	R2	1. Assembly instruction	8. Transfer to Process RA	Completed	R1
31. PCBA Transducer module	1. Flex interface to piezo signal	1. Flex damaged	1. No sound signal	31.1.1.1.1. Sharp edges on transducer housing	Cannot use device	None	None	S2	R2	1. Assembly instruction, handling procedure	8. Transfer to Process RA	Completed	
31. PCBA Transducer module	4. Solder interface to Transducer housing	1. Solderings fail	1. No shielding of transducer	31.4.1.1.1. Poor soldering process	Sound quality reduced	None	None	S2	R2	1. Training of personnel	8. Transfer to Process RA	Completed	
38. Diaphragm	4. Interface to human skin	1. Cannot achieve contact in concave body areas	1. Poor or no sound	38.4.1.1.1. Flat design	Sound quality reduced	None	None	S2	R2	1. 3M CVE	10. Design validation	On Hold	R1
10. PCB loudspeaker	5. Electrical limiting of battery short circuit current	1. Limiter short circuit	2. Heated chest piece surface if short circuits appears on Loudspeaker PCBA	10.5.1.2.1. Short circuits during use	Skin burns	Flex PCB limits current. Air barrier to Chest piece housing	Engineering test of short circuit temp	S3	R1	1. No further action		Completed	
25. PCBA Main	14. Provides insulation to Chest piece housing	1. Creep and air gaps insufficient	1. Chest piece housing can be connected to PCB potential	25.14.1.1.1. Poor layout	Electrical shock	Design review to check insulation distances. Needs a second failure to form a circuit	1. article inspection	S3	R1	1. IEC60601-1 Safety inspection by 3rd party	7. Design ver.	Completed	R1
26. Software	2. Delivers analog output to Loudspeaker	1. Acoustic power exceeds 140 dBA	1. Hazardous sound pressure applied to the ears	26.2.1.1.1. Software failure, leaves output amplifier in an oscillating state	Hearing impairment	Hardware protected. Worst case rail to rail output cannot exceed 140dBa	Max acoustic output verification test at single fault condition	S4	R1	1. No further action		Completed	

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Components	Function	Failure mode	Potential Hazards	Potential Causes	Effect to user, patient...	Current design control prevention	Current design control Detections	Severity	Before mitigation	Risk Control Activities			
										Recommended Risk Controls			After mitigation
									Risk Ranking	Description	Category	Status	Risk Ranking
26. Software	8. Controls Blue Tooth setup	1. Misleads BT setup parameters	1. Blue tooth output power set too high	26.8.1.1.1. Poor data integrity in flash memory	Could affect life sustaining/ monitoring equipment	Data integrity is controlled by processor firmware. Furthermore the 2 set (bytes) of BT parameters cannot conflict, checked by firmware. Output power can maximally be increased by a factor of 2 (hardware limited)	None	S4	R1	1. Functional test of output power at sub supplier	9. O-Agreement	Completed	R1
36. Foot	5. Provides insulation from Transducer module to Chest piece housing	1. Poor insulation	1. Ground potential to Chest piece housing	36.5.1.1.1. Poor design	Electrical shock	Design review to check insulation distances. Needs a second failure to form a circuit	1. article inspection	S3	R1	1. IEC60601-1 Safety inspection by 3. rd party	7. Design ver	Completed	R1

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6 Risk control

The status of implementation of the risk controls have been reviewed and updated

7 Conclusion

No risks with severity S5 were identified.
Two risks with severity S4 were identified:

- Sound pressure level exceeds 140dBA; Risk is mitigated by hardware protection
- BlueTooth antenna output power too high - disturbs other equipment; Risk is mitigated by hardware test and third party verification and certificate.

All risks have been mitigated to an acceptable level or transferred to the Process Risk Assessment worksheet, however, the following activities have not yet been completed:

- 3M CVE Design validation
- Wear test of new bayonet design (Project change order)

A final review of these activities will be made before Release for Sale.

This report concludes the design activities at Bang & Olufsen Medicom and will be attached to 3M Risk Management file: RISK MGMT-05-000265.xls.

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8 Version history

Version	Author	Date	Description	Reviewed by	EC number
1.00	SSR	11-12-2008	First edition	TRH	

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FDA CDRH DMC

DEC 29 2008

Received

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M3100-M3200
SRS SW Requirement Specification

Version: 2.00

File name: MBG0751C - SRS SW Requirement Specification for E3000 Plus.docx

Author

5/12-08
Date, Name – Software Designer

Approved by

5/12-08
Date, Name – Quality Assurance

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Version history

Version	Author	Date	Description	Reviewed by	EC number
0.1	MBG	20. dec 2008	Document created.		
0.2	MBG	11. feb 2008	Requrrements edited and "Req. by" added.		
0.3	MBG	20. feb 2008	Req by removed and Product Requirements added.		
0.4	MBG	28. feb 2008	Review comments added.	MBG, PMP, KHR, ABR, SFR	
0.5	MBG	16. May 2008	Sound Feedback tones defined.		
1.0	MBG	27. May 2008	Document ready for signing.		
1.10	CAP	9. Sep 2008	Document updated to implement new MMI and LCD according to EC Name changed to M3100-M3200 Section 1,2,3,4,5 updated SR:011 Updated: Third removed SR:075 New: Third filter added SR:013 Changed: Menu SR:015 Changed: Third filter requirements SR:017 Updated: Equally steps SR:020 Changed: Menu SR:021 Deleted SR:022 Deleted SR:035 Updated: Reference SR:040 Updated: Low level SR:041 Deleted SR:042 Deleted SR:044 Deleted SR:048 Changed: No double pressure SR:049 Changed: Menu SR:060 Deleted SR:076 New: Menu SR:058 Changed: Menu SR:059 Changed: Menu SR:077 New: LCD icons SR:078 New: LCD icons SR:079 New: Onboard storage SR:080 New: Onboard storage SR:081 New: Onboard storage SR:082 New: Menu SR:083 New: Upload data support SR:084 New: Onboard storage upload/download SR:085 New: Service counter		2008-117
1.20	CAP	25 Sep 2008	SR:074 Changed: Specification on steps removed to follow gain steps in chip. SR:014 SR:015 SR:016 Updated: Figure 1 added to specify filters		
1.30	PMP	8 oct 2008	SR:002 is corrected. SR:004 is corrected SR:006 is clarified SR:009 is corrected SR:010 is corrected		
1.40	MBG	27 nov 2008	SR:004 Edited to be more specific. SR:054 Deleted SR:086 New: M button stops recording, when in rec. SR:087 New: Remember pairing information for up to 8 Bluetooth devices. SR:071 Changed to match PR:126.		
2.00	MBG	04 dec 2008	Ready for signing		2008-201

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1 Purpose

This document list the requirements for the software developed to the E3000 Plus electronic stethoscope. E3000 plus is an update of the Model 3000 stethoscope and will be launched as Model 3100 and Model 3200.

Traceability to the product requirement is added in the tables and reported in the traceability analysis document .

2 Scope

Software requirements of both M3100 and M3200 are within this document. A column will identify in which product the requirement is implemented [8].

Model 3100: Holds the basic functions of the stethoscope.
Model 3200: Add more function as: Bluetooth link, third filter and onboard storage

3 References

[1] CAP0803a E3000 Plus Product requirements.doc
[2] AMI0803A E3000 plus Product Architecture Agreement.docx
[3] PMP0748C mmi state event action.vsd
[4] PMP0746A Bluetooth SPP protocol record specification.
[5] Appendix A to PMP0746A Bluetooth SPP protocol record specification.
[6] BUA0415a Design Verification Report - E3000 Frequency response and gain
[7] BUA0838a E3000 Plus Loop gain design verification protocol.
[8] MBG0809A - STA SW Traceability Analysis E3000 Plus

4 Reading guidance

The following section contains a general description of the E3000 plus stethoscope and its features. This is done to give an insight in the system and its functionality. After this, the actual requirements are stated.

During the description of button actions, there are two different ways of pressing a button.

Short pressure: 200-1000ms.
Long pressure: >1000ms

5 General description

5.1 System description

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[redacted]

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The user will use the electronic stethoscope in the same way as the Model 3000.

In addition to the Model 3000, the Model 3100 adds more software features:

- More acoustical amplification up to 28dB, [1].
- Separate on/off button (5 buttons keypad for operating the product).
- Power management with sleep state.
- Visual feedback via LCD with backlight.
- Heart rate monitor with Beats Per Minute (BPM) shown in the LCD.

In addition to the Model 3100, the Model 3200 adds more software features:

- Wireless communication via Bluetooth.
- Third filter option
- Onboard memory to store a sound track

A physical block diagram of the system is seen in Figure 1.

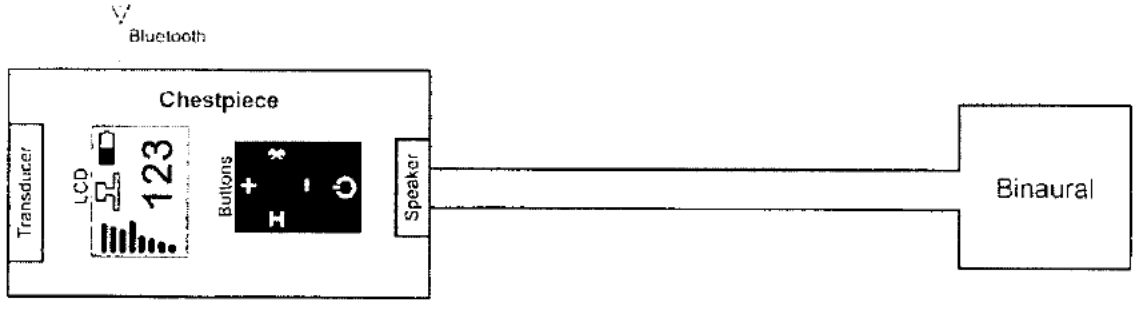

Figure 1: Physical block diagram of the E3000 Plus system.

The system consists of an active digital chest piece connected to passive binaurals thereby forming a complete stethoscope.

5.2 Functional description

For a functional description see "PMP0748C mmi state event action.vsd" [3].

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5.3 Software Features

A logical block diagram of the system is seen in Figure 2.

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Figure 2: Logical block diagram of the E3000 Plus system.

The DSP is responsible for the sound output to the binaural. Having received the sound input from the transducer in the chest piece, the sound is filtered and amplified as required before it is presented to the user by the loudspeaker via the binaurals.

The user acts upon the system by pressing the buttons, and the system responds with an acoustic and visual (LCD) feedback. The buttons can be pressed for a short or long time, which is defined in the word list in [1] .
By pressing the power button, when the stethoscope is powered off, it powers up in active mode. If the stethoscope is powered on and the power button is pressed shortly, the backlight is turned on. Pressing and holding the power button turns off the stethoscope.

The active filter can be selected by pressing the filter button and the volume can be regulated up or down using the [+],[-] keys. This can be done in single steps by pressing the volume button shortly, or continuous by pressing and holding down the volume button.

A configuration menu can be called by pressing the "M" button. Using the menu parameters such as default volume and default filter can be changed. For the M3200 the menu will have more items to enable Bluetooth and to make a recording.

A Battery powers the system whose condition must be monitored by the DSP in order to let the user know when it is time to change the battery.

5.4 System limitation

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5.5 User Characteristics

The user of the E3000 Plus is a medical professional, probably a person already accustomed to a mechanical stethoscope.

5.6 Development Requirements

The DSP used in this system is the (b)(4)Trade Secret [redacted]. In the development and implementation of software, the (b)(4)Trade Secret [redacted] Process-Product [redacted].

6 Specific Requirements

In the following sections a series of requirements are listed, which the M3100 and M3200 stethoscope must respect. This applies both for the architectural and the functional requirements.

The device is controlled through five buttons: a filter button, two volume buttons a menu button and a power on/off button. These buttons makes it possible for the user to control the device. In the requirements below, symbols are used for the different buttons. The symbol for each button is defined in Table 1. The symbols in Table 1 are not guaranteed to be in accordance with design specifications.

(b)(4)Trade Secret Process-Product Specs [redacted]

Button symbol	Function
	Filter button
	Menu button
	Power on/off button
	Increase volume button
	Decrease volume button

Table 1: Button symbols

6.1 Architecture

6.1.1 Performance Specifications

Number	Requirement	PR:	Implemented in model
SR:001	Requirement removed.	-	
SR:062	Amplification has to be 28dB measured at 100Hz at 25C±5C.	048	M3100 M3200
SR:063	Requirement removed.	-	
SR:064	(b)(4)Trade Secret Process-Product Specs [redacted]	052	M3100 M3200

6.2 Power Up

Number	Requirement	PR:	Implemented in model
SR:002	The device must power up by pressing the power on/off button ( ), when the device is powered off. There is no time-limit for releasing the button.	026	M3100 M3200
SR:003	The device power up in the filter-mode and volume level stored in non-volatile memory. Factory default will be diaphragm filter and volume level 3 as it is described in [2].	073 074	M3100 M3200
SR:004	The LCD lights up from cold boot within 2 sec. The LCD backlight turns off according to the chosen power profile described in [1] figure 2.	039	M3100 M3200
SR:005	A sound feedback must be given after a cold boot. The sound will be the sound associated with the stored filter (see table 2).	045	M3100 M3200
SR:066	The device must be ready for auscultation within 2 seconds when powering up from power off state.	075	M3100 M3200
SR:046	Stored user settings are loaded at startup. (see [3] on user settings.)	029 073 074 076	M3100 M3200

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6.3 Power Down

Number	Requirement	PR:	Implemented in model
SR:006	The device powers down within 2 seconds, showing the Littmann logo for 1 second ±100ms, after depressing the power on/off button ( ) with a long pressure. (See 4 for more detail on MMI)	040 026	M3100 M3200
SR:007	Not nessacery because of change in SR:006	-	
SR:008	Requirement removed.	-	
SR:009	Automatic power down will occur 30 min after entering stand by mode (timeframe can be varied by user in the configuration menu). (See 4 for more detail on MMI)	070 071	M3100 M3200
SR:010	A sound warning will notify the user of entering stand by mode 10 ± 2 seconds before it happens. (only if auto-off is not used)	047	M3100 M3200

6.4 Filter Mode

Number	Requirement	PR:	Implemented in model
SR:011	When the device is active, it must be possible to change between the Diaphragm and Bell filter by pushing the filter-button ( ). Information about the selected filter will be shown in the display in the form of an icon ( ). The icon changes appearance according to the selected filter.	028 053	M3100 M3200
SR:075	The M3200 will have a 3rd extended diaphragm filter. The filter will be selected in a list, which wraps around by pushing the filter-button.	053	M3200
SR:012	When another filter is selected, a sound feedback must be given to the user to indicate which filter is selected. (See related sounds in Table 2)	045	M3100 M3200
SR:013	A default filter mode can be stored using the configuration menu.	029 118	M3100 M3200

6.4.1 Bell Mode

Number	Requirement	PR:	Implemented in model
SR:014	The Bell filter must the same as implemented in M3000 within ± 2dB, see figure 1	053	M3100 M3200

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(b) (4) [redacted]

6.4.2 3rd Filter Mode

Number	Requirement	PR:	Implemented in model
SR:015	(b)(4)Trade Secret Process-Product Specs [redacted]	053	M3200

6.4.3 Diaphragm Mode

Number	Requirement	PR:	Implemented in model
SR:016	(b)(4)Trade Secret Process-Product Specs [redacted]	053	M3100 M3200

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[redacted]

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[redacted]

6.5 Volume Selection

Number	Requirement	PR:	Implemented in model
SR:017	It must be possible to turn the volume up and down with [redacted] and [redacted] respectively. Sound volume level steps up or down in 9 steps equally between level1 and level9 ±1dB. This will generate sound feedback and also change the volume indicator in the LCD.	030 031 051	M3100 M3200
SR:018	If the user holds either the volume up or down button for a long period, the volume is either turned up or down respectably, continuously.	030 031	M3100 M3200
SR:019	If the user tries to change the volume beyond the maximum or minimum sound level, the volume must stay unaffected and a feedback sound is not given to the user.	-	M3100 M3200
SR:020	A default volume level can be stored using the configuration menu. This will store the volume level in non-volatile memory. Next time the device power up, it will start up with this volume level.	128	M3100 M3200
SR:021	Deleted 2-9-2008		
SR:022	Deleted 2-9-2008		
SR:025	Removed as it is in SR:017	-	

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6.6 Dot-matrix LCD (Display)

Number	Requirement	PR:	Implemented in model
SR:077	The LCD must be a dot matrix monochrome display with a active area of 14x8mm the resolution is to be 56x32 dots having a dot pitch of 0.25mm.	036	
SR:078	The LCD views must be as defined in ref 3	023 025 043 126 130 131	
SR:023	The LCD backlight has to turn on when the power on/off button ( ) is pressed in normal operation states.	027	M3100 M3200
SR:027	Moved to SR:011	-	

6.7 Auto On/Off

Number	Requirement	PR:	Implemented in model
SR:030	The stethoscope should wake up from sleep mode, when it is triggered by an external trigger (button or sound activity), and then enter active mode. When entering active mode, the pre-emphasis filter circuit is powered up by the Bluecore5.	068 072	M3100 M3200
SR:031	The Auto off function drives the Bluecore5 into sleep mode, when no biometric sounds have has been detected for a period of 10 sec. (or for as long as set in the setup menu).	068	M3100 M3200
SR:032	When going into sleep mode (auto off) the emphasis filter circuitry is powered down.	-	M3100 M3200
SR:082	It must be possible through the menu to disable the auto-off and use time-out configuration	069	M3100 M3200

6.8 Heart Rate Monitor

Number	Requirement	PR:	Implemented in model
SR:033	Removed. Used in SR:034	-	
SR:034	(b)(4)Trade Secret Process-Product Specs [redacted]		M3100 M3200
SR:026	[redacted]		M3100 M3200

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6.9 Onboard storage

Number	Requirement	PR:	Implemented in model
SR:079	Using a menu command it must be possible to store a sound track of maximum 29 seconds	129 132	M3200
SR:080	Using a menu command it must be possible to play back the sound track	129 133	M3200
SR:081	The recorded signal is to be stored before filtering is applied	133	M3200
SR:086	The M button stops the recording if pressed during the recording.	137	M3200

6.10 Soft clipping output limiter

Number	Requirement	PR:	Implemented in model
SR:035	(b)(4)Trade Secret Process-Product Specs [redacted]	050	M3100 M3200

6.11 Sound feedback

The sound feedbacks mentioned in the requirements in the previous sections, are listed in Table 2.

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Function \ Sound	Power off	Bell	3rd Filter (M3200)	Diaphragm	Vol.	Store Volume & filter	Time warning	Playback
Power on ( )		X*	X*	X*				
Bell mode ( )		X						
3rd Filter (M3200) mode ( )			X					
Diaphragm mode ( )				X				
Volume step (or)					X			
Entering Sleep state**							X	
Playback alert.								X

Table 2: Overview of the feedback sounds given on user interaction

*Sound played depending on stored filter.
**Sound played when using timed off is selected, not when using auto-off.

The following sound feedbacks are made up of musical notes and are defined in notes and approximate frequencies. The duration of the tone is given in fractions of 4 second intervals.

6.11.1 Bell Filter

C6 (~500Hz), 16th-note (250ms).
Rest (0Hz), 16th-note (250ms).
C6 (~500Hz), 16th-note (250ms).

6.11.2 Diaphragm Filter

B6 (~1kHz), 16th-note (250ms).
Rest (0Hz), 16th-note (250ms).
B6 (~1kHz), 16th-note (250ms).

6.11.3 3rd Filter

C6 (~500Hz), 16th-note (250ms).
Rest (0Hz), 16th-note (250ms).
B6 (~1kHz), 16th-note (250ms).

6.11.4 Volume Change

G7 (~1.5kHz), 32nd-note (125ms).

6.11.5 Time Warning (Entering Sleep State)

B6 (~1kHz), 16th-note (250ms).
B7 (~2kHz), 32nd-note (125ms).

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6.11.6 Playback

B7 (~2kHz), 64th-note (62.5ms).

Specific requirements for the sound feedback:

Number	Requirement	PR:	Implemented in model
SR:036	The sound feedback given to the user, must comply with Table 2.	045 046 047	M3100 M3200
SR:037	Removed.	-	
SR:038	Removed.	-	

6.12 Battery Monitor

In this section, it is defined how the battery is monitored.

Number	Requirement	PR:	Implemented in model
SR:039	When "battery low"(level 1) is detected, the user must get a visual feedback (flashing visual indicator). Otherwise the device works normally.	041	M3100 M3200
	When the battery is degrading, this should be visually indicated by the graded battery indicator, which has at least 4 levels.	041	M3100 M3200
SR:041	Deleted 2-9-2008		
SR:042	Deleted 2-9-2008		
SR:044	Deleted 2-9-2008	-	
SR:065	When battery reaches minimum voltage for wireless data transmission an error message has to be sent to the external device.	067	M3100 M3200
SR:024	The LCD has to give information on battery level.	041	M3100 M3200

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6.13 Miscellaneous

6.13.1 Flash and PS – keys

The flash contains the (b)(4)Trade Secret Process-Product S, the application and the data used in the application stored as PS-keys (Persistence Storage keys) like volume, filters etc.

Number	Requirement	PR:	Implemented in model
SR:045	Removed.	-	

6.13.2 Button Commands

Number	Requirement	PR:	Implemented in model
SR:047	When a button command is acknowledged by the DSP, all buttons must be released before a new command can be acknowledged. This also applies for illegal button commands.	-	M3100 M3200
SR:048	Combinations of simultaneously pressed buttons are ignored	-	M3100 M3200

6.13.3 Configuration menu

Number	Requirement	PR:	Implemented in model
SR:049	The device will enter the configuration menu when the 'M' button (M) is pressed.	034	M3100 M3200
SR:050	The menu and setting options are shown in [3].	069 070 071 072 076 080	M3100 M3200
SR:060	Deleted 2-9-2008		
SR:061	The configuration menu has to be able to show SW version and identification number.	042	M3100 M3200
SR:076	With the menu active the buttons are reconfigured to navigate in the menu. "+" Scroll upwards in the menu list "-" Scroll downwards in the menu list "M" Select menu item. "Filter" Escape or step one level back in menu		M3100 M3200

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6.13.4 Service counters

Number	Requirement	PR:	Implemented in model
SR:085	Service counters must be implemented to track the use of the stethoscope. A minimum of counters are: - Number of key presses by key - Number of auto on activations - Time in active mode - Time in Bluetooth mode	136	M3100 M3200

7 External interface requirements

7.1 Communication Interface (Bluetooth)

Number	Requirement	PR:	Implemented in model
SR:051	(b)(4)Trade Secret Process-Product Specs	079	M3200
SR:052		078	M3200
SR:053	Audio feedback streamed from a connected device should be mixed over the biological sound picked up by the stethoscope at request.	-	M3200
SR:058	Bluetooth connection activates/de-activates using the menu and the device enters Active BT state.	032 068	M3200
SR:059	Bluetooth paring session is enabled through the menu.	033	M3200
SR:067	The Bluetooth link must comply with the protocol specified in ref. [4] and ref. [5].	081 121	M3200
SR:028	Bluetooth logo ( ) flashes when the device has lost its connection.	-	M3200
SR:029	Bluetooth logo ( ) is lit when a connection is established.	-	M3200
SR:070	During pairing with another Bluetooth device, the display shows two Bluetooth icons with an arrow moving between them (see [4] for display information).	043	M3200
SR:071	During playback from a Bluetooth device, if the sound is filtered in the stethoscope, the filter icon is shown and if the sound it not filtered, no filter icon is shown. (See [4] for display graphics)	126	M3200
SR:072	(b)(4)Trade Secret Process-Product Specs	077	M3200
SR:073	A notification (tone) must be given every 8 seconds in the binaurals when playback is in progress. (time has to be variable)	125	M3200
SR:074	The transmitted data from channel B has to have an independently program-controlled gain of minimum 24dB.	124	M3200
SR:083	The device must support received data of both : (b)(4)Trade Secret Process-Product Specs	127	M3200

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SR:084	A recorded sound track can be uploaded to a connected Bluetooth device and a sound track can be downloaded to the stethoscope.	134	M3200
SR:087	The stethoscope has to be able to be paired with up to 8 Bluetooth devices. This enables the stethoscope to connect to the 8 known devices without pairing again.	139	M3200

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7.2 SPI interface

Number	Requirement	PR:	Implemented in model
SR:068	(b)(4)Trade Secret Process-Product Specs [redacted]	120	M3100 M3200
SR:069	[redacted]	004	M3100 M3200

8 Performance requirements

8.1 User Response Times

Number	Requirement	PR:	Implemented in model
SR:054	Deleted 26-11-2008	-	M3100 M3200
SR:055	At power up, the device must be functional within 2 seconds of the activation.	026	M3100 M3200
SR:056	After a "power down" command is recognized the Littman logo is shown in the LCD, the device must wait at least 500ms before power down, to ensure that the user has released the button.	-	M3100 M3200
SR:057	At power down, the device must indicate full power down within 2 seconds.	040	M3100 M3200

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[redacted]

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7/2-08
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5/12-2008
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Version history

Version	Author	Date	Description	Reviewed by	EC number
0.1	MBG	9. jan 2008	Dokument created.		
0.2	MBG	11. feb 2008	New requirements were added, thus the new tests.		
1.00	PMP	06 oct 2008	version 1.00 of this acceptance test is intended for release of model 3100 software.		
1.10	MBG	27 nov 2008	Additional tests were added to include the M3200.		
1.11	MBG	28 nov 2008	AT:014 removed – testing SR:035 AT:031 removed – testing SR:062 + SR:064 See traceability to find test of these functions.	PMP,CAP,BUA, MBG	
1.20	MBG	04 dec 2008	Skill level added in section 4 and review comments added. AT:005 Edited to contain AT:007. AT:007 Deleted. AT:023 Deleted. AT:015 Deleted.		
2.00	MBG	04 dec 2008	Document ready for signing.		2008-201

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1 Purpose

The purpose of this document is to describe and list the tests, which are to be carried out to verify that the software is running as required in the software requirements.

2 Scope

This document describes the acceptance test of the software component of the E3000 Plus stethoscope. These tests will be carried out and there results will be shown in the Acceptance Test Report.

3 References

The E3000 Plus software requirement specification:

[1] MBG0751C - SRS SW Requirement Specification for E3000 Plus.docx
[2] BUA0415a Design Verification Report - E3000 Frequency response and gain.doc
[3] PMP0748C mmi state event action.vsd

4 Reading guidance

A note to the tables holding test cases:

- AT is short for Acceptance Test – the acceptance test number is indicated in this column.
- Step refers to the step within an acceptance test. Some acceptance test are composed of several steps that must be executed consecutively.
- SR refers to the software requirements that are tested by the acceptance test or test step.
- Some acceptance tests are composed of several steps that must be executed consecutively. The steps in acceptance tests are indicated by a letter after the test case number e.g. AT:017a.
- SR refers to the software requirements that are tested by the acceptance test or test step.

When buttons have to be activated in a test, the button must be held down for 0.5-1.5 sec unless specified otherwise. The different buttons on E3000 Plus are described in the table below. Note that the symbols might be slightly different on the assembled device.
The skill level of the person performing the tests has to be at a level, where he or she is able to pair and establish a Bluetooth connection on a PC. They also need to have a technical understanding covering the technical words and descriptions in the tests.

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Button symbol	Function
	Filter button
	Menu button
	Power on/off button
	Increase volume button
	Decrease volume button

Table 1: Button symbols

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5 TEST DESCRIPTION

The purpose of the software acceptance test is to verify that the requirements stated in [1] are implemented correctly.

5.1 Test Target

The software acceptance test is performed on the final software for the E3000 Plus stethoscope.
The specific stethoscope used is listed below.

Description	Identification
E3000 stethoscope	Software version: Serial number:
MkII-098 M3100 SW v. 00.95.00	0008090000000000
MkII-170 M3200 SW v. 00.95.00	0008120000424549

5.2 Test Configuration

The accept test is performed as a set of structured test cases. The test cases are detailed descriptions of user interaction and expected behaviour.

The test cases are designed so they can be performed by anyone on an assembled device. This avoids the use of large and complicated test/measurement setups, but still makes a thorough functionality test of E3000 Plus.

All tests must be performed at room temperature.

5.3 Test Approval

All errors found must be classified and the classification of errors must comply with the standard error classification used a(b)(4)Trade Secret Process- [redacted].

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6 TEST INSTRUCTIONS

Each test case contains nine description windows. Some of the windows are descriptors others are for the actual test results. A short description of each window is given here:

- ***Purpose***
  A short description of the purpose of the test.
- ***AT***
  The number of the Acceptance Test, this number is unique and can only be used in other test cases if the test has to be performed in steps and thereby indexed with a letter.
- ***SR***
  Indicates which software requirement is tested in the current acceptance test, see reference **Error! Reference source not found.Error! Reference source not found.** in section 3.
- ***Actions***
  Describes the test sequence, any presetting are also stated here.
- ***Expected result***
  The expected outcome of the test is listed in this window
- ***Result***
  The actual result after the test has been performed. If the result is as expected is allowed to comment the result by writing "OK".
- ***Test equipment and reference***
  Statement of the test equipment used to perform the test. All the equipment required to perform this acceptance test is listed in section 6.2.
- ***Comment***
  Notes and comments from the test performer, writing "No comment" is allowed if nothing unusual is observed.
- ***Date and initials***
  Test date and the initials of the person performing the test. If the test result can be accepted the **Pass** box should be marked with √ else the **Not Pass** is marked.

6.1 Software set-up in the test

The software is setup as it would be in the final product. All functions are active in the tested module.

6.2 Needed equipment

This chapter contains information on the equipment needed to perform the tests.
The tests have to be carried out on an M3100 and a M3200 stethoscope. Where the M3100 is not required to pass the acceptance test, it will not be listed in the column model.

Instruments

The instruments in the following table are needed to execute the tests. The FAA no. (or the instrument series number) must be written in the table for the used instruments, also the calibration date for the last calibration of the instrument must be written in the table.

Type	Manufacture and model number	FAA no./SN	Calibration date

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Test fixture
none

Other test equipment
none

6.3 Hints for the testing

none

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7 TEST CASES

7.1 Power Up timing

Purpose	Test that the E3000 Plus stethoscope powers up, when pressing the power button				
Test case	AT: 001	SR:	SR: 002, SR: 004, SR:055, SR: 066		
Action	1) E3000 Plus is powered down 2) Insert the E3000 Plus earplugs into your ears 3) Do stimuli				
Shot	Stimuli	Expected result	Result	Model	ref
A	Press shortly	Stethoscope power on	OK	M3100 M3200	SR: 002
B	Press until the stethoscope show normal display, then release the button	Stethoscope stay powered on	OK	M3100 M3200	SR: 002
C	Press shortly. Measure time from key pressed to backlight is on	less than 2 seconds	OK	M3100 M3200	SR: 066
D	Press shortly. Measure time from key pressed to sound is on	less than 2 seconds	OK	M3100 M3200	SR: 066 SR: 055
Test equipment and reference	Measure time with a stopwatch 5 times and calculate mean. This test also has to be done in an integration test, which is referred to here.				
Comment					
Pass X	**Not pass**	**Date:** 5/12 2008	**Sign:**		

7.2 Factory Default Settings1.

Purpose	Test factory default settings.		
Test case	AT:022	SR:	SR:003
Action	Use a new fresh produced stethoscope model 3200 turn stethoscope on		
Expected result	1) stethoscope does not enter Bluetooth 2) volume level 3. 3) diaphragm filter.		
Result	OK		
Test equipment and reference			
Comment			
Pass X	**Not pass**	**Date:** 5/12 2008	**Sign:**

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7.3 Factory Default Settings2.

Purpose	Test that the factory default settings are as specified.		
Test case	AT: 041	**SR**	SR:046
Action	1) E3000 Plus is powered on 2) Enter MENU → SETUP 3) Do stimuli		

Shot	Stimuli	Expected result	Result	Model	ref
A	Select POWER	LOW is indicated	OK	M3100 M3200	
B	Select Battery	ALKALINE is indicated	OK	M3100 M3200	
C	Select BACKLIGHT	ON DMND is indicated.	OK	M3100 M3200	
D	Select AUTO OFF	ENABLE is indicated.	OK	M3100 M3200	
E	Select FILTERS	3 is indicated.	OK	M3200.	
F	Select BT. COMM	MANUAL is indicated	OK	M3200	PR: 076

Test equipment and reference	
Comment	
Pass X **Not pass**	**Date:** 12/12-08 **Sign:** Mikkel Borgaard

7.4 Power up default settings

Purpose	Test that the E3000 Plus stethoscope powers up with the preset values		
Test case	AT: 002	**SR**	SR: 003, SR: 005
Action	1) Store pre settings, and turn stethoscope off. 2) Turn stethoscope on and verify settings		

Shot	Stimuli	Expected result	Result	Model	ref
A	Store bell filter setting and volume step 0 Press ⏻ shortly	Stethoscope power on and give 2 short 500 Hz beeps	OK	M3100 M3200	SR: 005
B		Stethoscope show bell filter and volume step 0	OK	M3100 M3200	SR: 003
C	Store diaphragm filter setting and volume step 8 Press ⏻ shortly	Stethoscope power on and give 2 short 1000 Hz beeps	OK	M3100 M3200	SR: 005
D		Stethoscope show diaphragm filter and volume step 8	OK	M3100 M3200	SR: 003
E	Store third filter setting and volume step 5 Press ⏻ shortly	Stethoscope power on and give 1 short 500 Hz beep and 1 short 1000 Hz beep	OK	M3200	SR: 005
F		Stethoscope show third filter and volume step 5	OK	M3200	SR: 003

Test equipment and reference	
Comment	
Pass X **Not pass**	**Date:** 12/12-08 **Sign:** Mikkel Borgaard

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7.5 Power Down

Test 1

Purpose	Test that the E3000 Plus stethoscope powers down, when pressing the power button for more than one second, while the stethoscope is powered on. The LCD should show the Littmann when powering down.			
Test case	AT: 003	**SR**	SR:006 SR:056 SR:057	**Model** M3100 M3200
Action	E3000 Plus is powered down 1) Insert the E3000 Plus earplugs into your ears 2) Press 3) Wait for 10 sec. and press the *power on/off* button again. The button must be pressed at least 1 second.			
Expected result	1) There are no sounds coming from the E3000 Plus (device is off). 2) The E3000 plus powers up. 3) The device indicates power down (showing the Littmann logo) and is fully powered down within 2 seconds.			
Result	OK			
Test equipment and reference				
Comment				
Pass x **Not pass**	**Date:** 5/10-2008	**Sign:**		

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Test 2

Purpose	Test that the E3000 Plus stethoscope enter standby automatically, when the power off timer runs out, while the stethoscope is powered on. The value of the timer is set in the configurations menu of the E3000 Plus.				
Test case	AT: 004	SR	SR: 004, SR: 009, SR: 010, SR:036		
Action	1) Power on the stethoscope and insert earplugs into your ears. 2) Store settings and measure the time until the stethoscope enters standby.				
Shot	Stimuli	Expected result	Result	Model	ref
A	Power = low, Auto off = disabled	Power On Time = 3 min. ± 10% Power Off Time = 30 min. ± 10% Backlight = 3 sec. ± 10% Warning tone is played 10 ± 2 sec. before entering standby : 1kHz ± 25%, 250ms ± 25%, 2kHz ± 25%, 125ms ± 25%	OK	M3100 M3200	
B	Power = medium, Auto off = disabled	Power On Time = 5 min. ± 10% Power Off Time = 2 hr. ± 10% Backlight = 5 sec. ± 10% Warning tone is played 10 ± 2 sec. before entering standby: 1kHz ± 25%, 250ms ± 25%, 2kHz ± 25%, 125ms ± 25%	OK	M3100 M3200	
C	Power = high, Auto off = disabled	Power On Time = 7 min. ± 10% Power Off Time = 5 hr. ± 10% Backlight = 5 sec. ± 10% Warning tone is played 10 ± 2 sec. before entering standby: 1kHz ± 25%, 250ms ± 25%, 2kHz ± 25%, 125ms ± 25%	OK	M3100 M3200	
D	Power = low, Auto off = enabled	Power On Time = 10 - 20 sec. Power Off Time = 30 min. ± 10% Backlight = 3 sec. ± 10%	OK	M3100 M3200	
E	Power = medium, Auto off = enabled	Power On Time = 20 - 30 sec. Power Off Time = 2 hr. ± 10% Backlight = 5 sec. ± 10%	OK	M3100 M3200	
F	Power = high, Auto off = enabled	Power On Time = 30 - 40 sec. Power Off Time = 5 hr. ± 10% Backlight = 5 sec. ± 10%	OK	M3100 M3200	
Test equipment and reference					
Comment	The Auto-off times are tested in AT:012				
Pass **Not pass**	**Date:** 8/12-2008	**Sign:** [signature]			
X					

7.6 Filter Mode

Test 1

Purpose	Test that the E3000 Plus stethoscope filter mode changes and that the correct mode is set.				
Test case	AT: 005	SR	SR: 011, SR: 012, SR:036		
Action	E3000 Plus is powered on 1) Insert the E3000 Plus earplugs into the Head and Torso Simulator (HATS). 2) Start logging data from HATS. 3) Do stimuli and compare result with expected result.				
Shot	Stimuli	Expected result	Result	Model	ref

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A	Press to Change filter to the extended filter.	First tone: 500Hz ± 25%, 250ms ± 25% Second tone: 1kHz ± 25%, 250ms ± 25% The correct filter icon is showed in the LCD.	OK	M3200	
B	Press to Change filter to the bell filter.	First tone: 500Hz ± 25%, 250ms ± 25% Second tone: 500Hz ± 25%, 250ms ± 25% The correct filter icon is showed in the LCD.	OK	M3100 M3200	
C	Press to Change filter to the diaphragm filter.	First tone: 1kHz ± 25%, 250ms ± 25% Second tone: 1kHz ± 25%, 250ms ± 25% The correct filter icon is showed in the LCD.	OK	M3100 M3200	

Test equipment and reference	
Comment	
Pass X / Not pass	Date: 12/12-08 Sign: Mikkel Borggaard

Test 2

Purpose	Test that the current filter mode is stored in non-volatile memory when storing filter in setup menu				
Test case	AT: 006	SR	SR: 013		
Action					
Shot	Stimuli	Expected result	Result	Model	ref
A	Select bell filter Store filter in setup menu Turn stethoscope off and on again.	Bell filter is used	OK	M3100 M3200	SR: 013
B	Select diaphragm filter Store filter in setup menu Turn stethoscope off and on again.	Diaphragm filter is used	OK	M3100 M3200	SR: 013
C	Select third filter Store filter in setup menu Turn stethoscope off and on again.	Third filter is used	OK	M3200	SR: 013

Test equipment and reference	
Comment	
Pass X / Not pass	Date: 8/12-2008 Sign: [signature]

Test 4

Purpose	Test that the number of filters available is the same as set in setup menu				
Test case	AT: 008	SR	SR: 075		
Action	Insert the E3000 Plus earplugs into your ears				
Shot	Stimuli	Expected result	Result	Model	ref
A	Set filters = 2 in setup menu press filter button more time.	The stethoscope toggle filter between bell and diaphragm	OK	M3100 M3200	SR: 075
B	Set filters = 3 in setup menu	The stethoscope		M3200	SR:

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	press filter button more time.	toggle filter between bell, diaphragm and third filter	Ok		075

Test equipment and reference	
Comment	ONLY WORKS ON E-3200
Pass x **Not pass**	**Date:** 8/12-2008 **Sign:**

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Test 5

Purpose	Test the frequency response of the three different filter modes.		
Test case	AT:009	**SR**	SR: 014 SR: 015 SR: 016
Action	E3000 Plus is powered down 1) Place the E3000 Plus into the Service Centre. 2) Press ⏻ 3) Select the *Bell* filter by pressing the filter button ▮ and run the frequency response test. 4) Look at the result from the Service Centre. 5) Select the *third* filter by pressing the filter button ▮ and run the frequency response test. 6) Look at the result from the Service Centre. 7) Select the *Diaphragm* filter by pressing the filter button ▮ and run the frequency response test. 8) Compare with the expected stethoscope filter response.		
Expected result	1) There are no sounds coming from the E3000 Plus (device is off). 2) The E3000 plus powers up. 3) The E3000 Plus changes filter mode to *Bell*. The matching filter symbol is shown in the display. 4) The frequency response matches the one found in [2] for the *Bell* filter. 5) The E3000 Plus changes filter mode to third filter. The matching filter symbol is shown in the display. 6) The frequency response matches the one found in [2] for the *third* filter. 7) The E3000 Plus changes filter mode to *Diaphragm*. The matching filter symbol is shown in the display. 8) The frequency response matches the one found in [2] for the *Diaphragm* filter.		
Result	OK		
Test equipment and reference			
Comment	Remember to turn up the volume.		
Pass ✓ **Not pass**	**Date:** 3/10. 2005	**Sign:**	

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7.7 Volume setting

Test 1

Purpose	Test that the volume changes, when the volume up or volume down button is pressed.		
Test case	AT:010	**SR**	SR:017 SR:018 SR:019 SR:036
Action	E3000 Plus is powered on 1) Insert the E3000 Plus earplugs into your ears. Setup HATS system to measure the tone. 2) Press the volume up button [redacted]. 3) Press the volume down button [redacted]. 4) Press and hold the volume up button [redacted]. 5) Press and hold the volume down button [redacted].		
Expected result	1) E3000 Plus is operational 2) The volume level is increased 1 step and feedback is given via sound and the LCD. 3) The volume level is decreased 1 step and feedback is given via sound and the LCD. 4) The volume level is increased all the way to max and feedback is given via sound and the LCD. When the volume reach the highest level it stops giving sound feedback 5) The volume level is decreased all the way to min and feedback is given via sound and the LCD. When the volume reach the lowest level it stops giving sound feedback 6) the audio feed back is a short 1500Hz ± 25% 125ms ± 25% beep (verify with measurements from HATS.)		
Result	OK		
Test equipment and reference			
Comment			
Pass / **Not pass**	**Date:**	**Sign:**	
X	12/11-08	Mikkel Bergaard	

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Test 2

Purpose	Test that the volume setting can be stored in non-volatile memory.
Test case	AT:011 SR: SR:020
Action	E3000 Plus is powered on 1) Insert the E3000 Plus earplugs into your ears 2) Change the volume setting by pressing . 3) Store the volume in setup menu 4) Turn off the stethoscope by pressing and holding the power on/off button for more than 1 second. 5) Turn on the stethoscope by pressing the power on/off button . 6) Listen to the body sounds (heart and respiration) and look at the LCD.
Expected result	1) E3000 Plus is operational 2) The volume level is increased 1 step and feedback is given via sound and the LCD. 3). 4) the stethoscope power off 5) The E3000 plus powers up. 6) The volume level is increased 1 step compared to the last time the stethoscope was powered up and feedback is given via the LCD.
Result	OK
Test equipment and reference	
Comment	
Pass x **Not pass**	**Date:** 8/12 2008 **Sign:**

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7.8 Auto On/Off

Purpose	Test that the Auto on/off system works. That is, that the E3000 Plus powers up from sleep mode, when the chest piece is placed on a body and that it powers off again, when no biological signal is measured. The power off function can be delayed by setting a timer in the configuration menu.		
Test case	AT: 012	SR:	SR:030, SR:031, SR:032
Action	Make settings as described in stimuli and then 1) Insert the E3000 Plus earplugs into your ears 2) Listen to a body sound and then place the stethoscope on table. 3) Wait till stethoscope automatically goes into standby. 4) Pick up the E3000 Plus, begin auscultation.		

Shot	Stimuli	Expected result	Result	Model	ref
A	Power = low, Auto off = enabled	Power On Time = 10 – 20 sec. Logo is showing in LCD.	Ok.	M3100 M3200	
B	Power = medium, Auto off = enabled	Power On Time = 20 – 30 sec. Logo is showing in LCD.	OK	M3100 M3200	
C	Power = high, Auto off = enabled	Power On Time = 30 – 40 sec. Logo is showing in LCD.	OK	M3100 M3200	

Test equipment and reference		
Comment		
Pass x **Not pass**	**Date:** 8/12 2008	**Sign:**

7.9 Heart Rate Monitor

Test1

Purpose	Test that the heart rate monitor is working and that the right heart rate is shown in the LCD.		
Test case	AT:013	SR:	SR:034 SR:026
Action	E3000 Plus is powered on and in active state 1) Insert the E3000 Plus earplugs into your ears 2) Place the chest piece on the shaker setup and set a frequency. 3) Read the display. Set a new frequency and wait 20 seconds and read the heart rate again. 4) Set the frequency of the shaker to zero and read the display.		
Expected result	1) E3000 Plus is operational 2) A heart beat can be heard and the LCD shows the heart beat in beats per minute (b) [redacted]. As the heart rate changes, it is updated in the LCD every 2 seconds. (4)Tra 3) The LCD shows the heart rate in bpm. 4) The heart beat is shown for 10 seconds after the loss of heart sound signal. Afterwards two lines are shown (— —) to indicate that no valid heart rate is measured.		
Result	OK		

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Test equipment and reference	Mini Shaker Type 4810, Impedance: 3.5 Ω, Input power 15VA max, Stroke ± 3mm max HP33120A 15MHz Function/Arbitrary waveform generator
Comment	Frequency used: 60 bpm & 75 bpm
Pass **Not pass**	**Date:** 5/12 2008 **Sign:** [signature]
x	

Display valid heart rates

Purpose	Heart rate monitor only shows values of 30 to 199 in the LCD.		
Test case	AT:032	**SR**	SR:026
Action	E3000 Plus is powered on and in active state 1) Place the chest piece on a shaker, which is creating at saw tooth signal with a freq. of 1Hz. 2) Read the display. 3) Set the shaker frequency to 0.4Hz 4) Read the display. 5) Set the shaker frequency to 3.5Hz 6) Read the display.		
Expected result	1) E3000 Plus is operational 2) A heart beat can be read in the LCD, 60bpm. 3) Wait for 15 seconds. 4) The lines are shown (— —) to indicate that no valid heart rate is measured. 5) Wait for 15 seconds. 6) The lines are shown (— —) to indicate that no valid heart rate is measured.		
Result	OK		
Test equipment and reference	Same as above		

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Comment	
Pass / Not pass	Date: 9/12.2008 Sign:

7.10 Battery Monitor

Level Indicator1.

Purpose	Test the different levels of the battery monitor.
Test case	AT: 016 SR: SR:039, SR:024, SR:040
Action	E3000 Plus is powered by special batteries. Four batteries of three different types. The four different batteries have four different amounts of power left in order to indicate the four different battery levels. 1) Insert the described battery and specify battery type in the setup of the stethoscope. 2) Look at the battery level indicator.

Shot	Stimuli	Expected result	Result	Model	ref
A	50 - 100% Alkaline battery. 1350mV	50 - 100% battery life is shown	Full	M3100 M3200	
B	25 - 50% Alkaline battery. 1280mV	25 - 50% battery life is shown	Half	M3100 M3200	
C	10 - 25% Alkaline battery. 1245mV	10 - 25% battery life is shown	1 bar	M3100 M3200	
D	0 - 10% Alkaline battery. 1210mV	0 - 10% battery life is shown and the battery icon flashes.	Empty Blinks	M3100 M3200	
E	50 - 100% Lithium battery. 1560mV	50 - 100% battery life is shown	Full	M3100 M3200	
F	25 - 50% Lithium battery. 1470mV	25 - 50% battery life is shown	Half	M3100 M3200	
G	10 - 25% Lithium battery. 1400mV	10 - 25% battery life is shown	1 bar	M3100 M3200	
H	0 - 10% Lithium battery. 1350mV	0 - 10% battery life is shown and the battery icon flashes.	Empty Blinks	M3100 M3200	
I	50 - 100% NIMH battery. 1280mV	50 - 100% battery life is shown	Full	M3100 M3200	
J	25 - 50% NIMH battery. 1250mV	25 - 50% battery life is shown	Half	M3100 M3200	
K	10 - 25% NIMH battery. 1240mV	10 - 25% battery life is shown	1 bar	M3100 M3200	
L	0 - 10% NIMH battery. 1210mV	0 - 10% battery life is shown and the battery icon flashes.	Empty Blinks	M3100 M3200	

Test equipment and reference	
Comment	
Pass / Not pass	Date: 17-12 2008 Sign:

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Level indicator2.

Purpose	Test the battery minimum voltage warning for the wireless data transmission. This warning is sent in order to notify that the connection is about to be closed. The E3k_Streamer program is necessary in this test. It should be installed on a PC with a Bluetooth connection.		
Test case	AT:035	**SR**	SR:065
Action	E3000 Plus is powered up via special low power batteries. 1) Establish a streaming connection to the PC. 2) Turn down the power supply until battery low level is reached. 3) Turn the power supply all the way down.		
Expected result	1) The E3000 Plus is streaming sound to a PC. 2) The battery level indicator flashes and an error bit is set in the header of the data stream. This will be visible in the error information in the PC program. 3) The E3000 Plus powers down, showing the Littmann logo and the wireless connection is lost.		
Result			
Test equipment and reference			
Comment	Acceptance test is done in SPP Command SW test SPP:051		
Pass **Not pass**	**Date:** 12/12-08	**Sign:** Mikkel Borggaard	

7.11 Miscellaneous

Button Commands

Purpose	Test multiple key pressing

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Test case	AT: 017	SR	SR:047, SR:048
Action	Turn stethoscope on		

Shot	Stimuli	Expected result	Result	ref
A	press and hold filter button pres and release + button	Change filter don't change volume	OK	SR: 048
B	press and hold - button pres and release M button	Change volume don't enter menu	OK	SR: 048
C	press and hold - button Press and release filter button	volume decrease Volume stop decreasing	OK	SR: 048
D	Press and hold M button Press and hold filter button release M button Press and hold + button Release M button release + button press - button	Enter menu "CONNECT" No change No change No change No change No change change to "DISCONNE"	OK	SR: 047, SR: 048

Test equipment and reference	
Comment	

Pass	Not pass	Date:	Sign:
X		9/10.2008	[illegible]

Configuration menu

Purpose	Test configuration menu		
Test case	AT: 018	SR	SR:049, SR:050, SR:082
Action			

Shot	Stimuli	Expected result	Result	ref
A	Model 3200 Press M button	enter menu main menu > "CONNECT"	OK	PR: 034
B	Model 3100 Press M button	Enter setup menu > "POWER"	OK	PR: 034
C	Select AUTO OFF = ENABLE Select POWER = LOW Use stethoscope	Stethoscope is on while places on body. The stethoscope enter stand by 10 -20 seconds after it is places on a table	OK	PR: 069
D	Select AUTO OFF = DISABLE Select POWER = LOW Use stethoscope	Stethoscope is on while placed on a table till 3 minutes after a key is pressed or released	OK	PR: 069, SR: 082
E	Select AUTO OFF = DISABLE Select POWER = LOW Place stethoscope on table	the stethoscope is in stand by 30 min ±10 %	OK	PR: 070
F	Select AUTO OFF = DISABLE Select POWER = MEDIUM Place stethoscope on table	the stethoscope is in stand by 60 min ±10 %	OK	PR: 070
G	Select AUTO OFF = ENABLE Select POWER = HIGH Place stethoscope on table	the stethoscope is in stand by 120 min ±10 %	OK	PR: 070
E H	Select AUTO OFF = DISABLE Select POWER = LOW Place stethoscope on table After 15 minutes press + button Observe the last stand by time	The stethoscope enter standby The stethoscope leave stand by when + button is pressed The stethoscope enter stand by after 3 min The stethoscope is in stand by 30 min ±10%	OK	PR: 071
F I	Select AUTO OFF = DISABLE Select POWER = LOW Place stethoscope on table after 2 minutes press filter button	The stethoscope enter standby 3 min ±10% after the filter button is released	OK	PR: 071
G J	Select AUTO OFF = DISABLE Select POWER = LOW	The stethoscope enter normal auscultation	OK	PR: 072

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	Place stethoscope on table. Wait till stethoscope enter standby, put stethoscope on chest	Stethoscope leave standby	OK	
Test equipment and reference				
Comment	Some of these tests might have been performed in T:004 already.			
Pass	Not pass	Date: 9/12-2008	Sign:	

Configuration menu 2

Purpose	Test configuration menu			
Test case	AT: 019	SR	SR:050	
Action				
Shot	Stimuli	Expected result	Result	ref
A	Model 3200 Select BT. COMM = MANUAL Turn stethoscope off, and on again	Stethoscope start i normal auscultation	OK	PR: 076
B	Model 3200 Select BT. COMM = AUTO Turn stethoscope off, and on again	Stethoscope start i bluetooth	OK	PR: 076
Test equipment and reference				
Comment				
Pass	Not pass	Date: 8/12-2008	Sign:	

Configuration menu 3

Purpose	Test configuration menu			
Test case	AT: 020	SR	SR:050, SR:061, SR:076	
Action				
Shot	Stimuli	Expected result	Result	ref
A	Enter ID menu observe serial number	Display show: SERIAL # 000809xx xxxxxxxx (0809 is production year and month, xxxxx is a decimal representation of the Bluetooth LAP)	OK	PR: 042
B	Enter ID menu press - button observe SW version	Display show: SW VER. xx.yy.00 (xx = major, yy = minor sw version)	OK	PR: 042
C	Model 3100 Press M button continue..	SETUP: >POWER	OK	
D	Press - button continue..	SETUP: >EXIT	OK	
E	Press + button until SETUP:>ID Press M button continue..	ID: SERIAL #	OK	
F	Press Filter button continue..	SETUP: >ID	OK	
G	Press filter button continue..	Exit menu	OK	
E' H	Model 3200	MAIN: >CONNECT	OK	

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	Press M button continue ...			
F I	Press + button twice Press M button continue ...	SETUP: >POWER	OK	
G J	Press + button twice press M button continue ...	ID: SERIAL #	OK	
H K	Press M button	exit menu	OK	

Test equipment and reference	
Comment	

Pass	Not pass	Date:	Sign:
X		12/12-09	Mikkel Borgaard

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Service counter

Purpose	Test service counter		
Testicase	AT: 021	SR	SR:085
Action	read service counters before and after stimuli		

Shot	Stimuli	Expected result	Result	ref
A	Press M button	M btn: = M btn: +1	OK	
B	Press + button 2 times	Plus btn: = Plus btn: + 2	OK	
C	Press + button 3 times	Minus btn: = Minus btn: + 3	OK	
D	Press filter button 4 times	Filter btn: = Filter btn: + 4	OK	
E	press on/off button 5 times	On/off btn: = On/off btn: + 5	OK	
F	Let stethoscope go into standby Put stethoscope on chest so it wake up	Auto on wkup: = Auto on wkup: + 1	OK	
G	AUTO ON = ENABLE leave stethoscope on table so it enter standby	Auto off evt: = Auto off evt: + 1 Auto off tos: = Auto off tos: + 1	OK	
E	AUTO ON = DISABLE leave stethoscope on table so it enter standby	Active tos: = Active tos: + 1	OK	
F	read service counters with 20 sec interval	Active T: = Active T: +20±2 Bluetoot T: = Bluetoot T: + 20 ±2	OK	
G	leave stethoscope 3,5 min in standby	Stand by T: = Stand by T: + 3	OK	
H	turn stethoscope off and on	Power on evt: = Power on evt: + 1	OK	

Test equipment and reference	
Comment	
Pass X **Not pass**	**Date:** 12/12-09 **Sign:** Mikkel Borggaard

Dot matrix display

Purpose	Test dot matrix		
Test case	AT:024	SR	SR:077
Action	measure and count dots		
Expected result	the active area is14x8 mm The number of dots are 56x32		
Result	OK		
Test equipment and reference			
Comment			
Pass X **Not pass**	**Date:** 12/12-09 **Sign:** Mikkel Borggaard		

Icons

Purpose	Test icons		
Test case	AT:025	SR	SR:078
Action	turn stethoscope on verify icons against figure 1 in product requirements.		

Shot	Stimuli	Expected result	Result	ref

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A	volume icon	Icon is there.	OK	PR: 023
B	filter icon	Icon is there.	OK	PR: 023
C	battery icon	Icon is there.	OK	PR: 023
D	Heart rate	Icon is there.	OK	PR: 023

Comment	
Pass / Not pass	Date: 5/12-2008 Sign:
x	

Backlight1

Purpose	Test backlight timeouts		
Test case	AT:026	SR	SR:023
Action	turn stethoscope on wait to backlight turns off		

Shot	Stimuli	Expected result	Result	ref
A	SET POWER = LOW press and release on/off button	backlight turn on, and turn off again 3 sec ±10% after the button is released	OK	
B	SET POWER = LOW press and release on/off button, press and release the on/off button again before the backlight turns off	backlight turn on, and turn off again 3 sec ±10% after the button is released last time	OK	
C	SET POWER = MEDIUM press and release on/off button	backlight turn on, and turn off again 5 sec ±10% after the button is released	OK	
D	SET POWER = HIGH press and release on/off button	backlight turn on, and turn off again 5 sec ±10% after the button is released	OK	

Comment	Some of these tests might have been performed in AT:004 already.
Pass / Not pass	Date: 5/12 2008 Sign:
x	

Backlight2

Purpose	Test the three Backlight settings.		
Test case	AT:036	SR	SR:023
Action	turn stethoscope on wait to backlight turns off Set Power = low.		

Shot	Stimuli	Expected result	Result	ref
A	BACKLIGHT = ON DMMD press and release on/off button	backlight turn on, and turn off again 3 sec ±10% after the button is released	OK	
B	BACKLIGHT = ALWAYS press and release on/off button.	backlight turn on, and turn down to approximately 50% light intensity after 3 sec ±10% and stays on.	OK	
C	BACKLIGHT = DISABLE	backlight is off and stays	OK	

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	press and release on/off button	off.	OK	
Comment:	Some of these tests might have been performed in AT:004 already.			
Pass X **Not pass**	**Date:** 12/12 08	**Sign:** Mikkel Borggaard		

Onboard Storage 1

Purpose	Storing recordings.		
Test case	AT:033	**SR**	SR:079 SR:080 SR:086
Action	The E3000 Plus is powered on (diaphragm filter is selected). 1) Place the stethoscope in the HATS and start recording on the connected PC (connected to the HATS). 2) Place the chest piece on the shaker and set shaker to give a 200Hz sine signal. 3) Press the M button to enter the menu. 4) Select RECORD in the menu, to start the recording. 5) Make recording for 35 seconds. 6) Press the menu button to stop the recording and turn off the signal generator. 7) Playback the recording by selecting PLAY in the menu. 8) Compare the 29 seconds of the recording with the first 35 seconds recorded on the PC. It should match the last 29 seconds of the 35 seconds.		
Expected result	1) PC is recording. 2) None. 3) enters menu. 4) Recording starts. 5) None. 6) Recording stops on the stethoscope. 7) Recording on the PC continues. 8) The first and last part of the recording on the PC are the same.		
Result	OK Bug Fixed		
Test equipment and reference	Brüel & Kjær HATS Type 4128C Mini shaker Type 4810, Impedance 3.5Ω, Input power 15 VAmax, Stroke ± 3 mm max HP 33120A 15MHz Function/Arbitrary waveform generator.		
Comment	Filtering filter changed from Chebyshev to Butterworth, to avoid too much ripple in passband, 1MHz memory instead of 2MHz.		
Pass X **Not pass**	**Date:** 17/12-08	**Sign:** Mikkel Borggaard	

Onboard Storage 2

Purpose	Show that the recording is done before the filter and it is played back through the filter.		
Test case	AT:034	**SR**	SR:081
Action	The E3000 Plus is powered on. 1) Select the Bell filter. 2) Press the M button to enter the menu. 3) Select RECORD in the menu, to start the recording. 4) Place the stethoscope above the heart and make a recording. 5) Playback the recording by selecting PLAY in the menu. 6) Keep the chest piece away from your body with the binaurals in your ears to hear the recording.		

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	7) Press the filter button to change the filter.
Expected result	1) Bell filter is selected. 2) The menu is shown. 3) The recording is started. 4) The sound of the heart is heard in the binaurals. 5) Playback is started. 6) The recording is heard in the binaurals. 7) The recording is now heard with the Diaphragm filter.
Result	OK
Test equipment and reference	
Comment	
Pass **Not pass**	**Date:** **Sign:**
✓	9/12 · 2008 [signature]

Playback

Purpose	Test the warning which alerts the user, that it is a streamed signal, which is being played.		
Test case	AT:040	**SR**	SR:073
Action	The E3000 Plus is powered on. 1) Stream a recording via Bluetooth. 2) Listen to the sound in the binaurals.		
Expected result	1-2) The playback icon is shown in the LCD and the streamed sound is heart in the binaurals.		
Result	OK		
Test equipment and reference			
Comment			
Pass **Not pass**	**Date:** **Sign:**		
X	9/12 · 2008 [signature]		

Bluetooth Pairing1.

Purpose	Making it possible to establish the Bluetooth connection with a Bluetooth device supporting Bluetooth v.2.0 or v.2.1.

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Test case	AT: 027	**SR**	SR:029 SR:059 SR:070 SR:078
Action	The E3000 Plus is powered on and the Bluetooth device is ready for pairing. 1) Press the M button. 2) Press MINUS once and press the M button again to select PAIR. 3) Chose to pair the Bluetooth device with the stethoscope. 4) Punch in the pairing code shown in the display of the stethoscope. 5) Chose to connect to the newly found (on the Bluetooth device) SPP device.		
Expected result	1) The M3200 enters the configuration menu. 2) The pairing logo should be shown: 3) The M3200 shows a four digit code in its display. 4) The LCD shows a flashing Bluetooth icon as in figure 1 in the product requirements. 5) The Bluetooth icon stops flashing and is lit.		
Result	OK		
Test equipment and reference			
Comment			
Pass **Not pass** x	**Date:** 3/12-2008	**Sign:**	

Bluetooth Pairing2.

Purpose	The stethoscope has to be able to be paired with up to 8 Bluetooth devices. This enables the stethoscope to connect to the 8 known devices without pairing again.		
Test case	AT:038	**SR**	SR:087
Action	The E3000 Plus is powered on and the Bluetooth device is ready for pairing.		

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	1) Pair the stethoscope with at least 3 devices. 2) Go back to the first device and chose CONNECT in the menu and connect on the Bluetooth device.
Expected result	1) The stethoscope is paired with at least 3 devices. 2) The stethoscope connects with the first Bluetooth device without re-pairing.
Result	OK
Test equipment and reference	
Comment	
Pass **Not pass** x	**Date:** 8/12-2008 **Sign:**

(b)(4)Trade Secret Process-Product Specs

Connecting Bluetooth.

Purpose	Establishing the Bluetooth connection.		
Test case	AT: 028	SR	SR:028 SR:029 SR:058 SR:072
Action	The E3000 Plus is powered on and is paired to the Bluetooth device, tough not connected. 1) Press the M button to enter the menu. 2) Press the M button again to connect to the Bluetooth device. 3) The connection is tested with E3k_streamer. 4) When steaming, walk away from the Bluetooth device until the connection is lost.		
Expected result	1) The menu is showing in the LCD. 2) The Bluetooth icon is initially flashing and shifts to being lit, when the connection is made. 3) The connection is usable. 4) The Bluetooth icon starts flashing when the connection is lost and the streaming to the Bluetooth device stops.		
Result	OK		
Test equipment and reference			
Comment			
Pass X **Not pass**	**Date:** 12/12-08	**Sign:** Mikkel Bryggaard	

Streaming.

Purpose	Show the appropriate filter icon when doing playback from the connected Bluetooth device.		
Test case	AT:039	SR	SR:071
Action	The E3000 Plus is powered on and is ready to playback from the connected Bluetooth device. The selected filter is Diaphragm.		

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	1) Start the playback streaming to input switch 1. 2) Look at the LCD. 3) Press the filter button. 4) Look at the LCD. 5) Start the playback streaming to input switch 2. 6) Look at the LCD.
Expected result	1) The streamed sound is heard in the binaurals. 2) The Diaphragm filter icon is shown in the LCD. 3) The sound of the filter change is heard in the binaurals. 4) The Bell filter icon is show in the LCD. 5) The streamed sound is heard in the binaurals. Now not filtered. 6) Not filter icon is shown in the LCD.
Result	OK
Test equipment and reference	
Comment	
Pass x **Not pass**	**Date:** 8/10-2005 **Sign:**

Bluetooth Transmission Range.

Purpose	Insight Bluetooth range.		
Test case	AT: 042	SR	SR:072
Action	The E3000 Plus is powered on and is connected and streaming. 1) Walk away from the streaming PC and look at the LCD.		
Expected result	1) The distance to the PC is 10, or more, meters.		
Result			
Test equipment and reference			

(b)(4)Trade Secret Process-Product Specs

Comment	Test is done in AT: 028
Pass Not pass	Date: 12/12-08 Sign: Mikkel Borggaard

Bluetooth up-/download.

Purpose	Test the upload and download function via the Bluetooth connection.		
Test case	AT: 029	SR	SR:084
Action	The E3000 Plus is powered on and paired with a PC, which is running our up-/download program. 1) Connect the stethoscope to the PC. 2) Record a sine signal of 300Hz via a shaker and a signal generator. 3) Upload the sound file to the PC. 4) Record heart sound on the stethoscope. 5) Play the sound file from the stethoscope by choosing play in the menu. 6) Download the 300Hz signal from the PC to the stethoscope. 7) Play the sound file on the stethoscope		
Expected result	1) The connection is established. 2) The 300Hz signal can be heard in the binaurals.. 3) The upload is being carried out. 4) Recording icon is shown in LCD. 5) The heart sound is heard in the binaurals. 6) The download is carried out. 7) A 300Hz sound is heard in the binaurals.		
Result			
Test equipment and reference			

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[redacted]

Comment	Tested in SPP: ~~036~~ 035
Pass **Not pass**	**Date:** 12/12-08 **Sign:** Mikkel Borggaard

Channel B gain.

Purpose	The digital gain in channel B has to be independently program-controlled compared to channel A.		
Test case	AT: 030	**SR**	SR:074
Action	The E3000 plus is turned on and is paired with a PC, which is running the E3k_streamer program, which is showing the sound streamed. 1) Place the binaurals in your ears and place the chest piece on the shaker and apply a 300Hz tone. 2) Turn up the gain on channel B from the PC. 3) Observe the level of the signal in the [redacted] program.		
Expected result	1) The 300Hz tone is heard in the binaurals and a signal is seen in the [redacted] program. 2-3) The heart sound stays the same in the binaurals, but the amplitude of the signal shown in the [redacted] program changes its amplitude to a higher level.		
Result			
Test equipment and reference			

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(b)(4)Trade Secret Process-Product Specs

Comment	Tested in SPP:036
Pass **Not pass**	**Date:** 12/12-08 **Sign:** Mikkel Borggaard

SPI interface.

Purpose	Test if it is possible to reprogram the stethoscope and thereby giving it a new identification number, software version number and model number. This information is stored in non-volatile memory.		
Test case	AT:037	**SR**	SR:068 SR:069
Action	The E3000 Plus is powered on. 1) Enter MENU->SETUP->ID. 2) Read SW version-, serial-, and model number. 3) Reprogram the stethoscope with an older release. [illegible] Mikkel Borggaard 4) Turn the stethoscope on and enter MENU->SETUP->ID. 5) Read SW version number to verify that the software has changed. 6) Reprogram the stethoscope with the original software.		
Expected result	1) LCD is showing stethoscope information. 2) It is necessary to scroll through the information with the + or - button. 3) The stethoscope is reprogrammed with another software version. 4) The stethoscope enters the menu under ID. 5) A different software version is displayed. 6) The stethoscope is reprogrammed with the original software.		
Result	OK		
Test equipment and reference			

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Comment	
Pass Not pass	Date: Sign:
X	11/12-08 Mikkel Borggaard

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(b)(4)Trade Secret Process-Product Specs

[redacted]

E3000 Plus
SVR SW Validation Report

Version 1.00
Page 1 of 5
File name: MBG0849A - SVR SW Validation Report.docx

Author

17/12-08 Mikkel Bergmand
Date, Name – Software Designer

Approved by

19-12-2008
Date, Name – Quality Assurance

MS00400, Version 4.00

(b)(4)Trade Secret Process-Product Specs

[redacted]

(b) (4) [redacted]

Version history

Version	Author	Date	Description	Reviewed by	EC number
0.01	MBG	05-12-2008	Document created		
1.00	MBG	17. dec 2008	Document ready for signing.	TRH	

(b) (4) [redacted]

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QMS0040b, version 4.00

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(b) (4) [redacted]

1 Purpose

The purpose with this document is to summarise the result from the different activities during the development of the software and then recommend the release of the software.

2 Scope

This validation report covers the software for the Littmann M3100 and M3200.

3 References

[1] CAP0803a E3000 plus Product Requirement
[2] MBG0808A – STP SW test plan E3000 Plus
[3] MBG0849C - E3000 Plus Module Test Report
[4] PMP0851B E3000 Plus Integration test report
[5] MBG0849B - SAR SW Acceptance Test Specification Report
[6] PMP0842C MMI acceptance test verification report
[7] PMP0851A SPP Communication SW acceptance test report

4 Test result

Test ID	Test area	Test result	Remark
[Ref. No]	[Name]	Passed / failed	
8.1	**Module test**	**Passed**	Four minor observations.
	App_timer.asm	Passed	
	switch.asm	Passed	
	keyboard_driver.asm	Passed	
	queue.asm	Passed	
	event_queue.asm	Passed	
	audio_modding.asm	Passed	
	stand_by.asm	Passed	
	Online_pskey.asm	Passed	
	vm_interface.asm	Passed	
	heart_rate.asm	Passed	
	spp_command_handler.asm	Passed	
	spp_communication.asm	Passed	
	scheduler.asm	Passed	
	main_kalimba.asm	Passed	
	lcd_device_driver.asm	Passed	
	Lcd_if_driver.asm	Passed	
	utilities.asm	Passed	
	control_output.asm	Passed	
	Error_information.asm	Passed	
	lcd_icons.asm	Passed	
	menu.asm	Passed	

(b) (4) [redacted]

Test ID	Test area	Test result	Remark
	CONT_MMI.ASM	Passed	
	Recorder.asm	Passed	
	Flash_handler.asm	Passed	
	service.asm	Passed	
	audio_handler.asm	Passed	
	buffer_handling.asm	Passed	
	crc16.asm	Passed	
	event_processing.asm	Passed	
	test_data.asm	Passed	
	uart_logging.asm	Passed	
	Spi_drv.asm	Passed	
	Main.c	Passed	
	RTX_kalimba.c	Passed	
	RTX_battery.c	Passed	
	RTX_display.c	Passed	
	RTX_tones.c	Passed	
8.2	**Integration test**	Passed	No Remarks
8.3	**SW Acceptance test**	Passed	No Remarks
	Mmi acceptance test	Passed	No Remarks
	Spp communication acceptance test	Passed	No Remarks

5 Discussion of test results

With the exception of the observations discussed below, all devices passed the tests without any remarks.

5.1 Module Test

4 minor observations regarding:

- Live_lock
- Service_counter
- Peak_Location
- Deviation

None of the errors has performance or visible effect for the user. The errors will be corrected if the modules are opened again.

6 Conclusion

Base on test result and discussion above it is the overall conclusion that the E3000 Plus stethoscope software has been developed and tested as specified in the Software test plan ref [2] and found in accordance with Software elements of the overall device requirement specification ref [1].

The software can be released for sale.

QMS00400, Version 4.00

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(b)(4) [redacted]

E3000 Plus
SRD SW Release Description

Version 8.00

File name: MBG0837A - SW Release Description E3000Plus.doc

Author

7/12-08
Date, Name – Software Designer

Approved by

12/12 2008
Date, Name – Quality Assurance

Approved by

12/12-08
Date, Name – Project Manager

QHS00399, Version 2.1.0

(b)(4) [redacted]

(b)(4)Trade Secret Process-Product Specs

Version history

Version	Author	Date	Description	Reviewed by	EC number
1.00	MBG	08-09-2008	SW release v. 00.50.00 for 3M verification .		
2.00	PMP	15-09-2008	SW release v. 00.60.00 for 3M verification .		
3.00	PMP	18-09-2008	SW release v. 00.65.00 for 3M verification .		
4.00	PMP	02-10-2008	SW release v 00.71.00 for medico verification (BUA)		
5.00	PMP	07-10-2008	SW release v. 00.73.00 for T&O production equipment		
6.00	PMP	30-10-2008	SW release v.00.90.00 for final verification and MS5 production		
7.00	pmp	02-12-2008	SW release v.00.95.00 for running the acceptance test.		
8.00	MBG	17-12-2008	SW release v. 01.00.00		

QM500359, Version 2.00

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QMS00395, version 2.00

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(b)(4)Trade Secret Process-Product Specs

1 Purpose

In order to be able to identify and rebuild different software version, this document describe the release, problems and current known problems.

2 Scope

Only stethoscope device software is covered by this release description

3 References

-

4 Description

The software is validated for first release.

5 Identification

This software is labelled "Release 01.00.00" in Visual Source Safe.
The software is identified on the stethoscope as 01.00.00

6 Known defects/problems/missing implementation

Recording is implemented with 14 sec recording only (due to small memory in device)
Service counter for measuring standby time measures one minute less than actual time.
The deviation test fails and does not limit the change allowed in the heart rate (30pct. from one bpm to another). But no wrong heart hates are displayed in the LCD.

7 Solved defects/problems/missing implementation

Battery monitor is working poorly on rev B Hardware unless it is renovated.
Timeout is not set when changing setup => auto off = enabled, and the stethoscope is not used.
(b)(4)Trade Secret Process-Product Specs [redacted].
Audio signal for battery warning at start up is removed (was not specified).
Audio Playback warning when doing playback from memory is removed (was not specified).
Bug fixed in setting filters from PC (Zargis ref. 72)
Recording is implemented.
PC_AUDIO_STREAM_CLOSE_RECORD_TYPE is implemented (Zargis ref 71)
E3K_AUDIO_BLOCK_REQUEST_RECORD_TYPE is changed so space in input fifo is reported. (Zargis ref 50)
Long key button key press is send to PC (Zargis ref 68).
Fix bug so filter icon is off when streaming to switch 2.
Fix bug so the actual pincode is displayed when pairing.

QMS00399, Version 2.00

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8 Release documentation reference

N/A

9 Conclusion

The software is ready for commercial release.

QM50C399, Version 2.00

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[redacted]

E3000 Plus EMC
Design verification protocol

Version 1.00
Page 1 of 8
File name: AMI0821a Design Verification Protocol - EMC

Author

1-9-2008
Date, Name - Designer

Approved by

1/9-2008
Date, Name - Quality Assurance

0086, Version 8.00

(b)(4)Trade Secret Process-Product Specs

[redacted]

(b)(4)Trade Secret Process-Product Specs

Version history

Version	Author	Date	Description	Reviewed by	EC number
0.01	AMI	29-may-2008	Initial version		
0.02	AMI	20-june-2008	Updated after review	CAP, SSR, TRH, TAD	
0.03	AMI	23-june-2008	Preconditioning updated	CAP, THR, SSR	
1.00	AMI	1-sep-2008	Released version		

QMS00086, Version 8.00

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(b)(4)Trade Secret Process-Product Specs

1 Purpose

The purpose of this document is to describe how to perform the Design Verification and define the acceptance criteria in order to verify if the requirements can be fulfilled. The protocol must be approved before the verification activities are carried out. Verification is to be performed at external test center.

2 Scope

The scope of this protocol covers E3000 Plus EMC.

3 References

[1] SSR 0807a Design control status overview E3100-E3200
[2] cap0803a E3000 Plus Product requirements
[3] TAD0816b Design verification plan E3000 Plus
[4] HLA0807A Functional Test Protocol IAD0007 E3000 Plus
[5] ISO 60601-1-2:2007

4 General

4.1 Test conditions

Unless otherwise specified in the test method, the tests are performed under the following conditions:

Temperature 18°C - 28°C
Humidity: 25 %RH – 75 %RH

These will be referred to as "Room climate" in the rest of the document.

4.2 Device preparation

- One device is to be used for ESD testing.
- One device is to be used for EMC testing.
- The devices shall be marked with ID no.
- Function test, must be performed before verification start on all devices to ensure that they are functioning.

4.3 Device storage

Samples and test specimens used for verification shall be stored in B&O Medicom items archive.

4.4 Verification working procedure

To carry out preconditioning or test, the following basic documents are needed:

1. The protocol
2. The matching registration sheet

(b)(4)Trade Secret
Process-Product Specs

The test results, deviations, date of test, initials on operator along with identification of the devices and the equipment used, are filled in the registration sheet.

4.5 Acceptance criteria

Acceptance criteria are described in the protocols.
In general the acceptance criterion is a function test, a visual inspection or both, which must be passed accordingly before and after the preconditioning

4.6 Test Method

4.6.1 EMC:001

Purpose
The purpose with RF-Field Emission measurement is to make sure that the stethoscope is not disturbing other apparatus. The protocol refers to PR:017 [2]

Standard

The test setup and method must be in accordance to EN 55011.

Preconditioning

The stethoscope must be setup with the following settings:

1. Active mode
2. Diaphragm filter
3. Maximum volume level
4. Backlight off
5. Auto-off deactivated
6. Measure the RF-Field emission
7. Ensure that the result is in accordance with the acceptance criterion.

Variation

Acceptance criterion

Results are to be in accordance with EN60601-1-2:2007 class B1 at a distance of 10m.

30 dBmV @30MHz to 250MHz

37 dBmV @250MHz to 1GHz

4.6.2 EMC:002

Purpose

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The purpose is to test the immunity of the stethoscope to radiated electromagnetic energy, which can be generated by such sources as small hand-held radio transceivers etc. and various industrial electromagnetic sources. The protocol refers to PR:018 [2]

Standard

The test setup and method must be in accordance to EN 61000-4-3.

Preconditioning

The stethoscope must be setup with the following settings:

1. Active mode
2. Diaphragm filter
3. Maximum volume level
4. Backlight off
5. Auto-off deactivated
6. Expose the stethoscope to 3V/m @80MHz to 2.5GHz
7. Ensure that the result is in accordance with the acceptance criterion

Variation

Acceptance criterion

Functional test (FT) is to be passed.
Change in default settings (PS keys) is not accepted.

Under testing the stethoscope may respond to the discharge is different manners of which some can be accepted and some cannot.

Under testing the following behaviour of the stethoscope is accepted:

1. Change in display graphics.
2. Momentary noise in binaural.
3. Reset of the stethoscope if reboot is initialized automatically.

Under testing the following behaviour of the stethoscope is NOT accepted:

1. Change of filter mode.
2. Change of volume level.
3. Activation of Bluetooth mode.

4.6.3 EMC:003

Purpose
The test are intended to demonstrate the immunity of equipment when subjected to power frequency magnetic fields related to the specific location and installation condition of the component. The protocol refers to PR:019 [2]

Standard

(b)(4)Trade Secret Process-Product Specs

The test setup and method must be in accordance to EN 61000-4-8.

Preconditioning

The stethoscope must be setup with the following settings:

1. Active mode
2. Diaphragm filter
3. Maximum volume level
4. Backlight off
5. Auto-off deactivated
6. Expose the stethoscope to 3A/m @ 50Hz and 60Hz
7. Ensure that the result is in accordance with the acceptance criterion.

Variation

Acceptance criterion

Functional test (FT) is to be passed.
Change in default settings (PS keys) is not accepted.

Under testing the stethoscope may respond to the magnetic filed in different manners of which some can be accepted and some cannot.

Under testing the following behaviour of the stethoscope is accepted:

1. Change in display graphics.
2. Momentary noise in binaural.
3. Reset of the stethoscope if reboot is initialized automatically.

Under testing the following behaviour of the stethoscope is NOT accepted:

1. Change of filter mode.
2. Change of volume level.
3. Activation of Bluetooth mode.

4.6.4 EMC:004

Purpose
The purpose with electrostatic discharge test is to simulate discharges which may occur from personnel to object near the stethoscope. The protocol refers to PR:020 [2]

Standard

The test setup and method must be in accordance to EN 61000-4-2.

Preconditioning

The stethoscope must be setup with the following settings:

1. Active mode

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2. Diaphragm filter
3. Maximum volume level
4. Backlight off
5. Auto-off deactivated
6. Expose the stethoscope to ±6 kV contact discharge and ±8 kV air discharge.
7. Ensure that the result is in accordance with the acceptance criterion

Variation

Acceptance criterion

Functional test (FT) is to be passed.
Change in default settings (PS keys) is not accepted.

Under testing the stethoscope may respond to the discharge in different manners of which some can be accepted and some cannot.

Under testing the following behaviour of the stethoscope is accepted:

1. Change in display graphics.
2. Momentary noise in binaural.
3. Reset of the stethoscope if reboot is initialized automatically.

Under testing the following behaviour of the stethoscope is NOT accepted:

1. Change of filter mode.
2. Change of volume level.
3. Activation of Bluetooth mode.

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Accredited Test House
Deutscher Akkreditierungs Rat
DAT-P-268/08

EMC TEST - REPORT

TEST REPORT NUMBER: G0M20810-2051-E-17

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1 General Information

1.1 Notes

The test results of this test report relate exclusively to the item tested as specified in 1.6.

The test report may only be reproduced or published in full.

Reproducing or publishing extracts of the report requires the prior written approval of the Eurofins Product Service GmbH.

1.2 Responsible staff

01.12.2008	A. Pflug	
Date	Name	Signature

Technical responsibility for area of testing:

01.12.2008	J. Zimmermann	
Date	Name	Signature

1.3 Testing laboratory

1.3.1 Location

EUROFINS PRODUCT SERVICE GMBH
STORKOWER STR. 38c
D-15526 REICHENWALDE B. BERLIN
GERMANY
Telephone : + 49 33631 888-00
Telefax : + 49 33631 888-660

1.3.2 Details of accreditation status

DAR ACCREDITED TESTING LABORATORY
DAR-REGISTRATION NUMBER: DAT-P-268/08

RECOGNIZED NOTIFIED BODY EMC
REGISTRATION NUMBER: BNetzA-bS EMV-07/61

RECOGNIZED NOTIFIED BODY R&TTE
REGISTRATION NUMBER: BNetzA-bS-02/51-53

FCC FILED TEST LABORATORY
REG.-NO. 96970

A2LA ACCREDITED TESTING LABORATORY
CERTIFICATE NO. 1983.01

BLUETOOTH QUALIFICATION TEST FACILITY (BQTF)
ACCREDITED BY BLUETOOTH QUALIFICATION REVIEW BOARD

INDUSTRY CANADA FILED TEST LABORATORY
REG. NO. IC 3470

1.3.3 Test location, if different

Name	: ./.
Street	: ./.
Town	: ./.
Country	: ./.
Telephone	: ./.
Fax	: ./.
Email	: ./.

1.4 Details of applicant

Name	: RTX Telecom A/S
Street	: Stroemmen 6,
Town	: DK-9400 Noerresundby,
Country	: Denmark
Telephone	: +45 96 3223 00
Fax	: +45 96 3223 10
Email	: miv@rtx.dk
Contact	: Mr. Mads Iversen
Telephone	: +45 96 3223 00

1.5 Application details

Date of receipt of application	: 05.11.2008
Date of receipt of test item	: 05.11.2008
Date of test	: 12.11.2008; 01.12.2008

1.6 Test item

1.6.1 Description of test item

Description of test item	: Bluetooth enabled stethoscope
Type identification	: M3200
Serial number	: withoutwithout
Power supply	: 1.5 V DC battery only
Additional information	: device with Bluetooth function
Connected lines	: n.a.
Performance criteria	: checking of the function (display). Bluetooth connection

1.6.2 Manufacturer (if different from applicant in point 1.4)

Name
Street
Town
Country

(b) (4) [redacted]

1.7 Test standards

Technical standard:

EN 301 489-1 V 1.6.1 : 2005
EN 301 489-17 V1.2.1 : 2002
EN 60601-1-2: 2007

1.8 List of EMC equipment

No.	Test Equipmen	Type	Manufacturer
ETS 0001	ESD Gun	SESD 30000	Schlöder
ETS 0008	Antenna	Loop antenna	Siemens
ETS 0012	Biconical Antenna	HK 116	R & S
ETS 0013	LPD Antenna	HL 223	R & S
ETS 0014	Log Periodical Antenna	HL 025	R & S
ETS 0018	Horn antenna	BBHA 9120 D	Schwarzbeck
ETS 0038	RF amplifier	150L	Amplifier Research
ETS 0032	Controller	HD 050	Heinrich Deisel
ETS 0039	Absorbing clamp	MDS 21	R & S
ETS 0040	Artificial Mains Network	ESH3-Z5	R & S
ETS 0041	T-Artificial Mains Network	ESH3-Z4	R & S
ETS 0042	Artificial Mains	ESH3-Z6	R & S
ETS 0045	Vehicle LISN	NNBM 8126D	Schwarzbeck
ETS 0052	Audio analyzer	UPA 4	R & S
ETS 0056	Ultra Compact Simulator	UCS 500 M4	EM Test
ETS 0057	Motor Variac	MV 2616	EM Test
ETS 0058	Capacitive coupling clamp	E 502 B	Keytek/ EMC
ETS 0059	Kikusui amplifier	PCR 2000L	Keytek/ EMC
ETS 0064	CDN IEC 61000-4-6		Keytek/ EMC
ETS 0066	EM Injection Clamp		FCC/ EMC
ETS 0076	Feeding bridge A	SBA 1000	ESP
ETS 0082	PC system		Esotronic
ETS 0085	Shielded room	SR 1	Frankonia
ETS 0086	Semi-Anechoic chamber	AC 1	Frankonia
ETS 0088	Color TV pattern Generator	PM 5518-TX VPS	Philips
ETS 0092	Power Amplifier	150W1000	AR Amplifier Research
ETS 0102	CDN	M3-801/6	MEB
ETS 0103	Magnetic field test set	MF1000	EMC-Partner
ETS 0148	RF Current Probe	F-65	FCC
ETS 0155	Signal Generator	SMG	R & S
ETS 0157	TV and Sat-Signalgenerator	VTG 700	Grundig
ETS 0161	Harmonic / Flicker Analyzer	HFA 3000	Schlöder
ETS 0178	Open area test side	10m	ETS
ETS 0233	Direction coupler	RK 100	MEB
ETS 0276	Audio Analyzer	UPL 16	R & S
ETS 0282	RF bridge 75 Ohm	86207 A	HP
ETS 0287	EMI Test receiver	ESHS10	R & S
ETS 0292	RF Generator	SMHU	R & S
ETS 0348	RF Millivolt meter	URV 55	R & S
ETS 0300	RF amplifier	75 A 250	Ar
ETS 0348	RF Millivolt meter	URV 55	R & S
ETS 0401	MPEG2 Generator	DVG	R & S
ETS 0402	TV Messender	SFQ	R & S
ETS 0409	Stripline	DC220	Schwarzbeck
ETS 0428	4-WIRE ISN with B1	ENY41	R & S
ETS 0448	RF Power Amplifier	AR 60S1G3	AR Amplifier Research
ETS 0472	Antenna	BTA-H	Frankonia
ETS 0474	EMI Test Receiver	ESCS 30	R&S
ETS 0485	Radio Communication Tester	CMU 200	R&S

2 Technical test

2.1 Summary of test results

The equipment under test fulfilled all applicable EMC requirements of the EN 301 489-1/-17 and 60601-1-2.

2.2 Test environment

Temperature	: 23 ° C
Relative humidity content	: 45 %
Air pressure	: 1003 hPa
Details of power supply	: 1.5 V DC Battery
Other parameters	: ./.

2.3 Test results overview

Reg. no. : G0M20810-2051-E-17

Device : BLUETOOTH ENABLED STETHOSCOPE

Model no. : M3200

Manufacturer : (b) (4) [redacted]

Date : 01.12.2008

Test Emission / Immunity			Done	Test passed	Test failed
Emission	Radiated Emissions	EN 301 489-1; subc.8.2	☒	☒	☐
Emission	Conducted Emissions	EN 301 489-1; subc.8.3; 8.4; 8.7	☐	☐	☐
Flicker	Voltage fluctuations and flicker	EN 301 489-1; subc.8.6	☐	☐	☐
RF - Field	Radiated Immunity	EN 301 489-1; subc.9.2	☒	☒	☐
ESD	Electrostatic Discharge	EN 301 489-1; subc.9.3	☒	☒	☐
Burst	Electrical Fast Transients	EN 301 489-1; subc.9.4	☐	☐	☐
RF com. mode	RF continues conducted	EN 301 489-1; subc.9.5	☐	☐	☐
Transient and surges	Transient and surges in vehiculars	EN 301 489-1; subc.9.6	☐	☐	☐
Magn.-Field	Magn.-Field Immunity	EN 6100-4-8	☒	☒	☐
V-dips	Voltage dips and interruptions	EN 301 489-1; subc.9.7	☐	☐	☐
Surge	Surges common & different mode	EN 301 489-1; subc.9.8	☐	☐	☐
Emission	Radiated Emissions	EN 301 489-1; subc.8.2	☐	☐	☐

2.4 Test conditions

2.4.1 Spurious Emission (EN 55022)

This test is only applicable to ancillary equipment not incorporated in the radio equipment and intended to be measured on a stand alone basis, as declared by the manufacturer. This test shall be performed on a representative configuration of the ancillary equipment.
This test is in accordance to subclause 8.2 of EN 301 489-1

Test Equipment

- ETS 0012
- ETS 0013
- ETS 0086
- ETS 0474
- Software: ES-K1, Vers. 1.6SP2

Test Procedures

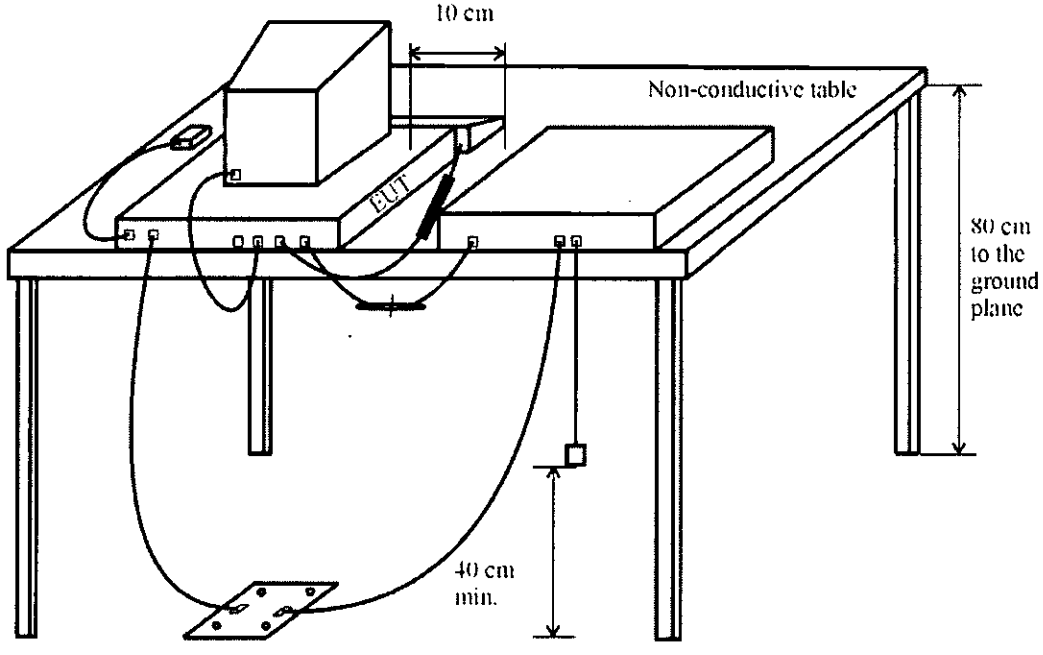
- Test configuration

The test configuration corresponds to the standard EN 55022 /4/. The equipment under test is placed on a non metallic table with 0,8 m height.
The power supply and the RF connection points are close to the equipment under test at the floor inside a connection box. The cables to this connection box are shielded and below the double floor. The receiving antenna is placed in a height at 1,0 m to 4,0 m, in a distance of 3 m. The measurement receiver is placed in a special room. (See picture 1) The observation of the equipment under test is realized by a video camera and by a microphone.

- Test parameters and marginal conditions

The test is carried out with horizontal and vertical polarization of the antenna in a frequency range of 30 MHz to 1000 MHz. For further information please see the test protocol.

Radiated Emission according to CISPR 22



EUT = Equipment under test

Picture 1

2.4.2 Electrostatic discharge

This test is applicable for base station, mobile, portable and ancillary equipment.
This test is in accordance to subclause 9.3 of EN 301 489-1

Test Equipment

- ETS 0001

Test Procedures

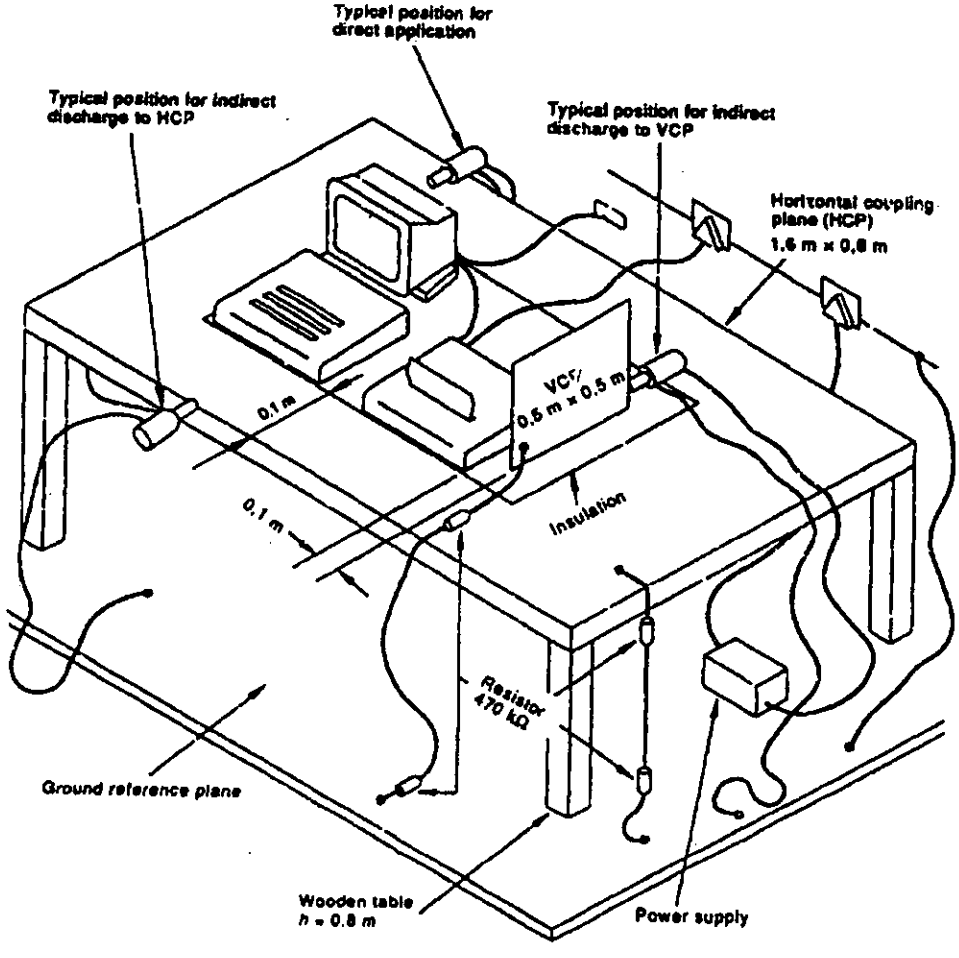
• Test configuration

The test configuration corresponds to the standard EN 61000-4-2 /5/. The test setup shall consist of a wooden table, 0.8 m high, standing on the ground reference plane. A horizontal coupling plane, 1.6 m x 0.8 m, shall be placed on the table. The EUT and cables shall be isolated from the HCP by an insulating support, 0.5 mm thick. Both metal plates are connected by two 470 kΩ resistors in series. (See Picture 2.)

• Test parameters and marginal conditions

The test is carried out with ±2kV, ±4kV and ±6kV contact discharge and ± 2 kV, ± 4 kV and ± 8 kV air discharge. The tested points are mentioned in the test protocol.

Electrostatic Discharge according To EN 61000-4-2



Picture 2

2.4.3 RF Electromagnetic field (80-2500 MHz)

This test is applicable for base station, portable and ancillary equipment
This test is in accordance to subclause 9.2 of EN 301 489-1

Test Equipment

- ETS 0086
- ETS 0155
- ETS 0448
- ETS 0472
- Software: ETS RF-Field v.27.09.2005

Test Procedures

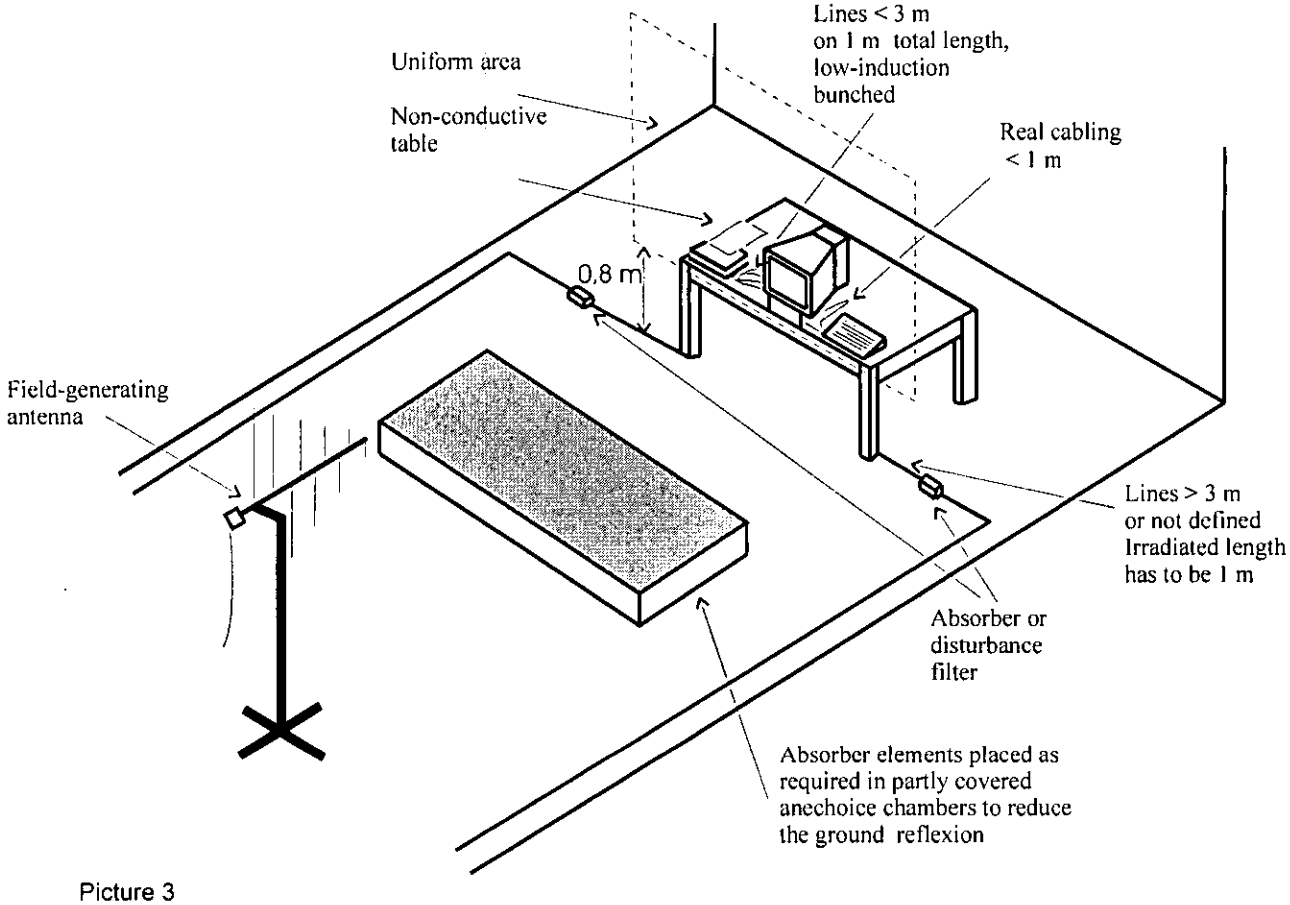
- Test configuration

The test is performed inside a shielded chamber and the configuration complies to the standard EN 61000-4-3 /6/. The equipment under test is placed in the facility on a wooden table, 0.8 m high, on the center axis of the chamber. The power supply and the RF connection points are close to the equipment under test at the floor of the chamber inside a connection box. The cables to this connection box are shielded and below the double floor. The transmitting antenna is placed in a height of 1.5m, in a distance of 3.0 m. The RF generators are placed in a special room adjacent to the chamber. The observation of the equipment under test is realized by 3 video cameras and a microphone. In order to establish the severity of the test for EUTs and wires which must be tested close to the earth reference plane or which have larger dimensions than 1,5 m x 1,5 m, the intensity of the field is also recorded at 0,4 m height, and for the full width and height of the EUT.

- Test parameters and marginal conditions

The tests are performed with a field strength of 3 V/m (measured in the unmodulated field) with amplitude modulated signal with a depth of 80 % by a sinusoidal signal of 1 kHz. The logarithmic step was 1 % and the dwell time was 1 s dependent on the EUT cycle time. For further information please see the test protocol.

RF - Field according to EN 61000 - 4 - 3



Picture 3

2.4.4 Power frequency magnetic field

This test is applicable for base station, mobile, portable and ancillary equipment.
This test is in accordance to EN 60601-1-2: 2007.

Test Equipment

- ETS 0059
- ETS 0155

Test Procedures

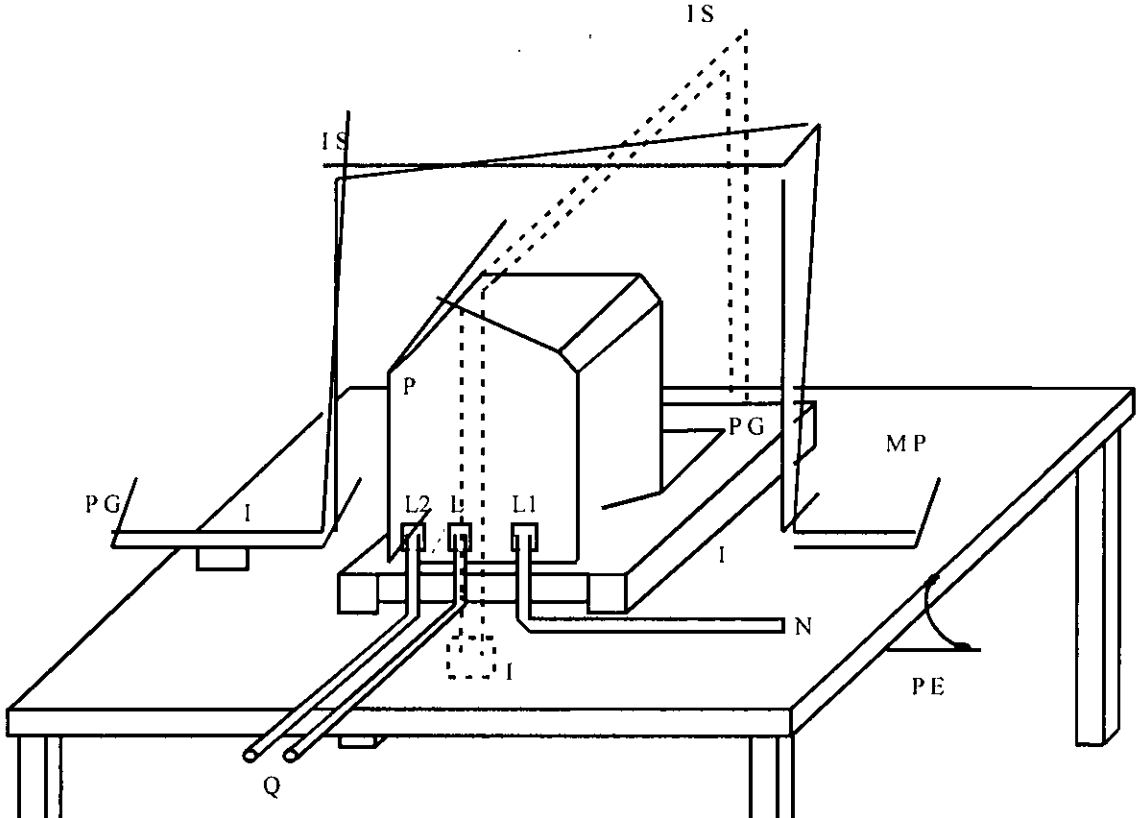
• Test configuration

The test configuration is in correspondence to the standard EN 61000-4-8 /7/. The equipment under test shall be arranged and connected to satisfy its functional requirements, and shall be placed at the centre of the coil system. (See picture 4.)
The cables supplied by the equipment manufacturer shall be used or, in their absence, suitable alternative cables of the type appropriate to the signals involved shall be used.

• Test parameters and marginal conditions.

The tests are carried out with a frequency of 50 or 60 Hz and a magnetic field of 30 A/m (r.m.s.). Additional information please find in the test protocol.

Example for set-up for immunity test to magnetic field according to EN 61000-4-8



M P	pasted plate
P E	safety earth
I	isolation
P	EUT
I S	induction spark coil
E	mass connection
L1	power line
L2	signal line
L	communication line
N	net
Q	to the signal source, to the simulator
P G	to the test generator

Picture 4

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2.5 EMC Test Results

Radiated emission	**18**
ESD	**19**
RF-Field	**21**
Magnetic Field	**22**

Radio Noise Field Strength

Emission

Standard : EN 301 489-1 subclause 8.2

Reg. no. : G0M20810-2051-E-17

Model no. : M3200

Date : 01.12.2008

Class : B

Frequency range / Polarization	Antenna	Passed	Failed	Number of rechecks
30 MHz - 200 MHz / vertical	HK 116	☒	☐	0
30 MHz - 200 MHz / horizontal	HK 116	☒	☐	0
200 MHz - 1000 MHz /vertical	HL 223	☒	☐	0
200 MHz - 1000 MHz / horizontal	HL 223	☒	☐	0

Instrumentation uncertainty: $U_{lab(rad)}$ = 5.3 dB

Comment: See attached diagrams in Annex B.

Electrostatic Discharge
ESD

Standard : EN 301 489-1 subclause 9.3

Reg. no. : G0M20810-2051-E-17

Model no. : M3200

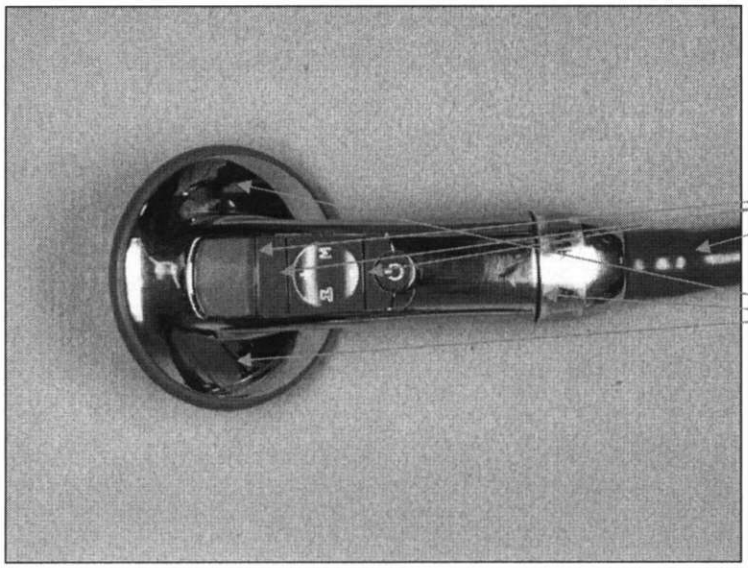
Date : 01.12.2008

Test point	Table (T) Floor (F)	Contact (C) Air (A)	Voltage (kV)	Polarity (+ / -)	Pass	Fail
Housing	T	A	2, 4, 8	+ / -	☒	☐
Housing	T	C	2, 4, 6	+ / -	☒	☐
Indirect	T	C	2, 4, 6	+ / -	☒	☐

At least 10 single discharges at each important point of the EUT (see picture) and both coupling plates.

Opinion:

The device fulfills the requirements of the ESD tests in accordance with 6.2.1.10 /3/.
Surveillance of the function (display). Bluetooth connection.


Air discharge
Contact discharge

Contact discharge
Air discharge

Interference Immunity Against Electromagnetic Irradiation

RF Field

Standard : EN 301 489-1 subclause 9.2

Reg. no. : G0M20810-2051-E-17

Model no. : M3200

Date : 01.12.2008

Test equipment : Anechoic chamber, generator SMG (R&S), monitoring system, amplifier: ar, antenna (BTA-H)

Frequency Range	Voltage (RMS)	Modulation Frequency	Opinion
80 MHz – 2.5 GHz	3 V/m	1 kHz (80 % AM)	A

Opinion:

The EUT fulfills the requirements according to clause 6.2.1.10 /3/. The test does not have influence on the essential performance features (see user manual) of the device.

Surveillance of the function (display). Bluetooth link control only.

Power frequency
-Magnetic field-
Immunity

Standard : EN 61000-4-8

Reg. no. : G0M20810-2051-E-17

Model no. : M3200

Date : 01.12.2008

Test equipment : Anechoic Chamber, Generator, Induction coil

Carrier Frequency : 50 Hz

Field Strength : 3 A/m

Duty Cycle : sinusoidal

Passed : yes / no

Comment: Bluetooth link only.

☒ 1 : No loss of performance or function
☐ 2 : Temporary loss of function or performance which is self-recoverable
☐ 3 : Temporary loss of function or perform. which req. operator intervention or system reset
☐ 4 : Loss of function which is not recoverable

3 Normative references

/1/ EN 301 489 – 1 V1.6.1 : 2005
Electromagnetic compatibility and Radio spectrum Matters (ERM);
Electromagnetic Compatibility (EMC) standard for radio equipment and services;
Part 1: Common technical requirements

/2/ EN 301 489 – 17 V1.2.1 : 2002
Electromagnetic compatibility and Radio spectrum Matters (ERM);
Electromagnetic Compatibility (EMC) standard for radio equipment and services;
Part 17: Specific conditions for 2,4 GHz wideband transmission systems and 5 GHz high Performance RLAN equipment

/3/ EN 60601-1-2 : 2007
Medical electrical equipment
Part 1: General requirements for safety
2. Collateral Standard : Electromagnetic Compatibility - Requirements and tests

/4/ EN 55022: 2006
„Limits and methods of measurement of radio interference characteristics of information technology equipment".

/5/ EN 61000-4-2: 1995 + A1: 1998 + A2: 2001
„Electromagnetic Compatibility (EMC); Part 4: Testing and measurements techniques - Section 2: Electrostatic discharge immunity test. Basic EMC publication".

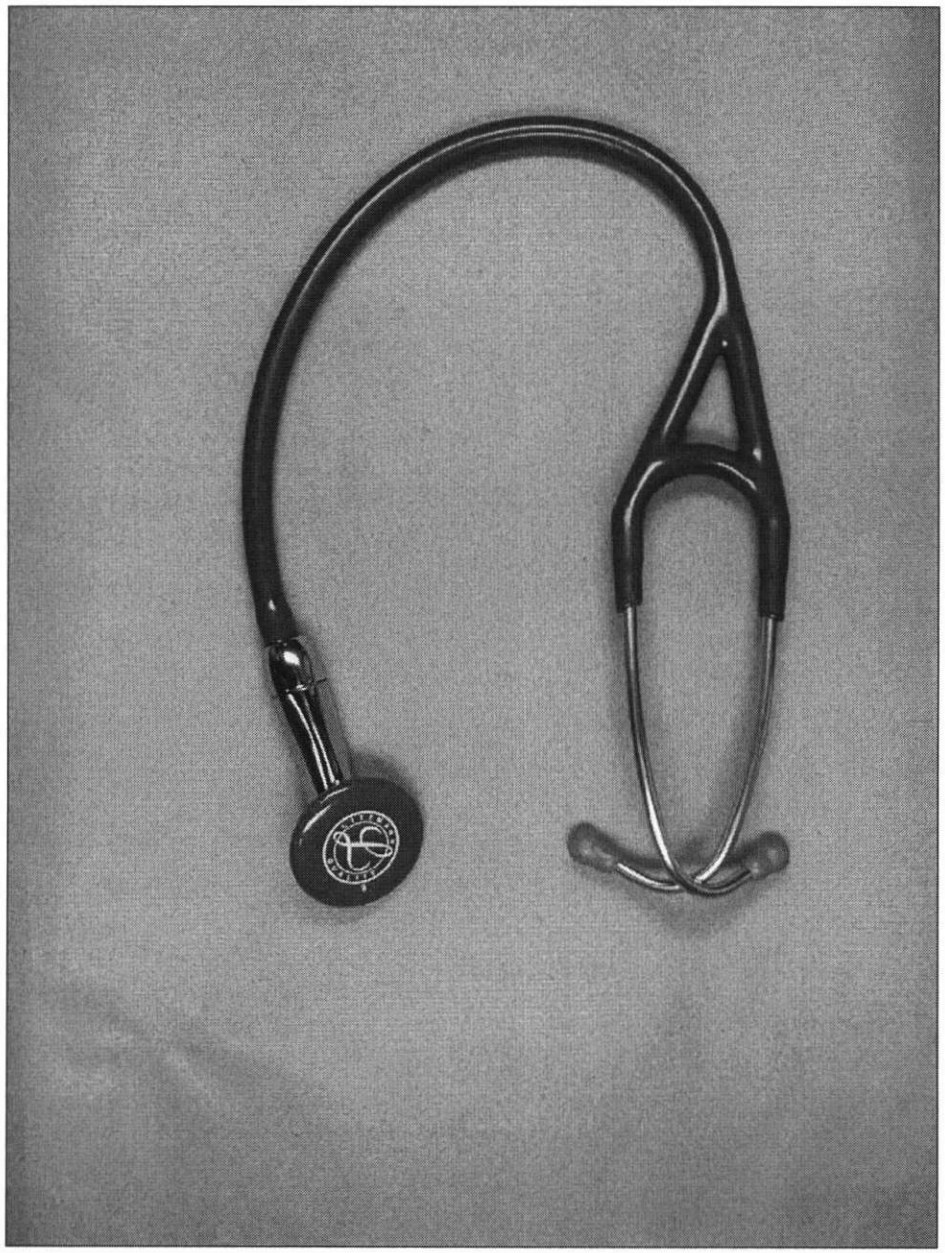
/6/ EN 61000-4-3: 2006
„Electromagnetic Compatibility - Basic immunity standard - Radiated, radio-frequency electromagnetic field. Immunity test".

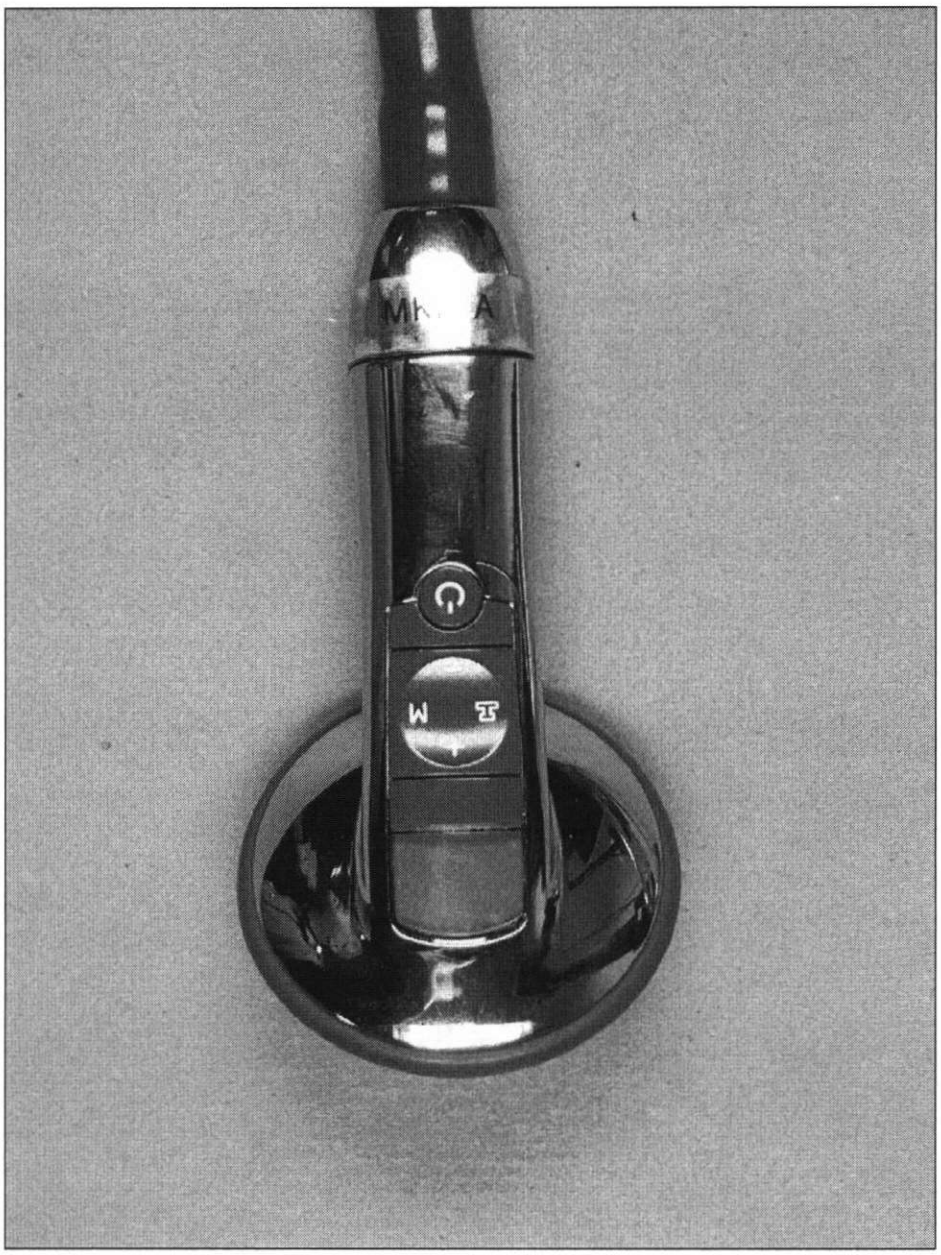
/7/ EN 61000-4-8: 1993 + A1: 2001
„Electromagnetic Compatibility - Testing and measurements techniques
Power frequency magnetic field immunity test".

Annex A:Pictures

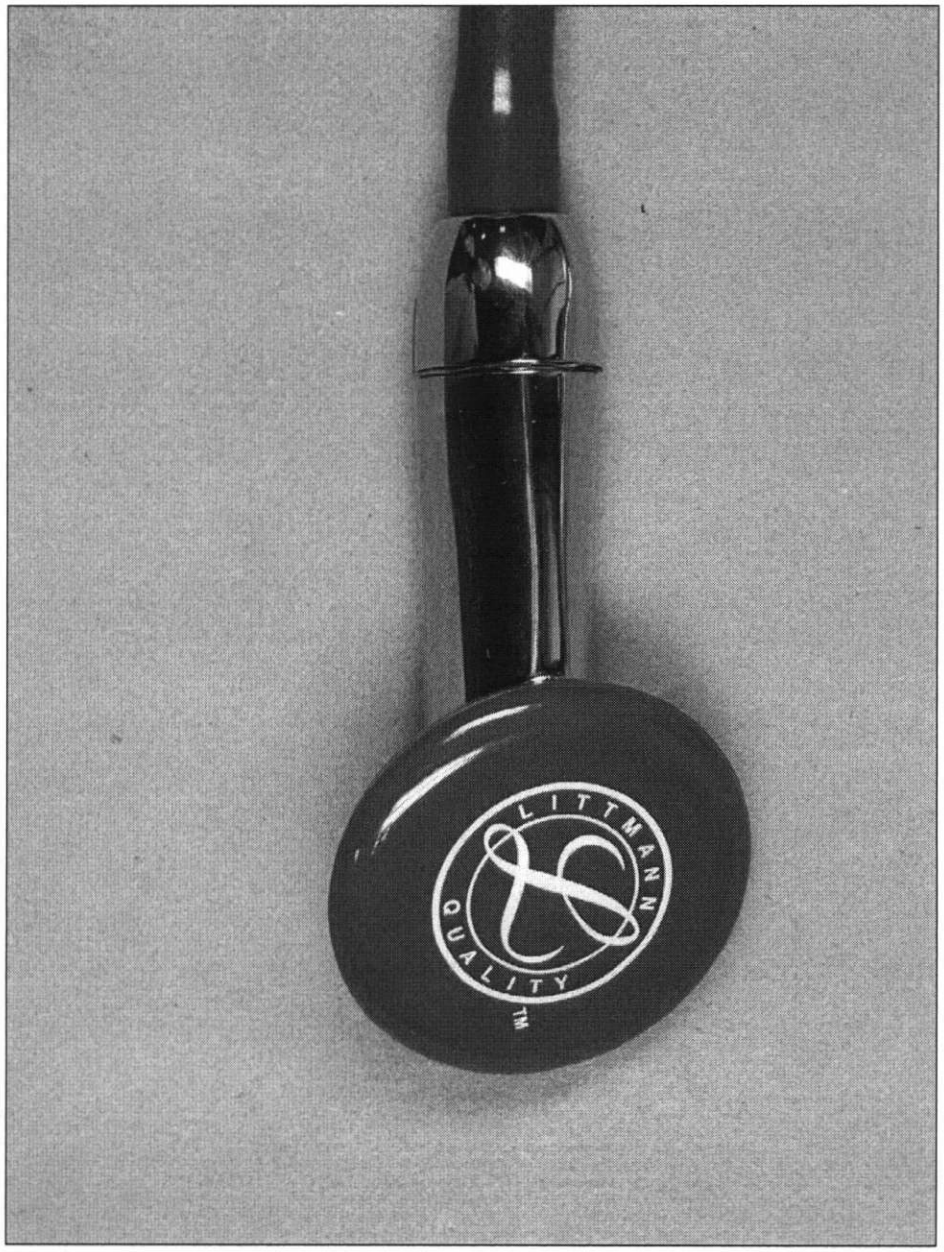
Annex A

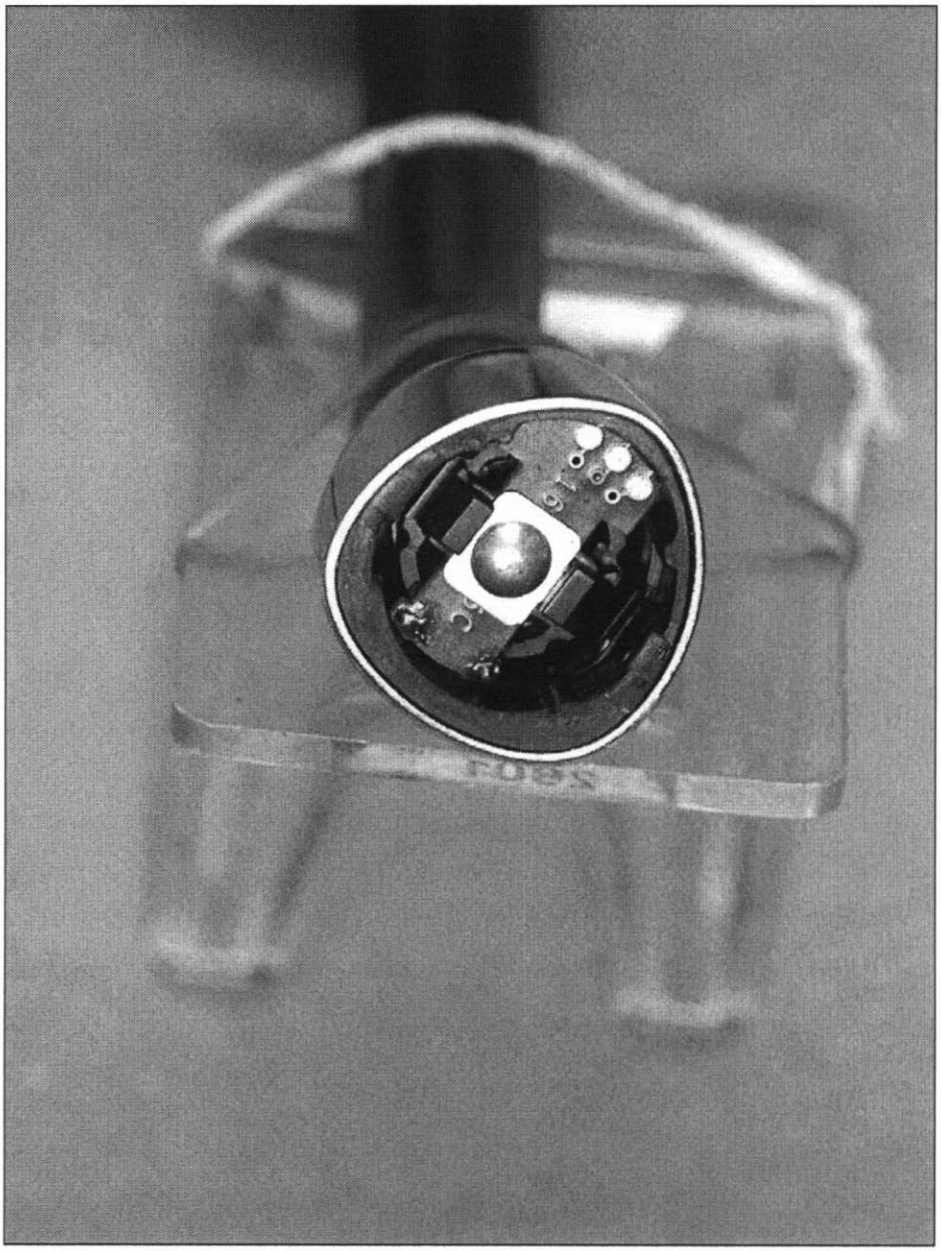
Pictures

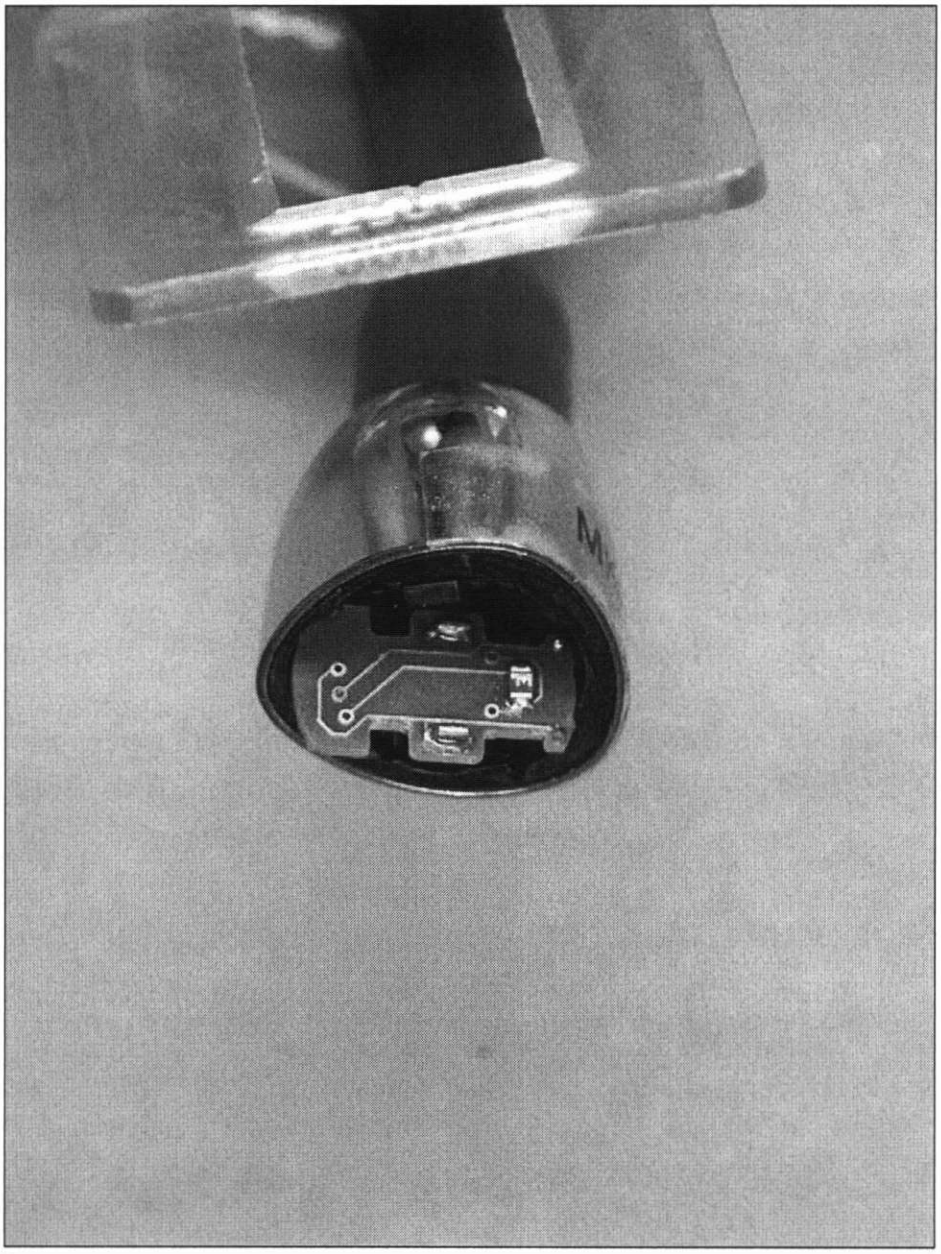


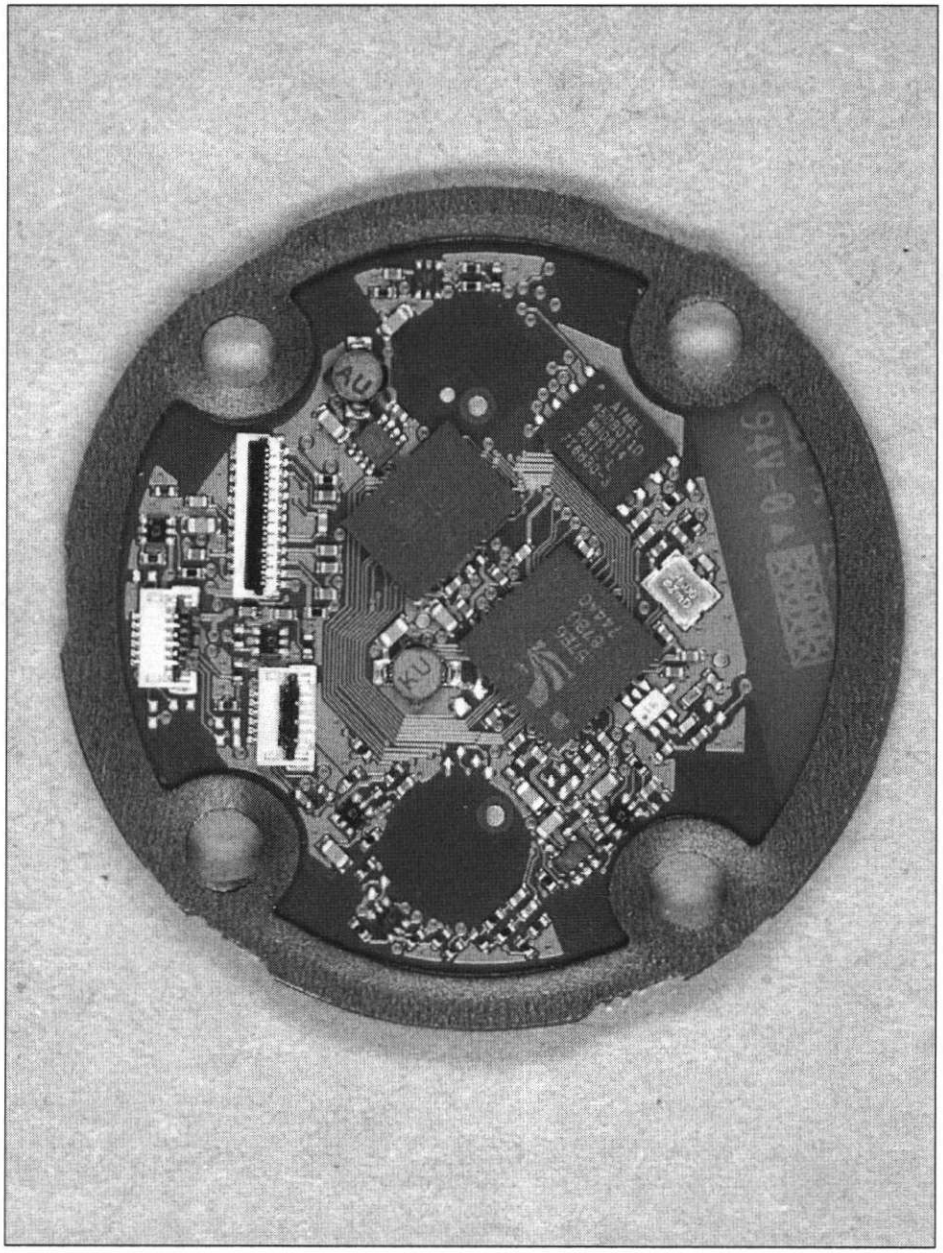


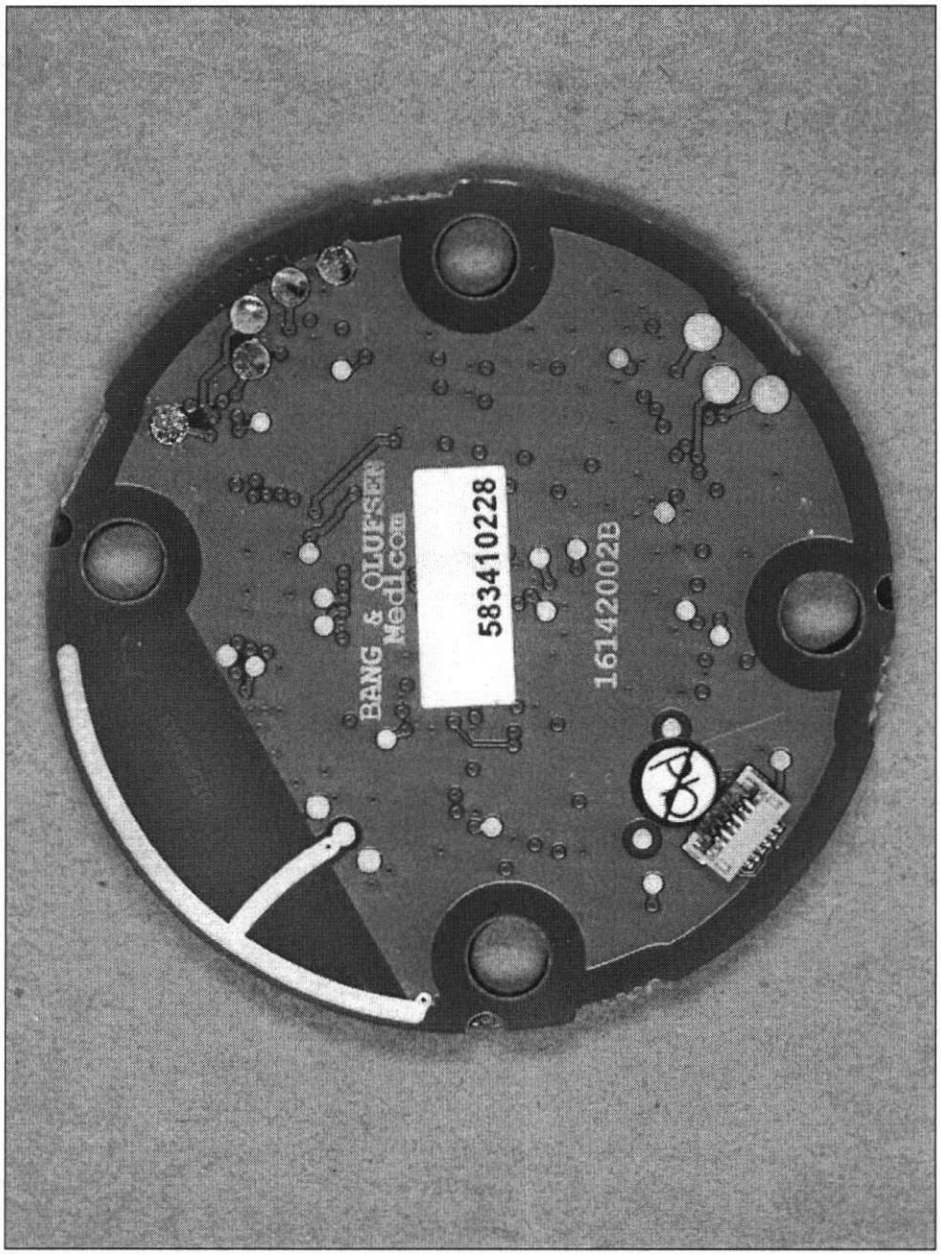
866


LITTMANN
QUALITY
TM







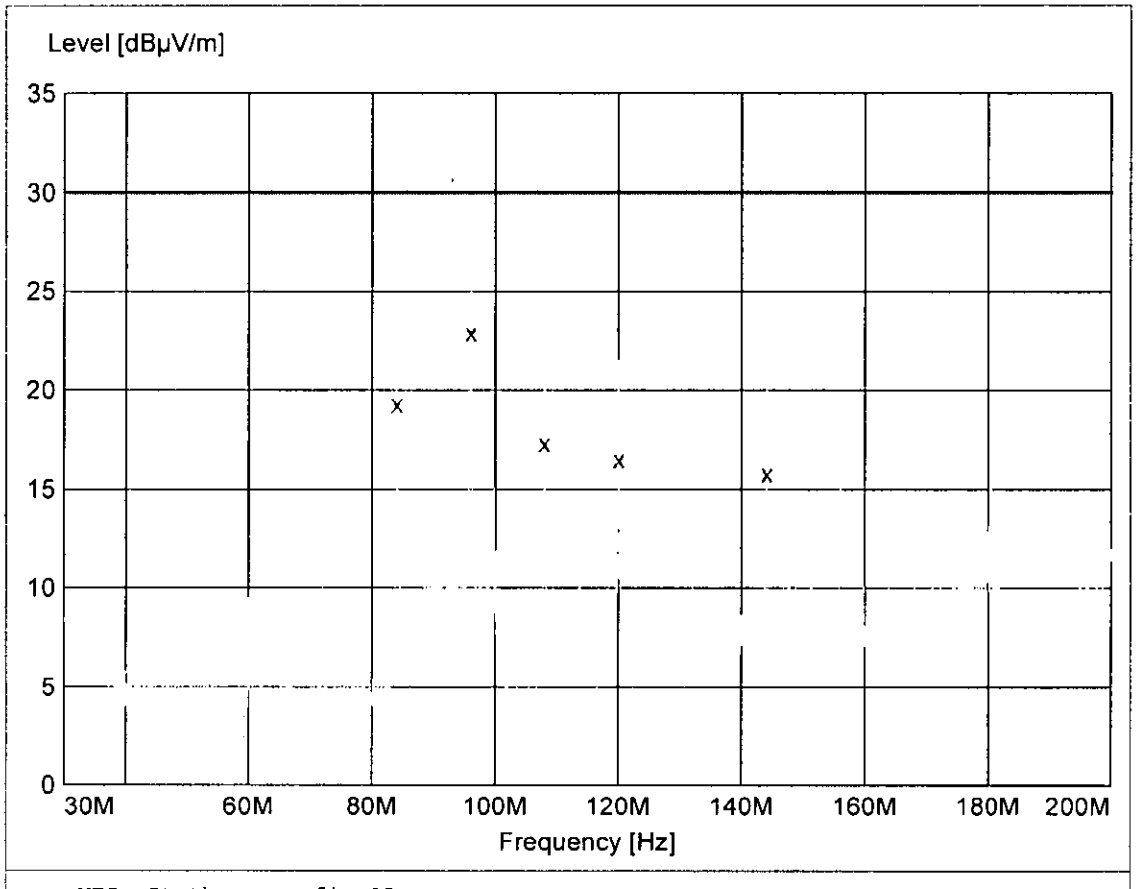


S71

Annex B:Diagrams

Spurious emission under normal conditions according to EN 55022 ***Ordernumber: G0M20810-2051***

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Medical Prod
EUT:	Bluetooth enabled stethoscope
Model:	Model 3200
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Klein
Test Conditions:	Tnom: 23°C, Unorm: Batt
Test Specification:	Ant: HK 116, vertical
Comment 1:	mode: Bluetooth
Comment 2:	mode:



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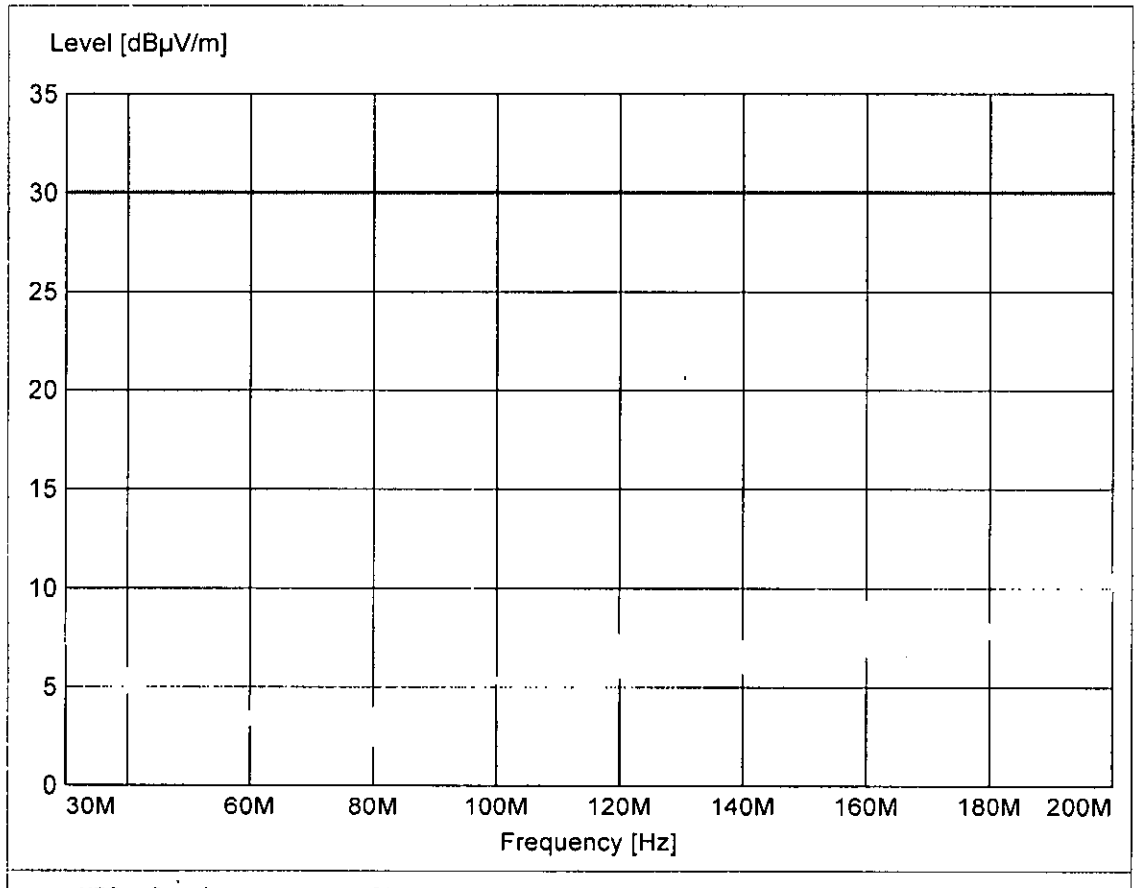
Spurious emission under normal conditions according to EN 55022 ***Ordernumber: G0M20810-2051***

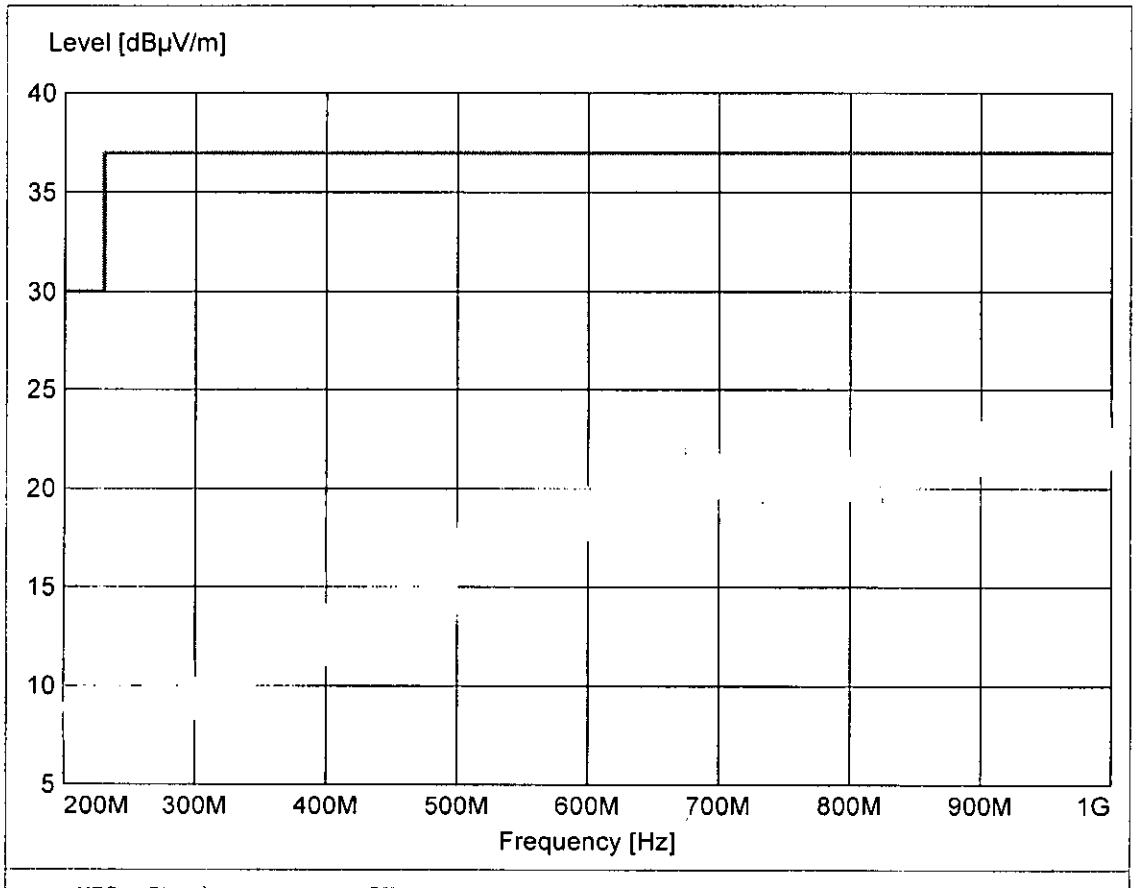
Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Medical Prod
EUT:	Bluetooth enabled stethoscope
Model:	Model 3200
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Klein
Test Conditions:	Tnom: 23°C, Unorm: Batt
Test Specification:	Ant: HK 116, horizontal
Comment 1:	mode: Bluetooth
Comment 2:	mode:



MES Stethoscope_pre PK
LIM EN 55022 F QP_B Field Strength QP Limit

Spurious emission under normal conditions according to EN 55022 ***Ordernumber: G0M20810-2051***

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Medical Prod
EUT:	Bluetooth enabled stethoscope
Model:	Model 3200
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Klein
Test Conditions:	Tnom: 23°C, Unorm: Batt
Test Specification:	Ant: HL 223, vertical
Comment 1:	mode: Bluetooth
Comment 2:	mode:

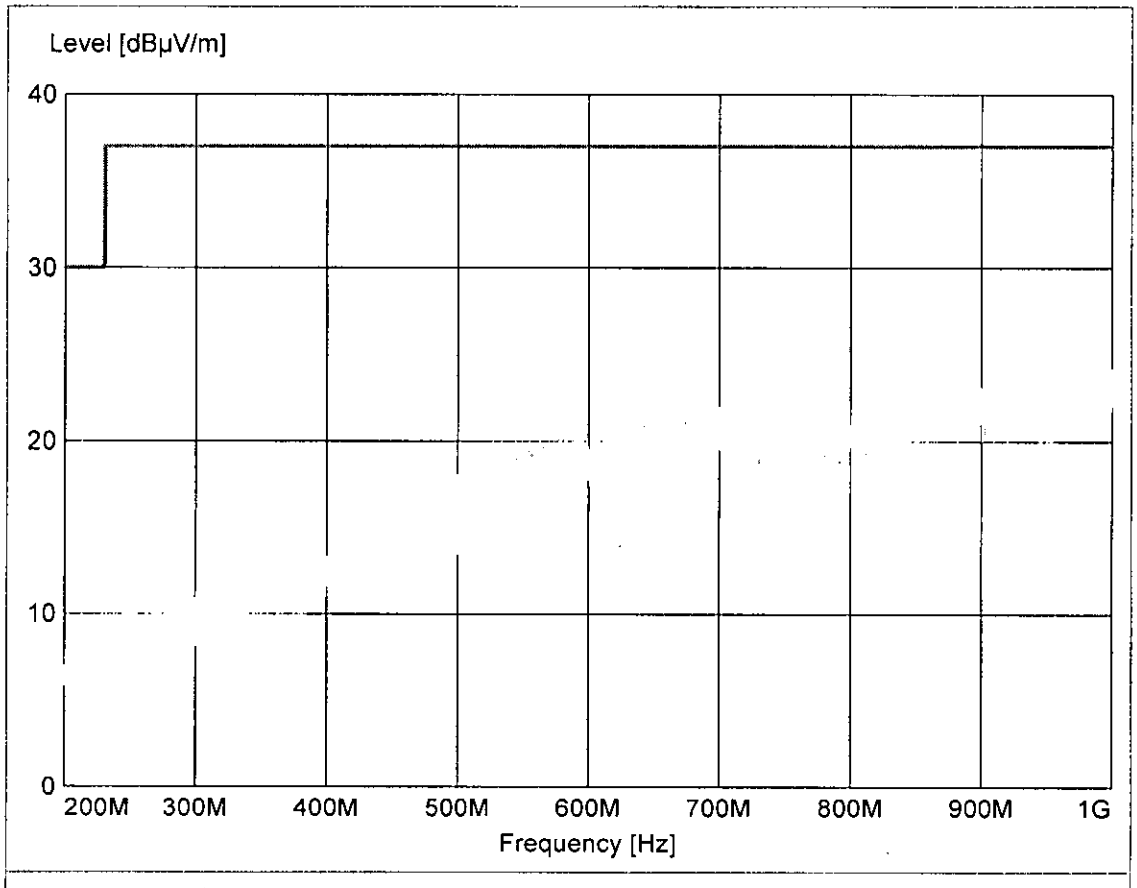


MES Stethoscope_pre PK
LIM EN 55022 F QP_B Field Strength QP Limit

875

Spurious emission under normal conditions according to EN 55022 ***Ordernumber: G0M20810-2051***

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Medical Prod
EUT:	Bluetooth enabled stethoscope
Model:	Model 3200
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Klein
Test Conditions:	Tnom: 23°C, Unorm: Batt
Test Specification:	Ant: HL 223, horizontal
Comment 1:	mode: Bluetooth
Comment 2:	mode:



MES Stethoscope_pre PK
LIM EN 55022 F QP_B Field Strength QP Limit

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TCB

GRANT OF EQUIPMENT AUTHORIZATION

TCB

Certification
Issued Under the Authority of the
Federal Communications Commission
By:

Eurofins ETS Product Service GmbH
Storkower Strasse 38c
D-15526 Reichenwalde,
Germany

Date of Grant: 12/19/2008

Application Dated: 12/19/2008

3M Safety & Security Systems Division
3M Center Bldg, 76-1-01
St Paul, MN 55144

Attention: Roger Kuhn , Regulatory Manager

NOT TRANSFERABLE

EQUIPMENT AUTHORIZATION is hereby issued to the named GRANTEE, and is VALID ONLY for the equipment identified hereon for use under the Commission's Rules and Regulations listed below.

FCC IDENTIFIER: DGFIPD3200
Name of Grantee: 3M Safety & Security Systems Division
Equipment Class: Part 15 Spread Spectrum Transmitter
Notes: Electronic Stethoscope

Grant Notes	FCC Rule Parts	Frequency Range (MHZ)	Output Watts	Frequency Tolerance	Emission Designator
	15C	2402.0 - 2480.0	0.0022		

Power output listed is conducted. This device and its antenna(s) must not be co-located or operating in conjunction with any other antenna or transmitter.

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EUROFINS PRODUCT SERVICE GMBH

TEST - REPORT

FCC RULES PARTS 15.247
IC RADIO STANDARDS RSS-210 Issue 7

FCC ID: DGFIPD3200
IC: 458A-IPD3200

Model Name: M3200

Test report no.: G0M20810-2051-P-15

ACCREDITED

Testing Cert #1983.01

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Eurofins Product Service GmbH
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Germany

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1 General information

1.1 Notes

The purpose of conformity testing is to increase the probability of adherence to the essential requirements or conformity specifications, as appropriate.
The complexity of the technical specifications, however, means that full and thorough testing is impractical for both technical and economic reasons.
Furthermore, there is no guarantee that a test sample which has passed all the relevant tests conforms to a specification.
Neither is there any guarantee that such a test sample will interwork with other genuinely open systems.
The existence of the tests nevertheless provides the confidence that the test sample possesses the qualities as maintained and that is performance generally conforms to representative cases of communications equipment.

The test results of this test report relate exclusively to the item tested as specified in 1.5.
The test report may only be reproduced or published in full.
Reproduction or publication of extracts from the report requires the prior written approval of the Eurofins Product Service GmbH.

Operator:

Date	Eurofins-Lab.	Name	Signature
13.11.2008		M. Handrik	

Technical responsibility for area of testing:

Date	Eurofins-Lab	Name	Signature
13.11.2008		J. Zimmermann	

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1.2 Testing laboratory

1.2.1 Location

EUROFINS PRODUCT SERVICE GMBH
Storkower Straße 38c
D-15526 Reichenwalde b. Berlin
Germany
Telephone : +49 33631 888 00
Telefax : +49 33631 888 660

1.2.2 Details of accreditation status

DAR ACCREDITED TESTING LABORATORY
DAR-REGISTRATION NUMBER: DAT-P-268/08

RECOGNIZED NOTIFIED BODY EMC
REGISTRATION NUMBER: BNetzA-bS EMV-07/61

RECOGNIZED NOTIFIED BODY R&TTE
REGISTRATION NUMBER: BNetzA-bS-02/51-53

FCC FILED TEST LABORATORY
REG.-NO. 96970

A2LA ACCREDITED TESTING LABORATORY
CERTIFICATE NO. 1983.01

BLUETOOTH QUALIFICATION TEST FACILITY (BQTF)
ACCREDITED BY BLUETOOTH QUALIFICATION REVIEW BOARD

INDUSTRY CANADA FILED TEST LABORATORY
REG. NO. IC 3470

1.3 Details of approval holder

Name	: 3M Health Care Patient Assessment Laboratory 3M Medical Products
Street	: 3M Center, Building 270-4N-09
Town	: Maplewood, MN 55144-1000
Country	: USA
Telephone	: +1 651-733-4531
Contact	: Mr. T.E. Drummond
E-Mail	: tedrummond@mmm.com

1.4 Application details

Date of receipt of application	: 05.11.2008
Date of receipt of test item	: 05.11.2008
Date of test	: 05.11.2008 – 12.11.2008

1.5 Test item

FCC ID	: DGFIPD3200
Description of test item	: Bluetooth enabled stethoscope
Type identification	: M3200
Serial number	: without
Photos	: See annex A.

Technical data

Frequency band	:	2.4 - 2.4835 GHz
Frequency Ch A	:	2402 MHz
Frequency Ch B	:	2441 MHz
Frequency Ch C	:	2480 MHz

Transmitter		**Vnom**
Power (ch A)	:	Conducted: 3.42 dBm
Power (ch B)	:	Conducted: 3.33 dBm
Power (ch C)	:	Conducted: 2.93 dBm

Antenna Type	:	internal antenna
Antenna Gain	:	-12 dBi
Power supply	:	1.5 V DC battery
Operating mode	:	duplex
Type of modulation	:	FHSS
Host device	:	none

Classification :

Fixed Device	☐
Mobile Device (Human Body distance > 20 cm)	☒
Portable Device (Human Body distance < 20 cm)	☐

Manufacturer:
(if applicable)

Name
Street
Town
Country

(b) (4)
[redacted]

Additional information:

The test sample is designed as Bluetooth Part of a composite device. Its pseudorandom hopping scheme, authentication, receiver parameters, synchronization procedure and other parameters are determined by Bluetooth Core Specification.

According to attached declaration of manufacturer this device don't work in master inquiry mode.
So we have only one frequency hopping system and the hopping sequence of the master inquiry mode is not verified.

1.6 Test standards

Technical standard:	FCC Parts:	15.247
	IC Standards:	RSS 210 Issue 7

2 Technical test

2.1 Summary of test results

No deviations from the technical specification(s) were ascertained in the course of the tests performed. ☒

or

The deviations as specified in 2.5 were ascertained in the course of the tests performed. ☐

2.2 Test environment

Temperature	: 25 ° C
Relative humidity content	: 20 ... 75 %
Air pressure	: 86 ... 103 kPa
Details of power supply	: 1.5 V DC battery

Extreme conditions parameters:	: test voltage - extreme	min.:	-- V DC (Vnom – 15%)
		max:	-- V DC (Vnom + 15%)

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2.3 Test equipment utilized

No.	Test equipment	Type	Manufacturer
ETS 0012	Biconical Antenna	HK 116	R & S
ETS 0013	LPD Antenna	HL'223	R & S
ETS 0015	Log Periodical Antenna	HL 025	R & S
ETS 0018	Horn antenna	BBHA 9120 D	Schwarzbeck
ETS 0253	Spectrum Analyzer	FSIQ 26	R & S
ETS 0271	Spectrum Analyzer	FSEK 30	R & S
ETS 0288	Artificial mains	ESH2-Z5	R & S
ETS 0311	Anechoic chamber	AC 4	Frankonia
ETS 0474	EMI Test Receiver	ESCS 30	R&S

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2.4 General test procedure

POWER LINE CONDUCTED INTERFERENCE: The procedure used was ANSI STANDARD C63.4-2003 5.2 using a 50 µH LISN (if necessary). Both lines were observed. The bandwidth of the spectrum analyzer was 10 kHz with an appropriate sweep speed.

RADIATION INTERFERENCE: The test procedure used was ANSI STANDARD C63.4-2003 6.4 using a spectrum analyzer. The resolution bandwidth of the spectrum analyzer was 100 kHz for measurements below 1 GHz and RBW 1 MHz was used above 1 GHz. The analyzer was calibrated in dB above a microvolt at the output of the antenna.

FORMULA OF CONVERSION FACTORS for Field strength: The Field Strength at 3 m was established by adding the meter reading of the spectrum analyzer (which is set to read in units of dBµV) to the antenna correction factor supplied by the antenna manufacturer. The antenna correction factors are stated in terms of dB.

Example:

Freq. (MHz)	METER READING + ACF + CABLE LOSS (to the receiver) = FS
33	20 dBµV + 10.36 dB + 6 dB = 36.36 dBµV/m @ 3 m

ANSI STANDARD C63.4-2003 6.2.1 MEASUREMENT PROCEDURES: The UUT was placed on a table 80 cm high and with dimensions of 1 m by 1.5 m (non metallic table). The UUT was placed in the center of the table. The table used for radiated measurements is capable of continuous rotation. The spectrum was scanned from 30 MHz to at least 10th harmonic of the fundamental.

Peak readings were taken in three (3) orthogonal planes and the highest readings.
Measurements were made by Eurofins Product Service GmbH at the registered open field test site located at Storkower Str. 38c, 15526 Reichenwalde, Germany.

When an emission was found, the table was rotated to produce the maximum signal strength. At this point, the antenna was raised and lowered from 1 m to 4 m. The antenna was placed in both the horizontal and vertical planes.

RF Exposure Compliance Requirements
According to FCC OET Bulletin 65 Edition 97-01 Supplement C and RSS-102 § 2.5, this spread spectrum transmitter is categorically excluded from routine environmental evaluation because of the low power level, where there is a high likelihood of compliance with RF exposure standards.
The antenna used for this transceiver must not be co-located or operating in conjunction with any other antenna or transmitter.

ANTENNA & GROUND:
This unit uses internal antenna.

2.5 Test results

☒ 1st test ☐ test after modification ☐ production test

SECT.	TEST CASE	FCC 47CFR PART	IC RSS-	Required	Test passed	Test failed
3	*TRANSMITTER PARAMETERS*					
3.1	RF power output conducted	15.247 (b)	210 A8.4	☒	☒	☐
3.2	RF power output radiated (EIRP)	15.247 (b)	210 A8.4	☐	☐	☐
3.3	20dB bandwidth	15.247 (a)(1)	210 A8.1	☒	☒	☐
3.4	Time of occupancy (dwell time)	15.247 (a)(1)	210 A8.1	☒	☒	☐
3.5	Number of hopping channels	15.247 (a)(1)	210 A8.1	☒	☒	☐
3.6	Carrier frequency separation	15.247 (a)(1)	210 A8.1	☒	☒	☐
3.7	Spurious emission conducted	15.247 (d)	210 A8.5	☐	☐	☐
3.8	Spurious emission radiated	15.247 (d)	210 A8.5	☒	☒	☐
3.9	Band-edge compliance	15.247 (d)	210 A8.5	☒	☒	☐
3.10	AC power line conducted emissions	15.207	Gen 7.2.2	☐	☐	☐
4	*RECEIVER PARAMETERS*					
4.1	Radiated emissions	15.107	Gen 7.2.3	☒	☒	☐

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3 Transmitter parameters

3.1 RF power output, conducted

Reference

FCC	47 CFR part 15.247 (b)
IC	RSS-210 A 8.4

Method of measurement

This measurement applies to equipment with an integral antenna and to equipment with an antenna connector and equipped with an antenna as declared by the applicant.

The power was measured with modulation (declared by the applicant).

Limits

Frequency band	FCC and IC
5725 - 5850 MHz	1 Watt (30 dBm) for systems with ≥ 75 hopping channels
2400 - 2483.5 MHz	1 Watt (30 dBm) for systems with ≥ 75 non - overlapping hopping channels 0.125 Watt (21 dBm) for all other hopping systems, but at least 15 hopping channels
902 - 928 MHz	1 Watt (30 dBm) for systems with ≥ 50 hopping channels 0.25 Watt (24 dBm) for all other hopping systems, but at least 25 hopping channels

Test results

Test conditions	Channel A	Channel B	Channel C
	[dBm]	[dBm]	[dBm]
T_{nom} = 25 ° C V_{nom} = 1.5 V	3.42	3.33	2.93
Measurement uncertainty	< 3 dB		

See attached diagrams

Test equipment: ETS 0253, ETS 0271

3.2 RF power output, radiated

Reference

FCC	47 CFR part 15.247 (b)
IC	RSS-210 A8.4

Method of measurement

This measurement applies to equipment with an integral antenna and to equipment with an antenna connector and equipped with an antenna as declared by the applicant.

The power was measured with modulation (declared by the applicant).

Limits

Frequency band	FCC and IC
5725 - 5850 MHz	4 Watt (36 dBm) for systems with ≥ 75 hopping channels.
2400 - 2483.5 MHz	4 Watt (36 dBm) for systems with ≥ 75 non – overlapping hopping channels 0.631 Watt (28 dBm) for all other hopping systems, but at least 15 hopping channels
902 - 928 MHz	4 Watt (36 dBm) for systems with ≥ 50 hopping channels 1.585 Watt (32 dBm) for all other hopping systems, but at least 25 hopping channels
FCC	The conducted output power limit specified in paragraph (b) of this section is based on the use of antennas with directional gains that do not exceed 6 dBi. Except as shown in paragraph (c) of this section, if transmitting antennas of directional gain greater than 6 dBi are used, the conducted output power from the intentional radiator shall be reduced below the stated values in paragraphs (b)(1), (b)(2), and (b)(3) of this section, as appropriate, by the amount in dB that the directional gain of the antenna exceeds 6 dBi.
IC	Systems in the 2400 - 2483.5 MHz and 5725 - 5850 MHz which have an e.i.r.p. above 4 W are permitted only for point-to-point systems (i.e. point-to-multipoint systems and multiple co-located transmitters transmitting the same information are prohibited from exceeding 4 W e.i.r.p.). Point-to-point systems in these two bands may use higher e.i.r.p. as necessary for satisfactory operation provided that the higher e.i.r.p. is achieved by employing higher gain directional antennas and not higher transmitter output powers. However, remote stations of point-to-multipoint systems shall be allowed to operate under the same condition as point-to-point systems.

Test Results

Test conditions	Channel A	Channel B	Channel C
	EIRP [dBm]	EIRP [dBm]	EIRP [dBm]
T_{nom} = 25 ° C V_{nom} = 1.5 V	--	--	--
Measurement uncertainty	< 3 dB		

Test equipment: --

3.3 20 dB bandwidth

Reference

FCC	CFR part 15.247 (a)(1)
IC	RSS-210 A8.1

Method of measurement

The 20 dB bandwidth is measured on the lowest, middle and highest hopping channel.
Frequency hopping systems shall have hopping channel carrier frequencies separated by a minimum of 25 kHz or the 20 dB bandwidth of the hopping channel, whichever is greater. Alternatively, frequency hopping systems operating in the 2400 - 2483.5 MHz band may have hopping channel carrier frequencies that are separated by 25 kHz or two-thirds of the 20 dB bandwidth of the hopping channel, whichever is greater, provided the systems operate with an output power no greater than 125 mW. Frequency hopping systems may avoid or suppress transmissions on a particular hopping frequency provided that a minimum of 15 channels are used.

Limits

Frequency band	FCC and IC
5725 - 5850 MHz	≤ 1 MHz
2400 - 2483.5 MHz	≤ carrier frequencies separation for hopping systems with max cond. power of 1 Watt ≤ 1.5 of the carrier frequencies separation for hopping systems with max cond. power of 0.125 Watt
902 - 928 MHz	< 250 kHz for systems with ≥ 50 hopping channels 250 kHz ≤ 500 kHz for all other hopping systems

Test results

Test conditions	Channel A	Channel B	Channel C
	MHz	MHz	MHz
T_{nom} = 25 °C V_{nom} = 1.5 V	0.934	0.934	0.934
Measurement uncertainty	< 10 Hz		

System receiver input bandwidth:
The manufacturer declares that the receiver input bandwidth matches to the bandwidth of the transmitter signal.

See attached diagrams

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Occupied Bandwidth (99%) – RSS Gen

Test conditions	Channel A	Channel B	Channel C
	MHz	MHz	MHz
T_{nom} = 25 °C V_{nom} = 1.5 V	2.31	2.24	1.78
Measurement uncertainty	< 10 Hz		

Test equipment: ETS 0271

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3.4 Time of occupancy (dwell time)

Reference

FCC	CFR part 15.247 (a)(1)
IC	RSS-210 A8.1

Method of measurement

The EUT has its hopping function enabled.
Spectrum analyzer settings:
Span: zero span, centered on hopping channel
RBW: 1 MHz
VBW: > RBW
Sweep: as necessary to capture the entire dwell time per hopping channel
Detector: peak
Trace: max hold

Limits

Frequency band	FCC and IC
5725 - 5850 MHz	≤ 0,4 s at measurement period of 30 seconds
2400 - 2483.5 MHz	≤ 0.4 s multiplied by the number of hopping channels employed
902 - 928 MHz	≤ 0,4 s at measurement period of 20 seconds for max 250 kHz 20 dB BW allowed ≤ 0,4 s at measurement period of 10 seconds for max 500 kHz 20 dB BW allowed

Test results

Test conditions	Operating mode	Measurement period	Time of occupancy
		[s]	[ms]
T_{nom} = 25 °C V_{nom} = 1.5 V	normal transmitting	31.6	180.873
	inquiry mode	--	--
Measurement uncertainty	< 1 µs		

See attached diagrams

Test equipment: ETS 0271

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3.5 Number of hopping channels

Reference

FCC	CFR part 15.247 (a)(1)
IC	RSS-210 A8.1

Method of measurement

According to FCC rules part 15 subpart C §15.247 frequency hopping systems operating in the 2400 - 2483.5 MHz and 5725 - 5850 MHz bands shall use at least 75 hopping frequencies.
According to FCC 00-312 appendix B systems in the 2400 - 2483,5 MHz band may utilize hopping channels whose 20 dB bandwidth is greater than 1 MHz provide the systems use at least 15 non-overlapping channels.

Limits

Frequency band	FCC and IC
5725 - 5850 MHz	≥ 75 hopping channels
2400 - 2483.5 MHz	≥ 75 hopping channels for >0.125 Watt ≥ 15 hopping channels for ≤0.125 Watt
902 - 928 MHz	≥ 50 hopping channels for >0.25 Watt ≥ 25 hopping channels for ≤0.25 Watt

Test results

Test conditions	Operating mode	Number of channel
T_{nom} = 25 °C	Normal transmitting	79
V_{nom} = 1.5 V	Inquiry mode	--

See attached diagrams

Test equipment: ETS 0271

Eurofins Product Service GmbH
Storkower Str. 38c, D-15526 Reichenwalde, Germany

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3.6 Carrier frequency separation

Reference

FCC	CFR part 15.247 (a)(1)
IC	RSS-210 A8.1

Method of measurement

Carrier frequency separation was measured with modulation (declared by manufacturer)

Limits

Frequency band	FCC and IC
5725 - 5850 MHz	minimum of 25 kHz or the 20 dB bandwidth of the hopping channel, whichever is greater, but ≤ 1 MHz
2400 - 2483.5 MHz	minimum of 25 kHz or the 20 dB bandwidth of the hopping channel, whichever is greater minimum of 25 kHz or 2/3 of the 20 dB bandwidth of the hopping channel, whichever is greater, for Pout ≤ 0.125 W
902 - 928 MHz	minimum of 25 kHz or the 20 dB bandwidth of the hopping channel, whichever is greater

Test results

Test conditions	Channel B	Channel Separation
	[GHz]	[kHz]
T_{nom} = 25 °C V_{nom} = 1.5 V	2.441	996.392
Measurement uncertainty	< 10 Hz	

See attached diagram

Test equipment: ETS 0271

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3.7 Spurious emission conducted

Reference

FCC	CFR part 15.247 (d)
IC	RSS-210 A8.5

Method of measurement

The EUT is connected to the spectrum analyzer via a low loss cable. If the EUT is not equipped with and antenna connector, a temporary antenna connector has to be installed. The EUT is switched on, the hopping function is disabled.
The analyzer setting was as following:

Frequency range	RES bandwidth		Video bandwidth	
	Pk	Avg	Pk	Avg
f < 1 GHz	100 kHz	100 kHz	100 kHz	100 kHz
f > 1 GHz	1 MHz	1 MHz	1 MHz	1 MHz

Limits

FCC	20 dB below peak output power
IC	20 dB below peak output power

Test results

Frequency	**Result [dBm]**	**Limit [dBm]**	**Margin [dB]**	**Reference level [dBm]**
--	--	--	--	--
--	--	--	--	--
--	--	--	--	--
--	--	--	--	--
--	--	--	--	--

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3.8 Spurious emission radiated

Reference

FCC	CFR part 15.247(d), 15.205. 15.209, 15.35
IC	RSS-210 A8.5, RSS-210 2.7

Method of measurement

Spurious emission was measured with modulation (declared by manufacturer).

According to 47 CFR 15, Part 15.247 (d): In any 100 kHz bandwidth outside the frequency band in which the spread spectrum or digitally modulated intentional radiator is operating, the radio frequency power that is produced by the intentional radiator shall be at least 20 dB below that in the 100 kHz bandwidth within the band that contains the highest level of the desired power, based on either an RF conducted or a radiated measurement, provided the transmitter demonstrates compliance with the peak conducted power limits.
If the transmitter complies with the conducted power limits based on the use of RMS averaging over a time interval, as permitted under paragraph (b)(3) of this section, the attenuation required under this paragraph shall be 30 dB instead of 20 dB. Attenuation below the general limits specified in Section 15.209(a) is not required.
In addition, radiated emissions which fall in the restricted bands, as defined in Section 15.205(a), must also comply with the radiated emission limits specified in Section 15.209(a) (see Section 15.205(c)).

Calculation of Limit:

All results are updated by an automatic measuring system in accordance to point 2.3

Limit = max. reading (because peak detector is used)
85.33 dBµV/m

Limit = Max. reading - 20 dB (because average detector is used)
85.33 dBµV/m - 20 dB = 65.33 dBµV/m

Limits for restricted bands

FCC & IC	20 dB below peak output power, emissions which fall in the restricted bands (15.205(a)) / (RSS-210 2.7) must comply the following limits: Frequencies below 1GHz:		
	Frequency of emission	Field strength	Field strength
	[MHz]	[µV / m]	[dBµV / m]
	30 - 88	100	40.0
	88 - 216	150	43.5
	216 - 960	200	46.0
	Above 960	500	54.0
	For frequencies above 1 GHz (Avg measurements): 54.0 dBµV / m For frequencies above 1 GHz (Pk measurements): Limit + 20 dB = 54.0 dBµV / m + 20 dB = 74 dBµV / m		

Calculation of test results:

Such factors like antenna correction, cable loss, external attenuation etc. are already included in the provided measurement results.

The peak and average spurious emission plots was measured with the average limits.
In the Table being listed the critical peak and average value an exhibit the compliance with the above calculated Limits.

If in the column's correction factor states a value then the max. Field strength in the same row is corrected by a value gained from the "Marker-Delta-Method" or the „Duty-Cycle Correction Factor".

15.35 (c) Duty cycle correction average value

When the radiated emission limits are expressed in terms of the average value of the emission, and pulsed operation is employed, the measurement field strength shall be determined by averaging over one complete pulse train, including blanking intervals, as long as the pulse train does not exceed 0.1 seconds.

Duty cycle correction = 20 log (dwell time / 100 ms or less)

DA 00-705 Duty cycle correction **peak value**

The analyzer setting was as following:

Frequency range	RES bandwidth		Video bandwidth	
	Pk	Avg	Pk	Avg
f < 1GHz	100 kHz	100 kHz	10 Hz	10 Hz
f > 1GHz	1 MHz	1 MHz	10 Hz	10 Hz

Set the VBW to 10 Hz, while maintaining all of the other instrument settings. This peak level, once corrected, must comply with the limit specified in Section 15.209. If the dwell time per channel of the hopping signal is less than 100 ms, then the reading obtained with the 10 Hz VBW may be further adjusted by a "duty cycle correction factor", derived from 20 log (dwell time / 100 ms), in an effort to demonstrate compliance with the 15.209 limit. Submit this data.

If the intentional radiator operates below 10 GHz: to the tenth harmonic of the highest fundamental frequency or to 40 GHz, whichever is lower.

Test results

Summary table with radiated data of the test plots

Freq.	Used Ch.	Frequency Marker [GHz]	Polari-zation	Δ correc-tions dB	Max. Field Strength [dBµV/m]	Compliance Limit [dBµV/m]	Detec-tor	BW [MHz]	Margin [dB]
4	L	4.802	V		54.24	74	P	1	-19.76
4	L	4.804	V		51.89	54	AV	1	-2.11
4	L	4.802	H		53.61	74	P	1	-20.39
4	L	4.804	H		50.45	54	AV	1	-3.55
4	M	4.882	V		53.79	74	P	1	-20.21
4	M	4.882	V		50.02	54	AV	1	-3.98
4	M	4.882	H		51.93	74	P	1	-22.07
4	M	4.882	H		49.02	54	AV	1	-4.98

Freq. - Frequency Range:

1: 30 – 200 MHz
2: 200 – 1000 MHz
3: 1 – 4 GHz
4: 4 – 8 GHz
5: 8 – 12 GHz
6: 12 – 17 GHz
7: 17 – 26,5 GHz

All other not noted test plots do not contain significant test results in relation to the limits.

See attached diagrams. No spurious emissions near by limit.

Test equipment: ETS 0012, ETS 0013, ETS 0015, ETS 0018, ETS 0271, ETS 0253, ETS 0311

3.9 Band edge compliance

Reference

FCC	CFR part 15.247 (d)
IC	RSS-210 A8.5

Method of measurement
In any 100 kHz bandwidth outside the frequency band in which the spread spectrum or digitally modulated intentional radiator is operating, the radio frequency power that is produced by the intentional radiator shall be at least 20 dB below that in the 100 kHz bandwidth within the band that contains the highest level of the desired power, based on either an RF conducted or a radiated measurement, provided the transmitter demonstrates compliance with the peak conducted power limits. If the transmitter complies with the conducted power limits based on the use of RMS averaging over a time interval, as permitted under paragraph (b)(3) of this section, the attenuation required under this paragraph shall be 30 dB instead of 20 dB. Attenuation below the general limits specified in Section 15.209(a) is not required.

In addition, radiated emissions which fall in the restricted bands, as defined in Section 15.205(a), must also comply with the radiated emission limits specified in Section 15.209(a) (see Section 15.205(c)).

Limits

FCC	20 dB below peak output power
IC	20 dB below peak output power

Test results

Test conditions	Single frequency (hopping disabled)	
	Lower band-edge	Upper band-edge
T_{nom} = 25 °C V_{nom} = 1.5 V	50.59dB	52.32 dB
Measurement uncertainty	< 100 Hz	

Test conditions	Hopping frequency (hopping enabled)	
	Lower band-edge	Upper band-edge
T_{nom} = 25 °C V_{nom} = 1.5 V	53.37 dB	50.92 dB
Measurement uncertainty	< 100 Hz	

See attached diagrams.

Test equipment: ETS 0271

3.10 AC power line conducted emissions

Reference

FCC	CFR part 15.207
IC	RSS-Gen 7.2.2

Method of measurement

For an intentional radiator which is designed to be connected to the public utility (AC) power line, the radio frequency voltage that is conducted back onto the AC line on any frequency or frequencies within the band 150 kHz to 30 MHz shall not exceed the limits. Compliance with this provision shall be based on the measurement of the radio frequency voltage between each power line and ground at the power terminals.

This measurement was transact first with instrumentation using an average and peak detector and a 10 kHz bandwidth. If the peak detector achieves a calculated level, the measurement is repeated by an instrumentation using a quasi-peak detector.

Limits

	Frequency of emission	Conducted limit field strength [dBµV]	
	[MHz]	Quasi Peak	Avg
FCC & IC	0.15 - 0.5	66 to 56	56 - 46
	0.5 - 5	56	46
	5 - 30	60	50

Test results

Frequency	Level	
	Quasi-peak	Average
150 kHz	--	--

Comment: not required.

Test equipment: --

dol

4 Receiver parameters

4.1 Radiated emissions

Reference

FCC	Part 15.109
IC	RSS-Gen 7.2.3

Method of measurement

The compliance of the EUT Receiver with the Limits of spurious emissions was performed according to the radiated measurement method.

The spectrum analyzer RBW was set to 100 kHz for measurements below 100 kHz and 1.0 MHz above 1.0 GHz. The measurement results are evaluated according to the procedure described in section 2.4 of this test report.

Limits

	Spurious frequency	Field strength
	MHz	microvolt/m at 3 meter
FCC & IC	30 - 88	100
	88 - 216	150
	216 - 960	200
	above 960	500

Test Results

Device Frequency	Frequency marker indication [MHz]	Antenna polarization	Worst case emission level [µV/m]	Compliance limit [µV/M]	Results [µV/M]
2441 MHz	198,637	V	36,22	150	-113,78
	179,218	H	38,99	150	-111,01
	830,060	V	50,35	200	-149,65
	830,060	H	31,88	200	-168,12
	3922,000	V	103,75	500	-396,25
	3838,000	H	110,15	500	-389,85
	7463,000	V	119,81	500	-380,19
	7030,000	H	109,65	500	-390,35

See attached diagrams.

Test equipment: ETS 0014, ETS 0294, ETS 0295, ETS 0310, ETS 0416, ETS 0484

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Annex

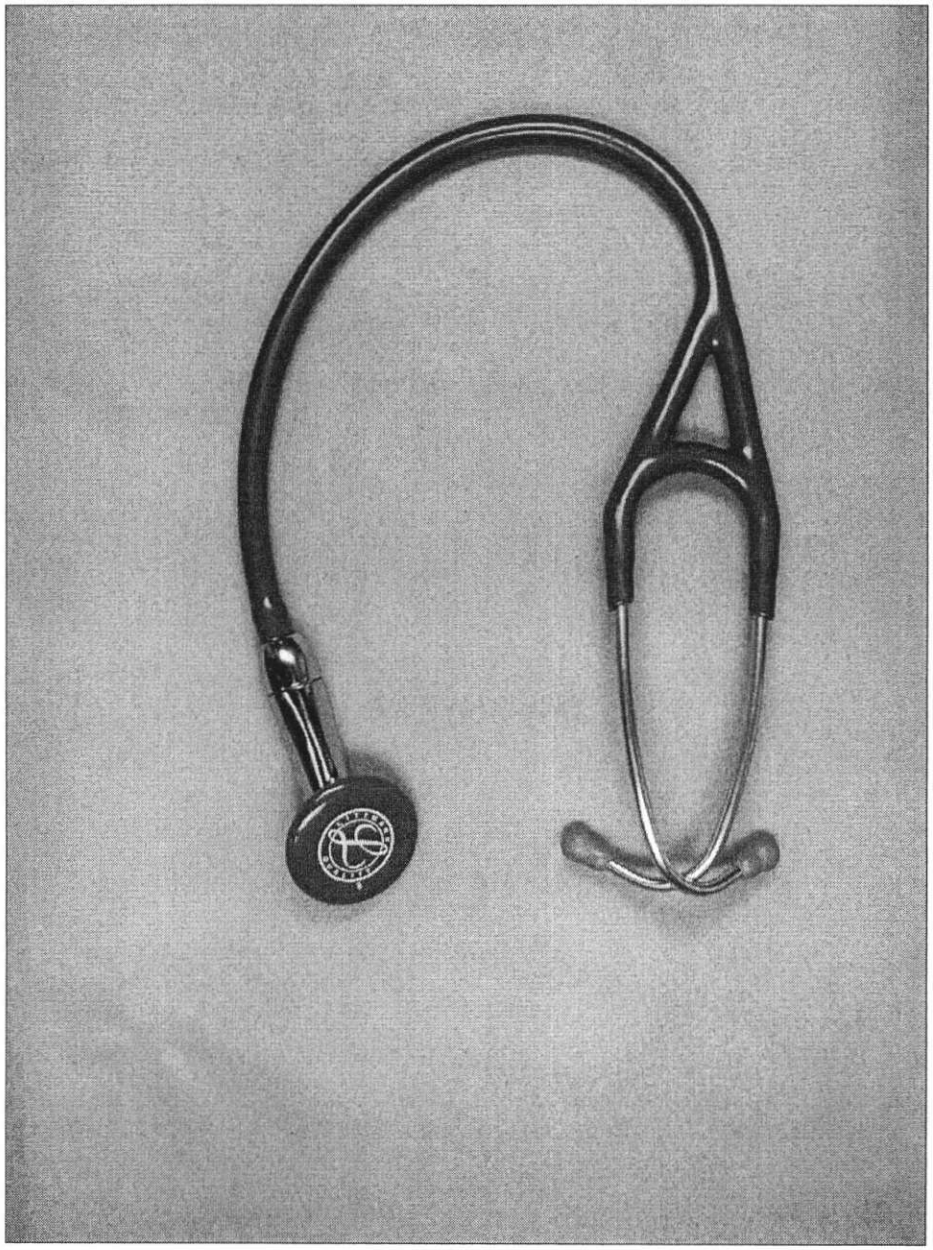
A	Pictures	9 pages
B	RF power output conducted	3 pages
C	20 dB bandwidth	6 pages
D	Time of occupancy (dwell time)	2 pages
E	Number of hopping frequencies	4 pages
F	Carrier frequency separation	1 page
G	Spurious emission radiated	49 pages
H	Band-edge compliance	4 pages
I	Receiver spurious emission	8 pages

Annex A

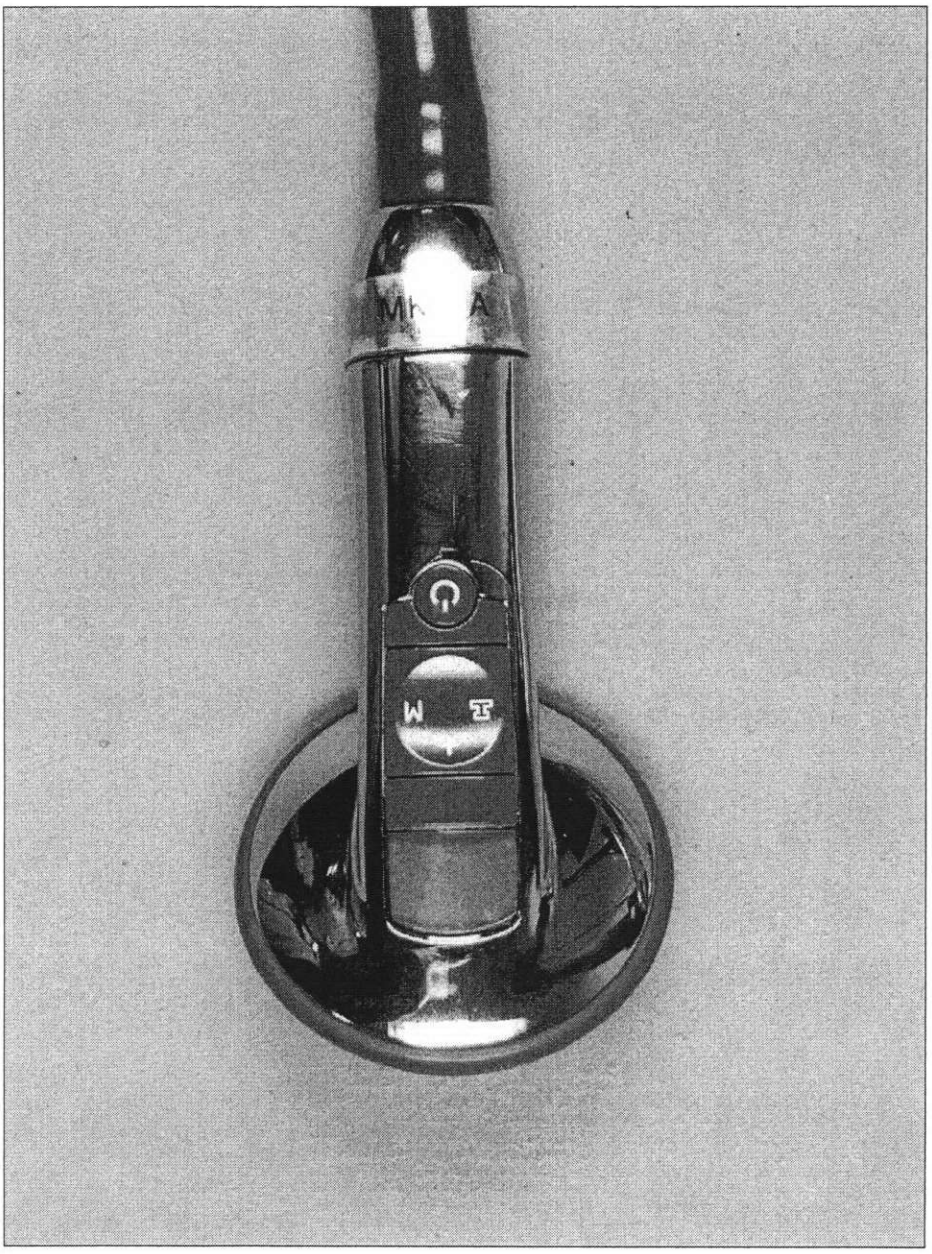
Pictures

Annex A

Pictures

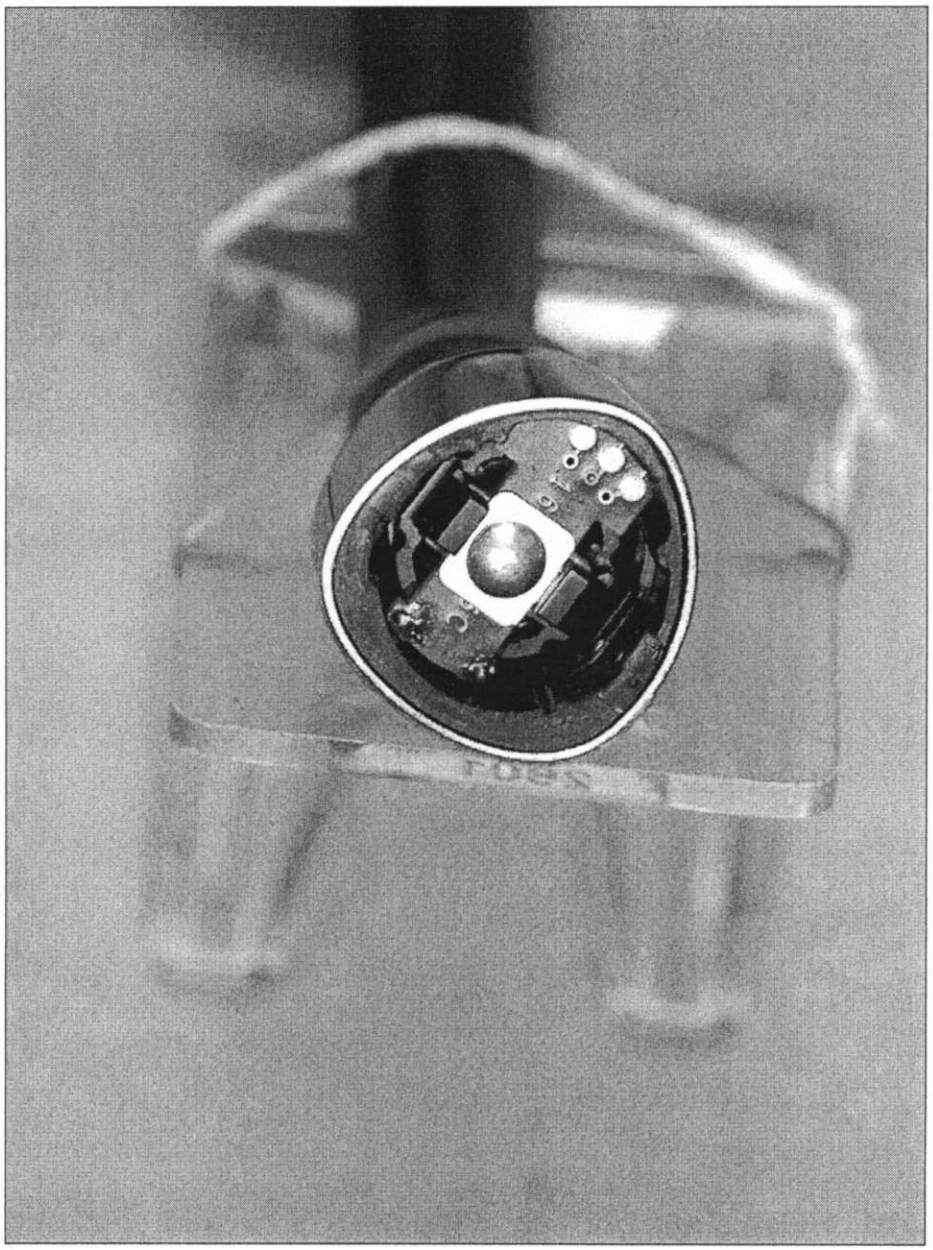


ACS

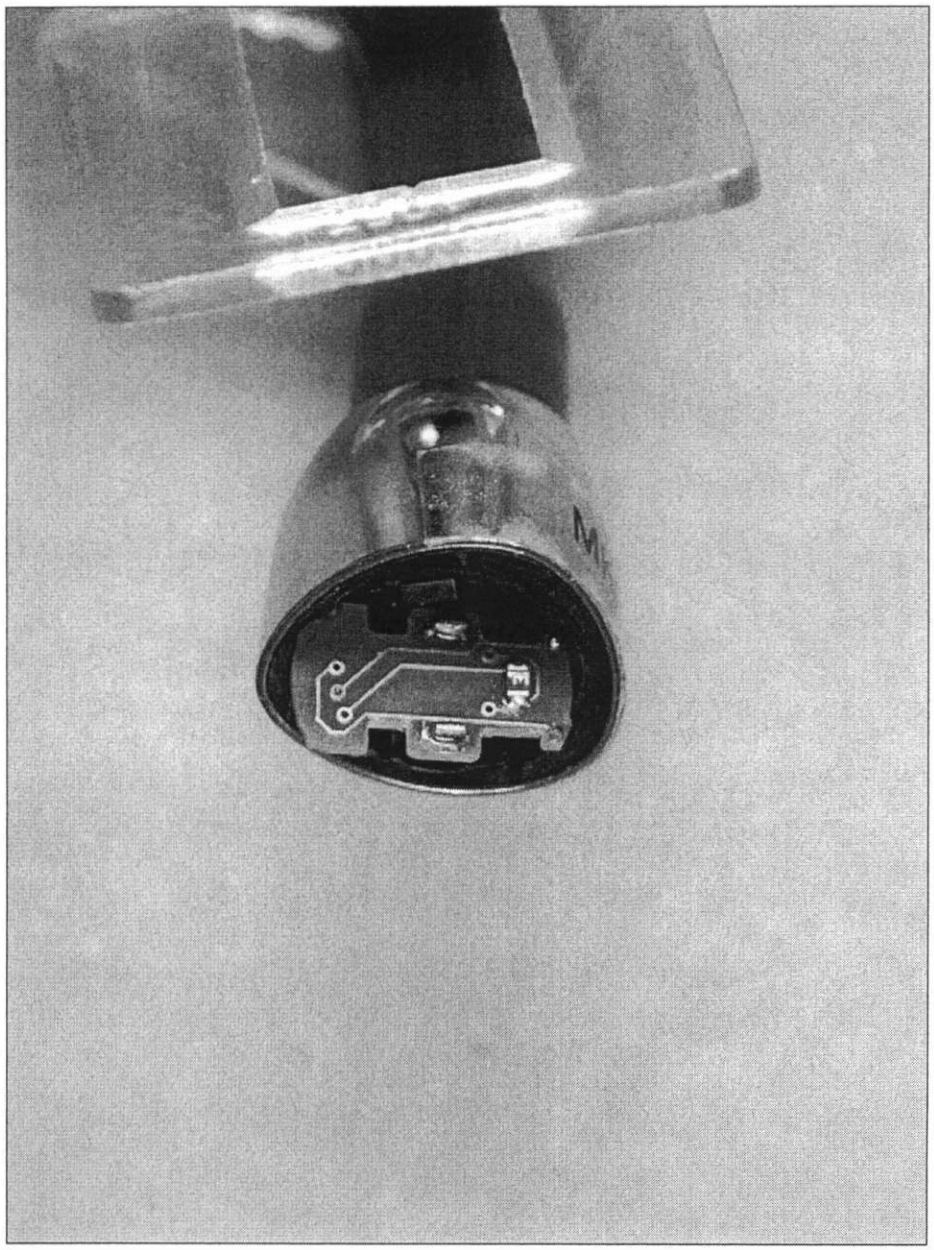


906

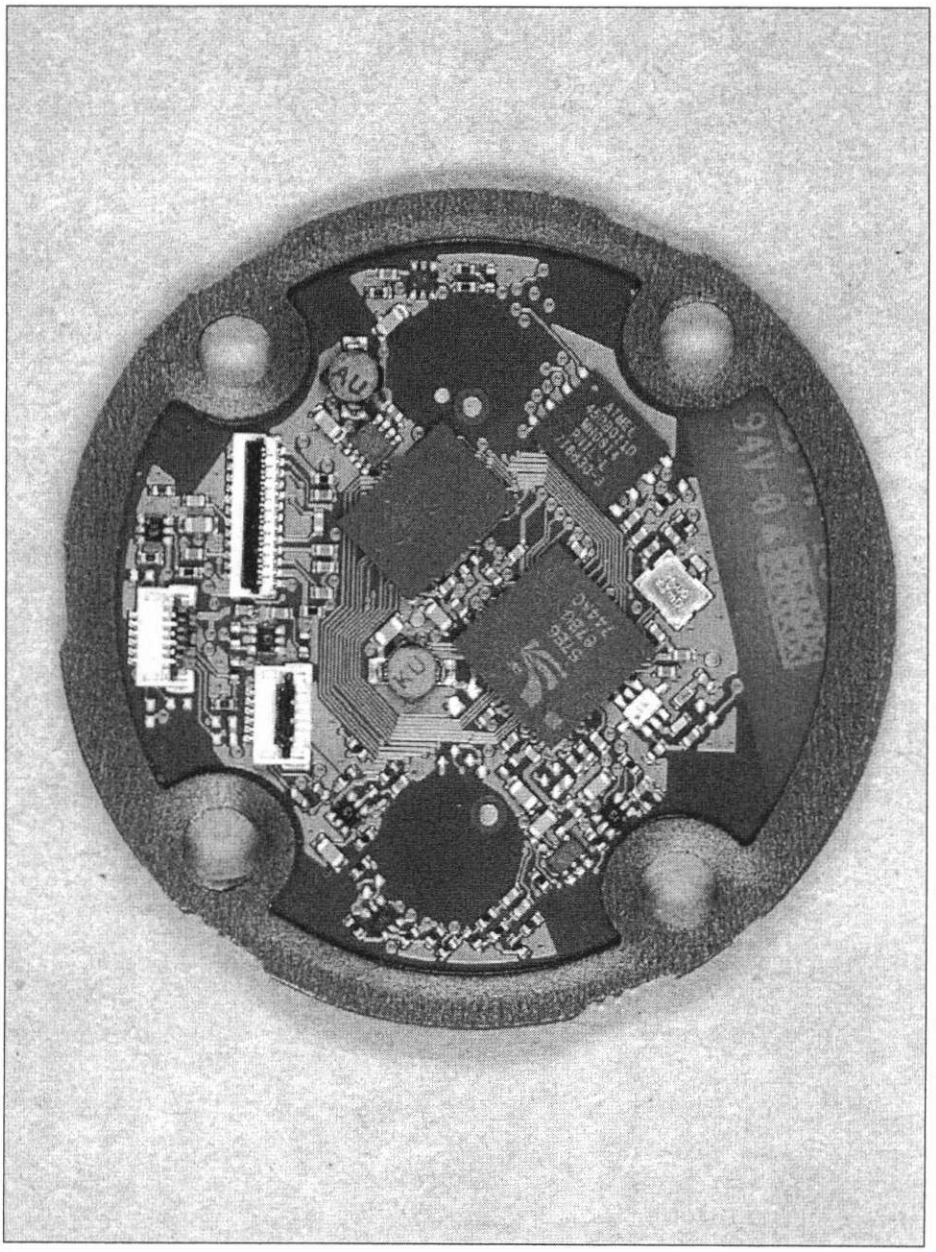
9-7



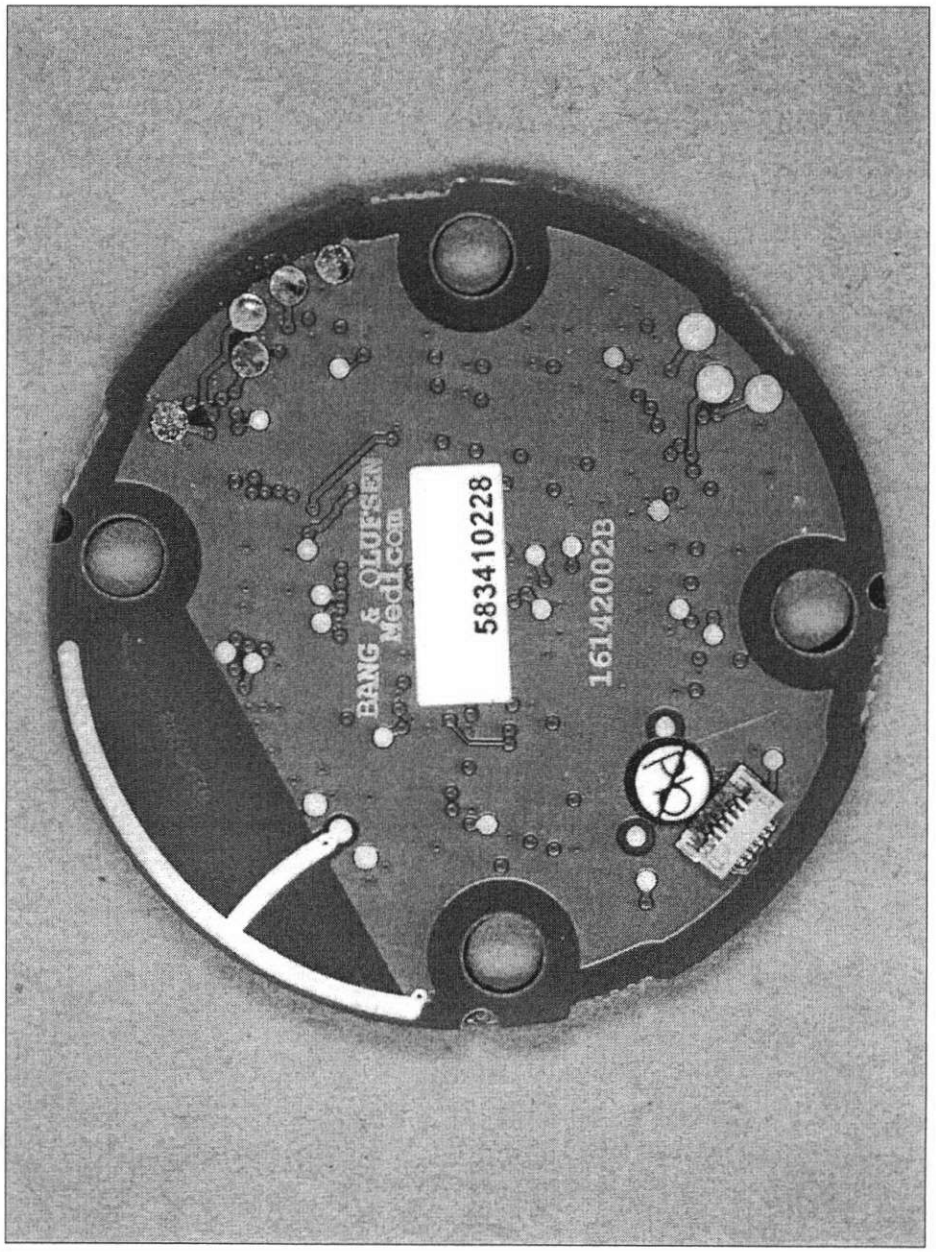
908



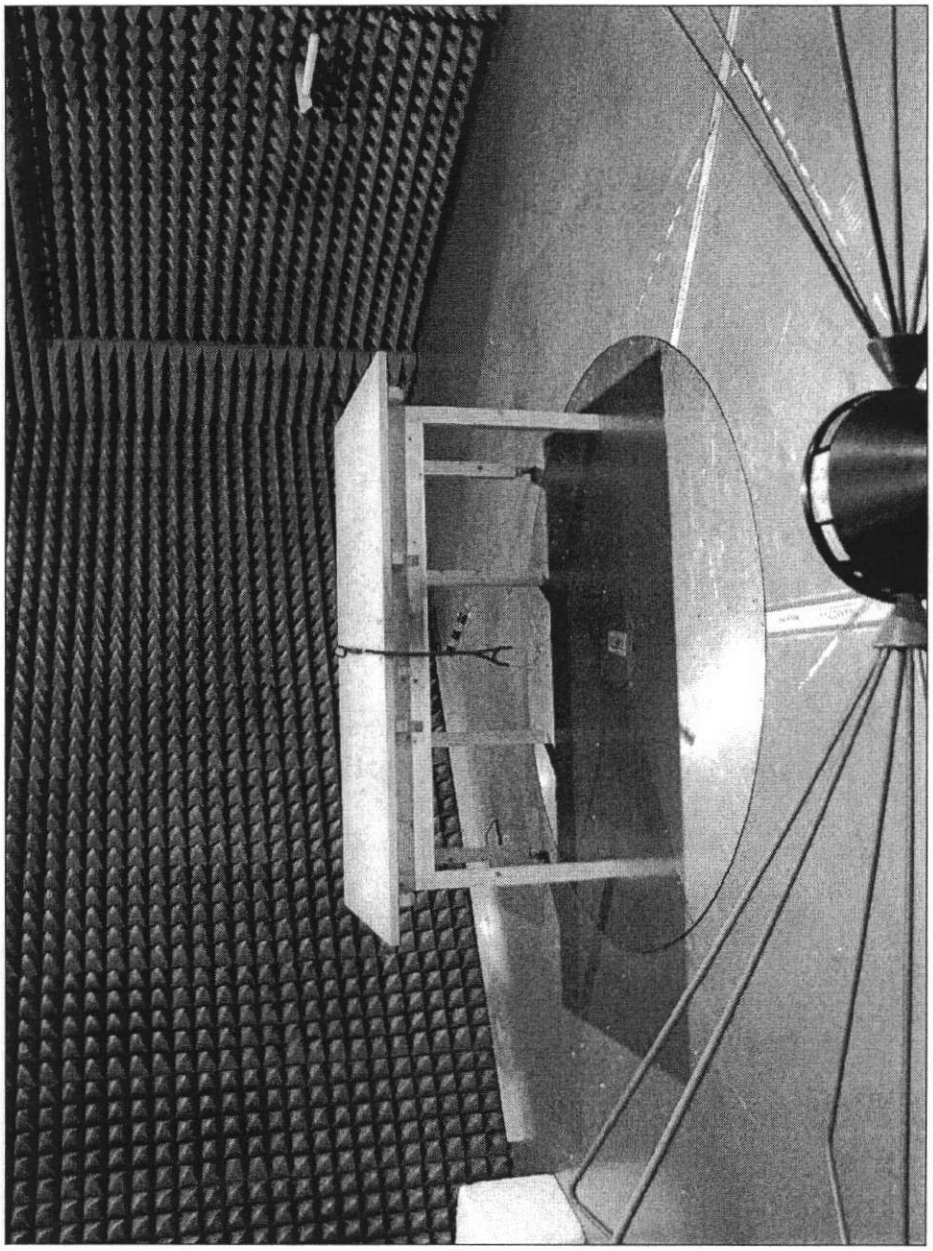
9.9

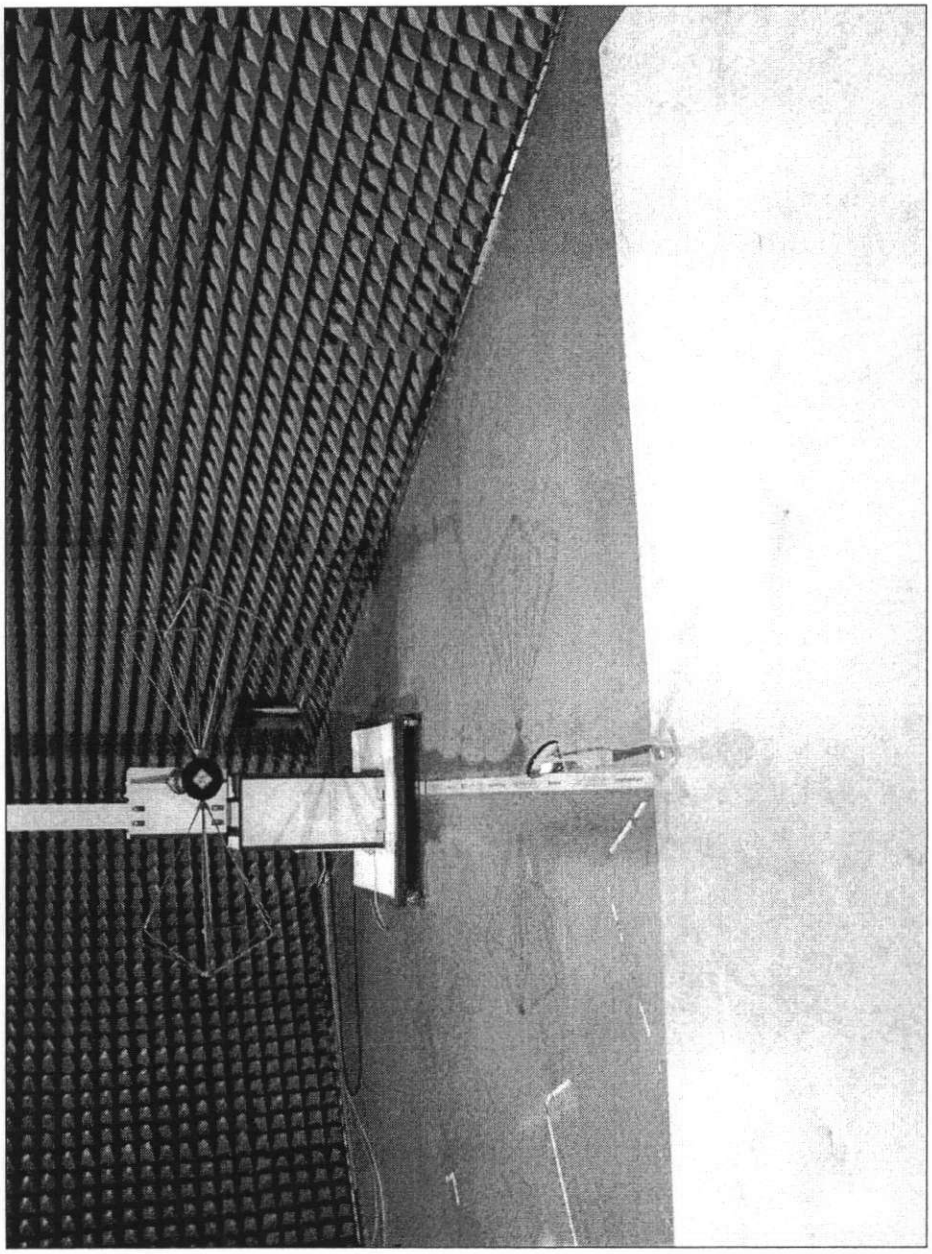


910



911





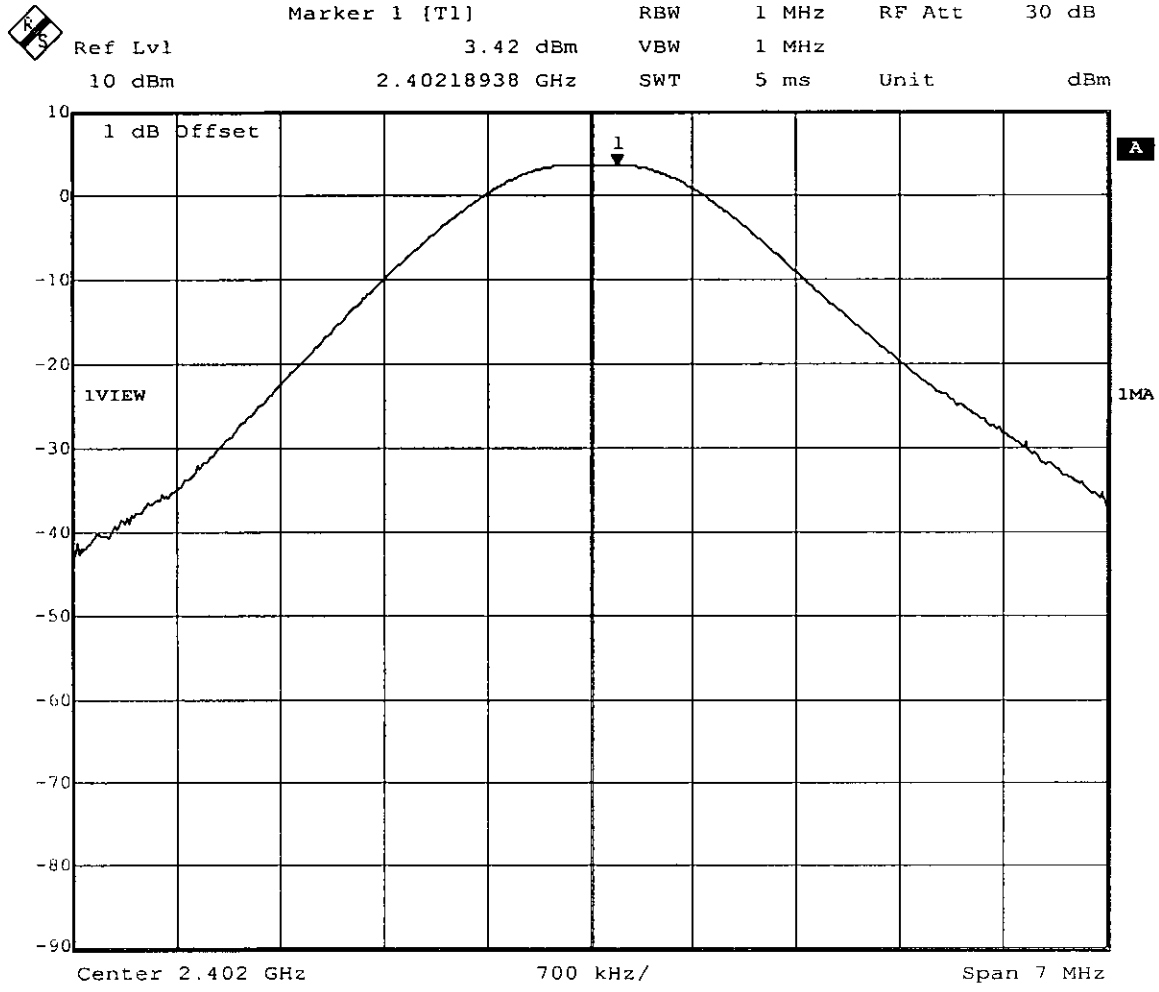
Annex B

RF power output conducted

eurofins | Eurofins Product Service

FCC part 15.247
Peak output power conducted

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(b)
Comment 1	Peak output power
Comment 2	Channel.: 0 / 2402 MHz
Comment 3	

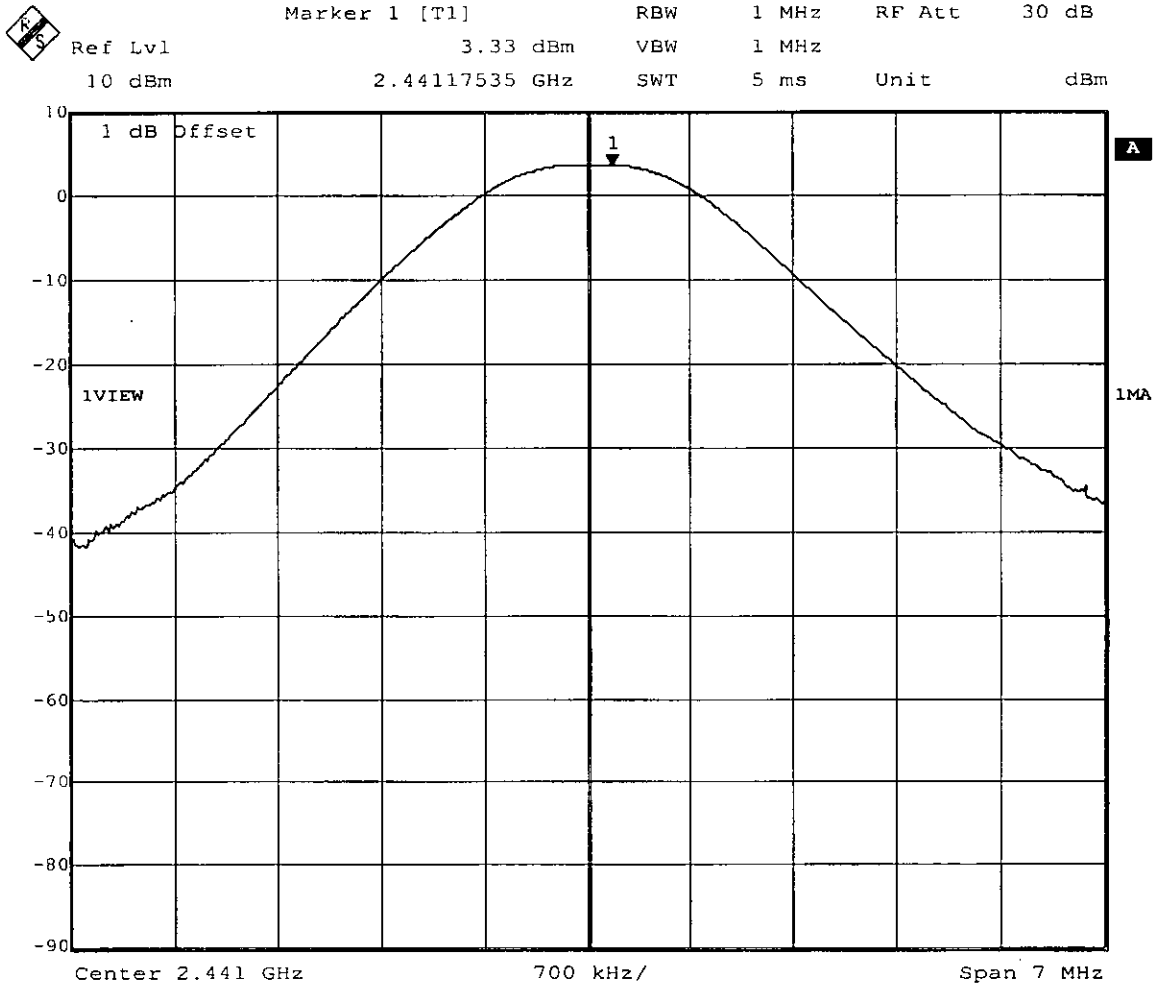


Comment A: Output power=3.42 dBm; verdict: PASS
Date: 10.NOV.2008 14:54:38

Measurement diagram

FCC part 15.247
Peak output power conducted

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(b)
Comment 1	Peak output power
Comment 2	Channel.: 39 / 2441 MHz
Comment 3	

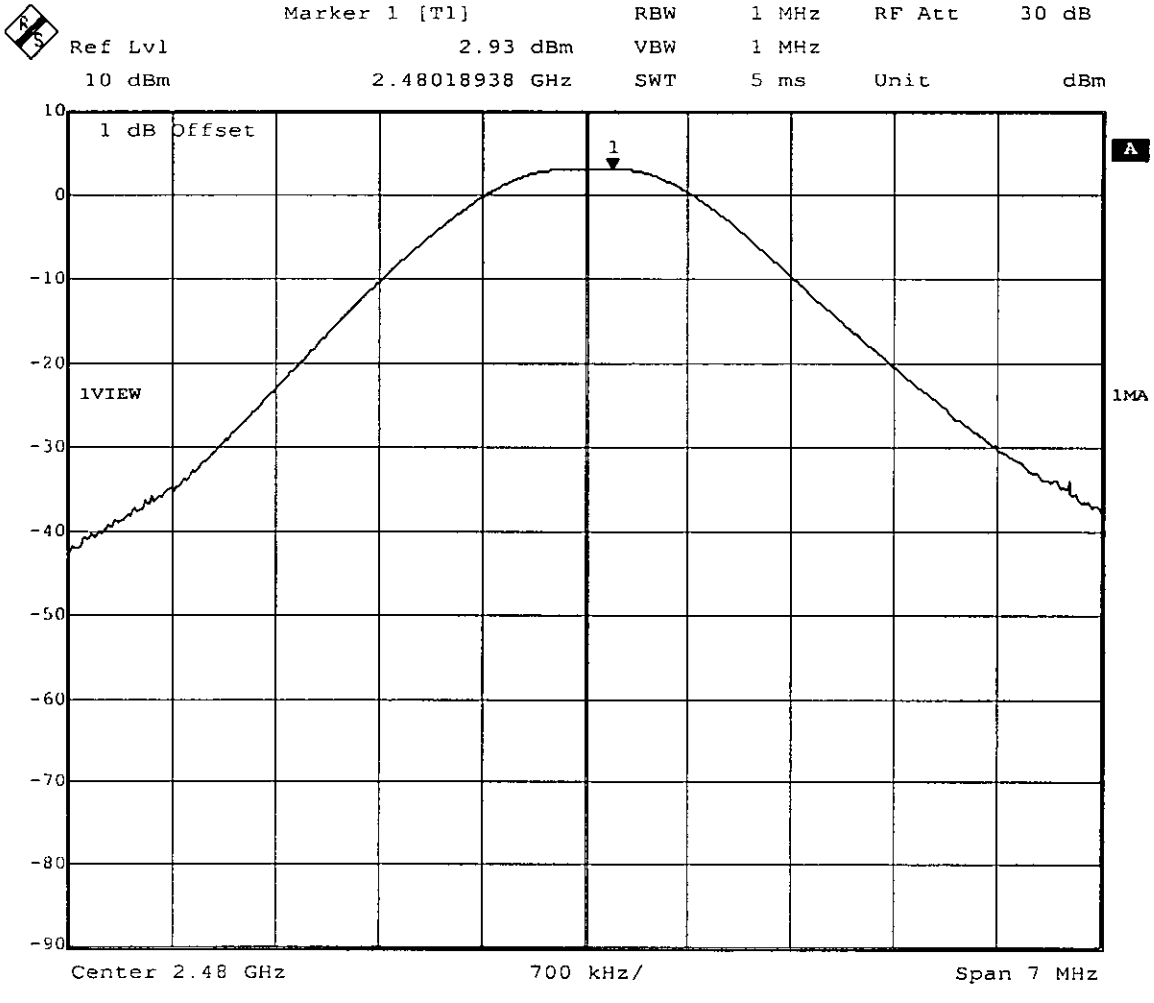


Comment A: Output power=3.33 dBm; verdict: PASS
Date: 10.NOV.2008 14:56:24

Measurement diagram

FCC part 15.247
Peak output power conducted

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(b)
Comment 1	Peak output power
Comment 2	Channel.: 78 / 2480 MHz
Comment 3	



Comment A: Output power=2.93 dBm; verdict: PASS
Date: 10.NOV.2008 14:57:22

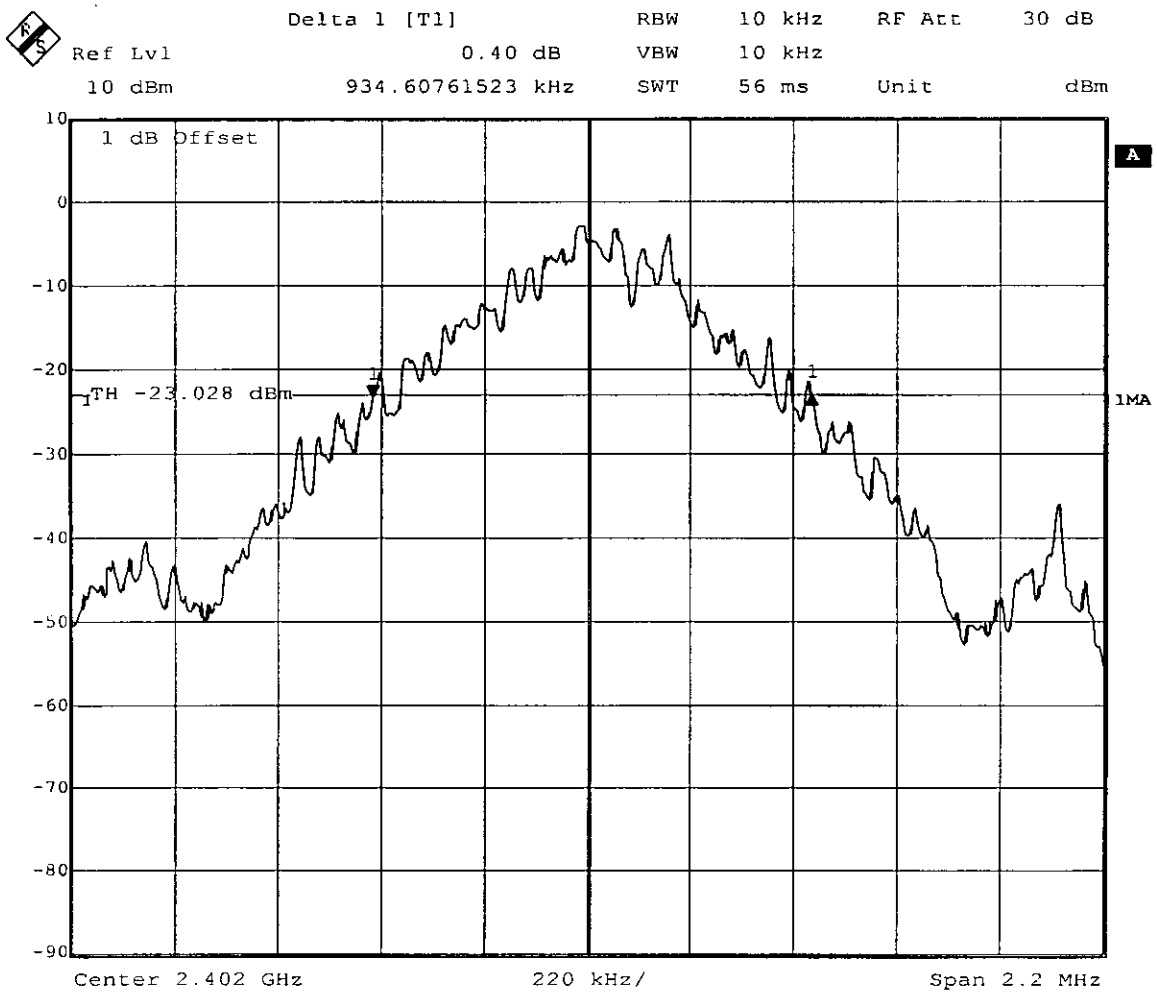
Measurement diagram

Annex C

20 dB bandwidth

FCC part 15.247
20 dB bandwidth

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(a)
Comment 1	20 dB bandwidth
Comment 2	Channel.: 0 / 2402 MHz
Comment 3	

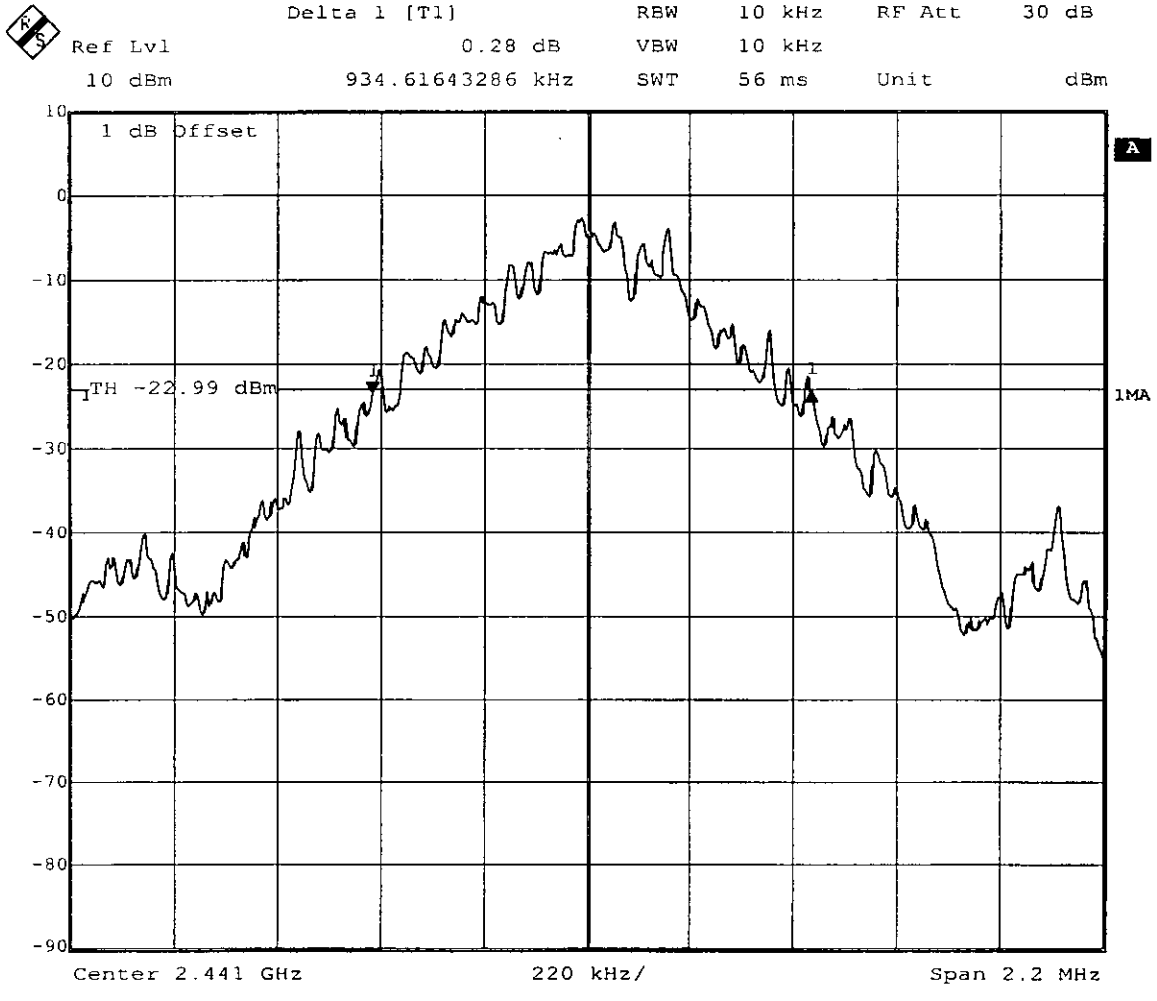


Comment A: 20 dB bandwidth: 934.6 KHz
Date: 10.NOV.2008 14:59:06

Measurement diagram

FCC part 15.247
20 dB bandwidth

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(a)
Comment 1	20 dB bandwidth
Comment 2	Channel.: 39 / 2441 MHz
Comment 3	



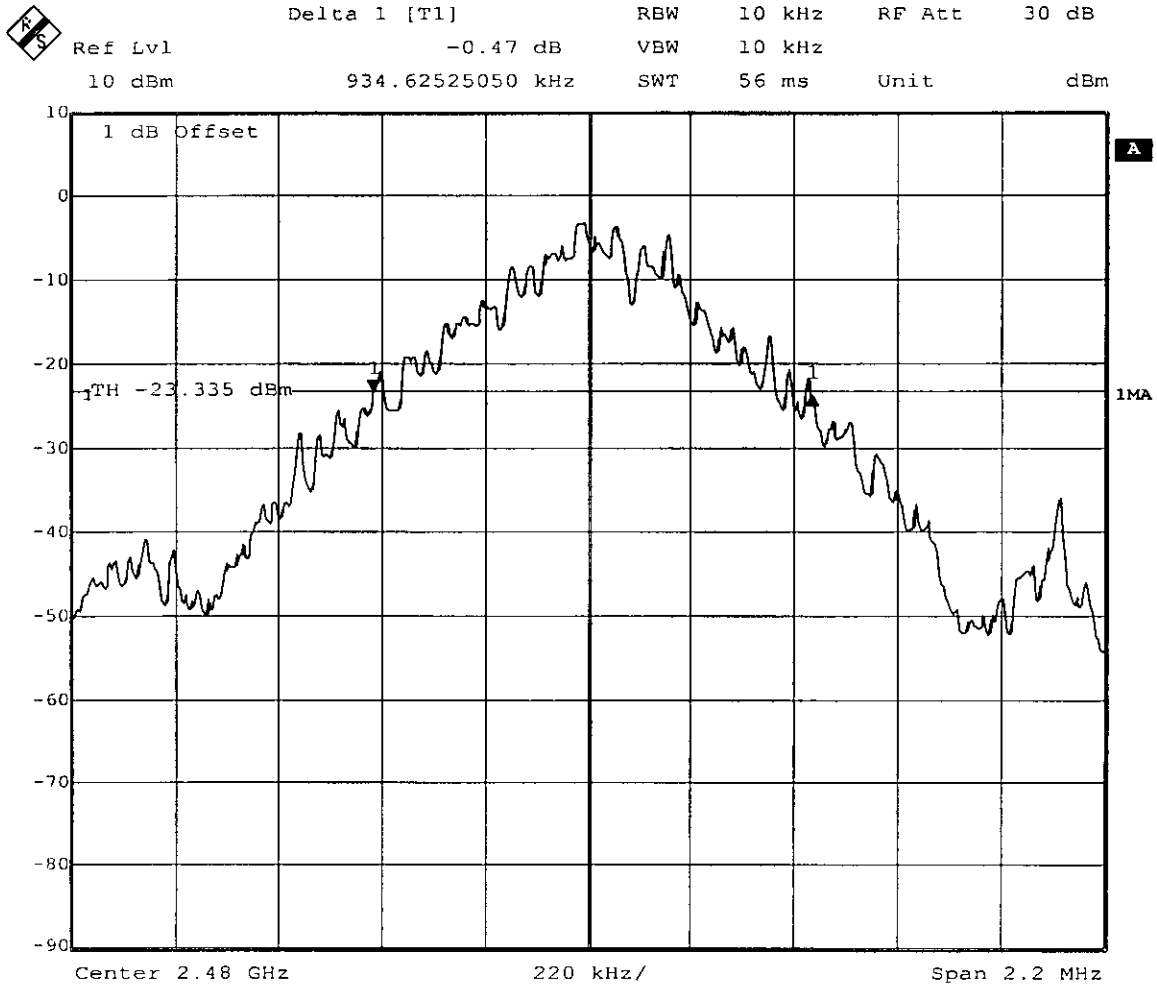
Comment A: 20 dB bandwidth: 934.6 KHz
Date: 10.NOV.2008 15:02:42

Measurement diagram

920

FCC part 15.247
20 dB bandwidth

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(a)
Comment 1	20 dB bandwidth
Comment 2	Channel.: 78 / 2480 MHz
Comment 3	



Comment A: 20 dB bandwidth: 934.6 KHz
Date: 10.NOV.2008 15:04:05

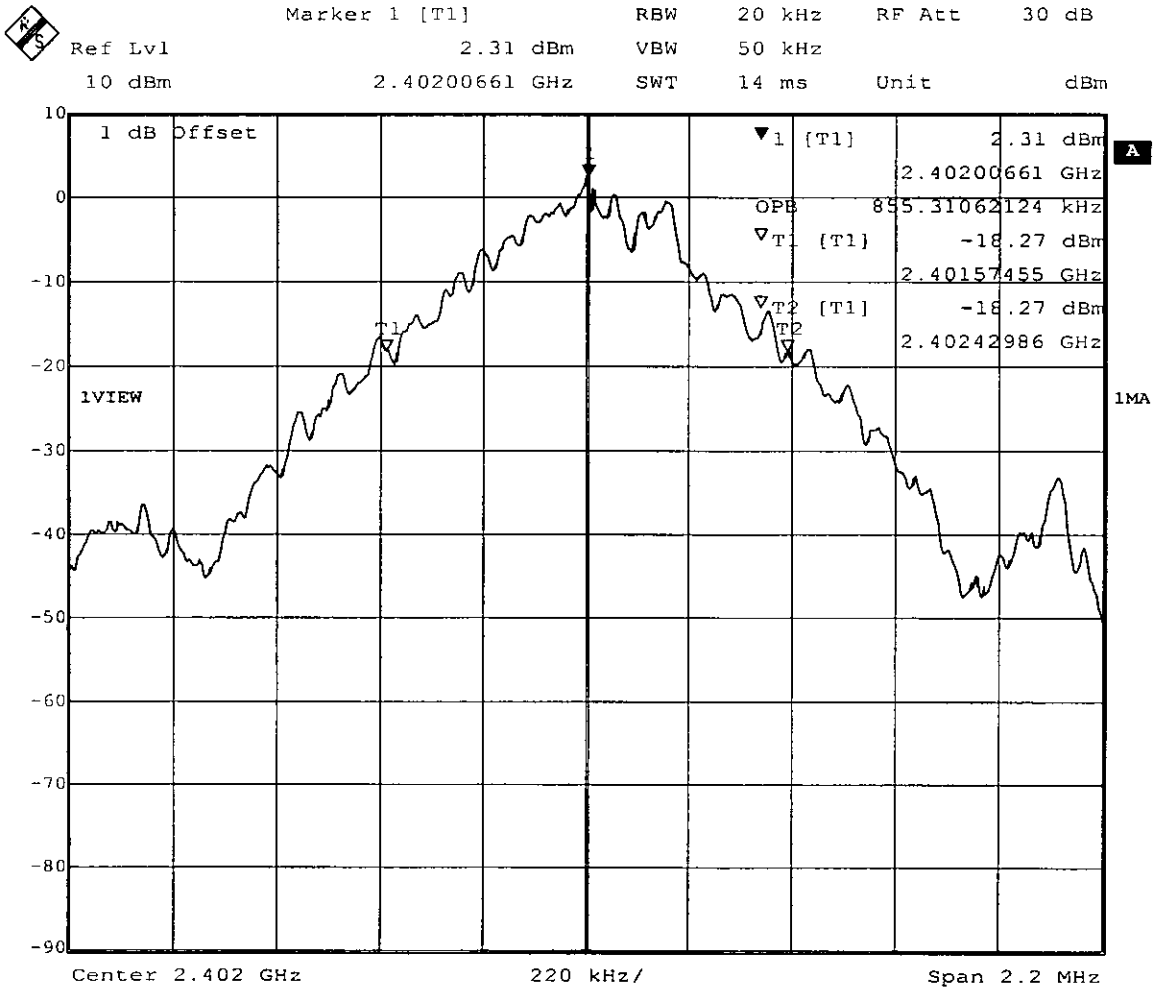
Measurement diagram

eurofins

Eurofins Product Service

RSS Gen
Occupied Bandwidth

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	4.4.1 Occupied Bandwidth
Comment 1	Channel.: 0 / 2402 MHz
Comment 2	A spectrum analyzer with an integrated 99% power bandwidth function is used
Comment 3	

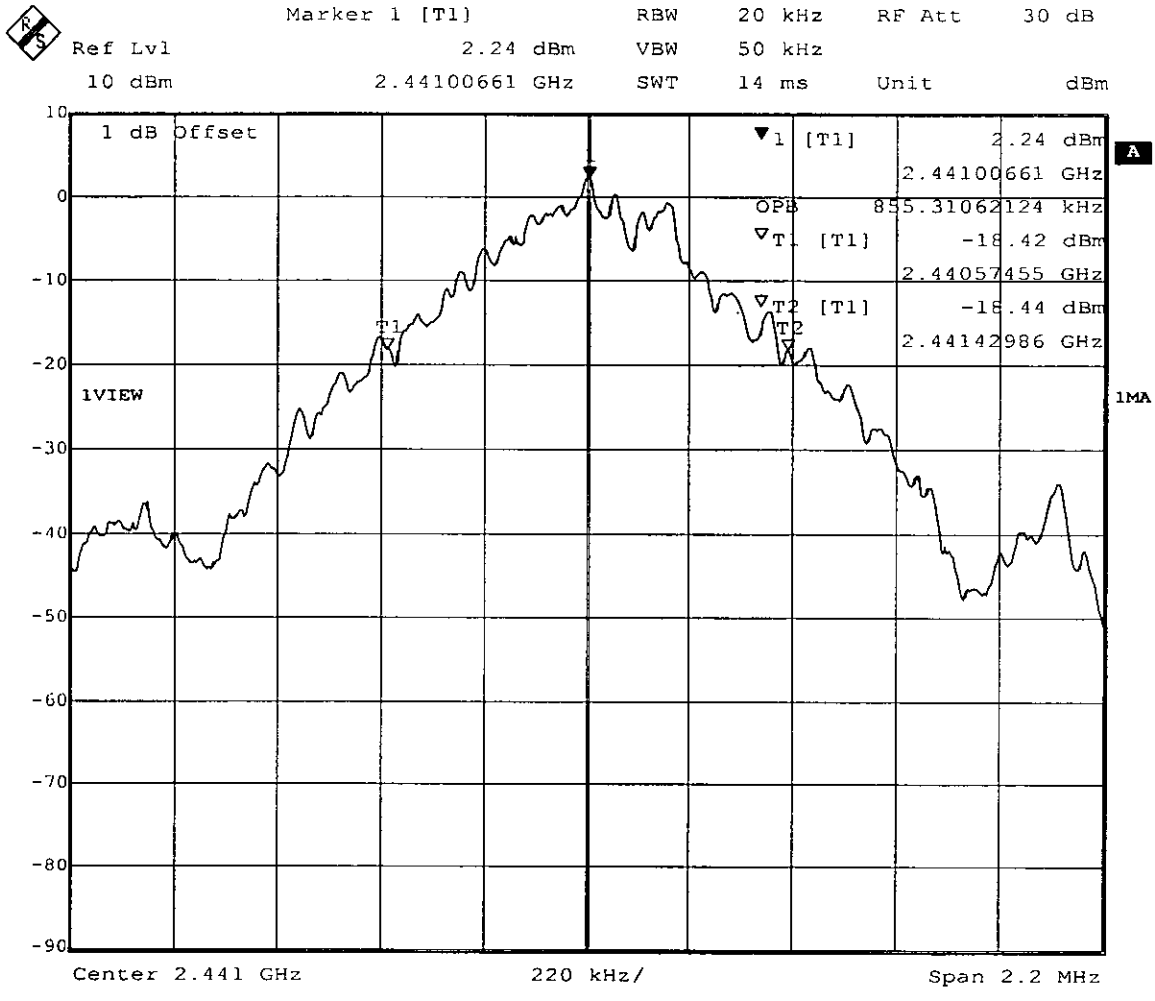


Comment A: Occupied bandwidth: 855.3 KHz
Date: 10.NOV.2008 15:38:52

Measurement diagram

RSS Gen
Occupied Bandwidth

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	4.4.1 Occupied Bandwidth
Comment 1	Channel.: 39 / 2441 MHz
Comment 2	A spectrum analyzer with an integrated 99% power bandwidth function is used
Comment 3	

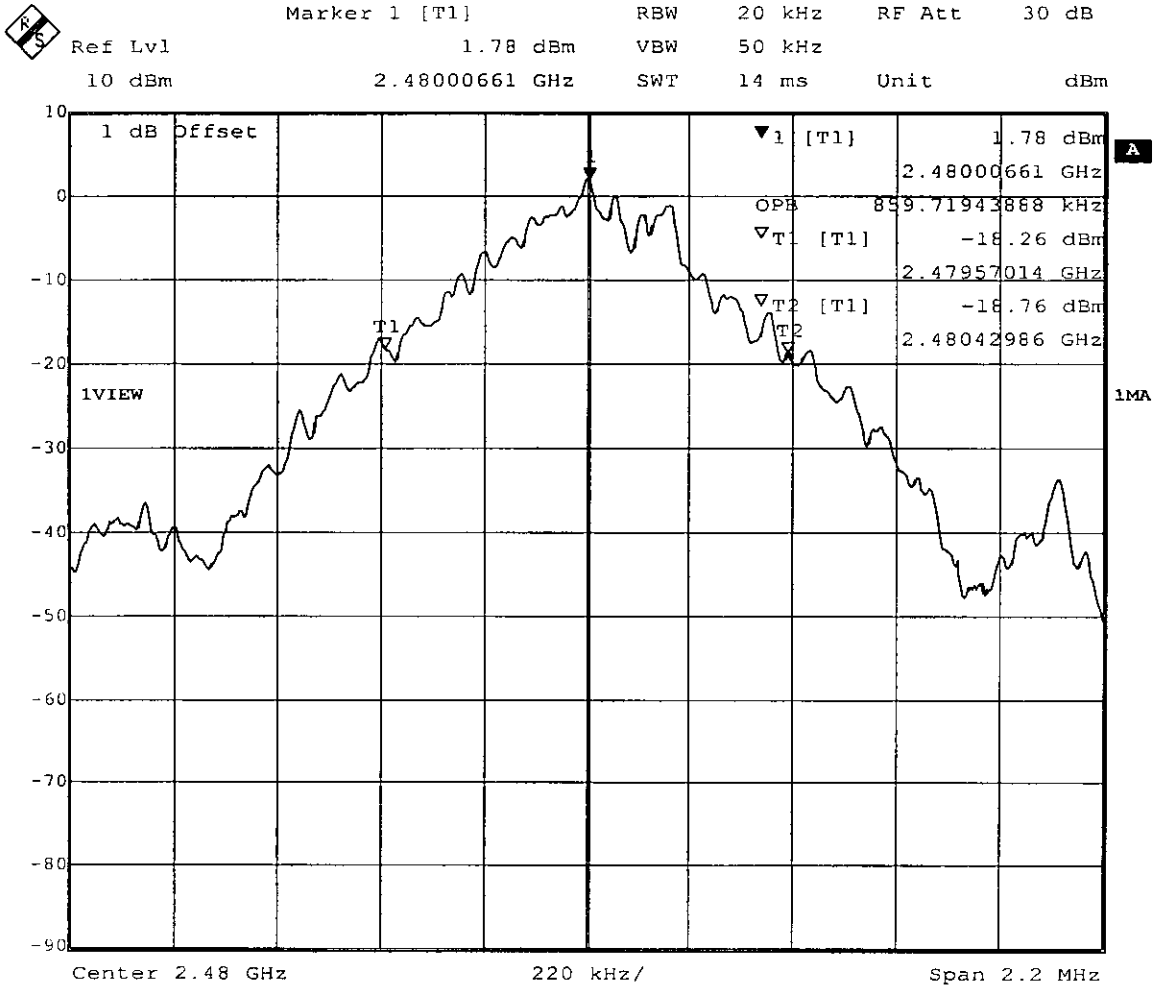


Comment A: Occupied bandwidth: 855.3 KHz
Date: 10.NOV.2008 15:41:04

913

RSS Gen
Occupied Bandwidth

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	4.4.1 Occupied Bandwidth
Comment 1	Channel.: 78 / 2480 MHz
Comment 2	A spectrum analyzer with an integrated 99% power bandwidth function is used
Comment 3	



Comment A: Occupied bandwidth: 859.7 KHz
Date: 10.NOV.2008 15:43:16

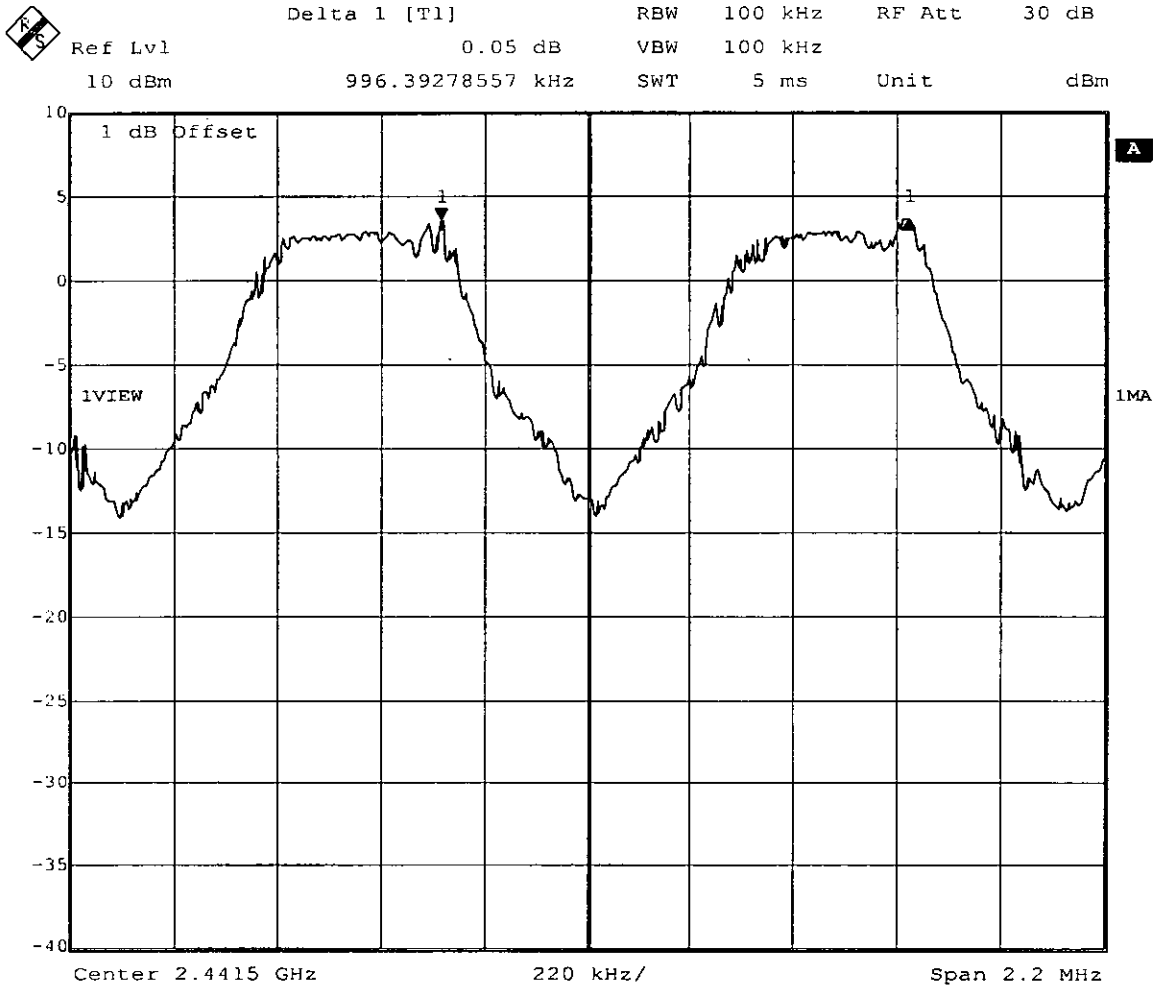
Measurement diagram

Annex D

Time of occupancy (dwell time)

FCC part 15.247
Carrier frequency separation

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(a)(1)
Comment 1	Carrier frequency separation
Comment 2	Channel.: 39/40 / 2441/2442 MHz
Comment 3	Hopping mode

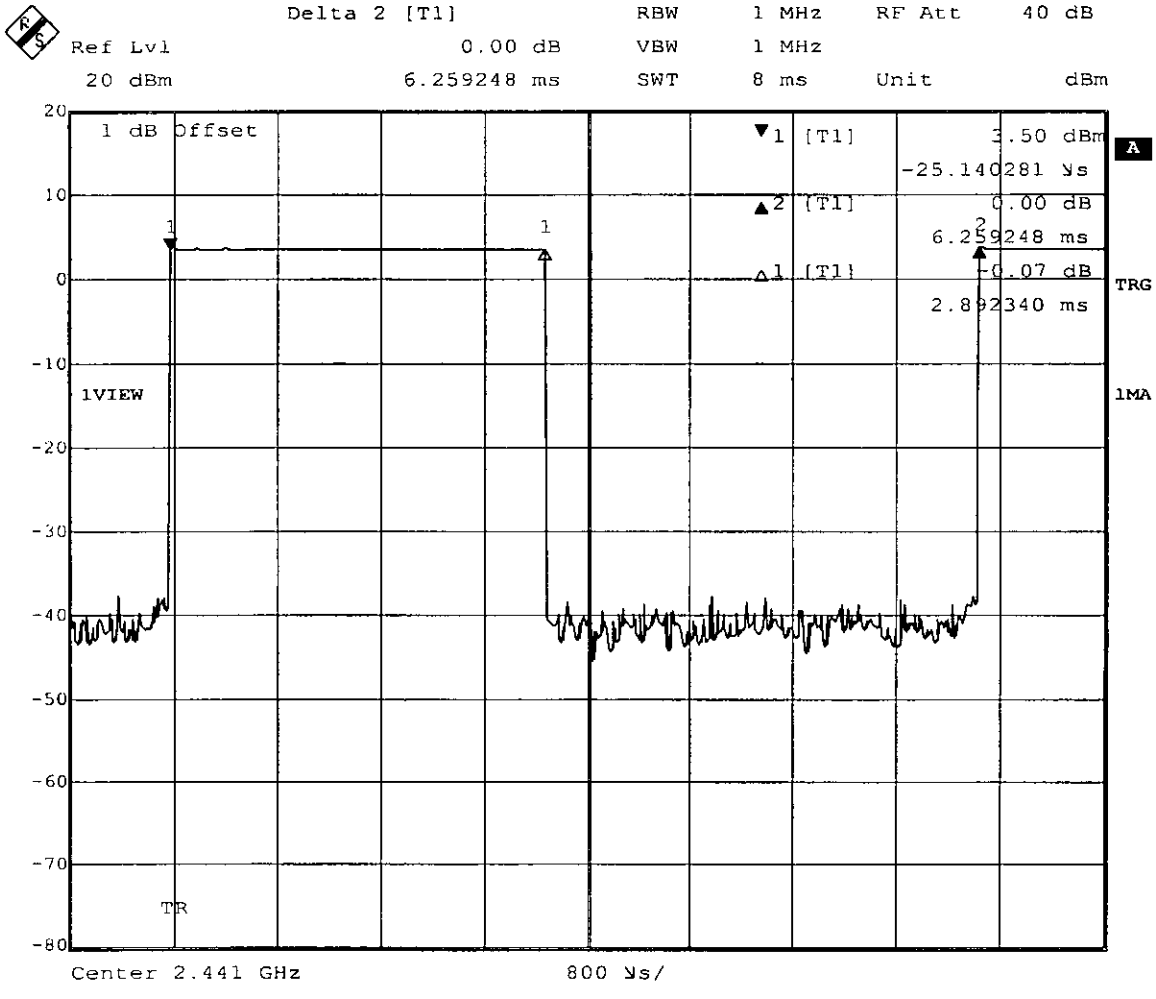


Comment A: Limit: > two-thirds of the 20 dB bandwidth ; Result: Pass
Date: 10.NOV.2008 15:20:05

Measurement diagram

FCC part 15.247
Duty cycle

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(b)
Comment 1	Duty cycle
Comment 2	Channel.: 39 / 2441 MHz
Comment 3	



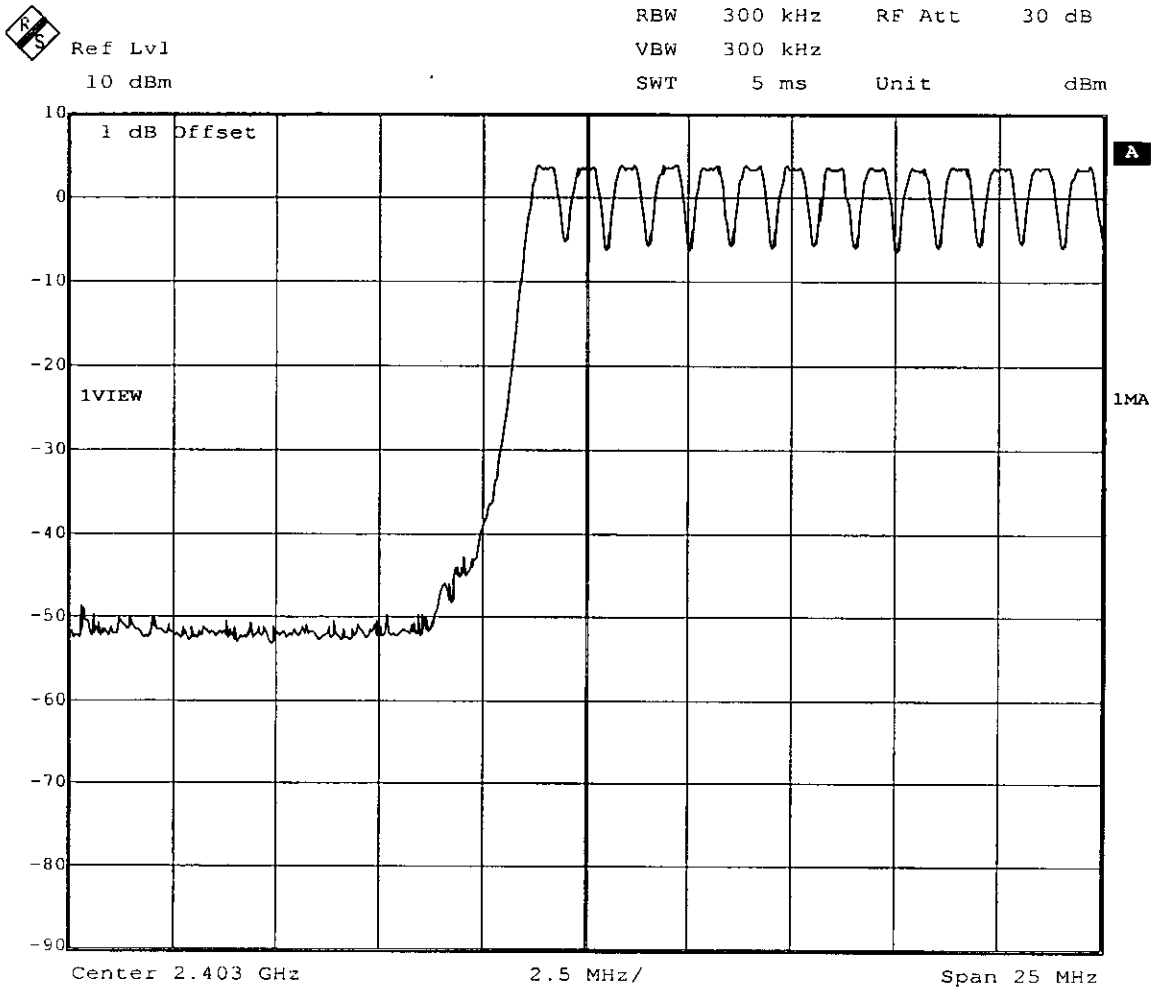
Comment A: Duty cycle=0.46
Date: 10.NOV.2008 15:32:55

Annex E

Number of hopping frequencies

FCC part 15.247
Number of hopping frequencies

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(a)
Comment 1	Number of hopping frequencies
Comment 2	Channel.: 0-13
Comment 3	

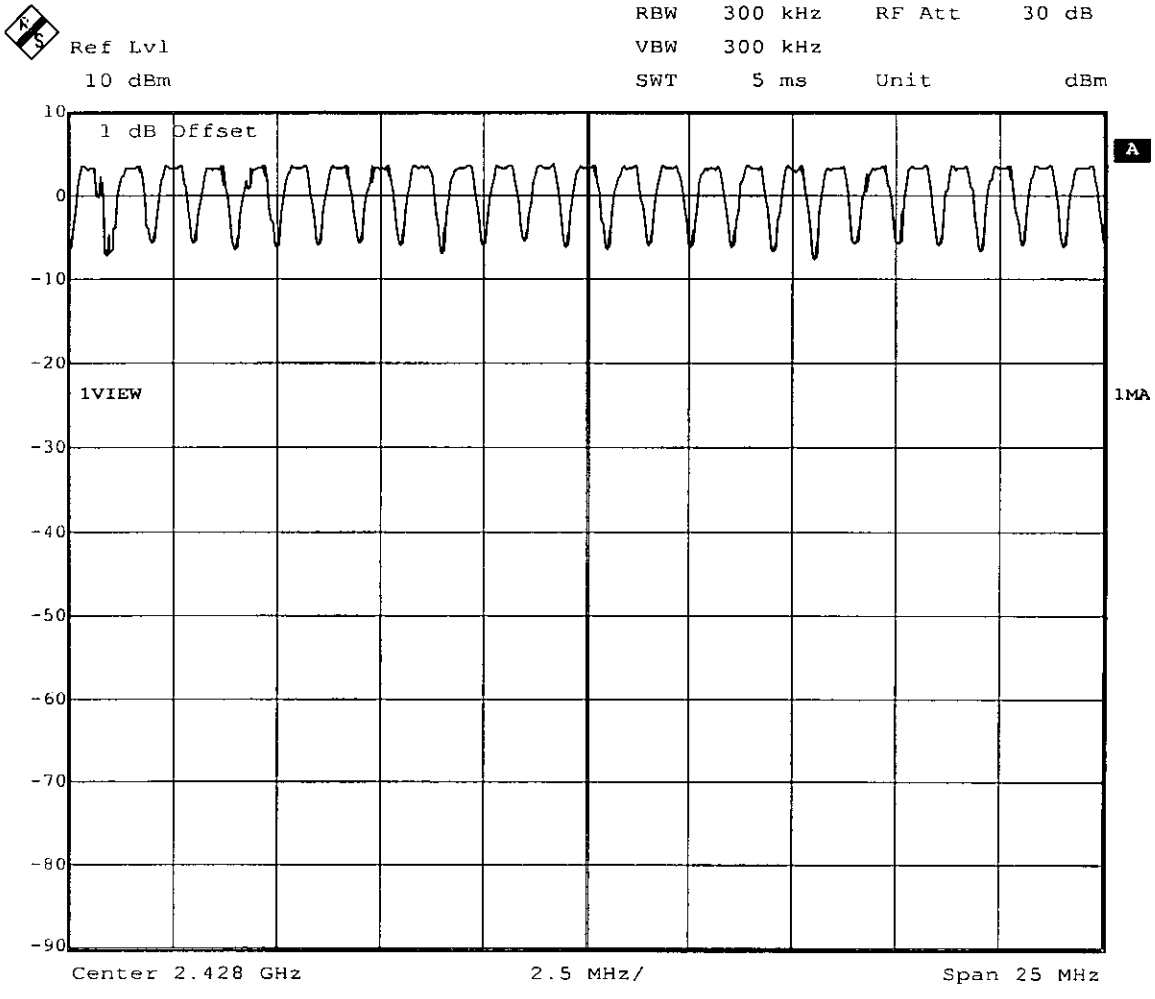


Comment A: Number of hopping frequencies
Date: 10.NOV.2008 15:23:56

Measurement diagram

FCC part 15.247
Number of hopping frequencies

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(a)
Comment 1	Number of hopping frequencies
Comment 2	Channel.: 14-38
Comment 3	

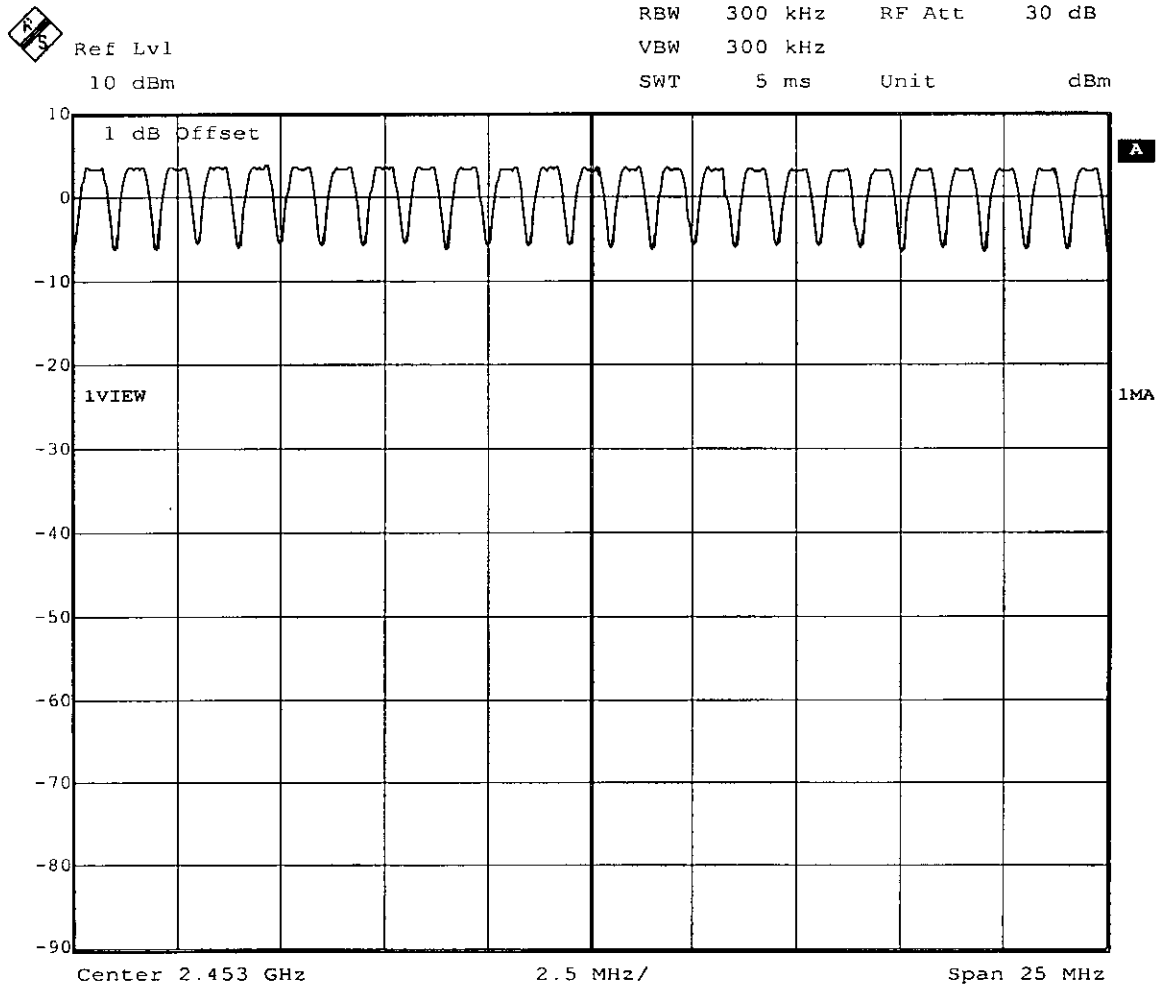


Comment A: Number of hopping frequencies
Date: 10.NOV.2008 15:25:24

Measurement diagram

FCC part 15.247
Number of hopping frequencies

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(a)
Comment 1	Number of hopping frequencies
Comment 2	Channel.:39-63
Comment 3	

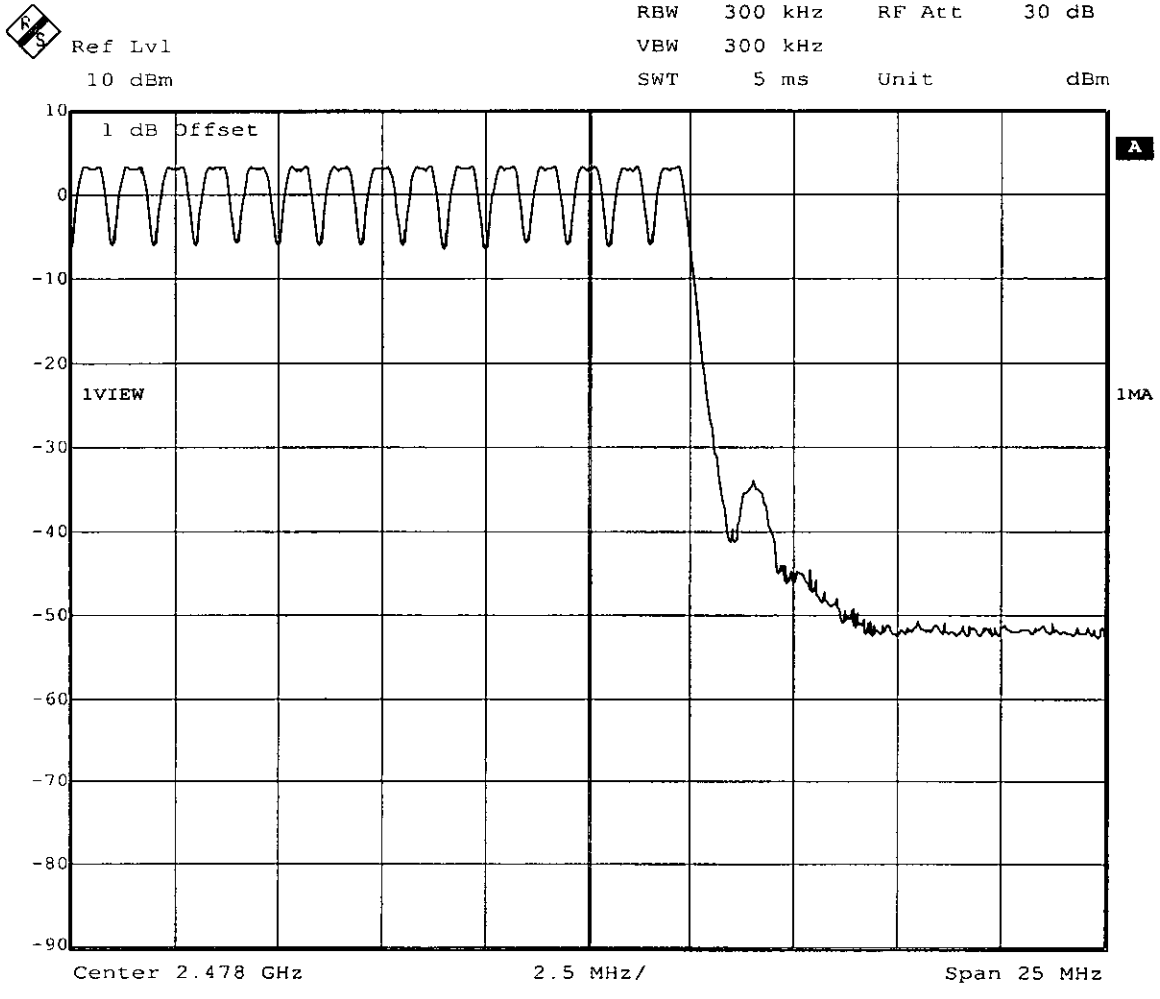


Comment A: Number of hopping frequencies
Date: 10.NOV.2008 15:27:33

Measurement diagram

FCC part 15.247
Number of hopping frequencies

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(a)
Comment 1	Number of hopping frequencies
Comment 2	Channel.: 64-78
Comment 3	



Comment A: Number of hopping frequencies
Date: 10.NOV.2008 15:30:26

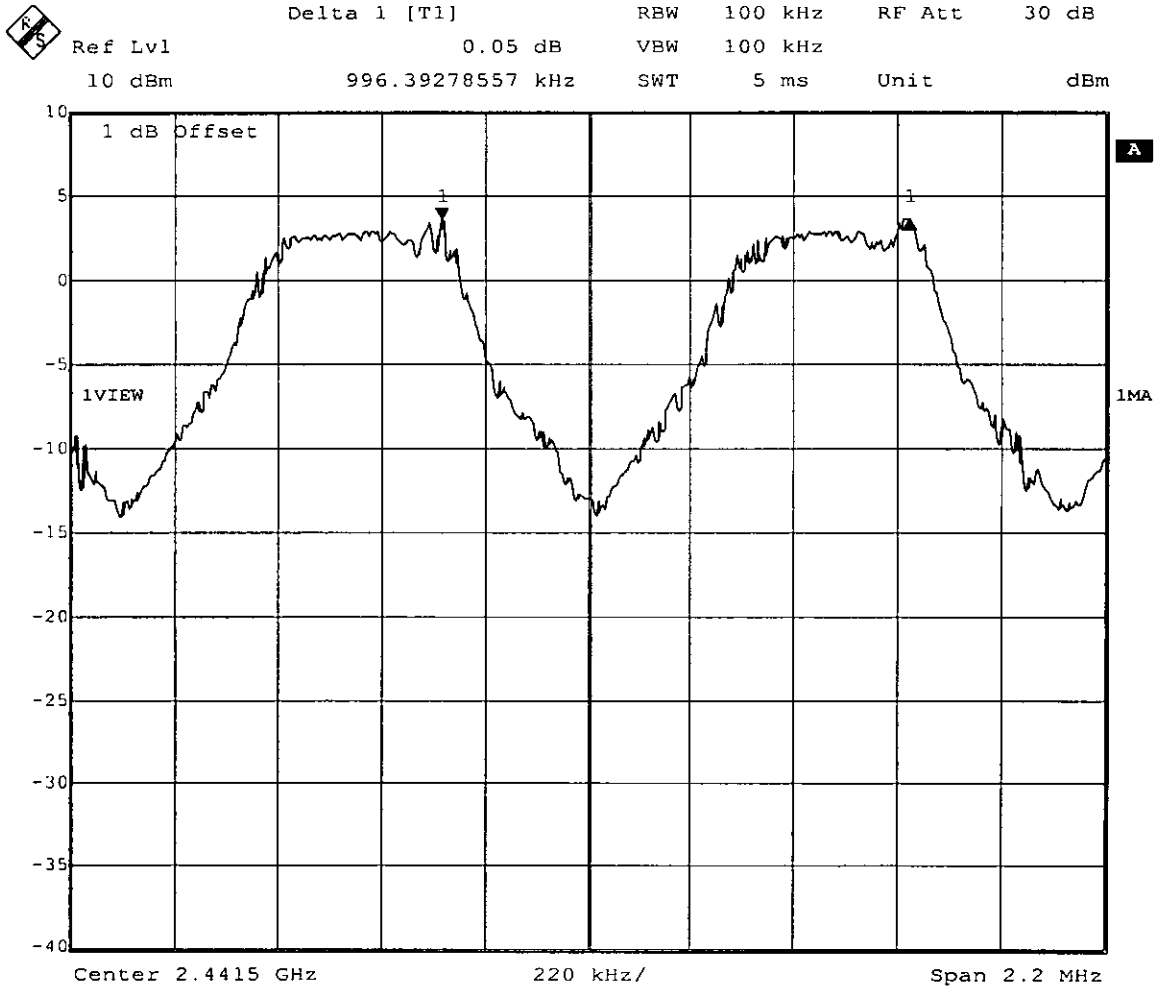
Measurement diagram

Annex F

Carrier frequency separation

FCC part 15.247
Carrier frequency separation

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(a)(1)
Comment 1	Carrier frequency separation
Comment 2	Channel.: 39/40 / 2441/2442 MHz
Comment 3	Hopping mode



Comment A: Limit: > two-thirds of the 20 dB bandwidth ; Result: Pass
Date: 10.NOV.2008 15:20:05

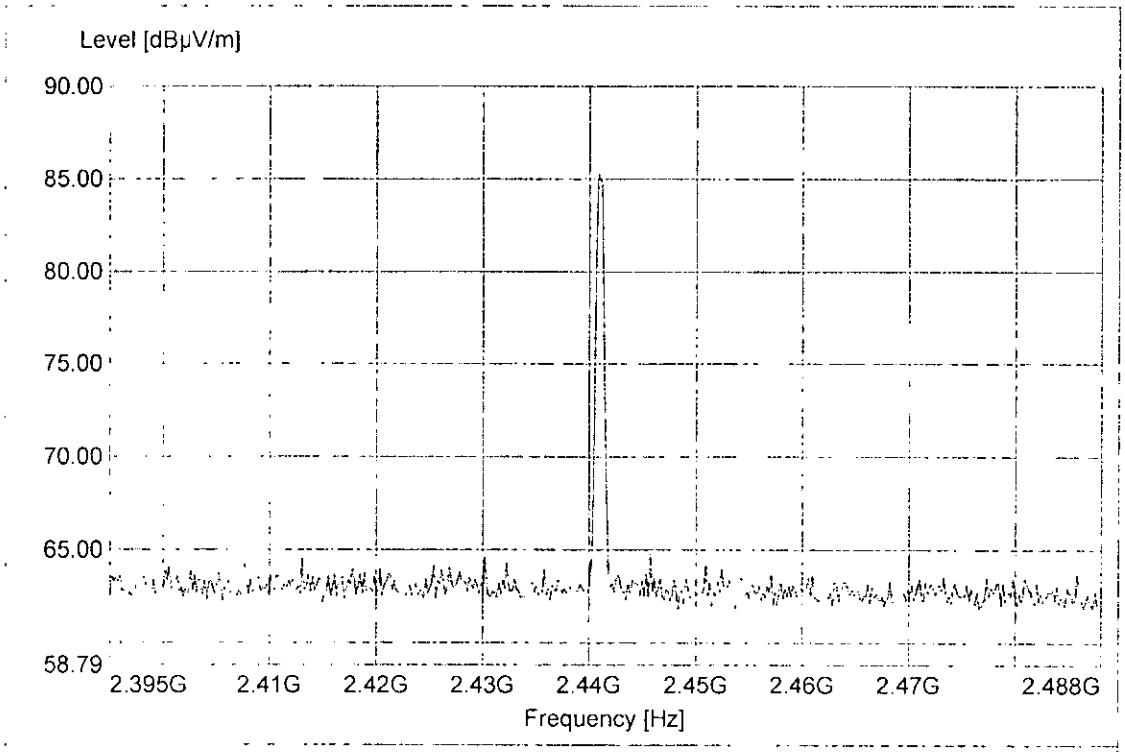
Measurement diagram

Annex G

Spurious emission radiated

Carrier power (Field Strength)
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247
Comment 1:	Dist.: 3m, Ant.: BBHA9120D
Comment 2:	Freq: 2.441GHz, Emax: 85.33dBµV/m, RBW: 100kHz

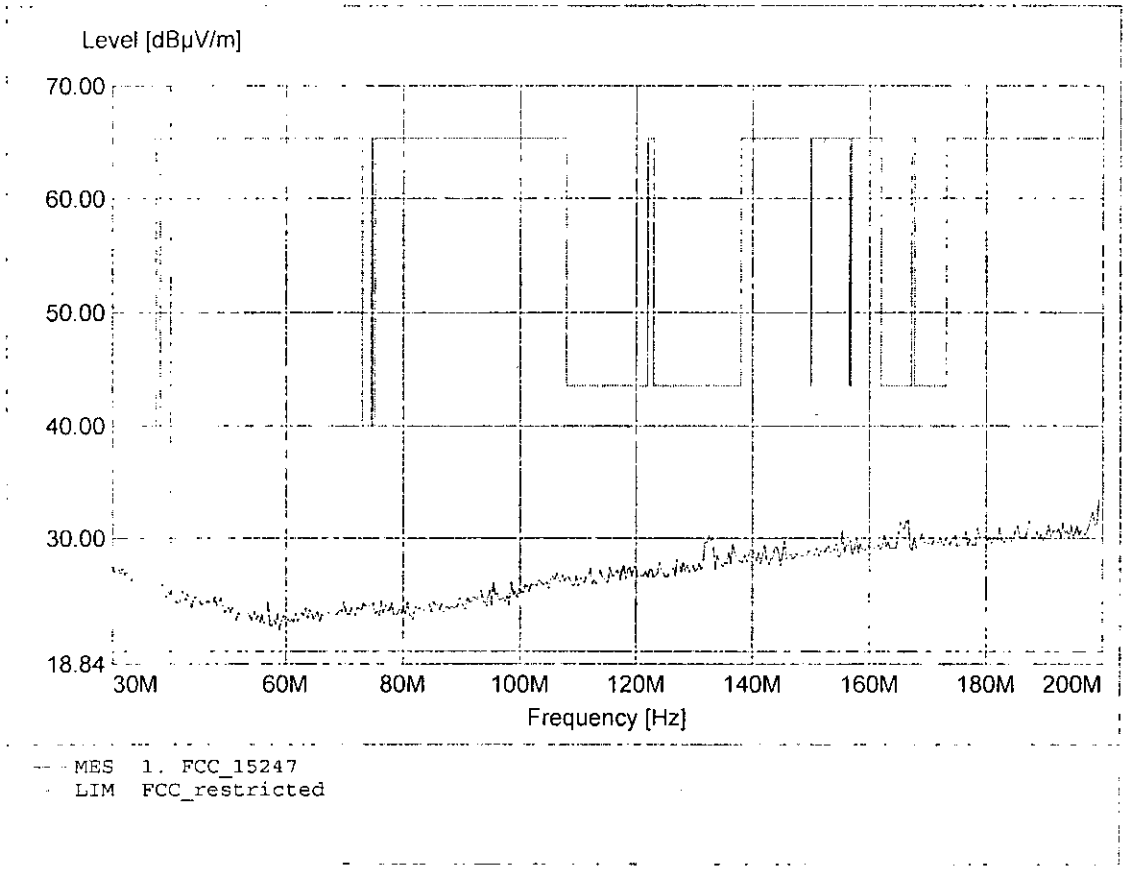


MES 8. FCC_15247_harm
LIM FCC_Tx

Page 1/1 11.11.08 15:36 Overview / Antenna horizontal

Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

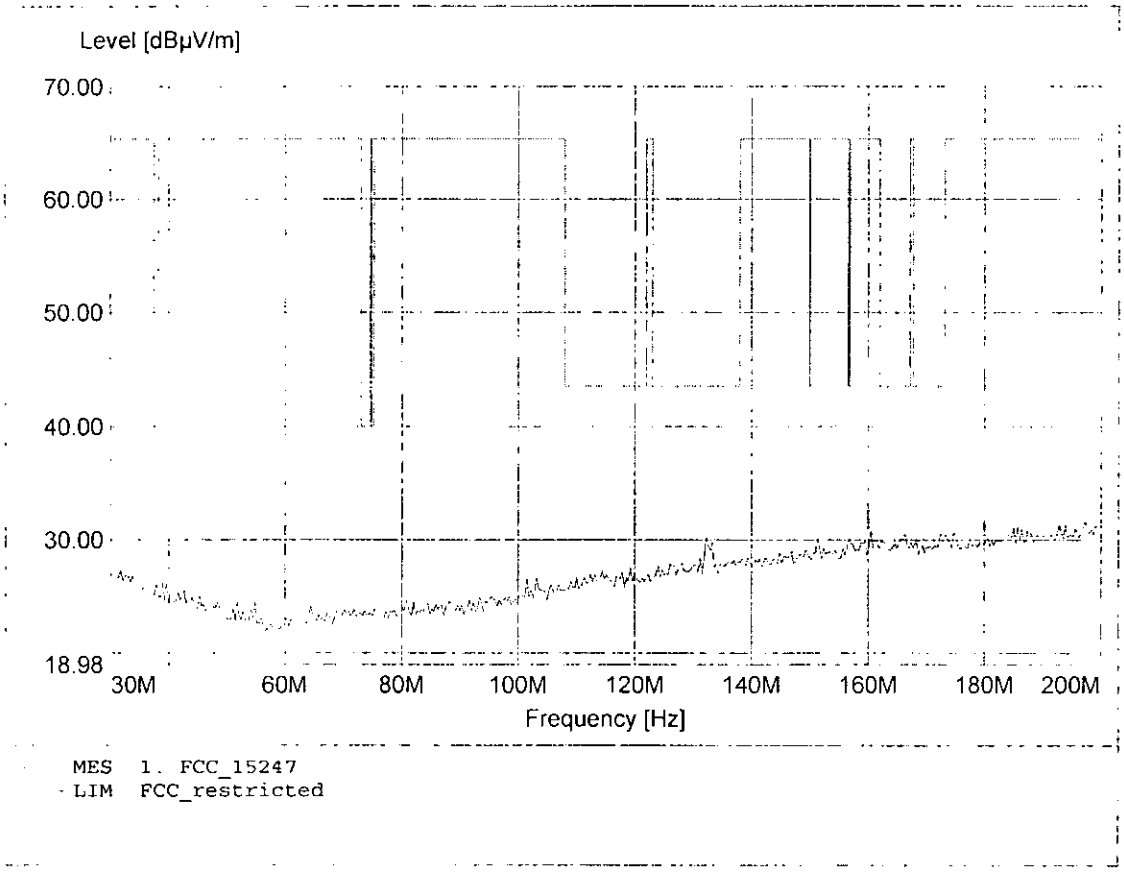
Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247
Comment 1:	Dist.: 3m, Ant.: HK 116
Comment 2:	Freq: 199.319MHz, Emax: 33.53dBµV/m, RBW: 100kHz



Page 1/1 12.11.08 12:50 Overview / Antenna vertical

Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

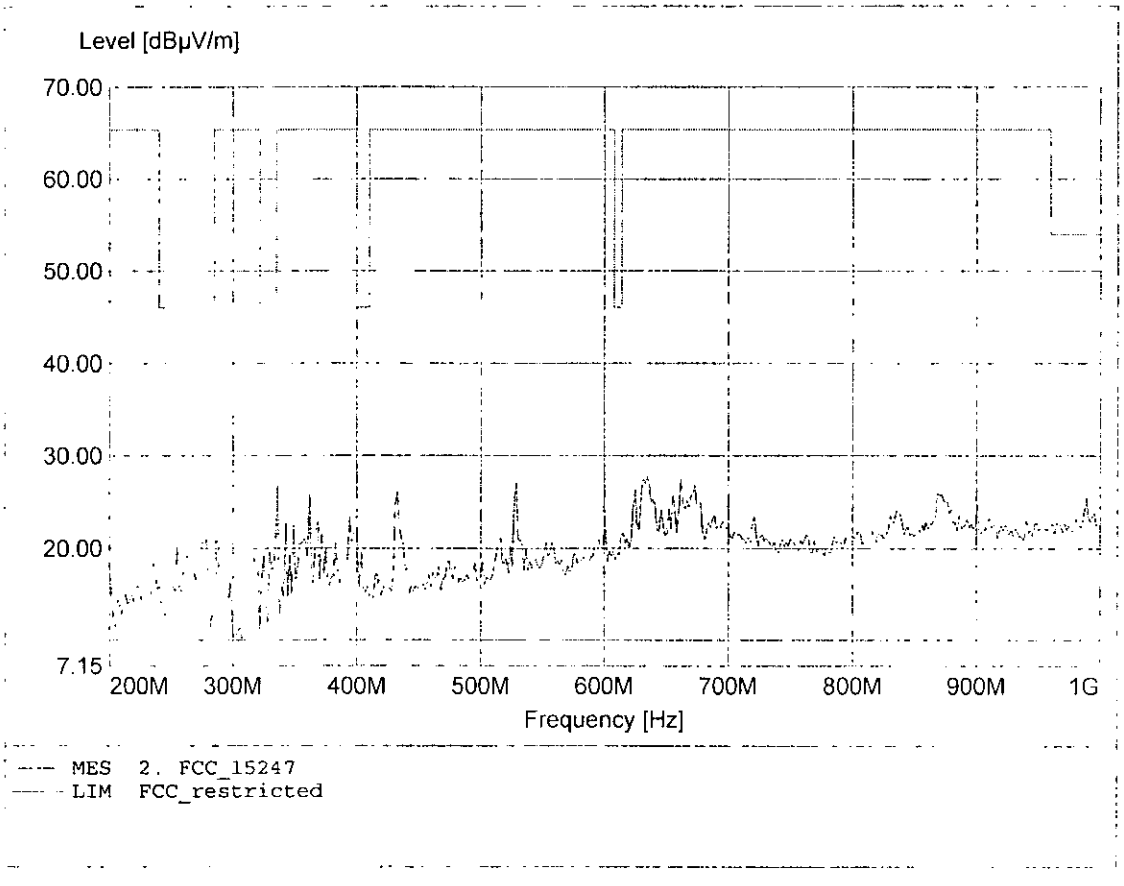
Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247
Comment 1:	Dist.: 3m, Ant.: HK 116
Comment 2:	Freq: 197.275MHz, Emax: 31.60dBµV/m, RBW: 100kHz



Page 1/1 12.11.08 12:52 Overview / Antenna horizontal

Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

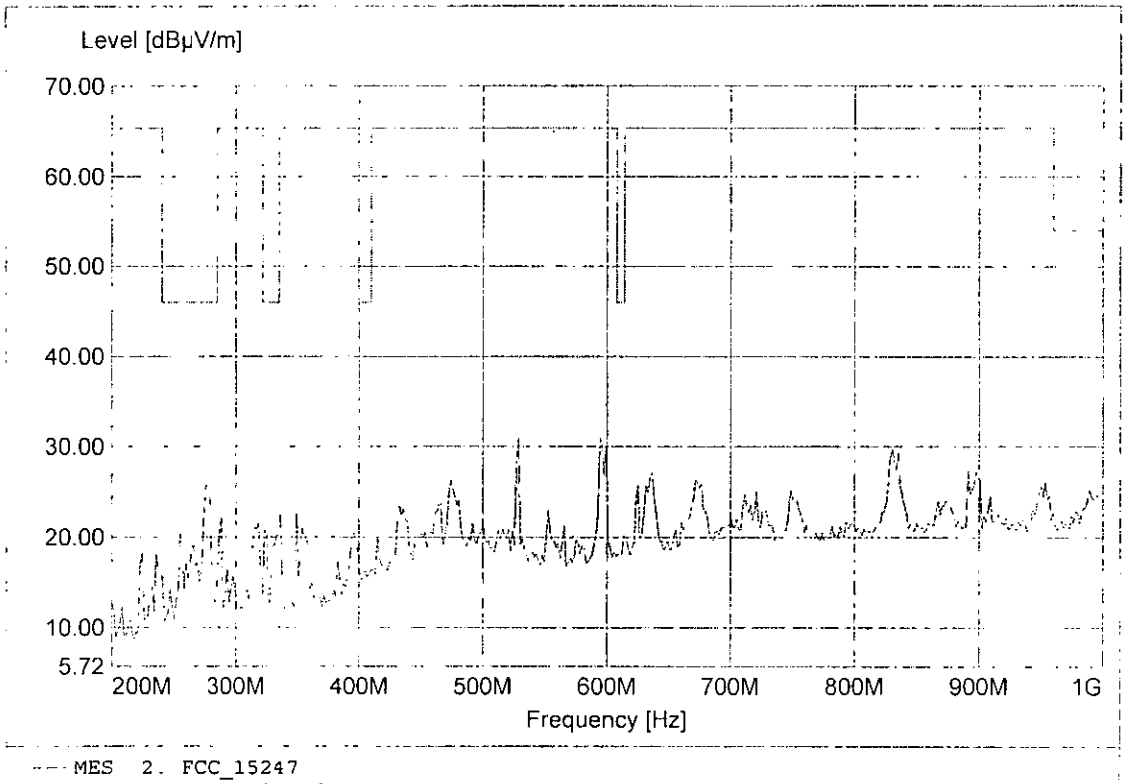
Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247
Comment 1:	Dist.: 3m, Ant.: HL 223, amplif.
Comment 2:	Freq: 634.469MHz, Emax: 27.79dBµV/m, RBW: 100kHz



Page 1/1 12.11.08 11:58 Overview / Antenna vertical

Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247
Comment 1:	Dist.: 3m, Ant.: HL 223, amplif.
Comment 2:	Freq: 528.657MHz, Emax: 31.06dBµV/m, RBW: 100kHz

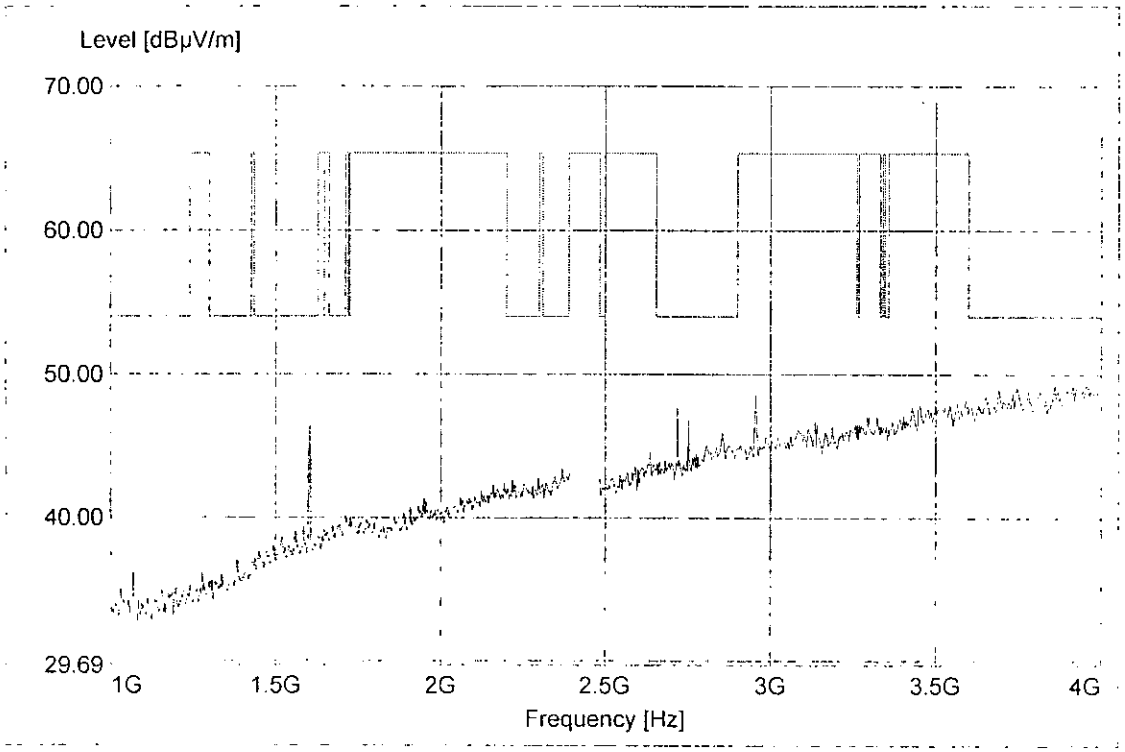


--- MES 2. FCC_15247
--- LIM FCC_restricted

Page 1/1 12.11.08 12:01 Overview / Antenna horizontal

Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: BBHA9120D, amplif.
Comment 2:	Freq: 3.860GHz, Emax: 49.34dBµV/m, RBW: 1MHz



MES 3. FCC_15247
LIM FCC_restricted

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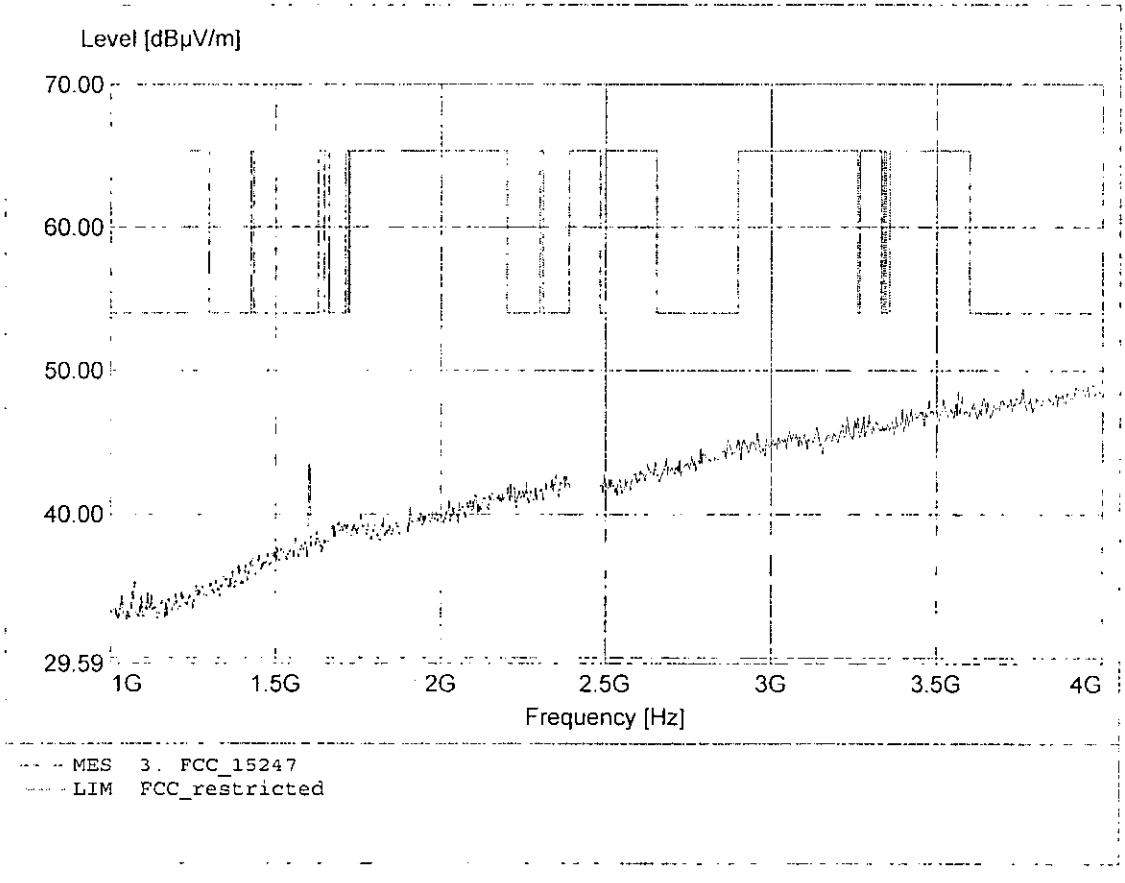
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

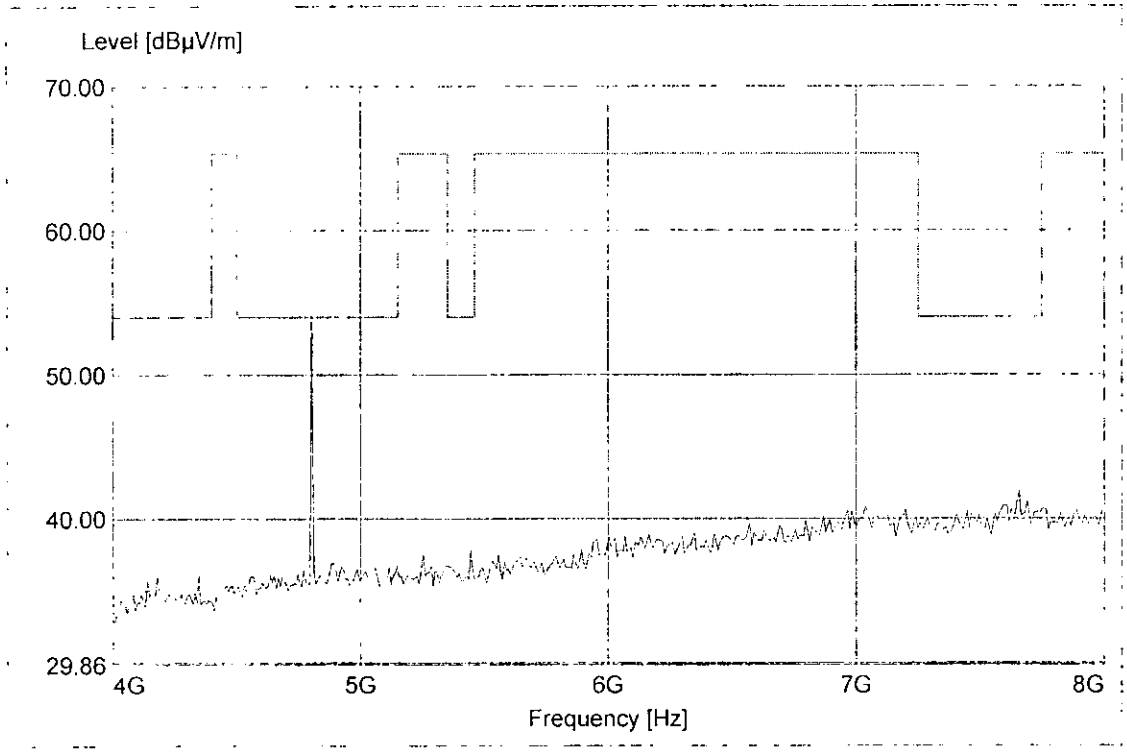
Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, amplif.
Comment 2:	Freq: 3.970GHz, Emax: 49.05dBµV/m, RBW: 1MHz



Page 1/1 12.11.08 08:51 Overview / Antenna horizontal

Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 4.802GHz, Emax: 54.24dBµV/m, RBW: 1MHz



MES 4. FCC_15247
LIM FCC_restricted

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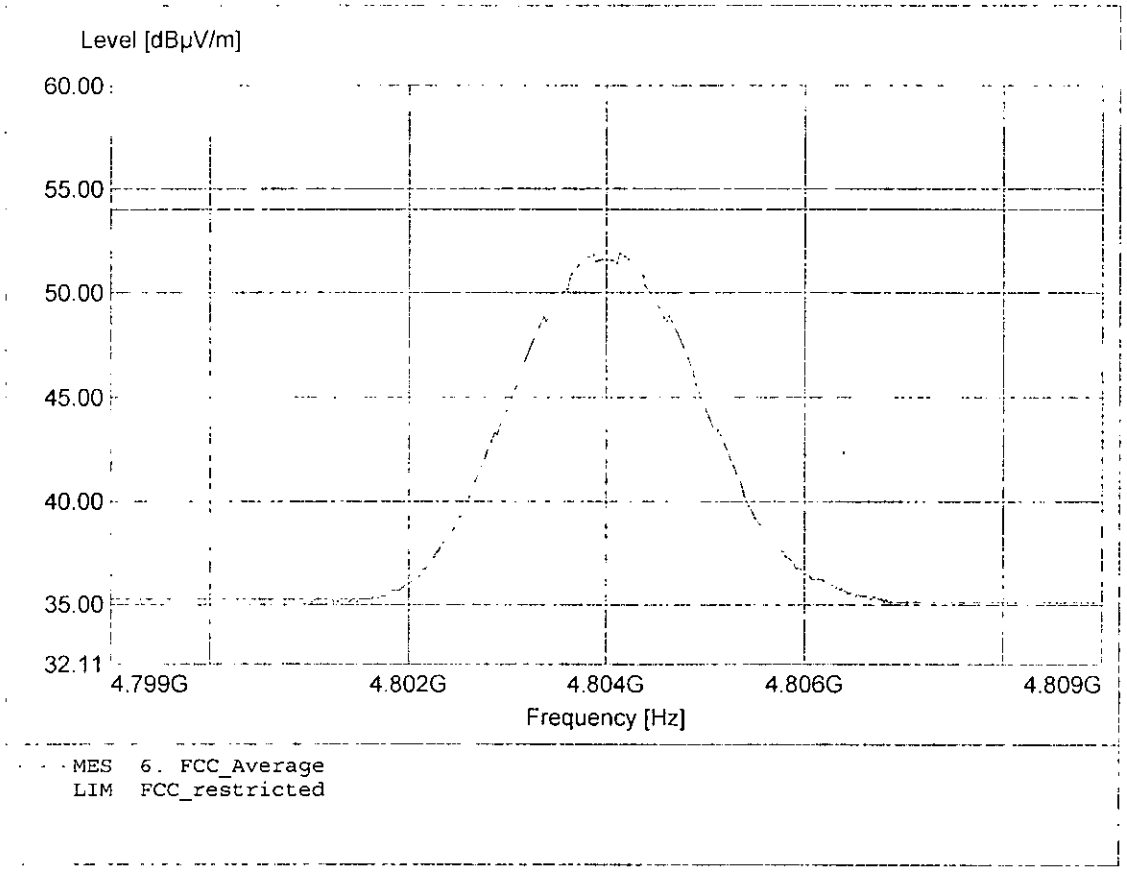
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

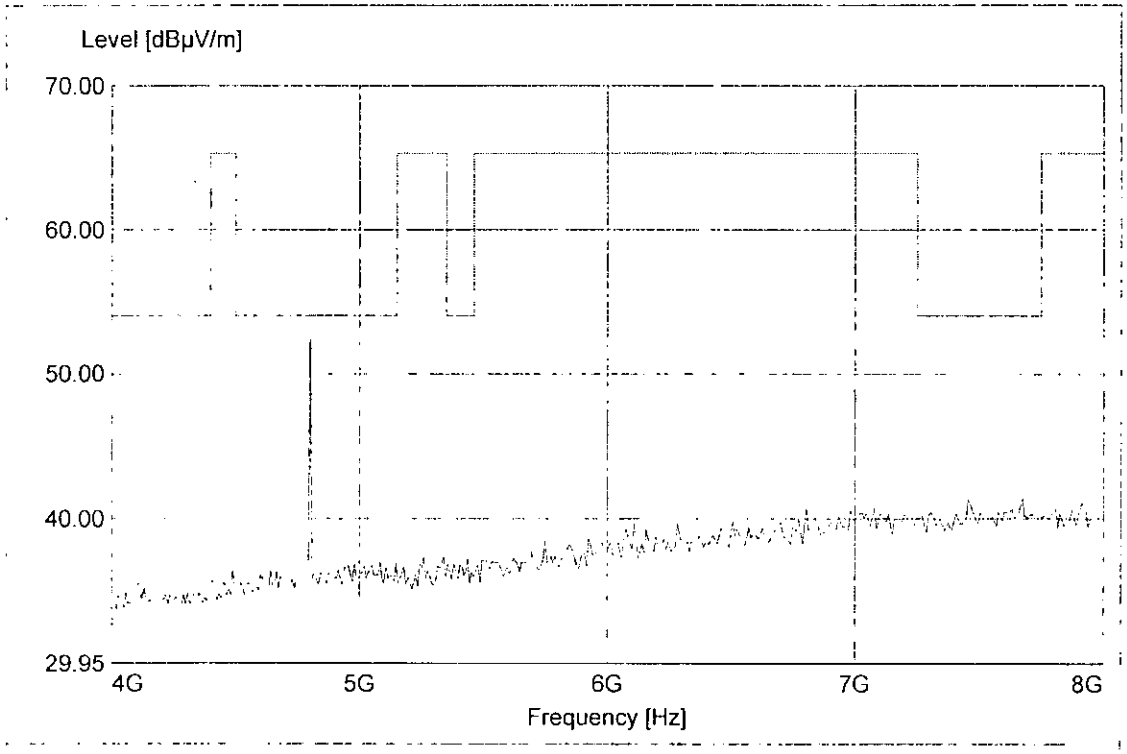
Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, average detector
Comment 1:	Dist.: 3m, Ant.: HL025, ampl.+HP.
Comment 2:	Freq: 4.804GHz, Emax: 51.89dBµV/m, RBW: 1MHz



Page 1/1 12.11.08 08:28 Overview / Antenna vertical

Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 4.802GHz, Emax: 53.61dBµV/m, RBW: 1MHz

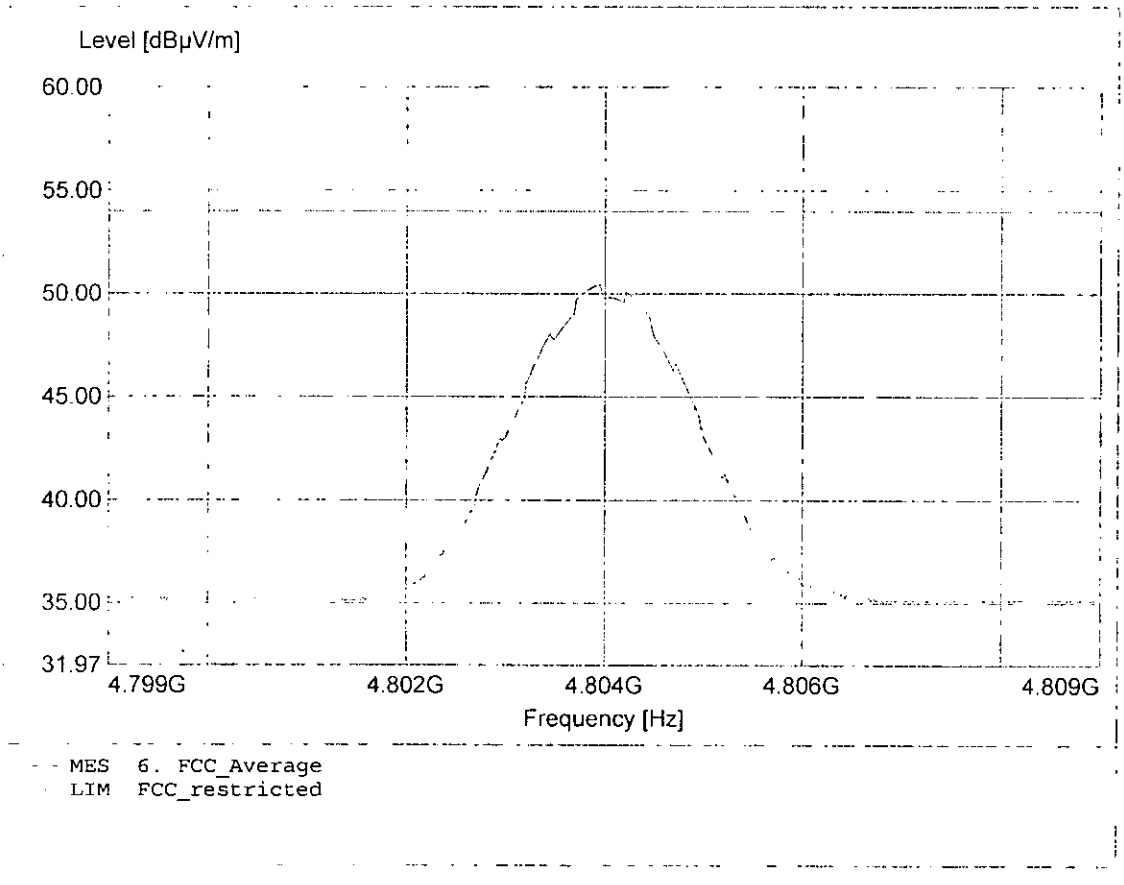


MES 4. FCC_15247
LIM FCC_restricted

Page 1/1 12.11.08 08:55 Overview / Antenna horizontal

Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, average detector
Comment 1:	Dist.: 3m, Ant.: HL025, ampl.+HP.
Comment 2:	Freq: 4.804GHz, Emax: 50.45dBµV/m, RBW: 1MHz



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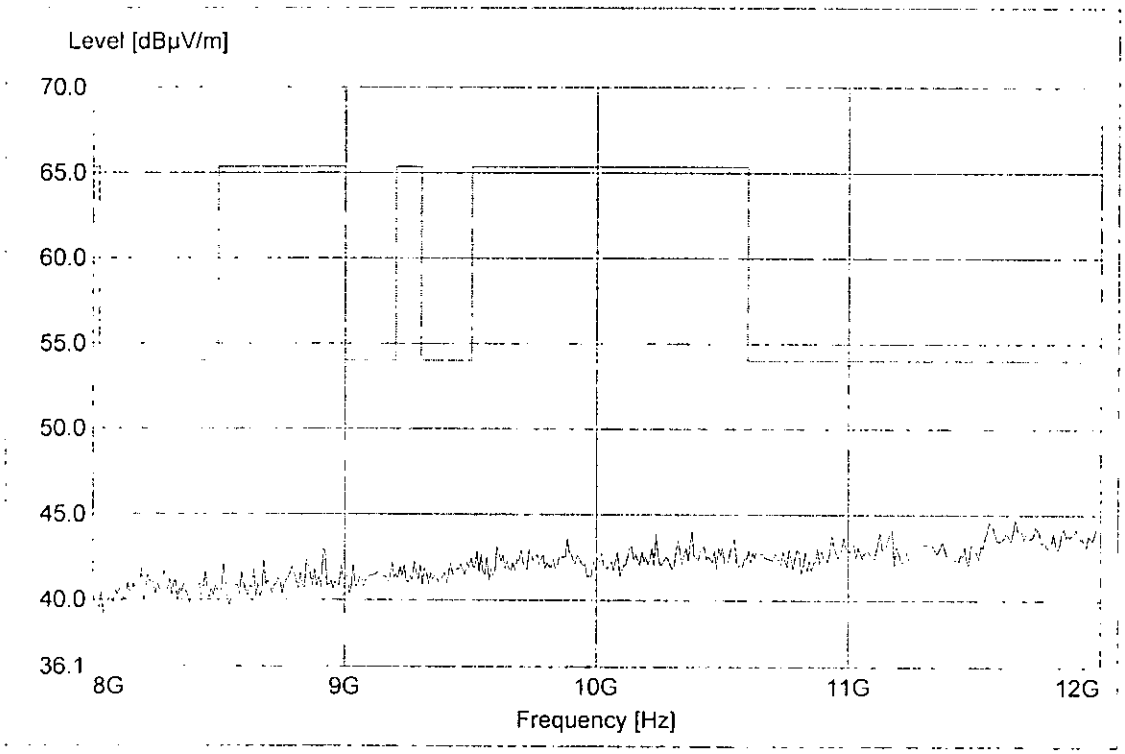
a46

Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5.V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 11.663GHz, Emax: 44.71dBµV/m, RBW: 1MHz

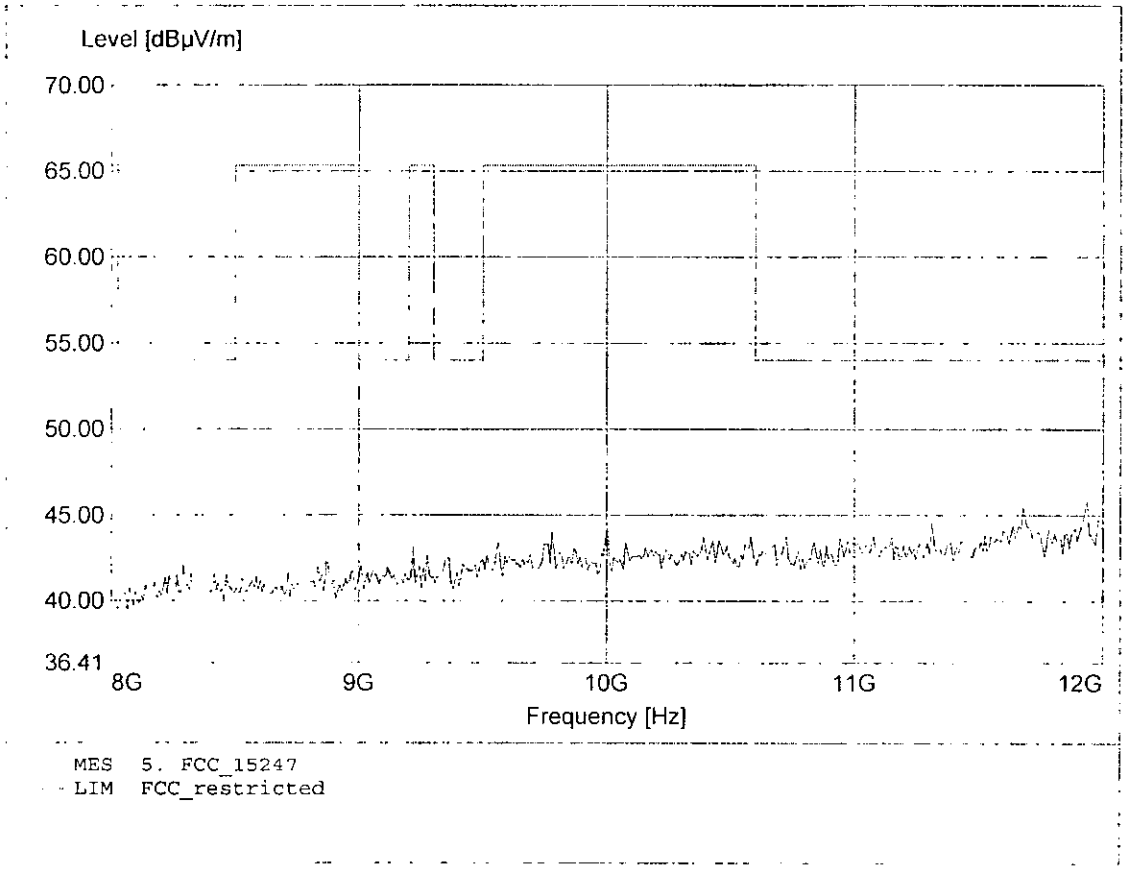


MES 5. FCC_15247
LIM FCC_restricted

Page 1/1 12.11.08 08:32 Overview / Antenna vertical

Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 11.936GHz, Emax: 45.86dBµV/m, RBW: 1MHz



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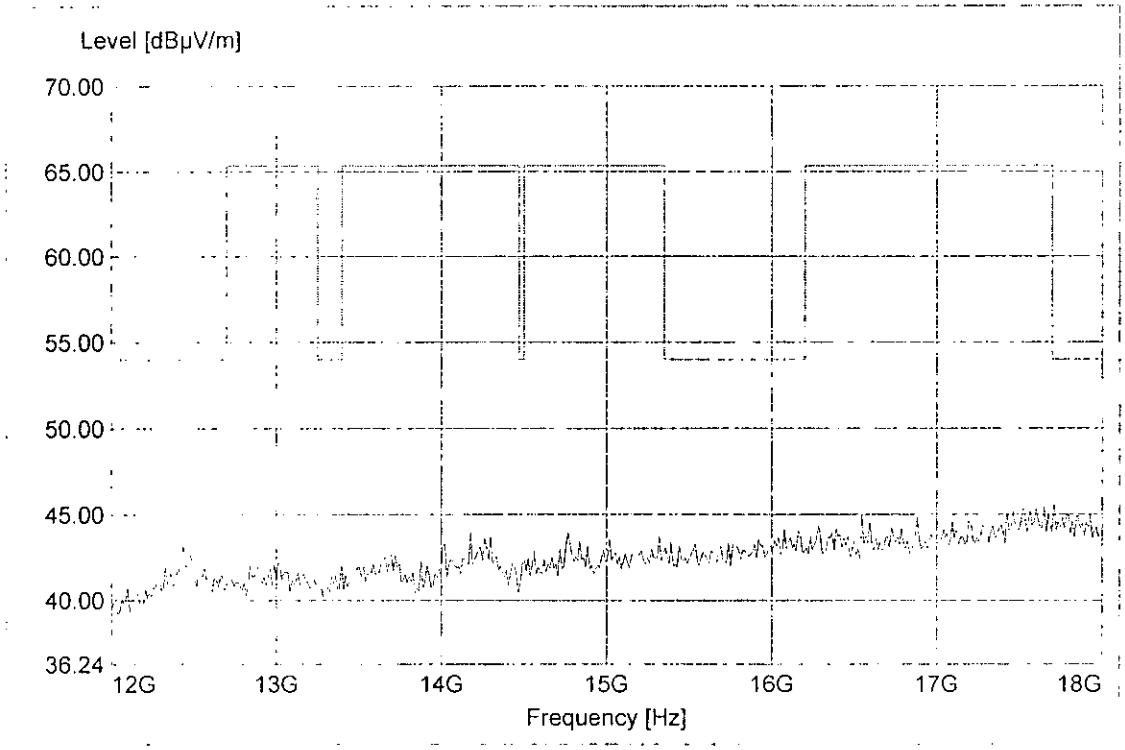
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 17.711GHz, Emax: 45.67dBµV/m, RBW: 1MHz



MES 6. FCC_15247
LIM FCC_restricted

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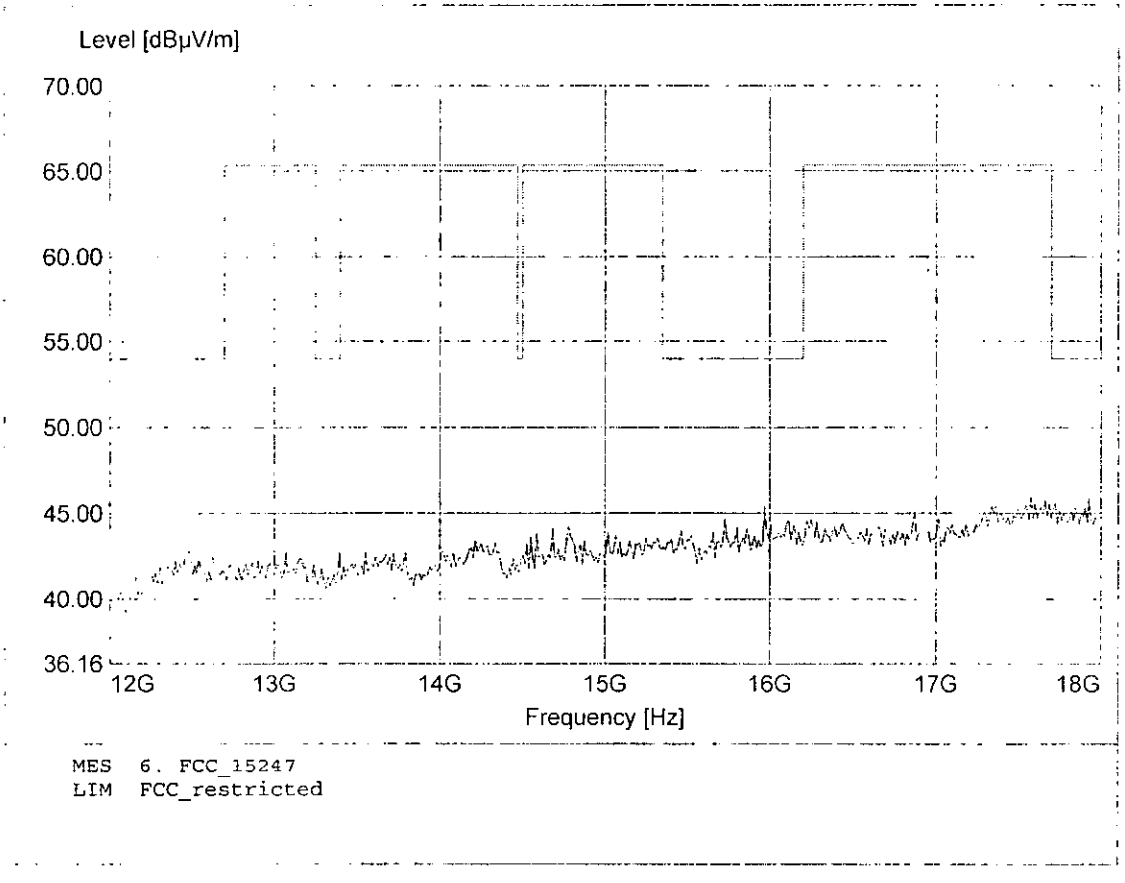
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 17.579GHz, Emax: 46.01dBµV/m, RBW: 1MHz



