



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)
FOLDER: K102893 - 287 pages
COMPANY: RNK PRODUCTS, INC. (RNKPRODA)
PRODUCT: STETHOSCOPE, ELECTRONIC (DQD)
SUMMARY: Product: PCP/PC STETHOSCOPE

DATE REQUESTED: Jan 21, 2016

DATE PRINTED: Jan 21, 2016

Note: Printed



RNK Products

FEB - 1 2011

**510(k) SUMMARY
RNK Products
PCP/PC Stethoscope**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K102893.

Submitter Information

Submitter: RNK Products
4195 US Hwy 1
Suite 101
Rockledge, FL 32955
Telephone: (321) 626-7717
Facsimile: (321) 305-5983

Contact Person: Charles R. Abbruscato
RNK Products
Telephone: (321) 626-7717
Facsimile: (321) 305-5983

Date Prepared: Sept. 3, 2010

Device Information

Name of Device RNK PCP/PC Stethoscope

Common or Usual Name Electronic Stethoscope

Classification Name Electronic Stethoscope

Predicate Devices RNK Products TR-1 Telephonic Stethoscope (034046)
RNK Products Precordial Stethoscope (K072026)

Device Description

The PCP/PC Stethoscope is comprised of a PCP/PC Chest Piece that plugs into a generic PC on an IP network (e.g. the Internet) and the streaming Stethoscope Over IP (sSOIP) software application running on the PC. It provides remote auscultation between a patient at one location and a clinician at another location.

The PCP/PC Chest Piece derives operating voltage from the bias voltage on the Microphone port of the PC. PCP/PC Chest Piece contains an embedded amplifier which amplifies the auscultation signal from the piezo sensor and presents it as an analog signal to the Microphone input of the PC.

Under direction of the sSOIP program, the analog signal is digitized in the PC, formatted and converted to IP packets for transport. At the receive end PC, the sSOIP program directs the acceptance of the IP packets, conversion of the signal back to analog and presentation of the analog signal to the Headset port of the PC.

Intended Use

The RNK PCP/PC Stethoscope is intended to transmit auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations.

Substantial Equivalence

The RNK PCP/PC Stethoscope uses a similar amplifier and chest piece sensor technology as the predicates. The RNK PCP/PC Stethoscope is substantially equivalent to the RNK Products, Inc. Telephonic Stethoscope Model TR-1 and Precordial Stethoscope. Bench testing and clinical testing was performed to verify specification and performance.

The RNK PCP/PC Stethoscope has the same intended use, principles of operation and technological characteristics as the predicate devices. 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

FEB - 1 2011

RNK Products, Inc.
c/o Mr. Charles R. Abbruscato
CEO
4195 US Hwy 1
Suite 101
Rockledge, FL 32955

Re: K102893
Trade Name: RNK PCP/PC Telephonic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: January 12, 2011
Received: January 14, 2011

Dear Mr. Abbruscato:

This letter corrects our substantially equivalent letter of January 20, 2011.

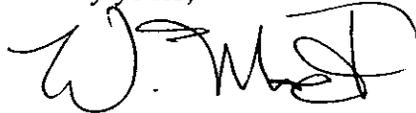
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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

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

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

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

Sincerely yours,



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

Enclosure

510(k) Number (if known): K102893

Device Name: PCP/PC Stethoscope

Indications for Use:

The RNK PCP/PC Stethoscope is intended to transmit auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations.

Prescription Use: X
(Part 21 CFR 801 Subpart D)

OR

Over-the-Counter Use _____
(Part 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 K102893



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

JAN 20 2011

RNK Products, Inc.
c/o Mr. Charles R. Abbruscato
CEO
12700 Diamond Drive
Burnsville, MN 55337

Re: K102893
Trade Name: RNK PCP/PC Telephonic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: January 12, 2011
Received: January 14, 2011

Dear Mr. Abbruscato:

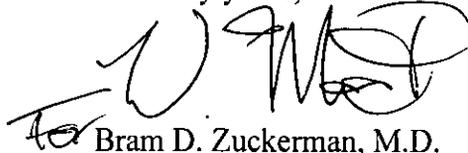
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Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is stylized and somewhat cursive.

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

Enclosure

510(k) Number (if known): K102893

Device Name: PCP/PC Stethoscope

Indications for Use:

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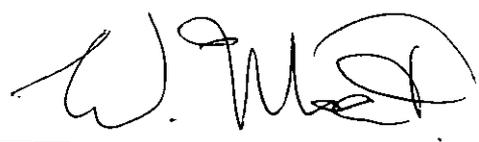
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Over-the-Counter Use _____
(Part 21 CRF 801 Subpart C)

(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 K102893

(Optional Format 1-2-96)



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

JAN 20 2011

RNK Products, Inc.
c/o Mr. Charles R. Abbruscato
CEO
12700 Diamond Drive
Burnsville, MN 55337

Re: K102893
Trade Name: RNK PCP/PC Telephonic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: January 12, 2011
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Dear Mr. Abbruscato:

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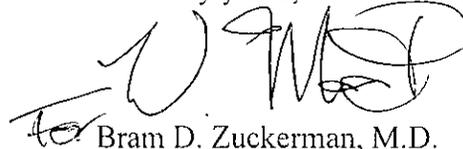
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Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K102893

Device Name: PCP/PC Stethoscope

Indications for Use:

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Prescription Use: X
(Part 21 CRF 801 Subpart D)

OR

Over-the-Counter Use _____
(Part 21 CRF 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 K102893

(Optional Format 1-2-96)



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

January 14, 2011

RNK PRODUCTS, INC.
4195 US HWY 1 SUITE 101
ROCKLEDGE, FLORIDA 32955
UNITED STATES
ATTN: CHARLES R. ABBRUSCATO

510k Number: K102893

Product: PCP/PC STETHOSCOPE

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/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).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

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.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Rich Abbruscato

From: Reilly, Sabina [Sabina.Reilly@fda.hhs.gov]
Sent: Tuesday, December 21, 2010 4:11 PM
To: Rich Abbruscato
Subject: K102893 - RNK PCP/PC Stethoscope

EMAIL REQUEST FOR ADDITIONAL INFORMATION

FROM:
Sabina Reilly
Reviewer
Office of Device Evaluation
Center for Devices and Radiological Health
FDA
10903 New Hampshire Ave
WO66, Rm 1252
Silver Spring, MD 20993
(301) 796-6324
Email: sabina.reilly@fda.hhs.gov

FDA CDRH DMC
JAN 14 2011
Received

TO:
RNK Products, Inc.
C/O Charles R. Abbruscato
4195 US Hwy 1
Suite 101
Rockledge, FL 32955
321-626-7717(tel)
321-305-5983(fax)

**RE: K102893
RNK PCP/PC Stethoscope**

December 21, 2010

Dear Mr. Abbruscato,
We have reviewed your Section 510(k) notification of intent to market the device referenced above. To complete the review of your submission, we require a response to the following deficiencies:

Regulatory

1. The indications for use statement you provide in the submission states that "The RNK PCP/PC Stethoscope is intended for use as a remote monitoring device..." This implies that the device is doing automated monitoring of the auscultation signals in some way. Please clarify whether the device is used simply to transmit auscultation sound data, or to monitor auscultation sound data. If it is used to monitor auscultation data, please provide a detailed explanation as to how the proposed device monitors patient data. If it only transmits data, please eliminate the words "remote monitoring device" from the indications for use statement.

Labeling

2. You indicate in the indications for use form that the proposed device is for prescription use. The labeling does not reflect this. Please include appropriate labeling in the user's manual to clearly convey that this device is for prescription use only under the supervision of trained medical personnel.

Software

K-5

3. We believe that the software verification and validation should be consistent with a moderate level of concern since we believe that the information provided by the subject device may be used by a physician to make clinical decisions. Please provide the requested information, as indicated in Table 1 of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", dated May 11, 2005. A copy of the guidance can be retrieved at our webpage of <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm#6>.

