



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (smw)
FOLDER: K101834 - 349 pages
COMPANY: 3M COMPANY (3M)
PRODUCT: TRANSMITTERS AND RECEIVERS, PHYSIOLOGICAL SIGNAL, RADIOFREQUENCY (DRG)
SUMMARY: Product: 3M LITTMANN SCOPE-TO SCOPE SOFTWARE SYSTEM

DATE REQUESTED: Oct 21, 2015

DATE PRINTED: Oct 21, 2015

Note: Printed



510(k) Premarket Notification for 3M™ Littmann® Scope-to-Scope Software System

5.0 Premarket Notification (510(k)) Summary

Sponsor Information:

SEP 3 2010

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

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

Date of Summary: June 30, 2010

Device Name and Classification:

Common or Usual Name: Telemedicine Module

Proprietary Name: 3M™ Littmann® Scope-to-Scope Software System

Classification Name: Transmitters and receivers, physiological signal,
radiofrequency (21 CFR § 870.2910)

Performance Standards: N/A

Predicate Device:

CareTone® Telephonic Stethoscope (K973873 American TeleCare's Digital Personal Telemedicine Module)

510(k) Premarket Notification for 3M™ Littmann® Scope-to-Scope Software System

Description of Device:

The 3M™ Littmann® Scope-to-Scope Software System consists of software on a CD working with two 3M Littmann® Model 3200 Electronic Stethoscopes (cleared under K083903), such that when the software program is installed onto a PC, the software provides and controls real time data transfer of body sounds between two 3M Littmann® Model 3200 Electronic Stethoscopes over a data network. The sound captured by the stethoscope at the Patient site can be heard equivalently at both the Patient and Consulting sites through the Model 3200 headsets. The Scope-to-Scope Software System can be used on any person undergoing a physical assessment, thereby enabling health care professionals in remote clinics to obtain a second opinion from clinicians in a different location.

Both sites' Model 3200 electronic stethoscopes are connected to Microsoft Windows-based PC's via a Bluetooth wireless link. The two PC's are then connected to each other over a TCP/IP data network. The software allows for the Consulting site to control the Patient site's filter settings remotely when connected. The software also provides for the ability to facilitate verbal communication using the stethoscope's 'talk-through' feature that utilizes an expanded frequency range to better capture voice audio. This allows the Consultant to provide verbal cues and/or directions to the Patient site.

Indications for Use:

The 3M™ Littmann® Scope-to-Scope software System is intended to provide and control the real time data transfer of body sounds between two 3M™ Littmann® Electronic Stethoscopes, Model 3200 over a data network. It can be used on any person undergoing a physical assessment.

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

Information provided in this 510(k) submission shows that the 3M™ Littmann® Scope-to-Scope Software System is substantially equivalent to the predicate device CareTone® Telephonic Stethoscope (American TeleCare's Digital Personal Telemedicine Module) cleared under K973873 in terms of intended use, indications for use, composition, physical properties and technological characteristics. There are no new questions of safety or effectiveness.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

SEP 3 2010

3M Company
3M Health Care
c/o Ms. Jizhong Jin
3M Health Center, Bldg. 275-05-W-06
St. Paul, MN 55144-1000

Re: K101834
Trade/Device Name: 3M Littman Scope to Scope Software System (TS1000P, RS1000C, 3200TMC)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: June 30, 2010
Received: July 1, 2010

Dear Ms. Jin:

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

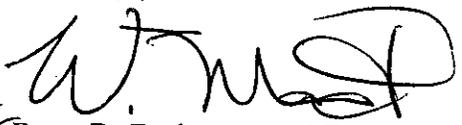
Page 2 - Ms. Jizhong Jin

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman

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

Enclosure

510(k) Premarket Notification for 3M™ Littmann® Scope-to-Scope Software System

4.0 Indications for Use Statement

SEP 3 2010

Indications for Use

510(k) Number (if known):

Device Name: 3M™ Littmann® Scope-to-Scope Software System

Indications For Use:

The 3M™ Littmann® Scope-to-Scope Software System is intended to provide and control the real time data transfer of body sounds between two 3M™ Littmann® Electronic Stethoscopes, Model 3200 over a data network. It can be used on any person undergoing a physical assessment.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

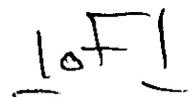
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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101834





Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

SEP 3 2010

3M Company
3M Health Care
c/o Ms. Jizhong Jin
3M Health Center, Bldg. 275-05-W-06
St. Paul, MN 55144-1000

Re: K101834
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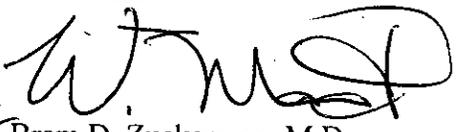
Page 2 - Ms. Jizhong Jin

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Sincerely yours,



Bram D. Zuckerman

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

Enclosure

510(k) Premarket Notification for 3M™ Littmann® Scope-to-Scope Software System

4.0 Indications for Use Statement

SEP 3 2010

Indications for Use

510(k) Number (if known):

Device Name: 3M™ Littmann® Scope-to-Scope Software System

Indications For Use:

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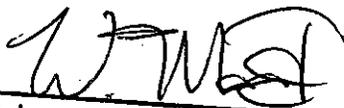
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

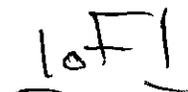
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number 6101834





U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center, WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 01, 2010

3M COMPANY
3M HEALTH CARE
3M CENTER, BLDG. 275-05-W-06
ST. PAUL, MINNESOTA 55144-1000
UNITED STATES
ATTN: JIZHONG JIN

510k Number: K101834
Received: 7/1/2010
Product: 3M LITTMANN SCOPE-TO SCOPE SOF

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

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

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

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

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

510(k) Premarket Notification for 3M™ Littmann® Scope-to-Scope Software System

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

Submission Date:
June 30, 2010

Contact: Jizhong Jin
Contact's Phone: (651) 733-6655
Contact's Fax: (651) 737-5320
Contact's Email: jjin1@mmm.com

K-64

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Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.		
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html				
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) 3M COMPANY CORP 3M CENTER BLDG 275 5W 06 ST PAUL MN 55144-1000 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****7775	2. CONTACT NAME Jizhong Jin 2.1 E-MAIL ADDRESS jjin1@mmm.com 2.2 TELEPHONE NUMBER (include Area code) 651-7336655 2.3 FACSIMILE (FAX) NUMBER (Include Area code)			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) Select an application type: <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice </td> <td style="width: 50%; vertical-align: top;"> 3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) </td> </tr> </table>			<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
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4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:				
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)				
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially </td> </tr> </table>			<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO				
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		21-Jun-2010		

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET	Form Approval OMB No. 0910-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.
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Date of Submission June 30, 2010	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
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SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name 3M Company	Establishment Registration Number (if known) 2110898		
Division Name (if applicable) 3M Health Care	Phone Number (including area code) 651-733-6655		
Street Address 3M Center, Building 275-05-W-06	FAX Number (including area code) 651-737-5320		
City St. Paul	State / Province Minnesota	ZIP/Postal Code 55144	Country USA
Contact Name Jizhong Jin			
Contact Title Regulatory Affairs Specialist		Contact E-mail Address jjin1@mmm.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager	
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment	
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address	
<input type="checkbox"/> Other Reason (<i>specify</i>):			

SECTION D2			REASON FOR APPLICATION - IDE
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing	
	<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		
<input type="checkbox"/> Other Reason (<i>specify</i>):			

SECTION D3			REASON FOR SUBMISSION - 510(k)
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology	
<input type="checkbox"/> Other Reason (<i>specify</i>):			

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	DRG	2	3	4	<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
5		6	7	8	

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

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K973873	CareTone® Telephonic Stethoscope - American TeleCare Digital Personal Telemedicine Module	American TeleCare, Inc.
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
 transmitters and receivers, physiological signal, radiofrequency

	Trade or Proprietary or Model Name for This Device	Model Number
1	3M™ Littmann® Scope-to-Scope Software System	1
2		2
3		3
4		4
5		5

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

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

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code DRG	C.F.R. Section (if applicable) 21 CFR 870.2910	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Cardiovascular		

Indications (from labeling)
 The 3M™ Littmann® Scope-to-Scope software System is intended to provide and control the real time data transfer of body sounds between two 3M™ Littmann® Electronic Stethoscopes, Model 3200 over a data network. It can be used on any person undergoing a physical assessment.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number (if known)	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	
<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler			
Company / Institution Name 3M Company		Establishment Registration Number 2110898	
Division Name (if applicable) 3M Health Care		Phone Number (including area code) 651-733-4365	
Street Address 3M Center, Bldg. 275-5W-06		FAX Number (including area code) 651-737-5320	
City St. Paul		State / Province Minnesota	ZIP Code 55144
		Country USA	
Contact Name Suzanne M. Danielson		Contact Title Director, Regulatory Affairs and Quality	Contact E-mail Address smdanielson@mmm.com
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	
<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler			
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City		State / Province	ZIP Code
		Country	
Contact Name		Contact Title	Contact E-mail Address
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	
<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler			
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City		State / Province	ZIP Code
		Country	
Contact Name		Contact Title	Contact E-mail Address

SECTION I UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 14971:2007	ISO	Medical Device - Application of Risk Management to Medical Devices	2nd edition	03/01/2007
2	IEC 80001-1	IEC	Application of risk management for IT-networks incorporating medical devices, Part 1: Roles, responsibilities and activities	1.0	08/11/2009
3	IEC 62304:2006	IEC/ISO	Medical device software -Software life cycle processes	1.0	05/01/2006
4					
5					
6					
7					

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

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

Department of Health and Human Services
 Food and Drug Administration
 Office of the Chief Information Officer (HFA-710)
 5600 Fishers Lane
 Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

3.0 510(k) Cover Letter

K101834

June 30, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

JUL 01 2010

Received

Re: 510(k) Premarket Notification for 3M™ Littmann® Scope-to-Scope Software System

Dear Sir or Madam:

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

3M™ Littmann® Scope-to-Scope Software System will be shown to be substantially equivalent to the CareTone® Telephonic Stethoscope (K973873 American TeleCare's Digital Personal Telemedicine Module) marketed by American TeleCare, Inc.

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

A wire transfer of \$4,007.00 was made to FDA on June 28, 2010 in support of this submission, and 3M's Medical Device User Fee Payment Identification Number for this submission is MD6050054-956733. Should you have any questions regarding this submission, please contact me at the phone number listed below.

Sincerely,



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

Phone (651) 733-6655
Fax: (651) 737-5320
jjin1@mmm.com

4.0 Indications for Use Statement

Indications for Use

510(k) Number (if known):

Device Name: 3M™ Littmann® Scope-to-Scope Software System

Indications For Use:

The 3M™ Littmann® Scope-to-Scope Software System is intended to provide and control the real time data transfer of body sounds between two 3M™ Littmann® Electronic Stethoscopes, Model 3200 over a data network. It can be used on any person undergoing a physical assessment.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

5.0 Premarket Notification (510(k)) Summary

Sponsor Information:

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

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

Date of Summary: June 30, 2010

Device Name and Classification:

Common or Usual Name: Telemedicine Module

Proprietary Name: 3M™ Littmann® Scope-to-Scope Software System

Classification Name: Transmitters and receivers, physiological signal,
radiofrequency (21 CFR § 870.2910)

Performance Standards: N/A

Predicate Device:

CareTone® Telephonic Stethoscope (K973873 American TeleCare's Digital Personal Telemedicine Module)

Description of Device:

The 3M™ Littmann® Scope-to-Scope Software System consists of software on a CD working with two 3M Littmann® Model 3200 Electronic Stethoscopes (cleared under K083903), such that when the software program is installed onto a PC, the software provides and controls real time data transfer of body sounds between two 3M Littmann® Model 3200 Electronic Stethoscopes over a data network. The sound captured by the stethoscope at the Patient site can be heard equivalently at both the Patient and Consulting sites through the Model 3200 headsets. The Scope-to-Scope Software System can be used on any person undergoing a physical assessment, thereby enabling health care professionals in remote clinics to obtain a second opinion from clinicians in a different location.

Both sites' Model 3200 electronic stethoscopes are connected to Microsoft Windows-based PC's via a Bluetooth wireless link. The two PC's are then connected to each other over a TCP/IP data network. The software allows for the Consulting site to control the Patient site's filter settings remotely when connected. The software also provides for the ability to facilitate verbal communication using the stethoscope's 'talk-through' feature that utilizes an expanded frequency range to better capture voice audio. This allows the Consultant to provide verbal cues and/or directions to the Patient site.

Indications for Use:

The 3M™ Littmann® Scope-to-Scope software System is intended to provide and control the real time data transfer of body sounds between two 3M™ Littmann® Electronic Stethoscopes, Model 3200 over a data network. It can be used on any person undergoing a physical assessment.

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

Information provided in this 510(k) submission shows that the 3M™ Littmann® Scope-to-Scope Software System is substantially equivalent to the predicate device CareTone® Telephonic Stethoscope (American TeleCare's Digital Personal Telemedicine Module) cleared under K973873 in terms of intended use, indications for use, composition, physical properties and technological characteristics. There are no new questions of safety or effectiveness.

6.0 Truthful and Accuracy Statement

Truthful and Accurate Statement

Pursuant to 21 CFR §807.87(k), I certify that, in my capacity as Regulatory Affairs Specialist 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.



Signature

Jizhong Jin

Typed Name

June 30, 2010

Date

7.0 Class III Summary and Certification

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

8.0 Financial Certification or Disclosure Statement

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

9.0 Declarations of Conformity and Summary Reports

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

10.0 Executive Summary

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

The following trade name is applicable to this device:

3M™ Littmann® Scope-to-Scope Software System

The common or usual names for this type of product:

Telemedicine Module

The classification name for this device:

Transmitters and receivers, physiological signal, radiofrequency
(21 CFR § 870.2910)

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

This 510(k) Premarket Notification is submitted by:

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

3M™ Littmann® Scope-to-Scope Software System is manufactured by:

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

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

Transmitters and receivers, physiological signal, radiofrequency
(21 CFR § 870.2910)

Product Code: DRG

The appropriate classification panel is Cardiovascular.

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

There are no mandatory performance standards under section 514 of the Act to which this device is subject.

10.5 Concise Description of Device

The 3M™ Littmann® Scope-to-Scope Software System consists of software on a CD working with two 3M Littmann® Model 3200 Electronic Stethoscopes (cleared under K083903), such that when the CD is installed onto a PC device, the software provides and controls real time data transfer of body sounds between two 3M Littmann® Model 3200 Electronic Stethoscopes over a data network. The Scope-to-Scope Software System can be used on any person undergoing a physical assessment, thereby enabling health care professionals in remote clinics to obtain a second opinion from clinicians in a different location.

Indications for Use:

The 3M™ Littmann® Scope-to-Scope Software System is intended to provide and control the real time data transfer of body sounds between two 3M™ Littmann® Electronic Stethoscopes, Model 3200 over a data network. It can be used on any person undergoing a physical assessment.

10.6 Device Comparison Table

Table of comparison of the 3M™ Littmann® Scope-to-Scope Software System and the CareTone® Telephonic Stethoscope (American TeleCare's Digital Personal Telemedicine Module)

Element		CareTone® Telephonic Stethoscope (American TeleCare's Digital Personal Telemedicine Module) (Predicate Device K973873)	3M™ Littmann® Scope-to-Scope Software System (New Device)	
Intended Use		Telemedicine programs	Telemedicine programs	
Indications for Use		Intended for use as a monitoring device, whereby a health care professional can, from a remote location, communicate with the patient between visits to gather blood pressure and pulse readings, as well as to listen to the patient's heart and lung sounds.	The 3M™ Littmann® Scope-to-Scope Software System is intended to provide and control the real time data transfer of body sounds between two 3M™ Littmann® Electronic Stethoscopes, Model 3200 over a data network. It can be used on any person undergoing a physical assessment.	
Sending Unit	Chest Piece	Yes	Yes	3M™ Littmann® Electronic Stethoscope, Model 3200 K083903
	Power Indicator Light	Yes	Yes	
	External Output	Yes	Yes	
Tele-communicating Unit		CareTone IP Software	3M™ Littmann® Scope to Scope Software	
Receiving Unit	Headphones	Yes	Headset with eartips	3M™ Littmann® Electronic Stethoscope, Model 3200
	Volume Control	Yes	Yes	

	Switch to Select either Bell or Diaphragm Frequency Sounds	Yes	Yes	K083903
Communication Interface		PC based	PC based	
Geographic Locations of the Devices	Remote Site (Patient's site)	Yes	Yes	
	Consultant Site (Doctor's site)	Yes	Yes	

Based on the above comparison, 3M finds the 3M™ Littmann® Scope-to-Scope Software System substantially equivalent to the CareTone® Telephonic Stethoscope (American TeleCare's Digital Personal Telemedicine Module).

The system proposed under this premarket notification submission is composed of the same or similar components, has same or similar performance features, same intended use and indications for use as the predicate device. There are no new questions of safety or effectiveness.

10.7 Concise Summary of Performance Testing

This submission includes data from bench testing to evaluate the performance of the 3M™ Littmann® Scope-to-Scope Software System. Although there are no specific performance standards for this device, the device was tested to meet the design specification requirements.

Please see Section 18 for additional details.

This submission does not include animal or clinical performance testing.

11.0 Device Description

11.1 General Description

The 3M™ Littmann® Scope-to-Scope Software System consists of software on a CD working with two 3M™ Littmann® Model 3200 Electronic Stethoscopes (cleared under K083903), such that when the software program is installed onto a PC, the software provides and controls real time data transfer of body sounds between two 3M™ Littmann® Model 3200 Electronic Stethoscopes over a data network. The sound captured by the stethoscope at the Patient site can be heard equivalently at both the Patient and Consulting sites through the Model 3200 headsets. The Scope-to-Scope Software System can be used on any person undergoing a physical assessment, thereby enabling health care professionals in remote clinics to obtain a second opinion from clinicians in a different location.

The scope to scope software system has the ability to:

- Discover and pair available Littmann® 3200 scopes via a Bluetooth® connection
- Store the names of scopes being available for future use
- Manage available remote connections through an address book (consultant site only)
- Establish a connection from one scope to another
- Manage volume and filter settings
- Monitor the connectivity status

Both the patient site and consultant site use Microsoft Windows® computers to run the Scope-to-Scope Software which is installed from a CD-ROM. The Scope-to-Scope software is used to maintain the connection with each scope via a Bluetooth® connection. Once scopes are connected to their respective computers, the two sites connect via a secured TCP/IP connection to allow the consultant site to hear the body sounds from the patient site. The consultant site is also able to control the patient site filter settings. In addition, the software provides a 'talk-through' mode that allows the consultant to privately communicate to the patient scope via the patient scope headset.

