# U.S. Department of Health & Human Services

**Food and Drug Administration**

## SAVE REQUEST

| | |
|---|---|
| **USER:** | (kml) |
| **FOLDER:** | K050159 - 209 pages |
| **COMPANY:** | 3M COMPANY (3M) |
| **PRODUCT:** | STETHOSCOPE, ELECTRONIC (DQD) |
| **SUMMARY:** | Product: MODIFICATION TO: 3M LITTMANN ELECTRONIC STETHOSCOPE, MODEL 3000 |
| **DATE REQUESTED:** | Jan 21, 2016 |
| **DATE PRINTED:** | Jan 21, 2016 |

**Note:** Printed

K050159

FEB 2 2 2005



# 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<br>Senior Regulatory Affairs Associate |
| Phone Number: | (651) 736-2101 |
| FAX Number: | (651) 737-5320 |
| Date of Summary: | January 24, 2005 |

## 2. Device Name and Classification:

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

## 3. Predicate Device:

3M™ Littmann® Electronic Stethoscope, Model 3000 (K041934)

K050159
p 1/3



## 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.

This submission describes modifications made to the device's embedded software. The modifications included in this submission do not affect the device's intended use or indications for use, performance features, labeling or claims. The modified device is substantially equivalent to the Model 3000 predicate device (K041934).

## 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 Model 3000 as modified in this special pre-market notification submission is composed of the same or substantially equivalent materials, has the same performance features, same intended use, same indications for use, and same labeling as the Model 3000 predicate device cleared under K041934.

## 7. Non-clinical (Biocompatibility) Summary:

3M has reviewed all components of the Model 3000 stethoscope 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 modified Littmann® Electronic Stethoscope Model 3000 is composed of the same or substantially equivalent materials as those in the Model 3000 predicate device.

3M concludes that all of the components of the modified Model 3000 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

FEB 2 2 2005

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

Re: K050159
Trade Name: 3M™ Littmann® Electronic Stethoscope Model 3000
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: January 24, 2005
Received: January 25, 2005

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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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 Statement

**510(k) Number (if known):** K050159

**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 sounds from heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

Prescription Use____ OR Over-The-Counter-Use XX

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Division of Cardiovascular Devices
510(k) Number K050159

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2005

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

Re: K050159
Trade Name: 3M™ Littmann® Electronic Stethoscope Model 3000
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: January 24, 2005
Received: January 25, 2005

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.

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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.

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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 Statement

**510(k) Number (if known):** K050159

**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 sounds from heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

Prescription Use____ OR Over-The-Counter-Use XX

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050159

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

January 27, 2005

3M COMPANY
3M CENTER, BLDG. 275-5W-06
ST. PAUL, MN 55133
ATTN: GINGER CANTOR

510(k) Number: K050159
Received: 12-JAN-2005
Product: MODIFICATION TO: 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

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

January 26, 2005

3M COMPANY
3M CENTER, BLDG. 275-5W-06
ST. PAUL, MN 55133
ATTN: GINGER CANTOR

510(k) Number: K050159
Received: 25-JAN-2005
Product: MODIFICATION TO: 3M
User Fee ID Number: 16892LECTRONIC
STETHOSCOPE, MODEL

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. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

| By Regular Mail | By Private Courier (e.g., Fed Ex, UPS, etc.) |
|---|---|
| Food and Drug Administration<br>P.O. Box 956733<br>St. Louis, MO 63195-6733. | U.S. Bank<br>956733<br>1005 Convention Plaza<br>St. Louis, MO 63101<br>(314) 418-4983 |

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at http://www.fda.gov/oc/mdufma.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/cdrh/dsmamain.html, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

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

3M Health Care Business

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

K050159

January 24, 2005

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: Special 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 Special 510(k) Premarket Notification for your review. In accordance with 21 CFR §807.90(c), this document is submitted in duplicate with this original cover letter; two additional copies of the cover letter are provided.

The purpose of this submission is to notify the Agency that the embedded software in the 3M™ Littmann® Electronic Stethoscope Model 3000 has been modified since the original 510K (K041934) was cleared by the Agency. Specifically, the software has been modified to change the internal signal processing model from a frequency-domain filter to a time-domain filter. There has been no change to the device specifications.

In addition, 3M notes that other minor modifications have been made to the device, and they are reported in this submission only for completeness. These minor modifications would not in themselves require the filing of a 510(k) submission and are not the primary subject of this submission.

Detailed information about the device modifications is included in Section 3.2 of the submission.

Design verification and validation testing confirm that the modifications described in this submission do not have a significant impact on the safety or efficacy of the device. The modifications do not alter the fundamental technology of the device, will not change the indications for use, the intended use, the labeling, or the device claims from those listed in the original 510(k) for the Model 3000 (K041934).

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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.

3M's Medical Device User Fee Payment Identification Number for this submission is (b) (4) [redacted]. A copy of this User Fee Cover Sheet is included as the first page of this submission.

3M made a wire transfer to FDA on January 12, 2005 in support of this submission. It appears from our records that the wire transfer from 3M's corporate payment systems was inadvertently made for a total of (b) (4) [redacted] while the user fee requirement for this submission is only (b) (4) [redacted]. Please note that the extra (b) (4) [redacted] is intended to be applied against another Special 510k submission for a different product which 3M is planning to submit in the very near future.

Should you have any questions regarding this submission or 3M's fee payment, please contact me as soon as possible by using any of the contact numbers listed below.

Sincerely,

Ginger Cantor

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

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

Medical Device User Fee Cover Sheet - Form FDA 3601 Page 1 of 1

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

| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>FOOD AND DRUG ADMINISTRATION<br>**MEDICAL DEVICE USER FEE COVER SHEET** | PAYMENT IDENTIFICATION NUMBER: (b) (4) [redacted]<br>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) | 2. CONTACT NAME<br>GINGER CANTOR |
|---|---|
| 3M HEALTH CARE<br>3M CENTER<br>BUILDING 275-5W-06<br>ST. PAUL, MN 55144-1000 | 2.1 E-MAIL ADDRESS<br>grcantor@mmm.com<br><br>2.2 TELEPHONE NUMBER (Include Area Code)<br>651-736-2101 |
| 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)<br>410417775 | 2.3 FACSIMILE (FAX) NUMBER (Include Area Code)<br>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 2005)

(b) [redacted]

Form FDA 3601 (08/2003)

# CDRH SUBMISSION COVER SHEET

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**
Premarket Submission Cover Sheet

**Date of Submission:** January 24, 2005 | **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 BI 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:** January 24, 2005 | **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 K041934 | 1 3M™ Littmann® Electronic Stethoscope Model 3000 | 1 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 IV

| | |
|---|---|
| **Date of Submission:** January 24, 2005 | **FDA Document Number:** |

# Section F Manufacturing / Packaging / Sterilization Sites

| | | | |
|---|---|---|---|
| ☒ Original<br>☐ Add ☐ Delete | **FDA Establishment Registration Number:** 2110898 | ☒ Manufacturer ☐ Contract Sterilizer<br>☐ Contract manufacturer ☐ 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<br>☐ Add ☐ Delete | **FDA Establishment Registration Number:** (b) [redacted] | ☐ Manufacturer ☐ Contract Sterilizer<br>☒ Contract manufacturer ☐ Repackager/relabeler | |
| **Company/Institution Name:** (b) (4) [redacted] | | | |
| **Plant Name:** (b) (4) [redacted] | | **Phone Number (include area code):** (b) (4) [redacted] | |
| **Street address:** (b) (4) [redacted] | | **Fax Number (include area code):** (b) (4) [redacted] | |
| **City:** (b) [redacted] | **State:** (b) (4) [redacted] | **Country:** (b) [redacted] | **Zip code:** (b) [redacted] |
| **Contact name:** (b) (4) [redacted] | | | |
| **Contact title:** (b) (4) [redacted] | | | |

| | | | |
|---|---|---|---|
| ☒ Original<br>☐ Add ☐ Delete | **FDA Establishment Registration Number:** 2183581 | ☒ Manufacturer ☐ Contract Sterilizer<br>☐ Contract manufacturer ☐ 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:** January 24, 2005 | | **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:** | | | |

# Special 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:
January 24, 2005

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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## Indications for Use Statement

**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 sounds from heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.

Prescription Use____ OR Over-The-Counter-Use _XX__

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

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

## 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*

Jun 24, 2005
*Date*

## 510(k) Decision-Making Process Flowchart

New Device is Compared to Marketed Device

Yes ↓

Does New Device Have Same Indication Statement?

Yes ↓

New Device Has Same Intended Use and May Be "Substantially Equivalent"

Yes ↓

Does New Device Have Same Technological Characteristics?

Yes ↓

Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

Yes ↓

Are Performance Data Available to Assess Equivalence?

Yes ↓

Performance Data Demonstrates Equivalence

Yes ↓

**Substantially Equivalent Determination**

# 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<br>Senior Regulatory Affairs Associate |
| Phone Number: | (651) 736-2101 |
| FAX Number: | (651) 737-5320 |

Date of Summary: January 24, 2005

## 2. Device Name and Classification:

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

## 3. Predicate Device:

3M™ Littmann® Electronic Stethoscope, Model 3000 (K041934)

## 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.

This submission describes modifications made to the device's embedded software. The modifications included in this submission do not affect the device's intended use or indications for use, performance features, labeling or claims. The modified device is substantially equivalent to the Model 3000 predicate device (K041934).

## 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 Model 3000 as modified in this special pre-market notification submission is composed of the same or substantially equivalent materials, has the same performance features, same intended use, same indications for use, and same labeling as the Model 3000 predicate device cleared under K041934.

## 7. Non-clinical (Biocompatibility) Summary:

3M has reviewed all components of the Model 3000 stethoscope 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 modified Littmann® Electronic Stethoscope Model 3000 is composed of the same or substantially equivalent materials as those in the Model 3000 predicate device.

3M concludes that all of the components of the modified Model 3000 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 Establishment 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 for general safety, electromagnetic compatibility, environmental (stress) and transport testing. Results of testing to these standards are discussed below and is summarized in Tables 1 through 4.

### 1.6.1 General Safety Testing

Testing for compliance with the voluntary standard IEC 60601-1:1998 *Medical Electrical Equipment – Part 1: General Requirements for Safety* 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.

General safety testing was conducted on the device as described in the original 510(k) for the Model 3000. The device modification described in this submission did not require repeating this safety testing; therefore only a copy of the original Certification of Compliance with IEC 60601-1:1998 *Medical Electrical Equipment – Part 1: General Requirements for Safety* is included in Appendix 1. The complete test report was included and may be referenced in the original 510(k) for the Model 3000 (K041934).

**Table 1 Medical Electrical Equipment General Safety Testing**

| Standard | Title | Acceptance Criteria<br><br>Test Report | Third Party Certification Yes or No Proof of Document (as Applicable) |
|---|---|---|---|
| IEC 60601-1:1998 + A1:1991 + A2: 1995<br><br>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<br><br>(Report No. E249052-A1-CB-1; refer to original Model 510K K041934) | Yes; Certificate Issued by UL International DEMKO A/S.<br><br>Appendix 1 of this submission contains a copy of third party certification issued by DEMKO: Certificate No. DK-8002 |



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### 1.6.2 Electromagnetic Compatibility (EMC) Testing

Delta Dansk Elektronik, Lys & Akustik conducted testing for compliance with the voluntary EMC standard IEC 60601-1-2:2001 *Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility- Requirements and Tests (Sections 3 and 36).*

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.

The device modification described in this submission did not require repeating the EMC testing, therefore only a copy of the Certification of Compliance with IEC 60601-1-2:2001 is included in Appendix 2. The complete test report was included and may be referenced in the original 510(k) for the Model 3000 (K041934).

## Table 2 Model 3000 Electromagnetic Compatibility Testing Summary

| Standard | Title | Acceptance Criteria<br><br>Test Report | Third Party Certification Yes or No Proof of Document (as Applicable) |
|---|---|---|---|
| IEC 60601-1-2:2001 Sections 3 and 36<br><br>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;<br><br>Test report DANAK- 19k0188 (refer to 510K K041934) | Yes;<br><br>Refer to Appendix 2 for copy of Delta Test Certificate No. 655 |
| EN 55011B | RF-Field Emission (Electromagnetic Disturbance of ISM Equipment) | Passed;<br><br>Test report DANAK- 19k0188 (refer to 510K K041934) | Yes;<br><br>Refer to Appendix 2 for copy of Delta Test Certificate No. 655 |
| EN 61000-4-2 | Electrostatic Discharge | Passed;<br><br>Test report DANAK- 19k0188 (refer to 510K K041934) | Yes;<br><br>Refer to Appendix 2 for copy of Delta Test Certificate No. 655 |
| EN 61000-4-3 | RF-Field, Immunity | Passed;<br><br>Test report DANAK- 19k0188 (refer to 510K K041934) | Yes;<br><br>Refer to Appendix 2 for copy of Delta Test Certificate No. 655 |
| EN 61000-4-8 | 50 Hz Magnetic Field | Passed;<br><br>Test report DANAK- 19k0188 (refer to 510K K041934) | Yes;<br><br>Refer to Appendix 2 for copy of Delta Test Certificate No. 655 |



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### 1.6.3 Environmental and Transport (Ship) Testing

The modified Model 3000 device was subjected to environmental and transport testing as part of design verification testing, as summarized in Tables 3 and 4. Each device was acoustically tested after the completion of the environmental testing to confirm acoustical performance.

Because this environmental and transport testing is partially related to a minor design modification and a commitment 3M made in the original Model 3000 510(k), please refer to Section 3.2.2 of this submission for additional information.

**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 | Report Eer0428a<br><br>Protocol Eer200338b<br><br>(Refer to Appendix 3) |
| Cold Storage | IEC60068-2-1 | -26.5C, 96 hours | Must pass functional test and visual inspection as defined in Design Verification Protocol Eer200338b | Pass | Report Eer0428a<br><br>Protocol Eer200338b<br><br>(Refer to Appendix 3) |
| Heat Function | IEC 60068-2-2 | +50°C | Must pass functional test defined in Design Verification Protocol Eer200338b | Pass | Report Eer0428a<br><br>Protocol Eer200338b<br><br>(Refer to Appendix 3) |



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| Table 3 Model 3000 Environmental Testing (Continued) | | | | | |
|---|---|---|---|---|---|
| **Test** | **Reference Standard** | **Exposure Conditions** | **Acceptance Criteria** | **Result (Pass/Fail)*** | **Documentation (Report) Reference(s)** |
| 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 | Report Eer0428a<br><br>Protocol Eer200338b<br><br>(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 | Pass | Report Eer0428a<br><br>Protocol Eer200338b<br><br>(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 | Pass | Report Eer0428a<br><br>Protocol Eer200338b<br><br>(Refer to Appendix 3) |
| Drop Test with Portable Device | IEC60068-2-32 (refer also to procedure MF3a in Protocol Eer200338b in Appendix 3 | 6 drops from 1meter | Must pass functional test defined in Design Verification Protocol Eer200338b | Pass | Report Eer0428a<br><br>Protocol Eer200338b<br><br>(Refer to Appendix 3) |

| Table 3 Model 3000 Environmental Testing (Continued) | | | | | |
|---|---|---|---|---|---|
| **Test** | **Reference Standard** | **Exposure Conditions** | **Acceptance Criteria** | **Result (Pass/Fail)*** | **Documentation (Report) Reference(s)** |
| Lifetime testing | Design Test (refer to Protocol Eer200338b in Appendix 3) | Lifetime testing to simulate use conditions over a 2-year warranty period. | 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 | Report Eer0428a<br><br>Protocol Eer200338b<br><br>(Refer to Appendix 3) |



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**Table 4 Modified Model 3000 Transport (Ship) Testing**

| Test | Reference Standard | Exposure Conditions | Acceptance Criteria | Result (Pass/Fail)* | Documentation (Report) Reference(s) |
|---|---|---|---|---|---|
| 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) | Pass | Report Eer0428a (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) | Pass | Report Eer0428a (refer to Appendix 3) |
| Sinusoidal vibration test with packed device (bulk packaging) | IEC60068-2-36 | IEC60068-2-36 (b)(4)Trade Secret Test method MV6 included in Protocol Eer200338b) | Must pass functional test defined in Design Verification Protocol Eer200338b (refer to Appendix 3) | Pass | Report Eer0428a (refer to Appendix 3) |
| Bump test of packed device (bulk packaging) | IEC60068-2-29 | IEC60068-2-29 (b)(4)Trade Secret Test method MB1 included in Protocol Eer200338b) | Must pass functional test defined in Design Verification Protocol Eer200338b (refer to Appendix 3) | Pass | Report Eer0428a (refer to Appendix 3) |
| Drop test with packed device (bulk packaging) | ASTM D5276 | ASTM D5276 (b)(4)Trade Secret Test method MF1 included in Protocol Eer200338b) | Must pass functional test defined in Design Verification Protocol Eer200338b (refer to Appendix 3) | Pass | Report Eer0428a (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.