Biocompatibility

4. Please provide information or an assessment of the biocompatibility of your device. In your assessment, include a list of materials that the device is made of, an assessment of device contact duration, and results of testing (if warranted). For assistance in assessing biocompatibility of devices, please consult, ISO 10993 Biological evaluation of medical devices - Part 1 Tests for consideration. To support a claim that additional biocompatibility testing is not needed (because identical materials are already in market approved devices), the following certification is needed. Note that certifications are appropriate only for comparison to devices manufactured by the same company. If the statement is true for all of the fabrication material formulations, and processes, then provide the following general statement:

"All of the materials used to fabricate the [subject device name] are identical to the [predicate device name] as it was approved/cleared in [PMA/510k/IDE number, approval date] in formulation, and processing, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

Your file will be placed on administrative hold until we receive the requested information. Please respond by email (sabina.reilly@fda.hhs.gov) **followed by a hardcopy** to the Document Mail Center. Please reference the 510(k) number on the cover letter to any correspondence submitted to the Agency. Please contact me if you have any questions.

Best regards,

Sabina Reilly

Biomedical Engineer
Center for Devices & Radiological Health
Division of Cardiovascular Devices
10903 New Hampshire Ave
WO66, Rm 1252
Silver Spring, MD 20993
(301) 796-6324

The opinions expressed in this message represent the best judgment of the sender and do not necessarily represent the formal position of the FDA under 21 CFR §10.85

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify Sabina Reilly by return e-mail or telephone at 301-796-6324.

K102893 RNK PCP/PC Stethoscope
Additional Information
Jan. 12, 2011

This document summarizes RNK Products' response to FDA's request for additional information or clarification to 510(k) submittal K102893 RNK PCP/PC Stethoscope.

Regulatory

1. The indications for use statement you provide in the submission states that "The RNK PCP/PC Stethoscope is intended for use as a remote monitoring device..." This implies that the device is doing automated monitoring of the auscultation signals in some way. Please clarify whether the device is used simply to transmit auscultation sound data, or to monitor auscultation sound data. If it is used to monitor auscultation data, please provide a detailed explanation as to how the proposed device monitors patient data. If it only transmits data, please eliminate the words "remote monitoring device" from the indications for use statement.

RNK Response: The RNK PCP/PC Stethoscope is intended to transmit auscultation data. The Indications for Use statement (attached) has been changed to reflect that intent.

Labeling

2. You indicate in the indications for use form that the proposed device is for prescription use. The labeling does not reflect this. Please include appropriate labeling in the user's manual to clearly convey that this device is for prescription use only under the supervision of trained medical personnel.

RNK Response: The user's manual has been updated to include the statement that the RNK PCP/PC Stethoscope is for prescription use only. (See bottom page 1 of the attached RNK PCP/PC sSOIP Installation and Operation Instructions Rev 1.4.)

Software

3. We believe that the software verification and validation should be consistent with a moderate level of concern since we believe that the information provided by the subject device may be used by a physician to make clinical decisions. Please provide the requested information, as indicated in Table 1 of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", dated May 11, 2005. A copy of the guidance can be retrieved at our webpage of <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm#6>.

RNK Response: Part of the documentation needed for Software with a Moderate Level of Concern was provided in Attachment 6 of the original submission (Software Description, Device Hazard Analysis, Architecture Design Chart, Traceability, Software Development Environment). The remaining documentation (software performance and UML diagrams to enhance the Software Requirements Specification and units tests and integration test for software verification testing) is attached.

Biocompatibility

4. Please provide information or an assessment of the biocompatibility of your device. In your assessment, include a list of materials that the device is made of, an assessment of device contact duration, and results of testing (if warranted). For assistance in assessing biocompatibility of devices, please consult, ISO 10993 Biological evaluation of medical devices - Part 1 Tests for consideration. To

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"All of the materials used to fabricate the [subject device name] are identical to the [predicate device name] as it was approved/cleared in [PMA/510k/IDE number, approval date] in formulation, and processing, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

RNK Response: A biocompatibility analysis (attached) along with the Materials Reports included in the original submission show that the RNK PCP/PC Stethoscope is safe to use for patient and clinician. Further, all the materials that a patient or clinician can touch are the same as were used in the previously cleared predicate device.

510(k) Number (if known): K102893

Device Name: PCP/PC Stethoscope

Indications for Use:

The RNK PCP/PC Stethoscope is intended to transmit auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations.

Prescription Use: X
(Part 21 CRF 801 Subpart D)

OR

Over-the-Counter Use
(Part 21 CRF 801 Subpart C)

(Please Do Not Write Below This Line – Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 1-2-96)

PCP/PC Stethoscope with sSOIP Installation and Operation Instructions

Rev 1.4
December 22, 2010

This document provides the patient operating instructions for the PCP/PC Stethoscope.



This product meets the safety requirements of EN 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety for Type BF protection using a power source providing 2 - 5 vdc. The device providing power should satisfy IEC 60950.

Vdc:

Type BF applied part:



Class II protection
against electrical shock:



This product meets the EMC Emissions and Immunity requirements of EN 60601-1-2 Medical Electrical Equipment Part 2 Collateral Standard: Electromagnetic Compatibility Requirements and Tests:

EN61000-4-2	Part 2: Electrostatic Discharge Requirements
EN61000-4-3	Part 3: Radiated Electromagnetic Field Requirements
EN61000-4-4	Part 4: Electrical Fast Transients/Bursts Requirements
EN61000-4-6	Part 6: Conducted Immunity Requirements
EN61000-4-8	Part 8: Power Frequency Magnetic Field Requirements

This product may be used in continuous operation.

This product is not a defibrillation-proof applied part. This product is not suitable for use in the presence of a flammable anesthetic mixture with air or with continuous oxygen or nitrous oxide.

Normal use for this product is at an ambient temperature range of +10° to +40°C, a relative humidity range of 30% to 75%, an atmospheric pressure range of 700 hPa to 1,065 hPa. It may be transported and stored at temperatures from 0°C to 50°C and relative humidity of 10% to 95%.

The device contains electronic components and disposal of it should in accordance with all federal and local laws.

Local laws may take priority over the above requirements. If in doubt, consult your local representative or the technical service department.

This device is for prescription use only under the supervision of trained medical personnel.

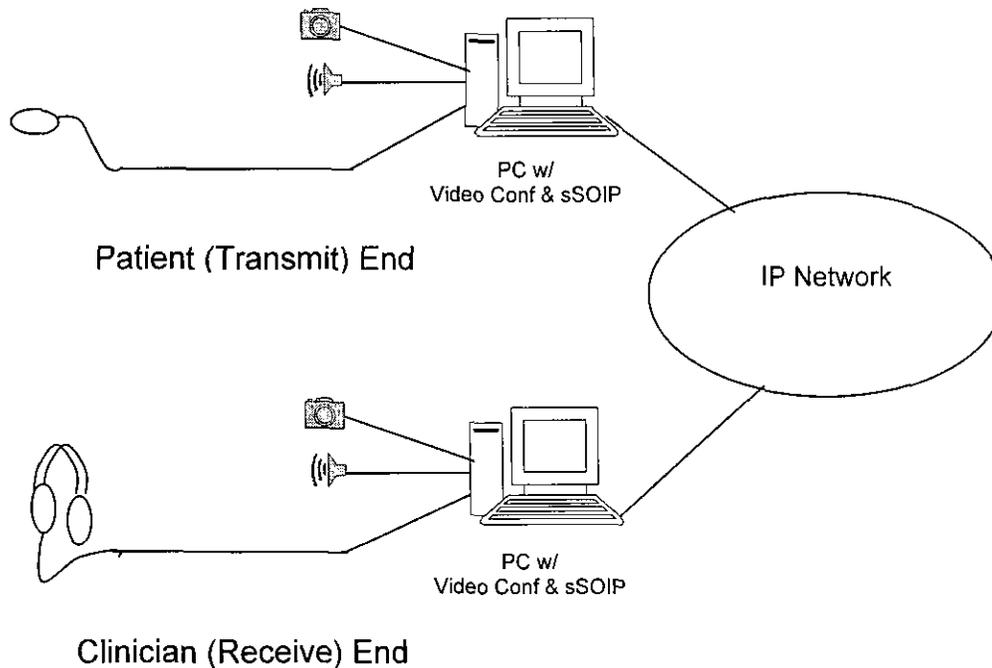
For questions or comments, contact RNK Products, Inc., 4195 US Hwy 1, Suite 101, Rockledge, FL 32955

*New R+
Statement
Submitted
Via Email
Jan 14, 2011*

I. Introduction

The PCP/PC Stethoscope Patient Station is comprised of a PCP/PC Chest Piece plugged into a generic PC on an IP network (e.g. the Internet) and the streaming Stethoscope Over IP (sSOIP) software application running on the PC. It provides remote auscultation between a patient at one location and a clinician at another location.