11.2 Digital Communication Feature

Transmission of sound data back and forth between patient and consultant scope to scope software is monitored for delay and accuracy. Sound quality errors or delays, the loss of packets or malformed packets are reported to the end user hearing the sound via an audible tone and an alert showing a network communications error/problem. Any condition impacting sound reproduction at the received site is identified via the error tone and visual indication on the application for that scope.

The system requires a TCP/IP network between the two computers that has the available bandwidth of 128K bps. This bandwidth is used for the communication of encrypted sound data and the control data utilized for managing the connection. Disruption of the required bandwidth is indicated through an audible error tone and visual indication on the application for that scope.

The general condition of the system is communicated by the Quality of Service Indicator (QSI) within the Scope-to-Scope Software. The QSI monitors the general condition of the Bluetooth connection to the connected scope and the TCP/IP connection to the remote computer. The QSI indicates three potential conditions:

1. Green – Good connection – Communication can occur as expected with no interruption.
2. Grey – Recovering connection – Bluetooth disconnect, network delay, data resynchronization, or low bandwidth.
3. Red – No connection

11.3 Available Models

TS1000P - Littmann® Scope-to-Scope Software System - Patient Edition
TS1000C - Littmann® Scope-to-Scope Software System - Consultant Edition
3200TMC - Littmann® Scope-to-Scope Starter Kit (includes Littmann® Electronic Stethoscope Model 3200 + TS1000C)

11.4 Proposed Claims

In addition to the indications for use, the claims to be used in the promotion and advertising of the 3M™ Littmann® Scope-to-Scope Software System are listed below.

- Digital, real-time communication between two (2) standard Model 3200 Littmann stethoscopes across a data network without limit in distance between Consultant and Patient sites.
 - Software enables real-time, digital sound transfer of Patient heart, lung or other body sounds to Consultant site.
- Software sends secure, encrypted digital signal across a network
- Sound reproduction in headset of 'Consultant' stethoscope equivalent ('has same superior Littmann sound') to that in headset of 'Patient' stethoscope.
 - Sounds heard at Consultant (remote) site are the same as heard at Patient (local).
 - Allows Consultant to hear in real-time the same digital sound captured at Patient site

- Consultant and Patient stethoscope users can independently control their own sound level without affecting the volume of the other stethoscope.
- Talk-through feature lets Consultant privately communicate with user of Patient site stethoscope.
 - Talk-through feature lets user of Consultant stethoscope speak into chestpiece while user of Patient stethoscope listens through their headset/eartips

Proposed claims will be substantiated prior to marketing product.

11.5 Performance Specification

	The 3M™ Littmann® Scope-to-Scope Software System
Intended Use	Telemedicine
Indications for Use	The 3M™ Littmann® Scope-to-Scope software System is intended to provide and control the real time data transfer of body sounds between two 3M™ Littmann® Electronic Stethoscopes, Model 3200 over a data network. It can be used on any person undergoing a physical assessment.
Platform	Microsoft Windows Platform
Network	TCP/IP Network
Bandwidth	128K bps or greater
Consultant Remote Filter Control	Yes
Local Patient Volume Control	Yes
Local Consultant Volume Control	Yes
Connection Indicator	Yes
Connection Quality Indication	Audible and Visual
Sound Characteristics	Same as Model 3200
Scope Characteristics	Same as Model 3200
Quality of Service Indicator (QSI)	Yes
Continuous Bandwidth Measurement	Yes

12.0 Substantial Equivalence Discussion

Summary Statement

The 3M™ Littmann® Scope-to-Scope Software System is substantially equivalent to the CareTone® Telephonic Stethoscope (American TeleCare's Digital Personal Telemedicine Module cleared under K973873).

The 3M™ Littmann® Scope-to-Scope Software System proposed under this new premarket notification submission is composed of the similar components, and has similar performance features, intended use and indications for use as the CareTone® Telephonic Stethoscope (American TeleCare's Digital Personal Telemedicine Module).

Table of comparison of the intended use and indications for use of the 3M™ Littmann® Scope-to-Scope Software System and the CareTone® Telephonic Stethoscope (American TeleCare's Digital Personal Telemedicine Module)

Element	CareTone® Telephonic Stethoscope (American TeleCare's Digital Personal Telemedicine Module) (Predicate Device K973873)	3M™ Littmann® Scope-to-Scope Software System (New Device)
Intended Use	Telemedicine programs	Telemedicine programs
Indications for Use	Intended for use as a monitoring device, whereby a health care professional can, from a remote location, communicate with the patient between visits to gather blood pressure and pulse readings, as well as to listen to the patient's heart and lung sounds.	The 3M™ Littmann® Scope-to-Scope Software System is intended to provide and control the real time data transfer of body sounds between two 3M™ Littmann® Electronic Stethoscopes, Model 3200 over a data network. It can be used on any person undergoing a physical assessment.

This table identifies the larger external components for the Littmann® Scope-to-Scope Software System and the CareTone® Telephonic Stethoscope (American TeleCare's Digital Personal Telemedicine Module)

Element		CareTone® Telephonic Stethoscope (American TeleCare's Digital Personal Telemedicine Module) (Predicate Device K973873)	3M™ Littmann® Scope-to-Scope Software System (New Device)	
Sending Unit	Chest Piece	Yes	Yes	3M™ Littmann® Electronic Stethoscope, Model 3200 K083903
	Power Indicator Light	Yes	Yes	
	External Output	Yes	Yes	
Tele-communicating Unit		CareTone IP Software	3M™ Littmann® Scope to Scope Software	
Receiving Unit	Headphones	Yes	Headset with eartips	3M™ Littmann® Electronic Stethoscope, Model 3200 K083903
	Volume Control	Yes	Yes	
	Switch to Select either Bell or Diaphragm Frequency Sounds	Yes	Yes	
Communication Interface		PC based	PC based	
Geographic Locations of the Devices	Remote Site (Patient's site)	Yes	Yes	
	Consultant Site (Doctor's site)	Yes	Yes	

This table summarizes the similar and different performance features of the Littmann® Scope to Scope Software Telemedicine System and American TeleCare’s Digital Personal Telemedicine Module

Element		CareTone® Telephonic Stethoscope (American TeleCare’s Digital Personal Telemedicine Module) (Predicate Device K973873)	3M™ Littmann® Scope-to-Scope Software System (New Device)
Auscultation Mode	Bell	Yes	Yes
	Diaphragm	Yes	Yes
Local communication protocol (scope to PC)		Serial communications using RS232.	Serial communications using wireless (Bluetooth)
Communication Protocol		TCP/IP	TCP/IP
Real time communication		Yes	Yes
True-to-life sound delivery		Yes	Yes

Conclusion

Based on the above comparison, 3M finds the 3M™ Littmann® Scope-to-Scope Software System substantially equivalent to the CareTone® Telephonic Stethoscope (American TeleCare’s Digital Personal Telemedicine Module K973873).

The system proposed under this premarket notification submission is composed of the same or similar components, has same or similar performance features, same intended use and indications for use as the predicate device. There are no new questions of safety or effectiveness.

13.0 Product Labeling

Copies of the proposed labeling for the 3M™ Littmann® Scope-to-Scope Software System are included in Appendix 1 of this submission. The User Manual is included in this submission in Appendix 2.

For Model 3200 TMC, each primary box contains one (1) Software CD, one (1) Model 3200 Electronic Stethoscope, the User Manual and the Quick Start Guide.

Reference labeling for the predicate device, CareTone® Telephonic Stethoscope (American TeleCare's Digital Personal Telemedicine Module), is included in Appendix 3

14.0 Sterilization and Shelf Life

14.1 Sterilization

Sterilization is not applicable. 3M™ Littmann® Scope-to-Scope Software System is not labeled nor otherwise represented as sterile, nor did it intend to be sterilized by the user.

14.2 Shelf Life

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

15. Biocompatibility

Not applicable, this device does not come into direct or indirect contact with patients.

16. Software

16.1 Overview

3M reviewed the ODE/OIVD Document "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices" issued May 11, 2005. This document requires the completion and submission of "Level of Concern" by the manufacturer. The manufacturer outlines the documentation required in the pre-market notification submission. 3M has determined that this software has a moderate level of concern, as illustrated in the following paragraphs.

1) Does the Software Device qualify as Blood Establishment Computer Software?

No, 3M™ Littmann® Scope-to-Scope Software System does not qualify as Blood Establishment Computer Software.

2) Is the Software Device intended to be used in combination with a drug or biologic?

No, 3M™ Littmann® Scope-to-Scope Software System is not intended to be used in combination with a drug or biologic.

3) Is the Software Device an accessory to a medical device that has a Major Level of Concern?

No, 3M™ Littmann® Scope-to-Scope Software System is not an accessory to a medical device that has a Major Level of Concern.

4) Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device?

No, a failure of 3M™ Littmann® Scope-to-Scope Software System could not result in death or serious injury, either to a patient or to a user of the device.

a) Does the Software Device control a life supporting or life sustaining function?

No, 3M™ Littmann® Scope-to-Scope Software System does not control a life supporting or life sustaining function

b) Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?

No, 3M™ Littmann® Scope-to-Scope Software System does not control the delivery of potentially harmful energy that could result in death or serious injury.

- c) Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?

No, 3M™ Littmann® Scope-to-Scope Software System does not control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury.

- d) Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?

No, 3M™ Littmann® Scope-to-Scope Software System does not provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death.

- e) Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?

No, 3M™ Littmann® Scope-to-Scope Software System does not provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary.

Moderate Level of Concern

- 1) Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?

3M™ Littmann® Scope-to-Scope Software System is not an accessory to a medical device that has a Moderate Level of Concern. The software system contains two 3M Littmann® Electronic Stethoscope Model 3200 which has a Moderate Level of Concern.

- 2) Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?

No, a failure of the 3M™ Littmann® Scope-to-Scope Software System could not result in Minor Injury, either to a patient or to a user of the device.

- 3) Could a malfunction of , or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?

Yes, a malfunction of , or a latent design flaw in, the Software Device **could** lead to a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

As summarized in the table below, because 3M has determined that the level of concern is "Moderate", 3M has provided the documentation required according to Table 3 of the Guidance Document as appendices to this submission.

Documentation Based on Level of Concern

Software Documentation	Requirements for "Moderate" Concern	Documentation Reference(s)	Appendices	Comments
Level of Concern	Required	Moderate: The rational is included above		
Software Description	Required		Appendix 4	
Device Hazard Analysis	Required	RISK-MGMT-GL-05-130740	Appendix 5	
Software Requirements Specification (SRS)	Required	DS-INPUT-05-128618	Appendix 6	The complete SRS document
Architecture Design Chart	Required	DS-INPUT-05-136719	Appendix 7	Section 5
Software Design Specification (SDS)	Required	DS-INPUT-05-136719	Appendix 7	
Traceability Analysis	Required	DS-VER-05-134069	Appendix 8	Section 9.3
Software Development Environment Description	Required	DS-SOFTWARE-05-137066	Appendix 9	Section 2.1.1.2 Summary of software life cycle development plan, including a summary of the configuration management and maintenance activities
Verification and Validation	Required	DS-VER-05-134069	Appendix 8	Description of V&V activities

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Documentation				at the unit, integration, and system level. System level test protocol, including pass/fail criteria, and tests results.
Revision Level History	Required	DS-SOFTWARE-05-137066	Appendix 9	Section 3.1.2.1
Unresolved Anomalies (Bugs or Defects)	Required	DS-VER-05-134069	Appendix 8	Section 9.4

Conclusion:

Based on the information and supporting data noted above, 3M considers the level of concern to be "Moderate". According to ODE/OIVD Document "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices" issued May 11, 2005, the definition of "Moderate" is as follows: "If a failure or latent design flaw could directly result in minor injury to the patient or operator, and/or if a failure or latent design flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider".

17.0 Electromagnetic Compatibility and Electrical Safety

Not applicable to the software part, the device design does not include an electronic component and the design does not result in patient contact. The 3M™ Littmann® Electronic Stethoscope, Model 3200 included in this submission has been cleared by FDA under K083903. All EMC and electrical safety issues related to the stethoscope have been addressed in its 510(k) filing.

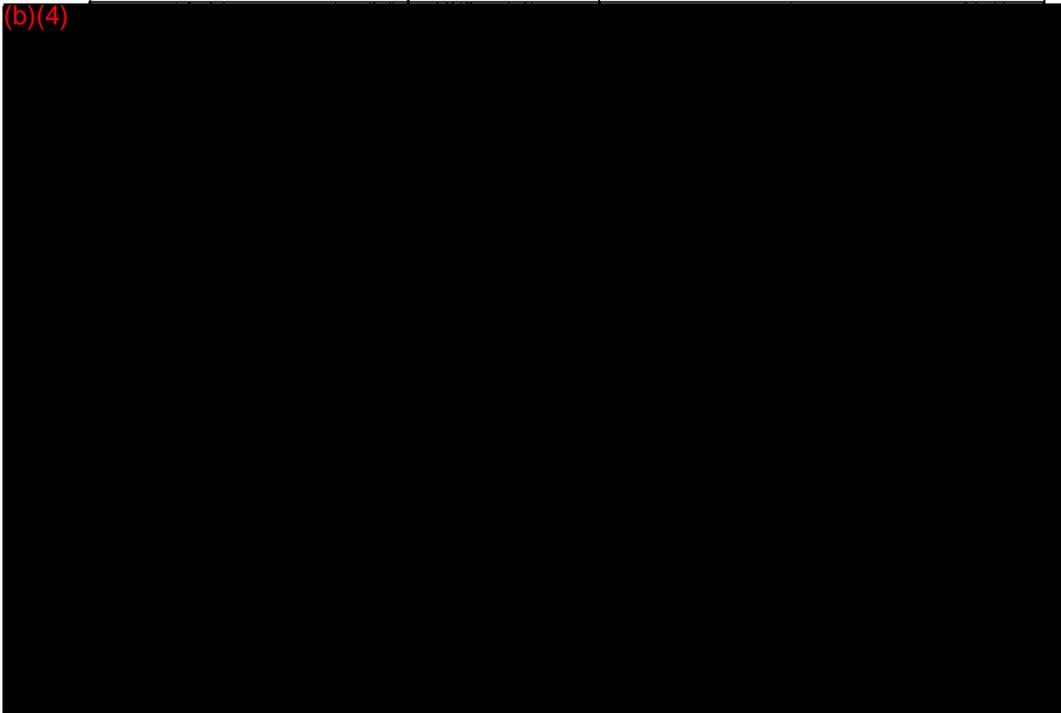
18.0 Performance Testing – Bench

The system was subjected to various sound quality and quality of service tests as part of design verification testing as summarized below. Each test was conducted on the platforms identified as compatible in the “Scope-to-Scope Software Verification Plan & Report” (DS-VER-05-134069; see Appendix 8).

Sound Quality and Quality of Service

Test	Test Results	Documentation Reference
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(b)(4)

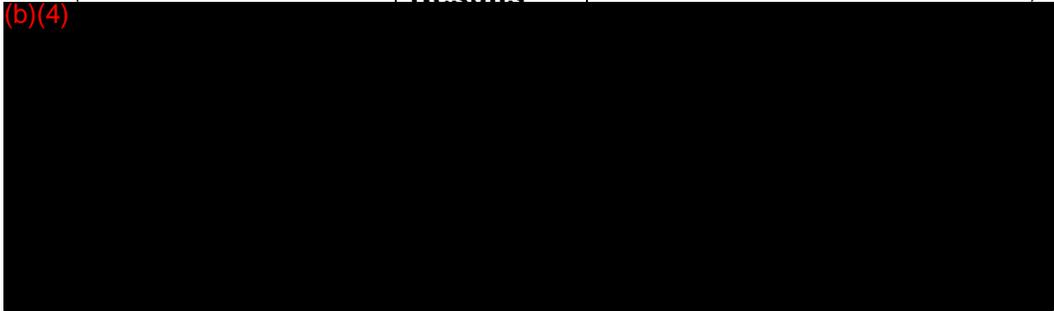


The system was subjected to network and connectivity testing as a part of the verification testing as summarized below. Each test was conducted on the platforms identified as compatible.