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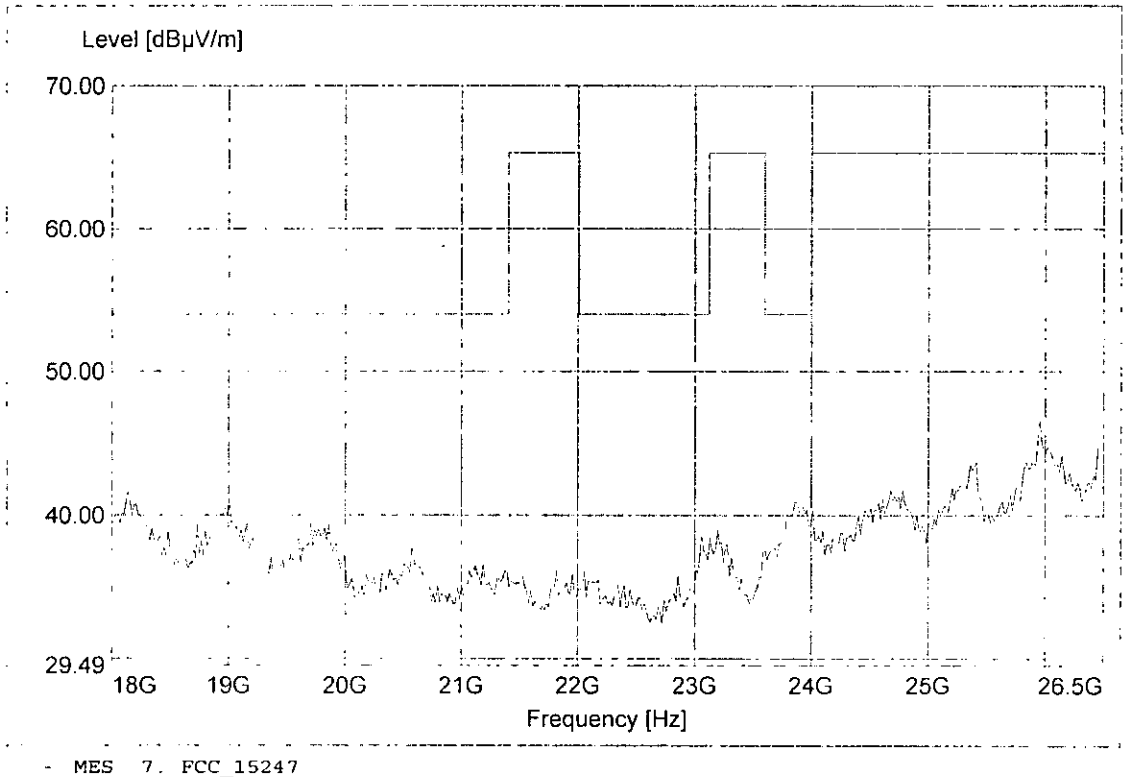
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak ,detector
Comment 1:	Dist.: 3m, Ant.: HL025, amplif.
Comment 2:	Freq: 25.955GHz, Emax: 46.76dBµV/m, RBW: 1MHz



- MES 7. FCC_15247
- LIM FCC_restricted

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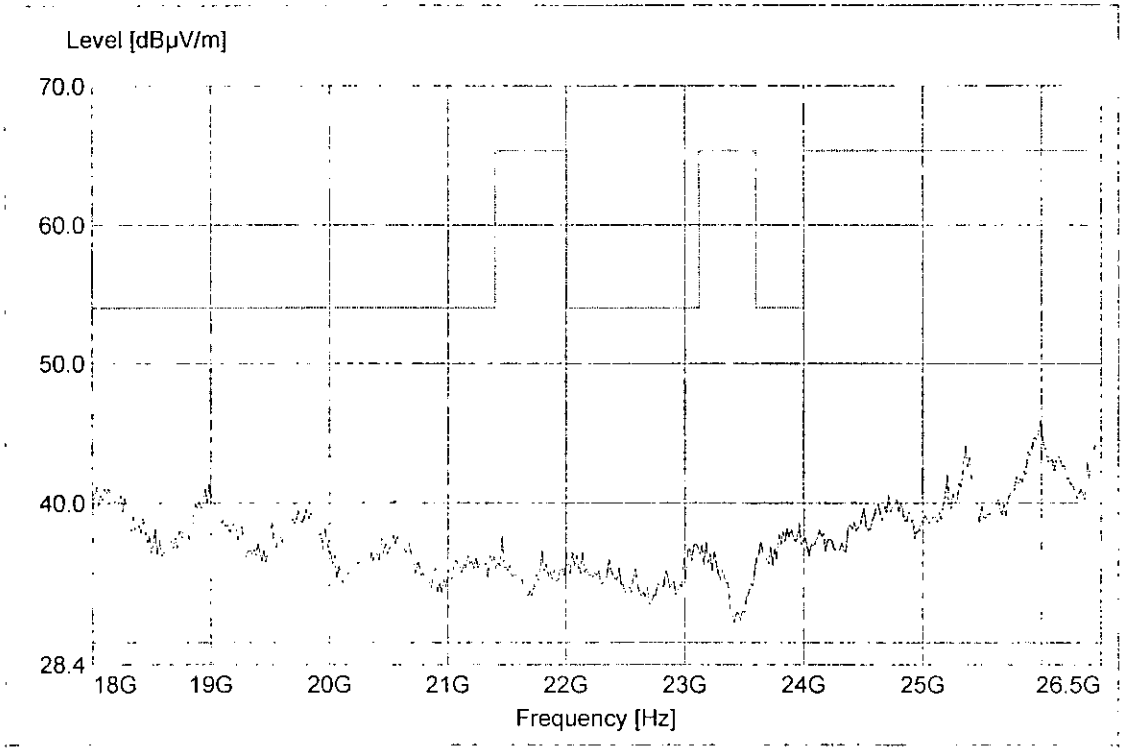
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2402 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL025, amplif.
Comment 2:	Freq: 25.989GHz, Emax: 46.01dBµV/m, RBW: 1MHz



MES 7. FCC_15247
LIM FCC_restricted

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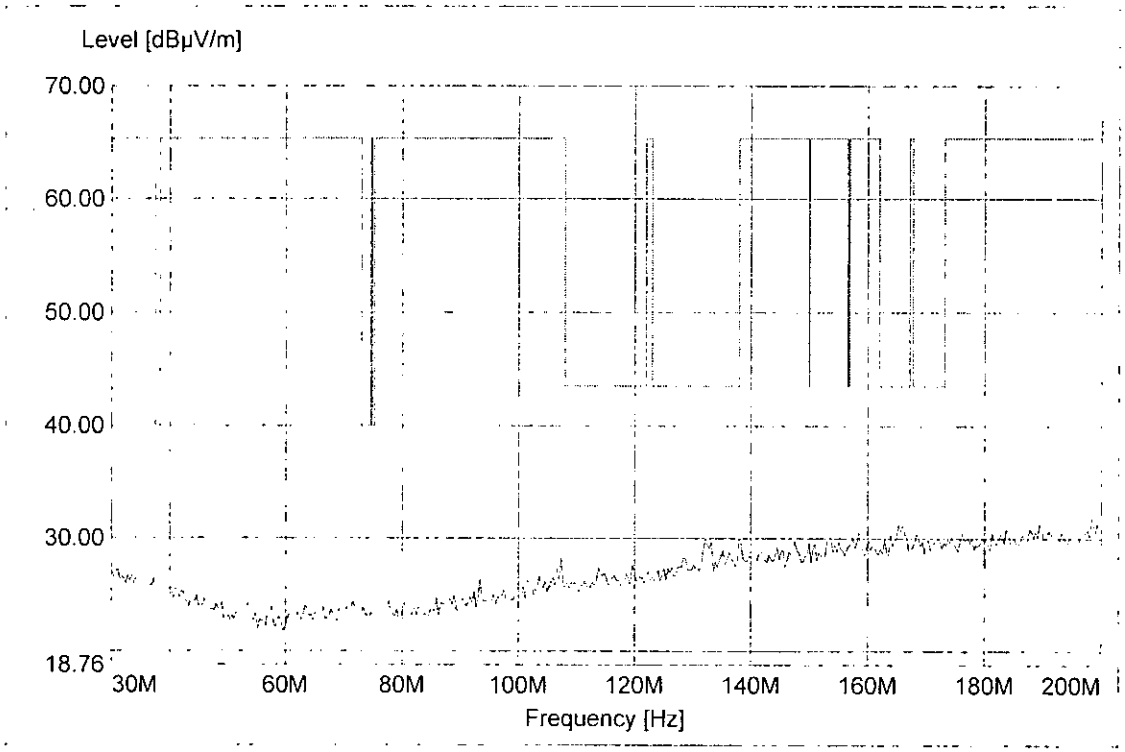
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247
Comment 1:	Dist.: 3m, Ant.: HK 116
Comment 2:	Freq: 198.297MHz, Emax: 31.84dBµV/m, RBW: 100kHz



MES 1. FCC_15247
LIM FCC_restricted

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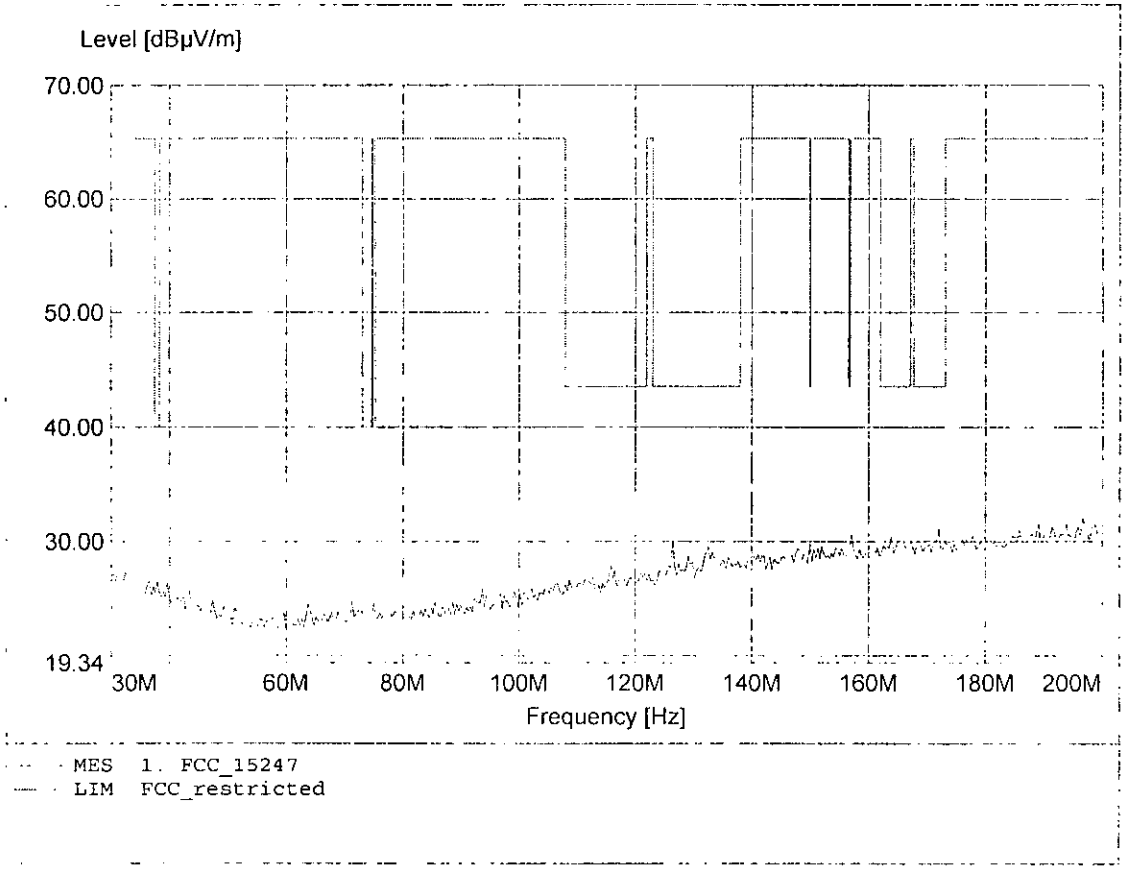
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247
Comment 1:	Dist.: 3m, Ant.: HK 116
Comment 2:	Freq: 196.593MHz, Emax: 32.05dBµV/m, RBW: 100kHz



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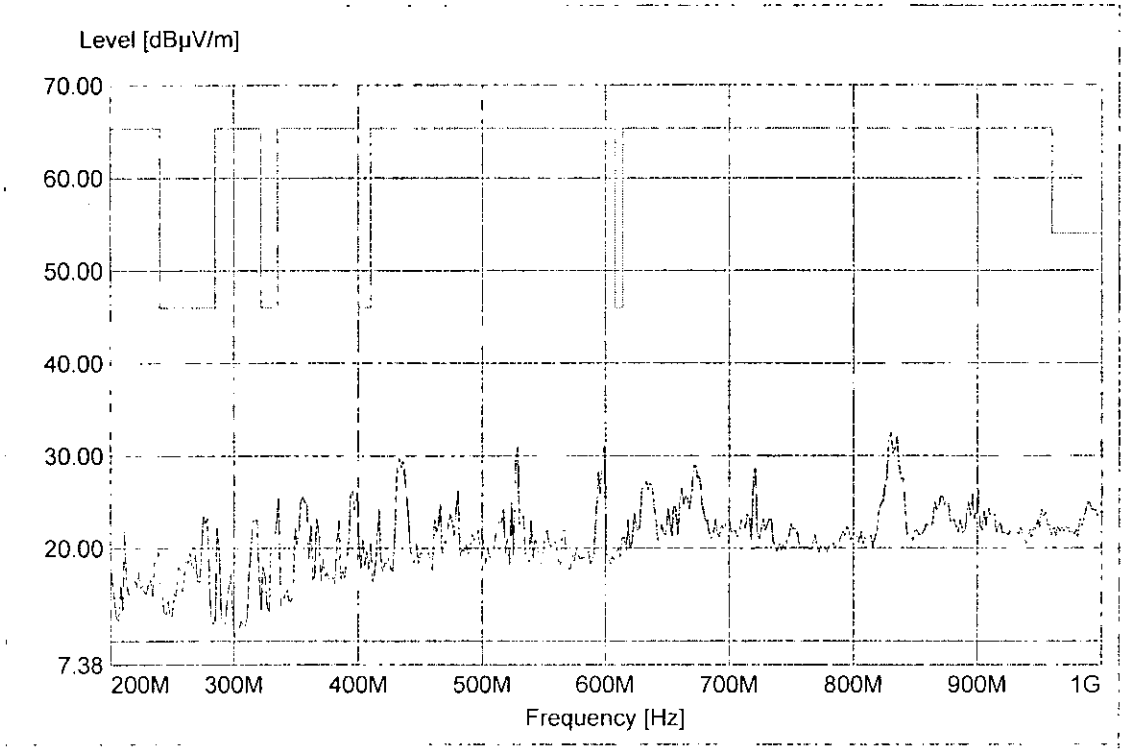
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247
Comment 1:	Dist.: 3m, Ant.: HL 223, amplif.
Comment 2:	Freq: 830.060MHz, Emax: 32.63dBµV/m, RBW: 100kHz



MES 2. FCC_15247
LIM FCC_restricted

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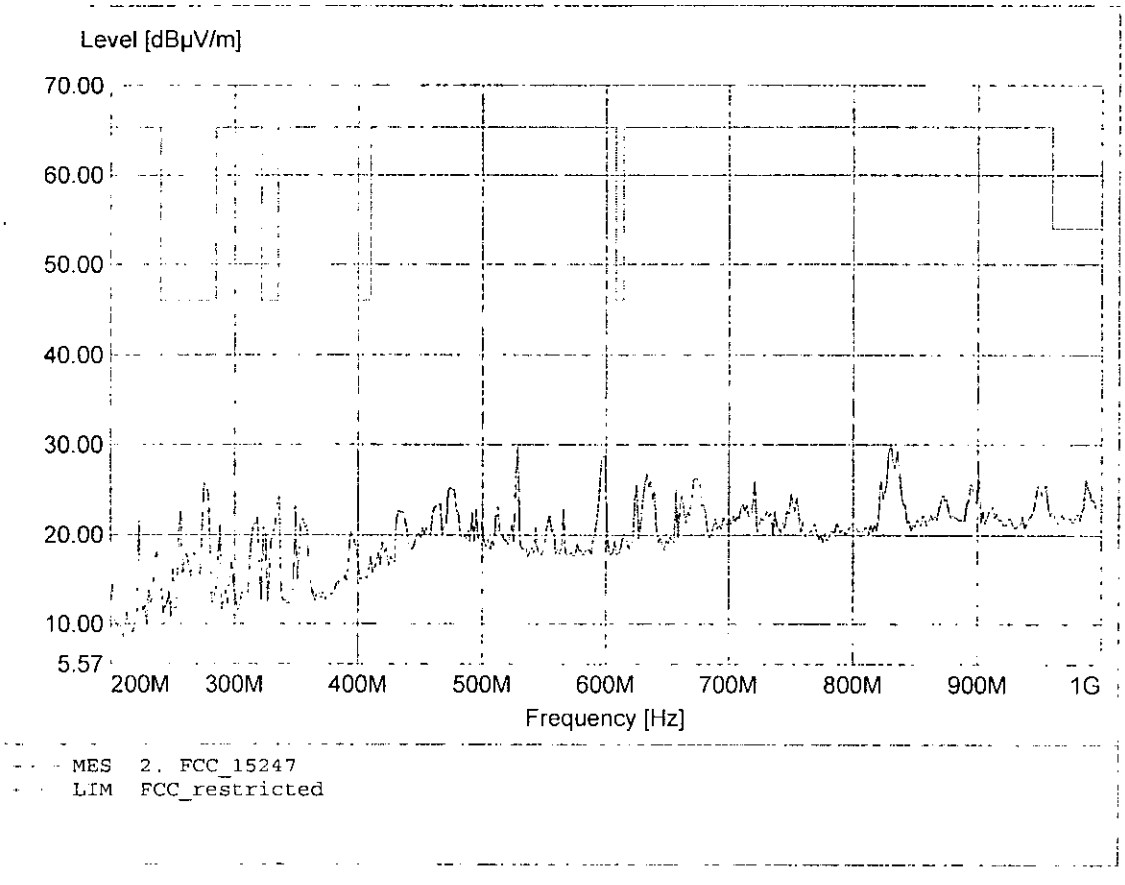
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247
Comment 1:	Dist.: 3m, Ant.: HL 223, amplif.
Comment 2:	Freq: 830.060MHz, Emax: 30.16dBµV/m, RBW: 100kHz



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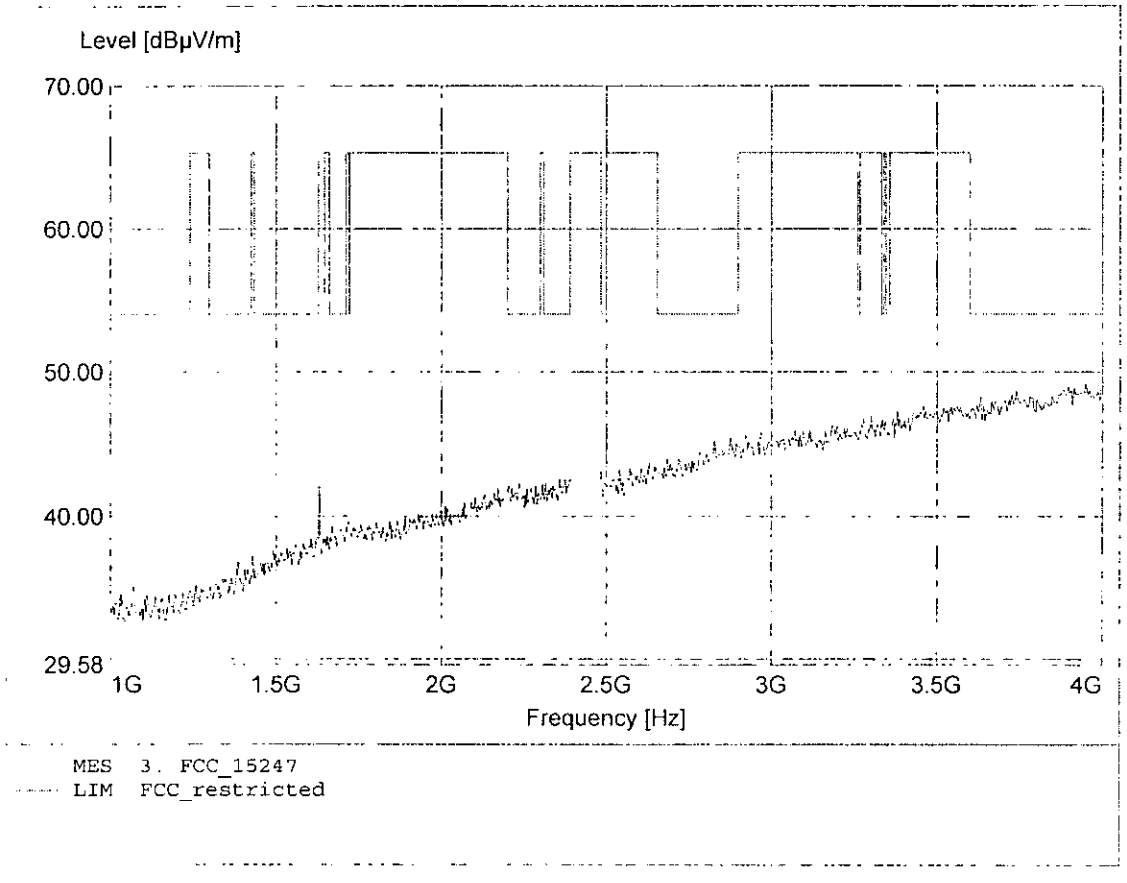
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, amplif.
Comment 2:	Freq: 3.948GHz, Emax: 49.25dBµV/m, RBW: 1MHz



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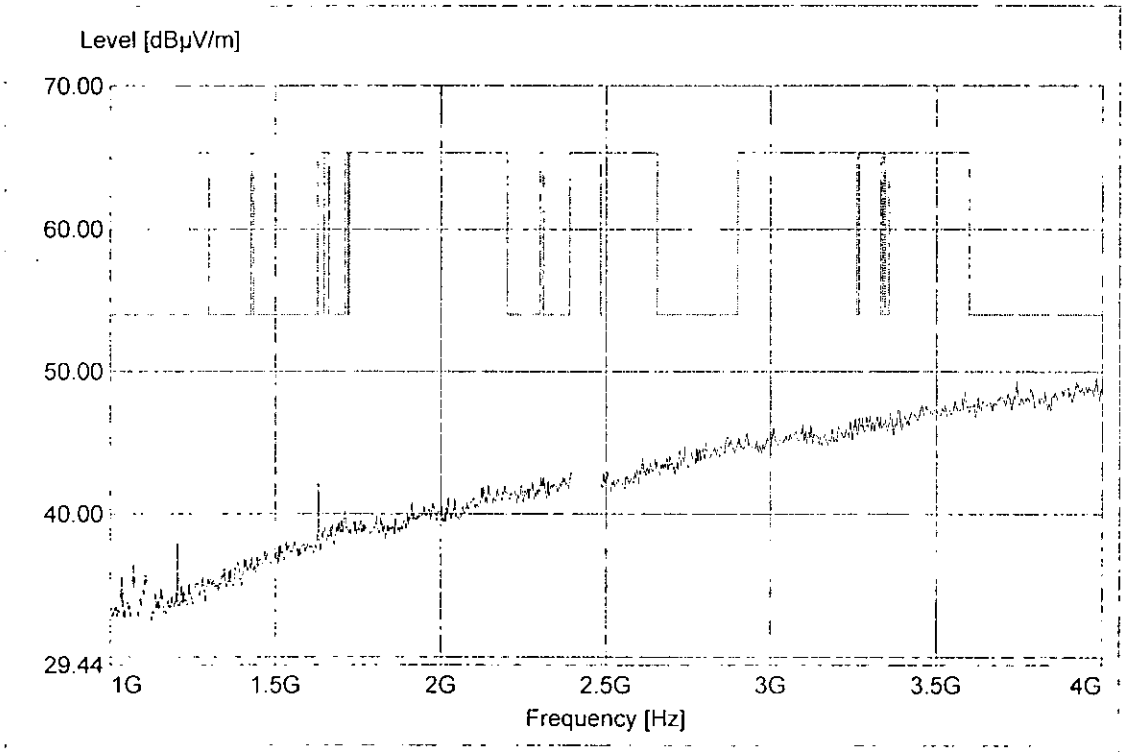
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, amplif.
Comment 2:	Freq: 3.982GHz, Emax: 49.70dBµV/m, RBW: 1MHz



MES 3. FCC_15247
LIM FCC_restricted

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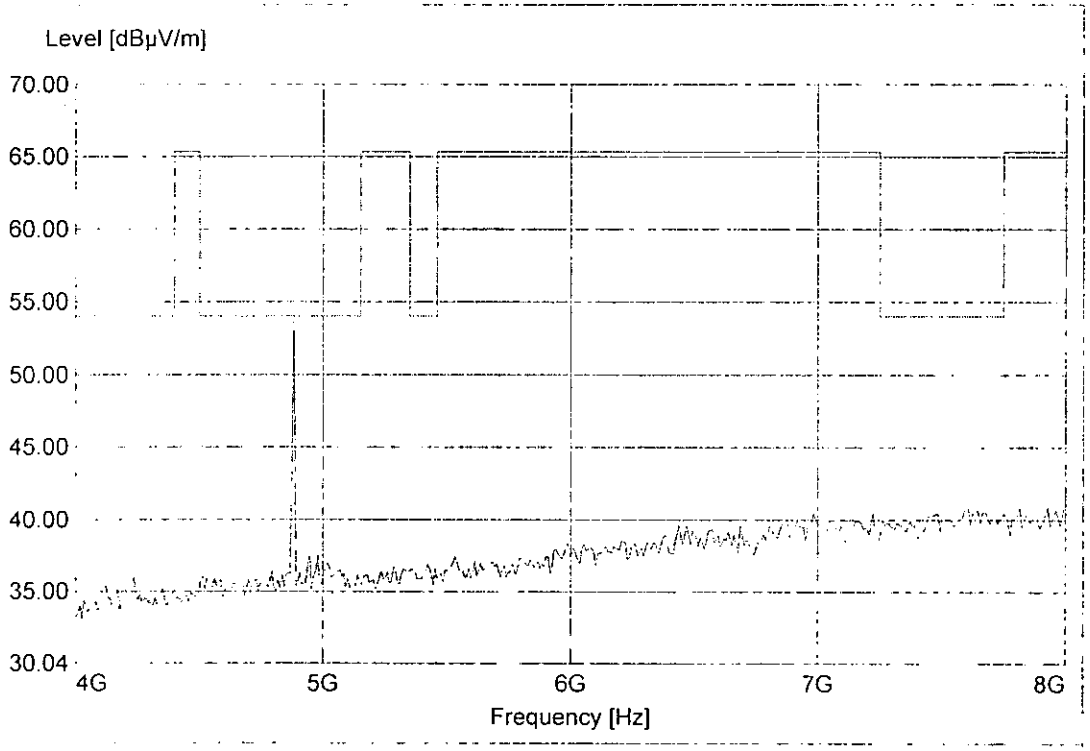
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 4.882GHz, Emax: 53.79dBµV/m, RBW: 1MHz



MES 4. FCC_15247
LIM FCC_restricted

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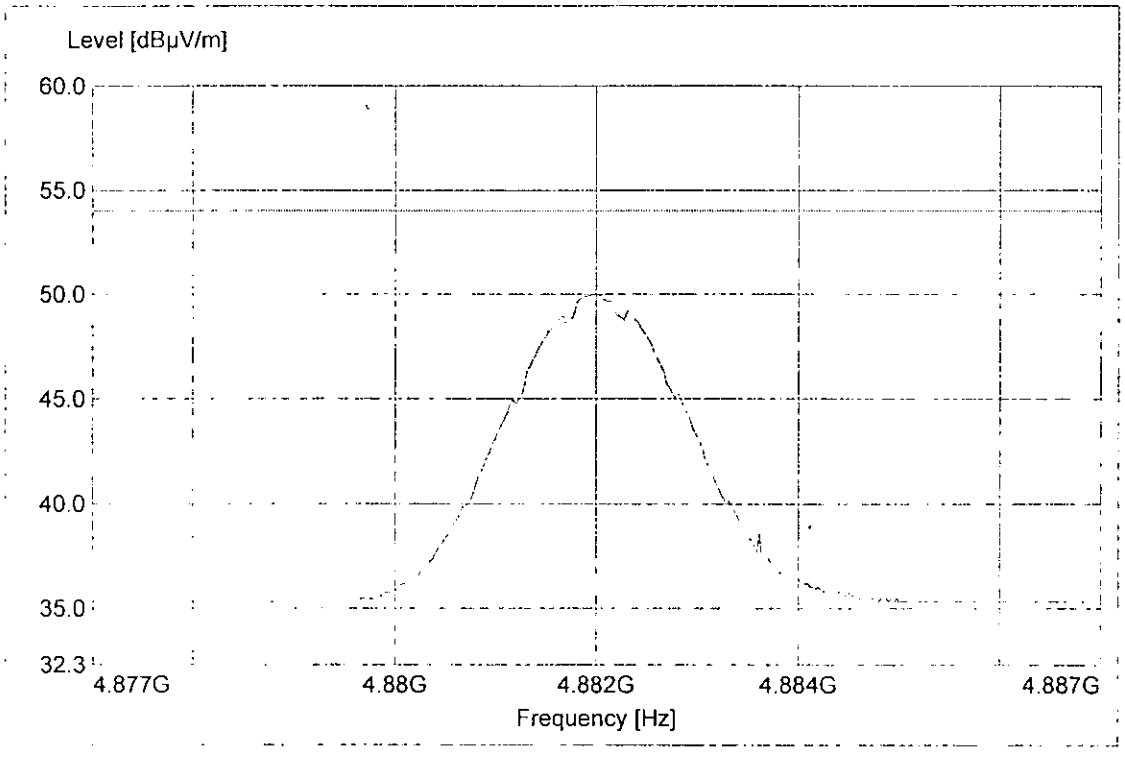
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, average detector
Comment 1:	Dist.: 3m, Ant.: HL025, amplif.
Comment 2:	Freq: 4.882GHz, Emax: 50.02dBµV/m, RBW: 1MHz



- MES 7. FCC_Average
- LIM FCC_restricted

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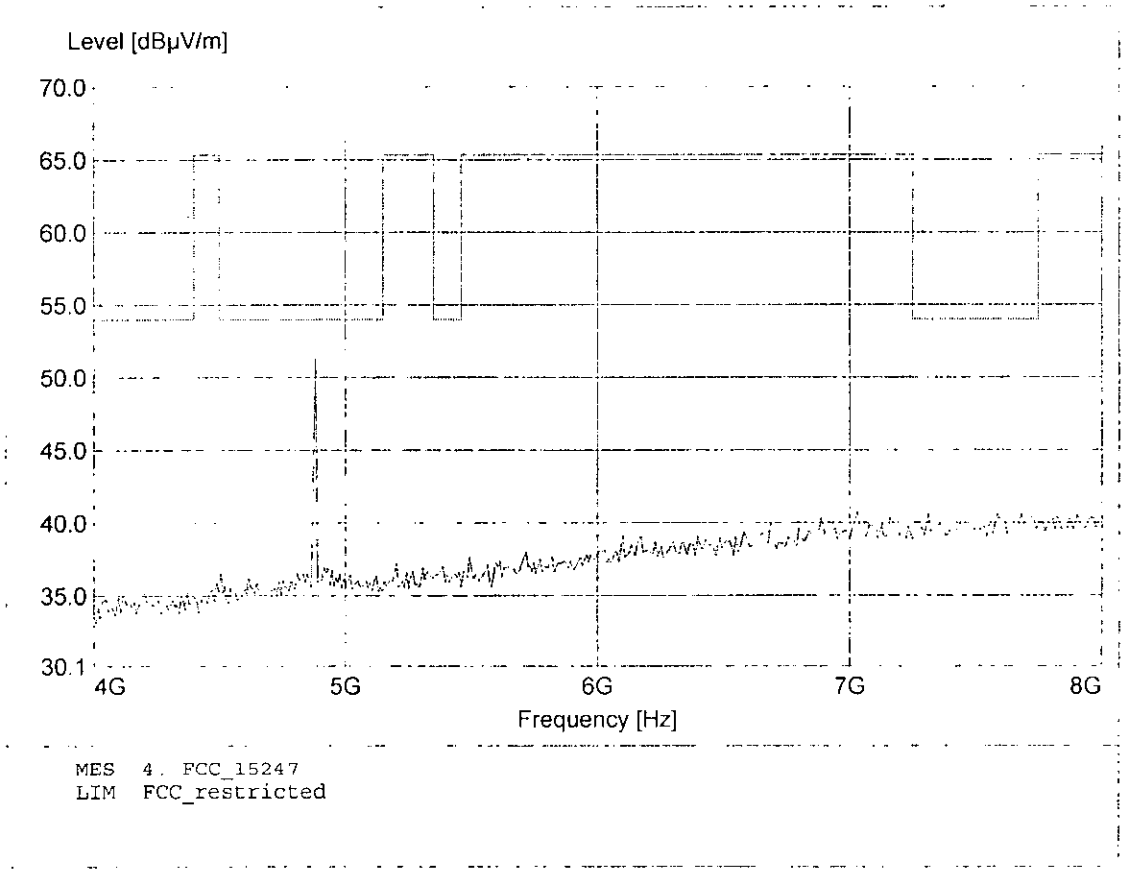
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 4.882GHz, Emax: 51.93dBµV/m, RBW: 1MHz



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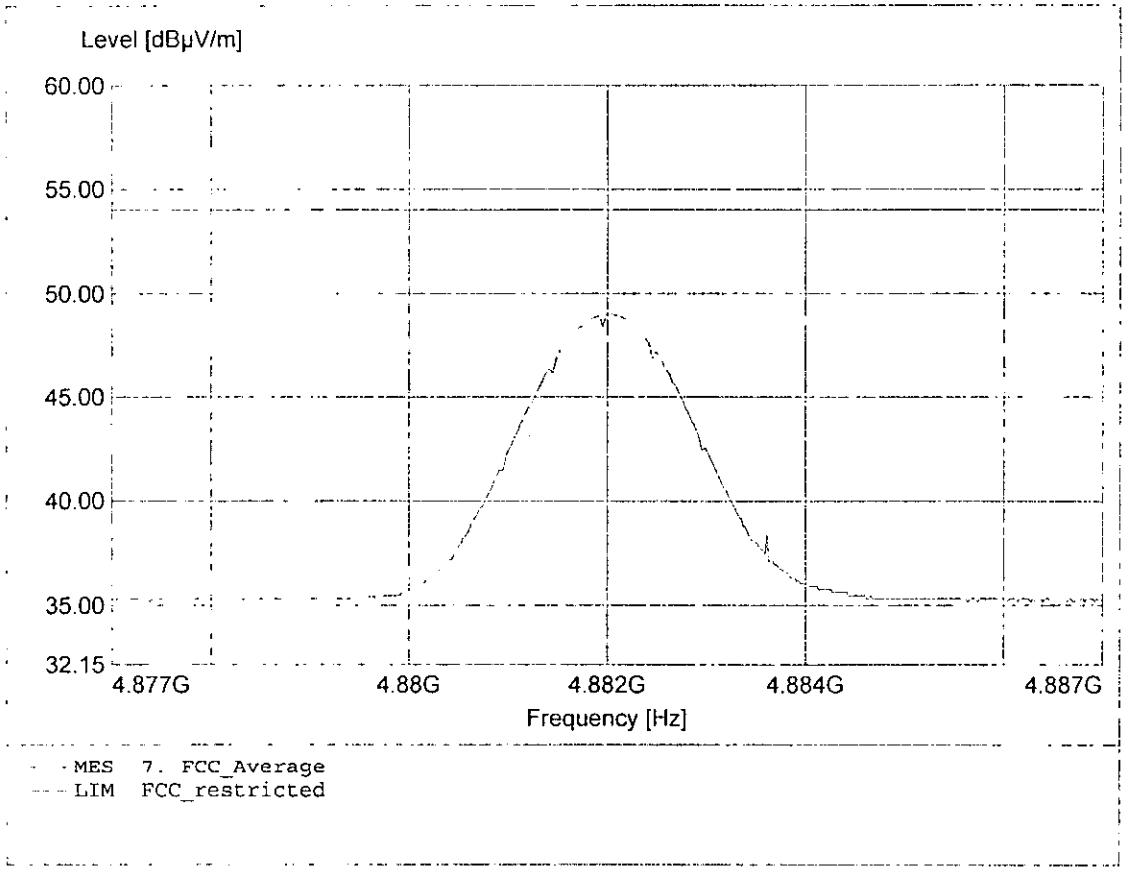
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, average detector
Comment 1:	Dist.: 3m, Ant.: HL025, amplif.
Comment 2:	Freq: 4.882GHz, Emax: 49.02dBµV/m, RBW: 1MHz



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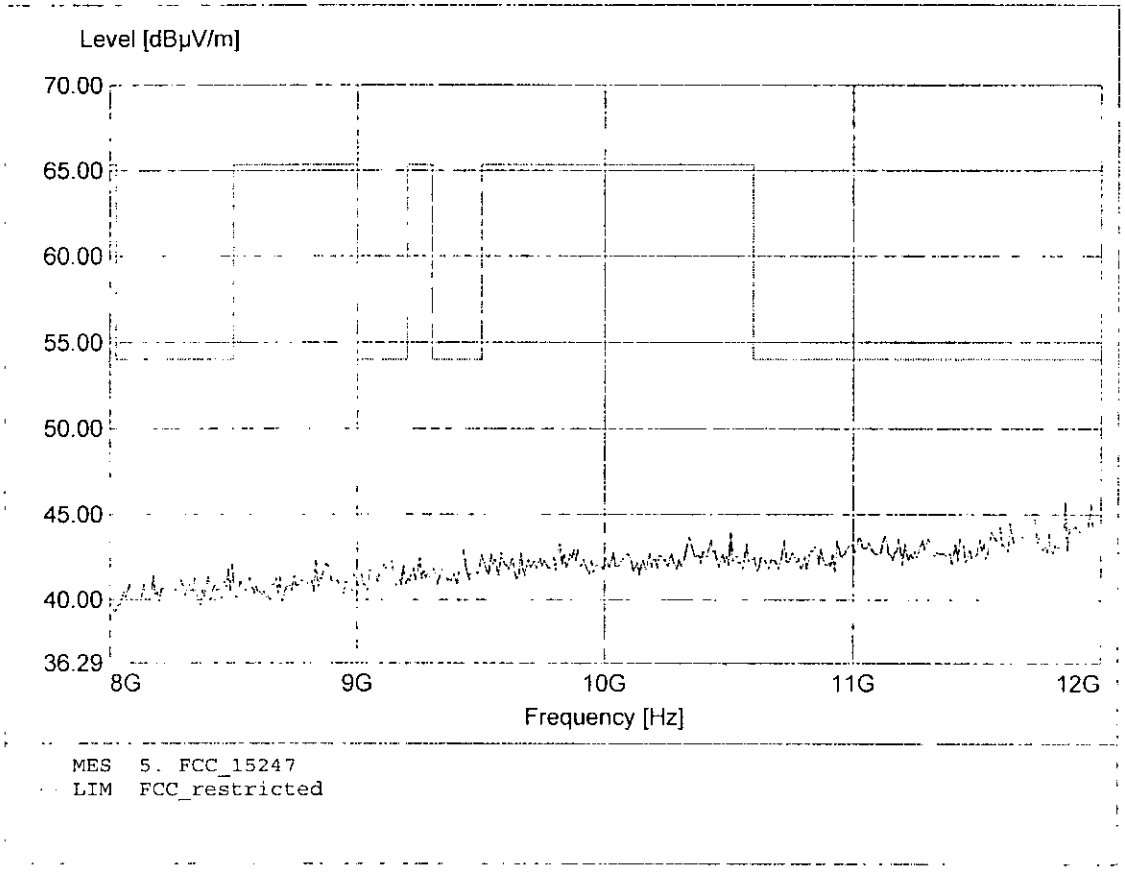
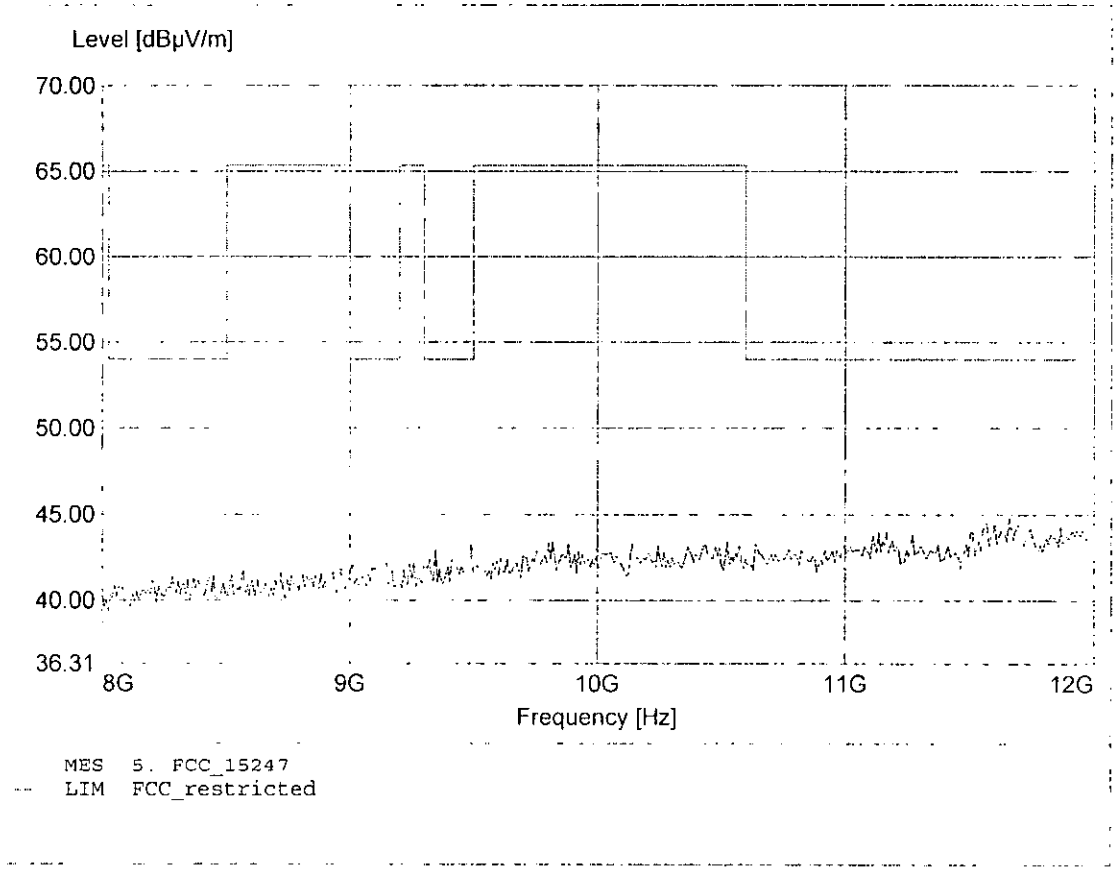
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 11.856GHz, Emax: 45.90dBµV/m, RBW: 1MHz



Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 11.655GHz, Emax: 44.89dBµV/m, RBW: 1MHz



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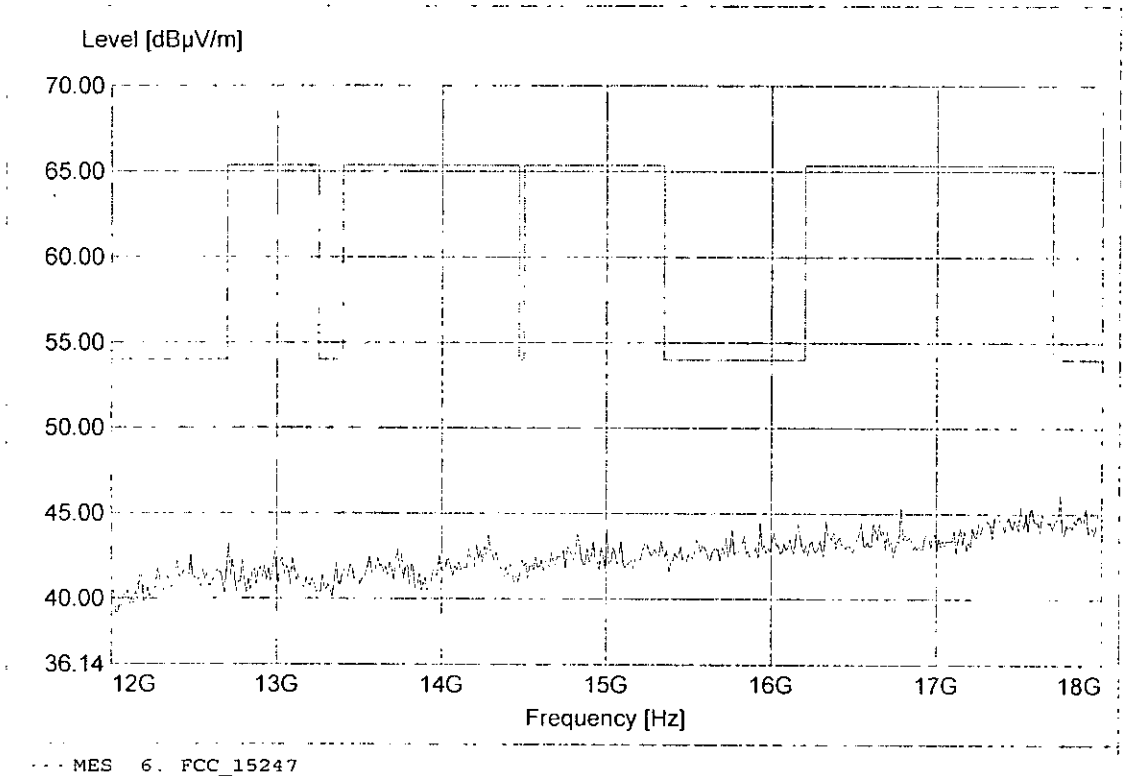
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 17.747GHz, Emax: 46.17dBµV/m, RBW: 1MHz



MES 6. FCC_15247
LIM FCC_restricted

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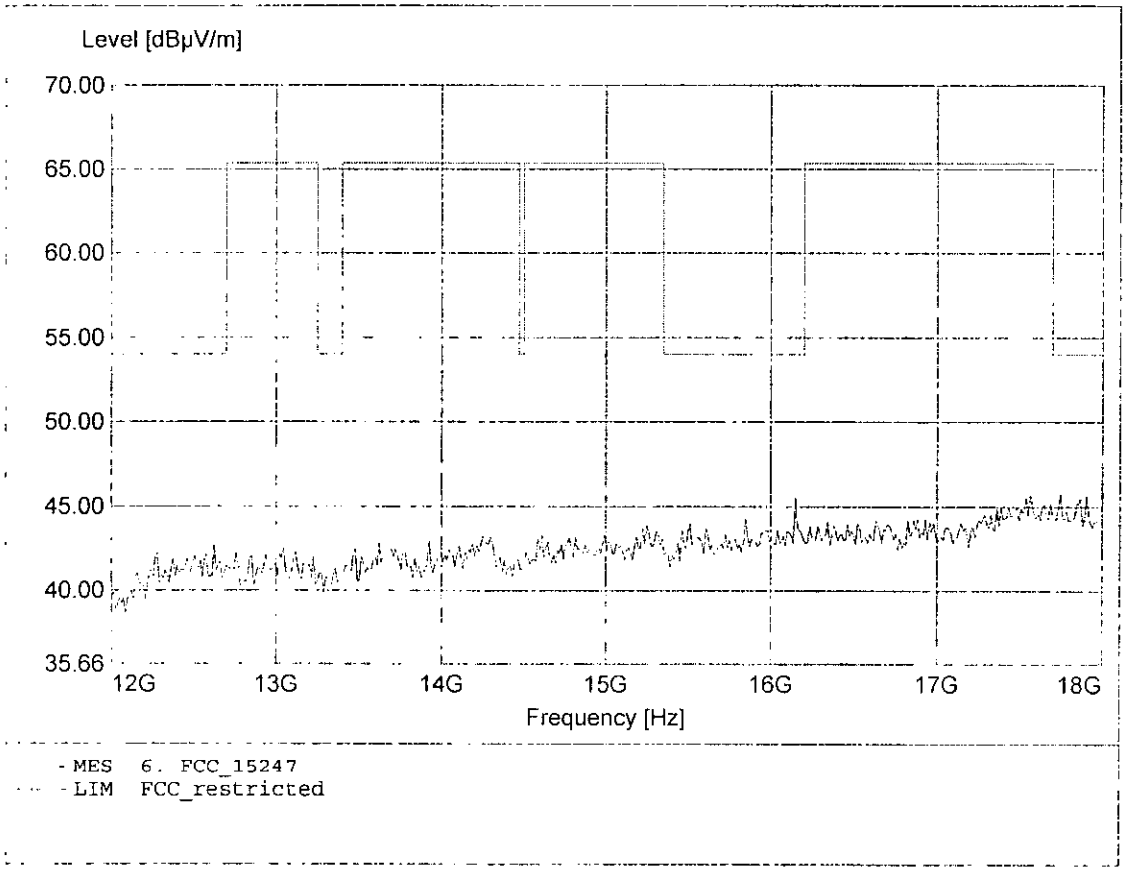
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 17.747GHz, Emax: 45.76dBµV/m, RBW: 1MHz



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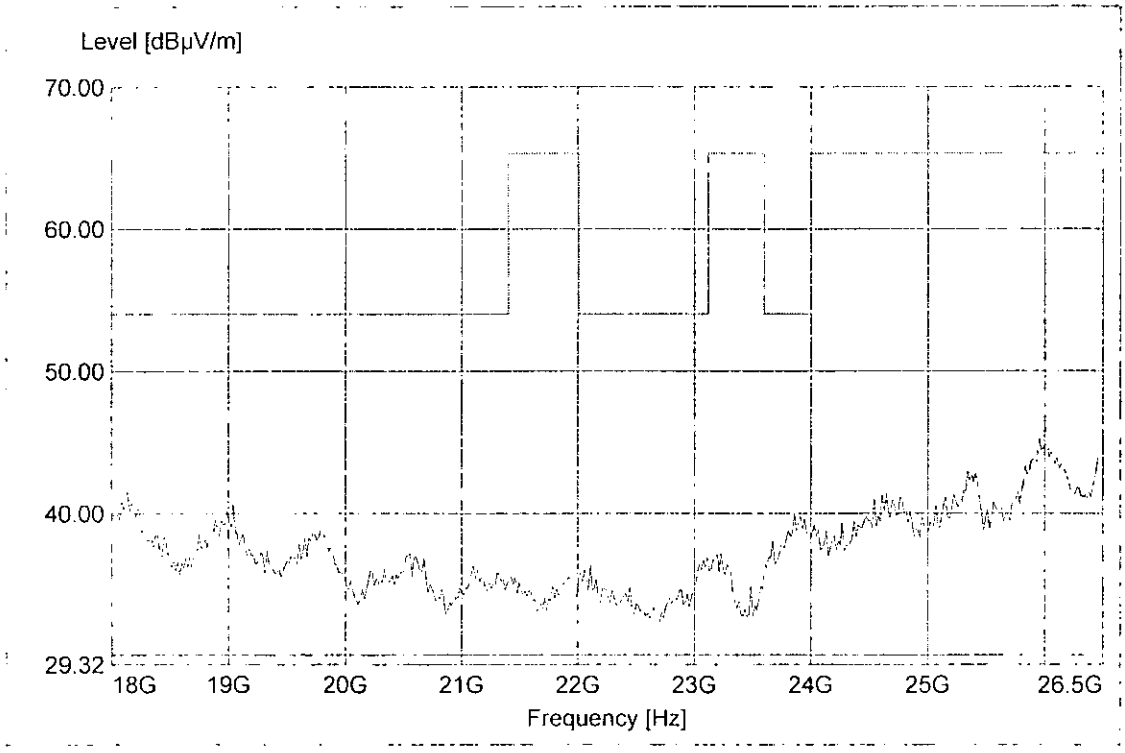
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL025, amplif.
Comment 2:	Freq: 25.955GHz, Emax: 45.32dBµV/m, RBW: 1MHz



MES 7. FCC_15247
LIM FCC_restricted

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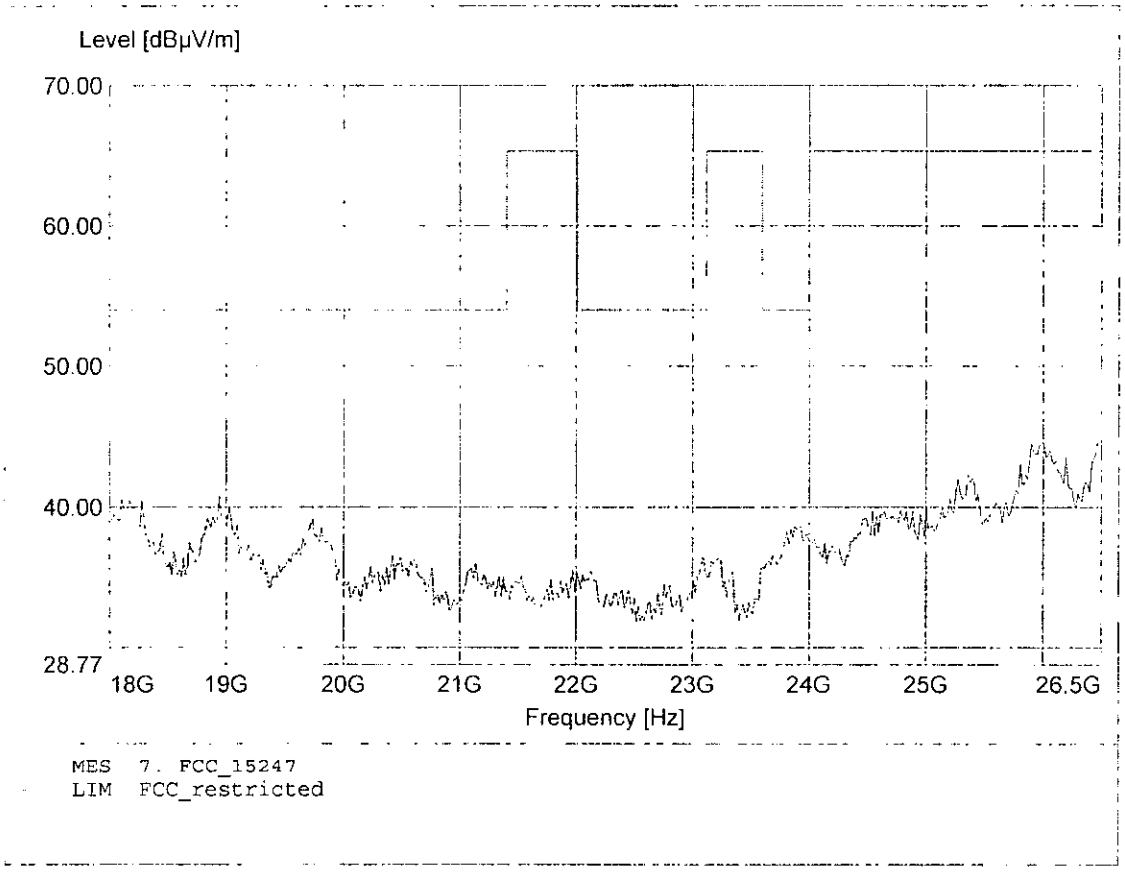
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL025, amplif.
Comment 2:	Freq: 26.466GHz, Emax: 44.65dBµV/m, RBW: 1MHz



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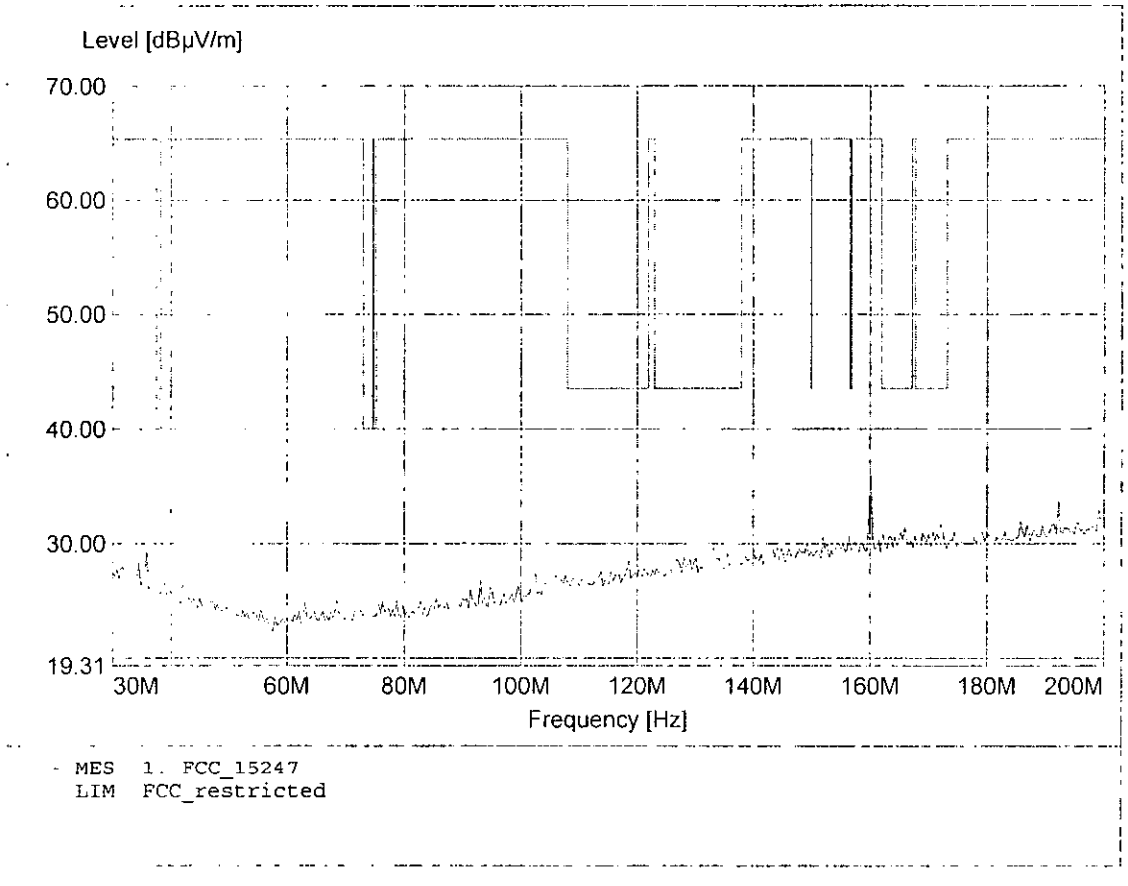
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247
Comment 1:	Dist.: 3m, Ant.: HK 116
Comment 2:	Freq: 160.140MHz, Emax: 36.07dBµV/m, RBW: 100kHz



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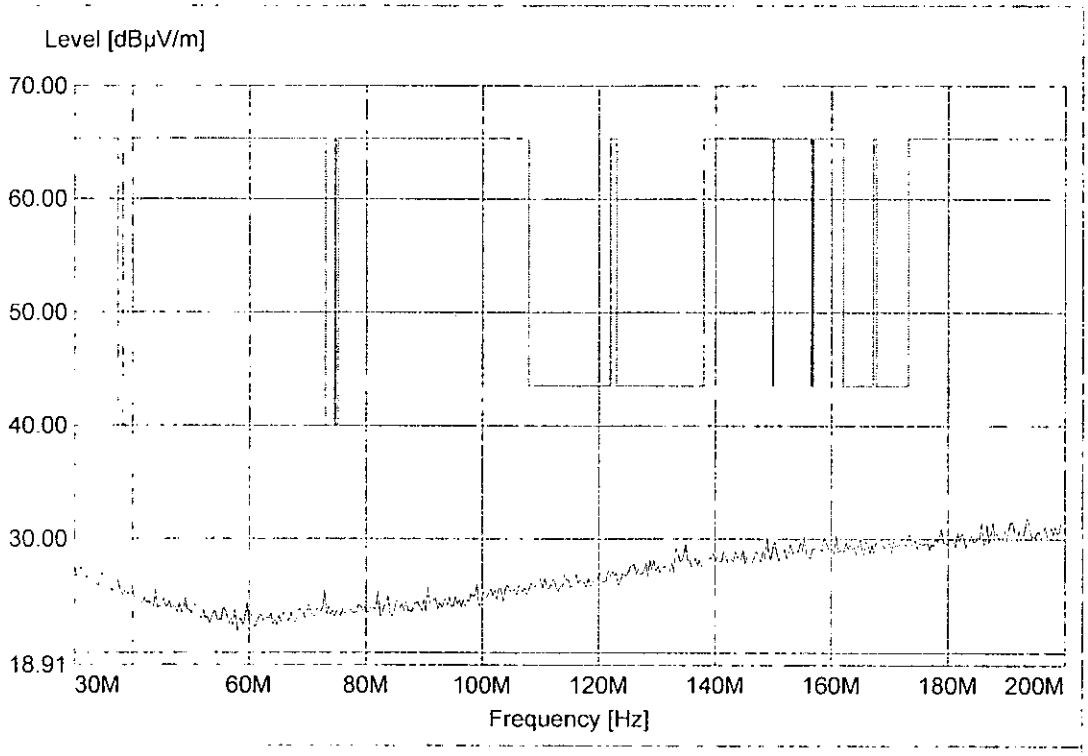
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247
Comment 1:	Dist.: 3m, Ant.: HK 116
Comment 2:	Freq: 193.527MHz, Emax: 31.91dBµV/m, RBW: 100kHz



MES 1. FCC_15247
LIM FCC_restricted

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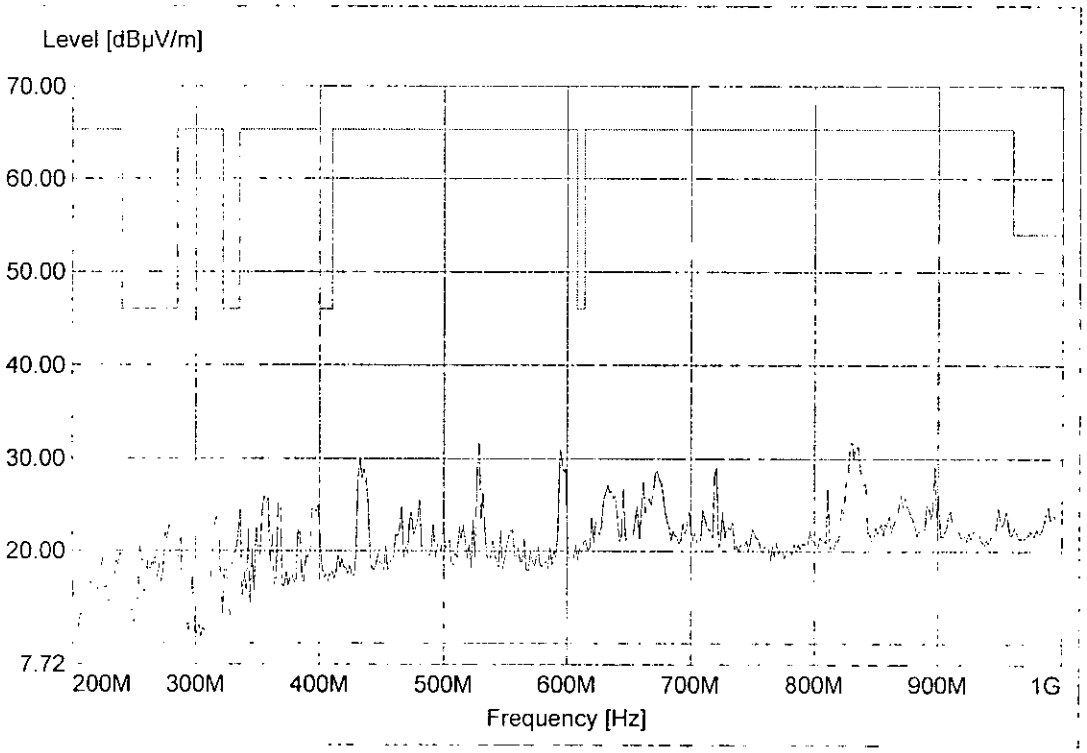
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

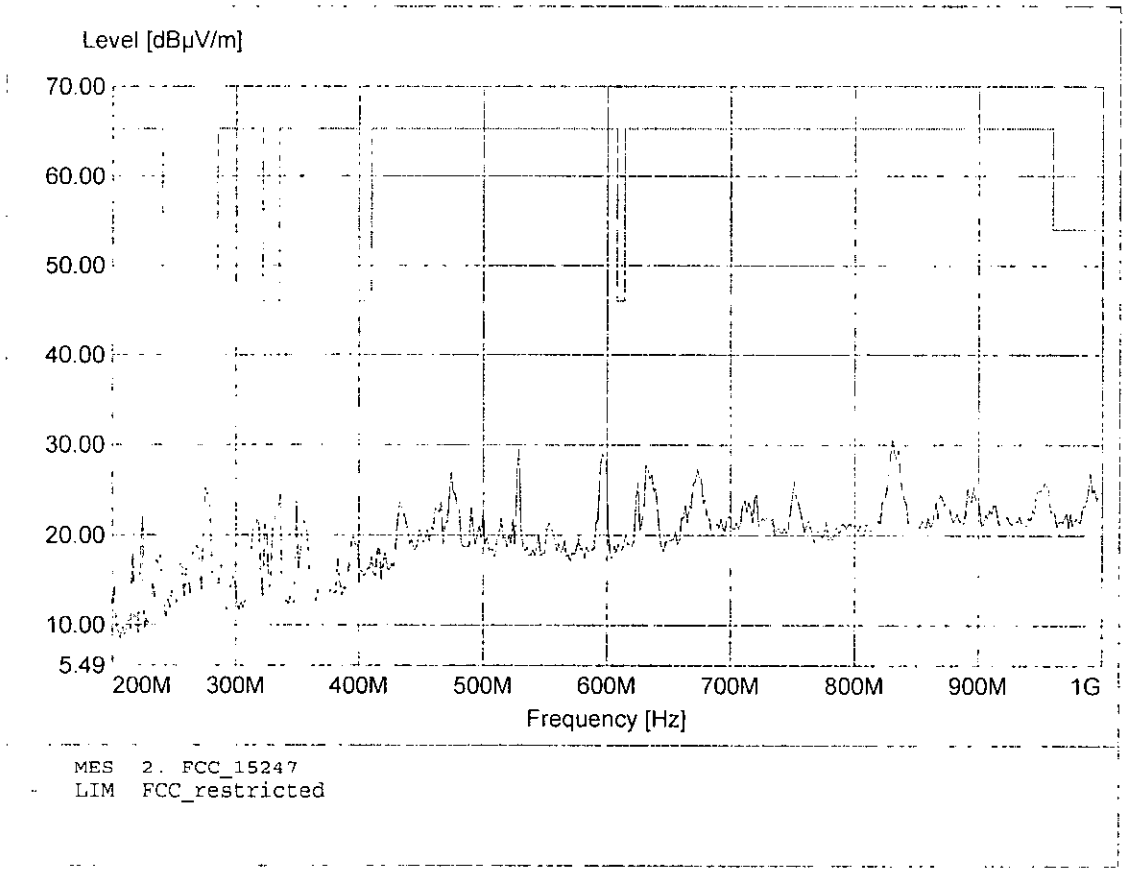
Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247
Comment 1:	Dist.: 3m, Ant.: HL 223, amplif.
Comment 2:	Freq: 830.060MHz, Emax: 31.89dBµV/m, RBW: 100kHz



MES 2. FCC_15247
LIM FCC_restricted

Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247
Comment 1:	Dist.: 3m, Ant.: HL 223, amplif.
Comment 2:	Freq: 830.060MHz, Emax: 30.74dBµV/m, RBW: 100kHz



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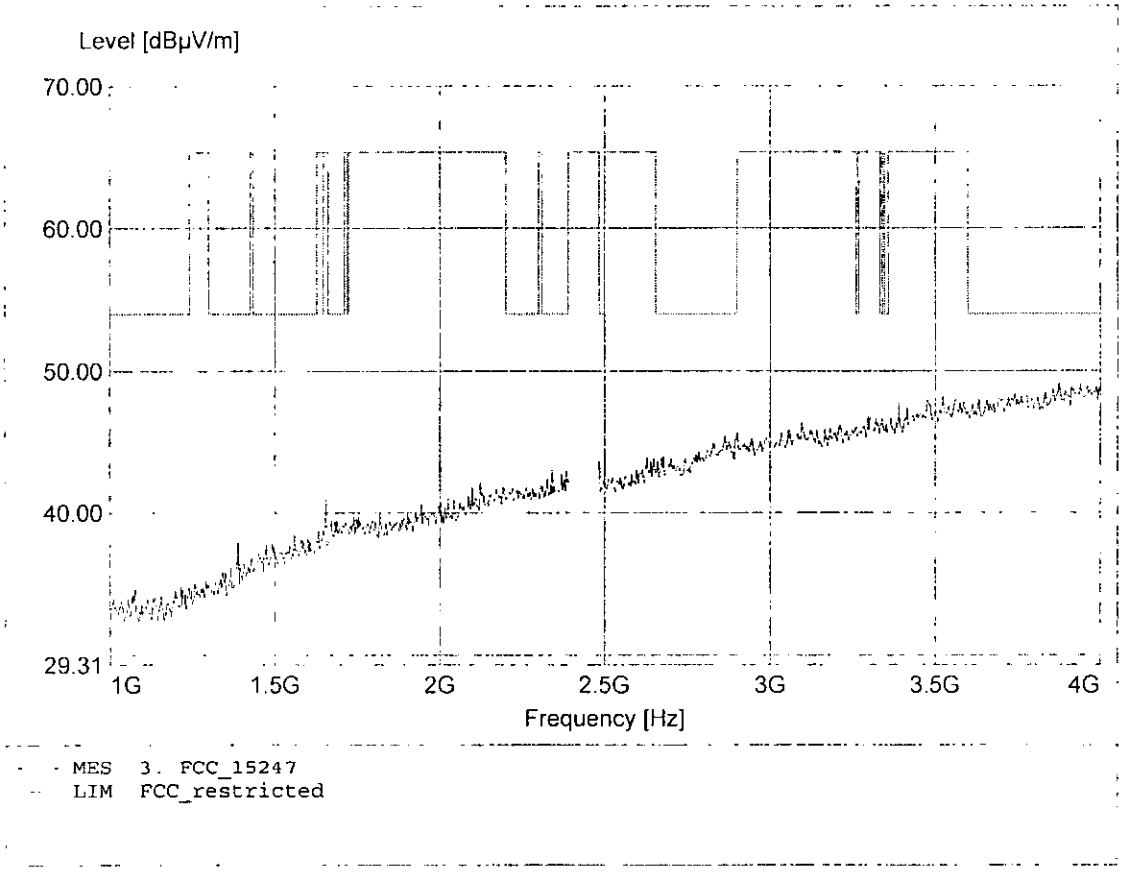
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, amplif.
Comment 2:	Freq: 3.875GHz, Emax: 49.23dBµV/m, RBW: 1MHz



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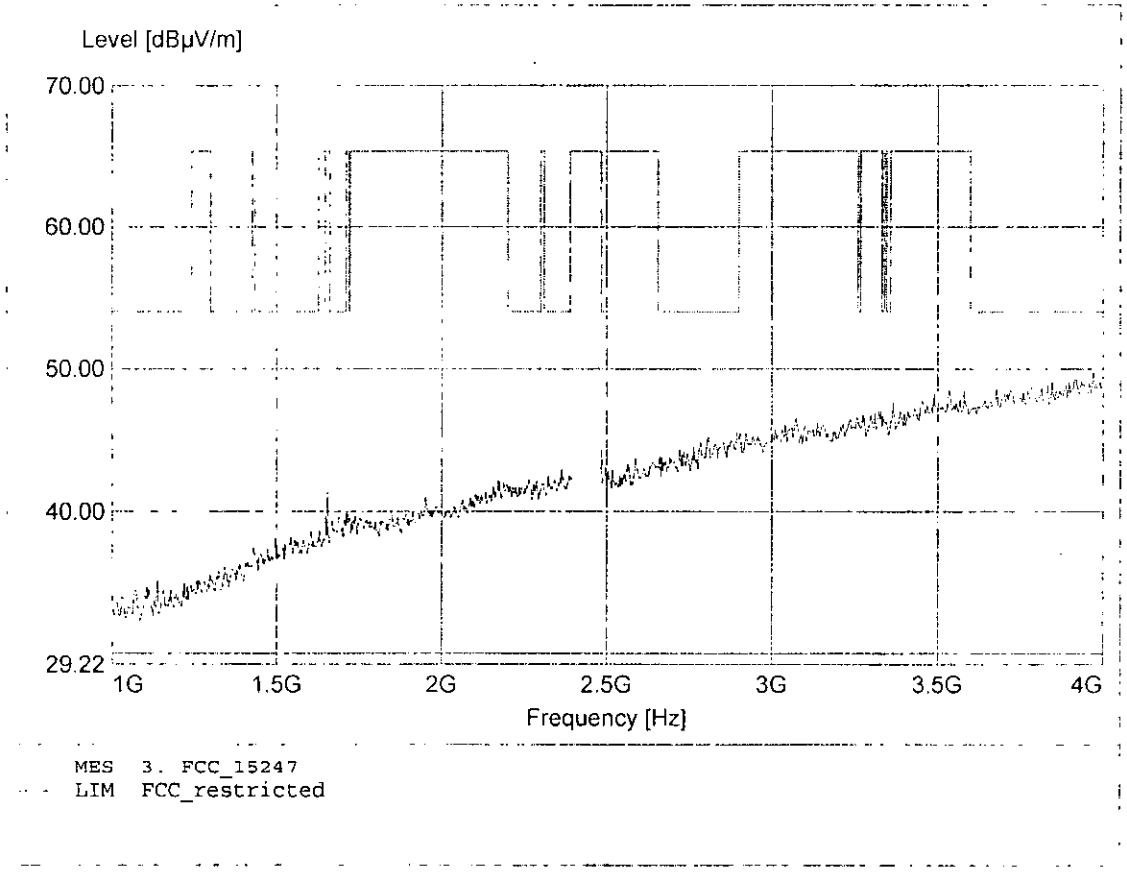
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

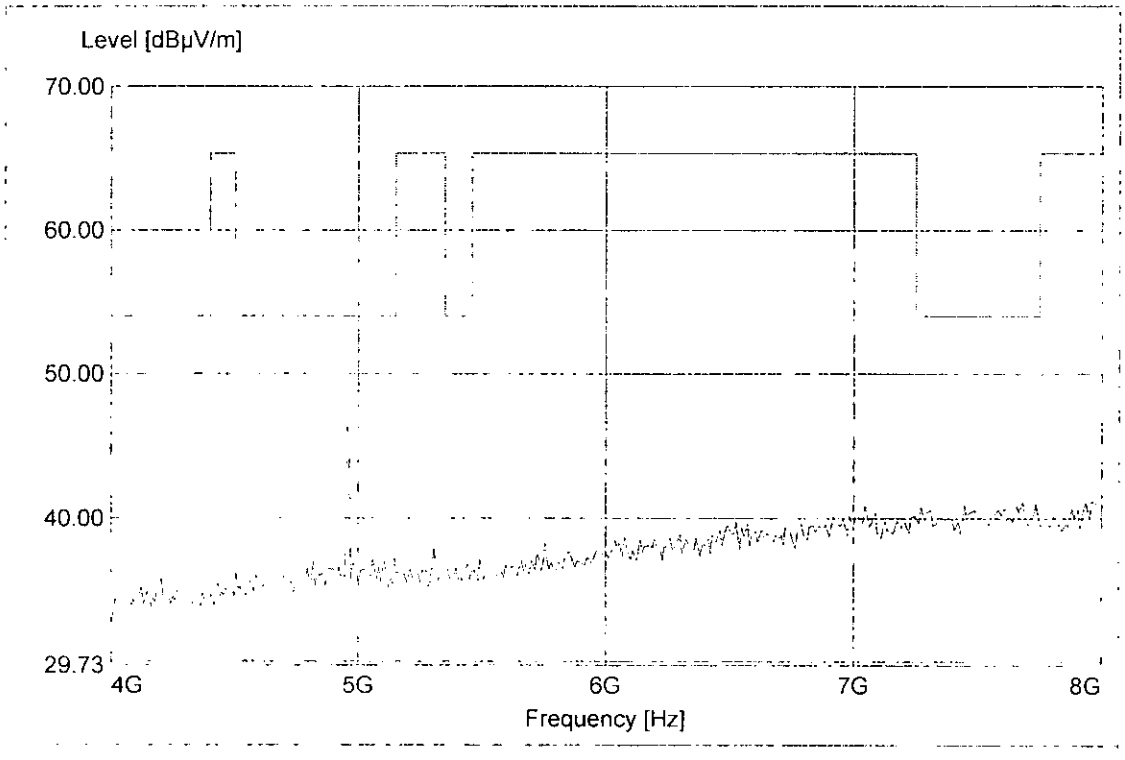
Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, amplif.
Comment 2:	Freq: 3.970GHz, Emax: 49.83dBµV/m, RBW: 1MHz



Page 1/1 12.11.08 11:10 Overview / Antenna horizontal

Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 4.954GHz, Emax: 46.36dBµV/m, RBW: 1MHz



MES 4. FCC_15247
LIM FCC_restricted

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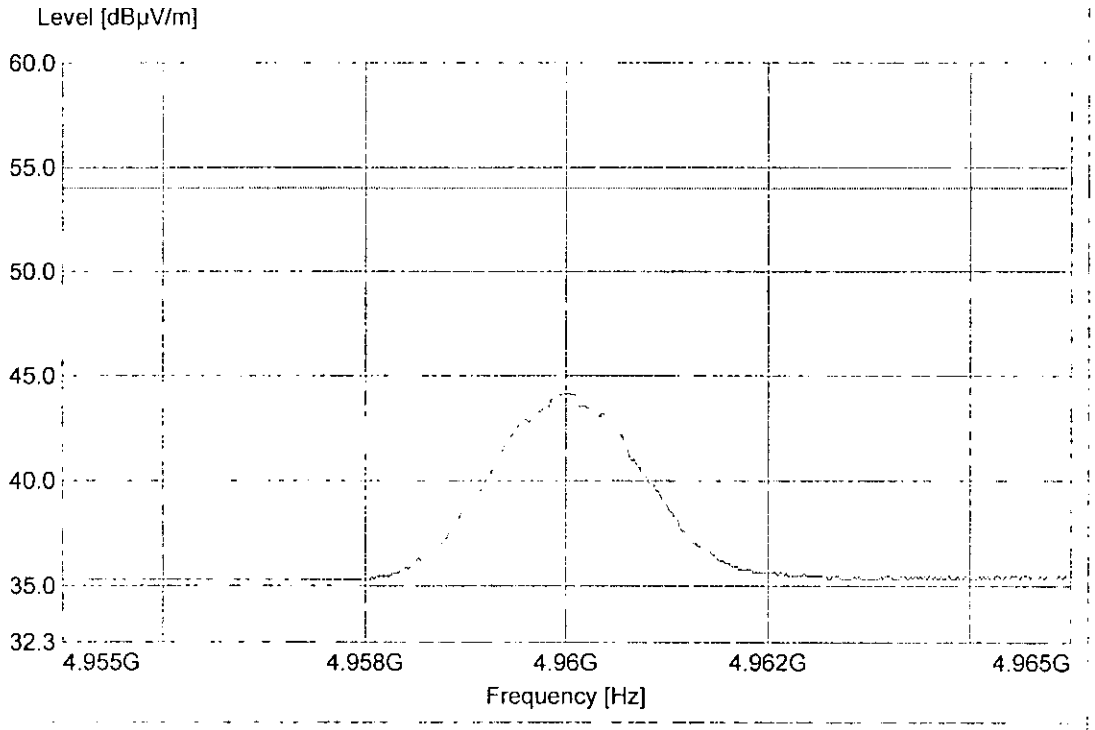
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, average detector
Comment 1:	Dist.: 3m, Ant.: HL025, amplif.
Comment 2:	Freq: 4.960GHz, Emax: 44.16dBµV/m, RBW: 1MHz



MES 8. FCC_Average
LIM FCC_restricted

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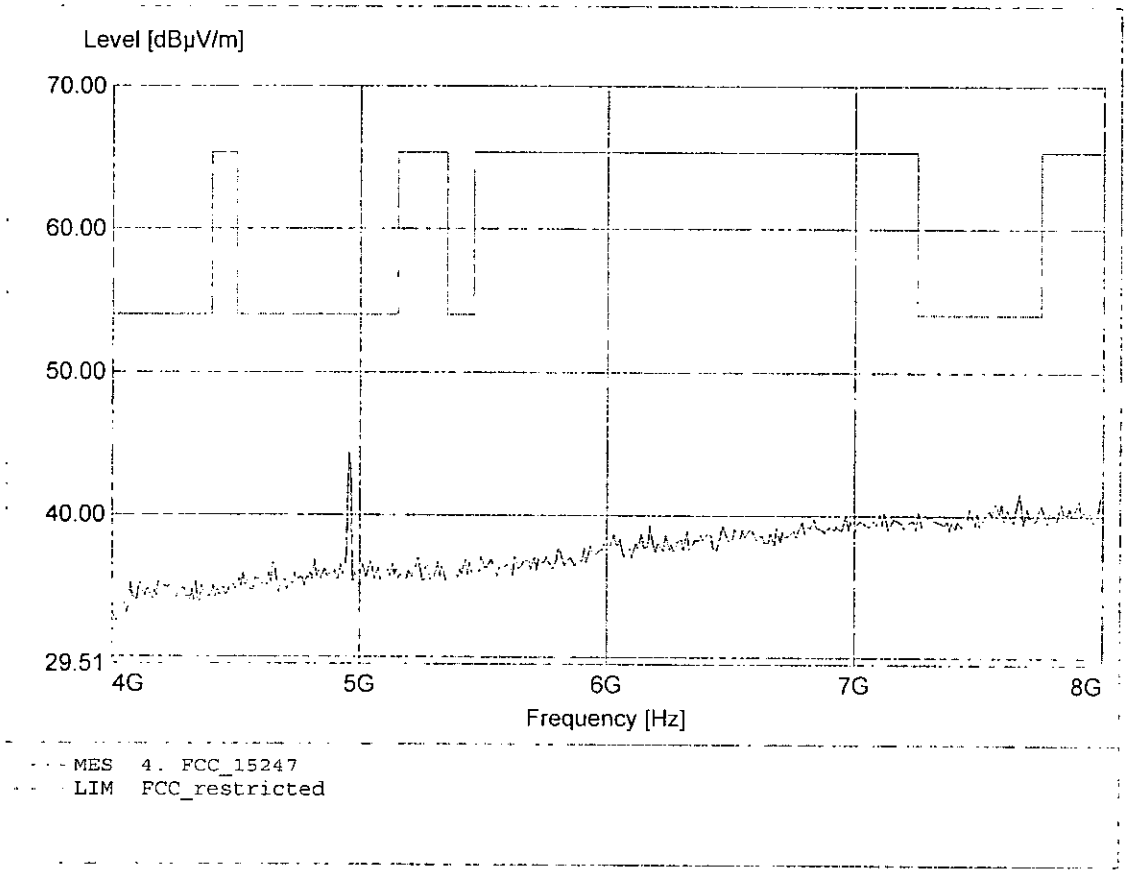
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 4.954GHz, Emax: 44.44dBµV/m, RBW: 1MHz



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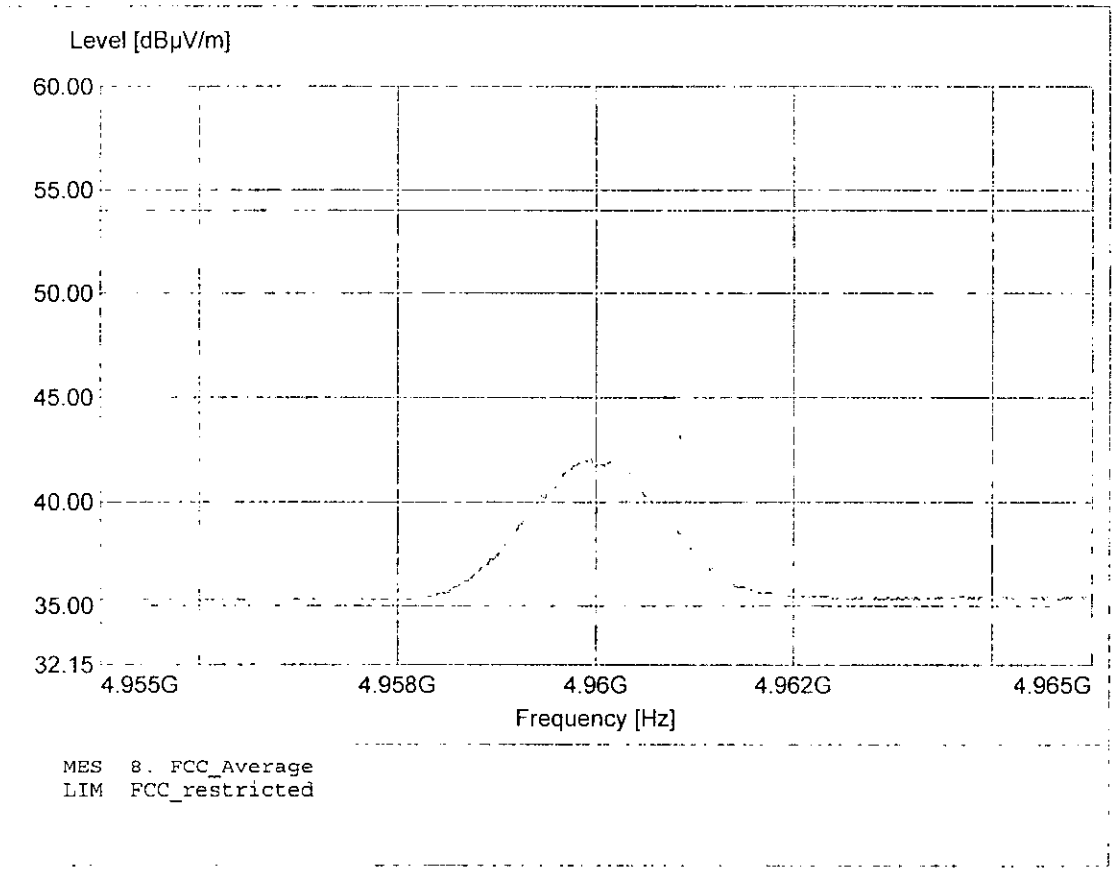
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, average detector
Comment 1:	Dist.: 3m, Ant.: HL025, amplif.
Comment 2:	Freq: 4.960GHz, Emax: 42.08dBµV/m, RBW: 1MHz



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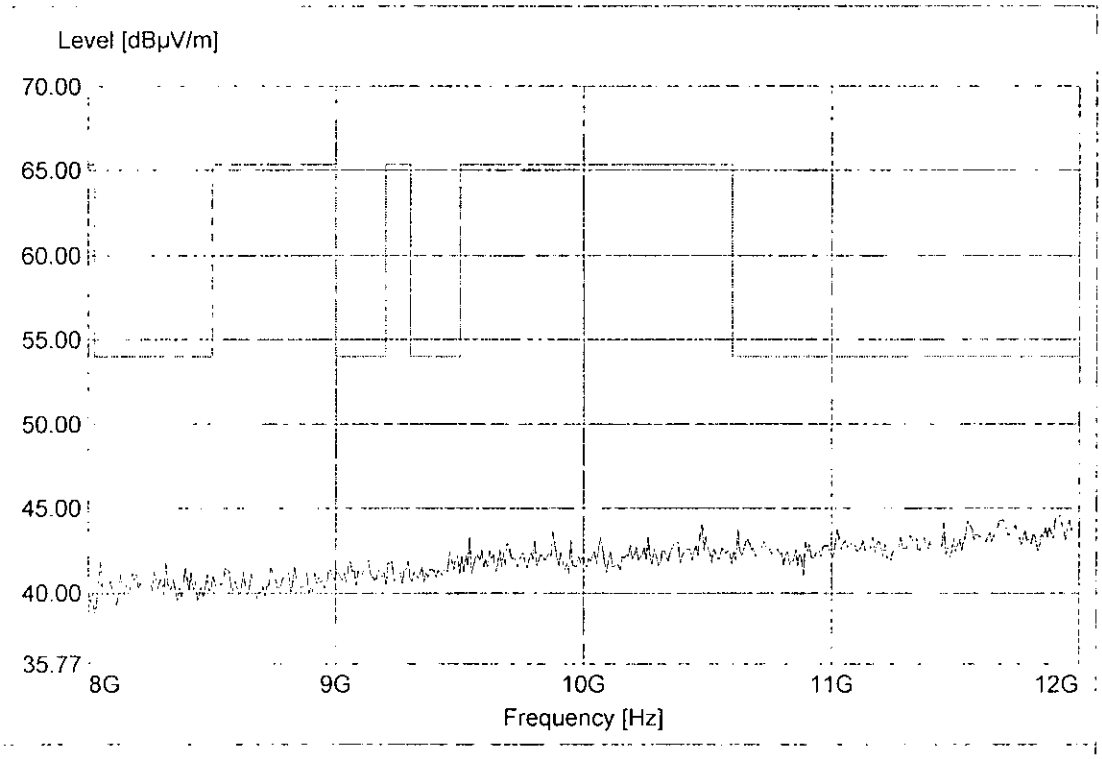
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 11.920GHz, Emax: 44.58dBµV/m, RBW: 1MHz



MES 5. FCC_15247
LIM FCC_restricted

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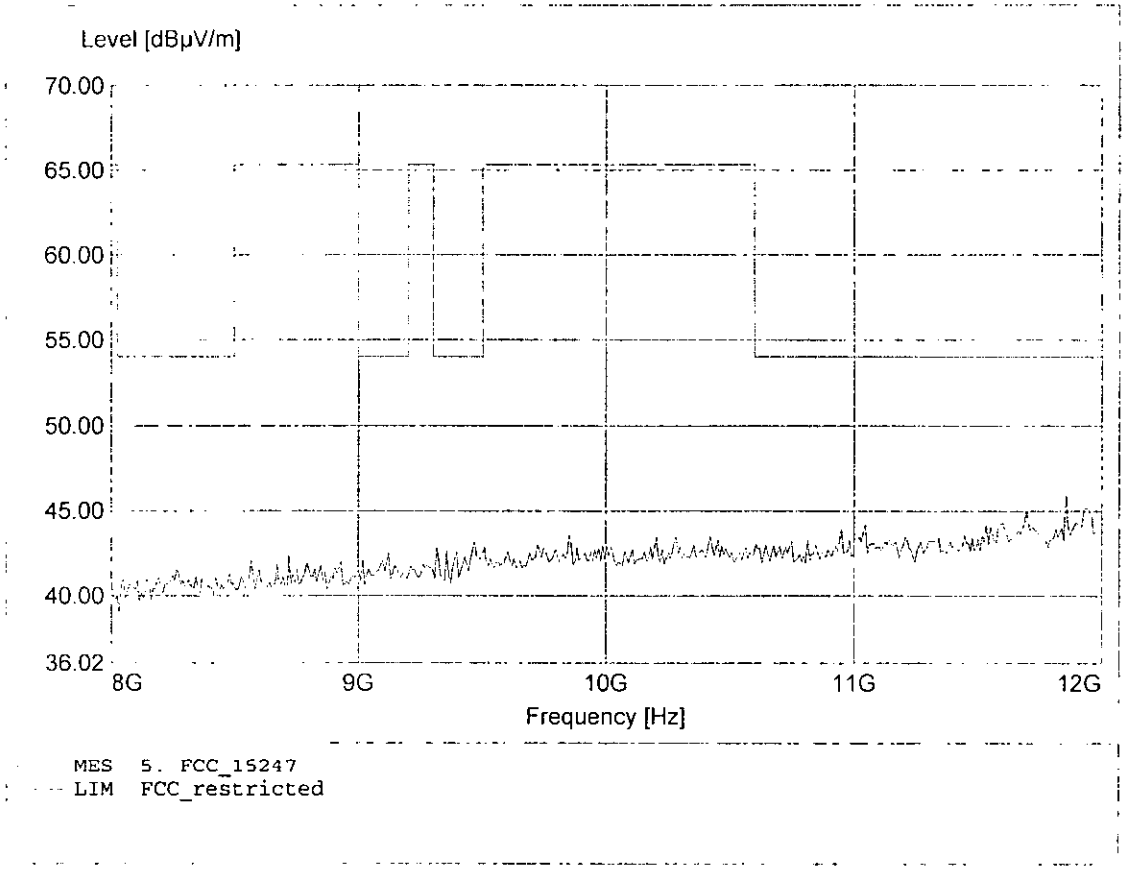
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

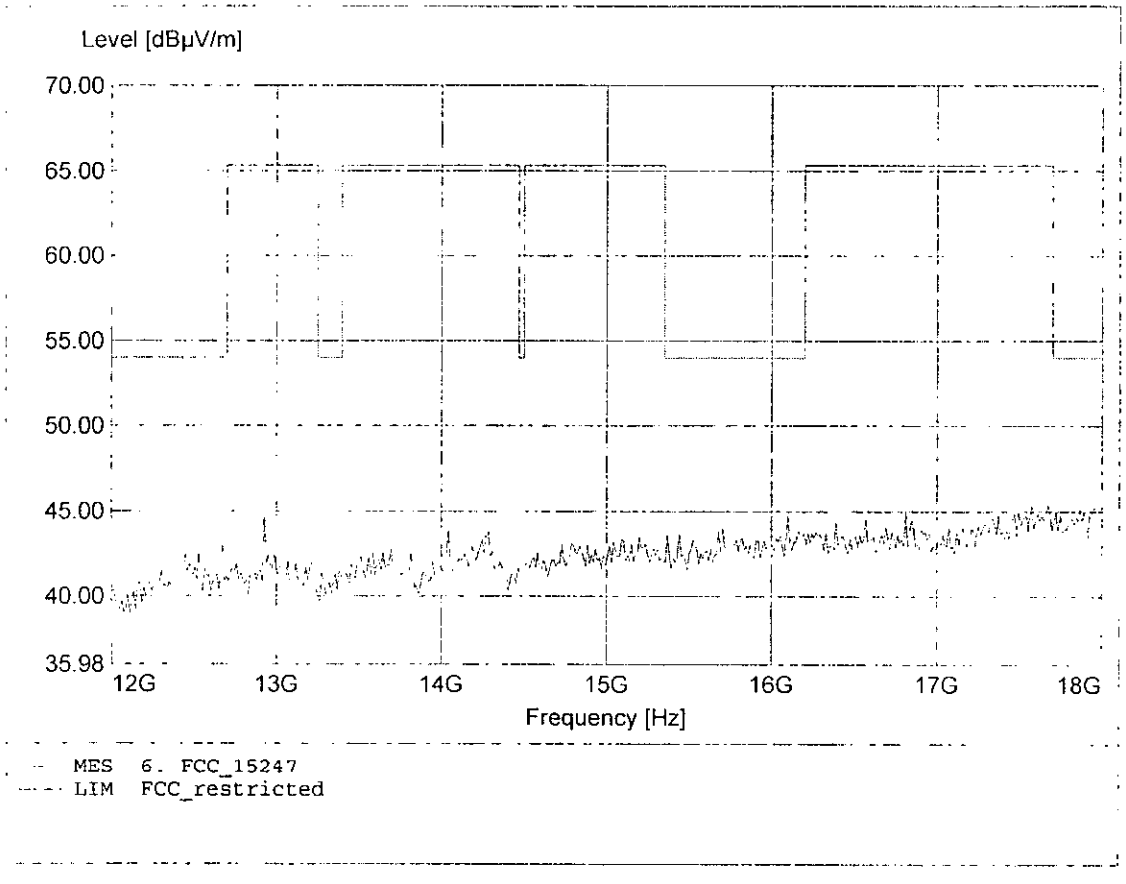
Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 11.856GHz, Emax: 46.09dBµV/m, RBW: 1MHz



Page 1/1 12.11.08 11:34 Overview / Antenna horizontal

Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 17.675GHz, Emax: 45.40dBµV/m, RBW: 1MHz



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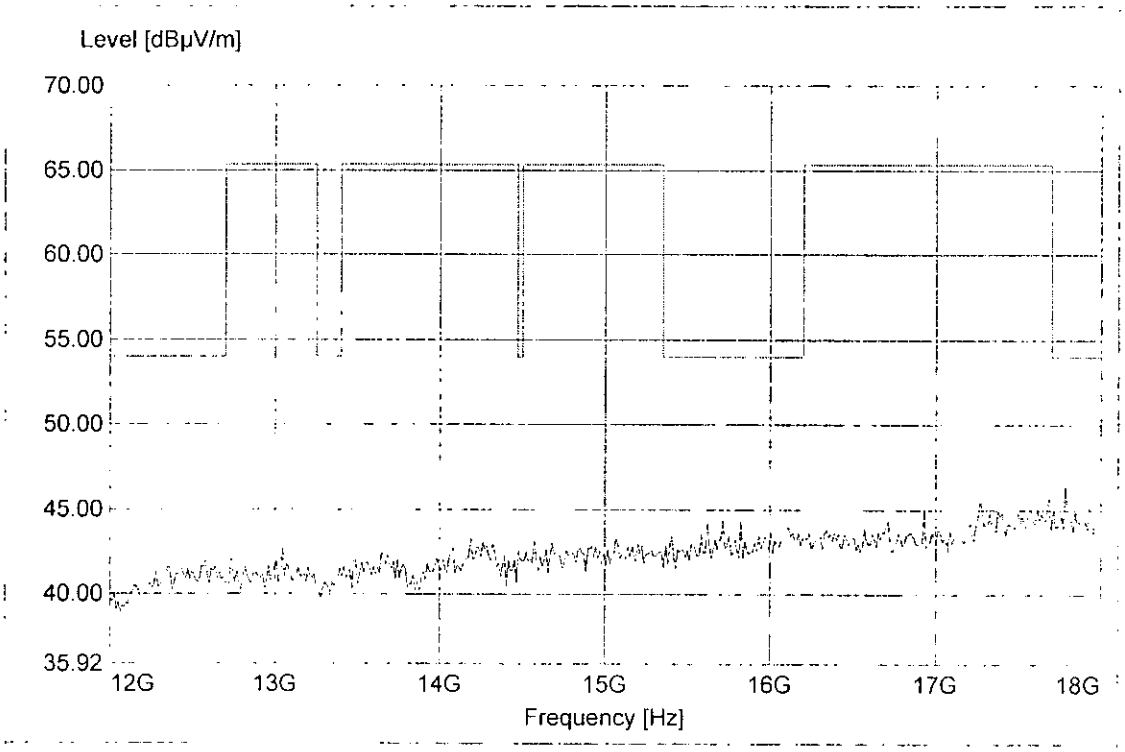
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL 025, ampl.+HP.
Comment 2:	Freq: 17.784GHz, Emax: 46.50dBµV/m, RBW: 1MHz



MES 6. FCC_15247
LIM FCC_restricted

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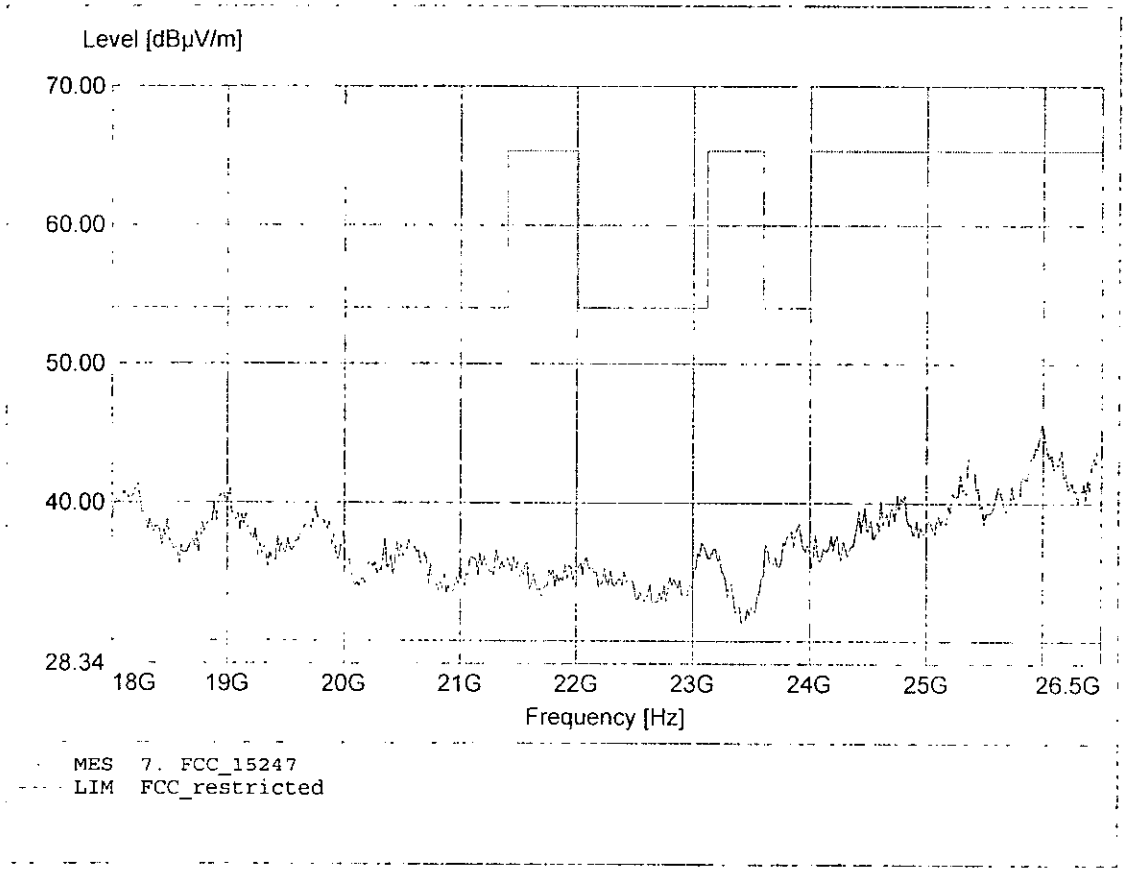
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL025, amplif.
Comment 2:	Freq: 25.989GHz, Emax: 45.71dBµV/m, RBW: 1MHz



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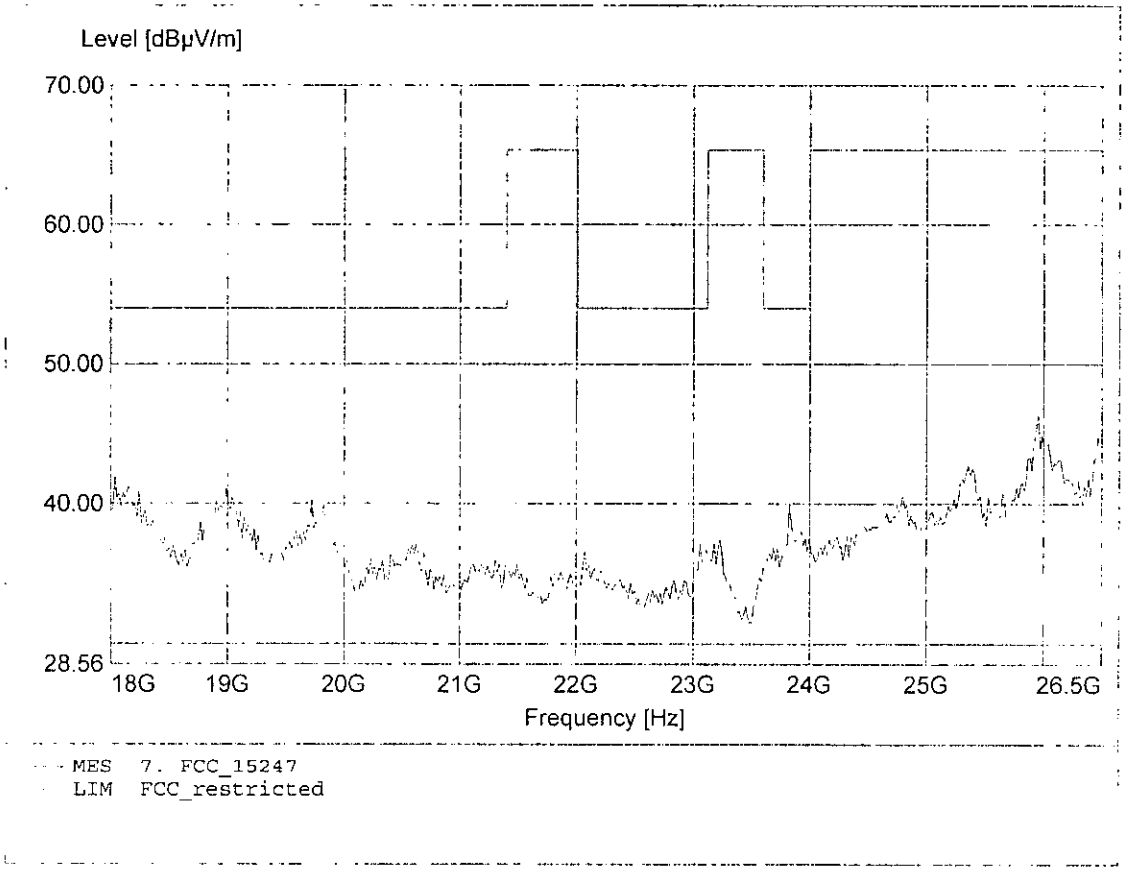
Spurious emissions Field Strength
FCC RULES PART 15, SUBPART C

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2480 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to §15.247, peak detector
Comment 1:	Dist.: 3m, Ant.: HL025, amplif.
Comment 2:	Freq: 25.955GHz, Emax: 46.45dBµV/m, RBW: 1MHz



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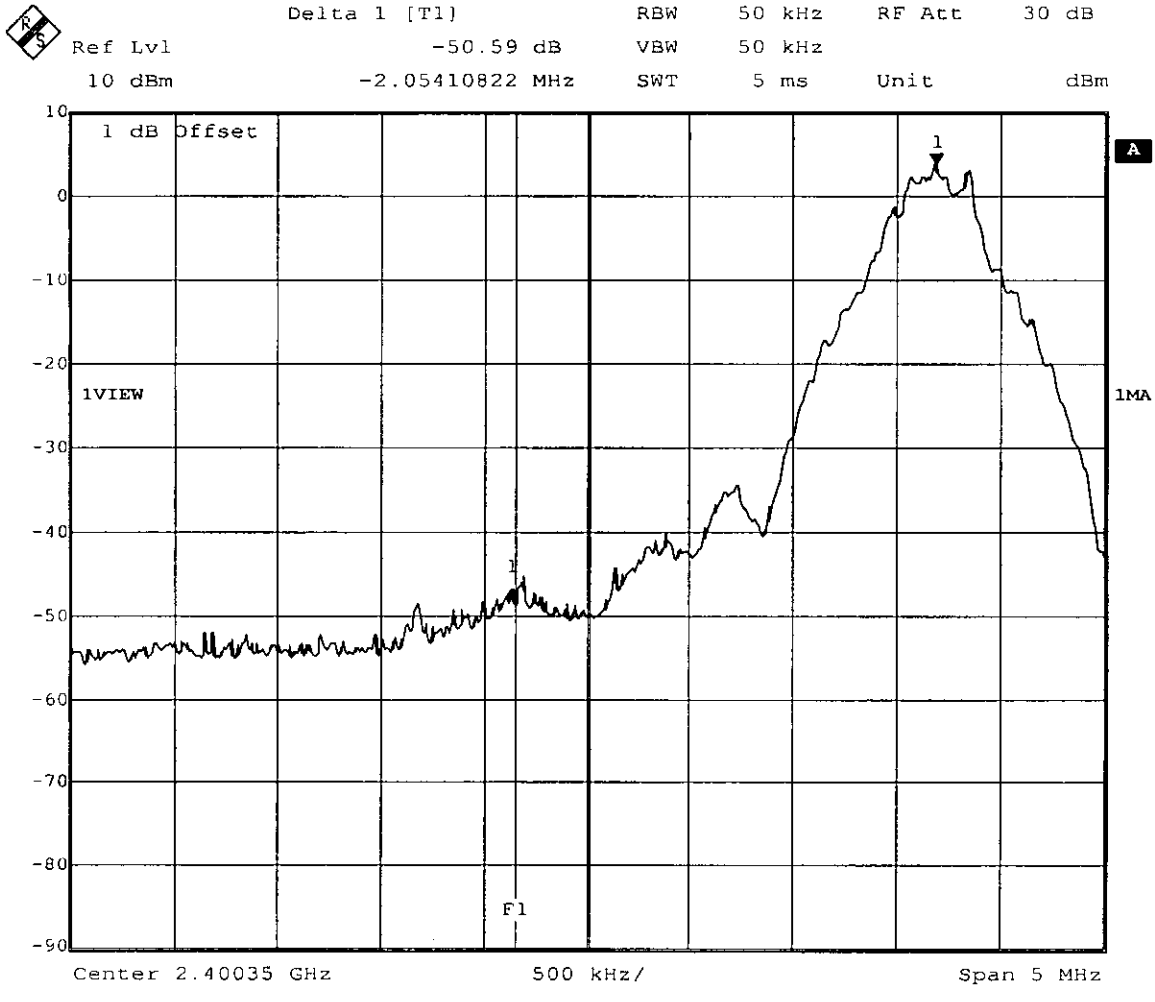
Annex H

Band-edge compliance

FCC part 15.247
Band-edge compliance of RF conducted emissions

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(c)
Comment 1	Band-edge compliance
Comment 2	Channel.: 0 / 2402 MHz
Comment 3	Single frequency mode

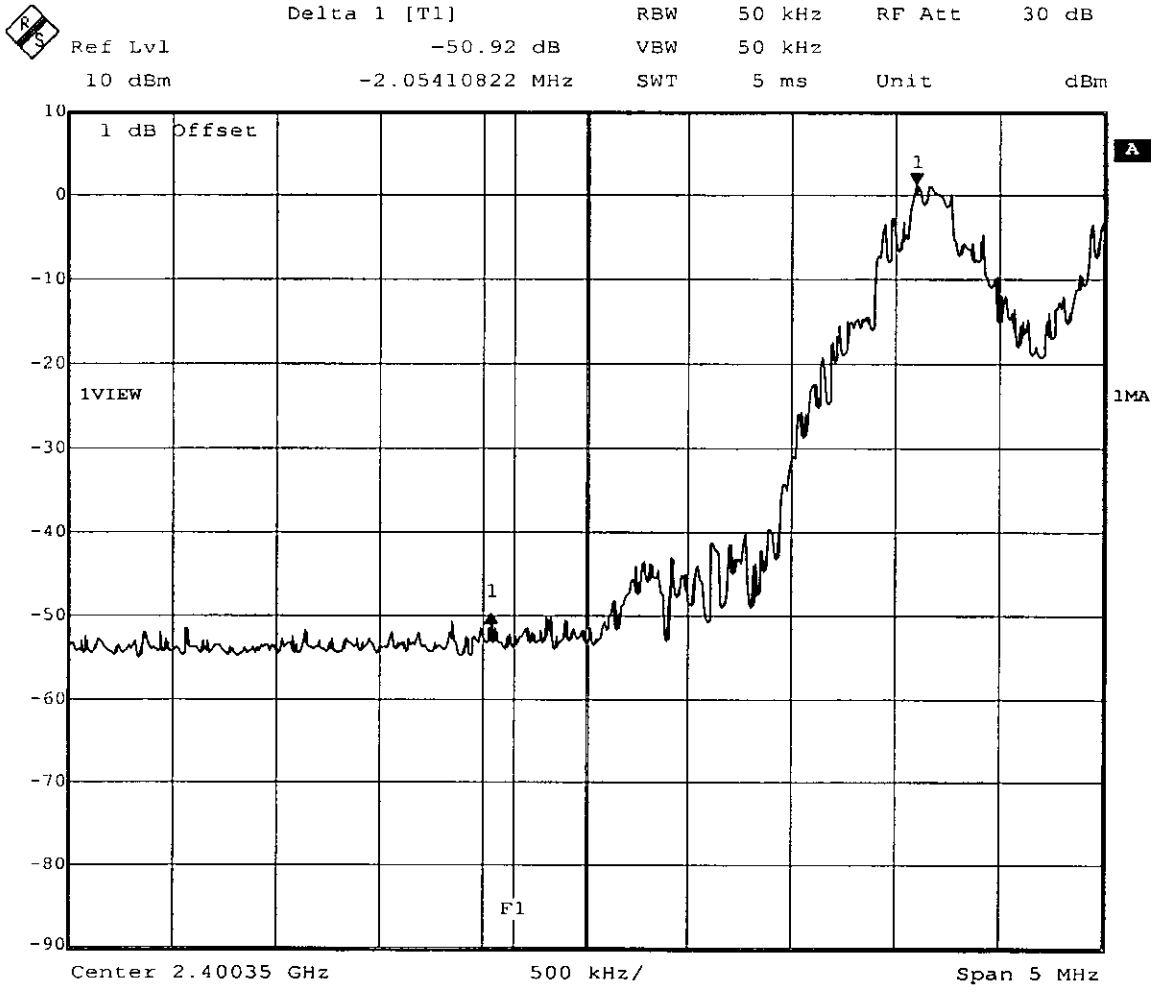


Comment A: Limit: Marker Delta value >20 dB; Result: PASS
Date: 10.NOV.2008 15:05:50

Measurement diagram

FCC part 15.247
Band-edge compliance of RF conducted emissions

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(c)
Comment 1	Band-edge compliance
Comment 2	Channel.: 0 / 2402 MHz
Comment 3	Hopping mode

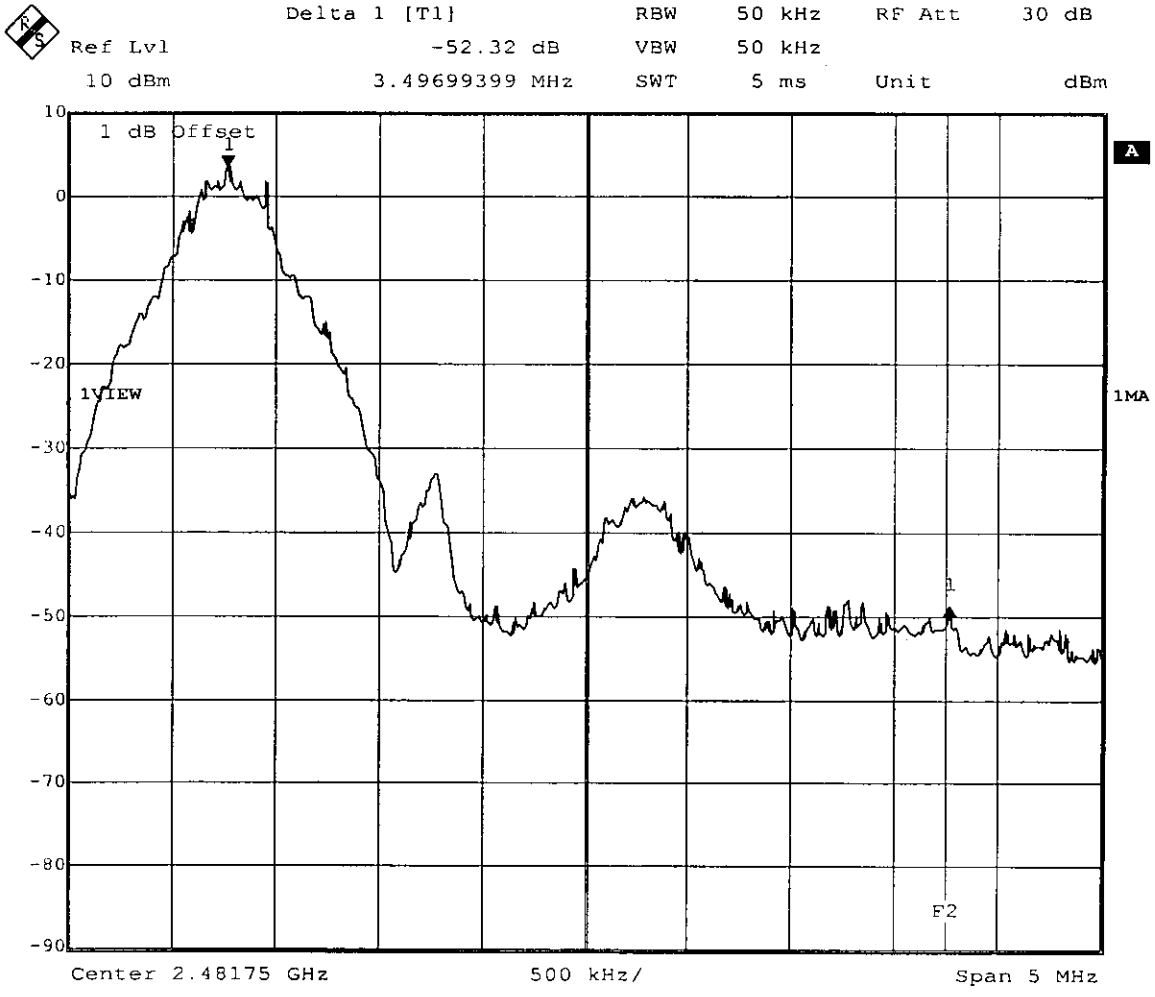


Comment A: Limit: Marker Delta value >20 dB; Result: PASS
Date: 10.NOV.2008 15:09:15

Measurement diagram

FCC part 15.247
Band-edge compliance of RF conducted emissions

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(c)
Comment 1	Band-edge compliance
Comment 2	Channel.: 78 / 2480 MHz
Comment 3	Single frequency mode

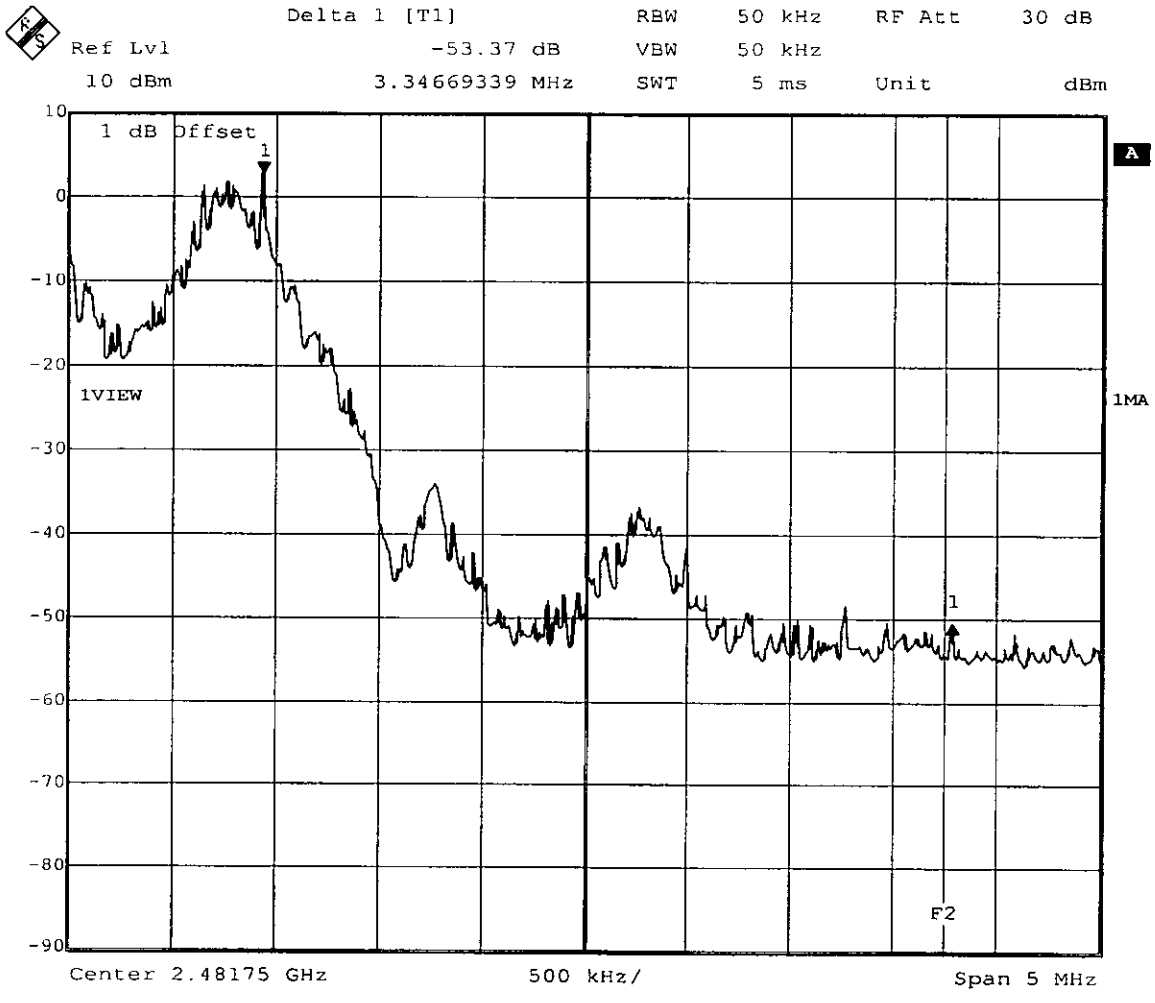


Comment A: Limit: Marker Delta value >20 dB; Result: PASS
Date: 10.NOV.2008 15:07:03

Measurement diagram

FCC part 15.247
Band-edge compliance of RF conducted emissions

EUT	Bluetooth enable stethoscope
Model	M3200
Approval Holder	3M Health Care Patient Assessment Laboratory 3M Medical Products
Temperature / Voltage	23°C / Vnom
Test Site / Operator	Eurofins Product Service GmbH / Mr. Handrik
Test Specification	FCC part 15 section 247(c)
Comment 1	Band-edge compliance
Comment 2	Channel.: 78 / 2480 MHz
Comment 3	Hopping mode



Comment A: Limit: Marker Delta value >20 dB; Result: PASS
Date: 10.NOV.2008 15:10:41

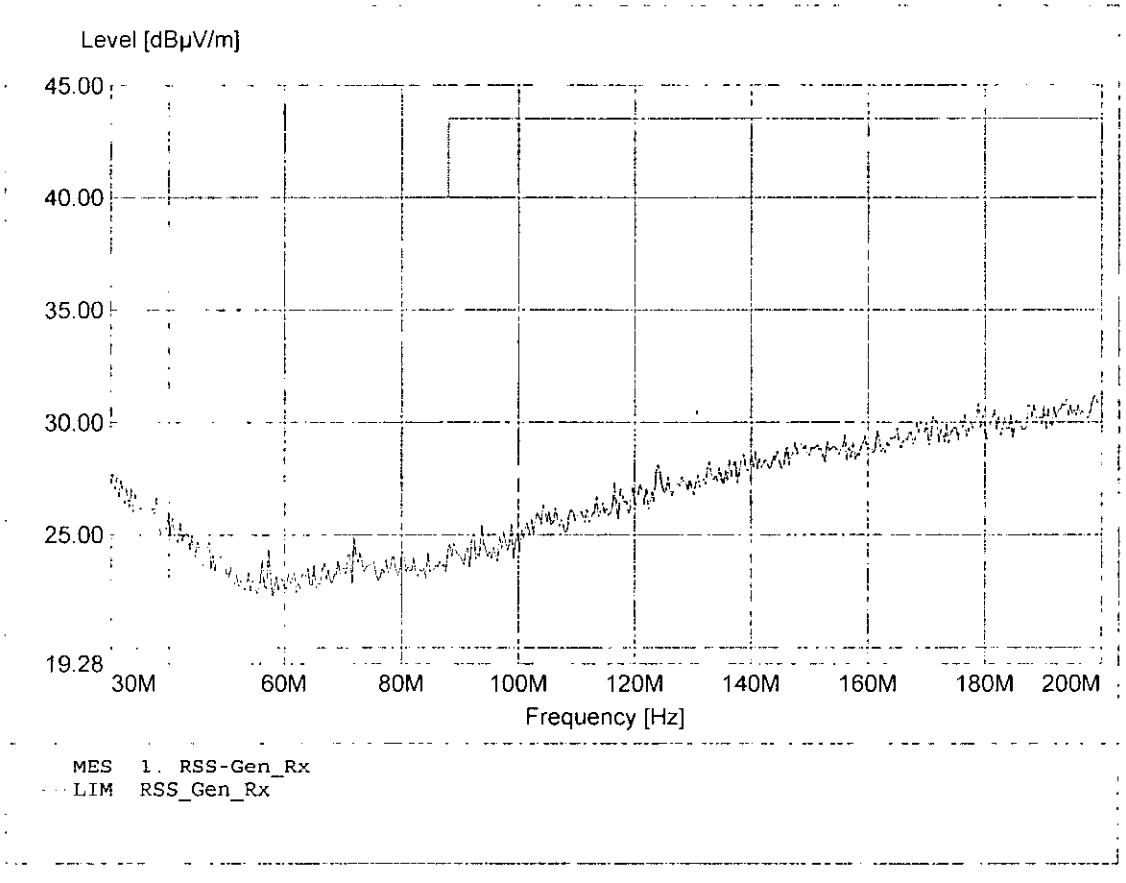
Measurement diagram

Annex I

Receiver spurious emissions

Field Strength under normal conditions
Standards Industry Canada, RSS-GEN

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to RSS-Gen Issue 1
Comment 1:	Dist.: 3m, Ant.: HK 116
Comment 2:	Freq:198.637MHz Emax:31.18dBµV/m RBW: 100 kHz



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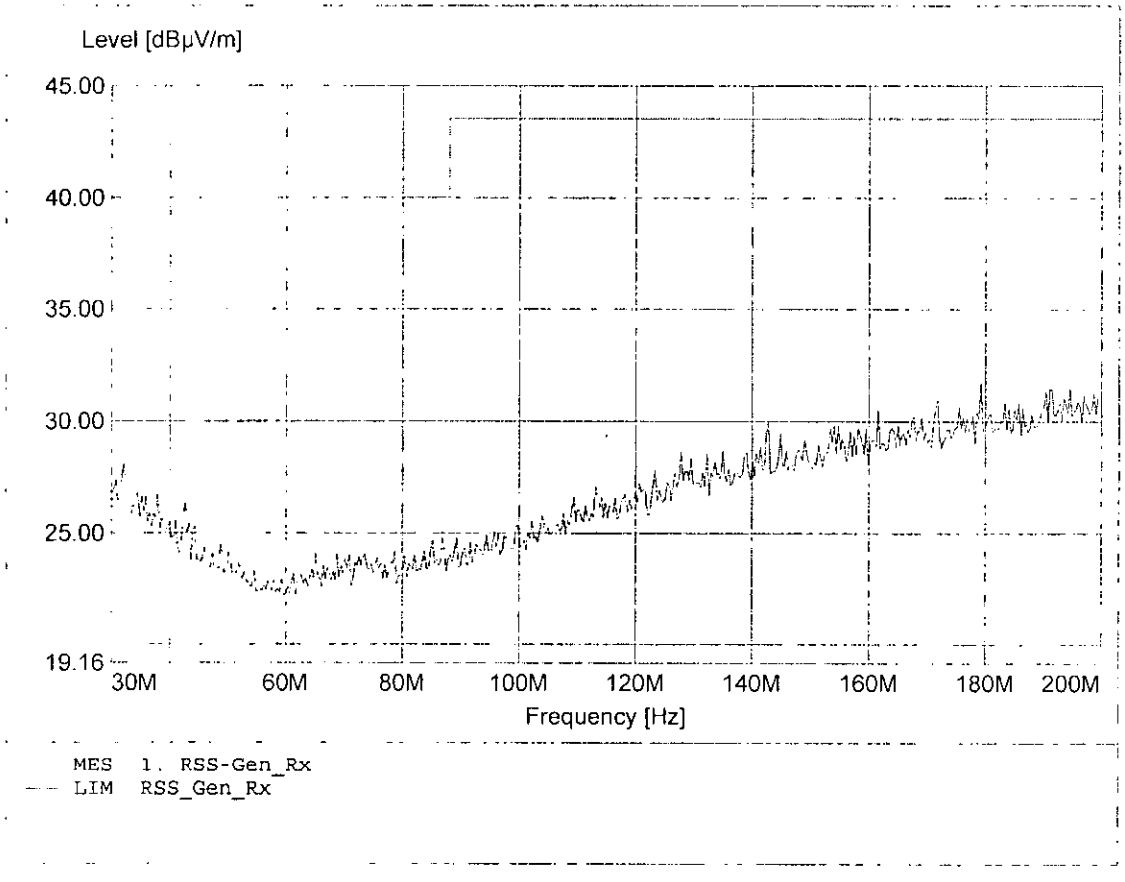
Field Strength under normal conditions
Standards Industry Canada, RSS-GEN

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to RSS-Gen Issue 1
Comment 1:	Dist.: 3m, Ant.: HK 116
Comment 2:	Freq:179.218MHz Emax:31.82dBµV/m RBW: 100 kHz



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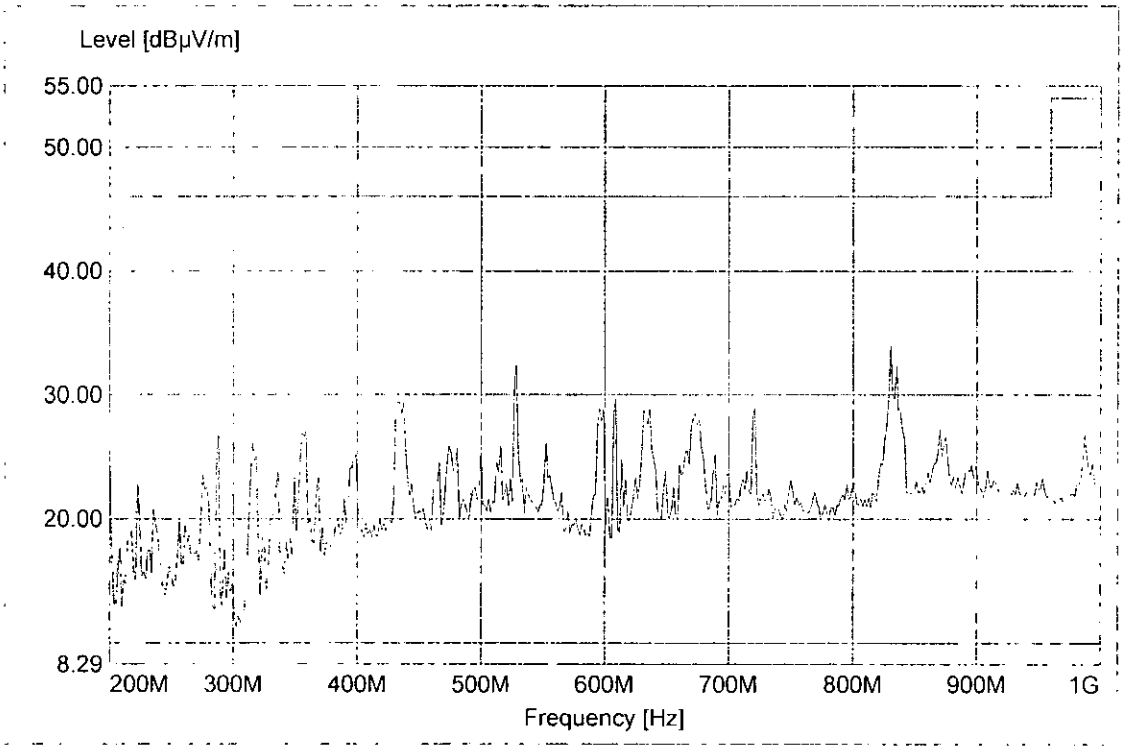
Field Strength under normal conditions
Standards Industry Canada, RSS-GEN

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to RSS-Gen Issue 1
Comment 1:	Dist.: 3m, Ant.: HL 223, ampl.
Comment 2:	Freq:830.060MHz Emax:34.04dBµV/m RBW: 100 kHz

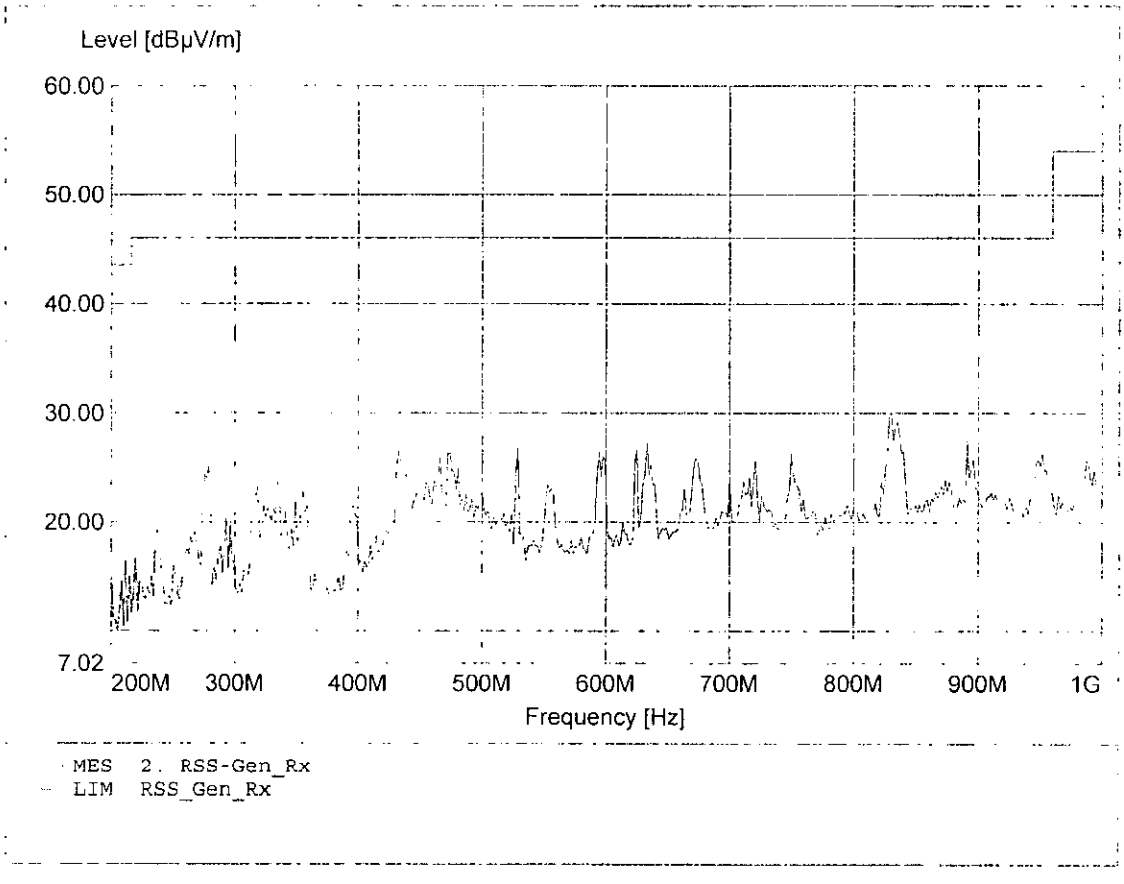


MES 2. RSS-Gen_Rx
LIM RSS_Gen_Rx

Page 1/1 12.11.08 13:20 Overview / Antenna vertical

Field Strength under normal conditions
Standards Industry Canada, RSS-GEN

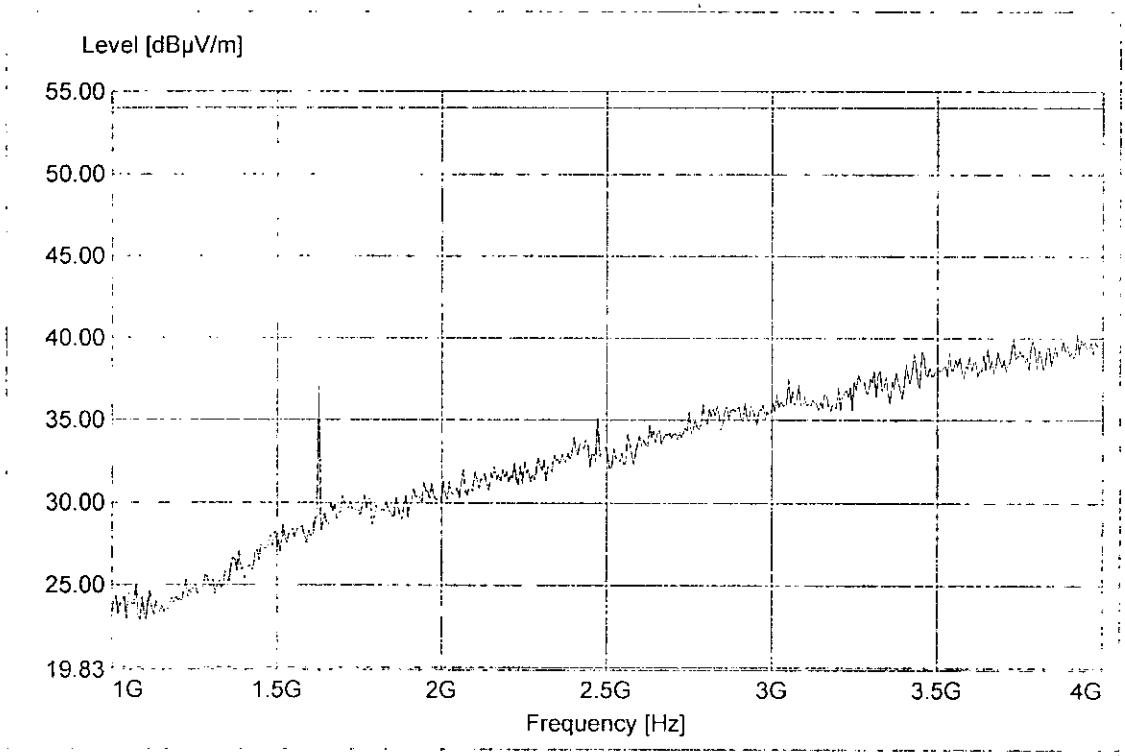
Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to RSS-Gen Issue 1
Comment 1:	Dist.: 3m, Ant.: HL 223, ampl.
Comment 2:	Freq:830.060MHz Emax:30.07dBµV/m RBW: 100 kHz



Page 1/1 12.11.08 13:28 Overview / Antenna horizontal

Field Strength under normal conditions
Standards Industry Canada, RSS-GEN

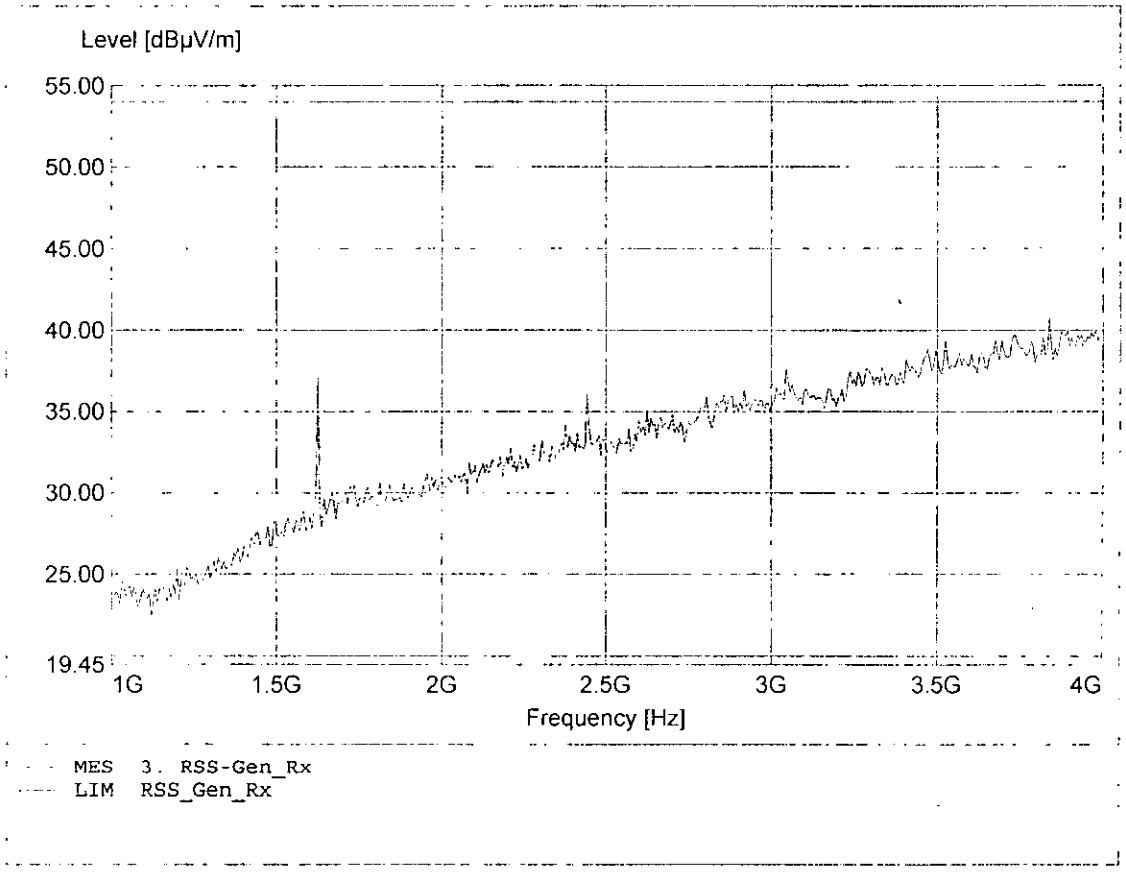
Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to RSS-Gen Issue 1
Comment 1:	Dist.: 3m, Ant.: HL025, ampl.
Comment 2:	Freq:3.922GHz Emax:40.32dBµV/m RBW: 1 MHz



Page 1/1 12.11.08 13:31 Overview / Antenna vertical

Field Strength under normal conditions
Standards Industry Canada, RSS-GEN

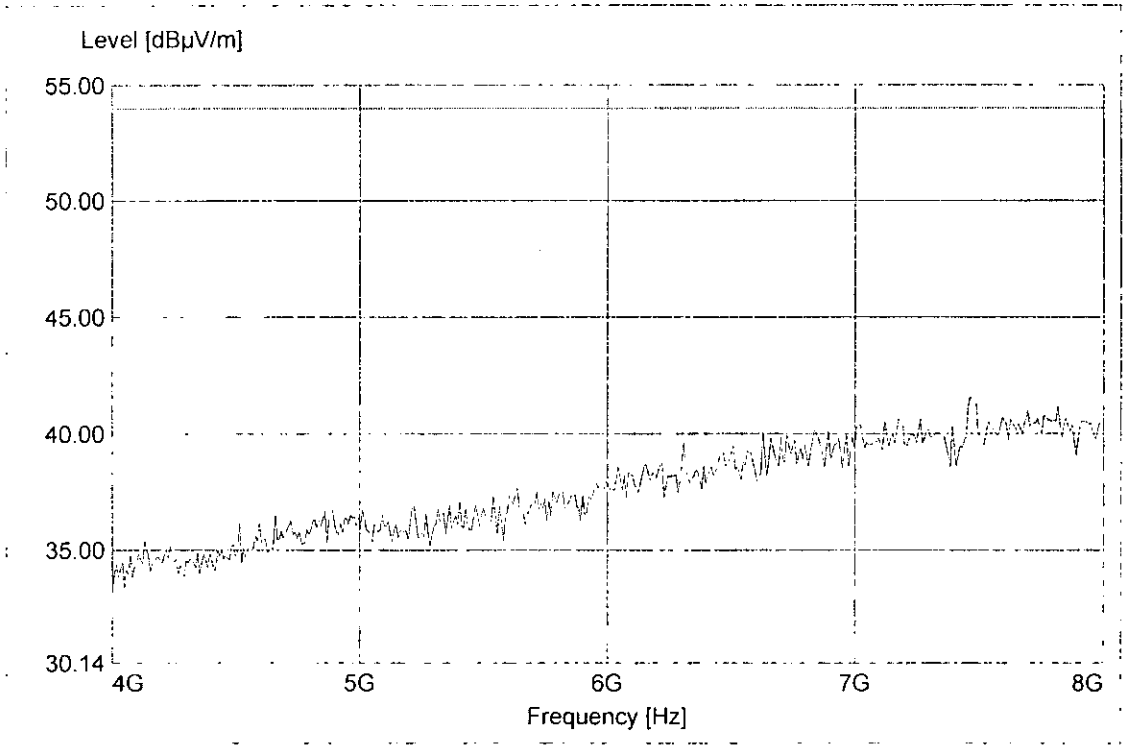
Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to RSS-Gen Issue 1
Comment 1:	Dist.: 3m, Ant.: HL025, ampl.
Comment 2:	Freq:3.838GHz Emax:40.84dBµV/m RBW: 1 MHz



Page 1/1 12.11.08 13:37 Overview / Antenna horizontal

Field Strength under normal conditions
Standards Industry Canada, RSS-GEN

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH./ Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to RSS-Gen Issue 1
Comment 1:	Dist.: 3m, Ant.: HL025, ampl.
Comment 2:	Freq:7.463GHz Emax:41.57dBµV/m RBW: 1 MHz

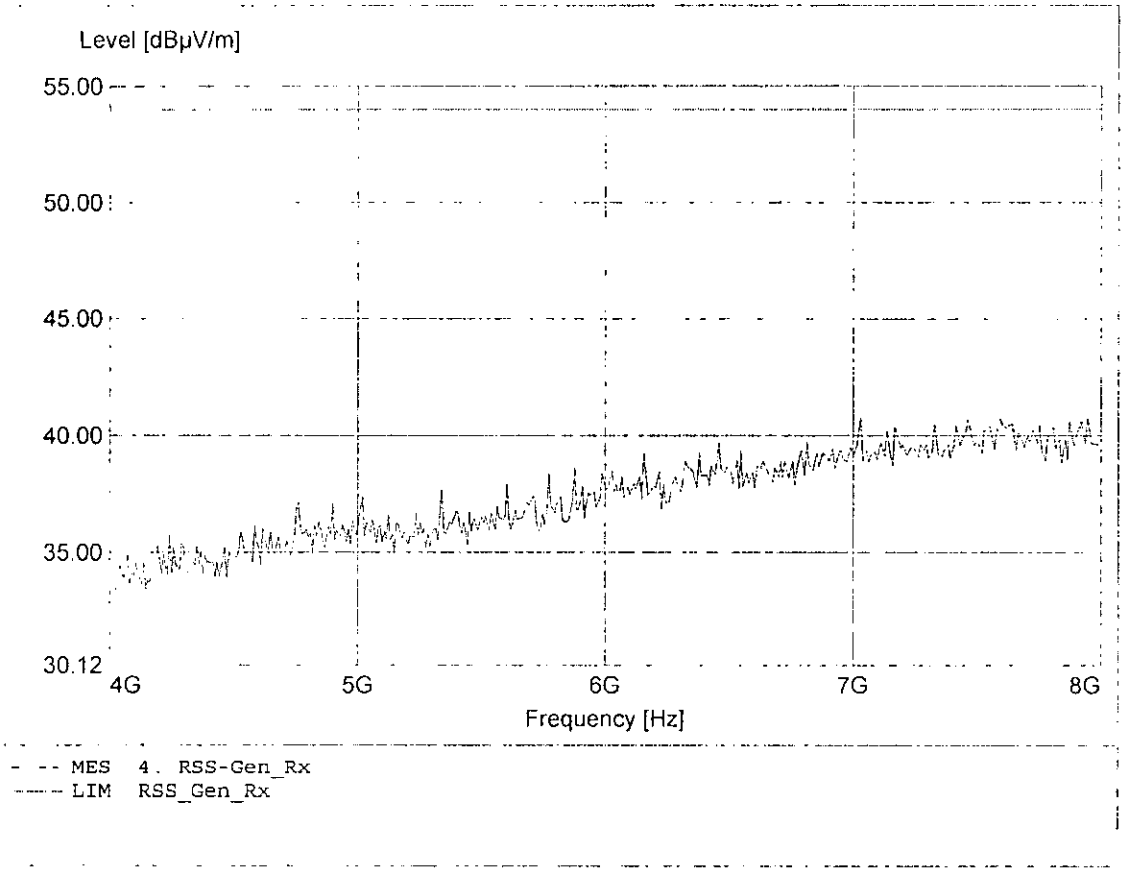


MES 4. RSS-Gen_Rx
LIM RSS_Gen_Rx

Page 1/1 12.11.08 13:35 Overview / Antenna vertical

Field Strength under normal conditions
Standards Industry Canada, RSS-GEN

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Med. Prod.
EUT :	Bluetooth enable stethoscope
Model:	M3200 / 2441 MHz
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Handrik
Test Conditions:	23°C / Unom.: 1.5 V DC
Test Specification:	according to RSS-Gen Issue 1
Comment 1:	Dist.: 3m, Ant.: HL025, ampl.
Comment 2:	Freq:7.030GHz Emax:40.80dBµV/m RBW: 1 MHz



Page 1/1 12.11.08 13:39 Overview / Antenna horizontal

EUROFINS PRODUCT SERVICE GMBH

TEST - REPORT

FCC RULES PART 15 / SUBPART B
IC RSS-GEN ISSUE 2

FCC ID: DGFIPD3200
IC: 458A-IPD3200

Test report no.:

G0M20810-2051-C-1

ACCREDITED
Testing Cert #1983.01

eurofins
Eurofins Product Service GmbH
Storkower Str. 38c, 15526 Reichenwalde,
Germany

Phone +49-33631-888 0
Fax +49-33631-888 660

999

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1 General Information

1.1 Notes

The purpose of conformity testing is to increase the probability of adherence to the essential requirements or conformity specifications, as appropriate.
The tests were carried out and passed in accordance to the standards:

FCC part 15B : September 2007

IC RSS-Gen Issue 2

The complexity of the technical specifications, however, means that full and thorough testing is impractical for both technical and economic reasons.
Furthermore, there is no guarantee that a test sample which has passed all the relevant tests conforms to a specification (only telecommunication products).
Neither is there any guarantee that such a test sample will interwork with other genuinely open systems.
The existence of the tests nevertheless provides the confidence that the test sample possesses the qualities as maintained and that its performance generally conforms to representative cases of communications equipment.

The test results of this test report relate exclusively to the item tested as specified in 1.6.
The test report may only be reproduced or published in full.
Reproduction or publication of extracts from the report requires the prior written approval of the Eurofins Product Service GmbH.

Important Notes:

Proper labeling is required for each device. Devices shall be labeled in accordance with labeling requirements pursuant to section 15.19 and section 2.1074 of the FCC rules.

Devices subject to a Declaration of Conformity shall be uniquely identified by the responsible party. This identification shall not be of a format which could be confused with the FCC Identifier required on certified, notified type accepted or type approved equipment.

The responsible party shall maintain adequate identification records to facilitate positive identification for each device.

The user manual or instruction manual shall included also a warning statement that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Reference Section 15.21

Furthermore information to the user regarding to the interference potential of the device and about simple measures that can be taken to correct interference is required.

Reference Section 15.105

The responsible party must warrant that each unit of equipment marketed under a Declaration of Conformity is identical to the unit tested and found acceptable with the standards and that the records maintained by the responsible party continue to reflect the equipment being produced under the Declaration of Conformity within the variation that can be expected due to quantity production and testing on a statistical basis.

1.2 Operator:

Date	Eurofins Lab.	Name	Signature
18.11.2008		M. Klein	

Technical responsibility for area of testing:

Date	Eurofins	Name	Signature
18.11.2008		J. Zimmermann	

1.3 Testing laboratory

1.3.1 Location

EUROFINS PRODUCT SERVICE GMBH
STORKOWER STR. 38c
D- 15526 REICHENWALDE B. BERLIN
GERMANY
Telephone: + 49 33631 888-00
Telefax: + 49 33631 888-660

1.3.2 Details of accreditation status

DAR ACCREDITED TESTING LABORATORY
DAR-REGISTRATION NUMBER: DAT-P-268/08

RECOGNIZED NOTIFIED BODY EMC
REGISTRATION NUMBER: BNetzA-bS EMV-07/61

RECOGNIZED NOTIFIED BODY R&TTE
REGISTRATION NUMBER: BNetzA-bS-02/51-53

FCC FILED TEST LABORATORY
REG.-NO. 96970

A2LA ACCREDITED TESTING LABORATORY
CERTIFICATE NO. 1983.01

BLUETOOTH QUALIFICATION TEST FACILITY (BQTF)
ACCREDITED BY BLUETOOTH QUALIFICATION REVIEW BOARD

INDUSTRY CANADA FILED TEST LABORATORY
REG. NO. IC 3470A

1.3.3 Test location, where different

Name	: ./.
Street	: ./.
Town	: ./.
Country	: ./.
Telephone	: ./.
Fax	: ./.

1.4 Details of applicant

Name	: 3M Health Care Patient Assessment Laboratory 3M Medical Products
Street	: 3M Center, Building 270-4N-09
Town	: Maplewood, MN 55144-1000
Country	: USA
Telephone	: +1 651-733-4531
E-mail	: tedrummond@mmm.com
Contact	: Mr. T.E. Drummond
Telephone	: +1 651-733-4531

1.5 Application details

Date of receipt of application	: 05.11.2008
Date of receipt of test item	: 05.11.2008
Date of test	: 11.11.2008

1.6 Test item

1.6.1 Description of test item

Type of product	: Bluetooth enabled stethoscope
Type identification	: M3200
Serial number	: without
Photos	: Please find in Annex.
Power supply	: 1.5 V DC
Equipment class	: JBP – Computing Device Peripheral

1.6.2 Manufacturer (if different from applicant in point 1.4)

Name
Street
Town
Country

(b) (4) [redacted]

1.6.3 Frequency behavior

Highest clock Frequency	< 200 MHz

1.7 Test standards

FCC part 15B : September 2007
IC RSS-Gen Issue 2 : June 2007

2 Technical test

2.1 Summary of test results

No deviations from the technical specification(s) were ascertained in the course of the tests performed. ☒

or

The deviations as specified in 2.3 were ascertained in the course of the tests performed. ☐

2.2 Test environment

Temperature	: 22 ° C
Relative humidity content	: 43 %
Air pressure	: 1007 hPa
Details of power supply	: 1.5 V DC
Other parameters	: ./.

2.3 Test results

☒ 1st test ☐ test after modification ☐ production test

Test Emission / Immunity			Done	Test passed	Test failed
Conducted Emission	FCC part 15.107	RSS-Gen 7.2.2	☐	☐	☐
Radiated Emission	FCC part 15.109	RSS-Gen 7.2.3	☒	☒	☐

2.4 Test equipment utilized

No.	Test Equipmen	Type	Manufacturer
ETS 0001	ESD Gun	SESD 30000	Schlöder
ETS 0008	Antenna	Loop antenna	Siemens
ETS 0012	Biconical Antenna	HK 116	R & S
ETS 0013	LPD Antenna	HL 223	R & S
ETS 0014	Log Periodical Antenna	HL 025	R & S
ETS 0038	RF amplifier	150L	Amplifier Research
ETS 0032	Controller	HD 050	Heinrich Deisel
ETS 0039	Absorbing clamp	MDS 21	R & S
ETS 0040	Artificial Mains Network	ESH3-Z5	R & S
ETS 0041	T-Artificial Mains Network	ESH3-Z4	R & S
ETS 0042	Artificial Mains	ESH3-Z6	R & S
ETS 0045	Vehicle LISN	NNBM 8126D	Schwarzbeck
ETS 0052	Audio analyzer	UPA 4	R & S
ETS 0056	Ultra Compact Simulator	UCS 500 M4	EM Test
ETS 0057	Motor Variac	MV 2616	EM Test
ETS 0058	Capacitive coupling clamp	E 502 B	Keytek/ EMC
ETS 0059	Kikusui amplifier	PCR 2000L	Keytek/ EMC
ETS 0064	CDN IEC 61000-4-6	-	Keytek/ EMC
ETS 0066	EM Injection Clamp		FCC/ EMC
ETS 0076	Feeding bridge A	SBA 1000	ESP
ETS 0082	PC system		Esotronic
ETS 0085	Shielded room	SR 1	Frankonia
ETS 0086	Semi-Anechoic chamber	AC 1	Frankonia
ETS 0088	Color TV pattern Generator	PM 5518-TX VPS	Philips
ETS 0092	Power Amplifier	150W1000	AR Amplifier Research
ETS 0102	CDN	M3-801/6	MEB
ETS 0103	Magnetic field test set	MF1000	EMC-Partner
ETS 0148	RF Current Probe	F-65	FCC
ETS 0155	Signal Generator	SMG	R & S
ETS 0157	TV and Sat-Signalgenerator	VTG 700	Grundig
ETS 0161	Harmonic / Flicker Analyzer	HFA 3000	Schlöder
ETS 0178	Open area test side	10m	ETS
ETS 0233	Direction coupler	RK 100	MEB
ETS 0276	Audio Analyzer	UPL 16	R & S
ETS 0282	RF bridge 75 Ohm	86207 A	HP
ETS 0287	EMI Test receiver	ESHS10	R & S
ETS 0288	Artificial mains	ESH2-Z5	R & S
ETS 0292	RF Generator	SMHU	R & S
ETS 0348	RF Millivolt meter	URV 55	R & S
ETS 0300	RF amplifier	75 A 250	Ar
ETS 0348	RF Millivolt meter	URV 55	R & S
ETS 0401	MPEG2 Generator	DVG	R & S
ETS 0402	TV Messender	SFQ	R & S
ETS 0409	Stripline	DC220	Schwarzbeck
ETS 0428	4-WIRE ISN with B1	ENY41	R & S
ETS 0448	RF Power Amplifier	AR 60S1G3	AR Amplifier Research
ETS 0472	Antenna	BTA-H	Frankonia
ETS 0474	EMI Test Receiver	ESCS 30	R&S
ETS 0485	Radio Communication Tester	CMU 200	R&S

2.4.1 Conducted Emission

2.4.1.1 Test Equipment

a) Artificial mains (ESH3-Z5)
For your reference please find it in our test equipment list at page 10 as number: **40.**
b) Artificial mains (ESH3-Z4)
For your reference please find it in our test equipment list at page 10 as number: **41.**
c) Test receiver (ESHS10)
For your reference please find it in our test equipment list at page 10 as number: **01.**
d) Monitoring System
For your reference please find it in our test equipment list at page 10 as number: **71.**
e) Inter phone System
For your reference please find it in our test equipment list at page 10 as number: **72.**
f) Shielded room
For your reference please find it in our test equipment list at page 10 as number: **85.**

2.4.1.2 Test Procedures

- Test configuration

The test configuration is contained inside of a shielded chamber and corresponds to the standard ANSI C.63.4: 2003. The equipment under test is placed in the facility on a wooden table 0.8m high. The equipment under test is connected with the artificial mains network (AMN) in a distance of 0,8m and also 0,8m from other subassembly and metallic area. The measurement receiver is placed in a special room adjacent to the chamber. The observation of the equipment under test is realized by 3 video cameras and by a microphone.

- Test parameters and marginal conditions

The tests are carried out with nominal impedance by 50 Ω / 50 μH of the AMN in a frequency range 150 kHz to 30 MHz. This measurement was transacted first with instrumentation using an average and peak detector and a 10 kHz bandwidth. If the peak detector achieves a calculated level, the measurement is repeated by an instrumentation using a quasi-peak detector,
Further information please find in test report.

2.4.2 Spurious Emission

2.4.2.1 Test Equipment

a) Antenna (HK116)
For your reference please find it in our test equipment list at page 10 as number: **12.**
b) Antenna (HL223)
For your reference please find it in our test equipment list at page 10 as number: **13.**
c) Video camera system
For your reference please find it in our test equipment list at page 10 as number: **71.**
d) Interphone System
For your reference please find it in our test equipment list at page 10 as number: **72.**
e) Semi anechoic chamber
For your reference please find it in our test equipment list at page 10 as number: **86.**
f) EMI test receiver ESCS-30
For your reference please find it in our test equipment list at page 10 as number: **474.**

2.4.2.2 Test Procedures

- Test configuration

The test configuration corresponds to the standard ANSI C 63.4: 2003. The equipment under test is placed on a non metallic table with 0,8 m height. The power supply and the RF connection points are close to the equipment under test at the floor inside a connection box. The cables to this connection box are shielded and below the double floor. The receiving antenna is placed in a height at 1,0 to 4,0 m, in a distance of 10 m. The measurement receiver is placed in a special room. The observation of the equipment under test is realized by 3 video cameras and by a microphone.

- Test parameters and marginal conditions

The test are carried out with horizontal and vertical polarization of the antenna in a frequency range of 30 MHz to 5 000 MHz. Further information please find in the test protocol.

2.5 Test protocols

Conducted Emission

Emission

Standard : FCC part 15.107; RSS-Gen 7.2.2

Reg.-no. : G0M20810-2051-C-1

Device : M3200

Date : 18.11.2008

Class : B

Frequency Range	Limit dBµV		Passed	Failed	Number of rechecks
	Quasi-peak	Average			
150 kHz - 500 kHz AC	66 to 56*	56 to 46*	☐	☐	0
500 kHz - 5 MHz AC	56	46	☐	☐	0
5 MHz - 30 MHz AC	60	50	☐	☐	0

* Decreases with logarithm of the frequency

Uncertainty: $U_{lab(cond)}$ = 3.8 dB.

Comment: not required.

Radio Noise Field Strength

Emission

Standard : FCC part 15.109; RSS-Gen 7.2.3
Reg.-no. : G0M20810-2051-C-1
Device : M3200
Date : 18.11.2008
Class : B

Frequency Range Polarization	Limit µV/m	Passed	Failed	Number of rechecks
30 MHz - 88 MHz	90	☒	☐	0
88 MHz - 216 MHz	150	☒	☐	0
216 MHz - 960 MHz	210	☒	☐	0
960 MHz - 5000 MHz	300	☒	☐	0

Uncertainty: $U_{lab(rad)}$ = 5.3 dB

Comment:: Above 1 GHz no relevant disturbances.
See attached diagrams in Annex B.

2.6 Equipment Modification

No modifications were installed by Eurofins Product Service GmbH.

3 Normative references

/1/ FCC part 15: September 2007
Radio Frequency Devises

/2/ CISPR 22: 2006
Limits and Methods of Measurement of Radio Interference Characteristics of Information Technology Equipment

/3/ ANSI C 63.4: 2003
American National Standard for Methods of Measurement of Radio-Noise Emission from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz

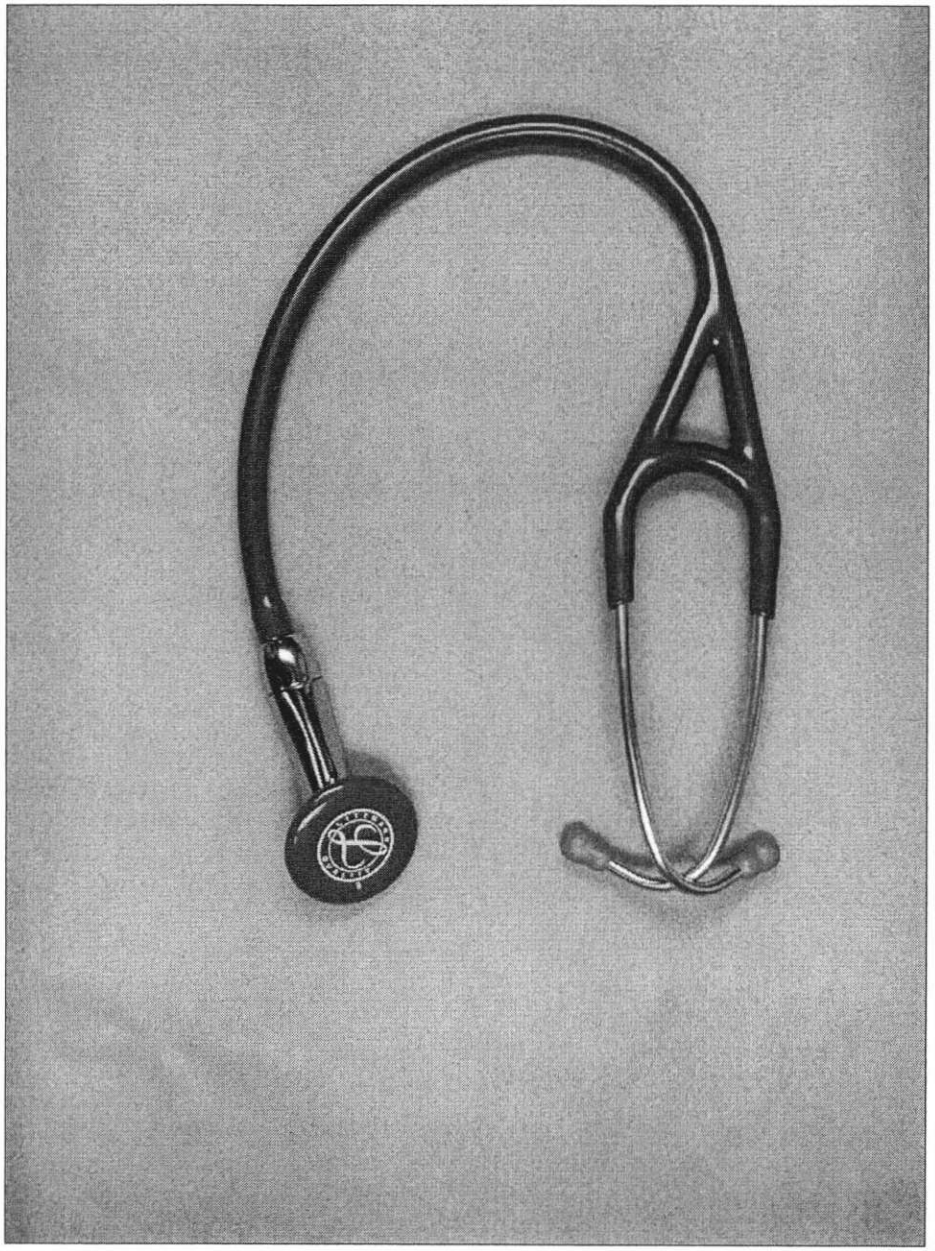
/4/ IC RSS-Gen Issue 2 June 2007
General Requirements and Information for the Certification of Radio communication Equipment

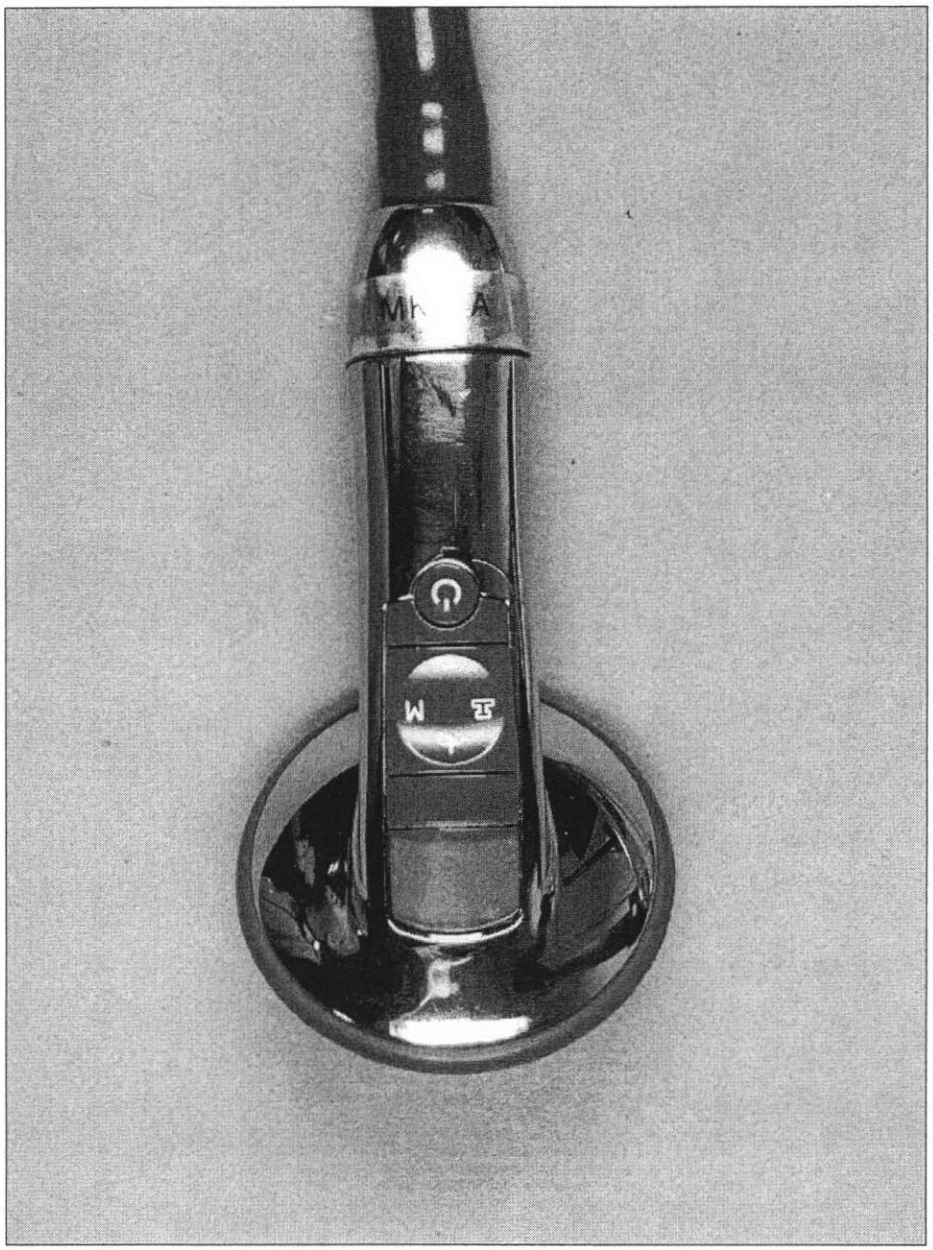
Annex A

Pictures

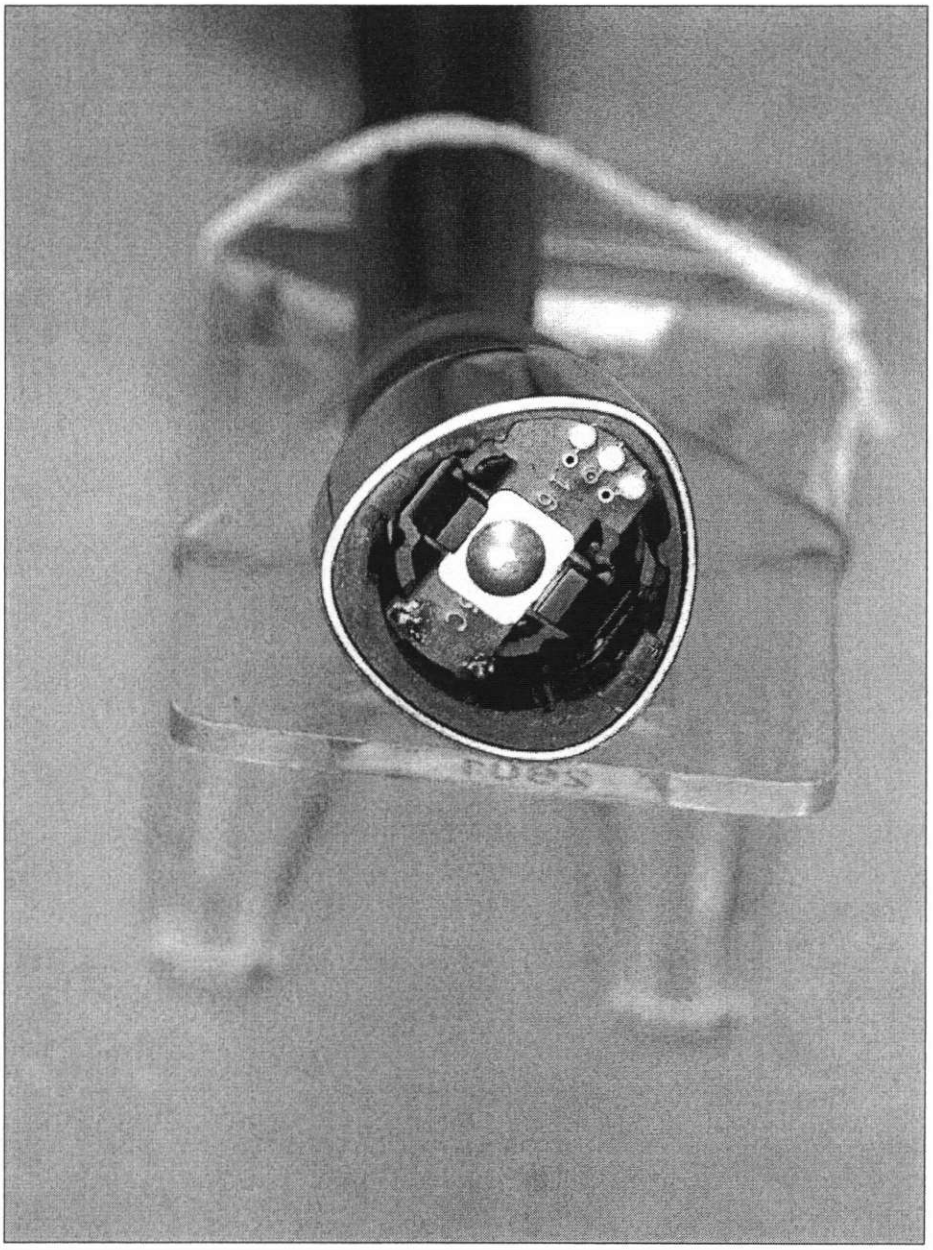
Annex A

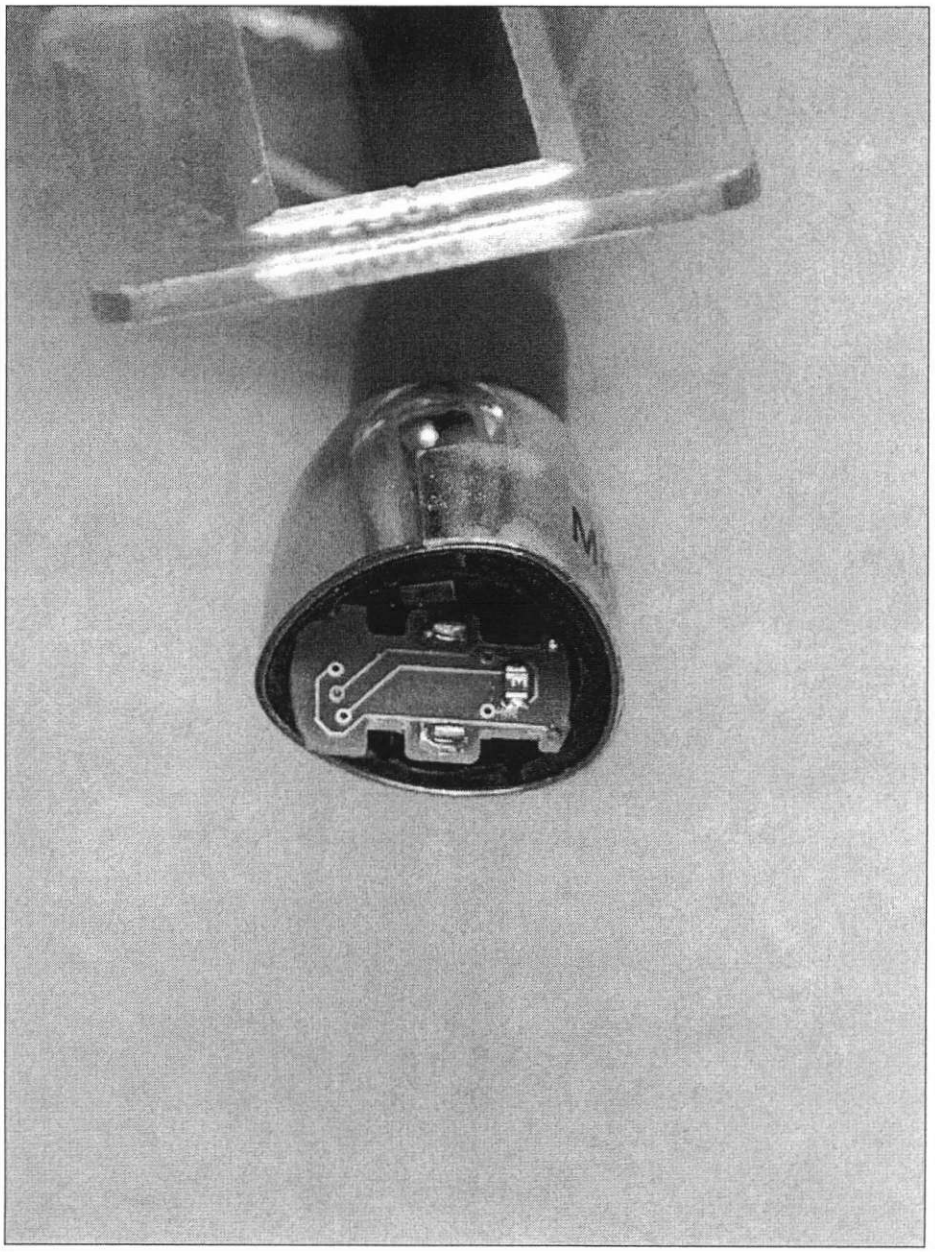
Pictures

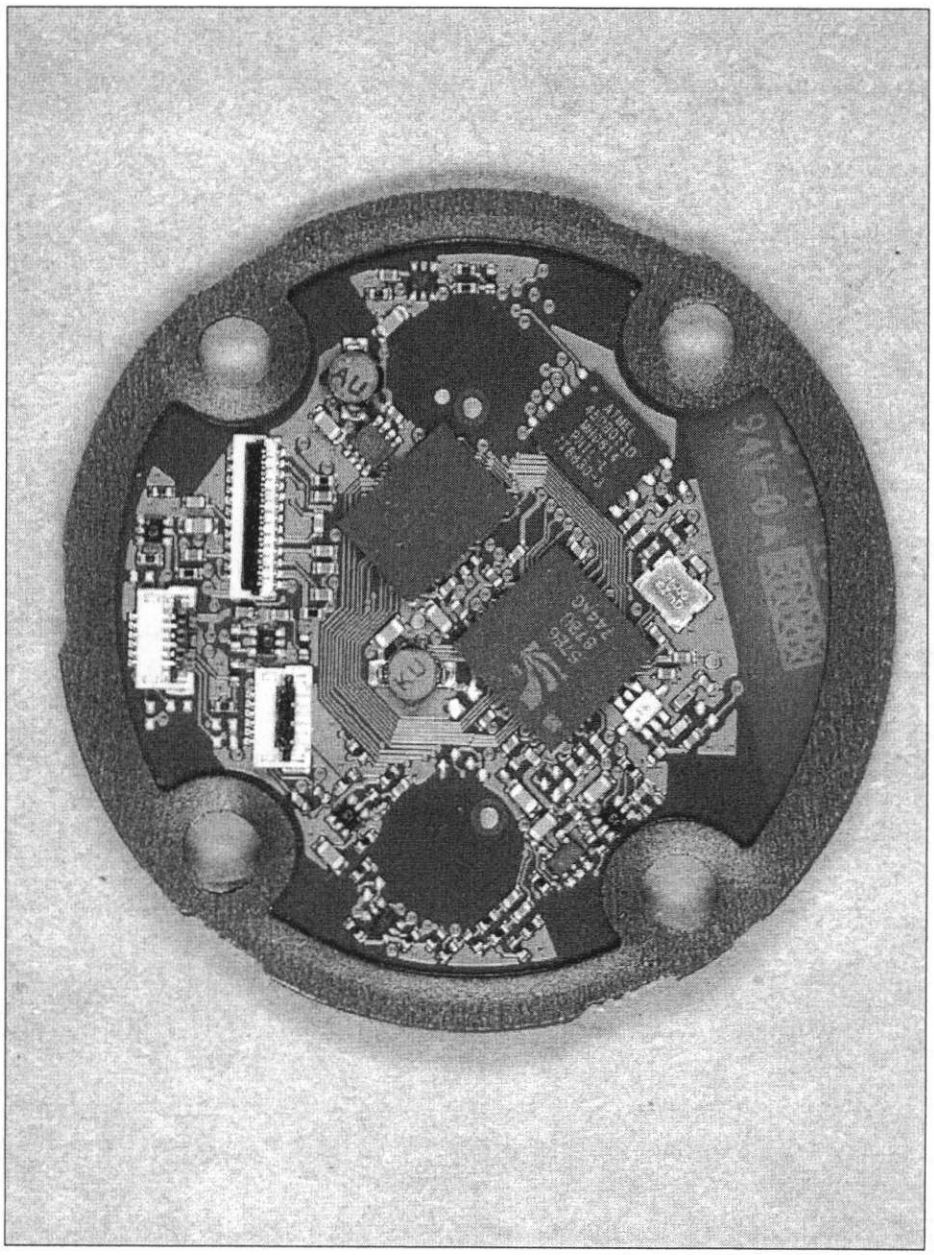


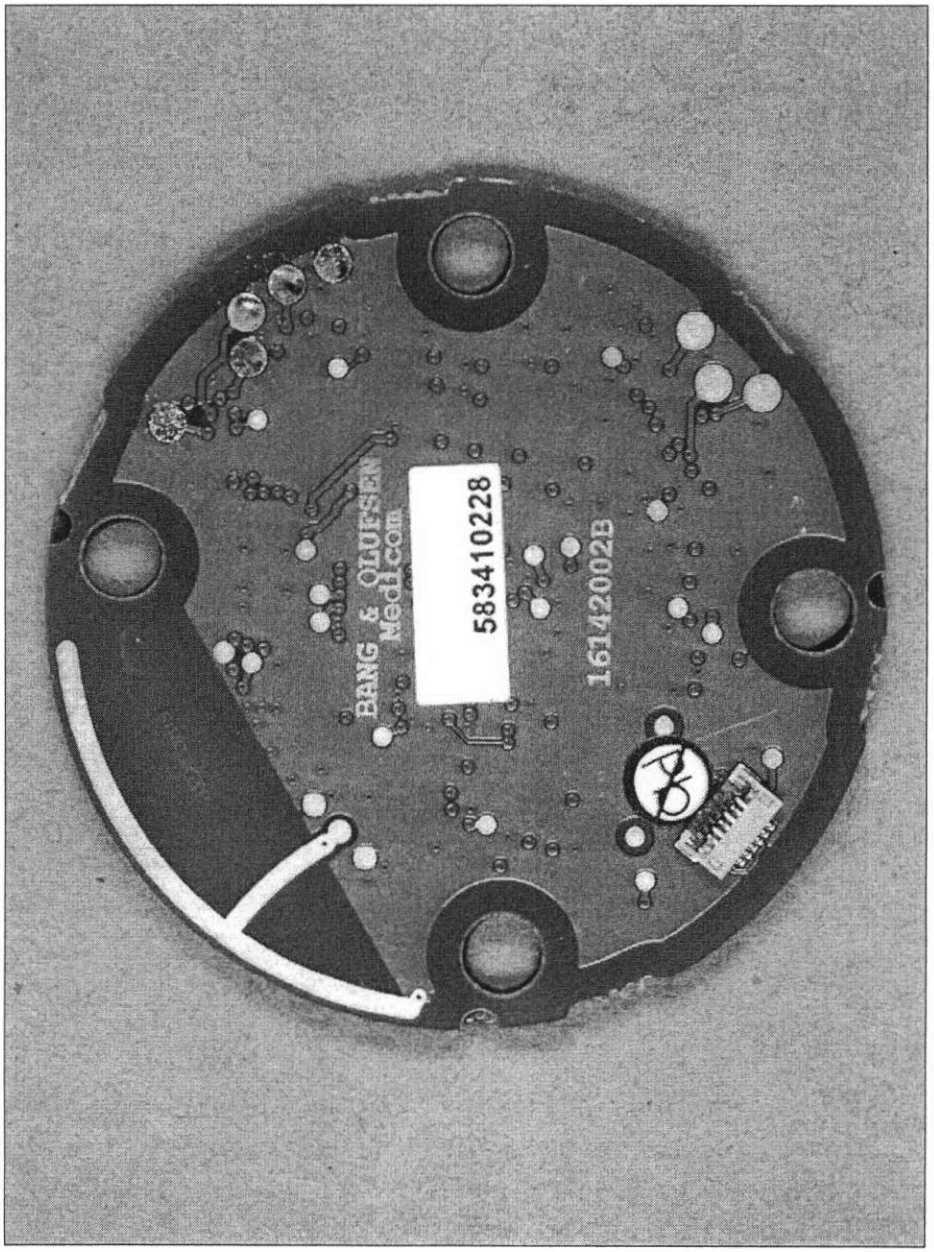

Mh
A
W

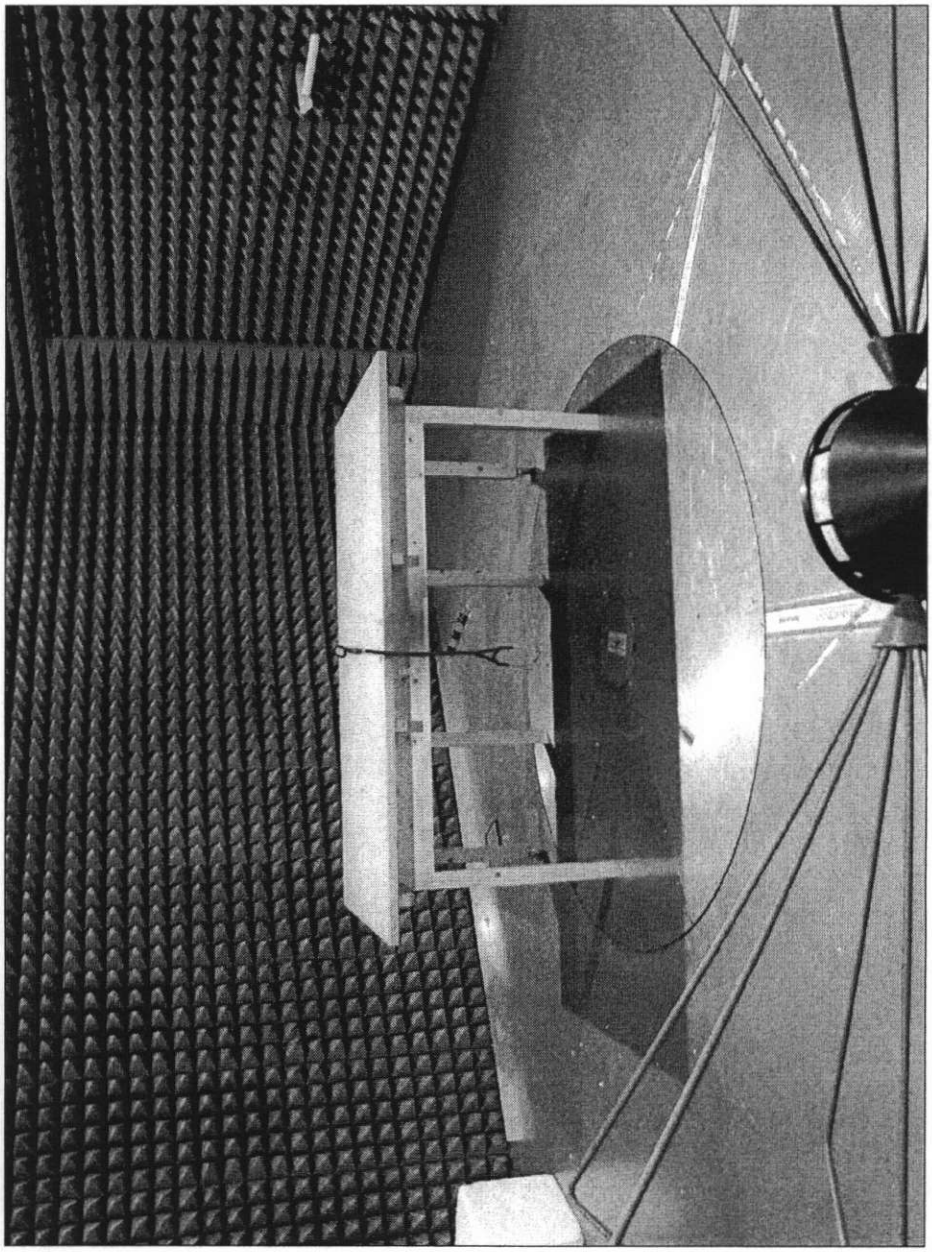
LITTMANN
QUALITY
TM

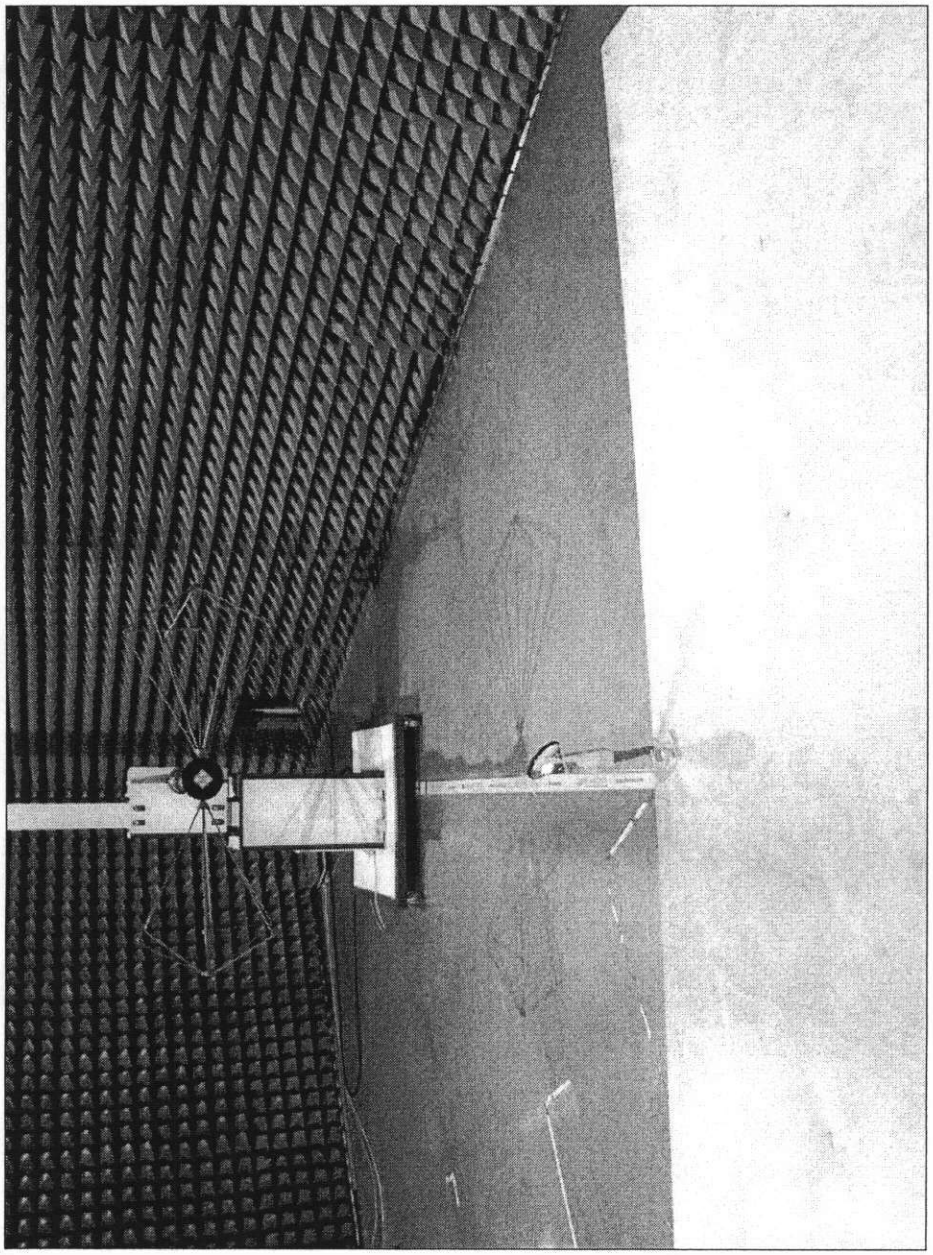







BANG & OLUFSEN
Medi.com
583410228
16142002B





1025

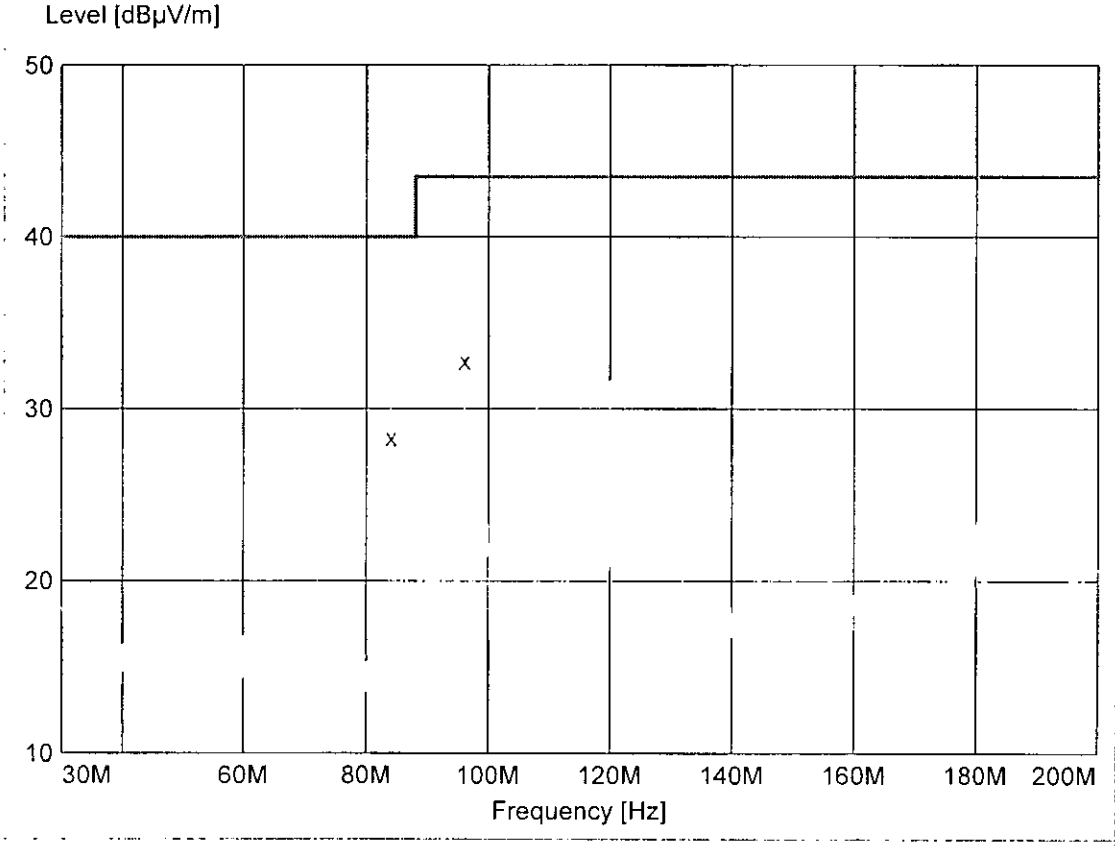
Annex B

Diagrams

Spurious emission under normal conditions according

to FCC part 15 *Ordernumber: G0M20810-2051*

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Medical Prod
EUT:	Bluetooth enabled stethoscope
Model:	Model 3200
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Klein
Test Conditions:	Unorm: Batt., Tnom: 23°C
Test Specification:	Ant: HK 116, vertical
Comment 1:	mode: Bluetooth
Comment 2:	mode:

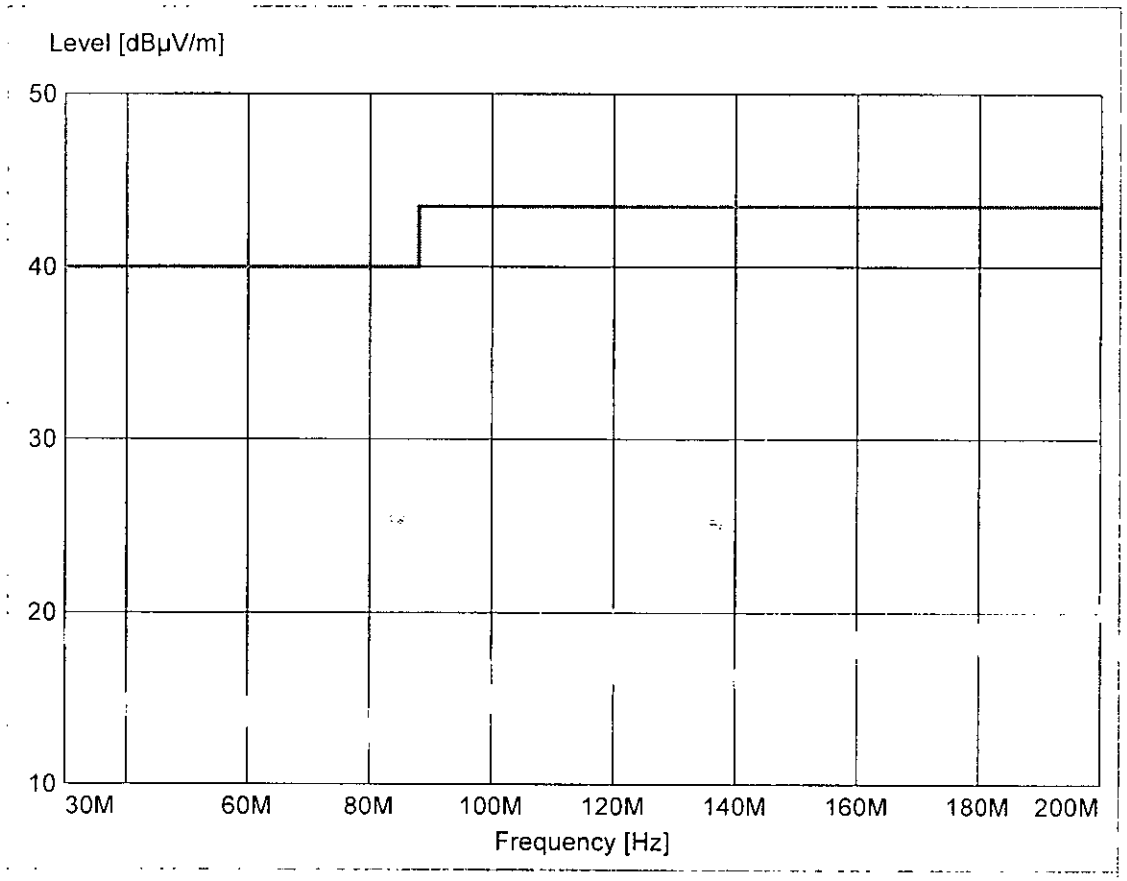


MES Stethoscope_fin QP
MES Stethoscope_pre PK
LIM FCC ClassB F QP/PK FCC ClassB, field strength 3m

Spurious emission under normal conditions according

to FCC part 15 *Ordernumber: G0M20810-2051*

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Medical Prod
EUT:	Bluetooth enabled stethoscope
Model:	Model 3200
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Klein
Test Conditions:	Unorm: Batt., Tnom: 23°C
Test Specification:	Ant: HK 116, horizontal
Comment 1:	mode: Bluetooth
Comment 2:	mode:

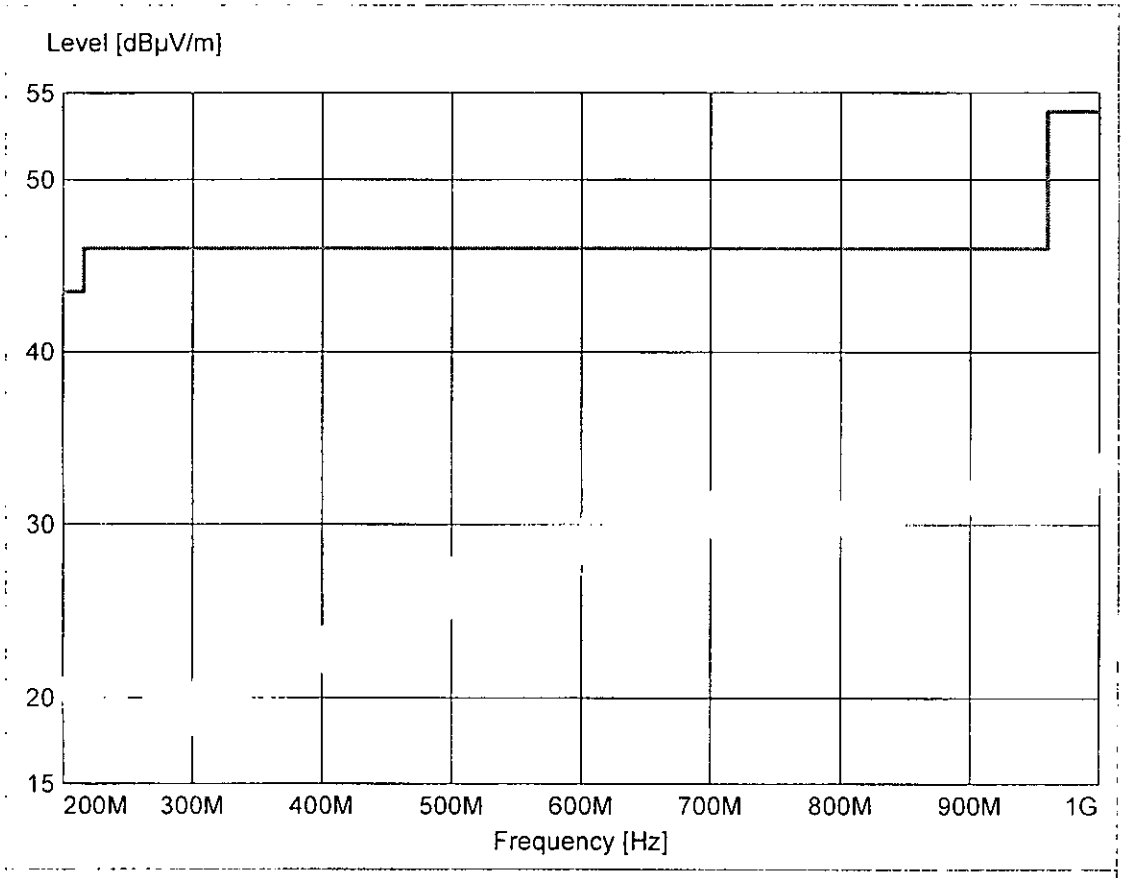


MES Stethoscope_pre PK
LIM FCC ClassB F QP/PK FCC ClassB, field strength 3m

Spurious emission under normal conditions according

to FCC part 15 *Ordernumber: G0M20810-2051*

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Medical Prod
EUT:	Bluetooth enabled stethoscope
Model:	Model 3200
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Klein
Test Conditions:	Unorm: Batt., Tnom: 23°C
Test Specification:	Ant: HL 223, vertical
Comment 1:	mode: Bluetooth
Comment 2:	mode:

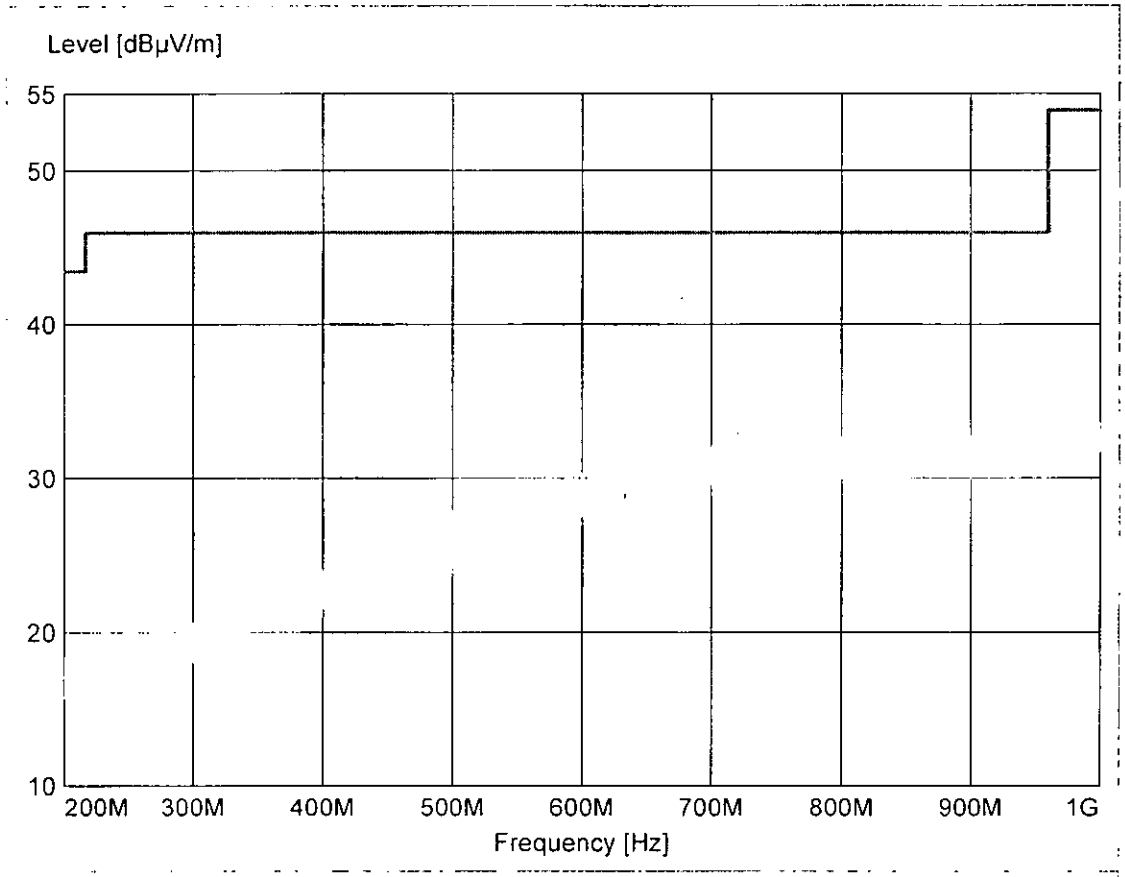


MES Stethoscope_pre PK
LIM FCC ClassB F QP/PK FCC ClassB, field strength 3m

Spurious emission under normal conditions according

to FCC part 15 *Ordernumber: G0M20810-2051*

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Medical Prod
EUT:	Bluetooth enabled stethoscope
Model:	Model 3200
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Klein
Test Conditions:	Unorm: Batt., Tnom: 23°C
Test Specification:	Ant: HL 223, horizontal
Comment 1:	mode: Bluetooth
Comment 2:	mode:



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K083903

FDA CDRH DMC

DEC 29 2008

Received

[63]

eurofins

EUROFINS PRODUCT SERVICE GMBH

Accredited Test House
Deutscher Akkreditierungs Rat
DAT-P-268/08

BLUETOOTH TEST - REPORT

TEST REPORT NUMBER:

G0M20810-2051-BlueT-71

eurofins
Eurofins Product Service GmbH
Storkower Str. 38c, 15526 Reichenwalde,
Germany

Phone +49-33631-888 0
Fax +49-33631-888 660

1632

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1 General Information

1.1 Notes

The purpose of conformity testing is to increase the probability of adherence to the essential requirements or conformity specifications, as appropriate.
The complexity of the technical specifications, however, means that full and thorough testing is impractical for both technical and economic reasons.
Furthermore, there is no guarantee that a test sample which has passed all the relevant tests conforms to a specification (only for telecommunication equipment).
Neither is there any guarantee that such a test sample will interwork with other genuinely open systems.
The existence of the tests nevertheless provides the confidence that the test sample possesses the qualities as maintained and that its performance generally conforms to representative cases of communications equipment.

The test results of this test report relate exclusively to the item tested as specified in 1.6.
The test report may only be reproduced or published in full.
Reproduction or publication of extracts from the report requires the prior written approval of the Eurofins Product Service GmbH.

1.2 Operator:

13.11.2008		W. Treffke	W. Treffke
Date	Eurofins-Lab.	Test Engineer	Signature

Technical responsibility for area of testing:

13.11.2008		J. Zimmermann	
Date	Eurofins	Name	Signature

1.3 Testing laboratory

1.3.1 Location

EUROFINS PRODUCT SERVICE GMBH
Storkower Str.38c
D - 15526 Reichenwalde
Germany
Telephone : + 49 33631 888-00
Telefax : + 49 33631 888-660

1.3.2 Details of accreditation status

DAR ACCREDITED TESTING LABORATORY
DAR-REGISTRATION NUMBER: DAT-P-268/08

RECOGNIZED NOTIFIED BODY EMC
REGISTRATION NUMBER: BNetzA-bS EMV-07/61

RECOGNIZED NOTIFIED BODY R&TTE
REGISTRATION NUMBER: BNetzA-bS-02/51-53

FCC FILED TEST LABORATORY
REG.-NO. 96970

A2LA ACCREDITED TESTING LABORATORY
CERTIFICATE NO. 1983.01

BLUETOOTH QUALIFICATION TEST FACILITY (BQTF)
ACCREDITED BY BLUETOOTH QUALIFICATION REVIEW BOARD

INDUSTRY CANADA FILED TEST LABORATORY
REG. NO. IC 3470

1.3.3 Test location, where different

Name :
Street :
Town :
Country :
Telephone :
Fax :
E-mail :

1.4 Details of approval holder

Name	: 3M Health Care Patient Assessment Laboratory 3M Medical Products
Street	: 3M Center, Building 270-4N-09
Town	: Maplewood, MN 55144-1000
Country	: USA
Telephone	: +1 651-733-4531
Contact	: Mr. T.E. Drummond
Telephone	: +1 651-733-4531
E-mail	: tedrummond@mmm.com

1.5 Application details

Date of receipt of application	: 05.11.2008
Date of receipt of test item	: 05.11.2008
Date of test	: 05.11.2008 – 12.11.2008

1.6 Test item

1.6.1 Description of test item

Description of test item	: Bluetooth enabled stethoscope
Type identification	: M3200
Serial number	: without
Power Class	: Class 2
Power Control supported	: ☒ Yes (Maximum Power) / ☐ No
Hardware version	: V3RB
Software version, date	: V0011
Antenna Gain	: -12 dBi
Additional information	: ./.

1.6.2 Manufacturer (if different from applicant in point 1.4)

(b) (4)

Name
Street
Town
Country

[redacted]

1.7 Test standards

Please note that category "A" tests have to be performed with validated test system and by accredited test laboratories only.

Sample 1: (name)	: like 1.6.1
Technical standard	: Test Specification for the Bluetooth Wireless Technology Radio layer, Radio Frequency, System Specification 1.2/2.0/2.0+EDR
Test specification version	: RF.TS/2.1.E.2
(if applicable) Sample 2: (name)	:
Technical standard	: Bluetooth test specification, details see test results.
Test specification version	:
Sample 3: (name)	:
Technical standard	: Bluetooth test specification, details see test results.
Test specification version	:

1.8 Test plan

According to the Test Case Reference List (TCRL) released 2008-06-02.

2 Technical test

2.1 Summary of test results

No deviations from the technical specification(s) were ascertained in the course of the tests performed. ☒

or

The deviations as specified in 3. were ascertained in the course of the tests performed. ☐

2.2 Test environment

Normal Conditions

Temperature	: 15 ... 35 ° C
Relative humidity content	: 20 % ... 75 %
Air pressure	: 860 ... 1060 hPa
Details of power supply	: 1.5 V DC (Manufacturer declaration)
Other parameters	: ./.

Extreme Conditions

Min. Temperature:	-30 ° C
Max. Temperature:	+60 ° C
Min. Voltage:	1.2 V DC
Max. Voltage:	1.8 V DC

Test Software

The EUT was put into test mode using:

Name:	BlueTest 3
Version:	1.2
Provider:	CSR

2.3 Test equipment utilized

No.	Measurement device:	Type:	Manufacturer:
ETS 0228	Climatic chamber	VT 4010	Vötsch
ETS 0252	System controller	PSM 12	R & S TS 8960
ETS 0253	Spectrum analyzer	FSIQ 26	R & S TS 8960
ETS 0254	RF generator	SMIQ 03	R & S TS 8960
ETS 0255	RF generator	SMIQ 03	R & S TS 8960
ETS 0256	RF generator	SMR 27	R & S TS 8960
ETS 0257	Step attenuator	RSP	R & S TS 8960
ETS 0258	Rubidium standard	RSTU	R & S TS 9860
ETS 0259	Power meter	NRVD	R & S TS 8960
ETS 0260	Power sensor	NRVD-Z1	R & S TS 8960
ETS 0261	Power sensor	NRVD-Z1	R & S TS 8960
ETS 0262	Switching unit	SSCU	R & S TS 8960
ETS 0263	Signaling unit	SU	R & S TS 8960
ETS 0270	RF signal generator	SMP 04	R & S

2.4 Measurement and test set-up

1. Bluetooth RF test system: TS 8960 by Rohde & Schwarz

   Configuration Version: 0.9

   Software Version: B 2_0305

2. Bluetooth protocol test system: PTW 60 by Rohde & Schwarz

   Configuration version: 1.0

   Software version: 5.45

Remarks: ./.

3 Test results

TEST REPORT RF

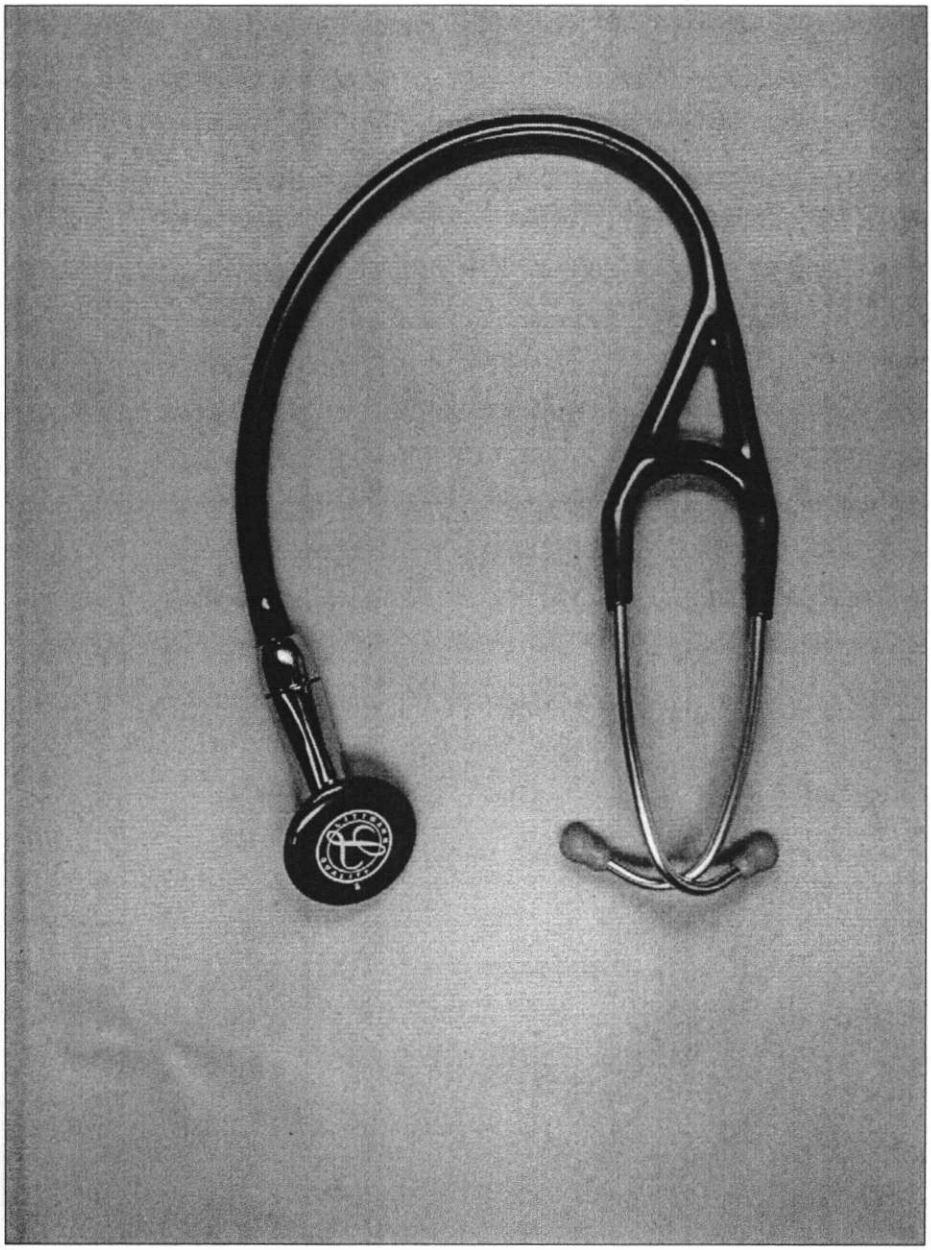
TC identifier	Description	Cat.	Test result			Comments
			Passed	Failed	No test	
TRM/CA/01/C	Output power	A	☒	☐	☐	
TRM/CA/02/C	Power Density	A	☒	☐	☐	
TRM/CA/03/C	Power Control	A	☒	☐	☐	
TRM/CA/04/C	TX Output Spectrum - Frequency range	A	☒	☐	☐	
TRM/CA/05/C	TX Output Spectrum - 20 dB Bandwidth	A	☒	☐	☐	
TRM/CA/06/C	TX Output Spectrum - Adjacent channel power	A	☒	☐	☐	
TRM/CA/07/C	Modulation Characteristics	A	☒	☐	☐	
TRM/CA/08/C	Initial Carrier Frequency Tolerance	A	☒	☐	☐	
TRM/CA/09/C	Carrier Frequency Drift	A	☒	☐	☐	
RCV/CA/01/C	Sensitivity - single slot packets	A	☒	☐	☐	
RCV/CA/02/C	Sensitivity - multi-slot packets	A	☒	☐	☐	
RCV/CA/03/C	C/I performance	A	☒	☐	☐	
RCV/CA/04C	Blocking performance	A	☒	☐	☐	
RCV/CA/05/C	Intermodulation Performance	A	☒	☐	☐	
RCV/CA/06/C	Maximum Input Level	A	☒	☐	☐	

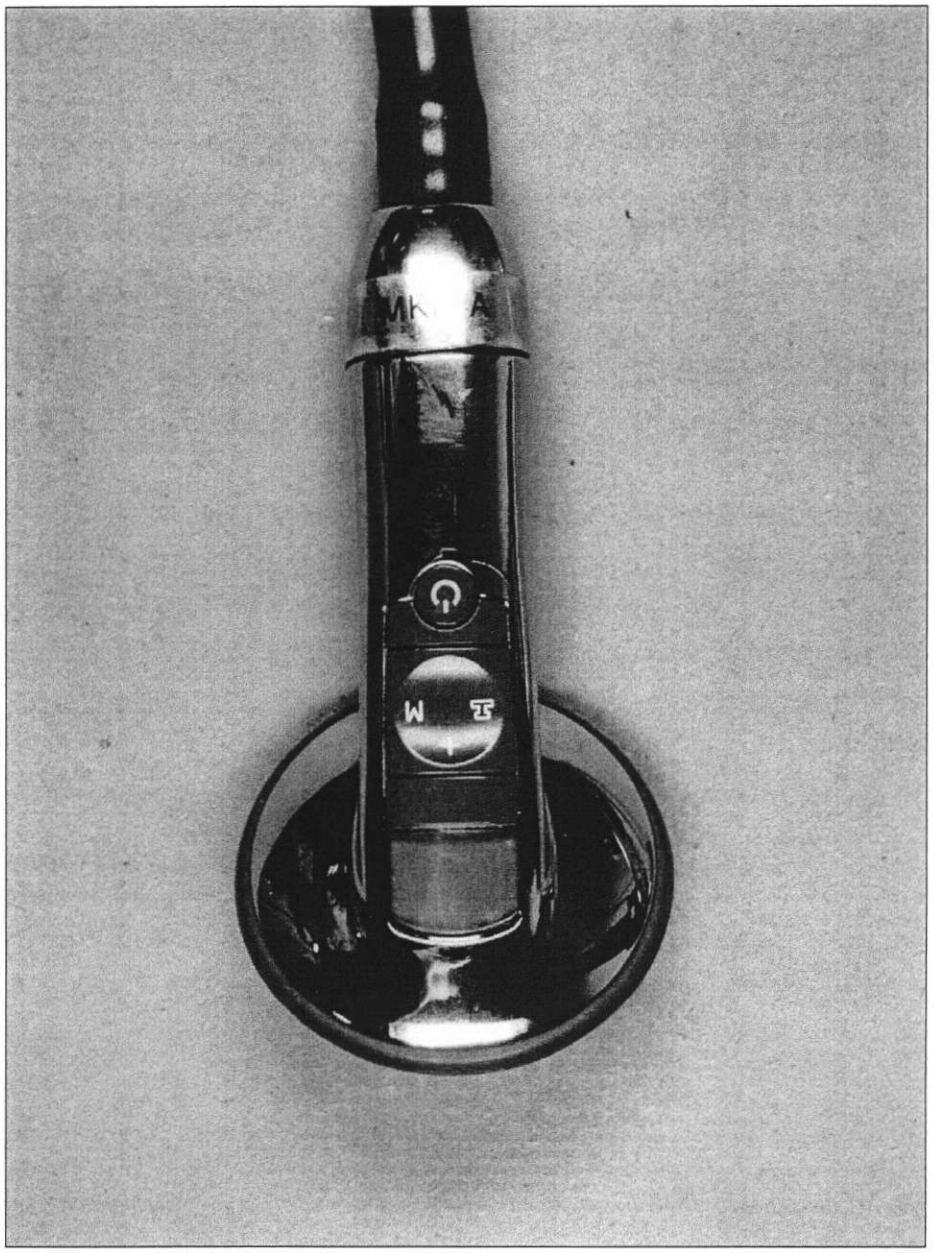
Annex

Annex A		Photos of the EUT
Annex B	TRM/CA/01/C	Output Power
Annex C	TRM/CA/02/C	Power Density
Annex D	TRM/CA/03/C	Power Control
Annex E	TRM/CA/04/C	TX Output Spectrum - Frequency Range
Annex F	TRM/CA/05/C	TX Output Spectrum - 20 dB Bandwidth
Annex G	TRM/CA/06/C	TX Output Spectrum - Adjacent Channel Power
Annex H	TRM/CA/07/C	Modulation Characteristics
Annex I	TRM/CA/08/C	Initial Carrier Frequency Tolerance
Annex J	TRM/CA/09/C	Carrier Frequency Drift
Annex K	RCV/CA/01/C	Sensitivity - Single Slot Packets
Annex L	RCV/CA/02/C	Sensitivity - Multi Slot Packets
Annex M	RCV/CA/03/C	C/I Performance
Annex N	RCV/CA/04/C	Blocking Performance
Annex O	RCV/CA/05/C	Intermodulation Performance
Annex P	RCV/CA/06/C	Maximum Input Level
Annex Q		System Parameter
Annex R		EUT Parameter
Annex S		Test Case Parameter
Annex T		Test Plan

Annex A

Pictures





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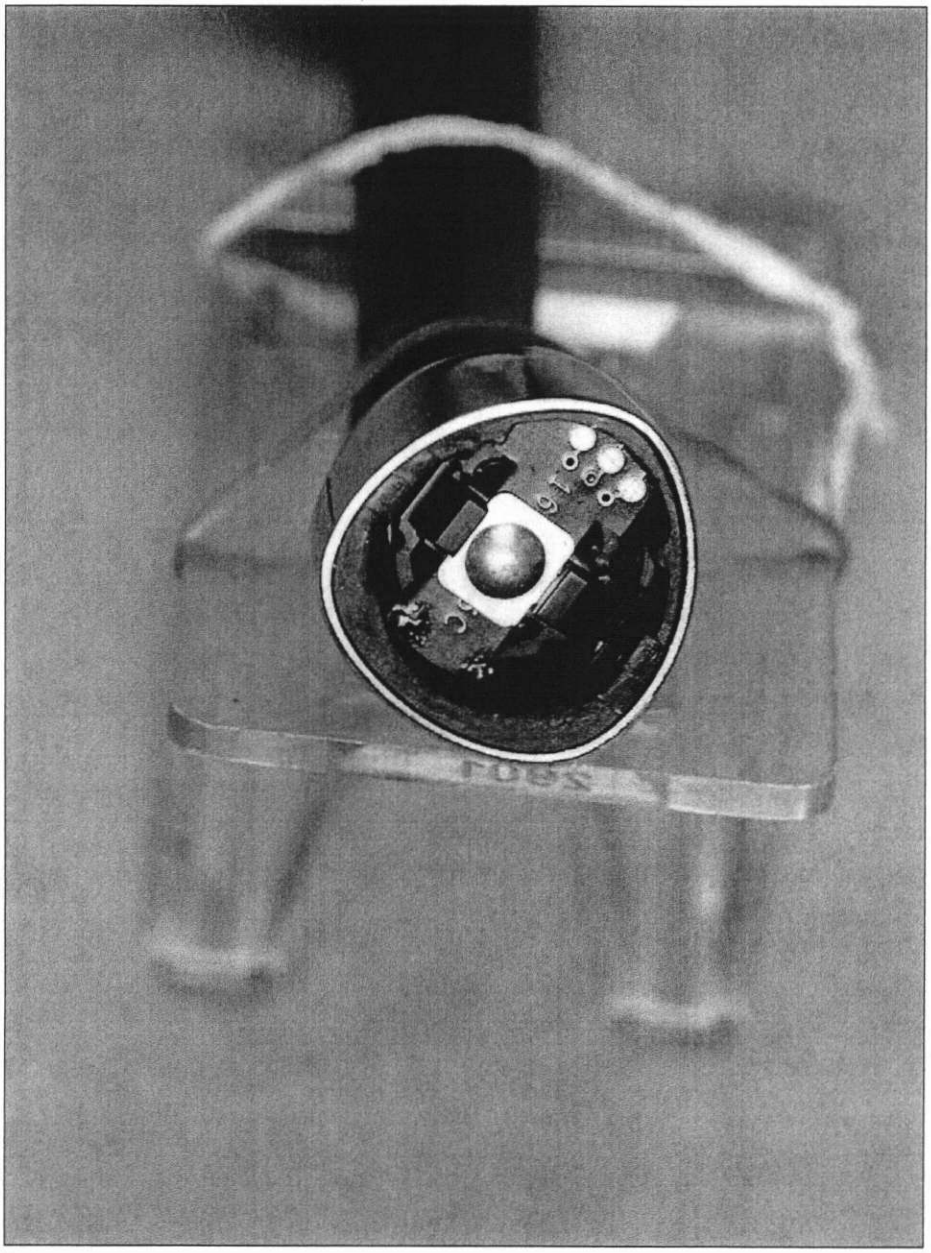
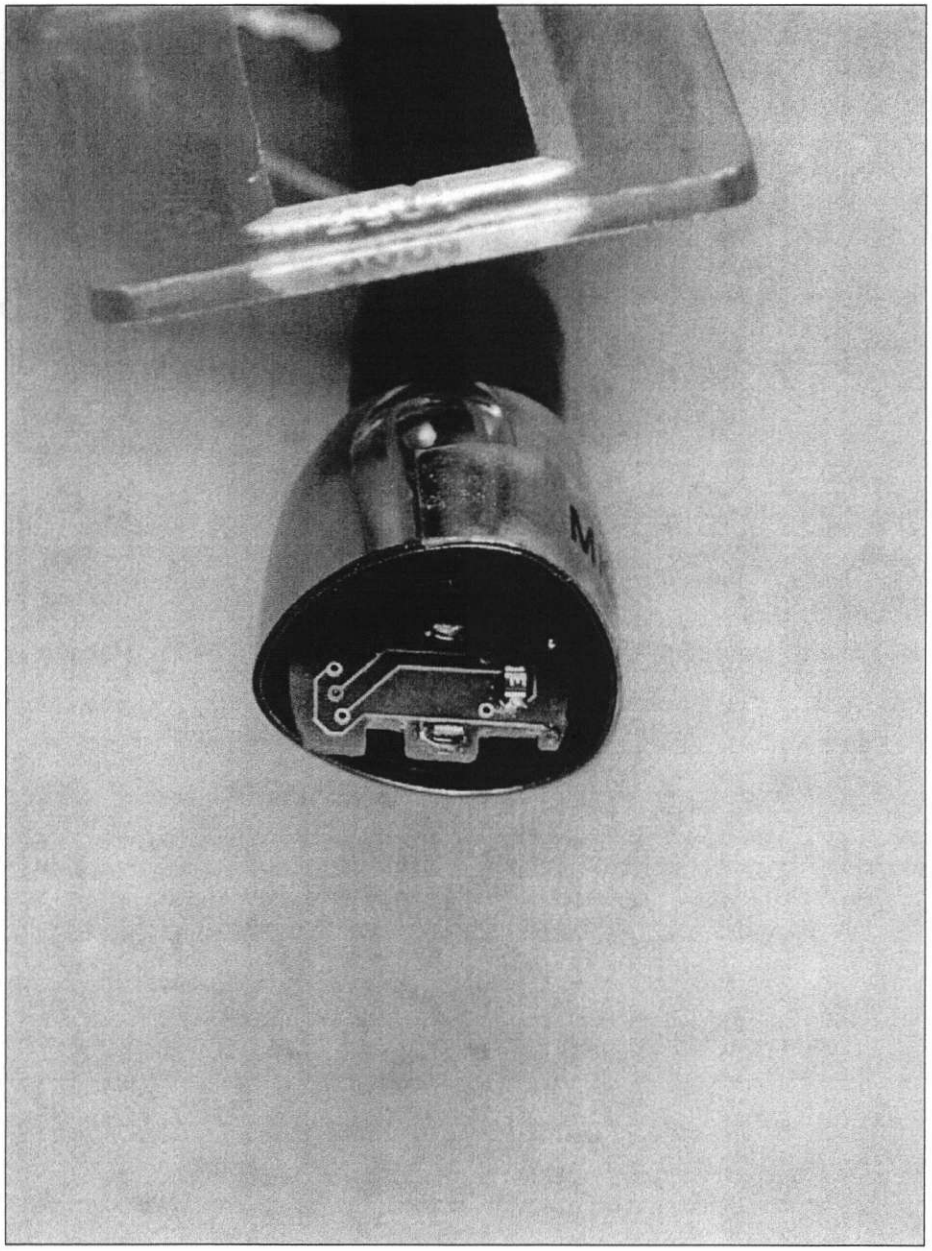
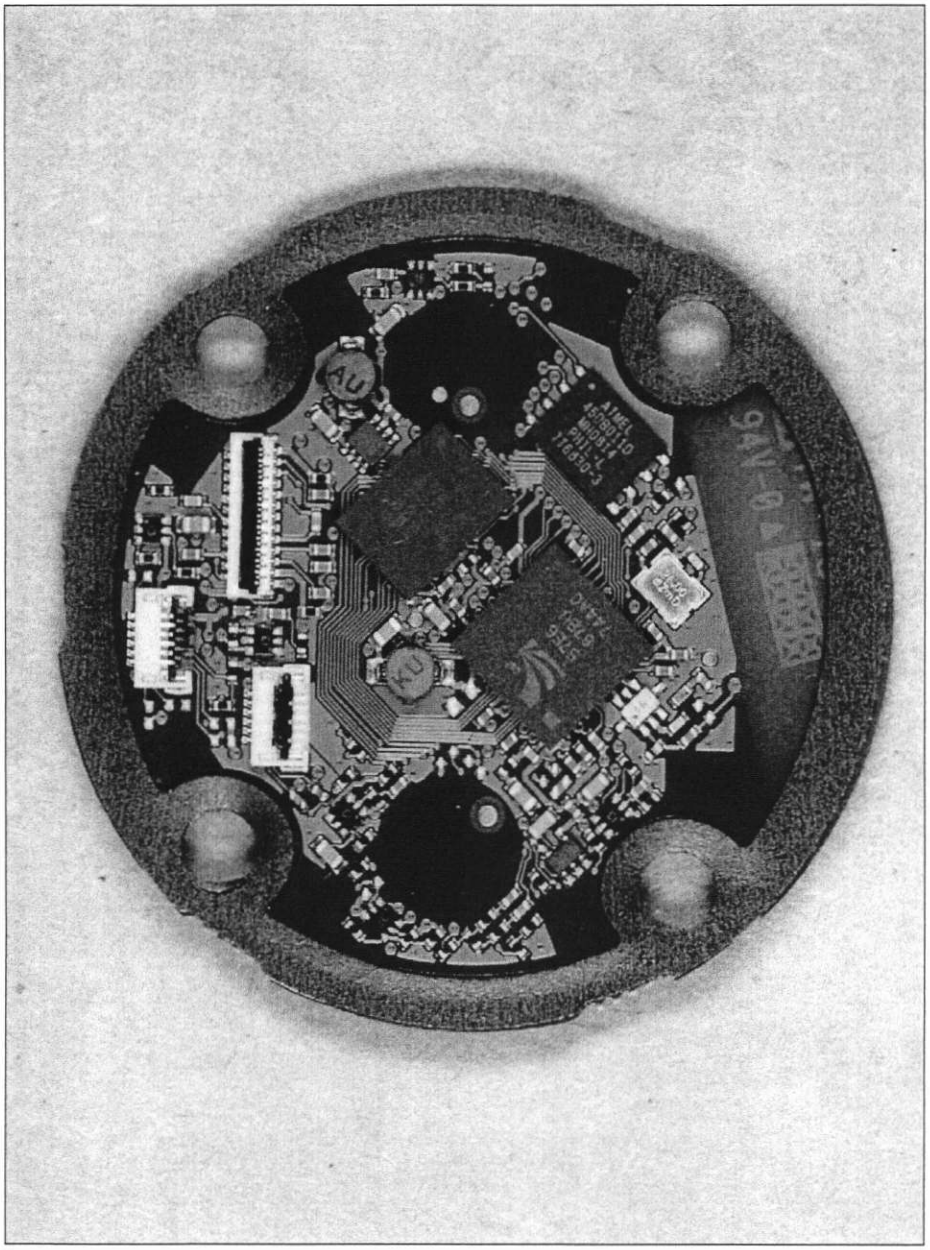
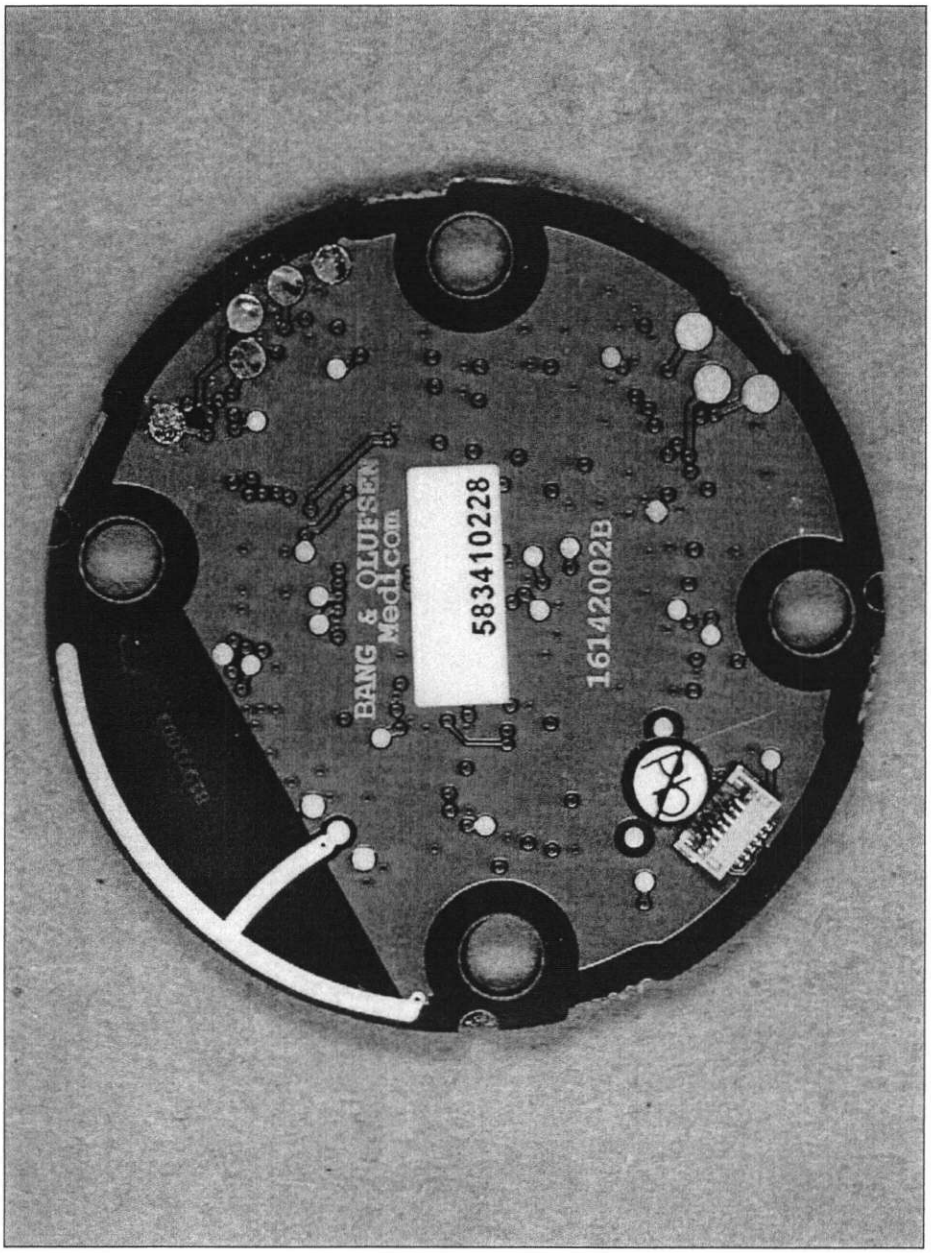







BANG & OLUFSEN
MedicCom
583410228
16142002B

Annex B

TRM/CA/01/C Output Power

Output Power

For system parameter see 0, "General Parameter 001"

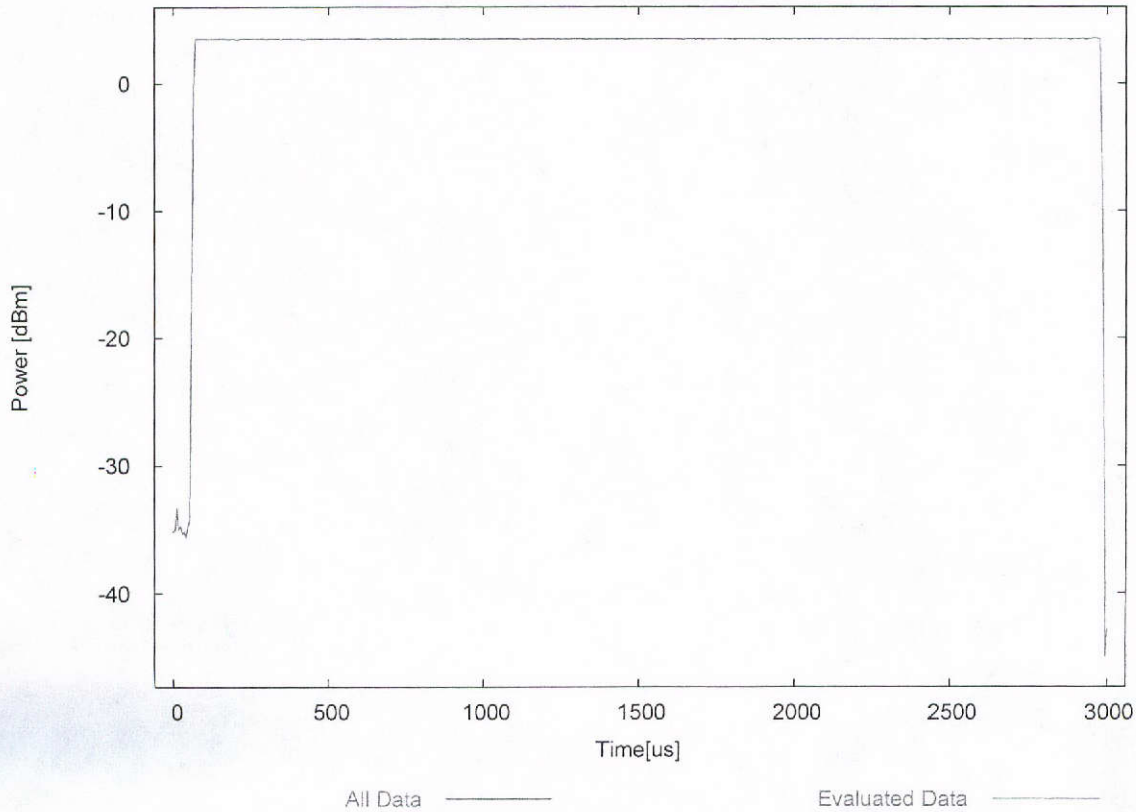
BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 001"
For test case parameter see 0, "Test Case Parameter 001"

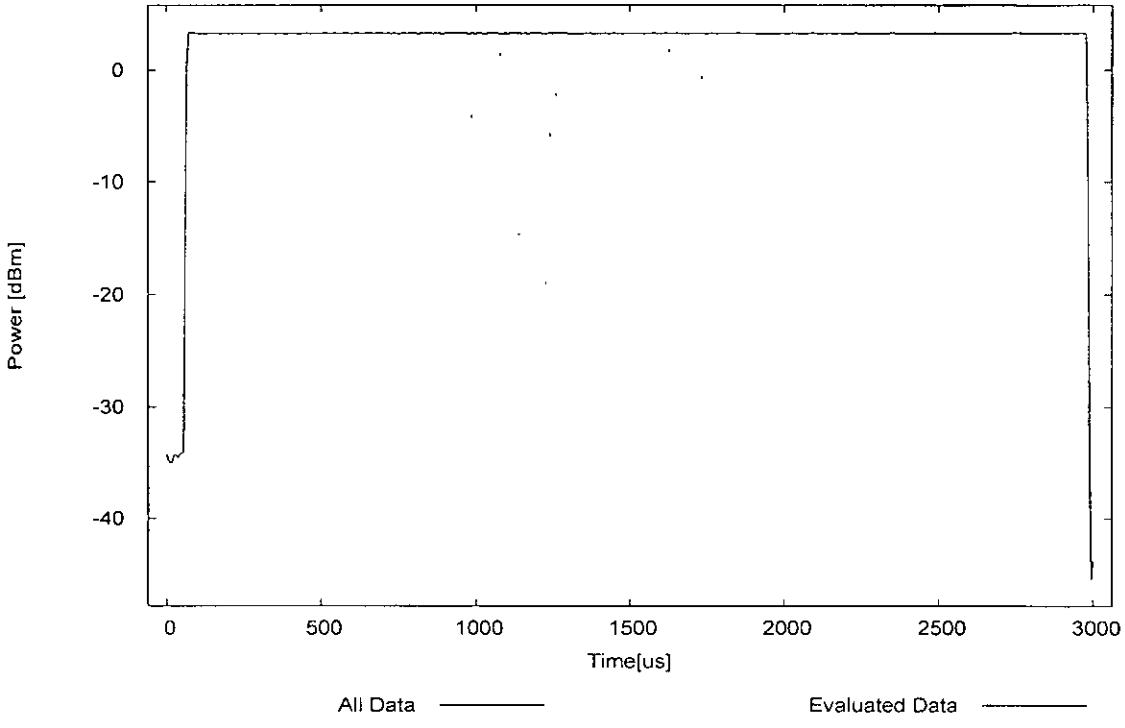
TX FREQ [MHz]	RX FREQ [MHz]	MEAS FREQ [MHz]	MEASUREMENT	LEVEL [dBm]		LIMIT [dBm]	VERDICT
hopping	hopping	2402.000	Average (+ gain)	-8.51	<	20.00	PASS
hopping	hopping	2402.000	Peak (+ gain)	-8.44	<	23.00	PASS
hopping	hopping	2402.000	Average	3.49	<	4.00	PASS
hopping	hopping	2402.000	Average	3.49	>	-6.00	PASS
hopping	hopping	2441.000	Average (+ gain)	-8.67	<	20.00	PASS
hopping	hopping	2441.000	Peak (+ gain)	-8.57	<	23.00	PASS
hopping	hopping	2441.000	Average	3.33	<	4.00	PASS
hopping	hopping	2441.000	Average	3.33	>	-6.00	PASS
hopping	hopping	2480.000	Average (+ gain)	-9.00	<	20.00	PASS
hopping	hopping	2480.000	Peak (+ gain)	-8.93	<	23.00	PASS
hopping	hopping	2480.000	Average	3.00	<	4.00	PASS
hopping	hopping	2480.000	Average	3.00	>	-6.00	PASS

Final Test Case Verdict . . . . . PASS 00:00:34

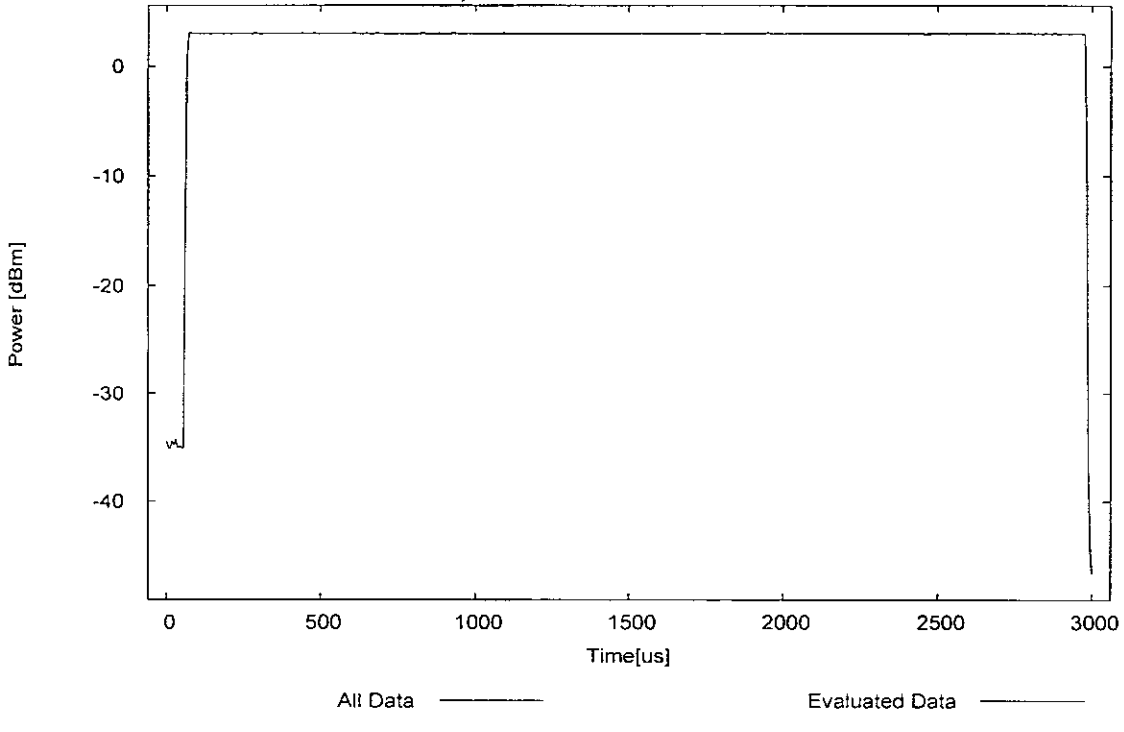
Measured Burst TC Output Power -Measured EUT: M3200 -EUT TX Frequency hopping (Meas: 2402.000 MHz)



Measured Burst TC Output Power -Measured EUT: M3200 -EUT TX Frequency hopping (Meas: 2441.000 MHz)



Measured Burst TC Output Power -Measured EUT: M3200 -EUT TX Frequency hopping (Meas: 2480.000 MHz)



Output Power

For system parameter see 0, "General Parameter 001"

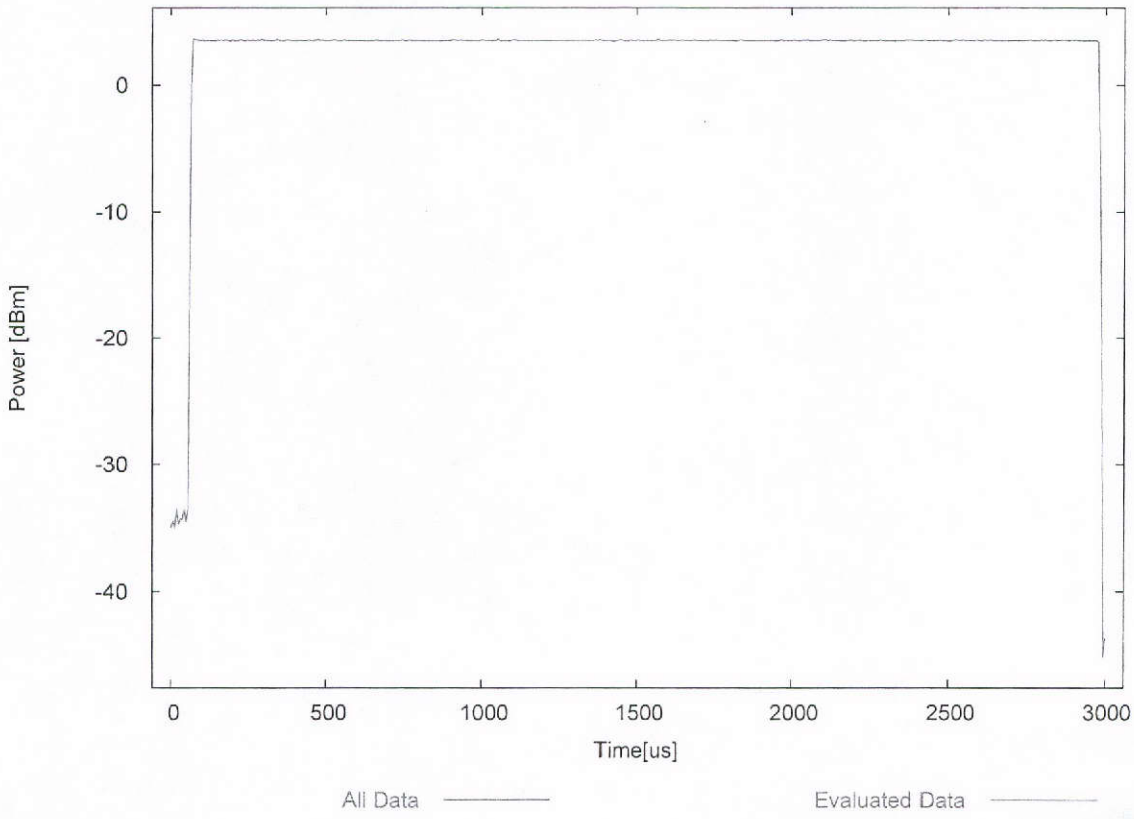
BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 005"
For test case parameter see 0, "Test Case Parameter 016"

TX FREQ [MHz]	RX FREQ [MHz]	MEAS FREQ [MHz]	MEASUREMENT	LEVEL [dBm]		LIMIT [dBm]	VERDICT
hopping	hopping	2402.000	Average (+ gain)	-8.46	<	20.00	PASS
hopping	hopping	2402.000	Peak (+ gain)	-8.34	<	23.00	PASS
hopping	hopping	2402.000	Average	3.54	<	4.00	PASS
hopping	hopping	2402.000	Average	3.54	>	-6.00	PASS
hopping	hopping	2441.000	Average (+ gain)	-8.59	<	20.00	PASS
hopping	hopping	2441.000	Peak (+ gain)	-8.57	<	23.00	PASS
hopping	hopping	2441.000	Average	3.41	<	4.00	PASS
hopping	hopping	2441.000	Average	3.41	>	-6.00	PASS
hopping	hopping	2480.000	Average (+ gain)	-8.98	<	20.00	PASS
hopping	hopping	2480.000	Peak (+ gain)	-8.91	<	23.00	PASS
hopping	hopping	2480.000	Average	3.02	<	4.00	PASS
hopping	hopping	2480.000	Average	3.02	>	-6.00	PASS

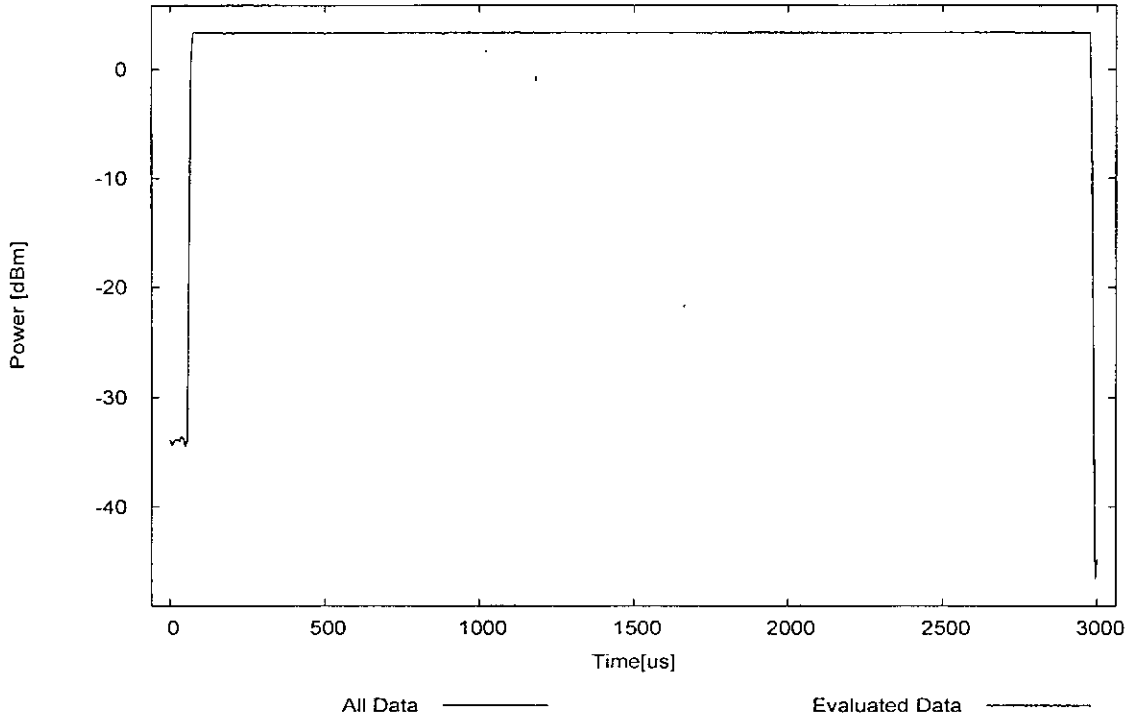
Final Test Case Verdict . . . . . PASS 00:00:36

Measured Burst TC Output Power -Measured EUT: M3200 -EUT TX Frequency hopping (Meas: 2402.000 MHz)

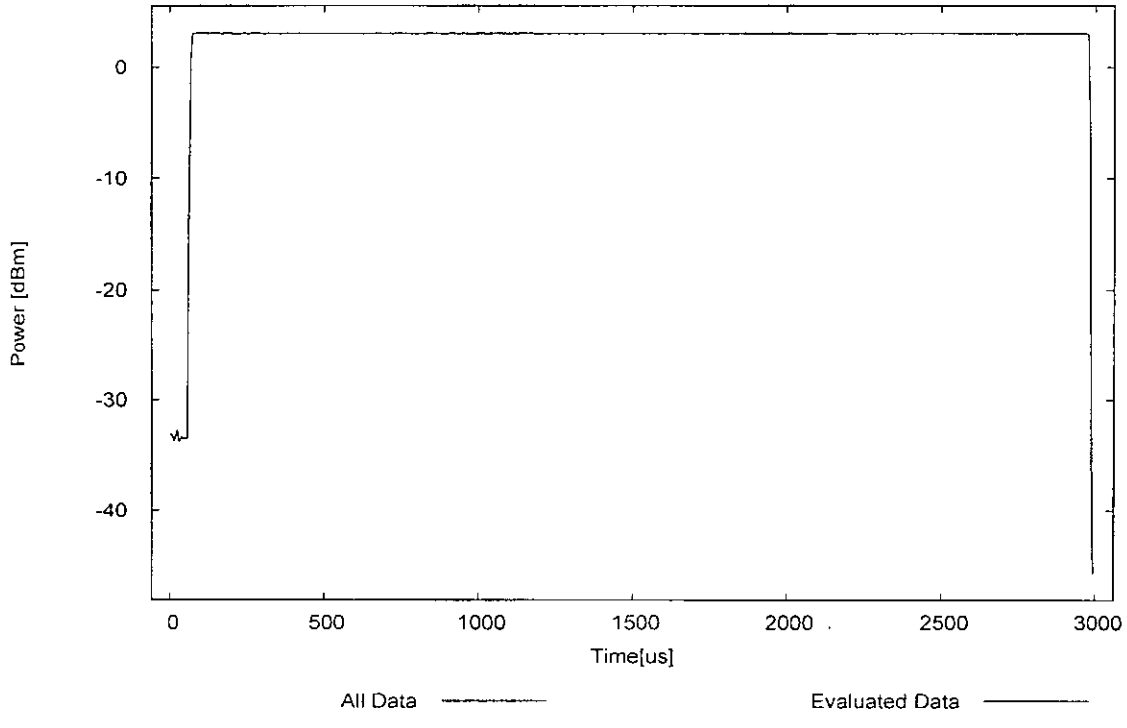


1052

Measured Burst TC Output Power -Measured EUT: M3200 -EUT TX Frequency hopping (Meas: 2441.000 MHz)



Measured Burst TC Output Power -Measured EUT: M3200 -EUT TX Frequency hopping (Meas: 2480.000 MHz)



Output Power

For system parameter see 0, "General Parameter 001"

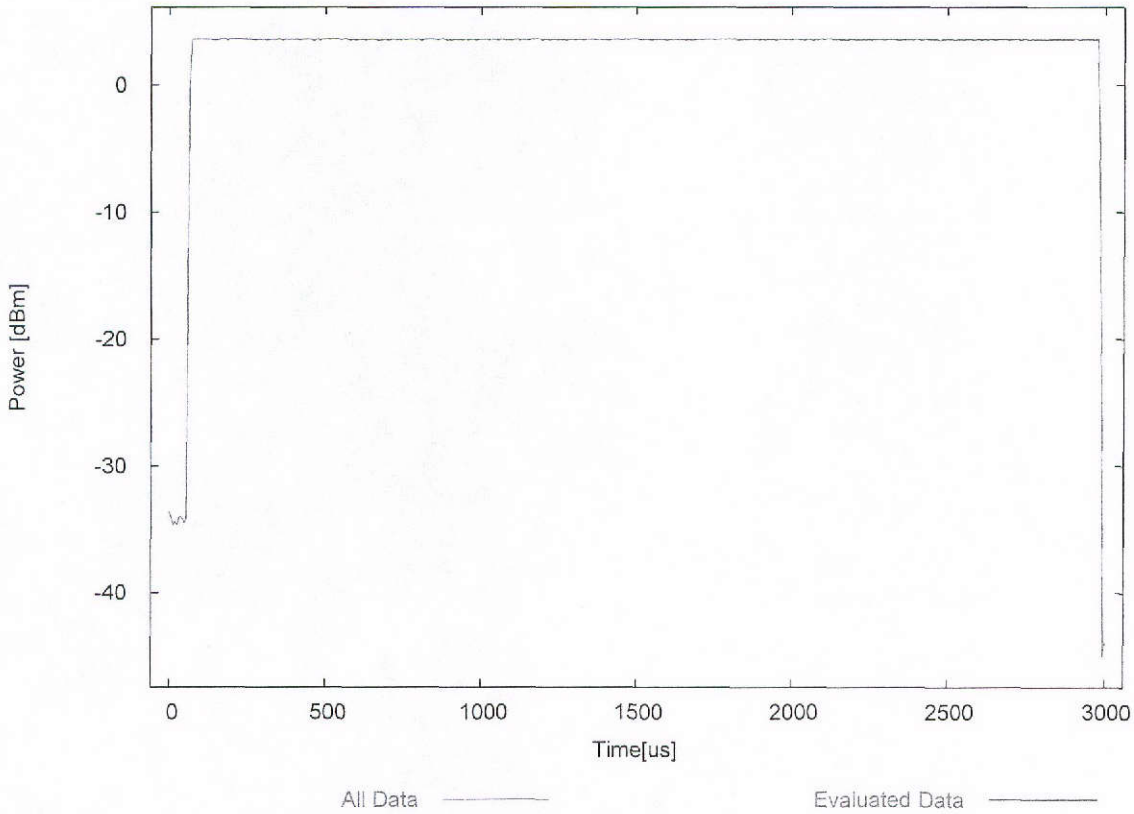
BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 006"
For test case parameter see 0, "Test Case Parameter 017"

TX FREQ [MHz]	RX FREQ [MHz]	MEAS FREQ [MHz]	MEASUREMENT	LEVEL [dBm]		LIMIT [dBm]	VERDICT
hopping	hopping	2402.000	Average (+ gain)	-8.40	<	20.00	PASS
hopping	hopping	2402.000	Peak (+ gain)	-8.31	<	23.00	PASS
hopping	hopping	2402.000	Average	3.60	<	4.00	PASS
hopping	hopping	2402.000	Average	3.60	>	-6.00	PASS
hopping	hopping	2441.000	Average (+ gain)	-8.55	<	20.00	PASS
hopping	hopping	2441.000	Peak (+ gain)	-8.47	<	23.00	PASS
hopping	hopping	2441.000	Average	3.45	<	4.00	PASS
hopping	hopping	2441.000	Average	3.45	>	-6.00	PASS
hopping	hopping	2480.000	Average (+ gain)	-8.92	<	20.00	PASS
hopping	hopping	2480.000	Peak (+ gain)	-8.83	<	23.00	PASS
hopping	hopping	2480.000	Average	3.08	<	4.00	PASS
hopping	hopping	2480.000	Average	3.08	>	-6.00	PASS

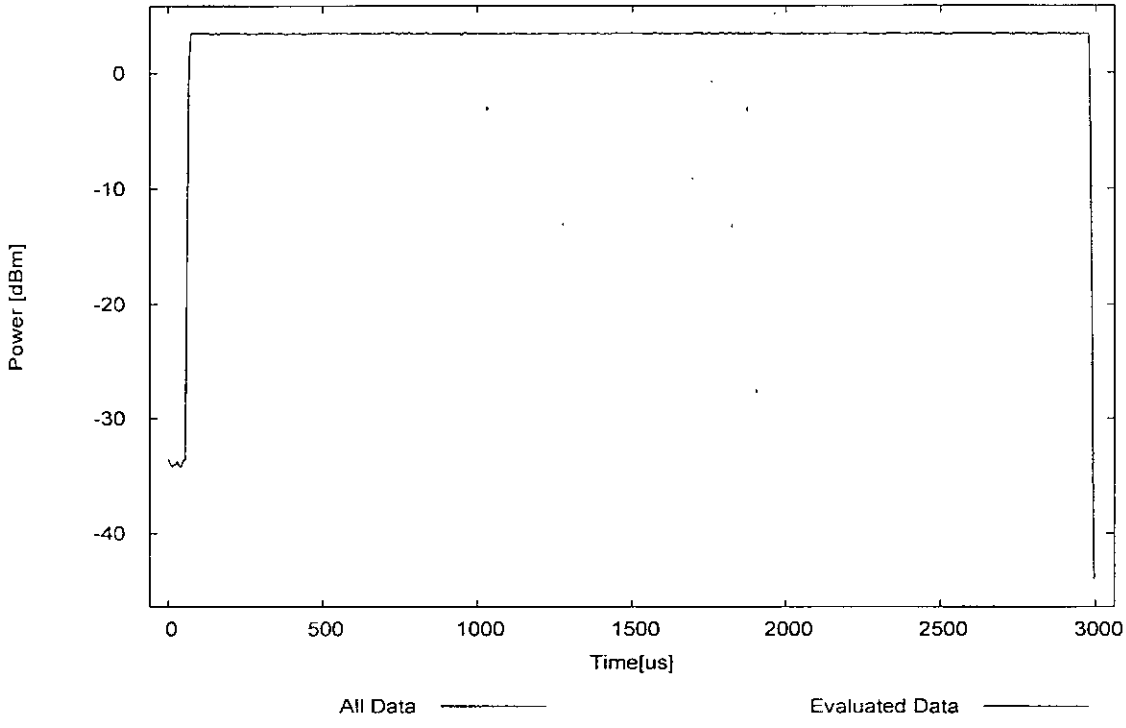
Final Test Case Verdict . . . . . PASS 00:00:37

Measured Burst TC Output Power -Measured EUT: M3200 -EUT TX Frequency hopping (Meas: 2402.000 MHz)

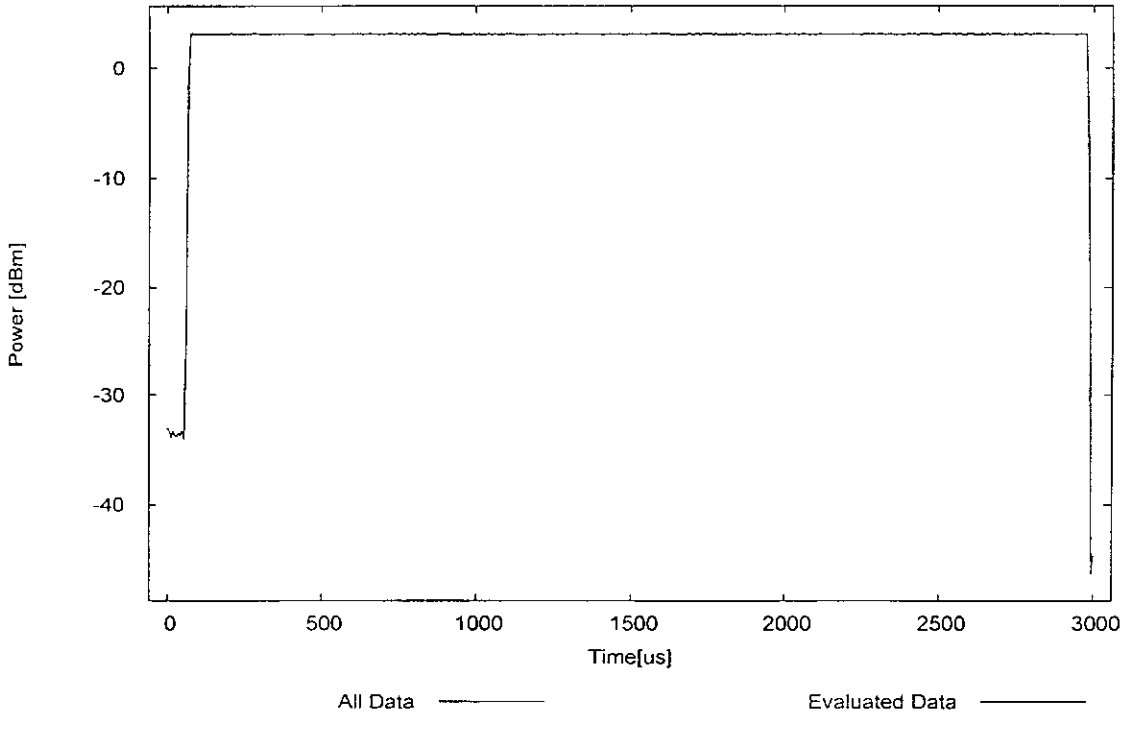


1054

Measured Burst TC Output Power -Measured EUT: M3200 -EUT TX Frequency hopping (Meas: 2441.000 MHz)



Measured Burst TC Output Power -Measured EUT: M3200 -EUT TX Frequency hopping (Meas: 2480.000 MHz)



Output Power

For system parameter see 0, "General Parameter 001"

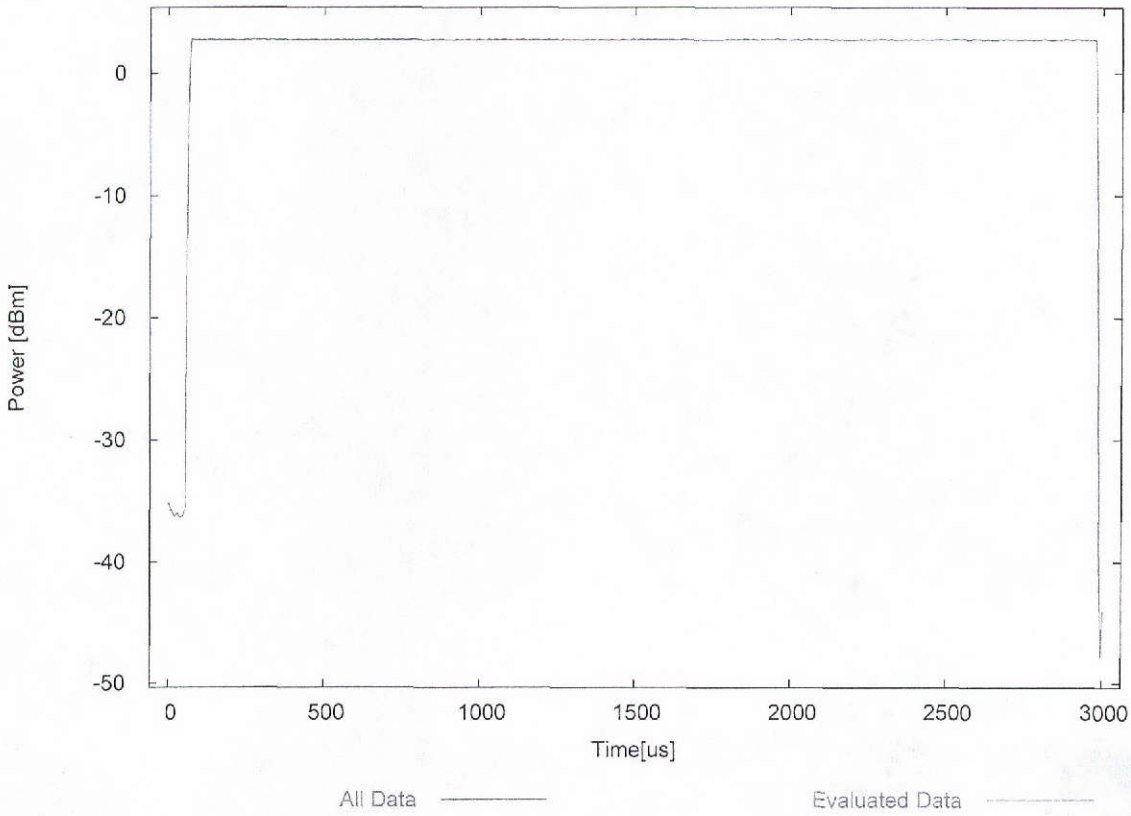
BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 009"
For test case parameter see 0, "Test Case Parameter 036"

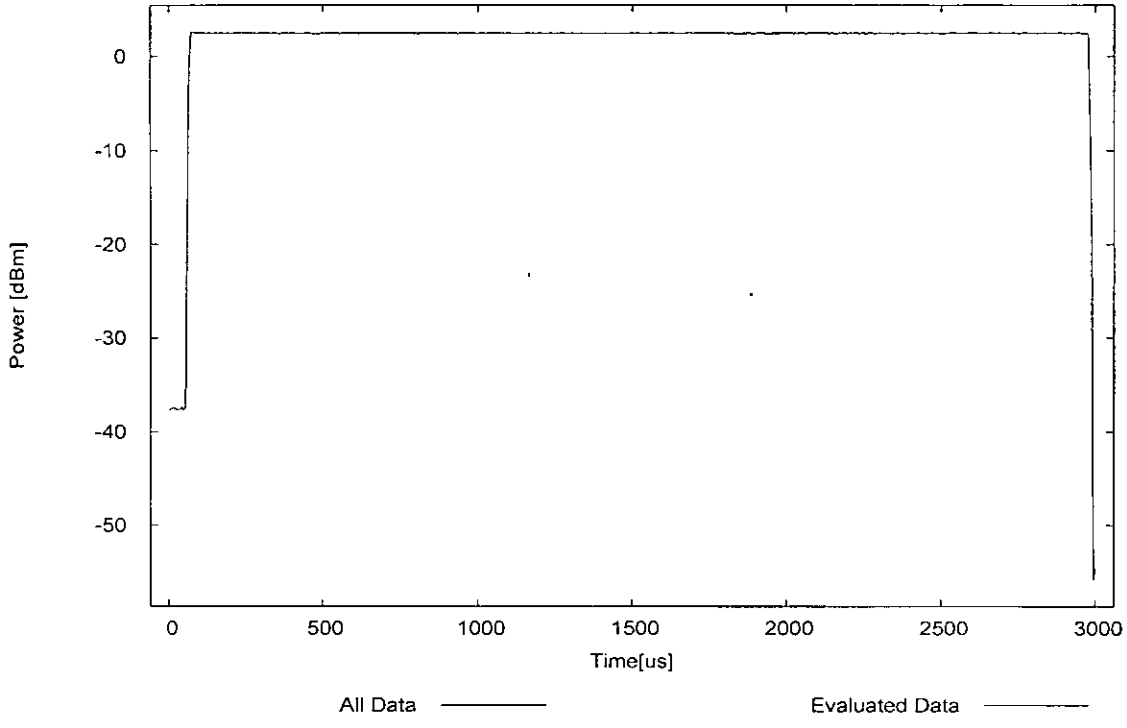
TX FREQ [MHz]	RX FREQ [MHz]	MEAS FREQ [MHz]	MEASUREMENT	LEVEL [dBm]		LIMIT [dBm]	VERDICT
hopping	hopping	2402.000	Average (+ gain)	-9.25	<	20.00	PASS
hopping	hopping	2402.000	Peak (+ gain)	-9.14	<	23.00	PASS
hopping	hopping	2402.000	Average	2.75	<	4.00	PASS
hopping	hopping	2402.000	Average	2.75	>	-6.00	PASS
hopping	hopping	2441.000	Average (+ gain)	-9.47	<	20.00	PASS
hopping	hopping	2441.000	Peak (+ gain)	-9.39	<	23.00	PASS
hopping	hopping	2441.000	Average	2.53	<	4.00	PASS
hopping	hopping	2441.000	Average	2.53	>	-6.00	PASS
hopping	hopping	2480.000	Average (+ gain)	-9.89	<	20.00	PASS
hopping	hopping	2480.000	Peak (+ gain)	-9.81	<	23.00	PASS
hopping	hopping	2480.000	Average	2.11	<	4.00	PASS
hopping	hopping	2480.000	Average	2.11	>	-6.00	PASS

Final Test Case Verdict . . . . . PASS 00:00:36

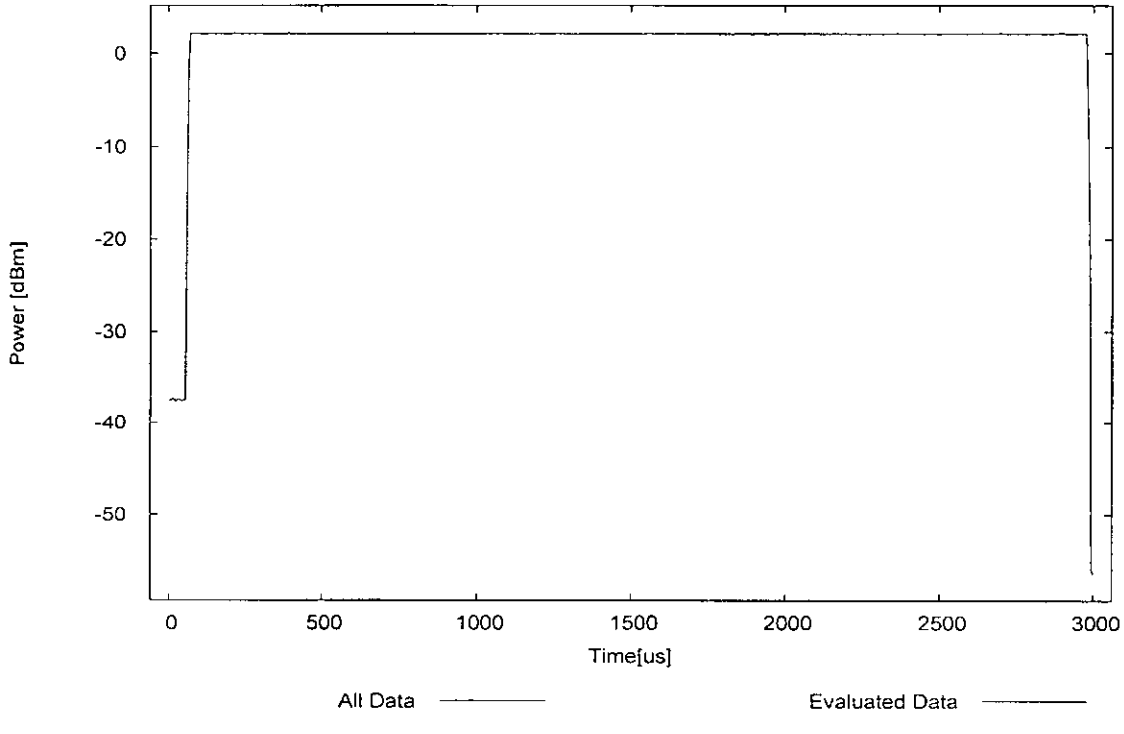
Measured Burst TC Output Power -Measured EUT: M3200 -EUT TX Frequency hopping (Meas: 2402.000 MHz)



Measured Burst TC Output Power -Measured EUT: M3200 -EUT TX Frequency hopping (Meas: 2441.000 MHz)



Measured Burst TC Output Power -Measured EUT: M3200 -EUT TX Frequency hopping (Meas: 2480.000 MHz)



Output Power

For system parameter see 0, "General Parameter 001"

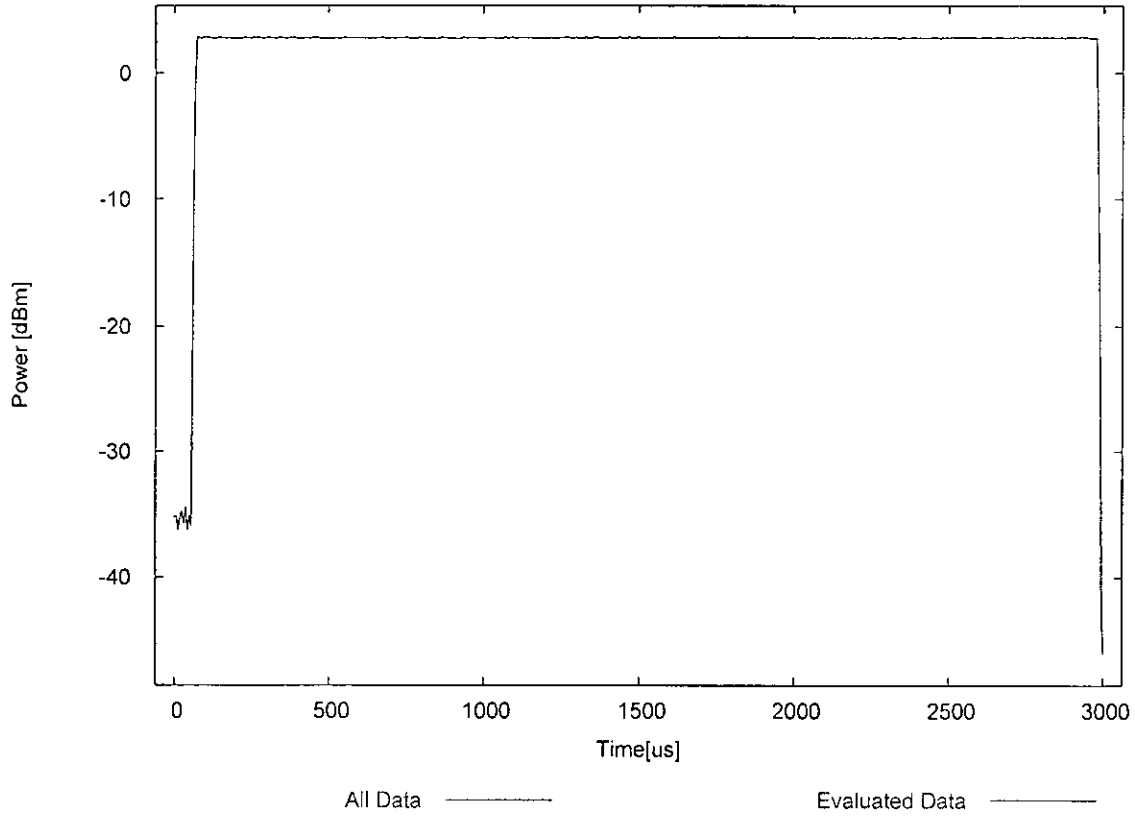
BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 010"
For test case parameter see 0, "Test Case Parameter 037"

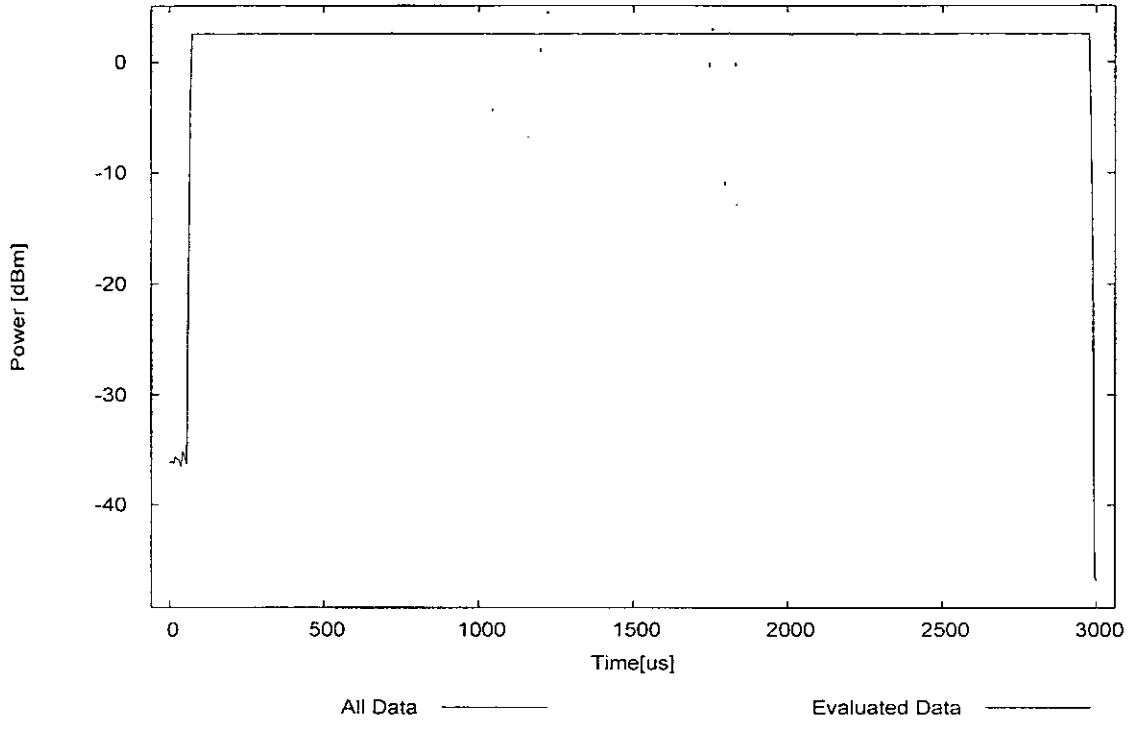
TX FREQ [MHz]	RX FREQ [MHz]	MEAS FREQ [MHz]	MEASUREMENT	LEVEL [dBm]	LIMIT [dBm]	VERDICT
hopping	hopping	2402.000	Average (+ gain)	-9.22 <	20.00	PASS
hopping	hopping	2402.000	Peak (+ gain)	-9.14 <	23.00	PASS
hopping	hopping	2402.000	Average	2.78 <	4.00	PASS
hopping	hopping	2402.000	Average	2.78 >	-6.00	PASS
hopping	hopping	2441.000	Average (+ gain)	-9.40 <	20.00	PASS
hopping	hopping	2441.000	Peak (+ gain)	-9.34 <	23.00	PASS
hopping	hopping	2441.000	Average	2.60 <	4.00	PASS
hopping	hopping	2441.000	Average	2.60 >	-6.00	PASS
hopping	hopping	2480.000	Average (+ gain)	-9.85 <	20.00	PASS
hopping	hopping	2480.000	Peak (+ gain)	-9.82 <	23.00	PASS
hopping	hopping	2480.000	Average	2.15 <	4.00	PASS
hopping	hopping	2480.000	Average	2.15 >	-6.00	PASS

Final Test Case Verdict . . . . . PASS 00:00:36

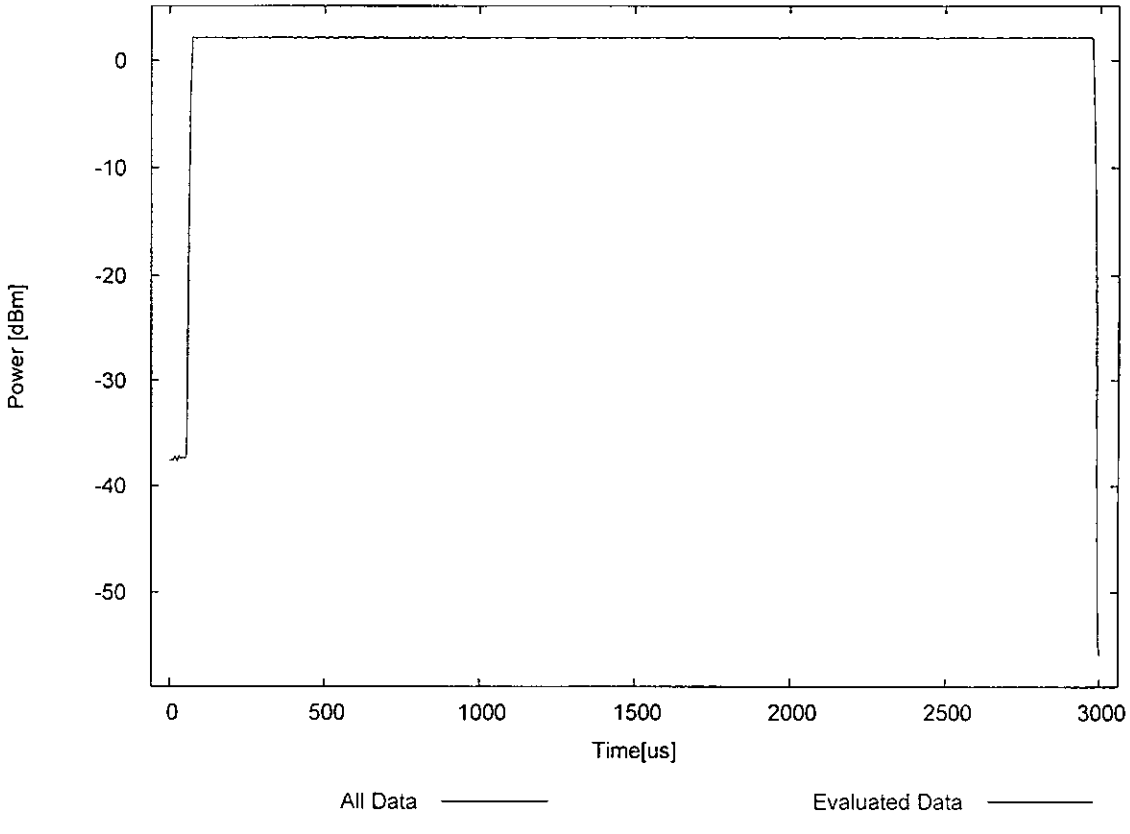
Measured Burst TC Output Power -Measured EUT: M3200 -EUT TX Frequency hopping (Meas: 2402.000 MHz)



Measured Burst TC Output Power -Measured EUT: M3200 -EUT TX Frequency hopping (Meas: 2441.000 MHz)



Measured Burst TC Output Power -Measured EUT: M3200 -EUT TX Frequency hopping (Meas: 2480.000 MHz)



Annex C

TRM/CA/02/C Power Density

Power Density

For system parameter see 0, "General Parameter 002"

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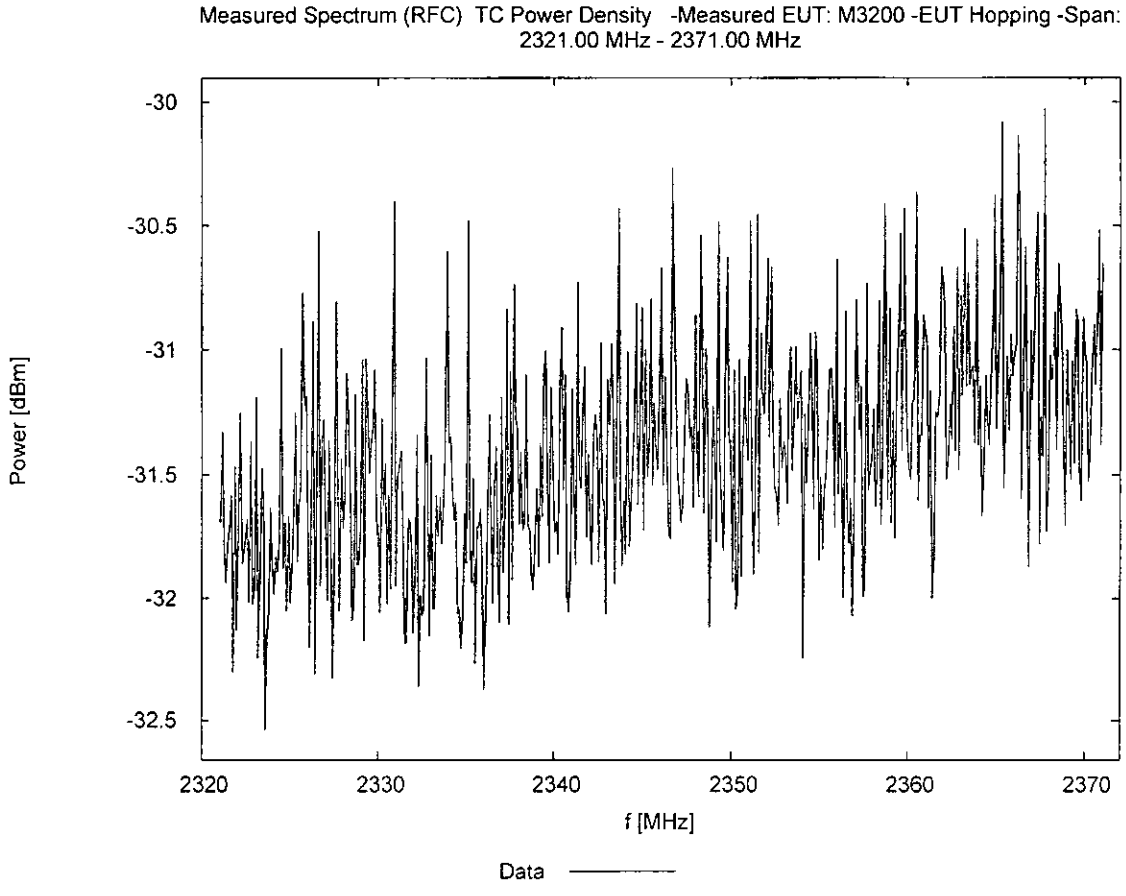
BT Test Specification Version:  1.2
```

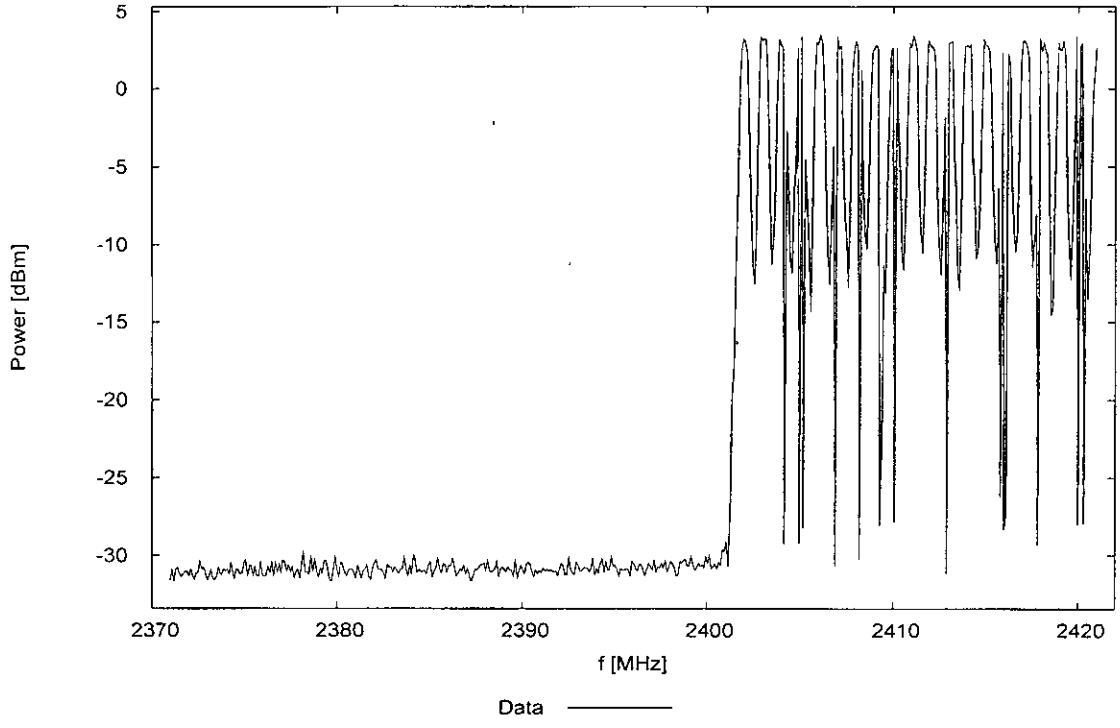
For EUT parameter see 0, "EUT Parameter 001"
For test case parameter see 0, "Test Case Parameter 002"

TX [MHz]	RX [MHz]	START [MHz]	STOP [MHz]	PEAK-FREQ [MHz]	LEVEL [dBm]	LIMIT [dBm]	VERDICT
hop	hop	2406.0	2406.0	2406.02555	-8.650 <	20.000	PASS

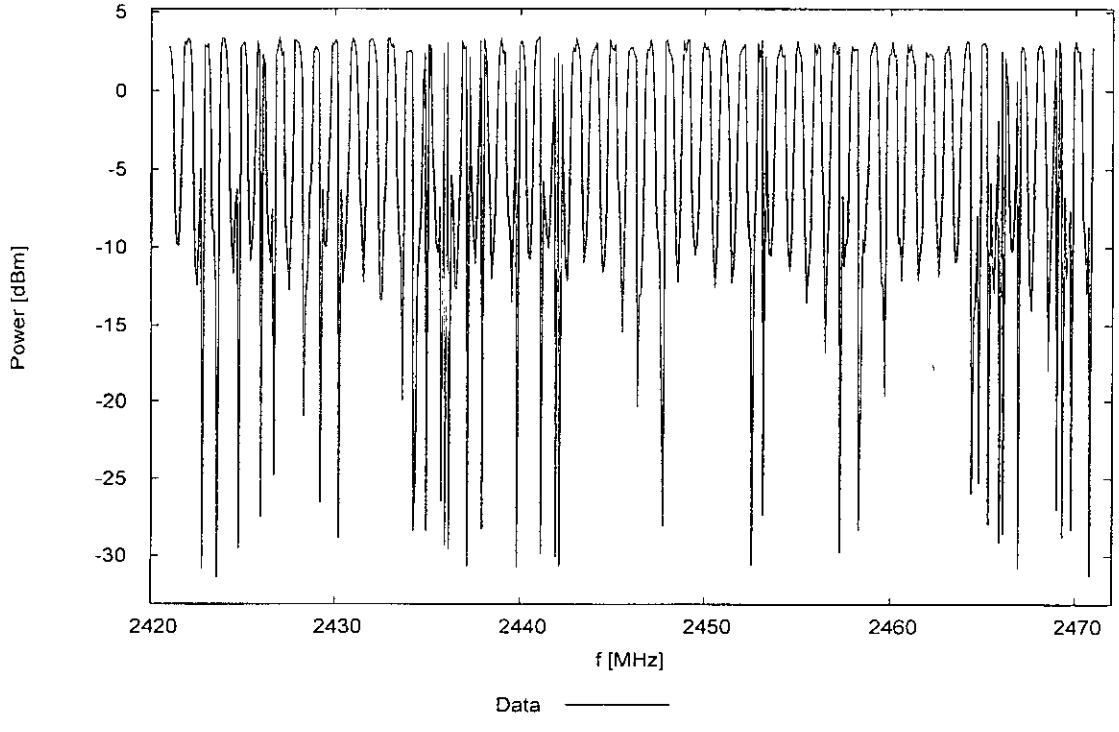
Final Test Case Verdict . . . . . PASS 00:41:34



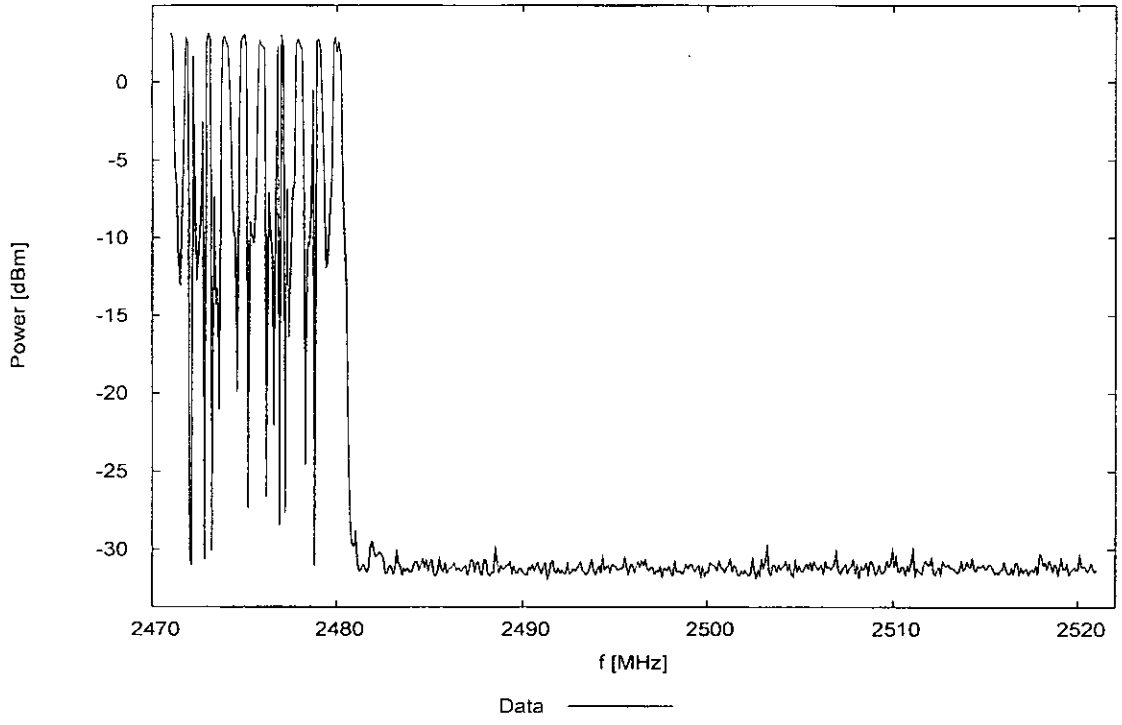
Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2371.00 MHz - 2421.00 MHz



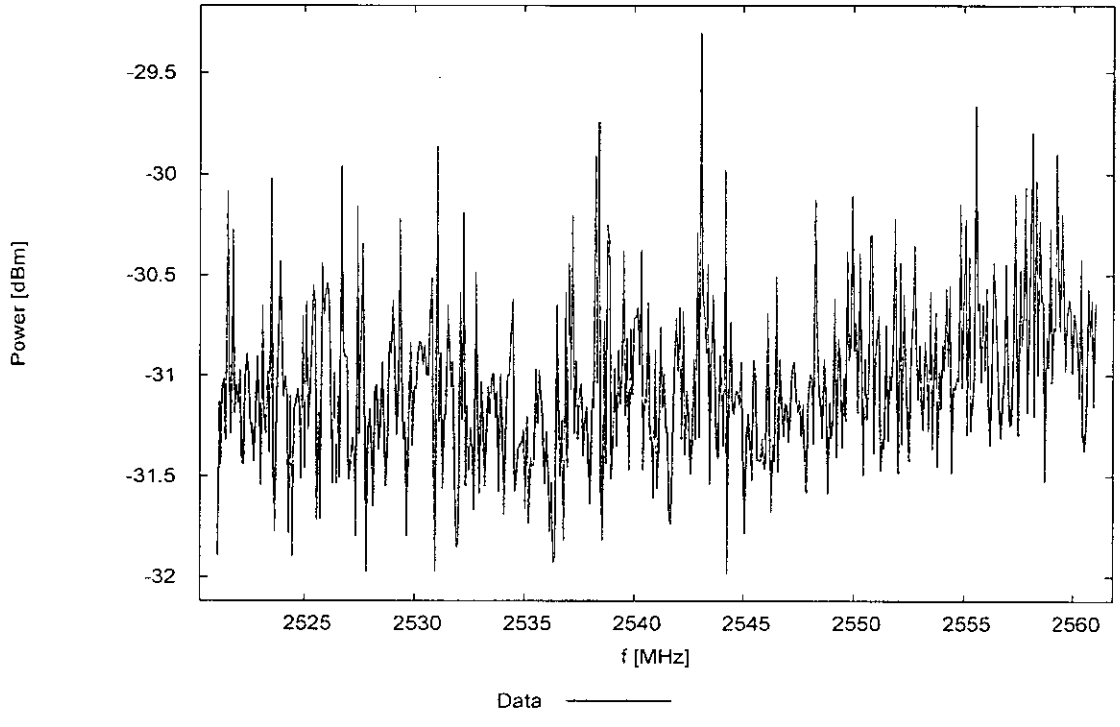
Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2421.00 MHz - 2471.00 MHz



Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2471.00 MHz - 2521.00 MHz



Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2521.00 MHz - 2561.00 MHz



Power Density

For system parameter see 0, "General Parameter 002"

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BT Test Specification Version:  1.2
```
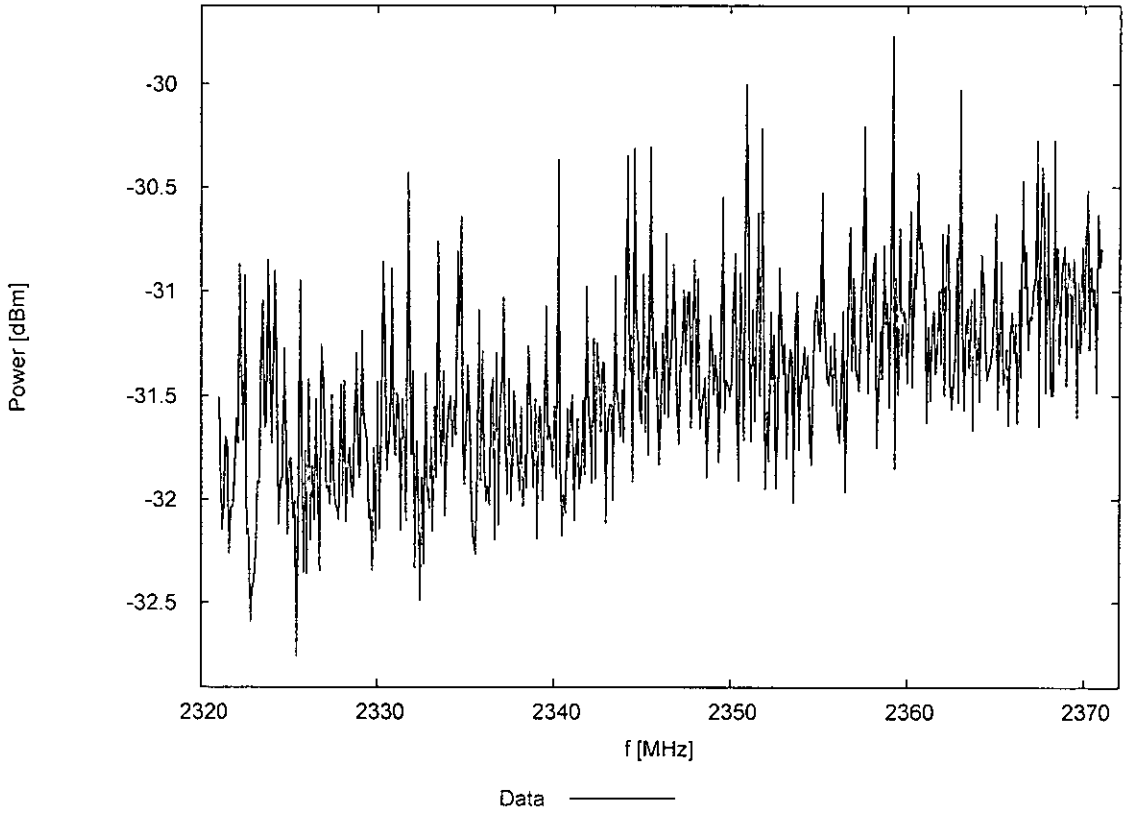

For EUT parameter see 0, "EUT Parameter 005"
For test case parameter see 0, "Test Case Parameter 018"

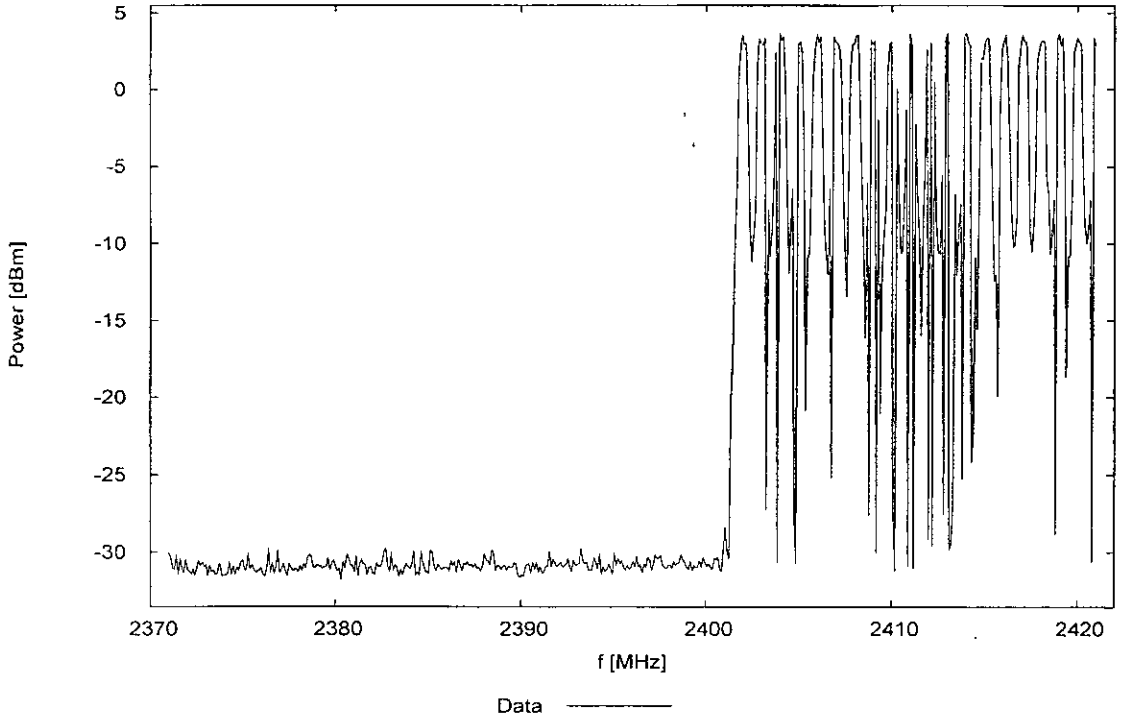
TX [MHz]	RX [MHz]	START [MHz]	STOP [MHz]	PEAK-FREQ [MHz]	LEVEL [dBm]	LIMIT [dBm]	VERDICT
hop	hop	2413.0	2413.0	2413.00852	-8.372 <	20.000	PASS

Final Test Case Verdict . . . . . PASS 00:41:39

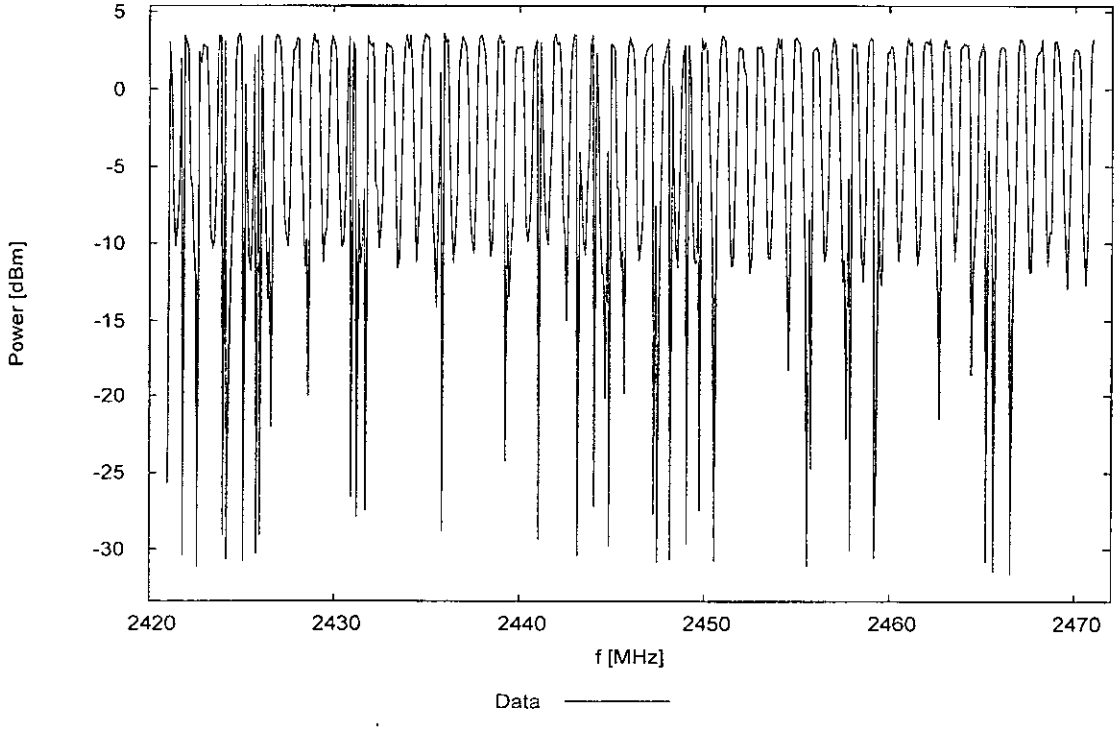
Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2321.00 MHz - 2371.00 MHz



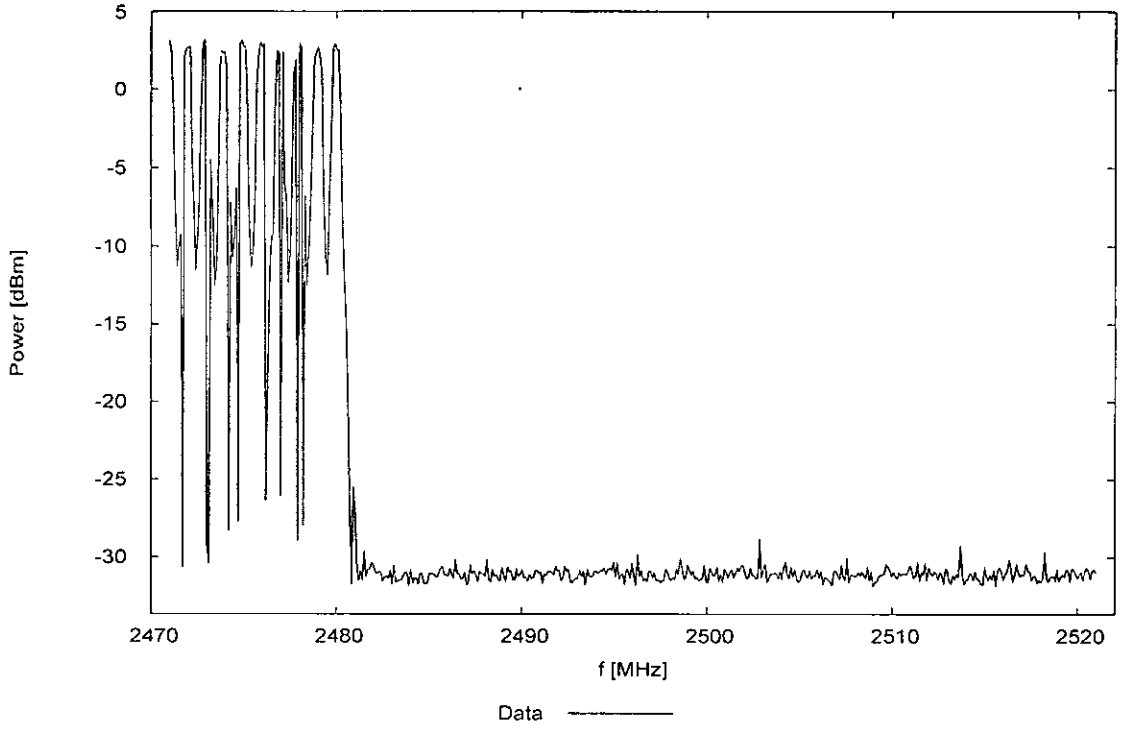
Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2371.00 MHz - 2421.00 MHz



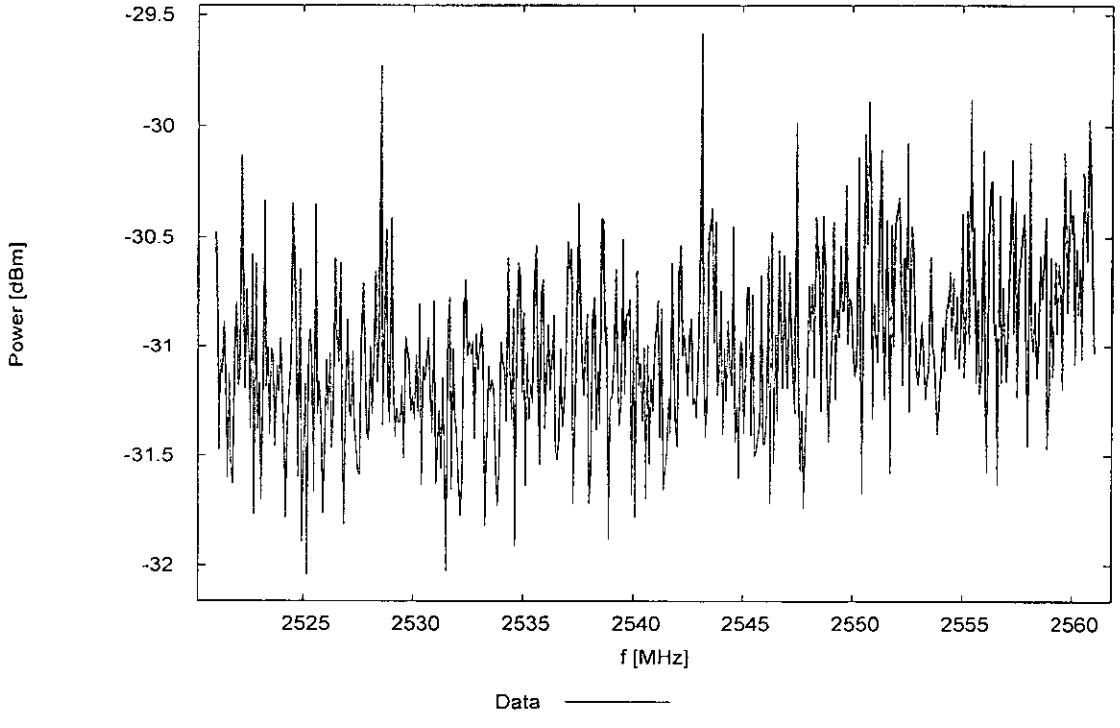
Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2421.00 MHz - 2471.00 MHz



Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2471.00 MHz - 2521.00 MHz



Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2521.00 MHz - 2561.00 MHz



Power Density

For system parameter see 0, "General Parameter 002"