## 2.2 Software Level of Concern

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 of the ODE document (Level of Concern) by the manufacturer. Section 3 of the ODE document outlines the documentation required in a manufacturer's pre-market notification submission. The documentation required by Section 3 varies depending on the Level of Concern established by Section 2.

The modifications to Model 3000 software as detailed in Section 3.2 of this submission do not change the Level of Concern from that claimed in the predicate Model 3000 510(k). 3M notes that in the ODE document, a "Minor" Level of Concern is defined as "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". 3M still considers the embedded software in the modified Model 300 to be a "Minor" Level of Concern for the reasons listed below.

- The device software does not control a life-supporting or life-sustaining device.
- No energy is delivered to the patient. Acoustic energy is delivered to the ears of the healthcare practitioner and is controlled by the embedded software to limit sound output to not exceed (b)(4) dB.
- The embedded software does not control any treatment delivery. In addition, the Model 3000 electronic stethoscope is not intended to control treatment delivery.
- 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.
- The Model 3000 electronic stethoscope does not provide vital signs monitoring and therefore the need for an alarm does not apply. It does not have an alarm.
- 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 of 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.

As summarized in Table 6 below, because 3M has 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 as appendices to this submission. Changes from the information submitted in the original 510(K) are clearly identified in Table 6 below; any unchanged documents are submitted only for completeness of this section.

The final version of software in this modified Model 3000 was fully tested and passed the final software acceptance test requirements detailed in document CBS0425a (refer to Appendix 8).

## Table 5 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 | Comments |
|---|---|---|---|---|
| 2, 3.1 | Level of Concern | Required in Submission | Level of Concern is included above. | No change from information submitted in Model 3000 510K (K041934) |
| 3.2 | Software Description | Required in Submission | CAJ0406A (b) [redacted] Software Design document, version 2.3)<br><br>Refer to Appendix 4 | CAJ0406A revised since submission of original Model 3000 510K (K041934) |
| 3.3, 4.3 | Device Hazard Analysis | Required in Submission | CAJ0413A (b) [redacted] Model 3000 (E3000) Risk Assessment Report, version 2.00)<br><br>Refer to Appendix 5 | CAJ0413a Document revised since submission of original Model 3000 510K (K041934) |
| 3.4, 4.2 | Software Requirements Specification | Required in Submission | CAJ0341A (b) [redacted] E3000 Software Requirement Specification, version 5.0)<br><br>Refer to Appendix 6 | CAJ0341a Document revised since submission of original Model 3000 510K (K041934) |
| 3.5 | Architecture Design Chart | A chart depicting the partitioning of the software system into functional subsystems | CAJ0406A (b) [redacted] Software Design document, version 2.3)<br><br>Refer to Appendix 7 | CAJ0406A revised since submission of original Model 3000 510K (K041934) |
| 3.6 | Design Specification | Not Required in Submission | Not Required | N/A |
| 3.7 | Traceability Analysis | Not Required in Submission | Not Required | N/A |

## Table 5 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 | Comments |
|---|---|---|---|---|
| 3.8, 4.1 | Development | Not Required in Submission | Not Required | N/A |
| 3.9 | Validation, Verification and Testing (VV&T) | Software functional test plan, pass/fail criteria, and results | CBS0425A (b) [redacted] E3000 (b)(4) Software Acceptance Test Specification, version 2.00)<br><br>CBS0426B (b) [redacted] E3000 (b)(4) Software Validation Report, version 2.00)<br><br>Refer to Appendix 8 | CBS0425A - No change<br><br>CBS0426B- revised since submission of original Model 3000 510K (K041934) |
| 3.10 | Revision Level History | Not Required in Submission | Not Required | N/A |
| 3.11 | Unresolved anomalies (bugs) | Not Required in Submission | Not Required | N/A |
| 3.12 | Release Version Number | Version number and date applicable to the product that will go to market. | CBS0453A (b) [redacted] Release of (b)(4) Software for E3000, version 2.03)<br><br>Refer to Appendix 9 | Note: CBS0453A replaces the original document (CBS0426A) submitted in the original Model 3000 510K (K041934) |



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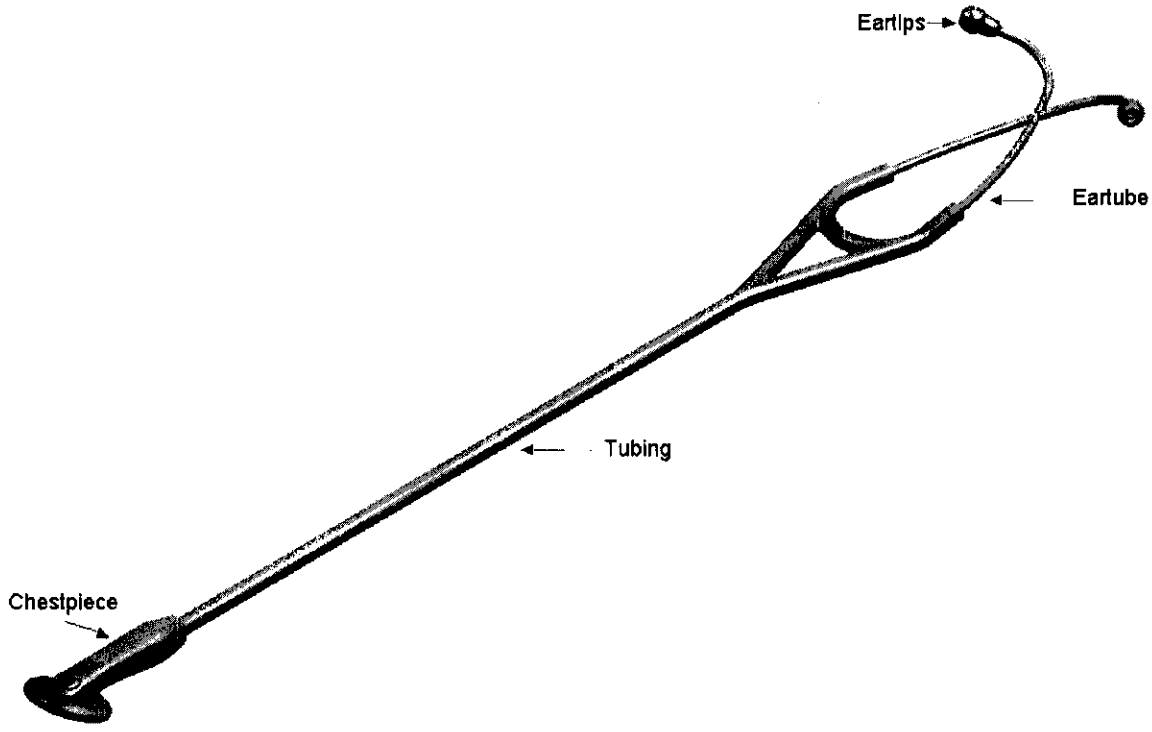
## 2.3 Device Drawings

Figure 1 represents a drawing of the modified 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 3 presents a schematic view of the chestpiece diaphragm from the bottom of the diaphragm.

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



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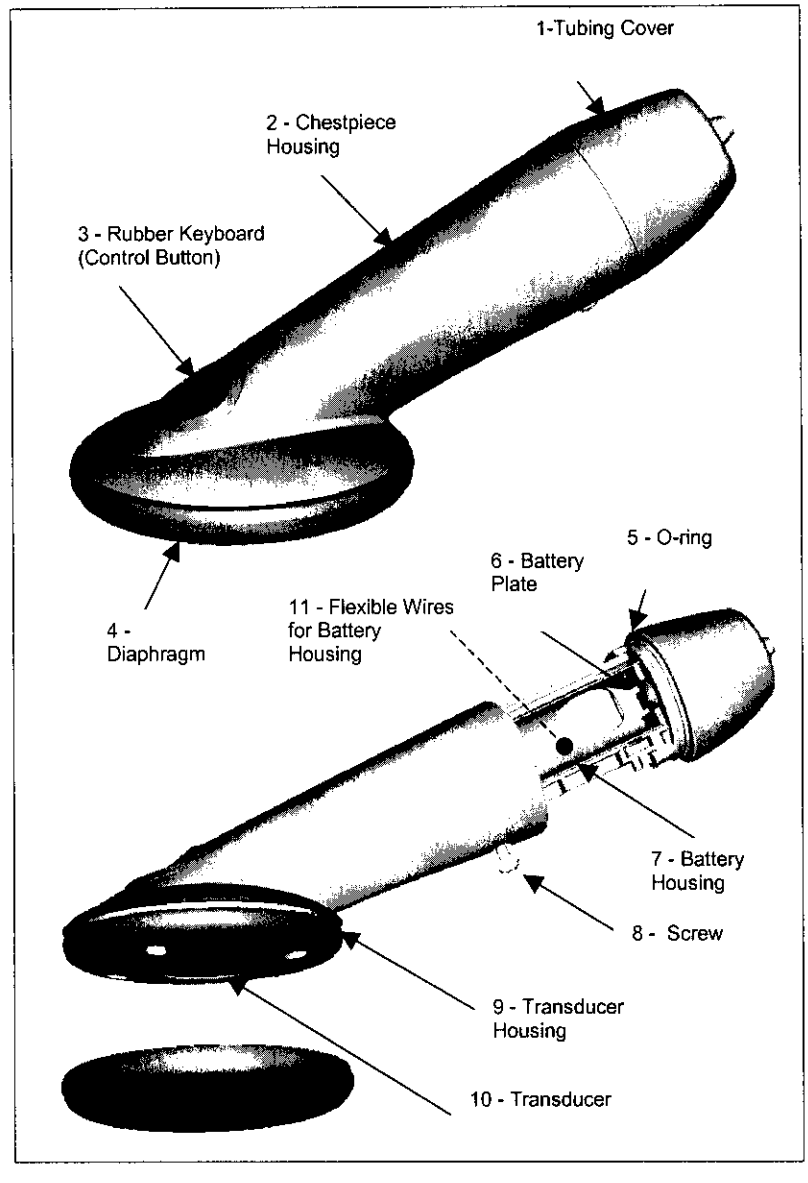
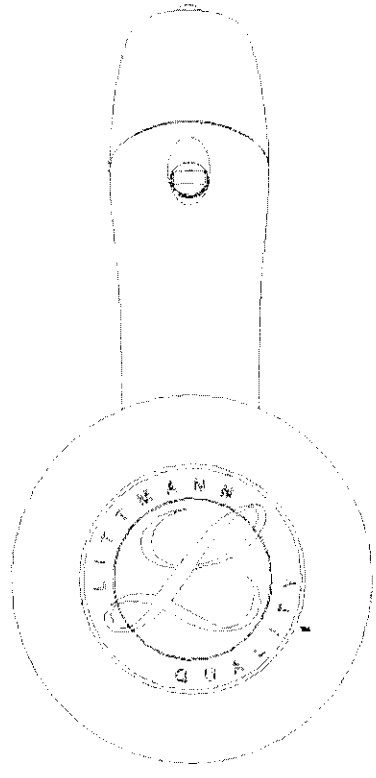
## Figure 2 Expanded View of Littmann® Electronic Stethoscope Model 3000 Chestpiece






47

## Figure 3 Model 3000 Chestpiece Diaphragm (Bottom View)



SH1 (DWG) WORK



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## 2.4 Labeling/Instructions for Use

The User Manual and labeling for the Model 3000 have not changed as a result of the modifications to the device.

Because they are the same as the User Manual and labeling of the predicate Model 3000, copies of the currently approved 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 only as a reference.

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.

## 2.5 Promotional Claims/Advertising

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

These claims are the same or are substantially equivalent to those listed for the predicate Model 3000 (K041934); only the fifth claim regarding passive noise reduction has been modified from the claims submitted in the original Model 3000 510(K).

The original claim in K041934 for passive noise reduction stated *"passive reduction technology provides a **minimum** of 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."* The modified claim changes the word **"minimum"** to the word **"average"** as shown below.

- 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 an **average** of 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 out of specification sound distortion 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 modified Model 3000 described in this special pre-market notification submission is composed of the same or substantially equivalent materials, has the same performance features, intended use and indications for use as the predicate Model 3000 cleared under K041934. 3M considers the modified Littmann® Electronic Stethoscope, Model 3000, to be substantially equivalent to the predicate Littmann® Electronic Stethoscope Model 3000, cleared under K041934.

### 3.2 Detailed Description of Device Modifications

The following modifications have been made to the Model 3000. 3M believes these modifications do not represent a change in the fundamental technology or performance of the device and they do not significantly impact the safety or efficacy of the Model 3000.

#### 3.2.1 Software Modification

The software has been modified to change the internal signal processing model from a [redacted] (b)(4) There has been no change to the device specifications. This change has provided for an improved acoustical fit to the software filters. This software modification also improves the device's electrical signal-to-noise ratio.

Design verification testing has confirmed that this change has no effect on the device specifications. Figure 4 presents a comparison of the frequency response curves for the modified Model 3000 versus the original (predicate) Model 3000 (K041934). In Figure 4, BELL represents the bell mode, and DIAP represents the diaphragm mode. Similarly, OLD represents results for the predicate Model 3000 and NEW represents results for the modified Model 3000.

**Figure 4 Comparison of Modified 3000 versus Predicate Model 3000 Frequency Response**

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

[redacted]

Other modifications made to the device that are not the subject of this submission are described below. They are only included for the sake of completeness of this submission. By themselves they would not have required a 510(K) filing.

### 3.2.2 Change to Assembly and Manufacturing Process for the Microphone and Mount .

Changes were made to the assembly and manufacturing process for the microphone and mount to improve the device's durability. These changes included a modification to the adhesive and the addition of a flexible circuit cable. There was no change to the core technology or device specifications.

Note that 3M identified the necessity for this change in the original 510(k) (K041934) for the predicate Model 3000 in which 3M reported that five (5) of the twenty-nine (29) devices tested 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).*

3M assessed the impact of this modification on device safety and efficacy.
3M believes this design modification has no significant impact on the safety or efficacy of the device and there is no change to the device's specifications.

Environmental (stress testing) was conducted on the modified Model 3000 to verify that corrective actions (i.e., new adhesive and flexible cable) taken to address this failure were effective. A summary of the environmental testing conducted is presented in Table 3 of this submission. This testing satisfies
3M's commitment in the predicate Model 3000 510(K) to take appropriate corrective actions and repeat testing prior to commercial launch of the device.

### 3.2.3 Material Changes to Diaphragm

The material for the patient interface portion of the diaphragm has been changed from a nitrile rubber to a silicone material and the Littmann brand logo is screened onto the silicone. A thin polyurethane coat has been applied over the logo and silicone. Refer to Figure 3 for picture of the diaphragm.

The change from nitrile to silicone was to made to provide a more secure fit of the diaphragm onto the chestpiece. The polyurethane coating was applied to the diaphragm to reduce frictional noise when the diaphragm is moved against the patient during auscultation.

3M concludes that these material changes do not provide any new or increased safety risk to the user or patient.

### 3.2.4 Changes to Battery Compartment

A silicone washer and foam pads were added to the battery compartment to reduce potential vibration of the battery spring and the slide. Neither of these materials are directly accessible to the user or patient.

3M concludes that these material changes do not provide any new or increased safety risk to the user or patient.

## 3.3 Equivalency Comparison

Tables 6, 7, and 8 provide comparison data for the purpose of demonstrating substantial equivalence between the modified Model 3000 and the original Model 3000.

Table 6 identifies the larger external components (including material composition) of the modified Model 3000 and the predicate Model 3000. Table 7 summarizes the similar and different performance features of the modified Model 3000 compared to the original Model 3000 (K041934). Table 8 presents a comparison of the intended use and indications for use of the modified Model 3000 and the predicate Model 3000.