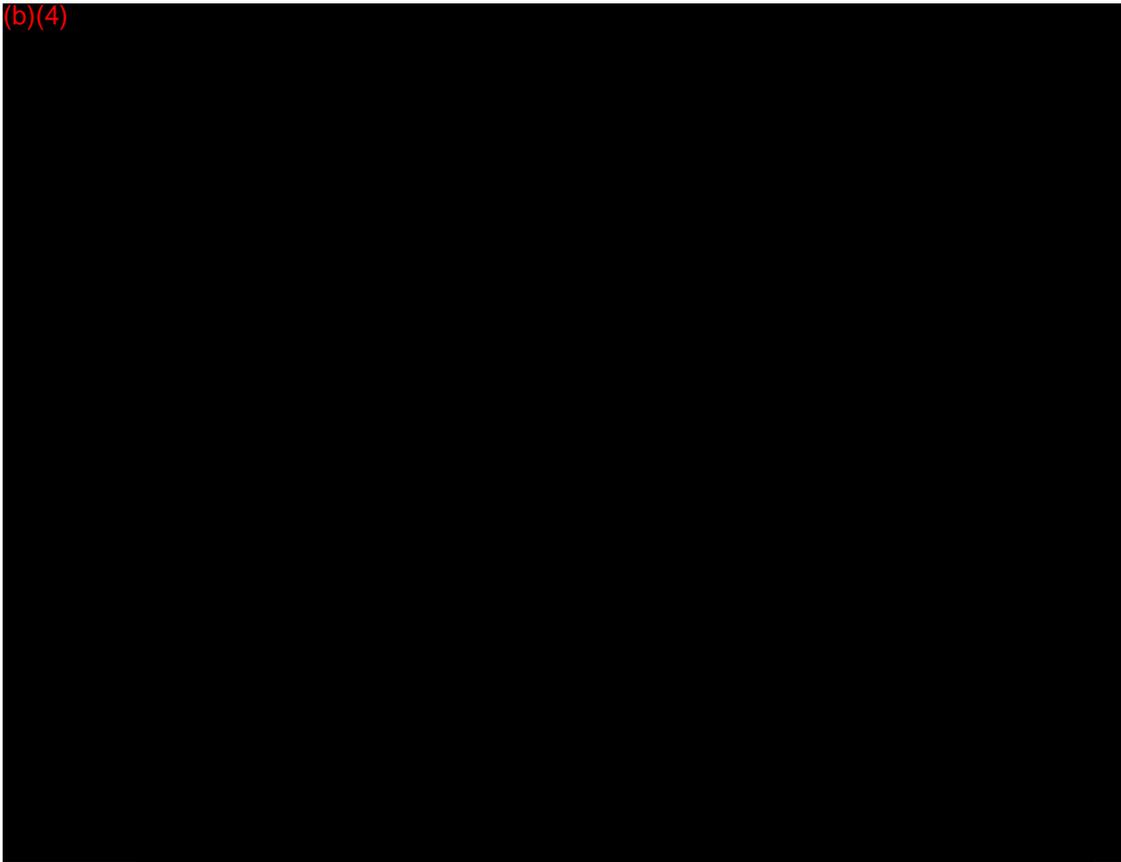
Network and Connectivity

Test	Test Results	Documentation Reference
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(b)(4)



(b)(4)

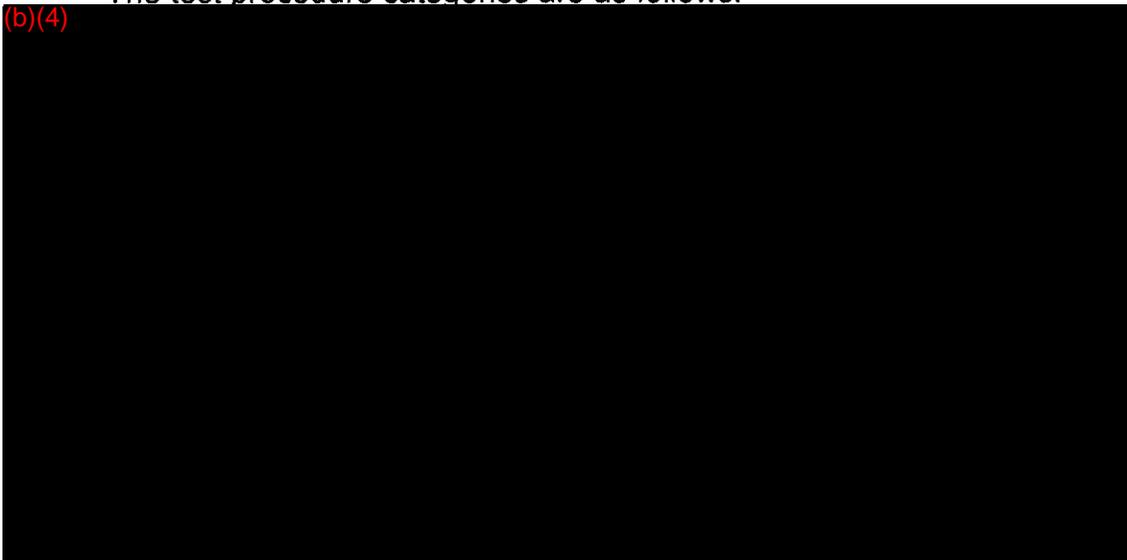


Individual test procedures are documented in the “Scope-to-Scope Test Procedures – Release 1.0” (see Appendix 8) with the platform and test execution information contained in the “Scope-to-Scope Software Verification Plan & Report” (DS-VER-05-134069; see Appendix 8).

Test procedures and results relating to licensing, user interface specifications, installation and platform verification can be found in addition to the categories listed above.

The test procedure categories are as follows:

(b)(4)



19.0 Performance Testing – Animal

Not applicable, this submission does not contain animal performance testing.

20.0 Performance Testing – Clinical

Not applicable, this submission does not contain clinical performance testing.

21.0 Risk Management

3M evaluated 3M™ Littmann® Scope-to-Scope Software System using a process compliant with ISO 14971:2007 Risk Management for Medical Devices, and specific procedures and practices outlined by division Standard Operating Procedures.

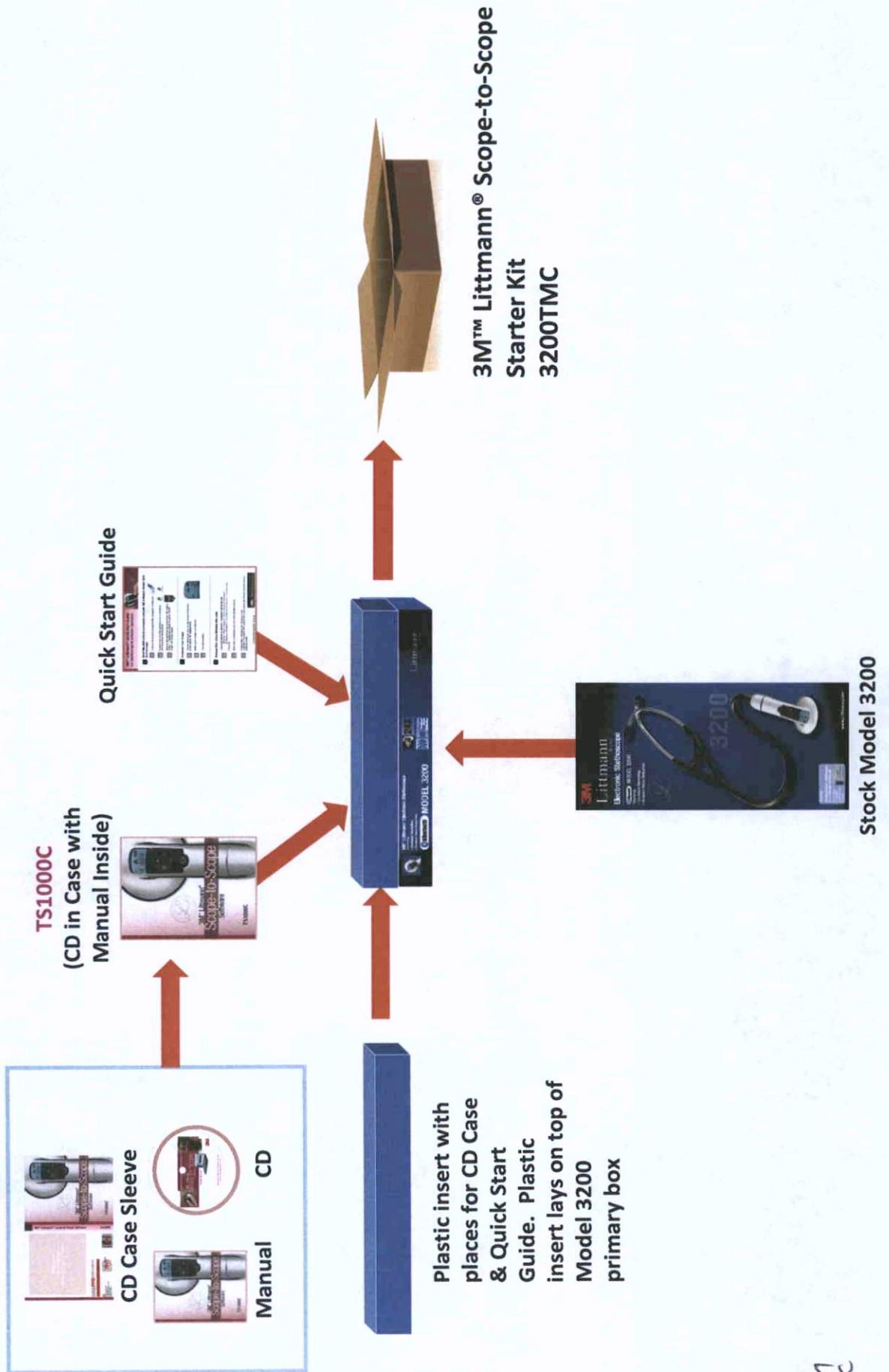
The 3M™ Littmann® Scope-to-Scope Software System has completed all risk management activities as identified in the product risk management plan. All known and foreseeable risks, both in normal and fault conditions, along with the overall residual risks, are at an acceptance level. Appropriate methods for monitoring of post production information have been established in the risk management plan.

Please refer to Appendix 5 for the copy of Risk Management.



3M™ Littmann® Scope-to-Scope Starter Kit 3200TMC

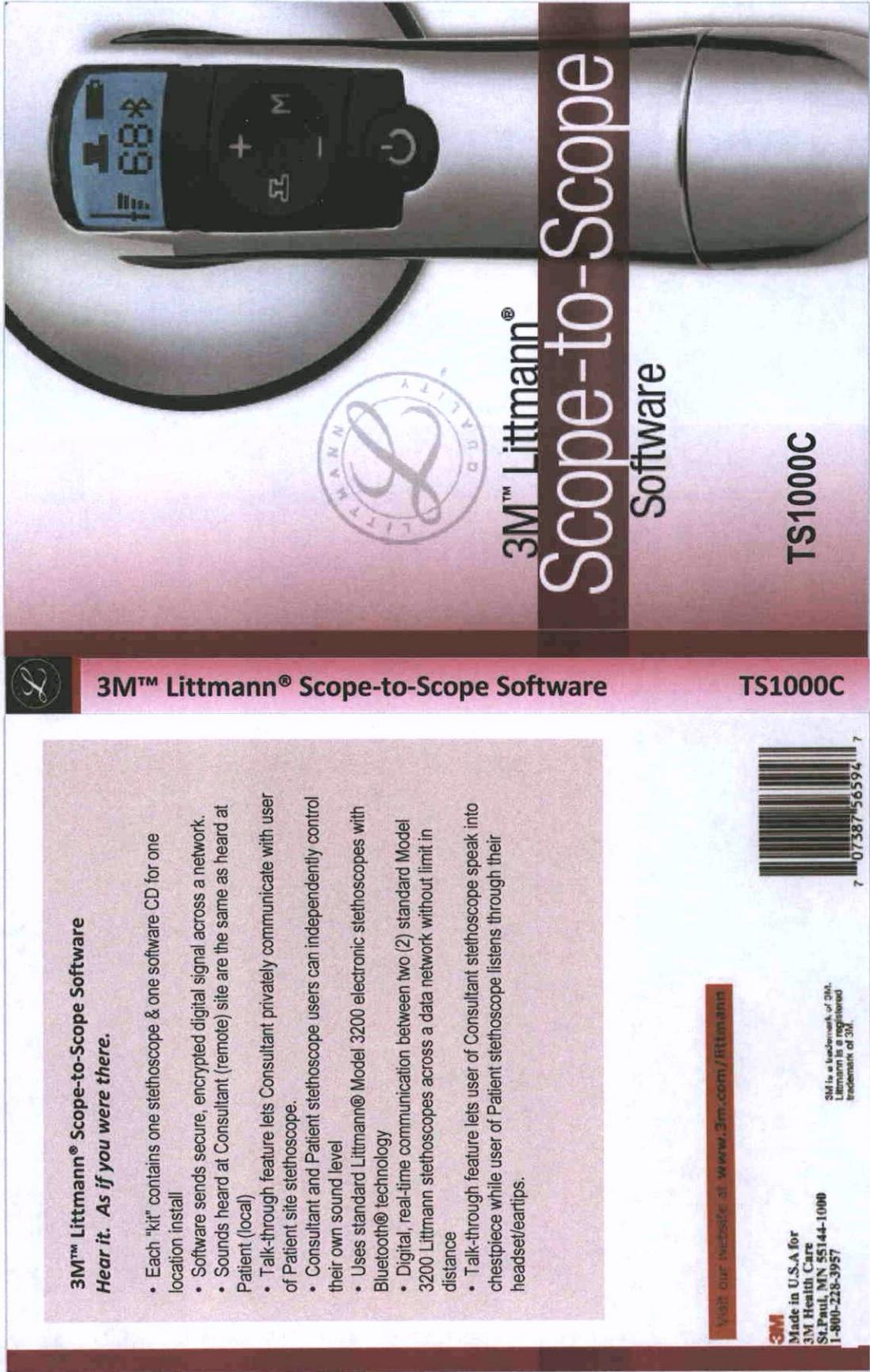
Components



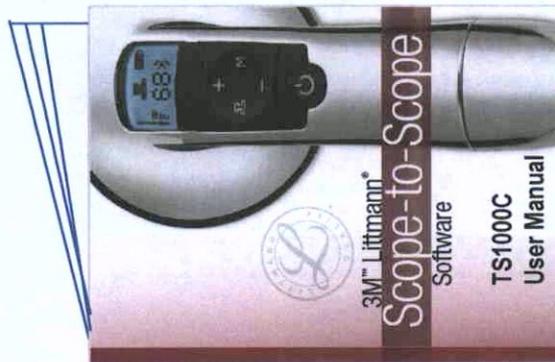
Scope-to-Scope CD



Scope-to-Scope DVD Cover Sleeve



Scope-to-Scope User Manual Cover



Scope-to-Scope Quick Start Guide – Laminated

3M™ Littmann® Quick Start Guide For Stethoscope & Software Operation

1 Start the S2S software program and pair 3M Littmann Model 3200 Stethoscope

- Connect Bluetooth dongle to the computer's USB port
- Double click the S2S desktop icon and follow the on-screen instructions
- Turn on the Stethoscope and press "M" button
Press "..." button four times to get to "PAIR"
Press "M" button again

2 Connect Your Scope

- Ensure Bluetooth icon on the scope is flashing
If not, press "M" button twice
- Select your scope from the list
- Click Next button

3 Patient Site: Allow Remote Site Link

- Click Add button to add the Consultant site to the list
Nickname = Name you give to remote site (can be any name)
IP Address or Hostname = Consultant site IP address or computer name
Click OK
- Select the Consultant site and click the Next button
- Patient Site: Waiting for Remote Link
Until the Consultant site makes the connection, the Patient site will show a waiting status



Connection indicator is gray

4 Consultant Site: Link Remote Site

- Click Add button to add the Patient site to the list
Nickname = Name you give to remote site (can be any name)
IP Address or Hostname = Patient site IP address or computer name
Click OK
- Select the Patient site and click the Next button

5 Connection is established:

Both Consultant and Patient connection indicators turn green



Consultant Site

Listen to Patient scope
Consultant scope can listen to Patient scope



Patient Site

Listen locally
Patient scope listens to patient



Click "M" button:
Consultant can talk into scope chestpiece



Patient scope can hear Consultant talk

Click "M" button again to disable Talk feature

Stethoscope Quick Reference



Three Filter settings: Bell, Diaphragm, and Extended Range

Once connection is made:

- The Consultant site controls the filter setting on both Consultant and Patient scopes
- The Consultant and Patient sites control their own volume

3M™ Littmann® Scope-to-Scope Software

Introduction

Congratulations and thank you for choosing to use the 3M™ Littmann® Scope-to-Scope Software and the 3M™ Littmann® Electronic Stethoscope Model 3200 for your tele-auscultation needs.

The combination of the Littmann® Scope-to-Scope Software and the award winning Littmann® Electronic Stethoscope Model 3200 deliver an exceptional sound experience for clinicians at either end of the tele-auscultation experience. It redefines the traditional limits of tele-auscultation by offering a digitally equivalent sound experience at the near (Consultant) site as heard thru the eartips of the headset of the Littmann® Model 3200 at the remote (Patient) site stethoscope.

Add features like wireless Bluetooth® connectivity, ambient noise reduction technology, and the ability to control the settings on the remote stethoscope and you'll soon discover the richness of the Littmann® Electronic Stethoscope Model 3200 tele-auscultation experience.

Whether you are auscultating infant, pediatric or adult patients, in quiet or noisy environments, or picking up difficult-to-hear heart and body sounds, you'll appreciate all the technology that's been brought to your tele-auscultation experience with the Littmann® Scope-to-Scope Software and the Littmann® Electronic Stethoscope Model 3200 with Bluetooth® technology.

Don't miss the sounds you need to hear!

SAFETY INFORMATION

Please read, understand, and follow all safety information contained in these instructions prior to using the Scope-to-Scope software program. Retain these instructions for future reference.

Explanation of Signal Word Consequences	
 CAUTION:	Indicates a hazardous situation, which, if not avoided, could result in minor injury and/or property damage.
NOTICE:	Indicates a hazardous situation, which, if not avoided, may result in property damage.

U.S.A. ONLY

Caution: Federal law restricts this device to sale by or on the order of a physician

Intended Use

The 3M™ Littmann® Scope-to-Scope Telemedicine software program is intended to provide and control real-time data transfer of body sounds between two 3M Littmann® Model 3200 electronic stethoscopes over a data network. The Scope-to-Scope Telemedicine software program can be used on any person undergoing a physical assessment.

Operator Profile

The 3M™ Littmann® Scope-to-Scope software program is designed to be used by anyone who is familiar with the 3M™ Littmann® Model 3200 electronic stethoscope and who wishes to transfer body sounds over a data network in real time. The 3M™ Littmann® Scope-to-Scope manual provides complete information on how to operate the software program; thus no additional operating training is required.

Functional Description

The Littmann® Scope-to-Scope Telemedicine Software provides for the real-time transmission of body sounds from one Model 3200 electronic stethoscope to another Model 3200 electronic stethoscope over a data network. The sound captured by the stethoscope chestpiece at the Patient site can be heard equivalently at both the Patient and Consulting sites through the Model 3200's binaural headset.

Both sites' Model 3200 electronic stethoscopes are connected to Microsoft Windows-based PC's via a Bluetooth wireless link. The two PC's are then connected to each other over a TCP/IP data network. The software allows for the Consulting site to remotely control the Patient site's filter settings when connected. The software also provides for the ability to facilitate verbal communication using the stethoscopes through a Talk-through feature that utilizes an expanded frequency range to better capture voice audio. This allows the Consultant to provide verbal cues and/or directions to the Patient site.

INSTRUCTIONS FOR USE

This User Manual provides instructions for use of the Scope-to-Scope software program and assumes the user is familiar with the Microsoft Windows operating system on PC's. Littmann recommends that all personnel who use this software program thoroughly read and understand this User Manual. Use this product only with the 3M Littmann Model 3200 electronic stethoscope or other 3M approved products.

NOTE: The Scope-to-Scope software program should only be installed on a PC that meets the Minimum System Requirements. Installation and activation of the Scope-to-Scope Software requires administrative privileges on the PC. Once the application has been activated, other non-administrative users of the PC can use the software.

System Requirements

- Windows XP SP2 & SP3, Vista SP2, Windows 7 32 & 64 bit
- 1 GB of RAM or more
- 1 GHz or faster processor
- 1024 x 768 or higher-resolution display
- USB 1.1 port or greater
- Network Port 3200 (default setting and can be changed)
- 128Kbps Minimum Dedicated Bandwidth

IT Network Requirements:

- A standard TCP/IP based network with DHCP or static IP address assignment. PC to PC connectivity is supported via hardwire (i.e. CAT5) or wireless (i.e. 802.11g). The minimum dedicated bandwidth required per active Consultant/Patient connection is 128kbps.
- The 3M Littmann® Scope-to-Scope Software product requires communication through a TCP/IP port assignment. The port utilized by the application is configurable but by default is set to port 3200. The Patient and Consultant applications use bidirectional TCP/IP communication.
- The 3M Littmann® Scope-to-Scope Software product incorporates standard encryption techniques to encrypt the network communications between the Patient and Consultant applications.