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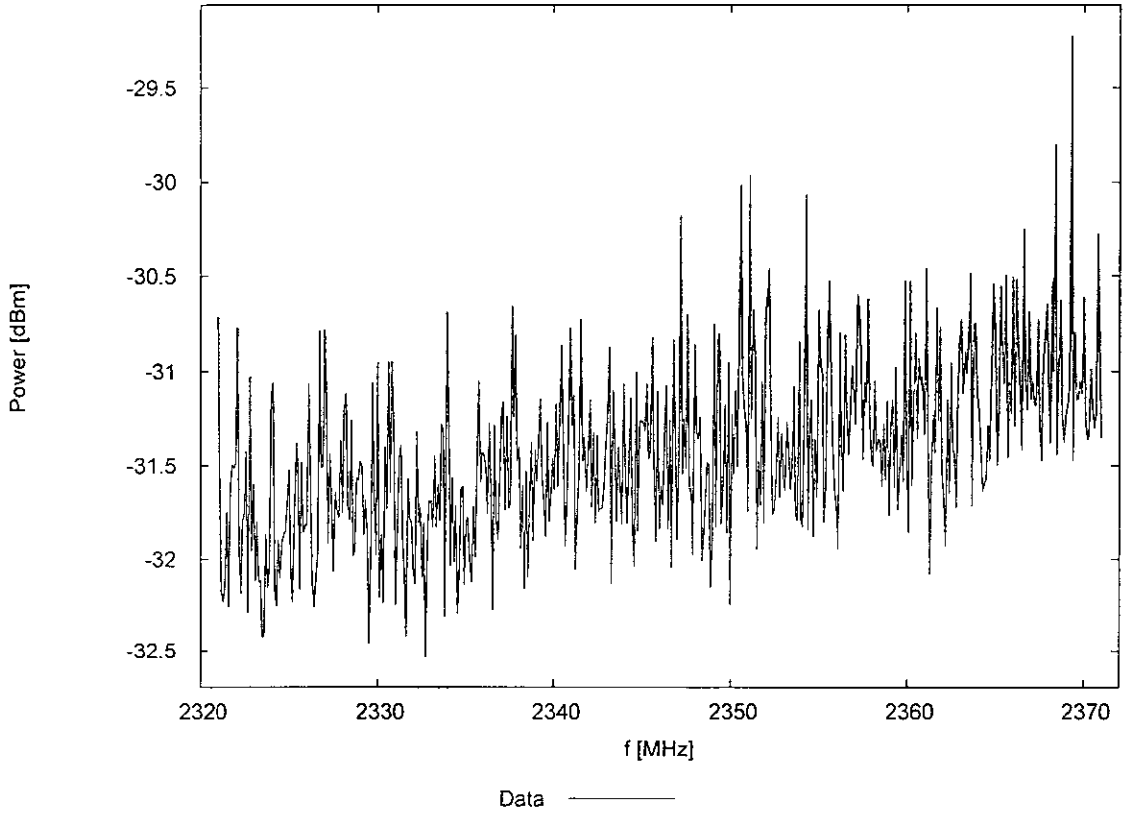
BT Test Specification Version:  1.2
```

For EUT parameter see 0, "EUT Parameter 006"
For test case parameter see 0, "Test Case Parameter 019"

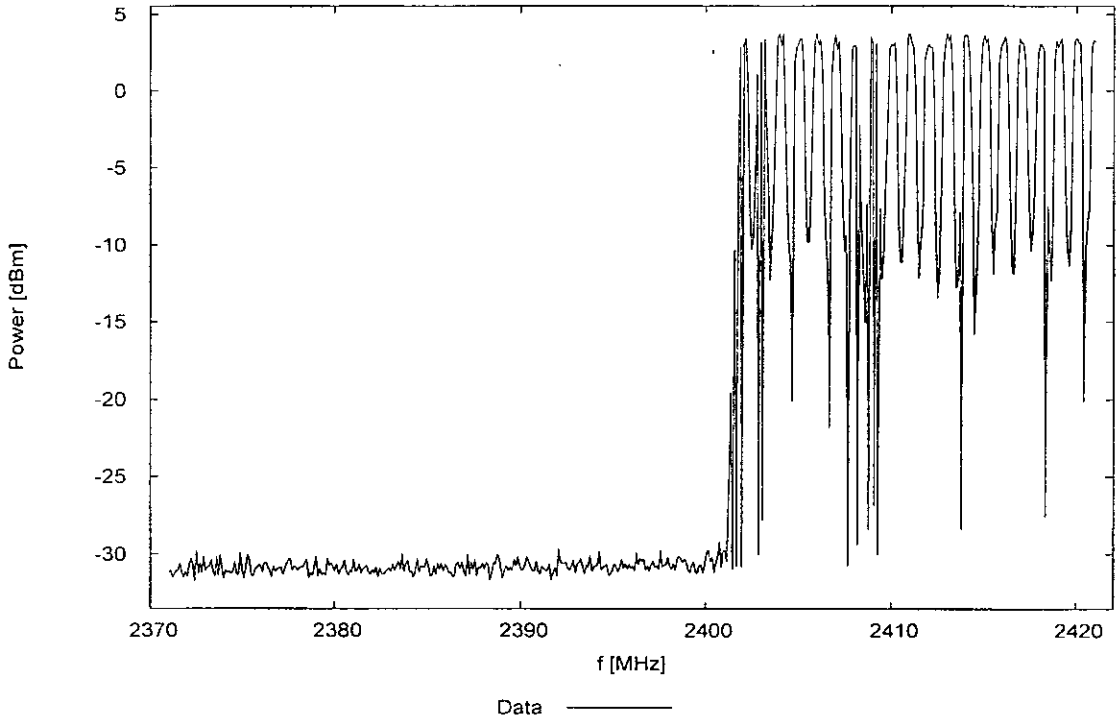
TX [MHz]	RX [MHz]	START [MHz]	STOP [MHz]	PEAK-FREQ [MHz]	LEVEL [dBm]	LIMIT [dBm]	VERDICT
hop	hop	2406.0	2406.0	2405.99950	-8.298 <	20.000	PASS

Final Test Case Verdict . . . . . PASS 00:41:50

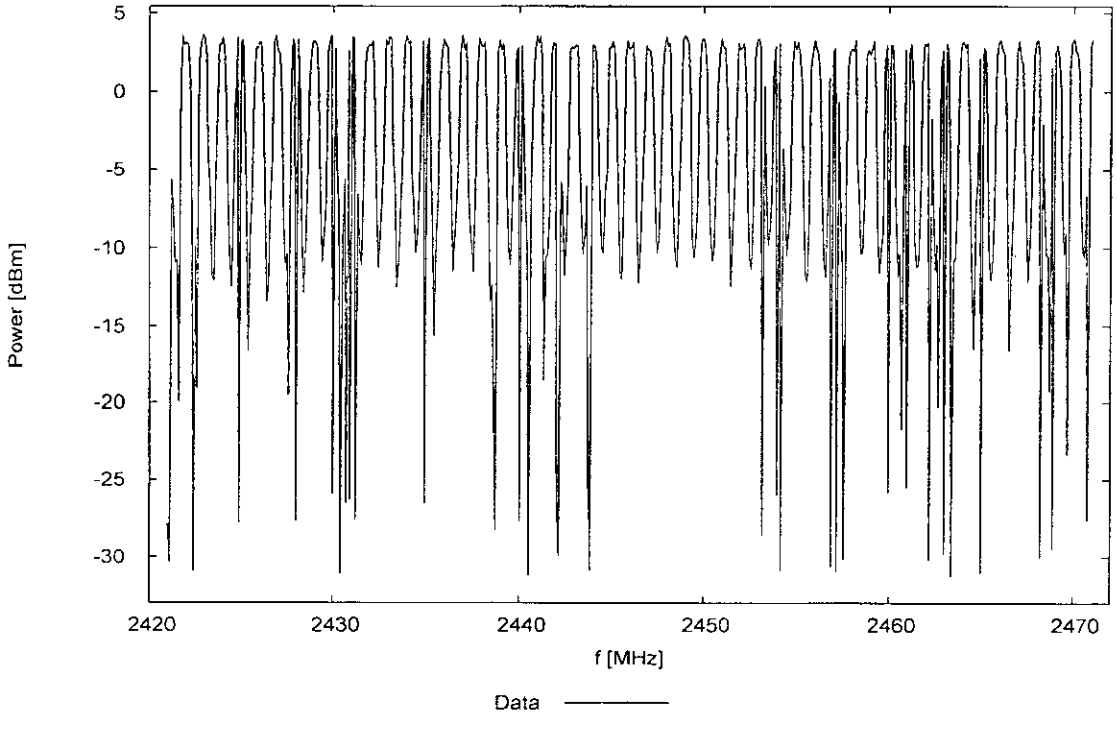
Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2321.00 MHz - 2371.00 MHz



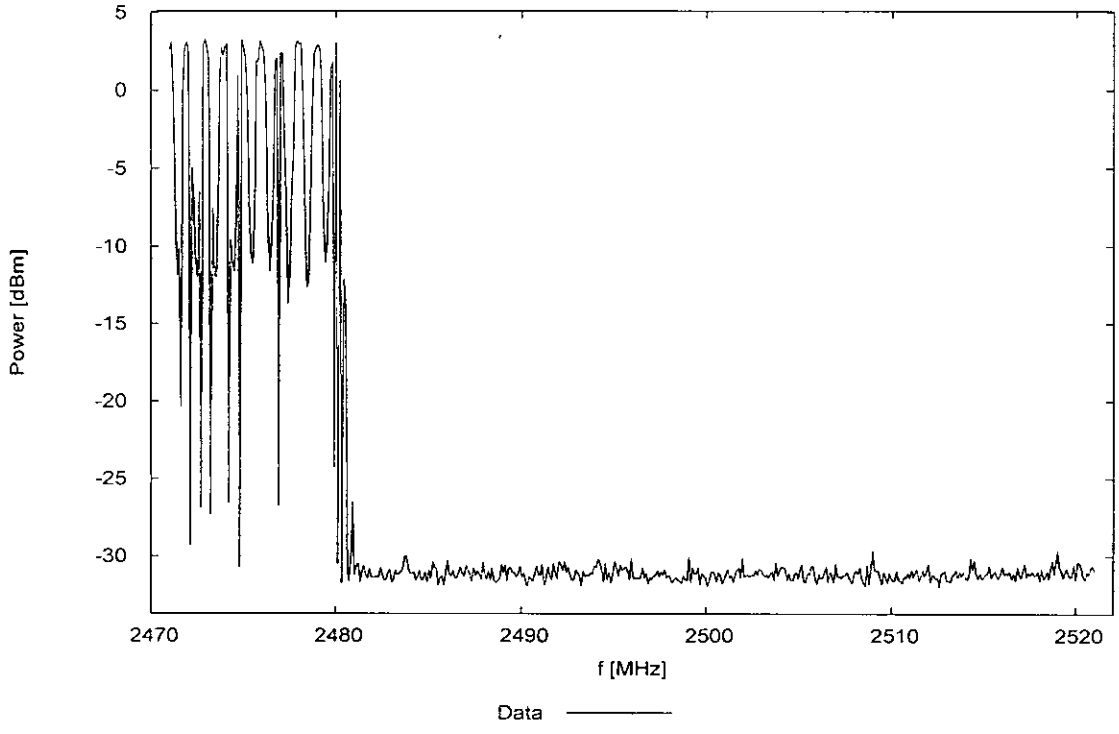
Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2371.00 MHz - 2421.00 MHz



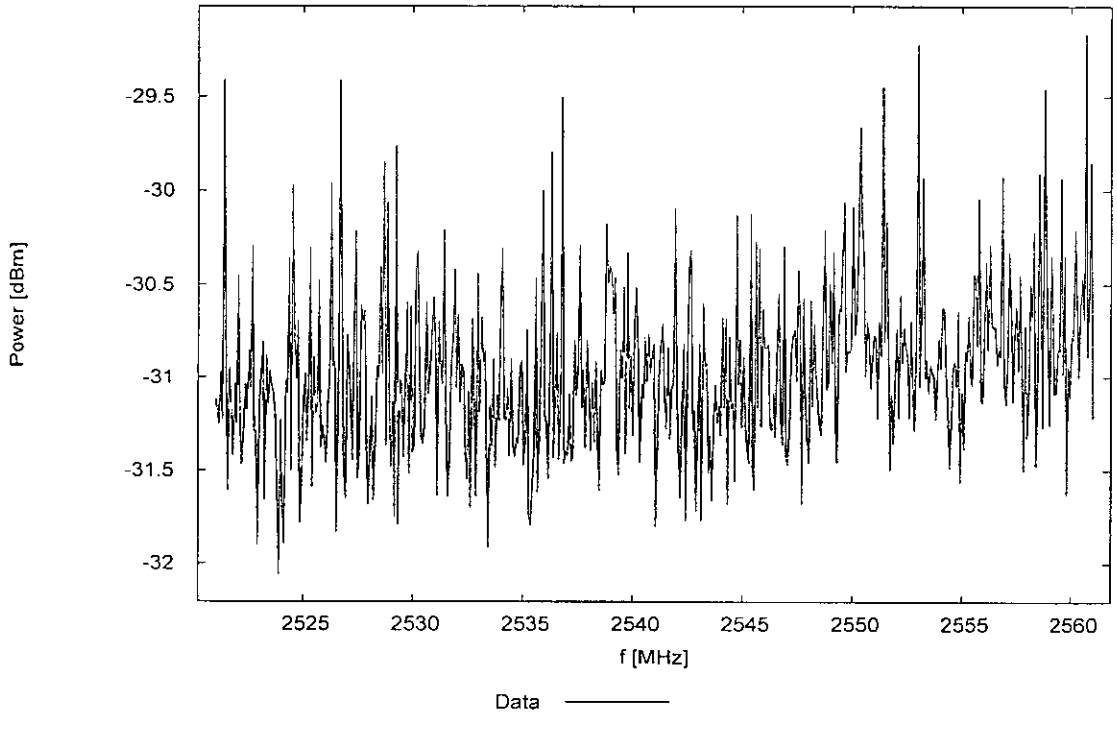
Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2421.00 MHz - 2471.00 MHz



Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2471.00 MHz - 2521.00 MHz



Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2521.00 MHz - 2561.00 MHz



Power Density

For system parameter see 0, "General Parameter 002"

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BT Test Specification Version:  1.2
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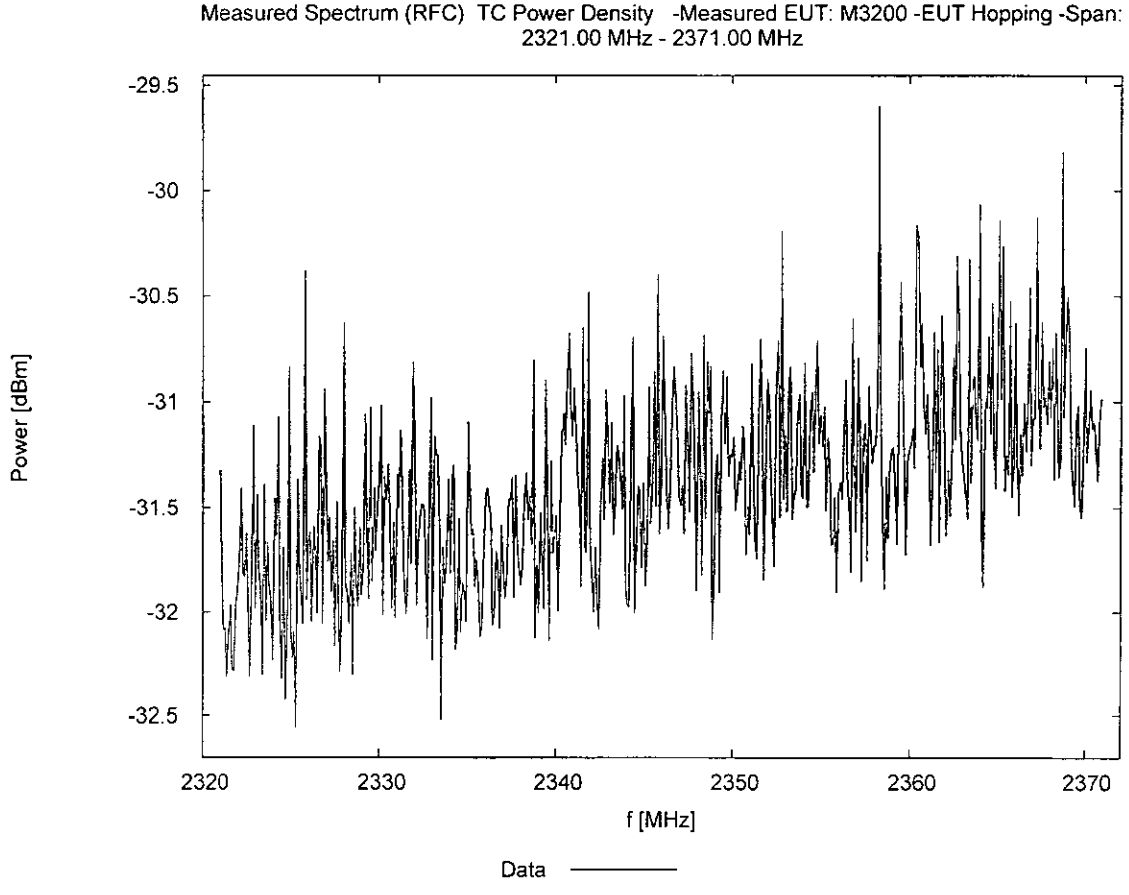
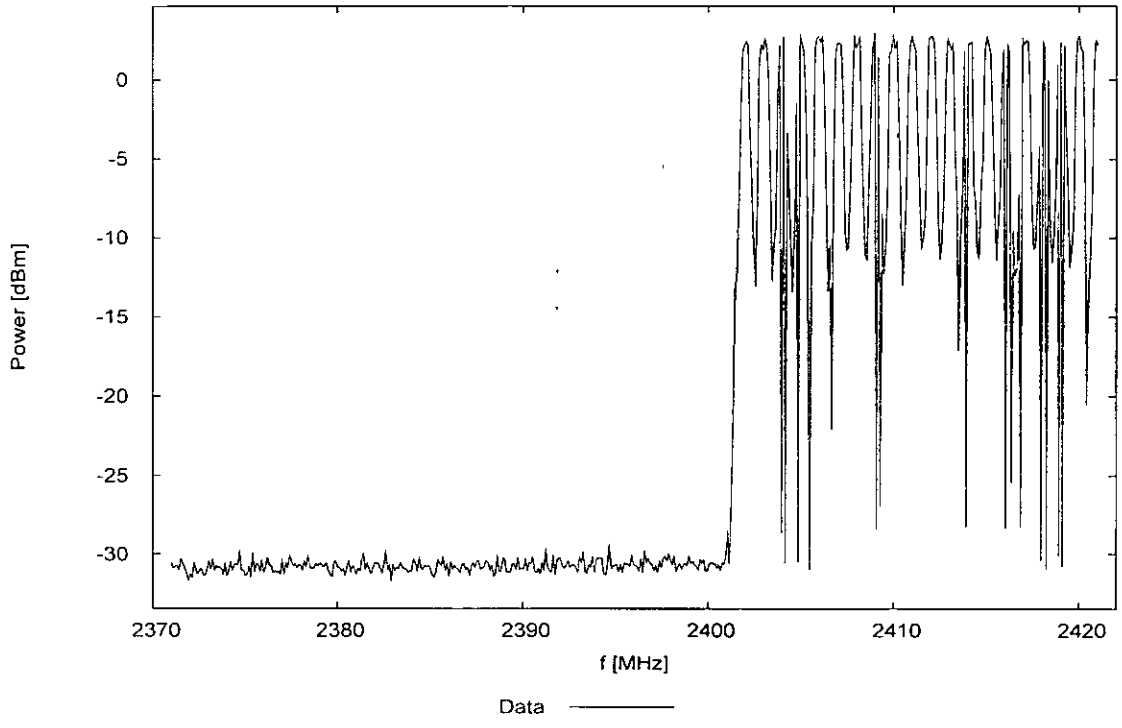
For EUT parameter see 0, "EUT Parameter 009"
For test case parameter see 0, "Test Case Parameter 038"

TX [MHz]	RX [MHz]	START [MHz]	STOP [MHz]	PEAK-FREQ [MHz]	LEVEL [dBm]	LIMIT [dBm]	VERDICT
hop	hop	2409.0	2409.0	2409.00852	-9.187 <	20.000	PASS

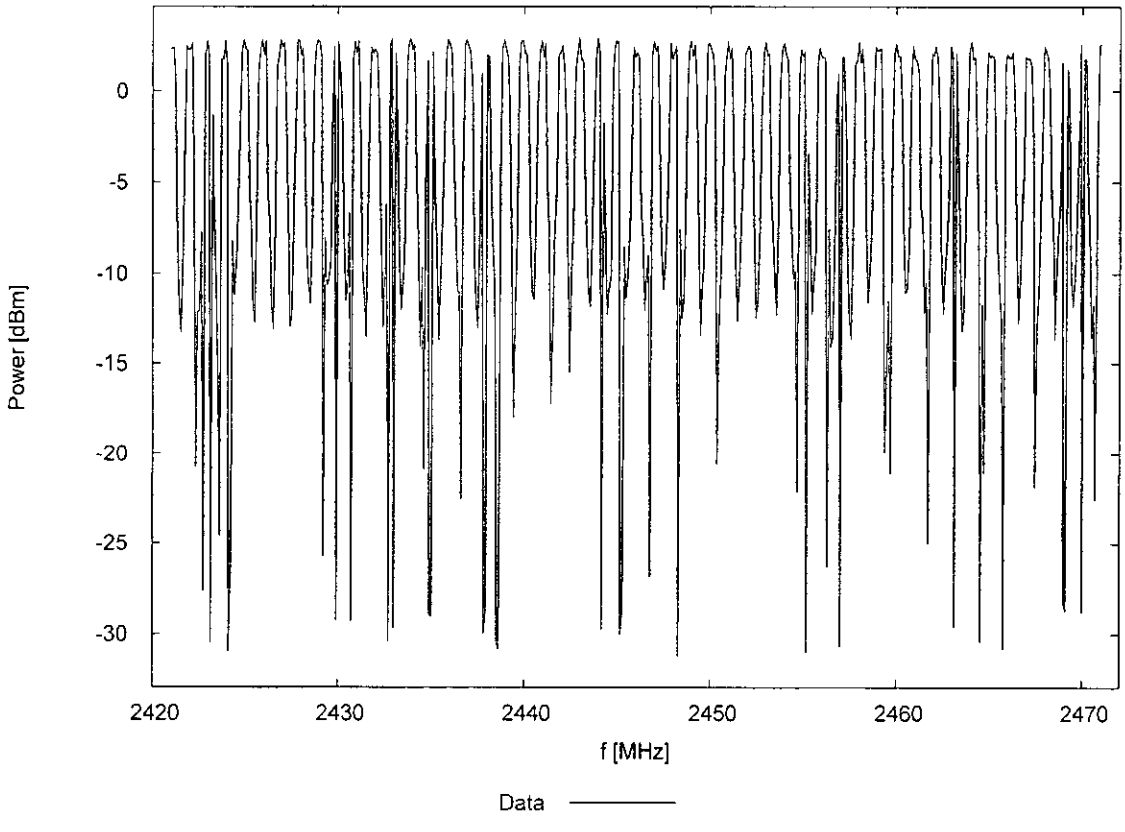
Final Test Case Verdict . . . . . PASS 00:41:41



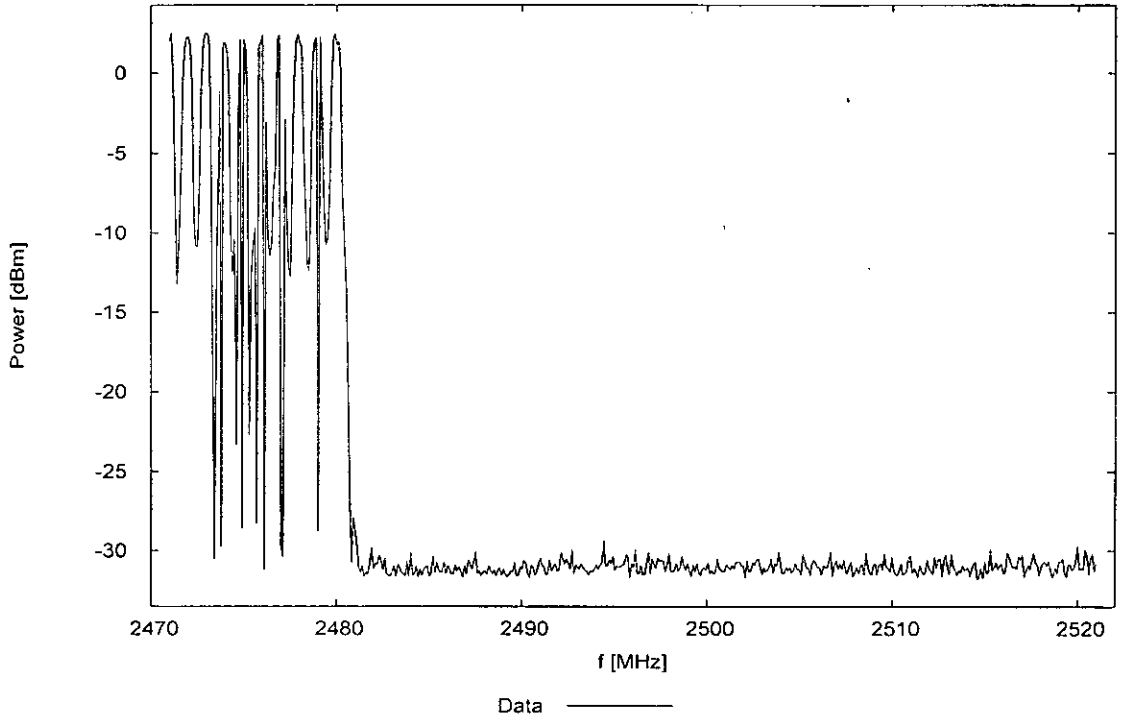
Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2371.00 MHz - 2421.00 MHz



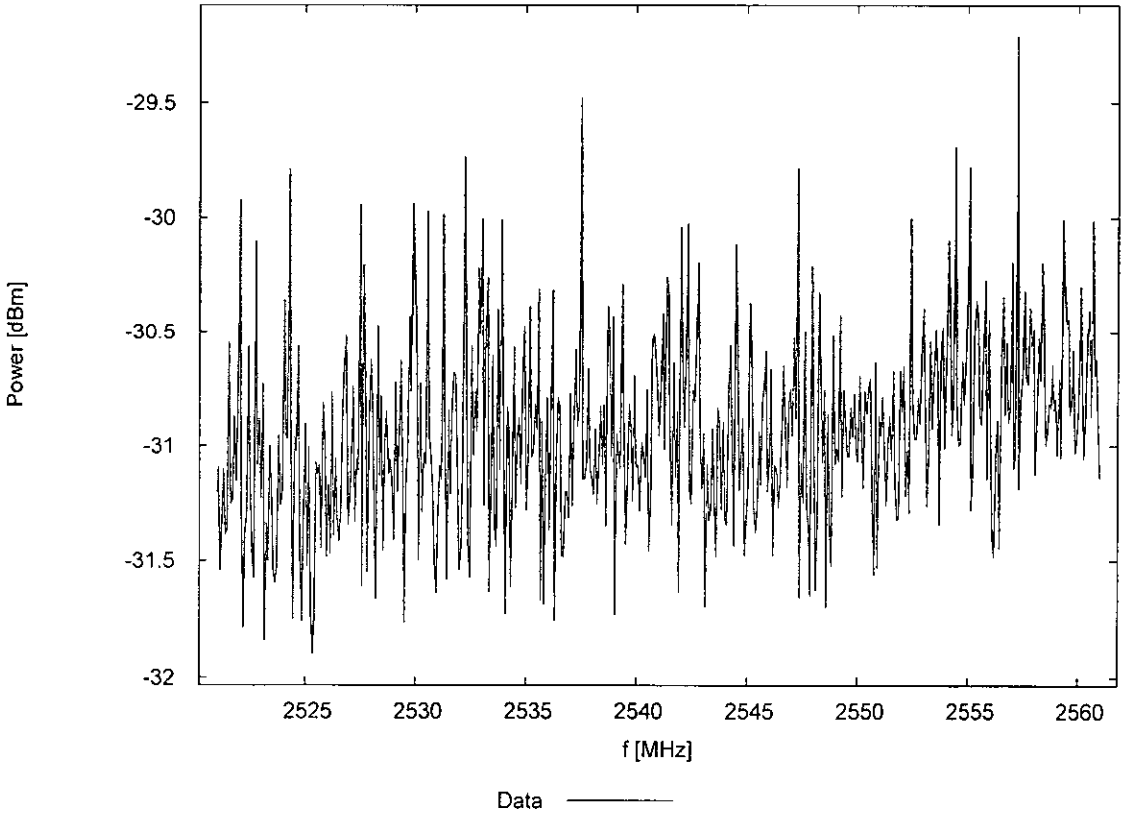
Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2421.00 MHz - 2471.00 MHz



Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2471.00 MHz - 2521.00 MHz



Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2521.00 MHz - 2561.00 MHz



Power Density

For system parameter see 0, "General Parameter 002"

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BT Test Specification Version:  1.2
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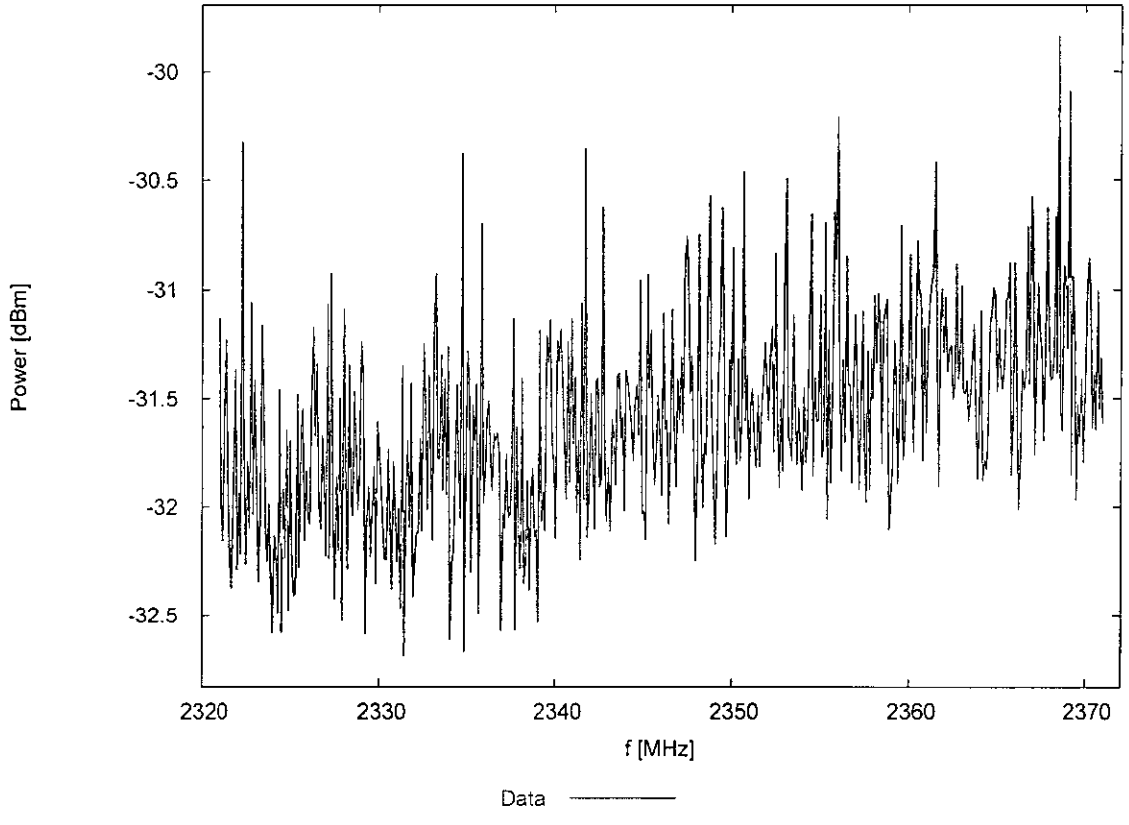
For EUT parameter see 0, "EUT Parameter 010"
For test case parameter see 0, "Test Case Parameter 039"

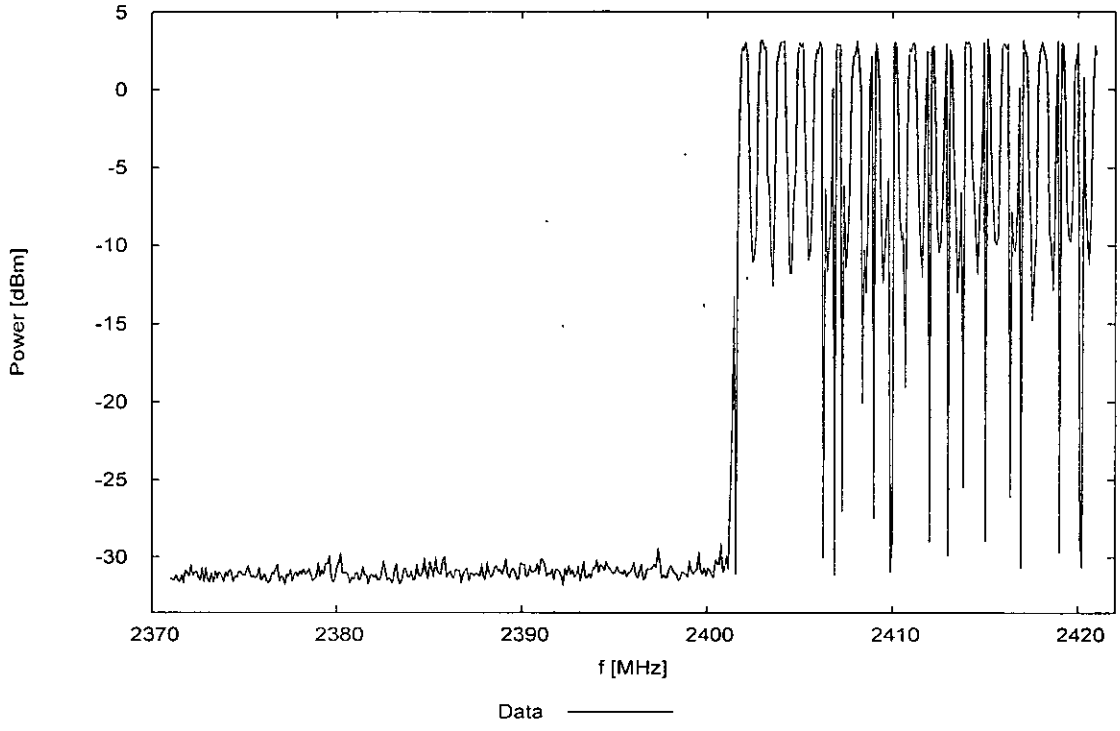
TX [MHz]	RX [MHz]	START [MHz]	STOP [MHz]	PEAK-FREQ [MHz]	LEVEL [dBm]	LIMIT [dBm]	VERDICT
hop	hop	2415.0	2415.0	2415.00651	-8.929 <	20.000	PASS

Final Test Case Verdict . . . . . PASS 00:41:38

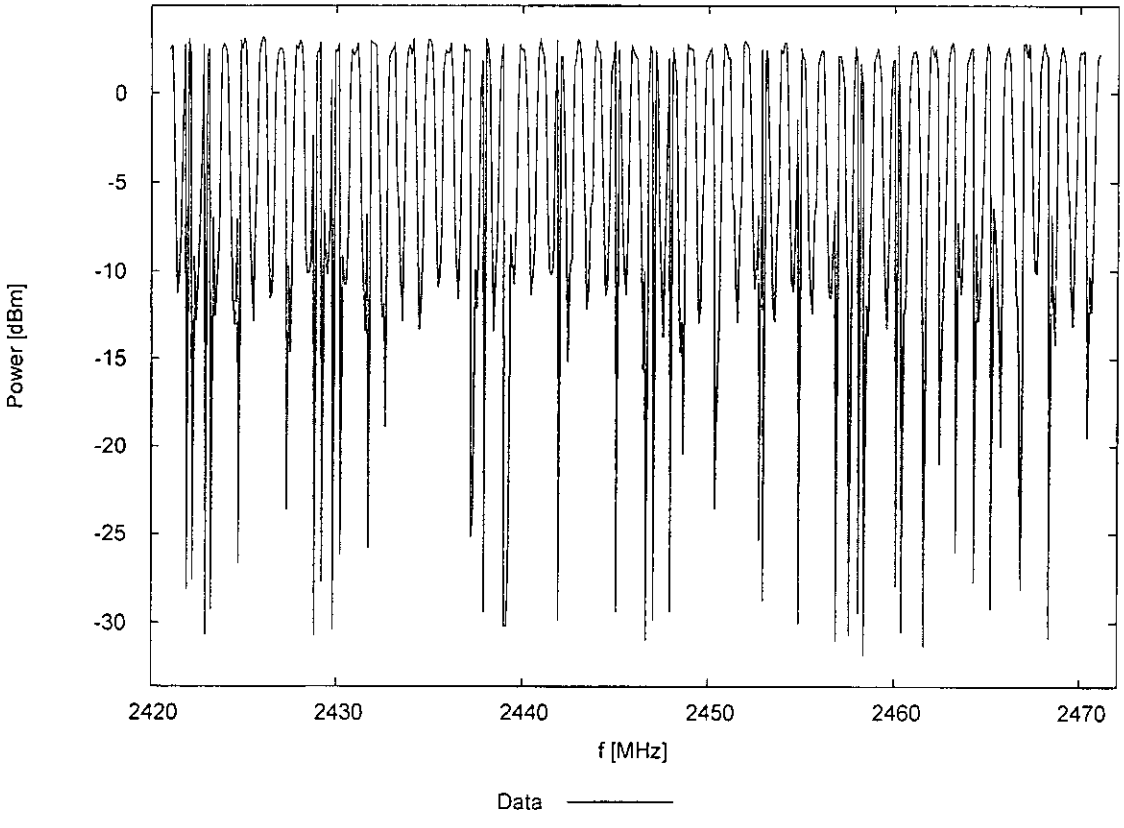
Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2321.00 MHz - 2371.00 MHz



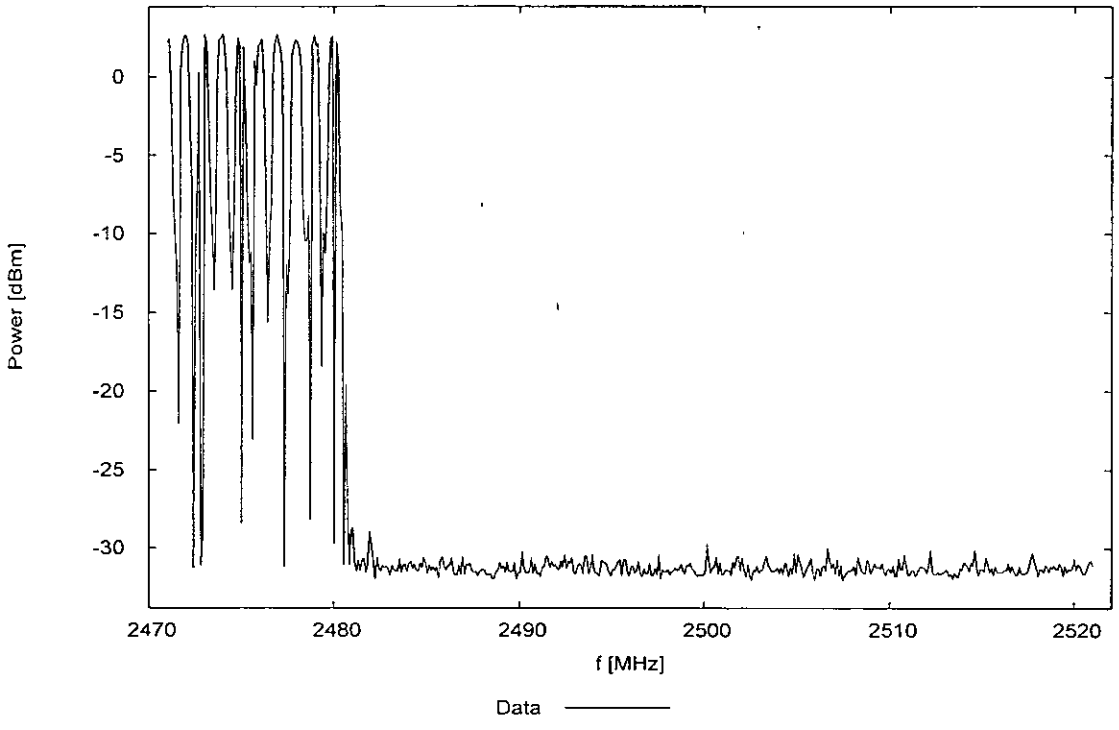
Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2371.00 MHz - 2421.00 MHz



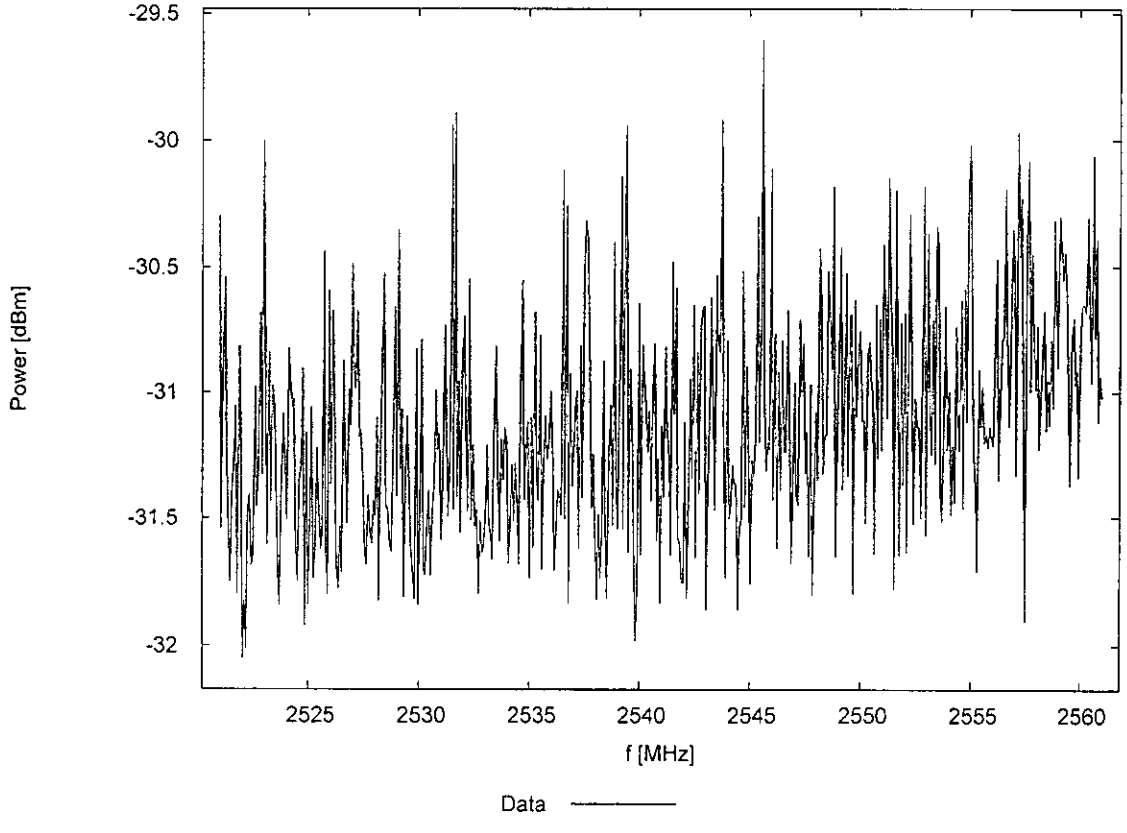
Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2421.00 MHz - 2471.00 MHz



Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2471.00 MHz - 2521.00 MHz



Measured Spectrum (RFC) TC Power Density -Measured EUT: M3200 -EUT Hopping -Span: 2521.00 MHz - 2561.00 MHz



Annex D

TRM/CA/03/C Power Control

Power Control

For system parameter see 0, "General Parameter 006"

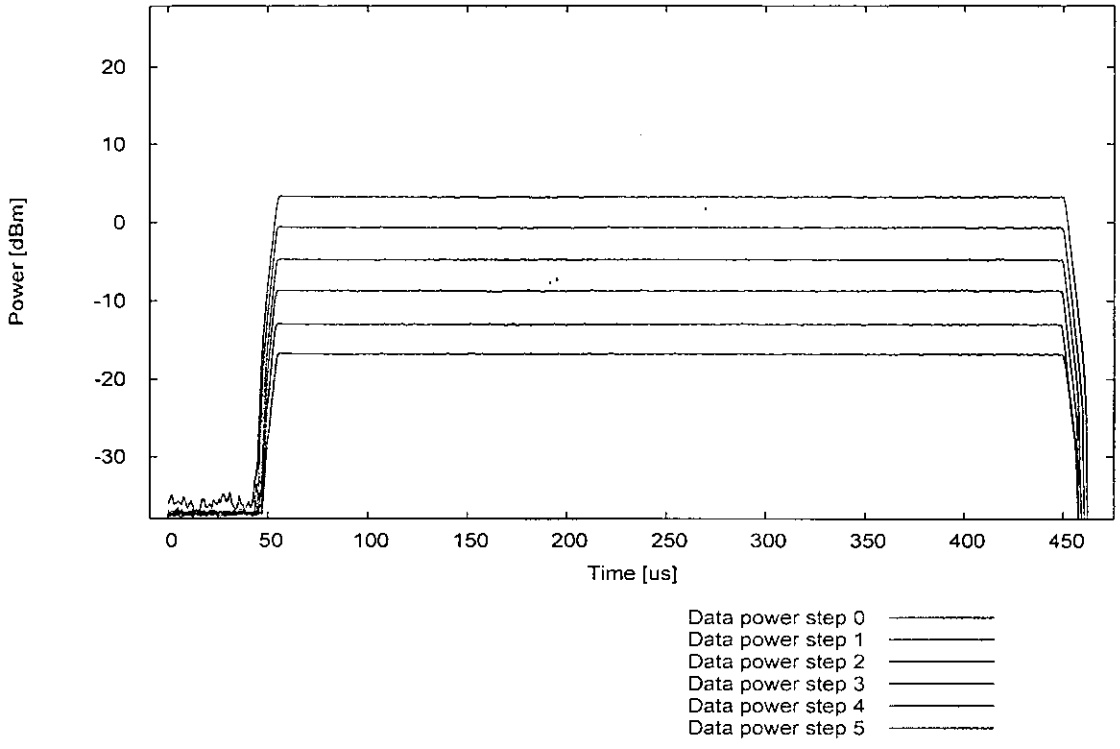
BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 003"
For test case parameter see 0, "Test Case Parameter 006"

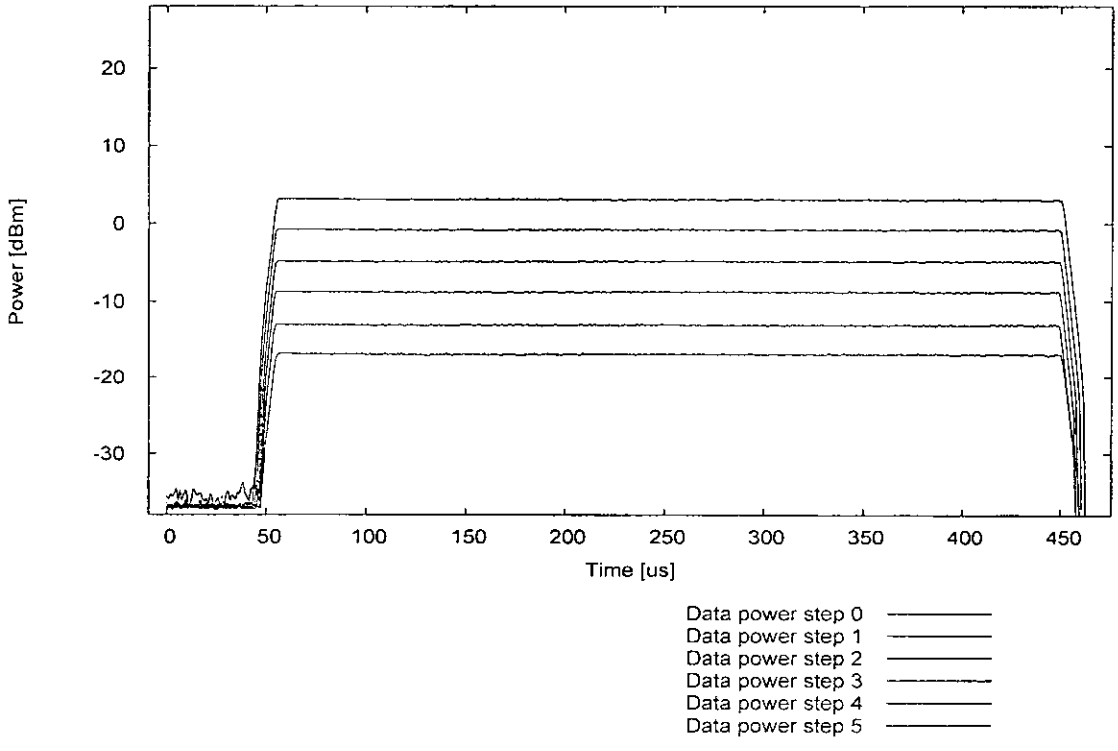
TX [MHz]	RX [MHz]	STEP	MEASUREMENT	LEVEL		LIMIT	VERDICT
2402.0	2480.0	1	Power Control	3.778 dB	>=	2.000 dB	PASS
2402.0	2480.0	1	Power Control	3.778 dB	<=	8.000 dB	PASS
2402.0	2480.0	2	Power Control	4.316 dB	>=	2.000 dB	PASS
2402.0	2480.0	2	Power Control	4.316 dB	<=	8.000 dB	PASS
2402.0	2480.0	3	Power Control	3.951 dB	>=	2.000 dB	PASS
2402.0	2480.0	3	Power Control	3.951 dB	<=	8.000 dB	PASS
2402.0	2480.0	4	Power Control	4.110 dB	>=	2.000 dB	PASS
2402.0	2480.0	4	Power Control	4.110 dB	<=	8.000 dB	PASS
2402.0	2480.0	5	Power Control	3.886 dB	>=	2.000 dB	PASS
2402.0	2480.0	5	Power Control	3.886 dB	<=	8.000 dB	PASS
2441.0	2402.0	1	Power Control	3.751 dB	>=	2.000 dB	PASS
2441.0	2402.0	1	Power Control	3.751 dB	<=	8.000 dB	PASS
2441.0	2402.0	2	Power Control	4.283 dB	>=	2.000 dB	PASS
2441.0	2402.0	2	Power Control	4.283 dB	<=	8.000 dB	PASS
2441.0	2402.0	3	Power Control	3.941 dB	>=	2.000 dB	PASS
2441.0	2402.0	3	Power Control	3.941 dB	<=	8.000 dB	PASS
2441.0	2402.0	4	Power Control	4.097 dB	>=	2.000 dB	PASS
2441.0	2402.0	4	Power Control	4.097 dB	<=	8.000 dB	PASS
2441.0	2402.0	5	Power Control	3.860 dB	>=	2.000 dB	PASS
2441.0	2402.0	5	Power Control	3.860 dB	<=	8.000 dB	PASS
2480.0	2402.0	1	Power Control	3.739 dB	>=	2.000 dB	PASS
2480.0	2402.0	1	Power Control	3.739 dB	<=	8.000 dB	PASS
2480.0	2402.0	2	Power Control	4.298 dB	>=	2.000 dB	PASS
2480.0	2402.0	2	Power Control	4.298 dB	<=	8.000 dB	PASS
2480.0	2402.0	3	Power Control	3.917 dB	>=	2.000 dB	PASS
2480.0	2402.0	3	Power Control	3.917 dB	<=	8.000 dB	PASS
2480.0	2402.0	4	Power Control	4.067 dB	>=	2.000 dB	PASS
2480.0	2402.0	4	Power Control	4.067 dB	<=	8.000 dB	PASS
2480.0	2402.0	5	Power Control	3.908 dB	>=	2.000 dB	PASS
2480.0	2402.0	5	Power Control	3.908 dB	<=	8.000 dB	PASS

Final Test Case Verdict . . . . . PASS 00:03:16

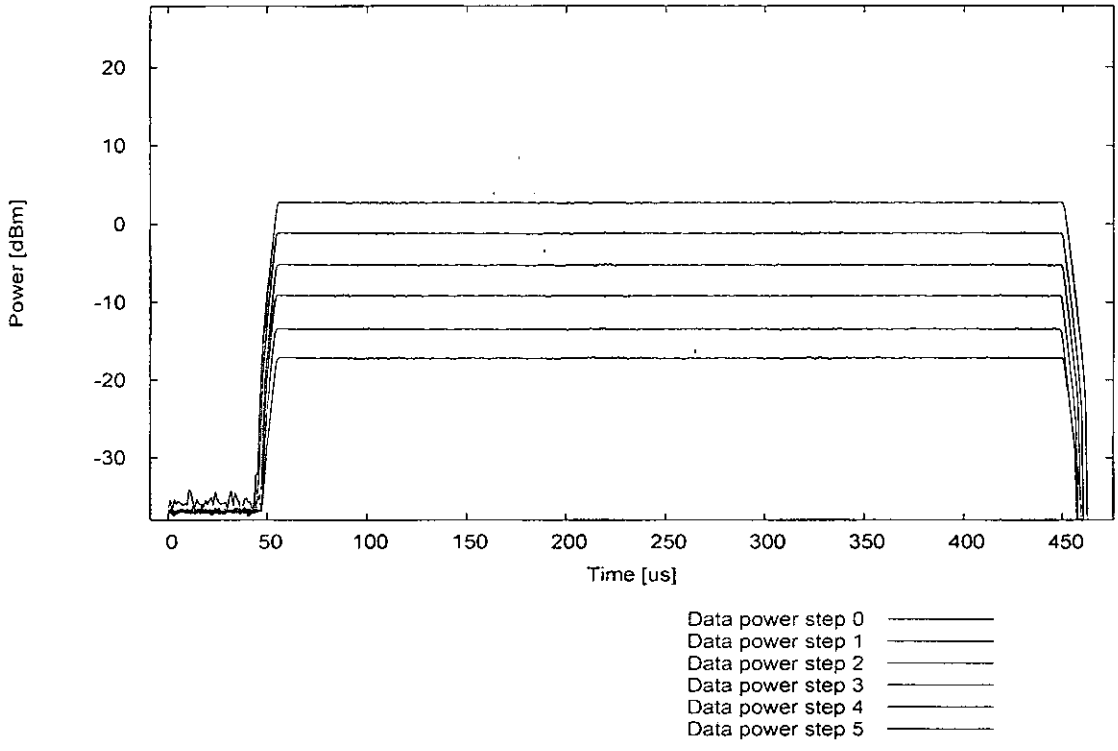
Measured Bursts TC Power Control -Measured EUT: M3200 -EUT TX Frequency 2402.000 MHz



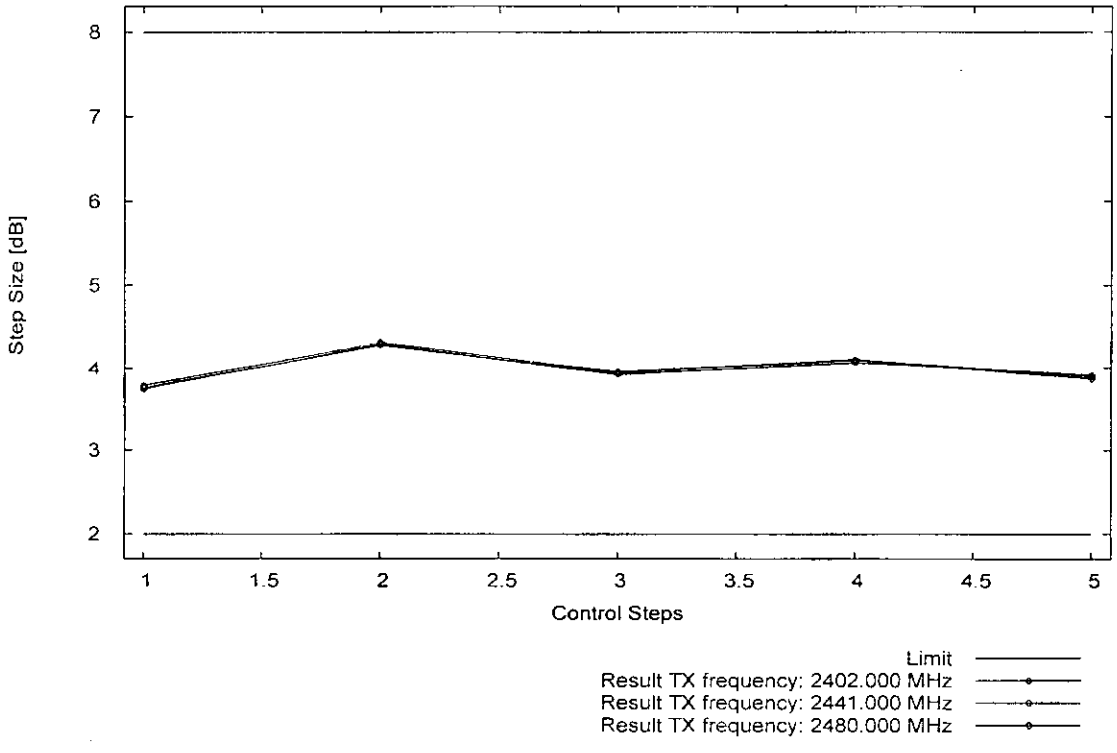
Measured Bursts TC Power Control -Measured EUT: M3200 -EUT TX Frequency 2441.000 MHz



Measured Bursts TC Power Control -Measured EUT: M3200 -EUT TX Frequency 2480.000 MHz



Results TC Power Control -Measured EUT: M3200



Annex E

TRM/CA/04/C TX Output Spectrum - Frequency Range

TX Output Spectrum - Frequency Range

For system parameter see 0, "General Parameter 003"

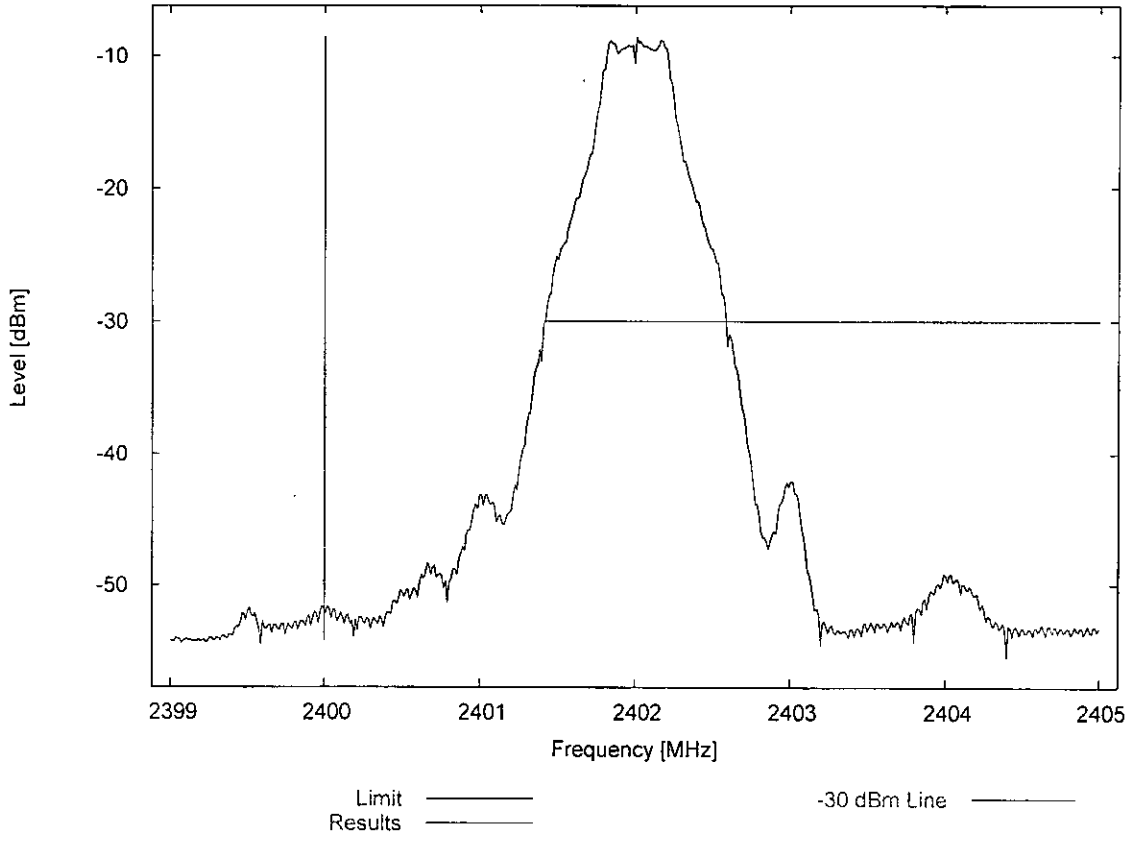
BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 002"
For test case parameter see 0, "Test Case Parameter 003"

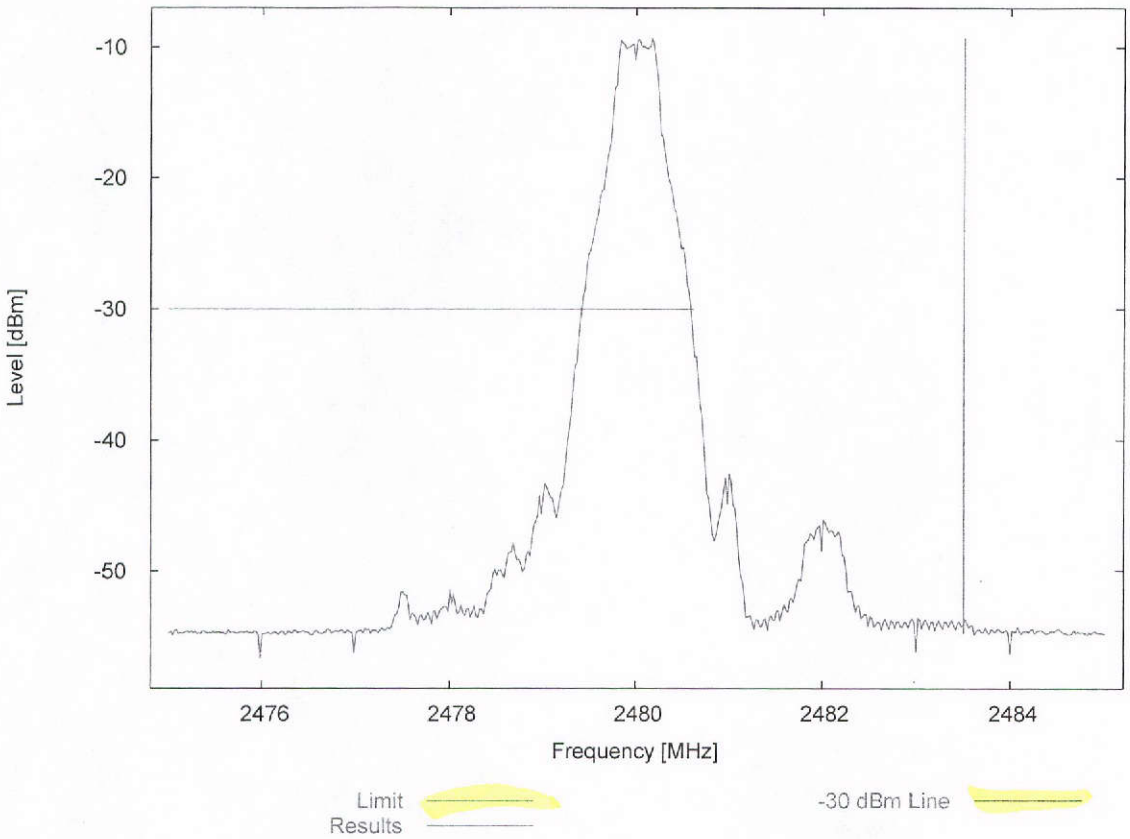
TX-FREQ [MHz]	RX-FREQ [MHz]	START [MHz]	STOP [MHz]	FREQ [MHz]		LIMIT [MHz]	VERDICT
2402.0	2480.0	2399.000	2405.000	2401.412	>=	2400.000	PASS
2480.0	2402.0	2475.000	2485.000	2480.620	<=	2483.500	PASS

Final Test Case Verdict . . . . . PASS 00:05:04

Results TC Frequency Range (Low) -EUT TX Frequency 2402.000 MHz



Results TC Frequency Range (High) -EUT TX Frequency 2480.000 MHz



TX Output Spectrum - Frequency Range

For system parameter see 0, "General Parameter 003"

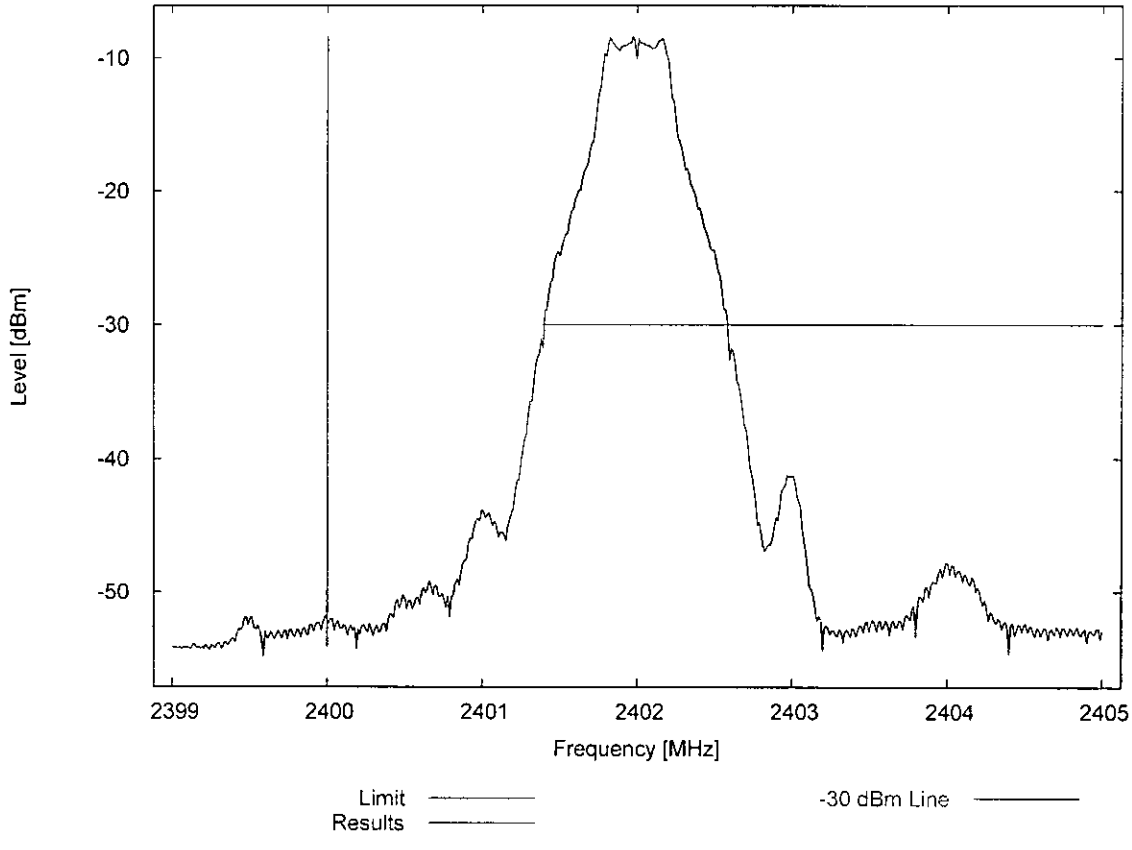
BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 005"
For test case parameter see 0, "Test Case Parameter 020"

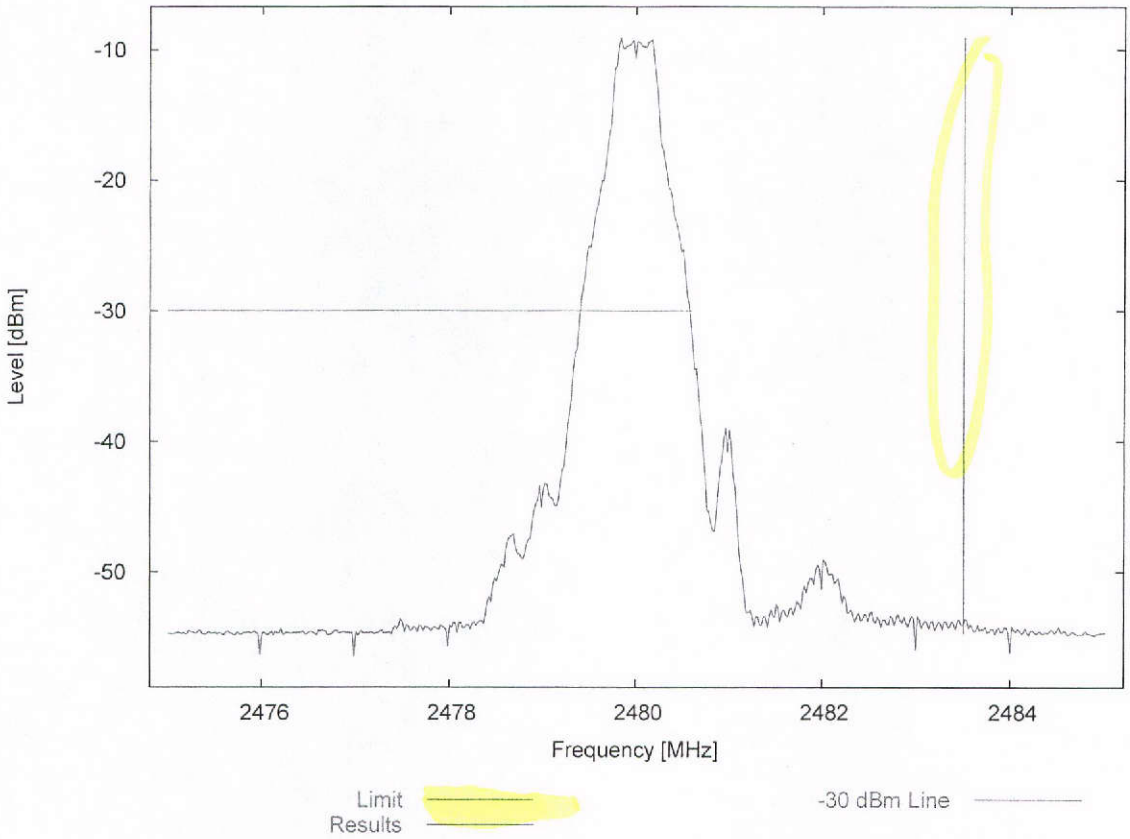
TX-FREQ [MHz]	RX-FREQ [MHz]	START [MHz]	STOP [MHz]	FREQ [MHz]		LIMIT [MHz]	VERDICT
2402.0	2480.0	2399.000	2405.000	2401.388	>=	2400.000	PASS
2480.0	2402.0	2475.000	2485.000	2480.600	<=	2483.500	PASS

Final Test Case Verdict . . . . . PASS 00:05:00

Results TC Frequency Range (Low) -EUT TX Frequency 2402.000 MHz



Results TC Frequency Range (High) -EUT TX Frequency 2480.000 MHz



TX Output Spectrum - Frequency Range

For system parameter see 0, "General Parameter 003"

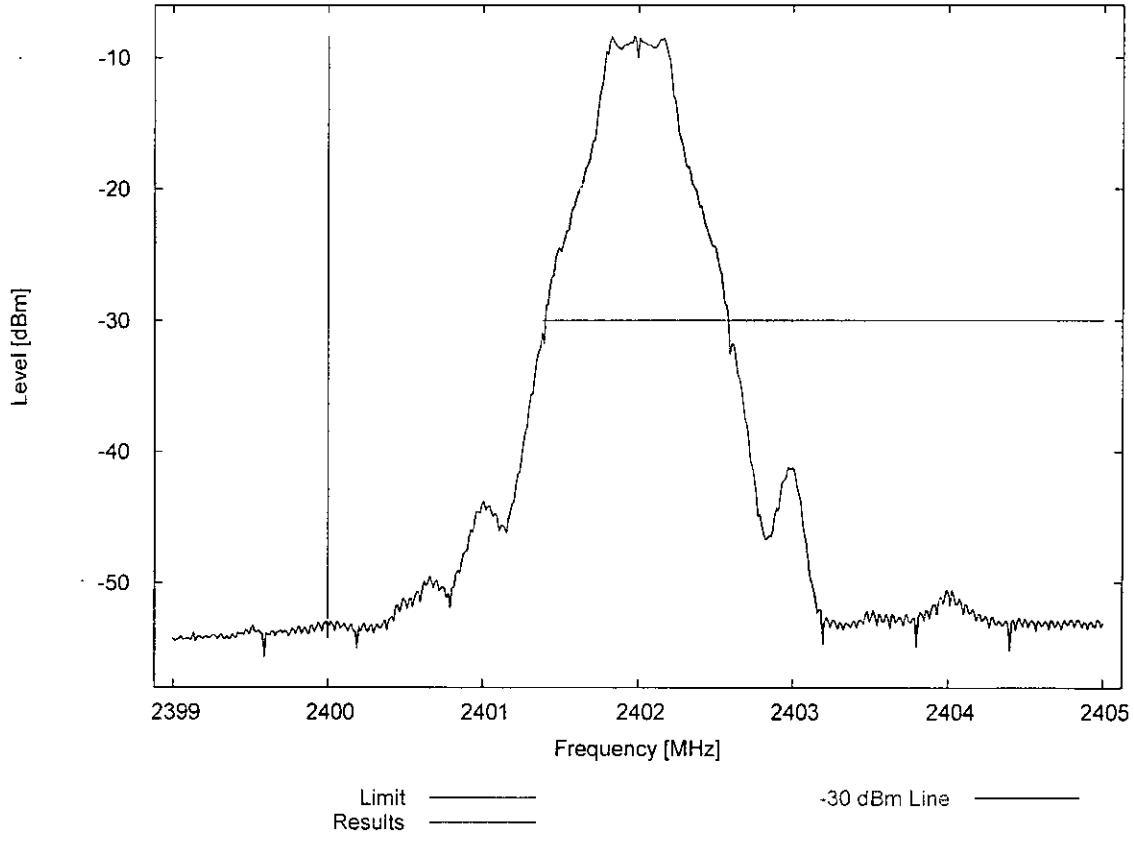
BT Test Specification Version: 1.2

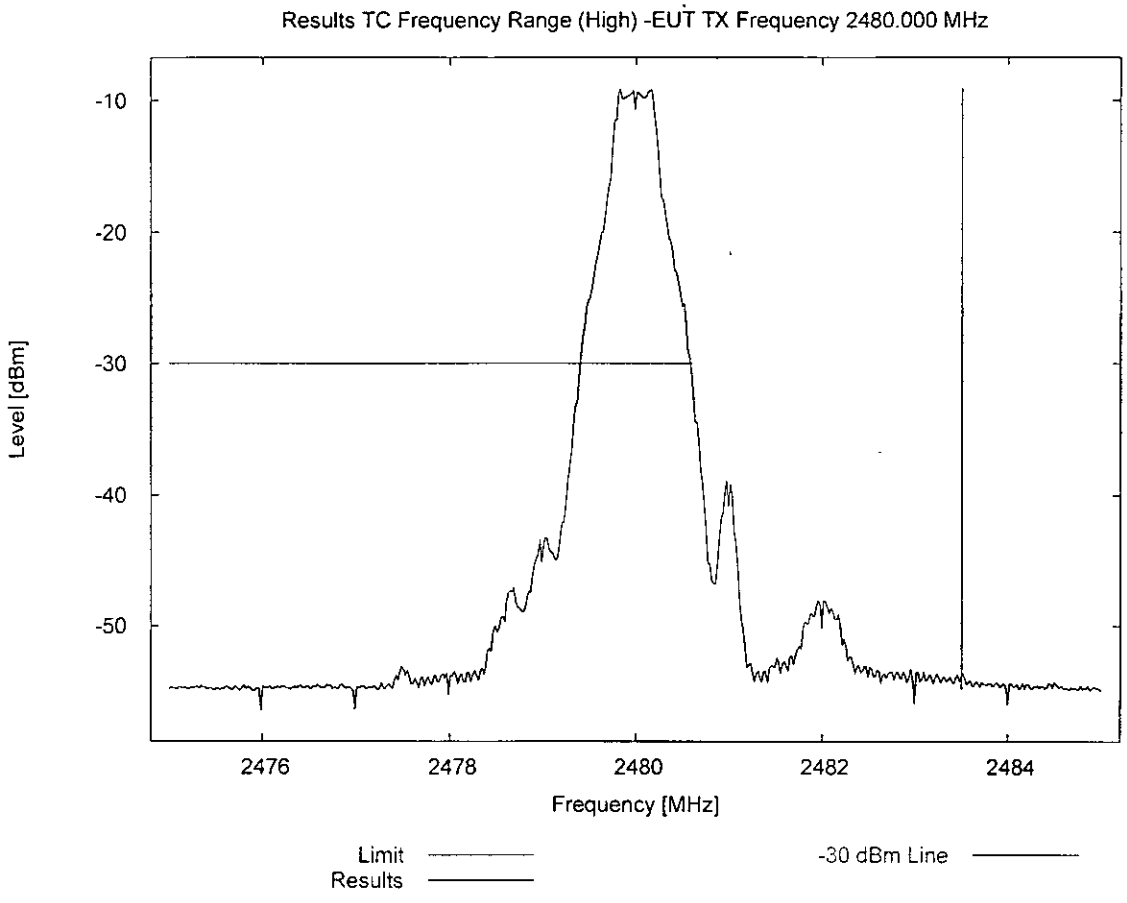
For EUT parameter see 0, "EUT Parameter 006"
For test case parameter see 0, "Test Case Parameter 021"

TX-FREQ [MHz]	RX-FREQ [MHz]	START [MHz]	STOP [MHz]	FREQ [MHz]		LIMIT [MHz]	VERDICT
2402.0	2480.0	2399.000	2405.000	2401.388	>=	2400.000	PASS
2480.0	2402.0	2475.000	2485.000	2480.600	<=	2483.500	PASS

Final Test Case Verdict . . . . . PASS 00:05:17

Results TC Frequency Range (Low) -EUT TX Frequency 2402.000 MHz




Results TC Frequency Range (High) -EUT TX Frequency 2480.000 MHz
-10
-20
-30
-40
-50
Level [dBm]
2476
2478
2480
2482
2484
Frequency [MHz]
Limit
Results
-30 dBm Line

TX Output Spectrum - Frequency Range

For system parameter see 0, "General Parameter 003"

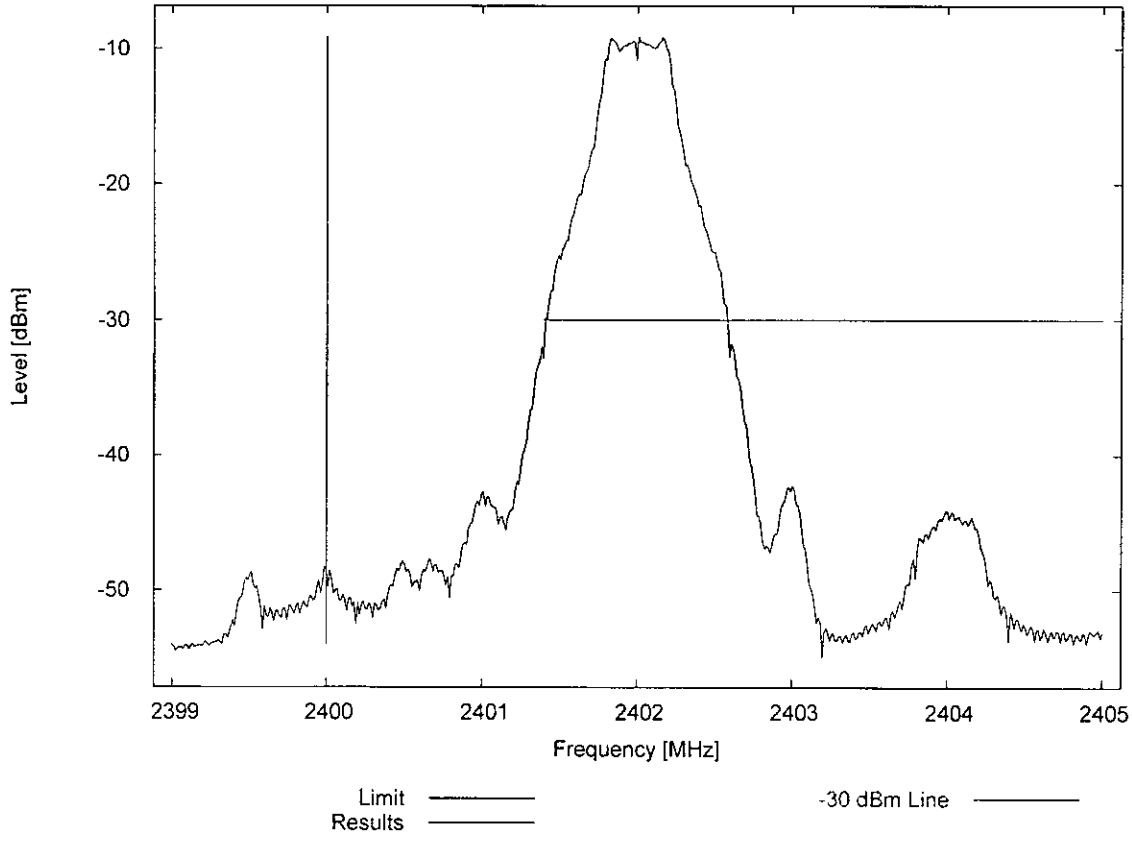
BT Test Specification Version: 1.2

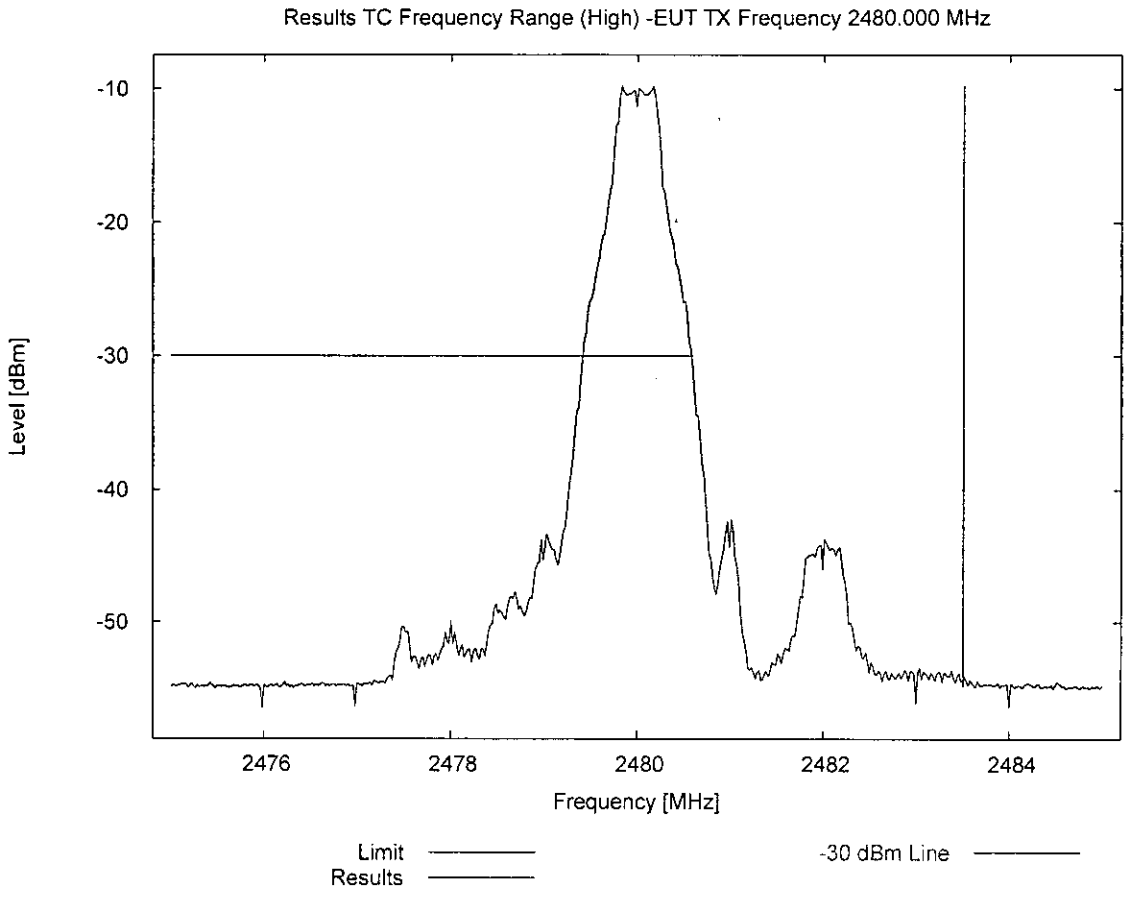
For EUT parameter see 0, "EUT Parameter 009"
For test case parameter see 0, "Test Case Parameter 040"

TX-FREQ [MHz]	RX-FREQ [MHz]	START [MHz]	STOP [MHz]	FREQ [MHz]		LIMIT [MHz]	VERDICT
2402.0	2480.0	2399.000	2405.000	2401.388	>=	2400.000	PASS
2480.0	2402.0	2475.000	2485.000	2480.600	<=	2483.500	PASS

Final Test Case Verdict . . . . . PASS 00:05:01

Results TC Frequency Range (Low) -EUT TX Frequency 2402.000 MHz




Results TC Frequency Range (High) -EUT TX Frequency 2480.000 MHz
-10
-20
-30
-40
-50
Level [dBm]
2476
2478
2480
2482
2484
Frequency [MHz]
Limit
Results
-30 dBm Line

108

TX Output Spectrum - Frequency Range

For system parameter see 0, "General Parameter 003"

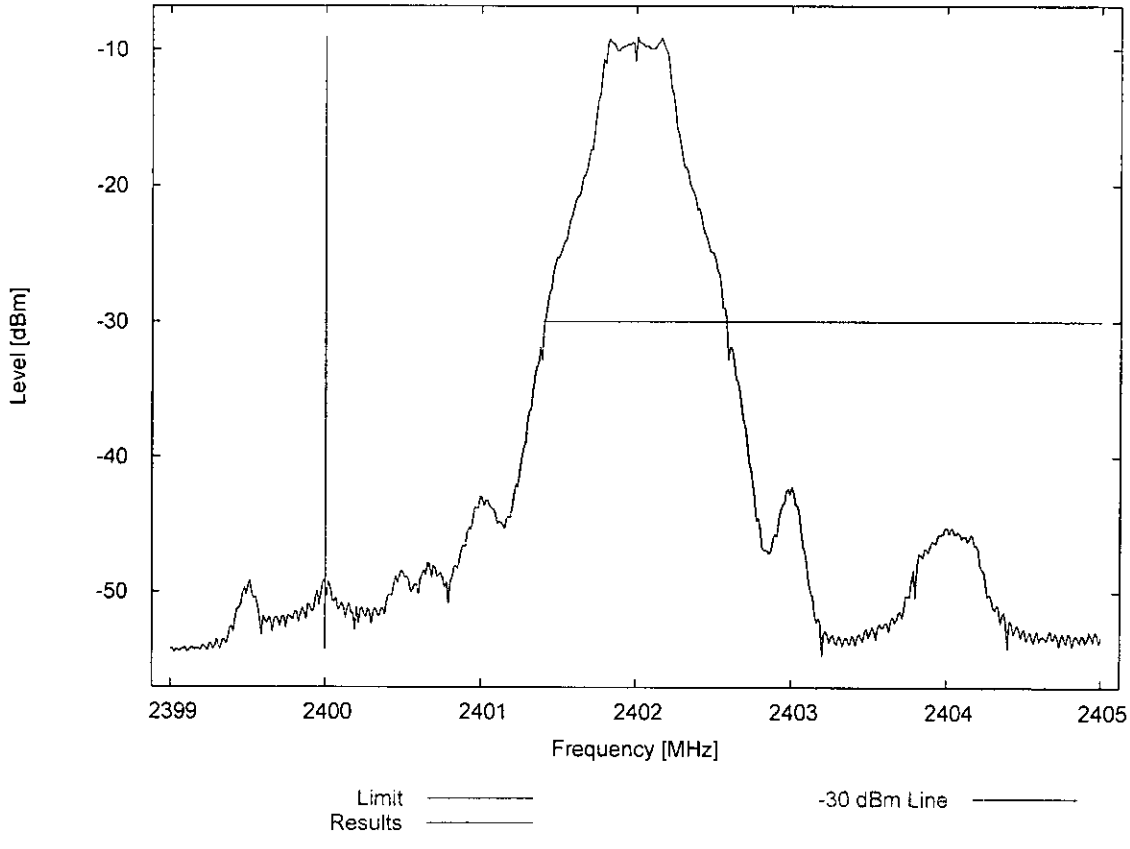
BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 010"
For test case parameter see 0, "Test Case Parameter 041"

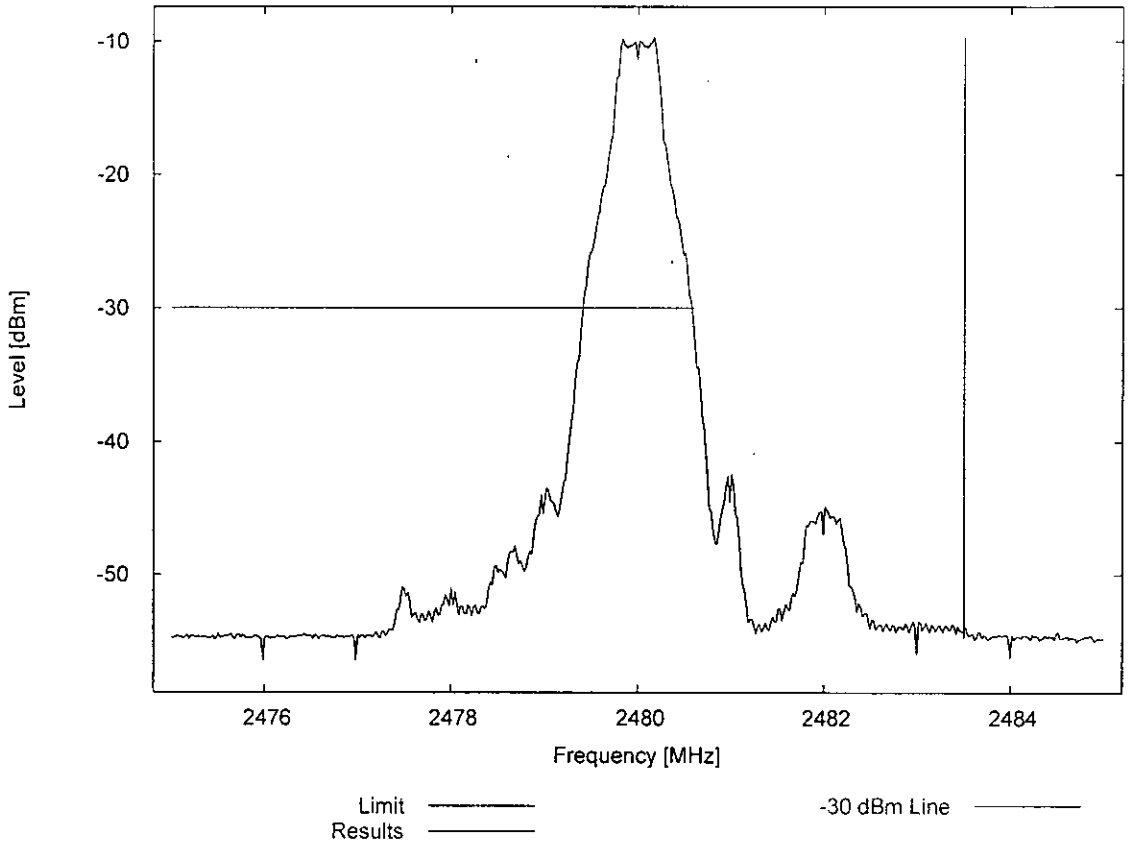
TX-FREQ [MHz]	RX-FREQ [MHz]	START [MHz]	STOP [MHz]	FREQ [MHz]		LIMIT [MHz]	VERDICT
2402.0	2480.0	2399.000	2405.000	2401.400	>=	2400.000	PASS
2480.0	2402.0	2475.000	2485.000	2480.600	<=	2483.500	PASS

Final Test Case Verdict . . . . . PASS 00:05:08

Results TC Frequency Range (Low) -EUT TX Frequency 2402.000 MHz



Results TC Frequency Range (High) -EUT TX Frequency 2480.000 MHz



Annex F

TRM/CA/05/C TX Output Spectrum - 20 dB Bandwidth

TX Output Spectrum - 20 dB Bandwidth

For system parameter see 0, "General Parameter 004"

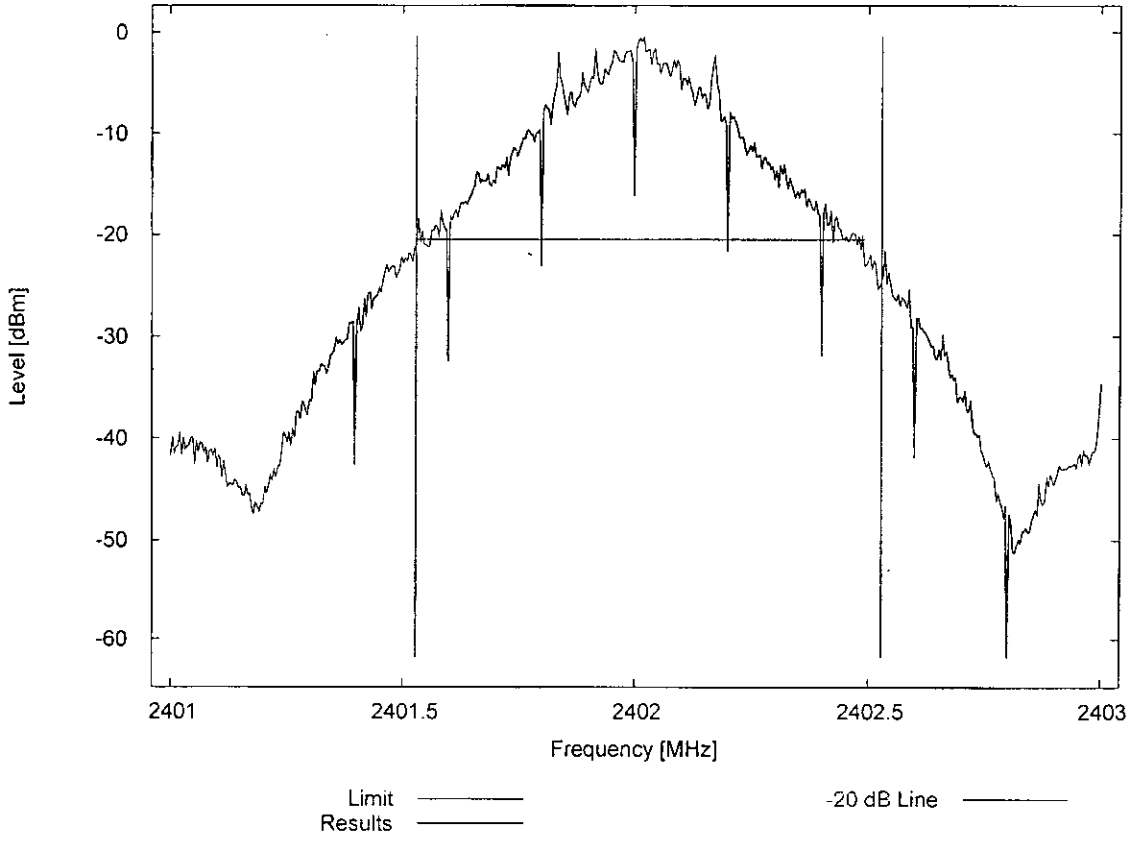
BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 002"
For test case parameter see 0, "Test Case Parameter 004"

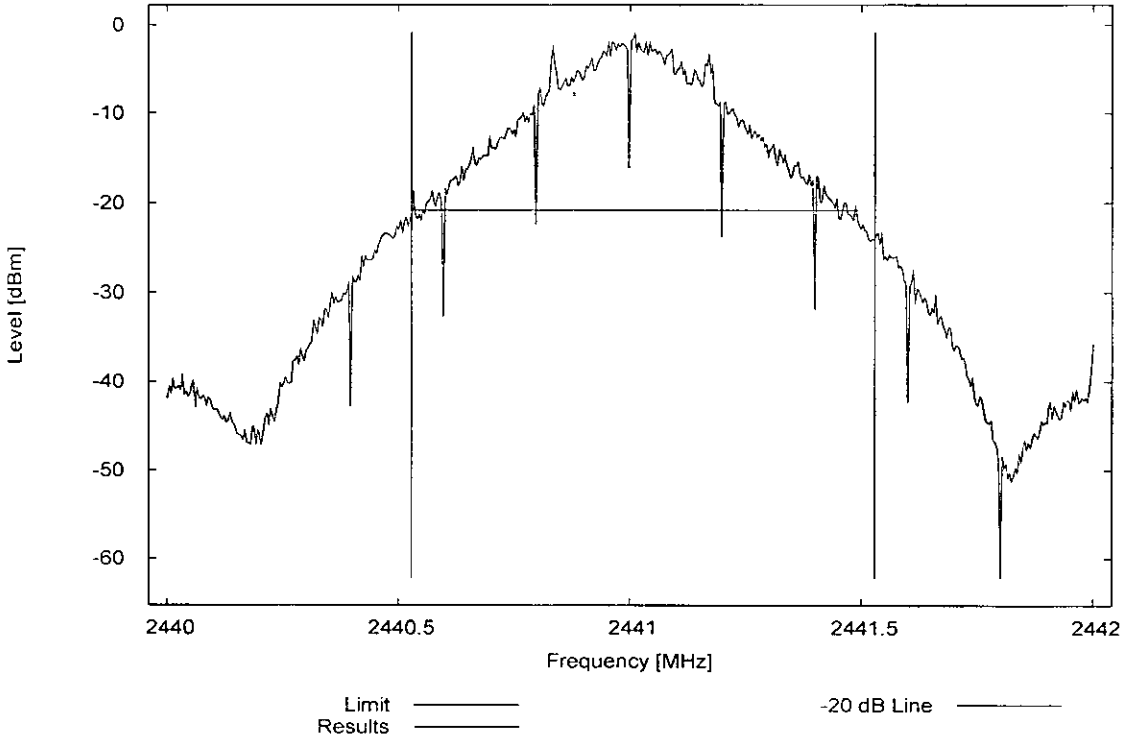
TX [MHz]	RX [MHz]	START [MHz]	STOP [MHz]	LOW [MHz]	HIGH [MHz]	BW [MHz]	LIMIT [MHz]	VERDICT
2402	2480	2401.0	2403.0	2401.528	2402.492	0.964	<= 1.000	PASS
2441	2402	2440.0	2442.0	2440.528	2441.492	0.964	<= 1.000	PASS
2480	2402	2479.0	2481.0	2479.524	2480.492	0.968	<= 1.000	PASS

Final Test Case Verdict . . . . . PASS 00:02:54

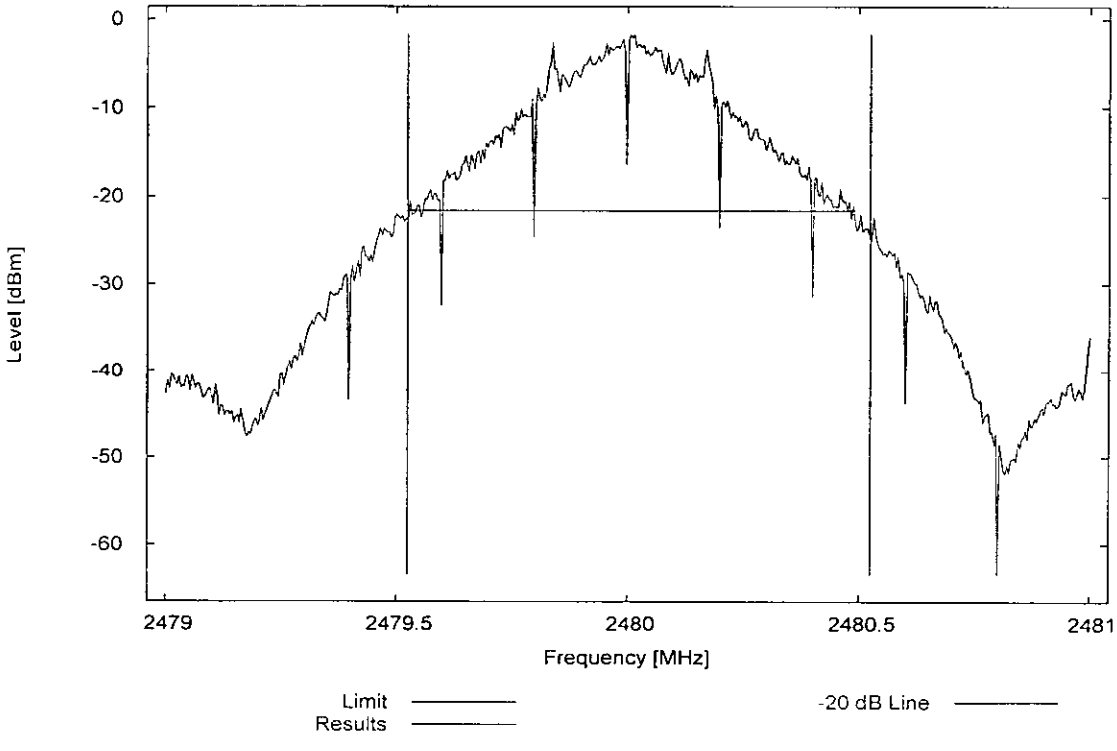
Results TC TX Output Spectrum - 20 dB Bandwidth -EUT TX Frequency 2402.000 MHz



Results TC TX Output Spectrum - 20 dB Bandwidth -EUT TX Frequency 2441.000 MHz



Results TC TX Output Spectrum - 20 dB Bandwidth -EUT TX Frequency 2480.000 MHz



TX Output Spectrum - 20 dB Bandwidth

For system parameter see 0, "General Parameter 004"

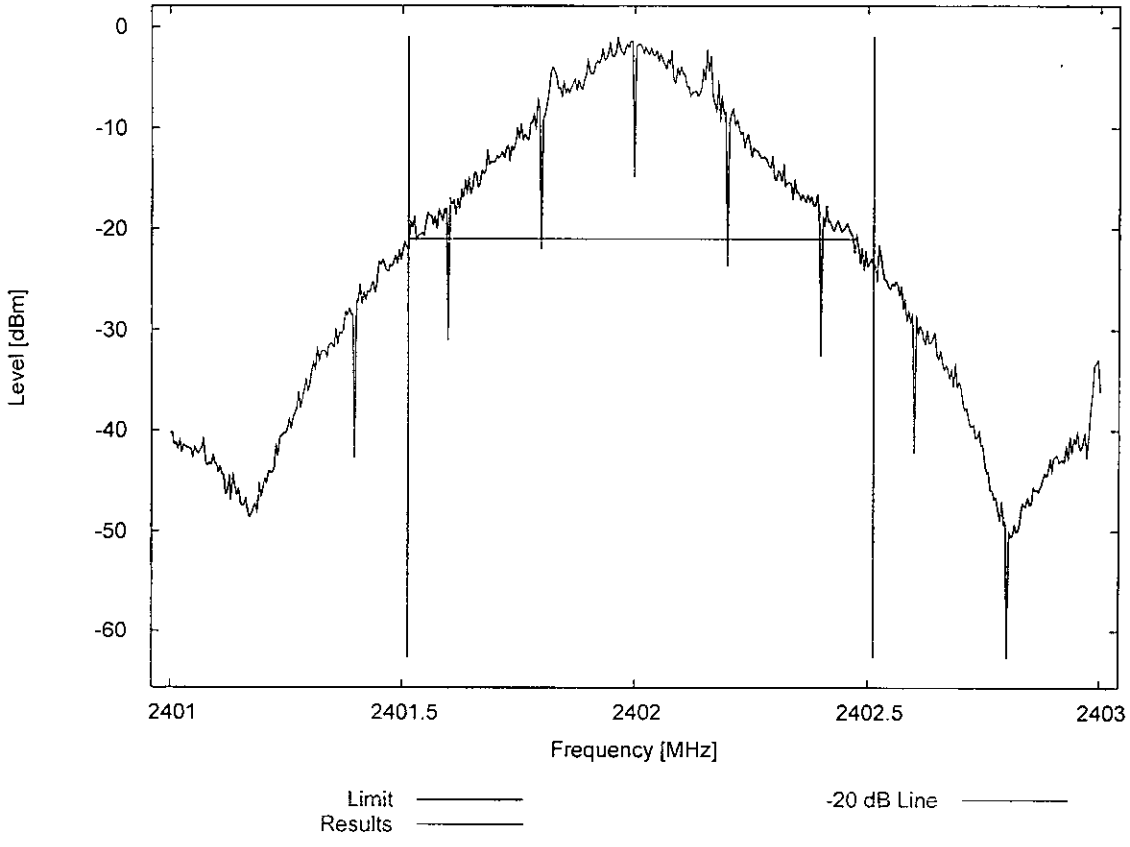
BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 005"
For test case parameter see 0, "Test Case Parameter 022"

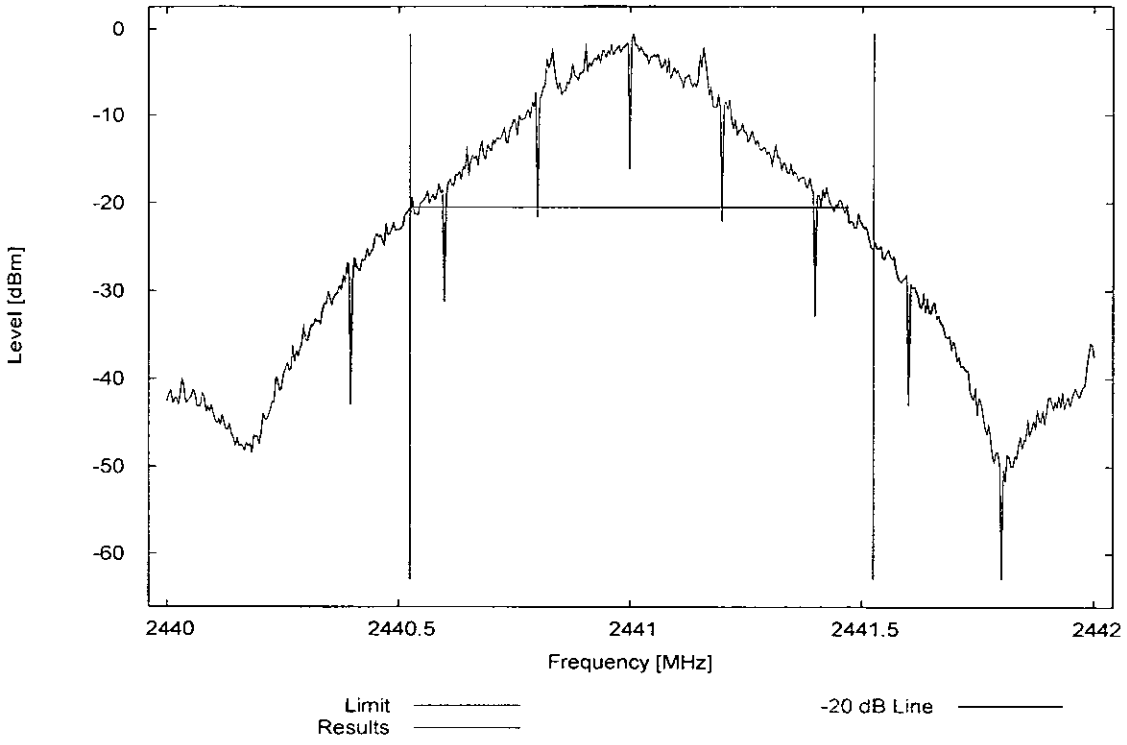
TX [MHz]	RX [MHz]	START [MHz]	STOP [MHz]	LOW [MHz]	HIGH [MHz]	BW [MHz]	LIMIT [MHz]	VERDICT
2402	2480	2401.0	2403.0	2401.512	2402.480	0.968	<= 1.000	PASS
2441	2402	2440.0	2442.0	2440.524	2441.472	0.948	<= 1.000	PASS
2480	2402	2479.0	2481.0	2479.516	2480.480	0.964	<= 1.000	PASS

Final Test Case Verdict . . . . . PASS 00:03:26

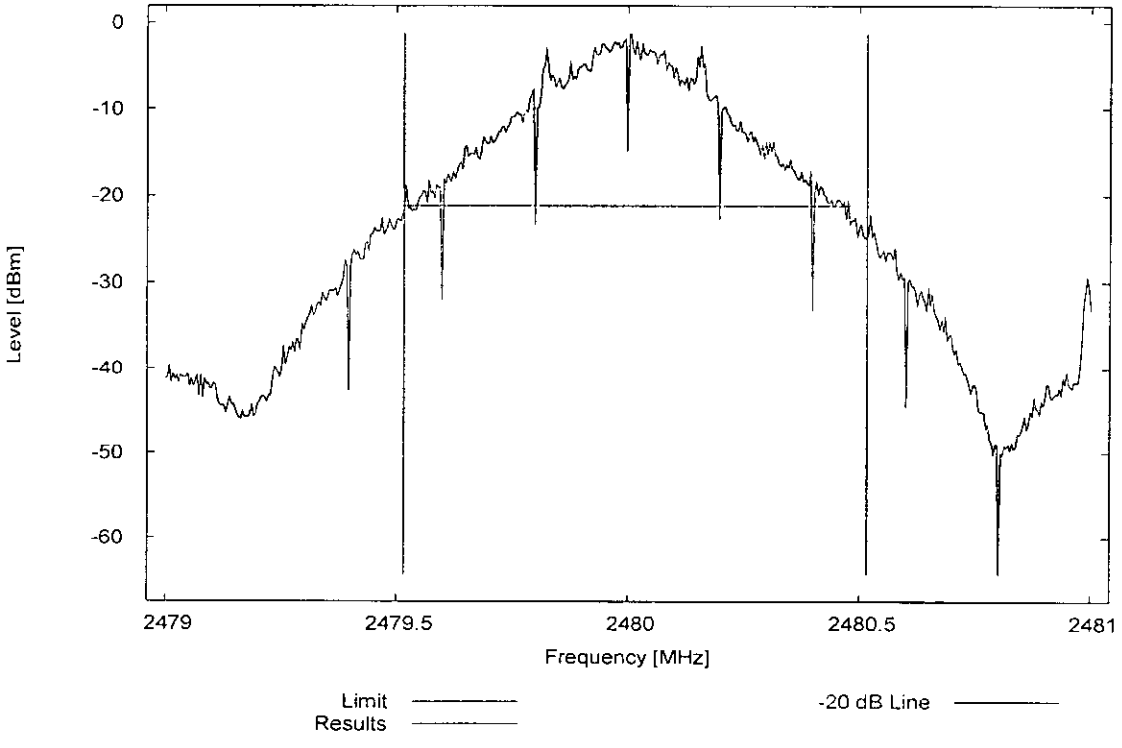
Results TC TX Output Spectrum - 20 dB Bandwidth -EUT TX Frequency 2402.000 MHz



Results TC TX Output Spectrum - 20 dB Bandwidth -EUT TX Frequency 2441.000 MHz



Results TC TX Output Spectrum - 20 dB Bandwidth -EUT TX Frequency 2480.000 MHz



TX Output Spectrum - 20 dB Bandwidth

For system parameter see 0, "General Parameter 004"

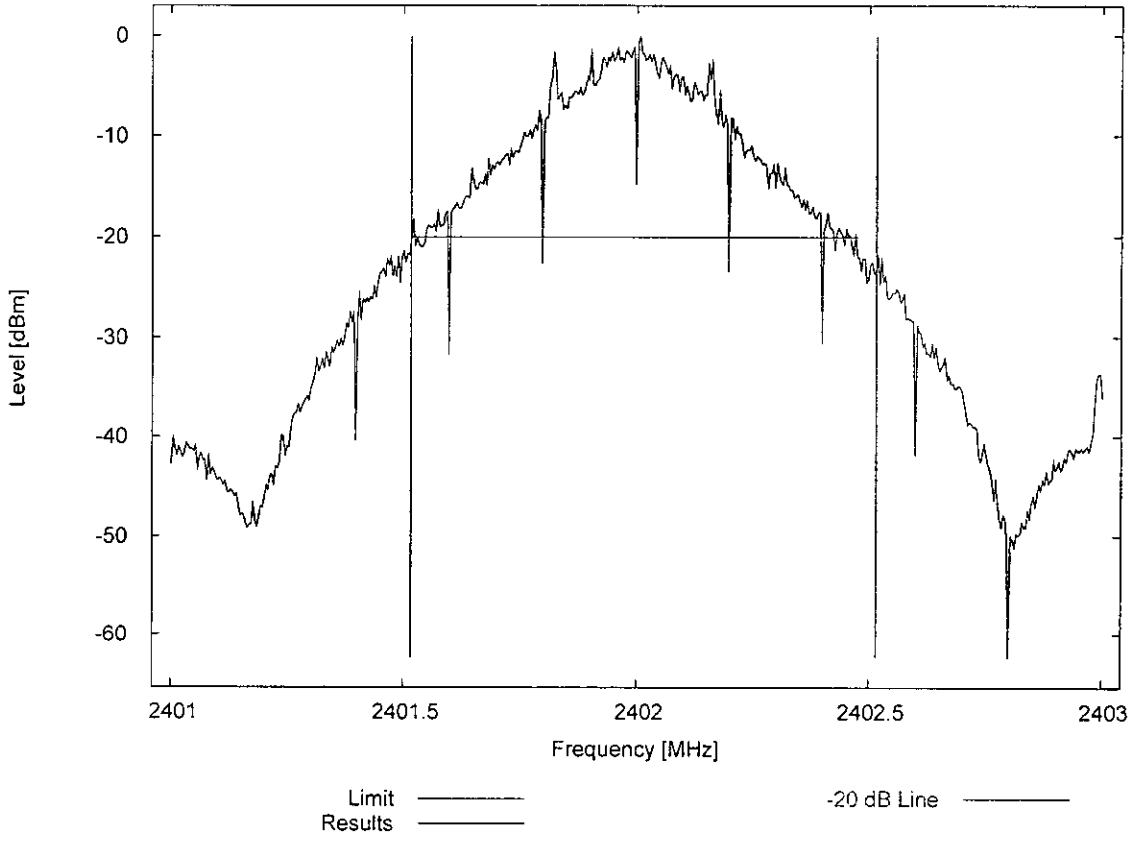
BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 006"
For test case parameter see 0, "Test Case Parameter 023"

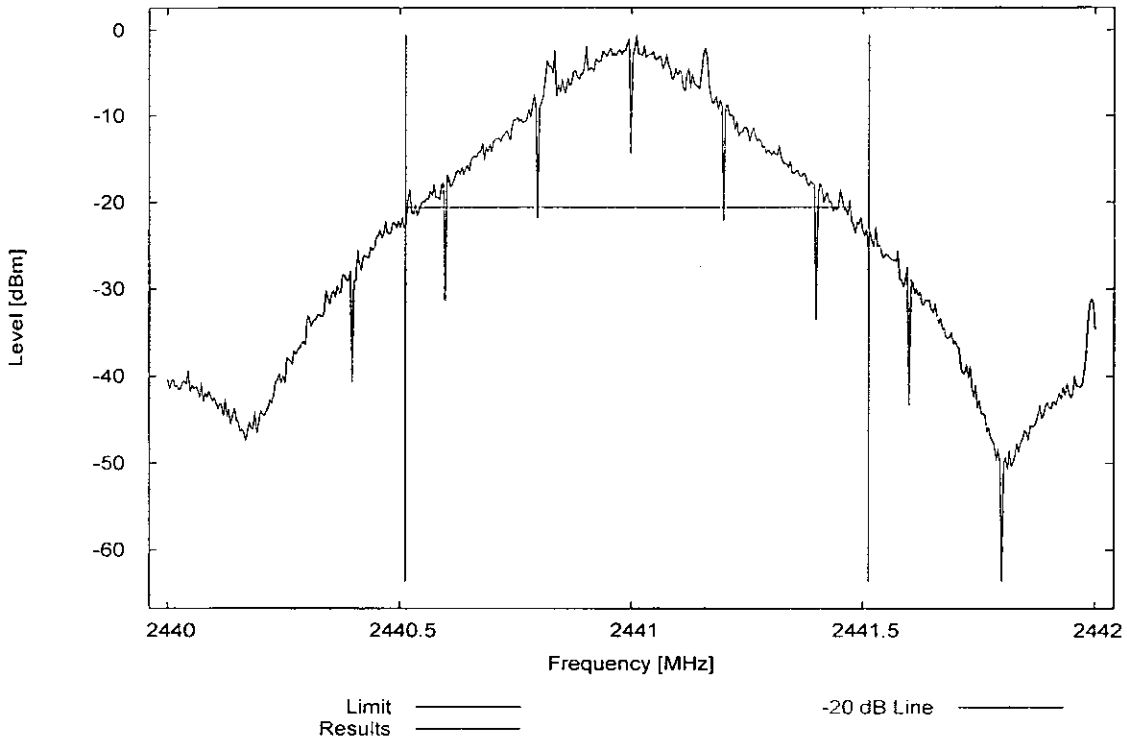
TX [MHz]	RX [MHz]	START [MHz]	STOP [MHz]	LOW [MHz]	HIGH [MHz]	BW [MHz]	LIMIT [MHz]	VERDICT
2402	2480	2401.0	2403.0	2401.516	2402.476	0.960	<= 1.000	PASS
2441	2402	2440.0	2442.0	2440.512	2441.476	0.964	<= 1.000	PASS
2480	2402	2479.0	2481.0	2479.512	2480.476	0.964	<= 1.000	PASS

Final Test Case Verdict . . . . . PASS 00:03:05

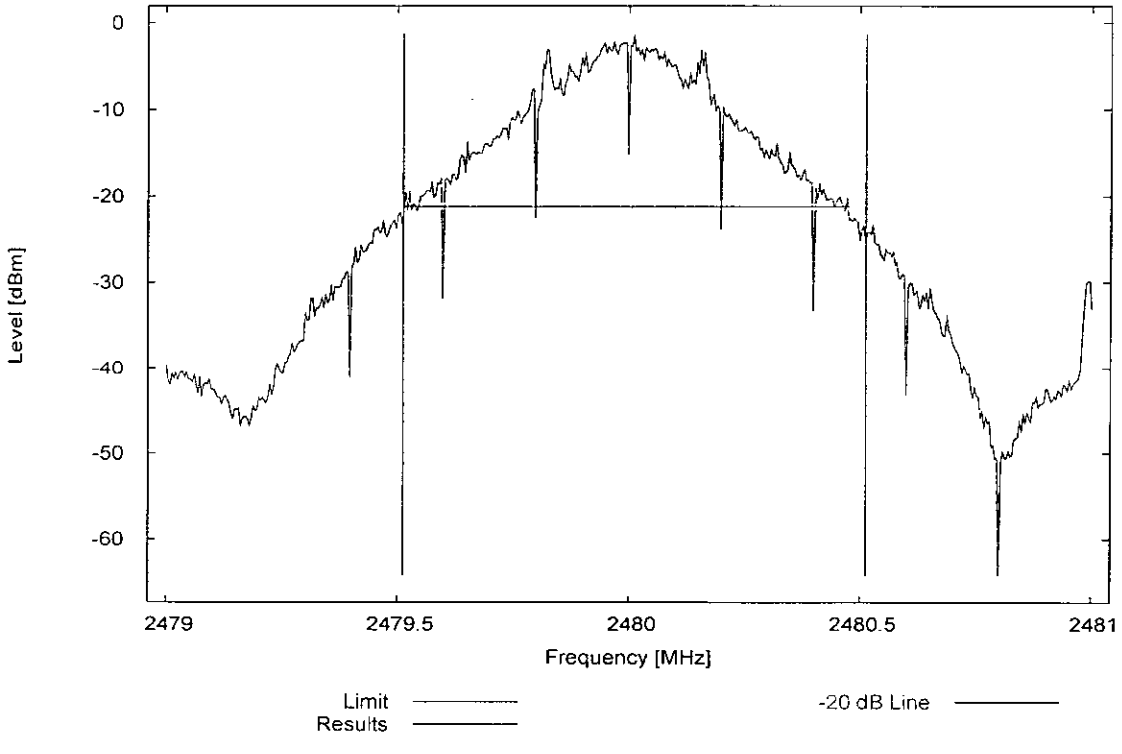
Results TC TX Output Spectrum - 20 dB Bandwidth -EUT TX Frequency 2402.000 MHz



Results TC TX Output Spectrum - 20 dB Bandwidth -EUT TX Frequency 2441.000 MHz



Results TC TX Output Spectrum - 20 dB Bandwidth -EUT TX Frequency 2480.000 MHz



TX Output Spectrum - 20 dB Bandwidth

For system parameter see 0, "General Parameter 004"

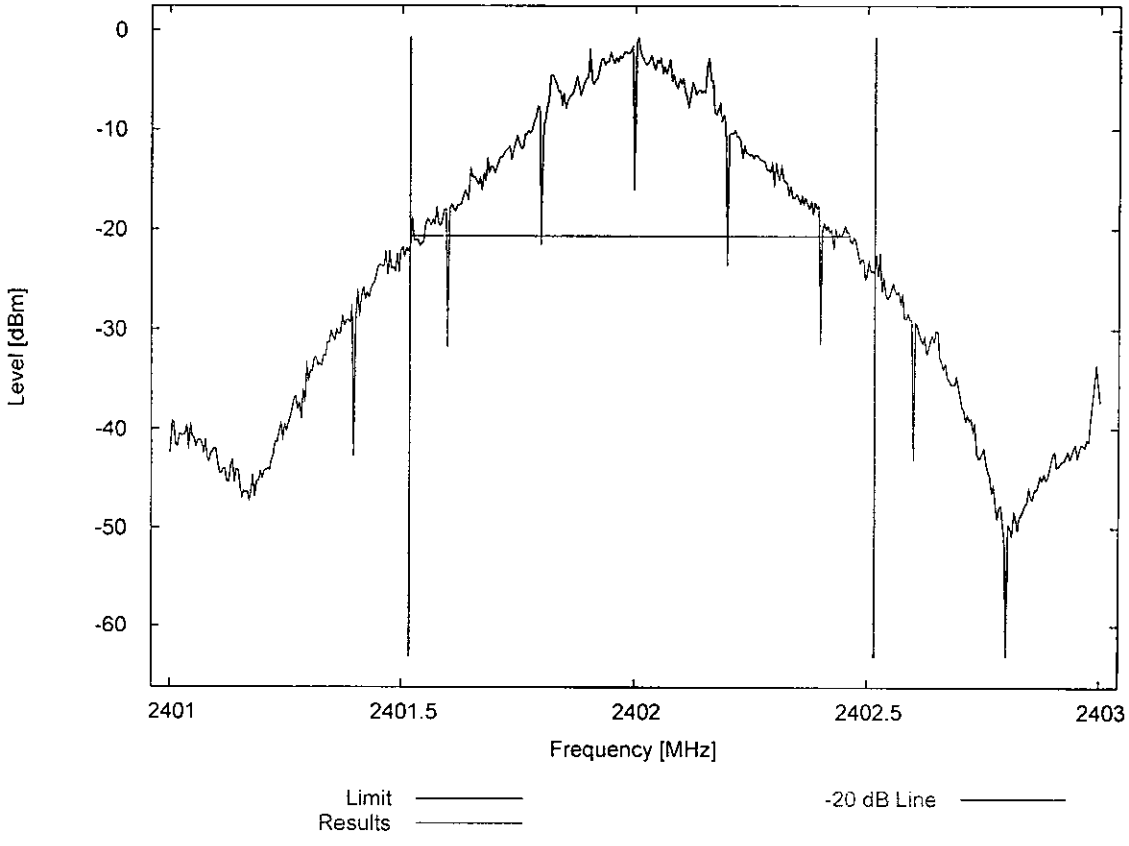
BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 009"
For test case parameter see 0, "Test Case Parameter 042"

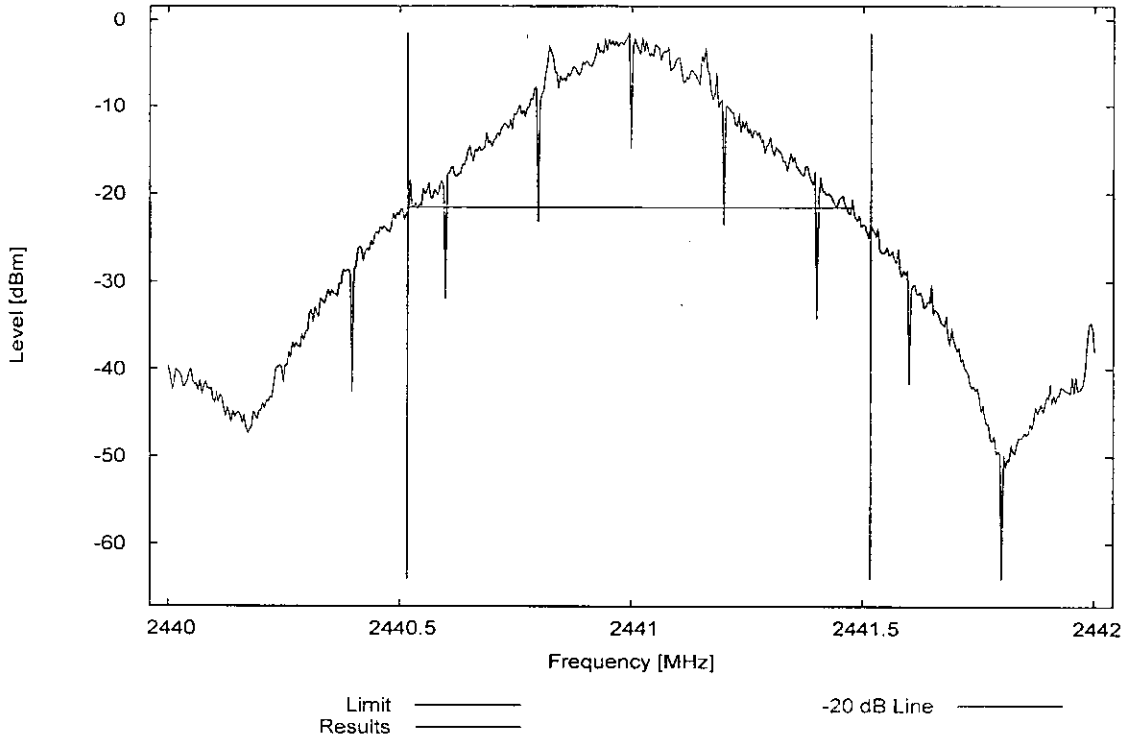
TX [MHz]	RX [MHz]	START [MHz]	STOP [MHz]	LOW [MHz]	HIGH [MHz]	BW [MHz]	LIMIT [MHz]	VERDICT
2402	2480	2401.0	2403.0	2401.516	2402.464	0.948	<= 1.000	PASS
2441	2402	2440.0	2442.0	2440.516	2441.480	0.964	<= 1.000	PASS
2480	2402	2479.0	2481.0	2479.512	2480.476	0.964	<= 1.000	PASS

Final Test Case Verdict . . . . . PASS 00:29:49

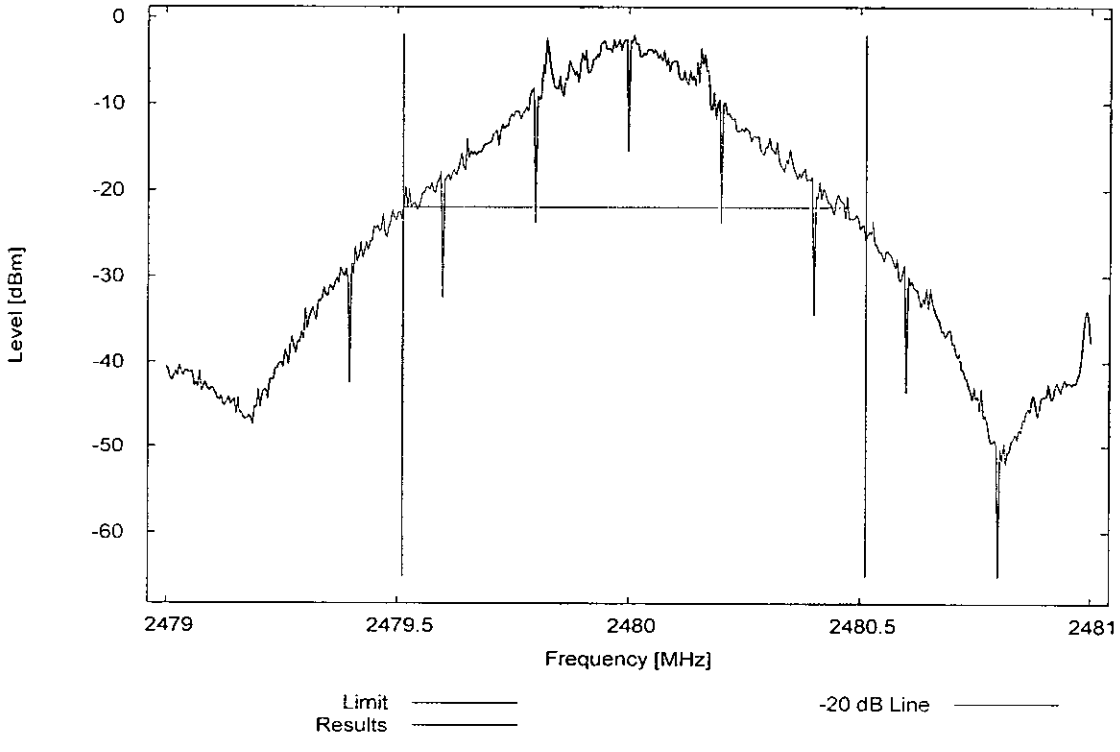
Results TC TX Output Spectrum - 20 dB Bandwidth -EUT TX Frequency 2402.000 MHz



Results TC TX Output Spectrum - 20 dB Bandwidth -EUT TX Frequency 2441.000 MHz



Results TC TX Output Spectrum - 20 dB Bandwidth -EUT TX Frequency 2480.000 MHz



TX Output Spectrum - 20 dB Bandwidth

For system parameter see 0, "General Parameter 004"

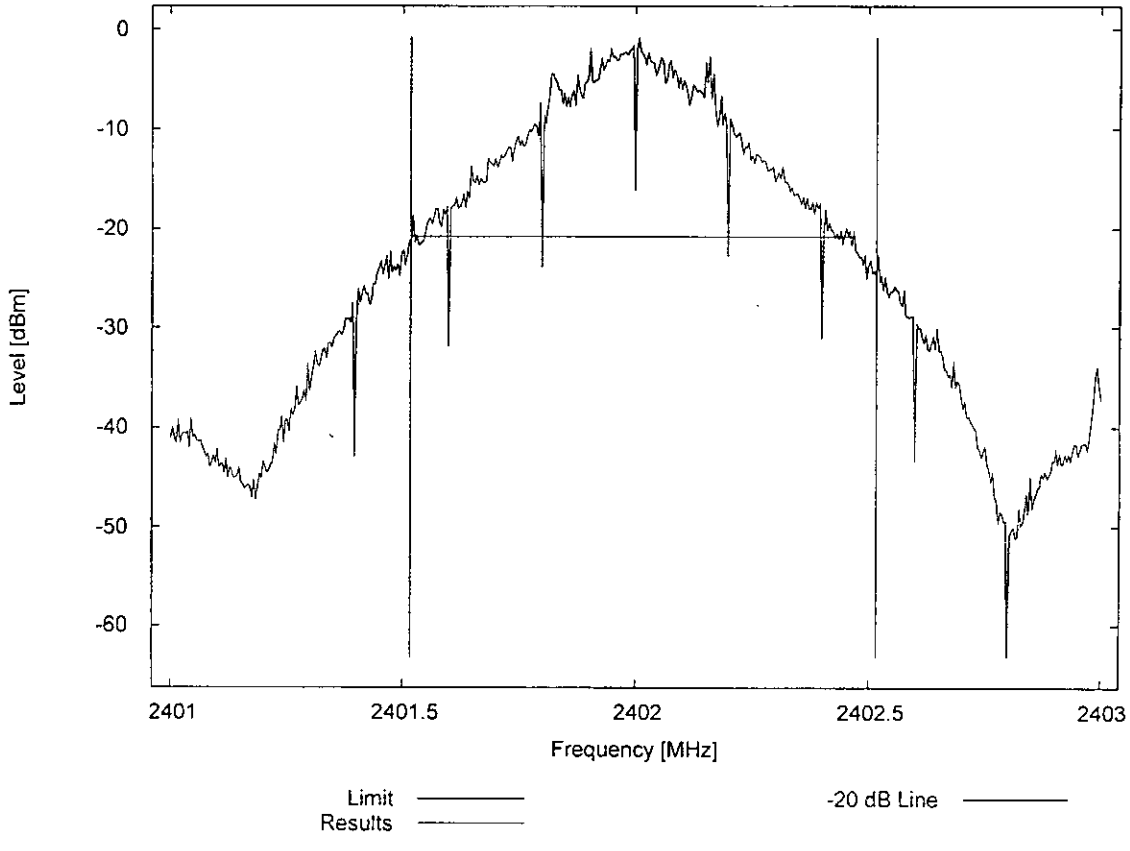
BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 010"
For test case parameter see 0, "Test Case Parameter 043"

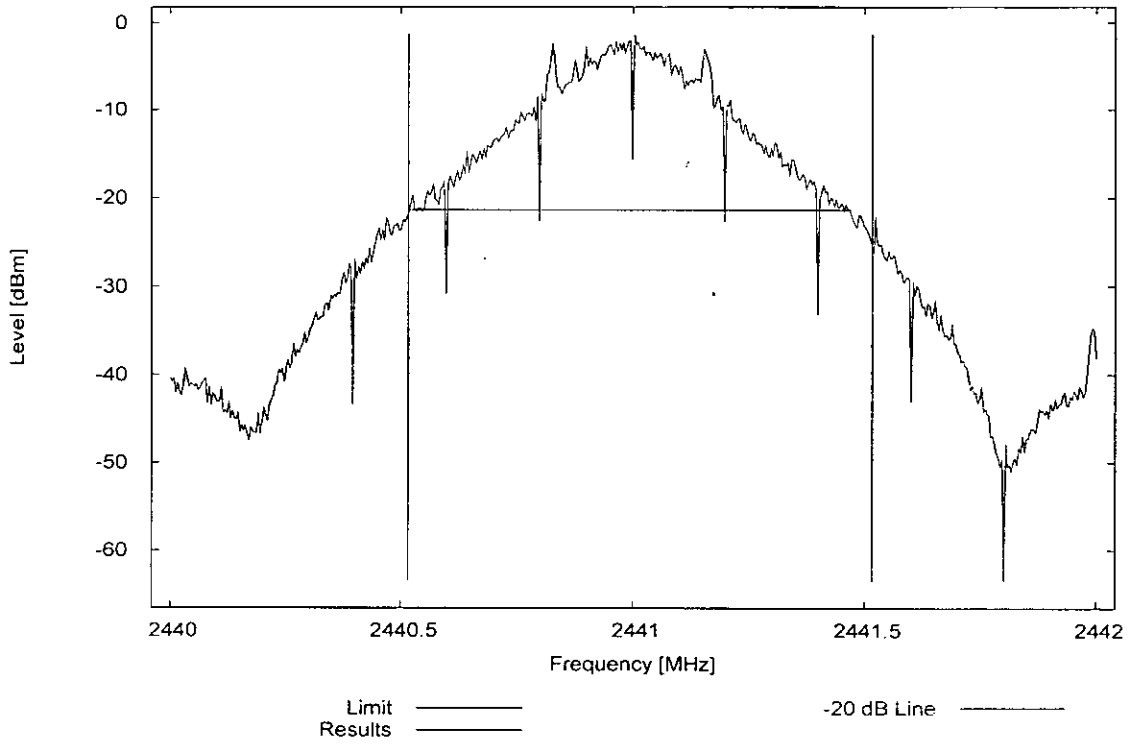
TX [MHz]	RX [MHz]	START [MHz]	STOP [MHz]	LOW [MHz]	HIGH [MHz]	BW [MHz]	LIMIT [MHz]	VERDICT
2402	2480	2401.0	2403.0	2401.516	2402.472	0.956	<= 1.000	PASS
2441	2402	2440.0	2442.0	2440.516	2441.472	0.956	<= 1.000	PASS
2480	2402	2479.0	2481.0	2479.484	2480.476	0.992	<= 1.000	PASS

Final Test Case Verdict . . . . . PASS 00:08:04

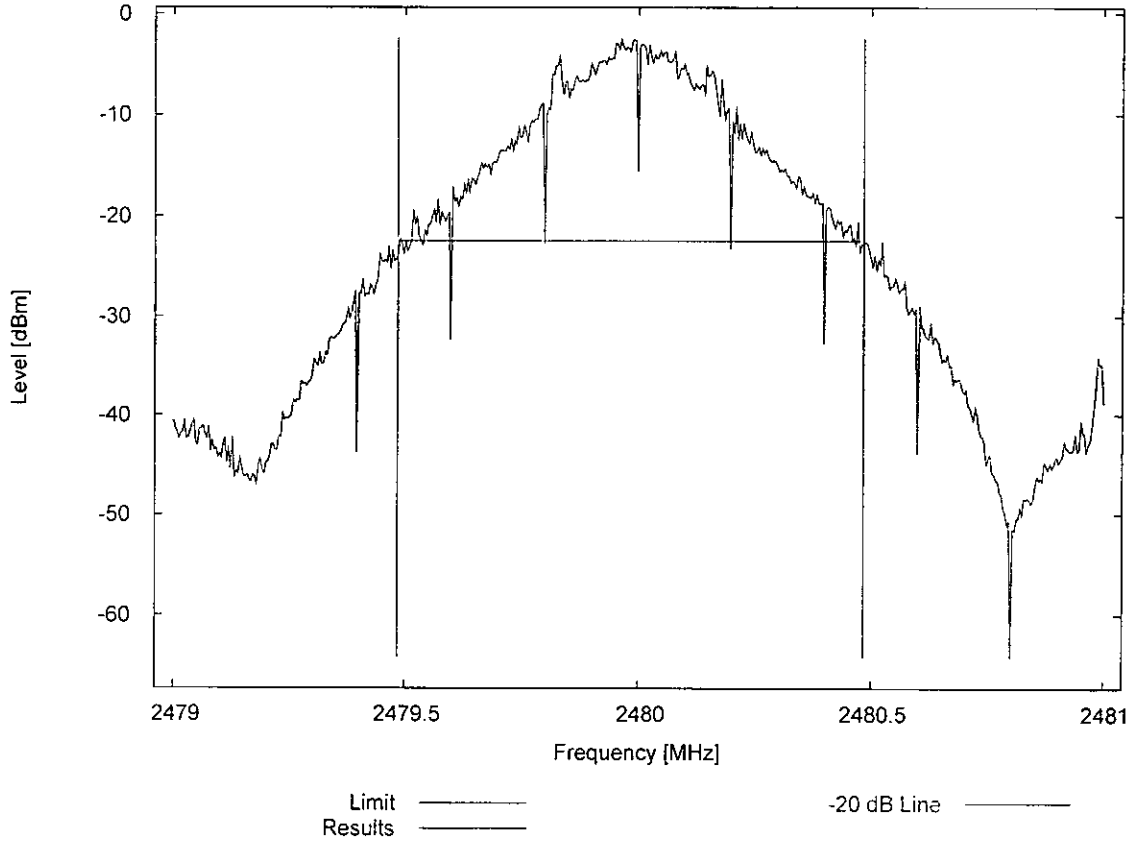
Results TC TX Output Spectrum - 20 dB Bandwidth -EUT TX Frequency 2402.000 MHz



Results TC TX Output Spectrum - 20 dB Bandwidth -EUT TX Frequency 2441.000 MHz



Results TC TX Output Spectrum - 20 dB Bandwidth -EUT TX Frequency 2480.000 MHz



Annex G

TRM/CA/06/C TX Output Spectrum - Adjacent Channel Power

TX Output Spectrum - Adjacent Channel Power

For system parameter see 0, "General Parameter 005"

BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 002"
For test case parameter see 0, "Test Case Parameter 005"

TX-FREQ [MHz]	RX-FREQ [MHz]	MEAS-FREQ [MHz]	LEVEL [dBm]		LIMIT [dBm]	(OUT)	VERDICT
2405.0	2480.0	2402.0	-50.613	<=	-40.000	(0)	PASS
2405.0	2480.0	2403.0	-43.462	<=	-20.000	(0)	PASS
2405.0	2480.0	2407.0	-40.869	<=	-20.000	(0)	PASS
2405.0	2480.0	2408.0	-44.911	<=	-40.000	(0)	PASS
2405.0	2480.0	2409.0	-48.176	<=	-40.000	(0)	PASS
2405.0	2480.0	2410.0	-53.627	<=	-40.000	(0)	PASS
2405.0	2480.0	2411.0	-57.671	<=	-40.000	(0)	PASS
2405.0	2480.0	2412.0	-58.061	<=	-40.000	(0)	PASS
2405.0	2480.0	2413.0	-57.485	<=	-40.000	(0)	PASS
2405.0	2480.0	2414.0	-58.608	<=	-40.000	(0)	PASS
2405.0	2480.0	2415.0	-58.575	<=	-40.000	(0)	PASS
2405.0	2480.0	2416.0	-58.797	<=	-40.000	(0)	PASS
2405.0	2480.0	2417.0	-58.267	<=	-40.000	(0)	PASS
2405.0	2480.0	2418.0	-58.647	<=	-40.000	(0)	PASS
2405.0	2480.0	2419.0	-59.013	<=	-40.000	(0)	PASS
2405.0	2480.0	2420.0	-59.024	<=	-40.000	(0)	PASS
2405.0	2480.0	2421.0	-58.516	<=	-40.000	(0)	PASS
2405.0	2480.0	2422.0	-59.264	<=	-40.000	(0)	PASS
2405.0	2480.0	2423.0	-59.008	<=	-40.000	(0)	PASS
2405.0	2480.0	2424.0	-59.202	<=	-40.000	(0)	PASS
2405.0	2480.0	2425.0	-59.387	<=	-40.000	(0)	PASS
2405.0	2480.0	2426.0	-59.543	<=	-40.000	(0)	PASS
2405.0	2480.0	2427.0	-59.486	<=	-40.000	(0)	PASS
2405.0	2480.0	2428.0	-59.426	<=	-40.000	(0)	PASS
2405.0	2480.0	2429.0	-59.686	<=	-40.000	(0)	PASS
2405.0	2480.0	2430.0	-59.689	<=	-40.000	(0)	PASS
2405.0	2480.0	2431.0	-55.549	<=	-40.000	(0)	PASS
2405.0	2480.0	2432.0	-59.675	<=	-40.000	(0)	PASS
2405.0	2480.0	2433.0	-59.778	<=	-40.000	(0)	PASS
2405.0	2480.0	2434.0	-59.707	<=	-40.000	(0)	PASS
2405.0	2480.0	2435.0	-59.692	<=	-40.000	(0)	PASS
2405.0	2480.0	2436.0	-59.721	<=	-40.000	(0)	PASS
2405.0	2480.0	2437.0	-59.758	<=	-40.000	(0)	PASS
2405.0	2480.0	2438.0	-59.864	<=	-40.000	(0)	PASS
2405.0	2480.0	2439.0	-59.677	<=	-40.000	(0)	PASS
2405.0	2480.0	2440.0	-59.861	<=	-40.000	(0)	PASS
2405.0	2480.0	2441.0	-59.858	<=	-40.000	(0)	PASS
2405.0	2480.0	2442.0	-59.785	<=	-40.000	(0)	PASS
2405.0	2480.0	2443.0	-59.896	<=	-40.000	(0)	PASS
2405.0	2480.0	2444.0	-59.911	<=	-40.000	(0)	PASS
2405.0	2480.0	2445.0	-59.887	<=	-40.000	(0)	PASS
2405.0	2480.0	2446.0	-59.719	<=	-40.000	(0)	PASS
2405.0	2480.0	2447.0	-60.051	<=	-40.000	(0)	PASS
2405.0	2480.0	2448.0	-59.994	<=	-40.000	(0)	PASS
2405.0	2480.0	2449.0	-59.843	<=	-40.000	(0)	PASS
2405.0	2480.0	2450.0	-59.897	<=	-40.000	(0)	PASS
2405.0	2480.0	2451.0	-59.944	<=	-40.000	(0)	PASS
2405.0	2480.0	2452.0	-59.951	<=	-40.000	(0)	PASS

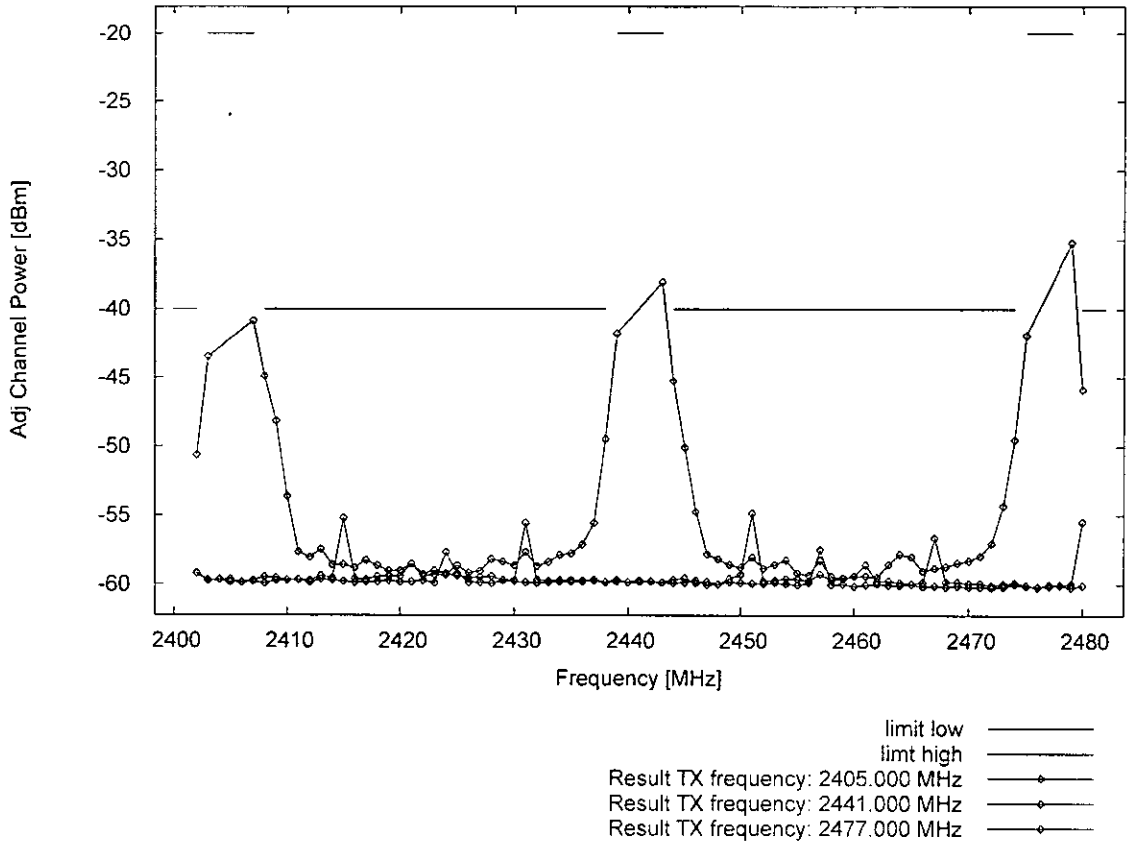
2405.0	2480.0	2453.0	-59.897	<=	-40.000	(0)	PASS
2405.0	2480.0	2454.0	-59.964	<=	-40.000	(0)	PASS
2405.0	2480.0	2455.0	-60.059	<=	-40.000	(0)	PASS
2405.0	2480.0	2456.0	-59.904	<=	-40.000	(0)	PASS
2405.0	2480.0	2457.0	-57.511	<=	-40.000	(0)	PASS
2405.0	2480.0	2458.0	-60.046	<=	-40.000	(0)	PASS
2405.0	2480.0	2459.0	-59.988	<=	-40.000	(0)	PASS
2405.0	2480.0	2460.0	-60.139	<=	-40.000	(0)	PASS
2405.0	2480.0	2461.0	-60.054	<=	-40.000	(0)	PASS
2405.0	2480.0	2462.0	-59.965	<=	-40.000	(0)	PASS
2405.0	2480.0	2463.0	-60.077	<=	-40.000	(0)	PASS
2405.0	2480.0	2464.0	-60.082	<=	-40.000	(0)	PASS
2405.0	2480.0	2465.0	-60.008	<=	-40.000	(0)	PASS
2405.0	2480.0	2466.0	-60.162	<=	-40.000	(0)	PASS
2405.0	2480.0	2467.0	-60.120	<=	-40.000	(0)	PASS
2405.0	2480.0	2468.0	-60.190	<=	-40.000	(0)	PASS
2405.0	2480.0	2469.0	-60.121	<=	-40.000	(0)	PASS
2405.0	2480.0	2470.0	-60.203	<=	-40.000	(0)	PASS
2405.0	2480.0	2471.0	-60.191	<=	-40.000	(0)	PASS
2405.0	2480.0	2472.0	-60.239	<=	-40.000	(0)	PASS
2405.0	2480.0	2473.0	-60.164	<=	-40.000	(0)	PASS
2405.0	2480.0	2474.0	-59.988	<=	-40.000	(0)	PASS
2405.0	2480.0	2475.0	-60.112	<=	-40.000	(0)	PASS
2405.0	2480.0	2476.0	-60.178	<=	-40.000	(0)	PASS
2405.0	2480.0	2477.0	-60.138	<=	-40.000	(0)	PASS
2405.0	2480.0	2478.0	-60.005	<=	-40.000	(0)	PASS
2405.0	2480.0	2479.0	-59.967	<=	-40.000	(0)	PASS
2405.0	2480.0	2480.0	-55.468	<=	-40.000	(0)	PASS
2441.0	2402.0	2402.0	-59.214	<=	-40.000	(0)	PASS
2441.0	2402.0	2403.0	-59.697	<=	-40.000	(0)	PASS
2441.0	2402.0	2404.0	-59.700	<=	-40.000	(0)	PASS
2441.0	2402.0	2405.0	-59.675	<=	-40.000	(0)	PASS
2441.0	2402.0	2406.0	-59.896	<=	-40.000	(0)	PASS
2441.0	2402.0	2407.0	-59.733	<=	-40.000	(0)	PASS
2441.0	2402.0	2408.0	-59.480	<=	-40.000	(0)	PASS
2441.0	2402.0	2409.0	-59.554	<=	-40.000	(0)	PASS
2441.0	2402.0	2410.0	-59.699	<=	-40.000	(0)	PASS
2441.0	2402.0	2411.0	-59.703	<=	-40.000	(0)	PASS
2441.0	2402.0	2412.0	-59.716	<=	-40.000	(0)	PASS
2441.0	2402.0	2413.0	-59.390	<=	-40.000	(0)	PASS
2441.0	2402.0	2414.0	-59.549	<=	-40.000	(0)	PASS
2441.0	2402.0	2415.0	-55.203	<=	-40.000	(0)	PASS
2441.0	2402.0	2416.0	-59.605	<=	-40.000	(0)	PASS
2441.0	2402.0	2417.0	-59.660	<=	-40.000	(0)	PASS
2441.0	2402.0	2418.0	-59.447	<=	-40.000	(0)	PASS
2441.0	2402.0	2419.0	-59.389	<=	-40.000	(0)	PASS
2441.0	2402.0	2420.0	-59.426	<=	-40.000	(0)	PASS
2441.0	2402.0	2421.0	-58.508	<=	-40.000	(0)	PASS
2441.0	2402.0	2422.0	-59.401	<=	-40.000	(0)	PASS
2441.0	2402.0	2423.0	-59.308	<=	-40.000	(0)	PASS
2441.0	2402.0	2424.0	-59.336	<=	-40.000	(0)	PASS
2441.0	2402.0	2425.0	-58.645	<=	-40.000	(0)	PASS
2441.0	2402.0	2426.0	-59.184	<=	-40.000	(0)	PASS
2441.0	2402.0	2427.0	-59.047	<=	-40.000	(0)	PASS
2441.0	2402.0	2428.0	-58.185	<=	-40.000	(0)	PASS
2441.0	2402.0	2429.0	-58.355	<=	-40.000	(0)	PASS
2441.0	2402.0	2430.0	-58.648	<=	-40.000	(0)	PASS
2441.0	2402.0	2431.0	-57.683	<=	-40.000	(0)	PASS
2441.0	2402.0	2432.0	-58.689	<=	-40.000	(0)	PASS
2441.0	2402.0	2433.0	-58.387	<=	-40.000	(0)	PASS
2441.0	2402.0	2434.0	-57.891	<=	-40.000	(0)	PASS
2441.0	2402.0	2435.0	-57.783	<=	-40.000	(0)	PASS
2441.0	2402.0	2436.0	-57.131	<=	-40.000	(0)	PASS
2441.0	2402.0	2437.0	-55.548	<=	-40.000	(0)	PASS
2441.0	2402.0	2438.0	-49.474	<=	-40.000	(0)	PASS

2441.0	2402.0	2439.0	-41.785	<=	-20.000	(0)	PASS
2441.0	2402.0	2443.0	-38.074	<=	-20.000	(0)	PASS
2441.0	2402.0	2444.0	-45.245	<=	-40.000	(0)	PASS
2441.0	2402.0	2445.0	-50.081	<=	-40.000	(0)	PASS
2441.0	2402.0	2446.0	-54.737	<=	-40.000	(0)	PASS
2441.0	2402.0	2447.0	-57.831	<=	-40.000	(0)	PASS
2441.0	2402.0	2448.0	-58.179	<=	-40.000	(0)	PASS
2441.0	2402.0	2449.0	-58.571	<=	-40.000	(0)	PASS
2441.0	2402.0	2450.0	-58.777	<=	-40.000	(0)	PASS
2441.0	2402.0	2451.0	-58.057	<=	-40.000	(0)	PASS
2441.0	2402.0	2452.0	-58.859	<=	-40.000	(0)	PASS
2441.0	2402.0	2453.0	-58.589	<=	-40.000	(0)	PASS
2441.0	2402.0	2454.0	-58.253	<=	-40.000	(0)	PASS
2441.0	2402.0	2455.0	-59.199	<=	-40.000	(0)	PASS
2441.0	2402.0	2456.0	-59.336	<=	-40.000	(0)	PASS
2441.0	2402.0	2457.0	-58.256	<=	-40.000	(0)	PASS
2441.0	2402.0	2458.0	-59.450	<=	-40.000	(0)	PASS
2441.0	2402.0	2459.0	-59.599	<=	-40.000	(0)	PASS
2441.0	2402.0	2460.0	-59.387	<=	-40.000	(0)	PASS
2441.0	2402.0	2461.0	-58.598	<=	-40.000	(0)	PASS
2441.0	2402.0	2462.0	-59.793	<=	-40.000	(0)	PASS
2441.0	2402.0	2463.0	-59.772	<=	-40.000	(0)	PASS
2441.0	2402.0	2464.0	-59.887	<=	-40.000	(0)	PASS
2441.0	2402.0	2465.0	-59.974	<=	-40.000	(0)	PASS
2441.0	2402.0	2466.0	-59.873	<=	-40.000	(0)	PASS
2441.0	2402.0	2467.0	-56.646	<=	-40.000	(0)	PASS
2441.0	2402.0	2468.0	-59.823	<=	-40.000	(0)	PASS
2441.0	2402.0	2469.0	-59.854	<=	-40.000	(0)	PASS
2441.0	2402.0	2470.0	-59.940	<=	-40.000	(0)	PASS
2441.0	2402.0	2471.0	-59.943	<=	-40.000	(0)	PASS
2441.0	2402.0	2472.0	-60.080	<=	-40.000	(0)	PASS
2441.0	2402.0	2473.0	-59.973	<=	-40.000	(0)	PASS
2441.0	2402.0	2474.0	-59.876	<=	-40.000	(0)	PASS
2441.0	2402.0	2475.0	-60.086	<=	-40.000	(0)	PASS
2441.0	2402.0	2476.0	-60.212	<=	-40.000	(0)	PASS
2441.0	2402.0	2477.0	-60.017	<=	-40.000	(0)	PASS
2441.0	2402.0	2478.0	-60.084	<=	-40.000	(0)	PASS
2441.0	2402.0	2479.0	-60.208	<=	-40.000	(0)	PASS
2441.0	2402.0	2480.0	-60.085	<=	-40.000	(0)	PASS
2477.0	2402.0	2402.0	-59.234	<=	-40.000	(0)	PASS
2477.0	2402.0	2403.0	-59.766	<=	-40.000	(0)	PASS
2477.0	2402.0	2404.0	-59.673	<=	-40.000	(0)	PASS
2477.0	2402.0	2405.0	-59.852	<=	-40.000	(0)	PASS
2477.0	2402.0	2406.0	-59.865	<=	-40.000	(0)	PASS
2477.0	2402.0	2407.0	-59.833	<=	-40.000	(0)	PASS
2477.0	2402.0	2408.0	-59.949	<=	-40.000	(0)	PASS
2477.0	2402.0	2409.0	-59.754	<=	-40.000	(0)	PASS
2477.0	2402.0	2410.0	-59.728	<=	-40.000	(0)	PASS
2477.0	2402.0	2411.0	-59.676	<=	-40.000	(0)	PASS
2477.0	2402.0	2412.0	-59.865	<=	-40.000	(0)	PASS
2477.0	2402.0	2413.0	-59.651	<=	-40.000	(0)	PASS
2477.0	2402.0	2414.0	-59.726	<=	-40.000	(0)	PASS
2477.0	2402.0	2415.0	-59.800	<=	-40.000	(0)	PASS
2477.0	2402.0	2416.0	-59.880	<=	-40.000	(0)	PASS
2477.0	2402.0	2417.0	-59.844	<=	-40.000	(0)	PASS
2477.0	2402.0	2418.0	-59.817	<=	-40.000	(0)	PASS
2477.0	2402.0	2419.0	-59.754	<=	-40.000	(0)	PASS
2477.0	2402.0	2420.0	-59.851	<=	-40.000	(0)	PASS
2477.0	2402.0	2421.0	-59.824	<=	-40.000	(0)	PASS
2477.0	2402.0	2422.0	-59.719	<=	-40.000	(0)	PASS
2477.0	2402.0	2423.0	-59.907	<=	-40.000	(0)	PASS
2477.0	2402.0	2424.0	-57.675	<=	-40.000	(0)	PASS
2477.0	2402.0	2425.0	-59.228	<=	-40.000	(0)	PASS
2477.0	2402.0	2426.0	-59.867	<=	-40.000	(0)	PASS
2477.0	2402.0	2427.0	-59.856	<=	-40.000	(0)	PASS

2477.0	2402.0	2428.0	-59.938	<=	-40.000	(0)	PASS
2477.0	2402.0	2429.0	-59.743	<=	-40.000	(0)	PASS
2477.0	2402.0	2430.0	-59.788	<=	-40.000	(0)	PASS
2477.0	2402.0	2431.0	-59.887	<=	-40.000	(0)	PASS
2477.0	2402.0	2432.0	-59.907	<=	-40.000	(0)	PASS
2477.0	2402.0	2433.0	-59.859	<=	-40.000	(0)	PASS
2477.0	2402.0	2434.0	-59.844	<=	-40.000	(0)	PASS
2477.0	2402.0	2435.0	-59.834	<=	-40.000	(0)	PASS
2477.0	2402.0	2436.0	-59.824	<=	-40.000	(0)	PASS
2477.0	2402.0	2437.0	-59.655	<=	-40.000	(0)	PASS
2477.0	2402.0	2438.0	-59.888	<=	-40.000	(0)	PASS
2477.0	2402.0	2439.0	-59.829	<=	-40.000	(0)	PASS
2477.0	2402.0	2440.0	-59.865	<=	-40.000	(0)	PASS
2477.0	2402.0	2441.0	-59.718	<=	-40.000	(0)	PASS
2477.0	2402.0	2442.0	-59.839	<=	-40.000	(0)	PASS
2477.0	2402.0	2443.0	-59.865	<=	-40.000	(0)	PASS
2477.0	2402.0	2444.0	-59.671	<=	-40.000	(0)	PASS
2477.0	2402.0	2445.0	-59.574	<=	-40.000	(0)	PASS
2477.0	2402.0	2446.0	-59.916	<=	-40.000	(0)	PASS
2477.0	2402.0	2447.0	-59.827	<=	-40.000	(0)	PASS
2477.0	2402.0	2448.0	-60.010	<=	-40.000	(0)	PASS
2477.0	2402.0	2449.0	-59.609	<=	-40.000	(0)	PASS
2477.0	2402.0	2450.0	-59.302	<=	-40.000	(0)	PASS
2477.0	2402.0	2451.0	-54.861	<=	-40.000	(0)	PASS
2477.0	2402.0	2452.0	-59.777	<=	-40.000	(0)	PASS
2477.0	2402.0	2453.0	-59.718	<=	-40.000	(0)	PASS
2477.0	2402.0	2454.0	-59.613	<=	-40.000	(0)	PASS
2477.0	2402.0	2455.0	-59.626	<=	-40.000	(0)	PASS
2477.0	2402.0	2456.0	-59.765	<=	-40.000	(0)	PASS
2477.0	2402.0	2457.0	-59.286	<=	-40.000	(0)	PASS
2477.0	2402.0	2458.0	-59.711	<=	-40.000	(0)	PASS
2477.0	2402.0	2459.0	-59.534	<=	-40.000	(0)	PASS
2477.0	2402.0	2460.0	-59.440	<=	-40.000	(0)	PASS
2477.0	2402.0	2461.0	-59.418	<=	-40.000	(0)	PASS
2477.0	2402.0	2462.0	-59.505	<=	-40.000	(0)	PASS
2477.0	2402.0	2463.0	-58.583	<=	-40.000	(0)	PASS
2477.0	2402.0	2464.0	-57.831	<=	-40.000	(0)	PASS
2477.0	2402.0	2465.0	-58.016	<=	-40.000	(0)	PASS
2477.0	2402.0	2466.0	-59.039	<=	-40.000	(0)	PASS
2477.0	2402.0	2467.0	-58.824	<=	-40.000	(0)	PASS
2477.0	2402.0	2468.0	-58.719	<=	-40.000	(0)	PASS
2477.0	2402.0	2469.0	-58.459	<=	-40.000	(0)	PASS
2477.0	2402.0	2470.0	-58.295	<=	-40.000	(0)	PASS
2477.0	2402.0	2471.0	-57.948	<=	-40.000	(0)	PASS
2477.0	2402.0	2472.0	-57.040	<=	-40.000	(0)	PASS
2477.0	2402.0	2473.0	-54.312	<=	-40.000	(0)	PASS
2477.0	2402.0	2474.0	-49.499	<=	-40.000	(0)	PASS
2477.0	2402.0	2475.0	-41.903	<=	-20.000	(0)	PASS
2477.0	2402.0	2479.0	-35.218	<=	-20.000	(0)	PASS
2477.0	2402.0	2480.0	-45.842	<=	-40.000	(0)	PASS

Final Test Case Verdict . . . . . PASS 01:02:57

Results TC TX Output Spectrum - Adjacent Channel Power -Measured EUT: M3200



TX Output Spectrum - Adjacent Channel Power

For system parameter see 0, "General Parameter 011"

BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 005"
For test case parameter see 0, "Test Case Parameter 024"

TX-FREQ [MHz]	RX-FREQ [MHz]	MEAS-FREQ [MHz]	LEVEL [dBm]		LIMIT [dBm]	(OUT)	VERDICT
2405.0	2480.0	2402.0	-51.657	<=	-40.000	(0)	PASS
2405.0	2480.0	2403.0	-45.463	<=	-20.000	(0)	PASS
2405.0	2480.0	2407.0	-41.974	<=	-20.000	(0)	PASS
2405.0	2480.0	2408.0	-44.096	<=	-40.000	(0)	PASS
2405.0	2480.0	2409.0	-48.591	<=	-40.000	(0)	PASS
2405.0	2480.0	2410.0	-54.216	<=	-40.000	(0)	PASS
2405.0	2480.0	2411.0	-56.620	<=	-40.000	(0)	PASS
2405.0	2480.0	2412.0	-57.414	<=	-40.000	(0)	PASS
2405.0	2480.0	2413.0	-55.459	<=	-40.000	(0)	PASS
2405.0	2480.0	2414.0	-57.877	<=	-40.000	(0)	PASS
2405.0	2480.0	2415.0	-57.916	<=	-40.000	(0)	PASS
2405.0	2480.0	2416.0	-57.936	<=	-40.000	(0)	PASS
2405.0	2480.0	2417.0	-57.831	<=	-40.000	(0)	PASS
2405.0	2480.0	2418.0	-58.048	<=	-40.000	(0)	PASS
2405.0	2480.0	2419.0	-58.294	<=	-40.000	(0)	PASS
2405.0	2480.0	2420.0	-58.502	<=	-40.000	(0)	PASS
2405.0	2480.0	2421.0	-58.209	<=	-40.000	(0)	PASS
2405.0	2480.0	2422.0	-58.431	<=	-40.000	(0)	PASS
2405.0	2480.0	2423.0	-58.457	<=	-40.000	(0)	PASS
2405.0	2480.0	2424.0	-58.559	<=	-40.000	(0)	PASS
2405.0	2480.0	2425.0	-58.903	<=	-40.000	(0)	PASS
2405.0	2480.0	2426.0	-58.886	<=	-40.000	(0)	PASS
2405.0	2480.0	2427.0	-59.034	<=	-40.000	(0)	PASS
2405.0	2480.0	2428.0	-58.993	<=	-40.000	(0)	PASS
2405.0	2480.0	2429.0	-59.279	<=	-40.000	(0)	PASS
2405.0	2480.0	2430.0	-59.151	<=	-40.000	(0)	PASS
2405.0	2480.0	2431.0	-55.246	<=	-40.000	(0)	PASS
2405.0	2480.0	2432.0	-59.312	<=	-40.000	(0)	PASS
2405.0	2480.0	2433.0	-59.423	<=	-40.000	(0)	PASS
2405.0	2480.0	2434.0	-59.397	<=	-40.000	(0)	PASS
2405.0	2480.0	2435.0	-59.591	<=	-40.000	(0)	PASS
2405.0	2480.0	2436.0	-59.481	<=	-40.000	(0)	PASS
2405.0	2480.0	2437.0	-59.239	<=	-40.000	(0)	PASS
2405.0	2480.0	2438.0	-59.637	<=	-40.000	(0)	PASS
2405.0	2480.0	2439.0	-59.524	<=	-40.000	(0)	PASS
2405.0	2480.0	2440.0	-59.584	<=	-40.000	(0)	PASS
2405.0	2480.0	2441.0	-59.525	<=	-40.000	(0)	PASS
2405.0	2480.0	2442.0	-59.763	<=	-40.000	(0)	PASS
2405.0	2480.0	2443.0	-59.743	<=	-40.000	(0)	PASS
2405.0	2480.0	2444.0	-59.823	<=	-40.000	(0)	PASS
2405.0	2480.0	2445.0	-59.689	<=	-40.000	(0)	PASS
2405.0	2480.0	2446.0	-59.688	<=	-40.000	(0)	PASS
2405.0	2480.0	2447.0	-59.840	<=	-40.000	(0)	PASS
2405.0	2480.0	2448.0	-59.831	<=	-40.000	(0)	PASS
2405.0	2480.0	2449.0	-59.523	<=	-40.000	(0)	PASS
2405.0	2480.0	2450.0	-59.730	<=	-40.000	(0)	PASS
2405.0	2480.0	2451.0	-59.932	<=	-40.000	(0)	PASS
2405.0	2480.0	2452.0	-59.918	<=	-40.000	(0)	PASS

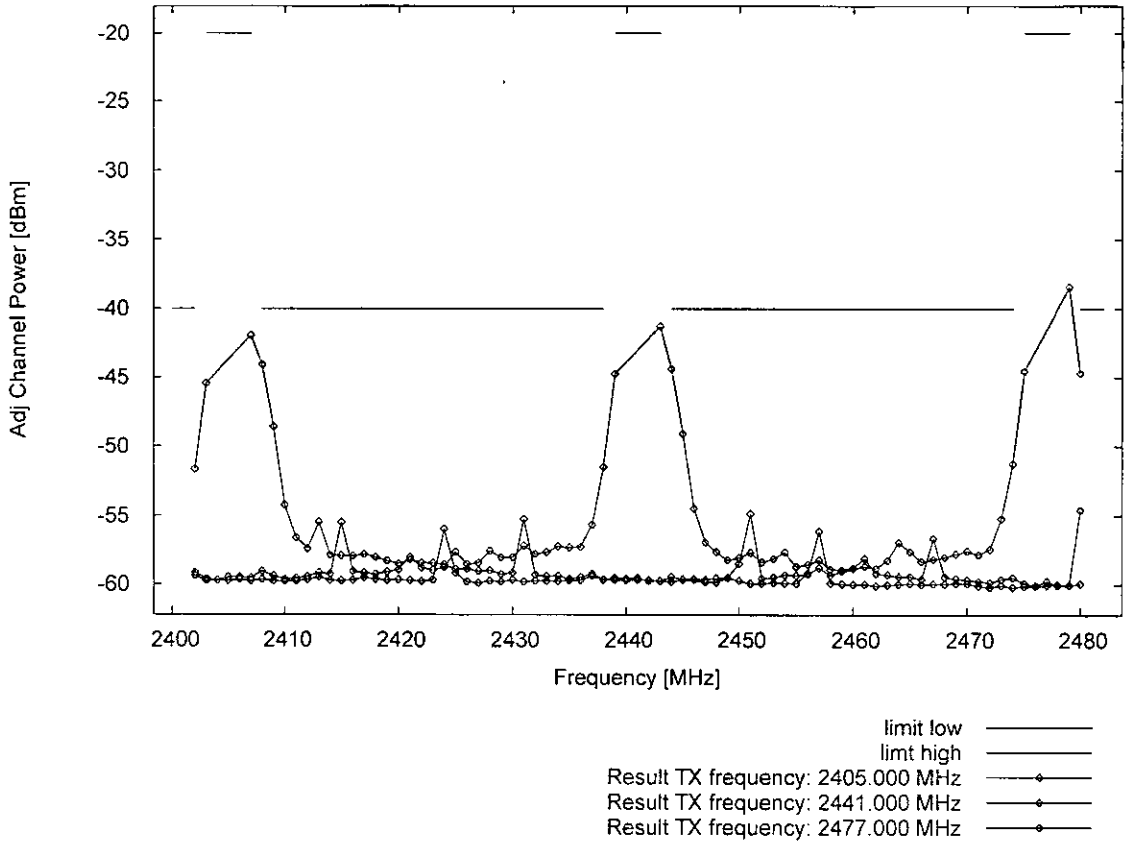
2405.0	2480.0	2453.0	-59.866	<=	-40.000	(0)	PASS
2405.0	2480.0	2454.0	-59.902	<=	-40.000	(0)	PASS
2405.0	2480.0	2455.0	-59.924	<=	-40.000	(0)	PASS
2405.0	2480.0	2456.0	-59.196	<=	-40.000	(0)	PASS
2405.0	2480.0	2457.0	-56.143	<=	-40.000	(0)	PASS
2405.0	2480.0	2458.0	-59.905	<=	-40.000	(0)	PASS
2405.0	2480.0	2459.0	-59.956	<=	-40.000	(0)	PASS
2405.0	2480.0	2460.0	-59.999	<=	-40.000	(0)	PASS
2405.0	2480.0	2461.0	-59.973	<=	-40.000	(0)	PASS
2405.0	2480.0	2462.0	-60.094	<=	-40.000	(0)	PASS
2405.0	2480.0	2463.0	-60.025	<=	-40.000	(0)	PASS
2405.0	2480.0	2464.0	-59.990	<=	-40.000	(0)	PASS
2405.0	2480.0	2465.0	-59.932	<=	-40.000	(0)	PASS
2405.0	2480.0	2466.0	-60.013	<=	-40.000	(0)	PASS
2405.0	2480.0	2467.0	-59.939	<=	-40.000	(0)	PASS
2405.0	2480.0	2468.0	-59.945	<=	-40.000	(0)	PASS
2405.0	2480.0	2469.0	-59.905	<=	-40.000	(0)	PASS
2405.0	2480.0	2470.0	-59.933	<=	-40.000	(0)	PASS
2405.0	2480.0	2471.0	-60.088	<=	-40.000	(0)	PASS
2405.0	2480.0	2472.0	-60.191	<=	-40.000	(0)	PASS
2405.0	2480.0	2473.0	-60.046	<=	-40.000	(0)	PASS
2405.0	2480.0	2474.0	-60.186	<=	-40.000	(0)	PASS
2405.0	2480.0	2475.0	-60.128	<=	-40.000	(0)	PASS
2405.0	2480.0	2476.0	-60.121	<=	-40.000	(0)	PASS
2405.0	2480.0	2477.0	-60.055	<=	-40.000	(0)	PASS
2405.0	2480.0	2478.0	-59.960	<=	-40.000	(0)	PASS
2405.0	2480.0	2479.0	-60.042	<=	-40.000	(0)	PASS
2405.0	2480.0	2480.0	-54.586	<=	-40.000	(0)	PASS
2441.0	2402.0	2402.0	-59.169	<=	-40.000	(0)	PASS
2441.0	2402.0	2403.0	-59.601	<=	-40.000	(0)	PASS
2441.0	2402.0	2404.0	-59.719	<=	-40.000	(0)	PASS
2441.0	2402.0	2405.0	-59.497	<=	-40.000	(0)	PASS
2441.0	2402.0	2406.0	-59.491	<=	-40.000	(0)	PASS
2441.0	2402.0	2407.0	-59.558	<=	-40.000	(0)	PASS
2441.0	2402.0	2408.0	-59.071	<=	-40.000	(0)	PASS
2441.0	2402.0	2409.0	-59.398	<=	-40.000	(0)	PASS
2441.0	2402.0	2410.0	-59.636	<=	-40.000	(0)	PASS
2441.0	2402.0	2411.0	-59.577	<=	-40.000	(0)	PASS
2441.0	2402.0	2412.0	-59.446	<=	-40.000	(0)	PASS
2441.0	2402.0	2413.0	-59.155	<=	-40.000	(0)	PASS
2441.0	2402.0	2414.0	-59.268	<=	-40.000	(0)	PASS
2441.0	2402.0	2415.0	-55.484	<=	-40.000	(0)	PASS
2441.0	2402.0	2416.0	-59.057	<=	-40.000	(0)	PASS
2441.0	2402.0	2417.0	-59.191	<=	-40.000	(0)	PASS
2441.0	2402.0	2418.0	-59.279	<=	-40.000	(0)	PASS
2441.0	2402.0	2419.0	-59.117	<=	-40.000	(0)	PASS
2441.0	2402.0	2420.0	-58.955	<=	-40.000	(0)	PASS
2441.0	2402.0	2421.0	-58.020	<=	-40.000	(0)	PASS
2441.0	2402.0	2422.0	-58.815	<=	-40.000	(0)	PASS
2441.0	2402.0	2423.0	-58.981	<=	-40.000	(0)	PASS
2441.0	2402.0	2424.0	-58.762	<=	-40.000	(0)	PASS
2441.0	2402.0	2425.0	-57.648	<=	-40.000	(0)	PASS
2441.0	2402.0	2426.0	-58.540	<=	-40.000	(0)	PASS
2441.0	2402.0	2427.0	-58.445	<=	-40.000	(0)	PASS
2441.0	2402.0	2428.0	-57.572	<=	-40.000	(0)	PASS
2441.0	2402.0	2429.0	-58.051	<=	-40.000	(0)	PASS
2441.0	2402.0	2430.0	-58.038	<=	-40.000	(0)	PASS
2441.0	2402.0	2431.0	-57.202	<=	-40.000	(0)	PASS
2441.0	2402.0	2432.0	-57.795	<=	-40.000	(0)	PASS
2441.0	2402.0	2433.0	-57.656	<=	-40.000	(0)	PASS
2441.0	2402.0	2434.0	-57.248	<=	-40.000	(0)	PASS
2441.0	2402.0	2435.0	-57.330	<=	-40.000	(0)	PASS
2441.0	2402.0	2436.0	-57.288	<=	-40.000	(0)	PASS
2441.0	2402.0	2437.0	-55.677	<=	-40.000	(0)	PASS
2441.0	2402.0	2438.0	-51.481	<=	-40.000	(0)	PASS

2441.0	2402.0	2439.0	-44.747	<=	-20.000	(0)	PASS
2441.0	2402.0	2443.0	-41.290	<=	-20.000	(0)	PASS
2441.0	2402.0	2444.0	-44.375	<=	-40.000	(0)	PASS
2441.0	2402.0	2445.0	-49.094	<=	-40.000	(0)	PASS
2441.0	2402.0	2446.0	-54.487	<=	-40.000	(0)	PASS
2441.0	2402.0	2447.0	-56.945	<=	-40.000	(0)	PASS
2441.0	2402.0	2448.0	-57.629	<=	-40.000	(0)	PASS
2441.0	2402.0	2449.0	-58.234	<=	-40.000	(0)	PASS
2441.0	2402.0	2450.0	-58.067	<=	-40.000	(0)	PASS
2441.0	2402.0	2451.0	-57.697	<=	-40.000	(0)	PASS
2441.0	2402.0	2452.0	-58.387	<=	-40.000	(0)	PASS
2441.0	2402.0	2453.0	-58.128	<=	-40.000	(0)	PASS
2441.0	2402.0	2454.0	-57.657	<=	-40.000	(0)	PASS
2441.0	2402.0	2455.0	-58.708	<=	-40.000	(0)	PASS
2441.0	2402.0	2456.0	-58.553	<=	-40.000	(0)	PASS
2441.0	2402.0	2457.0	-58.218	<=	-40.000	(0)	PASS
2441.0	2402.0	2458.0	-58.897	<=	-40.000	(0)	PASS
2441.0	2402.0	2459.0	-58.953	<=	-40.000	(0)	PASS
2441.0	2402.0	2460.0	-58.809	<=	-40.000	(0)	PASS
2441.0	2402.0	2461.0	-58.105	<=	-40.000	(0)	PASS
2441.0	2402.0	2462.0	-59.218	<=	-40.000	(0)	PASS
2441.0	2402.0	2463.0	-59.292	<=	-40.000	(0)	PASS
2441.0	2402.0	2464.0	-59.438	<=	-40.000	(0)	PASS
2441.0	2402.0	2465.0	-59.428	<=	-40.000	(0)	PASS
2441.0	2402.0	2466.0	-59.612	<=	-40.000	(0)	PASS
2441.0	2402.0	2467.0	-56.649	<=	-40.000	(0)	PASS
2441.0	2402.0	2468.0	-59.452	<=	-40.000	(0)	PASS
2441.0	2402.0	2469.0	-59.571	<=	-40.000	(0)	PASS
2441.0	2402.0	2470.0	-59.662	<=	-40.000	(0)	PASS
2441.0	2402.0	2471.0	-59.780	<=	-40.000	(0)	PASS
2441.0	2402.0	2472.0	-59.859	<=	-40.000	(0)	PASS
2441.0	2402.0	2473.0	-59.632	<=	-40.000	(0)	PASS
2441.0	2402.0	2474.0	-59.495	<=	-40.000	(0)	PASS
2441.0	2402.0	2475.0	-59.903	<=	-40.000	(0)	PASS
2441.0	2402.0	2476.0	-60.051	<=	-40.000	(0)	PASS
2441.0	2402.0	2477.0	-59.755	<=	-40.000	(0)	PASS
2441.0	2402.0	2478.0	-60.063	<=	-40.000	(0)	PASS
2441.0	2402.0	2479.0	-60.022	<=	-40.000	(0)	PASS
2441.0	2402.0	2480.0	-59.940	<=	-40.000	(0)	PASS
2477.0	2402.0	2402.0	-59.378	<=	-40.000	(0)	PASS
2477.0	2402.0	2403.0	-59.744	<=	-40.000	(0)	PASS
2477.0	2402.0	2404.0	-59.720	<=	-40.000	(0)	PASS
2477.0	2402.0	2405.0	-59.756	<=	-40.000	(0)	PASS
2477.0	2402.0	2406.0	-59.651	<=	-40.000	(0)	PASS
2477.0	2402.0	2407.0	-59.766	<=	-40.000	(0)	PASS
2477.0	2402.0	2408.0	-59.645	<=	-40.000	(0)	PASS
2477.0	2402.0	2409.0	-59.778	<=	-40.000	(0)	PASS
2477.0	2402.0	2410.0	-59.805	<=	-40.000	(0)	PASS
2477.0	2402.0	2411.0	-59.776	<=	-40.000	(0)	PASS
2477.0	2402.0	2412.0	-59.684	<=	-40.000	(0)	PASS
2477.0	2402.0	2413.0	-59.480	<=	-40.000	(0)	PASS
2477.0	2402.0	2414.0	-59.715	<=	-40.000	(0)	PASS
2477.0	2402.0	2415.0	-59.748	<=	-40.000	(0)	PASS
2477.0	2402.0	2416.0	-59.710	<=	-40.000	(0)	PASS
2477.0	2402.0	2417.0	-59.521	<=	-40.000	(0)	PASS
2477.0	2402.0	2418.0	-59.629	<=	-40.000	(0)	PASS
2477.0	2402.0	2419.0	-59.706	<=	-40.000	(0)	PASS
2477.0	2402.0	2420.0	-59.666	<=	-40.000	(0)	PASS
2477.0	2402.0	2421.0	-59.725	<=	-40.000	(0)	PASS
2477.0	2402.0	2422.0	-59.776	<=	-40.000	(0)	PASS
2477.0	2402.0	2423.0	-59.685	<=	-40.000	(0)	PASS
2477.0	2402.0	2424.0	-55.969	<=	-40.000	(0)	PASS
2477.0	2402.0	2425.0	-59.199	<=	-40.000	(0)	PASS
2477.0	2402.0	2426.0	-59.805	<=	-40.000	(0)	PASS
2477.0	2402.0	2427.0	-59.887	<=	-40.000	(0)	PASS

2477.0	2402.0	2428.0	-59.753	<=	-40.000	(0)	PASS
2477.0	2402.0	2429.0	-59.814	<=	-40.000	(0)	PASS
2477.0	2402.0	2430.0	-59.686	<=	-40.000	(0)	PASS
2477.0	2402.0	2431.0	-59.818	<=	-40.000	(0)	PASS
2477.0	2402.0	2432.0	-59.743	<=	-40.000	(0)	PASS
2477.0	2402.0	2433.0	-59.741	<=	-40.000	(0)	PASS
2477.0	2402.0	2434.0	-59.765	<=	-40.000	(0)	PASS
2477.0	2402.0	2435.0	-59.723	<=	-40.000	(0)	PASS
2477.0	2402.0	2436.0	-59.713	<=	-40.000	(0)	PASS
2477.0	2402.0	2437.0	-59.387	<=	-40.000	(0)	PASS
2477.0	2402.0	2438.0	-59.668	<=	-40.000	(0)	PASS
2477.0	2402.0	2439.0	-59.663	<=	-40.000	(0)	PASS
2477.0	2402.0	2440.0	-59.723	<=	-40.000	(0)	PASS
2477.0	2402.0	2441.0	-59.679	<=	-40.000	(0)	PASS
2477.0	2402.0	2442.0	-59.665	<=	-40.000	(0)	PASS
2477.0	2402.0	2443.0	-59.779	<=	-40.000	(0)	PASS
2477.0	2402.0	2444.0	-59.467	<=	-40.000	(0)	PASS
2477.0	2402.0	2445.0	-59.613	<=	-40.000	(0)	PASS
2477.0	2402.0	2446.0	-59.594	<=	-40.000	(0)	PASS
2477.0	2402.0	2447.0	-59.638	<=	-40.000	(0)	PASS
2477.0	2402.0	2448.0	-59.554	<=	-40.000	(0)	PASS
2477.0	2402.0	2449.0	-59.538	<=	-40.000	(0)	PASS
2477.0	2402.0	2450.0	-58.502	<=	-40.000	(0)	PASS
2477.0	2402.0	2451.0	-54.859	<=	-40.000	(0)	PASS
2477.0	2402.0	2452.0	-59.569	<=	-40.000	(0)	PASS
2477.0	2402.0	2453.0	-59.485	<=	-40.000	(0)	PASS
2477.0	2402.0	2454.0	-59.303	<=	-40.000	(0)	PASS
2477.0	2402.0	2455.0	-59.341	<=	-40.000	(0)	PASS
2477.0	2402.0	2456.0	-59.257	<=	-40.000	(0)	PASS
2477.0	2402.0	2457.0	-58.818	<=	-40.000	(0)	PASS
2477.0	2402.0	2458.0	-59.330	<=	-40.000	(0)	PASS
2477.0	2402.0	2459.0	-59.055	<=	-40.000	(0)	PASS
2477.0	2402.0	2460.0	-58.872	<=	-40.000	(0)	PASS
2477.0	2402.0	2461.0	-58.687	<=	-40.000	(0)	PASS
2477.0	2402.0	2462.0	-58.843	<=	-40.000	(0)	PASS
2477.0	2402.0	2463.0	-58.259	<=	-40.000	(0)	PASS
2477.0	2402.0	2464.0	-56.946	<=	-40.000	(0)	PASS
2477.0	2402.0	2465.0	-57.621	<=	-40.000	(0)	PASS
2477.0	2402.0	2466.0	-58.330	<=	-40.000	(0)	PASS
2477.0	2402.0	2467.0	-58.163	<=	-40.000	(0)	PASS
2477.0	2402.0	2468.0	-58.020	<=	-40.000	(0)	PASS
2477.0	2402.0	2469.0	-57.783	<=	-40.000	(0)	PASS
2477.0	2402.0	2470.0	-57.570	<=	-40.000	(0)	PASS
2477.0	2402.0	2471.0	-57.818	<=	-40.000	(0)	PASS
2477.0	2402.0	2472.0	-57.436	<=	-40.000	(0)	PASS
2477.0	2402.0	2473.0	-55.210	<=	-40.000	(0)	PASS
2477.0	2402.0	2474.0	-51.229	<=	-40.000	(0)	PASS
2477.0	2402.0	2475.0	-44.538	<=	-20.000	(0)	PASS
2477.0	2402.0	2479.0	-38.428	<=	-20.000	(0)	PASS
2477.0	2402.0	2480.0	-44.687	<=	-40.000	(0)	PASS

Final Test Case Verdict . . . . . PASS 00:57:41

Results TC TX Output Spectrum - Adjacent Channel Power -Measured EUT: M3200



TX Output Spectrum - Adjacent Channel Power

For system parameter see 0, "General Parameter 011"

BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 006"
For test case parameter see 0, "Test Case Parameter 025"

TX-FREQ [MHz]	RX-FREQ [MHz]	MEAS-FREQ [MHz]	LEVEL [dBm]		LIMIT [dBm]	(OUT)	VERDICT
2405.0	2480.0	2402.0	-52.190	<=	-40.000	(0)	PASS
2405.0	2480.0	2403.0	-45.705	<=	-20.000	(0)	PASS
2405.0	2480.0	2407.0	-38.861	<=	-20.000	(0)	PASS
2405.0	2480.0	2408.0	-44.186	<=	-40.000	(0)	PASS
2405.0	2480.0	2409.0	-48.724	<=	-40.000	(0)	PASS
2405.0	2480.0	2410.0	-54.432	<=	-40.000	(0)	PASS
2405.0	2480.0	2411.0	-56.756	<=	-40.000	(0)	PASS
2405.0	2480.0	2412.0	-57.597	<=	-40.000	(0)	PASS
2405.0	2480.0	2413.0	-55.562	<=	-40.000	(0)	PASS
2405.0	2480.0	2414.0	-57.906	<=	-40.000	(0)	PASS
2405.0	2480.0	2415.0	-57.958	<=	-40.000	(0)	PASS
2405.0	2480.0	2416.0	-58.001	<=	-40.000	(0)	PASS
2405.0	2480.0	2417.0	-57.887	<=	-40.000	(0)	PASS
2405.0	2480.0	2418.0	-58.047	<=	-40.000	(0)	PASS
2405.0	2480.0	2419.0	-58.397	<=	-40.000	(0)	PASS
2405.0	2480.0	2420.0	-58.327	<=	-40.000	(0)	PASS
2405.0	2480.0	2421.0	-57.934	<=	-40.000	(0)	PASS
2405.0	2480.0	2422.0	-58.581	<=	-40.000	(0)	PASS
2405.0	2480.0	2423.0	-58.625	<=	-40.000	(0)	PASS
2405.0	2480.0	2424.0	-58.598	<=	-40.000	(0)	PASS
2405.0	2480.0	2425.0	-58.823	<=	-40.000	(0)	PASS
2405.0	2480.0	2426.0	-58.919	<=	-40.000	(0)	PASS
2405.0	2480.0	2427.0	-58.979	<=	-40.000	(0)	PASS
2405.0	2480.0	2428.0	-58.879	<=	-40.000	(0)	PASS
2405.0	2480.0	2429.0	-59.282	<=	-40.000	(0)	PASS
2405.0	2480.0	2430.0	-59.222	<=	-40.000	(0)	PASS
2405.0	2480.0	2431.0	-55.374	<=	-40.000	(0)	PASS
2405.0	2480.0	2432.0	-59.400	<=	-40.000	(0)	PASS
2405.0	2480.0	2433.0	-59.416	<=	-40.000	(0)	PASS
2405.0	2480.0	2434.0	-59.416	<=	-40.000	(0)	PASS
2405.0	2480.0	2435.0	-59.514	<=	-40.000	(0)	PASS
2405.0	2480.0	2436.0	-59.388	<=	-40.000	(0)	PASS
2405.0	2480.0	2437.0	-59.345	<=	-40.000	(0)	PASS
2405.0	2480.0	2438.0	-59.604	<=	-40.000	(0)	PASS
2405.0	2480.0	2439.0	-59.495	<=	-40.000	(0)	PASS
2405.0	2480.0	2440.0	-59.752	<=	-40.000	(0)	PASS
2405.0	2480.0	2441.0	-59.776	<=	-40.000	(0)	PASS
2405.0	2480.0	2442.0	-59.752	<=	-40.000	(0)	PASS
2405.0	2480.0	2443.0	-59.718	<=	-40.000	(0)	PASS
2405.0	2480.0	2444.0	-59.769	<=	-40.000	(0)	PASS
2405.0	2480.0	2445.0	-59.818	<=	-40.000	(0)	PASS
2405.0	2480.0	2446.0	-59.818	<=	-40.000	(0)	PASS
2405.0	2480.0	2447.0	-59.902	<=	-40.000	(0)	PASS
2405.0	2480.0	2448.0	-59.804	<=	-40.000	(0)	PASS
2405.0	2480.0	2449.0	-59.656	<=	-40.000	(0)	PASS
2405.0	2480.0	2450.0	-59.907	<=	-40.000	(0)	PASS
2405.0	2480.0	2451.0	-59.938	<=	-40.000	(0)	PASS
2405.0	2480.0	2452.0	-59.978	<=	-40.000	(0)	PASS

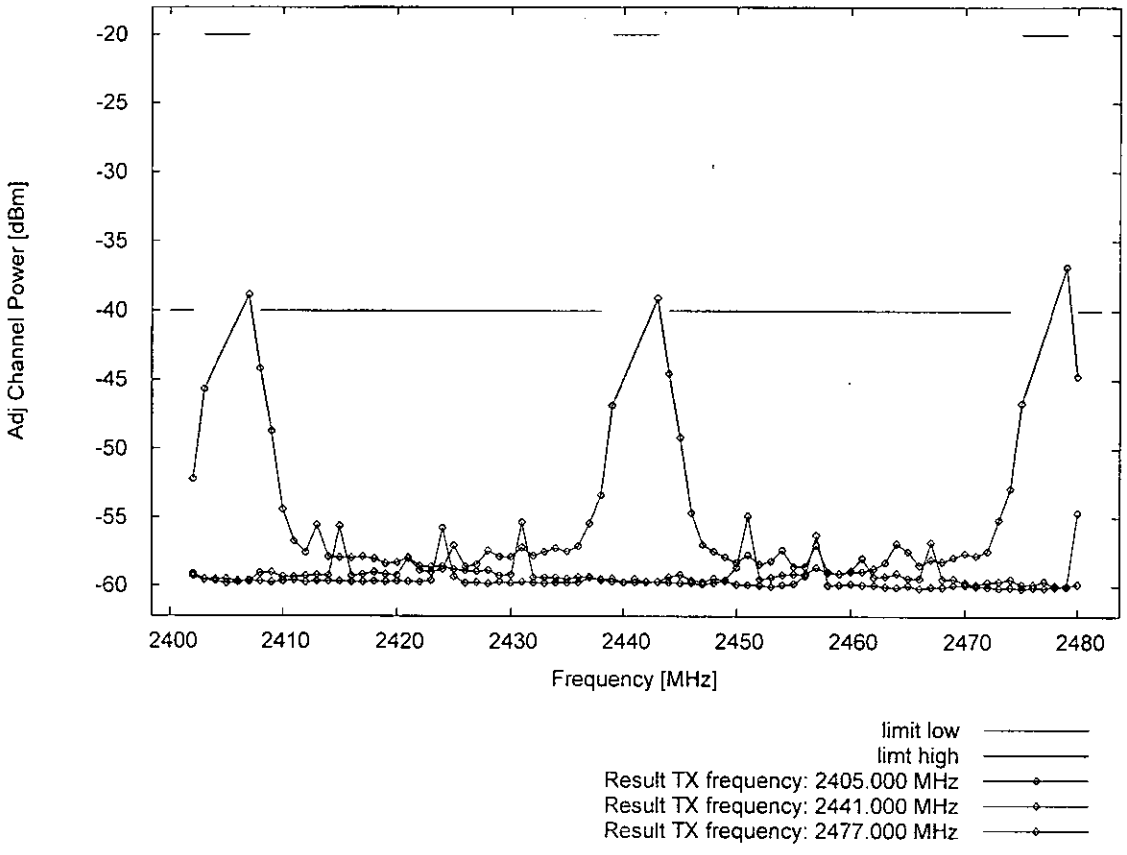
2405.0	2480.0	2453.0	-60.067	<=	-40.000	(0)	PASS
2405.0	2480.0	2454.0	-59:942	<=	-40.000	(0)	PASS
2405.0	2480.0	2455.0	-59.853	<=	-40.000	(0)	PASS
2405.0	2480.0	2456.0	-59.279	<=	-40.000	(0)	PASS
2405.0	2480.0	2457.0	-56.316	<=	-40.000	(0)	PASS
2405.0	2480.0	2458.0	-59.961	<=	-40.000	(0)	PASS
2405.0	2480.0	2459.0	-59.922	<=	-40.000	(0)	PASS
2405.0	2480.0	2460.0	-59.854	<=	-40.000	(0)	PASS
2405.0	2480.0	2461.0	-59.940	<=	-40.000	(0)	PASS
2405.0	2480.0	2462.0	-59.958	<=	-40.000	(0)	PASS
2405.0	2480.0	2463.0	-60.083	<=	-40.000	(0)	PASS
2405.0	2480.0	2464.0	-60.116	<=	-40.000	(0)	PASS
2405.0	2480.0	2465.0	-59.991	<=	-40.000	(0)	PASS
2405.0	2480.0	2466.0	-60.180	<=	-40.000	(0)	PASS
2405.0	2480.0	2467.0	-60.082	<=	-40.000	(0)	PASS
2405.0	2480.0	2468.0	-60.097	<=	-40.000	(0)	PASS
2405.0	2480.0	2469.0	-59.942	<=	-40.000	(0)	PASS
2405.0	2480.0	2470.0	-59.942	<=	-40.000	(0)	PASS
2405.0	2480.0	2471.0	-60.029	<=	-40.000	(0)	PASS
2405.0	2480.0	2472.0	-60.081	<=	-40.000	(0)	PASS
2405.0	2480.0	2473.0	-60.154	<=	-40.000	(0)	PASS
2405.0	2480.0	2474.0	-60.108	<=	-40.000	(0)	PASS
2405.0	2480.0	2475.0	-60.195	<=	-40.000	(0)	PASS
2405.0	2480.0	2476.0	-60.106	<=	-40.000	(0)	PASS
2405.0	2480.0	2477.0	-60.155	<=	-40.000	(0)	PASS
2405.0	2480.0	2478.0	-59.959	<=	-40.000	(0)	PASS
2405.0	2480.0	2479.0	-60.062	<=	-40.000	(0)	PASS
2405.0	2480.0	2480.0	-54.642	<=	-40.000	(0)	PASS
2441.0	2402.0	2402.0	-59.151	<=	-40.000	(0)	PASS
2441.0	2402.0	2403.0	-59.566	<=	-40.000	(0)	PASS
2441.0	2402.0	2404.0	-59.561	<=	-40.000	(0)	PASS
2441.0	2402.0	2405.0	-59.547	<=	-40.000	(0)	PASS
2441.0	2402.0	2406.0	-59.665	<=	-40.000	(0)	PASS
2441.0	2402.0	2407.0	-59.727	<=	-40.000	(0)	PASS
2441.0	2402.0	2408.0	-59.104	<=	-40.000	(0)	PASS
2441.0	2402.0	2409.0	-59.058	<=	-40.000	(0)	PASS
2441.0	2402.0	2410.0	-59.372	<=	-40.000	(0)	PASS
2441.0	2402.0	2411.0	-59.401	<=	-40.000	(0)	PASS
2441.0	2402.0	2412.0	-59.294	<=	-40.000	(0)	PASS
2441.0	2402.0	2413.0	-59.229	<=	-40.000	(0)	PASS
2441.0	2402.0	2414.0	-59.290	<=	-40.000	(0)	PASS
2441.0	2402.0	2415.0	-55.632	<=	-40.000	(0)	PASS
2441.0	2402.0	2416.0	-59.309	<=	-40.000	(0)	PASS
2441.0	2402.0	2417.0	-59.201	<=	-40.000	(0)	PASS
2441.0	2402.0	2418.0	-59.019	<=	-40.000	(0)	PASS
2441.0	2402.0	2419.0	-59.185	<=	-40.000	(0)	PASS
2441.0	2402.0	2420.0	-59.250	<=	-40.000	(0)	PASS
2441.0	2402.0	2421.0	-58.031	<=	-40.000	(0)	PASS
2441.0	2402.0	2422.0	-58.898	<=	-40.000	(0)	PASS
2441.0	2402.0	2423.0	-58.991	<=	-40.000	(0)	PASS
2441.0	2402.0	2424.0	-58.816	<=	-40.000	(0)	PASS
2441.0	2402.0	2425.0	-57.068	<=	-40.000	(0)	PASS
2441.0	2402.0	2426.0	-58.632	<=	-40.000	(0)	PASS
2441.0	2402.0	2427.0	-58.456	<=	-40.000	(0)	PASS
2441.0	2402.0	2428.0	-57.450	<=	-40.000	(0)	PASS
2441.0	2402.0	2429.0	-57.897	<=	-40.000	(0)	PASS
2441.0	2402.0	2430.0	-57.919	<=	-40.000	(0)	PASS
2441.0	2402.0	2431.0	-57.227	<=	-40.000	(0)	PASS
2441.0	2402.0	2432.0	-57.823	<=	-40.000	(0)	PASS
2441.0	2402.0	2433.0	-57.532	<=	-40.000	(0)	PASS
2441.0	2402.0	2434.0	-57.275	<=	-40.000	(0)	PASS
2441.0	2402.0	2435.0	-57.499	<=	-40.000	(0)	PASS
2441.0	2402.0	2436.0	-57.129	<=	-40.000	(0)	PASS
2441.0	2402.0	2437.0	-55.443	<=	-40.000	(0)	PASS
2441.0	2402.0	2438.0	-53.361	<=	-40.000	(0)	PASS

2441.0	2402.0	2439.0	-46.865	<=	-20.000	(0)	PASS
2441.0	2402.0	2443.0	-39.094	<=	-20.000	(0)	PASS
2441.0	2402.0	2444.0	-44.550	<=	-40.000	(0)	PASS
2441.0	2402.0	2445.0	-49.170	<=	-40.000	(0)	PASS
2441.0	2402.0	2446.0	-54.670	<=	-40.000	(0)	PASS
2441.0	2402.0	2447.0	-56.999	<=	-40.000	(0)	PASS
2441.0	2402.0	2448.0	-57.503	<=	-40.000	(0)	PASS
2441.0	2402.0	2449.0	-57.908	<=	-40.000	(0)	PASS
2441.0	2402.0	2450.0	-58.315	<=	-40.000	(0)	PASS
2441.0	2402.0	2451.0	-57.770	<=	-40.000	(0)	PASS
2441.0	2402.0	2452.0	-58.428	<=	-40.000	(0)	PASS
2441.0	2402.0	2453.0	-58.204	<=	-40.000	(0)	PASS
2441.0	2402.0	2454.0	-57.406	<=	-40.000	(0)	PASS
2441.0	2402.0	2455.0	-58.613	<=	-40.000	(0)	PASS
2441.0	2402.0	2456.0	-58.616	<=	-40.000	(0)	PASS
2441.0	2402.0	2457.0	-57.042	<=	-40.000	(0)	PASS
2441.0	2402.0	2458.0	-58.988	<=	-40.000	(0)	PASS
2441.0	2402.0	2459.0	-59.120	<=	-40.000	(0)	PASS
2441.0	2402.0	2460.0	-58.898	<=	-40.000	(0)	PASS
2441.0	2402.0	2461.0	-58.001	<=	-40.000	(0)	PASS
2441.0	2402.0	2462.0	-59.364	<=	-40.000	(0)	PASS
2441.0	2402.0	2463.0	-59.318	<=	-40.000	(0)	PASS
2441.0	2402.0	2464.0	-59.102	<=	-40.000	(0)	PASS
2441.0	2402.0	2465.0	-59.462	<=	-40.000	(0)	PASS
2441.0	2402.0	2466.0	-59.473	<=	-40.000	(0)	PASS
2441.0	2402.0	2467.0	-56.814	<=	-40.000	(0)	PASS
2441.0	2402.0	2468.0	-59.512	<=	-40.000	(0)	PASS
2441.0	2402.0	2469.0	-59.484	<=	-40.000	(0)	PASS
2441.0	2402.0	2470.0	-59.764	<=	-40.000	(0)	PASS
2441.0	2402.0	2471.0	-59.906	<=	-40.000	(0)	PASS
2441.0	2402.0	2472.0	-59.734	<=	-40.000	(0)	PASS
2441.0	2402.0	2473.0	-59.682	<=	-40.000	(0)	PASS
2441.0	2402.0	2474.0	-59.515	<=	-40.000	(0)	PASS
2441.0	2402.0	2475.0	-59.894	<=	-40.000	(0)	PASS
2441.0	2402.0	2476.0	-59.877	<=	-40.000	(0)	PASS
2441.0	2402.0	2477.0	-59.644	<=	-40.000	(0)	PASS
2441.0	2402.0	2478.0	-60.075	<=	-40.000	(0)	PASS
2441.0	2402.0	2479.0	-59.988	<=	-40.000	(0)	PASS
2441.0	2402.0	2480.0	-59.862	<=	-40.000	(0)	PASS
2477.0	2402.0	2402.0	-59.326	<=	-40.000	(0)	PASS
2477.0	2402.0	2403.0	-59.582	<=	-40.000	(0)	PASS
2477.0	2402.0	2404.0	-59.704	<=	-40.000	(0)	PASS
2477.0	2402.0	2405.0	-59.836	<=	-40.000	(0)	PASS
2477.0	2402.0	2406.0	-59.779	<=	-40.000	(0)	PASS
2477.0	2402.0	2407.0	-59.638	<=	-40.000	(0)	PASS
2477.0	2402.0	2408.0	-59.715	<=	-40.000	(0)	PASS
2477.0	2402.0	2409.0	-59.769	<=	-40.000	(0)	PASS
2477.0	2402.0	2410.0	-59.674	<=	-40.000	(0)	PASS
2477.0	2402.0	2411.0	-59.606	<=	-40.000	(0)	PASS
2477.0	2402.0	2412.0	-59.760	<=	-40.000	(0)	PASS
2477.0	2402.0	2413.0	-59.663	<=	-40.000	(0)	PASS
2477.0	2402.0	2414.0	-59.672	<=	-40.000	(0)	PASS
2477.0	2402.0	2415.0	-59.697	<=	-40.000	(0)	PASS
2477.0	2402.0	2416.0	-59.735	<=	-40.000	(0)	PASS
2477.0	2402.0	2417.0	-59.734	<=	-40.000	(0)	PASS
2477.0	2402.0	2418.0	-59.710	<=	-40.000	(0)	PASS
2477.0	2402.0	2419.0	-59.730	<=	-40.000	(0)	PASS
2477.0	2402.0	2420.0	-59.676	<=	-40.000	(0)	PASS
2477.0	2402.0	2421.0	-59.713	<=	-40.000	(0)	PASS
2477.0	2402.0	2422.0	-59.736	<=	-40.000	(0)	PASS
2477.0	2402.0	2423.0	-59.601	<=	-40.000	(0)	PASS
2477.0	2402.0	2424.0	-55.783	<=	-40.000	(0)	PASS
2477.0	2402.0	2425.0	-59.340	<=	-40.000	(0)	PASS
2477.0	2402.0	2426.0	-59.812	<=	-40.000	(0)	PASS
2477.0	2402.0	2427.0	-59.764	<=	-40.000	(0)	PASS

2477.0	2402.0	2428.0	-59.857	<=	-40.000	(0)	PASS
2477.0	2402.0	2429.0	-59.720	<=	-40.000	(0)	PASS
2477.0	2402.0	2430.0	-59.819	<=	-40.000	(0)	PASS
2477.0	2402.0	2431.0	-59.739	<=	-40.000	(0)	PASS
2477.0	2402.0	2432.0	-59.784	<=	-40.000	(0)	PASS
2477.0	2402.0	2433.0	-59.827	<=	-40.000	(0)	PASS
2477.0	2402.0	2434.0	-59.767	<=	-40.000	(0)	PASS
2477.0	2402.0	2435.0	-59.808	<=	-40.000	(0)	PASS
2477.0	2402.0	2436.0	-59.768	<=	-40.000	(0)	PASS
2477.0	2402.0	2437.0	-59.439	<=	-40.000	(0)	PASS
2477.0	2402.0	2438.0	-59.537	<=	-40.000	(0)	PASS
2477.0	2402.0	2439.0	-59.714	<=	-40.000	(0)	PASS
2477.0	2402.0	2440.0	-59.780	<=	-40.000	(0)	PASS
2477.0	2402.0	2441.0	-59.534	<=	-40.000	(0)	PASS
2477.0	2402.0	2442.0	-59.697	<=	-40.000	(0)	PASS
2477.0	2402.0	2443.0	-59.726	<=	-40.000	(0)	PASS
2477.0	2402.0	2444.0	-59.373	<=	-40.000	(0)	PASS
2477.0	2402.0	2445.0	-59.193	<=	-40.000	(0)	PASS
2477.0	2402.0	2446.0	-59.620	<=	-40.000	(0)	PASS
2477.0	2402.0	2447.0	-59.736	<=	-40.000	(0)	PASS
2477.0	2402.0	2448.0	-59.486	<=	-40.000	(0)	PASS
2477.0	2402.0	2449.0	-59.592	<=	-40.000	(0)	PASS
2477.0	2402.0	2450.0	-58.665	<=	-40.000	(0)	PASS
2477.0	2402.0	2451.0	-54.893	<=	-40.000	(0)	PASS
2477.0	2402.0	2452.0	-59.542	<=	-40.000	(0)	PASS
2477.0	2402.0	2453.0	-59.402	<=	-40.000	(0)	PASS
2477.0	2402.0	2454.0	-59.219	<=	-40.000	(0)	PASS
2477.0	2402.0	2455.0	-59.168	<=	-40.000	(0)	PASS
2477.0	2402.0	2456.0	-59.190	<=	-40.000	(0)	PASS
2477.0	2402.0	2457.0	-58.680	<=	-40.000	(0)	PASS
2477.0	2402.0	2458.0	-59.059	<=	-40.000	(0)	PASS
2477.0	2402.0	2459.0	-59.125	<=	-40.000	(0)	PASS
2477.0	2402.0	2460.0	-59.004	<=	-40.000	(0)	PASS
2477.0	2402.0	2461.0	-58.974	<=	-40.000	(0)	PASS
2477.0	2402.0	2462.0	-58.740	<=	-40.000	(0)	PASS
2477.0	2402.0	2463.0	-58.313	<=	-40.000	(0)	PASS
2477.0	2402.0	2464.0	-56.919	<=	-40.000	(0)	PASS
2477.0	2402.0	2465.0	-57.488	<=	-40.000	(0)	PASS
2477.0	2402.0	2466.0	-58.504	<=	-40.000	(0)	PASS
2477.0	2402.0	2467.0	-58.082	<=	-40.000	(0)	PASS
2477.0	2402.0	2468.0	-58.224	<=	-40.000	(0)	PASS
2477.0	2402.0	2469.0	-57.910	<=	-40.000	(0)	PASS
2477.0	2402.0	2470.0	-57.624	<=	-40.000	(0)	PASS
2477.0	2402.0	2471.0	-57.799	<=	-40.000	(0)	PASS
2477.0	2402.0	2472.0	-57.482	<=	-40.000	(0)	PASS
2477.0	2402.0	2473.0	-55.180	<=	-40.000	(0)	PASS
2477.0	2402.0	2474.0	-52.867	<=	-40.000	(0)	PASS
2477.0	2402.0	2475.0	-46.673	<=	-20.000	(0)	PASS
2477.0	2402.0	2479.0	-36.860	<=	-20.000	(0)	PASS
2477.0	2402.0	2480.0	-44.715	<=	-40.000	(0)	PASS

Final Test Case Verdict . . . . . PASS 00:57:44

Results TC TX Output Spectrum - Adjacent Channel Power -Measured EUT: M3200



TX Output Spectrum - Adjacent Channel Power

For system parameter see 0, "General Parameter 011"

BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 009"
For test case parameter see 0, "Test Case Parameter 044"

TX-FREQ [MHz]	RX-FREQ [MHz]	MEAS-FREQ [MHz]	LEVEL [dBm]		LIMIT [dBm]	(OUT)	VERDICT
2405.0	2480.0	2402.0	-47.475	<=	-40.000	(0)	PASS
2405.0	2480.0	2403.0	-40.369	<=	-20.000	(0)	PASS
2405.0	2480.0	2407.0	-37.448	<=	-20.000	(0)	PASS
2405.0	2480.0	2408.0	-44.828	<=	-40.000	(0)	PASS
2405.0	2480.0	2409.0	-47.125	<=	-40.000	(0)	PASS
2405.0	2480.0	2410.0	-53.860	<=	-40.000	(0)	PASS
2405.0	2480.0	2411.0	-57.731	<=	-40.000	(0)	PASS
2405.0	2480.0	2412.0	-58.384	<=	-40.000	(0)	PASS
2405.0	2480.0	2413.0	-57.649	<=	-40.000	(0)	PASS
2405.0	2480.0	2414.0	-58.941	<=	-40.000	(0)	PASS
2405.0	2480.0	2415.0	-58.844	<=	-40.000	(0)	PASS
2405.0	2480.0	2416.0	-59.020	<=	-40.000	(0)	PASS
2405.0	2480.0	2417.0	-58.550	<=	-40.000	(0)	PASS
2405.0	2480.0	2418.0	-59.075	<=	-40.000	(0)	PASS
2405.0	2480.0	2419.0	-59.207	<=	-40.000	(0)	PASS
2405.0	2480.0	2420.0	-59.311	<=	-40.000	(0)	PASS
2405.0	2480.0	2421.0	-59.098	<=	-40.000	(0)	PASS
2405.0	2480.0	2422.0	-59.440	<=	-40.000	(0)	PASS
2405.0	2480.0	2423.0	-59.498	<=	-40.000	(0)	PASS
2405.0	2480.0	2424.0	-59.195	<=	-40.000	(0)	PASS
2405.0	2480.0	2425.0	-59.510	<=	-40.000	(0)	PASS
2405.0	2480.0	2426.0	-59.568	<=	-40.000	(0)	PASS
2405.0	2480.0	2427.0	-59.750	<=	-40.000	(0)	PASS
2405.0	2480.0	2428.0	-59.590	<=	-40.000	(0)	PASS
2405.0	2480.0	2429.0	-59.758	<=	-40.000	(0)	PASS
2405.0	2480.0	2430.0	-59.676	<=	-40.000	(0)	PASS
2405.0	2480.0	2431.0	-56.043	<=	-40.000	(0)	PASS
2405.0	2480.0	2432.0	-59.799	<=	-40.000	(0)	PASS
2405.0	2480.0	2433.0	-59.828	<=	-40.000	(0)	PASS
2405.0	2480.0	2434.0	-59.713	<=	-40.000	(0)	PASS
2405.0	2480.0	2435.0	-59.845	<=	-40.000	(0)	PASS
2405.0	2480.0	2436.0	-59.948	<=	-40.000	(0)	PASS
2405.0	2480.0	2437.0	-59.714	<=	-40.000	(0)	PASS
2405.0	2480.0	2438.0	-59.882	<=	-40.000	(0)	PASS
2405.0	2480.0	2439.0	-59.931	<=	-40.000	(0)	PASS
2405.0	2480.0	2440.0	-59.883	<=	-40.000	(0)	PASS
2405.0	2480.0	2441.0	-59.924	<=	-40.000	(0)	PASS
2405.0	2480.0	2442.0	-59.882	<=	-40.000	(0)	PASS
2405.0	2480.0	2443.0	-59.975	<=	-40.000	(0)	PASS
2405.0	2480.0	2444.0	-60.014	<=	-40.000	(0)	PASS
2405.0	2480.0	2445.0	-60.012	<=	-40.000	(0)	PASS
2405.0	2480.0	2446.0	-59.967	<=	-40.000	(0)	PASS
2405.0	2480.0	2447.0	-60.114	<=	-40.000	(0)	PASS
2405.0	2480.0	2448.0	-60.025	<=	-40.000	(0)	PASS
2405.0	2480.0	2449.0	-60.026	<=	-40.000	(0)	PASS
2405.0	2480.0	2450.0	-59.961	<=	-40.000	(0)	PASS
2405.0	2480.0	2451.0	-60.064	<=	-40.000	(0)	PASS
2405.0	2480.0	2452.0	-59.891	<=	-40.000	(0)	PASS

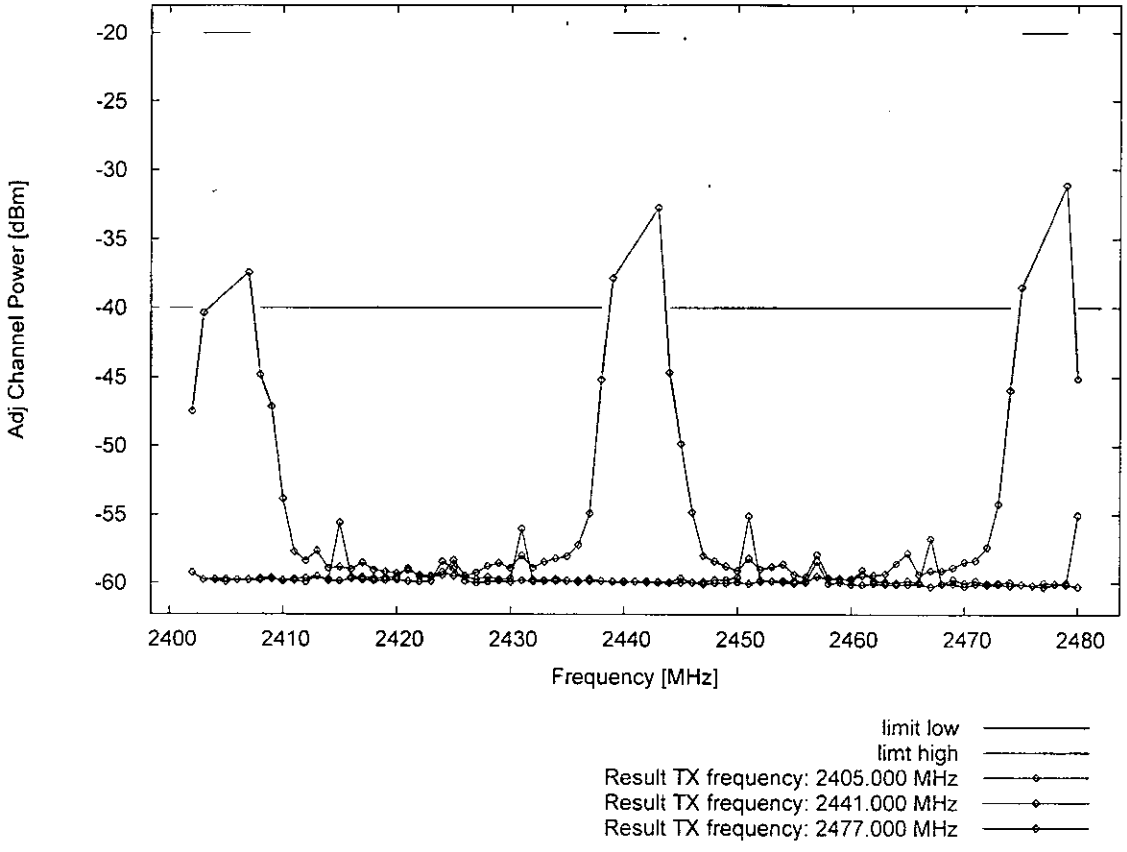
2405.0	2480.0	2453.0	-59.892	<=	-40.000	(0)	PASS
2405.0	2480.0	2454.0	-59.950	<=	-40.000	(0)	PASS
2405.0	2480.0	2455.0	-60.022	<=	-40.000	(0)	PASS
2405.0	2480.0	2456.0	-59.975	<=	-40.000	(0)	PASS
2405.0	2480.0	2457.0	-58.416	<=	-40.000	(0)	PASS
2405.0	2480.0	2458.0	-60.058	<=	-40.000	(0)	PASS
2405.0	2480.0	2459.0	-59.965	<=	-40.000	(0)	PASS
2405.0	2480.0	2460.0	-60.115	<=	-40.000	(0)	PASS
2405.0	2480.0	2461.0	-60.134	<=	-40.000	(0)	PASS
2405.0	2480.0	2462.0	-60.073	<=	-40.000	(0)	PASS
2405.0	2480.0	2463.0	-60.118	<=	-40.000	(0)	PASS
2405.0	2480.0	2464.0	-60.160	<=	-40.000	(0)	PASS
2405.0	2480.0	2465.0	-60.124	<=	-40.000	(0)	PASS
2405.0	2480.0	2466.0	-60.065	<=	-40.000	(0)	PASS
2405.0	2480.0	2467.0	-60.277	<=	-40.000	(0)	PASS
2405.0	2480.0	2468.0	-60.058	<=	-40.000	(0)	PASS
2405.0	2480.0	2469.0	-60.090	<=	-40.000	(0)	PASS
2405.0	2480.0	2470.0	-60.270	<=	-40.000	(0)	PASS
2405.0	2480.0	2471.0	-60.119	<=	-40.000	(0)	PASS
2405.0	2480.0	2472.0	-60.179	<=	-40.000	(0)	PASS
2405.0	2480.0	2473.0	-60.115	<=	-40.000	(0)	PASS
2405.0	2480.0	2474.0	-60.200	<=	-40.000	(0)	PASS
2405.0	2480.0	2475.0	-60.112	<=	-40.000	(0)	PASS
2405.0	2480.0	2476.0	-60.185	<=	-40.000	(0)	PASS
2405.0	2480.0	2477.0	-60.309	<=	-40.000	(0)	PASS
2405.0	2480.0	2478.0	-60.100	<=	-40.000	(0)	PASS
2405.0	2480.0	2479.0	-59.995	<=	-40.000	(0)	PASS
2405.0	2480.0	2480.0	-55.047	<=	-40.000	(0)	PASS
2441.0	2402.0	2402.0	-59.256	<=	-40.000	(0)	PASS
2441.0	2402.0	2403.0	-59.772	<=	-40.000	(0)	PASS
2441.0	2402.0	2404.0	-59.734	<=	-40.000	(0)	PASS
2441.0	2402.0	2405.0	-59.728	<=	-40.000	(0)	PASS
2441.0	2402.0	2406.0	-59.802	<=	-40.000	(0)	PASS
2441.0	2402.0	2407.0	-59.800	<=	-40.000	(0)	PASS
2441.0	2402.0	2408.0	-59.690	<=	-40.000	(0)	PASS
2441.0	2402.0	2409.0	-59.626	<=	-40.000	(0)	PASS
2441.0	2402.0	2410.0	-59.896	<=	-40.000	(0)	PASS
2441.0	2402.0	2411.0	-59.702	<=	-40.000	(0)	PASS
2441.0	2402.0	2412.0	-59.666	<=	-40.000	(0)	PASS
2441.0	2402.0	2413.0	-59.535	<=	-40.000	(0)	PASS
2441.0	2402.0	2414.0	-59.757	<=	-40.000	(0)	PASS
2441.0	2402.0	2415.0	-55.600	<=	-40.000	(0)	PASS
2441.0	2402.0	2416.0	-59.604	<=	-40.000	(0)	PASS
2441.0	2402.0	2417.0	-59.601	<=	-40.000	(0)	PASS
2441.0	2402.0	2418.0	-59.690	<=	-40.000	(0)	PASS
2441.0	2402.0	2419.0	-59.634	<=	-40.000	(0)	PASS
2441.0	2402.0	2420.0	-59.611	<=	-40.000	(0)	PASS
2441.0	2402.0	2421.0	-58.935	<=	-40.000	(0)	PASS
2441.0	2402.0	2422.0	-59.554	<=	-40.000	(0)	PASS
2441.0	2402.0	2423.0	-59.586	<=	-40.000	(0)	PASS
2441.0	2402.0	2424.0	-59.442	<=	-40.000	(0)	PASS
2441.0	2402.0	2425.0	-58.329	<=	-40.000	(0)	PASS
2441.0	2402.0	2426.0	-59.493	<=	-40.000	(0)	PASS
2441.0	2402.0	2427.0	-59.255	<=	-40.000	(0)	PASS
2441.0	2402.0	2428.0	-58.771	<=	-40.000	(0)	PASS
2441.0	2402.0	2429.0	-58.535	<=	-40.000	(0)	PASS
2441.0	2402.0	2430.0	-58.924	<=	-40.000	(0)	PASS
2441.0	2402.0	2431.0	-57.992	<=	-40.000	(0)	PASS
2441.0	2402.0	2432.0	-58.906	<=	-40.000	(0)	PASS
2441.0	2402.0	2433.0	-58.464	<=	-40.000	(0)	PASS
2441.0	2402.0	2434.0	-58.207	<=	-40.000	(0)	PASS
2441.0	2402.0	2435.0	-58.048	<=	-40.000	(0)	PASS
2441.0	2402.0	2436.0	-57.241	<=	-40.000	(0)	PASS
2441.0	2402.0	2437.0	-54.915	<=	-40.000	(0)	PASS
2441.0	2402.0	2438.0	-45.201	<=	-40.000	(0)	PASS

2441.0	2402.0	2439.0	-37.847	<=	-20.000	(0)	PASS
2441.0	2402.0	2443.0	-32.754	<=	-20.000	(0)	PASS
2441.0	2402.0	2444.0	-44.659	<=	-40.000	(0)	PASS
2441.0	2402.0	2445.0	-49.837	<=	-40.000	(0)	PASS
2441.0	2402.0	2446.0	-54.848	<=	-40.000	(0)	PASS
2441.0	2402.0	2447.0	-58.001	<=	-40.000	(0)	PASS
2441.0	2402.0	2448.0	-58.412	<=	-40.000	(0)	PASS
2441.0	2402.0	2449.0	-58.779	<=	-40.000	(0)	PASS
2441.0	2402.0	2450.0	-59.099	<=	-40.000	(0)	PASS
2441.0	2402.0	2451.0	-58.219	<=	-40.000	(0)	PASS
2441.0	2402.0	2452.0	-59.008	<=	-40.000	(0)	PASS
2441.0	2402.0	2453.0	-58.819	<=	-40.000	(0)	PASS
2441.0	2402.0	2454.0	-58.640	<=	-40.000	(0)	PASS
2441.0	2402.0	2455.0	-59.394	<=	-40.000	(0)	PASS
2441.0	2402.0	2456.0	-59.572	<=	-40.000	(0)	PASS
2441.0	2402.0	2457.0	-57.923	<=	-40.000	(0)	PASS
2441.0	2402.0	2458.0	-59.643	<=	-40.000	(0)	PASS
2441.0	2402.0	2459.0	-59.662	<=	-40.000	(0)	PASS
2441.0	2402.0	2460.0	-59.812	<=	-40.000	(0)	PASS
2441.0	2402.0	2461.0	-59.055	<=	-40.000	(0)	PASS
2441.0	2402.0	2462.0	-59.865	<=	-40.000	(0)	PASS
2441.0	2402.0	2463.0	-59.933	<=	-40.000	(0)	PASS
2441.0	2402.0	2464.0	-59.992	<=	-40.000	(0)	PASS
2441.0	2402.0	2465.0	-59.867	<=	-40.000	(0)	PASS
2441.0	2402.0	2466.0	-59.954	<=	-40.000	(0)	PASS
2441.0	2402.0	2467.0	-56.773	<=	-40.000	(0)	PASS
2441.0	2402.0	2468.0	-60.095	<=	-40.000	(0)	PASS
2441.0	2402.0	2469.0	-59.746	<=	-40.000	(0)	PASS
2441.0	2402.0	2470.0	-60.042	<=	-40.000	(0)	PASS
2441.0	2402.0	2471.0	-59.863	<=	-40.000	(0)	PASS
2441.0	2402.0	2472.0	-60.042	<=	-40.000	(0)	PASS
2441.0	2402.0	2473.0	-60.028	<=	-40.000	(0)	PASS
2441.0	2402.0	2474.0	-59.955	<=	-40.000	(0)	PASS
2441.0	2402.0	2475.0	-60.127	<=	-40.000	(0)	PASS
2441.0	2402.0	2476.0	-60.182	<=	-40.000	(0)	PASS
2441.0	2402.0	2477.0	-60.009	<=	-40.000	(0)	PASS
2441.0	2402.0	2478.0	-60.039	<=	-40.000	(0)	PASS
2441.0	2402.0	2479.0	-60.148	<=	-40.000	(0)	PASS
2441.0	2402.0	2480.0	-60.282	<=	-40.000	(0)	PASS
2477.0	2402.0	2402.0	-59.277	<=	-40.000	(0)	PASS
2477.0	2402.0	2403.0	-59.808	<=	-40.000	(0)	PASS
2477.0	2402.0	2404.0	-59.814	<=	-40.000	(0)	PASS
2477.0	2402.0	2405.0	-59.928	<=	-40.000	(0)	PASS
2477.0	2402.0	2406.0	-59.810	<=	-40.000	(0)	PASS
2477.0	2402.0	2407.0	-59.819	<=	-40.000	(0)	PASS
2477.0	2402.0	2408.0	-59.842	<=	-40.000	(0)	PASS
2477.0	2402.0	2409.0	-59.748	<=	-40.000	(0)	PASS
2477.0	2402.0	2410.0	-59.832	<=	-40.000	(0)	PASS
2477.0	2402.0	2411.0	-59.866	<=	-40.000	(0)	PASS
2477.0	2402.0	2412.0	-59.950	<=	-40.000	(0)	PASS
2477.0	2402.0	2413.0	-59.544	<=	-40.000	(0)	PASS
2477.0	2402.0	2414.0	-59.875	<=	-40.000	(0)	PASS
2477.0	2402.0	2415.0	-59.876	<=	-40.000	(0)	PASS
2477.0	2402.0	2416.0	-59.721	<=	-40.000	(0)	PASS
2477.0	2402.0	2417.0	-59.792	<=	-40.000	(0)	PASS
2477.0	2402.0	2418.0	-59.865	<=	-40.000	(0)	PASS
2477.0	2402.0	2419.0	-59.843	<=	-40.000	(0)	PASS
2477.0	2402.0	2420.0	-59.804	<=	-40.000	(0)	PASS
2477.0	2402.0	2421.0	-59.894	<=	-40.000	(0)	PASS
2477.0	2402.0	2422.0	-59.930	<=	-40.000	(0)	PASS
2477.0	2402.0	2423.0	-59.890	<=	-40.000	(0)	PASS
2477.0	2402.0	2424.0	-58.452	<=	-40.000	(0)	PASS
2477.0	2402.0	2425.0	-58.969	<=	-40.000	(0)	PASS
2477.0	2402.0	2426.0	-59.892	<=	-40.000	(0)	PASS
2477.0	2402.0	2427.0	-60.013	<=	-40.000	(0)	PASS

2477.0	2402.0	2428.0	-59.940	<=	-40.000	(0)	PASS
2477.0	2402.0	2429.0	-59.856	<=	-40.000	(0)	PASS
2477.0	2402.0	2430.0	-59.956	<=	-40.000	(0)	PASS
2477.0	2402.0	2431.0	-59.826	<=	-40.000	(0)	PASS
2477.0	2402.0	2432.0	-59.917	<=	-40.000	(0)	PASS
2477.0	2402.0	2433.0	-59.901	<=	-40.000	(0)	PASS
2477.0	2402.0	2434.0	-59.892	<=	-40.000	(0)	PASS
2477.0	2402.0	2435.0	-59.894	<=	-40.000	(0)	PASS
2477.0	2402.0	2436.0	-59.850	<=	-40.000	(0)	PASS
2477.0	2402.0	2437.0	-59.895	<=	-40.000	(0)	PASS
2477.0	2402.0	2438.0	-59.875	<=	-40.000	(0)	PASS
2477.0	2402.0	2439.0	-59.907	<=	-40.000	(0)	PASS
2477.0	2402.0	2440.0	-59.973	<=	-40.000	(0)	PASS
2477.0	2402.0	2441.0	-59.904	<=	-40.000	(0)	PASS
2477.0	2402.0	2442.0	-59.997	<=	-40.000	(0)	PASS
2477.0	2402.0	2443.0	-59.925	<=	-40.000	(0)	PASS
2477.0	2402.0	2444.0	-59.953	<=	-40.000	(0)	PASS
2477.0	2402.0	2445.0	-59.656	<=	-40.000	(0)	PASS
2477.0	2402.0	2446.0	-59.989	<=	-40.000	(0)	PASS
2477.0	2402.0	2447.0	-59.928	<=	-40.000	(0)	PASS
2477.0	2402.0	2448.0	-59.787	<=	-40.000	(0)	PASS
2477.0	2402.0	2449.0	-59.784	<=	-40.000	(0)	PASS
2477.0	2402.0	2450.0	-59.605	<=	-40.000	(0)	PASS
2477.0	2402.0	2451.0	-55.104	<=	-40.000	(0)	PASS
2477.0	2402.0	2452.0	-59.826	<=	-40.000	(0)	PASS
2477.0	2402.0	2453.0	-59.897	<=	-40.000	(0)	PASS
2477.0	2402.0	2454.0	-59.846	<=	-40.000	(0)	PASS
2477.0	2402.0	2455.0	-59.849	<=	-40.000	(0)	PASS
2477.0	2402.0	2456.0	-59.900	<=	-40.000	(0)	PASS
2477.0	2402.0	2457.0	-59.542	<=	-40.000	(0)	PASS
2477.0	2402.0	2458.0	-59.705	<=	-40.000	(0)	PASS
2477.0	2402.0	2459.0	-59.746	<=	-40.000	(0)	PASS
2477.0	2402.0	2460.0	-59.696	<=	-40.000	(0)	PASS
2477.0	2402.0	2461.0	-59.458	<=	-40.000	(0)	PASS
2477.0	2402.0	2462.0	-59.437	<=	-40.000	(0)	PASS
2477.0	2402.0	2463.0	-59.344	<=	-40.000	(0)	PASS
2477.0	2402.0	2464.0	-58.573	<=	-40.000	(0)	PASS
2477.0	2402.0	2465.0	-57.817	<=	-40.000	(0)	PASS
2477.0	2402.0	2466.0	-59.380	<=	-40.000	(0)	PASS
2477.0	2402.0	2467.0	-59.104	<=	-40.000	(0)	PASS
2477.0	2402.0	2468.0	-59.109	<=	-40.000	(0)	PASS
2477.0	2402.0	2469.0	-58.867	<=	-40.000	(0)	PASS
2477.0	2402.0	2470.0	-58.468	<=	-40.000	(0)	PASS
2477.0	2402.0	2471.0	-58.361	<=	-40.000	(0)	PASS
2477.0	2402.0	2472.0	-57.397	<=	-40.000	(0)	PASS
2477.0	2402.0	2473.0	-54.224	<=	-40.000	(0)	PASS
2477.0	2402.0	2474.0	-45.949	<=	-40.000	(0)	PASS
2477.0	2402.0	2475.0	-38.500	<=	-20.000	(0)	PASS
2477.0	2402.0	2479.0	-31.160	<=	-20.000	(0)	PASS
2477.0	2402.0	2480.0	-45.116	<=	-40.000	(0)	PASS

Final Test Case Verdict . . . . . PASS 00:57:58

Results TC TX Output Spectrum - Adjacent Channel Power -Measured EUT: M3200



TX Output Spectrum - Adjacent Channel Power

For system parameter see 0, "General Parameter 011"

BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 010"
For test case parameter see 0, "Test Case Parameter 045"

TX-FREQ [MHz]	RX-FREQ [MHz]	MEAS-FREQ [MHz]	LEVEL [dBm]		LIMIT [dBm]	(OUT)	VERDICT
2405.0	2480.0	2402.0	-45.738	<=	-40.000	(0)	PASS
2405.0	2480.0	2403.0	-38.748	<=	-20.000	(0)	PASS
2405.0	2480.0	2407.0	-33.616	<=	-20.000	(0)	PASS
2405.0	2480.0	2408.0	-44.416	<=	-40.000	(0)	PASS
2405.0	2480.0	2409.0	-47.309	<=	-40.000	(0)	PASS
2405.0	2480.0	2410.0	-53.925	<=	-40.000	(0)	PASS
2405.0	2480.0	2411.0	-57.959	<=	-40.000	(0)	PASS
2405.0	2480.0	2412.0	-58.391	<=	-40.000	(0)	PASS
2405.0	2480.0	2413.0	-56.954	<=	-40.000	(0)	PASS
2405.0	2480.0	2414.0	-58.796	<=	-40.000	(0)	PASS
2405.0	2480.0	2415.0	-58.884	<=	-40.000	(0)	PASS
2405.0	2480.0	2416.0	-58.961	<=	-40.000	(0)	PASS
2405.0	2480.0	2417.0	-58.655	<=	-40.000	(0)	PASS
2405.0	2480.0	2418.0	-59.096	<=	-40.000	(0)	PASS
2405.0	2480.0	2419.0	-59.375	<=	-40.000	(0)	PASS
2405.0	2480.0	2420.0	-59.238	<=	-40.000	(0)	PASS
2405.0	2480.0	2421.0	-58.669	<=	-40.000	(0)	PASS
2405.0	2480.0	2422.0	-59.387	<=	-40.000	(0)	PASS
2405.0	2480.0	2423.0	-59.307	<=	-40.000	(0)	PASS
2405.0	2480.0	2424.0	-59.401	<=	-40.000	(0)	PASS
2405.0	2480.0	2425.0	-59.641	<=	-40.000	(0)	PASS
2405.0	2480.0	2426.0	-59.677	<=	-40.000	(0)	PASS
2405.0	2480.0	2427.0	-59.640	<=	-40.000	(0)	PASS
2405.0	2480.0	2428.0	-59.608	<=	-40.000	(0)	PASS
2405.0	2480.0	2429.0	-59.771	<=	-40.000	(0)	PASS
2405.0	2480.0	2430.0	-59.701	<=	-40.000	(0)	PASS
2405.0	2480.0	2431.0	-56.223	<=	-40.000	(0)	PASS
2405.0	2480.0	2432.0	-59.685	<=	-40.000	(0)	PASS
2405.0	2480.0	2433.0	-59.812	<=	-40.000	(0)	PASS
2405.0	2480.0	2434.0	-59.759	<=	-40.000	(0)	PASS
2405.0	2480.0	2435.0	-59.767	<=	-40.000	(0)	PASS
2405.0	2480.0	2436.0	-59.888	<=	-40.000	(0)	PASS
2405.0	2480.0	2437.0	-59.735	<=	-40.000	(0)	PASS
2405.0	2480.0	2438.0	-59.765	<=	-40.000	(0)	PASS
2405.0	2480.0	2439.0	-59.727	<=	-40.000	(0)	PASS
2405.0	2480.0	2440.0	-59.830	<=	-40.000	(0)	PASS
2405.0	2480.0	2441.0	-59.820	<=	-40.000	(0)	PASS
2405.0	2480.0	2442.0	-59.879	<=	-40.000	(0)	PASS
2405.0	2480.0	2443.0	-59.865	<=	-40.000	(0)	PASS
2405.0	2480.0	2444.0	-59.876	<=	-40.000	(0)	PASS
2405.0	2480.0	2445.0	-59.859	<=	-40.000	(0)	PASS
2405.0	2480.0	2446.0	-59.956	<=	-40.000	(0)	PASS
2405.0	2480.0	2447.0	-59.963	<=	-40.000	(0)	PASS
2405.0	2480.0	2448.0	-60.063	<=	-40.000	(0)	PASS
2405.0	2480.0	2449.0	-59.955	<=	-40.000	(0)	PASS
2405.0	2480.0	2450.0	-60.044	<=	-40.000	(0)	PASS
2405.0	2480.0	2451.0	-60.096	<=	-40.000	(0)	PASS
2405.0	2480.0	2452.0	-60.016	<=	-40.000	(0)	PASS

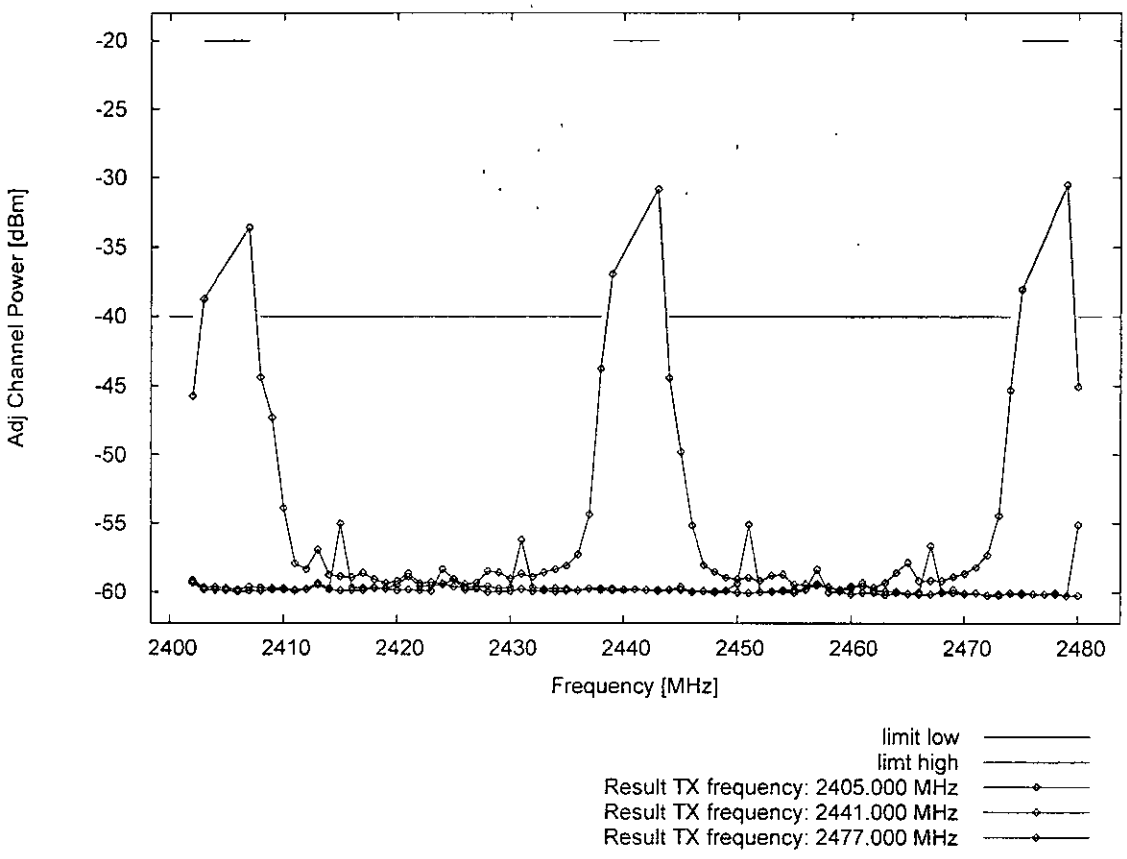
2405.0	2480.0	2453.0	-60.000	<=	-40.000	(0)	PASS
2405.0	2480.0	2454.0	-59.953	<=	-40.000	(0)	PASS
2405.0	2480.0	2455.0	-60.061	<=	-40.000	(0)	PASS
2405.0	2480.0	2456.0	-59.850	<=	-40.000	(0)	PASS
2405.0	2480.0	2457.0	-58.376	<=	-40.000	(0)	PASS
2405.0	2480.0	2458.0	-60.029	<=	-40.000	(0)	PASS
2405.0	2480.0	2459.0	-59.971	<=	-40.000	(0)	PASS
2405.0	2480.0	2460.0	-60.176	<=	-40.000	(0)	PASS
2405.0	2480.0	2461.0	-60.059	<=	-40.000	(0)	PASS
2405.0	2480.0	2462.0	-60.094	<=	-40.000	(0)	PASS
2405.0	2480.0	2463.0	-60.215	<=	-40.000	(0)	PASS
2405.0	2480.0	2464.0	-60.084	<=	-40.000	(0)	PASS
2405.0	2480.0	2465.0	-60.156	<=	-40.000	(0)	PASS
2405.0	2480.0	2466.0	-60.181	<=	-40.000	(0)	PASS
2405.0	2480.0	2467.0	-60.178	<=	-40.000	(0)	PASS
2405.0	2480.0	2468.0	-59.985	<=	-40.000	(0)	PASS
2405.0	2480.0	2469.0	-60.081	<=	-40.000	(0)	PASS
2405.0	2480.0	2470.0	-60.142	<=	-40.000	(0)	PASS
2405.0	2480.0	2471.0	-60.094	<=	-40.000	(0)	PASS
2405.0	2480.0	2472.0	-60.275	<=	-40.000	(0)	PASS
2405.0	2480.0	2473.0	-60.272	<=	-40.000	(0)	PASS
2405.0	2480.0	2474.0	-60.073	<=	-40.000	(0)	PASS
2405.0	2480.0	2475.0	-60.173	<=	-40.000	(0)	PASS
2405.0	2480.0	2476.0	-60.167	<=	-40.000	(0)	PASS
2405.0	2480.0	2477.0	-60.157	<=	-40.000	(0)	PASS
2405.0	2480.0	2478.0	-60.036	<=	-40.000	(0)	PASS
2405.0	2480.0	2479.0	-60.260	<=	-40.000	(0)	PASS
2405.0	2480.0	2480.0	-55.118	<=	-40.000	(0)	PASS
2441.0	2402.0	2402.0	-59.189	<=	-40.000	(0)	PASS
2441.0	2402.0	2403.0	-59.687	<=	-40.000	(0)	PASS
2441.0	2402.0	2404.0	-59.657	<=	-40.000	(0)	PASS
2441.0	2402.0	2405.0	-59.738	<=	-40.000	(0)	PASS
2441.0	2402.0	2406.0	-59.859	<=	-40.000	(0)	PASS
2441.0	2402.0	2407.0	-59.653	<=	-40.000	(0)	PASS
2441.0	2402.0	2408.0	-59.711	<=	-40.000	(0)	PASS
2441.0	2402.0	2409.0	-59.749	<=	-40.000	(0)	PASS
2441.0	2402.0	2410.0	-59.753	<=	-40.000	(0)	PASS
2441.0	2402.0	2411.0	-59.869	<=	-40.000	(0)	PASS
2441.0	2402.0	2412.0	-59.802	<=	-40.000	(0)	PASS
2441.0	2402.0	2413.0	-59.358	<=	-40.000	(0)	PASS
2441.0	2402.0	2414.0	-59.768	<=	-40.000	(0)	PASS
2441.0	2402.0	2415.0	-55.056	<=	-40.000	(0)	PASS
2441.0	2402.0	2416.0	-59.705	<=	-40.000	(0)	PASS
2441.0	2402.0	2417.0	-59.719	<=	-40.000	(0)	PASS
2441.0	2402.0	2418.0	-59.758	<=	-40.000	(0)	PASS
2441.0	2402.0	2419.0	-59.743	<=	-40.000	(0)	PASS
2441.0	2402.0	2420.0	-59.511	<=	-40.000	(0)	PASS
2441.0	2402.0	2421.0	-58.926	<=	-40.000	(0)	PASS
2441.0	2402.0	2422.0	-59.602	<=	-40.000	(0)	PASS
2441.0	2402.0	2423.0	-59.564	<=	-40.000	(0)	PASS
2441.0	2402.0	2424.0	-59.478	<=	-40.000	(0)	PASS
2441.0	2402.0	2425.0	-59.125	<=	-40.000	(0)	PASS
2441.0	2402.0	2426.0	-59.462	<=	-40.000	(0)	PASS
2441.0	2402.0	2427.0	-59.349	<=	-40.000	(0)	PASS
2441.0	2402.0	2428.0	-58.516	<=	-40.000	(0)	PASS
2441.0	2402.0	2429.0	-58.615	<=	-40.000	(0)	PASS
2441.0	2402.0	2430.0	-59.052	<=	-40.000	(0)	PASS
2441.0	2402.0	2431.0	-58.711	<=	-40.000	(0)	PASS
2441.0	2402.0	2432.0	-58.924	<=	-40.000	(0)	PASS
2441.0	2402.0	2433.0	-58.602	<=	-40.000	(0)	PASS
2441.0	2402.0	2434.0	-58.380	<=	-40.000	(0)	PASS
2441.0	2402.0	2435.0	-58.126	<=	-40.000	(0)	PASS
2441.0	2402.0	2436.0	-57.291	<=	-40.000	(0)	PASS
2441.0	2402.0	2437.0	-54.366	<=	-40.000	(0)	PASS
2441.0	2402.0	2438.0	-43.782	<=	-40.000	(0)	PASS

2441.0	2402.0	2439.0	-36.943	<=	-20.000	(0)	PASS
2441.0	2402.0	2443.0	-30.840	<=	-20.000	(0)	PASS
2441.0	2402.0	2444.0	-44.430	<=	-40.000	(0)	PASS
2441.0	2402.0	2445.0	-49.809	<=	-40.000	(0)	PASS
2441.0	2402.0	2446.0	-55.189	<=	-40.000	(0)	PASS
2441.0	2402.0	2447.0	-58.063	<=	-40.000	(0)	PASS
2441.0	2402.0	2448.0	-58.549	<=	-40.000	(0)	PASS
2441.0	2402.0	2449.0	-58.976	<=	-40.000	(0)	PASS
2441.0	2402.0	2450.0	-59.080	<=	-40.000	(0)	PASS
2441.0	2402.0	2451.0	-58.996	<=	-40.000	(0)	PASS
2441.0	2402.0	2452.0	-59.214	<=	-40.000	(0)	PASS
2441.0	2402.0	2453.0	-58.810	<=	-40.000	(0)	PASS
2441.0	2402.0	2454.0	-58.743	<=	-40.000	(0)	PASS
2441.0	2402.0	2455.0	-59.460	<=	-40.000	(0)	PASS
2441.0	2402.0	2456.0	-59.463	<=	-40.000	(0)	PASS
2441.0	2402.0	2457.0	-59.539	<=	-40.000	(0)	PASS
2441.0	2402.0	2458.0	-59.608	<=	-40.000	(0)	PASS
2441.0	2402.0	2459.0	-59.881	<=	-40.000	(0)	PASS
2441.0	2402.0	2460.0	-59.731	<=	-40.000	(0)	PASS
2441.0	2402.0	2461.0	-59.328	<=	-40.000	(0)	PASS
2441.0	2402.0	2462.0	-59.918	<=	-40.000	(0)	PASS
2441.0	2402.0	2463.0	-59.938	<=	-40.000	(0)	PASS
2441.0	2402.0	2464.0	-59.953	<=	-40.000	(0)	PASS
2441.0	2402.0	2465.0	-60.137	<=	-40.000	(0)	PASS
2441.0	2402.0	2466.0	-60.018	<=	-40.000	(0)	PASS
2441.0	2402.0	2467.0	-56.664	<=	-40.000	(0)	PASS
2441.0	2402.0	2468.0	-60.065	<=	-40.000	(0)	PASS
2441.0	2402.0	2469.0	-59.842	<=	-40.000	(0)	PASS
2441.0	2402.0	2470.0	-60.106	<=	-40.000	(0)	PASS
2441.0	2402.0	2471.0	-60.099	<=	-40.000	(0)	PASS
2441.0	2402.0	2472.0	-60.243	<=	-40.000	(0)	PASS
2441.0	2402.0	2473.0	-60.142	<=	-40.000	(0)	PASS
2441.0	2402.0	2474.0	-60.140	<=	-40.000	(0)	PASS
2441.0	2402.0	2475.0	-60.068	<=	-40.000	(0)	PASS
2441.0	2402.0	2476.0	-60.161	<=	-40.000	(0)	PASS
2441.0	2402.0	2477.0	-60.153	<=	-40.000	(0)	PASS
2441.0	2402.0	2478.0	-60.167	<=	-40.000	(0)	PASS
2441.0	2402.0	2479.0	-60.273	<=	-40.000	(0)	PASS
2441.0	2402.0	2480.0	-60.246	<=	-40.000	(0)	PASS
2477.0	2402.0	2402.0	-59.355	<=	-40.000	(0)	PASS
2477.0	2402.0	2403.0	-59.870	<=	-40.000	(0)	PASS
2477.0	2402.0	2404.0	-59.883	<=	-40.000	(0)	PASS
2477.0	2402.0	2405.0	-59.912	<=	-40.000	(0)	PASS
2477.0	2402.0	2406.0	-60.016	<=	-40.000	(0)	PASS
2477.0	2402.0	2407.0	-59.946	<=	-40.000	(0)	PASS
2477.0	2402.0	2408.0	-59.941	<=	-40.000	(0)	PASS
2477.0	2402.0	2409.0	-59.879	<=	-40.000	(0)	PASS
2477.0	2402.0	2410.0	-59.885	<=	-40.000	(0)	PASS
2477.0	2402.0	2411.0	-59.944	<=	-40.000	(0)	PASS
2477.0	2402.0	2412.0	-59.855	<=	-40.000	(0)	PASS
2477.0	2402.0	2413.0	-59.527	<=	-40.000	(0)	PASS
2477.0	2402.0	2414.0	-59.860	<=	-40.000	(0)	PASS
2477.0	2402.0	2415.0	-59.919	<=	-40.000	(0)	PASS
2477.0	2402.0	2416.0	-59.911	<=	-40.000	(0)	PASS
2477.0	2402.0	2417.0	-59.902	<=	-40.000	(0)	PASS
2477.0	2402.0	2418.0	-59.689	<=	-40.000	(0)	PASS
2477.0	2402.0	2419.0	-59.818	<=	-40.000	(0)	PASS
2477.0	2402.0	2420.0	-59.901	<=	-40.000	(0)	PASS
2477.0	2402.0	2421.0	-59.856	<=	-40.000	(0)	PASS
2477.0	2402.0	2422.0	-59.912	<=	-40.000	(0)	PASS
2477.0	2402.0	2423.0	-59.952	<=	-40.000	(0)	PASS
2477.0	2402.0	2424.0	-58.377	<=	-40.000	(0)	PASS
2477.0	2402.0	2425.0	-59.069	<=	-40.000	(0)	PASS
2477.0	2402.0	2426.0	-59.870	<=	-40.000	(0)	PASS
2477.0	2402.0	2427.0	-59.816	<=	-40.000	(0)	PASS

2477.0	2402.0	2428.0	-60.020	<=	-40.000	(0)	PASS
2477.0	2402.0	2429.0	-59.957	<=	-40.000	(0)	PASS
2477.0	2402.0	2430.0	-59.957	<=	-40.000	(0)	PASS
2477.0	2402.0	2431.0	-59.808	<=	-40.000	(0)	PASS
2477.0	2402.0	2432.0	-59.962	<=	-40.000	(0)	PASS
2477.0	2402.0	2433.0	-59.922	<=	-40.000	(0)	PASS
2477.0	2402.0	2434.0	-59.990	<=	-40.000	(0)	PASS
2477.0	2402.0	2435.0	-59.936	<=	-40.000	(0)	PASS
2477.0	2402.0	2436.0	-59.918	<=	-40.000	(0)	PASS
2477.0	2402.0	2437.0	-59.781	<=	-40.000	(0)	PASS
2477.0	2402.0	2438.0	-59.886	<=	-40.000	(0)	PASS
2477.0	2402.0	2439.0	-59.901	<=	-40.000	(0)	PASS
2477.0	2402.0	2440.0	-59.893	<=	-40.000	(0)	PASS
2477.0	2402.0	2441.0	-59.845	<=	-40.000	(0)	PASS
2477.0	2402.0	2442.0	-59.876	<=	-40.000	(0)	PASS
2477.0	2402.0	2443.0	-59.959	<=	-40.000	(0)	PASS
2477.0	2402.0	2444.0	-59.856	<=	-40.000	(0)	PASS
2477.0	2402.0	2445.0	-59.642	<=	-40.000	(0)	PASS
2477.0	2402.0	2446.0	-60.024	<=	-40.000	(0)	PASS
2477.0	2402.0	2447.0	-59.931	<=	-40.000	(0)	PASS
2477.0	2402.0	2448.0	-59.946	<=	-40.000	(0)	PASS
2477.0	2402.0	2449.0	-59.921	<=	-40.000	(0)	PASS
2477.0	2402.0	2450.0	-59.411	<=	-40.000	(0)	PASS
2477.0	2402.0	2451.0	-55.123	<=	-40.000	(0)	PASS
2477.0	2402.0	2452.0	-60.011	<=	-40.000	(0)	PASS
2477.0	2402.0	2453.0	-59.950	<=	-40.000	(0)	PASS
2477.0	2402.0	2454.0	-59.874	<=	-40.000	(0)	PASS
2477.0	2402.0	2455.0	-59.856	<=	-40.000	(0)	PASS
2477.0	2402.0	2456.0	-59.809	<=	-40.000	(0)	PASS
2477.0	2402.0	2457.0	-59.404	<=	-40.000	(0)	PASS
2477.0	2402.0	2458.0	-59.669	<=	-40.000	(0)	PASS
2477.0	2402.0	2459.0	-59.856	<=	-40.000	(0)	PASS
2477.0	2402.0	2460.0	-59.578	<=	-40.000	(0)	PASS
2477.0	2402.0	2461.0	-59.565	<=	-40.000	(0)	PASS
2477.0	2402.0	2462.0	-59.658	<=	-40.000	(0)	PASS
2477.0	2402.0	2463.0	-59.326	<=	-40.000	(0)	PASS
2477.0	2402.0	2464.0	-58.622	<=	-40.000	(0)	PASS
2477.0	2402.0	2465.0	-57.872	<=	-40.000	(0)	PASS
2477.0	2402.0	2466.0	-59.199	<=	-40.000	(0)	PASS
2477.0	2402.0	2467.0	-59.182	<=	-40.000	(0)	PASS
2477.0	2402.0	2468.0	-59.192	<=	-40.000	(0)	PASS
2477.0	2402.0	2469.0	-58.904	<=	-40.000	(0)	PASS
2477.0	2402.0	2470.0	-58.679	<=	-40.000	(0)	PASS
2477.0	2402.0	2471.0	-58.219	<=	-40.000	(0)	PASS
2477.0	2402.0	2472.0	-57.316	<=	-40.000	(0)	PASS
2477.0	2402.0	2473.0	-54.437	<=	-40.000	(0)	PASS
2477.0	2402.0	2474.0	-45.288	<=	-40.000	(0)	PASS
2477.0	2402.0	2475.0	-38.049	<=	-20.000	(0)	PASS
2477.0	2402.0	2479.0	-30.503	<=	-20.000	(0)	PASS
2477.0	2402.0	2480.0	-45.050	<=	-40.000	(0)	PASS

Final Test Case Verdict . . . . . PASS 00:58:04

Results TC TX Output Spectrum - Adjacent Channel Power -Measured EUT: M3200



Annex H

TRM/CA/07/C Modulation Characteristics

Modulation Characteristics

For system parameter see 0, "General Parameter 007"

BT Test Specification Version: 1.2

TS Errata Request: 277

For EUT parameter see 0, "EUT Parameter 002"
For test case parameter see 0, "Test Case Parameter 007"

Packet Nr.	LIMIT [kHz]		Average [kHz]		LIMIT [kHz]	Min [kHz]	Max [kHz]	VERDICT
1	140.000	<=	165.039	<=	175.000	160.154	171.190	PASS
2	140.000	<=	165.134	<=	175.000	160.535	170.365	PASS
3	140.000	<=	165.092	<=	175.000	159.791	170.433	PASS
4	140.000	<=	165.292	<=	175.000	159.656	169.878	PASS
5	140.000	<=	165.272	<=	175.000	160.559	171.617	PASS
6	140.000	<=	165.256	<=	175.000	160.401	170.086	PASS
7	140.000	<=	165.315	<=	175.000	159.724	171.050	PASS
8	140.000	<=	165.110	<=	175.000	160.497	170.306	PASS
9	140.000	<=	165.503	<=	175.000	160.332	170.806	PASS
10	140.000	<=	165.374	<=	175.000	159.947	171.354	PASS

Next measurement will be running with the following changed parameters:

B1 Signal Pattern: 01010101

Packet Nr.	Average	Min [kHz]		LIMIT [kHz]	Max [kHz]	VERDICT
1	154.706	141.082	>=	115.000	162.936	PASS
2	154.899	147.362	>=	115.000	161.978	PASS
3	155.946	144.969	>=	115.000	163.727	PASS
4	154.715	146.915	>=	115.000	163.127	PASS
5	154.968	145.180	>=	115.000	168.010	PASS
6	155.871	146.066	>=	115.000	163.714	PASS
7	154.751	147.171	>=	115.000	162.320	PASS
8	154.521	147.278	>=	115.000	161.443	PASS
9	155.460	145.922	>=	115.000	163.553	PASS
10	155.910	146.789	>=	115.000	163.047	PASS

F2 Outsides: 0 Measurements: 27040 Ratio: 0.00 % < 0.10 % PASS

F2/F1 (average min) [%]		LIMIT [%]	VERDICT
93.909	>=	80.000	PASS

Next measurement will be running with the following changed parameters:

EUT Tx Frequency: 2441.000 MHz
EUT Rx Frequency: 2402.000 MHz
B1 Signal Pattern: 00001111

Packet Nr.	LIMIT [kHz]		Average [kHz]		LIMIT [kHz]	Min [kHz]	Max [kHz]	VERDICT
1	140.000	<=	164.638	<=	175.000	158.566	170.669	PASS
2	140.000	<=	164.557	<=	175.000	156.881	170.480	PASS
3	140.000	<=	164.559	<=	175.000	159.533	171.213	PASS
4	140.000	<=	164.639	<=	175.000	159.348	169.849	PASS
5	140.000	<=	164.696	<=	175.000	158.957	170.588	PASS
6	140.000	<=	164.739	<=	175.000	158.832	170.256	PASS
7	140.000	<=	164.548	<=	175.000	159.539	170.442	PASS
8	140.000	<=	164.882	<=	175.000	158.508	171.946	PASS
9	140.000	<=	164.842	<=	175.000	159.381	170.035	PASS
10	140.000	<=	164.568	<=	175.000	158.756	170.335	PASS

Next measurement will be running with the following changed parameters:

B1 Signal Pattern: 01010101

Packet Nr.	Average	Min [kHz]		LIMIT [kHz]	Max [kHz]	VERDICT
1	156.209	147.374	>=	115.000	165.868	PASS
2	156.163	144.820	>=	115.000	163.601	PASS
3	156.076	147.249	>=	115.000	163.634	PASS
4	155.675	146.364	>=	115.000	163.130	PASS
5	156.181	144.718	>=	115.000	164.258	PASS
6	155.575	147.295	>=	115.000	164.987	PASS
7	155.486	146.754	>=	115.000	167.053	PASS
8	156.283	147.336	>=	115.000	162.999	PASS
9	155.581	144.586	>=	115.000	163.909	PASS
10	155.415	145.948	>=	115.000	163.995	PASS

F2 Outsides: 0 Measurements: 27040 Ratio: 0.00 % < 0.10 % PASS

F2/F1 (average min) [%]		LIMIT [%]	VERDICT
94.654	>=	80.000	PASS

Next measurement will be running with the following changed parameters:

EUT Tx Frequency: 2480.000 MHz
EUT Rx Frequency: 2402.000 MHz
B1 Signal Pattern: 00001111

Packet Nr.	LIMIT [kHz]		Average [kHz]		LIMIT [kHz]	Min [kHz]	Max [kHz]	VERDICT
1	140.000	<=	164.759	<=	175.000	157.920	169.892	PASS
2	140.000	<=	164.475	<=	175.000	158.113	170.270	PASS
3	140.000	<=	164.326	<=	175.000	157.192	171.733	PASS
4	140.000	<=	164.497	<=	175.000	155.575	171.272	PASS
5	140.000	<=	164.356	<=	175.000	157.975	170.011	PASS
6	140.000	<=	164.615	<=	175.000	158.703	169.852	PASS
7	140.000	<=	164.315	<=	175.000	158.296	170.904	PASS
8	140.000	<=	164.469	<=	175.000	158.015	171.558	PASS
9	140.000	<=	164.737	<=	175.000	158.645	171.143	PASS
10	140.000	<=	164.251	<=	175.000	158.495	170.968	PASS

Next measurement will be running with the following changed parameters:

B1 Signal Pattern: 01010101

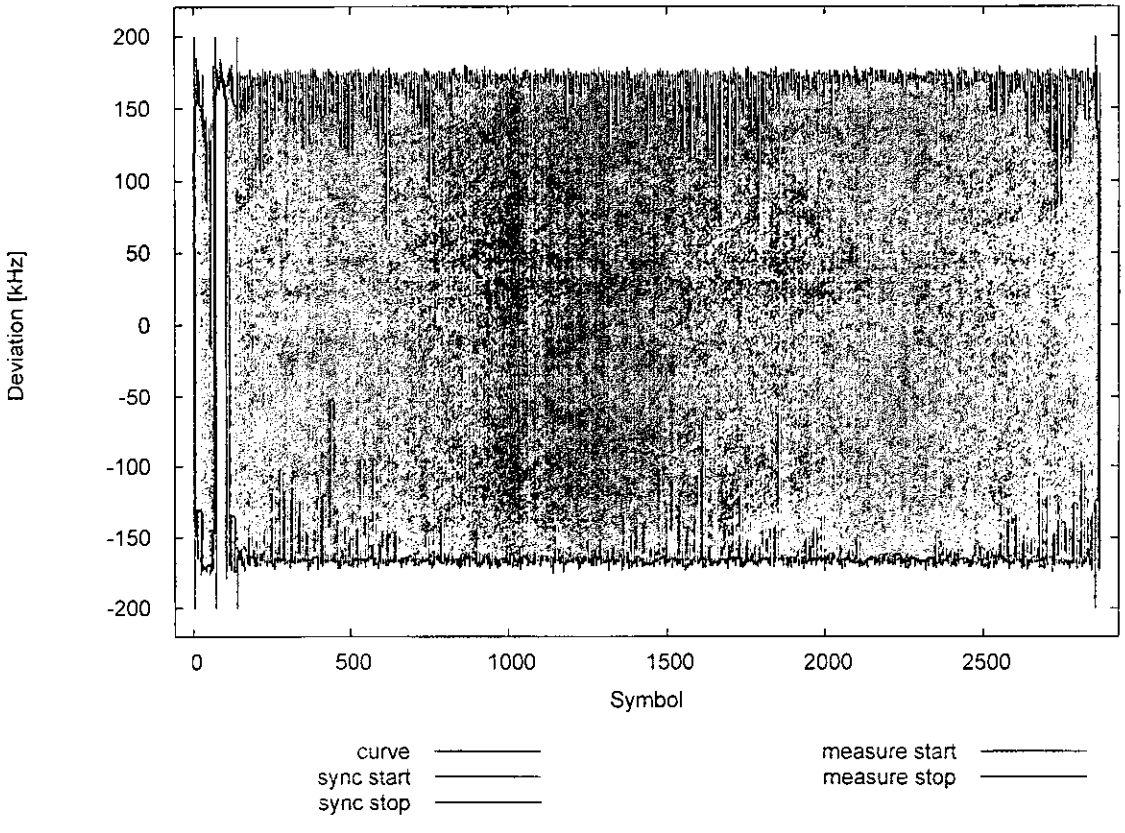
Packet Nr.	Average	Min [kHz]		LIMIT [kHz]	Max [kHz]	VERDICT
1	156.140	147.127	>=	115.000	163.819	PASS
2	156.544	148.644	>=	115.000	164.423	PASS
3	156.407	146.876	>=	115.000	164.457	PASS
4	156.236	147.622	>=	115.000	164.542	PASS
5	156.174	147.914	>=	115.000	164.062	PASS
6	156.108	147.975	>=	115.000	163.690	PASS
7	156.579	145.100	>=	115.000	164.831	PASS
8	156.554	145.055	>=	115.000	163.618	PASS
9	156.535	147.255	>=	115.000	164.373	PASS
10	156.230	143.937	>=	115.000	164.537	PASS

F2 Outsides: 0 Measurements: 27040 Ratio: 0.00 % < 0.10 % PASS

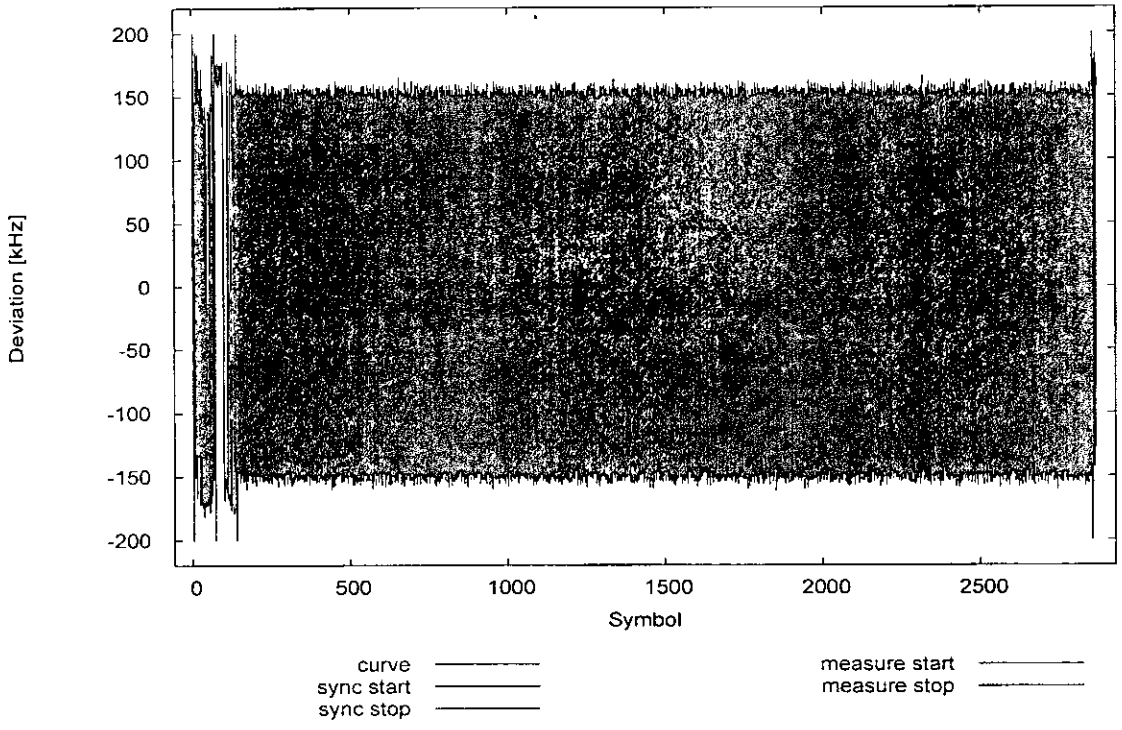
F2/F1 (average min) [%]		LIMIT [%]	VERDICT
95.058	>=	80.000	PASS

Final Test Case Verdict . . . . . PASS 00:27:16

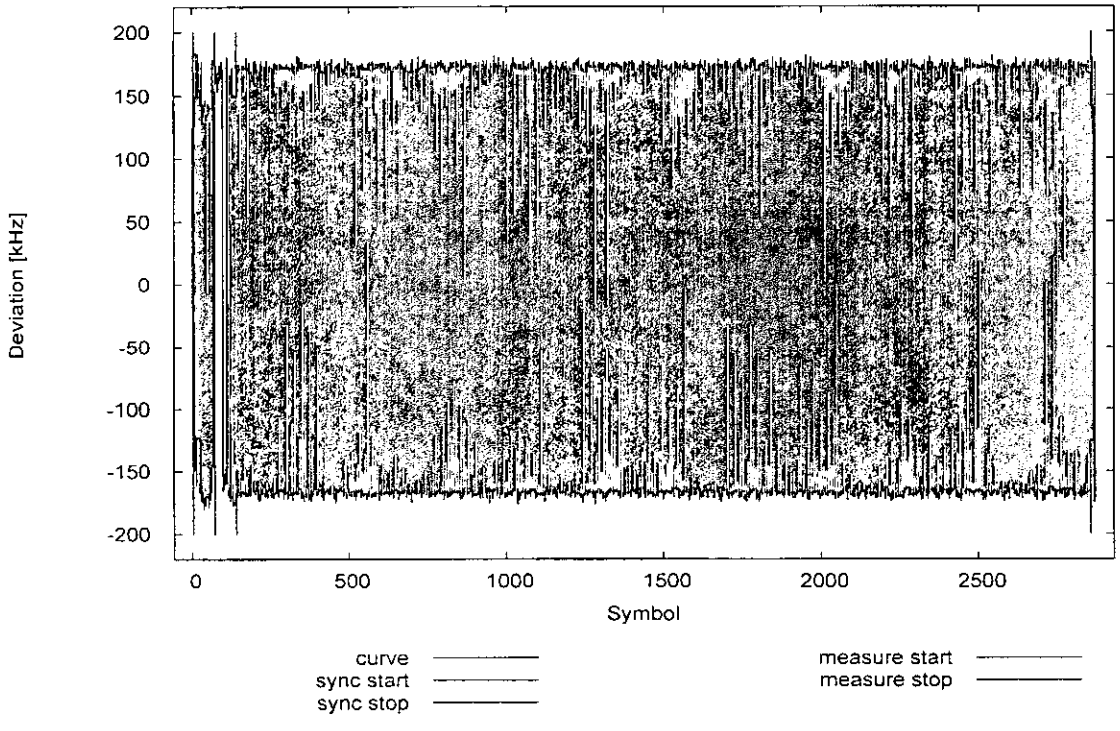
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1111000 pattern



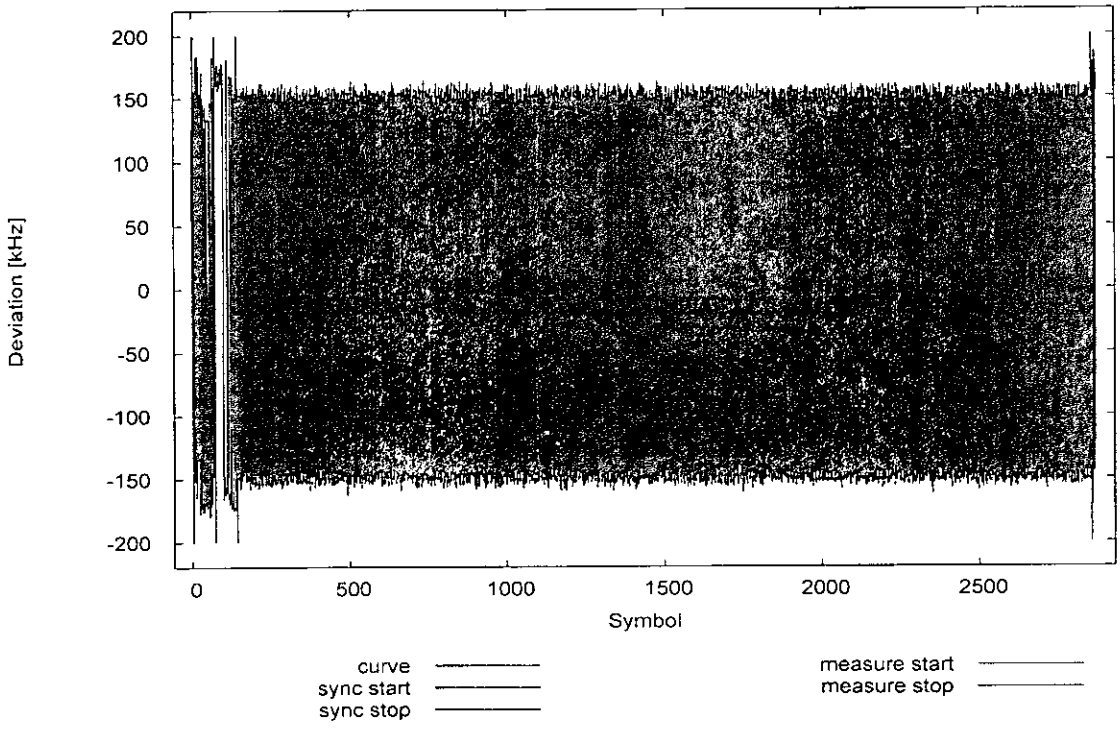
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern



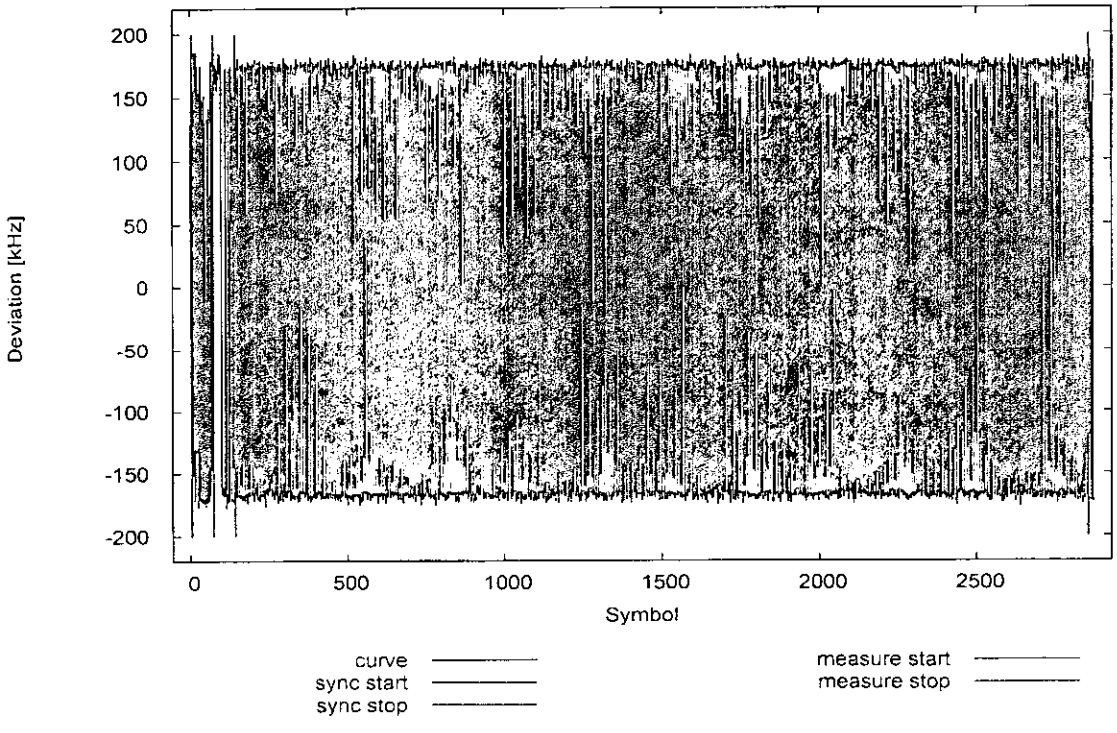
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1111000 pattern



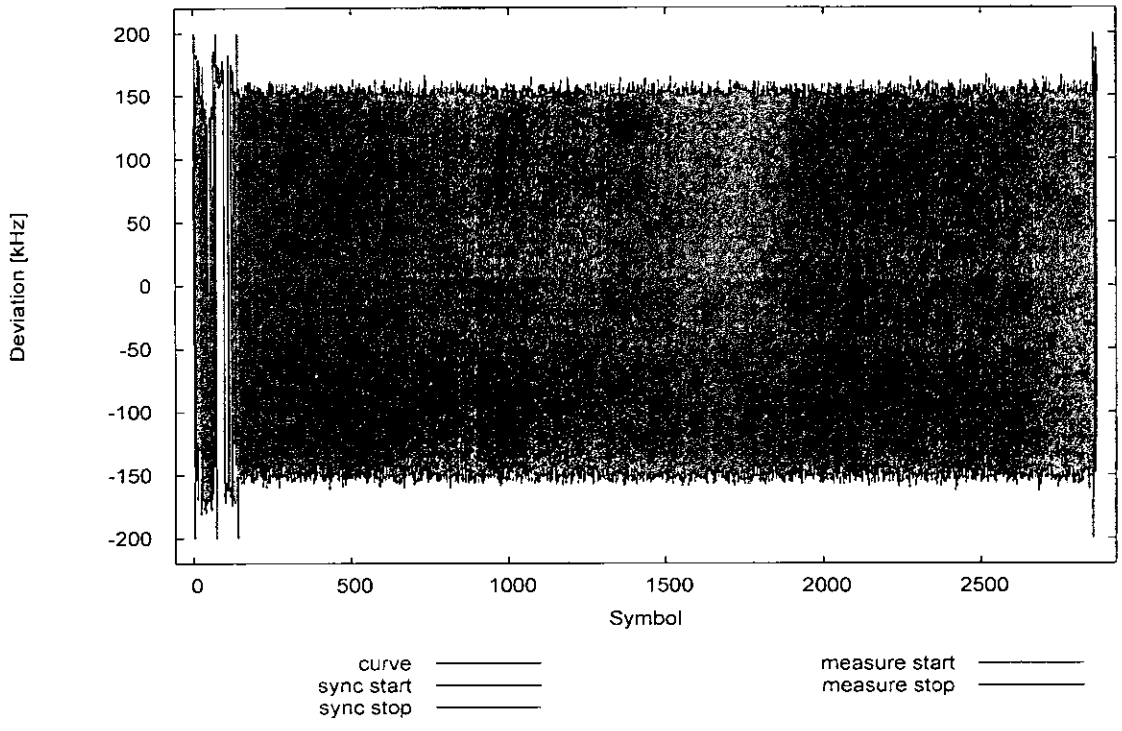
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern



Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1111000 pattern



Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern



Modulation Characteristics

For system parameter see 0, "General Parameter 007"

BT Test Specification Version: 1.2

TS Errata Request: 277

For EUT parameter see 0, "EUT Parameter 005"
For test case parameter see 0, "Test Case Parameter 026"

Packet Nr.	LIMIT [kHz]		Average [kHz]		LIMIT [kHz]	Min [kHz]	Max [kHz]	VERDICT
1	140.000	<=	164.649	<=	175.000	160.925	169.527	PASS
2	140.000	<=	165.028	<=	175.000	160.859	168.927	PASS
3	140.000	<=	164.829	<=	175.000	159.600	170.874	PASS
4	140.000	<=	164.622	<=	175.000	158.958	168.957	PASS
5	140.000	<=	164.936	<=	175.000	160.034	168.893	PASS
6	140.000	<=	164.597	<=	175.000	160.147	168.936	PASS
7	140.000	<=	164.854	<=	175.000	161.022	168.812	PASS
8	140.000	<=	164.832	<=	175.000	159.974	169.025	PASS
9	140.000	<=	164.960	<=	175.000	159.163	170.889	PASS
10	140.000	<=	164.616	<=	175.000	158.580	168.582	PASS

Next measurement will be running with the following changed parameters:

B1 Signal Pattern: 01010101

Packet Nr.	Average	Min [kHz]		LIMIT [kHz]	Max [kHz]	VERDICT
1	154.485	147.386	>=	115.000	162.342	PASS
2	155.440	148.167	>=	115.000	161.779	PASS
3	155.317	148.168	>=	115.000	161.877	PASS
4	154.400	147.222	>=	115.000	162.688	PASS
5	153.827	142.218	>=	115.000	163.222	PASS
6	155.033	147.326	>=	115.000	162.302	PASS
7	154.291	147.409	>=	115.000	160.177	PASS
8	155.697	146.821	>=	115.000	162.511	PASS
9	153.814	147.595	>=	115.000	161.527	PASS
10	154.141	145.621	>=	115.000	162.212	PASS

F2 Outsides: 0 Measurements: 27040 Ratio: 0.00 % < 0.10 % PASS

F2/F1 (average min) [%]		LIMIT [%]	VERDICT
93.842	>=	80.000	PASS

Next measurement will be running with the following changed parameters:

EUT Tx Frequency: 2441.000 MHz
EUT Rx Frequency: 2402.000 MHz
B1 Signal Pattern: 00001111

Packet Nr.	LIMIT [kHz]		Average [kHz]		LIMIT [kHz]	Min [kHz]	Max [kHz]	VERDICT
1	140.000	<=	164.719	<=	175.000	158.883	169.064	PASS
2	140.000	<=	164.428	<=	175.000	159.913	169.437	PASS
3	140.000	<=	164.613	<=	175.000	160.131	169.513	PASS
4	140.000	<=	164.873	<=	175.000	160.780	168.861	PASS
5	140.000	<=	164.796	<=	175.000	160.587	168.847	PASS
6	140.000	<=	164.824	<=	175.000	160.252	169.413	PASS
7	140.000	<=	164.468	<=	175.000	159.172	169.523	PASS
8	140.000	<=	164.870	<=	175.000	159.721	168.458	PASS
9	140.000	<=	164.575	<=	175.000	160.478	169.595	PASS
10	140.000	<=	164.581	<=	175.000	159.664	169.582	PASS

Next measurement will be running with the following changed parameters:

B1 Signal Pattern: 01010101

Packet Nr.	Average	Min [kHz]		LIMIT [kHz]	Max [kHz]	VERDICT
1	156.014	149.541	>=	115.000	163.154	PASS
2	156.088	145.782	>=	115.000	167.455	PASS
3	154.689	147.455	>=	115.000	161.514	PASS
4	154.900	146.326	>=	115.000	161.555	PASS
5	155.574	148.157	>=	115.000	162.516	PASS
6	155.754	146.785	>=	115.000	163.633	PASS
7	156.005	147.287	>=	115.000	162.654	PASS
8	156.047	148.366	>=	115.000	162.734	PASS
9	154.695	148.098	>=	115.000	162.623	PASS
10	154.473	147.699	>=	115.000	161.669	PASS

F2 Outsides: 0 Measurements: 27040 Ratio: 0.00 % < 0.10 % PASS

F2/F1 (average min) [%]		LIMIT [%]	VERDICT
94.382	>=	80.000	PASS

Next measurement will be running with the following changed parameters:

EUT Tx Frequency: 2480.000 MHz
EUT Rx Frequency: 2402.000 MHz
B1 Signal Pattern: 00001111

Packet Nr.	LIMIT [kHz]		Average [kHz]		LIMIT [kHz]	Min [kHz]	Max [kHz]	VERDICT
1	140.000	<=	164.474	<=	175.000	159.437	168.818	PASS
2	140.000	<=	164.578	<=	175.000	159.714	169.530	PASS
3	140.000	<=	164.528	<=	175.000	159.961	169.314	PASS
4	140.000	<=	164.707	<=	175.000	160.009	168.927	PASS
5	140.000	<=	164.669	<=	175.000	160.020	169.538	PASS
6	140.000	<=	164.458	<=	175.000	158.775	168.802	PASS
7	140.000	<=	164.534	<=	175.000	158.888	168.616	PASS
8	140.000	<=	164.480	<=	175.000	160.128	169.122	PASS
9	140.000	<=	164.533	<=	175.000	160.317	168.690	PASS
10	140.000	<=	164.369	<=	175.000	159.508	169.164	PASS

Next measurement will be running with the following changed parameters:

B1 Signal Pattern: 01010101

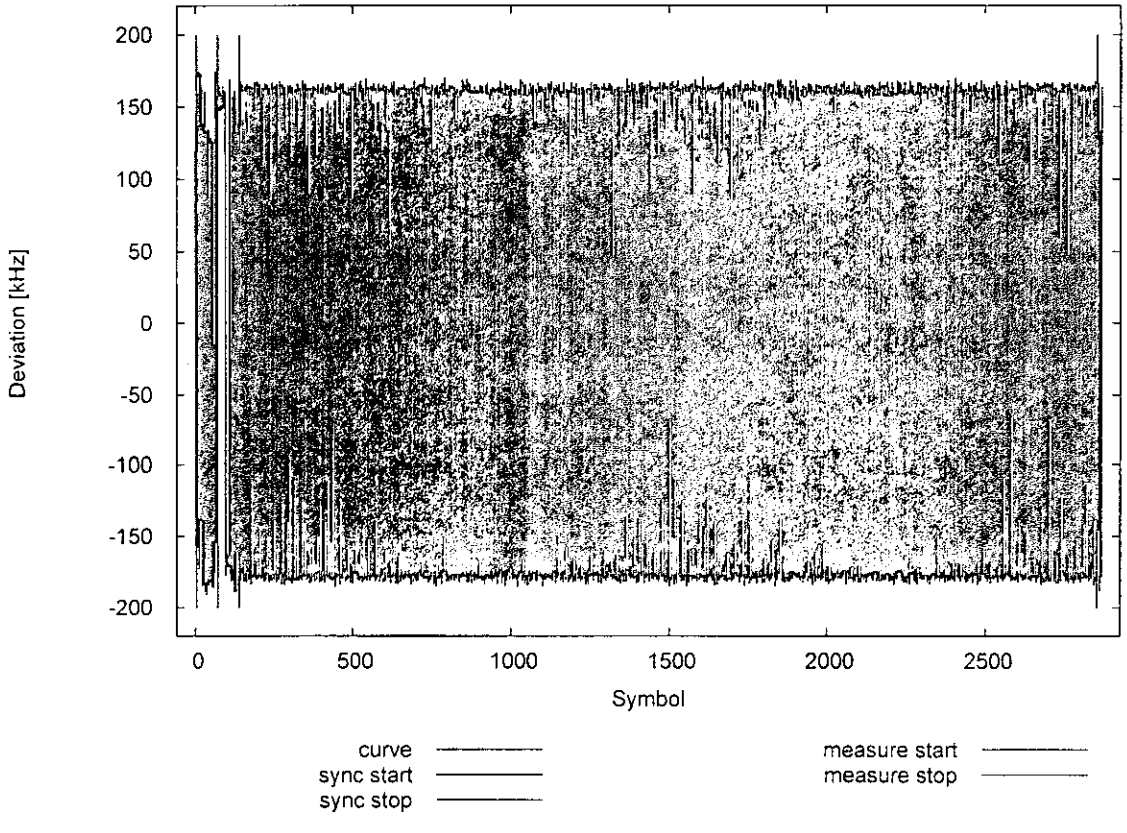
Packet Nr.	Average	Min [kHz]		LIMIT [kHz]	Max [kHz]	VERDICT
1	155.822	147.478	>=	115.000	163.812	PASS
2	155.917	149.213	>=	115.000	163.451	PASS
3	155.783	147.951	>=	115.000	162.754	PASS
4	155.947	149.074	>=	115.000	162.922	PASS
5	156.160	149.379	>=	115.000	164.571	PASS
6	155.243	147.634	>=	115.000	162.923	PASS
7	155.612	147.579	>=	115.000	162.550	PASS
8	155.861	148.943	>=	115.000	163.217	PASS
9	156.000	149.334	>=	115.000	162.962	PASS
10	155.453	148.857	>=	115.000	162.354	PASS

F2 Outsides: 0 Measurements: 27040 Ratio: 0.00 % < 0.10 % PASS

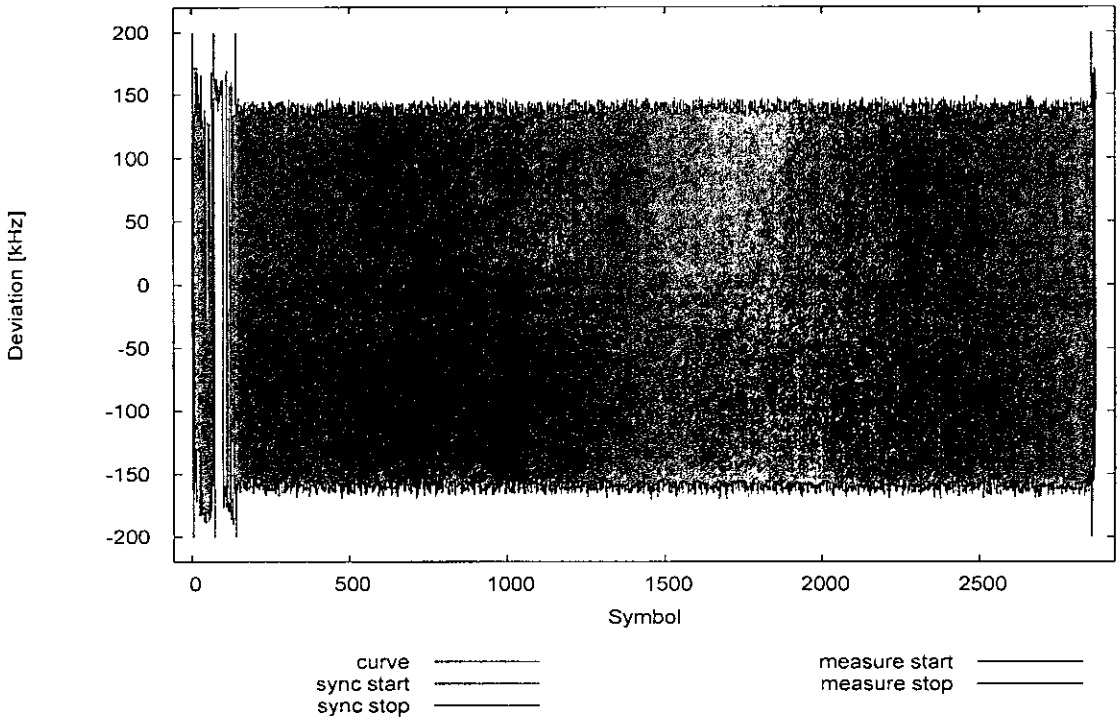
F2/F1 (average min) [%]		LIMIT [%]	VERDICT
94.680	>=	80.000	PASS

Final Test Case Verdict . . . . . PASS 00:30:20

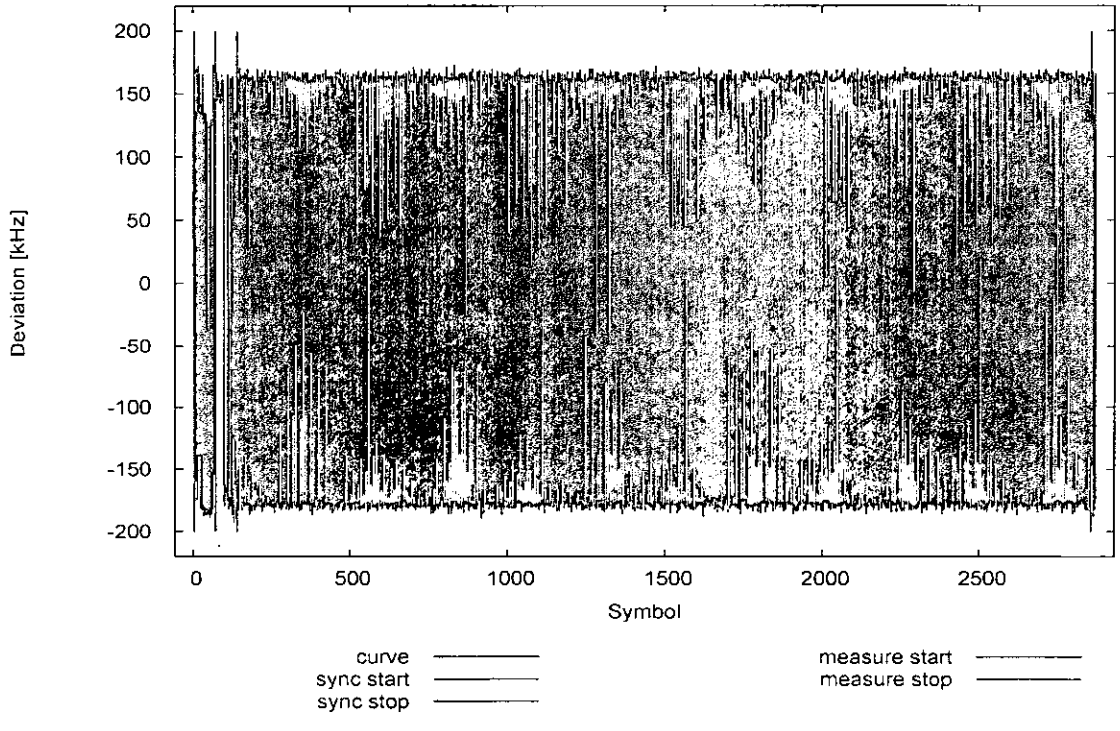
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1111000 pattern



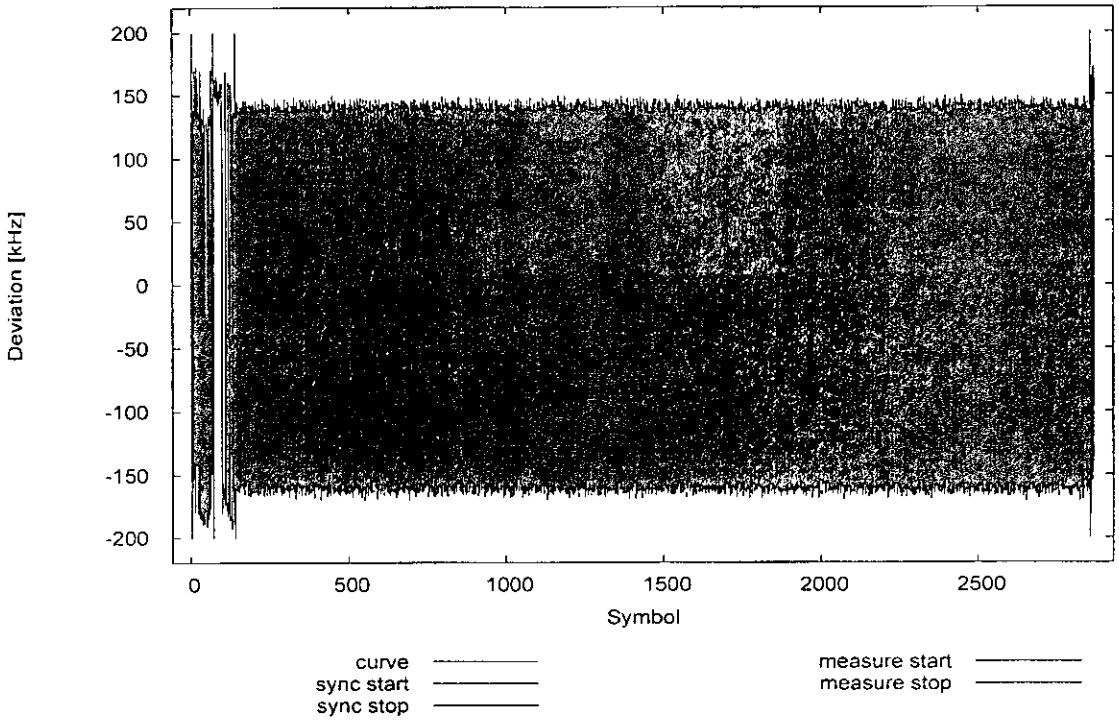
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern



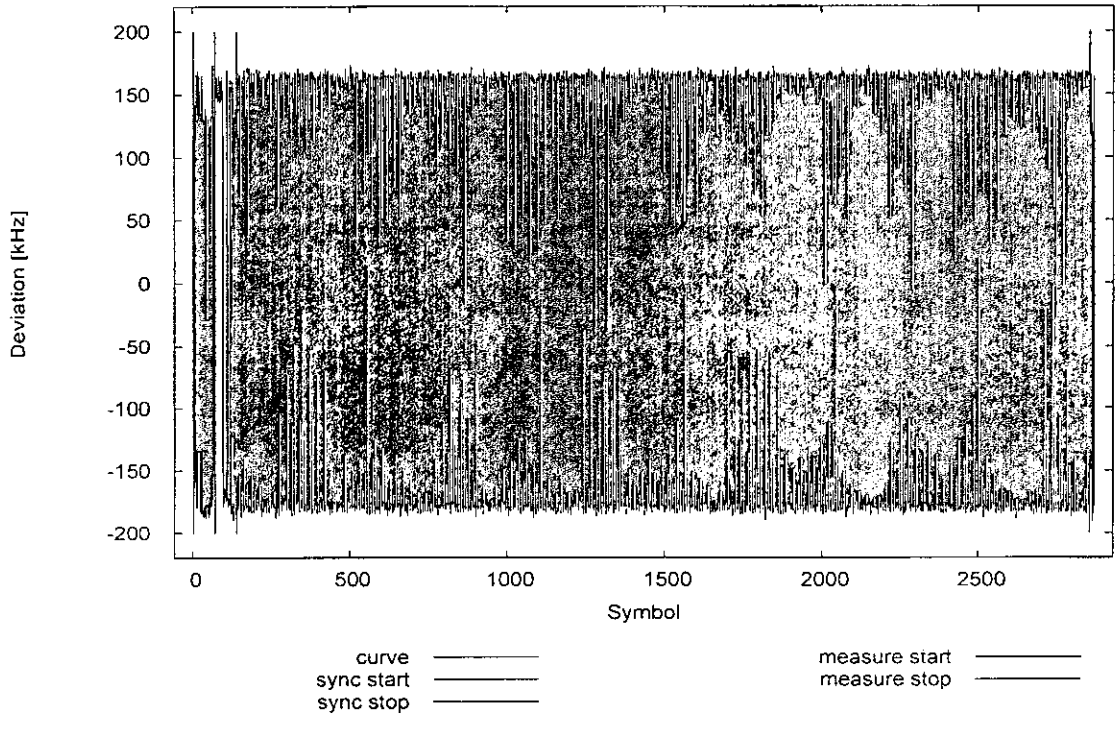
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1111000 pattern



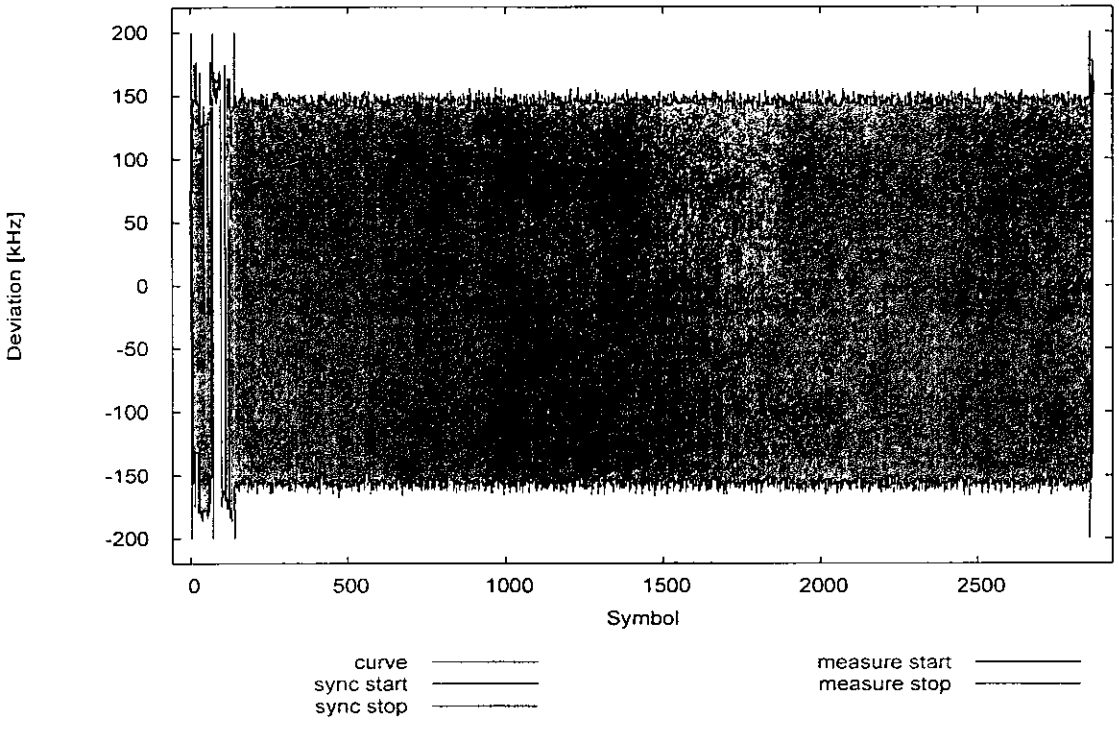
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern



Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1111000 pattern



Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern



Modulation Characteristics

For system parameter see 0, "General Parameter 007"

BT Test Specification Version: 1.2

TS Errata Request: 277

For EUT parameter see 0, "EUT Parameter 006"
For test case parameter see 0, "Test Case Parameter 027"

Packet Nr.	LIMIT [kHz]		Average [kHz]		LIMIT [kHz]	Min [kHz]	Max [kHz]	VERDICT
1	140.000	<=	164.917	<=	175.000	159.802	169.391	PASS
2	140.000	<=	164.976	<=	175.000	160.870	170.591	PASS
3	140.000	<=	164.657	<=	175.000	160.140	168.476	PASS
4	140.000	<=	164.617	<=	175.000	159.388	169.108	PASS
5	140.000	<=	164.717	<=	175.000	160.509	169.304	PASS
6	140.000	<=	164.812	<=	175.000	160.286	169.198	PASS
7	140.000	<=	164.706	<=	175.000	159.448	169.556	PASS
8	140.000	<=	164.554	<=	175.000	159.664	169.322	PASS
9	140.000	<=	164.647	<=	175.000	159.725	169.477	PASS
10	140.000	<=	165.816	<=	175.000	160.797	170.804	PASS

Next measurement will be running with the following changed parameters:

B1 Signal Pattern: 01010101

Packet Nr.	Average	Min [kHz]		LIMIT [kHz]	Max [kHz]	VERDICT
1	153.652	146.765	>=	115.000	160.268	PASS
2	154.758	148.148	>=	115.000	161.086	PASS
3	154.657	147.394	>=	115.000	160.712	PASS
4	153.480	145.414	>=	115.000	160.716	PASS
5	154.790	147.788	>=	115.000	160.123	PASS
6	153.152	147.004	>=	115.000	159.866	PASS
7	153.280	145.897	>=	115.000	159.960	PASS
8	155.433	148.848	>=	115.000	162.396	PASS
9	154.883	146.516	>=	115.000	161.035	PASS
10	154.139	146.419	>=	115.000	161.236	PASS

F2 Outsides: 0 Measurements: 27040 Ratio: 0.00 % < 0.10 % PASS

F2/F1 (average min) [%]		LIMIT [%]	VERDICT
93.558	>=	80.000	PASS

Next measurement will be running with the following changed parameters:

EUT Tx Frequency: 2441.000 MHz
EUT Rx Frequency: 2402.000 MHz
B1 Signal Pattern: 00001111

Packet Nr.	LIMIT [kHz]		Average [kHz]		LIMIT [kHz]	Min [kHz]	Max [kHz]	VERDICT
1	140.000	<=	164.105	<=	175.000	157.093	172.154	PASS
2	140.000	<=	164.378	<=	175.000	158.121	169.113	PASS
3	140.000	<=	164.310	<=	175.000	159.411	169.570	PASS
4	140.000	<=	164.435	<=	175.000	159.882	169.550	PASS
5	140.000	<=	164.154	<=	175.000	159.330	168.749	PASS
6	140.000	<=	164.464	<=	175.000	159.849	169.264	PASS
7	140.000	<=	164.458	<=	175.000	159.728	169.515	PASS
8	140.000	<=	164.431	<=	175.000	159.586	169.123	PASS
9	140.000	<=	164.321	<=	175.000	159.743	169.223	PASS
10	140.000	<=	164.560	<=	175.000	160.388	169.383	PASS

Next measurement will be running with the following changed parameters:

B1 Signal Pattern: 01010101

Packet Nr.	Average	Min [kHz]		LIMIT [kHz]	Max [kHz]	VERDICT
1	154.422	147.009	>=	115.000	160.564	PASS
2	154.524	143.184	>=	115.000	161.129	PASS
3	154.742	147.551	>=	115.000	161.482	PASS
4	154.364	147.604	>=	115.000	161.215	PASS
5	154.694	148.171	>=	115.000	161.302	PASS
6	154.126	146.894	>=	115.000	161.140	PASS
7	155.362	146.979	>=	115.000	165.173	PASS
8	155.502	148.727	>=	115.000	161.391	PASS
9	156.123	147.441	>=	115.000	163.195	PASS
10	154.672	148.098	>=	115.000	160.966	PASS

F2 Outsides: 0 Measurements: 27040 Ratio: 0.00 % < 0.10 % PASS

F2/F1 (average min) [%]		LIMIT [%]	VERDICT
94.215	>=	80.000	PASS

Next measurement will be running with the following changed parameters:

EUT Tx Frequency: 2480.000 MHz
EUT Rx Frequency: 2402.000 MHz
B1 Signal Pattern: 00001111

Packet Nr.	LIMIT [kHz]		Average [kHz]		LIMIT [kHz]	Min [kHz]	Max [kHz]	VERDICT
1	140.000	<=	164.985	<=	175.000	160.463	169.392	PASS
2	140.000	<=	165.141	<=	175.000	159.823	170.609	PASS
3	140.000	<=	165.098	<=	175.000	160.209	170.513	PASS
4	140.000	<=	165.258	<=	175.000	160.331	170.953	PASS
5	140.000	<=	164.942	<=	175.000	159.133	171.643	PASS
6	140.000	<=	164.939	<=	175.000	160.613	170.122	PASS
7	140.000	<=	164.813	<=	175.000	159.884	169.729	PASS
8	140.000	<=	164.955	<=	175.000	151.552	171.616	PASS
9	140.000	<=	165.278	<=	175.000	159.836	170.856	PASS
10	140.000	<=	164.969	<=	175.000	159.942	170.904	PASS

Next measurement will be running with the following changed parameters:

B1 Signal Pattern: 01010101

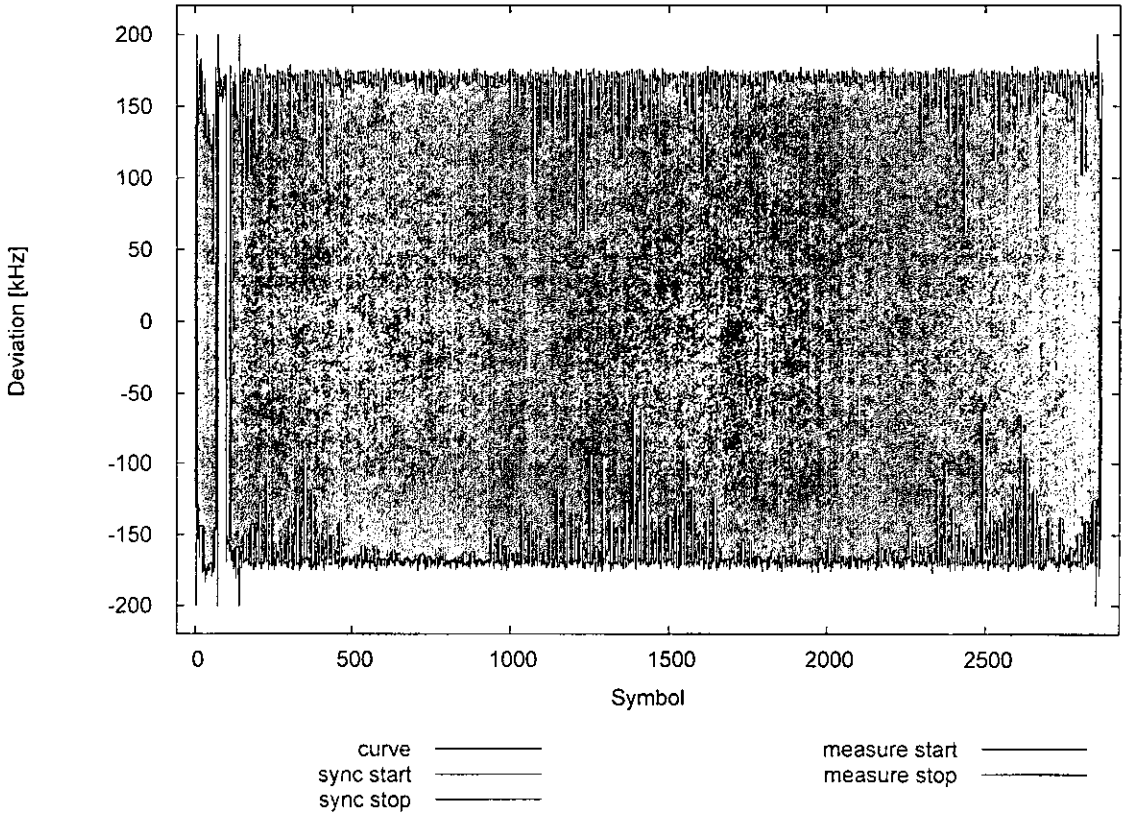
Packet Nr.	Average	Min [kHz]		LIMIT [kHz]	Max [kHz]	VERDICT
1	156.022	148.496	>=	115.000	162.331	PASS
2	155.958	147.466	>=	115.000	162.547	PASS
3	156.926	149.835	>=	115.000	163.972	PASS
4	155.571	147.802	>=	115.000	162.750	PASS
5	156.502	148.861	>=	115.000	163.420	PASS
6	156.121	148.864	>=	115.000	164.775	PASS
7	156.501	148.106	>=	115.000	164.691	PASS
8	156.424	148.928	>=	115.000	163.778	PASS
9	156.517	146.728	>=	115.000	163.360	PASS
10	155.741	146.687	>=	115.000	163.356	PASS

F2 Outsides: 0 Measurements: 27040 Ratio: 0.00 % < 0.10 % PASS

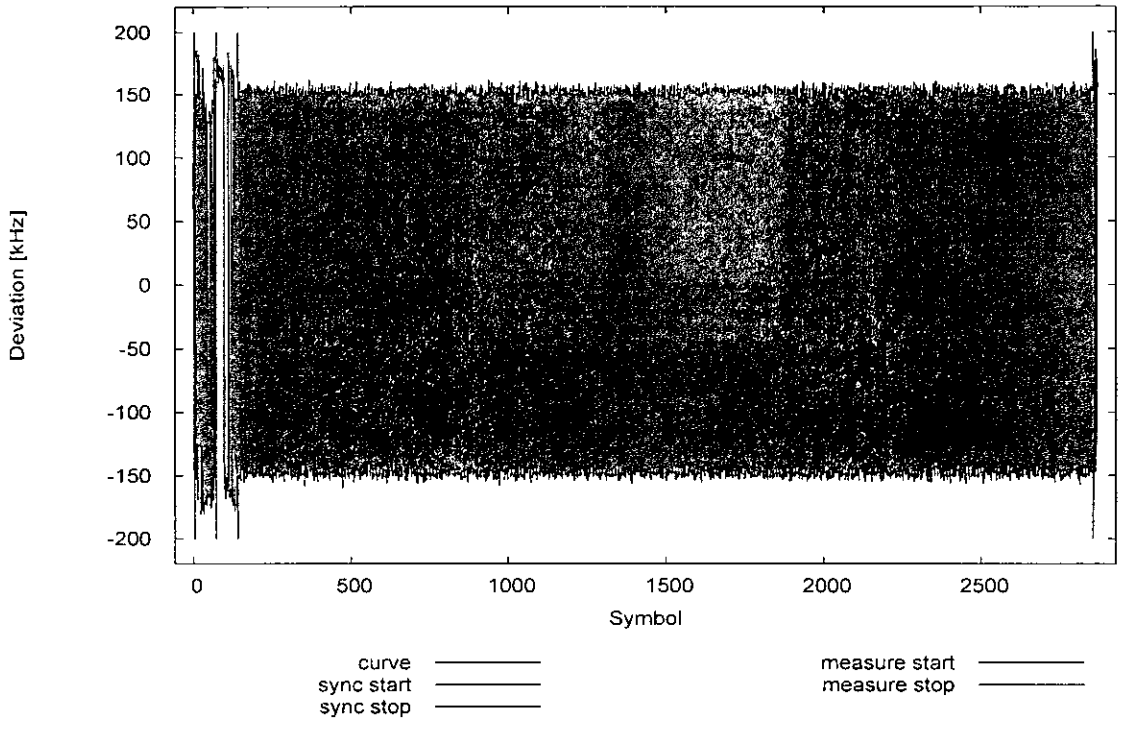
F2/F1 (average min) [%]		LIMIT [%]	VERDICT
94.662	>=	80.000	PASS

Final Test Case Verdict . . . . . PASS 00:29:38

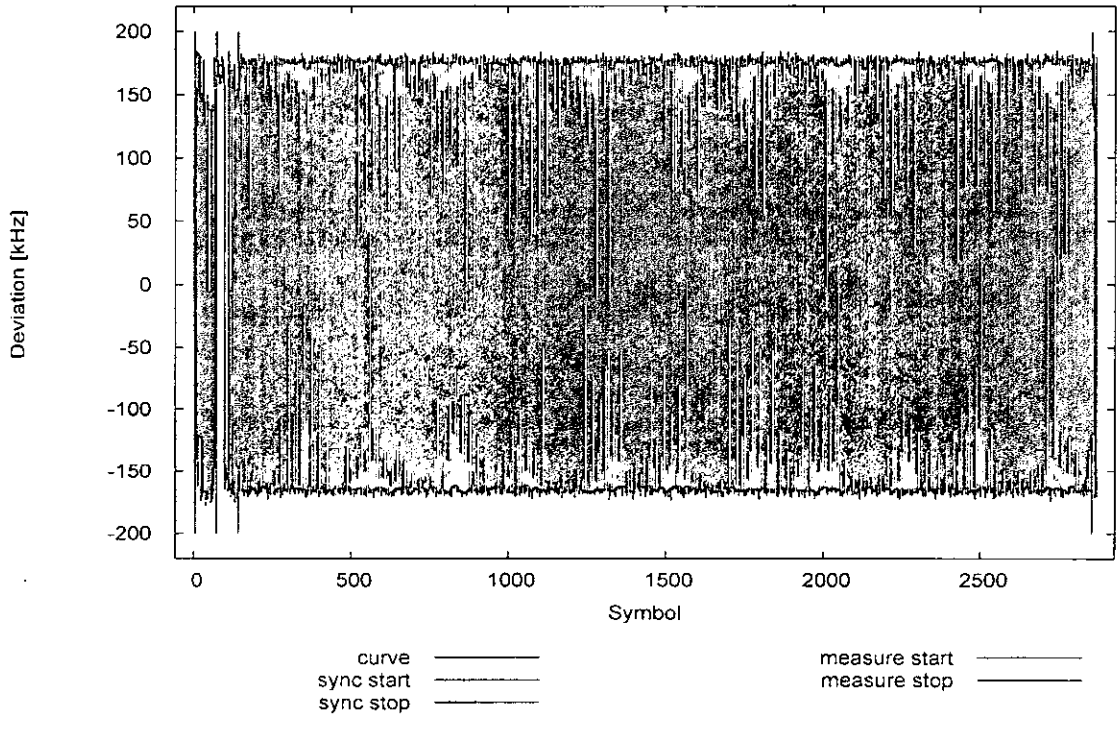
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1111000 pattern



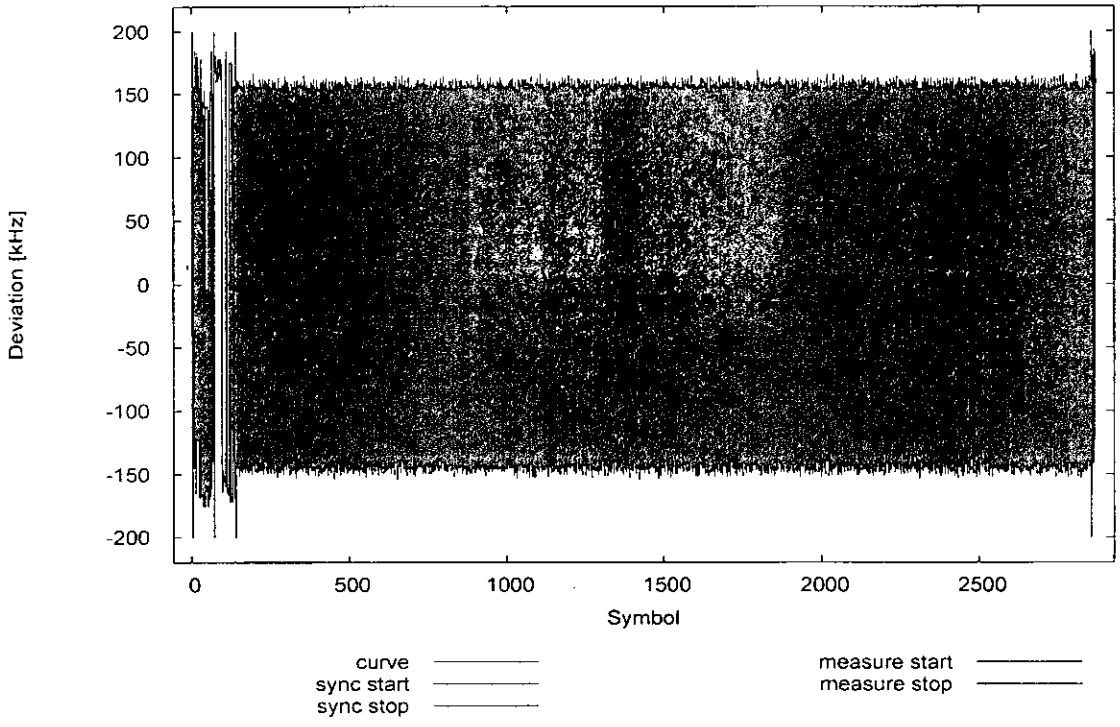
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern



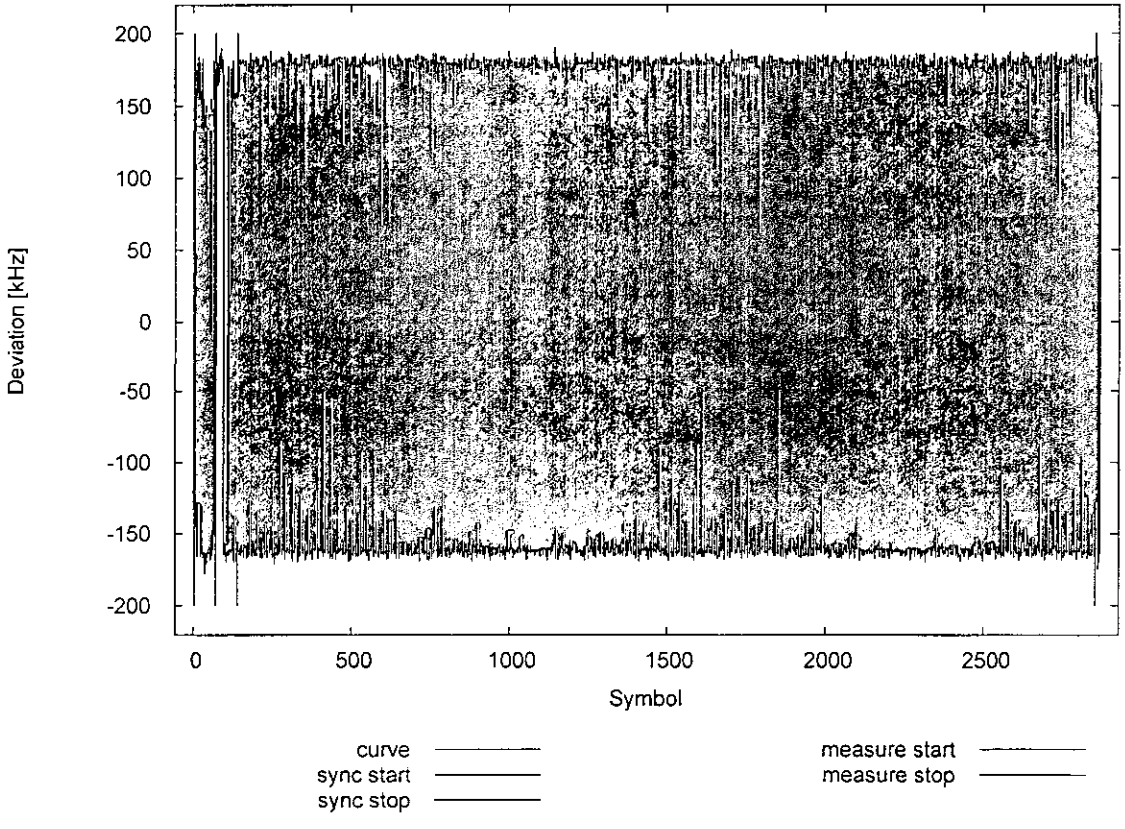
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1111000 pattern



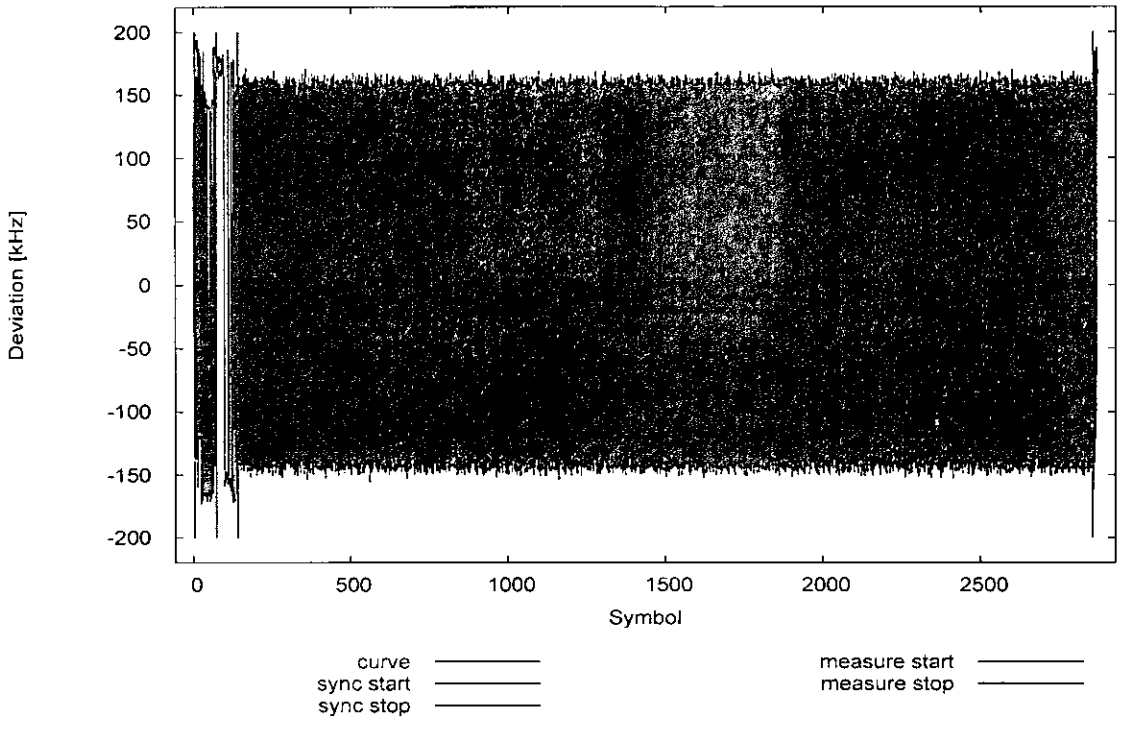
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern



Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1111000 pattern



Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern



Modulation Characteristics

For system parameter see 0, "General Parameter 007"

BT Test Specification Version: 1.2

TS Errata Request: 277

For EUT parameter see 0, "EUT Parameter 009"
For test case parameter see 0, "Test Case Parameter 046"

Packet Nr.	LIMIT [kHz]		Average [kHz]		LIMIT [kHz]	Min [kHz]	Max [kHz]	VERDICT
1	140.000	<=	165.153	<=	175.000	159.147	172.191	PASS
2	140.000	<=	165.290	<=	175.000	159.424	171.318	PASS
3	140.000	<=	165.195	<=	175.000	158.445	172.633	PASS
4	140.000	<=	165.285	<=	175.000	158.969	171.387	PASS
5	140.000	<=	165.482	<=	175.000	159.986	171.019	PASS
6	140.000	<=	165.108	<=	175.000	158.572	172.567	PASS
7	140.000	<=	165.551	<=	175.000	158.941	171.797	PASS
8	140.000	<=	165.049	<=	175.000	158.476	171.729	PASS
9	140.000	<=	165.301	<=	175.000	159.528	171.468	PASS
10	140.000	<=	165.378	<=	175.000	158.974	171.971	PASS

Next measurement will be running with the following changed parameters:

B1 Signal Pattern: 01010101

Packet Nr.	Average	Min [kHz]		LIMIT [kHz]	Max [kHz]	VERDICT
1	156.058	145.966	>=	115.000	164.688	PASS
2	153.935	144.282	>=	115.000	162.908	PASS
3	153.847	145.587	>=	115.000	163.686	PASS
4	155.658	147.706	>=	115.000	164.212	PASS
5	154.129	142.593	>=	115.000	166.316	PASS
6	154.776	145.919	>=	115.000	164.214	PASS
7	154.278	143.715	>=	115.000	163.682	PASS
8	155.654	147.175	>=	115.000	163.959	PASS
9	154.745	144.784	>=	115.000	163.512	PASS
10	155.060	146.867	>=	115.000	163.786	PASS

F2 Outsides: 0 Measurements: 27040 Ratio: 0.00 % < 0.10 % PASS

F2/F1 (average min) [%]		LIMIT [%]	VERDICT
93.668	>=	80.000	PASS

Next measurement will be running with the following changed parameters:

EUT Tx Frequency: 2441.000 MHz
EUT Rx Frequency: 2402.000 MHz
B1 Signal Pattern: 00001111

Packet Nr.	LIMIT [kHz]		Average [kHz]		LIMIT [kHz]	Min [kHz]	Max [kHz]	VERDICT
1	140.000	<=	165.387	<=	175.000	158.032	171.810	PASS
2	140.000	<=	165.049	<=	175.000	158.015	172.101	PASS
3	140.000	<=	165.281	<=	175.000	157.849	171.412	PASS
4	140.000	<=	165.285	<=	175.000	159.159	171.955	PASS
5	140.000	<=	165.169	<=	175.000	158.769	171.281	PASS
6	140.000	<=	165.356	<=	175.000	158.534	171.150	PASS
7	140.000	<=	165.144	<=	175.000	157.324	172.623	PASS
8	140.000	<=	164.983	<=	175.000	159.299	170.817	PASS
9	140.000	<=	165.162	<=	175.000	157.475	171.805	PASS
10	140.000	<=	165.133	<=	175.000	158.278	173.182	PASS

Next measurement will be running with the following changed parameters:

B1 Signal Pattern: 01010101

Packet Nr.	Average	Min [kHz]		LIMIT [kHz]	Max [kHz]	VERDICT
1	155.957	145.353	>=	115.000	164.534	PASS
2	155.954	145.607	>=	115.000	166.788	PASS
3	154.181	141.155	>=	115.000	164.238	PASS
4	154.178	144.209	>=	115.000	163.805	PASS
5	155.410	147.071	>=	115.000	164.034	PASS
6	154.132	144.530	>=	115.000	163.445	PASS
7	155.421	145.590	>=	115.000	165.358	PASS
8	154.395	142.720	>=	115.000	163.589	PASS
9	156.176	145.856	>=	115.000	165.003	PASS
10	155.951	145.072	>=	115.000	165.378	PASS

F2 Outsides: 0 Measurements: 27040 Ratio: 0.00 % < 0.10 % PASS

F2/F1 (average min) [%]		LIMIT [%]	VERDICT
93.935	>=	80.000	PASS

Next measurement will be running with the following changed parameters:

EUT Tx Frequency: 2480.000 MHz
EUT Rx Frequency: 2402.000 MHz
B1 Signal Pattern: 00001111

Packet Nr.	LIMIT [kHz]		Average [kHz]		LIMIT [kHz]	Min [kHz]	Max [kHz]	VERDICT
1	140.000	<=	165.074	<=	175.000	158.349	171.883	PASS
2	140.000	<=	164.905	<=	175.000	158.503	170.820	PASS
3	140.000	<=	165.882	<=	175.000	158.208	172.317	PASS
4	140.000	<=	164.993	<=	175.000	157.766	171.700	PASS
5	140.000	<=	165.120	<=	175.000	158.623	172.099	PASS
6	140.000	<=	165.077	<=	175.000	157.939	172.832	PASS
7	140.000	<=	165.112	<=	175.000	158.999	172.466	PASS
8	140.000	<=	164.951	<=	175.000	157.085	171.731	PASS
9	140.000	<=	165.273	<=	175.000	158.915	173.479	PASS
10	140.000	<=	164.919	<=	175.000	156.814	171.791	PASS

Next measurement will be running with the following changed parameters:

B1 Signal Pattern: 01010101

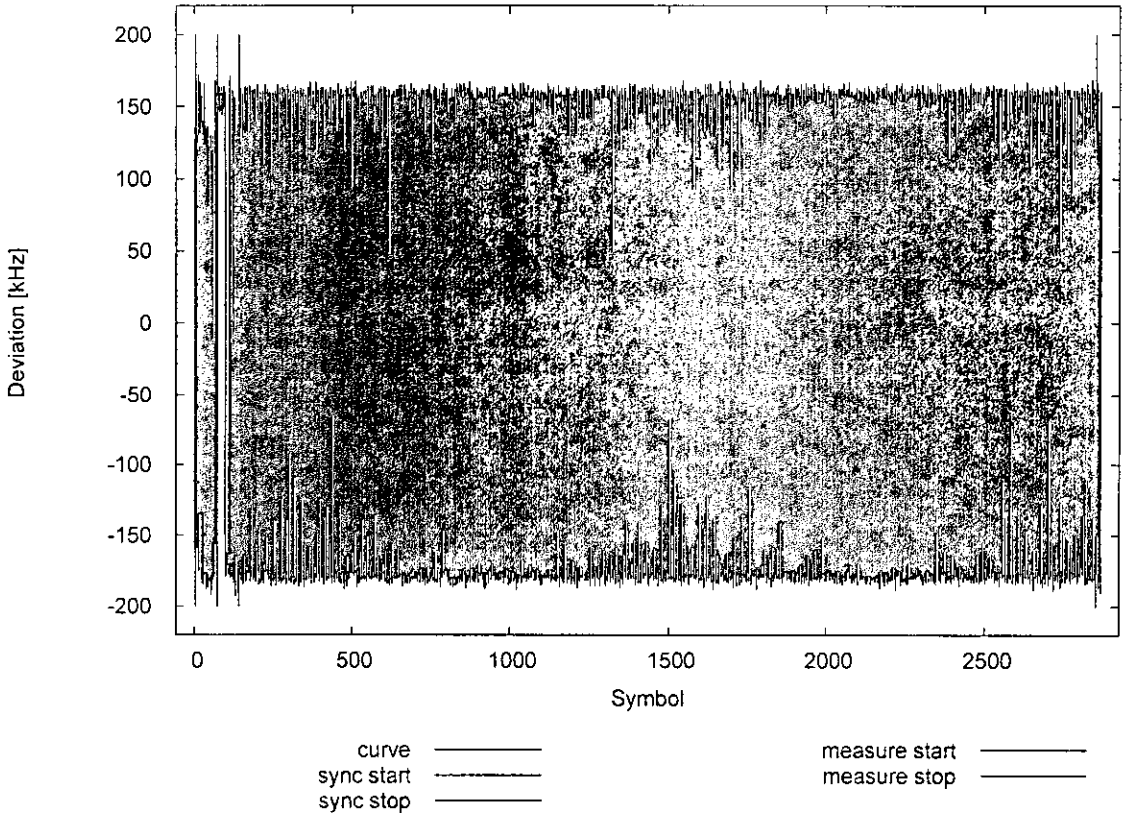
Packet Nr.	Average	Min [kHz]		LIMIT [kHz]	Max [kHz]	VERDICT
1	156.236	144.076	>=	115.000	166.334	PASS
2	156.211	146.001	>=	115.000	166.594	PASS
3	155.267	146.040	>=	115.000	167.032	PASS
4	155.483	145.749	>=	115.000	167.476	PASS
5	155.323	144.319	>=	115.000	165.296	PASS
6	155.164	144.116	>=	115.000	163.543	PASS
7	155.199	145.557	>=	115.000	166.512	PASS
8	156.052	147.353	>=	115.000	165.004	PASS
9	156.462	146.347	>=	115.000	164.916	PASS
10	155.156	144.470	>=	115.000	164.096	PASS

F2 Outsides: 0 Measurements: 27040 Ratio: 0.00 % < 0.10 % PASS

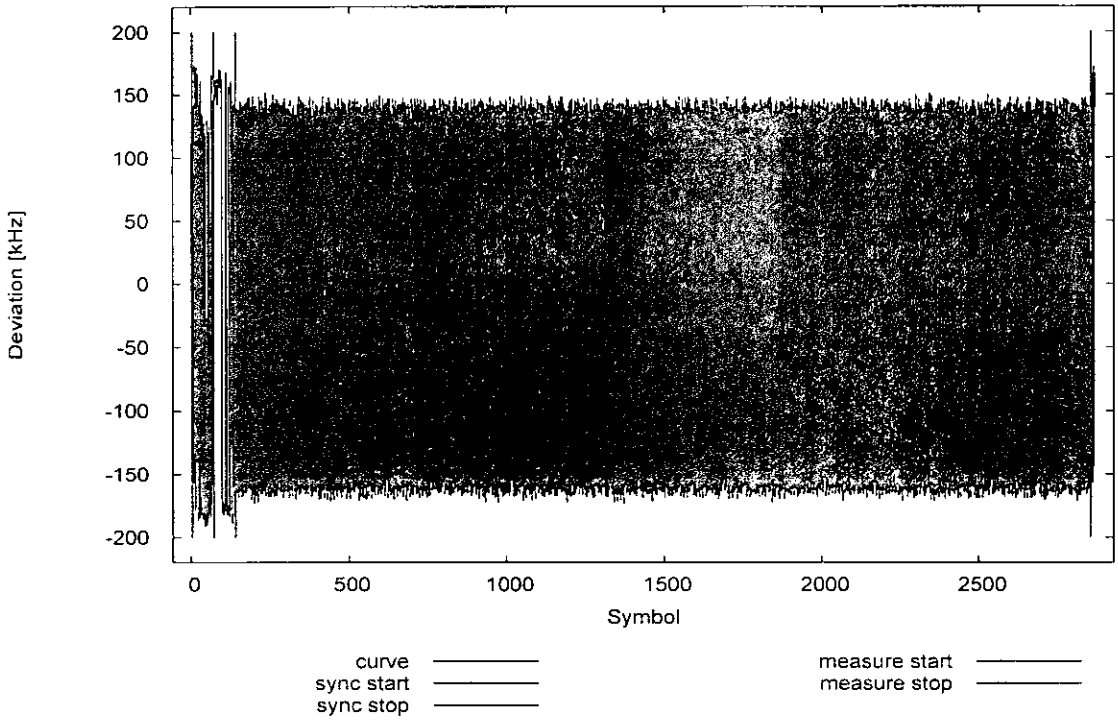
F2/F1 (average min) [%]		LIMIT [%]	VERDICT
94.262	>=	80.000	PASS

Final Test Case Verdict . . . . . PASS 00:34:35

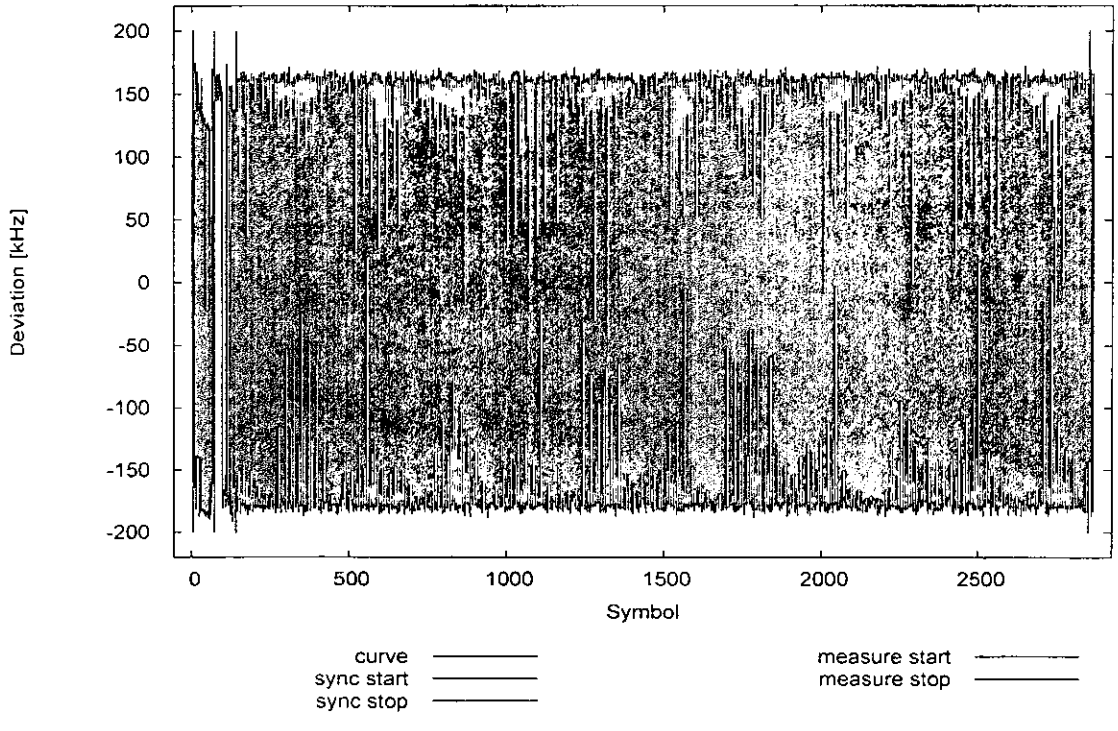
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1111000 pattern



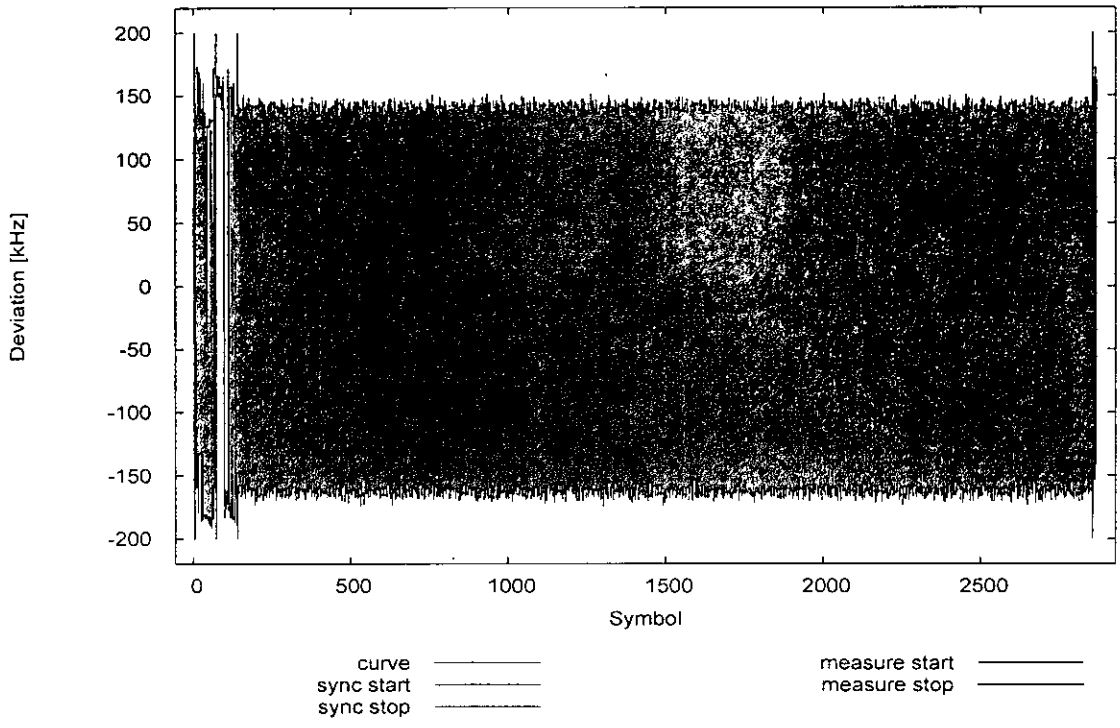
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern



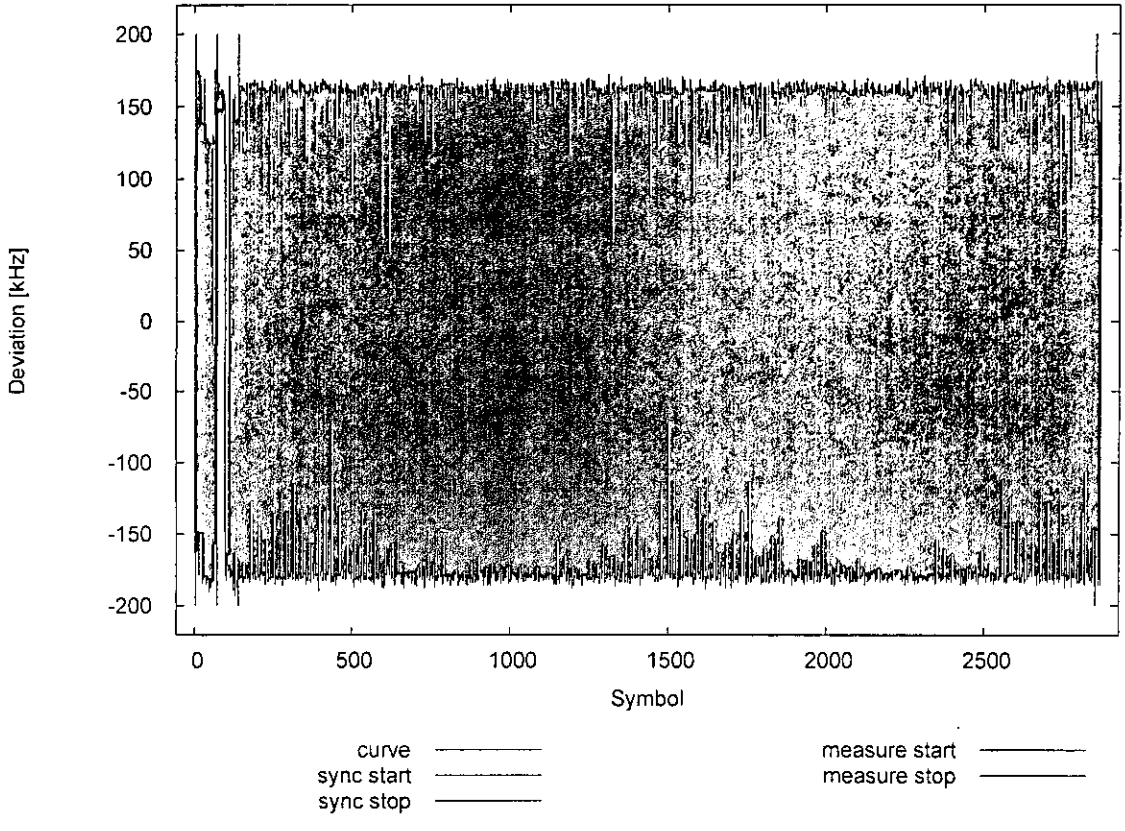
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1111000 pattern



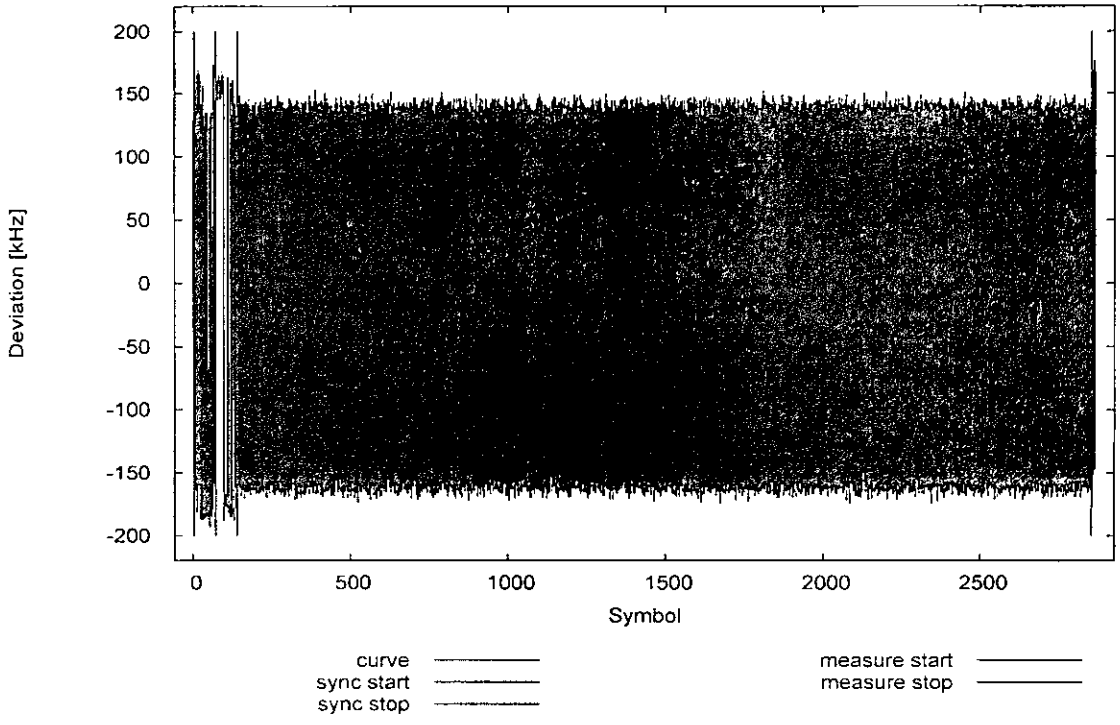
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern



Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1111000 pattern



Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern



Modulation Characteristics

For system parameter see 0, "General Parameter 007"

BT Test Specification Version: 1.2

TS Errata Request: 277

For EUT parameter see 0, "EUT Parameter 010"
For test case parameter see 0, "Test Case Parameter 047"

Packet Nr.	LIMIT [kHz]		Average [kHz]		LIMIT [kHz]	Min [kHz]	Max [kHz]	VERDICT
1	140.000	<=	165.091	<=	175.000	159.196	170.983	PASS
2	140.000	<=	165.407	<=	175.000	158.685	171.175	PASS
3	140.000	<=	165.465	<=	175.000	159.623	172.162	PASS
4	140.000	<=	165.164	<=	175.000	158.047	171.781	PASS
5	140.000	<=	165.415	<=	175.000	159.657	172.002	PASS
6	140.000	<=	165.075	<=	175.000	157.895	172.228	PASS
7	140.000	<=	165.638	<=	175.000	160.163	171.673	PASS
8	140.000	<=	165.313	<=	175.000	158.611	171.913	PASS
9	140.000	<=	165.580	<=	175.000	158.595	171.444	PASS
10	140.000	<=	165.459	<=	175.000	159.504	173.215	PASS

Next measurement will be running with the following changed parameters:

B1 Signal Pattern: 01010101

Packet Nr.	Average	Min [kHz]		LIMIT [kHz]	Max [kHz]	VERDICT
1	155.782	145.604	>=	115.000	164.475	PASS
2	153.770	143.588	>=	115.000	162.776	PASS
3	155.875	146.658	>=	115.000	164.770	PASS
4	153.686	145.407	>=	115.000	163.555	PASS
5	153.385	142.535	>=	115.000	163.117	PASS
6	154.024	142.601	>=	115.000	162.879	PASS
7	153.292	143.587	>=	115.000	162.450	PASS
8	154.586	145.876	>=	115.000	165.177	PASS
9	154.893	142.423	>=	115.000	163.758	PASS
10	155.773	146.613	>=	115.000	163.889	PASS

F2 Outsides: 0 Measurements: 27040 Ratio: 0.00 % < 0.10 % PASS

F2/F1 (average min) [%]		LIMIT [%]	VERDICT
93.436	>=	80.000	PASS

Next measurement will be running with the following changed parameters:

EUT Tx Frequency: 2441.000 MHz
EUT Rx Frequency: 2402.000 MHz
B1 Signal Pattern: 00001111

B1 Signal Pattern: 01010101

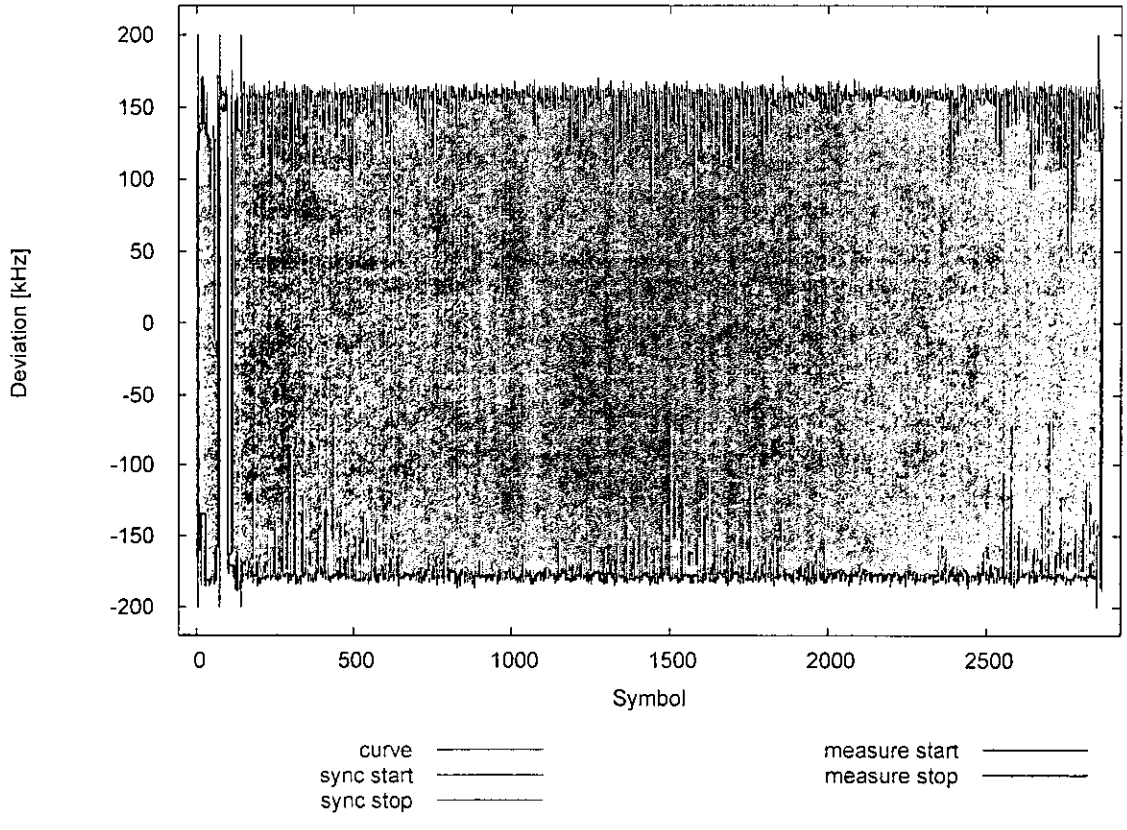
Packet Nr.	Average	Min [kHz]		LIMIT [kHz]	Max [kHz]	VERDICT
1	155.814	143.669	>=	115.000	164.837	PASS
2	155.190	144.557	>=	115.000	164.979	PASS
3	155.780	143.504	>=	115.000	164.999	PASS
4	155.407	145.893	>=	115.000	165.010	PASS
5	156.257	145.073	>=	115.000	165.503	PASS
6	155.203	136.684	>=	115.000	165.425	PASS
7	156.359	146.412	>=	115.000	165.926	PASS
8	155.927	146.930	>=	115.000	165.953	PASS
9	155.463	139.468	>=	115.000	168.222	PASS
10	156.001	147.380	>=	115.000	164.493	PASS

F2 Outsides: 0 Measurements: 27040 Ratio: 0.00 % < 0.10 % PASS

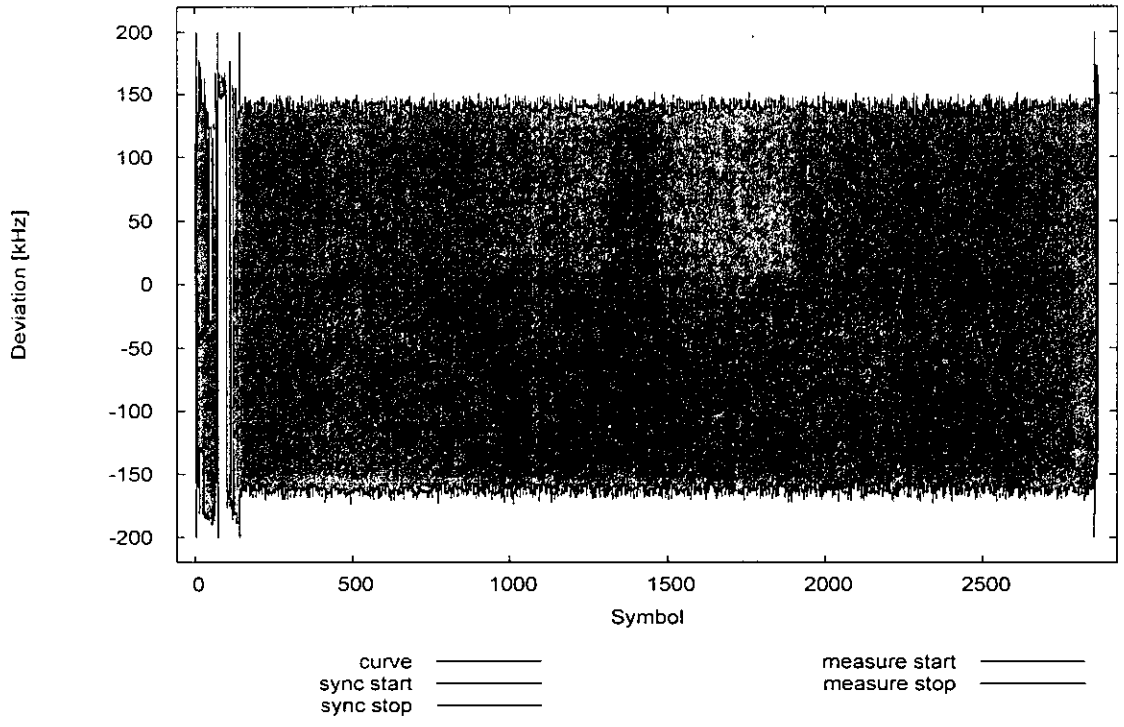
F2/F1 (average min) [%]		LIMIT [%]	VERDICT
94.320	>=	80.000	PASS

Final Test Case Verdict . . . . . PASS 00:25:49

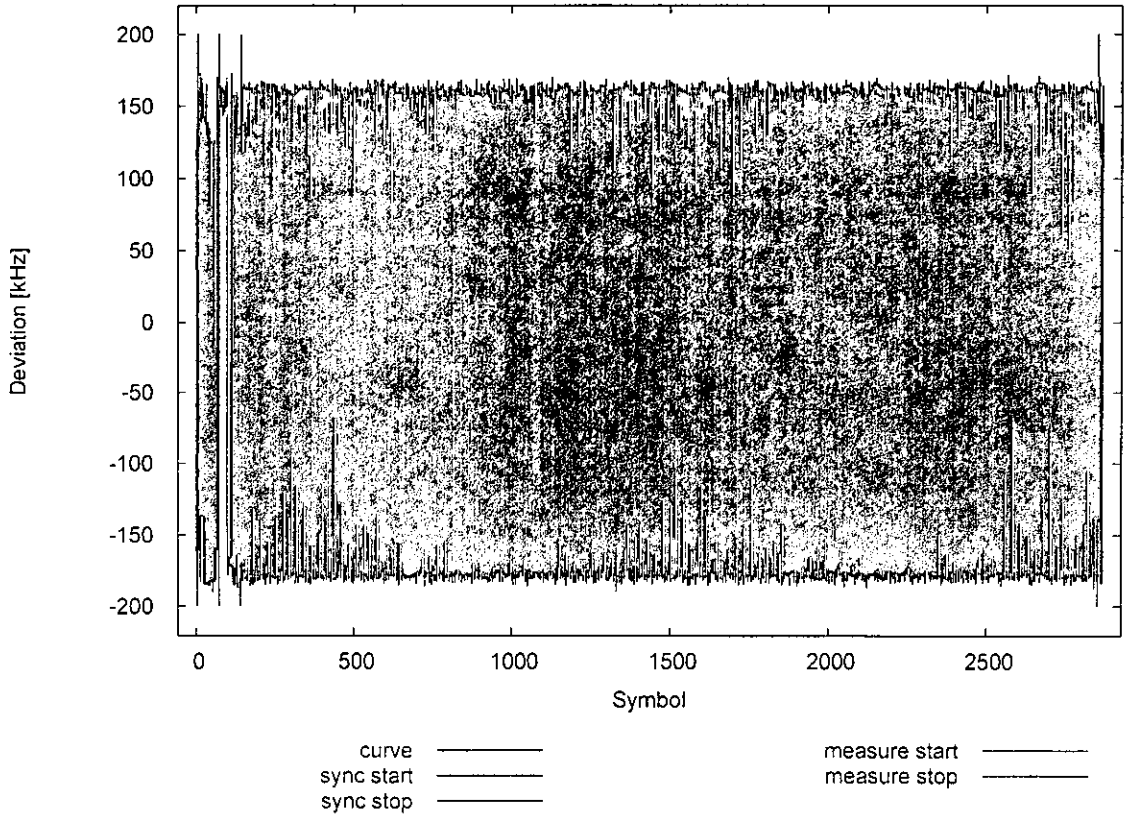
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1111000 pattern



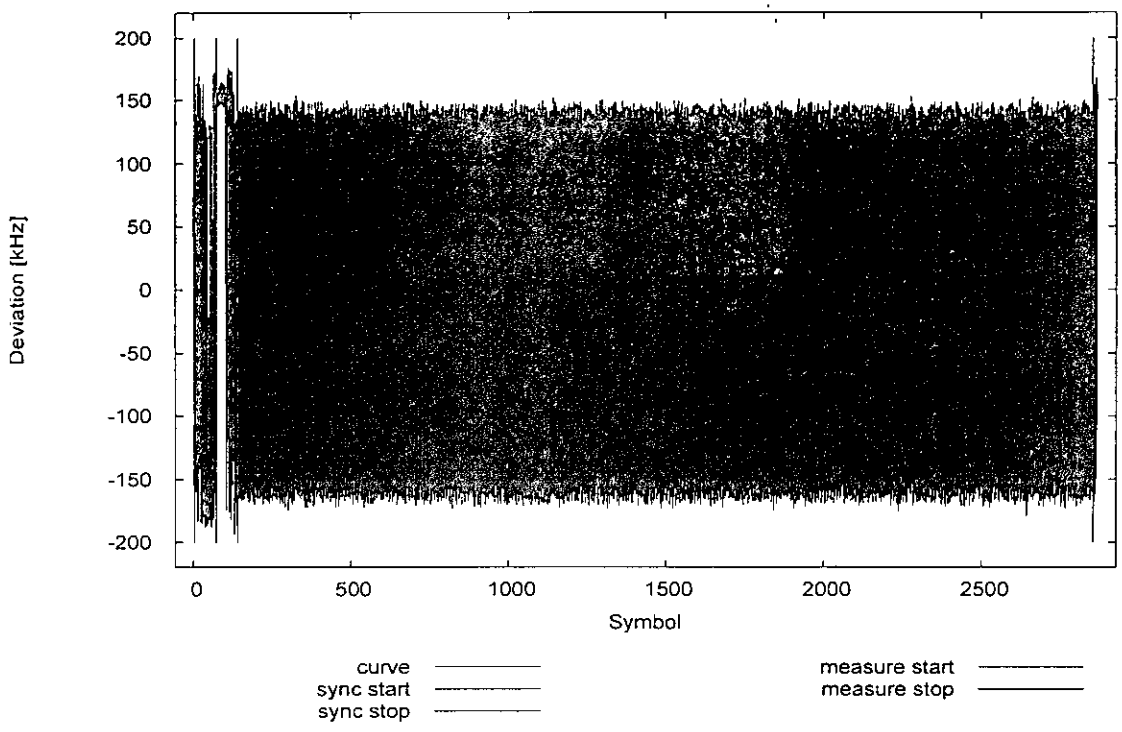
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern



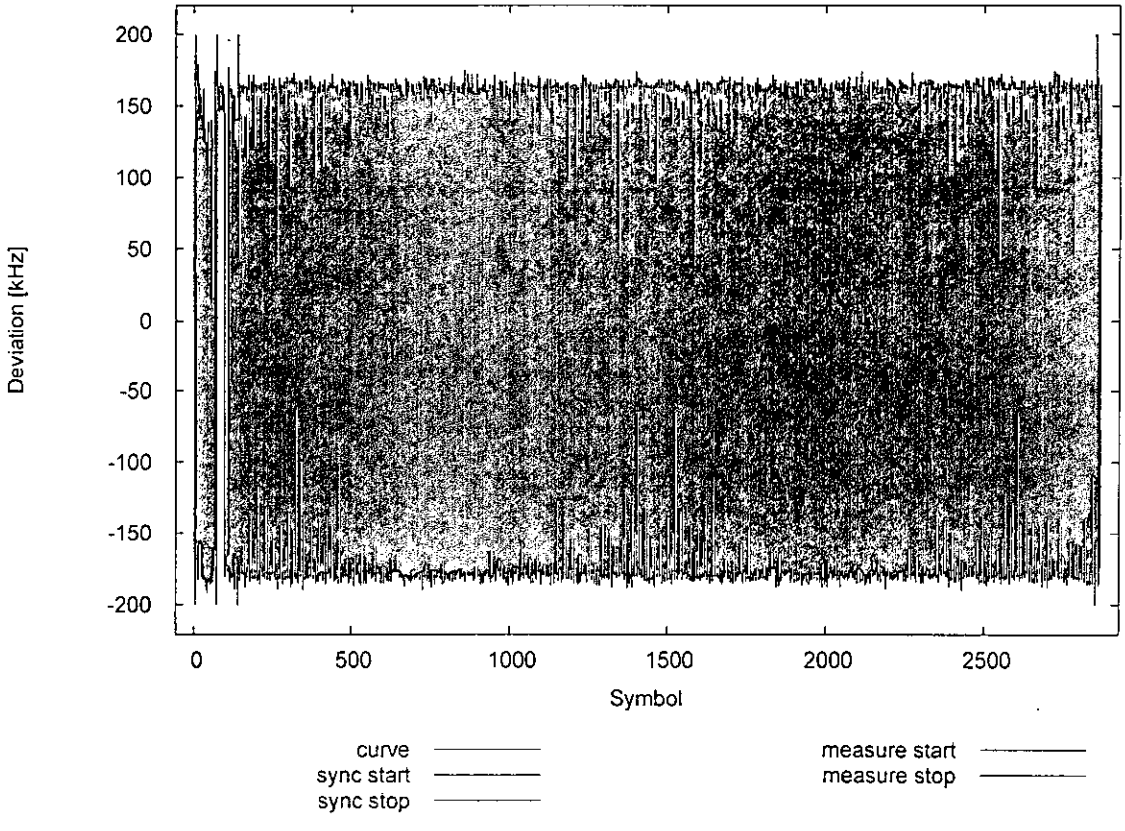
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1111000 pattern



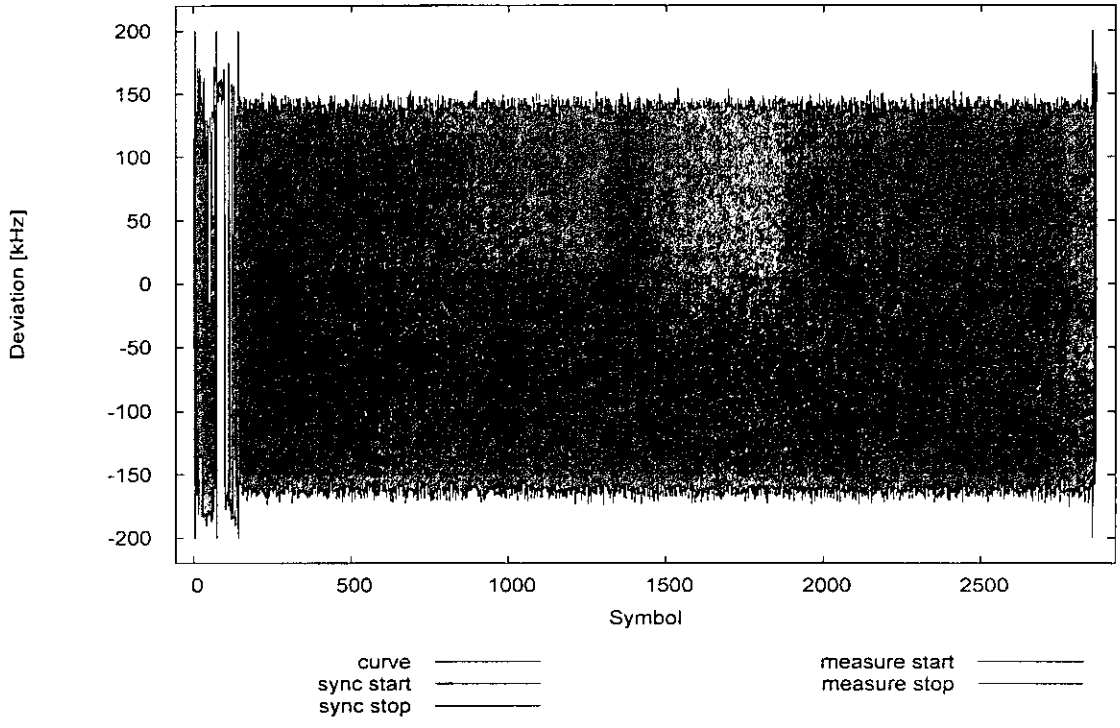
Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern



Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1111000 pattern



Measured Burst, FSK Signal TC Modulation Characteristics, packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern



Annex I

TRM/CA/08/C Initial Carrier Frequency Tolerance

Initial Carrier Frequency Tolerance

For system parameter see 0, "General Parameter 009"

BT Test Specification Version: 1.2

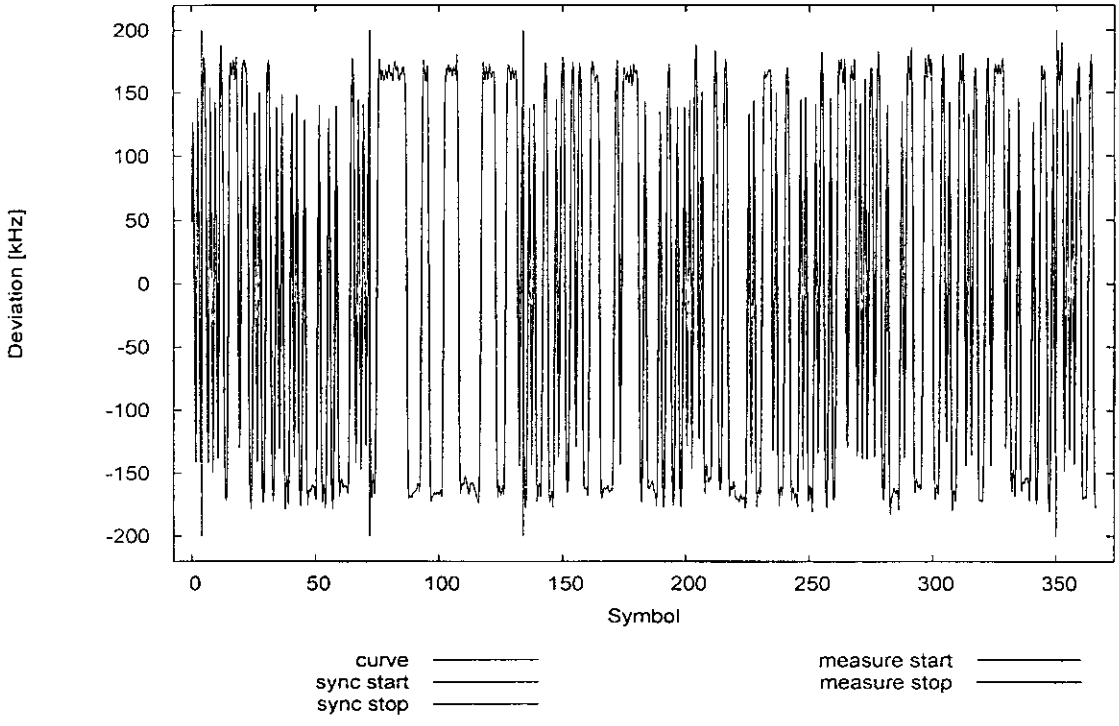
TS Errata Request: 191
TS Errata Request: 277

For EUT parameter see 0, "EUT Parameter 002"
For test case parameter see 0, "Test Case Parameter 009"

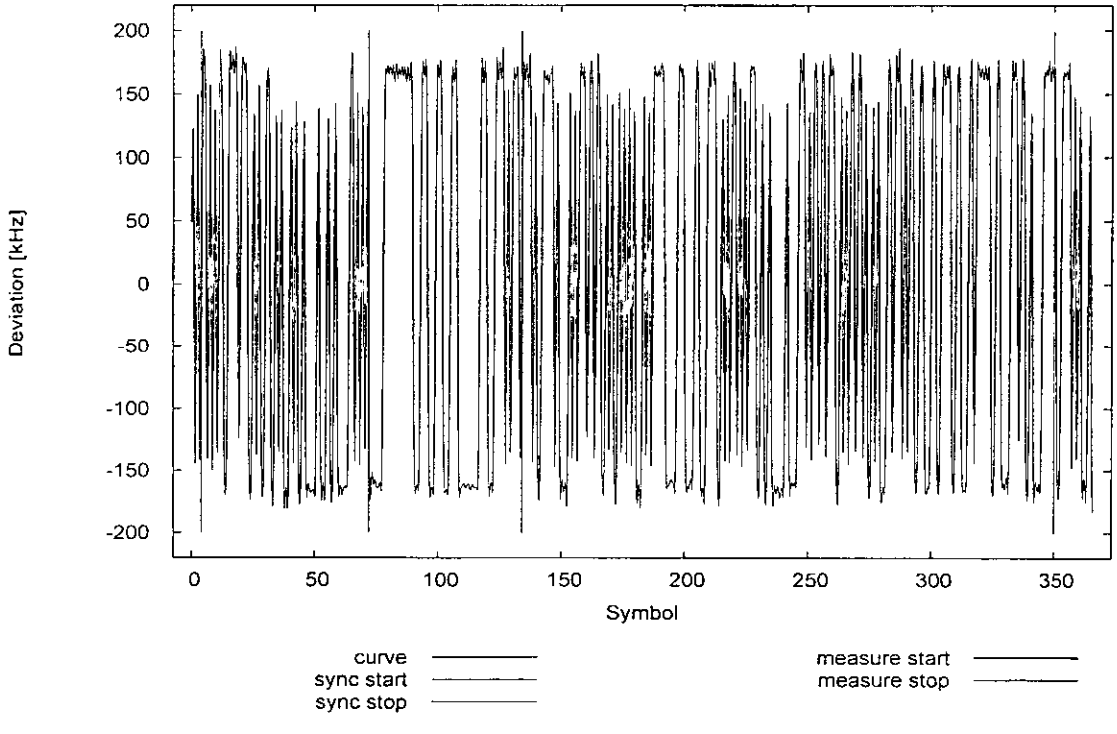
Packet Nr.	Freq [MHz]	Limit [kHz]		Value [kHz]		Limit [kHz]	Nominal [kHz]	VERDICT
1	2402	-75.000	<=	1.847	<=	75.000	0.000000	PASS
2	2402	-75.000	<=	-1.651	<=	75.000	0.000000	PASS
3	2402	-75.000	<=	-0.404	<=	75.000	0.000000	PASS
4	2402	-75.000	<=	-3.958	<=	75.000	0.000000	PASS
5	2402	-75.000	<=	-4.279	<=	75.000	0.000000	PASS
6	2402	-75.000	<=	-2.320	<=	75.000	0.000000	PASS
7	2402	-75.000	<=	-2.142	<=	75.000	0.000000	PASS
8	2402	-75.000	<=	-3.311	<=	75.000	0.000000	PASS
9	2402	-75.000	<=	-2.667	<=	75.000	0.000000	PASS
10	2402	-75.000	<=	-1.839	<=	75.000	0.000000	PASS
1	2441	-75.000	<=	1.556	<=	75.000	0.000000	PASS
2	2441	-75.000	<=	-1.977	<=	75.000	0.000000	PASS
3	2441	-75.000	<=	-3.303	<=	75.000	0.000000	PASS
4	2441	-75.000	<=	-1.235	<=	75.000	0.000000	PASS
5	2441	-75.000	<=	-0.651	<=	75.000	0.000000	PASS
6	2441	-75.000	<=	-2.764	<=	75.000	0.000000	PASS
7	2441	-75.000	<=	-3.049	<=	75.000	0.000000	PASS
8	2441	-75.000	<=	-1.973	<=	75.000	0.000000	PASS
9	2441	-75.000	<=	-3.633	<=	75.000	0.000000	PASS
10	2441	-75.000	<=	-1.987	<=	75.000	0.000000	PASS
1	2480	-75.000	<=	-0.562	<=	75.000	0.000000	PASS
2	2480	-75.000	<=	-3.772	<=	75.000	0.000000	PASS
3	2480	-75.000	<=	1.918	<=	75.000	0.000000	PASS
4	2480	-75.000	<=	-2.850	<=	75.000	0.000000	PASS
5	2480	-75.000	<=	2.220	<=	75.000	0.000000	PASS
6	2480	-75.000	<=	-6.462	<=	75.000	0.000000	PASS
7	2480	-75.000	<=	-0.918	<=	75.000	0.000000	PASS
8	2480	-75.000	<=	-2.208	<=	75.000	0.000000	PASS
9	2480	-75.000	<=	1.457	<=	75.000	0.000000	PASS
10	2480	-75.000	<=	-3.128	<=	75.000	0.000000	PASS

Final Test Case Verdict . . . . . PASS 00:09:12

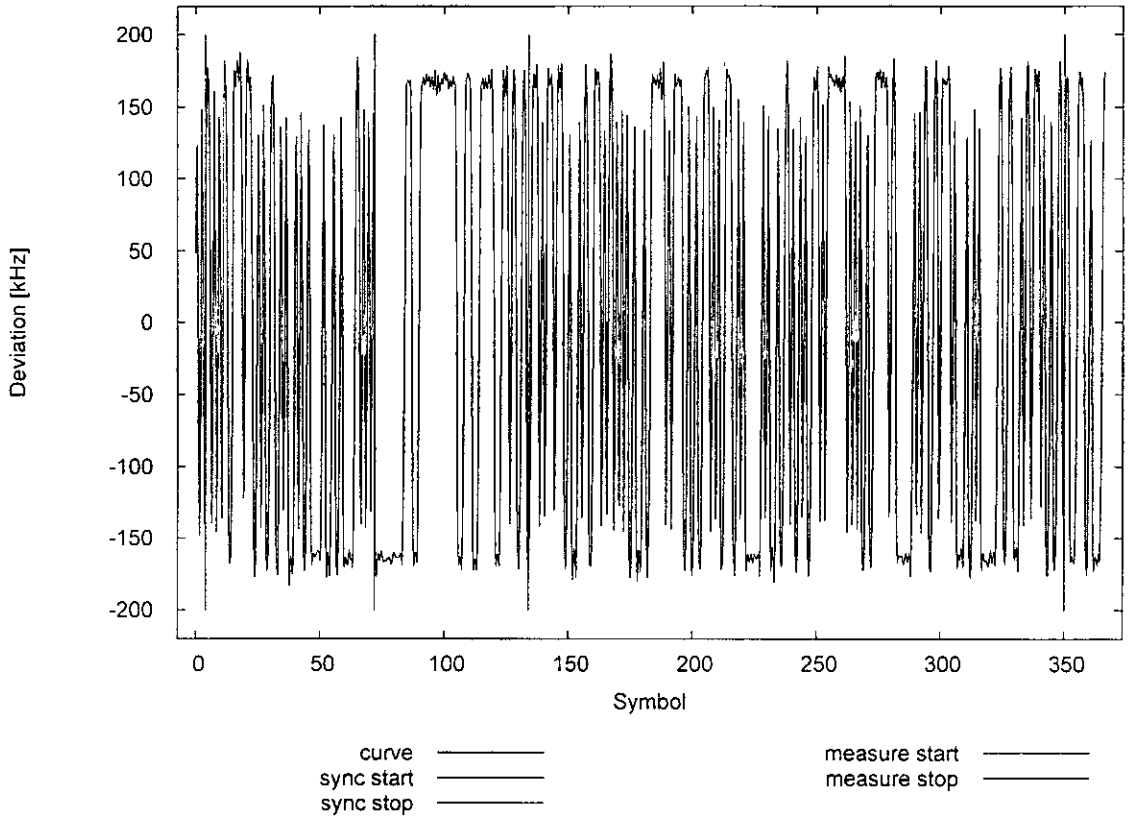
Measured Burst, FSK Signal TC Initial Carrier Frequency Tolerance packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2402.000 [MHz] - prbs9 pattern



Measured Burst, FSK Signal TC Initial Carrier Frequency Tolerance packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - prbs9 pattern



Measured Burst, FSK Signal TC Initial Carrier Frequency Tolerance packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - prbs9 pattern



Initial Carrier Frequency Tolerance

For system parameter see 0, "General Parameter 009"

BT Test Specification Version: 1.2

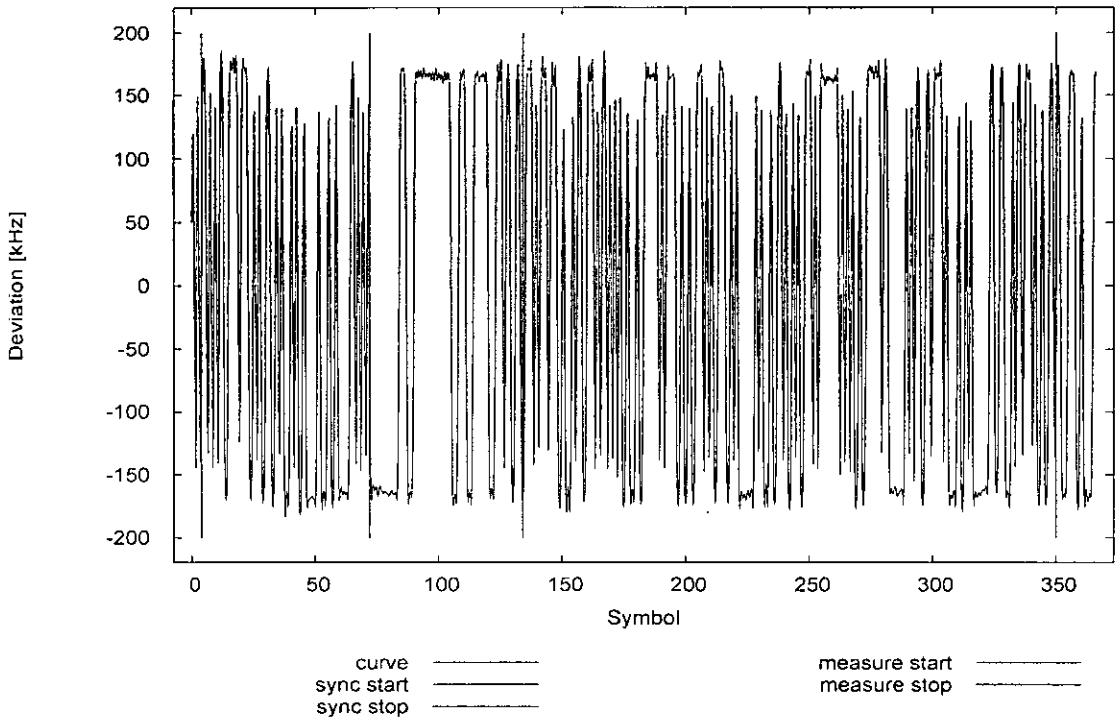
TS Errata Request: 191
TS Errata Request: 277

For EUT parameter see 0, "EUT Parameter 005"
For test case parameter see 0, "Test Case Parameter 028"

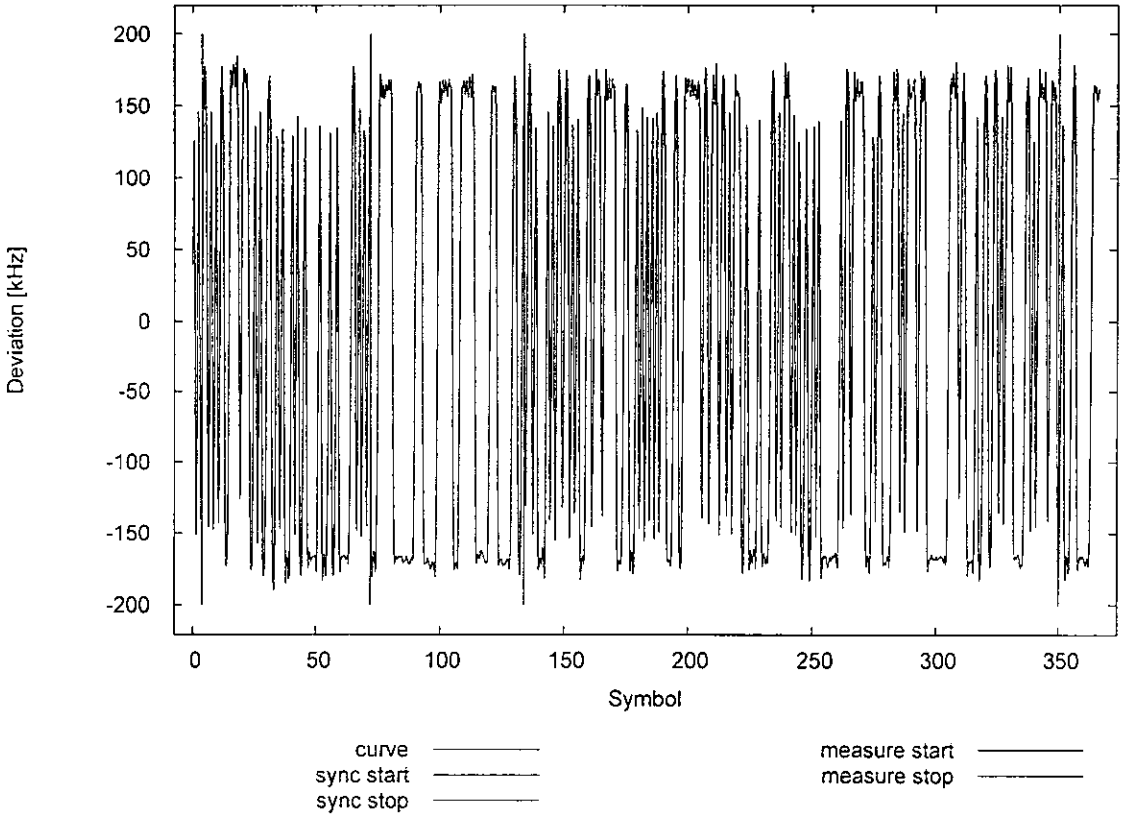
Packet Nr.	Freq [MHz]	Limit [kHz]		Value [kHz]		Limit [kHz]	Nominal [kHz]	VERDICT
1	2402	-75.000	<=	3.863	<=	75.000	0.000000	PASS
2	2402	-75.000	<=	4.377	<=	75.000	0.000000	PASS
3	2402	-75.000	<=	-1.855	<=	75.000	0.000000	PASS
4	2402	-75.000	<=	0.069	<=	75.000	0.000000	PASS
5	2402	-75.000	<=	0.947	<=	75.000	0.000000	PASS
6	2402	-75.000	<=	-1.592	<=	75.000	0.000000	PASS
7	2402	-75.000	<=	1.390	<=	75.000	0.000000	PASS
8	2402	-75.000	<=	-3.037	<=	75.000	0.000000	PASS
9	2402	-75.000	<=	-7.893	<=	75.000	0.000000	PASS
10	2402	-75.000	<=	-2.553	<=	75.000	0.000000	PASS
1	2441	-75.000	<=	-6.828	<=	75.000	0.000000	PASS
2	2441	-75.000	<=	-2.535	<=	75.000	0.000000	PASS
3	2441	-75.000	<=	-4.156	<=	75.000	0.000000	PASS
4	2441	-75.000	<=	-6.533	<=	75.000	0.000000	PASS
5	2441	-75.000	<=	-2.675	<=	75.000	0.000000	PASS
6	2441	-75.000	<=	-4.744	<=	75.000	0.000000	PASS
7	2441	-75.000	<=	-2.088	<=	75.000	0.000000	PASS
8	2441	-75.000	<=	-2.473	<=	75.000	0.000000	PASS
9	2441	-75.000	<=	-3.251	<=	75.000	0.000000	PASS
10	2441	-75.000	<=	-5.878	<=	75.000	0.000000	PASS
1	2480	-75.000	<=	-5.793	<=	75.000	0.000000	PASS
2	2480	-75.000	<=	-8.196	<=	75.000	0.000000	PASS
3	2480	-75.000	<=	-9.924	<=	75.000	0.000000	PASS
4	2480	-75.000	<=	-11.435	<=	75.000	0.000000	PASS
5	2480	-75.000	<=	-7.750	<=	75.000	0.000000	PASS
6	2480	-75.000	<=	-9.851	<=	75.000	0.000000	PASS
7	2480	-75.000	<=	-10.381	<=	75.000	0.000000	PASS
8	2480	-75.000	<=	-7.770	<=	75.000	0.000000	PASS
9	2480	-75.000	<=	-10.633	<=	75.000	0.000000	PASS
10	2480	-75.000	<=	-12.170	<=	75.000	0.000000	PASS

Final Test Case Verdict . . . . . PASS 00:09:05

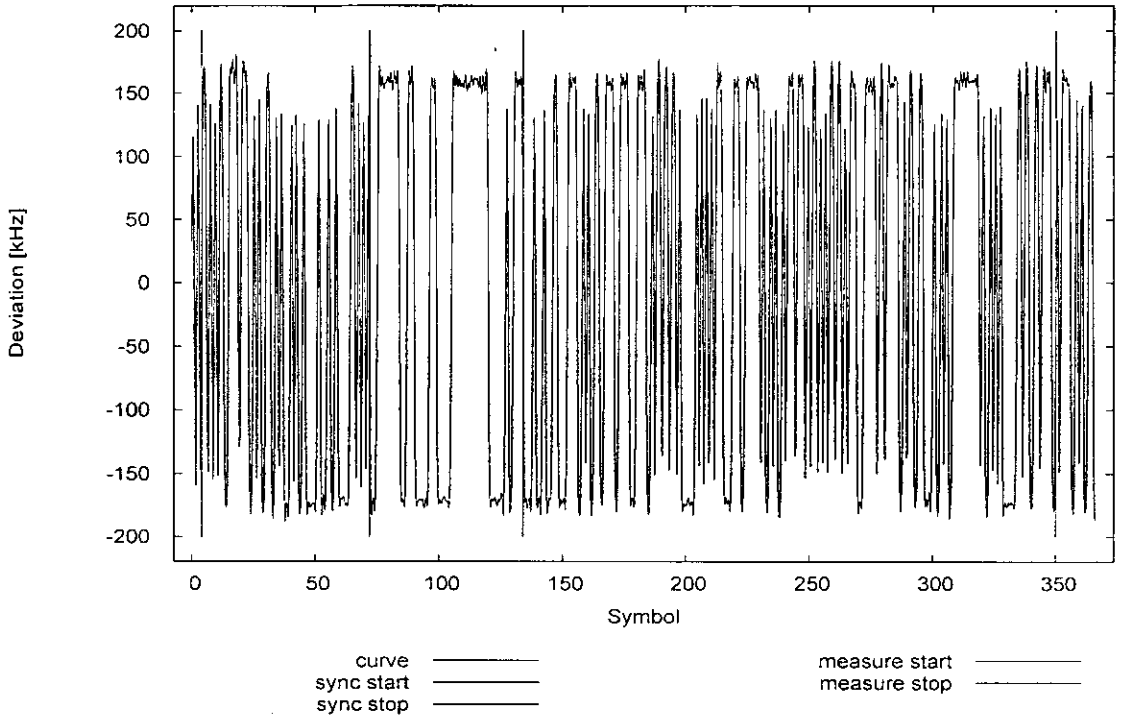
Measured Burst, FSK Signal TC Initial Carrier Frequency Tolerance packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2402.000 [MHz] - prbs9 pattern



Measured Burst, FSK Signal TC Initial Carrier Frequency Tolerance packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - prbs9 pattern



Measured Burst, FSK Signal TC Initial Carrier Frequency Tolerance packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - prbs9 pattern



Initial Carrier Frequency Tolerance

For system parameter see 0, "General Parameter 009"

BT Test Specification Version: 1.2

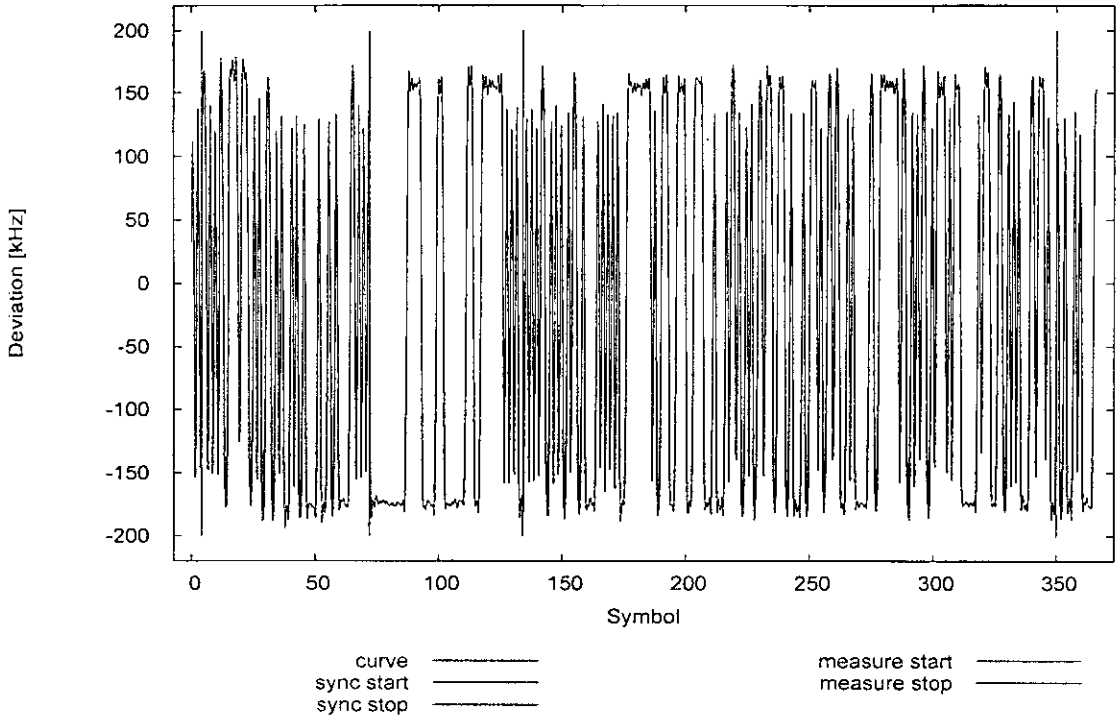
TS Errata Request: 191
TS Errata Request: 277

For EUT parameter see 0, "EUT Parameter 006"
For test case parameter see 0, "Test Case Parameter 029"

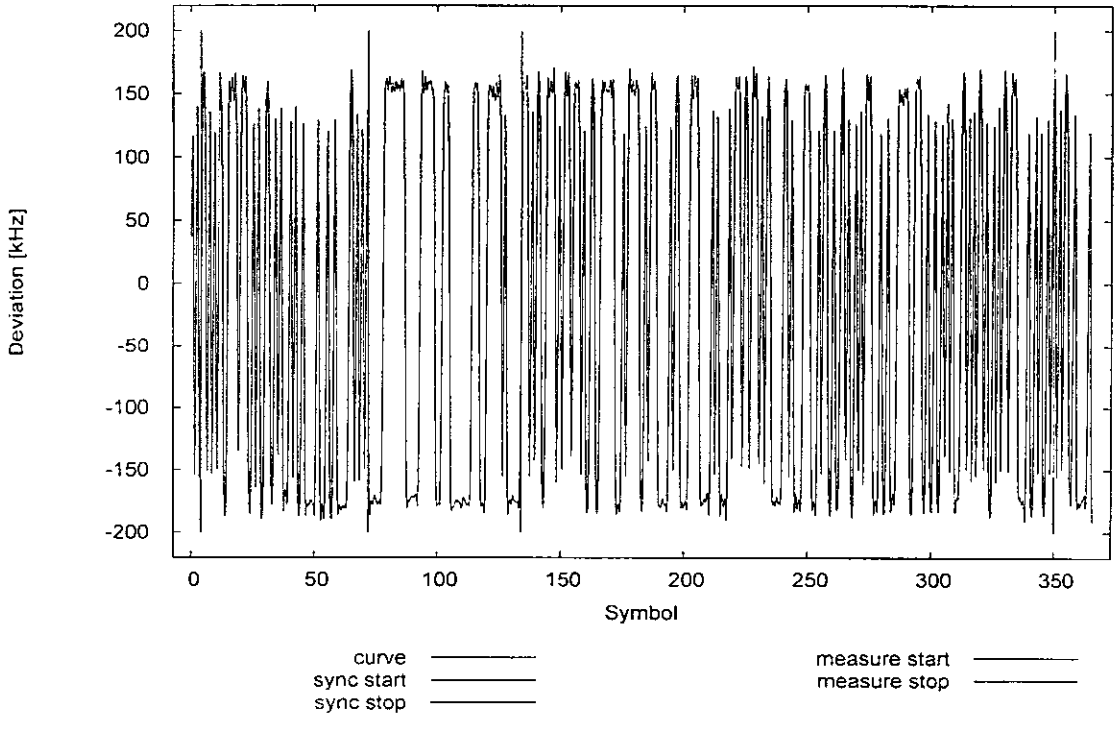
Packet Nr.	Freq [MHz]	Limit [kHz]		Value [kHz]		Limit [kHz]	Nominal [kHz]	VERDICT
1	2402	-75.000	<=	-10.737	<=	75.000	0.000000	PASS
2	2402	-75.000	<=	-13.173	<=	75.000	0.000000	PASS
3	2402	-75.000	<=	-9.115	<=	75.000	0.000000	PASS
4	2402	-75.000	<=	-12.759	<=	75.000	0.000000	PASS
5	2402	-75.000	<=	-12.133	<=	75.000	0.000000	PASS
6	2402	-75.000	<=	-10.332	<=	75.000	0.000000	PASS
7	2402	-75.000	<=	-11.095	<=	75.000	0.000000	PASS
8	2402	-75.000	<=	-14.096	<=	75.000	0.000000	PASS
9	2402	-75.000	<=	-12.182	<=	75.000	0.000000	PASS
10	2402	-75.000	<=	-12.704	<=	75.000	0.000000	PASS
1	2441	-75.000	<=	-14.964	<=	75.000	0.000000	PASS
2	2441	-75.000	<=	-12.473	<=	75.000	0.000000	PASS
3	2441	-75.000	<=	-13.465	<=	75.000	0.000000	PASS
4	2441	-75.000	<=	-12.701	<=	75.000	0.000000	PASS
5	2441	-75.000	<=	-14.404	<=	75.000	0.000000	PASS
6	2441	-75.000	<=	-14.879	<=	75.000	0.000000	PASS
7	2441	-75.000	<=	-15.158	<=	75.000	0.000000	PASS
8	2441	-75.000	<=	-13.144	<=	75.000	0.000000	PASS
9	2441	-75.000	<=	-14.685	<=	75.000	0.000000	PASS
10	2441	-75.000	<=	-13.689	<=	75.000	0.000000	PASS
1	2480	-75.000	<=	-14.138	<=	75.000	0.000000	PASS
2	2480	-75.000	<=	-16.394	<=	75.000	0.000000	PASS
3	2480	-75.000	<=	-15.938	<=	75.000	0.000000	PASS
4	2480	-75.000	<=	-14.441	<=	75.000	0.000000	PASS
5	2480	-75.000	<=	-15.279	<=	75.000	0.000000	PASS
6	2480	-75.000	<=	-13.442	<=	75.000	0.000000	PASS
7	2480	-75.000	<=	-17.116	<=	75.000	0.000000	PASS
8	2480	-75.000	<=	-9.840	<=	75.000	0.000000	PASS
9	2480	-75.000	<=	-12.125	<=	75.000	0.000000	PASS
10	2480	-75.000	<=	-12.483	<=	75.000	0.000000	PASS

Final Test Case Verdict . . . . . PASS 00:09:15

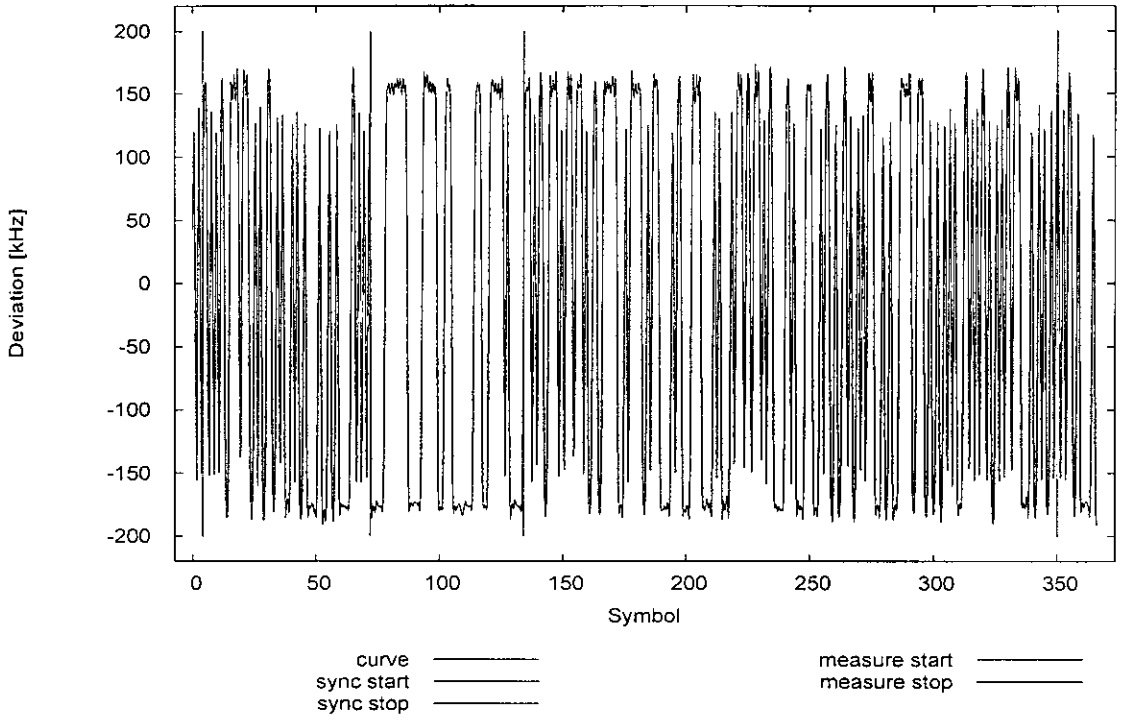
Measured Burst, FSK Signal TC Initial Carrier Frequency Tolerance packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2402.000 [MHz] - prbs9 pattern



Measured Burst, FSK Signal TC Initial Carrier Frequency Tolerance packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - prbs9 pattern



Measured Burst, FSK Signal TC Initial Carrier Frequency Tolerance packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - prbs9 pattern



Initial Carrier Frequency Tolerance

For system parameter see 0, "General Parameter 009"

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BT Test Specification Version:  1.2

TS Errata Request:              191
TS Errata Request:              277
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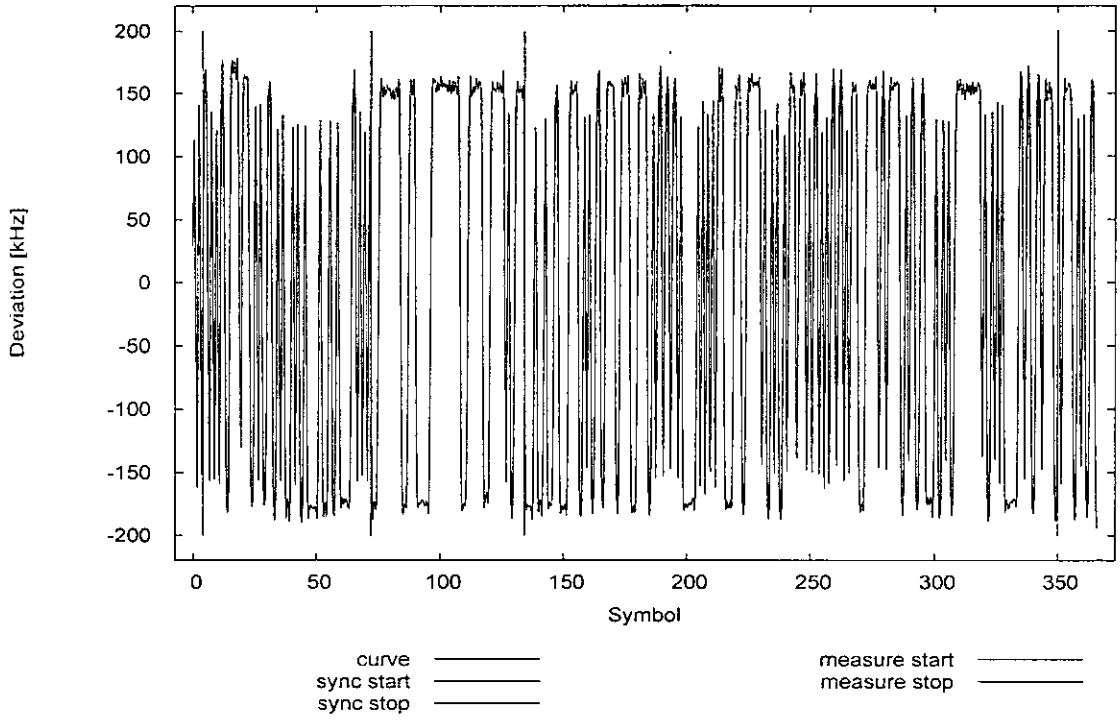
For EUT parameter see 0, "EUT Parameter 009"
For test case parameter see 0, "Test Case Parameter 048"

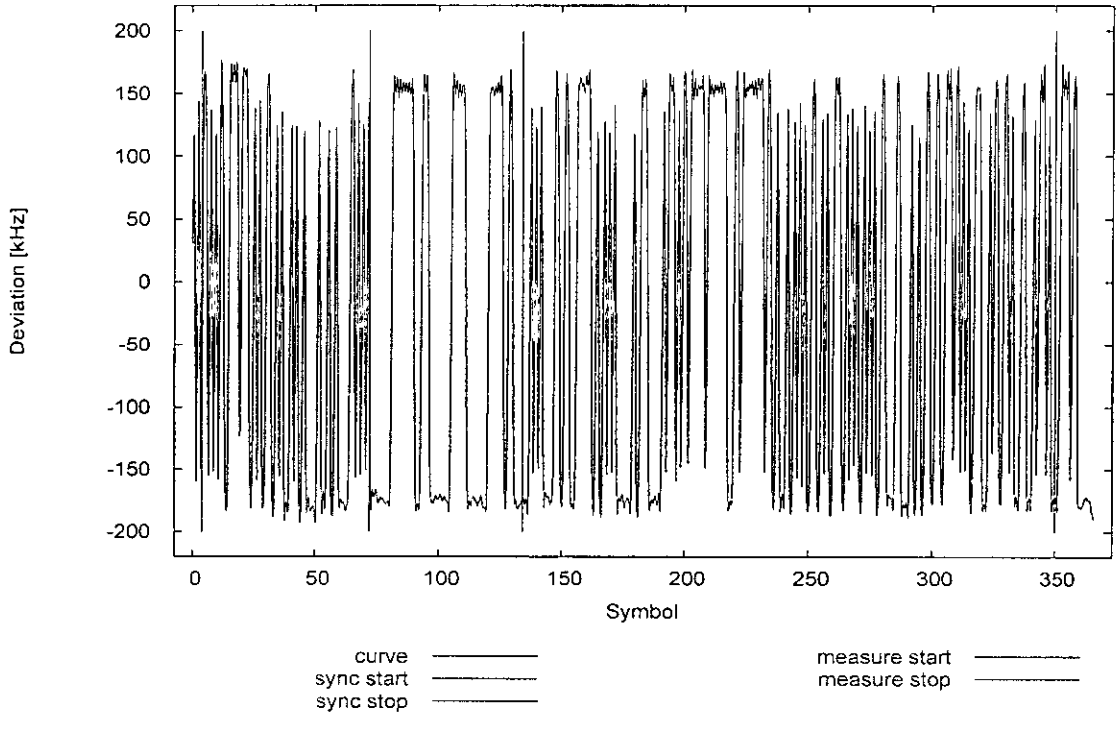
Packet Nr.	Freq [MHz]	Limit [kHz]		Value [kHz]		Limit [kHz]	Nominal [kHz]	VERDICT
1	2402	-75.000	<=	-11.125	<=	75.000	0.000000	PASS
2	2402	-75.000	<=	-17.152	<=	75.000	0.000000	PASS
3	2402	-75.000	<=	-12.359	<=	75.000	0.000000	PASS
4	2402	-75.000	<=	-19.345	<=	75.000	0.000000	PASS
5	2402	-75.000	<=	-13.110	<=	75.000	0.000000	PASS
6	2402	-75.000	<=	-14.459	<=	75.000	0.000000	PASS
7	2402	-75.000	<=	-13.882	<=	75.000	0.000000	PASS
8	2402	-75.000	<=	-16.798	<=	75.000	0.000000	PASS
9	2402	-75.000	<=	-13.366	<=	75.000	0.000000	PASS
10	2402	-75.000	<=	-15.743	<=	75.000	0.000000	PASS
1	2441	-75.000	<=	-15.487	<=	75.000	0.000000	PASS
2	2441	-75.000	<=	-16.026	<=	75.000	0.000000	PASS
3	2441	-75.000	<=	-15.762	<=	75.000	0.000000	PASS
4	2441	-75.000	<=	-14.029	<=	75.000	0.000000	PASS
5	2441	-75.000	<=	-13.039	<=	75.000	0.000000	PASS
6	2441	-75.000	<=	-13.989	<=	75.000	0.000000	PASS
7	2441	-75.000	<=	-14.551	<=	75.000	0.000000	PASS
8	2441	-75.000	<=	-18.038	<=	75.000	0.000000	PASS
9	2441	-75.000	<=	-16.111	<=	75.000	0.000000	PASS
10	2441	-75.000	<=	-13.000	<=	75.000	0.000000	PASS
1	2480	-75.000	<=	-15.692	<=	75.000	0.000000	PASS
2	2480	-75.000	<=	-15.166	<=	75.000	0.000000	PASS
3	2480	-75.000	<=	-18.226	<=	75.000	0.000000	PASS
4	2480	-75.000	<=	-17.556	<=	75.000	0.000000	PASS
5	2480	-75.000	<=	-17.991	<=	75.000	0.000000	PASS
6	2480	-75.000	<=	-19.012	<=	75.000	0.000000	PASS
7	2480	-75.000	<=	-11.990	<=	75.000	0.000000	PASS
8	2480	-75.000	<=	-14.505	<=	75.000	0.000000	PASS
9	2480	-75.000	<=	-18.343	<=	75.000	0.000000	PASS
10	2480	-75.000	<=	-19.761	<=	75.000	0.000000	PASS

Final Test Case Verdict . . . . . PASS 00:09:14

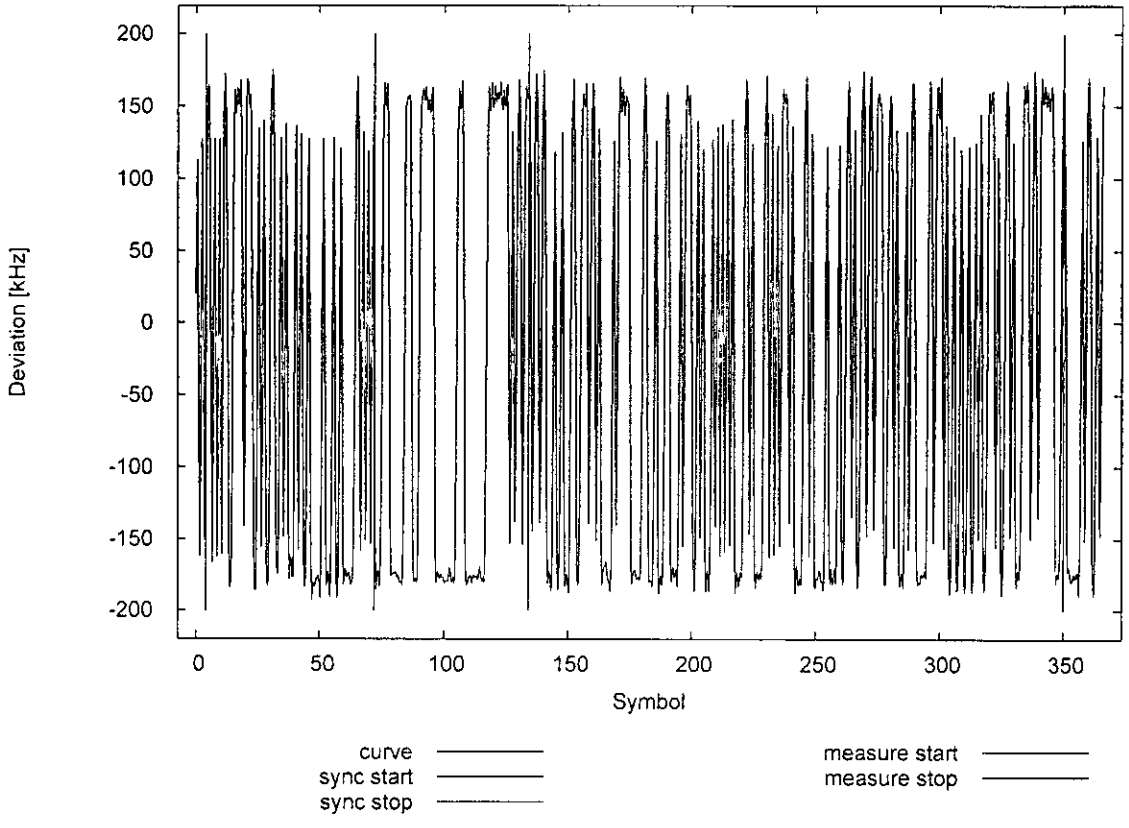
Measured Burst, FSK Signal TC Initial Carrier Frequency Tolerance packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2402.000 [MHz] - prbs9 pattern



Measured Burst, FSK Signal TC Initial Carrier Frequency Tolerance packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - prbs9 pattern



Measured Burst, FSK Signal TC Initial Carrier Frequency Tolerance packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - prbs9 pattern



Initial Carrier Frequency Tolerance

For system parameter see 0, "General Parameter 009"

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BT Test Specification Version:  1.2

TS Errata Request:              191
TS Errata Request:              277
```
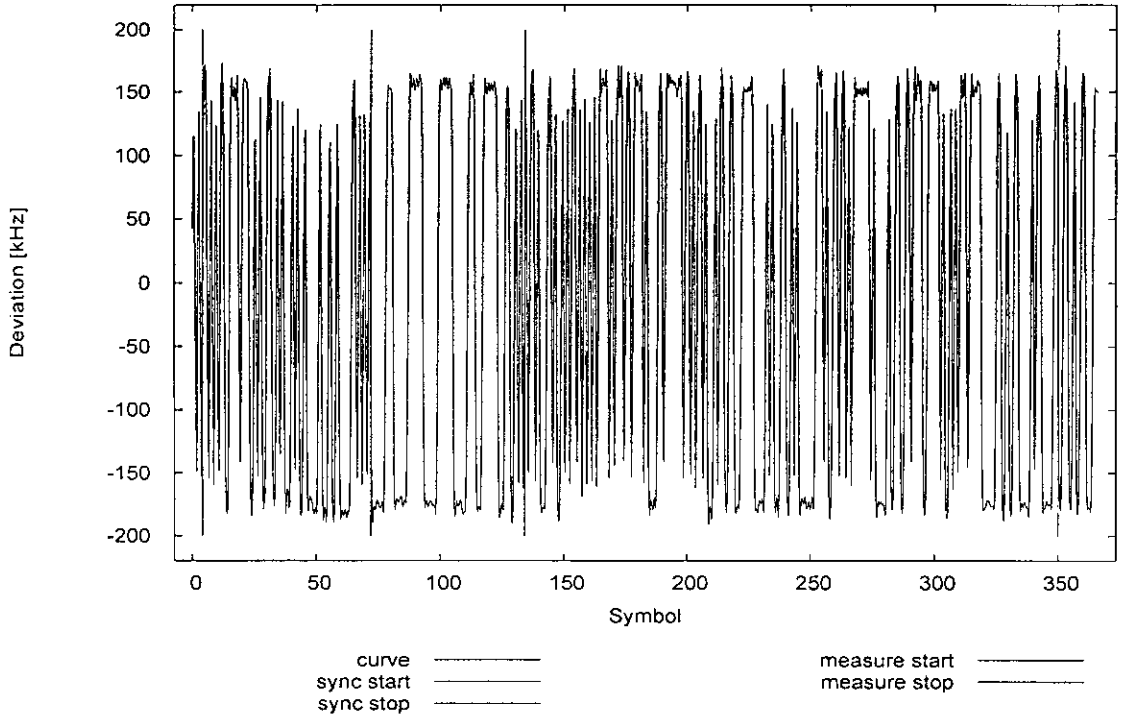