### Table 6 External Components

| Component and Material Type | Modified Model 3000 | Model 3000 (Predicate Device) K041934 |
|---|---|---|
| **Ear-tip (Ribbed Style)** | No Change | Silicone rubber |
| **Diaphragm (Microphone cover)** | Silicone material with Littmann™ brand logo and polyurethane coating | Nitrile rubber |
| **Tubing** | No Change | Vinyl compound |
| **Eartube Mount** | No Change | Anodized Aluminum |

### Table 7 Comparison of Performance Features

| Performance Features | Modified Model 3000 | Model 3000 (K041934) |
|---|---|---|
| Frequency Response | No Change | Bell (20-200 Hz) and Diaphragm (100-500 Hz) modes. |
| Amplification | No Change | Up to 25 dB acoustic gain, equivalent to 18 times amplification. |
| Maximum Sound Level | No Change | (b) dB SPL Max |
| Power Source | No Change | One (1) (AAA) alkaline battery |
| Low Battery Indicator | No Change | Includes a low battery indicator |
| Volume Control | No Change | 8 Step Volume Control |
| ON/OFF Switch Automatic Shut-off by Electronics | No Change | Yes |



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## Table 8 Intended and Indications for Use

| | **Modified Model 3000** | **Model 3000 (Predicate Device) K041934** |
|---|---|---|
| Intended Use | No Change | Electronic Stethoscope |
| Indications for Use | No Change | The 3M™ Littmann® Electronic Stethoscope, Model 3000, is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds of the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment. |

## 4.0 Summary of Safety and Biocompatibility Studies

### 4.1 Overview

3M has reviewed all components of the modified Model 3000 stethoscope 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.

## 5.0 Manufacturing

Note: There is no change in this section from the information submitted from that contained in the 510(k) for the predicate Model 3000 (K041934). This section is provided as reference only.

### 5.1 Summary

Figure 5 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:

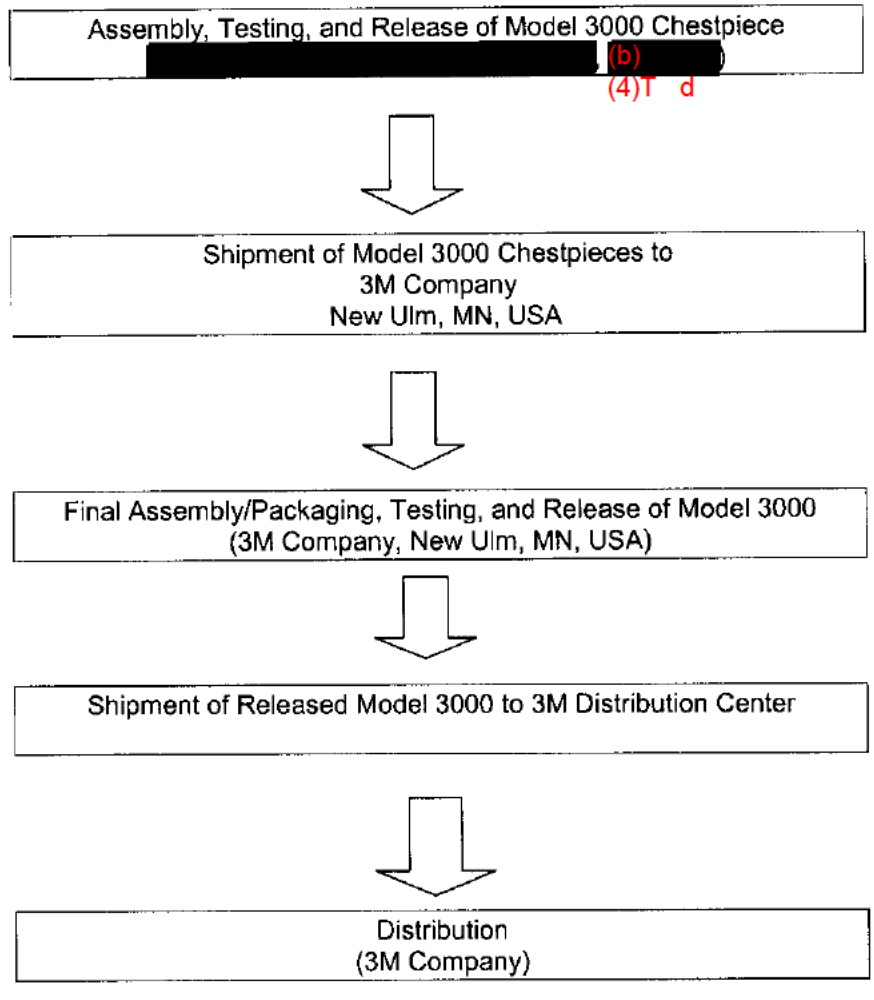
(b)(4)Trade Secret Process-Product specs

[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 5 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.



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## 6.0 Design Controls

### 6.1 Risk Analysis (Management)

The modifications made to the Model 3000 device described in Section 3.2 of this submission were conducted under (b)(4)Trade engineering change control system and appropriate 3M Design Control procedures. (b)(4)Tra reviewed and revised the original risk analysis in accordance with ISO/EN 14971:2000 and determined that there was no increased risk and no new risks to end-user or patient safety. Refer to Table 5 and Appendix 5 of this submission. 3M has also concluded that the modifications described in this submission do not increase risk, and no new risks to end-user or patient safety have been identified

### 6.2 Design Verification

Required design verification for the modified Model 3000 was successfully conducted by (b)(4)Tra. Copies of design verification reports for functional testing and software are included as Appendices 3 and 8 of this submission.

## 6.3 Declaration of Conformity with Design Controls

### 6.3.1 Design Verification and Validation Activities

As required by the risk analysis, designated individuals at 3M performed critical verification and/or validation activities and the results of the activities demonstrated that the predetermined acceptance criteria were met.

T.R. Drummond 1-24-05

Tom Drummond – Senior Product Engineering Specialist - 3M

Doug Mosier 1-24-05

Doug Mosier – Quality Assurance Specialist - 3M

Ginger Cantor 24 Jun 2005

Ginger Cantor – Senior Regulatory Affairs Associate - 3M

## Declaration of Conformity with Design Controls

### Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification of the Littmann™ Electronic Stethoscope Model 3000 were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

### Manufacturing Facility

The manufacturing facility, (b)(4)Trade Secret a/s is in conformance with the design control requirements as specified in 21 CFR 820. 30 and the records are available for review.

Name

21-01-2005
Date

(b)(4)Trade
Senior Manager Quality Assurance
(b)(4)Trade Secret Process-Product

### 6.3.2 3M Manufacturing Facility Conformance with Design Controls

The 3M New Ulm manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR § 820.30 and the records are available for review.

Suzanne M. Danielson

Suzanne M. Danielson, Director, Regulatory Affairs and Quality

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<br>*Produit* | Medical Stethoscope |
| Name and address of the applicant<br>*Nom et adresse du demandeur* | 3M Health Care<br>3M Center, Building 270-4N-09, Maplewood, MN 55144-1000,<br>Patient Assessment Laboratory, 3m Medical Products, USA |
| Name and address of the manufacturer<br>*Nom et adresse du fabricant* | 3M Health Care<br>3M Center, Building 270-4N-09, Maplewood, MN 55144-1000,<br>Patient Assessment Laboratory, 3m Medical Products, USA |
| Name and address of the factory<br>*Nom et adresse de l'usine* | (b)(4)Trade Secret Process-Product specs [redacted] |
| Rating and principal characteristics<br>*Valeurs nominales et caractéristiques principales* | 1.5V, IPX4 |
| Trade mark (if any)<br>*Marque de fabrique (si elle existe)* | 3M LITTMANN |
| Model/type Ref<br>*Réf. de type* | 3000 |
| Additional information (if necessary)<br>*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<br>*Un échantillon de ce produit a été essayé et a été considéré conforme à la* | PUBLICATION: IEC 60601-1:1988 + A1:1991 + A2:1995<br>EDITION: 2nd |
| as shown in the Test Report Ref. No. which form part of this certificate<br>*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 Certificate d'essai OC est établi par l'Organisme National de Certification*

(b)(4) [redacted]

*We help ideas meet the real world*

# 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) [redacted]

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

**Manufacturer**
[redacted] (b) [redacted]
(4)T d

**Technical report(s)**
DELTA test Report E401131, DANAK reg no. 19k0188

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


**DELTA**
Danish Electronics,
Light & Acoustics

Erhvervsvej 2 A
8653 Them
Denmark

Tel. (+45) 86 84 90 33
Fax (+45) 86 84 78 64
www.delta.dk


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.

Them 1 July 2004

Jørgen Mygind
Department Manager

DELTA

6.6

attestation_em

# Design Verification Protocol Mandatory Requirements E3000

Author

(b) (4)

QMS00086 version 02

## Version history

(b) (4)

[redacted]

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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

# 4 Protocol

## 4.1.1 Safety

| No. | Ref. No. | Description | Accept criteria | Exposure | No. of devices in test | Test & Reference |
|---|---|---|---|---|---|---|
| 30<br>34<br>36<br>54 | PR:035<br>PR:035<br>PR:037<br>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 | Lifetime test<br>(b) auscultatory exams per day<br>[redacted] minutes for average auscultatory exam, and<br>[redacted] work days per week<br>Average of [redacted] depressions of each button per auscultatory exam<br>[redacted] drop from shoulder of clinican per week<br>[redacted] 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 ok after test, visual defects such as scratches, small cracks and wear marks is allowed. | See description | 5 | Design test |

## 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<br>Chest piece housing, button and diaphragm. | Must pass visual inspection | C. - Cleansing agent containing (b)(4)Trade Secret Process-<br>D. – Water<br>Chest Piece assembly meets surface cleaning resistance of Isopropyl and detergent water pH (b) [redacted]<br>Dried body fluids (example:blood) can be cleaned of product. (dried 24h)<br>(b) [redacted] blood is used.) | 1 | DIN 53160 |
| 48 | PR:055 | OK3 Cosmetics test<br>Chest piece housing, button and diaphragm. | Must pass visual inspection | Level B | 1 | Internal Requirement, Test & Approval (b) [redacted]<br>(b) [redacted] |
| 49 | PR:056 | OK4 Sweat test<br>Chest piece housing, button and diaphragm. | Must pass visual inspection | Level B | 1 | DIN 53160 |
| 50 | PR:057 | OL3 Sunlight test<br>Chest piece housing, button and diaphragm. | Must pass visual inspection | Level B 48h | 1 | Test & Approval (b) [redacted]<br>ISO 105 B02 |
| 51 | PR:058 | OR2 Scratch test<br>Chest piece housing, button and diaphragm. | Must pass visual inspection | Level B | 1 | Test & Approval (b) [redacted] |
| 52 | PR:059 | OS6 Wear test<br>Chest piece housing, button and diaphragm. | Must pass visual inspection | Level C | 1 | Test & Approval (b) [redacted] |

### 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 | +50°C | 29 | KV1a, IEC 60068-2-2 |
| 35 | PR:036 | Cold function | Must pass FT1 | -10°C | 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: | Temperature ranges of at least -20 to 70 deg. Celsius. Relative humidity of maximum 90% | 5 | IEC 60068-2-2 |
| 38 | PR:043 | Cold storage | Must pass FT1 and VT | -26,5°C, 96 hours | 29 | KK2, IEC 60068-2-1 |
| 39 | PR:045 | Heat storage | Must pass FT1 and VT | +55°C, 96 hours | 29 | KV2, IEC 60068-2-2 |
| 40 | PR:046 | Cyclic Heat Storage – Humidity | Must pass FT1 | +25°C for 12hrs, +40°C for 12hrs, 93%RF, 2 cycles | 29 | KV3, IEC 60068-2-30 |
| 41 | PR:047 | Thermal shock test | Must pass FT1 | From -26,5°C for 3hrs, to +40°C for 3hrs. 5 cycles | 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 | 6 drops from (b)(4) | 29 | 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 | 29 | TS-9005 |
| 58 | PR:069 | Diaphragm tensile test | min (b) to pull diaphragm off of transducer housing | Perpendicular pull in diaphragm. | 29 | |

## 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 29 samples. If no failures are observed in these 29 samples, the true failure level is less than 10% with a confidence level of 95%.
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.

# 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 'Eer200338b Design verification protocol mandatory requirements'. Comparison against Model 4000 target frequency response for BELL filter mode, allowed deviation is +/- [redacted] dB over active stethoscope frequency range (20-1000 Hz).

### 5.2.2 Diaphragm frequency response

Assessment in accordance with 'Eer200338b Design verification protocol mandatory requirements'. Comparison against Model 4000 target frequency response for DIAP filter mode, allowed deviation is +/- [redacted] dB over active stethoscope frequency range (20-1000 Hz).

## 5.3 Lifetime test

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

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

Drop from shoulder:
[redacted] drop from shoulder of clinican per week x [redacted] weeks per year x [redacted] years = [redacted] drop
Device is dropped [redacted] times from various height [redacted] 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:
[redacted] minor impacts per day (bumping on bed rail or table edge) x [redacted] work days per week x [redacted] weeks per year x [redacted] years = [redacted] minor impacts.
Minor impacts on front of chestpiece housing, [redacted] impacts from approximate [redacted] 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.

## 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

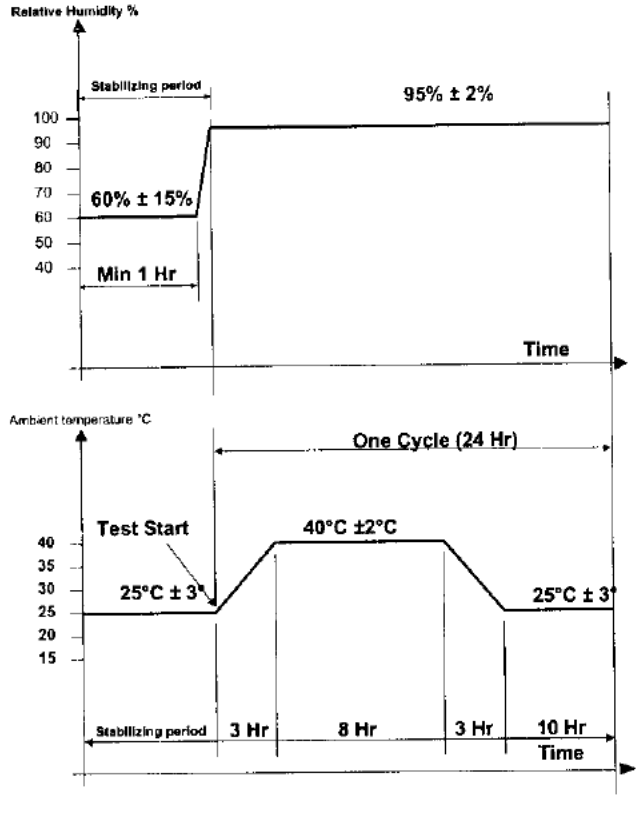
**Purpose**
The purpose of this test is to demonstrate the ability of the product to resist penetration of humidity into components while stored in high relative humidity and changing temperatures.

