U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K041934 - 398 pages
COMPANY:	3M COMPANY (3M)
PRODUCT:	STETHOSCOPE, ELECTRONIC (DQD)
SUMMARY:	Product: 3M LITTMANN ELECTRONIC STETHOSCOPE, MODEL 3000
DATE REQUESTED:	Jan 21, 2016
DATE PRINTED:	Jan 21, 2016
Note:	Printed

K041934

OCT 15 2004

Premarket Notification (510(k)) Summary

1. Sponsor Information:

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

Contact Person:	Ginger Cantor Senior Regulatory Affairs Associate
Phone Number:	(651) 736-2101
FAX Number:	(651) 737-5320

Date of Summary: July 16, 2004

2. Device Name and Classification:

Common or Usual Name: Electronic Stethoscope

Proprietary Name: 3M™ Littmann® Electronic Stethoscope, Model 3000

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

Performance Standards: None

3. Predicate Device:

3M™ Littmann® Electronic Stethoscope, Model 4000
3M™ Littmann® Electronic Stethoscope, Model 2000

4. Description of Device:

The 3M™ Littmann® Electronic Stethoscope, Model 3000 is a healthcare device that picks sounds of the heart, arteries, veins, lung and other internal organs, electronically amplifies, filters, and transfers them to the user's ears via an active speaker and passive sound tubes. The Model 3000 provides two filter frequency modes for auscultation: Bell (20-200 Hz) and Diaphragm (100-500 Hz).

The Model 3000 incorporates embedded software. The embedded software controls all of the various features found in the Model 3000 stethoscope, such as volume control and frequency mode selection. In addition, the embedded software provides digital signal processing (DSP) over the entire acoustic range of the stethoscope; DSP produces the bell and diaphragm frequency response modes that are used to listen to heart, lung, and other body sounds.

The Model 3000 does not incorporate any off-the-shelf (OTS) software.

The Model 3000 operates on one (1) AAA alkaline battery.

5. Indications for Use:

The 3M™ Littmann® Electronic Stethoscope Model 3000 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of 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.

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

The table below illustrates the similarities and differences of the new device (Model 3000) to the predicate devices (Model 4000 and Model 2000). The Model 3000 proposed under this new pre-market notification submission is composed of similar materials, and has similar performance features, intended use and indications for use as the Model 4000 cleared under K003723, and the Model 2000, cleared under K961848.

Comparison of Performance Features Littmann® Electronic Stethoscope Model 3000 versus Littmann® Electronic Stethoscope Model 4000 and Littmann® Electronic Stethoscope Model 2000

Performance Features	Model 3000 (New Device)	Model 4000 (Predicate Device) K003723	Model 2000 (Predicate Device) K961848
Frequency Response	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.	Bell (20-200 Hz), Diaphragm (100-500 Hz) and Extended Range (100-1000 Hz) modes.
Amplification	Up to 25 dB acoustic gain, equivalent to 18 times amplification.	Up to 25 dB acoustic gain, equivalent to 18 times amplification.	Up to 20 dB acoustic gain, equivalent to 14 times amplification.
Maximum Sound Level	140 dB SPL Max	140 dB SPL Max	140 dB SPL Max
Power Source	One (1) (AAA) alkaline battery	Two (2) (AAA) alkaline batteries	One (1) (AAA) alkaline battery
Low Battery Indicator	Includes a low battery indicator	Includes a low battery indicator	Includes a low battery indicator
Displays Heart Rate	No	Yes	No
Record and Playback Sounds	No	Yes	No
Permits Data Transfer of Stored Digital Signals to and from IBM-Compatible PC and Pocket PC and Palm Pilot*	No	Yes	No
Volume Control	8 Step Volume Control	8 Step Volume Control	Continuous Variable
ON/OFF Switch Automatic Shut-off by Electronics	Yes	Yes	Yes

*** With Infrared Port and Windows /98/2000/XP, Pocket PC 2002/2003 and Palm OP Sys 4/5**
Microsoft® and Windows™ are registered trademarks of Microsoft Corporation.

7. Non-clinical (Biocompatibility) Summary:

All components of the Model 3000 stethoscope have been reviewed 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.

The Littmann® Electronic Stethoscope Model 3000 is composed of the same or substantially equivalent materials as those in the Littmann® Electronic Stethoscope Model 4000 cleared under K003723, and the Littmann® Electronic Stethoscope Model 2000, cleared under K961848.

3M concludes that all of the components of the Model 3000 Stethoscope would have minimal potential for any adverse health concern.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2004

3M Company
c/o Ms. Ginger Cantor
Senior Regulatory Affairs Associate
3M Healthcare
3M Center, Bldg 275-5W-06
St Paul, MN 55144-1000

Re: K041934
Trade Name: 3M Littman Electronic Stethoscope, Model 3000
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: July 16, 2004
Received: July 19, 2004

Dear Ms. Cantor:

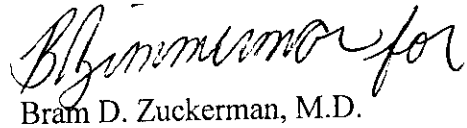
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 594-4648. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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): K041934

Device Name: 3M™ Littmann ® Electronic Stethoscope Model 3000

Indications For Use:
The 3M™ Littmann ® Electronic Stethoscope Model 3000 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of 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 _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

...on Sign-Off)
...n of Cardiovascular Devices
... Number K041934

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: 11/29/04

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K041934/A1

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; (Noitify company to submit a new 510(k);[Prepare the K30 Letter on the LAN]

__X__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: Felix Lloyd - FXA

Date: 12/1/04

Draft #2 : 9/8/99
Draft #3: 1/3/00
Draft #4: 3/7/03

3M Health Care Business

3M Center
St. Paul, MN 55144-1000
651 733 1110

K041934/A-1

November 23, 2004

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: Copies of Correspondence for Official 510(k) Premarket Notification File for 3M™ Littmann® Electronic Stethoscope, Model 3000 (K041934)

Dear Sir or Madam:

Please find enclosed in duplicate copies of 3M's correspondence with our CDRH reviewer, Dr. Felipe Aguel, dated September 28, 2004 and October 13, 2004 pertaining to 3M's 510(k) for the 3M™ Littmann® Electronic Stethoscope, Model 3000 (K041934). This correspondence comprises 3M's official responses to Dr. Aguel's electronic mail requests for additional information that he sent to 3M during the review of 3M's 510(k) application.

At Dr. Aguel's direction 3M's response was submitted directly to his attention, and inadvertently copies were not additionally sent to the official 510(k) file via attention of the Document Control Center. With submission of these copies, the 510(k) file for K041934 will be complete. Please note that 3M received a 510(k) SE clearance letter from CDRH for K041934 on October 15, 2004.

3M considers the information provided under this submission to be 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.

Should you have any questions regarding this submission, I may be contacted via any of the means below.

Sincerely,

Ginger Cantor

Ginger Cantor
3M Health Care Regulatory Affairs
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000
Phone (651) 736-2101
Fax: (651) 737-5320
grcantor@mmm.com

SK13

2

3M Health Care

3M Center
St. Paul, MN 55144-1000
612 733 1110

September 28, 2004

Felipe Aguel, Ph.D.
Staff Fellow
Food and Drug Administration
CDRH/ODE/DCD/CEMB
HFZ-450
9200 Corporate Blvd.
Rockville MD 20850

SUBJECT: Official Response to Request for Information E-mail of September 21, 2004 regarding review of the 510(k) 3M Littmann® Electronic Stethoscope Model 3000, K041934

Dear Dr. Aguel,

Please find enclosed 3M's official response to your e-mail of September 21, 2004 regarding the review 3M's 510(k) application for the 3M Littmann® Electronic Stethoscope Model 3000 (K041934). Your comments are presented in bold, with 3M's response directly below.

1. One of the functional differences between your device and the predicate device is the lack of an 'extended range' mode. As a result, the user can amplify sounds in the range of 20-200Hz or 100-500 Hz, but not sounds of frequencies higher than 500Hz. Please either
- include in the labeling:
a. which sounds can be heard in each mode and
b. a warning that sounds of frequencies higher than 500Hz will not be heard through this device.

3M disagrees with the statement that sounds above 500 Hz cannot be amplified on the 3M Littmann® Electronic Stethoscope Model 3000.

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

[redacted]

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

[redacted]

2. As of December 2003, FDA has been requesting the use of the attached indications for use form. Please note that the sponsor, not FDA, now indicates whether the device is for OTC and/or prescription use. Please fill out the attached form and send it to me either via email or fax (301 594 3076).

Please find enclosed a revised "Indications for Use" Statement attached to this submission.

If you have any comments or require additional clarification regarding this submission, please contact me directly using the contact information listed below.

Respectfully submitted,

Ginger Cantor
Senior Regulatory Affairs Associate
3M HealthCare, Medical Division
3M Center, Building 275-5W-06
St. Paul, MN 55144-1000
Phone: (651) 736-2101
Fax: (651) 737-5320
grcantor@mmm.com

Indications for Use Statement

510(k) Number (if known): K041934

Device Name: 3M™ Littmann® Electronic Stethoscope Model 3000

Indications for Use:
The 3M™ Littmann® Electronic Stethoscope Model 3000 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of 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 _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

3M Health Care Business

3M Center
St. Paul, MN 55144-1000
651 733 1110

October 13, 2004

Felipe Aguel, Ph.D.
Staff Fellow
Food and Drug Administration
CDRH/ODE/DCD/CEMB
HFZ-450
9200 Corporate Blvd.
Rockville MD 20850

SUBJECT: Official Response to Request for Information E-mail of October 13, 2004 regarding review of the 510(k) 3M Littmann® Electronic Stethoscope Model 3000, K041934

Dear Dr. Aguel,

In response to your e-mail of October 13, 2004 regarding the review of 3M's 510(k) application for the 3M Littmann Electronic Stethoscope Model 3000 (K041934), please find enclosed 3M's official response for your review files.

Your comments are presented in bold, with 3M's response directly below.

On the "Indications for Use" Form you emailed and later mailed in response to my inquiries, you've checked the "over-the-counter use" box. However, the predicate devices have been cleared for prescription use only. Please either:

- provide an updated indications for use form (please use the attached updated form) with only the 'prescription use' box checked and include "prescription use only" statement in the labeling

OR
- provide the 510(k) number of an alternate predicate device that has been cleared for over the counter use.

3M's analysis of competitors who have marketed electronic stethoscopes shows that while many are labeled as prescription devices, Andromed Inc. holds three more recently cleared 510(k)s for electronic stethoscopes that were "checked off" or "designated" by CDRH for OTC use. 3M's indications for use for the Littmann Electronic Stethoscope Model 3000 are substantially equivalent to the indications for use for these three specific Andromed devices.

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.

Additionally, please find enclosed in this submission a second revised "Indications for Use Statement" for the Littmann Electronic Stethoscope, Model 3000, with the correct "over-the-line/under-the-line" breakdown.

If you have any comments or require additional clarification regarding this submission, please contact me directly using the contact information listed below.

Respectfully submitted,

Ginger Cantor
Senior Regulatory Affairs Associate
3M HealthCare, Medical Division
3M Center, Building 275-5W-06
St. Paul, MN 55144-1000
Phone: (651) 736-2101
Fax: (651) 737-5320
grcantor@mmm.com

Indications for Use

510(k) Number (if known): K041934

Device Name: 3M™ Littmann ® Electronic Stethoscope Model 3000

Indications For Use:
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(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

BUCKMAN
COMPANY INCORPORATED

200 Gregory Lane, Suite C-100, Pleasant Hill, CA 94523-3389
(925) 356-2640 ■ FAX (925) 356-2654

November 15, 2004

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD. 20850

Re: K032786
OXYSWING® OXYGEN CONCENTRATORS

Dear Document Control:

Following discussions with the FDA reviewers, and at their recommendation, we are requesting an extension of the time required to respond to FDA questions. This letter serves as our second request for a time extension. We believe we need an additional 90 days within which to provide the necessary information. Thank you for your assistance.

Buckman Company, Inc. is the official correspondent for IGS Gas Systems for this submission. Please direct any questions or correspondence about this submission to my attention at the telephone number or address indicated.

Sincerely,

David Schlerf, Buckman Company, Inc.

DWS/db

cc: Mr. John Jensvold, Research Manager, Generon IGS

12/2/04 - spoke on phone - Jus
No resp - Add to File

SK21

9

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2004

3M Company
c/o Ms. Ginger Cantor
Senior Regulatory Affairs Associate
3M Healthcare
3M Center, Bldg 275-5W-06
St Paul, MN 55144-1000

Re: K041934
Trade Name: 3M Littman Electronic Stethoscope, Model 3000
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: July 16, 2004
Received: July 19, 2004

Dear Ms. Cantor:

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.

1

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 (301) 594-4648. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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): K041934

Device Name: 3M™ Littmann ® Electronic Stethoscope Model 3000

Indications For Use:
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Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Hammerman

on Sign-Off)
n of Cardiovascular Devices
Number K041934

3M Health Care Business

3M Center
St. Paul, MN 55144-1000
651 733 1110

October 13, 2004

Felipe Aguel, Ph.D.
Staff Fellow
Food and Drug Administration
CDRH/ODE/DCD/CEMB
HFZ-450
9200 Corporate Blvd.
Rockville MD 20850

SUBJECT: Official Response to Request for Information E-mail of October 13, 2004 regarding review of the 510(k) 3M Littmann® Electronic Stethoscope Model 3000, K041934

Dear Dr. Aguel,

In response to your e-mail of October 13, 2004 regarding the review of 3M's 510(k) application for the 3M Littmann Electronic Stethoscope Model 3000 (K041934), please find enclosed 3M's official response for your review files.

Your comments are presented in bold, with 3M's response directly below.

On the "Indications for Use" Form you emailed and later mailed in response to my inquiries, you've checked the "over-the-counter use" box. However, the predicate devices have been cleared for prescription use only. Please either:

- provide an updated indications for use form (please use the attached updated form) with only the 'prescription use' box checked and include "prescription use only" statement in the labeling

OR
- provide the 510(k) number of an alternate predicate device that has been cleared for over the counter use.

3M's analysis of competitors who have marketed electronic stethoscopes shows that while many are labeled as prescription devices, Andromed Inc. holds three more recently cleared 510(k)s for electronic stethoscopes that were "checked off" or "designated" by CDRH for OTC use. 3M's indications for use for the Littmann Electronic Stethoscope Model 3000 are substantially equivalent to the indications for use for these three specific Andromed devices.

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.
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3) Stethos Electronic Stethoscope, (K001306) cleared as substantially equivalent on July 20, 2000.

Additionally, please find enclosed in this submission a second revised "Indications for Use Statement" for the Littmann Electronic Stethoscope, Model 3000, with the correct "over-the-line/under-the-line" breakdown.

If you have any comments or require additional clarification regarding this submission, please contact me directly using the contact information listed below.

Respectfully submitted,

Ginger Cantor
Senior Regulatory Affairs Associate
3M HealthCare, Medical Division
3M Center, Building 275-5W-06
St. Paul, MN 55144-1000
Phone: (651) 736-2101
Fax: (651) 737-5320
grcantor@mmm.com

Indications for Use

510(k) Number (if known): K041934

Device Name: 3M™ Littmann ® Electronic Stethoscope Model 3000

Indications For Use:
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Prescription Use _____ AND/OR Over-The-Counter Use ____X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 19, 2004

3M COMPANY
3M HEALTH CARE
3M CENTER, BLDG. 275-5W-06
ST. PAUL, MN 55144
ATTN: GINGER CANTOR

510(k) Number: K041934
Received: 19-JUL-2004
Product: 3M LITTMANN ELECTRONIC STETHOSCOPE, MODEL 3000

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". 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. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

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 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.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

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

3M Health Care

3M Center
St. Paul, MN 55144-1000
651 733 1110

K041939

July 16, 2004

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

FDA/CDRH
2004 JUL 19 A 8:10

Re: Traditional 510(k) Premarket Notification for the 3M™ Littmann® Electronic Stethoscope Model 3000

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 3000 will be shown to be substantially equivalent to the 3M™ Littmann® Electronic Stethoscope Model 4000 and the Littmann® Electronic Stethoscope Model 2000.

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.

A wire transfer of (b)(4) was made to FDA on July 1, 2004 in support of this submission, and 3M's Medical Device User Fee Payment Identification Number for this submission is (b)(4). Should you have any questions regarding this submission, please contact me at the phone number listed below.

CV II

Sincerely,

Ginger Cantor

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

Phone (651) 736-2101
Fax: (651) 737-5320
grcantor@mmm.com

SK05

3M Health Care

3M Center
St. Paul, MN 55144-1000
651 733 1110

July 16, 2004

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 3000

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

Phone (651) 736-2101
Fax: (651) 737-5320
grcantor@mmm.com

3M Health Care

3M Center
St. Paul, MN 55144-1000
651 733 1110

3M

July 16, 2004

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 3000

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Sincerely,

Ginger Cantor

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

Phone (651) 736-2101
Fax: (651) 737-5320
grcantor@mmm.com

Form Approved:OMB No. 0910-0511 Expiration Date: August 31, 2006. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade [redacted]
Write the Payment Identification Number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)

3M HEALTH CARE
3M CENTER
BUILDING 275-5W-06
ST. PAUL, MN 55144-1000

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
410417775

2. CONTACT NAME
GINGER CANTOR

2.1 E-MAIL ADDRESS
grcantor@mmm.com

2.2 TELEPHONE NUMBER (Include Area Code)
651-736-2101

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)
651-737-5320

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:

- ☑ Premarket notification (510(k)); except for third party reviews
- ☐ Biologics License Application (BLA)
- ☐ Premarket Approval Application (PMA)
- ☐ Modular PMA
- ☐ Product Development Protocol (PDP)
- ☐ Premarket Report (PMR)

3.1 Select one of the types below:

- ☑ Original Application

Supplement Types:

- ☐ Efficacy (BLA)
- ☐ Panel Track (PMA, PMR, PDP)
- ☐ Real-Time (PMA, PMR, PDP)
- ☐ 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
- ☑ NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. 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, parents, and partner firms
- ☐ 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

6. 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 ☑ NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)

(b)[redacted]

Form FDA 3601 (08/2003)

CDRH SUBMISSION COVER SHEET

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: July 16, 2004

FDA Document Number:

Section A Type of Submission

- ☒ 510(k)
- ☐ 510(k) Add'l Information
- ☐ Track
- ☐ IDE
- ☐ IDE Amendment
- ☐ IDE Supplement
- ☐ IDE Report
- ☐ PMA
- ☐ PMA Amendment
- ☐ PMA Report
- ☐ PMA Supplement - Panel
- ☐ PMA Supplement – Regular
- ☐ PMA Supplement – Special
- ☐ PMA Supplement - 30 day

Section B1 Reason for Submission: 510(k)s Only

- ☒ New Device
- ☐ Additional or expanded Indications
- ☐ Change in technology, design, materials, or manufacturing process
- ☐ Other reason (specify):

Section B2 Reason for Submission: PMAs Only

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Labeling, change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify):
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive

  Other (specify below)
- ☐ Process change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Response to FDA correspondence (specify below)
- ☐ Request for applicant hold
- ☐ Request for extension
  - ☐ Request to remove or add manufacturing site
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment

Section B3 Reason for Submission: IDEs Only

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Emergency use:
  - ☐ Notification of emergency use
  - ☐ Additional information
- ☐ Other reason (specify):
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing
  - ☐ Protocol - feasibility
  - ☐ Protocol – other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ 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
- ☐ IOL submissions only:
  - ☐ Change in IOL style
  - ☐ Request for protocol waiver

Date of Submission: July 16, 2004	FDA Document Number:

Section C Product Classification

Product code: DQD suggested	CFR Classification: 870.1875(b)	Device Class:
Classification Panel:		☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Section D Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data: ☒ 510(k) Summary attached ☐ 510(k) Statement
1 DQD	2	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K003723	1 3M™ Littmann® Electronic Stethoscope Model 4000	1 3M Health Care
2 K961848	2 3M™ Littmann® Electronic Stethoscope Model 2000	2 3M Health Care
3	3	3
4	4	4
5	5	5

Section E: Product Information - Applicable to All Applications

Common or usual name or classification name:

Trade or proprietary or model name:	Model number
1 3M™ Littmann® Electronic Stethoscope Model 3000	1 Model 3000
2	2
3	3

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

1 None	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☒ Laboratory testing ☐ Animal trials ☐ Human trials

Indications (from labeling): See "Indications for Use" statement, page x.

Date of Submission: July 16, 2004	FDA Document Number:

Section F Manufacturing / Packaging / Sterilization Sites

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number: 2110898	☒ Manufacturer ☐ Contract manufacturer	☐ Contract Sterilizer ☐ Repackager/relabeler

Company/Institution Name: 3M Company	
Division Name (if applicable): 3M Health Care	Phone Number (include area code): (651) 733-4365
Street address: 3M Center, Bldg 275-5W-06	Fax Number (include area code): (651) 737-0230

City: St. Paul	State: MN	Country: USA	Zip code: 55144-1000

Contact name: Suzanne M. Danielson
Contact title: Director, Regulatory Affairs and Quality

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number: (b)(4)Trade Secret	☐ Manufacturer ☒ Contract manufacturer	☐ Contract Sterilizer ☐ Repackager/relabeler

Company/Institution Name: (b)(4)Trade Secret Process-)	
Plant Name: [redacted] (b) [redacted]	Phone Number (include area code): (b)(4)Trade
Street address: (b)(4)Trade	Fax Number (include area code): 45-9684-5701

City: (b)	State: (b)(4)Trade	Country (b)	Zip code: (b)

Contact name: (b)(4)Trade
Contact title: (b)(4)Trade Secret

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number: 2183581	☒ Manufacturer ☐ Contract manufacturer	☐ Contract Sterilizer ☐ Repackager/relabeler

Company/Institution Name: 3M Company (final device assembly, packaging, labeling)	
Division Name (if applicable):	Phone Number (include area code): 651-733-4365
Street address: 1617 North Front Street	Fax Number (include area code): 651-737-0230

City: New Ulm	State: MN	Country: USA	Zip code: 56073

Contact name: Suzanne M. Danielson
Contact title: Director, Regulatory Affairs and Quality

Date of Submission: July 16, 2004	**FDA Document Number:**		
Section G Applicant or Sponsor			
Company/Institution name: 3M Company			**FDA Establishment Number:** 2110898
Division name (if applicable): 3M Health Care			**Phone Number (include area code):** (651) 736-2101
Street address: 3M Center, Bldg 275-5W-06			**Fax Number (include area code):** (651) 737-5320
City: St. Paul	**State:** Minnesota	**Country:** USA	**Zip code:** 55144-1000
Signature: Ginger Cantor			
Contact name: Ginger Cantor			
Contact title: Senior Regulatory Affairs Associate			
Section H Submission correspondent (if different from above)			
Company/Institution name: N/A			**FDA Establishment Number:**
Division name (if applicable):			**Phone Number (include area code):**
Street address:			**Fax Number (include area code):**
City:	**State:**	**Country:**	**Zip code:**
Contact name:			
Contact title:			

510(k) Premarket Notification

for

3M™ Littmann® Electronic Stethoscope, Model 3000

Submitted by

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

Submission Date:
July 16, 2004

Contact: Ginger Cantor
Contact's Phone: (651) 736-2101
Contact's Fax: (651) 737-5320
Contact's Email: grcantor@mmm.com

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Appendix 10 Model 3000 Labeling
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Appendix 12 Model 3000 Biocompatibility

Indications for Use Statement

See corrected form in correspondence dated 10/13/06

510(k) Number (if known):_____

Device Name: 3M™ Littmann® Electronic Stethoscope Model 3000

Indications for Use:

The 3M™ Littmann® Electronic Stethoscope Model 3000 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of 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 ___

Truthful and Accurate Statement

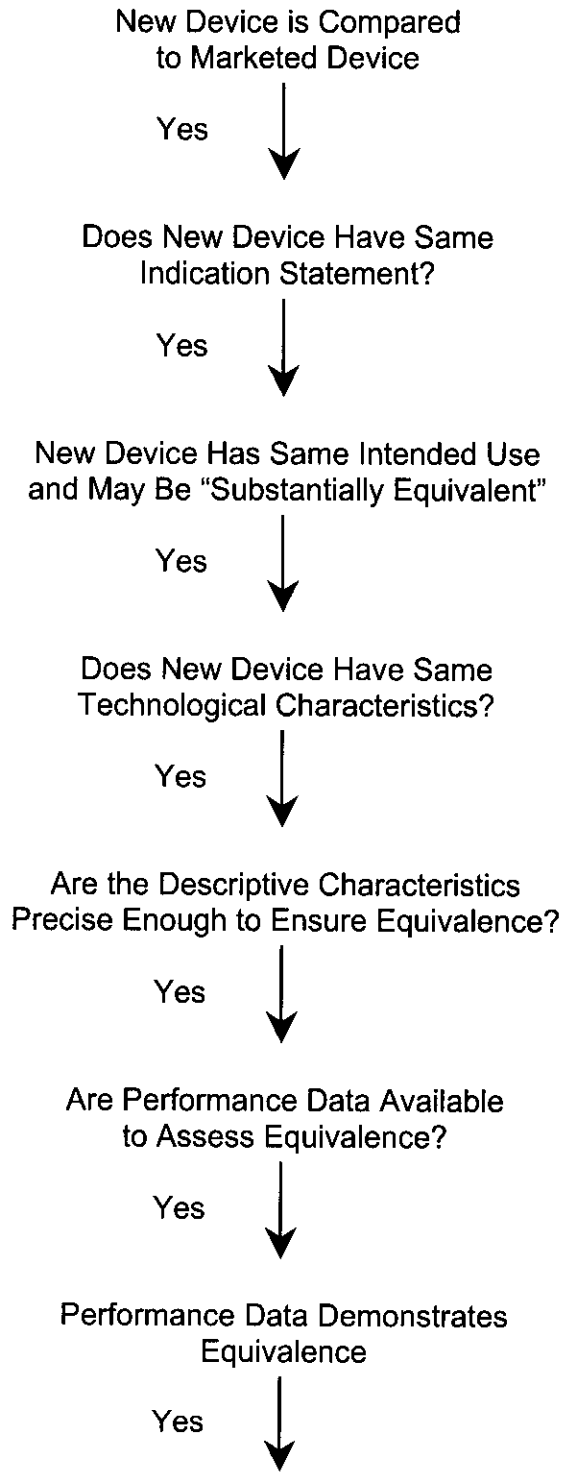
Pursuant to 21 CFR §807.87(k), I certify that, in my capacity as Senior Regulatory Affairs Associate for 3M Health Care, I believe to the best of my knowledge, that all data and information submitted in this Premarket Notification are truthful and accurate and that no material fact has been omitted.

Ginger Cantor
Signature

Ginger Cantor
Typed Name

July 16, 2024
Date

510(k) Decision-Making Process Flowchart



Premarket Notification (510(k)) Summary

1. Sponsor Information:

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

Contact Person:	Ginger Cantor Senior Regulatory Affairs Associate
Phone Number:	(651) 736-2101
FAX Number:	(651) 737-5320

Date of Summary: July 16, 2004

2. Device Name and Classification:

Common or Usual Name:	Electronic Stethoscope
Proprietary Name:	3M™ Littmann® Electronic Stethoscope, Model 3000
Classification Name:	Electronic Stethoscope (21 CFR § 870.1875(b))
Performance Standards:	None

3. Predicate Device:

3M™ Littmann® Electronic Stethoscope, Model 4000
3M™ Littmann® Electronic Stethoscope, Model 2000

4. Description of Device:

The 3M™ Littmann® Electronic Stethoscope, Model 3000 is a healthcare device that picks sounds of the heart, arteries, veins, lung and other internal organs, electronically amplifies, filters, and transfers them to the user's ears via an active speaker and passive sound tubes. The Model 3000 provides two filter frequency modes for auscultation: Bell (20-200 Hz) and Diaphragm (100-500 Hz).

The Model 3000 incorporates embedded software. The embedded software controls all of the various features found in the Model 3000 stethoscope, such as volume control and frequency mode selection. In addition, the embedded software provides digital signal processing (DSP) over the entire acoustic range of the stethoscope; DSP produces the bell and diaphragm frequency response modes that are used to listen to heart, lung, and other body sounds.

The Model 3000 does not incorporate any off-the-shelf (OTS) software.

The Model 3000 operates on one (1) AAA alkaline battery.

5. Indications for Use:

The 3M™ Littmann® Electronic Stethoscope Model 3000 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of 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.

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

The table below illustrates the similarities and differences of the new device (Model 3000) to the predicate devices (Model 4000 and Model 2000). The Model 3000 proposed under this new pre-market notification submission is composed of similar materials, and has similar performance features, intended use and indications for use as the Model 4000 cleared under K003723, and the Model 2000, cleared under K961848.

Comparison of Performance Features Littmann® Electronic Stethoscope Model 3000 versus Littmann® Electronic Stethoscope Model 4000 and Littmann® Electronic Stethoscope Model 2000

Performance Features	Model 3000 (New Device)	Model 4000 (Predicate Device) K003723	Model 2000 (Predicate Device) K961848
Frequency Response	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.	Bell (20-200 Hz), Diaphragm (100-500 Hz) and Extended Range (100-1000 Hz) modes.
Amplification	Up to 25 dB acoustic gain, equivalent to 18 times amplification.	Up to 25 dB acoustic gain, equivalent to 18 times amplification.	Up to 20 dB acoustic gain, equivalent to 14 times amplification.
Maximum Sound Level	140 dB SPL Max	140 dB SPL Max	140 dB SPL Max
Power Source	One (1) (AAA) alkaline battery	Two (2) (AAA) alkaline batteries	One (1) (AAA) alkaline battery
Low Battery Indicator	Includes a low battery indicator	Includes a low battery indicator	Includes a low battery indicator
Displays Heart Rate	No	Yes	No
Record and Playback Sounds	No	Yes	No
Permits Data Transfer of Stored Digital Signals to and from IBM-Compatible PC and Pocket PC and Palm Pilot*	No	Yes	No
Volume Control	8 Step Volume Control	8 Step Volume Control	Continuous Variable
ON/OFF Switch Automatic Shut-off by Electronics	Yes	Yes	Yes

*** With Infrared Port and Windows /98/2000/XP, Pocket PC 2002/2003 and Palm OP Sys 4/5**
Microsoft® and Windows™ are registered trademarks of Microsoft Corporation.

7. Non-clinical (Biocompatibility) Summary:

All components of the Model 3000 stethoscope have been reviewed 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.

The Littmann® Electronic Stethoscope Model 3000 is composed of the same or substantially equivalent materials as those in the Littmann® Electronic Stethoscope Model 4000 cleared under K003723, and the Littmann® Electronic Stethoscope Model 2000, cleared under K961848.

3M concludes that all of the components of the Model 3000 Stethoscope would have minimal potential for any adverse health concern.

1.0 General Device and Establishment Information

1.1 Device Proprietary Name

3M™ Littmann® Electronic Stethoscope, Model 3000

1.2 Device Common Name

Electronic Stethoscope

1.3 Device Classification and Product Code

Electronic Stethoscope, Class II (21 CFR §807.1875(b))
Product Code: DQD (Electronic Stethoscope) suggested

1.4 Establishment Information

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 chestpiece of the 3M™ Littmann® Electronic Stethoscope Model 3000 is contract manufactured for 3M by:

(b) (4) [redacted]

Final assembly, testing, and release of this device will be performed at the following 3M facility:

3M Company
1617 North Front Street
New Ulm, MN 56073
USA
FDA Registration No.: 2183581

1.5 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.

1.6 Voluntary Standards

Although there are no specific performance standards for this device, the device was tested for compliance with voluntary standards (i.e. for general safety, EMC, and environmental testing). Testing and results are summarized in Tables 1 through 3 below, with complete reports and certification of testing included in Appendices 1-3.

All general safety testing of the Model 3000 was performed by UL International Demko A/S (an affiliate of Underwriters Laboratories, Inc). UL International Demko A/S is an appointed Competent Body for EMC testing in Denmark.

Testing for compliance with the voluntary EMC standard was conducted by Delta Dansk Elektronik, Lys & Akustik; Delta's EMC department is certified to ISO17025, "*General Requirements for the Competence of Testing and Calibration Laboratories*" and Delta has been appointed as a Competent Body for EMC testing in Denmark.

Twenty-nine (29) devices were subjected to environmental testing as part of design verification testing, as summarized in Table 3. Each device was acoustically tested after the completion of the environmental testing to confirm acoustical performance.

Table 1 Medical Electrical Equipment Voluntary Standard

Standard	Title	Acceptance Criteria Test Report	Third Party Certification Yes or No Proof of Document (as Applicable)
IEC 60601-1:1998 + A1:1991 + A2: 1995 EN60601-1:1990 + A1:1993+ A2:1995+A13: 1996 (except EMC limitations: EN60601-1-2, Biocompatibility, EN10993-1)	Medical Electrical Equipment – Part 1: General Requirements for Safety	Passed (Report No. E249052-A1-CB-1; refer to Appendix 1)	Yes; Certificate Issued by UL International DEMKO A/S. Appendix 1 contains a copy of third party certification issued by DEMKO: Certificate No. DK-8002

Table 2 Model 3000 Electromagnetic Compatibility Testing Summary

Standard	Title	Acceptance Criteria Test Report	Third Party Certification Yes or No Proof of Document (as Applicable)
IEC 60601-1-2:2001 Sections 3 and 36 EN 60601-1-2:2001 Sections 3 and 36	Medical Electrical Equipment Part 1-2: General Requirements for Safety- Collateral Standard: Electromagnetic Compatibility- Requirements and Tests	Passed; Test report DANAK- 19k0188	Yes; Refer to Appendix 2 for copy of test report DANAK-19k0188 and Delta Test Certificate No. 655
EN 55011B	RF-Field Emission (Electromagnetic Disturbance of ISM Equipment)	Passed; Test report DANAK- 19k0188	Yes; Refer to Appendix 2 for copy of test report DANAK-19k0188 and Delta Test Certificate No. 655
EN 61000-4-2	Electrostatic Discharge	Passed; Test report DANAK- 19k0188	Yes; Refer to Appendix 2 for copy of test report DANAK-19k0188 and Delta Test Certificate No. 655
EN 61000-4-3	RF-Field, Immunity	Passed; Test report DANAK- 19k0188	Yes; Refer to Appendix 2 for copy of test report DANAK-19k0188 and Delta Test Certificate No. 655
EN 61000-4-8	50 Hz Magnetic Field	Passed; Test report DANAK- 19k0188	Yes; Refer to Appendix 2 for copy of test report DANAK-19k0188 and Delta Test Certificate No. 655

Table 3 Model 3000 Environmental Testing

Test	Reference Standard	Exposure Conditions	Acceptance Criteria	Test Result (Pass/Fail)*	Documentation (Report) Reference(s)
Cold Function	IEC 60068-2-1	-10°C	Must pass functional test defined in Design Verification Protocol Eer200338b	Pass	Eer0428a (Refer to Appendix 3 for copy of Protocol Eer200338b and Report Eer0428a)
Cold Storage	IEC60068-2-1	-26.5C, 96 hours	Must pass functional test and visual inspection as defined in Design Verification Protocol Eer200338b	Pass	Eer0428a (Refer to Appendix 3 for copy of Protocol Eer200338b and Report Eer0428a)
Heat Function	IEC 60068-2-2	+50°C	Must pass functional test defined in Design Verification Protocol Eer200338b	Pass	Eer0428a (Refer to Appendix 3 for copy of Protocol Eer200338b and Report Eer0428a)
Heat Storage Test	IEC60068-2-2	+55°C, 96 hours	Must pass functional test and visual inspection as defined in Design Verification Protocol Eer200338b	Pass	Eer0428a (Refer to Appendix 3 for copy of Protocol Eer200338b and Report Eer0428a)
Damp Cyclic Heat Test	IEC60068-2-30	+25°C for 12 hours, +40°C for 12 hours, 93% RH, 2 cycles	Must pass functional test defined in Design Verification Protocol Eer200338b	Fail*	Eer0428a (Refer to Appendix 3 for copy of Protocol Eer200338b and Report Eer0428a)

Table 3 Model 3000 Environmental Testing

Test	Reference Standard	Exposure Conditions	Acceptance Criteria	Test Result (Pass/Fail)*	Documentation (Report) Reference(s)
Thermal Shock Test	IEC60068-2-14 Test N	From –26.5°C for 3 hours, to +40°C for 3 hours, 5 cycles	Must pass functional test defined in Design Verification Protocol Eer200338b	Pass	Eer0428a (Refer to Appendix 3 for copy of Protocol Eer200338b and Report Eer0428a)
Drop Test with Portable Device	IEC60068-2-32 (refer also to procedure MF3a in Protocol Eer200338b in Appendix 3	(b) (4)	Must pass functional test defined in Design Verification Protocol Eer200338b	Pass	Eer0428a (Refer to Appendix 3 for copy of Protocol Eer200338b and Report Eer0428a)
Lifetime testing	Design Test (refer to Protocol Eer200338b in Appendix 3)	Lifetime test based on (b auscultatory exams per day, (minutes per exam and (work days a week. Average of(depressions of each button per auscultatory exam; (drop from shoulder of clinician per week, (b minor impacts per day (bumping on bed rail or table edge)	All devices must pass this test; frequency response and all safety issues must be acceptable after test. Visual defects, such as scratches, small cracks and wear marks are allowed.	Pass	Eer0428a (Refer to Appendix 3 for copy of Protocol Eer200338b and Report Eer0428a)

* It is important to note that five (5) of the twenty-nine (29) devices did not pass the requirements for cyclic heat testing according to IEC 60068-2-30 *Basic Environmental Testing: Procedures, Part 2- Tests, Test dB and Guidance: Damp Heat, Cyclic (12+ 12 hours)*. The initial tests indicate that the sensor, where electrical connections are adhered together, became unadhered between the flat cable and the actual sensor. The failure would result in very low or no stethoscope sound. As a result of the failure, 3M will modify the device by replacing the adhesive used to make the connection with a more robust adhesive.

3M assessed the impact of this modification on device safety and efficacy. With regard to device safety, 3M believes this design modification has no significant impact on the safety or efficacy of the device for the following reasons. First, there is no potential for this adhesive to contact either the physician or the patient, since the adhesive remains entirely inside the diaphragm and is completely cured. Second, the device is to be used as a diagnostic aide and does not make a 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.

With regard to efficacy of the device, 3M's assessment is that the change in adhesive used to secure and electrically connect the sensor would have no impact on the performance characteristics listed in Section 3.0 of this submission. However as part of our design control/design verification procedures under our quality system, 3M will confirm that the modification does not affect the frequency response of the Model 3000 and will perform the testing identified in Tables 4 and 5 on the modified device (i.e. with the new adhesive) prior to commercialization of the device, to ensure that the product meets its claimed performance specifications.

Table 4 Modified Model 3000 Planned Verification Testing

Test	Reference Standard	Exposure Conditions	Acceptance Criteria
Lifetime testing	Design Test (refer to Protocol Eer200338b in Appendix 3)	Lifetime test based on (b) auscultatory exams per day, (minutes per exam and (work days a week. Average of(depressions of each button per auscultatory exam; (drop from shoulder of clinician per week, (minor impacts per day (bumping on bed rail or table edge)	All devices must pass this test; frequency response and all safety issues must be acceptable after test. Visual defects, such as scratches, small cracks and wear marks are allowed.
Cold Function	IEC 60068-2-1	-10°C	Must pass functional test defined in Design Verification Protocol Eer200338b (refer to Appendix 3)
Cold Storage	IEC60068-2-1	-26.5°C, 96 hours	Must pass functional test and visual inspection as defined in Design Verification Protocol Eer200338b (refer to Appendix 3)

Table 4 Modified Model 3000 Planned Verification Testing

Test	Reference Standard	Exposure Conditions	Acceptance Criteria
Heat Function	IEC 60068-2-2	+50°C	Must pass functional test defined in Design Verification Protocol Eer200338b (refer to Appendix 3)
Heat Storage Test	IEC60068-2-2	+55°C, 96 hours	Must pass functional test and visual inspection as defined in Design Verification Protocol Eer200338b (refer to Appendix 3)
Damp Cyclic Heat Test	IEC60068-2-30	+25°C for 12 hours, +40°C for 12 hours, 93% RH, 2 cycles	Must pass functional test defined in Design Verification Protocol Eer200338b (refer to Appendix 3)
Thermal Shock Test	IEC60068-2-14 Test N	From –26.5°C for 3 hours, to +40°C for 3 hours, 5 cycles	Must pass functional test defined in Design Verification Protocol Eer200338b (refer to Appendix 3)
Drop Test with Portable Device	IEC60068-2-32 (refer also to procedure MF3a in Protocol Eer200338b in Appendix 3	IEC60068-2-32 (b)(4)Trade [redacted] Test method MF3a included in Protocol Eer200338b)	Must pass functional test defined in Design Verification Protocol Eer200338b (refer to Appendix 3)

Table 5 Modified Model 3000 Planned Transport Related Testing

Test	Reference Standard	Exposure Conditions	Acceptance Criteria
Chestpiece subassembly and bulk packaging transport testing	ASTM D5276/94 D4169 D999/91 D4278	Per ASTM Standards D5276/94 D4169 D999/91 D4278	Must pass functional test defined in Design Verification Protocol Eer200338b (refer to Appendix 3)
Transport simulation, packed device, bulk packaging	ASTM 999	ASTM 999	Must pass functional test defined in Design Verification Protocol Eer200338b (refer to Appendix 3)
Sinusoidal vibration test with packed device (bulk packaging)	IEC60068-2-36	IEC60068-2-36 (b)(4)Trade Test method SV6 included in Protocol Eer200338b)	Must pass functional test defined in Design Verification Protocol Eer200338b (refer to Appendix 3)
Bump test of packed device (bulk packaging)	IEC60068-2-29	IEC60068-2-29 (b)(4)Trade Test method SB1 included in Protocol Eer200338b)	Must pass functional test defined in Design Verification Protocol Eer200338b (refer to Appendix 3)
Drop test with packed device (bulk packaging)	ASTM D5276	ASTM D5276 (b)(4)Trade Test method MF1 included in Protocol Eer200338b)	Must pass functional test defined in Design Verification Protocol Eer200338b (refer to Appendix 3)

2.0 Device Description

2.1 Introduction and Technology Overview

The 3M™ Littmann® Electronic Stethoscope, Model 3000 is a healthcare device that picks sounds of the heart, arteries, veins, lung and other internal organs, electronically amplifies, filters, and transfers them to the user's ears via an active speaker and passive sound tubes. The Model 3000 provides two filter frequency modes for auscultation: Bell (20-200 Hz) and Diaphragm (100-500 Hz).

The Model 3000 incorporates embedded software. The embedded software controls all of the various features found in the Model 3000 stethoscope, such as volume control and frequency mode selection. In addition, the embedded software provides digital signal processing (DSP) over the entire acoustic range of the stethoscope; DSP produces the bell and diaphragm frequency response modes that are used to listen to heart, lung, and other body sounds.

The Model 3000 does not incorporate any off-the-shelf (OTS) software.

The Model 3000 operates on one (1) AAA alkaline battery.

Note that because the Model 3000 incorporates embedded software, 3M reviewed the ODE Document *"Guidance of the Content of Pre-market Submissions for Software Contained in Medical Devices"* issued May 29, 1998. 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.

2.2 Software Level of Concern

(Per Office of Device Evaluation (ODE) Document *"Guidance of the Content of Pre-market Submissions for Software Contained in Medical Devices"* issued May 29, 1998)

FDA Question 1): Does the device software control a life-supporting or life-sustaining device?

3M response to 1): No. The device software does not control a life-supporting or life-sustaining device. The Model 3000 stethoscope is not intended to support or sustain life.

FDA Question 2): Does the device software control the delivery of potentially harmful energy, which could result in death or serious injury, such as radiation treatment systems, defibrillators, and so forth?

3M response to 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 level to not exceed 140 dB.

FDA Question 3): Does the device software control treatment delivery, such that an error or malfunction with the delivery could result in death or serious injury?

3M Response to 3) No. The embedded software does not control any treatment delivery. In addition, the device (Model 3000 stethoscope) is not intended to control treatment delivery.

FDA Question 4):

Does the device provide diagnostic information on which treatment or therapy is based, such that if misapplied it could result in serious injury or death?

3M Response to 4):

No. 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.

FDA Question 5):

Does the device software provide vital signs monitoring and alarms for potentially life-threatening situations in which intervention is necessary?

3M Response to 5):

No. The Model 3000 Stethoscope does not provide vital signs monitoring. Therefore, the need for an alarm is not applicable.

FDA Question 6):

Does the software directly affect the patient so that failures or latent design flaws could result in death or serious injury to the patient, or does it indirectly affect the patient such that incorrect or delayed information could result in death or serious injury to the patient?

3M Response to 6):

No. The patient is not at risk for serious injury or death either directly or indirectly based on the embedded software. The risk to the patient due to software malfunction or failure is low to none because the health care practitioner also depends on other assessment devices and on the patient's vital signs and physical appearance to make a diagnosis.

Summary:

Based on the questions noted above and the response of "no" to all questions, 3M considers the level of concern to be "Minor". According to the ODE Guidance Document, *"Content of Pre-market Submissions for Software Contained in Medical Devices"* issued May 29, 1998. The definition of "Minor" is as follows: "the level of concern is minor if failures or latent design flaws would not be expected to result in any injury to the patient and/or operator."

As summarized in Table 6 below, because 3M determined that the Level of Concern is "Minor", 3M has provided the documentation required according to Table 1 of Section 3 of the ODE document.

Minor revisions to software are not uncommon during software development, and these changes to the embedded software are reflected in the enclosed software documentation as references to different revision levels tested (e.g. 1.01, 1.02, etc.). The final version of software in this device is version 1.04; this version was fully tested and passed the final software acceptance test requirements detailed in document CBS0425a (refer to Appendix 8).

Table 6 Software Documentation Required in the Premarket Submission

ODE Guidance Document Section Number(s)	Software Documentation	"Minor" Concern Documents Required in a 510(k) submission	Proof of Compliance
2, 3.1	Level of Concern	Required in Submission	Level of Concern is included above.
3.2	Software Description	Required in Submission	CAJ0406A [redacted](Software Design document, version 1.0) Refer to Appendix 4 of this submission for complete documentation.
3.3, 4.3	Device Hazard Analysis	Required in Submission	CAJ0413A [redacted](Model 3000 (E3000) Risk Assessment Report, version 1.0) CAJ0414A (b)(4) E3000 Software Risk Test, Version 1.00) Refer to Appendix 5 of this submission for complete documentation of these elements.
3.4, 4.2	Software Requirements Specification	Required in Submission	CAJ0341A [redacted](E3000 Software Requirement Specification, version 3.0) Refer to Appendix 6 of this submission for complete documentation.
3.5	Architecture Design Chart	A chart depicting the partitioning of the software system into functional subsystems	CAJ0406A (b)(4) E3000 Software Design, version 1.0) Refer to Appendix 7 of this submission for complete documentation.
3.6	Design Specification	Not Required in Submission	Not Required
3.7	Traceability Analysis	Not Required in Submission	Not Required
3.8, 4.1	Development	Not Required in Submission	Not Required

Table 6 Software Documentation Required in the Premarket Submission

ODE Guidance Document Section Number(s)	Software Documentation	"Minor" Concern Documents Required in a 510(k) submission	Proof of Compliance
3.9	Validation, Verification and Testing (VV&T)	Software functional test plan, pass/fail criteria, and results	CBS0425A [redacted](E3000 Software Acceptance Test Specification, version 2.00) CBS0426B (b) E3000 Software Validation Report, version 1.00) Refer to Appendix 8 of this submission for complete documentation of these required elements.
3.10	Revision Level History	Not Required in Submission	Not Required
3.11	Unresolved anomalies (bugs)	Not Required in Submission	Not Required
3.12	Release Version Number	Version number and date applicable to the product that will go to market.	CBS0426A [redacted](Release of Software for E3000, version 1.04) Refer to Appendix 9 of this submission for complete documentation.

5 C

2.3 Device Drawings

Figure 1 represents a drawing of the Model 3000 and its external components.

Figure 2 presents expanded views of the Model 3000 chestpiece; the chestpiece contains a microphone, amplification, filtering electronics, and a single manual control button. The filter circuitry included in the chestpiece provides two different frequency response modes: Bell (20-200 Hz) and Diaphragm (100-500 Hz). A more detailed view of the control button (identified as "Rubber keyboard, Item #3 in Figure 2) and the associated icons on the button is shown in the User Manual for the Model 3000 (refer to User Manual in Appendix 10).

Figure 1 3M™ Littmann® Electronic Stethoscope, Model 3000

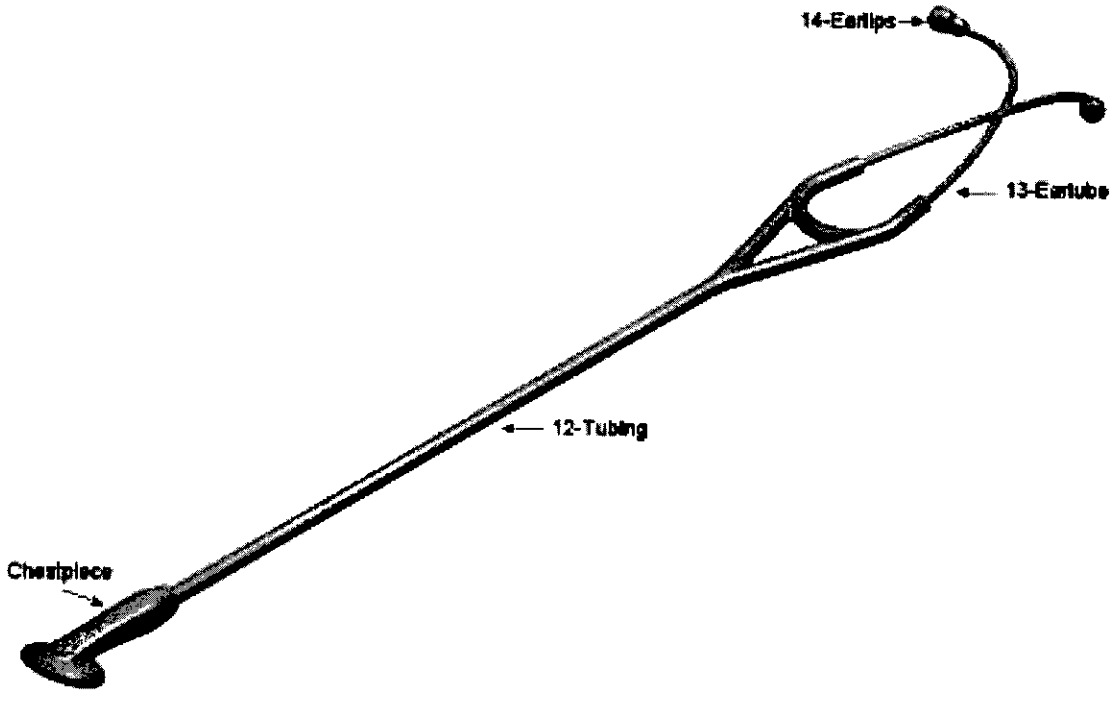
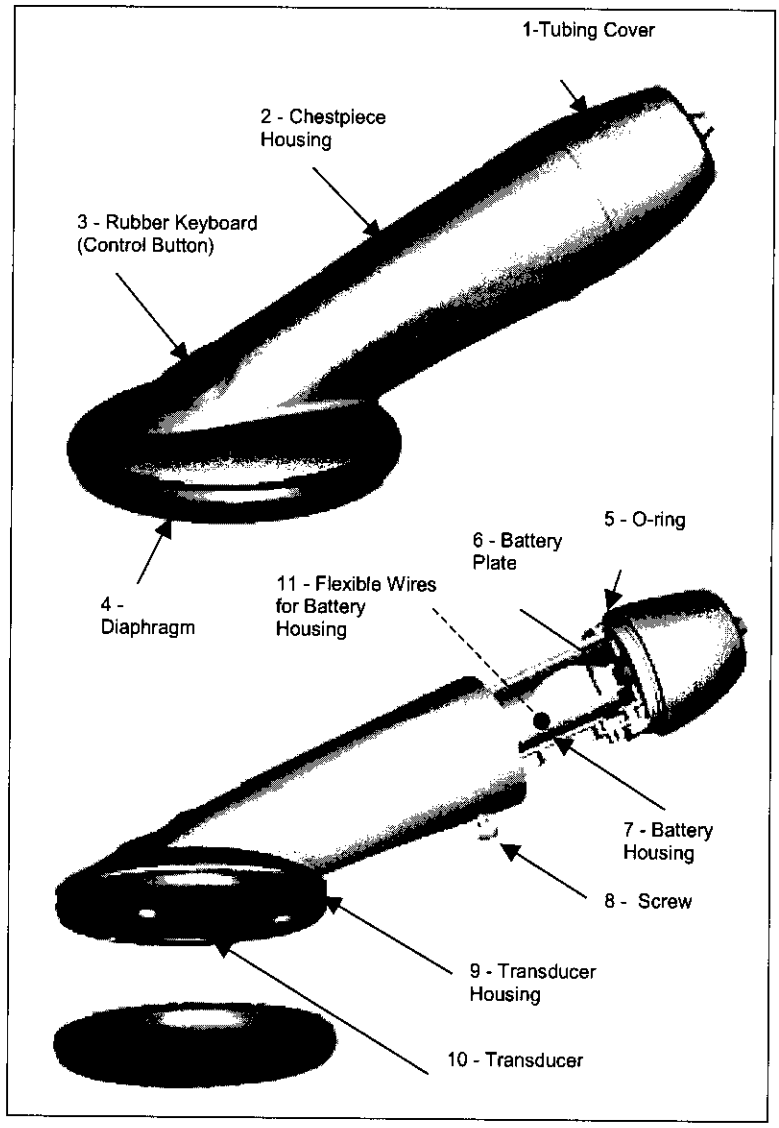


Figure 2 Expanded View of Littmann® Electronic Stethoscope Model 3000 Chestpiece



2.4 Labeling/Instructions for Use

Copies of the proposed labeling for the Model 3000 (i.e., the User Manual and primary box and master shipper carton) are included in Appendix 10 of this submission. The User Manual also includes directions for routine care and maintenance of the device.