The typical application for a telephonic stethoscope is in conjunction with a video conference session for telemedicine. With the video conference over IP, the stethoscope sounds will go over a separate socket from the video conferencing data.



The clinician at the receive end is in control of the connection and will Start or Stop the stethoscope exam from the receive end PC. When the clinician clicks on Connect, the IP connection between the two PCs will be completed. When Disconnect is clicked, the exam stops and the connection breaks at the transmit end so that no stethoscope data is sent over the IP network.

The SOIP program also provides the capability for recording stethoscope sound data into special files, saving those files and playing them back.

II. Installation

Before the PCP/PC Stethoscope can be used, the PCP/PC sSOIP application must be installed on the target PC, which must be on an IP network such as the Internet. Once the application software is installed, the PCP/PC Stethoscope must be configured (section III).

Insert the PCP/PC Stethoscope Patient Station CD into the PC and run the sSOIP Setup.exe installation program. This will start the installation process. Click on Next and continue to click on Next for subsequent screens unless you want to install the SOIP program into special folders of your choosing.



Figure 1: Installation Wizard

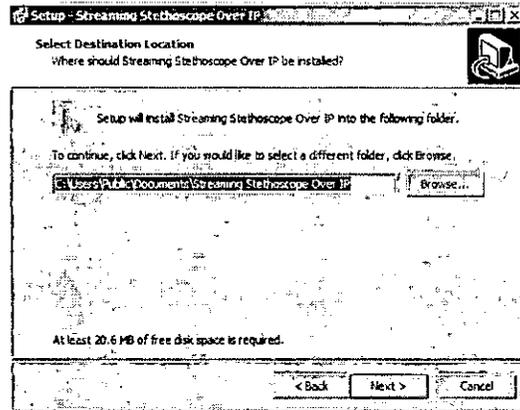


Figure 2: Select Destination Folder

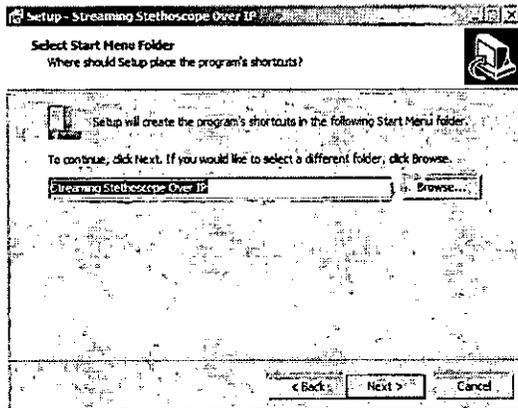


Figure 3: Select Start Menu Folder

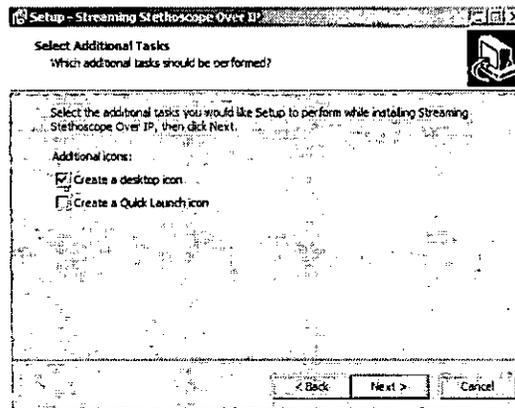


Figure 4: Create a Desktop Icon

Next in Figure 5 click on Install.

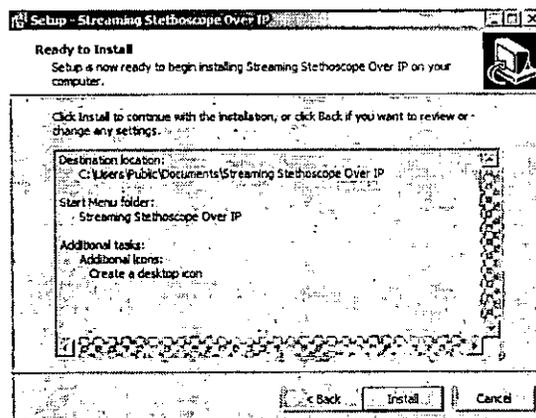


Figure 5: Install the Program

This will bring up Figure 6 asking if you want to delete the precious installation. Click on Yes.

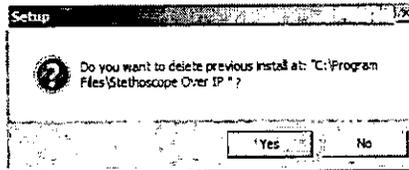


Figure 6: Delete Previous Installation

When the completion screen comes up, click on Finish.

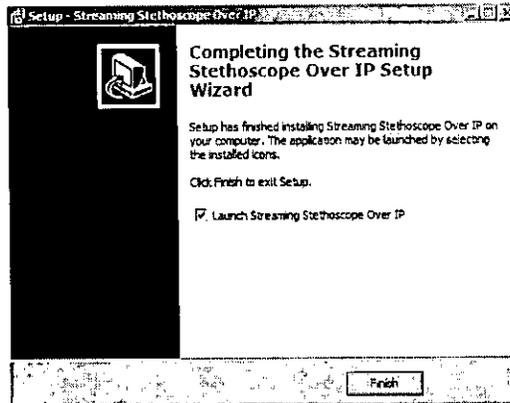


Figure 7: Installation Complete

III. Setup

A. Transmit Mode

Open the SOIP program using the desktop icon or the C:\Program Files\Stethoscope Over IP\SOIP.exe file. Whatever mode the program was in when it was last closed will be the mode that the program goes into when opened next. For example, if the SOIP program was configured for Transmit mode last time it was opened, then the Main screen shown in Figure 8 will display when the program is reopened.

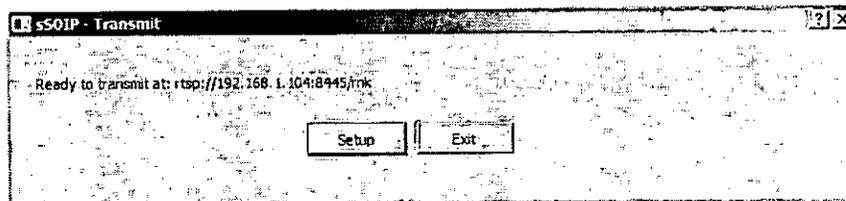


Figure 8: Main Screen – Ready to Transmit

Clicking on the Setup button brings up the screen for selecting the telephonic stethoscope model, the operating mode, the port assignments and the IP Address Book for entering IP addresses of remote site telephonic stethoscopes. Since the system would be in Transmit mode from Figure 8, the setup screen would show Transmit mode as shown in Figure 9.

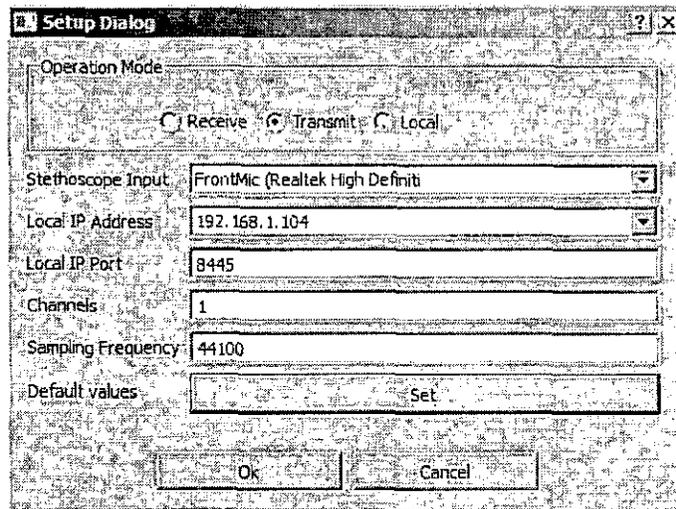


Figure 9: Setup Screen – Transmit Mode

The sSOIP program will detect the PCP/PC Chest Piece and display the audio port. It will also check for local IP addresses and display them. The default local IP port is 8445. If that is changed, then the Receive end sSOIP must select that same IP to be able to connect to this sSOIP station.