For EUT parameter see 0, "EUT Parameter 010"
For test case parameter see 0, "Test Case Parameter 049"

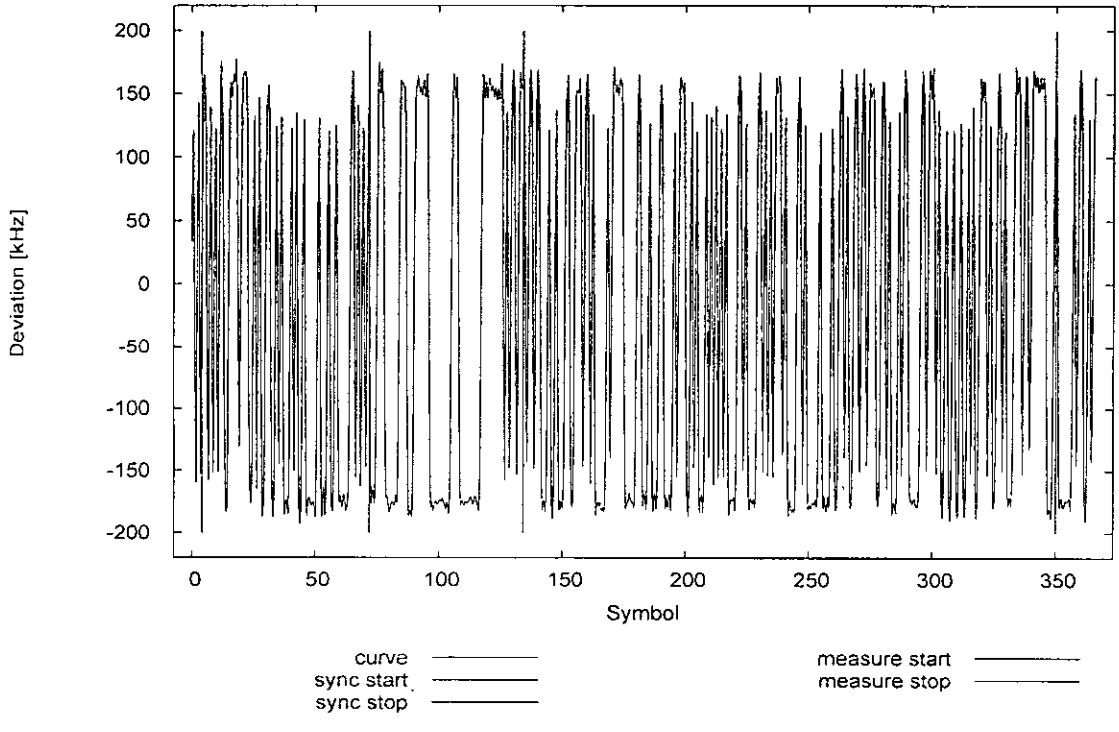
Packet Nr.	Freq [MHz]	Limit [kHz]		Value [kHz]		Limit [kHz]	Nominal [kHz]	VERDICT
1	2402	-75.000	<=	-11.287	<=	75.000	0.000000	PASS
2	2402	-75.000	<=	-14.206	<=	75.000	0.000000	PASS
3	2402	-75.000	<=	-13.251	<=	75.000	0.000000	PASS
4	2402	-75.000	<=	-14.411	<=	75.000	0.000000	PASS
5	2402	-75.000	<=	-15.346	<=	75.000	0.000000	PASS
6	2402	-75.000	<=	-12.717	<=	75.000	0.000000	PASS
7	2402	-75.000	<=	-15.145	<=	75.000	0.000000	PASS
8	2402	-75.000	<=	-13.883	<=	75.000	0.000000	PASS
9	2402	-75.000	<=	-14.434	<=	75.000	0.000000	PASS
10	2402	-75.000	<=	-11.773	<=	75.000	0.000000	PASS
1	2441	-75.000	<=	-12.864	<=	75.000	0.000000	PASS
2	2441	-75.000	<=	-15.914	<=	75.000	0.000000	PASS
3	2441	-75.000	<=	-14.161	<=	75.000	0.000000	PASS
4	2441	-75.000	<=	-12.533	<=	75.000	0.000000	PASS
5	2441	-75.000	<=	-14.407	<=	75.000	0.000000	PASS
6	2441	-75.000	<=	-17.205	<=	75.000	0.000000	PASS
7	2441	-75.000	<=	-16.027	<=	75.000	0.000000	PASS
8	2441	-75.000	<=	-14.304	<=	75.000	0.000000	PASS
9	2441	-75.000	<=	-15.652	<=	75.000	0.000000	PASS
10	2441	-75.000	<=	-14.721	<=	75.000	0.000000	PASS
1	2480	-75.000	<=	-19.485	<=	75.000	0.000000	PASS
2	2480	-75.000	<=	-16.788	<=	75.000	0.000000	PASS
3	2480	-75.000	<=	-14.047	<=	75.000	0.000000	PASS
4	2480	-75.000	<=	-19.126	<=	75.000	0.000000	PASS
5	2480	-75.000	<=	-18.847	<=	75.000	0.000000	PASS
6	2480	-75.000	<=	-19.780	<=	75.000	0.000000	PASS
7	2480	-75.000	<=	-11.149	<=	75.000	0.000000	PASS
8	2480	-75.000	<=	-16.411	<=	75.000	0.000000	PASS
9	2480	-75.000	<=	-12.105	<=	75.000	0.000000	PASS
10	2480	-75.000	<=	-16.536	<=	75.000	0.000000	PASS

Final Test Case Verdict . . . . . PASS 00:09:10

Measured Burst, FSK Signal TC Initial Carrier Frequency Tolerance packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2402.000 [MHz] - prbs9 pattern



Measured Burst, FSK Signal TC Initial Carrier Frequency Tolerance packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - prbs9 pattern



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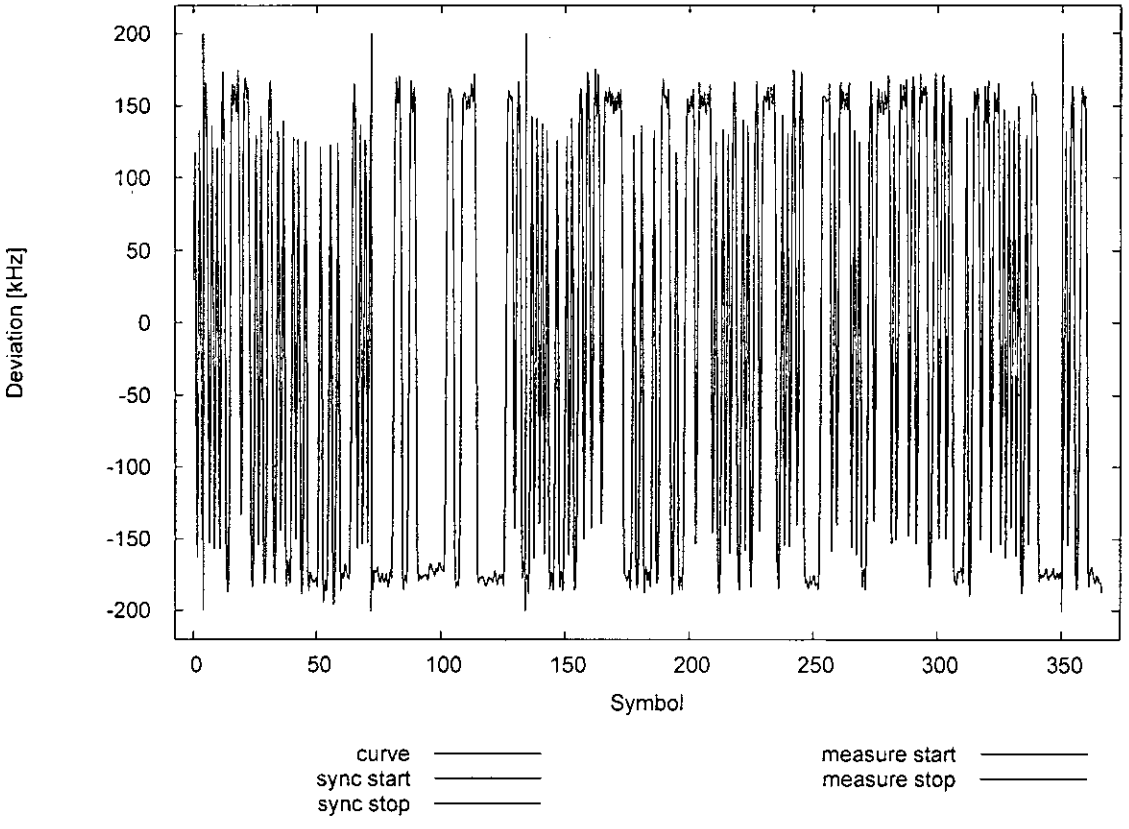
Measured Burst, FSK Signal TC Initial Carrier Frequency Tolerance packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - prbs9 pattern



Annex J

TRM/CA/09/C Carrier Frequency Drift

Carrier Frequency Drift

For system parameter see 0, "General Parameter 010"

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BT Test Specification Version:  1.2

TS Errata Request:              190
TS Errata Request:              277
```

For EUT parameter see 0, "EUT Parameter 002"
For test case parameter see 0, "Test Case Parameter 010"

Packet Nr.	Type	Freq [MHz]	Max Drift [kHz]		LIMIT [kHz]	Max Gradient [Hz/50us]		LIMIT [Hz/50us]	VERDICT
1	DH1	2402	5.171	<=	25.000				PASS
1	DH1	2402				2456.09	<=	20000.000	PASS
2	DH1	2402	8.000	<=	25.000				PASS
2	DH1	2402				3680.76	<=	20000.000	PASS
3	DH1	2402	3.320	<=	25.000				PASS
3	DH1	2402				3121.01	<=	20000.000	PASS
4	DH1	2402	5.000	<=	25.000				PASS
4	DH1	2402				4402.34	<=	20000.000	PASS
5	DH1	2402	6.091	<=	25.000				PASS
5	DH1	2402				4080.34	<=	20000.000	PASS
6	DH1	2402	4.360	<=	25.000				PASS
6	DH1	2402				2819.70	<=	20000.000	PASS
7	DH1	2402	3.486	<=	25.000				PASS
7	DH1	2402				4138.63	<=	20000.000	PASS
8	DH1	2402	7.257	<=	25.000				PASS
8	DH1	2402				2555.69	<=	20000.000	PASS
9	DH1	2402	8.221	<=	25.000				PASS
9	DH1	2402				3649.67	<=	20000.000	PASS
10	DH1	2402	7.479	<=	25.000				PASS
10	DH1	2402				3823.55	<=	20000.000	PASS
1	DH1	2441	5.748	<=	25.000				PASS
1	DH1	2441				5279.03	<=	20000.000	PASS
2	DH1	2441	5.997	<=	25.000				PASS
2	DH1	2441				4134.50	<=	20000.000	PASS
3	DH1	2441	8.410	<=	25.000				PASS
3	DH1	2441				3505.57	<=	20000.000	PASS
4	DH1	2441	3.462	<=	25.000				PASS
4	DH1	2441				3874.34	<=	20000.000	PASS
5	DH1	2441	6.774	<=	25.000				PASS
5	DH1	2441				2205.44	<=	20000.000	PASS
6	DH1	2441	4.053	<=	25.000				PASS
6	DH1	2441				6692.87	<=	20000.000	PASS
7	DH1	2441	7.089	<=	25.000				PASS
7	DH1	2441				3647.30	<=	20000.000	PASS
8	DH1	2441	5.816	<=	25.000				PASS
8	DH1	2441				2658.17	<=	20000.000	PASS
9	DH1	2441	7.609	<=	25.000				PASS
9	DH1	2441				1976.19	<=	20000.000	PASS
10	DH1	2441	9.489	<=	25.000				PASS
10	DH1	2441				2670.33	<=	20000.000	PASS
1	DH1	2480	5.504	<=	25.000				PASS
1	DH1	2480				3193.24	<=	20000.000	PASS
2	DH1	2480	4.653	<=	25.000				PASS
2	DH1	2480				3344.87	<=	20000.000	PASS
3	DH1	2480	8.111	<=	25.000				PASS
3	DH1	2480				2748.64	<=	20000.000	PASS

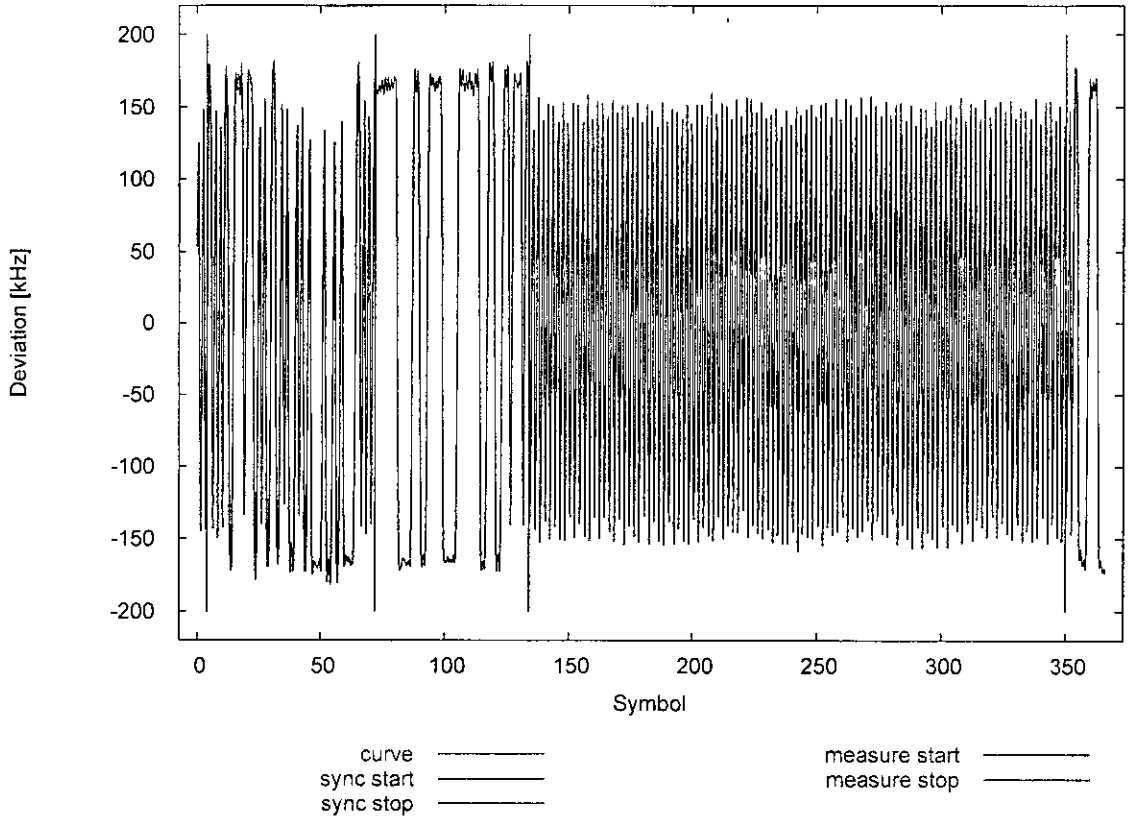
4	DH1	2480	5.558	<=	25.000				PASS
4	DH1	2480				3245.20	<=	20000.000	PASS
5	DH1	2480	5.711	<=	25.000				PASS
5	DH1	2480				3846.07	<=	20000.000	PASS
6	DH1	2480	5.993	<=	25.000				PASS
6	DH1	2480				2331.73	<=	20000.000	PASS
7	DH1	2480	7.052	<=	25.000				PASS
7	DH1	2480				3403.52	<=	20000.000	PASS
8	DH1	2480	8.957	<=	25.000				PASS
8	DH1	2480				3431.46	<=	20000.000	PASS
9	DH1	2480	5.507	<=	25.000				PASS
9	DH1	2480				3848.27	<=	20000.000	PASS
10	DH1	2480	5.778	<=	25.000				PASS
10	DH1	2480				3532.69	<=	20000.000	PASS
1	DH3	2402	5.083	<=	40.000				PASS
1	DH3	2402				4447.28	<=	20000.000	PASS
2	DH3	2402	9.472	<=	40.000				PASS
2	DH3	2402				4256.77	<=	20000.000	PASS
3	DH3	2402	13.128	<=	40.000				PASS
3	DH3	2402				8223.03	<=	20000.000	PASS
4	DH3	2402	3.677	<=	40.000				PASS
4	DH3	2402				4553.10	<=	20000.000	PASS
5	DH3	2402	5.466	<=	40.000				PASS
5	DH3	2402				5524.03	<=	20000.000	PASS
6	DH3	2402	5.606	<=	40.000				PASS
6	DH3	2402				5101.79	<=	20000.000	PASS
7	DH3	2402	10.862	<=	40.000				PASS
7	DH3	2402				4171.14	<=	20000.000	PASS
8	DH3	2402	7.153	<=	40.000				PASS
8	DH3	2402				5868.89	<=	20000.000	PASS
9	DH3	2402	8.808	<=	40.000				PASS
9	DH3	2402				5586.14	<=	20000.000	PASS
10	DH3	2402	8.043	<=	40.000				PASS
10	DH3	2402				5329.51	<=	20000.000	PASS
1	DH3	2441	3.183	<=	40.000				PASS
1	DH3	2441				3938.83	<=	20000.000	PASS
2	DH3	2441	5.776	<=	40.000				PASS
2	DH3	2441				5152.12	<=	20000.000	PASS
3	DH3	2441	8.414	<=	40.000				PASS
3	DH3	2441				6055.49	<=	20000.000	PASS
4	DH3	2441	7.689	<=	40.000				PASS
4	DH3	2441				3767.97	<=	20000.000	PASS
5	DH3	2441	7.402	<=	40.000				PASS
5	DH3	2441				5005.07	<=	20000.000	PASS
6	DH3	2441	7.866	<=	40.000				PASS
6	DH3	2441				4385.91	<=	20000.000	PASS
7	DH3	2441	7.130	<=	40.000				PASS
7	DH3	2441				4588.48	<=	20000.000	PASS
8	DH3	2441	6.129	<=	40.000				PASS
8	DH3	2441				4734.09	<=	20000.000	PASS
9	DH3	2441	7.752	<=	40.000				PASS
9	DH3	2441				4592.80	<=	20000.000	PASS
10	DH3	2441	9.335	<=	40.000				PASS
10	DH3	2441				4891.70	<=	20000.000	PASS
1	DH3	2480	3.512	<=	40.000				PASS
1	DH3	2480				4417.80	<=	20000.000	PASS
2	DH3	2480	5.543	<=	40.000				PASS
2	DH3	2480				4462.51	<=	20000.000	PASS
3	DH3	2480	4.503	<=	40.000				PASS
3	DH3	2480				5066.78	<=	20000.000	PASS
4	DH3	2480	6.234	<=	40.000				PASS
4	DH3	2480				3979.15	<=	20000.000	PASS
5	DH3	2480	6.820	<=	40.000				PASS
5	DH3	2480				6229.63	<=	20000.000	PASS
6	DH3	2480	5.402	<=	40.000				PASS

6	DH3	2480				5397.98	<= 20000.000	PASS
7	DH3	2480	5.638	<=	40.000			PASS
7	DH3	2480				5203.89	<= 20000.000	PASS
8	DH3	2480	9.566	<=	40.000			PASS
8	DH3	2480				6989.01	<= 20000.000	PASS
9	DH3	2480	4.189	<=	40.000			PASS
9	DH3	2480				5198.84	<= 20000.000	PASS
10	DH3	2480	3.646	<=	40.000			PASS
10	DH3	2480				5059.30	<= 20000.000	PASS
1	DH5	2402	8.936	<=	40.000			PASS
1	DH5	2402				4897.27	<= 20000.000	PASS
2	DH5	2402	9.731	<=	40.000			PASS
2	DH5	2402				5075.02	<= 20000.000	PASS
3	DH5	2402	6.998	<=	40.000			PASS
3	DH5	2402				4536.13	<= 20000.000	PASS
4	DH5	2402	7.055	<=	40.000			PASS
4	DH5	2402				5851.25	<= 20000.000	PASS
5	DH5	2402	8.805	<=	40.000			PASS
5	DH5	2402				9225.51	<= 20000.000	PASS
6	DH5	2402	8.603	<=	40.000			PASS
6	DH5	2402				4662.80	<= 20000.000	PASS
7	DH5	2402	4.656	<=	40.000			PASS
7	DH5	2402				3720.04	<= 20000.000	PASS
8	DH5	2402	7.607	<=	40.000			PASS
8	DH5	2402				4838.05	<= 20000.000	PASS
9	DH5	2402	9.602	<=	40.000			PASS
9	DH5	2402				5203.93	<= 20000.000	PASS
10	DH5	2402	5.064	<=	40.000			PASS
10	DH5	2402				5399.85	<= 20000.000	PASS
1	DH5	2441	7.565	<=	40.000			PASS
1	DH5	2441				5922.84	<= 20000.000	PASS
2	DH5	2441	7.524	<=	40.000			PASS
2	DH5	2441				4407.60	<= 20000.000	PASS
3	DH5	2441	5.457	<=	40.000			PASS
3	DH5	2441				5151.45	<= 20000.000	PASS
4	DH5	2441	7.189	<=	40.000			PASS
4	DH5	2441				4946.66	<= 20000.000	PASS
5	DH5	2441	7.227	<=	40.000			PASS
5	DH5	2441				5843.73	<= 20000.000	PASS
6	DH5	2441	6.919	<=	40.000			PASS
6	DH5	2441				4891.77	<= 20000.000	PASS
7	DH5	2441	8.916	<=	40.000			PASS
7	DH5	2441				4774.58	<= 20000.000	PASS
8	DH5	2441	6.196	<=	40.000			PASS
8	DH5	2441				5421.99	<= 20000.000	PASS
9	DH5	2441	7.390	<=	40.000			PASS
9	DH5	2441				5308.45	<= 20000.000	PASS
10	DH5	2441	7.131	<=	40.000			PASS
10	DH5	2441				5417.48	<= 20000.000	PASS
1	DH5	2480	9.989	<=	40.000			PASS
1	DH5	2480				5827.01	<= 20000.000	PASS
2	DH5	2480	9.801	<=	40.000			PASS
2	DH5	2480				7213.34	<= 20000.000	PASS
3	DH5	2480	12.286	<=	40.000			PASS
3	DH5	2480				5534.62	<= 20000.000	PASS
4	DH5	2480	8.074	<=	40.000			PASS
4	DH5	2480				8314.63	<= 20000.000	PASS
5	DH5	2480	8.643	<=	40.000			PASS
5	DH5	2480				5545.08	<= 20000.000	PASS
6	DH5	2480	5.959	<=	40.000			PASS
6	DH5	2480				5421.69	<= 20000.000	PASS
7	DH5	2480	11.520	<=	40.000			PASS
7	DH5	2480				7189.25	<= 20000.000	PASS
8	DH5	2480	7.852	<=	40.000			PASS
8	DH5	2480				5693.50	<= 20000.000	PASS

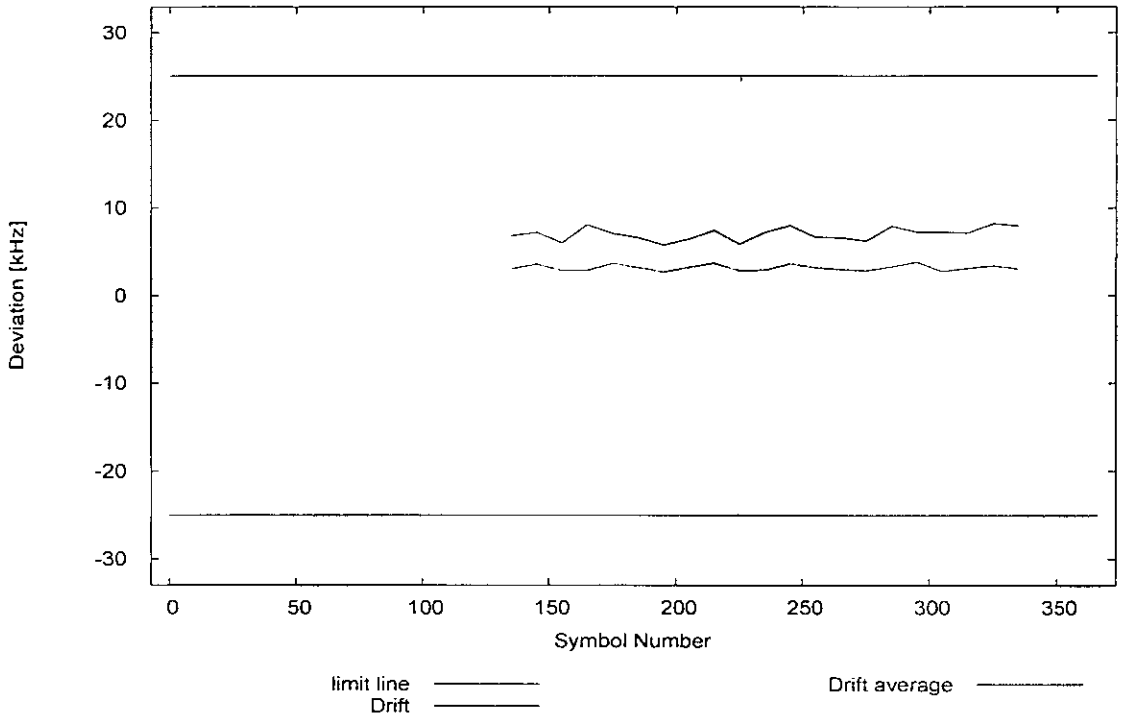
9	DH5	2480	6.009	<=	40.000			PASS
9	DH5	2480				5820.81	<= 20000.000	PASS
10	DH5	2480	5.817	<=	40.000			PASS
10	DH5	2480				5139.56	<= 20000.000	PASS

Final Test Case Verdict . . . . . PASS 00:31:48

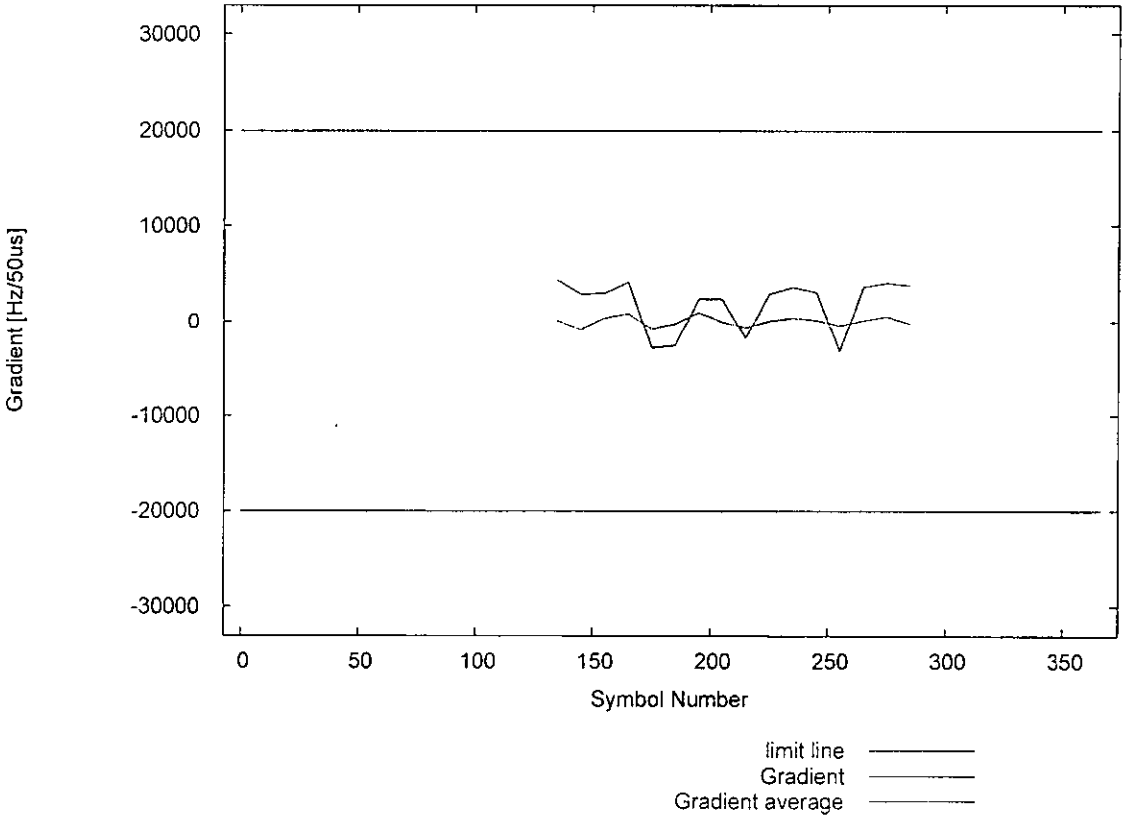
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH1 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern



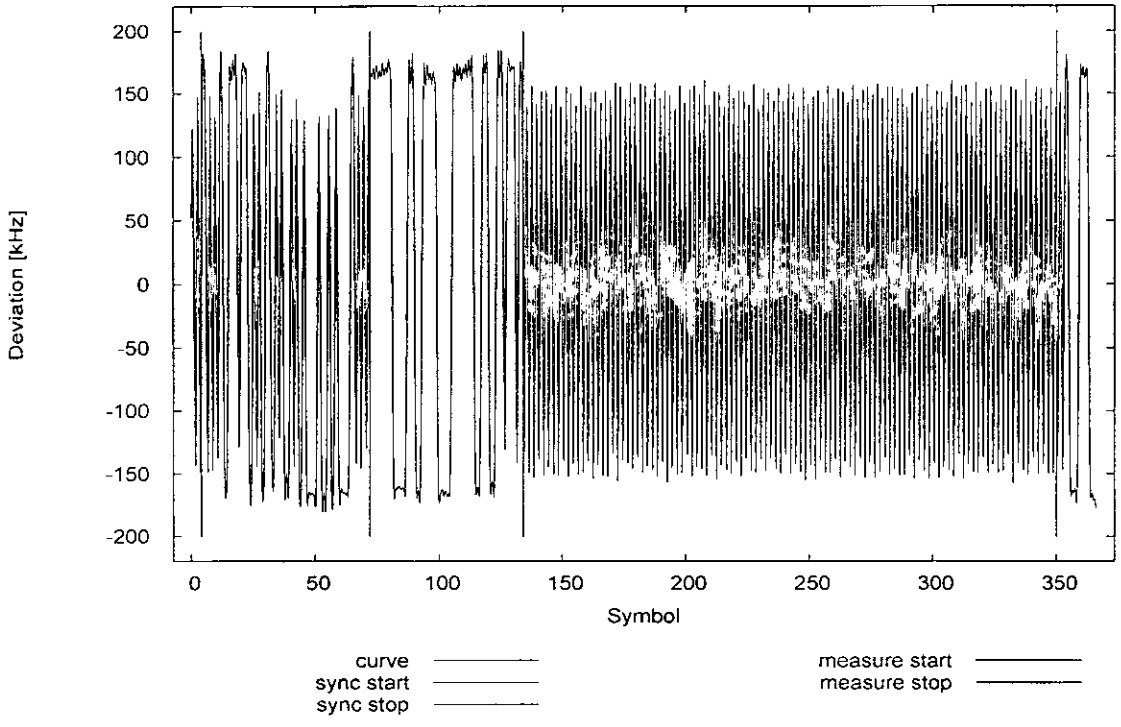
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2402.000 MHz



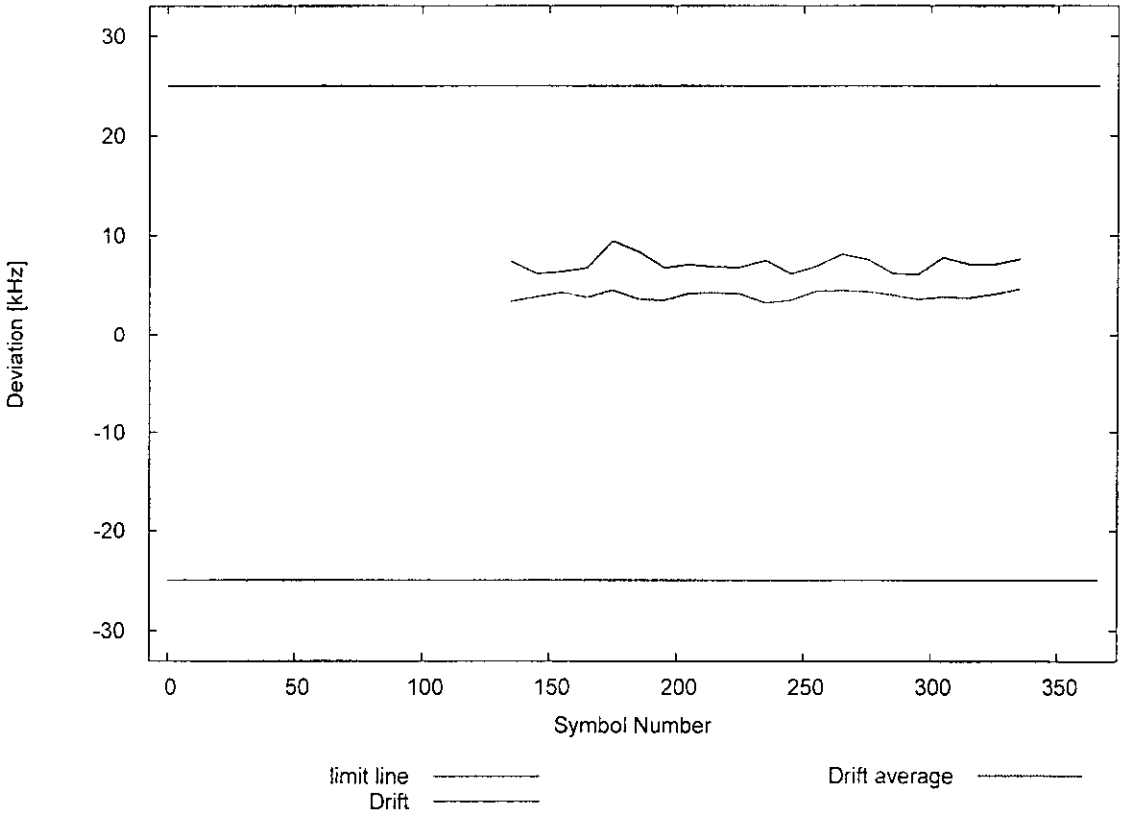
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2402.000 MHz



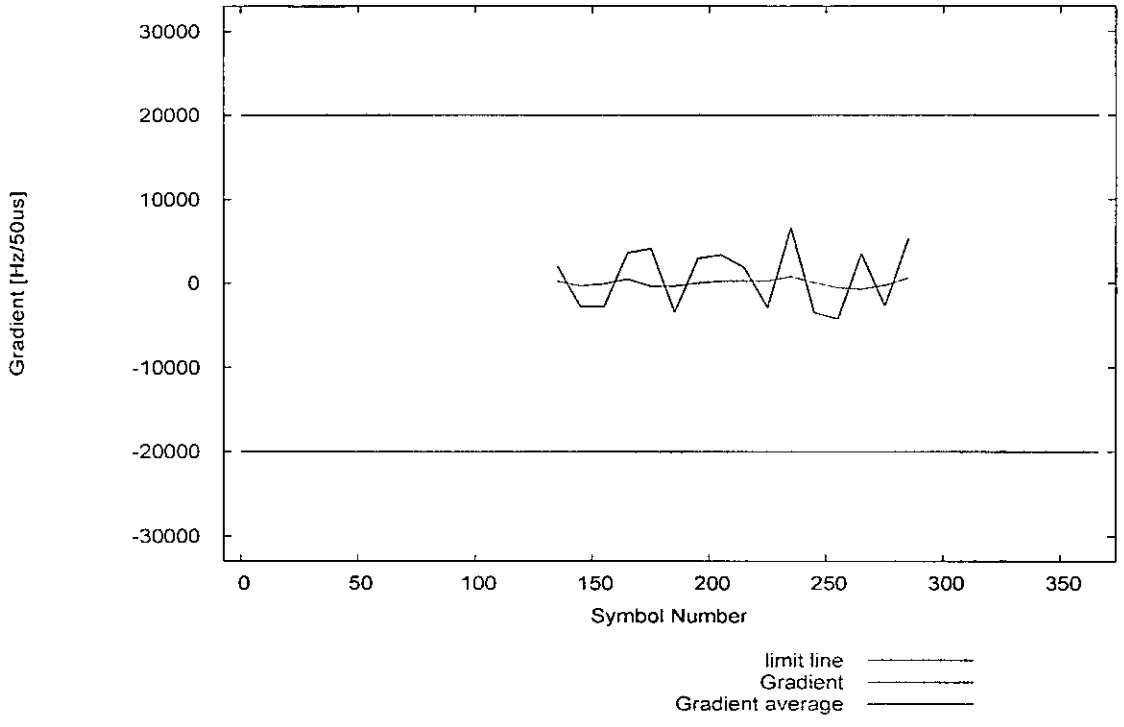
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern



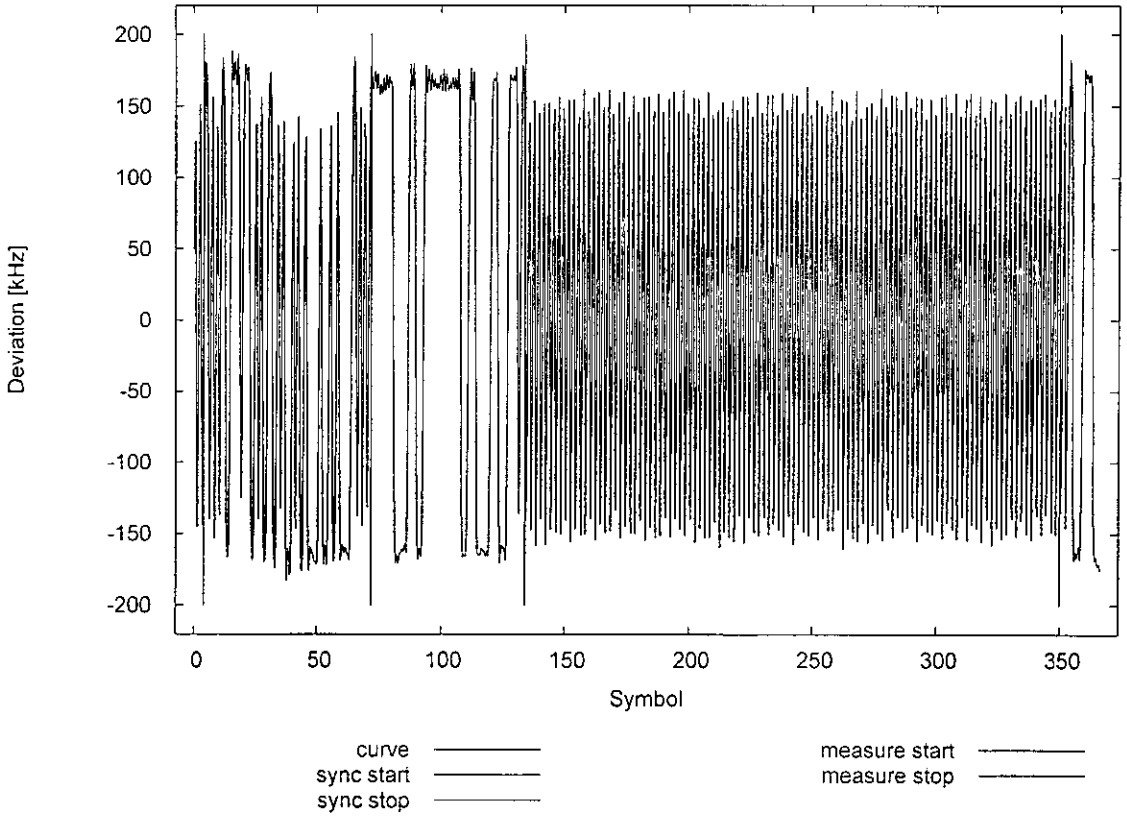
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2441.000 MHz



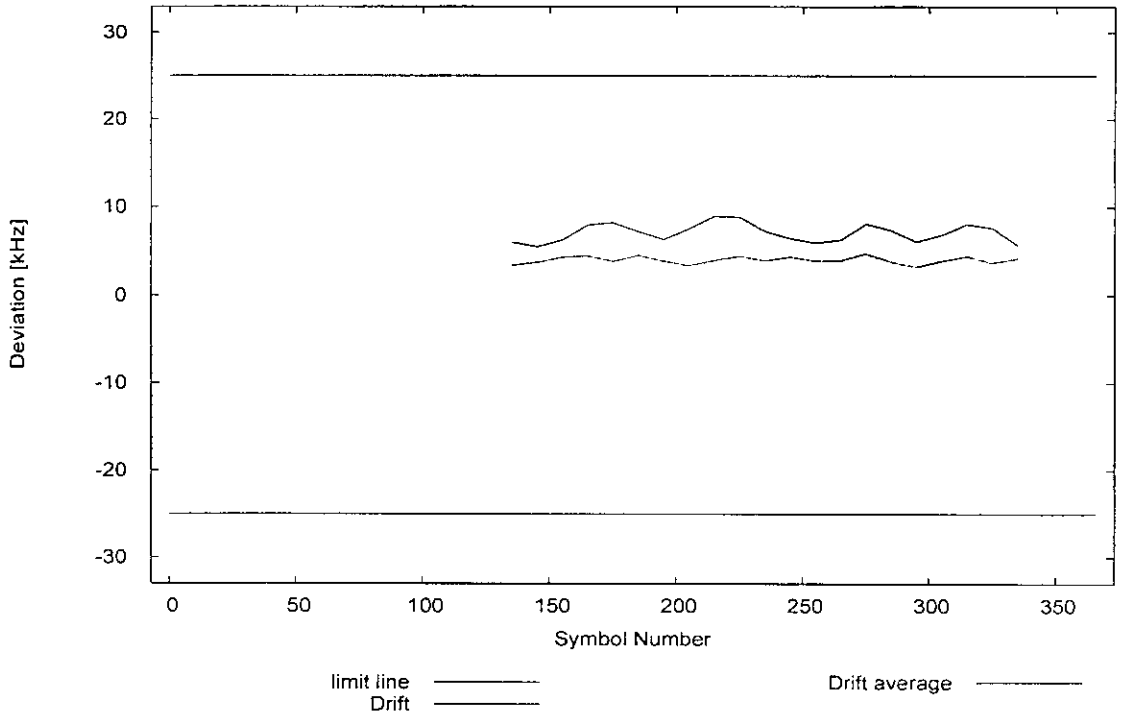
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2441.000 MHz



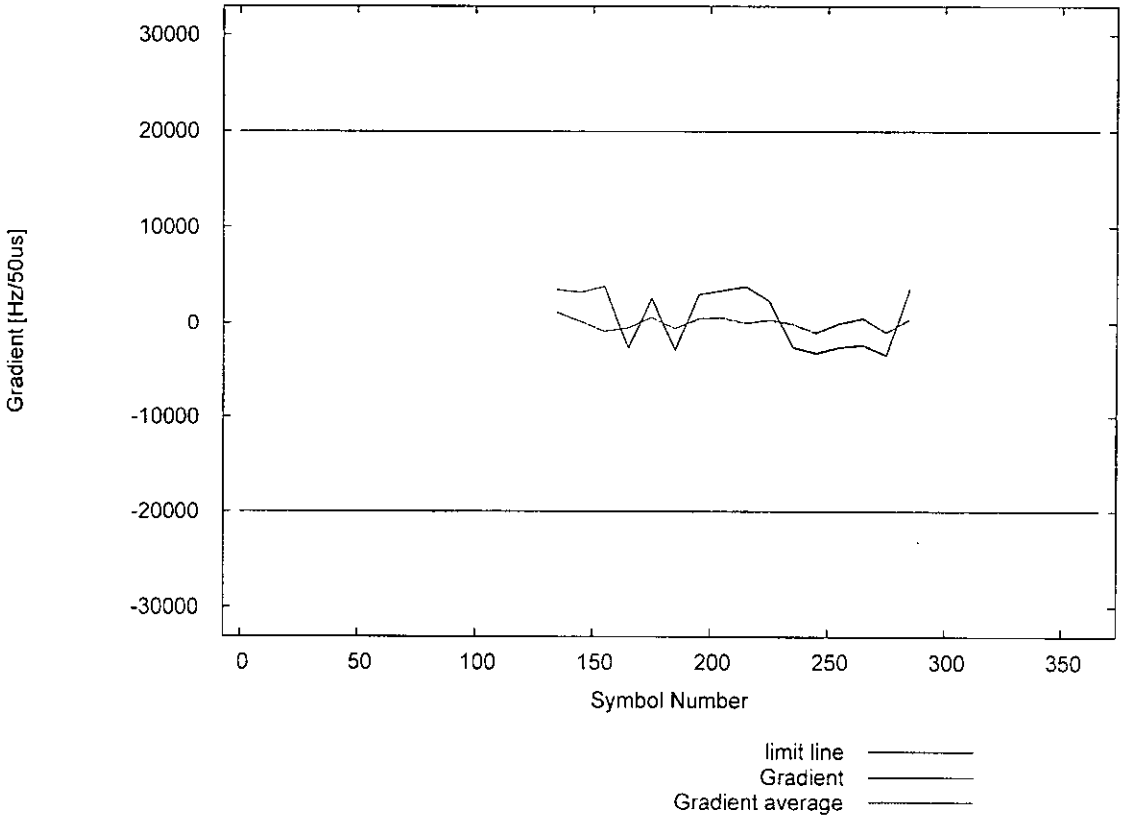
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern



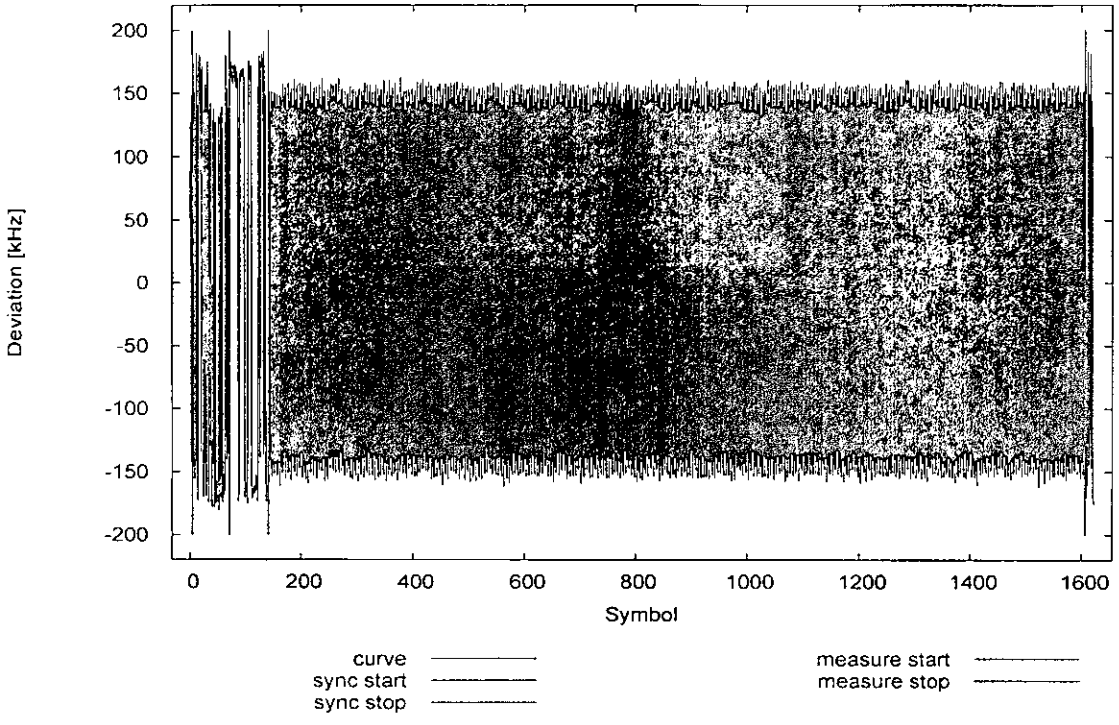
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2480.000 MHz



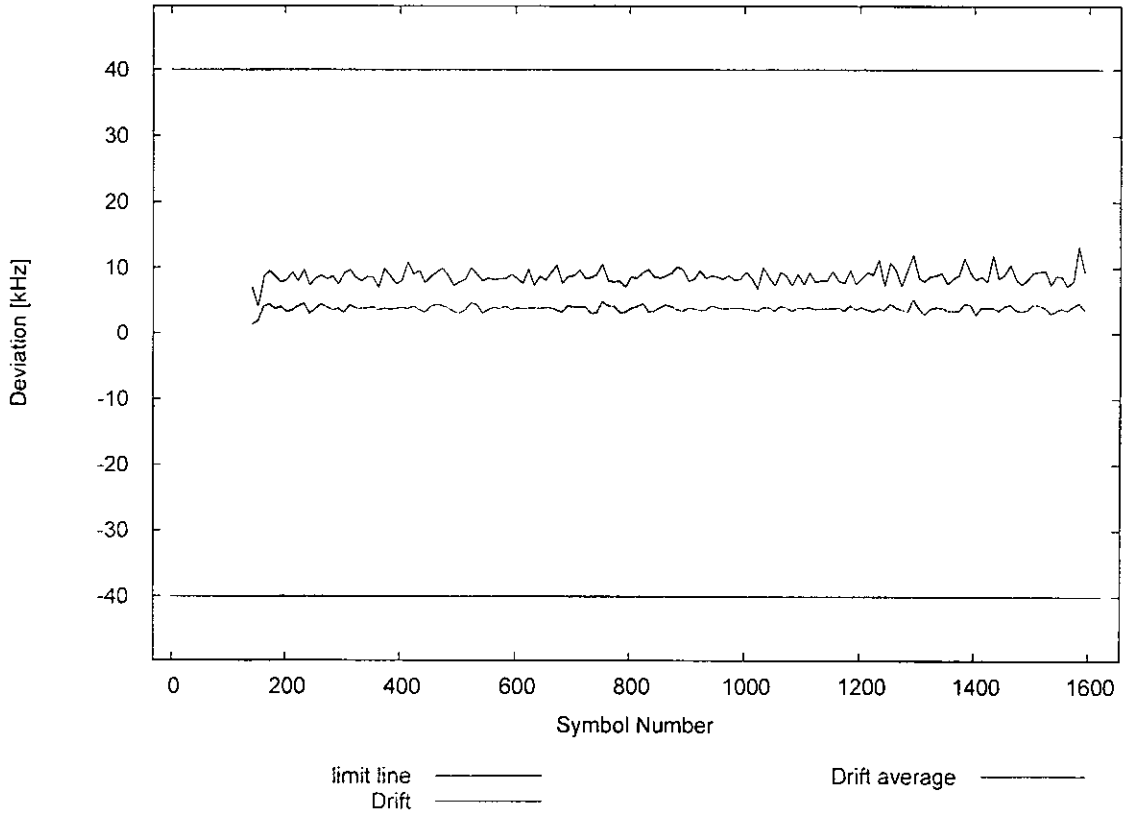
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2480.000 MHz



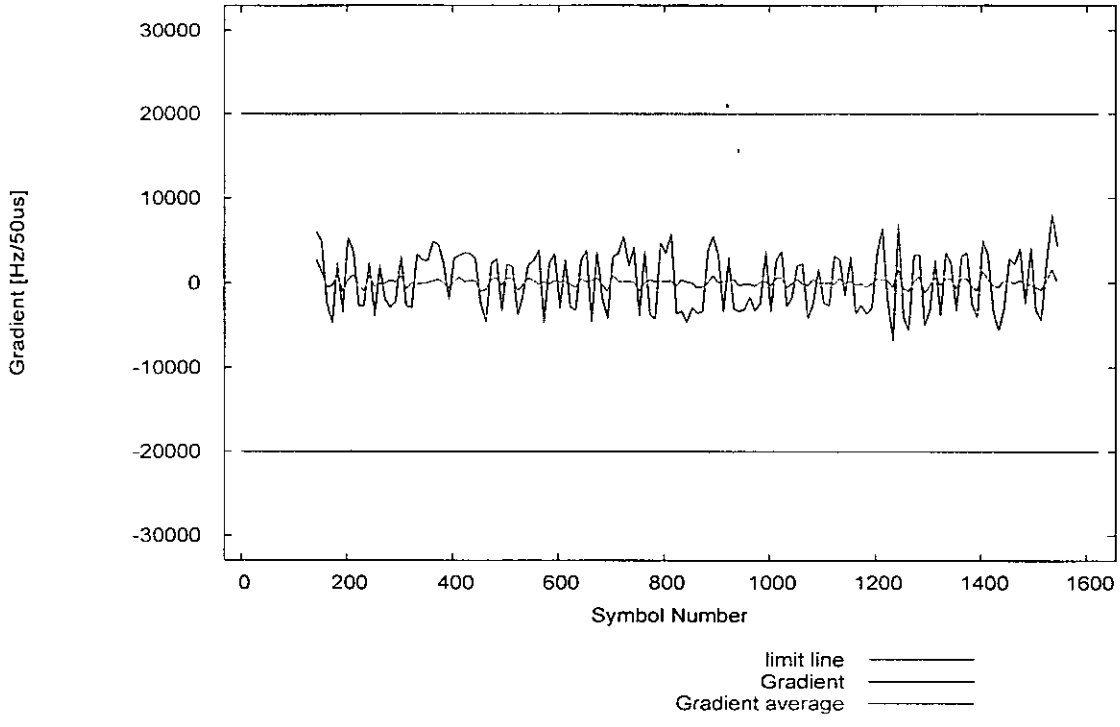
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern



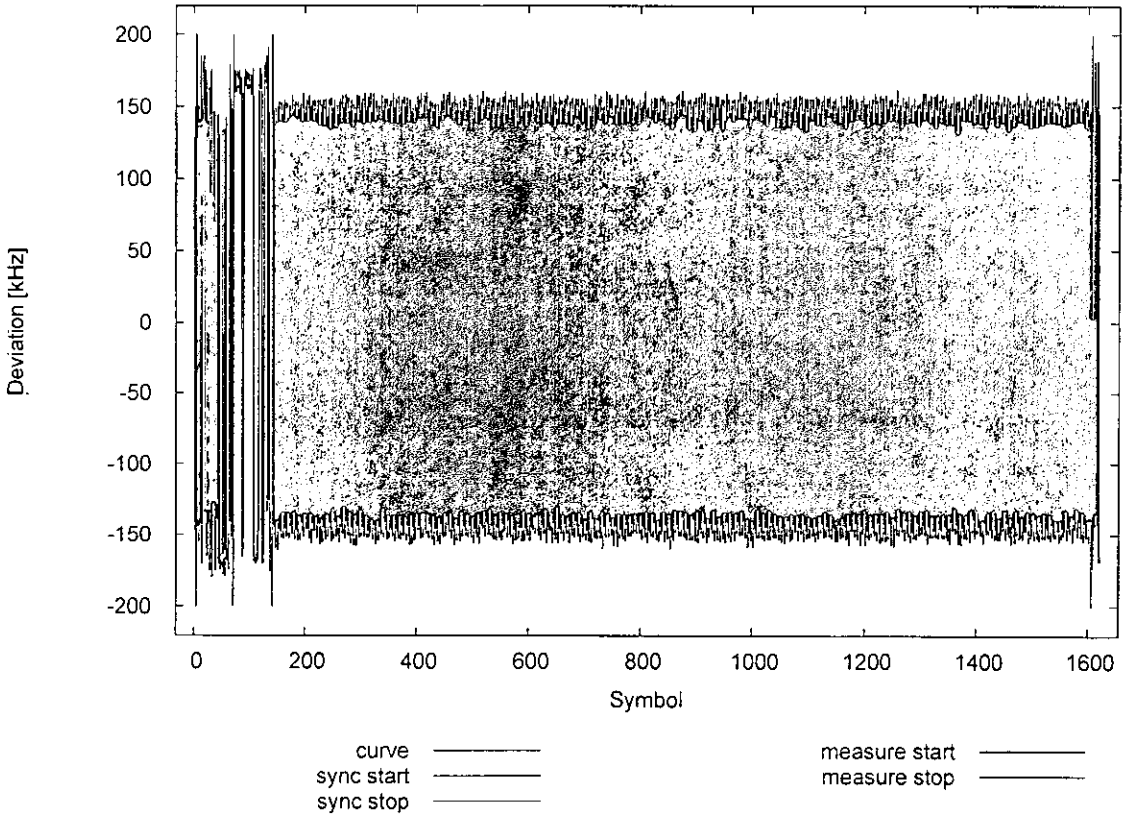
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2402.000 MHz



TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2402.000 MHz

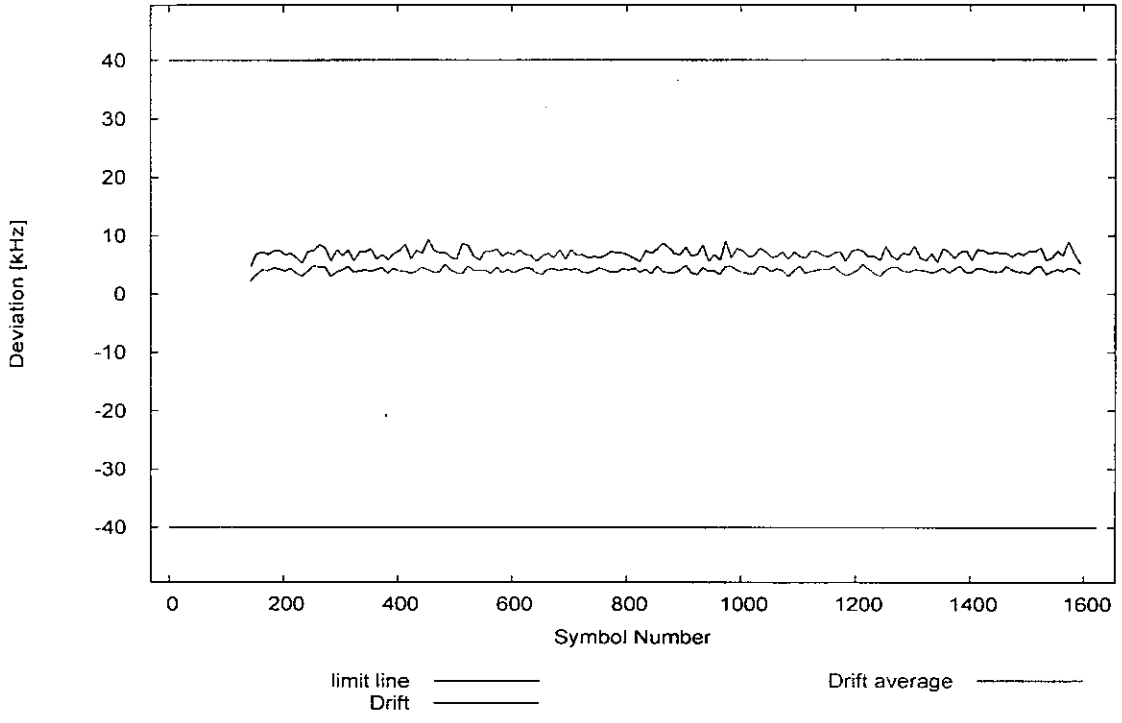


Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern

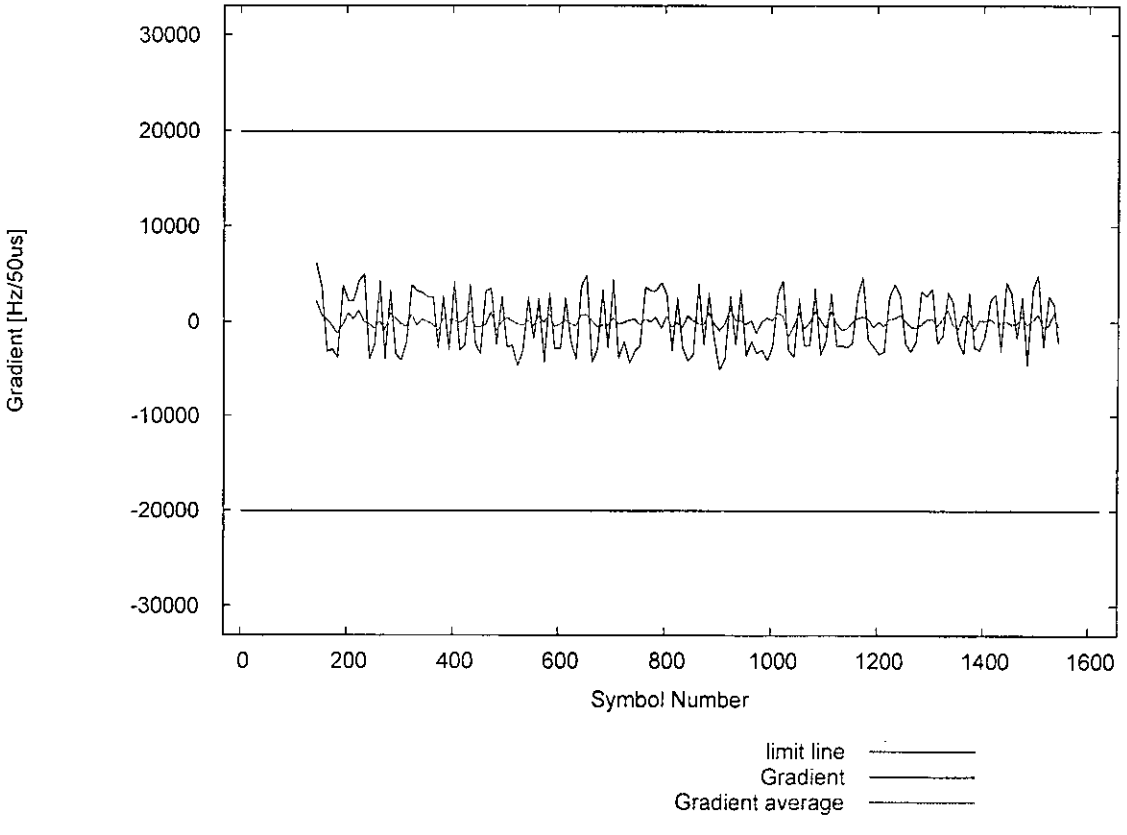


1134

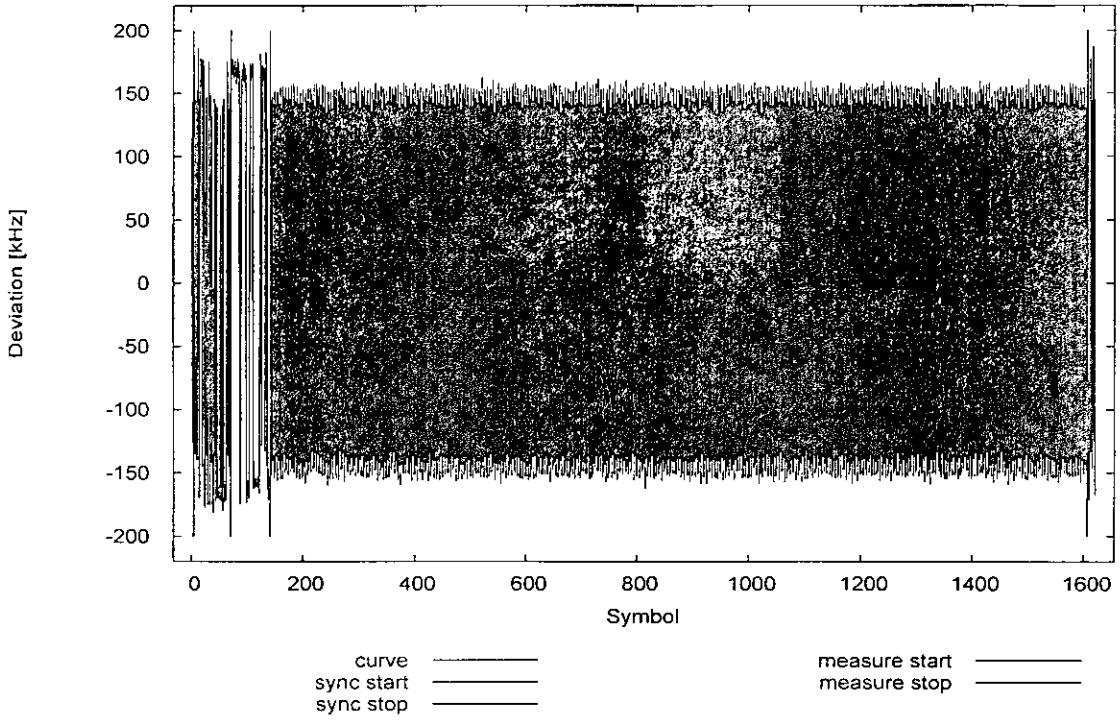
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2441.000 MHz



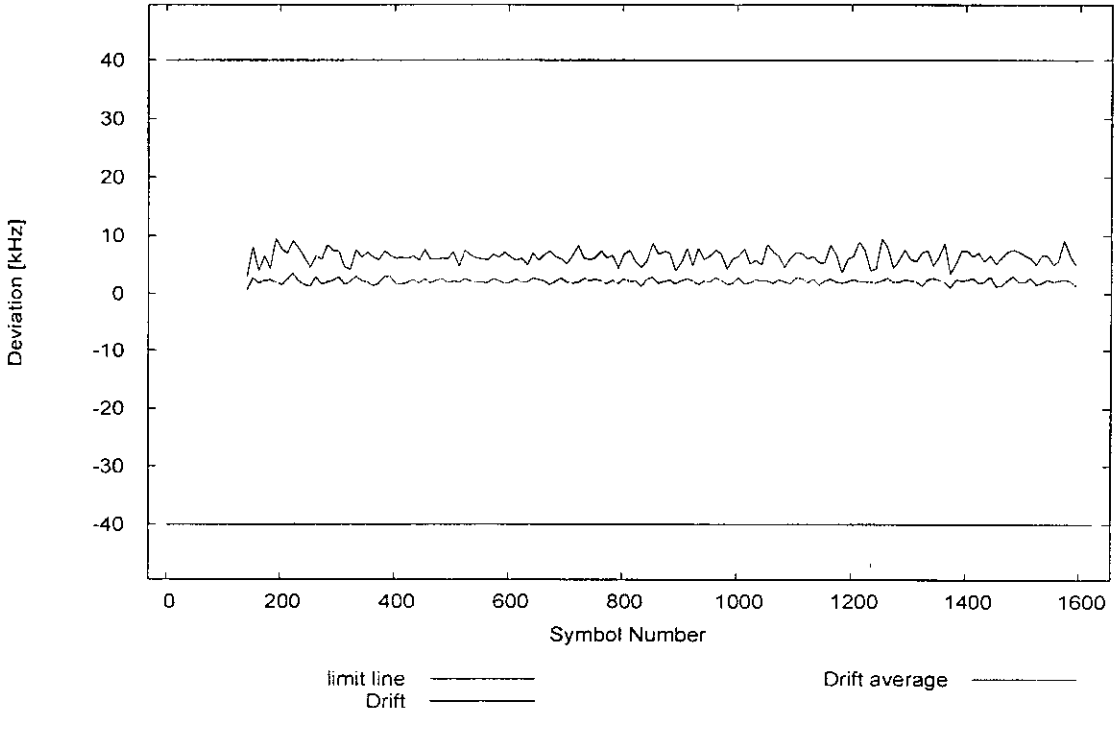
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2441.000 MHz



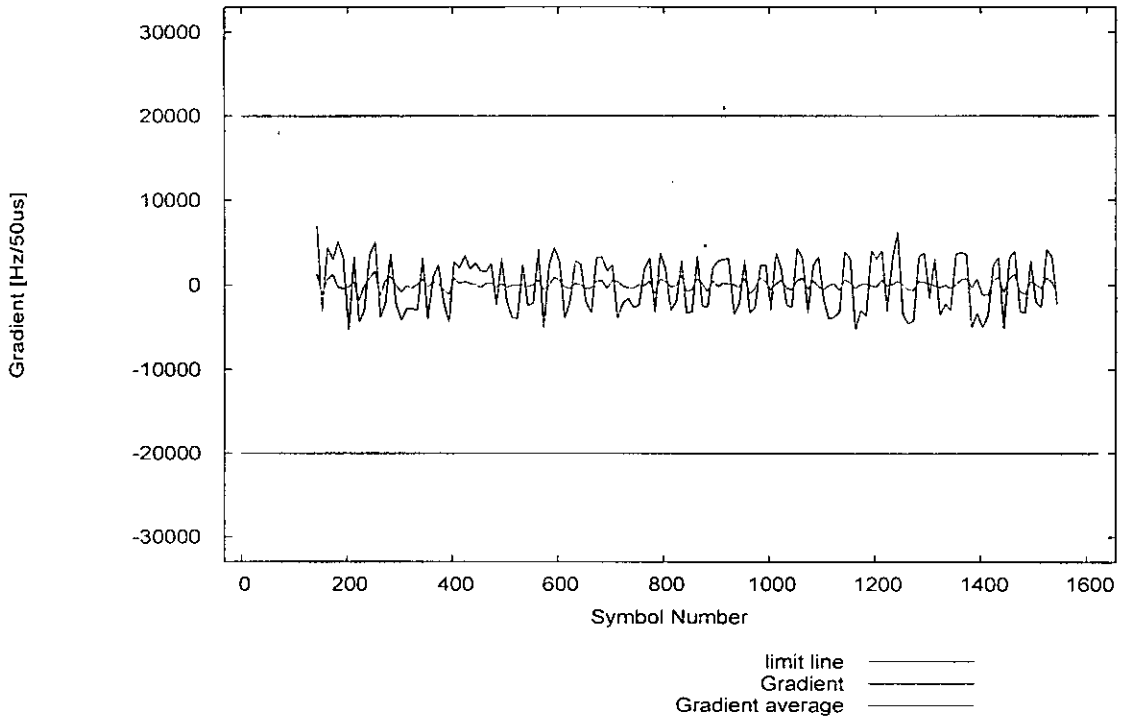
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern



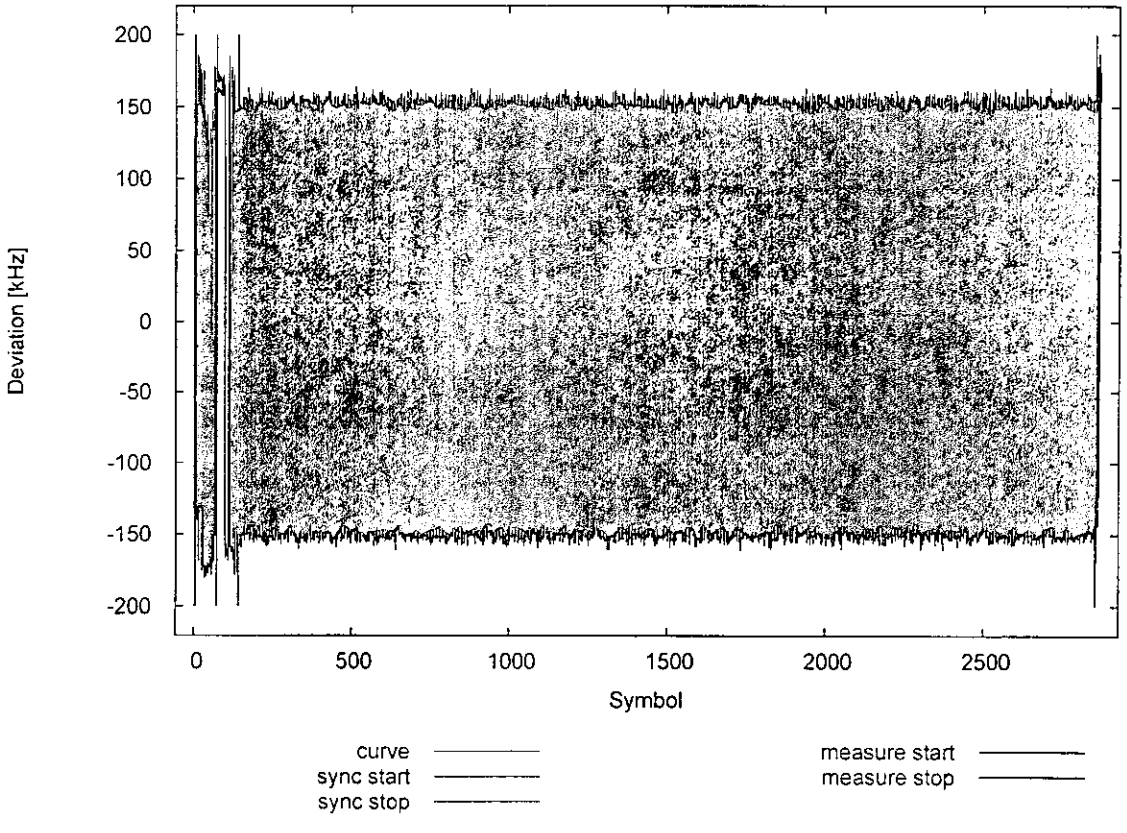
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2480.000 MHz



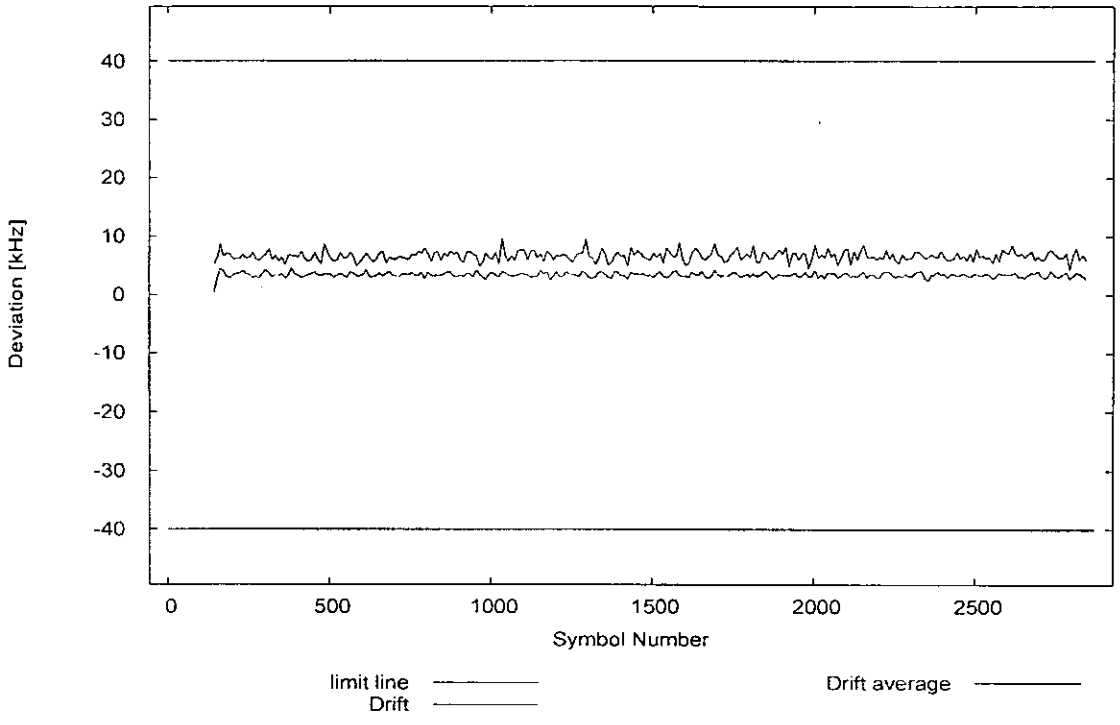
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2480.000 MHz



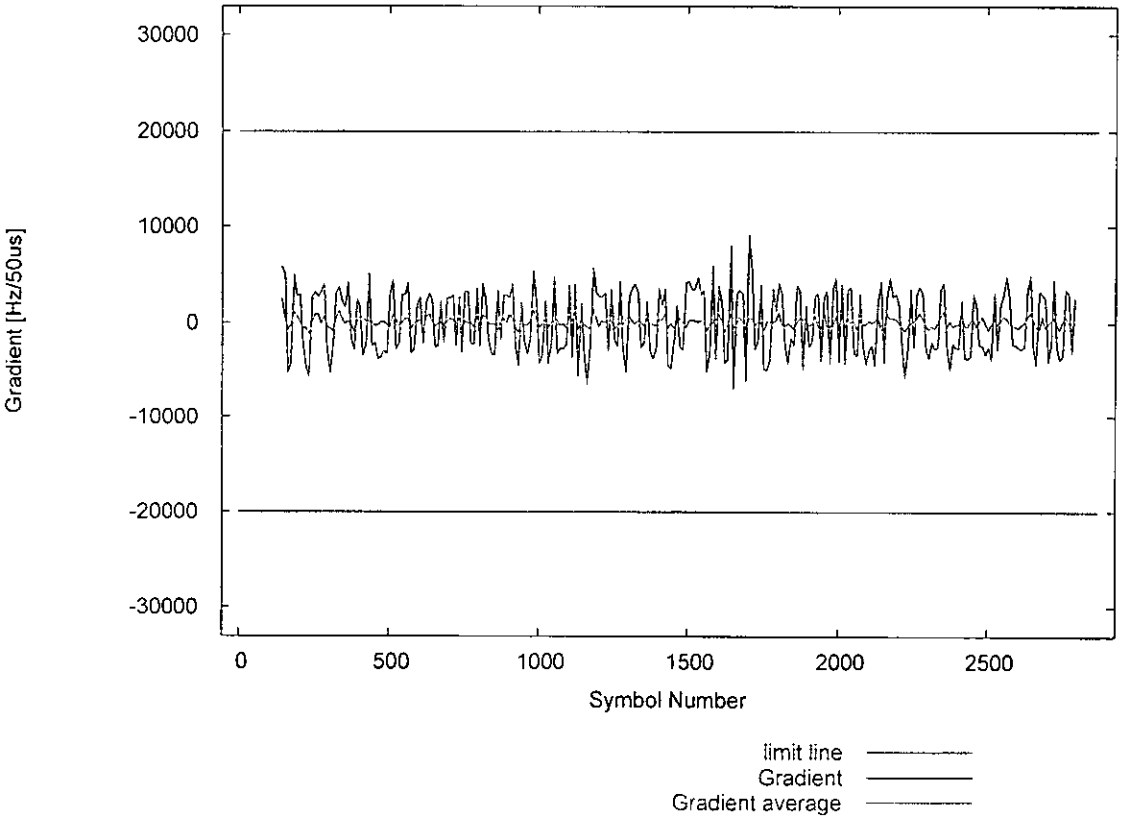
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern



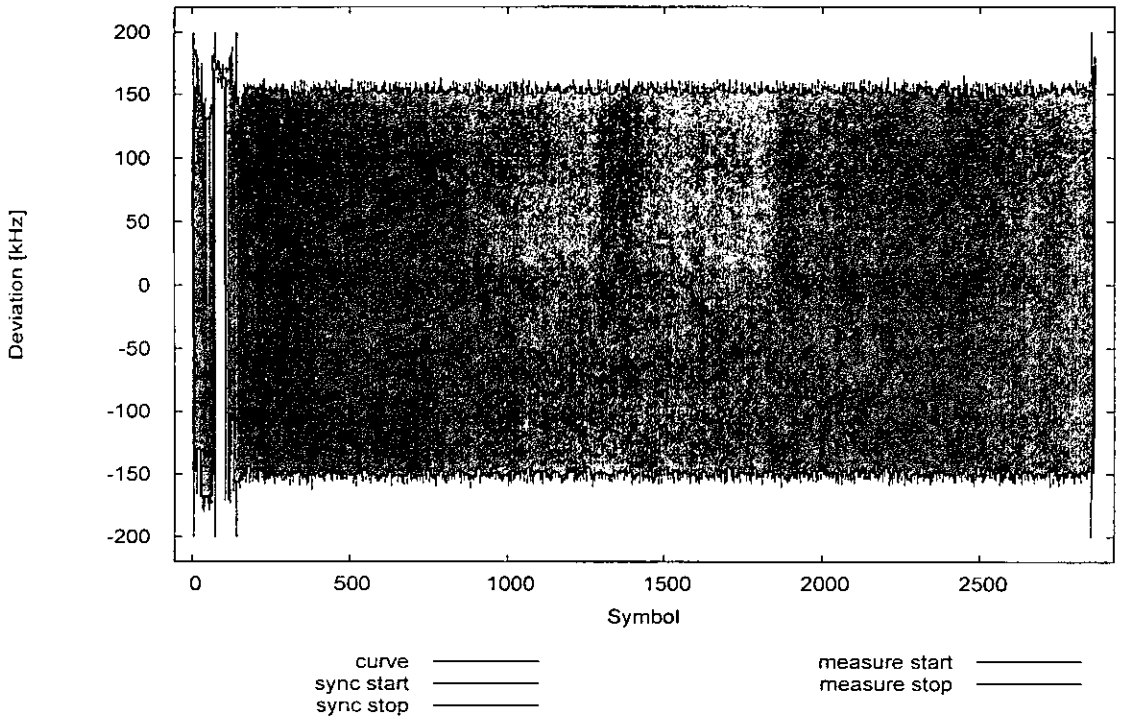
TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2402.000 MHz



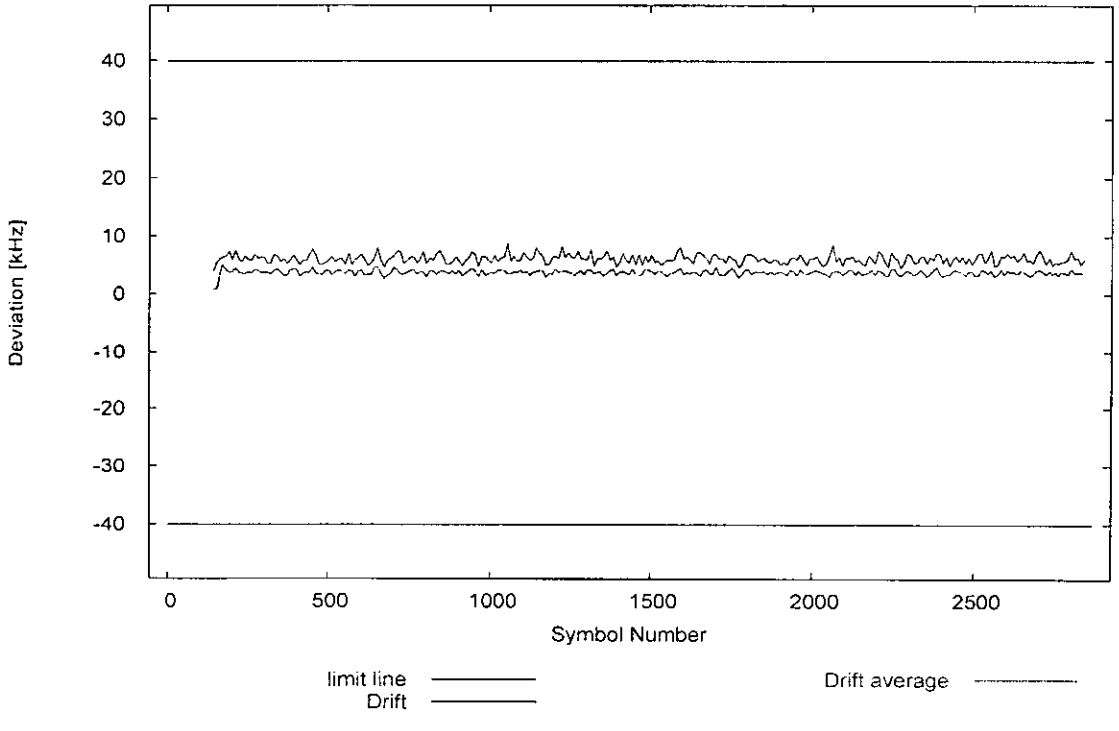
TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2402.000 MHz



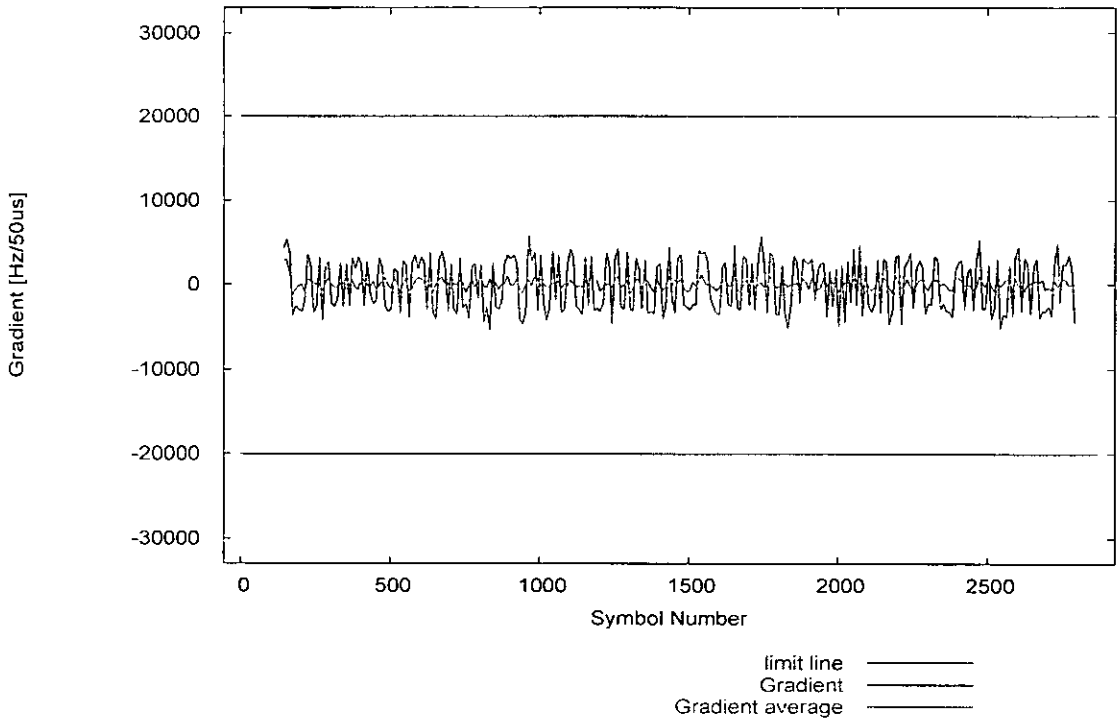
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern



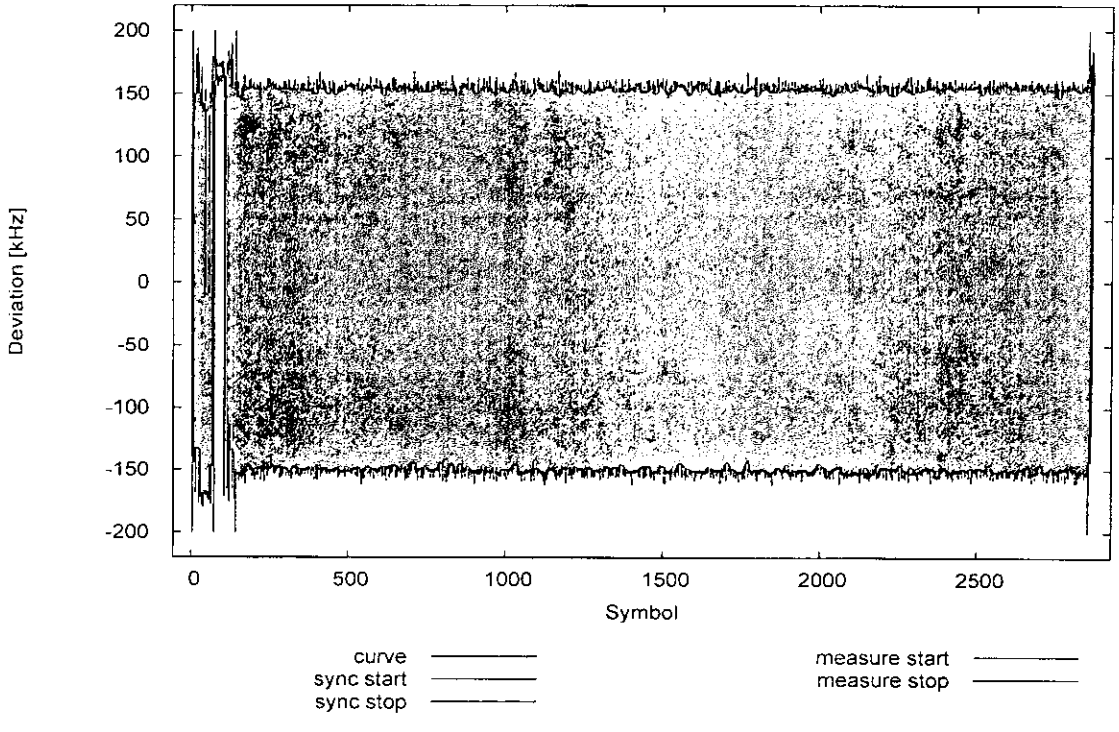
TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2441.000 MHz



TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2441.000 MHz

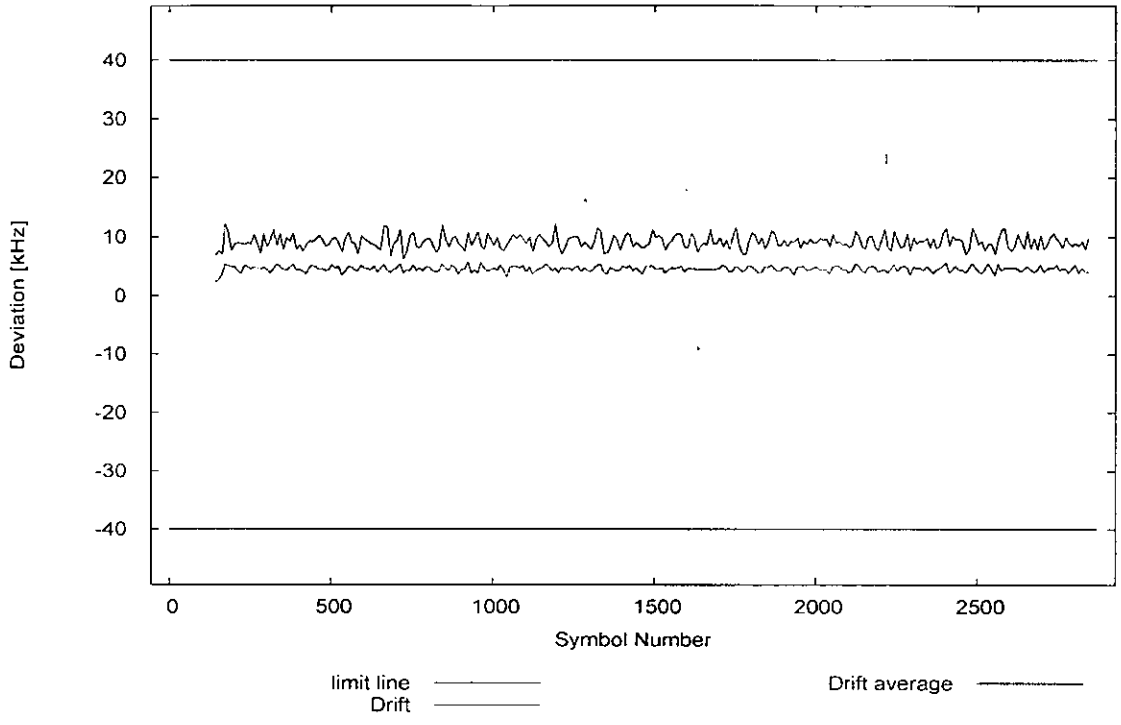


Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern

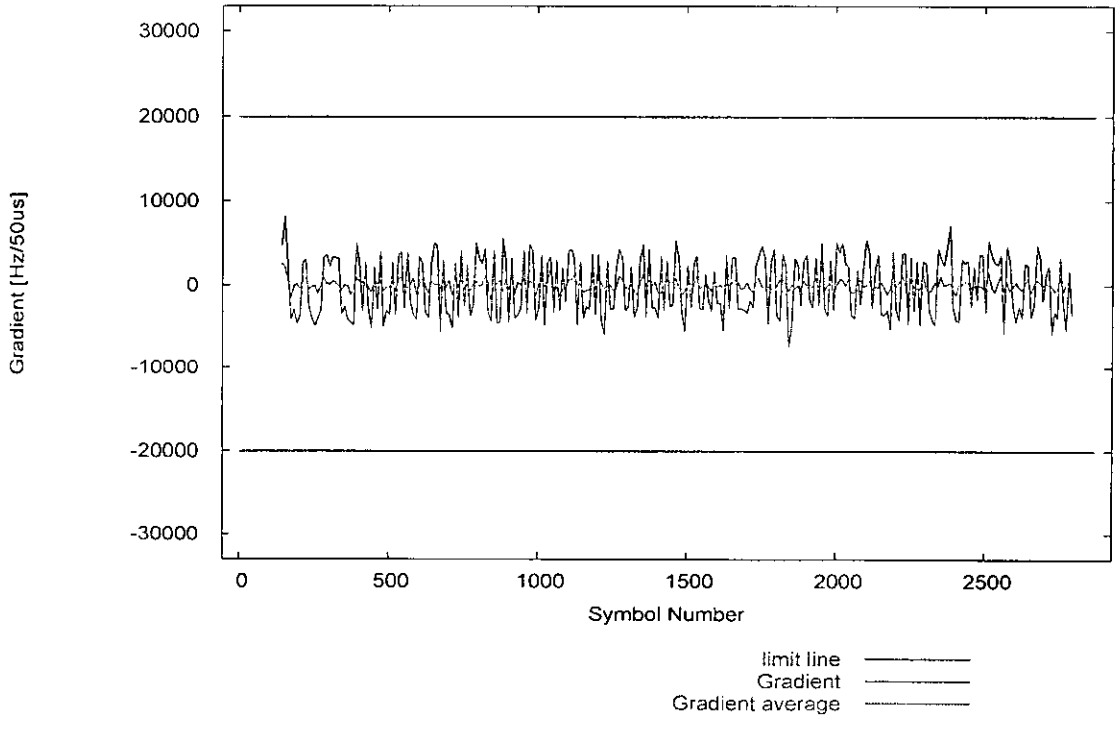


1190

TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2480.000 MHz



TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2480.000 MHz



Carrier Frequency Drift

For system parameter see 0, "General Parameter 010"

BT Test Specification Version: 1.2

TS Errata Request: 190
TS Errata Request: 277

For EUT parameter see 0, "EUT Parameter 005"
For test case parameter see 0, "Test Case Parameter 030"

Packet Nr.	Type	Freq [MHz]	Max Drift [kHz]		LIMIT [kHz]	Max Gradient [Hz/50us]		LIMIT [Hz/50us]	VERDICT
1	DH1	2402	6.262	<=	25.000				PASS
1	DH1	2402				2720.26	<=	20000.000	PASS
2	DH1	2402	4.667	<=	25.000				PASS
2	DH1	2402				2921.41	<=	20000.000	PASS
3	DH1	2402	5.856	<=	25.000				PASS
3	DH1	2402				3458.54	<=	20000.000	PASS
4	DH1	2402	5.263	<=	25.000				PASS
4	DH1	2402				1961.15	<=	20000.000	PASS
5	DH1	2402	5.890	<=	25.000				PASS
5	DH1	2402				2333.69	<=	20000.000	PASS
6	DH1	2402	4.191	<=	25.000				PASS
6	DH1	2402				3364.08	<=	20000.000	PASS
7	DH1	2402	6.178	<=	25.000				PASS
7	DH1	2402				2117.08	<=	20000.000	PASS
8	DH1	2402	6.521	<=	25.000				PASS
8	DH1	2402				2998.41	<=	20000.000	PASS
9	DH1	2402	8.561	<=	25.000				PASS
9	DH1	2402				2136.94	<=	20000.000	PASS
10	DH1	2402	6.135	<=	25.000				PASS
10	DH1	2402				5304.70	<=	20000.000	PASS
1	DH1	2441	7.358	<=	25.000				PASS
1	DH1	2441				1817.92	<=	20000.000	PASS
2	DH1	2441	3.852	<=	25.000				PASS
2	DH1	2441				2732.44	<=	20000.000	PASS
3	DH1	2441	6.059	<=	25.000				PASS
3	DH1	2441				3584.83	<=	20000.000	PASS
4	DH1	2441	6.952	<=	25.000				PASS
4	DH1	2441				3369.13	<=	20000.000	PASS
5	DH1	2441	5.504	<=	25.000				PASS
5	DH1	2441				3195.07	<=	20000.000	PASS
6	DH1	2441	6.341	<=	25.000				PASS
6	DH1	2441				2796.72	<=	20000.000	PASS
7	DH1	2441	9.654	<=	25.000				PASS
7	DH1	2441				6144.30	<=	20000.000	PASS
8	DH1	2441	6.051	<=	25.000				PASS
8	DH1	2441				2131.24	<=	20000.000	PASS
9	DH1	2441	3.132	<=	25.000				PASS
9	DH1	2441				2613.80	<=	20000.000	PASS
10	DH1	2441	6.206	<=	25.000				PASS
10	DH1	2441				2587.70	<=	20000.000	PASS
1	DH1	2480	6.316	<=	25.000				PASS
1	DH1	2480				2417.33	<=	20000.000	PASS
2	DH1	2480	9.572	<=	25.000				PASS
2	DH1	2480				2173.69	<=	20000.000	PASS
3	DH1	2480	6.470	<=	25.000				PASS
3	DH1	2480				4073.10	<=	20000.000	PASS

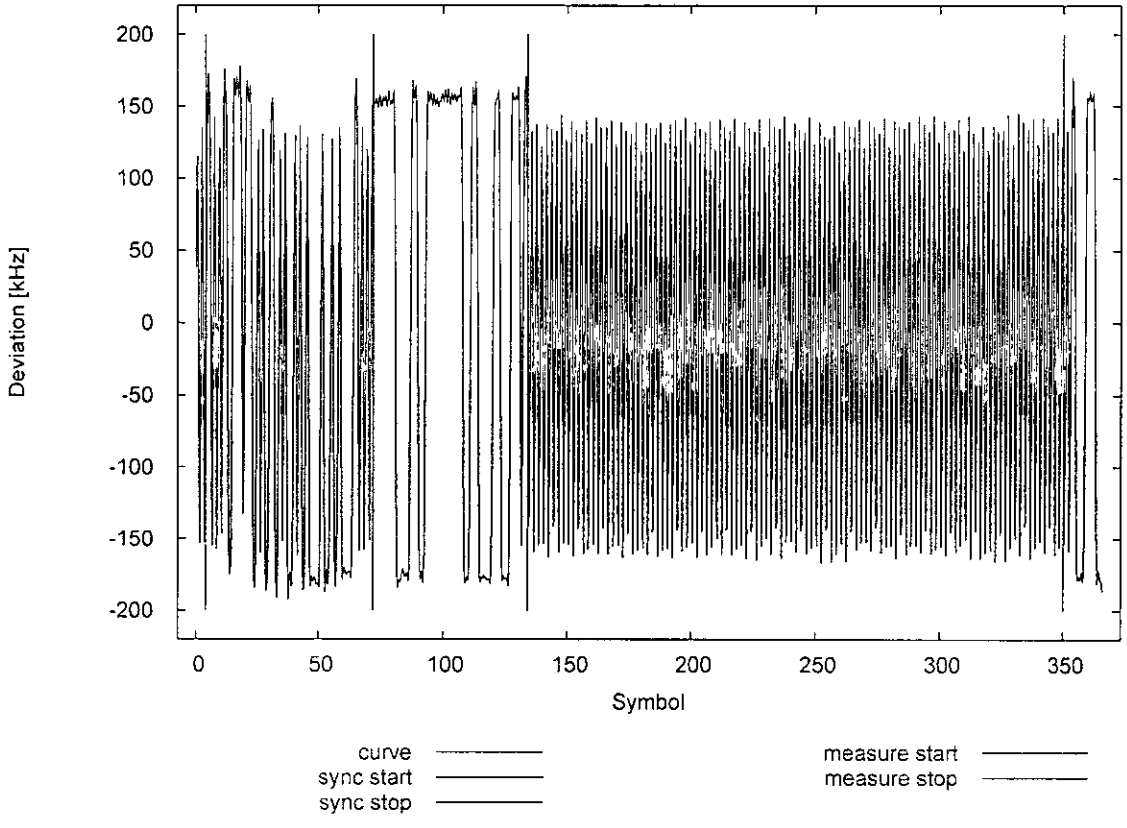
4	DH1	2480	6.258	<=	25.000			PASS
4	DH1	2480				3566.17	<= 20000.000	PASS
5	DH1	2480	2.813	<=	25.000			PASS
5	DH1	2480				2638.81	<= 20000.000	PASS
6	DH1	2480	4.847	<=	25.000			PASS
6	DH1	2480				1645.77	<= 20000.000	PASS
7	DH1	2480	8.794	<=	25.000			PASS
7	DH1	2480				3615.43	<= 20000.000	PASS
8	DH1	2480	6.197	<=	25.000			PASS
8	DH1	2480				2263.31	<= 20000.000	PASS
9	DH1	2480	3.242	<=	25.000			PASS
9	DH1	2480				4183.37	<= 20000.000	PASS
10	DH1	2480	4.956	<=	25.000			PASS
10	DH1	2480				3522.53	<= 20000.000	PASS
1	DH3	2402	3.587	<=	40.000			PASS
1	DH3	2402				4179.59	<= 20000.000	PASS
2	DH3	2402	2.990	<=	40.000			PASS
2	DH3	2402				4670.77	<= 20000.000	PASS
3	DH3	2402	3.966	<=	40.000			PASS
3	DH3	2402				4683.89	<= 20000.000	PASS
4	DH3	2402	3.822	<=	40.000			PASS
4	DH3	2402				3517.03	<= 20000.000	PASS
5	DH3	2402	4.082	<=	40.000			PASS
5	DH3	2402				4013.91	<= 20000.000	PASS
6	DH3	2402	5.324	<=	40.000			PASS
6	DH3	2402				3569.42	<= 20000.000	PASS
7	DH3	2402	4.158	<=	40.000			PASS
7	DH3	2402				3877.70	<= 20000.000	PASS
8	DH3	2402	2.937	<=	40.000			PASS
8	DH3	2402				3562.74	<= 20000.000	PASS
9	DH3	2402	4.371	<=	40.000			PASS
9	DH3	2402				4859.58	<= 20000.000	PASS
10	DH3	2402	6.180	<=	40.000			PASS
10	DH3	2402				4047.32	<= 20000.000	PASS
1	DH3	2441	6.865	<=	40.000			PASS
1	DH3	2441				4322.91	<= 20000.000	PASS
2	DH3	2441	3.565	<=	40.000			PASS
2	DH3	2441				4347.30	<= 20000.000	PASS
3	DH3	2441	11.765	<=	40.000			PASS
3	DH3	2441				7579.13	<= 20000.000	PASS
4	DH3	2441	3.080	<=	40.000			PASS
4	DH3	2441				4115.51	<= 20000.000	PASS
5	DH3	2441	4.359	<=	40.000			PASS
5	DH3	2441				4679.90	<= 20000.000	PASS
6	DH3	2441	10.119	<=	40.000			PASS
6	DH3	2441				3702.05	<= 20000.000	PASS
7	DH3	2441	5.414	<=	40.000			PASS
7	DH3	2441				4020.64	<= 20000.000	PASS
8	DH3	2441	3.403	<=	40.000			PASS
8	DH3	2441				5136.03	<= 20000.000	PASS
9	DH3	2441	6.498	<=	40.000			PASS
9	DH3	2441				5369.03	<= 20000.000	PASS
10	DH3	2441	5.861	<=	40.000			PASS
10	DH3	2441				3691.03	<= 20000.000	PASS
1	DH3	2480	5.482	<=	40.000			PASS
1	DH3	2480				3580.31	<= 20000.000	PASS
2	DH3	2480	6.523	<=	40.000			PASS
2	DH3	2480				3801.00	<= 20000.000	PASS
3	DH3	2480	4.830	<=	40.000			PASS
3	DH3	2480				3106.67	<= 20000.000	PASS
4	DH3	2480	6.157	<=	40.000			PASS
4	DH3	2480				4681.04	<= 20000.000	PASS
5	DH3	2480	5.509	<=	40.000			PASS
5	DH3	2480				4047.59	<= 20000.000	PASS
6	DH3	2480	3.675	<=	40.000			PASS

6	DH3	2480				3546.86	<= 20000.000	PASS
7	DH3	2480	3.688	<=	40.000			PASS
7	DH3	2480				3967.40	<= 20000.000	PASS
8	DH3	2480	2.603	<=	40.000			PASS
8	DH3	2480				4169.21	<= 20000.000	PASS
9	DH3	2480	4.571	<=	40.000			PASS
9	DH3	2480				4540.72	<= 20000.000	PASS
10	DH3	2480	5.802	<=	40.000			PASS
10	DH3	2480				3520.79	<= 20000.000	PASS
1	DH5	2402	4.742	<=	40.000			PASS
1	DH5	2402				4243.79	<= 20000.000	PASS
2	DH5	2402	7.861	<=	40.000			PASS
2	DH5	2402				5412.05	<= 20000.000	PASS
3	DH5	2402	5.827	<=	40.000			PASS
3	DH5	2402				4392.45	<= 20000.000	PASS
4	DH5	2402	6.000	<=	40.000			PASS
4	DH5	2402				4158.69	<= 20000.000	PASS
5	DH5	2402	5.885	<=	40.000			PASS
5	DH5	2402				3874.74	<= 20000.000	PASS
6	DH5	2402	7.560	<=	40.000			PASS
6	DH5	2402				4955.48	<= 20000.000	PASS
7	DH5	2402	13.646	<=	40.000			PASS
7	DH5	2402				8953.47	<= 20000.000	PASS
8	DH5	2402	9.585	<=	40.000			PASS
8	DH5	2402				4503.32	<= 20000.000	PASS
9	DH5	2402	6.737	<=	40.000			PASS
9	DH5	2402				4752.13	<= 20000.000	PASS
10	DH5	2402	7.828	<=	40.000			PASS
10	DH5	2402				4057.38	<= 20000.000	PASS
1	DH5	2441	7.902	<=	40.000			PASS
1	DH5	2441				6006.80	<= 20000.000	PASS
2	DH5	2441	8.227	<=	40.000			PASS
2	DH5	2441				4186.17	<= 20000.000	PASS
3	DH5	2441	9.007	<=	40.000			PASS
3	DH5	2441				4057.38	<= 20000.000	PASS
4	DH5	2441	13.298	<=	40.000			PASS
4	DH5	2441				6582.64	<= 20000.000	PASS
5	DH5	2441	8.729	<=	40.000			PASS
5	DH5	2441				4230.80	<= 20000.000	PASS
6	DH5	2441	8.196	<=	40.000			PASS
6	DH5	2441				4233.18	<= 20000.000	PASS
7	DH5	2441	5.752	<=	40.000			PASS
7	DH5	2441				3636.42	<= 20000.000	PASS
8	DH5	2441	8.799	<=	40.000			PASS
8	DH5	2441				5313.49	<= 20000.000	PASS
9	DH5	2441	6.213	<=	40.000			PASS
9	DH5	2441				4956.03	<= 20000.000	PASS
10	DH5	2441	4.148	<=	40.000			PASS
10	DH5	2441				4324.42	<= 20000.000	PASS
1	DH5	2480	10.240	<=	40.000			PASS
1	DH5	2480				5563.69	<= 20000.000	PASS
2	DH5	2480	6.524	<=	40.000			PASS
2	DH5	2480				4293.92	<= 20000.000	PASS
3	DH5	2480	5.206	<=	40.000			PASS
3	DH5	2480				4482.46	<= 20000.000	PASS
4	DH5	2480	5.526	<=	40.000			PASS
4	DH5	2480				4703.77	<= 20000.000	PASS
5	DH5	2480	3.978	<=	40.000			PASS
5	DH5	2480				5140.84	<= 20000.000	PASS
6	DH5	2480	6.025	<=	40.000			PASS
6	DH5	2480				3653.48	<= 20000.000	PASS
7	DH5	2480	6.086	<=	40.000			PASS
7	DH5	2480				4263.91	<= 20000.000	PASS
8	DH5	2480	7.741	<=	40.000			PASS
8	DH5	2480				4646.42	<= 20000.000	PASS

9	DH5	2480	7.686	<=	40.000			PASS
9	DH5	2480				4669.34	<= 20000.000	PASS
10	DH5	2480	4.548	<=	40.000			PASS
10	DH5	2480				6305.60	<= 20000.000	PASS

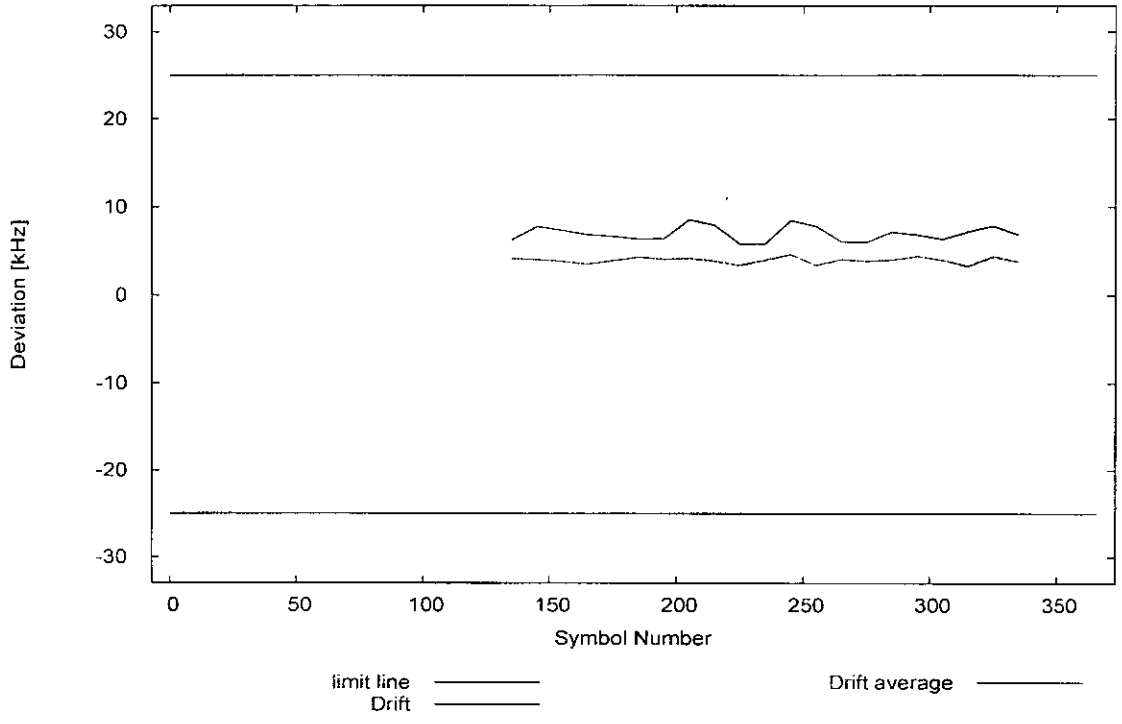
Final Test Case Verdict . . . . . PASS 00:33:54

Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH1 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern

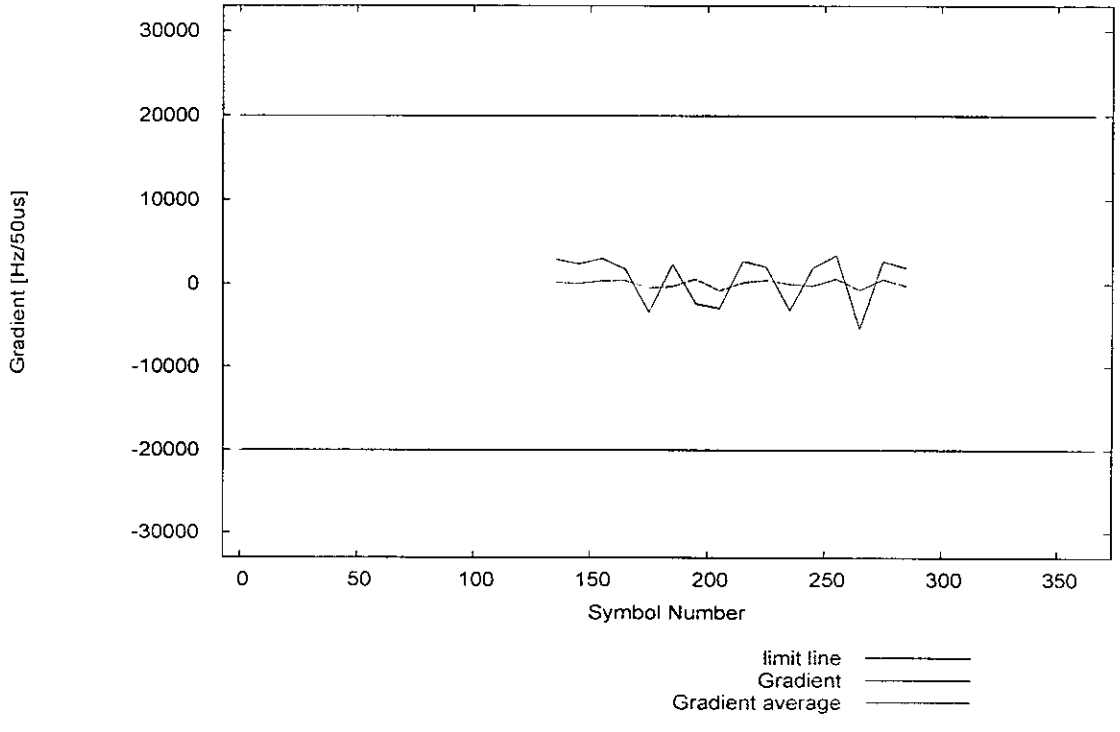


119S

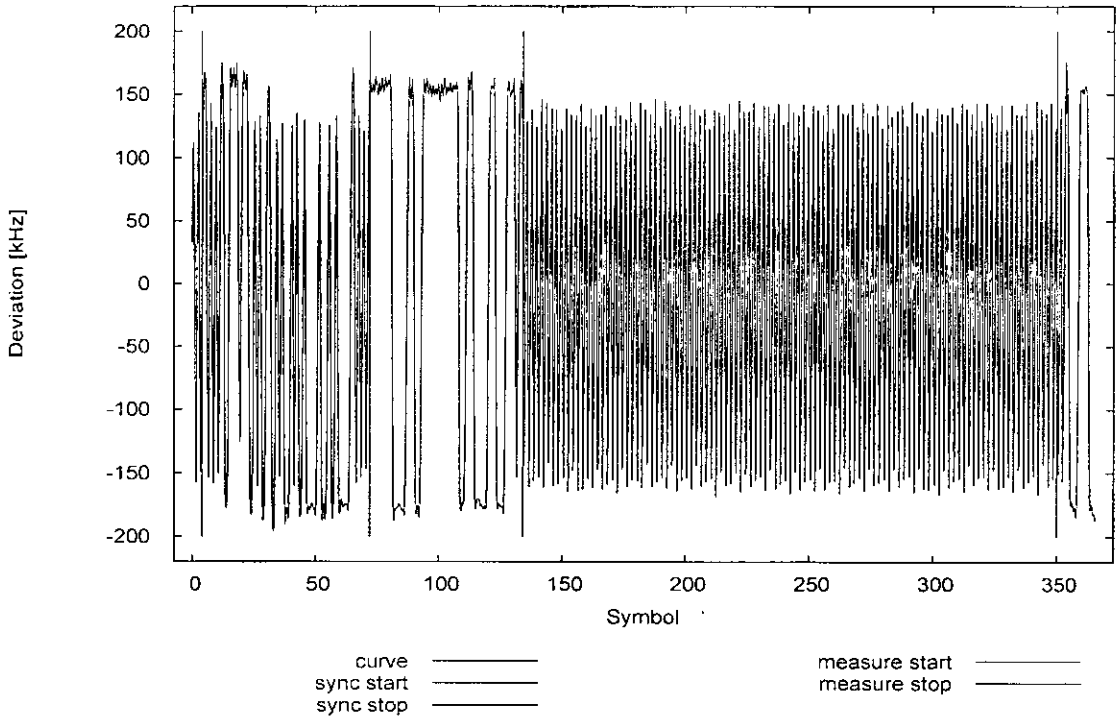
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2402.000 MHz



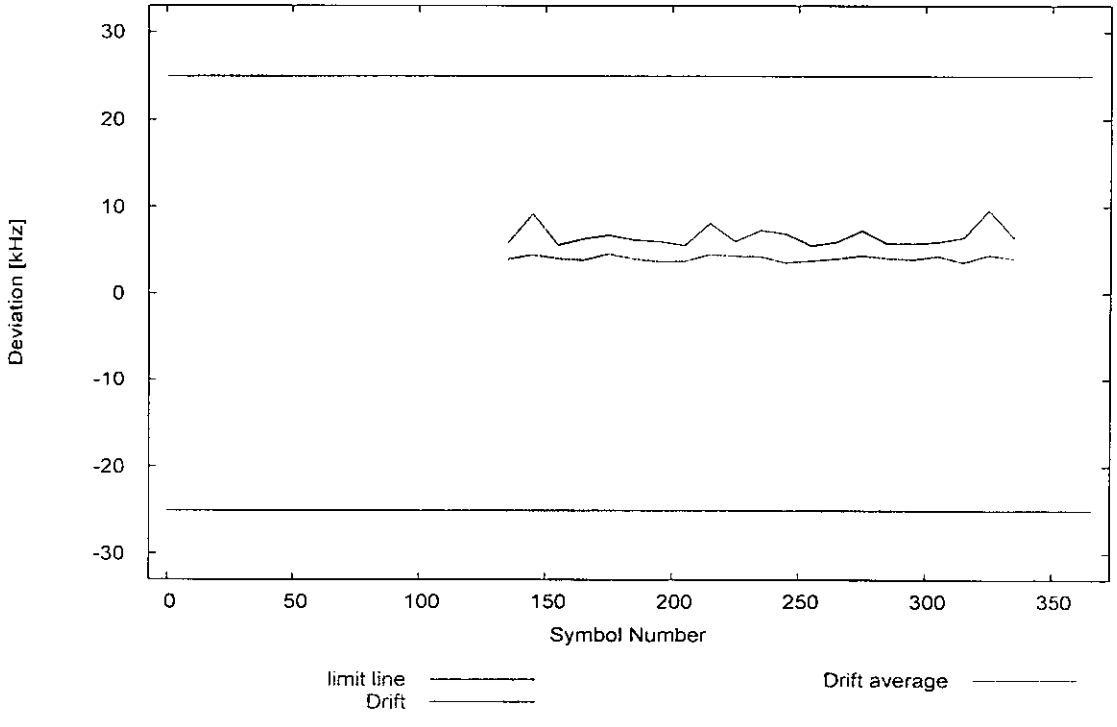
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2402.000 MHz



Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH1 Loop Back Mode -
Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern

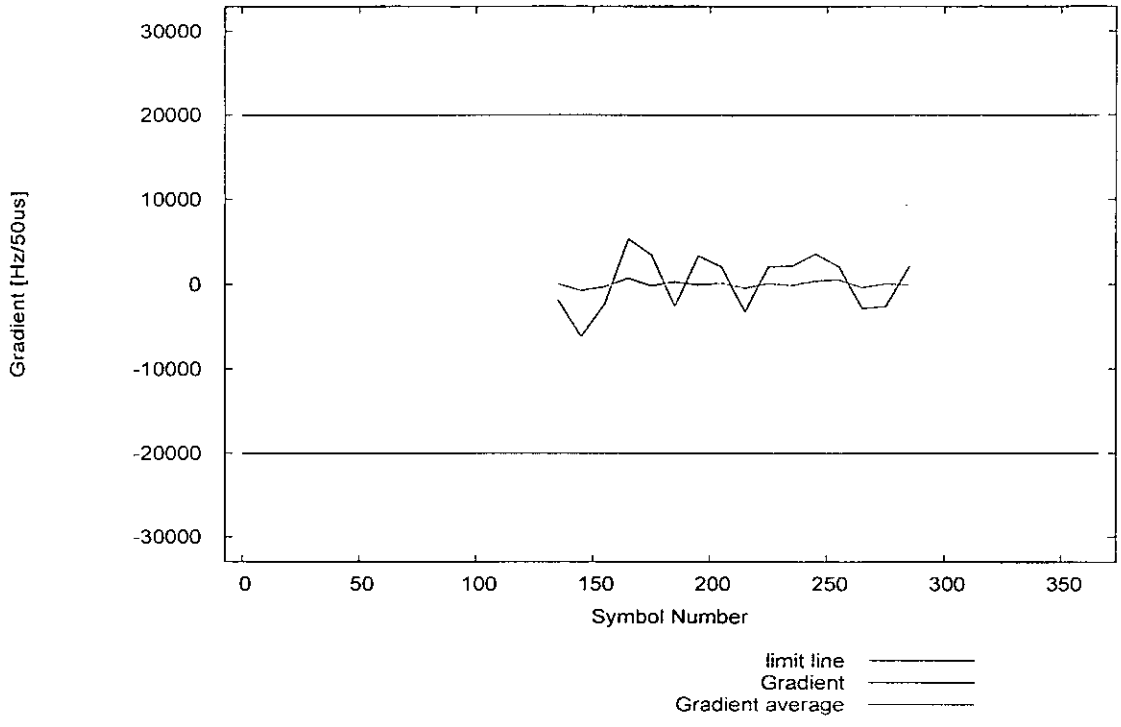


TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2441.000 MHz

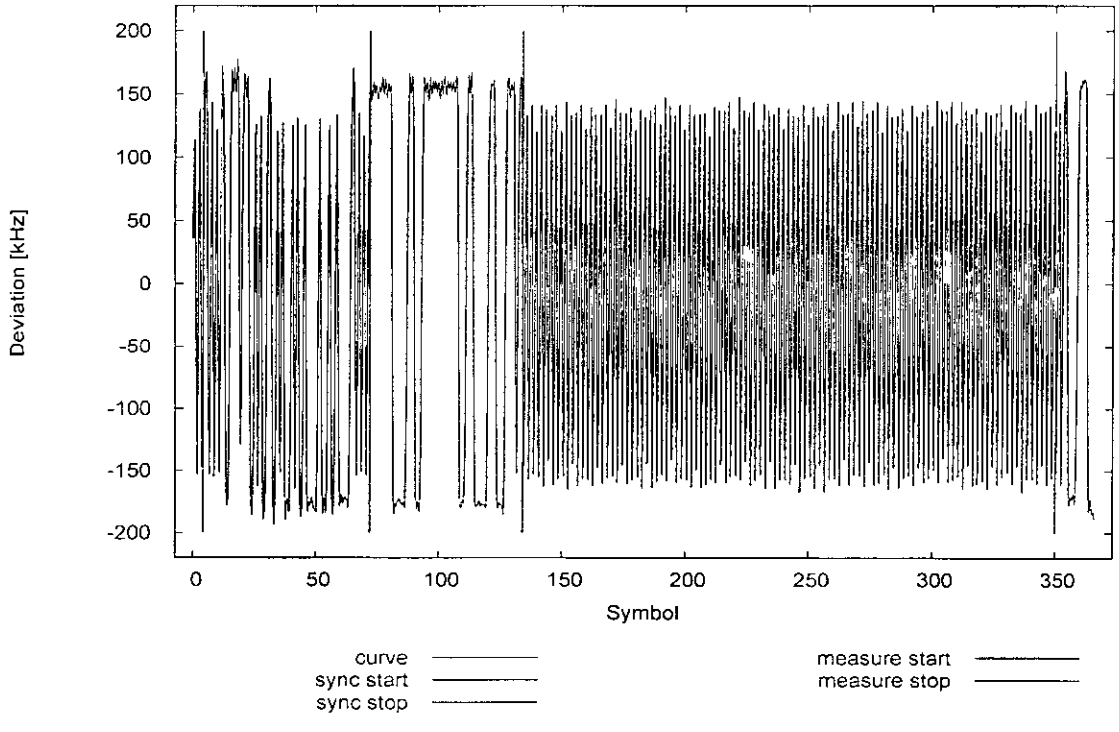


1197

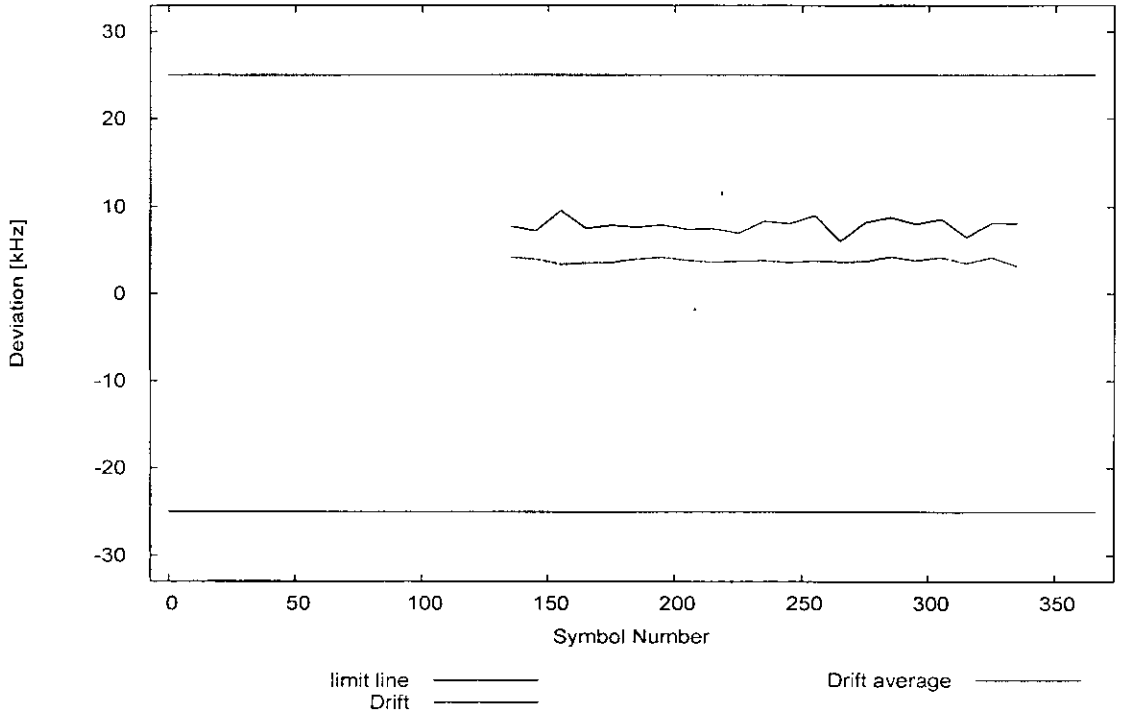
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2441.000 MHz



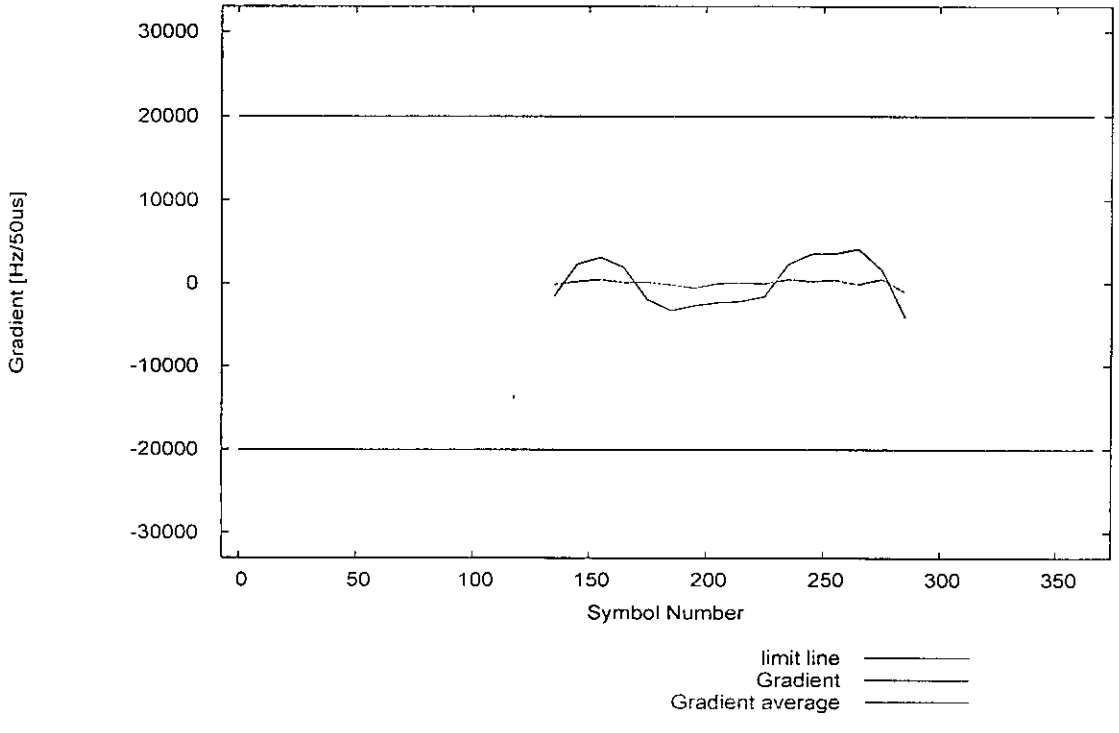
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern



TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2480.000 MHz

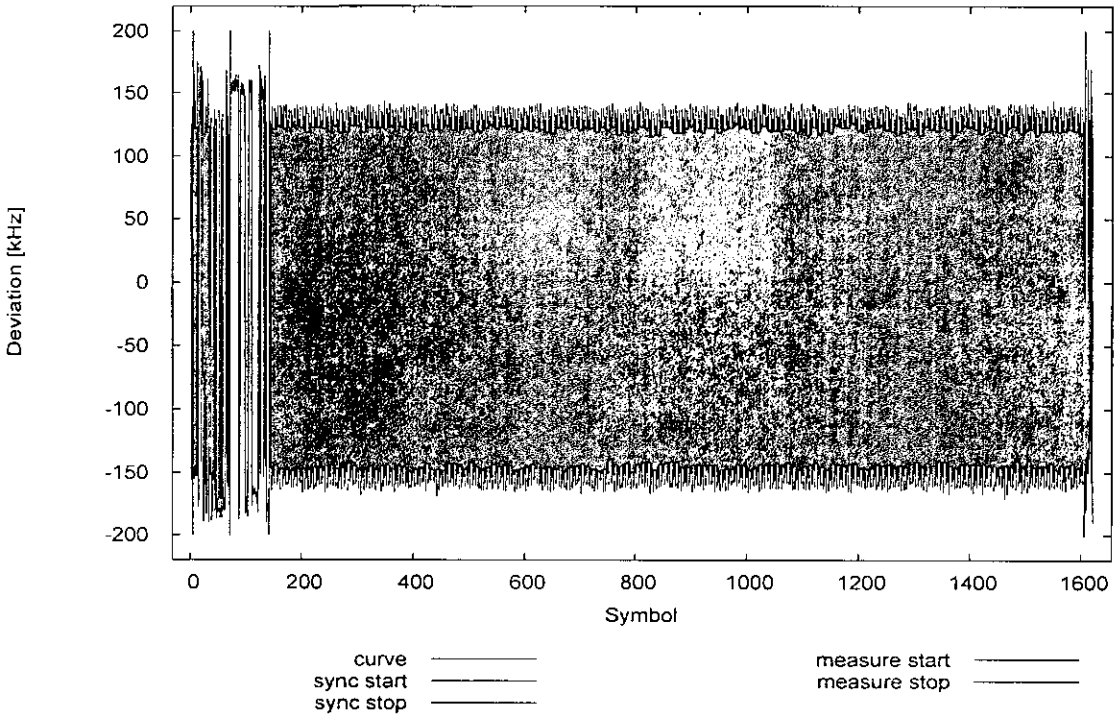


TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2480.000 MHz

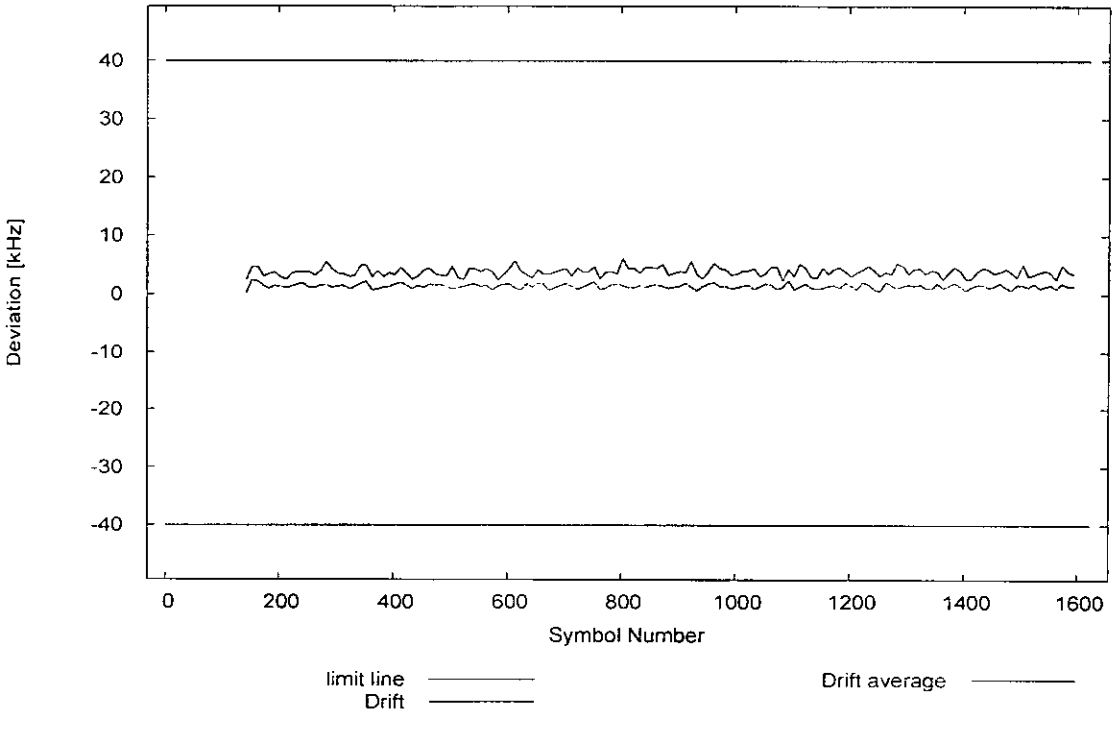


1199

Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH3 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern

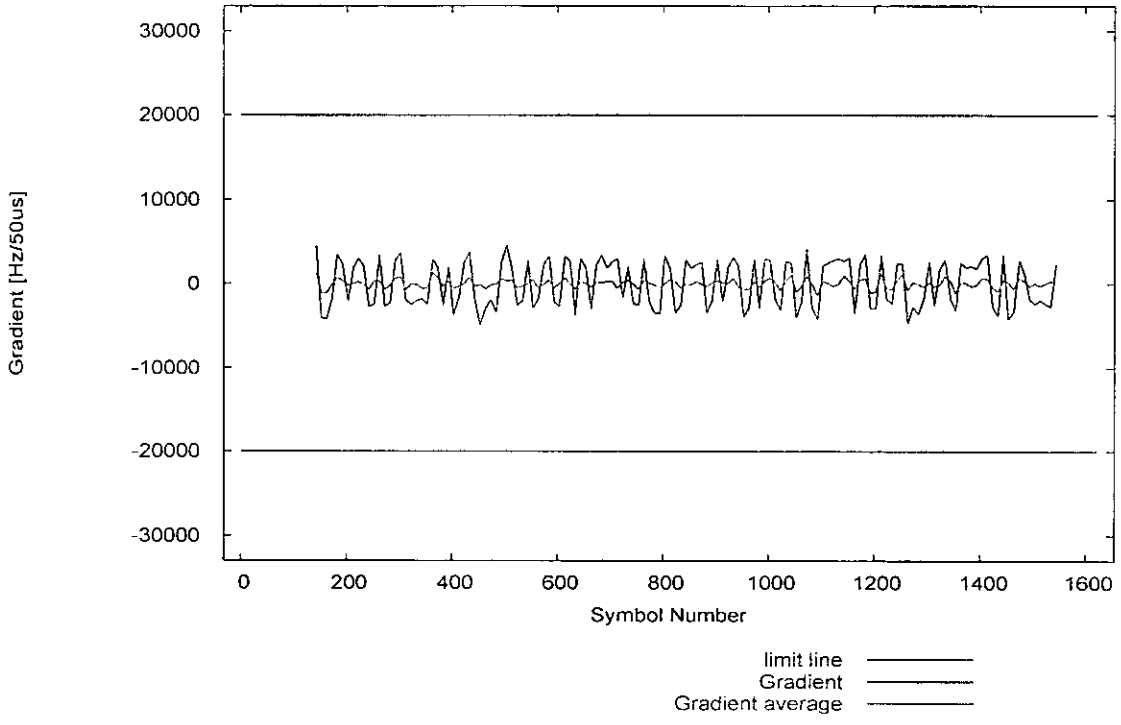


TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2402.000 MHz

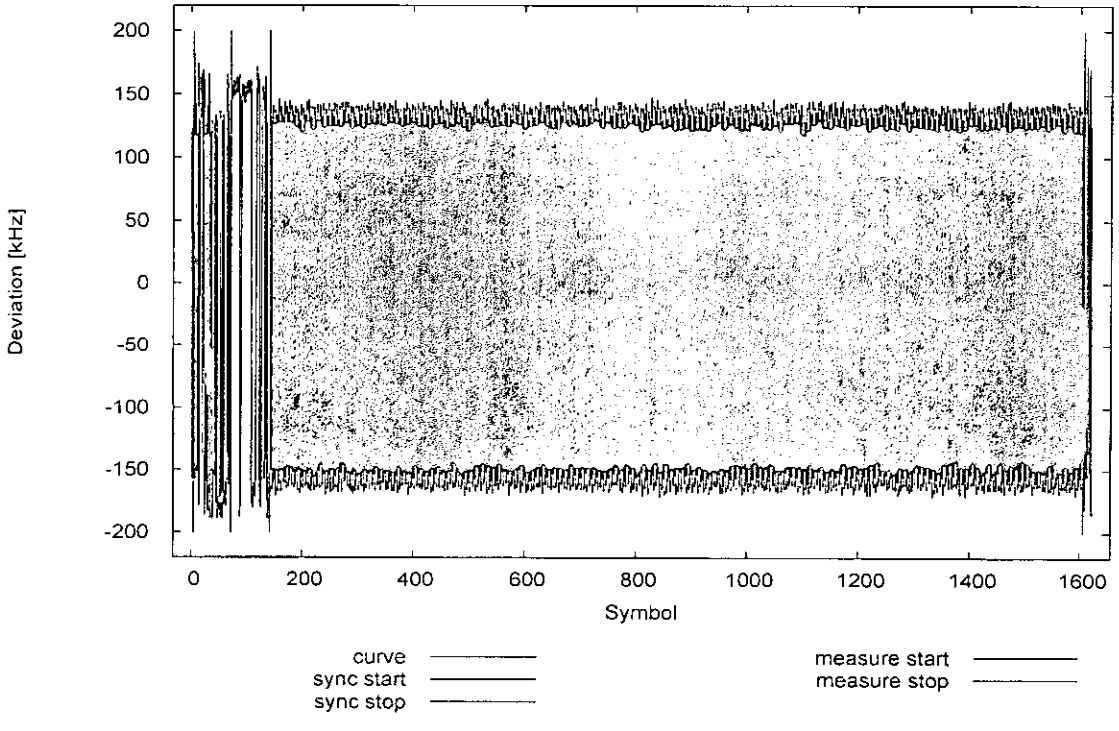


120

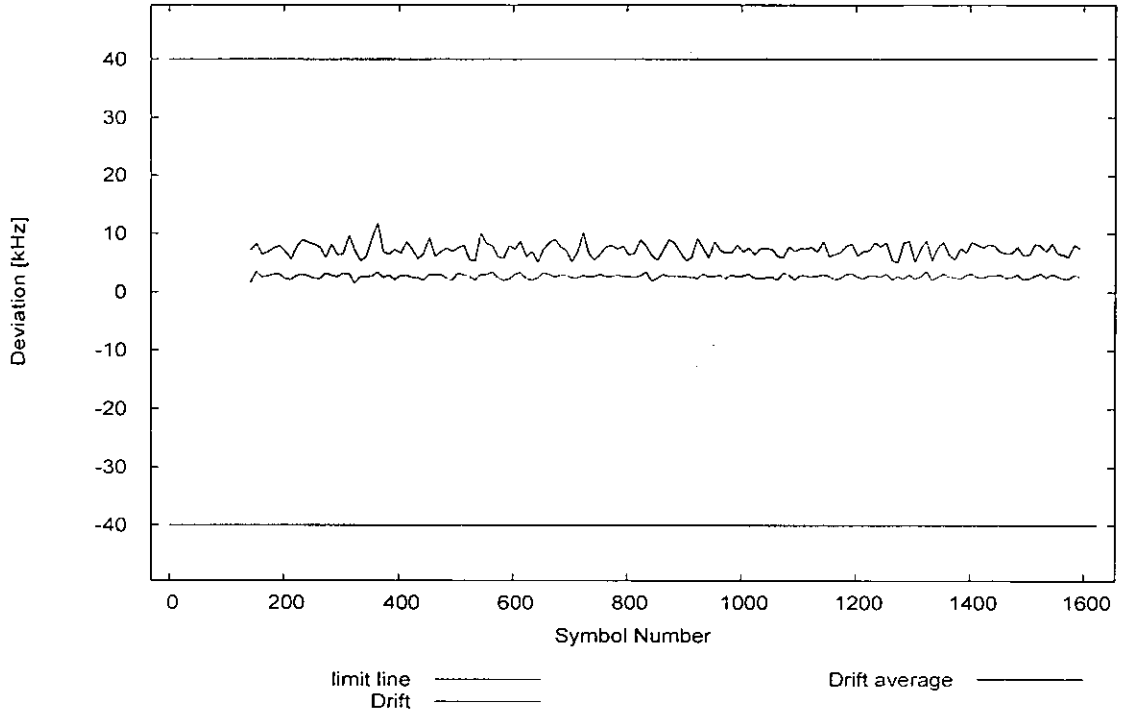
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2402.000 MHz



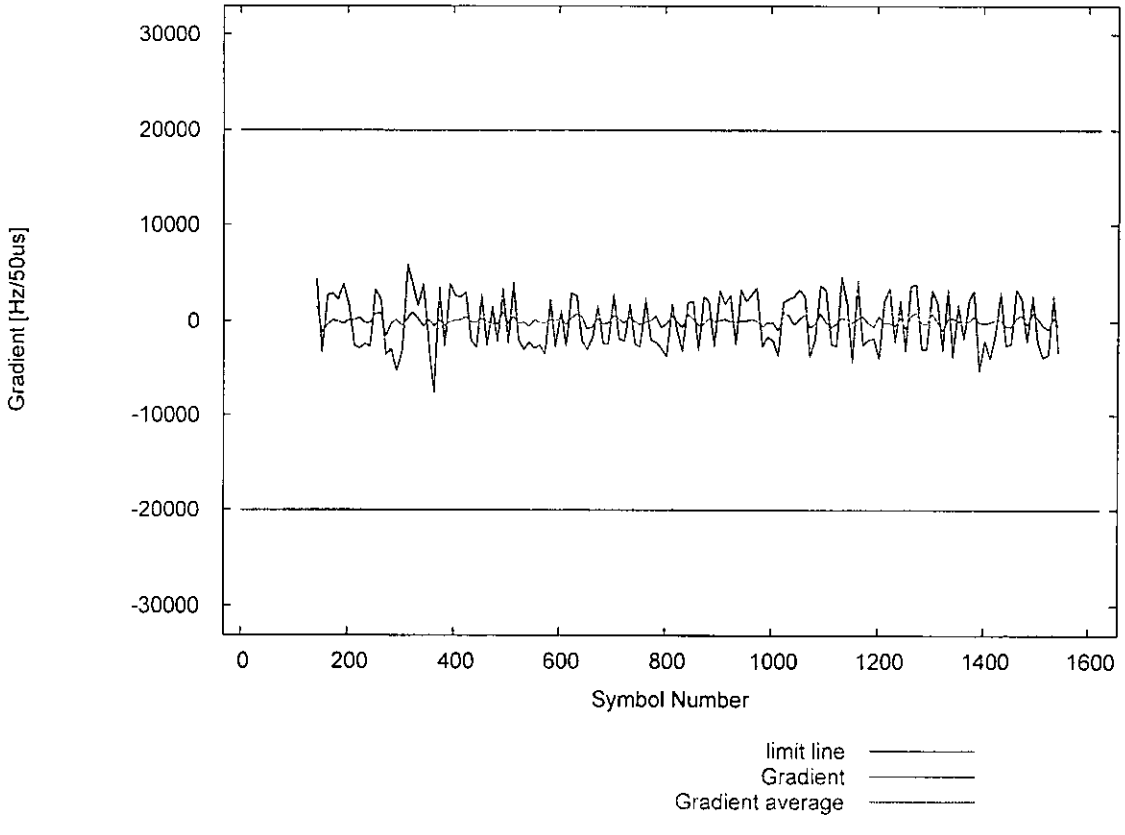
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern



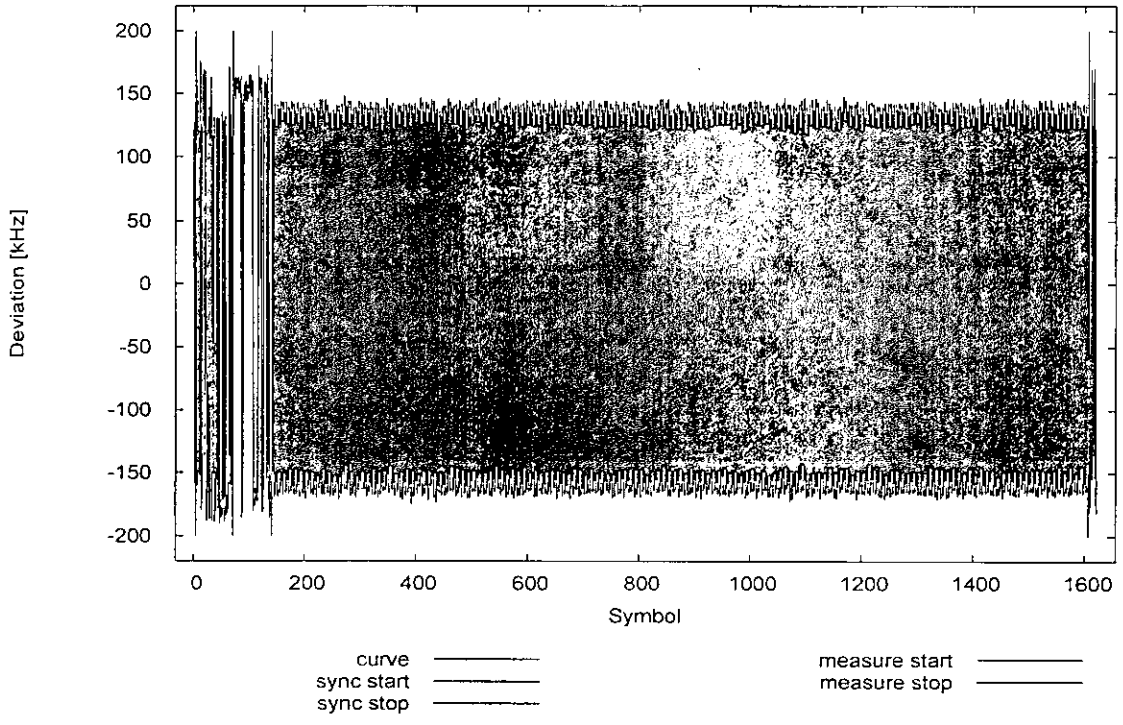
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2441.000 MHz



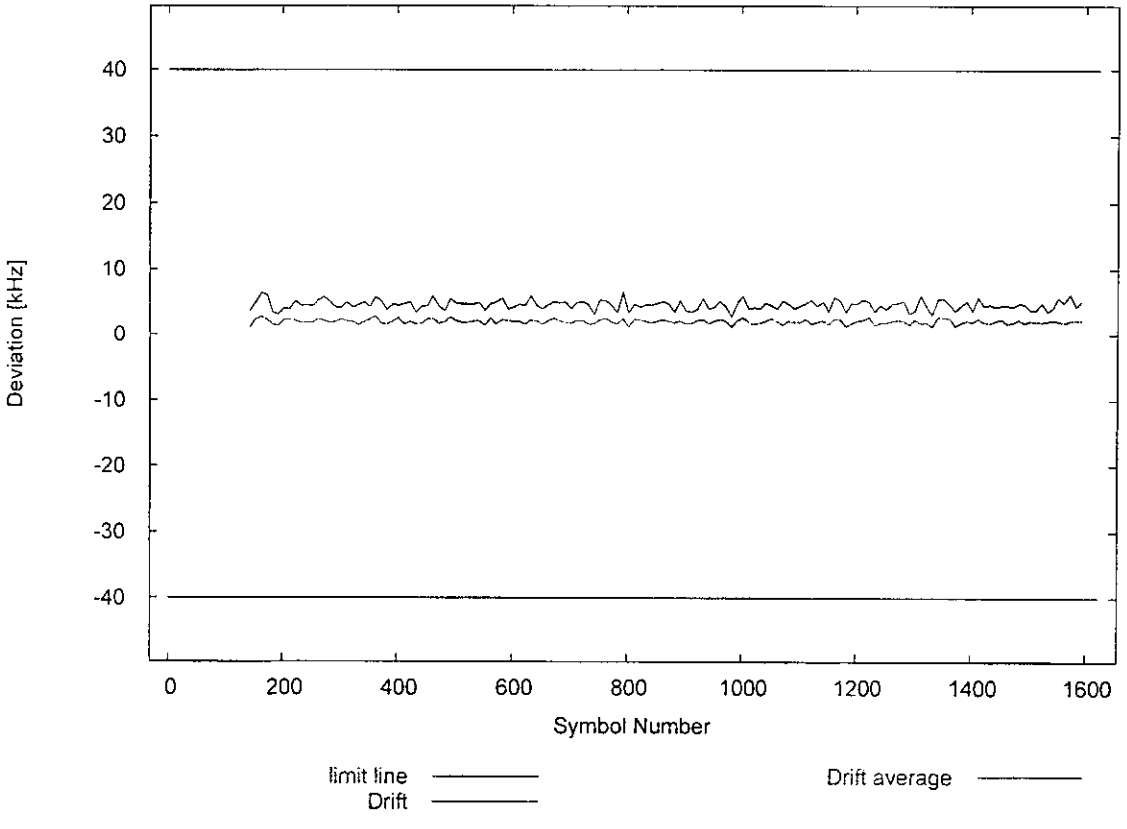
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2441.000 MHz



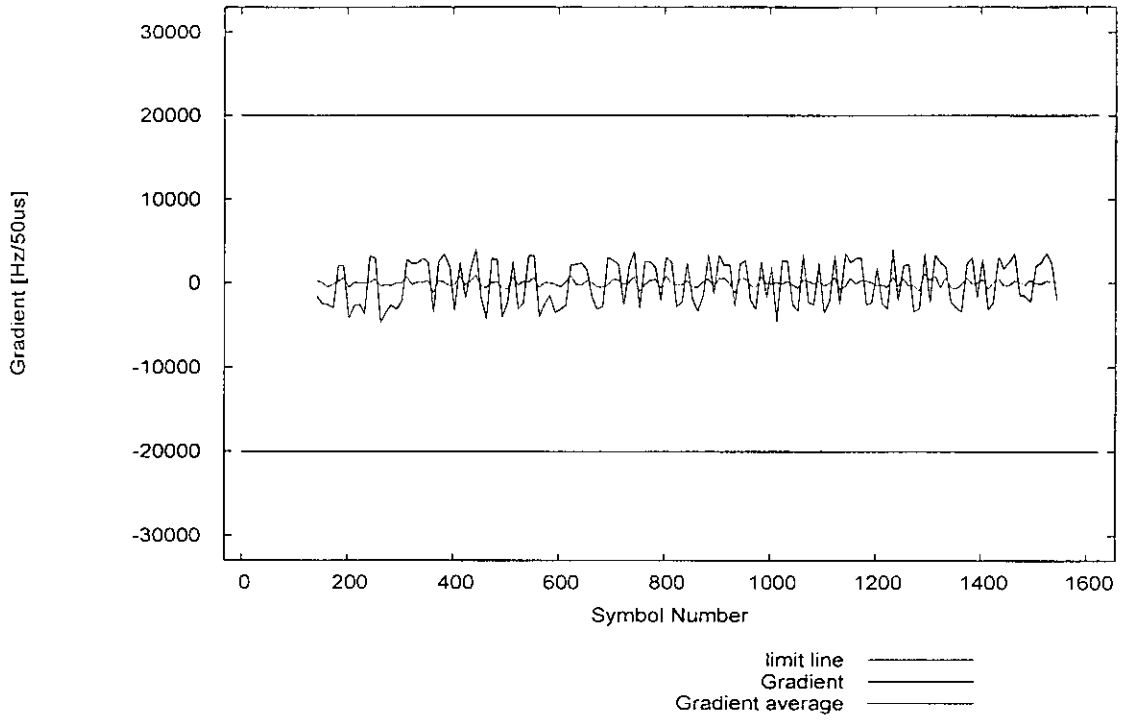
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern



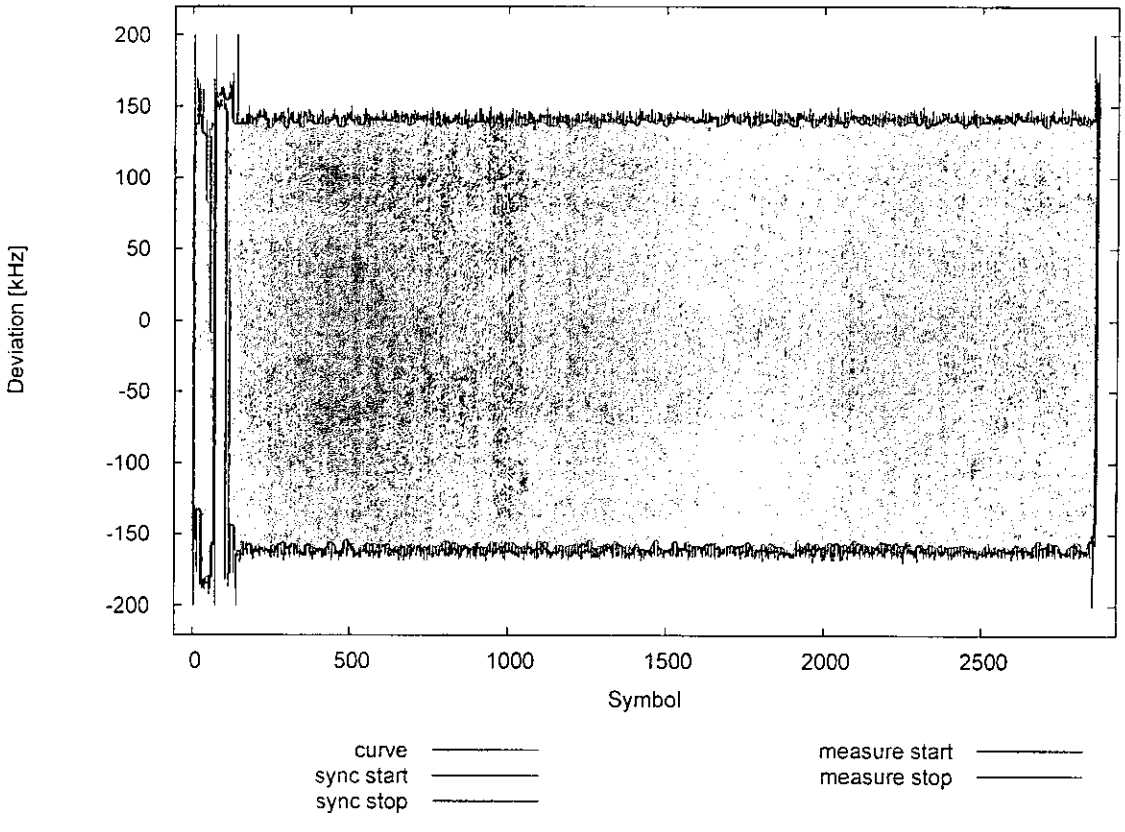
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2480.000 MHz



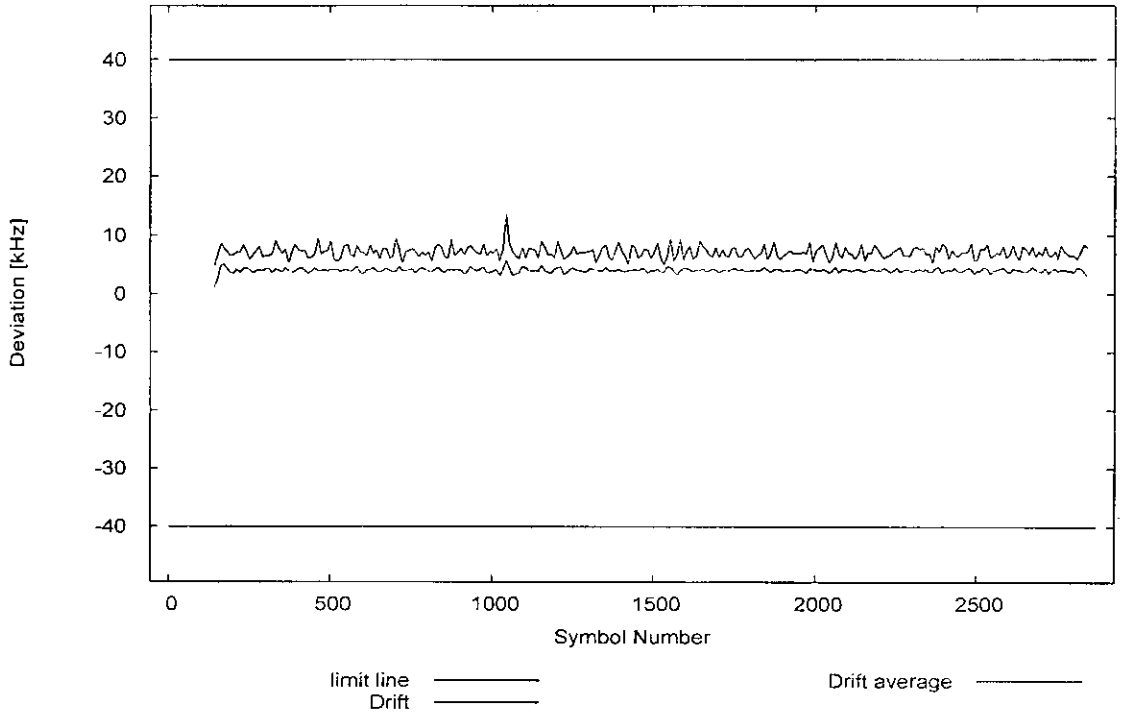
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2480.000 MHz



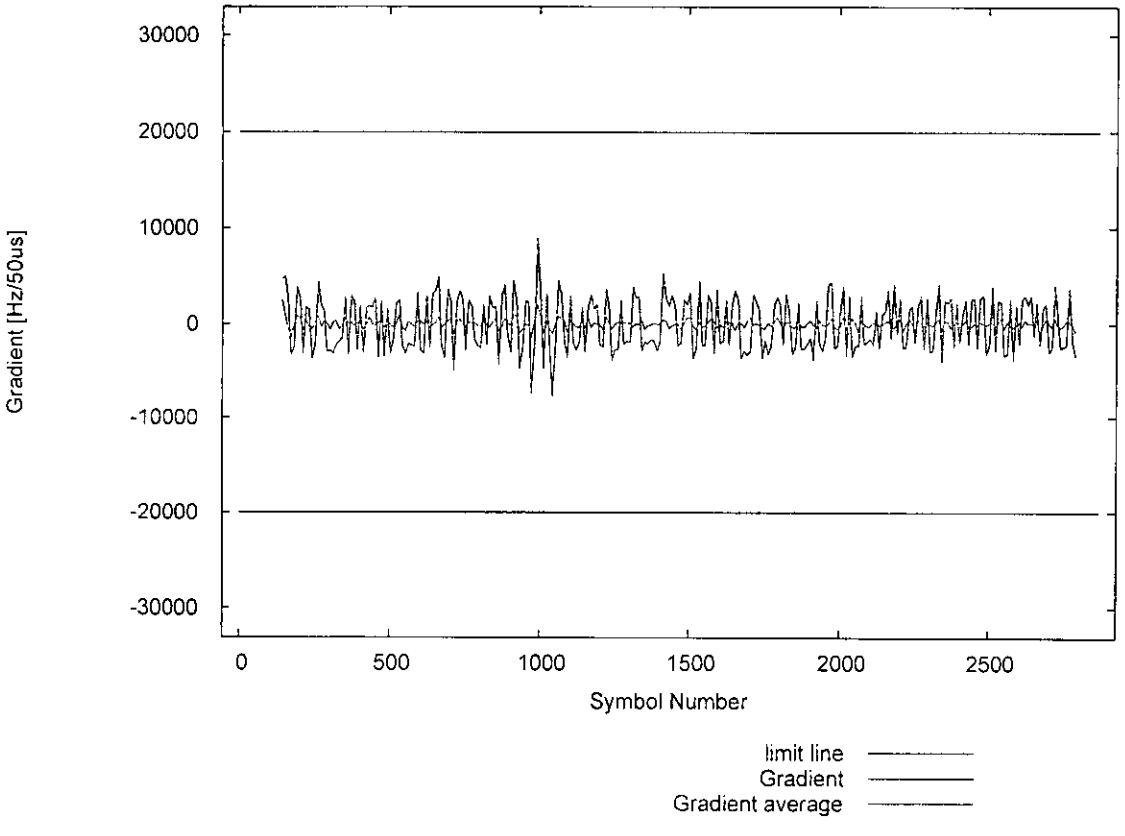
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern



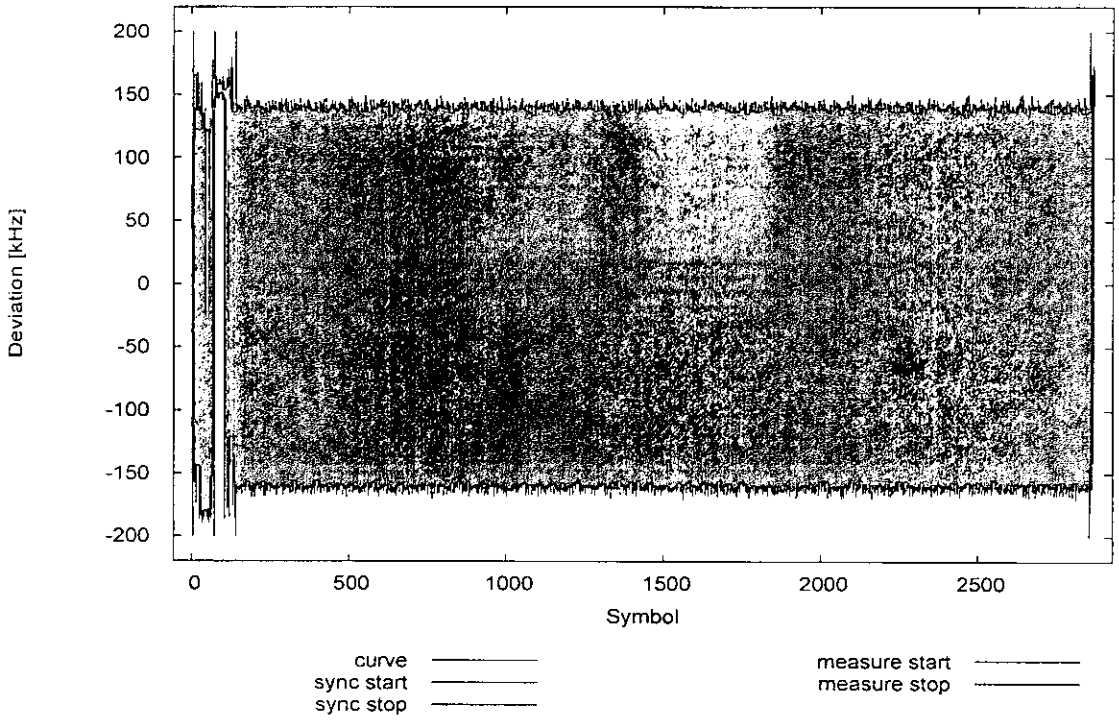
TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2402.000 MHz



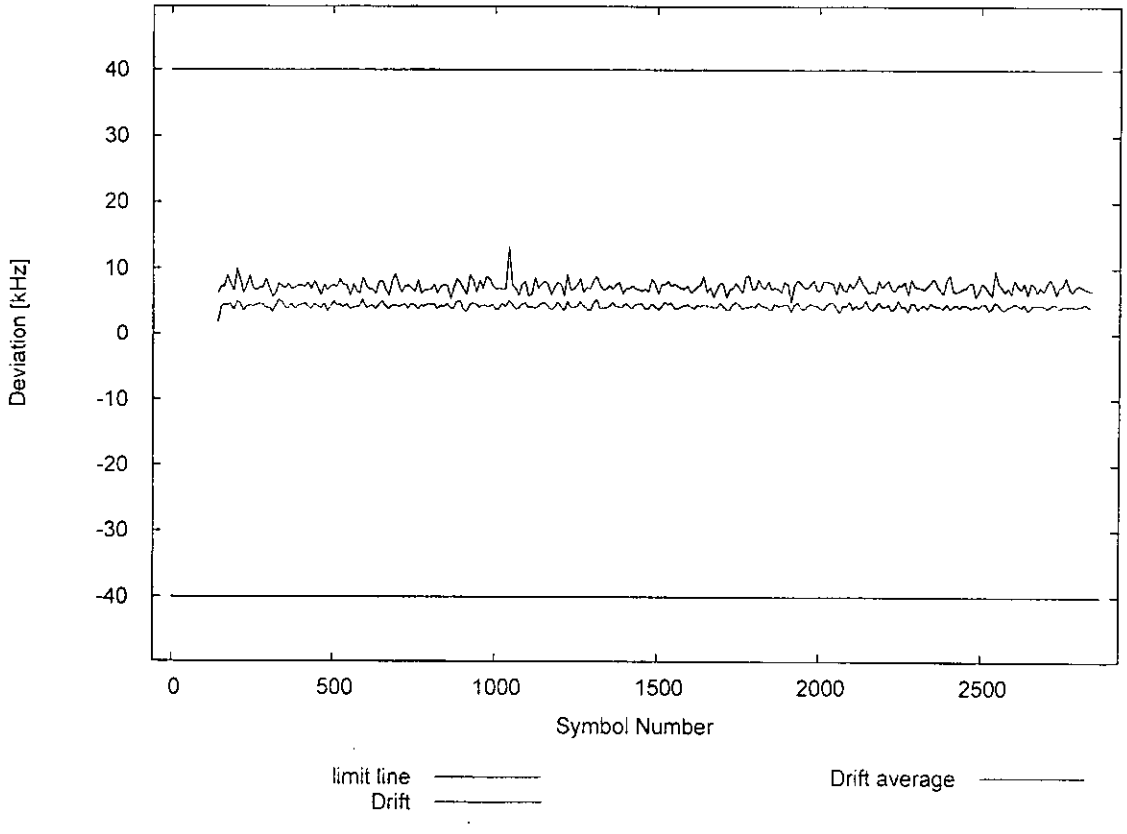
TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2402.000 MHz



Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern

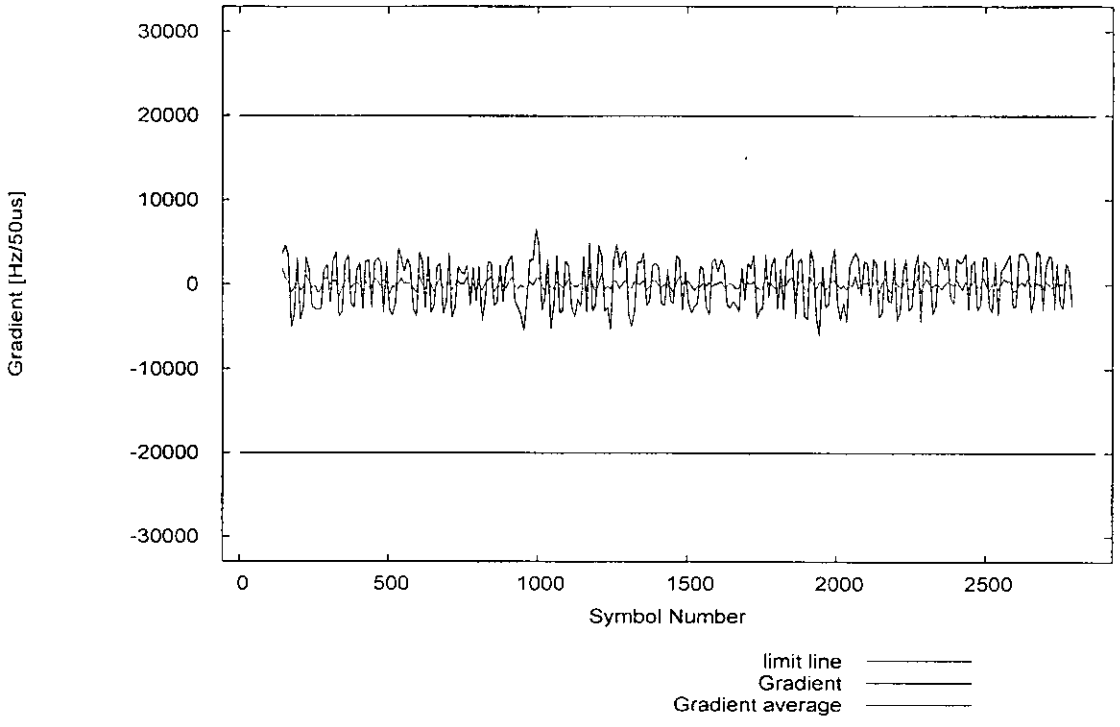


TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2441.000 MHz

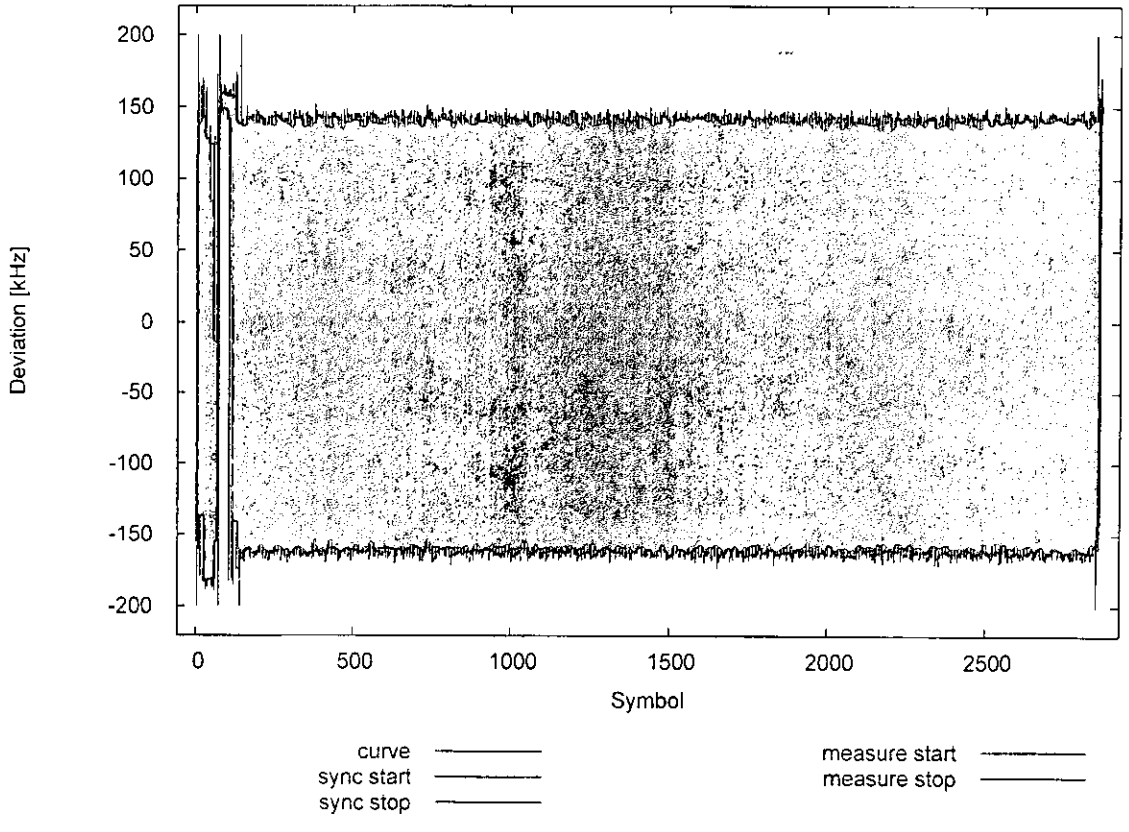


1206

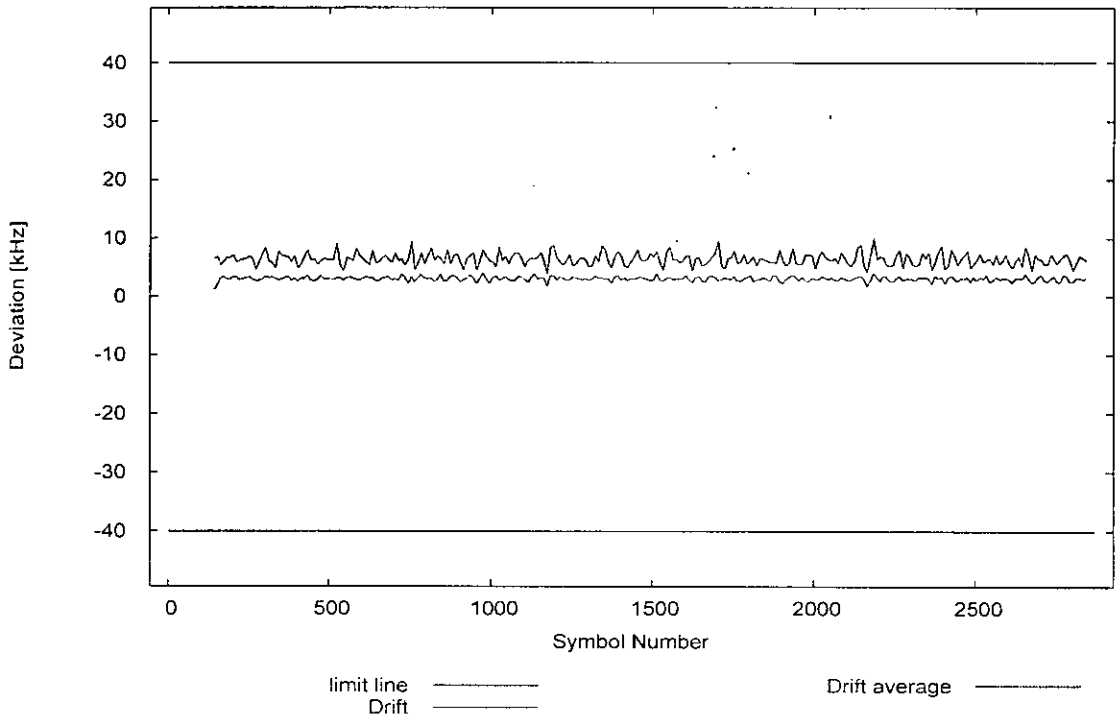
TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2441.000 MHz



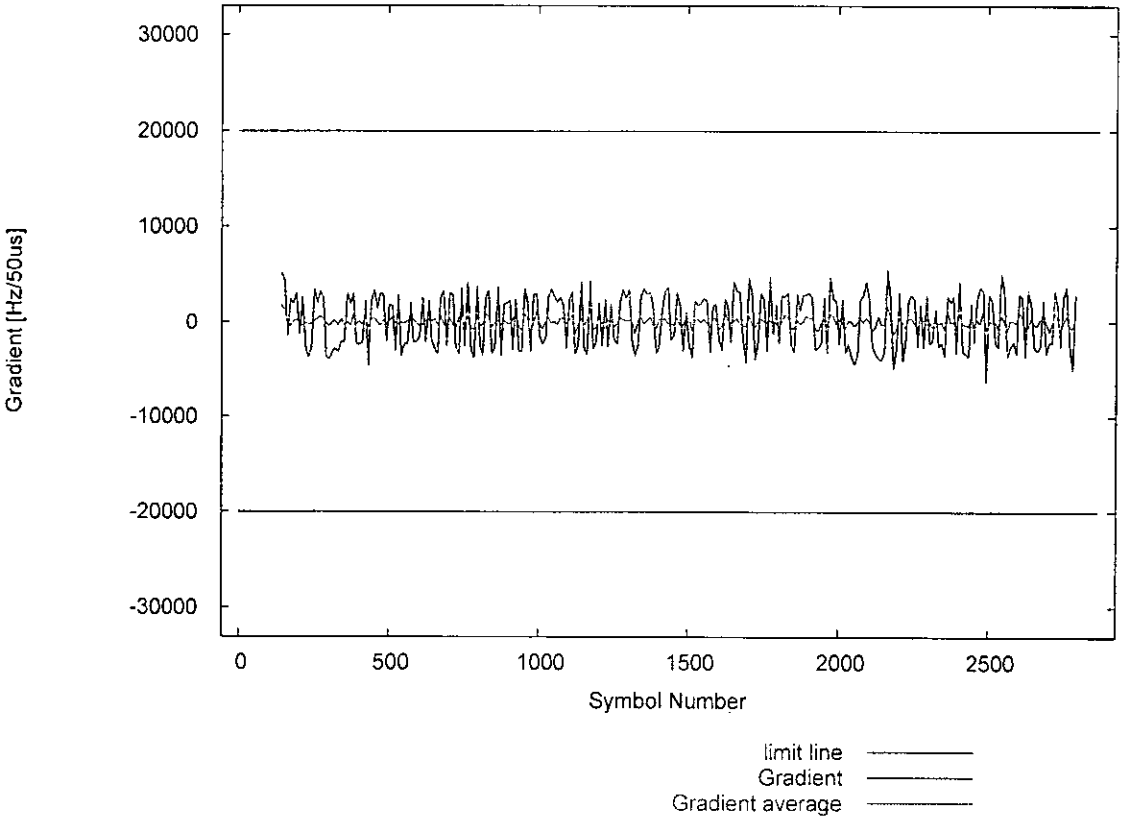
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern



TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2480.000 MHz



TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2480.000 MHz



Carrier Frequency Drift

For system parameter see 0, "General Parameter 010"

BT Test Specification Version: 1.2

TS Errata Request: 190
TS Errata Request: 277

For EUT parameter see 0, "EUT Parameter 006"
For test case parameter see 0, "Test Case Parameter 031"

Packet Nr.	Type	Freq [MHz]	Max Drift [kHz]		LIMIT [kHz]	Max Gradient [Hz/50us]		LIMIT [Hz/50us]	VERDICT
1	DH1	2402	2.726	<=	25.000				PASS
1	DH1	2402				2700.14	<=	20000.000	PASS
2	DH1	2402	5.030	<=	25.000				PASS
2	DH1	2402				3033.56	<=	20000.000	PASS
3	DH1	2402	2.976	<=	25.000				PASS
3	DH1	2402				3058.14	<=	20000.000	PASS
4	DH1	2402	3.617	<=	25.000				PASS
4	DH1	2402				1329.63	<=	20000.000	PASS
5	DH1	2402	7.029	<=	25.000				PASS
5	DH1	2402				3852.16	<=	20000.000	PASS
6	DH1	2402	2.689	<=	25.000				PASS
6	DH1	2402				2679.45	<=	20000.000	PASS
7	DH1	2402	5.312	<=	25.000				PASS
7	DH1	2402				2048.73	<=	20000.000	PASS
8	DH1	2402	5.142	<=	25.000				PASS
8	DH1	2402				1331.12	<=	20000.000	PASS
9	DH1	2402	2.407	<=	25.000				PASS
9	DH1	2402				2424.96	<=	20000.000	PASS
10	DH1	2402	3.171	<=	25.000				PASS
10	DH1	2402				1389.13	<=	20000.000	PASS
1	DH1	2441	5.188	<=	25.000				PASS
1	DH1	2441				3290.15	<=	20000.000	PASS
2	DH1	2441	5.774	<=	25.000				PASS
2	DH1	2441				4773.62	<=	20000.000	PASS
3	DH1	2441	5.707	<=	25.000				PASS
3	DH1	2441				3056.01	<=	20000.000	PASS
4	DH1	2441	3.004	<=	25.000				PASS
4	DH1	2441				3016.48	<=	20000.000	PASS
5	DH1	2441	7.483	<=	25.000				PASS
5	DH1	2441				1574.16	<=	20000.000	PASS
6	DH1	2441	3.359	<=	25.000				PASS
6	DH1	2441				3131.64	<=	20000.000	PASS
7	DH1	2441	4.186	<=	25.000				PASS
7	DH1	2441				3054.84	<=	20000.000	PASS
8	DH1	2441	7.310	<=	25.000				PASS
8	DH1	2441				2089.66	<=	20000.000	PASS
9	DH1	2441	3.853	<=	25.000				PASS
9	DH1	2441				3026.44	<=	20000.000	PASS
10	DH1	2441	5.706	<=	25.000				PASS
10	DH1	2441				4277.34	<=	20000.000	PASS
1	DH1	2480	9.323	<=	25.000				PASS
1	DH1	2480				2868.95	<=	20000.000	PASS
2	DH1	2480	7.977	<=	25.000				PASS
2	DH1	2480				1791.91	<=	20000.000	PASS
3	DH1	2480	3.694	<=	25.000				PASS
3	DH1	2480				2213.79	<=	20000.000	PASS

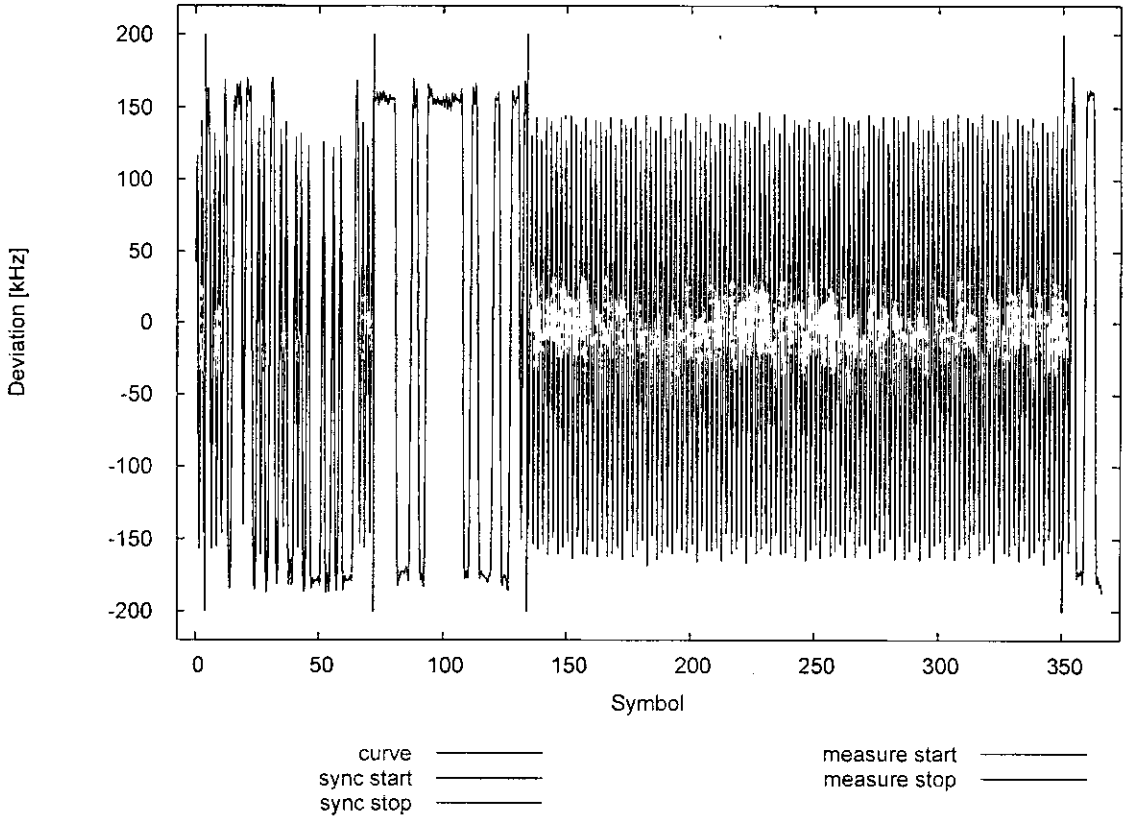
4	DH1	2480	7.225	<=	25.000			PASS
4	DH1	2480				4176.29	<= 20000.000	PASS
5	DH1	2480	6.658	<=	25.000			PASS
5	DH1	2480				3279.84	<= 20000.000	PASS
6	DH1	2480	2.905	<=	25.000			PASS
6	DH1	2480				2619.34	<= 20000.000	PASS
7	DH1	2480	5.195	<=	25.000			PASS
7	DH1	2480				2383.99	<= 20000.000	PASS
8	DH1	2480	8.358	<=	25.000			PASS
8	DH1	2480				3923.18	<= 20000.000	PASS
9	DH1	2480	4.259	<=	25.000			PASS
9	DH1	2480				3275.08	<= 20000.000	PASS
10	DH1	2480	4.898	<=	25.000			PASS
10	DH1	2480				2982.73	<= 20000.000	PASS
1	DH3	2402	4.652	<=	40.000			PASS
1	DH3	2402				4056.40	<= 20000.000	PASS
2	DH3	2402	3.963	<=	40.000			PASS
2	DH3	2402				4127.65	<= 20000.000	PASS
3	DH3	2402	5.777	<=	40.000			PASS
3	DH3	2402				4424.35	<= 20000.000	PASS
4	DH3	2402	3.706	<=	40.000			PASS
4	DH3	2402				3543.81	<= 20000.000	PASS
5	DH3	2402	4.609	<=	40.000			PASS
5	DH3	2402				6713.38	<= 20000.000	PASS
6	DH3	2402	7.471	<=	40.000			PASS
6	DH3	2402				4566.46	<= 20000.000	PASS
7	DH3	2402	4.361	<=	40.000			PASS
7	DH3	2402				3732.22	<= 20000.000	PASS
8	DH3	2402	7.301	<=	40.000			PASS
8	DH3	2402				4446.28	<= 20000.000	PASS
9	DH3	2402	7.146	<=	40.000			PASS
9	DH3	2402				4327.21	<= 20000.000	PASS
10	DH3	2402	4.476	<=	40.000			PASS
10	DH3	2402				4588.46	<= 20000.000	PASS
1	DH3	2441	3.875	<=	40.000			PASS
1	DH3	2441				3866.93	<= 20000.000	PASS
2	DH3	2441	9.119	<=	40.000			PASS
2	DH3	2441				5914.31	<= 20000.000	PASS
3	DH3	2441	4.595	<=	40.000			PASS
3	DH3	2441				3301.04	<= 20000.000	PASS
4	DH3	2441	7.766	<=	40.000			PASS
4	DH3	2441				4049.17	<= 20000.000	PASS
5	DH3	2441	3.676	<=	40.000			PASS
5	DH3	2441				4490.02	<= 20000.000	PASS
6	DH3	2441	3.714	<=	40.000			PASS
6	DH3	2441				4488.59	<= 20000.000	PASS
7	DH3	2441	4.730	<=	40.000			PASS
7	DH3	2441				4469.66	<= 20000.000	PASS
8	DH3	2441	7.228	<=	40.000			PASS
8	DH3	2441				4671.30	<= 20000.000	PASS
9	DH3	2441	6.725	<=	40.000			PASS
9	DH3	2441				4290.12	<= 20000.000	PASS
10	DH3	2441	5.925	<=	40.000			PASS
10	DH3	2441				6412.43	<= 20000.000	PASS
1	DH3	2480	4.635	<=	40.000			PASS
1	DH3	2480				4189.14	<= 20000.000	PASS
2	DH3	2480	3.890	<=	40.000			PASS
2	DH3	2480				4619.41	<= 20000.000	PASS
3	DH3	2480	9.808	<=	40.000			PASS
3	DH3	2480				9488.69	<= 20000.000	PASS
4	DH3	2480	5.120	<=	40.000			PASS
4	DH3	2480				4137.95	<= 20000.000	PASS
5	DH3	2480	6.456	<=	40.000			PASS
5	DH3	2480				3647.54	<= 20000.000	PASS
6	DH3	2480	4.954	<=	40.000			PASS

6	DH3	2480				4996.62	<= 20000.000	PASS
7	DH3	2480	6.715	<=	40.000			PASS
7	DH3	2480				4716.62	<= 20000.000	PASS
8	DH3	2480	5.654	<=	40.000			PASS
8	DH3	2480				4331.11	<= 20000.000	PASS
9	DH3	2480	6.505	<=	40.000			PASS
9	DH3	2480				3709.96	<= 20000.000	PASS
10	DH3	2480	6.745	<=	40.000			PASS
10	DH3	2480				5431.64	<= 20000.000	PASS
1	DH5	2402	5.587	<=	40.000			PASS
1	DH5	2402				4007.63	<= 20000.000	PASS
2	DH5	2402	6.822	<=	40.000			PASS
2	DH5	2402				5295.31	<= 20000.000	PASS
3	DH5	2402	4.752	<=	40.000			PASS
3	DH5	2402				6063.52	<= 20000.000	PASS
4	DH5	2402	7.549	<=	40.000			PASS
4	DH5	2402				4067.68	<= 20000.000	PASS
5	DH5	2402	5.025	<=	40.000			PASS
5	DH5	2402				4219.85	<= 20000.000	PASS
6	DH5	2402	7.267	<=	40.000			PASS
6	DH5	2402				3718.49	<= 20000.000	PASS
7	DH5	2402	5.815	<=	40.000			PASS
7	DH5	2402				4829.69	<= 20000.000	PASS
8	DH5	2402	8.765	<=	40.000			PASS
8	DH5	2402				5662.01	<= 20000.000	PASS
9	DH5	2402	3.519	<=	40.000			PASS
9	DH5	2402				4469.29	<= 20000.000	PASS
10	DH5	2402	7.653	<=	40.000			PASS
10	DH5	2402				4252.81	<= 20000.000	PASS
1	DH5	2441	3.405	<=	40.000			PASS
1	DH5	2441				5906.22	<= 20000.000	PASS
2	DH5	2441	7.711	<=	40.000			PASS
2	DH5	2441				4992.94	<= 20000.000	PASS
3	DH5	2441	5.858	<=	40.000			PASS
3	DH5	2441				4517.57	<= 20000.000	PASS
4	DH5	2441	7.002	<=	40.000			PASS
4	DH5	2441				3375.86	<= 20000.000	PASS
5	DH5	2441	8.789	<=	40.000			PASS
5	DH5	2441				4148.81	<= 20000.000	PASS
6	DH5	2441	8.687	<=	40.000			PASS
6	DH5	2441				4193.22	<= 20000.000	PASS
7	DH5	2441	5.308	<=	40.000			PASS
7	DH5	2441				5311.81	<= 20000.000	PASS
8	DH5	2441	5.912	<=	40.000			PASS
8	DH5	2441				3747.35	<= 20000.000	PASS
9	DH5	2441	8.700	<=	40.000			PASS
9	DH5	2441				5023.25	<= 20000.000	PASS
10	DH5	2441	4.972	<=	40.000			PASS
10	DH5	2441				4260.61	<= 20000.000	PASS
1	DH5	2480	4.885	<=	40.000			PASS
1	DH5	2480				4228.94	<= 20000.000	PASS
2	DH5	2480	9.180	<=	40.000			PASS
2	DH5	2480				5791.13	<= 20000.000	PASS
3	DH5	2480	7.219	<=	40.000			PASS
3	DH5	2480				7040.82	<= 20000.000	PASS
4	DH5	2480	7.836	<=	40.000			PASS
4	DH5	2480				5370.39	<= 20000.000	PASS
5	DH5	2480	7.805	<=	40.000			PASS
5	DH5	2480				5630.91	<= 20000.000	PASS
6	DH5	2480	3.916	<=	40.000			PASS
6	DH5	2480				3786.28	<= 20000.000	PASS
7	DH5	2480	5.451	<=	40.000			PASS
7	DH5	2480				4661.32	<= 20000.000	PASS
8	DH5	2480	6.256	<=	40.000			PASS
8	DH5	2480				4874.29	<= 20000.000	PASS

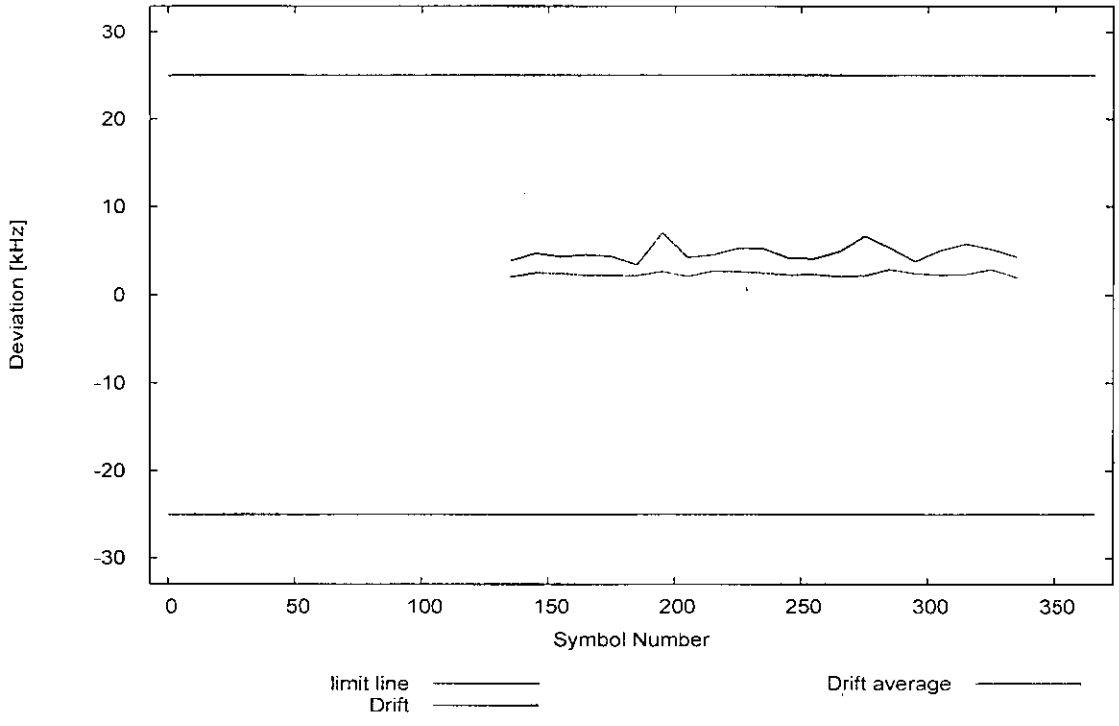
9	DH5	2480	4.698	<=	40.000			PASS
9	DH5	2480				5376.33	<= 20000.000	PASS
10	DH5	2480	8.733	<=	40.000			PASS
10	DH5	2480				3556.40	<= 20000.000	PASS

Final Test Case Verdict . . . . . PASS 00:33:17

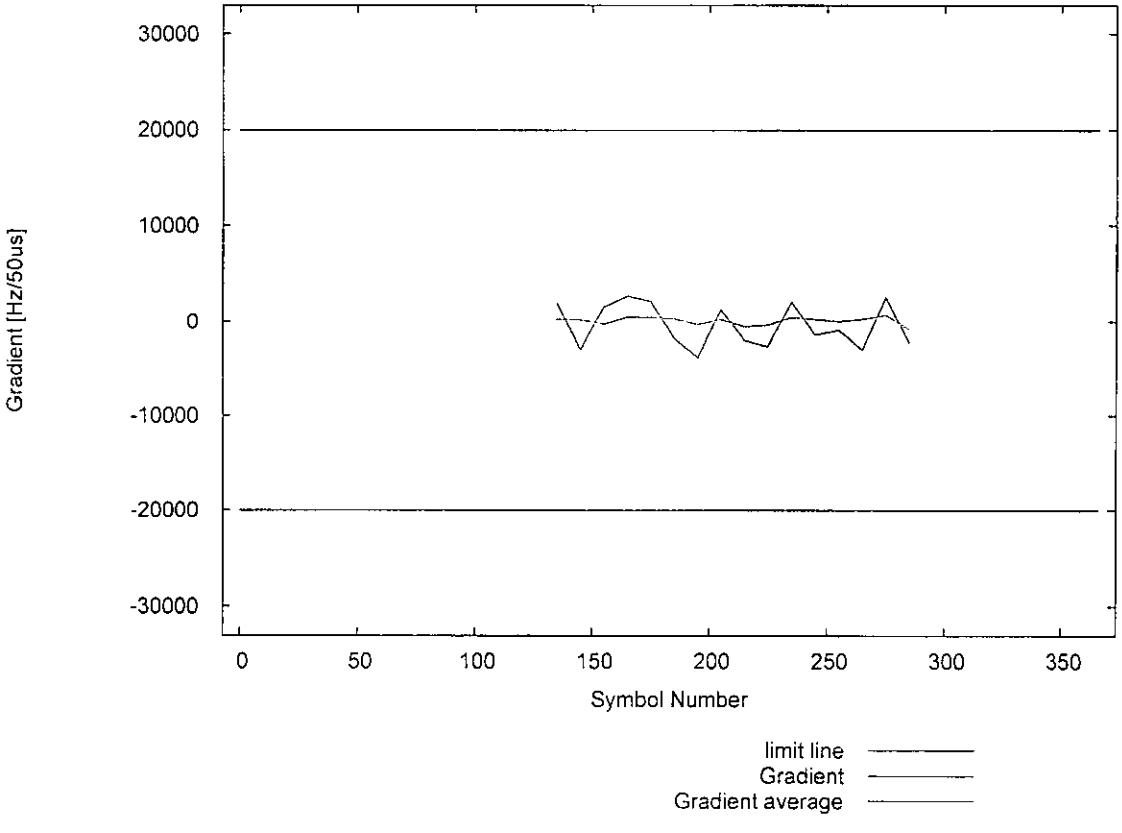
Measured Burst, FSK Signal TC·Carrier Frequency Drift packet DH1 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern



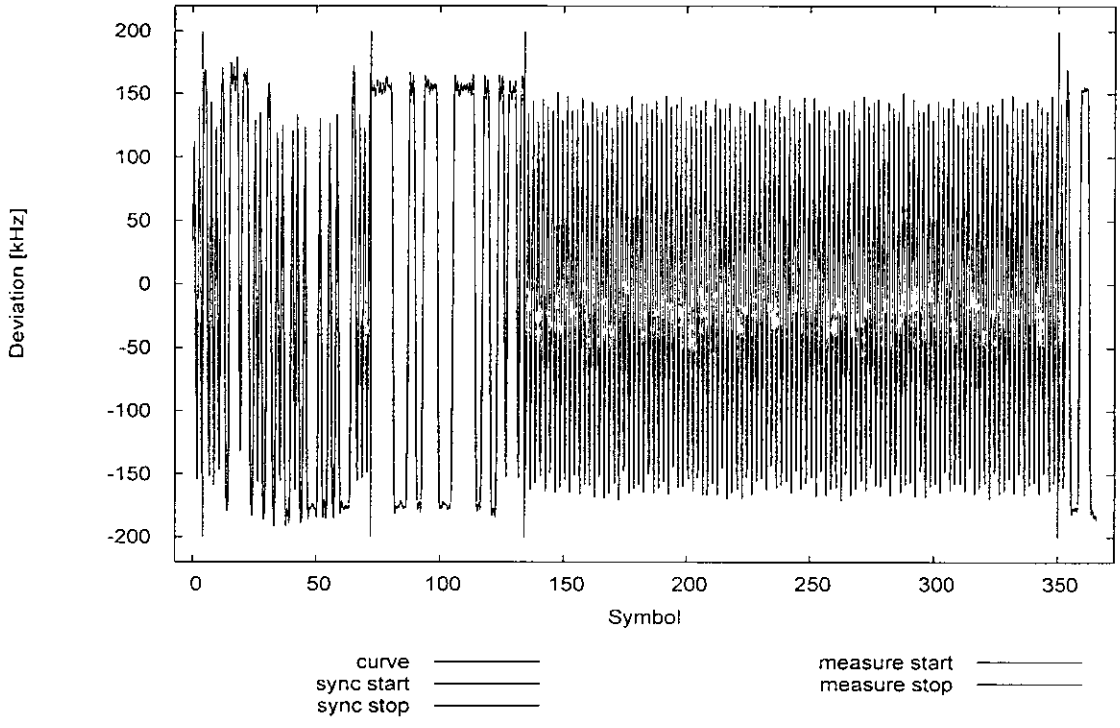
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2402.000 MHz



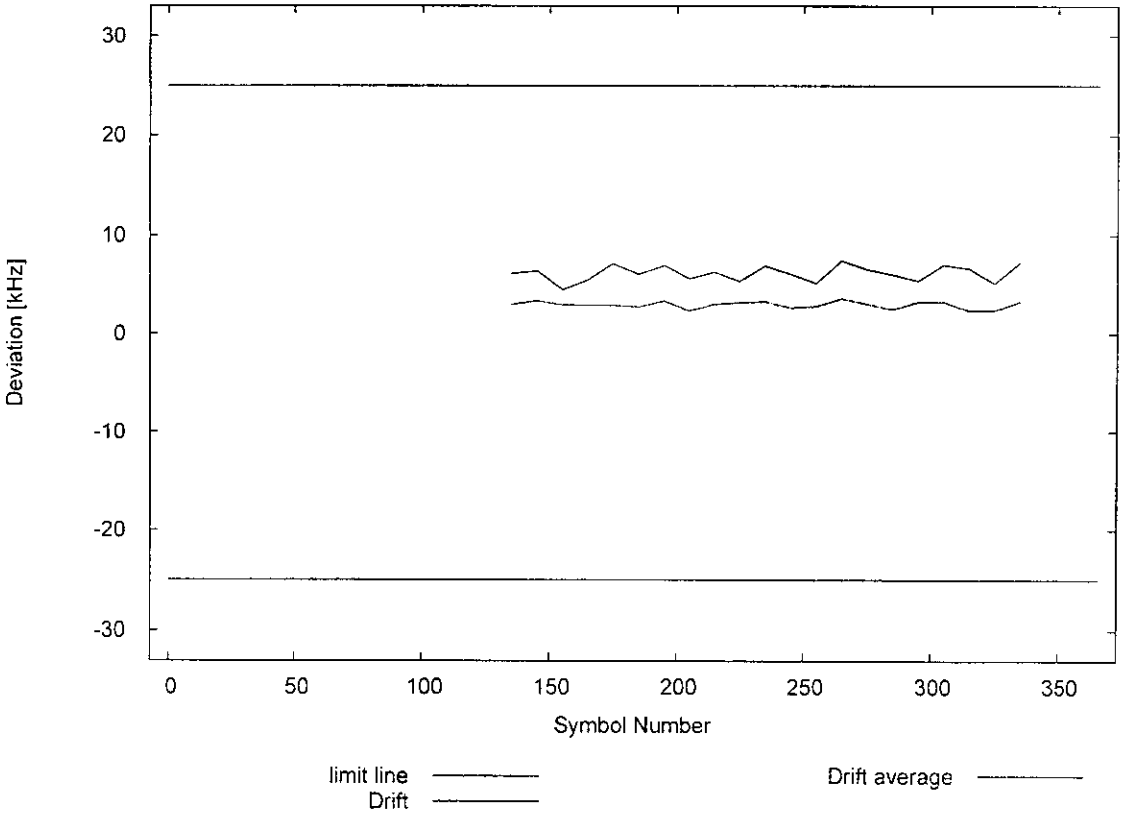
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2402.000 MHz



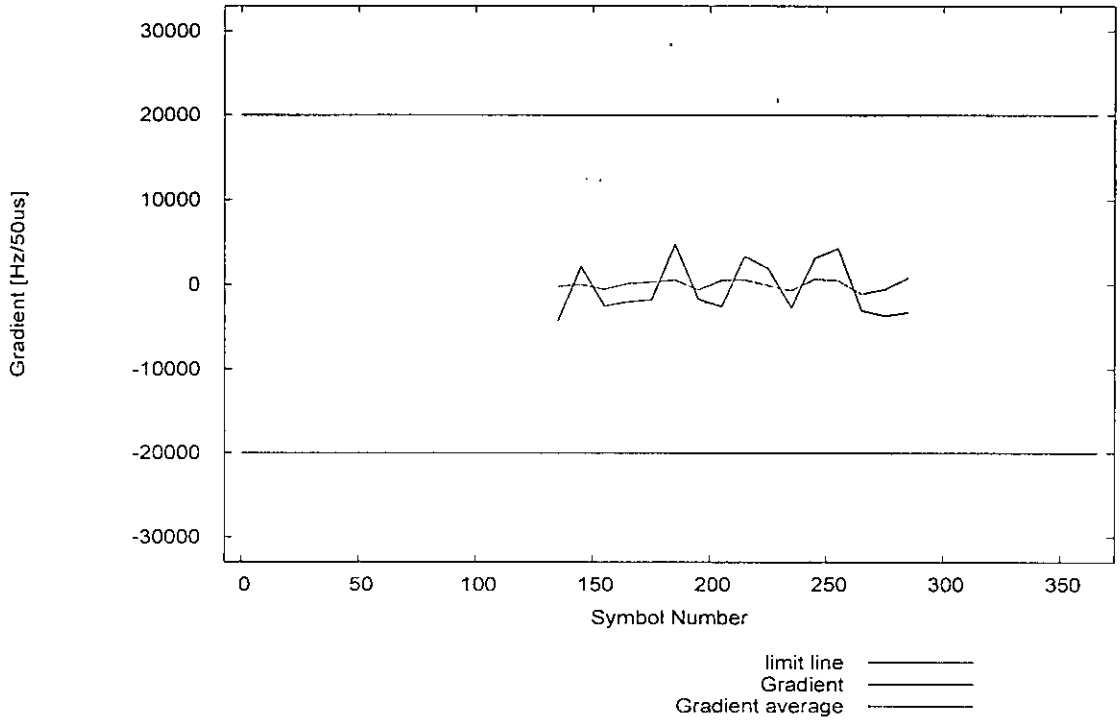
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern



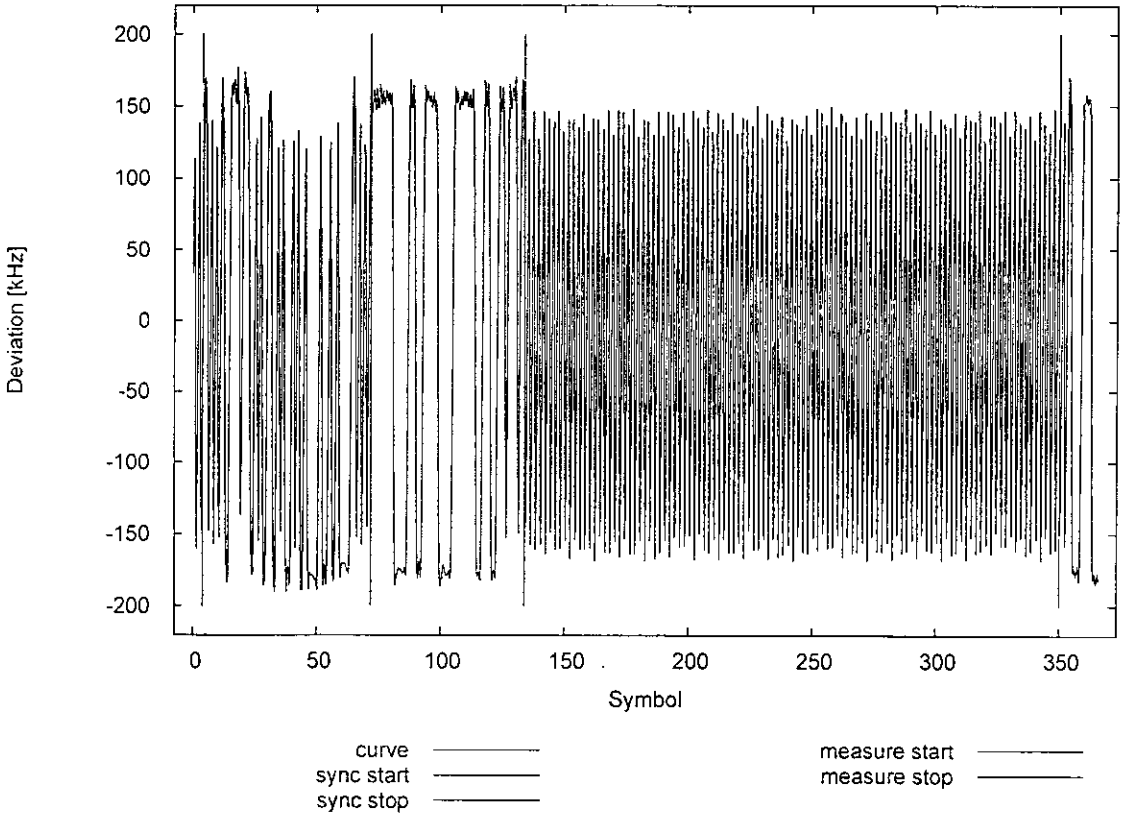
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2441.000 MHz



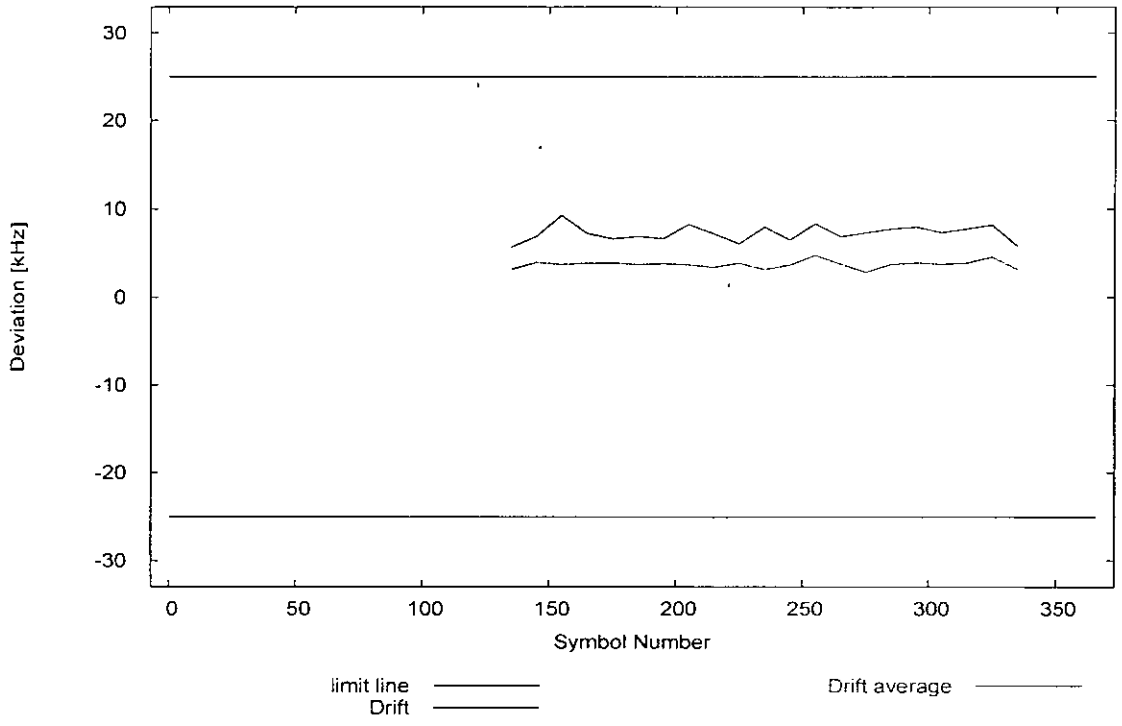
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2441.000 MHz



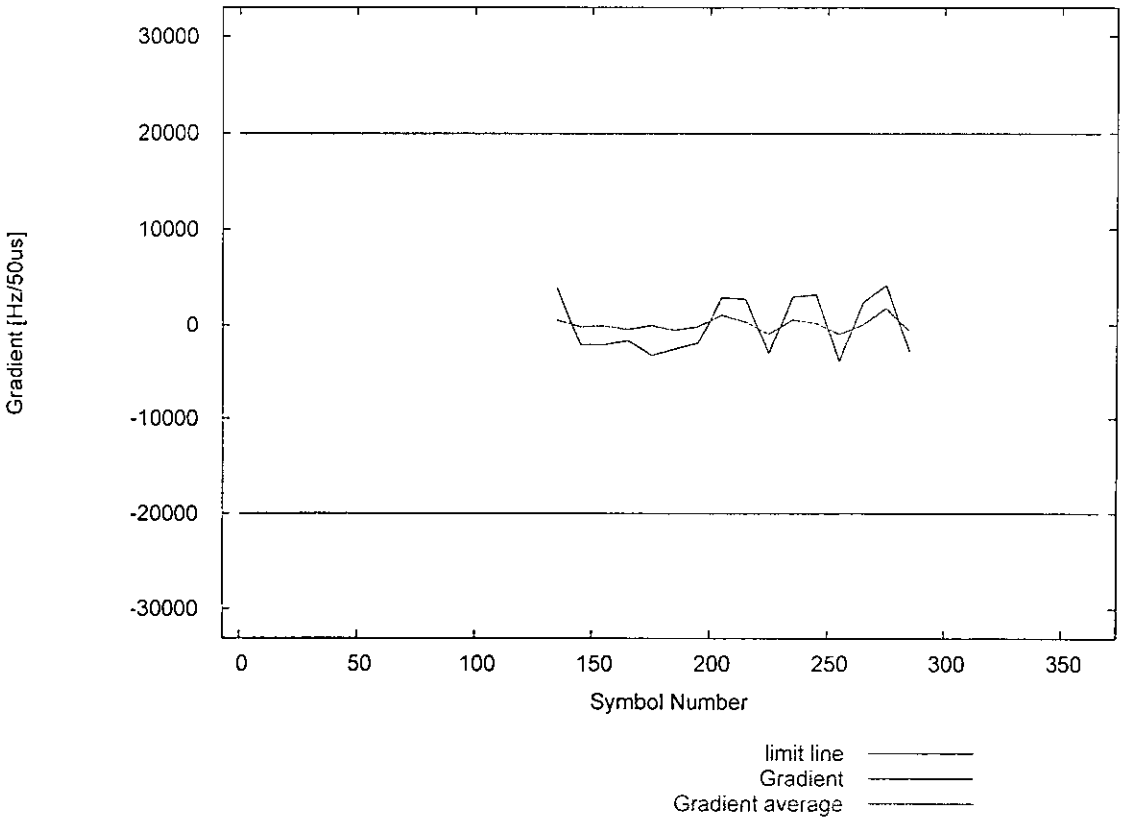
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern



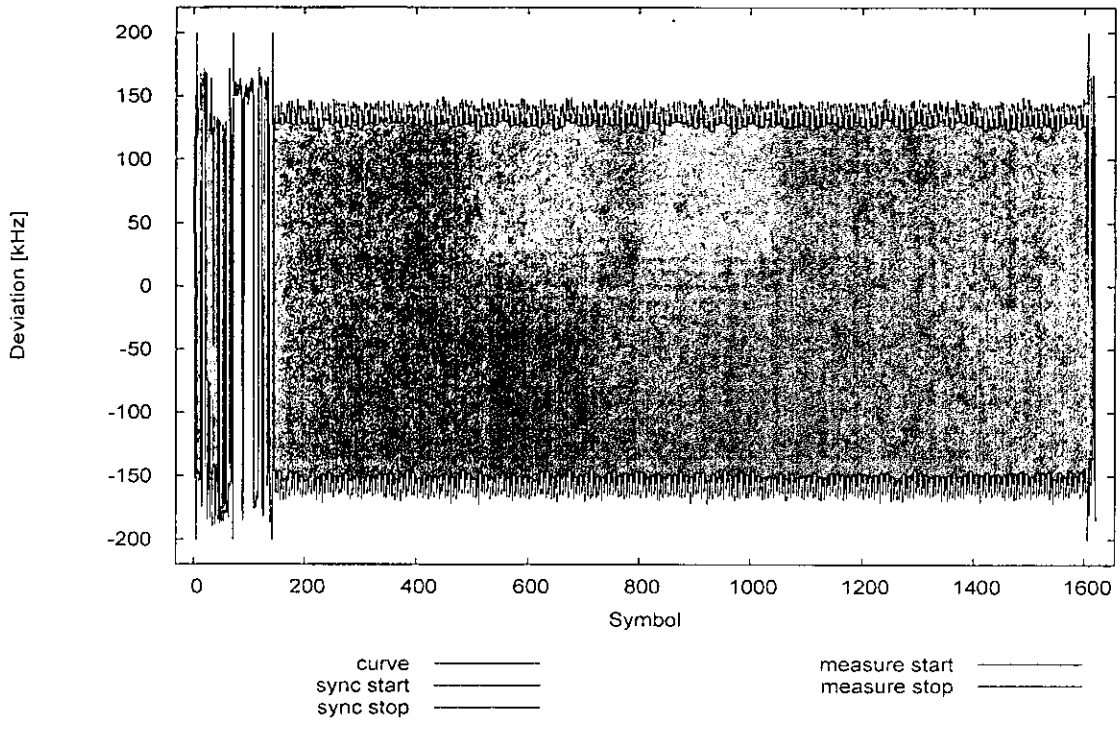
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2480.000 MHz



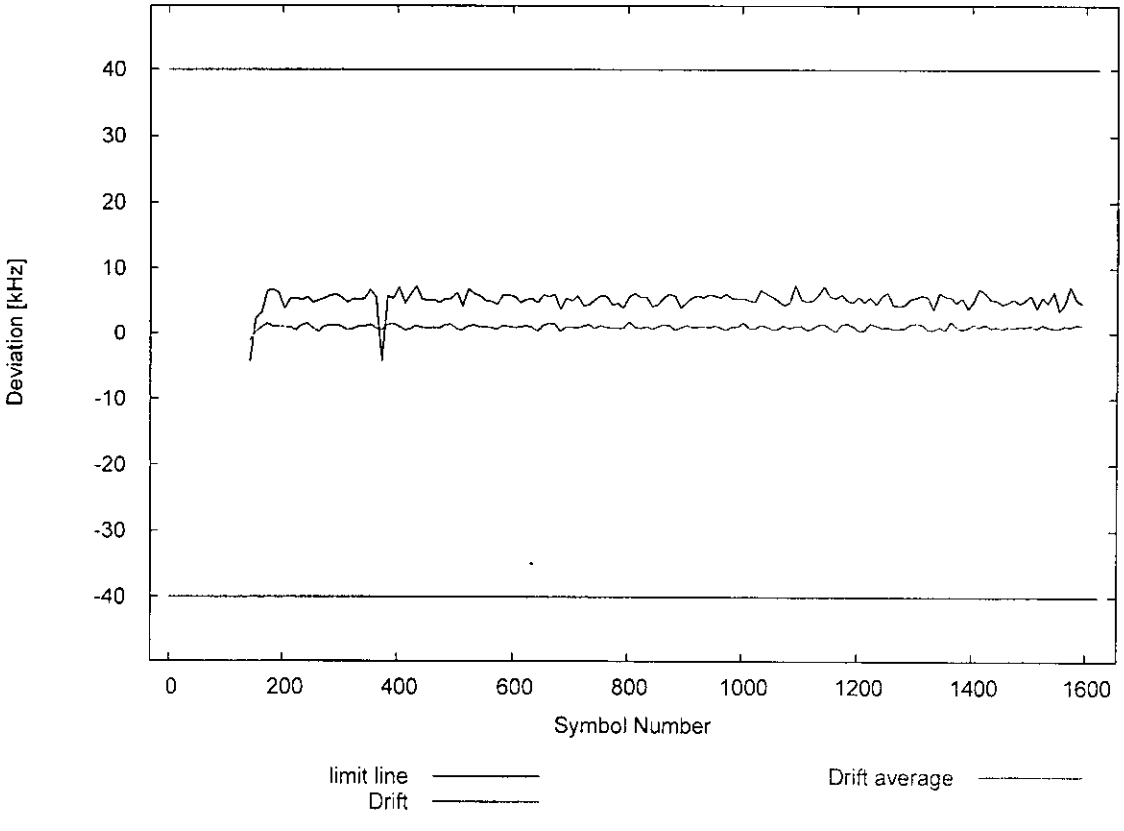
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2480.000 MHz



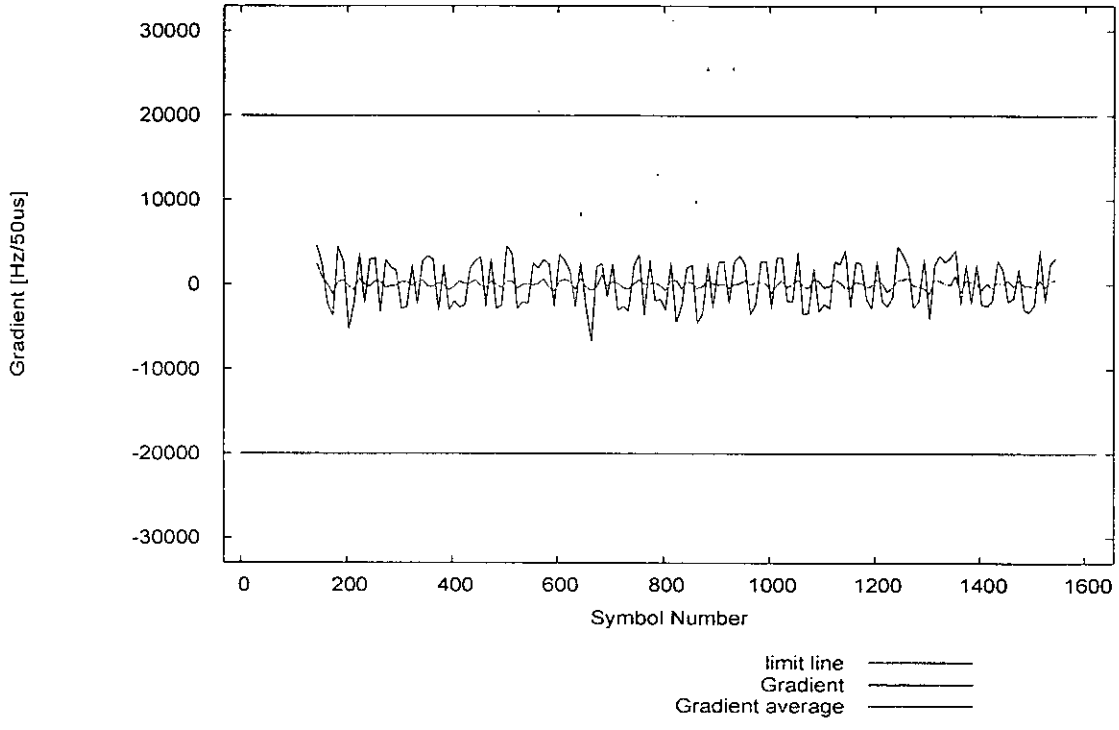
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH3 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern



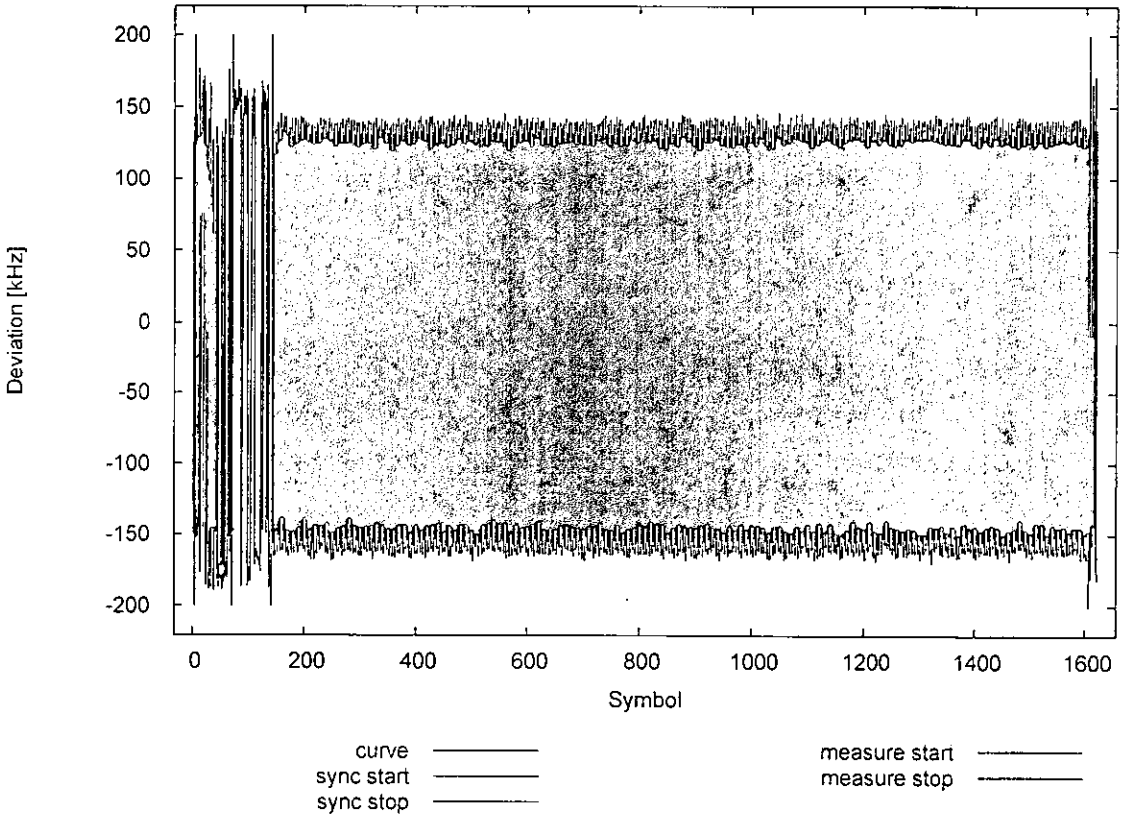
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2402.000 MHz



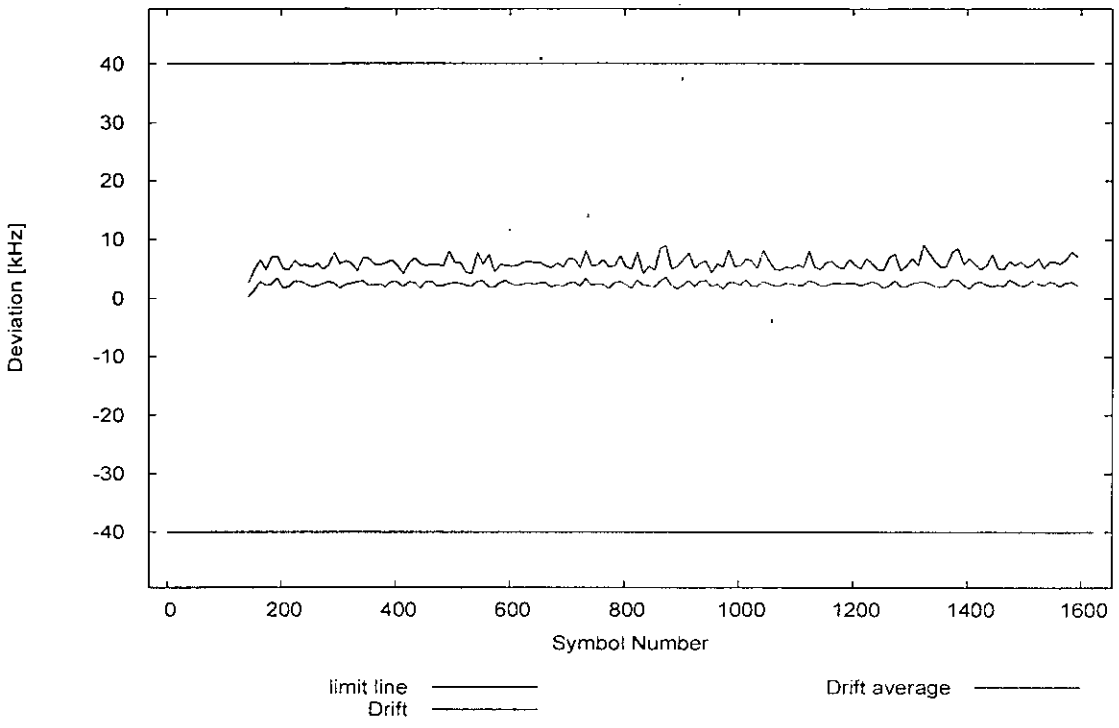
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2402.000 MHz



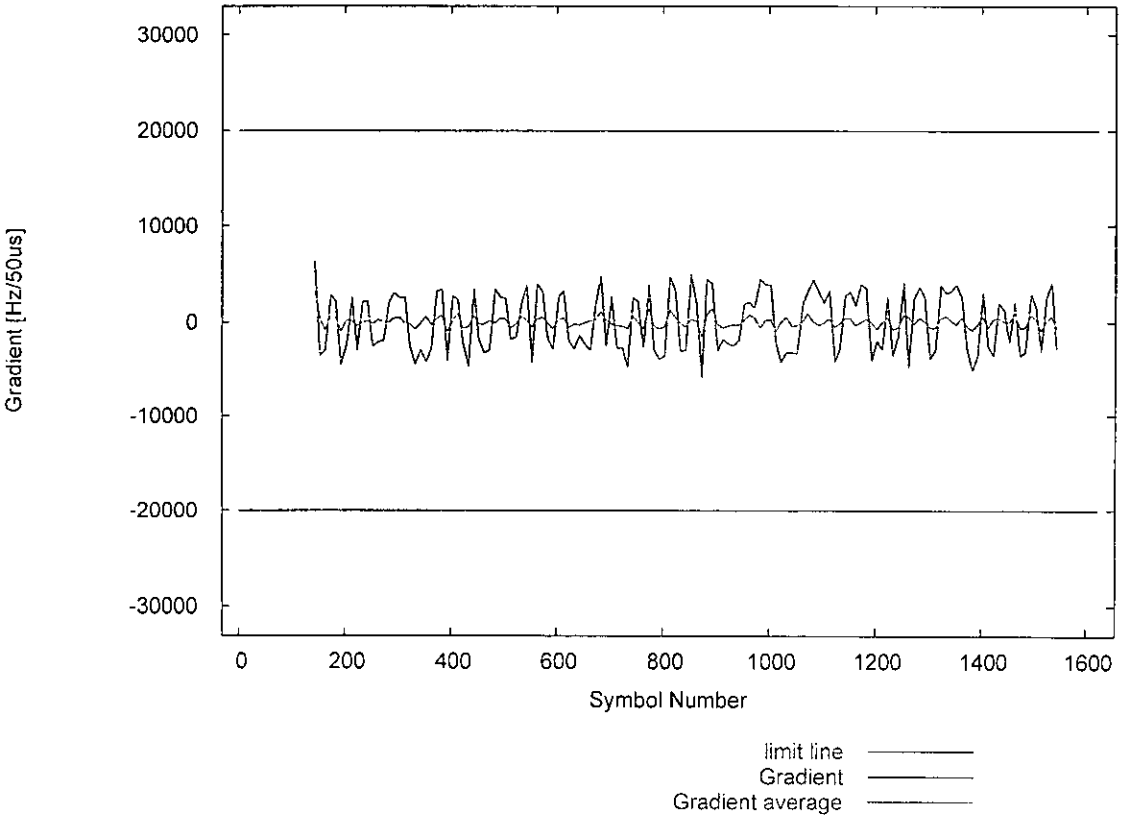
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern



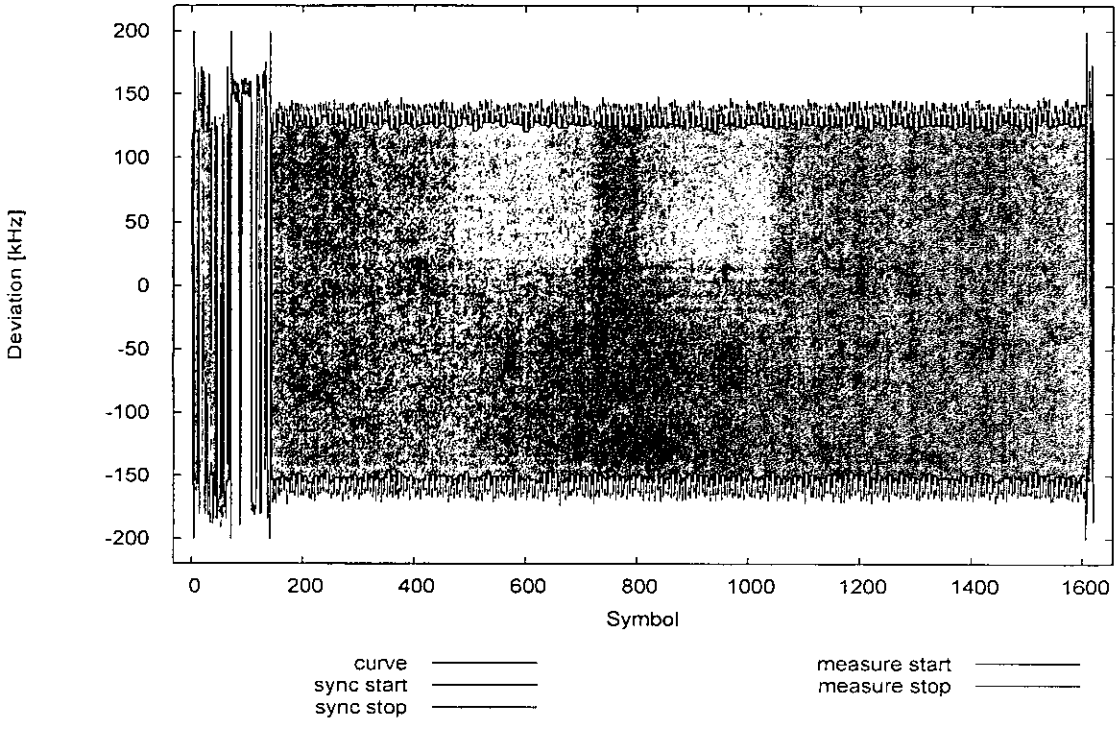
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2441.000 MHz



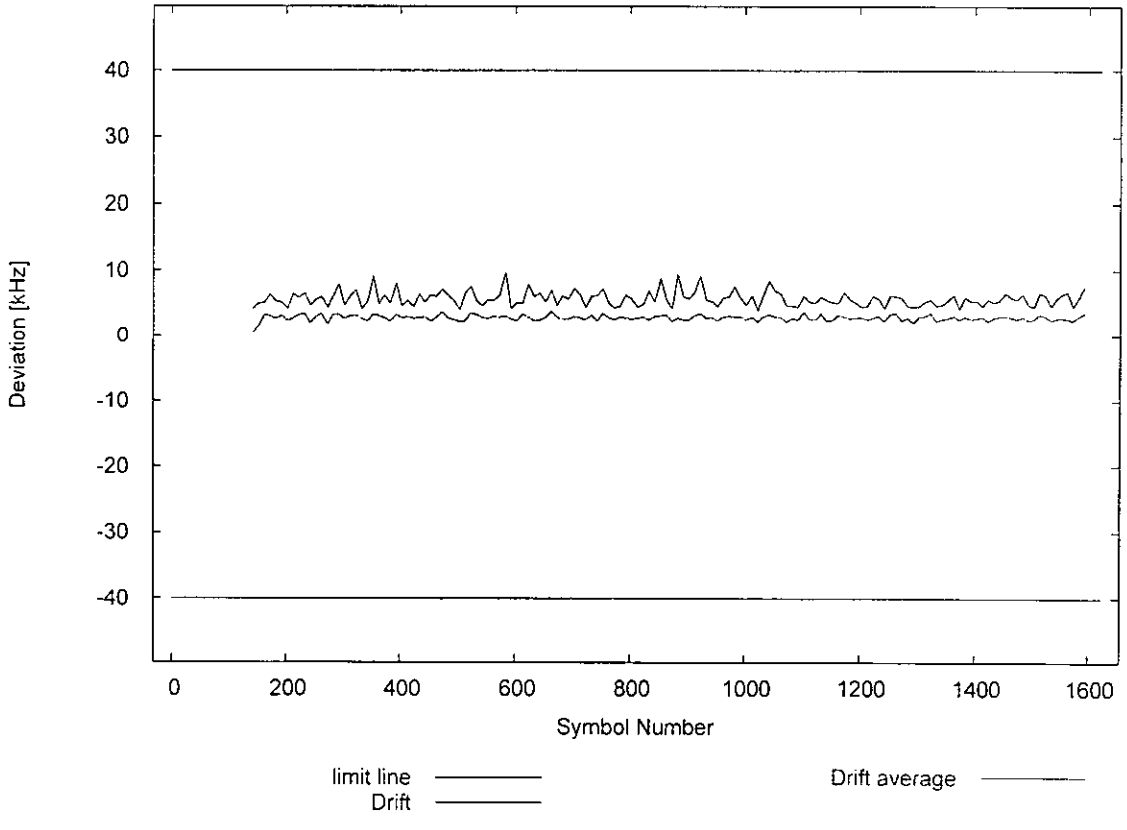
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2441.000 MHz



Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern

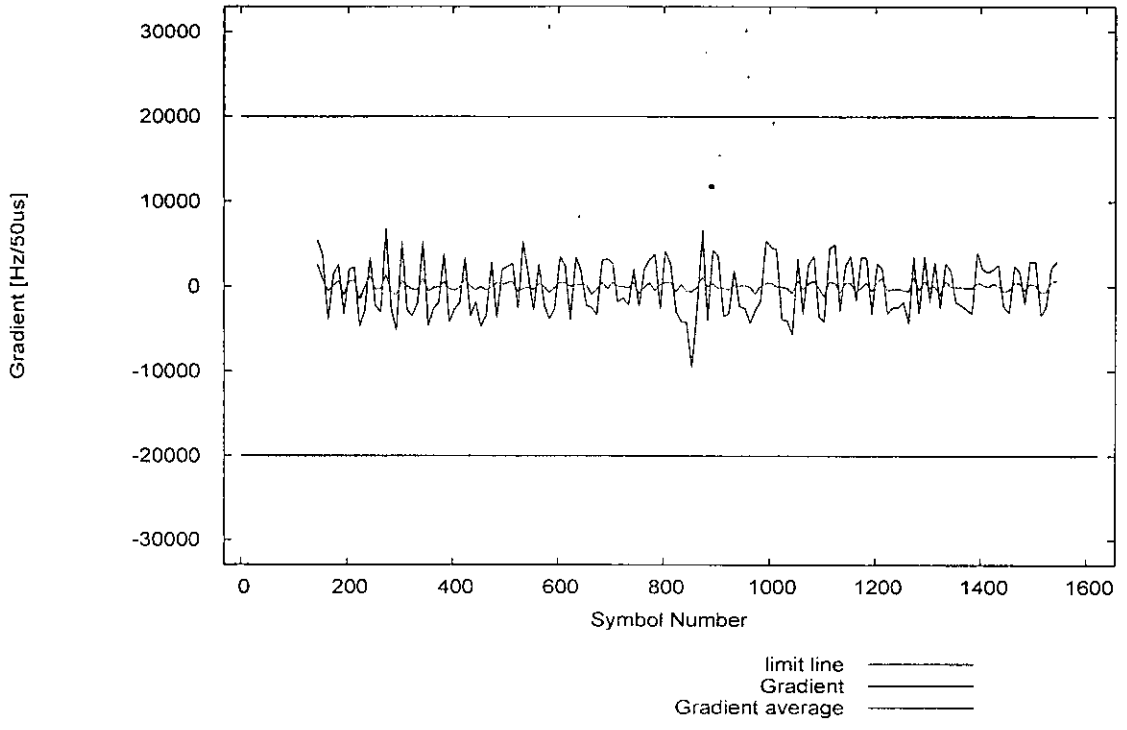


TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2480.000 MHz

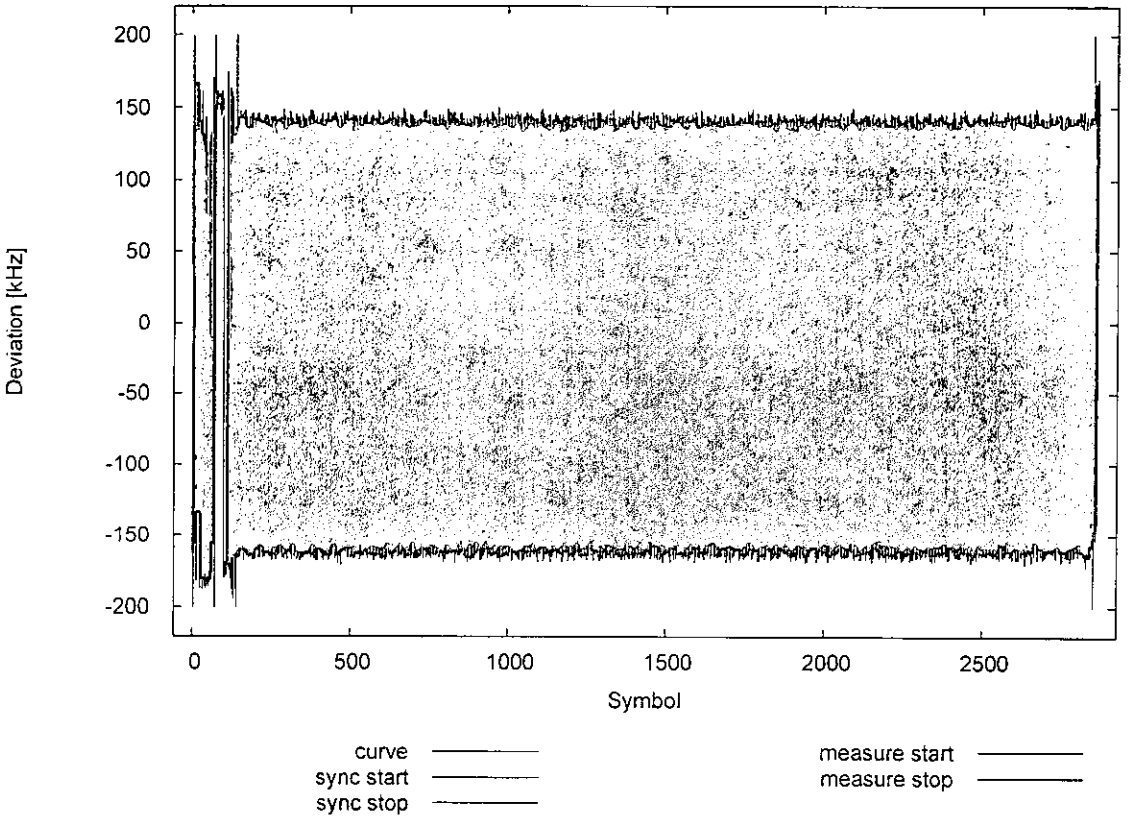


1220

TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2480.000 MHz

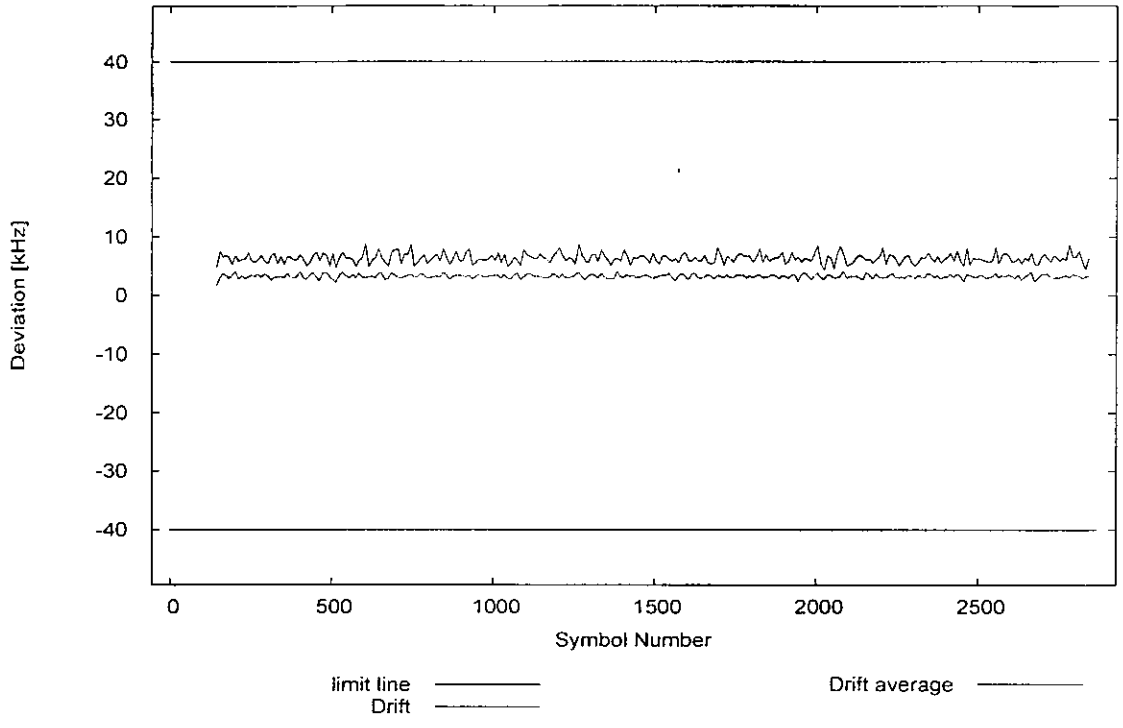


Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern

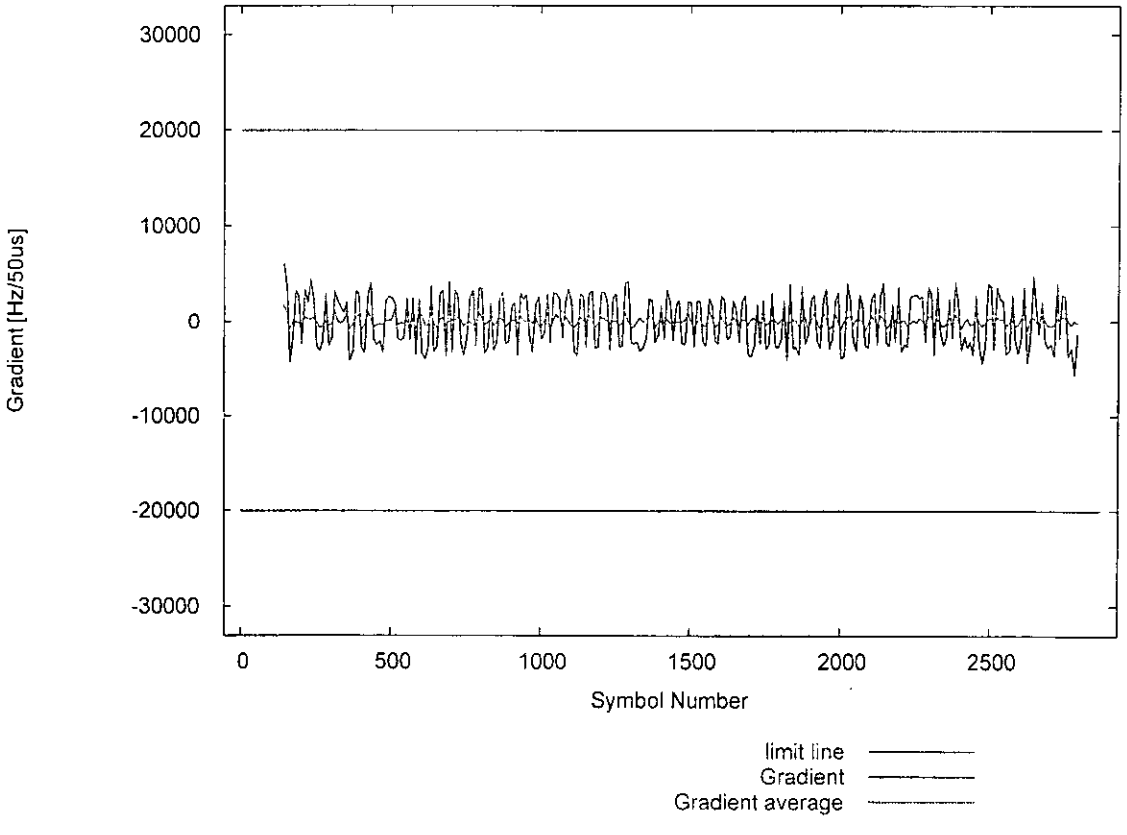


1221

TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2402.000 MHz

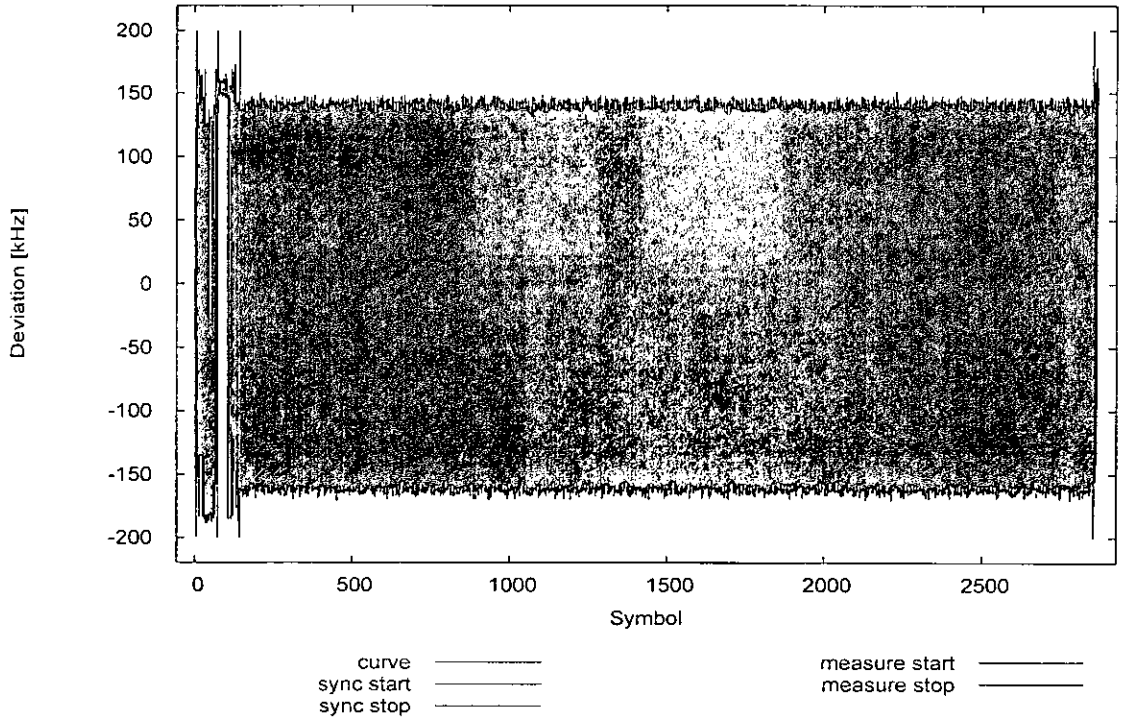


TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2402.000 MHz

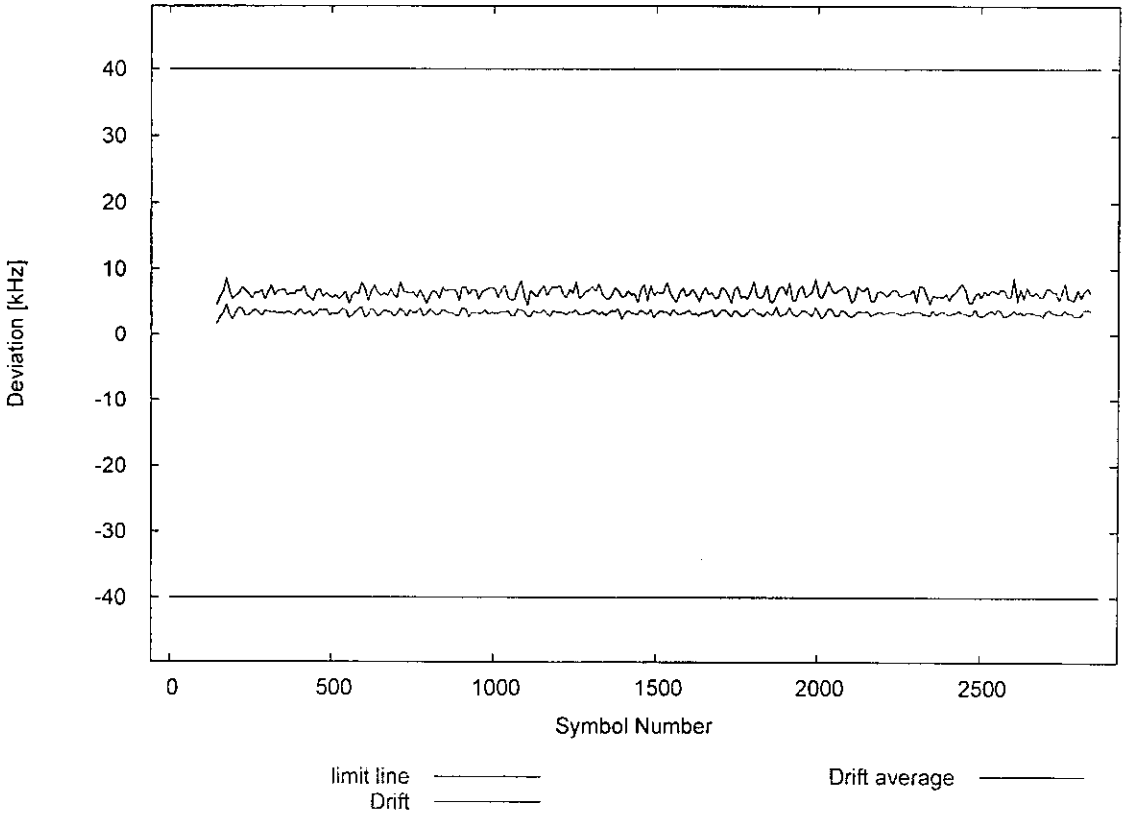


1222

Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH5 Loop Back Mode -
Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern

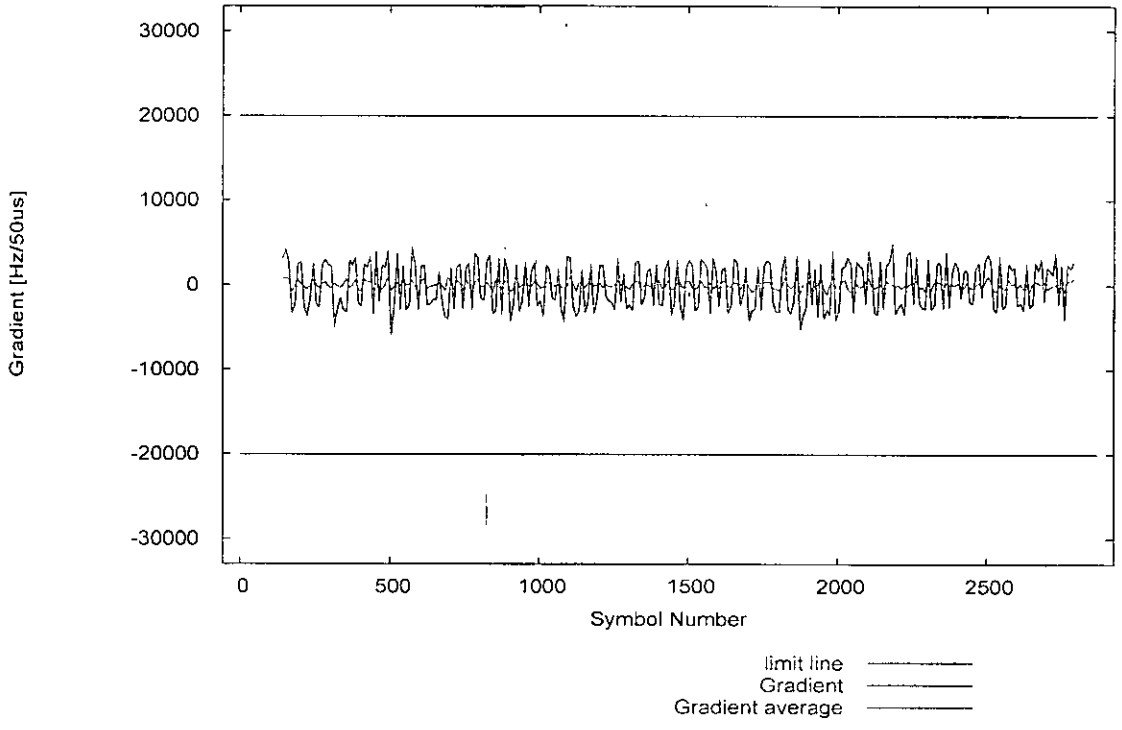


TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2441.000 MHz

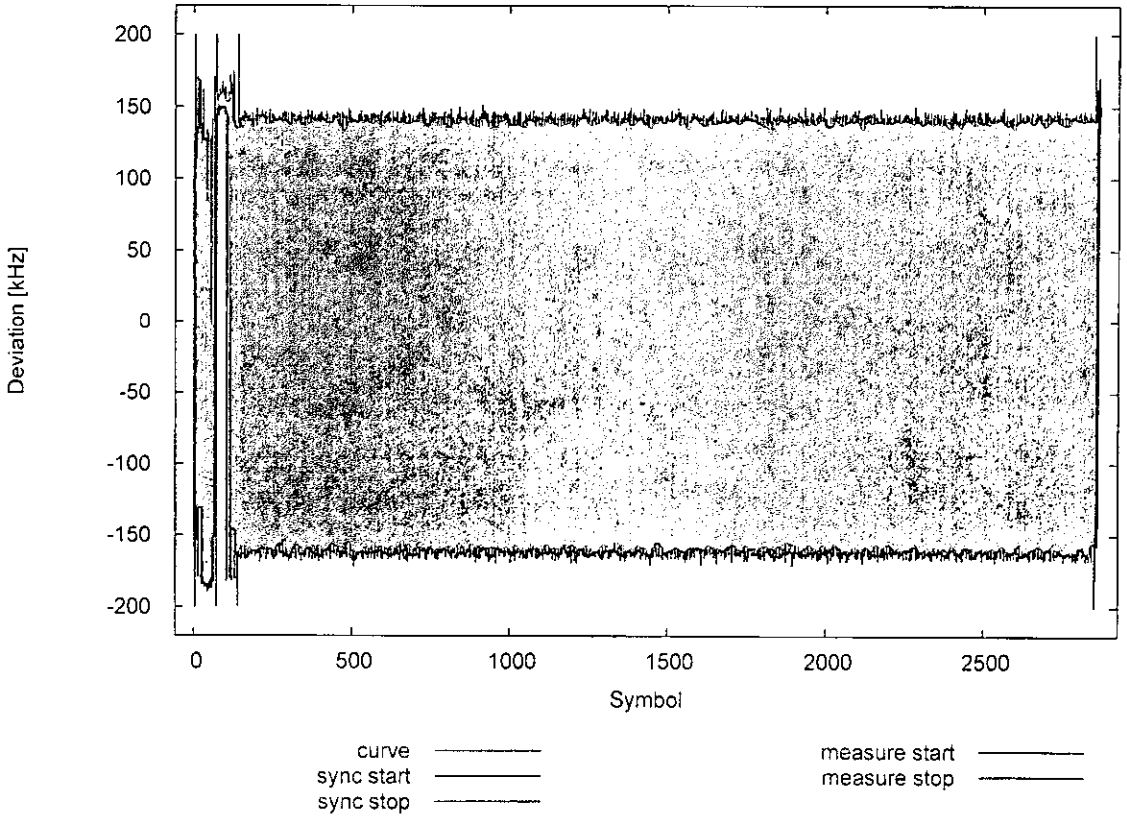


1223

TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2441.000 MHz

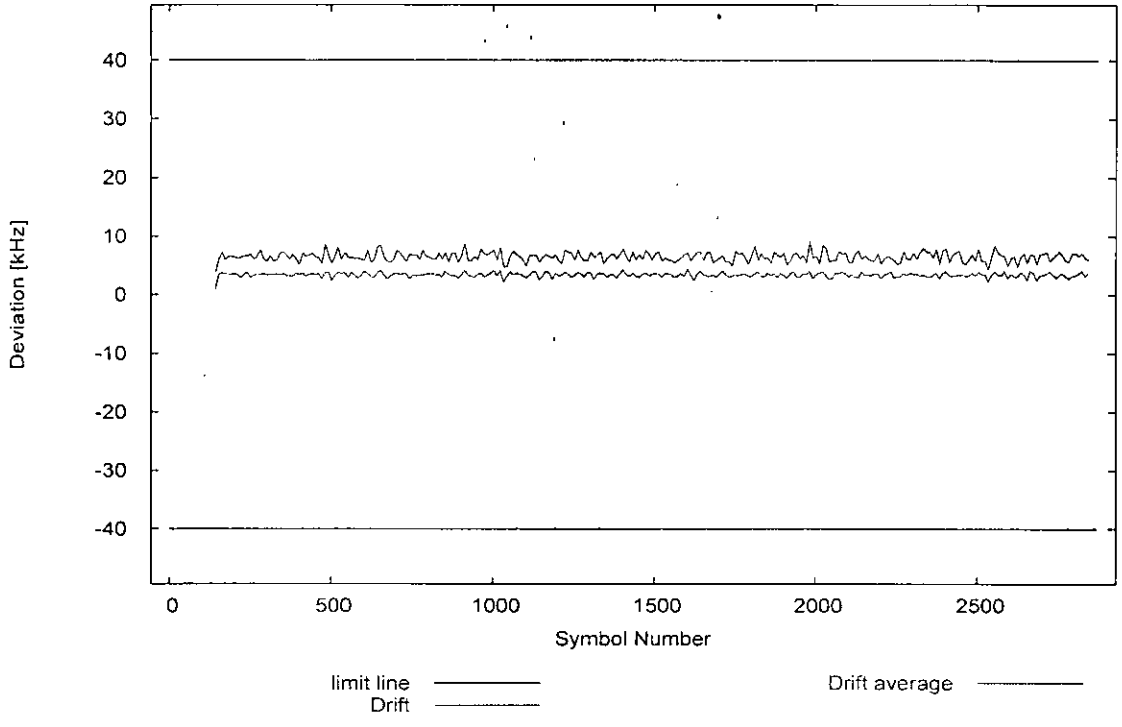


Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern

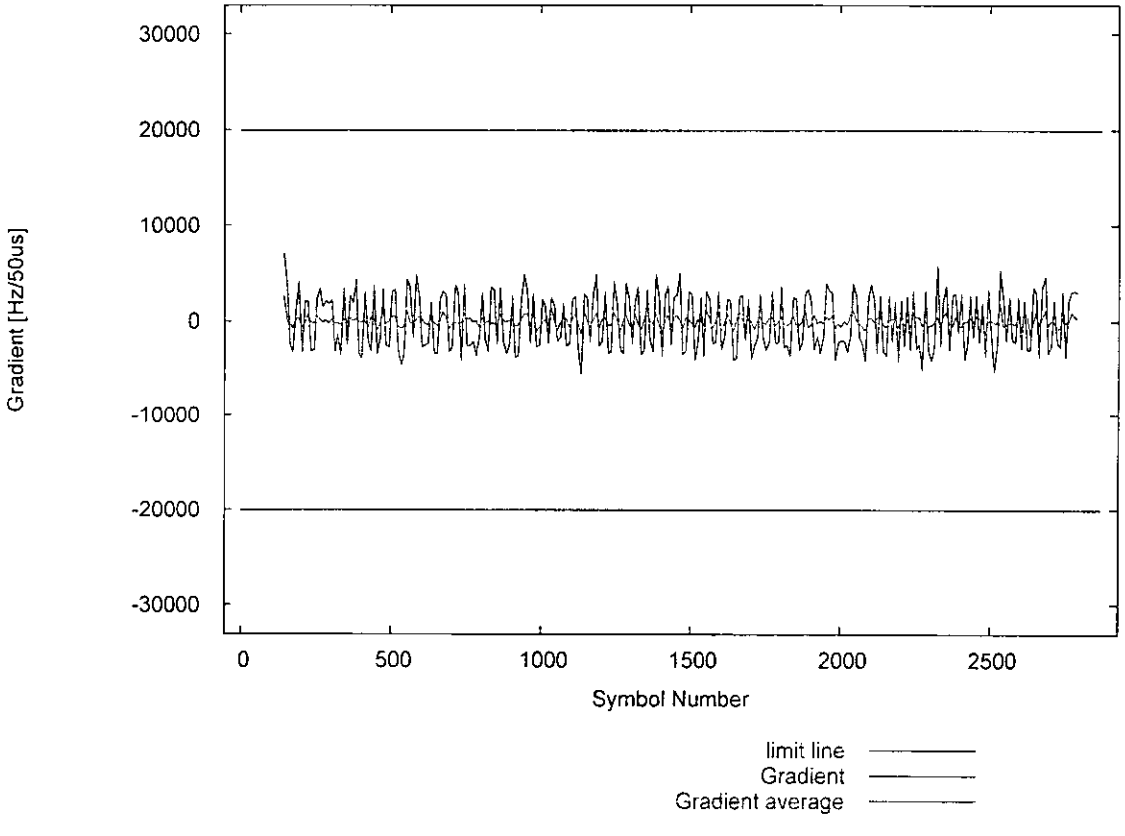


1224

TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2480.000 MHz



TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2480.000 MHz



Carrier Frequency Drift

For system parameter see 0, "General Parameter 010"

BT Test Specification Version: 1.2

TS Errata Request: 190
TS Errata Request: 277

For EUT parameter see 0, "EUT Parameter 009"
For test case parameter see 0, "Test Case Parameter 050"

Packet Nr.	Type	Freq [MHz]	Max Drift [kHz]		LIMIT [kHz]	Max Gradient [Hz/50us]		LIMIT [Hz/50us]	VERDICT
1	DH1	2402	7.948	<=	25.000				PASS
1	DH1	2402				3872.16	<=	20000.000	PASS
2	DH1	2402	7.406	<=	25.000				PASS
2	DH1	2402				4056.40	<=	20000.000	PASS
3	DH1	2402	8.195	<=	25.000				PASS
3	DH1	2402				2534.42	<=	20000.000	PASS
4	DH1	2402	8.950	<=	25.000				PASS
4	DH1	2402				3887.27	<=	20000.000	PASS
5	DH1	2402	5.526	<=	25.000				PASS
5	DH1	2402				4145.04	<=	20000.000	PASS
6	DH1	2402	7.829	<=	25.000				PASS
6	DH1	2402				2650.60	<=	20000.000	PASS
7	DH1	2402	3.050	<=	25.000				PASS
7	DH1	2402				5055.44	<=	20000.000	PASS
8	DH1	2402	7.888	<=	25.000				PASS
8	DH1	2402				3315.22	<=	20000.000	PASS
9	DH1	2402	7.768	<=	25.000				PASS
9	DH1	2402				2981.52	<=	20000.000	PASS
10	DH1	2402	7.692	<=	25.000				PASS
10	DH1	2402				2274.94	<=	20000.000	PASS
1	DH1	2441	10.785	<=	25.000				PASS
1	DH1	2441				2775.27	<=	20000.000	PASS
2	DH1	2441	10.723	<=	25.000				PASS
2	DH1	2441				4024.23	<=	20000.000	PASS
3	DH1	2441	10.069	<=	25.000				PASS
3	DH1	2441				3554.02	<=	20000.000	PASS
4	DH1	2441	5.477	<=	25.000				PASS
4	DH1	2441				4507.67	<=	20000.000	PASS
5	DH1	2441	7.736	<=	25.000				PASS
5	DH1	2441				3654.95	<=	20000.000	PASS
6	DH1	2441	7.466	<=	25.000				PASS
6	DH1	2441				3699.79	<=	20000.000	PASS
7	DH1	2441	10.152	<=	25.000				PASS
7	DH1	2441				4694.30	<=	20000.000	PASS
8	DH1	2441	8.528	<=	25.000				PASS
8	DH1	2441				5977.41	<=	20000.000	PASS
9	DH1	2441	8.750	<=	25.000				PASS
9	DH1	2441				3696.53	<=	20000.000	PASS
10	DH1	2441	10.161	<=	25.000				PASS
10	DH1	2441				3302.84	<=	20000.000	PASS
1	DH1	2480	7.847	<=	25.000				PASS
1	DH1	2480				3170.79	<=	20000.000	PASS
2	DH1	2480	9.471	<=	25.000				PASS
2	DH1	2480				3610.30	<=	20000.000	PASS
3	DH1	2480	9.186	<=	25.000				PASS
3	DH1	2480				4369.90	<=	20000.000	PASS

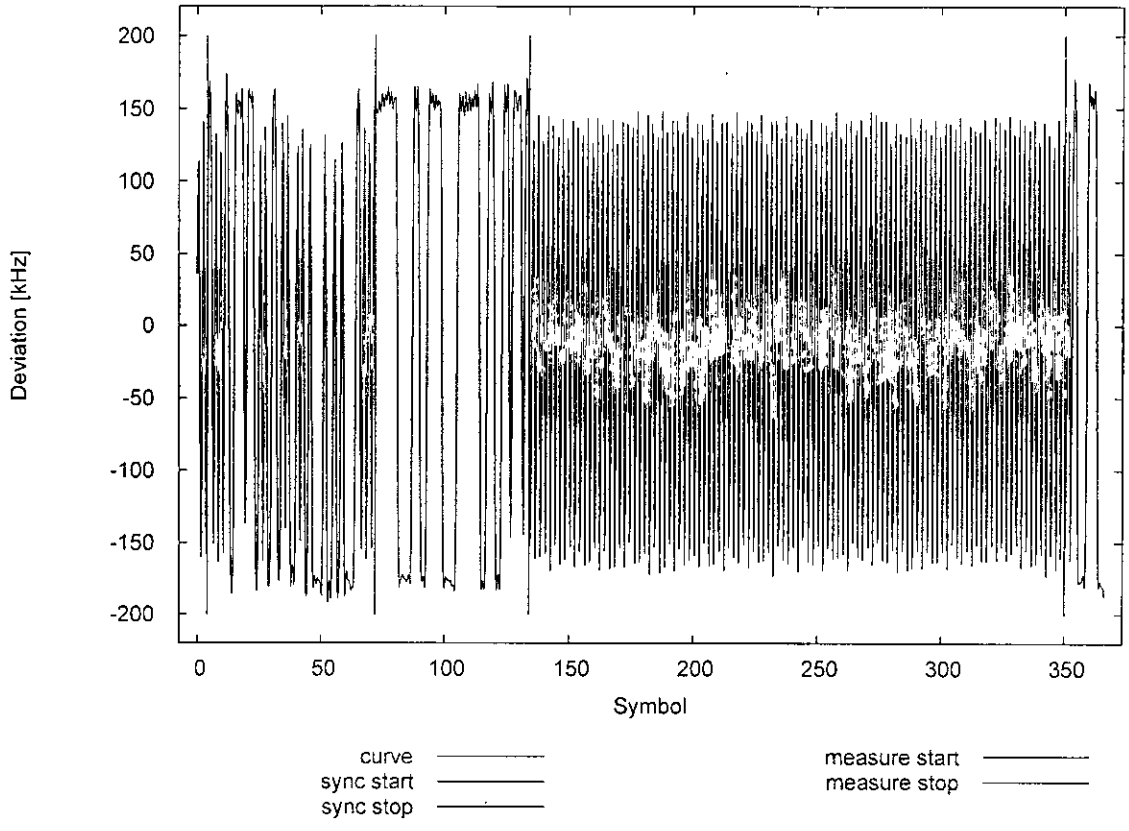
4	DH1	2480	7.809	<=	25.000			PASS
4	DH1	2480				5826.80	<= 20000.000	PASS
5	DH1	2480	8.120	<=	25.000			PASS
5	DH1	2480				3850.78	<= 20000.000	PASS
6	DH1	2480	8.482	<=	25.000			PASS
6	DH1	2480				2605.12	<= 20000.000	PASS
7	DH1	2480	4.492	<=	25.000			PASS
7	DH1	2480				4404.06	<= 20000.000	PASS
8	DH1	2480	11.830	<=	25.000			PASS
8	DH1	2480				3402.61	<= 20000.000	PASS
9	DH1	2480	5.033	<=	25.000			PASS
9	DH1	2480				3777.65	<= 20000.000	PASS
10	DH1	2480	7.825	<=	25.000			PASS
10	DH1	2480				3089.56	<= 20000.000	PASS
1	DH3	2402	7.360	<=	40.000			PASS
1	DH3	2402				4516.59	<= 20000.000	PASS
2	DH3	2402	4.801	<=	40.000			PASS
2	DH3	2402				5111.38	<= 20000.000	PASS
3	DH3	2402	6.594	<=	40.000			PASS
3	DH3	2402				4175.84	<= 20000.000	PASS
4	DH3	2402	5.299	<=	40.000			PASS
4	DH3	2402				5035.57	<= 20000.000	PASS
5	DH3	2402	5.502	<=	40.000			PASS
5	DH3	2402				4609.08	<= 20000.000	PASS
6	DH3	2402	3.996	<=	40.000			PASS
6	DH3	2402				5022.39	<= 20000.000	PASS
7	DH3	2402	4.254	<=	40.000			PASS
7	DH3	2402				5657.96	<= 20000.000	PASS
8	DH3	2402	8.206	<=	40.000			PASS
8	DH3	2402				4494.02	<= 20000.000	PASS
9	DH3	2402	4.742	<=	40.000			PASS
9	DH3	2402				5733.09	<= 20000.000	PASS
10	DH3	2402	11.979	<=	40.000			PASS
10	DH3	2402				5782.33	<= 20000.000	PASS
1	DH3	2441	6.965	<=	40.000			PASS
1	DH3	2441				5668.40	<= 20000.000	PASS
2	DH3	2441	11.631	<=	40.000			PASS
2	DH3	2441				6225.70	<= 20000.000	PASS
3	DH3	2441	5.694	<=	40.000			PASS
3	DH3	2441				8195.81	<= 20000.000	PASS
4	DH3	2441	5.642	<=	40.000			PASS
4	DH3	2441				5217.74	<= 20000.000	PASS
5	DH3	2441	6.713	<=	40.000			PASS
5	DH3	2441				5018.75	<= 20000.000	PASS
6	DH3	2441	9.657	<=	40.000			PASS
6	DH3	2441				5571.88	<= 20000.000	PASS
7	DH3	2441	6.266	<=	40.000			PASS
7	DH3	2441				4948.77	<= 20000.000	PASS
8	DH3	2441	6.952	<=	40.000			PASS
8	DH3	2441				4184.78	<= 20000.000	PASS
9	DH3	2441	7.577	<=	40.000			PASS
9	DH3	2441				5029.40	<= 20000.000	PASS
10	DH3	2441	6.040	<=	40.000			PASS
10	DH3	2441				4524.27	<= 20000.000	PASS
1	DH3	2480	10.906	<=	40.000			PASS
1	DH3	2480				6409.74	<= 20000.000	PASS
2	DH3	2480	9.200	<=	40.000			PASS
2	DH3	2480				5097.02	<= 20000.000	PASS
3	DH3	2480	9.731	<=	40.000			PASS
3	DH3	2480				4092.88	<= 20000.000	PASS
4	DH3	2480	8.390	<=	40.000			PASS
4	DH3	2480				5530.35	<= 20000.000	PASS
5	DH3	2480	8.534	<=	40.000			PASS
5	DH3	2480				7159.45	<= 20000.000	PASS
6	DH3	2480	9.886	<=	40.000			PASS

6	DH3	2480				6714.84	<=	20000.000	PASS
7	DH3	2480	9.061	<=	40.000				PASS
7	DH3	2480				6477.78	<=	20000.000	PASS
8	DH3	2480	5.328	<=	40.000				PASS
8	DH3	2480				4559.33	<=	20000.000	PASS
9	DH3	2480	5.870	<=	40.000				PASS
9	DH3	2480				4588.62	<=	20000.000	PASS
10	DH3	2480	9.979	<=	40.000				PASS
10	DH3	2480				6242.89	<=	20000.000	PASS
1	DH5	2402	10.263	<=	40.000				PASS
1	DH5	2402				5120.63	<=	20000.000	PASS
2	DH5	2402	11.001	<=	40.000				PASS
2	DH5	2402				5446.11	<=	20000.000	PASS
3	DH5	2402	14.289	<=	40.000				PASS
3	DH5	2402				6118.66	<=	20000.000	PASS
4	DH5	2402	11.451	<=	40.000				PASS
4	DH5	2402				4622.22	<=	20000.000	PASS
5	DH5	2402	9.053	<=	40.000				PASS
5	DH5	2402				6082.40	<=	20000.000	PASS
6	DH5	2402	10.082	<=	40.000				PASS
6	DH5	2402				6319.99	<=	20000.000	PASS
7	DH5	2402	8.861	<=	40.000				PASS
7	DH5	2402				4871.06	<=	20000.000	PASS
8	DH5	2402	6.332	<=	40.000				PASS
8	DH5	2402				4883.64	<=	20000.000	PASS
9	DH5	2402	10.342	<=	40.000				PASS
9	DH5	2402				5344.85	<=	20000.000	PASS
10	DH5	2402	8.762	<=	40.000				PASS
10	DH5	2402				7996.47	<=	20000.000	PASS
1	DH5	2441	12.354	<=	40.000				PASS
1	DH5	2441				5574.94	<=	20000.000	PASS
2	DH5	2441	9.414	<=	40.000				PASS
2	DH5	2441				4612.10	<=	20000.000	PASS
3	DH5	2441	14.024	<=	40.000				PASS
3	DH5	2441				4742.05	<=	20000.000	PASS
4	DH5	2441	7.042	<=	40.000				PASS
4	DH5	2441				5621.64	<=	20000.000	PASS
5	DH5	2441	7.398	<=	40.000				PASS
5	DH5	2441				4710.66	<=	20000.000	PASS
6	DH5	2441	11.545	<=	40.000				PASS
6	DH5	2441				6591.30	<=	20000.000	PASS
7	DH5	2441	13.204	<=	40.000				PASS
7	DH5	2441				6704.81	<=	20000.000	PASS
8	DH5	2441	8.267	<=	40.000				PASS
8	DH5	2441				5652.38	<=	20000.000	PASS
9	DH5	2441	9.047	<=	40.000				PASS
9	DH5	2441				7135.61	<=	20000.000	PASS
10	DH5	2441	8.208	<=	40.000				PASS
10	DH5	2441				5719.25	<=	20000.000	PASS
1	DH5	2480	10.376	<=	40.000				PASS
1	DH5	2480				5865.10	<=	20000.000	PASS
2	DH5	2480	8.704	<=	40.000				PASS
2	DH5	2480				6248.24	<=	20000.000	PASS
3	DH5	2480	12.779	<=	40.000				PASS
3	DH5	2480				6062.93	<=	20000.000	PASS
4	DH5	2480	11.882	<=	40.000				PASS
4	DH5	2480				5747.08	<=	20000.000	PASS
5	DH5	2480	8.959	<=	40.000				PASS
5	DH5	2480				6058.34	<=	20000.000	PASS
6	DH5	2480	8.110	<=	40.000				PASS
6	DH5	2480				6808.09	<=	20000.000	PASS
7	DH5	2480	12.140	<=	40.000				PASS
7	DH5	2480				6264.15	<=	20000.000	PASS
8	DH5	2480	12.309	<=	40.000				PASS
8	DH5	2480				6919.72	<=	20000.000	PASS

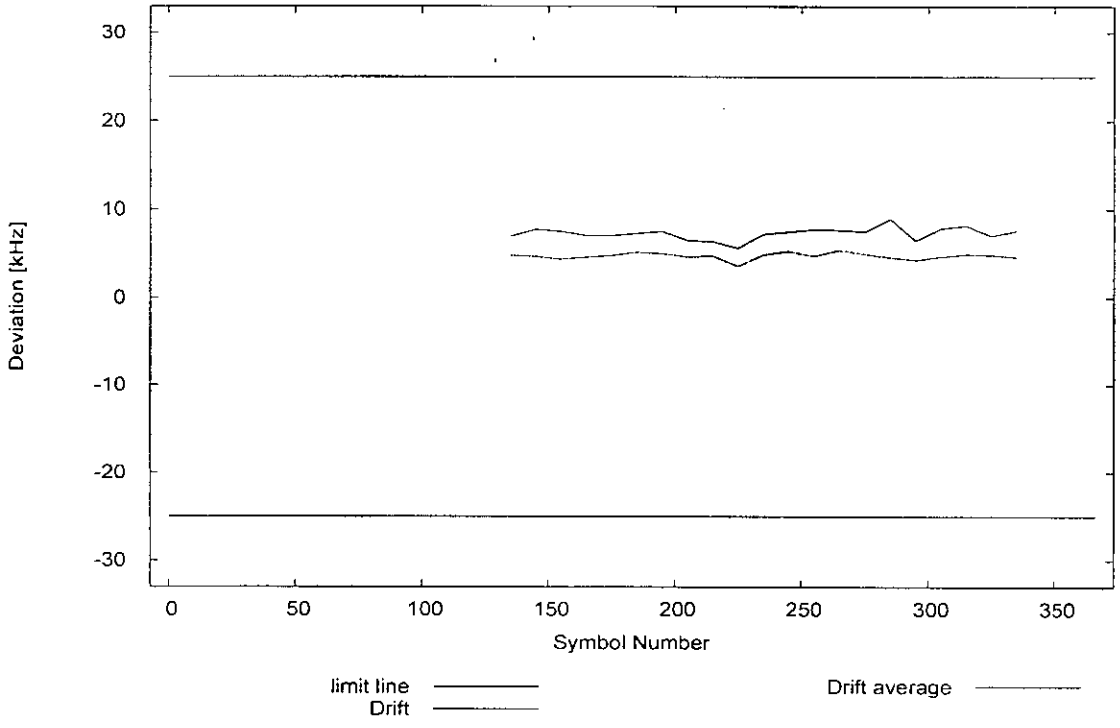
9	DH5	2480	10.953	<=	40.000			PASS
9	DH5	2480				4875.33	<= 20000.000	PASS
10	DH5	2480	10.538	<=	40.000			PASS
10	DH5	2480				6084.90	<= 20000.000	PASS

Final Test Case Verdict . . . . . PASS 00:33:06

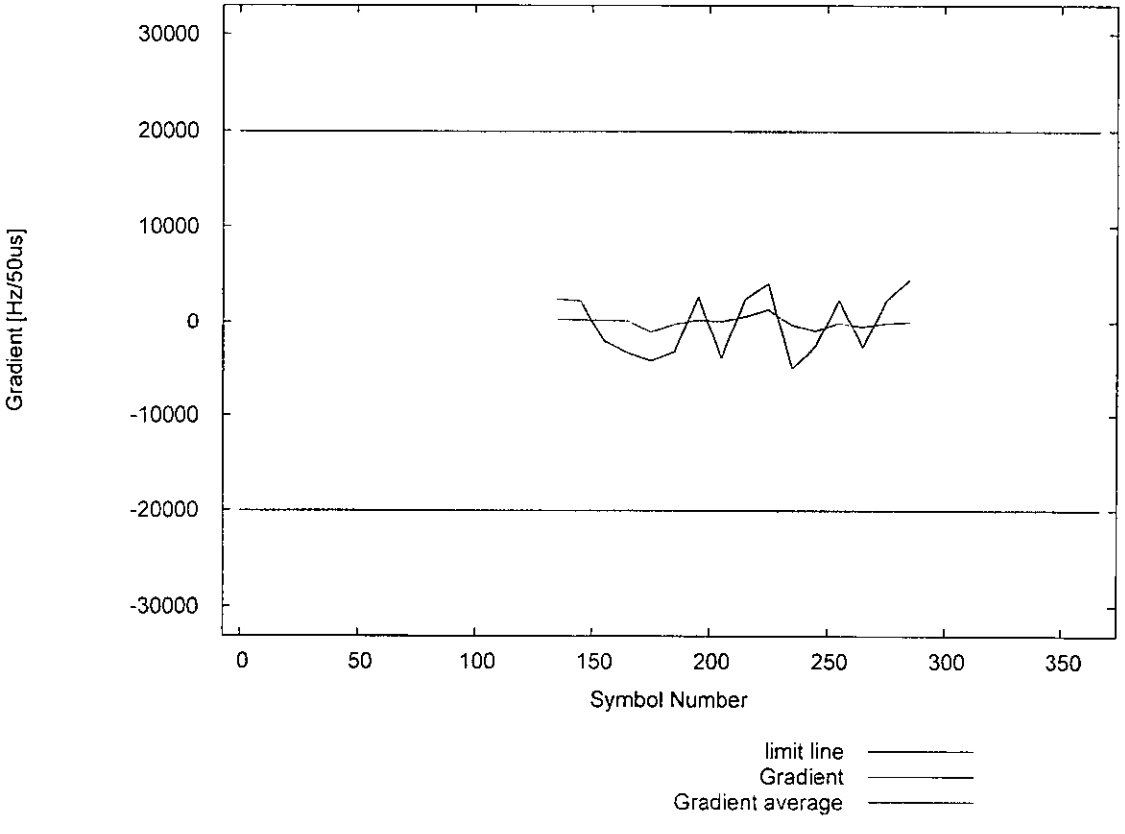
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH1 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern



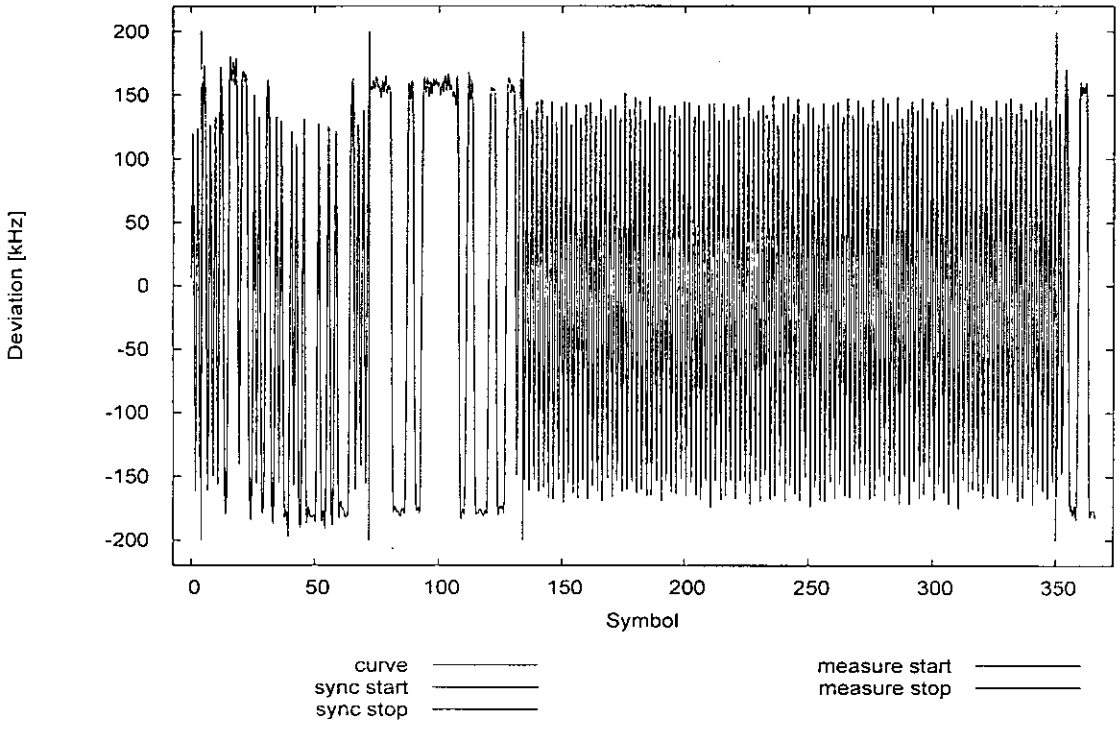
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2402.000 MHz



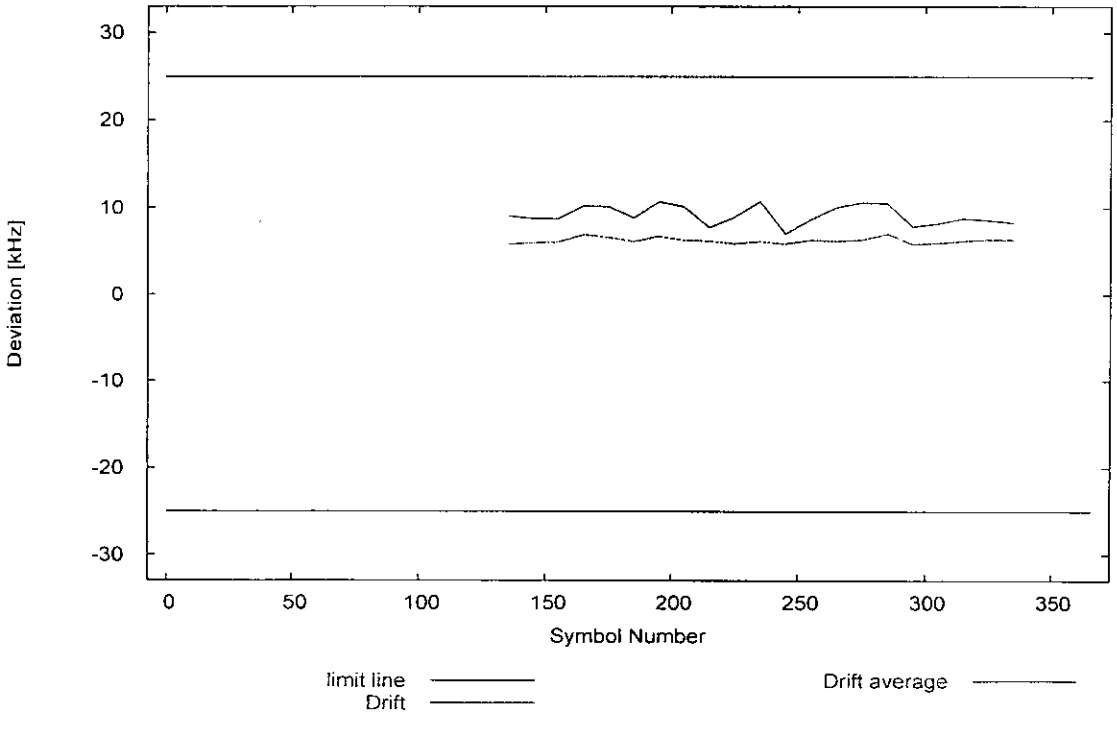
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2402.000 MHz



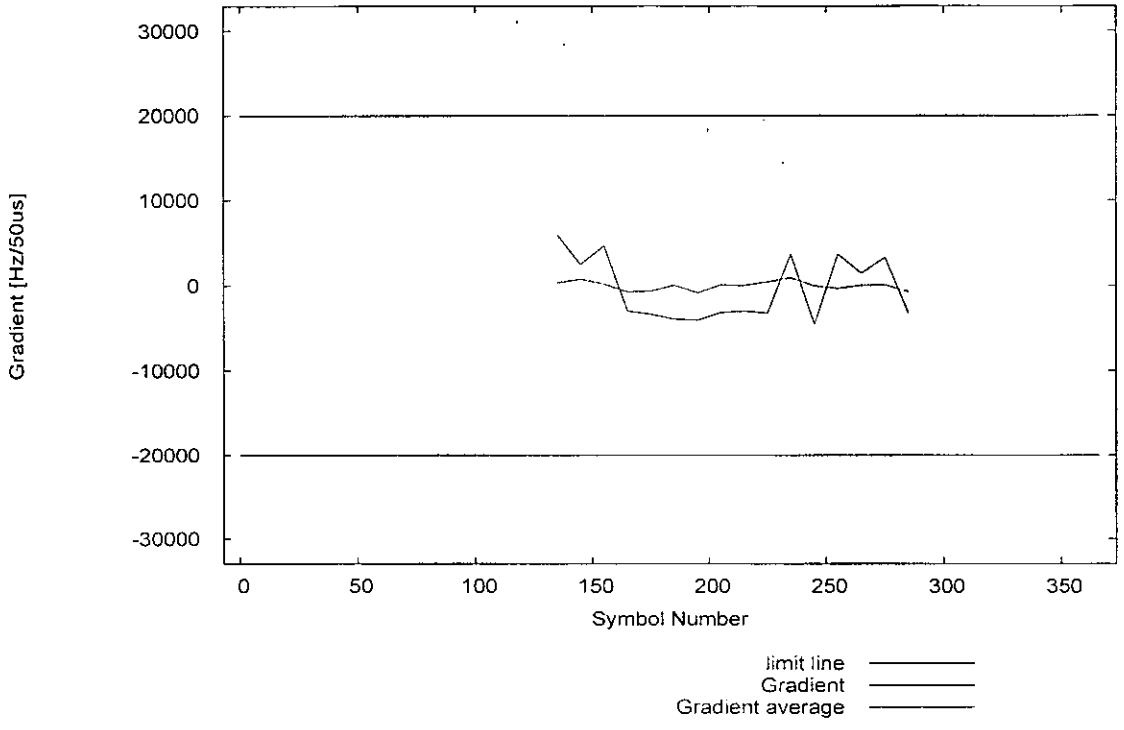
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH1 Loop Back Mode -
Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern



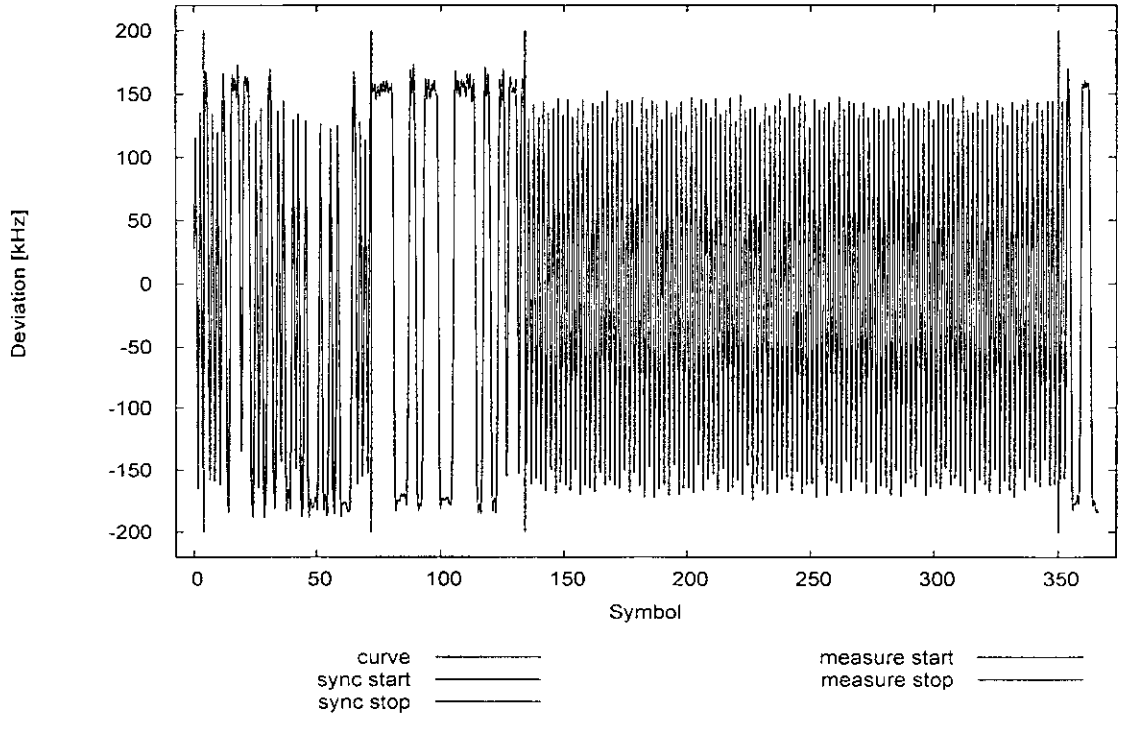
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2441.000 MHz



TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2441.000 MHz

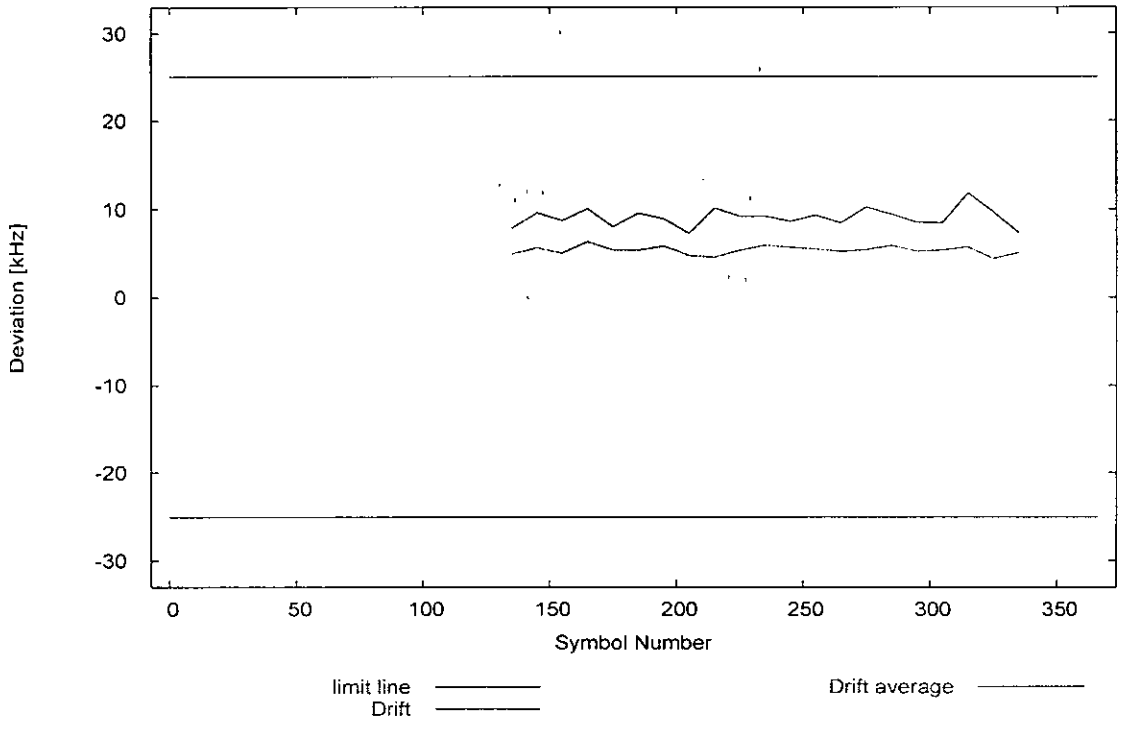


Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern

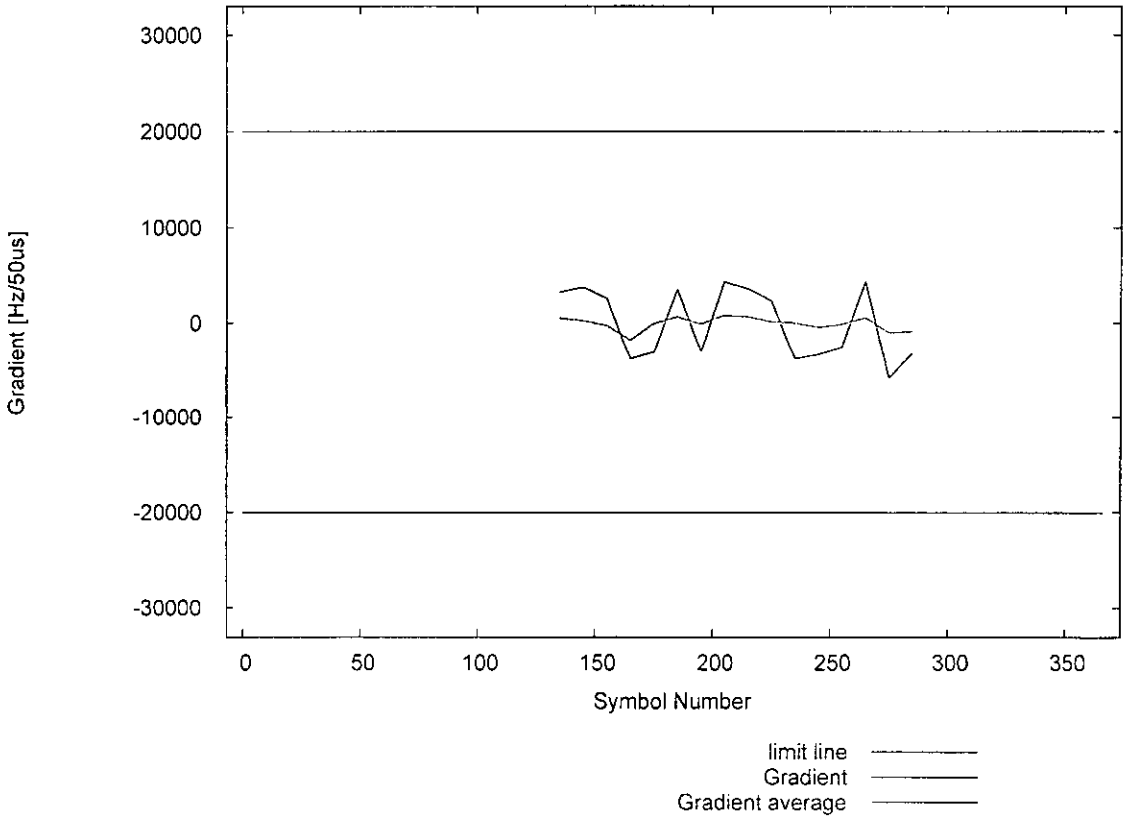


1232

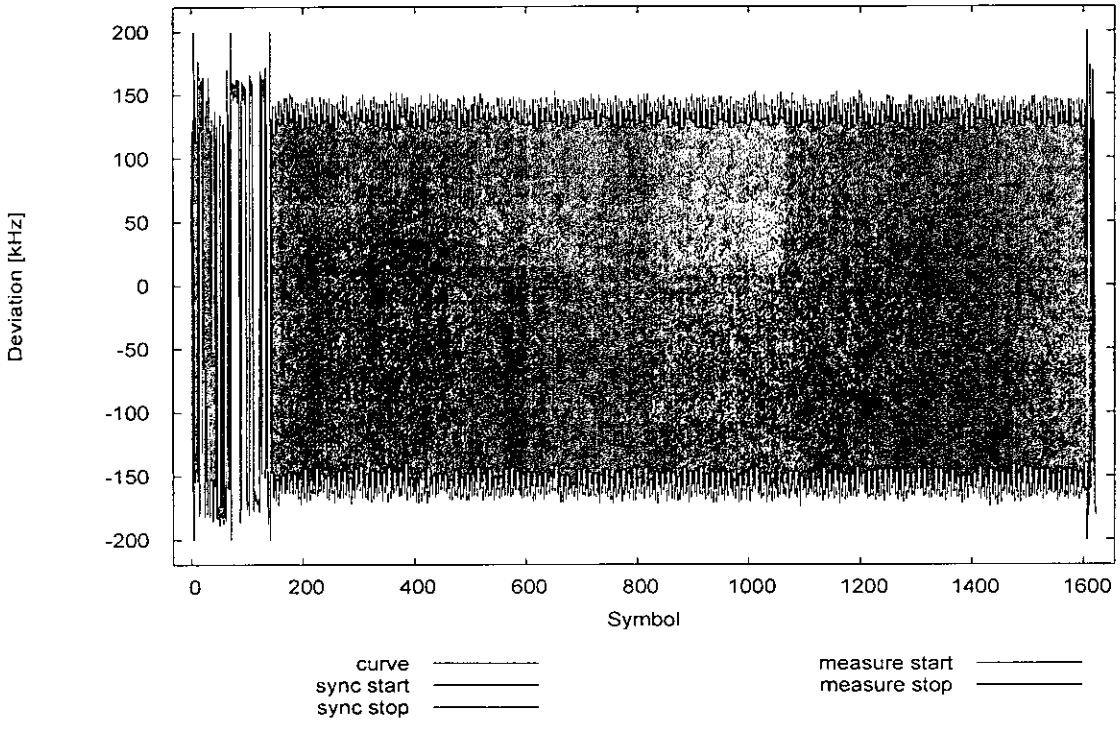
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2480.000 MHz



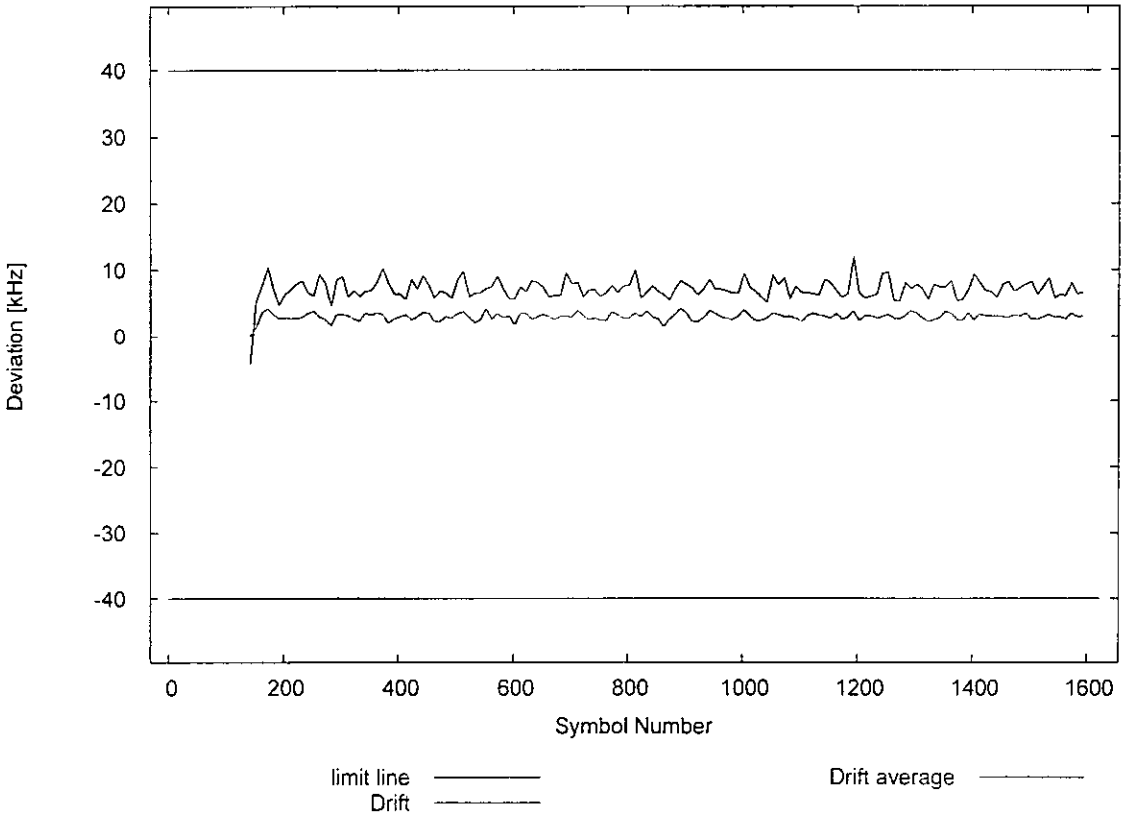
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2480.000 MHz



Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH3 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern

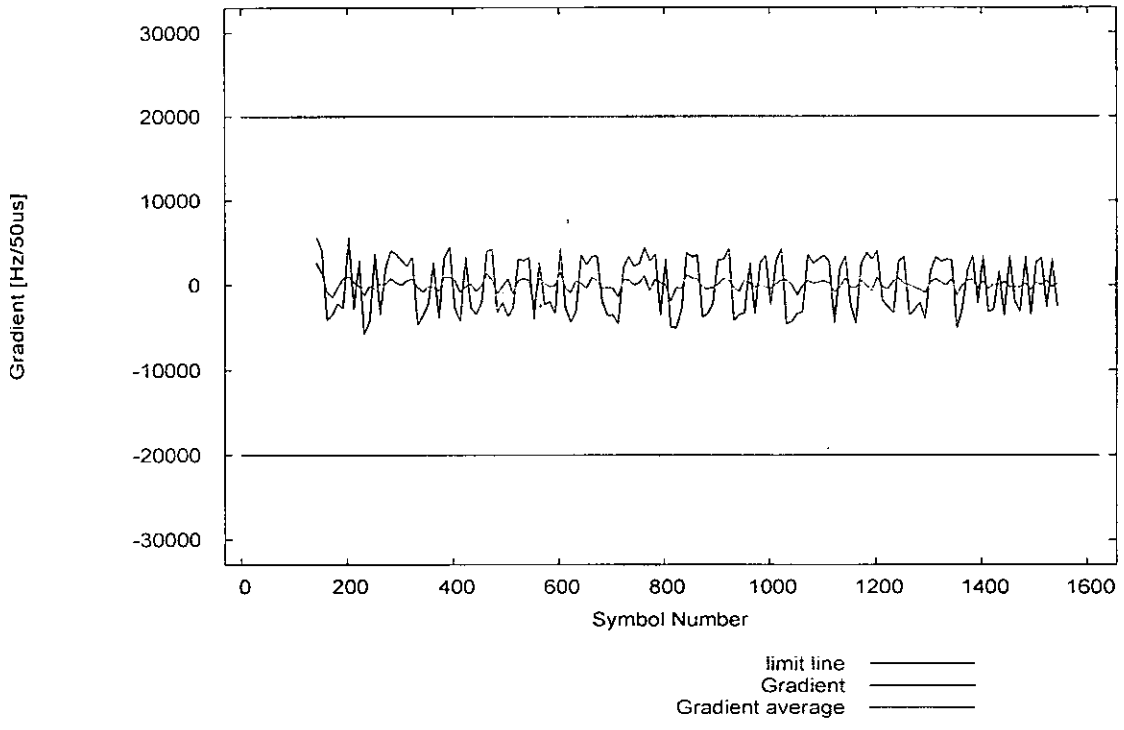


TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2402.000 MHz

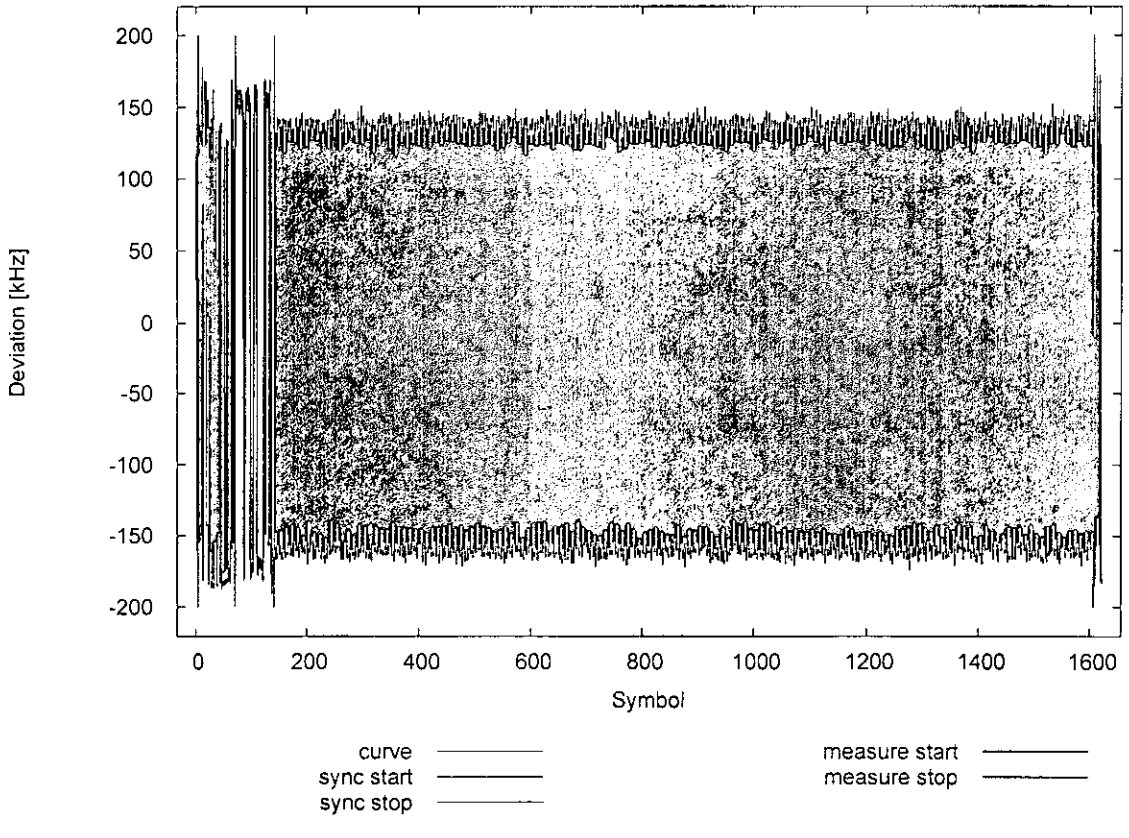


1234

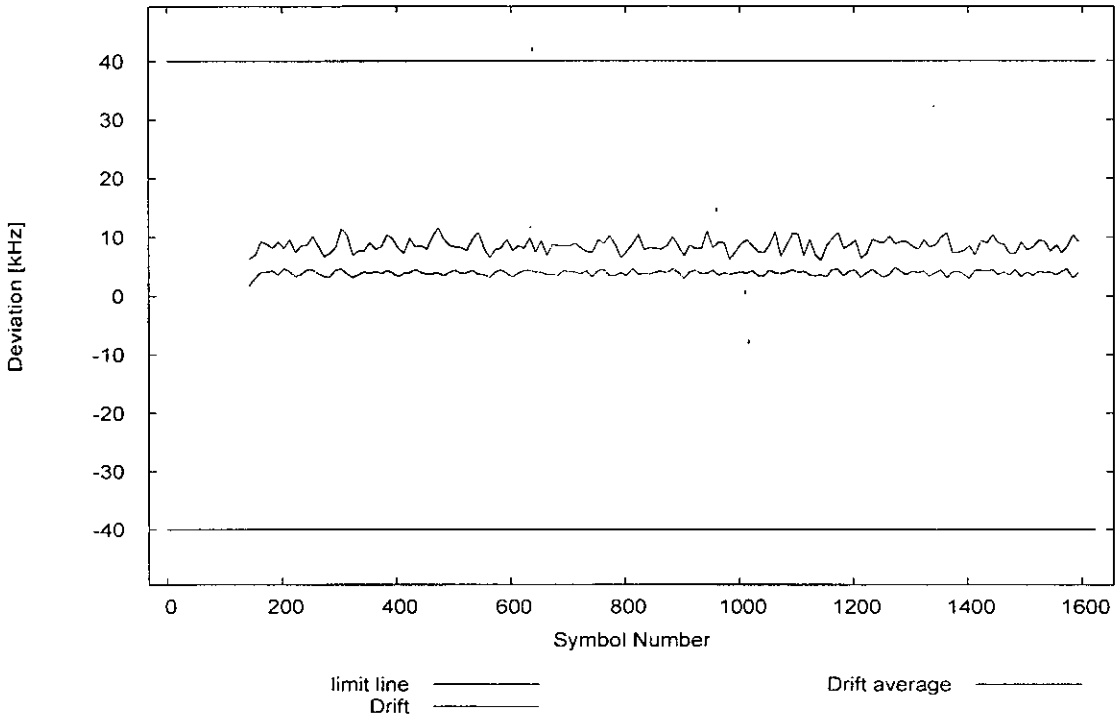
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2402.000 MHz



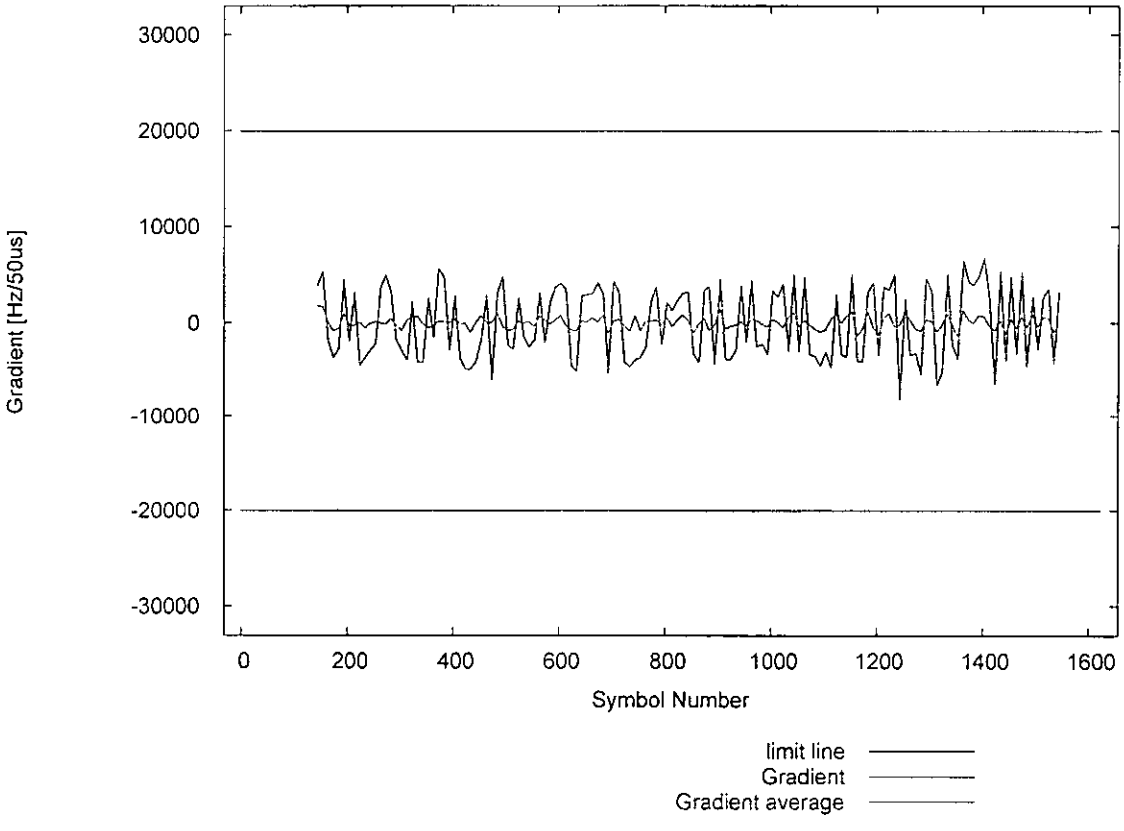
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern



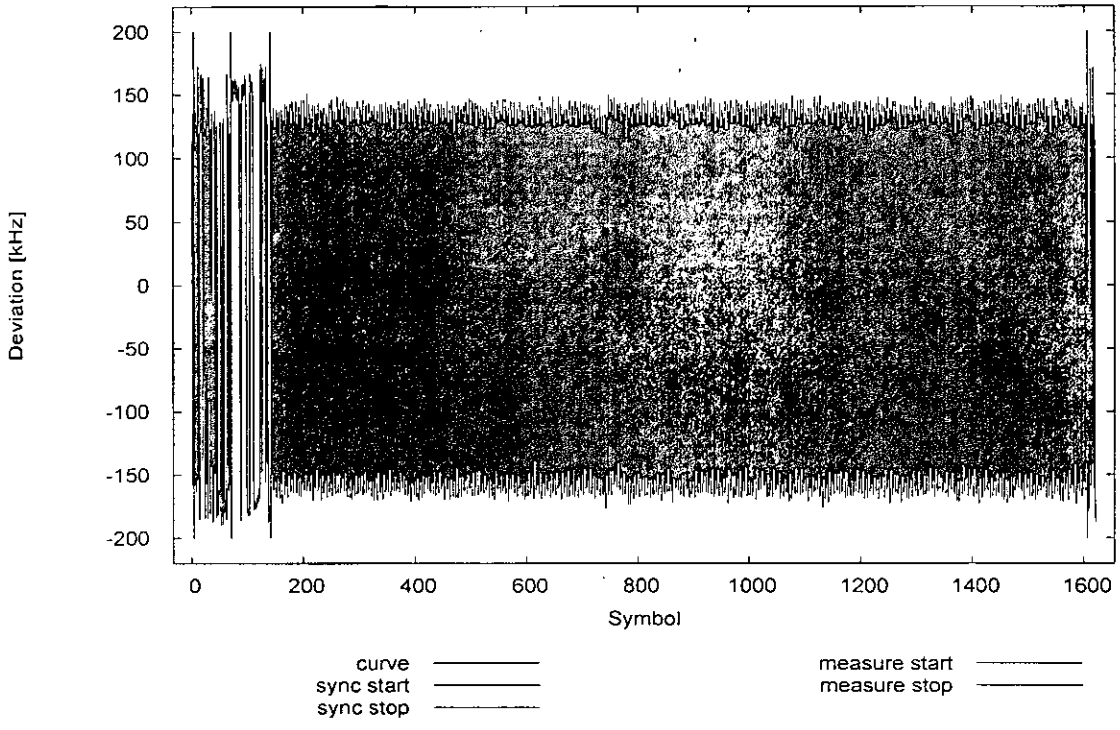
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2441.000 MHz



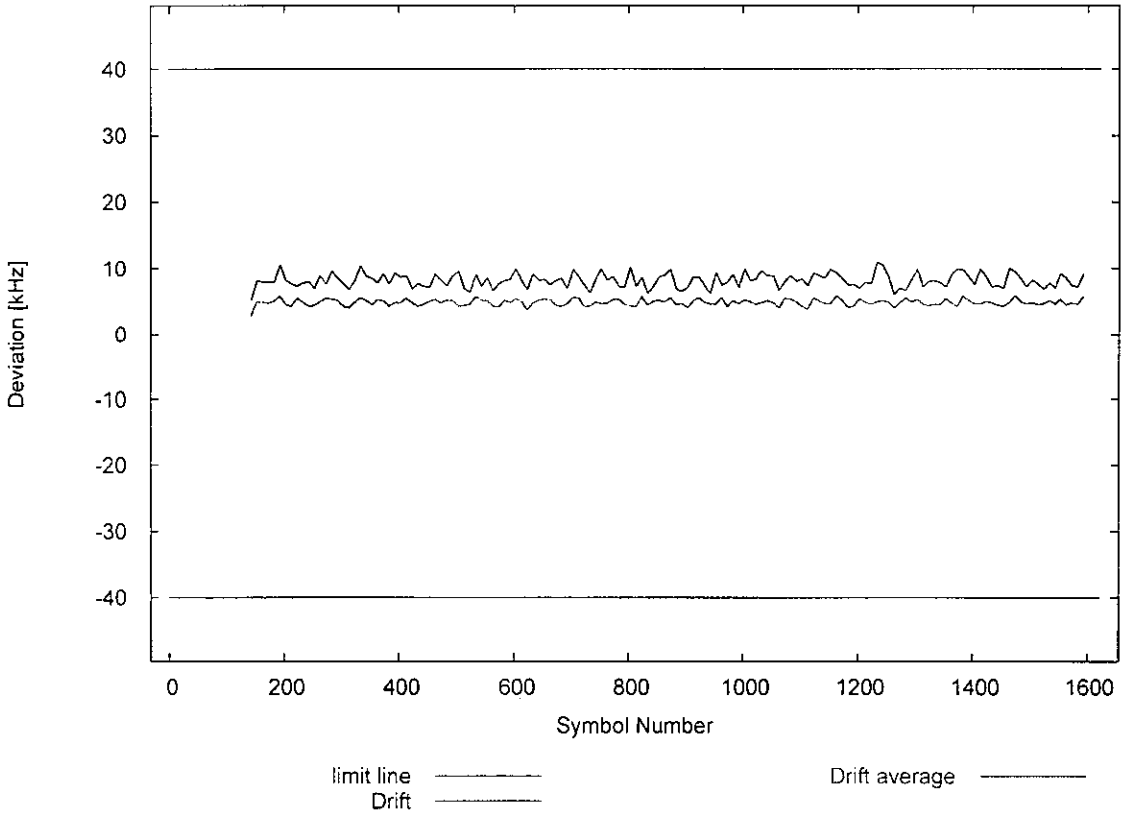
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2441.000 MHz



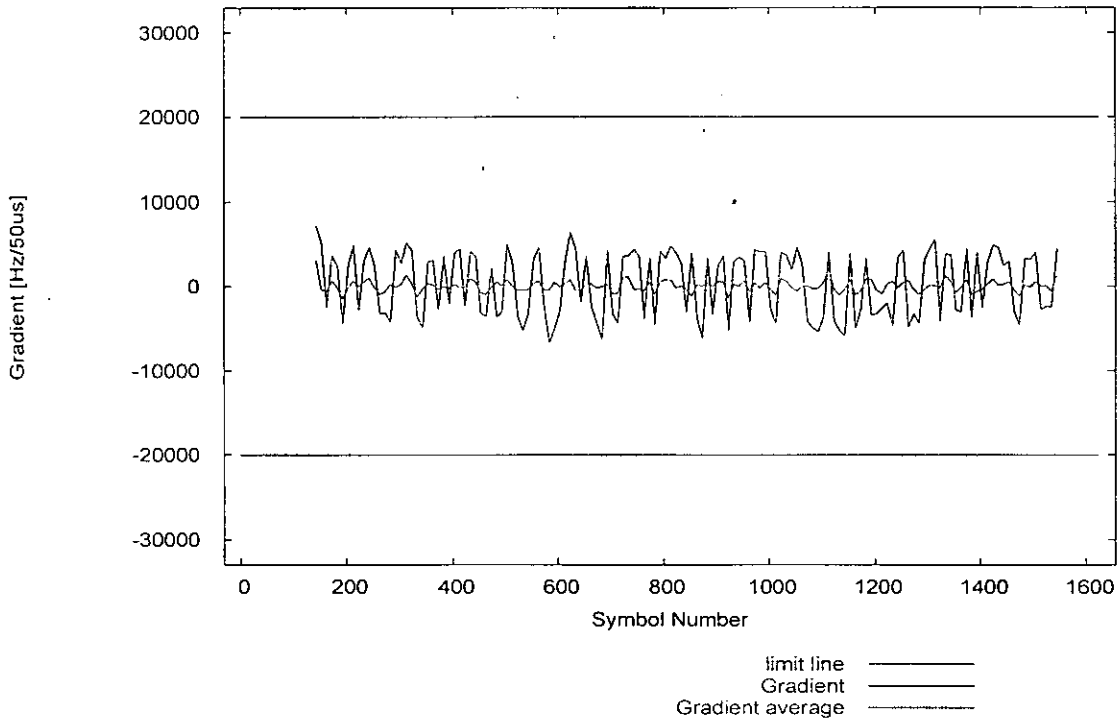
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern



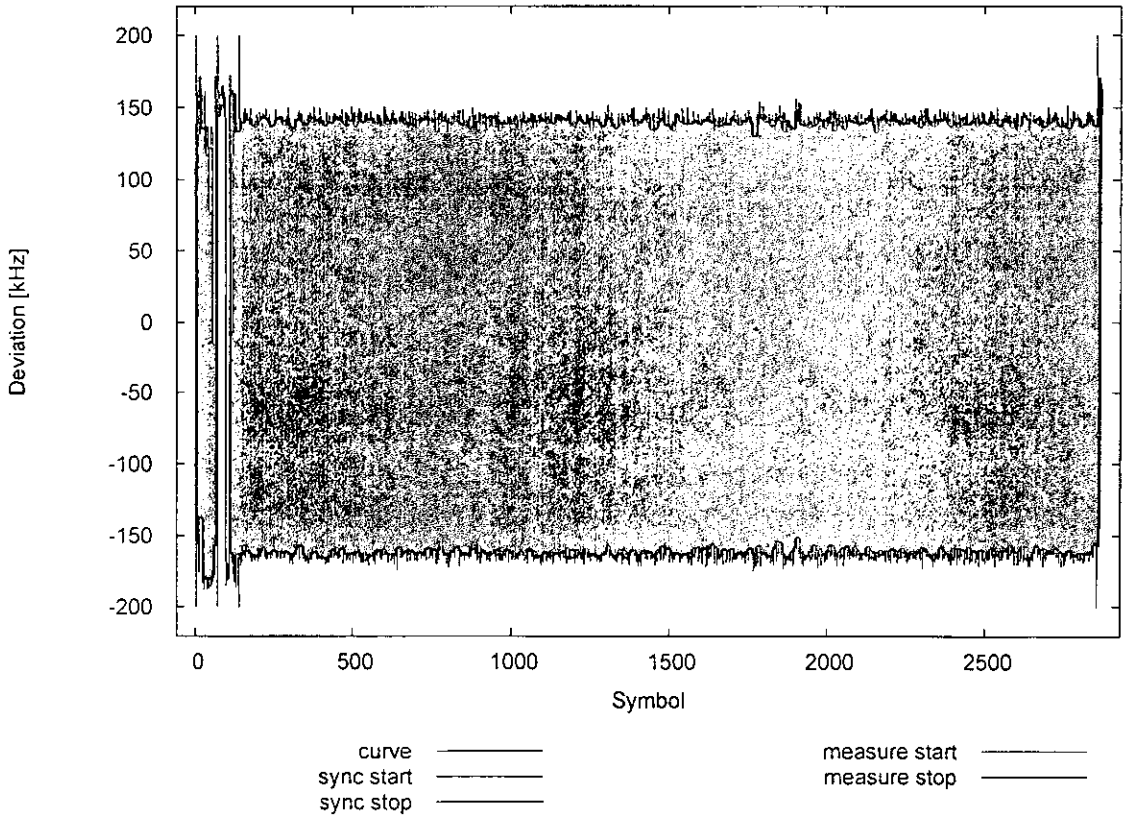
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2480.000 MHz



TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2480.000 MHz

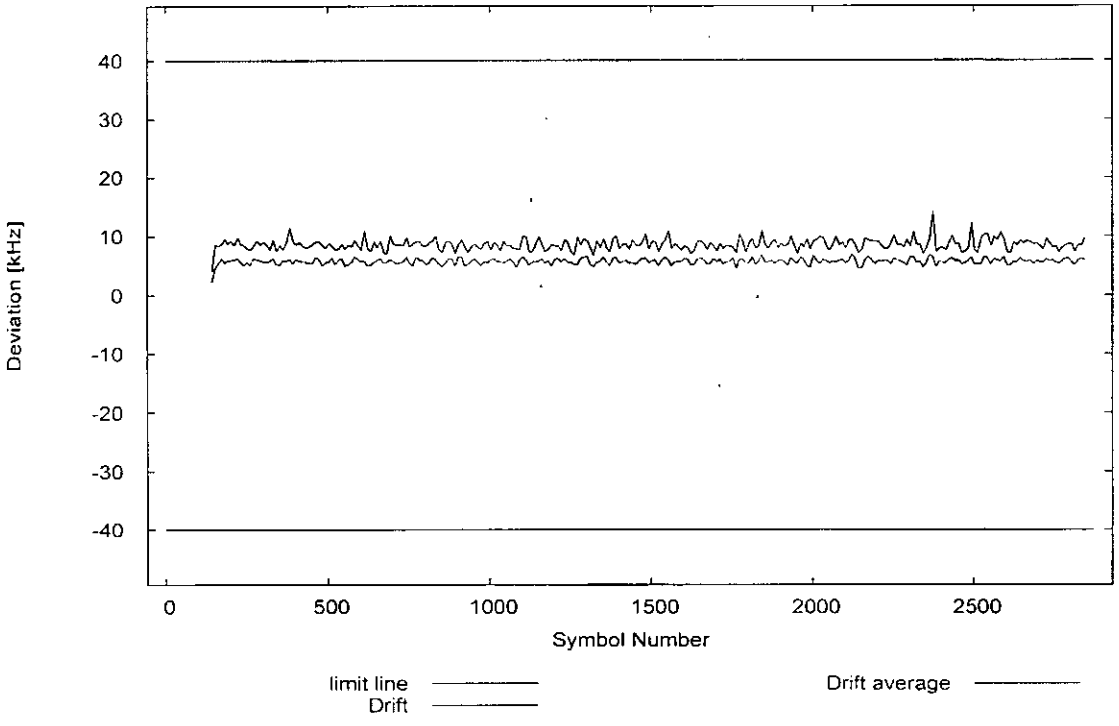


Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern

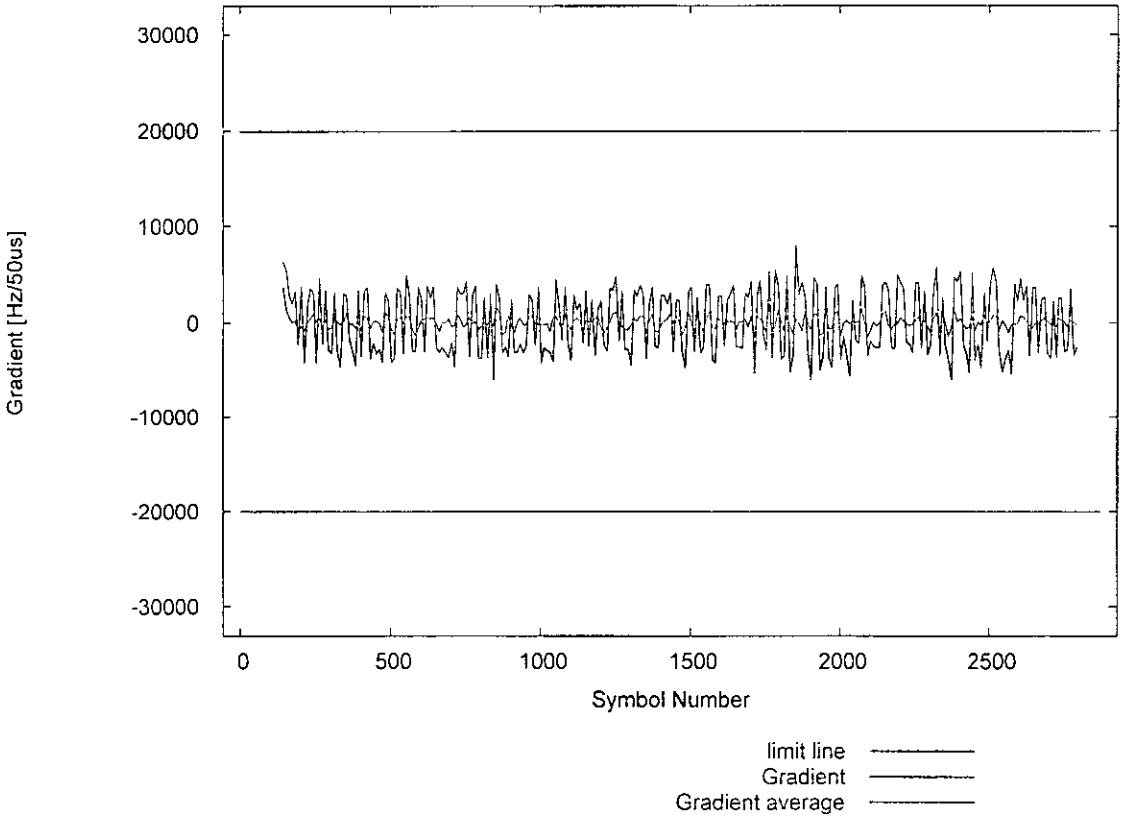


1238

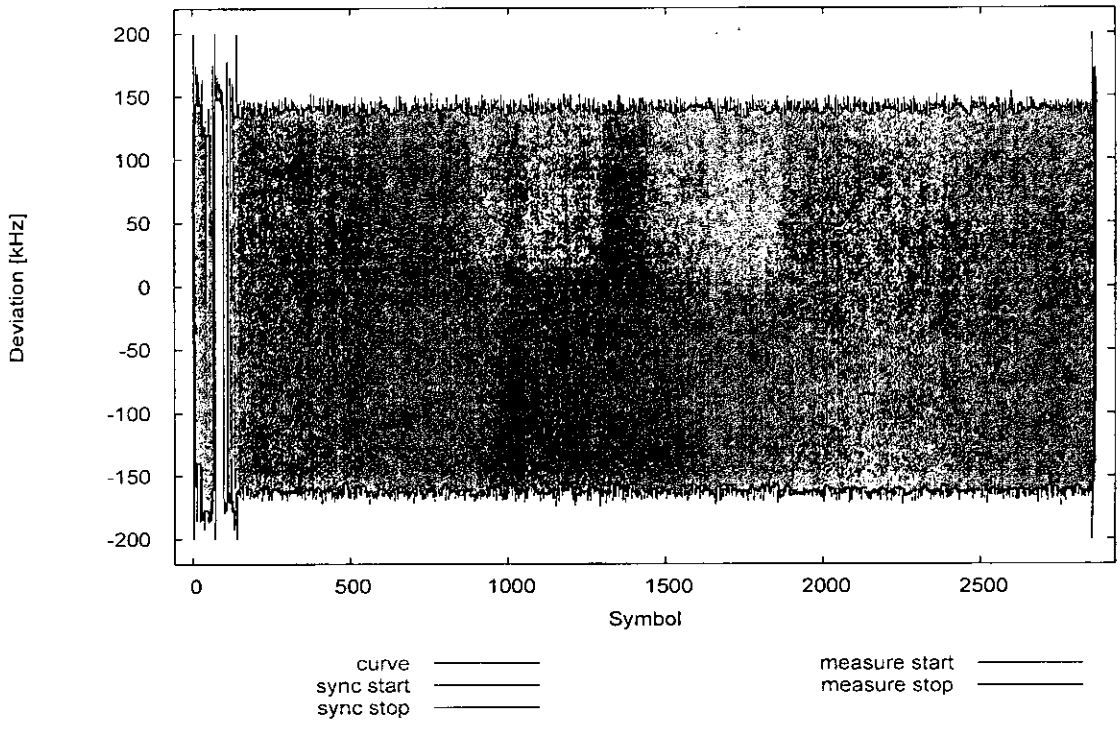
TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2402.000 MHz



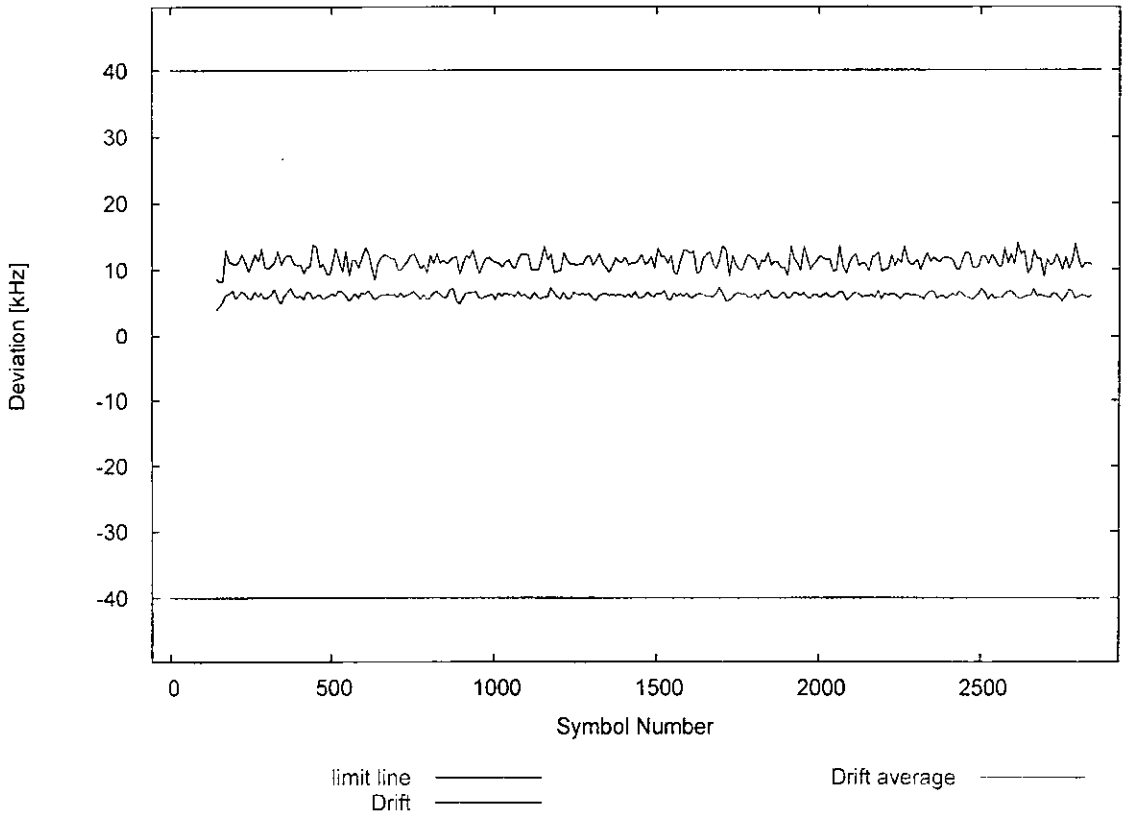
TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2402.000 MHz



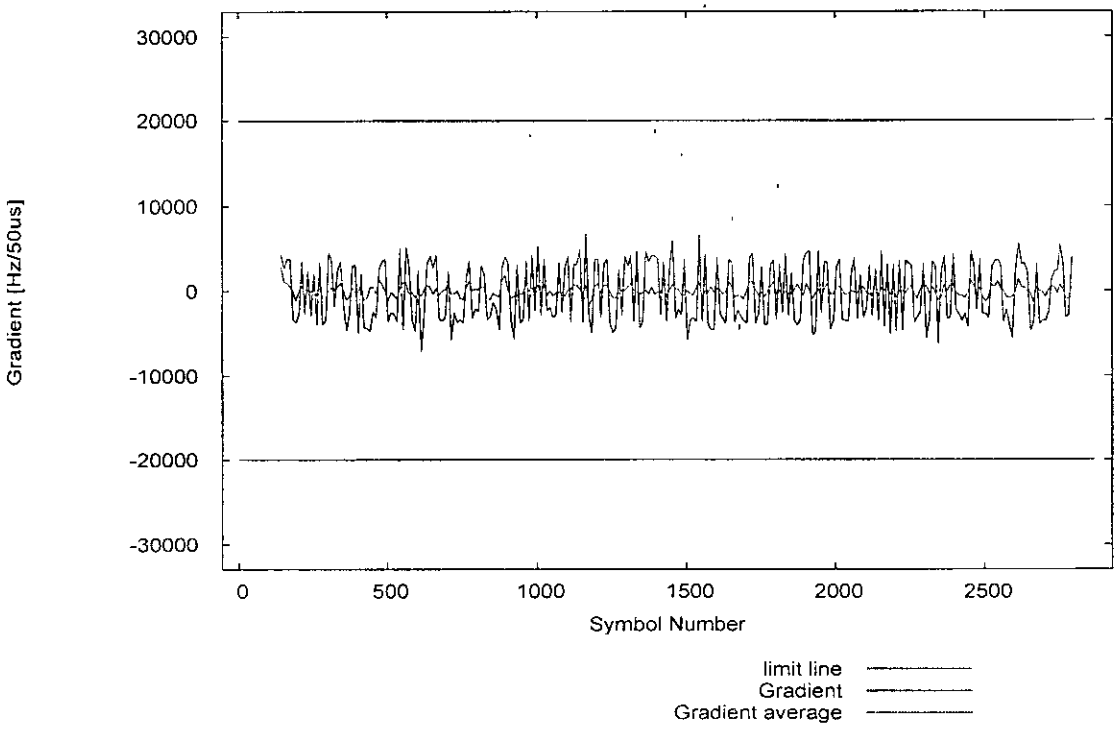
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern



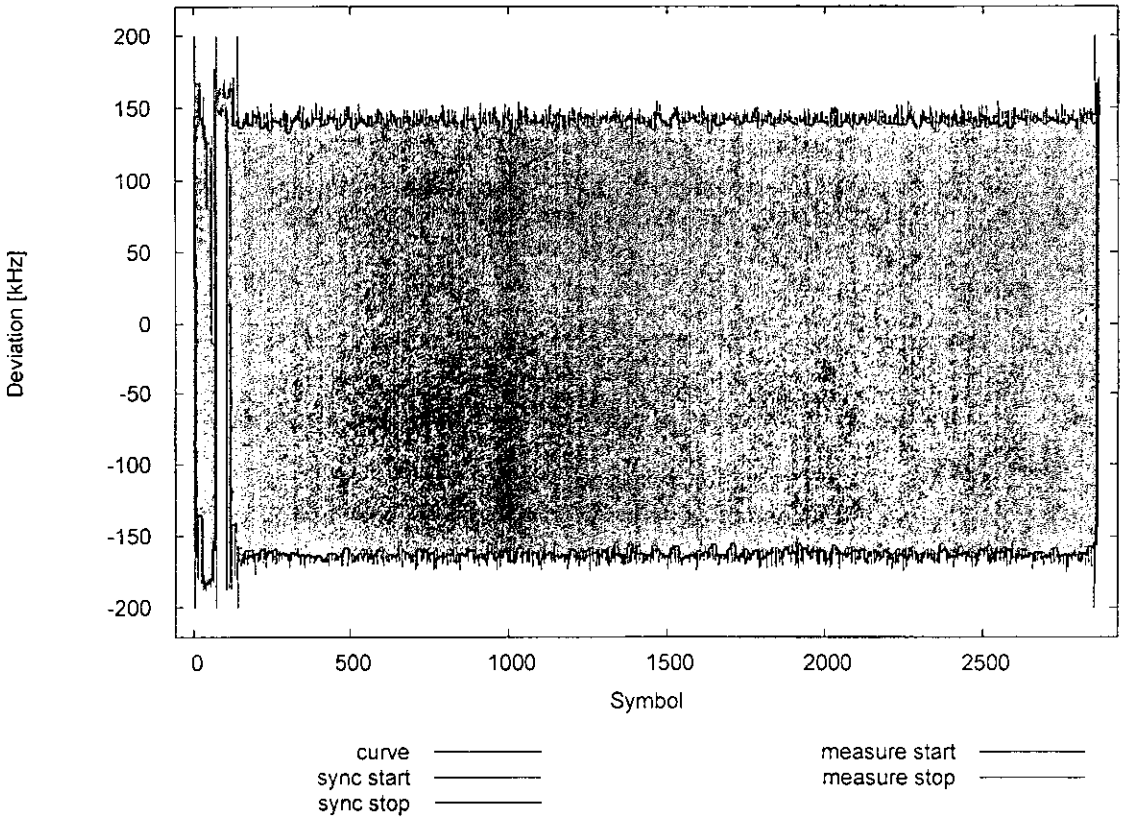
TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2441.000 MHz



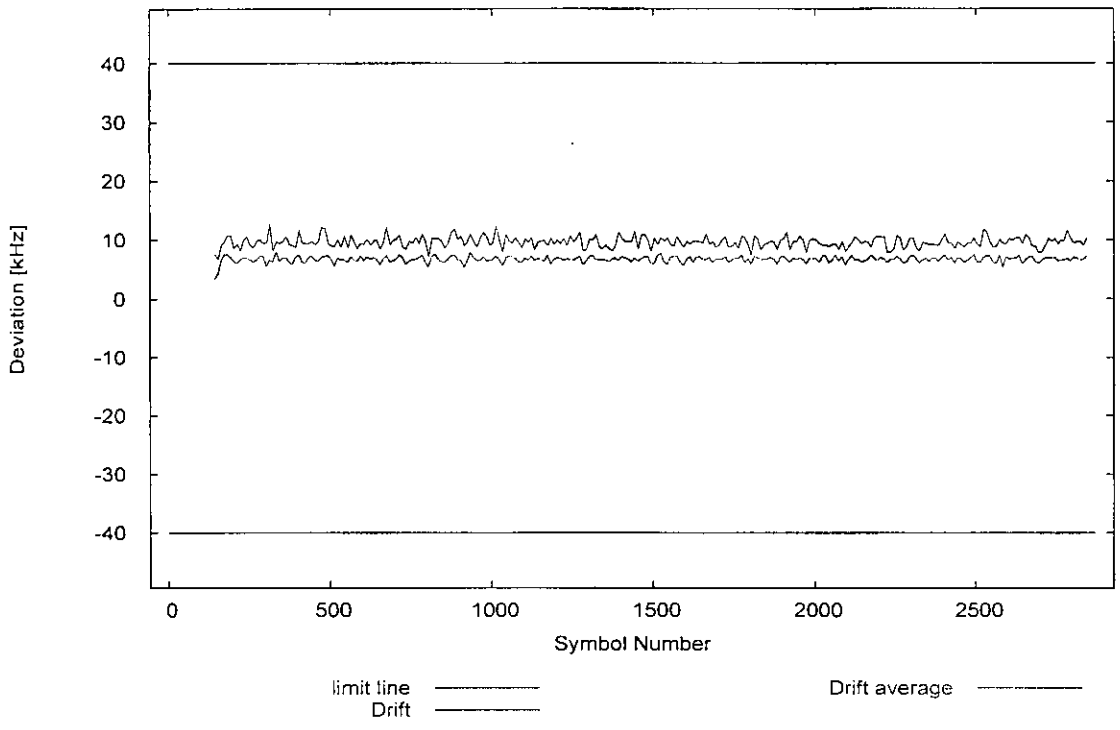
TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2441.000 MHz



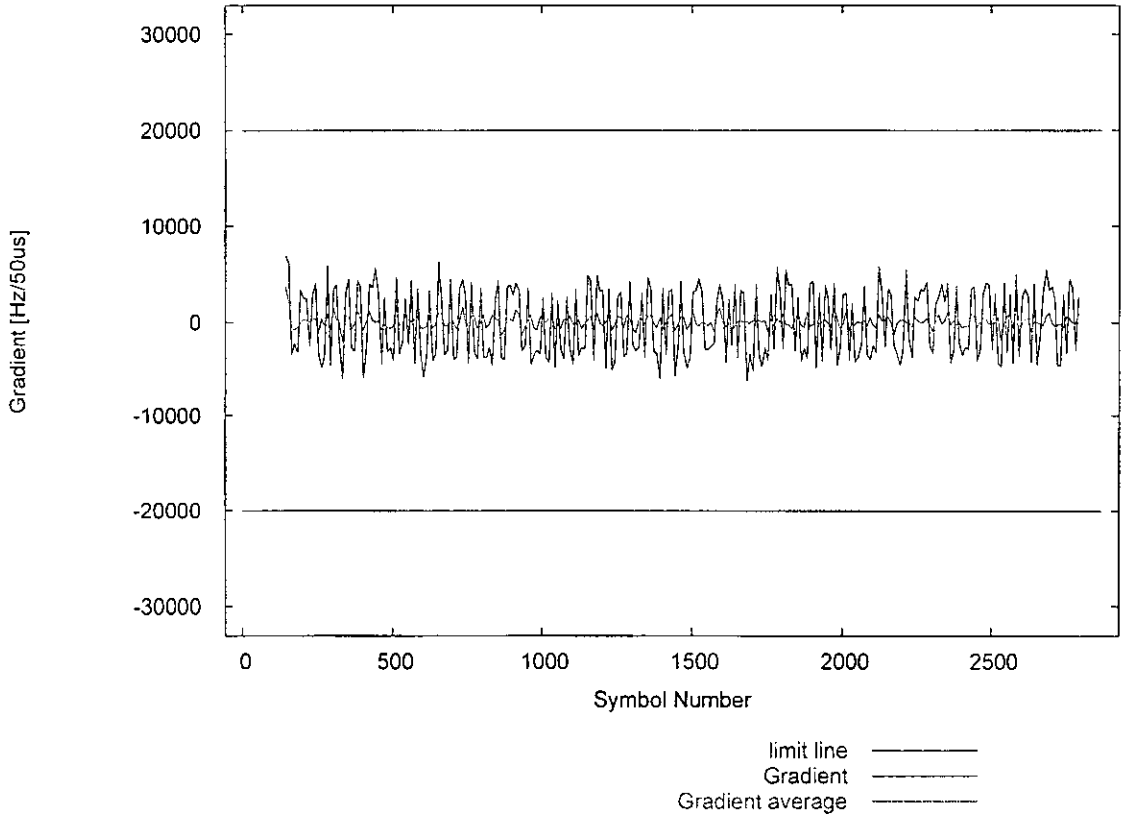
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern



TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2480.000 MHz



TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2480.000 MHz



Carrier Frequency Drift

For system parameter see 0, "General Parameter 010"

BT Test Specification Version: 1.2

TS Errata Request: 190
TS Errata Request: 277

For EUT parameter see 0, "EUT Parameter 010"
For test case parameter see 0, "Test Case Parameter 051"

Packet Nr.	Type	Freq [MHz]	Max Drift [kHz]		LIMIT [kHz]	Max Gradient [Hz/50us]		LIMIT [Hz/50us]	VERDICT
1	DH1	2402	3.730	<=	25.000				PASS
1	DH1	2402				3507.01	<=	20000.000	PASS
2	DH1	2402	8.546	<=	25.000				PASS
2	DH1	2402				3813.08	<=	20000.000	PASS
3	DH1	2402	2.257	<=	25.000				PASS
3	DH1	2402				3266.27	<=	20000.000	PASS
4	DH1	2402	6.829	<=	25.000				PASS
4	DH1	2402				4095.44	<=	20000.000	PASS
5	DH1	2402	8.342	<=	25.000				PASS
5	DH1	2402				4447.78	<=	20000.000	PASS
6	DH1	2402	7.569	<=	25.000				PASS
6	DH1	2402				3480.47	<=	20000.000	PASS
7	DH1	2402	5.023	<=	25.000				PASS
7	DH1	2402				5022.44	<=	20000.000	PASS
8	DH1	2402	5.199	<=	25.000				PASS
8	DH1	2402				5134.76	<=	20000.000	PASS
9	DH1	2402	7.668	<=	25.000				PASS
9	DH1	2402				3575.99	<=	20000.000	PASS
10	DH1	2402	8.126	<=	25.000				PASS
10	DH1	2402				3348.28	<=	20000.000	PASS
1	DH1	2441	13.236	<=	25.000				PASS
1	DH1	2441				11869.39	<=	20000.000	PASS
2	DH1	2441	6.722	<=	25.000				PASS
2	DH1	2441				5419.98	<=	20000.000	PASS
3	DH1	2441	8.126	<=	25.000				PASS
3	DH1	2441				2709.32	<=	20000.000	PASS
4	DH1	2441	5.263	<=	25.000				PASS
4	DH1	2441				3217.60	<=	20000.000	PASS
5	DH1	2441	4.313	<=	25.000				PASS
5	DH1	2441				3916.90	<=	20000.000	PASS
6	DH1	2441	7.299	<=	25.000				PASS
6	DH1	2441				4282.22	<=	20000.000	PASS
7	DH1	2441	8.377	<=	25.000				PASS
7	DH1	2441				5316.12	<=	20000.000	PASS
8	DH1	2441	8.211	<=	25.000				PASS
8	DH1	2441				2292.10	<=	20000.000	PASS
9	DH1	2441	10.090	<=	25.000				PASS
9	DH1	2441				3699.97	<=	20000.000	PASS
10	DH1	2441	11.256	<=	25.000				PASS
10	DH1	2441				3952.60	<=	20000.000	PASS
1	DH1	2480	8.338	<=	25.000				PASS
1	DH1	2480				5361.88	<=	20000.000	PASS
2	DH1	2480	9.413	<=	25.000				PASS
2	DH1	2480				2941.64	<=	20000.000	PASS
3	DH1	2480	7.220	<=	25.000				PASS
3	DH1	2480				5140.10	<=	20000.000	PASS

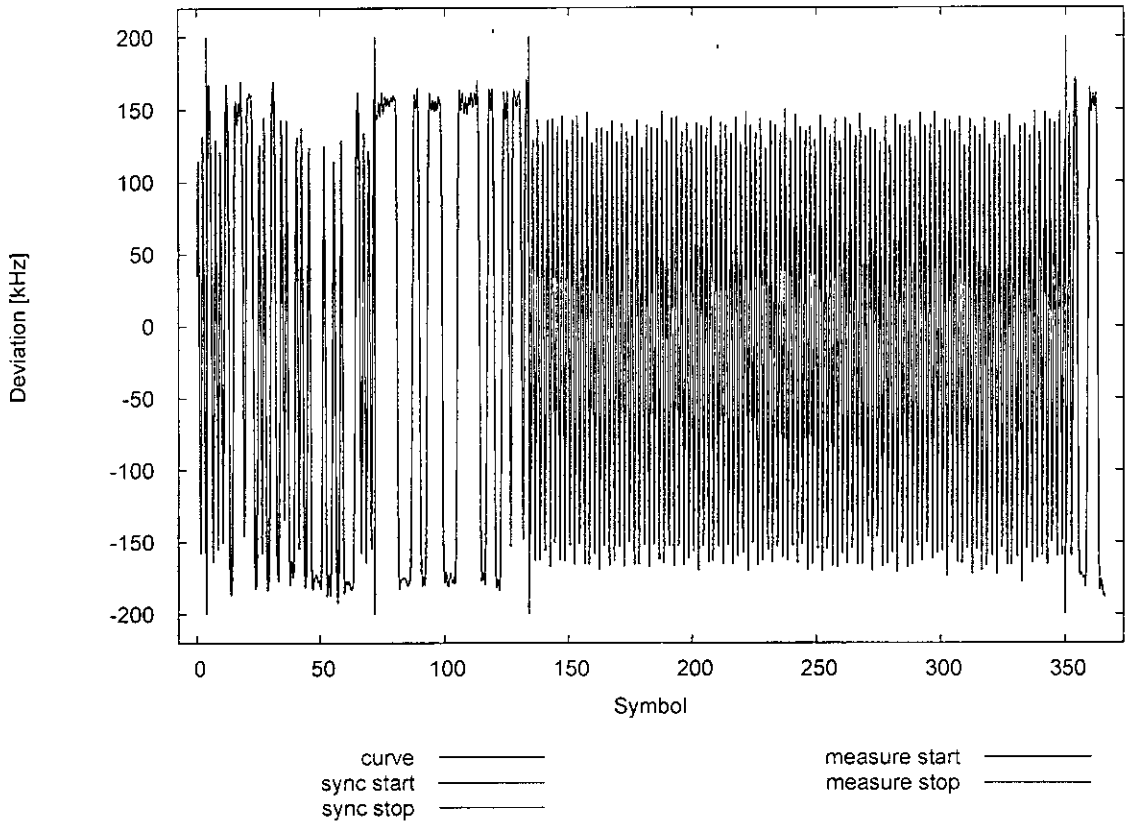
4	DH1	2480	6.698	<=	25.000			PASS
4	DH1	2480				4114.88	<= 20000.000	PASS
5	DH1	2480	7.819	<=	25.000			PASS
5	DH1	2480				2790.66	<= 20000.000	PASS
6	DH1	2480	8.920	<=	25.000			PASS
6	DH1	2480				5020.35	<= 20000.000	PASS
7	DH1	2480	9.914	<=	25.000			PASS
7	DH1	2480				2950.74	<= 20000.000	PASS
8	DH1	2480	9.996	<=	25.000			PASS
8	DH1	2480				3887.63	<= 20000.000	PASS
9	DH1	2480	5.631	<=	25.000			PASS
9	DH1	2480				3565.19	<= 20000.000	PASS
10	DH1	2480	9.418	<=	25.000			PASS
10	DH1	2480				3354.26	<= 20000.000	PASS
1	DH3	2402	6.278	<=	40.000			PASS
1	DH3	2402				5162.66	<= 20000.000	PASS
2	DH3	2402	9.486	<=	40.000			PASS
2	DH3	2402				3850.08	<= 20000.000	PASS
3	DH3	2402	4.197	<=	40.000			PASS
3	DH3	2402				3973.47	<= 20000.000	PASS
4	DH3	2402	8.050	<=	40.000			PASS
4	DH3	2402				6278.74	<= 20000.000	PASS
5	DH3	2402	10.361	<=	40.000			PASS
5	DH3	2402				6114.53	<= 20000.000	PASS
6	DH3	2402	4.648	<=	40.000			PASS
6	DH3	2402				5224.70	<= 20000.000	PASS
7	DH3	2402	8.371	<=	40.000			PASS
7	DH3	2402				5082.39	<= 20000.000	PASS
8	DH3	2402	4.889	<=	40.000			PASS
8	DH3	2402				5880.91	<= 20000.000	PASS
9	DH3	2402	8.495	<=	40.000			PASS
9	DH3	2402				5649.60	<= 20000.000	PASS
10	DH3	2402	11.688	<=	40.000			PASS
10	DH3	2402				4755.53	<= 20000.000	PASS
1	DH3	2441	11.395	<=	40.000			PASS
1	DH3	2441				5194.63	<= 20000.000	PASS
2	DH3	2441	7.396	<=	40.000			PASS
2	DH3	2441				4335.30	<= 20000.000	PASS
3	DH3	2441	5.733	<=	40.000			PASS
3	DH3	2441				4452.40	<= 20000.000	PASS
4	DH3	2441	10.891	<=	40.000			PASS
4	DH3	2441				4660.98	<= 20000.000	PASS
5	DH3	2441	6.656	<=	40.000			PASS
5	DH3	2441				5848.42	<= 20000.000	PASS
6	DH3	2441	9.767	<=	40.000			PASS
6	DH3	2441				4744.99	<= 20000.000	PASS
7	DH3	2441	7.909	<=	40.000			PASS
7	DH3	2441				6044.80	<= 20000.000	PASS
8	DH3	2441	7.495	<=	40.000			PASS
8	DH3	2441				5420.28	<= 20000.000	PASS
9	DH3	2441	7.665	<=	40.000			PASS
9	DH3	2441				6045.87	<= 20000.000	PASS
10	DH3	2441	7.260	<=	40.000			PASS
10	DH3	2441				5837.33	<= 20000.000	PASS
1	DH3	2480	8.199	<=	40.000			PASS
1	DH3	2480				5982.14	<= 20000.000	PASS
2	DH3	2480	5.437	<=	40.000			PASS
2	DH3	2480				3803.25	<= 20000.000	PASS
3	DH3	2480	5.935	<=	40.000			PASS
3	DH3	2480				4402.86	<= 20000.000	PASS
4	DH3	2480	7.415	<=	40.000			PASS
4	DH3	2480				6475.36	<= 20000.000	PASS
5	DH3	2480	5.032	<=	40.000			PASS
5	DH3	2480				4564.89	<= 20000.000	PASS
6	DH3	2480	4.953	<=	40.000			PASS

6	DH3	2480				5434.38	<= 20000.000	PASS
7	DH3	2480	11.001	<=	40.000			PASS
7	DH3	2480				5925.33	<= 20000.000	PASS
8	DH3	2480	7.516	<=	40.000			PASS
8	DH3	2480				4597.92	<= 20000.000	PASS
9	DH3	2480	6.527	<=	40.000			PASS
9	DH3	2480				5477.78	<= 20000.000	PASS
10	DH3	2480	9.553	<=	40.000			PASS
10	DH3	2480				6417.98	<= 20000.000	PASS
1	DH5	2402	8.901	<=	40.000			PASS
1	DH5	2402				5162.58	<= 20000.000	PASS
2	DH5	2402	10.295	<=	40.000			PASS
2	DH5	2402				5357.38	<= 20000.000	PASS
3	DH5	2402	11.139	<=	40.000			PASS
3	DH5	2402				8415.77	<= 20000.000	PASS
4	DH5	2402	8.663	<=	40.000			PASS
4	DH5	2402				4914.56	<= 20000.000	PASS
5	DH5	2402	10.825	<=	40.000			PASS
5	DH5	2402				4585.24	<= 20000.000	PASS
6	DH5	2402	10.783	<=	40.000			PASS
6	DH5	2402				5736.55	<= 20000.000	PASS
7	DH5	2402	9.013	<=	40.000			PASS
7	DH5	2402				6457.05	<= 20000.000	PASS
8	DH5	2402	10.538	<=	40.000			PASS
8	DH5	2402				11483.57	<= 20000.000	PASS
9	DH5	2402	6.481	<=	40.000			PASS
9	DH5	2402				5386.73	<= 20000.000	PASS
10	DH5	2402	8.147	<=	40.000			PASS
10	DH5	2402				6033.72	<= 20000.000	PASS
1	DH5	2441	12.800	<=	40.000			PASS
1	DH5	2441				5096.43	<= 20000.000	PASS
2	DH5	2441	10.607	<=	40.000			PASS
2	DH5	2441				4715.12	<= 20000.000	PASS
3	DH5	2441	8.434	<=	40.000			PASS
3	DH5	2441				5015.00	<= 20000.000	PASS
4	DH5	2441	10.594	<=	40.000			PASS
4	DH5	2441				6596.84	<= 20000.000	PASS
5	DH5	2441	6.819	<=	40.000			PASS
5	DH5	2441				7624.51	<= 20000.000	PASS
6	DH5	2441	7.190	<=	40.000			PASS
6	DH5	2441				5492.30	<= 20000.000	PASS
7	DH5	2441	11.279	<=	40.000			PASS
7	DH5	2441				7816.72	<= 20000.000	PASS
8	DH5	2441	7.152	<=	40.000			PASS
8	DH5	2441				5360.25	<= 20000.000	PASS
9	DH5	2441	8.499	<=	40.000			PASS
9	DH5	2441				7420.48	<= 20000.000	PASS
10	DH5	2441	6.792	<=	40.000			PASS
10	DH5	2441				5735.05	<= 20000.000	PASS
1	DH5	2480	4.247	<=	40.000			PASS
1	DH5	2480				5771.35	<= 20000.000	PASS
2	DH5	2480	6.952	<=	40.000			PASS
2	DH5	2480				6204.25	<= 20000.000	PASS
3	DH5	2480	11.400	<=	40.000			PASS
3	DH5	2480				5179.43	<= 20000.000	PASS
4	DH5	2480	9.783	<=	40.000			PASS
4	DH5	2480				5518.71	<= 20000.000	PASS
5	DH5	2480	7.131	<=	40.000			PASS
5	DH5	2480				6410.34	<= 20000.000	PASS
6	DH5	2480	11.851	<=	40.000			PASS
6	DH5	2480				5659.31	<= 20000.000	PASS
7	DH5	2480	10.717	<=	40.000			PASS
7	DH5	2480				7617.82	<= 20000.000	PASS
8	DH5	2480	9.331	<=	40.000			PASS
8	DH5	2480				6404.42	<= 20000.000	PASS

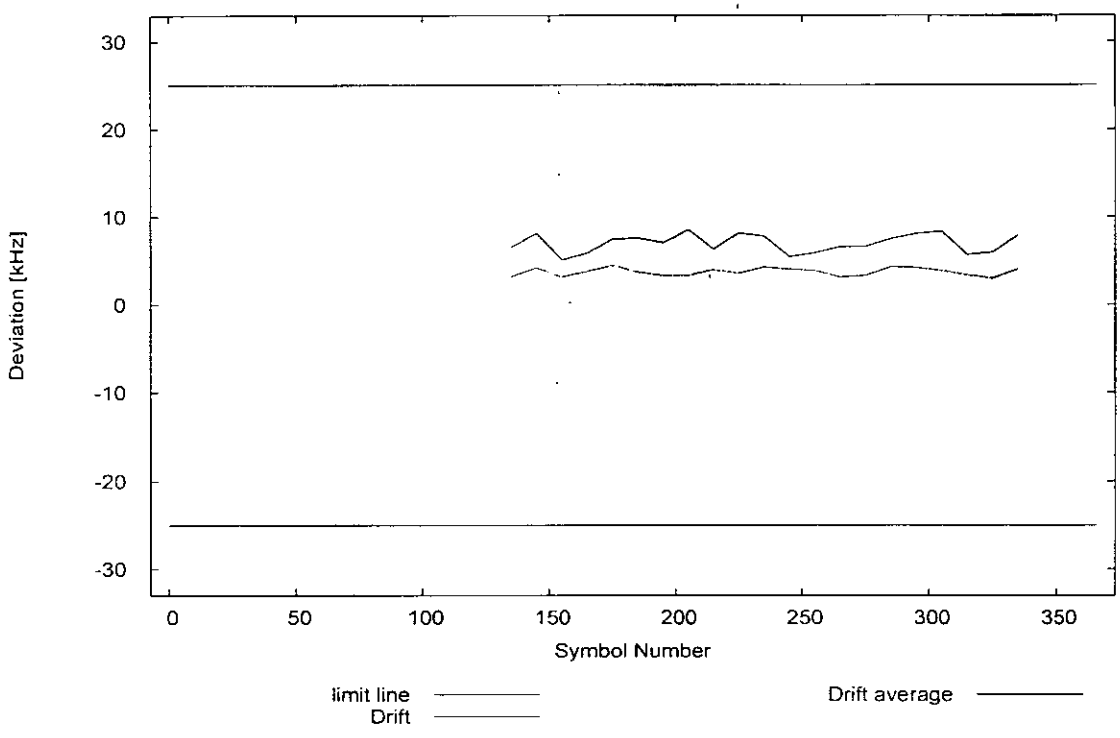
9	DH5	2480	10.176	<=	40.000			PASS
9	DH5	2480				6173.60	<= 20000.000	PASS
10	DH5	2480	9.908	<=	40.000			PASS
10	DH5	2480				5317.14	<= 20000.000	PASS

Final Test Case Verdict . . . . . PASS 00:32:11

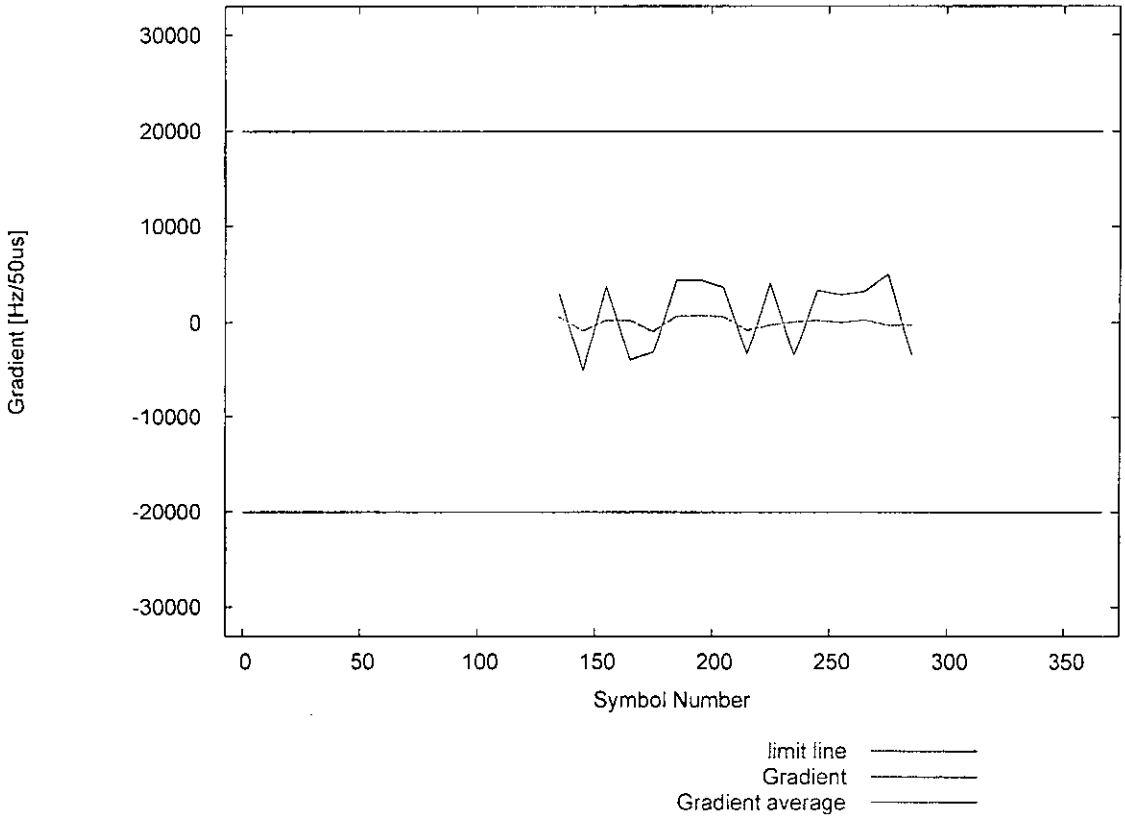
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH1 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern



TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2402.000 MHz

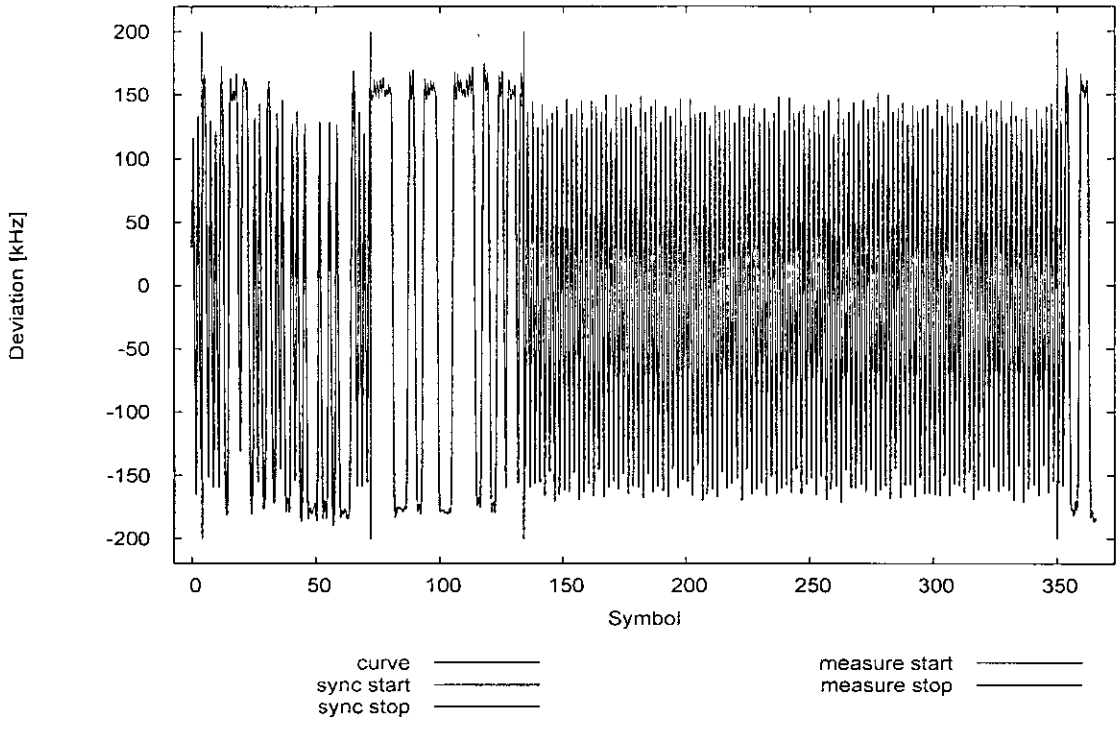


TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2402.000 MHz

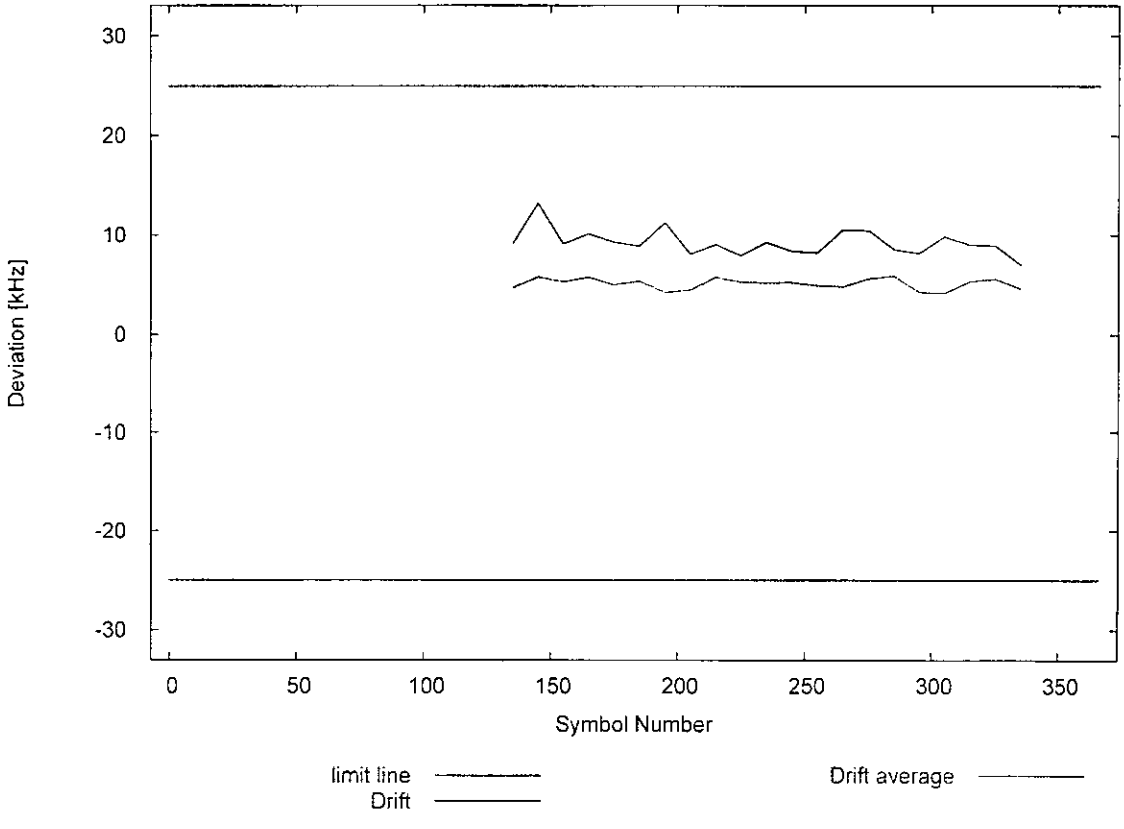


1247

Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH1 Loop Back Mode -
Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern

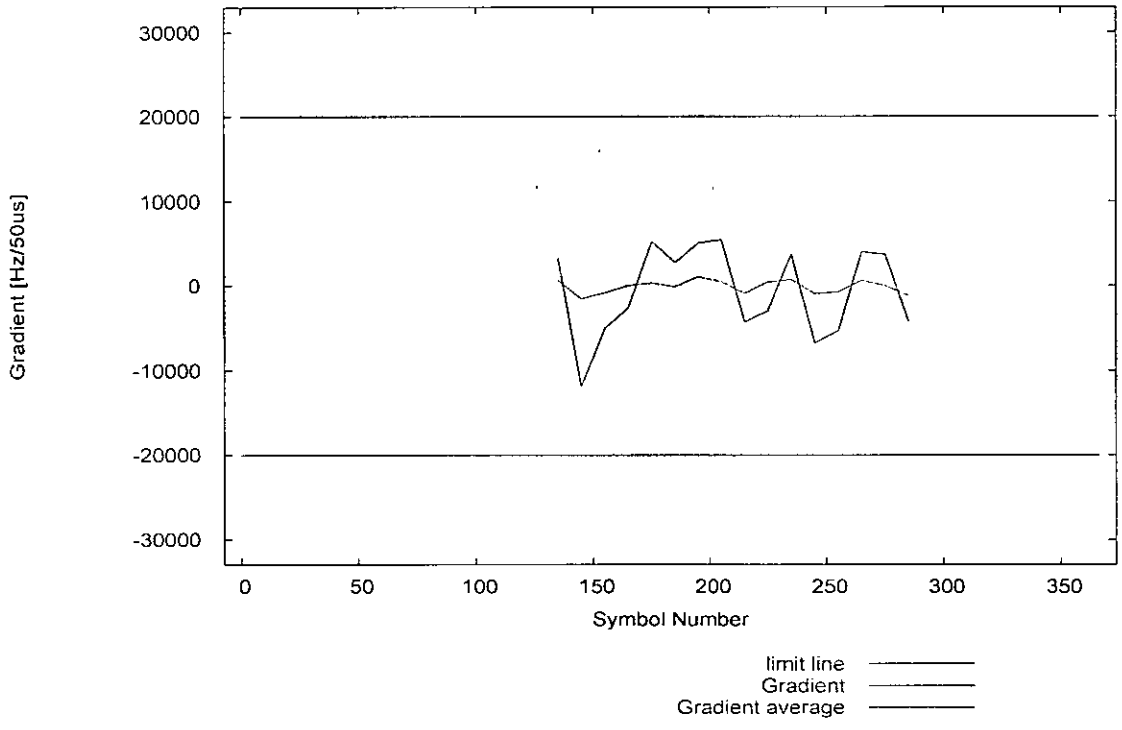


TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2441.000 MHz

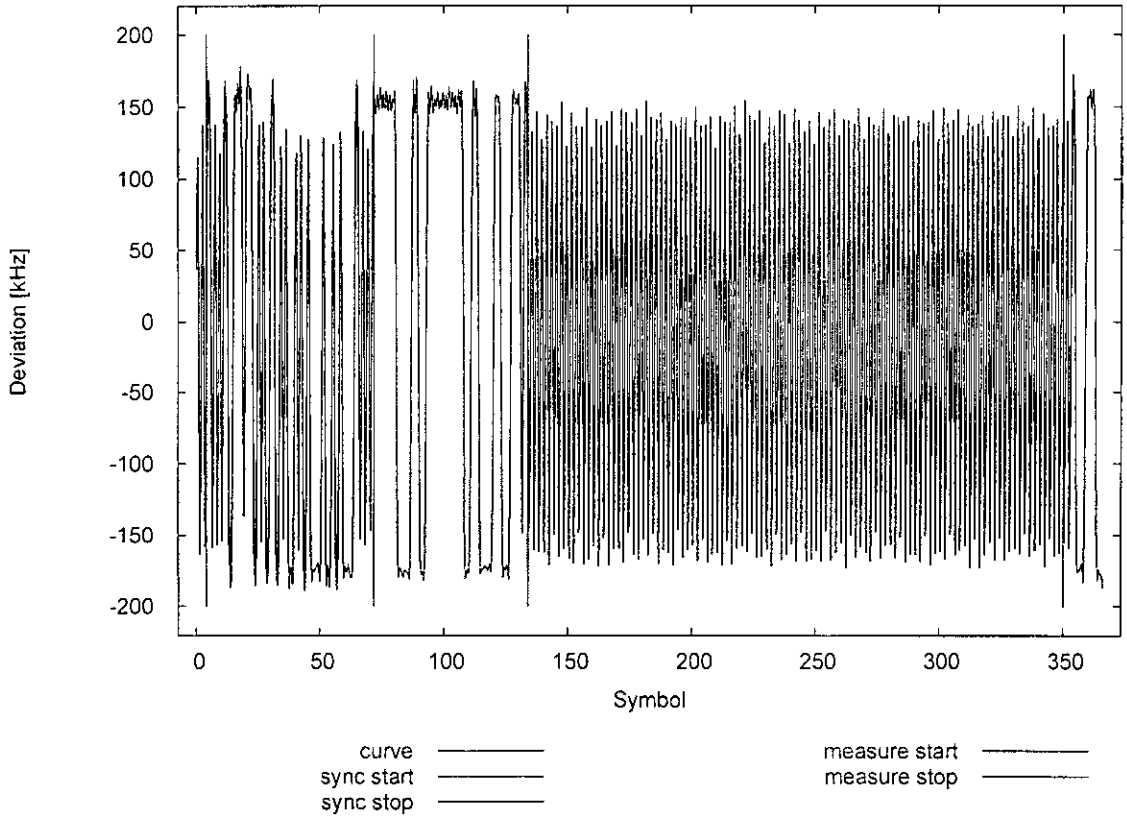


1218

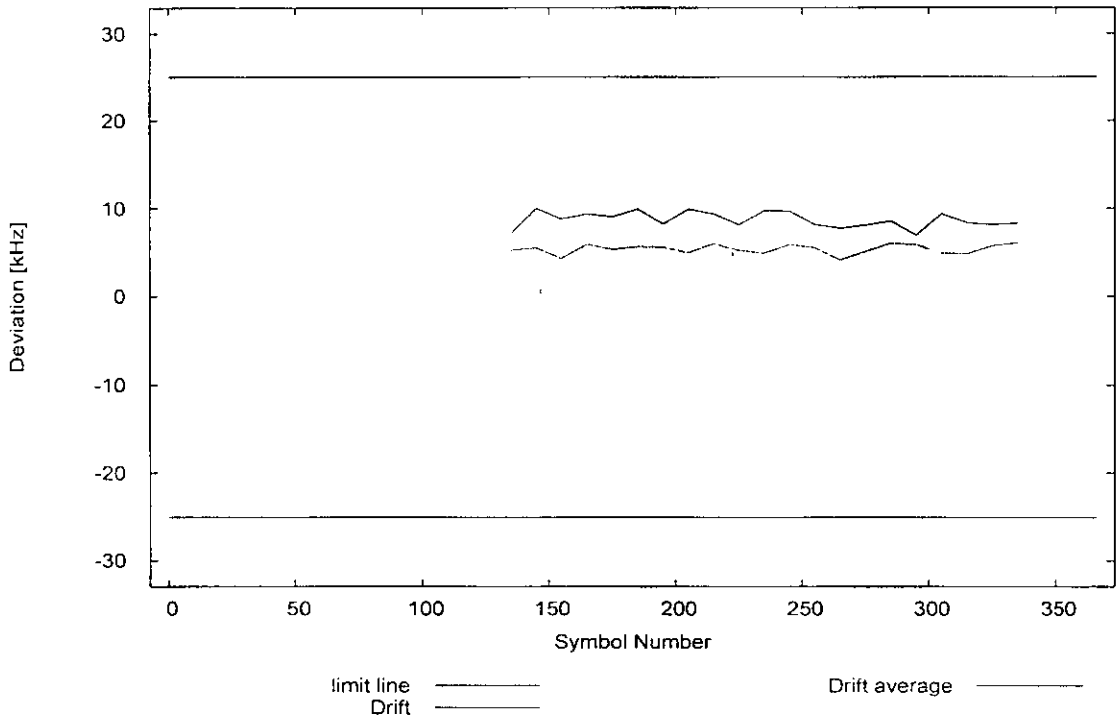
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2441.000 MHz



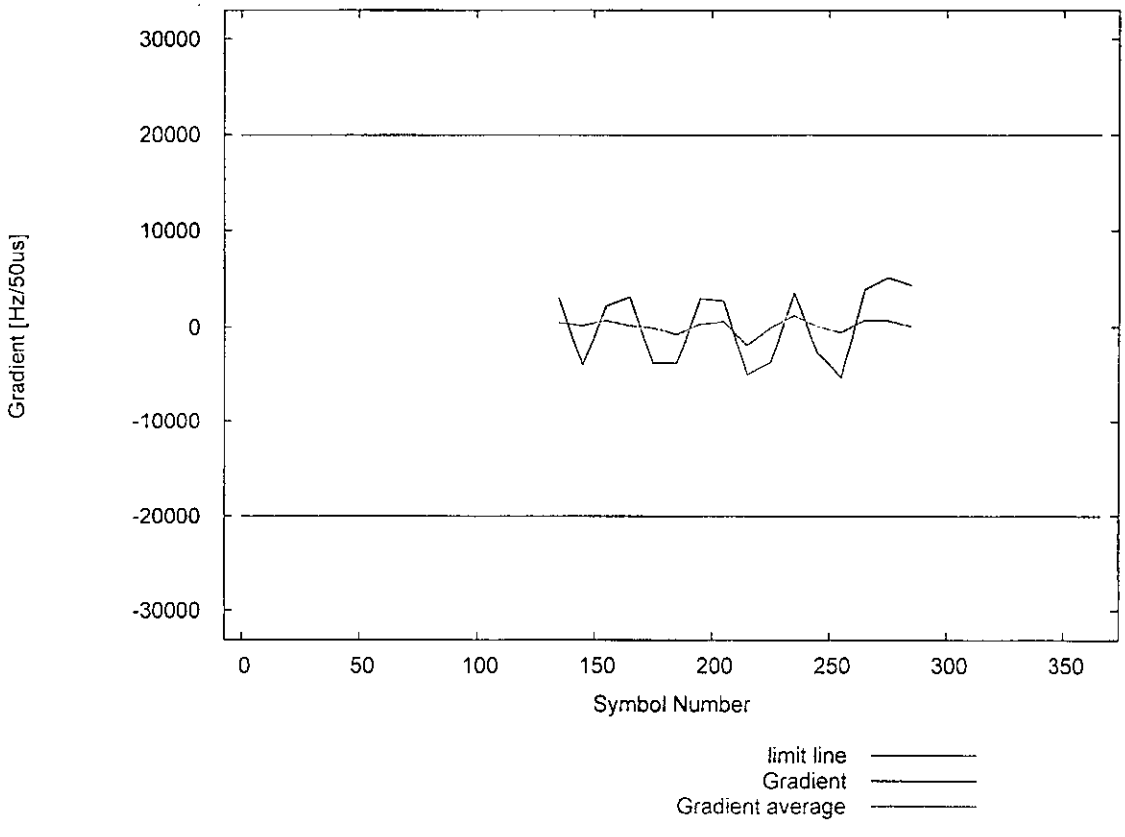
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern



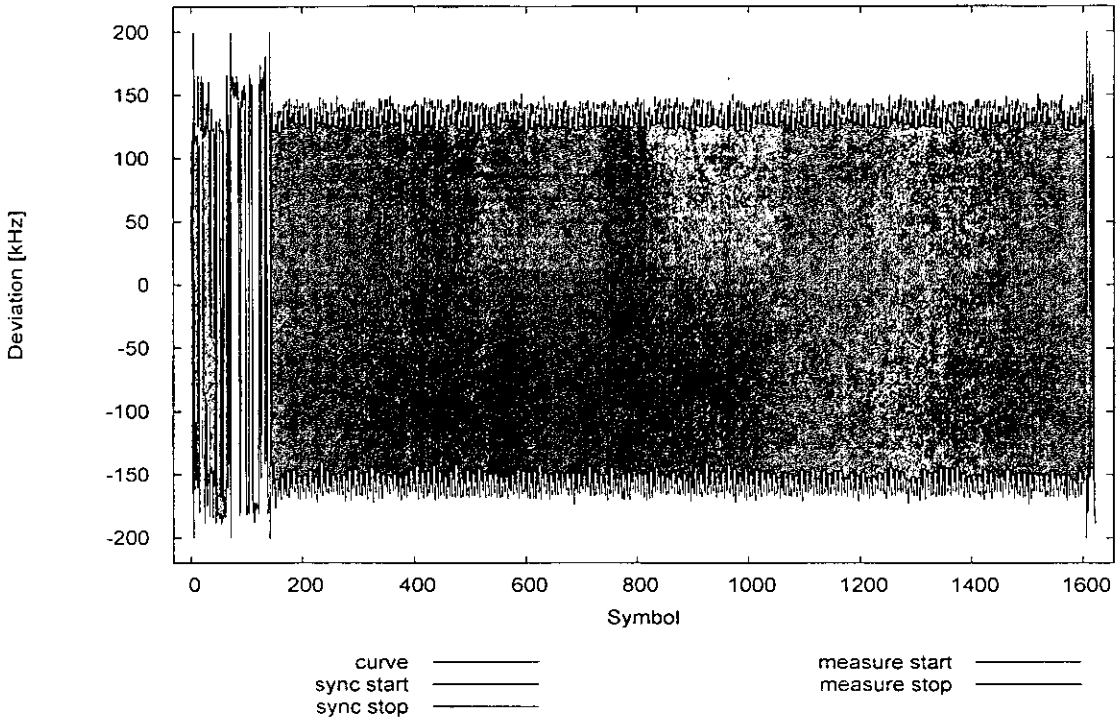
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2480.000 MHz



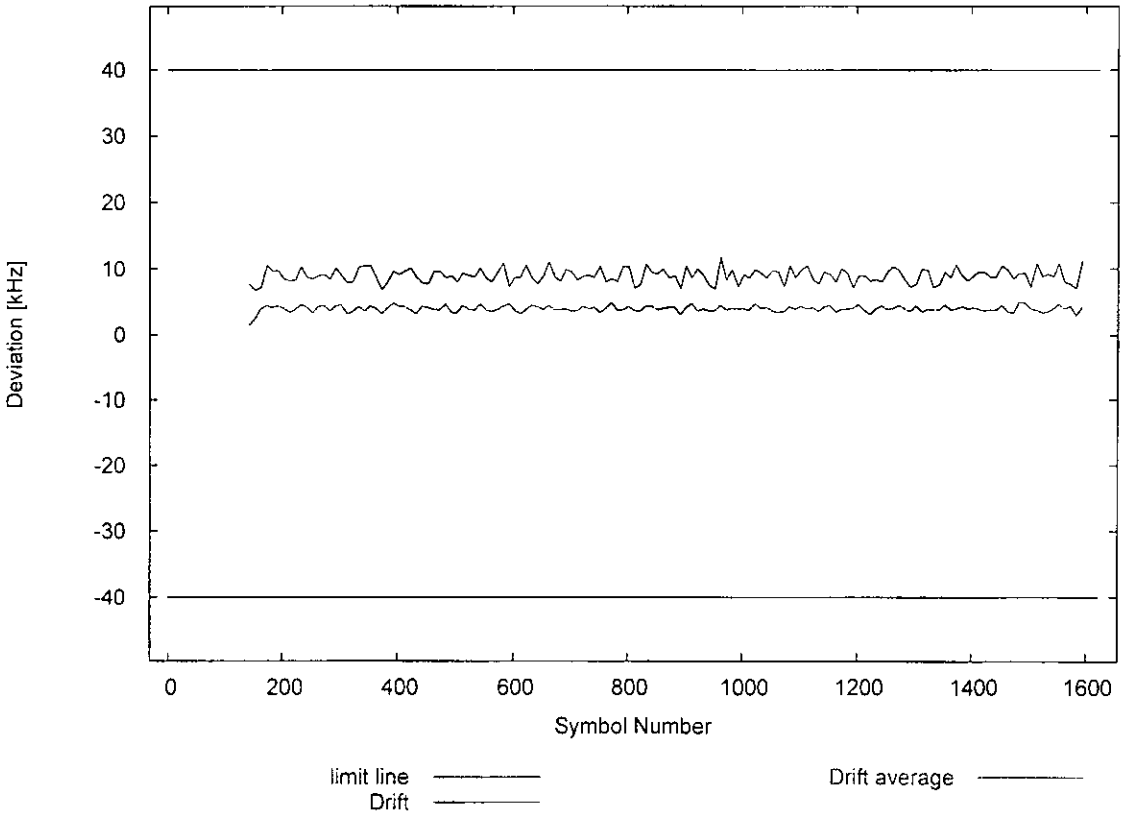
TC Carrier Frequency Drift packet DH1 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2480.000 MHz



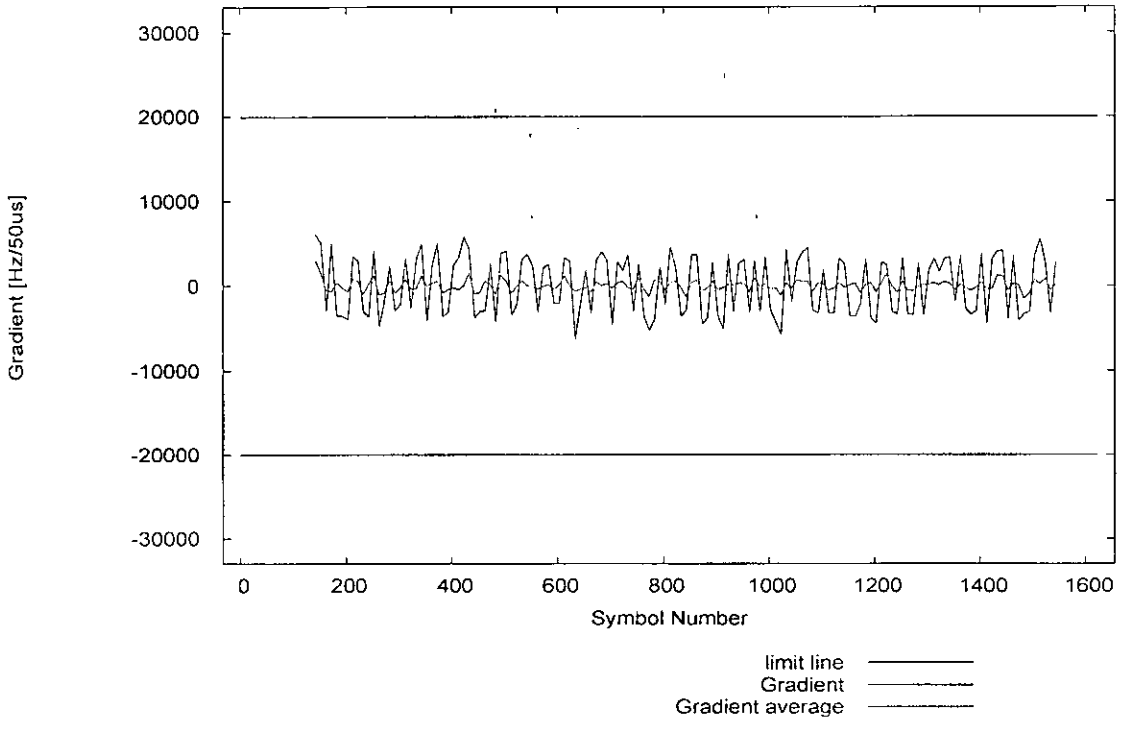
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH3 Loop Back Mode -
Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern



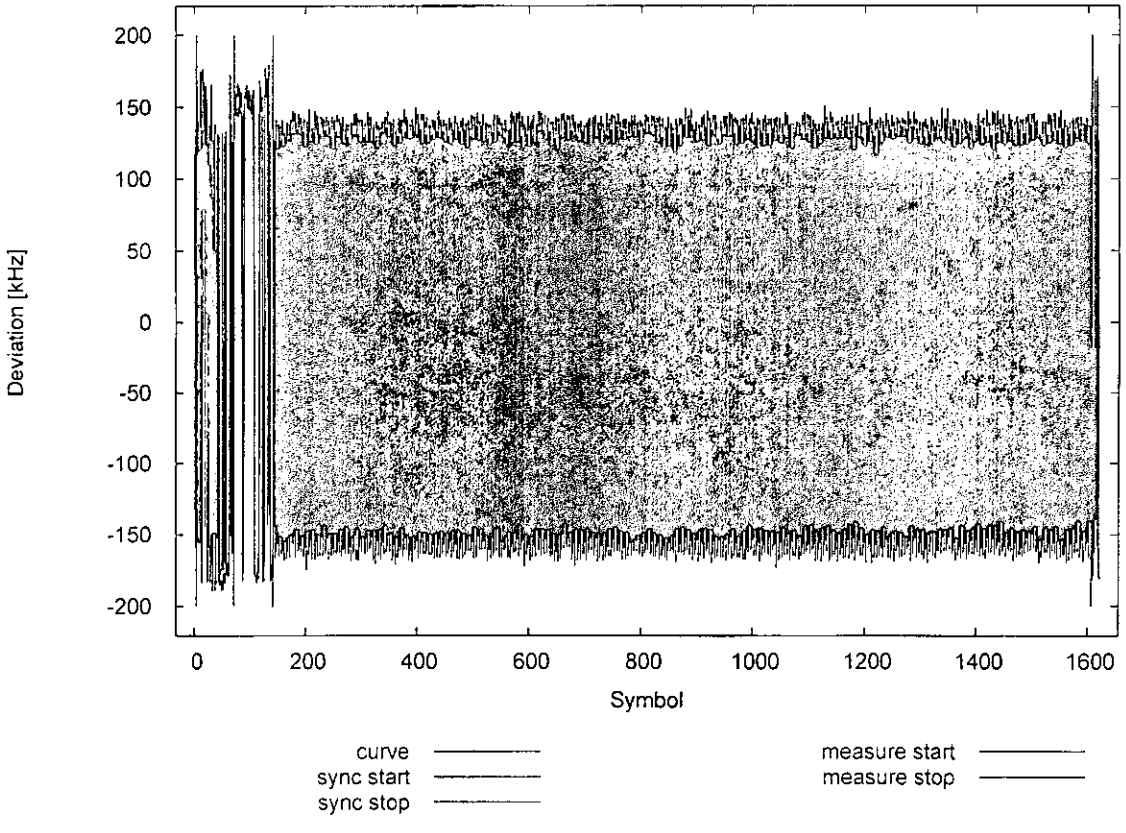
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2402.000 MHz



TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2402.000 MHz

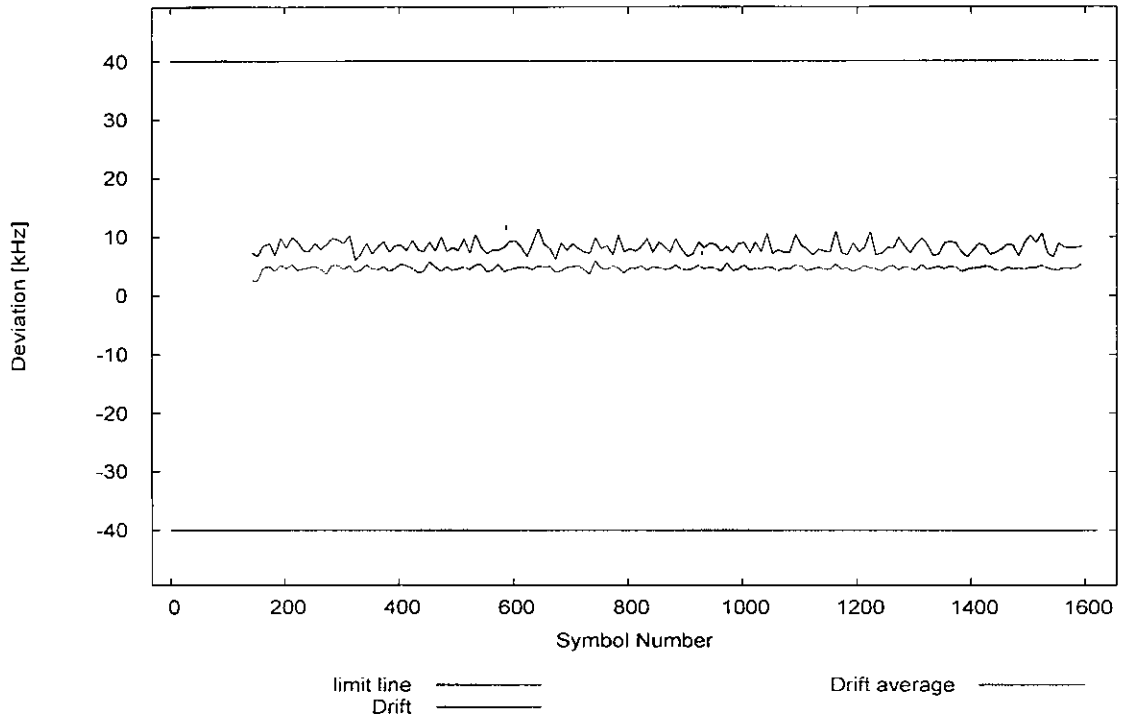


Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern

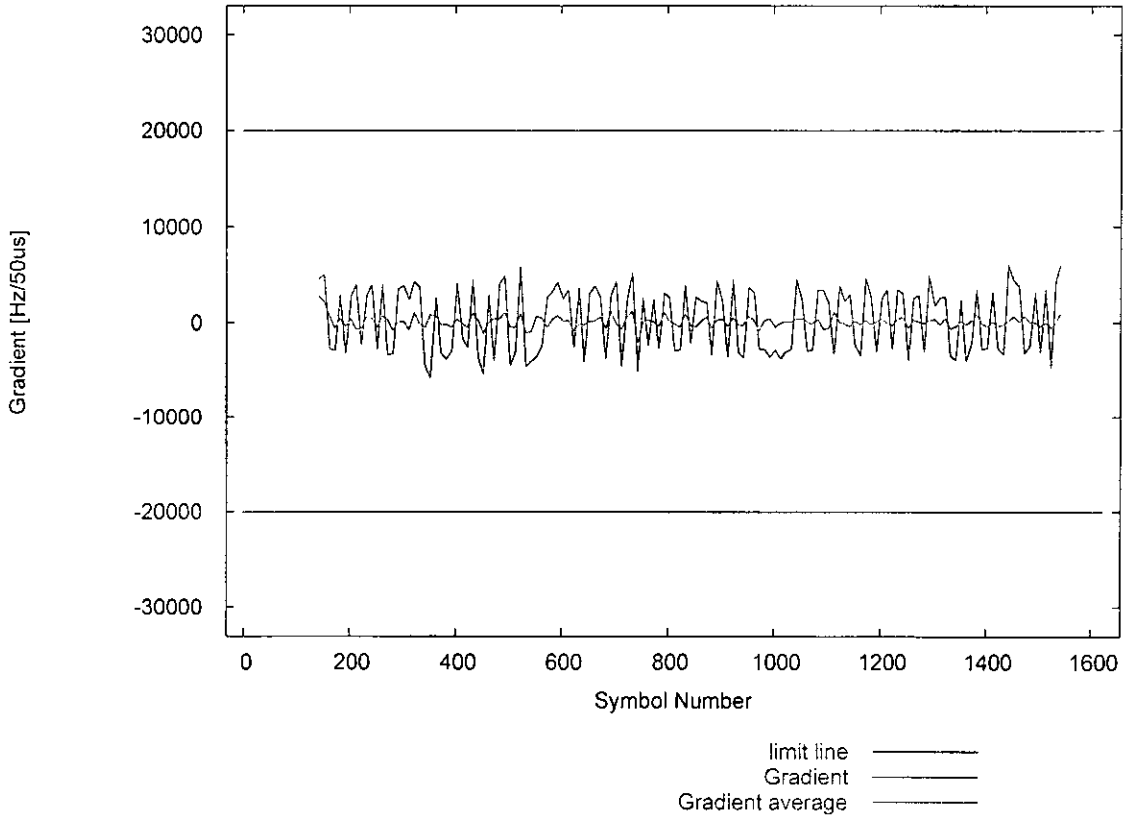


1252

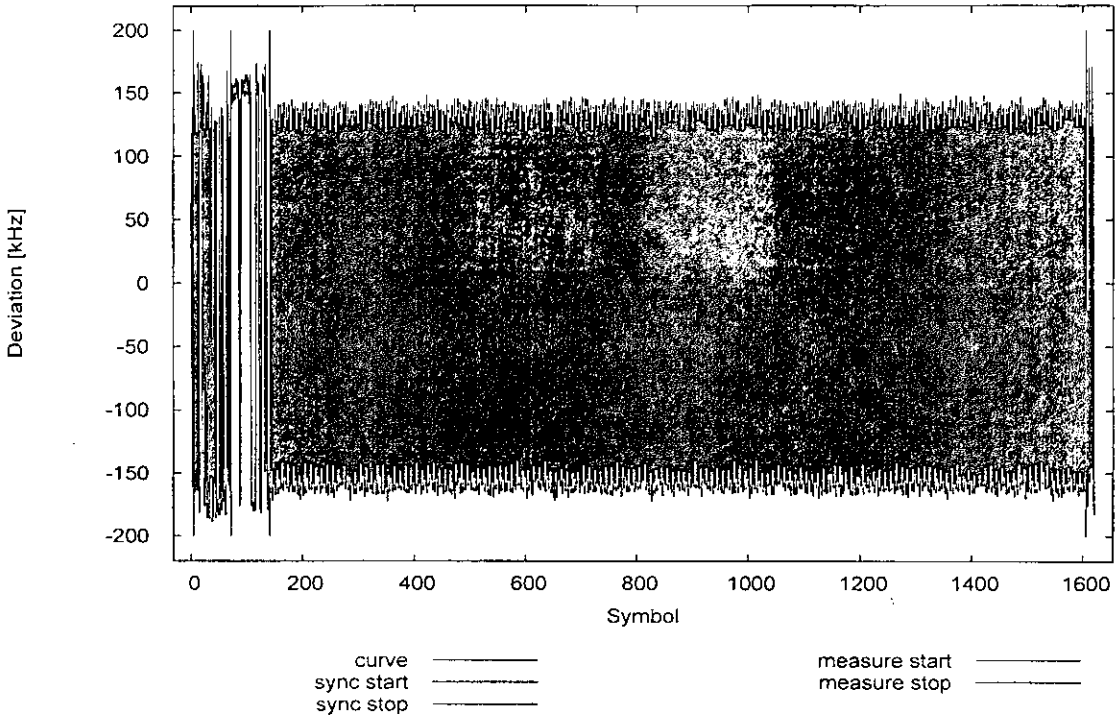
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2441.000 MHz



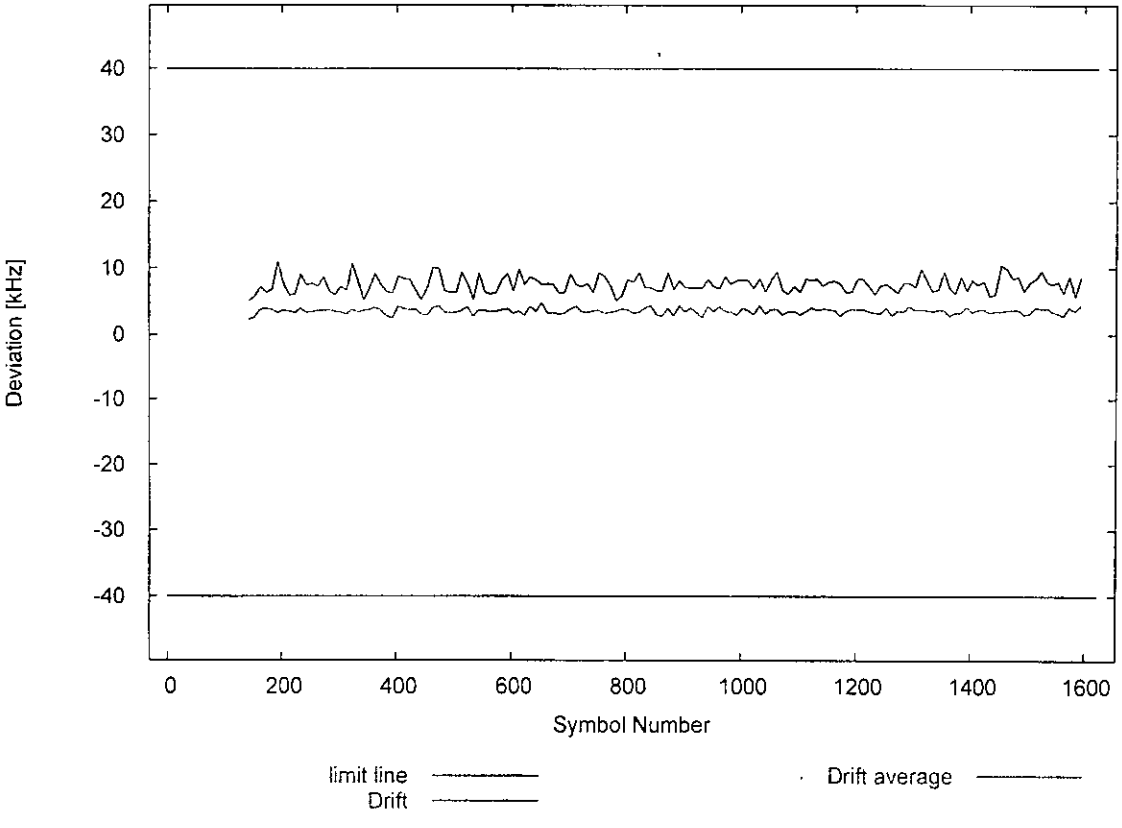
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2441.000 MHz



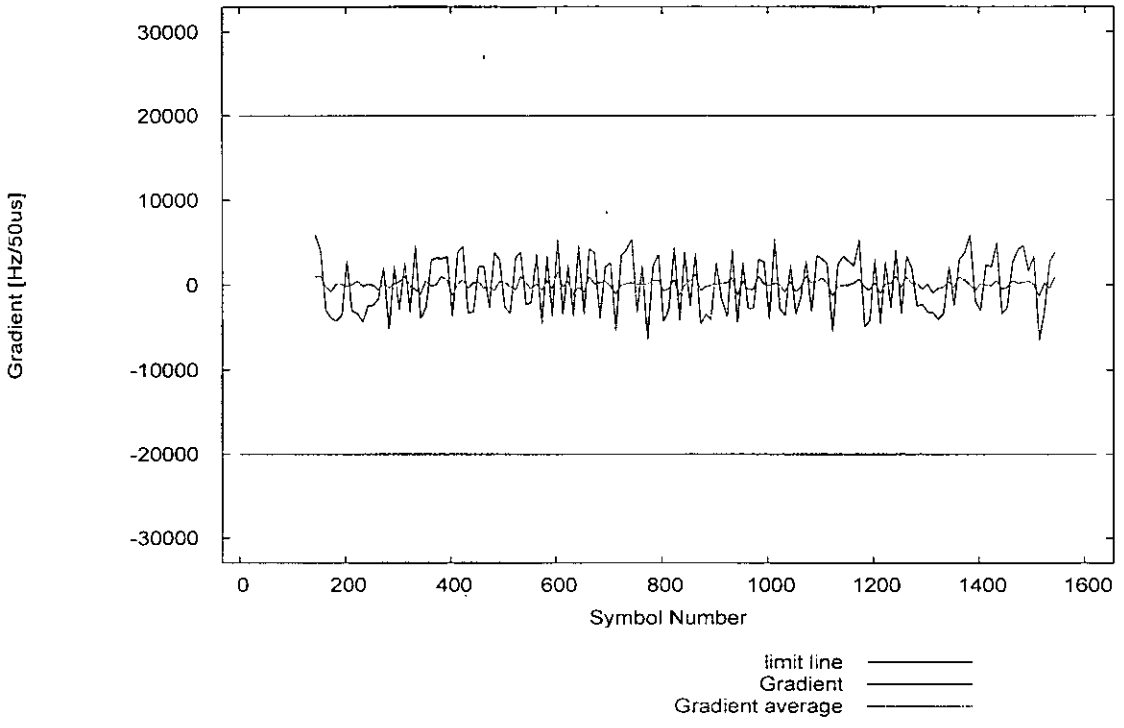
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH3 Loop Back Mode -
Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern



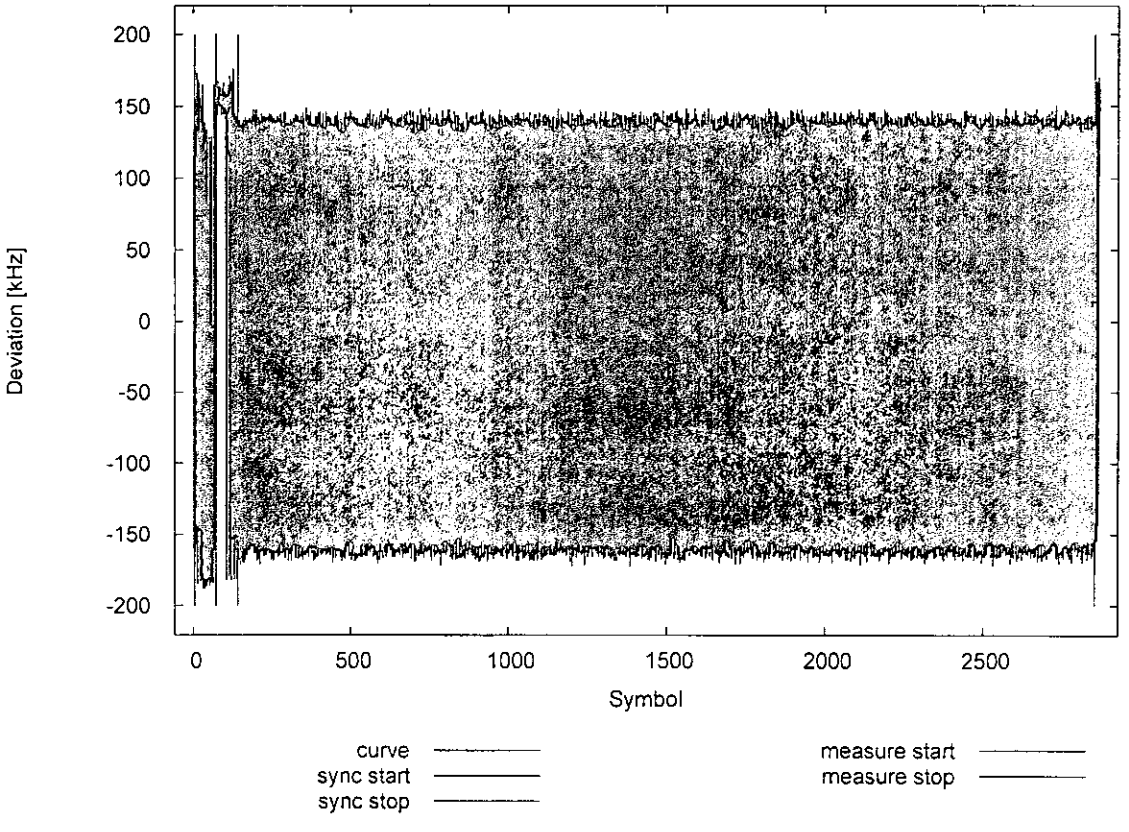
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2480.000 MHz



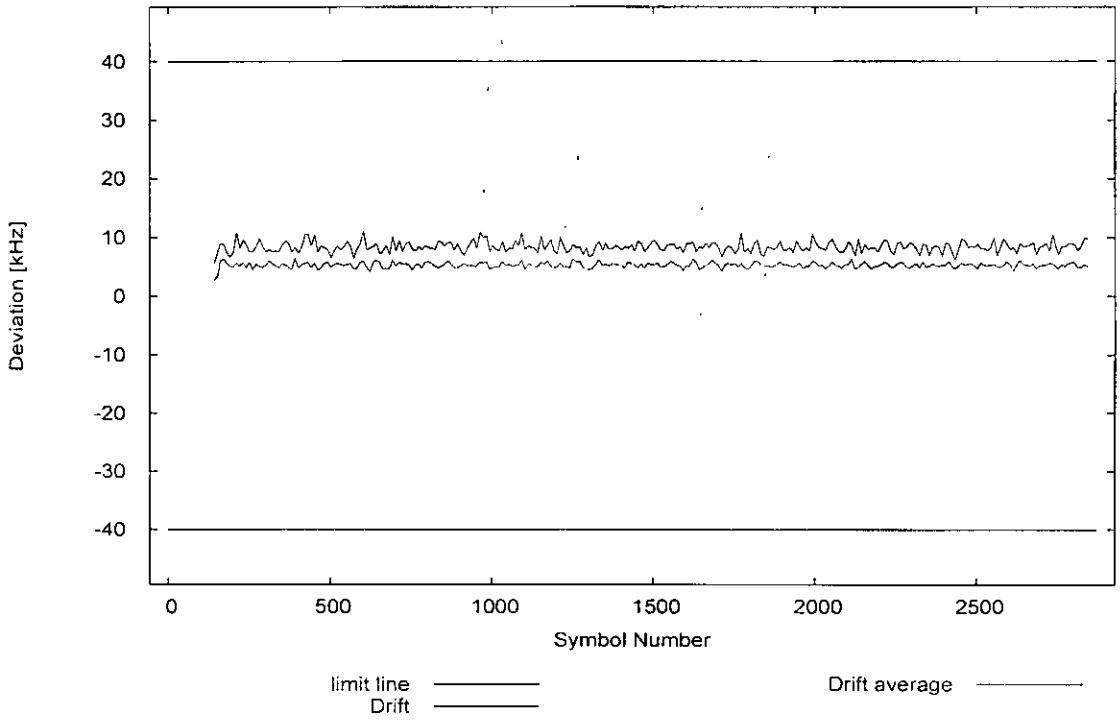
TC Carrier Frequency Drift packet DH3 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2480.000 MHz



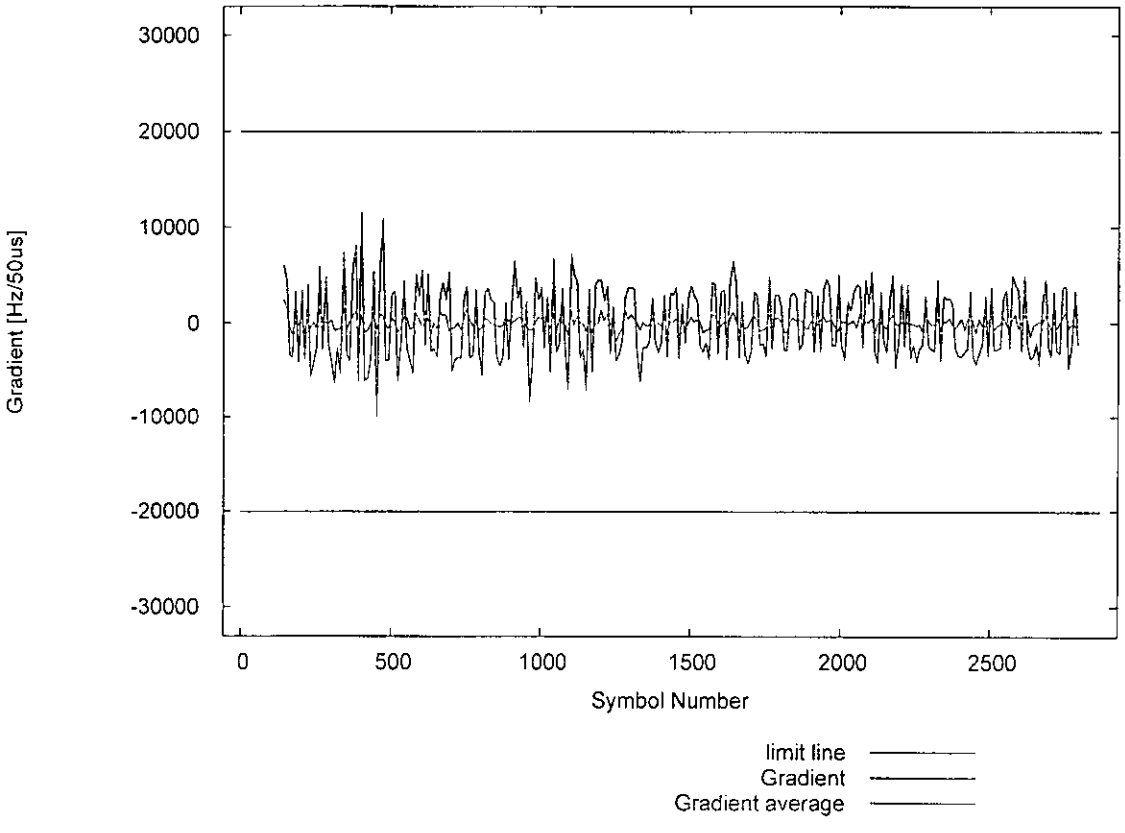
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - frequency: 2402.000 [MHz] - 1010 pattern



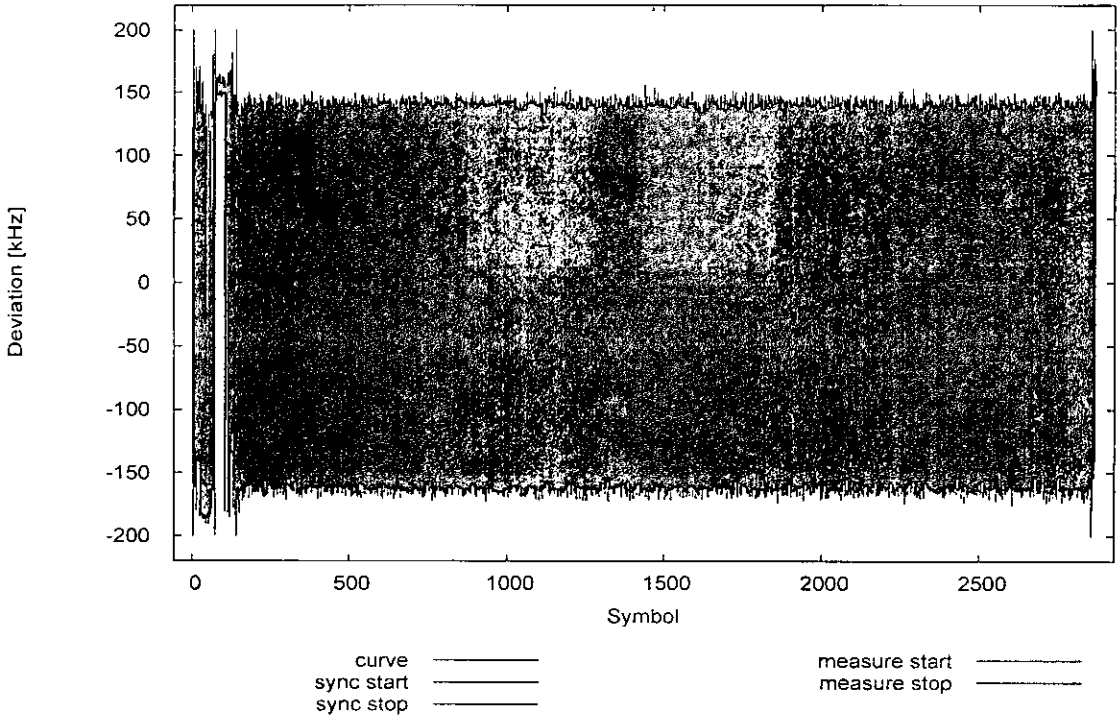
TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2402.000 MHz



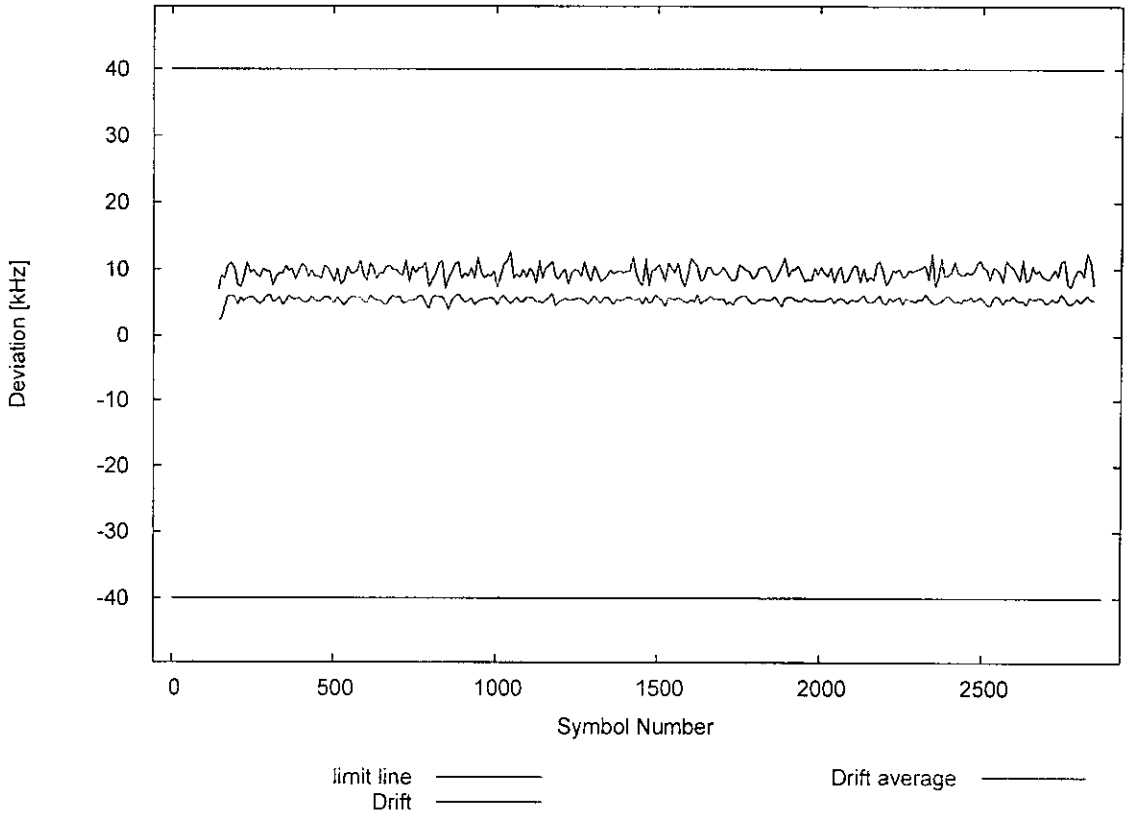
TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2402.000 MHz



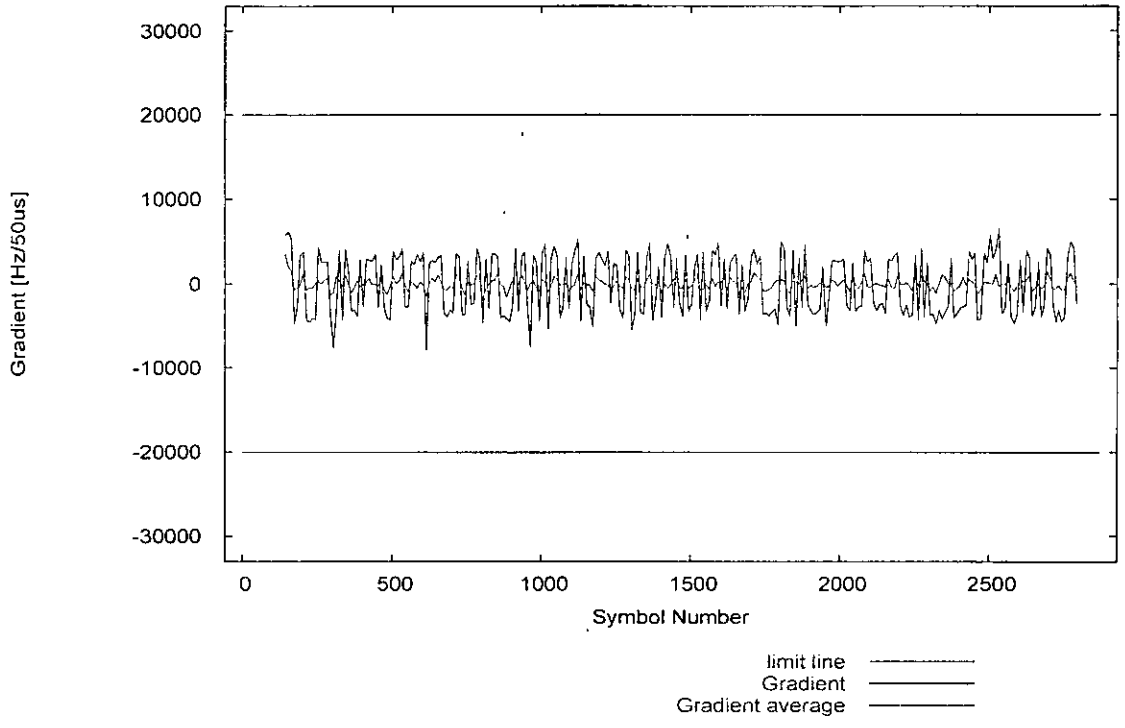
Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - frequency: 2441.000 [MHz] - 1010 pattern



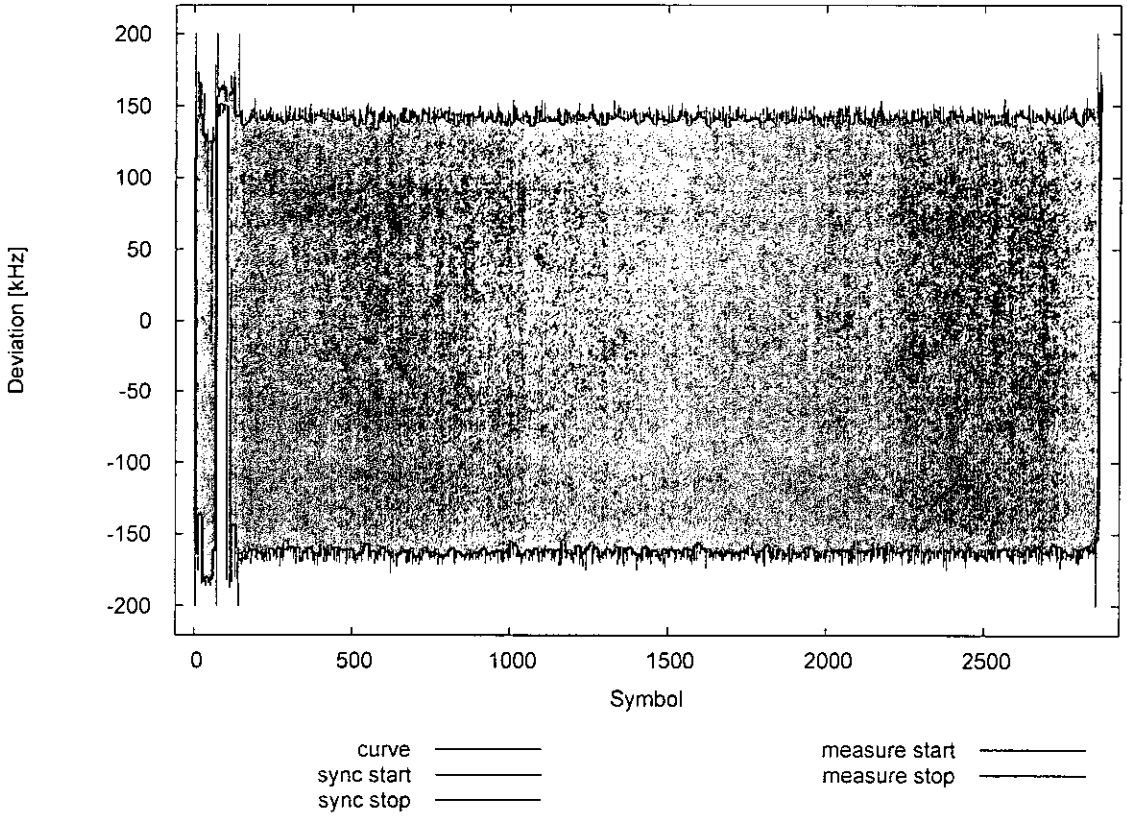
TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2441.000 MHz



TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2441.000 MHz

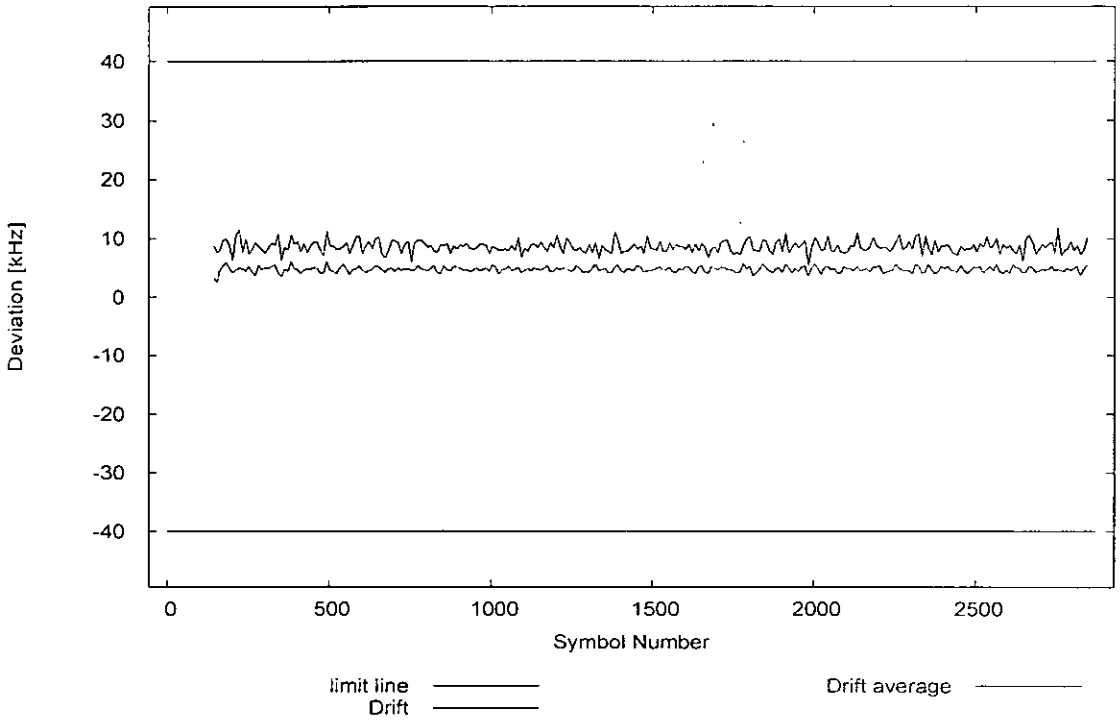


Measured Burst, FSK Signal TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - frequency: 2480.000 [MHz] - 1010 pattern

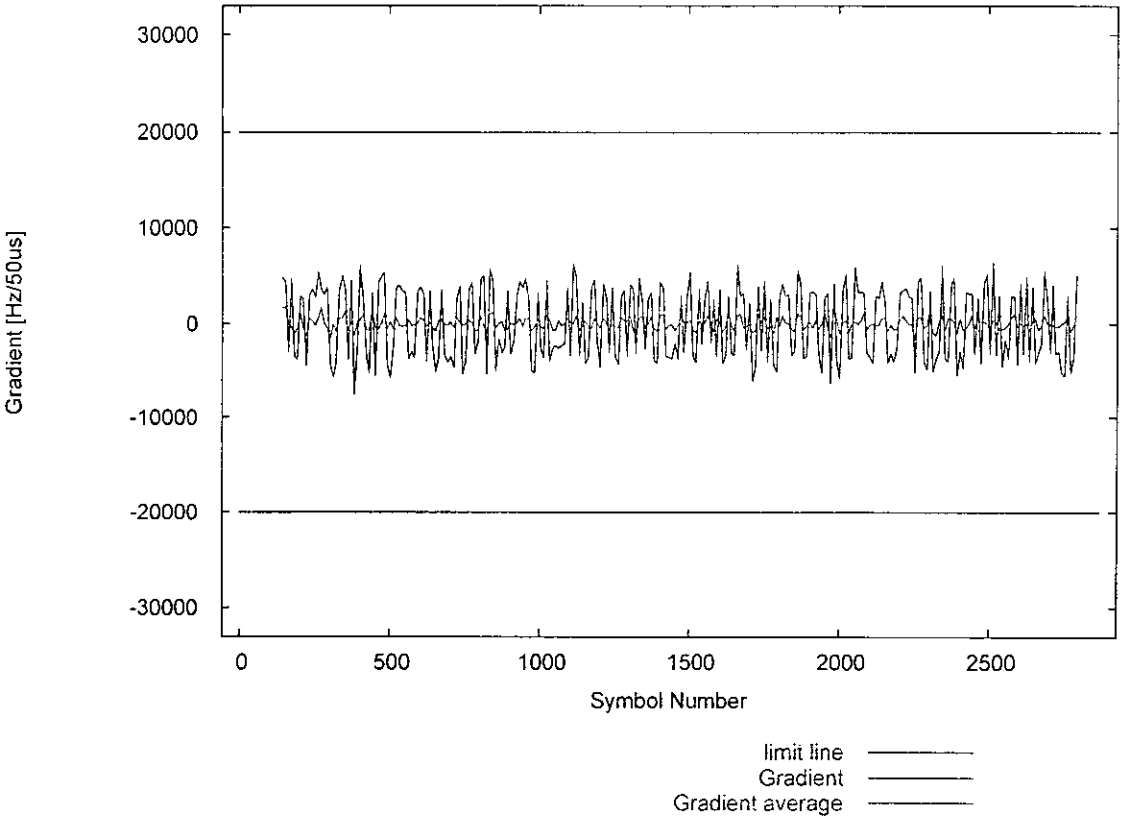


1258

TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift - frequency: 2480.000 MHz



TC Carrier Frequency Drift packet DH5 Loop Back Mode - Measured EUT: M3200 - Frequency drift gradient - frequency: 2480.000 MHz



Annex K

RCV/CA/01/C Sensitivity – Single Slot Packets

Sensitivity - Single Slot Packets

For system parameter see 0, "General Parameter 001"

BT Test Specification Version: 1.2

TS Errata Request: 287

For EUT parameter see 0, "EUT Parameter 004"
For test case parameter see 0, "Test Case Parameter 012"

TX-FREQ [MHz]	RX-FREQ [MHz]	Bit Error Rate [%]		LIMIT [%]	VERDICT
2480.0	2402.0	0.026	<=	0.100	PASS
2402.0	2441.0	0.021	<=	0.100	PASS
2402.0	2480.0	0.027	<=	0.100	PASS

Final Test Case Verdict . . . . . PASS 00:05:09

Sensitivity - Single Slot Packets

For system parameter see 0, "General Parameter 001"

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BT Test Specification Version:  1.2

TS Errata Request:              287
```