Each primary box contains one (1) Model 3000 stethoscope, the User Manual, two (2) spare pairs of ear tips and one (1) AAA 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: 2001, effective November 1, 2004), specific results for EMC testing are included in the User Manual for the Model 3000.

Reference labeling for the predicate devices, the Model 4000 and Model 2000 stethoscopes, is included in Appendix 11.

2.5 Promotional Claims/Advertising

In addition to the indications for use, the following claims to be used in the promotion and advertising of the 3M™ Littmann® Electronic Stethoscope, Model 3000 are:

- Up to 25 dB acoustic gain, equivalent to 18 times amplification or 16 times louder (when measured at 100 Hz) than the best conventional (i.e. non-electronic) Littmann® stethoscopes.
- Filter circuitry provides two frequency response modes – Bell (20-200 Hz) and Diaphragm (100-500 Hz).
- Digital signal processing over the entire acoustic range of the stethoscope.
- Electrical signal-to-noise ratio greater than 70 dB with less than 2% distortion.
- Passive noise reduction technology provides a minimum 12 dB or 75% reduction in distracting ambient noise (susceptibility) versus the Littmann® Electronic Stethoscope Model 4000 without loss of body sounds under typical use conditions.
- Acoustic control audio feedback for user when activating volume/filter button.
- Limits maximum sounds pressure at ear canals to 140 dB (transient) to protect user's hearing.
- Ergonomically designed chestpiece.
- Total weight no more than 220 grams.
- 8-step volume control in steps of 3 dB ± 1 dB.
- One button power-up; same button also selects the Bell or Diaphragm filters.
- Stethoscope able to start up with last programmed (or pre-set) volume setting (user option).
- "Latex-free" – Does not contain natural rubber latex or dry natural rubber as components in the product or its packaging.

- External materials meet ISO 10993-Part 1 for short term (<24 hours) skin contact.
- At least 200 hours continuous use with one (1) AAA alkaline battery.
- To extend battery life, automatic power shutdown 3 minutes (± 30 seconds) after last operation.
- Low battery indicator gives auditory warning with at least 2 hours before complete depletion.
- No sound distortion below specification when operating during low battery condition.
- Easy to use on start-up; easy battery replacement.
- Chestpiece sized for adult or pediatric patients.
- Excellent acoustic seal and comfortable fit with 3M™ Littmann® Snap-Tight Soft-Sealing Eartips.
- Non-chill patient interface (integrated diaphragm assembly).
- Chestpiece is splash proof.
- Exterior of stethoscope may be cleaned with alcohol or soap and water.

3.0 Substantial Equivalence

3.1 Summary Statement

The Littmann® Electronic Stethoscope, Model 3000 dressing is substantially equivalent to the Littmann® Electronic Stethoscope Model 4000, cleared under K003723 and the Littmann® Electronic Stethoscope Model 2000 cleared under K961848.

The Model 3000 proposed under this new pre-market notification submission is composed of the same or similar materials, and has similar performance features, intended use and indications for use as the Model 4000 cleared under K003723, and the Model 2000, cleared under K961848.

3.2 Equivalency Comparison

Tables 7, 8, and 9 provide comparison data for the purpose of demonstrating substantial equivalence between the Model 3000 (new device), the Model 4000 (predicate device) and the Model 2000 (predicate device).

Table 7 identifies the larger external components (including material composition) for the Model 3000, Model 4000, and Model 2000 stethoscopes.

Table 7 Model 3000 External Components

Component and Material Type	Model 3000 (New Device)	Model 4000 (Predicate Device) K003723	Model 2000 (Predicate Device) K961848
Ear-tip (Ribbed Style)	Silicone rubber (same as Model 4000 and Model 2000)	Silicone rubber (same as Model 3000 and Model 2000)	Silicone rubber (same as Model 3000 and Model 4000)
Rim	Not applicable	Polyurethane	Polyurethane
Diaphragm (Transducer cover)	Nitrile rubber*	Epoxy	Epoxy
Tube	Vinyl compound	Santoprene (b) [redacted]	Vinyl Compound
Eartube Mount	Anodized aluminum	Anodized Aluminum (4)	Anodized Aluminum
Yoke	PVC	Nitrile	PVC

- The nitrile material is also used on both the currently marketed 3M Littmann® Classic II S.E. and 3M Littmann® Cardiology III stethoscopes.

Table 8 summarizes the similar and different performance features of the Model 3000 compared to the Model 4000 and Model 2000 predicate devices.

Table 8 Comparison of Performance Features Littmann® Electronic Stethoscope Model 3000 versus Littmann® Electronic Stethoscope Model 4000 and Littmann® Electronic Stethoscope Model 2000

Performance Features	Model 3000 (New Device)	Model 4000 (Predicate Device) K003723	Model 2000 (Predicate Device) K961848
Frequency Response	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.	Bell (20-200 Hz), Diaphragm (100-500 Hz) and Extended Range (100-1000 Hz) modes.
Amplification	Up to 25 dB acoustic gain, equivalent to 18 times amplification.	Up to 25 dB acoustic gain, equivalent to 18 times amplification.	Up to 20 dB acoustic gain, equivalent to 14 times amplification.
Maximum Sound Level	(b) dB SPL Max	(b) dB SPL Max	(b) dB SPL Max (4)
Power Source	One (1) (AAA) alkaline battery	Two (2) (AAA) alkaline batteries	One (1) (AAA) alkaline battery
Low Battery Indicator	Includes a low battery indicator	Includes a low battery indicator	Includes a low battery indicator
Displays Heart Rate	No	Yes	No
Record and Playback Sounds	No	Yes	No
Permits Data Transfer of Stored Digital Signals to and from IBM-Compatible PC and Pocket PC and Palm Pilot*	No	Yes	No
Volume Control	8 Step Volume Control	8 Step Volume Control	Continuous Variable
ON/OFF Switch Automatic Shut-off by Electronics	Yes	Yes	Yes

*** With Infrared Port and Windows /98/2000/XP, Pocket PC 2002/2003 and Palm OP Sys 4/5**
Microsoft® and Windows™ are registered trademarks of Microsoft Corporation.

3M notes that conventional stethoscopes, such as the 3M Littmann Cardiology stethoscopes, do not have an "extended range" response and clinicians have used them successfully for years to perform patient auscultations. The Model 3000 is an entry-level cardiology grade electronic stethoscope and 3M has chosen not to include the extra feature of extended response that is possible only in electronic stethoscopes. The specifications for the bell and diaphragm modes of the Model 3000 stethoscope are equivalent to those of the predicate devices, the Model 4000 and the Model 2000 stethoscopes.

Table 9 presents a comparison of the intended use and indications for use of the Littmann® Model 3000, Model 4000, and Model 2000 Electronic Stethoscopes.

Table 9 Intended and Indications for Use Comparison: Model 3000, Model 4000 and Model 2000

	Model 3000 (New Device)	**Model 4000 (Predicate Device) K003723**	**Model 2000 (Predicate Device) K961848**
Intended Use	Electronic Stethoscope	Electronic Stethoscope	Electronic Stethoscope
Indications for Use	The 3M™ Littmann® Electronic Stethoscope, Model 3000, is intended for medical diagnostic purposes only. It may be used for the detection and amplification of 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 4000, is intended for medical diagnostic purposes only. It may be used for the detection and amplification of 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 2000, is intended for medical diagnostic purposes only. It may be used for the detection and amplification of 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.

4.0 Summary of Safety and Biocompatibility Studies

4.1 Overview

All components of the Model 3000 stethoscope have been reviewed 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. 3M concludes that all of the components of the Model 3000 Stethoscope would have minimal potential for any adverse health concern.

Refer to Appendix 12 for the complete copy of 3M's biocompatibility evaluation.

5.0 Manufacturing

5.1 Summary

Figure 3 provides a flowchart of the basic manufacturing process for the Model 3000 stethoscope.

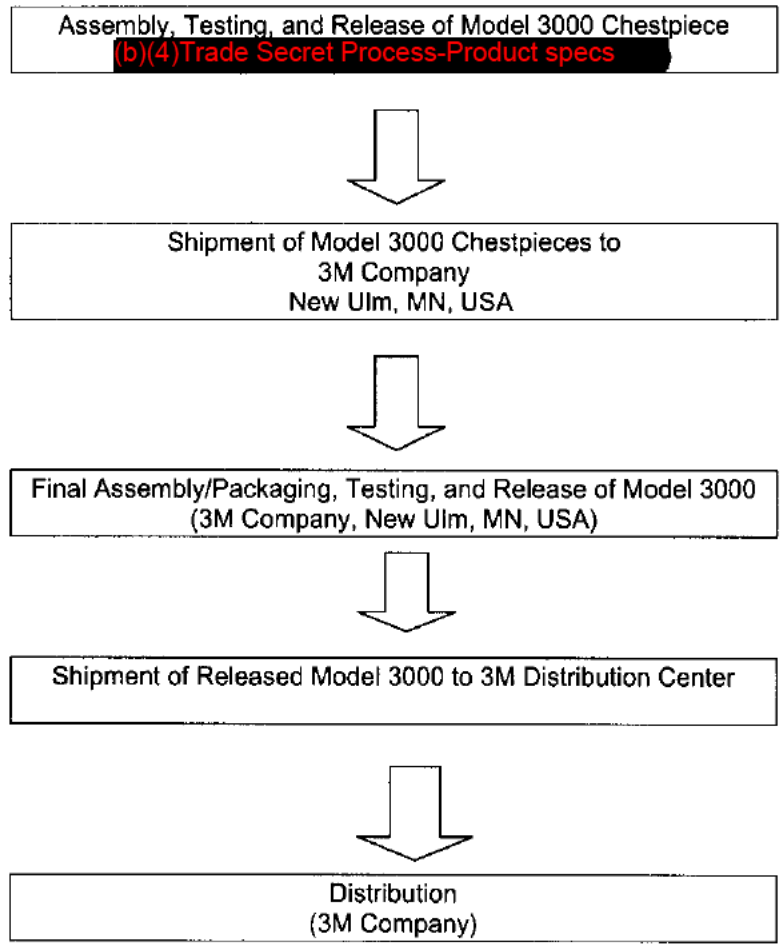
The chestpiece of the Model 3000 is contract manufactured for 3M by:

(b) (4) [redacted]

Final assembly, testing, and release of this device will be performed at the following 3M facility:

3M Company
1617 North Front Street
New Ulm, MN 56073
USA
FDA Registration No.: 2183581

Figure 3 Manufacturing Process Flow Chart for Littmann® Electronic Stethoscope, Model 3000



5.2 Device Shelf Life

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

Certificate – General Safety Testing IEC 60601-1

INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC)
COMMISSION ELECTROTECHNIQUE INTERNATIONALE (CEI)

Ref. Certif. No.
DK-8002

IEC SYSTEM FOR CONFORMITY TESTING AND CERTIFICATION OF ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTÈME CEI D'ESSAIS DE CONFORMITÉ ET DE CERTIFICATION DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE
CERTIFICAT D'ESSAI OC

Product *Produit*	Medical 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, USA
Name and address of the manufacturer *Nom et adresse du fabricant*	3M Health Care 3M Center, Building 270-4N-09, Maplewood, MN 55144-1000, Patient Assessment Laboratory, 3m Medical Products, USA
Name and address of the factory *Nom et adresse de l'usine*	(b) (4) [redacted]
Rating and principal characteristics *Valeurs nominales et caractéristiques principales*	1.5V, IPX4
Trade mark (if any) *Marque de fabrique (si elle existe)*	3M LITTMANN
Model/type Ref. *Ref. de type*	3000
Additional information (if necessary) *Information complémentaire (si nécessaire)*	One alkaline battery, type AAA, Type B Applied Part. Tested for Extended Environmental Temperature: 0 - 50°C

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

PUBLICATION	EDITION
IEC 60601-1:1988 + A1:1991 + A2:1995	2nd

as shown in the Test Report Ref. No. which form part of this certificate
comme indiqué dans le Rapport d'essais numéro de référence qui constitue une partie de ce certificat

E249052-A1-CB-1

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme National de Certification

Date 2004-06-30

Signature

Karina Christiansen
Certification Manager

UL International Demko A/S
Lyskaer 8, P.O. Box 514
DK-2730 Herlev, Denmark
Telephone: +45 44856565
Fax: +45 44856500

An Affiliate of
Underwriters Laboratories Inc.

Internal Ref.:
Ken Dybdahl

Test Report – General Safety Testing IEC 60601-1

COVER PAGE FOR TEST REPORT

Test Item Description:	Medical Stethoscope
Model/Type Reference:	Model 3000
Rating(s):	1.5Vdc. One alcaline battery, type AAA, Type B Applied Part, IPx4
Standards:	IEC 60601-1:1988 + A1:1991 + A2:1995
Applicant Name and Address:	(b) (4) [redacted] (b) (4) [redacted] (b) (4) [redacted] (b) (4) [redacted] (b) (4) [redacted]
This Report includes the following parts, in addition to this cover page:	1. Specific Technical Criteria 2. Clause Verdicts 3. Critical Components 4. Test Results 5. National Differences 6. Enclosures
All applicable tests according to the above standard(s) have been carried out. Test results are valid only for the tested equipment. This Test Report can be reproduced on in whole. Amendments and corrections can be reproduced only with the original CB Test Report. Written permission from UL International Demko A/S is required if the test report is copied in part.	

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TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1: General requirements for safety

Report Reference No ..... :	E249052-A1-CB-1
Compiled by (+ signature) ..... :	Ken Dybdahl
Reviewed by (+ signature) ..... :	Lars Grønnegaard
Approved by (+ signature) ..... :	Lars Grønnegaard
Date of issue ..... :	2004-07-06
CB Testing Laboratory ..... :	UL International Demko A/S
Address ..... :	Lyskaer 8, 2730, Herlev, Denmark
Testing location/procedure ..... :	CBTL [x] SMT [ ] TMP [ ] WMT [ ]
Address ..... :	UL International Demko A/S, Lyskaer 8, 2730, Herlev, Denmark
Applicant's name ..... :	(b) (4) [redacted]
Test specification:	
Standard ..... :	IEC 60601-1:1988 + A1:1991 + A2:1995
Test procedure ..... :	CB Scheme
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	IEC60601_1C/97-04
TRF originator ..... :	Underwriters Laboratories Inc.
Master TRF ..... :	dated 97-04

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Test item description ..... :	Medical Stethoscope
Trade Mark ..... :	None
Model/Type reference ..... :	Model 3000
Manufacturer ..... :	(b) (4) [redacted]
Rating ..... :	1.5Vdc. One alcaline battery, type AAA, Type B Applied Part, IPx4

Marking Plate - Refer to Enclosure titled Miscellaneous for copy.

GENERAL INFORMATION				
Test item particulars (see also clause 5):				
Classification of installation and use ..... :	Hand-held			
Supply connection ..... :	Internally powered			
Accessories and detachable parts included in the evaluation ..... :	None			
Options included ..... :	None			
Possible test case verdicts:				
- test case does not apply to the test object ..... :	N / A			
- test object does meet the requirement ..... :	P(Pass)			
- test object does not meet the requirement ..... :	F(Fail)			
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:

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 a NCB in accordance with IECEE 02.

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.
List of test equipment must be kept on file and be available for review.

"(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.

General Product Information:
Report Summary
All applicable tests according to the referenced standard(s) have been carried out.
Product Description
This electrical Stethoscope 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.
Model Differences

N/A	
Additional Information	
The equipment was intende for extended enviromental range as specified : 0°C to 50°C, 15 to 95% relative humidity, Pressure 700-1060 hPa. Based on these conditions, the following tests were considered to be conducted at extended temperatures: Mechanical Tests : Clause 21 Temperature test : Clause 42	
Technical Considerations	
The product was investigated to the following additional standards:	IEC60601-1:1988 + A1:1991 + A2:1995. EN 60601-1: 1990 + A1:1993 + A2:1995 + A13:1996; (except EMC limitations, EN 60601-1-2, Biocompatibility, EN 10993-1)
The degree of protection against harmful ingress of water is:	IPx4
The mode of operation is:	Continuous
Software is relied upon for meeting safety requirements related to mechanical, fire and shock:	No
The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide:	No
Engineering Conditions of Acceptability	
When installed in an end-product, consideration must be given to the following:	

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
3	**GENERAL REQUIREMENTS**		Pass
3.1	Equipment when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, causes no safety hazard which could reasonably be foreseen and which is not connected with its intended application in normal condition (N.C.) and in single fault condition (S.F.C.)	The equipment was intende for extended enviromental range as specified : 0°C to 50°C, 15 to 95% relative humidity Pressure 700-1060 hPa.	Pass
3.4	An alternative means of construction is used to that detailed in this standard and it can be demonstrated that an equivalent degree of safety is obtained		N/A

5	**CLASSIFICATION**		Pass
5.1	Type of protection against electric shock		Pass
	Class I equipment		N/A
	Class II equipment		N/A
	Internally powered equipment	Equipment power by one AAA-type alkaline battery. (1.5Vdc)	Pass
5.2	Degree of protection against electric shock		Pass
	Type B applied part	Type B applied. All equipment parts were considered applied part.	Pass
	Type BF applied part		N/A
	Type CF applied part		N/A
	Not classified - no applied parts		N/A
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1) .....:	IPx4. See Appended table 44.	Pass
5.4	Methods of sterilization or disinfection	Device not intended for sterilization or disinfections.	N/A
5.5	Equipment not suitable for use in the presence of flammable mixtures	Section "Caution", "Stethoscope not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE"	Pass

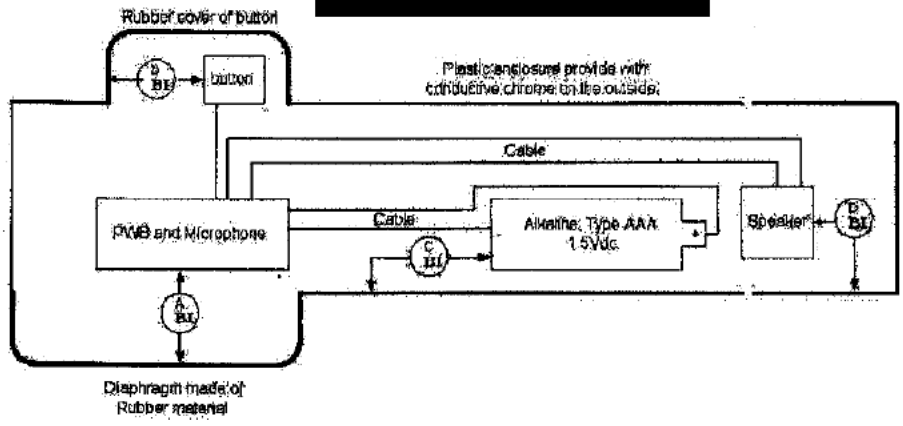
IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	Category AP equipment		N/A
	Category APG equipment		N/A
5.6	Mode of operation:		Pass
	-continuous operation		Pass
	-short-time operation, specified operation; period..:		
	-intermittent operation, specified operation; rest period .....:		
	-continuous operation with short-time, stated permissible loading time.....:		
	-continuous operation with intermittent, stated permissible loading/rest time.....:		

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM

Insulationdiagram

(b) (4)



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IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	TABLE: to insulation diagram						
Area	Insulation type: operational / basic / supplementary / double / reinforced	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remark
A	BI	1.5Vdc	1.7	0.8	Area No 1: 1.97mm	Area No 1: 1.97mm	PWB -> chrome part chestpiece.
B	BI	1.5Vdc	1.7	0.8	Area No 3: 3.09mm	Area No 3: 3.09mm	Electrical parts of button -> accessible surface of the button.
C	BI	1.5Vdc	1.7	0.8	Area No 4: 3.04mm	Area No 4: 3.04mm	Battery terminals -> chrome part chestpiece.
D	BI	1.5Vdc	1.7	0.8	Area No 5: 2.07mm	Area No 5: 2.07mm	Flex cable ->hrome part chestpiece.
.	.	.	.	.	Area No # referes to Enclosure 7-03	Area No # referes to Enclosure 7-03	.

INSULATION 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:

1. All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
2. Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional.
3. Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
4. Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.
5. Blocks containing the letter "Z" indicate protective impedance.
6. 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			
Clause	Requirement + Test	Result - Remark	Verdict
6	**IDENTIFICATION, MARKING AND DOCUMENTS**		Pass
6.1	Marking on the outside of equipment or equipment parts		Pass
6.1c	Markings of the specific power supply affixed		N/A
6.1d	If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents	Equipment provided with the following symbols: Table DI, No 14, table DII, No 1 and "IPx4". Explanation of the symbols was found in the accompanying documents.	Pass
6.1e	Name and/or trademark of the manufacturer or supplier.....:	3M Littmann	Pass
6.1f	Model or type reference .....:	Model 3000	Pass
6.1g	Rated supply voltages or voltage range(s)	Battery operated equipment	N/A
	Number of phases.....:	Battery operated equipment	N/A
	Type of current.....:	Battery operated equipment	N/A
6.1h	Rated frequency or rated frequency range(s) (Hz) :	Battery operated equipment	N/A
6.1j	Rated power input (VA, W or A).....:	Battery operated equipment	N/A
6.1k	Power output of auxillary mains socket - outlets		N/A
6.1l	Class II symbol	Battery operated equipment	N/A
	Symbol for degree of protection against ingress of water provided.....:	IPx4 according to IEC529. See appended table 44.	Pass
	Symbol for protection against electric shock.....:	Type B	Pass
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets	The Stethoscope was considered as one Applied Part.	N/A
	Symbol for protection of defibrillation-proof applied parts		N/A
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N/A
6.1m	Mode of operation (if no marking, suitable for continuous operation)	No marking. Continues operation.	N/A
6.1n	Types and rating of external accessible fuses.....:	No fuses.	N/A
6.1p	Ratings of external output: .....:		N/A
6.1q	Symbol for physiological effect(s):		N/A
	- attention, consult accompanying documents		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417		N/A
6.1r	Anaesthetic-proof symbol: AP or APG.....:		N/A
6.1s	Dangerous voltage symbol		N/A
6.1t	Special cooling requirements		N/A
6.1u	Limited mechanical stability		N/A
6.1v	Protective packing requirement(s)	Equipment provided with exclamation mark. Section "General Use and Maintenance", -20 to 60°C, 15 to 95% RH	Pass
	- Marking(s) for unpacking safety hazard(s)		N/A
	- Equipment or accessories supplied sterile, marked as sterile	Equipment not sterile.	N/A
6.1y	Potential equalization terminal		N/A
	- Functional earth terminal		N/A
6.1z	Removable protective means		N/A
	Durability of marking test	Markings laser-engraving into body of the equipment. See table 6.1 for details. See also enclosure 7-01	Pass
6.2	Marking on the inside of equipment or equipment parts		Pass
6.2a	Nominal voltage of permanently installed equipment	Portable equipment.	N/A
6.2b	Maximum power loading for heating elements or holders for heating lamps	No heating elements.	N/A
6.2c	Dangerous voltage symbol	max 1.8V dc.	N/A
6.2d	Type of battery and mode of insertion	Only AAA-type batteries fit into the battery compartment.Mode of insertion shown inside the battery compartment.	Pass
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator	Equipment provided with exclamation mark. Section "Battery" states for use with alkaline batteries. Section "Caution" states "Use only AAA alkaline batteries."	Pass
6.2e	Fuses accessible with a tool identified either by type and rating or by a reference to diagram	No fuses in equipment.	N/A

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IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
6.2f	Protective earth terminal	Internally power equipment.	N/A
6.2g	Functional earth terminal		N/A
6.2h	Supply neutral conductor in permanently installed equipment (N)		N/A
6.2j	Markings required in 6.2 f), h), k), and l) remain visible after connection and are not affixed to parts which have to be removed		N/A
	- Markings comply with IEC 445		N/A
6.2k	For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)		N/A
6.2l	Statement for suitable wiring materials at temperatures over 75°C	No temperature measurements does exceed 75 °C. See Cl.42	N/A
6.2n	Capacitors and/or circuit parts marked as required in Sub-clause 15c		N/A
6.3	Marking of controls and instruments		Pass
6.3a	Mains switch clearly identified	No mains switch	N/A
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light	The stethoscope turns on while pressing one of the filter mode buttons. The device automatically turns off after 3 minutes of idle operation.	N/A
6.3b	Indication of different positions of control devices and switches		N/A
6.3c	Indication of the direction in which the magnitude of the function changes, or an indicating device	Volume indicated with "+" or "-"	Pass
6.3f	The functions of operator controls and indicators are identified		Pass
6.3g	Numeric indications of parameters are in SI units except for units listed in Am. 2	No numeric parameters used.	N/A
6.4	Symbols		Pass
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	Tabel D1, Symbol 14 and Tabel D2, symbol 1	Pass
6.5	Colors of the insulation of conductors		N/A
6.5a	Protective earth conductor has green/yellow insulation	No protective earth.	N/A

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IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
6.5b	All insulations of internal protective earth conductors are green/yellow at least at their terminations		N/A
6.5c	Only protective or functional earthing, or potential equalization conductors are green/yellow	No protective or functional earthing, or potential equalization used.	N/A
6.5d	Color of neutral conductor.....:		N/A
6.5e	Colors of phase conductor(s).....:		N/A
	- Compliance with IEC 227 and IEC 245		N/A
6.5f	Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		N/A
6.6	Medical gas cylinders and connections		N/A
6.6a	In accordance with ISO ISO/R 32		N/A
6.6b	Identification of connection point		N/A
6.7	Indicator lights and push-buttons		N/A
6.7a	Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action	No indicator light	N/A
	- Yellow used to indicate caution or attention required		N/A
	- Green used to indicate ready for action	See also clause 56.8	N/A
6.7b	Color red used only for push-buttons by which a function is interrupted in case of emergency		N/A
6.8	ACCOMPANYING DOCUMENTS		Pass
6.8.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	One manual provided: "3M Littmann Electronic Stethoscope Model 3000 . Instruction for use"	Pass
	Classifications specified in Clause 5 included in both the instructions for use and the technical description		Pass
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment	Type B, Exclamation marks, IPx4. Explanation of markings provided in the manual.	Pass
	Warning statements and the explanation of warning symbols provided in the accompanying documents	Section "Caution" in the instruction for use manual.	Pass
6.8.2	Instructions for use		Pass
6.8.2a	General information provided in instructions for use		Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	- state the function and intended application of the equipment	Section "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. "	Pass
	- include an explanation of: the function of controls, displays and signals	Section "button functions"	Pass
	- the sequence of operation		Pass
	- the connection and disconnection of detachable parts and accessories .		N/A
	- the replacement of material which is consumed during operation	Section "battery".	Pass
	- information regarding potential electromagnetic or other interference and advice regarding avoidance		N/A
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety		N/A
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	Section "general use and maintenance".	Pass
	General information provided in instructions:		Pass
	- information for the safe performance or routine maintenance		Pass
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	Section "general use and maintenance". "If you experience any problems with the stethoscope, do not attempt to repair it yourself"	Pass
	- explanation of figures, symbols, warning statements and abbreviations on the equipment	All figures and symbols were explained in the instruction for use manual.	Pass
6.8.2c	Signal output or signal input parts intended only for connection to specified equipment described	No Signal output or signal input parts	N/A
6.8.2d	Details about acceptable cleaning, disinfection or sterilization methods included	Section "general use and maintenance". "Eartips, eartubes, plastic tubing and chestpiece can be wiped clean with alcohol".	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
6.8.2e	Warning statement for mains operated equipment with additional power source		N/A
6.8.2f	A warning to remove primary batteries if equipment is not likely to be used for some time	Section "general use and maintenance". "Remove the battery whenever the stethoscope is stored or will be used for several months".	Pass
6.8.2g	Instructions to ensure safe use and adequate maintenance of rechargeable batteries	Only for use with Alkaline batteries. Described in Instruction for use.	N/A
6.8.2h	Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1		N/A
6.8.2j	Identification of any risks associated with the disposal of waste products, residues, etc.		N/A
	- Advice in minimizing these risks		N/A
6.8.3	Technical description		Pass
6.8.3a	All characteristics essential for safe operation provided		Pass
6.8.3b	Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment	No fuses.	N/A
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use		N/A
6.8.3c	Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	3M will do all repairs.	Pass
6.8.3d	Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	Specified in "General Use and Maintenance". "Recommended Storage conditions are from -20°C to 60°C, 15 to 95% relative humidity, Pressure 700-1060 hPa".	Pass
7	**POWER INPUT**		N/A
	Power Input Measurements	Internal power equipment.	N/A

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IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
10	**ENVIRONMENTAL CONDITIONS**		Pass
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer		Pass
10.2.2a	Rated voltage not exceeding 250 V for hand-held equipment	1.5Vdc	Pass
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4kVA		N/A
	Rated voltage not exceeding 500 V for all other equipment		N/A
	Rated input frequency not more than 1kHz	dc	N/A
10.2.2b	Internal replaceable electrical power source specified		Pass
14	**REQUIREMENTS RELATED TO CLASSIFICATION**		N/A
14.4a	Class I and Class II equipment in addition to basic insulation provided with an additional protection	Internally powered equipment.	N/A
14.4b	Equipment supplied from external dc source of reverse polarity results in no safety hazard	Internally powered equipment.	N/A
14.5a	Dual classification for internally powered equipment with a means of connection to supply mains	No external Mains connection.	N/A
14.5b	Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected	Only internally powered equipment	N/A
14.6c	Applied parts intended for direct cardiac application are of type CF	Type B Applied Part.	N/A
15	**LIMITATION OF VOLTAGE AND/OR ENERGY**		N/A
15b	Voltage measured one sec after disconnection of the mains plug does not exceed 60V	Internal powered equipment.	N/A
15c	For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ		N/A
	Marking provided for manual discharging		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

16	**ENCLOSURES AND PROTECTIVE COVERS**		Pass
16a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)	No openings of equipment parts.	Pass
	Insertion or removal of lamps - protection against contact with live parts provided	No lamps.	N/A
16b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented	No openings.	N/A
16c	Conductive parts accessible after the removal of handles, knobs, levers		N/A
	- have a resistance of not more than 0.2 Ohm		N/A
	- separated from live parts by one of the means described in Sub-clause 17g		N/A
16d	Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact	Internal power equipment.	N/A
16e	Removable enclosures protecting against contact with live parts		Pass
	- Removal possible only with the aid of a tool		N/A
	- Use of automatic device making parts not live when the enclosure is opened or removed		N/A
	- Exception 16e applied to the following parts .....:	Cover over battery compartment	Pass
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts	No adjustment of controls.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
17	**SEPARATION**		Pass
17a	Separation method of the applied part from live parts:		Pass
	1) basic insulation: applied part earthed		N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N/A
	4) by double or reinforced insulation	All parts of the equipment were considered Applied parts. See insulation diagram.	Pass
	5) by protective impedances limiting current to applied part		N/A
	- Additional leakage current test in single fault conditions	BI shorted during test - See table 19 for details.	Pass
17c	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		N/A
17d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)	No motors.	N/A
17g	Separation method of accessible parts other than applied parts from live parts:		N/A
	1) basic insulation: accessible part earthed	All parts of the Stethoscope were considered Applied Part.	N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N/A
	4) by double or reinforced insulation		N/A
	5) by protective impedances limiting current to accessible part		N/A
	- Additional leakage current test in single fault conditions		N/A
17h	Arrangements used to isolate defibrillation-proof applied parts so designed that:		N/A
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator		N/A
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function		N/A

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IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
18	**PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION**		N/A
18a	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal		N/A
18b	Protective earth terminals suitable for connection to the protective earth conductor		N/A
18e	Potential equalization conductor		N/A
	- Readily accessible		N/A
	- Accidental disconnection prevented in normal use		N/A
	- Conductor detachable without the use of a tool		N/A
	- Power supply cord does not incorporate a potential equalization conductor		N/A
	- Connection means marked with Symbol 9, Table DI		N/A
18f	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part <= 0.1 Ohm	Internally power equipment.	N/A
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part <= 0.1 Ohm		N/A
	- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part <= 0.2 Ohm		N/A
18g	If the impedance of protective earth connections other than in Cl. 18 f) exceeds 0.1 Ohm, the allowable value of the enclosure leakage current is not exceeded in single fault condition		N/A
18k	Functional earth terminal not used to provide protective earthing	No functional earth.	N/A
18l	Class II equipment with isolated internal screens		N/A
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation		N/A
	- functional earth terminal clearly marked		N/A
	- explanation of functional earth terminal provided in the accompanying documents		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
19	**CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS**		Pass
19.1b	Leakage currents	See clause 19	Pass
	- earth leakage current		N/A
	- enclosure leakage current	See clause 19	Pass
	- patient leakage current	See clause 19	Pass
	- patient auxiliary current		N/A
20	**DIELECTRIC STRENGTH**		Pass
	Overall compliance with Clause 20	See table 20 for details.	Pass
21	**MECHANICAL STRENGTH**		Pass
21a	Sufficient rigidity of an enclosure tested by: force of 45 N	See table 21 for details	Pass
21b	Sufficient strength of an enclosure tested by: impact hammer	See table 21 for details	Pass
21c	On portable equipment carrying handles or grips withstand the requirements of the loading test	Handheld equipment.	N/A
21.3	No damage to parts of patient support and/or immobilization system after the loading test		N/A
21.5	Hand held equipment or equipment parts are safe after drop test	See table 21 for details	Pass
21.6	Portable and mobile equipment is able to withstand rough handling	Handheld equipment.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
22	**MOVING PARTS**		N/A
22.2a	Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment	No moving parts.	N/A
22.2b	Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation		N/A
22.3	Cords (ropes), chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices		N/A
	Guides or other safeguards are removable only with a tool		N/A
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation by the operator		N/A
22.6	Parts of equipment subject to mechanical wear are accessible for inspection		N/A
22.7	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard		N/A
	The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard		N/A
	Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents		N/A
	Means for stopping of movements operate as a result of one single action		N/A

23	**SURFACES, CORNERS AND EDGES**		Pass
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered	All metal and plastic parts were provided with round and smooth edges.	Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
24	**STABILITY IN NORMAL USE (see appended table 24)**		N/A
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°		N/A
24.3	Equipment overbalances when tilted through an angle of 10°		N/A
	- does not overbalance when tilted through an angle of 5° in any position excluding transport		N/A
	- carry a warning notice stating that transport should only be undertaken in a certain position		N/A
	- in the position specified for transport does not overbalance when tilted to an angle of 10°		N/A
24.6a	Equipment or its parts with a mass of more than 20 kg is provided with:		N/A
	- suitable handling devices (grips etc.), or		N/A
	- instructions for lifting and handling during assembly		N/A
24.6b	On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons	The weight of model 3000 was 150g	N/A
25	**EXPELLED PARTS**		N/A
25.1	Protective means are provided where expelled parts of the equipment could be a hazard	No expelled parts	N/A
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion	No display vacuum tubes provided.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
28	**SUSPENDED MASSES**		N/A
28.3	Suspension system with safety device		N/A
	Safety device provided where the integrity of a suspension depends on parts which may have hidden defects, or on parts having safety factors not complying with Sub-clause 28.4	No suspended masses.	N/A
	Safety device has safety factors complying with Sub-clause 28.4.2		N/A
	Clear indication to the operator that the safety device has been activated after failure of suspension means		N/A
28.4	Suspension systems of metal without safety devices		N/A
	1) Total load does not exceed the safe working load		N/A
	2) Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired		N/A
	3) Safety factors not less than 8 where impairment is expected		N/A
	4) Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5%		N/A
	5) Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement		N/A
29	**X-RADIATION**		N/A
29.2	EQUIPMENT not intended to produce X-radiation produces an exposure <= 130 nC/kg (0.5 mR)		N/A
36	**ELECTROMAGNETIC COMPATIBILITY**		N/A
	Equipment complies with IEC 601-1-2	Not evaluated by UL International Demko A/S	N/A
37	**COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT**		N/A
	Requirements for category AP and APG equipment (Cl. 37 - 41)		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
42	**EXCESSIVE TEMPERATURES**		Pass
42.1	Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures per Clause 10.2.1	See table 42. Ambient temperature was considered 50°C	Pass
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient		N/A
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C	See table 42 The Applied Part was only to be in contact with the patient during short periods and the limit was therefore considered 50°C	N/A
42.5	Guards to prevent contact with hot surfaces removable only with a tool		N/A
43	**FIRE PREVENTION**		Pass
	Strength and rigidity necessary to avoid a fire hazard	See table 21 for details.	Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
44	**OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION**		Pass
44.2	Equipment contain a liquid reservoir:		N/A
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min	No liquid container.	N/A
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favorable direction(s) (if necessary with refilling)		N/A
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)	Equipment does not requiring the use of liquids in NORMAL USE.	N/A
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		N/A
44.5	Equipment sufficiently protected against the effects of humidity	See table 44 for details.	Pass
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529	Equipment rated IPx4. See table 44 for details.	Pass
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions	See table 44 for details.	Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
45	**PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE**		N/A
45.2	Pressure vessel with pressure volume greater than 200 kPa x l and pressure greater than 50 kPa withstand the hydraulic test pressure		N/A
45.3	Maximum pressure does not exceed the maximum permissible working pressure for individual parts		N/A
45.7	Unless excessive pressure can not occur, pressure-relief device provided		N/A
45.7a	a) Pressure-relief device connected as close as possible to the pressure vessel		N/A
45.7b	b) Readily accessible for inspection		N/A
45.7c	c) Not capable of being adjusted or rendered inoperative without a tool		N/A
45.7d	d) Discharge opening located that the released material is not directed towards person		N/A
45.7e	e) Discharge opening located that operation will not deposit material which may cause a safety hazard		N/A
45.7f	f) Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure		N/A
45.7g	g) No shut-off valve between a pressure-relief device and the parts intended to be protected		N/A
45.7h	h) Minimum number of cycles of operation: 100.000		N/A

48	**BIOCOMPATIBILITY**		N/A
	Parts of equipment and accessories intended to come into contact with biological tissues, cells or body fluids are evaluated in accordance with ISO 10993-1	See enclosure 7-02 for a List of Composition Materials used in Model 3000	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
49	**INTERRUPTION OF THE POWER SUPPLY**		Pass
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard	No such components used.	N/A
49.2	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function	The Stethoscope does not have any memory function. It does not present any visible data.	Pass
49.3	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure		N/A
51	**PROTECTION AGAINST HAZARDOUS OUTPUT**		N/A
51.4	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

52	**ABNORMAL OPERATION AND FAULT CONDITIONS**		Pass
52.1	Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13)	The Battery was short according to Clause 56.7.a No other SFC was introduced due to less than 15W-power availability. See table "additional Test"	Pass
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4	Safety of this equipment does not depend upon programmable electronic systems	N/A
52.5.2	Failure of thermostats presents no safety hazards		N/A
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard		N/A
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C	No Impairment of cooling were introduced due to less than 15W power availability.	N/A
52.5.6	Locking of moving parts presents no safety hazard	No moving parts.	N/A
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	Motor capacitors not provided.	N/A
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8		N/A
52.5.9	Failure of one component at a time presents no safety hazard	No Failure of components were introduced due to less than 15W power availability.	N/A
52.5.10	Overload of heating elements presents no safety hazard	No heating elements.	N/A
52.5.10f	Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection	No motors.	N/A
52.5.10h	Equipment with three-phase motors can safely operate with one phase disconnected		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

56	**COMPONENTS AND GENERAL ASSEMBLY**		Pass
	List of critical components	See table 56 for details.	Pass
56.1b	Ratings of components not in conflict with the conditions of use in equipment		Pass
	Ratings of mains components are identified	Equipment internally powered only. No Mains components used.	N/A
56.1d	Components, movements of which could result in a safety hazard mounted securely	All components mounted securely.	Pass
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard		N/A
56.3a	Connectors provide separation required by Sub-clause 17g		N/A
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	Equipment not provided with patient circuit leads.	N/A
	Medical gas connections not interchangeable		N/A
56.3b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken	Equipment not provided with interconnection cords.	N/A
56.3c	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.	Equipment not provided with conductive leads.	N/A
56.4	Connections of capacitors		N/A
	Not connected between live parts and non-protectively earthed accessible parts		N/A
	If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14		N/A
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts		N/A
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs		N/A
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment	Equipment internally powered.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
56.6	Temperature and overload control devices		N/A
56.6a	Thermal cut-outs which have to be reset by a soldering not fitted in equipment	No temperature cut-outs.	N/A
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits	No thermal safety devices	N/A
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard		N/A
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times	No self-resetting thermal cut-outs	N/A
	Non-self resetting over-current releases operated 10 times		N/A
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard		N/A
56.6b	Thermostats with varying temperature settings clearly indicated		N/A
	Operating temperature of thermal cut-outs indicated		N/A
56.7	Batteries		Pass
56.7a	Battery compartments:		Pass
	- adequately ventilated		Pass
	- accidental short-circuiting is prevented	The battery was shorted - See Table 52 for details	N/A
56.7b	Incorrect polarity of connection prevented	The mechanical plastic structure in the + - pole region is design such that the metal part of the +-pole cannot create contact to the battery in case of reverse insertion into the battery compartment.	Pass
56.8	Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (color see 6.7):		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	- to indicate that equipment is energized	The only user indicators on the Model 3000 were a set of sound tones in the binaural. Tone are given for POWER ON, Filter Selection, Volume increase/decrease, Low/empty battery and automatic shut down. The stethoscope was not provided with visible indicators.	Pass
	- to indicate the operation of non-luminous heaters if a safety hazard could result		N/A
	- to indicate when output exists if a safety hazard could result		N/A
	- charging mode indicator provided		N/A
56.10	Actuating parts of controls		N/A
56.10b	Actuating parts are adequately secured to prevent them from working loose during normal use		N/A
	Controls are secured to prevent the movement relative to scale marking (safety related only)		N/A
	Detachable indicating devices are prevented from incorrect connection without the use of tool		N/A
56.10c	Stops are provided on rotating controls:		N/A
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard		N/A
	- to prevent damage to wiring		N/A
56.11	Cord-connected hand-held and foot-operated control devices		Pass
56.11a	Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g	Equipment is hand-held.	N/A
56.11b	Hand-held control devices comply with the requirement and test of Sub-clause 21.5		N/A
	- Foot-operated control devices designed to support the weight of an adult human being		N/A
56.11c	Devices not change their setting when inadvertently placed	The stethoscope was placed upside down without change of setting.	Pass
56.11d	Foot-operated control devices are at least IPX 1		N/A
	- For surgical use, electrical switching parts are IPX 8	Equipment intended for diagnostic use only.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
56.11e	Adequate strain relief at the cord entry provided		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

57	**MAINS PARTS, COMPONENTS AND LAYOUT**		Pass
57.1	Isolation from supply mains		N/A
57.1a	Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously	Internally powered equipment.	N/A
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents		N/A
57.1d	Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328		N/A
57.1f	Mains switches not incorporated in a power supply cord		N/A
57.1h	Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a		N/A
57.1m	Fuses and semiconductor devices not used as isolating devices		N/A
57.2	Mains connectors and appliance inlets		N/A
57.2e	Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug		N/A
57.2g	Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment		N/A
57.3	Power supply cords		N/A
57.3a	Not more than one connection to a particular supply mains	Internally powered equipment.	N/A
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously		N/A
	The mains plug has only one power supply cord		N/A
	Non-permanently connected equipment provided with power supply cord or appliance inlet		N/A
57.3b	Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53		N/A
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C		N/A
57.3c	Nominal cross-sectional area of conductors of power supply cords not less than in Table XV		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
57.3d	Stranded conductors not soldered if fixed by any clamping means		N/A
57.4	Connection of power supply cords		N/A
57.4a	Cord anchorages		N/A
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting		N/A
	Tying the cord into a knot or tying the ends with string not used		N/A
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation		N/A
	Cord anchorages made of metal provided with an insulating lining		N/A
	Clamping screws do not bear directly on the cord insulation		N/A
	Screws associated with cable replacement are not used to secure other components		N/A
	Conductors of the power supply cord arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals		N/A
57.4b	Power supply cord protected against excessive bending		N/A
57.4c	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		N/A
57.5	Mains terminal devices and wiring of mains part		N/A
	Mains connected equipment other than those with a detachable supply cord provided with mains terminals, where connections are made with screws, nuts or equally effective methods		N/A
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced		N/A
	Screws and nuts which clamp external conductors not serve to fix any other component		N/A
57.5b	Terminals closely grouped with any protective earth terminal		N/A
	Mains terminal devices accessible only with use of a tool		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Mains terminal devices located or shielded that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact		N/A
57.5c	Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened		N/A
57.5d	Cord terminals not require special preparation of the conductor		N/A
57.6	Mains fuses and overcurrent releases		N/A
	Fuses or over-current releases provided accordingly for Class I and Class II	No fuses.	N/A
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current		N/A
	Protective earth conductor not fused		N/A
	Neutral conductor not fused for permanently installed equipment		N/A
57.8	Wiring of the mains part		N/A
57.8a	Individual conductor in the mains part with insulation not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC Publications 227 or 245, treated as bare conductor		N/A
57.8b	Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply cord		N/A
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits sufficient to prevent any fire hazard		N/A
57.9	Mains supply transformers		N/A
57.9.1	Overheating		N/A
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative		N/A
57.9.1a	Short-circuit of secondary windings not caused excessive temperature		N/A
57.9.1b	Overload of secondary windings not caused excessive temperature		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests		N/A
57.9.4	Construction		N/A
57.9.4a	Separation of primary and secondary windings	No transformer.	N/A
	- separate bobbins or formers		N/A
	- one bobbin with insulating partition		N/A
	- one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13 mm		N/A
	- concentrically wound on one bobbin with windings separated by double insulation		N/A
57.9.4c	Means provided to prevent displacement of end turns		N/A
57.9.4d	Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn		N/A
57.9.4e	Insulation between the primary and secondary in transformers with double insulation		N/A
	- 1 insulation layer having a thickness of at least 1 mm		N/A
	- at least 2 insulation layers with a total thickness of at least 0.3 mm		N/A
	- three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation		N/A
57.9.4g	Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having total thickness at least 0.3 mm extending at least 20 mm outside the winding		N/A
57.10	Creepage distances and air clearances		Pass
57.10a	Values: compliance with at least the values of Table XVI	See the Insulation Table and enclosure 7-03 for detail on Creepage & Clearance.	Pass
	Creepage distances for slot insulation of motors at least 50% of the specified values	No motors.	N/A
57.10b	Minimum creepage distances and air clearances in the mains part between parts of opposite polarity not required if short-circuiting does not produce a safety hazard	No MAINS parts.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
57.10c	Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts	No defibrillation-proof applied parts.	N/A
58	**PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS**		N/A
58.1	Clamping means of the protective earth terminal		N/A
	Not be able to loosen without the aid of a tool		N/A
	Screws for internal earth connections are covered or protected against loosening from outside		N/A
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal		N/A
58.8	The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing		N/A
58.9	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
59	**CONSTRUCTION AND LAYOUT**		Pass
59.1	Internal wiring		Pass
59.1a	Cables and wiring protected against contact with a moving part	No moving parts.	N/A
	Wiring having basic insulation only protected by additional fixed sleeving		N/A
	Components are not likely to be damaged in the normal assembly or replacement of covers		Pass
59.1b	Movable leads are not bent around a radius of less than five times the outer diameter of the lead		N/A
59.1c	Insulating sleeving adequately secured	No sleeving used.	N/A
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric test		N/A
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material		N/A
59.1d	Aluminum wires of less than 16 mm2 cross-section not used		N/A
59.1f	Connecting cords between equipment parts considered as belonging to the equipment		N/A
59.2	Insulation		Pass
59.2b	Mechanical strength and resistance to heat and fires retained by all types of insulation	No internal parts produce heat due to very low power consumption	Pass
59.2c	Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts		N/A
	Parts of rubber resistant to ageing		N/A
59.3	Excessive current and voltage protection		Pass
	Internal electrical power source provided with device for protection against fire hazard	The battery was shorted as a SFC and Power Availability was measured to be less than 15 watt after one minute. Based on the two tests, no protective devices were considered required. See Table 52 and Table "additional Test" for details.	N/A
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.		N/A
59.4	Oil containers		N/A
	Oil containers adequately sealed	Equipment not provided with oil containers.	N/A
	Container allow for the expansion of the oil		N/A
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport		N/A
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

6.1	**TABLE: marking durability**	Pass
Marking tested		Remarks
Laser engraved text provided on the chestpiece. See enclosure 7-01 for details.		The markings were clearly readable
supplementary information:		
Tested with Distilled water, methylated spirit, isopropyl alcohol and with methylated spirit according to CSA 22.2 No. 601.1 defines : 90% Ethanol 9.5% Methanol 0.5% Pyridine		

7	**TABLE: power input**					N/A
Operating condition	Voltage	Frequency	Current	Power	Remarks	
supplementary information:						

15b	**TABLE: residual voltage in attachment plug**										N/A
Voltage measured between:	Measurements [V]										Remarks
	1	2	3	4	5	6	7	8	9	10	
supplementary information:											

15c	**TABLE: residual voltage or energy in capacitors**				N/A
Capacitor and its location	Residual voltage (V)	Time after disconnection (s)	Capacitance value (µF)	Residual energy (mJ)	Remarks
supplementary information:					

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

17h1	**TABLE: defibrillation-proof applied parts**				N/A
Test Condition: Fig. 50 or 51	Accessible part of measurement	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
supplementary information:					

17h2	**TABLE: defibrillation-proof recovery time**				N/A
Applied part with test voltage	Test voltage polarity	Recovery time from accompanying documents (s)	Measured recovery time (s)	Remarks	
supplementary information:					

18	**TABLE: protective earthing**				N/A
Test location	Test current (A)	Measured voltage (V)	Resistance (ohms)	Remarks	
supplementary information:					

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

19	**TABLE: leakage current**				Pass
Type of leakage current and test condition (including single faults)	Supply voltage	Supply frequency	Measured max. value	Remarks	
EN, NC, (B and A), Fig 23 used.	1.5V	dc	0uA	.	
EN, SFC, (B and A), Fig 23 used.	1.5V	dc	0uA	Note 1	
P, NC, (B and A), Fig 23 used.	1.5V	dc	0uA	.	
P, SFC, (B and A), Fig 23 used.	1.5V	dc	0uA	Note 1	
supplementary information:					
Note 1 : a) BI between PWB and microphone cover shorted. b) BI Between PWB and chrome surface of the chestpiece shorted.					
ER - Earth leakage current EN - Enclosure leakage current P - Patient leakage current PM - Patient leakage current with mains on the applied parts PA - Patient auxiliary current Fig. 15 - refers to Fig. 15 in IEC601-1 MD - Measuring device			A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition		

20	**TABLE: dielectric strength**				Pass
Insulation under test (area from insulation diagram)	Insulation type: (OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced)	Reference voltage (V)	Test voltage (V)	Remarks	
A	BI. PWB -> chrome part chestpiece.	1.5Vdc	500Vdc	Note 1	
B	BI. Electrical parts of button -> accessible surface of the button.	1.5Vdc	500Vdc	Note 1	
C	BI. Battery terminals -> chrome part chestpiece.	1.5Vdc	500Vdc	Note 1	
D	BI. Flex cable ->hrome part chestpiece.	1.5Vdc	500Vdc	Note 1	
supplementary information:					
Note 1 : No Dielectric Breakdown					

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IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

21	**TABLE: mechanical strength**		Pass
Part under test	Test (impact, drop, force, handle, rough handling, mobile)	Remarks	
Stethoscope, model 3000	Clause 21.a. force of 45 N applied over an area of 625 mm2	There was no cracking of the enclosure. There were no live parts that became accessible.	
Stethoscope, model 3000	Clause 21.b. impact hammer, 0.5Joule	There was no cracking of the enclosure. There were no live parts that became accessible.	
Stethoscope, model 3000	Clause 21.5. drop test, 1m	There was no damage to the interior or exterior of the tested sample which caused exposure to live parts or increased risk of electric shock.	
supplementary information:			
All tests conducted at operating temperature = 0°C. See General Product Information - Additional Informations			

24	**TABLE: - stability**		N/A
Part under test	Test condition	Remarks	
supplementary information:			

29	**TABLE: X - radiation**			N/A
Part under test	Test condition	Measured radiation (mR)	Remarks	
supplementary information:				

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

42	**TABLE: normal temperature**		Pass
Supply voltage: 1.5Vdc Ambient temperature: See below	Test Condition: The equipment was intended for extended environmental operating conditions of up to +50°C.		
Measuring location		Measured temperature (°C)	Remarks
PWB, inside chest piece.		50	Limit 105 °C, Corrected by +50°C.
Microphone membrane located on the chest piece. (Applied Part)		50	Limit 50°C (only short time contact with the patient),Corrected by +50°C.
Alkaline battery		50	Limit 75°C,Corrected by +50°C.
Metal enclosure of the Battery case		50	Limit 50°C (Short time patient contact). Corrected by +50°C.
COR - indicates measurements taken using change-of-resistance method			
supplementary information: Tested at operating temperature = 50°C. See General Product Information - "Additional Informations"			

44	**TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, desinfection**		Pass
Test type and condition		Part under test	Remarks
Clause 44.4 Humidity, 168 hours (Equipment rated IPx4). R/H=91%, Tepm=28.9°C.		Stethoscope, model 3000	No Dielectric breakdown
Clause 44.7 Cleaning. Eartips, eartubes, plastic tubing and chestpiece wiped clean with alcohol.		Stethoscope, model 3000	No Dielectric breakdown
Clause 44.6 Ingress of liquids. (Equipment rated IPx4)		Stethoscope, model 3000	The eartips were blocked during the test. Note 1
Clause 44.6 Ingress of liquids. (Equipment rated IPx4)		Alternate rubber button, No 2776088	Note 1.
supplementary information: Note 1 : Water did not enter the enclosure and did not interfere with the operation of the equipment. There was no indication of dielectric breakdown.			