**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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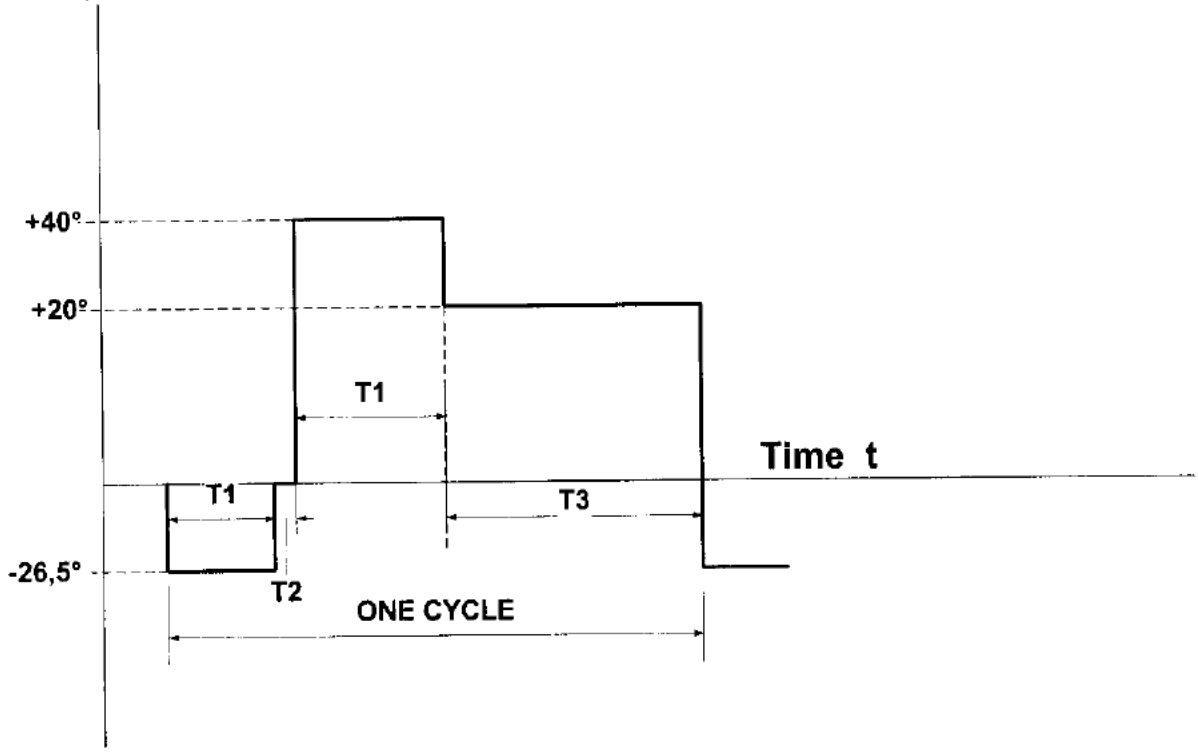
## 5.8 KS1

***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 [redacted] (b) 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 [redacted] (b) bumps per second.
*Products that (4) during transportation are strapped to a pallet, and therefore only will be transported on this side, must be subjected to the following exposures:* [redacted] (b) bumps on the bottom and [redacted] (b) bumps on each side. None at the top.
(4)

**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.

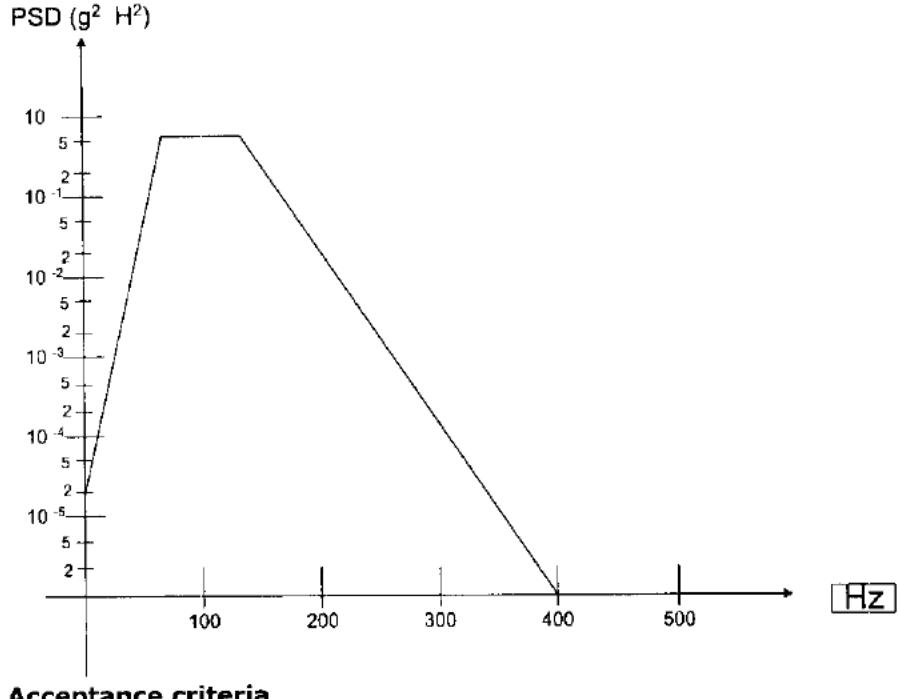
## 5.12 MV6

***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.



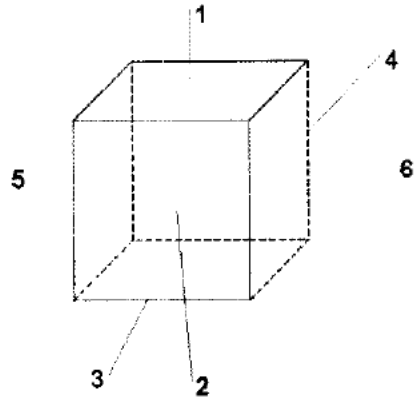

**Acceptance criteria**
Test the function of the product and inspect it visually before and after the exposure. If control data is measured, it should be stated in the report.

## 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.

## 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 (b) m for a weight < 2 kg.
-Height (b) m for a weight > 2 kg and < 5 kg.

Carry out (b) 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.
Chest Piece assembly meets surface cleaning resistance of Isopropyl and detergent water pH[redacted] (b)
Dried body fluids (example:blood) can be cleaned of product. (dried 24h)
(b)[redacted] blood is used.)
***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):

A. - Denaturized alcohol (ethanol 93%) - only surfaces, which encounter glass surfaces
B. - Benzene - only as guiding test, no demand
C. - Cleansing agent containing ammonia (b)[redacted] (4)T d

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

D. - Water
E. - Petroleum ether

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[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.

## 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**

**A.** [redacted]
**B.** (b)(4)Trade [redacted] b
**C.** (b)(4)Trade [redacted]

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 [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.

## 5.17 OK4

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

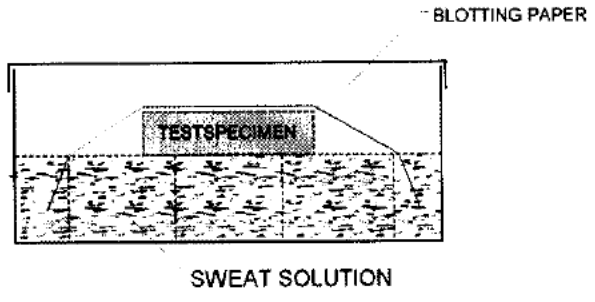
***Standard***
DIN 53160.
**Types of sweat**
Sweat solutions:

**Alkaline**: (pH =(b)[redacted])
Mix (b)[redacted]ml (b)(4)Trade Secret[redacted] with (b[redacted]gr (b)[redacted] and [redacted] g [redacted].

Add (b)[redacted] slowly (one grain at a time) until you reach pH (b)[redacted].
If necessary adjust with (b)(4)Trade[redacted])

**Acid**: (pH = (b)[redacted])
Add (b)[redacted] ml (b)(4)Trade[redacted] to (b)[redacted] of the above mixture until you reach pH (b)[redacted]

***Procedure***




**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 | Alkaline/Acid | (b[redacted] hrs |
| b | Alkaline/Acid | (b[redacted] 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[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.

## 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. (b)[redacted] hours exposure - Applies to zone 1 - 2 surfaces.
b. (b[redacted] 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 [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.

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

[redacted]

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 (b)(4)Trade [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.

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

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:** (b)(4) cycles. Applies to surfaces, which are exposed to sustained daily operation. E.g. buttons on a remote control.
(a: (b)(4) cycles.) Applies to same surfaces as above but where the demands are specified before September 1994.
**b:** (b)(4) cycles. Applies to surfaces, which are exposed shortly to daily operation. E.g. standby button on a product.
**c:** (b)(4) 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 (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.

# 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 | | | | | |
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| R4X26055 | | | | | |
| R4X26056 | | | | | |
| R4X26057 | | | | | |
| R4X26058 | | | | | |
| R4X26059 | | | | | |
| R4X26060 | | | | | |
| R4X26061 | | | | | |
| R4X26062 | | | | | |
| R4X26063 | | | | | |
| R4X26064 | | | | | |
| R4X26065 | | | | | |

General remarks

| Date | Init | Signature |
|---|---|---|
| | | |

# Design Verification Report
# Mandatory Requirements
# E3000

Author

20-01-2005 [signature] QA

Date; Name – function

Approved by

20-01-2005 [signature]

Date; Name – Quality Assurance

QM500247 version 1.80

# Version history

| Version | Author | Date | Description |
|---|---|---|---|
| 1.00 | EER | 11-07-04 | First version ready for approval |
| 2.00 | EER | 25-11-04 | Updated with test results from Design verifications models 1D |
| 2.10 | TBT/EER | 31-12-04 | PR007 open due to new reliability test |
| 2.20 | EER | 18-01-05 | This report is administrative substitution of version 2.10.<br>Ref. column to protocol added.<br>General remark from version 2.10 is closed, see remark in section 3 in this report.<br>Enclosures, section 6 added. |
| | | | |
| | | | |

# Table of Contents

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# 1 Purpose

The purpose of this report is to conclude on design verification for design verification models 1D.
In design verification models 1D new sensor design is implemented (ECR2004-165), and it was decided that verification of PR007, PR036, PR043, PR045, PR046, PR047, PR067 and PR068 must be repeated.
Shiptest (PR048-PR052) in bulk packaging was not performed on design verification models 1B due to packaging material was not arrived, shiptest is done on models 1D, and is reported in this report.

In this report the results for design verification on models 1B is listed to give an overview of the verification test results that relates to the current design.

The test in this report is according to protocol version 1.20, ref:[C].

# 2 References

[A]TBT0319b Product Requirements.doc
[B]EER200403b Design verification plan E3000
[C]EER200338b Design Verification Protocol Mandatory Requirements E3000 version 1.20
[D]EER0450d Design Verification Protocol E3000 Reliability testing

# 3 Test data

| Ref. to verification protocol [C] | Ref. to product requirement [A] | Requirement | Remark | Test result verification models 1B (version 1.00 of this report) | Test result verification models 1D |
|---|---|---|---|---|---|
| 30<br>34<br>36<br>54 | PR:035<br>PR:035<br>PR:037<br>PR:062 | Electrical Safety | UL/Demko report: E249052-A1-CB-1 | Passed. | Not repeated |
| 55 | PR:063 | Emission<br>30 dBµV ; 30 Mhz to 250 MHz<br>37 dBµV ; 250 MHz to 1 GHz<br>Immunity – Radiated RF 3 v/m; 80 MHz to 2,5 GHz<br>Immunity – ESD ± 6 kV contact ± 8 kV air | DELTA report : E401131 | Passed. | Not repeated |
| 6 | PR:007 | Lifetime test | (b) [redacted] depressions on rubber keyboard (2 devices)<br>Drop and minor impacts (5 devices)<br>Depressions on transducer, (b) [redacted] depressions (2 transducers) | Passed | Passed |
| 47 | PR:053 | Cleaning test<br>Chest piece housing, button and diaphragm. | (b) [redacted] OK1 test | Passed | Not repeated |
| 48 | PR:055 | Cosmetics test<br>Chest piece housing, button and diaphragm. | (b) [redacted] OK3 test | Passed | Not repeated |
| 49 | PR:056 | Sweat test<br>Chest piece housing, button and diaphragm. | (b) (4)Trade Secret Process -Product specs [redacted] OK4 test | Passed | Not repeated |
| 50 | PR:057 | Sunlight test<br>Chest piece housing, button and diaphragm. | [redacted] OL3 test | Passed | Not repeated |
| 52 | PR:059 | Wear test<br>Chest piece housing, button and diaphragm. | [redacted] OS6 test | Passed | Not repeated |
| 35 | PR:036 | Heat function | [redacted] KV1a test | Passed | Passed |
| 35 | PR:036 | Cold function | [redacted] KK1a test | Passed | Passed |
| 37 | PR:042 | Storage | N/A | Passed | Not repeated |
| 38 | PR:043 | Cold storage | (b) (4)Trade Secret [redacted] KK2 test | Passed | Passed |
| 39 | PR:045 | Heat storage | [redacted] KV2 test | Passed | Passed |
| 40 | PR:046 | Cyclic Heat Storage – Humidity | [redacted] KV3 test. (* see remark in section 3) | Failed (transducer) | Passed |
| 41 | PR:047 | Thermal shock test | (b) (4)T [redacted] KS1 test. (* see remark in section 3) | Passed | Passed |
| 16 | PR:018 | Mass of total device | N/A | Passed | Not repeated |

| Ref. to verification protocol [C] | Ref. to product requirement [A] | Requirement | Remark | Test result verification models 1B (version 1.00 of this report) | Test result verification models 1D |
|---|---|---|---|---|---|
| | | including battery | | | |
| 17 | PR:019 | Length of device from chest piece to ear tips | N/A | Passed | Not repeated |
| 42 | PR:048 | Chest Piece subassembly and bulk packaging meets American Standard Test Methods (ASTM) for transport. | (b) [redacted] MT1 test | Test result not ready yet. (bulk packaging not arrived) | Passed |
| 43 | PR:049 | Transport simulation Packed device (bulk packaging) | N/A | Test result not ready yet. (bulk packaging not arrived) | Passed |
| 44 | PR:050 | Sinusoidal vibration test with packed device (bulk packaging) | (b) [redacted] MV6 test | Test result not ready yet. (bulk packaging not arrived) | Passed |
| 45 | PR:051 | Bump test of packed device (bulk packaging) | (b) [redacted] MB1 test | Test result not ready yet. (bulk packaging not arrived) | Passed |
| 46 | PR:052 | Drop test with packed device (bulk packaging) | (b) [redacted] MF1 test | Test result not ready yet. (bulk packaging not arrived) | Passed |
| 56 | PR:067 | Drop test | (b) [redacted] MF3a test | Passed | Passed |
| 57 | PR:068 (PR:077) | Stethoscope Tubing to Chest Piece Bond Strength | N/A | Passed | Passed |
| 58 | PR:069 | Diaphragm tensile test | N/A | Passed | Not repeated |

*During verification an observation on Rubber Keyboard was made, on 3 devices Rubber Keyboard failed periodic. Technical analysis of the 3 Rubber Keyboards shows that the failure come of the supplier's assembly process, corrective action is started.*
The corrective action is now verified (see analysis report, enclosure [11] to this report).

# 4 Conclusion

All design verifications of mandatory requirements on device is passed.

# 5 Enclosures

[0] Comments to enclosure 1-9
[1] Raw data – Heat storage
[2] Raw data – Heat function
[3] Raw data – Cold storage
[4] Raw data – Cold function
[5] Raw data - Cyclic heat storage
[6] Raw data – Thermal shock test
[7/8] Raw data – Vibration/drop test
[9] Raw data – Lifetime test
[10] Raw data – Stethoscope tubing to chestpiece bond strength
[11] EER0503d Rubber Keyboard Analysis Report
[12] Raw data – Shiptest bulk packaging (PR048-PR052).

# E3000 SW Design

Author

27/12-2004

Date; Casper Sørensen - Development Engineer

Approved by

27/12-2004

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 |
| 2.0 | CBS | 27-10-2004 | Due to better sound performance the WOLA has been deactivated and (b)(4)T [redacted] filter are use instead (SW 2.00) |
| 2.1 | CBS | 5-11-2004 | Filters have been fine tuned |
| 2.2 | CBS | 1/12-2004 | (b)(4)Trade Secret Process-Product specs [redacted] |
| 2.3 | CBS | 27/12-2004 | Rearranging the order of filters and volume handling, to improve sound performance. ECR 2004 205 |

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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

[redacted] (b) [redacted] manuals:

[4] (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 [redacted]

## 4.2 Timers

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

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 [redacted] DC band and thereby a [redacted] (b)(4)Trade Secret

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 [redacted] (b)
- The group delay through the system must be as low as possible (b)(4)Trade [redacted]
- Minimize instructions consumed by control code by having large block sizes
- Reduce ripples in passband by choosing [redacted] (b) [redacted] (4)T d

Some of the criteria 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.

**Note:** In SW version 2.00 the WOLA co-processor is no longer used, however it is still initialised as described.

## 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. [redacted] volt) (b)(4)
The two thresholds are defined in the E3000 code as follows:

battery low = [redacted] volts (b)(4)
battery depleted = [redacted] volt (b)(4)

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

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) [redacted] contains (b) [redacted] word user data memory banks called X and Y data ram. Both (4) memory banks is designed in the following way:

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

[redacted]

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

[redacted]

**X-High memory:**

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

[redacted]

**Y-Low memory:**

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

[redacted]

**Y-High memory:**

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

[redacted]

## 5.2 EEPROM layout

The EEPROM layout consists of (b) [redacted] data areas, where (b) [redacted] of them are boot and system setup and the (b) [redacted] data area is the E3000 run-time code. (4)

Here is a short description of the seven 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] (b) [redacted] When the E3000 boots this watermark is checked and if the checksum of it is (4)Tvalid due to some unauthorized EEPROM manipulation the E3000 will enter a deadlock loop.
The watermark is [redacted] (b) [redacted]
checksum = (b) [redacted].