Specifications of the USB wireless dongle:

- Compliant with Bluetooth V1.1, V1.2 & V2.0.
- Supporting profiles: Networking, Dial-up, Fax, LAN access, and Headset.
- Operating system: Windows XP, Vista & 7.
- Interface: Compliant with USB 1.1 & 2.0.
- Data transmission rate: 3Mbps.
- Working distance: 5-10m.
- FCC approval: FCC ID - WQ7 I-BTD-04.

NOTE: The USB Transceiver device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: 1. This device may not cause harmful interference, and 2. This device must accept any interference received, including interference that may cause undesired operation.

FCC NOTE: THE MANUFACTURER IS NOT RESPONSIBLE FOR ANY RADIO OR TV INTERFERENCE CAUSED BY UNAUTHORIZED MODIFICATIONS TO THIS EQUIPMENT. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

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NOTE: The Scope-to-Scope software program contains two separate applications:

1. **Patient Site:** Intended to be used by the healthcare presenter - one who is intending to transmit patient sounds to a healthcare provider.
2. **Consultant Site:** Intended to be used by the healthcare provider - one who is intending to listen to a remote patient.

In order for the Scope-to-Scope software to function properly, two PC's must have the software installed. Furthermore, one PC must be running the Consultant Site application and one PC must be running the Patient Site application.

1. Install the Scope-to-Scope Software

1. Insert the CD into the CD-ROM drive on your computer.
2. The installation program will start automatically. If the program does not start, open the CD folder and double click the file labeled setup.exe.
3. Follow the on-screen instructions to guide you through the installation process.

2. Insert and Install the USB Wireless Adaptor (Dongle)

The USB dongle allows communication between the Littmann Model 3200 stethoscope and the PC on which the Scope-to-Scope software program is installed. The dongle receives and transmits data via the commonly accepted Bluetooth® short range wireless connectivity standard. To install the dongle, insert the device into an open USB port of the PC. The Add New Hardware Device Wizard should start and install the USB dongle driver automatically. When running properly, a green light on the USB dongle should flash.

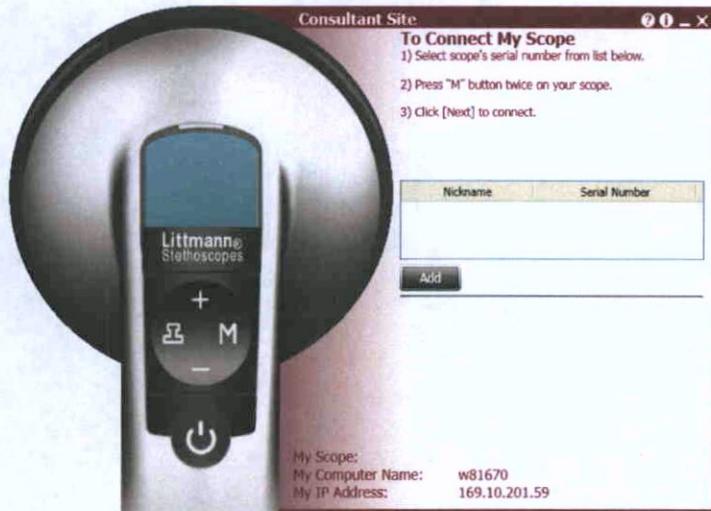
3. Start the Scope-to-Scope Software Program

With the USB dongle inserted into the PC, double click on either the Patient or Consultant desktop icon.

IMPORTANT: The dongle must be inserted into the USB port of the PC prior to starting the Scope-to-Scope software program.

4. Pair the Littmann Model 3200 Stethoscope to the Scope-to-Scope Software Program

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1. Click the [Add] button on the Scope-to-Scope software program to pair your Model 3200 stethoscope.
2. Turn on your Littmann® Model 3200 stethoscope.
3. Press the [M] button on the Model 3200 stethoscope to enter the Main menu.
4. In the Main menu, press the [-] button until [Pair] is selected.
5. Press the [M] button again to select [Pair].
6. Click the [OK] button on the Scope-to-Scope software program.

5. Connect the Littmann Model 3200 stethoscope to the Scope-to-Scope software program and connect the Patient and Consultant Sites.

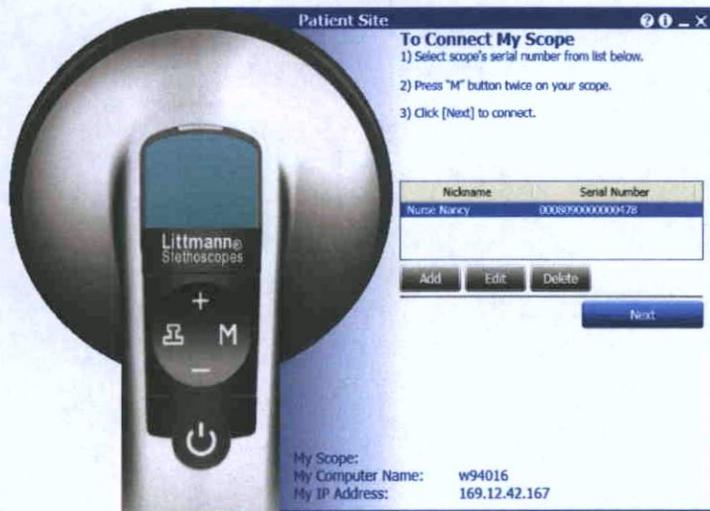
IMPORTANT: In order to establish a connection between the Patient and Consultant sites, the Patient Site must first connect the stethoscope to the Patient Scope-to-Scope software program. At which time the Patient Site will enter into a waiting status. The Consultant Site can then connect to the Patient Site.

Patient Site:

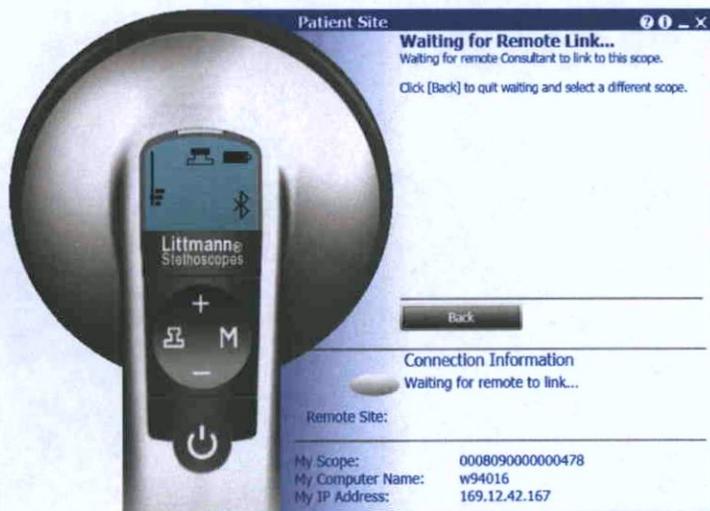
Connect the Littmann Model 3200 stethoscope to the Patient Scope-to-Scope software program

- a. Using the Littmann Model 3200 stethoscope, turn on the stethoscope and press the [M] button twice to select Connect. Ensure the Bluetooth icon on your stethoscope display is flashing.
- b. Using the Scope-to-Scope software program, select your stethoscope ID from the list. Click [Next] to continue.

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c. The Patient Site will now wait for the Consultant Site to make a connection.

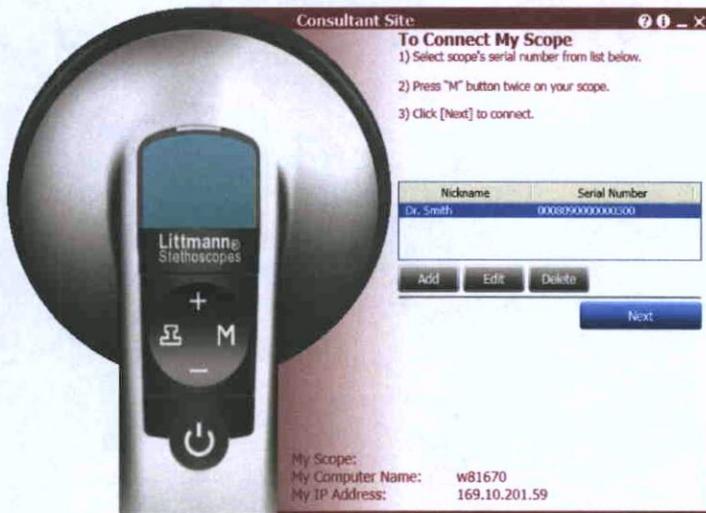


NOTE: If the stethoscope connection has been made, the Bluetooth icon on the stethoscope display will stop flashing and become solid. The display on the Scope-to-Scope software will show the volume and filter setting, the battery life indicator, and the solid Bluetooth icon. Adjusting the volume or filter setting on the Scope-to-Scope software will adjust the respective setting on the stethoscope, and visa versa.

Consultant Site:

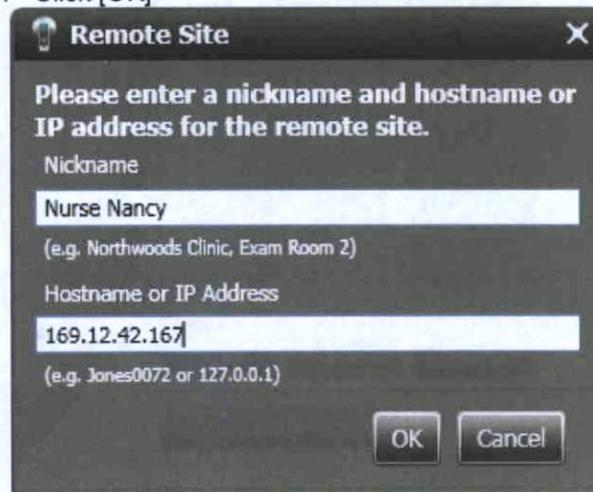
1. Connect the Littmann Model 3200 stethoscope to the Consultant Scope-to-Scope software program
 - a. Turn on the Model 3200 stethoscope and press the [M] button twice to select Connect. Ensure the Bluetooth icon on your stethoscope display is flashing.
 - b. Using the Scope-to-Scope software program, select your stethoscope ID from the list. Click [Next] to continue.

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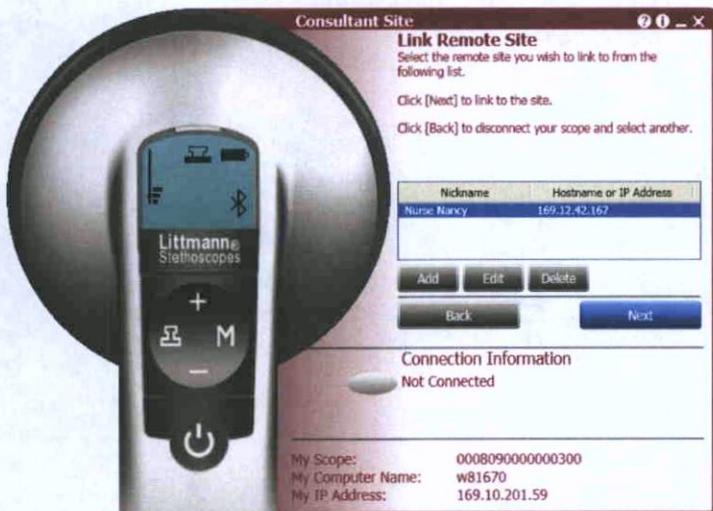
If the connection has been made, the Bluetooth icon on the stethoscope display will stop flashing and become solid. The display on the Scope-to-Scope software will show the volume and filter setting, the battery life indicator, and the solid Bluetooth icon. Adjusting the volume or filter setting on the Scope-to-Scope software will adjust the respective setting on the stethoscope, and visa versa.

2. Establish link to the Patient Site. Using the Scope-to-Scope software program:
 - a. Add a Patient Site
 - i. Click the [Add] button to add a Patient Site.
 - ii. Enter the IP Address or Hostname of the Patient Site. For your reference, the IP Address of *your* site is listed at the bottom of the Scope-to-Scope software program. Obtain the IP Address from the Patient Site and enter it into the IP Address or Hostname text box.
 - iii. Assign an Alias to the particular Patient Site for easy identification in the future.
 - iv. Click [OK]



- b. Select the Patient Site from the list

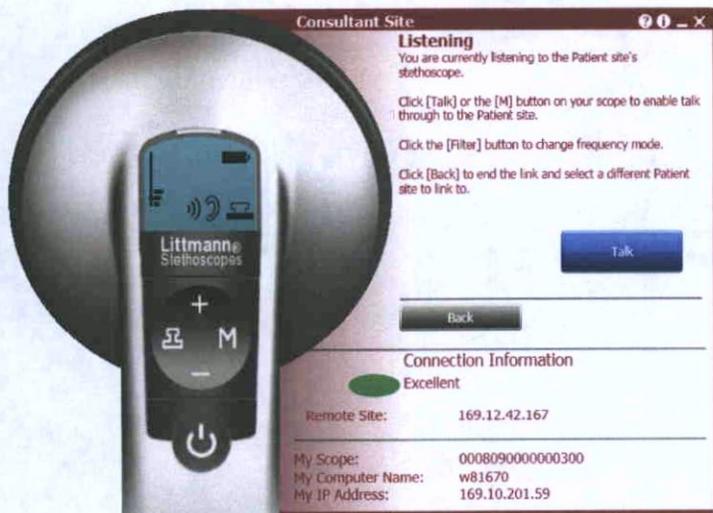
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- c. Click [Next]. The Consultant Site will now look for the Patient Site and make a connection.

6. Live Connection

If the connection is successful, you will notice a green oval on the Scope-to-Scope software program. You will also notice the Listen symbol on the Scope-to-Scope software display screen as well as on the Model 3200 stethoscope display screen.



During Listen mode, the stethoscope will display:



During Talk-through mode, the stethoscope will display:



- To initiate Talk-through mode (Consultant Site only), press the [M] button on the Consultant Site stethoscope. The user of the Consultant Site stethoscope can speak into the chestpiece while the user of Patient Site stethoscope listens through the eartips. Press the [M] button again to return to Listen mode.

- The Consultant Site stethoscope will be listening to the sounds originating from the Patient Stethoscope. The Consultant Site stethoscope chestpiece is inactive during Listen mode.
- The Patient Site stethoscope will also be listening to the sounds originating from the Patient Site stethoscope
- The volume is independently controlled on each stethoscope and does not impact the remote stethoscope
- The Consultant Site stethoscope controls the filter setting on both the Consultant and Patient stethoscopes
- The volume, filter, or Talk-through (Consultant Site only) features can be controlled using the stethoscopes themselves; interaction with the Scope-to-Scope software is not necessary.

7. Discontinue the Telemedicine Consultation

To discontinue the telemedicine consultation, press the [Back] button on either the Consultant or Patient Scope-to-Scope software program.

8. Disconnect the Littmann Model 3200 stethoscope from the Scope-to-Scope software program

To disconnect the Littmann Model 3200 stethoscope from the Scope-to-Scope software program, press the [Back] button on the Scope-to-Scope software Program. Or, press the power button on the stethoscope.

9. Other Features/Options

- To remove a stethoscope from the list, select the Stethoscope ID and then click the [Delete] button.
- To remove a Remote Site from the list, first connect a Littmann Model 3200 stethoscope to the Scope-to-Scope software program. Then, select the Remote Site ID and click the [Delete] button.
- Click the Help button for searchable help.
- Click the About button for software, version, and customer service information.

10. Methods and Technique for Proper Auscultation

When using the Littmann Model 3200 stethoscope, there are several techniques that are important to consider and can substantially improve your auscultation experience.

The sound sensor, where all sound acquisition occurs, is quite small and located in the very center of the chestpiece (peel off the diaphragm and look for the indentation under the white sticker). The area around the sound sensor does not contribute to sound acquisition. Therefore, it is important to focus the point of contact with the patient on the very center of the chestpiece.

Only light contact is necessary with the Littmann Model 3200 stethoscope. This includes both the handling of the stethoscope and the contact on the patient. Excessive pressure on the patient may result in artifact sounds.

The contact with the patient must remain steady and consistent for optimal sound quality. Movement with the chestpiece will induce frictional noise.



Finally, it is important to recognize the difference in technique between traditional stethoscopes and the Littmann electronic stethoscopes. Holding the Model 3200 stethoscope lightly, making light contact with the patient, focusing the point of contact on the center of the chestpiece, and remaining steady will assure the highest sound quality auscultation experience.

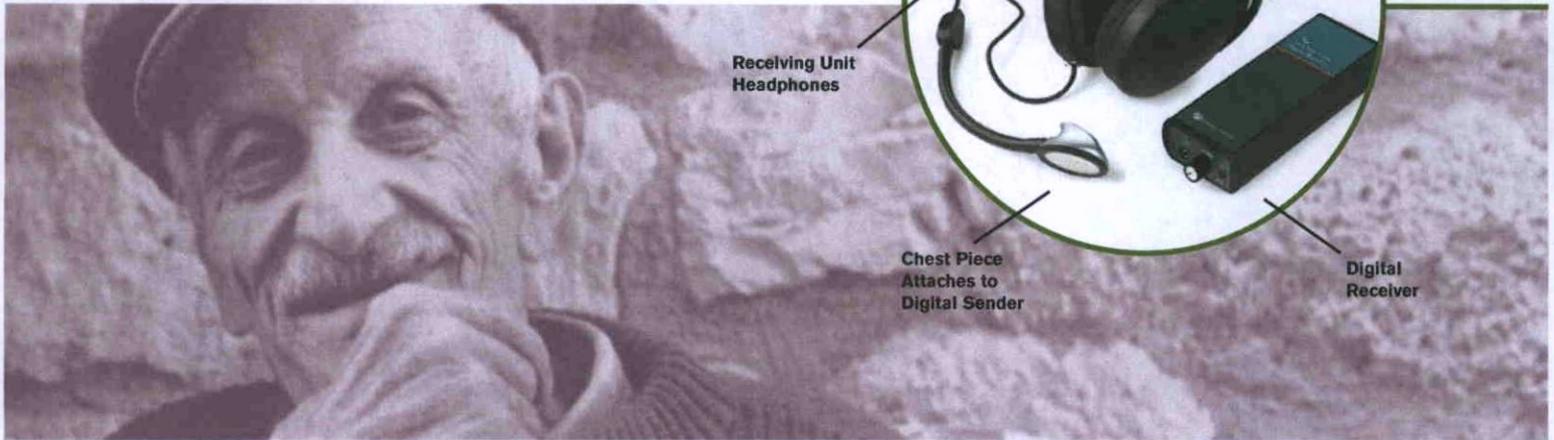
11. Troubleshooting

NOTE: Follow these tips to optimize Bluetooth communication and prevent lost wireless connections

- Auscultate the patient as close to the PC and Bluetooth dongle as possible.
- Avoid having objects or people between the stethoscope and the Bluetooth dongle.
- Avoid having your hand cover the entire chestpiece of the stethoscope (location of the Bluetooth® antenna.)
- Use a 90 degree USB extension or a USB extension cord to improve Bluetooth transmission.