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IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

45	**TABLE: hydrostatic pressure and pressure-relief device cycling test**		N/A
Test type and condition	Part under test	Test pressure	Remarks
supplementary information:			

52	**TABLE: abnormal operation**	Pass
Test type, condition and clause reference	Observed results	Remarks
The battery was shorted	Temperature was measured to 83°C on the surface of the battery. There was no ignition of fire or other deterioration of the plastic enclosure surrounding the battery.	.
supplementary information: .		

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IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

56.1	**TABLE: list of critical components**				Pass
object/part No.	manufacturer/ trademark	type/model	technical data	standard	mark(s) of conformity [1]
Battery housi	(b) (4)			UL746	N/A, N/A
Tubing Cover and Chestpie housing				UL746	N/A, N/A
Tubing cover and Chestpie housing, (chrome)				N/A	N/A, N/A
Coating,				N/A	N/A, N/A
Diaphragm				N/A	N/A, N/A
O-ring				N/A	N/A, N/A
Battery	Any manufacturer	Alkaline only. Type AAA only	1,5Vdc, not rechargeable	N/A	N/A, N/A
[1]) an asterisk indicates a mark which assures the agreed level of surveillance					

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IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

56.10	**TABLE: actuating parts and controls**		N/A
Part under test		Torque applied	Remarks
supplementary information:			

56.11b	**TABLE: foot operated control devices-loading**		N/A
Part under test		Observed results	Remarks
supplementary information:			

57.4	**TABLE: cord anchorages**				N/A
Cord under test	Mass of equipment	Pull	Torque	Remarks	
supplementary information:					

57.4b	**TABLE: cord bending**			N/A
Cord under test	Test mass	Measured curvature	Remarks	
supplementary information:				

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

57.9.1a	**TABLE: transformer short circuit**						N/A
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks	
		Primary	Secondary	Ambient			
supplementary information:							

57.9.1b	**TABLE: overload**						N/A
Winding under test	Protection	Measured temperatures (°C)			Test duration	Test current or thermal cutout temp.	Remarks
		Primary	Secondary	Ambient			
supplementary information:							

57.9.2	**TABLE: transformer dielectric strength**				N/A
Transformer under test	Test voltage applied to	Test voltage	Test frequency	Remarks	
supplementary information:					

	TABLE: additional tests		Pass
Clause	Test type and condition	Remarks and observed results	Verdict
Cl.52.4.1	Power availability of the one alkaline batteries was measured to 176mW after 1 minute.	No SFC was introduced due to less than 15W-power availability.	Pass
supplementary information:			

Enclosure
National Differences

(Total 2 Pages including this Cover Page)

No Countries Selected

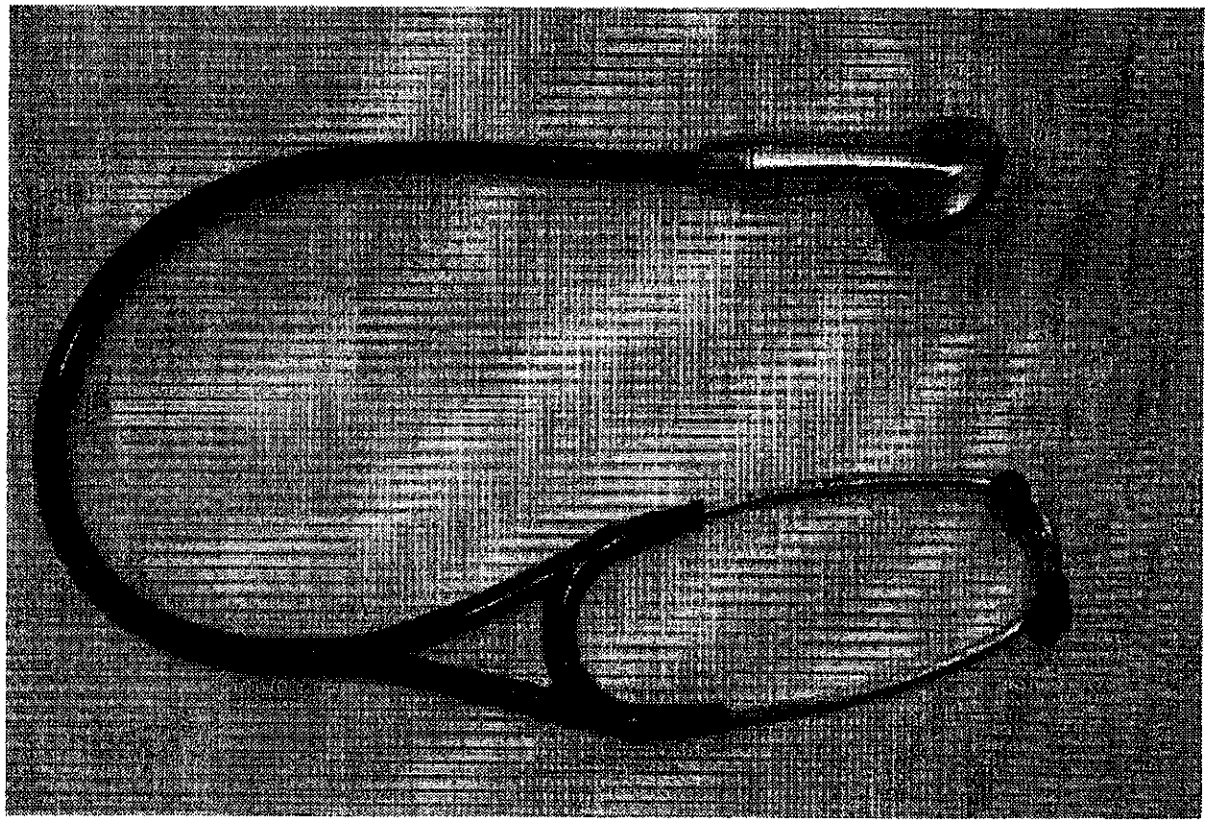
IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict

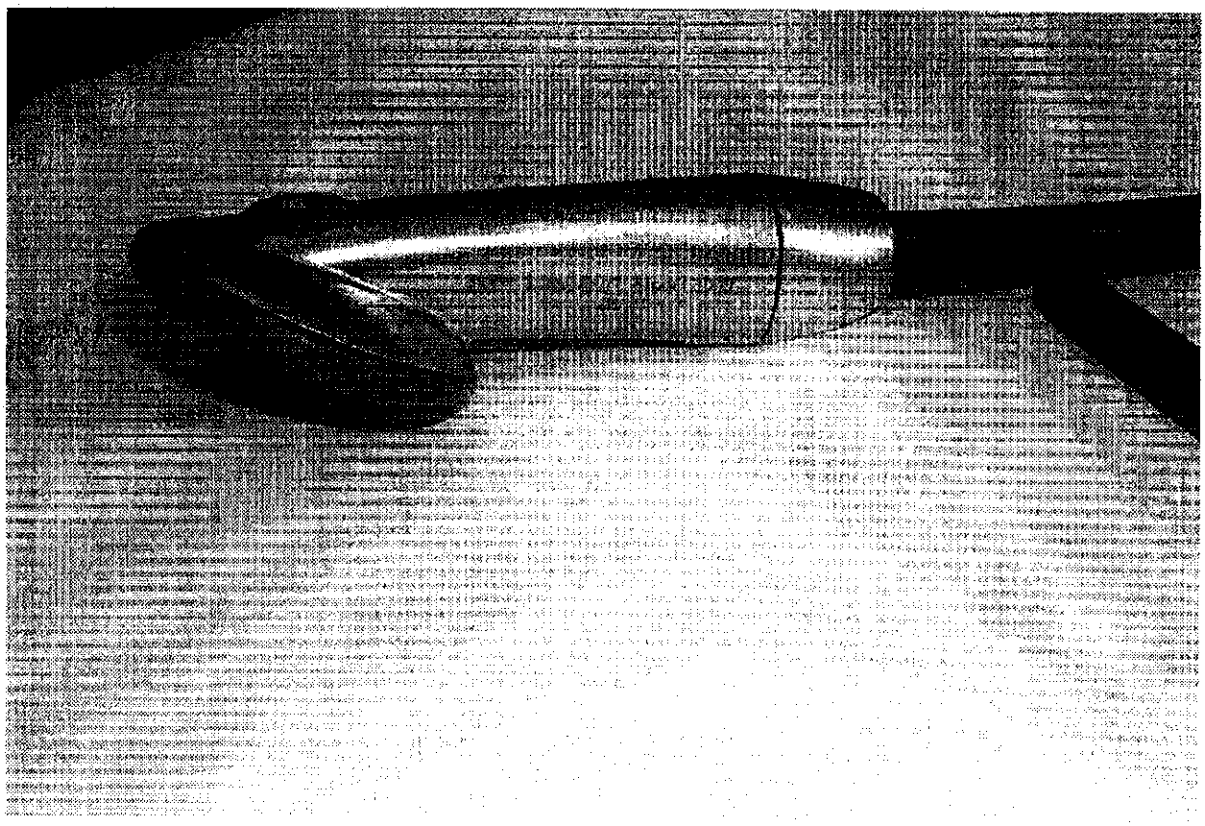
NOTE: National differences are not listed for countries that have no declared national differences or that conform to previously stated Group differences.

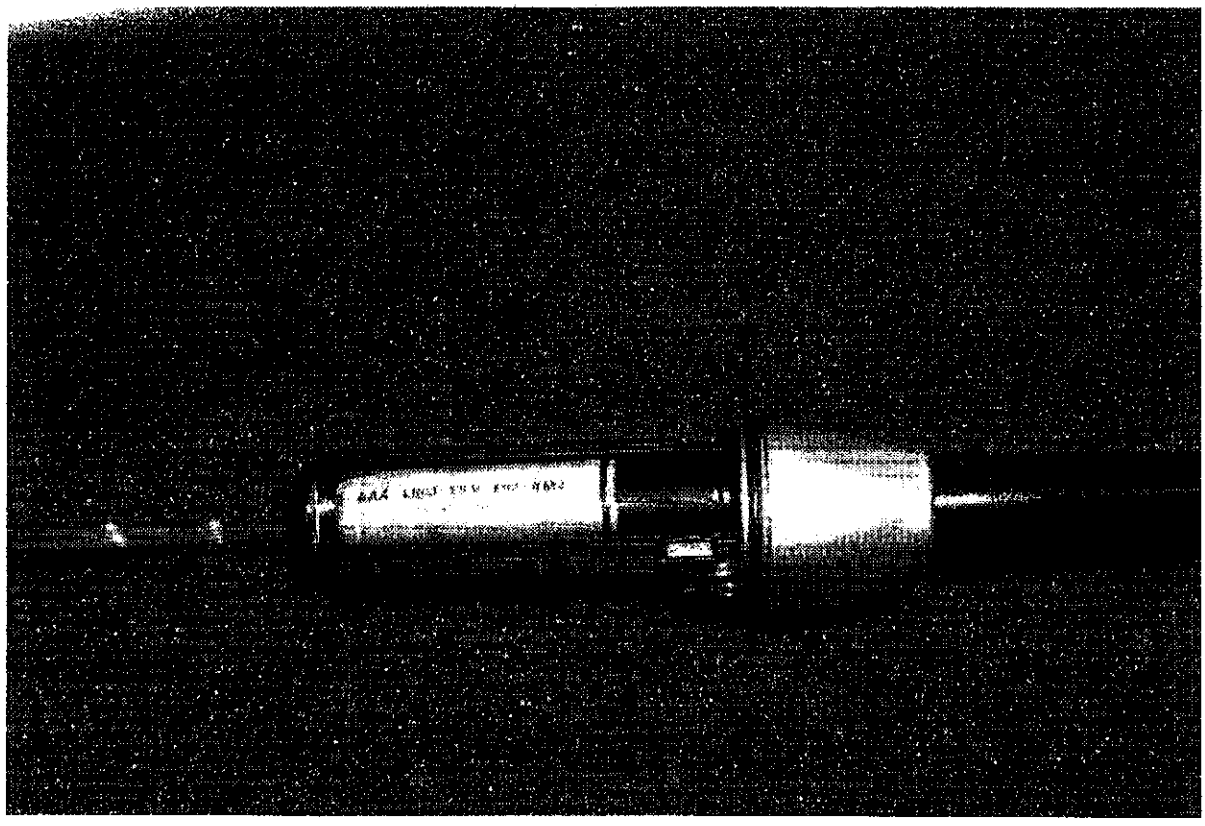
Enclosure
Photographs

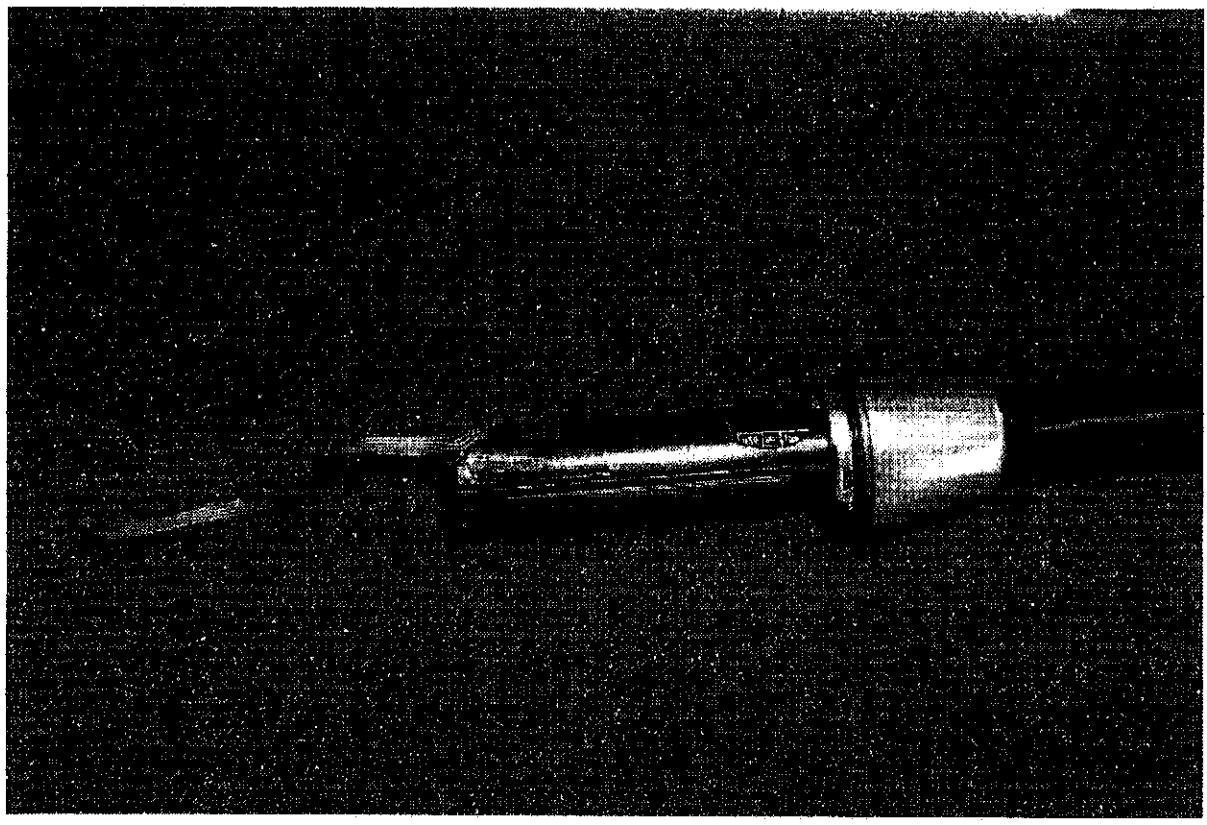
(Total 6 Pages including this Cover Page)

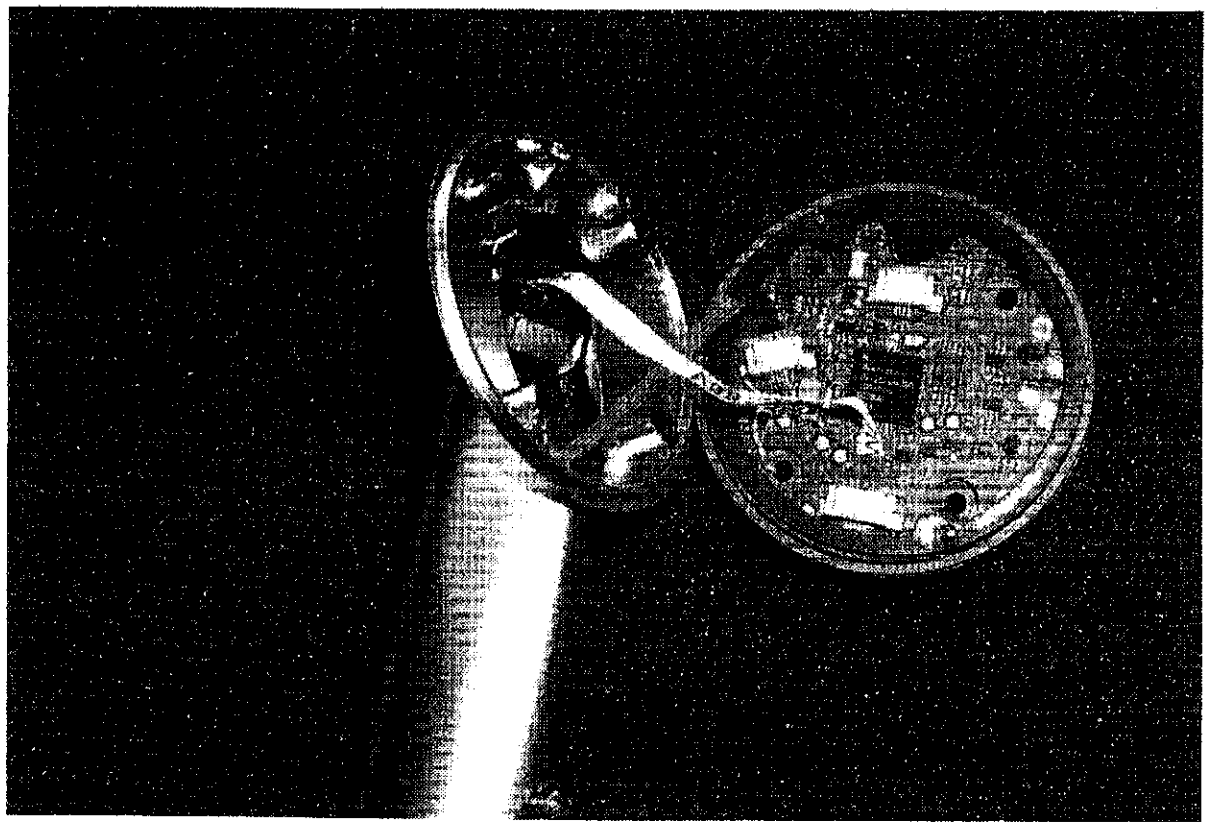
Supplement Id	Description
3-01	Overall Model 3000
3-02	chestpiece
3-03	Chestpiece internal #1
3-04	Chestpiece internal #2
3-05	PWB









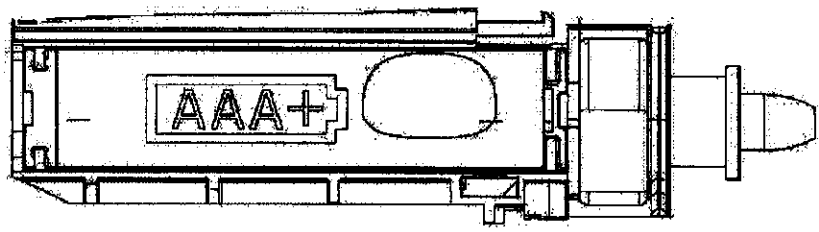


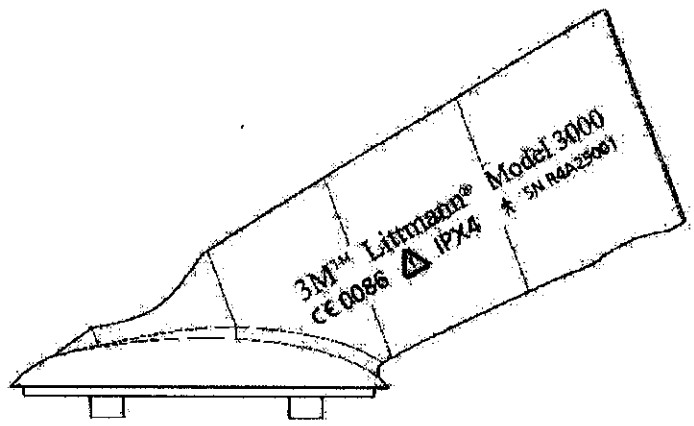
Enclosure

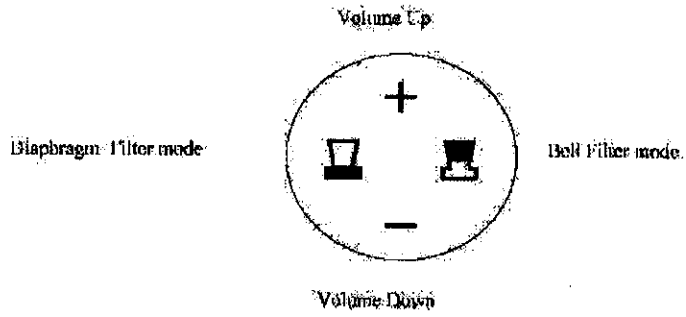
Miscellaneous

(Total 18 Pages including this Cover Page)

Supplement Id	Description
7-01	Marking provided on the chestpiece
7-02	Model 3000 Composition Material List
7-03	Creepage and Clearance evaluation for model 3000
7-04	mechanical drawing of model 3000


AAA+


3M™ Littmann®
CE 0086
IPX4
Model 3000
SN R4A2900


Volume Up
Diaphragm Filter mode
Bell Filter mode
Volume Down

Electronic Stethoscope
Model 3000

Material
Composition Document

Author

Date; Sven Erik Poulsen /SPL – Mechanical Designer

Approved by

Date; Tommy Buch Thinesen /TBT – Project Manager

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(b) (4) Model 3000

Version history

Version	Author	Date	Description
0.01	SPL	27-02-04	First Version
0.02	SPL	30-03-04	References added the document. Point 11 added to the picture on side 4. Grade added to the document under point 3. Poron added to the document under point 10. "Flex wires to battery housing" added to the document under point 11.
1.00	SPL	16-04-04	New references added under point 5, 6, 7, 8, 10 and 11. New material under point 7 New supplier under point 8 Grade added under point 6 and 10
1.10	SPL	14-05-04	Reference for chrome surface, added under point 1 & 2

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Table of Contents

1 Purpose 4
2 References 5
3 Materials 6

1 Purpose

To give an overview of the different parts and materials used in E3000. There is only a description of the materials, in which the user or patient of the stethoscope can be in skin contact with.

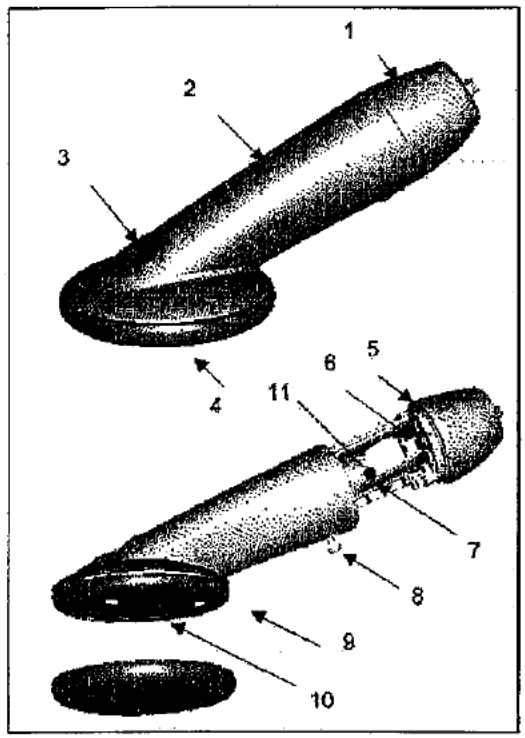


Figure 1

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

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

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

(b) (4) [redacted] E3000

Safety evaluation E3000

Author

Date; Sven Erik Poulsen /SPL – Mechanical Designer

Approved by

Date; Esben Lundgaard Ernstsen /EER – Quality Assurance

(b) (4) E3000

Version history

Version	Author	Date	Description
1.00	SPL	14-05-04	First Version

(b) (4) E3000

Table of Contents

1 Purpose 4
2 Evaluation data 4
3 Conclusion 8
4 Measure equipment 8

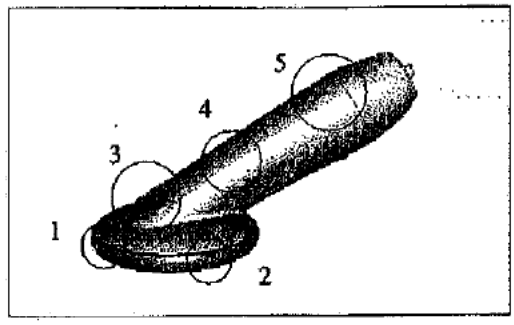
(b)(4)Trade Secret Process- E3000

1 Purpose

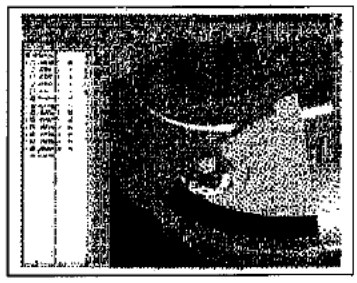
The purpose of this document is to check the safety with respect to the IEC 60601-1-1, standard and to check product requirement PR:014b (Wrong battery orientation)
The evaluation is made on design verification model 1A, build under DMR index V 1,10.

2 Evaluation data

The distance from the power connection inside the stethoscope to the surface ≥ 1,70 mm



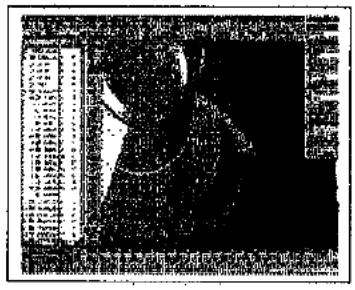
Area number 1



The distance from the PCB track, to the chrome surface on the chestpiece housing, is measured to **1,97 mm** on the PRO assembly.

(b) (4) E3000

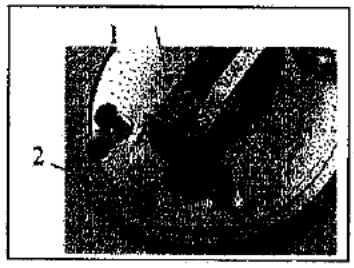
Area number 2



The distance from the PCB track, to the chrome surface on the chestpiece housing is:
Ø $_{\text{Chestpiece housing}}$= 40,71 mm. (Messured)
Ø $_{\text{Sealing for chestpiece housing}}$ = 37,60 mm. (Drawing)
High of Sealing for chestpiece housing= 0,96 mm. (Drawing)

(Ø $_{\text{Chestpiece housing}}$ - Ø $_{\text{Sealing for chestpiece housing}}$)/2 + high of Sealing for chestpiece housing=
(40,71 – 37,60)/2 + 0,96 = **2,52 mm**

Area number 3



1)
The distance from the PCB track on the button to the chrome surface on the chestpiece housing, is measured to:
Horizontal $_{\text{measured}}$ + Vertical $_{\text{PHO/E}}$= 2,09 + 1 = **3,09 mm**

2)
The distance from the PCB track to the chestpiece housing, is measured to:
Horizontal $_{\text{measured}}$ + Vertical $_{\text{measured}}$= (1,00+0,4) + 0,90 = **2.30 mm**

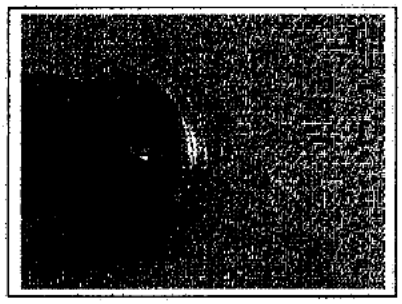
The distance from the PCB track for the button to the chrome surface on the chestpiece housing, is measured to:
Horizontal $_{measured}$ + Vertical $_{measured}$= 1,70 + (2,3-0,90-1,30)= **1,80 mm**

Area number 4

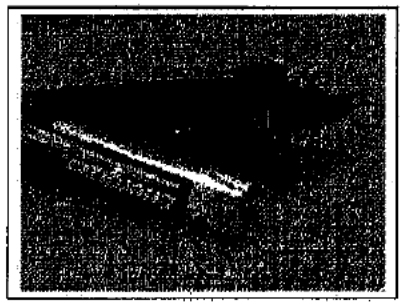
The distance from battery spring to the chrome surface on the chestpiece housing is measured to **3,04 mm**

(b)(4)Trade Secret Process- E3000

Area number 5



The distance from the soldering between battery plate and Flex wires for battery housing to the chrome surface on the tube cover is measured to **2,07 mm**



Check of wrong battery orientation (Δl ≥ 0 [mm])
The distance from the bullet on the battery plate to the wall for stop of Battery is measured. (Distance from the wall for stopping the battery to the end of the tube on battery housing - distance from the bullet on the battery plate to the end of the tube on battery housing)
Δl = 23,81 - 23,41= 0,40 mm.

Wrong orientation of the battery in battery housing is also verified with power meter, when battery was inserted and removed in battery housing and positioned in wrong/correct direction.

[redacted] (b) (4)T d [redacted] E3000

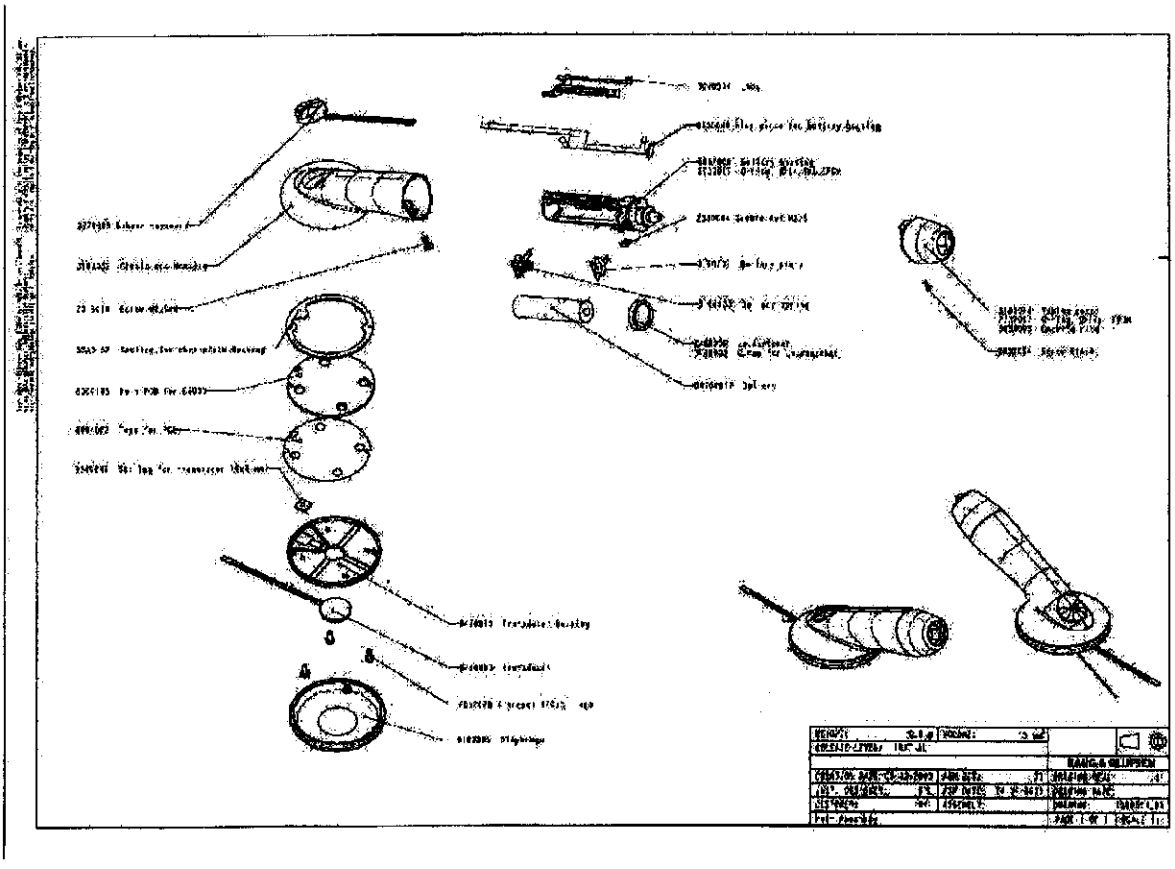
3 Conclusion

It is conclude that the E3000 meet the safety requirements with respect to the IEC 60601-1-1, Standard.
It is also conclude that the E3000 meet the product requirement PR:0146.

4 Measure equipment

Digital gauge, number: R2676

Agilent 34401A Digital Multimeter, FAA NR. 00000 36258



Certificate – EMC Testing IEC 60601-2

Attestation of Conformity

EMC test - Certificate no. 655

Since 1992 DELTA has been appointed Competent Body by the notified authority National Telecom Agency, Denmark. The attestation of conformity with the below mentioned standards and/or normative documents is based on accredited EMC test carried out at DELTA.

DELTA client
(b) (4) [redacted]

Product identification (type(s), serial no(s).)
Electronic Stethoscope Model E3000

Manufacturer
(b) (4) [redacted]

Technical report(s)
DELTA test Report B401131. DANAK reg no. 19k0188

Standards/Normative documents
EN 60601-1-2:2001, sections 3 and 36.

The product identified above has been assessed and complies with the specified standards/normative documents. The attestation does not include any market surveillance. It is the responsibility of the manufacturer that mass-produced apparatus have the same EMC quality. The attestation does not contain any statements pertaining to the EMC protection requirements pursuant to other laws and/or directives other than the above mentioned if any.

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Them 1 July 2004

Jørgen Mygind
Department Manager

DELTA

Test Report – EMC Testing IEC 60601-2:2001

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TEST REPORT

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EMC test on Electronic Stethoscope Model E3000
Performed for [redacted]
Project no.: E401131
Date: 2004-06-29

DELTA

Title	EMC test on Electronic Stethoscope Model E3000.
Test object	Electronic stethoscope.
Report no.	DANAK - 19K0188
Project no.	E401131
Test period	2004-06-09 to 2004-06-23
Client	(b)(4)Trade Secret Process-Product specs [redacted]
Contact person	Kåre Sørensen. Bang & Olufsen Medicom A/S.
Manufacturer	(b) (4) [redacted]
Persons attending tests.	Kåre Sørensen. (b) (4) [redacted]
Specifications	
EN 60601-1-2:2001	Medical Electric Equipment. Part 1: General requirements for safety. Part 1-2. Collateral Standard: Electromagnetic compatibility - requirements and tests.

Results	The tested Electronic Stethoscope Model E3000 complies with the specified requirements in EN60601-1-2:2001, sections 3 and 36.
Test personnel	Claus Grøn Lyngby, DELTA
Date	2004-06-29

Project manager

Claus Grøn Lyngby, DELTA

Responsible

Per Bo Sondrup, DELTA

1. Table of Contents.

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Annex 1: 14 pages
Annex 2: 2 pages.
Annex 3: 3 pages.

2. Summary of test result.

Immunity test:	**EN 60601-1-2 2001**
Electrostatic discharge Immunity	PASS
RF Field Immunity 80-1000MHz	PASS
RF Field Immunity 1GHz – 2,5MHz	PASS
Burst Immunity	Not relevant
Surge Immunity	Not relevant
RF Conducted Immunity	Not relevant
50 Hz Magnetic Field Immunity	PASS
Voltage variations (DIPS) Immunity	Not relevant
Emission test:	
RF Field emission	PASS
RF - conducted Voltage emission	Not relevant

The test results relate only to the individual item, which has been tested.

3. Test condition

Equipment:	E3000 Electronic Stethoscope. s/n R4X26066 and s/n R4X26067
Chassis:	Chrome coated plastic body with plastic tubes for earpieces.
Operating Condition:	ON mode: Emission: Max volume. Filter OFF Immunity: ESD: Volume 2 steps from max. Filter OFF Field: Max volume. Filter OFF
Cables:	No cable applies to the EUT. (Audio signal transferred via plastic tube).
Observation of fault:	Measurements with Audio-link. See chapter 7 for setup. The limit is set by the manufacturer to be 94 dB SPL. (Sound Pressure Level).
Auxiliary equipment:	None
Test Set-up:	See fig. 1.
Fault criteria:	The performance criteria used during the test are defined in chapter 4. The persons present during the test evaluate the test results.
Classification:	EUT is considered as Class B, Group 1 equipment, referring to CISPR11.
Climatic conditions:	Unless other is specified in the following chapters, the test is performed under the following climatic conditions: Temperature: 15 °C to 35 °C Relative humidity: 30 % to 60 % Atmosphere pressure: 86 kPa to 106 kPa (860 mbar to 1060 mbar)
Quality assurance:	DANAK = Danish Accreditation body.

3.1 Test Set-up

EUT

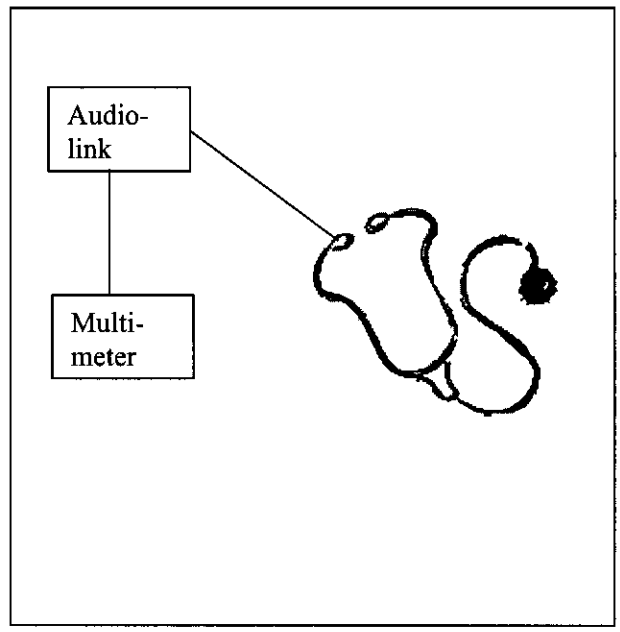


Fig. 1.

4. Performance criteria

The performance criteria from EN 60601-1-2 is listed below:

> *36.202.1.j)*
> *Under the test conditions specified in 36.202, the equipment or system shall be able to provide the essential performance and remain safe.....*
> *60601-1-2 IEC:2001*

5. Measurements and results, Immunity.

Tests and measurements that are marked with grey in this document are not performed.

5.1 Electrostatic Discharge, Immunity. EN 61000-4-2

The purpose with electrostatic discharge test is to simulate discharges which may occur from personnel to objects near EUT.
Test setup and method are in accordance to EN 61000-4-2.

Test:

At least 10 single discharges are applied to each test point, positive and negative polarity and at different levels.

Compliance: Equipment shall comply with the requirements specified in EN60601-1-2: 2001 chapter 36.202.1 j.

Test level:

Port	EN 60601-1-2 2001 Basic Standard: EN 61000-4-2
Chassis: **(conductive chassis-parts)**	± 6 kV contact discharge
Chassis: **(Electrical insulating chassis-parts)**	+ 8 kV air discharge
Horizontal and Vertical coupling plane	± 6 kV contact discharge

Results of test.

The EUT complies with the requirements in the specified standard.

Test sheets and setup: Annex 1 page 1 and photo in annex 3 no. 1.

5.2 RF - Field, Immunity. EN 61000-4-3

The purpose is to test the immunity of the EUT to radiated electromagnetic energy, which can be generated by such sources as small hand-held radio transceivers etc. and various industrial electromagnetic sources.

Test set-up and method are in accordance with EN 61000-4-3.

The test is performed in an anechoic chamber. The transmitting antenna is placed at a distance of 3 m from the EUT with horizontal and vertical polarisation respectively. The actual radiated field is obtained by pre-calibration of the empty chamber at 16 points in an area of 1.5 x 1.5 m, where the magnitude is within -0 to + 6 dB of the normal value over 75 % of the surface.

Compliance: Equipment shall comply with the requirements specified in EN60601-1-2: 2001 chapter 36.202.1 j.

Test requirements:

Port:	**EN 60601-1-2** 2001 Basic Standard: EN 61000-4-3
Chassis:	*)3V/m 1 KHz 80 % AM 80 - 2500 MHz

*) 10V/m is requirement for equipment used as life support equipment.

The standard specifies that the test shall be performed with the generating antenna facing each of the four sides of the EUT.

Measurement of SPL (Sound Pressure Level) with Audio link.

Results of test.

In the frequency range 80-1000MHz the test was performed with the generating antenna facing the sides bottom and horizontal side of circuit card only, as these were considered as the most sensitive sides of the EUT.
In the frequency range 1-2,5GHz the test was performed, with the generating antenna facing the lengthwise and crosswise side only, as this was considered as the most sensitive side of the EUT

Test sheets and setup 80-1000MHz: Annex 1 pages 2-5, and photo in annex 3 no 2.
Test sheets and setup 1-2,2GHz: Annex 1 pages 6-9, and photo in annex 3 no 3-4.
Test sheets and setup 2,2-2,5GHz: Annex 1 pages 10-13, and photo in annex 3 no 3-4.

The EUT complies with the requirements in the specified standard.

5.3 Burst, Immunity. EN 61000-4-4

The purpose of the burst test is to simulate the fast transients which will appear in any kind of relays and contacts.
Test setup and method are in accordance with EN 61000-4-4.

Pulse shape tr/th : 5 ns / 50 ns.

Test method on:
Power ports : Direct coupling positive and negative polarity, Common mode.
Signal ports : Capacitive coupling positive and negative, Common mode.

Compliance: Equipment shall comply with the requirements specified in EN60601-1-2: 2001 chapter 36.202.1 j.

Test levels:

Port:	**EN 60601-1-2** 2001 Basic Standard: EN 61000-4-4
AC power-port	± 2KV
DC power-port	± 2kV
Signal & communication, process measurements & control ports	± 1 kV
Separate earth connection	No requirements

Results of test.

Not relevant.

5.4 Surge, Immunity. EN 61000-4-5

The purpose of the surge test is to simulate the high-energy disturbance caused by over voltage from switching and lightning transients.
Test setup and method are in accordance with EN 61000-4-5.
The test will be repeated by 5 pulses at each test voltage, positive and negative polarity
Coupling of pulses to the AC power ports is done by 0° and 90° in accordance to the actual phase.

Pulse shape:	Open circuit voltage tr/th	1,2 / 50 µS.
	Short circuit current tr/th	8,0 / 20 µS.
Source impedance:	Power ports	2 Ω (DM)
		12 Ω (CM)

Compliance: Equipment shall comply with the requirements specified in EN60601-1-2: 2001 chapter 36.202.1 j.

Test level:

Port:	EN 60601-1-2 2001 Basic Standard: EN 61000-4-5
AC power port	2KV (CM) 1KV (DM)
DC power port	No requirements

Common mode: *Test at one line in accordance to reference ground (PE).*
Differential mode: *Test between 2 lines.*

Results of test.

Not relevant.

5.5 RF - Conducted, Immunity. EN 61000-4-6

The purpose is to test the immunity of the EUT to electromagnetic fields, which may occur from RF transmitters. The electromagnetic fields may act on the whole length of cables connected to the EUT. The frequency range is from 150 kHz to 80 MHz.

Test setup and method are in accordance to basic standard EN 61000-4-6.

Source impedance : 150 Ω

Compliance: Equipment shall comply with the requirements specified in EN60601-1-2: 2001 chapter 36.202.1 j.

Test level:

Port:	**EN 60601-1-2** 2001 Basic Standard: EN 61000-4-6
AC power-port	$3V_{RMS}$*)
DC power-port	$3V_{RMS}$*)
Signal & communication, process measurements & control ports	$3V_{RMS}$*)

*) $10V_{RMS}$ is requirement for equipment used as life support equipment.

Results of test.

Not relevant.

5.6 50 Hz Magnetic Field, EN 61000-4-8.

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 equipment (e.g. proximity of equipment to the disturbance source). The power frequency magnetic field is generated by power frequency current in conductors or, more seldom, from other devices (e.g. leakage of transformers) in the proximity of equipment.

Test setup and method are in accordance to EN 61000-4-8.

The EUT is operating at normal condition during the test.

Compliance: Equipment shall comply with the requirements specified in EN60601-1-2: 2001 chapter 36.202.1 j.

Test level:

Port:	**EN 60601-1-2** 2001 Basic Standard: EN 61000-4-6
Chassis	3A/m

Measurement of SPL (Sound Pressure Level) with Audio link.

Results of test.

Test sheets and setup: Annex 1 page 14 and photo in annex 3 no. 5.

The EUT complies with the requirements in the specified standard.

5.7 Voltage Dips, Interruptions and Variations, EN 61000-4-11.

The purpose of this test is to test the equipment connected to low-voltage power supply networks for voltage dips, short interruptions, and voltage variations.

Test setup and method are in accordance to EN 61000-4-11.

Compliance: Equipment shall comply with the requirements specified in EN60601-1-2: 2001 chapter 36.202.7 and 36.202.1 j.

Test level:
Tables from EN60601-1-2:2001

Table 210 – Immunity test levels for voltage dips

Voltage test level $\%\ U_T$	***Voltage dip*** $\%\ U_T$	***Duration*** *periods*
<5	*>95*	*0,5*
40	*60*	*5*
70	*30*	*25*
Note U_T is the a.c. mains voltage prior to application of the test level.		

Table 211 – Immunity test levels for voltage interruption

Voltage test level $\%\ U_T$	***Voltage dip*** $\%\ U_T$	***Duration*** *s*
<5	*>95*	*5*
Note U_T is the a.c. mains voltage prior to application of the test level.		

Results of test.

Not relevant.

6. Measurements and results, Emission.

Detector:

In the normally used basic standards for RF emission, the measurements are performed by quasi-peak and average detectors with a measurement time of 1 second.

In practice, to save some time, the measurements will be performed with a peak-detector. This measurement is also a "worst-case" measurement.

If the measurements with the peak-detector are close to or cross the specified limit, a measurement will be carried out with the correct detector.

Tests and measurements that are marked with grey in this document are not performed.

6.1 RF-Field Emission. EN 55011.

The purpose with RF-Field Emission measurement is to make sure that EUT is not disturbing other apparatus.

Test setup and method are in accordance with EN 55011.

The measurements for RF-Field Emission are done in the frequency range 30 - 1000 MHz with a bandwidth of 120 kHz.

Operation condition:

Limits:

Frequency Range [MHz]	EN 60601-1-2, 2001 class B		EN 60601-1-2, 2001 class A	
	Measuring distance = 10m 2) dBµV/m	Measuring distance = 3 m 3) dBµV/m	Measuring distance = 30m 2) dBµV/m	Measuring distance = 3 m 3) dBµV/m
30 - 230	30	40	30	50
230 - 1000	37	47	37	57

Measurements only on apparatus with internal clock frequency > 9 kHz.

1): *For equipment permanently installed in X-ray shielded locations an increase of 12dB of the limits is allowed.*
2): *May be measured at 10m distance using the limit increasing by 10dB.*
3): *Pre-scanned measurements.*

The pre-scanned measurements are performed in a shielded room at a distance of 3m. Even by increasing the limits - the results may vary significantly from the final results at the calibrated outdoor test setup (Open Area Test Site).
In the shielded room there will typically be a higher level of measured noise.

Results of test.

Pre-scanned measurements: Annex 2 pages 1-2 and photo in annex 3 no. 6.

Final measurements on 10m OATS: Due to the very radiation from the EUT at the pre-scan, no measurements on OATS were necessary.

The EUT complies with the requirements in the specified standard.

6.2 RF-Conducted Voltage Emission. EN 55011

The purpose of measuring the conducted emission is to make sure that EUT is not disturbing other apparatus.

Test setup and method are in accordance with EN 55011.

Line impedance stabilisation network: 50Ω // ($50\mu H + 5\Omega$)

Detector: Quasi-peak, bandwidth 9 kHz
Average, bandwidth 9 kHz

Limits:

Frequency Range [MHz]	EN 55011 Class B **EN 60601-1-2, 2001**		EN55011 Class A **EN 60601-1-2, 2001**	
	Quasi-peak dBµV	Average dBµV	Quasi-peak dBµV	Average dBµV
0.15 - 0,5	*) 66 - 56	*) 56 - 46	79	66
0,5 - 5,0	56	46	73	60
5,0 - 30,0	60	50	73	60

*) The limit decreases linearly with the logarithm of the frequency in the range 0,15 MHz to 0,50 MHz.

Results of test.

Not relevant.