B. Receive Mode

Clicking on Receive Mode brings up the screen in Figure 10.

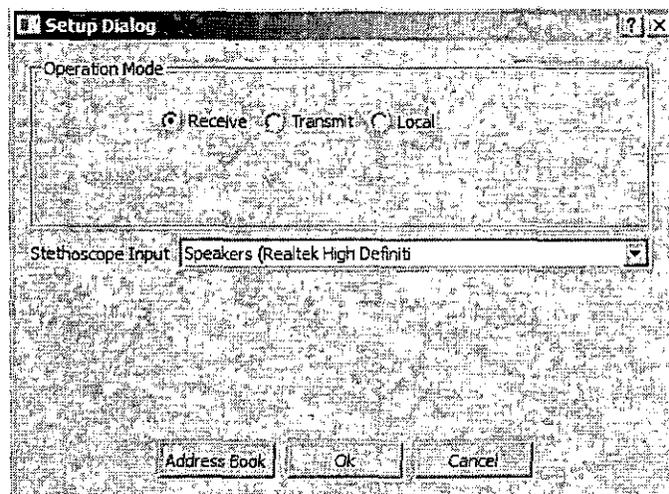


Figure 10: Setup Screen – Receive Mode

The audio output port is automatically detected and shown. Also a button for the IP Address Book is presented.

C. IP Address Book

Since the receive end initiates all connections, it is necessary to know the IP address of the transmit end. Multiple transmit end locations are handled through the IP Address Book, which allows the creation and storing of a list of IP addresses where the transmit end PCP/PC Stethoscope stations are located. Open the IP Address Book by clicking on the IP Address Book button.

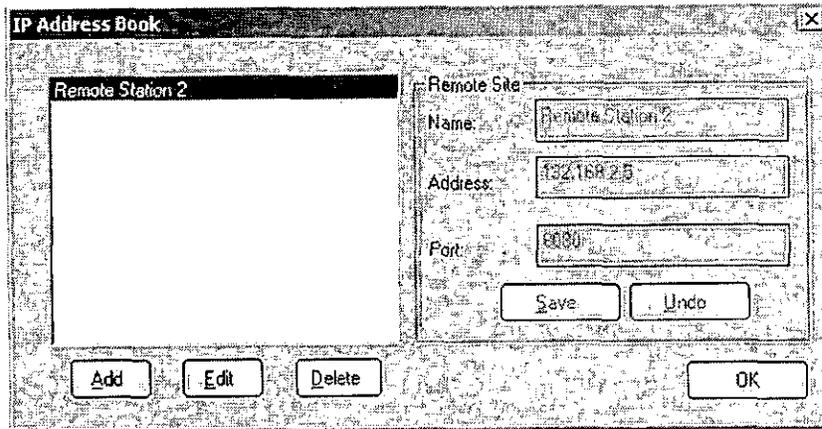


Figure 11: IP Address Book

To add a new location, click on Add, then enter the user friendly name you want to give for that location, the IP address and the port number. You can then either Save the address information or Undo it. Figure 11 shows Remote Station 2 in the IP Address Book.

An IP address can be edited by clicking on the name in the box on the left to highlight it, then clicking on Edit. Changes can be saved with Save or cancelled with Undo.

IV. Operation Mode

The sSOIP program has three modes of operation:

- Transmit mode is used at the patient end.
- Receive mode is used at the clinician end.
- Local is used for playing back recorded stethoscope files.

A. Transmit Mode

To set up for Transmit mode, from the Main screen, click on Setup. When the Setup window opens as shown in Figure 9, click on the Transmit radio button to enable Transmit Mode, then click on OK to get back to the Main screen as shown in Figure 8.

When the Status is Ready to Transmit, then the sSOIP program is waiting for a connection to be made from the far-end station, which would be in Receive mode. Once an IP connection is established, the Status will change to Transmitting Data.

B. Receive Mode

To set up for Receive mode, from the Main screen, click on Setup, then select the Receive radio button to display the screen shown in Figure 10. Then click the OK button to get to the Received end main screen as shown in Figure 12.

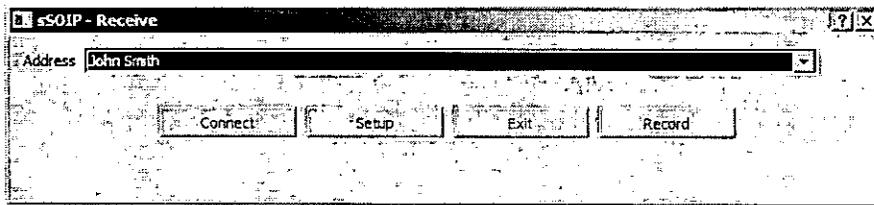


Figure 12: Main Screen in Receive Mode

In Receive mode, the program needs to know the IP address of the transmit end to which it wants to connect. The operator can create and access a list of IP addresses where the transmit end TR-x units are located. This is done in the Address Book as described in Section III C above.

Connections are initiated from the receive end where the consulting clinician is located. With sSOIP in Receive mode, select a patient (transmit end) location by clicking on the down arrow in the Address list box, then selecting the desired patient location. (If the desired patient location is not on the list, then go back to the Setup screen and use the IP Address Book to enter the information for the desired patient.) After selecting the patient location, click on the Connect button to initiate the IP connection. Once the connection is made, the Status will change from Ready to Receiving Data as shown in Figure 13. If a connection cannot be made, the connection attempt will time out and Status will return to Ready.

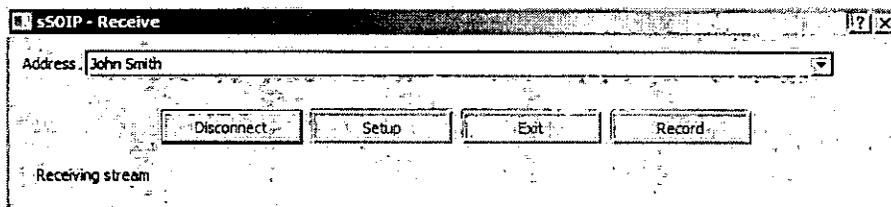


Figure 13: Main Screen while Receiving Data

C. Recording Stethoscope Sounds

With sSOIP receiving stethoscope data, click on Record to start recording. While recording the Record button changes to Stop Recording.

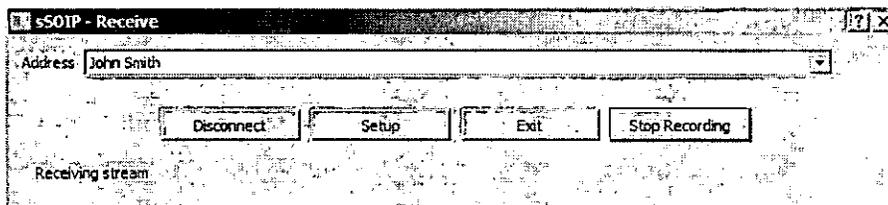


Figure 14: Main Screen while Recording Data

To stop recording, Click on the Stop Recording button. A new screen will pop up to allow the recording to be saved. Figure 15 shows the screen with Play Time and Creation Date entered automatically by sSOIP.

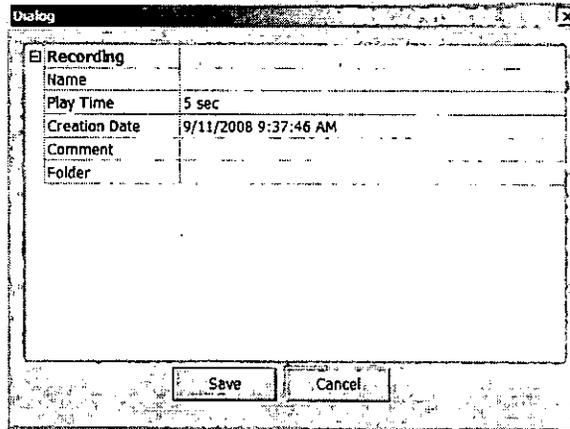


Figure 15: Adding a New Stethoscope File

Click on the fields next to Name and Comment to enter the patient’s name and a comment, respectively. Click on the field next to Folder, then click on the down arrow to display the list of folders available. Figure 16 shows an example where “John Smith” was entered in the Name field and “Heart sounds after walking up stairs” was entered in the Comment field. In his example, a folder for John Smith was already created (see Local Mode below).