CareTone[®] Telephonic Stethoscope

ati AmericanTeleCare



Live, real-time heart and lung sounds via telephone

American TeleCare's[®] patented family of CareTone[®] Telephonic Stethoscopes allows high-quality, real-time heart, lung and bowel sounds to transmit over a standard analog or digital telephone line. The CareTone Stethoscope comes standard with the 1010 Video Patient Stations and is an integral part of any total telemedicine program. It may also be purchased separately.

The excellence of this industry-leading stethoscope has been recognized by institutions such as NASA, which employed the device in its space shuttle program. The CareTone also has been integrated into many institutional and prison telemedicine programs both nationally and internationally.

Features of the CareTone Telephonic Stethoscope for telemedicine applications

The American TeleCare patented CareTone Telephonic Stethoscope transfers high-quality real-time heart, lung, and bowel sounds over ordinary (POTS) or digital (DSL, ISDN, T1) telephone lines, allowing this essential component of a medical assessment to be part of your home telemedicine program.

The CareTone Stethoscope consists of a sending and receiving unit and is designed for simplicity of use. The sending unit contains a high-quality chest piece, a power indicator light and stereo headphone jack for consolation where there is a clinician at both the remote and central sites. The receiving unit includes headphones, volume control and a switch to select either bell or diaphragm frequency sounds.

The CareTone Telephonic Stethoscope will interface with most existing telemedicine systems.

CareTone[®] Telephonic Stethoscope

Specifications:

CareTone

- Size:
1.4" x 2.6" x 9.3"
- Weight:
0.8 lbs.
- Power:
+12 V DC from wall
mount power supply
- Interface:
RJ-11C to POTS
(ordinary telephone line)
- FDA Clearance Class II
Device
- Frequency Range:
Size: Bell - 20Hz to
250Hz; Diaphragm -
20Hz to 500Hz
- Applications:
POTS or ISDN/TI video-
conferencing networks
(using Multi-point Control
Units which do not pass
auxiliary data channels)

CareTone Ultra

- Size:
1.4" x 2.6" x 6"
- Weight:
0.8 lbs.
- Power:
+12 V DC from wall
mount power supply
- Interface:
DB-9 to data channel
of POTS or ISDN/TI
video conferencing
at 9.6 kbps
- FDA Clearance Class II
Device
- Frequency Range:
Size:
Bell - 20Hz to 250Hz;
Diaphragm - 20Hz to
500Hz
- Applications:
POTS or ISDN/TI video-
conferencing systems
with data channel

CareTone IP Software:

American TeleCare's CareTone IP Software enables transmission of auscultation sounds from the CareTone and CareTone Ultra Digital Telephonic Stethoscope over an IP network.

The CareTone stethoscope sending and receiving units attach to networked PCs via the COM port. The stethoscope data is put into IP packets for transmission between stations over an IP network.

This facilitates the direct integration of the CareTone stethoscope with a PC-based telemedicine system using IP as the network communications protocol.

CareTone IP Software is available as an accessory with the purchase of the CareTone Ultra Digital Telephonic Stethoscope.

For detailed instructions in system operation, specifications, warnings, cautions, and additional information, please refer to the *Operators Manual* supplied with each product.

American TeleCare offers home telehealth programs tailored to your patient population and business models that include a variety of audio/video and monitoring stations with medical peripherals. Backed by superior customer service and technical support, American TeleCare solutions are at work helping to improve clinical outcomes, decrease costs, and increase clinician and patient satisfaction.

For more information, or to arrange an assessment to explore the advantages of home telehealth for your organization, call 1-800-323-6667.



American TeleCare, Inc.
7640 Golden Triangle Drive
Eden Prairie, MN 55344-3732
Customer and Clinical Services: 800-323-6667

Fax: 952-944-2247
infoati@americantelecare.com
Visit us at:

www.americantelecare.com

CareTone Specs

Specifications

Size: 1.4" x 2.6" x 9.3"

Weight: 0.8 lbs.

Power: +12 V DC from wall mount power supply

Interface Options: Serial or RJ45 cabling

Video Conferencing Equipment via Serial Port

PC via Serial Port

LAN port with Web Interface (additional option)

Ordinary Phone Line, (POTS)

Frequency Range:

Size: Bell – 20Hz to 250Hz

Diaphragm – 20Hz to 500Hz

Bandwidth Requirement

9.6 kbps minimum

Features and Benefits

Ultra-low bandwidth requirements – 9.6 kbps

International Patents

ISO 13485 – 2003 CMDCAS Standards – Certified

FDA 510-K Cleared Medical Device

Health Canada licensed medical device

99.9% Reliability

Detachable headset

Detachable chest piece

Volume Control for adjusting level to the headset

Transmits full auscultation bandwidth

Applications

Telemedicine Assessments

Cardiac

Arthritis

Carotid Artery

Pulmonary

Bowel Sound





CareTone[®] Ultra Digital Telephonic Stethoscope

Operator's Manual

PO63-001-OM
REV. 02
March 16, 2006

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Safety

FCC Part 15 Class B

This device complies with Part 15 of the FCC Rules. Operation is subject to the following conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Safety: CSA

For the safe operation of this device, these devices have been evaluated by CSA International for use up to 115/120 VAC.

Overview

The CareTone Ultra Telephonic Stethoscope is comprised of the CareTone Ultra Sender and the CareTone Ultra Receiver which allows for a health care professional to remotely access heart, lungs and bowel sounds remotely. The ability to auscultate these sounds remotely provides the health care professional with pertinent clinical data which assists in an overall clinical assessment.

The CareTone Ultra TelePhonic Stethoscope picks up the auscultated sounds, converts the sounds to a digital format, then transmits and receives the auscultated sounds as digital signals. In terms of data communication, the CareTone Ultra acts as a Data Terminal Equipment (DTE) and uses a standard DB-9 connector to communicate with the Data Communications Equipment (DCE). The CareTone Ultra relies on some form of DCE equipment (e.g. modem or multiplexer) to provide a network interface to the data transport network.

The data interface rate is 9.6 Kb/s and transmits/receives data in asynchronous data model (using an internal clock).

CareTone Ultra Components

For Health Care Professional:

- CareTone Ultra Receiver
- Wall mounted power supply
- Headphones

For Patient:

- CareTone Ultra Sender
- Wall mounted power supply
- Stethoscope
- Headphones

Installation

CareTone Ultra Sender

To install the CareTone Ultra Sender:

1. Connect the 9-pin connector end of the data cable into the CareTone Ultra Sender COM connector
2. Connect the opposite end into the DCE equipment
3. Connect the wall mounted power supply to a 115v AC outlet
4. Plug the other end of the power cable into the outlet at the rear of the CareTone Ultra Sender
5. Connect the stethoscope into the appropriately marked jack on the front of the CareTone Ultra Sender
6. Connect headphones into the appropriately marked jack on the front of the CareTone Ultra Sender

Note: The data that is transmitted from the CareTone Ultra Sender is on pin 3 (TXD).

- Pin 5-Ground
- Pin 4-DTR
- Pin 7-RTS

Operation

The CareTone Ultra units are always powered ON (as long as electricity is applied) and transmitting/receiving data.

The examiner guides the patient in the correct placement of the stethoscope. The examiner uses the headphones to begin their assessment. To place the stethoscope in Diaphragm mode for the auscultation of higher frequency sounds, the examiner places the toggle switch on the CareTone Ultra Receiver module to the up position, labeled *D*. To place the stethoscope in Bell mode for the auscultation of lower frequency sounds, the examiner places the toggle switch on the CareTone Ultra Receiver module to the down position, labeled *B*. To adjust the volume of the stethoscope sounds, turn the volume knob, labeled Vol, clockwise (CW) to increase volume and counterclockwise (CCW) to decrease the volume.

Troubleshooting

If you experience problems with stethoscope transmission of auscultated sounds, please check the following:

- Improper installation
- DCE not working properly
- Verify all connections

Note: The CareTone Ultra Receive and CareTone Ultra Sender units may be connected back-to-back for testing purposes. This testing requires a "crossover" or "null modem" adapter or cable. This type of cable will connect pin 3 of the CareTone Ultra Sender to pin 2 of the CareTone Ultra Receiver unit.

Practical solutions. Positive outcomes.™

ati AmericanTeleCare

15159 Technology Drive
Eden Prairie, MN 55344

Client Services: 1-800-323-6667
Fax 952-944-2247

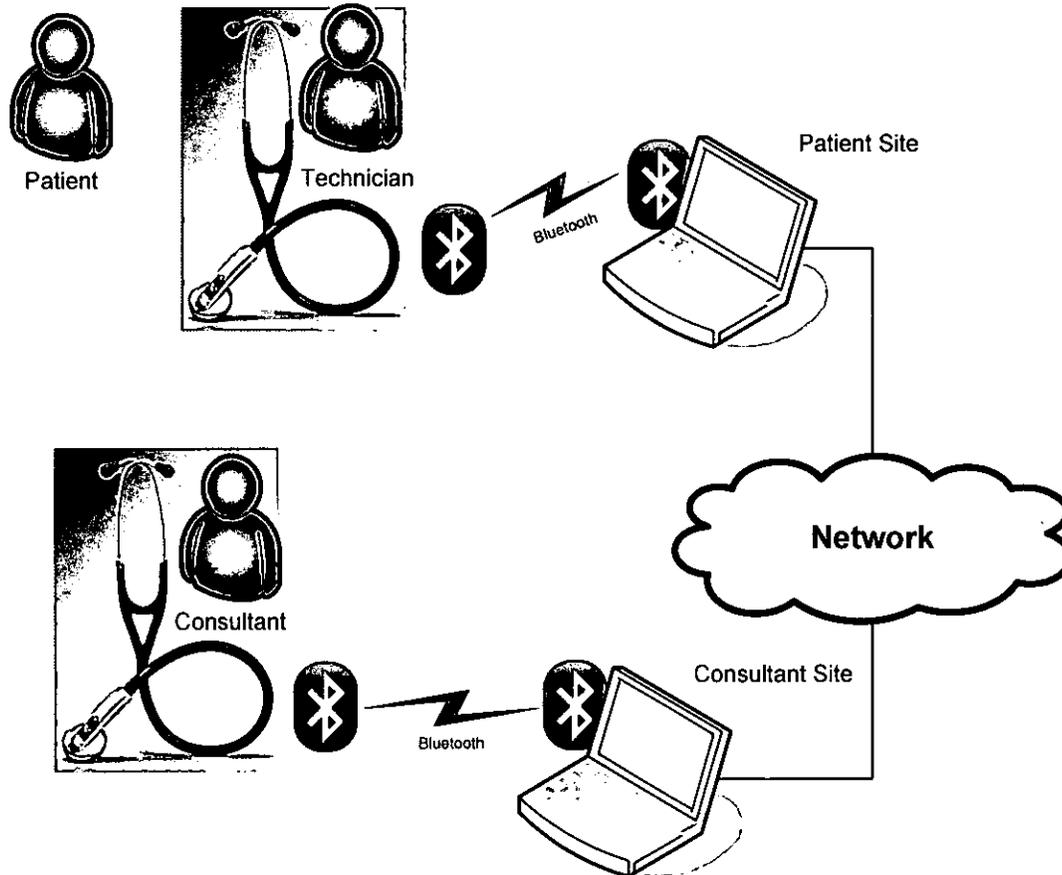
www.americantelecare.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Software Description

The purpose of the Littmann® Scope-to-Scope Software project is to commercialize software that enables the Littmann® Electronic Stethoscope Model 3200 to be used in conjunction with a second Littmann® Electronic Stethoscope Model 3200 in a telemedicine scenario over an IP-based network.



The application can be installed in 2 configurations, determined by a license key entered at the time of installation. Additional details can be found in the Software Design Specification (DS-INPUT-05-136719).

Cover Page

Document Name:	RISK-MGMT-GL-05-130740
Description:	Scope To Scope
Owner	Platt Jon C
State:	Review
Revision:	2
Release Date:	<dm_release_date>
Supceded Date:	

Approvers

<dms approvers>

RISK-MGMT-GL-05-130740, Scope To Scope, Review, <dm_release_date>

Risk Management Plan

Complete Each Of The Yellow Highlighted Boxes Below As Appropriate - See SOP-LAB-05-000026 Section 7.1															
Product Name & Model Number	3M Littmann® Scope-to-Scope Software Model TS1000P, TS1000C														
Intended Use Statement	The 3M Littmann® Scope-to-Scope Software product is intended to provide and control real time data transfer of body sounds between two Model 3200 electronic stethoscopes over a data network. It can be used on any person undergoing a physical assessment.														
Scope	<table border="1"> <thead> <tr> <th></th> <th>Check Each Appropriate Box</th> </tr> </thead> <tbody> <tr> <td>NPI Concept</td> <td></td> </tr> <tr> <td>NPI Feasibility</td> <td></td> </tr> <tr> <td>NPI Development</td> <td>X</td> </tr> <tr> <td>NPI Scale-Up</td> <td></td> </tr> <tr> <td>Production & Post Production</td> <td></td> </tr> <tr> <td>Other (if selected, provide description in "Other Comments" box below. Example: acquired products)</td> <td></td> </tr> </tbody> </table>		Check Each Appropriate Box	NPI Concept		NPI Feasibility		NPI Development	X	NPI Scale-Up		Production & Post Production		Other (if selected, provide description in "Other Comments" box below. Example: acquired products)	
	Check Each Appropriate Box														
NPI Concept															
NPI Feasibility															
NPI Development	X														
NPI Scale-Up															
Production & Post Production															
Other (if selected, provide description in "Other Comments" box below. Example: acquired products)															
Project's Design & Development Plan	DS-DD-PL-05-133240														
Review of Risk Management Activities	<table border="1"> <thead> <tr> <th></th> <th>Check Appropriate Box</th> </tr> </thead> <tbody> <tr> <td>As defined by the Project's Design & Development Plan</td> <td></td> </tr> <tr> <td>Other (if selected place an "X" in the field and provide description in "Other Comments" box below). Example: acquired products.</td> <td>X</td> </tr> </tbody> </table>		Check Appropriate Box	As defined by the Project's Design & Development Plan		Other (if selected place an "X" in the field and provide description in "Other Comments" box below). Example: acquired products.	X								
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As defined by the Project's Design & Development Plan															
Other (if selected place an "X" in the field and provide description in "Other Comments" box below). Example: acquired products.	X														
Verification Activities	Verification that risk control measures have been completed will be confirmed and documented in the Risk Analysis - Part 1 tab. Confirmation that all risk control measures have been completed will be included in the final design validation report.														
Post-Production Data Collection Activities	Post-production data collection will include complaint trending and monitoring of applicable standards.														
Other Comments (As applicable)	<p>* May 7, 2010 - Team review of Questionnaire and risk analysis tabs</p> <p>* Updated June 19, 2010 with changes in BLUE text that reflects continued work on risk mitigation.</p>														

RISK-MGMT-GL-05-130740, Scope To Scope, Review, <dm_release_date>

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Questionnaire - Part 1

Complete Each Of The Yellow Highlighted Boxes Below As Appropriate - See SOP-LAB-05-000026 Section 7.1

Regulatory Classification	USA: FDA Class 2 EU: Class IIa Canada: Japan: Other:
Applicable Standards	ISO/IEC 80001-1 Application of risk management for IT-networks incorporating medical devices IEC TIR80002-1 Guidance on the application of ISO14971 to medical device software
Lifetime Of The Product	Product is software. Support for the Product is expected to continue for at least two years past Product obsolescence.
Scope Of Risk Analysis	Risk management activities to include the design, development, manufacturing and support of this product.

Risk Management Team Members	
Name	Function
(b)(4)	Quality Assurance
(b)(4)	Lab - software design
(b)(4)	Clinical
(b)(4)	Regulatory
(b)(4)	Lab - Technical Service
(b)(4)	
(b)(4)	
(b)(4)	
(b)(4)	

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Questionnaire - Part 2

Complete Each Of The Yellow Highlighted Boxes Below As Appropriate - See SOP-LAB-05-000026 Section 7.1		
Questionnaire Ref Number	Questions that can be used to identify medical device characteristics that could impact on safety. Reference ISO 14971:2007 Annex C, H (IVD Medical Devices), and Annex I (Biological Hazards)	Instruction: Address each of the questions & comments found in column B by filling in the yellow highlighted area below. If not applicable, indicate with an N/A and provide information as to why not.
C.2.1 & H.2.1	What is the intended use and how is the medical device to be used? Factors that should be considered include what is the medical device's role relative to diagnosis, prevention, monitoring, treatment or alleviation of disease, compensation for injury or handicap or replacements of modification of anatomy, or control of conception? What are the indications for use (e.g. patient population)? Does the medical device sustain or support life? Is special intervention necessary in the case of failure of the medical device? (Note - For IVD Medical Devices, additional guidance is provided in ISO 14971:2007, Annex I, H.2.1, "Identification of intended users".)	Intended Use : <i>The 3M Littmann® Scope-to-Scope Software product is intended to provide and control real time data transfer of body sounds between two Model 3200 electronic stethoscopes over a data network. It can be used on any person undergoing a physical assessment.</i> The product does not sustain nor support life. In the event of device failure special intervention is not required. Product is not an IVD.
C.2.2	Is the medical device intended to be implanted? Factors that should be considered include the location of implantation, the characteristics of the patient population, age, weight, physical activity, the effect of ageing on implant performance, the expected lifetime of the implant, the reversibility of the implantation.	No, the product is software and is not for implantation.
C.2.3	Is the medical device intended to be in contact with the patient or other persons? Factors that should be considered include the nature of the intended contact, i.e. surface contact, invasive contact, or implantation and, for each, the period and frequency of contact.	No, the medical product is software and does not come into contact with the patient.
C.2.4	What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device? Factors that should be considered include compatibility with relevant substances, compatibility with tissues or body fluids, whether characteristics relevant to safety are known, and is the device manufactured utilizing materials of animal origin? (NOTE: ISO 10993-1 sets out the general principles for the biological evaluation of materials/medical devices while Annex I of ISO 14971:2007 provides guidance on the estimation of biological risks.)	The medical product is software to be contained on a CD. There are no materials or components that are relevant to safety.
C.2.5	Is energy delivered to or extracted from the patient? Factors that should be considered include the type of energy transferred, its control, quality, quantity, intensity and duration, whether energy levels are higher than those currently used for similar devices.	No, medical product is software.
C.2.6	Are substances delivered to or extracted from the patient? Factors that should be considered include whether the substance is delivered or extracted, whether it is a single substance or range of substances, and the maximum and minimum transfer rates and control thereof.	No, medical product is software.
C.2.7	Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation? Factors that should be considered include the type of process and substance(s) processed (e.g. auto transfusion, dialysis, blood component or cell therapy processing).	No, medical product is software.
C.2.8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable? Factors that should be considered include whether the medical device is intended for single use or re-use packaging, shelf-life issues, the limitation on the number of re-use cycles, the method of product sterilization, and the impact of other sterilization methods not intended by the manufacturer.	No, medical product is software.
C.2.9	Is the medical device intended to be routinely cleaned and disinfected by the user? Factors that should be considered include the types of cleaning or disinfecting agents to be used and any limitations on the number of cleaning cycles. The design of the medical device can influence the effectiveness of routine cleaning and disinfection. In addition, consideration should be given to the effects of cleaning and disinfecting agents on the safety or performance of the device.	No, medical product is software.
C.2.10	Is the medical device intended to modify the patient environment? Factors that should be considered include temperature, humidity, atmospheric gas composition, pressure, and light.	No, medical product is software.
C.2.11	Are measurements taken? Factors that should be considered include the variables measured and the accuracy and the precision of the measurement results.	No. The medical product does not measure any patient-related data.
C.2.12	Is the medical device interpretative? Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data, the algorithms used, and confidence limits. Special attention should be given to unintended applications of the data or algorithm.	No. the medical product does not provide interpretation.
C.2.13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies? Factors that should be considered include identifying any other medical devices, medicines or other medical technologies that can be involved and the potential problems associated with such interactions, as well as patient compliance with the therapy.	Yes. The software product is specifically designed to work in conjunction with the 3M Littmann Model 3200 electronic stethoscope.