For EUT parameter see 0, "EUT Parameter 007"
For test case parameter see 0, "Test Case Parameter 032"

TX-FREQ [MHz]	RX-FREQ [MHz]	Bit Error Rate [%]		LIMIT [%]	VERDICT
2480.0	2402.0	0.042	<=	0.100	PASS
2402.0	2441.0	0.042	<=	0.100	PASS
2402.0	2480.0	0.021	<=	0.100	PASS

Final Test Case Verdict . . . . . PASS 00:04:29

Sensitivity - Single Slot Packets

For system parameter see 0, "General Parameter 001"

BT Test Specification Version: 1.2

TS Errata Request: 287

For EUT parameter see 0, "EUT Parameter 008"
For test case parameter see 0, "Test Case Parameter 033"

TX-FREQ [MHz]	RX-FREQ [MHz]	Bit Error Rate [%]		LIMIT [%]	VERDICT
2480.0	2402.0	0.006	<=	0.100	PASS
2402.0	2441.0	0.015	<=	0.100	PASS
2402.0	2480.0	0.007	<=	0.100	PASS

Final Test Case Verdict . . . . . PASS 00:04:30

Sensitivity - Single Slot Packets

For system parameter see 0, "General Parameter 001"

BT Test Specification Version: 1.2

TS Errata Request: 287

For EUT parameter see 0, "EUT Parameter 011"
For test case parameter see 0, "Test Case Parameter 052"

TX-FREQ [MHz]	RX-FREQ [MHz]	Bit Error Rate [%]		LIMIT [%]	VERDICT
2480.0	2402.0	0.008	<=	0.100	PASS
2402.0	2441.0	0.008	<=	0.100	PASS
2402.0	2480.0	0.047	<=	0.100	PASS

Final Test Case Verdict . . . . . PASS 00:04:31

Sensitivity - Single Slot Packets

For system parameter see 0, "General Parameter 001"

BT Test Specification Version: 1.2

TS Errata Request: 287

For EUT parameter see 0, "EUT Parameter 012"
For test case parameter see 0, "Test Case Parameter 053"

TX-FREQ [MHz]	RX-FREQ [MHz]	Bit Error Rate [%]		LIMIT [%]	VERDICT
2480.0	2402.0	0.015	<=	0.100	PASS
2402.0	2441.0	0.046	<=	0.100	PASS
2402.0	2480.0	0.050	<=	0.100	PASS

Final Test Case Verdict . . . . . PASS 00:04:44

Annex L

RCV/CA/02/C Sensitivity - Multi Slot Packets

Sensitivity - Multi Slot Packets

For system parameter see 0, "General Parameter 002"

BT Test Specification Version: 1.2

TS Errata Request: 287

For EUT parameter see 0, "EUT Parameter 002"
For test case parameter see 0, "Test Case Parameter 011"

TX-FREQ [MHz]	RX-FREQ [MHz]	Bit Error Rate [%]		LIMIT [%]	VERDICT
2480.0	2402.0	0.000	<=	0.100	PASS
2402.0	2441.0	0.000	<=	0.100	PASS
2402.0	2480.0	0.000	<=	0.100	PASS

Final Test Case Verdict . . . . . PASS 00:02:18

Sensitivity - Multi Slot Packets

For system parameter see 0, "General Parameter 002"

```
BT Test Specification Version:  1.2

TS Errata Request:              287
```

For EUT parameter see 0, "EUT Parameter 005"
For test case parameter see 0, "Test Case Parameter 034"

TX-FREQ [MHz]	RX-FREQ [MHz]	Bit Error Rate [%]		LIMIT [%]	VERDICT
2480.0	2402.0	0.000	<=	0.100	PASS
2402.0	2441.0	0.000	<=	0.100	PASS
2402.0	2480.0	0.000	<=	0.100	PASS

Final Test Case Verdict . . . . . PASS 00:02:24

Sensitivity - Multi Slot Packets

For system parameter see 0, "General Parameter 002"

```
BT Test Specification Version:  1.2

TS Errata Request:              287
```

For EUT parameter see 0, "EUT Parameter 006"
For test case parameter see 0, "Test Case Parameter 035"

TX-FREQ [MHz]	RX-FREQ [MHz]	Bit Error Rate [%]		LIMIT [%]	VERDICT
2480.0	2402.0	0.000	<=	0.100	PASS
2402.0	2441.0	0.085	<=	0.100	PASS
2402.0	2480.0	0.000	<=	0.100	PASS

Final Test Case Verdict . . . . . PASS 00:04:36

Sensitivity - Multi Slot Packets

For system parameter see 0, "General Parameter 002"

```
BT Test Specification Version:  1.2

TS Errata Request:              287
```

For EUT parameter see 0, "EUT Parameter 009"
For test case parameter see 0, "Test Case Parameter 054"

TX-FREQ [MHz]	RX-FREQ [MHz]	Bit Error Rate [%]		LIMIT [%]	VERDICT
2480.0	2402.0	0.000	<=	0.100	PASS
2402.0	2441.0	0.000	<=	0.100	PASS
2402.0	2480.0	0.088	<=	0.100	PASS

Final Test Case Verdict . . . . . PASS 00:02:14

Sensitivity - Multi Slot Packets

For system parameter see 0, "General Parameter 002"

BT Test Specification Version: 1.2

TS Errata Request: 287

For EUT parameter see 0, "EUT Parameter 010"
For test case parameter see 0, "Test Case Parameter 055"

TX-FREQ [MHz]	RX-FREQ [MHz]	Bit Error Rate [%]		LIMIT [%]	VERDICT
2480.0	2402.0	0.000	<=	0.100	PASS
2402.0	2441.0	0.000	<=	0.100	PASS
2402.0	2480.0	0.000	<=	0.100	PASS

Final Test Case Verdict . . . . . PASS 00:02:03

Annex M

RCV/CA/03/C C/I Performance

C/I Performance

For system parameter see 0, "General Parameter 008"

BT Test Specification Version: 1.2

TS Errata Request: 327

For EUT parameter see 0, "EUT Parameter 002"
For test case parameter see 0, "Test Case Parameter 008"

POSITION B2	FREQUENCY [MHz]	B1 LEVEL [dBm]	B2 LEVEL [dBm]	BER [%]		BER LIMIT [%]	VERDICT
fimage	2402.00	-67.00	-58.00	0.000	<=	0.100	PASS
fimage+1	2403.00	-60.00	-47.00	0.000	<=	0.100	PASS
frx-1	2404.00	-60.00	-60.00	0.000	<=	0.100	PASS
frx	2405.00	-60.00	-71.00	0.000	<=	0.100	PASS
frx+1	2406.00	-60.00	-60.00	0.000	<=	0.100	PASS
frx+2	2407.00	-60.00	-30.00	0.000	<=	0.100	PASS
frx+3	2408.00	-67.00	-27.00	0.036	<=	0.100	PASS
frx+4	2409.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+5	2410.00	-67.00	-27.00	0.001	<=	0.100	PASS
frx+6	2411.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+7	2412.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+8	2413.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+9	2414.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+10	2415.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+11	2416.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+12	2417.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+13	2418.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+14	2419.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+15	2420.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+16	2421.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+17	2422.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+18	2423.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+19	2424.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+20	2425.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+21	2426.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+22	2427.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+23	2428.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+24	2429.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+25	2430.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+26	2431.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+27	2432.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+28	2433.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+29	2434.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+30	2435.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+31	2436.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+32	2437.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+33	2438.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+34	2439.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+35	2440.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+36	2441.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+37	2442.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+38	2443.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+39	2444.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+40	2445.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+41	2446.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+42	2447.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+43	2448.00	-67.00	-27.00	0.000	<=	0.100	PASS

frx+44	2449.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+45	2450.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+46	2451.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+47	2452.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+48	2453.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+49	2454.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+50	2455.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+51	2456.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+52	2457.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+53	2458.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+54	2459.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+55	2460.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+56	2461.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+57	2462.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+58	2463.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+59	2464.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+60	2465.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+61	2466.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+62	2467.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+63	2468.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+64	2469.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+65	2470.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+66	2471.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+67	2472.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+68	2473.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+69	2474.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+70	2475.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+71	2476.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+72	2477.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+73	2478.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+74	2479.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+75	2480.00	-67.00	-27.00	0.000	<=	0.100	PASS

Next measurement will be running with the following changed parameters:

EUT Tx Frequency: 2441.000 MHz
EUT Rx Frequency: 2441.000 MHz
Image Frequency: 2438.000 MHz

POSITION	B2 FREQUENCY [MHz]	B1 LEVEL [dBm]	B2 LEVEL [dBm]	BER [%]		BER LIMIT [%]	VERDICT
frx-39	2402.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-38	2403.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-37	2404.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-36	2405.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-35	2406.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-34	2407.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-33	2408.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-32	2409.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-31	2410.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-30	2411.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-29	2412.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-28	2413.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-27	2414.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-26	2415.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-25	2416.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-24	2417.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-23	2418.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-22	2419.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-21	2420.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-20	2421.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-19	2422.00	-67.00	-27.00	0.000	<=	0.100	PASS

frx-18	2423.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-17	2424.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-16	2425.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-15	2426.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-14	2427.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-13	2428.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-12	2429.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-11	2430.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-10	2431.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-9	2432.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-8	2433.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-7	2434.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-6	2435.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-5	2436.00	-67.00	-27.00	0.000	<=	0.100	PASS
fimage-1	2437.00	-67.00	-47.00	0.000	<=	0.100	PASS
fimage	2438.00	-67.00	-58.00	0.000	<=	0.100	PASS
fimage+1	2439.00	-60.00	-47.00	0.000	<=	0.100	PASS
frx-1	2440.00	-60.00	-60.00	0.000	<=	0.100	PASS
frx	2441.00	-60.00	-71.00	0.000	<=	0.100	PASS
frx+1	2442.00	-60.00	-60.00	0.000	<=	0.100	PASS
frx+2	2443.00	-60.00	-30.00	0.000	<=	0.100	PASS
frx+3	2444.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+4	2445.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+5	2446.00	-67.00	-27.00	0.002	<=	0.100	PASS
frx+6	2447.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+7	2448.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+8	2449.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+9	2450.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+10	2451.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+11	2452.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+12	2453.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+13	2454.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+14	2455.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+15	2456.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+16	2457.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+17	2458.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+18	2459.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+19	2460.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+20	2461.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+21	2462.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+22	2463.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+23	2464.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+24	2465.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+25	2466.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+26	2467.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+27	2468.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+28	2469.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+29	2470.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+30	2471.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+31	2472.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+32	2473.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+33	2474.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+34	2475.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+35	2476.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+36	2477.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+37	2478.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+38	2479.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx+39	2480.00	-67.00	-27.00	0.000	<=	0.100	PASS

Next measurement will be running with the following changed parameters:

EUT Tx Frequency:	2477.000	MHz
EUT Rx Frequency:	2477.000	MHz
Image Frequency:	2474.000	MHz

POSITION B2	FREQUENCY [MHz]	B1 LEVEL [dBm]	B2 LEVEL [dBm]	BER [%]		BER LIMIT [%]	VERDICT
frx-75	2402.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-74	2403.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-73	2404.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-72	2405.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-71	2406.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-70	2407.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-69	2408.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-68	2409.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-67	2410.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-66	2411.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-65	2412.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-64	2413.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-63	2414.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-62	2415.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-61	2416.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-60	2417.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-59	2418.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-58	2419.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-57	2420.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-56	2421.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-55	2422.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-54	2423.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-53	2424.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-52	2425.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-51	2426.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-50	2427.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-49	2428.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-48	2429.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-47	2430.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-46	2431.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-45	2432.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-44	2433.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-43	2434.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-42	2435.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-41	2436.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-40	2437.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-39	2438.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-38	2439.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-37	2440.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-36	2441.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-35	2442.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-34	2443.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-33	2444.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-32	2445.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-31	2446.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-30	2447.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-29	2448.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-28	2449.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-27	2450.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-26	2451.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-25	2452.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-24	2453.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-23	2454.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-22	2455.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-21	2456.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-20	2457.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-19	2458.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-18	2459.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-17	2460.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-16	2461.00	-67.00	-27.00	0.000	<=	0.100	PASS

frx-15	2462.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-14	2463.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-13	2464.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-12	2465.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-11	2466.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-10	2467.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-9	2468.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-8	2469.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-7	2470.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-6	2471.00	-67.00	-27.00	0.000	<=	0.100	PASS
frx-5	2472.00	-67.00	-27.00	0.000	<=	0.100	PASS
fimage-1	2473.00	-67.00	-47.00	0.000	<=	0.100	PASS
fimage	2474.00	-67.00	-58.00	0.000	<=	0.100	PASS
fimage+1	2475.00	-60.00	-47.00	0.000	<=	0.100	PASS
frx-1	2476.00	-60.00	-60.00	0.000	<=	0.100	PASS
frx	2477.00	-60.00	-71.00	0.000	<=	0.100	PASS
frx+1	2478.00	-60.00	-60.00	0.000	<=	0.100	PASS
frx+2	2479.00	-60.00	-30.00	0.000	<=	0.100	PASS
frx+3	2480.00	-67.00	-27.00	0.000	<=	0.100	PASS

Final Test Case Verdict . . . . . PASS 00:38:44

Annex N

RCV/CA/04/C Blocking Performance

Blocking Performance

For system parameter see 0, "General Parameter 008"

BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 002"
For test case parameter see 0, "Test Case Parameter 015"

B3 FREQUENCY [MHz]	B3 LEVEL [dBm]	BER SAMPLES	BER [%]		BER LIMIT [%]	VERDICT
30.00	-8.00	100000	0.000	<=	0.100	PASS
31.00	-8.00	100000	0.000	<=	0.100	PASS
32.00	-8.00	100000	0.000	<=	0.100	PASS
33.00	-8.00	100000	0.000	<=	0.100	PASS
34.00	-8.00	100000	0.000	<=	0.100	PASS
35.00	-8.00	100000	0.000	<=	0.100	PASS
36.00	-8.00	100000	0.000	<=	0.100	PASS
37.00	-8.00	100000	0.000	<=	0.100	PASS
38.00	-8.00	100000	0.000	<=	0.100	PASS
39.00	-8.00	100000	0.000	<=	0.100	PASS
40.00	-8.00	100000	0.000	<=	0.100	PASS
41.00	-8.00	100000	0.000	<=	0.100	PASS
42.00	-8.00	100000	0.000	<=	0.100	PASS
43.00	-8.00	100000	0.000	<=	0.100	PASS
44.00	-8.00	100000	0.000	<=	0.100	PASS
45.00	-8.00	100000	0.000	<=	0.100	PASS
46.00	-8.00	100000	0.000	<=	0.100	PASS
47.00	-8.00	100000	0.000	<=	0.100	PASS
48.00	-8.00	100000	0.000	<=	0.100	PASS
49.00	-8.00	100000	0.000	<=	0.100	PASS
50.00	-8.00	100000	0.000	<=	0.100	PASS
51.00	-8.00	100000	0.000	<=	0.100	PASS
52.00	-8.00	100000	0.000	<=	0.100	PASS
53.00	-8.00	100000	0.000	<=	0.100	PASS
54.00	-8.00	100000	0.000	<=	0.100	PASS
55.00	-8.00	100000	0.000	<=	0.100	PASS
56.00	-8.00	100000	0.000	<=	0.100	PASS
57.00	-8.00	100000	0.000	<=	0.100	PASS
58.00	-8.00	100000	0.000	<=	0.100	PASS
59.00	-8.00	100000	0.000	<=	0.100	PASS
60.00	-8.00	100000	0.000	<=	0.100	PASS
61.00	-8.00	100000	0.000	<=	0.100	PASS
62.00	-8.00	100000	0.000	<=	0.100	PASS
63.00	-8.00	100000	0.000	<=	0.100	PASS
64.00	-8.00	100000	0.000	<=	0.100	PASS
65.00	-8.00	100000	0.000	<=	0.100	PASS
66.00	-8.00	100000	0.000	<=	0.100	PASS
67.00	-8.00	100000	0.000	<=	0.100	PASS
68.00	-8.00	100000	0.000	<=	0.100	PASS
69.00	-8.00	100000	0.000	<=	0.100	PASS
70.00	-8.00	100000	0.000	<=	0.100	PASS
71.00	-8.00	100000	0.000	<=	0.100	PASS
72.00	-8.00	100000	0.000	<=	0.100	PASS
73.00	-8.00	100000	0.000	<=	0.100	PASS
74.00	-8.00	100000	0.000	<=	0.100	PASS
75.00	-8.00	100000	0.000	<=	0.100	PASS
76.00	-8.00	100000	0.000	<=	0.100	PASS

142.00	-8.00	100000	0.000	<=	0.100	PASS
143.00	-8.00	100000	0.000	<=	0.100	PASS
144.00	-8.00	100000	0.000	<=	0.100	PASS
145.00	-8.00	100000	0.000	<=	0.100	PASS
146.00	-8.00	100000	0.000	<=	0.100	PASS
147.00	-8.00	100000	0.000	<=	0.100	PASS
148.00	-8.00	100000	0.000	<=	0.100	PASS
149.00	-8.00	100000	0.000	<=	0.100	PASS
150.00	-8.00	100000	0.000	<=	0.100	PASS
151.00	-8.00	100000	0.000	<=	0.100	PASS
152.00	-8.00	100000	0.000	<=	0.100	PASS
153.00	-8.00	100000	0.000	<=	0.100	PASS
154.00	-8.00	100000	0.000	<=	0.100	PASS
155.00	-8.00	100000	0.000	<=	0.100	PASS
156.00	-8.00	100000	0.000	<=	0.100	PASS
157.00	-8.00	100000	0.000	<=	0.100	PASS
158.00	-8.00	100000	0.000	<=	0.100	PASS
159.00	-8.00	100000	0.000	<=	0.100	PASS
160.00	-8.00	100000	0.000	<=	0.100	PASS
161.00	-8.00	100000	0.000	<=	0.100	PASS
162.00	-8.00	100000	0.000	<=	0.100	PASS
163.00	-8.00	100000	0.000	<=	0.100	PASS
164.00	-8.00	100000	0.000	<=	0.100	PASS
165.00	-8.00	100000	0.000	<=	0.100	PASS
166.00	-8.00	100000	0.000	<=	0.100	PASS
167.00	-8.00	100000	0.000	<=	0.100	PASS
168.00	-8.00	100000	0.000	<=	0.100	PASS
169.00	-8.00	100000	0.000	<=	0.100	PASS
170.00	-8.00	100000	0.000	<=	0.100	PASS
171.00	-8.00	100000	0.000	<=	0.100	PASS
172.00	-8.00	100000	0.000	<=	0.100	PASS
173.00	-8.00	100000	0.000	<=	0.100	PASS
174.00	-8.00	100000	0.000	<=	0.100	PASS
175.00	-8.00	100000	0.000	<=	0.100	PASS
176.00	-8.00	100000	0.000	<=	0.100	PASS
177.00	-8.00	100000	0.000	<=	0.100	PASS
178.00	-8.00	100000	0.000	<=	0.100	PASS
179.00	-8.00	100000	0.000	<=	0.100	PASS
180.00	-8.00	100000	0.000	<=	0.100	PASS
181.00	-8.00	100000	0.000	<=	0.100	PASS
182.00	-8.00	100000	0.000	<=	0.100	PASS
183.00	-8.00	100000	0.000	<=	0.100	PASS
184.00	-8.00	100000	0.000	<=	0.100	PASS
185.00	-8.00	100000	0.000	<=	0.100	PASS
186.00	-8.00	100000	0.000	<=	0.100	PASS
187.00	-8.00	100000	0.000	<=	0.100	PASS
188.00	-8.00	100000	0.000	<=	0.100	PASS
189.00	-8.00	100000	0.000	<=	0.100	PASS
190.00	-8.00	100000	0.000	<=	0.100	PASS
191.00	-8.00	100000	0.000	<=	0.100	PASS
192.00	-8.00	100000	0.000	<=	0.100	PASS
193.00	-8.00	100000	0.000	<=	0.100	PASS
194.00	-8.00	100000	0.000	<=	0.100	PASS
195.00	-8.00	100000	0.000	<=	0.100	PASS
196.00	-8.00	100000	0.000	<=	0.100	PASS
197.00	-8.00	100000	0.000	<=	0.100	PASS
198.00	-8.00	100000	0.000	<=	0.100	PASS
199.00	-8.00	100000	0.000	<=	0.100	PASS
200.00	-8.00	100000	0.000	<=	0.100	PASS
201.00	-8.00	100000	0.000	<=	0.100	PASS
202.00	-8.00	100000	0.000	<=	0.100	PASS
203.00	-8.00	100000	0.000	<=	0.100	PASS
204.00	-8.00	100000	0.000	<=	0.100	PASS
205.00	-8.00	100000	0.000	<=	0.100	PASS
206.00	-8.00	100000	0.000	<=	0.100	PASS

12526.00	-8.00	100000	0.000	<=	0.100	PASS
12527.00	-8.00	100000	0.000	<=	0.100	PASS
12528.00	-8.00	100000	0.000	<=	0.100	PASS
12529.00	-8.00	100000	0.000	<=	0.100	PASS
12530.00	-8.00	100000	0.000	<=	0.100	PASS
12531.00	-8.00	100000	0.000	<=	0.100	PASS
12532.00	-8.00	100000	0.000	<=	0.100	PASS
12533.00	-8.00	100000	0.000	<=	0.100	PASS
12534.00	-8.00	100000	0.000	<=	0.100	PASS
12535.00	-8.00	100000	0.000	<=	0.100	PASS
12536.00	-8.00	100000	0.000	<=	0.100	PASS
12537.00	-8.00	100000	0.000	<=	0.100	PASS
12538.00	-8.00	100000	0.000	<=	0.100	PASS
12539.00	-8.00	100000	0.000	<=	0.100	PASS
12540.00	-8.00	100000	0.000	<=	0.100	PASS
12541.00	-8.00	100000	0.000	<=	0.100	PASS
12542.00	-8.00	100000	0.000	<=	0.100	PASS
12543.00	-8.00	100000	0.000	<=	0.100	PASS
12544.00	-8.00	100000	0.000	<=	0.100	PASS
12545.00	-8.00	100000	0.000	<=	0.100	PASS
12546.00	-8.00	100000	0.000	<=	0.100	PASS
12547.00	-8.00	100000	0.000	<=	0.100	PASS
12548.00	-8.00	100000	0.000	<=	0.100	PASS
12549.00	-8.00	100000	0.000	<=	0.100	PASS
12550.00	-8.00	100000	0.000	<=	0.100	PASS
12551.00	-8.00	100000	0.000	<=	0.100	PASS
12552.00	-8.00	100000	0.000	<=	0.100	PASS
12553.00	-8.00	100000	0.000	<=	0.100	PASS
12554.00	-8.00	100000	0.000	<=	0.100	PASS
12555.00	-8.00	100000	0.000	<=	0.100	PASS
12556.00	-8.00	100000	0.000	<=	0.100	PASS
12557.00	-8.00	100000	0.000	<=	0.100	PASS
12558.00	-8.00	100000	0.000	<=	0.100	PASS
12559.00	-8.00	100000	0.000	<=	0.100	PASS
12560.00	-8.00	100000	0.000	<=	0.100	PASS
12561.00	-8.00	100000	0.000	<=	0.100	PASS
12562.00	-8.00	100000	0.000	<=	0.100	PASS
12563.00	-8.00	100000	0.000	<=	0.100	PASS
12564.00	-8.00	100000	0.000	<=	0.100	PASS
12565.00	-8.00	100000	0.000	<=	0.100	PASS
12566.00	-8.00	100000	0.000	<=	0.100	PASS
12567.00	-8.00	100000	0.000	<=	0.100	PASS
12568.00	-8.00	100000	0.000	<=	0.100	PASS
12569.00	-8.00	100000	0.000	<=	0.100	PASS
12570.00	-8.00	100000	0.000	<=	0.100	PASS
12571.00	-8.00	100000	0.000	<=	0.100	PASS
12572.00	-8.00	100000	0.000	<=	0.100	PASS
12573.00	-8.00	100000	0.000	<=	0.100	PASS
12574.00	-8.00	100000	0.000	<=	0.100	PASS
12575.00	-8.00	100000	0.000	<=	0.100	PASS
12576.00	-8.00	100000	0.000	<=	0.100	PASS
12577.00	-8.00	100000	0.000	<=	0.100	PASS
12578.00	-8.00	100000	0.000	<=	0.100	PASS
12579.00	-8.00	100000	0.000	<=	0.100	PASS
12580.00	-8.00	100000	0.000	<=	0.100	PASS
12581.00	-8.00	100000	0.000	<=	0.100	PASS
12582.00	-8.00	100000	0.000	<=	0.100	PASS
12583.00	-8.00	100000	0.000	<=	0.100	PASS
12584.00	-8.00	100000	0.000	<=	0.100	PASS
12585.00	-8.00	100000	0.000	<=	0.100	PASS
12586.00	-8.00	100000	0.000	<=	0.100	PASS
12587.00	-8.00	100000	0.000	<=	0.100	PASS
12588.00	-8.00	100000	0.000	<=	0.100	PASS
12589.00	-8.00	100000	0.000	<=	0.100	PASS
12590.00	-8.00	100000	0.000	<=	0.100	PASS

12591.00	-8.00	100000	0.000	<=	0.100	PASS
12592.00	-8.00	100000	0.000	<=	0.100	PASS
12593.00	-8.00	100000	0.000	<=	0.100	PASS
12594.00	-8.00	100000	0.000	<=	0.100	PASS
12595.00	-8.00	100000	0.000	<=	0.100	PASS
12596.00	-8.00	100000	0.000	<=	0.100	PASS
12597.00	-8.00	100000	0.000	<=	0.100	PASS
12598.00	-8.00	100000	0.000	<=	0.100	PASS
12599.00	-8.00	100000	0.000	<=	0.100	PASS
12600.00	-8.00	100000	0.000	<=	0.100	PASS
12601.00	-8.00	100000	0.000	<=	0.100	PASS
12602.00	-8.00	100000	0.000	<=	0.100	PASS
12603.00	-8.00	100000	0.000	<=	0.100	PASS
12604.00	-8.00	100000	0.000	<=	0.100	PASS
12605.00	-8.00	100000	0.000	<=	0.100	PASS
12606.00	-8.00	100000	0.000	<=	0.100	PASS
12607.00	-8.00	100000	0.000	<=	0.100	PASS
12608.00	-8.00	100000	0.000	<=	0.100	PASS
12609.00	-8.00	100000	0.000	<=	0.100	PASS
12610.00	-8.00	100000	0.000	<=	0.100	PASS
12611.00	-8.00	100000	0.000	<=	0.100	PASS
12612.00	-8.00	100000	0.000	<=	0.100	PASS
12613.00	-8.00	100000	0.000	<=	0.100	PASS
12614.00	-8.00	100000	0.000	<=	0.100	PASS
12615.00	-8.00	100000	0.000	<=	0.100	PASS
12616.00	-8.00	100000	0.000	<=	0.100	PASS
12617.00	-8.00	100000	0.000	<=	0.100	PASS
12618.00	-8.00	100000	0.000	<=	0.100	PASS
12619.00	-8.00	100000	0.000	<=	0.100	PASS
12620.00	-8.00	100000	0.000	<=	0.100	PASS
12621.00	-8.00	100000	0.000	<=	0.100	PASS
12622.00	-8.00	100000	0.000	<=	0.100	PASS
12623.00	-8.00	100000	0.000	<=	0.100	PASS
12624.00	-8.00	100000	0.000	<=	0.100	PASS
12625.00	-8.00	100000	0.000	<=	0.100	PASS
12626.00	-8.00	100000	0.000	<=	0.100	PASS
12627.00	-8.00	100000	0.000	<=	0.100	PASS
12628.00	-8.00	100000	0.000	<=	0.100	PASS
12629.00	-8.00	100000	0.000	<=	0.100	PASS
12630.00	-8.00	100000	0.000	<=	0.100	PASS
12631.00	-8.00	100000	0.000	<=	0.100	PASS
12632.00	-8.00	100000	0.000	<=	0.100	PASS
12633.00	-8.00	100000	0.000	<=	0.100	PASS
12634.00	-8.00	100000	0.000	<=	0.100	PASS
12635.00	-8.00	100000	0.000	<=	0.100	PASS
12636.00	-8.00	100000	0.000	<=	0.100	PASS
12637.00	-8.00	100000	0.000	<=	0.100	PASS
12638.00	-8.00	100000	0.000	<=	0.100	PASS
12639.00	-8.00	100000	0.000	<=	0.100	PASS
12640.00	-8.00	100000	0.000	<=	0.100	PASS
12641.00	-8.00	100000	0.000	<=	0.100	PASS
12642.00	-8.00	100000	0.000	<=	0.100	PASS
12643.00	-8.00	100000	0.000	<=	0.100	PASS
12644.00	-8.00	100000	0.000	<=	0.100	PASS
12645.00	-8.00	100000	0.000	<=	0.100	PASS
12646.00	-8.00	100000	0.000	<=	0.100	PASS
12647.00	-8.00	100000	0.000	<=	0.100	PASS
12648.00	-8.00	100000	0.000	<=	0.100	PASS
12649.00	-8.00	100000	0.000	<=	0.100	PASS
12650.00	-8.00	100000	0.000	<=	0.100	PASS
12651.00	-8.00	100000	0.000	<=	0.100	PASS
12652.00	-8.00	100000	0.000	<=	0.100	PASS
12653.00	-8.00	100000	0.000	<=	0.100	PASS
12654.00	-8.00	100000	0.000	<=	0.100	PASS
12655.00	-8.00	100000	0.000	<=	0.100	PASS

12656.00	-8.00	100000	0.000	<=	0.100	PASS
12657.00	-8.00	100000	0.000	<=	0.100	PASS
12658.00	-8.00	100000	0.000	<=	0.100	PASS
12659.00	-8.00	100000	0.000	<=	0.100	PASS
12660.00	-8.00	100000	0.000	<=	0.100	PASS
12661.00	-8.00	100000	0.000	<=	0.100	PASS
12662.00	-8.00	100000	0.000	<=	0.100	PASS
12663.00	-8.00	100000	0.000	<=	0.100	PASS
12664.00	-8.00	100000	0.000	<=	0.100	PASS
12665.00	-8.00	100000	0.000	<=	0.100	PASS
12666.00	-8.00	100000	0.000	<=	0.100	PASS
12667.00	-8.00	100000	0.000	<=	0.100	PASS
12668.00	-8.00	100000	0.000	<=	0.100	PASS
12669.00	-8.00	100000	0.000	<=	0.100	PASS
12670.00	-8.00	100000	0.000	<=	0.100	PASS
12671.00	-8.00	100000	0.000	<=	0.100	PASS
12672.00	-8.00	100000	0.000	<=	0.100	PASS
12673.00	-8.00	100000	0.000	<=	0.100	PASS
12674.00	-8.00	100000	0.000	<=	0.100	PASS
12675.00	-8.00	100000	0.000	<=	0.100	PASS
12676.00	-8.00	100000	0.000	<=	0.100	PASS
12677.00	-8.00	100000	0.000	<=	0.100	PASS
12678.00	-8.00	100000	0.000	<=	0.100	PASS
12679.00	-8.00	100000	0.000	<=	0.100	PASS
12680.00	-8.00	100000	0.000	<=	0.100	PASS
12681.00	-8.00	100000	0.000	<=	0.100	PASS
12682.00	-8.00	100000	0.000	<=	0.100	PASS
12683.00	-8.00	100000	0.000	<=	0.100	PASS
12684.00	-8.00	100000	0.000	<=	0.100	PASS
12685.00	-8.00	100000	0.000	<=	0.100	PASS
12686.00	-8.00	100000	0.000	<=	0.100	PASS
12687.00	-8.00	100000	0.000	<=	0.100	PASS
12688.00	-8.00	100000	0.000	<=	0.100	PASS
12689.00	-8.00	100000	0.000	<=	0.100	PASS
12690.00	-8.00	100000	0.000	<=	0.100	PASS
12691.00	-8.00	100000	0.000	<=	0.100	PASS
12692.00	-8.00	100000	0.000	<=	0.100	PASS
12693.00	-8.00	100000	0.000	<=	0.100	PASS
12694.00	-8.00	100000	0.000	<=	0.100	PASS
12695.00	-8.00	100000	0.000	<=	0.100	PASS
12696.00	-8.00	100000	0.000	<=	0.100	PASS
12697.00	-8.00	100000	0.000	<=	0.100	PASS
12698.00	-8.00	100000	0.000	<=	0.100	PASS
12699.00	-8.00	100000	0.000	<=	0.100	PASS
12700.00	-8.00	100000	0.000	<=	0.100	PASS
12701.00	-8.00	100000	0.000	<=	0.100	PASS
12702.00	-8.00	100000	0.000	<=	0.100	PASS
12703.00	-8.00	100000	0.000	<=	0.100	PASS
12704.00	-8.00	100000	0.000	<=	0.100	PASS
12705.00	-8.00	100000	0.000	<=	0.100	PASS
12706.00	-8.00	100000	0.000	<=	0.100	PASS
12707.00	-8.00	100000	0.000	<=	0.100	PASS
12708.00	-8.00	100000	0.000	<=	0.100	PASS
12709.00	-8.00	100000	0.000	<=	0.100	PASS
12710.00	-8.00	100000	0.000	<=	0.100	PASS
12711.00	-8.00	100000	0.000	<=	0.100	PASS
12712.00	-8.00	100000	0.000	<=	0.100	PASS
12713.00	-8.00	100000	0.000	<=	0.100	PASS
12714.00	-8.00	100000	0.000	<=	0.100	PASS
12715.00	-8.00	100000	0.000	<=	0.100	PASS
12716.00	-8.00	100000	0.000	<=	0.100	PASS
12717.00	-8.00	100000	0.000	<=	0.100	PASS
12718.00	-8.00	100000	0.000	<=	0.100	PASS
12719.00	-8.00	100000	0.000	<=	0.100	PASS
12720.00	-8.00	100000	0.000	<=	0.100	PASS

12721.00	-8.00	100000	0.000	<=	0.100	PASS
12722.00	-8.00	100000	0.000	<=	0.100	PASS
12723.00	-8.00	100000	0.000	<=	0.100	PASS
12724.00	-8.00	100000	0.000	<=	0.100	PASS
12725.00	-8.00	100000	0.000	<=	0.100	PASS
12726.00	-8.00	100000	0.000	<=	0.100	PASS
12727.00	-8.00	100000	0.000	<=	0.100	PASS
12728.00	-8.00	100000	0.000	<=	0.100	PASS
12729.00	-8.00	100000	0.000	<=	0.100	PASS
12730.00	-8.00	100000	0.000	<=	0.100	PASS
12731.00	-8.00	100000	0.000	<=	0.100	PASS
12732.00	-8.00	100000	0.000	<=	0.100	PASS
12733.00	-8.00	100000	0.000	<=	0.100	PASS
12734.00	-8.00	100000	0.000	<=	0.100	PASS
12735.00	-8.00	100000	0.000	<=	0.100	PASS
12736.00	-8.00	100000	0.000	<=	0.100	PASS
12737.00	-8.00	100000	0.000	<=	0.100	PASS
12738.00	-8.00	100000	0.000	<=	0.100	PASS
12739.00	-8.00	100000	0.000	<=	0.100	PASS
12740.00	-8.00	100000	0.000	<=	0.100	PASS
12741.00	-8.00	100000	0.000	<=	0.100	PASS
12742.00	-8.00	100000	0.000	<=	0.100	PASS
12743.00	-8.00	100000	0.000	<=	0.100	PASS
12744.00	-8.00	100000	0.000	<=	0.100	PASS
12745.00	-8.00	100000	0.000	<=	0.100	PASS
12746.00	-8.00	100000	0.000	<=	0.100	PASS
12747.00	-8.00	100000	0.000	<=	0.100	PASS
12748.00	-8.00	100000	0.000	<=	0.100	PASS
12749.00	-8.00	100000	0.000	<=	0.100	PASS
12750.00	-8.00	100000	0.000	<=	0.100	PASS

Final Test Case Verdict . . . . . PASS 03:04:33

Annex O

RCV/CA/05/C Intermodulation Performance

Intermodulation Performance

For system parameter see 0, "General Parameter 008"

BT Test Specification Version: 1.2

For EUT parameter see 0, "EUT Parameter 002"
For test case parameter see 0, "Test Case Parameter 013"

TX-FREQ [MHz]	RX-FREQ [MHz]	B2-FREQ [MHz]	B3-FREQ [MHz]	BER [%]		LIMIT [%]	VERDICT
2402.0	2402.0	2412.0	2407.0	0.000	<=	0.100	PASS
2441.0	2441.0	2431.0	2436.0	0.000	<=	0.100	PASS
2441.0	2441.0	2451.0	2446.0	0.000	<=	0.100	PASS
2480.0	2480.0	2470.0	2475.0	0.000	<=	0.100	PASS

Final Test Case Verdict . . . . . PASS 00:01:52

Annex P

RCV/CA/06/C Maximum Input Level

Maximum Input Level

For system parameter see 0, "General Parameter 006"

```
BT Test Specification Version:  1.2
```

For EUT parameter see 0, "EUT Parameter 002"
For test case parameter see 0, "Test Case Parameter 014"

TX-FREQ [MHz]	RX-FREQ [MHz]	Bit Error Rate [%]		LIMIT [%]	VERDICT
2480.0	2402.0	0.000	<=	0.100	PASS
2402.0	2441.0	0.000	<=	0.100	PASS
2402.0	2480.0	0.000	<=	0.100	PASS

Final Test Case Verdict . . . . . PASS 00:01:27

Annex Q

System Parameter

Appendix -- System Parameter

General Parameter 001

```
#  Global Parameter Settings:
#
#  Wait On Compare                 :     No
#  Wait On OUTSIDE                 :     No
#  Wait On FAIL                    :     No
#  Abort On FAIL                   :     No
#  Skip Manual Interventions       :     No
#  Plots Disabled                  :     No
#  Remove Plots after Program Run  :     No
#  Info Enabled                    :     No
#  Short Mode                      :     No
#  Force Mode                      :     No
#  Part                            :      1
#
#-----------------------------------------------------------------------
```

General Parameter 002

```
#  Global Parameter Settings:
#
#  Wait On Compare                 :     No
#  Wait On OUTSIDE                 :     No
#  Wait On FAIL                    :     No
#  Abort On FAIL                   :     No
#  Skip Manual Interventions       :     No
#  Plots Disabled                  :     No
#  Remove Plots after Program Run  :     No
#  Info Enabled                    :     No
#  Short Mode                      :     No
#  Force Mode                      :     No
#  Part                            :      2
#
#-----------------------------------------------------------------------
```

General Parameter 003

```
#  Global Parameter Settings:
#
#  Wait On Compare                 :     No
#  Wait On OUTSIDE                 :     No
#  Wait On FAIL                    :     No
#  Abort On FAIL                   :     No
#  Skip Manual Interventions       :     No
#  Plots Disabled                  :     No
#  Remove Plots after Program Run  :     No
#  Info Enabled                    :     No
#  Short Mode                      :     No
#  Force Mode                      :     No
#  Part                            :      4
#
#-----------------------------------------------------------------------
```

General Parameter 004

```
#  Global Parameter Settings:
#
#  Wait On Compare                 :     No
#  Wait On OUTSIDE                 :     No
#  Wait On FAIL                    :     No
```

```
#  Abort On FAIL                  :     No
#  Skip Manual Interventions      :     No
#  Plots Disabled                 :     No
#  Remove Plots after Program Run :     No
#  Info Enabled                   :     No
#  Short Mode                     :     No
#  Force Mode                     :     No
#  Part                           :      5
#
#-----------------------------------------------------------------------
```

General Parameter 005

```
#  Global Parameter Settings:
#
#  Wait On Compare                :     No
#  Wait On OUTSIDE                :     No
#  Wait On FAIL                   :     No
#  Abort On FAIL                  :     No
#  Skip Manual Interventions      :     No
#  Plots Disabled                 :     No
#  Remove Plots after Program Run :     No
#  Info Enabled                   :     No
#  Short Mode                     :     No
#  Force Mode                     :     No
#  Part                           :      6
#
#-----------------------------------------------------------------------
```

General Parameter 006

```
#  Global Parameter Settings:
#
#  Wait On Compare                :     No
#  Wait On OUTSIDE                :     No
#  Wait On FAIL                   :     No
#  Abort On FAIL                  :     No
#  Skip Manual Interventions      :     No
#  Plots Disabled                 :     No
#  Remove Plots after Program Run :     No
#  Info Enabled                   :     No
#  Short Mode                     :     No
#  Force Mode                     :     No
#  Part                           :      3
#
#-----------------------------------------------------------------------
```

General Parameter 007

```
#  Global Parameter Settings:
#
#  Wait On Compare                :     No
#  Wait On OUTSIDE                :     No
#  Wait On FAIL                   :     No
#  Abort On FAIL                  :     No
#  Skip Manual Interventions      :     No
#  Plots Disabled                 :     No
#  Remove Plots after Program Run :     No
#  Info Enabled                   :     No
#  Short Mode                     :     No
#  Force Mode                     :     No
#  Part                           :      7
#
#-----------------------------------------------------------------------
```

General Parameter 008

```
#  Global Parameter Settings:
#
#  Wait On Compare                 :     No
#  Wait On OUTSIDE                 :     No
#  Wait On FAIL                    :     No
#  Abort On FAIL                   :     No
#  Skip Manual Interventions       :     No
#  Plots Disabled                  :     No
#  Remove Plots after Program Run  :     No
#  Info Enabled                    :     No
#  Short Mode                      :     No
#  Force Mode                      :     No
#  Part                            :      0
#
#-----------------------------------------------------------------------
```

General Parameter 009

```
#  Global Parameter Settings:
#
#  Wait On Compare                 :     No
#  Wait On OUTSIDE                 :     No
#  Wait On FAIL                    :     No
#  Abort On FAIL                   :     No
#  Skip Manual Interventions       :     No
#  Plots Disabled                  :     No
#  Remove Plots after Program Run  :     No
#  Info Enabled                    :     No
#  Short Mode                      :     No
#  Force Mode                      :     No
#  Part                            :      8
#
#-----------------------------------------------------------------------
```

General Parameter 010

```
#  Global Parameter Settings:
#
#  Wait On Compare                 :     No
#  Wait On OUTSIDE                 :     No
#  Wait On FAIL                    :     No
#  Abort On FAIL                   :     No
#  Skip Manual Interventions       :     No
#  Plots Disabled                  :     No
#  Remove Plots after Program Run  :     No
#  Info Enabled                    :     No
#  Short Mode                      :     No
#  Force Mode                      :     No
#  Part                            :      9
#
#-----------------------------------------------------------------------
```

General Parameter 011

```
#  Global Parameter Settings:
#
#  Wait On Compare                 :     No
#  Wait On OUTSIDE                 :     No
#  Wait On FAIL                    :     No
#  Abort On FAIL                   :     No
#  Skip Manual Interventions       :    Yes
#  Plots Disabled                  :     No
#  Remove Plots after Program Run  :     No
```

```
#  Info Enabled                    :     No
#  Short Mode                      :     No
#  Force Mode                      :     No
#  Part                            :      6
#
#-----------------------------------------------------------------------
```

Annex R

EUT Parameter

Appendix -- EUT Parameter

EUT Parameter 001

Next measurement will be running with the following EUT paramters:

Manufacturer:	3M Health Care Patient Assessment Laboratory 3M Medical Products	
Model:	M3200	
Serial No:	-	
Comment:	HW ver.: V3RB; SW ver.: V0011	
Setup mode:	Final Testing	
Test Mode Handle:	Once	
Country:	All	
Pseudo Whitening:	On	
Host Connection Request:	Yes	
EUT Address:	00087B00A990 hex	
Tester Address:	008037122094 hex	
Active Member Address:	00000007 hex	
Access Code from EUT:	AD59EE5328A41120D5 hex	
Access Code from SU:	AD59EE5328A41120D5 hex	
Connection Poll Period:	40	Time Slots
Connection Page TO:	9000	Time Slots
Test Parameter Setting Delay:	1000	ms
Power Class:	2	
Power Control:	Supported	
Gain:	-12.000	dBi
Add. Transmission (Receive):	-0.200	dB
Add. Transmission (Transmit):	-0.200	dB
Longest Packet Type:	DH5	
BER measurement:	System	
Unmod. part before Mod.:	10.000	us
Unmod. part after Mod.:	0.000	us
Payload Length DH1:	216	Bits
Payload Length DH3:	1464	Bits
Payload Length DH5:	2712	Bits
Intermediate Frequency:	1.500	MHz
Intermodulation Factor:	5	
LO position above RX Frequency:	No	
Voltage Value 1:	1.500	Volt
Voltage Value 2:	0.000	Volt
Temperature:	25.000	Deg C

EUT Parameter 002

Next measurement will be running with the following EUT paramters:

Manufacturer:	3M Health Care Patient Assessment Laboratory 3M Medical Products	
Model:	M3200	
Serial No:	-	
Comment:	HW ver.: V3RB; SW ver.: V0011	
Setup mode:	Final Testing	
Test Mode Handle:	Every Parameter Set	
Country:	All	
Pseudo Whitening:	On	
Host Connection Request:	Yes	
EUT Address:	00087B00A990 hex	
Tester Address:	008037122094 hex	
Active Member Address:	00000007 hex	
Access Code from EUT:	AD59EE5328A41120D5 hex	
Access Code from SU:	AD59EE5328A41120D5 hex	
Connection Poll Period:	40	Time Slots

Connection Page TO:	9000	Time Slots
Test Parameter Setting Delay:	1000	ms
Power Class:	2	
Power Control:	Supported	
Gain:	-12.000	dBi
Add. Transmission (Receive):	-0.200	dB
Add. Transmission (Transmit):	-0.200	dB
Longest Packet Type:	DH5	
BER measurement:	System	
Unmod. part before Mod.:	0.000	us
Unmod. part after Mod.:	0.000	us
Payload Length DH1:	216	Bits
Payload Length DH3:	1464	Bits
Payload Length DH5:	2712	Bits
Intermediate Frequency:	1.500	MHz
Intermodulation Factor:	5	
LO position above RX Frequency:	No	
Voltage Value 1:	1.500	Volt
Voltage Value 2:	0.000	Volt
Temperature:	25.000	Deg C

EUT Parameter 003

Next measurement will be running with the following EUT paramters:

Manufacturer:	3M Health Care Patient Assessment Laboratory 3M Medical Products	
Model:	M3200	
Serial No:	-	
Comment:	HW ver.: V3RB; SW ver.: V0011	
Setup mode:	Final Testing	
Test Mode Handle:	Every Parameter Set	
Country:	All	
Pseudo Whitening:	On	
Host Connection Request:	Yes	
EUT Address:	00087B00A990 hex	
Tester Address:	008037122094 hex	
Active Member Address:	00000007 hex	
Access Code from EUT:	AD59EE5328A41120D5 hex	
Access Code from SU:	AD59EE5328A41120D5 hex	
Connection Poll Period:	40	Time Slots
Connection Page TO:	9000	Time Slots
Test Parameter Setting Delay:	1000	ms
Power Class:	2	
Power Control:	Supported	
Wait time for power control:	1000	ms
Gain:	-12.000	dBi
Add. Transmission (Receive):	-0.200	dB
Add. Transmission (Transmit):	-0.200	dB
Longest Packet Type:	DH5	
BER measurement:	System	
Unmod. part before Mod.:	0.000	us
Unmod. part after Mod.:	0.000	us
Payload Length DH1:	216	Bits
Payload Length DH3:	1464	Bits
Payload Length DH5:	2712	Bits
Intermediate Frequency:	1.500	MHz
Intermodulation Factor:	5	
LO position above RX Frequency:	No	
Voltage Value 1:	1.500	Volt
Voltage Value 2:	0.000	Volt
Temperature:	25.000	Deg C

EUT Parameter 004

Next measurement will be running with the following EUT paramters:

Manufacturer:	3M Health Care Patient Assessment Laboratory 3M Medical Products	
Model:	M3200	
Serial No:	-	
Comment:	HW ver.: V3RB; SW ver.: V0011	
Setup mode:	Final Testing	
Test Mode Handle:	Every Parameter Set	
Country:	All	
Pseudo Whitening:	On	
Host Connection Request:	Yes	
EUT Address:	00087B00A990 hex	
Tester Address:	008037122094 hex	
Active Member Address:	00000007 hex	
Access Code from EUT:	AD59EE5328A41120D5 hex	
Access Code from SU:	AD59EE5328A41120D5 hex	
Connection Poll Period:	40	Time Slots
Connection Page TO:	9000	Time Slots
Test Parameter Setting Delay:	1000	ms
Power Class:	2	
Power Control:	Supported	
Gain:	-12.000	dBi
Add. Transmission (Receive):	-0.200	dB
Add. Transmission (Transmit):	-0.200	dB
Longest Packet Type:	DH5	
BER measurement:	System	
Unmod. part before Mod.:	0.000	us
Unmod. part after Mod.:	0.000	us
Payload Length DH1:	216	Bits
Intermediate Frequency:	1.500	MHz
Intermodulation Factor:	5	
LO position above RX Frequency:	No	
Voltage Value 1:	1.500	Volt
Voltage Value 2:	0.000	Volt
Temperature:	25.000	Deg C

EUT Parameter 005

Next measurement will be running with the following EUT paramters:

Manufacturer:	3M Health Care Patient Assessment Laboratory 3M Medical Products	
Model:	M3200	
Serial No:	-	
Comment:	HW ver.: V3RB; SW ver.: V0011	
Setup mode:	Final Testing	
Test Mode Handle:	Every Parameter Set	
Country:	All	
Pseudo Whitening:	On	
Host Connection Request:	Yes	
EUT Address:	00087B00A990 hex	
Tester Address:	008037122094 hex	
Active Member Address:	00000007 hex	
Access Code from EUT:	AD59EE5328A41120D5 hex	
Access Code from SU:	AD59EE5328A41120D5 hex	
Connection Poll Period:	40	Time Slots
Connection Page TO:	9000	Time Slots
Test Parameter Setting Delay:	1000	ms
Power Class:	2	
Power Control:	Supported	
Gain:	-12.000	dBi
Add. Transmission (Receive):	-0.200	dB
Add. Transmission (Transmit):	-0.200	dB
Longest Packet Type:	DH5	

BER measurement:	System	
Unmod. part before Mod.:	0.000	us
Unmod. part after Mod.:	0.000	us
Payload Length DH1:	216	Bits
Payload Length DH3:	1464	Bits
Payload Length DH5:	2712	Bits
Intermediate Frequency:	1.500	MHz
Intermodulation Factor:	5	
LO position above RX Frequency:	No	
Voltage Value 1:	1.200	Volt
Voltage Value 2:	0.000	Volt
Temperature:	-30.000	Deg C

EUT Parameter 006

Next measurement will be running with the following EUT paramters:

Manufacturer:	3M Health Care Patient Assessment Laboratory 3M Medical Products	
Model:	M3200	
Serial No:	-	
Comment:	HW ver.: V3RB; SW ver.: V0011	
Setup mode:	Final Testing	
Test Mode Handle:	Every Parameter Set	
Country:	All	
Pseudo Whitening:	On	
Host Connection Request:	Yes	
EUT Address:	00087B00A990 hex	
Tester Address:	008037122094 hex	
Active Member Address:	00000007 hex	
Access Code from EUT:	AD59EE5328A41120D5 hex	
Access Code from SU:	AD59EE5328A41120D5 hex	
Connection Poll Period:	40	Time Slots
Connection Page TO:	9000	Time Slots
Test Parameter Setting Delay:	1000	ms
Power Class:	2	
Power Control:	Supported	
Gain:	-12.000	dBi
Add. Transmission (Receive):	-0.200	dB
Add. Transmission (Transmit):	-0.200	dB
Longest Packet Type:	DH5	
BER measurement:	System	
Unmod. part before Mod.:	0.000	us
Unmod. part after Mod.:	0.000	us
Payload Length DH1:	216	Bits
Payload Length DH3:	1464	Bits
Payload Length DH5:	2712	Bits
Intermediate Frequency:	1.500	MHz
Intermodulation Factor:	5	
LO position above RX Frequency:	No	
Voltage Value 1:	1.800	Volt
Voltage Value 2:	0.000	Volt
Temperature:	-30.000	Deg C

EUT Parameter 007

Next measurement will be running with the following EUT paramters:

Manufacturer:	3M Health Care Patient Assessment Laboratory 3M Medical Products
Model:	M3200
Serial No:	-
Comment:	HW ver.: V3RB; SW ver.: V0011
Setup mode:	Final Testing
Test Mode Handle:	Every Parameter Set

Country:	All	
Pseudo Whitening:	On	
Host Connection Request:	Yes	
EUT Address:	00087B00A990 hex	
Tester Address:	008037122094 hex	
Active Member Address:	00000007 hex	
Access Code from EUT:	AD59EE5328A41120D5 hex	
Access Code from SU:	AD59EE5328A41120D5 hex	
Connection Poll Period:	40	Time Slots
Connection Page TO:	9000	Time Slots
Test Parameter Setting Delay:	1000	ms
Power Class:	2	
Power Control:	Supported	
Gain:	-12.000	dBi
Add. Transmission (Receive):	-0.200	dB
Add. Transmission (Transmit):	-0.200	dB
Longest Packet Type:	DH5	
BER measurement:	System	
Unmod. part before Mod.:	0.000	us
Unmod. part after Mod.:	0.000	us
Payload Length DH1:	216	Bits
Intermediate Frequency:	1.500	MHz
Intermodulation Factor:	5	
LO position above RX Frequency:	No	
Voltage Value 1:	1.200	Volt
Voltage Value 2:	0.000	Volt
Temperature:	-30.000	Deg C

EUT Parameter 008

Next measurement will be running with the following EUT paramters:

Manufacturer:	3M Health Care Patient Assessment Laboratory 3M Medical Products	
Model:	M3200	
Serial No:	-	
Comment:	HW ver.: V3RB; SW ver.: V0011	
Setup mode:	Final Testing	
Test Mode Handle:	Every Parameter Set	
Country:	All	
Pseudo Whitening:	On	
Host Connection Request:	Yes	
EUT Address:	00087B00A990 hex	
Tester Address:	008037122094 hex	
Active Member Address:	00000007 hex	
Access Code from EUT:	AD59EE5328A41120D5 hex	
Access Code from SU:	AD59EE5328A41120D5 hex	
Connection Poll Period:	40	Time Slots
Connection Page TO:	9000	Time Slots
Test Parameter Setting Delay:	1000	ms
Power Class:	2	
Power Control:	Supported	
Gain:	-12.000	dBi
Add. Transmission (Receive):	-0.200	dB
Add. Transmission (Transmit):	-0.200	dB
Longest Packet Type:	DH5	
BER measurement:	System	
Unmod. part before Mod.:	0.000	us
Unmod. part after Mod.:	0.000	us
Payload Length DH1:	216	Bits
Intermediate Frequency:	1.500	MHz
Intermodulation Factor:	5	
LO position above RX Frequency:	No	
Voltage Value 1:	1.800	Volt
Voltage Value 2:	0.000	Volt

Temperature: -30.000 Deg C

EUT Parameter 009

Next measurement will be running with the following EUT paramters:

Manufacturer: 3M Health Care Patient Assessment Laboratory 3M Medical Products
Model: M3200
Serial No: -
Comment: HW ver.: V3RB; SW ver.: V0011
Setup mode: Final Testing
Test Mode Handle: Every Parameter Set
Country: All
Pseudo Whitening: On
Host Connection Request: Yes
EUT Address: 00087B00A990 hex
Tester Address: 008037122094 hex
Active Member Address: 00000007 hex
Access Code from EUT: AD59EE5328A41120D5 hex
Access Code from SU: AD59EE5328A41120D5 hex
Connection Poll Period: 40 Time Slots
Connection Page TO: 9000 Time Slots
Test Parameter Setting Delay: 1000 ms
Power Class: 2
Power Control: Supported
Gain: -12.000 dBi
Add. Transmission (Receive): -0.200 dB
Add. Transmission (Transmit): -0.200 dB
Longest Packet Type: DH5
BER measurement: System
Unmod. part before Mod.: 0.000 us
Unmod. part after Mod.: 0.000 us
Payload Length DH1: 216 Bits
Payload Length DH3: 1464 Bits
Payload Length DH5: 2712 Bits
Intermediate Frequency: 1.500 MHz
Intermodulation Factor: 5
LO position above RX Frequency: No
Voltage Value 1: 1.200 Volt
Voltage Value 2: 0.000 Volt
Temperature: 60.000 Deg C

EUT Parameter 010

Next measurement will be running with the following EUT paramters:

Manufacturer: 3M Health Care Patient Assessment Laboratory 3M Medical Products
Model: M3200
Serial No: -
Comment: HW ver.: V3RB; SW ver.: V0011
Setup mode: Final Testing
Test Mode Handle: Every Parameter Set
Country: All
Pseudo Whitening: On
Host Connection Request: Yes
EUT Address: 00087B00A990 hex
Tester Address: 008037122094 hex
Active Member Address: 00000007 hex
Access Code from EUT: AD59EE5328A41120D5 hex
Access Code from SU: AD59EE5328A41120D5 hex
Connection Poll Period: 40 Time Slots
Connection Page TO: 9000 Time Slots
Test Parameter Setting Delay: 1000 ms

Power Class:	2	
Power Control:	Supported	
Gain:	-12.000	dBi
Add. Transmission (Receive):	-0.200	dB
Add. Transmission (Transmit):	-0.200	dB
Longest Packet Type:	DH5	
BER measurement:	System	
Unmod. part before Mod.:	0.000	us
Unmod. part after Mod.:	0.000	us
Payload Length DH1:	216	Bits
Payload Length DH3:	1464	Bits
Payload Length DH5:	2712	Bits
Intermediate Frequency:	1.500	MHz
Intermodulation Factor:	5	
LO position above RX Frequency:	No	
Voltage Value 1:	1.800	Volt
Voltage Value 2:	0.000	Volt
Temperature:	60.000	Deg C

EUT Parameter 011

Next measurement will be running with the following EUT paramters:

Manufacturer:	3M Health Care Patient Assessment Laboratory 3M Medical Products	
Model:	M3200	
Serial No:	-	
Comment:	HW ver.: V3RB; SW ver.: V0011	
Setup mode:	Final Testing	
Test Mode Handle:	Every Parameter Set	
Country:	All	
Pseudo Whitening:	On	
Host Connection Request:	Yes	
EUT Address:	00087B00A990 hex	
Tester Address:	008037122094 hex	
Active Member Address:	00000007 hex	
Access Code from EUT:	AD59EE5328A41120D5 hex	
Access Code from SU:	AD59EE5328A41120D5 hex	
Connection Poll Period:	40	Time Slots
Connection Page TO:	9000	Time Slots
Test Parameter Setting Delay:	1000	ms
Power Class:	2	
Power Control:	Supported	
Gain:	-12.000	dBi
Add. Transmission (Receive):	-0.200	dB
Add. Transmission (Transmit):	-0.200	dB
Longest Packet Type:	DH5	
BER measurement:	System	
Unmod. part before Mod.:	0.000	us
Unmod. part after Mod.:	0.000	us
Payload Length DH1:	216	Bits
Intermediate Frequency:	1.500	MHz
Intermodulation Factor:	5	
LO position above RX Frequency:	No	
Voltage Value 1:	1.200	Volt
Voltage Value 2:	0.000	Volt
Temperature:	60.000	Deg C

EUT Parameter 012

Next measurement will be running with the following EUT paramters:

Manufacturer:	3M Health Care Patient Assessment Laboratory 3M Medical Products
Model:	M3200

Serial No:	-	
Comment:	HW ver.: V3RB; SW ver.: V0011	
Setup mode:	Final Testing	
Test Mode Handle:	Every Parameter Set	
Country:	All	
Pseudo Whitening:	On	
Host Connection Request:	Yes	
EUT Address:	00087B00A990 hex	
Tester Address:	008037122094 hex	
Active Member Address:	00000007 hex	
Access Code from EUT:	AD59EE5328A41120D5 hex	
Access Code from SU:	AD59EE5328A41120D5 hex	
Connection Poll Period:	40	Time Slots
Connection Page TO:	9000	Time Slots
Test Parameter Setting Delay:	1000	ms
Power Class:	2	
Power Control:	Supported	
Gain:	-12.000	dBi
Add. Transmission (Receive):	-0.200	dB
Add. Transmission (Transmit):	-0.200	dB
Longest Packet Type:	DH5	
BER measurement:	System	
Unmod. part before Mod.:	0.000	us
Unmod. part after Mod.:	0.000	us
Payload Length DH1:	216	Bits
Intermediate Frequency:	1.500	MHz
Intermodulation Factor:	5	
LO position above RX Frequency:	No	
Voltage Value 1:	1.800	Volt
Voltage Value 2:	0.000	Volt
Temperature:	60.000	Deg C

Annex S

Test Case Parameter

Appendix -- Test Case Parameter

Test Case Parameter 001

Next measurement will be running with the following parameters:

Voltage:	Middle
Temperature:	Middle
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback
B1 Signal Packet Type:	DH5
B1 Signal Pattern:	PRBS 9
Whitening:	Yes
Number of Packets:	1
EUT Tx Frequency:	Hopping
EUT Rx Frequency:	Hopping
B1 Signalling Level:	-55.000 dBm

Test Case Parameter 002

Next measurement will be running with the following parameters:

Voltage:	Middle
Temperature:	Middle
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback
B1 Signal Packet Type:	DH5
B1 Signal Pattern:	PRBS 9
Whitening:	Yes
EUT Tx Frequency:	Hopping
EUT Rx Frequency:	Hopping
Measurement Frequency Start:	2321.000 MHz
Measurement Frequency Stop:	2561.000 MHz
B1 Signalling Level:	-55.000 dBm

Test Case Parameter 003

Next measurement will be running with the following parameters:

Voltage:	Middle
Temperature:	Middle
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback
B1 Signal Packet Type:	DH5
B1 Signal Pattern:	PRBS 9
Whitening:	Yes
EUT Tx Frequency:	2402.000 MHz
EUT Rx Frequency:	2480.000 MHz
B1 Signalling Level:	-55.000 dBm
Number of Sweeps:	50

Test Case Parameter 004

Next measurement will be running with the following parameters:

Voltage:	Middle
Temperature:	Middle

Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
EUT Tx Frequency:	2402.000	MHz
EUT Rx Frequency:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Number of Sweeps:	10	

Test Case Parameter 005

Next measurement will be running with the following parameters:

Voltage:	Middle	
Temperature:	Middle	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
EUT Tx Frequency:	2405.000	MHz
EUT Rx Frequency:	2480.000	MHz
Measurement Frequency Start:	2402.000	MHz
Measurement Frequency Stop:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm

Test Case Parameter 006

Next measurement will be running with the following parameters:

Voltage:	Middle	
Temperature:	Middle	
Power Mode:	Power Controlled	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
Number of Packets:	1	
EUT Tx Frequency:	2402.000	MHz
EUT Rx Frequency:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm

Test Case Parameter 007

Next measurement will be running with the following parameters:

Voltage:	Middle	
Temperature:	Middle	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	00001111	
Number of Packets:	10	
EUT Tx Frequency:	2402.000	MHz
EUT Rx Frequency:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Synchronisation Length:	68	Bits

Synchr. Start Position:	5	. Bit
Evaluated Payload Bits	100	%

Test Case Parameter 008

Next measurement will be running with the following parameters:

Voltage:	Middle	
Temperature:	Middle	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B2 Signal Packet Type:	continuous modulation	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
B2 Signal Pattern:	PRBS 15	
EUT Tx Frequency:	2405.000	MHz
EUT Rx Frequency:	2405.000	MHz
B2 Signal Start Frequency:	2402.000	MHz
B2 Signal Stop Frequency:	2480.000	MHz
B2 Signal Step Size:	1	MHz
B2 Bursted:	No	
B1 Signal Delta Level:	0.000	dB
B2 Signal Delta Level:	0.000	dB
Final Limits	Yes	
BER Number of Bits:	1600000	
BER Limit:	0.100	%
Image Frequency:	2402.000	MHz

Test Case Parameter 009

Next measurement will be running with the following parameters:

Voltage:	Middle	
Temperature:	Middle	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
Number of Packets:	10	
EUT Tx Frequency:	Hopping	
EUT Rx Frequency:	Hopping	
Measurement Frequency Start:	2402.000	MHz
Measurement Frequency Stop:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Synchronisation Length:	68	Bits
Synchr. Start Position:	5	. Bit

Test Case Parameter 010

Next measurement will be running with the following parameters:

Voltage:	Middle
Temperature:	Middle
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback
B1 Signal Packet Type:	DH1
B1 Signal Pattern:	01010101

Number of Packets:	10	
EUT Tx Frequency:	Hopping	
EUT Rx Frequency:	Hopping	
Measurement Frequency Start:	2402.000	MHz
Measurement Frequency Stop:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Synchronisation Length:	68	Bits
Synchr. Start Position:	5	Bit
Evaluated Payload Bits	100	%

Test Case Parameter 011

Next measurement will be running with the following parameters:

Voltage:	Middle	
Temperature:	Middle	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
B1 Signalling Level:	-70.000	dBm
BER Number of Bits:	1600000	
BER Limit:	0.100	%

Test Case Parameter 012

Next measurement will be running with the following parameters:

Voltage:	Middle	
Temperature:	Middle	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
B1 Signalling Level:	-70.000	dBm
BER Number of Bits:	1600000	
BER Limit:	0.100	%

Test Case Parameter 013

Next measurement will be running with the following parameters:

Voltage:	Middle	
Temperature:	Middle	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B2 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
B2 Signal Pattern:	PRBS 15	
EUT Tx Frequency:	2402.000	MHz
EUT Rx Frequency:	2402.000	MHz
B1 Signalling Level:	-64.000	dBm
B2 Signal Frequency:	2412.000	MHz
B2 Bursted:	No	
B2 Signal Level:	-39.000	dBm

B3 Signal Frequency:	2407.000	MHz
B3 Signal Level:	-39.000	dBm
BER Number of Bits:	1600000	
BER Limit:	0.100	%

Test Case Parameter 014

Next measurement will be running with the following parameters:

Voltage:	Middle	
Temperature:	Middle	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
B1 Signalling Level:	-20.000	dBm
BER Number of Bits:	1600000	
BER Limit:	0.100	%

Test Case Parameter 015

Next measurement will be running with the following parameters:

Voltage:	Middle	
Temperature:	Middle	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
EUT Tx Frequency:	2460.000	MHz
EUT Rx Frequency:	2460.000	MHz
B1 Signalling Level:	-67.000	dBm
B3 Signal Start Frequency:	30.000	MHz
B3 Signal Stop Frequency:	12750.000	MHz
B3 Signal Step Size:	1	MHz
B1 Signal Delta Level:	0.000	dB
B3 Signal Delta Level:	0.000	dB
BER Limit:	0.100	%

Test Case Parameter 016

Next measurement will be running with the following parameters:

Voltage:	Low	
Temperature:	Low	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
Number of Packets:	1	
EUT Tx Frequency:	Hopping	
EUT Rx Frequency:	Hopping	
B1 Signalling Level:	-55.000	dBm

Test Case Parameter 017

Next measurement will be running with the following parameters:

Voltage:	High
Temperature:	Low
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback
B1 Signal Packet Type:	DH5
B1 Signal Pattern:	PRBS 9
Whitening:	Yes
Number of Packets:	1
EUT Tx Frequency:	Hopping
EUT Rx Frequency:	Hopping
B1 Signalling Level:	-55.000 dBm

Test Case Parameter 018

Next measurement will be running with the following parameters:

Voltage:	Low
Temperature:	Low
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback
B1 Signal Packet Type:	DH5
B1 Signal Pattern:	PRBS 9
Whitening:	Yes
EUT Tx Frequency:	Hopping
EUT Rx Frequency:	Hopping
Measurement Frequency Start:	2321.000 MHz
Measurement Frequency Stop:	2561.000 MHz
B1 Signalling Level:	-55.000 dBm

Test Case Parameter 019

Next measurement will be running with the following parameters:

Voltage:	High
Temperature:	Low
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback
B1 Signal Packet Type:	DH5
B1 Signal Pattern:	PRBS 9
Whitening:	Yes
EUT Tx Frequency:	Hopping
EUT Rx Frequency:	Hopping
Measurement Frequency Start:	2321.000 MHz
Measurement Frequency Stop:	2561.000 MHz
B1 Signalling Level:	-55.000 dBm

Test Case Parameter 020

Next measurement will be running with the following parameters:

Voltage:	Low
Temperature:	Low
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback

B1 Signal Packet Type:	DH5
B1 Signal Pattern:	PRBS 9
Whitening:	Yes
EUT Tx Frequency:	2402.000 MHz
EUT Rx Frequency:	2480.000 MHz
B1 Signalling Level:	-55.000 dBm
Number of Sweeps:	50

Test Case Parameter 021

Next measurement will be running with the following parameters:

Voltage:	High
Temperature:	Low
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback
B1 Signal Packet Type:	DH5
B1 Signal Pattern:	PRBS 9
Whitening:	Yes
EUT Tx Frequency:	2402.000 MHz
EUT Rx Frequency:	2480.000 MHz
B1 Signalling Level:	-55.000 dBm
Number of Sweeps:	50

Test Case Parameter 022

Next measurement will be running with the following parameters:

Voltage:	Low
Temperature:	Low
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback
B1 Signal Packet Type:	DH5
B1 Signal Pattern:	PRBS 9
Whitening:	Yes
EUT Tx Frequency:	2402.000 MHz
EUT Rx Frequency:	2480.000 MHz
B1 Signalling Level:	-55.000 dBm
Number of Sweeps:	10

Test Case Parameter 023

Next measurement will be running with the following parameters:

Voltage:	High
Temperature:	Low
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback
B1 Signal Packet Type:	DH5
B1 Signal Pattern:	PRBS 9
Whitening:	Yes
EUT Tx Frequency:	2402.000 MHz
EUT Rx Frequency:	2480.000 MHz
B1 Signalling Level:	-55.000 dBm
Number of Sweeps:	10

Test Case Parameter 024

Next measurement will be running with the following parameters:

Voltage:	Low	
Temperature:	Low	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
EUT Tx Frequency:	2405.000	MHz
EUT Rx Frequency:	2480.000	MHz
Measurement Frequency Start:	2402.000	MHz
Measurement Frequency Stop:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm

Test Case Parameter 025

Next measurement will be running with the following parameters:

Voltage:	High	
Temperature:	Low	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
EUT Tx Frequency:	2405.000	MHz
EUT Rx Frequency:	2480.000	MHz
Measurement Frequency Start:	2402.000	MHz
Measurement Frequency Stop:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm

Test Case Parameter 026

Next measurement will be running with the following parameters:

Voltage:	Low	
Temperature:	Low	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	00001111	
Number of Packets:	10	
EUT Tx Frequency:	2402.000	MHz
EUT Rx Frequency:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Synchronisation Length:	68	Bits
Synchr. Start Position:	5	. Bit
Evaluated Payload Bits	100	%

Test Case Parameter 027

Next measurement will be running with the following parameters:

Voltage:	High
Temperature:	Low
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback

B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	00001111	
Number of Packets:	10	
EUT Tx Frequency:	2402.000	MHz
EUT Rx Frequency:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Synchronisation Length:	68	Bits
Synchr. Start Position:	5	. Bit
Evaluated Payload Bits	100	%

Test Case Parameter 028

Next measurement will be running with the following parameters:

Voltage:	Low	
Temperature:	Low	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
Number of Packets:	10	
EUT Tx Frequency:	Hopping	
EUT Rx Frequency:	Hopping	
Measurement Frequency Start:	2402.000	MHz
Measurement Frequency Stop:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Synchronisation Length:	68	Bits
Synchr. Start Position:	5	. Bit

Test Case Parameter 029

Next measurement will be running with the following parameters:

Voltage:	High	
Temperature:	Low	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
Number of Packets:	10	
EUT Tx Frequency:	Hopping	
EUT Rx Frequency:	Hopping	
Measurement Frequency Start:	2402.000	MHz
Measurement Frequency Stop:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Synchronisation Length:	68	Bits
Synchr. Start Position:	5	. Bit

Test Case Parameter 030

Next measurement will be running with the following parameters:

Voltage:	Low
Temperature:	Low
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback
B1 Signal Packet Type:	DH1

B1 Signal Pattern:	01010101	
Number of Packets:	10	
EUT Tx Frequency:	Hopping	
EUT Rx Frequency:	Hopping	
Measurement Frequency Start:	2402.000	MHz
Measurement Frequency Stop:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Synchronisation Length:	68	Bits
Synchr. Start Position:	5	. Bit
Evaluated Payload Bits	100	%

Test Case Parameter 031

Next measurement will be running with the following parameters:

Voltage:	High	
Temperature:	Low	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	01010101	
Number of Packets:	10	
EUT Tx Frequency:	Hopping	
EUT Rx Frequency:	Hopping	
Measurement Frequency Start:	2402.000	MHz
Measurement Frequency Stop:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Synchronisation Length:	68	Bits
Synchr. Start Position:	5	. Bit
Evaluated Payload Bits	100	%

Test Case Parameter 032

Next measurement will be running with the following parameters:

Voltage:	Low	
Temperature:	Low	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
B1 Signalling Level:	-70.000	dBm
BER Number of Bits:	1600000	
BER Limit:	0.100	%

Test Case Parameter 033

Next measurement will be running with the following parameters:

Voltage:	High	
Temperature:	Low	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
B1 Signalling Level:	-70.000	dBm
BER Number of Bits:	1600000	

BER Limit:	0.100	%

Test Case Parameter 034

Next measurement will be running with the following parameters:

Voltage:	Low	
Temperature:	Low	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
B1 Signalling Level:	-70.000	dBm
BER Number of Bits:	1600000	
BER Limit:	0.100	%

Test Case Parameter 035

Next measurement will be running with the following parameters:

Voltage:	High	
Temperature:	Low	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
B1 Signalling Level:	-70.000	dBm
BER Number of Bits:	1600000	
BER Limit:	0.100	%

Test Case Parameter 036

Next measurement will be running with the following parameters:

Voltage:	Low	
Temperature:	High	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
Number of Packets:	1	
EUT Tx Frequency:	Hopping	
EUT Rx Frequency:	Hopping	
B1 Signalling Level:	-55.000	dBm

Test Case Parameter 037

Next measurement will be running with the following parameters:

Voltage:	High	
Temperature:	High	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	

B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
Number of Packets:	1	
EUT Tx Frequency:	Hopping	
EUT Rx Frequency:	Hopping	
B1 Signalling Level:	-55.000	dBm

Test Case Parameter 038

Next measurement will be running with the following parameters:

Voltage:	Low	
Temperature:	High	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
EUT Tx Frequency:	Hopping	
EUT Rx Frequency:	Hopping	
Measurement Frequency Start:	2321.000	MHz
Measurement Frequency Stop:	2561.000	MHz
B1 Signalling Level:	-55.000	dBm

Test Case Parameter 039

Next measurement will be running with the following parameters:

Voltage:	High	
Temperature:	High	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
EUT Tx Frequency:	Hopping	
EUT Rx Frequency:	Hopping	
Measurement Frequency Start:	2321.000	MHz
Measurement Frequency Stop:	2561.000	MHz
B1 Signalling Level:	-55.000	dBm

Test Case Parameter 040

Next measurement will be running with the following parameters:

Voltage:	Low	
Temperature:	High	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
EUT Tx Frequency:	2402.000	MHz
EUT Rx Frequency:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Number of Sweeps:	50	

Test Case Parameter 041

Next measurement will be running with the following parameters:

Voltage:	High
Temperature:	High
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback
B1 Signal Packet Type:	DH5
B1 Signal Pattern:	PRBS 9
Whitening:	Yes
EUT Tx Frequency:	2402.000 MHz
EUT Rx Frequency:	2480.000 MHz
B1 Signalling Level:	-55.000 dBm
Number of Sweeps:	50

Test Case Parameter 042

Next measurement will be running with the following parameters:

Voltage:	Low
Temperature:	High
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback
B1 Signal Packet Type:	DH5
B1 Signal Pattern:	PRBS 9
Whitening:	Yes
EUT Tx Frequency:	2402.000 MHz
EUT Rx Frequency:	2480.000 MHz
B1 Signalling Level:	-55.000 dBm
Number of Sweeps:	10

Test Case Parameter 043

Next measurement will be running with the following parameters:

Voltage:	High
Temperature:	High
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback
B1 Signal Packet Type:	DH5
B1 Signal Pattern:	PRBS 9
Whitening:	Yes
EUT Tx Frequency:	2402.000 MHz
EUT Rx Frequency:	2480.000 MHz
B1 Signalling Level:	-55.000 dBm
Number of Sweeps:	10

Test Case Parameter 044

Next measurement will be running with the following parameters:

Voltage:	Low
Temperature:	High
Power Mode:	Maximum Power
Measurement:	Conducted
EUT Test Mode:	Loopback
B1 Signal Packet Type:	DH1
B1 Signal Pattern:	PRBS 9

Whitening:	Yes	
EUT Tx Frequency:	2405.000	MHz
EUT Rx Frequency:	2480.000	MHz
Measurement Frequency Start:	2402.000	MHz
Measurement Frequency Stop:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm

Test Case Parameter 045

Next measurement will be running with the following parameters:

Voltage:	High	
Temperature:	High	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
EUT Tx Frequency:	2405.000	MHz
EUT Rx Frequency:	2480.000	MHz
Measurement Frequency Start:	2402.000	MHz
Measurement Frequency Stop:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm

Test Case Parameter 046

Next measurement will be running with the following parameters:

Voltage:	Low	
Temperature:	High	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	00001111	
Number of Packets:	10	
EUT Tx Frequency:	2402.000	MHz
EUT Rx Frequency:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Synchronisation Length:	68	Bits
Synchr. Start Position:	5	. Bit
Evaluated Payload Bits	100	%

Test Case Parameter 047

Next measurement will be running with the following parameters:

Voltage:	High	
Temperature:	High	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	00001111	
Number of Packets:	10	
EUT Tx Frequency:	2402.000	MHz
EUT Rx Frequency:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Synchronisation Length:	68	Bits
Synchr. Start Position:	5	. Bit
Evaluated Payload Bits	100	%

Test Case Parameter 048

Next measurement will be running with the following parameters:

Voltage:	Low	
Temperature:	High	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
Number of Packets:	10	
EUT Tx Frequency:	Hopping	
EUT Rx Frequency:	Hopping	
Measurement Frequency Start:	2402.000	MHz
Measurement Frequency Stop:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Synchronisation Length:	68	Bits
Synchr. Start Position:	5	. Bit

Test Case Parameter 049

Next measurement will be running with the following parameters:

Voltage:	High	
Temperature:	High	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
Number of Packets:	10	
EUT Tx Frequency:	Hopping	
EUT Rx Frequency:	Hopping	
Measurement Frequency Start:	2402.000	MHz
Measurement Frequency Stop:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Synchronisation Length:	68	Bits
Synchr. Start Position:	5	. Bit

Test Case Parameter 050

Next measurement will be running with the following parameters:

Voltage:	Low	
Temperature:	High	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	01010101	
Number of Packets:	10	
EUT Tx Frequency:	Hopping	
EUT Rx Frequency:	Hopping	
Measurement Frequency Start:	2402.000	MHz
Measurement Frequency Stop:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Synchronisation Length:	68	Bits
Synchr. Start Position:	5	. Bit

Evaluated Payload Bits	100	%

Test Case Parameter 051

Next measurement will be running with the following parameters:

Voltage:	High	
Temperature:	High	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	01010101	
Number of Packets:	10	
EUT Tx Frequency:	Hopping	
EUT Rx Frequency:	Hopping	
Measurement Frequency Start:	2402.000	MHz
Measurement Frequency Stop:	2480.000	MHz
B1 Signalling Level:	-55.000	dBm
Synchronisation Length:	68	Bits
Synchr. Start Position:	5	. Bit
Evaluated Payload Bits	100	%

Test Case Parameter 052

Next measurement will be running with the following parameters:

Voltage:	Low	
Temperature:	High	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
B1 Signalling Level:	-70.000	dBm
BER Number of Bits:	1600000	
BER Limit:	0.100	%

Test Case Parameter 053

Next measurement will be running with the following parameters:

Voltage:	High	
Temperature:	High	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH1	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
B1 Signalling Level:	-70.000	dBm
BER Number of Bits:	1600000	
BER Limit:	0.100	%

Test Case Parameter 054

Next measurement will be running with the following parameters:

Voltage:	Low
Temperature:	High

Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
B1 Signalling Level:	-70.000	dBm
BER Number of Bits:	1600000	
BER Limit:	0.100	%

Test Case Parameter 055

Next measurement will be running with the following parameters:

Voltage:	High	
Temperature:	High	
Power Mode:	Maximum Power	
Measurement:	Conducted	
EUT Test Mode:	Loopback	
B1 Signal Packet Type:	DH5	
B1 Signal Pattern:	PRBS 9	
Whitening:	Yes	
B1 Signalling Level:	-70.000	dBm
BER Number of Bits:	1600000	
BER Limit:	0.100	%

Annex T

Test plan

eurofins

RF TESTPLAN - BLUETOOTH QUALIFICATION (Basic)

EUT: **Bluetooth enabled stethoscope** ORDER NO: * **2051**

Model no: **M3200**

Applicant: **3M Health Care Patient Assessment Laboratory**

Test identifier	Description ☐V1.1 ☐V1.2 ☑V2.0 ☐V2.0+EDR	NTC	VL/TL	VH/TL	VL/TH	VH/TH
TRM/CA/01/C	Output Power	pass	pass	pass	pass	pass
TRM/CA/02/C	Power Density	pass	pass	pass	pass	pass
TRM/CA/03/C	Tx Power Control	pass				
TRM/CA/04/C	Tx Output Spectrum – Frequency range	pass	pass	pass	pass	pass
TRM/CA/05/C	Tx Output Spectrum - 20dB Bandwidth	pass	pass	pass	pass	pass
TRM/CA/06/C	Tx Output Spectrum - Adjacent channel power	pass	pass	pass	pass	pass
TRM/CA/07/C	Modulation Characteristics	pass	pass	pass	pass	pass
TRM/CA/08/C	Intial Carrier Frequency Tolerance	pass	pass	pass	pass	pass
TRM/CA/09/C	Carrier Frequency Drift	pass	pass	pass	pass	pass
RCV/CA/01/C	Sensitivity – single slot packets	pass	pass	pass	pass	pass
RCV/CA/02/C	Sensitivity - multi-slot packets	pass	pass	pass	pass	pass
RCV/CA/03/C	C/I performance	pass				
RCV/CA/04C	Blocking performance	pass				
RCV/CA/05/C	Intermodulation Performance	pass				
RCV/CA/06/C	Maximum Input Level	pass				
TP/PHYS/TRX/BV-01-C	Baseband master TX timing					

PIXIT - protocol implementation extra information for test			
Value	Identifier	Qualified component used: name, version, manufacturer	
2	Power Class	RF	
Yes	Power control		
Yes	3-slot packet (DH3)		
Yes	5-slot packet (DH5)		
direct	Type of power source		
1.5	Nominal power source voltage (V)		
-30	Operating temperature range (°C) min. **TL**		
60	Operating temperature range (°C) max. **TH**		
1.2	Extreme power source voltage (V) min. **VL**		
1.8	Extreme power source voltage (V) max. **VH**		
-12	Antenna gain (dBi)		

NTC = normal test conditions

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FDA CDRH DMC

DEC 29 2008

Received

Ref. Certif. No.

SE-56568

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE

CERTIFICAT D'ESSAI OC

Product Produit	Stethoscope
Name and address of the applicant Nom et adresse du demandeur	3M Health Care, 3M Center, Building 270-4N-09, Maplewood, MN 55144-1000, Patient Assessment Laboratory 3M Medical Products, UNITED STATES
Name and address of the manufacturer Nom et adresse du fabricant	Same as applicant
Name and address of the factory Nom et adresse de l'usine	(b) (4) [redacted]
Ratings and principal characteristics Valeurs nominales et caractéristiques principales	Type B, IPX4, Battery type AA
Trademark (if any) Marque de fabrique (si elle existe)	3M™ Littmann®
Model / Type Ref Ref. De type	E3100 and E3200
Additional information (if necessary) Les informations complémentaires (si nécessaire)	See page 2
A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la	IEC 60601-1:2005 and C1 IEC 60601-1-6:2006
As shown in the Test Report Ref. No. which forms part of this Certificate Comme indiqué dans le Rapport d'essais numéro de réference qui constitue partie de ce Certificat	809546

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme National de Certification

Intertek Semko AB
Box 1103
SE-164 22 Kista, Sweden
Int +46 8 750 00 00

Intertek ETL SEMKO

Signature:

Mikael Goffhé

Date: 10 December 2008

Mandated reviewer: PEL

DAH/ASG

1325

Additional information (if necessary)

Biocompatibility according to EN ISO 10993 has not been evaluated.

Bluetooth on E3200 has not been evaluated.

Date: 10 December 2008

Signature:

Test Report issued under the responsibility of

Intertek

IEC 60601-1 / EN 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No.....:	809546-1
Date of issue.....:	2008-12-10
Total number of pages .....:	155
CB Testing Laboratory.....:	Intertek Semko AB
Address .....:	Box 1103 SE-164 22 Kista SWEDEN
Applicant's name.....:	3M Health Care
Address .....:	3M Center, Building 270-4N-09 Maplewood, MN 55144-1000 Patient Assessment Laboratory 3M Medical Products, USA
Test specification:	
Standard.....:	IEC 60601-1: 2005
Test procedure .....:	CB/CCA
Non-standard test method.....:	N/A
Test Report Form No.....:	IEC60601_1D
Test Report Form Originator .....:	Underwriters Laboratories Inc.
Master TRF.....:	Dated 2006-07

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Test item description .....:	Stethoscope
Trade Mark .....:	3M™ Littmann®
Manufacturer	(b) (4) [redacted]
Model/Type reference	
Ratings .....:	Type B, IPX4, Battery type AA

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Testing procedure and testing location:

☒ **CB Testing Laboratory:**

Testing location/ address.....: Torshamnsgatan 43
SE-164 22 Kista
SWEDEN

☐ **Associated CB Test Laboratory:**

Testing location/ address.....:

Tested by (name + signature) .....: Ansis Graufelds

Approved by (+ signature).....: Peter Lymeus

☐ Testing procedure: TMP

Tested by (name + signature) .....:

Approved by (+ signature).....:

Testing location/ address.....:

☐ Testing procedure: WMT

Tested by (name + signature) .....:

Witnessed by (+ signature).....:

Approved by (+ signature).....:

Testing location/ address.....:

☐ Testing procedure: SMT

Tested by (name + signature) .....:

Approved by (+ signature).....:

Supervised by (+ signature) .....:

Testing location/ address.....:

☐ Testing procedure: RMT

Tested by (name + signature) .....:

Approved by (+ signature).....:

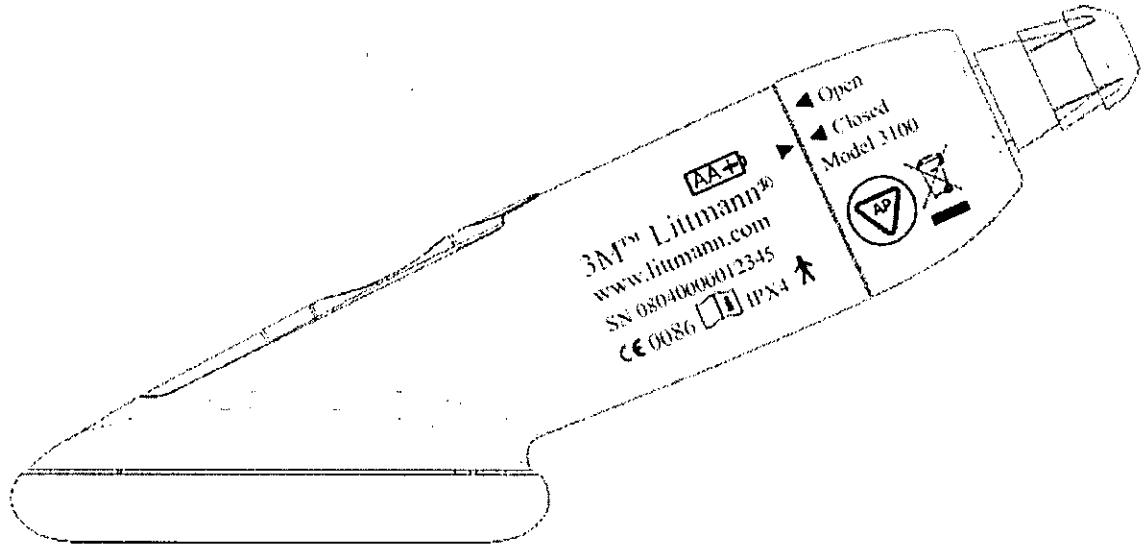
Supervised by (+ signature) .....:

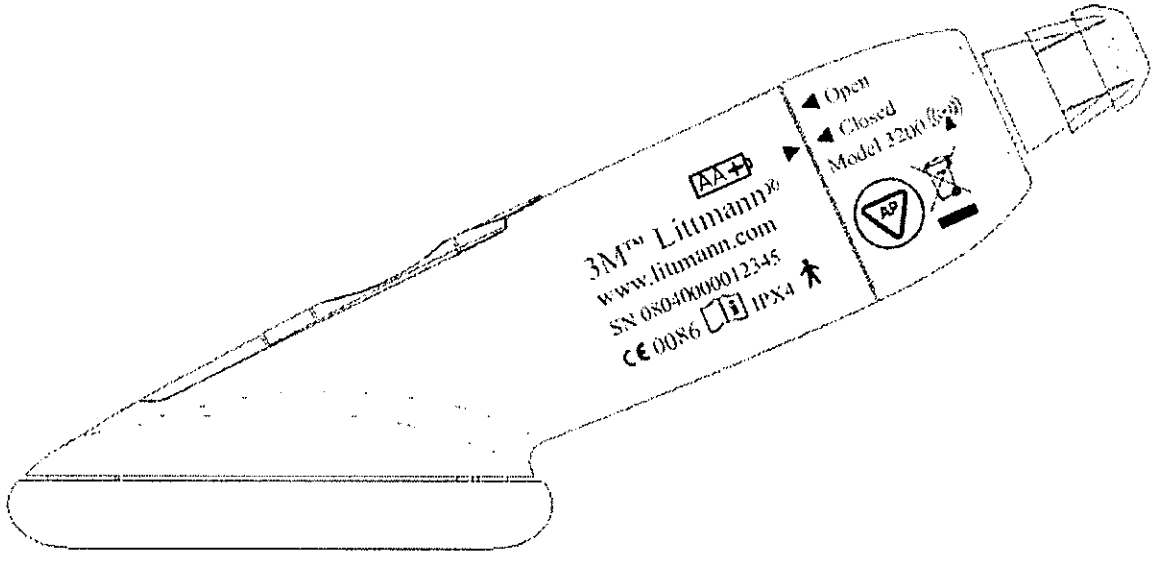
Testing location/ address.....:

Summary of testing	
Tests performed (name of test and test clause):	**Testing location:**
All applicable tests	**Intertek Semko AB**
Summary of compliance with National Differences:	
-	

1329

Copy of marking plate





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GENERAL INFORMATION

Test item particulars (see also Clause 5):

Classification of installation and use	Hand-held
Device type	Stethoscope
Clinical application	Medical diagnostic
Mode of operation	Continuous
Surface temperature of APPLIED PART	40°C
Supply connection	Internally powered
Accessories and detachable parts included	-
Other options include	-

Testing

Date of receipt of test item(s)	2008-08-04
Dates tests performed	2008-08-04 to 2008-09-17

Possible test case verdicts:

- test case does not apply to the test object	N / A
- test object does meet the requirement	Pass (P)
- test object does not meet the requirement	Fail (F)

Abbreviations used in the report:

- normal condition	N.C.	- single fault condition	S.F.C.
- operational insulation	OP	- basic insulation	BI
- basic insulation between parts of opposite polarity	BOP	- supplementary insulation	SI
- double insulation	DI	- reinforced insulation	RI

General remarks:

"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report a point is used as the decimal separator.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

General product information:

The electronic stethoscope model 3100 & 3200 is intended for medical diagnosis. It may be used for the detection and amplification of heart, lungs, arteries, veins and other internal organs. It can be used on any person undergoing a physical assessment.

The electronic stethoscope picks up sounds from patients body, amplifies and filters it. The sounds are sent to the user through a binaural headset.

The user interface for the stethoscope includes a 5 button keypad and an LCD display. Sound processing is carried out with the aid of a digital signal processor. The model 3200 does also have a Bluetooth wireless link. The stethoscope can exchange audio data with an external device such as a PC, and possibility of onboard recording.

The Stethoscope power is provided by a single AA battery in the chest piece. A power management system is included to prolong battery life.

B31

INSULATION DIAGRAM

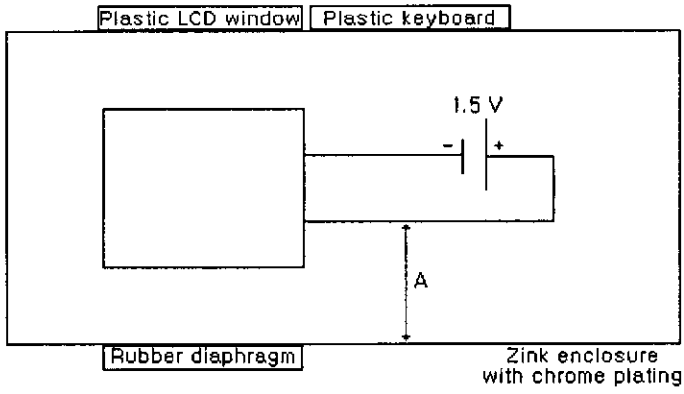

	TABLE: To insulation diagram						P
Area	Insulation type: OPERATIONAL / BASIC / SUPPLEMENTARY / DOUBLE / REINFORCED	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A	DI	1.5	3.4	1.6	3.5	1.65	
B							
C							
D							
E							
F							
G							
H							
I							

NSULATION DIAGRAM CONVENTIONS:

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.

Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional

Applied parts are extended beyond the equipment enclosure and terminated with an arrow.

Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

Blocks containing the letter "Z" indicate protective impedance.