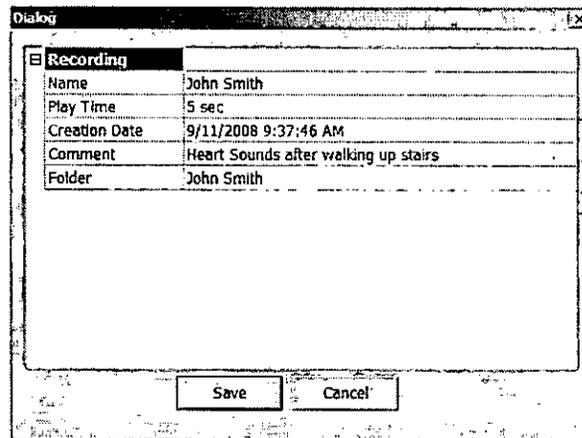


Figure 16: Example of New Stethoscope File

Clicking on the Save button saves the file, closes the window and goes back to the Main window in Receive mode. When the stethoscope session is over, click on Disconnect to terminate the connection.

D. Local Mode

The sSOIP program provides the capability for recording stethoscope sound data into special files, saving those files and playing them back. While recording may be done in either Receive or Local mode, playback can only be performed while in Local mode. All file management functions are done in Local Mode.

To get into Local mode, start from the Main screen and click on Setup to bring up the Setup screen shown in Figure 17.

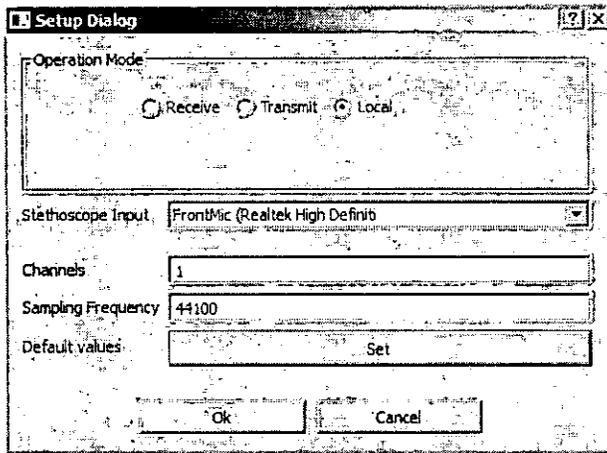


Figure 17: Setup Screen Selecting Local Mode

Click the radio button for Local then click on the OK button. That will go back to the Main screen in Local mode as shown in Figure 18.

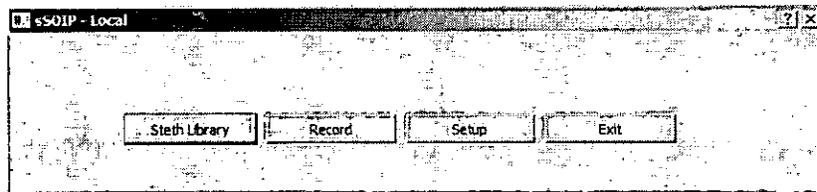


Figure 18: Main Screen in Local Mode

To access the file management functions or to playback a file, click on Steth Library. Figure 19 shows a blank Steth Files window.

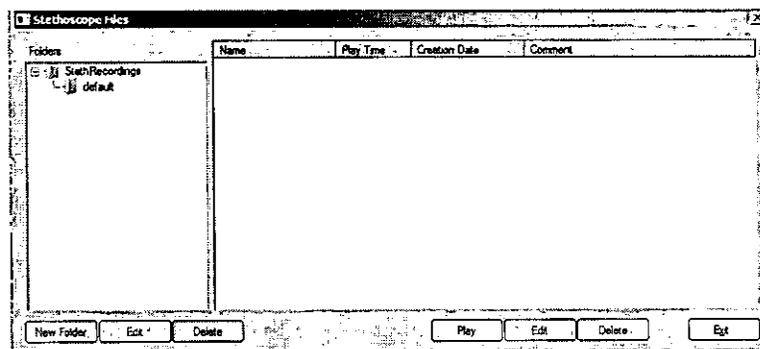


Figure 19: Steth Files Window

To add a new folder for a patient, click on the New Folder button, then next to Name and Description fields enter appropriate information on that patient. Figure 20 shows an example where a new Folder for John Smith was created.

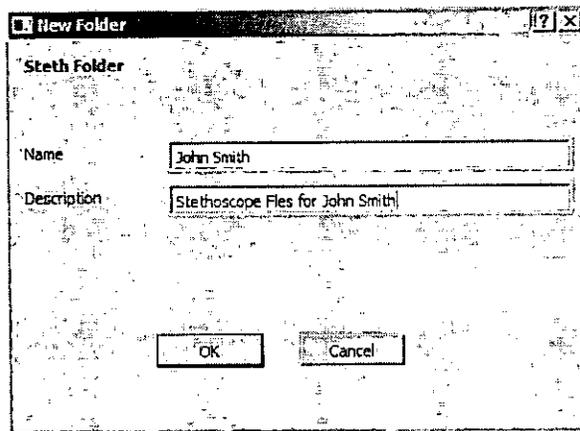


Figure 20: Create New Patient Folder

Click on OK to finish the creation of the folder. A folder can be edited by clicking on the folder to highlight it, then clicking on Edit. That brings up the Steth Folder window again. Make the desired changes then click on OK. To delete a folder, click on the folder to highlight it, then click on Delete. A window will pop up to confirm that you want to delete the folder. If you are sure, click on Yes, otherwise click on No.

In the previous section, an example stethoscope sound file was saved for John Smith. The files for this patient example can be accessed by clicking on the folder name on the right side of the Steth Files window. In this example, the window in Figure 21 would show.

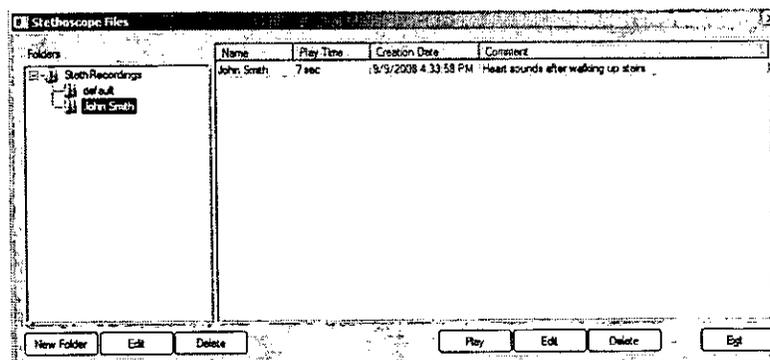


Figure 21: Steth Files Screen Showing Files

To play back a saved file, click on the desired file to highlight it, then click on Play. The stethoscope sound file will playback through the attached Headset. Clicking on Stop stops the playback.

The information for a stethoscope file can be edited by selecting the file to highlight it, then clicking on the Edit button. Make the desired changes to either the Name or Comment field, then click on Save. A file can be deleted by selecting the file to highlight it, then clicking on the Delete button. A window will pop up to confirm that you want to delete the file. If you are sure, click on Yes, otherwise click on No.

E. Auscultation Session Connection Overview

The transmit end locations (where the patients will be) should be in Transmit Mode with their Main screens open and status at Ready to Transmit.

At the receive end, the clinician can choose which patient location to connect to by using the Address drop down list box. Clicking on the down arrow pulls down the list box showing all the patient location choices previously entered. The clinician selects one by clicking on it. That brings back the Main screen with that location showing in the Location field.

The clinician then clicks on Connect to complete the connection to the PCP/PC Stethoscope at that location. The Connect button changes to Disconnect. To terminate the auscultation session the clinician clicks on the Disconnect button.

To close the sSOIP program, click on Exit.

V. Cleaning, Preventive Inspection, Maintenance and Calibration

The PCP/PC Stethoscope requires no preventive inspection, no preventive or routine maintenance, and it does not have to be calibrated.

The PCP/PC Stethoscope is not a sterile device and does not require sterilization or disinfection. It can be cleaned, as required, by wiping with a moist cloth, alcohol or a sanitizing towelette.