7. Test setups.

Specification for Test Setup's used at DELTA, Them

Test set up	ID no.	Description	Manufacturer	Type no.	Set up uncert.
G + OATS	0161	Measuring receiver	Rohde & Schwarz	ESVS 10	± 2,2 dB
		Antenna mast	HD Diesel	MA240	
		Turn table	HD Diesel	DT 430	
	0241	Amplifier	Mini circuit	ZFL-1000H	
	0254	Bilog Antenna	Chase	CBL 6111 A	
	K087	Cable	Suhner	Sucoflex104PA	
	0237	Bilog Antenna	Chase	CBL 6111 A	
	K088	Cable	Suhner	Sucoflex104PA	
	K012	Cable	Suhner	RG213	
	K113	Cable	Suhner	RG213	
	K090	Cable	Suhner	RG213	
	D061	Caox-switch	Daiwa	CS-201	

Test set up	ID no.	Description	Manufacturer	Type no.	Set up uncert.
L	29785	Amplifier	Amplifier Research	1000L	± 20,8 %
EN61000-4-3	29786	Amplifier	Amplifier Research	500/1000M5	
	29984	Amplifier	Milmega	AS0822-200B	
		Amplifier	Keltec	SR625-20	
	29271	Antenna	Logimetrics Inc.	AN8200	
	0234	Signal generator	Marconi Instrument	2024	
	K067	Cable	Gold Star	RG058	
	0295	Power meter	Rohde & Schwarz	NAP/NAP-25	
	0299	Antenna	Amplifier Research	AT1080	
	K042	Cable	Suhner	CellflexHFC½"	
	0105	Antenna	Vianello	PMM	
	K110	Cable	Suhner	RG400	
	0303	Compact Chamber	Frankonia		
	0305	Field sensor	Amplifier Research	FP 2000	
	0256	Multimeter	Hewlett Packard	3478A	

K003	Cable		RG 214
K014	Cable	Suhner	RG213
K086	Cable gen.	Spinner	BN204213
K085	Cable ant.	Suhner	RG214
K118	Cable	Suhner	RG214
K119	Cable	Suhner	RG214

Test set up	ID no.	Description	Manufacturer	Type no.	Set up uncert.
N	0239	ESD generator unit	Compliance instr.	ESDC 30	± 5,8 %
	0240	ESD gun	Compliance instr.	ESDP 33	
	0330	Coupling plane	Jyske EMC		

Test set up	ID no.	Description	Manufacturer	Type no.	Set up uncert.
R	005	Power magnetic Helmholz-Coil	Jyske EMC		± 11,7 %
	0319	AC power source	California instr.	500li	

Specification for Test Setup used at DELTA, Hørsholm. (RF Field Immunity)

NO.	DESCRIPTION	MANUFACTURER	TYPE NO.
29342	REFLECTOMETER COUPLER, 600-4200 MHz	ROHDE & SCHWARZ	ZPD
29687	LOW-LOSS u-WAVE CABLE	LOGIMETRICS	905023-3
29689	3.5 GHz. LP FILTER.	LOGIMETRICS	LPF - 3.5
29690	2-8 GHz. TWT POWER AMPLIFIER	LOGIMETRICS	A600/EH
29691	0.01 - 20 GHz. SYNTH. SWEEPER	HEWLETT-PACKARD	83620A
29694	1-12 GHz. HORN ANTENNA.	LOGIMETRICS	AN 8200 F
29775	"CABLE#12", LOW-LOSS uWAVE CABLE, SMA-SMA, 5 m	SUHNER	SUCOFLEX 104A
29984	RF POWER AMPLIFIER, 0.8-2.2 GHz, 200W	MILMEGA	AS0822-200
49002	SINGLE CHANNEL POWER METER DISPLAY UNIT	ROHDE & SCHWARZ	NRVS
49003	THERMAL POWER SENSOR, DC-18 GHz	ROHDE & SCHWARZ	NRV-Z51
49064	"CABLE#46", 1,5 m, 50 Ohm COAX CABLE, N(straight)-N(straight)	CELLFLEX	

Acoustic measure-link for EMC-tests. (Audio-link). (Hørsholm and Them).

TAL No	Instrument	Type	Art	Delta Nr	Ser No
1406	Calibrator	B&K 4231		3352	2326298
708	Measurement amplifier	GRAS 12AK	power module I		21214
515	Microphone preamplifier	GRAS 26AK	1/2"		35804
222	Microphone capsule	GRAS 40AG (inde i 711)	1/2" Tryk		35177
2619	Kobler	GRAS RA0045	711		36777
	Multimeter	HP3478A		ID0256	
	Multimeter	HP34401A		29975	

Annex 1.

Immunity test sheets.
(14 pages)

Immunity test: Electrostatic Discharges

Basic test standard: EN 61000-4-2 | **Enclosure port**

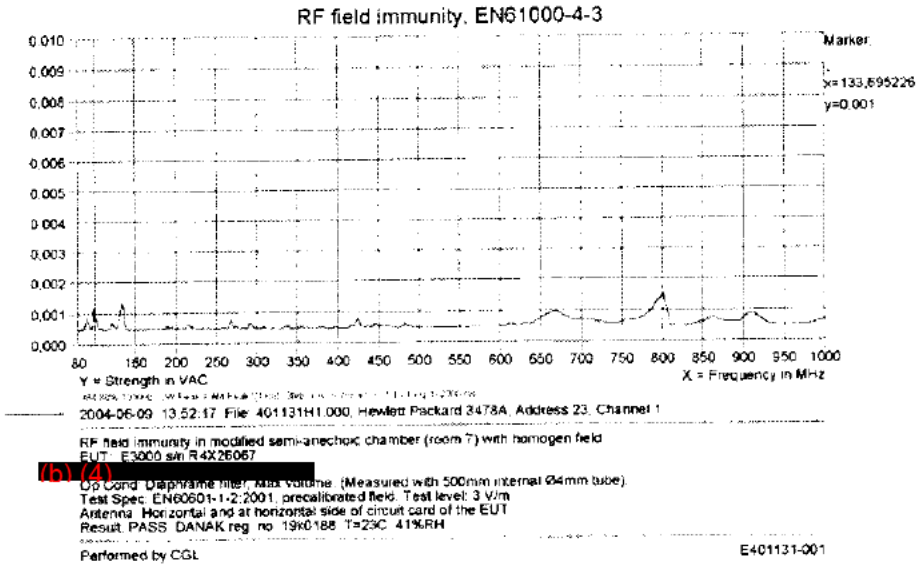
Test points	Discharge requirements, level and test results										
Air discharge method used to following items	Test level [kV]: >	-2	+2	-4	+4	-8	+8	-15	+15	Special	
	Requirement: >					X	X			-	+
	Fault level [kV]: >									kV	kV
Rubber foot		OK	OK	OK	OK	OK	OK				
Button		OK	OK	OK	OK	OK	OK				
Contact discharge method used to following items	Test level [kV]: >	-2	+2	-4	+4	-6	+6	-8	+8	Special	
	Requirement: >					X	X			-	+
	Fault level [kV]: >									kV	kV
Chest peace		OK	OK	OK	OK	OK	OK				
Tubing cover		OK	OK	OK	OK	OK	OK				
Transducer		OK	OK	OK	OK	OK	OK				
Screws @ transducer		OK	OK	OK	OK	OK	OK				
Coupling plane H/V		OK	OK	OK	OK	OK	OK				

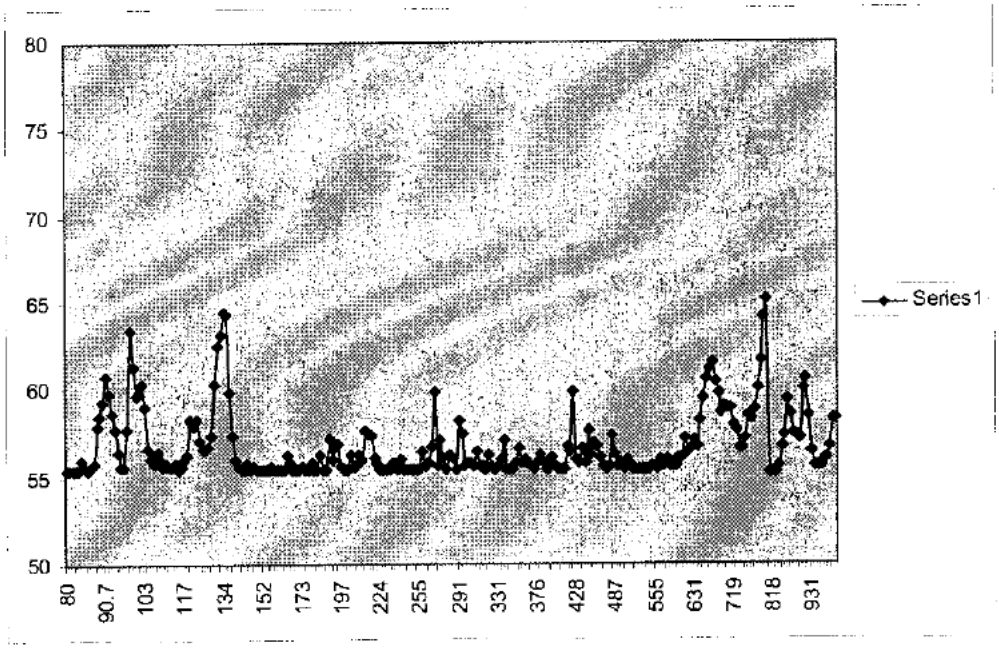
Test setup		**Equipment**	**DELTA ID no.**
	M001	ESDC 30 ESD generator	226
		ESDP 33 air/contact pistol	227
		ESD accessories	116
X	N001	ESDC 30 ESD generator	239
		ESDP 33 air/contact pistol	240

Test performed as:		**Remarks to test**
X	Table top appliance	Test mode: 2 steps from max volume. Filter ON At least 1 discharges @ each level and polarity.
	Floor standing appliance	

Used immunity standard:				**Status of test:**		**EUT:**	**E3000 s/n R4X26067**
	EN 61000-6-1	Year	2001		Non Accredited test	Test responsible:	PBS
	EN 61000-6-2	Year	2001	X	Accredited test	Test performed by:	CGL
X	EN 60601-1-2	Year	2001		DANAK reg. no 19K 0188	Project no.	E401131
					Room humidity 38 %	Date	2004-06-21
					Room temp. 22 °C	Time:	0945

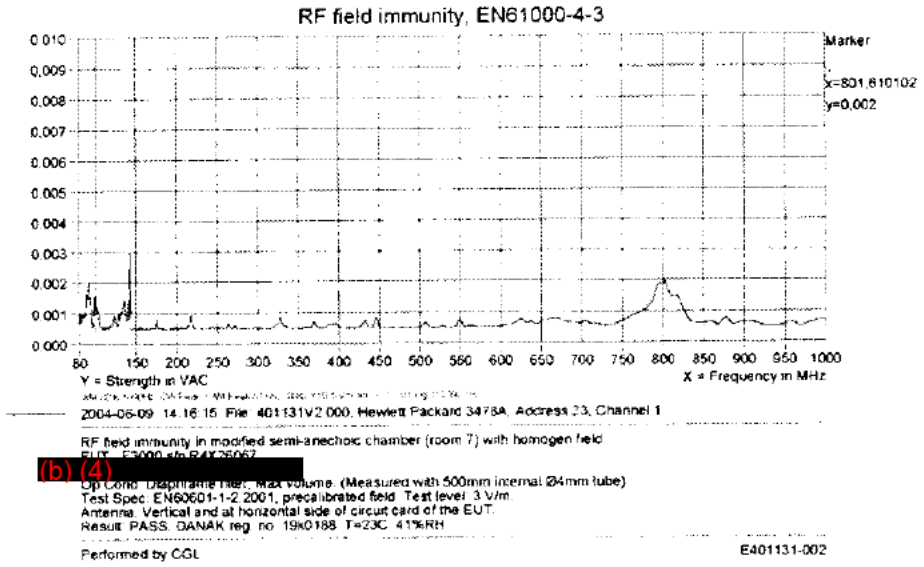
Test result:		**Comments to result:**
X	PASS	**Fulfils performance criteria as specified in used standard chapter 36.202.1 j**
	FAIL	

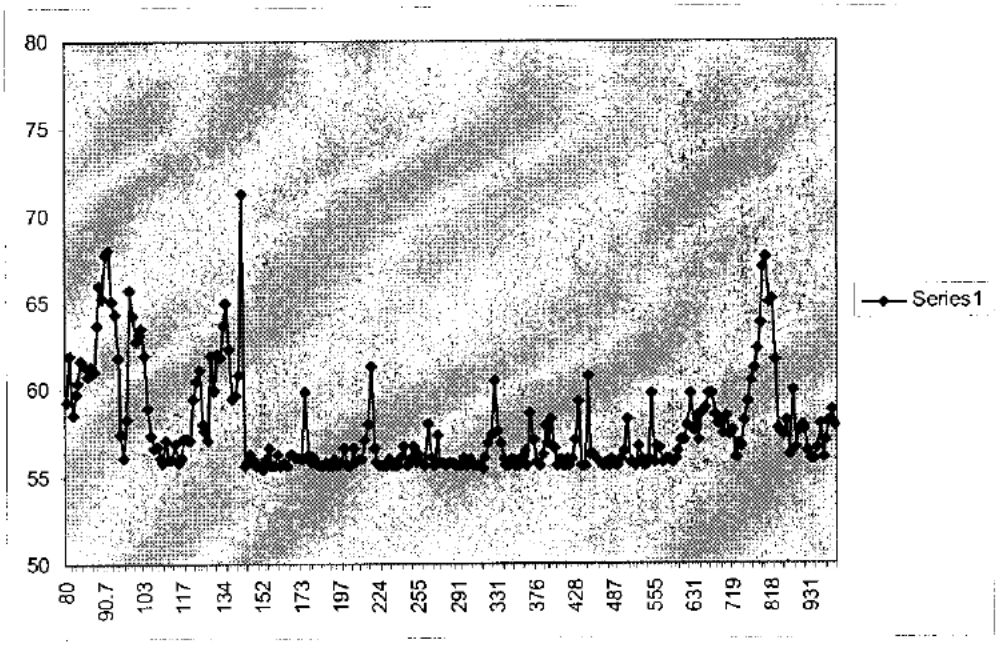




X-axis = Freq [MHz], Y-axis =SPL [dB].
Measurements converted from VAC measurements to dB SPL.
Limit 94 dB SPL. (Sound Pressure Level).

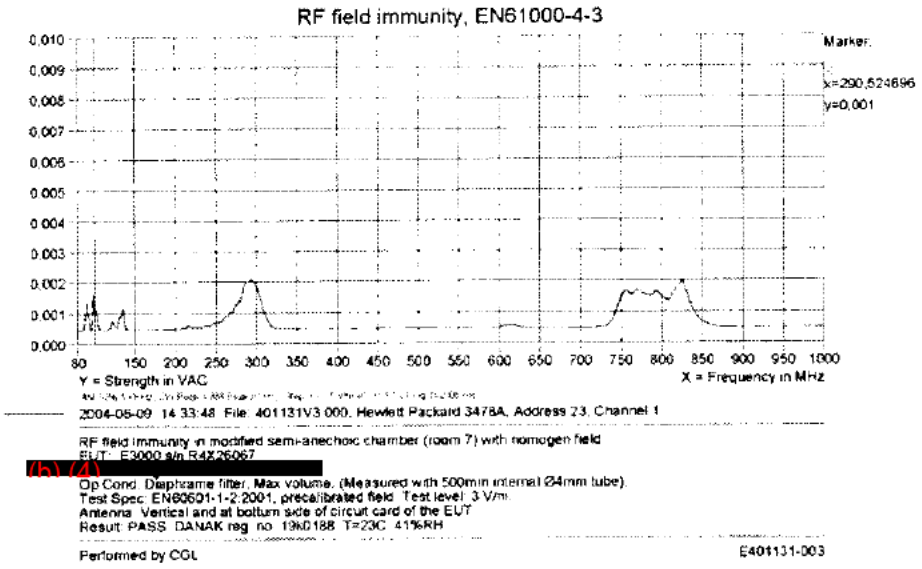
Result: PASS

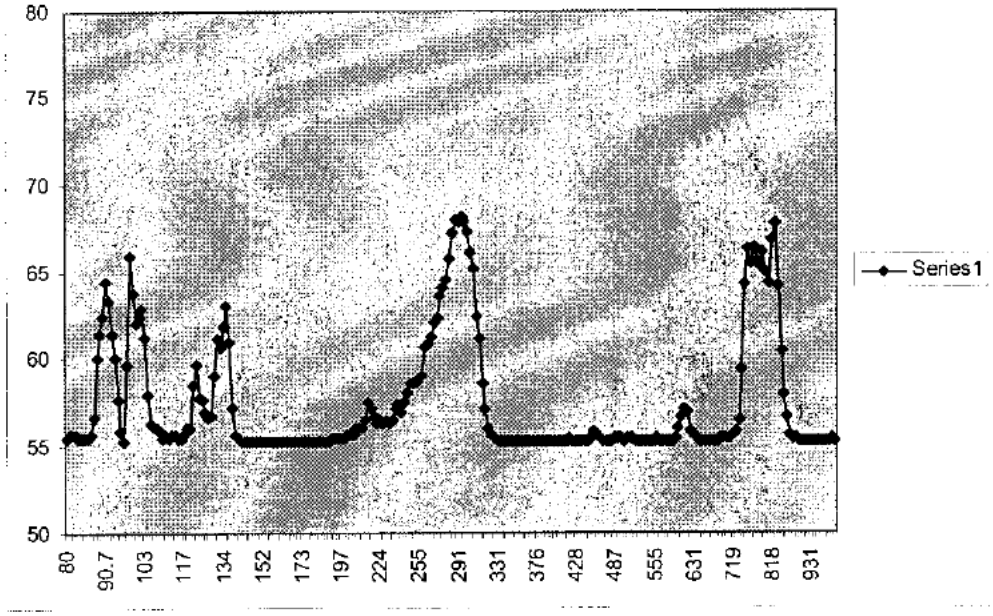




X-axis = Freq [MHz], Y-axis =SPL [dB].
Measurements converted from VAC measurements to dB SPL.
Limit 94 dB SPL. (Sound Pressure level).

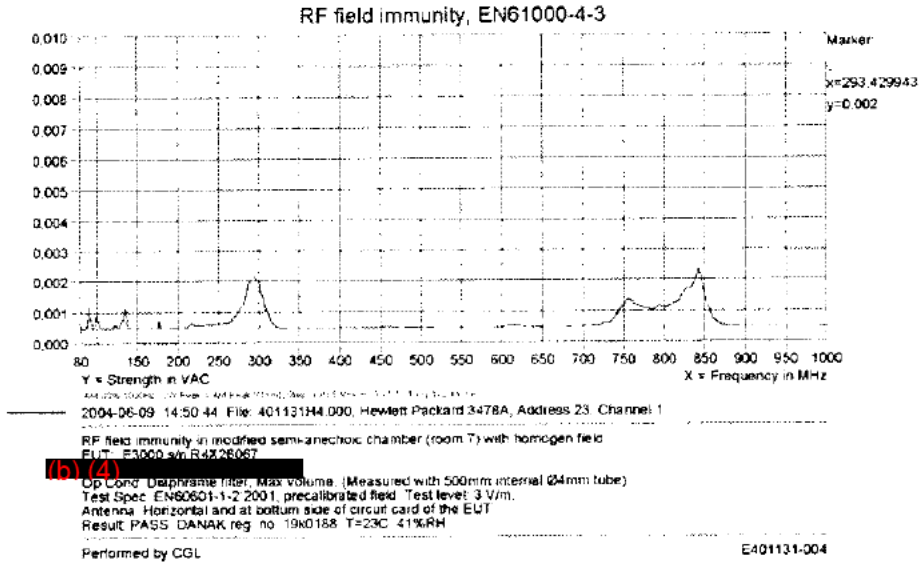
Result: PASS

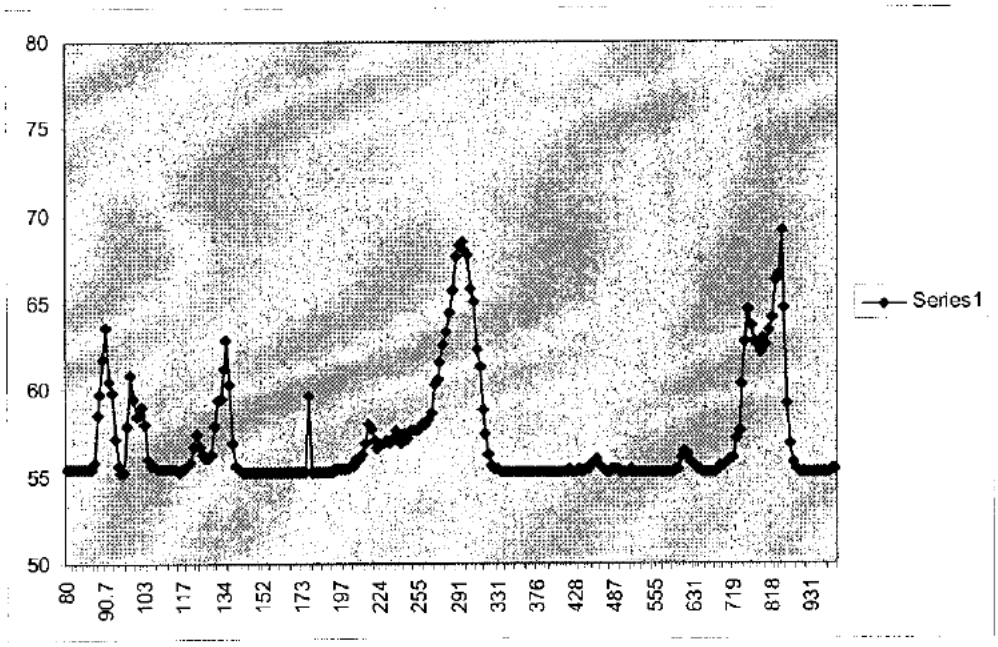




X-axis = Freq [MHz], Y-axis =SPL [dB].
Measurements converted from VAC measurements to dB SPL.
Limit 94 dB SPL. (Sound Pressure Level).

Result: PASS





X-axis = Freq [MHz], Y-axis =SPL [dB].
Measurements converted from VAC measurements to dB SPL.
Limit 94 dB SPL. (Sound Pressure Level).

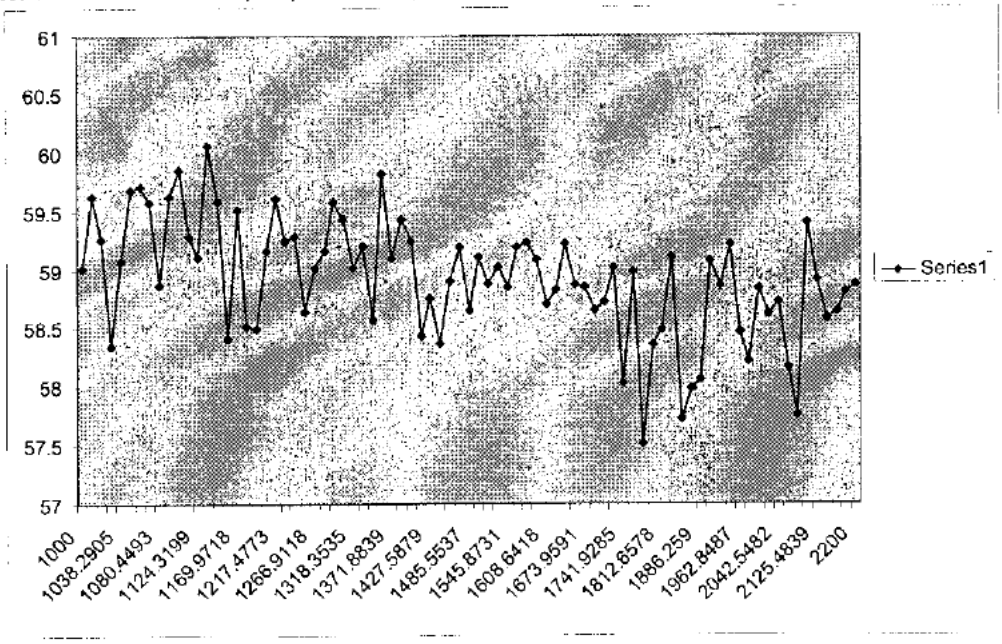
Result: PASS

DELTA EMC, Hørsholm – RF Field immunity test, EN61000-4-3

Client: (b) (4)
EUT: E3000 Stethoscope. s/n R4X26066
Operating conditions: Diaphrame filter. Max volume. (Measured with 500mm internal Ø4 mm tube).
Test spec. EN 60601-1-2:2001. Test level 3V/m.
Antenna: Polarisation: Horizontal. EUT position: Crosswise
Test site: ROOM 1
Test:
1000 to 2200MHz: AM 80% 1000Hz, CW Peak = AM Peak /(1+m), Step: X=1:1,01 log, t=3000 ms
Field strength 3V/m
Start time=23-06-2004 15:29:59

Test personnel init: JWH
DELTA Project No: E401131. DANAK reg. no. 19k0188. T=23°C. 48%RH.

Hewlett Packard 34401A, AC, Address 26, Channel 1



1-2GEN_H_Kryds
X-axis = Freq [MHz], Y-axis =SPL [dB].
Measurements converted from VAC measurements to dB SPL.
Limit 94 dB SPL. (Sound Pressure Level).

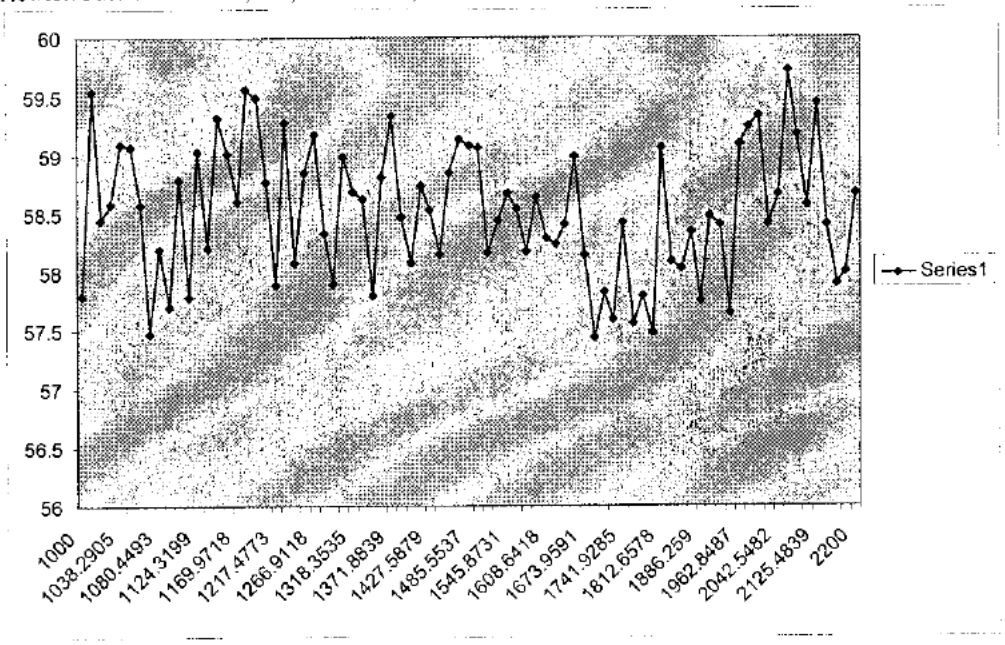
Result: PASS

DELTA EMC, Hørsholm – RF Field immunity test, EN61000-4-3

Client: [redacted] (b)
EUT: E3000 Stethoscope. s/n R4X26066
Operating conditions: Diaphrame filter. Max volume. (Measured with 500mm internal Ø4 mm tube).
Test spec. EN 60601-1-2:2001. Test level 3V/m.
Antenna: Polarisation: Horizontal. EUT position: Crosswise
Test site: ROOM 1
Test:
1000 to 2200MHz: AM 80% 1000Hz, CW Peak = AM Peak /(1+m), Step: X=1:1,01 log, t=3000 ms
Field strength 3V/m
Start time=23-06-2004 15:17:35

Test personnel init: JWH
DELTA Project No: E401131. DANAK reg. no. 19k0188. T=23°C. 48%RH.

Hewlett Packard 34401A, AC, Address 26, Channel 1



1-2GEN_V_Kryds
X-axis = Freq [MHz], Y-axis =SPL [dB].
Measurements converted from VAC measurements to dB SPL.
Limit 94 dB SPL. (Sound Pressure Level).

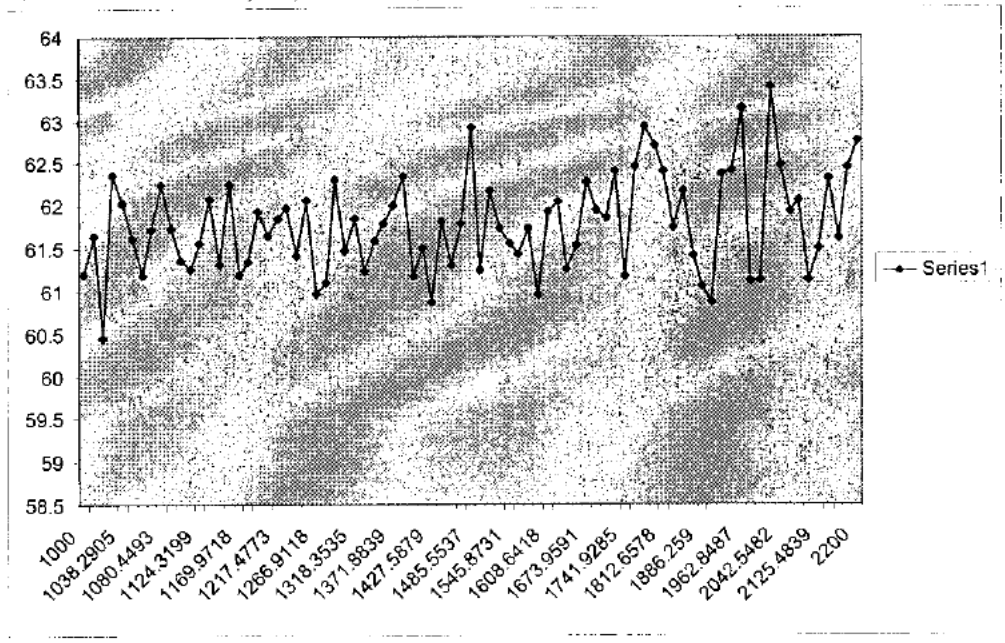
Result: PASS

DELTA EMC, Hørsholm – RF Field immunity test, EN61000-4-3

Client: (b) (4)
EUT: E3000 Stethoscope. s/n R4X26066
Operating conditions: Diaphrame filter. Max volume. (Measured with 500mm internal Ø4 mm tube).
Test spec. EN 60601-1-2:2001. Test level 3V/m.
Antenna: Polarisation: Horizontal. EUT position: Lengthwise
Test site: ROOM 1
Test:
1000 to 2200MHz: AM 80% 1000Hz, CW Peak = AM Peak /(1+m), Step: X=1:1,01 log, t=3000 ms
Field strength 3V/m
Start time=23-06-2004 14:50:15

Test personnel init: JWH
DELTA Project No: E401131. DANAK reg. no. 19k0188. T=23°C. 48%RH.

Hewlett Packard 34401A, AC, Address 26, Channel 1



1-2GEN_H_Langs
X-axis = Freq [MHz], Y-axis =SPL [dB].
Measurements converted from VAC measurements to dB SPL.
Limit 94 dB SPL. (Sound Pressure Level).

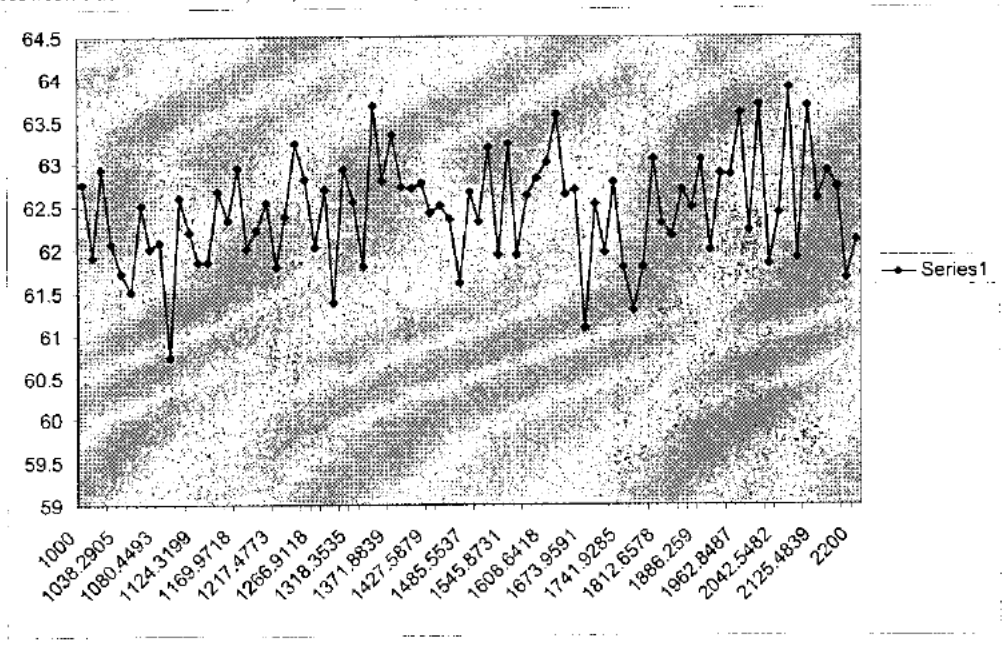
Result: PASS

DELTA EMC, Hørsholm – RF Field immunity test, EN61000-4-3

Client: (b) (4)
EUT: E3000 Stethoscope. s/n R4X26066
Operating conditions: Diaphrame filter. Max volume. (Measured with 500mm internal Ø4 mm tube).
Test spec. EN 60601-1-2:2001. Test level 3V/m.
Antenna: Polarisation: Horizontal. EUT position: Lengthwise
Test site: ROOM 1
Test:
1000 to 2200MHz: AM 80% 1000Hz, CW Peak = AM Peak /(1+m), Step: X=1:1,01 log, t=3000 ms
Field strength 3V/m
Start time=23-06-2004 15:03:03

Test personnel init: JWH
DELTA Project No: E401131. DANAK reg. no. 19k0188. T=23°C. 48%RH.

Hewlett Packard 34401A, AC, Address 26, Channel 1



1-2GEN_V_Langs
X-axis = Freq [MHz], Y-axis =SPL [dB].
Measurements converted from VAC measurements to dB SPL.
Limit 94 dB SPL. (Sound Pressure Level).

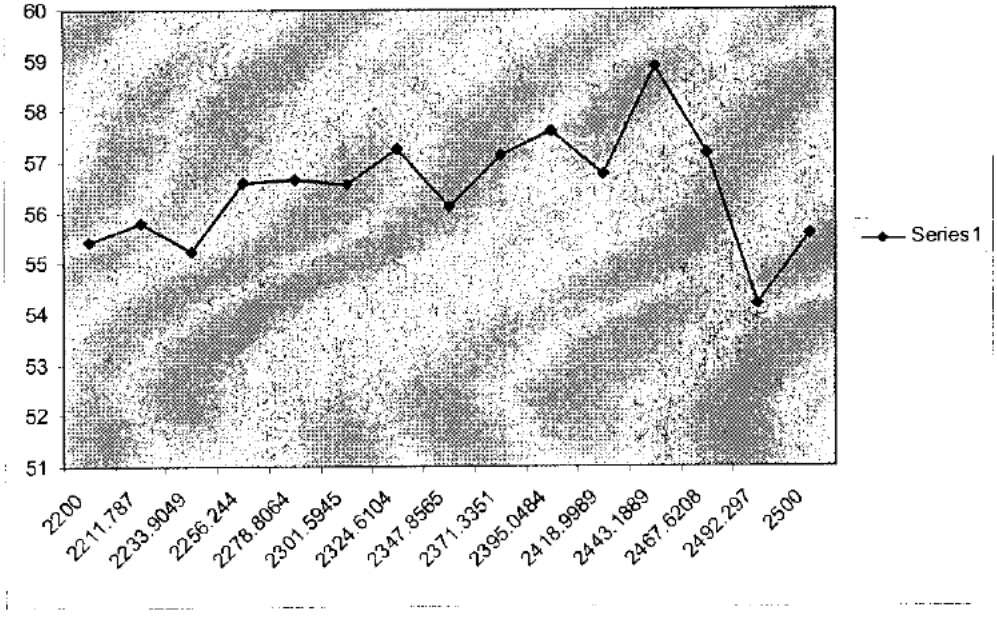
Result: PASS

DELTA EMC, Hørsholm – RF Field immunity test, EN61000-4-3

Client: (b) (4)
EUT: E3000 Stethoscope. s/n R4X26066
Operating conditions: Diaphrame filter. Max volume. (Measured with 500mm internal Ø4 mm tube).
Test spec. EN 60601-1-2:2001. Test level 3V/m.
Antenna: Polarisation: Horizontal. EUT position: Crosswise
Test site: ROOM 1
Test:
2200 to 3500MHz: AM 80% 1000Hz, CW Peak = AM Peak /(1+m), Step: X=1:1,01 log, t=3000 ms
Field strength 3V/m
Start time=23-06-2004 14:09:02

Test personnel init: JWH
DELTA Project No: E401131. DANAK reg. no. 19k0188. T=23°C. 48%RH.

Hewlett Packard 34401A, AC, Address 26, Channel 1



GEN3500H_Kryds
X-axis = Freq [MHz], Y-axis =SPL [dB].
Measurements converted from VAC measurements to dB SPL.
Limit 94 dB SPL. (Sound Pressure Level).

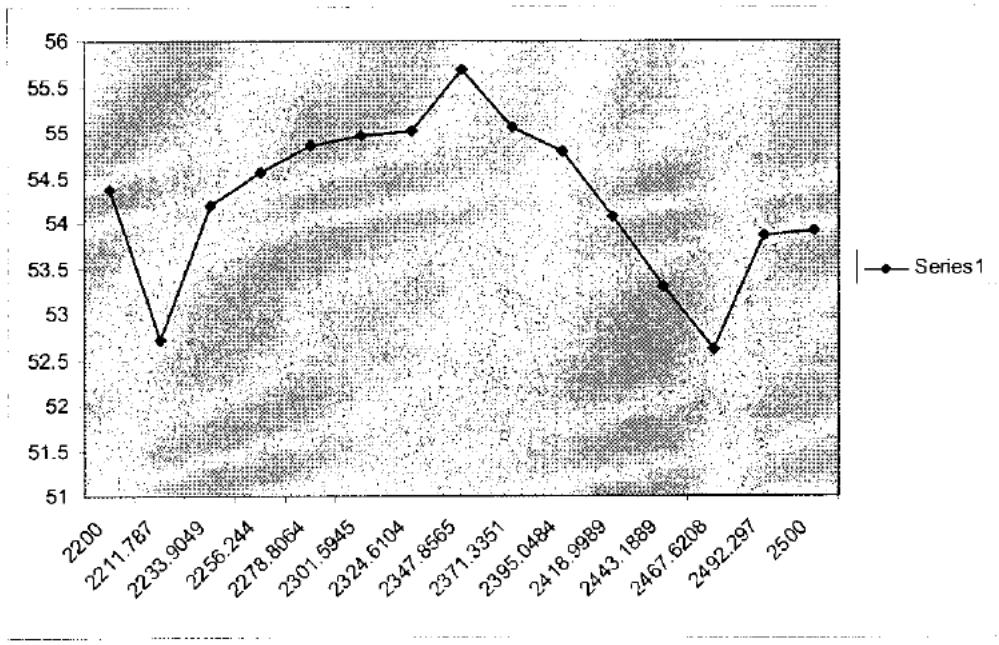
Result: PASS

DELTA EMC, Hørsholm – RF Field immunity test, EN61000-4-3

Client: (b) (4)
EUT: E3000 Stethoscope. s/n R4X26066
Operating conditions: Diaphrame filter. Max volume. (Measured with 500mm internal Ø4 mm tube).
Test spec. EN 60601-1-2:2001. Test level 3V/m.
Antenna: Polarisation: Horizontal. EUT position: Crosswise
Test site: ROOM 1
Test:
2200 to 3500MHz: AM 80% 1000Hz, CW Peak = AM Peak /(1+m), Step: X=1:1,01 log, t=3000 ms
Field strength 3V/m
Start time=23-06-2004 14:17:05

Test personnel init: JWH
DELTA Project No: E401131. DANAK reg. no. 19k0188. T=23°C. 48%RH.

Hewlett Packard 34401A, AC, Address 26, Channel 1



GEN3500V_Kryds
X-axis = Freq [MHz], Y-axis =SPL [dB].
Measurements converted from VAC measurements to dB SPL.
Limit 94 dB SPL. (Sound Pressure Level).

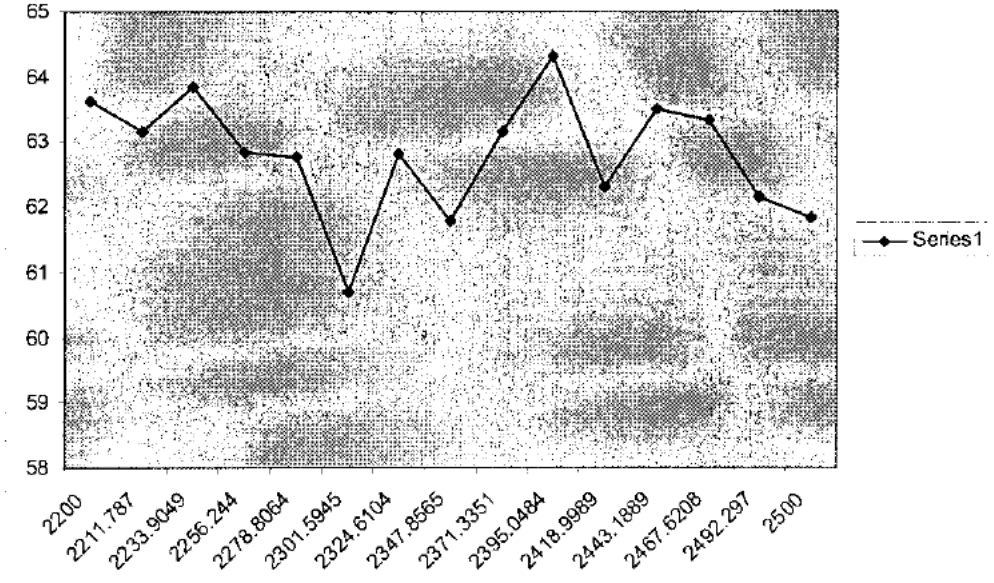
Result: PASS

DELTA EMC, Hørsholm – RF Field immunity test, EN61000-4-3

Client: (b) (4)
EUT: E3000 Stethoscope. s/n R4X26066
Operating conditions: Diaphrame filter. Max volume. (Measured with 500mm internal Ø4 mm tube).
Test spec. EN 60601-1-2:2001. Test level 3V/m.
Antenna: Polarisation: Horizontal. EUT position: Lengthwise
Test site: ROOM 1
Test:
2200 to 3500MHz: AM 80% 1000Hz, CW Peak = AM Peak /(1+m), Step: X=1:1,01 log, t=3000 ms
Field strength 3V/m
Start time=23-06-2004 14:31:06

Test personnel init: JWH
DELTA Project No: E401131. DANAK reg. no. 19k0188. T=23°C. 48%RH.

Hewlett Packard 34401A, AC, Address 26, Channel 1



GEN3500H_Langs
X-axis = Freq [MHz], Y-axis =SPL [dB].
Measurements converted from VAC measurements to dB SPL.
Limit 94 dB SPL. (Sound Pressure Level).

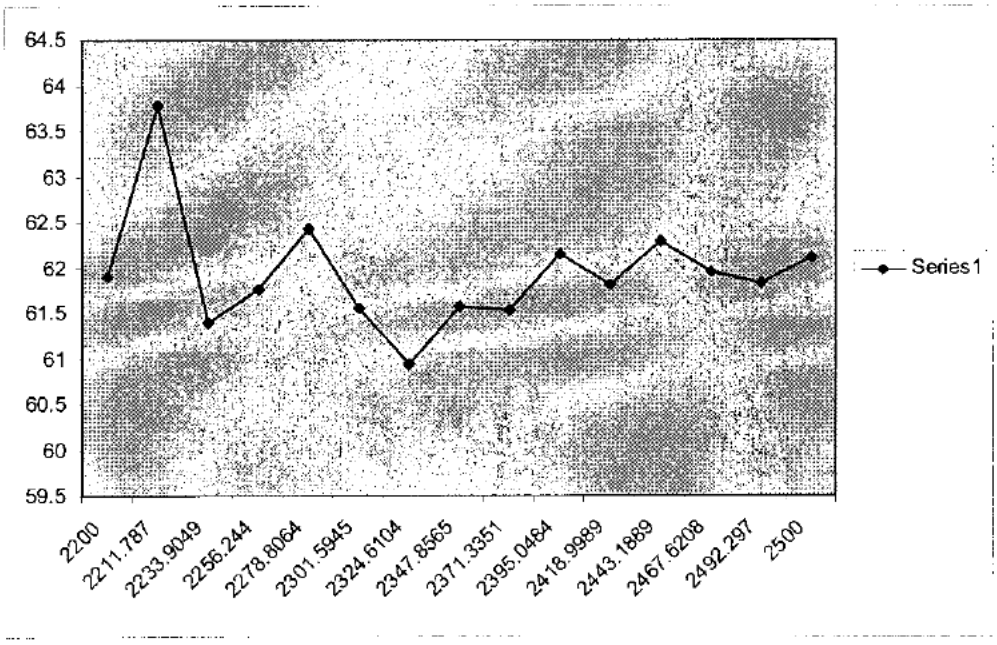
Result: PASS

DELTA EMC, Hørsholm – RF Field immunity test, EN61000-4-3

Client: (b) (4)
EUT: E3000 Stethoscope. s/n R4X26066
Operating conditions: Diaphrame filter. Max volume. (Measured with 500mm internal Ø4 mm tube).
Test spec. EN 60601-1-2:2001. Test level 3V/m.
Antenna: Polarisation: Horizontal. EUT position: Lengthwise
Test site: ROOM 1
Test:
2200 to 3500MHz: AM 80% 1000Hz, CW Peak = AM Peak /(1+m), Step: X=1:1,01 log, t=3000 ms
Field strength 3V/m
Start time=23-06-2004 14:24:18

Test personnel init: JWH
DELTA Project No: E401131. DANAK reg. no. 19k0188. T=23°C. 48%RH.

Hewlett Packard 34401A, AC, Address 26, Channel 1



GEN3500V_Langs
X-axis = Freq [MHz], Y-axis =SPL [dB].
Measurements converted from VAC measurements to dB SPL.
Limit 94 dB SPL. (Sound Pressure Level).

Result: PASS

Immunity test: Power frequency magnetic field

Basic test standard: EN 61000-4-8 | **Enclosure port.**

	Test requirements			Correct EUT function at level:	
	A	B	C		Comment
EUT position in the Helmholtz inductor	EN 61000-6-1: 2001	EN 61000-6-1: 2001	EN 60601-1-2: 2001		
	Basis standard: EN 61000-4-8				
	A/m	A/m	A/m	A/m	Measurements
EUT placed along the X-axis			3	3	@ 50Hz: 14,3mVAC @ 60Hz: 18,7mVAC No change OK
EUT placed along the Y-axis			3	3	@ 50Hz: 17mVAC @ 60Hz: 15,6mVAC No change OK
EUT placed along the Z-axis			3	3	@ 50Hz: 15,8mVAC @ 60Hz: 18,9mVAC No change OK
CTR disturbance allowed above level:	3A/m	30A/m			

	Test setup	Equipment	DELTA ID no.
X	Setup no 1	Helmholtz inductor	0005
		California Instruments 5001i	0319
		Multimeter ($10A_{RMS}$) range	
	Setup no 2	Helmholtz inductor	0005
		Hameg HM 8030-2 LF signal generator	0124
		Vector Research LF amplifier	0075
		Multimeter ($10A_{RMS}$) range	

Remarks to test:
Measurements performed with HP3478A (ID256) with 19kHz filter + audio-link
Tests were performed with 50Hz and 60Hz magnetic field

Used immunity standard:				**Status of test:**		**EUT:**	**E3000 s/n R4X26067**
	EN 61000-6-1	Year	2001		Non Accredited test	Test responsible:	PBS
	EN 61000-6-2	Year	2001	X	Accredited test	Test performed by:	CGL
X	EN60601-1-2	Year	2001		DANAK reg. no 19K 0188	Project no.	E401131
					Room humidity 41 %	Date	2004-06-09
					Room temp. 23 °C	Time:	1600

Test result:		**Comments to result:**
X	PASS	**Fulfils performance criteria as specified in used standard chapter 36.202.1 j**
	FAIL	

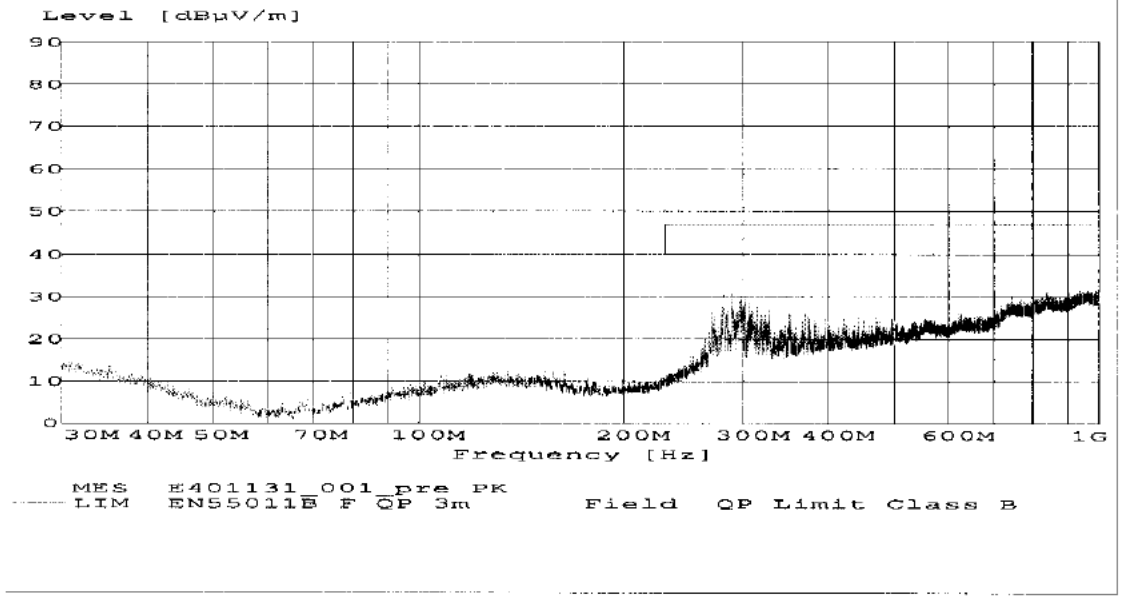
Annex 2.
Emission test sheets.
(2 pages)

DELTA Project no. E401131
R&S ESVS. RF Field Emission.

EUT: E3000 s/n R4X26067
Manufacturer: (b) (4)
Operating Condition: Max volume
Test Site: Room 5. 3m Prescan. Horizontal.
Operator: CGL
Test Specification: EN 60601-1-2. (EN 55011B).
Comment: DANAK reg. no. 19k0188. T=22C. 38%RH.
Start of Test: 21-06-2004 / 08:34:25

SCAN TABLE: "SG ID254"
Short Description: RF-Field Emission

Start Frequency	Stop Frequency	Step Width	Detector	Meas. Time	IF Bandw.	Transducer
30.0 MHz	60.5 MHz	50.0 kHz	MaxPeak	10.0 ms	120 kHz	CBL 6111 ID 254
60.5 MHz	122.0 MHz	50.0 kHz	MaxPeak	10.0 ms	120 kHz	CBL 6111 ID 254
122.0 MHz	246.0 MHz	50.0 kHz	MaxPeak	10.0 ms	120 kHz	CBL 6111 ID 254
246.0 MHz	496.0 MHz	50.0 kHz	MaxPeak	10.0 ms	120 kHz	CBL 6111 ID 254
496.0 MHz	1.0 GHz	50.0 kHz	MaxPeak	10.0 ms	120 kHz	CBL 6111 ID 254

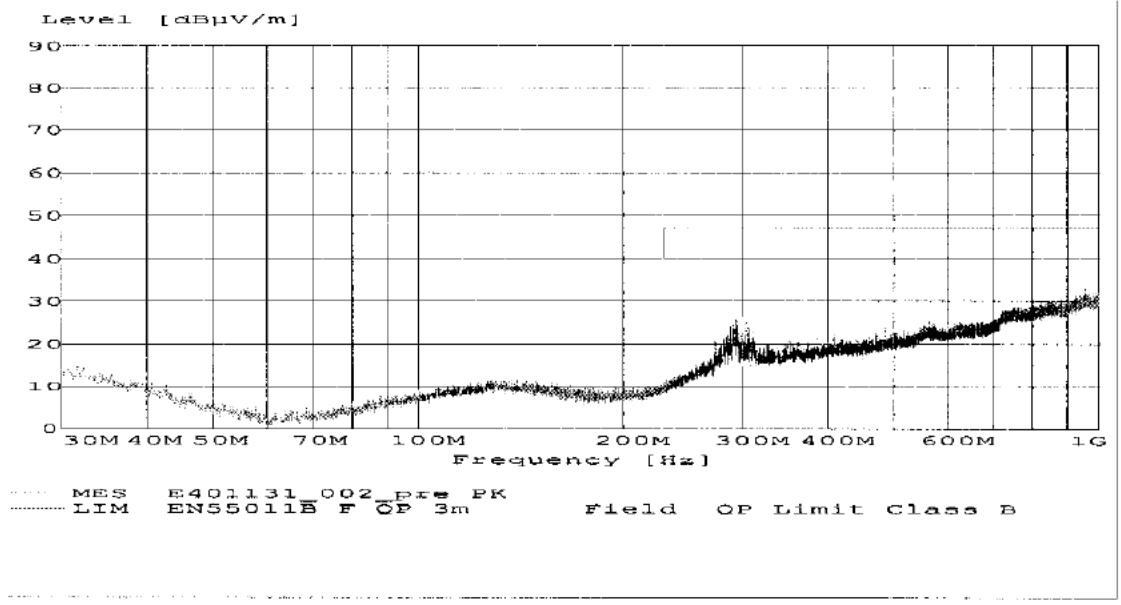


DELTA Project no. E401131
R&S ESVS. RF Field Emission.