Operational Insulation (OP) - indicates insulation that may be required for function of the equipment, but is not required or relied on for compliance with the requirements of clauses 17, 20 and 57.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
4	**GENERAL REQUIREMENTS**		P
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse		P
	Definitions/ requirements using the term PATIENT considered as applicable to individual(s) for whom ME EQUIPMENT or ME SYSTEM is designed for	Noted	P
4.2	A RISK MANAGEMENT PROCESS complying with ISO 14971 was performed .....:	Described in Risk Management Plan (RMF)	P
	ISO 14971applied with the specified considerations:		P
	– Term "medical device" assumed same as ME EQUIPMENT or ME SYSTEM		P
	– Term "fault conditions" not limited to SINGLE FAULT CONDITIONS		P
	– Policy to determine acceptable RISK, and acceptability of RESIDUAL RISK(s) established by MANUFACTURER		P
	– Verifiable requirements of this and associated standards complied with for particular RISKS including RESIDUAL RISKs presumed to be acceptable unless there was OBJECTIVE EVIDENCE to the contrary		P
	Requirements for inspection of RISK MANAGEMENT FILE considered satisfied based on MANUFACTURER'S established RISK MANAGEMENT PROCESS, acceptable levels of RISK, and acceptable RESIDUAL RISK(s) according to the policy for determining acceptable RISK		P
4.3	ESSENTIAL PERFORMANCE functions identified according to MANUFACTURER'S policy for RISK acceptability in RISK MANAGEMENT FILE	See RMF – Questionnaire Part 2 Question C.2.34	P
	ESSENTIAL PERFORMANCE functions maintained following particular tests as applicable		P
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE	See RMF – Lifetime Of The Product: Warranty period of 2 years with a service life (design life) of 5 years. See also DRS 1.1	P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
4.5	Alternative means of addressing particular RISKS considered acceptable based on MANUFACTURER'S justification that RESIDUAL RISKS resulting from application of alternative means are ≤ to RESIDUAL RISKS resulting from requirements of this standard		N/A
4.6	RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS subjected to the requirements for APPLIED PARTS, except for 7.2.10		N/A
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by 4.2		P
	a) ME EQUIPMENT with a single means of reducing a RISK having negligible probability of failure considered SINGLE FAULT SAFE, or	Also see appended Table 8.10	P
	b) a SINGLE FAULT CONDITION occurred, except as follows:		P
	– initial fault detected during EXPECTED SERVICE LIFE of ME EQUIPMENT and before a second means for reducing a RISK failed (e.g. suspended masses with MECHANICAL PROTECTIVE DEVICES), or		N/A
	– probability that the second means of reducing the RISK would fail during EXPECTED SERVICE LIFE of ME EQUIPMENT was negligible		N/A
	Two failures resulting from a SINGLE FAULT CONDITION causing a secondary SINGLE FAULT CONDITION considered as one SINGLE FAULT CONDITION		P
	Only one fault applied at a time during the tests under SINGLE FAULT CONDITION		P
	Results of RISK ANALYSIS used to determine which failures should be tested		P
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically		P
	RISK associated with failure of component during EXPECTED SERVICE LIFE of ME EQUIPMENT taken into account to evaluate if a component should be subjected to failure simulation		P
	Evaluation done by applying the principles of RISK MANAGEMENT taking into account reliability, TENSILE SAFETY FACTORS, and rating of components		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	During simulation of SINGLE FAULT CONDITIONS, highly probable or undetectable component failures simulated		P
	Requirements and relevant tests of this clause not applied to failures of DOUBLE or REINFORCED INSULATION or COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS		P
	Specific requirements and tests associated with SINGLE FAULT CONDITIONS in 13.2 applied together with the tests for failures identified from evaluation of the results of RISK ANALYSIS		P
	SINGLE FAULT CONDITIONS applied one at a time as described in 13.2 did not lead directly to the HAZARDOUS SITUATIONS in 13.1, or any other outcome resulting in an unacceptable RISK		P
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used in accordance with their applicable ratings, except as specified, or by RISK MANAGEMENT PROCESS		P
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following:		P
	a) applicable safety requirements of a relevant IEC or ISO standard ..... :		P
	b) requirements of this standard applied in the absence of a relevant IEC or ISO standard		P
	Tests conducted on motors (13.28 & 13.2.13.3) and transformers (15.5.3) together with evaluation of their insulation system according to Table 22 represent all required tests		N/A
	ME SYSTEM components providing isolation from non-ME EQUIPMENT evaluated to Clause 16		N/A
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided because a fault in a particular component can generate an unacceptable RISK	See appended Table 8.10	P
	COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS selected and evaluated consistent with their conditions of use and reasonable foreseeable misuse during EXPECTED SERVICE LIFE of ME EQUIPMENT by reviewing RISK MANAGEMENT FILE	PTC	P
4.10	Power supply		P

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
4.10.1	ME EQUIPMENT is suitable for connection to a SUPPLY MAINS, specified to be connected to a separate power supply, can be powered by an INTERNAL ELECTRICAL POWER SOURCE, or a combination of the three ..... :	Internal electrical power source	P
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS is 250 V for HAND-HELD ME EQUIPMENT (V) ..... :		N/A
	– 250 V d.c. or single-phase a.c., or 500 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V)..... :		N/A
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS		N/A
	SUPPLY MAINS characteristics are as follows:		N/A
	– overvoltage category II for mains transients, except when a higher category specified by MANUFACTURER ..... :		N/A
	– no voltage >110 % or < 90 % of NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (% of NOMINAL voltage) ..... :		N/A
	– voltages that are practically sinusoidal and forming a practically symmetrical supply system in case of poly-phase supply		N/A
	– a frequency of ≤ 1 kHz (Hz)..... :		N/A
	– a frequency deviation of ≤ 1 Hz from NOMINAL frequency up to 100 Hz and ≤ 1 % from NOMINAL frequency from 100 Hz to 1 kHz (Hz, or % deviation from NOMINAL frequency) ..... :		N/A
	– protective measures per IEC 60364-4-41..... :		N/A
	– a d.c. voltage (as measured by a moving coil meter or equivalent method) having a peak-to-peak ripple ≤ 10 % of average value (V dc)..... :		N/A
	Peak voltage applied when peak-to-peak ripple exceeded 10 % of average value		N/A
	Additional safety measures applied to ME EQUIPMENT or ME SYSTEM intended to be operated from a SUPPLY MAINS with characteristics different from SUPPLY MAINS described in this clause ..... :		N/A
4.11	Power input		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in instructions for use did not exceed marked rating by more than 10 % :	Internally powered See appended Table 4.11	N/A
	– Measurements on ME EQUIPMENT or a ME SYSTEM marked with one or more RATED voltage ranges made at both upper and lower limits of the range		N/A
	Measurements made at a voltage equal to the mean value of the range when each marking of RATED input was related to the mean value of relevant voltage range		N/A
	– Steady state current measured with a true r.m.s reading instrument		N/A
	Power input, expressed in volt-amperes, measured with a volt-ampere meter or calculated as the product of steady state current (measured as described above) and supply voltage		N/A
	A supplier certification used in place of the above measurement as the basis for steady state current or power input specification		N/A

5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		P
5.1	TYPE TESTS determined in consideration of Clause 4, in particular 4.2		P
	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods .....:		N/A
	Results of RISK ANALYSIS used to determine combination(s) of simultaneous faults to be tested	See RMF – Risk analysis	P
	RISK ANALYSIS revised, necessarily, based on test results	See RMF – Risk analysis	P
5.2	TYPE TESTS conducted on one representative sample under investigation		P
	Multiple samples used simultaneously when validity of results was not significantly affected		P
5.3	a) Tests conducted within the range of environmental conditions specified in the technical description .....:	20°C to 24°C	P
	b) ME EQUIPMENT shielded from other influences that might affect the validity of tests		P

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Clause	Requirement + Test	Result - Remark	Verdict
	c) Test conditions modified and results adjusted accordingly when ambient temperature could not be maintained	Tests recalculated to temperature ranges specified in manual, -30°C to 40°C	P
5.4	a) ME EQUIPMENT tested under least favorable working conditions specified in instructions for use and identified during RISK ANALYSIS, except as noted		P
	b) ME EQUIPMENT with adjustable or controlled operating values by anyone other than SERVICE PERSONNEL adjusted to values least favorable for the relevant test according to instructions for use		P
	c) When test results influenced by inlet pressure and flow or chemical composition of a cooling liquid, tests performed within the limits of these characteristics based on technical description		N/A
	d) Potable water used for cooling		N/A
5.5	a) Effects of deviations of supply voltage from its RATED value on test results taken into account		P
	Supply voltage during tests was the least favorable of the voltages specified in 4.10 or voltages marked on ME EQUIPMENT (V) ..... :	AA battery, 1.5 V	P
	b) ME EQUIPMENT with a MAINS PART intended for connection to a.c. SUPPLY MAINS tested only with a.c. at marked RATED frequency ± 1 Hz up to and including 100 Hz, and ± 1 % above 100 Hz ..... :	Not intended for connection to supply mains	N/A
	ME EQUIPMENT marked with a RATED frequency range tested at the least favorable frequency within the range (Hz) ..... :	No rated frequency	N/A
	c) ME EQUIPMENT with more than one RATED voltage, or for both a.c. and d.c., tested in conditions (see 5.4) related to the least favorable voltage, nature of supply, and type of current..... :	Only one rated voltage and only in d c conditions	N/A
	Some tests performed to determine the least favorable supply configuration		N/A
	d) ME EQUIPMENT with a MAINS PART for connection to d.c. SUPPLY MAINS tested with d.c. only		N/A
	Possible effects of polarity on operation of ME EQUIPMENT was taken into account based on instructions for use	No connection with reversed battery.	P

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Clause	Requirement + Test	Result - Remark	Verdict
	e) ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favorable conditions ..... :	No accessories	N/A
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use . :	No separate power supply	N/A
5.6	When failure occurred or probability of future failure detected during sequence of tests, per agreement with manufacturer, all tests affecting results conducted on a new sample		N/A
	Alternatively, upon repair and modification of the sample, only the relevant tests conducted		N/A
5.7	ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of 8.7.4 and 8.8.3		P
	Manually detachable parts removed and treated concurrently with major parts and manually removable ACCESS COVERS opened and detached		P
	ME EQUIPMENT heated to a temperature between T and T + 4 °C for at least 4 h and placed in a humidity chamber with a relative humidity of 93 % ± 3 % and an ambient within 2 °C of T in the range of + 20 °C to + 32 °C for 48 h		P
	When RISK MANAGEMENT PROCESS indicated ME EQUIPMENT can be exposed to high humidity for extended periods (i.e., out-door use), test time extended proportionally (h)..... :	See RMF – Risk analysis, C.2.15 and C.2.16	P
	ME EQUIPMENT reassembled after humidity treatment when necessary		P
5.8	Unless stated otherwise, tests in this standard sequenced as in Annex B to prevent results of one test on a subsequent test		P
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		P
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS ... :		P
5.9.2	ACCESSIBLE PARTS		P
5.9.2.1	ACCESSIBLE PARTS identified by inspection		P
	Accessibility, when necessary, determined using standard test finger of Fig 6 applied in a bent or straight position as follows:		P

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Clause	Requirement + Test	Result - Remark	Verdict
	– for all positions in NORMAL USE, except ME EQUIPMENT for use on the floor with a mass in any operational condition > 45 kg not tilted		N/A
	Cabinet mounted ME EQUIPMENT tested in final mounting position		N/A
	–after opening of ACCESS COVERS and removal of parts, including lamps, fuses and fuse-holders, without a TOOL or based on instructions for use		P
	Openings preventing entry of test finger of Fig 6 mechanically tested with a straight un-jointed test finger of the same dimensions with a force of 30 N		P
	When the straight un-jointed test finger entered, test with the standard test finger (Fig 6) was repeated, if necessary, by pushing the finger through the opening		P
5.9.2.2	Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s		P
	All additional parts that became accessible checked using standard test finger and by inspection		P
5.9.2.3	Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS		P
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, etc. required use of a TOOL, and inspection of RISK MANAGEMENT FILE indicated the relevant part is unlikely to detach unintentionally during EXPECTED SERVICE LIFE of ME EQUIPMENT		N/A

6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		P
6.1	ME EQUIPMENT, parts thereof, and APPLIED PARTS, classified against electric shock as follows:		P
6.2	CLASS I ME EQUIPMENT, externally powered		N/A
	CLASS II ME EQUIPMENT, externally powered		N/A
	INTERNALLY POWERED ME EQUIPMENT		P

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Clause	Requirement + Test	Result - Remark	Verdict
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with the requirements for CLASS I or CLASS II ME EQUIPMENT when so connected, and with the requirements for INTERNALLY POWERED ME EQUIPMENT when not connected to SUPPLY MAINS		N/A
	TYPE B APPLIED PART		P
	TYPE BF APPLIED PART		N/A
	TYPE CF APPLIED PART		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS		N/A
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter (IPN_1N_2) as detailed in IEC 60529..... :	IPX4	P
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use (e.g., by ethylene oxide gas, gamma ray irradiation, etc.).. :		N/A
6.5	ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2	See annex G	P
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION..... :	Continuous	P

7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		P
7.1.1	RISK of poor USABILITY associated with the design of ME EQUIPMENT'S identification and marking addressed in a USABILITY ENGINEERING PROCESS		P
7.1.2	Markings specified in 7.2-7.6 met the requirements when ME EQUIPMENT or its parts were so positioned that viewpoint was the intended position of the OPERATOR; or at any point within the base of a cone subtended by an angle of 30° to the axis normal to center of plane of marking and at 1 m		P
	Ambient luminance was the least favorable level in the range of 100 to 1500 lx, and observer had a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20), corrected when necessary (lx) ..... :		P
	– markings were clearly legible for warning statements, instructive statements, safety signs, and drawings on outside of ME EQUIPMENT from position of person performing related function		P

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Clause	Requirement + Test	Result - Remark	Verdict
	– markings were clearly legible for FIXED ME EQUIPMENT when the ME EQUIPMENT mounted in its position of NORMAL USE		P
	– markings were clearly legible for TRANSPORTABLE and STATIONARY ME EQUIPMENT not FIXED in NORMAL USE or after dislodging ME EQUIPMENT from a wall against which it was positioned, or after turning ME EQUIPMENT from its position of NORMAL USE and for dismountable rack units, after removal from rack		P
	– markings inside ME EQUIPMENT or parts were clearly legible when viewed from the intended position of person performing related function		P
7.1.3	Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE	Marking engraved	P
	a) After tests, adhesive labels didn't loosen up or curl up at edges and markings complied with 7.1.2		P
	b) Markings required by 7.2-7.6 remained CLEARLY LEGIBLE after durability of marking test	See appended Tables 7.1.3 and 8.10	P
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		P
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings .....:	See marking plate on page 4 of this test report	P
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS.....:		P
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT.....:		N/A
	A material, component, ACCESSORY, or ME EQUIPMENT intended for a single use, or its packaging marked "Do Not Reuse" or with symbol 28 of Table D.1 (ISO 7000-1051, DB:2004-01).....:		N/A
7.2.2	Name or trademark of MANUFACTURER marked on ME EQUIPMENT and its detachable components .....:	3M™ Littmann®	P
	MODEL OR TYPE REFERENCE also marked, except when misidentification would not present an unacceptable RISK.....:	Model 3100 / Model 3200	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Software forming part of a PEMS identified with a unique identifier, such as revision level or date of release/issue, and identification are available to designated persons (e.g., SERVICE PERSONNEL) ..... :	Software version 00.03.00	P
	Marking identification on outside of ME EQUIPMENT considered optional		N/A
7.2.3	Symbol 11 on Table D.1 (ISO 7000-1641, DB: 2004-01) used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS		P
	Safety sign 10 on Table D.2 (safety sign IEC 60878 Safety 01) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted ..... :		N/A
7.2.4	ACCESSORIES marked with name or trademark of their MANUFACTURER or supplier, and with a MODEL or TYPE REFERENCE ..... :	No accessories	N/A
	Markings applied to individual packaging when not practical to apply to ACCESSORIES		N/A
7.2.5	MODEL or TYPE REF. of equipment to be connected to ME EQUIPMENT to provide power, is marked adjacent to the relevant connection point when this connection could result in an unacceptable RISK..... :		N/A
7.2.6	Following markings appear on outside of part containing SUPPLY MAINS connection and, preferably, adjacent to connection point, except for PERMANENTLY INSTALLED ME EQUIPMENT		N/A
	NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT, preferably, adjacent to supply connection terminals for PERMANENTLY INSTALLED ME EQUIPMENT (V, V-V) ..... :		N/A
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V) ..... :		N/A
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V) ..... :		N/A
	– nature of supply (e.g., No. of phases, except single-phase) and type of current ..... :		N/A
	Symbols 1-5, Table D.1 (symbols of IEC 60417-5032, 5032-1, 5032-2, 5031, and 5033, all DB: 2002-10) used, optionally, for same parameters.... :		N/A
	– RATED supply frequency or RATED frequency range in hertz ..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– symbol 9 of Table D.1 (symbol IEC 60417-5172, DB: 2003-02) used for CLASS II ME EQUIPMENT:		N/A
7.2.7	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W) .....:		N/A
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (VA) .....:		N/A
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (VA) .....:		N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA) .....:		N/A
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (VA).....:		N/A
7.2.8	Output connectors		N/A
7.2.8.1	See 16.9.2.1 b) for MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT		N/A
7.2.8.2	Output connectors of ME EQUIPMENT, except MULTIPLE SOCKET-OUTLETS or connectors intended only for specified equipment or ACCESSORIES, marked with RATED output voltage, RATED current or power and output frequency (when applicable) .....:		N/A
7.2.9	ME EQUIPMENT or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2) .....:	IPX4	P
	Marking of IPX0 and IP0X Codes optional		P
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols as follows (not applied to parts identified according to 4.6):	Type B	P
	TYPE B APPLIED PARTS with symbol 19 of Table D.1 (IEC 60417-5840, DB: 2002-10), not applied to give impression of being inscribed within a square to differentiate with symbol IEC 60417-5333.....:		P
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1 (IEC 60417-5333, DB: 2002-10) .....:		N/A
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1 (IEC 60417-5335, DB: 2002-10) .....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1 (IEC 60417-5841, IEC 60417-5334, or IEC 60417-5336, all DB: 2002-10) ..... :		N/A
	Proper symbol marked adjacent to or on connector for APPLIED PART, except marked on APPLIED PART when there is no connector, or connector used for more than one APPLIED PART and different APPLIED PARTS with different classifications ..... :		N/A
	Safety sign 2 of Table D.2 (safety sign ISO 7010-W001) placed near relevant outlet when protection against effect of discharge of a cardiac defibrillator is partly in the PATIENT cable ..... :		N/A
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of appropriate cables included in instructions for use ..... :		N/A
7.2.11	ME EQUIPMENT not marked to the contrary assumed to be suitable for CONTINUOUS OPERATION		P
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time .... :		N/A
7.2.12	Type and full rating of a fuse (voltage, current, operating speed and breaking capacity) marked adjacent to ACCESSIBLE fuse-holder ..... :	No fuse	N/A
7.2.13	A safety sign CLEARLY LEGIBLE and visible after INSTALLATION in NORMAL USE applied to a prominent location of EQUIPMENT that produce physiological effects capable of causing HARM to PATIENT or OPERATOR not obvious to OPERATOR ..... :		N/A
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use ..... :		P
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10)		N/A
7.2.15	Requirements for cooling provisions marked (e.g., supply of water or air) ..... :		N/A
7.2.16	ME EQUIPMENT with limited mechanical stability		N/A
7.2.17	Packaging marked with special handling instructions for transport and/or storage ..... :		N/A
	Permissible environmental conditions for transport and storage marked on outside of packaging ..... :	Thermometer: -20°C to 55°C	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK ..... :		N/A
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile ..... :		N/A
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector ..... :		N/A
7.2.19	Symbol 7 of Table D.1 (IEC 60417-5017, DB:2002-10) marked on FUNCTIONAL EARTH TERMINAL:		N/A
7.2.20	Protective means, required to be removed to use a particular function of ME EQUIPMENT with alternate applications, marked to indicate the necessity for replacement when the function is no longer needed ..... :		N/A
	No marking applied when an interlock provided		N/A
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts		
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near heater or in heater itself (W) ..... :		N/A
	An identifying marking referring to instruction in ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for use with heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL ..... :		N/A
7.3.2	Symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10), or safety sign 3 of Table D.2 used to mark presence of HIGH VOLTAGE parts ..... :		N/A
7.3.3	Type of battery and mode of insertion when applicable is marked ..... :	AA battery, + marking inside of cap	P
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL ..... :		N/A
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement by inadequately trained personnel would result in an unacceptable RISK (e.g., excessive temperatures, fire or explosion) ..... :	Battery short circuit safe	N/A
	An identifying marking also provided referring to instructions in ACCOMPANYING DOCUMENTS .. :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.3.4	Fuses and replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible only by a TOOL, identified by type and full rating adjacent to component (V, A, operating speed and breaking capacity), or by a reference to information in ACCOMPANYING DOCUMENTS..... :		N/A
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1 (IEC 60417-5019, DB: 2002-10), except for the PROTECTIVE EARTH TERMINAL in an APPLIANCE INLET according to IEC 60320-1..... :		N/A
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made		N/A
7.3.6	Symbol 7 of Table D.1 (IEC 60417-5017, DB: 2002 -10) marked on FUNCTIONAL EARTH TERMINALS ..... :		N/A
7.3.7	Terminals for supply conductors marked adjacent to terminals, except when interchanging connections would not result in a HAZARD		N/A
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings		N/A
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3 (Code in IEC 60445)		N/A
	When marking for connection to a 3-phase supply is necessary, it complies with IEC 60445		N/A
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		N/A
7.3.8	Statement, "For supply connections, use wiring materials suitable for at least X °C" (X > than max temperature measured in terminal box or wiring compartment under NORMAL USE and CONDITIONS)", or equivalent marked at or near the point supply connections made under conditions of this clause		N/A
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		N/A
7.4	Marking of controls and instruments		P

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Clause	Requirement + Test	Result - Remark	Verdict
7.4.1	The "on" and "off" positions of switch used to control power to ME EQUIPMENT or its parts, including mains switch, marked with symbols 12 and 13 of Table D.1 (IEC 60417-5007, DB: 2002-10, and IEC 60417-5008, DB: 2002-10), or		N/A
	– indicated by an adjacent indicator light, or		N/A
	– indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1 (IEC 60417-5010 DB: 2002-10), and		N/A
	– status indicated by an adjacent indicator light, or		N/A
	– status indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 (symbol 60417-5011 DB: 2002-10), or		N/A
	– status indicated by an adjacent indicator light, or		N/A
	– status indicated by other unambiguous means		N/A
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means	⏻ Symbol IEC 60878-5009 used as power button	P
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE, or		N/A
	– an indication of direction in which magnitude of the function changes	+ and - symbols for volume	P
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 31 except the base quantities listed in Table 1 expressed in the indicated units	BPM (Beats Per Minute) is an established unit	P
	ISO 1000 applied for application of SI units, their multiples, and certain other units		N/A
	All Markings in Subclause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3	Marking	P
7.5	Safety signs		P
	Markings used to convey a warning, prohibition or mandatory action mitigating a RISK not obvious to OPERATOR are safety signs from ISO 7010		N/A
	One of the following methods used when a safety sign was not available to indicate a particular desired meaning:		N/A
	a) A safety sign constructed according to safety signs 1.4 and 8 of Table D.2 (i.e., ISO 3864-1:2002, Clause 7)		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Safety sign 2 of Table D.2 (general warning sign ISO 7010:2003-W001) placed together with a supplementary symbol or an affirmative statement describing the anticipated principal RISK(S) (e.g., "Causes burns", "Risk of explosion", etc.)		N/A
	c) Safety sign 4 of Table D.2 (general prohibition sign ISO 7010:2003-P001) placed together with a supplementary symbol or a statement describing what is prohibited ("Do not open", etc.)		N/A
	d) Safety sign 9 of Table D.2 (general mandatory action sign ISO 7010:2003-M001) placed together with a supplementary symbol or a text statement consisting of a command describing the required action (e.g., "Wear protective gloves", etc.)		N/A
	Affirmative statement together with safety sign placed in instructions for use due to insufficient space on ME EQUIPMENT	AP symbol to big for the equipment. A smaller symbol without color is used instead.	P
	Specified colors in ISO 3864-1 used for safety signs ..... :	Adding colours on label will generate handling noise and degree the essential function of the stethoscope. The correct colors of AP symbol (symbol 22 table D1) are placed in the user manual.	N/A
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)		P
	Safety signs including any supplementary symbols or text described in instructions for use		P
7.6	Symbols		P
7.6.1	Meanings of symbols used for marking described in instructions for use		P
7.6.2	Symbols required by this standard conform to IEC or ISO publication referenced		P
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable		P
7.7	Colors of the insulation of conductors		N/A
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation		N/A
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations		N/A
7.7.3	Green and yellow insulation identify only following conductors:		N/A
	– PROTECTIVE EARTH CONDUCTORS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– conductors specified in 7.7.2		N/A
	– POTENTIAL EQUALIZATION CONDUCTORS		N/A
	– FUNCTIONAL EARTH CONDUCTORS		N/A
7.7.4	Neutral conductors of POWER SUPPLY CORDS are "light blue" specified in IEC 60227-1 or IEC 60245-1		N/A
7.7.5	Colors of conductors in POWER SUPPLY CORDS are in accordance with IEC 60227-1 or IEC 60245-1		N/A
7.8	Indicator lights and controls		N/A
7.8.1	Colors of indicator lights and their meanings are as follows (Dot-matrix and other alphanumeric displays not considered indicator lights):		N/A
	Red: Warning (i.e., immediate response by OPERATOR required)		N/A
	Yellow: Caution (i.e., prompt response by OPERATOR required)		N/A
	Green: Ready for use		N/A
	Other color: Meaning other than red, yellow, or green (color, meaning) ..... :		N/A
7.8.2	Red used only for emergency control		N/A
7.9	ACCOMPANYING DOCUMENTS		
7.9.1	ME EQUIPMENT accompanied by documents containing at least instructions for use, and a technical description	E3200 User guide Draft v0.4 E3100 User guide V1.2a Instruction for Use, **IFU**	P
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		P
	– name or trade-name of MANUFACTURER and an address the RESPONSIBLE ORGANIZATION can be referred to ..... :	Trade-name: 3M™ Littmann® Electronic Stethoscope Contacts: User guide Maintenance & warranty	P
	– MODEL or TYPE REFERENCE ..... :	Model 3100 Model 3200	P
	When ACCOMPANYING DOCUMENTS provided electronically (e.g., on CDROM), RISK MANAGEMENT PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT (to cover emergency operation)		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	Risk Management Plan **RMF** Ref no: C.2.26 E3200 / E3100 User guide IFU	P
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended	E3200 / E3100 User guide IFU	P
7.9.2	Instructions for use include the required information		
7.9.2.1	– intended use of ME EQUIPMENT,	E3200 / E3100 User guide Intended use	P
	– frequently used functions, and	E3200 / E3100 User guide IFU	P
	– known contraindication(s) to use of ME EQUIPMENT	No contraindications	N/A
	Classifications specified in Clause 6, all markings specified in 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT	E3200 / E3100 User guide Safety information	P
	Instructions for use are in a language acceptable to the intended operator	Draft in English	P
7.9.2.2	Instructions for use include all warning and safety notices	E3200 / E3100 User guide	P
	Warning statement for CLASS I ME EQUIPMENT indicating: "WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth"	Internal powered battery operated.	N/A
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	E3200 / E3100 User guide Safety information	P
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	E3200 / E3100 User guide Safety information	P
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET indicating, "connecting electrical equipment to MSO effectively leads to creating an ME SYSTEM, and can result in a reduced level of safety"		N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS		N/A
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply indicating "power supply is specified as a part of ME EQUIPMENT or combination is specified as a ME SYSTEM"	Internally powered	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.4	Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source	Internally powered	N/A
	Warning to remove primary batteries when ME EQUIPMENT is not likely to be used for some time when leakage from battery would result in an unacceptable RISK	E3200 / E3100 User guide Ch. 10 Other operating considerations	P
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided:	E3200 / E3100 User guide Ch. 9 Customer configuration	P
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK	Internally powered	N/A
7.9.2.5	Instructions for use includes a description of ME EQUIPMENT, its functions, and significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, and other persons near ME EQUIPMENT in NORMAL USE	E3200 / E3100 User guide	P
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to when such exposure can constitute an unacceptable RISK		N/A
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected	Bluetooth not evaluated by Intertek	-
	APPLIED PARTS specified		P
7.9.2.6	Information provided indicating where the installation instructions may be found (e.g. technical description), or information on qualified personnel who can perform the installation	No installation required.	N/A
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device when an APPLIANCE COUPLER or separable plug is used as isolation means to meet 8.11.1 a)	Hand-held device	N/A
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation including initial control settings, and connection to or positioning of PATIENT together with information on treatment and handling required prior to use of ME EQUIPMENT, its parts, or ACCESSORIES	E3200 / E3100 User guide IFU	P

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Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.9	All necessary information provided to operate ME EQUIPMENT according to its specification including explanation of controls, displays and signals, sequence of operation, connection/disconnection of detachable parts or ACCESSORIES, replacement of material consumed during operation	E3200 / E3100 User guide **IFU**	P
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	E3200 / E3100 User guide **IFU**	P
7.9.2.10	A list of all system messages, error messages, and fault messages provided, except when messages are self-explanatory, an explanation of messages including important causes and possible action(s) that can be taken to resolve the problem indicated by the message	E3200 / E3100 User guide **IFU**	P
7.9.2.11	Necessary information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	E3200 / E3100 User guide **IFU**	P
7.9.2.12	Detailed information provided on cleaning, disinfection, and sterilization methods, and applicable parameters (i.e., temperature, pressure, humidity, time limits and number of cycles) that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified	E3200 / E3100 User guide Maintenance & warranty	P
	Not applied to materials, components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use		N/A
7.9.2.13	Detailed instructions provided on preventive inspection, maintenance, calibration, and frequency of such maintenance	No maintenance or calibration is required	N/A
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	No maintenance or calibration is required	N/A
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application, but not necessarily details of actual performance of such maintenance	No maintenance or calibration is required	N/A
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries intended to be maintained by anyone other than SERVICE PERSONNEL	No maintenance or calibration is required	N/A
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	E3200 / E3100 User guide **IFU**	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Other equipment providing power to ME SYSTEM sufficiently described (e.g. part number, RATED VOLTAGE, max or min power, protection class, intermittent or continuous service) to ensure compliance with this standard	Internally powered	N/A
7.9.2.15	RISKS associated with disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified, and instructions provided on minimizing these RISKS	E3200 / E3100 User guide	P
7.9.2.16	Information specified in 7.9.3 or where it can be found (e.g. in a service manual) included in instructions for use	Included in instruction for use	P
7.9.3	Technical description		P
7.9.3.1	All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use including the following:	Part of the User guide	P
	– information in clause 7.2		P
	– permissible environmental conditions of use including conditions for transport and storage	E3200 / E3100 User guide Ch. 13 Other operating considerations	P
	– all characteristics of ME EQUIPMENT including range(s), accuracy, and precision of displayed values or where they can be found	E3200 / E3100 User guide Ch. 7 Monitor patient heart rate	P
	– special installation requirements such as max. permissible apparent impedance of SUPPLY MAINS	No installation	N/A
	– permissible range of values of inlet pressure and flow, and chemical composition of cooling liquid used for cooling	No installation	N/A
	– a description of means of isolating ME EQUIPMENT from SUPPLY MAINS, when such means not in ME EQUIPMENT	Internal powered	N/A
	– a description of means for checking oil level in partially sealed oil filled ME EQUIPMENT or its parts when applicable		N/A
	– a warning statement addressing HAZARDS that can result from unauthorized modification of ME EQUIPMENT according to following examples:		P
	"WARNING: No modification of this equipment is allowed"		P
	"WARNING: Do not modify this equipment without authorization of the manufacturer"		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	"WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment"		N/A
	Technical description separable from instructions for use contains required information, as follows		N/A
	– information in Clause 7.2	All information in E3200 / E3100 User guide	N/A
	– all applicable classifications specified in Clause 6, and warning and safety notices and explanation of safety signs marked on ME EQUIPMENT	All information in E3200 / E3100 User guide	N/A
	– a brief description of ME EQUIPMENT, how it functions, and its significant physical and performance characteristics	All information in E3200 / E3100 User guide	N/A
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description	All information in E3200 / E3100 User guide	N/A
7.9.3.2	The technical description contains the following required information		P
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT, when type and rating of fuses are not apparent from information on RATED current and mode of operation of ME EQUIPMENT	Internal powered	N/A
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and if so, instructions for correct connection and anchoring to ensure compliance with 8.11.3	Internal powered	N/A
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	E3200 / E3100 User guide Ch. 1 Insert battery	P
	– warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component	No unacceptable risk identified for changing parts	N/A
7.9.3.3	A statement in technical description indicates, upon request, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions, or other information to assist SERVICE PERSONNEL to repair parts	Repair must be done at 3M service center. E3200 / E3100 User guide Maintenance & warranty	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description	Internal powered	N/A
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		P
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS		P
	NORMAL CONDITION considered as simultaneous occurrence of situations identified in Clause 8.1a)		P
	SINGLE FAULT CONDITION considered to include the occurrences as specified in Clause 8.1b)		P
	ACCESSIBLE PARTS determined according to 5.9		P
	LEAKAGE CURRENTS measured according to 8.7		P
8.2	Requirements related to power sources		N/A
8.2.1	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM		N/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified		N/A
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		N/A
8.2.2	No HAZARDOUS SITUATION other than absence of ESSENTIAL PERFORMANCE developed when a connection with wrong polarity made for ME EQUIPMENT supplied from an external d.c. source		N/A
	ME EQUIPMENT connected with correct polarity did not present an unacceptable RISK		N/A
	Protective devices that can be reset by anyone without a TOOL restore correct operation on reset		N/A
8.3	Classification of APPLIED PARTS		P
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART		N/A
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	Type B	P
	d) Requirements of a TYPE B APPLIED PART applied to a part in 4.6 to be subjected to requirements for an APPLIED PART (except marking)		N/A
	Requirements for a TYPE BF or CF APPLIED PART applied as in RISK MANAGEMENT PROCESS		N/A
8.4	Limitation of voltage, current or energy		P
8.4.1	Limits specified in 8.4.2 not applied to currents intended to flow through body of PATIENT to produce a physiological effect during NORMAL USE	No such currents	P
8.4.2	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT per Tables 3 and 4 when measured per Cl. 8.7.4 ..... :		N/A
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT in Cl. 8.7.3 c) when measured per Clause 8.7.4 (mA) ..... :		N/A
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, was negligible in NORMAL USE, and the OPERATOR is instructed not to touch relevant part and PATIENT simultaneously:		N/A
	– accessible contacts of connectors		N/A
	– contacts of fuseholders accessible during replacement of fuse		N/A
	– contacts of lampholders accessible after removal of lamp		N/A
	– parts inside an ACCESS COVER that can be opened without a TOOL, or where a TOOL is needed but the instructions for use instruct an OPERATOR other than SERVICE PERSONNEL to open the relevant ACCESS COVER		N/A
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.) ..... :	1. 5 V	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Limit of 60 V d.c applied with no more than 10 % peak-to-peak ripple, and when ripple > specified value, 42.4 V peak limit applied (V d.c.) ..... :		N/A
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential up to 2 V (VA or J) ..... :		N/A
	LEAKAGE CURRENT limits referred to in 8.4.2 b) applied when voltages higher than limits in 8.4.2 c) were present (mA) ..... :		N/A
	d) Voltage and energy limits specified in c) above also applied to the following:		N/A
	– internal parts, other than contacts of plugs, connectors and socket-outlets, touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and		P
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length of 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls using a TOOL		P
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		P
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N		P
	Test repeated with a TOOL specified in instructions for use		N/A
	Test rod freely and vertically suspended through openings on top of ENCLOSURE		P
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION		N/A
	A TOOL is required when it is possible to prevent the devices from operating		N/A
8.4.3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one s after disconnecting the plug of ME EQUIPMENT or its parts (V) ..... :	Internally powered	N/A
	A triggering circuit used to ensure disconnection occurred at peak of supply voltage waveform		N/A
	When voltage exceeded 60 V, measured or calculated stored charge did not exceed 45 µC .. :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.4.4	Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, did not exceed 60 V or calculated stored charge did not exceed 45 µC .. :	1.5 V battery	N/A
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL		N/A
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1 (IEC 60417-5036, DB: 2002-10), and manual discharging device specified in technical description ..... :		N/A
8.5	Separation of parts		P
8.5.1	MEANS OF PROTECTION (MOP)		P
8.5.1.1	Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in Cl. 8.4		P
	Each MEANS OF PROTECTION categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION, taking into account 4.6, and flow chart in Fig A.12		P
	Varnishing, enameling, oxidation, and similar protective finishes and coatings with sealing compounds replasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION		P
	Coatings and other insulation intended as a MEANS OF PROTECTION complying with IEC 60950-1:2001 considered acceptable as a MEANS OF OPERATOR PROTECTION but not automatically as a MEANS OF PATIENT PROTECTION		N/A
	RISK MANAGEMENT PROCESS taken into consideration for MEANS OF PATIENT PROTECTION		P
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		P
	Insulation, CREEPAGE, CLEARANCES, components or earth connections not complying with 8.5.1.2 and 8.5.1.3 not considered as MEANS OF PROTECTION, and failure of these parts regarded as NORMAL CONDITION		P
8.5.1.2	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test of 8.8 at test voltage of Table 6		P

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Clause	Requirement + Test	Result - Remark	Verdict
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		P
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with 8.6		N/A
	A Y1 capacitor complying with IEC 60384-14 and having passed dielectric strength test for two MEANS OF PATIENT PROTECTION considered equivalent to one MEANS OF PATIENT PROTECTION		N/A
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance (V_{TW}, C_N) :		N/A
8.5.1.3	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		N/A
	– dielectric strength test of 8.8 at test voltage of Table 6; or		N/A
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		N/A
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		N/A
	– limits of Tables 13 to 16 (inclusive); or		N/A
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6, or		N/A
	– requirements and tests of IEC 60950-1 for protective earthing		N/A
	A Y2 capacitor complying with IEC 60384-14 and passing dielectric strength test for one MEANS OF OPERATOR PROTECTION considered equivalent to one MEANS OF OPERATOR PROTECTION		N/A
	A Y1 capacitor complying with IEC 60384-14 and having passed dielectric strength test for two MEANS OF OPERATOR PROTECTION considered equivalent to two MEANS OF OPERATOR PROTECTION		N/A
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance (V_{TW}, C_N)		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Points where insulation, CREEPAGE, CLEARANCES, impedances of components, or PROTECTIVE EARTH CONNECTIONS prevent ACCESSIBLE PARTS from exceeding limits in 8.4 identified for tests relative to 8.5.1.1 to 8.5.1.3, and if a failure at that point regarded as a NORMAL or SINGLE FAULT CONDITION		N/A
	Each MEANS OF PROTECTION categorized relative to ME EQUIPMENT part(s) it protects from exceeding the allowable limits		N/A
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements as APPLIED PARTS, considered MEANS OF PATIENT PROTECTION		P
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION		N/A
8.5.2	Separation of PATIENT CONNECTIONS		P
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAX. MAINS VOLTAGE and complied with limit for PATIENT LEAKAGE CURRENT with 110 % of MAX. MAINS VOLTAGE applied (mA)..... :		N/A
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART		N/A
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function		N/A
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS		N/A
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART		N/A
	LEAKAGE CURRENT tests conducted per 8.7.4		N/A
	Dielectric strength test conducted per 8.8.3		N/A
	CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable		N/A
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.5.2.2	PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED,		N/A
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and		P
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low		P
	LEAKAGE CURRENT tests conducted per 8.7.4	See appended Table 8.7	P
	Dielectric strength test conducted per 8.8.3	See appended Table 8.8.3	P
	Relevant CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable		P
	The RISK MANAGEMENT FILE reviewed		P
8.5.2.3	A connector on a PATIENT lead located at the end of the lead remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE		N/A
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT	No leads or connectors	N/A
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter		N/A
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm		N/A
	– conductive part pluggable into a mains socket protected from making contact with parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a dielectric strength of 1500 V, and complying with 8.8.4.1		N/A
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N, except when RISK MANAGEMENT PROCESS indicated no unacceptable RISK existed from contact with objects other than a mains socket or a flat surface		N/A
8.5.3	MAXIMUM MAINS VOLTAGE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– MAXIMUM MAINS VOLTAGE determined to be the highest RATED supply voltage for single-phase or d.c. SUPPLY MAINS powered ME EQUIPMENT including INTERNALLY POWERED ME EQUIPMENT with a means of connection to a SUPPLY MAINS (V) ..... :		N/A
	When less than 100 V, MAXIMUM MAINS VOLTAGE was 250 V		N/A
	– MAXIMUM MAINS VOLTAGE was the highest RATED phase to neutral supply voltage for polyphase ME EQUIPMENT (V)..... :		N/A
	– for other INTERNALLY POWERED ME EQUIPMENT, maximum mains voltage was 250 V		N/A
8.5.4	WORKING VOLTAGE		P
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED voltage range resulting in highest measured value (V).... :		N/A
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple did not exceed 10 % of average value or peak voltage when peak-to-peak ripple exceeded 10 % of average value (V) ..... :	1.5 V battery	P
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V)..... :	1.5 V battery	P
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth		N/A
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V)..... :		N/A
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages		N/A
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V) ..... :		N/A
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.5.5.1	Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety, but not separate functions of same APPLIED PART		N/A
	Possibility of an OPERATOR receiving a shock from such parts taken into consideration in RISK MANAGEMENT PROCESS		N/A
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:		N/A
	a) Hazardous electrical energies, during a discharge of a cardiac defibrillator to a PATIENT connected to a DEFIBRILLATION PROOF APPLIED PART, as determined by peak voltage measured between points Y1 and Y2 of Figs 9 and 10 exceeding 1 V, did not appear on:		N/A
	– ENCLOSURE including connectors in PATIENT leads and cables when connected to ME EQUIPMENT, and excluding connecting lead from a DEFIBRILLATION-PROOF APPLIED PART or its connector when it was disconnected from ME EQUIPMENT (V_P) ..... :		N/A
	– SIGNAL INPUT/OUTPUT PARTS (V_P) ..... :		N/A
	– test metal foil with minimum area equal to base of ME EQUIPMENT where ME EQUIPMENT was placed on (V_P) ..... :		N/A
	– or, PATIENT CONNECTIONS of other APPLIED PARTS regardless of classification as a DEFIBRILLATION-PROOF APPLIED PART (V_P):		N/A
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS		N/A
	ME EQUIPMENT connected to circuit of Fig 9 for common-mode test, and test voltage applied to all PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PART connected together, excluding those PROTECTIVELY EARTHED or functionally earthed		N/A
	Peak voltage at Y1 and Y2 after operation of S (V_P)..... :		N/A
	Peak voltage at Y1 and Y2 after operation of S with V_T reversed (V_P) ..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT connected to circuit of Fig 10 for differential-mode test, and voltage applied to each PATIENT connection of DEFIBRILLATION-PROOF APPLIED PART in turn with all remaining PATIENT CONNECTIONS of the same DEFIBRILLATION-PROOF APPLIED PART connected to earth		N/A
	A single PATIENT CONNECTION APPLIED PART not subjected to differential-mode test		N/A
	– ME EQUIPMENT, except for PERMANENTLY INSTALLED ME EQUIPMENT, tested with and without PROTECTIVE EARTH CONDUCTOR connected		N/A
	– insulating surfaces of APPLIED PARTS covered with metal foil or, when appropriate, immersed in a 0.9 % saline solution		N/A
	– external connections to a FUNCTIONAL EARTH TERMINAL removed		N/A
	– parts specified in 8.5.5.1 a) not PROTECTIVELY EARTHED connected in turn to a display device		N/A
	– ME EQUIPMENT connected to SUPPLY MAINS and operated in accordance with instructions for use		N/A
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 1 with 2,3, & 4 connected to earth (V_P) ..... :		N/A
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 2 with 1,3, & 4 connected to earth (V_P) ..... :		N/A
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 3 with 1, 2, & 4 connected to earth (V_P) ..... :		N/A
	Peak voltage at Y1 and Y2 after the operation of S, V_T applied to PATIENT CONNECTION 4 with 1, 2, & 3 connected to earth (V_P) ..... :		N/A
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 1 with 2,3, & 4 connected to earth, V_T reversed (V_P) ..... :		N/A
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 2 with 1,3, & 4 connected to earth, V_T reversed (V_P) ..... :		N/A
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 3 with 1, 2, & 4 connected to earth, V_T reversed (V_P) ..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 4 with 1, 2, & 3 connected to earth, V_T reversed (V_P) ..... :		N/A
	ME EQUIPMENT continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE after the recovery time stated in ACCOMPANYING DOCUMENTS		N/A
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load to at least 90 % of energy delivered to this load with ME EQUIPMENT disconnected (J) ..... :		N/A
	Test voltage applied to each PATIENT CONNECTION or APPLIED PART in turn with all remaining PATIENT CONNECTIONS of same APPLIED PART connected to earth using circuit of Fig 11 and ACCESSORIES recommended by instructions as follows:		N/A
	a) APPLIED PART or PATIENT CONNECTION connected to test circuit		N/A
	b) Capacitor C charged to 5 kV d.c. with switch S in position A		N/A
	c) Capacitor C discharged by actuating switch S to position B, and measured energy E1 delivered to 100 Ω load (E1, J)..... :		N/A
	d) ME EQUIPMENT under test removed from test circuit and repeated steps b) and c), measuring energy E2 delivered to 100 Ω load (E2, J) ..... :		N/A
	e) Energy E1 was at least 90 % of E2 (E1, J) ..... :		N/A
8.6	Protective earthing, functional earthing and potential equalization of ME EQUIPMENT		N/A
8.6.1	Requirements of 8.6.2 to 8.6.8 applied		N/A
	Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8		N/A
8.6.2	PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR ..... :		N/A
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and clamping means cannot be loosened without TOOL		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Screws for internal PROTECTIVE EARTH CONNECTIONS are completely covered or protected against accidental loosening from outside ..... :		N/A
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		N/A
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		N/A
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part, except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE		N/A
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop		N/A
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits		N/A
8.6.5	Poorly conducting surface coatings on conductive elements removed at the point of contact		N/A
	Coating not removed when requirements for impedance and current-carrying capacity met		N/A
8.6.6	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections		N/A
	This requirement applied also where interchangeable parts are PROTECTIVELY EARTHED		N/A
8.6.7	Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR complies with following:		N/A
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE		N/A
	– RISK of accidental disconnection minimized in NORMAL USE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Terminal allows conductor to be detached without a TOOL		N/A
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		N/A
	– Terminal marked with symbol 8 of Table D.1 (i.e., symbol IEC 60417-5021, DB: 2002-10)		N/A
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		N/A
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		N/A
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION		N/A
8.6.9	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used only as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL and colored green and yellow		N/A
	Two MEANS OF PROTECTION provided by insulation of internal screens and all internal wiring connected to them with a related explanation in technical description..... :		N/A
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3		N/A
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Tables 8.7A, 8.7B, 8.7C, and 8.7.4.7	See appended Tables 8.7A, 8.7B, 8.7C, & 8.7.4.7	P
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except		P
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		N/A
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		N/A
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION		P

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Clause	Requirement + Test	Result - Remark	Verdict
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE		P
8.7.3	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b), and limits apply to d.c., a.c., composite waveforms, and unless otherwise stated, they are d.c. or r.m.s	See appended Tables 8.7A-8.7C, & 8.7.4.7	P
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 and 4, and values of a.c. are relative to currents having a frequency not less than 0.1 Hz	See appended Tables 8.7A-8.7C, & 8.7.4.7	P
	c) TOUCH CURRENT did not exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC})..... :		N/A
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC}) ..... :		P
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 [10] (I_{ENC}, I_{ESFC}) ..... :		N/A
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device..... :		N/A
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements		N/A
8.7.4.1	Figs 13-19 used to measure LEAKAGE and PATIENT AUXILIARY CURRENTS	Internal battery	N/A
	When other test Figs. yielding accurate results used, but results appeared close to permissible values, or when validity of results was in question, applicable test Figs used as deciding factor		N/A
	a) EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and AUXILIARY CURRENTS measured with ME EQUIPMENT running at operating temperature of 11.1.3 c)	See 8.7.3	P
	b) Number of tests reduced when examination of circuit arrangement, components, and materials of ME EQUIPMENT indicated no possibility of any HAZARDOUS SITUATION		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.7.4.2	ME EQUIPMENT for connection to a SUPPLY MAINS connected to an appropriate power source		N/A
	Tests on single-phase ME EQUIPMENT conducted at both supply polarities		N/A
	INTERNALLY POWERED ME EQUIPMENT tested without connections to a measuring supply circuit		P
8.7.4.3	a) CORD connected ME EQUIPMENT tested using the cord	Internally powered	N/A
	b) ME EQUIPMENT with an APPLIANCE INLET connected to measuring supply circuit via a 3 m DETACHABLE POWER SUPPLY CORD or a length and type specified in instructions for use (m) ..... :		N/A
	c) PERMANENTLY INSTALLED ME EQUIPMENT connected to measuring supply circuit by shortest possible connection		N/A
	d) Measuring arrangements were as follows:		N/A
	1) APPLIED PARTS, including PATIENT cables (when present), placed on an insulating surface with a dielectric constant of approximately 1 (e.g., expanded polystyrene) and approximately 200 mm above an earthed metal surface		N/A
	2) Reference earth of measuring circuits connected to protective earth of SUPPLY MAINS when an isolating transformer was not used for LEAKAGE CURRENT measurements		N/A
8.7.4.4	a) Source of LEAKAGE CURRENT loaded with measuring device or PATIENT AUXILIARY CURRENT with an impedance of approximately 1000 Ω for d.c., a.c. and composite waveforms ≤ 1 MHz		P
	b) Evaluation of current and current components based on 8.7.3 a) obtained automatically when a measuring device in Fig 12a) or a similar circuit used, allowing measurement of total effect of all frequencies with a single instrument		P
	When currents and current components with frequencies >1 kHz exceeded 10 mA limit in 8.7.3 e), they were measured by appropriate means		P
	c) Voltage measuring instrument in Fig 12 a) used with a min input resistance of 1 M Ω and a max input capacitance of 150 pF indicating true r.m.s. value of voltage with an indicating error ≤ ± 5 % of indicated value		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Scale indicates current through measuring device including automatic evaluation of components with frequencies > 1 kHz enabling direct comparison of reading with limits in 8.7.3		P
	Requirements limited to a frequency < than 1 MHz when proven by oscilloscope frequencies > such an upper limit do not occur in measured current (Max Frequency Hz)..... :		N/A
8.7.4.5	a) CLASS I ME EQUIPMENT tested based on Fig 13		N/A
	b) Current measured on more than one PROTECTIVE EARTH CONDUCTOR was aggregate current in protective earthing system of installation		N/A
	c) MANUFACTURER specified a test PROCEDURE and configuration for measurement of EARTH LEAKAGE CURRENT for FIXED ME EQUIPMENT with connections to earth through building structure		N/A
8.7.4.6	a) ME EQUIPMENT tested according to Fig 14, using an appropriate measuring supply circuit		N/A
	Measurement made with MD between earth and each part of the ENCLOSURE not PROTECTIVELY EARTHED		N/A
	Measurement made with MD between parts of ENCLOSURE not PROTECTIVELY EARTHED		P
	Measurement made with MD between earth and any part of ENCLOSURE, normally, PROTECTIVELY EARTHED under SINGLE FAULT CONDITION of interruption of any PROTECTIVE EARTH CONDUCTOR		N/A
	INTERNALLY POWERED ME EQUIPMENT investigated for TOUCH CURRENT only between parts of ENCLOSURE, not between ENCLOSURE and earth, except when 8.7.4.6 c) was applicable		P
	b) A metal foil 20x10 cm max applied in contact with ENCLOSURE or relevant part of ENCLOSURE made fully or partly of insulating material		P
	Metal foil shifted, when possible, to determine highest value of TOUCH CURRENT		P
	Metal foil was not in touch with any PROTECTIVELY EARTHED metal parts of ENCLOSURE, except metal parts of ENCLOSURE not PROTECTIVELY EARTHED partly or fully covered by metal foil		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Metal foil arranged to contact parts of ENCLOSURE normally PROTECTIVELY EARTHED when measuring TOUCH CURRENT under SINGLE FAULT CONDITION of interruption of a PROTECTIVE EARTH CONDUCTOR		N/A
	Foil size increased based on area of contact when surface of ENCLOSURE in contact with PATIENT or OPERATOR was larger than 20x10 cm (cmxcm) ..... :		N/A
	c) ME EQUIPMENT with a SIGNAL INPUT/OUTPUT PART additionally tested using transformer T2 when required (see 8.1 a))		N/A
	Transformer T2 voltage set at 110 % of MAXIMUM MAINS VOLTAGE, and specific pin configuration used when applying external voltage determined to be worst case based on test or circuit analysis		N/A
8.7.4.7	a) ME EQUIPMENT with an APPLIED PART tested based on Fig 15, and an ENCLOSURE, other than an APPLIED PART, of insulating material placed in a position of NORMAL USE on a flat metal surface and connected to earth		N/A
	b) ME EQUIPMENT with an F-TYPE APPLIED PART additionally tested based on Fig 16, and SIGNAL INPUT/OUTPUT PARTS not previously permanently earthed connected to earth		N/A
	Transformer T2 voltage in Fig 16 set at 110 % of MAXIMUM MAINS VOLTAGE		N/A
	Non-PROTECTIVELY EARTHED metal ACCESSIBLE PARTS including PATIENT CONNECTIONS of other APPLIED PARTS, when present, connected to earth		N/A
	c) ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART, additionally tested according to Fig 17when required		N/A
	Transformer T2 voltage set at 110 % of MAXIMUM MAINS VOLTAGE, and specific pin configuration used when applying external voltage was worst case based on test or circuit analysis		N/A
	d) ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART not PROTECTIVELY EARTHED or a TYPE BF APPLIED PART with metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED additionally tested based on Fig 18	Enclosure continuous part of the Applied part.	N/A
	Transformer T2 voltage set at 110 % of MAXIMUM MAINS VOLTAGE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Due to adequate separation of parts involved, this test was not conducted		N/A
	e) An APPLIED PART with an insulating surface tested using metal foil as in 8.7.4.6, or it was immersed in a 0.9 % saline solution ..... :		N/A
	Size of foil increased corresponding to area of contact when surface of APPLIED PART in contact with PATIENT was larger than 20 cm x 10 cm (cm x cm) ..... :		N/A
	Metal foil or saline solution considered as the only patient connection for APPLIED PART concerned		N/A
	f) Fluid used as PATIENT CONNECTION replaced by 0.9 % saline solution, and electrode placed in saline solution considered as PATIENT CONNECTION for APPLIED PART concerned		N/A
	g) PATIENT LEAKAGE CURRENT for TYPE B and TYPE BF APPLIED PARTS measured from and to all PATIENT CONNECTIONS of a single function connected directly together or loaded as in NORMAL USE		P
	– PATIENT LEAKAGE CURRENT for TYPE CF APPLIED PARTS measured from and to every PATIENT CONNECTION in turn		N/A
	PATIENT LEAKAGE CURRENT measurements made with the least favorable detachable part specified in instructions for use		P
	h) Total PATIENT LEAKAGE CURRENT measured from and to all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B, BF, or CF APPLIED PARTS) connected together		N/A
	Functional earth disconnected before the test when necessary		N/A
	i) Measuring device connected to each PATIENT CONNECTION in turn since PATIENT CONNECTIONS of APPLIED PART are loaded under NORMAL USE		N/A
8.7.4.8	ME EQUIPMENT with an APPLIED PART except for one with only a single PATIENT CONNECTION tested based on Fig 19 with a measuring supply circuit		N/A
	PATIENT AUXILIARY CURRENT measured between a single PATIENT CONNECTION and all other PATIENT CONNECTIONS, connected directly together or loaded as in NORMAL USE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.7.4.9	PATIENT LEAKAGE and AUXILIARY CURRENTS for ME EQUIPMENT with multiple PATIENT CONNECTIONS did not exceed limits for NORMAL CONDITION while one or more PATIENT CONNECTIONS are		N/A
	– disconnected from the PATIENT; and		N/A
	– disconnected from the PATIENT and earthed		N/A
	Actual measurements limited to representative number of combinations .....:		N/A
8.8	Insulation		P
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION and insulation between parts of opposite polarity of MAINS PART on SUPPLY MAINS side of mains fuse or OVER-CURRENT RELEASE (as one MEANS OF PROTECTION)		P
	Insulation exempted from test (complies with 4.8)		P
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8		N/A
8.8.2	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		N/A
	a) 0.4 mm, min, distance through insulation, or		N/A
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		N/A
	– at least two layers of material, each passed the appropriate dielectric strength test, or		N/A
	– three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test		N/A
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		N/A
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		P
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		N/A
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		N/A
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L		N/A
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		N/A
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		N/A
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded		N/A
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values		N/A
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension..... :		N/A
	Finished component complied with routine dielectric strength tests of 8.8.3	See appended Table 8.8.3A & 8.8.3B	P
	Tests of Annex L not repeated since material data sheets confirm compliance		N/A
8.8.3	Solid insulating materials with a safety function withstood dielectric strength test voltages applied in accordance with methods of this Clause	See appended Table 8.8.3A & 8.8.3B	P
	a) Waveform and frequency of test voltage resulted in dielectric stress on insulation at least equal to that in NORMAL USE		P
	Test voltage with a different waveform and frequency than the voltage in NORMAL USE applied when manufacturer demonstrated dielectric stress on insulation tested was not diminished (waveform, frequency Hz) ..... :	Waveform: sinusoidal Frequency = 50 Hz	P
	Test performed with a 50 or 60 Hz sinusoidal voltage in NORMAL USE, and relevant insulation subjected to a non-sinusoidal a.c. voltage		P
	Test voltage for WORKING VOLTAGE applicable to insulation was ≥ than in Table 6		P
	b) No breakdown occurred during tests		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Breakdown indicated by a rapid uncontrolled increase in current when insulation unable to restrict flow of current		N/A
	Corona discharge or a single momentary flashover not regarded as insulation breakdown		N/A
	c) A large part or entire ME EQUIPMENT tested when individual solid insulation could not be tested, different types and levels of insulation not overstressed, and following was considered		N/A
	– Metal foil used on non-conductive surfaces of ENCLOSURE or part of it positioned to prevent flashover at edges of insulation linings		N/A
	When applicable, metal foil moved to test all parts of surface		N/A
	– Circuits on either side of insulation under test connected or short-circuited to prevent stress on components within circuits		N/A
	– IEC 60384-14 Certified capacitors across insulation under test disconnected during test		N/A
8.8.4	Insulation other than wire insulation		P
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT		P
	ME EQUIPMENT and RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests	RMF includes storage temperature, operating temperature, exposure to liquids, and transportation.	P
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat		N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat:	No heat produced	N/A
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using apparatus of Fig 21	Metal enclosure	N/A
	Surface of part placed in a heating cabinet at 75° C ± 2 °C or ambient temperature indicated in technical description ± 2 ° C plus temperature rise of relevant part of insulating material measured during test of 11.1, higher of the two (° C)..... :		N/A
	A steel ball 5 mm in diameter pressed against the surface with a force of 20 N		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ± 2 °C plus temperature rise determined during test of 11.1 of relevant part, higher of the two (° C) ..... :		N/A
	Impression made by the ball after 1 h was 2 mm or less in diameter (mm)..... :		N/A
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION		N/A
8.8.4.2	Resistance to environmental stress		P
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt or dust resulting from wear of parts within ME EQUIPMENT to the extent CREEPAGE and CLEARANCES would be reduced below 8.9	No such parts	N/A
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION		N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION		N/A
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen not less than 97 % pure, to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples		N/A
	Samples kept in cylinder at 70 °C ± 2 °C for 96 h, and immediately afterwards, taken out of cylinder and left at room temperature for at least 16 h		N/A
	There were no cracks visible to naked eyes		N/A
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		P
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are ≥ to values in Tables 11 to 16 (inclusive), except as specified in Clauses 8.9.1.2 to 8.9.1.15	Comply with table 12	P
8.9.1.2	Tables 11 to 16 (inclusive) not applied to CREEPAGE and CLEARANCES forming MEANS OF OPERATOR PROTECTION per IEC 60950-1 for INSULATION CO-ORDINATION and used under conditions compliance was tested		P

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Clause	Requirement + Test	Result - Remark	Verdict
8.9.1.3	Specified min CLEARANCE applied as min CREEPAGE for CREEPAGE DISTANCES across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics		N/A
8.9.1.4	When min CREEPAGE derived from Tables 11 to 16 (inclusive) was less than min applicable CLEARANCE, value of min CLEARANCE applied as min CREEPAGE DISTANCE		N/A
8.9.1.5	ME EQUIPMENT RATED to operate at an altitude of 2000 m		P
	ME EQUIPMENT RATED to operate at an altitude specified by MANUFACTURER (m) ..... :		N/A
	Operating altitude corresponding to actual air pressure for ME EQUIPMENT intended for pressurized environments (e.g., aircraft) used in determining multiplication factor from Table 8, and AIR CLEARANCE was multiplied by this factor		N/A
	CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE		N/A
8.9.1.6	When WORKING VOLTAGE was between those in Tables 11 to 16 (inclusive), CREEPAGE and CLEARANCES calculated as follows:		P
	– CREEPAGE DISTANCES determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) ..... :		P
	– CLEARANCES for PEAK WORKING VOLTAGES above 2800 V peak or d.c. determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) ..... :		N/A
	– for AIR CLEARANCES corresponding to PEAK WORKING VOLTAGE up to 2800 V peak or d.c., the higher of the two values applied		P
8.9.1.7	Material groups classified in accordance with Table 9 (Material Group) ..... :	Assumed IIIb	P
	Material group evaluated using 50 drops of solution A based on test data for material according to IEC 60112		N/A
	Material of unknown group considered group IIIb		P
8.9.1.8	– Pollution degree 1: Micro-environment sealed to exclude dust and moisture		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Pollution degree 2: Micro-environment with non-conductive pollution, except occasional temporary conductivity caused by condensation		P
	– Pollution degree 3: Micro-environment subject to conductive pollution, or dry non-conductive pollution that could become conductive due to expected condensation		N/A
	– Pollution degree 4: Micro-environment where continuous conductivity occurs due to conductive dust, rain, or other wet conditions		N/A
	Pollution degree 4 not used for insulation providing a MEANS OF PROTECTION		N/A
	Where insulation between MAINS PART and earth might be compromised, measures such as maintenance ensure that micro-environment is mitigated to a lower pollution degree		N/A
8.9.1.9	Applicable value of MAINS TRANSIENT VOLTAGE determined from overvoltage category according to IEC 60664-1 and NOMINAL a.c. MAINS VOLTAGE using Table 10 (V_{MT} peak, V_{MN} r.m.s.) ..... :		N/A
8.9.1.10	Required CLEARANCE for MAINS PARTS operating on RATED MAINS VOLTAGES up to 300 V were values for r.m.s. or d.c. RATED MAINS VOLTAGE in Table 13 plus additional CLEARANCE in Table 14 for PEAK WORKING VOLTAGE		N/A
8.9.1.11	Overvoltage category II applied according to IEC 60664-1		N/A
	For ME EQUIPMENT intended for overvoltage category III, Tables 13 to 15 (inclusive) not used for clearance, instead values in the next MAINS TRANSIENT VOLTAGE column upwards used		N/A
	When PATIENT protection (Table 12) was required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, guidance provided on values required in the rationale for 8.9 used		N/A
8.9.1.12	A SECONDARY CIRCUIT derived from a SUPPLY MAINS, normally, considered to be overvoltage category I according to IEC 60664-1 when the MAINS PART is overvoltage category II (Table 15)		N/A
	Table 15 applied to earthed SECONDARY CIRCUIT or INTERNALLY POWERED ME EQUIPMENT		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Requirements for primary circuits in Tables 13 and 14 used for an unearthed SECONDARY CIRCUIT derived from a SUPPLY MAINS		N/A
	Table 15 applied when SECONDARY CIRCUIT was separated from MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients in SECONDARY CIRCUIT were below the levels expected for overvoltage category I		N/A
	Table 15 column for circuits not subject to transient overvoltages applied to:		P
	– d.c. SECONDARY CIRCUITS reliably connected to earth and have capacitive filtering limiting peak-to-peak ripple to 10 % of d.c. voltage, and		N/A
	– circuits in INTERNALLY POWERED ME EQUIPMENT		P
8.9.1.13	Table 15 for PEAK WORKING VOLTAGES above 1400 V peak or d.c. not applied because all the following conditions were met:		N/A
	– CLEARANCE was at least 5 mm		N/A
	– insulation complied with dielectric strength test of 8.8.3 using an a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, or		N/A
	– a d.c. test voltage equal to peak value of a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, and		N/A
	– CLEARANCE path was partly or entirely through air or along the surface of an insulating material of material group I		N/A
	Dielectric strength test conducted only across part(s) of the path that are through air when CLEARANCE path was also partly along surface of a non- group I material		N/A
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION obtained by doubling values in Table 16 for one MEANS OF OPERATOR PROTECTION		N/A
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION for insulation in MAINS PART between parts of opposite polarity, therefore, min CREEPAGE and CLEARANCES not applied	See appended Table 8.9.2	P
	b) Contribution to CREEPAGE DISTANCES of grooves or air gaps less than 1 mm wide limited to widths		P
	c) Relative positioning of CLEARANCE providing a MEANS OF PROTECTION is such that the relevant parts are rigid and located by molding, or there is no reduction of a distance below specified value by deformation or movement of parts		P
	Normal or likely limited movements of relevant parts taken into consideration when calculating minimum AIR CLEARANCE		P
8.9.3	Spaces filled by insulating compound		N/A
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound were such that CLEARANCES and CREEPAGE DISTANCES do not exist		N/A
	Thermal cycling, humidity preconditioning, and dielectric strength tests in 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4 conducted		N/A
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (clause 8.8.3), test voltage multiplied by 1.6		N/A
	Cracks or voids in insulating compound affecting homogeneity of material did not occur		N/A
8.9.3.3	For situations where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint		N/A
	A winding of solvent-based enameled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:		N/A
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling, it was subjected to dielectric strength test of 8.8.3 except at 1.6 times the test voltage		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of 8.8.3 at 1.6 times the test voltage		N/A
8.9.3.4	One sample containing the cemented joint subjected to a sequence of temperature cycling tests for 10 times		N/A
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES		P
	CREEPAGE AND CLEARANCES measured using Figs 22 to 31 (inclusive)		P
	Corners with included angles less than 80° assumed to be bridged with an insulating link of 1 mm moved into the least favorable position		P
	Distance of 1 mm or more across the top of a groove did not constitute a CREEPAGE DISTANCE		P
	CREEPAGE and CLEARANCES between parts moving relative to each other measured with the parts in their least favorable positions		P
	Calculated CREEPAGE DISTANCE was never less than measured AIR CLEARANCE		P
	Coatings of varnish, enamel, or oxide disregarded		P
	Coverings of insulating materials equivalent to a sheet of insulating material of equal thickness with respect to their electrical, thermal, and mechanical properties considered as insulation		P
	Minimum values in Tables 11 to 16 (inclusive) applied to sum of sections for CREEPAGE or CLEARANCES for one or two MEANS OF PROTECTION interrupted by one or more floating conductive parts (distances less than 1 mm disregarded)		P
	Walls of grooves transverse to CREEPAGE DISTANCE counted as CREEPAGE DISTANCE only when width of the groove was more than 1 mm, otherwise grooves disregarded		P
	CREEPAGE DISTANCES for a barrier placed on surface of insulation or held in a recess measured over barrier only when dust and moisture could not penetrate into the joint or recess		P
	Measurements for ME EQUIPMENT with an APPLIANCE INLET made with an appropriate connector inserted		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	For other ME EQUIPMENT with POWER SUPPLY CORDS measurements made with conductors of largest cross-sectional area specified by MANUFACTURER and without conductors		N/A
	Movable parts placed in the least favorable position, and nuts and screws with non-circular heads tightened in the least favorable position		N/A
	CREEPAGE and CLEARANCES through slots or openings in external parts measured to the standard test finger of Fig 6		N/A
	Measurements made applying a 2 N force on points of bare conductors using a standard test finger (as in Fig 6) complied with requirements for CREEPAGE DISTANCES and AIR CLEARANCES		N/A
	Measurements made applying a 30 N force to outside of metal ENCLOSURE using a standard test finger (as in Fig 6) complied with requirements for CREEPAGE and CLEARANCES		P
	When relevant, CREEPAGE and CLEARANCES measured after use of test hook in 5.9.2.2		N/A
8.10	Components and wiring		P
8.10.1	Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely as indicated in RISK MANAGEMENT FILE		P
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION		N/A
	Conductors and connectors of ME EQUIPMENT when breaking free at their joint and moving about their support point are not capable of touching circuit points resulting in a HAZARDOUS SITUATION as indicated in RISK MANAGEMENT FILE		N/A
	Breaking free of one means of mechanical restraint considered a SINGLE FAULT CONDITION	Only flat cables used	N/A
	Stranded conductors are not solder-coated when secured by clamping means to prevent poor contact which could create HAZARDOUS SITUATIONS	Only flat cables used	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.10.3	Flexible cords detachable without a TOOL used to interconnect different parts of ME EQUIPMENT provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS of 8.4 when a connection is loosened or broken as indicated by measurement or using test finger		N/A
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		N/A
8.10.4.1	Control devices of ME EQUIPMENT and their associated connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION		N/A
	d.c. limit of 60 V applied to d.c. with no more than 10 % peak-to-peak ripple		N/A
	42.4 V peak limit applied when ripple exceeded 10 % peak-to-peak limit		N/A
8.10.4.2	Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT at both ends of cable to control device complied with 8.11.3 when breaking free or shorting between conductors could result in a HAZARDOUS SITUATION		N/A
	This requirement applied to other HAND-HELD parts when disturbance or breaking of one or more of connections could result in a HAZARDOUS SITUATION		N/A
8.10.5	Mechanical protection of wiring		
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION		N/A
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION as shown by manual tests and RISK MANAGEMENT FILE		P
8.10.6	Guiding rollers of insulated conductors prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead concerned in NORMAL USE		N/A
8.10.7	a) Insulating sleeve that can only be removed by breaking or cutting, or secured at both ends, is used on internal wiring of when needed		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics		N/A
	c) Insulated conductors subject to temperatures > 70 °C in NORMAL USE provided with insulation of heat-resistant material when compliance is likely to be impaired due to deterioration of insulation		N/A
8.11	MAINS PARTS, components and layout		N/A
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles		N/A
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)		N/A
	b) Means of isolation incorporated in ME EQUIPMENT, and external means described in technical description		N/A
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE and CLEARANCES in IEC 61058-1 for a MAINS TRANSIENT VOLTAGE of 4 kV		N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or other external flexible lead		N/A
	e) Direction of movement of actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447		N/A
	f) A suitable plug device such as an APPLIANCE COUPLER or a flexible cord with a MAINS PLUG used in non-PERMANENTLY INSTALLED ME EQUIPMENT to isolate it from SUPPLY MAINS considered to comply with 8.11.1 a)		N/A
	g) A fuse or a semiconductor device not used as an isolating means in the sense of this clause		N/A
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering		N/A
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage (symbol 10 of Table D.1 is insufficient)		N/A
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause		N/A
	Standard test finger of Fig 6 applied		N/A
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2		N/A
8.11.3	POWER SUPPLY CORDS		N/A
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD		N/A
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, designation 53)		N/A
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE		N/A
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 (mm^2 Cu) ..... :		N/A
8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6		N/A
8.11.3.5	Cord anchorage (for APPLIANCE COUPLERS not complying with IEC 60320-1)		N/A
	a) Conductors of POWER SUPPLY CORD provided with strain relieve and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Cord anchorage of POWER SUPPLY CORD is made of and arranged as follows when a total insulation failure of POWER SUPPLY CORD caused conductive non-PROTECTIVELY EARTHED ACCESSIBLE PARTS to exceed limits of 8.4:		N/A
	– insulating material, or		N/A
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or		N/A
	– metal provided with an insulating lining affixed to cord anchorage, except when it is a flexible bushing forming part of the cord guard in 8.11.3.6, and complying with the requirements for one MEANS OF PROTECTION		N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		N/A
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components other than parts of cord anchorage		N/A
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals when cord anchorage fails		N/A
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		N/A
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18		N/A
	Cord subjected to a torque in Table 18 for 1 min immediately after pull tests		N/A
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their normally connected position		N/A
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		N/A
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.11.3.6	POWER SUPPLY CORDS other than for STATIONARY ME EQUIPMENT protected against excessive bending at inlet opening of equipment or of MAINS CONNECTOR by means of an insulating cord guard or by means of an appropriately shaped opening		N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		N/A
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D^2 gram (D in mm) attached to the free end of cord (g)..... :		N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		N/A
	Radius of curvature of the cord, immediately after mass was attached, was not less than 1.5 x D ..		N/A
8.11.4	MAINS TERMINAL DEVICES		N/A
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD replaceable by SERVICE PERSONNEL provided with MAINS TERMINAL DEVICES ensuring reliable connection		N/A
	Terminals alone are not used to keep conductors in position, except when barriers are provided such that CREEPAGE and CLEARANCES cannot be reduced below 8.9 if any conductor breaks away		N/A
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked according to 7.3.7 used as terminals intended for external conductors		N/A
	Screws and nuts clamping external conductors do not serve to secure any other component, except they also clamp internal conductors when unlikely to be displaced when fitting the supply conductors		N/A
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		N/A
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL closely grouped to provide convenient means of connection		N/A
	b) PROTECTIVE EARTH CONDUCTOR connections complied with 8.6		N/A
	c) Marking of MAINS TERMINAL DEVICES complied with 7.3		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		N/A
	e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area in Table 17 stripped 8 mm and with a single free wire bent in every possible direction without pulling back insulating sheath or making sharp bends around partitions		N/A
8.11.4.3	Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced below 8.9 after fastening and loosening a conductor of largest cross-sectional area 10 times		N/A
8.11.4.4	Terminals with clamping means for a rewirable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened as verified by test of 8.11.3.4		N/A
8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewirable POWER SUPPLY CORD to allow easy introduction and connection of conductors, and covers fitted without damage to conductors or their insulation		N/A
	Correct connection and positioning of conductors before ACCESS COVER was fitted verified by an installation test		N/A
8.11.5	Mains fuses and OVER-CURRENT RELEASES		N/A
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection according to 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT		N/A
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT		N/A
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts of opposite polarity within MAINS PART, and between all parts of MAINS PART and earth, and such provisions continued within all components		N/A
	Effect of short-circuit fault conditions in other circuits taken into consideration before eliminating fuses or OVER-CURRENT RELEASES		N/A
	Protective devices have adequate breaking capacity to interrupt the maximum fault current including the available short-circuit		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		N/A
	Fuses complying with IEC 60127 have high breaking capacity (1 500 A) and prospective short-circuit current > 35 A or 10 times current rating of the fuse, whichever is greatero		N/A
	Justification for omission of fuses or OVER-CURRENT RELEASES is in RISK MANAGEMENT FILE		N/A
8.11.6	Internal wiring of the MAINS PART		N/A
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE and protective devices is not < minimum required for POWER SUPPLY CORD as in 8.11.3.3 (mm^2 Cu) ..... :		N/A
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits sufficient to prevent fire in case of fault currents		N/A
	When necessary, ME EQUIPMENT connected to a SUPPLY MAINS with max available short-circuit fault, and subsequent simulation of a fault in a single insulation in MAINS PART did not result in any of the HAZARDOUS SITUATIONS in 13.1.2		N/A
9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		P
9.1	ME EQUIPMENT complies with Clause 4 for design and manufacture, and mechanical strength (15.3)		P
9.2	HAZARDS associated with moving parts		N/A
9.2.1	When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level	No moving parts	N/A
	RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)		N/A
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its function		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Warnings marked on ME EQUIPMENT or included in instructions for use when HAZARDS persisted after implementing all reasonable protective measures		N/A
9.2.2	TRAPPING ZONE		N/A
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:		N/A
	– Gaps in Clause 9.2.2.2, or		N/A
	– Safe distances in Clause 9.2.2.3, or		N/A
	– GUARDS and protective measures in 9.2.2.4, or		N/A
	– Continuous activation in Clause 9.2.2.5		N/A
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM		N/A
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions specified in Table 20		N/A
9.2.2.3	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13852		N/A
	Distances measured from expected positions of OPERATOR, PATIENT, and others near EQUIPMENT in NORMAL USE or under foreseeable misuse		N/A
9.2.2.4	GUARDS and protective measures		N/A
9.2.2.4.1	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when GUARDS and protective measures were of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK based on results of applicable tests in 15.3 for ENCLOSURES		N/A
9.2.2.4.2	FIXED GUARDS securely held in place by systems that cannot be dismantled without a TOOL		N/A
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,		N/A
	– absence or failure of one of their components prevents starting, and stops moving parts		N/A
	Movable GUARDS complied with all applicable tests as confirmed by review of RISK MANAGEMENT FILE		N/A
9.2.2.4.4	Protective measures provided in control system prevented moving parts from starting to move while in reach of persons		N/A
	– protective measures prevented TRAPPING ZONE from reach, or, when it was reached, system movement stopped once ME EQUIPMENT started to move, and in the latter case, no HAZARD or damage resulted		N/A
	– when protective measure was in a SINGLE FAULT CONDITION, and an unacceptable RISK could arise, one or more emergency stopping device(s) provided		N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N/A
9.2.2.5	Continuous activation		N/A
	TRAPPING ZONE not considered to present a MECHANICAL HAZARD where impractical to make TRAPPING ZONE inaccessible when:		N/A
	a) movement was in OPERATOR'S field of view		N/A
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR as long as OPERATOR response to deactivate device relied upon to prevent HARM		N/A
	Manually operated movements complied with this clause since mass and velocity allowed adequate control of positioning without causing an unacceptable RISK		N/A
	c) when in a SINGLE FAULT CONDITION of continuous activation system an unacceptable RISK could arise, one or more emergency stopping device(s) provided in ME EQUIPMENT		N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT, when contact with ME EQUIPMENT could result in a HAZARDOUS SITUATION, limited to allow OPERATOR control of positioning without resulting in an unacceptable RISK		N/A
	Over travel (stopping distance) of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK		N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N/A
9.2.3	Other HAZARDS associated with moving parts		N/A
9.2.3.1	Controls positioned, recessed, or protected by other means and could not be accidentally actuated to result in unacceptable RISK, except when ergonomic considerations for a PATIENT with special needs require otherwise		N/A
9.2.3.2	RISK due to over travel (past range limits) of ME EQUIPMENT parts reduced to an acceptable level, and stops or other means with mechanical strength to withstand intended loading in NORMAL USE and foreseeable misuse provided limiting measure in NORMAL and SINGLE FAULT CONDITION		N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N/A
9.2.4	Emergency stopping devices		N/A
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power:		N/A
	a) Emergency stopping device reduced RISK to an acceptable level		N/A
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		N/A
	c) Emergency stopping device actuator was readily accessible to OPERATOR		N/A
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		N/A
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original HAZARD		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		N/A
	g) Means for stopping of movements operate as a result of one single action		N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		N/A
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 (symbol IEC 60417-5638, DB:2002-10) or "STOP"		N/A
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed		N/A
	k) Emergency stopping device is suitable for its application		N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N/A
9.2.5	Means provided to permit Quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a protective measure, or emergency stopping, and		N/A
	– Uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented		N/A
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented		N/A
	– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way		N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N/A
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in an unacceptable RISK avoided or covered		P
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		P
9.4	Instability HAZARDS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.4.1	ME EQUIPMENT, other than FIXED and hand-held, for placement on a surface did not overbalance (tip over) or move unexpectedly, to the degree that it could present an unacceptable RISK to PATIENT, or OPERATOR as tested in 9.4.2 to 9.4.4		N/A
9.4.2	Instability – overbalance		N/A
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when not specified, as in 9.4.2.2, and placed on a 10° inclined plane from horizontal consisting of a hard and flat surface (e.g., concrete floor covered with 2 to 4 mm thick vinyl material)		N/A
9.4.2.2	Instability excluding transport		N/A
	ME EQUIPMENT or its parts prepared based on a) to g), inclusive, did not overbalance when placed in different positions of NORMAL USE, except transport positions, on a 5° inclined plane from horizontal consisting of a hard and flat surface		N/A
	A warning notice provided stating "Transport only under conditions clearly described in instructions for use or marked on ME EQUIPMENT with an indication of RESIDUAL RISK if ME EQUIPMENT or its parts overbalances" when overbalance occurred during 10° inclined plane test		N/A
9.4.2.3	Instability from horizontal and vertical forces		N/A
	a) ME EQUIPMENT with a mass of 25 kg or more, other than FIXED ME EQUIPMENT for use on floor, did not overbalance due to pushing, resting, etc		N/A
	Surfaces of ME EQUIPMENT where a RISK of overbalancing exists from pushing, leaning, resting etc., permanently marked with a CLEARLY LEGIBLE warning of the RISK (e.g., safety sign 5 of Table D.2, safety sign ISO 7010-P017)		N/A
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a force of 25 % of its weight, but not more than 220 N, applied in different directions, except a direction with an upward component		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) ME EQUIPMENT, other than FIXED ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping, except when a legible warning of this RISK, provided on ME EQUIPMENT (e.g., safety signs 6 and 7 of Table D.2, safety signs ISO 7010-P018, or ISO 7010-P019 as appropriate)		N/A
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a constant downward force of 800 N applied at the point of maximum moment to working surfaces, offering an foothold or sitting surface of a min 20 x 20 cm area, and at a height ≤ 1 m from the floor		N/A
9.4.2.4	Castors and wheels		N/A
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT (e.g., castors or wheels) did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE		N/A
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT along a hard and flat horizontal surface did not exceed 200 N applied at a height of 1 m above floor or highest point on ME EQUIPMENT when < 1 m high, except when instructions for use indicated more than one person needed (N)..... :		N/A
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg configured with a SAFE WORKING LOAD, moved as in NORMAL USE 10 times in forward direction over (up and down) a solid vertical plane obstruction installed on the floor with wheels impacting the obstruction at a speed of 0.4 m/s ± 0.1 m/s for manual or with max speed for motor driven MOBILE ME EQUIPMENT		N/A
	ME EQUIPMENT went up the obstruction without overbalancing or any other unacceptable RISK as determined by examination of ME EQUIPMENT, its parts, and RISK MANAGEMENT FILE		N/A
	There was no reduction of CREEPAGE and CLEARANCES below 8.9, no access to parts exceeding limits in 8.4, and no access to moving parts capable of causing HARM, and		N/A
	– Assessment criteria in Clause 9 and 11.6 used		N/A
	– Dielectric strength test of 8.8.3 conducted to evaluate integrity of solid SUPPLEMENTARY or REINFORCED INSULATION		N/A
	– CREEPAGE DISTANCES and AIR CLEARANCES measured compared favorably with min distances in clause 8.9		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Small chips not adversely affecting protection against electric shock or moisture, disregarded		N/A
9.4.3	Instability from unwanted lateral movement (including sliding)		N/A
9.4.3.1	a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control		N/A
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements of ME EQUIPMENT or its parts in transport position		N/A
	c) No unacceptable RISK due to unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position or worst case NORMAL USE position with SAFE WORKING LOAD, and locking device activated, on a 10° inclined hard flat surface with castors in the worst-case position		N/A
	Following initial elastic movement, creepage, and pivoting of castors, no further movement of MOBILE ME EQUIPMENT > 50 mm (in relation to inclined plane) occurred (mm) ..... :		N/A
	RISK due to any initial movement assessed taking into consideration NORMAL USE of ME EQUIPMENT		N/A
9.4.3.2	Instability excluding transport		N/A
	a) Further movement of ME EQUIPMENT (after initial elastic movement) was less than 50 mm when MOBILE ME EQUIPMENT with a SAFE WORKING LOAD positioned on a 5° inclined hard flat surface with wheel locked or braking system activated (mm) ..... :		N/A
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT		N/A
	b) TRANSPORTABLE or STATIONARY ME EQUIPMENT for use on the floor and with a SAFE WORKING LOAD prepared as in 9.4.2.2 and placed on a horizontal plane with locking device activated and castors, when supplied, in their worst –case position		N/A
	Further movement of ME EQUIPMENT (after initial elastic movement), was no more than 50 mm when a force of 25 % of weight of unit, but less than 220 N, applied in different directions, except a direction with an upwards component, at highest point of ME EQUIPMENT but ≤ 1.5 m from floor ..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT		N/A
9.4.4	Grips and other handling devices		N/A
	a) ME EQUIPMENT other than PORTABLE EQUIPMENT or its part with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method, except when handling is obvious and causing HAZARDS		N/A
	Handles, when supplied, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS		N/A
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carring by two or more persons as confirmed by actual carrying		N/A
	c) Carrying handles and grips and their means of attachment withstood application of a force four times weight of ME EQUIPMENT in different directions of NORMAL USE and transport (N).... :		N/A
	Force distributed between multiple handles, when supplied, of PORTABLE ME EQUIPMENT by measuring percentage of ME EQUIPMENT weight sustained by each handle with ME EQUIPMENT in normal carrying position (N)..... :		N/A
	Each handle of ME EQUIPMENT with multiple handles able of be carried by only one handle was capable of sustaining total force (N)..... :		N/A
	Force applied uniformly over a 7 cm length of handle at centre, starting at zero and gradually increased to test value in 5 to 10 s and maintained for 1 min		N/A
	Handles did not break loose, did not exhibit permanent distortion, cracking, or other evidence of breakdown		N/A
9.5	Expelled parts HAZARD		N/A
9.5.1	Suitability of means of protecting against unacceptable RISK of expelled parts determined by assessment and examination of RISK MANAGEMENT FILE		N/A
9.5.2	Cathode ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965		N/A
9.6	Acoustic energy (including infra- and ultrasound) and vibration		P

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Clause	Requirement + Test	Result - Remark	Verdict
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK as confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and tests of 9.6.2 and 9.6.3		P
9.6.2	Acoustic energy		
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE, except for auditory alarm signals		P
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA) ..... :		N/A
	– 140 dB un-weighted sound pressure level for impulsive or impact acoustic energy (noise) (dB) :	The peak sound pressure is always below 140dB	P
	Maximum A-weighted sound pressure level was measured at min distances of PATIENT, OPERATOR, or other persons from source of noise in NORMAL USE (or calculated per ISO 3746, ISO 9614-1 or IEC61672-1) under following conditions:		P
	a) ME EQUIPMENT operated under worst-case NORMAL CONDITION		P
	b) All protective means provided or called for in ACCOMPANYING DOCUMENTS were in place during sound measurement		P
	c) Sound level meters used in measurement conform to IEC 61672-1 and IEC 61672-2		P
	d) Test room was semi-reverberant with hard reflecting floor, distance between any wall or other object and surface of ME EQUIPMENT was ≥ 3 m		P
9.6.2.2	RISK MANAGEMENT FILE examined for RISKS associated with infrasound or ultrasound, when present, addressed in RISK MANAGEMENT PROCESS		N/A
9.6.3	Hand-transmitted vibration		N/A
	Means provided, except for INTENDED USE vibrations, to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values measured per ISO 5349-1 at points of hand contact with PATIENT or OPERATOR		N/A
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2) ..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Accelerations for different times, inversely proportional to square root of time (m/s^2) ..... :		N/A
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		N/A
9.7.1	Requirements of this clause applied to vessels and parts of ME EQUIPMENT subject to pressure resulting in rupture and unacceptable RISK		N/A
	Parts of a pneumatic or hydraulic system used as a support system, additionally, complied with 9.8		N/A
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met following requirements based on examination of RISK MANAGEMENT FILE:		N/A
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum		N/A
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure		N/A
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects		N/A
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply		N/A
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		N/A
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity		N/A
9.7.3	Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:		N/A
	a) RATED maximum supply pressure from an external source		N/A
	b) Pressure setting of a pressure-relief device provided as part of assembly		N/A
	c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.7.4	Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by examination of ME EQUIPMENT and RISK MANAGEMENT FILE, and by functional tests		N/A
9.7.5	A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was > 50 kPa, and product of pressure and volume was > 200 kPa.l		N/A
	HYDRAULIC TEST PRESSURE was MAXIMUM PERMISSIBLE WORKING PRESSURE times a factor obtained from Fig 32, and pressure was gradually raised to specified test value and held for 1 min		N/A
	Sample did not burst, was not permanently deformed, and no leaks developed		N/A
	No leakage occurred at a gasket at a pressure below 40 % of required test value, or below MAXIMUM PERMISSIBLE WORKING PRESSURE ..... :		N/A
	No leakage occurred for pressure vessels intended for toxic, flammable, or otherwise hazardous substances, and for other pressure vessels, leakage resulting in an unacceptable RISK did not occur (e.g., high pressure fluid jet)		N/A
	When unmarked pressure vessels and pipes could not be hydraulically tested, integrity verified by other suitable tests..... :		N/A
9.7.6	Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device under different conditions of NORMAL USE		N/A
9.7.7	Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests:		N/A
	a) Connected as close as possible to pressure vessel or parts of system it is intended to protect		N/A
	b) Installed to be readily accessible for inspection, maintenance, and repair		N/A
	c) Could be adjusted or rendered inoperative without a TOOL		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	d) With discharge opening located and directed as to not to release material towards any person		N/A
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK		N/A
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure		N/A
	g) No shut-off valve provided between a pressure-relief device and parts it is intended to protect		N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		N/A
9.8	HAZARDS associated with support systems		N/A
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK		N/A
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD		N/A
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK		N/A
	– RISK ANALYSIS of support systems included HAZARDS from static, dynamic, vibration, impact and pressure loading, foundation and other movements, temperature, environmental, manufacture and service conditions		N/A
	– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES		N/A
	– Instructions on attachment of structures to a floor, wall, ceiling, etc. included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials		N/A
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.8.2	Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or when support is a foot rest		N/A
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and processing of materials		N/A
	When test results were part of information, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK		N/A
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems		N/A
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS minimize RISK of physical injuries and accidental loosening of secured joints		N/A
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported or suspended by ME EQUIPMENT or its parts		N/A
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER		N/A
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications		N/A
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS		N/A
	Max allowable PATIENT mass > 135 kg stated in ACCOMPANYING DOCUMENTS		N/A
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance		N/A
9.8.3.2	Part of SAFE WORKING LOAD representing mass of PATIENTS or OPERATORS is distributed on support/suspension surface representing human body as in Fig A.19		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Part of SAFE WORKING LOAD representing mass of ACCESSORIES deployed as in NORMAL USE and, when not defined, at worst case position permitted by configuration or ACCESSORIES attachment on support/suspension parts		N/A
	a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m^2 on a foot rest temporarily supporting a standing PATIENT or OPERATOR		N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing, and tests:		N/A
	PATIENT support/suspension system positioned horizontally in most disadvantageous position in NORMAL USE, and a mass 2 x 135 kg or twice intended person's load (the greater used), applied to foot rest over an area of 0.1 m^2 for 1 min (Kg) :		N/A
	Damage or deflection resulting in an unacceptable RISK did not occur on foot rest and its secured joints		N/A
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK		N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing, and by a test:		N/A
	PATIENT support/suspension system set in most unfavorable NORMAL USE position, and a mass of 60 % of part of SAFE WORKING LOAD simulating PATIENT or OPERATOR, or a min 80 kg, placed on support or suspension system with center of load 60 mm from outer edge of support or suspension system for at least one minute (Kg) ..... :		N/A
	Deflection of support/suspension system resulting in an unacceptable RISK did not occur		N/A
9.8.3.3	Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE did not result in an unacceptable RISK as confirmed by following test:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	PATIENT support/suspension system set in most unfavorable NORMAL USE position, and a mass as in Fig 33 equal to SAFE WORKING LOAD simulating PATIENT or OPERATOR dropped from 150 mm above seat area on an area of support/ suspension a PATIENT or OPERATOR can sit (Kg)..... :		N/A
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES		N/A
9.8.4.1	a) A MECHANICAL PROTECTIVE DEVICE provided when a support system or its parts impaired by wear have a TENSILE SAFETY FACTOR ≥ to values in Table 21, rows 5 and 6, but less than 3 and 4		N/A
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:		N/A
	– Designed based on TOTAL LOAD, and includes effects of SAFE WORKING LOAD when applicable		N/A
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7		N/A
	– Activated before travel (movement) produced an unacceptable RISK		N/A
	– Takes into account Clauses 9.2.5 and 9.8.4.3		N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing		N/A
9.8.4.2	Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE (e.g., a secondary cable)		N/A
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced		N/A
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended to function once		N/A
	– Further use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE		N/A
	– ACCOMPANYING DOCUMENTS instruct once MECHANICAL PROTECTIVE DEVICE is activated, SERVICE PERSONNEL shall be called, and MECHANICAL PROTECTIVE DEVICE must be replaced before ME EQUIPMENT can be used again		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.2 (i.e., safety sign 7010-W001)		N/A
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE or its location relative to MECHANICAL PROTECTIVE DEVICE is obvious to service personnel		N/A
	– Compliance confirmed by examination of ME EQUIPMENT, ACCOMPANYING DOCUMENTS, RISK MANAGEMENT FILE, specifications and processing of materials, and following test:		N/A
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT		N/A
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR		N/A
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function		N/A
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES		N/A
	Support system parts have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 1 and 2, and are not impaired by wear		N/A
	Support system parts impaired by wear, however, they have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 3 and 4		N/A
	Examination of ME EQUIPMENT and RISK MANAGEMENT FILE confirmed compliance		N/A

10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		N/A
10.1	X-Radiation		N/A
10.1.1	X-radiation dose-rate was ≤ 36 pA/kg (5 μSv/h) (0.5 mR/h) 5 cm from surface of ME EQUIPMENT including background radiation for ME EQUIPMENT not producing therapeutic/diagnostic X-radiation but producing ionizing radiation	See Table 10.1.1	N/A
	Amount of radiation measured by means of an ionizing chamber radiation monitor with an effective area of 10 cm^2 or by other instruments producing equal results		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT operated as in NORMAL USE at most unfavorable RATED MAINS VOLTAGE and controls adjusted to emit maximum radiation		N/A
	Internal preset controls not intended for adjustment during EXPECTED SERVICE LIFE of ME EQUIPMENT not taken into consideration		N/A
10.1.2	RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE (see IEC 60601-1-3 & 1.3)		N/A
10.2	RISK associated with alpha, beta, gamma, neutron, and other particle radiation, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE		N/A
10.3	RISK associated with microwave radiation, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE		N/A
10.4	Relevant requirements of IEC 60825-1:1993 applied to lasers, light emitting diodes (LEDs), and laser light barriers or similar products		N/A
10.5	RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE		N/A
10.6	RISK associated with infrared radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE		N/A
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE		N/A

11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		**P**
11.1	Excessive temperatures in ME EQUIPMENT		P
11.1.1	Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and 23 operating in worst-case NORMAL USE at maximum rated ambient operating temperature T	Engineering judgement	P
	Surfaces of test corner did not exceed 90 °C		N/A
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
11.1.2	Temperature of APPLIED PARTS		P
11.1.2.1	Temperatures, hot or cold surfaces, and when appropriate, clinical effects of APPLIED PARTS supplying heat to a PATIENT determined and documented in RISK MANAGEMENT FILE and instructions for use		N/A
11.1.2.2	APPLIED PARTS not supplying heat to a PATIENT met Table 24 with max surface temperatures > 41 °C disclosed in instructions for use, and clinical effects with respect to body surface, maturity of PATIENTS, medications taken, surface pressure, as documented in RISK MANAGEMENT FILE	Will maintain the same temperature as the patient and operator	P
	Surfaces of APPLIED PARTS cooled below ambient temperatures that can also result in HAZARD evaluated as part of RISK MANAGEMENT PROCESS		N/A
11.1.3	Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE	Engineering judgement Maximum power of 3.52 W Using a hardware "bottom-up" risk assessment we calculated the dispatched effect in each component. As it is a low power product all effects are very small and will not heat up to 150°C. Max 1°C increase above ambient temperature.	P
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE		P
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE		P
	a) ME EQUIPMENT positioned for tests in accordance with this clause		N/A
	b) Supply voltage was in accordance with this clause		N/A
	c) Thermal stabilization for temperature tests has been established, and		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Non-CONTINUOUS OPERATION: After operating in standby/quiescent mode until THERMAL STABILITY reached, ME EQUIPMENT operated in NORMAL USE over consecutive cycles until THERMAL STABILITY was achieved again, or for 7 h, the shorter of the two, and RATED "on"/"off" periods used		N/A
	– CONTINUOUS OPERATION: ME EQUIPMENT operated until THERMAL STABILITY reached		N/A
	d) Temperatures measured based on this clause using thermocouples and/or for copper windings, by-the-change-of-resistance method		N/A
	e) THERMAL CUT-OUTS were not de-activated, and test criteria was based on this clause		N/A
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL		N/A
11.2	Fire prevention		
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire caused by reasonably foreseeable misuse and met mechanical strength tests for ENCLOSURES in 15.3		P
11.2.2	Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS		P
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of fire under NORMAL or SINGLE FAULT CONDITIONS when source of ignition is in contact with ignitable material	See Attachment # and appended Table 8.10	P
	Requirements of 13.1.1 applied to oxygen concentrations up to 25 % at one atmosphere or partial pressures up to 27.5 kPa for higher atmospheric pressures		P
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT in NORMAL and SINGLE FAULT CONDITIONS under any of following conditions:	Equipment complies with Annex G, Category AP Component temperature <150°C	P
	1) when temperature of material raised to its ignition temperature		N/A
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures resulting in sparking or increasing material temperature to its ignition temperature		N/A
	3) when parts affecting safety cracked or changed their outer shape exposing temperatures > 300 °C or sparks due to overheating		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	4) when temperatures of parts or components exceeded 300 °C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE		N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively		N/A
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three ..... :		N/A
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, each by itself, or in combination		N/A
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3		N/A
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%) ..... :		N/A
	3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes		N/A
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases having reached PATIENT		N/A
11.2.2.2	RISK of ignition under least favorable conditions did not occur and oxygen concentration did not exceed 25% in immediate surroundings due to appropriate location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT when electrical components mounted on the outside of ME EQUIPMENT or an ME SYSTEM		N/A
11.2.2.3	Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks due to loosening or breaking, except when limited in power and energy to values in 11.2.2.1 a) 5)		N/A
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques		N/A
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means		N/A
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered		
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2) ..... :		N/A
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) ..... :		N/A
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a) ..... :	Equipment complies with Annex G, Category AP Component temperature <150°C	P
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a)..... :		N/A
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas..... :		N/A
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT		P

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2		N/A
	Following constructional requirements were met		N/A
	Or, following constructional requirements specifically analyzed in RISK MANAGEMENT FILE		N/A
	Specific justification provided when requirement not met		N/A
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials		N/A
	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as determined by examination of data on materials		N/A
	In absence of Certification, FV tests based on EC 60695-11-10 conducted on 3 samples of complete parts or sections of a part, including area with minimum thickness and ventilation openings		N/A
	b) Fire ENCLOSURE met following:		N/A
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm		N/A
	2) No openings on the sides within the area that is included within the inclined line C in Fig 39		N/A
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and made of metal, except magnesium, or of non-metallic materials, except constructions based on Table 25 and a mesh, FV-2 or better for TRANSPORTABLE ME EQUIPMENT and FV-1 or better for fixed ME EQUIPMENT, or STATIONARY ME EQUIPMENT per IEC 60695-11-10, as determined by examination of ENCLOSURE or flammability classification based on 11.3 a)		N/A
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anesthetics		P
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable anesthetics (CATEGORY AP) or anesthetics with oxidants (CATEGORY APG) comply with Annex G	Category AP, see Annex G	P

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Clause	Requirement + Test	Result - Remark	Verdict
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents		P
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE	Category AP, see Annex G The device may be used in or around explosive gases.	P
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT		P
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT		P
11.6.2	Overflow in ME EQUIPMENT		N/A
	Liquid reservoir liable to be overfilled or to overflow in NORMAL USE completely filled and 15 % of its capacity poured in over a period of 1 min, and except when restricted, TRANSPORTABLE ME EQUIPMENT tilted through an angle of 15° in least favorable direction(s), and when necessary refilled starting from position of NORMAL USE		N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION were not wet		N/A
11.6. 3	Spillage on ME EQUIPMENT and ME SYSTEM		N/A
	ME EQUIPMENT and ME SYSTEMS handling liquids in NORMAL USE positioned as in 5.4 a) and liquid with composition, volume, duration of spill, point of contact, and test conditions based on RISK MANAGEMENT PROCESS poured steadily on a point on top of ME EQUIPMENT		N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION were not wet		N/A
11.6.4	Leakage	See 13.2.6	N/A
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		
	ME EQUIPMENT with IP Code placed in least favorable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code) ..... :	Marked IPX4	P

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in a HAZARDOUS SITUATION in NORMAL CONDITION or in a SINGLE FAULT CONDITION	See appended Tables 8.7A, 8.7.3A-8.7.3D, 8.7.4.7, 8.8.3A, and 8.8.3B	P
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS		P
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected once in accordance with methods specified in instructions for use including any cooling or drying period		P
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there was no deterioration resulting in an unacceptable RISK	See appended Tables 8.7A-8.7C, 8.7.3A-8.7.3D, 8.7.4.7, 8.8.3A, and 8.8.3B	P
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT, their parts and ACCESSORIES, evaluated by MANUFACTURER and assurance that no unacceptable RISK will occur verified by RISK MANAGEMENT FILE review		P
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented according to ISO 11134, ISO 11135, or ISO 11137 as appropriate		N/A
	After the test, ME EQUIPMENT complied with the appropriate dielectric strength and LEAKAGE CURRENT tests and there was no deterioration resulting in an unacceptable RISK		N/A
11.6.8	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE		N/A
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented according to ISO 10993	Not evaluated by Intertek	-
11.8	Interruption and restoration of power supply did not result in a HAZARDOUS SITUATION, except interruption of its intended function	Internally powered	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		P
12.1	RISKS associated with accuracy of controls and instruments stated in RISK MANAGEMENT PROCESS confirmed by RISK MANAGEMENT FILE review	See RMF Questioner C.2.11 and risk analysis	N/A
12.2	RISK of poor USABILITY, including those associated with identification, marking, and documents addressed in a USABILITY ENGINEERING PROCESS as confirmed by review of provided records	See report 809546-2	P
12.3	The need for alarm systems as a means of RISK CONTROL and RISKS associated with operation or failure of alarm system addressed in RISK MANAGEMENT PROCESS	The device does not use an alarm system	N/A
12.4	Protection against hazardous output		P
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE	It is not possible for the user to change any parameters in the device.	N/A
12.4.2	When applicable, need for indication of parameters associated with hazardous output addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE		N/A
12.4.3	RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit designed to provide low and high-intensity outputs for different treatments addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE		N/A
12.4.4	When applicable, RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE		P
12.4.5	Diagnostic or therapeutic radiation		N/A
12.4.5.1	Adequate provisions made to protect PATIENTS, OPERATORS, other persons, and sensitive devices in vicinity of unwanted or excessive radiation emitted by ME EQUIPMENT designed to produce radiation for diagnostic or therapeutic purposes		N/A
	Radiation safety ensured by compliance with requirements of appropriate standards		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
12.4.5.2	RISKS associated with diagnostic X-rays addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE		N/A
12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE		N/A
12.4.5.4	RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE		N/A
12.4.6	When applicable, RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE		N/A
13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		P
13.1	Specific HAZARDOUS SITUATIONS		P
13.1.1	None of HAZARDOUS SITUATIONS in 13.1.2-13.1.4, inclusive, occurred when SINGLE FAULT CONDITIONS applied, one at a time, as in 4.7 and 13.2		P
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature		P
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		P
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		P
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 when measured as in 11.1.3		P
	– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23 when measured and adjusted as in 11.1.3		P
	–Allowable values for "other components and materials" in Table 22 times 1.5 minus 12.5 °C were not exceeded		P
	Limits for windings in Tables 26, 27, and 31 not exceeded		N/A
	Table 22 not exceeded in all other cases		N/A
	Temperatures measured according to 11.1.3	Calculated	P

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Clause	Requirement + Test	Result - Remark	Verdict
	SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where:		P
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit, or	Certified PTC limits the energy to 3.52 W	P
	– Parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by examination of design documentation		N/A
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function		N/A
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION based on 8.7.3 did not exceed		N/A
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS in 8.4.2 did not exceed		N/A
13.1.4	ME EQUIPMENT complied with the requirements of 9.1 to 9.8 for specific MECHANICAL HAZARDS		P
13. 2	SINGLE FAULT CONDITIONS		P
13.2.1	During application of SINGLE FAULT CONDITIONS in 13.2.2 -13.2.13, inclusive, NORMAL CONDITIONS in 8.1 a) also applied in least favorable combination	See appended Table 13.2	P
13.2.2 – 13.2.12	ME EQUIPMENT complied with 13.2.2 -13.2.12	See appended Table 13.2	P
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to room temperature		N/A
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		N/A
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION (see 8.8), the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).		N/A
13.2.13.2	ME EQUIPMENT with heating elements		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, or for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests of 13.2.13.2 b) & 13.2.13.2 c)		N/A
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests of 13.2.13.2 b) and 13.2.13.2 c)		N/A
	a 3) other ME EQUIPMENT with heating elements met test of 13.2.13.2 b)		N/A
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively		N/A
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration		N/A
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part		N/A
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself		N/A
	b) ME EQUIPMENT with heating elements tested per 11.1without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favorable of the two (V)..... :		N/A
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY		N/A
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted		N/A
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION		N/A
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and		N/A
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS		N/A
	2) When more than one control provided, they were disabled in turn		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time		N/A
13.2.13.3	ME EQUIPMENT with motors		N/A
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable		N/A
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test		N/A
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor and heating parts operated simultaneously to produce the least favorable condition		N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT		N/A
	b) Motor met running overload protection test of this clause when:		N/A
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or		N/A
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended		N/A
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C)..... :		N/A
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps		N/A
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload		N/A
	Test not conducted where electronic drive circuits maintained a substantially constant drive current		N/A
	Test not conducted based on other justifications (justification)..... :		N/A
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
13.2.13.4	ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION		N/A
	ME EQUIPMENT other than HAND-HELD EQUIPMENT, EQUIPMENT kept switched on manually or kept under load by hand, and with a timer and a back-up timer system, operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated		N/A
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle		N/A
	Motor winding temperatures did not exceed values in 13.2.10 (Insulation Class, Maximum temperature measured °C) ..... :		N/A
14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		N/A
14.1	Requirements of this clause not applied to PESS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE; or		N/A
	when application of ISO 14971 showed that failure of PESS does not lead to unacceptable RISK	There are no risks with a severity of 4 (critical) or above controlled by the software alone. Acoustical energy (volume) are controlled by software , but also by physical limitations in the hardware. RF transmitted (Bluetooth M3200) energy is measured during production for compliance and not controlled by software.	N/A
	Every PROCESS has been followed throughout the PEMS DEVELOPMENT LIFE-CYCLE and a RECORD of PROCESS has been made available as confirmed by examination of RISK MANAGEMENT FILE and assessment of PROCESSES cited in this Clause		N/A
	MANUFACTURER considered the need for additional RISK CONTROL measures when unable to follow all PROCESSES identified in Clause 14 for each constituent component of PEMS as confirmed by examination of RISK MANAGEMENT FILE and assessment of PROCESSES cited in this Clause		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Assessment of PROCESSES cited in this Clause made by internal audits		N/A
14.2	Documents produced from application of Clause 14 have been maintained and form a part of RISK MANAGEMENT FILE in addition to RECORDS and documents required by ISO 14971		N/A
	Documents required by Clause 14 reviewed, approved, issued and changed in accordance with a formal document control PROCEDURE		N/A
14.3	RISK MANAGEMENT plan required by 3.5 of ISO 14971 includes reference to PEMS VALIDATION plan		N/A
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented		N/A
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined		N/A
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone		N/A
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules		N/A
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements		N/A
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained where appropriate		N/A
	Problem resolution system meets the prescribed criteria depending on type of product:		N/A
	– it is documented as a part of PEMS DEVELOPMENT LIFE-CYCLE		N/A
	– it allows reporting of potential or existing problems affecting BASIC SAFETY or ESSENTIAL PERFORMANCE		N/A
	– it includes an assessment of each problem for associated RISKS		N/A
	– it identifies criteria that must be met for the issue to be closed		N/A
	– it identifies the action to be taken to resolve each problem		N/A
14.6	RISK MANAGEMENT PROCESS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including NETWORK/DATA COUPLING, components of third-party origin and legacy subsystems when compiling list of known or foreseeable HAZARDS		N/A
	In addition to the material in ISO 14971, Annex D, list of possible sources for HAZARDS associated with PEMS includes specified causes		N/A
	– failure of NETWORK/DATA COUPLING to provide characteristics necessary for PEMS to achieve its BASIC SAFETY or ESSENTIAL PERFORMANCE		N/A
	– undesired feedback [physical and data] (possibilities include: unsolicited input, out of range or inconsistent input, and input originating from electromagnetic interference)		N/A
	– unavailable data		N/A
	– lack of integrity of data		N/A
	– incorrect data		N/A
	– incorrect timing of data		N/A
	– unintended interactions within and among PESS		N/A
	– unknown aspects or quality of third-party software		N/A
	– unknown aspects or quality of third-party PESS		N/A
	– lack of data security, particularly vulnerability to tampering, unintended interaction with other programs and viruses		N/A
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 6.1 of ISO 14971		N/A
14.7	There is a documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem		N/A
14.8	An architecture satisfying the requirement is specified for PEMS and each of its subsystems		N/A
	The architecture specification makes use of considers the specified items to reduce RISK to an acceptable level, where appropriate:		N/A
	a) COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) fail-safe functions		N/A
	c) redundancy		N/A
	d) diversity;		N/A
	e) partitioning of functionality		N/A
	f) defensive design potentially limiting hazardous effects by restricting available output power or by introducing means to limit travel of actuators		N/A
	g) allocation of RISK CONTROL measures to subsystems and components of PEMS		N/A
	h) failure modes of components and their effects;		N/A
	i) common cause failures		N/A
	j) systematic failures		N/A
	k) test interval duration and diagnostic coverage		N/A
	l) maintainability		N/A
	m) protection from reasonably foreseeable misuse		N/A
	n) NETWORK/DATA COUPLING specification, when applicable		N/A
14.9	Design is broken up into subsystems, each with a design and test specification where appropriate, and descriptive data on design environment included in RISK MANAGEMENT FILE		N/A
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures:		N/A
	– milestone(s) when VERIFICATION is to be performed for each function		N/A
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION		N/A
	– selection and utilization of VERIFICATION tools		N/A
	– coverage criteria for VERIFICATION		N/A
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY and ESSENTIAL PERFORMANCE and requiring checks for unintended functioning of PEMS used to perform and document PEMS VALIDATION		N/A
	The person with overall responsibility for PEMS VALIDATION is independent of design team, and no member of a design team can be responsible for PEMS VALIDATION of their own design		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE referencing methods and results of PEMS VALIDATION		N/A
14.12	This Clause applied when any or all of the design was result of a modification of an earlier design		N/A
	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE		N/A
14.13	Technical description includes the following information when PEMS is intended to be connected to other equipment outside control of PEMS MANUFACTURER by NETWORK/DATA COUPLING:		N/A
	a) characteristics of NETWORK/DATA COUPLING necessary for PEMS to achieve its INTENDED USE		N/A
	b) list of HAZARDOUS SITUATIONS resulting from a failure of NETWORK/DATA COUPLING to provide the specified characteristics		N/A
	c) instructions to RESPONSIBLE ORGANIZATION containing following information and warnings:		N/A
	– connection of PEMS to a NETWORK/DATA COUPLING that includes other equipment could result in previously unidentified RISKS to PATIENTS, or OPERATORS and RESPONSIBLE ORGANIZATION should identify, analyze, and control such RISKS		N/A
	– subsequent changes to NETWORK/DATA COUPLING introducing new RISKS and requiring new analysis; and changes to NETWORK/DATA COUPLING include:		N/A
	– changes in NETWORK/DATA COUPLING configuration		N/A
	– connection of additional items to NETWORK/DATA COUPLING		N/A
	– disconnecting items from NETWORK/DATA COUPLING		N/A
	– update of equipment connected to NETWORK/DATA COUPLING		N/A
	– upgrade of equipment connected to NETWORK/DATA COUPLING		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
15	**CONSTRUCTION OF ME EQUIPMENT**		P
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS, as confirmed by examination of RISK MANAGEMENT FILE	RMF	P
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, and environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance		N/A
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		N/A
15.3	Mechanical strength		P
15.3.1	Mold stress relief, push, impact, drop, and rough handling tests did not result in unacceptable RISK and ME EQUIPMENT displayed adequate mechanical strength		P
15.3.2	Push test conducted by subjecting external parts of ENCLOSURE to a steady force of 250 N ± 10 N for 5 s applied to a circular plane surface 30 mm in diameter, except bottom of ENCLOSURE of an ME EQUIPMENT >18 kg, using a suitable test tool		P
	No damage resulting in an unacceptable RISK sustained as determined by examination of RISK MANAGEMENT FILE		P
15.3.3	Impact test conducted by subjecting a complete ENCLOSURE or its largest non-reinforced area, except for HAND-HELD ME EQUIPMENT and parts, to a free falling 500 g ± 25 g solid smooth steel ball, approx. 50 mm in diameter from a height of 1.3 m		N/A
	Test not applied to flat panel displays, platen glass of ME EQUIPMENT, or cathode ray tubes		N/A
	No damage resulting in an unacceptable RISK sustained as shown in RISK MANAGEMENT FILE		N/A
15.3.4	Drop test		P

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Clause	Requirement + Test	Result - Remark	Verdict
15.3.4.1	Each sample of HAND-HELD ME EQUIPMENT and HAND-HELD part with SAFE WORKING LOAD allowed to fall freely once from each of 3 different positions as in NORMAL USE from height specified in ACCOMPANYING DOCUMENTS, or from 1 m onto a 50 mm ± 5 mm thick hardwood board (hardwood > 600 kg/m3) lying flat on a concrete or rigid base		P
	No unacceptable RISK resulted		P
15.3.4.2	Each sample of PORTABLE ME EQUIPMENT and PORTABLE part with SAFE WORKING LOAD lifted to a height as in Table 29 above a 50 mm ± 5 mm thick hardwood board at least the size of sample lying flat on a concrete floor or rigid base, dropped 3 times from each orientation in NORMAL USE		N/A
	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE		N/A
15.3.5	Each sample of MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed specified tests:		N/A
	a) Ascending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s against an ascending hardwood step obstruction attached to a floor without the sample going over obstruction		N/A
	b) Descending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s in order to fall over a vertical step affixed flat on a rigid base with direction of movement perpendicular to face of descending step until full descent was achieved		N/A
	c) Door frame shock test conducted on the sample by moving it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s, or for motor driven EQUIPMENT, at maximum possible speed against a hardwood vertical obstacle higher than EQUIPMENT contact point(s) affixed to a vertical rigid support with movement perpendicular to face of obstacle		N/A
	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
15.3.6	When appropriate, review of available data and examination of ENCLOSURE constructed from molded or formed thermoplastic material indicated shrinkage or distortion of material due to release of internal stresses caused by molding or forming operations will not result in an unacceptable RISK		N/A
	Mould stress relief test conducted in the absence of data by placing one sample of complete ME EQUIPMENT, ENCLOSURE and framework, or for large EQUIPMENT, a portion of ENCLOSURE, in a circulating air oven at 10 °C over than max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C, for 7 h		N/A
	No damage resulting in an unacceptable RISK		N/A
15.3.7	INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT		N/A
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK	No risks	P
15.4	ME EQUIPMENT components and general assembly		P
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, in particular:		N/A
	a) Plugs for connection of PATIENT leads cannot be connected to other outlets on same ME EQUIPMENT intended for other functions, except when RISK MANAGEMENT FILE provides proof that no unacceptable RISK could result		N/A
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable as verified by review of RISK MANAGEMENT FILE		N/A
15.4.2	Temperature and overload control devices		N/A
15.4.2.1	a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could result in a HAZARDOUS SITUATION by resetting action as verified by review of RISK MANAGEMENT FILE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) THERMAL CUT-OUTS with a safety function to be reset by a soldering operation affecting operating value not fitted in ME EQUIPMENT as verified by examination of design and RISK MANAGEMENT FILE		N/A
	c) An independent non-SELF-RESETTING THERMAL CUT-OUT is, additionally, provided where a failure of a THERMOSTAT could constitute a HAZARD as verified by examination of design and RISK MANAGEMENT FILE		N/A
	d) Based on design and RISK MANAGEMENT FILE review, loss of function of ME EQUIPMENT due to operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION		N/A
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS		N/A
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety of ME EQUIPMENT as verified by following tests:		N/A
	Positive temperature coefficient devices (PTC's) complied with IEC 60730-1: 1999, clauses 15, 17, J.15, and J.17 as applicable		N/A
	ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13		N/A
	SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) Certified in accordance with appropriate IEC standards		N/A
	In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) operated 200 times		N/A
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards		N/A
	In the absence of certification per IEC standards, or data from MANUFACTURER demonstrating reliability of component to perform its safety-related function, manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted		N/A
	g) Protective device, provided on ME EQUIPMENT incorporating a fluid filled container with heating means, operated when heater switched on with container empty preventing occurrence of an unacceptable RISK due to overheating		N/A
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating in both leads where a conductive connection to earth could result in overheating as verified by examination of design and RISK MANAGEMENT FILE		N/A
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS		N/A
15.4.3	Batteries		P
15.4.3.1	Battery housings from which gases can escape during charging or discharging likely to result in a HAZARD ventilated to minimize RISK of accumulation and ignition as verified by examination of design and RISK MANAGEMENT FILE		N/A
	Battery compartments prevent accidental short circuiting of battery when this could result in a HAZARDOUS SITUATION as verified by examination of design and RISK MANAGEMENT FILE	No connection if reversed	P
15.4.3.2	Means provided to prevent incorrect connection of polarity when a HAZARDOUS SITUATION may develop by incorrect connection or replacement of a battery		N/A
15.4.3.3	Overcharging of battery prevented by virtue of design when it could result in an unacceptable RISK as verified by review of design		N/A
15.4.3.4	Lithium batteries that could become a HAZARD complied with appropriate tests of IEC 60086-4	No charging. AA type battery short circuit proof	P
	Tests of IEC 60086-4 waived on the lithium battery based on examination of design		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire caused by excessive currents when in case of a short circuit cross-sectional area and layout of internal wiring or rating of connected components can result in a fire	PTC regulates	P
	Protective device has adequate breaking capacity to interrupt the maximum fault current		N/A
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is included in RISK MANAGEMENT FILE		N/A
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for NORMAL USE, except when apparent to OPERATOR from normal operating position, and marking of 7.4.1 are insufficient for this purpose	When power is turned on the display turns on with backlight, backlight time depend on the settings.	P
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s, except when apparent to OPERATOR from normal operating position		N/A
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational when a HAZARDOUS SITUATION could exist, except when apparent to OPERATOR from normal operating position		N/A
	Requirement not applied to heated stylus-pens for recording purposes		N/A
	Indicator lights provided on ME EQUIPMENT to indicate an output exists where an accidental or prolonged operation of output circuit could constitute a HAZARDOUS SITUATION		N/A
	Colors of indicator lights complied with 7.8.1		N/A
	Charging mode visibly indicated in ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE	Not possible to charge	N/A
15.4.5	RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS when applicable as verified by review of RISK MANAGEMENT FILE		N/A
15.4.6	Actuating parts of controls of ME EQUIPMENT		
15.4.6.1	a) Actuating parts cannot be pulled off or loosened up during NORMAL USE		P

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Indication of scales (e.g., "on" "off" positions, etc.) always corresponds to position of controls with adjustment that can result in a HAZARDOUS SITUATION for PATIENT or OPERATOR while ME EQUIPMENT is in use		N/A
	c) Incorrect connection of indicating device to relevant component prevented by adequate construction when it could be separated without use of a TOOL		N/A
	When torque values in Table 30 applied between control knob and shaft of rotating controls for not less than 2 s, 10 times in each direction, knobs did not rotate with respect to shaft		N/A
	Tests conducted by applying an axial force of 60 N for electrical components and 100 N for other components for 1 min when an axial pull was required in NORMAL USE with no unacceptable RISK		N/A
15.4.6.2	Stops of adequate mechanical strength provided on rotating or movable parts of controls of ME EQUIPMENT where necessary to prevent an unexpected change from maximum to minimum, or vice-versa, of the controlled parameter when this could cause a HAZARDOUS SITUATION		N/A
	Torque values in Table 30 applied 10 times in each direction to rotating controls for minimum 2 s		N/A
	Application of an axial force of 60 N for electrical components and 100 N for other components to rotating or movable parts of controls for 1 min when an axial pull was required in NORMAL USE		N/A
15.4.7	Cord-connected HAND-HELD and foot-operated control devices		
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1	No remote controls	N/A
	b) Foot-operated control device supported an actuating force of 1350 N (i.e., weight of an adult human being) for 1 min applied over an area of 30 mm diameter in its position of NORMAL USE with no damage to device causing an unacceptable RISK		N/A
15.4.7.2	Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface		N/A
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position		N/A
15.4.7.3	a) Foot-operated control device is at least IPX1 and complies with tests of IEC 60529 (IP Code). :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6 and complies with IEC 60529 if in NORMAL USE liquids are likely to be found (IP Code)..... :		N/A
	Probability of occurrence estimated as part of RISK MANAGEMENT PROCESS		N/A
	ACCOMPANYING DOCUMENTS, design, and RISK MANAGEMENT FILE examined to confirm compliance		N/A
15.4.8	Aluminum wires less than 16 mm^2 in cross-sectional area not used	No aluminium wires	P
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed to prevent loss of oil in any position		N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport		N/A
	A pressure-release device operating during NORMAL USE is, optionally, provided		N/A
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements		N/A
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5		N/A
15.5.1	Overheating		N/A
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating in the event of short circuit or overload of output windings and comply with this Clause and tests of 15.5.1.2 and 15.5.1.3		N/A
	During tests, windings didn't open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		N/A
	Dielectric strength test of 8.8.3 conducted on transformer after short circuit and overload tests		N/A
15.5.1.2	Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved		N/A
	Short circuit applied directly across output windings for transformers not tested according to 5X frequency and 5X voltage test of 15.5.2		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
15.5.1.3	Multiple overload tests conducted on windings with more than one protective device to evaluate worst-case NORMAL USE loading and protection		N/A
15.5.2	Transformer windings provided with adequate insulation to prevent internal short-circuits that could cause overheating which could result in a HAZARDOUS SITUATION		N/A
	Dielectric strength tests were conducted in accordance with requirements of this Subclause with no breakdown of insulation system and no detectable deterioration of transformer		N/A
	a) For RATED voltage ≤ 500 V or RATED frequency ≤ 60 Hz, test voltage = 5 times RATED voltage or 5 times upper limit of RATED voltage range of that winding and a frequency ≥ 5 times RATED frequency (RATED frequency is the normal operating frequency of transformer input voltage)		N/A
	b) For rated voltage > 500 V or RATED frequency > 60 Hz = twice RATED voltage or twice the upper limit of RATED voltage range of that winding and a frequency ≥ twice RATED frequency		N/A
	Test voltage at winding with highest RATED voltage did not exceed test voltage in Table 6 for one MEANS OF PROTECTION, when RATED voltage of such a winding was considered as WORKING VOLTAGE		N/A
	When above occurred, test voltage on primary winding reduced accordingly, and test frequency adapted to produce in the core approximately magnetic induction present in NORMAL USE		N/A
	– 3-phase transformers tested using a 3-phase testing device or by 3 consecutive tests using a single-phase testing device		N/A
	– Value of test voltage with respect to core and to any screen between primary and secondary windings was based on specification of relevant transformer		N/A
	Connection point for neutral of SUPPLY MAINS on primary winding connected to core and screen when provided, except when core and screen are for connection to an unearthed part of circuit		N/A
	Connections to core omitted where core of transformer was isolated from all external conductive connections		N/A
	Core and screen connected to a source with an appropriate voltage and frequency with respect to neutral connection point		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	In the absence of a neutral connection point, each side of primary winding in turn connected to core and screen when provided, except when core and screen specified for connection to an unearthed part of circuit		N/A
	Core and screen connected to a source with an appropriate voltage and frequency with respect to each side of primary winding in turn		N/A
	– All windings not intended for connection to SUPPLY MAINS left open, and common earth connection point of windings or a point nearly at earth potential connected to core, except when core is for connection to an unearthed circuit part		N/A
	Core connected to a source with an appropriate voltage and frequency with respect to windings		N/A
	– Initially, no more than half prescribed voltage applied and raised over 10 s to full value, maintained for 1 min, and then reduced gradually and switched off		N/A
	– Tests not conducted at resonant frequencies		N/A
	Slight corona discharges neglected, provided they ceased when test voltage temporarily dropped to a lower value higher than WORKING VOLTAGE and discharges did not provoke a drop in test voltage		N/A
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with IEC 61558-1:1997, Clause 5.12		N/A

16	**ME SYSTEMS**		N/A
16.1	ME SYSTEM did not result in an unacceptable RISK after installation or subsequent modification		N/A
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM taken into account		N/A
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard		N/A
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards		N/A
	– tests performed in NORMAL CONDITION, except as specified		N/A
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated		N/A
	RISK MANAGEMENT methods, optionally, used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR to determine configurations with highest RISKS and measures needed to ensure ME SYSTEM will not present an unacceptable RISK in any configuration		N/A
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards		N/A
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM		N/A
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM		N/A
	Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM		N/A
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM		N/A
	ACCOMPANYING DOCUMENTS are, optionally, provided in electronic format (e.g. electronic file format or CD ROM) and ME SYSTEM is capable of displaying or printing these documents		N/A
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER		N/A
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER		N/A
	c) the required information is provided:		N/A
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM		N/A
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard		N/A
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– additional safety measures to be applied during installation of ME SYSTEM		N/A
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT		N/A
	– additional measures to be applied during preventive maintenance		N/A
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor		N/A
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM		N/A
	– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM		N/A
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM		N/A
	– instructions indicating MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM to be used only for supplying power to equipment intended to form part of ME SYSTEM		N/A
	– an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer		N/A
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET		N/A
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage		N/A
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT		N/A
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:		N/A
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES		N/A
	– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
16.3	Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, sufficiently, describe the other equipment to ensure compliance with these requirements		N/A
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, etc., after removal of covers, connectors, etc., without use of a TOOL operated at a voltage ≤ voltage in 8.4.2 c) supplied from a source separated from SUPPLY MAINS by two MEANS OF OPERATOR PROTECTION		N/A
16.5	Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed		N/A
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION appropriate for highest voltage occurring across SEPARATION DEVICE during a fault condition		N/A
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V) ..... :		N/A
16.6	LEAKAGE CURRENTS		N/A
16.6.1	TOUCH CURRENT in NORMAL CONDITION, from or between parts of ME SYSTEM within the PATIENT ENVIRONMENT, did not exceed 100 µA		N/A
	TOUCH CURRENT did not exceed 500 µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, from or between parts of ME SYSTEM within PATIENT ENVIRONMENT		N/A
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET did not exceed 5 mA ..... :		N/A
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values specified for ME EQUIPMENT in Tables 3 and 4		N/A
	Total PATIENT LEAKAGE CURRENT, optionally, measured at installation		N/A
	Measurements made using a device as in 8.7.4.4		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
16.6.4	Measurements		N/A
16.6.4.1	a) TOUCH CURRENT, PATIENT and total EARTH LEAKAGE CURRENTS of MULTIPLE SOCKET-OUTLET measured after ME SYSTEM reached operating temperature as follows:		N/A
	– ME SYSTEMS intended for non-CONTINUOUS OPERATION operated in standby/quiescent mode until THERMAL STABILITY, and then ME SYSTEM operated in NORMAL USE over consecutive cycles at RATED "on"/"off" periods until THERMAL STABILITY was again achieved, or for 7h, whichever shorter		N/A
	– ME SYSTEMS intended for CONTINUOUS OPERATION operated until THERMAL STABILITY		N/A
	b) ME SYSTEM connected to a supply at highest RATED MAINS VOLTAGE		N/A
	ME SYSTEM connected to local SUPPLY MAINS prior to its clinical use when characteristics of SYSTEM could only be measured properly after installation at RESPONSIBLE ORGANIZATION		N/A
	Number of tests reduced where examination of circuit arrangement, components, and materials of ME SYSTEM indicated no possibility of HAZARD		N/A
16.6.4.2	a) ME SYSTEM tested after assembly based on ACCOMPANYING DOCUMENTS		N/A
	b) The reference earth of measuring circuits connected to protective earth of SUPPLY MAINS when an isolating transformer not used for LEAKAGE CURRENT measurements		N/A
16.7	ME SYSTEM complied with applicable requirements of Clause 9 when a MECHANICAL HAZARD existed		N/A
16.8	Interruption and restoration of relevant power connections of ME SYSTEM one at a time and all connections simultaneously did not result in a HAZARDOUS SITUATION other than interruption of its intended function		N/A
16.9	ME SYSTEM connections and wiring		N/A
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where a HAZARDOUS SITUATION could otherwise exist		N/A
	– Connectors complied with Clause 15.4.1		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Plugs for connection of PATIENT leads could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no HAZARDOUS SITUATION could result		N/A
16.9.2	MAINS PARTS, components and layout		N/A
16.9.2.1	a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or		N/A
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or		N/A
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer		N/A
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 (i.e., safety sign ISO 7010-W001) visible in NORMAL USE, and		N/A
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or		N/A
	– marked to indicate the equipment or equipment parts it may safely be attached to		N/A
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT		N/A
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:		N/A
	– CREEPAGE and CLEARANCES complied with 8.9		N/A
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets		N/A
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6, except total impedance for ME SYSTEM was up to 400 mΩ, or higher when conditions of 8.6.4 b) met (mΩ) ..... :		N/A
	– ENCLOSURE complied with 8.4.2 d)		N/A
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable		N/A
	– RATINGS of components are not in conflict with conditions of use		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL		N/A
	– POWER SUPPLY CORD complied with 8.11.3		N/A
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:		N/A
	– Separating transformer complied with IEC 61558-2-1, except requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 were not applied		N/A
	– Separating transformer is CLASS I		N/A
	– Degree of protection against ingress of water specified as in IEC 60529		N/A
	– Separating transformer assembly marked according to 7.2 and 7.3		N/A
	– MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083		N/A
16.9.2.2	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part of ME SYSTEM without simultaneous disconnection of electrical supply to that part		N/A
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by a TOOL		N/A
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage		N/A

17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		P
	RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review ..... :	See accredited Eurofins EMC test report no.: G0M20810-2051-E-17 and G0M20808-1969-E-17	P
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS ..... :		P

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Clause	Requirement + Test	Result - Remark	Verdict
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems		P
G	**ANNEX G, PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**		P
G.2	Locations and basic requirements		P
G.2.1	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5		P
G.2.2	FLAMMABLE ANESTHETIC MIXTURE WITH AIR occurring due to a leakage or discharge of a FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE from an ENCLOSURE considered 5 to 25 cm from point of occurrence	No flammable anestheetic mixure with air in the equipment	N/A
G.2.3	A FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE contained in a completely or partly enclosed ME EQUIPMENT part and in PATIENT'S respiratory tract 5 cm from an ENCLOSURE part where leakage or discharge occurs	No flammable anestheetic mixure with oxygen or nitrous oxide in the equipment	N/A
G.2.4	ME EQUIPMENT or parts thereof specified for use with FLAMMABLE ANESTHETIC MIXTURE WITH AIR (in a location defined in G.2.2) are CATEGORY AP or APG ME EQUIPMENT and complied with G.4 and G.5	Category AP	P
G.2.5	ME EQUIPMENT or parts thereof for use with FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE (location per G.2.2) are CATEGORY APG ME EQUIPMENT and comply with G.4 and G.6		N/A
	ME EQUIPMENT in G.2.3 to G.2.5 met appropriate tests of G.3-G.5 conducted after tests of 11.6.6 and 11.6.7	Cleaning	P
G.3	Marking, ACCOMPANYING DOCUMENTS		P
G.3.1	CATEGORY APG ME EQUIPMENT marked on a prominent location with a green-colored band ≥ 2 cm wide imprinted with characters "APG" according to symbol 23 in Table D.1 (i.e., symbol IEC 60417-5332, DB: 2002-10) ..... :	Not category APG	N/A
	Length of green-colored band is ≥ 4 cm, and size of marking is as large as possible for particular case		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	When above marking not possible, relevant information included in instructions for use ..... :		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.2	CATEGORY AP ME EQUIPMENT marked on a prominent location with a green-colored circle ≥ 2 cm in diameter, imprinted with characters "AP" according to symbol 22 in Table D.1 (i.e., symbol IEC 60417- 5331, DB: 2002-10) ..... :	See copies of Marking Labels on page 4. Adding labels on the stethoscope will generate handling noise and degrade the essential function of the stethoscope. Therefore the marking is engraved without color and the correct symbol is placed with the relevant information in the user manual	P
	Marking is as large as possible for the particular case		P
	When above marking not possible, the relevant information included in instructions for use ..... :		P
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		P
G.3.3	The marking according to G.3.2 and G.3.3 placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts, and not repeated on detachable parts that can only be used with the marked EQUIPMENT		P
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts	Whole unit is category AP	P
G.3.5	Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG	Whole unit is category AP	N/A
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT		N/A
G.4.1	a) CREEPAGE and CLEARANCES between points of POWER SUPPLY CORD connection are according to Table 12 for one MEANS OF PATIENT PROTECTION	No power supply cord	N/A
	b) Connections, except those in circuits described in G.5.3 and G.6.3, protected against accidental disconnection in NORMAL USE or connection and disconnection can be performed only with a TOOL		N/A
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD, except when circuit complied with G.5.3 and G.6.3		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
G.4.2	Construction details		P
	a) Opening of an ENCLOSURE providing protection against penetration of gases or vapors into ME EQUIPMENT or its parts possible only with a TOOL		N/A
	b) ENCLOSURE complies with requirements to minimize arcing and sparking due to penetration of foreign objects ..... :	See appended Table 8.10	P
	– no openings on top covers of ENCLOSURE, except for openings for controls covered by control knobs		P
	– openings in side-covers prevented penetration of a solid cylindrical test rod of 4 mm in diameter applied in all possible directions without appreciable force		P
	– openings in base plates prevented penetration of a solid cylindrical test rod of 12 mm in diameter applied in all directions without appreciable force		P
	c) Short circuiting conductor(s) to a conductive part without presence of explosive gasses where insulation may contact a part containing a FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE, ignitable gases alone, or oxygen, did not result in loss of integrity of the part, an unacceptable temperature, or other HAZARD	Category AP	N/A
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures	The stethoscope is a handheld device, the device will hold the same electrostatic charge as the user.	N/A
	– Use of antistatic materials with a limited electrical resistance as specified in G.4.3 b) ..... :		N/A
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor of medical room		N/A
	b) Electrical resistance limits of anesthetic tubing, mattresses and pads, castor tires, and other antistatic material complied with ISO 2882 based on measurements according to ISO 1853, ISO 2878 and ISO 23529 ..... :		N/A
G.4.4	Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or more than 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components thereof		P
G.5.1	ME EQUIPMENT, its parts or components do not ignite FLAMMABLE ANESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5 (inclusive)		P
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5 ..... :		N/A
G.5.2	ME EQUIPMENT, its parts, and components in contact with gas mixtures in NORMAL USE and CONDITIONS not producing sparks and not resulting in surface temperatures above 150 °C in case of restricted vertical air circulation by convection, or 200 °C in case of unrestricted vertical air circulation measured at 25 °C comply with G.5.1 ..... :	The PTC resistor limits the power to maximum 3.52W (1.6Vx2.2A) when tripped, which will not heat up to 150°C.	P
G.5.3	ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:		P
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1 ..... :	U_{MAX} = 6.3 V	N/A
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 ..... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 ..... :	$I_{MAX,PEAK}$ = 192 mA	N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.3 ..... :		N/A
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1	P_{MAX} = 360 µW	P
	No extrapolation made for voltages above 42 V		N/A
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2$ mJ extrapolated from Fig G.2	C_{MAX} = 19.7 µJ	P
	No extrapolation made for voltages above 242 V		N/A
	U_{max}, additionally, determined using actual resistance R when the equivalent resistance R was less than 8000 Ω		P
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3	L_{MAX} = 10.6 µJ	P

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Clause	Requirement + Test	Result - Remark	Verdict
	No extrapolation made for inductances larger than 900 mH		N/A
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open, taking into consideration MAINS VOLTAGE variations in 4.10		N/A
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed, taking into consideration MAINS VOLTAGE variations required in 4.10		N/A
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks		P
	– Peak value taken into account when a.c. supplied		N/A
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :		P
	Temperature measurements made according to 11.1, and U_{max}, I_{max}, R, L_{max} , and C_{max} determined together with application of Figs G.1-G.3 ..... :		N/A
	Alternatively, compliance was verified by examination of design data		P
G.5.4	External ventilation with internal overpressure		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:		N/A
	a) FLAMMABLE ANESTHETIC MIXTURES WITH AIR that might have penetrated into ENCLOSURE of ME EQUIPMENT or part removed by ventilation before EQUIPMENT energized, and penetration of such mixtures during operation was prevented by maintenance of overpressure by means of air without flammable gases, or by physiologically acceptable inert gas (e.g., nitrogen)		N/A
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa)..... :		N/A
	Overpressure maintained at the site of potential ignition even when air or inert gas could escape through openings in ENCLOSURE necessary for normal operation of ME EQUIPMENT or its parts		N/A
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE so that the displaced volume of air or inert gas was at least five times the volume of ENCLOSURE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present		N/A
	c) Ignition sources de-energized automatically by means located in a place where G.4 does not apply, or complied with G.5 when during operation overpressure dropped below 50 Pa (Pa)..... :		N/A
	d) External surface of ENCLOSURE in which internal overpressure was maintained did not exceed 150 °C in 25 °C ambient under NORMAL USE and CONDITION (°C)..... :		N/A
G.5.5	ENCLOSURES with restricted breathing		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:		N/A
	a) A FLAMMABLE ANESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing when it was surrounded by a FLAMMABLE ANESTHETIC MIXTURE WITH AIR of a high concentration for at least 30 min without any pressure difference inside ENCLOSURE		N/A
	b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h.. :		N/A
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained when the cords were stressed by bending or pulling		N/A
	Cords are fitted with adequate anchorages to limit stresses		N/A
	After the test in G.5.4 b), an internal overpressure of 400 Pa was created and 30 pulls of the value in Table G.1 applied to each flexible cord in axial direction of cord inlet and in the least favorable perpendicular direction for 1 s		N/A
	Overpressure not reduced below 200 Pa		N/A
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)		N/A
	Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C) ..... :		N/A
	Steady state operating temperature of ENCLOSURE also measured (°C) ..... :		N/A
G.6	Requirements and tests for CATEGORY APG ME EQUIPMENT, parts and components thereof		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
G.6.1	ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION		N/A
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test after attaining thermal steady state (max. 3 h) over a period of 10 min in a 12.2 % ± 0.4 ether by volume/oxygen mixture		N/A
G.6.2	Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to at least one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION..... :		N/A
G.6.3	Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS ..... :		N/A
	a) no sparks produced and temperatures did not exceed 90 °C, or		N/A
	b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except U_{max} and I_{max} occurring in their circuits complied with the requirements, taking C_{max} and L_{max} into consideration:		N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 ..... :		N/A
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5 ..... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 ..... :		N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.6 ..... :		N/A
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated		N/A
	– U_{max} was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10		N/A
	– I_{max} was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10		N/A
	– C_{max} and L_{max} are values occurring in relevant circuit		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω		N/A
	– Peak value taken into consideration when a.c. supplied		N/A
	– An equivalent circuit calculated to determine max capacitance, inductance, and U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :		N/A
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage limiting or current-limiting devices preventing limits of Figs G.4- G.6 from exceeding, two independent components applied, to obtain the required limitation even in case of a first fault (short or open circuit) in one of these components		N/A
	Above requirement not applied to transformers complying with this standard		N/A
	Above requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture		N/A
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or		N/A
	Temperature measurements made in accordance with 11.1, or		N/A
	U_{max}, I_{max}, R, L_{max} and C_{max} determined together with application of Figs G.4-G.6 ..... :		N/A
	Alternatively, compliance verified by comparison with design data		N/A
G.6.4	ME EQUIPMENT, its parts, and components heating a FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1		N/A
	Current-carrying part of heating element is not in direct contact with FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE		N/A
G.7	Test apparatus for flammable mixtures		N/A
	Test apparatus used was in accordance with this Clause and Fig G.7		N/A

L	**ANNEX L, INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
L.1	BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex covering round winding wires between 0.05 mm and 5.00 mm diameters		N/A
L.2	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component		N/A
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		N/A
L.3	The wire subjected to tests of L.3.1 to L.3.4 at a temperature between 15 °C and 35 °C and a relative humidity between 45 % and 75 %, unless otherwise specified (°C, % Humidity) ..... :		N/A
L.3.1	Dielectric strength test of 8.8.3 for the appropriate type and number of MOP(s) conducted by preparing the sample according to IEC 60851-5:1996, Clause 4.4.1 for a twisted pair with test voltages at least twice Tables 6 and 7, but not less than following with no breakdown:		N/A
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 6000 V for REINFORCED INSULATION (V).... :		N/A
L.3.2	Sample subjected to flexibility and adherence test 8 of IEC 60851-3:1996, clause 5.1.1, using mandrel diameters of Table L.1		N/A
	Sample examined according to IEC 60851-3: 1997, clause 5.1.1.4, followed by dielectric test of clause 8.8.3, except test voltage applied between wire and mandrel with no breakdown		N/A
	Test voltage was at least the voltage in Tables 6 and 7but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V for REINFORCED INSULATION (V).... :		N/A
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa		N/A
L.3.3	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3, except test voltage applied between the wire and mandrel		N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V for REINFORCED INSULATION (V).... :		N/A
	Oven temperature set based on Table L.2 (°C) .. :		N/A
	Mandrel diameter and tension applied as in L.3.2, ((118 MPa ± 11.8 MPa (118 N/mm^2 ± 11.8 N/mm^2))..... :		N/A
	Dielectric strength test conducted at room temperature after removal from the oven		N/A
L.3.4	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests by removing each sample from the mandrel and placing it in a container surrounded by min. 5 mm of metal shot		N/A
	The ends of conductor in the sample were sufficiently long to avoid flash over, and the shot was no more than 2 mm in diameter and consisted of stainless, nickel, or nickel-plated iron		N/A
	The shot was gently poured into container until sample covered by at least 5 mm of shot, and the shot cleaned periodically with a suitable solvent (e.g., 1.1,1-trichloroethane)		N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V for REINFORCED INSULATION (V).... :		N/A
	Test voltage applied between the shot and conductor.		N/A
	Mandrel diameter and tension applied as in L.3.2, ((118 MPa ± 11.8 MPa (118 N/mm^2 ± 11.8 N/mm^2))..... :		N/A
L.4	Tests during manufacture		N/A
L.4.1	Production line dielectric strength tests conducted by the manufacture according to L.4.2 and L.4.3		N/A
L.4.2	Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:		N/A
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V) ..... :		N/A
L.4.3	Sampling tests conducted using twisted pair samples according to IEC 60851-5:1996, clause 4.4.1		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Minimum breakdown test voltage is at least twice the voltage in Tables 6 and 7 but not less than:		N/A
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION		N/A
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

4.11	TABLE: Power Input				N/A
Operating Conditions / Ratings	Voltage, (V)	Frequency, (Hz)	Current, (A)	Power, (W)	Remarks
Supplementary Information:					

7.1.3	TABLE: Durability of marking test [1]	P
Characteristics of the Marking Label tested:		Remarks
Material (composition) of Marking Label .....:	Engraved on enclosure	
Ink/other printing material or process.....:	N/A	
Method of application of ink to the Label.....:	N/A	
Other.....:	-	
Material (composition) of Warning Label .....:	-	
Ink/other printing material or process.....:	-	
Method of application of ink to the Label.....:	-	
Other.....:	-	

Supplementary information:

[1] Marking rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit, and then for 15 s with a cloth rag soaked with isopropyl alcohol.

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Clause	Requirement + Test	Result - Remark	Verdict

8.4.3	**TABLE: ME EQUIPMENT intended to be connected to a power source by a plug-measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply**	N/A

Maximum allowable voltage (V) .....:	60										Remarks
Voltage measured (V)											
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10	
Plug pins 1 and 2											
Plug pin 1 and plug earth pin											
Plug pin 2 and plug earth pin											
Plug pin 1 and enclosure											
Plug pin 2 and enclosure											

Maximum allowable stored charge when measured voltage exceeded 60 V (μC) .....:	45										Remarks
Calculated stored charge (μC)											
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10	
Plug pins 1 & 2											
Plug pin 1 & plug earth pin											
Plug pin 2 and plug earth pin											
Plug pin 1 and enclosure											
Plug pin 2 and enclosure											

Supplementary information:

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Clause	Requirement + Test	Result - Remark	Verdict

8.4.4	**TABLE: Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT**	N/A
Maximum allowable residual voltage (V)..... :		60 V
Maximum allowable stored charge when residual voltage exceeded 60 V (μC)		45 V

Description of the capacitive circuit (i.e., accessible capacitor or circuit parts)	Measured residual voltage (V)	Calculated stored charge (μC)	Remarks

Supplementary information:

8.5.5.1a	**TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies**	N/A

Test Condition: Figs. 9 & 10	Measurement made on accessible part	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks

Supplementary information:

8.5.5.1b	**TABLE: defibrillation-proof applied parts – verification of recovery time**	N/A

Applied part with test voltage	Test voltage polarity	Recovery time from documents (s)	Measured recovery time (s)	Remarks

Supplementary information:

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Clause	Requirement + Test	Result - Remark	Verdict

8.5.5.2	**TABLE: DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load**	N/A

Test Voltage applied to	Measured Energy E1, (mJ)	Measured Energy E2, (mJ)	Energy E1 as % of E2, (%)
PATIENT CONNECTION 1 or APPLIED PART with PATIENT CONNECTIONS 2, 3, and 4 of the same APPLIED PART connected to earth			
PATIENT CONNECTION 2 or APPLIED PART with PATIENT CONNECTIONS 1, 3, and 4 of the same APPLIED PART connected to earth			
PATIENT CONNECTION 3 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 4 of the same APPLIED PART connected to earth			
PATIENT CONNECTION 4 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 3 of the same APPLIED PART connected to earth			

Supplementary information:

8.6.4	**TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS**	N/A

Type of ME EQUIPMENT & impedance measured between parts	Test current (A)	Voltage drop measured between parts, (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)
PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part				100
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part				100
ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part				200

Supplementary information:

1455

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.7A	**TABLE: PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL & SINGLE FAULT CONDITIONS – TYPE B APPLIED PARTS (μA)**	P

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10	N/A	50	N/A
				a.c	100	N/A	500	N/A
PATIENT LEAKAGECURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10	0	50	0
				a.c	100	N/A	500	N/A
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10	N/A	50	N/A
				a.c	100	N/A	500	N/A
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	50	N/A	100	N/A
				a.c	500	N/A	1000	N/A
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	50	N/A	100	N/A
				a.c	500	N/A	1000	N/A

Supplementary information:

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d)
Note 2: For TOUCH CURRENT see 8.7.3 c)
Note 3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

Note 4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

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Clause	Requirement + Test	Result - Remark	Verdict

8.7B	**TABLE: PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL & SINGLE FAULT CONDITIONS – TYPE BF APPLIED PARTS (μA)**	N/A

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10		50	
				a.c	100		500	
PATIENT LEAKAGECURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10		50	
				a.c	100		500	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10		50	
				a.c	100		500	
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	50		100	
				a.c	500		1000	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	50		100	
				a.c	500		1000	

Supplementary information:

1: For EARTH LEAKAGE CURRENT see 8.7.3 d)

2: For TOUCH CURRENT see 8.7.3 c)

3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

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Clause	Requirement + Test	Result - Remark	Verdict

8.7C	**TABLE: PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL & SINGLE FAULT CONDITIONS – TYPE CF APPLIED PARTS (μA)**	N/A

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10		50	
				a.c	10		50	
PATIENT LEAKAGECURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10		50	
				a.c	10		50	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10		50	
				a.c	10		50	
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	50		100	
				a.c	50		100	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	50		100	
				a.c	50		100	

Supplementary information:

1: For EARTH LEAKAGE CURRENT see 8.7.3 d)
2: For TOUCH CURRENT see 8.7.3 c)
3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

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Clause	Requirement + Test	Result - Remark	Verdict

8.7.3A	**TABLE: PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL & SINGLE FAULT CONDITIONS – TYPE B APPLIED PARTS (mA r.m.s) – measurements made with a non-frequency-weighted device (μA)**	P

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10	N/A	10	N/A
				a.c	10	N/A	10	N/A
PATIENT LEAKAGECURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10	0	10	0
				a.c	10	N/A	10	N/A
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10	N/A	10	N/A
				a.c	10	N/A	10	N/A
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	10	N/A	10	N/A
				a.c	10	N/A	10	N/A
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	10	N/A	10	N/A
				a.c	10	N/A	10	N/A

Supplementary information:

1: For EARTH LEAKAGE CURRENT see 8.7.3 d)

2: For TOUCH CURRENT see 8.7.3 c)

3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

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Clause	Requirement + Test	Result - Remark	Verdict

8.7.3B	**TABLE: PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL & SINGLE FAULT CONDITIONS – TYPE BF APPLIED PARTS (mA r.m.s) – measurements made with a non-frequency-weighted device (μA)**	N/A

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10		10	
				a.c	10		10	
PATIENT LEAKAGECURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10		10	
				a.c	10		10	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10		10	
				a.c	10		10	
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	10		10	
				a.c	10		10	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	10		10	
				a.c	10		10	

Supplementary information:

1: For EARTH LEAKAGE CURRENT see 8.7.3 d)

2: For TOUCH CURRENT see 8.7.3 c)

3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.7.3C	**TABLE: PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL & SINGLE FAULT CONDITIONS – TYPE CF APPLIED PARTS (mA r.m.s) – measurements made with a non-frequency-weighted device (μA)**	N/A

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10		10	
				a.c	10		10	
PATIENT LEAKAGECURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10		10	
				a.c	10		10	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10		10	
				a.c	10		10	
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	10		10	
				a.c	10		10	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	10		10	
				a.c	10		10	

Supplementary information:

1: For EARTH LEAKAGE CURRENT see 8.7.3 d)

2: For TOUCH CURRENT see 8.7.3 c)

3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.7.3D	TABLE: PATIENT LEAKAGE CURRENTS under special test conditions identified in 8.7.4.7 (mA r.m.s) –measurement with a non-frequency-weighted device (μA)								N/A
Current Type	Description (Note 1)	Clause Ref.	Measuring Circuit	TYPE B APPLIED PART allowed	TYPE B APPLIED PART actual	TYPE BF APPLIED PART allowed	TYPE BF APPLIED PART actual	TYPE CF APPLIED PART allowed	TYPE CF APPLIED PART actual
PATIENT LEAKAGECURRENT	Caused by an external voltage on PATIENT CONN of an F-TYPE APPLIED PART	8.7.4.7 b	Fig 16	N/A	N/A	10	N/A	10	N/A
	Caused by an external voltage on ACCESSIBLE metal part not PROTECTIVELY EARTHED	8.7.4.7 d	Fig 18	10	N/A	10	N/A	See Note 3	See Note 3
Total PATIENT LEAKAGE CURRENT See NOTE 3	Caused by an external voltage on PATIENT CONN of an F-TYPE APPLIED PART	8.7.4.7 b and 8.7.4.7 h	Fig 16 and Fig 20	N/A	N/A	10	N/A	10	N/A
	Caused by an external voltage on ACCESSIBLE metal part not PROTECTIVELY EARTHED	8.7.4.7 d and 8.7.4.7 h	Fig 18 and Fig 20	10	N/A	10	N/A	See Note 3	See Note 3

Supplementary information:

1: The condition referred to in Table IV of the second edition as "MAINS VOLTAGE ON APPLIED PART", and treated in that edition as a SINGLE FAULT CONDITION, is treated in this edition as a special test condition. The test with MAXIMUM MAINS VOLTAGE on a non-PROTECTIVELY EARTHED ACCESSIBLE PART is also a special test condition, but the allowable values are the same as for SINGLE FAULT CONDITION. See the rationales for 8.5.2.2 and 8.7.4.7d.

2: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

3: This condition is not tested with TYPE CF APPLIED PARTS because it is covered by the test with MAXIMUM MAINS VOLTAGE on the APPLIED PART. See also the rationale for 8.7.4.7 d).

4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.7.4.7	TABLE: PATIENT LEAKAGE CURRENTS under special test conditions identified in 8.7.4.7 (μA)								N/A
Current Type	Description (Note 1)	Clause Ref.	Measuring Circuit	TYPE B APPLIED PART allowed	TYPE B APPLIED PART actual	TYPE BF APPLIED PART allowed	TYPE BF APPLIED PART actual	TYPE CF APPLIED PART allowed	TYPE CF APPLIED PART actual
PATIENT LEAKAGE CURRENT	Caused by an external voltage on PATIENT CONN of an F-TYPE APPLIED PART	8.7.4.7b	Fig 16	N/A	N/A	5000		50	
	Caused by an external voltage on ACCESSIBLE metal part not PROTECTIVELY EARTHED	8.7.4.7d	Fig 18	500		500		See Note 3	See Note 3
Total PATIENT LEAKAGE CURRENT See NOTE 3	Caused by an external voltage on PATIENT CONN of an F-TYPE APPLIED PART	8.7.4.7b and 8.7.4.7h	Fig 16 and Fig 20	N/A	N/A	5000		100	
	Caused by an external voltage on ACCESSIBLE metal part not PROTECTIVELY EARTHED	8.7.4.7d and 8.7.4.7h	Fig 18 and Fig 20	1000		1000		See Note 3	See Note 3

Supplementary information:

1: The condition referred to in Table IV of the second edition as "MAINS VOLTAGE ON APPLIED PART", and treated in that edition as a SINGLE FAULT CONDITION, is treated in this edition as a special test condition. The test with MAXIMUM MAINS VOLTAGE on a non-PROTECTIVELY EARTHED ACCESSIBLE PART is also a special test condition, but the allowable values are the same as for SINGLE FAULT CONDITION. See the rationales for 8.5.2.2 and 8.7.4.7d.

2: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

3: This condition is not tested with TYPE CF APPLIED PARTS because it is covered by the test with MAXIMUM MAINS VOLTAGE on the APPLIED PART. See also the rationale for 8.7.4.7 d).

4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.8.3 A	**TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) - 1 min duration**						P
PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.	A.C. test voltages in V r.m.s[1]					Dielectric breakdown[2] Yes/No
		Type of insulation tested (area from insulation diagram)	MEANS OF OPERATOR PROTECTION (MOOP)				
			Protection from MAINS PART		Protection from SECONDARY CIRCUITS		
			One MOOP	Two MOOP	One MOOP	Two MOOP	
-	1.5	DI				No test	

Supplementary information:

[1] Alternatively, as specified in the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.

[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.8.3 B	**TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF PATIENT PROTECTION (MOPP) - 1 min duration**						P
PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.	A.C. test voltages in V r.m.s[1]					Dielectric breakdown[2] Yes/No
		Type of insulation tested (area from insulation diagram)	MEANS OF PATIENT PROTECTION (MOPP)				
			Protection from MAINS PART		Protection from SECONDARY CIRCUITS		
			One MOPP	Two MOPP	One MOPP	Two MOPP	
-	1.5	DI				1000	No

Supplementary information:

[1] Alternatively, as specified in the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.

[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.9.2	**TABLE: Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4**	P

Specific areas of circuits short-circuited and test conditions	Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE[1]	HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No	Remarks
SC battery poles		NO	PTC regulates the current to 2.20 A

Supplementary information:
Note 1: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.2	**Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts**	N/A

Test Sequence No.	Each test duration and temperature	Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)	Dielectric strength test immediately after humidity preconditioning according to 5.7 except for 48 h only, Breakdown: Yes/No
1	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
2	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
3	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
4	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		

Supplementary information:

[1] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.4	**Table: Thermal cycling tests on one sample of cemented joint (see 8.9.3.3)**		N/A
Test Sequence No.	Each test duration and temperature	Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)	Dielectric strength test immediately after humidity preconditioning according to 5.7 except for 48 h only, Breakdown: Yes/No
1	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
2	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
3	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
4	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information: [1] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

8.10	**TABLE: List of critical components**				
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity [1]
PTC	Littelfuse	nanoSMDC110F	I_{hold} 1.10 A I_{trip} 2.20 A		$_{c}UR_{US}$, E183209 TUV
Battery	Any	LR6, AA	1.5 V		

Supplementary information:
1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.

9.2.2.2	**TABLE: Measurement of gap "a" according to Table 20 (ISO 13852: 1996)**				N/A
Part of body	Allowable adult gap[1], mm	Measured adult gap, mm	Allowable children gap[1], mm	Measured children gap, mm	Remarks
Body	> 500		> 500		
Head	> 300 or < 120		> 300 or < 60		
Leg	> 180		> 180		
Foot	> 120 or < 35		> 120 or < 25		
Toes	> 50		> 50		
Arm	> 120		> 120		
Hand, wrist, fist	> 100		> 100		
Finger	> 25 or < 8		> 25 or < 4		

Supplementary information:
[1] In general, gaps for adults used, except when the device is specifically designed for use with children, values for children applied.

10.1.1	**TABLE: Measurement of X - radiation**		N/A
Maximum allowable radiation pA/kg (µSv/h) (mR/h)		36 (5 µSv/h) (0.5 mR/h)	
Surface area under test Surface no./ Description[1]		Measured radiation pA/kg (µSv/h) (mR/h)	Remarks

Supplementary information:
[1] Measurements made at a distance of 5 cm from any surface to which OPERATOR (other than SERVICE PERSONNEL) can gain access without a TOOL, is deliberately provided with means of access, or is instructed to enter regardless of whether or not a TOOL is needed to gain access (pA/kg)

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.	**TABLE: Excessive temperatures in ME EQUIPMENT**				N/A
Model No./Part No./Type No. .....:					
Maximum rated ambient operating temperature T (°C) .....:					
Supply voltage, 110 % of max. RATED voltage, for ME EQUIPMENT with heating elements operated as in NORMAL USE, all heating elements energized unless prevented by switching interlocks (V)					
Supply voltage, least favorable voltage between 90 % of min. RATED voltage and 110 % of max. RATED voltage, for motor operated ME EQUIPMENT operated under normal load and normal DUTY CYCLE (V)					
Normal DUTY CYCLE for motor operated ME EQUIPMENT (s on, s off)					
Supply voltage, 110 % of max. RATED voltage for combined heating, motor operated, and other ME EQUIPMENT (V)					
Supply voltage, 90 % of min. RATED voltage for combined heating, motor operated, and other ME EQUIPMENT (V)					
Class of insulation system (A, E, B, F, H)					
Classification of individual insulating materials or Relative Thermal Index (°C)					
Supplementary information:					

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT – measurement of maximum temperature during NORMAL USE for parts other than APPLIED PARTS and parts likely to be touched**				N/A
Model No. ..... :					
Test ambient (°C) ..... :					
RATED supply voltage (V)..... :					

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22 or 23, (°C)	Max measured temperature[2], (°C)	Remarks

Supplementary information:
[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3 e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.

11.1.2.1	**TABLE: Excessive temperatures in ME EQUIPMENT – measurement of temperatures, hot or cold surfaces, during NORMAL USE for APPLIED PARTS intended to supply heat to a PATIENT**				N/A
Model No. ..... :					
Test ambient (°C) ..... :					
RATED supply voltage (V)..... :					

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from RISK MANAGEMENT FILE, (°C)	Max measured temperature[2], (°C)	Remarks

Supplementary information:
[1] See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.
[2] Max temperature determined in accordance with 11.1.3 e)

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.2.2	**TABLE: Excessive temperatures in ME EQUIPMENT – measurement of maximum temperature during NORMAL USE for APPLIED PARTS not intended to supply heat to a PATIENT**				N/A
Model No. ..... :					
Test ambient (°C) ..... :					
RATED supply voltage (V)..... :					

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 24 (°C)	Max measured temperature[1], (°C)	Remarks

Supplementary information:

[1] Max temperature determined in accordance with 11.1.3 e)

11.1.3d	**TABLE: Temperature of windings by change-of-resistance method**						N/A
Temperature T of winding:	t_1 (°C)	R_1 (Ω)	t_2 (°C)	R_2 (Ω)	T (°C)	Allowed T_{max} (°C)	Insulation class

Supplementary information:

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.2.2.1	**TABLE: alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source**	N/A

Areas where sparking might cause ignition:	Remarks
1.	
2.	
3.	
5.	
6.	

Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):	Remarks
1.	
2.	
3.	
4.	
5.	
6.	

Test parameters selected representing worst case conditions for ME EQUIPMENT:		Remarks
Oxygen concentration (%) ..... :		
Fuel ..... :		
Current (A) ..... :		
Voltage (V) ..... :		
Capacitance (μF) ..... :		
Inductance or resistance (h or Ω) ..... :		
No. of trials (300 Min) ..... :		
Sparks resulted in ignition (Yes/No) ..... :		

Supplementary information:

Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst case values with other parameters set at worst case values to determine if ignition can occur.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

13.1.2	**TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances**	N/A

Power dissipated less than (W) ..... :	15
Energy dissipated less than (J)..... :	900

Part or component tested	Measured power dissipated (W)	Calculated energy dissipated (J)	SINGLE FAULT CONDITIONS waived (Yes/No)	Remarks

Supplementary information:

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

13.2	**TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive**		P
Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.2	Electrical SINGLE FAULT CONDITIONS according to 8.1:	—	—
	SC Battery	PTC regulates the current to 2.2 A	NO
13.2.3	Overheating of transformers according to 15.5:	—	—
13.2.4	Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favorable of the two:	—	—
13.2.5	Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favorable of the two:	—	—
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	—	—
13.2.7	Impairment of cooling that could result in a HAZARD using test method of 11.1:	—	—
	Single ventilation fans locked consecutively		
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls		
	Simulated blocking of filters		
	Flow of a cooling agent interrupted		
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	—	—
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10	—	—
		V measured =	
		V measured =	

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.10	Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9: .	—	—
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or at the upper limit of RATED voltage range for specified time:		
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices		
	Temperatures measured as specified in 11.1.3 d)		
	Temperatures did not exceed limits of Table 26		
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:	—	—
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	—	—

Supplementary information:
[1] Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.

15.4.6	**TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests**	N/A

Rotating control under test	Torque from Table 30 (Nm)	Gripping diameter "d" of control knob (mm) [1]	Axial force applied (N)	Unacceptable RISK occurred Yes/No	Remarks

Supplementary information:
[1] Gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer)

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.5.1.2	**TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION**	N/A
Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V) [1] ..... :		—
RATED input frequency (Hz) ..... :		—

Winding tested	Class of insulation (A, B, E, F, or H)	Type of protective device (fuse, circuit breaker) /Ratings	Protective device operated Yes/No	Time to THERMAL STABILITY when protective device did not operate (Min)	Maximum allowed temp from Table 31 (°C)	Maximum winding temp measured (°C)	Ambient (°C)

Supplementary information:
[1] Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.5.1.3	**TABLE: transformer overload test – conducted only when protective device under short-circuit test operated**	N/A

Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)[1]:	
RATED input frequency (Hz) ..... :	
Test current just below minimum current that would activate protective device & achieve THERMAL STABILITY under method a) (A)..... :	
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A) :	

Winding tested	Class of insulation (A, B, E, F, H)	Type of protective device used (fuse, circuit breaker)/Ratings	Maximum allowed temp from Table 31 (°C)	Maximum winding temp measured (°C)	Ambient (°C)

Supplementary information:

[1] Loads on other windings between no load and their NORMAL USE load.

Time durations:

- IEC 60127-1 fuse: 30 min at current from Table 32.
  Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing-time current data available, test current from Table 32 used until THERMAL STABILITY achieved.
- Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a).

This portion concluded at specified time or when a second protective device opened.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7				N/A
Transformer Model/Type/Part No.	Test voltage applied between	Test voltage (V)	Test frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No
	Primary & secondary windings				
	Primary winding & frame				
	Secondary winding & frame				

Supplementary information:
Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for test parameters & other details

16.6.1	TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS			N/A
Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	Allowable TOUCH CURRENT in NORMAL CONDITION (μA)	Measured TOUCH CURRENT in NORMAL CONDITION (μA)	Allowable TOUCH CURRENT in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, (μA)	Measured TOUCH CURRENT in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, (μA)
	100		500	
	100		500	
	100		500	
	100		500	
	100		500	
	100		500	
	100		500	
	100		500	
	100		500	
	100		500	

Supplementary information:

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Attachment No. 1
ISO 14971 Gap Analysis Checklist
(optional)

Clause	Title	Item	Comments
3.2	Risk Management process	**Procedure describing the risk management process**	Attachment No.1 not applied
3.3	Management Responsibilities	a. **Policy** for determining acceptable risk. b. Assignment of group/individual with risk management responsibility. c. **Procedure for assigning staff** to risk management work. d. **Procedure(s) for review of risk management**, e.g., management design reviews, internal audits, etc.	
3.4	Qualification of personnel	Training records for risk management training, tools training, etc.	
3.5	Risk Management Plan	a. **Procedure for plan development.** b. Description of device. c. Verification plan. d. Allocation of responsibilities. e. Summary of review activities. f. **Evidence of risk acceptability criteria.**	
3.6	Risk Management File	Evidence of file structure for all risk management activities.	
4.1	Risk Analysis Procedure	**Procedure for risk analysis.**	
4.2	Intended use/intended purpose, etc.	Record of safety issue analysis.	
4.3	Hazard Identification	Record of hazard analysis	
4.4	Risk estimation	a. **Definition of methods used for estimating risks.** b. Description of method(s) used. c. Record of risk estimation activities.	
5.0	Risk evaluation	a. Record of risk evaluation activities. b. **Method(s) for dealing with non-quantifiable risks**	

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Clause	Title	Item	Comments
6.1	Risk reduction	**Procedure for risk control activities**	
6.2	Option analysis	Record of risk control option analysis (including risk-benefit analysis, if appropriate).	
6.3	Implementation of risk control measures	Design inputs from risk management activities	
6.4	Residual risk evaluation	Evidence, e.g., from design verification activities.	
6.5	Risk-Benefit Analysis	Evidence as necessary...see 6.2.	
6.6	Other generated hazards	Record of review of all risk controls for impact on new hazards.	
7	Overall risk evaluation	Records of related meetings, analysis, etc.	
8	Risk management report	a. **Procedure for generating a Risk Management report.**	
		b. Summary of risk management activities.	
		c. Traceability of hazards to residual risks.	
		d. Clearances.	
9	Post-production information	a. **Procedures for linking information into risk management review:**	
		• Manufacturing	
		• CAPA	
		• Servicing	
		• Purchasing	
		• etc.	
		b. Records implementing procedures	

Note: Bold letters indicate critical elements that should be present even at the very beginning of implementation.

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Test Report issued under the responsibility of

Intertek

IEC 60601-1-6 / EN 60601-1-6

Medical electrical equipment

Part 1-6: General requirements for safety - Collateral Standard: Usability

Report Reference No.	809546-2
Compiled by (+ signature)	Ansis Graufelds
Approved by (+ signature)	Peter Lymeus
Date of issue	2008-12-10
Total number of pages	13

CB Testing Laboratory	Intertek Semko AB
Address	Box 1103 SE-164 22 Kista, SWEDEN
Testing location/procedure	CBTL ☒ RMT ☐ SMT ☐ WMT ☐ TMP ☐
Address	Same as above
Applicant's name	3M Health Care
Address	3M Center, Building 270-4N-09 Maplewood, MN 55144-1000 Patient Assessment Laboratory 3M Medical Products, USA

Test specification:

Standard	IEC 60601-1-6: 2006, Second Edition
Test procedure	CB Scheme
Non-standard test method	N/A

Test Report Form No.	IEC60601_1_6C
Test Report Form Originator	Underwriters Laboratories Inc.
Master TRF	Dated 2007-02

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Test item description	Stethoscope
Trade Mark	3M™ Littmann®
Manufacturer	(b) (4) [redacted]
Model/Type reference	
Ratings	Type B, IPX4, Battery type AA

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Test Report issued under the responsibility of

Intertek

IEC 60601-1-6 / EN 60601-1-6

Medical electrical equipment

Part 1-6: General requirements for safety - Collateral Standard: Usability

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Test specification:

Standard	IEC 60601-1-6: 2006, Second Edition
Test procedure	CB Scheme
Non-standard test method	N/A

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Test item description	Stethoscope
Trade Mark	3M™ Littmann®
Manufacturer	(b) (4) [redacted]
Model/Type reference	
Ratings	Type B, IPX4, Battery type AA

1483

Test Report issued under the responsibility of

Intertek

IEC 60601-1-6 / EN 60601-1-6

Medical electrical equipment

Part 1-6: General requirements for safety - Collateral Standard: Usability

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Test specification:

Standard	IEC 60601-1-6: 2006, Second Edition
Test procedure	CB Scheme
Non-standard test method	N/A

Test Report Form No.	IEC60601_1_6C
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Test item description	Stethoscope
Trade Mark	3M™ Littmann®
Manufacturer	(b) (4) [redacted]
Model/Type reference	
Ratings	Type B, IPX4, Battery type AA

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Testing procedure and testing location:

☒ **CB Testing Laboratory**:

Testing location/ address ..... : Torshamnsgatan 43
SE-164 22 Kista, SWEDEN

☐ **Associated CB Test Laboratory:**

Testing location/ address ..... :

Tested by (name + signature) ..... : Ansis Graufelds

Approved by (+ signature)..... : Peter Lymeus

☐ Testing procedure: TMP

Tested by (name + signature) ..... :

Approved by (+ signature)..... :

Testing location/ address ..... :

☐ Testing procedure: WMT

Tested by (name + signature) ..... :

Witnessed by (+ signature) ..... :

Approved by (+ signature)..... :

Testing location/ address ..... :

☐ Testing procedure: SMT

Tested by (name + signature) ..... :

Approved by (+ signature)..... :

Supervised by (+ signature) ..... :

Testing location/ address ..... :

☐ Testing procedure: RMT

Tested by (name + signature) ..... :

Approved by (+ signature)..... :

Supervised by (+ signature) ..... :

Testing location/ address ..... :

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Summary of testing:	
Tests performed (name of test and test clause):	**Testing location:**
Summary of compliance with National Differences: -	
Copy of marking plate See report 809546-1	

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Test item particulars ..... :	
Classification of installation and use ..... :	See IEC 60601-1 Test Report
Clinical application ..... :	Medical diagnostic
Mode of operation ..... :	Continuous
Surface temperature of APPLIED PART ..... :	40°C
Possible test case verdicts:	
- test case does not apply to the test object ..... :	N/A
- test object does meet the requirement ..... :	Pass (P)
- test object does not meet the requirement ..... :	Fail (F)
Testing:	
Date of receipt of test items ..... :	2008-11-10
Date of performance of tests ..... :	2008-12-09

Abbreviations used in the report:

- normal condition:	N.C.	- single fault condition:	S.F.C.
- operational insulation:	OP	- basic insulation:	BI
- double insulation:	DI	- supplementary insulation:	SI
- basic insulation between parts of opposite polarity:	BOP	- reinforced insulation:	RI

General remarks:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

"(see Enclosure #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.

Throughout this report, a point is used as the decimal separator.

List of test equipment must be kept on file and available for review.

This Test Report contains the general safety requirements as related to the usability of Medical Electrical Equipment. It can only be used together with IEC 60601-1 Test Report.

General product information:

See Test Report 809546-1.

IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	GENERAL REQUIREMENTS		P
4.1	ME EQUIPMENT provides adequate USABILITY, and the RISKS resulting from NORMAL USE and USE ERRORS are acceptable	Risk management file (ISO 14971), Residual Risk Levels are primarily at a risk acceptability level of R1 (the most broadly acceptable risk level). The R2 residual risks are related to EMC and RF coexistence with other medical devices.	P
4.2	Inspection of USABILITY ENGINEERING FILE assessing all RISK ANALYSIS considerations	Reference: Risk Management File: "RISK MGMT-05-000265.xls" Potential hazards are identified by the product's cross functional Risk Management team and addressed during risk management. The risk management process addresses these areas of potential hazard in it's Questionnaire section with the requirement that any identified hazard is then carried over to risk assessment & control.	P
5	**IDENTIFICATION, MARKING AND DOCUMENTS**		
5.1	ACCOMPANYING DOCUMENTS	Model 3100 User Guide, v1.2 Model 3200 User Guide, Draft v0.4.	P

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IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	A brief description of EQUIPMENT, its physical operating principles, and significant physical and performance characteristics relevant to its USABILITY included in the instructions for use	The equipment is an electronic stethoscope. This stethoscope includes a microphone, digital filtering, and a binaural headset. The user interface for the stethoscope features a 5-button keypad and an LCD display for controlling the stethoscope during everyday use, plus access to less often-used menus and communication configuration options. The stethoscope functions include digital sound processing to produce the conventional stethoscope Bell and Diaphragm frequency response. The Model 3200 also features a third frequency response in addition to the Bell and Diaphragm modes. The Model 3200 stethoscope includes a Bluetooth wireless link that allows the stethoscope to exchange audio data with an external device such as a personal computer (PC). The stethoscope power is provided by a single AA battery that is located in the chestpiece. A power management system is included to prolong battery life.	P
	The same information, when provided as a separate document, included in the technical description	No separate documents.	N/A
	ACCOMPANYING DOCUMENTS for equipment are, optionally, provided electronically, e.g., by electronic file format or CD-ROM ..... :	No electronic media provided	N/A
	USABILITY ENGINEERING PROCESS includes the information that will need to be provided as a hard copy or as markings on EQUIPMENT (e.g., to cover emergency operation) when ACCOMPANYING DOCUMENTS are provided electronically	No electronic media provided	N/A

IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	ACCOMPANYING DOCUMENTS include a description of the OPERATOR PROFILE	See page 4 IFU	P
	ACCOMPANYING DOCUMENTS are written at a level consistent with the intended OPERATOR PROFILE	User Guides are written at a level consistent with the intended operator profile.	P
5.2	TRAINING and materials for TRAINING		P
	–necessary TRAINING materials required for PRIMARY OPERATING FUNCTIONS of EQUIPMENT provided by the manufacturer	The 3100/3200 User Guides include information that servers as training material for the operation of these products. Equipment specific information includes: How to: - Insert Battery - Position and Adjust Headset - Turn On/Off - Select Filter - Adjust Sound - Monitor Heart Rate - Custom configuration - Other Operating Conditions	P
	–TRAINING materials are available; or	No training material is required or provided.	N/A
	– the manufacturer provides TRAINING	No training material is required or provided.	N/A
	INTENDED USE is the basis for TRAINING and TRAINING material	No training is required.	N/A
	Instructions for use indicate the available TRAINING options and when specific TRAINING for the EQUIPMENT is required	No specific training is provided.	N/A

6	**USE ERROR and USABILITY**	P
6.1	Safety for the PATIENT, OPERATOR and other persons	P

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IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	A USABILITY ENGINEERING PROCESS conducted to provide safety for the PATIENT, OPERATOR and other persons related to USABILITY of the OPERATOR-EQUIPMENT INTERFACE	3M Medical maintain an ISO 13485 and FDA QSR compliant Quality Management System (QMS). Within our QMS we maintain a New Product Introduction (NPI) life cycle model that incorporates all of the elements of Design Control including risk management. Specific to this product, Section 6.0 of DS-INPUT-05-000273 is for "Safety Requirements" and is where we identify what are the applicable safety regulations such as IEC 60601 (6.4) which include 60601-1-6.	P
6.2	USABILITY ENGINEERING PROCESS		P
6.2.1	The results of the USABILITY ENGINEERING PROCESS recorded in the USABILITY ENGINEERING FILE	Reference: "Littman_Usability Engineering File.doc"	P
	The records and other documents that make up the USABILITY ENGINEERING FILE form part of other documents(e.g., a MANUFACTURER'S product file or RISK MANAGEMENT FILE)	Reference – Risk Assessment file: "RISK MGMT-05-000265.xls"	P
	The USABILITY ENGINEERING PROCESS scaled based on the significance of any modifications depending on the results of the RISK ANALYSIS		N/A
6.2.2	Input for the USABILITY ENGINEERING PROCESS		P
6.2.2.1	ME EQUIPMENT application specification		P
	Application of ME EQUIPMENT in the USABILITY ENGINEERING FILE specified by the MANUFACTURER and includes		P
	– medical purpose {e.g., conditions(s) or disease(s) to be screened, monitored, treated, or diagnosed};	Reference: "cap0803a E3000 Plus Product requirements.pdf " Section 12 on Product Requirements	P
	– PATIENT population (e.g., age, weight, region of body, health, condition);	Reference - 3100/3200 User Guide, Functional Description	P
	– part of the body or type of tissue applied to or interacted with;	Reference - 3100/3200 User Guide, Intended Use	P
	– intended OPERATOR PROFILE; and	The Model 3100/3200 electronic stethoscope is used to listen to heart, lung, and other body sounds.	P

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IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	– application (e.g.. environment, frequency of use, location, mobility)		P
	A summary of the ME EQUIPMENT application specification included in the instructions for use		P
6.2.2.2	PRIMARY OPERATING FUNCTIONS		P
	The MANUFACTURER has determined the PRIMARY OPERATING FUNCTIONS and recorded them in the USABILITY ENGINEERING FILE	Reference - "cap0803a E3000 Plus Product requirements.pdf"	P
6.2.2.3	Information for safety as a RISK CONTROL		
	For RISK CONTROL related to USABILITY, the MANUFACTURER has decided what information is required for BASIC SAFETY or ESSENTIAL PERFORMANCE (e.g., warnings or limitation of use in the ACCOMPANYING DOCUMENTS, marking, etc.)	Reference - Model 3100 User Guide.doc and Model 3200 User Guide.doc	P
	Such information was subject to the USABILITY ENGINEERING PROCESS		P
	Disregarding this information considered ABNORMAL USE	Potential misuse is included in Risk Assessment document	P
	RISK CONTROL consisted of an integrated approach using		P
	a) inherent SAFETY by design;	Ongoing safety emphasis during design process documented in 3M Risk Management process	P
	b) protective measures in ME EQUIPMENT itself or in the manufacturing PROCESS (e.g., ALARMSYSTEMS)	- Battery use indicator, alerts user when battery level is low - Filter indicator, indicates which mode is currently being used (diaphragm or bell mode) - Backlight for use in low light environments	P
	c) information for safety (e.g., warnings in the instructions for use, display of a monitored variable)	Reference – "RISK MGMT-05-000265.xls" Rows AI – AJ: misuse	P
	The results of the RISK ANALYSIS or a reference to the location of the results of the RISK ANALYSIS recorded in the USABILITY ENGINEERING FILE	Reference – "Littman Usability Engineering File.doc"	P
	The RISK ANALYSIS for the ME EQUIPMENT or for the corresponding generic device type was an input for the USABILITY SPECIFICATION as required for the USABILITY ENGINEERING PROCESS.		P

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IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	Any RESIDUAL RISK evaluation took into consideration the results of the USABILITY VALIDATION	Reference – "Final E3000 VOC Report.ppt"	P
	The evaluation of post-production information (post-market surveillance) included USABILITY (see ISO 14971:2000, Clause 9)	Reference – "RISK MGMT – 05-000265.xls" 3M will monitor of complaint trends (3M CFR data)	P
6.2.3	USABILITY SPECIFICATION		P
	MANUFACTURER developed a USABILITY SPECIFICATIONrecorded in USABILITY ENGINEERING FILE as part of the USABILITY ENGINEERING PROCESS	Reference: Customer specification DS-INPUT-05-000273	P
	The USABILITY SPECIFICATION integrated into other specifications and based on the following:		P
	– application specification (see 6.2.2.1);	References - "Model 3100 User Guide.doc" "Model 3200 User Guide.doc" "cap0803a E3000 Plus Product requirements ver2.00.pdf" PR:092, PR:093 and PR:098	P
	– HAZARDS related to the use of the ME EQUIPMENT (results from RISK ANALYSIS described in 4.2); and	Reference - "RISK MGMT-05-000265.xls", Section: Risk Identification, Potential Hazardous Situations	P
	– predictable USE ERRORS associated with the ME EQUIPMENT	Reference – "RISK MGMT-05-000265.xls" Risk Assessment file	P
	The USABILITY SPECIFICATION describes at least:		P
	– USE SCENARIOS for the ME EQUIPMENT;	Reference – - Littmann_Usability Engineering File.doc" - Risk Assessment file: "RISK MGMT-05-000265.xls" - ESC Recap Notes.doc	P
	– OPERATOR actions related to the PRIMARY OPERATING FUNCTIONS;	Reference - "cap0803a E3000 Plus Product requirements.pdf" Section 12.3	P

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IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	– OPERATOR-EQUIPMENT INTERFACE requirements for the PRIMARY OPERATING FUNCTIONS; and	Reference - "DS-INPUT-05-000273 .pdf" 3.4 (Ease of use) 4.4 (Ergonomic design facilitates use of stethoscope) 4.5 (Single hand operates stethoscope and all primary functions) 4.6 (Easy selection of controls) 4.7 (Chestpiece can be gripped multiple ways).	P
	– requirements for determining whether PRIMARY OPERATING FUNCTIONS are easily recognizable by the OPERATOR	Reference – "Report - AHA Focus Groups - Stethoscope - November 2007 - 11-9-07.pdf" - Interview results - Focus group results - User observations and comments	P
6.2.4	USABILITY VERIFICATION		P
	MANUFACTURER verified the OPERATOR-EQUIPMENT interface design according to the USABILITY SPECIFICATION as part of the ME EQUIPMENT DESIGN	References - "Littman_Usability Engineering File.doc" "DS-INPUT-05-000273 v5.pdf"	P
	The results of the verification are recorded in USABILITY ENGINEERING FILE	References - "Littman_Usability Engineering File.doc"	P
6.2.5	The MANUFACTURER has developed and maintains a USABILITY VALIDATION plan specifying:	Reference - "CUST-CVE-05-000051.doc" Document includes the quantitative criteria for acceptance in the usability/field evaluation questionnaire. TEAM-MISC-05-005873.pdf	P
	– any method used for VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS;	Reference – "CUST-CVE-05-000051.doc" "TEAM-MISC-05-005873.doc" "Littman_Usability Engineering File.doc"	P

IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	– the criteria for determining successful VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS (see Table D.5); and	Reference – "CUST-CVE-05-000051.doc"	P
	– the involvement of representative intended OPERATORS (see D.4.3.2)	Reference – "CUST-CVE-05-000051.doc"	P
	USABILITY VALIDATION performed in a laboratory setting ..... :	3M usability specialists reviewed the initial production models in a laboratory setting to validate the usability in a simulated use environment.	P
	USABILITY VALIDATION performed in a simulated use environment..... :	Reference – "CUST-CVE-05-000051.doc"	P
	USABILITY VALIDATION performed in the actual use environment..... :	Reference – "CUST-CVE-05-000051.doc"	P
	The USABILITY VALIDATION plan addressed:		P
	– worst case USE SCENARIOS derived from: • the application specification (see 6.2.2.1), • predictable USE ERRORS, and • the results of the RISK ANALYSIS; and	Reference – "Littman_Usability Engineering File.doc" Usability validation includes **usability testing in a laboratory setting** that will address worst case use scenarios derived from: - use scenarios - predicted use errors - risk analysis	P
	– USE SCENARIOS representing frequent application situations identified in the USABILITY SPECIFICATION	Reference – "CUST-CVE-05-000051.doc" "TEAM-MISC-05-005873.doc" Usability validation plan includes gathering feedback from typical use scenarios	P
	The USABILITY VALIDATION plan recorded in the USABILITY ENGINEERING FILE		P
6.2.6	USABILITY VALIDATION		P
	The MANUFACTURER validated OPERATOR-EQUIPMENT INTERFACE design according to the USABILITY VALIDATION plan	Reference – "CUST-CVE-05-000051.doc" "TEAM-MISC-05-005873.doc"	P
	The results, including any required design modification needed to satisfy the criteria as defined in the USABILITY VALIDATION plan, recorded	Post-production plans to usability-related design modifications include monitoring of complaint trends (3M CFR data) and warranty and repair data (Health Care Service Center data).	P

IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	The ACCOMPANYING DOCUMENTS are part of the ME EQUIPMENT and are also subject to activities for validating USABILITY	Reference – "CUST-CVE-05-000051.doc" Usability validation includes evaluation of the supporting documentation supplied with the Model 3100/3200 Electronic Stethoscope.	P
	Individuals that were not directly involved in the OPERATOR-EQUIPMENT INTERFACE design were involved in the USABILITY VALIDATION	Usability validation evaluation will be completed by technical service staff and usability specialists	P

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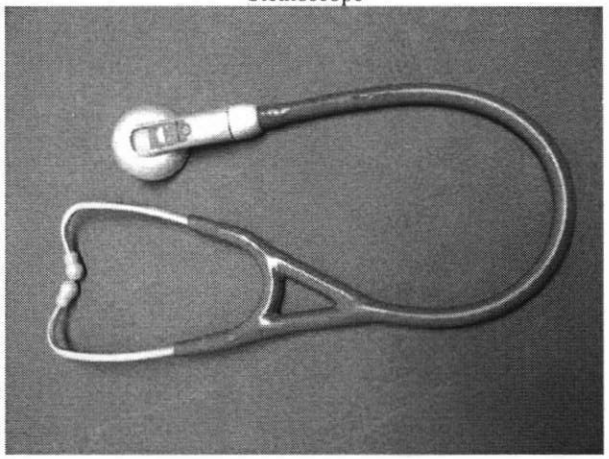
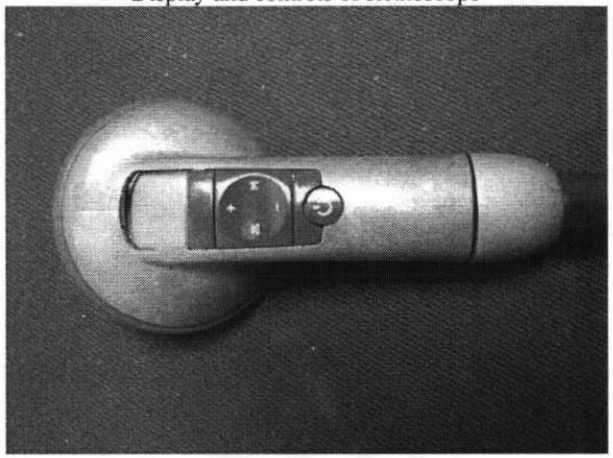
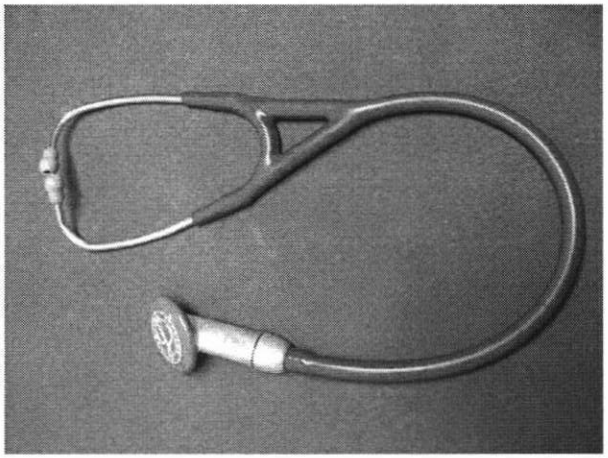
Attachment A

Stethoscope

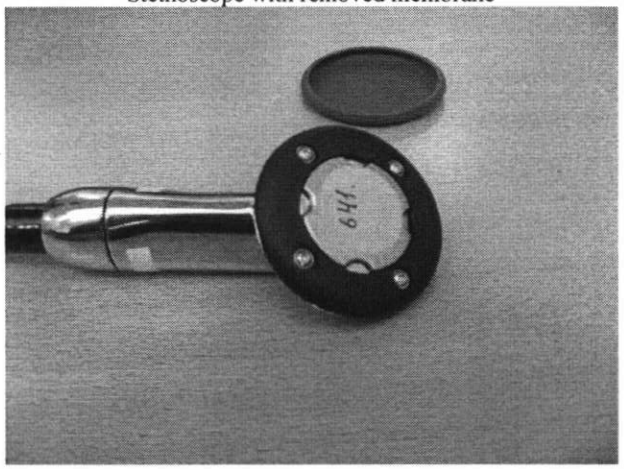


Display and controls of stethoscope





Stethoscope with removed membrane



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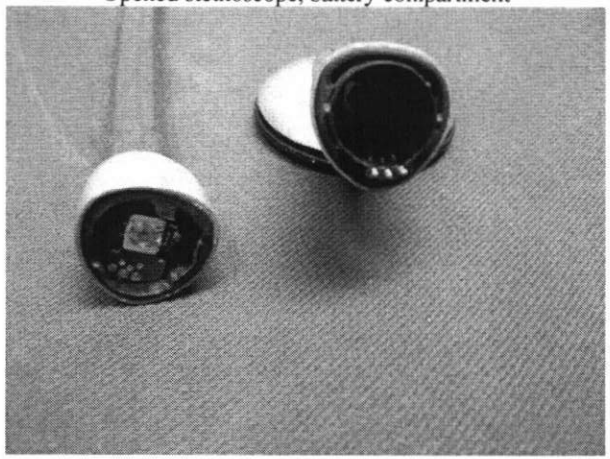
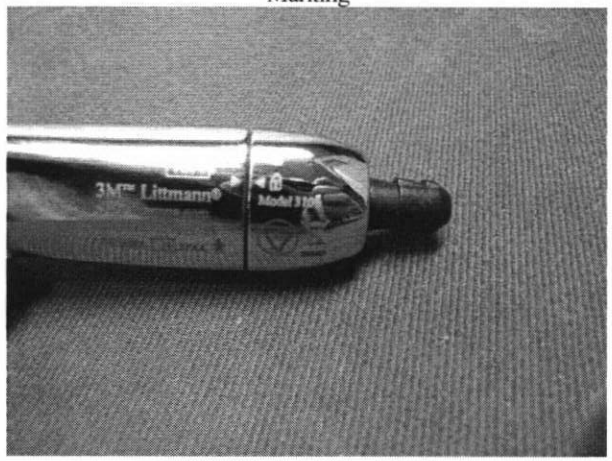
Attachment A

Opened stethoscope, battery compartment



Marking



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(b)(4)

[redacted]

E3000 Plus
Design verification protocol mandatory requirements

Version 2.00

File name: TAD0821a Design verification protocol - mandatory requirements E3000 Plus

Author

26.08.2005

Date, Name – Quality Assurance

Approved by

Date, Name – Quality Assurance

QM500434 Version 4.00

(b)(4)

[redacted]

Version history

Version	Author	Date	Description	Reviewed by	EC number
0.01	TAD	22.05.08.	Document initiated		
0.10	TAD	17.06.08.	Document finalized for review	CAP; SSR; TRH	
1.00	TAD	30.06.08.	Document finalized		
2.00	TAD	28.08.08.	Figure 1 updated; sequence added + number of samples corrected + sinusoidal vibration test deleted		

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(b)(4) [redacted]

1 Purpose

The purpose is to describe how to perform the E3000 Plus design verification according to claim standards and define the acceptance criteria.

2 Scope

The document covers verification of Product requirements according to claim standards.
In this protocol only parameters which are variable (time, temperature etc.) are listed in the individual procedures. Requirements which is not variable (heating up times, airflow, etc.) are not written in the procedures, to make sure that the tests are done in compliance with the requirements one must refer to the standards.

3 References

[1] TAD0816b Design verification plan E3000 Plus
[2] SSR0807a Design control status overview E3100-E3200
[3] HLA0807a Functional test protocol
[4] ISO 11608-1:2000
[5] EN 60068-2-1: 2007 Environmental testing – Part 2-1: Tests – Test A: Cold,
[6] EN 60068-2-2: 2007 Environmental testing – Part 2-2: Tests – Test B: Dry Heat,
[7] EN 60068-2-78: 2001 Environmental testing – Part 2-78: Tests – Test Cab: Damp heat, steady state
[8] EN 60068-2-6: 1995 Environmental testing – Part 2: Tests- Tests Fc: Vibration (sinusoidal):
[9] EN 60068-2-14: 2001, Environmental testing - Part 2: Tests – Test N: Change in temperature, amendment 1:1986
[10] EN 60068-2-30: 1980, Environmental testing. Test methods. Test Db and guidance: damp heat, cyclic (12 + 12 hour cycle)
[11] EN 60068-2-64: 1997 environmental testing – Part 2: test methods – test Fh: Vibration, broadband random (digital control) and guidance

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(b)(4) [redacted]

4 Execution of verification

4.1 Verification description

The design verification is carried out in the sequence as shown below.

Sequence	Preconditioning	Number of samples, or test specimen	
[no.]	[name]	Pre verification	Design verification
A 1-31	Cold storage atmosphere	3	8
B 1-31	Cold operating atmosphere	3	31
A 1-31	Dry heat storage atmosphere	3	8
B 1-31	Dry heat operating atmosphere	3	31
B 1-31	Damp heat, steady state	2	31
C 1-31	Change of temperature	3	31
B 1-31	Damp heat, cyclic (12+12 hour cycle)	3	31
B 1-31	Vibration, broad band random	3	31

Figure 1 Design Verification Sequence overview

4.2 Device preparation

- The devices shall be marked with ID no.
- Function test, FT (ref. [3]) shall be performed before verification start on all devices to ensure that they are functioning.
- Visually the devices shall be inspected in regard to colour, cracks, gloss and roughness before verification start on all devices to ensure that they have no obvious defects.

4.3 Device storage

Samples and test specimens used for verification shall be stored in B&O Medicom items archive.

4.4 Verification working procedure

To carry out preconditioning or test, the following basic documents are needed:

1. The protocol
2. The matching registration sheet

The test results, deviations, date of test, initials on operator along with identification of the devices and the equipment used, are filled in the registration sheet.

4.5 Acceptance criteria

Acceptance criteria are described in the protocols.
In general the acceptance criterion is

(b)(4) [redacted]

- a function test, a visual inspection or both, which must be passed accordingly before and after the preconditioning

4.6 Function test

Device functionality is tested in FT. See [3].

4.7 Visual inspection

Purpose
The purpose of this inspection is to show that preconditioning has not influenced the appearance of the device.

Acceptance criterion
Preconditioning must not influence appearance.
Visually the devices shall appear as before preconditioning in regard to colour, cracks, gloss and roughness.

4.8 General test conditions

Unless otherwise specified in the test methods, the FT shall be performed under the circumstances described in ISO 11608-1:2000 chapter 6.1, see [4].

These conditions are called "room climate" in the rest of this document:

- 18°C - 28°C
- 25% RH - 75% RH

FT and visual inspection shall be carried out after the specified acclimatization period.

(b)(4) [redacted]

5 Test methods

5.1 Cold storage atmosphere

PR:110 : Ship/Storage conditions: -40°C to +55°C, 15-95% humidity with battery.

Purpose
The purpose of this test is to show the ability of the product to be stored or transported at low temperatures and be able to operate again after an acclimatization period in room temperature

Standard
EN 60068-2-1: 2007, amendment 1:1993, amendment 2:1994. Test Ab.
Test Ab is chosen as the device to be tested is non heat-dissipating.

Equipment
- Device
- Lithium battery (may not be used previously)
- Climate cabinet
- Registration sheet

Preconditioning
1. Set the temperature on -40°C
2. Switch on the cabinet
3. Place the device in the climate cabinet when correct temperature is reached
4. Turn on the device
5. After 96 hours, remove the device from the cabinet and place it at room climate
6. Leave it for acclimatization for a minimum of 1 hour

Variation
Maximum variation on temperature: ± 3°C.

Acceptance criterion
Must pass FT and be visual inspected before and after preconditioning.

Comments

Battery must be placed in device during preconditioning and test.

It makes no sense specifying the humidity when testing at very low temperatures. The amount of water will be very low which will make a specified % RH very uncertain.

5.2 Cold operating atmosphere

PR:104 : Environments ranging from -30°C to +55°C, 15-95% relative humidity. For temperatures below -18°C a Lithium battery must be used.

Purpose
The purpose of this test is to show the ability of the device to function in a low temperature environment.

Standard
EN 60068-2-1: 2007 amendment 1:1993, amendment 2:1994. Test Ab.
Test Ab is chosen as the device to be tested is non heat-dissipating.

Equipment
- Device
- Lithium battery (may not be used previously)
- Climate cabinet
- Registration sheet

Preconditioning
1. Place the device in cabinet
2. Set the temperature on -33°C on a climate cabinet and switch it on
3. Let the cabinet acclimatize
4. Turn on the device
5. Leave the device for 2 hours
6. Carry out FT in the cabinet doorway/alternatively in the cabinet

Variation
Maximum variation on temperature: ± 3°C.

Acceptance criterion
Must pass FT and be visual inspected before preconditioning and immediately after preconditioning.

Comments

Battery must be placed in device during preconditioning and test.

It makes no sense specifying the humidity when testing at very low temperatures. The amount of water will be very low which will make a specified % RH very uncertain.

When following the standard a temperature on -30°C is no possibility. The temperature -33°C is chosen instead.

(b)(4) [redacted]

5.3 Dry heat storage atmosphere

PR:110 : Ship/Storage conditions: -40°C to +55°C, 15-95% humidity with battery.

Purpose
The purpose of this test is to show the resistance of the product when stored or transported at high temperatures.

Standard
EN 60068-2-2: 2007, Test Bb.
Test Bb is chosen as the device to be tested is non heat-dissipating.

Equipment
- Device
- Alkaline battery (may not be used previously)
- Climate cabinet
- Registration sheet

Preconditioning
1. Set the temperature on +55°C
2. Set the humidity on 15% RH
3. Switch on the cabinet
4. Place the device in the climate cabinet when correct temperature is reached.
5. Turn on the device
6. After 96 hours, remove the product from the cabinet and place it at room climate
7. Leave the device for acclimatization for a minimum of 1 hour

Variation
Maximum variation on temperature: ± 2°C and
Variation on humidity: the absolute humidity shall not exceed 20g/m^3, which at 35°C corresponds to approximately 50%RH. When tested at lower temperatures the %RH shall not exceed 50%.

Acceptance criterion
Must pass FT and be visual inspected before and after preconditioning.

Comments
Battery must be placed in device during preconditioning and test.

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(b)(4) [redacted]

5.4 Dry heat operating atmosphere

PR:104 : Environments ranging from -30°C to +55°C, 15-95% relative humidity. For temperatures below -18°C a Lithium battery must be used.

Purpose
The purpose of this test is to show the ability of the device to function in a high temperature environment.

Standard
CEI IEC 60068-2-2: 2007, amendment 1:1993, amendment 2:1994. Test Bb.
Test Bb is chosen as the device to be tested is non heat-dissipating.

Equipment
- Device
- Alkaline battery (may not be used previously)
- Climate cabinet
- Registration sheet

Preconditioning
1. Place the device in cabinet
2. Set the humidity on 15% RH
3. Set the temperature on +55°C on the climate cabinet and switch it on
4. Let the cabinet acclimatize
5. Turn on the device
6. Leave the device for 2 hours
7. Carry out FT in the cabinet doorway/alternatively in the cabinet

Variation
Maximum variation on temperature: ± 2°C
Variation on humidity: the absolute humidity shall not exceed 20g/m^3, which at 35°C corresponds to approximately to 50%RH. When tested at lower temperatures the %RH shall not exceed 50%.

Acceptance criterion
Must pass FT and be visual inspected before preconditioning and immediately after preconditioning.

Comments

Battery must be placed in device during preconditioning and test.

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(b)(4) [redacted]

5.5 Damp heat, steady state

Purpose
The purpose of this test is to show the ability of the device to function after storage in a high temperature and high humidity environment.

Standard
EN 60068-2-78: 2001

Equipment
- Device
- Alkaline battery (may not be used previously)
- Climate cabinet
- Registration sheet

Preconditioning
1. Place the device in climate cabinet
2. Set the temperature on 40°C and the humidity on 93%RH on a climate cabinet and switch it on
3. Let the cabinet acclimatize
4. Leave the device for 10 days
5. Take the device out of the climate cabinet and subject it to room climate for a minimum of 1 hour

Variation
Maximum variation on temperature: ± 2°C
Maximum variation on humidity is ± 3%RH

Acceptance criterion
Must pass FT and be visual inspected before and when performed after preconditioning.

QMS00434, Version 4.00

1509

(b)(4) [redacted]

5.6 Change of temperature

PR:109 : The device must pass thermal shock test, from -26,5°C for 3 hours to +40°C for 3 hours. 5 cycles.

Purpose
The purpose of the test is to show that the device can operate after being subjected to changes in temperature.

Standard
EN 60068-2-14: 2001 Test Na, Amendment 1:1986

Equipment
Device
Lithium battery (may not be used previously)
Climate cabinets (1 for low temperature and 1 for high temperature)
Registration sheet

Preconditioning
1. Set the cold climate cabinet on -33°C
2. Transfer the device to the cold climate cabinet
3. Leave the device in the cold climate cabinet for 3 hours
4. Set the hot climate cabinet on +55°C
5. Transfer the device to the hot climate cabinet
6. Leave the device in the hot climate cabinet for 3 hours

1.-6. makes up a cycle, consisting of 2 exposure times and 2 transfer times
The device shall be subjected to 5 cycles
After 5 cycles let the device acclimatize for 1 hour

Variation
The maximum variation on temperature is ±2°C
The maximum variation on exposure time is 10% of the chosen exposure time, (t)
Transfer period from hot to cold and cold to hot: not less than 2 minutes and not more than 3 minutes.
The absolute humidity should not exceed 20 g/m^3

Acceptance
The device must pass FT and be visual inspected before and after preconditioning

Comments
The actual temperatures are chosen to cover the full specified temperature range of the stethoscope.

If it is not possible to commence the next transition from low to high temperature, or vice versa, immediately after the appropriate time, the specimens may remain in the cold or hot chamber (preferably cold) for example overnight or during a weekend.

QRS00434, Version 4.00

1510

(b)(4) [redacted]

5.7 Damp heat, Cyclic (12 + 12 hour cycle)

PR:108 : The device must pass the cyclic heat test +25°C in 24 hours, +40°C in 12 hours, 93% RH. 2 cycles.

Purpose
The purpose of this test is to show the resistance of the device to high humidity and changing temperatures when stored or transported.

Standard
EN 60068-2-30:2005
(Variant 1)

Equipment
- Device
- Alkaline battery (may not be used previously)
- Programmable climate cabinet
- Registration sheet

Preconditioning
See figures 1 and 2a below
The heating time of the cabinet between temperature levels must take 3 hours ±30 min.
The cooling must take 3 to 6 hours.

1. Place the device in a climate cabinet
2. Program the climate cabinet according to figures 1 and 2
3. Set maximum temperature on +40°C
4. Set the program on 2 cycles
5. Switch on the cabinet
6. Remove the device from the cabinet and place it at room climate
7. Leave it for acclimatization 4 hours

Variation
See figures 1 and 2 below

Acceptance criterion
The device must pass FT and be visual inspected before and after preconditioning.

(b)(4) [redacted]

(b) (4) [redacted]

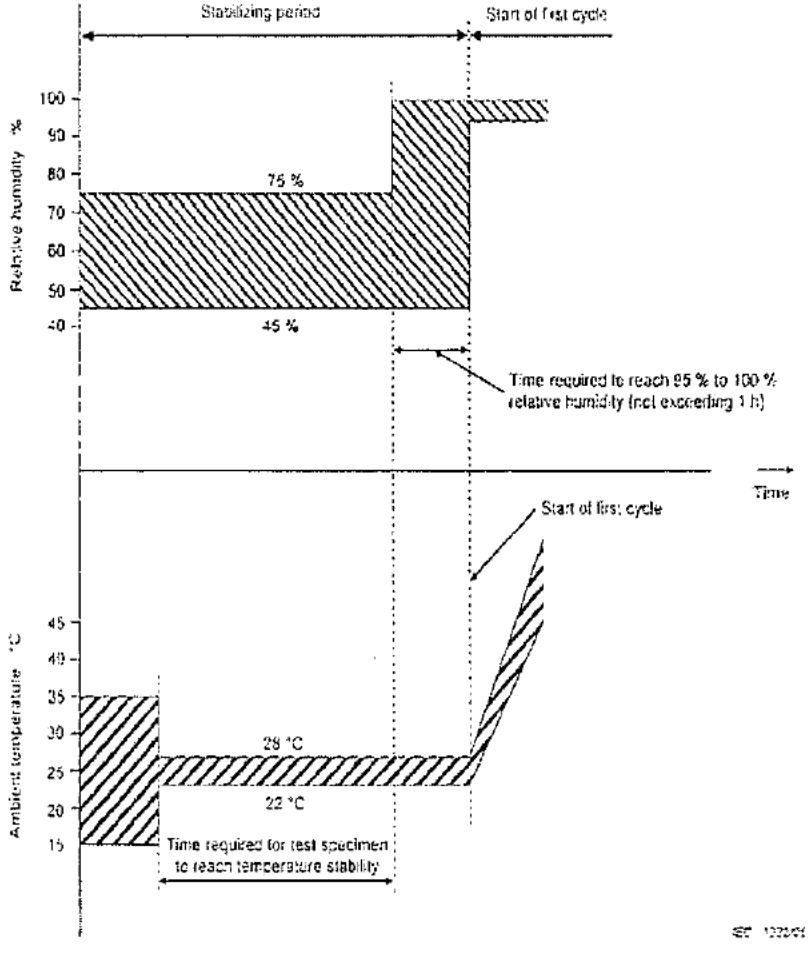

Figure 1 – Test Db – Stabilizing period

Figure 1: Test Db Stabilizing period

1512

(b)(4) [redacted]

Licens købt af: Bang & Olufsen A/S, Peter Bangs Vej 15, 7600 Struer

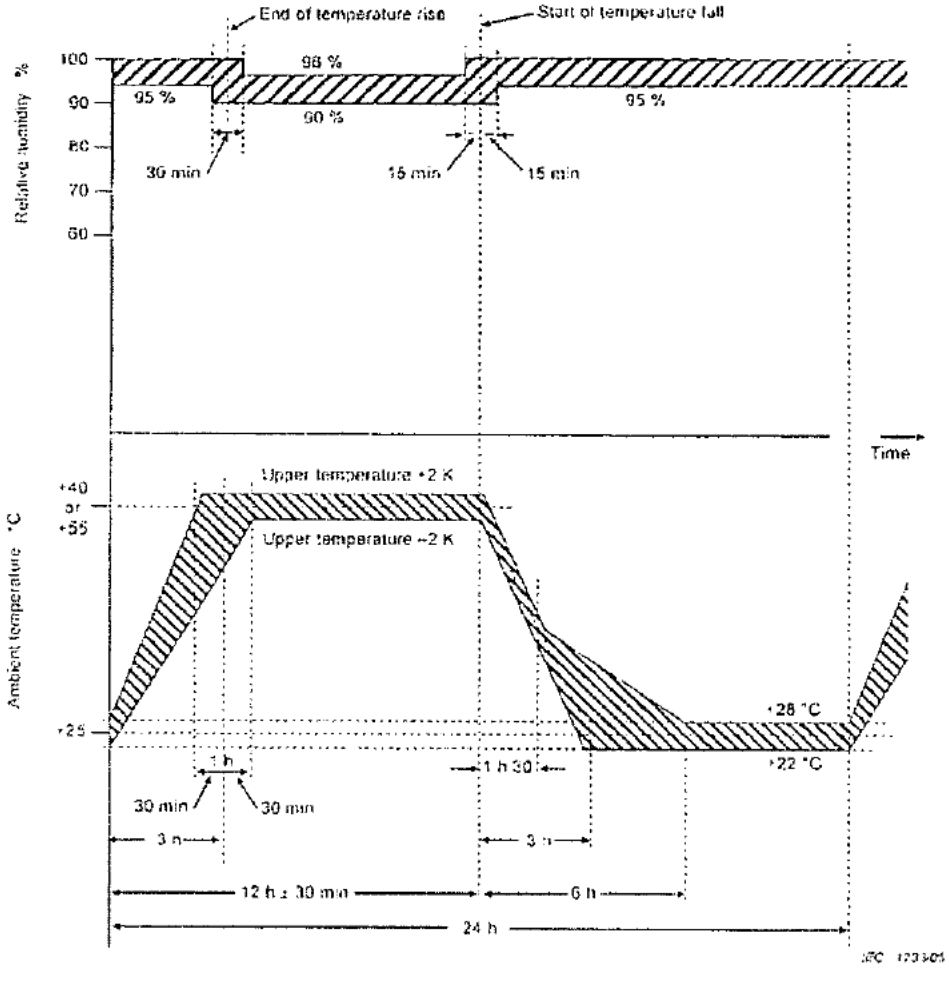

Figure 2a – Test Db – Test cycle – Variant 1

Figure 2: Test Db Test cycle variant 1

1513

(b)(4) [redacted]

5.8 Vibration, broad band random

Purpose
The purpose of this test is to verify the ability of the product to withstand vibrations during transport.

Standard
EN 60068-2-64:1993

Equipment
- Device
- Alkaline battery (may not be used previously)
- Vibration table
- Registration sheet

Preconditioning
Strap the product to the fixture plate. Carry out the vibration test in three perpendicular directions.

Test Demands

Frequency range:	5-500 Hz
Acceleration Spectral density	0,05 g^2/Hz
Duration of conditioning	30 minutes in each axis

Variation
According to standard

Acceptance
The device must pass FT and be visual inspected before and after preconditioning.

QM500434, Version 4.00

1514

6 Registration sheets

Registration sheets needed for the verification tests are to be found on the next pages. There is one sheet for every test.

(b)(4) [redacted]

Test method:	**5.1 Cold storage atmosphere**
Protocol reference:	TAD0821a Design verification prtocol - mandatory requirements E3000 Plus

Product

Series name/number	Material number	Material name

Batch number	DMR version	Deviations yes/no

Equipment

Description	Identification (R-number or FAA-number)	Calibration date

Test result

ID	Before test	After test	Observation/remarks
[Device/component No.]	[OK/not OK]	[OK/not OK]	[Text]

Activity performed by

Date	Initials	Sign

©MS00434, Version 4.00

1516

Test method:	**5.2 Cold operating atmosphere**
Protocol reference:	TAD0821a Design verification prtocol - mandatory requirements E3000 Plus

Product

Series name/number	Material number	Material name

Batch number	DMR version	Deviations yes/no

Equipment

Description	Identification (R-number or FAA-number)	Calibration date

Test result

ID	Before test	After test	Observation/remarks
[Device/component No.]	[OK/not OK]	[OK/not OK]	[Text]

Activity performed by

Date	Initials	Sign

QM500434, Version 4.00

Test method:	**5.3 Dry heat storage atmosphere**
Protocol reference:	TAD0821a Design verification prtocol – mandatory requirements E3000 Plus

Product

Series name/number	Material number	Material name

Batch number	DMR version	Deviations yes/no

Equipment

Description	Identification (R-number or FAA-number)	Calibration date

Test result

ID	Before test	After test	Observation/remarks
[Device/component No.]	[OK/not OK]	[OK/not OK]	[Text]

Activity performed by

Date	Initials	Sign

(b)(4) [redacted]

Test method:	**5.4 Dry heat operating atmosphere**
Protocol reference:	TAD0821a Design verification prtocol – mandatory requirements E3000 Plus

Product

Series name/number	Material number	Material name

Batch number	DMR version	Deviations yes/no

Equipment

Description	Identification (R-number or FAA-number)	Calibration date

Test result

ID	Before test	After test	Observation/remarks
[Device/component No.]	[OK/not OK]	[OK/not OK]	[Text]

Activity performed by

Date	Initials	Sign

QHS00434, Version 5.00

1519

(b)(4) [redacted]

Test method:	**5.5 Damp heat, steady state**
Protocol reference:	TAD0821a Design verification prtocol - mandatory requirements E3000 Plus

Product

Series name/number	Material number	Material name

Batch number	DMR version	Deviations yes/no

Equipment

Description	Identification (R-number or FAA-number)	Calibration date

Test result

ID	Before test	After test	Observation/remarks
[Device/component No.]	[OK/not OK]	[OK/not OK]	[Text]

Activity performed by

Date	Initials	Sign

File name: TAD0821a Design verification protocol - mandatory requirements E3000 Plus Page 22 of 25

1520

(b)(4) [redacted]

Test method:	**5.6 Change of temperature**
Protocol reference:	TAD0821a Design verification prtocol – mandatory requirements E3000 Plus

Product

Series name/number	Material number	Material name

Batch number	DMR version	Deviations yes/no

Equipment

Description	Identification (R-number or FAA-number)	Calibration date

Test result

ID	Before test	After test	Observation/remarks
[Device/component No.]	[OK/not OK]	[OK/not OK]	[Text]

Activity performed by

Date	Initials	Sign

QM50043n, Version 4.00

(b)(4) [redacted]

Test method:	**5.7 Damp heat, Cyclic (12+12 hour cycle)**
Protocol reference:	TAD0821a Design verification prtocol – mandatory requirements E3000 Plus

Product

Series name/number	Material number	Material name

Batch number	DMR version	Deviations yes/no

Equipment

Description	Identification (R-number or FAA-number)	Calibration date

Test result

ID	Before test	After test	Observation/remarks
[Device/component No.]	[OK/not OK]	[OK/not OK]	[Text]

Activity performed by

Date	Initials	Sign

GHS00034, Version 4.00

1522

(b)(4) [redacted]

Test method:	**5.8 Vibration, broad band random**
Protocol reference:	TAD0821a Design verification prtocol – mandatory requirements E3000 Plus

Product

Series name/number	Material number	Material name

Batch number	DMR version	Deviations yes/no

Equipment

Description	Identification (R-number or FAA-number)	Calibration date

Test result

ID	Before test	After test	Observation/remarks
[Device/component No.]	[OK/not OK]	[OK/not OK]	[Text]

Activity performed by

Date	Initials	Sign

1523

(b)(4)

[redacted]

E3000 Plus
Design verification report - Mandatory requirements

Version 1.0

File name: trh0839a Design verification report- Mandatory requirements E3000 plus

Author

Date, Anne Marie Seerup – QA

Approved by

Date, Torben Riis Houe – Manager QA

(b)(4)

[redacted]

1509

(b)(4) [redacted]

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3 References 3
4 Test result 3
5 Discussion of test results 3
6 Conclusion 4
7 Enclosures 5
8 Version history 6

QMS00242, Version 3.00

1525

(b)(4) [redacted]

1 Purpose

The purpose is to document and conclude on the result of the Design verification activities conducted with references to Requirements, Plan, and Design Verification Protocol stated below.

2 Scope

This report covers the verification of mandatory requirements of the E3000 plus stethoscope according to ref [3].

3 References

[1] CAP0803a E3000 plus Product Requirement
[2] TAD0816b Design verification plan E3000 plus
[3] TAD0821a Design verification protocol – mandatory requirements E3000 plus

4 Test result

Test ID	Test method	Test result	Remark
[Ref. No]	[Name]		
5.1	Cold storage atmosphere	Passed	N/A
5.2	Cold operating atmosphere	Passed	See note under discussion
5.3	Dry heat storage atmosphere	Passed	N/A
5.4	Dry heat operating atmosphere	Passed	Display flashes when the device is turned on
5.5	Damp heat, steady state	Passed	N/A
5.6	Change of temperature	Passed	N/A
5.7	Damp heat, Cyclic (12 + 12 hour cycle)	Passed	N/A
5.8	Vibration, broad band random	Passed	N/A

5 Discussion of test results

With the exception of the two observations discussed below, all devices passed the tests Without any remarks.

5.2 Cold Operating atmosphere

All devises showed a minor drop in frequency response when measured at -30 ºC, the majority in the area 2-5 db max. It is known that low temperature is influencing the gain in the transducer system, and therefore it is specified, that the frequency response curve may drop as much as 0,2 db pr degree from 25 ºC, allowing an up to 11 db drop below the frequency response tolerance at -30 ºC. During the test the highest drop observed (as a single point on the curve) was <8 db.

QMS003247, Version 3.00

1526

(b)(4) [redacted]

Although a drop in frequency response was observed during the test, no devices dropped below the standard frequency response curve for 25 °C. All devices have passed the cold operating atmosphere test within the specified frequency response tolerances.

5.4 Dry heat operating atmosphere

Under Dry heat storage, one device (# 91) was seen flashing in the display when turned on. Apart from the flashing display the device was fully functioning.

Failure investigation

1. The acoustical and electrical performance of the stethoscope was found to be fully functioning according to specifications, including frequency response and button operations.
2. The connection of the display wire to the PCB was examined and it could be seen that the cable for the LCD was not assembled correctly (it was not fully inserted in the cable connector).
3. The cable for the LCD was mounted correctly and the device reassembled and tested. All tests were passed.

In the device the cable is unstressed after assembly with no possibility of relative movement between the two cable ends unless the device is structural damaged.

Since there are no indications of structural damage, and the failure can be corrected by "correct insertion of LCD cable in cable connector", it is the conclusion that the root cause to the failure is not the test exposure but the wrong assembly.

To support the conclusion the result from all tests conducted have been reviewed, no other examples of loose connection failures have been identified, indicating that there are no systematic weakens.

Corrective action

The device was reassembled correctly and tested according to test protocol.

A specific instruction for inline control of correct assembly of cable for LCD are placed in the assembly instruction (this will be in place before release of production).

Verification of corrective action

The correctly reassembled device passed according to specifications and protocol.

Conclusion

Of the tests used during design verification several are intended and designed to introduce stress on potential loose connections and components, e.g. vibrations, drop and minor impact. Therefore based on the analysis above and especially the absence of loose connection observation after other tests, it is the conclusion that the root cause to the failure is the wrong assembly and that the device successfully has sustained and passed the exposure to dry heat storage.

6 Conclusion

Base on test result and discussion above it is the overall conclusion that the E3000 Plus stethoscope has passed the Mandatory requirement protocol in accordance with the requirement of ref [3].

QMS00247, Version 3.00

(b)(4) [redacted]

7 Enclosures

1. Data test 5.1 Cold storage atmosphere
2. Data test 5.2 Cold operating atmosphere
3. Data test 5.3 Dry heat storage atmosphere
4. Data test 5.4 Dry heat operating atmosphere
5. Data test 5.5 Damp heat, steady state
6. Data test 5.6 Change of temperature
7. Data test 5.7 Damp heat, Cyclic (12 + 12 hour cycle)
8. Data test 5.8 Vibration, broad band random

QMS00247, Version 3.00

1528

(b)(4) [redacted]

8 Version history

Version	Author	Date	Description	Reviewed by	EC number
1.0	ams	21-11-2008	First version	trh	

QMS00242, Version 3.00

1529

Device Hazard Analysis – Littmann Electronic Stethoscope, Model 3200

A risk management process, as defined by ISO 14971:2007, has been applied to the design, development, and manufacturing of the Model 3200. In accordance with this standard, division management has established acceptable levels of risk for the products that are marketed by 3M Infection Prevention Division and it is these criteria against which the risks identified for the Model 3200 were evaluated.

The following table lists all potential hazards, along with their corresponding potential hazardous situation, potential effect, potential cause, and resulting risk control measures. Software errors have been considered within the scope of potential causes for a given potential hazard. For an example, see row six in the table below.

Following risk control measures, all identified potential hazards are reduced to a broadly acceptable level.

	Potential Hazard	Potential Hazardous Situation	Potential Effect(s)	Potential Cause(s)	Risk Control Measures to be Implemented
1	Biocompatibility - allergenicity/irritancy	Patient and/or user skin contact with scope	Skin rash, irritation	Scope housing and/or eartip made from materials not compatible with human contact such as latex.	All contact materials will be subjected to ISO10993 Part 1 for short term (<24 hrs) skin contact Product design to not include natural rubber latex.
2	Biological - cross contamination	Patient contact with stethoscope containing infection.	Non infected patient becomes infected.	No cleaning or disinfection instructions	Instructions for cleaning and disinfecting to be included in the IFU.
3				Scope user does not periodically clean or disinfect scope.	IFU to contain caution statement regarding the need to periodically clean and disinfect scope
4				Scope design is resistant to being cleaned and disinfected.	Mechanical design to allow cleaning & disinfection.
5	Incorrect measurement - heart rate	Displayed heart rate not clinically correct - accuracy worse than +/- 12 bpm (based on clinical testing of E4100 and customer usage)	Care provider requests additional tests for the patient	Algorithm error	Verification and validation testing
6				Coding (software) error	Application of software engineering & quality principles, verification, and validation
7				Accuracy of system doesn't meet customer needs	Validation testing
8	Erroneous RF data transfer	Heart sound data sent from the stethoscope to an external application on its RF link is unknowingly corrupted	Care provider requests additional tests for the patient or can not use data	RF link susceptible to noise, interference, signal drop out.	Use of high level error checking communications protocol (Bluetooth), verification & validation
9				Coding (software) error in stethoscope	Application of software engineering & quality principles, verification, and validation
10		Sounds sent from an external application to the stethoscope on its RF link is unknowingly corrupted	User misses audible commands causing delays in examination	RF link susceptible to noise, interference, signal drop out.	Use of high level error checking communications protocol - Bluetooth.

	Potential Hazard	Potential Hazardous Situation	Potential Effect(s)	Potential Cause(s)	Risk Control Measures to be Implemented
11	Wireless coexistence with other medical devices that also contain RF links	Use of stethoscope's RF link while within range of other medical devices that also use an RF link for essential performance task(s).	Other medical device not able to communicate - "jammed".	Lack of design for coexistence	Use of spread spectrum low power communications protocol. Verification and validation testing.
12	Acoustic energy	Stethoscope exposed to loud sounds while using maximum amplification and while eartips in users ears	Short or long term loss of users hearing	Sound output from stethoscope too loud.	Scope designed not to exceed known safety sound pressure levels.
13	Thermal energy	Chestpiece surface becomes hot and is touched by user and/or patient	Mild burn	Short circuit of battery within device	AA battery contains minimal energy and is housed inside of scope. Battery current is limited by a resistor to help address potential short circuits.
14		Rapid current rush from battery causing hot battery.	Mild or moderate burn if user contacts battery	User installs wrong battery type or wrong battery polarity	Battery compartment designed to fit only AA type, battery polarity is mechanically protected, battery compartment marked with "+" symbol, and PTC resistor is used to limit current.
15	Electromagnetic fields (EMC)	Stethoscope is located close to other medical devices.	Other medical devices operate erratically (RF link OFF)	Stethoscope produces strong electromagnetic fields.	Design, testing to EMC standards
16			Other medical devices operate erratically (RF link ON)	Stethoscopes RF transmission (radiated RF)	Use lowest RF output power required. IFU labeling. Validation testing.
17			Increased difficulty in auscultation exam due to unexpected results causes delays or missing clinically significant sound	Stethoscope is susceptible to electromagnetic fields	Testing to EMC standards and statement for IFU to move away from strong RF sources. Immunity levels listed in IFU.
18	Electrostatic discharge (ESD)	User contacts stethoscope, or stethoscope contacts patient, with high surface charge (static electricity)		Design is susceptible to ESD.	Testing to EMC standards. Immunity levels listed in IFU
19	Transportation - vibration	Final device subjected to shipping.		Poor mechanical design of stethoscope and packaging materials	Design and tested to pass ship (vibration) testing
20	High Temperature, High Humidity & Low Storage Temperature	Final device subjected to temperature extremes during shipping and storage		Poor mechanical design of stethoscope and/or inadequate package labeling	Design and tested to pass storage temperature & humidity requirements. Product labeling to include storage temperature range.

	Potential Hazard	Potential Hazardous Situation	Potential Effect(s)	Potential Cause(s)	Risk Control Measures to be Implemented
21	High & Low Operating Temperature	Stethoscope subject to temperatures extremes during use.		Poor design. Derating of dynamic range at low temp -> low sensitivity -> auto on/off or heart rate may fail	Design and tested to pass operating temperature requirements
22				User is using the product outside of its intended temperature range	Product labeling to include operating temperature range.
23				Acoustic leaks	Designed for full operating temp. and tested at cyclic temp to provke sealing setting
24	Liquid	Ingress of liquid		Stethoscope exposed to liquid	Stethoscope designed to IPX-4 (protection against splashing water). IFU to contain caution statement not to immerse.
25	Explosion	Exposure with flammable anesthetics	Patient thermal burns	Stethoscope design contains an ignition source	Design & testing to meet IEC 60601-1 3rd edition, Annex G.
26	Battery voltage	Scope does not work	Care provider misses clinically significant sounds	User inserts wrong type of battery	Stethoscope designed for AA battery. IFU to include types of AA batteries that may be used.
27				Bayonet connector for battery replacement not properly locked	Visual identificaiton and click sound feedback for proper assemby
28				Depleted battery	IFU includes instruction as to when to replace battery
29	Incorrect or inappropriate functionality	Sound not clear	Care provider misses clinically significant sounds	Algorithm error	Verification and validation testing
30				Coding (software) error	Application of software engineering & quality principles, verification, and validation
31				Error in updating software by Service Center	Verification and validation of software update tools.
32	Gravity - falling	Drop onto a hard surface	Increased difficulty in auscultation exam due to unexpected results causes delays or missing clinically significant sounds	Poor mechanical design that is susceptible to impact damage	Drop testing with the battery access feature opened and closed
33	Keyboard switches fail	Wear of contacts	No or unexpected function or performance	Poor design of keyboard switches.	Durability testing to demonstrate mission requirements
34	Environmental - disposal	Disposal of stethoscope containing hazardous materials	Human exposure to toxic materials	Use of unsafe materials and unsafe disposal.	Product design to meet WEEE/RoHS. IFU to contain disposal information

	Potential Hazard	Potential Hazardous Situation	Potential Effect(s)	Potential Cause(s)	Risk Control Measures to be Implemented
35	Use error - user interface	Listening to heart sounds thinking that the stethoscope is in one mode when its actually in a different mode.	Increased difficulty in auscultation exam due to unexpected results causes delays or missing clinically significant sounds	Poor location, poor labeling, of buttons	VOC testing
36	Use error - distractions	Listening to heart sounds thinking that the stethoscope is in one mode when its actually in a different mode.		User distracted and pushes wrong button	Design - audible indications of frequency mode selection
37	Use error - menu structure	Listening to heart sounds thinking that the stethoscope is in one mode when its actually in a different mode.		Menu structure is too confusing.	Usability to be addressed by compliance to 60601-1-6
38	Leakage current	Electrical shock	Patient or user injury	Excessive leakage current. Note: Concern if user removes the diaphragm and a single fault places 1.5 V to the chestpiece housing.	Design, product design and tested to meet IEC 60601-1 for type B equipment. Third party inspection of insulation barriers. Instruction in IFU not to remove diaphragm. Battery and supply voltages are too low to be perceptible.
39	Labeling	Improper use of stethoscope	Increased difficultly in auscultation exam due to unexpected results causes delays or missing clinically significant sounds	Incomplete instructions for use.	Design validation includes IFU
40				Control symbols confusing	Use internationally recognized or commonly understood symbols for buttons and controls
41				Quick Start Guide is English Only & non-English user	Use internationally recognized or commonly understood symbols for buttons and controls and IFU is multilingual
42	Sharps - missing eartip(s)	User places in ears	Damage to care providers inner ear	Ear tips removed by user and not remounted correctly	IFU to contain information for proper removal and remounting of ear tips.
43	Misuse	Scope operates erratically and/or frequency response out of specification	Care provider misses clinically significant sounds	User immerse the scope in liquid or attempts to sterilize	IFU to contain information not to immerse scope, not to sterilize
44				User fails to follow directions in IFU	IFU to contain Caution statement to follow IFU
45				User attempts to repair or modify scope themselves	IFU to contain information that users is not to attempt repair.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

Fr Reviewer Name CHARLES HO

Subject: 510(k) Number K083903/S1

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category N, see ...://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO...BINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
N. .echnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		✓

Regulation Number	Class*	Product Code
21 CFR 870.1875	II (two)	DQD

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: (Branch Chief) CEMB (Branch Code) 07/14/09 (Date)

Final Review: (Division Director) for B Zuckerman 7/15/09 (Date)

5

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K083903/S1

Date: July 14, 2009
To: The Record
From: Charles Ho, Ph.D.

Office: ODE
Division: DCD

510(k) Holder: 3M Health Care
Device Name: 3M™ Littmann® Electronic Stethoscope, Model 3200

New contact
(Added by official letter dated March 27, 2009)
Mr. Jizhong Jin
3M Infection Prevention Division
3M Center, Bldg 275-05-W-06
St. Paul, MN 55144-1000
Phone: 651-733-6655
Fax: 651-737-5320
Email: jjin1@mmm.com

Contact
3M Health Care
c/o Ms. Rica Morris

[Note: Only when I received her voice mail on March 16, 2009 that I realized that she is a lady, not a man.]

Senior Regulatory Affairs Associate
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000
Phone: 651-733-6791
Fax: 651-737-5320
Email: remorris2@mmm.com

Note: Information from Mr. Jin on May 11, 2009, indicates that Ms. Morris has left 3M.

6

Contract manufacturer
(b)(4)Trade Secret Process-Product Specs
[redacted]

I. Purpose and Submission Summary

The 510(k) holder would like to introduce into interstate commerce the 3M™ Littmann® Electronic Stethoscope, Model 3200. Section 11.4 indicates that there will be additional models with various colors and tube lengths. The present supplement is the manufacturer's responses to our questions emailed to him on Feb. 23, May 11 and July 5, 2009.

II. Administrative Requirements

		Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	Prescription	X		
Truthful and Accuracy Statement		X		
510(k) Summary or 510(k) Statement	Summary	X		
Standards Form		X		

In section 9 of the submittal, the manufacturer claims that summary reports are not applicable and that "There is no recognized standard or guidance for subject medical device." This may be true for stethoscopes, but there are several recognized standards for medical devices in general, such as IEC 60601-1 and 60601-1-2, which the manufacturer has provided test reports on, and has claimed compliance for (see section 11.5 for EMC claim). Hence, the standards forms (FDA 3654) for these standards will be requested. These forms are now received.

The Indications for Use statement has not checked the prescription use entry, although Appendix 6 describes the user as a professional, probably already accustomed to a mechanical stethoscope. The device is for prescription use.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	

	Yes	No	N/A
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

All deficiencies are now resolved, July 14, 2009.

The subject device is an electronic stethoscope. The main new item compared to the predicate(s) from the same manufacturer is the new Bluetooth (BT) feature for transmitting the detected sound to a BT-enabled PC for further processing, and also to receive sound files from the PC.

The device detects sounds through its single transducer (chest piece). After amplification and filtering (3 ranges), the sounds are transferred to the user's ears via an active speaker and passive sound tubes.

The three ranges are:

Bell: 20 - 200 Hz
Diaphragm: 100 - 500 Hz
Extended range: 50 - 500 Hz

The extended range is new, since its range is not indicated in the two predicates. Although page 10 of 18 in Appendix 6 presents a figure of gain vs frequency, the figure has the following issues: (Q. 3)

a. The figure is probably a color figure, but is presented to us in black and white.

b. The figure seems to be a device specification. And page 15 of 36 in Appendix 7 refers to running the frequency response tests for the 3 frequency ranges. But since the extended range seems to be new, we will need the test data.

c. We will need a simplified version of the figure in the User Manual.

From page 17 of 18 in Appendix 6, the device's A/D converter samples at 4 KHz, 16-bit resolution. The data stream for BT uses CRC 16 error checking.

The frequency ranges, amplification, BT mode, auto-off time, etc. can be selected by 4 buttons on the device. Additionally, there is an On/Off button. There is a dot matrix monochrome LCD display for various icons to the user.

The device is powered by one AA battery, which can be alkaline, lithium or NiMH. However, the specific battery type has to be selected by the user, as indicated on page 10 of 25 of the User

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Manual. What happens if the user forgets to select the correct battery type? Further, this choice of batteries is new, since the predicates use only alkaline batteries. Q. 4.

For reference, the manufacturer indicates that the NiMH battery is rechargeable, while Lithium is non-rechargeable, although I know of rechargeable Lithium batteries.

One feature is that the device can display heart rate, as does the predicate cleared under K051790. From page 12 of 18 in Appendix 6, the heart rate value is updated every 2 seconds after initial sampling (5 sec.) and the value is shown in the LCD for 10 seconds after loss of heart signal. Such a long latching time should be justified. Q. 5.

Below is the excerpt from AAMI EC13:2002 covering the heart rate alarm recommendations:
"

4.2.8.4 Time to alarm for cardiac standstill
The time to alarm for a step change in heart rate from 80 bpm to 0 bpm, with the lower alarm limit set closest to 60 bpm, shall not exceed 10 seconds.

4.2.8.5 Time to alarm for low heart rate
The time to alarm for a step change in heart rate from 80 bpm to 40 bpm, with the lower alarm limit set closest to 60 bpm, shall not exceed 10 seconds.

4.2.8.6 Time to alarm for high heart rate
The time to alarm for a step change in heart rate from 80 bpm to 120 bpm, with the upper alarm limit set closest to 100 bpm, shall not exceed 10 seconds"

Section 11.4 indicates that the device has a proprietary passive ambient noise reduction (ANR) technology. This feature is included in the predicate, as shown in the comparison table with predicates, in section 12.0.

We will ask whether the present submittal includes the software in the PC for receiving and processing the received sound file. If yes, we need documentation for this software in the PC. For reference, one predicate can communicate with a PC via infrared. Q. 6.

The sound file is 29 seconds long, which is also the memory size of the stethoscope.

Bluetooth (BT)

Via BT, the device can transmit a sound file (up to 29 seconds long) to an BT-enabled PC, and also receive a sound file from the PC, for storage in the stethoscope, and for playing back as audio sound to the user.

The BT is implemented via a single CSR BC5 Bluetooth chip with integrated Kalimba DSP co-processor.

From section 11.2, the BT is Class 2 BT link, and has a maximum range of 10 m. From

Appendix 1, the BT operates at a frequency of 2.4 GHz using GFSK modulation with a maximum power of 230 microW. (b)(4)Trade Secret [redacted]. The BT standard is (b)(4)Trade [redacted].

Although section 11.2 states, "The Model 3200 can only communicate with one PC at a time.", page 15 of 25 in the User Manual indicates that the stethoscope can pair (under BT) with up to 8 devices (but not with another stethoscope) at a time. This 8 BT devices pairing is also indicated on page 18 of 18 in Appendix 6. And page 30 of 36 in Appendix 7 reports tests on pairing the stethoscope with at least 3 BT-enabled devices. Here, the manufacturer seems to distinguish between "pairing" and "connecting" to a BT device to really communicate. If indeed the subject device can communicate with more than one BT-enabled devices simultaneously (or in rapid succession), the concern will be how the device can distinguish one PC from another, and thus not mix up the sound files of different patients. And, the security issues will be huge since BT does not require line of sight for communications. Labeling should also be revised to highlight this difference between pairing and connecting. Q. 14.

From page 14 of 25 in the User Manual, the BT mode can be manually selected, but also automatically selected whenever the stethoscope is in an active mode. I believe that this auto mode for BT is a bit dangerous since the risks for unauthorized eavesdropping and interfering other devices are higher. Q. 15.

A worrying item is that page 16 of 25 of the User Manual states, "When connected by a Bluetooth link, external Bluetooth-enabled devices can take control of the display and keypad of the Model 3200 stethoscope. They can also transfer audio (ex. voice prompts) to the Model 3200 headset. During audio transfers to the stethoscope, a tone will be sounded every 8 seconds." This external control via BT is troubling since it goes beyond transfer of data (sound files) only. Q. 16.

Yet, later on the same page, the manufacturer asks the user to "Consult application software for details on initiating real-time transfer, the process may vary by computer platform utilized." I believe that the manufacturer should describe at least one application software for this purpose. Q. 17.

Note: On page 16 of 18 in Appendix 6, the manufacturer uses the term "PS-keys" to mean "Persistence Storage keys".

The manufacturer has provided a BT test report written by Eurofins located in Germany. However, the tests covered only the basic characteristics such as frequency hopping, radiated power, but not the issue of co-existence with other emitters.

Note that Appendix 15, Risk Management, indicates using spread spectrum low power communication protocol and V and V testing to support co-existence with other emitters. However, I do not see the actual test report. Q. 14 also.

IV. <u>Indications for Use</u>

Copied from submitted Indications for Use statement,

*** Beginning of copying ***

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment."

*** End of copying ****

V. Predicate Device Comparison

The claimed predicates are:

3M™ Littmann® Electronic Stethoscope, Model 3000, cleared under K050159; and

3M™ Littmann® Electronic Stethoscope, Model 4100, cleared under K051790. This last predicate uses infrared light for communications.

Section 12.0 indicates that the diaphragm (transducer cover) is silicone with polyacrylate coating, which is not found in the two predicates. See below.

The subject device can amplify sound up to 28 dB acoustic gain, while the predicates only 25 dB. However, the maximum sound level is still (b)(4) dB SPL max, same as the predicates.

VI. Labeling

The manufacturer has provided a reasonable set of instructions, including the instructions for operation and cleaning in between patients. However, there are the following issues:

Appendix 1, page 3 of 25, indicates that the device protected against splashing liquid (chest piece only), under IPX4. We will require the test results to substantiate this claim. Q. 7.

Appendix 1, page 3 of 25, indicates that the device is tested for use with flammable anesthetic mixture with air. We will require the test results to substantiate this claim. Q. 8.

VII. Sterilization/Shelf Life/Reuse

N/A

VIII. Biocompatibility

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Section 12.0 indicates that the diaphragm (transducer cover) is silicone with polyacrylate coating, which is not found in the two predicates.

In appendix 3, the manufacturer has provided an analysis of biocompatibility for the patient contacting and user contacting components of the device. However, for the new transducer cover (the diaphragm) the proof is only that "No adverse health effects are expected from the use of this material." Hence, we will ask for the 3 biocompatibility tests on the diaphragm for less than 24 hours of contact, especially since Appendix 15 refers to the patient contacting, and/or user skin contacting parts of the device to be subjected to ISO 10993-1 tests. Q. 18.

This is resolved by the manufacturer clarifying that the diaphragm was used in a predicate from the same manufacturer.

IX. Software

Version: 1.0 (v.01.00.00)		
Level of Concern: Moderate		
	Yes	No
Software description:	X	
Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:	X	
Design Specifications:	X	
Traceability Analysis/Matrix:	X	
Software Development Environment Description	X	
Verification & Validation Testing:	X	
Revision level history:	X	
Unresolved anomalies:	X	

The manufacturer has reported different versions for the software:

On page 2 of 18 in Appendix 6, he/she indicates the version as 2.00 dated 04 dec 2008 and ready for signing. However, on page 2 of 5 in Appendix 9, version 2.00 was dated 15-09-2008. And version 8.00 dated 17-12-2008 will be SW release v. 01.00.00. These issues in version number will be requested. Q. 19.

In section 16 the manufacturer has indicated a Minor level of concern for software in the device since he/she thinks that the stethoscope does not provide diagnostic information. But I believe

that the indication of heart rate is diagnostic and the sound amplified by the device is also important-- erroneous sound amplification can lead to misdiagnosis. Hence, I believe that the level of concern should be Moderate. The manufacturer has provided some of the required software documentation, but Architecture Design Chart, Design Specifications, Software Development Environment Description and Unresolved anomalies have not been provided. Q. 20.

For the risk assessment report provided in Appendix 5, the font size of the table starting from page 4 of 13 to page 11 of 13, inclusive, is too small to read. We will need a larger printout with larger font size. Q. 21.

Page 4 of 5 in Appendix 9 refers to a known defect in which the displayed heart rate may be (b) (4) pct (probably percent) different from one beat to another. But no wrong heart hates (probably rates) are displayed in the LCD. This begs the question on the smoothing (or averaging) function of the heart rate display. Q. 5 also.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The manufacturer has provided the EMC test report with passing results:

Radiated emissions: according to CISPR 22
RF immunity: 3 V/m
ESD: +/- 2, 4 and 6 KV for contact discharges and +/- 2, 4 and 8 KV for air discharges.
50 Hz magnetic field immunity: 30 A/m rms.

I note that CISPR 22 is the EMC standard for information technology equipment, not medical devices. Further, page 13 of 23 in the EMC test report written by Eurofins referred to subclause 9.2 of EN 301 489-1 as the test protocol. However, I believe that FDA uses the CISPR 11 standard for radiated emissions testing, referred to by IEC 60601-1-2. Q. 9.

Further, the acceptance criterion allowed some device behaviors (see pages 6 of 8 and 8 of 8 in the E3000 Plus EMC Design Verification Protocol):

1. Change in display graphics
2. Momentary noise in binaural
3. Reset of the stethoscope if reboot is initialized automatically.

We will ask for some justification of the criterion, and if the actual test results utilized this criterion to be called Passing. Q. 10.

There is also a report on BT performance. However, I am not sure if the co-existence issue is adequately covered or not. Q. 14 also.

The manufacturer has provided many bench tests for the device, including those under IEC 60601-1, with passing results.

XI. Performance Testing – Bench

In Appendix 7, the manufacturer has provided a test report on the device's operation, with passing results. Items tested include powering up and down, filter setting, battery power management, heart beat detection, BT communications, etc.

In Appendix 13, the manufacturer has provided a test report for the IEC 60601-1 standard, with passing results.

In Appendix 14, the manufacturer has provided a test report for the operating and storage environment of the device, with passing results.

However, I have the following issues:

Page 30 of 36 in Appendix 7 refers to pairing the subject device with at least 3 BT devices only. It is not clear how many BT devices were paired with the subject stethoscope during the test. If this number is not 8, the manufacturer should repeat the test using 8 BT devices if this is what he/she claims. This issue is discussed above.

The device under test is sometimes described as the E3000 plus (on page 1 of 36) and sometimes as M3200 (on page 29 of 36 in Appendix 7). Then page 14 of 36 displays a hand-written statement of "Only works on E-3200". And page 22 of 36 refers to the Model 3200. Please explain how test results from a model that is 3200 can be transferred to the Model 3200. Q. 11.

Page 5 of 5 in Appendix 8 refers to 4 minor observations. Please provide more details on these observations, and why these observations can be tolerated: (Q. 12)

Live_lock
Service_counter
Peak_Location
Deviation

Page 4 of 5 in Appendix 9 refers to several known defects: (Q. 13)

Recording is implemented with 14 sec. recording only (not 29 seconds indicated elsewhere).

Service counter for measuring standby time measures one minute less than actual time.

XII. Performance Testing – Animal

None

XIII. Performance Testing – Clinical

None

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?		X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?	X		If NO = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

3. Describe the new technological characteristics:
One of the predicates uses IR for wireless communications while the subject device uses Bluetooth.

4. Explain how new characteristics could or could not affect safety or effectiveness:
The use of wireless technology to transmit and receive patient information can affect safety and effectiveness.

5. Explain how descriptive characteristics are not precise enough:
The transmission of patient information wirelessly has to be verified quantitatively.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
The manufacturer has provided bench data to show that the subject device can indeed perform as specified, similar to the two predicates.

Issue of substantial equivalence
At this moment in time, the manufacturer has addressed all my concerns as follow:

* The device differs from the predicates from the same manufacturer mainly in the new Bluetooth feature, whereas one predicate communicates wirelessly using IR (infrared).

* This feature has now been validated via testing, including tests of co-existence with other RF emitters.

* The risk of the device being used to record conversation surreptitiously has been avoided by the need to manually press the keys on the device once every 90 seconds.

* The device has been bench tested, for example, for the IPX4 claim for the chest piece.

* Labeling has been improved.

Therefore, I recommend SE.

XV. Deficiencies
When developing deficiencies please consider the following "Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA" (http://www.fda.gov/cdrh/modact/guidance/1195.html) and "A Suggested Approach to Resolving Least Burdensome Issues" (http://www.fda.gov/cdrh/modact/leastburdensome.html).

All resolved now.

XVI. Contact History

A. Feb. 23, 2009, I sent the attached email to the manufacturer to indicate my hold recommendation.

B. May 11, 2009, I sent a set of follow-up questions to the manufacturer.

C. July 5, 2009, I sent a set of follow-up questions to the manufacturer.

XVII. Recommendation
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic stethoscope
Regulatory Class: Class II (two)
Product Code: DQD

Substantially equivalence

Reviewer — Date: July 14, 2009

Branch Chief — Date: 07/14/09

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The following is my review of the manufacturer's (draft) responses to our questions emailed to him/her on Feb. 23, 2009:

3M™ Littmann® Electronic Stethoscope, Model 3200

Regulatory

1. In section 9 you have indicated that summary reports are not applicable and that there is no recognized standard or guidance for subject medical device. This may be true for stethoscopes, but there are several FDA recognized standards for medical devices in general, such as IEC 60601-1 and IEC 60601-1-2, which you have provided test reports for, and have claimed compliance with. Hence, please provide the standards form (FDA 3654, attached) for each of the standards that you claim compliance for the subject device.

Response:
The manufacturer has now provided the requested FDA 3654 forms for the following:

IEC 60601-1,
ISO 10993 and 14971.

However, although the manufacturer refers to IEC 60601-1-2 (for EMC testing) this form is not provided. This will be f/u.

2. Please revise the Indications for Use statement to check the prescription use entry, since you intend the intended user to be a professional, probably already accustomed to a mechanical stethoscope.

Response:
The manufacturer has resisted our prescription use only request. After discussing this with the CEMB members via email, I believe that prescription is needed for the following reasons:

a. The subject device reports a heart rate (in addition to heart sound). This heart rate feature makes the device a monitor, necessitating a prescription use only designation.

b. The predicate from the same manufacturer is also prescription use only; it also has the heart rate reporting feature.

(For reference, the Branch's consensus is that simple electronic stethoscopes (used just to amplify sounds) can be OTC.)

This will be f/u.

Engineering (except BT)

3. Please address the following issues concerning the device's frequency ranges:

   a. Please provided test data to show that the device indeed has the frequency responses specified by the figure on page 10 of 18 in Appendix 6.

   Response:
   The manufacturer has provided the test data to support the frequency responses. The response is adequate.

   b. The above figure is probably a color figure, but it is presented to us in black and white. Please provide a color version of the figure.

   Response:
   The manufacturer has provided a color version of the figure, which is reasonable. The response is adequate.

   c. Please revise the User Manual to include a simplified version of the figure.

   Response:
   The manufacturer has declined to include the figure for fear of giving out trade secrets. However, he/she has provided a textual summary of the main points of the 3 modes, as follows:

   "

   The electronic stethoscope allows the user to select between three different digital frequency filters to better emphasize the specific patient sounds of interest.
   1. The Bell Mode amplifies sounds from 20 – 1000Hz and emphasizes lower frequency sounds between 20 – 200 Hz.
   2. The Diaphragm Mode amplifies sounds from 20 – 2000Hz and emphasizes the higher frequency sounds between 100 – 500Hz.
   3. The Extended Diaphragm Mode amplifies sounds from 50 – 2000Hz similar to the Diaphragm Mode but provides more low frequency response between 50 – 500Hz."

   The response is adequate.

4. The device is powered by one AA battery, which can be alkaline, lithium or NiMH, and the specific battery type has to be selected by the user, as indicated on page 10 of 25 of the User Manual. Please revise the User Manual to inform the user of the risks, if any, of forgetting to select the correct battery type.

Response:
The manufacturer has replied that mis-identifying the correct battery type will only make the battery longevity estimate not reliable (which is already indicated in the manual); all

other device functions are unaffected. Hence, the manufacturer has declined to change the manual. The response is adequate.

5. Please address the following issues on the device's heart rate display:

   a. From page 12 of 18 in Appendix 6, the heart rate value is updated every 2 seconds after initial sampling (5 sec.) and the value is shown in the LCD for 10 seconds after loss of heart signal. Such a long latching time for the heart rate display seems to be on the boundary of acceptance of common ECG standards, such as Association for the Advancement of Medical Instrumentation (AAMI) EC13:2002 standard, clause 4.2.8.4. Please explain if your device's heart rate meter complies with this clause of EC13.

   Response:
   The manufacturer has replied that the 10 second period is intended to allow the physician to remove the chest piece from the patient and to view the display comfortably afterwards. The fact that the chest piece is removed from the patient is an indication that the heart rate info is historical, not real-time. I believe then this idea has to be stated in the labeling. This will be f/u.

   b. Page 4 of 5 in Appendix 9 refers to a known defect in which the displayed heart rate may be (b)(4) pct (probably, percent) different from one beat to another. But no wrong heart hates (probably, rates) are displayed in the LCD. Please explain whether the device's algorithm for smoothing (or averaging) heart rates needs improvement.

   Response:
   The manufacturer has clarified that the (b)(4) difference is not a pass/fail criterion; it refers to (b)(4)Trade Secret Process-Product Specs [redacted] te.

6. Please clarify if the present submittal includes the software in the personal computer (PC) for receiving and processing the sound files received via Bluetooth (BT) from the subject stethoscope. If yes, please provide description and proof of safety and effectiveness for the software.

Response:
The manufacturer has replied that the software in the PC is not included in the present submittal. Hence, I will ask the manufacturer to point to a commercially available (in the U.S.) BT enabled PC that can serve as the receiver for the subject device. This will be

f/u.

7. Appendix 1, page 3 of 25, indicates that the device is protected against splashing liquid (chest piece only), under IPX4. Please provide the test report to substantiate this claim.

Response:
The manufacturer claims to have provided the test report in Appendix 13 to support this claim. But there is no Appendix 13 for testing this feature. This will be f/u.

8. Appendix 1, page 3 of 25, indicates that the device is tested for use with flammable anesthetic mixture with air. Please provide the test report to substantiate this claim.

Response:
The manufacturer claims to have provided the test report in Appendix 13 to support this claim. But there is no Appendix 13 for testing this feature. This will be f/u.

9. The subject device is tested for radiated emissions under CISPR 22, which is the electromagnetic compatibility (EMC) standard for information technology equipment, not medical devices. Further, page 13 of 23 in the EMC test report written by Eurofins refers to subclause 9.2 of EN 301 489-1 as the test protocol. Please explain how the device's radiated emissions are compliant with the FDA recognized IEC 60601-1-2 standard, which is compatible with the CISPR 11 standard for medical devices.

Response:
The manufacturer has clarified that the Model 3100 (which differs from the subject device Model 3200 only in the lack of BT) was tested for EMC in accordance with IEC 60601-1-2, as reported in G0M20808-1969-E-17. Although this report is claimed to be located in Appendix 2, is not available there. This will be f/u.

10. The acceptance criterion in the EMC tests allowed the following device behaviors (see for example pages 6 of 8 and 8 of 8 in the E3000 Plus EMC Design Verification Protocol):

    a. change in display graphics;
    b. momentary noise in binaural; and
    c. reset of the stethoscope if reboot is initialized automatically.

    Please justify this criterion since a change in display graphics and automatic reset of the device may damage the device and/or present erroneous information to the operator. Did the test results include such device characteristics?

Response:

The manufacturer has replied that the change in display (a) refers to flickers in the display. And as the device updates every 200 ms, flickers will be removed when the device updates in the next 200 ms. For noise (b) , the manufacturer indicates that momentary noise should be obvious to the user. For reset (c), the device will generate a beep to notify the user of resetting. Thus, I believe that the user is aware of these device behaviors. The response is adequate.

11. The device under test is sometimes described as the E3000 Plus (on page 1 of 36 in Appendix 7) and sometimes as M3200 (on pages 22 and 29 of 36 in Appendix 7). Then page 14 of 36 displays a hand-written statement of "Only works on E-3200". Please explain how test results from a model (or models) that is not 3200 can be transferred to the Model 3200.

Response:

The manufacturer has replied the E3000 Plus refers to both the M3100 and M3200, and the M3100 differs from the M3200 only in its lack of BT. Thus, all BT tests were done on the M3200. The E3200 is an abbreviation for the electronic 3200. The response is adequate.

12. Page 5 of 5 in Appendix 8 refers to 4 minor observations. Please provide more details on these observations, and why these observations can be tolerated:

    a. Live_lock

    Response:

    The manufacturer has replied that when the Model 3200 is first turned on, both the M3200 internal microprocessor and the audio processor have to boot up. If for some reason the audio processor does not boot up, the internal microprocessor will be in Live_lock mode, resulting in a blank LCD display. Thus, the user knows not to use the device. The response is adequate.

    b. Service_counter

    Response:

    The manufacturer has replied that the service counter is an internal feature accessible by 3M personnel only, and is used to count the time (in minutes) when the device is idle, before automatic shut down. For some reason, this counter is off by one minute. As this is an internal feature not accessible to the use, the response is adequate.

    c. Peak_Location

    Response:

    The manufacturer has replied that this issue relates to the counting of heartbeats used in reporting a heart rate. Since the initial heart beat is call beat zero, there is an issue

on how to count new heart beats. Anyway, since the heart rate feature has been validated, there is no need to pursue this issue any further, the response is adequate.

d. Deviation

Response:
The manufacturer has replied that this is the same issue in Q. 5b, in that the subject device does not have to limit the incoming cardiac sound signal to a heart rate change of less than (b [redacted]%. The response is adequate.

13. Page 4 of 5 in Appendix 9 refers to some known defects. Please provide more details on these defects, and why these defects can be tolerated:

a. Recording is implemented with 14 sec. recording only (not the 29 seconds indicated elsewhere).

Response:
The manufacturer has replied that this came from the fact that the units used for testing had only [redacted]MB of memory, resulting in 14 seconds of recording. New units of the device with (b [redacted]MB of memory will be able to record 29 seconds. However, we will need the actual test results. This will be f/u.

b. Service counter for measuring standby time measures one minute less than actual time.

Same response as Q. 12 b.

Bluetooth (BT)

14. Although section 11.2 states, "The Model 3200 can only communicate with one PC at a time.", page 15 of 25 in the User Manual indicates that the stethoscope can pair with up to 8 devices (but not with another stethoscope) at a time. Please address the following:

a. You seem to distinguish between "pairing" and "connecting or communicating" to a BT device. Please explain the differences between these two terms, especially in view of the above statement. Labeling should also be revised to highlight the differences between "pairing" and "connecting or communicating".

Response:
The manufacturer has replied that pairing refers to exchanging PIN codes (or passkeys) so that the subject device recognizes the BT-enabled PC. The device can pair with up to 8 such PCs at a time. To communicate means actually transmitting files between the subject device and a paired PC. The subject device can communicate with only one PC at any time. In order to connect to a different paired

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PC, the existing connection must be terminated first. The response is adequate.

b. If indeed the subject device can communicate with more than one BT-enabled PCs simultaneously (or in rapid succession by connecting to various PCs sequentially), please explain how the subject device can distinguish one PC from another, and avoid mixing up the sound files of different patients.

Response:
The manufacturer has replied that pairing requires the use of PIN codes (or passkeys) so that the subject device can distinguish one PC from another. Further, the subject device can communicate with only one PC at any time. In order to connect to a different paired PC, the existing connection must be terminated first. The response is adequate.

c. Security is always a major concern for radiofrequency (RF) wireless communications since no line of sight is needed. Here, the subject device has the added capability of pairing with up to 8 devices at the same time. Hence, please explain how you have ensured the security of the subject device in its transmission and reception of sound files to and from up to 8 BT-enabled devices.

Response:
The manufacturer has replied that BT uses 128 bit data encryption algorithm. Pairing requires the use of PIN codes (or passkeys) so that the subject device can distinguish one PC from another. Further, during paring, both device exchange a generated keys, not the actual passkey. The response is adequate.

d. You have provided some test data to support the pairing of at least 3 BT-enabled devices. Please clarify if you used 8 BT-enabled PCs to pair with the subject device in the test. If not, please provide the test report using 8 BT-enabled PCs. We believe that you can claim only the number of BT-enabled devices that you have tested safely and securely.

Response:
The manufacturer has now provided bench test data using 8 BT-enabled PCs to show that the subject device can pair with up to 8 BT-enabled PCs simultaneously. The response is adequate.

e. Please provide further test report(s) to verify that the subject device can co-exist wirelessly with other active RF emitters (including paired and unpaired BT emitters, and other RF emitters using different communications standards) in its vicinity.

Response:
The manufacturer has now provided bench test data using the following:

Three Model 3200s paired with their respective BT-enabled PCs.
one WiFi transmitter

one PC receiving streaming video
one cordless phone running at 2.4 GHz (which is the same nominal frequency as BT)

There was only one error during the tests. The response is adequate.

15. From page 14 of 25 in the User Manual, the BT mode can be manually selected, but also automatically selected whenever the stethoscope is in an active mode. Please explain why this auto mode for BT is safe since the risks for unauthorized eavesdropping and electromagnetic interference are higher compared to the BT mode into which the user has to intentionally enter.

Response:
The manufacturer has replied that this feature is only designed for BT communications between paired PCs and the subject device. In other words, a rouge PC will not be able to communicate via BT with the subject device without the user pairing them first. However, this idea of auto select applies only to "paired" BT-enabled PCs is not reflected in the labeling. This will be f/u.

16. Page 16 of 25 of the User Manual states, "When connected by a Bluetooth link, external Bluetooth-enabled devices can take control of the display and keypad of the Model 3200 stethoscope." This external control via BT configuration is troublesome since it goes beyond pure transfer of data (sound files). Please explain why this external control configuration should not be deleted.

Response:
The manufacturer has replied that

> "The external Bluetooth-enabled device can only control a portion of stethoscopes LCD display and emulate keypad activation. The external Bluetooth-enabled device does not have any other control above and beyond this. This capability is needed to optimize the usability of the Model 3200 and the external software.
>
> For example, when sounds are being transmitted from the PC to the stethoscope via Bluetooth communication, the display of the Model 3200 can be adjusted by the external software so that the correct filter mode is synchronized with the sound recording that is being sent to the stethoscope."

I believe that this should be labeled. This will be f/u.

17. On page 16 of 25 in the User Manual, you have asked the user to "Consult application

software for details on initiating real-time transfer, the process may vary by computer platform utilized." Please revise the User Manual to include an example of the steps needed to transmit and receive sound files from the subject device to a BT-enabled device using a legally marketed software piece.

Response:
The manufacturer has provided a basic description of the steps needed for BT communications. The response is adequate.

Biocompatibility

18. Section 12.0 indicates that the diaphragm (transducer cover) is silicone with polyacrylate coating, which is not found in the two predicates. Hence, please provide the 3 biocompatibility tests in accordance with ISO 10993-1-- irritation, sensitization and cytotoxicity--, especially since Appendix 15 refers to the ISO 10993-1 standard.

Response:
In the present response, the manufacturer has not provided a good response, on my inquiry, the manufacturer sent me an email dated March 26, 2009, to indicate that the same diaphragm material is used 3M stethoscopes cleared under K050159 and K051790. The response is adequate.

Software

19. On page 2 of 18 in Appendix 6, you indicate the software version as 2.00 dated 04 dec 2008 and ready for signing. However, on page 2 of 5 in Appendix 9, version 2.00 was dated 15-09-2008. And version 8.00 dated 17-12-2008 will be SW release v. 01.00.00. Please clarify the version number issue.

Response:
The manufacturer has clarified that some of the versions I have referred to are document versions, not software versions. Suffice it to say that the final software version to be market release is version 1.0 (v.01.00.00). The response is adequate.

20. In section 16 you have indicated a Minor level of concern for the software in the device since you think that the stethoscope does not provide diagnostic information. However, we believe that the indication of heart rate is diagnostic and that the sound amplified by the device is also important-- erroneously amplified sounds can lead to misdiagnosis. Hence, please revise the software documentation to that of a Moderate level of concern. We note that you have already provided a lot of the required software documentation for a Moderate level of concern. Please add Architecture Design Chart, Design Specifications, Software Development Environment Description and Unresolved Anomalies.

Response:

The manufacturer has insisted on a Minor level while I believe that the information provided by the device is important and if erroneous, can lead to patient injury, thus making the case for Moderate level of concern. This will be f/u.

21. For the risk assessment report provided in Appendix 5, the font size of the table starting from page 4 of 13 to page 11 of 13, inclusive, is too small to read. Please provide a larger printout with larger font size.

Response:

The manufacturer has provided a revised version of the document with larger font size. Most of the common risks are considered. However, page 12 of 13 indicates that 2 activities have not been completed:

3M CVE Design validation
Wear test of new bayonet design

These will be f/u.

Attachment: Form FDA 3654

K083903 3M F/u questions on May 11, 2009

1. In response to our questions dated Feb. 23, 2009, you have provided some forms FDA 3654. However, although you refer to IEC 60601-1-2 (for EMC testing) this form is not provided. Please provide form FDA 3654 for this standard.

2. We believe that the subject device is for prescription use only, for the following reasons:

   a. The subject device reports a heart rate (in addition to heart sounds). This heart rate feature makes the device a monitor, necessitating a prescription use only designation.

   b. The predicate from the same manufacturer is also prescription use only; it also has the heart rate reporting feature.

   Hence, please revise the Instructions for Use statement, and the IFU, to indicate for prescription use only, as requested by our previous Q. 2.

3. Please revise the IFU to inform the user that the patient's heart rate is updated every 2 seconds after initial sampling (5 sec.). For ease of viewing by the physician this heart rate is shown in the LCD display of the stethoscope for 10 seconds after removal of the chest piece from the patient.

4. As requested by our previous Q. 6, please point to a legally marketed BT-enabled PC that can communicate with the subject device via BT.

5. Your responses to our previous Q. 7 and 8 refer to Appendix 13. Somehow, this appendix is not available. Please re-transmit it to FDA.

6. Your response to our previous Q. 9 refers to Appendix 2. Somehow, this appendix is not available. Please re-transmit it to FDA.

7. Your response to our previous Q. 13 indicates that testing utilized a unit of the subject device with only [redacted] MB of memory, resulting in a record of only 14 sec. Hence, please provide test data on the subject device with [redacted] MB of memory in order to validate the device's ability to record 29 seconds of acoustic data.

8. In response to our previous Q. 15, you have clarified that the Auto mode for the device's BT feature will work only on BT-enabled PCs (or similar devices) that have been successfully paired with the subject device. Please revise the IFU to highlight this requirement of successful pairing, before the Auto mode can start.

9. In response to our previous Q. 16, you seem to state that an external device's control of the subject device via BT is intended only to help the subject device reproduce sounds using the correct filters (filters that were used to record the original sounds). No other control is afforded to the external device. If this interpretation is correct, please revise the IFU to reflect this idea in BT communications.

10. As requested by our previous Q. 20, please revise the software documentation to be consistent with a Moderate level of concern, since the information provided by the device is important and if erroneous, can lead to patient injury.

11. In your response to our previous Q. 21, you have provided a risk assessment report. However, the report indicates that 2 activities have not been completed:

    a. 3M CVE Design validation
    b. Wear test of new bayonet design

    Please clarify the final status of these two activities.

IFU = Instructions for Use

The following is my review of the manufacturer's responses to our f/u questions emailed to him on May 11, 2009. This set of responses is part of the S1 supplement.

1. In response to our questions dated Feb. 23, 2009, you have provided some forms FDA 3654. However, although you refer to IEC 60601-1-2 (for EMC testing) this form is not provided. Please provide form FDA 3654 for this standard.

Response:

Although the manufacturer indicates that a new FDA 3654 form is provided in his response, the actual form refers to IEC 60601, not IEC 60601-1-2 for EMC testing. This will be f/u.

2. We believe that the subject device is for prescription use only, for the following reasons:

   a. The subject device reports a heart rate (in addition to heart sounds). This heart rate feature makes the device a monitor, necessitating a prescription use only designation.

   b. The predicate from the same manufacturer is also prescription use only; it also has the heart rate reporting feature.

   Hence, please revise the Instructions for Use statement, and the IFU, to indicate for prescription use only, as requested by our previous Q. 2.

Response:

Although the manufacturer has indicated agreement to prescription use, and has revised the IFU accordingly, the new Indications for use form has not checked the prescription use entry. This will be f/u.

3. Please revise the IFU to inform the user that the patient's heart rate is updated every 2 seconds after initial sampling (5 sec.). For ease of viewing by the physician this heart rate is shown in the LCD display of the stethoscope for 10 seconds after removal of the chest piece from the patient.

Response:

The manufacturer has revised labeling accordingly. The response is adequate.

4. As requested by our previous Q. 6, please point to a legally marketed BT-enabled PC that can communicate with the subject device via BT.

Response:

The manufacturer has provided the specifications for such a BT-enabled PC and also listed an example, HP EliteBook 6930p Notebook. The response is adequate.

5. Your responses to our previous Q. 7 and 8 refer to Appendix 13. Somehow, this appendix is not available. Please re-transmit it to FDA.

Response:

The manufacturer has provided the Appendix 13, which are two test reports on IEC 60601-1. These reports indeed indicate P (for passing) for the IPX4 and for the claim for suitability for use inside flammable anesthetic gas environment-- the device is claimed to be category AP, based on Annex G. However, I do not see the actual test report to support the claim of IPX4 (which should involving sending various amount of water to the device) and the Annex G for use in a flammable gas environment. These will be f/u.

6. Your response to our previous Q. 9 refers to Appendix 2. Somehow, this appendix is not available. Please re-transmit it to FDA. (Note: This should be attachment 2, not Appendix 2.)

Response:

The manufacturer has clarified that this was provided as Appendix 10 on EMC testing in the original submittal. The results are reasonable. The response is adequate.

7. Your response to our previous Q. 13 indicates that testing utilized a unit of the subject device with only [redacted] MB of memory, resulting in a record of only 14 sec. Hence, please provide test data on the subject device with (b)(4) [redacted] of memory in order to validate the device's ability to record 29 seconds of acoustic data.

Response:

The manufacturer has provided the test report to indicate recording 29 seconds of acoustic data. The response is adequate.

8. In response to our previous Q. 15, you have clarified that the Auto mode for the device's BT feature will work only on BT-enabled PCs (or similar devices) that have been successfully paired with the subject device. Please revise the IFU to highlight this requirement of successful pairing, before the Auto mode can start.

Response:

The manufacturer has revised labeling accordingly. The response is adequate.

9. In response to our previous Q. 16, you seem to state that an external device's control of the subject device via BT is intended only to help the subject device reproduce sounds using the correct filters (filters that were used to record the original sounds). No other control is afforded to the external device. If this interpretation is correct, please revise

the IFU to reflect this idea in BT communications.

Response:

The manufacturer has replied as follows:

"

The 3200 stethoscope has the capability to communicate and receive control commands wirelessly via the Bluetooth link to a trusted PC computer running validated software.

When running in this mode, the user operating the PC software has the primary control of the recording features of the 3200 stethoscope. Under secured software control, the 3200 stethoscope has the following remote features:

(b)(4)Trade Secret Process-Product Specs

[redacted]

We have revised the IFU to include these potential remote capabilities as follows:

1. "The Bluetooth interface provides a means of exchanging audio data with external devices such as a Bluetooth enabled PC. Audio data can be sent in near real time, permitting the visual presentation, recording, and analysis by applications software complying with communication protocols used by the Model 3200 stethoscope."

2. "In order to transfer data between two Bluetooth devices, they must first be "paired" electronically. Pairing is a discovery and authentication process that allows your Bluetooth equipped Model 3200 stethoscope to communicate with another Bluetooth equipped device and establishes the link between these two devices as a trusted pair. The pairing process requires user operations to be performed on both the Model 3200 and the external device."

3. "When connected by a Bluetooth link, external Bluetooth-enabled devices may take control of the display and keypad of the Model 3200 stethoscope. The external device may also transfer audio playback or other information through the Model 3200 headset. When the external device transfers audio playback back to the stethoscope, the sounds will be preceded by a beep.""

However, my opinion is that these features are very powerful, and in fact changes the stethoscope into a (maybe illegal) eavesdropping device on unsuspecting persons who may be carrying on confidential conversations. And this near real-time transmission of conversations seems to be continuous for as long as the battery inside the device lasts. Is there a predicate stethoscope with this feature? This will be f/u.

10. As requested by our previous Q. 20, please revise the software documentation to be consistent with a Moderate level of concern, since the information provided by the device is important and if erroneous, can lead to patient injury.

Response:

The manufacturer has provided software documentation consistent with a Moderate level of concern. The response is adequate.

11. In your response to our previous Q. 21, you have provided a risk assessment report. However, the report indicates that 2 activities have not been completed:

    a. 3M CVE Design validation
    b. Wear test of new bayonet design

    Please clarify the final status of these two activities.

Response:

The manufacturer has clarified that the item a will be completed on June 5. But I do not see a report for its completion today. Item b on torquing the new bayonet design has been completed, with a successful test report. Hence, item a will be f/u.

IFU = Instructions for Use

K083903/S1 f/u questions on July 5, 2009:

A. In response to our f/u Q. 1 emailed to you on May 11, 2009, you have provided a new FDA 3654 form, but it is entitled IEC 60601, not IEC 60601-1-2 for EMC testing. Please re-transmit a FDA 3654 form for the correct IEC 60601-1-2.

B. In response to our previous Q. 2, you have provided a new Indications for use form. But you have forgotten to check the prescription use entry blank. Further, the prescription use line should be located above the FDA concurrence line, as shown in the attached blank form. Please revise the Indications for Use form accordingly.

C. In response to our previous Q. 5, you have provided two test reports on IEC 60601-1, which indicate that the subject device is rated IPX4 (for the chest piece only) and can be used inside a flammable anesthetic gas environment. However, the IEC test reports are summary reports since they do not contain the actual test report(s) describing how water was used to test the subject device for the IPX4 claim. Similarly, Annex G, which seems to substantiate the claim for use in a flammable gas environment, is not provided. Hence, please provide these two documents for FDA to review.

D. In your response to our previous Q. 9 on the PC's remote control of the subject stethoscope, we see the PC's control of the stethoscope is so thorough that it in fact turns the stethoscope into an eavesdropping device on unsuspecting persons. And this near real-time transmission of patient sounds (and any other sound or conversation near the stethoscope) can be continuously on for as long as the battery inside the device lasts. Please explain how this remote recording and near real-time transmission feature will not conflict with laws against eavesdropping. Is there a predicate stethoscope with this feature?

E. In your response to our previous Q. 11, you have indicated that a test report on 3M CVE Design validation would be available on June 5. Yet up to now, we have not received this report. Please provide the test report.

Attachment: Indications for Use form (blank)

The following is my review of the manufacturer's response to the K083903/S1 f/u questions emailed to him/her on July 5, 2009:

A. In response to our f/u Q. 1 emailed to you on May 11, 2009, you have provided a new FDA 3654 form, but it is entitled IEC 60601, not IEC 60601-1-2 for EMC testing. Please re-transmit a FDA 3654 form for the correct IEC 60601-1-2.

Response:
The manufacturer has clarified that the FDA 3654 form in fact includes IEC 60601-1-2 as a sub-section, although not as the main title. As this is a minor issue only, the response is adequate.

B. In response to our previous Q. 2, you have provided a new Indications for use form. But you have forgotten to check the prescription use entry blank. Further, the prescription use line should be located above the FDA concurrence line, as shown in the attached blank form. Please revise the Indications for Use form accordingly.

Response:
The manufacturer has revised the Indications for Use statement accordingly. The response is adequate.

C. In response to our previous Q. 5, you have provided two test reports on IEC 60601-1, which indicate that the subject device is rated IPX4 (for the chest piece only) and can be used inside a flammable anesthetic gas environment. However, the IEC test reports are summary reports since they do not contain the actual test report(s) describing how water was used to test the subject device for the IPX4 claim. Similarly, Annex G, which seems to substantiate the claim for use in a flammable gas environment, is not provided. Hence, please provide these two documents for FDA to review.

Response:
The manufacturer has pointed to sections and tables in the test reports that can be interpreted to indicate that the tester indeed did the IPX4 test. Further, Annex G is indeed included in the report, and it really discusses checking that there is no source of ignition in the device, and that the wattage is small enough. The response is adequate.

D. In your response to our previous Q. 9 on the PC's remote control of the subject stethoscope, we see the PC's control of the stethoscope is so thorough that it in fact turns the stethoscope into a eavesdropping device on unsuspecting persons. And this near real-time transmission of patient sounds (and any other sound or conversation near the stethoscope) can be continuously on for as long as the battery inside the device lasts. Please explain how this remote recording and near real-time transmission feature will not conflict with laws against eavesdropping. Is there a predicate stethoscope with this feature?

Response:

The manufacturer has replied as follows:

"With current PC software, the maximum time for a single recording session to the PC is 60 seconds. It can only be initiated with a button press by the stethoscope with an active Bluetooth connection. Subsequent recordings by the PC require setup at the PC and another press at the stethoscope to initiate the recording. Inactivity by the stethoscope will end the Bluetooth connection after 90 seconds."

Hence, I believe that the operator's actions will give warning to the patients and the bystanders that sound recording is being performed. The response is adequate.

E. In your response to our previous Q. 11, you have indicated that a test report on 3M CVE Design validation would be available on June 5. Yet up to now, we have not received this report. Please provide the test report.

Response:

The manufacturer has sent me a list of the issues that have now been resolved. He/she declines to provide the full report since it contained items not involved with the present submittal. The list of issues is copied below:

" * 3M CVE has confirmed that the failure modes identified in the Risk Assessment Report (IAD0007 E3100-E3200) have been successfully mitigated through the design control process by the device manufacturer.

Components	Potential Hazards	3M CVE results
10	PCB (printed circuit board) falls out during battery replacement	Did not occur

12	Battery supply missing (POGO pin)	Did not occur
15	Battery supply or loudspeaker signals missing	Did not occur
26	Wrong heart rate displayed	Did not occur
27	Device turns on under storage condition in pocket etc	Did not occur
27	Device turns off during examination. Device can still be turned on by the On switch	Did not occur
38	Poor or no sound	Did not occur

|----------+----------+----------|"

Since the issues have now been resolved, the response is adequate.

Ho, Charles S.

From: jjin1@mmm.com
Sent: Monday, July 13, 2009 12:56 PM
To: Ho, Charles S.
Subject: RE: K083903/S1 F/U Questions

Importance: High

Dear Dr. Ho,

Please see the answers below. Please let me know if you have additional questions as soon as possible.

Regards,

Jizhong Jin
International Regulatory Affairs
3M Infection Prevention Division
3M Center, Bldg 275-05-W-06
St. Paul, MN 55144-1000
Tel: 651-733-6655
Fax: 651-737-5320
e-mail: jjin1@mmm.com

"Ho, Charles S." <Charles.Ho@fda.hhs.gov>
07/09/2009 06:26 PM

To <jjin1@mmm.com>
cc "Ho, Charles S." <Charles.Ho@fda.hhs.gov>
Subject RE: K083903/S1 F/U Questions

Dear Mr. Jin:

Here are my remaining issues:

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· For Q. C, you have referred me to that IEC test report, which showed that the tester checked the entry indicating that the device is IPX4. But I still do not see the actual test report of sending water to the device, and afterwards checking that the device could still function as specified. Please provide the actual IPX4 test report.

The detailed test requirement for ingress of water is listed on pages 87 and 88 of the test report in Appendix 13 of the 510(k) submission, Intertek IEC 60601-1 test report (Report Reference No. 809546-1, date of issue 2008-12-10). The test protocols are listed on page 88 of the report in the result section. The more detailed information is listed in appended tables in the test report.

(By the way, the issue of use in a flammable gas environment is resolved. I have found Annex G as you pointed out, thank you!)

· For Q. D on the issue of recording conversation, please confirm what you said today, namely that the stethoscope will time out after 60 seconds during a BT session (due to no key press), and that operator intervention via key press(es) at the stethoscope is needed to reactivate the stethoscope to continue recording sound. Thus, I believe the actions of the operator will provide warning to patients and bystanders that the device is recording sound.

With current PC software, the maximum time for a single recording session to the PC is 60 seconds. It can only be initiated with a button press by the stethoscope with an active Bluetooth connection. Subsequent recordings by the PC require setup at the PC and another button press at the stethoscope to initiate the recording. Inactivity by the stethoscope will end the Bluetooth connection after 90 seconds.

· For Q. E on the 3M CVE Design validation report, please provide a summary of the failures that were found, corrected, and retested successfully. I do not need the full report if it contains information not intended for the present submittal.

3M CVE has confirmed that the failure modes identified in the Risk Assessment Report (IAD0007 E3100-E3200) have been successfully mitigated through the design control process by the device manufacturer.

Components	Potential Hazards	3M CVE results
10	PCB (printed circuit board) falls out	Did not occur

40

	during battery replacement	
12	Battery supply missing (POGO pin)	Did not occur
15	Battery supply or loudspeaker signals missing	Did not occur
26	Wrong heart rate displayed	Did not occur
27	Device turns on under storage condition in pocket etc	Did not occur
27	Device turns off during examination. Device can still be turned on by the On switch	Did not occur
38	Poor or no sound	Did not occur

At present, the file is still under review.

Regards,

Charles

Charles Ho, Ph.D.
Scientific Reviewer
FDA/CDRH/ODE
Phone: 240-276-4077
Fax: 240-276-4002
Email: Charles.ho@fda.hhs.gov

-----Original Message-----
m: Ho, Charles S.
Sent: Thursday, July 09, 2009 6:49 PM
To: 'jjin1@mmm.com'

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Cc: Ho, Charles S.
Subject: RE: K083903/S1 F/U Questions

Dear Mr. Jin:

Please call me to discuss your file. I will be at my desk for another hour, so that we can discuss before your vacation tomorrow.

Regards,

Charles

Charles Ho, Ph.D.
Scientific Reviewer
FDA/CDRH/ODE
Phone: 240-276-4077
Fax: 240-276-4002
Email: Charles.ho@fda.hhs.gov

-----Original Message-----
From: jjin1@mmm.com [mailto:jjin1@mmm.com]
Sent: Monday, July 06, 2009 4:39 PM
To: Ho, Charles S.
Subject: Re: K083903/S1 F/U Questions
Importance: High

Dear Dr. Ho,

Please see 3M's response attached, let me know if you have additional questions as soon as possible. Please also inform me if I should send this to the documentation room.

Regards,

Jizhong

(See attached file: INDICATIONS FOR USE FORM ODE REVISED_Jul052009.DOC)(See attached file: Response to FDA July 6, 2009.doc)

Jizhong Jin
International Regulatory Affairs
3M Infection Prevention Division
3M Center, Bldg 275-05-W-06
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Tel: 651-733-6655
Fax: 651-737-5320

e-mail: jjin1@mmm.com

"Ho, Charles S."
<Charles.Ho@fda.h
hs.gov> To
<jjin1@mmm.com>
07/05/2009 06:44 cc
PM "Ho, Charles S."
<Charles.Ho@fda.hhs.gov>
Subject
K083903/S1 F/U Questions

Dear Mr. Jin:

Thanks for waiting! I have done a more thorough review of your official response, and have some f/u questions, attached. Please see if you can respond to them quickly. At present I am still keeping your file under review in your office. Please call me to discuss your draft response since I can wait only a few more days before placing the file on hold again.

Regards,

Charles

Charles Ho, Ph.D.
Scientific Reviewer
FDA/CDRH/ODE
Phone: 240-276-4077
Fax: 240-276-4002
Email: Charles.ho@fda.hhs.gov

[attachment "INDICATIONS FOR USE FORM ODE REVISED_Jul052009.DOC" deleted

by Jizhong Jin/US-Corporate/3M/US] [attachment "K083903_S1 f_U Q_Jul052009.doc" deleted by Jizhong Jin/US-Corporate/3M/US]

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K083903/S1 f/u questions on July 5, 2009:

A. In response to our f/u Q. 1 emailed to you on May 11, 2009, you have provided a new FDA 3654 form, but it is entitled IEC 60601, not IEC 60601-1-2 for EMC testing. Please re-transmit a FDA 3654 form for the correct IEC 60601-1-2.

   3M has provided the FDA 3654 form of IEC 60601-1-2 on May 28, 2009. The IEC 60601-1-2 is listed on the second page of the form.

B. In response to our previous Q. 2, you have provided a new Indications for use form. But you have forgotten to check the prescription use entry blank. Further, the prescription use line should be located above the FDA concurrence line, as shown in the attached blank form. Please revise the Indications for Use form accordingly.

   Please see the indication for use statement attached.

C. In response to our previous Q. 5, you have provided two test reports on IEC 60601-1, which indicate that the subject device is rated IPX4 (for the chest piece only) and can be used inside a flammable anesthetic gas environment. However, the IEC test reports are summary reports since they do not contain the actual test report(s) describing how water was used to test the subject device for the IPX4 claim. Similarly, Annex G, which seems to substantiate the claim for use in a flammable gas environment, is not provided. Hence, please provide these two documents for FDA to review.

   In Appendix 13 of the 510(k) submission, Intertek IEC 60601-1 test report (Report Reference No. 809546-1, date of issue 2008-12-10) documents testing and test results for ingress of water (IPX4) and fire prevention (AP rating) for use in a flammable gas environment.

   Clause 11.6.5 of IEC 60601-1 and of this test report documents ingress of water testing per IEC 60529. Level four, or "IPX4", is protection against splashing liquids and is consistent with the level of protection provided on previous models of 3M Littmann electronic stethoscopes. Ingress of liquids exposure is used to precondition the stethoscope (as defined in IEC 60529 and Level 4) prior to testing for dielectric strength and leakage current (as defined by IEC 60601-1 Clause 11.6.5). The "Results" and "Verdict" section of the test report (Clause 11.6.5) document the results.

   Clause 11.2.1 documents the protection against fire. Specifically, the "Results" section of Clause 11.2.2.1a provides expert analysis stating that the equipment complies to IEC 60601-1 Annex G and that there are no sources of ignition in normal and single fault conditions. Annex G is also included in the same test report starting on page 115.

D. In your response to our previous Q. 9 on the PC's remote control of the subject stethoscope, we see the PC's control of the stethoscope is so thorough that it in fact turns the stethoscope into a eavesdropping device on unsuspecting persons. And this near real-

time transmission of patient sounds (and any other sound or conversation near the stethoscope) can be continuously on for as long as the battery inside the device lasts. Please explain how this remote recording and near real-time transmission feature will not conflict with laws against eavesdropping. Is there a predicate stethoscope with this feature?

General knowledge indicates that eavesdropping is defined as surreptitiously listening to a private conversation, which is commonly thought to be unethical.

The E3200 stethoscope's intended use is for medical diagnostics purpose only. Furthermore, it is classified as a Prescription Device, to be purchased only by healthcare professionals.

The primary control against wireless eavesdropping is the fact that only one Bluetooth device can be connected at a time to a E3200 stethoscope via an encrypted link. Furthermore, the stethoscope user controls which single PC is paired and connected.

The software (on the PC) will only stream audio during a recording session that is initiated by the stethoscope user with the M key. Each single record session in the PC software is limited to 60 seconds and thus is unable to record continuously. Without the 3M proprietary communication protocol, the transmission of sounds cannot not be programmed for continuous streaming. Eavesdropping would be much easier to do with a cellular phone or digital recorder.

E. In your response to our previous Q. 11, you have indicated that a test report on 3M CVE Design validation would be available on June 5. Yet up to now, we have not received this report. Please provide the test report.

   3M CVE has confirmed that the failure modes identified in the Risk Assessment Report have been successfully mitigated through the design control process by the device manufacturer.

Attachment: Indications for Use form (blank)

Indications for Use

510(k) Number (if known): K083903

Device Name: 3M™ Littmann® Electronic Stethoscope Model 3200

Indications For Use: The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

Prescription Use ____X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

47

5.0 Premarket Notification (510(k)) Summary

Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person:	Jizhong Jin Senior Regulatory Affairs Associate
Phone Number:	(651) 733-6655
FAX Number:	(651) 737-5320

Date of Summary:	December 22, 2008

Device Name and Classification:

Common or Usual Name:	Electronic Stethoscope
Proprietary Name:	3M™ Littmann® Electronic Stethoscope Model 3200
Classification Name:	Electronic Stethoscope (21 CFR § 870.1875(b))
Performance Standards:	None

Predicate Device:

3M™ Littmann® Electronic Stethoscope, Model 3000
3M™ Littmann® Electronic Stethoscope, Model 4100

Description of Device:

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is a healthcare device that picks up sounds of the heart, arteries, veins, lungs and other internal organs with the use of selective frequency ranges. After amplification and filtering, the sounds are transferred to the user's ears via an active speaker and passive sound tubes.

The Model 3200 can also exchange audio data with a personal computing device (PC) using wireless Bluetooth link.

The user interface includes a 5-button keypad and an LCD display. Sound processing is carried out with the aid of a digital signal processor.
The Model 3200 does not incorporate any off-the-shelf (OTS) software.
The Model 3200 operates on one (1) AA alkaline, lithium, or NiMH battery.

Indications for Use:

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Information provided in this 510(k) submission shows that 3M™ Littmann® Electronic Stethoscope, Model 3200 is substantially equivalent to the predicate device 3M™ Littmann® Electronic Stethoscope, Model 3000, cleared under K050159 and Littmann® Electronic Stethoscope, Model 4100, cleared under K051790 in terms of intended use, indications for use, composition, physical properties and technological characteristics. There are no new questions of safety or effectiveness.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name CHARLES HO

Subject: 510(k) Number K083903

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☑ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			

Rev. 7/2/07

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number Class* Product Code

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____ (Branch Chief) CEMB (Branch Code) 02/23/09 (Date)

Final Review: _____ (Division Director) (Date)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K083903

Date: Feb. 23, 2009
To: The Record
From: Charles Ho, Ph.D.

Office: ODE
Division: DCD

510(k) Holder: 3M Health Care
Device Name: 3M™ Littmann® Electronic Stethoscope, Model 3200

Contact
3M Health Care
c/o Mr. Rica Morris
Senior Regulatory Affairs Associate
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000
Phone: 651-733-6791
Fax: 651-737-5320
Email: remorris2@mmm.com

Contract manufacturer
Bang & Olufsen Medicom A/S
20 Gimsinglundvej
Struer, DENMARK DK-7600

I. Purpose and Submission Summary

The 510(k) holder would like to introduce into interstate commerce the 3M™ Littmann® Electronic Stethoscope, Model 3200. Section 11.4 indicates that there will be additional models with various colors and tube lengths.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		

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	Yes	No	N/A
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form			

In section 9 of the submittal, the manufacturer claims that summary reports are not applicable and that "There is no recognized standard or guidance for subject medical device." This may be true for stethoscopes, but there are several recognized standards for medical devices in general, such as IEC 60601-1 and 60601-1-2, which the manufacturer has provided test reports on, and has claimed compliance for (see section 11.5 for EMC claim). Hence, the standards forms (FDA 3654) for these standards will be requested. Q. 1.

The Indications for Use statement has not checked the prescription use entry, although Appendix 6 describes the user as a professional, probably already accustomed to a mechanical stethoscope. Q. 2.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

The subject device is an electronic stethoscope. The main new item compared to the predicate(s) from the same manufacturer is the new Bluetooth (BT) feature for transmitting the detected sound to a BT-enabled PC for further processing, and also to receive sound files from the PC.

The device detects sounds through its single transducer (chest piece). After amplification and filtering (3 ranges), the sounds are transferred to the user's ears via an active speaker and passive sound tubes.

The three ranges are:

Bell: 20 - 200 Hz
Diaphragm: 100 - 500 Hz
Extended range: 50 - 500 Hz

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The extended range is new, since its range is not indicated in the two predicates. Although page 10 of 18 in Appendix 6 presents a figure of gain vs frequency, the figure has the following issues: (Q. 3)

a. The figure is probably a color figure, but is presented to us in black and white.

b. The figure seems to be a device specification. And page 15 of 36 in Appendix 7 refers to running the frequency response tests for the 3 frequency ranges. But since the extended range seems to be new, we will need the test data.

c. We will need a simplified version of the figure in the User Manual.

From page 17 of 18 in Appendix 6, the device's A/D converter samples at 4 KHz, 16-bit resolution. The data stream for BT uses CRC 16 error checking.

The frequency ranges, amplification, BT mode, auto-off time, etc. can be selected by 4 buttons on the device. Additionally, there is an On/Off button. There is a dot matrix monochrome LCD display for various icons to the user.

The device is powered by one AA battery, which can be alkaline, lithium or NiMH. However, the specific battery type has to be selected by the user, as indicated on page 10 of 25 of the User Manual. What happens if the user forgets to select the correct battery type? Further, this choice of batteries is new, since the predicates use only alkaline batteries. Q. 4.

For reference, the manufacturer indicates that the NiMH battery is rechargeable, while Lithium is non-rechargeable, although I know of rechargeable Lithium batteries.

One feature is that the device can display heart rate, as does the predicate cleared under K051790. From page 12 of 18 in Appendix 6, the heart rate value is updated every 2 seconds after initial sampling (5 sec.) and the value is shown in the LCD for 10 seconds after loss of heart signal. Such a long latching time should be justified. Q. 5.

Below is the excerpt from AAMI EC13:2002 covering the heart rate alarm recommendations:
"

4.2.8.4 Time to alarm for cardiac standstill
The time to alarm for a step change in heart rate from 80 bpm to 0 bpm, with the lower alarm limit set closest to 60 bpm, shall not exceed 10 seconds.

4.2.8.5 Time to alarm for low heart rate
The time to alarm for a step change in heart rate from 80 bpm to 40 bpm, with the lower alarm limit set closest to 60 bpm, shall not exceed 10 seconds.

4.2.8.6 Time to alarm for high heart rate
The time to alarm for a step change in heart rate from 80 bpm to 120 bpm, with the upper alarm limit set closest to 100 bpm, shall not exceed 10 seconds"

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Section 11.4 indicates that the device has a proprietary passive ambient noise reduction (ANR) technology. This feature is included in the predicate, as shown in the comparison table with predicates, in section 12.0.

We will ask whether the present submittal includes the software in the PC for receiving and processing the received sound file. If yes, we need documentation for this software in the PC. For reference, one predicate can communicate with a PC via infrared. Q. 6.

The sound file is 29 seconds long, which is also the memory size of the stethoscope.

Bluetooth (BT)

Via BT, the device can transmit a sound file (up to 29 seconds long) to an BT-enabled PC, and also receive a sound file from the PC, for storage in the stethoscope, and for playing back as audio sound to the user.

The BT is implemented via a singl(b)(4)Trade Secret Process-Product Specs [redacted].

From section 11.2, the BT is Class 2 BT link, and has a maximum range of 10 m. From Appendix 1, the BT operates at a frequency of 2.4 GHz using GFSK modulation with a maximum power of 230 microW. The protocol is SPP. The BT standard is V2.0 or V2.1.

Although section 11.2 states, "The Model 3200 can only communicate with one PC at a time.", page 15 of 25 in the User Manual indicates that the stethoscope can pair (under BT) with up to 8 devices (but not with another stethoscope) at a time. This 8 BT devices pairing is also indicated on page 18 of 18 in Appendix 6. And page 30 of 36 in Appendix 7 reports tests on pairing the stethoscope with at least 3 BT-enabled devices. Here, the manufacturer seems to distinguish between "pairing" and "connecting" to a BT device to really communicate. If indeed the subject device can communicate with more than one BT-enabled devices simultaneously (or in rapid succession), the concern will be how the device can distinguish one PC from another, and thus not mix up the sound files of different patients. And, the security issues will be huge since BT does not require line of sight for communications. Labeling should also be revised to highlight this difference between pairing and connecting. Q. 14.

From page 14 of 25 in the User Manual, the BT mode can be manually selected, but also automatically selected whenever the stethoscope is in an active mode. I believe that this auto mode for BT is a bit dangerous since the risks for unauthorized eavesdropping and interfering other devices are higher. Q. 15.

A worrying item is that page 16 of 25 of the User Manual states, "When connected by a Bluetooth link, external Bluetooth-enabled devices can take control of the display and keypad of the Model 3200 stethoscope. They can also transfer audio (ex. voice prompts) to the Model 3200 headset. During audio transfers to the stethoscope, a tone will be sounded every 8 seconds." This external control via BT is troubling since it goes beyond transfer of data (sound files) only.

Q. 16.

Yet, later on the same page, the manufacturer asks the user to "Consult application software for details on initiating real-time transfer, the process may vary by computer platform utilized." I believe that the manufacturer should describe at least one application software for this purpose. Q. 17.

Note: On page 16 of 18 in Appendix 6, the manufacturer uses the term "PS-keys" to mean "Persistence Storage keys".

The manufacturer has provided a BT test report written by Eurofins located in Germany. However, the tests covered only the basic characteristics such as frequency hopping, radiated power, but not the issue of co-existence with other emitters.

Note that Appendix 15, Risk Management, indicates using spread spectrum low power communication protocol and V and V testing to support co-existence with other emitters. However, I do not see the actual test report. Q. 14 also.

IV. Indications for Use

Copied from submitted Indications for Use statement,

*** Beginning of copying ***

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment."

*** End of copying ****

V. Predicate Device Comparison

The claimed predicates are:

3M™ Littmann® Electronic Stethoscope, Model 3000, cleared under K050159; and

3M™ Littmann® Electronic Stethoscope, Model 4100, cleared under K051790. This last predicate uses infrared light for communications.

Section 12.0 indicates that the diaphragm (transducer cover) is silicone with polyacrylate coating, which is not found in the two predicates. See below.

The subject device can amplify sound up to 28 dB acoustic gain, while the predicates only 25

dB. However, the maximum sound level is still (b) (4) dB SPL max, same as the predicates.

VI. Labeling

The manufacturer has provided a reasonable set of instructions, including the instructions for operation and cleaning in between patients. However, there are the following issues:

Appendix 1, page 3 of 25, indicates that the device protected against splashing liquid (chest piece only), under IPX4. We will require the test results to substantiate this claim. Q. 7.

Appendix 1, page 3 of 25, indicates that the device is tested for use with flammable anesthetic mixture with air. We will require the test results to substantiate this claim. Q. 8.

VII. Sterilization/Shelf Life/Reuse

N/A

VIII. Biocompatibility

Section 12.0 indicates that the diaphragm (transducer cover) is silicone with polyacrylate coating, which is not found in the two predicates.

In appendix 3, the manufacturer has provided an analysis of biocompatibility for the patient contacting and user contacting components of the device. However, for the new transducer cover (the diaphragm) the proof is only that "No adverse health effects are expected from the use of this material." Hence, we will ask for the 3 biocompatibility tests on the diaphragm for less than 24 hours of contact, especially since Appendix 15 refers to the patient contacting, and/or user skin contacting parts of the device to be subjected to ISO 10993-1 tests. Q. 18.

IX. Software

Version: See below.		
Level of Concern: The manufacturer indicates Minor, while I indicate Moderate		
	Yes	No
Software description:	X	
Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:		
Design Specifications:		

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Traceability Analysis/Matrix:	X	
Software Development Environment Description		
Verification & Validation Testing:	X	
Revision level history:	X	
Unresolved anomalies:		

The manufacturer has reported different versions for the software:

On page 2 of 18 in Appendix 6, he/she indicates the version as 2.00 dated 04 dec 2008 and ready for signing. However, on page 2 of 5 in Appendix 9, version 2.00 was dated 15-09-2008. And version 8.00 dated 17-12-2008 will be SW release v. 01.00.00. These issues in version number will be requested. Q. 19.

In section 16 the manufacturer has indicated a Minor level of concern for software in the device since he/she thinks that the stethoscope does not provide diagnostic information. But I believe that the indication of heart rate is diagnostic and the sound amplified by the device is also important-- erroneous sound amplification can lead to misdiagnosis. Hence, I believe that the level of concern should be Moderate. The manufacturer has provided some of the required software documentation, but Architecture Design Chart, Design Specifications, Software Development Environment Description and Unresolved anomalies have not been provided. Q. 20.

For the risk assessment report provided in Appendix 5, the font size of the table starting from page 4 of 13 to page 11 of 13, inclusive, is too small to read. We will need a larger printout with larger font size. Q. 21.

Page 4 of 5 in Appendix 9 refers to a known defect in which the displayed heart rate may be 30 pct (probably percent) different from one beat to another. But no wrong heart hates (probably rates) are displayed in the LCD. This begs the question on the smoothing (or averaging) function of the heart rate display. Q. 5 also.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The manufacturer has provided the EMC test report with passing results:

Radiated emissions: according to CISPR 22
RF immunity: 3 V/m
ESD: +/- 2, 4 and 6 KV for contact discharges and +/- 2, 4 and 8 KV for air discharges.
50 Hz magnetic field immunity: 30 A/m rms.

I note that CISPR 22 is the EMC standard for information technology equipment, not medical devices. Further, page 13 of 23 in the EMC test report written by Eurofins referred to

subclause 9.2 of EN 301 489-1 as the test protocol. However, I believe that FDA uses the CISPR 11 standard for radiated emissions testing, referred to by IEC 60601-1-2. Q. 9.

Further, the acceptance criterion allowed some device behaviors (see pages 6 of 8 and 8 of 8 in the E3000 Plus EMC Design Verification Protocol):

1. Change in display graphics
2. Momentary noise in binaural
3. Reset of the stethoscope if reboot is initialized automatically.

We will ask for some justification of the criterion, and if the actual test results utilized this criterion to be called Passing. Q. 10.

There is also a report on BT performance. However, I am not sure if the co-existence issue is adequately covered or not. Q. 14 also.

The manufacturer has provided many bench tests for the device, including those under IEC 60601-1, with passing results.

XI. Performance Testing – Bench

In Appendix 7, the manufacturer has provided a test report on the device's operation, with passing results. Items tested include powering up and down, filter setting, battery power management, heart beat detection, BT communications, etc.

In Appendix 13, the manufacturer has provided a test report for the IEC 60601-1 standard, with passing results.

In Appendix 14, the manufacturer has provided a test report for the operating and storage environment of the device, with passing results.

However, I have the following issues:

Page 30 of 36 in Appendix 7 refers to pairing the subject device with at least 3 BT devices only. It is not clear how many BT devices were paired with the subject stethoscope during the test. If this number is not 8, the manufacturer should repeat the test using 8 BT devices if this is what he/she claims. This issue is discussed above.

The device under test is sometimes described as the E3000 plus (on page 1 of 36) and sometimes as M3200 (on page 29 of 36 in Appendix 7). Then page 14 of 36 displays a hand-written statement of "Only works on E-3200". And page 22 of 36 refers to the Model 3200. Please explain how test results from a model that is 3200 can be transferred to the Model 3200. Q. 11.

Page 5 of 5 in Appendix 8 refers to 4 minor observations. Please provide more details on these

observations, and why these observations can be tolerated: (Q. 12)

Live_lock
Service_counter
Peak_Location
Deviation

Page 4 of 5 in Appendix 9 refers to several known defects: (Q. 13)

Recording is implemented with 14 sec. recording only (not 29 seconds indicated elsewhere).

Service counter for measuring standby time measures one minute less than actual time.

XII. Performance Testing – Animal

None

XIII. Performance Testing – Clinical

None

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XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?			If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?			If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?			If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?			If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

When developing deficiencies please consider the following "Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA" (http://www.fda.gov/cdrh/modact/guidance/1195.html) and "A Suggested Approach to Resolving Least Burdensome Issues" (http://www.fda.gov/cdrh/modact/leastburdensome.html).

See below.

XVI. Contact History

A. Feb. 23, 2009, I sent the attached email to the manufacturer to indicate my hold recommendation.

XVII. Recommendation

Regulation Number: 21 CFR XXX.XXXX [Only one regulation can be used.]
Regulation Name:
Regulatory Class: Class I, II, III, or Unclassified [Should correspond to regulation.]
Product Code: XYZ [Note: The first code should correspond with the regulation and class thereafter, multiple product codes can be used even if they fall under a different regulation and class.]

Telephone Hold

Reviewer — Date: Feb. 23, 2009

Branch Chief — Date: 02/23/09

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K083903 questions Feb. 23, 2009

3M™ Littmann® Electronic Stethoscope, Model 3200

Regulatory

1. In section 9 you have indicated that summary reports are not applicable and that there is no recognized standard or guidance for subject medical device. This may be true for stethoscopes, but there are several FDA recognized standards for medical devices in general, such as IEC 60601-1 and IEC 60601-1-2, which you have provided test reports for, and have claimed compliance with. Hence, please provide the standards form (FDA 3654, attached) for each of the standards that you claim compliance for the subject device.

2. Please revise the Indications for Use statement to check the prescription use entry, since you intend the intended user to be a professional, probably already accustomed to a mechanical stethoscope.

Engineering (except BT)

3. Please address the following issues concerning the device's frequency ranges:

   a. Please provided test data to show that the device indeed has the frequency responses specified by the figure on page 10 of 18 in Appendix 6.

   b. The above figure is probably a color figure, but it is presented to us in black and white. Please provide a color version of the figure.

   c. Please revise the User Manual to include a simplified version of the figure.

4. The device is powered by one AA battery, which can be alkaline, lithium or NiMH, and the specific battery type has to be selected by the user, as indicated on page 10 of 25 of the User Manual. Please revise the User Manual to inform the user of the risks, if any, of forgetting to select the correct battery type.

5. Please address the following issues on the device's heart rate display:

   a. From page 12 of 18 in Appendix 6, the heart rate value is updated every 2 seconds after initial sampling (5 sec.) and the value is shown in the LCD for 10 seconds after loss of heart signal. Such a long latching time for the heart rate display seems to be on the boundary of acceptance of common ECG standards, such as Association for the Advancement of Medical Instrumentation (AAMI) EC13:2002 standard, clause 4.2.8.4. Please explain if your device's heart rate meter complies with this clause of EC13.

   b. Page 4 of 5 in Appendix 9 refers to a known defect in which the displayed heart rate

may be [redacted] pct (probably, percent) different from one beat to another. But no wrong heart hates (probably, rates) are displayed in the LCD. Please explain whether the device's algorithm for smoothing (or averaging) heart rates needs improvement.

6. Please clarify if the present submittal includes the software in the personal computer (PC) for receiving and processing the sound files received via Bluetooth (BT) from the subject stethoscope. If yes, please provide description and proof of safety and effectiveness for the software.

7. Appendix 1, page 3 of 25, indicates that the device is protected against splashing liquid (chest piece only), under IPX4. Please provide the test report to substantiate this claim.

8. Appendix 1, page 3 of 25, indicates that the device is tested for use with flammable anesthetic mixture with air. Please provide the test report to substantiate this claim.

9. The subject device is tested for radiated emissions under CISPR 22, which is the electromagnetic compatibility (EMC) standard for information technology equipment, not medical devices. Further, page 13 of 23 in the EMC test report written by Eurofins refers to subclause 9.2 of EN 301 489-1 as the test protocol. Please explain how the device's radiated emissions are compliant with the FDA recognized IEC 60601-1-2 standard, which is compatible with the CISPR 11 standard for medical devices.

10. The acceptance criterion in the EMC tests allowed the following device behaviors (see for example pages 6 of 8 and 8 of 8 in the E3000 Plus EMC Design Verification Protocol):

    a. change in display graphics;
    b. momentary noise in binaural; and
    c. reset of the stethoscope if reboot is initialized automatically.

    Please justify this criterion since a change in display graphics and automatic reset of the device may damage the device and/or present erroneous information to the operator. Did the test results include such device characteristics?

11. The device under test is sometimes described as the E3000 Plus (on page 1 of 36 in Appendix 7) and sometimes as M3200 (on pages 22 and 29 of 36 in Appendix 7). Then page 14 of 36 displays a hand-written statement of "Only works on E-3200". Please explain how test results from a model (or models) that is not 3200 can be transferred to the Model 3200.

12. Page 5 of 5 in Appendix 8 refers to 4 minor observations. Please provide more details on these observations, and why these observations can be tolerated:

    a. Live_lock
    b. Service_counter
    c. Peak_Location

d. Deviation

13. Page 4 of 5 in Appendix 9 refers to some known defects. Please provide more details on these defects, and why these defects can be tolerated:

    a. Recording is implemented with 14 sec. recording only (not the 29 seconds indicated elsewhere).
    b. Service counter for measuring standby time measures one minute less than actual time.

Bluetooth (BT)

14. Although section 11.2 states, "The Model 3200 can only communicate with one PC at a time.", page 15 of 25 in the User Manual indicates that the stethoscope can pair with up to 8 devices (but not with another stethoscope) at a time. Please address the following:

    a. You seem to distinguish between "pairing" and "connecting or communicating" to a BT device. Please explain the differences between these two terms, especially in view of the above statement. Labeling should also be revised to highlight the differences between "pairing" and "connecting or communicating".

    b. If indeed the subject device can communicate with more than one BT-enabled PCs simultaneously (or in rapid succession by connecting to various PCs sequentially), please explain how the subject device can distinguish one PC from another, and avoid mixing up the sound files of different patients.

    c. Security is always a major concern for radiofrequency (RF) wireless communications since no line of sight is needed. Here, the subject device has the added capability of pairing with up to 8 devices at the same time. Hence, please explain how you have ensured the security of the subject device in its transmission and reception of sound files to and from up to 8 BT-enabled devices.

    d. You have provided some test data to support the pairing of at least 3 BT-enabled devices. Please clarify if you used 8 BT-enabled PCs to pair with the subject device in the test. If not, please provide the test report using 8 BT-enabled PCs. We believe that you can claim only the number of BT-enabled devices that you have tested safely and securely.

    e. Please provide further test report(s) to verify that the subject device can co-exist wirelessly with other active RF emitters (including paired and unpaired BT emitters, and other RF emitters using different communications standards) in its vicinity.

15. From page 14 of 25 in the User Manual, the BT mode can be manually selected, but also automatically selected whenever the stethoscope is in an active mode. Please explain why this auto mode for BT is safe since the risks for unauthorized eavesdropping and electromagnetic interference are higher compared to the BT mode into which the user has

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to intentionally enter.

16. Page 16 of 25 of the User Manual states, "When connected by a Bluetooth link, external Bluetooth-enabled devices can take control of the display and keypad of the Model 3200 stethoscope." This external control via BT configuration is troublesome since it goes beyond pure transfer of data (sound files). Please explain why this external control configuration should not be deleted.

17. On page 16 of 25 in the User Manual, you have asked the user to "Consult application software for details on initiating real-time transfer, the process may vary by computer platform utilized." Please revise the User Manual to include an example of the steps needed to transmit and receive sound files from the subject device to a BT-enabled device using a legally marketed software piece.

Biocompatibility

18. Section 12.0 indicates that the diaphragm (transducer cover) is silicone with polyacrylate coating, which is not found in the two predicates. Hence, please provide the 3 biocompatibility tests in accordance with ISO 10993-1-- irritation, sensitization and cytotoxicity--, especially since Appendix 15 refers to the ISO 10993-1 standard.

Software

19. On page 2 of 18 in Appendix 6, you indicate the software version as 2.00 dated 04 dec 2008 and ready for signing. However, on page 2 of 5 in Appendix 9, version 2.00 was dated 15-09-2008. And version 8.00 dated 17-12-2008 will be SW release v. 01.00.00. Please clarify the version number issue.

20. In section 16 you have indicated a Minor level of concern for the software in the device since you think that the stethoscope does not provide diagnostic information. However, we believe that the indication of heart rate is diagnostic and that the sound amplified by the device is also important-- erroneously amplified sounds can lead to misdiagnosis. Hence, please revise the software documentation to that of a Moderate level of concern. We note that you have already provided a lot of the required software documentation for a Moderate level of concern. Please add Architecture Design Chart, Design Specifications, Software Development Environment Description and Unresolved Anomalies.

21. For the risk assessment report provided in Appendix 5, the font size of the table starting from page 4 of 13 to page 11 of 13, inclusive, is too small to read. Please provide a larger printout with larger font size.

Attachment: Form FDA 3654

Ho, Charles S.

From: Ho, Charles S.
ent: Monday, February 23, 2009 11:21 AM
To: 'remorris2@mmm.com'
Cc: Mallis, Elias; Ho, Charles S.
Subject: K083903 3M
Attachments: Standards Data Report FDA-3654.pdf; K083903 Q_Feb232009.doc

Dear Mr. Morris:

I am the FDA reviewer of the above file, for which you serve as the contact person. I have some questions on the file, attached. Please see if you can respond to them in 30 days. Feel free to contact me for any clarification of the questions. The file is hereby recommended for hold.

Please confirm receipt of this email.

Regards,

Charles

Charles Ho, Ph.D.
Scientific Reviewer
FDA/CDRH/ODE
Phone: 240-276-4077
Fax: 240-276-4002
Email: Charles.ho@fda.hhs.gov

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

K083903 questions Feb. 23, 2009

3M™ Littmann® Electronic Stethoscope, Model 3200

Regulatory

1. In section 9 you have indicated that summary reports are not applicable and that there is no recognized standard or guidance for subject medical device. This may be true for stethoscopes, but there are several FDA recognized standards for medical devices in general, such as IEC 60601-1 and IEC 60601-1-2, which you have provided test reports for, and have claimed compliance with. Hence, please provide the standards form (FDA 3654, attached) for each of the standards that you claim compliance for the subject device.

2. Please revise the Indications for Use statement to check the prescription use entry, since you intend the intended user to be a professional, probably already accustomed to a mechanical stethoscope.

Engineering (except BT)

3. Please address the following issues concerning the device's frequency ranges:

   a. Please provided test data to show that the device indeed has the frequency responses specified by the figure on page 10 of 18 in Appendix 6.

   b. The above figure is probably a color figure, but it is presented to us in black and white. Please provide a color version of the figure.

   c. Please revise the User Manual to include a simplified version of the figure.

4. The device is powered by one AA battery, which can be alkaline, lithium or NiMH, and the specific battery type has to be selected by the user, as indicated on page 10 of 25 of the User Manual. Please revise the User Manual to inform the user of the risks, if any, of forgetting to select the correct battery type.

5. Please address the following issues on the device's heart rate display:

   a. From page 12 of 18 in Appendix 6, the heart rate value is updated every 2 seconds after initial sampling (5 sec.) and the value is shown in the LCD for 10 seconds after loss of heart signal. Such a long latching time for the heart rate display seems to be on the boundary of acceptance of common ECG standards, such as Association for the Advancement of Medical Instrumentation (AAMI) EC13:2002 standard, clause 4.2.8.4. Please explain if your device's heart rate meter complies with this clause of EC13.

   b. Page 4 of 5 in Appendix 9 refers to a known defect in which the displayed heart rate

may be (b)(4) pct (probably, percent) different from one beat to another. But no wrong heart hates (probably, rates) are displayed in the LCD. Please explain whether the device's algorithm for smoothing (or averaging) heart rates needs improvement.

6. Please clarify if the present submittal includes the software in the personal computer (PC) for receiving and processing the sound files received via Bluetooth (BT) from the subject stethoscope. If yes, please provide description and proof of safety and effectiveness for the software.

7. Appendix 1, page 3 of 25, indicates that the device is protected against splashing liquid (chest piece only), under IPX4. Please provide the test report to substantiate this claim.

8. Appendix 1, page 3 of 25, indicates that the device is tested for use with flammable anesthetic mixture with air. Please provide the test report to substantiate this claim.

9. The subject device is tested for radiated emissions under CISPR 22, which is the electromagnetic compatibility (EMC) standard for information technology equipment, not medical devices. Further, page 13 of 23 in the EMC test report written by Eurofins refers to subclause 9.2 of EN 301 489-1 as the test protocol. Please explain how the device's radiated emissions are compliant with the FDA recognized IEC 60601-1-2 standard, which is compatible with the CISPR 11 standard for medical devices.

10. The acceptance criterion in the EMC tests allowed the following device behaviors (see for example pages 6 of 8 and 8 of 8 in the E3000 Plus EMC Design Verification Protocol):

    a. change in display graphics;
    b. momentary noise in binaural; and
    c. reset of the stethoscope if reboot is initialized automatically.

    Please justify this criterion since a change in display graphics and automatic reset of the device may damage the device and/or present erroneous information to the operator. Did the test results include such device characteristics?

11. The device under test is sometimes described as the E3000 Plus (on page 1 of 36 in Appendix 7) and sometimes as M3200 (on pages 22 and 29 of 36 in Appendix 7). Then page 14 of 36 displays a hand-written statement of "Only works on E-3200". Please explain how test results from a model (or models) that is not 3200 can be transferred to the Model 3200.

12. Page 5 of 5 in Appendix 8 refers to 4 minor observations. Please provide more details on these observations, and why these observations can be tolerated:

    a. Live_lock
    b. Service_counter
    c. Peak_Location

d. Deviation

13. Page 4 of 5 in Appendix 9 refers to some known defects. Please provide more details on these defects, and why these defects can be tolerated:

    a. Recording is implemented with 14 sec. recording only (not the 29 seconds indicated elsewhere).
    b. Service counter for measuring standby time measures one minute less than actual time.

Bluetooth (BT)

14. Although section 11.2 states, "The Model 3200 can only communicate with one PC at a time.", page 15 of 25 in the User Manual indicates that the stethoscope can pair with up to 8 devices (but not with another stethoscope) at a time. Please address the following:

    a. You seem to distinguish between "pairing" and "connecting or communicating" to a BT device. Please explain the differences between these two terms, especially in view of the above statement. Labeling should also be revised to highlight the differences between "pairing" and "connecting or communicating".

    b. If indeed the subject device can communicate with more than one BT-enabled PCs simultaneously (or in rapid succession by connecting to various PCs sequentially), please explain how the subject device can distinguish one PC from another, and avoid mixing up the sound files of different patients.

    c. Security is always a major concern for radiofrequency (RF) wireless communications since no line of sight is needed. Here, the subject device has the added capability of pairing with up to 8 devices at the same time. Hence, please explain how you have ensured the security of the subject device in its transmission and reception of sound files to and from up to 8 BT-enabled devices.

    d. You have provided some test data to support the pairing of at least 3 BT-enabled devices. Please clarify if you used 8 BT-enabled PCs to pair with the subject device in the test. If not, please provide the test report using 8 BT-enabled PCs. We believe that you can claim only the number of BT-enabled devices that you have tested safely and securely.

    e. Please provide further test report(s) to verify that the subject device can co-exist wirelessly with other active RF emitters (including paired and unpaired BT emitters, and other RF emitters using different communications standards) in its vicinity.

15. From page 14 of 25 in the User Manual, the BT mode can be manually selected, but also automatically selected whenever the stethoscope is in an active mode. Please explain why this auto mode for BT is safe since the risks for unauthorized eavesdropping and electromagnetic interference are higher compared to the BT mode into which the user has

to intentionally enter.

16. Page 16 of 25 of the User Manual states, "When connected by a Bluetooth link, external Bluetooth-enabled devices can take control of the display and keypad of the Model 3200 stethoscope." This external control via BT configuration is troublesome since it goes beyond pure transfer of data (sound files). Please explain why this external control configuration should not be deleted.

17. On page 16 of 25 in the User Manual, you have asked the user to "Consult application software for details on initiating real-time transfer, the process may vary by computer platform utilized." Please revise the User Manual to include an example of the steps needed to transmit and receive sound files from the subject device to a BT-enabled device using a legally marketed software piece.

Biocompatibility

18. Section 12.0 indicates that the diaphragm (transducer cover) is silicone with polyacrylate coating, which is not found in the two predicates. Hence, please provide the 3 biocompatibility tests in accordance with ISO 10993-1-- irritation, sensitization and cytotoxicity--, especially since Appendix 15 refers to the ISO 10993-1 standard.

Software

19. On page 2 of 18 in Appendix 6, you indicate the software version as 2.00 dated 04 dec 2008 and ready for signing. However, on page 2 of 5 in Appendix 9, version 2.00 was dated 15-09-2008. And version 8.00 dated 17-12-2008 will be SW release v. 01.00.00. Please clarify the version number issue.

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Attachment: Form FDA 3654

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☐
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

June 18, 2009

3M COMPANY
INFECTION PREVENTION DIVISION
3M CENTER, BLDG. 275-5W-06
ST. PAUL, MINNESOTA 55144-1000
UNITED STATES
ATTN: JIZHONG JIN

510k Number: K083903

Product: 3M LITTMANN ELECTRONIC

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

S/

3M Health Care Business

3M Center, Bldg. 0275-05-W-06
St. Paul, MN 55144-1000
651 733 1110

K083903/S1

3M

June 16, 2009

FDA CDRH DMC

JUN 17 2009

Received

Dr. Charles Ho
Scientific Reviewer
Food and Drug Administration
Center for Device and Radiological Health
Office of Device Evaluation [510(k)]
Document Control Center HFZ-401
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: Supplement to Traditional 510(k) Premarket Notification for the 3M Littmann Electronic Stethoscope, Model 3200
K083903

Dear Dr. Ho,

Reference is made to our December 22, 2008 request for evaluation of traditional premarket notification for the 3M Littmann Electronic Stethoscope, Model 3200, K083903. As we discussed via email communications, attached is the supplement to the original submission that provides the answers to your questions in a chronological order.

Sincerely,

Jizhong Jin
Regulatory Affairs
3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

K 87

S2

4.0 Indications for Use Statement

Indications for Use Statement

510(k) Number (if known):_K083903_____

Device Name: 3M™ Littmann® Electronic Stethoscope Model 3200

Indications for Use:

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter-Use___

5.0 Premarket Notification (510(k)) Summary

Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person:	Jizhong Jin Senior Regulatory Affairs Associate
Phone Number:	(651) 733-6655
FAX Number:	(651) 737-5320

Date of Summary: December 22, 2008

Device Name and Classification:

Common or Usual Name:	Electronic Stethoscope
Proprietary Name:	3M™ Littmann® Electronic Stethoscope Model 3200
Classification Name:	Electronic Stethoscope (21 CFR § 870.1875(b))
Performance Standards:	None

Predicate Device:

3M™ Littmann® Electronic Stethoscope, Model 3000
3M™ Littmann® Electronic Stethoscope, Model 4100

Description of Device:

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is a healthcare device that picks up sounds of the heart, arteries, veins, lungs and other internal organs with the use of selective frequency ranges. After amplification and filtering, the sounds are transferred to the user's ears via an active speaker and passive sound tubes.

The Model 3200 can also exchange audio data with a personal computing device (PC) using wireless Bluetooth link.

The user interface includes a 5-button keypad and an LCD display. Sound processing is carried out with the aid of a digital signal processor.
The Model 3200 does not incorporate any off-the-shelf (OTS) software.
The Model 3200 operates on one (1) AA alkaline, lithium, or NiMH battery.

Indications for Use:

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Information provided in this 510(k) submission shows that 3M™ Littmann® Electronic Stethoscope, Model 3200 is substantially equivalent to the predicate device 3M™ Littmann® Electronic Stethoscope, Model 3000, cleared under K050159 and Littmann® Electronic Stethoscope, Model 4100, cleared under K051790 in terms of intended use, indications for use, composition, physical properties and technological characteristics. There are no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

February 25, 2009

510k Number: K083903
Product: 3M LITTMANN ELECTRONIC STETHOS

3M COMPANY
3M CENTER, BLDG. 275-5W-06
ST. PAUL, MINNESOTA 55133-3275
UNITED STATES
ATTN: RICA MORRIS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Rica E. Morris/US-Corporate/3M/US
03/27/2009 09:23 AM

To Jizhong Jin/US-Corporate/3M/US@3M-Corporate
cc
bcc
Subject Deficiency letter

Original email from FDA reviewer.

Kind Regards,
Rica

Rica Morris, RAC-US
International Regulatory Affairs
3M Health Care, Medical Division
Bldg. 275-5W-06
Phone: 651-733-6791
Fax: 651-737-5320
Email: remorris2@mmm.com

----- Forwarded by Rica E. Morris/US-Corporate/3M/US on 03/27/2009 09:23 AM -----

"Ho, Charles S." <charles.ho@fda.hhs.gov>
02/23/2009 10:21 AM

To remorris2@mmm.com
cc "Mallis, Elias" <elias.mallis@fda.hhs.gov>
"Ho, Charles S." <charles.ho@fda.hhs.gov>
Subject K083903 3M

Dear Mr. Morris:

I am the FDA reviewer of the above file, for which you serve as the contact person. I have some questions on the file, attached. Please see if you can respond to them in 30 days. Feel free to contact me for any clarification of the questions. The file is hereby recommended for hold.

Please confirm receipt of this email.

Regards,

Charles

Charles Ho, Ph.D.
Scientific Reviewer
FDA/CDRH/ODE
Phone: 240-276-4077
Fax: 240-276-4002

Email: Charles.ho@fda.hhs.gov

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

Standards Data Report FDA-3654.pdf K083903 Q_Feb232009.doc

K083903 questions Feb. 23, 2009

3M™ Littmann® Electronic Stethoscope, Model 3200

Regulatory

1. In section 9 you have indicated that summary reports are not applicable and that there is no recognized standard or guidance for subject medical device. This may be true for stethoscopes, but there are several FDA recognized standards for medical devices in general, such as IEC 60601-1 and IEC 60601-1-2, which you have provided test reports for, and have claimed compliance with. Hence, please provide the standards form (FDA 3654, attached) for each of the standards that you claim compliance for the subject device.

2. Please revise the Indications for Use statement to check the prescription use entry, since you intend the intended user to be a professional, probably already accustomed to a mechanical stethoscope.

Engineering (except BT)

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   a. Please provided test data to show that the device indeed has the frequency responses specified by the figure on page 10 of 18 in Appendix 6.

   b. The above figure is probably a color figure, but it is presented to us in black and white. Please provide a color version of the figure.

   c. Please revise the User Manual to include a simplified version of the figure.

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   a. From page 12 of 18 in Appendix 6, the heart rate value is updated every 2 seconds after initial sampling (5 sec.) and the value is shown in the LCD for 10 seconds after loss of heart signal. Such a long latching time for the heart rate display seems to be on the boundary of acceptance of common ECG standards, such as Association for the Advancement of Medical Instrumentation (AAMI) EC13:2002 standard, clause 4.2.8.4. Please explain if your device's heart rate meter complies with this clause of EC13.

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may be (b) (4) pct (probably, percent) different from one beat to another. But no wrong heart hates (probably, rates) are displayed in the LCD. Please explain whether the device's algorithm for smoothing (or averaging) heart rates needs improvement.

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7. Appendix 1, page 3 of 25, indicates that the device is protected against splashing liquid (chest piece only), under IPX4. Please provide the test report to substantiate this claim.

8. Appendix 1, page 3 of 25, indicates that the device is tested for use with flammable anesthetic mixture with air. Please provide the test report to substantiate this claim.

9. The subject device is tested for radiated emissions under CISPR 22, which is the electromagnetic compatibility (EMC) standard for information technology equipment, not medical devices. Further, page 13 of 23 in the EMC test report written by Eurofins refers to subclause 9.2 of EN 301 489-1 as the test protocol. Please explain how the device's radiated emissions are compliant with the FDA recognized IEC 60601-1-2 standard, which is compatible with the CISPR 11 standard for medical devices.

10. The acceptance criterion in the EMC tests allowed the following device behaviors (see for example pages 6 of 8 and 8 of 8 in the E3000 Plus EMC Design Verification Protocol):

    a. change in display graphics;
    b. momentary noise in binaural; and
    c. reset of the stethoscope if reboot is initialized automatically.

    Please justify this criterion since a change in display graphics and automatic reset of the device may damage the device and/or present erroneous information to the operator. Did the test results include such device characteristics?

11. The device under test is sometimes described as the E3000 Plus (on page 1 of 36 in Appendix 7) and sometimes as M3200 (on pages 22 and 29 of 36 in Appendix 7). Then page 14 of 36 displays a hand-written statement of "Only works on E-3200". Please explain how test results from a model (or models) that is not 3200 can be transferred to the Model 3200.

12. Page 5 of 5 in Appendix 8 refers to 4 minor observations. Please provide more details on these observations, and why these observations can be tolerated:

    a. Live_lock
    b. Service_counter
    c. Peak_Location

d. Deviation

13. Page 4 of 5 in Appendix 9 refers to some known defects. Please provide more details on these defects, and why these defects can be tolerated:

    a. Recording is implemented with 14 sec. recording only (not the 29 seconds indicated elsewhere).
    b. Service counter for measuring standby time measures one minute less than actual time.

Bluetooth (BT)

14. Although section 11.2 states, "The Model 3200 can only communicate with one PC at a time.", page 15 of 25 in the User Manual indicates that the stethoscope can pair with up to 8 devices (but not with another stethoscope) at a time. Please address the following:

    a. You seem to distinguish between "pairing" and "connecting or communicating" to a BT device. Please explain the differences between these two terms, especially in view of the above statement. Labeling should also be revised to highlight the differences between "pairing" and "connecting or communicating".

    b. If indeed the subject device can communicate with more than one BT-enabled PCs simultaneously (or in rapid succession by connecting to various PCs sequentially), please explain how the subject device can distinguish one PC from another, and avoid mixing up the sound files of different patients.

    c. Security is always a major concern for radiofrequency (RF) wireless communications since no line of sight is needed. Here, the subject device has the added capability of pairing with up to 8 devices at the same time. Hence, please explain how you have ensured the security of the subject device in its transmission and reception of sound files to and from up to 8 BT-enabled devices.

    d. You have provided some test data to support the pairing of at least 3 BT-enabled devices. Please clarify if you used 8 BT-enabled PCs to pair with the subject device in the test. If not, please provide the test report using 8 BT-enabled PCs. We believe that you can claim only the number of BT-enabled devices that you have tested safely and securely.

    e. Please provide further test report(s) to verify that the subject device can co-exist wirelessly with other active RF emitters (including paired and unpaired BT emitters, and other RF emitters using different communications standards) in its vicinity.

15. From page 14 of 25 in the User Manual, the BT mode can be manually selected, but also automatically selected whenever the stethoscope is in an active mode. Please explain why this auto mode for BT is safe since the risks for unauthorized eavesdropping and electromagnetic interference are higher compared to the BT mode into which the user has

to intentionally enter.

16. Page 16 of 25 of the User Manual states, "When connected by a Bluetooth link, external Bluetooth-enabled devices can take control of the display and keypad of the Model 3200 stethoscope." This external control via BT configuration is troublesome since it goes beyond pure transfer of data (sound files). Please explain why this external control configuration should not be deleted.

17. On page 16 of 25 in the User Manual, you have asked the user to "Consult application software for details on initiating real-time transfer, the process may vary by computer platform utilized." Please revise the User Manual to include an example of the steps needed to transmit and receive sound files from the subject device to a BT-enabled device using a legally marketed software piece.

Biocompatibility

18. Section 12.0 indicates that the diaphragm (transducer cover) is silicone with polyacrylate coating, which is not found in the two predicates. Hence, please provide the 3 biocompatibility tests in accordance with ISO 10993-1-- irritation, sensitization and cytotoxicity--, especially since Appendix 15 refers to the ISO 10993-1 standard.

Software

19. On page 2 of 18 in Appendix 6, you indicate the software version as 2.00 dated 04 dec 2008 and ready for signing. However, on page 2 of 5 in Appendix 9, version 2.00 was dated 15-09-2008. And version 8.00 dated 17-12-2008 will be SW release v. 01.00.00. Please clarify the version number issue.

20. In section 16 you have indicated a Minor level of concern for the software in the device since you think that the stethoscope does not provide diagnostic information. However, we believe that the indication of heart rate is diagnostic and that the sound amplified by the device is also important-- erroneously amplified sounds can lead to misdiagnosis. Hence, please revise the software documentation to that of a Moderate level of concern. We note that you have already provided a lot of the required software documentation for a Moderate level of concern. Please add Architecture Design Chart, Design Specifications, Software Development Environment Description and Unresolved Anomalies.

21. For the risk assessment report provided in Appendix 5, the font size of the table starting from page 4 of 13 to page 11 of 13, inclusive, is too small to read. Please provide a larger printout with larger font size.

Attachment: Form FDA 3654

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☐
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Rica E. Morris/US-Corporate/3M/US
03/26/2009 01:46 PM

To "Ho, Charles S." <Charles.Ho@fda.hhs.gov>
cc Scott Sardeson/US-Corporate/3M/US
Jizhong Jin/US-Corporate/3M/US@3M-Corporate
bcc
Subject [Response Part 1]: K083903 3M

History: This message has been forwarded.

Hello Dr. Ho,

Attached please find the response to your e-mail of February 23, 2009 regarding the review of 3M's 510(k) application for the 3M Littmann® Electronic Stethoscope Model 3200 (K083903).
We are still working on Question 14e and 16, so those responses are missing from the attached, but we will send you the response to those questions as soon as they are complete.

Due to the file size, I am sending you two emails today. This email contains the response.

Response_deficiency letter 3200_sent March26.2009.doc

If you have any problem opening the attached file.

Thank you very much and looking forward to hearing from you soon.

Kind Regards,
Rica

Rica Morris, RAC-US
International Regulatory Affairs
3M Health Care, Medical Division
Bldg. 275-5W-06
Phone: 651-733-6791
Fax: 651-737-5320
Email: remorris2@mmm.com

3M Health Care
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3M

March 26, 2009

Charles Ho, Ph.D.
Scientific Reviewer
Food and Drug Administration
FDA/CDRH/ODE
9200 Corporate Blvd.
Rockville MD 20850

SUBJECT: Official Response to Question to K083903 E-mail of February 23, 2009 regarding review of the 510(k) 3M™ Littmann® Electronic Stethoscope Model 3200, K083903

Dear Dr. Ho,

In response to your e-mail of February 23, 2009 regarding the review of 3M's 510(k) application for the 3M™ Littmann® Electronic Stethoscope Model 3200 (K083903), please find enclosed 3M's official response for your review files.

Your comments are presented in bold, with 3M's response directly below.

Regulatory

1. **In section 9 you have indicated that summary reports are not applicable and that there is no recognized standard or guidance for subject medical device. This may be true for stethoscopes, but there are several FDA recognized standards for medical devices in general, such as IEC 60601-1 and IEC 60601-1-2, which you have provided test reports for, and have claimed compliance with. Hence, please provide the standards form (FDA 3654, attached) for each of the standards that you claim compliance for the subject device.**

   Please find enclosed Form 3654 for FDA recognized standards. The forms are filled out for the following standards:
   Attachment 1: IEC 60601-1, IEC 60601-1-2
   Attachment 2: ISO 10993
   Attachment 3: ISO 14971

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3M Infection Prevention

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St. Paul, MN 55144-1000
651 733 1110

2. **Please revise the Indications for Use statement to check the prescription use entry, since you intend the intended user to be a professional, probably already accustomed to a mechanical stethoscope.**

   Please find enclosed a revised "Indications for Use" Statement attached to this submission (Attachment 4).

   While many of cleared electronic stethoscopes are indeed designated for prescription use, there are some electronic stethoscopes that are cleared for OTC use. In fact, one of the predicate devices for Model 3200, 3M™ Littmann® Electronic Stethoscope Model 3000, has been cleared for OTC use. Additionally, 3M's analysis of competitors shows that Andromed Inc. holds three cleared 510(k)s for electronic stethoscopes that are designated by CDRH for OTC use. 3M's indications for use for the Littmann Electronic Stethoscope Model 3200 are substantially equivalent to the indications for use of Littmann Model 3000 as well as to the three Andromed devices. Therefore 3M recommends Littmann Model 3200 to be cleared for OTC use.

   The Andromed electronic stethoscope devices cleared for OTC use are:

   1) I-Stethos Link Electronic Stethoscope (K022298) cleared as substantially equivalent on October 1, 2002.
   2) Agilent Electronic Stethoscope Models 4530, 4532A, 4533A, and 4534A, (K010729) cleared as substantially equivalent on October 26, 2001.
   3) Stethos Electronic Stethoscope, (K001306) cleared as substantially equivalent on July 20, 2000.

Table of Contents

1 Purpose 3
2 Scope 3
3 References 3
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5 Discussion of data 3
6 Conclusion 5
7 Version history 6

(b)(4) [redacted]

1 Purpose

The purpose is to document and conclude on a specific Design verification performed with references to Requirements, Plan, and Design Verification Protocol.

2 Scope

The scope of this protocol is limited to the product requirements concerning battery cap torque in connection switch of battery.

3 References

[1] SPL0908d Design verification protocol – Battery access torque
[2] SPL0908f Registration sheet

4 Test data

For test data, registration sheet appendix 1

5 Discussion of data

During the test 1 device (#3) exceeded the max tolerance of 0,550 Nm, and 2 devices (#3 and #30) has been excluded from the statistical data.

Device #3
Torque ON after test indicated an average of 0,591 Nm, which is outside the tolerance.

The device was examined, and it was concluded, that the cause of the increased Torque ON was a deformation of the cap resulting in friction between Loudspeaker housing and Battery housing. The deformation is caused by the fixation of the device in the test fixture, and is not a result of normal wear as simulated in the test. This is confirmed by the facts that while the rest of the test devices, as expected, shows almost the same or Torque ON, this is the only device showing a significantly higher Torque ON after test.

Because the device has been damage by the test, the device has been excluded from the statistical calculations to avoid a falsely high standard deviation.

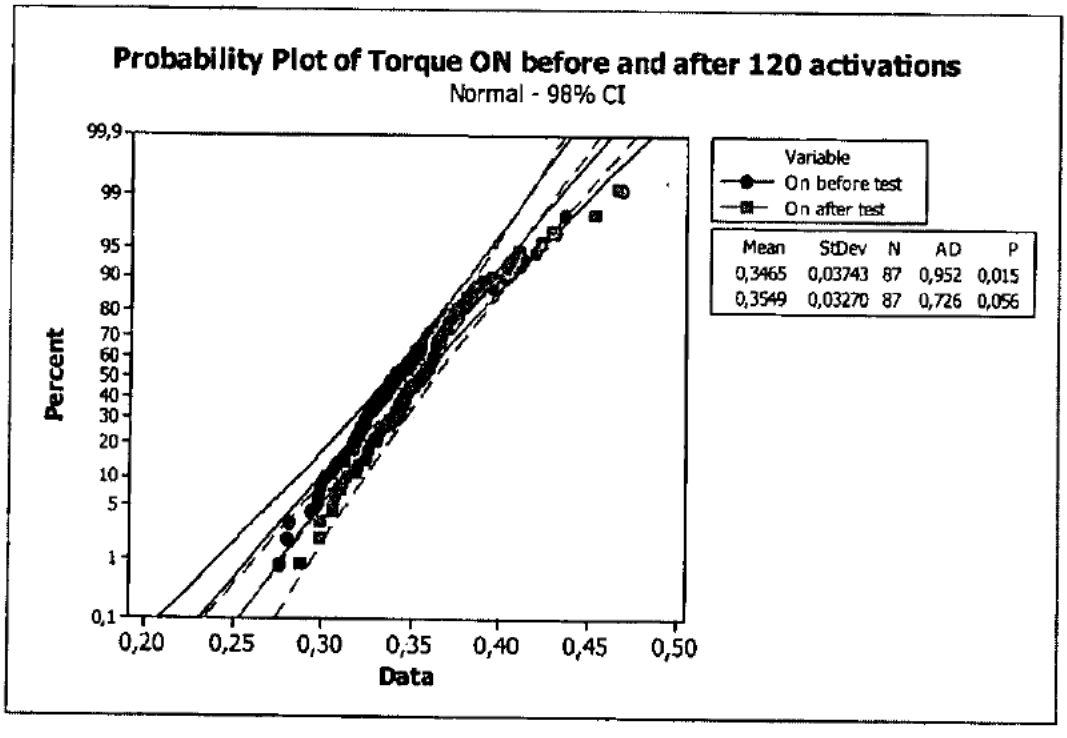
Device #30
Torque ON before test indicated an average of 0,535 Nm, which is significantly above the averages for the rest of the population of 0,343 Nm.

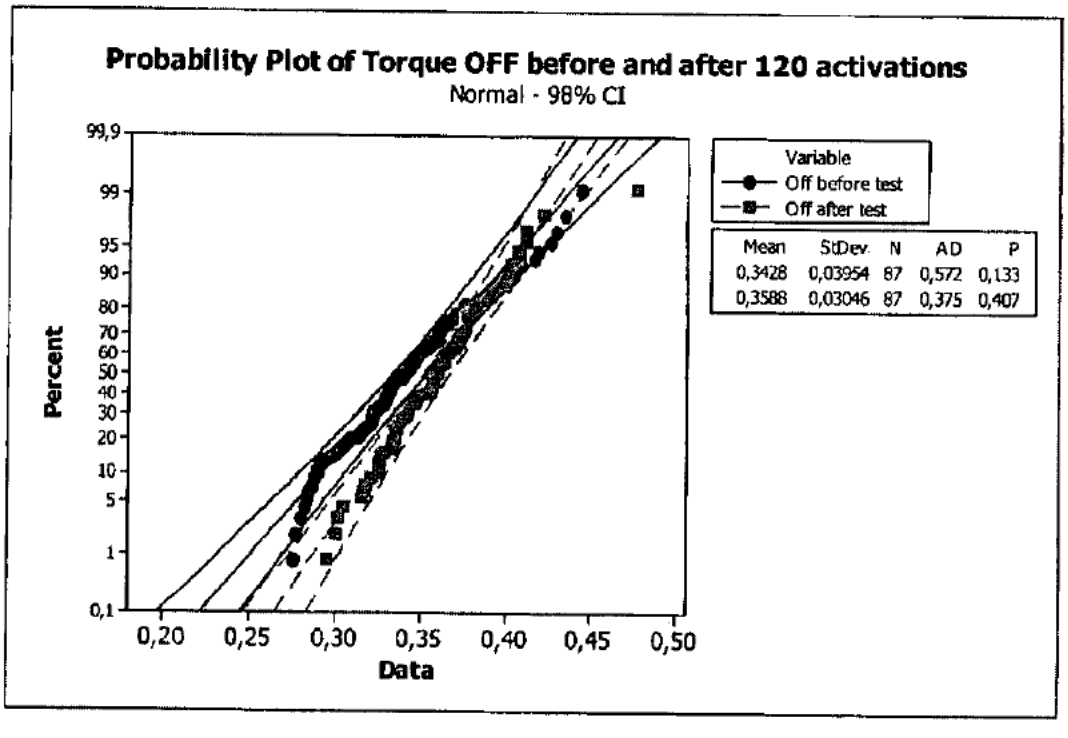
The device was examined, and it was concluded that the cause of the increased Torque ON was a misplacement of the sealing. The misplacement only affected the Torque ON.
The test was continued and during the 120 activations the sealing moved into place and consequently the Torque ON after fell to a level comparable with the rest of the population.