VI. Trouble Shooting

Failure to operate: If an IP connection cannot be established to the transmit end station, service personnel from the company that provided the PCP/PC should check the following:

- Insure the transmit end sSOIP application is open and ready to transmit.
- Insure the transmit end PC is connected to the Internet and can access the Internet.
- Insure the assigned IP address of the transmit end is properly entered into the received end sSOIP application.
- Insure the receive end PC is connected to the Internet and can access the Internet.
- Check for a failed PCP/PC Chest Piece by substituting it with a replacement PCP/PC Chest Piece. (Note that the date of manufacture of the PCP/PC Chest Piece is a two hexadecimal (0, 1, 2, 3, 4, 5, 6, 7, 8, 9, A, B, C, D, E, and F) character code where the first character is the number of the month and the second character is the last two digits of the year. For example, August 2010 is 8A.)
- Check for an improperly operating sSOIP by reloading sSOIP.

If taking the above steps does not remedy the problem, contact your provider of the PCP/PC Stethoscope for assistance and product resolution.

Interference: This product is classified as medical electronic equipment and thus needs special precautions regarding EMC and needs to be installed in accordance with the instructions in this Manual. Portable and mobile RF communications equipment can affect medical electrical equipment.

If interference from other equipment is heard from the PCP/PC during a stethoscope session, the problem may be resolved by relocating other equipment so that it is farther from the PCP/PC. The

provider of the PCP/PC Stethoscope will assist in resolving any interference problems. If the interference problems cannot be resolved and the interference does not permit auscultation sounds from being heard, then the PCP/PC should not be used in that location.

sSOIP Software Performance
January 12, 2011

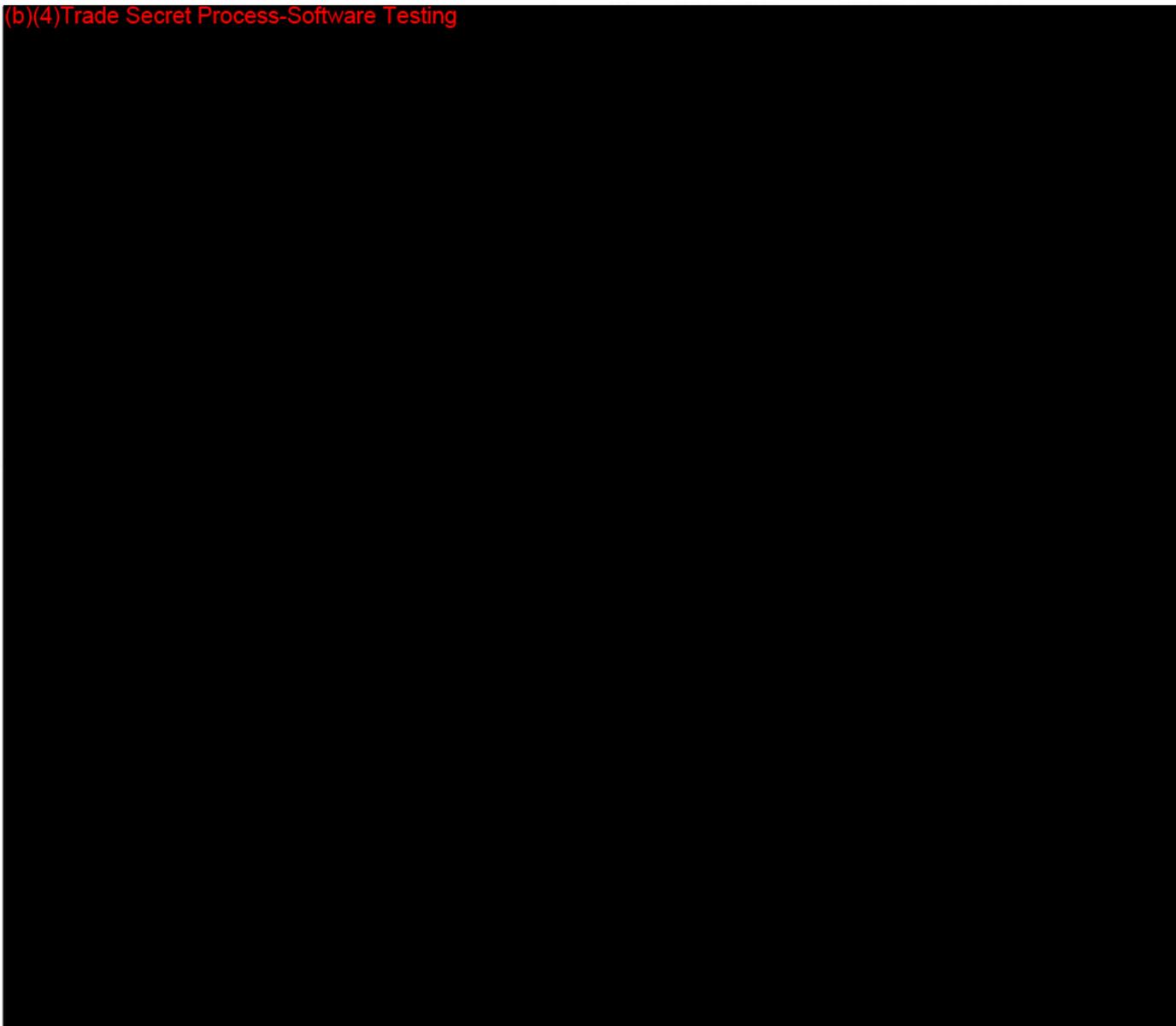
Requirements:

(b)(4)Trade Secret Process-Software Testing

A large black rectangular redaction box covering the majority of the Requirements section.

Test:

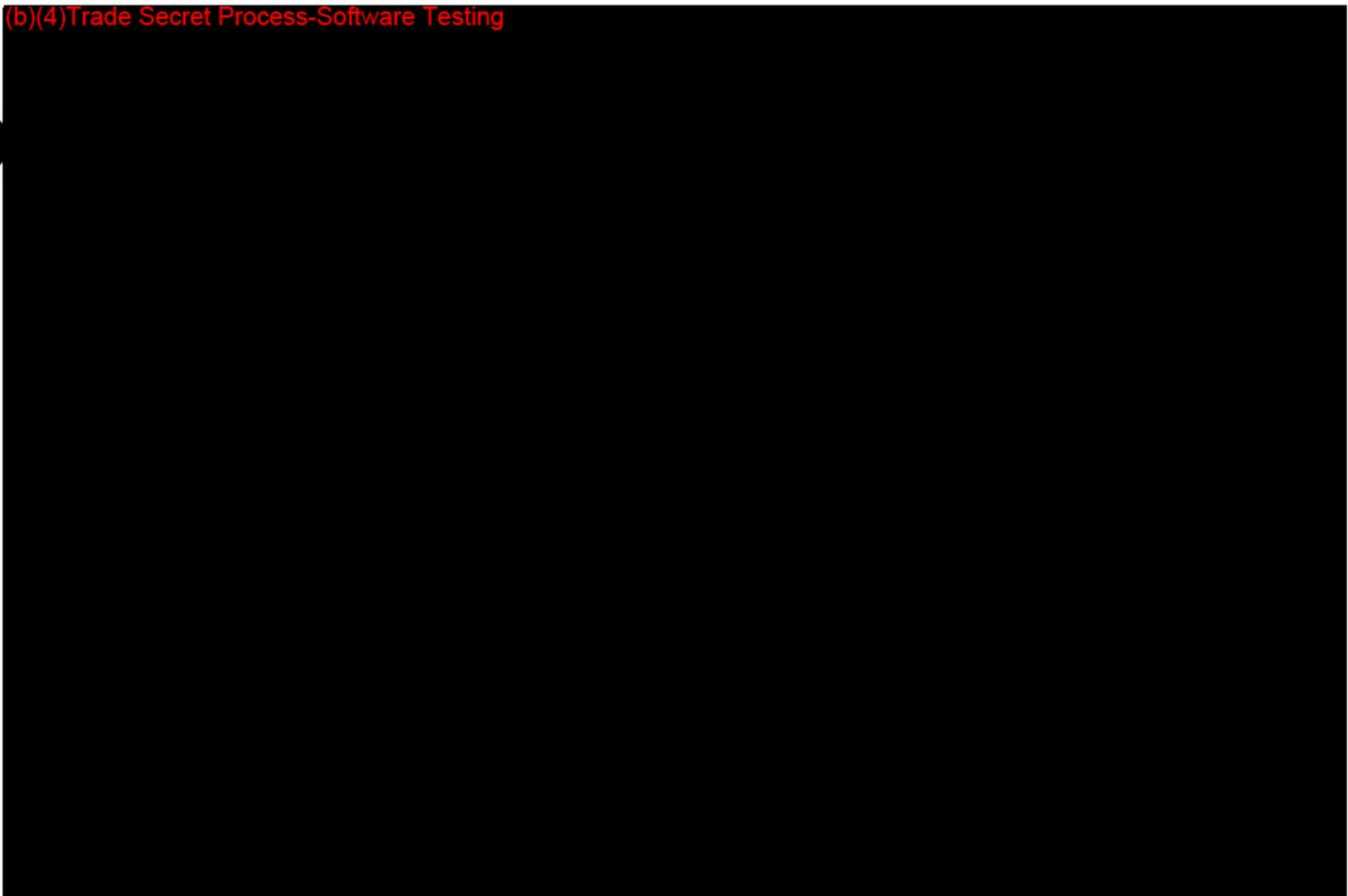
(b)(4)Trade Secret Process-Software Testing