Complete Each Of The Yellow Highlighted Boxes Below As Appropriate - See SOP-LAB-05-000026 Section 7.1		
Questionnaire Ref Number	Questions that can be used to identify medical device characteristics that could impact on safety. Reference ISO 14971:2007 Annex C, H (IVD Medical Devices), and Annex I (Biological Hazards)	Instruction: Address each of the questions & comments found in column B by filling in the yellow highlighted area below. If not applicable, indicate with an N/A and provide information as to why not.
C.2.14	Are there unwanted outputs of energy or substances? Energy-related factors that should be considered include noise and vibration, heat, radiation (including ionizing, non-ionizing, and ultraviolet/visible/infrared radiation), contact temperatures, leakage currents, and electric or magnetic fields. Substance-related factors that should be considered include substances used in manufacturing, cleaning or testing having unwanted physiological effects if they remain in the product - for these situations consider using a process FMEA or other additional risk management technique.. Other substance-related factors that should be considered include discharge of chemicals, waste products, and body fluids.	No, the medical product is software.
C.2.15	Is the medical device susceptible to environmental influences? Factors that should be considered include the operational, transport and storage environments. These include light, temperature, humidity, vibrations, spillage, susceptibility to variations in power and cooling supplies, and electromagnetic interference.	Yes. The medical product is software contained on a CD. The CD may be susceptible to damage during handling and shipping.
C.2.16	Does the medical device influence the environment? Factors that should be considered include the effects on power and cooling supplies, emission of toxic materials, and the generation of electromagnetic disturbance.	No, the medical product is software contained on a CD.
C.2.17	Are there essential consumables or accessories associated with the medical device? Factors that should be considered include specifications for such consumables or accessories and any restrictions placed upon the users in their selection of these.	No, there are no accessories nor consumables.
C.2.18	Is maintenance or calibration necessary? Factors that should be considered include whether maintenance or calibration are to be carried out by the operator or user or by a specialist, and are special substances or equipment necessary for proper maintenance or calibration ?	No, there are no maintenance nor calibration requirements.
C.2.19	Does the medical device contain software? Factors that should be considered include whether software is intended to be installed, verified, modified or exchanged by the operator or user or by a specialist.	Yes. Medical device is software. Software is installed by the user and does not require a specialist.
C.2.20	Does the medical device have a restricted shelf-life? Factors that should be considered include labeling or indicators and the disposal of such medical devices when the expiration date is reached.	No, the medical product is software contained on a CD.
C.2.21	Are there any delayed or long-term use effects? Factors that should be considered include ergonomic and cumulative effects. Examples could include pumps for saline that corrode over time, mechanical fatigue, loosening of straps and attachments, vibration effects, labels that wear or fall off, long term material degradation.	No, the medical product is software contained on a CD.
C.2.22	To what mechanical forces will the medical device be subjected? Factors that should be considered include whether the forces to which the medical device will be subjected are under the control of the user or controlled by interaction with other persons.	None. The CD will be subject to forces during transit, but that is addressed in C.2.15
C.2.23	What determines the lifetime of the medical device? Factors that should be considered include ageing and battery depletion.	Medical product is software. Primary determination is ongoing product support past its date of obsolesce.
C.2.24	Is the medical device intended for single use? Factors that should be considered include: does the medical device self-destruct after use ? Is it obvious that the device has been used ?	No, the medical product is software contained on a CD.
C.2.25	Is safe decommissioning or disposal of the medical device necessary? Factors that should be considered include the waste products that are generated during the disposal of the medical device itself. For example, does it contain toxic or hazardous materials, or is the material recyclable ?	No. Software is contained on a CD. There are no toxic nor hazardous materials.
C.2.26	Does installation or use of the medical device require special training or special skills ? Factors that should be considered include the novelty of the medical device and the likely skill and training of the person installing the device.	No. Installation of the software does not require special training or special skills outside of what is normal (common) skills for installation of PC software from a CD. <i>Operator Profile: The Littmann Scope-to-Scope software program is designed to be used by anyone who is familiar with the Littmann Model 3200 and who wishes to transfer body sounds over a data network in real time. The Littmann Scope-to-Scope manual provides complete information on how to operate the software program so that no additional operating training is required.</i>
C.2.27	How will information for safe use be provided? Factors that should be considered include whether information will be provided directly to the end user by the manufacturer or will it involve the participation of third parties such as installers, care providers, health care professionals or pharmacists and whether this will have implications for training; commissioning and handling over to the end user and whether it is likely/possible that installation can be carried out by people without the necessary skills; and based on the expected life of the device, whether retraining or recertification of operators or service personnel would be required.	Information for safe use shall be provided in the Instructions For Use. Installation is by the user with no special skills or training required (software is on a CD with an installation wizard).

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Complete Each Of The Yellow Highlighted Boxes Below As Appropriate - See SOP-LAB-05-000026 Section 7.1		
Questionnaire Ref Number	Questions that can be used to identify medical device characteristics that could impact on safety. Reference ISO 14971:2007 Annex C, H (IVD Medical Devices), and Annex I (Biological Hazards)	Instruction: Address each of the questions & comments found in column B by filling in the yellow highlighted area below. If not applicable, indicate with an N/A and provide information as to why not.
C.2.28	Will new manufacturing processes need to be established or introduced? Factors that should be considered include new technology or a new scale of production. - for these situations consider using a process FMEA or other additional risk management technique.	(b)(4)
C.2.29	Is successful application of the medical device critically dependent on human factors such as the user interface? Use errors include actions not intended by the manufacturer, such as procedure shortcuts, optimization attempts and improvisation, as well as omissions of actions intended by the manufacturer, such as those prescribed in the instructions for use. (Note - For IVD Medical Devices, additional guidance is provided in ISO 14971:2007, Annex I, H.2.2, "Identification of possible use errors").	Yes. The product makes significant use of a control interface
C.2.29.1	Can the user interface design features contribute to use error? Factors that should be considered are user interface design features that can contribute to use error. Examples of interface design features include: control and indicators, symbols used, ergonomic features, physical design and layout, hierarchy of operation, menus for software driven devices, visibility of warnings, audibility of alarms, standardization of color coding. See IEC 60601-1-6 for additional guidance on usability and IEC 60601-1-8 for guidance on alarms.	Yes. The product does not contain any warnings or alarms. The user will be interacting with the screen to connect with their local Model 3200 stethoscope as well as to control the remote 3200 stethoscope
C.2.29.2	Is the medical device used in an environment where distractions can cause use error? Factors that should be considered include the consequence of use error, whether the distractions are commonplace, and whether the user can be disturbed by an infrequent distraction.	Yes. Distractions may occur that could cause the user to be distracted, confused, or to walk away from the product (application) and then return.
C.2.29.3	Does the medical device have connecting parts or accessories? Factors that should be considered include the possibility of wrong connections, similarity to other products' connections, connection force, feedback on connection integrity, and over and under tightening.	No, the medical device does not have any connecting parts nor accessories.
C.2.29.4	Does the medical device have a control interface? Factors that should be considered include spacing, coding, grouping, mapping, modes of feedback, blunders, slips, control differentiation, visibility, direction of activation or change, whether the controls are continuous or discrete, and the reversibility of settings or actions.	Yes, the product does have a control interface.
C.2.29.5	Does the medical device display information? Factors that should be considered include visibility in various environments, orientation, the visual capabilities of the user, populations and perspectives, clarity of the presented information, units, color coding, and the accessibility of critical information.	Yes. Volume and filter settings
C.2.29.6	Is the medical device controlled by a menu? Factors that should be considered include complexity and number of layers, awareness of state, location of settings, navigation method, number of steps per action, sequence clarity and memorization problems, and importance of control function relative to its accessibility and the impact of deviating from specified operating procedures.	Yes. Connect/disconnect and Wizard processes
C.2.29.7	Will the medical device be used by persons with special needs? Factors that should be considered include the user, their mental and physical abilities, skill and training, ergonomic aspects, the use environment, installation requirements, and the patient's capability to control or influence the use of the medical device. Special attention should be paid to users with special needs, such as handicapped persons, the elderly and children. Their special needs might include assistance by another person to enable the use of a medical device. Is the medical device intended to be used by individuals with various skill levels and cultural backgrounds?	No, the medical product is not intended to be used by persons with special needs.
C.2.29.8	Can the user interface be used to initiate user actions? Factors that should be considered include the possibility of initializing a deliberate action for the user to enter a controlled operation mode, which enlarges the risk for the patient and which creates awareness for the user for this condition.	No, the user's interface cannot be used to initiate user actions by design.
H.2.4	For IVD medical devices, review ISO 14971:2007, Annex I, H.2.4 to identify potential known and foreseeable patient hazards.	Medical product is not an IVD.
C.2.30	Does the medical device use an alarm system? Factors that should be considered are the risk of false alarms, missing alarms, disconnected alarm systems, unreliable remote alarm systems, and the medical staff's possibility of understanding how the alarm system works. Guidance for alarm systems is given in IEC 60601-1-8.	No, the medical device does not use an alarm system.
C.2.31 & H.2.4	In what way(s) might the medical device be deliberately misused? Factors that should be considered are incorrect use of connectors, disabling safety features or alarms, neglect of manufacturer's recommended maintenance. (Note - For IVD Medical Devices, additional guidance is provided in ISO 14971:2007, Annex I, H.2.4, "Identification of known and foreseeable hazards").	The medical product does not contain any connectors, safety features or alarms, nor requirements for maintenance. Possible deliberate misuses are: 1) User may attempt to use another electronic stethoscope other than the Model 3200. 2) User may install the software (product) on a system with less than minimal requirements. 3) User may use the product to transmit/receive other sounds other than body sounds. 4) Digital sound data sent from one PC to another over a Data Network may be accessed, intentionally or unintentionally, by others (data security)

RISK MGMT-CL-05-136748, Scope To Scope, Review, <dm_release_date>

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Complete Each Of The Yellow Highlighted Boxes Below As Appropriate - See SOP-LAB-05-000026 Section 7.1		
Questionnaire Ref Number	Questions that can be used to identify medical device characteristics that could impact on safety. Reference ISO 14971:2007 Annex C, H (IVD Medical Devices), and Annex I (Biological Hazards)	Instruction: Address each of the questions & comments found in column B by filling in the yellow highlighted area below. If not applicable, indicate with an N/A and provide information as to why not.
C.2.32	Does the medical device hold data critical to patient care? Factors that should be considered include the consequence of the data being modified or corrupted.	No, medical device does not hold any data that is critical to patient care.
C.2.33	Is the medical device intended to be mobile or portable? Factors that should be considered are the necessary grips, handles, wheels, brakes, mechanical stability and durability.	No, the medical device is software on a CD.
C.2.34	Does the use of the medical device depend on essential performance? Factors that should be considered are, for example, the characteristics of the output of life-supporting devices or the operation of an alarm. See IEC 60601-1 for a discussion of essential performance of medical electrical equipment and medical electrical systems.	No, the medical device does not depend on essential performance
H.2.3	For IVD medical devices, review ISO 14971:2007, Annex I, H.2.3 to identify IVD performance characteristics that may be related to safety.	Medical product is not an IVD.
Ancillary 1	Are there potential hazards that may be introduced by suppliers? Identify potential hazards arising from suppliers. Risk control measures may include identification of purchasing control measures such as supplier selection and establishing acceptance requirements.	(b)(4)
Ancillary 2	Are there any potential hazards arising from the manufacturing process? Consider what may go wrong at each processing step and any controls in place to detect and prevent failures. Establishment of the suitability of the manufacturing equipment, its cleaning, maintenance and calibration should be considered. The risk management file may be augmented by the application of process specific risk management tools (HAZOP, FMEA, etc) using the high level process map from LCM (consider attaching HAZOP, FMEA, etc to this file) - see Annex G of ISO 14971:2010. Potential hazards arising from Servicing (repair and maintenance activities) should be considered	

Risk Analysis - Part 1

Risk Analysis (See SOP-LAB-05-000026, Section 7.1)																			
Risk Identification					Risk Evaluation					Risk Control					Residual Risk Evaluation				
Questionnaire Reference Number (if applicable)	Potential Hazard	Potential Hazardous Situation See Table E1 in ISO 14971	Potential Effect(s)	Potential Cause(s)	Severity (Table One)	Occurrence (Table Two)	Risk Level (Table Three)	Risk Control Measures to be Implemented	DRS/DS Section Applicable to Risk Control Measure(s)	Assigned To	Date Completed	Verification Reference	Severity (Table One)	Occurrence (Table Two)	Risk Level (Table Three)	New or Modified Risk (Table Three)			
C.2.13 C.2.31	Function - Inappropriate functionality	Product is used with an Blue Tooth equipped stethoscope, or other product, other than the Model 3200. Unintended users may be able to access patient heart sounds.	Unknown operation of other Blue Tooth equipped product. Loss of patient data security - product cannot be used as desired.	Design of product allows for any Blue Tooth communication protocol to be used. Data transmission on data network is not secured.	3	2	R2	(b)(4) * IFU to include table to only use with Model 3200	6.1.1	C. Morgan T. Chismar	6/21/2010 6/21/2010	DS-VER-05-134069 Manual-User-05-136281	3	1	R1	N			
C.2.15	Mechanical energy - transporation	CD that contains product arrives broken - cannot install. User cannot install software	Delay in auscultation of patient by remote expert. Device cannot be used as desired. Delay in auscultation of patient by remote expert. Device cannot be used as desired.	Poor design of CD packaging Error in design of installation wizard Lack of installation instructions for the user Error in manufacturing - Manufacturer lacks appropriate Quality Management System. Error in manufacturing - Poor process controls	2	3	R2	Use of std CD-ROM packaging design. Verification & validation testing IFU to include installation instructions.	9.2 10.1 9.4	J. Platt C. Morgan T. Chismar	6/21/2010 6/21/2010 6/21/2010	PKG-REQ-05-136203 DS-VER-05-134069 Manual-User-05-136281	2	2	R1	N			
C.2.19 C.2.28	Function - Inappropriate functionality	Heart & body sounds are not clear	Care provider misses clinically significant sounds The data network does not meet minimum required characteristics and configuration Software coding error or problem with SOUP software Incomplete instructions for use Control symbols are confusing Delay in auscultation of patient by remote expert. Device cannot be used as desired	* Design of robust error detection algorithm. * Verification * Validation (Clinical) * Verification * IFU to include information about network requirements as described by ISO/IEC 80001-1 * Verification * IFU to include information about network requirements as described by ISO/IEC 80001-1 IFU to contain minimum network requirements as described by ISO/IEC 80001-1 Compliance to EN 62304 * Verification testing * Validation testing * IFU compliant to EN 1041 * Design validation IFU compliant to EN 980 IFU is written in native language for marketed countries	2	3	R2	(b)(4)	3.3.2 6.2.1 6.3.1	C. Morgan T. Chismar M. Walt C. Morgan T. Chismar	6/21/2010 6/21/2010 6/21/2010	DS-VER-05-134069 Clinical Study-05-011309 DS-VER-05-134069 Manual-User-05-136281	2	2	R1	N			
		User not familiar with installation or operation of the software	Delay in auscultation of patient by remote expert. Device cannot be used as desired	Not written in native language	2	3	R2	IFU is written in native language for marketed countries	9.3	T. Chismar	6/21/2010	Manual-User-05-136281	2	2	R1	N			