Although inside the tolerance the device has been excluded from the statistical calculations to avoid a falsely high standard deviation.

QMS00247, Version 3.00

(b)(4) [redacted]





As seen from the two plots above all data are well inside the tolerances of 0,350 Nm +/- 0,200 Nm, and there are almost no difference in the before and after torque. The overall tendency is

(b)(4) [redacted]

a slight increase in mean value and decrease in std deviation, most probably caused by the wear and smoothening of the components.

6 Conclusion

Based upon the discussion above it is the overall conclusion that the torque is inside the range of [0,232 – 0,489] Nm with 98% reliability and 98% confidence.

The design verification of the device is passed.

(b)(4) [redacted]

7 Version history

Version	Author	Date	Description	Reviewed by	EC number
1.0	SPL	20-02-2009	First version, due to update of product requirement	TRH	2009-026

QMS00247, Version 3.00

(b)(4) [redacted]

E3000 plus
SPL0908f Registration sheet

Design verification registration sheet

Test method:	Battery access torque
Protocol reference:	spl0908d Design verification protocol

Product

Series name/number	Material number	Material name
na.	19300051	Stethoscope 3100

Lot number	DMR version	Deviations yes/no
B0006986	✓ 8.00	no

Equipment

Description	Identification (R-number or FAA-number)	Calibration date
moment måler	R 2540	19. nov 2009

Test result

START

Device #	ON	ON	ON	OFF	OFF	OFF
1	0,413	0,369	0,363	0,321	0,343	0,403
2	0,336	0,344	0,347	0,416	0,429	0,355
3	0,368	0,366	0,381	0,476	0,415	0,457
4	0,324	0,317	0,325	0,408	0,341	0,355
5	0,352	0,358	0,406	0,345	0,370	0,322
6	0,323	0,312	0,323	0,366	0,329	0,317
7	0,298	0,349	0,323	0,361	0,331	0,359
8	0,317	0,307	0,328	0,360	0,344	0,334
9	0,300	0,320	0,319	0,331	0,297	0,283
10	0,395	0,326	0,352	0,418	0,373	0,321
11	0,333	0,341	0,350	0,394	0,328	0,339
12	0,359	0,375	0,356	0,394	0,340	0,333
13	0,332	0,321	0,338	0,387	0,349	0,332

QMS00473, Version 1.00

(b) (4) [redacted]

(b)(4) [redacted]

E3000 plus

SPL0908f Registration sheet

14	0,338	0,349	0,369	0,395	0,333	0,324
15	0,411	0,388	0,381	0,435	0,444	0,351
16	0,315	0,330	0,341	0,390	0,345	0,343
17	0,321	0,336	0,340	0,357	0,362	0,375
18	0,308	0,302	0,319	0,361	0,313	0,305
19	0,317	0,330	0,336	0,397	0,339	0,336
20	0,381	0,358	0,403	0,359	0,347	0,348
21	0,366	0,337	0,348	0,382	0,325	0,329
22	0,358	0,298	0,423	0,370	0,322	0,314
23	0,395	0,334	0,341	0,318	0,291	0,290
24	0,280	0,276	0,281	0,287	0,276	0,280
25	0,299	0,356	0,356	0,321	0,293	0,284
26	0,351	0,367	0,327	0,300	0,288	0,277
27	0,294	0,313	0,305	0,309	0,307	0,282
28	0,350	0,379	0,385	0,352	0,290	0,303
29	0,431	0,468	0,420	0,426	0,365	0,322
30	0,530	0,539	0,538	0,366	0,320	0,339
31	0,437	0,366	0,377	0,375	0,332	0,328

After 120 Times

Device #	ON	ON	ON	OFF	OFF	OFF
1	0,453	0,355	0,388	0,407	0,402	0,392
2	0,429	0,410	0,466	0,355	0,372	0,364
3	0,648	0,591	0,535	0,390	0,374	0,359
4	0,370	0,370	0,386	0,364	0,342	0,325
5	0,362	0,367	0,366	0,340	0,305	0,326
6	0,381	0,369	0,359	0,321	0,302	0,295
7	0,376	0,361	0,351	0,376	0,359	0,356
8	0,306	0,334	0,342	0,376	0,370	0,369
9	0,324	0,310	0,287	0,325	0,328	0,335
10	0,395	0,404	0,423	0,375	0,367	0,373

QMS004/3, Version 1.00

(b) (4) [redacted]

(b)(4) [redacted]

E3000 plus

SPL0908f Registration sheet

11	0,384	0,360	0,345	0,379	0,391	0,881
12	0,359	0,379	0,363	0,407	0,411	0,400
13	0,331	0,361	0,343	0,375	0,364	0,357
14	0,354	0,350	0,376	0,325	0,339	0,348
15	0,390	0,408	0,405	0,411	0,422	0,476
16	0,323	0,330	0,345	0,375	0,359	0,372
17	0,319	0,311	0,330	0,341	0,356	0,371
18	0,313	0,353	0,331	0,356	0,373	0,382
19	0,354	0,341	0,344	0,334	0,359	0,363
20	0,324	0,337	0,347	0,377	0,364	0,374
21	0,348	0,359	0,373	0,399	0,389	0,398
22	0,362	0,346	0,346	0,357	0,366	0,357
23	0,362	0,338	0,366	0,336	0,334	0,337
24	0,381	0,299	0,306	0,352	0,336	0,318
25	0,319	0,307	0,299	0,341	0,316	0,300
26	0,341	0,325	0,356	0,358	0,317	0,326
27	0,357	0,318	0,340	0,360	0,335	0,336
28	0,343	0,332	0,325	0,345	0,347	0,335
29	0,372	0,346	0,364	0,397	0,333	0,387
30	0,442	0,401	0,387	0,366	0,318	0,327
31	0,362	0,364	0,370	0,355	0,345	0,342

Activity performed by

Date	Initials	Sign
20. febr. 2009	JKP	Jens Kristian N. Pedersen

QMSP0473, Version 1.00

(b) (4) [redacted]

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651 733 1110

Engineering (except BT)

3. **Please address the following issues concerning the device's frequency ranges:**

   a. **Please provided test data to show that the device indeed has the frequency responses specified by the figure on page 10 of 18 in Appendix 6.**

   Please refer to Attachment 5, Verification Report for Frequency Range.

   b. **The above figure is probably a color figure, but it is presented to us in black and white. Please provide a color version of the figure.**

   Please see a color version of the figure below. This graph is also shown in Page 4 of 20 of Attachment 5.

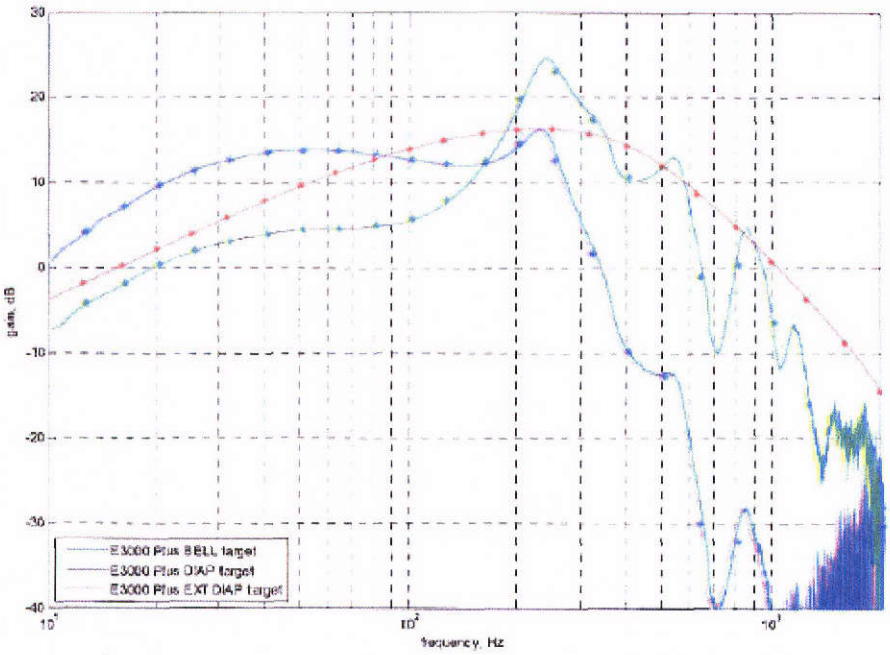

Figure 1 *E3000 Plus target frequency responses for Bell, Diaphragm and Extended Diaphragm filter mode.*

c. **Please revise the User Manual to include a simplified version of the figure.**

The graph contains information that 3M considers proprietary and thus 3M believes it should not be included in the User Manual. However, similar information may be helpful to be included in the User Manual, therefore 3M recommends adding a verbal description of frequency ranges, instead of simplified figure.

Below is the verbal description of frequency ranges 3M proposes to include in the User Manual:

The electronic stethoscope allows the user to select between three different digital frequency filters to better emphasize the specific patient sounds of interest.

1. The Bell Mode amplifies sounds from 20 – 1000Hz and emphasizes lower frequency sounds between 20 – 200 Hz.
2. The Diaphragm Mode amplifies sounds from 20 – 2000Hz and emphasizes the higher frequency sounds between 100 – 500Hz.
3. The Extended Diaphragm Mode amplifies sounds from 50 – 2000Hz similar to the Diaphragm Mode but provides more low frequency response between 50 – 500Hz.

Please refer to Page 9 of 25 of Attachment 6 for the revised User Manual.

4. **The device is powered by one AA battery, which can be alkaline, lithium or NiMH, and the specific battery type has to be selected by the user, as indicated on page 10 of 25 of the User Manual. Please revise the User Manual to inform the user of the risks, if any, of forgetting to select the correct battery type.**

The User Manual states on page 10 of 25 that "...battery type must be specified to ensure a reliable battery life indication". When an incorrect battery type is selected by user, the display of remaining battery life may not accurately indicate the actual remaining life of the battery being used. However, according to our risk assessment, there is a limited or minimal risk of harm to the user or patient, or damage to the stethoscope when an incorrect battery type is selected. As such, 3M would like to keep the User Manual as is.

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651 733 1110

5. **Please address the following issues on the device's heart rate display:**

   a. **From page 12 of 18 in Appendix 6, the heart rate value is updated every 2 seconds after initial sampling (5 sec.) and the value is shown in the LCD for 10 seconds after loss of heart signal. Such a long latching time for the heart rate display seems to be on the boundary of acceptance of common ECG standards, such as Association for the Advancement of Medical Instrumentation (AAMI) EC13:2002 standard, clause 4.2.8.4. Please explain if your device's heart rate meter complies with this clause of EC13.**

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is not a heart rate monitor and therefore is not intended to comply with ECG standards such as AAMI EC13:2002. The Model 3200 heart rate readout algorithm is not based on an electrical signal like an ECG, but is instead based on the same acoustical signal that the care provider is hearing. Once a stable heart rate is detected and displayed on the Model 3200 LCD the 10 second hold period allows for adequate time for the care provider to remove the stethoscope chest piece from the patient and to read the heart rate information. Because of the user correlation between the heart rate read out, how it operates, and what the care provider is actually hearing at the same time, there is no risk of confusing one heart rate from one patient with a heart rate from another based on this 10 second hold time. Littmann Model 3200 is not intended to monitor heart rate. Furthermore, this feature is also available in one of the predicate devices, 3M™ Littmann® Electronic Stethoscope, Model 4100 and has been used safely.

   b. **Page 4 of 5 in Appendix 9 refers to a known defect in which the displayed heart rate may be 30 pct (probably, percent) different from one beat to another. But no wrong heart hates (probably, rates) are displayed in the LCD. Please explain whether the device's algorithm for smoothing (or averaging) heart rates needs improvement.**

In the Model 3200, a robust algorithm is used for computing the average heart rate that minimizes false signals. The algorithm incorporates a rolling five-second average and updates the results on the stethoscope LCD every 2 seconds. The display shows the correct computed values and does not place a limit on the percentage change from one displayed heart rate and the next. If the change in heart rate was greater than 30%, it would display the results as computed, without clipping or limiting.

In an earlier electronic stethoscope (i.e. Model 4100), there was a 30% limit specified from one displayed heart rate to the next. A test protocol was

developed to verify that the 4100 display was limited. This test protocol was applied to the Model 3200 scope, and correctly identified that the there is no imposed limitation of the change allowed from one displayed value to the next (noted as a "failure" to limit).

In summary, the statement in Appendix 9 meant that when the Model 3200 was tested to this test protocol, it did not meet this specification because the Model 3200 did not limit displaying the heart rate even when it was more than 30% different from the previous displayed heart rate, and correctly displayed calculated heart rate.

6. **Please clarify if the present submittal includes the software in the personal computer (PC) for receiving and processing the sound files received via Bluetooth (BT) from the subject stethoscope. If yes, please provide description and proof of safety and effectiveness for the software.**

   No, this 510(k) application only covers 3M™ Littmann® Electronic Stethoscope, Model 3200, and does not include a software that can be used for receiving and processing the sound files on the personal computer (PC) via Bluetooth (BT) from the Model 3200. We provide a secure and proprietary Bluetooth communication interface in the Model 3200 that will permit only validated software from third-party manufacturers to interface a personal computer for receiving and processing the sound signals.

7. **Appendix 1, page 3 of 25, indicates that the device is protected against splashing liquid (chest piece only), under IPX4. Please provide the test report to substantiate this claim.**

   Please refer to Appendix 13, IEC 60601-1 Report 809546-1, Section 11.6.5 "Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS" on Page 87 of 155. The Littmann Model 3200 was tested against splashing liquid (chest piece only) and passed this requirement.

8. **Appendix 1, page 3 of 25, indicates that the device is tested for use with flammable anesthetic mixture with air. Please provide the test report to substantiate this claim.**

   Please refer to Appendix 13, IEC 60601-1 Report 809546-1, Section 11.4 "ME EQUIPMENT and ME SYSTEMS intended for use with flammable anesthetics" on Page 86 of 155. The Littmann Model 3200 has been tested and passed the AP safety level required per IEC 60601-1.

3M Health Care
3M Infection Prevention

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St. Paul, MN 55144-1000
651 733 1110

9. **The subject device is tested for radiated emissions under CISPR 22, which is the electromagnetic compatibility (EMC) standard for information technology equipment, not medical devices. Further, page 13 of 23 in the EMC test report written by Eurofins refers to subclause 9.2 of EN 301 489-1 as the test protocol. Please explain how the device's radiated emissions are compliant with the FDA recognized IEC 60601-1-2 standard, which is compatible with the CISPR 11 standard for medical devices.**

   The scope of the EMC tests conducted was to ensure the device's radiated emissions are in compliance with CISPR 11 (compatible with FDA recognized IEC 60601-1-2) and CISPR 22. Section 1.7 of Eurofins EMC Test Report G0M20810-2051-E-17, Appendix 10 for the 3M Model 3200 Electronic Stethoscope lists both EN 301 489 as well as EN 60601-1-2 EMC test standards. However, this report only contains the testing to EN 301 489, *"Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services"*. Testing to EN 60601-1-2 is documented in a second EMC report, Eurofins EMC Test Report G0M20808-1969-E-17, that was not included in 3M's original premarket notification. This test report, G0M20808-1969-E-17, documents EN 60601-1-2 EMC testing for the 3M Model 3100 Electronic Stethoscope. The Model 3100 and 3200 Electronic Stethoscopes have identical construction, and the only difference is that the Bluetooth feature is enabled in the Model 3200. As the Model 3100 and 3200 are equivalent from an EMC perspective (outside of Bluetooth), the Model 3200 EMC Test Report (Eurofins G0M20810-2051-E-17) builds on top of the previous conducted EMC test report for the Model 3100 (Eurofins G0M20808-1969-E-17). Radiated emissions testing was conducted on the Model 3100 following EN 55011 (formally CISPER 11) as documented on page 10-11, and page 19 of the Eurofin G0M20808-1969-E-17 EMC report. Please refer to Attachment 2 for Eurofin G0M20808-1969-E-17 EMC report.

10. The acceptance criterion in the EMC tests allowed the following device behaviors (see for example pages 6 of 8 and 8 of 8 in the E3000 Plus EMC Design Verification Protocol):

a. change in display graphics;
b. momentary noise in binaural; and
c. reset of the stethoscope if reboot is initialized automatically.

Please justify this criterion since a change in display graphics and automatic reset of the device may damage the device and/or present erroneous information to the operator. Did the test results include such device characteristics?

A change in display graphics, momentary noise in the binaural, and/or a reset of the stethoscope were allowed as possible transient events during EMC susceptibility testing as these features are not related to Essential Performance. Further discussion for each criterion is indicated below.

a. change in display graphics:
Changes (flicker) in the display graphic was allowed as the display is updated by the internal microprocessor every 200ms. In case of a change in the display during testing, the stethoscope will automatically obtain a correct display view after 200ms and therefore, no erroneous information would be given to the operator.

b. momentary noise in binaural; and
c. reset of the stethoscope if reboot is initialized automatically:
Momentary noise in the binaural and a reset of the stethoscope would be obvious to the users and therefore would not lead to erroneous information. During reboot, the stethoscope would beep through the binaural to notify the user.

Furthermore, the User Manual contains a caution statement concerning the risk(s) associated with operating the electronic stethoscope in very strong electromagnetic fields as well as instructions to move away from the radio transmitting antenna. As a part of the EMC test protocol for the Model 3200 electronic stethoscope, functional testing of the test sample was conducted both before and after EMC testing to confirm that there was no permanent damage.

11. **The device under test is sometimes described as the E3000 Plus (on page 1 of 36 in Appendix 7) and sometimes as M3200 (on pages 22 and 29 of 36 in Appendix 7). Then page 14 of 36 displays a hand-written statement of "Only works on E-3200". Please explain how test results from a model (or models) that is not 3200 can be transferred to the Model 3200.**

    E3000 Plus was a project name for 3M™ Littmann® Electronic Stethoscope Model 3100 and 3200. During development, some of the testing was conducted under the project name E3000 Plus. The Model 3100 and 3200 Electronic Stethoscopes have identical construction, and the only difference is that the Bluetooth feature is enabled in the Model 3200. Therefore any testing associated with Bluetooth was conducted on the Model 3200. The Model 3200 was referred to as both the M3200 (an abbreviation of Model 3200) and the E-3200 (an abbreviation of Electronic stethoscope 3200).

12. **Page 5 of 5 in Appendix 8 (Software Validation Report) refers to 4 minor observations. Please provide more details on these observations, and why these observations can be tolerated:**

    The four minor observations noted in this report were generated during software testing and reflect the nuance of how the Model 3200 software functions. These observations have no impact to the products performance and are tolerated. Detail for each observation is provided as follows.

    a. **Live_lock**

    This comment describes how the Model 3200 internal microprocessor and audio processor work with each other. When the Model 3200 is turned on, both the microprocessor and the audio processor start to communicate with each other during the boot-up process. If the audio processor does not successfully start (boot), the microprocessor will be in *Live_lock* mode. In *Live_lock* mode, even if the microprocessor is turned on, the Model 3200 does not operate and the LCD display remains blank. *Live_lock* represents an unexpected error condition, but should it occur the Model 3200 fails in a safe way as the product does not function.

    b. **Service_counter**

    Service counters are internal software-based counters that are accessible only by 3M during service or repair. Specifically, when the Model 3200 is in standby mode, it (internally) counts how many minutes have passed to determine if it should shut down. There is an error in the software that results in this count being off by one count. For example, if the power-down

mode is set to 120 minutes, the *service counter* will count 119 minutes when it shuts down rather than 120 minutes. The information from *service counters* is not seen by the user, and does not affect performance of the Model 3200.

c. Peak_Location

The heart rate monitor uses an auto-correlation function to detect the time between heart beats. Within this algorithm, once the heart beat peak is found, then the number of data samples between heart beats is counted to determine the heart rate interval. The comment made by the software tester reflects an expectation as to where this counting starts and then stop. The algorithm starts counting from 0 (zero), and thus it is proper for the monitor to end one location earlier in order to determine the proper count heart rate. The accuracy of the Model 3200 heart rate algorithm has been verified with bench testing and validated with customer testing.

d. Deviation

As explained in Question 5b response, one of the predicate devices, the Model 4100 electronic stethoscope had a heart rate algorithm that if the detected heart rate changed more than 30%, then that rate would not be used for the overall average heart rate that is displayed. Although this specification was not carried over to the Model 3200 electronic stethoscope heart rate algorithm, the older Model 4100 test protocol was used. As such, the Model 3200 was tested to a specification that does not exist for the product; hence it did not meet the test. The accuracy of the Model 3200 heart rate algorithm has been verified with bench testing and validated with customer testing.

13. **Page 4 of 5 in Appendix 9 (Software Release Description) refers to some known defects. Please provide more details on these defects, and why these defects can be tolerated:**

    a. **Recording is implemented with 14 sec. recording only (not the 29 seconds indicated elsewhere).**

    Model 3200 electronic stethoscopes that were built for verification and process validation were built with 1 MB of internal memory that supports up to 14 seconds of recorded heart sounds. In order to achieve the full 29 seconds of recording time, the Model 3200 electronic stethoscopes would contain 2 MB of memory.

    b. **Service counter for measuring standby time measures one minute less than actual time.**

    As mentioned in Question 12b response, *service counters* are internal software-based counters that are accessible only by 3M during service or repair. Specifically, when the Model 3200 is in standby mode, it (internally) counts how many minutes have passed to determine if it should shut down. There is an error in the software that results in this count being off by one count. For example, if the power-down mode is set to 120 minutes, the *service counter* will count 119 minutes when it shuts down rather than 120 minutes. The information from *service counters* is not seen by the user, and does not affect performance of the Model 3200.

14. **Although section 11.2 states, "The Model 3200 can only communicate with one PC at a time.", page 15 of 25 in the User Manual indicates that the stethoscope can pair with up to 8 devices (but not with another stethoscope) at a time. Please address the following:**

    a. **You seem to distinguish between "pairing" and "connecting or communicating" to a BT device. Please explain the differences between these two terms, especially in view of the above statement. Labeling should also be revised to highlight the differences between "pairing" and "connecting or communicating".**

    Bluetooth "pairing" is an exchange of PIN code (or passkey) between a host (ex: BT-enabled PC) and a guest device (ex: stethoscope). "Pairing" must be initiated from both the PC and a stethoscope in order to complete the exchange of information. When the PC and Model 3200 are initiating "pairing", the Model 3200 would display "PAIR" on its LCD screen. The Model 3200 has the capability of remembering up to eight "paired or

trusted" PCs. "Pairing" between the PC and Model 3200 must be completed before they can "communicate" with each other.

"Connection or communication" is a synchronization of the BT-enabled PC and Model 3200 that have already been paired. Both the PC and Model 3200 must be set to a connection mode (LCD display on Model 3200 would say "CONNECT"). The PC must initiate connection with Model 3200 which is actively trying to accept connection with any of its trusted pairing partner devices. Either device may disconnect and break the Bluetooth wireless connection.

The Model 3200 does not "communicate or connect" to more than one BT-enabled PC simultaneously. As described above, the Model 3200 has the capability of remembering up to eight "paired" PC targets but it can only connect to one BT-enabled PC at a time. In order to connect to a different secured computer, the existing connection must be terminated first.

b. **If indeed the subject device can communicate with more than one BT-enabled PCs simultaneously (or in rapid succession by connecting to various PCs sequentially), please explain how the subject device can distinguish one PC from another, and avoid mixing up the sound files of different patients.**

The Model 3200 does not communicate (or "connect") to more than one BT-enabled PC simultaneously. In order to connect to a different secured computer, the existing connection must be terminated.

Each PC has a unique passkey (PIN code) that must be paired with Model 3200 before they can start communication. Once paired to the stethoscope, the PC passkey is placed on the stethoscope's trusted list where Bluetooth connection may be established.

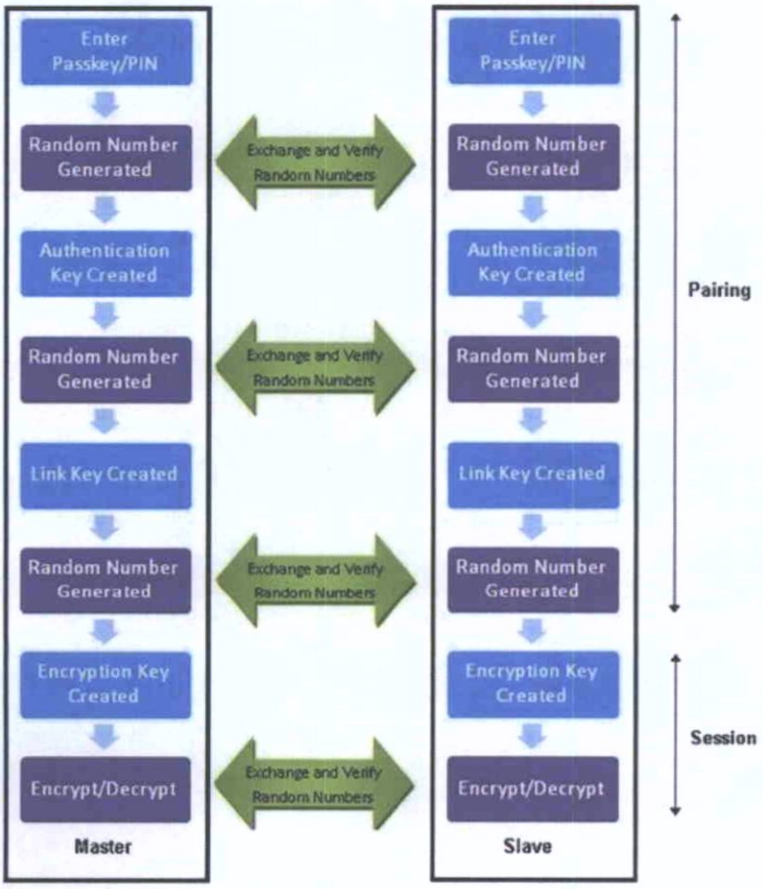
c. **Security is always a major concern for radiofrequency (RF) wireless communications since no line of sight is needed. Here, the subject device has the added capability of pairing with up to 8 devices at the same time. Hence, please explain how you have ensured the security of the subject device in its transmission and reception of sound files to and from up to 8 BT-enabled devices.**

The Bluetooth core specifications (part of the Bluetooth specifications themselves) use a 128 bit data encryption algorithm, which is extremely secure. Once Bluetooth devices pair with one another, they too are

effectively secure. Bluetooth devices will not communicate with each other until they have successfully paired.

Bluetooth pairing occurs when two Bluetooth devices agree to communicate with each other and establish a connection. In order to pair two Bluetooth wireless devices, a passkey (PIN code) has to be exchanged between the two devices. A passkey is a code shared by both Bluetooth devices, which proves that both users have agreed to pair with each other. During pairing, the two devices exchange the generated keys and not the actual passkey. This reduces the risk of someone getting the passkey code.

The Pairing Process between a Master (PC) and a device Slave (stethoscope) is shown below:



The pairing needs to be done only once. If the pairs go out of range or lose connection, they create a new session with a new Encryption key, when they come back together. This enhances security without having to redo the pairing

process. Authentication is performed by using Link keys as shown in a figure above.

d. **You have provided some test data to support the pairing of at least 3 BT-enabled devices. Please clarify if you used 8 BT-enabled PCs to pair with the subject device in the test. If not, please provide the test report using 8 BT-enabled PCs. We believe that you can claim only the number of BT-enabled devices that you have tested safely and securely.**

Please refer to Attachment 7 and 8 for revised BT pairing test report. The data now supports the pairing with up to 8 BT-enabled PCs.

e. **Please provide further test report(s) to verify that the subject device can co-exist wirelessly with other active RF emitters (including paired and unpaired BT emitters, and other RF emitters using different communications standards) in its vicinity.**

3M will respond to this question later.

15. **From page 14 of 25 in the User Manual, the BT mode can be manually selected, but also automatically selected whenever the stethoscope is in an active mode. Please explain why this auto mode for BT is safe since the risks for unauthorized eavesdropping and electromagnetic interference are higher compared to the BT mode into which the user has to intentionally enter.**

For additional technical details regarding secure communication between Model 3200 and BT-enabled PC, please refer to Question 14 responses.

The automated mode was intended for users that would use the BT-enabled feature of the scope almost exclusively. The "auto-on" feature allows the scope to be "discovered" by BT-enabled PC that has already been paired with Model 3200. The BT-enabled stethoscope can only connect to "paired or trusted" BT-enabled PCs that have completed the highly secured pairing process with each other.

If there is not a "paired or trusted" BT-enable PC that is trying to connect to the Model 3200, then no BT data would be transmitted. In this case, there is no transmission of patient data.
Furthermore, eavesdropping devices would not be able to decipher 128-bit encryption that is set up during the secure pairing process.

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16. **Page 16 of 25 of the User Manual states, "When connected by a Bluetooth link, external Bluetooth-enabled devices can take control of the display and keypad of the Model 3200 stethoscope." This external control via BT configuration is troublesome since it goes beyond pure transfer of data (sound files). Please explain why this external control configuration should not be deleted.**

    3M will respond to this question later.

17. **On page 16 of 25 in the User Manual, you have asked the user to "Consult application software for details on initiating real-time transfer, the process may vary by computer platform utilized." Please revise the User Manual to include an example of the steps needed to transmit and receive sound files from the subject device to a BT-enabled device using a legally marketed software piece.**

    3M will revise the User Manual per suggested. Please see Attachment 6, Page 15 of 25 and 16 of 25 for the revised User Manual. The revision includes an example of the steps needed to transmit and receive sound files from the Model 3200 to a BT-enabled device using legally marketed software.

18. **Section 12.0 indicates that the diaphragm (transducer cover) is silicone with polyacrylate coating, which is not found in the two predicates. Hence, please provide the 3 biocompatibility tests in accordance with ISO 10993-1-- irritation, sensitization and cytotoxicity--, especially since Appendix 15 refers to the ISO 10993-1 standard.**

    After further analysis, 3M found out from the contract manufacturer that the diaphragm for Model 3200 indeed uses the exactly same material as Model 3000 and Model 4100. It is made out of silicone with polyurethane coating, which is identical to that of Model 3000 and Model 4100. The contract manufacturer purchases the material from the same supplier. However the internal documentation as well as the information listed in 510(k) was misleading thus 3M has updated the biocompatibility assessment to clarify this confusion as follows. The revision is shown in bold fonts.

    Part # 7 (Page 5 of 9, Table 1)
    Component Name - Diaphragm
    Material - **polyurethane-coated silicone rubber**

    Component Description (Page 6 of 9)

#7 – Diaphragm

The diaphragm is made of silicone rubber (ShinEtsu KE-951-U, Shin-Etsu Chemical Co., Ltd.). **It is coated with a polyurethane coating (Glossy PU 0043PU, Sheng Tsiung Printing Co. Ltd.). This polyurethane coating is made by reacting a hydroxyl-bearing polyacrylate (Desmophen A575X, Bayer Material Science) with a polyisocyanate to create a highly cross-linked polymer that is very inert.** The 3M Littmann logo on the diaphragm is printed with a silicone encapsulant/adhesive (TSE3221, GE Toshiba Silicones Co.). No adverse health effects are expected from the use of these materials.

19. **On page 2 of 18 in Appendix 6, you indicate the software version as 2.00 dated 04 dec 2008 and ready for signing. However, on page 2 of 5 in Appendix 9, version 2.00 was dated 15-09-2008. And version 8.00 dated 17-12-2008 will be SW release v. 01.00.00. Please clarify the version number issue.**

    The version numbers listed on the pages mentioned in these appendices are versions of the documentations and not software versions.
    Appendix 6, M3100-M3200 SRS SW Requirement Specification (File name: MBG0751C – SRS SW Requirement Specification for E3000 Plus. docx) was ready to be signed off on December 4, 2008 as Version 2.0.
    Appendix 9, E3000 Plus SRD SW Release Description (File name: MBG0837A – SW Release Description E3000Plus.doc), indicates that Version 8.0 of this report would release software as Version 1.00 (v.01.00.00).

20. **In section 16 you have indicated a Minor level of concern for the software in the device since you think that the stethoscope does not provide diagnostic information. However, we believe that the indication of heart rate is diagnostic and that the sound amplified by the device is also important-- erroneously amplified sounds can lead to misdiagnosis. Hence, please revise the software documentation to that of a Moderate level of concern. We note that you have already provided a lot of the required software documentation for a Moderate level of concern. Please add Architecture Design Chart, Design Specifications, Software Development Environment Description and Unresolved Anomalies.**

    3M reviewed the ODE/OIVD Document "Guidance of the Content of Pre-market Submissions for Software Contained in Medical Devices" issued May 11, 2005. It says that "If answers to all of the questions in Table 1 and 2 above are No, the Level of Concern in Minor". 3M have reviewed all the questions and has answered "No" to all of the questions raised in this guidance. The

stethoscope is but one of the tools used by a trained health professional as one part of a physical assessment. Because a stethoscope is never used by itself when the user makes diagnosis, that even if sound was amplified erroneously, it is highly unlikely to lead to misdiagnosis. The health professional relies on a complete set of assessment tools to arrive at a diagnosis.

Moreover, 3M reviewed the same guidance and concluded that the software embedded in the predicate devices 3M™ Littmann® Electronic Stethoscope Model 3000 and 3M™ Littmann® Electronic Stethoscope Model 4100 both have minor level of concern. The software used in the Model 3200 is substantially equivalent to the software of Model 3000 and 4100. Therefore 3M believes the software level of concern for Model 3200 is considered minor.

21. **For the risk assessment report provided in Appendix 5, the font size of the table starting from page 4 of 13 to page 11 of 13, inclusive, is too small to read. Please provide a larger printout with larger font size.**

    Please find enclosed Attachment 11 for the requested documents in larger font.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601, Medical Electrical Equipment

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 5-4		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Radio-Frequency Wireless Technology in Medical Devices, January 3, 2007

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601, Medical Electrical Equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
IEC 60601-1	Part 1: General requirement for basic safety and essential performance	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
IEC 60601-1-2	Part 2: Electromagnetic Compatibility - Requirements and tests	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
IEC 60601-1-6	Part 1-6: Usability	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993 Biological evaluation of medical devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 2-98		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: FDA Memorandum G95-1 was also considered.

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993 Biological evaluation of medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ISO 10993-1: 2003	Part 1: Evaluation and Testing	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971:2007 Medical Devices - Application of Risk Management to Medical Devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 5-40		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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4.0 Indications for Use Statement

Indications for Use Statement

510(k) Number (if known):_____

Device Name: 3M™ Littmann® Electronic Stethoscope Model 3200

Indications for Use:

The 3M™ Littmann® Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

Prescription Use____ OR Over-The-Counter-Use _X_
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____
Concurrence of CDRH, Office of Device Evaluation (ODE)

(b)(4) [redacted]

E3000 Plus Frequency response and gain
Design verification report

Version 1.10

File name: BUA0839e Design Verification Report - Frequency response and gain.docx

Author

12/11-08

Date, BUA-60

Approved by

14/11-08

Date, TRH-70

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(b)(4) [redacted]

(b)(4) [redacted]

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1 Purpose

The purpose is to document and conclude on a specific Design verification performed with references to Requirements, Plan, and Design Verification Protocol.

2 Scope

The scope of this document is to report the results obtained by the Design Verification of the electrical signal to noise ratio (SNR) of the E3000 Plus stethoscope.

3 References

[1] AMI0821h Design Verification Protocol – Frequency response and gain
[2] BUA0415a Design Verification Report – E3000 Frequency response and gain
[3] BUA0426a Comparison of frequency response on E3000 to E2000
[4] BUA9950a

4 Measurements and results

Measurements have been performed on the following E3000 Plus devices: SN 015, SN 037 and SN 045.

Measurements of stethoscope electrical signal to noise ratio (SNR) are carried out using the air-coupler input sound source (input directly from the HP 33120A arbitrary generator adjusted to 250 Hz sine at variable amplitude setting) and monitoring of stethoscope output using ear-simulators in B&K 4128C (head and torso simulator). Equipment used for the test is the following:

- B&K 4231, calibrator (SN: 2450780) (Instrument no. 256973)
- B&K 2690, measuring amplifier (SN: 2069254, B&O FAA: 26602)
- B&K 4128C, head and torso simulator, HATS (SN: 2217849, B&O FAA: 30796)
- HP33120A, arbitrary waveform generator (B&O FAA: 16595)
- NI PCI-4451, data acquisition PC board (B&O FAA: 26950)

5 Introduction

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(b)(4) [redacted]

6 Fitting of stethoscope filters and gain

The following described the process of fitting filters for the E3000 Plus, the filter fitting shall be made using fully functional devices to capture the most realistic electro-acoustic response .

6.1 E3000 Plus frequency response targets

The E3000 Plus shall provide three distinct filter modes, the Bell and Diaphragm filters equivalent to those of the E3000 stethoscope and then an extended Diaphragm filter including somewhat more low-frequency signal compared to standard Diaphragm. The following figure and table shows target frequency response functions for BELL and DIAP filter modes (from [2] but raised approximately 3 dB to meet expectations for higher gain in the E3000 Plus) and then the empirically defined Extended Diaphragm filter.

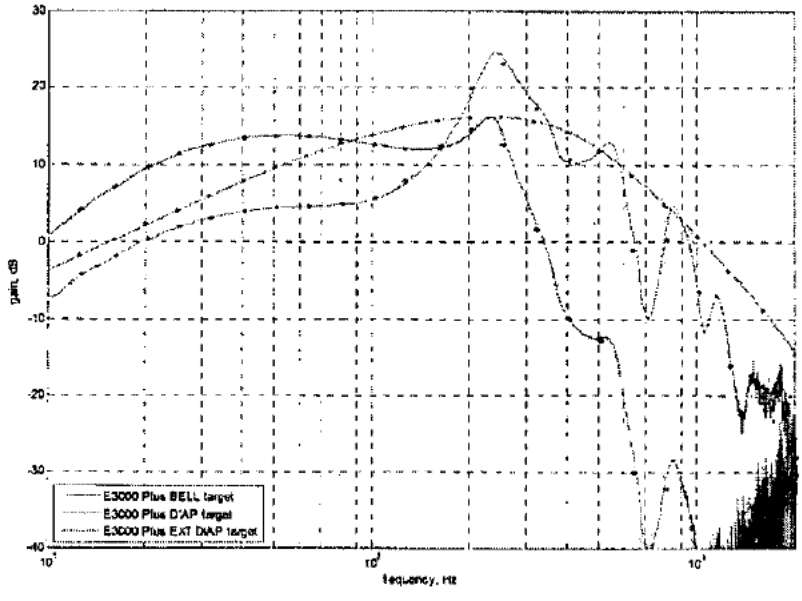

Figure 1 E3000 Plus target frequency responses for Bell, Diaphragm and Extended Diaphragm filter mode.

1/3-octave frequency, Hz	Bell target, dB	Diap target, dB	Ext Diap target, dB
20	9,7	0,5	2,3
25	11,4	1,9	4,1
31,5	12,7	3,1	6,0
40	13,5	4,0	7,9
50	13,8	4,4	9,6
63	13,7	4,6	11,2
80	13,2	4,9	12,8

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100	12,7	5,7	14,0
125	12,1	7,9	15,0
160	12,3	12,5	15,8
200	14,6	19,7	16,2
250	12,7	23,0	16,3
315	1,7	17,4	15,8
400	-9,8	10,7	14,3
500	-12,9	11,9	12,0
630	-30,2	-1,1	8,7
800	-32,3	0,4	4,9
1000	-42,0	-6,4	0,8

Table 1 Target frequency responses in 1/3-octave bands between 20-1000 Hz for BELL, DIAP and EXT DIAP filters

Apart from following the overall shape of the Diaphragm filter the E3000 Plus shall, like the E300 does, provide an elevated high-frequency portion equivalent to that of the E4000/E4100 Extended range filter (se [2] and [3] for details).

6.2 Filter fitting

The following figure 2 shows the native electro-acoustic response from 24 samples MK2 devices containing SW without DSP filters. Based on this response and the target frequency responses from above the fitting of digital filters can be carried out.

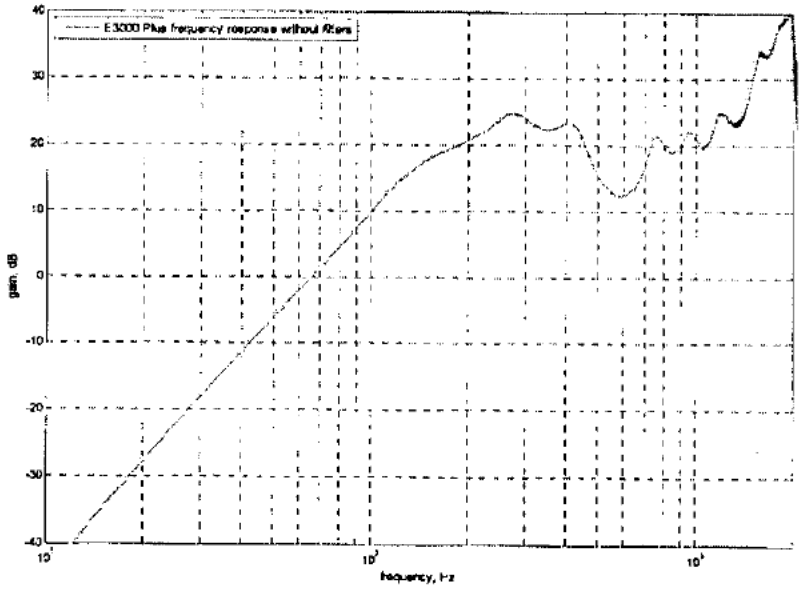

Figure 2 E3000 Plus frequency response without filters running in the DSP (effect of analogue circuitry and A/D-D/A converters).

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Through dividing the above target frequency responses with the response without any active filters the filter targets are established. From that point the design of the filters is based on a numerical search in MatLab where the input conditions are that the filters should be of the 9th order. The following figures show the filter fit to the respective filters. Each graph shows the filter target, the filter fit, the difference (error) and then the difference in 1/3-octave bands. The red '*' indicates points where the response falls outside the +/- 2 dB range.

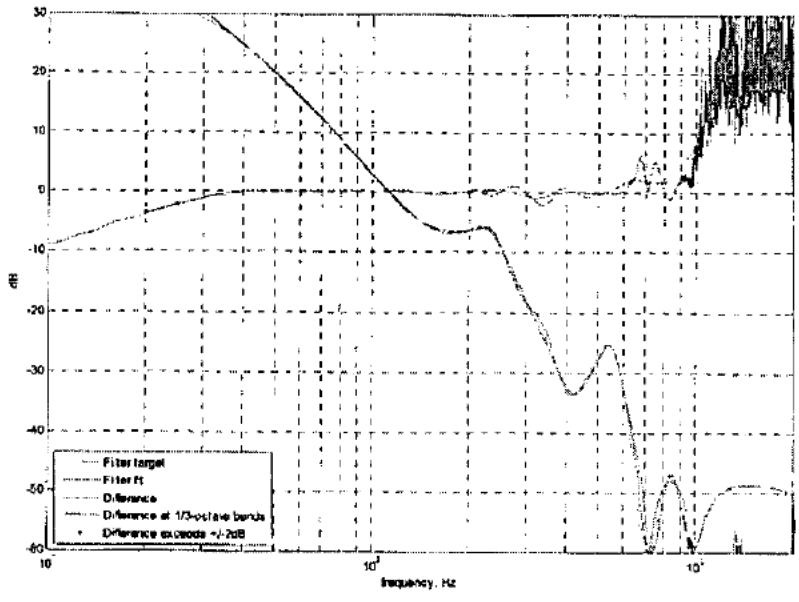

Figure 3 Final filter fit for the BELL mode filter.

Each of the red '*' in the above filter fitting results figures represents 1/3-octave bands where the fit is outside a +/- 2dB range around 0 dB. The maximum-minimum error range in across 1/3-octave frequency bands are however within the expected +/-2 dB and indicated in this table:

Filter mode	Nominal range	Minimum	Maximum	Frequency range	Comment
BELL	20-200 Hz	-3,5 dB	0,3 dB	20-500 Hz	Inaudible errors above 500 Hz
DIAP	50-500 Hz	-2,6 dB	0,7 dB	20-800 Hz	7,1 dB @ 1000 Hz expected acc. [2]
EXT DIAP	20-1000 Hz	-3,4 dB	0,6 dB	20-1000 Hz	-

Table 1 Resulting filter fitting errors in 1/3-octave bands

The Bell filter does not meet the desired precision at individual frequencies above 500 Hz, since however the gain level here is approximately 50 dB below that at 50 Hz these errors are inaudible to any user. The Diaphragm filter delivers precise fit across the entire frequency range and at 1000 Hz it furthermore provides an elevated response which is entirely in line with the design specification from E3000 which provides a 7,9 dB lift at 1000 Hz according to [2] and [3]. The her observed 7,1 dB error is within 2 dB of the 7,9 dB from E3000 DIAP filter response.

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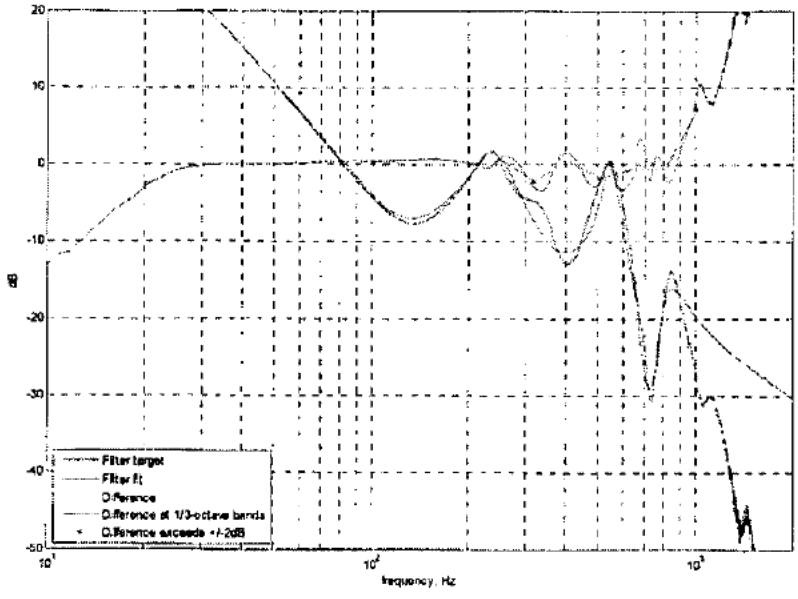

Figure 4 Final filter fit for the DIAP mode filter.

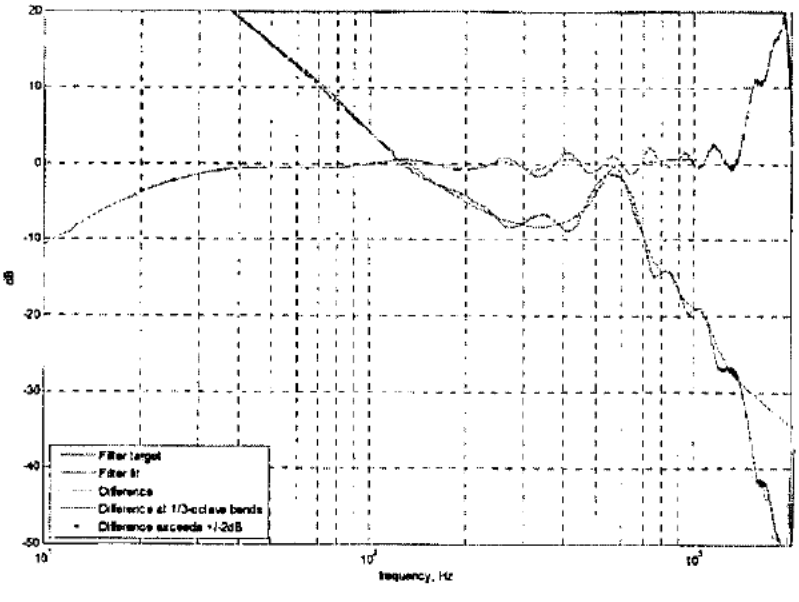

Figure 5 Final filter fit for the EXT DIAP mode filter.

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6.3 DSP filter coefficients

In order to facilitate practical DSP implementation of the above fitted responses, thereby ensuring that the filter coefficients show a numerical maximum of 2, the gain in each filter has been reduced by a factor 4 and instead replaced by manually inserting a double left-shift (2LS) just after the last filter section which thereby re-establishes original filter gain (or alternative ways to add 4 times amplification separate from the filter coefficients). The following table shows the resulting filter coefficients for each of the three filters.

Bi-Quad sections		b0	b1	b2	a0	a1	a2
BELL	Section 1	0,656367129	-0,970727876	0,698496967	1	-1,37781876	0,793981133
	2	0,183473072	-0,314948469	0,187933306	1	-1,7703828	0,941923619
	3	0,378667195	-0,689371903	0,348685221	1	-1,916728225	0,947091387
	4	0,123460016	-0,233890952	0,112356226	1	-1,95853199	0,959263617
	5	0,131496457	0,384334861	0	1	-0,98633149	0
DIAP	Section 1	0,153516707	-0,266771027	0,126320011	1	-1,912996894	0,94717849
	2	0,633804832	-1,629249179	1,338744876	1	-1,519321341	0,885785588
	3	0,518778323	-0,863194932	0,504944237	1	-1,789709501	0,965719152
	4	0,242114221	0,17554335	0	1	-0,609018831	0
	5	0,762275743	-1,468950903	0,713800508	1	-1,982335709	0,982680543
EXT DIAP	Section 1	0,81308179	-1,265871432	0,765108924	1	-1,562081821	0,951480386
	2	0,091397462	-0,105901207	0,072001181	1	-1,733429211	0,920489957
	3	1,043908601	-1,899627898	0,863907401	1	-1,232389085	0,850739265
	4	1,572911136	-1,838548395	0,591989778	1	-1,937369005	0,938503261
	5	0,091870803	0,123887868	0	1	-0,989999616	0

Table 2 Filter coefficients for BELL, DIAP and EXT DIAP filter modes. Gain in each filter reduced 4 times which then is implemented separately in the DSP signal path.

a)	ADC	-3.5 dB (setting#14)
b)	8 Left Shift	Move from 16 bits precision to 24 bits
c)	Input gain correction	Based on individual calibration
d)	Bi-quad #1	Filter coefficients contain 4 times attenuation
e)	Bi-quad #2	"
f)	Bi-quad #3	"
g)	Bi-quad #4	"
h)	Volume control	0 dB maximum throughput
i)	3 Left shift	Compensate for lack of filter gain (+ 6dB more)
j)	Soft-clipper	Maximum output amplitude 75 % MSB
k)	8 RS	Move from 24 bits precision to 16 bits
l)	Output gain correction	Based on individual calibration
m)	DAC	0 dB (setting #15)

Table 3 Stages in the implemented signal path

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To verify the successful implementation in SW the following figure shows the filters as implemented on E3000 Plus SN 045. The figure shows the measured frequency response on air-coupler sound source [4] for all three filters in volume level 9.

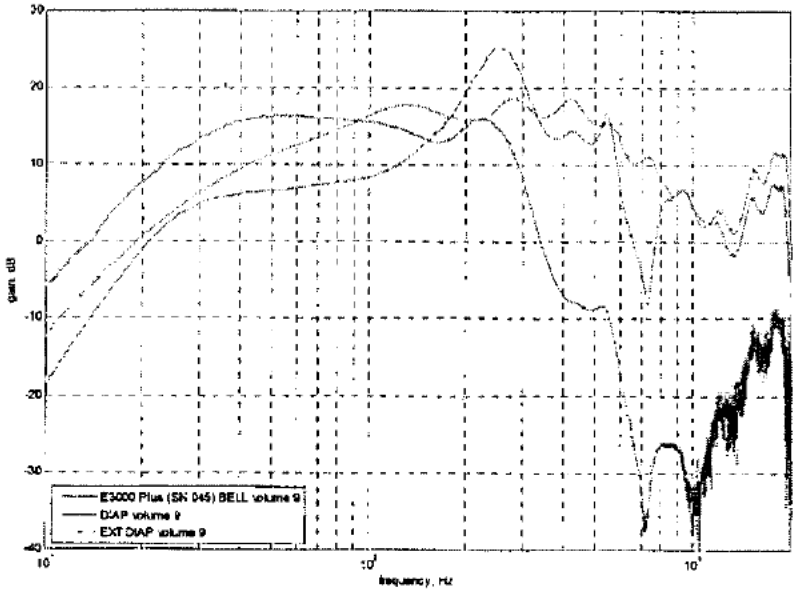

Figure 6 *Air-coupler measurements of E3000 Plus frequency response for BELL (blue), DIAP (green) and EXT DIAP (red) filters in volume level 9 (upper graph) and volume level 4 (middle graph). Furthermore the differences between the two volume setting's measurements (lower graph) are shown.*

7 Verification of overall gain level

After having fitted and implemented the individual filters the following demonstrates the loudness balancing between the Littmann Cardiology III Bell and the E3000 Plus operating in Bell filter mode at volume level 1. This assessment is carried out in accordance with the protocol specified in [1].

From the measured, A-weighted sound pressure levels at the Head and torso simulator's ear, the RMS peak amplitudes are identified through the steps of calculating the RMS signal (1 Hz LP for averaging) followed by a peak identification. The following figures shows the signal used to generate an artificial heart sound played back using the Thorax simulator (repeated at least 10 cycles) and then examples of the identified peak amplitude levels for the Littmann Cardiology III and the E3000 Plus respectively.

(b)(4) [redacted]

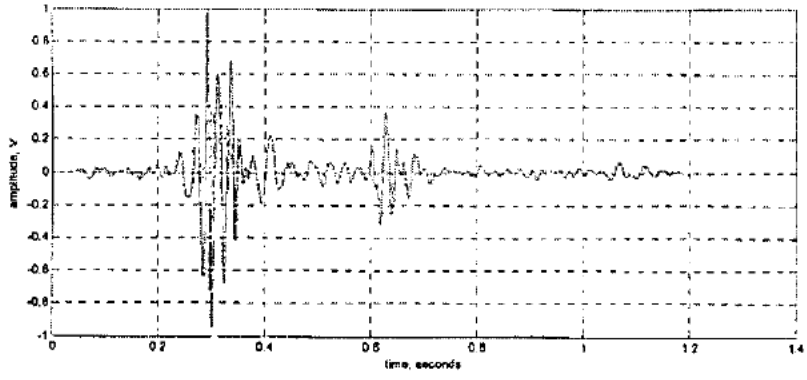

Figure 7 *Input signal when performing the balancing test between E3000 Plus Bell (volume 1) filter and the Littmann Cardiology III Bell.*

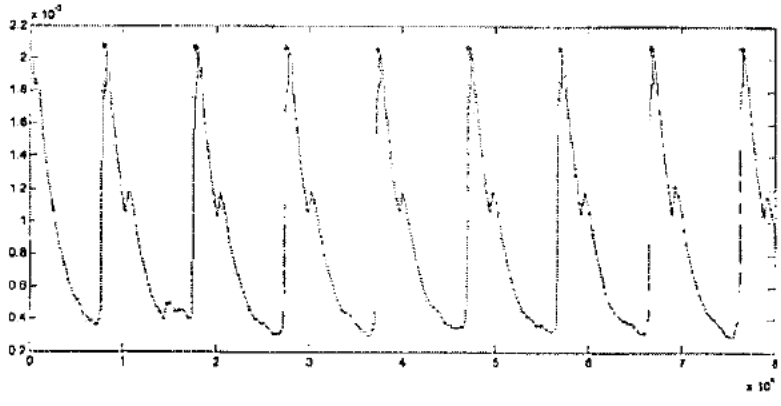

Figure 8 *Example on identification of peak levels with Littmann Cardiology III Bell*

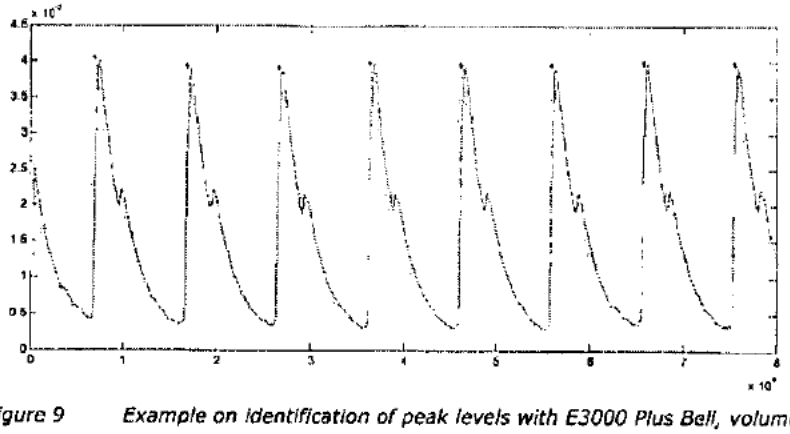

Figure 9 *Example on identification of peak levels with E3000 Plus Bell, volume 1*

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(b)(4) [redacted]

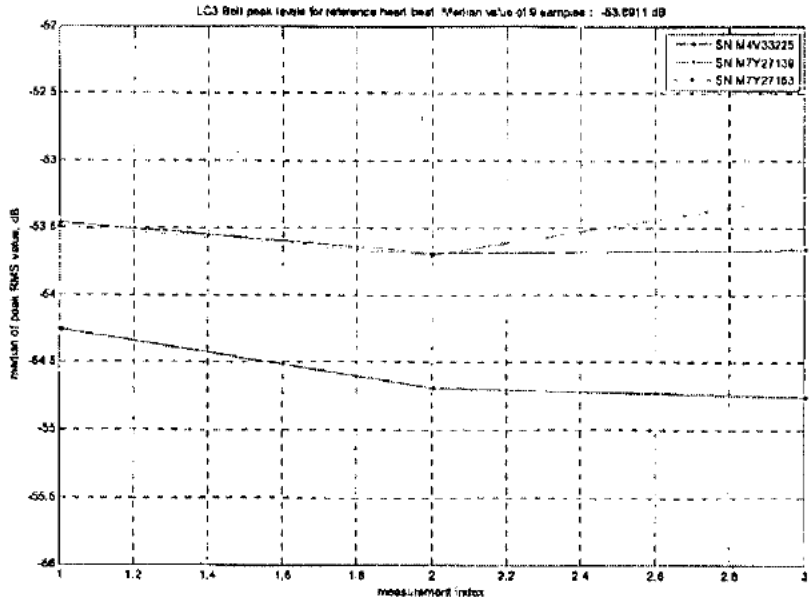

Figure 10 *Sensitivity measurements obtained from three samples of Littmann Cardiology III Bell.*

The recorded median peak levels for the three samples Littmann Cardiology III Bell are displayed in the above figure 10 and the resulting reference sensitivity RMS dB level for this stethoscope type is defined as the median across the 9 data points, thereby establishing the reference peak RMS dB level at -53.6 dB.

In the same setup the 31 samples E3000 Plus MK2 devices produces the median peak RMS dB levels as presented in below figure 11, ranging from approximately -53 dB and up to -46 dB. Upon calibration of these 31 stethoscopes their overall gain level shall be brought to level with the reference level (-53.6 dB) by simple correction of each individual stethoscope's overall gain (employing corrections ranging from -0.6 dB to -9.6 dB for these 31 devices).

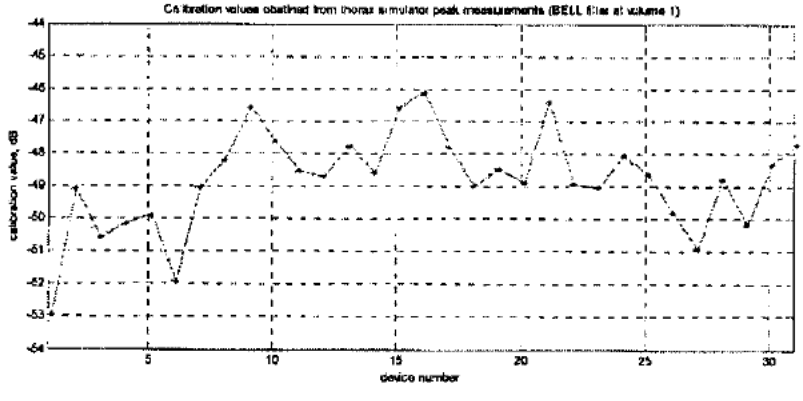

Figure 11 *Sensitivity measurements obtained from 31 samples of E3000 Plus operated in Bell filter mode and volume level 1 (A-weighted recordings).*

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(b)(4) [redacted]

From the above data there appears to exist some uncertainty on measuring the gain level whereby e.g. the nine Littmann Cardiology data points, ideally representing equal mechanical systems, vary more than 1.5 dB (especially one device separates from the other two). From experience it is well known that measurements on thorax simulator devices (soft contact surfaces through elastic materials) are highly sensitive to positioning and measuring errors can easily be in the order of +/- 2 dB or more when including repositioning (not only repetition using same positioning where the error is significantly less). This complicates the practical correction to be performed in running production as the requirement is an individual correction to within +/- 1 dB which is only achievable using air-coupler measurement of stethoscope frequency response. In consequence the knowledge from the above gain comparison exercise needs to be transferred to the air-coupler measurement setup and in order to be introduced to the production line.

7.1 Practical stethoscope calibration in running production

The following will demonstrate a way to implement the production calibration based on air-coupler frequency response measurements instead of the thorax simulator setup employed above. The idea is to base the calibration on the air-coupler assessment of stethoscope frequency response which routinely is performed during outgoing acoustical inspection of each individual device and use this to control the implemented correction of each specific E3000 Plus device.

To prove the principle all 31 E3000 Plus devices from the gain level comparison testing above have been subjected to frequency response testing using air-coupler in order to specify the transformation from gain level value to a best equipped subset of the air-coupler frequency response characteristic. More specific, the gain level value shall be compared to the air-coupler amplitude average over a certain frequency range (or for a set of individual frequencies) in search for the best possible linear relationship between the two data sets.

After setting up the comparison the comparison in made with various frequency ranges and it is concluded that the best linear relationship is achieved using a narrow range around 50-60 Hz. The following figure 12 shows the air-coupler frequency response measurement in average over the frequency range 55-57 Hz for the 31 MK2 E3000 Plus devices (these measurements are based on linear frequency weighting in oppose to the A-weighting employed in the above peak RMS assessment using thorax simulator).

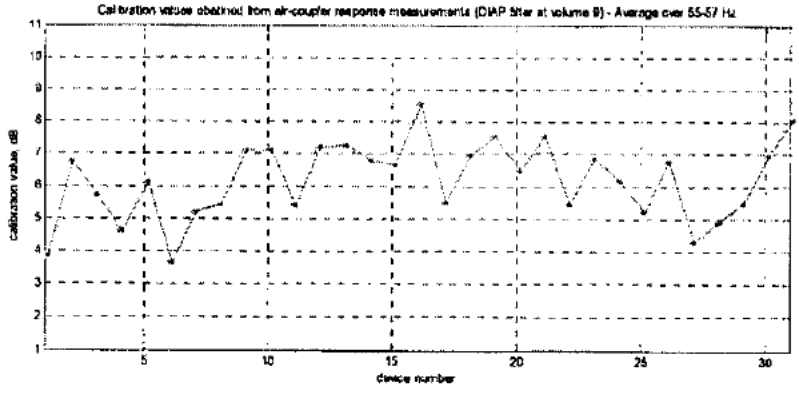

Figure 12 Air-coupler frequency response measurement in average over the frequency range 55-57 Hz for the 31 MK2 E3000 Plus devices.

To asses the viability of basing device correction on this information the following figure 13 shows the difference between these numbers and those from above figure 11 while correcting these by subtracting the reference peak value of -53.6 dB: $Diff = Lair - (Lpeak - Lref)$

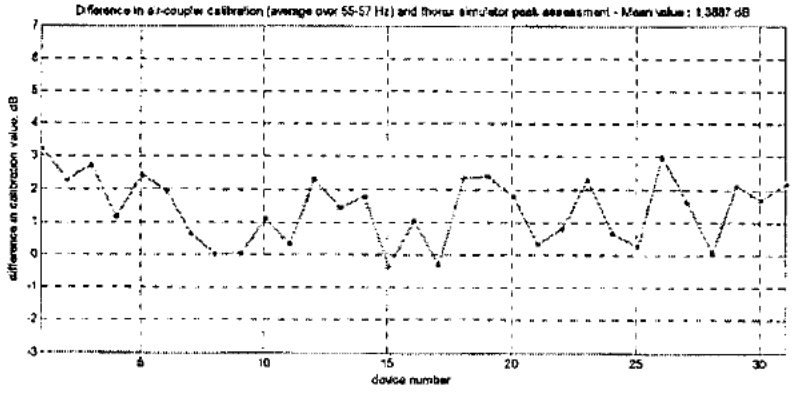

Figure 13 *Difference between the air-coupler frequency response based correction values from figure 12 and the correction factors from figure 11 subtracted by the reference value -53.6 dB.*

The result shown above shows a good agreement between the two approaches when using the narrow frequency range 55-57 Hz from the air-coupler measurement. It is noted that the difference curve is offset by 1.39 dB why the practical calibration of the E3000 Plus device is now proposed being carried out based directly on the measured Diaphragm frequency response in volume setting 9 taken (in dB) in average over 55-57 Hz and following subtracting 1.39 dB. The 1.39 dB value is specific for the laboratory air-coupler measuring setup and need to be re-assessed when transporting this formula from the laboratory setup to the in-line acoustical test system.

The specification basis for the E3000 Plus has suggested using average sensitivity in the 50 to 500 Hz range however as demonstrated in the following figure 14 the accuracy of linear relationship drops dramatically compared to the more 55-57 Hz frequency range and resulting calibration (including measuring uncertainties etc.) is closer to +/- 5 dB compared to the +/- 1.8 dB for the 55-57 Hz frequency range.

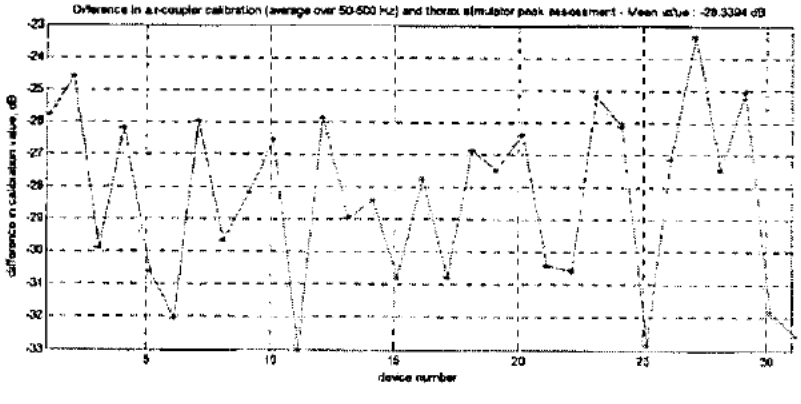

Figure 14 *Difference between the air-coupler frequency response based correction values obtained using the frequency range 50-500 Hz and the correction factors from figure 11 subtracted by the reference value -53.6 dB.*

These tolerances include measuring uncertainties from both measurements supporting the reported values and hence the resulting +/- 1.8 dB uncertainty for the narrow frequency band comparison should not be considered alarmingly high as the thorax simulator measurement in itself may hold uncertainties of this size whereby the error is most likely to originate from these measurements alone.

The practical implementation of gain correction in to the E3000 Plus production devices from the outgoing air-coupler inspection measurement (combined effort of input- and output correction) is a trivial matter and shall not be presented here. This practical control ensuring that a stethoscope delivers the correct gain is to have +/- 1 dB acceptance limits around the target amplification at the reference frequencies 55-57 Hz.

8 Verification of frequency response

Since there is a deterministic relationship between the frequency responses of Bell, Diaphragm and Extended diaphragm filter modes due to the implementation in DSP SW (with the filter coefficients presented above) the focus hereafter will be only on the Diaphragm mode filter response and the conclusions drawn from this mode will automatically apply to the two other filter modes also.

From the 31 MK2 samples the Diaphragm frequency response is measured and the overall level is adjusted in accordance with the guidelines from above. The average frequency response for the group is plotted in the figure below and the associated 1/3-octave frequency band levels are listed in the following table together with the target levels and the calculated difference.

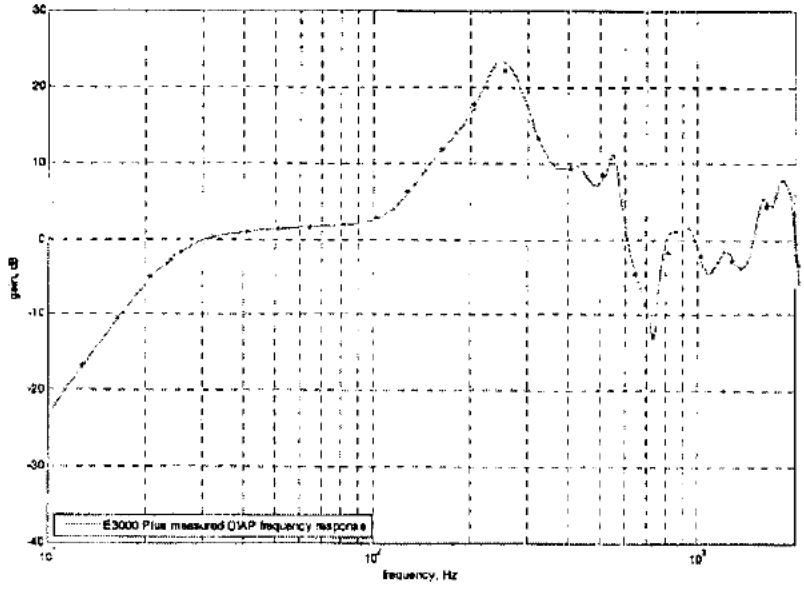

Figure 15 Measured average DIAP frequency response in 1/3-octave bands for E3000 Plus.

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(b)(4) [redacted]

1/3-octave frequency, Hz	Target DIAP response	Measured DIAP response	Difference, dB
20	0,5	-5,1	-5,6*
25	1,9	-1,6	-3,5
31,5	3,1	0,2	-2,9
40	4	1	-3
50	4,4	1,4	-3
63	4,6	1,6	-3
80	4,9	1,9	-3
100	5,7	2,9	-2,8
125	7,9	6,3	-1,6
160	12,5	11,9	-0,6
200	19,7	17,8	-1,9
250	23	22,1	-0,9
315	17,4	13,4	-4
400	10,7	9,3	-1,4
500	11,9	8,6	-3,3
630	-1,1	-4,6	-3,5
800	0,4	-1,8	-2,2
1000	-6,4	-2,1	4,3

Table 4 Comparison between target and average measured DIAP response.

From inspection of the above difference between target and measured Diaphragm filter response in 1/3-octave it is concluded that the Diaphragm response complies with the target curve shape and therefore provides the intended frequency response in overall agreement with the Diaphragm filter response. For all 1/3-octave frequencies between 31.5 Hz and 1000 Hz the observed difference is within a 2.9 dB range (-3.5 dB to -0.6 dB) similar to what was observed after the filter fitting above.

At the 20 Hz band the observed difference is outside the +/- 2 dB range by -1 dB, since however this error is easily contributed to measuring errors and uncertainties, and further that such difference of 1 dB is inaudible to any user, this inconsistency in reported data will not disqualify this verification of E3000 Plus overall frequency response.

9 Verification of volume control function

Verification of the volume control function and step size is based on measurements on a single device as it is an integrated element of the implemented DSP SW ensuring that it will work equally on all devices equipped with this SW release.

The following shows measurements on E3000 Plus SN 045 in Diaphragm filter mode at volume levels 1 to 9. The lower plot shows the difference in relation to response at volume level 9 and the red circles shows expected 3.5 dB intervals from 0 dB down to -28 dB.

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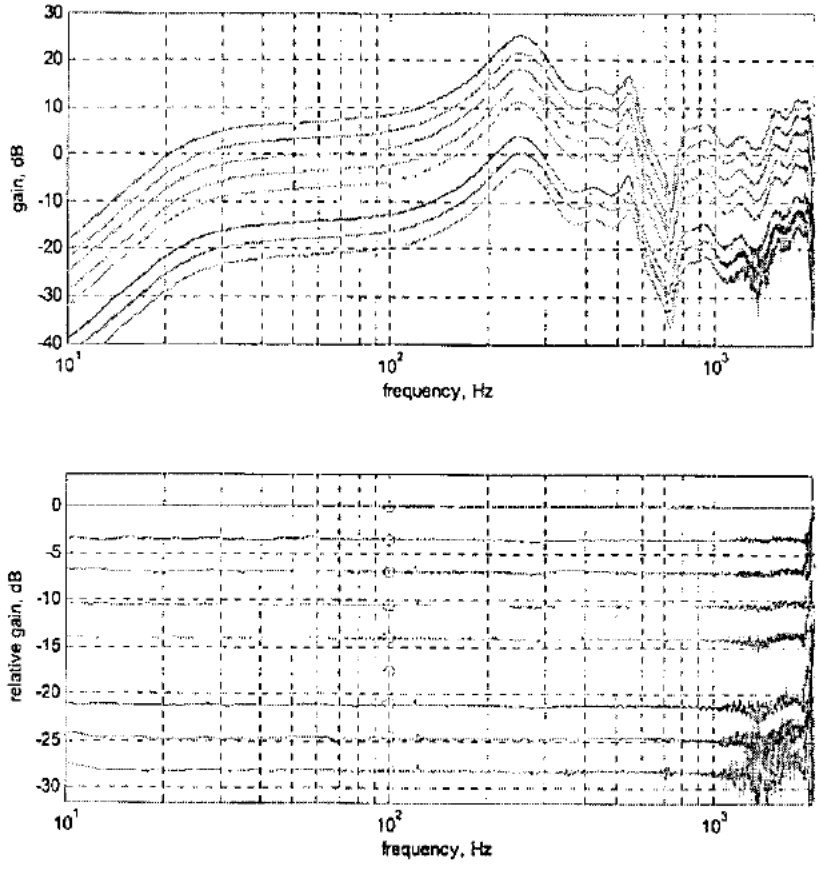

Figure 16 *Air-coupler measurements on E3000 Plus SN 045 in DIAP filter mode at volume levels 1 to 9 (upper plot). The lower plot shows the difference from the volume level 9 measurement and the red circles shows expected 3.5 dB intervals from 0 dB down to -28 dB.*

The step sizes are seen to clearly match the expected levels throughout the operating frequency range of the E3000 Plus.

10 Verification of temperature sensitivity

In order to verify the temperature gradient of the E3000 plus stethoscope assessment of the frequency response function have been made at -30, -15, 0, +25 and +50 °C in accordance with the protocol. All measurements have been performed on the 3M Service Center test equipment and the following devices were used for this verification: E3000 Plus SN 239, SN 244, SN 267, SN 270 and SN 273. The following figures 17 through 21 shows the impact from temperature on the total frequency characteristic of the specific stethoscope. Furthermore figure 22 shows the normalized data for the isolated frequency 100 Hz.

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(b)(4) [redacted]

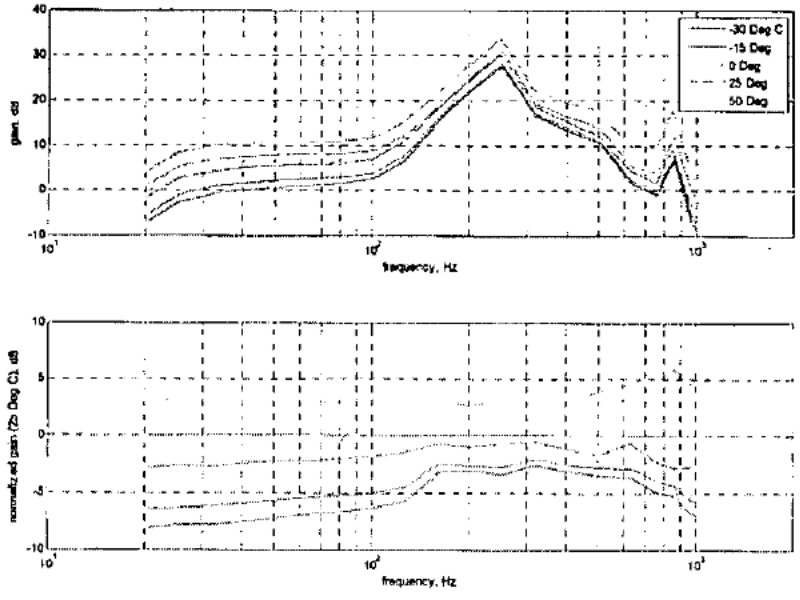

Figure 17 *Influence from temperature on gain for stethoscope SN 273 (upper graph) and the data normalized to the 25 °C reading.*

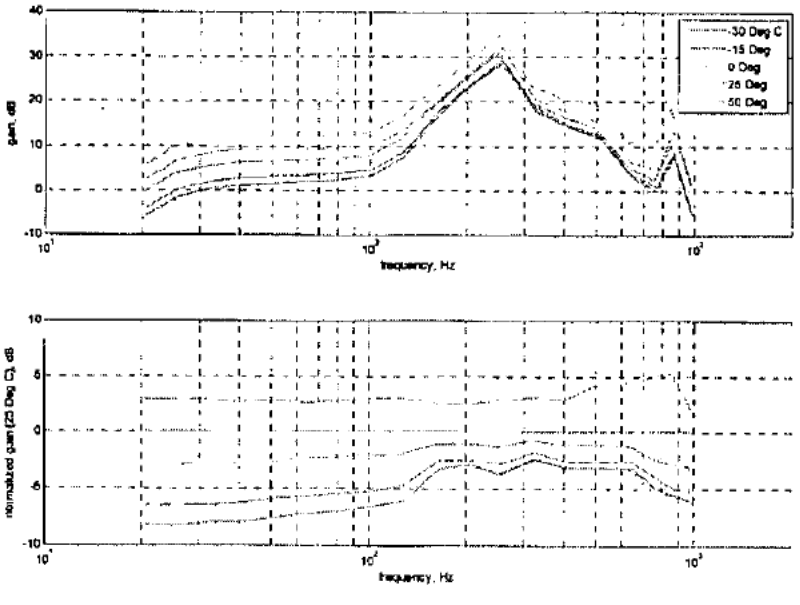

Figure 18 *Influence from temperature on gain for stethoscope SN 270 (upper graph) and the data normalized to the 25 °C reading.*

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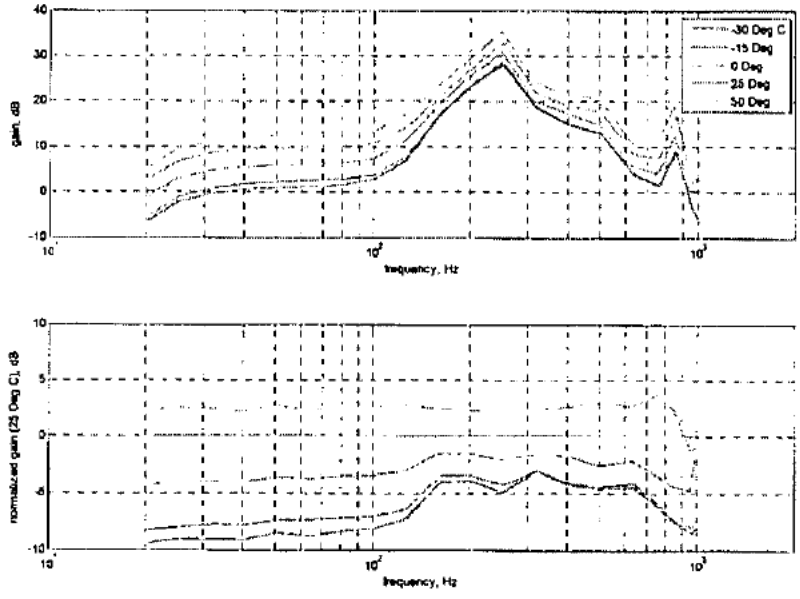

Figure 19 *Influence from temperature on gain for stethoscope SN 267 (upper graph) and the data normalized to the 25 °C reading.*

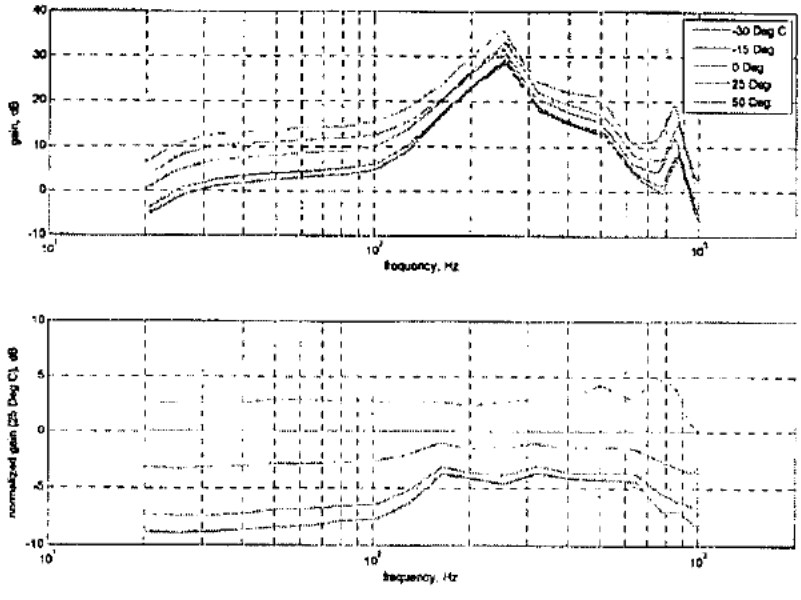

Figure 20 *Influence from temperature on gain for stethoscope SN 244 (upper graph) and the data normalized to the 25 °C reading.*

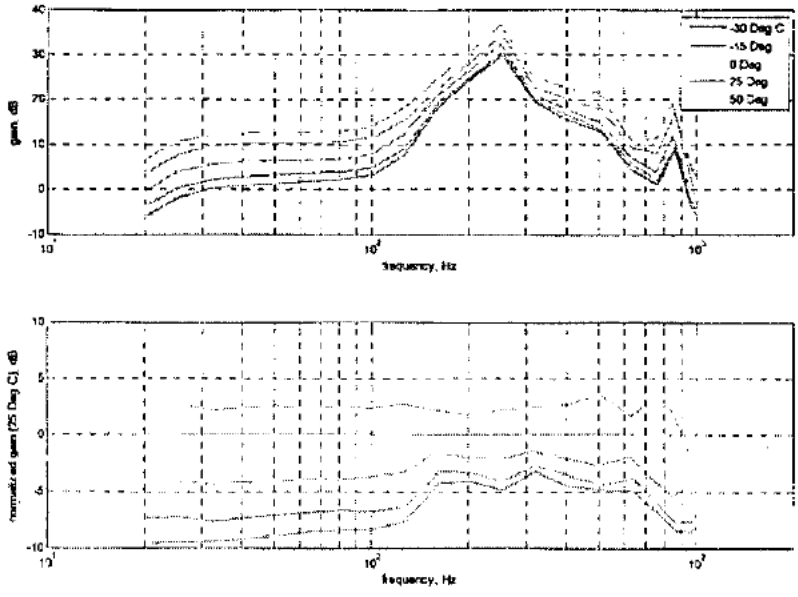

Figure 21 *Influence from temperature on gain for stethoscope SN 239 (upper graph) and the data normalized to the 25 °C reading.*

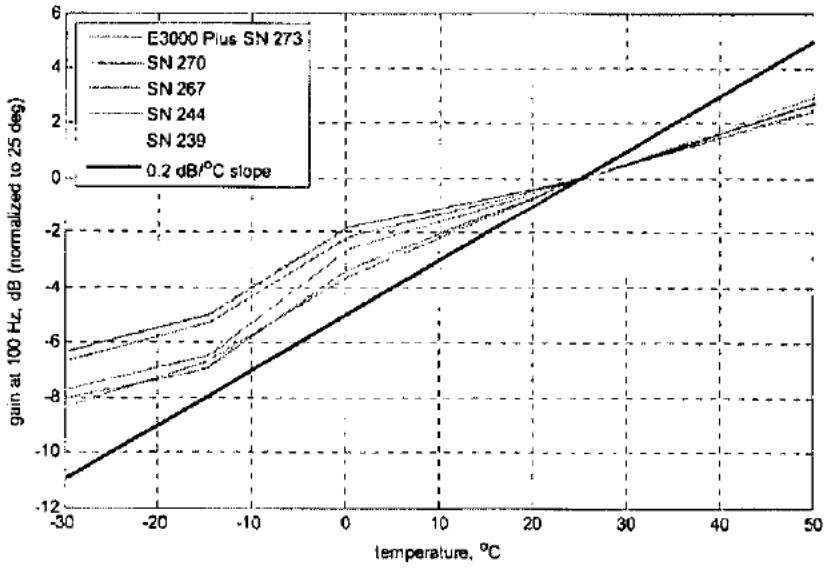

Figure 22 *E3000 Plus gain at 100 Hz together with average over temperature normalized to the 25 °C reading. Highest observed temperature coefficient less than 0.135 dB/°C.*

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(b)(4) [redacted]

As seen in the above figure 22 the E3000 Plus stethoscopes demonstrate a almost linear relationship between gain and temperature at 100 Hz. Based on the presented numbers in the extreme the maximum observed temperature coefficient is seen to 0.135 dB/°C well below the specified 0.2 dB/°C.

11 Conclusion

The present report verifies a list of properties around the E3000 Plus electro-acoustic performance: Overall gain level is verified positively and the practical handling of this gain adjustment in running production is detailed providing resulting homogeneity of +/- 1 dB.

Furthermore the frequency response and volume control function of the stethoscope is verified positively in accordance with the specifications.

Finally the temperature sensitivity of the E3000 Plus stethoscope is verified positively to be within the specified limit.

12 Version history

Version	Author	Date	Description	Reviewed by	EC number
1.00	BUA	22-sep-2008		AMI, TRH	
1.10	BUA	7-nov-2008	Updates on temperature coefficient performance	CAP, MBG, TRH	

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E3200 User Guide – English Version

(Cover)

(Fit graphics of package front & copy to front cover)

(Inside Cover)

(Translations for user guide front copy)

(English Section)

(VERY BOLD "English" at top of each page within booklet. Consider black box with white Arial Black text)

3M™ Littmann® Electronic Stethoscope
Model 3200
With Ambient Noise Reduction

Introduction
Congratulations and thank you for choosing the 3M™ Littmann® Electronic Stethoscope Model 3200.

The Model 3200 brings you the very latest in advanced auscultation and wireless electronics technology in a highly ergonometric and easy-to-use format.

The Model 3200's combination of Ambient Noise Reduction technology, frictional noise dampening materials, electronic amplification (conventional bell / diaphragm modes plus an "extended" mode), Bluetooth data transfer, and an all-new user interface takes you to the next level of performance and ease of use.

Whether you are auscultating infant, pediatric or adult patients, in quiet or noisy environments, or picking up difficult-to-hear heart and body sounds, you'll appreciate the technology that's been built into this latest electronic stethoscope bearing the Littmann® brand.

Don't miss the sounds you need to hear!

SAFETY INFORMATION

Please read, understand, and follow all safety information contained in these instructions prior to using this electronic stethoscope. Retain these instructions for future reference.

Explanation of Safety Related Labels and Symbols

	Indicates Type B Equipment: The equipment provides protection against electrical shock and electrical current leakage. Applied parts are considered to be the complete chestpiece with diaphragm and binaural.
	Consult instructions for use.
IPX4	Protected against splashing liquid (chestpiece only).
	This product contains electrical and electronic components and must not be disposed of using standard refuse collection. Please consult local directives for disposal of electrical and electronic equipment.
	This product and packaging does not contain natural rubber latex.
	Indicates Category AP Equipment. Tested for use with flammable anesthetic mixture with air.

Explanation of Signal Word Consequences

⚠ **CAUTION:**	Indicates a hazardous situation, which, if not avoided, could result in minor injury and/or property damage.
NOTICE:	Indicates a hazardous situation, which, if not avoided, may result in property damage.

⚠ CAUTION

- **To reduce the risks associated with infection** follow all cleaning and disinfecting instructions included in this manual. Establish and follow a cleaning and disinfecting schedule.
- **To reduce the risks associated with very strong electromagnetic fields** avoid using the stethoscope near strong radio frequency signals or portable and/or mobile RF devices. If you hear sudden or unexpected sounds, move away from any radio transmitting antennas.
- **To reduce the risks associated with sharp edges** make sure that the soft sealing eartips are snapped firmly into position as shown in this manual. Use only Littmann replaceable eartips.
- **To reduce the risks associated with an incorrect result** store and operate this stethoscope only as instructed in this manual. As there is no acoustic (non-amplified) mode available with this stethoscope, replace the battery within two hours of the battery life icon beginning to flash in the LCD display. Replace battery with only type AA. Also, do not immerse the stethoscope in a liquid or subject it to any sterilization processes.
- **To reduce the risk associated with an electrical shock** do not use the stethoscope on patients without the stethoscope's diaphragm cover in place
- **The Model E3200 Electronic Stethoscope contains a Bluetooth wireless data link.** This radio frequency data link operates at a frequency of 2.4 GHz using GFSK modulation and with a maximum transmit power of 230 microwatts (0.000230 watts). The maximum radio frequency field strength generated by the stethoscope is below three volts per meter, a level that is considered safe to use with other medical devices. However, if electromagnetic interference is encountered due to the Bluetooth wireless data link, immediately move the stethoscope away from that device and/or turn the Bluetooth feature OFF.

NOTICE

- **To reduce the risks associated with environmental contamination** follow applicable regulations when disposing of this stethoscope. Properly dispose of, or recycle, spent batteries.
- **No modification of this equipment is allowed.** Use only authorized 3M service personnel to repair this stethoscope. Read, understand, and follow all the safety information on the battery package.

EMC Compliance

FCC Intentional Radiator Certification

3M Littmann Electronic Stethoscope Model 3200

FCC ID: DGFIPD3200

This equipment contains an intentional radiator approved by the FCC under the FCC ID numbers shown above. This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesirable operation.

NO MODIFICATION: Modifications to this device shall not be made without the written consent of the 3M Company. Unauthorized modifications may void the authority granted under Federal Communications Commission rules permitting the operation of this device.

Industry Canada radio frequency rules and regulations

IC: 458A-IPD3200

This Class A digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe A est conforme à la norme NMB-003 du Canada.

EMC compliance Europe

This equipment complies with the EMC requirements of the IEC 60601-1-2.

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Intended Use

The 3M™ Littmann® Electronic Stethoscope Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of selective frequency ranges. It can be used on any person undergoing a physical assessment.

Operator Profile

The 3M Littmann® Electronic Stethoscope Model 3200 is designed to be used by anyone who wishes to listen to sounds as described in the Intended Use section above. This manual provides complete information on how to operate the Model 3200 so that no additional operating training is required.

Functional Description

The Model 3200 electronic stethoscope picks up sounds, such as heart and lung sounds, from a patient's body. After amplification and filtering, the sounds are sent to the user through a binaural headset. The stethoscope chestpiece is designed for use with adult, pediatric, and infant patients.

The user interface for the stethoscope includes a 5-button keypad and an LCD display. Sound processing is carried out with the aid of a digital signal processor. Stethoscope power is provided by a single AA battery in the chestpiece. A power management system is included to prolong battery life. Using its Bluetooth wireless link, the stethoscope can exchange audio data with an external device such as a personal computer (PC).

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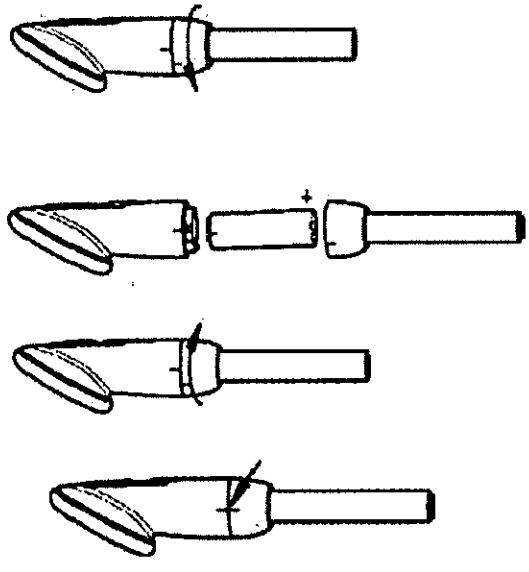
Serial Number
Each Littmann Electronic Stethoscope Model 3200 comes with a unique serial number on the chestpiece for easy identification. Please record your serial number in this manual for future reference:

_____

INSTRUCTIONS FOR USE

1. Insert Battery
Insert AA battery (provided in package) into Stethoscope.

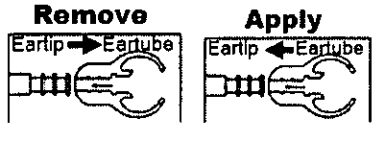


1. Hold chestpiece in one hand while slightly twisting the battery cap approximately 25° counter-clockwise. Remove battery cap.
2. Insert new battery with positive end out (plus sign will be visible in the battery compartment)
3. Remount battery cap, twisting cap approximately 25° clockwise until locked.
4. Make sure the two marks are aligned

2. Position Headset
Eartips should point in a forward direction as you insert them into your ear canals. When ear tips are properly positioned, diaphragm will face towards your body.

Your new Littmann Electronic Stethoscope is designed to give you a very comfortable, acoustically sealed fit. It comes with two sizes of eartips to assure a perfect fit. The large eartips are pre-installed. Smaller eartips are included in package. Please choose the set that is most comfortable for you.

To remove eartips, pull eartips firmly away from eartube. To apply new eartips, push eartip firmly onto eartube to secure.



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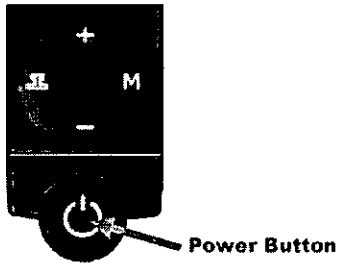
3. Adjust Headset for Comfort

To reduce spring tension in the headset, hold each eartube at the bend near the eartips and gradually pull apart until fully extended (180 degrees).

To increase spring tension, grasp the headset with one hand where the metal eartubes enter the plastic tubing, and squeeze until the plastic tubing on one eartube touches the other. Repeat as necessary.

4. Turn On / Off

This stethoscope comes equipped with an advanced power management system.



- **Manual Turn On:** Depress and release power button. LCD display will activate, indicating stethoscope is on.
- **Manual Turn Off:** Depress and **hold** power button for two seconds. LCD display will shut off, indicating stethoscope is off.
- **Auto-on with Standby Feature:** After manual turn-on, stethoscope will stay on during use, but switch to a power-saving standby mode after 10 seconds of inactivity. LCD display will display the Littmann® logo during "standby mode." When stethoscope diaphragm or any button is pressed, LCD display settings will reappear and stethoscope will be ready to use. After 30 minutes of non-use, stethoscope will leave "standby mode" and fully power down. You may customize on-time and off-time to meet your own personal needs. See **Custom Configuration** section below.
- **LCD Display Backlight:** Backlight options are available for use at low ambient light levels. By default, depressing and releasing the power button at any time ("on demand") will illuminate the LCD display for 3 seconds.

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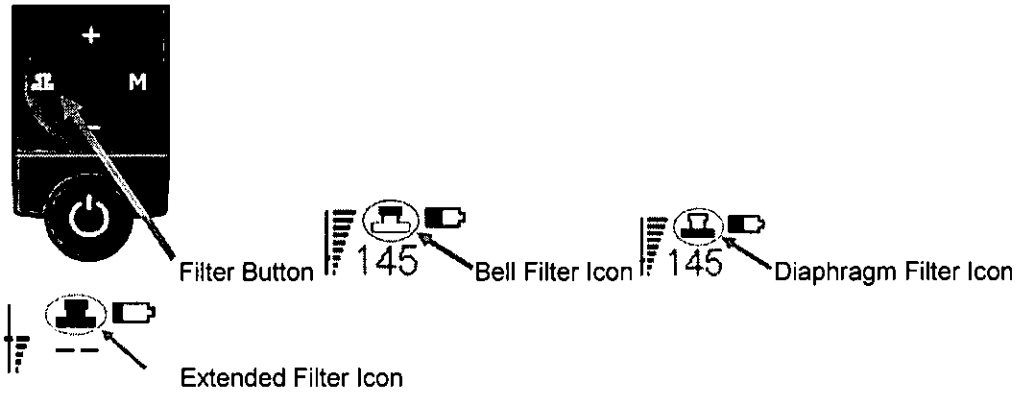
5. Select Filter

This electronic stethoscope allows the user to select between three different digital frequency filters to better emphasize the specific patient sounds of interest.

- The Bell mode amplifies sounds from 20 – 1000Hz and emphasizes lower frequency sounds between 20 – 200 Hz.
- The Diaphragm mode amplifies sounds from 20 – 2000Hz and emphasizes the higher frequency sounds between 100 – 500Hz.
- The Extended Range Diaphragm mode amplifies sounds from 20 – 2000Hz similar to the Diaphragm Mode but provides more low frequency response between 50 – 500Hz.

The default filter setting is the Diaphragm mode. Instructions for changing the default filter setting are given in the **Custom Configuration** section below.

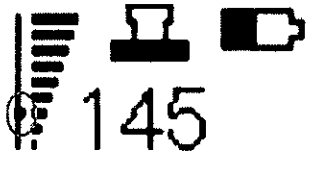
To select filter: Depress and release filter button (as shown in diagram) until desired filter mode appears on the LCD display.



6. Adjust Sound Amplification Level

The Model 3200 sound level can be amplified in 8 increments up to 24X amplification of a non-electronic (cardiology-level) stethoscope. Level 1 is equal to a non-electronic stethoscope. Level 9 is equal to 24X amplification of a non-electronic stethoscope. The greater the amplification, the more bars you will see.

A default start-up amplification level can be set using the instructions provided in the **Custom Configuration** section below. The default setting is marked by the box on the vertical bar shown in the volume icon in the LCD display. The illustration shows a default amplification setting at Level 3.



- **Increase Amplification:** Press (+) button until desired amplification level is achieved
- **Decrease Amplification:** Press (-) button until desired amplification level is achieved

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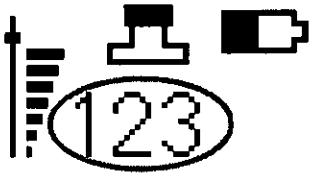
7. Monitor Patient Heart Rate

The Model 3200 detects and displays an acoustic-based heart rate when presented with consistent heart sounds (heart rate variation < 10%). It takes five seconds to compute the initial heart rate and updates are provided every two seconds. Prior to the initial reading, the display shows two dashes (--). For heart rates outside a range of 30-199 bpm, the display will also show two dashes (--).

The acoustic-based heart rate display functions best when the Model 3200 is placed near the apex of the patient's heart and can be monitored while using any filter mode and/or volume level. If the heart rate changes from consistent to inconsistent or if there is excessive ambient noise, patient movement or lung sounds during auscultation, the heart rate display number will display two dashes (--).



8. Monitor Battery Life

Battery life is indicated by an icon in the LCD display.

The Model 3200 comes with a AA Alkaline battery. Battery will provide approximately 50-60 hours of continuous use, depending on the frequency of Bluetooth data transfers. In a typical clinical setting, this represents about three months of use.

As the battery life depletes, the icon will change as follows:

= 50 -100% battery life

= 25 – 50% battery life

= 10 – 25% battery life

= 0 – 10% battery life

The battery icon begins to blink when only a few hours of battery capacity remains.

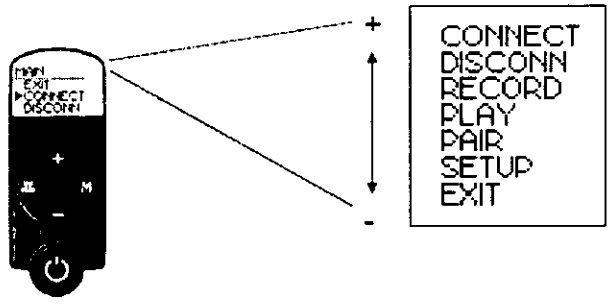
⚠**CAUTION:** When the battery is completely depleted the scope becomes inoperable. No sound will be transmitted without a functioning battery.

IMPORTANT! NiMH (rechargeable) and Lithium batteries may also be used in the Model 3200. However, battery type must be specified to ensure a reliable battery life indication (see **Custom Configuration** section below).

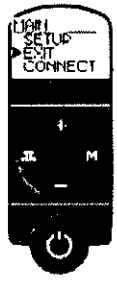
9. Custom Configuration

The Model 3200 stethoscope has several operational settings that can be changed using its configuration menu system. Within this menu system, the (+) and (-) buttons are used for scrolling and the (M) button is used for selecting options. The Filter button acts as an "escape" key, used for returning to the previous menu or to the operating mode of the stethoscope.

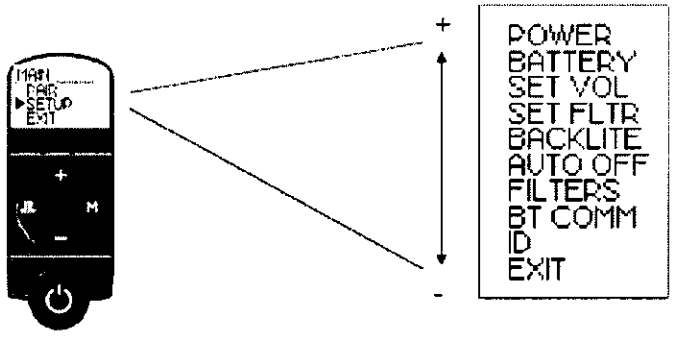
To access the Main menu: Depress and release the (M) button. The "MAIN" menu will be displayed, with the CONNECT option highlighted (NOTE: Only 3 options will be visible at a time. All options can be viewed in sequence upon scrolling with either the (+) or (-) buttons):



To leave the Main menu: Use the (M) button to select the "EXIT" option. This will return the stethoscope to its normal operating state.



To enter the Setup Menu: Use the (-) button to scroll down the list of Special Functions until "SETUP" is highlighted. Select the Setup option by pressing and releasing the (M) button. This will display the following menu:



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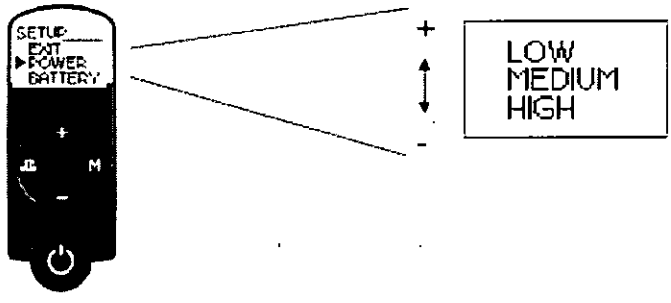
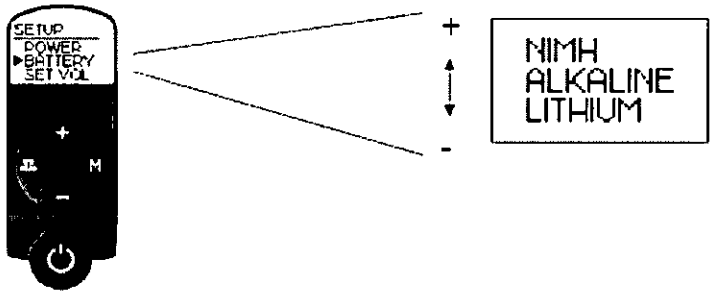
To set Power: Select the "POWER" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of power settings. Press and release the (M) button to select a setting.



The power settings provide different degrees of power consumption. In general, the longer the stethoscope remains in an active mode, the greater its power consumption. The factory default is the LOW level. (NOTE: The Auto Off power management feature is further described below)

	Auto Off ENABLED			Auto Off DISABLED		
Power Level	Low	Medium	High	Low	Medium	High
Power On Time	10 sec	20 sec	30 sec	3 min	5 min	7 min
Power Off Time	30 min	2 hr	5 hr	30 min	2 hr	5 hr
Backlight	3 sec	5 sec	5 sec	3 sec	5 sec	5 sec

To specify the battery type: Select the "BATTERY" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of battery types. The LITHIUM battery is a non-rechargeable cell especially recommended for low-temperature operation of the stethoscope. The NIMH battery is rechargeable (external charger required). Press and release the (M) button to select a setting. The factory default is the ALKALINE battery.



To specify the preset (default) volume level: Select the "SET VOL" option in the Setup menu. Press and release the (M) button to select the current volume level as default. The factory default is level 3.

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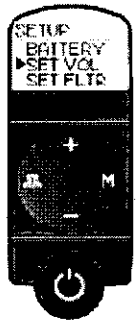
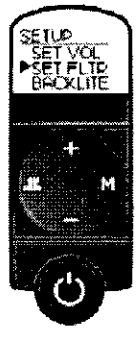
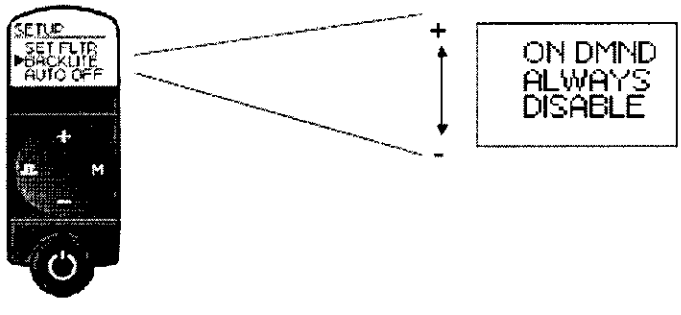


To specify the preset (default) filter setting: Select the "SET FLTR" option in the Setup menu. Press and release the (M) button to select the current filter as default. The factory default is the diaphragm filter.



To specify Backlighting duration: Select the "BACKLITE" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of options. Press and release the (M) button to select. The factory default is "ON DMND" ("On Demand" - backlight will illuminate for three seconds by depressing and releasing the power button). The "DISABLE" option disables the backlight at all times and will conserve power. The "ALWAYS" option will illuminate the backlight at all times at a reduced level while the stethoscope is powered on and not in standby mode.



To select Auto Off power management: Select the "AUTO OFF" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of options. Press and release the (M) button to select. The factory default is "ENABLE".

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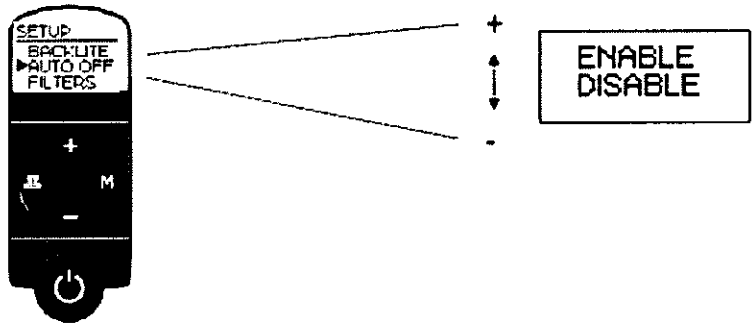
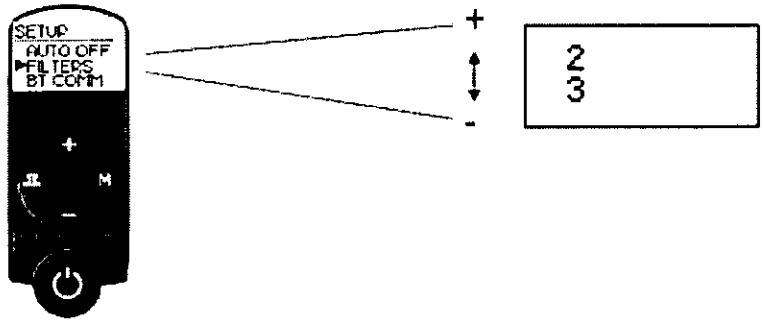
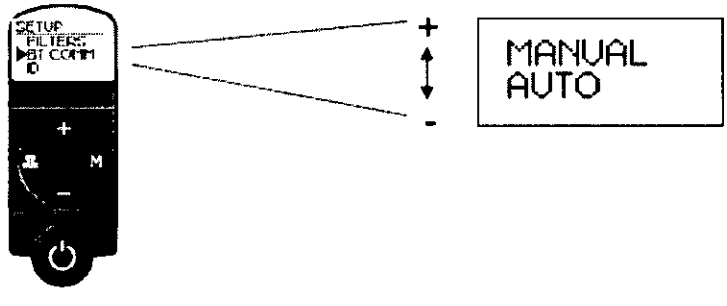


When the Auto Off feature is enabled, the stethoscope will enter standby mode after a period of time dictated by the Power setting if there is no contact detected on the diaphragm AND the buttons are not activated. When the Auto Off feature is disabled, the stethoscope will enter standby mode after a period of time dictated by the Power setting from the last button activation. In addition, when the Auto Off feature is disabled, there will be an audible alert 10 seconds prior to entering standby mode. After entering standby mode, the Model 3200 will be powered on when contact is detected on the diaphragm or by button activation. Otherwise, the Model 3200 will completely power down after the period of time dictated by the Power setting.

To set number of frequency ranges: Select the "FILTERS" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of options. Option "2" supports toggling between two filters (bell and diaphragm) with the FILTER button. With option "3" the FILTER button cycles the stethoscope through each of three filter modes (bell, diaphragm, and extended). Press and release the (M) button to select. The factory default is three filters.



To specify Bluetooth mode: Select the "BT COMM" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of options. The MANUAL option means that the Bluetooth link can be used for data transfers but requires user activation. The AUTO option means that the Bluetooth link is powered whenever the stethoscope is in an active mode. Press and release the (M) button to select an option. The factory default is "MANUAL."



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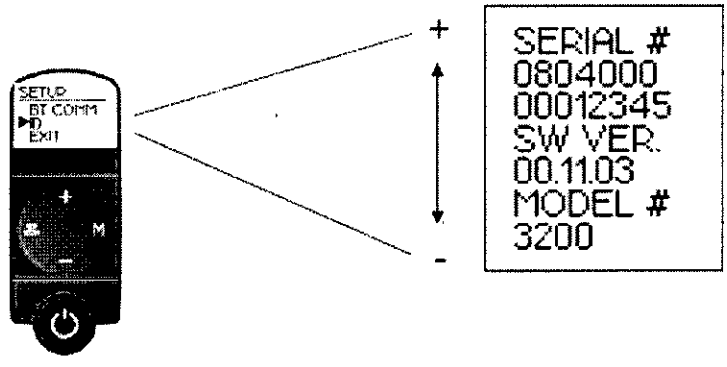
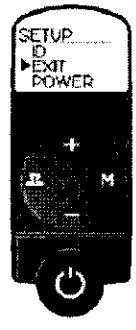
To obtain model and software version information: Select the "ID" option in the Setup menu. Use the (-) and (+) buttons to scroll through the list of reference numbers. Press "M" to return to the operating mode of the stethoscope.



To leave the Setup menu: Use the (M) button to select the "EXIT" entry and return to the operating mode of the stethoscope.



11. Using the Bluetooth Interface

The Bluetooth interface provides a means of exchanging audio data with external devices such as a Bluetooth-enabled PC. Audio data can be sent in near real time, permitting their visual presentation, recording, and analysis by applications software complying with communication protocols used by the Model 3200 stethoscope.

IMPORTANT! The Model 3200 uses a Class 2 Bluetooth link, with a maximum range of 10m.

In order to transfer data between two Bluetooth devices, they must first be "paired" electronically. Pairing is a discovery and authentication process that allows your Bluetooth equipped Model 3200 stethoscope to communicate with another Bluetooth equipped device and establishes the link between these two devices as a trusted pair. The pairing process requires user operations to be performed on both the Model 3200 and the external device. While the Model 3200 can remember trusted pairing with up to eight different Bluetooth devices, it will only communicate with one paired device at a time. In addition, you cannot pair a Model 3200 with a second Model 3200.

How to pair the Model 3200 with an external device:

1. **Initiate pairing process**: On the Model 3200, depress and release the (M) button. The "MAIN" menu will be displayed. Use the (-) button to scroll down the list of Actions until "PAIR" is highlighted. Select this option by pressing and releasing the (M) button. The LCD screen will signal that pairing is in progress with the following animated display:

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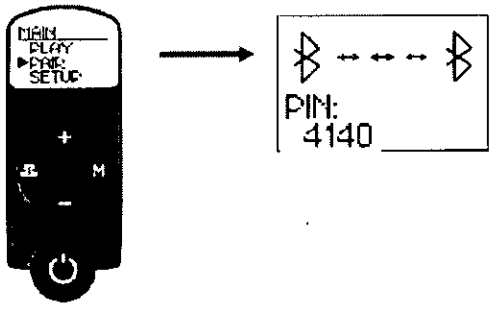
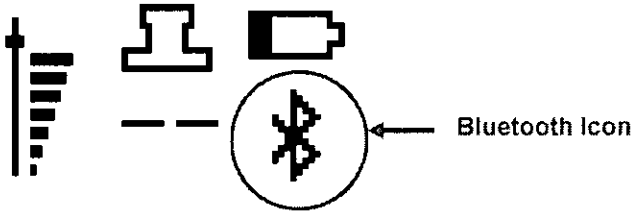


During the pairing process the Model 3200 will make itself discoverable to other Bluetooth equipped devices. Note: The Personal Identification Number (PIN) for Bluetooth pairing is displayed in the lower left-hand corner of the LCD screen

2. **Select Model 3200 stethoscope on external Bluetooth device**: Follow the "pairing" instructions found with your Bluetooth equipped device. In general, you will need to make sure that the Bluetooth mode is enabled on the device, and once the Model 3200 has indicated the external device has been found, you may need to confirm the connection on the external device. Please remember that the distance between the Model 3200 and the Bluetooth device is limited to no more than 10 meters. If pairing is successful, the LCD display of the Model 3200 will show a flashing Bluetooth icon and the stethoscope will be ready for wireless operations.



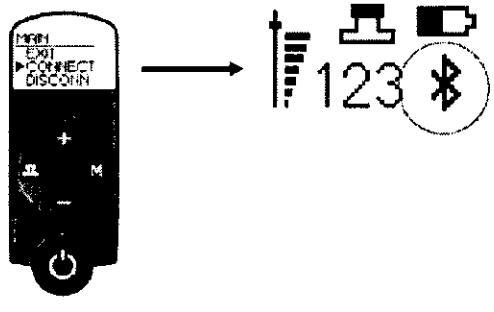
If the Bluetooth connection with the external device is subsequently lost or times out, the Bluetooth icon will disappear from the LCD display.

When connected by a Bluetooth link, external, Bluetooth-enabled devices can take control of the display and keypad of the Model 3200 stethoscope. They can also transfer audio (ex. voice prompts) to the Model 3200 headset. During audio transfers to the stethoscope, the sounds will be preceded by a beep.

How to transfer real-time data to an external device:

1. Ensure the Model 3200 is paired with the external device.

2. Depress and release the (M) button. The "MAIN" menu will be displayed with the "CONNECT" option highlighted. Select this option by pressing and releasing the (M) button. The LCD screen will signal that the Bluetooth link is active. The stethoscope will automatically return to operational status. Consult application software for details on initiating real-time transfer, the process may vary by computer platform utilized.



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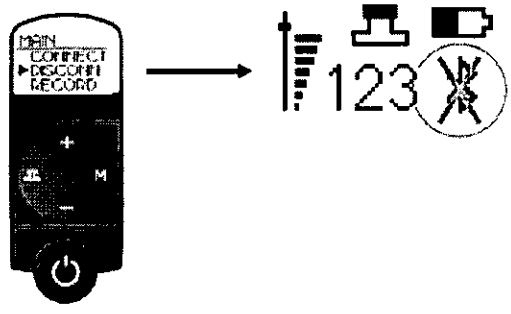
A Bluetooth connection with the stethoscope will automatically be ended if no data transfers occur in a 90 second period. Alternatively, the connection can be manually ended using the "DISCONN" (disconnect) option of the Main menu. If you are listening to the Model 3200 electronic stethoscope using its Bluetooth feature and you exceed the maximum communication range of approximately 10 meters, you may hear a rapid series of beeps. Should this occur, shorten the physical distance between your Model 3200 and the Bluetooth equipped device.



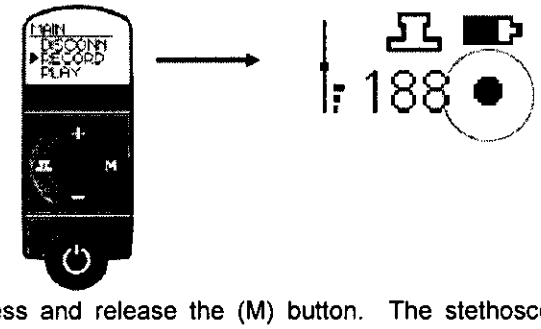
12. Using Onboard Recording

Onboard recording provides a means to acquire and play an auscultation sound track. This track can be uploaded to an external device using the Bluetooth link and the software accompanying the Model 3200 stethoscope.

How to record a sound track:

1. **Enter the recording mode:** Depress and release the (M) button. The "MAIN" menu will be displayed. Use the (-) button to scroll down the list of options until "RECORD" is highlighted.

2. **Begin the recording**: Depress and release the (M) button. The stethoscope will start recording and the LCD screen will show a "recording" icon.



3. **End the recording**: Depress and release the (M) button. The stethoscope will stop recording and the recording icon will disappear from the LCD display. If the time between the beginning and ending of the recording session is greater than 29 seconds, only the last 29 seconds will be saved.

How to play back a sound track:

1. **Enter the playback mode:** Depress and release the (M) button. The "MAIN" menu will be displayed. Use the (-) button to scroll down the list of options until "PLAY" is highlighted. Select this option by pressing and releasing the (M) button. The LCD screen will show a "PLAY" icon and the sound track will "loop" continuously.

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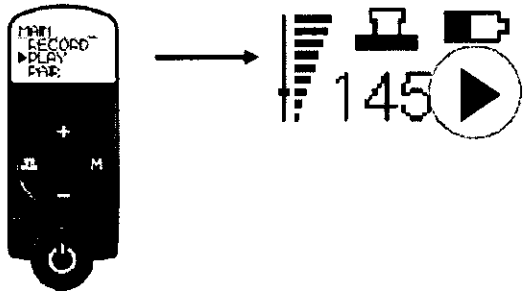

2. **End playback**: Depress and release the (M) button. The stethoscope will stop playing the sound track and will return to its previous operational mode.

Uploading a sound track to an external device:

1. **Prepare the external device to receive the sound file.** Start the Model 3200 software program on the external device.

2. **Initiate a Bluetooth connection with the Model 3200.** Use the same procedure as described above for initiating real-time data transfers to an external device.

3. **Return to operating mode:** When transmission of the sound track is complete, the Bluetooth link to the external device can be disconnected and the Model 3200 will return to its previous operating mode.

13. Other Operating Considerations

Operating range is -22° to 104°F (-30° to 40°C), 15 to 93% relative humidity.
Storage and transport range is -40° to 131° F (-40° to 55°C), 15 to 93% relative humidity.

To extend the life of your stethoscope, avoid extreme heat, cold, solvents and oils. Remove the battery whenever the stethoscope will not be used for several months.

If you plan to use the stethoscope below 0°F (-18°C) you should use a lithium battery to insure proper function.

Failure to follow care and maintenance recommendations could result in damage to the internal components of the Littmann Electronic Stethoscope. Internal damage could cause malfunction of the product, ranging from a slight decrease in auditory response to complete failure of the product.

If you experience any problems with the electronic stethoscope, do not attempt to repair it yourself. Please notify our 3M Health Care Service Center for directions on shipping and receiving.

MAINTENANCE & WARRANTY

Cleaning
Cleaning of stethoscope should be done between each patient use.

Cleaning the Chestpiece
Under normal conditions, it is unnecessary to remove the diaphragm for cleaning. The diaphragm can easily be cleaned by using an alcohol wipe. If however, it is necessary to remove the diaphragm, carefully follow the instructions below:

- **Diaphragm Removal**: With diaphragm side up, using a thumbnail, lift the underside portion of the diaphragm out of its designated groove, and peel it off of the chestpiece. The groove that holds the diaphragm in place can be cleaned by sliding the edge of an alcohol swab around the groove. All parts of the chestpiece can be wiped down with alcohol. IMPORTANT: The stethoscope should not be immersed in any solution. Excess liquid used in the cleaning process may result in moisture getting into the internal components.

- **Diaphragm Reassembly**: Once the diaphragm is completely dry, insert the diaphragm into the groove of the rim, starting at one point, and run your finger around the diaphragm until it is seated back in the groove.

Cleaning Other Parts of the Stethoscope
Eartips, eartubes, plastic tubing and chestpiece can be wiped clean with alcohol. Eartips may be removed for a more thorough cleaning.

***NOTICE*: Do not immerse the stethoscope in any liquid or subject it to any sterilization process!**

Service & Warranty Program
Your Littmann Electronic Stethoscope comes with the finest service and warranty policy in the industry. The Littmann Electronic Stethoscope Model 3200 is warranted against any defects in material and manufacture for a period of two years. If a material or manufacturing defect is discovered during the warranty period, repairs will be made without charge upon the return of the instrument to 3M, except in cases of obvious abuse or accidental damage.

For Maintenance or Repair Services

Please include your name, physical address, e-mail address, and phone number inside with your stethoscope.

In the U.S.A., send your stethoscope directly to:

3M Health Care Service Center
3M Bldg 502-1W-01
3350 Granada Ave N
Suite 200
Oakdale, MN 55128
1-800-292-6298

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In Canada, send your stethoscope directly to:

3M Health Care Service Centre
3M Canada, Inc.
80 Enterprise Drive South
London, Ontario
Canada, N6N1C2
1-800-563-2921

Outside of the U.S.A. and Canada, contact your local 3M subsidiary for maintenance and repair information.

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APPENDIX

Declaration – Electromagnetic Emissions		
The 3M Littmann® Electronic Stethoscope, Model 3200, is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 3200 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment –guidance**
RF emissions CISPR 11	Group 2	Model 3200 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	Model 3200 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

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Declaration – electromagnetic immunity

The 3M Littmann® Electronic Stethoscope, Model 3200, is intended for use in the electromagnetic environment specified below. The customer or the user of Model 3200 should assure that it is used in such an environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for supply lines ± 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial magnetic field or hospital environment
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycle 70 % UT (30 % dip in UT) for 25 cycle < 5% UT (>95 % dip in UT) for 5 sec	Not applicable	

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Declaration – electromagnetic immunity - continued

The 3M Littmann® Electronic Stethoscope, Model 3200, is intended for use in the electromagnetic environment specified below. The customer or the user of Model 3200 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Model 3200 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	$d = 1{,}2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1{,}2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range, [b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 3200 is used exceeds the applicable RF compliance level above, the Model 3200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 3200.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the 3M™ Littmann® Electronic Stethoscope Model 3200

The Model 3200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 3200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 3200 as recommended below, according to the maximum output of the communications equipment.

Rated maximum output power of transmitter, P [W]	**Separation distance according to frequency of transmitters, d [m]**		
	150 kHz to 80 MHz	80 Mz to 800 MHz $d = 1{,}2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Revision History

Version	Released Date	Log Entry
2.3	23 Mar 2009 00:00	Clarified Filter, Pairing, and Auto Off descriptions
2.0	18 Feb 2009 17:52	Moved Bluetooth disclaimer from Notice to Caution section; added preceding tone in external device to scope transfer
1.0	22 Jan 2009 15:09	Establish User Manual

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(b)(4)

[redacted]

E3000 Plus
SAR SW Acceptance Test Report

Version 1.00
Page 1 of 3
File name: PMP0910D - SAR BT pairing Report.doc

Author

4-3-2009
Date, name – SW R&D

Approved by

04-03-2009
Date, name – QA

QMS00247, Version 3.00

(b)(4)

[redacted]

(b) (4) [redacted]

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2 Scope 3
3 References 3
4 Tests 3
5 Conclusion 3
6 Version history 3

QMS00247, Version 3.00

(b) (4) [redacted]

1 Purpose

The purpose is to document and conclude on the acceptance test of the Bluetooth pairing to 8 PC's

2 Scope

This test is an addition to the main SAS

3 References

PMP0910C SAS BT pairing.doc

4 Tests

The tests are described in the acceptance test specifications, which have been carried out.

Acceptance test	Passed	Failed	Comment
BT:001A	X		
BT:001B	X		
BT:001C	X		
BT:001D	X		
BT:001E	X		
BT:001F	X		
BT:001G	X		
BT:001H	X		
BT:001I	X		
BT:001J	X		
BT:001K	X		
BT:001L	X		
BT:001M	X		
BT:001N	X		
BT:001O	X		
BT:001P	X		

5 Conclusion

All tests have been conducted with acceptable results.

6 Version history

Version	Author	Date	Description	Reviewed by	EC number
1.00	PMP	04-03-2009	First version		

QMS00247, Version 3.00

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(b) (4)

[redacted]

Appendix A to PMP0910D - SAS BT pairing Report.doc

IAD0007 - E3000 Plus SAS BT pairing

Version 1.00
Page 1 of 7
File name: PMP0910C SAS BT pairing.doc

Author	Approved by
4-3-2009 [illegible]	[illegible]
Date, Name - Software Designer	Date, Name - Quality Assurance

QMS00228, Version 2.0

(b) (4)

[redacted]

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(b) (4) [redacted]

Version history

Version	Author	Date	Description	Reviewed by	EC number
1.00	PMP	04-03-2009	First version		

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(b) (4) [redacted]

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7.1.1 Pair to 8 PC's 7

Q9500730, Version 1.00

K/8

(b) (4)

1 Purpose

Test Bluetooth pairing to 8 PC's

2 Scope

This test just test that the stethoscope can pair to 8 PC at one time

3 References

none

4 Reading guidance

none

(b) (4) [redacted]

5 TEST DESCRIPTION

5.1 Test Target

Assembled stethoscope

5.2 Test Configuration

-

5.3 Test Approval

Test must pass

QMS00238, Version 1.00

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(b) (4) [redacted]

6 TEST INSTRUCTIONS

6.1 Software set-up in the test

-

6.2 Needed equipment

-

6.2.1 Instruments

Type	Manufacture and model number	FAA no.	Calibration date
-			

6.2.2 Test fixture

-

6.2.3 Other test equipment

-

6.3 Hints for the testing

-

7 TEST CASES

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(b) (4) [redacted]

7.1 Test that the stethoscope can pair to 8 PC

7.1.1 Pair to 8 PC's

Purpose					
Test case	BT:001	**SR**	PR:139, SR:087		
Action					
Shot	Stimuli	Expected result	Result	Model	ref
A	Pair Stethoscope to the first PC	Pairing	Pair	M3200	
B	Test connection with PC #1	Communication OK	Connection ok	M3200	
C	Pair and connect to PC #2	Pairing and connect	Pair + connect	M3200	
D	Pair and connect to PC #3	Pairing and connect	Pair + connect	M3200	
E	Pair and connect to PC #4	Pairing and connect	Pair + connect	M3200	
F	Pair and connect to PC #5	Pairing and connect	Pair + connect	M3200	
G	Pair and connect to PC #6	Pairing and connect	Pair + connect	M3200	
H	Pair and connect to PC #7	Pairing and connect	Pair + connect	M3200	
I	Pair and connect to PC #8	Pairing and connect	Pair + connect	M3200	
J	Test connection with PC #1	Communication OK	Connection ok	M3200	
K	Test connection with PC #4	Communication OK	Connection ok	M3200	
L	Pair and connect to PC #9	Pairing and connect	Pair + connect		
M	Test connection with PC #4	Communication OK	Connection ok	M3200	
N	Test connection with PC #1	No connect	No connection	M3200	
O	Pair and connect to PC #1	Pairing and connect	Pair + connect	M3200	
P	Test connection with PC #1	Communication OK	Connection ok	M3200	
Test equipment and reference					
Comment					
Pass	**Not pass**	**Date:**	**Sign:**		
X		4-3-2009	[illegible]		

152

"Ho, Charles S."
<Charles.Ho@fda.hhs.gov>
03/26/2009 02:16 PM

To remorris2@mmm.com
cc ssardeson@mmm.com
jjin1@mmm.com
bcc
Subject RE: [Response Part 1]: K083903 3M

Dear Ms. Morris:

I happen to be at my computer now. I tried reading several attached files from your 3 Emails and they seemed OK.

A quick scan has resulted in one quick question:

Your response to my Q. 18 is a bit hard to decipher. Do you mean that the diaphragm is made of materials from a predicate from your own firm, and processed in an identical manner? If yes, please provide the 510(k) number for my record. If not, please provide the 3 biocompatibility tests requested by my Q. 18. Q. 18 is repeated below, together with your response.

18. Section 12.0 indicates that the diaphragm (transducer cover) is silicone with polyacrylate coating, which is not found in the two predicates. Hence, please provide the 3 biocompatibility tests in accordance with ISO 10993-1-- irritation, sensitization and cytotoxicity--, especially since Appendix 15 refers to the ISO 10993-1 standard.

After further analysis, 3M found out from the contract manufacturer that the diaphragm for Model 3200 indeed uses the exactly same material as Model 3000 and Model 4100. It is made out of silicone with polyurethane coating, which is identical to that of Model 3000 and Model 4100. The contract manufacturer purchases the material from the same supplier. However the internal documentation as well as the information listed in 510(k) was misleading thus 3M has updated the biocompatibility assessment to clarify this confusion as follows. The revision is shown in bold fonts.

Part # 7 (Page 5 of 9, Table 1)
Component Name - Diaphragm
Material - polyurethane-coated silicone rubber

Component Description (Page 6 of 9)

#7 – Diaphragm

The diaphragm is made of silicone rubber (b)(4)Trade Secret Process-Product Specs, (b)(4)Trade Secret. It is coated with a polyurethane coating (b)(4)Trade Secret Process-Product Specs, (b)(4)Trade Secret Process-Product Specs. This polyurethane coating is made by reacting a hydroxyl-bearing polyacrylate (b)(4)Trade Secret Process-Product Specs with a polyisocyanate to create a highly cross-linked polymer that is very inert. The 3M Littmann logo on the diaphragm is printed with a silicone encapsulant/adhesive (b)(4)Trade Secret Process-Product Specs. No adverse health effects are expected from the use of these materials.

Regards,

Charles

Charles Ho, Ph.D.
Scientific Reviewer
FDA/CDRH/ODE
Phone: 240-276-4077
Fax: 240-276-4002
Email: Charles.ho@fda.hhs.gov

-----Original Message-----
From: remorris2@mmm.com [mailto:remorris2@mmm.com]
Sent: Thursday, March 26, 2009 2:46 PM
To: Ho, Charles S.
Cc: ssardeson@mmm.com; jjin1@mmm.com
Subject: [Response Part 1]: K083903 3M

Hello Dr. Ho,

Attached please find the response to your e-mail of February 23, 2009 regarding the review of 3M's 510(k) application for the 3M Littmann® Electronic Stethoscope Model 3200 (K083903).
We are still working on Question 14e and 16, so those responses are missing from the attached, but we will send you the response to those questions as soon as they are complete.

Due to the file size, I am sending you two emails today. This email

contains the response.

(See attached file: Response_deficiency letter 3200_sent March26.2009.doc)

If you have any problem opening the attached file.

Thank you very much and looking forward to hearing from you soon.

Kind Regards,
Rica

Rica Morris, RAC-US
International Regulatory Affairs
3M Health Care, Medical Division
Bldg. 275-5W-06
Phone: 651-733-6791
Fax: 651-737-5320
Email: remorris2@mmm.com

Rica E. Morris/US-Corporate/3M/US
03/26/2009 04:01 PM

To "Ho, Charles S." <Charles.Ho@fda.hhs.gov>
cc jjin1@mmm.com
ssardeson@mmm.com
bcc
Subject RE: [Response Part 1]: K083903 3M

History: This message has been forwarded.

Hi Dr. Ho,

I apologize that the response to Question 18 was not very clear -- yes, the diaphragm is made out of the same materials as the predicate devices of 3M, and are manufactured in the same manner from the same supplier.

Here are the 510(k) numbers for your referene:
3M Littmann® Electronic Stethoscope, Model 3000: K050159
Littmann® Electronic Stethoscope, Model 4100: K051790

I also wanted to let you know that I will no longer be supporting this project, so for future correspondence, please contact Jizhong Jin (jjin1@mmm.com).

Thank you very much.

Kind Regards,
Rica

Rica Morris, RAC-US
International Regulatory Affairs
3M Health Care, Medical Division
Bldg. 275-5W-06
Phone: 651-733-6791
Fax: 651-737-5320
Email: remorris2@mmm.com

"Ho, Charles S." <Charles.Ho@fda.hhs.gov>

"Ho, Charles S." <Charles.Ho@fda.hhs.gov>
03/26/2009 02:17 PM

To remorris2@mmm.com
cc ssardeson@mmm.com
jjin1@mmm.com
Subject RE: [Response Part 1]: K083903 3M

Dear Ms. Morris:

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Part # 7 (Page 5 of 9, Table 1)
Component Name - Diaphragm
Material - polyurethane-coated silicone rubber

Component Description (Page 6 of 9)

#7 – Diaphragm

The diaphragm is made of silicone rubber [redacted] It is coated with a polyurethane coating [redacted] This polyurethane coating is made by reacting a hydroxyl-bearing polyacrylate [redacted] with a polyisocyanate to create a highly cross-linked polymer that is very inert. The 3M Littmann logo on the diaphragm is printed with a silicone encapsulant/adhesive [redacted] No adverse health effects are expected from the use of these materials.

Regards,

Charles

Charles Ho, Ph.D.
Scientific Reviewer
FDA/CDRH/ODE
Phone: 240-276-4077
Fax: 240-276-4002
Email: Charles.ho@fda.hhs.gov

-----Original Message-----
From: remorris2@mmm.com [mailto:remorris2@mmm.com]
Sent: Thursday, March 26, 2009 2:46 PM
To: Ho, Charles S.
Cc: ssardeson@mmm.com; jjin1@mmm.com
Subject: [Response Part 1]: K083903 3M

Hello Dr. Ho,

Attached please find the response to your e-mail of February 23, 2009 regarding the review of 3M's 510(k) application for the 3M Littmann® Electronic Stethoscope Model 3200 (K083903).
We are still working on Question 14e and 16, so those responses are missing from the attached, but we will send you the response to those questions as soon as they are complete.

Due to the file size, I am sending you two emails today. This email contains the response.

(See attached file: Response_deficiency letter 3200_sent March26.2009.doc)

If you have any problem opening the attached file.

Thank you very much and looking forward to hearing from you soon.

Kind Regards,
Rica

Rica Morris, RAC-US
International Regulatory Affairs

3M Health Care, Medical Division
Bldg. 275-5W-06
Phone: 651-733-6791
Fax: 651-737-5320
Email: remorris2@mmm.com

3M Health Care
3M Infection Prevention

3M Center, Bldg. 0275-05-W-06
St. Paul, MN 55144-1000
651 733 1110

3M

March 27, 2009

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
CDRH/ODE
Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SUBJECT: Change to the correspondent for the 510(k) 3M™ Littmann® Electronic Stethoscope Model 3200, K083903

Dear Ms. Shulman,

This letter is to let you know that Jizhong Jin will be the official correspondent for 510(k) 3M™ Littmann® Electronic Stethoscope Model 3200, K083903.

His contact information is as follows:
Jizhong Jin
3M Infection Prevention Division
3M Center, Bldg 275-05-W-06
St. Paul, MN 55144-1000
Tel: 651-733-6655
Fax: 651-737-5320
e-mail: jjin1@mmm.com

Sincerely,

Rica Morris

Rica Morris

cc: Charles Ho, Ph.D
Jizhong Jin

160

Jizhong
Jin/US-Corporate/3M/US
04/03/2009 11:51 AM

To Charles.Ho@fda.hhs.gov
cc
bcc
Subject K083903 3M

Dear Dr. Ho,

Attached please find the ADDITIONAL response to your e-mail of February 23, 2009 regarding the review of 3M's 510(k) application for the 3M Littmann® Electronic Stethoscope Model 3200 (K083903).

The following materials are the supplements to the files that Rica has sent.

14. **Although section 11.2 states, "The Model 3200 can only communicate with one PC at a time.", page 15 of 25 in the User Manual indicates that the stethoscope can pair with up to 8 devices (but not with another stethoscope) at a time. Please address the following:**

    e. **Please provide further test report(s) to verify that the subject device can co-exist wirelessly with other active RF emitters (including paired and unpaired BT emitters, and other RF emitters using different communications standards) in its vicinity.**

Littmann M3200 Wireless Coexistence Test Report.pdf Littmann M3200 Wireless Coexistence Test Plan.pdf

16. **Page 16 of 25 of the User Manual states, "When connected by a Bluetooth link, external Bluetooth-enabled devices can take control of the display and keypad of the Model 3200 stethoscope." This external control via BT configuration is troublesome since it goes beyond pure transfer of data (sound files). Please explain why this external control configuration should not be deleted.**

    The external Bluetooth-enabled device can only control a portion of the stethoscopes LCD display and emulate keypad activation. The external Bluetooth-enabled device does not have any other control above and beyond this. This capability is needed to optimize the usability of the Model 3200 and the external software.

    For example, when sounds are being transmitted from the PC to the stethoscope via Bluetooth communication, the display of the Model 3200 can be adjusted by the external software so that the correct filter mode is synchronized with the sound recording that is being sent to the stethoscope. Otherwise the display could show a filter setting that is different than what was used when the sound recording was made.

Regards,

Jizhong

Jizhong Jin
Regulatory Affairs
3M Medical Division
3M Center, Bldg 275-05-W-06
St. Paul, MN 55144-1000

Tel: 651-733-6655
Fax: 651-737-5320
e-mail: jjin1@mmm.com

Littmann Model 3200
Wireless Coexistence Test Report

Version 1.00
DS-VALID-05-000359

File name: Littmann M3200 Wireless Coexistence Test Report

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Confidential Document – 3M Company.

1. Purpose

The purpose of this report is to verify and document that multiple Littmann Model 3200 stethoscopes can coexistence wirelessly each communicating with a different host PC in an environment with other active RF emitters. The Model 3200 stethoscopes communicate via Bluetooth protocol with a host PC's operating a (b)(4)Trade [redacted]. The test was conducted per the Littmann Model 3200 Wireless Coexistence Test Plan.

2. Scope

This document applies to the wireless coexistence of multiple Littmann Model 3200 stethoscopes using a (b)(4)Trade Secret Process-Product Specs [redacted] operating on PC's. Test involves operation in an environment with active in band RF emitters including (b)(4)Trade Secret [redacted] and (b)(4)Trade Secret [redacted] in their vicinity. This document is intended to respond to coexistence testing requirements for compliance with the FDA QSR on Design Controls (§21CFR 820.30) and specified by *Draft Guidance for Industry and FDA Staff- Radio-Frequency Wireless Technology in Medical Devices, Jan. 3, 2007.* http://www.fda.gov/cdrh/osel/guidance/1618.html.

3. References

[1] DS-VALID-05-000358 Littmann Model 3200 Wireless Coexistence Test Plan.
[2] 001-DC-0007a Zargis Wireless Coexistence Test Plan.
[3] Question to K083903 E-mail of February 23, 2009 regarding review of the 510(k) 3MTM Littmann® Electronic Stethoscope Model 3200, K083903

4. Test Data

4.1. Test Setup and Format

(b)(4)Trade Secret Process-Product Specs

[redacted]

(b)(4)Trade Secret Process-Product Specs

[redacted]

4.2. Test Results

(b)(4)Trade Secret Process-Product Specs

[redacted]

(b)(4)Trade Secret Process-Product Specs

[redacted]

5. Conclusions

There were no issues with the all aspects of successful wireless communication of three Littmann Model 3200 stethoscopes operating in the close vicinity with each other and (b)(4)Trade [redacted] emitters. During Bluetooth paring, the (b)(4)Trade Secret [redacted] software was able to detect and identify multiple stethoscopes before correctly pairing with its intended partner stethoscope. Once paired to a stethoscope, the (b)(4)Trade [redacted] program ignored all other stethoscopes attempting to pair.

A (b)(4)Trade Secret [redacted] also coexisted with a complete test session on Model 3200 stethoscope. An incorrect PIN code error message on the first attempt was the only delay but even this was a passing test outcome.

6. Attachments

(b)(4)Trade Secret Process-Product Specs

[redacted]

(b)(4)Trade Secret Process-Product Specs

[redacted]

(b)(4)Trade Secret Process-Product Specs

[redacted]

Littmann Model 3200 Wireless Coexistence Test Plan

Version 1.00
DS-VALID-05-000358

File name: Littmann M3200 Wireless Coexistence Test Plan

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[redacted]

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[redacted]

(b)(4)Trade Secret Process-Product Specs

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1. Introduction

1.1. Purpose

The purpose of this document is to describe wireless coexistence testing 3M plans to perform on the Littmann Model 3200 stethoscope. This stethoscope will communicate via Bluetooth with a PC running [redacted] designed to communicate with and control the M3200 for the purpose of recording, playback and display of auscultation audio files. Test will utilize a [redacted] software operating on a PC. This document will define the testing procedures, the required test documentation, rationale for the test procedures and the quantification of test results for all wireless coexistence testing.

(b)(4)Trade Secret

(b)(4)Trade Secret Process-Product Specs

1.2. Scope

This document applies to the creation of a test plan for the wireless coexistence testing of Littmann Model 3200 stethoscope using A [redacted]. This document is intended to meet all aspects of coexistence testing required for compliance with the FDA QSR on Design Controls (§21CFR 820.30) and specified by *Draft Guidance for Industry and FDA Staff-Radio-Frequency Wireless Technology in Medical Devices, Jan. 3, 2007.* http://www.fda.gov/cdrh/osel/guidance/1618.html.

(b)(4)Trade Secret Process-Product Specs

2. Test Activities

2.1. Test Planning and Justification

2.1.1. Introduction

The goal of this testing plan is to demonstrate that the RF component of Littmann Model 3200 stethoscope can operate safely and effectively in an environment with existing RF technology. M3200 relies on a Class 2 Bluetooth device to replace the wired or optical connection between the stethoscope and computer that is present in the prior versions of the Littmann electronic stethoscope.

In order to maximize the safety of the wireless transmission, while retaining an overall efficacy similar to a wired connection, 3M decided to implement a Bluetooth wireless connection as the solution.

2.1.2. Overview of Bluetooth

Bluetooth is a wireless hardware and communications standard defined by the Bluetooth Special Interest Group[1]. As an RF wireless standard, Bluetooth possesses a number of benefits that define it as preferable to other wireless standards and protocols.

---

[1] Bluetooth Special Interest Group. http://bluetooth.com

- Bluetooth operates on the unlicensed ISM band at 2.4GHz
- Bluetooth employs adaptive frequency hopping to minimize interference and collisions
  - The frequency hopping transceiver jumps between 79 different frequencies to avoid potential interference
  - The adaptive frequency hopping technology excludes frequencies as hopping targets when static collocated devices are detected on the same frequencies
- Bluetooth v.2.1 w/EDR has a large 3 Mb/s data transfer rate.
- Bluetooth utilizes a targeted connection methodology where only specified recipients, defined by a MAC address, can be involved in the conversation
- Bluetooth utilizes an authentication protocol so that only approved devices can be connected.

2.1.3.Bluetoot h Specifications[2]

This section describes the functional and performance specifications of Bluetooth as relevant to the M3200 stethoscope device.

2.1.3.1. Radiated Power

The M3200 makes use of a Class 2 Bluetooth transceiver. The radiated power specifications are listed highlighted in green in Table 1.

Table 1. Radiated power standards for Bluetooth radio hardware

Power Class	Maximum Output Power (Pmax)	Nominal Output Power	Minimum Output Power*	Power Control
1	100 mW (20 dBm)	N/A	1 mW (0 dBm)	Pmin<+4 dBm to Pmax Optional: Pmin** to Pmax
2	2.5 mW (4 dBm)	1 mW (0 dBm)	0.25 mW (-6 dBm)	Optional: Pmin** to Pmax
3	1 mW (0 dBm)	N/A	N/A	Optional: Pmin2** to Pmax

**Minimum output power at maximum power setting.*
*** The lower power limit Pmin<-30dBm is suggested but is not mandatory, and may be chosen according to application needs.*

2.1.3.2. Frequency and Scheme

Bluetooth radios utilize 79 frequencies in an 83.5MHz frequency band between 2.4GHz and 2.4835GHz. Each of the 79 channel bands is defined by 2402 + k MHz; k=0,..., 78 with a tolerance of $\pm$ 75kHz.

2.1.3.3. Modulation

Bluetooth contains two separate data rates: Basic and Enhanced. The Basic Data Rate utilizes Gaussian Frequency Shift Keying as its modulation

[2] *Specification of the Bluetooth System. Volume 2, Core System Package [Controller Volume].* Bluetooth Special Interest Group. v. 2.1 + EDR, July 6, 2007.

methodology while the Enhanced Data Rate relies on Phase Shift Keying. Additional specifics can be found beginning on page 33 of the attached reference standard.

2.1.3.4. Data Rate

Bluetooth contains two separate data rates: Basic and Enhanced. The Basic Data Rate has fundamental data rate of 1Mb/s. The Enhanced Data Rate has a minimum data throughput of 2Mb/s with an optional peak of 3Mb/s.

2.1.3.5. Hardware Protocol[3]

(b)(4)Trade Secret Process-Product Specs

[redacted]

232 baud rates.

2.1.3.6. Software Messaging Protocol

(b)(4)Trade Secret Process-Product Specs

[redacted]

2.1.3.7. Security and Networking

(b)(4)Trade Secret Process-Product Specs

[redacted]

[3] *RFCOMM with TS 07.10, Serial Port Emulation.* Bluetooth Special Interest Group v.1.1., June 5,2003.

(b)(4)Trade Secret Process-Product Specs

[redacted]

(b)(4)Trade Secret Process-Product Specs

[redacted]

2.1.4.Anti cipated Usage Environments

In order to properly define the necessary wireless coexistence testing, the anticipated usage environments need to be defined. The sound analysis program is designed to be a decision-support device for assisting in auscultation. The expected environment is a primary-care clinical setting. This is defined as a physician's office, clinic or a hospital.

(b)(4)Trade Secret on the other hand is designed as a laboratory Bluetooth communication tool. Its function is to exercise any of the commands available to the M3200 stethoscope and detect communication quality and status by detecting and counting any packet errors. It can connect, send and receive sound files as well as monitor Bluetooth communication protocol from the M3200.

2.1.5.Antici pated Coexisting RF and Interfering Devices

A number of potential coexisting devices are possible in the anticipated usage environments. A physician's office and clinic can have a number of RF-based communication devices including:

(b)(4)Trade Secret Process-Product Specs

[redacted]

Additionally, a hospital environment m(b)(4)Trade Secret Process-Product Specs

[redacted]

Lastly, (b)(4)Trade Secret Process-Product Specs have been established as an interfering device for Bluetooth communications. (b)(4)Trade Secret Process-Product Specs can be plausibly located in all office and hospital settings.

2.1.6.Coexis tence Test Planning and Strategy

(b)(4)Trade Secret Process-Product Specs

[redacted]

(b)(4)Trade Secret Process-Product Specs

[redacted]

[4] *IEEE Standard for Information Technology, Part 11: Wireless LAN Medium Access Control and Physical Layer Specifications.* IEEE Computer Society. June 12, 2007.

[5] *FCC Online Table of Frequency Allocations 47 CFR 2.106.* http://www.fcc.gov/oet/spectrum/table/fcctable.pdf September, 23,2008.

(b)(4)Trade Secret Process-Product Specs

[redacted]

[6] Walling, Mats K. E. B. and Wajntraub, Samson. *Evaluation of Bluetooth as a Replacement for Cables in Intensive Care and Surgery*. Anesth Analg. 2004, 98:763-7.

[7] Rondeau *et al. Residential Microwave Oven Interference on Bluetooth Data Performance.* IEEE Transactions on Consumer Electronics, 50(3). August 2004.

2.2. Test Case Structure

Each test case for the described tests above must consist of the following:

1. Test Name
2. Test Description
3. Test Scope
4. Tester Name
5. Date of testing
6. Test equipment and configuration
7. Test methods
8. Data analysis methods
9. Pass/Fail criteria

3. Test Description: Coexisting Bluetooth & (b)(4)Trade Secret Process-[redacted]s

3.1. Introduction

3.1.1.Description

(b)(4)Trade Secret Process-Product Specs

[redacted]

3.1.2.Scope

This test will cover all Bluetooth interaction testing for the M3200 with (b)(4)Trade Secret Process-[redacted]. The second test case will include a PC running (b)(4)Trade [redacted].

3.1.3.Definitions

N/A

3.2. General Instructions

All test steps must be completed and either a Pass or Fail must be recorded for each test case

3.3. Test Setup and Format

(b)(4)Trade Secret Process-Product Specs

[redacted]

3.3.1.2. Test Methods

(b)(4)Trade Secret Process-Product Specs

[redacted]

3.3.1.3. Analysis Methods and Pass/Fail criteria

During each recording session, the users will verify that the proper scope is connected. The users will verify that each sound analysis program session completes properly with no failures, hanging or missing data. The Pass/Fail criteria are as follow:

Test Step	Pass/Fail Description
Pair each scope with the sound analysis program	Pass: Proper scope is paired or user receives an error message stating that there is a problem with the connection Fail: Unreported errors, improper scope pairs
Connect each scope to the sound analysis program	Pass: Proper scope is connected or user receives an error message stating that there is a problem with the connection Fail: Unreported errors, improper scope pairs
Perform the sound analysis program sessions	Pass: Record and Playback to stethoscope sessions completed normally or user receives an error message stating the connection is down Fail: Dropped connection with an error message or bad/corrupted data.
Disconnect Scope	Pass: Scope disconnects

	Fail: Scope fails to disconnect

3.3.2.T est Case 2: (b)(4)Trade Secret Process-Product Specs [redacted] y.

3.3.2.1. Equipment and Setup

In this test case, there will be:

(b)(4)Trade Secret Process-Product Specs [redacted]

3.3.2.2. Test Methods

(b)(4)Trade Secret Process-Product Specs [redacted]

3.3.2.3. Analysis Methods and Pass/Fail criteria

During each recording session, the users will verify that the proper scope is connected. The users will verify that each sound analysis program session completes properly with no failures, hanging or missing data. The third PC will record audio data from the scope logging the number of missed packets. The Pass/Fail criteria are as follows:

Test Step	Pass/Fail Description
Pair each scope with a sound analysis program or the PC Bluetooth device manager	Pass: Proper scope is paired or user receives an error message stating that there is a problem with the connection Fail: Unreported errors, improper scope pairs
Connect each scope to a sound analysis program or (b)(4)Trade Secret	Pass: Proper scope is connected or user receives an error message stating that there is a problem with the connection Fail: Unreported errors, improper scope pairs
Perform the sound analysis program sessions	Pass: Record and Playback to stethoscope Sessions completed normally or user receives an error message stating the connection is down Fail: Dropped connection with an error message or bad/corrupted data.
Or Perform (b)(4)Trade Secret Session	Pass: Record audio data from stethoscope using (b)(4)Trade Secret. Log fewer than 3 packet errors. Fail: Dropped connection or greater than 2 packet errors.
Disconnect Scope	Pass: Scope disconnects Fail: Scope fails to disconnect

4. Test Description: Coexisting (b)(4)Trade Secret Process-Product Specs

4.1. Introduction

4.1.1. Description

(b)(4)Trade Secret Process-Product Specs

4.1.2. Scope

(b)(4)Trade Secret Process-Product Specs

4.1.3. Definitions

N/A

4.2. General Instructions

All test steps must be completed and either a Pass or Fail must be recorded for each test case

4.3. Test Setup (b)(4)Trade Secret Process-Product Specs

4.3.1.2. Test Methods

(b)(4)Trade Secret Process-Product Specs

4.3.1.3. Analysis Methods and Pass/Fail criteria

During the recording session, the user will verify that the scope is connected. The user will then verify that the sound analysis program session completes properly with no failures, hanging or missing data. The Pass/Fail criteria are as follow:

Test Step	Pass/Fail Description
Pair scope with a sound analysis program	Pass: Proper scope is paired or user receives an error message stating that there is a problem with the connection Fail: Unreported errors, improper scope pairs
Connect scope to a sound analysis program	Pass: Proper scope is connected or user receives an error message stating that there is a problem with the connection Fail: Unreported errors, improper scope pairs
Perform the sound analysis program sessions	Pass: Record and Playback to stethoscope Sessions completed normally or user receives an

	error message stating the connection is down Fail: Dropped connection with an error message or bad/corrupted data.
Disconnect Scope	Pass: Scope disconnects Fail: Scope fails to disconnect

K083903 3M F/u questions on May 11, 2009

1. In response to our questions dated Feb. 23, 2009, you have provided some forms FDA 3654. However, although you refer to IEC 60601-1-2 (for EMC testing) this form is not provided. Please provide form FDA 3654 for this standard.

2. We believe that the subject device is for prescription use only, for the following reasons:

   a. The subject device reports a heart rate (in addition to heart sounds). This heart rate feature makes the device a monitor, necessitating a prescription use only designation.

   b. The predicate from the same manufacturer is also prescription use only; it also has the heart rate reporting feature.

   Hence, please revise the Instructions for Use statement, and the IFU, to indicate for prescription use only, as requested by our previous Q. 2.

3. Please revise the IFU to inform the user that the patient's heart rate is updated every 2 seconds after initial sampling (5 sec.). For ease of viewing by the physician this heart rate is shown in the LCD display of the stethoscope for 10 seconds after removal of the chest piece from the patient.

4. As requested by our previous Q. 6, please point to a legally marketed BT-enabled PC that can communicate with the subject device via BT.

5. Your responses to our previous Q. 7 and 8 refer to Appendix 13. Somehow, this appendix is not available. Please re-transmit it to FDA.

6. Your response to our previous Q. 9 refers to Appendix 2. Somehow, this appendix is not available. Please re-transmit it to FDA.

7. Your response to our previous Q. 13 indicates that testing utilized a unit of the subject device with only 1 MB of memory, resulting in a record of only 14 sec. Hence, please provide test data on the subject device with 2 MB of memory in order to validate the device's ability to record 29 seconds of acoustic data.

8. In response to our previous Q. 15, you have clarified that the Auto mode for the device's BT feature will work only on BT-enabled PCs (or similar devices) that have been successfully paired with the subject device. Please revise the IFU to highlight this requirement of successful pairing, before the Auto mode can start.

9. In response to our previous Q. 16, you seem to state that an external device's control of the subject device via BT is intended only to help the subject device reproduce sounds using the correct filters (filters that were used to record the original sounds). No other control is afforded to the external device. If this interpretation is correct, please revise the IFU to reflect this idea in BT communications.

10. As requested by our previous Q. 20, please revise the software documentation to be consistent with a Moderate level of concern, since the information provided by the device is important and if erroneous, can lead to patient injury.

11. In your response to our previous Q. 21, you have provided a risk assessment report. However, the report indicates that 2 activities have not been completed:

    a. 3M CVE Design validation
    b. Wear test of new bayonet design

    Please clarify the final status of these two activities.

IFU = Instructions for Use

Jizhong Jin/US-Corporate/3M/US

05/28/2009 10:03 PM

To Charles.Ho@fda.hhs.gov

cc

bcc Catherine H. Behun/US-Corporate/3M/US@3M-Corporate
Scott Sardeson/US-Corporate/3M/US@3M-Corporate
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Ned C. Hancock/US-Corporate/3M/US@3M-Corporate
Tim Chismar/US-Corporate/3M/US@3M-Corporate

Subject Response to the FDA's 2nd deficient letter May 28 09 - K083903

Dear Dr. Ho,

Attached please find the response to your e-mail of May 11, 2009 regarding the review of 3M's 510(k) application for the 3M Littmann® Electronic Stethoscope Model 3200 (K083903).

K083903 F_U Q_May112009 - Response from 3M May 28 2009.pdf

Due to the file size, I am sending you the files via drop boxes.

Thank you very much and looking forward to hearing from you soon.

Jizhong Jin
International Regulatory Affairs
3M Infection Prevention Division
3M Center, Bldg 275-05-W-06
St. Paul, MN 55144-1000
Tel: 651-733-6655
Fax: 651-737-5320
e-mail: jjin1@mmm.com

K083903 3M F/u questions on May 11, 2009

1. In response to our questions dated Feb. 23, 2009, you have provided some forms FDA 3654. However, although you refer to IEC 60601-1-2 (for EMC testing) this form is not provided. Please provide form FDA 3654 for this standard.

   Provided to the FDA via email on May 21.

2. We believe that the subject device is for prescription use only, for the following reasons:

   a. The subject device reports a heart rate (in addition to heart sounds). This heart rate feature makes the device a monitor, necessitating a prescription use only designation.

   b. The predicate from the same manufacturer is also prescription use only; it also has the heart rate reporting feature.

   Hence, please revise the Instructions for Use statement, and the IFU, to indicate for prescription use only, as requested by our previous Q. 2.

   We have amended the Instruction for Use statement on page 18 and the IFU on page 2 in blue indicating this device is prescription use device. Please see attached product manual (HRDGD-UM-05-000062 Ver. 2.10.doc).

3. Please revise the IFU to inform the user that the patient's heart rate is updated every 2 seconds after initial sampling (5 sec.). For ease of viewing by the physician this heart rate is shown in the LCD display of the stethoscope for 10 seconds after removal of the chest piece from the patient.

   This part has been revised. Please see attached manual (HRDGD-UM-05-000062 Ver. 2.10.doc) on page 10 highlighted in Blue.

4. As requested by our previous Q. 6, please point to a legally marketed BT-enabled PC that can communicate with the subject device via BT.

   Any PC meeting or exceeding the following system requirements with a Bluetooth dongle meeting the dongle specifications below and plugged into one of the PC's USB port will enable communication with the Littmann Model 3200 stethoscope.

   PC System Requirements:

- Windows XP SP2 or later or Vista 32-bit.
- 512MB of RAM.
- Intel Pentium 4 compatible or later.
- 1024 x 600 graphic display or better.
- USB 1.1 port or better.

  The specifications of the USB wireless dongle are as follows:

- Compliant with Bluetooth V1.1, V1.2 & V2.0.

- Supporting profiles: Networking, Dial-up, Fax, LAN access, and Headset.
- Operating system: Windows XP and Vista.
- Interface: Compliant with USB 1.1 & 2.0.
- Data transmission rate: 3Mbps.
- Working distance: 5-10m.
- FCC approval: FCC ID - WQ7 I-BTD-04.

  NOTE: The USB Transceiver device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: 1. This device may not cause harmful interference, and 2. This device must accept any interference received, including interference that may cause undesired operation.
  FCC NOTE: THE MANUFACTURER IS NOT RESPONSIBLE FOR ANY RADIO OR TV INTERFERENCE CAUSED BY UNAUTHORIZED MODIFICATIONS TO THIS EQUIPMENT. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

  One example of a Notebook PC for sale online today meeting the above PC system requirements is given below:
  HP EliteBook 6930p Notebook Intel Core 2 Duo T9400 2.53GHz
  802.11a/b/g/n Wireless 14.1" WXGA+ 4GB DDR2 SDRAM 160GB
  Windows Vista Business DVD-Writer (DVD-RAM/+R DL/-R DL/+RW/-RW) Black

5. Your responses to our previous Q. 7 and 8 refer to Appendix 13. Somehow, this appendix is not available. Please re-transmit it to FDA.

   Provided to the FDA via email on May 21.

6. Your response to our previous Q. 9 refers to Appendix ~~2~~ 10. Somehow, this appendix is not available. Please re-transmit it to FDA.

   Provided to the FDA via email on May 22.

7. Your response to our previous Q. 13 indicates that testing utilized a unit of the subject device with only [redacted] MB of memory, resulting in a record of only 14 sec. Hence, please provide test data on the subject device with [redacted] MB of memory in order to validate the device's ability to record 29 seconds of acoustic data.

   See attachment MBG0849B and Appendix A to MBG0849B

8. In response to our previous Q. 15, you have clarified that the Auto mode for the device's BT feature will work only on BT-enabled PCs (or similar devices) that have been successfully paired with the subject device. Please revise the IFU to highlight this

requirement of successful pairing, before the Auto mode can start.

This part has been revised. Please see attached manual (HRDGD-UM-05-000062 Ver. 2.10.doc) on page 14 highlighted in Blue.

9. In response to our previous Q. 16, you seem to state that an external device's control of the subject device via BT is intended only to help the subject device reproduce sounds using the correct filters (filters that were used to record the original sounds). No other control is afforded to the external device. If this interpretation is correct, please revise the IFU to reflect this idea in BT communications.

   See attachments – 1) RESPONSE TO QUESTION 9
   2) Littmann M3200 Wireless Coexistence Test Plan - attachment to RESPONSE TO QUESTION 9
   3) Littmann M3200 Wireless Coexistence Test Report - attachment to RESPONSE TO QUESTION 9

10. As requested by our previous Q. 20, please revise the software documentation to be consistent with a Moderate level of concern, since the information provided by the device is important and if erroneous, can lead to patient injury.

    As requested by the FDA, we have provided additional documentation on the E3200 software to support a Moderate level of concern.

I. Software Architecture Design Chart
II. Software Design Specifications
III. Software Development Environment Description

(1) Architecture Design Chart: These are attached below. MBG0851A and MBG0851B are the main documents that references the 11 PDF files.

MBG0851A - SW Architecture Design Charts E3000 Plus.pdf
MBG0851B - Software Description E3000 Plus.pdf

(a) e3000_plus_context.pdf
(b) e3000_plus.pdf
(c) handle_e3000_plus.pdf
(d) handle_system_and_irq.pdf
(e) handle_io_driver.pdf
(f) handle_audio.pdf
(g) handle_spp_communication.pdf
(h) handle_events.pdf
(i) handle_auto-off.pdf
(j) handle_heart_rate.pdf
(k) control mmi.pdf

(2) Design Specifications

The Software Design Requirements Specifications for the 3200 stethoscope has been attached below.

MBG0751C - SRC SW Requirement Specification for E3000 Plus.pdf

(3) Software Development Environment Description

The Software Development Environment Description for the 3200 stethoscope is attached below.
MBG0807a and MBG0851C are the main documents that cover the Software Quality Plan and Maintenance.
Support references have also been included.

MBG0807a SQA SW Quality Plan.pdf
MBG0851C - SMA SW Maintenance E3000 Plus.pdf

(a) MBG0849A - SVR SW Validation Report.pdf
(b) MBG0808A - STA SW Traceability Analysis E3000 Plus.pdf
(c) MBG0802a - SAS SW Acceptance Test Specification for E3000 Plus.pdf

11. In your response to our previous Q. 21, you have provided a risk assessment report. However, the report indicates that 2 activities have not been completed:

    a. 3M CVE Design validation

    The CVE is planned to be completed on Friday, June 5th.

    b. Wear test of new bayonet design

    See attachment - trh0909d E3000 plus Design verification report, Battery access torque

    Please clarify the final status of these two activities.

IFU = Instructions for Use

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601, Medical Electrical Equipment

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 5-4		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Radio-Frequency Wireless Technology in Medical Devices, January 3, 2007

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601, Medical Electrical Equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
IEC 60601-1	Part 1: General requirement for basic safety and essential performance	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
IEC 60601-1-2	Part 2: Electromagnetic Compatibility - Requirements and tests	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
IEC 60601-1-6	Part 1-6: Usability	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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Approvers: (Automatically populated from assigned approver list)

<<Approver List>>

Required Approvers: Hub team members

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E3200 User Guide – English Version

(Cover)

(Fit graphics of package front & copy to front cover)

(Inside Cover)

(Translations for user guide front copy)

(English Section)

(VERY BOLD "English" at top of each page within booklet. Consider black box with white Arial Black text)

3M™ Littmann® Electronic Stethoscope
Model 3200
With Ambient Noise Reduction

Introduction

Congratulations and thank you for choosing the 3M™ Littmann® Electronic Stethoscope Model 3200.

The Model 3200 brings you the very latest in advanced auscultation and wireless electronics technology in a highly ergonomic and easy-to-use format.

The Model 3200's combination of Ambient Noise Reduction technology, frictional noise dampening materials, electronic amplification (conventional bell / diaphragm modes plus an extended range mode), Bluetooth data transfer, and an all-new user interface takes you to the next level of performance and ease of use.

Whether you are auscultating infant, pediatric or adult patients, in quiet or noisy environments, or picking up difficult-to-hear heart and body sounds, you'll appreciate the technology that's been built into this latest electronic stethoscope bearing the Littmann® brand.

Don't miss the sounds you need to hear!

SAFETY INFORMATION

Please read, understand, and follow all safety information contained in these instructions prior to using this electronic stethoscope. Retain these instructions for future reference.

In the U.S.A. only

Caution: Federal law restricts this device to sale by or on the order of a physician

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Explanation of Safety Related Labels and Symbols

	Indicates Type B Equipment: The equipment provides protection against electrical shock and electrical current leakage. Applied parts are considered to be the complete chestpiece with diaphragm and binaural.
	Consult instructions for use.
IPX4	Protected against splashing liquid (chestpiece only).
	This product contains electrical and electronic components and must not be disposed of using standard refuse collection. Please consult local directives for disposal of electrical and electronic equipment.
	This product and packaging does not contain natural rubber latex.
	Indicates Category AP Equipment. Tested for use with flammable anesthetic mixture with air.

Explanation of Signal Word Consequences

⚠ **CAUTION:**	Indicates a hazardous situation, which, if not avoided, could result in minor injury and/or property damage.
NOTICE:	Indicates a hazardous situation, which, if not avoided, may result in property damage.

⚠ CAUTION

- **To reduce the risks associated with infection** follow all cleaning and disinfecting instructions included in this manual. Establish and follow a cleaning and disinfecting schedule.
- **To reduce the risks associated with very strong electromagnetic fields** avoid using the stethoscope near strong radio frequency signals or portable and/or mobile RF devices. If you hear sudden or unexpected sounds, move away from any radio transmitting antennas.
- **To reduce the risks associated with sharp edges** make sure that the soft sealing eartips are snapped firmly into position as shown in this manual. Use only Littmann replaceable eartips.
- **To reduce the risks associated with an incorrect result** store and operate this stethoscope only as instructed in this manual. As there is no acoustic (non-amplified) mode available with this stethoscope, replace the battery within two hours of the battery life icon beginning to flash in the LCD display. Replace battery with only type AA. Also, do not immerse the stethoscope in a liquid or subject it to any sterilization processes.
- **To reduce the risk associated with an electrical shock** do not use the stethoscope on patients without the stethoscope's diaphragm cover in place
- **The Model E3200 Electronic Stethoscope contains a Bluetooth Class 2 wireless data link.** This radio frequency data link operates at a frequency of 2.4 GHz using GFSK modulation and with a maximum transmit power of 2.5mW (0.00250 watts). The maximum radio frequency field strength generated by the stethoscope is below three volts per meter, a level that is considered safe to use with other medical devices. However, if electromagnetic interference is encountered due to the Bluetooth wireless data link, immediately move the stethoscope away from that device and/or turn the Bluetooth feature OFF.

NOTICE

- **To reduce the risks associated with environmental contamination** follow applicable regulations when disposing of this stethoscope. Properly dispose of, or recycle, spent batteries.
- **No modification of this equipment is allowed.** Use only authorized 3M service personnel to repair this stethoscope. Read, understand, and follow all the safety information on the battery package.

EMC Compliance

FCC Intentional Radiator Certification

3M Littmann Electronic Stethoscope Model 3200

FCC ID: DGFIPD3200

This equipment contains an intentional radiator approved by the FCC under the FCC ID numbers shown above. This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesirable operation.

NO MODIFICATION: Modifications to this device shall not be made without the written consent of the 3M Company. Unauthorized modifications may void the authority granted under Federal Communications Commission rules permitting the operation of this device.

Industry Canada radio frequency rules and regulations

IC: 458A-IPD3200

This Class A digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe A est conforme à la norme NMB-003 du Canada.

EMC compliance Europe

This equipment complies with the EMC requirements of the IEC 60601-1-2.

NOTE: **The official document is electronic. Paper copies are uncontrolled.**

Intended Use

The 3M™ Littmann® Electronic Stethoscope Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of selective frequency ranges. It can be used on any person undergoing a physical assessment.

Operator Profile

The 3M Littmann® Electronic Stethoscope Model 3200 is designed to be used by anyone who wishes to listen to sounds as described in the Intended Use section above. This manual provides complete information on how to operate the Model 3200 so that no additional operating training is required.

Functional Description

The Model 3200 electronic stethoscope picks up sounds, such as heart and lung sounds, from a patient's body. After amplification and filtering, the sounds are sent to the user through a binaural headset. The stethoscope chestpiece is designed for use with adult, pediatric, and infant patients.

The user interface for the stethoscope includes a 5-button keypad and an LCD display. Sound processing is carried out with the aid of a digital signal processor. Stethoscope power is provided by a single AA battery in the chestpiece. A power management system is included to prolong battery life. Using its Bluetooth wireless link, the stethoscope can exchange audio data with an external device such as a personal computer (PC).

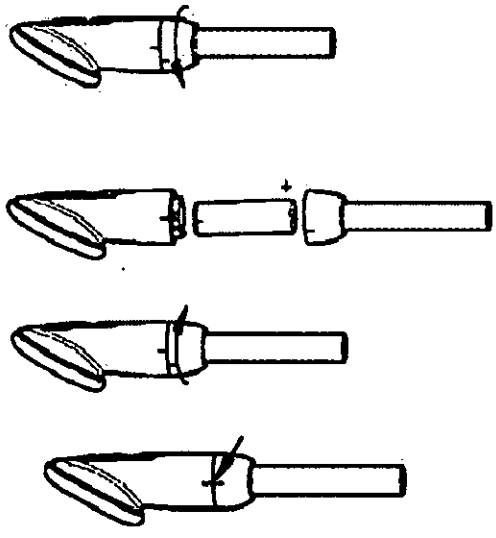
NOTE: **The official document is electronic. Paper copies are uncontrolled.**

Serial Number
Each Littmann Electronic Stethoscope Model 3200 comes with a unique serial number on the chestpiece for easy identification. Please record your serial number in this manual for future reference:

_____

INSTRUCTIONS FOR USE

1. Insert Battery
Insert AA battery (provided in package) into Stethoscope.

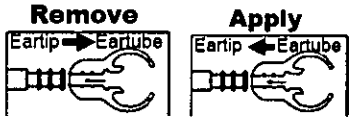


1. Hold chestpiece in one hand while slightly twisting the battery cap approximately 25° counter-clockwise. Remove battery cap.
2. Insert new battery with positive end out (plus sign will be visible in the battery compartment)
3. Remount battery cap, twisting cap approximately 25° clockwise until locked.
4. Make sure the two marks are aligned

2. Position Headset
Eartips should point in a forward direction as you insert them into your ear canals. When ear tips are properly positioned, diaphragm will face towards your body.

Your new Littmann Electronic Stethoscope is designed to give you a very comfortable, acoustically sealed fit. It comes with two sizes of eartips to assure a perfect fit. The large eartips are pre-installed. Smaller eartips are included in package. Please choose the set that is most comfortable for you.

To remove eartips, pull eartips firmly away from eartube. To apply new eartips, push eartip firmly onto eartube to secure.



NOTE: **The official document is electronic. Paper copies are uncontrolled.**

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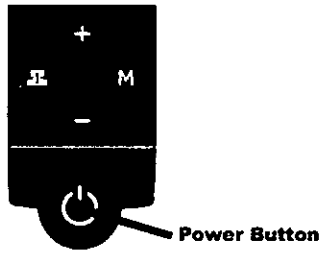
3. Adjust Headset for Comfort

To reduce spring tension in the headset, hold each eartube at the bend near the eartips and gradually pull apart until fully extended (180 degrees).

To increase spring tension, grasp the headset with one hand where the metal eartubes enter the plastic tubing, and squeeze until the plastic tubing on one eartube touches the other. Repeat as necessary.

4. Turn On / Off

This stethoscope comes equipped with an advanced power management system.



- **Manual Turn On:** Depress and release power button. LCD display will activate, indicating stethoscope is on.
- **Manual Turn Off:** Depress and **hold** power button for two seconds. LCD display will shut off, indicating stethoscope is off.
- **Auto Off with Standby Feature:** After manual turn-on, stethoscope will stay on during use, but switch to a power-saving "standby" mode after 20 seconds of inactivity. LCD display will display the Littmann® logo during standby mode. When stethoscope diaphragm or any button is pressed, LCD display settings will reappear and stethoscope will be ready to use. After two hours of non-use, the stethoscope will leave standby mode and fully power off. You may customize on-time and off-time to meet your own personal needs. See **Custom Configuration** section below.
- **LCD Display Backlight:** Backlight options are available for use at low ambient light levels. By default, depressing and releasing the power button at any time will illuminate the LCD display for five seconds.

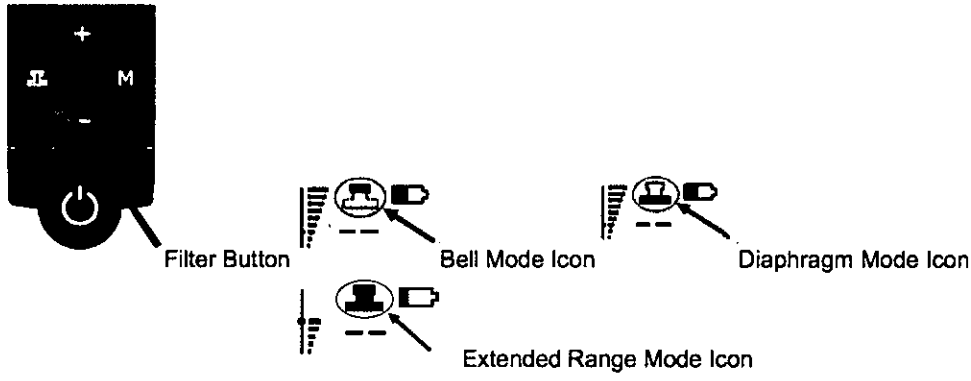
5. Select Filter

This electronic stethoscope allows the user to select between three different digital frequency filters to better emphasize the specific patient sounds of interest.

- The Bell mode amplifies sounds from 20 – 1000Hz, but emphasizes lower frequency sounds between 20 – 200 Hz.
- The Diaphragm mode amplifies sounds from 20 – 2000Hz, but emphasizes the sounds between 100 – 500Hz.
- The Extended Range mode amplifies sounds from 20 – 2000Hz similar to the Diaphragm Mode, but provides more low frequency response between 50 – 500Hz.

The default setting is the Diaphragm filter. Instructions for changing the default filter setting are given in the **Custom Configuration** section below.

To select filter: Depress and release filter button (as shown in diagram) until desired filter mode appears on the LCD display.



6. Adjust Sound Amplification Level

The Model 3200 sound level can be amplified in 8 increments up to 24X amplification of a non-electronic (cardiology-level) stethoscope. Level 1 is equal to a non-electronic stethoscope. Level 9 is equal to 24X amplification of a non-electronic stethoscope. The greater the amplification, the more bars you will see.

A default start-up amplification level can be set using the instructions provided in the **Custom Configuration** section below. The default setting is marked by the box on the vertical bar shown in the volume icon in the LCD display. The illustration shows the default amplification setting at Level 3.

- **Increase Amplification:** Press (+) button until desired amplification level is achieved
- **Decrease Amplification:** Press (–) button until desired amplification level is achieved

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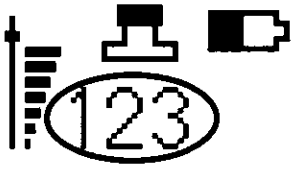
7. Monitor Patient Heart Rate

The Model 3200 detects and displays an acoustic-based heart rate when presented with consistent heart sounds (heart rate variation < 10%). **It takes five seconds to compute the initial heart rate and updates are provided every two seconds. The heart rate will then be displayed for 10 seconds after removal of the chestpiece from the patient.** Prior to the initial reading, the display shows two dashes (--). For heart rates outside a range of 30-199 bpm, the display will also show two dashes (--).

The acoustic-based heart rate display functions best when the Model 3200 is placed near the apex of the patient's heart and can be monitored while using any filter mode and/or volume level. If the heart rate changes from consistent to inconsistent or if there is excessive ambient noise, patient movement or lung sounds during auscultation, the heart rate display number will display two dashes (--).



8. Monitor Battery Life

Battery life is indicated by an icon in the LCD display.

The Model 3200 comes with a AA Alkaline battery. Battery will provide approximately 50-60 hours of continuous use, depending on the frequency of Bluetooth data transfers. In a typical clinical setting, this represents about three months of use.

As the battery life depletes, the icon will change as follows:

= 50 -100% battery life

= 25 – 50% battery life

= 10 – 25% battery life

= 0 – 10% battery life

The battery icon begins to blink when only a few hours of battery capacity remains.

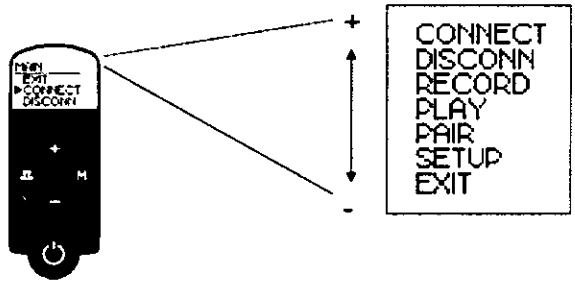
⚠**CAUTION:** When the battery is completely depleted the scope becomes inoperable. No sound will be transmitted without a functioning battery.

IMPORTANT! NiMH (rechargeable) and Lithium batteries may also be used in the Model 3200. However, battery type must be specified to ensure a reliable battery life indication (see **Custom Configuration** section below).

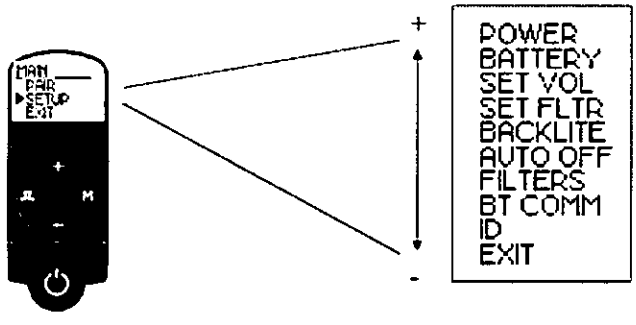
9. Custom Configuration

The Model 3200 stethoscope has several operational settings that can be changed using its configuration menu system. Within this menu system, the (+) and (-) buttons are used for scrolling and the (M) button is used for selecting options. The Filter button acts as an escape key, used for returning to the previous menu or to the operating mode of the stethoscope.

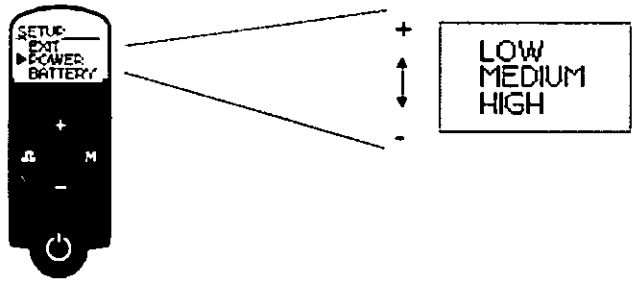
To access the Main menu: Depress and release the (M) button. The Main menu will be displayed (NOTE: Only 3 options will be visible at a time. All options can be viewed in sequence upon scrolling with either the (+) or (-) buttons):



To enter the Setup Menu: Use the (-) button to scroll down the list of Special Functions until SETUP is highlighted. Select the SETUP option by pressing and releasing the (M) button. This will display the following menu:



To select the power setting: Select the POWER option in the SETUP menu. Use the (-) and (+) buttons to scroll through the list of power settings. Press and release the (M) button to select a setting.



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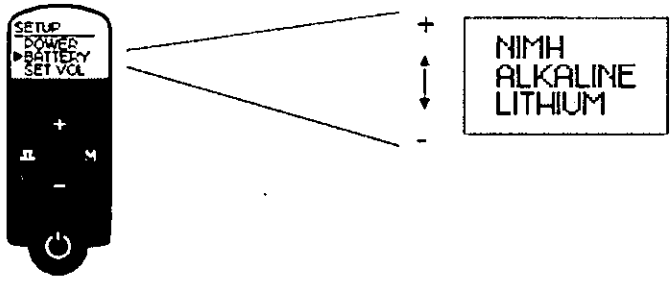
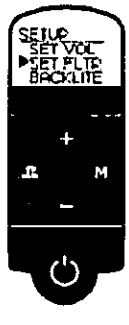
The power settings provide different degrees of power consumption. In general, the longer the stethoscope remains in an active mode, the greater its power consumption. The factory default is the MEDIUM level. (NOTE: The Auto Off power management feature is further described below)

To select the battery type: Select the BATTERY option in the SETUP menu. Use the (-) and (+) buttons to scroll through the list of battery types. The LITHIUM battery is a non-rechargeable cell especially recommended for low-temperature operation of the stethoscope. The NIMH battery is rechargeable (external charger required). Press and release the (M) button to select a setting. The factory default is the ALKALINE battery.

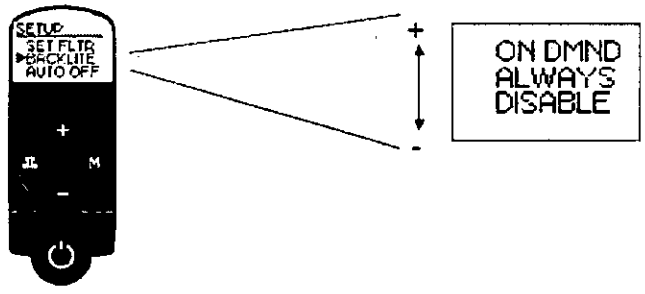


To select the preset (default) volume level: Select the SET VOL option in the SETUP menu. Press and release the (M) button to select the current volume level as default. The factory default is level 3.

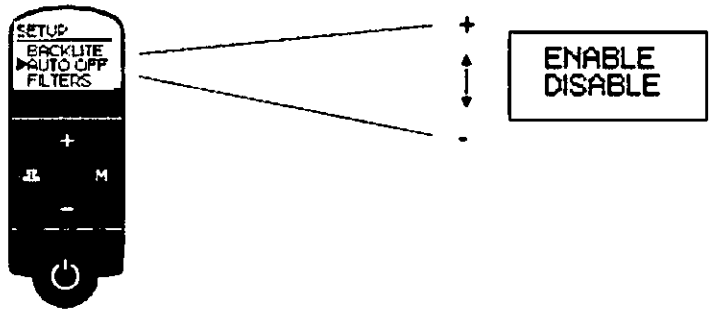
To select the preset (default) filter setting: Select the SET FLTR option in the SETUP menu. Press and release the (M) button to select the current filter as default. The factory default is the diaphragm filter.



To select the backlight setting: Select the BACKLITE option in the SETUP menu. Use the (-) and (+) buttons to scroll through the list of options. Press and release the (M) button to select. The factory default is ALWAYS. The ALWAYS option will illuminate the backlight at all times at a reduced level while the stethoscope is powered on and not in standby mode. The ON DMND option will illuminate the backlight for five seconds by depressing and releasing the power button. The DISABLE option disables the backlight at all times and will conserve power.



To select Auto Off power management: Select the AUTO OFF option in the SETUP menu. Use the (-) and (+) buttons to scroll through the list of options. Press and release the (M) button to select. The factory default is ENABLE.



Two different settings work together to influence the length of time the Model 3200 is on full power: The AUTO OFF setting (ENABLE vs. DISABLE) and the POWER setting (HIGH, MEDIUM, and LOW - HIGH setting uses more battery power, LOW setting uses less battery power). To increase battery life, ENABLE the Auto Off feature and select the LOW power setting.

When the AUTO OFF feature is enabled, the stethoscope will enter standby mode after a period of time determined by the POWER setting if there is no contact detected on the diaphragm AND the buttons are not activated. When the AUTO OFF feature is disabled, the stethoscope will enter standby mode after a period of time determined by the POWER setting from the last button activation. In addition, when the AUTO OFF feature is disabled, there will be an audible alert 10 seconds prior to entering standby mode. After entering standby mode, the Model 3200 will be powered on when contact is detected on the diaphragm or by button activation. Otherwise, the Model 3200 will completely power off after the period of time determined by the POWER setting (see below).

With AUTO OFF feature ENABLED:

SETUP	Options	Detail
POWER	HIGH	Remains on full power for **30 seconds** before entering standby
		Remains in standby for **5 hours** before powering off
		Backlight remains lit for **5 seconds** after pressing the power button
	MEDIUM	Remains on full power for **20 seconds** before entering standby
		Remains in standby for **2 hours** before powering off
		Backlight remains lit for **5 seconds** after pressing the power button
	LOW	Remains on full power for **10 seconds** before entering standby
		Remains in standby for **30 minutes** before powering off
		Backlight remains lit for **3 seconds** after pressing power button

With AUTO OFF feature DISABLED:

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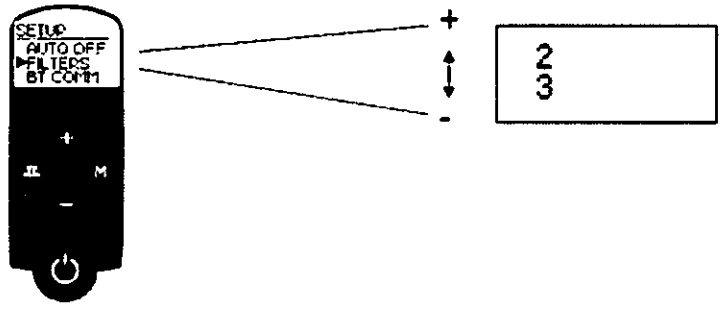
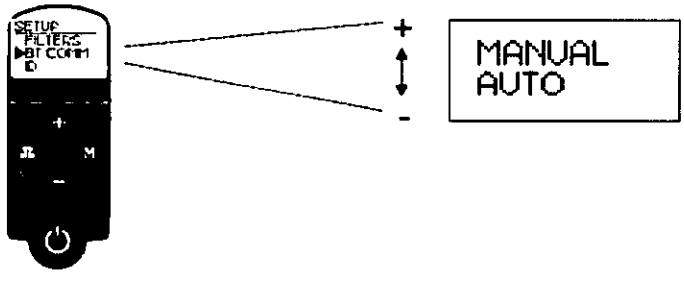
SETUP	Options	Detail
POWER	HIGH	Remains on full power for **7 minutes** before entering standby
		Remains in standby for **5 hours** before powering off
		Backlight remains lit for **5 seconds** after pressing power button
	MEDIUM	Remains on full power for **5 minutes** before entering standby
		Remains in standby for **2 hours** before powering off
		Backlight remains lit **5 seconds** after pressing power button
	LOW	Remains on full power for **3 minutes** before entering standby
		Remains in standby for **30 minutes** before powering off
		Backlight remains lit **3 seconds** after pressing power button

To select the number of filter modes: Select the FILTERS option in the SETUP menu. Use the (-) and (+) buttons to scroll through the list of options. With option "2", the FILTER button cycles between two filters modes (bell and diaphragm). With option "3", the FILTER button cycles through three filter modes (bell, diaphragm, and extended range). Press and release the (M) button to select. The factory default is "3" filters.



To select Bluetooth mode: Select the BT COMM option in the SETUP menu. Use the (-) and (+) buttons to scroll through the list of options. The MANUAL option means that the Bluetooth link can be used for data transfers but requires user activation. The AUTO option means that the Bluetooth link is continuously powered and ready to connect to an external device to which it has been previously paired. Press and release the (M) button to select an option. The factory default is MANUAL.



To obtain model and software version information: Select the ID option in the SETUP menu. Use the (-) and (+) buttons to scroll through the list of reference numbers. Press (M) to return to the operating mode of the stethoscope.

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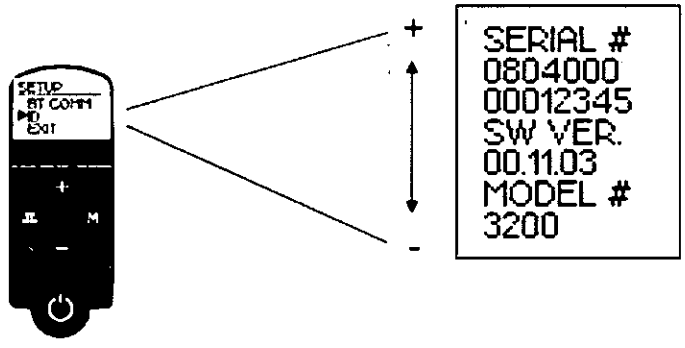

To leave the Main menu: Press the Filter button or press the (M) button to select the EXIT option. This will return the stethoscope to its normal operating state.

11. Using the Bluetooth Interface

The Bluetooth interface provides a means of exchanging audio data with external devices such as a Bluetooth-enabled PC. Audio data can be sent in near real time, permitting the visual presentation, recording, and analysis by applications software complying with communication protocols used by the Model 3200 stethoscope.

IMPORTANT! The Model 3200 uses a Class 2 Bluetooth link, with a maximum range of 10m. The Bluetooth range will be reduced when objects (walls, furniture, people, etc) are in-between the Model 3200 and the external device. To improve Bluetooth communication, reduce the distance and/or allow a line of sight between the Model 3200 and the external device.

In order to transfer data between two Bluetooth devices, they must first be "paired" electronically. Pairing is a discovery and authentication process that allows your Bluetooth equipped Model 3200 stethoscope to communicate with another Bluetooth equipped device and establishes the link between these two devices as a trusted pair. The pairing process requires user operations to be performed on both the Model 3200 and the external device. While the Model 3200 can remember trusted pairing with up to eight different Bluetooth devices, it will only communicate with one paired device at a time. In addition, you cannot pair a Model 3200 with a second Model 3200.

How to pair the Model 3200 with an external device:

1. **Initiate pairing process**: On the Model 3200, depress and release the (M) button. The Main menu will be displayed. Use the (-) button to scroll down to the PAIR option. Select this option by pressing and releasing the (M) button. The LCD screen will signal that pairing is in progress with the following animated display:

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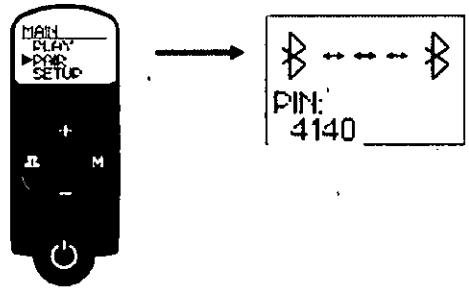
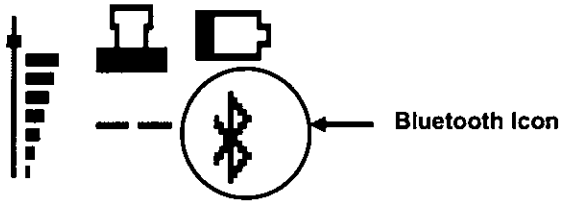


During the pairing process the Model 3200 will make itself discoverable to other Bluetooth equipped devices. Note: The Personal Identification Number (PIN) for Bluetooth pairing is displayed in the lower left-hand corner of the LCD screen

2. **Select Model 3200 stethoscope on external Bluetooth device**: Follow the pairing instructions found with your Bluetooth equipped device. In general, you will need to make sure that the Bluetooth mode is enabled on the device, and once the Model 3200 has indicated the external device has been found, you may need to confirm the connection on the external device. Please remember that the distance between the Model 3200 and the Bluetooth device is limited to no more than 10 meters. If pairing is successful, the LCD display of the Model 3200 will show a flashing Bluetooth icon and the stethoscope will be ready for wireless operations. Once the Model 3200 is connected to the external device, the Bluetooth icon will stop flashing and be displayed continuously.

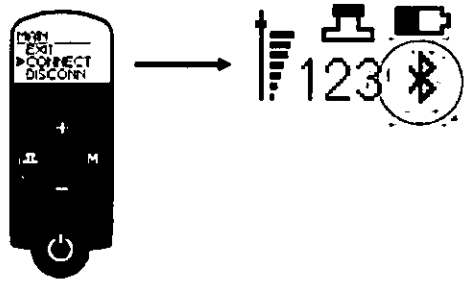


If the Bluetooth connection with the external device is subsequently lost or times out, the Bluetooth icon will disappear from the LCD display.

How to transfer real-time data to an external device:

1. Ensure the Model 3200 is paired with the external device.

2. Depress and release the (M) button. Select the CONNECT option by again pressing and releasing the (M) button. The LCD screen will signal that the Bluetooth link is active. The stethoscope will automatically return to operational status. Consult application software for details on initiating real-time transfer, the process may vary by computer platform utilized.



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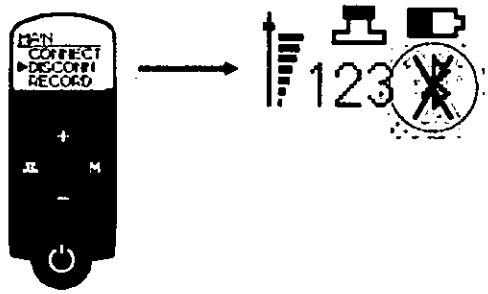
When connected by a Bluetooth link, external Bluetooth-enabled devices may take control of the display and keypad of the Model 3200 stethoscope. The external device may also transfer audio playback or other information through the Model 3200 headset. When the external device transfers audio playback back to the stethoscope, the sounds will be preceded by a beep.

A Bluetooth connection with the stethoscope will automatically be ended if no data transfers occur in a 90 second period. Alternatively, the connection can be manually ended using the DISCONN (disconnect) option of the Main menu. If you are listening to the Model 3200 electronic stethoscope using its Bluetooth feature and you exceed the maximum communication range of approximately 10 meters, you may hear a rapid series of beeps. Should this occur, shorten the physical distance between your Model 3200 and the Bluetooth equipped device.



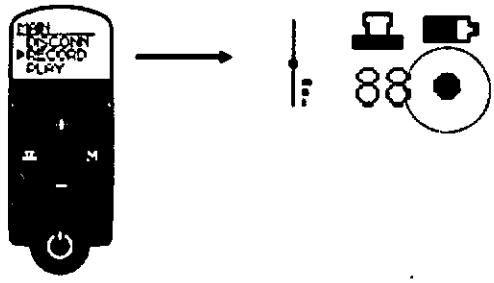
12. Using Onboard Recording

Onboard recording provides a means to acquire and play one auscultation sound track for a maximum of 29 seconds. This track can be uploaded to an external device using the Bluetooth link and the software accompanying the Model 3200 stethoscope.

How to record a sound track:

1. **Enter the recording mode:** Depress and release the (M) button. The Main menu will be displayed. Use the (-) button to scroll to the RECORD option.

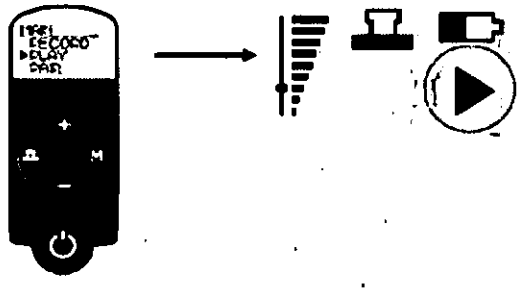
2. **Begin the recording:** Depress and release the (M) button. The stethoscope will start recording and the LCD screen will show a "recording" icon.



3. **End the recording:** Depress and release the (M) button. The stethoscope will stop recording and the recording icon will disappear from the LCD display. If the time between the beginning and ending of the recording session is greater than 29 seconds, only the last 29 seconds will be saved.

How to play back a sound track:

1. **Enter the playback mode:** Depress and release the (M) button. The Main menu will be displayed. Use the (-) button to scroll to the PLAY option. Select this option by pressing and releasing the (M) button. The LCD screen will show a "play" icon and the sound track will loop continuously.



2. **End playback**: Depress and release the (M) button. The stethoscope will stop playing the sound track and will return to its previous operational mode.

Uploading a sound track to an external device:

1. **Prepare the external device to receive the sound file.** Start the software program on the external device. Consult application software for details.

2. **Initiate a Bluetooth connection with the Model 3200.** Use the same procedure as described above for initiating real-time data transfers to an external device.

3. **Return to operating mode:** When transmission of the sound track is complete, the Bluetooth link to the external device can be disconnected and the Model 3200 will return to its previous operating mode.

13. Other Operating Considerations

Operating range is -22° to 104°F (-30° to 40°C), 15 to 93% relative humidity.
Storage and transport range is -40° to 131° F (-40° to 55°C), 15 to 93% relative humidity.

To extend the life of your stethoscope, avoid extreme heat, cold, solvents and oils. Remove the battery whenever the stethoscope will not be used for several months.

If you plan to use the stethoscope below 0°F (-18°C) you should use a lithium battery to insure proper function.

Failure to follow care and maintenance recommendations could result in damage to the internal components of the Littmann Electronic Stethoscope. Internal damage could cause malfunction of the product, ranging from a slight decrease in auditory response to complete failure of the product.

If you experience any problems with the electronic stethoscope, do not attempt to repair it yourself. Please notify our 3M Health Care Service Center for directions on shipping and receiving.

14. In the U.S.A. only

Caution: Federal law restricts this device to sale by or on the order of a physician

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MAINTENANCE & WARRANTY

Cleaning
Cleaning of stethoscope should be done between each patient use.

Cleaning the Chestpiece
Under normal conditions, it is unnecessary to remove the diaphragm for cleaning. The diaphragm can easily be cleaned by using an alcohol wipe. If however, it is necessary to remove the diaphragm, carefully follow the instructions below:

- **Diaphragm Removal**: With diaphragm side up, using a thumbnail, lift the underside portion of the diaphragm out of its designated groove, and peel it off of the chestpiece. The groove that holds the diaphragm in place can be cleaned by sliding the edge of an alcohol swab around the groove. All parts of the chestpiece can be wiped down with alcohol. IMPORTANT: The stethoscope should not be immersed in any solution. Excess liquid used in the cleaning process may result in moisture getting into the internal components.

- **Diaphragm Reassembly**: Once the diaphragm is completely dry, insert the diaphragm into the groove of the rim, starting at one point, and run your finger around the diaphragm until it is seated back in the groove.

Cleaning Other Parts of the Stethoscope
Eartips, eartubes, plastic tubing and chestpiece can be wiped clean with alcohol. Eartips may be removed for a more thorough cleaning.

***NOTICE*: Do not immerse the stethoscope in any liquid or subject it to any sterilization process!**

Service & Warranty Program
Your Littmann Electronic Stethoscope comes with the finest service and warranty policy in the industry. The Littmann Electronic Stethoscope Model 3200 is warranted against any defects in material and manufacture for a period of two years. If a material or manufacturing defect is discovered during the warranty period, repairs will be made without charge upon the return of the instrument to 3M, except in cases of obvious abuse or accidental damage.

For Maintenance or Repair Services

Please include your name, physical address, e-mail address, and phone number inside with your stethoscope.

In the U.S.A., send your stethoscope directly to:

3M Health Care Service Center
3M Bldg 502-1W-01
3350 Granada Ave N
Suite 200
Oakdale, MN 55128
1-800-292-6298

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In Canada, send your stethoscope directly to:

3M Health Care Service Centre
3M Canada, Inc.
80 Enterprise Drive South
London, Ontario
Canada, N6N1C2
1-800-563-2921

Outside of the U.S.A. and Canada, contact your local 3M subsidiary for maintenance and repair information.

APPENDIX

Declaration – Electromagnetic Emissions		
The 3M Littmann® Electronic Stethoscope, Model 3200, is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 3200 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment –guidance**
RF emissions CISPR 11	Group 2	Model 3200 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	Model 3200 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

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Declaration – electromagnetic immunity			
The 3M Littmann® Electronic Stethoscope, Model 3200, is intended for use in the electromagnetic environment specified below. The customer or the user of Model 3200 should assure that it is used in such an environment			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for supply lines ± 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial magnetic field or hospital environment
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycle 70 % UT (30 % dip in UT) for 25 cycle < 5% UT (>95 % dip in UT) for 5 sec	Not applicable	

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Declaration – electromagnetic immunity - continued

The 3M Littmann® Electronic Stethoscope, Model 3200, is intended for use in the electromagnetic environment specified below. The customer or the user of Model 3200 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Model 3200 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	$d = 1{,}2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1{,}2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range, [b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 3200 is used exceeds the applicable RF compliance level above, the Model 3200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 3200.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the 3M™ Littmann® Electronic Stethoscope Model 3200

The Model 3200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 3200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 3200 as recommended below, according to the maximum output of the communications equipment.

Rated maximum output power of transmitter, P [W]	**Separation distance according to frequency of transmitters, d [m]**		
	150 kHz to 80 MHz	80 Mz to 800 MHz $d = 1{,}2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Revision History

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		Ref. Certif. No.
IEC / IECEE CB SCHEME		SE-56568

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE

CERTIFICAT D'ESSAI OC

Product Produit	Stethoscope
Name and address of the applicant Nom et adresse du demandeur	3M Health Care, 3M Center, Building 270-4N-09, Maplewood, MN 55144-1000, Patient Assessment Laboratory 3M Medical Products, UNITED STATES
Name and address of the manufacturer Nom et adresse du fabricant	Same as applicant
Name and address of the factory Nom et adresse de l'usine	(b) (4) [redacted]
Ratings and principal characteristics Valeurs nominales et caractéristiques principales	Type B, IPX4, Battery type AA
Trademark (if any) Marque de fabrique (si elle existe)	3M™ Littmann®
Model / Type Ref. Ref. De type	E3100 and E3200
Additional information (if necessary) Les informations complémentaires (si nécessaire)	See page 2
A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la	IEC 60601-1:2005 and C1 IEC 60601-1-6:2006
As shown in the Test Report Ref. No. which forms part of this Certificate Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat	809546

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme National de Certification

Intertek Semko AB
Box 1103
SE-164 22 Kista, Sweden
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Intertek ETL SEMKO

Signature:

Mikael Goffhé

Date: 10 December 2008

Mandated reviewer: PEL

DAH/ASG

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Additional information (if necessary)

Biocompatibility according to EN ISO 10993 has not been evaluated.

Bluetooth on E3200 has not been evaluated.

Date: 10 December 2008

Signature:

Test Report issued under the responsibility of

Intertek

IEC 60601-1 / EN 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No.....:	809546-1
Date of issue.....:	2008-12-10
Total number of pages .....:	155
CB Testing Laboratory.....:	Intertek Semko AB
Address .....:	Box 1103 SE-164 22 Kista SWEDEN
Applicant's name.....:	3M Health Care
Address .....:	3M Center, Building 270-4N-09 Maplewood, MN 55144-1000 Patient Assessment Laboratory 3M Medical Products, USA
Test specification:	
Standard.....:	IEC 60601-1: 2005
Test procedure .....:	CB/CCA
Non-standard test method.....:	N/A
Test Report Form No.....:	IEC60601_1D
Test Report Form Originator .....:	Underwriters Laboratories Inc.
Master TRF.....:	Dated 2006-07

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Test item description .....:	Stethoscope
Trade Mark .....:	3M™ Littmann®
Manufacturer .....:	(b) (4) [redacted]
Model/Type reference .....:	
Ratings .....:	Type B, IPX4, Battery type AA

Testing procedure and testing location:

☒ **CB Testing Laboratory:**

Testing location/ address.....: Torshamnsgatan 43
SE-164 22 Kista
SWEDEN

☐ **Associated CB Test Laboratory:**

Testing location/ address.....:

Tested by (name + signature) .....: Ansis Graufelds

Approved by (+ signature).....: Peter Lymeus

☐ Testing procedure: TMP

Tested by (name + signature) .....:

Approved by (+ signature).....:

Testing location/ address.....:

☐ Testing procedure: WMT

Tested by (name + signature) .....:

Witnessed by (+ signature).....:

Approved by (+ signature).....:

Testing location/ address.....:

☐ Testing procedure: SMT

Tested by (name + signature) .....:

Approved by (+ signature).....:

Supervised by (+ signature) .....:

Testing location/ address.....:

☐ Testing procedure: RMT

Tested by (name + signature) .....:

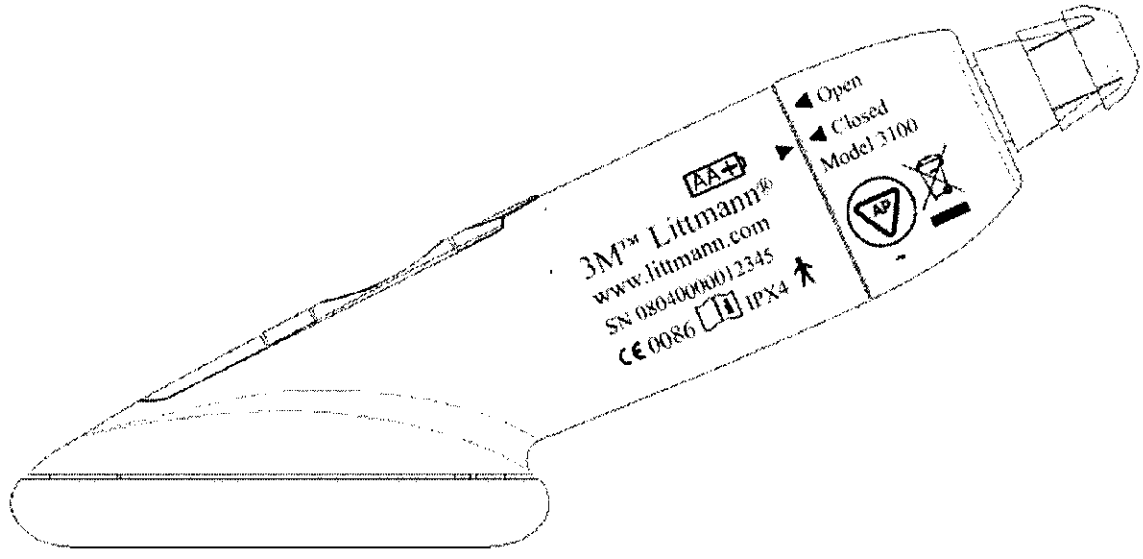
Approved by (+ signature).....:

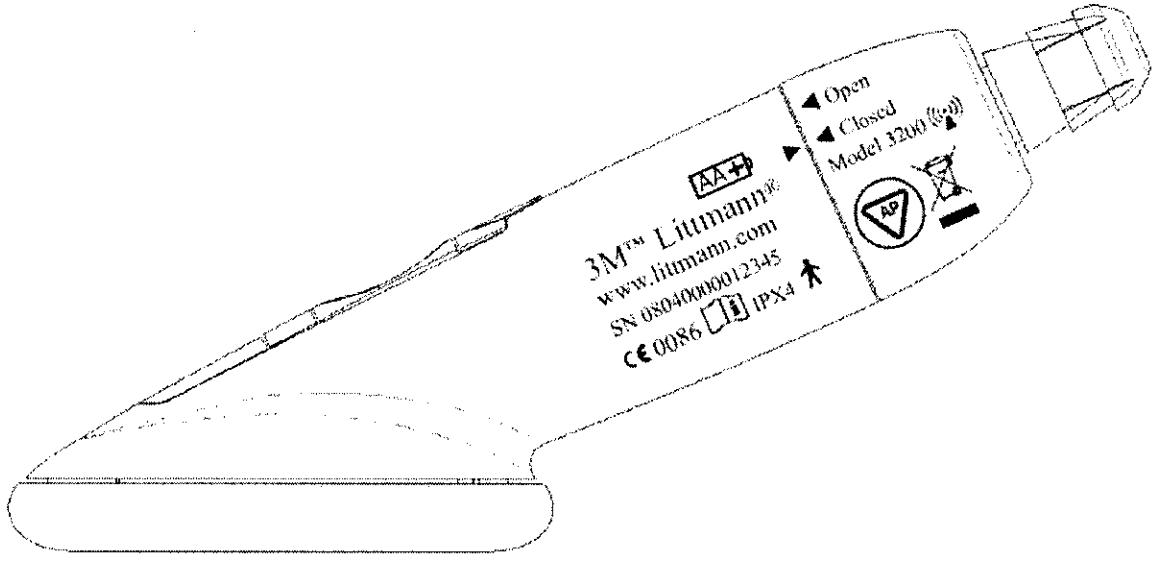
Supervised by (+ signature) .....:

Testing location/ address.....:

Summary of testing	
Tests performed (name of test and test clause):	**Testing location:**
All applicable tests	**Intertek Semko AB**
Summary of compliance with National Differences:	
-	

Copy of marking plate





GENERAL INFORMATION

Test item particulars (see also Clause 5):

Classification of installation and use	:	Hand-held
Device type	:	Stethoscope
Clinical application	:	Medical diagnostic
Mode of operation	:	Continuous
Surface temperature of APPLIED PART	:	40°C
Supply connection	:	Internally powered
Accessories and detachable parts included	:	-
Other options include	:	-

Testing

Date of receipt of test item(s)	:	2008-08-04
Dates tests performed	:	2008-08-04 to 2008-09-17

Possible test case verdicts:

- test case does not apply to the test object	N / A
- test object does meet the requirement	Pass (P)
- test object does not meet the requirement	Fail (F)

Abbreviations used in the report:

- normal condition	N.C.	- single fault condition	S.F.C.
- operational insulation	OP	- basic insulation	BI
- basic insulation between parts of opposite polarity	BOP	- supplementary insulation	SI
- double insulation	DI	- reinforced insulation	RI

General remarks:

"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report a point is used as the decimal separator.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

General product information:

The electronic stethoscope model 3100 & 3200 is intended for medical diagnosis. It may be used for the detection and amplification of heart, lungs, arteries, veins and other internal organs. It can be used on any person undergoing a physical assessment.

The electronic stethoscope picks up sounds from patients body, amplifies and filters it. The sounds are sent to the user through a binaural headset.

The user interface for the stethoscope includes a 5 button keypad and an LCD display. Sound processing is carried out with the aid of a digital signal processor. The model 3200 does also have a Bluetooth wireless link. The stethoscope can exchange audio data with an external device such as a PC, and possibility of onboard recording.

The Stethoscope power is provided by a single AA battery in the chest piece. A power management system is included to prolong battery life.

INSULATION DIAGRAM

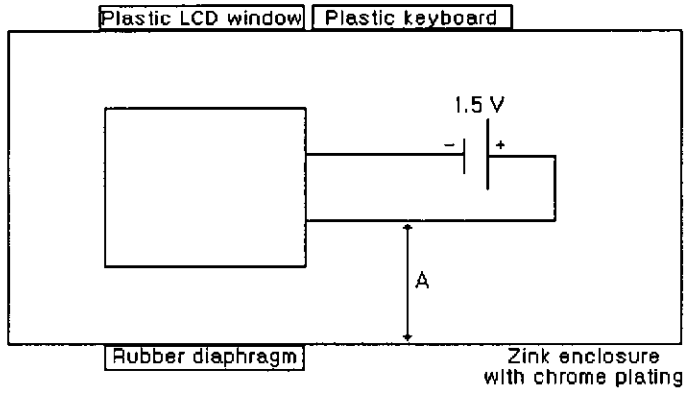


	TABLE: To insulation diagram						P
Area	Insulation type: OPERATIONAL / BASIC / SUPPLEMENTARY / DOUBLE / REINFORCED	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A	DI	1.5	3.4	1.6	3.5	1.65	
B							
C							
D							
E							
F							
G							
H							
I							

NSULATION DIAGRAM CONVENTIONS:

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.

Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional

Applied parts are extended beyond the equipment enclosure and terminated with an arrow.

Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

Blocks containing the letter "Z" indicate protective impedance.

Operational Insulation (OP) - indicates insulation that may be required for function of the equipment, but is not required or relied on for compliance with the requirements of clauses 17, 20 and 57.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
4	**GENERAL REQUIREMENTS**		P
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse		P
	Definitions/ requirements using the term PATIENT considered as applicable to individual(s) for whom ME EQUIPMENT or ME SYSTEM is designed for	Noted	P
4.2	A RISK MANAGEMENT PROCESS complying with ISO 14971 was performed .....:	Described in Risk Management Plan (RMF)	P
	ISO 14971applied with the specified considerations:		P
	– Term "medical device" assumed same as ME EQUIPMENT or ME SYSTEM		P
	– Term "fault conditions" not limited to SINGLE FAULT CONDITIONS		P
	– Policy to determine acceptable RISK, and acceptability of RESIDUAL RISK(s) established by MANUFACTURER		P
	– Verifiable requirements of this and associated standards complied with for particular RISKS including RESIDUAL RISKs presumed to be acceptable unless there was OBJECTIVE EVIDENCE to the contrary		P
	Requirements for inspection of RISK MANAGEMENT FILE considered satisfied based on MANUFACTURER'S established RISK MANAGEMENT PROCESS, acceptable levels of RISK, and acceptable RESIDUAL RISK(s) according to the policy for determining acceptable RISK		P
4.3	ESSENTIAL PERFORMANCE functions identified according to MANUFACTURER'S policy for RISK acceptability in RISK MANAGEMENT FILE	See RMF – Questionnaire Part 2 Question C.2.34	P
	ESSENTIAL PERFORMANCE functions maintained following particular tests as applicable		P
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE	See RMF – Lifetime Of The Product: Warranty period of 2 years with a service life (design life) of 5 years. See also DRS 1.1	P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
4.5	Alternative means of addressing particular RISKS considered acceptable based on MANUFACTURER'S justification that RESIDUAL RISKS resulting from application of alternative means are ≤ to RESIDUAL RISKS resulting from requirements of this standard		N/A
4.6	RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS subjected to the requirements for APPLIED PARTS, except for 7.2.10		N/A
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by 4.2		P
	a) ME EQUIPMENT with a single means of reducing a RISK having negligible probability of failure considered SINGLE FAULT SAFE, or	Also see appended Table 8.10	P
	b) a SINGLE FAULT CONDITION occurred, except as follows:		P
	– initial fault detected during EXPECTED SERVICE LIFE of ME EQUIPMENT and before a second means for reducing a RISK failed (e.g. suspended masses with MECHANICAL PROTECTIVE DEVICES), or		N/A
	– probability that the second means of reducing the RISK would fail during EXPECTED SERVICE LIFE of ME EQUIPMENT was negligible		N/A
	Two failures resulting from a SINGLE FAULT CONDITION causing a secondary SINGLE FAULT CONDITION considered as one SINGLE FAULT CONDITION		P
	Only one fault applied at a time during the tests under SINGLE FAULT CONDITION		P
	Results of RISK ANALYSIS used to determine which failures should be tested		P
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically		P
	RISK associated with failure of component during EXPECTED SERVICE LIFE of ME EQUIPMENT taken into account to evaluate if a component should be subjected to failure simulation		P
	Evaluation done by applying the principles of RISK MANAGEMENT taking into account reliability, TENSILE SAFETY FACTORS, and rating of components		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	During simulation of SINGLE FAULT CONDITIONS, highly probable or undetectable component failures simulated		P
	Requirements and relevant tests of this clause not applied to failures of DOUBLE or REINFORCED INSULATION or COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS		P
	Specific requirements and tests associated with SINGLE FAULT CONDITIONS in 13.2 applied together with the tests for failures identified from evaluation of the results of RISK ANALYSIS		P
	SINGLE FAULT CONDITIONS applied one at a time as described in 13.2 did not lead directly to the HAZARDOUS SITUATIONS in 13.1, or any other outcome resulting in an unacceptable RISK		P
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used in accordance with their applicable ratings, except as specified, or by RISK MANAGEMENT PROCESS		P
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following:		P
	a) applicable safety requirements of a relevant IEC or ISO standard ..... :		P
	b) requirements of this standard applied in the absence of a relevant IEC or ISO standard		P
	Tests conducted on motors (13.28 & 13.2.13.3) and transformers (15.5.3) together with evaluation of their insulation system according to Table 22 represent all required tests		N/A
	ME SYSTEM components providing isolation from non-ME EQUIPMENT evaluated to Clause 16		N/A
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided because a fault in a particular component can generate an unacceptable RISK	See appended Table 8.10	P
	COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS selected and evaluated consistent with their conditions of use and reasonable foreseeable misuse during EXPECTED SERVICE LIFE of ME EQUIPMENT by reviewing RISK MANAGEMENT FILE	PTC	P
4.10	Power supply		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
4.10.1	ME EQUIPMENT is suitable for connection to a SUPPLY MAINS, specified to be connected to a separate power supply, can be powered by an INTERNAL ELECTRICAL POWER SOURCE, or a combination of the three .....:	Internal electrical power source	P
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS is 250 V for HAND-HELD ME EQUIPMENT (V) ..... :		N/A
	– 250 V d.c. or single-phase a.c., or 500 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V)..... :		N/A
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS		N/A
	SUPPLY MAINS characteristics are as follows:		N/A
	– overvoltage category II for mains transients, except when a higher category specified by MANUFACTURER ..... :		N/A
	– no voltage >110 % or < 90 % of NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (% of NOMINAL voltage) ..... :		N/A
	– voltages that are practically sinusoidal and forming a practically symmetrical supply system in case of poly-phase supply		N/A
	– a frequency of ≤ 1 kHz (Hz)..... :		N/A
	– a frequency deviation of ≤ 1 Hz from NOMINAL frequency up to 100 Hz and ≤ 1 % from NOMINAL frequency from 100 Hz to 1 kHz (Hz, or % deviation from NOMINAL frequency) ..... :		N/A
	– protective measures per IEC 60364-4-41..... :		N/A
	– a d.c. voltage (as measured by a moving coil meter or equivalent method) having a peak-to-peak ripple ≤ 10 % of average value (V dc)..... :		N/A
	Peak voltage applied when peak-to-peak ripple exceeded 10 % of average value		N/A
	Additional safety measures applied to ME EQUIPMENT or ME SYSTEM intended to be operated from a SUPPLY MAINS with characteristics different from SUPPLY MAINS described in this clause ..... :		N/A
4.11	Power input		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in instructions for use did not exceed marked rating by more than 10 % :	Internally powered See appended Table 4.11	N/A
	– Measurements on ME EQUIPMENT or a ME SYSTEM marked with one or more RATED voltage ranges made at both upper and lower limits of the range		N/A
	Measurements made at a voltage equal to the mean value of the range when each marking of RATED input was related to the mean value of relevant voltage range		N/A
	– Steady state current measured with a true r.m.s reading instrument		N/A
	Power input, expressed in volt-amperes, measured with a volt-ampere meter or calculated as the product of steady state current (measured as described above) and supply voltage		N/A
	A supplier certification used in place of the above measurement as the basis for steady state current or power input specification		N/A

5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		P
5.1	TYPE TESTS determined in consideration of Clause 4, in particular 4.2		P
	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods .....:		N/A
	Results of RISK ANALYSIS used to determine combination(s) of simultaneous faults to be tested	See RMF – Risk analysis	P
	RISK ANALYSIS revised, necessarily, based on test results	See RMF – Risk analysis	P
5.2	TYPE TESTS conducted on one representative sample under investigation		P
	Multiple samples used simultaneously when validity of results was not significantly affected		P
5.3	a) Tests conducted within the range of environmental conditions specified in the technical description .....:	20°C to 24°C	P
	b) ME EQUIPMENT shielded from other influences that might affect the validity of tests		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) Test conditions modified and results adjusted accordingly when ambient temperature could not be maintained	Tests recalculated to temperature ranges specified in manual, -30°C to 40°C	P
5.4	a) ME EQUIPMENT tested under least favorable working conditions specified in instructions for use and identified during RISK ANALYSIS, except as noted		P
	b) ME EQUIPMENT with adjustable or controlled operating values by anyone other than SERVICE PERSONNEL adjusted to values least favorable for the relevant test according to instructions for use		P
	c) When test results influenced by inlet pressure and flow or chemical composition of a cooling liquid, tests performed within the limits of these characteristics based on technical description		N/A
	d) Potable water used for cooling		N/A
5.5	a) Effects of deviations of supply voltage from its RATED value on test results taken into account		P
	Supply voltage during tests was the least favorable of the voltages specified in 4.10 or voltages marked on ME EQUIPMENT (V) ..... :	AA battery, 1.5 V	P
	b) ME EQUIPMENT with a MAINS PART intended for connection to a.c. SUPPLY MAINS tested only with a.c. at marked RATED frequency ± 1 Hz up to and including 100 Hz, and ± 1 % above 100 Hz ..... :	Not intended for connection to supply mains	N/A
	ME EQUIPMENT marked with a RATED frequency range tested at the least favorable frequency within the range (Hz) ..... :	No rated frequency	N/A
	c) ME EQUIPMENT with more than one RATED voltage, or for both a.c. and d.c., tested in conditions (see 5.4) related to the least favorable voltage, nature of supply, and type of current..... :	Only one rated voltage and only in d c conditions	N/A
	Some tests performed to determine the least favorable supply configuration		N/A
	d) ME EQUIPMENT with a MAINS PART for connection to d.c. SUPPLY MAINS tested with d.c. only		N/A
	Possible effects of polarity on operation of ME EQUIPMENT was taken into account based on instructions for use	No connection with reversed battery.	P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	e) ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favorable conditions ..... :	No accessories	N/A
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use . :	No separate power supply	N/A
5.6	When failure occurred or probability of future failure detected during sequence of tests, per agreement with manufacturer, all tests affecting results conducted on a new sample		N/A
	Alternatively, upon repair and modification of the sample, only the relevant tests conducted		N/A
5.7	ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of 8.7.4 and 8.8.3		P
	Manually detachable parts removed and treated concurrently with major parts and manually removable ACCESS COVERS opened and detached		P
	ME EQUIPMENT heated to a temperature between T and T + 4 °C for at least 4 h and placed in a humidity chamber with a relative humidity of 93 % ± 3 % and an ambient within 2 °C of T in the range of + 20 °C to + 32 °C for 48 h		P
	When RISK MANAGEMENT PROCESS indicated ME EQUIPMENT can be exposed to high humidity for extended periods (i.e., out-door use), test time extended proportionally (h) ..... :	See RMF – Risk analysis, C.2.15 and C.2.16	P
	ME EQUIPMENT reassembled after humidity treatment when necessary		P
5.8	Unless stated otherwise, tests in this standard sequenced as in Annex B to prevent results of one test on a subsequent test		P
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		P
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS ... :		P
5.9.2	ACCESSIBLE PARTS		P
5.9.2.1	ACCESSIBLE PARTS identified by inspection		P
	Accessibility, when necessary, determined using standard test finger of Fig 6 applied in a bent or straight position as follows:		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– for all positions in NORMAL USE, except ME EQUIPMENT for use on the floor with a mass in any operational condition > 45 kg not tilted		N/A
	Cabinet mounted ME EQUIPMENT tested in final mounting position		N/A
	–after opening of ACCESS COVERS and removal of parts, including lamps, fuses and fuse-holders, without a TOOL or based on instructions for use		P
	Openings preventing entry of test finger of Fig 6 mechanically tested with a straight un-jointed test finger of the same dimensions with a force of 30 N		P
	When the straight un-jointed test finger entered, test with the standard test finger (Fig 6) was repeated, if necessary, by pushing the finger through the opening		P
5.9.2.2	Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s		P
	All additional parts that became accessible checked using standard test finger and by inspection		P
5.9.2.3	Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS		P
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, etc. required use of a TOOL, and inspection of RISK MANAGEMENT FILE indicated the relevant part is unlikely to detach unintentionally during EXPECTED SERVICE LIFE of ME EQUIPMENT		N/A

6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		P
6.1	ME EQUIPMENT, parts thereof, and APPLIED PARTS, classified against electric shock as follows:		P
6.2	CLASS I ME EQUIPMENT, externally powered		N/A
	CLASS II ME EQUIPMENT, externally powered		N/A
	INTERNALLY POWERED ME EQUIPMENT		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with the requirements for CLASS I or CLASS II ME EQUIPMENT when so connected, and with the requirements for INTERNALLY POWERED ME EQUIPMENT when not connected to SUPPLY MAINS		N/A
	TYPE B APPLIED PART		P
	TYPE BF APPLIED PART		N/A
	TYPE CF APPLIED PART		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS		N/A
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter (IPN_1N_2) as detailed in IEC 60529..... :	IPX4	P
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use (e.g., by ethylene oxide gas, gamma ray irradiation, etc.).. :		N/A
6.5	ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2	See annex G	P
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION..... :	Continuous	P

7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		P
7.1.1	RISK of poor USABILITY associated with the design of ME EQUIPMENT'S identification and marking addressed in a USABILITY ENGINEERING PROCESS		P
7.1.2	Markings specified in 7.2-7.6 met the requirements when ME EQUIPMENT or its parts were so positioned that viewpoint was the intended position of the OPERATOR; or at any point within the base of a cone subtended by an angle of 30° to the axis normal to center of plane of marking and at 1 m		P
	Ambient luminance was the least favorable level in the range of 100 to 1500 lx, and observer had a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20), corrected when necessary (lx) ..... :		P
	– markings were clearly legible for warning statements, instructive statements, safety signs, and drawings on outside of ME EQUIPMENT from position of person performing related function		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– markings were clearly legible for FIXED ME EQUIPMENT when the ME EQUIPMENT mounted in its position of NORMAL USE		P
	– markings were clearly legible for TRANSPORTABLE and STATIONARY ME EQUIPMENT not FIXED in NORMAL USE or after dislodging ME EQUIPMENT from a wall against which it was positioned, or after turning ME EQUIPMENT from its position of NORMAL USE and for dismountable rack units, after removal from rack		P
	– markings inside ME EQUIPMENT or parts were clearly legible when viewed from the intended position of person performing related function		P
7.1.3	Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE	Marking engraved	P
	a) After tests, adhesive labels didn't loosen up or curl up at edges and markings complied with 7.1.2		P
	b) Markings required by 7.2-7.6 remained CLEARLY LEGIBLE after durability of marking test	See appended Tables 7.1.3 and 8.10	P
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		P
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings .....:	See marking plate on page 4 of this test report	P
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS.....:		P
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT.....:		N/A
	A material, component, ACCESSORY, or ME EQUIPMENT intended for a single use, or its packaging marked "Do Not Reuse" or with symbol 28 of Table D.1 (ISO 7000-1051, DB:2004-01).....:		N/A
7.2.2	Name or trademark of MANUFACTURER marked on ME EQUIPMENT and its detachable components .....:	3M™ Littmann®	P
	MODEL OR TYPE REFERENCE also marked, except when misidentification would not present an unacceptable RISK.....:	Model 3100 / Model 3200	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Software forming part of a PEMS identified with a unique identifier, such as revision level or date of release/issue, and identification are available to designated persons (e.g., SERVICE PERSONNEL) ..... :	Software version 00.03.00	P
	Marking identification on outside of ME EQUIPMENT considered optional		N/A
7.2.3	Symbol 11 on Table D.1 (ISO 7000-1641, DB: 2004-01) used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS		P
	Safety sign 10 on Table D.2 (safety sign IEC 60878 Safety 01) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted ..... :		N/A
7.2.4	ACCESSORIES marked with name or trademark of their MANUFACTURER or supplier, and with a MODEL or TYPE REFERENCE ..... :	No accessories	N/A
	Markings applied to individual packaging when not practical to apply to ACCESSORIES		N/A
7.2.5	MODEL or TYPE REF. of equipment to be connected to ME EQUIPMENT to provide power, is marked adjacent to the relevant connection point when this connection could result in an unacceptable RISK..... :		N/A
7.2.6	Following markings appear on outside of part containing SUPPLY MAINS connection and, preferably, adjacent to connection point, except for PERMANENTLY INSTALLED ME EQUIPMENT		N/A
	NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT, preferably, adjacent to supply connection terminals for PERMANENTLY INSTALLED ME EQUIPMENT (V, V-V) ..... :		N/A
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V) ..... :		N/A
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V) ..... :		N/A
	– nature of supply (e.g., No. of phases, except single-phase) and type of current ..... :		N/A
	Symbols 1-5, Table D.1 (symbols of IEC 60417-5032, 5032-1, 5032-2, 5031, and 5033, all DB: 2002-10) used, optionally, for same parameters.... :		N/A
	– RATED supply frequency or RATED frequency range in hertz..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– symbol 9 of Table D.1 (symbol IEC 60417-5172, DB: 2003-02) used for CLASS II ME EQUIPMENT:		N/A
7.2.7	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W) .....:		N/A
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (VA) .....:		N/A
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (VA) .....:		N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA) .....:		N/A
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (VA).....:		N/A
7.2.8	Output connectors		N/A
7.2.8.1	See 16.9.2.1 b) for MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT		N/A
7.2.8.2	Output connectors of ME EQUIPMENT, except MULTIPLE SOCKET-OUTLETS or connectors intended only for specified equipment or ACCESSORIES, marked with RATED output voltage, RATED current or power and output frequency (when applicable) .....:		N/A
7.2.9	ME EQUIPMENT or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2) .....:	IPX4	P
	Marking of IPX0 and IP0X Codes optional		P
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols as follows (not applied to parts identified according to 4.6):	Type B	P
	TYPE B APPLIED PARTS with symbol 19 of Table D.1 (IEC 60417-5840, DB: 2002-10), not applied to give impression of being inscribed within a square to differentiate with symbol IEC 60417-5333.....:		P
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1 (IEC 60417-5333, DB: 2002-10) .....:		N/A
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1 (IEC 60417-5335, DB: 2002-10) .....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1 (IEC 60417-5841, IEC 60417-5334, or IEC 60417-5336, all DB: 2002-10) ..... :		N/A
	Proper symbol marked adjacent to or on connector for APPLIED PART, except marked on APPLIED PART when there is no connector, or connector used for more than one APPLIED PART and different APPLIED PARTS with different classifications ..... :		N/A
	Safety sign 2 of Table D.2 (safety sign ISO 7010-W001) placed near relevant outlet when protection against effect of discharge of a cardiac defibrillator is partly in the PATIENT cable ..... :		N/A
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of appropriate cables included in instructions for use ..... :		N/A
7.2.11	ME EQUIPMENT not marked to the contrary assumed to be suitable for CONTINUOUS OPERATION		P
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time .... :		N/A
7.2.12	Type and full rating of a fuse (voltage, current, operating speed and breaking capacity) marked adjacent to ACCESSIBLE fuse-holder ..... :	No fuse	N/A
7.2.13	A safety sign CLEARLY LEGIBLE and visible after INSTALLATION in NORMAL USE applied to a prominent location of EQUIPMENT that produce physiological effects capable of causing HARM to PATIENT or OPERATOR not obvious to OPERATOR ..... :		N/A
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use ..... :		P
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10)		N/A
7.2.15	Requirements for cooling provisions marked (e.g., supply of water or air) ..... :		N/A
7.2.16	ME EQUIPMENT with limited mechanical stability		N/A
7.2.17	Packaging marked with special handling instructions for transport and/or storage ..... :		N/A
	Permissible environmental conditions for transport and storage marked on outside of packaging ..... :	Thermometer: -20°C to 55°C	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK ..... :		N/A
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile ..... :		N/A
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector ..... :		N/A
7.2.19	Symbol 7 of Table D.1 (IEC 60417-5017, DB:2002-10) marked on FUNCTIONAL EARTH TERMINAL :		N/A
7.2.20	Protective means, required to be removed to use a particular function of ME EQUIPMENT with alternate applications, marked to indicate the necessity for replacement when the function is no longer needed ..... :		N/A
	No marking applied when an interlock provided		N/A
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts		
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near heater or in heater itself (W) ..... :		N/A
	An identifying marking referring to instruction in ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for use with heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL ..... :		N/A
7.3.2	Symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10), or safety sign 3 of Table D.2 used to mark presence of HIGH VOLTAGE parts ..... :		N/A
7.3.3	Type of battery and mode of insertion when applicable is marked ..... :	AA battery, + marking inside of cap	P
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL ..... :		N/A
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement by inadequately trained personnel would result in an unacceptable RISK (e.g., excessive temperatures, fire or explosion) ..... :	Battery short circuit safe	N/A
	An identifying marking also provided referring to instructions in ACCOMPANYING DOCUMENTS .. :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.3.4	Fuses and replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible only by a TOOL, identified by type and full rating adjacent to component (V, A, operating speed and breaking capacity), or by a reference to information in ACCOMPANYING DOCUMENTS ..... :		N/A
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1 (IEC 60417-5019, DB: 2002-10), except for the PROTECTIVE EARTH TERMINAL in an APPLIANCE INLET according to IEC 60320-1 ..... :		N/A
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made		N/A
7.3.6	Symbol 7 of Table D.1 (IEC 60417-5017, DB: 2002 -10) marked on FUNCTIONAL EARTH TERMINALS ..... :		N/A
7.3.7	Terminals for supply conductors marked adjacent to terminals, except when interchanging connections would not result in a HAZARD		N/A
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings		N/A
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3 (Code in IEC 60445)		N/A
	When marking for connection to a 3-phase supply is necessary, it complies with IEC 60445		N/A
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		N/A
7.3.8	Statement, "For supply connections, use wiring materials suitable for at least X °C" (X > than max temperature measured in terminal box or wiring compartment under NORMAL USE and CONDITIONS)", or equivalent marked at or near the point supply connections made under conditions of this clause		N/A
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		N/A
7.4	Marking of controls and instruments		P

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Clause	Requirement + Test	Result - Remark	Verdict
7.4.1	The "on" and "off" positions of switch used to control power to ME EQUIPMENT or its parts, including mains switch, marked with symbols 12 and 13 of Table D.1 (IEC 60417-5007, DB: 2002-10, and IEC 60417-5008, DB: 2002-10), or		N/A
	– indicated by an adjacent indicator light, or		N/A
	– indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1 (IEC 60417-5010 DB: 2002-10), and		N/A
	– status indicated by an adjacent indicator light, or		N/A
	– status indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 (symbol 60417-5011 DB: 2002-10), or		N/A
	– status indicated by an adjacent indicator light, or		N/A
	– status indicated by other unambiguous means		N/A
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means	⏻ Symbol IEC 60878-5009 used as power button	P
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE, or		N/A
	– an indication of direction in which magnitude of the function changes	+ and - symbols for volume	P
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 31 except the base quantities listed in Table 1 expressed in the indicated units	BPM (Beats Per Minute) is an established unit	P
	ISO 1000 applied for application of SI units, their multiples, and certain other units		N/A
	All Markings in Subclause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3	Marking	P
7.5	Safety signs		P
	Markings used to convey a warning, prohibition or mandatory action mitigating a RISK not obvious to OPERATOR are safety signs from ISO 7010		N/A
	One of the following methods used when a safety sign was not available to indicate a particular desired meaning:		N/A
	a) A safety sign constructed according to safety signs 1.4 and 8 of Table D.2 (i.e., ISO 3864-1:2002, Clause 7)		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Safety sign 2 of Table D.2 (general warning sign ISO 7010:2003-W001) placed together with a supplementary symbol or an affirmative statement describing the anticipated principal RISK(S) (e.g., "Causes burns", "Risk of explosion", etc.)		N/A
	c) Safety sign 4 of Table D.2 (general prohibition sign ISO 7010:2003-P001) placed together with a supplementary symbol or a statement describing what is prohibited ("Do not open", etc.)		N/A
	d) Safety sign 9 of Table D.2 (general mandatory action sign ISO 7010:2003-M001) placed together with a supplementary symbol or a text statement consisting of a command describing the required action (e.g., "Wear protective gloves", etc.)		N/A
	Affirmative statement together with safety sign placed in instructions for use due to insufficient space on ME EQUIPMENT	AP symbol to big for the equipment. A smaller symbol without color is used instead.	P
	Specified colors in ISO 3864-1 used for safety signs ..... :	Adding colours on label will generate handling noise and degree the essential function of the stethoscope. The correct colors of AP symbol (symbol 22 table D1) are placed in the user manual.	N/A
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)		P
	Safety signs including any supplementary symbols or text described in instructions for use		P
7.6	Symbols		P
7.6.1	Meanings of symbols used for marking described in instructions for use		P
7.6.2	Symbols required by this standard conform to IEC or ISO publication referenced		P
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable		P
7.7	Colors of the insulation of conductors		N/A
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation		N/A
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations		N/A
7.7.3	Green and yellow insulation identify only following conductors:		N/A
	– PROTECTIVE EARTH CONDUCTORS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– conductors specified in 7.7.2		N/A
	– POTENTIAL EQUALIZATION CONDUCTORS		N/A
	– FUNCTIONAL EARTH CONDUCTORS		N/A
7.7.4	Neutral conductors of POWER SUPPLY CORDS are "light blue" specified in IEC 60227-1 or IEC 60245-1		N/A
7.7.5	Colors of conductors in POWER SUPPLY CORDS are in accordance with IEC 60227-1 or IEC 60245-1		N/A
7.8	Indicator lights and controls		N/A
7.8.1	Colors of indicator lights and their meanings are as follows (Dot-matrix and other alphanumeric displays not considered indicator lights):		N/A
	Red: Warning (i.e., immediate response by OPERATOR required)		N/A
	Yellow: Caution (i.e., prompt response by OPERATOR required)		N/A
	Green: Ready for use		N/A
	Other color: Meaning other than red, yellow, or green (color, meaning) ..... :		N/A
7.8.2	Red used only for emergency control		N/A
7.9	ACCOMPANYING DOCUMENTS		
7.9.1	ME EQUIPMENT accompanied by documents containing at least instructions for use, and a technical description	E3200 User guide Draft v0.4 E3100 User guide V1.2a Instruction for Use, **IFU**	P
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		P
	– name or trade-name of MANUFACTURER and an address the RESPONSIBLE ORGANIZATION can be referred to ..... :	Trade-name: 3M™ Littmann® Electronic Stethoscope Contacts: User guide Maintenance & warranty	P
	– MODEL or TYPE REFERENCE ..... :	Model 3100 Model 3200	P
	When ACCOMPANYING DOCUMENTS provided electronically (e.g., on CDROM), RISK MANAGEMENT PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT (to cover emergency operation)		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	Risk Management Plan **RMF** Ref no: C.2.26 E3200 / E3100 User guide IFU	P
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended	E3200 / E3100 User guide IFU	P
7.9.2	Instructions for use include the required information		
7.9.2.1	– intended use of ME EQUIPMENT,	E3200 / E3100 User guide Intended use	P
	– frequently used functions, and	E3200 / E3100 User guide IFU	P
	– known contraindication(s) to use of ME EQUIPMENT	No contraindications	N/A
	Classifications specified in Clause 6, all markings specified in 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT	E3200 / E3100 User guide Safety information	P
	Instructions for use are in a language acceptable to the intended operator	Draft in English	P
7.9.2.2	Instructions for use include all warning and safety notices	E3200 / E3100 User guide	P
	Warning statement for CLASS I ME EQUIPMENT indicating: "WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth"	Internal powered battery operated.	N/A
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	E3200 / E3100 User guide Safety information	P
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	E3200 / E3100 User guide Safety information	P
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET indicating, "connecting electrical equipment to MSO effectively leads to creating an ME SYSTEM, and can result in a reduced level of safety"		N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS		N/A
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply indicating "power supply is specified as a part of ME EQUIPMENT or combination is specified as a ME SYSTEM"	Internally powered	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.4	Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source	Internally powered	N/A
	Warning to remove primary batteries when ME EQUIPMENT is not likely to be used for some time when leakage from battery would result in an unacceptable RISK	E3200 / E3100 User guide Ch. 10 Other operating considerations	P
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided:	E3200 / E3100 User guide Ch. 9 Customer configuration	P
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK	Internally powered	N/A
7.9.2.5	Instructions for use includes a description of ME EQUIPMENT, its functions, and significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, and other persons near ME EQUIPMENT in NORMAL USE	E3200 / E3100 User guide	P
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to when such exposure can constitute an unacceptable RISK		N/A
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected	Bluetooth not evaluated by Intertek	-
	APPLIED PARTS specified		P
7.9.2.6	Information provided indicating where the installation instructions may be found (e.g. technical description), or information on qualified personnel who can perform the installation	No installation required.	N/A
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device when an APPLIANCE COUPLER or separable plug is used as isolation means to meet 8.11.1 a)	Hand-held device	N/A
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation including initial control settings, and connection to or positioning of PATIENT together with information on treatment and handling required prior to use of ME EQUIPMENT, its parts, or ACCESSORIES	E3200 / E3100 User guide **IFU**	P

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Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.9	All necessary information provided to operate ME EQUIPMENT according to its specification including explanation of controls, displays and signals, sequence of operation, connection/disconnection of detachable parts or ACCESSORIES, replacement of material consumed during operation	E3200 / E3100 User guide **IFU**	P
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	E3200 / E3100 User guide **IFU**	P
7.9.2.10	A list of all system messages, error messages, and fault messages provided, except when messages are self-explanatory, an explanation of messages including important causes and possible action(s) that can be taken to resolve the problem indicated by the message	E3200 / E3100 User guide **IFU**	P
7.9.2.11	Necessary information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	E3200 / E3100 User guide **IFU**	P
7.9.2.12	Detailed information provided on cleaning, disinfection, and sterilization methods, and applicable parameters (i.e., temperature, pressure, humidity, time limits and number of cycles) that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified	E3200 / E3100 User guide Maintenance & warranty	P
	Not applied to materials, components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use		N/A
7.9.2.13	Detailed instructions provided on preventive inspection, maintenance, calibration, and frequency of such maintenance	No maintenance or calibration is required	N/A
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	No maintenance or calibration is required	N/A
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application, but not necessarily details of actual performance of such maintenance	No maintenance or calibration is required	N/A
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries intended to be maintained by anyone other than SERVICE PERSONNEL	No maintenance or calibration is required	N/A
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	E3200 / E3100 User guide **IFU**	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Other equipment providing power to ME SYSTEM sufficiently described (e.g. part number, RATED VOLTAGE, max or min power, protection class, intermittent or continuous service) to ensure compliance with this standard	Internally powered	N/A
7.9.2.15	RISKS associated with disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified, and instructions provided on minimizing these RISKS	E3200 / E3100 User guide	P
7.9.2.16	Information specified in 7.9.3 or where it can be found (e.g. in a service manual) included in instructions for use	Included in instruction for use	P
7.9.3	Technical description		P
7.9.3.1	All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use including the following:	Part of the User guide	P
	– information in clause 7.2		P
	– permissible environmental conditions of use including conditions for transport and storage	E3200 / E3100 User guide Ch. 13 Other operating considerations	P
	– all characteristics of ME EQUIPMENT including range(s), accuracy, and precision of displayed values or where they can be found	E3200 / E3100 User guide Ch. 7 Monitor patient heart rate	P
	– special installation requirements such as max. permissible apparent impedance of SUPPLY MAINS	No installation	N/A
	– permissible range of values of inlet pressure and flow, and chemical composition of cooling liquid used for cooling	No installation	N/A
	– a description of means of isolating ME EQUIPMENT from SUPPLY MAINS, when such means not in ME EQUIPMENT	Internal powered	N/A
	– a description of means for checking oil level in partially sealed oil filled ME EQUIPMENT or its parts when applicable		N/A
	– a warning statement addressing HAZARDS that can result from unauthorized modification of ME EQUIPMENT according to following examples:		P
	"WARNING: No modification of this equipment is allowed"		P
	"WARNING: Do not modify this equipment without authorization of the manufacturer"		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	"WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment"		N/A
	Technical description separable from instructions for use contains required information, as follows		N/A
	– information in Clause 7.2	All information in E3200 / E3100 User guide	N/A
	– all applicable classifications specified in Clause 6, and warning and safety notices and explanation of safety signs marked on ME EQUIPMENT	All information in E3200 / E3100 User guide	N/A
	– a brief description of ME EQUIPMENT, how it functions, and its significant physical and performance characteristics	All information in E3200 / E3100 User guide	N/A
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description	All information in E3200 / E3100 User guide	N/A
7.9.3.2	The technical description contains the following required information		P
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT, when type and rating of fuses are not apparent from information on RATED current and mode of operation of ME EQUIPMENT	Internal powered	N/A
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and if so, instructions for correct connection and anchoring to ensure compliance with 8.11.3	Internal powered	N/A
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	E3200 / E3100 User guide Ch. 1 Insert battery	P
	– warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component	No unacceptable risk identified for changing parts	N/A
7.9.3.3	A statement in technical description indicates, upon request, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions, or other information to assist SERVICE PERSONNEL to repair parts	Repair must be done at 3M service center. E3200 / E3100 User guide Maintenance & warranty	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description	Internal powered	N/A
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		P
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS		P
	NORMAL CONDITION considered as simultaneous occurrence of situations identified in Clause 8.1a)		P
	SINGLE FAULT CONDITION considered to include the occurrences as specified in Clause 8.1b)		P
	ACCESSIBLE PARTS determined according to 5.9		P
	LEAKAGE CURRENTS measured according to 8.7		P
8.2	Requirements related to power sources		N/A
8.2.1	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM		N/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified		N/A
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		N/A
8.2.2	No HAZARDOUS SITUATION other than absence of ESSENTIAL PERFORMANCE developed when a connection with wrong polarity made for ME EQUIPMENT supplied from an external d.c. source		N/A
	ME EQUIPMENT connected with correct polarity did not present an unacceptable RISK		N/A
	Protective devices that can be reset by anyone without a TOOL restore correct operation on reset		N/A
8.3	Classification of APPLIED PARTS		P
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART		N/A
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	Type B	P
	d) Requirements of a TYPE B APPLIED PART applied to a part in 4.6 to be subjected to requirements for an APPLIED PART (except marking)		N/A
	Requirements for a TYPE BF or CF APPLIED PART applied as in RISK MANAGEMENT PROCESS		N/A
8.4	Limitation of voltage, current or energy		P
8.4.1	Limits specified in 8.4.2 not applied to currents intended to flow through body of PATIENT to produce a physiological effect during NORMAL USE	No such currents	P
8.4.2	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT per Tables 3 and 4 when measured per Cl. 8.7.4 ..... :		N/A
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT in Cl. 8.7.3 c) when measured per Clause 8.7.4 (mA) ..... :		N/A
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, was negligible in NORMAL USE, and the OPERATOR is instructed not to touch relevant part and PATIENT simultaneously:		N/A
	– accessible contacts of connectors		N/A
	– contacts of fuseholders accessible during replacement of fuse		N/A
	– contacts of lampholders accessible after removal of lamp		N/A
	– parts inside an ACCESS COVER that can be opened without a TOOL, or where a TOOL is needed but the instructions for use instruct an OPERATOR other than SERVICE PERSONNEL to open the relevant ACCESS COVER		N/A
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.) ..... :	1. 5 V	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Limit of 60 V d.c applied with no more than 10 % peak-to-peak ripple, and when ripple > specified value, 42.4 V peak limit applied (V d.c.) ..... :		N/A
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential up to 2 V (VA or J) ..... :		N/A
	LEAKAGE CURRENT limits referred to in 8.4.2 b) applied when voltages higher than limits in 8.4.2 c) were present (mA) ..... :		N/A
	d) Voltage and energy limits specified in c) above also applied to the following:		N/A
	– internal parts, other than contacts of plugs, connectors and socket-outlets, touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and		P
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length of 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls using a TOOL		P
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		P
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N		P
	Test repeated with a TOOL specified in instructions for use		N/A
	Test rod freely and vertically suspended through openings on top of ENCLOSURE		P
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION		N/A
	A TOOL is required when it is possible to prevent the devices from operating		N/A
8.4.3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one s after disconnecting the plug of ME EQUIPMENT or its parts (V) ..... :	Internally powered	N/A
	A triggering circuit used to ensure disconnection occurred at peak of supply voltage waveform		N/A
	When voltage exceeded 60 V, measured or calculated stored charge did not exceed 45 µC .. :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.4.4	Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, did not exceed 60 V or calculated stored charge did not exceed 45 µC .. :	1.5 V battery	N/A
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL		N/A
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1 (IEC 60417-5036, DB: 2002-10), and manual discharging device specified in technical description ..... :		N/A
8.5	Separation of parts		P
8.5.1	MEANS OF PROTECTION (MOP)		P
8.5.1.1	Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in Cl. 8.4		P
	Each MEANS OF PROTECTION categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION, taking into account 4.6, and flow chart in Fig A.12		P
	Varnishing, enameling, oxidation, and similar protective finishes and coatings with sealing compounds replasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION		P
	Coatings and other insulation intended as a MEANS OF PROTECTION complying with IEC 60950-1:2001 considered acceptable as a MEANS OF OPERATOR PROTECTION but not automatically as a MEANS OF PATIENT PROTECTION		N/A
	RISK MANAGEMENT PROCESS taken into consideration for MEANS OF PATIENT PROTECTION		P
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		P
	Insulation, CREEPAGE, CLEARANCES, components or earth connections not complying with 8.5.1.2 and 8.5.1.3 not considered as MEANS OF PROTECTION, and failure of these parts regarded as NORMAL CONDITION		P
8.5.1.2	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test of 8.8 at test voltage of Table 6		P

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Clause	Requirement + Test	Result - Remark	Verdict
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		P
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with 8.6		N/A
	A Y1 capacitor complying with IEC 60384-14 and having passed dielectric strength test for two MEANS OF PATIENT PROTECTION considered equivalent to one MEANS OF PATIENT PROTECTION		N/A
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance (V_{TW}, C_N) :		N/A
8.5.1.3	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		N/A
	– dielectric strength test of 8.8 at test voltage of Table 6; or		N/A
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		N/A
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		N/A
	– limits of Tables 13 to 16 (inclusive); or		N/A
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6, or		N/A
	– requirements and tests of IEC 60950-1 for protective earthing		N/A
	A Y2 capacitor complying with IEC 60384-14 and passing dielectric strength test for one MEANS OF OPERATOR PROTECTION considered equivalent to one MEANS OF OPERATOR PROTECTION		N/A
	A Y1 capacitor complying with IEC 60384-14 and having passed dielectric strength test for two MEANS OF OPERATOR PROTECTION considered equivalent to two MEANS OF OPERATOR PROTECTION		N/A
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance (V_{TW}, C_N)		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Points where insulation, CREEPAGE, CLEARANCES, impedances of components, or PROTECTIVE EARTH CONNECTIONS prevent ACCESSIBLE PARTS from.exceeding limits in 8.4 identified for tests relative to 8.5.1.1 to 8.5.1.3, and if a failure at that point regarded as a NORMAL or SINGLE FAULT CONDITION		N/A
	Each MEANS OF PROTECTION categorized relative to ME EQUIPMENT part(s) it protects from exceeding the allowable limits		N/A
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements as APPLIED PARTS, considered MEANS OF PATIENT PROTECTION		P
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION		N/A
8.5.2	Separation of PATIENT CONNECTIONS		P
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAX. MAINS VOLTAGE and complied with limit for PATIENT LEAKAGE CURRENT with 110 % of MAX. MAINS VOLTAGE applied (mA)..... :		N/A
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART		N/A
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function		N/A
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS		N/A
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART		N/A
	LEAKAGE CURRENT tests conducted per 8.7.4		N/A
	Dielectric strength test conducted per 8.8.3		N/A
	CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable		N/A
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.5.2.2	PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED,		N/A
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and		P
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low		P
	LEAKAGE CURRENT tests conducted per 8.7.4	See appended Table 8.7	P
	Dielectric strength test conducted per 8.8.3	See appended Table 8.8.3	P
	Relevant CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable		P
	The RISK MANAGEMENT FILE reviewed		P
8.5.2.3	A connector on a PATIENT lead located at the end of the lead remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE		N/A
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT	No leads or connectors	N/A
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter		N/A
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm		N/A
	– conductive part pluggable into a mains socket protected from making contact with parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a dielectric strength of 1500 V, and complying with 8.8.4.1		N/A
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N, except when RISK MANAGEMENT PROCESS indicated no unacceptable RISK existed from contact with objects other than a mains socket or a flat surface		N/A
8.5.3	MAXIMUM MAINS VOLTAGE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– MAXIMUM MAINS VOLTAGE determined to be the highest RATED supply voltage for single-phase or d.c. SUPPLY MAINS powered ME EQUIPMENT including INTERNALLY POWERED ME EQUIPMENT with a means of connection to a SUPPLY MAINS (V) ..... :		N/A
	When less than 100 V, MAXIMUM MAINS VOLTAGE was 250 V		N/A
	– MAXIMUM MAINS VOLTAGE was the highest RATED phase to neutral supply voltage for polyphase ME EQUIPMENT (V)..... :		N/A
	– for other INTERNALLY POWERED ME EQUIPMENT, maximum mains voltage was 250 V		N/A
8.5.4	WORKING VOLTAGE		P
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED voltage range resulting in highest measured value (V).... :		N/A
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple did not exceed 10 % of average value or peak voltage when peak-to-peak ripple exceeded 10 % of average value (V) ..... :	1.5 V battery	P
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V)..... :	1.5 V battery	P
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth		N/A
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V)..... :		N/A
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages		N/A
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V) ..... :		N/A
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.5.5.1	Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety, but not separate functions of same APPLIED PART		N/A
	Possibility of an OPERATOR receiving a shock from such parts taken into consideration in RISK MANAGEMENT PROCESS		N/A
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:		N/A
	a) Hazardous electrical energies, during a discharge of a cardiac defibrillator to a PATIENT connected to a DEFIBRILLATION PROOF APPLIED PART, as determined by peak voltage measured between points Y1 and Y2 of Figs 9 and 10 exceeding 1 V, did not appear on:		N/A
	– ENCLOSURE including connectors in PATIENT leads and cables when connected to ME EQUIPMENT, and excluding connecting lead from a DEFIBRILLATION-PROOF APPLIED PART or its connector when it was disconnected from ME EQUIPMENT (V_P) ..... :		N/A
	– SIGNAL INPUT/OUTPUT PARTS (V_P) ..... :		N/A
	– test metal foil with minimum area equal to base of ME EQUIPMENT where ME EQUIPMENT was placed on (V_P)..... :		N/A
	– or, PATIENT CONNECTIONS of other APPLIED PARTS regardless of classification as a DEFIBRILLATION-PROOF APPLIED PART (V_P):		N/A
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS		N/A
	ME EQUIPMENT connected to circuit of Fig 9 for common-mode test, and test voltage applied to all PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PART connected together, excluding those PROTECTIVELY EARTHED or functionally earthed		N/A
	Peak voltage at Y1 and Y2 after operation of S (V_P)..... :		N/A
	Peak voltage at Y1 and Y2 after operation of S with V_T reversed (V_P) ..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT connected to circuit of Fig 10 for differential-mode test, and voltage applied to each PATIENT connection of DEFIBRILLATION-PROOF APPLIED PART in turn with all remaining PATIENT CONNECTIONS of the same DEFIBRILLATION-PROOF APPLIED PART connected to earth		N/A
	A single PATIENT CONNECTION APPLIED PART not subjected to differential-mode test		N/A
	– ME EQUIPMENT, except for PERMANENTLY INSTALLED ME EQUIPMENT, tested with and without PROTECTIVE EARTH CONDUCTOR connected		N/A
	– insulating surfaces of APPLIED PARTS covered with metal foil or, when appropriate, immersed in a 0.9 % saline solution		N/A
	– external connections to a FUNCTIONAL EARTH TERMINAL removed		N/A
	– parts specified in 8.5.5.1 a) not PROTECTIVELY EARTHED connected in turn to a display device		N/A
	– ME EQUIPMENT connected to SUPPLY MAINS and operated in accordance with instructions for use		N/A
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 1 with 2,3, & 4 connected to earth (V_P) ..... :		N/A
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 2 with 1,3, & 4 connected to earth (V_P) ..... :		N/A
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 3 with 1, 2, & 4 connected to earth (V_P) ..... :		N/A
	Peak voltage at Y1 and Y2 after the operation of S, V_T applied to PATIENT CONNECTION 4 with 1, 2, & 3 connected to earth (V_P) ..... :		N/A
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 1 with 2,3, & 4 connected to earth, V_T reversed (V_P) ..... :		N/A
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 2 with 1,3, & 4 connected to earth, V_T reversed (V_P) ..... :		N/A
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 3 with 1, 2, & 4 connected to earth, V_T reversed (V_P) ..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 4 with 1, 2, & 3 connected to earth, V_T reversed (V_P) ..... :		N/A
	ME EQUIPMENT continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE after the recovery time stated in ACCOMPANYING DOCUMENTS		N/A
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load to at least 90 % of energy delivered to this load with ME EQUIPMENT disconnected (J) ..... :		N/A
	Test voltage applied to each PATIENT CONNECTION or APPLIED PART in turn with all remaining PATIENT CONNECTIONS of same APPLIED PART connected to earth using circuit of Fig 11 and ACCESSORIES recommended by instructions as follows:		N/A
	a) APPLIED PART or PATIENT CONNECTION connected to test circuit		N/A
	b) Capacitor C charged to 5 kV d.c. with switch S in position A		N/A
	c) Capacitor C discharged by actuating switch S to position B, and measured energy E1 delivered to 100 Ω load (E1, J)..... :		N/A
	d) ME EQUIPMENT under test removed from test circuit and repeated steps b) and c), measuring energy E2 delivered to 100 Ω load (E2, J) ..... :		N/A
	e) Energy E1 was at least 90 % of E2 (E1, J) ..... :		N/A
8.6	Protective earthing, functional earthing and potential equalization of ME EQUIPMENT		N/A
8.6.1	Requirements of 8.6.2 to 8.6.8 applied		N/A
	Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8		N/A
8.6.2	PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR ..... :		N/A
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and clamping means cannot be loosened without TOOL		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Screws for internal PROTECTIVE EARTH CONNECTIONS are completely covered or protected against accidental loosening from outside ..... :		N/A
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		N/A
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		N/A
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part, except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE		N/A
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop		N/A
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits		N/A
8.6.5	Poorly conducting surface coatings on conductive elements removed at the point of contact		N/A
	Coating not removed when requirements for impedance and current-carrying capacity met		N/A
8.6.6	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections		N/A
	This requirement applied also where interchangeable parts are PROTECTIVELY EARTHED		N/A
8.6.7	Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR complies with following:		N/A
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE		N/A
	– RISK of accidental disconnection minimized in NORMAL USE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Terminal allows conductor to be detached without a TOOL		N/A
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		N/A
	– Terminal marked with symbol 8 of Table D.1 (i.e., symbol IEC 60417-5021, DB: 2002-10)		N/A
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		N/A
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		N/A
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION		N/A
8.6.9	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used only as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL and colored green and yellow		N/A
	Two MEANS OF PROTECTION provided by insulation of internal screens and all internal wiring connected to them with a related explanation in technical description..... :		N/A
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3		N/A
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Tables 8.7A, 8.7B, 8.7C, and 8.7.4.7	See appended Tables 8.7A, 8.7B, 8.7C, & 8.7.4.7	P
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except		P
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		N/A
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		N/A
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION		P

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Clause	Requirement + Test	Result - Remark	Verdict
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE		P
8.7.3	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b), and limits apply to d.c., a.c., composite waveforms, and unless otherwise stated, they are d.c. or r.m.s	See appended Tables 8.7A-8.7C, & 8.7.4.7	P
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 and 4, and values of a.c. are relative to currents having a frequency not less than 0.1 Hz	See appended Tables 8.7A-8.7C, & 8.7.4.7	P
	c) TOUCH CURRENT did not exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC})..... :		N/A
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC}) ..... :		P
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 [10] (I_{ENC}, I_{ESFC}) ..... :		N/A
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device..... :		N/A
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements		N/A
8.7.4.1	Figs 13-19 used to measure LEAKAGE and PATIENT AUXILIARY CURRENTS	Internal battery	N/A
	When other test Figs. yielding accurate results used, but results appeared close to permissible values, or when validity of results was in question, applicable test Figs used as deciding factor		N/A
	a) EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and AUXILIARY CURRENTS measured with ME EQUIPMENT running at operating temperature of 11.1.3 c)	See 8.7.3	P
	b) Number of tests reduced when examination of circuit arrangement, components, and materials of ME EQUIPMENT indicated no possibility of any HAZARDOUS SITUATION		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.7.4.2	ME EQUIPMENT for connection to a SUPPLY MAINS connected to an appropriate power source		N/A
	Tests on single-phase ME EQUIPMENT conducted at both supply polarities		N/A
	INTERNALLY POWERED ME EQUIPMENT tested without connections to a measuring supply circuit		P
8.7.4.3	a) CORD connected ME EQUIPMENT tested using the cord	Internally powered	N/A
	b) ME EQUIPMENT with an APPLIANCE INLET connected to measuring supply circuit via a 3 m DETACHABLE POWER SUPPLY CORD or a length and type specified in instructions for use (m) ..... :		N/A
	c) PERMANENTLY INSTALLED ME EQUIPMENT connected to measuring supply circuit by shortest possible connection		N/A
	d) Measuring arrangements were as follows:		N/A
	1) APPLIED PARTS, including PATIENT cables (when present), placed on an insulating surface with a dielectric constant of approximately 1 (e.g., expanded polystyrene) and approximately 200 mm above an earthed metal surface		N/A
	2) Reference earth of measuring circuits connected to protective earth of SUPPLY MAINS when an isolating transformer was not used for LEAKAGE CURRENT measurements		N/A
8.7.4.4	a) Source of LEAKAGE CURRENT loaded with measuring device or PATIENT AUXILIARY CURRENT with an impedance of approximately 1000 Ω for d.c., a.c. and composite waveforms ≤ 1 MHz		P
	b) Evaluation of current and current components based on 8.7.3 a) obtained automatically when a measuring device in Fig 12a) or a similar circuit used, allowing measurement of total effect of all frequencies with a single instrument		P
	When currents and current components with frequencies >1 kHz exceeded 10 mA limit in 8.7.3 e), they were measured by appropriate means		P
	c) Voltage measuring instrument in Fig 12 a) used with a min input resistance of 1 M Ω and a max input capacitance of 150 pF indicating true r.m.s. value of voltage with an indicating error ≤ ± 5 % of indicated value		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Scale indicates current through measuring device including automatic evaluation of components with frequencies > 1 kHz enabling direct comparison of reading with limits in 8.7.3		P
	Requirements limited to a frequency < than 1 MHz when proven by oscilloscope frequencies > such an upper limit do not occur in measured current (Max Frequency Hz)..... :		N/A
8.7.4.5	a) CLASS I ME EQUIPMENT tested based on Fig 13		N/A
	b) Current measured on more than one PROTECTIVE EARTH CONDUCTOR was aggregate current in protective earthing system of installation		N/A
	c) MANUFACTURER specified a test PROCEDURE and configuration for measurement of EARTH LEAKAGE CURRENT for FIXED ME EQUIPMENT with connections to earth through building structure		N/A
8.7.4.6	a) ME EQUIPMENT tested according to Fig 14, using an appropriate measuring supply circuit		N/A
	Measurement made with MD between earth and each part of the ENCLOSURE not PROTECTIVELY EARTHED		N/A
	Measurement made with MD between parts of ENCLOSURE not PROTECTIVELY EARTHED		P
	Measurement made with MD between earth and any part of ENCLOSURE, normally, PROTECTIVELY EARTHED under SINGLE FAULT CONDITION of interruption of any PROTECTIVE EARTH CONDUCTOR		N/A
	INTERNALLY POWERED ME EQUIPMENT investigated for TOUCH CURRENT only between parts of ENCLOSURE, not between ENCLOSURE and earth, except when 8.7.4.6 c) was applicable		P
	b) A metal foil 20x10 cm max applied in contact with ENCLOSURE or relevant part of ENCLOSURE made fully or partly of insulating material		P
	Metal foil shifted, when possible, to determine highest value of TOUCH CURRENT		P
	Metal foil was not in touch with any PROTECTIVELY EARTHED metal parts of ENCLOSURE, except metal parts of ENCLOSURE not PROTECTIVELY EARTHED partly or fully covered by metal foil		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Metal foil arranged to contact parts of ENCLOSURE normally PROTECTIVELY EARTHED when measuring TOUCH CURRENT under SINGLE FAULT CONDITION of interruption of a PROTECTIVE EARTH CONDUCTOR		N/A
	Foil size increased based on area of contact when surface of ENCLOSURE in contact with PATIENT or OPERATOR was larger than 20x10 cm (cmxcm) ..... :		N/A
	c) ME EQUIPMENT with a SIGNAL INPUT/OUTPUT PART additionally tested using transformer T2 when required (see 8.1 a))		N/A
	Transformer T2 voltage set at 110 % of MAXIMUM MAINS VOLTAGE, and specific pin configuration used when applying external voltage determined to be worst case based on test or circuit analysis		N/A
8.7.4.7	a) ME EQUIPMENT with an APPLIED PART tested based on Fig 15, and an ENCLOSURE, other than an APPLIED PART, of insulating material placed in a position of NORMAL USE on a flat metal surface and connected to earth		N/A
	b) ME EQUIPMENT with an F-TYPE APPLIED PART additionally tested based on Fig 16, and SIGNAL INPUT/OUTPUT PARTS not previously permanently earthed connected to earth		N/A
	Transformer T2 voltage in Fig 16 set at 110 % of MAXIMUM MAINS VOLTAGE		N/A
	Non-PROTECTIVELY EARTHED metal ACCESSIBLE PARTS including PATIENT CONNECTIONS of other APPLIED PARTS, when present, connected to earth		N/A
	c) ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART, additionally tested according to Fig 17when required		N/A
	Transformer T2 voltage set at 110 % of MAXIMUM MAINS VOLTAGE, and specific pin configuration used when applying external voltage was worst case based on test or circuit analysis		N/A
	d) ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART not PROTECTIVELY EARTHED or a TYPE BF APPLIED PART with metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED additionally tested based on Fig 18	Enclosure continuous part of the Applied part.	N/A
	Transformer T2 voltage set at 110 % of MAXIMUM MAINS VOLTAGE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Due to adequate separation of parts involved, this test was not conducted		N/A
	e) An APPLIED PART with an insulating surface tested using metal foil as in 8.7.4.6, or it was immersed in a 0.9 % saline solution..... :		N/A
	Size of foil increased corresponding to area of contact when surface of APPLIED PART in contact with PATIENT was larger than 20 cm x 10 cm (cm x cm) ..... :		N/A
	Metal foil or saline solution considered as the only patient connection for APPLIED PART concerned		N/A
	f) Fluid used as PATIENT CONNECTION replaced by 0.9 % saline solution, and electrode placed in saline solution considered as PATIENT CONNECTION for APPLIED PART concerned		N/A
	g) PATIENT LEAKAGE CURRENT for TYPE B and TYPE BF APPLIED PARTS measured from and to all PATIENT CONNECTIONS of a single function connected directly together or loaded as in NORMAL USE		P
	– PATIENT LEAKAGE CURRENT for TYPE CF APPLIED PARTS measured from and to every PATIENT CONNECTION in turn		N/A
	PATIENT LEAKAGE CURRENT measurements made with the least favorable detachable part specified in instructions for use		P
	h) Total PATIENT LEAKAGE CURRENT measured from and to all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B, BF, or CF APPLIED PARTS) connected together		N/A
	Functional earth disconnected before the test when necessary		N/A
	i) Measuring device connected to each PATIENT CONNECTION in turn since PATIENT CONNECTIONS of APPLIED PART are loaded under NORMAL USE		N/A
8.7.4.8	ME EQUIPMENT with an APPLIED PART except for one with only a single PATIENT CONNECTION tested based on Fig 19 with a measuring supply circuit		N/A
	PATIENT AUXILIARY CURRENT measured between a single PATIENT CONNECTION and all other PATIENT CONNECTIONS, connected directly together or loaded as in NORMAL USE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.7.4.9	PATIENT LEAKAGE and AUXILIARY CURRENTS for ME EQUIPMENT with multiple PATIENT CONNECTIONS did not exceed limits for NORMAL CONDITION while one or more PATIENT CONNECTIONS are		N/A
	– disconnected from the PATIENT; and		N/A
	– disconnected from the PATIENT and earthed		N/A
	Actual measurements limited to representative number of combinations .....:		N/A
8.8	Insulation		P
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION and insulation between parts of opposite polarity of MAINS PART on SUPPLY MAINS side of mains fuse or OVER-CURRENT RELEASE (as one MEANS OF PROTECTION)		P
	Insulation exempted from test (complies with 4.8)		P
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8		N/A
8.8.2	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		N/A
	a) 0.4 mm, min, distance through insulation, or		N/A
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		N/A
	– at least two layers of material, each passed the appropriate dielectric strength test, or		N/A
	– three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test		N/A
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		N/A
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		P
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		N/A
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		N/A
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L		N/A
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		N/A
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		N/A
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded		N/A
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values		N/A
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension..... :		N/A
	Finished component complied with routine dielectric strength tests of 8.8.3	See appended Table 8.8.3A & 8.8.3B	P
	Tests of Annex L not repeated since material data sheets confirm compliance		N/A
8.8.3	Solid insulating materials with a safety function withstood dielectric strength test voltages applied in accordance with methods of this Clause	See appended Table 8.8.3A & 8.8.3B	P
	a) Waveform and frequency of test voltage resulted in dielectric stress on insulation at least equal to that in NORMAL USE		P
	Test voltage with a different waveform and frequency than the voltage in NORMAL USE applied when manufacturer demonstrated dielectric stress on insulation tested was not diminished (waveform, frequency Hz)..... :	Waveform: sinusoidal Frequency = 50 Hz	P
	Test performed with a 50 or 60 Hz sinusoidal voltage in NORMAL USE, and relevant insulation subjected to a non-sinusoidal a.c. voltage		P
	Test voltage for WORKING VOLTAGE applicable to insulation was ≥ than in Table 6		P
	b) No breakdown occurred during tests		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Breakdown indicated by a rapid uncontrolled increase in current when insulation unable to restrict flow of current		N/A
	Corona discharge or a single momentary flashover not regarded as insulation breakdown		N/A
	c) A large part or entire ME EQUIPMENT tested when individual solid insulation could not be tested, different types and levels of insulation not overstressed, and following was considered		N/A
	– Metal foil used on non-conductive surfaces of ENCLOSURE or part of it positioned to prevent flashover at edges of insulation linings		N/A
	When applicable, metal foil moved to test all parts of surface		N/A
	– Circuits on either side of insulation under test connected or short-circuited to prevent stress on components within circuits		N/A
	– IEC 60384-14 Certified capacitors across insulation under test disconnected during test		N/A
8.8.4	Insulation other than wire insulation		P
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT		P
	ME EQUIPMENT and RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests	RMF includes storage temperature, operating temperature, exposure to liquids, and transportation.	P
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat		N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat:	No heat produced	N/A
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using apparatus of Fig 21	Metal enclosure	N/A
	Surface of part placed in a heating cabinet at 75° C ± 2 °C or ambient temperature indicated in technical description ± 2 ° C plus temperature rise of relevant part of insulating material measured during test of 11.1, higher of the two (° C)..... :		N/A
	A steel ball 5 mm in diameter pressed against the surface with a force of 20 N		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ± 2 °C plus temperature rise determined during test of 11.1 of relevant part, higher of the two (° C) ..... :		N/A
	Impression made by the ball after 1 h was 2 mm or less in diameter (mm)..... :		N/A
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION		N/A
8.8.4.2	Resistance to environmental stress		P
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt or dust resulting from wear of parts within ME EQUIPMENT to the extent CREEPAGE and CLEARANCES would be reduced below 8.9	No such parts	N/A
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION		N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION		N/A
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen not less than 97 % pure, to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples		N/A
	Samples kept in cylinder at 70 °C ± 2 °C for 96 h, and immediately afterwards, taken out of cylinder and left at room temperature for at least 16 h		N/A
	There were no cracks visible to naked eyes		N/A
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		P
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are ≥ to values in Tables 11 to 16 (inclusive), except as specified in Clauses 8.9.1.2 to 8.9.1.15	Comply with table 12	P
8.9.1.2	Tables 11 to 16 (inclusive) not applied to CREEPAGE and CLEARANCES forming MEANS OF OPERATOR PROTECTION per IEC 60950-1 for INSULATION CO-ORDINATION and used under conditions compliance was tested		P

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Clause	Requirement + Test	Result - Remark	Verdict
8.9.1.3	Specified min CLEARANCE applied as min CREEPAGE for CREEPAGE DISTANCES across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics		N/A
8.9.1.4	When min CREEPAGE derived from Tables 11 to 16 (inclusive) was less than min applicable CLEARANCE, value of min CLEARANCE applied as min CREEPAGE DISTANCE		N/A
8.9.1.5	ME EQUIPMENT RATED to operate at an altitude of 2000 m		P
	ME EQUIPMENT RATED to operate at an altitude specified by MANUFACTURER (m) ..... :		N/A
	Operating altitude corresponding to actual air pressure for ME EQUIPMENT intended for pressurized environments (e.g., aircraft) used in determining multiplication factor from Table 8, and AIR CLEARANCE was multiplied by this factor		N/A
	CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE		N/A
8.9.1.6	When WORKING VOLTAGE was between those in Tables 11 to 16 (inclusive), CREEPAGE and CLEARANCES calculated as follows:		P
	– CREEPAGE DISTANCES determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) ..... :		P
	– CLEARANCES for PEAK WORKING VOLTAGES above 2800 V peak or d.c. determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) ..... :		N/A
	– for AIR CLEARANCES corresponding to PEAK WORKING VOLTAGE up to 2800 V peak or d.c., the higher of the two values applied		P
8.9.1.7	Material groups classified in accordance with Table 9 (Material Group) ..... :	Assumed IIIb	P
	Material group evaluated using 50 drops of solution A based on test data for material according to IEC 60112		N/A
	Material of unknown group considered group IIIb		P
8.9.1.8	– Pollution degree 1: Micro-environment sealed to exclude dust and moisture		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Pollution degree 2: Micro-environment with non-conductive pollution, except occasional temporary conductivity caused by condensation		P
	– Pollution degree 3: Micro-environment subject to conductive pollution, or dry non-conductive pollution that could become conductive due to expected condensation		N/A
	– Pollution degree 4: Micro-environment where continuous conductivity occurs due to conductive dust, rain, or other wet conditions		N/A
	Pollution degree 4 not used for insulation providing a MEANS OF PROTECTION		N/A
	Where insulation between MAINS PART and earth might be compromised, measures such as maintenance ensure that micro-environment is mitigated to a lower pollution degree		N/A
8.9.1.9	Applicable value of MAINS TRANSIENT VOLTAGE determined from overvoltage category according to IEC 60664-1 and NOMINAL a.c. MAINS VOLTAGE using Table 10 (V_{MT} peak, V_{MN} r.m.s.) .....:		N/A
8.9.1.10	Required CLEARANCE for MAINS PARTS operating on RATED MAINS VOLTAGES up to 300 V were values for r.m.s. or d.c. RATED MAINS VOLTAGE in Table 13 plus additional CLEARANCE in Table 14 for PEAK WORKING VOLTAGE		N/A
8.9.1.11	Overvoltage category II applied according to IEC 60664-1		N/A
	For ME EQUIPMENT intended for overvoltage category III, Tables 13 to 15 (inclusive) not used for clearance, instead values in the next MAINS TRANSIENT VOLTAGE column upwards used		N/A
	When PATIENT protection (Table 12) was required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, guidance provided on values required in the rationale for 8.9 used		N/A
8.9.1.12	A SECONDARY CIRCUIT derived from a SUPPLY MAINS, normally, considered to be overvoltage category I according to IEC 60664-1 when the MAINS PART is overvoltage category II (Table 15)		N/A
	Table 15 applied to earthed SECONDARY CIRCUIT or INTERNALLY POWERED ME EQUIPMENT		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Requirements for primary circuits in Tables 13 and 14 used for an unearthed SECONDARY CIRCUIT derived from a SUPPLY MAINS		N/A
	Table 15 applied when SECONDARY CIRCUIT was separated from MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients in SECONDARY CIRCUIT were below the levels expected for overvoltage category I		N/A
	Table 15 column for circuits not subject to transient overvoltages applied to:		P
	– d.c. SECONDARY CIRCUITS reliably connected to earth and have capacitive filtering limiting peak-to-peak ripple to 10 % of d.c. voltage, and		N/A
	– circuits in INTERNALLY POWERED ME EQUIPMENT		P
8.9.1.13	Table 15 for PEAK WORKING VOLTAGES above 1400 V peak or d.c. not applied because all the following conditions were met:		N/A
	– CLEARANCE was at least 5 mm		N/A
	– insulation complied with dielectric strength test of 8.8.3 using an a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, or		N/A
	– a d.c. test voltage equal to peak value of a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, and		N/A
	– CLEARANCE path was partly or entirely through air or along the surface of an insulating material of material group I		N/A
	Dielectric strength test conducted only across part(s) of the path that are through air when CLEARANCE path was also partly along surface of a non- group I material		N/A
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION obtained by doubling values in Table 16 for one MEANS OF OPERATOR PROTECTION		N/A
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION for insulation in MAINS PART between parts of opposite polarity, therefore, min CREEPAGE and CLEARANCES not applied	See appended Table 8.9.2	P
	b) Contribution to CREEPAGE DISTANCES of grooves or air gaps less than 1 mm wide limited to widths		P
	c) Relative positioning of CLEARANCE providing a MEANS OF PROTECTION is such that the relevant parts are rigid and located by molding, or there is no reduction of a distance below specified value by deformation or movement of parts		P
	Normal or likely limited movements of relevant parts taken into consideration when calculating minimum AIR CLEARANCE		P
8.9.3	Spaces filled by insulating compound		N/A
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound were such that CLEARANCES and CREEPAGE DISTANCES do not exist		N/A
	Thermal cycling, humidity preconditioning, and dielectric strength tests in 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4 conducted		N/A
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (clause 8.8.3), test voltage multiplied by 1.6		N/A
	Cracks or voids in insulating compound affecting homogeneity of material did not occur		N/A
8.9.3.3	For situations where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint		N/A
	A winding of solvent-based enameled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:		N/A
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling, it was subjected to dielectric strength test of 8.8.3 except at 1.6 times the test voltage		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of 8.8.3 at 1.6 times the test voltage		N/A
8.9.3.4	One sample containing the cemented joint subjected to a sequence of temperature cycling tests for 10 times		N/A
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES		P
	CREEPAGE AND CLEARANCES measured using Figs 22 to 31 (inclusive)		P
	Corners with included angles less than 80° assumed to be bridged with an insulating link of 1 mm moved into the least favorable position		P
	Distance of 1 mm or more across the top of a groove did not constitute a CREEPAGE DISTANCE		P
	CREEPAGE and CLEARANCES between parts moving relative to each other measured with the parts in their least favorable positions		P
	Calculated CREEPAGE DISTANCE was never less than measured AIR CLEARANCE		P
	Coatings of varnish, enamel, or oxide disregarded		P
	Coverings of insulating materials equivalent to a sheet of insulating material of equal thickness with respect to their electrical, thermal, and mechanical properties considered as insulation		P
	Minimum values in Tables 11 to 16 (inclusive) applied to sum of sections for CREEPAGE or CLEARANCES for one or two MEANS OF PROTECTION interrupted by one or more floating conductive parts (distances less than 1 mm disregarded)		P
	Walls of grooves transverse to CREEPAGE DISTANCE counted as CREEPAGE DISTANCE only when width of the groove was more than 1 mm, otherwise grooves disregarded		P
	CREEPAGE DISTANCES for a barrier placed on surface of insulation or held in a recess measured over barrier only when dust and moisture could not penetrate into the joint or recess		P
	Measurements for ME EQUIPMENT with an APPLIANCE INLET made with an appropriate connector inserted		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	For other ME EQUIPMENT with POWER SUPPLY CORDS measurements made with conductors of largest cross-sectional area specified by MANUFACTURER and without conductors		N/A
	Movable parts placed in the least favorable position, and nuts and screws with non-circular heads tightened in the least favorable position		N/A
	CREEPAGE and CLEARANCES through slots or openings in external parts measured to the standard test finger of Fig 6		N/A
	Measurements made applying a 2 N force on points of bare conductors using a standard test finger (as in Fig 6) complied with requirements for CREEPAGE DISTANCES and AIR CLEARANCES		N/A
	Measurements made applying a 30 N force to outside of metal ENCLOSURE using a standard test finger (as in Fig 6) complied with requirements for CREEPAGE and CLEARANCES		P
	When relevant, CREEPAGE and CLEARANCES measured after use of test hook in 5.9.2.2		N/A
8.10	Components and wiring		P
8.10.1	Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely as indicated in RISK MANAGEMENT FILE		P
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION		N/A
	Conductors and connectors of ME EQUIPMENT when breaking free at their joint and moving about their support point are not capable of touching circuit points resulting in a HAZARDOUS SITUATION as indicated in RISK MANAGEMENT FILE		N/A
	Breaking free of one means of mechanical restraint considered a SINGLE FAULT CONDITION	Only flat cables used	N/A
	Stranded conductors are not solder-coated when secured by clamping means to prevent poor contact which could create HAZARDOUS SITUATIONS	Only flat cables used	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.10.3	Flexible cords detachable without a TOOL used to interconnect different parts of ME EQUIPMENT provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS of 8.4 when a connection is loosened or broken as indicated by measurement or using test finger		N/A
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		N/A
8.10.4.1	Control devices of ME EQUIPMENT and their associated connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION		N/A
	d.c. limit of 60 V applied to d.c. with no more than 10 % peak-to-peak ripple		N/A
	42.4 V peak limit applied when ripple exceeded 10 % peak-to-peak limit		N/A
8.10.4.2	Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT at both ends of cable to control device complied with 8.11.3 when breaking free or shorting between conductors could result in a HAZARDOUS SITUATION		N/A
	This requirement applied to other HAND-HELD parts when disturbance or breaking of one or more of connections could result in a HAZARDOUS SITUATION		N/A
8.10.5	Mechanical protection of wiring		
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION		N/A
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION as shown by manual tests and RISK MANAGEMENT FILE		P
8.10.6	Guiding rollers of insulated conductors prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead concerned in NORMAL USE		N/A
8.10.7	a) Insulating sleeve that can only be removed by breaking or cutting, or secured at both ends, is used on internal wiring of when needed		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics		N/A
	c) Insulated conductors subject to temperatures > 70 °C in NORMAL USE provided with insulation of heat-resistant material when compliance is likely to be impaired due to deterioration of insulation		N/A
8.11	MAINS PARTS, components and layout		N/A
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles		N/A
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)		N/A
	b) Means of isolation incorporated in ME EQUIPMENT, and external means described in technical description		N/A
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE and CLEARANCES in IEC 61058-1 for a MAINS TRANSIENT VOLTAGE of 4 kV		N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or other external flexible lead		N/A
	e) Direction of movement of actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447		N/A
	f) A suitable plug device such as an APPLIANCE COUPLER or a flexible cord with a MAINS PLUG used in non-PERMANENTLY INSTALLED ME EQUIPMENT to isolate it from SUPPLY MAINS considered to comply with 8.11.1 a)		N/A
	g) A fuse or a semiconductor device not used as an isolating means in the sense of this clause		N/A
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering		N/A
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage (symbol 10 of Table D.1 is insufficient)		N/A
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause		N/A
	Standard test finger of Fig 6 applied		N/A
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2		N/A
8.11.3	POWER SUPPLY CORDS		N/A
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD		N/A
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, designation 53)		N/A
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE		N/A
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 (mm^2 Cu) ..... :		N/A
8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6		N/A
8.11.3.5	Cord anchorage (for APPLIANCE COUPLERS not complying with IEC 60320-1)		N/A
	a) Conductors of POWER SUPPLY CORD provided with strain relieve and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Cord anchorage of POWER SUPPLY CORD is made of and arranged as follows when a total insulation failure of POWER SUPPLY CORD caused conductive non-PROTECTIVELY EARTHED ACCESSIBLE PARTS to exceed limits of 8.4:		N/A
	– insulating material, or		N/A
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or		N/A
	– metal provided with an insulating lining affixed to cord anchorage, except when it is a flexible bushing forming part of the cord guard in 8.11.3.6, and complying with the requirements for one MEANS OF PROTECTION		N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		N/A
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components other than parts of cord anchorage		N/A
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals when cord anchorage fails		N/A
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		N/A
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18		N/A
	Cord subjected to a torque in Table 18 for 1 min immediately after pull tests		N/A
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their normally connected position		N/A
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		N/A
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.11.3.6	POWER SUPPLY CORDS other than for STATIONARY ME EQUIPMENT protected against excessive bending at inlet opening of equipment or of MAINS CONNECTOR by means of an insulating cord guard or by means of an appropriately shaped opening		N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		N/A
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D^2 gram (D in mm) attached to the free end of cord (g)..... :		N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		N/A
	Radius of curvature of the cord, immediately after mass was attached, was not less than 1.5 x D ..		N/A
8.11.4	MAINS TERMINAL DEVICES		N/A
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD replaceable by SERVICE PERSONNEL provided with MAINS TERMINAL DEVICES ensuring reliable connection		N/A
	Terminals alone are not used to keep conductors in position, except when barriers are provided such that CREEPAGE and CLEARANCES cannot be reduced below 8.9 if any conductor breaks away		N/A
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked according to 7.3.7 used as terminals intended for external conductors		N/A
	Screws and nuts clamping external conductors do not serve to secure any other component, except they also clamp internal conductors when unlikely to be displaced when fitting the supply conductors		N/A
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		N/A
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL closely grouped to provide convenient means of connection		N/A
	b) PROTECTIVE EARTH CONDUCTOR connections complied with 8.6		N/A
	c) Marking of MAINS TERMINAL DEVICES complied with 7.3		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		N/A
	e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area in Table 17 stripped 8 mm and with a single free wire bent in every possible direction without pulling back insulating sheath or making sharp bends around partitions		N/A
8.11.4.3	Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced below 8.9 after fastening and loosening a conductor of largest cross-sectional area 10 times		N/A
8.11.4.4	Terminals with clamping means for a rewirable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened as verified by test of 8.11.3.4		N/A
8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewirable POWER SUPPLY CORD to allow easy introduction and connection of conductors, and covers fitted without damage to conductors or their insulation		N/A
	Correct connection and positioning of conductors before ACCESS COVER was fitted verified by an installation test		N/A
8.11.5	Mains fuses and OVER-CURRENT RELEASES		N/A
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection according to 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT		N/A
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT		N/A
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts of opposite polarity within MAINS PART, and between all parts of MAINS PART and earth, and such provisions continued within all components		N/A
	Effect of short-circuit fault conditions in other circuits taken into consideration before eliminating fuses or OVER-CURRENT RELEASES		N/A
	Protective devices have adequate breaking capacity to interrupt the maximum fault current including the available short-circuit		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		N/A
	Fuses complying with IEC 60127 have high breaking capacity (1 500 A) and prospective short-circuit current > 35 A or 10 times current rating of the fuse, whichever is greatero		N/A
	Justification for omission of fuses or OVER-CURRENT RELEASES is in RISK MANAGEMENT FILE		N/A
8.11.6	Internal wiring of the MAINS PART		N/A
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE and protective devices is not < minimum required for POWER SUPPLY CORD as in 8.11.3.3 (mm^2 Cu) ..... :		N/A
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits sufficient to prevent fire in case of fault currents		N/A
	When necessary, ME EQUIPMENT connected to a SUPPLY MAINS with max available short-circuit fault, and subsequent simulation of a fault in a single insulation in MAINS PART did not result in any of the HAZARDOUS SITUATIONS in 13.1.2		N/A
9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		P
9.1	ME EQUIPMENT complies with Clause 4 for design and manufacture, and mechanical strength (15.3)		P
9.2	HAZARDS associated with moving parts		N/A
9.2.1	When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level	No moving parts	N/A
	RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)		N/A
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its function		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Warnings marked on ME EQUIPMENT or included in instructions for use when HAZARDS persisted after implementing all reasonable protective measures		N/A
9.2.2	TRAPPING ZONE		N/A
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:		N/A
	– Gaps in Clause 9.2.2.2, or		N/A
	– Safe distances in Clause 9.2.2.3, or		N/A
	– GUARDS and protective measures in 9.2.2.4, or		N/A
	– Continuous activation in Clause 9.2.2.5		N/A
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM		N/A
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions specified in Table 20		N/A
9.2.2.3	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13852		N/A
	Distances measured from expected positions of OPERATOR, PATIENT, and others near EQUIPMENT in NORMAL USE or under foreseeable misuse		N/A
9.2.2.4	GUARDS and protective measures		N/A
9.2.2.4.1	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when GUARDS and protective measures were of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK based on results of applicable tests in 15.3 for ENCLOSURES		N/A
9.2.2.4.2	FIXED GUARDS securely held in place by systems that cannot be dismantled without a TOOL		N/A
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,		N/A
	– absence or failure of one of their components prevents starting, and stops moving parts		N/A
	Movable GUARDS complied with all applicable tests as confirmed by review of RISK MANAGEMENT FILE		N/A
9.2.2.4.4	Protective measures provided in control system prevented moving parts from starting to move while in reach of persons		N/A
	– protective measures prevented TRAPPING ZONE from reach, or, when it was reached, system movement stopped once ME EQUIPMENT started to move, and in the latter case, no HAZARD or damage resulted		N/A
	– when protective measure was in a SINGLE FAULT CONDITION, and an unacceptable RISK could arise, one or more emergency stopping device(s) provided		N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N/A
9.2.2.5	Continuous activation		N/A
	TRAPPING ZONE not considered to present a MECHANICAL HAZARD where impractical to make TRAPPING ZONE inaccessible when:		N/A
	a) movement was in OPERATOR'S field of view		N/A
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR as long as OPERATOR response to deactivate device relied upon to prevent HARM		N/A
	Manually operated movements complied with this clause since mass and velocity allowed adequate control of positioning without causing an unacceptable RISK		N/A
	c) when in a SINGLE FAULT CONDITION of continuous activation system an unacceptable RISK could arise, one or more emergency stopping device(s) provided in ME EQUIPMENT		N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT, when contact with ME EQUIPMENT could result in a HAZARDOUS SITUATION, limited to allow OPERATOR control of positioning without resulting in an unacceptable RISK		N/A
	Over travel (stopping distance) of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK		N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N/A
9.2.3	Other HAZARDS associated with moving parts		N/A
9.2.3.1	Controls positioned, recessed, or protected by other means and could not be accidentally actuated to result in unacceptable RISK, except when ergonomic considerations for a PATIENT with special needs require otherwise		N/A
9.2.3.2	RISK due to over travel (past range limits) of ME EQUIPMENT parts reduced to an acceptable level, and stops or other means with mechanical strength to withstand intended loading in NORMAL USE and foreseeable misuse provided limiting measure in NORMAL and SINGLE FAULT CONDITION		N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N/A
9.2.4	Emergency stopping devices		N/A
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power:		N/A
	a) Emergency stopping device reduced RISK to an acceptable level		N/A
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		N/A
	c) Emergency stopping device actuator was readily accessible to OPERATOR		N/A
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		N/A
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original HAZARD		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		N/A
	g) Means for stopping of movements operate as a result of one single action		N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		N/A
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 (symbol IEC 60417-5638, DB:2002-10) or "STOP"		N/A
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed		N/A
	k) Emergency stopping device is suitable for its application		N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N/A
9.2.5	Means provided to permit Quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a protective measure, or emergency stopping, and		N/A
	– Uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented		N/A
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented		N/A
	– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way		N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N/A
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in an unacceptable RISK avoided or covered		P
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		P
9.4	Instability HAZARDS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.4.1	ME EQUIPMENT, other than FIXED and hand-held, for placement on a surface did not overbalance (tip over) or move unexpectedly, to the degree that it could present an unacceptable RISK to PATIENT, or OPERATOR as tested in 9.4.2 to 9.4.4		N/A
9.4.2	Instability – overbalance		N/A
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when not specified, as in 9.4.2.2, and placed on a 10° inclined plane from horizontal consisting of a hard and flat surface (e.g., concrete floor covered with 2 to 4 mm thick vinyl material)		N/A
9.4.2.2	Instability excluding transport		N/A
	ME EQUIPMENT or its parts prepared based on a) to g), inclusive, did not overbalance when placed in different positions of NORMAL USE, except transport positions, on a 5° inclined plane from horizontal consisting of a hard and flat surface		N/A
	A warning notice provided stating "Transport only under conditions clearly described in instructions for use or marked on ME EQUIPMENT with an indication of RESIDUAL RISK if ME EQUIPMENT or its parts overbalances" when overbalance occurred during 10° inclined plane test		N/A
9.4.2.3	Instability from horizontal and vertical forces		N/A
	a) ME EQUIPMENT with a mass of 25 kg or more, other than FIXED ME EQUIPMENT for use on floor, did not overbalance due to pushing, resting, etc		N/A
	Surfaces of ME EQUIPMENT where a RISK of overbalancing exists from pushing, leaning, resting etc., permanently marked with a CLEARLY LEGIBLE warning of the RISK (e.g., safety sign 5 of Table D.2, safety sign ISO 7010-P017)		N/A
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a force of 25 % of its weight, but not more than 220 N, applied in different directions, except a direction with an upward component		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) ME EQUIPMENT, other than FIXED ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping, except when a legible warning of this RISK provided on ME EQUIPMENT (e.g., safety signs 6 and 7 of Table D.2, safety signs ISO 7010-P018, or ISO 7010-P019 as appropriate)		N/A
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a constant downward force of 800 N applied at the point of maximum moment to working surfaces, offering an foothold or sitting surface of a min 20 x 20 cm area, and at a height ≤ 1 m from the floor		N/A
9.4.2.4	Castors and wheels		N/A
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT (e.g., castors or wheels) did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE		N/A
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT along a hard and flat horizontal surface did not exceed 200 N applied at a height of 1 m above floor or highest point on ME EQUIPMENT when < 1 m high, except when instructions for use indicated more than one person needed (N)..... :		N/A
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg configured with a SAFE WORKING LOAD, moved as in NORMAL USE 10 times in forward direction over (up and down) a solid vertical plane obstruction installed on the floor with wheels impacting the obstruction at a speed of 0.4 m/s ± 0.1 m/s for manual or with max speed for motor driven MOBILE ME EQUIPMENT		N/A
	ME EQUIPMENT went up the obstruction without overbalancing or any other unacceptable RISK as determined by examination of ME EQUIPMENT, its parts, and RISK MANAGEMENT FILE		N/A
	There was no reduction of CREEPAGE and CLEARANCES below 8.9, no access to parts exceeding limits in 8.4, and no access to moving parts capable of causing HARM, and		N/A
	– Assessment criteria in Clause 9 and 11.6 used		N/A
	– Dielectric strength test of 8.8.3 conducted to evaluate integrity of solid SUPPLEMENTARY or REINFORCED INSULATION		N/A
	– CREEPAGE DISTANCES and AIR CLEARANCES measured compared favorably with min distances in clause 8.9		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Small chips not adversely affecting protection against electric shock or moisture, disregarded		N/A
9.4.3	Instability from unwanted lateral movement (including sliding)		N/A
9.4.3.1	a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control		N/A
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements of ME EQUIPMENT or its parts in transport position		N/A
	c) No unacceptable RISK due to unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position or worst case NORMAL USE position with SAFE WORKING LOAD, and locking device activated, on a 10° inclined hard flat surface with castors in the worst-case position		N/A
	Following initial elastic movement, creepage, and pivoting of castors, no further movement of MOBILE ME EQUIPMENT > 50 mm (in relation to inclined plane) occurred (mm) ..... :		N/A
	RISK due to any initial movement assessed taking into consideration NORMAL USE of ME EQUIPMENT		N/A
9.4.3.2	Instability excluding transport		N/A
	a) Further movement of ME EQUIPMENT (after initial elastic movement) was less than 50 mm when MOBILE ME EQUIPMENT with a SAFE WORKING LOAD positioned on a 5° inclined hard flat surface with wheel locked or braking system activated (mm) ..... :		N/A
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT		N/A
	b) TRANSPORTABLE or STATIONARY ME EQUIPMENT for use on the floor and with a SAFE WORKING LOAD prepared as in 9.4.2.2 and placed on a horizontal plane with locking device activated and castors, when supplied, in their worst –case position		N/A
	Further movement of ME EQUIPMENT (after initial elastic movement), was no more than 50 mm when a force of 25 % of weight of unit, but less than 220 N, applied in different directions, except a direction with an upwards component, at highest point of ME EQUIPMENT but ≤ 1.5 m from floor..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT		N/A
9.4.4	Grips and other handling devices		N/A
	a) ME EQUIPMENT other than PORTABLE EQUIPMENT or its part with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method, except when handling is obvious and causing HAZARDS		N/A
	Handles, when supplied, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS		N/A
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carring by two or more persons as confirmed by actual carrying		N/A
	c) Carrying handles and grips and their means of attachment withstood application of a force four times weight of ME EQUIPMENT in different directions of NORMAL USE and transport (N) .... :		N/A
	Force distributed between multiple handles, when supplied, of PORTABLE ME EQUIPMENT by measuring percentage of ME EQUIPMENT weight sustained by each handle with ME EQUIPMENT in normal carrying position (N)..... :		N/A
	Each handle of ME EQUIPMENT with multiple handles able of be carried by only one handle was capable of sustaining total force (N)..... :		N/A
	Force applied uniformly over a 7 cm length of handle at centre, starting at zero and gradually increased to test value in 5 to 10 s and maintained for 1 min		N/A
	Handles did not break loose, did not exhibit permanent distortion, cracking, or other evidence of breakdown		N/A
9.5	Expelled parts HAZARD		N/A
9.5.1	Suitability of means of protecting against unacceptable RISK of expelled parts determined by assessment and examination of RISK MANAGEMENT FILE		N/A
9.5.2	Cathode ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965		N/A
9.6	Acoustic energy (including infra- and ultrasound) and vibration		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK as confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and tests of 9.6.2 and 9.6.3		P
9.6.2	Acoustic energy		
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE, except for auditory alarm signals		P
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA) ..... :		N/A
	– 140 dB un-weighted sound pressure level for impulsive or impact acoustic energy (noise) (dB) :	The peak sound pressure is always below 140dB	P
	Maximum A-weighted sound pressure level was measured at min distances of PATIENT, OPERATOR, or other persons from source of noise in NORMAL USE (or calculated per ISO 3746, ISO 9614-1 or IEC61672-1) under following conditions:		P
	a) ME EQUIPMENT operated under worst-case NORMAL CONDITION		P
	b) All protective means provided or called for in ACCOMPANYING DOCUMENTS were in place during sound measurement		P
	c) Sound level meters used in measurement conform to IEC 61672-1 and IEC 61672-2		P
	d) Test room was semi-reverberant with hard reflecting floor, distance between any wall or other object and surface of ME EQUIPMENT was ≥ 3 m		P
9.6.2.2	RISK MANAGEMENT FILE examined for RISKS associated with infrasound or ultrasound, when present, addressed in RISK MANAGEMENT PROCESS		N/A
9.6.3	Hand-transmitted vibration		N/A
	Means provided, except for INTENDED USE vibrations, to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values measured per ISO 5349-1 at points of hand contact with PATIENT or OPERATOR		N/A
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2) ..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Accelerations for different times, inversely proportional to square root of time (m/s^2) ..... :		N/A
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		N/A
9.7.1	Requirements of this clause applied to vessels and parts of ME EQUIPMENT subject to pressure resulting in rupture and unacceptable RISK		N/A
	Parts of a pneumatic or hydraulic system used as a support system, additionally, complied with 9.8		N/A
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met following requirements based on examination of RISK MANAGEMENT FILE:		N/A
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum		N/A
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure		N/A
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects		N/A
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply		N/A
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		N/A
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity		N/A
9.7.3	Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:		N/A
	a) RATED maximum supply pressure from an external source		N/A
	b) Pressure setting of a pressure-relief device provided as part of assembly		N/A
	c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.7.4	Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by examination of ME EQUIPMENT and RISK MANAGEMENT FILE, and by functional tests		N/A
9.7.5	A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was > 50 kPa, and product of pressure and volume was > 200 kPa.l		N/A
	HYDRAULIC TEST PRESSURE was MAXIMUM PERMISSIBLE WORKING PRESSURE times a factor obtained from Fig 32, and pressure was gradually raised to specified test value and held for 1 min		N/A
	Sample did not burst, was not permanently deformed, and no leaks developed		N/A
	No leakage occurred at a gasket at a pressure below 40 % of required test value, or below MAXIMUM PERMISSIBLE WORKING PRESSURE ..... :		N/A
	No leakage occurred for pressure vessels intended for toxic, flammable, or otherwise hazardous substances, and for other pressure vessels, leakage resulting in an unacceptable RISK did not occur (e.g., high pressure fluid jet)		N/A
	When unmarked pressure vessels and pipes could not be hydraulically tested, integrity verified by other suitable tests..... :		N/A
9.7.6	Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device under different conditions of NORMAL USE		N/A
9.7.7	Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests:		N/A
	a) Connected as close as possible to pressure vessel or parts of system it is intended to protect		N/A
	b) Installed to be readily accessible for inspection, maintenance, and repair		N/A
	c) Could be adjusted or rendered inoperative without a TOOL		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	d) With discharge opening located and directed as to not to release material towards any person		N/A
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK		N/A
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure		N/A
	g) No shut-off valve provided between a pressure-relief device and parts it is intended to protect		N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		N/A
9.8	HAZARDS associated with support systems		N/A
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK		N/A
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD		N/A
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK		N/A
	– RISK ANALYSIS of support systems included HAZARDS from static, dynamic, vibration, impact and pressure loading, foundation and other movements, temperature, environmental, manufacture and service conditions		N/A
	– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES		N/A
	– Instructions on attachment of structures to a floor, wall, ceiling, etc. included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials		N/A
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.8.2	Support systems maintain structural integrity , during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or when support is a foot rest		N/A
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and processing of materials		N/A
	When test results were part of information, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK		N/A
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems		N/A
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS minimize RISK of physical injuries and accidental loosening of secured joints		N/A
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported or suspended by ME EQUIPMENT or its parts		N/A
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER		N/A
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications		N/A
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS		N/A
	Max allowable PATIENT mass > 135 kg stated in ACCOMPANYING DOCUMENTS		N/A
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance		N/A
9.8.3.2	Part of SAFE WORKING LOAD representing mass of PATIENTS or OPERATORS is distributed on support/suspension surface representing human body as in Fig A.19		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Part of SAFE WORKING LOAD representing mass of ACCESSORIES deployed as in NORMAL USE and, when not defined, at worst case position permitted by configuration or ACCESSORIES attachment on support/suspension parts		N/A
	a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m^2 on a foot rest temporarily supporting a standing PATIENT or OPERATOR		N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing, and tests:		N/A
	PATIENT support/suspension system positioned horizontally in most disadvantageous position in NORMAL USE, and a mass 2 x 135 kg or twice intended person's load (the greater used), applied to foot rest over an area of 0.1 m^2 for 1 min (Kg) :		N/A
	Damage or deflection resulting in an unacceptable RISK did not occur on foot rest and its secured joints		N/A
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK		N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing, and by a test:		N/A
	PATIENT support/suspension system set in most unfavorable NORMAL USE position, and a mass of 60 % of part of SAFE WORKING LOAD simulating PATIENT or OPERATOR, or a min 80 kg, placed on support or suspension system with center of load 60 mm from outer edge of support or suspension system for at least one minute (Kg) ..... :		N/A
	Deflection of support/suspension system resulting in an unacceptable RISK did not occur		N/A
9.8.3.3	Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE did not result in an unacceptable RISK as confirmed by following test:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	PATIENT support/suspension system set in most unfavorable NORMAL USE position, and a mass as in Fig 33 equal to SAFE WORKING LOAD simulating PATIENT or OPERATOR dropped from 150 mm above seat area on an area of support/ suspension a PATIENT or OPERATOR can sit (Kg)..... :		N/A
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES		N/A
9.8.4.1	a) A MECHANICAL PROTECTIVE DEVICE provided when a support system or its parts impaired by wear have a TENSILE SAFETY FACTOR ≥ to values in Table 21, rows 5 and 6, but less than 3 and 4		N/A
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:		N/A
	– Designed based on TOTAL LOAD, and includes effects of SAFE WORKING LOAD when applicable		N/A
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7		N/A
	– Activated before travel (movement) produced an unacceptable RISK		N/A
	– Takes into account Clauses 9.2.5 and 9.8.4.3		N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing		N/A
9.8.4.2	Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE (e.g., a secondary cable)		N/A
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced		N/A
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended to function once		N/A
	– Further use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE		N/A
	– ACCOMPANYING DOCUMENTS instruct once MECHANICAL PROTECTIVE DEVICE is activated, SERVICE PERSONNEL shall be called, and MECHANICAL PROTECTIVE DEVICE must be replaced before ME EQUIPMENT can be used again		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.2 (i.e., safety sign 7010-W001)		N/A
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE or its location relative to MECHANICAL PROTECTIVE DEVICE is obvious to service personnel		N/A
	– Compliance confirmed by examination of ME EQUIPMENT, ACCOMPANYING DOCUMENTS, RISK MANAGEMENT FILE, specifications and processing of materials, and following test:		N/A
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT		N/A
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR		N/A
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function		N/A
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES		N/A
	Support system parts have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 1 and 2, and are not impaired by wear		N/A
	Support system parts impaired by wear, however, they have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 3 and 4		N/A
	Examination of ME EQUIPMENT and RISK MANAGEMENT FILE confirmed compliance		N/A
10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		N/A
10.1	X-Radiation		N/A
10.1.1	X-radiation dose-rate was ≤ 36 pA/kg (5 μSv/h) (0.5 mR/h) 5 cm from surface of ME EQUIPMENT including background radiation for ME EQUIPMENT not producing therapeutic/diagnostic X-radiation but producing ionizing radiation	See Table 10.1.1	N/A
	Amount of radiation measured by means of an ionizing chamber radiation monitor with an effective area of 10 cm^2 or by other instruments producing equal results		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT operated as in NORMAL USE at most unfavorable RATED MAINS VOLTAGE and controls adjusted to emit maximum radiation		N/A
	Internal preset controls not intended for adjustment during EXPECTED SERVICE LIFE of ME EQUIPMENT not taken into consideration		N/A
10.1.2	RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE (see IEC 60601-1-3 & 1.3)		N/A
10.2	RISK associated with alpha, beta, gamma, neutron, and other particle radiation, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE		N/A
10.3	RISK associated with microwave radiation, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE		N/A
10.4	Relevant requirements of IEC 60825-1:1993 applied to lasers, light emitting diodes (LEDs), and laser light barriers or similar products		N/A
10.5	RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE		N/A
10.6	RISK associated with infrared radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE		N/A
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE		N/A

11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		**P**
11.1	Excessive temperatures in ME EQUIPMENT		P
11.1.1	Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and 23 operating in worst-case NORMAL USE at maximum rated ambient operating temperature T	Engineering judgement	P
	Surfaces of test corner did not exceed 90 °C		N/A
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
11.1.2	Temperature of APPLIED PARTS		P
11.1.2.1	Temperatures, hot or cold surfaces, and when appropriate, clinical effects of APPLIED PARTS supplying heat to a PATIENT determined and documented in RISK MANAGEMENT FILE and instructions for use		N/A
11.1.2.2	APPLIED PARTS not supplying heat to a PATIENT met Table 24 with max surface temperatures > 41 °C disclosed in instructions for use, and clinical effects with respect to body surface, maturity of PATIENTS, medications taken, surface pressure, as documented in RISK MANAGEMENT FILE	Will maintain the same temperature as the patient and operator	P
	Surfaces of APPLIED PARTS cooled below ambient temperatures that can also result in HAZARD evaluated as part of RISK MANAGEMENT PROCESS		N/A
11.1.3	Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE	Engineering judgement Maximum power of 3.52 W Using a hardware "bottom-up" risk assessment we calculated the dispatched effect in each component. As it is a low power product all effects are very small and will not heat up to 150°C. Max 1°C increase above ambient temperature.	P
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE		P
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE		P
	a) ME EQUIPMENT positioned for tests in accordance with this clause		N/A
	b) Supply voltage was in accordance with this clause		N/A
	c) Thermal stabilization for temperature tests has been established, and		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Non-CONTINUOUS OPERATION: After operating in standby/quiescent mode until THERMAL STABILITY reached,.ME EQUIPMENT operated in NORMAL USE over consecutive cycles until THERMAL STABILITY was achieved again, or for 7 h, the shorter of the two, and RATED "on"/"off" periods used		N/A
	– CONTINUOUS OPERATION: ME EQUIPMENT operated until THERMAL STABILITY reached		N/A
	d) Temperatures measured based on this clause using thermocouples and/or for copper windings, by-the-change-of-resistance method		N/A
	e) THERMAL CUT-OUTS were not de-activated, and test criteria was based on this clause		N/A
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL		N/A
11.2	Fire prevention		
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire caused by reasonably foreseeable misuse and met mechanical strength tests for ENCLOSURES in 15.3		P
11.2.2	Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS		P
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of fire under NORMAL or SINGLE FAULT CONDITIONS when source of ignition is in contact with ignitable material	See Attachment # and appended Table 8.10	P
	Requirements of 13.1.1 applied to oxygen concentrations up to 25 % at one atmosphere or partial pressures up to 27.5 kPa for higher atmospheric pressures		P
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT in NORMAL and SINGLE FAULT CONDITIONS under any of following conditions:	Equipment complies with Annex G, Category AP Component temperature <150°C	P
	1) when temperature of material raised to its ignition temperature		N/A
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures resulting in sparking or increasing material temperature to its ignition temperature		N/A
	3) when parts affecting safety cracked or changed their outer shape exposing temperatures > 300 °C or sparks due to overheating		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	4) when temperatures of parts or components exceeded 300 °C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE		N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively		N/A
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three ..... :		N/A
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, each by itself, or in combination		N/A
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3		N/A
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%) ..... :		N/A
	3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes		N/A
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases having reached PATIENT		N/A
11.2.2.2	RISK of ignition under least favorable conditions did not occur and oxygen concentration did not exceed 25% in immediate surroundings due to appropriate location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT when electrical components mounted on the outside of ME EQUIPMENT or an ME SYSTEM		N/A
11.2.2.3	Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks due to loosening or breaking, except when limited in power and energy to values in 11.2.2.1 a) 5)		N/A
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques		N/A
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means		N/A
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered		
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2) ..... :		N/A
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) ..... :		N/A
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a) ..... :	Equipment complies with Annex G, Category AP Component temperature <150°C	P
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a) ..... :		N/A
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas ..... :		N/A
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT		P

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2		N/A
	Following constructional requirements were met		N/A
	Or, following constructional requirements specifically analyzed in RISK MANAGEMENT FILE		N/A
	Specific justification provided when requirement not met		N/A
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials		N/A
	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as determined by examination of data on materials		N/A
	In absence of Certification, FV tests based on EC 60695-11-10 conducted on 3 samples of complete parts or sections of a part, including area with minimum thickness and ventilation openings		N/A
	b) Fire ENCLOSURE met following:		N/A
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm		N/A
	2) No openings on the sides within the area that is included within the inclined line C in Fig 39		N/A
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and made of metal, except magnesium, or of non-metallic materials, except constructions based on Table 25 and a mesh, FV-2 or better for TRANSPORTABLE ME EQUIPMENT and FV-1 or better for fixed ME EQUIPMENT, or STATIONARY ME EQUIPMENT per IEC 60695-11-10, as determined by examination of ENCLOSURE or flammability classification based on 11.3 a)		N/A
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anesthetics		P
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable anesthetics (CATEGORY AP) or anesthetics with oxidants (CATEGORY APG) comply with Annex G	Category AP, see Annex G	P

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Clause	Requirement + Test	Result - Remark	Verdict
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents		P
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE	Category AP, see Annex G The device may be used in or around explosive gases.	P
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT		P
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT		P
11.6.2	Overflow in ME EQUIPMENT		N/A
	Liquid reservoir liable to be overfilled or to overflow in NORMAL USE completely filled and 15 % of its capacity poured in over a period of 1 min, and except when restricted, TRANSPORTABLE ME EQUIPMENT tilted through an angle of 15° in least favorable direction(s), and when necessary refilled starting from position of NORMAL USE		N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION were not wet		N/A
11.6. 3	Spillage on ME EQUIPMENT and ME SYSTEM		N/A
	ME EQUIPMENT and ME SYSTEMS handling liquids in NORMAL USE positioned as in 5.4 a) and liquid with composition, volume, duration of spill, point of contact, and test conditions based on RISK MANAGEMENT PROCESS poured steadily on a point on top of ME EQUIPMENT		N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION were not wet		N/A
11.6.4	Leakage	See 13.2.6	N/A
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		
	ME EQUIPMENT with IP Code placed in least favorable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code) ..... :	Marked IPX4	P

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in a HAZARDOUS SITUATION in NORMAL CONDITION or in a SINGLE FAULT CONDITION	See appended Tables 8.7A, 8.7.3A-8.7.3D, 8.7.4.7, 8.8.3A, and 8.8.3B	P
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS		P
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected once in accordance with methods specified in instructions for use including any cooling or drying period		P
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there was no deterioration resulting in an unacceptable RISK	See appended Tables 8.7A-8.7C, 8.7.3A-8.7.3D, 8.7.4.7, 8.8.3A, and 8.8.3B	P
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT, their parts and ACCESSORIES, evaluated by MANUFACTURER and assurance that no unacceptable RISK will occur verified by RISK MANAGEMENT FILE review		P
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented according to ISO 11134, ISO 11135, or ISO 11137 as appropriate		N/A
	After the test, ME EQUIPMENT complied with the appropriate dielectric strength and LEAKAGE CURRENT tests and there was no deterioration resulting in an unacceptable RISK		N/A
11.6.8	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE		N/A
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented according to ISO 10993	Not evaluated by Intertek	-
11.8	Interruption and restoration of power supply did not result in a HAZARDOUS SITUATION, except interruption of its intended function	Internally powered	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		P
12.1	RISKS associated with accuracy of controls and instruments stated in RISK MANAGEMENT PROCESS confirmed by RISK MANAGEMENT FILE review	See RMF Questioner C.2.11 and risk analysis	N/A
12.2	RISK of poor USABILITY, including those associated with identification, marking, and documents addressed in a USABILITY ENGINEERING PROCESS as confirmed by review of provided records	See report 809546-2	P
12.3	The need for alarm systems as a means of RISK CONTROL and RISKS associated with operation or failure of alarm system addressed in RISK MANAGEMENT PROCESS	The device does not use an alarm system	N/A
12.4	Protection against hazardous output		P
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE	It is not possible for the user to change any parameters in the device.	N/A
12.4.2	When applicable, need for indication of parameters associated with hazardous output addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE		N/A
12.4.3	RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit designed to provide low and high-intensity outputs for different treatments addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE		N/A
12.4.4	When applicable, RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE		P
12.4.5	Diagnostic or therapeutic radiation		N/A
12.4.5.1	Adequate provisions made to protect PATIENTS, OPERATORS, other persons, and sensitive devices in vicinity of unwanted or excessive radiation emitted by ME EQUIPMENT designed to produce radiation for diagnostic or therapeutic purposes		N/A
	Radiation safety ensured by compliance with requirements of appropriate standards		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
12.4.5.2	RISKS associated with diagnostic X-rays addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE		N/A
12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE		N/A
12.4.5.4	RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE		N/A
12.4.6	When applicable, RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE		N/A
13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		P
13.1	Specific HAZARDOUS SITUATIONS		P
13.1.1	None of HAZARDOUS SITUATIONS in 13.1.2-13.1.4, inclusive, occurred when SINGLE FAULT CONDITIONS applied, one at a time, as in 4.7 and 13.2		P
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature		P
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		P
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		P
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 when measured as in 11.1.3		P
	– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23 when measured and adjusted as in 11.1.3		P
	–Allowable values for "other components and materials" in Table 22 times 1.5 minus 12.5 °C were not exceeded		P
	Limits for windings in Tables 26, 27, and 31 not exceeded		N/A
	Table 22 not exceeded in all other cases		N/A
	Temperatures measured according to 11.1.3	Calculated	P

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Clause	Requirement + Test	Result - Remark	Verdict
	SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where:		P
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit, or	Certified PTC limits the energy to 3.52 W	P
	– Parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by examination of design documentation		N/A
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function		N/A
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION based on 8.7.3 did not exceed		N/A
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS in 8.4.2 did not exceed		N/A
13.1.4	ME EQUIPMENT complied with the requirements of 9.1 to 9.8 for specific MECHANICAL HAZARDS		P
13. 2	SINGLE FAULT CONDITIONS		P
13.2.1	During application of SINGLE FAULT CONDITIONS in 13.2.2 -13.2.13, inclusive, NORMAL CONDITIONS in 8.1 a) also applied in least favorable combination	See appended Table 13.2	P
13.2.2 – 13.2.12	ME EQUIPMENT complied with 13.2.2 -13.2.12	See appended Table 13.2	P
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to room temperature		N/A
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		N/A
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION (see 8.8), the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).		N/A
13.2.13.2	ME EQUIPMENT with heating elements		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, or for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests of 13.2.13.2 b) & 13.2.13.2 c)		N/A
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests of 13.2.13.2 b) and 13.2.13.2 c)		N/A
	a 3) other ME EQUIPMENT with heating elements met test of 13.2.13.2 b)		N/A
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively		N/A
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration		N/A
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part		N/A
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself		N/A
	b) ME EQUIPMENT with heating elements tested per 11.1without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favorable of the two (V)..... :		N/A
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY		N/A
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted		N/A
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION		N/A
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and		N/A
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS		N/A
	2) When more than one control provided, they were disabled in turn		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time		N/A
13.2.13.3	ME EQUIPMENT with motors		N/A
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable		N/A
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test		N/A
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor and heating parts operated simultaneously to produce the least favorable condition		N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT		N/A
	b) Motor met running overload protection test of this clause when:		N/A
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or		N/A
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended		N/A
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C) ..... :		N/A
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps		N/A
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload		N/A
	Test not conducted where electronic drive circuits maintained a substantially constant drive current		N/A
	Test not conducted based on other justifications (justification)..... :		N/A
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
13.2.13.4	ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION		N/A
	ME EQUIPMENT other than HAND-HELD EQUIPMENT, EQUIPMENT kept switched on manually or kept under load by hand, and with a timer and a back-up timer system, operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated		N/A
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle		N/A
	Motor winding temperatures did not exceed values in 13.2.10 (Insulation Class, Maximum temperature measured °C) ..... :		N/A
14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		N/A
14.1	Requirements of this clause not applied to PESS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE; or		N/A
	when application of ISO 14971 showed that failure of PESS does not lead to unacceptable RISK	There are no risks with a severity of 4 (critical) or above controlled by the software alone. Acoustical energy (volume) are controlled by software , but also by physical limitations in the hardware. RF transmitted (Bluetooth M3200) energy is measured during production for compliance and not controlled by software.	N/A
	Every PROCESS has been followed throughout the PEMS DEVELOPMENT LIFE-CYCLE and a RECORD of PROCESS has been made available as confirmed by examination of RISK MANAGEMENT FILE and assessment of PROCESSES cited in this Clause		N/A
	MANUFACTURER considered the need for additional RISK CONTROL measures when unable to follow all PROCESSES identified in Clause 14 for each constituent component of PEMS as confirmed by examination of RISK MANAGEMENT FILE and assessment of PROCESSES cited in this Clause		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Assessment of PROCESSES cited in this Clause made by internal audits		N/A
14.2	Documents produced from application of Clause 14 have been maintained and form a part of RISK MANAGEMENT FILE in addition to RECORDS and documents required by ISO 14971		N/A
	Documents required by Clause 14 reviewed, approved, issued and changed in accordance with a formal document control PROCEDURE		N/A
14.3	RISK MANAGEMENT plan required by 3.5 of ISO 14971 includes reference to PEMS VALIDATION plan		N/A
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented		N/A
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined		N/A
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone		N/A
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules		N/A
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements		N/A
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained where appropriate		N/A
	Problem resolution system meets the prescribed criteria depending on type of product:		N/A
	– it is documented as a part of PEMS DEVELOPMENT LIFE-CYCLE		N/A
	– it allows reporting of potential or existing problems affecting BASIC SAFETY or ESSENTIAL PERFORMANCE		N/A
	– it includes an assessment of each problem for associated RISKS		N/A
	– it identifies criteria that must be met for the issue to be closed		N/A
	– it identifies the action to be taken to resolve each problem		N/A
14.6	RISK MANAGEMENT PROCESS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including NETWORK/DATA COUPLING, components of third-party origin and legacy subsystems when compiling list of known or foreseeable HAZARDS		N/A
	In addition to the material in ISO 14971, Annex D, list of possible sources for HAZARDS associated with PEMS includes specified causes		N/A
	– failure of NETWORK/DATA COUPLING to provide characteristics necessary for PEMS to achieve its BASIC SAFETY or ESSENTIAL PERFORMANCE		N/A
	– undesired feedback [physical and data] (possibilities include: unsolicited input, out of range or inconsistent input, and input originating from electromagnetic interference)		N/A
	– unavailable data		N/A
	– lack of integrity of data		N/A
	– incorrect data		N/A
	– incorrect timing of data		N/A
	– unintended interactions within and among PESS		N/A
	– unknown aspects or quality of third-party software		N/A
	– unknown aspects or quality of third-party PESS		N/A
	– lack of data security, particularly vulnerability to tampering, unintended interaction with other programs and viruses		N/A
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 6.1 of ISO 14971		N/A
14.7	There is a documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem		N/A
14.8	An architecture satisfying the requirement is specified for PEMS and each of its subsystems		N/A
	The architecture specification makes use of considers the specified items to reduce RISK to an acceptable level, where appropriate:		N/A
	a) COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) fail-safe functions		N/A
	c) redundancy		N/A
	d) diversity;		N/A
	e) partitioning of functionality		N/A
	f) defensive design potentially limiting hazardous effects by restricting available output power or by introducing means to limit travel of actuators		N/A
	g) allocation of RISK CONTROL measures to subsystems and components of PEMS		N/A
	h) failure modes of components and their effects;		N/A
	i) common cause failures		N/A
	j) systematic failures		N/A
	k) test interval duration and diagnostic coverage		N/A
	l) maintainability		N/A
	m) protection from reasonably foreseeable misuse		N/A
	n) NETWORK/DATA COUPLING specification, when applicable		N/A
14.9	Design is broken up into subsystems, each with a design and test specification where appropriate, and descriptive data on design environment included in RISK MANAGEMENT FILE		N/A
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures:		N/A
	– milestone(s) when VERIFICATION is to be performed for each function		N/A
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION		N/A
	– selection and utilization of VERIFICATION tools		N/A
	– coverage criteria for VERIFICATION		N/A
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY and ESSENTIAL PERFORMANCE and requiring checks for unintended functioning of PEMS used to perform and document PEMS VALIDATION		N/A
	The person with overall responsibility for PEMS VALIDATION is independent of design team, and no member of a design team can be responsible for PEMS VALIDATION of their own design		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE referencing methods and results of PEMS VALIDATION		N/A
14.12	This Clause applied when any or all of the design was result of a modification of an earlier design		N/A
	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE		N/A
14.13	Technical description includes the following information when PEMS is intended to be connected to other equipment outside control of PEMS MANUFACTURER by NETWORK/DATA COUPLING:		N/A
	a) characteristics of NETWORK/DATA COUPLING necessary for PEMS to achieve its INTENDED USE		N/A
	b) list of HAZARDOUS SITUATIONS resulting from a failure of NETWORK/DATA COUPLING to provide the specified characteristics		N/A
	c) instructions to RESPONSIBLE ORGANIZATION containing following information and warnings:		N/A
	– connection of PEMS to a NETWORK/DATA COUPLING that includes other equipment could result in previously unidentified RISKS to PATIENTS, or OPERATORS and RESPONSIBLE ORGANIZATION should identify, analyze, and control such RISKS		N/A
	– subsequent changes to NETWORK/DATA COUPLING introducing new RISKS and requiring new analysis; and changes to NETWORK/DATA COUPLING include:		N/A
	– changes in NETWORK/DATA COUPLING configuration		N/A
	– connection of additional items to NETWORK/DATA COUPLING		N/A
	– disconnecting items from NETWORK/DATA COUPLING		N/A
	– update of equipment connected to NETWORK/DATA COUPLING		N/A
	– upgrade of equipment connected to NETWORK/DATA COUPLING		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

15	**CONSTRUCTION OF ME EQUIPMENT**		P
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS, as confirmed by examination of RISK MANAGEMENT FILE	RMF	P
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, and environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance		N/A
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		N/A
15.3	Mechanical strength		P
15.3.1	Mold stress relief, push, impact, drop, and rough handling tests did not result in unacceptable RISK and ME EQUIPMENT displayed adequate mechanical strength		P
15.3.2	Push test conducted by subjecting external parts of ENCLOSURE to a steady force of 250 N ± 10 N for 5 s applied to a circular plane surface 30 mm in diameter, except bottom of ENCLOSURE of an ME EQUIPMENT >18 kg, using a suitable test tool		P
	No damage resulting in an unacceptable RISK sustained as determined by examination of RISK MANAGEMENT FILE		P
15.3.3	Impact test conducted by subjecting a complete ENCLOSURE or its largest non-reinforced area, except for HAND-HELD ME EQUIPMENT and parts, to a free falling 500 g ± 25 g solid smooth steel ball, approx. 50 mm in diameter from a height of 1.3 m		N/A
	Test not applied to flat panel displays, platen glass of ME EQUIPMENT, or cathode ray tubes		N/A
	No damage resulting in an unacceptable RISK sustained as shown in RISK MANAGEMENT FILE		N/A
15.3.4	Drop test		P

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Clause	Requirement + Test	Result - Remark	Verdict
15.3.4.1	Each sample of HAND-HELD ME EQUIPMENT and HAND-HELD part with SAFE WORKING LOAD allowed to fall freely once from each of 3 different positions as in NORMAL USE from height specified in ACCOMPANYING DOCUMENTS, or from 1 m onto a 50 mm ± 5 mm thick hardwood board (hardwood > 600 kg/m3) lying flat on a concrete or rigid base		P
	No unacceptable RISK resulted		P
15.3.4.2	Each sample of PORTABLE ME EQUIPMENT and PORTABLE part with SAFE WORKING LOAD lifted to a height as in Table 29 above a 50 mm ± 5 mm thick hardwood board at least the size of sample lying flat on a concrete floor or rigid base, dropped 3 times from each orientation in NORMAL USE		N/A
	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE		N/A
15.3.5	Each sample of MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed specified tests:		N/A
	a) Ascending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s against an ascending hardwood step obstruction attached to a floor without the sample going over obstruction		N/A
	b) Descending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s in order to fall over a vertical step affixed flat on a rigid base with direction of movement perpendicular to face of descending step until full descent was achieved		N/A
	c) Door frame shock test conducted on the sample by moving it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s, or for motor driven EQUIPMENT, at maximum possible speed against a hardwood vertical obstacle higher than EQUIPMENT contact point(s) affixed to a vertical rigid support with movement perpendicular to face of obstacle		N/A
	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
15.3.6	When appropriate, review of available data and examination of ENCLOSURE constructed from molded or formed thermoplastic material indicated shrinkage or distortion of material due to release of internal stresses caused by molding or forming operations will not result in an unacceptable RISK		N/A
	Mould stress relief test conducted in the absence of data by placing one sample of complete ME EQUIPMENT, ENCLOSURE and framework, or for large EQUIPMENT, a portion of ENCLOSURE, in a circulating air oven at 10 °C over than max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C, for 7 h		N/A
	No damage resulting in an unacceptable RISK		N/A
15.3.7	INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT		N/A
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK	No risks	P
15.4	ME EQUIPMENT components and general assembly		P
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, in particular:		N/A
	a) Plugs for connection of PATIENT leads cannot be connected to other outlets on same ME EQUIPMENT intended for other functions, except when RISK MANAGEMENT FILE provides proof that no unacceptable RISK could result		N/A
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable as verified by review of RISK MANAGEMENT FILE		N/A
15.4.2	Temperature and overload control devices		N/A
15.4.2.1	a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could result in a HAZARDOUS SITUATION by resetting action as verified by review of RISK MANAGEMENT FILE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) THERMAL CUT-OUTS with a safety function to be reset by a soldering operation affecting operating value not fitted in ME EQUIPMENT as verified by examination of design and RISK MANAGEMENT FILE		N/A
	c) An independent non-SELF-RESETTING THERMAL CUT-OUT is, additionally, provided where a failure of a THERMOSTAT could constitute a HAZARD as verified by examination of design and RISK MANAGEMENT FILE		N/A
	d) Based on design and RISK MANAGEMENT FILE review, loss of function of ME EQUIPMENT due to operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION		N/A
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS		N/A
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety of ME EQUIPMENT as verified by following tests:		N/A
	Positive temperature coefficient devices (PTC's) complied with IEC 60730-1: 1999, clauses 15, 17, J.15, and J.17 as applicable		N/A
	ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13		N/A
	SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) Certified in accordance with appropriate IEC standards		N/A
	In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) operated 200 times		N/A
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards		N/A
	In the absence of certification per IEC standards, or data from MANUFACTURER demonstrating reliability of component to perform its safety-related function, manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted		N/A
	g) Protective device, provided on ME EQUIPMENT incorporating a fluid filled container with heating means, operated when heater switched on with container empty preventing occurrence of an unacceptable RISK due to overheating		N/A
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating in both leads where a conductive connection to earth could result in overheating as verified by examination of design and RISK MANAGEMENT FILE		N/A
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS		N/A
15.4.3	Batteries		P
15.4.3.1	Battery housings from which gases can escape during charging or discharging likely to result in a HAZARD ventilated to minimize RISK of accumulation and ignition as verified by examination of design and RISK MANAGEMENT FILE		N/A
	Battery compartments prevent accidental short circuiting of battery when this could result in a HAZARDOUS SITUATION as verified by examination of design and RISK MANAGEMENT FILE	No connection if reversed	P
15.4.3.2	Means provided to prevent incorrect connection of polarity when a HAZARDOUS SITUATION may develop by incorrect connection or replacement of a battery		N/A
15.4.3.3	Overcharging of battery prevented by virtue of design when it could result in an unacceptable RISK as verified by review of design		N/A
15.4.3.4	Lithium batteries that could become a HAZARD complied with appropriate tests of IEC 60086-4	No charging. AA type battery short circuit proof	P
	Tests of IEC 60086-4 waived on the lithium battery based on examination of design		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire caused by excessive currents when in case of a short circuit cross-sectional area and layout of internal wiring or rating of connected components can result in a fire	PTC regulates	P
	Protective device has adequate breaking capacity to interrupt the maximum fault current		N/A
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is included in RISK MANAGEMENT FILE		N/A
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for NORMAL USE, except when apparent to OPERATOR from normal operating position, and marking of 7.4.1 are insufficient for this purpose	When power is turned on the display turns on with backlight, backlight time depend on the settings.	P
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s, except when apparent to OPERATOR from normal operating position		N/A
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational when a HAZARDOUS SITUATION could exist, except when apparent to OPERATOR from normal operating position		N/A
	Requirement not applied to heated stylus-pens for recording purposes		N/A
	Indicator lights provided on ME EQUIPMENT to indicate an output exists where an accidental or prolonged operation of output circuit could constitute a HAZARDOUS SITUATION		N/A
	Colors of indicator lights complied with 7.8.1		N/A
	Charging mode visibly indicated in ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE	Not possible to charge	N/A
15.4.5	RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS when applicable as verified by review of RISK MANAGEMENT FILE		N/A
15.4.6	Actuating parts of controls of ME EQUIPMENT		
15.4.6.1	a) Actuating parts cannot be pulled off or loosened up during NORMAL USE		P

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Indication of scales (e.g., "on" "off" positions, etc.) always corresponds to position of controls with adjustment that can result in a HAZARDOUS SITUATION for PATIENT or OPERATOR while ME EQUIPMENT is in use		N/A
	c) Incorrect connection of indicating device to relevant component prevented by adequate construction when it could be separated without use of a TOOL		N/A
	When torque values in Table 30 applied between control knob and shaft of rotating controls for not less than 2 s, 10 times in each direction, knobs did not rotate with respect to shaft		N/A
	Tests conducted by applying an axial force of 60 N for electrical components and 100 N for other components for 1 min when an axial pull was required in NORMAL USE with no unacceptable RISK		N/A
15.4.6.2	Stops of adequate mechanical strength provided on rotating or movable parts of controls of ME EQUIPMENT where necessary to prevent an unexpected change from maximum to minimum, or vice-versa, of the controlled parameter when this could cause a HAZARDOUS SITUATION		N/A
	Torque values in Table 30 applied 10 times in each direction to rotating controls for minimum 2 s		N/A
	Application of an axial force of 60 N for electrical components and 100 N for other components to rotating or movable parts of controls for 1 min when an axial pull was required in NORMAL USE		N/A
15.4.7	Cord-connected HAND-HELD and foot-operated control devices		
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1	No remote controls	N/A
	b) Foot-operated control device supported an actuating force of 1350 N (i.e., weight of an adult human being) for 1 min applied over an area of 30 mm diameter in its position of NORMAL USE with no damage to device causing an unacceptable RISK		N/A
15.4.7.2	Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface		N/A
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position		N/A
15.4.7.3	a) Foot-operated control device is at least IPX1 and complies with tests of IEC 60529 (IP Code). :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6 and complies with IEC 60529 if in NORMAL USE liquids are likely to be found (IP Code)..... :		N/A
	Probability of occurrence estimated as part of RISK MANAGEMENT PROCESS		N/A
	ACCOMPANYING DOCUMENTS, design, and RISK MANAGEMENT FILE examined to confirm compliance		N/A
15.4.8	Aluminum wires less than 16 mm^2 in cross-sectional area not used	No aluminium wires	P
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed to prevent loss of oil in any position		N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport		N/A
	A pressure-release device operating during NORMAL USE is, optionally, provided		N/A
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements		N/A
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5		N/A
15.5.1	Overheating		N/A
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating in the event of short circuit or overload of output windings and comply with this Clause and tests of 15.5.1.2 and 15.5.1.3		N/A
	During tests, windings didn't open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		N/A
	Dielectric strength test of 8.8.3 conducted on transformer after short circuit and overload tests		N/A
15.5.1.2	Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved		N/A
	Short circuit applied directly across output windings for transformers not tested according to 5X frequency and 5X voltage test of 15.5.2		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
15.5.1.3	Multiple overload tests conducted on windings with more than one protective device to evaluate worst-case NORMAL USE loading and protection		N/A
15.5.2	Transformer windings provided with adequate insulation to prevent internal short-circuits that could cause overheating which could result in a HAZARDOUS SITUATION		N/A
	Dielectric strength tests were conducted in accordance with requirements of this Subclause with no breakdown of insulation system and no detectable deterioration of transformer		N/A
	a) For RATED voltage ≤ 500 V or RATED frequency ≤ 60 Hz, test voltage = 5 times RATED voltage or 5 times upper limit of RATED voltage range of that winding and a frequency ≥ 5 times RATED frequency (RATED frequency is the normal operating frequency of transformer input voltage)		N/A
	b) For rated voltage > 500 V or RATED frequency > 60 Hz = twice RATED voltage or twice the upper limit of RATED voltage range of that winding and a frequency ≥ twice RATED frequency		N/A
	Test voltage at winding with highest RATED voltage did not exceed test voltage in Table 6 for one MEANS OF PROTECTION, when RATED voltage of such a winding was considered as WORKING VOLTAGE		N/A
	When above occurred, test voltage on primary winding reduced accordingly, and test frequency adapted to produce in the core approximately magnetic induction present in NORMAL USE		N/A
	– 3-phase transformers tested using a 3-phase testing device or by 3 consecutive tests using a single-phase testing device		N/A
	– Value of test voltage with respect to core and to any screen between primary and secondary windings was based on specification of relevant transformer		N/A
	Connection point for neutral of SUPPLY MAINS on primary winding connected to core and screen when provided, except when core and screen are for connection to an unearthed part of circuit		N/A
	Connections to core omitted where core of transformer was isolated from all external conductive connections		N/A
	Core and screen connected to a source with an appropriate voltage and frequency with respect to neutral connection point		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	In the absence of a neutral connection point, each side of primary winding in turn connected to core and screen when provided, except when core and screen specified for connection to an unearthed part of circuit		N/A
	Core and screen connected to a source with an appropriate voltage and frequency with respect to each side of primary winding in turn		N/A
	– All windings not intended for connection to SUPPLY MAINS left open, and common earth connection point of windings or a point nearly at earth potential connected to core, except when core is for connection to an unearthed circuit part		N/A
	Core connected to a source with an appropriate voltage and frequency with respect to windings		N/A
	– Initially, no more than half prescribed voltage applied and raised over 10 s to full value, maintained for 1 min, and then reduced gradually and switched off		N/A
	– Tests not conducted at resonant frequencies		N/A
	Slight corona discharges neglected, provided they ceased when test voltage temporarily dropped to a lower value higher than WORKING VOLTAGE and discharges did not provoke a drop in test voltage		N/A
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with IEC 61558-1:1997, Clause 5.12		N/A

16	**ME SYSTEMS**		N/A
16.1	ME SYSTEM did not result in an unacceptable RISK after installation or subsequent modification		N/A
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM taken into account		N/A
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard		N/A
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards		N/A
	– tests performed in NORMAL CONDITION, except as specified		N/A
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated		N/A
	RISK MANAGEMENT methods, optionally, used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR to determine configurations with highest RISKS and measures needed to ensure ME SYSTEM will not present an unacceptable RISK in any configuration		N/A
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards		N/A
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM		N/A
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM		N/A
	Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM		N/A
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM		N/A
	ACCOMPANYING DOCUMENTS are, optionally, provided in electronic format (e.g. electronic file format or CD ROM) and ME SYSTEM is capable of displaying or printing these documents		N/A
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER		N/A
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER		N/A
	c) the required information is provided:		N/A
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM		N/A
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard		N/A
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– additional safety measures to be applied during installation of ME SYSTEM		N/A
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT		N/A
	– additional measures to be applied during preventive maintenance		N/A
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor		N/A
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM		N/A
	– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM		N/A
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM		N/A
	– instructions indicating MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM to be used only for supplying power to equipment intended to form part of ME SYSTEM		N/A
	– an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer		N/A
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET		N/A
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage		N/A
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT		N/A
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:		N/A
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES		N/A
	– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
16.3	Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, sufficiently, describe the other equipment to ensure compliance with these requirements		N/A
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, etc., after removal of covers, connectors, etc., without use of a TOOL operated at a voltage ≤ voltage in 8.4.2 c) supplied from a source separated from SUPPLY MAINS by two MEANS OF OPERATOR PROTECTION		N/A
16.5	Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed		N/A
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION appropriate for highest voltage occurring across SEPARATION DEVICE during a fault condition		N/A
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V) ..... :		N/A
16.6	LEAKAGE CURRENTS		N/A
16.6.1	TOUCH CURRENT in NORMAL CONDITION, from or between parts of ME SYSTEM within the PATIENT ENVIRONMENT, did not exceed 100 µA		N/A
	TOUCH CURRENT did not exceed 500 µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, from or between parts of ME SYSTEM within PATIENT ENVIRONMENT		N/A
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET did not exceed 5 mA ..... :		N/A
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values specified for ME EQUIPMENT in Tables 3 and 4		N/A
	Total PATIENT LEAKAGE CURRENT, optionally, measured at installation		N/A
	Measurements made using a device as in 8.7.4.4		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
16.6.4	Measurements		N/A
16.6.4.1	a) TOUCH CURRENT, PATIENT and total EARTH LEAKAGE CURRENTS of MULTIPLE SOCKET-OUTLET measured after ME SYSTEM reached operating temperature as follows:		N/A
	– ME SYSTEMS intended for non-CONTINUOUS OPERATION operated in standby/quiescent mode until THERMAL STABILITY, and then ME SYSTEM operated in NORMAL USE over consecutive cycles at RATED "on"/"off" periods until THERMAL STABILITY was again achieved, or for 7h, whichever shorter		N/A
	– ME SYSTEMS intended for CONTINUOUS OPERATION operated until THERMAL STABILITY		N/A
	b) ME SYSTEM connected to a supply at highest RATED MAINS VOLTAGE		N/A
	ME SYSTEM connected to local SUPPLY MAINS prior to its clinical use when characteristics of SYSTEM could only be measured properly after installation at RESPONSIBLE ORGANIZATION		N/A
	Number of tests reduced where examination of circuit arrangement, components, and materials of ME SYSTEM indicated no possibility of HAZARD		N/A
16.6.4.2	a) ME SYSTEM tested after assembly based on ACCOMPANYING DOCUMENTS		N/A
	b) The reference earth of measuring circuits connected to protective earth of SUPPLY MAINS when an isolating transformer not used for LEAKAGE CURRENT measurements		N/A
16.7	ME SYSTEM complied with applicable requirements of Clause 9 when a MECHANICAL HAZARD existed		N/A
16.8	Interruption and restoration of relevant power connections of ME SYSTEM one at a time and all connections simultaneously did not result in a HAZARDOUS SITUATION other than interruption of its intended function		N/A
16.9	ME SYSTEM connections and wiring		N/A
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where a HAZARDOUS SITUATION could otherwise exist		N/A
	– Connectors complied with Clause 15.4.1		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Plugs for connection of PATIENT leads could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no HAZARDOUS SITUATION could result		N/A
16.9.2	MAINS PARTS, components and layout		N/A
16.9.2.1	a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or		N/A
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or		N/A
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer		N/A
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 (i.e., safety sign ISO 7010-W001) visible in NORMAL USE, and		N/A
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or		N/A
	– marked to indicate the equipment or equipment parts it may safely be attached to		N/A
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT		N/A
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:		N/A
	– CREEPAGE and CLEARANCES complied with 8.9		N/A
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets		N/A
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6, except total impedance for ME SYSTEM was up to 400 mΩ, or higher when conditions of 8.6.4 b) met (mΩ) ..... :		N/A
	– ENCLOSURE complied with 8.4.2 d)		N/A
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable		N/A
	– RATINGS of components are not in conflict with conditions of use		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL		N/A
	– POWER SUPPLY CORD complied with 8.11.3		N/A
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:		N/A
	– Separating transformer complied with IEC 61558-2-1, except requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 were not applied		N/A
	– Separating transformer is CLASS I		N/A
	– Degree of protection against ingress of water specified as in IEC 60529		N/A
	– Separating transformer assembly marked according to 7.2 and 7.3		N/A
	– MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083		N/A
16.9.2.2	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part of ME SYSTEM without simultaneous disconnection of electrical supply to that part		N/A
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by a TOOL		N/A
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage		N/A

17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		P
	RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review ..... :	See accredited Eurofins EMC test report no.: G0M20810-2051-E-17 and G0M20808-1969-E-17	P
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS ..... :		P

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Clause	Requirement + Test	Result - Remark	Verdict
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems		P
G	**ANNEX G, PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**		P
G.2	Locations and basic requirements		P
G.2.1	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5		P
G.2.2	FLAMMABLE ANESTHETIC MIXTURE WITH AIR occurring due to a leakage or discharge of a FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE from an ENCLOSURE considered 5 to 25 cm from point of occurrence	No flammable anestheetic mixure with air in the equipment	N/A
G.2.3	A FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE contained in a completely or partly enclosed ME EQUIPMENT part and in PATIENT'S respiratory tract 5 cm from an ENCLOSURE part where leakage or discharge occurs	No flammable anestheetic mixure with oxygen or nitrous oxide in the equipment	N/A
G.2.4	ME EQUIPMENT or parts thereof specified for use with FLAMMABLE ANESTHETIC MIXTURE WITH AIR (in a location defined in G.2.2) are CATEGORY AP or APG ME EQUIPMENT and complied with G.4 and G.5	Category AP	P
G.2.5	ME EQUIPMENT or parts thereof for use with FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE (location per G.2.2) are CATEGORY APG ME EQUIPMENT and comply with G.4 and G.6		N/A
	ME EQUIPMENT in G.2.3 to G.2.5 met appropriate tests of G.3-G.5 conducted after tests of 11.6.6 and 11.6.7	Cleaning	P
G.3	Marking, ACCOMPANYING DOCUMENTS		P
G.3.1	CATEGORY APG ME EQUIPMENT marked on a prominent location with a green-colored band ≥ 2 cm wide imprinted with characters "APG" according to symbol 23 in Table D.1 (i.e., symbol IEC 60417-5332, DB: 2002-10) ..... :	Not category APG	N/A
	Length of green-colored band is ≥ 4 cm, and size of marking is as large as possible for particular case		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	When above marking not possible, relevant information included in instructions for use ..... :		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.2	CATEGORY AP ME EQUIPMENT marked on a prominent location with a green-colored circle ≥ 2 cm in diameter, imprinted with characters "AP" according to symbol 22 in Table D.1 (i.e., symbol IEC 60417- 5331, DB: 2002-10) ..... :	See copies of Marking Labels on page 4. Adding labels on the stethoscope will generate handling noise and degrade the essential function of the stethoscope. Therefore the marking is engraved without color and the correct symbol is placed with the relevant information in the user manual	P
	Marking is as large as possible for the particular case		P
	When above marking not possible, the relevant information included in instructions for use ..... :		P
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		P
G.3.3	The marking according to G.3.2 and G.3.3 placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts, and not repeated on detachable parts that can only be used with the marked EQUIPMENT		P
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts	Whole unit is category AP	P
G.3.5	Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG	Whole unit is category AP	N/A
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT		N/A
G.4.1	a) CREEPAGE and CLEARANCES between points of POWER SUPPLY CORD connection are according to Table 12 for one MEANS OF PATIENT PROTECTION	No power supply cord	N/A
	b) Connections, except those in circuits described in G.5.3 and G.6.3, protected against accidental disconnection in NORMAL USE or connection and disconnection can be performed only with a TOOL		N/A
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD, except when circuit complied with G.5.3 and G.6.3		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
G.4.2	Construction details		P
	a) Opening of an ENCLOSURE providing protection against penetration of gases or vapors into ME EQUIPMENT or its parts possible only with a TOOL		N/A
	b) ENCLOSURE complies with requirements to minimize arcing and sparking due to penetration of foreign objects ..... :	See appended Table 8.10	P
	– no openings on top covers of ENCLOSURE, except for openings for controls covered by control knobs		P
	– openings in side-covers prevented penetration of a solid cylindrical test rod of 4 mm in diameter applied in all possible directions without appreciable force		P
	– openings in base plates prevented penetration of a solid cylindrical test rod of 12 mm in diameter applied in all directions without appreciable force		P
	c) Short circuiting conductor(s) to a conductive part without presence of explosive gasses where insulation may contact a part containing a FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE, ignitable gases alone, or oxygen, did not result in loss of integrity of the part, an unacceptable temperature, or other HAZARD	Category AP	N/A
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures	The stethoscope is a handheld device, the device will hold the same electrostatic charge as the user.	N/A
	– Use of antistatic materials with a limited electrical resistance as specified in G.4.3 b) ..... :		N/A
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor of medical room		N/A
	b) Electrical resistance limits of anesthetic tubing, mattresses and pads, castor tires, and other antistatic material complied with ISO 2882 based on measurements according to ISO 1853, ISO 2878 and ISO 23529 ..... :		N/A
G.4.4	Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or more than 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components thereof		P
G.5.1	ME EQUIPMENT, its parts or components do not ignite FLAMMABLE ANESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5 (inclusive)		P
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5 ..... :		N/A
G.5.2	ME EQUIPMENT, its parts, and components in contact with gas mixtures in NORMAL USE and CONDITIONS not producing sparks and not resulting in surface temperatures above 150 °C in case of restricted vertical air circulation by convection, or 200 °C in case of unrestricted vertical air circulation measured at 25 °C comply with G.5.1 ..... :	The PTC resistor limits the power to maximum 3.52W (1.6Vx2.2A) when tripped, which will not heat up to 150°C.	P
G.5.3	ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:		P
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1 ..... :	U_{MAX} = 6.3 V	N/A
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 ..... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 ..... :	$I_{MAX,PEAK}$ = 192 mA	N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.3 ..... :		N/A
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1	P_{MAX} = 360 µW	P
	No extrapolation made for voltages above 42 V		N/A
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2$ mJ extrapolated from Fig G.2	C_{MAX} = 19.7 µJ	P
	No extrapolation made for voltages above 242 V		N/A
	U_{max}, additionally, determined using actual resistance R when the equivalent resistance R was less than 8000 Ω		P
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3	L_{MAX} = 10.6 µJ	P

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Clause	Requirement + Test	Result - Remark	Verdict
	No extrapolation made for inductances larger than 900 mH		N/A
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open, taking into consideration MAINS VOLTAGE variations in 4.10		N/A
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed, taking into consideration MAINS VOLTAGE variations required in 4.10		N/A
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks		P
	– Peak value taken into account when a.c. supplied		N/A
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :		P
	Temperature measurements made according to 11.1, and U_{max}, I_{max}, R, L_{max}, and C_{max} determined together with application of Figs G.1-G.3 ..... :		N/A
	Alternatively, compliance was verified by examination of design data		P
G.5.4	External ventilation with internal overpressure		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:		N/A
	a) FLAMMABLE ANESTHETIC MIXTURES WITH AIR that might have penetrated into ENCLOSURE of ME EQUIPMENT or part removed by ventilation before EQUIPMENT energized, and penetration of such mixtures during operation was prevented by maintenance of overpressure by means of air without flammable gases, or by physiologically acceptable inert gas (e.g., nitrogen)		N/A
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa)..... :		N/A
	Overpressure maintained at the site of potential ignition even when air or inert gas could escape through openings in ENCLOSURE necessary for normal operation of ME EQUIPMENT or its parts		N/A
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE so that the displaced volume of air or inert gas was at least five times the volume of ENCLOSURE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present		N/A
	c) Ignition sources de-energized automatically by means located in a place where G.4 does not apply, or complied with G.5 when during operation overpressure dropped below 50 Pa (Pa)..... :		N/A
	d) External surface of ENCLOSURE in which internal overpressure was maintained did not exceed 150 °C in 25 °C ambient under NORMAL USE and CONDITION (°C)..... :		N/A
G.5.5	ENCLOSURES with restricted breathing		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:		N/A
	a) A FLAMMABLE ANESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing when it was surrounded by a FLAMMABLE ANESTHETIC MIXTURE WITH AIR of a high concentration for at least 30 min without any pressure difference inside ENCLOSURE		N/A
	b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h.. :		N/A
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained when the cords were stressed by bending or pulling		N/A
	Cords are fitted with adequate anchorages to limit stresses		N/A
	After the test in G.5.4 b), an internal overpressure of 400 Pa was created and 30 pulls of the value in Table G.1 applied to each flexible cord in axial direction of cord inlet and in the least favorable perpendicular direction for 1 s		N/A
	Overpressure not reduced below 200 Pa		N/A
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)		N/A
	Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C) ..... :		N/A
	Steady state operating temperature of ENCLOSURE also measured (°C) ..... :		N/A
G.6	Requirements and tests for CATEGORY APG ME EQUIPMENT, parts and components thereof		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
G.6.1	ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION		N/A
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test after attaining thermal steady state (max. 3 h) over a period of 10 min in a 12.2 % ± 0.4 ether by volume/oxygen mixture		N/A
G.6.2	Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to at least one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION..... :		N/A
G.6.3	Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS ..... :		N/A
	a) no sparks produced and temperatures did not exceed 90 °C, or		N/A
	b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except U_{max} and I_{max} occurring in their circuits complied with the requirements, taking C_{max} and L_{max} into consideration:		N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 ..... :		N/A
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5 ..... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 ..... :		N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.6 ..... :		N/A
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated		N/A
	– U_{max} was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10		N/A
	– I_{max} was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10		N/A
	– C_{max} and L_{max} are values occurring in relevant circuit		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω		N/A
	– Peak value taken into consideration when a.c. supplied		N/A
	– An equivalent circuit calculated to determine max capacitance, inductance, and U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :		N/A
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage limiting or current-limiting devices preventing limits of Figs G.4- G.6 from exceeding, two independent components applied, to obtain the required limitation even in case of a first fault (short or open circuit) in one of these components		N/A
	Above requirement not applied to transformers complying with this standard		N/A
	Above requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture		N/A
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or		N/A
	Temperature measurements made in accordance with 11.1, or		N/A
	U_{max}, I_{max}, R, L_{max} and C_{max} determined together with application of Figs G.4-G.6 ..... :		N/A
	Alternatively, compliance verified by comparison with design data		N/A
G.6.4	ME EQUIPMENT, its parts, and components heating a FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1		N/A
	Current-carrying part of heating element is not in direct contact with FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE		N/A
G.7	Test apparatus for flammable mixtures		N/A
	Test apparatus used was in accordance with this Clause and Fig G.7		N/A

L	**ANNEX L, INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
L.1	BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex covering round winding wires between 0.05 mm and 5.00 mm diameters		N/A
L.2	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component		N/A
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		N/A
L.3	The wire subjected to tests of L.3.1 to L.3.4 at a temperature between 15 °C and 35 °C and a relative humidity between 45 % and 75 %, unless otherwise specified (°C, % Humidity) ..... :		N/A
L.3.1	Dielectric strength test of 8.8.3 for the appropriate type and number of MOP(s) conducted by preparing the sample according to IEC 60851-5:1996, Clause 4.4.1 for a twisted pair with test voltages at least twice Tables 6 and 7, but not less than following with no breakdown:		N/A
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 6000 V for REINFORCED INSULATION (V).... :		N/A
L.3.2	Sample subjected to flexibility and adherence test 8 of IEC 60851-3:1996, clause 5.1.1, using mandrel diameters of Table L.1		N/A
	Sample examined according to IEC 60851-3: 1997, clause 5.1.1.4, followed by dielectric test of clause 8.8.3, except test voltage applied between wire and mandrel with no breakdown		N/A
	Test voltage was at least the voltage in Tables 6 and 7but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V for REINFORCED INSULATION (V).... :		N/A
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa		N/A
L.3.3	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3, except test voltage applied between the wire and mandrel		N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V for REINFORCED INSULATION (V).... :		N/A
	Oven temperature set based on Table L.2 (°C) .. :		N/A
	Mandrel diameter and tension applied as in L.3.2, ((118 MPa ± 11.8 MPa (118 N/mm^2 ± 11.8 N/mm^2))..... :		N/A
	Dielectric strength test conducted at room temperature after removal from the oven		N/A
L.3.4	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests by removing each sample from the mandrel and placing it in a container surrounded by min. 5 mm of metal shot		N/A
	The ends of conductor in the sample were sufficiently long to avoid flash over, and the shot was no more than 2 mm in diameter and consisted of stainless, nickel, or nickel-plated iron		N/A
	The shot was gently poured into container until sample covered by at least 5 mm of shot, and the shot cleaned periodically with a suitable solvent (e.g., 1.1,1-trichloroethane)		N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V for REINFORCED INSULATION (V).... :		N/A
	Test voltage applied between the shot and conductor.		N/A
	Mandrel diameter and tension applied as in L.3.2, ((118 MPa ± 11.8 MPa (118 N/mm^2 ± 11.8 N/mm^2))..... :		N/A
L.4	Tests during manufacture		N/A
L.4.1	Production line dielectric strength tests conducted by the manufacture according to L.4.2 and L.4.3		N/A
L.4.2	Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:		N/A
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V) ..... :		N/A
L.4.3	Sampling tests conducted using twisted pair samples according to IEC 60851-5:1996, clause 4.4.1		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Minimum breakdown test voltage is at least twice the voltage in Tables 6 and 7 but not less than:		N/A
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION		N/A
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

4.11	TABLE: Power Input				N/A
Operating Conditions / Ratings	Voltage, (V)	Frequency, (Hz)	Current, (A)	Power, (W)	Remarks
Supplementary Information:					

7.1.3	TABLE: Durability of marking test [1]	P
Characteristics of the Marking Label tested:		Remarks
Material (composition) of Marking Label .....:	Engraved on enclosure	
Ink/other printing material or process.....:	N/A	
Method of application of ink to the Label.....:	N/A	
Other.....:	-	
Material (composition) of Warning Label .....:	-	
Ink/other printing material or process.....:	-	
Method of application of ink to the Label.....:	-	
Other.....:	-	

Supplementary information:

[1] Marking rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit, and then for 15 s with a cloth rag soaked with isopropyl alcohol.