# 6 Signal Processing in E3000

## 6.1 Signal flow diagram

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

[redacted]

E3000 Signal Path

## 6.2 Implemented filters

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

[redacted]

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

[redacted]

## 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] (b) dB, the values is as follows.

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

[redacted]

# Risk Assessment Report E3000 SW Design

Author

20-01-2005 Gert Andersen

date; Gert Andersen – Quality Assurance

Approved by

20-01-2005

date; Torben Riis Houe – Manager Quality Assurance

QM500347 version 1.00



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## 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 2B.1 changed after review by EER. The change is explained in the "risk control" section. | EER | - |
| 1.01 | GAN | 19-01-2005 | Update for review<br><br>The Risk Assessment Report for the E3000 SW Design has been updated to reflect the engineering changes implemented since last version. The EC numbers are stated in the right column.<br>A Risk Assessment document is made separately according to these engineering changes and will be added to the references in this document.<br>During this update the risk analysis scheme (excel sheet) has also been updated according to the current design.<br><br>The report has in general been updated to ensure compliance with the risk management standard EN ISO 14971:2000.<br><br>Ref [5] CAJ0414a E3000 Software risk test.doc has been removed. The document not relevant since the risk control activities are documented in the update of this report and in ref. [4]<br><br>Ref [1 [redacted] (b) E3000 Claims.doc, 3M Claims has been removed. The document does not exist as a controlled document. Drafts of 3M claims were made in the early phase of the risk management process. | SJA, EER | 2004-161<br>2004-167<br>2004-184<br>2004-205 |
| 2.00 | GAN | 20-01-2005 | Update after review and released. | - | - |

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# 1 Scope & Strategy

## 1.1 Purpose

The purpose of this report is to document the risk management of the E3000 SW Design.

## 1.2 Scope

The risk management does cover the risk assessment and risk control elements for the software design of the E3000 digital stethoscope. The software design is an important parameter since the software design might affect the user perception of the experiences functionality – e.g. buttons functionality and sound performance.

The risk management will be focused on risks related to user related hazards, design related hazards and how to control these risks through out the total lifetime of the stethoscope.

This assessment is one of more elements concerning risk management of the E3000 digital stethoscope. Other areas of risk management are risks related to the device concept/system, hardware design, mechanical design and production processes.

## 1.3 Resources

| | |
|---|---|
| CBS and CAJ: | SW Design Engineers |
| GAN: | Quality Engineer, Risk management consultancy |
| EER: | Quality Engineer, Quality Assurance reviewer |
| SJA: | Manager Development Dept., Independent reviewer |
| TRH: | Manager Quality Assurance, Management representative |

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## 1.4 Method

The risk management is made in accordance with EN ISO 14971:2000 with a few exceptions described below.

Relevant elements of EN ISO 14971:2000 are:

**Section 3 - General requirements for risk management**
This is in general achieved by [redacted] (b) [redacted] Quality Management procedures. In this case a risk management plan is not established as a separately document. Responsibilities, criteria for acceptability etc. are documented in this assessment report instead.

**Section 4 - Risk Analysis**
Risk analysis documented in ref [4] and [6].
The analysis is based on the HAZOP methodology is used.

**Section 5 – Risk evaluation**
The risk is evaluated using the risk acceptability criteria given in this document.

**Section 6 - Risk control**
The risk control is described in this report.

**Section 7 – Overall residual risk evaluation**
This is evaluated in this report concerning SW design related risks.

**Section 8 – Risk management report**
This report will be part of a final risk management report, which will be prepared when all risk assessments have been completed.

**Section 9 – Post-production information**
This section is relevant when the design is released and might result in updates to the risk management of the device.

## 1.5 References

[2] CAJ0341a E3000 SRS.doc
[3] CAJ0406a E3000 SW Design.doc
[4] CBS0345c E3000 SW Risk Analysis.xls

## 1.6 Requirements for review

This section is added to this standard template since a risk management plan not has been established.

The risk management activities according to SW Design should be reviewed by at least one independent person.

The review must be documented using the template QMS00018 (Design Review Report).

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## 1.7 Criteria for risk acceptability

This section is added to this standard template since a risk management plan not has been established.

Risk assessment is based on two main parameters: **Severity** of the possible consequence and the **Probability** of the actual hazardous situation.
The classification of user risk is illustrated in the figure below (some text is repeated in Danish).

The Broadly acceptable region does not require further actions.
The ALARP region is in general not acceptable. The risk should be reduced to the Broadly acceptable region.
The unacceptable region should not be permitted at all. Products should not be released to market.

**Overall residual risk evaluation**
It is defined as a management decision to judge if the overall residual risk is acceptable based on the risk assessments and the results of the implemented risk control measures.

**5 1 Classification of user risk**

There are 3 classes: "Broadly acceptable", "ALARP" (As Low As Reasonbly Practical) and "Unacceptable".

| P Harm | Probability *Sandsynlighed* | Risk *Risiko* | | | | |
|---|---|---|---|---|---|---|
| P6 | Frequent *Ofte* | [redacted] | | | | |
| P5 | Probable *Sandsynlig* | | | | | |
| P4 | Occasional *Til tider* | | | | | |
| P3 | Remote *Sjælden* | | ALARP *ALARP* | | | |
| P2 | Improbable *Usandsynlig* | Broadly acceptable *Umodelhart acceptabelt* region | | | | |
| P1 | Incredible *Højst usansynlig* | | | | | |
| | | **Negligible** Negligible functional failure and cosmetic defects | **Marginal** Functional failures without medical significance | **Critical** Might cause minor deterioration of health | **Serious** Might cause serious deterioration of health | **Catastrophic** Might cause death |
| | | ***Uvæsentlig*** *Kan forårsage uvæsentlige funktionsfejl og kosmetiske fejl* | ***Marginal*** *Kan forårsage væsentlige funktionsfejl uden medicinsk betydning* | ***Betydende*** *Kan forårsage mindre forværring af helbredstilstand* | ***Alvorlig*** *Kan forårsage alvorlig forværring af helbredstilstand* | ***Katastrofal*** *Kan forårsage dødsfald* |
| | | S1 | S2 | S3 | S4 | S5 |
| | | Severity *Fejlklasser (alvorlighed)* | | | | |

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# 2 Analysis

The analysis is documented in the excel spreadsheet ref [4].

A few comments to the spreadsheet are given here:

**$P_{hazard}$:** State the probability of the actual hazard to become a hazardous situation with the existing (planned) risk control in terms of P1 to P6.

P1: Incredible
P2: Improbable
P3: Remote
P4: Occasional
P5: Probable
P6: Frequent

If the failure is prevented by a robust design it might be stated that the probability of the actual hazard to become a hazardous situation is incredible or even not possible at all. The assessment of probability does not say anything of the statistical evidence required for any risk control measures.

**$P_{not-req}$:** State the probability of discovering the actual hazardous situation before it will result (lead to actual harm) in the stated consequence in terms of I1 to I3. The need for separate failure detection of redundant elements during operation should be considered.

I1: Recognised. The user recognises the hazard with 99% probability.
I2: Partly recognised. The user recognises the hazard with 90% probability.
I3: Not recognised. The user does not recognise the hazard.

An acoustical signal/warning could be an example of a possibility for the user to recognise a hazardous situation.

**$P_{damage}$:** $P_{hazard}$ and $P_{not-req}$ are weighted. If $P_{not-req}$ is I1 or I2 the resulting $P_{damage}$ is less than the assessed $P_{hazard}$.

**Severity Classification:** The classification is described as S1 to S5 and explained in the figure in previous chapter.

**Risk Classification:** Is the result of the Severity Classification and the assessed $P_{damage}$. The classification is described in previous chapter.

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## 3 Critical list

No items related to the SW design have been stated as potential critical, which means that all identified potential risks are acceptable and the severity classification of all potential hazards does not compromise user safety.

## 4 Assessment

The assessment is documented in ref [4] and not discussed further here since there are no items listed as potential critical.

## 5 Risk control

The risk control activities are documented in ref [4] and not discussed further here since there are no items listed as potential critical.

## 6 Overall residual risk evaluation

The risk management of the SW design shows that the overall risk is acceptable. There are no critical items identified. All potential risks related to the SW design have low severity and the implemented controls are found acceptable.

QM50C347 Version 1.00

# Software Requirement Specification

Author

20/1-2005

Date; Casper Sørensen – Development Engineer

Approved by

20-01-05

Date; Esben Lundgård Ernstsen – Quality Assurance

QMS0022 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<br>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 | (b)(4)Trade Secret Process-Product specs [redacted]<br>SR:028 changed<br>SR:050 added |
| 3.0 | CBS | 25-06-04 | Requirement SR:002 is removed, it is not a user requirement |
| 4.0 | CBS | 26-10-04 | Due to the use o(b)(4)Trade Secret Process-[redacted]igure 3 is updated |
| 5.0 | CBS | 20-01-05 | List to references is updated to the final reference documents. |

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# 1 Purpose

E3000 is a limited feature electronic stethoscope based upon a digital sound processing and amplification chip-set [redacted] (b) [redacted].
The device contains mechanical and electronically parts as well as a software program. The (4) 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] TBT0319b IAD0004 Product Requirements.doc
[2] BUA0347a Acoustic input to E3000 filters.doc, Acoustical Specifications

# 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 [redacted] (b) [redacted].
The user will apply this device much the same way as he would with a standard, mechanical (4) 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.

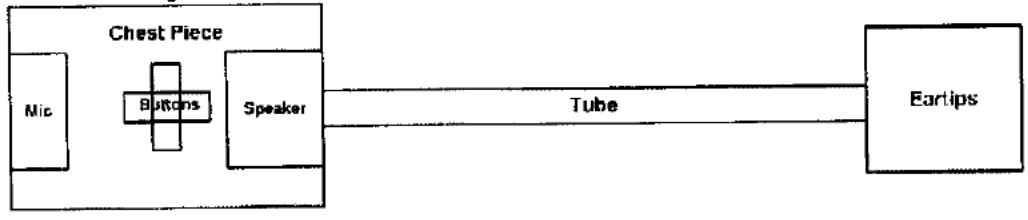


*Figure 1: Physical block diagram of the E3000 system.*

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

## (b)(4) [redacted] Software Features

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

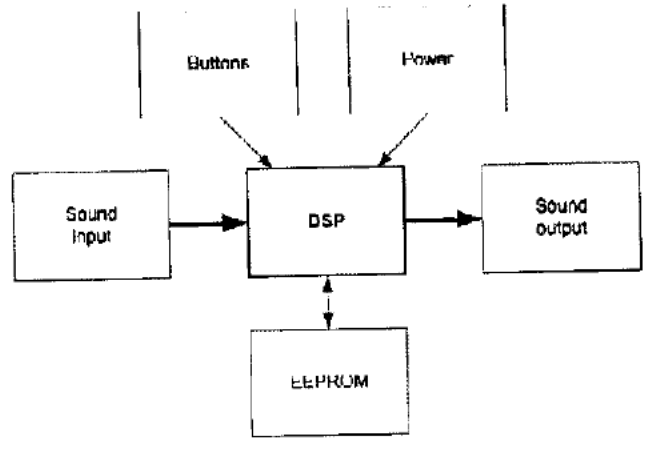


*Figure 2: Logical block diagram of the E3000 system.*

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.
An EEPROM is holding the program code and parameters representing factory setup.

## 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 time-domain.

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

[redacted]

*Figure 3: Signal and control flow of the E3000 software.*

## 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 chipset [redacted] [redacted] [redacted] (b) [redacted] 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:

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

# 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] (b)(4) reproduce an auscultation signal. |
| SR:0043 | The input signal to the DSP must allow frequencies up to about [redacted] (b)(4) kHz because of the [redacted] (b)(4) 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 [2] (b)(4)Trade dB. |

### 4.4.2 Diaphragm mode

| Number | Requirement |
|---|---|
| SR:013 | The Diaphragm filter must comply with the acoustic requirements in [2] ± (b) dB. |

## 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 3dB +1dB. |
| 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.<br><br>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. |



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## 4.6 Sound feedback

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

| Sound / Function | 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 [redacted] (b)

The device boots from the boot ROM in the DSP. The boot ROM loads the bootloader into program memory of the DSP where after 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 occurs 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 necessary 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 30 seconds ±5 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 two hours 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.<br><br>If the button is not released when the device power down, it will power up immediately after power down. |

# E3000 SW Design

Author

27/12-2004

Date; Casper Sørensen - Development Engineer

Approved by

27/12-2004

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 |
| 2.0 | CBS | 27-10-2004 | Due to better sound performance the [redacted] (b)(4) |
| 2.1 | Cbs | 5-11-2004 | Filters have been fine tuned |
| 2.2 | CBS | 1/12-2004 | In order to handle [redacted] (b)(4)Trade |
| 2.3 | CBS | 27/12-2004 | Rearranging the order of filters and volume handling, to improve sound performance. ECR 2004 205 |

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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

[redacted] ([redacted]s:

[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 [redacted]

## 4.2 Timers

The (b)(4)Trade [redacted] general-purpose timer is configured as follows:

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

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

[redacted]

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 [redacted]
- The group delay through the system must be as low as possible (b) [redacted]
- Minimize instructions consumed by control code by having large (b)(4)Trade Secret block sizes
- Reduce ripples in passband by choosing (b)(4)Trade Secret [redacted]

Some of the criteria 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.

**Note:** In SW version 2.00 the WOLA co-processor is no longer used, however it is still initialised as described.

## 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) volt

The internal battery level monitor uses the MCLK to time battery measurements. The MCLK used in E3000 generates a battery measurement each 107ms.
In order to remove battery level glitches the E3000 battery monitor operates on battery data picked up over a (b) period. To determine the state of the battery the output of the internal battery monito(4) is compared to a fixed state change threshold of (b) of maximum count. (4)T

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.



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# 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

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

[redacted]

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

[redacted]

**X-High memory:**

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

[redacted]

**Y-Low memory:**

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

[redacted]

**Y-High memory:**

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

[redacted]

## 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 seven 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] (b)(4)Trade [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]
checksum = [redacted]

# 6 Signal Processing in E3000

## 6.1 Signal flow diagram

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

[redacted]

**E3000 Signal Path**

***All time domain filter are 2th order IIR filters.***



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## 6.2 Implemented filters

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

[redacted]

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

[redacted]

## 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)[redacted]dB, the values is as follows.

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

[redacted]

# E3000 SAS Software Acceptance Test Specification

Author

16/6-2004

Date; Casper Sørensen – Development engineer

Protocol Approved by

16/06-2004

Date; Esben Lundgård Ernstsen – Quality Assurance

Report Approved by

Date; Esben Lundgård Ernstsen – Quality Assurance

| Summary of report: |
| --- |
| TESTS ARE OK |
| NO COMMENTS |

## 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 | [redacted] ts 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 [redacted] (b) (4) has developed the E3000 stethoscope in cooperation with 3M Littmann. 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: 2.03<br>Serial number: R4725081 |
| | |
| | |

## 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) [redacted]

# 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 | – | – |
| BATTER SUPPLY | B&G MEDICOM | – | – |
| MULTIMETER | PREMA 5017 | R2707 | 22-04-2004 |
| | | | |
| | | | |
| | | | |



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# 4 TEST CASES

## 4.1 Power up

### 4.1.1 TEST 1

| | | | |
|---|---|---|---|
| **Purpose** | Test that the E3000 starts when pressing the bell button | | |
| **Test case** | AT: 001a | **SR** | SR: 003<br>SR: 004<br>SR: 005 |
| **Action** | E3000 is powered down<br>1) Insert the E3000 earplugs into your ears<br>2) Press ▼<br>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)<br>2) The E3000 powers up and *bell* sound feedback is played<br>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 (N.C.) | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

4.1.2 TEST 2

| | | | |
|---|---|---|---|
| **Purpose** | Test that the E3000 starts when pressing the diaphragm button | | |
| **Test case** | AT: 001b | **SR** | SR: 003<br>SR: 004<br>SR: 005 |
| **Action** | E3000 is powered down<br>1) Insert the E3000 earplugs into your ears<br>2) Press ▽<br>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)<br>2) The E3000 powers up and *diaphragm* sound feedback is played<br>3) Heart sounds are weak and respiration sound are powerful (compared to Test case 1a) | | |
| **Result** | OK | | |
| **Test equipment and reference** | NONE | | |
| **Comment** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

## 4.2 Power down

### 4.2.1 TEST 1

| | | | |
|---|---|---|---|
| **Purpose** | Test the automatic power off function | | |
| **Test case** | AT: 002 | **SR** | SR: 006<br>SR: 009 |
| **Action** | E3000 is powered down<br>1) Insert the E3000 earplugs into your ears<br>2) Press ▼<br>3) Wait until the E3000 automatically power down | | |
| **Expected result** | 1) There are no sound from the E3000<br>2) The E3000 powers up, a *bell* sound feedback and sound picked up by the is played in the binaural<br>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** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