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Risk Analysis - Part 1

C.2.27	Labeling information - incomplete or inadequate IFU	Connecting the device to a network that contains other medical devices	Interference with the operations or output of other devices that are connected to the same data network	Product is highly demanding of data network bandwidth and is non-compliant with shared network design concepts	3	2	R2	* Design is tolerant of network demands * IFU to contain network system requirements per IEC 80001-1	6.3.1	C. Morgan T. Chismar	6/21/2010 6/21/2010	DS-VER-05-134069 Manual-User-05-136281	3	1	R1	N
C.2.29.1	Operational - use error	User operates the system without consulting the IFU User operates the system after reading the IFU but is confused by the interface design.	Delay in auscultation of patient by remote expert. Device cannot be used as desired.	Responsible organization (product user) is not provided network operating requirements	3	2	R2	IFU compliant with IEC 80001-1 for medical device manufacturer	6.3.1	T. Chismar	6/21/2010	Manual-User-05-136281	3	1	R1	N
C.2.29.2	Operational - use error, distractions	During connection, operator on either end is distracted by events in their environment (phone call, discussions, etc)	No potential effects - may cause some patient frustration.	Interface design is to replicate the Model 3200 layout and operation. Those familiar with the Model 3200 will have the same familiarity with the interface as it's the same.	2	3	R2		3.2	C. Morgan T. Chismar	6/21/2010	DS-VER-05-134069 CVE	2	2	R1	N
C.2.29.3	Operational - use error, control interface	User believes that they are connected to the remote stethoscope (and are hearing the remote patient) when they are not.	Delay in auscultation of patient by remote expert. Device cannot be used as desired.	Poor location, poor labeling, poor size/operation of buttons on screen, labels not understood	2	3	R2	* IFU compliant to EN 980. * Customer testing.	3.1 9.3.1	T. Chismar	6/21/2010	Manual-User-05-136281 CVE	2	2	R1	N
C.2.29.4	Operational - use error, display information	During operation with a remote stethoscope the user is not clear as to what the filter mode setting is.	Care provider misses clinically significant sounds	Product used in a location where distractions may occur	1	3	R1									
C.2.29.5	Operational - use error, menu	User attempts to connect to a Model 3200 (Blue Tooth) or a remote site (over the data network), but makes menu errors	No potential effects - may cause some patient frustration.	Control interface lacks clarity as to when connected and in control the remote stethoscope	2	2	R1									
C.2.29.6	Operational - use error, menu functionality	User installs the product on a PC with less than minimum system requirements	Delay in auscultation of patient by remote expert. Device cannot be used as desired.	User is not familiar with Model 3200 filter mode display	2	3	R2	IFU to indicate that the product is to be used only with the Model 3200.	n/a	T. Chismar	6/21/2010	Manual-User-05-136281	2	2	R1	N
C.2.31	Misuse - used to send/receive sounds other than body sounds expected	Sounds are not reproduced as expected	Product can not be used as desired	User cannot see/read interface display	2	3	R2	* By design the interface will appear exactly like the Model 3200. * Customer testing.	3.2	C. Morgan T. Chismar	6/21/2010	DS-VER-05-134069 CVE	2	2	R1	N
Anc 2	Function - inappropriate functionality	User cannot install software or software will not run.	Delay in auscultation of patient by remote expert. Device cannot be used as desired	Menu design is complex and/or IFU is incomplete.	1	3	R1									
				Lack of minimum system requirements information in IFU	2	3	R2	IFU to contain information for minimum system configuration.	10.3	T. Chismar	6/21/2010	Manual-User-05-136281	2	2	R1	N
				IFU lacks clear indication of intended use	2	3	R2	IFU to contain information that intended use is to convey heart and other body sounds and to not use it for other sounds	9.3.2	T. Chismar	6/21/2010	Manual-User-05-136281	2	2	R1	N
				Manufacturer replicates wrong gold standard Manufacturer uses wrong CD artwork Manufacturer lacks process controls and final QC check	2	3	R2	* Establish co-approved Commercial Supplier Std * Process controls at supplier * QC control at suppliers	n/a	R. Jarboe		(b)(4)	2	2	R1	N

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Risk Analysis - Part 2

<p>Complete Each Of The Yellow Highlighted Boxes Below As Appropriate - See SOP-LAB-05-000026 Section 7.1)</p> <p><u>Instruction:</u> Following Risk Control measures, if the residual risk(s) is judged to be not acceptable using the criteria established in the risk management plan (Risk Level(s) > RL1 remain) and further risk control is not practicable, conduct a risk/benefit analysis in the space below. Gather and review data and literature to determine if the product benefits of the intended use outweigh the residuals risks. If the evidence does not support the conclusion that the benefits outweigh the residual risk, then the risk remains unacceptable. <u>All risk/benefit analysis must be reviewed and approved by both the Medical Division Technical and Regulatory Directors.</u></p>	
<p>Is a risk/benefit analysis required for this product ?</p>	<p>No</p>
<p>If yes, place risk/benefit analysis here or reference its location.</p>	<p>N/A</p>

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Risk Management Report

Complete Each Of The Yellow Highlighted Boxes Below As Appropriate - See SOP-LAB-05-000026 Section 7.1)

Instruction: Prior to product launch, the team leader shall insure that the following report has been completed. The report shall include a statement indicating that 1) the risk management plan has been appropriately implemented, 2) that the overall residual risk is acceptable, and 3) confirm that appropriate methods are in place to obtain relevant production and post production information.

Risk Management Report: The Littmann Scope-To-Scope software product has completed all risk management activities as identified in the products risk management plan with the exception of those few relating to design validation. All known and foreseeable risks, both in normal and fault conditions, along with the overall residual risk, are at an acceptable level. The report will be updated at the conclusion of design validation and prior to product release. Appropriate methods for monitoring of post production information have been established in the risk management plan.

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Post Production Info

Complete Each Of The Yellow Highlighted Boxes Below As Appropriate			
Information To			
Evaluated By	Date	Complaint Trends	Service Trends (if applicable)
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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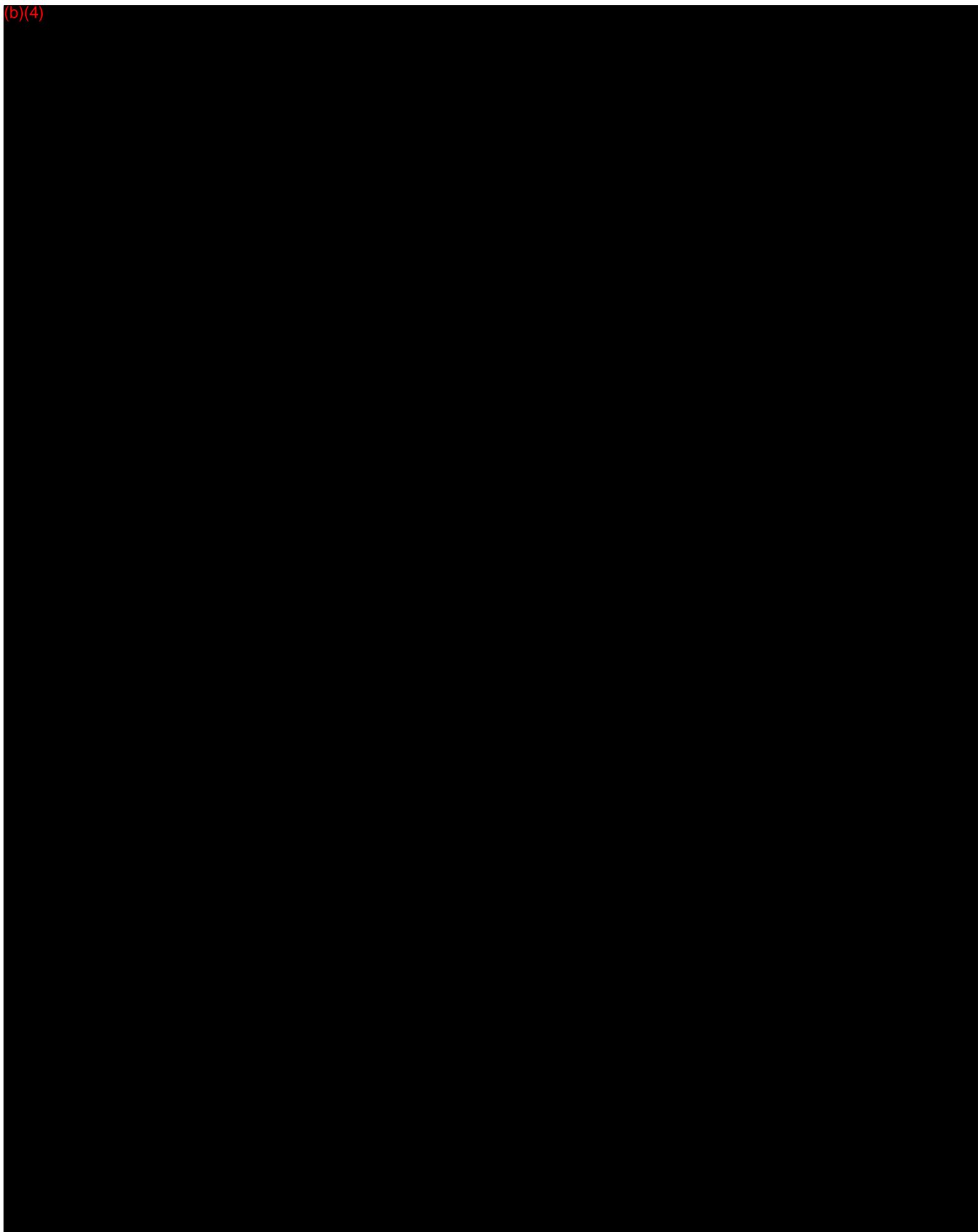
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Post Production Info

Appropriate - See SOP-LAB-05-000026 Section 7.1		
Be Reviewed		
New or revised applicable standards	Review of publicly available information on similar devices	Other
[REDACTED]	[REDACTED]	[REDACTED]

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(b)(4)





**Design Requirements Specification
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& Device Specification (DS)**

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Status: Review
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Link to Current SOP: SOP-LAB-05-000006

Document Title: Littmann Scope-to-Scope Software Requirements Specification

Release Date: <<Release Date>>

Superseded Date:

Owner: US338770 Morgan Curtis P

Location: MAPLEWOOD-3MUS-MN 3M HEADQUARTERS - 01J9C020

Approvers: Minimum Required Approvers: QA Engineer and Lab Manager

SIGNERS:

Signer	Role	Date Signed
No Data		

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**eMatrix Medical Vault
Relationships to Document**

Related (eMatrix) Documents

Design and Development: DS-DEV-CHG-05-136532, Design and Development: DS-INPUT-05-136719, Design and Development: DS-R-RPT-05-136533, Design and Development: DS-VER-05-134069, Design and Development: DS-VER-05-134069

Supporting Documents

Division Product Code

Division Subproduct (Commodity) Code

Division Global Sales Code

Model (Catalog) Numbers

Division Project (Development) Number

Name, Description, State

PROJ-05-132392, Scope to Scope Software - Telemedicine Software for the Littmann business, Active

Reference (3M ID) Part

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1.0 Product Description

Product Name	Littmann® Scope-to-Scope Software
Product Family	Littmann® Brand Products
Project Number	0055000072
Model Number(s)	TS1000P, TS1000C, 3200TMC
FDA Classification	Class II
MDD Classification	Ila
GMDN Code	
Global Regions of Sale	US & International English Speaking Countries
Intended Use(s)	The 3M Littmann® Scope-to-Scope Software product TS1000P, TS1000C & 3200 TMC is intended to provide and control real time data transfer of body sounds between two Model 3200 electronic stethoscopes over a data network. It can be used on any person undergoing a physical assessment.

2.0 Reference Documents

Document Name	Document Title
DS-DEV-CHG-05-136532	
DS-INPUT-05-136719	
DS-R-RPT-05-136533	
DS-VER-05-134069	
DS-VER-05-134069	

3.0 Product Design Requirements

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Introduction

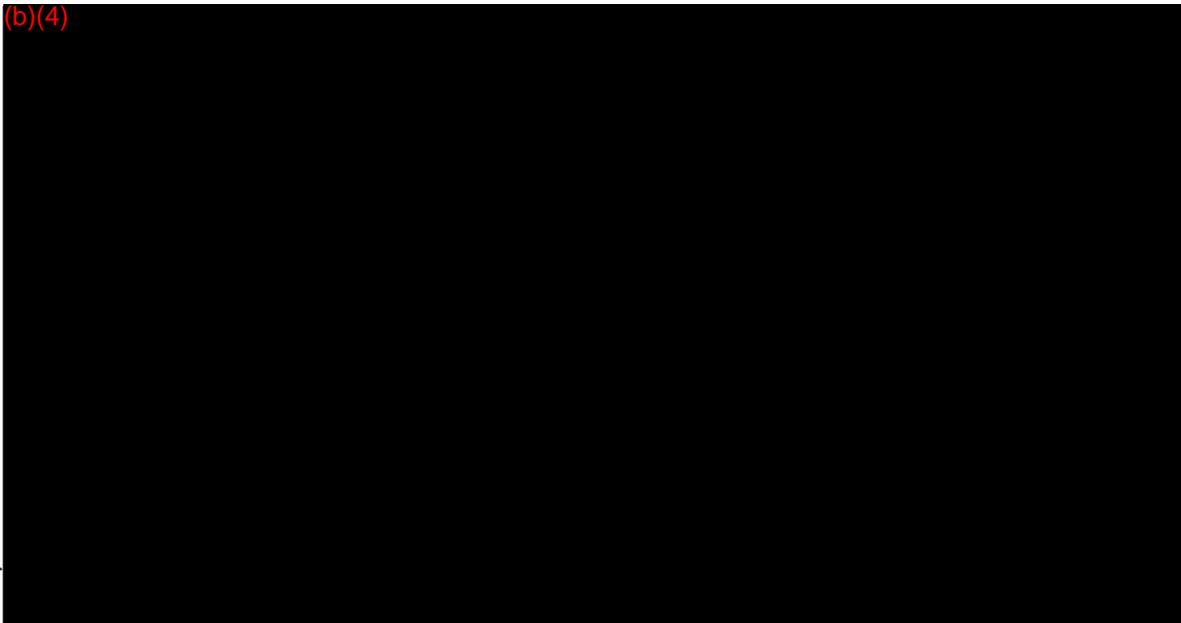
Purpose

This document will discuss the software requirements for the host PC software that will be used to control and transmit audio and control data between Littmann 3200 Stethoscopes. The intended use of this document is for developers designing these software components and testers testing them.

Scope

The scope of this document is limited to the interactions between PCs and the interaction from PC to Stethoscope. This document does not describe stethoscope firmware or stethoscope mechanical requirements.

Terminology





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Approvers: Minimum Required Approvers: QA Engineer and Lab Manager

SIGNERS:

Signer	Role	Date Signed
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**eMatrix Medical Vault
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Related (eMatrix) Documents

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Supporting Documents

<<Files>>

Division Product Code

<<mmm_product_code>>

Division Subproduct (Commodity) Code

<<mmm_sub_product_code>>

Division Global Sales Code

<<mmm_global_sales_code>>

Model (Catalog) Numbers

<<mmm_model>>

Division Project (Development) Number

<<mmm_division_project>>

Reference (3M ID) Part

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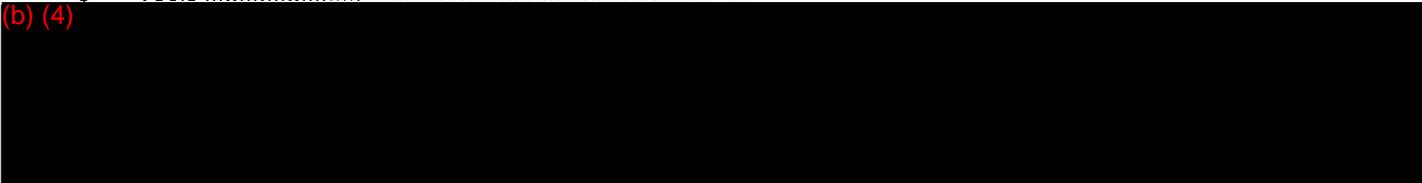
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**Design Requirements Specification
(DRS)
& Device Specification (DS)**

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Version: <<Version>>
Status: <<Status>>
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**Design Requirements Specification
(DRS)
& Device Specification (DS)**

<<Name>>
Version: <<Version>>
Status: <<Status>>
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1 Product Description

Product Name	Littmann® Scope-to-Scope Software
Product Family	Littmann® Brand Products
Project Number	0055000072
Model Number(s)	TS1000P, TS1000C, 3200TMC
FDA Classification	Class II
MDD Classification	IIa
GMDN Code	
Global Regions of Sale	US & International English Speaking Countries
Intended Use(s)	The 3M Littmann® Scope-to-Scope Software product TS1000P, TS1000C & 3200 TMC is intended to provide and control real time data transfer of body sounds between two Model 3200 electronic stethoscopes over a data network. It can be used on any person undergoing a physical assessment.

2 Reference Documents

Document Name	Document Title
SOP-LAB-05-000006	Design Input SOP
DS-INPUT-05-130331_2	Littmann® Scope-to-Scope Software Design Requirements Specification
DS-VER-05-134069_3	Littmann® Scope-to-Scope Software Verification Plan & Report
DS-INPUT-05-128618_3	Littmann® Scope-to-Scope Software Requirements Specification

<<Title>>

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**Design Requirements Specification
(DRS)
& Device Specification (DS)**

<<Name>>
Version: <<Version>>
Status: <<Status>>
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9 Attachments:

10 Version History:

<<History>>

Version History Details

1	Release 1 (Initial Release)
---	-----------------------------

<<Title>>

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**Design Verification
Plan & Report**

<<Object Name>>
Version: <<Version>>
Status: <<Status>>
Page 1 of 60

Link to Current SOP: [SOP-LAB-05-000009](#)

Document Title: <<Title>>

Release Date: <<Release Date>>

Superseded Date: <<Superseded Date>>

Owner: <<User ID>> <<Owner>>

Location: <<mmmLocationGroup>>

Approvers: Minimum Required Approvers: QA Engineer and Lab Manager

SIGNERS:

Signer	Role	Date Signed
No Data		

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<<Title>>
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**Design Verification
Plan & Report**

<<Object Name>>
Version: <<Version>>
Status: <<Status>>
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**eMatrix Medical Vault
Relationships to Document**

Related (eMatrix) Documents
<<mmmRelDocGroup>>

Supporting Documents
<<Files>>

Division Product Code
<<mmm_product_code>>

Division Subproduct (Commodity) Code
<<mmm_sub_product_code>>

Division Global Sales Code
<<mmm_global_sales_code>>

Model (Catalog) Numbers
<<mmm_model>>

Division Project (Development) Number
<<mmm_division_project>>

Reference (3M ID) Part
<<mmm_part>>

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<<Title>>
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1.0 Product Description

Name	Littmann® Scope-to-Scope Software
Product Family	Littmann® Brand Products
Model Number	TS1000P, TS1000C, 3200TMC
FDA Classification	Class II
MDD Classification	Ila
Intended Use(s)	The 3M Littmann® Scope-to-Scope Software product TS1000P, TS1000C, & 3200TMC is intended to provide and control real time data transfer of body sounds between two Model 3200 electronic stethoscopes over a data network. It can be used on any person undergoing a physical assessment.
Project Number	0055000072

2.0 Reference Documents

Document Name	Document Title
SOP-LAB-05-000009	Design Verification SOP
DS-INPUT-05-128618_3	Littmann® Scope-to-Scope Software SRS (Software Requirements Specification)
DS-R-RPT-05-136865	Littmann® Scope-to-Scope Design Verification Plan & Report - Release 1.0 - Review Report
DS-DEV-CHG-05-137040	Littmann® Scope-to-Scope Software changes from Release 0.3 to 1.0

Note: Include all applicable industry, regulatory, and internal verified methods that will be utilized or referenced during Design Verification.