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Clause	Requirement + Test	Result - Remark	Verdict

8.4.3	**TABLE: ME EQUIPMENT intended to be connected to a power source by a plug-measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply**	N/A

Maximum allowable voltage (V) .....:	60	Remarks

Voltage measured (V)											
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10	
Plug pins 1 and 2											
Plug pin 1 and plug earth pin											
Plug pin 2 and plug earth pin											
Plug pin 1 and enclosure											
Plug pin 2 and enclosure											

Maximum allowable stored charge when measured voltage exceeded 60 V (μC) ..... :	45	Remarks

Calculated stored charge (μC)											
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10	
Plug pins 1 & 2											
Plug pin 1 & plug earth pin											
Plug pin 2 and plug earth pin											
Plug pin 1 and enclosure											
Plug pin 2 and enclosure											

Supplementary information:

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Clause	Requirement + Test	Result - Remark	Verdict

8.4.4	**TABLE: Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT**		N/A
Maximum allowable residual voltage (V)..... :			60 V
Maximum allowable stored charge when residual voltage exceeded 60 V (μC)			45 V
Description of the capacitive circuit (i.e., accessible capacitor or circuit parts)	Measured residual voltage (V)	Calculated stored charge (μC)	Remarks
Supplementary information:			

8.5.5.1a	**TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies**				N/A
Test Condition: Figs. 9 & 10	Measurement made on accessible part	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
Supplementary information:					

8.5.5.1b	**TABLE: defibrillation-proof applied parts – verification of recovery time**			N/A
Applied part with test voltage	Test voltage polarity	Recovery time from documents (s)	Measured recovery time (s)	Remarks
Supplementary information:				

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Clause	Requirement + Test	Result - Remark	Verdict

8.5.5.2	**TABLE: DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load**	N/A

Test Voltage applied to	Measured Energy E1, (mJ)	Measured Energy E2, (mJ)	Energy E1 as % of E2, (%)
PATIENT CONNECTION 1 or APPLIED PART with PATIENT CONNECTIONS 2, 3, and 4 of the same APPLIED PART connected to earth			
PATIENT CONNECTION 2 or APPLIED PART with PATIENT CONNECTIONS 1, 3, and 4 of the same APPLIED PART connected to earth			
PATIENT CONNECTION 3 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 4 of the same APPLIED PART connected to earth			
PATIENT CONNECTION 4 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 3 of the same APPLIED PART connected to earth			

Supplementary information:

8.6.4	**TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS**	N/A

Type of ME EQUIPMENT & impedance measured between parts	Test current (A)	Voltage drop measured between parts, (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)
PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part				100
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part				100
ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part				200

Supplementary information:

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Clause	Requirement + Test	Result - Remark	Verdict

8.7A	**TABLE: PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL & SINGLE FAULT CONDITIONS – TYPE B APPLIED PARTS (μA)**	P

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10	N/A	50	N/A
				a.c	100	N/A	500	N/A
PATIENT LEAKAGECURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10	0	50	0
				a.c	100	N/A	500	N/A
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10	N/A	50	N/A
				a.c	100	N/A	500	N/A
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	50	N/A	100	N/A
				a.c	500	N/A	1000	N/A
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	50	N/A	100	N/A
				a.c	500	N/A	1000	N/A

Supplementary information:

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d)
Note 2: For TOUCH CURRENT see 8.7.3 c)
Note 3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

Note 4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

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Clause	Requirement + Test	Result - Remark	Verdict

8.7B	**TABLE: PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL & SINGLE FAULT CONDITIONS – TYPE BF APPLIED PARTS (μA)**	N/A

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10		50	
				a.c	100		500	
PATIENT LEAKAGECURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10		50	
				a.c	100		500	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10		50	
				a.c	100		500	
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	50		100	
				a.c	500		1000	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	50		100	
				a.c	500		1000	

Supplementary information:

1: For EARTH LEAKAGE CURRENT see 8.7.3 d)

2: For TOUCH CURRENT see 8.7.3 c)

3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.7C	**TABLE: PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL & SINGLE FAULT CONDITIONS – TYPE CF APPLIED PARTS (μA)**	N/A

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10		50	
				a.c	10		50	
PATIENT LEAKAGECURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10		50	
				a.c	10		50	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10		50	
				a.c	10		50	
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	50		100	
				a.c	50		100	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	50		100	
				a.c	50		100	

Supplementary information:

1: For EARTH LEAKAGE CURRENT see 8.7.3 d)
2: For TOUCH CURRENT see 8.7.3 c)
3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.7.3A	**TABLE: PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL & SINGLE FAULT CONDITIONS – TYPE B APPLIED PARTS (mA r.m.s) – measurements made with a non-frequency-weighted device (μA)**	P

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10	N/A	10	N/A
				a.c	10	N/A	10	N/A
PATIENT LEAKAGECURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10	0	10	0
				a.c	10	N/A	10	N/A
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10	N/A	10	N/A
				a.c	10	N/A	10	N/A
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	10	N/A	10	N/A
				a.c	10	N/A	10	N/A
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	10	N/A	10	N/A
				a.c	10	N/A	10	N/A

Supplementary information:

1: For EARTH LEAKAGE CURRENT see 8.7.3 d)

2: For TOUCH CURRENT see 8.7.3 c)

3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.7.3B	**TABLE: PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL & SINGLE FAULT CONDITIONS – TYPE BF APPLIED PARTS (mA r.m.s) – measurements made with a non-frequency-weighted device (μA)**	N/A

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10		10	
				a.c	10		10	
PATIENT LEAKAGECURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10		10	
				a.c	10		10	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10		10	
				a.c	10		10	
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	10		10	
				a.c	10		10	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	10		10	
				a.c	10		10	

Supplementary information:

1: For EARTH LEAKAGE CURRENT see 8.7.3 d)
2: For TOUCH CURRENT see 8.7.3 c)
3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.7.3C	**TABLE: PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL & SINGLE FAULT CONDITIONS – TYPE CF APPLIED PARTS (mA r.m.s) – measurements made with a non-frequency-weighted device (μA)**	N/A

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10		10	
				a.c	10		10	
PATIENT LEAKAGECURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10		10	
				a.c	10		10	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10		10	
				a.c	10		10	
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	10		10	
				a.c	10		10	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	10		10	
				a.c	10		10	

Supplementary information:

1: For EARTH LEAKAGE CURRENT see 8.7.3 d)
2: For TOUCH CURRENT see 8.7.3 c)
3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

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Clause	Requirement + Test	Result - Remark	Verdict

8.7.3D	TABLE: PATIENT LEAKAGE CURRENTS under special test conditions identified in 8.7.4.7 (mA r.m.s) –measurement with a non-frequency-weighted device (μA)								N/A
Current Type	Description (Note 1)	Clause Ref.	Measuring Circuit	TYPE B APPLIED PART allowed	TYPE B APPLIED PART actual	TYPE BF APPLIED PART allowed	TYPE BF APPLIED PART actual	TYPE CF APPLIED PART allowed	TYPE CF APPLIED PART actual
PATIENT LEAKAGECURRENT	Caused by an external voltage on PATIENT CONN of an F-TYPE APPLIED PART	8.7.4.7 b	Fig 16	N/A	N/A	10	N/A	10	N/A
	Caused by an external voltage on ACCESSIBLE metal part not PROTECTIVELY EARTHED	8.7.4.7 d	Fig 18	10	N/A	10	N/A	See Note 3	See Note 3
Total PATIENT LEAKAGE CURRENT See NOTE 3	Caused by an external voltage on PATIENT CONN of an F-TYPE APPLIED PART	8.7.4.7 b and 8.7.4.7 h	Fig 16 and Fig 20	N/A	N/A	10	N/A	10	N/A
	Caused by an external voltage on ACCESSIBLE metal part not PROTECTIVELY EARTHED	8.7.4.7 d and 8.7.4.7 h	Fig 18 and Fig 20	10	N/A	10	N/A	See Note 3	See Note 3

Supplementary information:

1: The condition referred to in Table IV of the second edition as "MAINS VOLTAGE ON APPLIED PART", and treated in that edition as a SINGLE FAULT CONDITION, is treated in this edition as a special test condition. The test with MAXIMUM MAINS VOLTAGE on a non-PROTECTIVELY EARTHED ACCESSIBLE PART is also a special test condition, but the allowable values are the same as for SINGLE FAULT CONDITION. See the rationales for 8.5.2.2 and 8.7.4.7d.

2: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

3: This condition is not tested with TYPE CF APPLIED PARTS because it is covered by the test with MAXIMUM MAINS VOLTAGE on the APPLIED PART. See also the rationale for 8.7.4.7 d).

4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

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Clause	Requirement + Test	Result - Remark	Verdict

8.7.4.7	TABLE: PATIENT LEAKAGE CURRENTS under special test conditions identified in 8.7.4.7 (μA)								N/A
Current Type	Description (Note 1)	Clause Ref.	Measuring Circuit	TYPE B APPLIED PART allowed	TYPE B APPLIED PART actual	TYPE BF APPLIED PART allowed	TYPE BF APPLIED PART actual	TYPE CF APPLIED PART allowed	TYPE CF APPLIED PART actual
PATIENT LEAKAGE CURRENT	Caused by an external voltage on PATIENT CONN of an F-TYPE APPLIED PART	8.7.4.7b	Fig 16	N/A	N/A	5000		50	
	Caused by an external voltage on ACCESSIBLE metal part not PROTECTIVELY EARTHED	8.7.4.7d	Fig 18	500		500		See Note 3	See Note 3
Total PATIENT LEAKAGE CURRENT See NOTE 3	Caused by an external voltage on PATIENT CONN of an F-TYPE APPLIED PART	8.7.4.7b and 8.7.4.7h	Fig 16 and Fig 20	N/A	N/A	5000		100	
	Caused by an external voltage on ACCESSIBLE metal part not PROTECTIVELY EARTHED	8.7.4.7d and 8.7.4.7h	Fig 18 and Fig 20	1000		1000		See Note 3	See Note 3

Supplementary information:

1: The condition referred to in Table IV of the second edition as "MAINS VOLTAGE ON APPLIED PART", and treated in that edition as a SINGLE FAULT CONDITION, is treated in this edition as a special test condition. The test with MAXIMUM MAINS VOLTAGE on a non-PROTECTIVELY EARTHED ACCESSIBLE PART is also a special test condition, but the allowable values are the same as for SINGLE FAULT CONDITION. See the rationales for 8.5.2.2 and 8.7.4.7d.

2: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

3: This condition is not tested with TYPE CF APPLIED PARTS because it is covered by the test with MAXIMUM MAINS VOLTAGE on the APPLIED PART. See also the rationale for 8.7.4.7 d).

4: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

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Clause	Requirement + Test	Result - Remark	Verdict

8.8.3 A	**TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) - 1 min duration**						P
PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.	A.C. test voltages in V r.m.s[1]					Dielectric breakdown[2] Yes/No
		Type of insulation tested (area from insulation diagram)	MEANS OF OPERATOR PROTECTION (MOOP)				
			Protection from MAINS PART		Protection from SECONDARY CIRCUITS		
			One MOOP	Two MOOP	One MOOP	Two MOOP	
-	1.5	DI				No test	

Supplementary information:

[1] Alternatively, as specified in the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.

[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.8.3 B	**TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF PATIENT PROTECTION (MOPP) - 1 min duration**						P
PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.	A.C. test voltages in V r.m.s[1]					Dielectric breakdown[2] Yes/No
		Type of insulation tested (area from insulation diagram)	MEANS OF PATIENT PROTECTION (MOPP)				
			Protection from MAINS PART		Protection from SECONDARY CIRCUITS		
			One MOPP	Two MOPP	One MOPP	Two MOPP	
-	1.5	DI				1000	No

Supplementary information:

[1] Alternatively, as specified in the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.

[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.9.2	**TABLE: Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4**	P

Specific areas of circuits short-circuited and test conditions	Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE[1]	HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No	Remarks
SC battery poles		NO	PTC regulates the current to 2.20 A

Supplementary information:
Note 1: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.2	**Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts**	N/A

Test Sequence No.	Each test duration and temperature	Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)	Dielectric strength test immediately after humidity preconditioning according to 5.7 except for 48 h only, Breakdown: Yes/No
1	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
2	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
3	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
4	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		

Supplementary information:

[1] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

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Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.4	**Table: Thermal cycling tests on one sample of cemented joint (see 8.9.3.3)**		N/A
Test Sequence No.	Each test duration and temperature	Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)	Dielectric strength test immediately after humidity preconditioning according to 5.7 except for 48 h only, Breakdown: Yes/No
1	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
2	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
3	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
4	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information: [1] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

8.10 **TABLE: List of critical components**

Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity [1]
PTC	Littelfuse	nanoSMDC110F	I_{hold} 1.10 A I_{trip} 2.20 A		$_{c}UR_{US}$, E183209 TUV
Battery	Any	LR6, AA	1.5 V		

Supplementary information:
1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.

9.2.2.2 **TABLE: Measurement of gap "a" according to Table 20 (ISO 13852: 1996)** N/A

Part of body	Allowable adult gap[1], mm	Measured adult gap, mm	Allowable children gap[1], mm	Measured children gap, mm	Remarks
Body	> 500		> 500		
Head	> 300 or < 120		> 300 or < 60		
Leg	> 180		> 180		
Foot	> 120 or < 35		> 120 or < 25		
Toes	> 50		> 50		
Arm	> 120		> 120		
Hand, wrist, fist	> 100		> 100		
Finger	> 25 or < 8		> 25 or < 4		

Supplementary information:
[1] In general, gaps for adults used, except when the device is specifically designed for use with children, values for children applied.

10.1.1 **TABLE: Measurement of X - radiation** N/A

Maximum allowable radiation pA/kg (µSv/h) (mR/h)	36 (5 µSv/h) (0.5 mR/h)	
Surface area under test Surface no./ Description[1]	Measured radiation pA/kg (µSv/h) (mR/h)	Remarks

Supplementary information:
[1] Measurements made at a distance of 5 cm from any surface to which OPERATOR (other than SERVICE PERSONNEL) can gain access without a TOOL, is deliberately provided with means of access, or is instructed to enter regardless of whether or not a TOOL is needed to gain access (pA/kg)

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.	**TABLE: Excessive temperatures in ME EQUIPMENT**				N/A
Model No./Part No./Type No. .....:					
Maximum rated ambient operating temperature T (°C) .....:					
Supply voltage, 110 % of max. RATED voltage, for ME EQUIPMENT with heating elements operated as in NORMAL USE, all heating elements energized unless prevented by switching interlocks (V)					
Supply voltage, least favorable voltage between 90 % of min. RATED voltage and 110 % of max. RATED voltage, for motor operated ME EQUIPMENT operated under normal load and normal DUTY CYCLE (V)					
Normal DUTY CYCLE for motor operated ME EQUIPMENT (s on, s off)					
Supply voltage, 110 % of max. RATED voltage for combined heating, motor operated, and other ME EQUIPMENT (V)					
Supply voltage, 90 % of min. RATED voltage for combined heating, motor operated, and other ME EQUIPMENT (V)					
Class of insulation system (A, E, B, F, H)					
Classification of individual insulating materials or Relative Thermal Index (°C)					
Supplementary information:					

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT – measurement of maximum temperature during NORMAL USE for parts other than APPLIED PARTS and parts likely to be touched**				N/A
Model No. ..... :					
Test ambient (°C) ..... :					
RATED supply voltage (V) ..... :					

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22 or 23, (°C)	Max measured temperature[2], (°C)	Remarks

Supplementary information:
[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3 e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.

11.1.2.1	**TABLE: Excessive temperatures in ME EQUIPMENT – measurement of temperatures, hot or cold surfaces, during NORMAL USE for APPLIED PARTS intended to supply heat to a PATIENT**				N/A
Model No. ..... :					
Test ambient (°C) ..... :					
RATED supply voltage (V) ..... :					

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from RISK MANAGEMENT FILE, (°C)	Max measured temperature[2], (°C)	Remarks

Supplementary information:
[1] See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.
[2] Max temperature determined in accordance with 11.1.3 e)

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.2.2	**TABLE: Excessive temperatures in ME EQUIPMENT – measurement of maximum temperature during NORMAL USE for APPLIED PARTS not intended to supply heat to a PATIENT**				N/A
Model No. ..... :					
Test ambient (°C) ..... :					
RATED supply voltage (V)..... :					

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 24 (°C)	Max measured temperature[1], (°C)	Remarks

Supplementary information:

[1] Max temperature determined in accordance with 11.1.3 e)

11.1.3d	**TABLE: Temperature of windings by change-of-resistance method**						N/A
Temperature T of winding:	t_1 (°C)	R_1 (Ω)	t_2 (°C)	R_2 (Ω)	T (°C)	Allowed T_{max} (°C)	Insulation class

Supplementary information:

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.2.2.1	**TABLE: alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source**	N/A

Areas where sparking might cause ignition:	Remarks
1.	
2.	
3.	
5.	
6.	

Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):	Remarks
1.	
2.	
3.	
4.	
5.	
6.	

Test parameters selected representing worst case conditions for ME EQUIPMENT:		Remarks
Oxygen concentration (%) .....:		
Fuel .....:		
Current (A) .....:		
Voltage (V) .....:		
Capacitance (μF) .....:		
Inductance or resistance (h or Ω) .....:		
No. of trials (300 Min) .....:		
Sparks resulted in ignition (Yes/No) .....:		

Supplementary information:

Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst case values with other parameters set at worst case values to determine if ignition can occur.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

13.1.2	**TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances**	N/A

Power dissipated less than (W) ..... :	15
Energy dissipated less than (J)..... :	900

Part or component tested	Measured power dissipated (W)	Calculated energy dissipated (J)	SINGLE FAULT CONDITIONS waived (Yes/No)	Remarks

Supplementary information:

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

13.2	**TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive**		P
Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.2	Electrical SINGLE FAULT CONDITIONS according to 8.1:	—	—
	SC Battery	PTC regulates the current to 2.2 A	NO
13.2.3	Overheating of transformers according to 15.5:	—	—
13.2.4	Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favorable of the two:	—	—
13.2.5	Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favorable of the two:	—	—
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	—	—
13.2.7	Impairment of cooling that could result in a HAZARD using test method of 11.1:	—	—
	Single ventilation fans locked consecutively		
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls		
	Simulated blocking of filters		
	Flow of a cooling agent interrupted		
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	—	—
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10	—	—
		V measured =	
		V measured =	

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.10	Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:	—	—
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or at the upper limit of RATED voltage range for specified time:		
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices		
	Temperatures measured as specified in 11.1.3 d)		
	Temperatures did not exceed limits of Table 26		
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:	—	—
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	—	—

Supplementary information:
[1] Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.

15.4.6	**TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests**	N/A

Rotating control under test	Torque from Table 30 (Nm)	Gripping diameter "d" of control knob (mm) [1]	Axial force applied (N)	Unacceptable RISK occurred Yes/No	Remarks

Supplementary information:
[1] Gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer)

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.5.1.2	**TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION**	N/A
Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V) [1] ..... :		—
RATED input frequency (Hz) ..... :		—

Winding tested	Class of insulation (A, B, E, F, or H)	Type of protective device (fuse, circuit breaker) /Ratings	Protective device operated Yes/No	Time to THERMAL STABILITY when protective device did not operate (Min)	Maximum allowed temp from Table 31 (°C)	Maximum winding temp measured (°C)	Ambient (°C)

Supplementary information:
[1] Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.5.1.3	**TABLE: transformer overload test – conducted only when protective device under short-circuit test operated**	N/A

Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)[1]:	
RATED input frequency (Hz) ..... :	
Test current just below minimum current that would activate protective device & achieve THERMAL STABILITY under method a) (A) ..... :	
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A) :	

Winding tested	Class of insulation (A, B, E, F, H)	Type of protective device used (fuse, circuit breaker)/Ratings	Maximum allowed temp from Table 31 (°C)	Maximum winding temp measured (°C)	Ambient (°C)

Supplementary information:

[1] Loads on other windings between no load and their NORMAL USE load.

Time durations:

- IEC 60127-1 fuse: 30 min at current from Table 32.
  Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing-time current data available, test current from Table 32 used until THERMAL STABILITY achieved.
- Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a).

This portion concluded at specified time or when a second protective device opened.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7				N/A
Transformer Model/Type/Part No.	Test voltage applied between	Test voltage (V)	Test frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No
	Primary & secondary windings				
	Primary winding & frame				
	Secondary winding & frame				

Supplementary information:
Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for test parameters & other details

16.6.1	TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS			N/A
Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	Allowable TOUCH CURRENT in NORMAL CONDITION (μA)	Measured TOUCH CURRENT in NORMAL CONDITION (μA)	Allowable TOUCH CURRENT in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, (μA)	Measured TOUCH CURRENT in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, (μA)
	100		500	
	100		500	
	100		500	
	100		500	
	100		500	
	100		500	
	100		500	
	100		500	
	100		500	
	100		500	

Supplementary information:

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Attachment No. 1
ISO 14971 Gap Analysis Checklist
(optional)

Clause	Title	Item	Comments
3.2	Risk Management process	**Procedure describing the risk management process**	Attachment No.1 not applied
3.3	Management Responsibilities	a. **Policy** for determining acceptable risk.	
		b. Assignment of group/individual with risk management responsibility.	
		c. **Procedure for assigning staff** to risk management work.	
		d. **Procedure(s) for review of risk management**, e.g., management design reviews, internal audits, etc.	
3.4	Qualification of personnel	Training records for risk management training, tools training, etc.	
3.5	Risk Management Plan	a. **Procedure for plan development.**	
		b. Description of device.	
		c. Verification plan.	
		d. Allocation of responsibilities.	
		e. Summary of review activities.	
		f. Evidence of risk acceptability criteria.	
3.6	Risk Management File	Evidence of file structure for all risk management activities.	
4.1	Risk Analysis Procedure	**Procedure for risk analysis.**	
4.2	Intended use/intended purpose, etc.	Record of safety issue analysis.	
4.3	Hazard Identification	Record of hazard analysis	
4.4	Risk estimation	**a. Definition of methods used for estimating risks.**	
		b. Description of method(s) used.	
		c. Record of risk estimation activities.	
5.0	Risk evaluation	a. Record of risk evaluation activities.	
		b. Method(s) for dealing with non-quantifiable risks	

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Clause	Title	Item	Comments
6.1	Risk reduction	**Procedure for risk control activities**	
6.2	Option analysis	Record of risk control option analysis (including risk-benefit analysis, if appropriate).	
6.3	Implementation of risk control measures	Design inputs from risk management activities	
6.4	Residual risk evaluation	Evidence, e.g., from design verification activities.	
6.5	Risk-Benefit Analysis	Evidence as necessary...see 6.2.	
6.6	Other generated hazards	Record of review of all risk controls for impact on new hazards.	
7	Overall risk evaluation	Records of related meetings, analysis, etc.	
8	Risk management report	a. **Procedure for generating a Risk Management report.**	
		b. Summary of risk management activities.	
		c. Traceability of hazards to residual risks.	
		d. Clearances.	
9	Post-production information	a. **Procedures for linking information into risk management review**:	
		• Manufacturing	
		• CAPA	
		• Servicing	
		• Purchasing	
		• etc.	
		b. Records implementing procedures	

Note: Bold letters indicate critical elements that should be present even at the very beginning of implementation.

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Test Report issued under the responsibility of

Intertek

IEC 60601-1-6 / EN 60601-1-6

Medical electrical equipment

Part 1-6: General requirements for safety - Collateral Standard: Usability

Report Reference No.	809546-2
Compiled by (+ signature)	Ansis Graufelds
Approved by (+ signature)	Peter Lymeus
Date of issue	2008-12-10
Total number of pages	13

CB Testing Laboratory	Intertek Semko AB
Address	Box 1103 SE-164 22 Kista, SWEDEN
Testing location/procedure	CBTL ☒ RMT ☐ SMT ☐ WMT ☐ TMP ☐
Address	Same as above
Applicant's name	3M Health Care
Address	3M Center, Building 270-4N-09 Maplewood, MN 55144-1000 Patient Assessment Laboratory 3M Medical Products, USA

Test specification:

Standard	IEC 60601-1-6: 2006, Second Edition
Test procedure	CB Scheme
Non-standard test method	N/A

Test Report Form No.	IEC60601_1_6C
Test Report Form Originator	Underwriters Laboratories Inc.
Master TRF	Dated 2007-02

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This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description	Stethoscope
Trade Mark	3M™ Littmann®
Manufacturer	(b) (4) [redacted]
Model/Type reference	
Ratings	Type B, IPX4, Battery type AA

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Testing procedure and testing location:	
☒ **CB Testing Laboratory:**	
Testing location/ address ..... :	Torshamnsgatan 43 SE-164 22 Kista, SWEDEN
☐ **Associated CB Test Laboratory:**	
Testing location/ address ..... :	
Tested by (name + signature)..... :	Ansis Graufelds
Approved by (+ signature)..... :	Peter Lymeus
☐ Testing procedure: TMP	
Tested by (name + signature)..... :	
Approved by (+ signature)..... :	
Testing location/ address ..... :	
☐ Testing procedure: WMT	
Tested by (name + signature)..... :	
Witnessed by (+ signature) ..... :	
Approved by (+ signature)..... :	
Testing location/ address ..... :	
☐ Testing procedure: SMT	
Tested by (name + signature)..... :	
Approved by (+ signature)..... :	
Supervised by (+ signature) ..... :	
Testing location/ address ..... :	
☐ Testing procedure: RMT	
Tested by (name + signature)..... :	
Approved by (+ signature)..... :	
Supervised by (+ signature) ..... :	
Testing location/ address ..... :	

Summary of testing:	
Tests performed (name of test and test clause):	**Testing location:**
Summary of compliance with National Differences: -	
Copy of marking plate See report 809546-1	

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Test item particulars ..... :	
Classification of installation and use ..... :	See IEC 60601-1 Test Report
Clinical application ..... :	Medical diagnostic
Mode of operation ..... :	Continuous
Surface temperature of APPLIED PART ..... :	40°C
Possible test case verdicts:	
- test case does not apply to the test object ..... :	N/A
- test object does meet the requirement ..... :	Pass (P)
- test object does not meet the requirement ..... :	Fail (F)
Testing:	
Date of receipt of test items ..... :	2008-11-10
Date of performance of tests ..... :	2008-12-09

Abbreviations used in the report:

- normal condition:	N.C.	- single fault condition:	S.F.C.
- operational insulation:	OP	- basic insulation:	BI
- double insulation:	DI	- supplementary insulation:	SI
- basic insulation between parts of opposite polarity:	BOP	- reinforced insulation:	RI

General remarks:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

"(see Enclosure #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.

Throughout this report, a point is used as the decimal separator.

List of test equipment must be kept on file and available for review.

This Test Report contains the general safety requirements as related to the usability of Medical Electrical Equipment. It can only be used together with IEC 60601-1 Test Report.

General product information:

See Test Report 809546-1.

IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	GENERAL REQUIREMENTS		P
4.1	ME EQUIPMENT provides adequate USABILITY, and the RISKS resulting from NORMAL USE and USE ERRORS are acceptable	Risk management file (ISO 14971), Residual Risk Levels are primarily at a risk acceptability level of R1 (the most broadly acceptable risk level). The R2 residual risks are related to EMC and RF coexistence with other medical devices.	P
4.2	Inspection of USABILITY ENGINEERING FILE assessing all RISK ANALYSIS considerations	Reference: Risk Management File: "RISK MGMT-05-000265.xls" Potential hazards are identified by the product's cross functional Risk Management team and addressed during risk management. The risk management process addresses these areas of potential hazard in it's Questionnaire section with the requirement that any identified hazard is then carried over to risk assessment & control.	P
5	**IDENTIFICATION, MARKING AND DOCUMENTS**		
5.1	ACCOMPANYING DOCUMENTS	Model 3100 User Guide, v1.2 Model 3200 User Guide, Draft v0.4.	P

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IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	A brief description of EQUIPMENT, its physical operating principles, and significant physical and performance characteristics relevant to its USABILITY included in the instructions for use	The equipment is an electronic stethoscope. This stethoscope includes a microphone, digital filtering, and a binaural headset. The user interface for the stethoscope features a 5-button keypad and an LCD display for controlling the stethoscope during everyday use, plus access to less often-used menus and communication configuration options. The stethoscope functions include digital sound processing to produce the conventional stethoscope Bell and Diaphragm frequency response. The Model 3200 also features a third frequency response in addition to the Bell and Diaphragm modes. The Model 3200 stethoscope includes a Bluetooth wireless link that allows the stethoscope to exchange audio data with an external device such as a personal computer (PC). The stethoscope power is provided by a single AA battery that is located in the chestpiece. A power management system is included to prolong battery life.	P
	The same information, when provided as a separate document, included in the technical description	No separate documents.	N/A
	ACCOMPANYING DOCUMENTS for equipment are, optionally, provided electronically, e.g., by electronic file format or CD-ROM ..... :	No electronic media provided	N/A
	USABILITY ENGINEERING PROCESS includes the information that will need to be provided as a hard copy or as markings on EQUIPMENT (e.g., to cover emergency operation) when ACCOMPANYING DOCUMENTS are provided electronically	No electronic media provided	N/A

IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	ACCOMPANYING DOCUMENTS include a description of the OPERATOR PROFILE	See page 4 **IFU**	P
	ACCOMPANYING DOCUMENTS are written at a level consistent with the intended OPERATOR PROFILE	User Guides are written at a level consistent with the intended operator profile.	P
5.2	TRAINING and materials for TRAINING		P
	–necessary TRAINING materials required for PRIMARY OPERATING FUNCTIONS of EQUIPMENT provided by the manufacturer	The 3100/3200 User Guides include information that servers as training material for the operation of these products. Equipment specific information includes: How to: - Insert Battery - Position and Adjust Headset - Turn On/Off - Select Filter - Adjust Sound - Monitor Heart Rate - Custom configuration - Other Operating Conditions	P
	–TRAINING materials are available; or	No training material is required or provided.	N/A
	– the manufacturer provides TRAINING	No training material is required or provided.	N/A
	INTENDED USE is the basis for TRAINING and TRAINING material	No training is required.	N/A
	Instructions for use indicate the available TRAINING options and when specific TRAINING for the EQUIPMENT is required	No specific training is provided.	N/A

6	**USE ERROR and USABILITY**	P
6.1	Safety for the PATIENT, OPERATOR and other persons	P

IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	A USABILITY ENGINEERING PROCESS conducted to provide safety for the PATIENT, OPERATOR and other persons related to USABILITY of the OPERATOR-EQUIPMENT INTERFACE	3M Medical maintain an ISO 13485 and FDA QSR compliant Quality Management System (QMS). Within our QMS we maintain a New Product Introduction (NPI) life cycle model that incorporates all of the elements of Design Control including risk management. Specific to this product, Section 6.0 of DS-INPUT-05-000273 is for "Safety Requirements" and is where we identify what are the applicable safety regulations such as IEC 60601 (6.4) which include 60601-1-6.	P
6.2	USABILITY ENGINEERING PROCESS		P
6.2.1	The results of the USABILITY ENGINEERING PROCESS recorded in the USABILITY ENGINEERING FILE	Reference: "Littman_Usability Engineering File.doc"	P
	The records and other documents that make up the USABILITY ENGINEERING FILE form part of other documents(e.g., a MANUFACTURER'S product file or RISK MANAGEMENT FILE)	Reference – Risk Assessment file: "RISK MGMT-05-000265.xls"	P
	The USABILITY ENGINEERING PROCESS scaled based on the significance of any modifications depending on the results of the RISK ANALYSIS		N/A
6.2.2	Input for the USABILITY ENGINEERING PROCESS		P
6.2.2.1	ME EQUIPMENT application specification		P
	Application of ME EQUIPMENT in the USABILITY ENGINEERING FILE specified by the MANUFACTURER and includes		P
	– medical purpose {e.g., conditions(s) or disease(s) to be screened, monitored, treated, or diagnosed};	Reference: "cap0803a E3000 Plus Product requirements.pdf " Section 12 on Product Requirements	P
	– PATIENT population (e.g., age, weight, region of body, health, condition);	Reference - 3100/3200 User Guide, Functional Description	P
	– part of the body or type of tissue applied to or interacted with;	Reference - 3100/3200 User Guide, Intended Use	P
	– intended OPERATOR PROFILE; and	The Model 3100/3200 electronic stethoscope is used to listen to heart, lung, and other body sounds.	P

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IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	– application (e.g.. environment, frequency of use, location, mobility)		P
	A summary of the ME EQUIPMENT application specification included in the instructions for use		P
6.2.2.2	PRIMARY OPERATING FUNCTIONS		P
	The MANUFACTURER has determined the PRIMARY OPERATING FUNCTIONS and recorded them in the USABILITY ENGINEERING FILE	Reference - "cap0803a E3000 Plus Product requirements.pdf"	P
6.2.2.3	Information for safety as a RISK CONTROL		
	For RISK CONTROL related to USABILITY, the MANUFACTURER has decided what information is required for BASIC SAFETY or ESSENTIAL PERFORMANCE (e.g., warnings or limitation of use in the ACCOMPANYING DOCUMENTS, marking, etc.)	Reference - Model 3100 User Guide.doc and Model 3200 User Guide.doc	P
	Such information was subject to the USABILITY ENGINEERING PROCESS		P
	Disregarding this information considered ABNORMAL USE	Potential misuse is included in Risk Assessment document	P
	RISK CONTROL consisted of an integrated approach using		P
	a) inherent SAFETY by design;	Ongoing safety emphasis during design process documented in 3M Risk Management process	P
	b) protective measures in ME EQUIPMENT itself or in the manufacturing PROCESS (e.g., ALARMSYSTEMS)	- Battery use indicator, alerts user when battery level is low - Filter indicator, indicates which mode is currently being used (diaphragm or bell mode) - Backlight for use in low light environments	P
	c) information for safety (e.g., warnings in the instructions for use, display of a monitored variable)	Reference – "RISK MGMT-05-000265.xls" Rows AI – AJ: misuse	P
	The results of the RISK ANALYSIS or a reference to the location of the results of the RISK ANALYSIS recorded in the USABILITY ENGINEERING FILE	Reference – "Littman Usability Engineering File.doc"	P
	The RISK ANALYSIS for the ME EQUIPMENT or for the corresponding generic device type was an input for the USABILITY SPECIFICATION as required for the USABILITY ENGINEERING PROCESS.		P

IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	Any RESIDUAL RISK evaluation took into consideration the results of the USABILITY VALIDATION	Reference – "Final E3000 VOC Report.ppt"	P
	The evaluation of post-production information (post-market surveillance) included USABILITY (see ISO 14971:2000, Clause 9)	Reference – "RISK MGMT – 05-000265.xls" 3M will monitor of complaint trends (3M CFR data)	P
6.2.3	USABILITY SPECIFICATION		P
	MANUFACTURER developed a USABILITY SPECIFICATIONrecorded in USABILITY ENGINEERING FILE as part of the USABILITY ENGINEERING PROCESS	Reference: Customer specification DS-INPUT-05-000273	P
	The USABILITY SPECIFICATION integrated into other specifications and based on the following:		P
	– application specification (see 6.2.2.1);	References - "Model 3100 User Guide.doc" "Model 3200 User Guide.doc" "cap0803a E3000 Plus Product requirements ver2.00.pdf" PR:092, PR:093 and PR:098	P
	– HAZARDS related to the use of the ME EQUIPMENT (results from RISK ANALYSIS described in 4.2); and	Reference - "RISK MGMT-05-000265.xls", Section: Risk Identification, Potential Hazardous Situations	P
	– predictable USE ERRORS associated with the ME EQUIPMENT	Reference – "RISK MGMT-05-000265.xls" Risk Assessment file	P
	The USABILITY SPECIFICATION describes at least:		P
	– USE SCENARIOS for the ME EQUIPMENT;	Reference – - Littmann_Usability Engineering File.doc" - Risk Assessment file: "RISK MGMT-05-000265.xls" - ESC Recap Notes.doc	P
	– OPERATOR actions related to the PRIMARY OPERATING FUNCTIONS;	Reference - "cap0803a E3000 Plus Product requirements.pdf" Section 12.3	P

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IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	– OPERATOR-EQUIPMENT INTERFACE requirements for the PRIMARY OPERATING FUNCTIONS; and	Reference - "DS-INPUT-05-000273 .pdf" 3.4 (Ease of use) 4.4 (Ergonomic design facilitates use of stethoscope) 4.5 (Single hand operates stethoscope and all primary functions) 4.6 (Easy selection of controls) 4.7 (Chestpiece can be gripped multiple ways).	P
	– requirements for determining whether PRIMARY OPERATING FUNCTIONS are easily recognizable by the OPERATOR	Reference – "Report - AHA Focus Groups - Stethoscope - November 2007 - 11-9-07.pdf" - Interview results - Focus group results - User observations and comments	P
6.2.4	USABILITY VERIFICATION		P
	MANUFACTURER verified the OPERATOR-EQUIPMENT interface design according to the USABILITY SPECIFICATION as part of the ME EQUIPMENT DESIGN	References - "Littman_Usability Engineering File.doc" "DS-INPUT-05-000273 v5.pdf"	P
	The results of the verification are recorded in USABILITY ENGINEERING FILE	References - "Littman_Usability Engineering File.doc"	P
6.2.5	The MANUFACTURER has developed and maintains a USABILITY VALIDATION plan specifying:	Reference - "CUST-CVE-05-000051.doc" Document includes the quantitative criteria for acceptance in the usability/field evaluation questionnaire. TEAM-MISC-05-005873.pdf	P
	– any method used for VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS;	Reference – "CUST-CVE-05-000051.doc" "TEAM-MISC-05-005873.doc" "Littman_Usability Engineering File.doc"	P

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IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	– the criteria for determining successful VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS (see Table D.5); and	Reference – "CUST-CVE-05-000051.doc"	P
	– the involvement of representative intended OPERATORS (see D.4.3.2)	Reference – "CUST-CVE-05-000051.doc"	P
	USABILITY VALIDATION performed in a laboratory setting ..... :	3M usability specialists reviewed the initial production models in a laboratory setting to validate the usability in a simulated use environment.	P
	USABILITY VALIDATION performed in a simulated use environment..... :	Reference – "CUST-CVE-05-000051.doc"	P
	USABILITY VALIDATION performed in the actual use environment..... :	Reference – "CUST-CVE-05-000051.doc"	P
	The USABILITY VALIDATION plan addressed:		P
	– worst case USE SCENARIOS derived from: • the application specification (see 6.2.2.1), • predictable USE ERRORS, and • the results of the RISK ANALYSIS; and	Reference – "Littman_Usability Engineering File.doc" Usability validation includes **usability testing in a laboratory setting** that will address worst case use scenarios derived from: - use scenarios - predicted use errors - risk analysis	P
	– USE SCENARIOS representing frequent application situations identified in the USABILITY SPECIFICATION	Reference – "CUST-CVE-05-000051.doc" "TEAM-MISC-05-005873.doc" Usability validation plan includes gathering feedback from typical use scenarios	P
	The USABILITY VALIDATION plan recorded in the USABILITY ENGINEERING FILE		P
6.2.6	USABILITY VALIDATION		P
	The MANUFACTURER validated OPERATOR-EQUIPMENT INTERFACE design according to the USABILITY VALIDATION plan	Reference – "CUST-CVE-05-000051.doc" "TEAM-MISC-05-005873.doc"	P
	The results, including any required design modification needed to satisfy the criteria as defined in the USABILITY VALIDATION plan, recorded	Post-production plans to usability-related design modifications include monitoring of complaint trends (3M CFR data) and warranty and repair data (Health Care Service Center data).	P

IEC 60 601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	The ACCOMPANYING DOCUMENTS are part of the ME EQUIPMENT and are also subject to activities for validating USABILITY	Reference – "CUST-CVE-05-000051.doc" Usability validation includes evaluation of the supporting documentation supplied with the Model 3100/3200 Electronic Stethoscope.	P
	Individuals that were not directly involved in the OPERATOR-EQUIPMENT INTERFACE design were involved in the USABILITY VALIDATION	Usability validation evaluation will be completed by technical service staff and usability specialists	P

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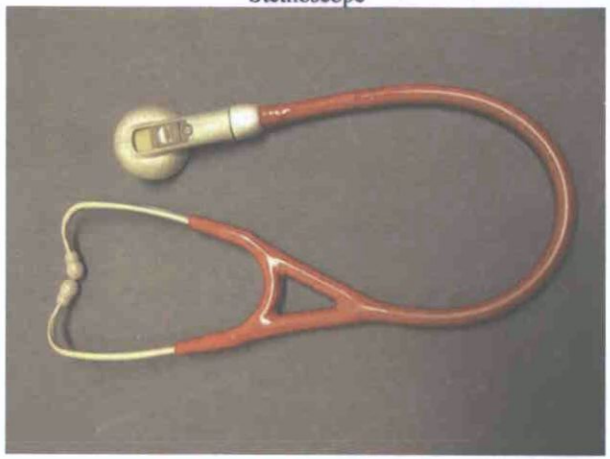
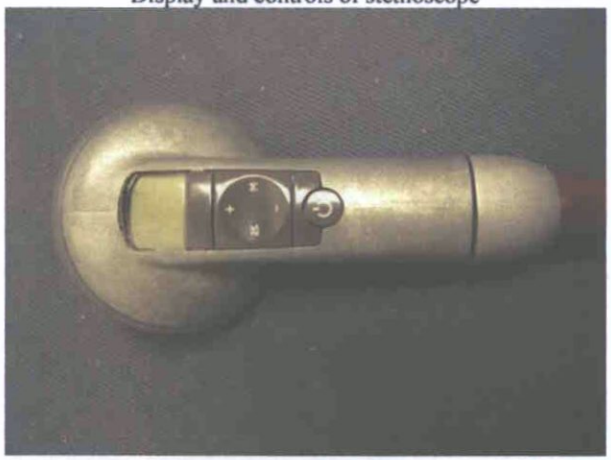
Attachment A

Stethoscope



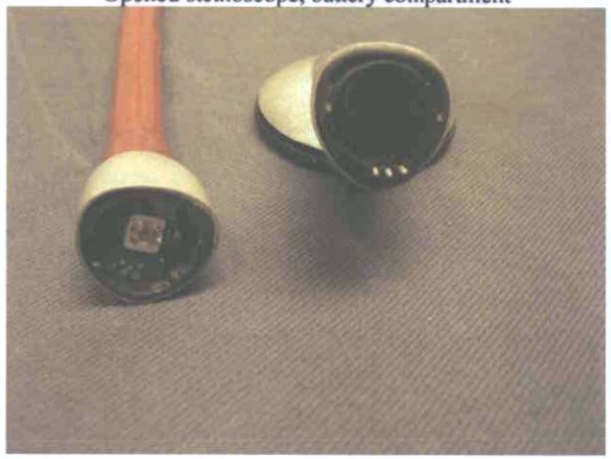
Display and controls of stethoscope



Stethoscope with removed membrane

Attachment A

Opened stethoscope, battery compartment



Marking

(b) (4)

[redacted]

E3000 Plus EMC
Design verification protocol

Version 1.00

File name: AMI0821a Design Verification Protocol - EMC

Author

1-9-2008
Date, Name - Designer

Approved by

1/9-2008
Date, Name - Quality Assurance

QMS00086, Version 8.00

(b) (4)

[redacted]

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Version history

Version	Author	Date	Description	Reviewed by	EC number
0.01	AMI	29-may-2008	Initial version		
0.02	AMI	20-june-2008	Updated after review	CAP, SSR, TRH, TAD	
0.03	AMI	23-june-2008	Preconditioning updated	CAP, THR, SSR	
1.00	AMI	1-sep-2008	Released version		

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1 Purpose

The purpose of this document is to describe how to perform the Design Verification and define the acceptance criteria in order to verify if the requirements can be fulfilled. The protocol must be approved before the verification activities are carried out. Verification is to be performed at external test center.

2 Scope

The scope of this protocol covers E3000 Plus EMC.

3 References

[1] SSR 0807a Design control status overview E3100-E3200
[2] cap0803a E3000 Plus Product requirements
[3] TAD0816b Design verification plan E3000 Plus
[4] HLA0807A Functional Test Protocol IAD0007 E3000 Plus
[5] ISO 60601-1-2:2007

4 General

4.1 Test conditions

Unless otherwise specified in the test method, the tests are performed under the following conditions:

Temperature 18°C - 28°C
Humidity: 25 %RH – 75 %RH

These will be referred to as "Room climate" in the rest of the document.

4.2 Device preparation

- One device is to be used for ESD testing.
- One device is to be used for EMC testing.
- The devices shall be marked with ID no.
- Function test, must be performed before verification start on all devices to ensure that they are functioning.

4.3 Device storage

Samples and test specimens used for verification shall be stored in B&O Medicom items archive.

4.4 Verification working procedure

To carry out preconditioning or test, the following basic documents are needed:

1. The protocol
2. The matching registration sheet

(b) (4)

The test results, deviations, date of test, initials on operator along with identification of the devices and the equipment used, are filled in the registration sheet.

4.5 Acceptance criteria

Acceptance criteria are described in the protocols.
In general the acceptance criterion is a function test, a visual inspection or both, which must be passed accordingly before and after the preconditioning

4.6 Test Method

4.6.1 EMC:001

Purpose
The purpose with RF-Field Emission measurement is to make sure that the stethoscope is not disturbing other apparatus. The protocol refers to PR:017 [2]

Standard

The test setup and method must be in accordance to EN 55011.

Preconditioning

The stethoscope must be setup with the following settings:

1. Active mode
2. Diaphragm filter
3. Maximum volume level
4. Backlight off
5. Auto-off deactivated
6. Measure the RF-Field emission
7. Ensure that the result is in accordance with the acceptance criterion.

Variation

Acceptance criterion

Results are to be in accordance with EN60601-1-2:2007 class B1 at a distance of 10m.

30 dBmV @30MHz to 250MHz

37 dBmV @250MHz to 1GHz

4.6.2 EMC:002

Purpose

(b) (4)

[redacted]

The purpose is to test the immunity of the stethoscope to radiated electromagnetic energy, which can be generated by such sources as small hand-held radio transceivers etc. and various industrial electromagnetic sources. The protocol refers to PR:018 [2]

Standard

The test setup and method must be in accordance to EN 61000-4-3.

Preconditioning

The stethoscope must be setup with the following settings:

1. Active mode
2. Diaphragm filter
3. Maximum volume level
4. Backlight off
5. Auto-off deactivated
6. Expose the stethoscope to 3V/m @80MHz to 2.5GHz
7. Ensure that the result is in accordance with the acceptance criterion

Variation

Acceptance criterion

Functional test (FT) is to be passed.
Change in default settings (PS keys) is not accepted.

Under testing the stethoscope may respond to the discharge is different manners of which some can be accepted and some cannot.

Under testing the following behaviour of the stethoscope is accepted:

1. Change in display graphics.
2. Momentary noise in binaural.
3. Reset of the stethoscope if reboot is initialized automatically.

Under testing the following behaviour of the stethoscope is NOT accepted:

1. Change of filter mode.
2. Change of volume level.
3. Activation of Bluetooth mode.

4.6.3 EMC:003

Purpose
The test are intended to demonstrate the immunity of equipment when subjected to power frequency magnetic fields related to the specific location and installation condition of the component. The protocol refers to PR:019 [2]

Standard

(b) (4) [redacted]

The test setup and method must be in accordance to EN 61000-4-8.

Preconditioning

The stethoscope must be setup with the following settings:

1. Active mode
2. Diaphragm filter
3. Maximum volume level
4. Backlight off
5. Auto-off deactivated
6. Expose the stethoscope to 3A/m @ 50Hz and 60Hz
7. Ensure that the result is in accordance with the acceptance criterion.

Variation

Acceptance criterion

Functional test (FT) is to be passed.
Change in default settings (PS keys) is not accepted.

Under testing the stethoscope may respond to the magnetic filed in different manners of which some can be accepted and some cannot.

Under testing the following behaviour of the stethoscope is accepted:

1. Change in display graphics.
2. Momentary noise in binaural.
3. Reset of the stethoscope if reboot is initialized automatically.

Under testing the following behaviour of the stethoscope is NOT accepted:

1. Change of filter mode.
2. Change of volume level.
3. Activation of Bluetooth mode.

4.6.4 EMC:004

Purpose
The purpose with electrostatic discharge test is to simulate discharges which may occur from personnel to object near the stethoscope. The protocol refers to PR:020 [2]

Standard

The test setup and method must be in accordance to EN 61000-4-2.

Preconditioning

The stethoscope must be setup with the following settings:

1. Active mode

(b) (4)

2. Diaphragm filter
3. Maximum volume level
4. Backlight off
5. Auto-off deactivated
6. Expose the stethoscope to ±6 kV contact discharge and ±8 kV air discharge.
7. Ensure that the result is in accordance with the acceptance criterion

Variation

Acceptance criterion

Functional test (FT) is to be passed.
Change in default settings (PS keys) is not accepted.

Under testing the stethoscope may respond to the discharge in different manners of which some can be accepted and some cannot.

Under testing the following behaviour of the stethoscope is accepted:

1. Change in display graphics.
2. Momentary noise in binaural.
3. Reset of the stethoscope if reboot is initialized automatically.

Under testing the following behaviour of the stethoscope is NOT accepted:

1. Change of filter mode.
2. Change of volume level.
3. Activation of Bluetooth mode.

eurofins

EUROFINS PRODUCT SERVICE GMBH

Accredited Test House
Deutscher Akkreditierungs Rat
DAT-P-268/08

EMC TEST - REPORT

TEST REPORT NUMBER: G0M20810-2051-E-17

eurofins
Eurofins Product Service GmbH
Storkower Str. 38c, 15526 Reichenwalde,
Germany

Phone +49-33631-888 0
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Annex A: Pictures **7 pages**

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1 General Information

1.1 Notes

The test results of this test report relate exclusively to the item tested as specified in 1.6.

The test report may only be reproduced or published in full.

Reproducing or publishing extracts of the report requires the prior written approval of the Eurofins Product Service GmbH.

1.2 Responsible staff

Date	Name	Signature
01.12.2008	A. Pflug	

Technical responsibility for area of testing:

Date	Name	Signature
01.12.2008	J. Zimmermann	

4c/

1.3 Testing laboratory

1.3.1 Location

EUROFINS PRODUCT SERVICE GMBH
STORKOWER STR. 38c
D-15526 REICHENWALDE B. BERLIN
GERMANY
Telephone : + 49 33631 888-00
Telefax : + 49 33631 888-660

1.3.2 Details of accreditation status

DAR ACCREDITED TESTING LABORATORY
DAR-REGISTRATION NUMBER: DAT-P-268/08

RECOGNIZED NOTIFIED BODY EMC
REGISTRATION NUMBER: BNetzA-bS EMV-07/61

RECOGNIZED NOTIFIED BODY R&TTE
REGISTRATION NUMBER: BNetzA-bS-02/51-53

FCC FILED TEST LABORATORY
REG.-NO. 96970

A2LA ACCREDITED TESTING LABORATORY
CERTIFICATE NO. 1983.01

BLUETOOTH QUALIFICATION TEST FACILITY (BQTF)
ACCREDITED BY BLUETOOTH QUALIFICATION REVIEW BOARD

INDUSTRY CANADA FILED TEST LABORATORY
REG. NO. IC 3470

1.3.3 Test location, if different

Name	: ./.
Street	: ./.
Town	: ./.
Country	: ./.
Telephone	: ./.
Fax	: ./.
Email	: ./.

1.4 Details of applicant

Name	: RTX Telecom A/S
Street	: Stroemmen 6,
Town	: DK-9400 Noerresundby,
Country	: Denmark
Telephone	: +45 96 3223 00
Fax	: +45 96 3223 10
Email	: miv@rtx.dk
Contact	: Mr. Mads Iversen
Telephone	: +45 96 3223 00

1.5 Application details

Date of receipt of application	: 05.11.2008
Date of receipt of test item	: 05.11.2008
Date of test	: 12.11.2008; 01.12.2008

1.6 Test item

1.6.1 Description of test item

Description of test item	: Bluetooth enabled stethoscope
Type identification	: M3200
Serial number	: withoutwithout
Power supply	: 1.5 V DC battery only
Additional information	: device with Bluetooth function
Connected lines	: n.a.
Performance criteria	: checking of the function (display). Bluetooth connection

1.6.2 Manufacturer (if different from applicant in point 1.4)

Name	(b) (4) [redacted]
Street	
Town	
Country	

1.7 Test standards

Technical standard:

EN 301 489-1 V 1.6.1 : 2005
EN 301 489-17 V1.2.1 : 2002
EN 60601-1-2: 2007

1.8 List of EMC equipment

No.	Test Equipmen	Type	Manufacturer
ETS 0001	ESD Gun	SESD 30000	Schlöder
ETS 0008	Antenna	Loop antenna	Siemens
ETS 0012	Biconical Antenna	HK 116	R & S
ETS 0013	LPD Antenna	HL 223	R & S
ETS 0014	Log Periodical Antenna	HL 025	R & S
ETS 0018	Horn antenna	BBHA 9120 D	Schwarzbeck
ETS 0038	RF amplifier	150L	Amplifier Research
ETS 0032	Controller	HD 050	Heinrich Deisel
ETS 0039	Absorbing clamp	MDS 21	R & S
ETS 0040	Artificial Mains Network	ESH3-Z5	R & S
ETS 0041	T-Artificial Mains Network	ESH3-Z4	R & S
ETS 0042	Artificial Mains	ESH3-Z6	R & S
ETS 0045	Vehicle LISN	NNBM 8126D	Schwarzbeck
ETS 0052	Audio analyzer	UPA 4	R & S
ETS 0056	Ultra Compact Simulator	UCS 500 M4	EM Test
ETS 0057	Motor Variac	MV 2616	EM Test
ETS 0058	Capacitive coupling clamp	E 502 B	Keytek/ EMC
ETS 0059	Kikusui amplifier	PCR 2000L	Keytek/ EMC
ETS 0064	CDN IEC 61000-4-6		Keytek/ EMC
ETS 0066	EM Injection Clamp		FCC/ EMC
ETS 0076	Feeding bridge A	SBA 1000	ESP
ETS 0082	PC system		Esotronic
ETS 0085	Shielded room	SR 1	Frankonia
ETS 0086	Semi-Anechoic chamber	AC 1	Frankonia
ETS 0088	Color TV pattern Generator	PM 5518-TX VPS	Philips
ETS 0092	Power Amplifier	150W1000	AR Amplifier Research
ETS 0102	CDN	M3-801/6	MEB
ETS 0103	Magnetic field test set	MF1000	EMC-Partner
ETS 0148	RF Current Probe	F-65	FCC
ETS 0155	Signal Generator	SMG	R & S
ETS 0157	TV and Sat-Signalgenerator	VTG 700	Grundig
ETS 0161	Harmonic / Flicker Analyzer	HFA 3000	Schlöder
ETS 0178	Open area test side	10m	ETS
ETS 0233	Direction coupler	RK 100	MEB
ETS 0276	Audio Analyzer	UPL 16	R & S
ETS 0282	RF bridge 75 Ohm	86207 A	HP
ETS 0287	EMI Test receiver	ESHS10	R & S
ETS 0292	RF Generator	SMHU	R & S
ETS 0348	RF Millivolt meter	URV 55	R & S
ETS 0300	RF amplifier	75 A 250	Ar
ETS 0348	RF Millivolt meter	URV 55	R & S
ETS 0401	MPEG2 Generator	DVG	R & S
ETS 0402	TV Messender	SFQ	R & S
ETS 0409	Stripline	DC220	Schwarzbeck
ETS 0428	4-WIRE ISN with B1	ENY41	R & S
ETS 0448	RF Power Amplifier	AR 60S1G3	AR Amplifier Research
ETS 0472	Antenna	BTA-H	Frankonia
ETS 0474	EMI Test Receiver	ESCS 30	R&S
ETS 0485	Radio Communication Tester	CMU 200	R&S

4c5

2 Technical test

2.1 Summary of test results

The equipment under test fulfilled all applicable EMC requirements of the EN 301 489-1/-17 and 60601-1-2.

2.2 Test environment

Temperature	: 23 ° C
Relative humidity content	: 45 %
Air pressure	: 1003 hPa
Details of power supply	: 1.5 V DC Battery
Other parameters	: ./.

2.3 Test results overview

Reg. no. : G0M20810-2051-E-17

Device : BLUETOOTH ENABLED STETHOSCOPE

Model no. : M3200

Manufacturer : (b) (4) [redacted]

Date : 01.12.2008

Test Emission / Immunity			Done	Test passed	Test failed
Emission	Radiated Emissions	EN 301 489-1; subc.8.2	☒	☒	☐
Emission	Conducted Emissions	EN 301 489-1; subc.8.3; 8.4; 8.7	☐	☐	☐
Flicker	Voltage fluctuations and flicker	EN 301 489-1; subc.8.6	☐	☐	☐
RF - Field	Radiated Immunity	EN 301 489-1; subc.9.2	☒	☒	☐
ESD	Electrostatic Discharge	EN 301 489-1; subc.9.3	☒	☒	☐
Burst	Electrical Fast Transients	EN 301 489-1; subc.9.4	☐	☐	☐
RF com. mode	RF continues conducted	EN 301 489-1; subc.9.5	☐	☐	☐
Transient and surges	Transient and surges in vehiculars	EN 301 489-1; subc.9.6	☐	☐	☐
Magn.-Field	Magn.-Field Immunity	EN 6100-4-8	☒	☒	☐
V-dips	Voltage dips and interruptions	EN 301 489-1; subc.9.7	☐	☐	☐
Surge	Surges common & different mode	EN 301 489-1; subc.9.8	☐	☐	☐
Emission	Radiated Emissions	EN 301 489-1; subc.8.2	☐	☐	☐

2.4 Test conditions

2.4.1 Spurious Emission (EN 55022)

This test is only applicable to ancillary equipment not incorporated in the radio equipment and intended to be measured on a stand alone basis, as declared by the manufacturer. This test shall be performed on a representative configuration of the ancillary equipment.
This test is in accordance to subclause 8.2 of EN 301 489-1

Test Equipment

- ETS 0012
- ETS 0013
- ETS 0086
- ETS 0474
- Software: ES-K1, Vers. 1.6SP2

Test Procedures

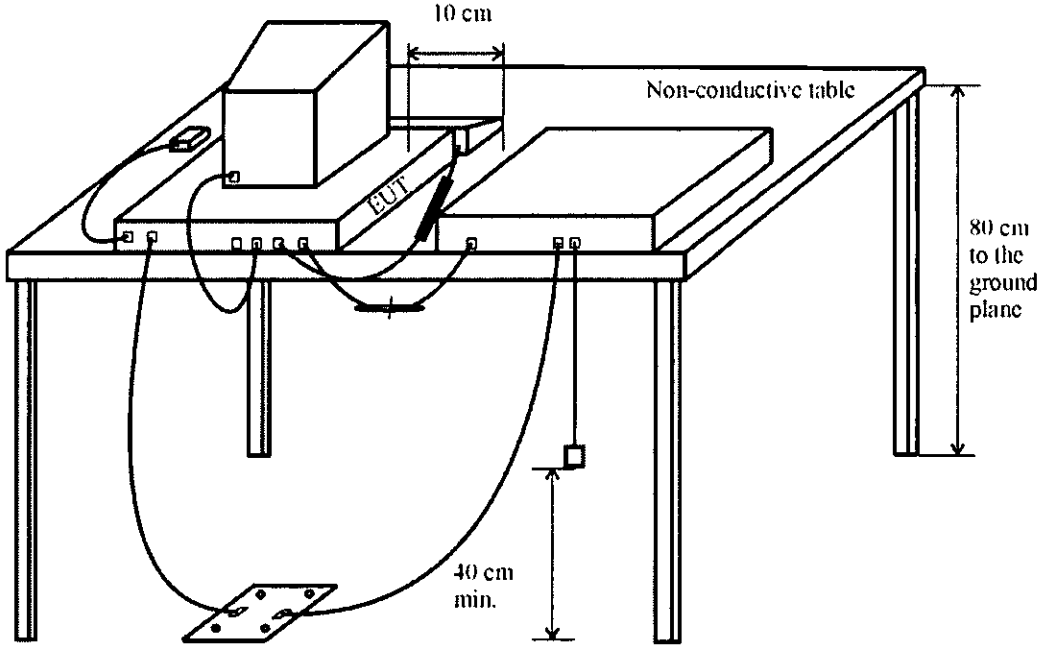
- Test configuration

The test configuration corresponds to the standard EN 55022 /4/. The equipment under test is placed on a non metallic table with 0,8 m height.
The power supply and the RF connection points are close to the equipment under test at the floor inside a connection box. The cables to this connection box are shielded and below the double floor. The receiving antenna is placed in a height at 1,0 m to 4,0 m, in a distance of 3 m. The measurement receiver is placed in a special room. (See picture 1) The observation of the equipment under test is realized by a video camera and by a microphone.

- Test parameters and marginal conditions

The test is carried out with horizontal and vertical polarization of the antenna in a frequency range of 30 MHz to 1000 MHz. For further information please see the test protocol.

Radiated Emission according to CISPR 22



EUT = Equipment under test

Picture 1

2.4.2 Electrostatic discharge

This test is applicable for base station, mobile, portable and ancillary equipment.
This test is in accordance to subclause 9.3 of EN 301 489-1

Test Equipment

- ETS 0001

Test Procedures

• Test configuration

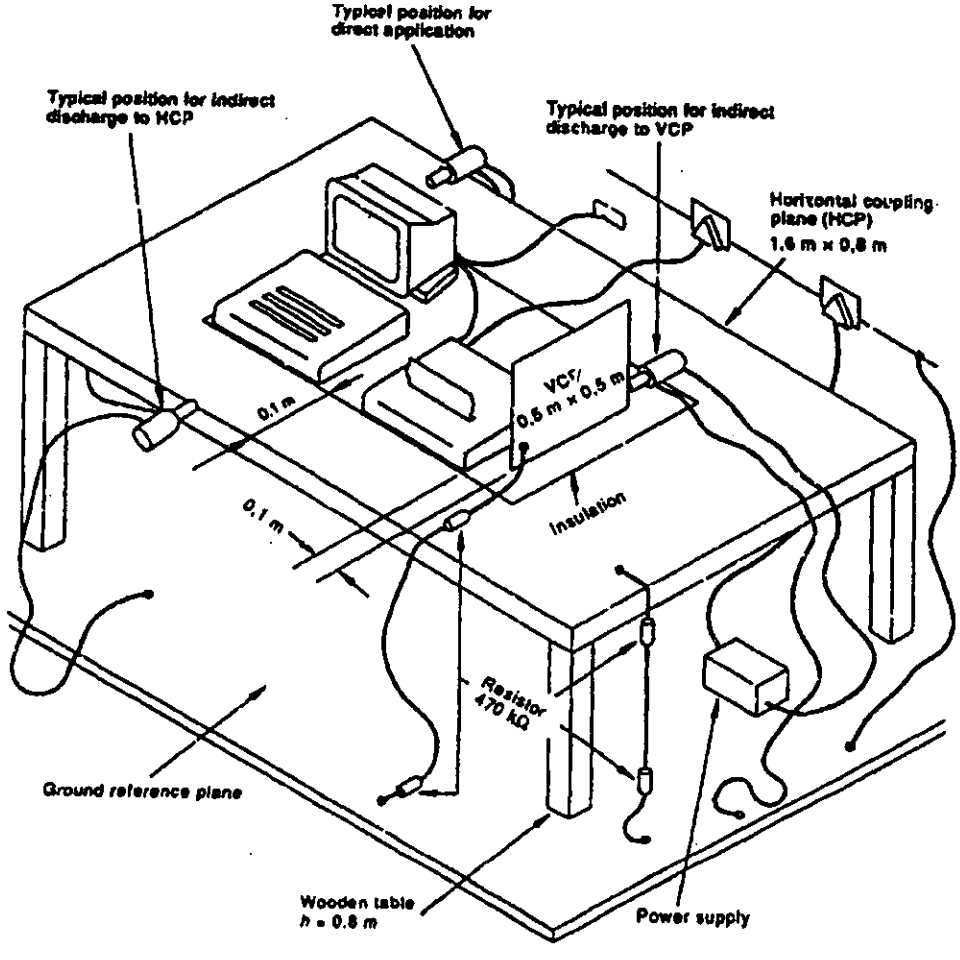
The test configuration corresponds to the standard EN 61000-4-2 /5/. The test setup shall consist of a wooden table, 0.8 m high, standing on the ground reference plane. A horizontal coupling plane, 1.6 m x 0.8 m, shall be placed on the table. The EUT and cables shall be isolated from the HCP by an insulating support, 0.5 mm thick. Both metal plates are connected by two 470 kΩ resistors in series. (See Picture 2.)

• Test parameters and marginal conditions

The test is carried out with ±2kV, ±4kV and ±6kV contact discharge and ± 2 kV, ± 4 kV and ± 8 kV air discharge. The tested points are mentioned in the test protocol.

4/0

Electrostatic Discharge according To EN 61000-4-2



Picture 2

2.4.3 RF Electromagnetic field (80-2500 MHz)

This test is applicable for base station, portable and ancillary equipment
This test is in accordance to subclause 9.2 of EN 301 489-1

Test Equipment

- ETS 0086
- ETS 0155
- ETS 0448
- ETS 0472
- Software: ETS RF-Field v.27.09.2005

Test Procedures

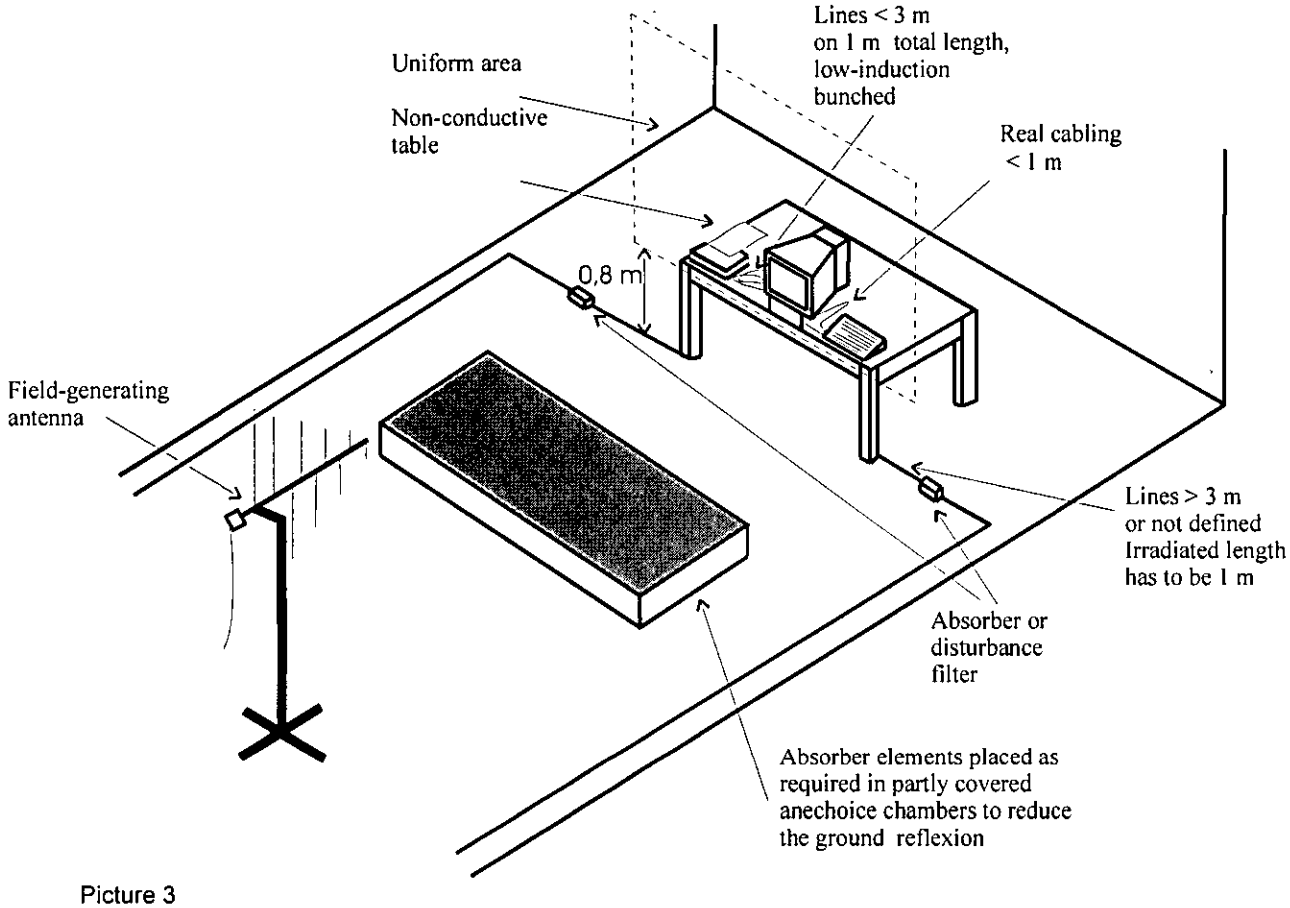
- Test configuration

The test is performed inside a shielded chamber and the configuration complies to the standard EN 61000-4-3 /6/. The equipment under test is placed in the facility on a wooden table, 0.8 m high, on the center axis of the chamber. The power supply and the RF connection points are close to the equipment under test at the floor of the chamber inside a connection box. The cables to this connection box are shielded and below the double floor. The transmitting antenna is placed in a height of 1.5m, in a distance of 3.0 m. The RF generators are placed in a special room adjacent to the chamber. The observation of the equipment under test is realized by 3 video cameras and a microphone. In order to establish the severity of the test for EUTs and wires which must be tested close to the earth reference plane or which have larger dimensions than 1,5 m x 1,5 m, the intensity of the field is also recorded at 0,4 m height, and for the full width and height of the EUT.

- Test parameters and marginal conditions

The tests are performed with a field strength of 3 V/m (measured in the unmodulated field) with amplitude modulated signal with a depth of 80 % by a sinusoidal signal of 1 kHz. The logarithmic step was 1 % and the dwell time was 1 s dependent on the EUT cycle time. For further information please see the test protocol.

RF - Field according to EN 61000 - 4 - 3



Picture 3

2.4.4 Power frequency magnetic field

This test is applicable for base station, mobile, portable and ancillary equipment.
This test is in accordance to EN 60601-1-2: 2007.

Test Equipment

- ETS 0059
- ETS 0155

Test Procedures

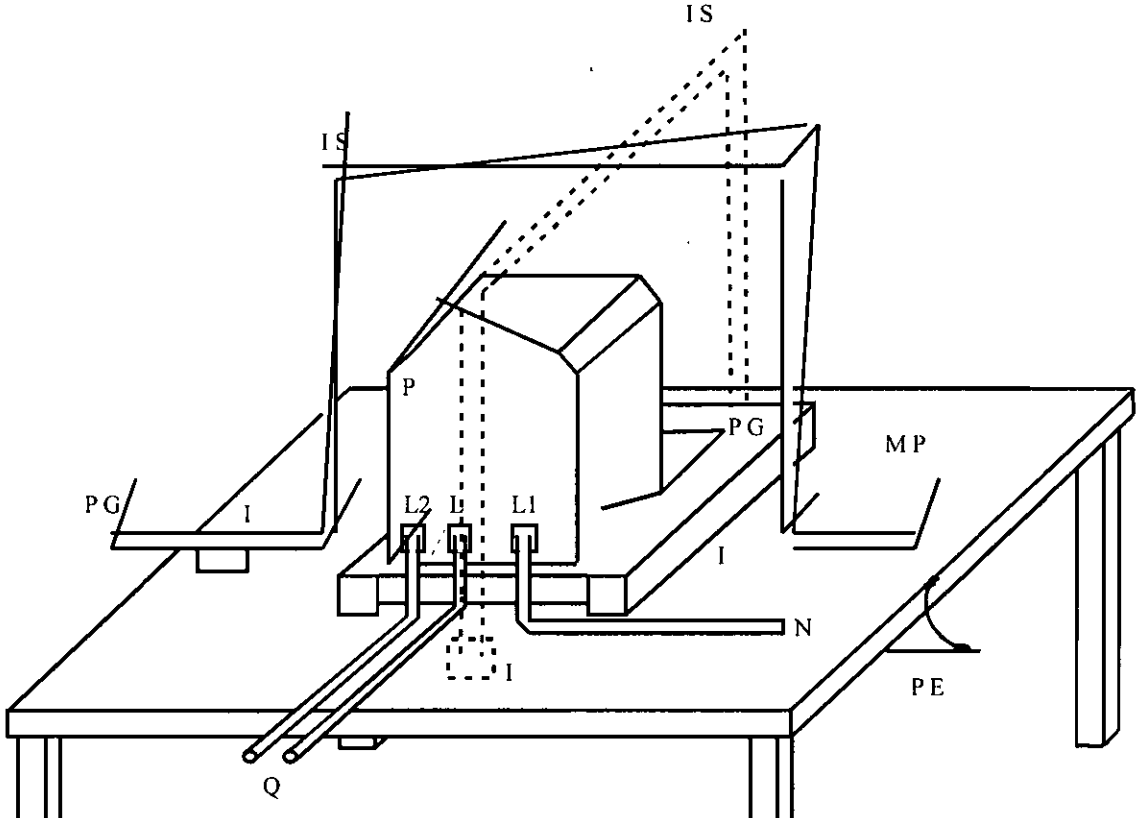
• Test configuration

The test configuration is in correspondence to the standard EN 61000-4-8 /7/. The equipment under test shall be arranged and connected to satisfy its functional requirements, and shall be placed at the centre of the coil system. (See picture 4.)
The cables supplied by the equipment manufacturer shall be used or, in their absence, suitable alternative cables of the type appropriate to the signals involved shall be used.

• Test parameters and marginal conditions.

The tests are carried out with a frequency of 50 or 60 Hz and a magnetic field of 30 A/m (r.m.s.). Additional information please find in the test protocol.

Example for set-up for immunity test to magnetic field according to EN 61000-4-8



M P	pasted plate
P E	safety earth
I	isolation
P	EUT
I S	induction spark coil
E	mass connection
L1	power line
L2	signal line
L	communication line
N	net
Q	to the signal source, to the simulator
P G	to the test generator

Picture 4

2.5 EMC Test Results

Radiated emission 18

ESD 19

RF-Field 21

Magnetic Field 22

Radio Noise Field Strength

Emission

Standard : EN 301 489-1 subclause 8.2

Reg. no. : G0M20810-2051-E-17

Model no. : M3200

Date : 01.12.2008

Class : B

Frequency range / Polarization	Antenna	Passed	Failed	Number of rechecks
30 MHz - 200 MHz / vertical	HK 116	☒	☐	0
30 MHz - 200 MHz / horizontal	HK 116	☒	☐	0
200 MHz - 1000 MHz /vertical	HL 223	☒	☐	0
200 MHz - 1000 MHz / horizontal	HL 223	☒	☐	0

Instrumentation uncertainty: $U_{lab(rad)}$ = 5.3 dB

Comment: See attached diagrams in Annex B.

Electrostatic Discharge
ESD

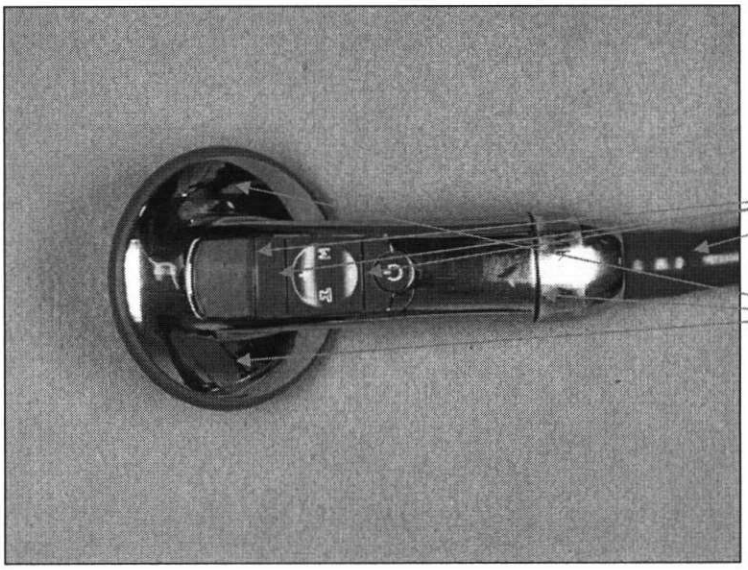
Standard : EN 301 489-1 subclause 9.3
Reg. no. : G0M20810-2051-E-17
Model no. : M3200
Date : 01.12.2008

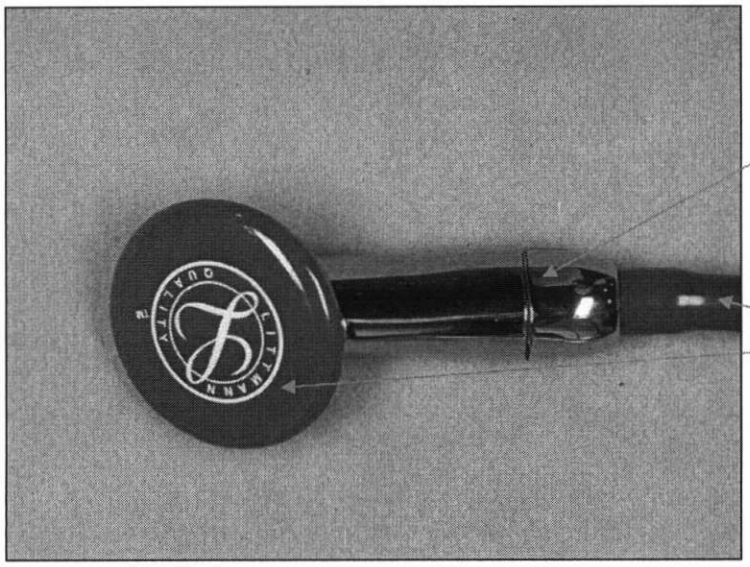
Test point	Table (T) Floor (F)	Contact (C) Air (A)	Voltage (kV)	Polarity (+ / -)	Pass	Fail
Housing	T	A	2, 4, 8	+ / -	☒	☐
Housing	T	C	2, 4, 6	+ / -	☒	☐
Indirect	T	C	2, 4, 6	+ / -	☒	☐

At least 10 single discharges at each important point of the EUT (see picture) and both coupling plates.

Opinion:

The device fulfills the requirements of the ESD tests in accordance with 6.2.1.10 /3/.
Surveillance of the function (display). Bluetooth connection.


Air discharge
Contact discharge


Contact discharge
Air discharge

Interference Immunity Against Electromagnetic Irradiation

RF Field

Standard : EN 301 489-1 subclause 9.2

Reg. no. : G0M20810-2051-E-17

Model no. : M3200

Date : 01.12.2008

Test equipment : Anechoic chamber, generator SMG (R&S), monitoring system, amplifier: ar, antenna (BTA-H)

Frequency Range	Voltage (RMS)	Modulation Frequency	Opinion
80 MHz – 2.5 GHz	3 V/m	1 kHz (80 % AM)	A

Opinion:

The EUT fulfills the requirements according to clause 6.2.1.10 /3/. The test does not have influence on the essential performance features (see user manual) of the device.

Surveillance of the function (display). Bluetooth link control only.

Power frequency
-Magnetic field-
Immunity

Standard : EN 61000-4-8
Reg. no. : G0M20810-2051-E-17
Model no. : M3200
Date : 01.12.2008

Test equipment : Anechoic Chamber, Generator, Induction coil
Carrier Frequency : 50 Hz
Field Strength : 3 A/m
Duty Cycle : sinusoidal

Passed : yes / no

Comment: Bluetooth link only.

☒ 1 : No loss of performance or function
☐ 2 : Temporary loss of function or performance which is self-recoverable
☐ 3 : Temporary loss of function or perform. which req. operator intervention or system reset
☐ 4 : Loss of function which is not recoverable

3 Normative references

/1/ EN 301 489 – 1 V1.6.1 : 2005
Electromagnetic compatibility and Radio spectrum Matters (ERM);
Electromagnetic Compatibility (EMC) standard for radio equipment and services;
Part 1: Common technical requirements

/2/ EN 301 489 – 17 V1.2.1 : 2002
Electromagnetic compatibility and Radio spectrum Matters (ERM);
Electromagnetic Compatibility (EMC) standard for radio equipment and services;
Part 17: Specific conditions for 2,4 GHz wideband transmission systems and 5 GHz high Performance RLAN equipment.

/3/ EN 60601-1-2 : 2007
Medical electrical equipment
Part 1: General requirements for safety
2. Collateral Standard : Electromagnetic Compatibility - Requirements and tests

/4/ EN 55022: 2006
„Limits and methods of measurement of radio interference characteristics of information technology equipment".

/5/ EN 61000-4-2: 1995 + A1: 1998 + A2: 2001
„Electromagnetic Compatibility (EMC); Part 4: Testing and measurements techniques - Section 2: Electrostatic discharge immunity test. Basic EMC publication".

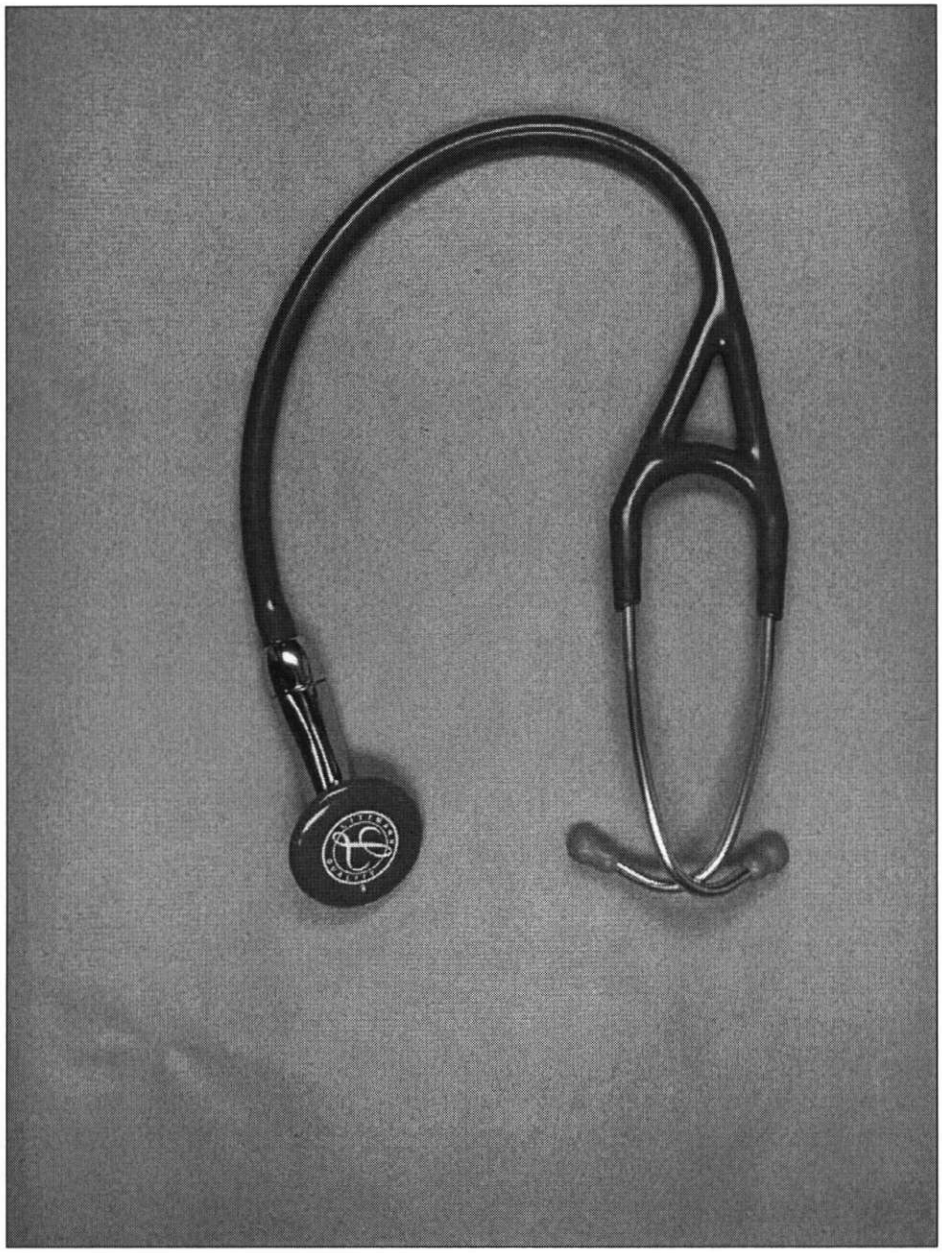
/6/ EN 61000-4-3: 2006
„Electromagnetic Compatibility - Basic immunity standard - Radiated, radio-frequency electromagnetic field. Immunity test".

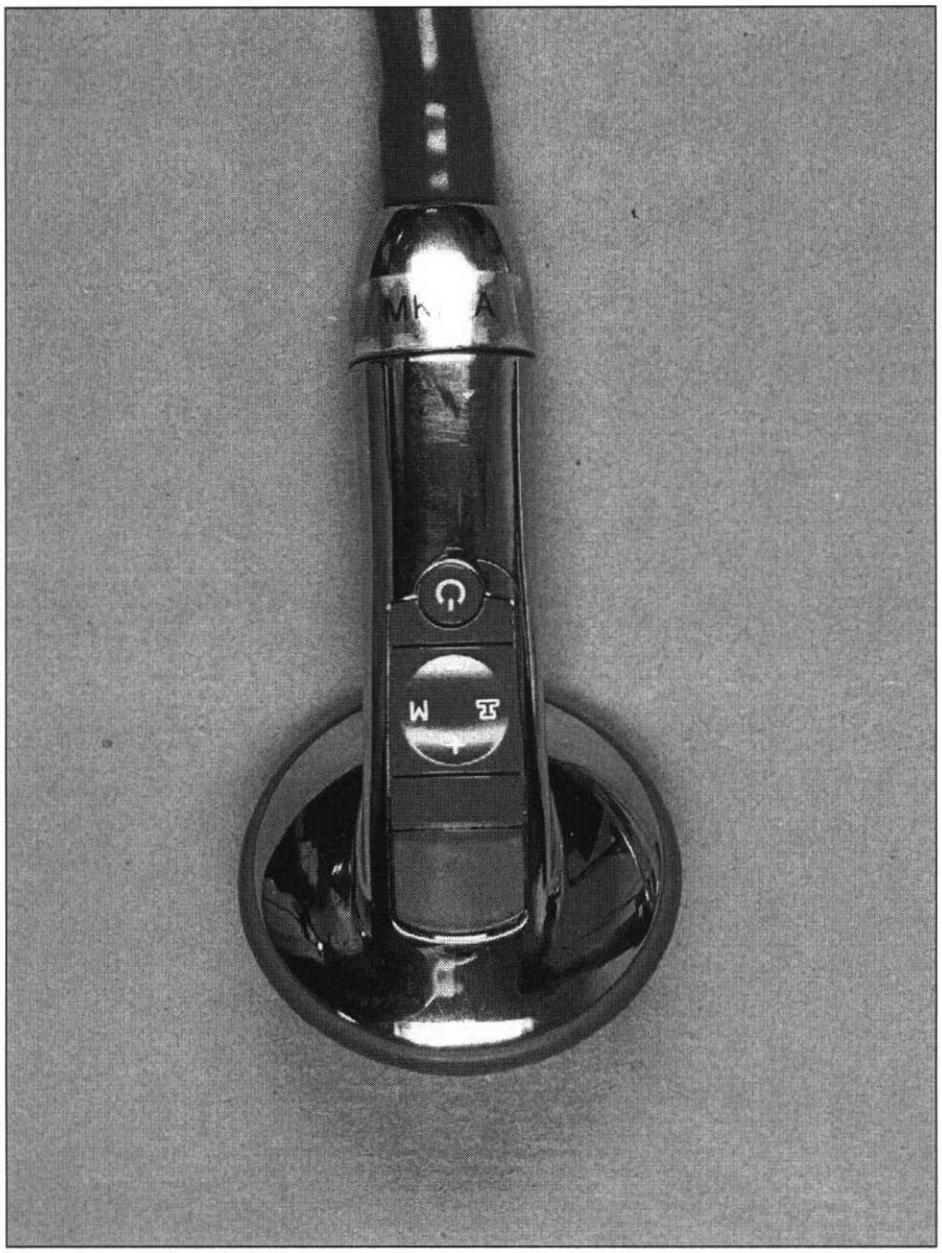
/7/ EN 61000-4-8: 1993 + A1: 2001
„Electromagnetic Compatibility - Testing and measurements techniques
Power frequency magnetic field immunity test".

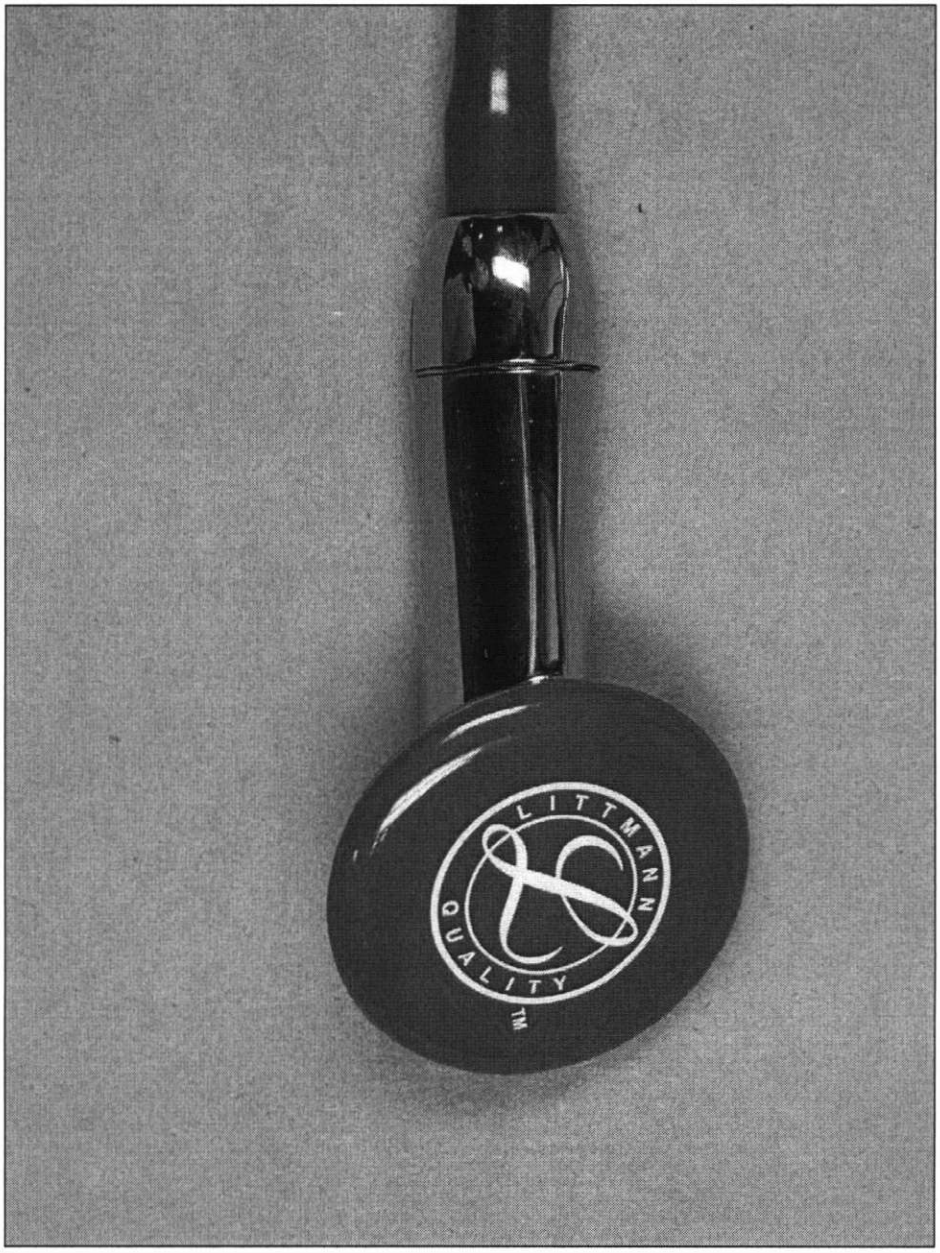
Annex A:Pictures

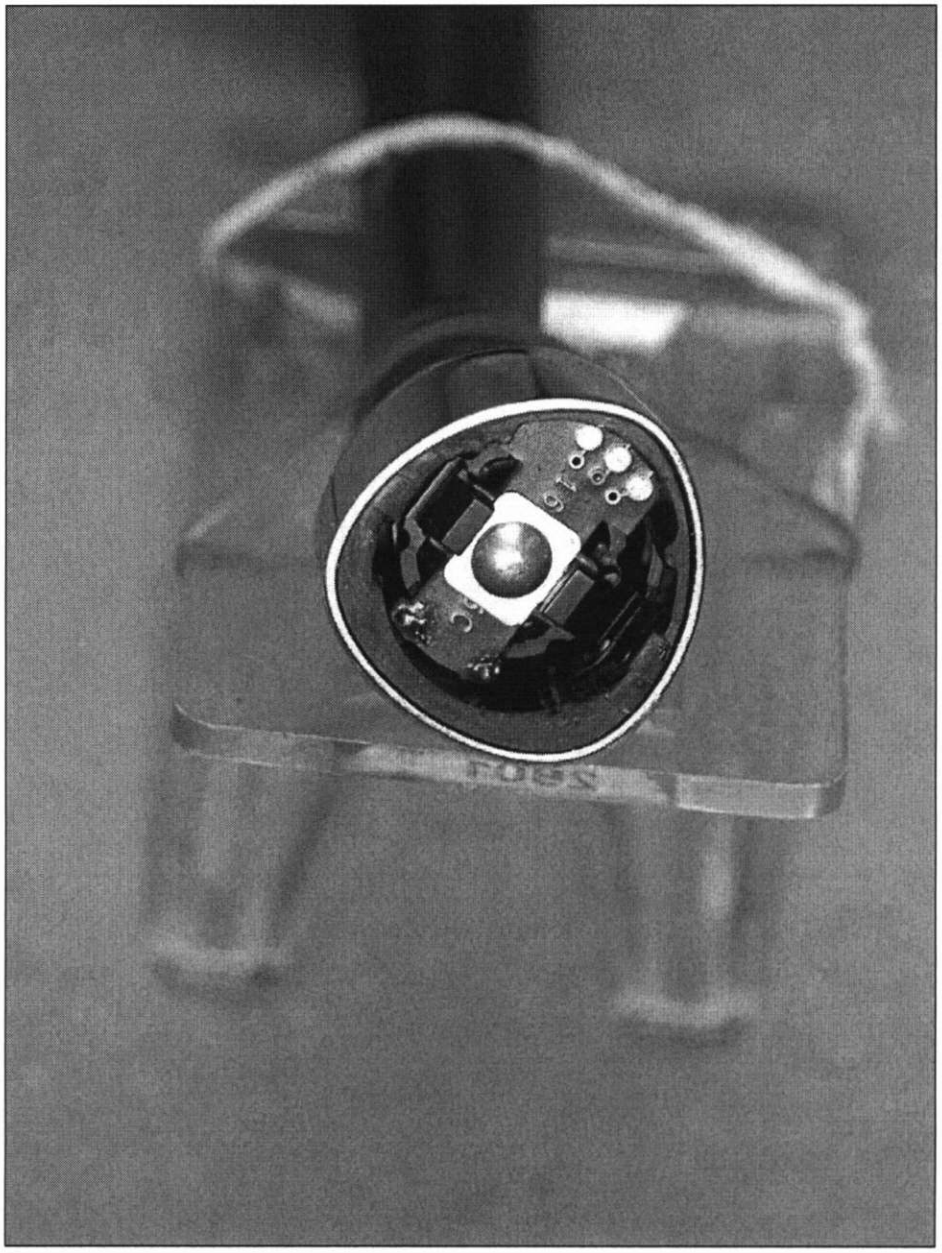
Annex A

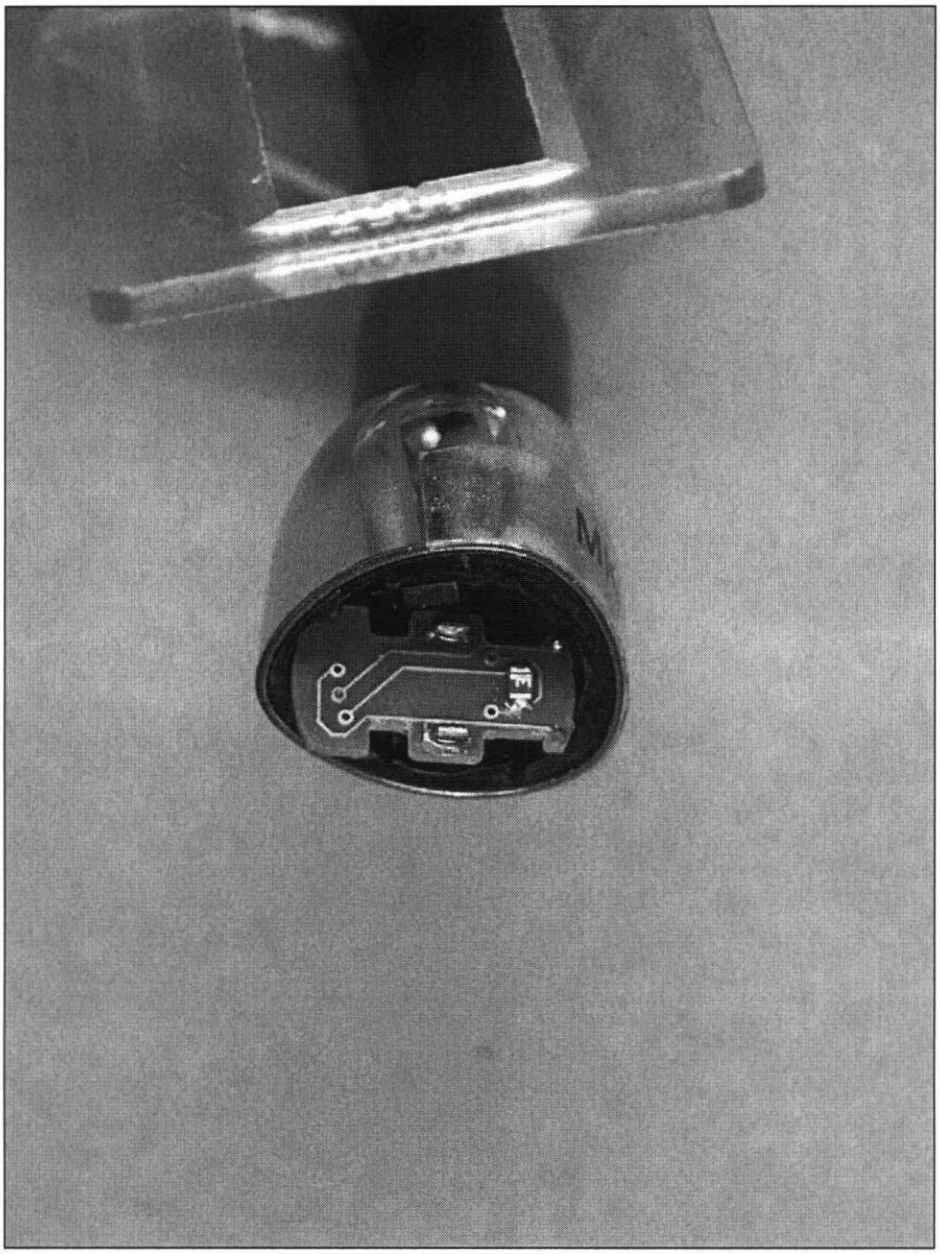
Pictures

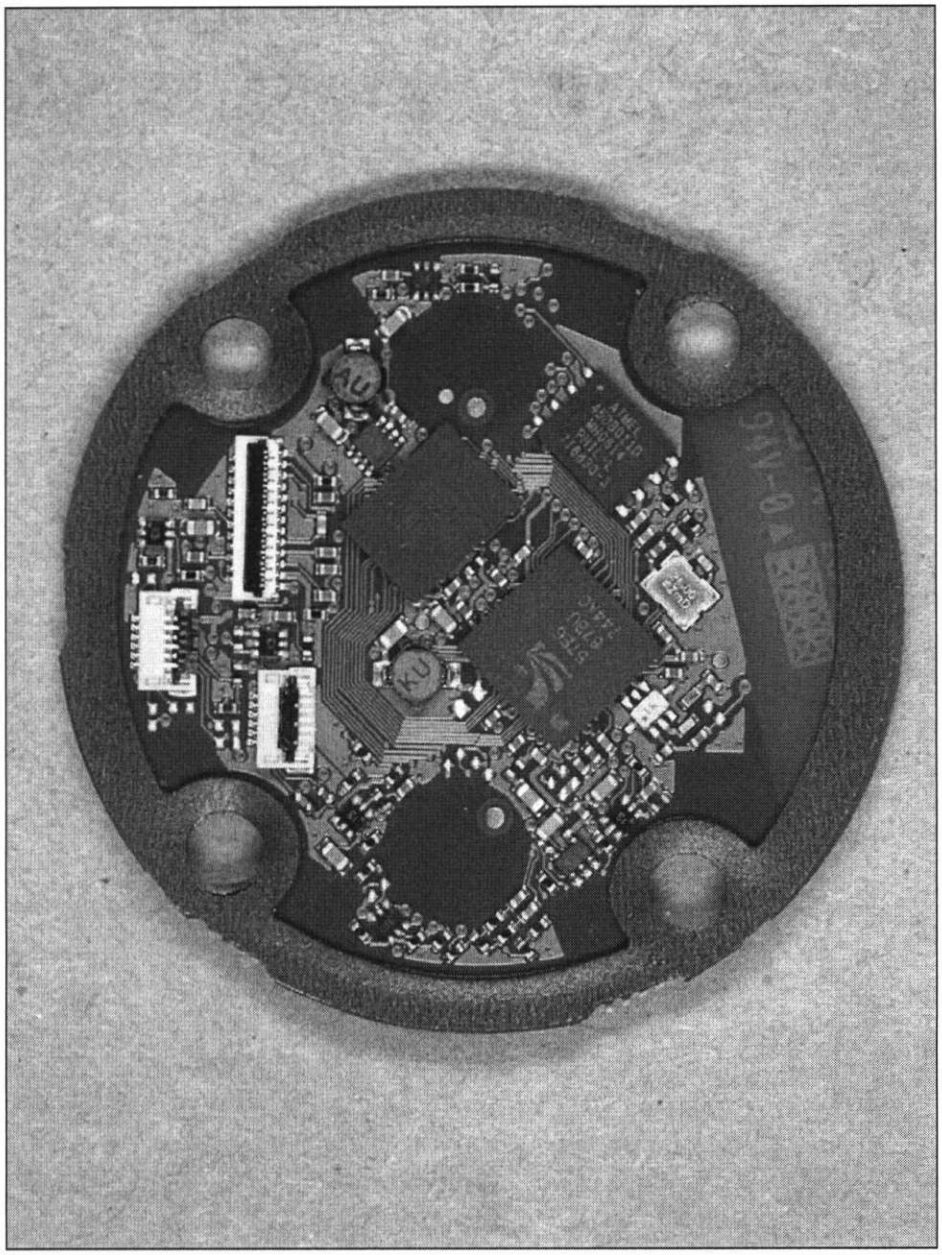


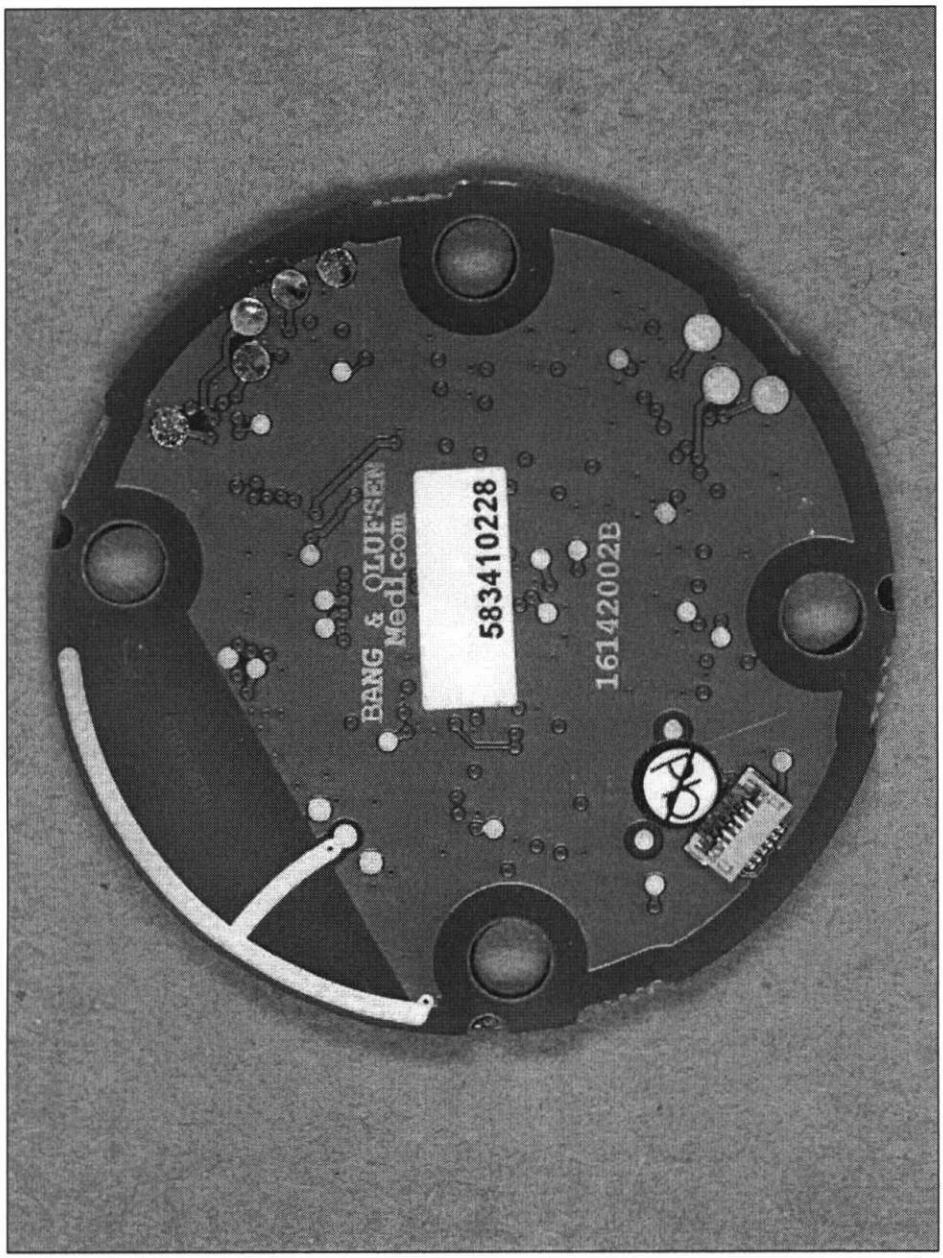



LITTMANN
QUALITY
TM





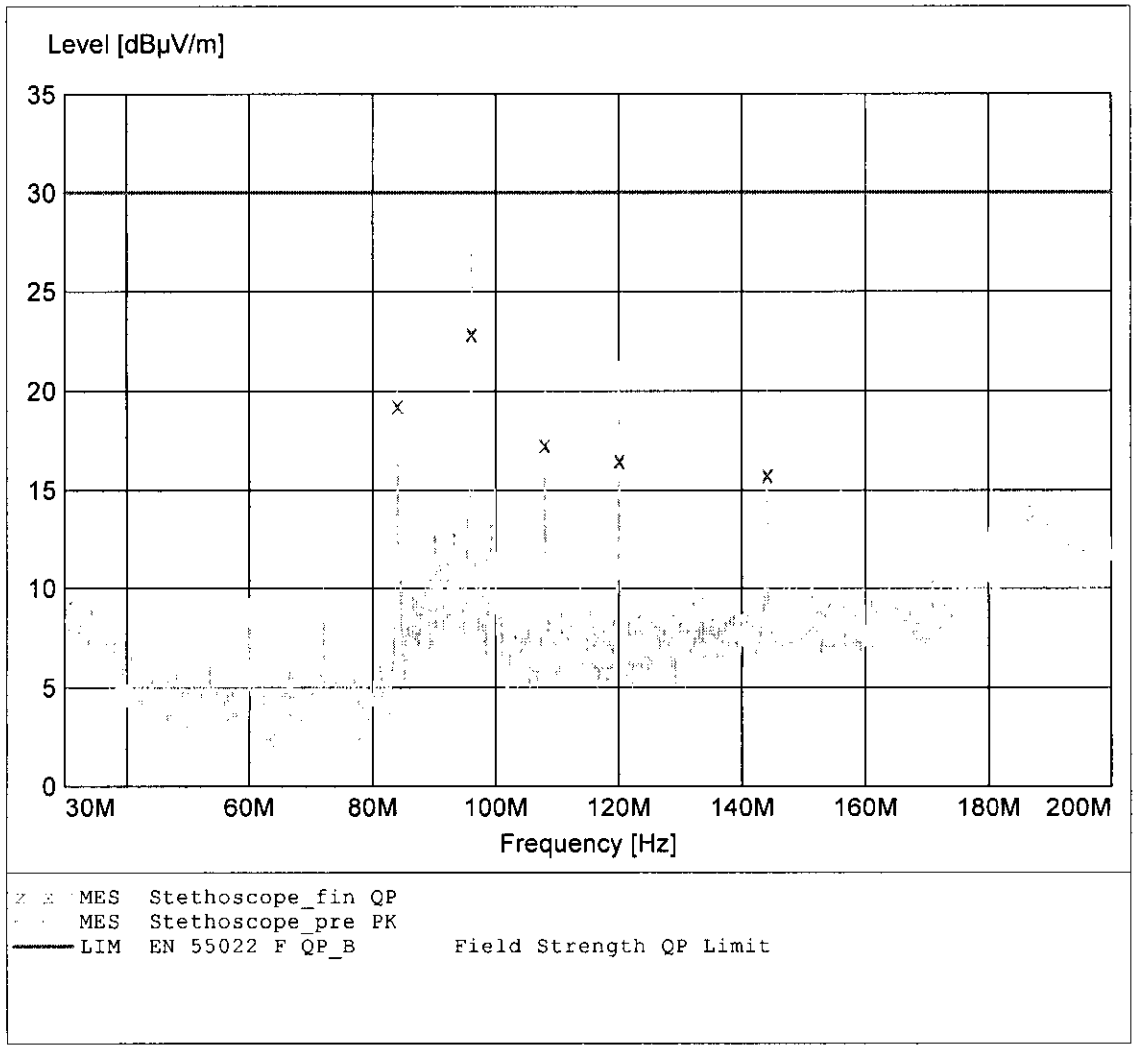



BANG & OLUFSEN
Medicom
583410228
16142002B

Annex B: Diagrams

Spurious emission under normal conditions according to EN 55022 ***Ordernumber: G0M20810-2051***

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Medical Prod
EUT:	Bluetooth enabled stethoscope
Model:	Model 3200
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Klein
Test Conditions:	Tnom: 23°C, Unorm: Batt
Test Specification:	Ant: HK 116, vertical
Comment 1:	mode: Bluetooth
Comment 2:	mode:



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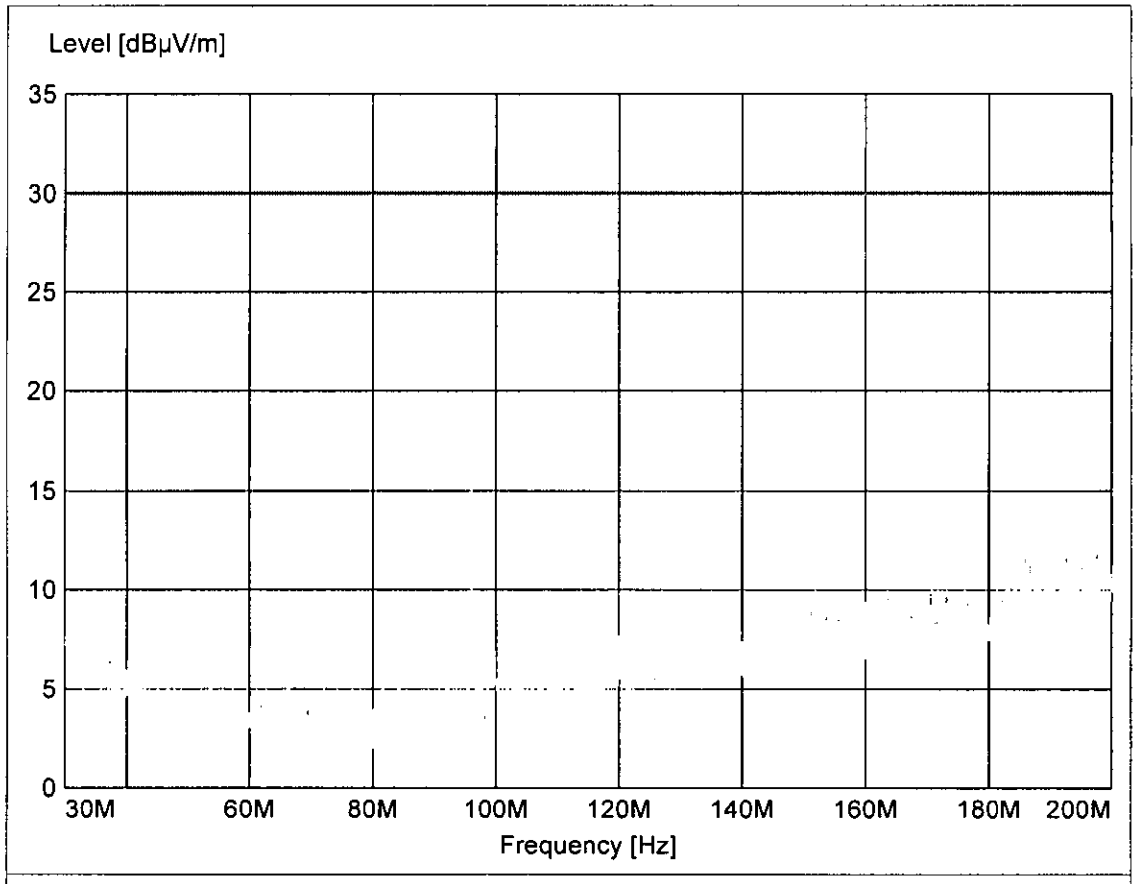
Spurious emission under normal conditions according to EN 55022 ***Ordernumber: G0M20810-2051***

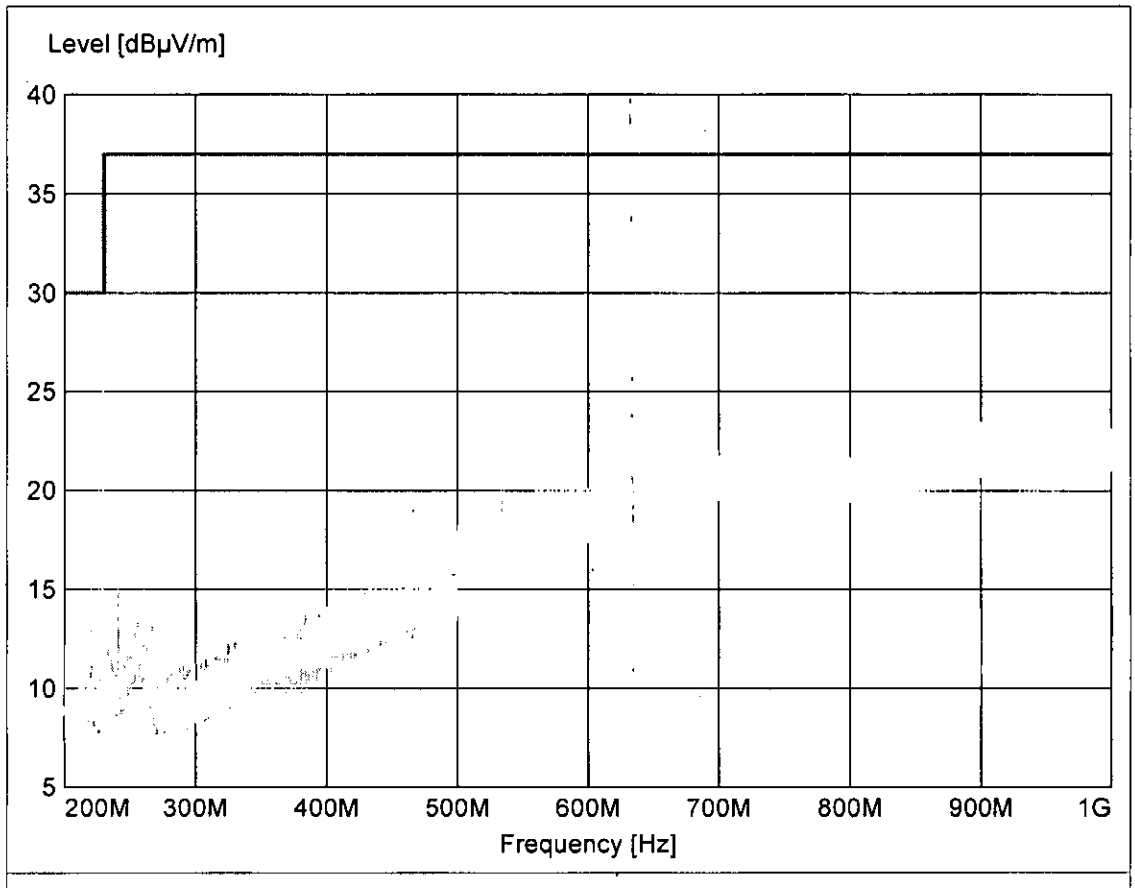
Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Medical Prod
EUT:	Bluetooth enabled stethoscope
Model:	Model 3200
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Klein
Test Conditions:	Tnom: 23°C, Unorm: Batt
Test Specification:	Ant: HK 116, horizontal
Comment 1:	mode: Bluetooth
Comment 2:	mode:



MES Stethoscope_pre PK
LIM EN 55022 F QP_B Field Strength QP Limit

Spurious emission under normal conditions according to EN 55022 ***Ordernumber: G0M20810-2051***

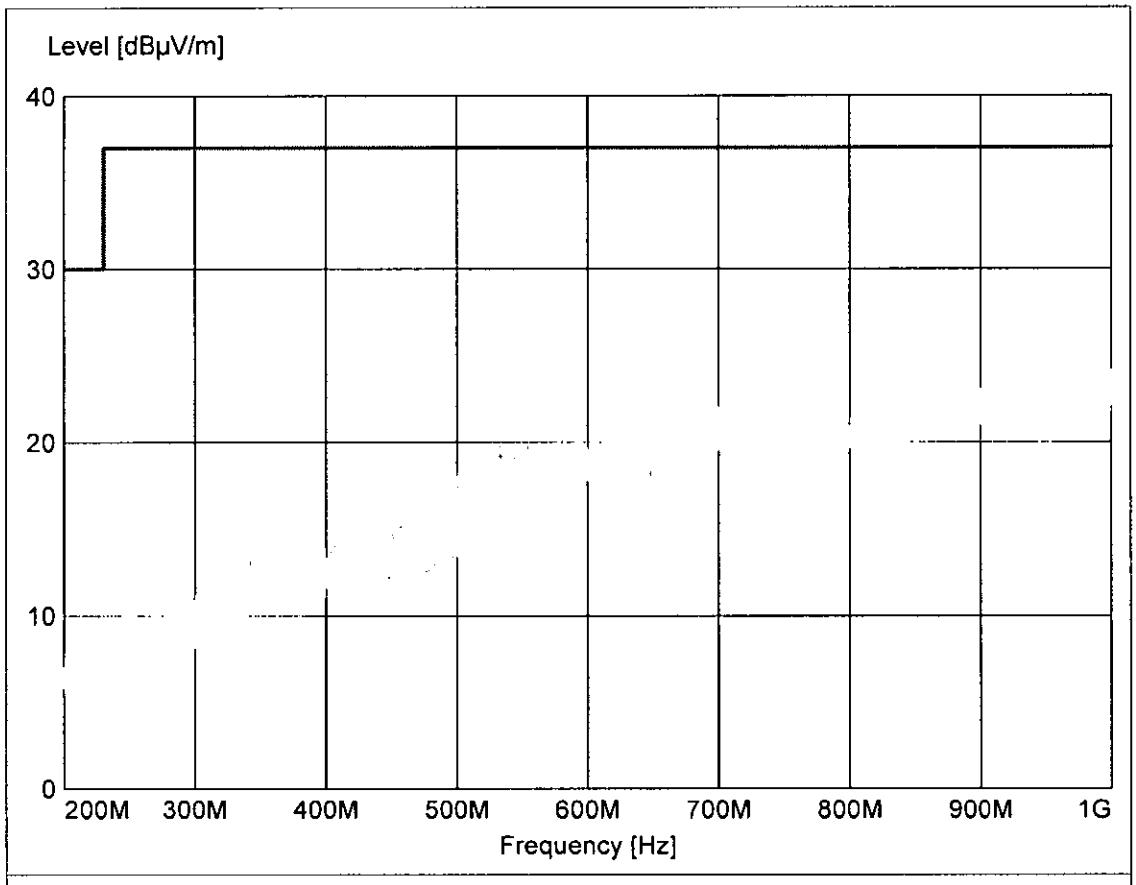
Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Medical Prod
EUT:	Bluetooth enabled stethoscope
Model:	Model 3200
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Klein
Test Conditions:	Tnom: 23°C, Unorm: Batt
Test Specification:	Ant: HL 223, vertical
Comment 1:	mode: Bluetooth
Comment 2:	mode:



MES Stethoscope_pre PK
LIM EN 55022 F QP_B Field Strength QP Limit

Spurious emission under normal conditions according to EN 55022 ***Ordernumber: G0M20810-2051***

Approval Holder:	3M Health Care Patient Assessment Laboratory 3M Medical Prod
EUT:	Bluetooth enabled stethoscope
Model:	Model 3200
Test Site / Operator:	Eurofins Product Service GmbH / Mr. Klein
Test Conditions:	Tnom: 23°C, Unorm: Batt
Test Specification:	Ant: HL 223, horizontal
Comment 1:	mode: Bluetooth
Comment 2:	mode:



(b) (4)

[redacted]

E3000 Plus
SAR SW Acceptance Test Report

Version 6.00
Page 1 of 6
File name: MBG0849B - SAR SW Acceptance Test Specification Report.doc

Author	Approved by
30-4-2009	30-04-2009
Date, Name – SW R&D	Date, Name – QA

QMS00247, Version 3.00

(b) (4)

[redacted]

(b) (4) [redacted]

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1 Purpose 3
2 Scope 3
3 References 3
4 Tests 3
5 Conclusion 5
6 Version history 6

QMS00747, Version 3.00

(b) (4) [redacted]

1 Purpose

The purpose is to document and conclude on the acceptance test specifications for the software in general described in [1].

2 Scope

The SAR SW Acceptance Test Specification Report covers the report of the Software Acceptance Test Specification.
Only tests for verifying stethoscope functions are performed. Performance measurements have been done in an earlier test.

3 References

[1] MBG0802a - SAS SW Acceptance Test Specification for E3000 Plus

4 Tests

The tests are described in the acceptance test specifications, which have been carried out.
The results can be seen in Appendix A to this document

Acceptance test	Passed	Failed	Comment
AT:001A	X		
AT:001B	X		
AT:001C	x		
AT:001D	x		
AT:002A	x		Code changed so test pass
AT:002B	x		
AT:002C	x		
AT:002D	x		
AT:002E	x		Code changed so test pass
AT:002F	x		
AT:003	x		
AT:004A	x		
AT:004B	x		
AT:004C	x		
AT:004D	x		
AT:004E	x		
AT:004F	x		
AT:005A	x		
AT:005B	x		
AT:005C	x		
AT:006A	x		
AT:006B	x		
AT:006C	x		
AT:008A	x		
AT:008B	x		
AT:009	x		
AT:010	x		
AT:011	x		
AT:012A	x		

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(b) (4) [redacted]

AT:012B	x		
AT:012C	x		
AT:013	x		
AT:016A	x		
AT:016B	x		
AT:016C	x		
AT:016D	x		
AT:016E	x		
AT:016F	x		
AT:016G	x		
AT:016H	x		
AT:016I	x		
AT:016J	x		
AT:016K	x		
AT:016L	x		
AT:017A	x		
AT:017B	x		
AT:017C	x		
AT:017D	x		
AT:018A	x		
AT:018B	x		
AT:018C	x		
AT:018D	x		
AT:018E	x		
AT:018F	x		
AT:018G	x		
AT:018H	x		
AT:018I	x		
AT:018J	x		
AT:019A	x		
AT:019B	x		
AT:020A	x		
AT:020B	x		
AT:020C	x		
AT:020D	x		
AT:020E	x		
AT:020F	x		
AT:020G	x		
AT:020H	x		
AT:020I	x		
AT:020J	x		
AT:020K	x		
AT:021A	x		
AT:021B	x		
AT:021C	x		
AT:021D	x		
AT:021E	x		
AT:021F	x		
AT:021G	x		
AT:021H	x		

(b) (4) [redacted]

AT:021I	x		
AT:021J	x		
AT:021K	x		
AT:022	x		
AT:024	x		
AT:025A	x		
AT:025B	x		
AT:025C	x		
AT:025D	x		
AT:026A	x		
AT:026B	x		
AT:026C	x		
AT:026D	x		
AT:027	x		
AT:028	x		
AT:029	x		
AT:030	x		
AT:032	x		
AT:033	x		
AT:034	x		
AT:035	x		
AT:036A	x		
AT:036B	x		
AT:036C	x		
AT:037	x		
AT:038	x		
AT:039	x		
AT:040	x		
AT:041A	x		
AT:041B	x		
AT:041C	x		
AT:041D	x		
AT:041E	x		
AT:041F	x		
AT:042	x		

5 Conclusion

The tests have passed after a small change in main_kalimba.asm.
Sw is retested after the change.
Version 1.90.00 have a error. The stethoscope always play diaphragm signal at power on. This is changed for the next version (2.00.00), so correct filter signal is played at power on.

Based on the conclusion above, the software is determined to be ready for release.

(b) (4) [redacted]

6 Version history

Version	Author	Date	Description	Reviewed by	EC number
0.01	MBG	05-12-2008	Document created.		
1.00	MBG	17. dec 2008	Document ready for signing.	TRH, CAP	
2.00	pmp	06-02-2009	Test after changes according to ECR		2009 - 026
3.00	PMP	06-03-2009	Test after changes according to ECR		2009 – 062
4.00	PMP	03-04-2009	Test after changes according to ECR		2009-158
5.00	PMP	17-04-2009	Test after changes according to ECR		2009-196
6.00	PMP	30-04-2009	Test after changes according to ECR		2009-210

Appendix A to MBG0849B -
SAR SW Acceptance Test specification Report.

(b) (4)
[redacted]

E3000 Plus
SAS, SW Acceptance Test Specification

Version 5.00

File name: MBG0802a - SAS SW Acceptance Test Specification for E3000 Plus.doc

Author

16-4-2009
Date, Name – Software Designer

Approved by

17-4-2009
Date, Name – Quality Assurance

(b) (4)
[redacted]

(b) (4) [redacted]

Version history

Version	Author	Date	Description	Reviewed by	EC number
0.1	MBG	9. jan 2008	Dokument created.		
0.2	MBG	11. feb 2008	New requirements were added, thus the new tests.		
1.00	PMP	06 oct 2008	version 1.00 of this acceptance test is intended for release of model 3100 software.		
1.10	MBG	27 nov 2008	Additional tests were added to include the M3200.		
1.11	MBG	28 nov 2008	AT:014 removed - testing SR:035 AT:031 removed - testing SR:062 + SR:064 See traceability to find test of these functions.	PMP,CAP,BUA, MBG	
1.20	MBG	04 dec 2008	Skill level added in section 4 and review comments added. AT:005 Edited to contain AT:007. AT:007 Deleted. AT:023 Deleted. AT:015 Deleted.		
2.00	MBG	04 dec 2008	Document ready for signing.		2008-201
3.00	PMP	03-feb-2009	AT:040 changed		2009-026
4.00	PMP	23-feb-2009	AT: 018 is changed		2009-061
5.00	PMP	16-04-2009	AT:041 is changed		2009-196

File name: MBG0802a - SAS SW Acceptance Test Specification for E3000 Plus.doc Page 2 of 36

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(b) (4) [redacted]

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QMS80738, Version 2.00

yuy

(b) (4) [redacted]

1 Purpose

The purpose of this document is to describe and list the tests, which are to be carried out to verify that the software is running as required in the software requirements.

2 Scope

This document describes the acceptance test of the software component of the E3000 Plus stethoscope. These tests will be carried out and there results will be shown in the Acceptance Test Report.

3 References

The E3000 Plus software requirement specification:

[1] MBG0751C - SRS SW Requirement Specification for E3000 Plus.docx
[2] BUA0415a Design Verification Report - E3000 Frequency response and gain.doc
[3] PMP0748C mmi state event action.vsd

4 Reading guidance

A note to the tables holding test cases:

- AT is short for Acceptance Test – the acceptance test number is indicated in this column.
- Step refers to the step within an acceptance test. Some acceptance test are composed of several steps that must be executed consecutively.
- SR refers to the software requirements that are tested by the acceptance test or test step.
- Some acceptance tests are composed of several steps that must be executed consecutively. The steps in acceptance tests are indicated by a letter after the test case number e.g. AT:017a.
- SR refers to the software requirements that are tested by the acceptance test or test step.

When buttons have to be activated in a test, the button must be held down for 0.5-1.5 sec unless specified otherwise. The different buttons on E3000 Plus are described in the table below. Note that the symbols might be slightly different on the assembled device.
The skill level of the person performing the tests has to be at a level, where he or she is able to pair and establish a Bluetooth connection on a PC. They also need to have a technical understanding covering the technical words and descriptions in the tests.

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(b) (4) [redacted]

Button symbol	Function
	Filter button
	Menu button
	Power on/off button
	Increase volume button
	Decrease volume button

Table 1: Button symbols

44C

(b) (4) [redacted]

5 TEST DESCRIPTION

The purpose of the software acceptance test is to verify that the requirements stated in **Error! Reference source not found.** are implemented correctly.

5.1 Test Target

The software acceptance test is performed on the final software for the E3000 Plus stethoscope.
The specific stethoscope used is listed below.

Description	Identification
E3000 stethoscope	Software version: 1.90.00 Serial number:

5.2 Test Configuration

The accept test is performed as a set of structured test cases. The test cases are detailed descriptions of user interaction and expected behaviour.

The test cases are designed so they can be performed by anyone on an assembled device. This avoids the use of large and complicated test/measurement setups, but still makes a thorough functionality test of E3000 Plus.

All tests must be performed at room temperature.

5.3 Test Approval

All errors found must be classified and the classification of errors must comply with the standard error classification used at Bang & Olufsen Medicom a/s.

QMS00238, Version 2.00
File name: MBG0802a - SAS SW Acceptance Test Specification for E3000 Plus.doc Page 6 of 36
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(b) (4) [redacted]

6 TEST INSTRUCTIONS

Each test case contains nine description windows. Some of the windows are descriptors others are for the actual test results. A short description of each window is given here:

- ***Purpose***
  A short description of the purpose of the test.
- ***AT***
  The number of the Acceptance Test, this number is unique and can only be used in other test cases if the test has to be performed in steps and thereby indexed with a letter.
- ***SR***
  Indicates which software requirement is tested in the current acceptance test, see reference **Error! Reference source not found.** in section 3.
- ***Actions***
  Describes the test sequence, any presetting are also stated here.
- ***Expected result***
  The expected outcome of the test is listed in this window
- ***Result***
  The actual result after the test has been performed. If the result is as expected is allowed to comment the result by writing "OK".
- ***Test equipment and reference***
  Statement of the test equipment used to perform the test. All the equipment required to perform this acceptance test is listed in section 6.2.
- ***Comment***
  Notes and comments from the test performer, writing "No comment" is allowed if nothing unusual is observed.
- ***Date and initials***
  Test date and the initials of the person performing the test. If the test result can be accepted the **Pass** box should be marked with √ else the **Not Pass** is marked.

6.1 Software set-up in the test

The software is setup as it would be in the final product. All functions are active in the tested module.

6.2 Needed equipment

This chapter contains information on the equipment needed to perform the tests.
The tests have to be carried out on an M3100 and a M3200 stethoscope. Where the M3100 is not required to pass the acceptance test, it will not be listed in the column model.

Instruments

The instruments in the following table are needed to execute the tests. The FAA no. (or the instrument series number) must be written in the table for the used instruments, also the calibration date for the last calibration of the instrument must be written in the table.

Type	Manufacture and model number	FAA no./SN	Calibration date
54648D	HP	30825	21-1-2009

4018

(b) (4) [redacted]

Test fixture
none

Other test equipment
none

6.3 Hints for the testing

none

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(b) (4) [redacted]

7 TEST CASES

7.1 Power Up timing

Purpose	Test that the E3000 Plus stethoscope powers up, when pressing the power button				
Test case	AT: 001	SR	SR: 002, SR: 004, SR:055, SR: 066		
Action	1) E3000 Plus is powered down 2) Insert the E3000 Plus earplugs into your ears 3) Do stimuli				
Shot	Stimuli	Expected result	Result	Model	ref
A	Press shortly	Stethoscope power on	Pow on	M3100 M3200	SR: 002
B	Press until the stethoscope show normal display, then release the button	Stethoscope stay powered on	Stay Pow on	M3100 M3200	SR: 002
C	Press shortly. Measure time from key pressed to backlight is on	less than 2 seconds 1,45 1,44 1,82 1,58 1,59	1,57	M3100 M3200	SR: 066
D	Press shortly. Measure time from key pressed to sound is on	less than 2 seconds 1,91 1,99 1,89 1,93 1,91	1,90	M3100 M3200	SR: 066 SR: 055
Test equipment and reference	Measure time with a stopwatch 5 times and calculate mean. This test also has to be done in an integration test, which is referred to here.				
Comment					
Pass X **Not pass**	**Date:** 30-4-2009 **Sign:** PMP				

7.2 Factory Default Settings1.

Purpose	Test factory default settings.		
Test case	AT:022	SR	SR:003
Action	Use a new fresh produced stethoscope model 3200 turn stethoscope on		
Expected result	1) stethoscope does not enter Bluetooth 2) volume level 3. 3) diaphragm filter.		
Result	No BT Vol 3 dia filter		
Test equipment and reference			
Comment			
Pass X **Not pass**	**Date:** 30-4-2009 **Sign:** PMP		

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(b) (4) [redacted]

7.3 Factory Default Settings2.

Purpose	Test that the factory default settings are as specified.				
Test case	AT: 041	SR	SR:046		
Action	1) E3000 Plus is powered on 2) Enter MENU → SETUP 3) Do stimuli				
Shot	**Stimuli**	**Expected result**	**Result**	**Model**	**ref**
A	Select POWER	MEDIUM is indicated	Medium	M3100 M3200	
B	Select Battery	ALKALINE is indicated	Alkaline	M3100 M3200	
C	Select BACKLIGHT	ALWAYS is indicated.	Always	M3100 M3200	
D	Select AUTO OFF	ENABLE is indicated.	Enable	M3100 M3200	
E	Select FILTERS	2 is indicated.	2 *	M3100	
F	Select FILTERS	3 is indicated.	3	M3200	
G	Select BT. COMM	MANUAL is indicated	Manual	M3200	PR: 076
Test equipment and reference					
Comment	* Toggle between Bell and Dia. filter				
Pass / **Not pass**	**Date:** 30-4-2009	**Sign:** PMP			

7.4 Power up default settings

Purpose	Test that the E3000 Plus stethoscope powers up with the preset values				
Test case	AT: 002	SR	SR: 003, SR: 005		
Action	1) Store pre settings, and turn stethoscope off. 2) Turn stethoscope on and verify settings				
Shot	**Stimuli**	**Expected result**	**Result**	**Model**	**ref**
A	Store bell filter setting and volume step 0 Press shortly	Stethoscope power on and give 2 short 500 Hz beeps	2 × 526 Hz	M3100 M3200	SR: 005
B		Stethoscope show bell filter and volume step 0	Vol = 0	M3100 M3200	SR: 003
C	Store diaphragm filter setting and volume step 8 Press shortly	Stethoscope power on and give 2 short 1000 Hz beeps	2 × 1000 Hz	M3100 M3200	SR: 005
D		Stethoscope show diaphragm filter and volume step 8	Dia. filter Vol = 8	M3100 M3200	SR: 003
E	Store third filter setting and volume step 5 Press shortly	Stethoscope power on and give 1 short 500 Hz beep and 1 short 1000 Hz beep	526 Hz 982 Hz	M3200	SR: 005
F		Stethoscope show third filter and volume step 5	Vol = 5	M3200	SR: 003
Test equipment and reference					
Comment	Change in main kalibo. usa				

Oersted-Ais, Version 2.06

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(b) (4) [redacted]

Pass	Not pass	Date:	Sign:
X		30-4-2009	PMP

7.5 Power Down

Test 1

Purpose	Test that the E3000 Plus stethoscope powers down, when pressing the power button for more than one second, while the stethoscope is powered on. The LCD should show the Littmann when powering down.			
Test case	AT: 003	**SR**	SR:006 SR:056 SR:057	Model M3100 M3200
Action	E3000 Plus is powered down 1) Insert the E3000 Plus earplugs into your ears 2) Press 3) Wait for 10 sec. and press the *power on/off* button again. The button must be pressed at least 1 second.			
Expected result	1) There are no sounds coming from the E3000 Plus (device is off). 2) The E3000 plus powers up. 3) The device indicates power down (showing the Littmann logo) and is fully powered down within 2 seconds.			
Result	1/ No sound 2/ Power up 3/ power down in 2 sec.			
Test equipment and reference				
Comment				
Pass	**Not pass**	**Date:**	**Sign:**	
X		30-4-2009	PMP	

(b) (4) [redacted]

Test 2

Purpose	Test that the E3000 Plus stethoscope enter standby automatically, when the power off timer runs out, while the stethoscope is powered on. The value of the timer is set in the configurations menu of the E3000 Plus.				
Test case	AT: 004	SR	SR: 004, SR: 009, SR: 010, SR:036		
Action	1) Power on the stethoscope and insert earplugs into your ears. 2) Store settings and measure the time until the stethoscope enters standby.				
Shot	Stimuli	Expected result	Result	Model	ref
A	Power = low, Auto off = disabled	Power On Time = 3 min. ± 10% Power Off Time = 30 min. ± 10% Backlight = 3 sec. ± 10% Warning tone is played 10 ± 2 sec. before entering standby : 1kHz ± 25%, 250ms ± 25%, 2kHz ± 25%, 85ms ± 25%	3:01 30:39 2,99 sec 10 sec 990 Hz 252 ms 1980 Hz 83 ms	M3100 M3200	
B	Power = medium, Auto off = disabled	Power On Time = 5 min. ± 10% Power Off Time = 2 hr. ± 10% Backlight = 5 sec. ± 10% Warning tone is played 10 ± 2 sec. before entering standby: 1kHz ± 25%, 250ms ± 25%, 2kHz ± 25%, 85ms ± 25%	5:01 2:00:44 4,96 sec 10 sec	M3100 M3200	
C	Power = high, Auto off = disabled	Power On Time = 7 min. ± 10% Power Off Time = 5 hr. ± 10% Backlight = 5 sec. ± 10% Warning tone is played 10 ± 2 sec. before entering standby: 1kHz ± 25%, 250ms ± 25%, 2kHz ± 25%, 85ms ± 25%	7:00 5:00:50 5,04 sec 10 sec	M3100 M3200	
D	Power = low, Auto off = enabled	Power On Time = 10 - 20 sec. Power Off Time = 30 min. ± 10% Backlight = 3 sec. ± 10%	17 sec 34:40 3,13 sec	M3100 M3200	
E	Power = medium, Auto off = enabled	Power On Time = 20 - 30 sec. Power Off Time = 2 hr. ± 10% Backlight = 5 sec. ± 10%	26 sec 2:00:39 5,05 sec	M3100 M3200	
F	Power = high, Auto off = enabled	Power On Time = 30 - 40 sec. Power Off Time = 5 hr. ± 10% Backlight = 5 sec. ± 10%	35 sec 5:00:47 5,02 sec	M3100 M3200	
Test equipment and reference					
Comment	The Auto-off times are tested in AT:012				
Pass / **Not pass**	**Date:** 30-4-2009	**Sign:** PMP			

7.6 Filter Mode

Test 1

Purpose	Test that the E3000 Plus stethoscope filter mode changes and that the correct mode is set.				
Test case	AT: 005	SR	SR: 011, SR: 012, SR:036		
Action	E3000 Plus is powered on 1) Insert the E3000 Plus earplugs into the Head and Torso Simulator (HATS). 2) Start logging data from HATS. 3) Do stimuli and compare result with expected result.				
Shot	Stimuli	Expected result	Result	Model	ref

(b) (4) [redacted]

A	Press H to change filter to the extended filter.	First tone: 500Hz ± 25%, 250ms ± 25% Second tone: 1kHz ± 25%, 200ms ± 25% The correct filter icon is showed in the LCD.	523 Hz 244ms 988 Hz 206 ms Third filter icon	M3200	
B	Press H to change filter to the bell filter.	First tone: 500Hz ± 25%, 250ms ± 25% Second tone: 500Hz ± 25%, 200ms ± 25% The correct filter icon is showed in the LCD.	523 Hz 240 ms 525 Hz 206ms bell filter icon	M3100 M3200	
C	Press H to change filter to the diaphragm filter.	First tone: 1kHz ± 25%, 250ms ± 25% Second tone: 1kHz ± 25%, 200ms ± 25% The correct filter icon is showed in the LCD.	992 Hz 241ms 990 Hz 204ms dia. icon	M3100 M3200	
Test equipment and reference	measured on loudspeak output				
Comment					
Pass X	**Not pass**	**Date:** 30-4-2009	**Sign:** PMP		

Test 2

Purpose	Test that the current filter mode is stored in non-volatile memory when storing filter in setup menu				
Test case	AT: 006	SR	SR: 013		
Action					
Shot	Stimuli	Expected result	Result	Model	ref
A	Select bell filter Store filter in setup menu Turn stethoscope off and on again.	Bell filter is used	Bell filter	M3100 M3200	SR: 013
B	Select diaphragm filter Store filter in setup menu Turn stethoscope off and on again.	Diaphragm filter is used	Dia. filter	M3100 M3200	SR: 013
C	Select third filter Store filter in setup menu Turn stethoscope off and on again.	Third filter is used	Third filter	M3200	SR: 013
Test equipment and reference					
Comment					
Pass X	**Not pass**	**Date:** 30-4-2009	**Sign:** PMP		

Test 4

Purpose:	Test that the number of filters available is the same as set in setup menu				
Test case	AT: 008	SR	SR: 075		
Action	Insert the E3000 Plus earplugs into your ears				
Shot	Stimuli	Expected result	Result	Model	ref
A	Set filters = 2 in setup menu press filter button more time.	The stethoscope toggle filter between bell and diaphragm	Toggle between 2 filters	M3100 M3200	SR: 075
B	Set filters = 3 in setup menu	The stethoscope		M3200	SR:

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(b) (4) [redacted]

	press filter button more time.	toggle filter between belt, diaphragm and third filter	Toggle between 3 filters		075

Test equipment and reference	
Comment	
Pass X **Not pass**	**Date:** 30-4-2009 **Sign:** PMP

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(b) (4) [redacted]

Test 5

Purpose	Test the frequency response of the three different filter modes.		
Test case	AT:009	**SR**	SR: 014 SR: 015 SR: 016
Action	E3000 Plus is powered down 1) Place the E3000 Plus into the Service Centre. 2) Press ⏻ 3) Select the *Bell* filter by pressing the filter button I and run the frequency response test. 4) Look at the result from the Service Centre. 5) Select the *third* filter by pressing the filter button I and run the frequency response test. 6) Look at the result from the Service Centre. 7) Select the *Diaphragm* filter by pressing the filter button I and run the frequency response test. 8) Compare with the expected stethoscope filter response.		
Expected result	1) There are no sounds coming from the E3000 Plus (device is off). 2) The E3000 plus powers up. 3) The E3000 Plus changes filter mode to *Bell*. The matching filter symbol is shown in the display. 4) The frequency response matches the one found in [2] for the *Bell* filter. 5) The E3000 Plus changes filter mode to third filter. The matching filter symbol is shown in the display. 6) The frequency response matches the one found in [2] for the *third* filter. 7) The E3000 Plus changes filter mode to *Diaphragm*. The matching filter symbol is shown in the display. 8) The frequency response matches the one found in [2] for the *Diaphragm* filter.		
Result			
Test equipment and reference			
Comment			
Pass / **Not pass**	**Date:**	**Sign:**	
X	30/4-09		

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7.7 Volume setting

Test 1

Purpose	Test that the volume changes, when the volume up or volume down button is pressed.
Test case	AT:010 — SR: SR:017, SR:018, SR:019, SR:036
Action	E3000 Plus is powered on 1) Insert the E3000 Plus earplugs into your ears. Setup HATS system to measure the tone. 2) Press the volume up button [redacted]. 3) Press the volume down button [redacted]. 4) Press and hold the volume up button [redacted]. 5) Press and hold the volume down button [redacted].
Expected result	1) E3000 Plus is operational 2) The volume level is increased 1 step and feedback is given via sound and the LCD. 3) The volume level is decreased 1 step and feedback is given via sound and the LCD. 4) The volume level is increased all the way to max and feedback is given via sound and the LCD. When the volume reach the highest level it stops giving sound feedback 5) The volume level is decreased all the way to min and feedback is given via sound and the LCD. When the volume reach the lowest level it stops giving sound feedback 6) the audio feed back is a short 1500Hz ± 25% 85ms ± 25% beep (verify with measurements from HATS.)
Result	1) operational 2) increase 1 step sound + LCD 3) Decrease 1 step sound + LCD 4) increase to max, stop increase stop sound feedback 5) Decrease to min, stop Decrease stop sound feedback 6) 88 ms 1565 Hz
Test equipment and reference	Measured on loudspeaker output
Comment	
Pass **Not pass**	**Date:** **Sign:**
X	30-4-2008 PMP

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Test 2

Purpose	Test that the volume setting can be stored in non-volatile memory.
Test case	AT:011 SR:020
Action	E3000 Plus is powered on 1) Insert the E3000 Plus earplugs into your ears 2) Change the volume setting by pressing . 3) Store the volume in setup menu 4) Turn off the stethoscope by pressing and holding the power on/off button for more than 1-second. 5) Turn on the stethoscope by pressing the power on/off button . 6) Listen to the body sounds (heart and respiration) and look at the LCD.
Expected result	1) E3000 Plus is operational 2) The volume level is increased 1 step and feedback is given via sound and the LCD. 3). 4) the stethoscope power off 5) The E3000 plus powers up. 6) The volume level is increased 1 step compared to the last time the stethoscope was powered up and feedback is given via the LCD.
Result	1) Operational 2) increase volume 3) Store - 2 beeps 4) Stethoscope off 5) power on 6) volume is at the stored value
Test equipment and reference	
Comment	
Pass **Not pass**	**Date:** **Sign:**
✓	30-4-2009 PRP

(b) (4) [redacted]

7.8 Auto On/Off

Purpose	Test that the Auto on/off system works. That is, that the E3000 Plus powers up from sleep mode, when the chest piece is placed on a body and that it powers off again, when no biological signal is measured. The power off function can be delayed by setting a timer in the configuration menu.
Test case	AT: 012 SR: SR:030, SR:031, SR:032
Action	Make settings as described in stimuli and then 1) Insert the E3000 Plus earplugs into your ears 2) Listen to a body sound and then place the stethoscope on table. 3) Wait till stethoscope automatically goes into standby. 4) Pick up the E3000 Plus, begin auscultation.

Shot	Stimuli	Expected result	Result	Model	ref
A	Power = low, Auto off = enabled	Power On Time = 10 - 20 sec. Logo is showing in LCD.	13 sec	M3100 M3200	
B	Power = medium, Auto off = enabled	Power On Time = 20 - 30 sec. Logo is showing in LCD.	24 sec	M3100 M3200	
C	Power = high, Auto off = enabled	Power On Time = 30 - 40 sec. Logo is showing in LCD.	34 sec	M3100 M3200	

Test equipment and reference	
Comment	
Pass X **Not pass**	**Date:** 30-4-2009 **Sign:** PMP

7.9 Heart Rate Monitor

Test1

Purpose	Test that the heart rate monitor is working and that the right heart rate is shown in the LCD.
Test case	AT:013 SR: SR:034 SR:026
Action	E3000 Plus is powered on and in active state 1) Insert the E3000 Plus earplugs into your ears 2) Place the chest piece on the shaker setup and set a frequency. 3) Read the display. Set a new frequency and wait 20 seconds and read the heart rate again. 4) Set the frequency of the shaker to zero and read the display.
Expected result	1) E3000 Plus is operational 2) A heart beat can be heard and the LCD shows the heart beat in beats per minute (varying <10%) after 5 seconds of measuring. As the heart rate changes, it is updated in the LCD every 2 seconds. 3) The LCD shows the heart rate in bpm. 4) The heart beat is shown for 10 seconds after the loss of heart sound signal. Afterwards two lines are shown (— —) to indicate that no valid heart rate is measured.
Result	1 Hz tested: shows 60 BPM 2 Hz tested: shows 120 BPM

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(b) (4) [redacted]

Test equipment and reference	
Comment	
Pass X **Not pass**	**Date:** 30/4-09 **Sign:**

Display valid heart rates

Purpose	Heart rate monitor only shows values of 30 to 199 in the LCD.		
Test case	AT:032	**SR**	SR:026
Action	E3000 Plus is powered on and in active state 1) Place the chest piece on a shaker, which is creating at saw tooth signal with a freq. of 1Hz. 2) Read the display. 3) Set the shaker frequency to 0.4Hz 4) Read the display. 5) Set the shaker frequency to 3.5Hz 6) Read the display.		
Expected result	1) E3000 Plus is operational 2) A heart beat can be read in the LCD, 60bpm. 3) Wait for 15 seconds. 4) The lines are shown (— —) to indicate that no valid heart rate is measured. 5) Wait for 15 seconds. 6) The lines are shown (— —) to indicate that no valid heart rate is measured.		
Result	Follows expected result.		
Test equipment and reference			

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(b) (4) [redacted]

Comment	
Pass / Not pass: X	Date: 30/4-09 Sign:

7.10 Battery Monitor

Level Indicator1.

Purpose	Test the different levels of the battery monitor.
Test case	AT: 016 SR: SR:039, SR:024, SR:040
Action	E3000 Plus is powered by special batteries. Four batteries of three different types. The four different batteries have four different amounts of power left in order to indicate the four different battery levels. 1) Insert the described battery and specify battery type in the setup of the stethoscope. 2) Look at the battery level indicator.

Shot	Stimuli	Expected result	Result	Model	ref
A	50 - 100% Alkaline battery.	50 - 100% battery life is shown	→ 1295mv	M3100 M3200	
B	25 - 50% Alkaline battery.	25 - 50% battery life is shown	1295mv 1250mv	M3100 M3200	
C	10 - 25% Alkaline battery.	10 - 25% battery life is shown	1250 mv 1223mv	M3100 M3200	
D	0 - 10% Alkaline battery.	0 - 10% battery life is shown and the battery icon flashes.	1223mv →	M3100 M3200	
E	50 - 100% Lithium battery.	50 - 100% battery life is shown	→ 1492mv	M3100 M3200	
F	25 - 50% Lithium battery.	25 - 50% battery life is shown	1492mv 1447mv	M3100 M3200	
G	10 - 25% Lithium battery.	10 - 25% battery life is shown	1447mv 1383mv	M3100 M3200	
H	0 - 10% Lithium battery.	0 - 10% battery life is shown and the battery icon flashes.	1383mv →	M3100 M3200	
I	50 - 100% NIMH battery.	50 - 100% battery life is shown	→ 1269mv	M3100 M3200	
J	25 - 50% NIMH battery.	25 - 50% battery life is shown	1269mv 1255mv	M3100 M3200	
K	10 - 25% NIMH battery.	10 - 25% battery life is shown	1255mv 1235mv	M3100 M3200	
L	0 - 10% NIMH battery.	0 - 10% battery life is shown and the battery icon flashes.	1235mv →	M3100 M3200	

Test equipment and reference	Battery simulator
Comment	Voltage is measured at TP22 over TP18
Pass / Not pass: X	Date: 29-4-2009 Sign: PMP

(b) (4) [redacted]

Level indicator2.

Purpose	Test the battery minimum voltage warning for the wireless data transmission. This warning is sent in order to notify that the connection is about to be closed. The E3k_Streamer program is necessary in this test. It should be installed on a PC with a Bluetooth connection.		
Test case	AT:035	SR	SR:065
Action	E3000 Plus is powered up via special low power batteries. 1) Establish a streaming connection to the PC. 2) Turn down the power supply until battery low level is reached. 3) Turn the power supply all the way down.		
Expected result	1) The E3000 Plus is streaming sound to a PC. 2) The battery level indicator flashes and an error bit is set in the header of the data stream. This will be visible in the error information in the PC program. 3) The E3000 Plus powers down, showing the Littmann logo and the wireless connection is lost.		
Result	1) streams 2) PC recieve Battery Wrong bit 3) Power down without littman logo		
Test equipment and reference			
Comment	Test spec error: Littman logo can't be shown when battery level goes below reset		
Pass X **Not pass**	**Date:** 30-4-2009	**Sign:** PMP	

7.11 Miscellaneous

Button Commands

Purpose	Test multiple key pressing

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Test case	AT: 017	**SR**	SR:047, SR:048
Action	Turn stethoscope on		

Shot	Stimuli	Expected result	Result	ref
A	press and hold filter button pres and release + button	Change filter don't change volume	Ch. filt no vol chase	SR: 048
B	press and hold - button pres and release M button	Change volume don't enter menu	chang volu don't enter menu	SR: 048
C	press and hold - button Press and release filter button	volume decrease Volume stop decreasing	decrease vol stop dec vol	SR: 048
D	Press and hold M button Press and hold filter button release M button Press and hold + button Release M button release + button press - button	Enter menu "CONNECT" No change No change No change No change No change change to "DISCONNE"	Connect NC NC NC NC NC Disconnect	SR: 047, SR: 048

Test equipment and reference	
Comment	

Pass	Not pass	Date:	Sign:
X		30-4-2009	PHP

Configuration menu

Purpose	Test configuration menu		
Test case	AT: 018	**SR**	SR:049, SR:050, SR:082
Action			

Shot	Stimuli	Expected result	Result	ref
A	Model 3200 Press M button	enter menu main menu > "CONNECT"	CONNECT	PR: 034
B	Model 3100 Press M button	Enter setup menu > "POWER"	POWER	PR: 034
C	Select AUTO OFF = ENABLE Select POWER = LOW Use stethoscope	Stethoscope is on while places on body. The stethoscope enter stand by 10 -20 seconds after it is places on a table	ST by after 14 sec	PR: 069
D	Select AUTO OFF = DISABLE Select POWER = LOW Use stethoscope	Stethoscope is on while placed on a table till 3 minutes after a key is pressed or released	3 min.	PR: 069, SR: 082
E	Select AUTO OFF = DISABLE Select POWER = LOW Place stethoscope on table	the stethoscope is in stand by 30 min ±10 %	30:39 see AT004/A	PR: 070
F	Select AUTO OFF = DISABLE Select POWER = MEDIUM Place stethoscope on table	the stethoscope is in stand by 120 min ±10 %	2:00:44 see AT004/B	PR: 070
G	Select AUTO OFF = ENABLE Select POWER = HIGH Place stethoscope on table	the stethoscope is in stand by 300 min ±10 %	5:00:47 see AT004/F	PR: 070
E	Select AUTO OFF = DISABLE Select POWER = LOW Place stethoscope on table After 15 minutes press + button Observe the last stand by time	The stethoscope enter standby The stethoscope leave stand by when + button is pressed The stethoscope enter stand by after 3 min The stethoscope is in stand by 30 min ±10%	enter STby leave STby enter standby after 3 min Turn off after 33 min	PR: 071
F	Select AUTO OFF = DISABLE Select POWER = LOW Place stethoscope on table after 2 minutes press filter button	The stethoscope enter standby 3 min ±10% after the filter button is released	3 min after release	PR: 071
G	Select AUTO OFF = DISABLE Select POWER = LOW	The stethoscope enter normal auscultation	Turn on	PR: 072

(b) (4) [redacted]

	Place stethoscope on table. Wait till stethoscope enter standby, put stethoscope on chest			
Test equipment and reference				
Comment	Some of these tests might have been performed in T:004 already.			
Pass	**Not pass**	**Date:** 30-4-2009	**Sign:** PMP	
X				

Configuration menu 2

Purpose	Test configuration menu			
Test case	AT: 019	**SR**	SR:050	
Action				
Shot	**Stimuli**	**Expected result**	**Result**	**ref**
A	Model 3200 Select BT. COMM = MANUAL Turn stethoscope off, and on again	Stethoscope start i normal auscultation	Start normal	PR: 076
B	Model 3200 Select BT. COMM = AUTO Turn stethoscope off, and on again	Stethoscope start i bluetooth	Pairing OR ~~Connection~~ State	PR: 076
Test equipment and reference				
Comment				
Pass	**Not pass**	**Date:** 30-4-2009	**Sign:** PMP	
X				

Configuration menu 3

Purpose	Test configuration menu			
Test case	AT: 020	**SR**	SR:050, SR:061, SR:076	
Action				
Shot	**Stimuli**	**Expected result**	**Result**	**ref**
A	Enter ID menu observe serial number	Display show: SERIAL # 000809xx xxxxxxxx (0809 is production year and month, xxxxx is a decimal representation of the Bluetooth LAP)	000809 00 00050010	PR: 042
B	Enter ID menu press - button observe SW version	Display show: SW VER. xx.yy.00 (xx = major, yy = minor sw version)	1.90.00	PR: 042
C	Model 3100 Press M button continue..	SETUP: >~~POWER~~ BATTERY Rollet 30-4-2009 PMP	Power	
D	Press - button continue..	SETUP: >EXIT	Battery	
E	Press + button until SETUP:>ID Press M button continue..	ID: SERIAL #	Serial #	
F	Press Filter button continue..	SETUP: >ID	ID	
G	Press filter button continue..	Exit menu	Exit Menu	
E	Model 3200	MAIN: >CONNECT		

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(b) (4) [redacted]

	Press M button continue ...		Connect	
F	Press + button twice Press M button continue ...	SETUP: >POWER	Power	
G	Press + button twice press M button continue ...	ID: SERIAL #	Serial #	
H	Press M button	exit menu	exit Menu	
Test equipment and reference				
Comment	error in test case C. Spec error.			
Pass	**Not pass**	**Date:**	**Sign:**	
X		30-4-2009	PMP	

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(b) (4) [redacted]

Service counter

Purpose	Test service counter		
Test case	AT: 021	SR	SR:085
Action	read service counters before and after stimuli		

Shot	Stimuli	Expected result	Result	ref
A	Press M button	M btn: = M btn: + 1	+1	
B	Press + button 2 times	Plus btn: = Plus btn: + 2	+2	
C	Press + button 3 times	Minus btn: = Minus btn: + 3	+3	
D	Press filter button 4 times	Filter btn: = Filter btn: + 4	+4	
E	press on/off button 5 times	On/off btn: = On/off btn: + 5	+5	
F	Let stethoscope go into standby Put stethoscope on chest so it wake up	Auto on wkup: = Auto on wkup: + 1	+1	
G	AUTO ON = ENABLE leave stethoscope on table so it enter standby	Auto off evt: = Auto off evt: + 1 Auto off tos: = Auto off tos: + 1	+3 +1	
E	AUTO ON = DISABLE leave stethoscope on table so it enter standby	Active tos: = Active tos: + 1	+1	
F	read service counters with 20 sec interval	Active T: = Active T: +20±2 Bluetoot T: = Bluetoot T: + 20 ±2	22 22	
G	leave stethoscope 3,5 min in standby	Stand by T: = Stand by T: + 3	+3	
H	turn stethoscope off and on	Power on evt: = Power on evt: + 1	+1	

Test equipment and reference	
Comment	
Pass X **Not pass**	**Date:** 30-4-2009 **Sign:** PMP

Dot matrix display

Purpose	Test dot matrix		
Test case	AT:024	SR	SR:077
Action	measure and count dots		
Expected result	the active area is14x8 mm The number of dots are 56x32	14 X 8,18	56 X 32
Result		14 X 8,18	56 X 32
Test equipment and reference			
Comment			
Pass X **Not pass**	**Date:** 30-4-2009	**Sign:** PMP	

Icons

Purpose	Test icons		
Test case	AT:025	SR	SR:078
Action	turn stethoscope on verify icons against figure 1 in product requirements		

Shot	Stimuli	Expected result	Result	ref

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(b) (4) [redacted]

A	volume icon	Icon is there.	Vol. Icon	PR: 023
B	filter icon	Icon is there.	Filter Icon	PR: 023
C	battery icon	Icon is there.	Battery Icon	PR: 023
D	Heart rate	Icon is there.	Heart Rate	PR: 023

Comment	
Pass X **Not pass**	**Date:** 30-4-2009 **Sign:** PMP

Backlight1

Purpose	Test backlight timeouts		
Test case	AT:026	SR	SR:023
Action	turn stethoscope on wait to backlight turns off		

Shot	Stimuli	Expected result	Result	ref
A	SET POWER = LOW press and release on/off button	backlight turn on, and turn off again 3 sec ±10% after the button is released	3 sec	
B	SET POWER = LOW press and release on/off button, press and release the on/off button again before the backlight turns off	backlight turn on, and turn off again 3 sec ±10% after the button is released last time	3 sec	
C	SET POWER = MEDIUM press and release on/off button	backlight turn on, and turn off again 5 sec ±10% after the button is released	5 sec	
D	SET POWER = HIGH press and release on/off button	backlight turn on, and turn off again 5 sec ±10% after the button is released	5 sec	

Comment	Some of these tests might have been performed in AT:004 already.
Pass X **Not pass**	**Date:** 30-4-2009 **Sign:** PMP

Backlight2

Purpose	Test the three Backlight settings.		
Test case	AT:036	SR	SR:023
Action	turn stethoscope on wait to backlight turns off Set Power = low.		

Shot	Stimuli	Expected result	Result	ref
A	BACKLIGHT = ON DIMMD press and release on/off button	backlight turn on, and turn off again 3 sec ±10% after the button is released	On in 3 sec Then off	
B	BACKLIGHT = ALWAYS press and release on/off button.	backlight turn on, and turn down to approximately 50% light intensity after 3 sec ±10% and stays on.	Full already in 3 sec Then dimmed	
C	BACKLIGHT = DISABLE	backlight is off and stays	off	

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(b) (4) [redacted]

	press and release on/off button	off.		
Comment	Some of these tests might have been performed in AT:004 already.			
Pass **Not pass**	**Date:**	**Sign:**		
X	30-4-2009	PMP		

Onboard Storage 1

Purpose	Storing recordings.		
Test case	AT:033	**SR**	SR:079 SR:080 SR:086
Action	The E3000 Plos is powered on (diaphragm filter is selected). 1) Place the stethoscope in the HATS and start recording on the connected PC (connected to the HATS). 2) Place the chest piece on the shaker and set shaker to give a 200Hz sine signal. 3) Press the M button to enter the menu. 4) Select RECORD in the menu, to start the recording. 5) Make recording for 35 seconds. 6) Press the menu button to stop the recording and turn off the signal generator. 7) Playback the recording by selecting PLAY in the menu. 8) Compare the 29 seconds of the recording with the first 35 seconds recorded on the PC. It should match the last 29 seconds of the 35 seconds.		
Expected result	1) PC is recording. 2) None. 3) enters menu. 4) Recording starts. 5) None. 6) Recording stops on the stethoscope. 7) Recording on the PC continues. 8) The first and last part of the recording on the PC are the same.		
Result	The last 29 sec is recorded.		
Test equipment and reference			
Comment	Test is done by recording a voice counting from 1-35 (one/sec) Play back is from 6-35.		
Pass **Not pass**	**Date:**	**Sign:**	
X	30-4-2009	PMP	

Onboard Storage 2

Purpose	Show that the recording is done before the filter and it is played back through the filter.		
Test case	AT:034	**SR**	SR:081
Action	The E3000 Plus is powered on. 1) Select the Bell filter. 2) Press the M button to enter the menu. 3) Select RECORD in the menu, to start the recording. 4) Place the stethoscope above the heart and make a recording. 5) Playback the recording by selecting PLAY in the menu. 6) Keep the chest piece away from your body with the binaurals in your ears to hear the recording.		

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(b) (4) [redacted]

	7) Press the filter button to change the filter.
Expected result	1) Bell filter is selected. 2) The menu is shown. 3) The recording is started. 4) The sound of the heart is heard in the binaurals. 5) Playback is started. 6) The recording is heard in the binaurals. 7) The recording is now heard with the Diaphragm filter.
Result	The sound change when filter is changed
Test equipment and reference	
Comment	
Pass X **Not pass**	**Date:** 30-4-2009 **Sign:** PMP

Playback

Purpose	Test the warning which alerts the user, that it is a streamed signal, which is being played.		
Test case	AT:040	**SR**	SR:073 PR:125
Action	The E3000 Plus is powered on. 1) Stream a recording via Bluetooth. 2) Listen to the sound in the binaurals.		
Expected result	1) steraming starts with a playback warning tone (beep). 2) The playback icon is shown in the LCD and the streamed sound is heart in the binaurals. 3) the beep must be given less than 1000 ms after stream start		
Result	A 50 ms beep is heard 28 ms after streaming start.		
Test equipment and reference			
Comment			
Pass X **Not pass**	**Date:** 30-4-2009 **Sign:** PMP		

Bluetooth Pairing1.

Purpose	Making it possible to establish the Bluetooth connection with a Bluetooth device supporting

(b) (4) [redacted]

	Bluetooth v.2.0 or v.2.1.		
Test case	AT: 027	**SR**	SR:029 SR:059 SR:070 SR:078
Action	The E3000 Plus is powered on and the Bluetooth device is ready for pairing. 1) Press the M button. 2) Press MINUS once and press the M button again to select PAIR. 3) Chose to pair the Bluetooth device with the stethoscope. 4) Punch in the pairing code shown in the display of the stethoscope. 5) Chose to connect to the newly found (on the Bluetooth device) SPP device.		
Expected result	1) The M3200 enters the configuration menu. 2) The pairing logo should be shown: 3) The M3200 shows a four digit code in its display. 4) The LCD shows a flashing Bluetooth icon as in figure 1 in the product requirements. 5) The Bluetooth icon stops flashing and is lit.		
Result	1/ config menu 2/ Pairing display 3/ Show Pincode 4/ flashes BT icon 5/ Steady BT icon		
Test equipment and reference			
Comment			
Pass **Not pass**	**Date:** **Sign:**		
Y	30-4-2009 PMP		

Bluetooth Pairing2.

Purpose	The stethoscope has to be able to be paired with up to 8 Bluetooth devices. This enables the stethoscope to connect to the 8 known devices without pairing again.		
Test case	AT:038	**SR**	SR:087

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(b) (4) [redacted]

Action	The E3000 Plus is powered on and the Bluetooth device is ready for pairing. 1) Pair the stethoscope with at least 3 devices. 2) Go back to the first device and chose **CONNECT** in the menu and connect on the Bluetooth device.
Expected result	1) The stethoscope is paired with at least 3 devices. 2) The stethoscope connects with the first Bluetooth device without re-pairing.
Result	Pair with 3 PC connect to first without pairing
Test equipment and reference	
Comment	
Pass / **Not pass**	**Date:** / **Sign:**
X	30-4-2003 PRP

(b) (4) [redacted]

Connecting Bluetooth.

Purpose	Establishing the Bluetooth connection.		
Test case	AT: 028	**SR**	SR:028 SR:029 SR:058 SR:072
Action	The E3000 Plus is powered on and is paired to the Bluetooth device, tough not connected. 1) Press the M button to enter the menu. 2) Press the M button again to connect to the Bluetooth device. 3) The connection is tested with E3k_streamer. 4) When steaming, walk away from the Bluetooth device until the connection is lost.		
Expected result	1) The menu is showing in the LCD. 2) The Bluetooth icon is initially flashing and shifts to being lit, when the connection is made. 3) The connection is usable. 4) The Bluetooth icon starts flashing when the connection is lost and the streaming to the Bluetooth device stops.		
Result	1/ menu 2/ BT icon flash - steady after connect on PC 3/ streaming. 4/ BT icon flash when connection is lost.		
Test equipment and reference			
Comment			
Pass / **Not pass**	**Date:**	**Sign:**	
X	30-4-2009	PMP	

Streaming.

Purpose	Show the appropriate filter icon when doing playback from the connected Bluetooth device.		
Test case	AT:039	**SR**	SR:071
Action	The E3000 Plus is powered on and is ready to playback from the connected Bluetooth device. The selected filter is Diaphragm.		

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(b) (4) [redacted]

	1) Start the playback streaming to input switch 1. 2) Look at the LCD. 3) Press the filter button. 4) Look at the LCD. 5) Start the playback streaming to input switch 2. 6) Look at the LCD.
Expected result	1) The streamed sound is heard in the binaurals. 2) The Diaphragm filter icon is shown in the LCD. 3) The sound of the filter change is heard in the binaurals. 4) The Bell filter icon is show in the LCD. 5) The streamed sound is heard in the binaurals. Now not filtered. 6) Not filter icon is shown in the LCD.
Result	1/ Shown 2/ Show filter 3/ Sound Change 4/ Bell filter Icon 5/ Sound Don't change with the filter button 6. NO Filter icon
Test equipment and reference	
Comment	
Pass X **Not pass**	**Date:** 30-4-2009 **Sign:** PMP

Bluetooth Transmission Range.

Purpose	Insight Bluetooth range.		
Test case	AT: 042	SR:	SR:072
Action	The E3000 Plus is powered on and is connected and streaming. 1) Walk away from the streaming PC and look at the LCD.		
Expected result	1) The distance to the PC is 10, or more, meters.		
Result	>10 m		
Test equipment and reference			

(b) (4) [redacted]

Comment	
Pass **Not pass**	**Date:** **Sign:**
X	30-4-2009

Bluetooth up-/download.

Purpose	Test the upload and download function via the Bluetooth connection.		
Test case	AT: 029	**SR**	SR:084
Action	The E3000 Plus is powered on and paired with a PC, which is running our up-/download program. 1) Connect the stethoscope to the PC. 2) Record a sine signal of 300Hz via a shaker and a signal generator. 3) Upload the sound file to the PC. 4) Record heart sound on the stethoscope. 5) Play the sound file from the stethoscope by choosing play in the menu. 6) Download the 300Hz signal from the PC to the stethoscope. 7) Play the sound file on the stethoscope		
Expected result	1) The connection is established. 2) The 300Hz signal can be heard in the binaurals.. 3) The upload is being carried out. 4) Recording icon is shown in LCD. 5) The heart sound is heard in the binaurals. 6) The download is carried out. 7) A 300Hz sound is heard in the binaurals.		
Result	upload Recording to PC Record Heart sound. Play hard sound with playback Download first recording. Play first recording.		
Test equipment and reference			

474

(b) (4) [redacted]

Comment	
Pass **Not pass**	**Date:** **Sign:**
X	30-4-2009 PHP

Channel B gain.

Purpose	The digital gain in channel B has to be independently program-controlled compared to channel A.		
Test case	AT: 030	**SR**	SR:074
Action	The E3000 plus is turned on and is paired with a PC, which is running the E3k_streamer program, which is showing the sound streamed. 1) Place the binaurals in your ears and place the chest piece on the shaker and apply a 300Hz tone. 2) Turn up the gain on channel B from the PC. 3) Observe the level of the signal in the E3k_streamer program.		
Expected result	1) The 300Hz tone is heard in the binaurals and a signal is seen in the E3k_streamer program. 2-3) The heart sound stays the same in the binaurals, but the amplitude of the signal shown in the E3k_streamer program changes its amplitude to a higher level.		
Result	Showing level is changing Sound level in binaurals is steady		
Test equipment and reference			

475

(b) (4) [redacted]

Comment	
Pass / **Not pass**	**Date:** / **Sign:**
X	30-4-2009 PMP

SPI interface.

Purpose	Test if it is possible to reprogram the stethoscope and thereby giving it a new identification number, software version number and model number. This information is stored in non-volatile memory.		
Test case	AT:037	**SR**	SR:068 SR:069
Action	The E3000 Plus is powered on. 1) Enter MENU->SETUP->ID. 2) Read SW version-, serial-, and model number. 3) Reprogram the stethoscope with an older release. 4) Turn the stethoscope on and enter MENU->SETUP->ID. 5) Read SW version number to verify that the software has changed. 6) Reprogram the stethoscope with the original software.		
Expected result	1) LCD is showing stethoscope information. 2) It is necessary to scroll through the information with the + or – button. 3) The stethoscope is reprogrammed with another software version. 4) The stethoscope enters the menu under ID. 5) A different software version is displayed. 6) The stethoscope is reprogrammed with the original software.		
Result	2) SW Version = 1.90.00 5) SW Version = 1.22.00		
Test equipment and reference			

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(b) (4) [redacted]

Comment	
Pass Not pass	Date: Sign:
X	30-4-2009 PMP

(b)(4)Trade Secret Process-Design

[redacted]

RESPONSE TO QUESTION (9): External Control of 3200 via Bluetooth

(b)(4)Trade Secret Process-Product Specs

[redacted]

We have revised the IFU to include these potential remote capabilities as follows:

1. "The Bluetooth interface provides a means of exchanging audio data with external devices such as a Bluetooth enabled PC. Audio data can be sent in near real time, permitting the visual presentation, recording, and analysis by applications software complying with communication protocols used by the Model 3200 stethoscope."

2. "In order to transfer data between two Bluetooth devices, they must first be "paired" electronically. Pairing is a discovery and authentication process that allows your Bluetooth equipped Model 3200 stethoscope to communicate with another Bluetooth equipped device and establishes the link between these two devices as a trusted pair. The pairing process requires user operations to be performed on both the Model 3200 and the external device."

3. "When connected by a Bluetooth link, external Bluetooth-enabled devices may take control of the display and keypad of the Model 3200 stethoscope. The external device may also transfer audio playback or other information through the Model 3200 headset. When the external device transfers audio playback back to the stethoscope, the sounds will be preceded by a beep."

We have carefully designed the remote operation of the 3200 stethoscope to provide extremely safe, reliable, and secure Bluetooth wireless communication and control in a clinical environment without interference. The key features of this secured control link are as follows.

(b)(4)Trade Secret Process-Product Specs

[redacted]

(b)(4)Trade Secret Process-Product Specs

[redacted]

(b)(4)Trade Secret Process-Testing

(b)(4)Trade Secret Process-Testing

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(b)(4)Trade Secret Process-Testing

(b)(4)Trade Secret Process-Testing

I. Software Architecture Design Chart

<u>(1) Architecture Design Chart:</u> These are attached below. MBG0851A and MBG0851B are the main documents that reference the 11 PDF files.

MBG0851A - SW Architecture Design Charts E3000 Plus.pdf
MBG0851B - Software Description E3000 Plus.pdf

(a) e3000_plus_context.pdf
(b) e3000_plus.pdf
(c) handle_e3000_plus.pdf
(d) handle_system_and_irq.pdf
(e) handle_io_driver.pdf
(f) handle_audio.pdf
(g) handle_spp_communication.pdf
(h) handle_events.pdf
(i) handle_auto-off.pdf
(j) handle_heart_rate.pdf
(k) control mmi.pdf

(b)(4)Trade Secret Process-Software Design

(b)(4)Trade Secret Process-Software Design

(b)(4)Trade Secret Process-Software Design

(b)(4)Trade Secret Process-Software Design

(b)(4)Trade Secret Process-Software Design

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(b)(4)Trade Secret Process-Software Design

[redacted]

E3000 Plus
Software Architecture Design Charts

Version 1.00

File name: MBG0851A - SW Architecture Design Charts E3000 Plus.docx

Author

17/12-08 [signature]
Date, Name – Software Designer

Approved by

17-12-2008 [signature]
Date, Name – Quality Assurance

(b)(4)Trade Secret Process-Software Design

[redacted]

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(b)(4)Trade Secret Process-Software Design

Version history

Version	Author	Date	Description	Reviewed by	EC number
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517

(b)(4)Trade Secret Process-Software Design

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2 Scope 4
3 References 4
4 Flow Charts 4

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(b)(4)Trade Secret Process-Software Design

1 Purpose

The purpose with this document is to collect the software architecture design charts.

2 Scope

This document covers the software design of the M3100 and the M3200.

3 References

[1] None.

4 Flow Charts

The chart on the next page is an overview chart, which shows the link between the charts. The following hyperlinks open PDF-files showing the architecture itself.

Context.pdf
E3000_plus.pdf
Handle_e3000_plus.pdf
Handle_system_and_irq.pdf
Handle_io_driver.pdf
Handle_audio.pdf
Handle_spp_communication.pdf
Handle_events.pdf
Handle_auto-off.pdf
Handle_heart_rate.pdf
Control_mmi.pdf

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(b)(4)Trade Secret Process-Software Design

(b)(4)Trade Secret Process-Software Design

Overview

S20

(b)(4)Trade Secret
Process-Software
Design

521

(b)(4)Trade Secret Process-Software Design

[redacted]

E3000 Plus
Software Description

Version 1.00
Page 1 of 4
File name: MBG0851B - Software Description E3000 Plus.docx

Author

17/12-08 [signature]
Date, Name – Software Designer

Approved by

19/12-08 [signature]
Date, Name – Quality Assurance

(b)(4)Trade Secret Process-Software Design

[redacted]

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(b)(4)Trade Secret Process-Software Design

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523

(b)(4)Trade Secret Process-Software Design

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3 Design Description Documents 4
4 Design simulation 4
5 Software description. 4

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(b)(4)Trade Secret Process-Software Design

1 Purpose

The purpose with this document is to collect the software design documents and make an overview of these documents.

2 Scope

This document covers the software design of the M3100 and the M3200.

3 Design Description Documents

(b)(4)Trade Secret Process-Software Design

[redacted]

4 Design simulation

A simulation of the design can be found in the folder 'E3000plus_simulator_Matlab', which contains a (b)(4)Trade Secret Process-Software Design [redacted].

5 Software description.

(b)(4)Trade Secret Process-Software Design

[redacted]

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II. Software Design Specifications

The Software Design Requirements Specifications for the 3200 stethoscope has been attached below.

MBG0751C - SRC SW Requirement Specification for E3000 Plus.pdf

(b)(4)Trade Secret Process-Software Design

[redacted]

M3100-M3200
SRS SW Requirement Specification

Version: 2.00

File name: MBG0751C - SRS SW Requirement Specification for E3000 Plus.docx

Author

5/12-08
Date, Name – Software Designer

Approved by

5/12-08
Date, Name – Quality Assurance

(b)(4)Trade Secret Process-Software Design

[redacted]

(b)(4)Trade Secret Process-Software Design

Version history

Version	Author	Date	Description	Reviewed by	EC number
0.1	MBG	20. dec 2008	Document created.		
0.2	MBG	11. feb 2008	Requrrements edited and "Req. by" added.		
0.3	MBG	20. feb 2008	Req by removed and Product Requirements added.		
0.4	MBG	28. feb 2008	Review comments added.	MBG, PMP, KHR, ABR, SFR	
0.5	MBG	16. May 2008	Sound Feedback tones defined.		
1.0	MBG	27. May 2008	Document ready for signing.		
1.10	CAP	9. Sep 2008	Document updated to implement new MMI and LCD according to EC Name changed to M3100-M3200 Section 1,2,3,4,5 updated SR:011 Updated: Third removed SR:075 New: Third filter added SR:013 Changed: Menu SR:015 Changed: Third filter requirements SR:017 Updated: Equally steps SR:020 Changed: Menu SR:021 Deleted SR:022 Deleted SR:035 Updated: Reference SR:040 Updated: Low level SR:041 Deleted SR:042 Deleted SR:044 Deleted SR:048 Changed: No double pressure SR:049 Changed: Menu SR:060 Deleted SR:076 New: Menu SR:058 Changed: Menu SR:059 Changed: Menu SR:077 New: LCD icons SR:078 New: LCD icons SR:079 New: Onboard storage SR:080 New: Onboard storage SR:081 New: Onboard storage SR:082 New: Menu SR:083 New: Upload data support SR:084 New: Onboard storage upload/download SR:085 New: Service counter		2008-117
1.20	CAP	25 Sep 2008	SR:074 Changed: Specification on steps removed to follow gain steps in chip. SR:014 SR:015 SR:016 Updated: Figure 1 added to specify filters		
1.30	PMP	8 oct 2008	SR:002 is corrected. SR:004 is corrected SR:006 is clarified SR:009 is corrected SR:010 is corrected		
1.40	MBG	27 nov 2008	SR:004 Edited to be more specific. SR:054 Deleted SR:086 New: M button stops recording, when in rec. SR:087 New: Remember pairing information for up to 8 Bluetooth devices. SR:071 Changed to match PR:126.		
2.00	MBG	04 dec 2008	Ready for signing		2008-201

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(b)(4)Trade Secret Process-Software Design

1 Purpose

This document list the requirements for the software developed to the E3000 Plus electronic stethoscope. E3000 plus is an update of the Model 3000 stethoscope and will be launched as Model 3100 and Model 3200.

Traceability to the product requirement is added in the tables and reported in the traceability analysis document .

2 Scope

Software requirements of both M3100 and M3200 are within this document. A column will identify in which product the requirement is implemented [8].

Model 3100: Holds the basic functions of the stethoscope.
Model 3200: Add more function as: Bluetooth link, third filter and onboard storage

3 References

(b)(4)Trade Secret Process-Software Design

[redacted]

4 Reading guidance

The following section contains a general description of the E3000 plus stethoscope and its features. This is done to give an insight in the system and its functionality. After this, the actual requirements are stated.

During the description of button actions, there are two different ways of pressing a button.

Short pressure: 200-1000ms.
Long pressure: >1000ms

5 General description

5.1 System description

(b)(4)Trade Secret Process-Software Design

[redacted]

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(b)(4)Trade Secret Process-Software Design

The user will use the electronic stethoscope in the same way as the Model 3000.

In addition to the Model 3000, the Model 3100 adds more software features:

- More acoustical amplification up to 28dB, [1].
- Separate on/off button (5 buttons keypad for operating the product).
- Power management with sleep state.
- Visual feedback via LCD with backlight.
- Heart rate monitor with Beats Per Minute (BPM) shown in the LCD.

In addition to the Model 3100, the Model 3200 adds more software features:

- Wireless communication via Bluetooth.
- Third filter option
- Onboard memory to store a sound track

A physical block diagram of the system is seen in Figure 1.

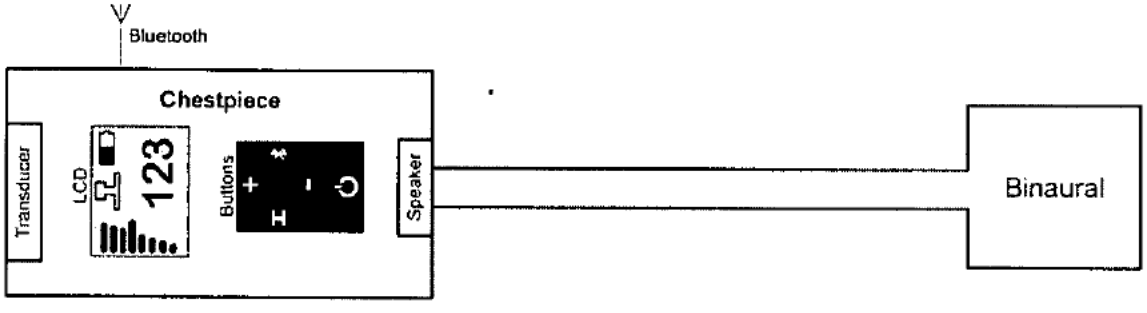

Figure 1: Physical block diagram of the E3000 Plus system.

The system consists of an active digital chest piece connected to passive binaurals thereby forming a complete stethoscope.

5.2 Functional description

For a functional description see "PMP0748C mmi state event action.vsd" [3].

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5.3 Software Features

A logical block diagram of the system is seen in Figure 2.

(b)(4)Trade Secret Process-Software Design

[redacted]

(b)(4)Trade Secret Process-Software Design [redacted]

The user acts upon the system by pressing the buttons, and the system responds with an acoustic and visual (LCD) feedback. The buttons can be pressed for a short or long time, which is defined in the word list in [1] .
By pressing the power button, when the stethoscope is powered off, it powers up in active mode. If the stethoscope is powered on and the power button is pressed shortly, the backlight is turned on. Pressing and holding the power button turns off the stethoscope.

The active filter can be selected by pressing the filter button and the volume can be regulated up or down using the [+],[-] keys. This can be done in single steps by pressing the volume button shortly, or continuous by pressing and holding down the volume button.

A configuration menu can be called by pressing the "M" button. Using the menu parameters such as default volume and default filter can be changed. For the M3200 the menu will have more items to enable Bluetooth and to make a recording.

A Battery powers the system whose condition must be monitored by the DSP in order to let the user know when it is time to change the battery.

5.4 System limitation

(b)(4)Trade Secret Process-Software Design [redacted].

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5.5 User Characteristics

The user of the E3000 Plus is a medical professional, probably a person already accustomed to a mechanical stethoscope.

5.6 Development Requirements

(b)(4)Trade Secret Process-Software Design [redacted]

6 Specific Requirements

In the following sections a series of requirements are listed, which the M3100 and M3200 stethoscope must respect. This applies both for the architectural and the functional requirements.

The device is controlled through five buttons: a filter button, two volume buttons a menu button and a power on/off button. These buttons makes it possible for the user to control the device. In the requirements below, symbols are used for the different buttons. The symbol for each button is defined in Table 1. The symbols in Table 1 are not guaranteed to be in accordance with design specifications.

Button symbol	Function
	Filter button
	Menu button
	Power on/off button
	Increase volume button
	Decrease volume button

Table 1: Button symbols

6.1 Architecture

6.1.1 Performance Specifications

Number	Requirement	PR:	Implemented in model
SR:001	Requirement removed.	-	
SR:062	Amplification has to be 28dB measured at 100Hz at 25C±5C.	048	M3100 M3200
SR:063	Requirement removed.	-	
SR:064	(b)(4)Trade Secret Process-Software Design [redacted]	[redacted]	[redacted] M3200

6.2 Power Up

Number	Requirement	PR:	Implemented in model
SR:002	The device must power up by pressing the power on/off button ( ), when the device is powered off. There is no time-limit for releasing the button.	026	M3100 M3200
SR:003	The device power up in the filter-mode and volume level stored in non-volatile memory. Factory default will be diaphragm filter and volume level 3 as it is described in [2].	073 074	M3100 M3200
SR:004	The LCD lights up from cold boot within 2 sec. The LCD backlight turns off according to the chosen power profile described in [1] figure 2.	039	M3100 M3200
SR:005	A sound feedback must be given after a cold boot. The sound will be the sound associated with the stored filter (see table 2).	045	M3100 M3200
SR:066	The device must be ready for auscultation within 2 seconds when powering up from power off state.	075	M3100 M3200
SR:046	Stored user settings are loaded at startup. (see [3] on user settings.)	029 073 074 076	M3100 M3200

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6.3 Power Down

Number	Requirement	PR:	Implemented in model
SR:006	The device powers down within 2 seconds, showing the Littmann logo for 1 second ±100ms, after depressing the power on/off button ( ) with a long pressure. (See 4 for more detail on MMI)	040 026	M3100 M3200
SR:007	Not nessacery because of change in SR:006	-	
SR:008	Requirement removed.	-	
SR:009	Automatic power down will occur 30 min after entering stand by mode (timeframe can be varied by user in the configuration menu). (See 4 for more detail on MMI)	070 071	M3100 M3200
SR:010	A sound warning will notify the user of entering stand by mode 10 ± 2 seconds before it happens. (only if auto-off is not used)	047	M3100 M3200

6.4 Filter Mode

Number	Requirement	PR:	Implemented in model
SR:011	When the device is active, it must be possible to change between the Diaphragm and Bell filter by pushing the filter-button ( ). Information about the selected filter will be shown in the display in the form of an icon ( ). The icon changes appearance according to the selected filter.	028 053	M3100 M3200
SR:075	The M3200 will have a 3rd extended diaphragm filter. The filter will be selected in a list, which wraps around by pushing the filter-button.	053	M3200
SR:012	When another filter is selected, a sound feedback must be given to the user to indicate which filter is selected. (See related sounds in Table 2)	045	M3100 M3200
SR:013	A default filter mode can be stored using the configuration menu.	029 118	M3100 M3200

6.4.1 Bell Mode

Number	Requirement	PR:	Implemented in model
SR:014	The Bell filter must the same as implemented in M3000 within (b) , see figure 1	053	M3100 M3200

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6.4.2 3rd Filter Mode

Number	Requirement	PR:	Implemented in model
SR:015	The extended diaphragm filter must overlap the bell and diaphragm filter within [redacted], see figure 1	053	M3200

6.4.3 Diaphragm Mode

Number	Requirement	PR:	Implemented in model
SR:016	The Diaphragm filter must the same as implemented in M3000 within ± [redacted], see figure 1	053	M3100 M3200

(b)(4)Trade Secret

(b)(4)Trade Secret Process-Software Design

[redacted]

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(b)(4)Trade Secret Process-Software Design

(b)(4)Trade Secret Process-Software Design

[redacted]

6.5 Volume Selection

Number	Requirement	PR:	Implemented in model
SR:017	It must be possible to turn the volume up and down with [redacted] and [redacted] respectively. Sound volume level steps up or down in 9 steps equally between level1 and level9 ±1dB. (b)(4)Trade Secret [redacted] and also change the volume indicator in the LCD.	030 031 (b	M3100 M3200
SR:018	If the user holds either the volume up or down button for a long period, the volume is either turned up or down respectably, continuously.	030 031	M3100 M3200
SR:019	If the user tries to change the volume beyond the maximum or minimum sound level, the volume must stay unaffected and a feedback sound is not given to the user.	-	M3100 M3200
SR:020	A default volume level can be stored using the configuration menu. This will store the volume level in non-volatile memory. Next time the device power up, it will start up with this volume level.	128	M3100 M3200
SR:021	Deleted 2-9-2008		
SR:022	Deleted 2-9-2008	-	
SR:025	Removed as it is in SR:017	-	

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6.6 Dot-matrix LCD (Display)

Number	Requirement	PR:	Implemented in model
SR:077	The LCD must be a dot matrix monochrome display with a active area of 14x8mm the resolution is to be 56x32 dots having a dot pitch of 0.25mm.	036	
SR:078	The LCD views must be as defined in ref 3	023 025 043 126 130 131	
SR:023	The LCD backlight has to turn on when the power on/off button ( ) is pressed in normal operation states.	027	M3100 M3200
SR:027	Moved to SR:011	-	

6.7 Auto On/Off

Number	Requirement	PR:	Implemented in model
SR:030	The stethoscope should wake up from sleep mode, when it is triggered by an external trigger (button or sound activity), and then enter active mode. When entering active mode, the pre-emphasis filter circuit is powered up by the Bluecore5.	068 072	M3100 M3200
SR:031	The Auto off function drives the Bluecore5 into sleep mode, when no biometric sounds have has been detected for a period of 10 sec. (or for as long as set in the setup menu).	068	M3100 M3200
SR:032	When going into sleep mode (auto off) the emphasis filter circuitry is powered down.	-	M3100 M3200
SR:082	It must be possible through the menu to disable the auto-off and use time-out configuration	069	M3100 M3200

6.8 Heart Rate Monitor

Number	Requirement	PR:	Implemented in model
SR:033	Removed. Used in SR:034	-	
SR:034	The heat rate is updated every 2 seconds after initial sampling (5 sec.) and the value is shown in the LCD for 10 seconds after loss of heart signal. Se section 6.6 for details on presentation of the heart rate.	044	M3100 M3200
SR:026	The LCD has to give information on the current heart rate, between 30 and 199 beats per minute varying (b), if this information is present. If it is not, the display should show two horizontal bars ( ).	044	M3100 M3200

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6.9 Onboard storage

Number	Requirement	PR:	Implemented in model
SR:079	Using a menu command it must be possible to store a sound track of maximum 29 seconds	129 132	M3200
SR:080	Using a menu command it must be possible to play back the sound track	129 133	M3200
SR:081	The recorded signal is to be stored before filtering is applied	133	M3200
SR:086	The M button stops the recording if pressed during the recording.	137	M3200

(b)(4)Trade Secret Process-Software Design

[redacted]

6.11 Sound feedback

The sound feedbacks mentioned in the requirements in the previous sections, are listed in Table 2.

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Function \ Sound	Power off	Bell	3rd Filter (M3200)	Diaphragm	Vol.	Store Volume & filter	Time warning	Playback
Power on ( )		X*	X*	X*				
Bell mode ( )		X						
3rd Filter (M3200) mode ( )			X					
Diaphragm mode ( )				X				
Volume step (or)					X			
Entering Sleep state**							X	
Playback alert.								X

Table 2: Overview of the feedback sounds given on user interaction

*Sound played depending on stored filter.
**Sound played when using timed off is selected, not when using auto-off.

The following sound feedbacks are made up of musical notes and are defined in notes and approximate frequencies. The duration of the tone is given in fractions of 4 second intervals.

6.11.1 Bell Filter

C6 (~500Hz), 16th-note (250ms).
Rest (0Hz), 16th-note (250ms).
C6 (~500Hz), 16th-note (250ms).

6.11.2 Diaphragm Filter

B6 (~1kHz), 16th-note (250ms).
Rest (0Hz), 16th-note (250ms).
B6 (~1kHz), 16th-note (250ms).

6.11.3 3rd Filter

C6 (~500Hz), 16th-note (250ms).
Rest (0Hz), 16th-note (250ms).
B6 (~1kHz), 16th-note (250ms).

6.11.4 Volume Change

G7 (~1.5kHz), 32nd-note (125ms).

6.11.5 Time Warning (Entering Sleep State)

B6 (~1kHz), 16th-note (250ms).
B7 (~2kHz), 32nd-note (125ms).

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(b)(4)Trade Secret Process-Software Design

6.11.6 Playback

B7 (~2kHz), 64th-note (62.5ms).

Specific requirements for the sound feedback:

Number	Requirement	PR:	Implemented in model
SR:036	The sound feedback given to the user, must comply with Table 2.	045 046 047	M3100 M3200
SR:037	Removed.		
SR:038	Removed.	-	

6.12 Battery Monitor

In this section, it is defined how the battery is monitored.

Number	Requirement	PR:	Implemented in model
SR:039	When "battery low"(level 1) is detected, the user must get a visual feedback (flashing visual indicator). Otherwise the device works normally.	041	M3100 M3200
	When the battery is degrading, this should be visually indicated by the graded battery indicator, which has at least 4 levels.	041	M3100 M3200
	(b)(4)Trade Secret Process-Software Design [redacted]		
SR:041	Deleted 2-9-2008		
SR:042	Deleted 2-9-2008		
SR:044	Deleted 2-9-2008	-	
SR:065	When battery reaches minimum voltage for wireless data transmission an error message has to be sent to the external device.	067	M3100 M3200
SR:024	The LCD has to give information on battery level.	041	M3100 M3200

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6.13 Miscellaneous

6.13.1 Flash and PS – keys

(b)(4)Trade Secret Process-Software Design [redacted], the application and the data used in the application stored as PS-keys (Persistence Storage keys) like volume, filters etc.

Number	Requirement	PR:	Implemented in model
SR:045	Removed.	-	

6.13.2 Button Commands

Number	Requirement	PR:	Implemented in model
SR:047	When a button command is acknowledged by the DSP, all buttons must be released before a new command can be acknowledged. This also applies for illegal button commands.	-	M3100 M3200
SR:048	Combinations of simultaneously pressed buttons are ignored	-	M3100 M3200

6.13.3 Configuration menu

Number	Requirement	PR:	Implemented in model
SR:049	The device will enter the configuration menu when the 'M' button (M) is pressed.	034	M3100 M3200
SR:050	The menu and setting options are shown in [3].	069 070 071 072 076 080	M3100 M3200
SR:060	Deleted 2-9-2008		
SR:061	The configuration menu has to be able to show SW version and identification number.	042	M3100 M3200
SR:076	With the menu active the buttons are reconfigured to navigate in the menu. "+" Scroll upwards in the menu list "-" Scroll downwards in the menu list "M" Select menu item. "Filter" Escape or step one level back in menu		M3100 M3200

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6.13.4 Service counters

Number	Requirement	PR:	Implemented in model
SR:085	Service counters must be implemented to track the use of the stethoscope. A minimum of counters are: - Number of key presses by key - Number of auto on activations - Time in active mode - Time in Bluetooth mode	136	M3100 M3200

7 External interface requirements

7.1 Communication Interface (Bluetooth)

Number	Requirement	PR:	Implemented
(b)(4)Trade Secret Process-Software Design [redacted]			
SR:052	(b)(4)Trade Secret Process-Software Design [redacted]	078	M3200
(b)(4)Trade Secret Process-Software Design [redacted]			
SR:058	Bluetooth connection activates/de-activates using the menu and the device enters Active BT state.	032 068	M3200
SR:059	Bluetooth paring session is enabled through the menu.	033	M3200
SR:067	The Bluetooth link must comply with the protocol specified in ref. [4] and ref. [5].	081 121	M3200
SR:028	Bluetooth logo ( ) flashes when the device has lost its connection.	-	M3200
SR:029	Bluetooth logo ( ) is lit when a connection is established.	-	M3200
SR:070	During pairing with another Bluetooth device, the display shows two Bluetooth icons with an arrow moving between them (see [4] for display information).	043	M3200
SR:071	During playback from a Bluetooth device, if the sound is filtered in the stethoscope, the filter icon is shown and if the sound it not filtered, no filter icon is shown. (See [4] for display graphics)	126	M3200
SR:072	The Bluetooth connection must comply with the [redacted] Bluetooth standard.	077	M3200
SR:073	A notification (tone) must be given every 8 seconds in the binaurals when playback is in progress. (time has to be variable)	125	M3200
SR:074	The transmitted data from channel B has to have an independently program-controlled gain of minimum [redacted]	124	M3200
SR:083	The device must support received data of both : (b)(4)Trade Secret Process-Software Design [redacted]	127	M3200

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SR:084	A recorded sound track can be uploaded to a connected Bluetooth device and a sound track can be downloaded to the stethoscope. [redacted] (b) [redacted]	134	M3200
SR:087	The stethoscope has to be able to be paired with up to 8 Bluetooth devices. This enables the stethoscope to connect to the 8 known devices without pairing again.	139	M3200

(b)(4)Trade Secret Process-Software Design

[redacted]

8 Performance requirements

8.1 User Response Times

Number	Requirement	PR:	Implemented in model
SR:054	Deleted 26-11-2008	-	M3100 M3200
SR:055	At power up, the device must be functional within 2 seconds of the activation.	026	M3100 M3200
SR:056	After a "power down" command is recognized the Littman logo is shown in the LCD, the device must wait at least 500ms before power down, to ensure that the user has released the button.	-	M3100 M3200
SR:057	At power down, the device must indicate full power down within 2 seconds.	040	M3100 M3200

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III. Software Development Environment Description

The Software Development Environment Description for the 3200 stethoscope is attached below.
MBG0807a and MBG0851C are the main documents that cover the Software Quality Plan and Maintenance.
Support references have also been included.

MBG0807a SQA SW Quality Plan.pdf
MBG0851C - SMA SW Maintenance E3000 Plus.pdf

(a) MBG0849A - SVR SW Validation Report.pdf
(b) MBG0808A - STA SW Traceability Analysis E3000 Plus.pdf
(c) MBG0802a - SAS SW Acceptance Test Specification for E3000 Plus.pdf

(b)(4)Trade Secret Process-Software Plan

[redacted]

E3000 Plus
SQA, Software Quality Plan

Version 1.00

File name: MBG0807a SQA SW Quality Plan E3000 Plus

Author

6/3-08 Mikkel Borggaard
Date, Name – Software Designer

Approved by

06.03.2008.
Date, Name – Quality Assurance

(b)(4)Trade Secret Process-Software Plan

[redacted]

(b)(4)Trade Secret Process-Software Plan

Version history

Version	Author	Date	Description	Reviewed by	EC number
0.10	MBG	11. feb 2008	Document created.		
0.20	MBG	04. mar 2008	Review comments added.	PMP,MBG	
1.00	MBG	06. mar 2008	Document ready for signing.		

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(b)(4)Trade Secret Process-Software Plan

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1 Purpose

Software validation is accomplished through a series of different activities and tasks that are planned and executed at various stages of the software development life cycle. This document describes the different tasks that must be performed during development of the E3000 Plus stethoscope software.

The E3000 Plus stethoscope software is developed so it fulfils the requirement for FDA medical devices.

2 References

[1] SSR0808a Risk Management Plan E3100-E3200.doc
[2] cap0741c E3000 Plus Master Project Plan.mpp
[3] PMP0810a RTX Interface Product Requirement.doc
[4] MBG0810a E3000 Plus SW Error Report.xls

3 Life cycle activity

All activities during the life cycle model are described in the "Software method" as a part of the validated Quality system at (b)(4)Trade Secret [redacted]. Please see the description of the software life cycle model in QMS.

The following activities are:

Activities in the developing phases (CC – SC)

Software quality planning, this document
Software requirement specification
Software acceptance test specification
Review of specifications

Activities in the implementation phases (SC – PPC)

Software design
Software design review
Software test plan
Software traceability
Software code guideline description
Software implementation
Software Error Reporting
Software module test
Software acceptance test report
Software validation report

Activities in the realizations phases (PPC - PE)

No activities

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4 Risk Management Plan

The risk associated with the software will be covered by [1].

5 Configuration Management Plan

The E3000 Plus stethoscope software development follows the documented software life cycle model at [redacted], see section 3. Management controls are necessary to ensure positive and correct correspondence among all approved versions of the specification documents, source code, design documents and verification that comprise the software. The management control also ensure accurate identification of, and access to, the currently approved versions of the software.

5.1 Version Control System

Visual Source Safe (VSS) controls management and control of the software platform and all related documents. VSS can maintain multiple versions of a file, including a record of the changes to the file from version to version.

Version control addresses the following areas:

- Team coordination — making sure, by default, that only one person at a time is modifying a file. This prevents files from accidentally being replaced by another user's changes.
- Version tracking — archiving and tracking old versions of source code and other files, which can be retrieved for bug tracking and other purposes.
- Cross-platform development — tracking portability issues involved in maintaining one code base across multiple development platforms.

5.2 Administrator and users

To secure that only the software project team does have the access to the VSS database, VSS must be configured and set-up so the administrator does have the full access to the database and the user does have the right for checking in and out.

VSS administrator:
Mikkel Borggaard, MBG
Per Mølgaard Pedersen, PMP

VSS user:
Bjørn K. Andersen, BUA

5.3 Configuration

The system configuration is described in the following sections.

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5.3.1 Directory structure

This chapter describe the different directories in VSS and the related files.
Figure 1 illustrates the VSS directory structure of the Code folder.

(b)(4)Trade Secret Process-Software Plan

[redacted]

5.3.2 NOTES archive

All documents according the QMS requirement for archive, are archived in the Notes database "IAD0007"

6 Software Verification and Validation Plan

Verification and validation of the E3000 Plus stethoscope software is performed during software test. All verification and validations task is documented in the final validation report.

6.1 Verification and Validation Tasks, and Acceptance Criteria

All acceptance criteria are specified in each test specification. About review please see the description of executing review in the quality system, QMS.

(b)(4)Trade Secret Process-Software

6.2 Schedule and Resource Allocating

(b)(4)Trade Secret Process-Software Plan

[redacted]

6.3 Reporting Requirement

The software design will be verified in at verification document and the results of acceptance tests will be given in a report.

6.4 Review Activities

The followings review activities are performed during the E3000 Plus software development.

Review of the E3000 Plus SRS SW Requirement Specification
Review of the E3000 Plus SAS SW Acceptance test Specification
Review of the E3000 Plus SW Design

7 SW Error Reporting

During the developing phase and the implementations phase, all errors and problems are reported in the error report for the software development, [4].

8 Other Support Activities

According to the FDA Guidance of software validation, any "off the shelf" (OTS) software used in the developed device software has to be validated. (b)(4)Trade Secret Process-Software [redacted]. The validation is mainly based upon the software test results, which are acceptance- and module-tests made to verify the stethoscope requirements, but any known tool anomalies are also validated.

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(b)(4)Trade Secret Process-Product Specs

[redacted]

E3000 Plus
SMA SW Maintenance

Version 1.00

File name: MGB0851C - SMA SW Maintenance E3000 Plus.doc

Author

5/1-09 Mikkel Borgquist
Date, Name – Software Designer

QM500398, Version 2.00

(b)(4)Trade Secret Process-Product Specs

[redacted]

(b)(4)Trade Secret Process-Product Specs

Version history

Version	Author	Date	Description	Reviewed by	EC number
1.00	MBG	05. jan. 2009	Document created.		

QMS00396, Version 2.00

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(b)(4)Trade Secret Process-Product Specs

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(b)(4)Trade Secret Process-Product Specs

1 Purpose

This document is a guide and activity list for making changes in the E3000 Plus software. Making new variants is also covered by this guide.
This guide keeps information about how to make a new version of the software, and where to find relevant information for making an update of the software. The guide should ensure that relevant documents are updated.

2 Scope

This document covers the (b)(4)Trade Secret Process-Product for the E3000 Plus stethoscope. A general description of the E3000 Plus document/QMS requirements is located in [2].

3 References

[1] SSR0850A Risk Assesment Report E3000+
[2] MBG0807A SQA SW Quality Plan E3000 Plus
[3] MBG0849A – SVR SW Validation Report
[4] MBG0902A – SW Build and Programming Guide E3000 Plus
[5] MBG0837A – SW Release Description E3000 Plus
[6] MBG0809A – STA SW Traceability Analysis E3000 Plus
[7] MBG0851B Software Description
[8] MBG0851A – SW Architecture Design Chart E3000 Plus
[9] MBG0814A – SCG SW Code Guideline E3000 Plus
[10] MBG0802A – SAS SW Acceptance Test Specification for E3000 Plus
[11] MBG0810a E3000 Plus Error Report

4 Handling Changes

Changes in the device software are controlled by QMS's ECR/ECO/ECN.
In addition to this procedure, the following activities must be carried out:

- If the change is caused by an error the error database [11] must be updated, with new errors and changes, as well as the solved problems.
- If code is changed or added, updating design documentation [7] and [8] must be considered.
- If code is changed or added, it should be considered to carry out a code review/inspection.
- If functions has been altered or added, it must be considered to update risk assessment [1].
- If changes causes add-on cases in module tests, risk analysis or SW specification the traceability document [6] must be updated.

5 Handling New Variants

If a new variant is required it should normally be handled as a change.

6 Building software

A description of how the software should be build is located in [4].
How to install and configure the software development tool is also described in [4].

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(b)(4)Trade Secret Process-Product Specs

7 Verification and validation

7.1 Change verification

All change in the code must be verified with tests that verify the correctness of the added or changed code. It must be aimed at covering all code and all branches.
The tests named above are component tests and an integration test. These tests can be done on PCB, or emulator.

A test must also verify that code functions around the change are unaltered. This is done by performing the SW acceptance test [10] on a fully functional E3000.

The standard procedure when the SW is released for production is to make a verification of the added/changed code.

7.2 Software Functionality Validation

The validation [3] must be updated so that it sum up on the latest activities/tests made on the final device.
The release document [5] must be updated, with change/functionality description.

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(b) (4)

[redacted]

E3000 Plus
SVR SW Validation Report

Version 7.00

File name: MBG0849A - SVR SW Validation Report.docx

Author

30-4-2009
Date, Name – Software Designer

Approved by

30-04-2009
Date, Name – Quality Assurance

(b) (4)

[redacted]

(b) (4) [redacted]

Version history

Version	Author	Date	Description	Reviewed by	EC number
0.01	MBG	05-12-2008	Document created		
1.00	MBG	17. dec 2008	Document ready for signing.	TRH	
2.00	MBG	11. jan 2009	Section "Additional Remarks" has been added for the filter update of Bell, Diap, ext.		2009-002
3.00	PMP	06-02-2009	Bell filter and PB timer update		2009-026
4.00	PMP	06-03-2009	SW bug fixes: Correct standby timer values, and Stream buffer control limit reset at connect.		2009 - 062
5.00	PMP	03-04-2009	Remove Bluetooth enable in M3100		2009-158
6.00	PMP	17-04-2009	Cgange power and backlight default setting		2009-196
7.00	PMP	30-04-2009	2Mbit memory, M3200 sw		2009-210

(b) (4) [redacted]

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(b) (4) [redacted]

1 Purpose

The purpose with this document is to summarise the result from the different activities during the development of the software and then recommend the release of the software.

2 Scope

This validation report covers the software for the Littmann M3100 and M3200.

3 References

[1] CAP0803a E3000 plus Product Requirement
[2] MBG0808A – STP SW test plan E3000 Plus
[3] MBG0849C - E3000 Plus Module Test Report
[4] PMP0851B E3000 Plus Integration test report
[5] MBG0849B - SAR SW Acceptance Test Specification Report
[6] PMP0842C MMI acceptance test verification report
[7] PMP0851A SPP Communication SW acceptance test report

4 Test result

Test ID	Test area	Test result	Remark
[Ref. No]	[Name]	Passed / failed	
8.1	**Module test**	**Passed**	Four minor observations.
	App_timer.asm	Passed	
	switch.asm	Passed	
	keyboard_driver.asm	Passed	
	queue.asm	Passed	
	event_queue.asm	Passed	
	audio_modding.asm	Passed	
	stand_by.asm	Passed	
	Online_pskey.asm	Passed	
	vm_interface.asm	Passed	
	heart_rate.asm	Passed	
	spp_command_handler.asm	Passed	
	spp_communication.asm	Passed	
	scheduler.asm	Passed	
	main_kalimba.asm	Passed	
	lcd_device_driver.asm	Passed	
	Lcd_if_driver.asm	Passed	
	utilities.asm	Passed	
	control_output.asm	Passed	
	Error_information.asm	Passed	
	lcd_icons.asm	Passed	
	menu.asm	Passed	

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(b) (4) [redacted]

Test ID	Test area	Test result	Remark
	CONT_MMI.ASM	Passed	
	Recorder.asm	Passed	
	Flash_handler.asm	Passed	
	service.asm	Passed	
	audio_handler.asm	Passed	
	buffer_handling.asm	Passed	
	crc16.asm	Passed	
	event_processing.asm	Passed	
	test_data.asm	Passed	
	uart_logging.asm	Passed	
	Spi_drv.asm	Passed	
	Main.c	Passed	
	RTX_kalimba.c	Passed	
	RTX_battery.c	Passed	
	RTX_display.c	Passed	
	RTX_tones.c	Passed	
8.2	**Integration test**	Passed	
8.3	**SW Acceptance test**	Passed	
	Mmi acceptance test	Passed	
	Spp communication acceptance test	Passed	

5 Discussion of test results

With the exception of the observations discussed below, all devices passed the tests without any remarks.

5.1 Module Test

4 minor observations regarding:

- Live_lock
- Service_counter
- Peak_Location
- Deviation

None of the errors has performance or visible effect for the user. The errors will be corrected if the modules are opened again.

5.2 SW Acceptance test

Version 1.90.00 have a error. The stethoscope always play diaphragm signal at power on. This is changed for the next version (2.00.00), so correct filter signal is played at power on.

6 Additional Remarks

none

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(b) (4) [redacted]

7 Conclusion

Base on test result and discussion above it is the overall conclusion that the E3000 Plus stethoscope software has been developed and tested as specified in the Software test plan ref [2] and found in accordance with Software elements of the overall device requirement specification ref [1].

The software version 1.90.00 can be released for CVE.

The identified sw error has no performance consequences and will be corrected in final release 2.00

SC3

(b) (4)

[redacted]

E3000 Plus
STA, Software Traceability Analysis

Version 1.00

File name: MBG0809A - STA SW Traceability Analysis E3000 Plus.doc

Author	Approved by
12/12-08 Mikkel Bergquist	12/12-08 [illegible]
Date, Name – Software Designer	Date, Name – Quality Assurance

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(b) (4)

[redacted]

(b) (4) [redacted]

Version history

Version	Author	Date	Description	Reviewed by	EC number
0.01	MBG	16. May 2008	Frist draft.		
0.02	MBG	14. Nov 2008	SR and PR switched places in the table in section 4.		
0.03	MBG	27. Nov 2008	Accept tests added.		
0.04	MBG	28. nov 2008	AT:014 replaced by MAX:001. AT:031 replaced by FREQ:001 and FREQ:003.		
1.00	MBG	11. dec 2008	SW test, implementation, and design added to the table.		

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(b) (4) [redacted]

1 Purpose

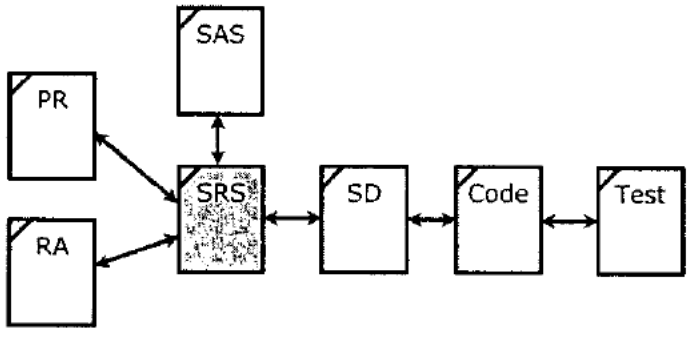
The purpose with the traceability analysis is to document the links between all requirements to the final test of the software. This will show the link between the different documents in the software development process.

2 References

[1] cap0803a - E3000 Plus Product requirements
[2] MBG0751C - SRS SW Requirement Specification for E3000 Plus
[3] MBG0802a - SAS SW Acceptance Test Specification for E3000 Plus

3 Reading guidance

The traceability analysis is split up in several parts. Each part represents a sub section of the software requirement specification and how it is linked to all the other documents.



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[redacted] (b) (4)

4 Traceability Matrices

There are 3 Acceptance test protocols. AT:nnn is in MBG0802a - SAS SW Acceptance Test Specification for E3000 Plus.doc, and FREQ:nnn is in AMI0821H Design verification protocol – Frequency response and gain.doc, and MAX:nnn is in AMI0821f – Design Verification Protocol – maximum acoustic output.doc.

Product requirement	SW requirement specification	Risk analysis SSR0808b Risk assessment Component Design E3000 plus.fmea	SW design E3000PLc.bcp (main design) The interaction between modules is shown in the main design.	SW impl.	SW test	SW Acceptance Test	Comments
PR:026	SR:002	26.6.1.1.1 26.6.2.1.1	PMP0819A keyboard_scan_design.vsd	Keyboard_driver.asm	EXTKLU0834c- Keyboard-driver modul test spec.doc	AT:001A AT:001B	
PR:073	SR:003		PMP0748C mmi state event action.vsd	Online_pskey.asm	EXTKLU0837c- Online-pskey modul test spec.doc	AT:002B AT:002D AT:002F	
PR:073	SR:003		PMP0748C mmi state event action.vsd	Online_pskey.asm	EXTKLU0837c- Online-pskey modul test spec.doc	AT:022	
PR:074	SR:003		PMP0748C mmi state event action.vsd	Online_pskey.asm	EXTKLU0837c- Online-pskey modul test spec.doc	AT:002B AT:002D AT:002F	
PR:074	SR:003		PMP0748C mmi state event action.vsd	Online_pskey.asm	EXTKLU0837c- Online-pskey modul test spec.doc	AT:022	
PR:039	SR:004		PMP0748C mmi state event action.vsd	Scheduler.asm Menu.asm	PMP0838A Menu module test specification.doc	AT:001C AT:004	
PR:045	SR:005		PMP0810A RTX Interface Product Requirement Specification.doc	RTX_tones.c	EXTMIV0838C Stream and CODEC module test specification.doc	AT:002A AT:002C AT:002E	
PR:026	SR:006	26.6.1.1.1 26.6.2.1.1	PMP0819A keyboard_scan_design.vsd	Keyboard_driver.asm	EXTKLU0834c- Keyboard-driver modul test spec.doc	AT:003	
PR:040	SR:006			LCD_driver.asm	No test	AT:003	
PR:070	SR:009			Scheduler.asm	No test	AT:004	
PR:071	SR:009			App_timer.asm	EXTKLU0832d- App-	AT:004	

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Product requirement	SW requirement specification	Risk analysis SSR0808b Risk assessment Component Design E3000 plus.fmea	SW design E3000PLc.bcp (main design) The interaction between modules is shown in the main design.	SW impl.	SW test	SW Acceptance Test	Comments
					timer modul test spec.doc		
PR:047	SR:010		PMP0810A RTX Interface Product Requirement Specification.doc	App_timer.asm RTX_tones.c	EXTKLU0832d- App-timer modul test spec.doc EXTMIV0838C Stream and CODEC module test specification.doc	AT:004	
PR:028	SR:011	26.6.1.1.1 26.6.2.1.1	PMP0819A keyboard_scan_design.vsd	LCD_driver.asm LCD_icons.asm LCD_if_driver.asm Keyboard_driver.asm	EXTKLU0834c-Keyboard-driver modul test spec.doc	AT:005	
PR:053	SR:011	26.1.3.1.1 26.1.4.1.1	MBG0751B Signal Path.vsd	Audio_modding.asm	EXTKLU0835d – Audio modding module test.doc	AT:005	
PR:045	SR:012	26.1.3.1.1 26.1.4.1.1	MBG0751B Signal Path.vsd PMP0810A RTX Interface Product Requirement Specification.doc	Audio_modding.asm RTX_tones.c	EXTKLU0835d – Audio modding module test.doc EXTMIV0838C Stream and CODEC module test specification.doc	AT:005	
PR:029	SR:013		PMP0748C mmi state event action.vsd	Menu.asm Online_pskey.asm	PMP0838A Menu module test specification.doc EXTKLU0837c- Online-pskey modul test spec.doc	AT:006	
PR:118	SR:013		PMP0748C mmi state event action.vsd	Menu.asm Online_pskey.asm	PMP0838A Menu module test specification.doc EXTKLU0837c- Online-pskey modul test spec.doc	AT:006	
PR:053	SR:014	26.1.3.1.1 26.1.4.1.1	MBG0751B Signal Path.vsd	Audio_modding.asm Buffer_handling.asm	EXTKLU0835d – Audio modding module test.doc	AT:009	
PR:053	SR:015	26.1.3.1.1 26.1.4.1.1	MBG0751B Signal Path.vsd	Audio_modding.asm Buffer_handling.asm	EXTKLU0835d – Audio modding module test.doc	AT:009	
PR:053	SR:016	26.1.3.1.1 26.1.4.1.1	MBG0751B Signal Path.vsd	Audio_modding.asm Buffer_handling.asm	EXTKLU0835d – Audio modding module test.doc	AT:009	
PR:030	SR:017	26.1.3.1.1 26.1.4.1.1	MBG0751B Signal Path.vsd PMP0819A keyboard_scan_design.vsd PMP0810A RTX Interface Product	Audio_modding.asm LCD_driver.asm LCD_icons.asm LCD_if_driver.asm	EXTKLU0835d – Audio modding module test.doc EXTKLU0834c-	AT:010	

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Product requirement	SW requirement specification	Risk analysis SSR0808b Risk assessment Component Design E3000 plus.fmea	SW design E3000PLc.bcp (main design) The interaction between modules is shown in the main design.	SW impl.	SW test	SW Acceptance Test	Comments
			Requirement Specification.doc	Keyboard_driver.asm RTX_tones.c	Keyboard-driver modul test spec.doc EXTMIV0838C Stream and CODEC module test specification.doc		
PR:031	SR:017	26.1.3.1.1 26.1.4.1.1 26.6.1.1.1 26.6.2.1.1	MBG0751B Signal Path.vsd PMP0819A keyboard_scan_design.vsd PMP0810A RTX Interface Product Requirement Specification.doc	Audio_modding.asm LCD_driver.asm LCD_icons.asm LCD_if_driver.asm Keyboard_driver.asm RTX_tones.c	EXTKLU0835d - Audio modding module test.doc EXTKLU0834c-Keyboard-driver modul test spec.doc EXTMIV0838C Stream and CODEC module test specification.doc	AT:010	
PR:051	SR:017	26.1.3.1.1 26.1.4.1.1 26.6.1.1.1 26.6.2.1.1	MBG0751B Signal Path.vsd PMP0819A keyboard_scan_design.vsd PMP0810A RTX Interface Product Requirement Specification.doc	Audio_modding.asm LCD_driver.asm LCD_icons.asm LCD_if_driver.asm Keyboard_driver.asm RTX_tones.c	EXTKLU0835d - Audio modding module test.doc EXTKLU0834c-Keyboard-driver modul test spec.doc EXTMIV0838C Stream and CODEC module test specification.doc	AT:010 FREQ:003	Tested in both HW and SW
PR:030	SR:018	26.1.3.1.1 26.1.4.1.1 26.6.1.1.1 26.6.2.1.1	MBG0751B Signal Path.vsd PMP0819A keyboard_scan_design.vsd	Audio_modding.asm LCD_driver.asm LCD_icons.asm LCD_if_driver.asm Keyboard_driver.asm	EXTKLU0835d - Audio modding module test.doc EXTKLU0834c-Keyboard-driver modul test spec.doc	AT:010	
PR:031	SR:018	26.1.3.1.1 26.1.4.1.1 26.6.1.1.1 26.6.2.1.1	MBG0751B Signal Path.vsd PMP0819A keyboard_scan_design.vsd	Audio_modding.asm LCD_driver.asm LCD_icons.asm LCD_if_driver.asm Keyboard_driver.asm	EXTKLU0835d - Audio modding module test.doc EXTKLU0834c-Keyboard-driver modul test spec.doc	AT:010	
None	SR:019	26.1.3.1.1 26.1.4.1.1	MBG0751B Signal Path.vsd	Audio_modding.asm	EXTKLU0835d - Audio modding module test.doc	AT:010	
PR:128	SR:020		PMP0748C mmi state event action.vsd	Menu.asm Online_pskey.asm	PMP0838A Menu module test specification.doc EXTKLU0837c- Online-pskey modul test spec.doc	AT:011	

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Product requirement	SW requirement specification	Risk analysis SSR0808b Risk assessment Component Design E3000 plus.fmea	SW design E3000PLc.bcp (main design) The interaction between modules is shown in the main design.	SW impl.	SW test	SW Acceptance Test	Comments
PR:027	SR:023	26.6.1.1.1 26.6.2.1.1	PMP0819A keyboard_scan_design.vsd	Keyboard_driver.asm CONT_MMI.ASM control_output.asm	EXTKLU0834c- Keyboard-driver modul test spec.doc	AT:026	
PR:041	SR:024		PMP0804A Keypad and display layout.vsd	RTX_battery.c vm_interface.asm lcd_icons.asm	EXTMIV0839A Miscellaneous module test specification_27Nov08.doc EXTMIV0838B Miscellaneous module test specification.doc	AT:016	
PR:044	SR:026	26.1.2.1.1	PMP0804A Keypad and display layout.vsd	Heart_rate.asm LCD_driver.asm LCD_if_driver.asm	EXTKLU0839b- Heart Rate modul test spec.doc	AT:013 AT:032	
None	SR:028		PMP0804A Keypad and display layout.vsd	LCD_driver.asm LCD_icons.asm LCD_if_driver.asm spp_command_handler.asm	No test	AT:028	
None	SR:029		PMP0804A Keypad and display layout.vsd	LCD_driver.asm LCD_icons.asm LCD_if_driver.asm spp_command_handler.asm	No test	AT:027 AT:028	
PR:068	SR:030	26.6.1.1.1 26.6.2.1.1 26.7.1.1.1	PMP0819A keyboard_scan_design.vsd	Keyboard_driver.asm stand_by.asm	EXTKLU0834c- Keyboard-driver modul test spec.doc EXTKLU0836b- Standby modul test spec.doc	AT:012	
PR:072	SR:030	26.6.1.1.1 26.6.2.1.1 26.7.1.1.1	PMP0819A keyboard_scan_design.vsd	Keyboard_driver.asm stand_by.asm	EXTKLU0834c- Keyboard-driver modul test spec.doc EXTKLU0836b- Standby modul test spec.doc	AT:012	
PR:068	SR:031	26.1.3.1.1 26.1.4.1.1 26.7.1.1.1	MBG0751B Signal Path.vsd	Audio_modding.asm stand_by.asm	EXTKLU0835d – Audio modding module test.doc EXTKLU0836b- Standby modul test spec.doc	AT:012	
None	SR:032	26.1.3.1.1 26.1.4.1.1 26.7.1.1.1	MBG0751B Signal Path.vsd	Audio_modding.asm stand_by.asm	EXTKLU0835d – Audio modding module test.doc EXTKLU0836b- Standby modul test spec.doc	AT:012	
PR:044	SR:034	26.1.2.1.1		Heart_rate.asm	EXTKLU0839b- Heart Rate modul test	AT:013	

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Product requirement	SW requirement specification	Risk analysis SSR0808b Risk assessment Component Design E3000 plus.fmea	SW design E3000PLc.bcp (main design) The interaction between modules is shown in the main design.	SW impl.	SW test	SW Acceptance Test	Comments
					spec.doc		
PR:050	SR:035	26.1.3.1.1 26.1.4.1.1	MBG0751B Signal Path.vsd	Audio_modding.asm	EXTKLU0835d – Audio modding module test.doc	MAX:001	
PR:045	SR:036			RTX_tones.c vm_interface.asm	EXTMIV0838C Stream and CODEC module test specification.doc EXTKLU0839b-vm_interface modul test spec.doc	AT:004 AT:005 AT:010	
PR:046	SR:036			RTX_tones.c vm_interface.asm	EXTMIV0838C Stream and CODEC module test specification.doc EXTKLU0839b-vm_interface modul test spec.doc	AT:004 AT:005 AT:010	
PR:047	SR:036			RTX_tones.c vm_interface.asm	EXTMIV0838C Stream and CODEC module test specification.doc EXTKLU0839b-vm_interface modul test spec.doc	AT:004 AT:005 AT:010	
PR:041	SR:039		PMP0804A Keypad and display layout.vsd	LCD_driver.asm LCD_icons.asm LCD_if_driver.asm	No test	AT:016	
PR:041	SR:040		PMP0804A Keypad and display layout.vsd	LCD_driver.asm LCD_icons.asm LCD_if_driver.asm	No test	AT:016	
PR:029	SR:046			online_pskey.asm	EXTKLU0837c- Online-pskey modul test spec.doc	AT:041	
PR:076	SR:046			online_pskey.asm	EXTKLU0837c- Online-pskey modul test spec.doc	AT:041	
None	SR:047	26.6.1.1.1 26.6.2.1.1		Keyboard_driver.asm	EXTKLU0834c-Keyboard-driver modul test spec.doc	AT:017D	
None	SR:048	26.6.1.1.1 26.6.2.1.1		Keyboard_driver.asm	EXTKLU0834c-Keyboard-driver modul test spec.doc	AT:017A AT:017B AT:017C AT:017D	

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[redacted] (b) (4)

Product requirement	SW requirement specification	Risk analysis SSR0808b Risk assessment Component Design E3000 plus.fmea	SW design E3000PLc.bcp (main design) The interaction between modules is shown in the main design.	SW impl.	SW test	SW Acceptance Test	Comments
PR:034	SR:049	26.6.1.1.1 26.6.2.1.1		Keyboard_driver.asm Menu.asm	EXTKLU0834c-Keyboard-driver modul test spec.doc	AT:018A AT:018B	
PR:069	SR:050		PMP0748C mmi state event action.vsd	Menu.asm CONT_MMI.ASM	PMP0838A Menu module test specification.doc	AT:018All AT:019A AT:019B AT:020All	
PR:070	SR:050		PMP0748C mmi state event action.vsd	Menu.asm CONT_MMI.ASM	PMP0838A Menu module test specification.doc	AT:018All AT:019A AT:019B AT:020All	
PR:071	SR:050		PMP0748C mmi state event action.vsd	Menu.asm CONT_MMI.ASM	PMP0838A Menu module test specification.doc	AT:018All AT:018G AT:019A AT:019B AT:020All	
PR:072	SR:050		PMP0748C mmi state event action.vsd	Menu.asm CONT_MMI.ASM	PMP0838A Menu module test specification.doc	AT:018All AT:019A AT:019B AT:020All	
PR:076	SR:050		PMP0748C mmi state event action.vsd	Menu.asm CONT_MMI.ASM	PMP0838A Menu module test specification.doc	AT:018All AT:019A AT:019B AT:020All	
PR:080	SR:050		PMP0748C mmi state event action.vsd	Menu.asm CONT_MMI.ASM	PMP0838A Menu module test specification.doc	AT:018All AT:019A AT:019B AT:020All	
PR:079	SR:051	26.10.1.1.1	PMP0845 Signal path interface.vsd	spp_command_handler.asm spp_communication.asm control_output.asm switch.asm	EXTKLU0845b-Spp communication modul test spec.doc EXTKLU0833c- Switch modul test spec.doc	SPP:030	Bluetooth accepttest (PMP)

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Product requirement	SW requirement specification	Risk analysis SSR0808b Risk assessment Component Design E3000 plus.fmea	SW design E3000PLc.bcp (main design) The interaction between modules is shown in the main design.	SW impl.	SW test	SW Acceptance Test	Comments
PR:078	SR:052	26.10.1.1.1	PMP0845 Signal path interface.vsd	spp_command_handler.asm spp_communication.asm control_output.asm switch.asm crc16.asm	EXTKLU0845b-Spp communication modul test spec.doc EXTKLU0833c- Switch modul test spec.doc	SPP:033	Bluetooth accepttest (PMP)
None	SR:053	26.10.1.1.1	PMP0845 Signal path interface.vsd	spp_command_handler.asm spp_communication.asm control_output.asm switch.asm	EXTKLU0845b-Spp communication modul test spec.doc EXTKLU0833c- Switch modul test spec.doc	SPP:032	Bluetooth accepttest (PMP)
PR:026	SR:055		PMP0810A RTX Interface Product Requirement Specification.doc	Main_kalimba.asm Main.c RTX_kalimba.c	EXTMIV0839A Miscellaneous module test specification_27Nov08.doc EXTMIV0838A General module test specification.doc EXTMIV0838B Miscellaneous module test specification.doc EXTMIV0838C Stream and CODEC module test specification.doc EXTMIV0838D Pairing and connect module test specification.doc	AT:001D	
None	SR:056	26.6.1.1.1 26.6.2.1.1		Keyboard_driver.asm LCD_driver.asm LCD_Icons.asm LCD_lf_driver.asm Aap_timer.asm	EXTKLU0834c-Keyboard-driver modul test spec.doc	AT:003	Logo at power-down
PR:040	SR:057	26.6.1.1.1 26.6.2.1.1		Keyboard_driver.asm Aap_timer.asm	EXTKLU0834c-Keyboard-driver modul test spec.doc EXTKLU0832d- App-timer modul test spec.doc	AT:003	
PR:032	SR:058	26.10.1.1.1	PMP0748C mmi state event action.vsd	Menu.asm spp_command_handler.asm	PMP0838A Menu module test specification.doc	AT:028	Bluetooth
PR:068	SR:058	26.10.1.1.1	PMP0748C mmi state event action.vsd	Menu.asm spp_command_handler.asm	PMP0838A Menu module test specification.doc	AT:028	Bluetooth

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Product requirement	SW requirement specification	Risk analysis SSR0808b Risk assessment Component Design E3000 plus.fmea	SW design E3000PLc.bcp (main design) The interaction between modules is shown in the main design.	SW impl.	SW test	SW Acceptance Test	Comments
PR:033	SR:059	26.10.1.1.1	PMP0748C mmi state event action.vsd	Menu.asm	PMP0838A Menu module test specification.doc	AT:027	Bluetooth
PR:042	SR:061		PMP0748C mmi state event action.vsd PMP0827A ID number format for E3000 Plus stethoscope.doc	Menu.asm Online_pskey.asm	PMP0838A Menu module test specification.doc EXTKLU0837c- Online-pskey modul test spec.doc	AT:020	
PR:048	SR:062	26.1.3.1.1 26.1.4.1.1	MBG0751B Signal Path.vsd PMP0845 Signal path interface.vsd	Audio_modding.asm	EXTKLU0835d - Audio modding module test.doc	FREQ:003	Amp. 28dB 100Hz at 25 deg. C +-5
PR:052	SR:064	26.1.3.1.1 26.1.4.1.1	MBG0751B Signal Path.vsd PMP0845 Signal path interface.vsd	Audio_modding.asm	EXTKLU0835d - Audio modding module test.doc	FREQ:001	Lowest vol. Level. Cardiology III
PR:067	SR:065			spp_command_handler.asm error_information.asm	No test	AT:035 SPP:051	Low batt. Send message to ext. Device
PR:075	SR:066		PMP0810A RTX Interface Product Requirement Specification.doc	App_timer.asm Main.c RTX_kalimba.c	EXTKLU0832d- App-timer modul test spec.doc EXTMIV0839A Miscellaneous module test specification_27Nov08.doc EXTMIV0838A General module test specification.doc EXTMIV0838B Miscellaneous module test specification.doc EXTMIV0838C Stream and CODEC module test specification.doc EXTMIV0838D Pairing and connect module test specification.doc	AT:001D	
PR:081	SR:067	26.10.1.1.1		spp_communication.asm spp_command_handler.asm queue.asm	EXTKLU0845b-Spp communication modul test spec.doc EXTKLU0833d- Queue	-	SPP Command SW Acceptance Test.

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Product requirement	SW requirement specification	Risk analysis SSR0808b Risk assessment Component Design E3000 plus.fmea	SW design E3000PLc.bcp (main design) The interaction between modules is shown in the main design.	SW impl.	SW test	SW Acceptance Test	Comments
					modul test spec.doc		
PR:121	SR:067	26.10.1.1.1		spp_communication.asm spp_command_handler.asm queue.asm	EXTKLU0845b-Spp communication modul test spec.doc EXTKLU0833d- Queue modul test spec.doc	-	SPP Command SW Acceptance Test.
PR:120	SR:068	26.9.1.1.1 26.9.2.1.1		spi_drv.asm	EXTKLU0850b - spi-drv modul test spec.doc	AT:037	Re-program via SPI
PR:004	SR:069			Online_pskey.asm	EXTKLU0837c- Online-pskey modul test spec.doc	AT:037	Sw ver. ID nr. store in memory.
PR:043	SR:070		PMP0804A Keypad and display layout.vsd	LCD_driver.asm LCD_icons.asm LCD_if_driver.asm	No test	AT:027	Pairing shown in LCD.
PR:126	SR:071		PMP0804A Keypad and display layout.vsd	LCD_driver.asm LCD_icons.asm LCD_if_driver.asm	No test	AT:039	Playback filter or no filter
PR:077	SR:072	26.10.1.1.1		spp_command_handler.asm spp_communication.asm queue.asm	EXTKLU0845b-Spp communication modul test spec.doc EXTKLU0833d- Queue modul test spec.doc	-	External Bluetooth compliance test
PR:077	SR:072	26.10.1.1.1		spp_command_handler.asm spp_communication.asm queue.asm	EXTKLU0845b-Spp communication modul test spec.doc EXTKLU0833d- Queue modul test spec.doc	AT:042	BT range test.
PR:125	SR:073	26.10.1.1.1	PMP0810A RTX Interface Product Requirement Specification.doc	RTX_tones.c spp_command_handler.asm flash_handler.asm	EXTMIV0838C Stream and CODEC module test specification.doc	AT:040	Playback warning.
PR:124	SR:074	26.10.1.1.1	PMP0810A RTX Interface Product Requirement Specification.doc	Main.c RTX_kalimba.c Online_pskey.asm	EXTMIV0839A Miscellaneous module test specification_27Nov08.doc EXTMIV0838A General module test specification.doc EXTMIV0838B Miscellaneous module test specification.doc EXTMIV0838C Stream and CODEC module test	AT:030 SPP:036	B channel has independant gain.

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Product requirement	SW requirement specification	Risk analysis SSR0808b Risk assessment Component Design E3000 plus.fmea	SW design E3000PLc.bcp (main design) The interaction between modules is shown in the main design.	SW impl.	SW test	SW Acceptance Test	Comments
					specification.doc EXTMIV0838D Pairing and connect module test specification.doc EXTKLU0837c- Online-pskey modul test spec.doc		
PR:053	SR:075	26.1.3.1.1 26.1.4.1.1	PMP0748C mmi state event action.vsd MBG0751B Signal Path.vsd PMP0845 Signal path interface.vsd	Menu.asm Audio_modding.asm	PMP0838A Menu module test specification.doc EXTKLU0835d – Audio modding module test.doc	AT:008	
None	SR:076	26.6.1.1.1 26.6.2.1.1	PMP0748C mmi state event action.vsd	Menu.asm Keyboard_driver.asm	PMP0838A Menu module test specification.doc EXTKLU0834c-Keyboard-driver modul test spec.doc	AT:020	
PR:036	SR:077			LCD_driver.asm	No test	AT:024	
PR:023	SR:078		PMP0804A Keypad and display layout.vsd	LCD_icons.asm	No test	None (was AT:025)	Tested in THR0839C
PR:025	SR:078		PMP0804A Keypad and display layout.vsd	LCD_icons.asm	No test	AT:025	
PR:043	SR:078		PMP0804A Keypad and display layout.vsd	LCD_icons.asm	No test	AT:027	
PR:126	SR:078		PMP0804A Keypad and display layout.vsd	LCD_icons.asm	No test	AT:025	
PR:130	SR:078		PMP0804A Keypad and display layout.vsd	LCD_icons.asm	No test	AT:025	
PR:131	SR:078		PMP0804A Keypad and display layout.vsd	LCD_icons.asm	No test	AT:025	
PR:129	SR:079	26.9.1.1.1 26.9.2.1.1	PMP0748C mmi state event action.vsd PMP0845 Signal path interface.vsd	Menu.asm Recorder.asm Spi_drv.asm Flash_handler.asm	PMP0838A Menu module test specification.doc EXTKLU0848b- Recorder modul test spec.doc EXTKLU0850b - spi-drv modul test spec.doc	AT:033	
PR:132	SR:079	26.9.1.1.1 26.9.2.1.1	PMP0748C mmi state event action.vsd PMP0845 Signal path interface.vsd	Menu.asm Recorder.asm Spi_drv.asm Flash_handler.asm	PMP0838A Menu module test specification.doc EXTKLU0848b- Recorder modul test spec.doc EXTKLU0850b - spi-drv modul test spec.doc	AT:033	

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Product requirement	SW requirement specification	Risk analysis SSR0808b Risk assessment Component Design E3000 plus.fmea	SW design E3000PLc.bcp (main design) The interaction between modules is shown in the main design.	SW impl.	SW test	SW Acceptance Test	Comments
PR:129	SR:080	26.9.1.1.1 26.9.2.1.1	PMP0748C mmi state event action.vsd PMP0845 Signal path interface.vsd	Menu.asm Recorder.asm Spi_drv.asm Flash_handler.asm	PMP0838A Menu module test specification.doc EXTKLU0848b- Recorder modul test spec.doc EXTKLU0850b - spi-drv modul test spec.doc	AT:033	
PR:133	SR:080	26.9.1.1.1 26.9.2.1.1	PMP0748C mmi state event action.vsd PMP0845 Signal path interface.vsd	Menu.asm Recorder.asm Spi_drv.asm Flash_handler.asm	PMP0838A Menu module test specification.doc EXTKLU0848b- Recorder modul test spec.doc EXTKLU0850b - spi-drv modul test spec.doc	AT:033	
PR:133	SR:081		MBG0751B Signal Path.vsd	Audio_handler.asm	No test	AT:034	
PR:069	SR:082	26.7.1.1.1	PMP0748C mmi state event action.vsd	Menu.asm CONT_MMI.ASM	PMP0838A Menu module test specification.doc	AT:018	
PR:127	SR:083	26.10.1.1.1		spp_communication.asm	EXTKLU0845b-Spp communication modul test spec.doc	SPP:034	Bluetooth accepttest (PMP)
PR:134	SR:084	26.10.1.1.1		Flash_handler.asm	No test	AT:029 SPP:035	
PR:136	SR:085		PMP0833A Service counter specification.doc	service.asm	No test	AT:021	
PR:137	SR:086			Flash_handler.asm Event_queue.asm	EXTKLU0833d- Queue modul test spec.doc	AT:033	
PR:139	SR:087	26.10.1.1.1		spp_command_handler.asm online_pskey.asm	EXTKLU0837c- Online-pskey modul test spec.doc	AT:038	

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E3000 Plus
SAS, SW Acceptance Test Specification

Version 5.00

File name: MBG0802a - SAS SW Acceptance Test Specification for E3000 Plus.doc

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(b) (4)

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Version history

Version	Author	Date	Description	Reviewed by	EC number
0.1	MBG	9. jan 2008	Dokument created.		
0.2	MBG	11. feb 2008	New requirements were added, thus the new tests.		
1.00	PMP	06 oct 2008	version 1.00 of this acceptance test is intended for release of model 3100 software.		
1.10	MBG	27 nov 2008	Additional tests were added to include the M3200.		
1.11	MBG	28 nov 2008	AT:014 removed - testing SR:035 AT:031 removed - testing SR:062 + SR:064 See traceability to find test of these functions.	PMP,CAP,BUA, MBG	
1.20	MBG	04 dec 2008	Skill level added in section 4 and review comments added. AT:005 Edited to contain AT:007. AT:007 Deleted. AT:023 Deleted. AT:015 Deleted.		
2.00	MBG	04 dec 2008	Document ready for signing.		2008-201
3.00	PMP	03-feb-2009	AT:040 changed		2009-026
4.00	PMP	23-feb-2009	AT: 018 is changed		2009-061
5.00	PMP	16-04-2009	AT:041 is changed		2009-196

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1 Purpose

The purpose of this document is to describe and list the tests, which are to be carried out to verify that the software is running as required in the software requirements.

2 Scope

This document describes the acceptance test of the software component of the E3000 Plus stethoscope. These tests will be carried out and there results will be shown in the Acceptance Test Report.

3 References

The E3000 Plus software requirement specification:

[1] MBG0751C - SRS SW Requirement Specification for E3000 Plus.docx
[2] BUA0415a Design Verification Report - E3000 Frequency response and gain.doc
[3] PMP0748C mmi state event action.vsd

4 Reading guidance

A note to the tables holding test cases:

- AT is short for Acceptance Test – the acceptance test number is indicated in this column.
- Step refers to the step within an acceptance test. Some acceptance test are composed of several steps that must be executed consecutively.
- SR refers to the software requirements that are tested by the acceptance test or test step.
- Some acceptance tests are composed of several steps that must be executed consecutively. The steps in acceptance tests are indicated by a letter after the test case number e.g. AT:017a.
- SR refers to the software requirements that are tested by the acceptance test or test step.

When buttons have to be activated in a test, the button must be held down for 0.5-1.5 sec unless specified otherwise. The different buttons on E3000 Plus are described in the table below. Note that the symbols might be slightly different on the assembled device.
The skill level of the person performing the tests has to be at a level, where he or she is able to pair and establish a Bluetooth connection on a PC. They also need to have a technical understanding covering the technical words and descriptions in the tests.

SBC

Button symbol	Function
I	Filter button
M	Menu button
⏻	Power on/off button
⊞	Increase volume button
⊟	Decrease volume button

Table 1: Button symbols

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(b) (4) [redacted]

5 TEST DESCRIPTION

The purpose of the software acceptance test is to verify that the requirements stated in **Error! Reference source not found.** are implemented correctly.

5.1 Test Target

The software acceptance test is performed on the final software for the E3000 Plus stethoscope.
The specific stethoscope used is listed below.

Description	Identification
E3000 stethoscope	Software version: Serial number:

5.2 Test Configuration

The accept test is performed as a set of structured test cases. The test cases are detailed descriptions of user interaction and expected behaviour.

The test cases are designed so they can be performed by anyone on an assembled device. This avoids the use of large and complicated test/measurement setups, but still makes a thorough functionality test of E3000 Plus.

All tests must be performed at room temperature.

5.3 Test Approval

All errors found must be classified and the classification of errors must comply with the standard error classification used at Bang & Olufsen Medicom a/s.

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(b) (4) [redacted]

6 TEST INSTRUCTIONS

Each test case contains nine description windows. Some of the windows are descriptors others are for the actual test results. A short description of each window is given here:

- ***Purpose***
  A short description of the purpose of the test.
- ***AT***
  The number of the Acceptance Test, this number is unique and can only be used in other test cases if the test has to be performed in steps and thereby indexed with a letter.
- ***SR***
  Indicates which software requirement is tested in the current acceptance test, see reference **Error! Reference source not found.** in section 3.
- ***Actions***
  Describes the test sequence, any presetting are also stated here.
- ***Expected result***
  The expected outcome of the test is listed in this window
- ***Result***
  The actual result after the test has been performed. If the result is as expected is allowed to comment the result by writing "OK".
- ***Test equipment and reference***
  Statement of the test equipment used to perform the test. All the equipment required to perform this acceptance test is listed in section 6:2.
- ***Comment***
  Notes and comments from the test performer, writing "No comment" is allowed if nothing unusual is observed.
- ***Date and initials***
  Test date and the initials of the person performing the test. If the test result can be accepted the **Pass** box should be marked with √ else the **Not Pass** is marked.

6.1 Software set-up in the test

The software is setup as it would be in the final product. All functions are active in the tested module.

6.2 Needed equipment

This chapter contains information on the equipment needed to perform the tests.
The tests have to be carried out on an M3100 and a M3200 stethoscope. Where the M3100 is not required to pass the acceptance test, it will not be listed in the column model.

Instruments

The instruments in the following table are needed to execute the tests. The FAA no. (or the instrument series number) must be written in the table for the used instruments, also the calibration date for the last calibration of the instrument must be written in the table.

Type	Manufacture and model number	FAA no./SN	Calibration date

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Test fixture
none

Other test equipment
none

6.3 Hints for the testing

none

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S&C

(b) (4) [redacted]

7 TEST CASES

7.1 Power Up timing

Purpose	Test that the E3000 Plus stethoscope powers up, when pressing the power button				
Test case	AT: 001	SR:	SR: 002, SR: 004, SR:055, SR: 066		
Action	1) E3000 Plus is powered down 2) Insert the E3000 Plus earplugs into your ears 3) Do stimuli				
Shot	Stimuli	Expected result	Result	Model	ref
A	Press shortly	Stethoscope power on		M3100 M3200	SR: 002
B	Press until the stethoscope show normal display, then release the button	Stethoscope stay powered on		M3100 M3200	SR: 002
C	Press shortly. Measure time from key pressed to backlight is on	less than 2 seconds		M3100 M3200	SR: 066
D	Press shortly. Measure time from key pressed to sound is on	less than 2 seconds		M3100 M3200	SR: 066 SR: 055
Test equipment and reference	Measure time with a stopwatch 5 times and calculate mean. This test also has to be done in an integration test, which is referred to here.				
Comment					
Pass Not pass	**Date:** **Sign:**				

7.2 Factory Default Settings1.

Purpose	Test factory default settings.		
Test case	AT:022	SR:	SR:003
Action	Use a new fresh produced stethoscope model 3200 turn stethoscope on		
Expected result	1) stethoscope does not enter Bluetooth 2) volume level 3. 3) diaphragm filter.		
Result			
Test equipment and reference			
Comment			
Pass Not pass	**Date:** **Sign:**		

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(b) (4) [redacted]

7.3 Factory Default Settings2.

Purpose	Test that the factory default settings are as specified.				
Test case	AT: 041	SR:	SR:046		
Action	1) E3000 Plus is powered on 2) Enter MENU → SETUP 3) Do stimuli				
Shot	Stimuli	Expected result	Result	Model	ref
A	Select POWER	MEDIUM is indicated		M3100 M3200	
B	Select Battery	ALKALINE is indicated		M3100 M3200	
C	Select BACKLIGHT	ALWAYS is indicated.		M3100 M3200	
D	Select AUTO OFF	ENABLE is indicated.		M3100 M3200	
E	Select FILTERS	2 is indicated.		M3100	
F	Select FILTERS	3 is indicated.		M3200	
G	Select BT. COMM	MANUAL is indicated		M3200	PR: 076
Test equipment and reference					
Comment					
Pass **Not pass**	**Date:** **Sign:**				

7.4 Power up default settings

Purpose	Test that the E3000 Plus stethoscope powers up with the preset values				
Test case	AT: 002	SR:	SR: 003, SR: 005		
Action	1) Store pre settings, and turn stethoscope off. 2) Turn stethoscope on and verify settings				
Shot	Stimuli	Expected result	Result	Model	ref
A	Store bell filter setting and volume step 0 Press ⏻ shortly	Stethoscope power on and give 2 short 500 Hz beeps		M3100 M3200	SR: 005
B		Stethoscope show bell filter and volume step 0		M3100 M3200	SR: 003
C	Store diaphragm filter setting and volume step 8 Press ⏻ shortly	Stethoscope power on and give 2 short 1000 Hz beeps		M3100 M3200	SR: 005
D		Stethoscope show diaphragm filter and volume step 8		M3100 M3200	SR: 003
E	Store third filter setting and volume step 5 Press ⏻ shortly	Stethoscope power on and give 1 short 500 Hz beep and 1 short 1000 Hz beep		M3200	SR: 005
F		Stethoscope show third filter and volume step 5		M3200	SR: 003
Test equipment and reference					
Comment					

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(b) (4) [redacted]

Pass	Not pass		Date:	Sign:

7.5 Power Down

Test 1

Purpose	Test that the E3000 Plus stethoscope powers down, when pressing the power button for more than one second, while the stethoscope is powered on. The LCD should show the Littmann when powering down.			
Test case	AT: 003	**SR**	SR:006 SR:056 SR:057	Model M3100 M3200
Action	E3000 Plus is powered down 1) Insert the E3000 Plus earplugs into your ears 2) Press 3) Wait for 10 sec. and press the *power on/off* button again. The button must be pressed at least 1 second.			
Expected result	1) There are no sounds coming from the E3000 Plus (device is off). 2) The E3000 plus powers up. 3) The device indicates power down (showing the Littmann logo) and is fully powered down within 2 seconds.			
Result				
Test equipment and reference				
Comment				
Pass	**Not pass**	**Date:**	**Sign:**	

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(b) (4) [redacted]

Test 2

Purpose	Test that the E3000 Plus stethoscope enter standby automatically, when the power off timer runs out, while the stethoscope is powered on. The value of the timer is set in the configurations menu of the E3000 Plus.				
Test case	AT: 004	**SR:**	SR: 004, SR: 009, SR: 010, SR:036		
Action	1) Power on the stethoscope and insert earplugs into your ears. 2) Store settings and measure the time until the stethoscope enters standby.				
Shot	Stimuli	Expected result	Result	Model	ref
A	Power = low, Auto off = disabled	Power On Time = 3 min. ± 10% Power Off Time = 30 min. ± 10% Backlight = 3 sec. ± 10% Warning tone is played 10 ± 2 sec. before entering standby : 1kHz ± 25%, 250ms ± 25%, 2kHz ± 25%, 85ms ± 25%		M3100 M3200	
B	Power = medium, Auto off = disabled	Power On Time = 5 min. ± 10% Power Off Time = 2 hr. ± 10% Backlight = 5 sec. ± 10% Warning tone is played 10 ± 2 sec. before entering standby: 1kHz ± 25%, 250ms ± 25%, 2kHz ± 25%, 85ms ± 25%		M3100 M3200	
C	Power = high, Auto off = disabled	Power On Time = 7 min. ± 10% Power Off Time = 5 hr. ± 10% Backlight = 5 sec. ± 10% Warning tone is played 10 ± 2 sec. before entering standby: 1kHz ± 25%, 250ms ± 25%, 2kHz ± 25%, 85ms ± 25%		M3100 M3200	
D	Power = low, Auto off = enabled	Power On Time = 10 - 20 sec. Power Off Time = 30 min. ± 10% Backlight = 3 sec. ± 10%		M3100 M3200	
E	Power = medium, Auto off = enabled	Power On Time = 20 - 30 sec. Power Off Time = 2 hr. ± 10% Backlight = 5 sec. ± 10%		M3100 M3200	
F	Power = high, Auto off = enabled	Power On Time = 30 - 40 sec. Power Off Time = 5 hr. ± 10% Backlight = 5 sec. ± 10%		M3100 M3200	
Test equipment and reference					
Comment	The Auto-off times are tested in AT:012				
Pass **Not pass**	**Date:** **Sign:**				

7.6 Filter Mode

Test 1

Purpose	Test that the E3000 Plus stethoscope filter mode changes and that the correct mode is set.				
Test case	AT: 005	**SR:**	SR: 011, SR: 012, SR:036		
Action	E3000 Plus is powered on 1) Insert the E3000 Plus earplugs into the Head and Torso Simulator (HATS). 2) Start logging data from HATS. 3) Do stimuli and compare result with expected result.				
Shot	Stimuli	Expected result	Result	Model	ref

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A	Press I to change filter to the extended filter.	First tone: 500Hz ± 25%, 250ms ± 25% Second tone: 1kHz ± 25%, 200ms ± 25% The correct filter icon is showed in the LCD.		M3200	
B	Press I to change filter to the bell filter.	First tone: 500Hz ± 25%, 250ms ± 25% Second tone: 500Hz ± 25%, 200ms ± 25% The correct filter icon is showed in the LCD.		M3100 M3200	
C	Press I to change filter to the diaphragm filter.	First tone: 1kHz ± 25%, 250ms ± 25% Second tone: 1kHz ± 25%, 200ms ± 25% The correct filter icon is showed in the LCD.		M3100 M3200	
Test equipment and reference					
Comment					
Pass **Not pass**		**Date:** **Sign:**			

Test 2

Purpose	Test that the current filter mode is stored in non-volatile memory when storing filter in setup menu				
Test case	AT: 006	**SR**	SR: 013		
Action					
Shot	Stimuli	Expected result	Result	Model	ref
A	Select bell filter Store filter in setup menu Turn stethoscope off and on again.	Bell filter is used		M3100 M3200	SR: 013
B	Select diaphragm filter Store filter in setup menu Turn stethoscope off and on again.	Diaphragm filter is used		M3100 M3200	SR: 013
C	Select third filter Store filter in setup menu Turn stethoscope off and on again.	Third filter is used		M3200	SR: 013
Test equipment and reference					
Comment					
Pass **Not pass**	**Date:** **Sign:**				

Test 4

Purpose	Test that the number of filters available is the same as set in setup menu				
Test case	AT: 008	**SR**	SR: 075		
Action	Insert the E3000 Plus earplugs into your ears				
Shot	Stimuli	Expected result	Result	Model	ref
A	Set filters = 2 in setup menu press filter button more time.	The stethoscope toggle filter between bell and diaphragm		M3100 M3200	SR: 075
B	Set filters = 3 in setup menu	The stethoscope		M3200	SR:

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(b) (4) [redacted]

	press filter button more time.	toggle filter between bell, diaphragm and third filter			075
Test equipment and reference					
Comment					
Pass **Not pass**	**Date:** **Sign:**				

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(b) (4) [redacted]

Test 5

Purpose	Test the frequency response of the three different filter modes.		
Test case	AT:009	**SR**	SR: 014 SR: 015 SR: 016
Action	E3000 Plus is powered down 1) Place the E3000 Plus into the Service Centre. 2) Press ⏻ 3) Select the *Bell* filter by pressing the filter button H and run the frequency response test. 4) Look at the result from the Service Centre. 5) Select the *third* filter by pressing the filter button H and run the frequency response test. 6) Look at the result from the Service Centre. 7) Select the *Diaphragm* filter by pressing the filter button H and run the frequency response test. 8) Compare with the expected stethoscope filter response.		
Expected result	1) There are no sounds coming from the E3000 Plus (device is off). 2) The E3000 plus powers up. 3) The E3000 Plus changes filter mode to *Bell*. The matching filter symbol is shown in the display. 4) The frequency response matches the one found in [2] for the *Bell* filter. 5) The E3000 Plus changes filter mode to third filter. The matching filter symbol is shown in the display. 6) The frequency response matches the one found in [2] for the *third* filter. 7) The E3000 Plus changes filter mode to *Diaphragm*. The matching filter symbol is shown in the display. 8) The frequency response matches the one found in [2] for the *Diaphragm* filter.		
Result			
Test equipment and reference			
Comment			
Pass **Not pass**	**Date:** **Sign:**		

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(b) (4) [redacted]

7.7 Volume setting

Test 1

Purpose	Test that the volume changes, when the volume up or volume down button is pressed.		
Test case	AT:010	SR:	SR:017 SR:018 SR:019 SR:036
Action	E3000 Plus is powered on 1) Insert the E3000 Plus earplugs into your ears. Setup HATS system to measure the tone. 2) Press the volume up button [redacted]. 3) Press the volume down button [redacted]. 4) Press and hold the volume up button [redacted]. 5) Press and hold the volume down button [redacted].		
Expected result	1) E3000 Plus is operational 2) The volume level is increased 1 step and feedback is given via sound and the LCD. 3) The volume level is decreased 1 step and feedback is given via sound and the LCD. 4) The volume level is increased all the way to max and feedback is given via sound and the LCD. When the volume reach the highest level it stops giving sound feedback 5) The volume level is decreased all the way to min and feedback is given via sound and the LCD. When the volume reach the lowest level it stops giving sound feedback 6) the audio feed back is a short 1500Hz ± 25% 85ms ± 25% beep (verify with measurements from HATS.)		
Result			
Test equipment and reference			
Comment			
Pass Not pass	**Date:** **Sign:**		

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(b) (4) [redacted]

Test 2

Purpose	Test that the volume setting can be stored in non-volatile memory.
Test case	AT:011 SR:[redacted] SR:020
Action	E3000 Plus is powered on 1) Insert the E3000 Plus earplugs into your ears 2) Change the volume setting by pressing . 3) Store the volume in setup menu 4) Turn off the stethoscope by pressing and holding the power on/off button for more than 1 second. 5) Turn on the stethoscope by pressing the power on/off button . 6) Listen to the body sounds (heart and respiration) and look at the LCD.
Expected result	1) E3000 Plus is operational 2) The volume level is increased 1 step and feedback is given via sound and the LCD. 3). 4) the stethoscope power off 5) The E3000 plus powers up. 6) The volume level is increased 1 step compared to the last time the stethoscope was powered up and feedback is given via the LCD.
Result	
Test equipment and reference	
Comment	
Pass **Not pass**	**Date:** **Sign:**

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(b) (4) [redacted]

7.8 Auto On/Off

Purpose	Test that the Auto on/off system works. That is, that the E3000 Plus powers up from sleep mode, when the chest piece is placed on a body and that it powers off again, when no biological signal is measured. The power off function can be delayed by setting a timer in the configuration menu.		
Test case	AT: 012	SR	SR:030, SR:031, SR:032
Action	Make settings as described in stimuli and then 1) Insert the E3000 Plus earplugs into your ears 2) Listen to a body sound and then place the stethoscope on table. 3) Wait till stethoscope automatically goes into standby. 4) Pick up the E3000 Plus, begin auscultation.		

Shot	Stimuli	Expected result	Result	Model	ref
A	Power = low, Auto off = enabled	Power On Time = 10 - 20 sec. Logo is showing in LCD.		M3100 M3200	
B	Power = medium, Auto off = enabled	Power On Time = 20 - 30 sec. Logo is showing in LCD.		M3100 M3200	
C	Power = high, Auto off = enabled	Power On Time = 30 - 40 sec. Logo is showing in LCD.		M3100 M3200	

Test equipment and reference	
Comment	
Pass Not pass	**Date:** **Sign:**

7.9 Heart Rate Monitor

Test1

Purpose	Test that the heart rate monitor is working and that the right heart rate is shown in the LCD.		
Test case	AT:013	SR	SR:034 SR:026
Action	E3000 Plus is powered on and in active state 1) Insert the E3000 Plus earplugs into your ears 2) Place the chest piece on the shaker setup and set a frequency. 3) Read the display. Set a new frequency and wait 20 seconds and read the heart rate again. 4) Set the frequency of the shaker to zero and read the display.		
Expected result	1) E3000 Plus is operational 2) A heart beat can be heard and the LCD shows the heart beat in beats per minute (varying <10%) after 5 seconds of measuring. As the heart rate changes, it is updated in the LCD every 2 seconds. 3) The LCD shows the heart rate in bpm. 4) The heart beat is shown for 10 seconds after the loss of heart sound signal. Afterwards two lines are shown (— —) to indicate that no valid heart rate is measured.		
Result			

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(b) (4) [redacted]

Test equipment and reference	
Comment	
Pass **Not pass**	**Date:** **Sign:**

Display valid heart rates

Purpose	Heart rate monitor only shows values of 30 to 199 in the LCD.		
Test case	AT:032	SR	SR:026
Action	E3000 Plus is powered on and in active state 1) Place the chest piece on a shaker, which is creating at saw tooth signal with a freq. of 1Hz. 2) Read the display. 3) Set the shaker frequency to 0.4Hz 4) Read the display. 5) Set the shaker frequency to 3.5Hz 6) Read the display.		
Expected result	1) E3000 Plus is operational 2) A heart beat can be read in the LCD, 60bpm. 3) Wait for 15 seconds. 4) The lines are shown (— —) to indicate that no valid heart rate is measured. 5) Wait for 15 seconds. 6) The lines are shown (— —) to indicate that no valid heart rate is measured.		
Result			
Test equipment and reference			

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(b) (4)

Comment	
Pass **Not pass**	**Date:** **Sign:**

7.10 Battery Monitor

Level Indicator1.

Purpose	Test the different levels of the battery monitor.		
Test case	AT: 016	**SR**	SR:039, SR:024, SR:040
Action	E3000 Plus is powered by special batteries. Four batteries of three different types. The four different batteries have four different amounts of power left in order to indicate the four different battery levels. 1) Insert the described battery and specify battery type in the setup of the stethoscope. 2) Look at the battery level indicator.		

Shot	Stimuli	Expected result	Result	Model	ref
A	50 - 100% Alkaline battery.	50 - 100% battery life is shown		M3100 M3200	
B	25 - 50% Alkaline battery.	25 - 50% battery life is shown		M3100 M3200	
C	10 - 25% Alkaline battery.	10 - 25% battery life is shown		M3100 M3200	
D	0 - 10% Alkaline battery.	0 - 10% battery life is shown and the battery icon flashes.		M3100 M3200	
E	50 - 100% Lithium battery.	50 - 100% battery life is shown		M3100 M3200	
F	25 - 50% Lithium battery.	25 - 50% battery life is shown		M3100 M3200	
G	10 - 25% Lithium battery.	10 - 25% battery life is shown		M3100 M3200	
H	0 - 10% Lithium battery.	0 - 10% battery life is shown and the battery icon flashes.		M3100 M3200	
I	50 - 100% NIMH battery.	50 - 100% battery life is shown		M3100 M3200	
J	25 - 50% NIMH battery.	25 - 50% battery life is shown		M3100 M3200	
K	10 - 25% NIMH battery.	10 - 25% battery life is shown		M3100 M3200	
L	0 - 10% NIMH battery.	0 - 10% battery life is shown and the battery icon flashes.		M3100 M3200	

Test equipment and reference	
Comment	
Pass **Not pass**	**Date:** **Sign:**

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(b) (4) [redacted]

Level indicator2.

Purpose	Test the battery minimum voltage warning for the wireless data transmission. This warning is sent in order to notify that the connection is about to be closed. The E3k_Streamer program is necessary in this test. It should be installed on a PC with a Bluetooth connection.		
Test case	AT:035	**SR**	SR:065
Action	E3000 Plus is powered up via special low power batteries. 1) Establish a streaming connection to the PC. 2) Turn down the power supply until battery low level is reached. 3) Turn the power supply all the way down.		
Expected result	1) The E3000 Plus is streaming sound to a PC. 2) The battery level indicator flashes and an error bit is set in the header of the data stream. This will be visible in the error information in the PC program. 3) The E3000 Plus powers down, showing the Littmann logo and the wireless connection is lost.		
Result			
Test equipment and reference			
Comment			
Pass **Not pass**	**Date:** **Sign:**		

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7.11 Miscellaneous

Button Commands

Purpose	Test multiple key pressing

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Test case	AT: 017	SR	SR:047, SR:048		
Action	Turn stethoscope on				
Shot	Stimuli		Expected result	Result	ref
A	press and hold filter button pres and release + button		Change filter don't change volume		SR: 048
B	press and hold - button pres and release M button		Change volume don't enter menu		SR: 048
C	press and hold - button Press and release filter button		volume decrease Volume stop decreasing		SR: 048
D	Press and hold M button Press and hold filter button release M button Press and hold + button Release M button release + button press - button		Enter menu "CONNECT" No change No change No change No change No change change to "DISCONNE"		SR: 047, SR: 048
Test equipment and reference					
Comment					
Pass	Not pass	Date:	Sign:		

Configuration menu

Purpose	Test configuration menu				
Test case	AT: 018	SR	SR:049, SR:050, SR:082		
Action					
Shot	Stimuli		Expected result	Result	ref
A	Model 3200 Press M button		enter menu main menu > "CONNECT"		PR: 034
B	Model 3100 Press M button		Enter setup menu > "POWER"		PR: 034
C	Select AUTO OFF = ENABLE Select POWER = LOW Use stethoscope		Stethoscope is on while places on body. The stethoscope enter stand by 10 -20 seconds after it is places on a table		PR: 069
D	Select AUTO OFF = DISABLE Select POWER = LOW Use stethoscope		Stethoscope is on while placed on a table till 3 minutes after a key is pressed or released		PR: 069, SR: 082
E	Select AUTO OFF = DISABLE Select POWER = LOW Place stethoscope on table		the stethoscope is in stand by 30 min ±10 %		PR: 070
F	Select AUTO OFF = DISABLE Select POWER = MEDIUM Place stethoscope on table		the stethoscope is in stand by 120 min ±10 %		PR: 070
G	Select AUTO OFF = ENABLE Select POWER = HIGH Place stethoscope on table		the stethoscope is in stand by 300 min ±10 %		PR: 070
E	Select AUTO OFF = DISABLE Select POWER = LOW Place stethoscope on table After 15 minutes press + button Observe the last stand by time		The stethoscope enter standby The stethoscope leave stand by when + button is pressed The stethoscope enter stand by after 3 min The stethoscope is in stand by 30 min ±10%		PR: 071
F	Select AUTO OFF = DISABLE Select POWER = LOW Place stethoscope on table after 2 minutes press filter button		The stethoscope enter standby 3 min ±10% after the filter button is released		PR: 071
G	Select AUTO OFF = DISABLE Select POWER = LOW		The stethoscope enter normal auscultation		PR: 072

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	Place stethoscope on table. Wait till stethoscope enter standby, put stethoscope on chest			
Test equipment and reference				
Comment	Some of these tests might have been performed in T:004 already.			
Pass **Not pass**	**Date:** **Sign:**			

Configuration menu 2

Purpose	Test configuration menu			
Test case	AT: 019	**SR**	SR:050	
Action				
Shot	Stimuli	Expected result	Result	ref
A	Model 3200 Select BT. COMM = MANUAL Turn stethoscope off, and on again	Stethoscope start i normal auscultation		PR: 076
B	Model 3200 Select BT. COMM = AUTO Turn stethoscope off, and on again	Stethoscope start i bluetooth		PR: 076
Test equipment and reference				
Comment				
Pass **Not pass**	**Date:** **Sign:**			

Configuration menu 3

Purpose	Test configuration menu			
Test case	AT: 020	**SR**	SR:050, SR:061, SR:076	
Action				
Shot	Stimuli	Expected result	Result	ref
A	Enter ID menu observe serial number	Display show: SERIAL # 000809xx xxxxxxxx (0809 is production year and month, xxxxx is a decimal representation of the Bluetooth LAP)		PR: 042
B	Enter ID menu press - button observe SW version	Display show: SW VER. xx.yy.00 (xx = major, yy = minor sw version)		PR: 042
C	Model 3100 Press M button continue..	SETUP: >POWER		
D	Press – button continue..	SETUP: >EXIT		
E	Press + button until SETUP:>ID Press M button continue..	ID: SERIAL #		
F	Press Filter button continue..	SETUP: >ID		
G	Press filter button continue..	Exit menu		
E	Model 3200	MAIN: >CONNECT		

	Press M button continue ...			
F	Press + button twice Press M button continue ...	SETUP: >POWER		
G	Press + button twice press M button continue ...	ID: SERIAL #		
H	Press M button	exit menu		
Test equipment and reference				
Comment				
Pass	**Not pass**	**Date:**	**Sign:**	

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(b) (4) [redacted]

Service counter

Purpose	Test service counter			
Test case	AT: 021	SR	SR:085	
Action	read service counters before and after stimuli			
Shot	Stimuli	Expected result	Result	ref
A	Press M button	M btn: = M btn: +1		
B	Press + button 2 times	Plus btn: = Plus btn: + 2		
C	Press + button 3 times	Minus btn: = Minus btn: + 3		
D	Press filter button 4 times	Filter btn: = Filter btn: + 4		
E	press on/off button 5 times	On/off btn: = On/off btn: + 5		
F	Let stethoscope go into standby Put stethoscope on chest so it wake up	Auto on wkup: = Auto on wkup: + 1		
G	AUTO ON = ENABLE leave stethoscope on table so it enter standby	Auto off evt: = Auto off evt: + 1 Auto off tos: = Auto off tos: + 1		
E	AUTO ON = DISABLE leave stethoscope on table so it enter standby	Active tos: = Active tos: + 1		
F	read service counters with 20 sec interval	Active T: = Active T: +20±2 Bluetoot T: = Bluetoot T: + 20 ±2		
G	leave stethoscope 3,5 min in standby	Stand by T: = Stand by T: + 3		
H	turn stethoscope off and on	Power on evt: = Power on evt: + 1		
Test equipment and reference				
Comment				
Pass **Not pass**	**Date:** **Sign:**			

Dot matrix display

Purpose	Test dot matrix		
Test case	AT:024	SR	SR:077
Action	measure and count dots		
Expected result	the active area is14x8 mm The number of dots are 56x32		
Result			
Test equipment and reference			
Comment			
Pass **Not pass**	**Date:** **Sign:**		

Icons

Purpose	Test icons			
Test case	AT:025	SR	SR:078	
Action	turn stethoscope on verify icons against figure 1 in product requirements.			
Shot	Stimuli	Expected result	Result	ref

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(b) (4) [redacted]

A	volume icon	Icon is there.		PR: 023
B	filter icon	Icon is there.		PR: 023
C	battery icon	Icon is there.		PR: 023
D	Heart rate	Icon is there.		PR: 023
Comment				
Pass **Not pass**	**Date:** **Sign:**			

Backlight1

Purpose	Test backlight timeouts		
Test case	AT:026	**SR**	SR:023
Action	turn stethoscope on wait to backlight turns off		

Shot	Stimuli	Expected result	Result	ref
A	SET POWER = LOW press and release on/off button	backlight turn on, and turn off again 3 sec ±10% after the button is released		
B	SET POWER = LOW press and release on/off button, press and release the on/off button again before the backlight turns off	backlight turn on, and turn off again 3 sec ±10% after the button is released last time		
C	SET POWER = MEDIUM press and release on/off button	backlight turn on, and turn off again 5 sec ±10% after the button is released		
D	SET POWER = HIGH press and release on/off button	backlight turn on, and turn off again 5 sec ±10% after the button is released		
Comment	Some of these tests might have been performed in AT:004 already.			
Pass **Not pass**	**Date:** **Sign:**			

Backlight2

Purpose	Test the three Backlight settings.		
Test case	AT:036	**SR**	SR:023
Action	turn stethoscope on wait to backlight turns off Set Power = low.		

Shot	Stimuli	Expected result	Result	ref
A	BACKLIGHT = ON DMMD press and release on/off button	backlight turn on, and turn off again 3 sec ±10% after the button is released		
B	BACKLIGHT = ALWAYS press and release on/off button.	backlight turn on, and turn down to approximately 50% light intensity after 3 sec ±10% and stays on.		
C	BACKLIGHT = DISABLE	backlight is off and stays		

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(b) (4) [redacted]

	press and release on/off button	off.		
Comment	Some of these tests might have been performed in AT:004 already.			
Pass **Not pass**	**Date:** **Sign:**			

Onboard Storage 1

Purpose	Storing recordings.		
Test case	AT:033	**SR**	SR:079 SR:080 SR:086
Action	The E3000 Plus is powered on (diaphragm filter is selected). 1) Place the stethoscope in the HATS and start recording on the connected PC (connected to the HATS). 2) Place the chest piece on the shaker and set shaker to give a 200Hz sine signal. 3) Press the M button to enter the menu. 4) Select RECORD in the menu, to start the recording. 5) Make recording for 35 seconds. 6) Press the menu button to stop the recording and turn off the signal generator. 7) Playback the recording by selecting PLAY in the menu. 8) Compare the 29 seconds of the recording with the first 35 seconds recorded on the PC. It should match the last 29 seconds of the 35 seconds.		
Expected result	1) PC is recording. 2) None. 3) enters menu. 4) Recording starts. 5) None. 6) Recording stops on the stethoscope. 7) Recording on the PC continues. 8) The first and last part of the recording on the PC are the same.		
Result			
Test equipment and reference			
Comment			
Pass **Not pass**	**Date:** **Sign:**		

Onboard Storage 2

Purpose	Show that the recording is done before the filter and it is played back through the filter.		
Test case	AT:034	**SR**	SR:081
Action	The E3000 Plus is powered on. 1) Select the Bell filter. 2) Press the M button to enter the menu. 3) Select RECORD in the menu, to start the recording. 4) Place the stethoscope above the heart and make a recording. 5) Playback the recording by selecting PLAY in the menu. 6) Keep the chest piece away from your body with the binaurals in your ears to hear the recording.		

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(b) (4) [redacted]

	7) Press the filter button to change the filter.
Expected result	1) Bell filter is selected. 2) The menu is shown. 3) The recording is started. 4) The sound of the heart is heard in the binaurals. 5) Playback is started. 6) The recording is heard in the binaurals. 7) The recording is now heard with the Diaphragm filter.
Result	
Test equipment and reference	
Comment	
Pass Not pass	**Date: Sign:**

Playback

Purpose	Test the warning which alerts the user, that it is a streamed signal, which is being played.		
Test case	AT:040	**SR**	SR:073 PR:125
Action	The E3000 Plus is powered on. 1) Stream a recording via Bluetooth. 2) Listen to the sound in the binaurals.		
Expected result	1) steraming starts with a playback warning tone (beep). 2) The playback icon is shown in the LCD and the streamed sound is heart in the binaurals. 3) the beep must be given less than 1000 ma after stream start		
Result			
Test equipment and reference			
Comment			
Pass Not pass	**Date: Sign:**		

Bluetooth Pairing1.

Purpose	Making it possible to establish the Bluetooth connection with a Bluetooth device supporting

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(b) (4) [redacted]

	Bluetooth v.2.0 or v.2.1.		
Test case	AT: 027	**SR**	SR:029 SR:059 SR:070 SR:078
Action	The E3000 Plus is powered on and the Bluetooth device is ready for pairing. 1) Press the M button. 2) Press MINUS once and press the M button again to select PAIR. 3) Chose to pair the Bluetooth device with the stethoscope. 4) Punch in the pairing code shown in the display of the stethoscope. 5) Chose to connect to the newly found (on the Bluetooth device) SPP device.		
Expected result	1) The M3200 enters the configuration menu. 2) The pairing logo should be shown: 3) The M3200 shows a four digit code in its display. 4) The LCD shows a flashing Bluetooth icon as in figure 1 in the product requirements. 5) The Bluetooth icon stops flashing and is lit.		
Result			
Test equipment and reference			
Comment			
Pass Not pass	**Date:** **Sign:**		

Bluetooth Pairing2.

Purpose	The stethoscope has to be able to be paired with up to 8 Bluetooth devices. This enables the stethoscope to connect to the 8 known devices without pairing again.		
Test case	AT:038	**SR**	SR:087

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Action	The E3000 Plus is powered on and the Bluetooth device is ready for pairing. 1) Pair the stethoscope with at least 3 devices. 2) Go back to the first device and chose CONNECT in the menu and connect on the Bluetooth device.
Expected result	1) The stethoscope is paired with at least 3 devices. 2) The stethoscope connects with the first Bluetooth device without re-pairing.
Result	
Test equipment and reference	
Comment	
Pass **Not pass**	**Date:** **Sign:**

(b) (4) [redacted]

Connecting Bluetooth.

Purpose	Establishing the Bluetooth connection.		
Test case	AT: 028	**SR**	SR:028 SR:029 SR:058 SR:072
Action	The E3000 Plus is powered on and is paired to the Bluetooth device, tough not connected. 1) Press the M button to enter the menu. 2) Press the M button again to connect to the Bluetooth device. 3) The connection is tested with E3k_streamer. 4) When steaming, walk away from the Bluetooth device until the connection is lost.		
Expected result	1) The menu is showing in the LCD. 2) The Bluetooth icon is initially flashing and shifts to being lit, when the connection is made. 3) The connection is usable. 4) The Bluetooth icon starts flashing when the connection is lost and the streaming to the Bluetooth device stops.		
Result			
Test equipment and reference			
Comment			
Pass Not pass	**Date:** **Sign:**		

Streaming.

Purpose	Show the appropriate filter icon when doing playback from the connected Bluetooth device.		
Test case	AT:039	**SR**	SR:071
Action	The E3000 Plus is powered on and is ready to playback from the connected Bluetooth device. The selected filter is Diaphragm.		

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(b) (4) [redacted]

	1) Start the playback streaming to input switch 1. 2) Look at the LCD. 3) Press the filter button. 4) Look at the LCD. 5) Start the playback streaming to input switch 2. 6) Look at the LCD.
Expected result	1) The streamed sound is heard in the binaurals. 2) The Diaphragm filter icon is shown in the LCD. 3) The sound of the filter change is heard in the binaurals. 4) The Bell filter icon is show in the LCD. 5) The streamed sound is heard in the binaurals. Now not filtered. 6) Not filter icon is shown in the LCD.
Result	
Test equipment and reference	
Comment	
Pass Not pass	**Date: Sign:**

Bluetooth Transmission Range.

Purpose	Insight Bluetooth range.		
Test case	AT: 042	**SR**	SR:072
Action	The E3000 Plus is powered on and is connected and streaming. 1) Walk away from the streaming PC and look at the LCD.		
Expected result	1) The distance to the PC is 10, or more, meters.		
Result			
Test equipment and reference			

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(b) (4) [redacted]

Comment	
Pass **Not pass**	**Date:** **Sign:**

Bluetooth up-/download.

Purpose	Test the upload and download function via the Bluetooth connection.		
Test case	AT: 029	**SR**	SR:084
Action	The E3000 Plus is powered on and paired with a PC, which is running our up-/download program. 1) Connect the stethoscope to the PC. 2) Record a sine signal of 300Hz via a shaker and a signal generator. 3) Upload the sound file to the PC. 4) Record heart sound on the stethoscope. 5) Play the sound file from the stethoscope by choosing play in the menu. 6) Download the 300Hz signal from the PC to the stethoscope. 7) Play the sound file on the stethoscope		
Expected result	1) The connection is established. 2) The 300Hz signal can be heard in the binaurals.. 3) The upload is being carried out. 4) Recording icon is shown in LCD. 5) The heart sound is heard in the binaurals. 6) The download is carried out. 7) A 300Hz sound is heard in the binaurals.		
Result			
Test equipment and reference			

(b) (4) [redacted]

Comment	
Pass **Not pass**	**Date:** **Sign:**

Channel B gain.

Purpose	The digital gain in channel B has to be independently program-controlled compared to channel A.		
Test case	AT: 030	**SR**	SR:074
Action	The E3000 plus is turned on and is paired with a PC, which is running the E3k_streamer program, which is showing the sound streamed. 1) Place the binaurals in your ears and place the chest piece on the shaker and apply a 300Hz tone. 2) Turn up the gain on channel B from the PC. 3) Observe the level of the signal in the E3k_streamer program.		
Expected result	1) The 300Hz tone is heard in the binaurals and a signal is seen in the E3k_streamer program. 2-3) The heart sound stays the same in the binaurals, but the amplitude of the signal shown in the E3k_streamer program changes its amplitude to a higher level.		
Result			
Test equipment and reference			

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(b) (4) [redacted]

Comment	
Pass **Not pass**	**Date:** **Sign:**

SPI interface.

Purpose	Test if it is possible to reprogram the stethoscope and thereby giving it a new identification number, software version number and model number. This information is stored in non-volatile memory.		
Test case	AT:037	**SR**	SR:068 SR:069
Action	The E3000 Plus is powered on. 1) Enter MENU->SETUP->ID. 2) Read SW version-, serial-, and model number. 3) Reprogram the stethoscope with an older release. 4) Turn the stethoscope on and enter MENU->SETUP->ID. 5) Read SW version number to verify that the software has changed. 6) Reprogram the stethoscope with the original software.		
Expected result	1) LCD is showing stethoscope information. 2) It is necessary to scroll through the information with the + or – button. 3) The stethoscope is reprogrammed with another software version. 4) The stethoscope enters the menu under ID. 5) A different software version is displayed. 6) The stethoscope is reprogrammed with the original software.		
Result			
Test equipment and reference			

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(b) (4)

Comment	
Pass Not pass	Date: Sign:

(b)(4)Trade Secret Process-Product Specs

[redacted]

E3000 Plus
Design verification report

Version 1.00

File name: trh0909d Design verification report - Battery access torque

Author

20-02-2009
Date, Svend Eric Poulsen – Designer

Approved by

20-02-2009
Date, Torben Riis Houe – QA

(b)(4)Trade Secret Process-Product Specs

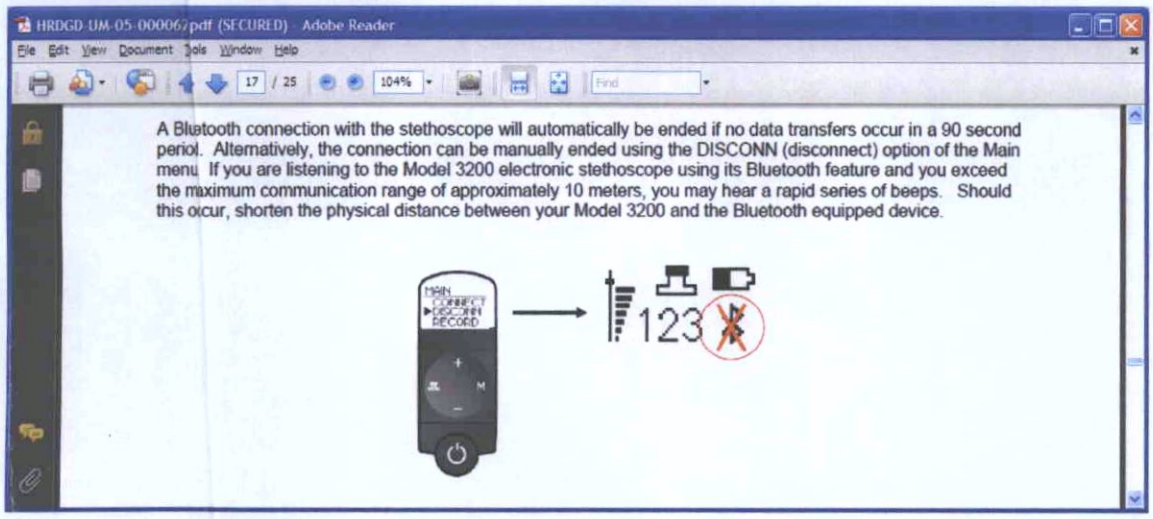
[redacted]

Dear Mr. Jin:

Thanks for providing me with the voluminous information! It is good, except for the following issues:

1. When the BT-enabled PC is taking control of the subject stethoscope in a BT communications session, how can the user use the stethoscope's menu to display the DISCONN command in order to end the BT
session? If this is possible, please revise the User Manual to reflect this idea of ending the BT session.

The user can disable PC control by disconnecting from Bluetooth at any time using the disconnect command on the stethoscope. This function is described in the section 11 of the user manual with the graphic display.



Please also include another way to
end the BT session, by turning off the stethoscope manually.

It is inherent in the design of the Model 3200 that the BT session will end when the stethoscope is manually turned off.

2. You have claimed that the subject device is compliant with IEC
60601-1-2 on EMC, as shown on page 5 of 25 of the User Manual. Please clarify if you mean IEC 60601-1-2, ed. 2.1. Please note that ed. 2.1 is version of the IEC 60601-1-2 standard that is recognized by FDA, and this ed. 2.1 is slightly different from older editions of the IEC standard. (You can access our website to check the supplemental information sheet on this standard, by going to www.fda.gov.)

EMC testing was conducted using EN 60601-1-2:2007. This standard is equivalent to the IEC standard. The 2007 version (edition 3.0) is the most current version of 60601-1-2 that incorporates edition 2:2001 with Amendment 1:2004, and it overrides the previous versions in medical device manufacturing.