4.2.2 TEST 2

| | | | |
|---|---|---|---|
| **Purpose** | Test the automatic power off function | | |
| **Test case** | AT: 003 | **SR** | SR: 006<br>SR: 009 |
| **Action** | E3000 is powered down<br>1) Insert the E3000 earplugs into your ears<br>2) Press ▼<br>3) Wait 60 seconds and press ▼<br>4) Wait until the E3000 automatically power down | | |
| **Expected result** | 1) There are no sound from the E3000<br>2) The E3000 powers up, a *bell* sound feedback and sound picked up by the is played in the binaural<br>3) *Bell* sound feedback is played again.<br>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** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

4.2.3 TEST 3

| | | | |
|---|---|---|---|
| **Purpose** | Test the manual power off function | | |
| **Test case** | AT: 004 | **SR** | SR: 007<br>SR: 009<br>SR: 046 |
| **Action** | E3000 is powered up<br>1) Insert the E3000 earplugs into your ears<br>2) Press and hold ⏻<br>3) Release ⏻ when the *power down* sound feedback occurs | | |
| **Expected result** | 1) The E3000 is operational<br>2) *Bell* sound feedback is played<br>3a) Approx. 3 sec after the ⏻ button has been pressed the *power down* sound feedback occurs<br>3b) After the sound feedback stops the E3000 powers down, there are no sound from the E3000 | | |
| **Result** | OK | | |
| **Test equipment and reference** | NONE | | |
| **Comment** | N. C. | | |
| **Ok** ☑ | **Date:** 27/11-2004 **Sign:** | | |

4.2.4 TEST 4

| | | | |
|---|---|---|---|
| **Purpose** | Test the manual power off function | | |
| **Test case** | AT: 005 | **SR** | SR: 007<br>SR: 009<br>SR: 046 |
| **Action** | E3000 is powered up<br>1) Insert the E3000 earplugs into your ears<br>2) Press and hold ▽<br>3) Release ▽ when the *power down* sound feedback occurs | | |
| **Expected result** | 1) The E3000 is operational<br>2) *Diaphragm* sound feedback is played<br>3a) Approx. 3 sec after the ▽ button has been pressed the *power down* sound feedback occurs<br>3b) After the sound feedback stops the E3000 powers down, there are no sound from the E3000 | | |
| **Result** | OK | | |
| **Test equipment and reference** | NONE | | |
| **Comment** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

## 4.3 Filter mode

### 4.3.1 TEST 1

| | | | |
|---|---|---|---|
| **Purpose** | Test the change between filters | | |
| **Test case** | AT: 006 | **SR:** | SR: 010<br>SR: 011 |
| **Action** | E3000 is powered down<br>1) Insert the E3000 earplugs into your ears<br>2) Press ▼<br>3) Place the chestpiece on the chest and listen to the body sounds (heart and respiration)<br>4) Press ▼ again<br>5) Press the ▽<br>6) Listen to the body sounds (heart and respiration)<br>7) Press ▽ again<br>8) Press ▼<br>9) Listen to the body sounds (heart and respiration) | | |
| **Expected result** | 1) There are no sound from the E3000 (device is off)<br>2) The E3000 powers up and *bell* sound feedback is played.<br>3) Heart sounds are powerful and respiration sound are weak<br>4) *Bell* sound feedback is played, body sounds are as in 3)<br>5) *Diaphragm* sound feedback is played<br>6) Heart sounds are weak and respiration sound are powerful<br>7) *Diaphragm* sound feedback is played, body sounds are as in 6)<br>8) *Bell* sound feedback is played<br>9) Body sounds are as in 3) | | |
| **Result** | Ok | | |
| **Test equipment and reference** | NONE | | |
| **Comment** | N.C. | | |
| Ok ☑ | **Date:** 27/12-2004 | **Sign:** | |

## 4.4 Volume selection

### 4.4.1 TEST 1

| | | | |
|---|---|---|---|
| **Purpose** | Test volume selection | | |
| **Test case** | AT: 007 | **SR** | SR: 014<br>SR: 015<br>SR: 016 |
| **Action** | E3000 is powered up<br>1) Press + repeatedly 7 times (1 second pause between activations)<br>2) Insert the E3000 earplugs into your ears<br>3) Place the chestpiece on the chest and listen to the body sounds<br>4) Press + again<br>5) Press — repeatedly 7 times (1 second pause between activations), listen for feedback and body sounds<br>6) Press — again | | |
| **Expected result** | 1) E3000 is forced into maximum volume<br>2) The E3000 is operational<br>3) Body sounds are audible<br>4) No change in sound/no volume feedback<br>5a) *Volume* feedback is given at each activation<br>5b) Body sounds loudness is lowered<br>6) No change in sound/no volume feedback | | |
| **Result** | Ok | | |
| **Test equipment and reference** | NONE | | |
| **Comment** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

4.4.2 TEST 2

| | | | |
|---|---|---|---|
| **Purpose** | Test volume storage | | |
| **Test case** | AT: 008a | **SR** | SR: 047<br>SR: 048<br>SR: 049<br>SR: 026 |
| **Action** | E3000 is powered up<br>1) Press + repeatedly 7 times (1 second pause between activations)<br>2) Insert the E3000 earplugs into your ears<br>3) Press and hold +<br>4) Release + when the *store volume* sound feedback occurs<br>5) Press and hold ▽<br>6) Release ▽ when the *power down* sound feedback occurs | | |
| **Expected result** | 1) E3000 is forced into maximum volume<br>2) The E3000 is operational<br>3) No change in sound/no volume feedback<br>4) Approx. 2 sec after the + button has been pressed the *Store volume* sound feedback is played<br>5) *Diaphragm* sound feedback is played<br>6a) Approx. 3 sec after the ▽ button has been pressed the *power down* sound feedback occurs<br>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** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

4.4.3 TEST 3

| | | | |
|---|---|---|---|
| **Purpose** | Test volume storage | | |
| **Test case** | AT: 008b | **SR** | SR: 047<br>SR: 048<br>SR: 049<br>SR: 026 |
| **Action** | E3000 is powered down<br>1) Press ⏻, to turn E3000 on<br>2) Insert the E3000 earplugs into your ears<br>3) Press and hold —<br>4) Release — when the *store volume* sound feedback occurs<br>5) Press and hold ⏻<br>6) Release ⏻ when the *power down* sound feedback occurs | | |
| **Expected result** | 1) Powers E3000 up and stored volume is applied<br>2) The E3000 is operational<br>3) *Volume* feedback is played<br>4) Approx. 2 sec after the — button has been pressed the *Store volume* sound feedback is played<br>5) *Diaphragm* sound feedback is played<br>6a) Approx. 3 sec after the ⏻ button has been pressed the *power down* sound feedback occurs<br>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** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

4.4.4 TEST 4

| | | | |
|---|---|---|---|
| **Purpose** | Test volume storage | | |
| **Test case** | AT: 008c | **SR** | SR: 047<br>SR: 048<br>SR: 049<br>SR: 026 |
| **Action** | E3000 is powered down<br>1) Press ⏻, to turn E3000 on<br>2) Insert the E3000 earplugs into your ears<br>3) Press +<br>4) Press —<br>5) Press and hold +<br>6) Release + when the *store volume* sound feedback occurs<br>7) Press and hold ⏻<br>8) Release ⏻ when the *power down* sound feedback occurs | | |
| **Expected result** | 1) Powers E3000 up and stored volume is applied<br>2) The E3000 is operational<br>3) No change in sound/no volume feedback<br>4) *Volume* feedback is played<br>5) *Volume* feedback is played<br>6) Approx. 2 sec after the + button has been pressed the *Store volume* sound feedback is played<br>7) *Diaphragm* sound feedback is played<br>8a) Approx. 3 sec after the ⏻ button has been pressed the *power down* sound feedback occurs<br>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** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

4.4.5 TEST 5

| | | | |
|---|---|---|---|
| **Purpose** | Test volume storage | | |
| **Test case** | AT: 008d | **SR** | SR: 047<br>SR: 048<br>SR: 049<br>SR: 026 |
| **Action** | E3000 is powered down<br>1) Press ⏻, to turn E3000 on<br>2) Insert the E3000 earplugs into your ears<br>3) Press +<br>4) Press + again<br>5) Press — repeatedly 7 times (1 second pause between activations)<br>6) Press and hold —<br>7) Release — when the *store volume* sound feedback occurs<br>8) Press and hold ⏻<br>9) Release ⏻ when the *power down* sound feedback occurs | | |
| **Expected result** | 1) Powers E3000 up and stored volume is applied<br>2) The E3000 is operational<br>3) *Volume* feedback is played<br>4) No change in sound/no volume feedback<br>5) Forced to minimum volume, *Volume* sound feedback is played at each activation<br>6) No change in sound/no volume feedback<br>7) Approx. 2 sec after the — button has been pressed the *Store volume* sound feedback is played<br>8) *Diaphragm* sound feedback is played<br>9a) Approx. 3 sec after the ⏻ button has been pressed the *power down* sound feedback occurs<br>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** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |



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4.4.6 TEST 6

| | | | |
|---|---|---|---|
| **Purpose** | Test volume storage | | |
| **Test case** | AT: 008e | **SR** | SR: 047<br>SR: 048<br>SR: 049<br>SR: 026 |
| **Action** | E3000 is powered down<br>1) Press ⏻, to turn E3000 on<br>2) Insert the E3000 earplugs into your ears<br>3) Press and hold +<br>4) Release + when the *store volume* sound feedback occurs<br>5) Press and hold ⏻<br>6) Release ⏻ when the *power down* sound feedback occurs | | |
| **Expected result** | 1) Powers E3000 up and stored volume is applied<br>2) The E3000 is operational<br>3) *Volume* feedback is played<br>4) Approx. 2 sec after the + button has been pressed the *Store volume* sound feedback is played<br>5) *Diaphragm* sound feedback is played<br>6a) Approx. 3 sec after the ⏻ button has been pressed the *power down* sound feedback occurs<br>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** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

4.4.7 TEST 7

| | | | |
|---|---|---|---|
| **Purpose** | Test volume storage | | |
| **Test case** | AT: 008f | **SR** | SR: 047<br>SR: 048<br>SR: 049<br>SR: 026 |
| **Action** | E3000 is powered down<br>1) Press ⏻, to turn E3000 on<br>2) Insert the E3000 earplugs into your ears<br>3) Press —<br>4) Press +<br>5) Press and hold —<br>6) Release — when the *store volume* sound feedback occurs<br>7) Press and hold ⏻<br>8) Release ⏻ when the *power down* sound feedback occurs | | |
| **Expected result** | 1) Powers E3000 up and stored volume is applied<br>2) The E3000 is operational<br>3) No change in sound/no volume feedback<br>4) *Volume* feedback is played<br>5) *Volume* feedback is played<br>6) Approx. 2 sec after the — button has been pressed the *Store volume* sound feedback is played<br>7) *Diaphragm* sound feedback is played<br>8a) Approx. 3 sec after the ⏻ button has been pressed the *power down* sound feedback occurs<br>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** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

4.4.8 TEST 8

| | | | |
|---|---|---|---|
| **Purpose** | Test volume storage | | |
| **Test case** | AT: 008g | **SR** | SR: 047<br>SR: 048<br>SR: 049<br>SR: 026 |
| **Action** | E3000 is powered down<br>1) Press ▽, to turn E3000 on<br>2) Insert the E3000 earplugs into your ears<br>3) Press —<br>4) Press — | | |
| **Expected result** | 1) Powers E3000 up and stored volume is applied<br>2) The E3000 is operational<br>3) *Volume* feedback is played<br>4) No change in sound/no volume feedback | | |
| **Result** | OK | | |
| **Test equipment and reference** | NONE | | |
| **Comment** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2009 | **Sign:** | |



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## 4.5 Sound feedback

### 4.5.1 TEST 1

| | | | |
|---|---|---|---|
| **Purpose** | Test sound feedback events | | |
| **Test case** | AT: 009a | **ISR** | SR: 018 |
| **Action** | E3000 is powered down, volume level 4 is stored<br>1) Insert the E3000 earplugs into your ears<br>2) Press ▼<br>3) Press ▼ again<br>4) Press ▽<br>5) Press +<br>6) Press — and hold<br>7) Release — when the *store volume* sound feedback occurs<br>8) Press and hold ▽<br>9) Release ▽ when the *power down* sound feedback occurs | | |
| **Expected result** | 1) There are no sound from the E3000 (device is off)<br>2) The E3000 powers up and *bell* sound feedback is played<br>3) *Bell* sound feedback is played<br>4) *Diaphragm* sound feedback is played<br>5) *Volume* feedback is played<br>6) *Volume* feedback is played<br>7) Approx. 2 sec after the — button has been pressed the *Store volume* sound feedback is played<br>8) *Diaphragm* sound feedback is played<br>9a) Approx. 3 sec after the ▽ button has been pressed the *power down* sound feedback occurs<br>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** | N.C. | | |
| Ok ☑ | **Date:** 27/12-2004 | **Sign:** [signature] | |

4.5.2 TEST 2

| | | | |
|---|---|---|---|
| **Purpose** | Test sound feedback events | | |
| **Test case** | AT: 009b | **SR** | SR: 018 |
| **Action** | E3000 is powered down<br>1) Insert the E3000 earplugs into your ears<br>2) Press ▽<br>3) Press ▽ again<br>4) Press ▼<br>5) Press —<br>6) Press + and hold<br>7) Release + when the *store volume* sound feedback occurs<br>8) Press and hold ▼<br>9) Release ▼ when the *power down* sound feedback occurs | | |
| **Expected result** | 1) There are no sound from the E3000 (device is off)<br>2) The E3000 powers up and *diaphragm* sound feedback is played<br>3) *Diaphragm* sound feedback is played<br>4) *Bell* sound feedback is played<br>5) *Volume* feedback is played<br>6) *Volume* feedback is played<br>7) Approx. 2 sec after the + button has been pressed the *Store volume* sound feedback is played<br>8) *Bell* sound feedback is played<br>9a) Approx. 3 sec after the ▼ button has been pressed the *power down* sound feedback occurs<br>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** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

4.5.3 TEST 3

| | | | |
|---|---|---|---|
| **Purpose** | Test sound feedback events, battery low | | |
| **Test case** | AT: 010 | **SR** | SR: 018<br>SR: 031 |
| **Action** | E3000 is powered down, battery supply is set to low level<br>1) Insert the E3000 earplugs into your ears<br>2) Press ☑<br>3) Wait 1 minute | | |
| **Expected result** | 1) There are no sound from the E3000 (device is off)<br>2) The E3000 powers up and *diaphragm* sound feedback is played<br>3) *Battery low* sound feedback is played | | |
| **Result** | OK | | |
| **Test equipment and reference** | BATTERY SUPPLY<br>MULTIMETER | | |
| **Comment** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

4.5.4 TEST 4

| | | | |
|---|---|---|---|
| **Purpose** | Test sound feedback events, battery depleted | | |
| **Test case** | AT: 011 | **SR:** | SR: 018<br>SR: 037 |
| **Action** | E3000 is powered down, battery supply is set to depleted level<br>1) Insert the E3000 earplugs into your ears<br>2) Press ▽ | | |
| **Expected result** | 1) There are no sound from the E3000 (device is off)<br>2a) The E3000 powers up, *battery low* sound feedback is played follow by a *power down* feedback<br>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<br>MULTIMETER | | |
| **Comment** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

4.5.5 TEST 5

| | | | |
|---|---|---|---|
| **Purpose** | Test sound feedback events, battery depleted | | |
| **Test case** | AT: 012 | **SR:** | SR: 018<br>SR: 037 |
| **Action** | E3000 is powered down, battery supply is set to depleted level<br>1) Insert the E3000 earplugs into your ears<br>2) Press ▼ | | |
| **Expected result** | 1) There are no sound from the E3000 (device is off)<br>2a) The E3000 powers up, *battery low* sound feedback is played follow by a *power down* feedback<br>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<br>MULTIMETER | | |
| **Comment** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12/2004 | **Sign:** | |

4.5.6 TEST 6

| | | | |
|---|---|---|---|
| **Purpose** | Test sound feedback events | | |
| **Test case** | AT: 013 | **ISR** | SR: 019 |
| **Action** | E3000 is powered down, volume level 1 (minimum) is stored<br>1) Insert the E3000 earplugs into your ears<br>2) Press ▼<br>3) Press + repeatedly 7 times (1 second pause between activations) | | |
| **Expected result** | 1) There are no sound from the E3000 (device is off)<br>2) The E3000 powers up and *bell* sound feedback is played<br>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** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