EUT: E3000 s/n R4X26067
Manufacturer: (b) (4)
Operating Condition: Max Volume
Test Site: Room 5. 3m Prescan. Vertical.
Operator: CGL
Test Specification: EN 60601-1-2. (EN 55011B).
Comment: DANAK reg. no. 19k0188. T=22C. 38%RH.
Start of Test: 21-06-2004 / 08:51:16

SCAN TABLE: "SG ID254"
Short Description: RF-Field Emission

Start Frequency	Stop Frequency	Step Width	Detector	Meas. Time	IF Bandw.	Transducer
30.0 MHz	60.5 MHz	50.0 kHz	MaxPeak	10.0 ms	120 kHz	CBL 6111 ID 254
60.5 MHz	122.0 MHz	50.0 kHz	MaxPeak	10.0 ms	120 kHz	CBL 6111 ID 254
122.0 MHz	246.0 MHz	50.0 kHz	MaxPeak	10.0 ms	120 kHz	CBL 6111 ID 254
246.0 MHz	496.0 MHz	50.0 kHz	MaxPeak	10.0 ms	120 kHz	CBL 6111 ID 254
496.0 MHz	1.0 GHz	50.0 kHz	MaxPeak	10.0 ms	120 kHz	CBL 6111 ID 254



Annex 3.

Photos of test setup.
(3 pages)

Annex 3.

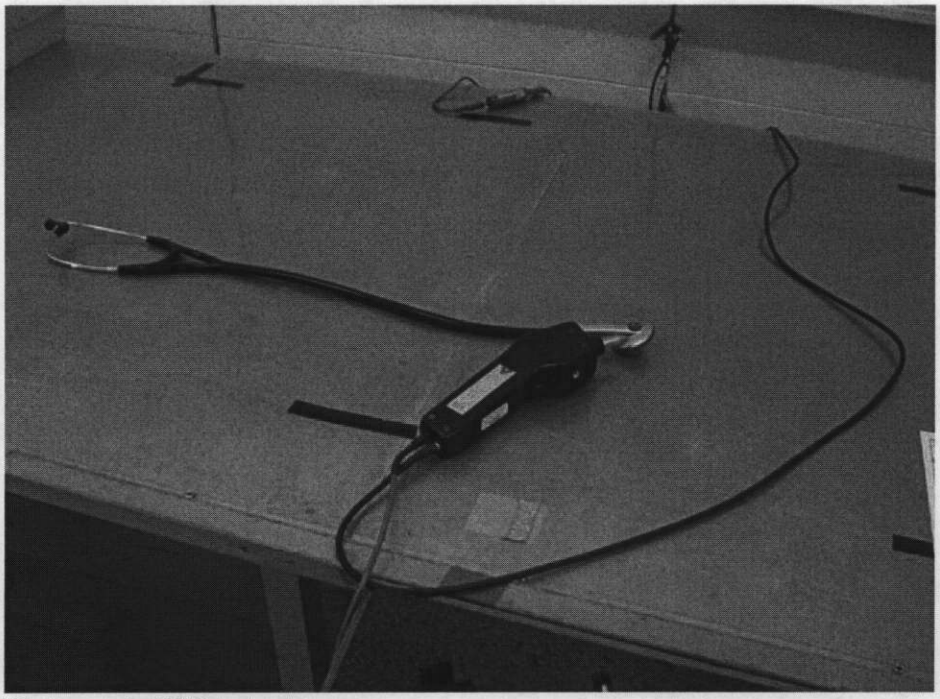


Photo no. 1: ESD test setup.

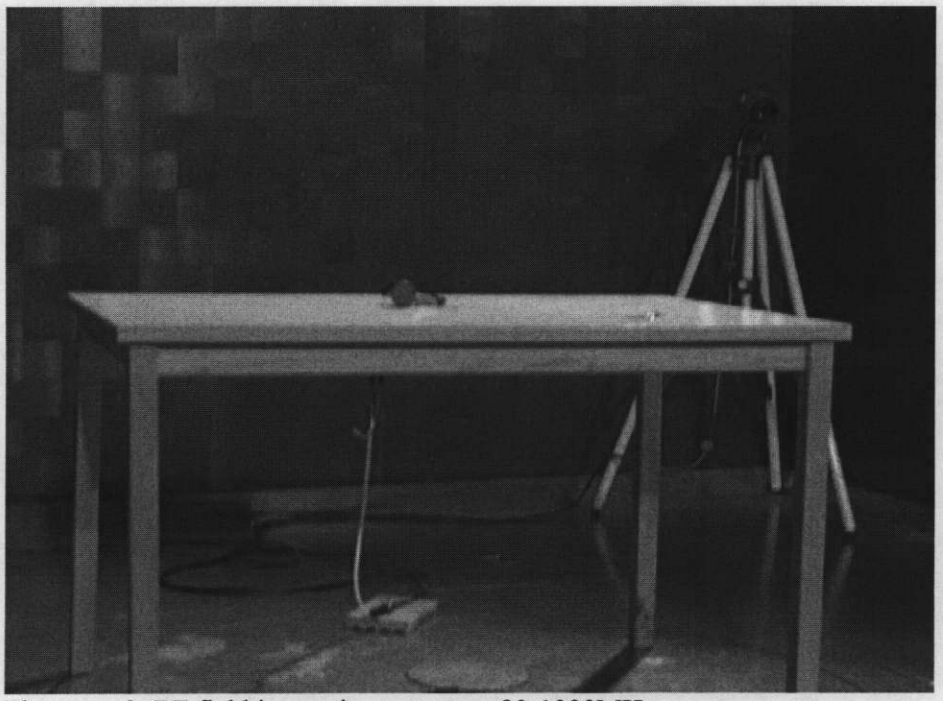


Photo no. 2: RF field immunity test setup, 80-1000MHz.

Photo no. 3: RF field immunity test setup. Lengthwise. 1000-2500MHz.

Photo no. 4: RF field immunity test setup. Crosswise. 1000-2500MHz.

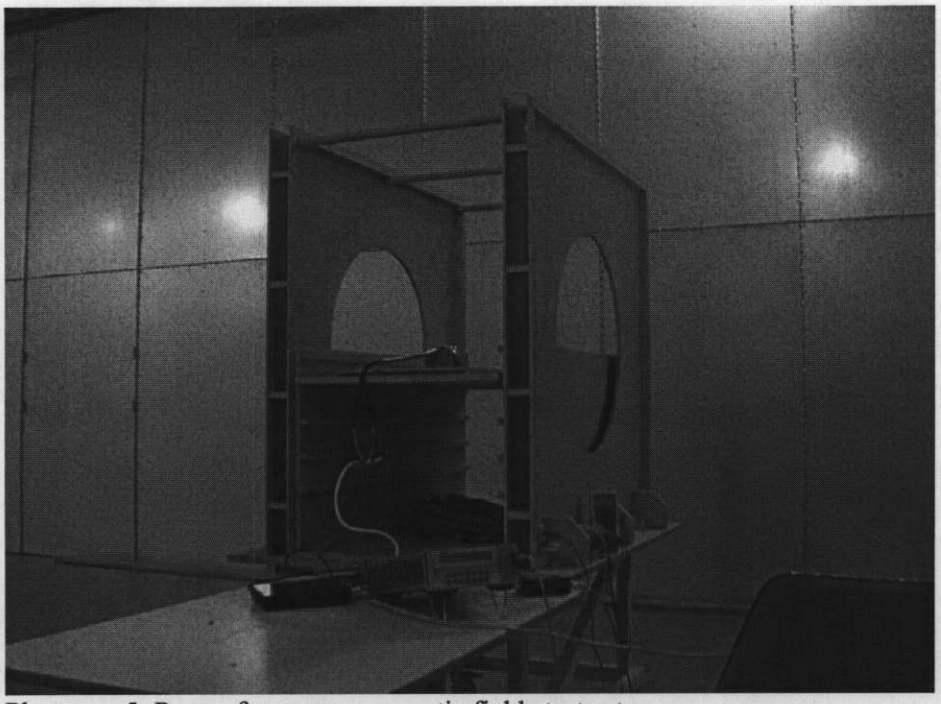


Photo no. 5: Power frequency magnetic fields test setup.

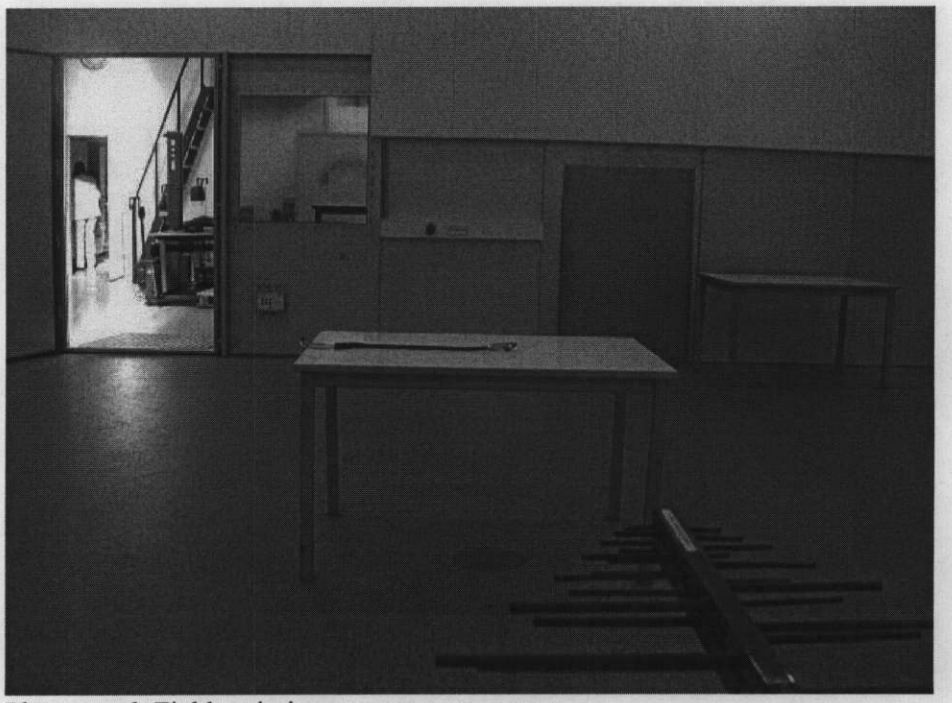


Photo no. 6: Field emission test setup, pre-scan.

Design Verification Protocol Eer200338b

Design Verification Protocol
Mandatory Requirements E3000

Author

15/7 2004 E. Lundgård

Date; Esben Lundgård – Quality Assurance

Approved

15/7-2004 Tommy Thinesen

Date; Tommy Buch Thinesen – Project Manager

Version history

Version	Author	Date	Description
0.01	EER	05-09-03	Document initiated
1.00	EER	23-06-04	First version ready for approval
1.10	EER/TBT	15-07-04	Mistake in KV1a corrected (55°C to 50°C). Mistake in KK2 corrected (-20°C to -26,5°C). Lifetime test description added.

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1 Purpose

The purpose is to describe how to perform the Design Verification for the defined Mandatory Requirements.

2 Scope

The scope of this protocol is limited to the Product Requirements concerning Mandatory Requirements of the E3000 Stethoscope.

3 References

3.1 Documents

Ref 1: TBT0319b Product Requirements.doc
Ref 2: EER200403b Design verification plan E3000

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4 Protocol

4.1.1 Safety

No.	Ref. No.	Description	Accept criteria	Exposure	No. of devices in test	Test & Reference
30 34 36 54	PR:035 PR:035 PR:037 PR:062	Electrical Safety	UL/DEMKO approval/certificate	External	2	IEC60601-1, General requirements for Safety for medical electrical equipment

4.1.2 EMC

No.	Ref. No.	Description	Accept criteria	Exposure	No. of devices in test	Test & Reference
55	PR:063	Emission	DELTA approval/ certificate	Emission 30 dBµV ; 30 Mhz to 250 MHz 37 dBµV ; 250 MHz to 1 GHz	1	IEC60601-1-2
55		Immunity		Immunity – Radiated RF 3 v/m; 80 MHz to 2,5 GHz	1	IEC60601-1-2
55		Immunity		Immunity – ESD ± 6 kV contact ± 8 kV air	1	IEC60601-1-2

4.1.3 Lifetime conditions

No.	Ref. No.	Description	Accept criteria	Exposure	No. of devices in test	Test & Reference
6	PR:007	(b) (4)				

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4.1.4 Surface resistance

No.	Ref. No.	Description	Accept criteria	Exposure	No. of devices in test	Test & Reference
47	PR:053	OK1 Cleaning test Chest piece housing, button and diaphragm.	Must pass visual inspection	C. - Cleansing agent containing ammonia (e.g. (b) (4)	1	DIN 53160
48	PR:055	OK3 Cosmetics test Chest piece housing, button and diaphragm.	Must pass visual inspection	Level B	1	Internal Requirement, Test & Approval (b) (b)
49	PR:056	OK4 Sweat test Chest piece housing, button and diaphragm.	Must pass visual inspection	Level B	1	DIN 53160
50	PR:057	OL3 Sunlight test Chest piece housing, button and diaphragm.	Must pass visual inspection	Level B 48h	1	Test & Approval (b)(4)Trade Secret Process ISO 105 B02
51	PR:058	OR2 Scratch test Chest piece housing, button and diaphragm.	Must pass visual inspection	Level B	1	Test & Approval (b)(4)Trade S t P
52	PR:059	OS6 Wear test Chest piece housing, button and diaphragm.	Must pass visual inspection	Level C	1	Test & Approval (b)(4)Trade Secret Process

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4.1.5 Climatic Requirements

No.	Ref. No.	Description	Accept criteria	Exposure	No. of devices in test	Test & Reference
35	PR:036	Heat function	Must pass FT1	(b) (4)T	29	KV1a, IEC 60068-2-2
35	PR:036	Cold function	Must pass FT1	(b)	29	KK1a, IEC 60068-2-1
37	PR:042	Storage	Electrical performance must remain within prescribed tolerances following exposure for 21 consecutive days of packaged device to:	(b)(4)Trade ranges of at (b)(4)Trade Secret Process-Product specs	5	IEC 60068-2-2
38	PR:043	Cold storage	Must pass FT1 and VT	(b) hours(4)	29	KK2, IEC 60068-2-1
39	PR:045	Heat storage	Must pass FT1 and VT	(b) hours	29	KV2, IEC 60068-2-2
40	PR:046	Cyclic Heat Storage – Humidity	Must pass FT1	(b) for (b) for (b) (4)Tr ade	29	KV3, IEC 60068-2-30
41	PR:047	Thermal shock test	Must pass FT1	From (b) for (b) (b) (b) (4)T	29	KS1 IEC 60068-2-14 N

4.1.6 Mechanical Requirements

No.	Ref. No.	Description	Accept criteria	Exposure	No. of devices in test	Test & Reference
16	PR:018	Mass of total device including battery	not to exceed 220 gram	Design test	1	
17	PR:019	Length of device from chest piece to ear tips	69 cm ± 3cm	Design test	1	
42	PR:048	Chest Piece subassembly and bulk packaging meets American Standard Test Methods (ASTM) for transport.	Must pass FT1	D5276/94, D4169 D999/91, D4728	shipping unit filled with devices	D5276/94, D4169 D999/91, D4728 MT1
43	PR:049	Transport simulation Packed device (bulk packaging)	Must pass FT1		shipping unit filled with devices	ASTM std. D999
44	PR:050	Sinusoidal vibration test with packed device (bulk packaging)	Must pass FT1		shipping unit filled with devices	IEC 60068-2-36 MV6
45	PR:051	Bump test of packed device (bulk packaging)	Must pass FT1		shipping unit filled with devices	IEC 60068-2-29 MB1
46	PR:052	Drop test with packed device (bulk packaging)	Must pass FT1		shipping unit filled with devices	ASTM std. D5276 MF1
56	PR:067	Drop test	Must pass FT1	(b)(4)Trade (b	(b	IEC 60068-2-32 MF3a
57 (26)	PR:068 (PR:027)	Stethoscope Tubing to Chest Piece Bond Strength	Must pass FT1	3M Test method TS-9005	(b	TS-9005
58	PR:069	Diaphragm tensile test	min. 5N to pull diaphragm off of transducer housing	(b)(4)Trade pull in diaphragm.	(	

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4.2 Verification description

The verifications are based on the methods described in the appendix.
A functional test description FT1 is used were functional test is mentioned. FT1 is described in the Appendix.
General safety is verified by UL/DEMKO, and EMC is verified by DELTA.
Specific requirements concerning functional test and device setup have not been identified by this protocol.

4.3 Statistical rationale

All custom design elements (e.g. plastic parts) used for these ***device verification activities*** must be processed from same series that are used for verification of these parts. If any parts do fail in the verification it must be considered if any of the device verification activities covered by this protocol must be re-done.

PR:027,PR:036,PR:043,PR:045,PR:046,PR:047,PR:067,PR:068 and PR:069 are all verified on (b)(4)Trade. If no failures are observed in these (b)(4)Trade Secret Process-Product specs [redacted].
These requirements are considered as essential for the product functionality during lifetime.

4.4 Acceptance criteria

In the appendix, specific verification protocols are described including acceptance criteria. In general the acceptance criteria is supported by a functional test, FT1, a visually inspection or both.

Functional test
The device must pass the functional test FT1 where this is required according to the test verification descriptions in the appendix. FT1 is described in appendix.

Visually inspection
Subjective parameters like surfaces, noise, mechanical moving performances etc. must be checked where this is required according to the test verification descriptions in the appendix. The visually inspection can involve the manager from QA production, the project manager and the project QA resource in decisions whether the verification result can be passed or must be rejected.

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5 Appendix

5.1 Device setup

All devices must be configured with a unique serial number and some default data, which can be controlled during and after the tests.

5.2 FT1

The functional test FT1 is used to control some basically functionality of the device in order to decide if the verification result can be approved or rejected.

1. Insert the ear tips in our ears and place the diaphragm on our chest.
2. Press diaphragm button, the device power up and gives a diaphragm feedback and listen to the body sounds.
3. Press Bell button the device should give a bell feedback and listen to the body sounds, the heart sound should be stronger that when listening to the body sounds using Diaphragm mode.
4. Press volume up, volume is increased and volume feedback is given.
5. Press volume down, volume is decreased and volume feedback is given.
6. Increase the volume until maximum volume is reached, volume feedback is no longer given when the volume up button is pressed.
7. Press and hold volume down until volume storage feedback is given.
8. Press and hold Diaphragm button until power off feedback is given.
9. Wait until the device powers off.
10. Press the Bell button, the device power up and gives a bell feedback.
11. Press the volume up button, there is no volume feedback given.

5.2.1 Bell frequency response

Assessment in accordance with 'BUA9950a'. Comparison against (b) target frequency response for BELL filter mode, allowed deviation is (b) dB over active stethoscope frequency range (20-1000 Hz).

5.2.2 Diaphragm frequency response

Assessment in accordance with 'BUA9950a'. Comparison against (b)(4)Trade target frequency response for DIAP filter mode, allowed deviation is (b) dB over active stethoscope frequency range (20-1000 Hz).

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5.3 Lifetime test

Device must be designed to last at least(years when operated as intended, assuming the following usage level:
(b) auscultatory exams per day
(minutes for average auscultatory exam, and
(bwork days per week
Average of (depressions of each button per auscultatory exam
(drop from shoulder of clinican per week
(minor impacts per day (bumping on bed rail or table edge)
b

Buttons:
(b) auscultatory exams per day x (bdepressions x (work days per week x (weeks per year x (years = (despressions.
Test with "finger" (air cylinder simulating finger depression(depressions on each button (4 buttons on E3000).
After test, buttons must work probably, minor cracks in rubber is allowed.

Drop from shoulder:
(b) drop from shoulder of clinican per week x(b) weeks per year x (years = (drop
(4)Tra Device is dropped (times from various height (b) m, and in various directions.
After test visual defects such as scratches, small cracks and wear marks is allowed, frequency response and all safety issues must be ok after test.

Minor impacts:
(b) minor impacts per day (bumping on bed rail or table (b) 5 work days per week x (b)
(4)Tra weeks per year x (years = (minor impacts. (4)Trade
Minor impacts on front of chestpiece housing, (b) impacts from approximate (b) cm on hard wood simulating bed rail or table edge.
After test visual defects such as scratches, small cracks and wear marks is allowed, frequency response and all safety issues must be ok after test.

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5.4 KK1a

Purpose

The purpose of this test is to show the ability of the product to function in a cold environment and with which guarantee the product stays within the margin of this demand.
The demand applies to all products containing electronics.

Standard

IEC-standard 68-2-1.

Procedure

Exposure

Place the product in the test chamber. Switch on the chamber and cool it to -10°C (±1°C). When the temperature is reached, leave the product for 2 hours. Then carry out the function test.

Acceptance criteria

Check all relevant functions of the product according to FT1 before it is placed in the test chamber. Check the functions again in the test chamber after a period of two hours.
The exposure must not cause malfunctions.

5.5 KK2

Purpose
The purpose of this test is to show the ability of the product to be stored at low temperatures, and to be operable again after an acclimatization period of max. 24hrs at room temperature. The demand applies to all products, which should be able to stand storage and transportation.

Standard
IEC-standard 68-2-1.

Procedure

Exposure
Place the product in a test chamber which is cooled down to -26,5°C (± 2°C).
Leave the product at this temperature for 96hrs. Then remove it and place it at standard room temperature (15-35°C / 45-75%RH)

Acceptance criteria
Check the product functionally and visually before and after the exposure.
The function test after exposure should be carried out at zero hrs, -at T+3hrs, -at T+6hrs, and at T+24hrs (approx.).
The first 3 function tests must not cause lasting malfunctions, but the product doesn't have to function properly. At the T+24hrs test, however, the product must operate perfectly.
If control data is measured, these should be stated in the test report.

5.6 KV2

Purpose
The purpose of this test is to demonstrate the ability of the product to be stored at high temperatures.
This demand applies to all products, which are supposed to stand storage and transportation.

Standard
IEC-standard 68-2-2.

Procedure

Exposure

Place the unplugged product in a heat chamber. Switch on the chamber and heat it to a temperature of +55°C (±2°C). After a period of 96hrs, remove the product from the chamber and place it at 15-35°C - 45 - 75% RH, equal to normal room climate, for at least 2 hrs.

Acceptance criteria
Check the set functionally and visually before and after the test. If control data is measured, it should be stated in the test report. No malfunctions must occur in connection with the test.

5.7 KV3

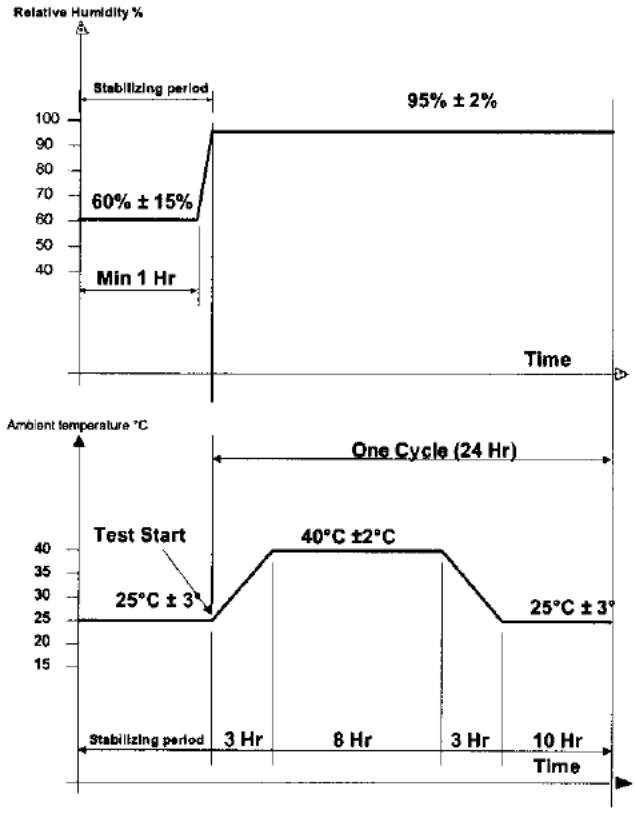
Purpose
The purpose of this test is to demonstrate the ability of the product to resist penetration of humidity into components while stored in high relative humidity and changing temperatures.

Standard
IEC-standard 68-2-30.

Procedure

Exposure
Place the product in the climatic chamber. After a stabilizing period, where the temperature of the product is at +25°C (±3°C), turn up the humidity to 96-100%RF and let the chamber run two cycles at a max. temperature of 40°C (±2°C).

Acceptance criteria
Test all relevant functions before the test. After the 2 cycles, bring the clima back to the initial condition and remove the product from the chamber. Carry out a function test again at the earliest one hour and at the latest 2 hours after the product is removed.
If control data is measured it should be stated in the test report. No malfunctions must occur as a result of the exposure.



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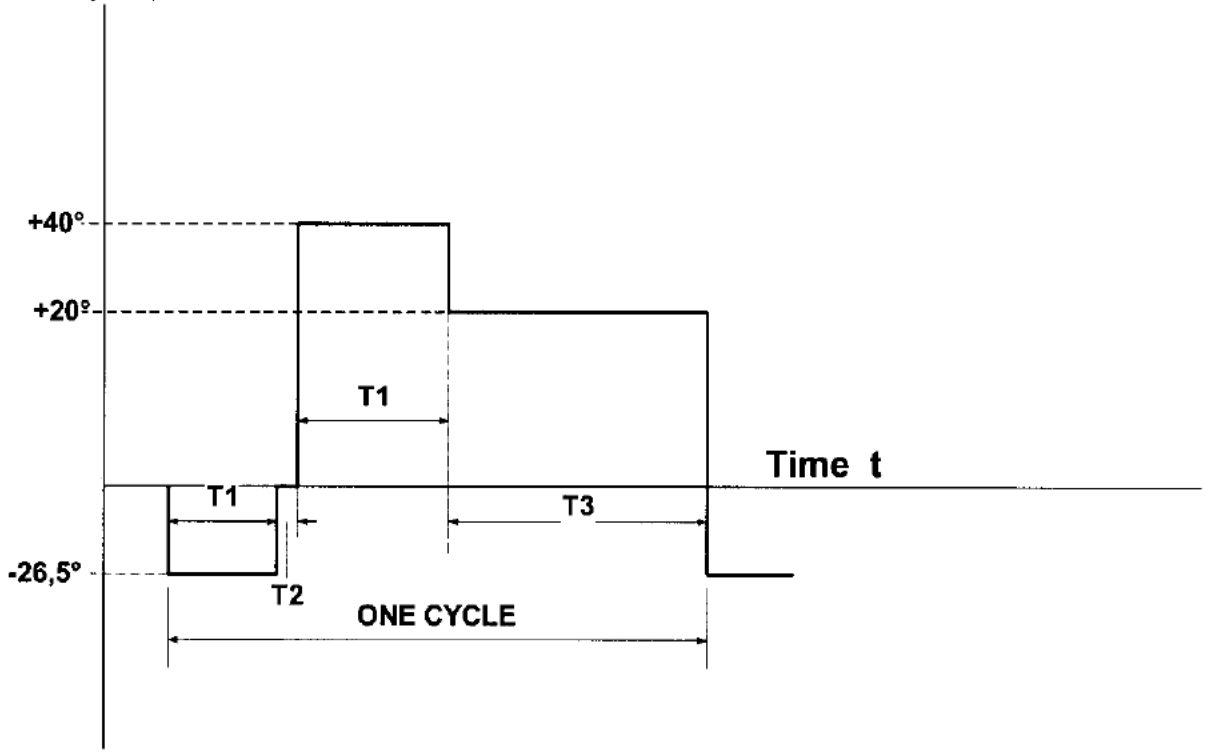
5.8 KS1

Purpose
The purpose of this test is to demonstrate the product's ability to resist quick changes in temperature. This demand applies to all products, which should be able to stand storage/transport.

Standard
IEC-standard 68-2-14 test N.

Procedure

Exposure
Expose the product to quick changes in temperature by moving it between two different test chambers. One at -26,5°C and one at +40°C. The time of exposure, T1, is 3 hours. The moving time, T2, is approx. 2-3 minutes. The duration time, T3, is approx. 18 hours. Carry out 5 cycles, that is 5x24 hours.



Acceptance criteria
Check the product functionally and visually before and after the test.
If control data is measured it should be stated in the test report. No malfunctions must occur as a result of the exposure.

5.9 KV1a

Purpose
The purpose of this test is to demonstrate the ability of the product to function in a hot environment. This demand applies to all products containing electronics.

Standard
IEC-standard 68-2-2.

Procedure

Exposure
Place the product in a heat chamber. Switch on the chamber and heat it up to +50°C + delta t.

For finished products delta t = 0.

For spare parts, delta t is equal to the expected rise in temperature when the part is built into the set.

When the required temperature has been reached, the product is turned on, and is left "on", at least 2 hours before the function test is carried out.

Acceptance criteria
Check all relevant functions of the product before it is placed in the test chamber. After the two-hour period, check these functions again in the chamber.
The exposure must not cause malfunctions.

5.10 MB1

Purpose
The purpose of this test is to demonstrate the resistance of the product to the repeated bumps of which the product probably will be exposed to in use and during transport.

Standard
IEC-standard 68-2-29.

Procedure

Exposure
Attach the product to the bump fixture at the bump tester, supported as in the contemplated package. Adjust the total impact weight to about 250 lbs. by means of the ballast weights.
Expose all sides, except from the top of the product, to bumps.
Expose each side to 1000 bumps. The shape of the pulse should be approximately half sinusoidal with an acceleration of approx. 10G. The pulse period should be 16 ms and the bump rate 2-4 bumps per second.
Products that during transportation are strapped to a pallet, and therefore only will be transported on this side, must be subjected to the following exposures: 1000 bumps on the bottom and 250 bumps on each side. None at the top.

Acceptance criteria
Check the set functionally and visually before and after the test.
If control data is measured, it should be stated in the report. No malfunctions must occur because of the exposure.

5.11 MT1

Purpose
The purpose of the test is to demonstrate the ability of the packaging to protect the contents.

Standard
ASTM-standard D999.

Procedure

Exposure
Place the packed product on the vibration platform. Turn on the transportation simulation equipment and adjust the speed so that the package keeps a position at the middle of the platform.
The duration time for the test is 6 hours in the development phase and three hours in the operational phase.

With normal packages, half of the test is performed when the packages are bottom faced, and the other half is performed when they are standing on one of the long sides.
For products, which are strapped on a pallet during delivery, the test is carried out on bottom faced only, but after half of the time, the pallet is rotated 90°

Acceptance criteria
Inspect the package visually and check the functions and surfaces of the product before and after the test. If control data is measured, it must be stated in the report.

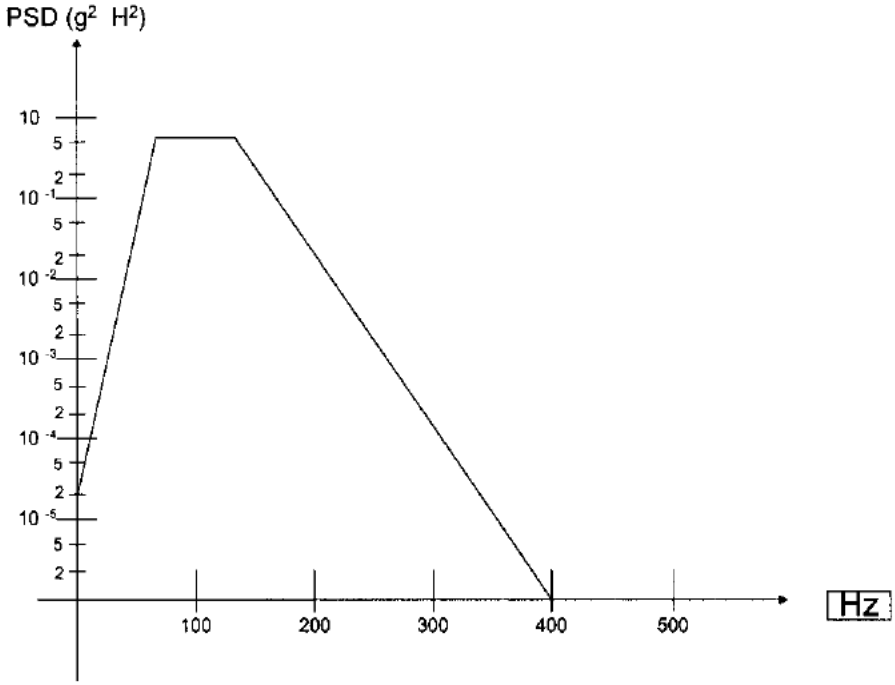
5.12 MV6

Purpose
The purpose of the test is to demonstrate the resistance of the product to vibrations during transport.

Standard
IEC-standard 68-2-36.

Procedure
Secure the packed product to the vibration fixture plate. Carry out the vibration test in three perpendicular directions.

Test demands
Total G RMS: 2.3 (the power of the vibrations). Test time per direction: 20 minutes.



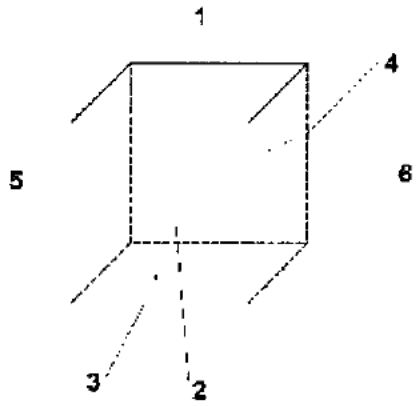
Acceptance criteria
Test the function of the product and inspect it visually before and after the exposure. If control data is measured, it should be stated in the report.

5.13 MF1

Purpose
The purpose of this test is to demonstrate the ability of the packaging to protect the contents, and to verify the results of the mechanical bump test.

Standard
ASTM-standard D775.

Procedure



Exposure
Number the sides of the package in the following way: Top: 1, Front: 2, Bottom: 3, Back: 4, Left side: 5, Right side: 6
The two sides that form the edge, e.g. 1-2, name an edge drop. A corner drop is named similarly, e.g. 1-2-5.

To simulate the handling that takes place during all sorts of transport except freight or general cargo and postal packets, the packaged product must be drop tested from the demanded height in the following sequence:

-Drop flat on side 3.
-Drop flat on side 2.
-Drop flat on side 5
-Drop flat on side 4
-Drop flat on side 6
-Drop flat on side 1

Corner drop on 3-4-6, or at the most dangerous corner.

-Edge drop on 2-3
-Edge drop on 3-5
-Edge drop on 4-5
-Edge drop on 3-4

Use the following drop heights (cm) for all types of products:

Drop on	Bottom	3	Side	2-5-4-6	Top 1	and corner	Edges 4-5	2-3,3-5	Edge	3-4
Weight of packa-ge in kg's	Approval test	Test during produc-tion	Approval test	Test during produc-tion	Approval test	Test during productio n	Approval test	Test during produc-tion	Approval test	Test during produc-tion
0-10	86	76	86	76	76	45	76	45		
11-20	86	76	76	60	60	40	60	40		
21-30	76	60	66	50	45		45	30		
31-50	69	55	58	45	35		35	30		
51-100	60	50	50	40					45	35

Acceptance criteria

Check the device functionally and visually before and after the test.
If control data is measured it should be stated in the report. No malfunctions must occur which are caused by the exposure.

2/2

5.14 MF3a

Purpose
The purpose of this test is to demonstrate the ability of portable sets to resist drops onto the floor

Standard
IEC-standard 68-2-32.

Definition
A portable product is a product that is designed for use while being carried, such as phone, remote control, radio receiver and similar products with a weight below 5 kg.

Procedure

Exposure
The drop plate must be wooden and plane, at least 15 mm thick (chip board).
The height of the drop must be adjusted to the weight of the product as shown below.

-Height 0.8 m for a weight < 2 kg.
-Height 0.5 m for a weight > 2 kg and < 5 kg.

Carry out 6 drops - one on each side. Half of the drops must be don with the cover open.

Acceptance Criteria
Make a function test and a visual examination before and after each exposure.
Please observe the requirements in "SAFE 21" regarding products containing small batteries.

5.15 OK1

Purpose
The purpose of the test is to demonstrate the resistance of surfaces to cleaning agents.

Procedure

Exposure
The surface is to be rubbed with 5 light rubs by using a cotton cloth, which is moistened with each of the following liquids (one liquid at a time):

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

For testing the approval marking (IEC-65), use the following:

(b)
(4)Trade

After the exposure, wipe off the surface with a moist cloth, and then with a dry cloth. The visual inspection can now be carried out as described in OIN

Min 24 hours after the exposure, the rubbed surface can be tested for scratch firmness as described in OR2.

Acceptance criteria
The surface must not show any visible corrosion (gloss, shades of colour stains). The scratch firmness must not be reduced after the cleansing exposure. A slight polishing of non-gloss surfaces can be accepted.

NB: If the surface treatment is less than 3 weeks old, this test can only be used as a guidance, and should not be evaluated as a compliance of (b)(4)Trade demands.
Alternatively the surface treatment may be artificially aged in a heat chamber at 40° Celsius for 3 days (72 hrs) and then acclimatized at room temperature for 2 hrs before the test.

5.16 OK3

Purpose
The purpose of the test is to demonstrate the resistance of the external surfaces to cosmetics after being touched.

Procedure

Exposure
An amount (about 20mm x 3mm) of each of the following types of lotion is applied to the surface. Then the test object is placed in an oven at 45°C (±2°) with dry heat.

Lotion types
(b)(4)Trade Secret Process-Product specs

After the exposure the surface is wiped off with a dry cloth and possibly with a detergent damped cloth. Then the visual inspection can be carried out as described in OIN.
Min. 24 hrs after the exposure, the surfaces are tested with regard to scratch firmness (OR2) and adherence ability (the grading cut OV4 or/and the tape test OV5).

Test demands
a. 72hrs at 45°C
Applies to surfaces, which daily will be exposed to long lasting touch.
b. 24hrs at 45°C
Applies to surfaces, which daily will be exposed to short lasting touch.
c. 24hrs at 45°C
Applies to surfaces, which may be touched once daily at the most. This test is carried out in the same manner as demand "b" but instead of using a portion of lotion (20x3mm), do this instead: Dip one finger in the lotion and spread it evenly over the fingertip, then make a "fingerprint" on the test object.

Acceptance criteria
No visible changes (gloss, colour tones, stains etc.) are allowed.
The scratch firmness and adherence ability must not be weakened as a result of the exposure.

NB: If the surface treatment is less than 3 weeks old, this test can only be used as a guidance, and should not be evaluated as a compliance of (b)(4)Trade demands.
Alternatively the surface treatment may be artificially aged in a heat chamber at 40° Celsius for 3 days (72 hrs) and then acclimatized at room temperature for 2 hrs before the test.

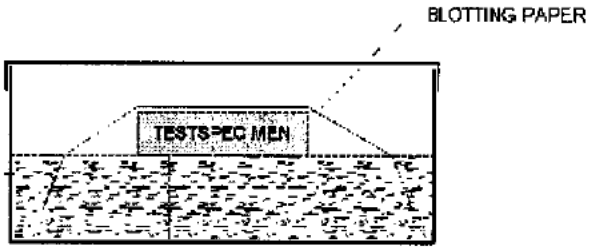
5.17 OK4

Purpose
The purpose of this test is to demonstrate the resistance of the external surfaces to human sweat after being touched.

Standard
DIN 53160.
Types of sweat
Sweat solutions:

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

Procedure



SWEAT SOLUTION

Exposure
Position the test object as shown on the figure. Place the arrangement in an oven at 40°C (± 2°C) in dry heat. The time of exposure varies according to table below.
After exposure the object should be cleaned with water and then wiped off with a dry cloth.

Test demands
a - All surfaces which daily may be exposed to touching for a long time.
b - All surfaces which daily may be exposed to touching for a short time.

Demands	Solvents	Exposure time
a	(b)(4)Trade Secret Process-Product specs	96 hrs
b		24 hrs

Acceptance criteria
No visible changes (gloss, colour changes or stains) are allowed. The visual inspection may be carried out according to OIN.
The adherence ability may be evaluated by using the grating cut test(OV4) or the tape test(OV5), but at the earliest 24hrs after the test.

NB: If the surface treatment is less than 3 weeks old, this test can only be used as a guidance, and should not be evaluated as a compliance of (b)(4)Trade Secret demands.
Alternatively the surface treatment may be artificially aged in a heat chamber at 40° Celsius for 3 days (72 hrs) and then acclimatized at room temperature for 2 hrs before the test.

5.18 OL3

Purpose
The purpose of the test is to demonstrate the resistance of the external surfaces against sunlight through window glass.

Standard
ISO 105 B02.

Procedure

Exposure
Place the test object at the bottom of the sun tester (Sun tester type - Heraeus - No. 55007011) and expose it by means of a Xenon lamp (Type NXe 1500 A). The exposure is carried out through a filter (Type 5600 9562). Cover a part of the surface.

Test demands
a. 96 hours exposure - Applies to zone 1 - 2 surfaces.
b. 48 hours exposure - Applies to all other external surfaces.

NB. The test does not apply to wooden surfaces.

Acceptance criteria
There must be no visible difference between the covered and the uncovered part of the surface after the exposure.
In case of doubt, the surface has to be examined by the orthospectral light cabinet according to OIN

If the surface treatment is less than 3 weeks old, this test can only be used as a guidance, and should not be evaluated as a compliance of (b)(4)Trade demands.
Alternatively the surface treatment may be artificially aged in a heat chamber at 40° Celsius for 3 days (72 hrs) and then acclimatized at room temperature for 2 hrs before the test.

5.19 OR2

Purpose
The purpose of the test is to demonstrate the resistance of external surfaces against scratching. The scratching may be due to touching, operating, cleaning etc.

Procedure

Exposure
A 4 mm thick brass weight with a diameter of 30 mm (static load 3,44 g/cm²) is provided with a thin double-coated tape (e.g. Crown sellotape 654-0041). The bottom side of the tape is covered with abrasive grits made of potassium magnesium sulphate (K, mg) SO4, 17,4% mg, 11,7% Mg. The size of grits is between 0.15 - 0.50 mm.

The weight is pulled slowly (approx. 10 cm/sec.) across the test surface, which then is examined for scratches afterwards. If no scratches appear, the weight is increased in steps of 12,56 g/cm2 (corresponding brass weights with the thickness of 15 mm are placed on top). The test is repeated until scratches appear, or until the maximum static load of 53,68 g/cm2.

When this series of tests have been carried out, replace the tape and the abrasive grits before testing the next surface.

Test demands
a: Applies to zone 1 and 2 surfaces. No visible scratches at a load of 16 gr/cm2 (as with one more weight) are acceptable.
b: Applies to zone 3 and 4 surfaces. No visible scratches at a load of 3.44 gr/cm2 (without extra weights) are acceptable.

Acceptance criteria
The tested surface is examined for any scratch marks. In case of doubt, the visual inspection can be carried out according to OIN.
To meet the test demand, no visible scratch marks must be found.

NB: If the surface treatment is less than 3 weeks old, this test can only be used as a guidance, and should not be evaluated as a compliance of [redacted]emands.
Alternatively the surface treatment may be artificially aged in a heat chamber at 40° Celsius for 3 days (72 hrs) and then acclimatized at room temperature for 2 hrs before the test.

5.20 OS6

Purpose
The purpose of the test is to demonstrate the resistance of lacquered or printed surfaces against wear. Touching, operating, cleaning, handling and transport would cause the wear.

Procedure

Exposure
An approx. 7 mm long grinding wheel, (Brand: CRATEX, 6FX dimensions: 1/4" x 7/8") is horizontally pulled back and forth on the test surface with a speed of 0.3 - 3 m/min. The grinding wheel must be loaded with a normal force of 1.67N, which must be transferred by the whole length of the wheel.
Place a piece of waterproof silicon carbide paper (grade 1200) at one end of the test area by means of thin double-coated tape (e.g. 3M 465). The carbide paper should be at the same level as the test surface.
The grinding wheel has to move approx. 5 mm on this carbide paper in order to be clean from grinded off particles.
Use a new grinding wheel and a new piece of silicon carbide paper for each test.
A cycle corresponds to one forth and back pull in the drag mark.

The number of cycles, which the grinding wheel can run over the test surface, before the lacquer is worn out or the text is possibly difficult to read, - is written down.
The test may be supplemented with a layer thickness measurement of the tested surface.

After the demand is fulfilled, continue the wearing in order to clarify the constancy of the surface according to the acceptance criteria.

Acceptance criteria
a: 3000 cycles. Applies to surfaces, which are exposed to sustained daily operation. E.g. buttons on a remote control.
(a: 1600 cycles.) Applies to same surfaces as above but where the demands are specified before September 1994.
b: 500 cycles. Applies to surfaces, which are exposed shortly to daily operation. E.g. standby button on a product.
c: 300 cycles. Applies to surfaces, which are not touched every day. E.g. the logo and the secondary operation button on a television or radio.

NB: If the surface treatment is less than 3 weeks old, this test can only be used as a guidance, and should not be evaluated as a compliance of [redacted] demands.
Alternatively the surface treatment may be artificially aged in a heat chamber at 40° Celsius for 3 days (72 hrs) and then acclimatized at room temperature for 2 hrs before the test.

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6 Test Sheet

Prototype serie name/number	Material number	DMR Version	Test number
Verification model	9300004	1.10	
Equipment:			Identification

Products in test:

SN number	Before test: Accept		After test: Accept		Remarks
	Yes	No	Yes	No	
R4X26037					
R4X26038					
R4X26039					
R4X26040					
R4X26041					
R4X26042					
R4X26043					
R4X26044					
R4X26045					
R4X26046					
R4X26047					
R4X26048					
R4X26049					
R4X26050					
R4X26051					
R4X26052					
R4X26053					
R4X26054					
R4X26055					
R4X26056					
R4X26057					
R4X26058					
R4X26059					
R4X26060					
R4X26061					
R4X26062					
R4X26063					
R4X26064					
R4X26065					

General remarks

Date	Init	Signature

Design Verification Report Eer0428a

Design Verification Report
Mandatory Requirements
E3000

Author

13/07-2004 Tommy Thim

Date; Name – function

Approved by

13/07-2004 E. Lauritsen

Date; Name – Quality Assurance

Version history

Version	Author	Date	Description
1.00	EER	11-07-04	First version ready for approval

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1 Purpose

The purpose is to document and conclude on Design verification – Mandatory Requirements for electronic stethoscope E3000, performed with references to Requirements, Plan, and Design Verification Protocol.

2 References

TBT0319b Product Requirements.doc
EER200403b Design verification plan E3000
EER200338b Design Verification Protocol Mandatory Requirements E3000

3 Test data

Test ID	Requirement	Remark	Test result
PR:035 PR:035 PR:037 PR:062	Electrical Safety	UL/Demko report: E249052-A1-CB-1	Passed.
PR:063	Emission 30 dBµV ; 30 Mhz to 250 MHz 37 dBµV ; 250 MHz to 1 GHz Immunity – Radiated RF 3 v/m; 80 MHz to 2,5 GHz Immunity – ESD ± 6 kV contact ± 8 kV air	DELTA report : E401131	Passed.
PR:007	Lifetime test		Passed
PR:053	OK1 Cleaning test Chest piece housing, button and diaphragm.		Passed
PR:055	OK3 Cosmetics test Chest piece housing, button and diaphragm.		Passed
PR:056	OK4 Sweat test Chest piece housing, button and diaphragm.		Passed
PR:057	OL3 Sunlight test Chest piece housing, button and diaphragm.		Passed
PR:059	OS6 Wear test Chest piece housing, button and diaphragm.		Passed
PR:036	Heat function		Passed
PR:036	Cold function		Passed
PR:042	Storage	See PR:046	
PR:043	Cold storage		Passed
PR:045	Heat storage		Passed
PR:046	Cyclic Heat Storage - Humidity	In the test (Cyclic Heat Storage – Humidity PR:046) 5 out of 29 devices failed after exposure, the cause is malfunction in the microphone sensor. The initial tests indicate that the sensor, where the electrical connections are glued together, lost connection between the flat cable and the actual sensor. The failure will correlate to the stethoscope as very low or no sound at all, no risk or safety issues for user or patient.	Failed
PR:047	Thermal shock test		Passed
PR:018	Mass of total device including battery		Passed
PR:019	Length of device from chest piece to ear tips		Passed
PR:048	Chest Piece subassembly and bulk packaging meets American Standard Test Methods (ASTM) for transport.	Test result not ready yet. (bulk packaging not arrived)	

PR:049	Transport simulation Packed device (bulk packaging)	Test result not ready yet. (bulk packaging not arrived)	
PR:050	Sinusoidal vibration test with packed device (bulk packaging)	Test result not ready yet. (bulk packaging not arrived)	
PR:051	Bump test of packed device (bulk packaging)	Test result not ready yet. (bulk packaging not arrived)	
PR:052	Drop test with packed device (bulk packaging)	Test result not ready yet. (bulk packaging not arrived)	
PR:067	Drop test		Passed
PR:068 (PR:027)	Stethoscope Tubing to Chest Piece Bond Strength		Passed
PR:069	Diaphragm tensile test		Passed

4 Conclusion

All design verifications of mandatory requirements except one is passed without remarks.
In the test (Cyclic Heat Storage – Humidity PR:046) 5 out of 29 devices failed after exposure, the cause is malfunction in the microphone sensor. The initial tests indicate that the sensor, where the electrical connections are glued together, lost connection between the flat cable and the actual sensor.
The failure will correlate to the stethoscope as very low or no sound at all, no risk or safety issues for user or patient.
Test result for PR48-PR52 not ready yet (transport tests bulk packaging (b)(4)T 3M).

Software Design Document CAJ0406a

E3000 SW Design

Author

6/7-04 Carsten H. Jensen

Date; Carsten Højgård Jensen - Development Engineer

Approved by

7/7-2004 E. Ernstsen

Date; Esben Ernstsen - Quality Assurance

Version history

Version	Author	Date	Description
0.1	CAJ	02-02-2004	Document created
0.2	CAJ	03-06-2004	First draft
0.3	CBS	23-06-2004	Text added
0.4	CAJ	30-06-2004	Filter description added, sound feedback description added
1.0	CAJ	05-07-2004	First version

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1 Purpose

The purpose of this document is to give a short description the software design and setup of the E3000 digital stethoscope. A more detailed description of the software design and implementation can be found in the assembler source code.

2 Scope

This design document covers the software part of the E3000 digital stethoscope. The design is based on the SW requirement specification [1], the SW design [2] and the risk analysis [3].

3 References

E3000 software requirement specification document:
[1] CAJ0341a E3000 SRS.doc

E3000 software design document:
[2] E3000.bcp

E3000 software risk analysis document:
[3] CBS0345c E3000 SW Risk Analysis.xls

DSPfactory BelaSigma 200 manuals:
[4] Firmware reference manual
[5] Hardware reference manual

4 E3000 System Setup

4.1 Sampling frequency

The internal system clock is used to run the E3000. The clocks are configured as follows:

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

4.2 Timers

The BelaSigma 200 general-purpose timer is configured as follows:

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

The E3000 system timer values are based upon this setup, they are defined as follows:

- SHORT_ACK_TIME: 50ms (0x2) button_acknowledge_time
- LONG_ACK_TIME_FILTER: 3s (0x78) power off request
- LONG_ACK_TIME_VOLUME: 2s (0x50) volume storage request
- BATTERY_INIT_TIME: 125ms (0x5) initial battery test wait time
- BATTERY_MEASUREMENT_TIME: 15s (0x258) battery test wait time
- AUTO_POWER_OFF_TIME: 180s (0x1C20) auto power off timer

4.3 WOLA setup

The E3000 WOLA parameters are configured as follows:

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

The WOLA setup above has been chosen on the basis of some of the following criteria:

- It is desired to have a high frequency resolution as possible (b)(4)Trade
- The group delay through the system must be as low as possible (b)
- Minimize instructions consumed by control code by having large block sizes (4)Tr d
- Reduce ripples in passband by (b)(4)Trade Secret Process-

P d t

Some of the criterie above are in conflict with each other. Therefore the final setup has been chosen as the setup, which gives the best compromise of e.g. the requirement for low group delay and large block size.