3.0 Verification Purpose (Check appropriate option)

	Verify New Design
X	Verify Design Change

3M Littmann Scope to Scope Software - Test Procedures

Release 1.0

June 25, 2010

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Software Development Plan

COVER PAGE

Document Title: <<Title>>

Effective Dates

Release Date: <<Release Date>>

Superseded Date: <<Superseded Date>>

Owner: <<User ID>> <<Owner>>

Location: <<mmmLocationGroup>>

SIGNERS:

Signer	Role	Date Signed

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Software Development Plan

eMatrix Medical Vault Relationships to Document

Related (eMatrix) Documents

<<mmmRelDocGroup>>

Supporting Documents

<<Files>>

Division Product Code

<<mmm_product_code>>

Division Subproduct (Commodity) Code

<<mmm_sub_product_code>>

Division Global Sales Code

<<mmm_global_sales_code>>

Model (Catalog) Numbers

<<mmm_model>>

Division Project (Development) Number

<<mmm_division_project>>

Reference (3M ID) Part

<<mmm_part>>

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Software Development Plan

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COVER SHEET MEMORANDUM

From: Reviewer Name Libet Garber
 Subject: 510(k) Number K101834
 To: The Record

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE) SE with Limitations, NSE, Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age ≤ 21		✓	
Neonate/Newborn (Birth to 28 days)		✓	
Infant (29 days - < 2 years old)		✓	
Child (2 years - < 12 years old)		✓	
Adolescent (12 years - < 18 years old)		✓	
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		✓	

Transitional Adolescent B (18 <= 21; No special considerations compared to adults => 21 years old)
Nanotechnology
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>) Contact OC.

Regulation Number	Class*	Product Code
CFR 270.2910	II	DRG

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: F. J. [Signature] CE4B 8/23/10
(Branch Chief) (Branch Code) (Date)

Final Review: W. M. [Signature] For Backman 9/2/10
(Division Director) (Date)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review

K101834

Date: August 17, 2010

To: The Record

Office: ODE

From: Libet Garber

Division: DCD

510(k) Holder: 3M Company Corp.

Device Name: 3M Littman Scope to Scope Software System (TS1000P, RS1000C, 3200TMC)

Contact: Jizhong Jin

Phone: 651-733-6655

Email: jjin@mmm.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the 3M Littman Scope to Scope Software System into interstate commerce. 3M Company Corp. has submitted a traditional premarket notification (510(k)). The predicate devices for the 3M Littman Scope to Scope Software System is the CareTone Telephonic Stethoscope cleared under 510(k) number K973873.

Upon marketing clearance, the proposed devices would be classified under 21 CFR 870.2910, as Class II with product code DRG.

I recommend that this device be found substantially equivalent.

II. Administrative Requirements

	Yes	No/ Inadequate	N/A
Indications for Use page (Indicate if: Prescription or OTC)	Rx		
Truthful and Accuracy Statement	x		
510(k) Summary or 510(k) Statement	x		

510(k) SUMMARY REQUIREMENTS CHECKLIST
21 CFR 807.92

All 510(k) summaries shall contain the following information:		Y	N	N/A
1	The submitter's name, address, telephone number, a contact person, and the date the summary was prepared.	x		
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name	x		
3	An identification of the legally marketed device(s) to which the submitter claims equivalence.	x		
4	A description of the device that is the subject of the 510(k), including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device (e.g., device design, material used, and physical properties)	x		
5	A statement of the indications for use of the device that is the subject of the 510(k), including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is indicated. Or, if the indication statements are different from those of the legally marketed device(s) identified in paragraph (3) of this section, an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, surgical or other use of the device, and why the differences do not affect the safety and effectiveness of the device when used as indicated.	x		
6	If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source, etc.) as the predicate device(s) identified in paragraph(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified in paragraph (3) of this section.	x		
510(k) summaries for those 510(k)s in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information				
7	A brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence			x
8	A summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. (There can not be any patient identifier information in the summary.)			x
9	The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed device identified in paragraph(3) of this section.			x

III. Device Description

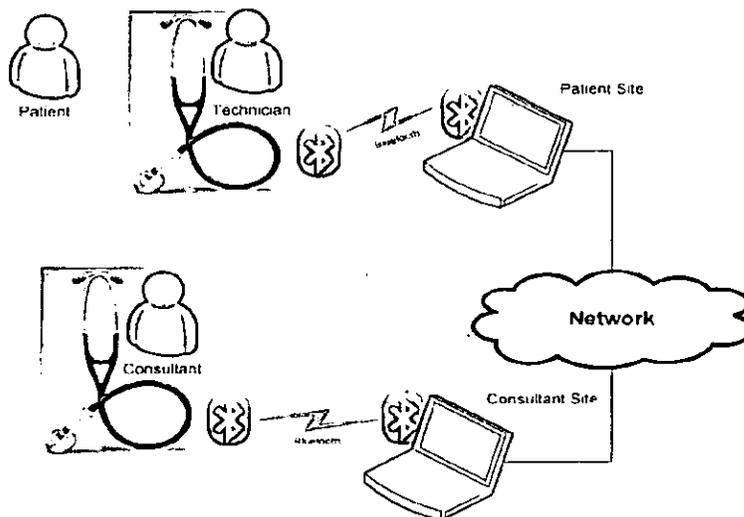
	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?		X	

(Adapted from sponsor)

The 3M Littmann® Scope-to-Scope Software System consists of software on a CD working with two 3M Littmann® Model 3200 Electronic Stethoscopes (cleared under K083903), such that when the software program is installed onto a PC, the software provides and controls real time data transfer of body sounds between two 3M Littmann® Model 3200 Electronic Stethoscopes over a data network. The sound captured by the stethoscope at the Patient site can be heard equivalently at both the Patient and Consulting sites through the Model 3200 headsets. The Scope-to-Scope Software System can be used on any person undergoing a physical assessment, thereby enabling health care professionals in remote clinics to obtain a second opinion from clinicians in a different location.

Both sites Model 3200 electronic stethoscopes are connected to Microsoft Windows based PC's via a Bluetooth wireless link. The two PC's are then connected to each other over a TCP/IP data network. The software allows for the Consulting site to control the Patient site's filter settings remotely when connected. The software also provides for the ability to facilitate verbal communication using the stethoscope's 'talk-through' feature that utilizes an expanded frequency range to better capture voice audio. This allows the Consultant to provide verbal cues and/or directions to the Patient site.

The system requires a TCP/IP network between the two computers that has the available bandwidth of 128K bps. This bandwidth is used for the communication of encrypted sound data and the control data utilized for managing the connection. Disruption of the required bandwidth is indicated through an audible error tone and visual indication on the application for that scope.



IV. Indications for Use

The Indication for Use (IFU) statement reads as follow:

“The 3MTM Littmann® Scope-to-Scope software System is intended to provide and control the real time data transfer of body sounds between two 3M Littmann® Electronic Stethoscopes, Model 3200 over a data network. It can be used on any person undergoing a physical assessment.”

This device is intended to be marketed as a prescription device.

The IFU statement is equivalent to that of the predicate devices. The predicate device has the ability to transmit blood pressure and pulse reading. Because the features of the new device are included in its predicate, it does not pose a new intended use. This information is adequate.

V. Predicate Device Comparison

The device technological characteristics and features are equivalent to those of the predicate. The proposed device does not have any additional feature that poses a new question of safety and effectiveness. The proposed device uses the 3200 stethoscope, which was cleared (K083903)

Characteristics	Proposed Device 3M Littman Scope to Scope	Predicate Device CADIScope Electronic ECG Stethoscope
Indications for Use	See section IV	Equivalence
Technology	3M Littman Scope to Scope Software	Care Tone IP software
Communication Interface	PC based	PC based
Sound operating modes	Bell, Diaphragm, Wide	Equivalence
Receiving Unit	Littman Stethoscope	Headset with Ear tips
Geographic location	Remote site Consultant site	Equivalence

VI. Labeling

The package contains a software CD, one 3200 Stethoscope, a user manual and a Quick Start guide. The device’s manual includes the IFU statement, PC system requirement to run the software, installation and connection instructions for the patient and the consultant sites and troubleshooting information. The labeling information is adequate.

VII. Sterilization/Shelf Life/Reuse

This information is not necessary as this device is not sterile

VIII. Biocompatibility

This information is not necessary as the only patient contacting materials (3M Littman Electronic Stethoscope) has been cleared under K083903.

IX. Software

The sponsor submitted the necessary software information required for a device with a moderate label of concern. The sponsor did a good job documenting the software development and testing at each step.

	Yes	No
Version: 1.09		
Level of Concern: Moderate		
Software description: the sponsor has provided an overview of the software that includes a diagram to explain the software and network functions. The device description section also references the software requirements and functionalities in detail.	X	
Device Hazard Analysis: the sponsor has provided an adequate analysis that identifies all the possible risk of the device. The hazard analysis evaluation also contains the actions that were taken to mitigate this risk to an appropriate and acceptable level. For more information refer to section 5 in the submission.	X	
Software Requirements Specifications: The sponsor has provided detailed requirements for the software and PC functions to work properly in this product. These include the design objectives, a system block diagram that depicts the operation of the system as a whole. The sponsor explained how the software integrates and displays the functions of these components. This document is adequate and can be found in Appendix 6 in the submission.	X	
Architecture Design Chart: the flowchart depicts the functionalities of the software from a high design level. This chart elucidates the inputs and outputs of the systems as it interacts with the user. The sponsor also submitted a detail design that included the system design diagram and a patient state diagram. This information is adequate.	X	
Design Specifications: this document demonstrates the design process of the software. It includes flow charts to portray how this process was conducted. It also depicts the network connection and Bluetooth handling.	X	
Traceability Analysis/Matrix: the sponsor has provided a chart to demonstrate each of the software functions in detail. This information can be found in the Design verification report.	X	

Development: the sponsor specified the software configuration. The sponsor included a chart in page 296 that portrays the development process and integrates the testing during the design steps. The device includes two different software configurations. One for the patient site and another one for the consultant site.

Patient Version

The Patient version of the application is limited in that it can only operate in a telemedicine session if it is contacted by the Consultant version of the application. If connected to a Consultant version, it enables the Consultant version user to listen to body sounds at the Patient version site. The Patient version of the application is unable to initiate a session without the consultant version, or to listen to body sounds at the Consultant version site.

X

Consultant Version

The Consultant version of the application is a super set of the Patient version. It can operate as either the Consultant or Patient version. When operating as a Consultant version, it is able to initiate a session with a Patient version. During an active session, the Consultant is also able to give private instructions' to the user at the Patient site by enabling talk-through mode and speaking into the sound-sensor. The instructions are heard through the Patient user's stethoscope ear-tips.

(b) (4)

Verification & Validation Testing: The sponsor updated this information for a moderate level of concern. The sponsor included a list of each test and whether the software passed or failed. The minor issues that were identified in the testing were resolved and re-verified in revision 1.09. The issues that were not re-verified were considered minor. The design verification reports were conducted after connection was established between the patient and consultant sites. (b) (4)

X

(b) (4)

This document is adequate.

Revision level history: The sponsor has provided a revision level history which includes the testing and changes that were made for each revision. This is adequate.

X

Unresolved anomalies: The remaining unresolved anomalies were reviewed and considered not to affect the safety and effectiveness of the product. This information is adequate.

X

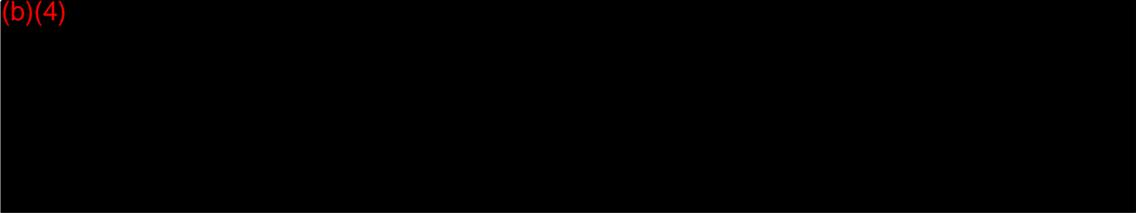
X. ^{Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015}
Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety
Not applicable to the software part, the device design does not include an electronic component and the design does not result in patient contact. The 3M Littmann® Electronic Stethoscope, Model 3200 included in this submission has been cleared by FDA under K083903. All EMC and electrical safety issues related to the stethoscope have been addressed in its 510(k) filing.

XI. Performance Testing – Bench

The sponsor tested the sounds and the service quality. The following testing was done to verify the device. The test report can be found in appendix 8 of the submission. The unresolved anomalies were verified and found to not affect safety and effectiveness.

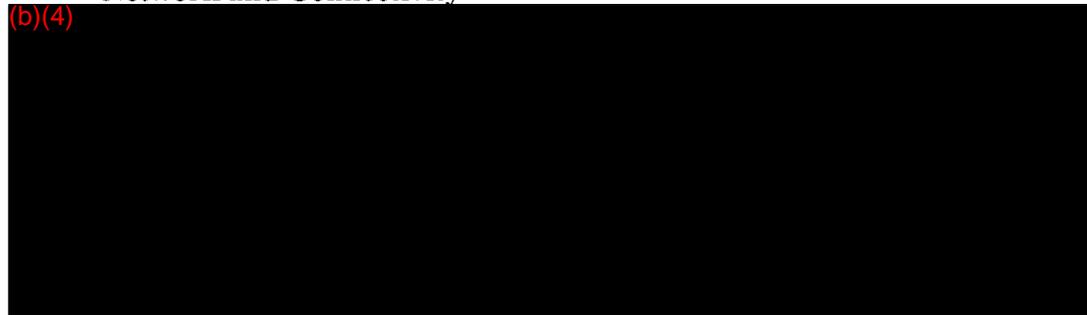
Sounds and Quality of service

(b)(4)



Network and Connectivity

(b)(4)



XII. Performance Testing – Animal

This information is not necessary to validate this device.

XIII. Performance Testing – Clinical

This information is not necessary to validate this device.

1. Same Indication Statement?	X	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	X	If YES = Stop NSE
3. Same Technological Characteristics?	X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?	X	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?		If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision: Hold

Note: See

<http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/04148/FLOWCHART%20DECISION%20TREE%20.DOC> for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
The predicate device has functionalities that are not included in the proposed device.
2. Explain why there is or is not a new effect or safety or effectiveness issue:
The proposed device can only be used to talk and to transmit sounds from the stethoscope. It does not transmit blood pressure measurements, which is an accessory in the predicate.
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

14

XV. Deficiencies

The sponsor did a great job documenting the software development and verifying the functionality of the software. This device has the same function and technology as the predicate and the sponsor has demonstrated the robustness of the data transmission. I do not need any additional information from the sponsor.

XVI. Contact History

This is my first review of this submission.

XVII. Recommendation

I recommend that this device be found substantial equivalent to its predicate.

Regulation Number: 21 CFR 870.2910

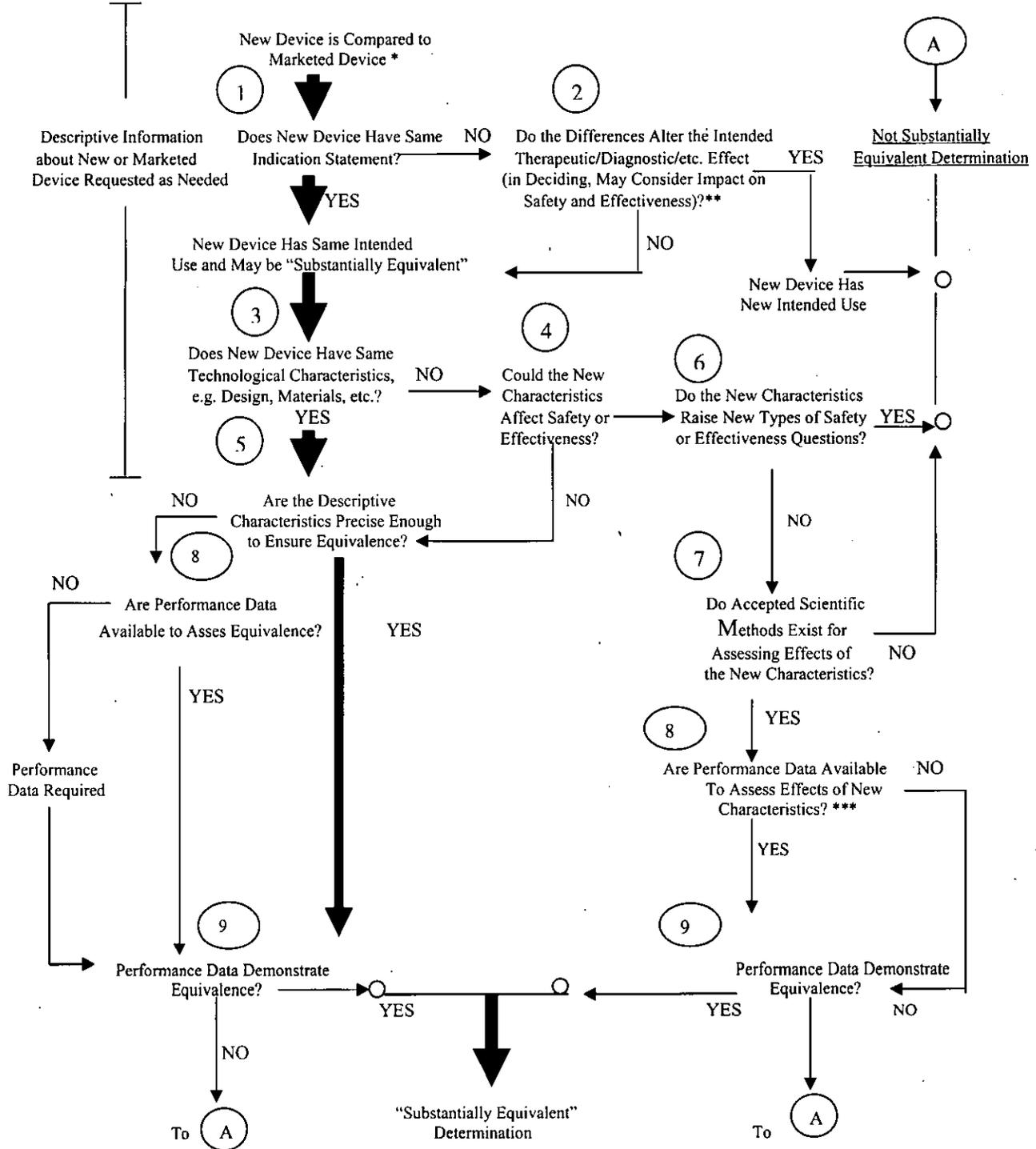
Regulation Name: Radiofrequency physiological signal transmitter and receiver

Regulatory Class: Class II

Product Code: DRG

<u>Harbo</u>	<u>8/18/2010</u>
Reviewer	Date
<u>J. G. [Signature]</u>	<u>8/23/10</u>
Branch Chief	Date

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.