## 4.6 Miscellaneous

### 4.6.1 TEST 1

| | | | |
|---|---|---|---|
| **Purpose** | Test of multiple button commands | | |
| **Test case** | AT: 014 | **SR** | SR: 045 |
| **Action** | E3000 is powered up<br>1) Insert the E3000 earplugs into your ears<br>2) Press ▼ and hold<br>3) Press ▽ and hold when the *bell* sound feedback plays<br>4) Release ▼<br>5) Press — and hold<br>6) Press + and hold<br>7) Release —<br>8) Release +<br>9) Release ▽<br>10) Press ▽ | | |
| **Expected result** | 1) E3000 is operational<br>2) *Bell* sound feedback is played<br>3) No sound feedback<br>4) No sound feedback<br>5) No sound feedback<br>6) No sound feedback<br>7) No sound feedback<br>8) No sound feedback<br>9) No sound feedback<br>10) *Diaphragm* sound feedback is played | | |
| **Result** | OK | | |
| **Test equipment and reference** | None | | |
| **Comment** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

4.6.2 TEST 2

| | | | |
|---|---|---|---|
| **Purpose** | Test of multiple button commands | | |
| **Test case** | AT: 015 | **SR** | SR: 029 |
| **Action** | E3000 is powered up<br>1) Insert the E3000 earplugs into your ears<br>2) Press ▼ and ▽<br>3) Press ▼ and —<br>4) Press ▼ and +<br>5) Press ▽ and —<br>6) Press ▽ and +<br>7) Press — and +<br>8) Press ▼, ▽ and —<br>9) Press ▼, ▽ and +<br>10) Press ▼, — and +<br>11) Press ▽, — and +<br>12) Press ▼, ▽, — and + | | |
| **Expected result** | 1) E3000 is operational<br>2-12) No sound feedback | | |
| **Result** | Ok | | |
| **Test equipment and reference** | NONE | | |
| **Comment** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

4.6.3 TEST 3

| | | | |
|---|---|---|---|
| **Purpose** | Test of the battery monitor | | |
| **Test case** | AT: 016 | **SR** | SR: 032 |
| **Action** | E3000 is powered up, set battery voltage to low level<br>1) Insert the E3000 earplugs into your ears<br>2) Listen for 4 minutes | | |
| **Expected result** | 1) E3000 is operational<br>2) *Battery low* sound feedback is played every 30s ± 5s | | |
| **Result** | OK | | |
| **Test equipment and reference** | BATTERY SUPPLY<br>MULTIMETER<br>WATCH | | |
| **Comment** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** | |

4.6.4 TEST 4

| | | | |
|---|---|---|---|
| **Purpose** | Test of the battery monitor | | |
| **Test case** | AT: 017 | **SR** | SR: 035<br>SR: 036 |
| **Action** | E3000 is powered up<br>1) Insert the E3000 earplugs into your ears<br>2) Adjust the battery voltage to empty level | | |
| **Expected result** | 1) E3000 is operational<br>2a) *Battery low* sound followed by *power down* sound feedback is played<br>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<br>MULTIMETER | | |
| **Comment** | N.C | | |
| Ok ☑ | **Date:** 27/12-2004 | **Sign:** | |

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<br>1) Insert the E3000 earplugs into your ears<br>2) Press ▽ | | |
| **Expected result** | 1) There are no sound from the E3000 (device is off)<br>2) No change in device state | | |
| **Result** | OK | | |
| **Test equipment and reference** | BATTERY SUPPLY<br>MULTIMETER | | |
| **Comment** | N.C. | | |
| **Ok** ☑ | **Date:** 27/12-2004 | **Sign:** [signature] | |

# E3000 Software Validation Report

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20/1-2005

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Approved by

20-01-2005

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## Version history

| Version | Author | Date | Description |
|---|---|---|---|
| 0.1 | CBS | 22-06-2004 | Draft |
| 1.00 | CBS | 7-7-2004 | Updated |
| 2.00 | CBS | 19-01-2005 | Report updated before release for Sale. Status covers current software release 2.03<br>1.Purpose. Comment about status for software release 2.03<br>5. Validation activities updated<br>6. Conclusion updated to cover release 2.03 |

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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.

Version 1.00 of the software validation plan documented the status of the validation activities July 2004. This version updates the status of the validation activities performed until January 2005, where software version 2.03 is released.

# 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 [redacted] (b)(4)

# 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.

# 5 E3000 software and development tool validation activities

| Validation activity [1] | Reference, Protocol/Report | Current version | Have all results passed the acceptance criteria | Remarks |
|---|---|---|---|---|
| Review of SW engineering requirements | CAJ0402a E3000 SRS Review Report.doc | 1.0 | N/A | N/A |
| Review of SW design | CAJ0414b E3000 SW Design Review Report.doc | 1.0 | N/A | N/A |
| Review of Code | CBS0414a E3000 SW Code Review Report.doc | 1.0 | N/A | N/A |
| Review of Accept test | CBS0413a E3000 SW Acceptance test Review Report.doc | 1.0 | N/A | N/A |
| Module and integration test | CAJ0421a E3000 SW handle_buttons.ss Component Verifications Protocol/report | 1.0 | Yes | N/A |
| | CAJ0422a E3000 SW handle_sound.ss Component Verifications Protocol/Report | 2.0 | Yes | N/A |
| | CAJ0422b E3000 SW handle_irq.ss Component Verifications Protocol.doc | 2.01 | Yes | N/A |
| | CBS0447B E3000 SW handle_irq.ss Component Verifications Report | 2.00 | | |
| | CBS0420A E3000 SW handle_rcore.ss Component Verifications Protocol/Report | 1.00 | Yes | N/A |
| | CBS0420B E3000 SW analyse_signal.ss Component Verifications Protocol/Report | 1.00 | Yes | N/A |
| | CBS0421A E3000 SW handle_power.ss Component Verifications Protocol Report | 1.00 | Yes | N/A |
| | CBS0424a E3000 SW handle_init.ss Component Verifications Protocol/Report | 1.00 | Yes | N/A |
| | CAJ0426a E3000 SW System Verifications Protocol.doc | 2.00 | Yes | N/A |
| | CBS0447C E3000 SW System Verifications Report | 2.00 | | |
| Accept test | CBS0425a E3000 SAS Software Acceptance Test Specification.doc | 2.00 | Yes | N/A |
| | CBS0450B E3000 SAS Software Acceptance Test Report | 2.01 | | |
| SW Traceability analysis | CBS0804a E3000 STA SW Traceability Analysis.doc | 1.00 | N/A | N/A |
| SW Error reporting | cbs2404a E3000 software error report.doc | 1.00 | N/A | N/A |
| SW Design risk analysis | CBS0345c E3000 SW Risk Analysis.xls | 3.00 | N/A | N/A |
| | CAJ0413a E3000 Risk Assessment Report.doc | 2.00 | N/A | N/A |

# 6 Conclusion

The software validations activities supporting release of software version 2.03 have passed the acceptance criteria.

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

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

| | |
|---|---|
| Title<br>Release of software for E3000 "version 2.03" | Date<br>27-12-2004 |
| Project<br>E3000, IAD0004 | From<br>Casper Sørensen - Development Engineer |
| To<br>Project archive | Sign |
| File name<br>CBS0453a Release of SW for E3000 version 2.03.doc | |

## Release of software for E3000 "version 2.03"

### Description

- This version of the software for the E3000 is "version 2.03. The difference between this version and the previous official release 2.02 is that the handling order of (b)(4)Trade Secret [redacted] is changed, which gives an improved sound performance and especially at low volume settings.

### Approval

Following persons have approved the release of the E3000 software, **"version 2.03"**.

Tommy Buch Thinesen (TBT)
Project Manager

Esben Lundgård Ernstsen (EER)
Quality Engineer

### Identification

Label in the visual source safe: "version 2.03"
The E3000 production EEPROM file is named "E3000.o"

### Conclusion

The software version 2.03 for the E3000 stethoscope is completed. The software has been developed according to the software procedure a[redacted] (b)(4)Trade [redacted]
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 [redacted]

# User Manual

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

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

3M is a trademark of 3M.
Littmann is a registered trademark of 3M.
38-9018-3873-0

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3M

# Littmann®
Brand

## Electronic Stethoscope
MODEL 3000
*with Ambient Noise Reduction*

3000

**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

Featuring Ambient Noise Reduction

| | |
|---|---|
| **Artwork No.:** | **38-9018-3873-0** |
| Date: | **12/6/04** |
| Author: | **S Barker** |
| Supersedes: | **NA** |
| Pkg Spec Ref: | **34-7056-4772-4** |
| Structure: | **Booklet Cover** |

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

193

193

English

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

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

This powerful, electronic stethoscope provides the superior acoustic sensitivity users have come to expect from the Littmann brand, **and more**. It includes state-of-the-art amplification and filtering systems, ideal for picking up difficult-to-hear heart and other body sounds. It features 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).

LATEX • This product and package do not contain natural rubber latex.

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

### Indications:

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

### ⚠ Caution:

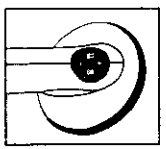
Failure to follow the directions in this manual could result in damage to the device or possible injury to the user.

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

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

## 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 button

▼ or ▽ .

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

## Operation

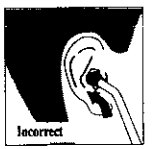
Select the frequency mode desired for auscultation by pushing either the bell or diaphragm filter symbol (this is accomplished when activating the stethoscope initially). Adjust the volume to the desired level by pushing either the plus or minus symbol. At the 3rd volume level, the stethoscope is set 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.

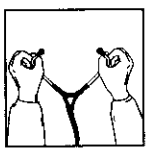
Auscultate as you would using an acoustic stethoscope. It is important to find a comfortable grip that allows you to hold the stethoscope in a secure but relaxed manner. Use the bell and diaphragm modes to accentuate or attenuate different heart and body sounds. Low frequency sounds have a tendency to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



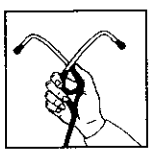
## Headset Positioning



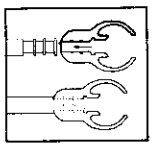

Your new Littmann Electronic Stethoscope is designed to give you a very comfortable, acoustically sealed ear fit. Notice that the eartubes are permanently set at an angle to accommodate the typical anatomy of the ear canal. The eartips should point in a forward direction as you insert them into your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


Reduce Tension

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


Increase Tension

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



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

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

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

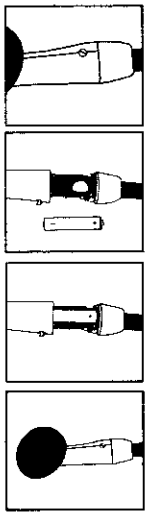
## Turning Off the Stethoscope

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

## Battery Life

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

## 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 | Model 3000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | Model 3000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/flicker emmisions 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<br>± 8 kV air | ± 6 kV contact<br>± 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<br>± 1 kV for input/output lines | Not applicable | |
| Surge IEC 61000-4-5 | ± 1 kV differential mode<br>± 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<br>40 % $U_T$ (60 % dip in $U_T$) for 5 cycle<br>70 % $U_T$ (30 % dip in $U_T$) for 25 cycle<br>< 5% $U_T$ (>95 % dip in $U_T$) for 5 sec | Not applicable | |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial magnetic field or hospital environment. |



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**Table 204**

**Declaration – Electromagnetic Immunity (Continued)**

The 3M Littmann® Electronic Stethoscope, Model 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.<br>**Recommended separation distance** |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | Not applicable | d = 1.2 √ P |
| Radiated RF | 3 V/m | 3 V/m | d = 1.2 √ P 80 MHz to 800 MHz |
| IEC 61000-4-3 | 80 MHz to 2.5 GHz | 80 MHz to 2.5 GHz | d = 2.3 √ P 800 MHz to 2,5 GHz<br>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).<br>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 distance between portable and mobile RF communications equipment (transmitters) and the Model 3000 as recommended below, according to the maximum output of the communications equipment.

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

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

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

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



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# Primary Box Artwork

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

Littmann® Brand

Electronic Stethoscope Model 3000

CE 0086 **3M Health Care** D-41453 Neuss, Germany

⚠ Attention: see instructions for use

LATEX

3M

# Littmann®
Brand

## Electronic Stethoscope
MODEL 3000
*with Ambient Noise Reduction*

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

- Amplification up to 18 times greater than the best conventional Littmann stethoscopes
- Reduction of unwanted ambient noise by 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

Featuring **Ambient Noise Reduction**

Electronic Stethoscopes ○ ○ Model 3000 ● Model 4100
Cardiology Stethoscopes ●
Classic Stethoscopes ●
Select / Lightweight ●

**3M™ Littmann® Electronic Stethoscope**
Model 3000 With Ambient Noise Reduction
2 Year Warranty

60°C 140°F
-20°C -4°F
15–95% Humid.

**3M™ Littmann® Electronic Stethoscope**
Model 3000 With Ambient Noise Reduction
2 Year Warranty

Littmann® Brand

3M

Littmann®
Brand

Electronic Stethoscope Model 3000
With Ambient Noise Reduction

**3M™ Littmann® Electronic Stethoscope Model 3000**
**3000BK29 Black ●**
70-2007-4494-7
**● 29 in. / 70 cm**
7 07387 56550 3

| | |
|---|---|
| Artwork No.: | 38-9018-5462-0 |
| Date: | 11/29/04 |
| Author: | S Barker |
| Supersedes: | 38-9018-3869-8 |
| Pkg Spec Ref: | 34-7057-4656-7 |
| Structure: | PC Cover Wrap |

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

200

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

Stéthoscope électronique 3M™ Littmann® modèle 3000, avec réduction des bruits ambiants
Amplification sélective des sons d'auscultation
- Amplification jusqu'à 18 fois supérieure à celle d'un stéthoscope Littmann traditionnel
- Diminution jusqu'à 75% des bruits parasites
- Permutation facile entre les modes de fréquences cloche et diaphragme.
- Léger et équilibré
- Le pavillon s'adapte aux nourissons, enfants et adultes
- Ergonomique, une seule touche commande les différentes fonctions
- Fonctionne avec une pile AAA

3M™ Elektronisches Stethoskop Modell 3000 mit Störgeräuschunterdrückung (ANR-Technologie)
Verstärken Sie Geräusche, die Sie hören möchten, mit deutlich reduzierten Störgeräuschen
- Bis zu 18-fache Verstärkung gegenüber dem besten konventionellen Littmann Stethoskop
- Reduzierung von nicht gewünschten Nebengeräuschen um bis zu 75%
- Einfaches Wechseln zwischen den Frequenzbereichen Trichter- und Membran
- Leichtgewichtig und gut ausbalanciert
- Das vielseitige Bruststück kann für die Auskultation von Säuglingen, Kindern und erwachsenen Patienten verwendet warden
- Ergonomische Einknopf-Bedienung
- Betrieb mit einer AAA-Batterie

3M™ Littmann® Stetoscopio Elettronico 3000 con riduzione del rumore di fondo
Amplifica i suoni che si vogliono auscultare riducendo il rumore di fondo
- Amplificazione fino a 18 volte maggiore del miglior stetoscopio Littman di tipo convenzionale
- Riduzione di oltre il 75% dei rumori di fondo
- Possibilità di passare facilmente dalla modalitaà diaframma a quella campana
- Leggero e bilanciato
- La testina versatile ne consente l'utilizzo per pazienti neonatali, pediatrici ed adulti
- Ergonomico
- Utilizza una batteria AAA

Fonendoscopio Electrónico 3M™ Littmann® Modelo 3000 con Reducción de Ruido Ambiental
Amplifica los sonidos que se quieren oir con menor ruido ambiental
- Amplificación hasta 18 veces superior a la del mejor fonendoscopio Littmann convencional
- Reducción de ruido ambiental indeseable hasta un 75 %
- Fácil de cambiar entre los modos de frecuencia campana y membrana
- Ligero y equilibrado
- Campana versátil que se acomoda a uso en pacientes pediátricos y adultos
- Ergonómico, y fácil de usar
- Utiliza sólo una pila de tipo AAA