4.4 Electrical interface

4.4.1 Power off

The DSP is powered off by setting GPIO3 to high from the software. This resets a flip-flop so that the supply to the chip is removed. Pushing one of the filter buttons sets the flip-flop again, the supply is restored to the DSP and it reboots.

Before power off it is however necessary to GPIO6 to high to minimise the standby durrent of the system. Setting the GPIO6 to high also resets a flip-flop into a mode, where it minimises the current draw.

The power off sequence in the software (handle_power.ss) is therefore:

- Set GPIO6 to high
- Wait for GPIO6 to settle (2 seconds)
- Set GPIO3 to high

4.4.2 Button pins

The two filter mode buttons and the filter logic button are attached to three of the low-speed AD converters: LSAD0, LSAD1 and LSAD2. The AD converters are configured to have a dynamic range from (b) . If the values read from the converters are higher than AD_HIGH_LIMI( ) they are acknowledged as high (button pushed) otherwise they are acknowledged as low (no buttons pushed).

The volume buttons are connected to two digital inputs: GPIO0 and GPIO1. Because these pins can only be high or low, the software also reads them as "1" or "0".

4.5 Battery monitoring

The internal battery level monitor [5] is used in order to control the work area of the E3000. The battery monitor operates on two thresholds, one states low battery and the other one states depleted battery. Finally there is the battery state (threshold) where the DSP is not capable to boot/operate this is HW depended and denoted battery empty (approx. (b)(4) volt)
The two thresholds are defined in the E3000 code as follows:

battery low = (b)(4) volts
battery depleted = (b)(4) volt

The internal battery level monitor uses the MCLK to time battery measurements. The MCLK used in E3000 generates a battery measurement (b)(4) ms.
In order to remove battery level glitches the E3000 battery monitor operates on battery data picked up over a (b)(4) period. To determine the state of the battery the output of the internal battery monitor is compared to a fixed state change threshold of (b)(4) of maximum count.

When the E3000 is booted an initial battery check is made to check if the battery is depleted and therefore have to power automatically to prevent use. This check is based upon one measurement only in order to create a rapid device startup, however the price is that it more sensitive to battery level glitches than the normal run-time battery monitoring.

5 E3000 Memory Layout

This section describes the memory layout of the E3000 DSP and EEPROM. The EEPROM layout is made according to [4].

5.1 User data memory layout

The Belasigna (b)(4)Trade s two (b) user data memory banks called X and Y data ram. Both memory banks is designed in the following way:

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

In the following the E3000 data memory layout of low and high memory is stated.

X-Low memory:

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

X-High memory:

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

Y-Low memory:

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

Y-High memory:

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

5.2 EEPROM layout

The EEPROM layout consists of [redacted] data areas, where [redacted] of them are boot and system setup and the [redacted] data area is the E3000 run-time code.

Here is a short description of the [redacted] data areas and some of the most important parameters:

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

[redacted]

5.3 Copy protection

The copyright protection is made in order to create a "watermark" in the EEPROM that states that the code is created by [redacted]. When the E3000 boots this watermark is checked and if the checksum of it is invalid due to some unauthorized EEPROM manipulation the E3000 will enter a deadlock loop.
The watermark is [redacted] and its checksum = [redacted]

(b)(4)Trade Secret Process-Design

(b)(4)Trade Secret Process-Design

(b)(4)Trade Secret Process-Design

6.3 Button sound feedback

The feedback sounds used in E3000 are described below and a wav file is included for each sound.

6.3.1 Bell filter sound

```
Bell.wav:
------------
      , 100ms
500Hz, 600ms
```

Bell.wav

6.3.2 Diaphragm filter sound

```
Diaphragm.wav:
---------------
      , 100ms
500Hz, 300ms
      , 250ms
500Hz, 300ms
```

Diaphragm.wav

6.3.3 Volume sound

```
Volume.wav:
------------
       , 100ms
1.5kHz , 100ms
```

Volume.wav

6.3.4 Store volume sound

```
Store_volume.wav:
-----------------
       , 100ms
1.5kHz , 100ms
       , 80ms
1.5kHz , 100ms
```

Store_volume.wav

6.3.5 Battery low sound

```
Battery.wav:
-------------
      , 100ms
1.5kHz, 300ms
      , 250ms
1.5kHz, 300ms
      , 250ms
1.5kHz, 300ms
```

Battery.wav

6.3.6 Power off sound

```
Off.wav:
-------------
        , 100ms
2kHz    , 125ms
        , 13ms
1.5kHz  , 125ms
        , 13ms
1kHz    , 125ms
```

Off.wav

6.4 Volume table

The E3000 volume table consists of eight levels, with steps of [redacted]dB, the values is as follows.

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

[redacted]

FD-

Model 3000 Risk Assessment Report CAJ0413a

E3000 Risk Assessment Report

Author

2/4-04

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Approved by

2/04-04

date; Esben Lundgård Ernstsen – Quality Assurance

QMS003a7 version 1.00

Version history

Version	Author	Date	Description	Reviewed by	EC number
0.1	CAJ	22-03-2004	Initial document	EER	
1.0	CAJ	02-04-2004	Classification of 20.1 changed after review by EER. The change is explained in the "risk control" section.	EER	

QMS00347 version 1.00

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QMSC0347 version 1.03

1 Scope & Strategy

1.1 Purpose

Based on the Product- and Engineering Requirements and the prototypes generated a Design Risk Analysis is performed focusing on user related hazards, consequences of hazards and possibility of barriers.

1.2 Scope

This analysis covers the software part of the E3000 digital stethoscope. The risk analysis is based on the SW requirement specification [2] and the SW design document [3].

1.3 Resources

CAJ and CBS:	Authors
GAN and EER:	Review
EER:	Approval

1.4 Method

The HAZOP method is used.

The risk analysis is used as a working document and is closed by the completion of the SW implementation.

1.5 References

[1] [redacted]
[2] CAJ0341a E3000 SRS.doc
[3] CAJ0406a E3000 SW Design.doc
[4] CBS0345c E3000 SW Risk Analysis.xls
[5] CAJ0414a E3000 Software risk test.doc

2 Analysis

About the $P_{not\text{-}req}$ classification
The probability that the user discovers an error ($P_{not\text{-}req}$) must be seen as the probability of discovery before the user actually performs any action. In the first version of the SW risk analysis document ([4], version 0.01), the $P_{not\text{-}req}$ classification has been evaluated as the probability of discovering an error during normal operation.

As a result of this, the $P_{not\text{-}req}$ classifications are changed to I3 in version 0.02 of [4] since it is not very likely that the errors are discovered in advance of any user action.

The result of the analysis (After the $P_{not\text{-}req}$ classification was changed) is documented in [4]. 7 risks result in an ***ALARP*** score while no risks scored ***unacceptable***. The highest classified risks are listed in Table 1.

3 Critical list

The highest classified risks are listed below. They are all classified as ALARP.

Table 1 Highest classified risks

ID	User related hazards	Cause of hazards	Consequence		Barrier established	Probability P			Hazard class S	RPF	Risk classification
			Technical	User		P_{hazard}	$P_{occ-rnc}$	P_{damage}		P_{damage}*S	
1A.5	Fails to turn device ON	Battery depleted	Device won't work	User can not turn device on		P3	I3	P3	S2	1	ALARP
1B.4	Device power on immediately after power down	Buttons are not released after power down command is acknowledged	Device is ON	The user must power down again	1s delay introduced before power down	P4	I3	P4	S1	1	ALARP
1C.6	A volume change results in no or opposite level change (within boundary)	AGC counteract for the change in volume	AGC state changes	Device does not provide the desired sound level	Evaluation of AGC parameters before final release	P4	I3	P4	S1	1	ALARP
1D.1	Sound distortion	Internal signal saturation in software even when the AGC is active	Poor sound quality	Weak body sounds or not able to hear some of the body sounds		P4	I3	P4	S1	1	ALARP
2A.1	Several single button commands given within a short time	To many user events	Events can be lost	The desired actions are not performed or sound feedback is interrupt by next event	Event timing is made to handle/ignore too fast user handling	P4	I3	P4	S1	1	ALARP
2A.2	More than one button pressed simultaneously	Illegal device events	Events does not exist	No action are performed	Event handling is made to ignore illegal user events	P4	I3	P4	S1	1	ALARP
2B.1	Depleted battery inserted	Unstable device operation	The device can suddenly shut down without any warning	Device shuts down		P4	I3	P4	S2	10	ALARP

4 Assessment

In the following section all the critical risks from Table 1 will be explained in detail and evaluated.

1A.5 Fails to turn device ON
If a user tries to turn ON a device with a depleted battery nothing will happen. The software prevents the power up to avoid that the processor can start up in an unknown state.

This make up a hazard when the user needs the device in an emergency situation and he relies on the device to work and it then turns out that it does not.

When the device is used regularly it is however not very likely that this situation will appear, since the user will get a battery low warning with a remaining battery life time of at least two hours. There is then plenty of time to replace the batteries before the device will stop working.

The alternative would be, that the device is allowed to turn on in a state, which might be unstable. This is however estimated to be an even greater hazard, since the user might get a wrong signal from device, which could lead to a wrong diagnosis.

1B.4 Device power on immediately after power down
When a user wants to turn the device OFF he/she pushes one of the filter mode buttons until the power off sound is heard whereupon the device starts its power down sequence. If the user does not release the filter mode button before the power down sequence is complete, the device will power up again.

This happens because the same buttons are used to turn the device ON and OFF: Pressing one of the filter buttons clears a flip-flop to apply supply voltage to the DSP. At the end of the power down sequence the same flip-flop is set to remove the power to the device. If the user has not released the filter button at this time, the pressed button will clear the flip-flop immediately after it was set by the DSP and the device powers up again.

This is not estimated to constitute any risk to either the user or the patient. The consequences are, that the device uses more power than it otherwise would have done and thereby reduces the lifetime of the battery. Furthermore it can be annoying that the device is functional when the user believes it to be powered down. The reason for the high rating in the HAZOP analysis is the high probality that the user will experience the problem.

1C.6 A volume change results in no or opposite level change (within boundary)
Because of the software limiter in the device, volume changes by the user can results in no level change or even opposite change that expected (The device reduces the signal after volume up is pressed).

This could happen at signal levels just below where the limiter gets active. A "volume up" command can then cause the signal to increase so much that the limiter is activated. The reduction of the limiter will most likely exceed the level increase from the volume command and the resulting level change will therefore be a reduction on the "volume up" command.

The opposite can happen when the limiter is active and a "volume down" command. The volume reduction can cause level of the signal to come under the level where the limiter is active causing the overall signal level to increase from the "volume down" command.

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Again this is not estimated to constitue any risk to either the user or the patient but is seen more as an annoying property of the device. The reason for the high rating in the HAZOP analysis is the high probability that the user will experience the problem.

1I.1 Sound distortion
When a very high signal is applied on the transducer of the device it possible, that the limiter is not able to avoid the signal from saturation in the DSP. This will result in distorted signal and poor sound quality.

In worst case the distortion can affect the body sounds so much that it is not possible to hear them. It could be argued if this could cause the user to put a wrong diagnosis, but the distortion is estimated to be so obvious that the user will recognise the hazard and retry the auscultation another place. It is therefore not estimated to make any risk to either the user or the patient.

2A.1 Several single button commands given within a short time
When a user gives a button command to the device before the sound feedback from the previous command is finished, the software specification ([2]) says the the ongoing feedback will be interrupted by the sound feedback corresponding to the new button command.

If a user gives fast succesive buttons commands to the device, some of the feedback sound may be so short that it is not possible to detect all the commands given. It it estimated that this only appears when a user does it deliberately. It is therefore not estimated to be a risk to either the user or the patient since the user should expect this behaviour.

2A.2 More than one button pressed simultaneously
When a user presses a button, the device recognizes the command within 50ms. If a user by accident also pushes another button within the 50ms this will be regarded as an illegal command by the device and therefore discarded.

When the device has recognized a command the user has to release all buttons before a new command can be given to the device. If the user instead pushes another or more buttons before releasing the first button, these button commands will be discarded as illegal commands.

This is not estimated to be a risk to either the user or the patient since the user should expect this behaviour from the device.

2B.1 Depleted battery inserted
If a depleted battery is inserted into the device may show unexpected behaviour. When the battery is inserted the voltage of the battery can be acceptable and therefore allow the device to turn ON, but since the voltage of a depleted battery often drops very fast, a shutdown may happen before the device can give a signal to user or perhaps the voltage drops so fast that the device enters an unknown state before it has time to shutdown.

This is not expected to be a risk to either the user or the patient. The biggest problem is probably if the user believes he/she has equipped the device with a new battery and it does not give the battery-depleted signal before it shuts down. From a user point-of-view the device would then look as if it is broken.

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Besides the seven ALARP risks from the table, a few subjects came up in the review of the risk analysis:

Wrong filter

Q: Can a wrong filter (either chosen by the user or caused by a software error) result in a wrong diagnosis?

A: A diagnosis is made by the doctor using the device and not by the device itself; therefore it is not found that the device can cause a wrong diagnosis.

Maximum output sound pressure level

According to the claims in [1] the sound pressure from the device must not exceed (b)(4) dB. It is therefore necessary to implement a limitation in either software or hardware if the device can give an output higher than (b)(4) dB.

5 Risk control

After the risk assessment in the previous section it is now necessary to decide the necessary precautions to ensure that the critical issues are controlled.

1A.5 Fails to turn device ON

After evaluation of the risk it is chosen to change the $P_{not-req}$ classification to I2 (The user recognises the hazard with 90% probability) because the device will give the user a battery-low warning for some time before the depleted state is reached and it should therefore not come as a surprise that the battery is suddenly empty.

1B.4 Device power on immediately after power down

This event will always be possible because of the way the hardware is designed. To minimize the probability of its occurrence it is chosen to insert a suitable delay (~2 seconds) between the power-down feedback sound and the actual power down. It is however necessary to test the chosen delay in an acceptance test to ensure that the chosen value has a satisfactory effect.

Furthermore there is a barrier in the software; which ensures that the device power OFF after 3 minutes idle time to extend the lifetime of the battery. This means that even though the user accidently power up the device, it will shutdown if it is not used in 3 minutes.

1C.6 A volume change results in no or opposite level change (within boundary)

After evaluation of this risk it is chosen to change its P_{hazard} classification to P3 (Remote probability) since it is not very likely that the user will turn up the volume at a time where the signal is almost saturated in the device, since the sound level is already sufficiently high.

1I.1 Sound distortion

It is necessary to evaluate this risk in a module or an acceptance test to establish the actual behaviour of this problem. How obvious is the distortion? How often will it happen? Does the limiter remove the chance of distortion?

2A.1 Several single button commands given within a short time

From the assessment above it is chosen to change the $P_{not-req}$ classification for this risk to I2 (The user recognises the hazard with 90% probability) since it is estimated that the user is aware that he/she is misusing the device and therefore expect the event to occur.

2A.2 More than one button pressed simultaneously
From the assessment above it is chosen to change the $P_{not-req}$ classification for this risk to I2 (The user recognises the hazard with 90% probability) since it is estimated that the user is aware that he/she is misusing the device and therefore expect the event to occur.

2B.1 Depleted battery inserted
It is estimated that it will only happen remotely that at user inserts a depleted battery into the device. The P_{hazard} classification is therefore changed to P3 (Remote probability).

Furthermore the hazard classification is changed to **S1** (negligible severity) because it is estimated that a battery change is a task, which the user will perform in a controlled situation.

As a consequence of these two changes the event changes classification to acceptable risk.

6 Conclusion

An analysis of the risks related to the software design of the E3000 stethoscope has been conducted. After the risk assessment it was chosen to change some of the classifications, which removed some of the ALARP risks. The changes are introduced in version 0.03 and 0.04 of [4].

It is necessary to analyse the remaining ALARP risks in module and acceptance test to verify that the risks are acceptable. The result of these tests is documented to reflect the actual risk of each event. The result of this task is documented in [5].

QMS00347 version 1.00

Model 3000 Software Risk Test CAJ0414a

E3000 Software Risk Test

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Date; Esben Ernstsen – Quality Assurance

Version history

Version	Author	Date	Description
1.00	CAJ	06-07-2004	First version

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1 Purpose

The purpose it is described how to ALARP classified risks are tested to verify that the risks are acceptable and thereby fulfill the requirements.

2 Scope

This report describes the risk test method and results for the E3000 stethoscope.

3 References

E3000 software risk analysis:
CBS0345c E3000 SW Risk Analysis.xls

E3000 software risk assesment report:
CAJ0413a E3000 Risk Assessment Report.doc

E3000 software system verification:
CAJ0426a E3000 SW System Verifications Protocol.doc
CAJ0427a E3000 SW System Verification Report-Enclosure.doc

E3000 software accept test:
CBS0425a E3000 SAS Software Acceptance Test Specification.doc

3.1 Documents

This section is intentionally left blank

3.2 Product or Parts

The source files tested:
E3000.o

The software and related files for generating the software is labelled with the following label in the VSS project tool:
"**Version** _____"

4 Verification

4.1 Power off

4.1.1 Device power on immediately after power down

The result of the system test showed that a delay of 2 seconds was implemented between the end of the power off sound feedback to the user, and the time where the power was removed from the device.

For the device to power on immediately after power down, a user must therefore press and hold one of the filters buttons 2 seconds after the sound feedback has stopped. This is not thought to be very likely in a normalt user situation. It is more likely to happen if the device stuck between two items e.g. in a bag or a pocket.

Also the acceptance test and the daily use during development have shown that this does not happen by accident.

4.2 Sound performance

4.2.1 Sound distortion

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

Model 3000 Software Requirement Specification CAJ0341a

Software Requirement Specification

Author

25/6-2004 [signature]

Date; Casper Sørensen – Development Engineer

Approved by

25/6-2004 Tommy Thinesen /TBT

Date; Tommy Buch Thinesen – Project Manager

QMS00022 version 01

Version history

Version	Author	Date	Description
0.1	CAJ	14-10-03	Initial document
0.2	CAJ	04-12-03	Corrections after review by BUA, KSS, TBT
0.3	CAJ	06-01-04	Corrections after review by HLJ, ODA, PMP Furthermore the specifications for the HMI interface have changed (power off and store sound level).
0.4	CAJ	02-02-04	References to the SW design document have been added for the requirements without testable limits.
1.0	CBS	12-02-04	Updated to version 1.0
2.0	CAJ	08-06-04	Scratch reduction, mute and soft clipper (AGC) removed SR:028 changed SR:050 added
3.0	CBS	25-06-04	Requirement SR:002 is removed, it is not a user requirement

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1 Purpose

E3000 is a limited feature electronic stethoscope based upon a digital sound processing and amplification chip-set obtained from a modern digital hearing aid.
The device contains mechanical and electronically parts as well as a software program. The software controls the device and implements part of the signal path, with the signal processing part of the software implementing several of the sound features of the product.

This document describes the requirements of the software component of the E3000 stethoscope.

2 References

[1] (b)(4)Trade Secret Process-
[2] TBT0340a E3000 Device Specification.doc, Device Specifications
[3] TBT3903a E3000 Project Plan v1.mpp, Project Plan
[4] BUA0347a Acoustic input to E3000 filters.doc, Acoustical Specifications
[5] CAJ0406a E3000 SW Design.doc

3 General description

This chapter contains the general description of the product and of the software part of it.

3.1 System Description

The E3000 is an electronic stethoscope based on a DSP designed for low power applications for hearing aids and headsets.
The user will apply this device much the same way as he would with a standard, mechanical stethoscope.

In addition to the features offered by the traditional stethoscope, the E3000 adds more features:

- Acoustical gain adjustable up to 25dB, [1]
- 2 sound filters, which simulates the traditional 'bell' and 'diaphragm' sounds
- Output limitation: Max acoustic output level limited to 140 dB SPL, [1]
- 4 buttons for operating the product
- A single loudspeaker unit for generating sound in both sides of the binaurals.
- Auto power down when the device is not used
- Acoustic control user feedback

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

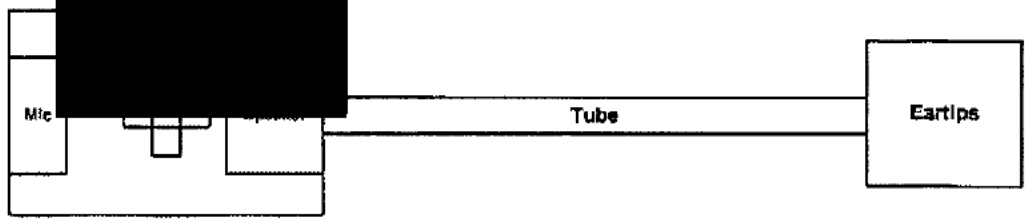

Figure 1: Physical block diagram of the E3000 system.

The system consists of an active digital chestpiece connected to passive tubing and binaurals thereby forming a complete stethoscope.

3.2 Software Features

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

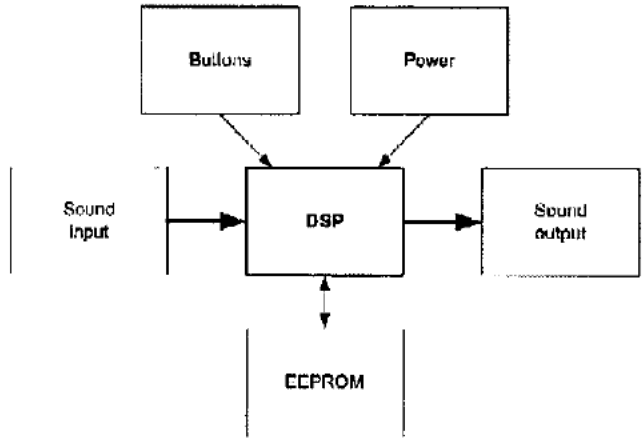

Figure 2: Logical block diagram of the E3000 system.

The DSP is responsible for the sound channel. 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 in the sound output channel.

The user acts upon the system by pressing one or more button, and the system responds with an acoustic feedback and changing the sound characteristics. The DSP monitors the states of the four buttons.
Batteries power the system whose condition must be monitored by the DSP in order to let the user know when it is time to change the batteries.
(b)(4)Trade Secret Process-Product Specs [redacted]

3.3 Data-flow diagram

Figure 3 is an overview of the signal and control path through the E3000 stethoscope. It appears from the figure, that the manipulation of the signal is done in the "wola gain" function. The "gain controller" collects the results from the signal analysis and the user commands and changes the gain tables in the wola to obtain the correct frequency response.

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

3.4 Software Limitations

- There are no diagnostic capabilities in this device.

3.5 User Characteristics

The user of the E3000 is a medical professional, probably a person already accustomed to a mechanical stethoscope.
The E3000 is intended to be the primary stethoscope for the users. This implies that it probably will be used for normal auscultation several times in a workday.

3.6 Development Requirements

The DSP used in this system is the (b)(4)Trade Secret Process-Product Specs.
The internal (b)(4)Trade Secret Process- should be used for sound filtering purpose whenever possible to reduce power consumption.
The internal battery monitor should be used to estimate the residual capacity of the battery.

Regarding documentation, this must comply with:

- ISO 60601-1-4
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff. Document issued on: January 11, 2002.

3.7 Delivery

According to project plan [3].

4 Design requirements

In the following sections a series of requirements are listed, which the E3000 stethoscope must respect. This both apply for the architectural and the functional requirements.

As mentioned above, the device is controlled through four buttons: a Bell filter button, a diaphragm filter button and two volume buttons. 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
▼	Bell filter button
▽	Diaphragm filter button
+	Increase volume button
−	Decrease volume button

Table 1: Button symbols

In the following sections the time constant button_acknowledge_time is used to indicate the time from button activation to action is taken. This time is set in order to ensure that the correct button combinations are observed. The button_acknowledge_time is determined in the software design process, based upon experiments.

4.1 Architecture

4.1.1 Performance specifications

Number	Requirement
SR:001	The DSP must be able to play frequencies up to [redacted] kHz, to reproduce an auscultation signal.
SR:0043	The input signal to the DSP must allow frequencies up to about [redacted] kHz because of the (b)(4)Trade [redacted] detection algorithm.
SR:002	Requirement removed.

4.2 Power up

Number	Requirement
SR:003	The device must be powered up by pushing one of the two filter-mode buttons (▼ or ▽).
SR:004	The device power up in the filter-mode, corresponding to the button pushed.
SR:005	A sound feedback (Bell or Diaphragm, see Table 2) must be given to the user according the filter key pressed at power up.

4.3 Power down

Number	Requirement
SR:006	The device must automatically power down 3 minutes ±15 seconds after the last actuation of any button.
SR:007	It must be possible to manually power down the device by pushing and holding one of the filter-mode buttons (▼ or ▽) for 3 seconds ±100ms.
SR:046	When pressing and holding one of the filter buttons for power off, the device detects and executes the filter mode command at button_acknowledge_time. After three seconds, the power off command is acknowledged and executed.
SR:008	Requirement removed.
SR:009	A sound feedback (Power_down, Table 2) must be given immediately before power down as indication to the user.

4.4 Filter mode

Number	Requirement
SR:010	When the device is active, it must be possible to change between the Bell and Diaphragm filter modes by pushing one of the two filter-buttons (▼ or ▽).
SR:011	When a filter command is detected, a sound feedback must be given to the user to indicate which filter is selected.

4.4.1 Bell mode

Number	Requirement
SR:012	The Bell filter must comply with the acoustic requirements in [4] ± (b)(4) dB.

4.4.2 Diaphragm mode

Number	Requirement
SR:013	The Diaphragm filter must comply with the acoustic requirements in [4] ± (b)(4)T

4.5 Volume selection

Number	Requirement
SR:014	It must be possible to turn the volume up and down with + and − respectively. Sound volume level steps up or down in 8 steps of (b)(4)T d
SR:015	A feedback sound must be given to the user, when the volume is changed.
SR:016	If the user tries to change the volume beyond the maximum or minimum sound level, the volume must stay unaffected and no feedback sound must be given to the user.
SR:017	Requirement removed
SR:047	It must be possible to personalize the volume setup by selecting the desired sound level and pressing and holding on of the volume buttons for 2 seconds +100ms. This will store the sound level in the EEPROM. Next time the device power up, it will start up with this sound level.
SR:048	When holding pressing and holding one of the volume buttons, this will be recognized as a volume command at button_acknowledge_time. At this time the volume command will be executed; changing sound level and playing sound feedback in binaural if necessary. After holding the button in 2 seconds ±100ms, the Store_volume command is recognized and the sound level is changed back to the previous value before it is stored.
SR:049	When storing the default sound level, a sound feedback must be given in the binaural (see Table 2) to indicate that the sound level has been stored.

4.6 Sound feedback

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

Function \ Sound	Bell	Diaphragm	Power_down	Volume	Store_volume	Battery_low
Power on (▼)	X					
Power on (⧖)		X				
Bell mode (▼)	X					
Diaphragm mode (⧖)		X				
Manual power down (Holding ▼ or ⧖)			X			
Volume step (+ or −)				X		
Store volume (Holding + or −)					X	
Battery depleted on power up (▼ or ⧖)			X (2)			X (1)
Battery low detected						X

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

Specific requirements for the sound feedback is:

Number	Requirement
SR:018	The sound feedback given to the user, must comply with Table 2.
SR:044	To simplify the implementation of the sound feedback the feedback sounds must be composed of one or more sinusoidal tones.
SR:019	The intensity of all feedback sounds in the binaural must be overall volume level dependent. E.g. the level of the "Volume" sound feedback increases if the + button is pressed.

Number	Requirement
SR:020	Requirement removed
SR:021	Requirement removed
SR:022	Requirement removed
SR:023	Requirement removed
SR:024	Requirement removed
SR:025	Requirement removed

4.7 Miscellaneous

4.7.1 EEPROM

The EEPROM contains the Basic Operating Software (BOS), the (b)(4)Trade Secret Process-Product S, bootloader, the application and the data used in the application (volume, filters etc.).

The device boots from the boot ROM in the DSP. The boot ROM loads the bootloader into program memory of the DSP whereafter the bootloader loads the application and data into memory and finally starts the application.

Number	Requirement
SR:026	At power up, the device must load the volume setting from the EEPROM.
SR:027	If the volume loaded from the EEPROM is out of range (invalid), a default volume must be used.

4.7.2 Checksum dependability

Number	Requirement
SR:042	E3000 must verify the checksum when transferring the bootloader from EEPROM to DSP. This is done to ensure that the data in the EEPROM do not change unintentionally and that the communication between the two devices is working properly.
SR:028	If a checksum error occurds during boot of the device, the device automatically reboots.
SR:050	If a checksum error occurs during initialisation of the device must halt to prevent wrong functionality. When a device halts, it is necesarry to remove the battery to clear the error and to be able to start up the device again.

4.7.3 Button commands

Number	Requirement
SR:045	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.
SR:029	Combinations of simultaneously pressed buttons, pressed within the button_acknowledge_time, are ignored if they are not mentioned in Table 2 (Both volume buttons, three or four buttons simultaneously).
SR:030	Requirement removed

4.7.4 Battery monitor

In this section, it is defined how the battery is monitored and what steps must be taken when the battery starts to deteriorate (*battery low*), when a battery is almost depleted (*battery depleted*) and in case of a completely depleted battery (*battery empty*).

Number	Requirement
SR:031	When "battery low" is detected, the user must get a sound feedback (Battery_low from Table 2).
SR:032	The low battery indication must be repeated to the user every (b) seconds (b) seconds. Otherwise the device works normally.
SR:033	The Battery_low sound feedback from Table 2 must be overruled by the other sound feedbacks from the table, if e.g. a user command is given at the same time.
SR:034	The low battery indication must start at least (b) (4) of continuous use before depleted battery.
SR:035	When "battery depleted" is detected, the device automatically shuts down.
SR:036	A Power_down sound feedback must be given to the user, immediately before power down, when "battery depleted" is detected.
SR:037	If "battery depleted" is detected when the user tries to power up the device, a Battery_low sound feedback followed by a Power_down feedback must be given in the binaural to indicate depleted battery. After the sound feedback is finished, the device power down.
SR:038	If the battery is completely depleted (battery empty) at startup, the DSP is not guaranteed to initialise and work properly. If this is the case, nothing must happen, when the user presses a button in the attempt to power up the device.

5 Performance requirements

5.1 User Response Times

Number	Requirement
SR:039	Generally the time from a user action to the system response (sound feedback to the user) must be negligible to the user. The sound feedback must be started immediately after the command is acknowledged (at button_acknowledge_time). Power on is a special case and may have longer response time.
SR:040	At power up, the device must be functional within 2 seconds of the activation.
SR:041	After a "power down" command is recognized and the Power_down sound feedback is given in the binaural, the device must wait at least 500ms before power down, to ensure that the user has released the button. If the button is not released when the device power down, it will power up immediately after power down.

Software Design Document CAJ0406a

E3000 SW Design

Author

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Approved by

7/7-2004 E. Ernstsen

Date; Esben Ernstsen - Quality Assurance

Version history

Version	Author	Date	Description
0.1	CAJ	02-02-2004	Document created
0.2	CAJ	03-06-2004	First draft
0.3	CBS	23-06-2004	Text added
0.4	CAJ	30-06-2004	Filter description added, sound feedback description added
1.0	CAJ	05-07-2004	First version

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1 Purpose

The purpose of this document is to give a short description the software design and setup of the E3000 digital stethoscope. A more detailed description of the software design and implementation can be found in the assembler source code.

2 Scope

This design document covers the software part of the E3000 digital stethoscope. The design is based on the SW requirement specification [1], the SW design [2] and the risk analysis [3].

3 References

E3000 software requirement specification document:

[1] CAJ0341a E3000 SRS.doc

E3000 software design document:

[2] E3000.bcp

E3000 software risk analysis document:

[3] CBS0345c E3000 SW Risk Analysis.xls

(b)(4)Trade Secret manuals:

[4] Firmware reference manual

[5] Hardware reference manual

4 E3000 System Setup

4.1 Sampling frequency

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

4.2 Timers

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

The E3000 system timer values are based upon this setup, they are defined as follows:

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

4.3 WOLA setup

The E3000 WOLA parameters are configured as follows:

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

The WOLA setup above has been chosen on the basis of some of the following criteria:

- It is desired to have a high frequency resolution as possible (b)(4)Trade
- The group delay through the system must be as low as possible (b)
- Minimize instructions consumed by control code by having large block sizes
- Reduce ripples in passband by (b)(4)Trade Secret Process-

P d t S

Some of the criterie above are in conflict with each other. Therefore the final setup has been chosen as the setup, which gives the best compromise of e.g. the requirement for low group delay and large block size.

4.4 Electrical interface

4.4.1 Power off

The DSP is powered off by setting GPIO3 to high from the software. This resets a flip-flop so that the supply to the chip is removed. Pushing one of the filter buttons sets the flip-flop again, the supply is restored to the DSP and it reboots.

Before power off it is however necessary to GPIO6 to high to minimise the standby durrent of the system. Setting the GPIO6 to high also resets a flip-flop into a mode, where it minimises the current draw.

The power off sequence in the software (handle_power.ss) is therefore:

- Set GPIO6 to high
- Wait for GPIO6 to settle (2 seconds)
- Set GPIO3 to high

4.4.2 Button pins

The two filter mode buttons and the filter logic button are attached to three of the low-speed AD converters: LSAD0, LSAD1 and LSAD2. The AD converters are configured to have a dynamic range from 0 to 1V. If the values read from the converters are higher than AD_HIGH_LIMIT (500mV) they are acknowledged as high (button pushed) otherwise they are acknowledged as low (no buttons pushed).

The volume buttons are connected to two digital inputs: GPIO0 and GPIO1. Because these pins can only be high or low, the software also reads them as "1" or "0".

4.5 Battery monitoring

The internal battery level monitor [5] is used in order to control the work area of the E3000. The battery monitor operates on two thresholds, one states low battery and the other one states depleted battery. Finally there is the battery state (threshold) where the DSP is not capable to boot/operate this is HW depended and denoted battery empty (approx. (b) volt)
The two thresholds are defined in the E3000 code as follows:

battery low = (b) volts
battery depleted = (b)(4) volt

The internal battery level monitor uses the MCLK to time battery measurements. The MCLK used in E3000 generates a battery measurement each (b) ms.
In order to remove battery level glitches the E3000 battery monitor operates on battery data picked up over a (b) s period. To determine the state of the battery the output of the internal battery monitor is compared to a fixed state change threshold of (b) of maximum count.

When the E3000 is booted an initial battery check is made to check if the battery is depleted and therefore have to power automatically to prevent use. This check is based upon one measurement only in order to create a rapid device startup, however the price is that it more sensitive to battery level glitches than the normal run-time battery monitoring.

5 E3000 Memory Layout

This section describes the memory layout of the E3000 DSP and EEPROM. The EEPROM layout is made according to [4].

5.1 User data memory layout

The (b)(4)Trade contains two (b) user data memory banks called X and Y data ram. Both memory banks is designed in the following way:

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

In the following the E3000 data memory layout of low and high memory is stated.

X-Low memory:

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

X-High memory:

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

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Y-Low memory:

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

Y-High memory:

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

5.2 EEPROM layout

The EEPROM layout consists (b)(4)Trade areas, where (b) of them are boot and system setup and the (b) data area is the E3000 run-time code.

Here is a short description of the seven data areas and some of the most important parameters:

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

5.3 Copy protection

The copyright protection is made in order to create a "watermark" in the EEPROM that states that the code is created by (b)(4)Trade Secret Process-. When the E3000 boots this watermark is checked and if the checksum of it is invalid due to some unauthorized EEPROM manipulation the E3000 will enter a deadlock loop.
The watermark is (b)(4)Trade Secret Process-Product Specs " and its checksum = (b) (4)T d.

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(b)(4)Trade Secret Process-Design

(b)(4)Trade Secret Process-Design

(b)(4)Trade Secret Process-Design

6.3 Button sound feedback

The feedback sounds used in E3000 are described below and a wav file is included for each sound.

6.3.1 Bell filter sound

```
Bell.wav:
------------
      , 100ms
500Hz, 600ms
```

Bell.wav

6.3.2 Diaphragm filter sound

```
Diaphragm.wav:
---------------
      , 100ms
500Hz, 300ms
      , 250ms
500Hz, 300ms
```

Diaphragm.wav

6.3.3 Volume sound

```
Volume.wav:
------------
       , 100ms
1.5kHz , 100ms
```

Volume.wav

6.3.4 Store volume sound

```
Store_volume.wav:
-----------------
       , 100ms
1.5kHz , 100ms
       , 80ms
1.5kHz , 100ms
```

Store_volume.wav

6.3.5 Battery low sound

```
Battery.wav:
-------------
      , 100ms
1.5kHz, 300ms
      , 250ms
1.5kHz, 300ms
      , 250ms
1.5kHz, 300ms
```

Battery.wav

6.3.6 Power off sound

```
Off.wav:
-------------
        , 100ms
2kHz    , 125ms
        , 13ms
1.5kHz  , 125ms
        , 13ms
1kHz    , 125ms
```

Off.wav

6.4 Volume table

The E3000 volume table consists of eight levels, with steps of (b)(4) dB, the values is as follows.

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

Model 3000 Software Acceptance Test Specification CBS0425a

E3000 SAS Software Acceptance Test Specification

Author

5/7-2004

Date; Casper Sørensen – Development engineer

Protocol Approved by

Date; Esben Lundgård Ernstsen – Quality Assurance

Report Approved by

7/7-2004

Date; Esben Lundgård Ernstsen – Quality Assurance

Summary of report:
TEST OK
NO COMMENT

Version history

Version	Author	Date	Description
0.01	CBS	17-02-2004	Initial version.
1.00	CBS	25-03-2004	Input from review added
2.00	CBS	14-06-2004	Scratch and mute tests are removed

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1 INTRODUCTION

1.1 Purpose

The E3000 is an electronic stethoscope used for auscultation. The E3000 main software features are: adjustment of volume and selection of auscultation filter. (b)(4)Trade Secret Process-Product Specs

This document contains the software acceptance test requirement specification of the E3000 stethoscope.

1.2 References

The E3000 software requirement specification:

[1] CAJ0341a E3000 SRS.doc, version 1.0
[2] CAJ0406a E3000 SW Design.doc

1.3 Reading guidance

Section 1 contains an introduction to this document.
Section 2 contains a description of the acceptance test.
Section 3 contains the test instructions.
Section 4 contains test cases - that is the actual test.

A note to the tables holding test cases:

- Some test cases are composed of several steps that must be executed consecutively. The steps in test case are indicated by a letter after the test case number e.g. AT:017a.
- SR refers to the requirements that are tested by the test case or test step according to the references in section 1.2.

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 is described in the table below. Note that the symbols might be slightly different on the assembled device.

Button symbol	Function
▼	Bell filter button
▽	Diaphragm filter button
+	Increase volume button
—	Decrease volume button

2 TEST DESCRIPTION

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

2.1 Test Target

The software acceptance test is performed on the final software for the E3000 stethoscope.

Description	Identification
E3000 stethoscope	Software version: 1.04 Serial number: R4X26042

2.2 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. Some tests includes timing guidelines, these tests does not require calibrated measurement equipment, since the actual timing verification is perform in software verification tests. Therefore a simple watch, able to display seconds, is sufficient for performing the tests.

All tests must be performed at room temperature.

Reference [2], contains description/definition of the feedback sounds made by E3000. Battery level definitions are also to be found in this document.

2.3 Test Approval

All errors found must be classified and the classification of errors must comply with the standard error classification used at [redacted]

b

3 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.
- ***Test Case***
  The number of the current test case, 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 (see also section 1.3).
- ***SR***
  Indicates which software requirement is tested in current test, see reference in section 1.2
- ***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 3.1.1
- ***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 **OK** box should be marked with √ else it should be left cleared.

3.1 Needed equipment

3.1.1 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. (Series number)	Calibration date
WATCH	CERTINA DS	-11-	-11-
MULTIMETER	PREMA 5017	R2707	22/4-2004
POWER SUPPLY	BKO SN16A	9000205495	-11-
BATTERY SUPPLY	-11-	-11-	-11-

4 TEST CASES

4.1 Power up

4.1.1 TEST 1

Purpose	Test that the E3000 starts when pressing the bell button		
Testcase	AT: 001a	SR: [redacted]	SR: 003 SR: 004 SR: 005
Action	E3000 is powered down 1) Insert the E3000 earplugs into your ears 2) Press ▼ 3) Place the chestpiece on the chest and listen to the body sounds (heart and respiration)		
Expected result	1) There are no sound from the E3000 (device is off) 2) The E3000 powers up and *bell* sound feedback is played 3) Heart sounds are powerful and respiration sound are weak (compared to Test case 1b)		
Result	OK.		
Test equipment and reference	NONE		
Comment	No Comment		
Ok ☑	**Date:** 5/7-2004	**Sign:** [signature]	

4.1.2 TEST 2

Purpose	Test that the E3000 starts when pressing the diaphragm button		
Test case	AT: 001b	SR	SR: 003 SR: 004 SR: 005
Action	E3000 is powered down 1) Insert the E3000 earplugs into your ears 2) Press ▽ 3) Place the chestpiece on the chest and listen to the body sounds (heart and respiration)		
Expected result	1) There are no sound from the E3000 (device is off) 2) The E3000 powers up and *diaphragm* sound feedback is played 3) Heart sounds are weak and respiration sound are powerful (compared to **Test case 1a)**		
Result	OK		
Test equipment and reference	NONE		
Comment	NO COMMENT		
Ok ☑	**Date:** 5/7-2004 **Sign:**		

4.2 Power down

4.2.1 TEST 1

Purpose	Test the automatic power off function		
Test case	AT: 002	SR [redacted]	SR: 006 SR: 009
Action	E3000 is powered down 1) Insert the E3000 earplugs into your ears 2) Press ▼ 3) Wait until the E3000 automatically power down		
Expected result	1) There are no sound from the E3000 2) The E3000 powers up, a *bell* sound feedback and sound picked up by the is played in the binaural 3) After 3min ± 15sec the *power down* sound feedback is played and afterwards there is no sound from the E3000		
Result	ok		
Test equipment and reference	WATCH		
Comment	No comment		
Ok ☑	**Date:** 5/7 2014	**Sign:** [signature]	

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4.2.2 TEST 2

Purpose	Test the automatic power off function		
Test case	AT: 003	SR [redacted]	SR: 006 SR: 009
Action	E3000 is powered down 1) Insert the E3000 earplugs into your ears 2) Press ▼ 3) Wait 60 seconds and press ▼ 4) Wait until the E3000 automatically power down		
Expected result	1) There are no sound from the E3000 2) The E3000 powers up, a *bell* sound feedback and sound picked up by the is played in the binaural 3) *Bell* sound feedback is played again. 4) After 3min ± 15sec after the last button activation the *power down* sound feedback is played and afterwards there is no sound from the E3000		
Result	OK.		
Test equipment and reference	WATCH		
Comment	NO COMMENT		
Ok ☑	**Date:** 5/7-2004	**Sign:**	

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4.2.3 TEST 3

Purpose:	Test the manual power off function		
Test case:	AT: 004	SR: [redacted]	SR: 007 SR: 009 SR: 046
Action	E3000 is powered up 1) Insert the E3000 earplugs into your ears 2) Press and hold ▼ 3) Release ▼ when the *power down* sound feedback occurs		
Expected result	1) The E3000 is operational 2) *Bell* sound feedback is played 3a) Approx. 3 sec after the ▼ button has been pressed the *power down* sound feedback occurs 3b) After the sound feedback stops the E3000 powers down, there are no sound from the E3000		
Result	OK		
Test equipment and reference	~~Ear~~ WATCH		
Comment	NO COMMENT		
Ok ☑	**Date:** 5/7-2004	**Sign:** [signature]	

4.2.4 TEST 4

Purpose	Test the manual power off function		
Test case	AT: 005	**SR**	SR: 007 SR: 009 SR: 046
Action	E3000 is powered up 1) Insert the E3000 earplugs into your ears 2) Press and hold ▽ 3) Release ▽ when the *power down* sound feedback occurs		
Expected result	1) The E3000 is operational 2) *Diaphragm* sound feedback is played 3a) Approx. 3 sec after the ▽ button has been pressed the *power down* sound feedback occurs 3b) After the sound feedback stops the E3000 powers down, there are no sound from the E3000		
Result	OK		
Test equipment and reference	WATCH		
Comment	NO COMMENT		
Ok ☑	**Date:** 5/7-2004	**Sign:**	

4.3 Filter mode

4.3.1 TEST 1

Purpose	Test the change between filters
Test case	AT: 006 SR: [redacted] SR: 010 SR: 011
Action	E3000 is powered down 1) Insert the E3000 earplugs into your ears 2) Press ▼ 3) Place the chestpiece on the chest and listen to the body sounds (heart and respiration) 4) Press ▼ again 5) Press the ▽ 6) Listen to the body sounds (heart and respiration) 7) Press ▽ again 8) Press ▼ 9) Listen to the body sounds (heart and respiration)
Expected result	1) There are no sound from the E3000 (device is off) 2) The E3000 powers up and *bell* sound feedback is played. 3) Heart sounds are powerful and respiration sound are weak 4) *Bell* sound feedback is played, body sounds are as in 3) 5) *Diaphragm* sound feedback is played 6) Heart sounds are weak and respiration sound are powerful 7) *Diaphragm* sound feedback is played, body sounds are as in 6) 8) *Bell* sound feedback is played 9) Body sounds are as in 3)
Result	OK
Test equipment and reference	NONE
Comment	NO COMMENT
Ok ☑	**Date:** 5/7-2004 **Sign:** [signature]

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4.4 Volume selection

4.4.1 TEST 1

Purpose	Test volume selection
Test case	AT: 007 SR [redacted] SR: 014 SR: 015 SR: 016
Action	E3000 is powered up 1) Press + repeatedly 7 times (1 second pause between activations) 2) Insert the E3000 earplugs into your ears 3) Place the chestpiece on the chest and listen to the body sounds 4) Press + again 5) Press − repeatedly 7 times (1 second pause between activations), listen for feedback and body sounds 6) Press − again
Expected result	1) E3000 is forced into maximum volume 2) The E3000 is operational 3) Body sounds are audible 4) No change in sound/no volume feedback 5a) *Volume* feedback is given at each activation 5b) Body sounds loudness is lowered 6) No change in sound/no volume feedback
Result	OK
Test equipment and reference	NONE
Comment	NO Comment
Ok ☑	Date: 5/7-2009 Sign: [signature]

4.4.2 TEST 2

Purpose	Test volume storage		
Test case	AT: 008a	SR	SR: 047 SR: 048 SR: 049 SR: 026
Action	E3000 is powered up 1) Press + repeatedly 7 times (1 second pause between activations) 2) Insert the E3000 earplugs into your ears 3) Press and hold + 4) Release + when the *store volume* sound feedback occurs 5) Press and hold ▽ 6) Release ▽ when the *power down* sound feedback occurs		
Expected result	1) E3000 is forced into maximum volume 2) The E3000 is operational 3) No change in sound/no volume feedback 4) Approx. 2 sec after the + button has been pressed the *Store volume* sound feedback is played 5) *Diaphragm* sound feedback is played 6a) Approx. 3 sec after the ▽ button has been pressed the *power down* sound feedback occurs 6b) After the sound feedback stops the E3000 powers down, there are no sound from the E3000		
Result	OK		
Test equipment and reference	None		
Comment	No Comment		
Ok ☑	**Date:** 5/7-2004	**Sign:**	

4.4.3 TEST 3

Purpose	Test volume storage		
Test case	AT: 008b	SR	SR: 047 SR: 048 SR: 049 SR: 026
Action	E3000 is powered down 1) Press ⏻, to turn E3000 on 2) Insert the E3000 earplugs into your ears 3) Press and hold — 4) Release — when the *store volume* sound feedback occurs 5) Press and hold ⏻ 6) Release ⏻ when the *power down* sound feedback occurs		
Expected result	1) Powers E3000 up and stored volume is applied 2) The E3000 is operational 3) *Volume* feedback is played 4) Approx. 2 sec after the — button has been pressed the *Store volume* sound feedback is played 5) *Diaphragm* sound feedback is played 6a) Approx. 3 sec after the ⏻ button has been pressed the *power down* sound feedback occurs 6b) After the sound feedback stops the E3000 powers down, there are no sound from the E3000		
Result	OK		
Test equipment and reference	None		
Comment	No comment		
Ok ☑	Date: 5/7.2009	Sign:	

3007

4.4.4 TEST 4

Purpose	Test volume storage		
Test case	AT: 008c	**SR**	SR: 047 SR: 048 SR: 049 SR: 026
Action	E3000 is powered down 1) Press ⏻, to turn E3000 on 2) Insert the E3000 earplugs into your ears 3) Press + 4) Press − 5) Press and hold + 6) Release + when the *store volume* sound feedback occurs 7) Press and hold ⏻ 8) Release ⏻ when the *power down* sound feedback occurs		
Expected result	1) Powers E3000 up and stored volume is applied 2) The E3000 is operational 3) No change in sound/no volume feedback 4) *Volume* feedback is played 5) *Volume* feedback is played 6) Approx. 2 sec after the + button has been pressed the *Store volume* sound feedback is played 7) *Diaphragm* sound feedback is played 8a) Approx. 3 sec after the ⏻ button has been pressed the *power down* sound feedback occurs 8b) After the sound feedback stops the E3000 powers down, there are no sound from the E3000		
Result	OK		
Test equipment and reference	None		
Comment	No Comment		
Ok ☑	**Date:** 9/7-2004	**Sign:**	

SC 3

4.4.5 TEST 5

Purpose	Test volume storage		
Test case	AT: 008d	SP	SR: 047 SR: 048 SR: 049 SR: 026
Action	E3000 is powered down 1) Press ▽, to turn E3000 on 2) Insert the E3000 earplugs into your ears 3) Press + 4) Press + again 5) Press — repeatedly 7 times (1 second pause between activations) 6) Press and hold — 7) Release — when the *store volume* sound feedback occurs 8) Press and hold ▽ 9) Release ▽ when the *power down* sound feedback occurs		
Expected result	1) Powers E3000 up and stored volume is applied 2) The E3000 is operational 3) *Volume* feedback is played 4) No change in sound/no volume feedback 5) Forced to minimum volume, *Volume* sound feedback is played at each activation 6) No change in sound/no volume feedback 7) Approx. 2 sec after the — button has been pressed the *Store volume* sound feedback is played 8) *Diaphragm* sound feedback is played 9a) Approx. 3 sec after the ▽ button has been pressed the *power down* sound feedback occurs 9b) After the sound feedback stops the E3000 powers down, there are no sound from the E3000		
Result	OK		
Test equipment and reference	None		
Comment	NO Comment		
Ok ☑	Date: 5/7-2004	Sign:	

4.4.6 TEST 6

Purpose	Test volume storage		
Testcase	AT: 008e	**SR**	SR: 047 SR: 048 SR: 049 SR: 026
Action	E3000 is powered down 1) Press ⏻, to turn E3000 on 2) Insert the E3000 earplugs into your ears 3) Press and hold + 4) Release + when the *store volume* sound feedback occurs 5) Press and hold ⏻ 6) Release ⏻ when the *power down* sound feedback occurs		
Expected result	1) Powers E3000 up and stored volume is applied 2) The E3000 is operational 3) *Volume* feedback is played 4) Approx. 2 sec after the + button has been pressed the *Store volume* sound feedback is played 5) *Diaphragm* sound feedback is played 6a) Approx. 3 sec after the ⏻ button has been pressed the *power down* sound feedback occurs 6b) After the sound feedback stops the E3000 powers down, there are no sound from the E3000		
Result	OK		
Test equipment and reference	None		
Comment	No Comment		
Ok ☑	**Date:** 5/5-2004	**Sign:**	

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4.4.7 TEST 7

Purpose	Test volume storage
Test case	AT: 008f SR: SR: 047 SR: 048 SR: 049 SR: 026
Action	E3000 is powered down 1) Press ▽, to turn E3000 on 2) Insert the E3000 earplugs into your ears 3) Press — 4) Press + 5) Press and hold — 6) Release — when the *store volume* sound feedback occurs 7) Press and hold ▽ 8) Release ▽ when the *power down* sound feedback occurs
Expected result	1) Powers E3000 up and stored volume is applied 2) The E3000 is operational 3) No change in sound/no volume feedback 4) *Volume* feedback is played 5) *Volume* feedback is played 6) Approx. 2 sec after the — button has been pressed the *Store volume* sound feedback is played 7) *Diaphragm* sound feedback is played 8a) Approx. 3 sec after the ▽ button has been pressed the *power down* sound feedback occurs 8b) After the sound feedback stops the E3000 powers down, there are no sound from the E3000
Result	OK
Test equipment and reference	NONE
Comment	NO COMMENTS
Ok ☑	Date: 5/7-2004 Sign:

4.4.8 TEST 8

Purpose	Test volume storage		
Test case	AT: 008g	**SR**	SR: 047 SR: 048 SR: 049 SR: 026
Action	E3000 is powered down 1) Press ▽, to turn E3000 on 2) Insert the E3000 earplugs into your ears 3) Press — 4) Press —		
Expected result	1) Powers E3000 up and stored volume is applied 2) The E3000 is operational 3) *Volume* feedback is played 4) No change in sound/no volume feedback		
Result	OK		
Test equipment and reference	None		
Comment	No Comment		
Ok ☑	**Date:** 5/5-2004	**Sign:**	

4.5 Sound feedback

4.5.1 TEST 1

Purpose	Test sound feedback events		
Test case	AT: 009a	SR	SR: 018
Action	E3000 is powered down, volume level 4 is stored 1) Insert the E3000 earplugs into your ears 2) Press ▼ 3) Press ▼ again 4) Press ▽ 5) Press + 6) Press − and hold 7) Release − when the *store volume* sound feedback occurs 8) Press and hold ▽ 9) Release ▽ when the *power down* sound feedback occurs		
Expected result	1) There are no sound from the E3000 (device is off) 2) The E3000 powers up and *bell* sound feedback is played 3) *Bell* sound feedback is played 4) *Diaphragm* sound feedback is played 5) *Volume* feedback is played 6) *Volume* feedback is played 7) Approx. 2 sec after the − button has been pressed the *Store volume* sound feedback is played 8) *Diaphragm* sound feedback is played 9a) Approx. 3 sec after the ▽ button has been pressed the *power down* sound feedback occurs 9b) After the sound feedback stops the E3000 powers down, there are no sound from the E3000		
Result	Ok		
Test equipment and reference	None		
Comment	No Comment		
Ok ☑	**Date:** 5/7/2009	**Sign:**	

4.5.2 TEST 2

Purpose	Test sound feedback events		
Test case	AT: 009b	SR	SR: 018
Action	E3000 is powered down 1) Insert the E3000 earplugs into your ears 2) Press ▽ 3) Press ▽ again 4) Press ▼ 5) Press — 6) Press + and hold 7) Release + when the *store volume* sound feedback occurs 8) Press and hold ▼ 9) Release ▼ when the *power down* sound feedback occurs		
Expected result	1) There are no sound from the E3000 (device is off) 2) The E3000 powers up and *diaphragm* sound feedback is played 3) *Diaphragm* sound feedback is played 4) *Bell* sound feedback is played 5) *Volume* feedback is played 6) *Volume* feedback is played 7) Approx. 2 sec after the + button has been pressed the *Store volume* sound feedback is played 8) *Bell* sound feedback is played 9a) Approx. 3 sec after the ▼ button has been pressed the *power down* sound feedback occurs 9b) After the sound feedback stops the E3000 powers down, there are no sound from the E3000		
Result	Ok		
Test equipment and reference	None		
Comment	No Comments		
Ok ☑	**Date:** 5/7/2014	**Sign:**	

4.5.3 TEST 3

Purpose	Test sound feedback events, battery low
Test case	AT: 010 SR: SR: 018 SR: 031
Action	E3000 is powered down, battery supply is set to low level 1) Insert the E3000 earplugs into your ears 2) Press ▽ 3) Wait 1 minute
Expected result	1) There are no sound from the E3000 (device is off) 2) The E3000 powers up and *diaphragm* sound feedback is played 3) *Battery low* sound feedback is played
Result	OK.
Test equipment and reference	WATCH, BATTERY SUPPLY, MULTIMETER
Comment	NO COMMENT
Ok ☑	**Date:** 5/7-2004 **Sign:**

4.5.4 TEST 4

Purpose	Test sound feedback events, battery depleted		
Test case	AT: 011	SR	SR: 018 SR: 037
Action	E3000 is powered down, battery supply is set to depleted level 1) Insert the E3000 earplugs into your ears 2) Press ▽		
Expected result	1) There are no sound from the E3000 (device is off) 2a) The E3000 powers up, *battery low* sound feedback is played follow by a *power down* feedback 2b) After the sound feedbacks stops the E3000 powers down, there are no sound from the E3000		
Result	OK		
Test equipment and reference	BATTERY SUPPLY, MULTIMETER		
Comment	NO COMMENT		
Ok ☑	**Date:** 5/7-2004	**Sign:**	

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4.5.5 TEST 5

Purpose	Test sound feedback events, battery depleted		
Test case	AT: 012	SR	SR: 018 SR: 037
Action	E3000 is powered down, battery supply is set to depleted level 1) Insert the E3000 earplugs into your ears 2) Press ▼		
Expected result	1) There are no sound from the E3000 (device is off) 2a) The E3000 powers up, *battery low* sound feedback is played follow by a *power down* feedback 2b) After the sound feedbacks stops the E3000 powers down, there are no sound from the E3000		
Result	OK		
Test equipment and reference	BATTERY SUPPLY, MULTIMETER		
Comment	NO COMMENT		
Ok ☑	Date: 5/7-2004	Sign:	

4.5.6 TEST 6

Purpose	Test sound feedback events
Test case	AT: 013 CR [redacted] SR: 019
Action	E3000 is powered down, volume level 1 (minimum) is stored 1) Insert the E3000 earplugs into your ears 2) Press ▼ 3) Press + repeatedly 7 times (1 second pause between activations)
Expected result	1) There are no sound from the E3000 (device is off) 2) The E3000 powers up and *bell* sound feedback is played 3) *Volume* feedback is played each time the button is pressed the loudness of the sound is increased
Result	OK
Test equipment and reference	NONE
Comment	NO COMMENT
Ok ☑	**Date:** 5/7-2004 **Sign:** [signature]

4.6 Miscellaneous

4.6.1 TEST 1

Purpose	Test of multiple button commands
Test case	AT: 014 SR: [redacted] SR: 045
Action	E3000 is powered up 1) Insert the E3000 earplugs into your ears 2) Press ▼ and hold 3) Press ▽ and hold when the *bell* sound feedback plays 4) Release ▼ 5) Press — and hold 6) Press + and hold 7) Release — 8) Release + 9) Release ▽ 10) Press ▽
Expected result	1) E3000 is operational 2) *Bell* sound feedback is played 3) No sound feedback 4) No sound feedback 5) No sound feedback 6) No sound feedback 7) No sound feedback 8) No sound feedback 9) No sound feedback 10) *Diaphragm* sound feedback is played
Result	OK
Test equipment and reference	NONE
Comment	NO COMMENT
Ok ☑	**Date:** 5/7.2004 **Sign:** [signature]

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4.6.2 TEST 2

Purpose	Test of multiple button commands		
Test case	AT: 015	**SR**	SR: 029
Action	E3000 is powered up 1) Insert the E3000 earplugs into your ears 2) Press ▼ and ▽ 3) Press ▼ and — 4) Press ▼ and + 5) Press ▽ and — 6) Press ▽ and + 7) Press — and + 8) Press ▼, ▽ and — 9) Press ▼, ▽ and + 10) Press ▼, — and + 11) Press ▽, — and + 12) Press ▼, ▽, — and +		
Expected result	1) E3000 is operational 2-12) No sound feedback		
Result	OK		
Test equipment and reference	NONE		
Comment	NO COMMENT		
Ok ☑	**Date:** 5/7-2004 **Sign:**		

4.6.3 TEST 3

Purpose	Test of the battery monitor	
Test case	AT: 016	SR: 032
Action	E3000 is powered up, set battery voltage to low level 1) Insert the E3000 earplugs into your ears 2) Listen for 4 minutes	
Expected result	1) E3000 is operational 2) *Battery low* sound feedback is played every 30s ± 5s	
Result	OK, PUSH A BUTTON DURING THE TEST TO REFRESH THE AUTO POWER OFF (3 min) !	
Test equipment and reference	WATCH, BATTERY SUPPLY, MULTIMETER	
Comment	NO COMMENT	
Ok ☑	Date: 5/7-2004	Sign:

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4.6.4 TEST 4

Purpose	Test of the battery monitor
Test case	AT: 017 SR [redacted] SR: 035 SR: 036
Action	E3000 is powered up 1) Insert the E3000 earplugs into your ears 2) Adjust the battery voltage to empty level
Expected result	1) E3000 is operational 2a) *Battery low* sound followed by *power down* sound feedback is played 2b) After the sound feedbacks stops the E3000 powers down, there are no sound from the E3000
Result	OK
Test equipment and reference	Battery supply, Multimeter
Comment	NO COMMENT
Ok ☑	Date: 5/7-2004 Sign: [signature]

4.6.5 TEST 5

Purpose	Test of the battery monitor		
Test case	AT: 018	SR	SR: 038
Action	E3000 is powered down, battery level is set to 0.3 V 1) Insert the E3000 earplugs into your ears 2) Press ▽		
Expected result	1) There are no sound from the E3000 (device is off) 2) No change in device state		
Result	OK		
Test equipment and reference	Power supply, multimeter		
Comment	No comment		
Ok ☑	Date: 5/7-2004	Sign:	

Model 3000 Software Validation Report Cbs0426b

E3000 Software Validation Report

Author

7/7 2004
Date; Casper Sørensen – Development Engineer

Approved by

7/7-2004
Date; Esben Lundgård Ernstsen – Quality Assurance

Version history

Version	Author	Date	Description
0.1	CBS	22-06-2004	Draft
1.00	CBS	7-7-2004	Updated

Table of Contents

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1 Purpose

The purpose with this document is to summarise the result from the different activities during the development of the software.

2 Scope

In this document it is described how the E3000 software and the Digital Signal Processing (DSP) software development tool used in the E3000 project were validated. The E3000 DSP software development tool is "DSPfactor(b)(4)Trade Secret Process-Product Specs (b)(4)Trade [2]. This tool is designed for developing and testing assembler code made for the (b)(4)Trade Secret processor.

P P d tS

3 References

[1] CBS0340a SQA E3000 SW quality plan.doc
[2] CAJ0339a E3000 Software Code Guideline.doc
[3] Cbs0426d E3000 SW test Plan.doc

4 E3000 software and development tool validation

The validation of the E3000 software and development tool is divided into two evaluation modules [3]. One module tests the combination of compiler and linker. The second one tests the final E3000 program, which includes compilation, linking and EEPROM programming.

- The behaviour of the first validation is tested in the E3000 software module and integration tests. Here small modules of the E3000 code are compiled and linked. Each of these modules tests a special part/functionality of the E3000 code. Furthermore the boundaries of each module are tested to verify if they match specification. In order to test the boundaries of a module, the module is initialised with known parameters, afterwards the module is "compiled" and simulated. Finally the results of the simulated module are compared with the specified results and if they match, both the module and "compilation" is accepted.
- The second validation of the E3000 software and development tool is tested by means of an E3000 acceptance test. Here the entire E3000 code is compiled and linked. The output from the linker is programmed in the E3000 EEPROM. The E3000 stethoscope boundaries are then tested according to specifications, in exactly the same manner as they where tested in the module tests. If the test results of the E3000 stethoscope match specifications, both code and "compilation" is accepted.

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5 E3000 software and development tool validation activities

Validation activity [1]	Reference, Report	Have all results passed the acceptance criteria	After re-validation	Remarks
Review of SW engineering requirements	CAJ0402a E300C SRS Review Report.doc	Yes		
Review of SW design	CAJ0414a E3000 SW Design Review Report.doc	Yes		
Review of Code	CBS0414a E3000 SW Code Review Report.doc	Yes		
Review of Accept test	CBS0413a E3000 SW Acceptance test Review Report.doc	Yes		
Module and integration test	CAJ0421a E300C SW handle_buttons.ss Component Verifications Protocol.doc CAJ0422a E300C SW handle_sound.ss Component Verifications Protocol.doc CAJ0422a E3000 SW handle_irq.ss Component Verifications Protocol.doc CBS0345B E3000 SW handle_init.ss Component Verifications Protocol.doc CBS0420A E3000 SW handle_room.ss Component Verifications Protocol.doc CBS0420B E3000 SW analyse_signal.ss Component Verifications Protocol.doc CBS0421A E3000 SW handle_power.ss Component Verifications Protocol.doc CBS0424a E3000 SW handle_init.ss Component Verifications Protocol.doc CAJ0426a E300C SW System Verifications Protocol.doc	Yes		
Accept test	CBS0425a E3000 SAS Software Acceptance Test Specification.doc	Yes		
SW Traceability analysis	CBS0804a E3000 STA SW Traceability Analysis.doc	Yes		
SW Error reporting	cbs2404a E3000 software error report.doc	Yes		
SW Design risk analysis	CBS0345c E3000 SW Risk Analysis.xls CAJ0413a E3000 Risk Assessment Report.doc	Yes		

6 Conclusion

The software validations activities have passed the acceptance criteria.

Model 3000 Software Release Document CBS0426a

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

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

Title	Release of software for E3000 "version 1.04"	Date	05-07-2004
Project	E3000, IAD0004	From	Casper Sørensen - Development Engineer
To	Project archive	Sign	5/7-2004 CBS
File name	CBS0426a Release of SW for E3000 version 1.04.doc		

Release of software for E3000 "version 1.04"

Description

- This version of the software for the E3000 is "version 1.04. The difference between this version and the previous official release 1.00 is that minor errors are corrected (see cbs2404a E3000 software error report.doc).

Approval

Following persons have approved the release of the E3000 software, **"version 1.04"**.

Tommy Buch Thinesen (TBT)
Project Manager 7/7-2004 Tommy Thinesen

Esben Lundgård Ernstsen (EER)
Quality Engineer 7/7-2004 E. Ernstsen

Identification

Label in the visual source safe: "version 1.04"
The E3000 production EEPROM file is named "E3000.o"

Conclusion

The software version 1.04 for the E3000 stethoscope is completed. The software has been developed according to the software procedure at [redacted] (b
All errors described in the E3000 SW database are closed.

Note the following features are not implemented in the SW:

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

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User Manual, 3M™ Littmann® Electronic Stethoscope Model 3000

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 patented ambient noise reduction technology that reduces up to 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).

•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.

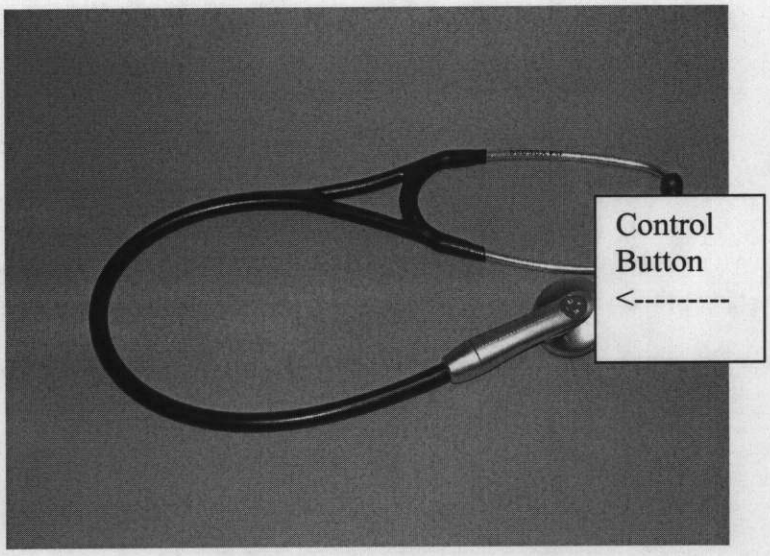
- At the end of this device's useful life, dispose or recycle in accordance with your local, state, and governmental regulations.

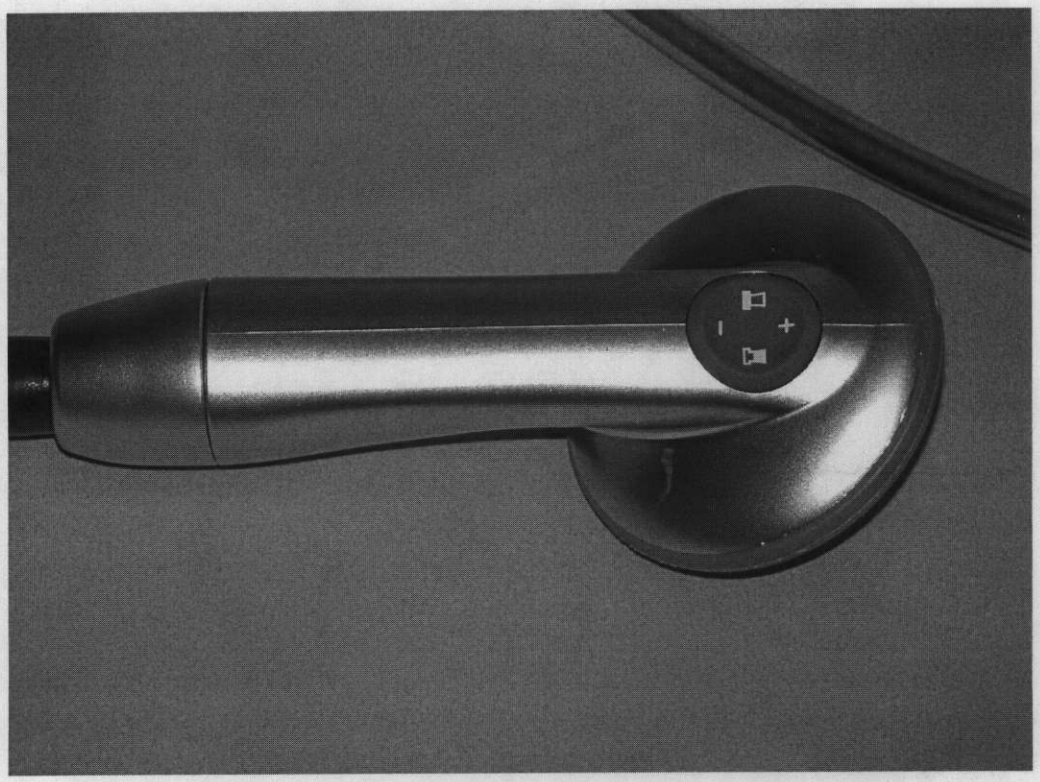
- Refer to appendix for information relating to electromagnetic compatibility testing

- 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.

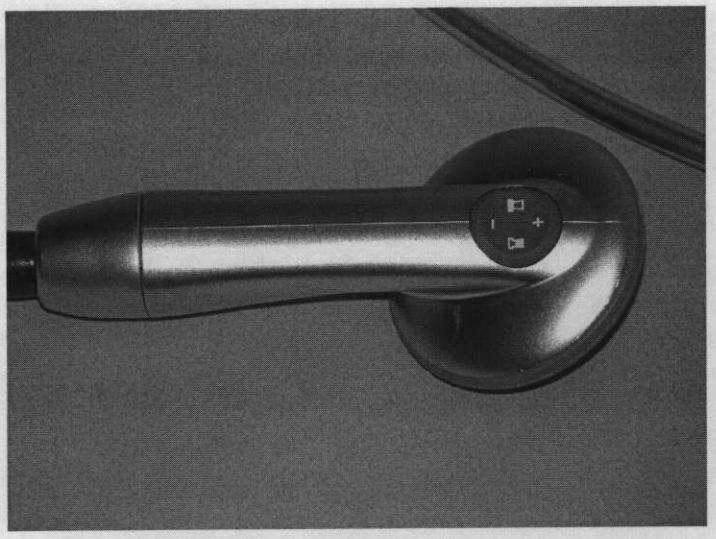
Instructions for Use:

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 (20-200 Hz) Single Tone
▽	Diaphragm filter button (100-500 Hz) 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 buttons ▼ or ▽.
(The specific identifying filter tone will be heard upon activation)

Operation

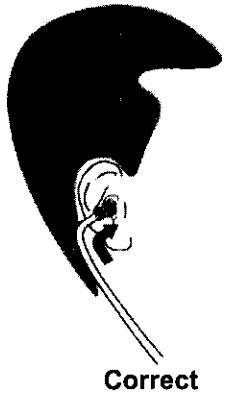
Select the frequency mode desired for auscultation by pushing either the bell or diaphragm filter symbol (this is accomplished when activating the stethoscope initially). Adjust the volume to the desired level by pushing either the plus or minus symbol. At the 3rd volume level, the stethoscope is set to the approximate gain of a typical acoustic stethoscope (this is the preset volume level when you receive the 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.

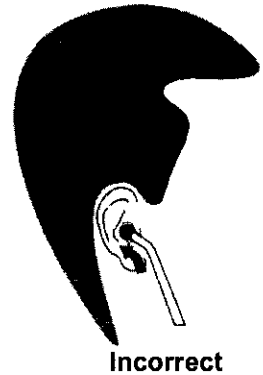
Auscultate as you would using an acoustic stethoscope. It is important to find a comfortable grip that allows you to hold the stethoscope in a secure but relaxed manner. Use the bell and diaphragm modes to accentuate or attenuate different heart and body sounds. Low frequency sounds have a tendency to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

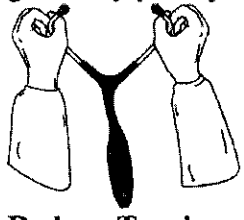


Correct



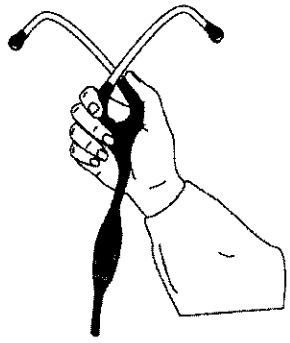
Incorrect

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).



Reduce Tension

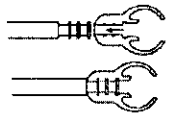
To increase spring tension, grasp the headset with one hand where the eartubes enter the plastic tubing and squeeze until the plastic tubing on one eartube touches the other. Repeat as necessary.



Increase Tension

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.



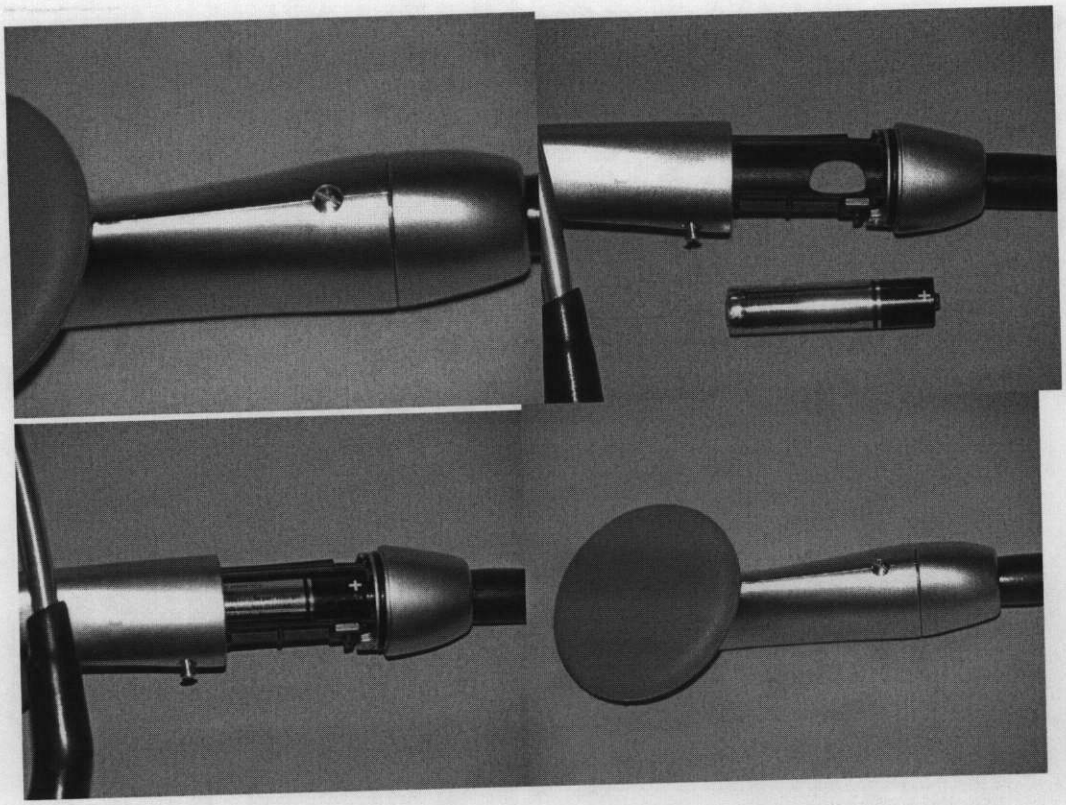
Additional Littmann eartips are available. To order, contact your Littmann Stethoscope distributor or the 3M Health Care Service Center.

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.



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 14° to 122°F (-10 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	E3000 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	E3000 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 the electromagnetic environment in which the RF disturbances are controlled. The customer or the user of the Model 3000 can help prevent electromagnetic interference by maintaining a minimum disturbance 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.

Primary Box Label
3M™ Littmann® Electronic Stethoscope Model 3000

Littmann Brand

Electronic Stethoscope Model 3000

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

△ Attention, see instructions for use
CE 0086 3M Health Care D-41453 Neuss, Germany

3M

Littmann®

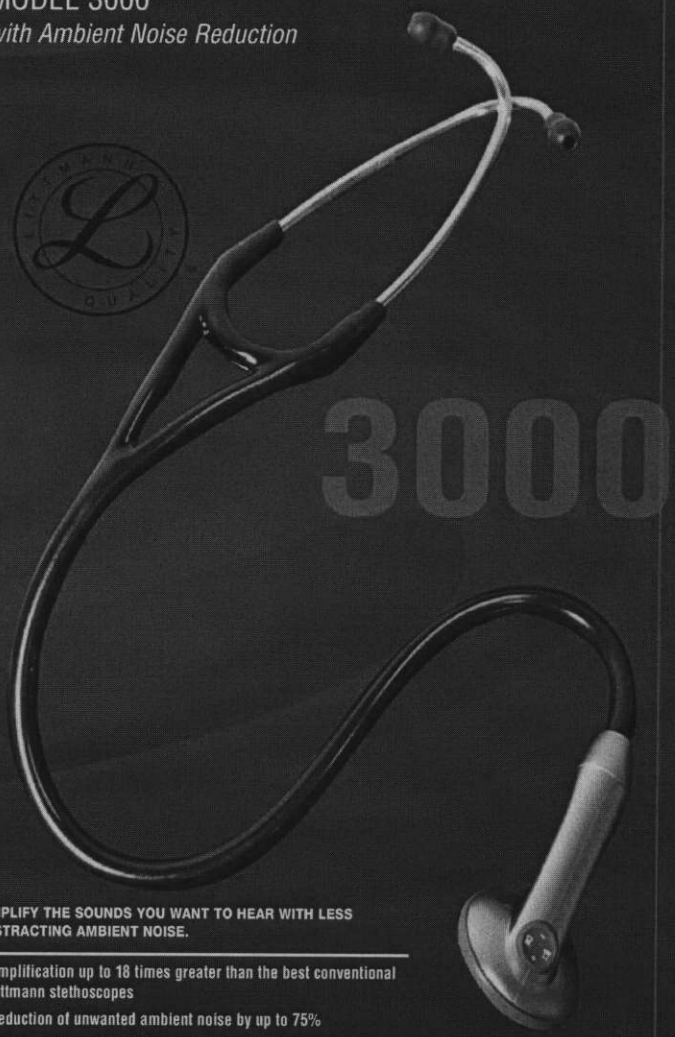
Electronic Stethoscope

MODEL 3000

with Ambient Noise Reduction

Electronic Stethoscopes ○
Cardiology Stethoscopes ●
Classic Stethoscopes ●
Select / Lightweight ●

○ Model 3000 ● Model 4100



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 up to 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

Littmann® Brand

3M™ Littmann® Electronic Stethoscope
Model 3000 with Ambient Noise Reduction
2 Year Warranty

3M™ Littmann® Electronic Stethoscope
Model 3000 with Ambient Noise Reduction
2 Year Warranty

3M

Littmann® Brand

Electronic Stethoscope Model 3000

Littmann®
Electronic Stethoscope
Model 3000

70-2007-4245-3

● 28 in. / 71 cm

0 51131 39000 3

347

Master Shipper Label
3M™ Littmann® Electronic Stethoscope Model 3000

3M

Littmann®

Electronic Stethoscope

With Ambient Noise Reduction

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

3000 | **28 in · 71 cm** | **1 Each/Box**

3 Each QTY. B.U.

70-2007-4245-3 3M I.D. NO.

(01) 5 07 07387 56345 0

LOT XXXXXXXX

User Manual, 3M™ Littmann® Electronic Stethoscope Model 4000

Littmann® Brand

Made in Denmark for **3M Health Care**, St. Paul, MN 55144
(U.S.A.) 1 800 228-3957 • Fax 612 736-2803
Visit our web site: http://www.3M.com/Littmann

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

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38-9017-7823-3

3M

Littmann® Brand

Littmann® Electronic Stethoscope

Model 4000

- Superior acoustics
- Amplification up to 18 times greater than best conventional Littmann stethoscopes
- Three frequency response modes: bell, diaphragm, and extended range
- Recording and playback capabilities
- Heart rate display
- Uses two AAA batteries

4000

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3M™ Littmann® Electronic Stethoscope Model 4000

- *Superior acoustics*
- *Amplification up to 18 times greater than best conventional Littmann stethoscopes*
- *Three frequency response modes: bell, diaphragm and extended range*
- *Recording and playback capabilities*
- *Heart rate display*
- *Uses 2 AAA batteries*

- *Qualité acoustique supérieure*
- *Amplification jusqu'à 18 fois supérieure à celle des stéthoscopes standard*
- *Trois modes de réponse en fréquence : cloche, membrane et gamme étendue*
- *Fonctions d'enregistrement et de lecture*
- *Affichage de la fréquence cardiaque*
- *Fonctionne avec deux piles AAA*

- *Hervorragende akustische Performance*
- *Signalverstärkung bis zu 18 mal höher als bei konventionellen Stethoskopen*
- *Drei verschiedene Frequenzbereiche: Trichter, Membran, erweiterter Modus*
- *Tonaufnahme- und Wiedergabe-Möglichkeit*
- *Herzfrequenz-Display*
- *Stromversorgung: 2 Batterien Typ Micro AAA MK 2400 LR03 1.5 Volt*

- *Acustica superiore*
- *Amplificazione fino a 18 volte superiore a quella degli stetoscopi standard*
- *Tre modalità di frequenza: Campana, Membrana e Gamma estesa*
- *Capacità di registrazione e riproduzione*
- *Visualizzazione frequenza cardiaca*
- *Utilizza 2 batterie AAA*

- *Excelente acústica*
- *Amplificación hasta 18 veces mayor que un fonendoscopio tradicional*
- *Respuesta en tres modos de frecuencia : campana, diafragma y rango extendido*
- *Capacidad de grabar y de reproducir*
- *Muestra el pulso cardiaco*
- *Funciona con 2 pilas AAA*

- *Superieure geluidsweergave*
- *Versterkt tot 18 keer beter dan een standaardstethoscoop.*
- *Er zijn drie frequentiemodi voor de respons: bell (bel), diaphragm (membraan) en extended range (uitgebreid bereik)*
- *Opname- en weergavemogelijkheden*
- *Display voor de hartslag*
- *Gebruikt 2 AAA batterijen*

- *Optimal akustisk ljudåtergivning*
- *Förstärker ljud upp till 18 gånger bättre än standardstetoskop*
- *Tre frekvenslägen: Klocka, membran och utökat område*
- *Inspelnings- och uppspelningsmöjligheter*
- *Hjärtfrekvens display*
- *Använder 2 AAA-batterier*

- *Suveræn lydgengivelse*
- *Lyden forstærkes op til 18 gange i forhold til et traditionelt stetoskop*
- *Tre frekvensområder: klokke, membran og udvidet frekvensområde*
- *Mulighed for indspilning og afspilning*
- *Display af hjertefrekvens*
- *Anvender 2 AAA batterier*

- *Fremragende akustikk*
- *Forsterker inntil 18 ganger bedre enn et vanlig stetoskop.*
- *Tre frekvensmuligheter: klokke, membran og utvidet frekvensskala*
- *Mulighet for lagring og avspilling*
- *Display for hjertefrekvens*
- *Bruker 2 AAA batterier*

- *Ensiluokkainen akustiikka*
- *Vahvistus on jopa 18 kertaa suurempi kuin normaalistetoskoopissa*
- *Kolme taajuutta: suppilo, kalvo ja laajennettu alue*
- *Tallennus- ja toisto-ominaisuudet*
- *Pulssin näyttö*
- *Toimii 2:lla AAA-paristolla*

- *Excelente acústica*
- *Amplificação até 18 vezes superior aos estetoscópios convencionais*
- *Resposta em três modos de frequência: campânula, diafragma e modalidade extensivel*
- *Capacidade de gravar e reproduzir*
- *Mostra a pulsação cardíaca*
- *Funciona com 2 pilhas AAA*
- *Εξαιρετική ακουστική απόκριση*
- *Ενίσχυση ήχου 18 φορές περισσότερη του καλύτερου συμβατού τύπου*
- *Ενίσχυση ήχου σε τρεις ζώνες συχνοτήτων: κώδωνα, διάφραγμα διευρυμένης περιοχής*
- *Δυνατότητα εγγραφής και αναπαραγωγής*
- *Ρύθμιση έντασης ήχου*
- *Χρησιμοποιεί αλκαλική μπαταρία τύπου AAA*

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3M™ Littmann® Electronic Stethoscope Model 4000

Congratulations on the purchase of your new Littmann Electronic Stethoscope Model 4000, the next generation electronic stethoscope that offers the very latest in advanced auscultation technology.

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 4000 is specially designed to pick up difficult-to-hear heart and other body sounds. Three frequency modes are available for optimal heart and lung auscultation: Bell, Diaphragm and Extended Range.

The Littmann Electronic Stethoscope Model 4000 offers recording, storage and playback capabilities on six different soundtracks. Instant playback is available at normal and half speed.

Additionally, the Model 4000 provides infrared data transmission of recorded sounds to either another Model 4000 or an IBM-compatible PC, 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 rim, and patented 3M™ Littmann® Snap Tight Soft-Sealing Eartips for excellent acoustic seal and comfortable fit. Plus, the Model 4000 operates on just two AAA alkaline batteries.

Most of all, know that the Model 4000 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 • Avoid penetration of fluids into the eartip openings. The remainder of stethoscope is protected against splashing liquid.

LATEX • This product and package do not contain natural rubber latex.

Each Littmann Electronic Stethoscope Model 4000 has a serial number beginning with "SN P".

Indications

The Littmann Electronic Stethoscope Model 4000 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 4000 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

- 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 4000 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. When using the stethoscope, if sudden or unexpected sounds are heard, the Model 4000 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 4000 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 4000 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 4000, do not attempt to repair it yourself. Refer to the Service and Warranty section of this manual.

Instructions For Use

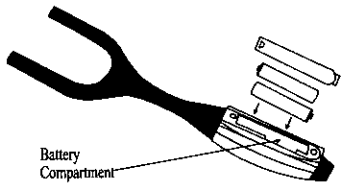
Battery

When used in a typical setting, the Littmann Electronic Stethoscope Model 4000 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.

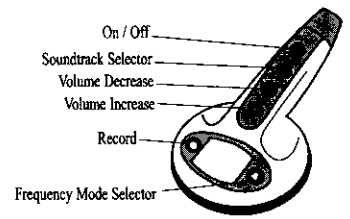
When the batteries are no longer able to power the Model 4000 stethoscope, the stethoscope will automatically turn off. All recorded sounds and settings are saved. The Model 4000 will not function if the batteries are depleted.

Insert batteries as shown

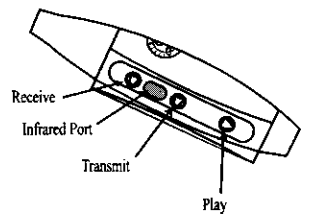


Electronic Controls

The chestpiece of the Littmann Electronic Stethoscope Model 4000 contains six buttons:



The battery compartment of the Model 4000 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 Selector — There are six soundtracks available on the Model 4000. 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.

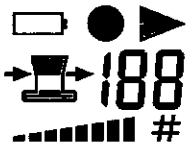
Frequency Mode Selector — Press the FREQUENCY MODE SELECTOR button to select Bell, Diaphragm or Extended Range.

Receive — Press the RECEIVE button to receive a soundtrack from another Model 4000 or computer.

Transmit — Press the TRANSMIT button to transmit the displayed soundtrack to another Model 4000 or computer.

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 4000 display panel. As a functional test, when the Model 4000 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.
	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.
	If the display is blinking 199, the heart rate is above 199 bpm and cannot be displayed.
	Error Message. See Error Message section of this manual

Operation

Power On — Press the ON/OFF button on the Littmann Electronic Stethoscope Model 4000. The factory or personalized setting will be in operation.

Automatic Power Off

The Model 4000 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 4000 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.

Personalized Setup

The Model 4000 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 4000 will now function with these settings on startup.

Heart Rate

The Model 4000 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 4000 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 soundtracks 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 indicates a recorded soundtrack. Recording on a soundtrack that displays the 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 two seconds. This will erase all soundtracks. Erased soundtracks cannot be recovered.

Data transmission to another Littmann Electronic Stethoscope Model 4000

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 4000 then press the TRANSMIT button on the transmitting Model 4000. The arrow will blink until the infrared connection is made.
4. Transmission is indicated on the Model 4000 display by a rotating .
5. Progress of the transmission is shown on the Model 4000 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® 95/98/2000[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 4000 TRANSMIT button. The arrow will blink until the infrared connection is made.
4. Transmission is indicated on the Model 4000 display by a rotating . The computer status bar will display two red lights flashing towards one another.
5. Progress of the transmission is shown on the Model 4000 display with the symbol.
6. ***WINDOWS 95/98*** – Downloaded soundtracks are stored in: C:\My Received Files.

1. Prompts may vary between versions of Windows and are the responsibility of the Microsoft. References to Windows as it pertains to use of the Littmann Electronic Stethoscope Model 4000 are for clarification only. Please consult your Microsoft users 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® 95/98/2000[2] with an infrared (IR) port

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.

WINDOWS 95/98 - 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 4000 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 4000 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 4000 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 4000 display with the symbol.

Note: The soundtrack filename is not transmitted to the stethoscope. If Er 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 4000 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 4000 was removed before the soundtrack was completely transferred. Do not move the stethoscopes until the is finished rotating.
- The Model 4000 may be exposed to excessive EMI/RFI, electromagnetic noise. Remove the source of noise.

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

2. Prompts may vary between versions of Windows and are the responsibility of the Microsoft. References to Windows as it pertains to use of the Littmann Electronic Stethoscope Model 4000 are for clarification only. Please consult your Microsoft users manual for specific instructions.
Microsoft® and Windows® are trademarks of Microsoft Corporation

Headset Positioning

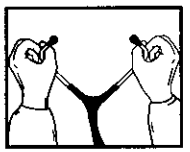
The Littmann Electronic Stethoscope Model 4000 is designed to provide a comfortable, acoustically sealed ear fit. Notice that the eartubes are permanently set at an angle to accommodate the typical anatomy of the ear canal. The eartips should point in a forward direction when inserted into the ear canals.

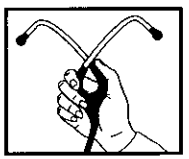
Correct

Incorrect

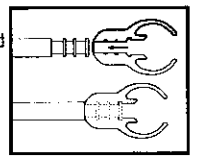
To reduce spring tension in the headset, hold each eartube at the bend near the eartip and gradually pull apart until fully extended.

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 3M™ Littmann® Soft-Sealing Eartips are provided with the stethoscope. The stethoscope utilizes a unique design for attaching the eartip to the eartube.

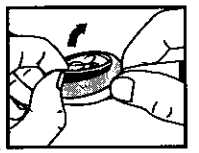


The eartips are pushed onto the end of the eartube and snapped in place. To remove, pull firmly on the eartip.

Diaphragm Removal and Replacement

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

Rim Removal:

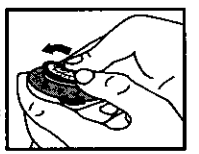


- With diaphragm side up, using a thumbnail, pry the rim out of its designated groove, and pull towards you. If the diaphragm does not come off along with the rim, remove this separately. Do not disturb the components located under the diaphragm once it is removed.

Cleaning of the Rim and Diaphragm:

- Separate the diaphragm from the rim, and clean with mild soapy water and/or alcohol. The surface of the chestpiece can also be wiped with alcohol. Take care not to saturate the chestpiece. Excess liquid used in the cleaning process can result in moisture getting into the internal components.

Diaphragm and Rim Reassembly:



- Once the rim and diaphragm are completely dry, place the rim on a firm surface. Insert the diaphragm into the inside

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groove of the rim, starting at one point, and running your finger around the inside of the rim. This technique will position the diaphragm properly in the designated groove.

- Place the rim and diaphragm assembly on the chestpiece surface. Totally engage the assembly in the groove on chestpiece at one point and hold in place with thumb. Slowly roll the rim around the chestpiece edge using both thumbs moving in opposite directions.

General Use and Maintenance

- 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 storage conditions are from -4°F to 140°F (-20°C to 60°C), 15 to 95% relative humidity.

Failure to follow care and maintenance recommendations could result in damage to the internal components of the Model 4000. 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 4000 do not attempt to repair it yourself. Please notify the 3M Health Care Service Center for directions on shipping and receiving.

Littmann Stethoscope Service and Warranty Program

The Littmann Electronic Stethoscope Model 4000 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.

Stéthoscope électronique 3M™ Littmann® modèle 4000

Nous vous remercions d'avoir choisi le nouveau stéthoscope électronique Littmann modèle 4000, le dernier-né de la gamme Littmann.

Equipé des toutes dernières technologies en matière d'auscultation, ce stéthoscope électronique offre une qualité acoustique supérieure. Avec une amplification jusqu'à 18 fois supérieure à celle des meilleurs stéthoscopes traditionnels, le modèle 4000 est spécialement apte à détecter des bruits organiques (cardiaques ou autres) difficiles à entendre. Trois modes de réponse en fréquence sont disponibles pour une auscultation optimale du cœur et des poumons : Cloche, Membrane et Gamme étendue.

Le stéthoscope électronique 3M™ Littmann® modèle 4000 est équipé de fonctions d'enregistrement, de mémorisation, et de lecture sur six bandes sonores. La lecture instantanée est disponible à vitesse normale et à vitesse lente.

Il permet de transmettre par infrarouge les sons enregistrés à d'autres modèles 4000 ou à des ordinateurs compatibles IBM, ce qui vous permet de faire écouter des sons ou de les archiver.

Le modèle 4000 permet également le traitement numérique des sons sur toute la gamme acoustique. Son écran incorporé permet de visualiser la fréquence cardiaque. Il est muni d'une bague anti-froid pour le confort du patient et d'embouts auriculaires 3M™ Littmann® brevetés souples et étanches qui garantissent une excellente isolation acoustique et une insertion confortable. Le modèle 4000 fonctionne avec deux piles alcalines de type AAA.

Le modèle 4000 est un stéthoscope Littmann, marque reconnue dans le monde entier pour sa fiabilité et sa qualité sans égales. Marque leader sur le marché de l'auscultation, la marque Littmann est une garantie de qualité acoustique supérieure, de design innovant et de performance exceptionnelle.

Explication des symboles suivants :

⚠ • Attention, consulter la notice d'utilisation.

• Appareil dit de type B : cet appareil est équipé d'une protection contre les chocs électriques et les coupures de courant électrique.

IPX4 • Empêche la pénétration des liquides dans les embouts auriculaires. Le reste du stéthoscope est protégé des éclaboussures de liquides.

(LATEX) • Aucune trace de latex dans le produit ni dans l'emballage

Chaque stéthoscope électronique Littmann modèle 4000 est doté d'un numéro de série commençant par « SN P ».

Utilisation

Le stéthoscope électronique Littmann modèle 4000 a été conçu pour établir un diagnostic médical seulement. Il peut être utilisé pour amplifier les sons provenant du cœur, des poumons ou d'autres organes avec un filtrage de fréquences sélectif. Cet appareil permet également d'enregistrer, de ré-écouter et de transmettre ou recevoir des sons. Ce produit n'a pas été conçu, mis en vente, ni prévu pour un usage autre que celui indiqué.

⚠ **Mise en garde**

- Respecter les recommandations d'utilisation et d'entretien qui suivent sous peine d'endommager l'appareil ou d'encourir d'éventuelles blessures. Tout dommage peut entraîner un mauvais fonctionnement de l'appareil, pouvant aller d'une légère baisse de performance acoustique à une panne complète.
- La lecture à vitesse lente ne doit pas servir seule de base au diagnostic.
- Le médecin est responsable de l'archivage des données dans le dossier du patient concerné.
- La transmission des bandes sonores à un ordinateur ne doit

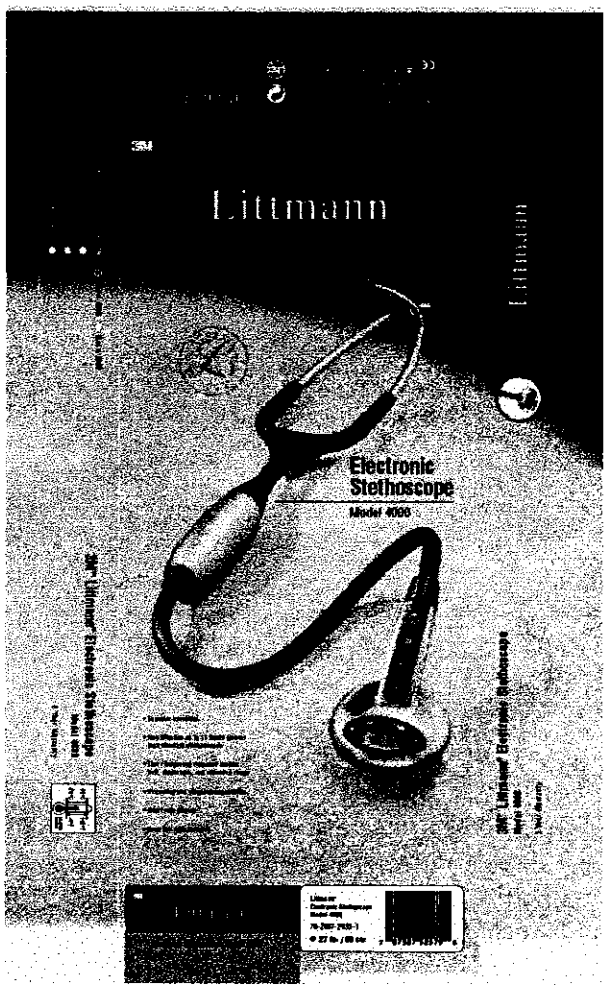
Primary Box Label
3M™ Littmann® Electronic Stethoscope Model 4000

Artwork #: 30-0010-1440-0
Date: 11-09-98
Author: R Wyhre
Expiration: 10-0001-0079-4
Pkg. Spec Reference: 34-7935-3154-2
Directions: PC

SCALE: |+++++++| 1 inch

artwork prints 4 color

3M™ Littmann® Electronic Stethoscope
Model 4000



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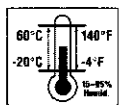
Master Shipper Label
3M™ Littmann® Electronic Stethoscope Model 4000

3M

Electronic Stethoscope Model 4000 Black



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

27 in • 68 cm

1 each / Box

34-7049-7484-8

3 Each

QTY. B.U.

4000

70-2007-2935-1

3M I.D. NO.

CE 0086

LOT

Artwork Number:	**38-9001-3239-0**
Date:	**12-01-2000**
Author:	**Go East Design**
Supersedes:	**Not Applicable**
Pkg. Spec. Reference:	**34-7049-7484-8**
Structure:	**MC PP**

SCALE: |+++++++++| **1 Inch**

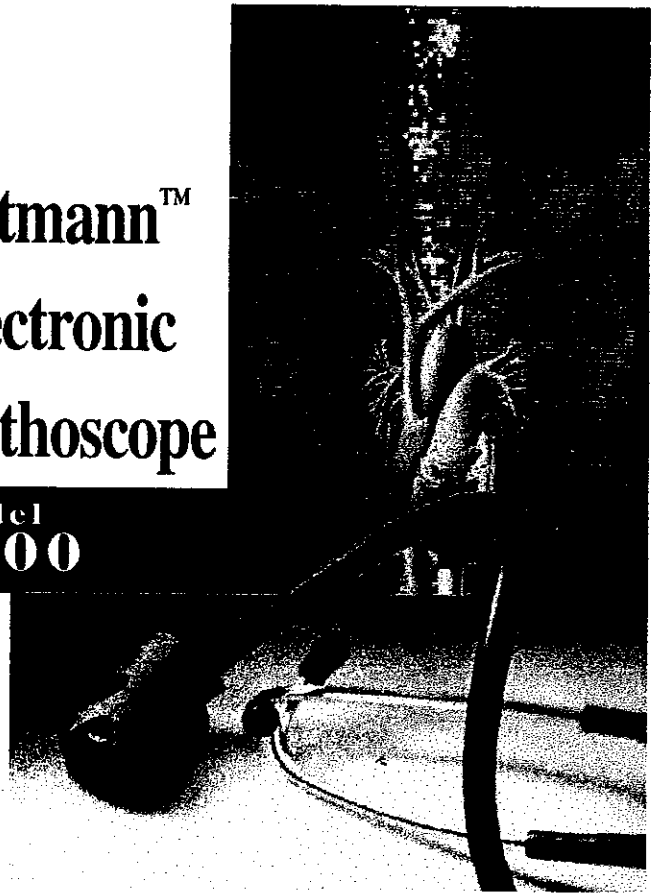
all artwork prints black

User Manual, 3M™ Littmann® Electronic Stethoscope Model 2000

3M

Littmann™ Electronic Stethoscope

Model 2000



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3M™ Littmann™ Electronic Stethoscope Model 2000

- Superior acoustics
- Versatile adult- or pediatric-sized chestpiece
- Advanced electronic filtering
- 3 frequency response modes: bell, diaphragm & extended range
- Amplification up to four times greater than standard stethoscopes
- Uses 1 AAA battery

- Acoustique supérieure
- Pavillon polyvalent pour adultes et enfants
- Filtrage électronique de pointe
- 3 modes de réponse en fréquence : cloche, membrane et plage de fréquences étendue
- Amplification jusqu'à quatre fois supérieure à celle des stéthoscopes standard
- Fonctionne avec 1 pile de type AAA (fournie)

- Überragende Akustik
- Für die Auskultation von Erwachsenen und Kindern geeignet
- Moderne elektronische Filtertechnik
- 3 Frequenzgangmodi: Trichter, Membran und erweiterter Bereich
- Verstärkung bis zu viermal größer als bei Standardstethoskopen
- Inklusicve 1.5 V AAA, LR03(T) Batterie

- Sensibilità acustica superiore
- Testina versatile per pazienti adulti o pediatrici
- Filtrazione elettronica avanzata
- Modalità di risposta a 3 frequenze: a campana, a diaframma e a gamma estesa
- Amplificazione decisamente superiore a quella degli stetoscopi standard
- Utilizza 1 batteria AAA (inclusa)

- Acústica excepcional
- Campana versátil que se adapta a pacientes pediátricos y adultos
- Avanzado filtrado electrónico
- Tres modalidades de respuesta de frecuencia: campana, diafragma y modo extendido
- Amplificación hasta 4 veces mayor que la de los fonendoscopio normales
- Emplea 1 pila AAA (incluida)

- Superieure geluidsweergave
- Veelzijdig borststuk aangepast aan volwassenen en kinderen
- Geavanceerde elektronische filtering
- 3 frequentieresponsmodes: bel, membraan en uitgebreid bereik
- Tot viermaal meer versterking dan bij standaard stethoscopen
- Werkt op 1 AAA batterij (bijgevoegd)

- Optimal akustisk ljudåtergivning
- Bröststycke som kan användas till både barn och vuxna
- Avancerat elektroniskt filtreringssystem
- 3 frekvensfunktioner: klocka, membran och utökat frekvensområde
- Upp till fyra gånger högre ljudförstärkning än i akustiska stetoskop
- Drivs av 1 st AAA-batteri (medföljer)

- Enestående akustik
- Bryststykke til både voksne og børn
- Avanceret elektronisk filtreringssystem
- Tre frekvensfunktioner: klokke, membran og udvidet frekvensområde
- Op til fire gange større lydforstærkning sammenlignet med traditionelle stetoskoper
- Bruger et stk. IEC LR03 1,5 V batteri eller AAA-batteri (ikke-genopladeligt) (vedlagt)

- Fremragende akustikk
- Stetoskophode som kan brukes på både voksne og barn
- Avansert elektronisk filtrering
- 3 frekvensfunksjoner: klokke, membran og utvidet frekvensskala
- Opp til fire ganger bedre forsterkning enn vanlig stetoskop
- Benytter 1 AAA batteri (vedlagt)

- Ylivoimaiset akustiset ominaisuudet
- Monipuolinen yhdistelmätyyppinen kuuntelinosa
- Tehokas elektroninen taajuuksien suodatus
- Kuuntelumahdollisuus kolmella eri taajuusalueella suppilo, kalvoa ja laajennettua taajuusaluetta käyttäen
- Vahvistaa ääniä jopa neljä kertaa paremmin kuin tavalliset stetoskoopit
- Toimii yhdellä IEC LR03 1,5V -paristolla (toimitetaan mukana)

- Excepcional acústica
- A campânula versátil adapta-se a pacientes jovens e adultos
- Avançado filtro electrónico
- Três modalidades de resposta de frequência: campânula, diafragma e de maior amplitude.
- Amplificação 4 vezes superior à dos estetoscópios correntes
- Possui uma pilha AAA (anexo)

- Εξαίρετη ακουστική
- Επιστήθιο τμήμα ενηροσάρμοστο για ενήλικες ή παιδιά
- Προηγμένος ηλεκτρονικός φιλτραρισμός
- Επιλογή τριών περιοχών συχνότητας: κώδωνα, διαφράγματος και διευρυμένη έκταση
- Ενίσχυση του ήχου μέχρι και τέσσερις φορές μεγαλύτερη από τα κλασσικά στηθοσκόπια
- Χρησιμοποιεί 1 μπαταρία AAA (περιλαμβάνεται)

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Owning a 3M™ Littmann™ Electronic Stethoscope Model 2000

The 3M Littmann Electronic Stethoscope Model 2000 provides the same superior acoustics you've come to expect from a Littmann Stethoscope. It also includes state-of-the-art amplification and filtering systems, ideal for picking up difficult-to-hear heart and other body sounds. The chestpiece is sized for use with adult or pediatric patients. What's more, the Littmann Electronic Stethoscope is ergonomically designed to look and feel like a standard Littmann stethoscope.