3M™ Littmann® Electronic Stethoscope Model 3000 met Ambient Noise Reduction
Verterkt de geluiden die u wil horen met een vermindering van het achtergrond lawaai
- Versterking tot 18 maal groter dan die van de beste conventionele Littmann stethoscoop
- Reduceert hinderlijk achtergrond lawaai tot 75%
- Gemakkelijk om te schakelen tussen klok en membraan frequentie mode
- Lichtgewicht
- Veelzijdig borsstuk voor auscultatie van zowel babies, kinderen als volwassenen
- Ergonomisch, kan worden bediend met slecht één knop
- Maakt gebruik van één AAA-batterij

Elektroniskt 3M™ Littmann® stetoskop modell 3000 med reducerat bakgrundsljud
Förstärk ljuden du vill höra, men med mindre störande bakrundsljud
- Upp till 18 gånger högre förstärkning än det bästa konventionella Littmannstetoskopet
- 75% reducerat bakgrundsljud
- Lätt att byta mellan klocka och membranfunktion
- Lätt och välbalanserat
- Bröststycke med många funktioner. Kan användas på spädbarn, barn och vuxna
- Ergonomiskt utformat, med enknappsfunktioner
- Använder ett AAA-batteri

3M Littmann® elektronisk stetoskop model 3000 reducerer udefrakommende støj
Forstærker de ønskede lyde og mindsker forstyrrende baggrundsstøj
- Forstærker lyden op til 18 gange mere end det bedste Littmann stetoskop
- Reducerer uønsket omgivende støj med op til 75%
- Nem at skifte mellem klokke- og membran frekvenser
- Letvægts og velafbalanceret
- Bevægelig bryststykke kan bruges på baby-, børn- og voksen patienter
- Ergonomisk, enkelt-knap system
- Bruger ét AAA batteri

3M™ Littmann® Elektronisk Stetoskop Modell 3000 Ambient Noise Reduction
Forsterker de lydene du vil høre og reduserer uønsket bakgrunnstøy
- Amplifikasjon opp til 18 ganger høyere enn det beste tradisjonelle Littmann stetoskop
- Reduserer uønsket bakgrunnstøy med opptil 75%
- Enkelt å skifte mellom klokke og membran frekvenser
- Lav vekt og velbalansert
- Stetoskophode tilpasset auskultasjon på spedbarn, barn og voksne pasienter
- Ergonomisk, single-button navigering
- Bruker ett AAA batteri

3M™ Littmann® Elektroninen stetoskooppi Malli 3000, jossa mukana ympäristön häiriöäänien vähennys
Vahvistaa äänet, jotka haluat kuulla, vähentää häiriöääniä
- Äänet voidaan kuunnella jopa 18 kertaa vahvistettuna
- Vähentää ei-toivottujen häiriöäänien määrää jopa 75 prosenttia
- Taajuuksia on helppo vaihtaa matalien ja korkeiden äänien välillä
- Kevyt ja tasapainoinen
- Monipuolisella rintakappaleella voi kuunnella sekä vastasyntyneitä, lapsia että aikuisia
- Ergonominen, toimii yhdellä napinpainalluksella
- Toimii yhdellä AAA alkaliparistolla

3M™ Littmann® Estetoscópio Electrónico Modelo 3000 com Redução do Ruído Ambiente
Amplifique os sons que deseja ouvir sem interferência do ruído ambiente
- Amplificação 18 vezes superior à do melhor estetoscópio convencional Littmann
- Redução do ruído ambiente incómodo até 75%
- Fácil alternância entre os modos de frequência da campânula e o diafragma
- Leve, permite um manuseamento equilibrado
- A versatilidade da campânula permite a utilização tanto em pacientes pediátricos como em adultos
- Ergonómico, com um só botão de funcionamento
- Utiliza uma pilha alcalina AAA

3M™ Littmann® Ηλεκτρονικό Στηθοσκόπιο Μοντέλο 3000 με το Νέο Χαρακτηριστικό Μείωσης Θορύβου
Ενίσχυση των ήχων που θέλετε να ακούσετε με ταυτόχρονη μειωση ανεπιθύμητων περιβαλλοντικών θορύβων
- Ενίσχυση ήχου μέχρι 18 φορές μεγαλύτερη από τα καλύτερα συμβατά στηθοσκόπια Littmann
- Μείωση ανεπιθύμητου θορύβου μέχρι και 75%
- Εύκολη αλλαγή συχνοτήτων από Bell (Κώδωνας) σε Diaphragm (Διάφραγμα)
- Ελαφρύ και καλά-ισορροπημένο
- Ο ευέλικτος κώδωνας του στηθοσκοπίου προσαρμόζεται για βρέφη, παιδιά και ενήλικες
- Εργονομικό, λειτουργία με το πάτημα ενός μόνο πλήκτρου
- Χρησιμοποιεί μία μπαταρία AAA (Απλή)

LOT

| | |
|---|---|
| Artwork No.: | 38-9018-5462-0 |
| Date: | 12/13/04 |
| Author: | S Barker |
| Supersedes: | 38-9018-3869-8 |
| Pkg Spec Ref: | 34-7057-4656-7 |
| Structure: | PC Base Wrap |

Scale: 1 Inch
all artwork prints black

201

# Master Shipper Label

3M

**Electronic Stethoscope Model 3000** **Black**
**with Ambient Noise Reduction**

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

**29 in • 70 cm** **1 Each / Box**

38-9018-3870-6

**3 Each**
QTY. B.U.

**3000BK29**

**70-2007-4494-7**
3M I.D. NO.

LOT

(01) 5 07 07387 56550 8

SCALE: 1 Inch
All prints black

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

3M

**Electronic Stethoscope Model 3000** **Black**
**with Ambient Noise Reduction**

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

**29 in • 70 cm** **1 Each / Box**

38-9018-3870-6

**3 Each**
QTY. B.U.

**3000BK29**

**70-2007-4494-7**
3M I.D. NO.

LOT

(01) 5 07 07387 56550 8

**Artwork #:** 38-9018-3870-6
Date: 8-18-04
Author: R Myhre
Supersedes: N/A
Pkg. Spec. Reference: Thermal
Structure: MCL

203

**SPECIAL 510(k): Device Modification**
**ODE Review Memorandum (Decision Making Document is Attached)**

**To:** THE FILE **RE:** DOCUMENT NUMBER K__050159_

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed.**

   **This change was for** changing the filtering from frequency domain filtering to time domain filtering.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and _____.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

(Reviewer's Signature) 02/16/2005 (Date)

Comments

revised:8/1/03

02/17/05

6

REVISED:3/14/95

**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

K 050159

Reviewer: Barun Maskara

Division/Branch: DCD/CEMB

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

Product To Which Compared (510(K) Number If Known): K050159

| | YES | NO | |
|---|---|---|---|
| 1. Is Product A Device | √ | | If **NO** = Stop |
| 2. Is Device Subject To 510(k)? | √ | | If **NO** = Stop |
| 3. Same Indication Statement? | √ | | 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<br>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 3M™ Littmann® Electronic Stethoscope Model 3000 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from 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 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. It is different from the predicate in that it does the filtering of sounds in time domain instead of frequency domain.

**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:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

# Memorandum

**DATE:** February 16, 2005

**FROM:** Barun Maskara
Cardiac Electrophysiology and Monitoring Branch/DCD, HFZ-450

**SUBJECT:** K050159- **Special**
3M™ Littmann® Electronic Stethoscope Model 3000
3M Health Care

**CONTACT:** Ginger Cantor
Senior Regulatory Affairs Associate
3M Health Care
3M Center, Bldg 275-5W-06
St. Paul, Minnesota- 55144-1000
Tel: 651-736-2101
Fax: 651-737-5320
Email: grcantor@mmm.com

**TO:** The Record

## BACKGROUND/ REGULATORY HISTORY

3M Health Care has submitted this 510(k) premarket notification for the 3M™ Littmann® Electronic Stethoscope Model 3000, to notify of a modification to the original device that was cleared under K041934. This 510(k) is a special 510(k) submission.

This is my first comprehensive review of this 510(k). Upon marketing clearance, the proposed device would be classified as Class II, under 21 CFR §870.1875, with panel and product code 74 DQD (Electronic Stethoscope).

## INTENDED USE

As taken from indications for use form, "The 3M™ Littmann® Electronic Stethoscope Model 3000 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from 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."

## DEVICE DESCRIPTION

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). Bell mode is primarily used for heart sounds auscultation and diaphragm mode is used for respiration sounds.

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. The level of concern of the software for the proposed device is stated to be minor by the sponsor.

The Model 3000 operates on one AAA alkaline battery.

## STERILIZATION

Sterilization is not an issue with the proposed device as the device is not intended to come in contact with any body fluid or is not intended to be internalized.

## MATERIALS/BIOCOMPATIBILITY

There is no change in the materials for the modifications in this submission. Hence no new issue of biocompatibility arises for the scope of modifications in this submission.

## SUBSTANTIAL EQUIVALENCE

*Modifications to the original device*

According to the sponsor, the modification that is the subject of this submission is the change in software. Software has been modified to change the internal signal processing



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model from a [redacted] There has been no change to the device specifications. This change provides for an improved acoustical fit to the (b)(4)Trade Secret Process. This software modification also improves the device's electrical signal-to-noise ratio. Sponsor has provided frequency response curves (page 20 of the submission) that show that the frequency response of the proposed device is very similar to the predicate device for both the modes of operation.

There are some other modifications made to the assembly and manufacturing process for the microphone and mount to improve the device's durability. Sponsor states that these modifications would not have required a 510(k) submission in itself, but just for the sake of completion, they include these changes in this submission. These changes include a modification to the adhesive and the addition of a flexible circuit cable. Also, the material for the patient interface portion of the diaphragm has been changed from a nitrile rubber to a silicone material and the Littmann brand logo is screened onto the silicone. This change was made to provide a more secure fit of the diaphragm onto the chestpiece. A thin polyurethane coat has been applied over the diaphragm to reduce frictional noise when the diaphragm is moved against the patient during auscultation. 3M concludes that these material changes do not provide any new or increased safety risk to the user or patient.

## PERFORMANCE TESTING

To support the safety and effectiveness of the modified device, 3M has performed the following design controls: Risk Analysis, Design Verification and Validation testing.

### Electrical Safety

Sponsor states that general safety testing was conducted on the original device and that the device modifications did not require repeating this safety testing. I believe that for the modifications stated in this submission it is acceptable.

### Verification and Validation plan

3M performed design verification activities for functional testing and software and have included the reports in Appendices 3 and 5 of the submission.

### Risk Analysis

After revising the original risk analysis, 3M concluded that the modifications described in this submission do not increase risk, and no new risks to the end-user or patient safety have been identified.

## Software Documentation

For software device application, adequate documentation on the software requirements, design, developmental processes, verification and validation testing is needed. The sponsor determines that the appropriate software classification is Minor level of concern and the software version used in the proposed device is 2.03.

Risk Assessment

Risk assessment has been performed and the report is presented in Appendix 5 of the submission. It states that all identified potential risks are acceptable and the severity classification of all potential hazards does not compromise user safety.

System Requirements and Design Plan

Appendices 6 and 7 provide with the software requirements and design plan.

The embedded software in E3000 mainly controls the 4 button controls and also performs the required filtering of the sound signal.

The hardware architecture consists of a [redacted]

Overall, the documentation submitted to describe the system requirements and design is adequate.

Software Verification and Validation Testing

Documentation regarding the verification and validation tests for E3000 is provided in Appendix 8.

## LABELING

The labeling for the proposed device consists of the User Manual, primary box artwork and Label set for the 3M Littmann Electronic Stethoscope Model 3000. The device is for OTC use.

User Manual provides an overview of the device including indications for use, instructions, information about general use and maintenance, device specifications and contact information of the manufacturer.

## REGULATORY INFORMATION

3M has submitted a 510(k) summary as per 21 CFR §807.92, a Truthful and Accurate Statement as per §807.87 and an Indications for Use Form.

## RECOMMENDATION

I recommend that the proposed device be found **Substantially Equivalent** to legally marketed Class II Electronic Stethoscope, as classified under 21 CFR §~~807~~ 870.1875 with a panel and product code 74 DQD.

| | | | |
|---|---|---|---|
| Barun Maskara | 02/16/05 Date | Elias Mallis<br>Branch Chief, CEMB | 02/17/05 Date |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) BARUN MASKARA

Subject: 510(k) Number K050159

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

| | | |
|---|---|---|
| Is this 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)? Please fill out form on H Drive 510k/boilers | ☐ YES | ☑ NO |

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☑ A 510(k) summary OR ☐ A 510(k) statement

N/A ☐ The required certification and summary for class III devices

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

The submitter requests under 21 CFR 807.95 (~~doesn't apply for SEs~~):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: DQD Class II

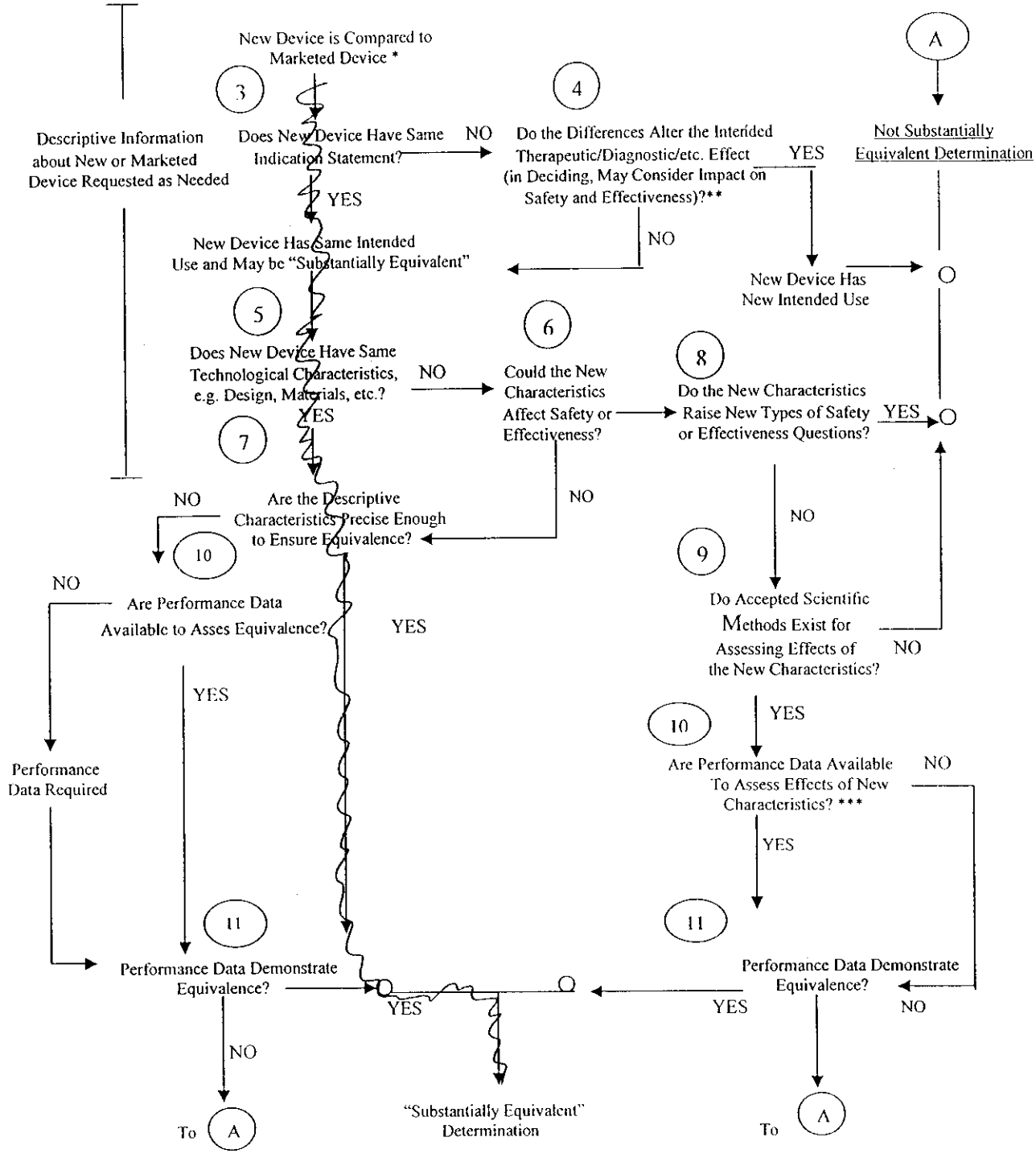
Additional Product Code(s) with panel (optional):

Review: [signature] (Branch Chief) CEMB (Branch Code) 02/17/05 (Date)

Final Review: [signature] (Division Director) 2/22/05 (Date)

Revised:4/2/03

# 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.