Powered by a single AAA battery, the stethoscope is easily activated by a button on top of the chestpiece. Three frequency modes are available—standard bell, diaphragm, and extended range. The extended range mode amplifies sounds in a broader frequency range than the traditional diaphragm mode. The range includes both higher and lower sounds where some lung and heart sounds may occur. An electronic amplification system allows for volume adjustment. And an advanced filtering system provides enhanced clarity.

The Littmann Electronic Stethoscope also features a patented nonchill rim for patient comfort, as well as 3M™ Littmann™ Soft-Sealing Eartips for top acoustic performance.

With its ergonomic design, state-of-the-art amplification and filtering systems, and extended frequency range, the Littmann Electronic Stethoscope is a powerful, effective tool for health care professionals.

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).

Each Littmann Electronic Stethoscope Model 2000 has a serial number beginning with the letter "N".

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.

Use only AAA alkaline batteries. Carefully follow all cautions, warnings, and instructions on the battery package.
When the Low Battery Indicator Light comes on, replace the battery within eight hours.

There is no acoustic (nonamplified) 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. 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.

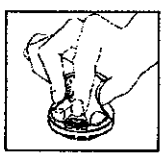
Do not immerse the stethoscope in any liquid or subject it to any sterilization processes.

At the end of this device's useful life, dispose or recycle in accordance with your local, state, and governmental regulations.

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 for directions on shipping and receiving at 1-800-292-6298.

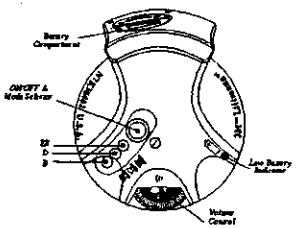
Instructions for Use:

Holding the Chestpiece
The chestpiece is designed to be held as shown. However, you may find other ways to hold the stethoscope that are more comfortable or more familiar to you.



Electronic Controls
To turn on the stethoscope, press the ON/OFF and Mode Selector button once. This button is located on top of the chestpiece. The stethoscope moves to a new mode each time this button is pressed. The Mode Indicator Lights tell you which mode is activated. The first time you press this button, the bell mode (B) is activated; the second time, the diaphragm mode (D); the third time, the extended range mode (ER). When you press the button a fourth time, the stethoscope returns to the bell mode. The stethoscope will automatically shut off approximately three minutes after the last time the button is pressed. At that time you can reactivate the power and select the appropriate frequency mode. By pressing and holding the ON/OFF and Mode Selector button for a two-to-three second period, you can manually shut down the power to the stethoscope to conserve battery life.

Bell Mode (B)	20-200 Hz
Diaphragm Mode (D)	100-500 Hz
Extended Range Mode (ER)	100-1000 Hz



Operation
Select one of the three frequency modes desired for auscultation by following the preceding instructions.

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Owning a 3M™ Littmann™ Electronic Stethoscope Model 2000

The 3M Littmann Electronic Stethoscope Model 2000 provides the same superior acoustics you've come to expect from a Littmann Stethoscope. It also includes state-of-the-art amplification and filtering systems, ideal for picking up difficult-to-hear heart and other body sounds. The chestpiece is sized for use with adult or pediatric patients. What's more, the Littmann Electronic Stethoscope is ergonomically designed to look and feel like a standard Littmann stethoscope.

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IPX4 • Protected against splashing liquid (chestpiece only).

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⚠ 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.

Use only AAA alkaline batteries. Carefully follow all cautions, warnings, and instructions on the battery package.
When the Low Battery Indicator Light comes on, replace the battery within eight hours.

There is no acoustic (nonamplified) 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. 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.

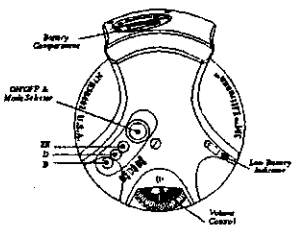
If you experience any problems with the Littmann Electronic Stethoscope, do not attempt to repair it yourself. Please notify the 3M Health Care Service Center for directions on shipping and receiving at 1-800-292-6298.

Instructions for Use:

Holding the Chestpiece
The chestpiece is designed to be held as shown. However, you may find other ways to hold the stethoscope that are more comfortable or more familiar to you.

Electronic Controls
To turn on the stethoscope, press the ON/OFF and Mode Selector button once. This button is located on top of the chestpiece. The stethoscope moves to a new mode each time this button is pressed. The Mode Indicator Lights tell you which mode is activated. The first time you press this button, the bell mode (B) is activated; the second time, the diaphragm mode (D); the third time, the extended range mode (ER). When you press the button a fourth time, the stethoscope returns to the bell mode. The stethoscope will automatically shut off approximately three minutes after the last time the button is pressed. At that time you can reactivate the power and select the appropriate frequency mode. By pressing and holding the ON/OFF and Mode Selector button for a two-to-three second period, you can manually shut down the power to the stethoscope to conserve battery life.

Bell Mode (B)	20-200 Hz
Diaphragm Mode (D)	100-500 Hz
Extended Range Mode (ER)	100-1000 Hz



Operation
Select one of the three frequency modes desired for auscultation by following the preceding instructions.

Adjust the volume control knob to the desired level. It is located on the front of the chestpiece next to the mode selector button. Numbers are provided on this knob for your reference. By positioning the volume control in the 1.5 to 2 range, the stethoscope is set to the approximate gain of a typical acoustic stethoscope.

Auscultate as you would using an acoustic stethoscope and adjust the volume as necessary. It is important to find a comfortable grip that allows you to hold the stethoscope in a secure but relaxed manner.

Auscultation
Use the bell and diaphragm modes to accentuate or attenuate different heart and body sounds. The extended range mode picks up frequency sounds that occur above the range provided by the diaphragm mode in normal acoustic stethoscopes. In addition, this mode slightly attenuates low frequency sounds as compared with the bell mode. These low frequency sounds have a tendency to mask or obscure the high frequency sounds. Adjust volume control as necessary.

Battery Life
The battery will last for about 40 hours of continuous use. In a typical clinical setting, this represents one month of use.When the Low Battery Indicator Light comes on, sufficient battery power remains for normal auscultation activities for several days of typical use. It is recommended that the battery be replaced as soon as this indicator light comes on, or within eight hours. You may wish to carry a spare battery, or have spares readily available in your clinic or hospital. It is important to remember that there is no acoustic (nonamplified) mode available in the Littmann Electronic Stethoscope, so when the battery is finally exhausted, the stethoscope will not operate.

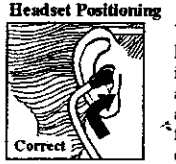
Battery Replacement
To replace the battery, insert a coin into the battery door slot and turn counterclockwise 1/4 turn. Turn the battery door so that the dot (•) on the door and the (o) symbol on the chestpiece line up. Remove the door with the battery from the chestpiece. Pull out the old battery and slide the "+" (positive) end of a new battery into the door. Insert the battery in the chestpiece and replace door. Again, line up with the (o) symbol on the chestpiece, then reverse the process above using the coin in the door slot to secure the battery door into place.

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

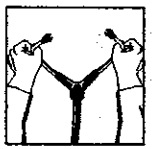
Use AAA alkaline batteries only (IEC LR03, 1.5V ⎓). Rechargeable batteries provide only about 30 minutes of power after the Low Battery Indicator Light comes on. Carefully follow all instructions and warnings on the battery label and package.

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

Headset Positioning

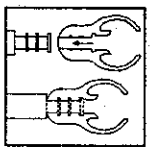


Your new Littmann Electronic Stethoscope is designed to give you a very comfortable, acoustically sealed ear fit. Notice that the eartubes are permanently set at an angle to accommodate the typical anatomy of the ear canal. The eartips should point in a forward direction as you insert them into your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



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

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.

General Use and Maintenance

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

Rim Removal:
With diaphragm side up, using a thumbnail, pry the underside portion of the rim out of its designated groove, and pull towards you. If the diaphragm does not come off along with the rim, remove this separately. Do not disturb the components located under the diaphragm once it is removed.

Cleaning of the Rim and Diaphragm:
Separate the diaphragm from the rim, and clean with a mild soapy water and/or alcohol. The surface of the chestpiece can also be wiped with alcohol. Care should be taken as to not saturate the chestpiece. Excess liquid used in the cleaning process can result in moisture getting into the internal components.

Diaphragm and Rim Reassembly:
Once the rim and diaphragm are completely dry, place the rim on a firm surface. Insert the diaphragm into the inside groove of the rim, starting at one point, and running your finger around the inside of the rim. This technique will position the diaphragm properly in the designated groove.

Place the rim and diaphragm assembly on the chestpiece surface. Totally engage the assembly in groove on chestpiece at one point and hold in place with thumb. Slowly roll the rim

around the chestpiece edge using both thumbs moving in opposite directions.

- 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 is stored or will not be used for several months.
- Recommended storage conditions are from -4° to 140°F (-20 to 60°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 2000 is warranted against any defects in material and manufacture for a period of one year. 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.

Français

Stéthoscope électronique 3M Littmann modèle 2000

Le stéthoscope électronique 3M™ Littmann™ fournit la même acoustique exceptionnelle attendue d'un stéthoscope 3M Littmann. Il inclut également des systèmes d'amplification et de filtrage de pointe, parfaits pour percevoir les sons cardiaques et autres sons corporels difficiles à entendre. Le pavillon peut être utilisé sur des adultes ou des enfants. Qui plus est, le stéthoscope électronique a été conçu de manière ergonomique pour se manipuler aussi facilement que tout autre stéthoscope 3M Littmann.

Alimenté par une pile de type AAA, le stéthoscope s'actionne par une simple pression sur un bouton, situé sur le dessus du pavillon. Trois modes de fréquence sont disponibles : cloche standard, membrane et plage de fréquences étendue. Ce dernier mode amplifie les sons dans une plage de fréquences plus large que celle du mode membrane traditionnel. Cette plage inclut à la fois des hautes et basses fréquences, là où certains sons cardiaques ou pulmonaires risquent de figurer. Un système d'amplification électronique permet de régler le volume et un système de filtrage de pointe permet d'obtenir des sons d'une netteté exceptionnelle.

Le stéthoscope électronique 3M Littmann est également équipé d'une bague anti-froid brevetée, pour le plus grand confort du patient et d'embouts auriculaires souples et étanches 3M Littmann.

Avec sa forme ergonomique, ses systèmes d'amplification et de filtrage de pointe et sa plage de fréquences élargie, le stéthoscope électronique 3M Littmann est un outil précis et performant destiné aux professionnels de la santé.

Les symboles suivants sont applicables pour cet appareil :

⚠ • Attention, se référer aux instructions pour l'utilisation.

• Appareil dit de type B : cet appareil est équipé d'une protection contre les chocs électriques et les coupures de courant électrique.

IPX4 • L'appareil est protégé contre les éclaboussures de liquides (pavillon seulement).

Chaque stéthoscope électronique 3M Littmann modèle 2000 possède un numéro de série commençant par la lettre "N".

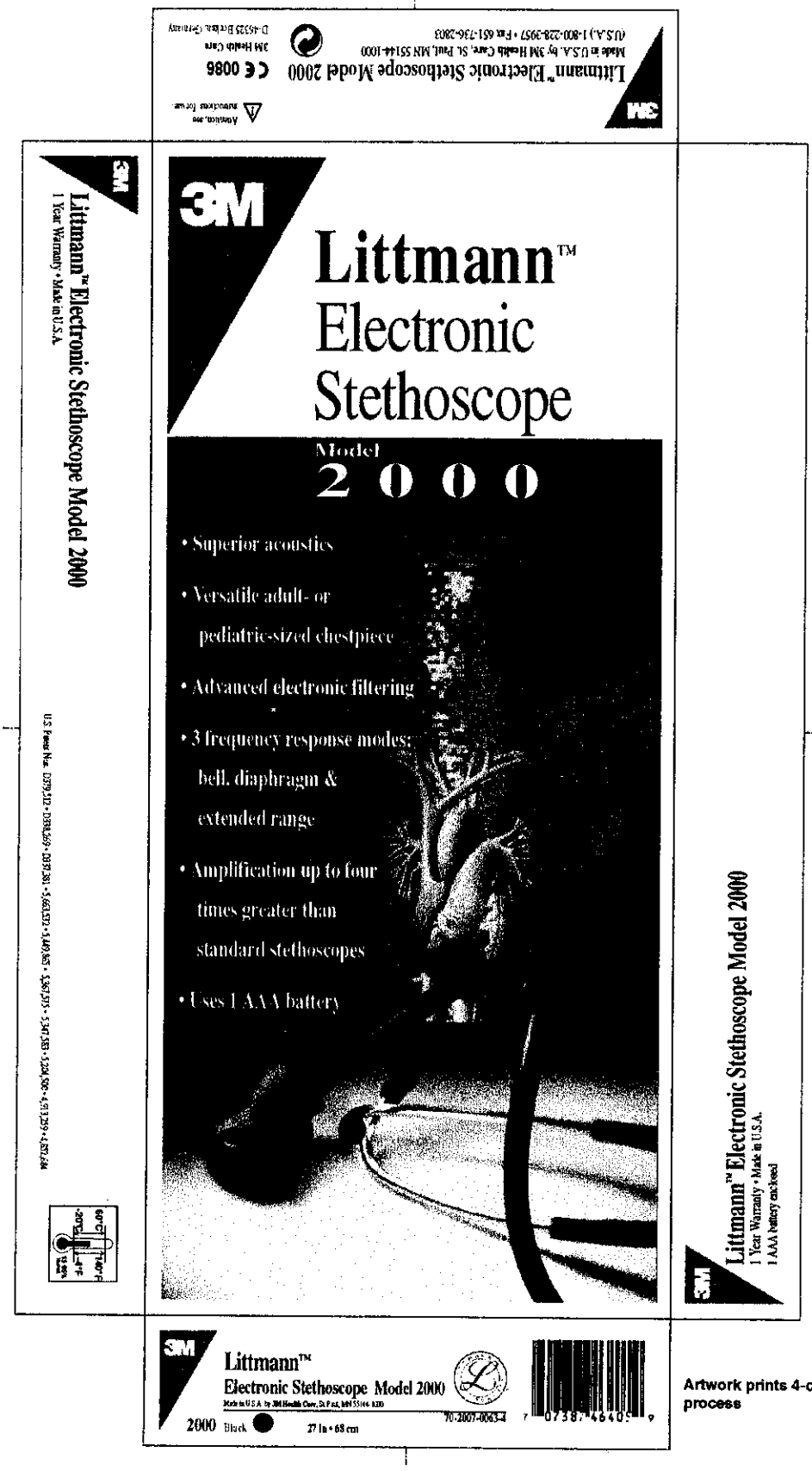
Indications d'usage
Ce dispositif a été conçu pour les diagnostics médicaux uniquement. Il peut servir à amplifier les sons d'un cœur faible, des sons pulmonaires et autres sons corporels, mais peut également être utilisé pour une auscultation normale et le filtrage sélectif des fréquences. Ce produit n'a pas été conçu, vendu ni prévu pour un usage autre que celui indiqué.

⚠ Mise en garde
Respecter les instructions de ce manuel sous peine d'endommager l'appareil ou d'encourir d'éventuelles blessures.

Respecter les recommandations d'utilisation et d'entretien sous peine d'endommager les composants internes du stéthoscope électronique. Tout dommage interne risque de fausser le fonctionnement du stéthoscope , cela pouvant aller d'une légère diminution de la réponse auditive jusqu'à la panne complète de l'appareil.

Utiliser uniquement des piles de type AAA alcalines. Suivre scrupuleusement toutes les mises en garde, tous les avertissements et toutes les

Primary Box Label
3M™ Littmann® Electronic Stethoscope Model 2000



Artwork prints 4-color process

Artwork #:	**38-9000-7240-6**
Date:	4/22/98 • •
Author:	WC Moran
Supersedes:	NA
Pkg. Spec. Reference:	34-7042-1292-6
Structure:	PC Top

SCALE: 1 inch

370

Master Shipper Label
3M™ Littmann® Electronic Stethoscope Model 2000

3M

Electronic Stethoscope Model 2000 Black

Made in U.S.A. by 3M Health Care, St. Paul, MN 55144-1000

27 in • 68 cm **1 Each / Box**

3 Each
QTY. B.U.

38-9001-4834-7

2000

70-2007-0063-4
3M I.D. NO.

LOT

(01) 5 07 07387 46405 4

3M

Electronic Stethoscope Model 2000 Black

Made in U.S.A. by 3M Health Care, St. Paul, MN 55144-1000

27 in • 68 cm 1 Each / Box

3 Each
QTY. B.U.

38-9001-4834-7

2000

70-2007-0063-4
3M I.D. NO.

LOT

(01) 5 07 07387 46405 4

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Model 3000 Biocompatibility Summary

Biocompatibility Summary for the 3M™ Littmann® Electronic Stethoscope, Model 3000

Introduction

All components of the 3M™ Littmann® Model 3000 stethoscope have been reviewed for biocompatibility with respect to ISO10993-Part 1 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. When applicable, material use in a legally marketed device was documented in this assessment.

The final conclusion is that all of the components of the 3M Littmann Model 3000 Stethoscope would have minimal potential for any adverse health concern.

DIAGRAM 1
3M LITTMANN ELECTRONIC STETHOSCOPE, MODEL 3000
(Note: Numbers correspond to the Component Listing in Table I.)

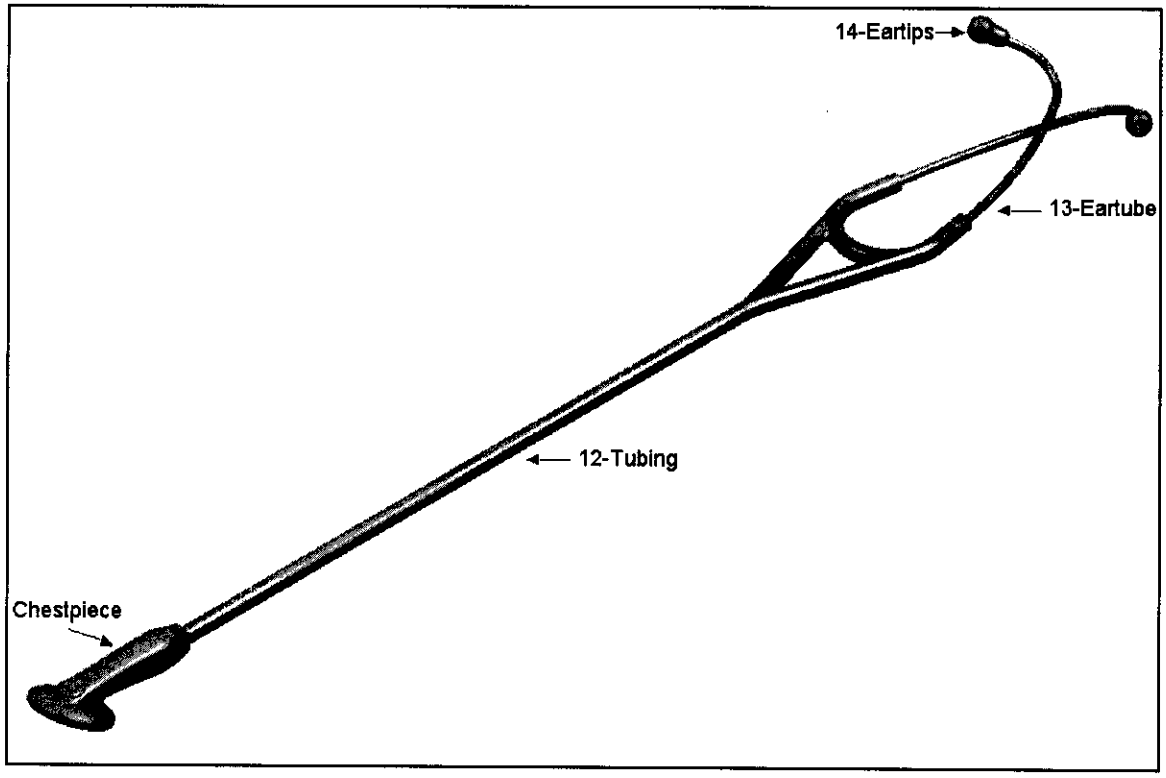

DIAGRAM 2
CHESTPIECE FOR 3M LITTMANN
ELECTRONIC STETHOSCOPE, MODEL 3000
(Note: Numbers correspond to the Component Listing in Table I.)

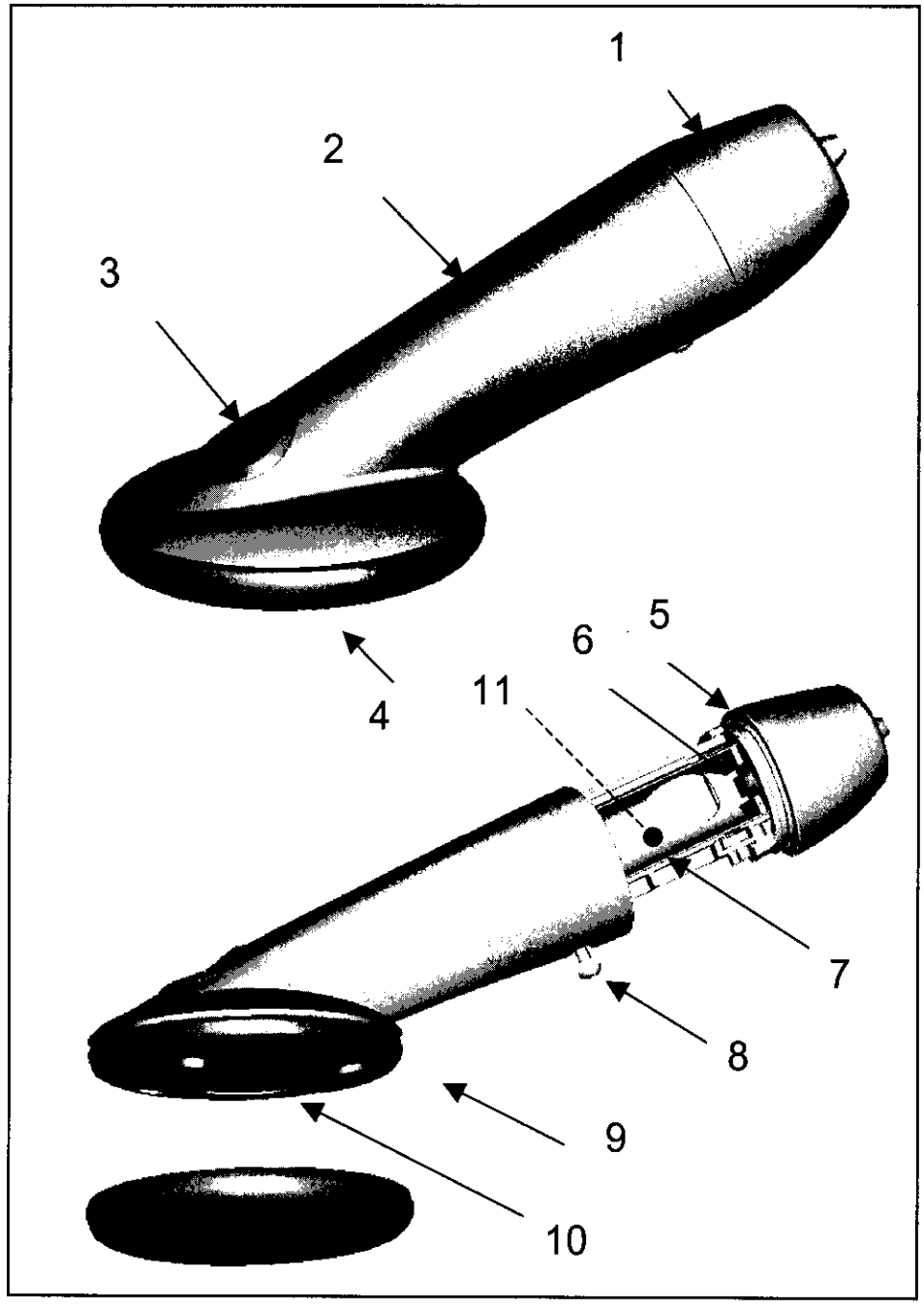

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TABLE I

COMPONENT LISTING OF THE 3M™ LITTMANN® ELECTRONIC STETHOSCOPE, MODEL 3000

#	Component	Material
1	Tubing Cover	Polycarbonate/ABS copolymer coated with chrome
2	Chestpiece Housing	Polycarbonate/ABS copolymer coated with chrome
3	Rubber Keyboard	Silicone rubber
4	Diaphragm	Nitrile rubber
5	O-ring	EPDM
6	Battery Plate	Tin
7	Battery Housing	Polyester
8	Screw	Stainless steel
9	Transducer Housing	Polyester
10	Transducer	Stainless steel Polyurethane
11	Flex Wires for Battery Housing	Polyimide
12	Sound Tubing	PVC
13	Eartube	Anodized aluminum
14	Eartip	Silicone rubber

COMPONENT SAFETY REVIEW

Note: The numbers above each component relate to the number designation found in Table I.

#1 & #2
TUBING COVER & CHESTPIECE HOUSING

Both the tubing cover and the chestpiece housing are made from a molded [redacted] and plated with a chrome metal coating. [redacted] is also used in the chestpiece foot of the currently marketed 3M Littmann Model 4000 Stethoscope (k003723). The chrome coating may contact the user. Chrome-plated parts are also used in 3M Littmann Model 4000 stethoscope.

#3
RUBBER KEYBOARD

The rubber keyboard is made of silicone rubber. Silicone rubber is also used in the eartip of 3M Littmann Model 4000 Stethoscope and all conventional, non-electronic 3M Littmann stethoscopes such as the 3M Littmann Classic II S.E. .

#4
DIAPHRAGM

The diaphragm is composed of nitrile rubber [redacted] manufactured by [redacted]. This material is also used on both the currently marketed 3M Littmann Classic II S.E. and 3M Littmann Cardiology III stethoscopes. No health concerns would be expected from this material in this application.

#5
O-RING

The O-ring is composed of EPDM manufactured by [redacted]. This part has a very limited potential for exposure to the user. No health effects would occur from this component.

#6
BATTERY PLATE

The battery plate is made of tin. Exposure to this part is minimal and no health effects would occur from this component.

#7
BATTERY HOUSING

The battery housing is made of polyester [redacted]). This is the same base material used in the currently marketed 3M Littmann Lightweight II S.E. dual barb & insert. Polyesters have been used in the medical field and are generally recognized as safe. No health effects would occur from this component.

#8
SCREW

The screw is made of stainless steel. No health effects would occur from this component.

#9
TRANSDUCER HOUSING

The transducer housing is made of polyester (b)(4)Trade Secret Process-Product Specs. This is the same base material used in the chestpiece of the currently marketed 3M Littmann Lightweight II S.E. stethoscope. Polyesters have been used in the medical field and are generally recognized as safe. No health effects would occur from this component.

#10
TRANSDUCER

The transducer is made of stainless steel and polyurethane. Polyurethanes have been used in the medical device field for years as wound dressing, tape backings, and padding materials without any adverse health effects.

#11
FLEX WIRES FOR BATTERY HOUSING

The flex wires are coated with polyimide film. Exposure to this part is minimal and no health effects would occur from this component.

12
EARTIP

The eartips are made of silicone rubber and are the same as those of the 3M Littmann Model E4000 Stethoscope and other 3M stethoscopes. The results of the cytotoxicity test showed a minimal response ([redacted]) when test [redacted] (b)(4)Trade Secret Process-Product Specs. 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.

13
EARTUBE

The eartubes are made of aluminum and are the same as those of the 3M Littmann E4000 Stethoscope and other stethoscopes.

#14
SOUND TUBING

The tubing is made of PVC and is the same material in the currently marketed 3M Littmann (b)(4)Trade Secret Process-Product Specs stethoscopes.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Felipe Aguel

Subject: ~~K042505~~ K041934

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review _____.
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is the device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☐ YES	☒ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)	☐ YES	☒ NO
Abbreviated 510(k)	☐ YES	☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ ~~The required certification and summary for class III devices~~ N/A

☒ The Indication for Use form

~~Combination Product Category:~~ _____ N/A

Material of Biological Origin ☐ YES ☒ NO

☐ ~~Animal Source Material~~ ☐ ~~Human Tissue Product~~ ☐ ~~Human Cell Product~~ ☐ ~~Human Extraction Product~~ N/A

The submitter requests under 21 CFR 807.95 (doesn't apply for SE's):

☒ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with Class: 74 DQD Class II

Additional Product Code(s) with panel (optional) _____

Review:

(Branch Chief) (Branch Code) (Date)

Final Review: [signature] 10/14/04

(Division Director) (Date)

Revised: 6/5/98, 4/2/03, 10/7/03 FA

4

REVISED:3/14/95, 10/8/2003 FA

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K041934

Reviewer: Felipe Aguel

Division/Branch:DCD/CEMB

Device Name: 3M Littman Electronic Stethoscope, Model 3000

Product To Which Compared (510(K) Number If Known): K961848, K003723, K022298, K010729, K001306

	YES	NO	
1. Is Product A Device	☒	☐	If **NO** = Stop
2. Is Device Subject To 510(k)?	☒	☐	If **NO** = Stop
3. Same Indication Statement? **See note below**	☒	☐	If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	☐	☐	If **YES** = Stop **NE**
5. Same Technological Characteristics?	☒	☐	If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?	☐	☐	If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?	☒	☐	If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?	☐	☐	If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?	☐	☐	If **NO** = Stop **NE**
10. Performance Data Available?	☐	☐	If **NO** = Request Data
11. Data Demonstrate Equivalence?	☐	☐	Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

The proposed device is intended for medical diagnostic purposes only. It may be used for the detection and amplification of 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.

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

The proposed device is an electronic stethoscope used to listen to heart, lung, blood vessel and other body sounds. The device is different from the predicate devices in that it is indicated for OTC use, and it does not contain an "extended range" mode. Upon request the sponsor has provided more predicate devices which were cleared for OTC use. See review memo for details.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

The proposed device is intended for OTC use and the original predicates cited (K961848, K003723) were cleared for prescription use. Upon request, the sponsor provided the 510(k) numbers for 3 electronic stethoscopes that were cleared for OTC use.

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

See review memo

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration

Memorandum

DATE: October 14, 2004

FROM: Felipe Aguel, Staff Fellow
CEMB/DCD, HFZ-450

SUBJECT: K041934 – **Traditional 510(k)**
3M Littman Electronic Stethoscope, Model 3000
3M Company
3M Center, Bldg 275-5W-06
St Paul MN 55144-1000

CONTACT: Ms. Ginger Cantor
Senior Regulatory Affairs Associate
3M Company
3M Health Care
3M Center, Bldg 275-5W-06
St Paul MN 55144-1000

Tel: (651) 736-2101
Fax: (651) 737-5320
Email: grcantor@mmm.com

TO: The Record

BACKGROUND

The sponsor, 3M Company, has submitted an original premarket notification [510(k)] to seek market clearance for the 3M Littman Electronic Stethoscope, Model 3000, and has identified this application as a **Traditional 510(k)** submission.

The predicate devices cited are the 3M Littman Electronic Stethoscope Model 4000 (K003723) and the 3M Littman Electronic Stethoscope Model 2000 (K961848). Additional predicates cleared for over the counter use were cited in email correspondence with the sponsor: I-Stethos Link Electronic Stethoscope (K022298), Agilent Electronic Stethoscope Model 4530, 4533A, 4534A (K010729), and Stethos Electronic Stethoscope (K001306).

This is my first review of this 510(k) application. Upon marketing clearance, the proposed device would be classified under 21 CFR §870.1875, as Class II with panel and product code of 74 DQD.

INTENDED USE

As taken from the indications for use statement (attachment 10 of submission), the proposed device is intended for medical diagnostic purposes only. It may be used for the detection and amplification of 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 sponsor has indicated over the counter use of this device. I contacted the sponsor asking them to either change the indication for prescription use or to provide alternate predicates that have been cleared for OTC use. The sponsor replied by providing the following electronic stethoscopes cleared for OTC use: K022298, K010729, and K001306. In reviewing the memos for these files, it is evident that K001306 was a submission whose purpose was conversion from prescription use only to OTC use. Thus, indicating proposed device for OTC use seems appropriate.

The indications for use statement is equivalent to those of the predicate devices'. The predicates manufactured by the sponsor were cleared for prescription use only, and the three predicates not manufactured by the sponsor were cleared for over the counter use.

SUMMARY

Is the device life-supporting or life-sustaining?	☐ Yes	☒ No	
Is the device an implant (short-term or long-term)?	☐ Yes	☒ No	
Is the device sterile?	☐ Yes	☒ No	
Is the device for single use?	☐ Yes	☒ No	
Is the device for prescription use?	☐ Yes	☒ No	
Is the device for OTC use?	☒ Yes	☐ No	
Is the device a combination product?	☐ Yes	☒ No	
Is the device a kit?	☐ Yes	☒ No	
Is this device software driven?	☒ Yes	☐ No	
What is the estimated level of concern?	☐ Major	☐ Moderate	☒ Minor
Is the device electrically operated?	☒ Yes	☐ No	

DEVICE DESCRIPTION

The proposed device is an electronic stethoscope with Bell and Diaphragm Modes. Bell mode amplifies sounds from 20-200Hz, and Diaphragm mode amplifies sounds from 100-500 Hz. It has no storage, analysis, or transmission capability. The device consists of a microphone sensor and digital signal processing circuitry and software use to amplify sounds according to the mode

- Auscultation sound bandwidth:
  - Bell mode: 20-200Hz
  - Diaphragm mode: 100-500Hz

SUBSTANTIAL EQUIVALENCE

Description of Change - comparison to predicate

The predicate devices cited in the original submission are two electronic stethoscopes also manufactured by the sponsor. Upon request, the sponsor has provided an indications for use form designating the device for over the counter use. The sponsor also provided the 510(k) numbers for three other electronic stethoscopes cleared for over the counter use (K022298, K010729, and K001306). The significant differences between the proposed device and the predicate devices are summarized below:

- The predicate devices both feature bell, diaphragm, and extended frequency modes, but the proposed device only features bell and diaphragm modes.
- The proposed device does not feature heart rate measurement, record/playback capability, or data transfer capability.
- The proposed device is for OTC use.

Predicate Comparison Chart

Device Characteristic	Predicate device (K961848)	Predicate device (K003723)	Proposed device
Name	3M Littman Electronic Stethoscope, Model 2000	3M Littman Electronic Stethoscope, Model 4000	3M Littman Electronic Stethoscope, Model 3000
Amplification	Up to 20 dB acoustic gain	Up to 25 dB acoustic gain	Up to 25 dB acoustic gain
Maximum sound lvl.	(b)(4)Trade S t Max	(b)(4)Trade S t Max	*Same*

Device Characteristic	Predicate device (K961848)	Predicate device (K003723)	Proposed device
Indication for use	Diagnostic aid and is used as part of a physical assessment of a patient by a of a patient by a health care professional. It can be used for the amplification of faint heart, lung and other body sounds as well as normal auscultation and selective frequency filtering. The extended range mode amplifies sound over a broad range of frequencies, including the range where some lung and prosthetic heart valve sounds occur. Prescription Use	Medical diagnostic purposes only. It can be used for the amplification of heart, lungs, and other body sounds with the use of a selective frequency and can be used on any patient undergoing a physical assessment. Prescription Use	Medical diagnostic purposes only. It may be used for the detection and amplification of 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. *Equivalent to predicates* *OTC Use*
Functionality	Amplification of sounds in three frequency modes	Amplification of sounds in three frequency modes Heart rate measurement Recording and Playback of sounds Data transfer of signals to PC	*Amplification of sounds in two frequency modes*
Bell/Diaphragm Bandwidths	Bell: 20-200 Hz Dia: 100-500 Hz Ext: 20-1000 Hz	Bell 20-200 Hz Dia: 100-500 Hz Ext: 20-1000 Hz	*Same* *Same* Mode not available
Power Source	1 AAA battery	2 AAA batteries	1 AAA battery

MATERIALS/BIOCOMPATIBILITY

A materials table and biomaterials review are provided in appendix 12 of the submission. The following are identified as patient-contacting components:

Ear-tip: silicone rubber; same as that used in Models 2000 and 4000.

Diaphragm: nitrile rubber; same as that used in 3M Littman Classic II S.E. and 3M Littman Cardiology III stethoscopes.

Tube: Vinyl compound; same as that used in Model 2000.

Eartube mount: Anodized aluminum; same as that used in Models 2000 and 4000.

Yoke: PVC; same as that used in Models 2000 and 4000.

All patient contacting materials are used in the predicate devices or in other cleared 3M Littman stethoscopes. Because all patient contacting materials are the same as those used in other 3M Littman Electronic Stethoscopes, there are no biocompatibility issues.

STERILIZATION

The sponsor does not claim that the proposed device is sterile, and the proposed device does not need to be sterile to function safely and effectively. Sterility is therefore not an issue.

LABELING

The Instructions for use are adequate considering the device is for over the counter use.

One of the major differences between the proposed device and the cited predicates is the absence of an "extended range" mode. As a result, I asked the sponsor to include in the labeling a list of sounds that could be heard in each mode and a statement that some high frequency sounds may not be heard with this stethoscope. The sponsor instead provided a frequency response curve for the proposed device in diaphragm mode and the two predicate devices in 'extended range' mode. The amplification of frequencies for the proposed device was comparable to that of the predicate devices (see letter dated September 28, 2004). This is an justification for not including the statement that certain sounds will not be heard with the proposed device. This is an adequate response to my inquiry.

DEVICE VALIDATION

Appendix 3 of the submission includes a Design Verification Protocol including specifications that the frequency response curves in bell and frequency modes will be within (b)(4) dB of the corresponding frequency response curves of the 3M Littman Model 4000 stethoscope. Also included are results for mechanical, electrical, storage, and environmental tests, including cold function, cold storage, heat function, heat storage, damp cyclic heat test, thermal shock, drop

test, and lifetime test. All tests passed according to the acceptance criteria listed in the Design Verification Protocol, with the exception of the cyclic heat storage test where five out of 29 articles failed due to a malfunction in the microphone sensor due to an adhesive failure. The sponsor states this adhesive will be replaced with a more robust adhesive. Testing will be repeated, and the modified device will be shown to pass the environmental tests. The frequency response of the device after the modification will also be verified prior to marketing.

This modification in the adhesive used between the microphone and wires in the chestpiece subassembly poses no significant risk to the patient or user. Therefore the sponsor's statement that testing will be repeated after the new adhesive is used is adequate.

ELECTRICAL SAFETY

Appendix 1 of the submission includes a test certificate certifying conformance to IEC 60601-1:1988 + A1:1991 + A2:1995, and a test summary tabulating the results of each test specified in each clause of IEC60601. Tests passed include leakage current, dielectric strength, and battery requirements.

ELECTROMAGNETIC COMPATIBILITY

Appendix 2 of the submission includes an Attestation of Conformance to standard EN60601-1-2, sections 3 and 36. Test results for electrostatic discharge immunity, RF field immunity, 50Hz magnetic field immunity, and RF field emission all passed the relevant requirements of EN60601-1-2. Because this is a battery operated device, many the EMC tests associated with an AC power source are not applicable.

SOFTWARE

The sponsor provides Software documentation in appendices 4 through 9 of the submission, including Software Design, Software Hazard Analysis, Software Requirement Specification, Software Architecture Chart, Software Specification and Validation Report, and Software Release (version 1.04). The sponsor indicates that all errors in the software database for the proposed device are closed. The provided software documentation is adequate for a minor level of concern.

REGULATORY INFORMATION

The sponsor has provided a truth and accuracy statement as required by 21 CFR §807.87, a 510(k) summary in accordance with 21 CFR 807.92, and an indications for use statement.

RECOMMENDATION

I recommend that the proposed device be found substantially equivalent to legally marketed electronic stethoscopes, classified as follows:

- Class II
- 21 CFR 870.1875
- 74-DQD

Felipe Aguel

October 14, 2004
Date

3M Health Care Business

3M Center
St. Paul, MN 55144-1000
651 733 1110

October 13, 2004

Felipe Aguel, Ph.D.
Staff Fellow
Food and Drug Administration
CDRH/ODE/DCD/CEMB
HFZ-450
9200 Corporate Blvd.
Rockville MD 20850

SUBJECT: Official Response to Request for Information E-mail of October 13, 2004 regarding review of the 510(k) 3M Littmann® Electronic Stethoscope Model 3000, K041934

Dear Dr. Aguel,

In response to your e-mail of October 13, 2004 regarding the review of 3M's 510(k) application for the 3M Littmann Electronic Stethoscope Model 3000 (K041934), please find enclosed 3M's official response for your review files.

Your comments are presented in bold, with 3M's response directly below.

On the "Indications for Use" Form you emailed and later mailed in response to my inquiries, you've checked the "over-the-counter use" box. However, the predicate devices have been cleared for prescription use only. Please either:

- provide an updated indications for use form (please use the attached updated form) with only the 'prescription use' box checked and include "prescription use only" statement in the labeling

OR
- provide the 510(k) number of an alternate predicate device that has been cleared for over the counter use.

3M's analysis of competitors who have marketed electronic stethoscopes shows that while many are labeled as prescription devices, Andromed Inc. holds three more recently cleared 510(k)s for electronic stethoscopes that were "checked off" or "designated" by CDRH for OTC use. 3M's indications for use for the Littmann Electronic Stethoscope Model 3000 are substantially equivalent to the indications for use for these three specific Andromed devices.

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.

Additionally, please find enclosed in this submission a second revised "Indications for Use Statement" for the Littmann Electronic Stethoscope, Model 3000, with the correct "over-the-line/under-the-line" breakdown.

If you have any comments or require additional clarification regarding this submission, please contact me directly using the contact information listed below.

Respectfully submitted,

Ginger Cantor
Senior Regulatory Affairs Associate
3M HealthCare, Medical Division
3M Center, Building 275-5W-06
St. Paul, MN 55144-1000
Phone: (651) 736-2101
Fax: (651) 737-5320
grcantor@mmm.com

Indications for Use

510(k) Number (if known): K041934

Device Name: 3M™ Littmann ® Electronic Stethoscope Model 3000

Indications For Use:
The 3M™ Littmann ® Electronic Stethoscope Model 3000 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of 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 _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Aguel, Felipe

From: grcantor@mmm.com
:nt: Wednesday, October 13, 2004 3:24 PM
To: Aguel, Felipe
Subject: Re: K041934 510(k) submission for 3M Littmann Electronic Stethoscope, Model 3000

Hello Dr. Aguel,

I'm glad we we able to speak directly on the phone today. As we discussed, my analysis of competitors who have marketed electronic stethoscopes shows that while many are labeled as prescription devices, Andromed Inc. holds three more recently cleared 510(k)s for electronic stethoscopes that were "checked off" or "designated" by CDRH for OTC use. 3M's indications for use for the Littmann Electronic Stethoscope Model 3000 are substantially equivalent to the indications for use for these three specific Andromed devices.

The Andromed electronic stethoscope devices cleared for OTC use are:

1) I-Stethos Link Electronic Stethoscope (K022298) cleared as SE on October 1, 2002.
2) Agilent Electronic Stethoscope Model 4530, 4532A, 4533A, and 4534A, (K010729) cleared as SE October 26, 2001.
3) Stethos Electronic Stethoscope, (K001306) cleared as SE on July 20, 2000.

If I have filled out the incorrect version of the "Indications for Use Statement" with respect to the above-the-line, below-the-line issue, I would be happy to submit a second revised Statement to your attention.

I look forward to hearing from you soon.

Best regards,

Ginger Cantor
Senior Regulatory Affairs Associate
3M Medical Division
3M Center
Building 275-5W-06
St. Paul, MN 55144-1000
Tel: 651-736-2101
Fax: 651-737-5320
E-mail: grcantor@mmm.com

"Aguel, Felipe "
<FXA@CDRH.FDA.GOV>

10/13/2004 12:32 PM

To: "'grcantor@mmm.com'" <grcantor@mmm.com>
cc:
Subject: K041934 510(k) submission for 3M Littman Electronic Stethoscope, Model 3000

Dear Ms. Cantor,

I noticed that on the Indications for use form you emailed and later mailed in response to my inquiries, you've checked the "over-i counter use" box. However, the predicate devices have been cleared for prescription use only. Please either:

- provide an updated indications for use form (please use the attached updated form) with only the 'prescription use' box checked and include "prescription use only" statement in the labeling

OR

- provide the 510(k) number of an alternate predicate device that has been cleared for over the counter use.

.se reply to this email to acknowledge receipt.

Best regards,

Felipe

Felipe Aguel, Ph.D.
Staff Fellow
Food and Drug Administration
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fax: (301) 594-3076

3M Health Care

3M Center
St. Paul, MN 55144-1000
612 733 1110

September 28, 2004

Felipe Aguel, Ph.D.
Staff Fellow
Food and Drug Administration
CDRH/ODE/DCD/CEMB
HFZ-450
9200 Corporate Blvd.
Rockville MD 20850

SUBJECT: Official Response to Request for Information E-mail of September 21, 2004 regarding review of the 510(k) 3M Littmann® Electronic Stethoscope Model 3000, K041934

Dear Dr. Aguel,

Please find enclosed 3M's official response to your e-mail of September 21, 2004 regarding the review 3M's 510(k) application for the 3M Littmann® Electronic Stethoscope Model 3000 (K041934). Your comments are presented in bold, with 3M's response directly below.

1. One of the functional differences between your device and the predicate device is the lack of an 'extended range' mode. As a result, the user can amplify sounds in the range of 20-200Hz or 100-500 Hz, but not sounds of frequencies higher than 500Hz. Please either
- include in the labeling:
a. which sounds can be heard in each mode and
b. a warning that sounds of frequencies higher than 500Hz will not be heard through this device.

3M disagrees with the statement that sounds above 500 Hz cannot be amplified on the 3M Littmann® Electronic Stethoscope Model 3000.

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

[redacted]

The Model 3000 is intended to be an **entry**-level cardiology-grade electronic stethoscope. As such, 3M has chosen not to include or claim the extra feature of "extended range" response, a feature which combines the Bell and Diaphragm modes, even though Figure 1 demonstrates the capability of the Model 3000 to amplify above 500 Hz.

From a technical point of view and to retain consistency with the labeling of the predicate devices, 3M believes that the current labeling correctly represents the function of the device. Therefore, 3M recommends that the labeling remain unchanged.

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

2. As of December 2003, FDA has been requesting the use of the attached indications for use form. Please note that the sponsor, not FDA, now indicates whether the device is for OTC and/or prescription use. Please fill out the attached form and send it to me either via email or fax (301 594 3076).

Please find enclosed a revised "Indications for Use" Statement attached to this submission.

If you have any comments or require additional clarification regarding this submission, please contact me directly using the contact information listed below.

Respectfully submitted,

Ginger Cantor
Senior Regulatory Affairs Associate
3M HealthCare, Medical Division
3M Center, Building 275-5W-06
St. Paul, MN 55144-1000
Phone: (651) 736-2101
Fax: (651) 737-5320
grcantor@mmm.com

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See updated form in correspondence dated 10/13/04

Indications for Use Statement

510(k) Number (if known): K041934

Device Name: 3M™ Littmann® Electronic Stethoscope Model 3000

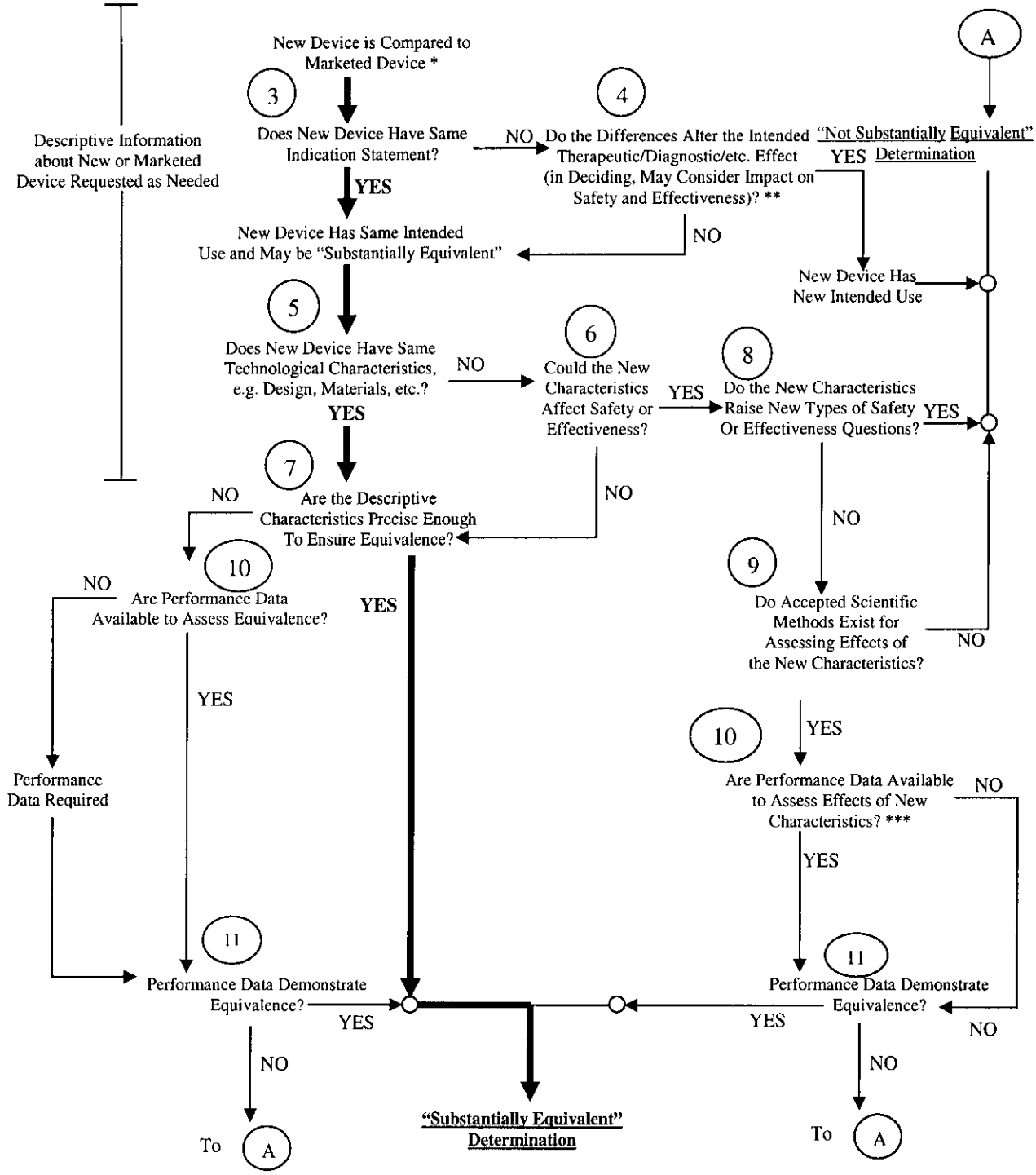
Indications for Use:
The 3M™ Littmann® Electronic Stethoscope Model 3000 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person 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 _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.