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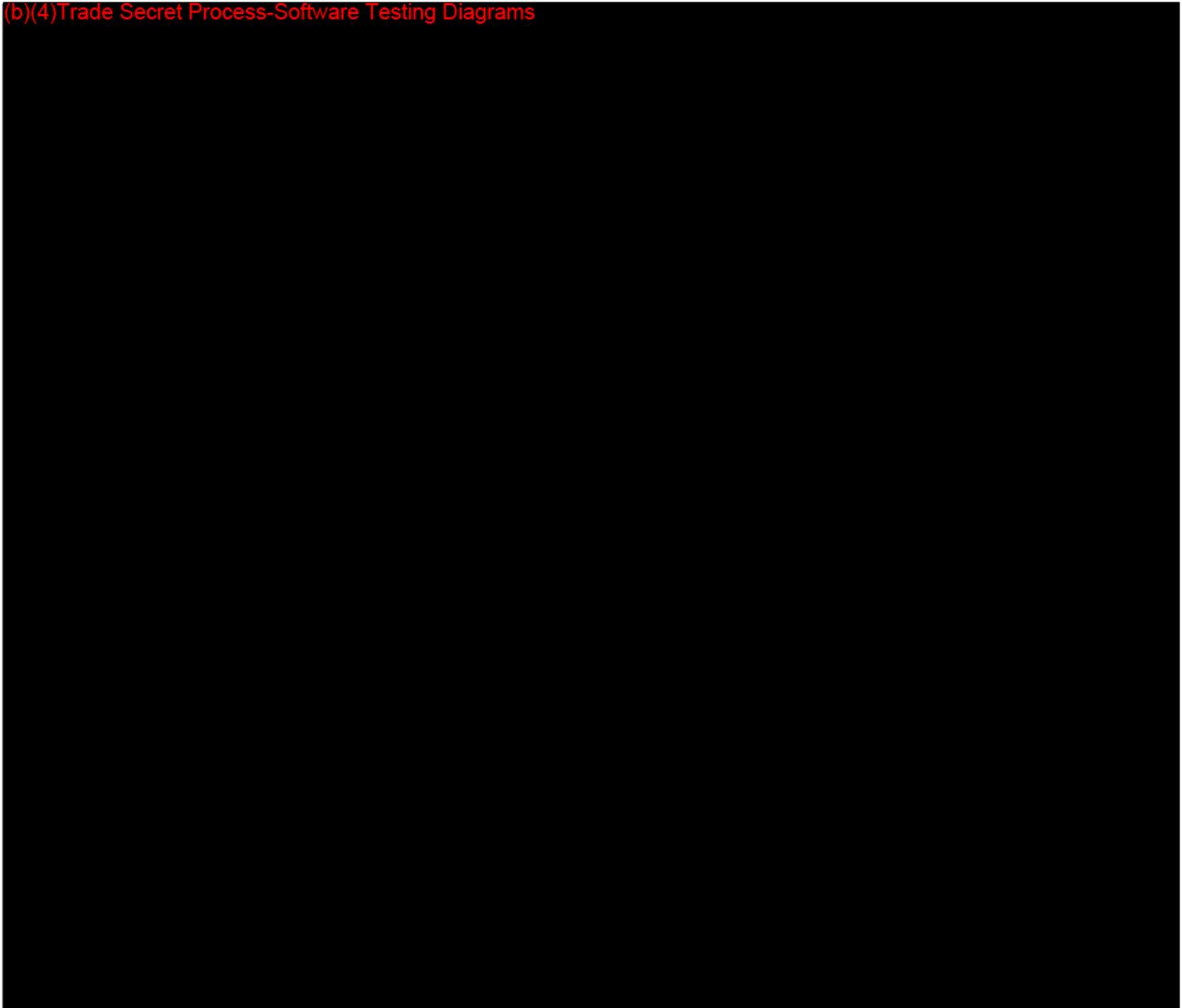
Results:

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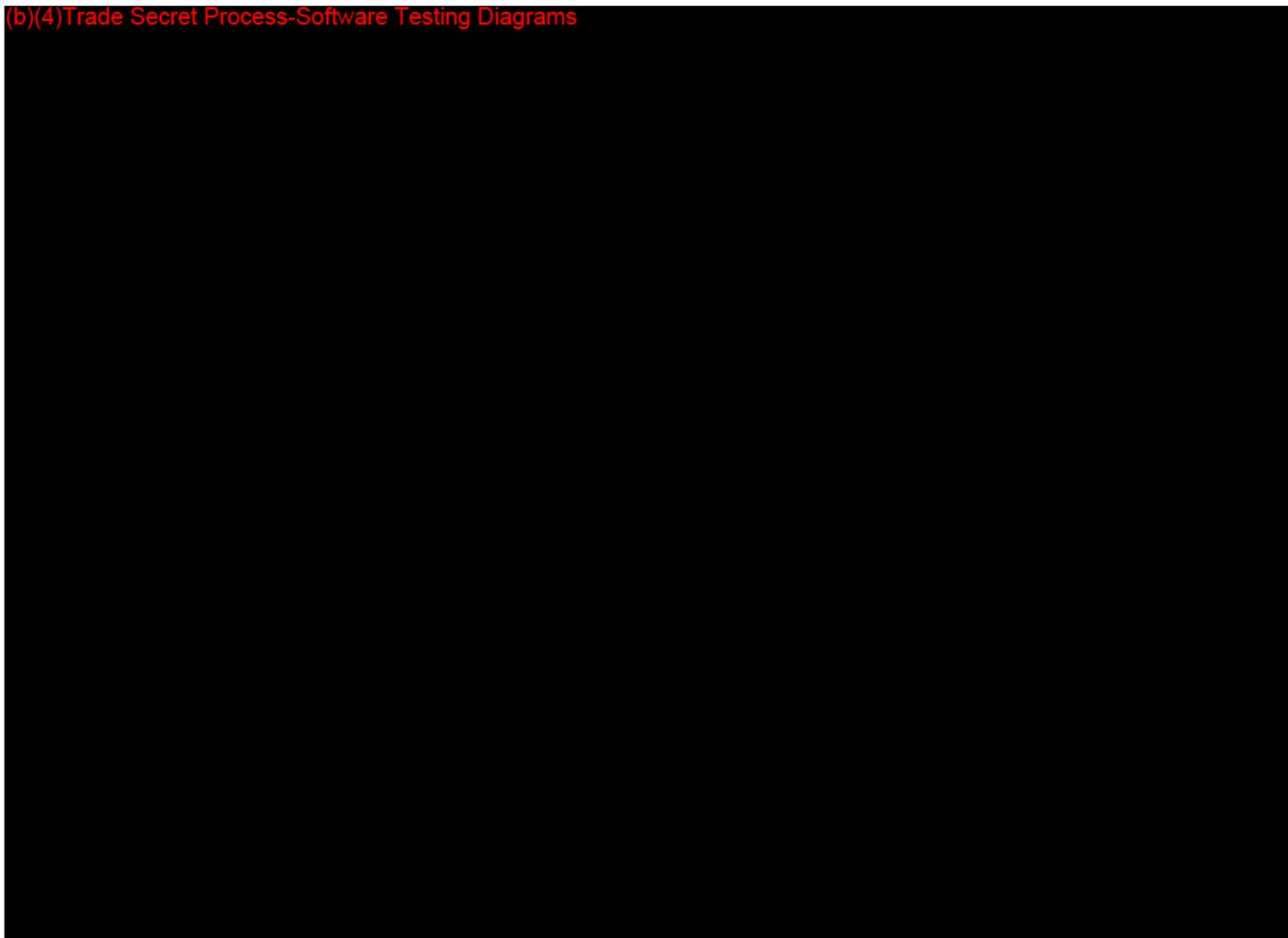
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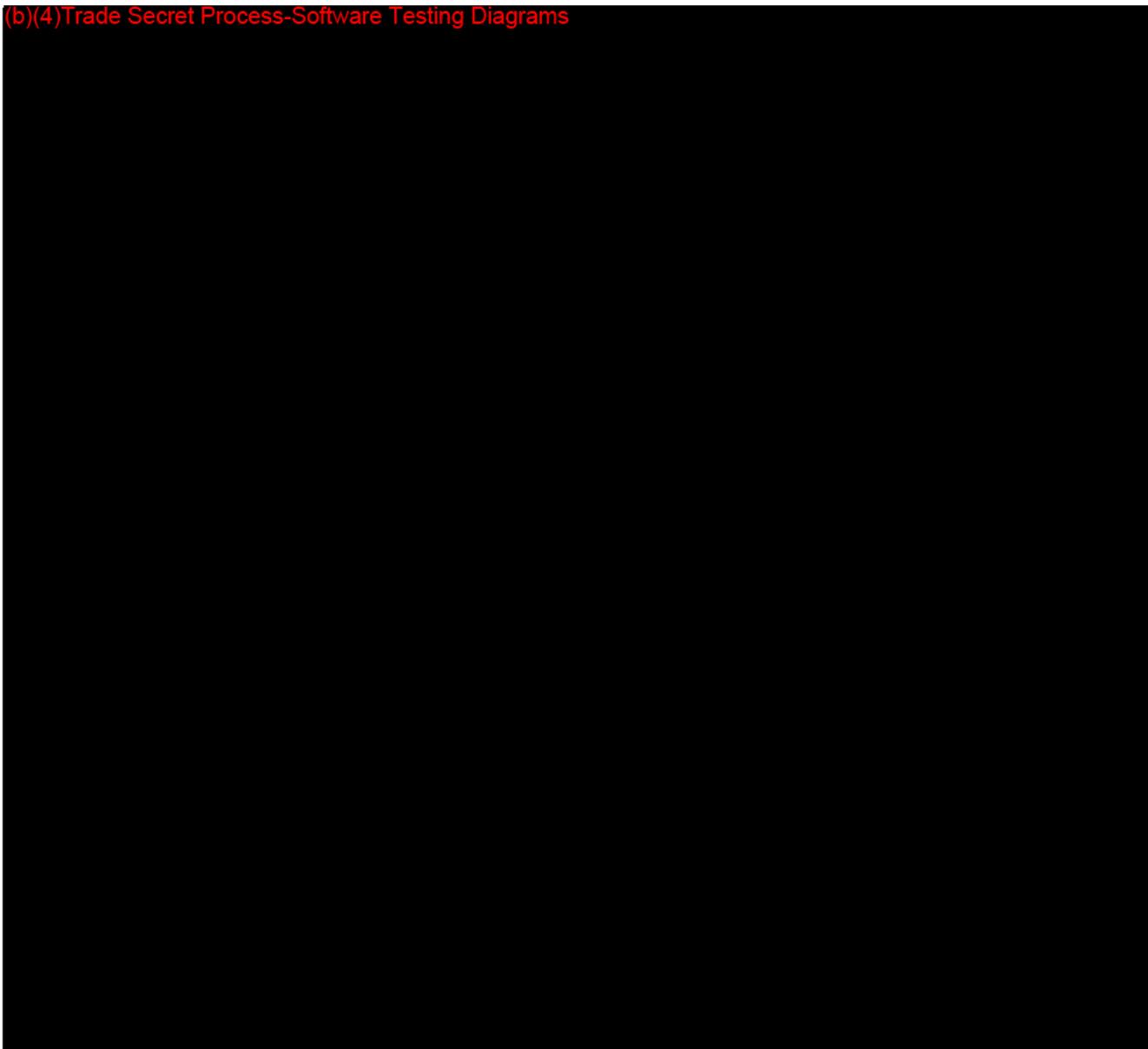
(b)(4)Trade Secret Process-Software Testing Diagrams



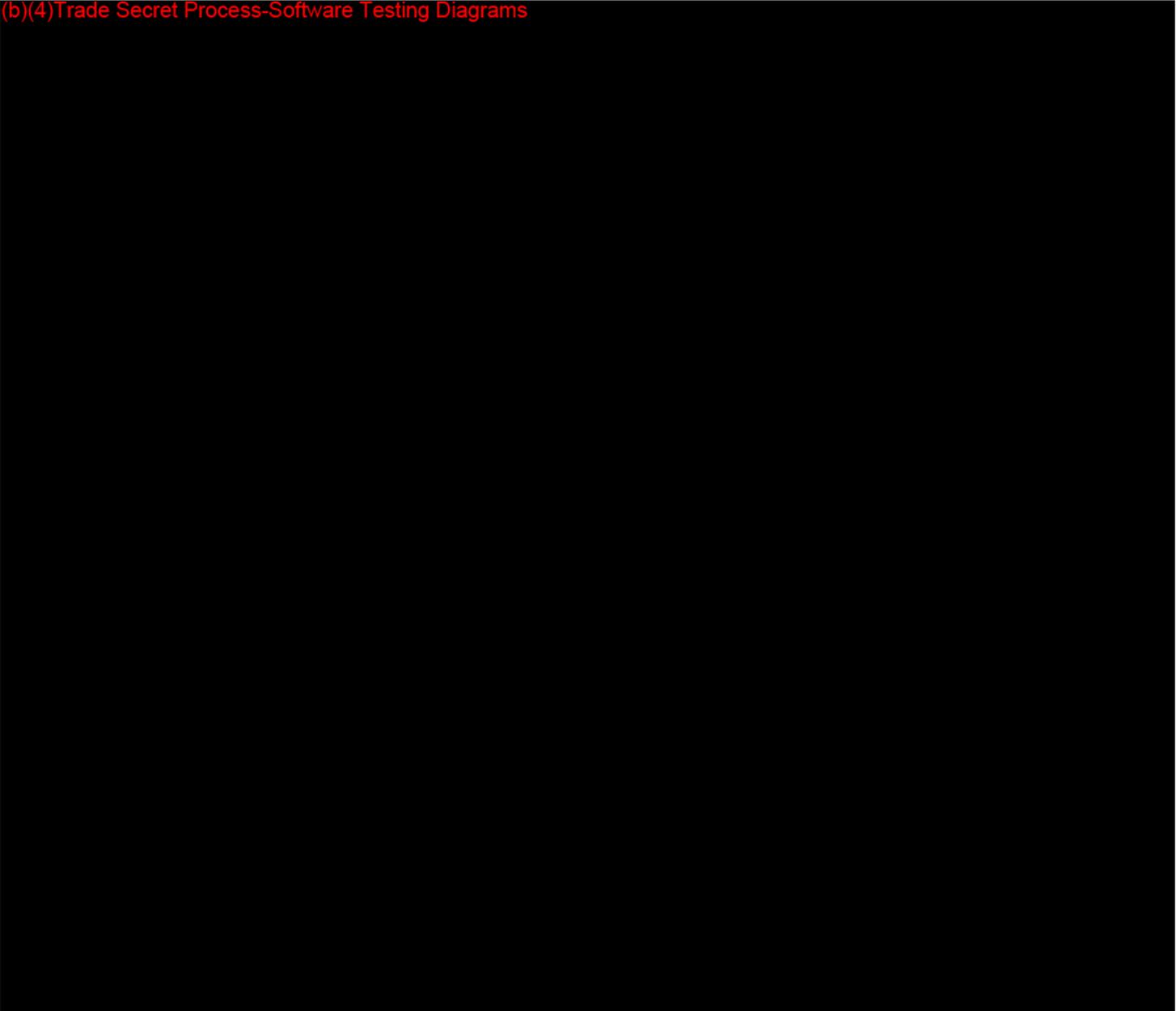
(b)(4)Trade Secret Process-Software Testing Diagrams



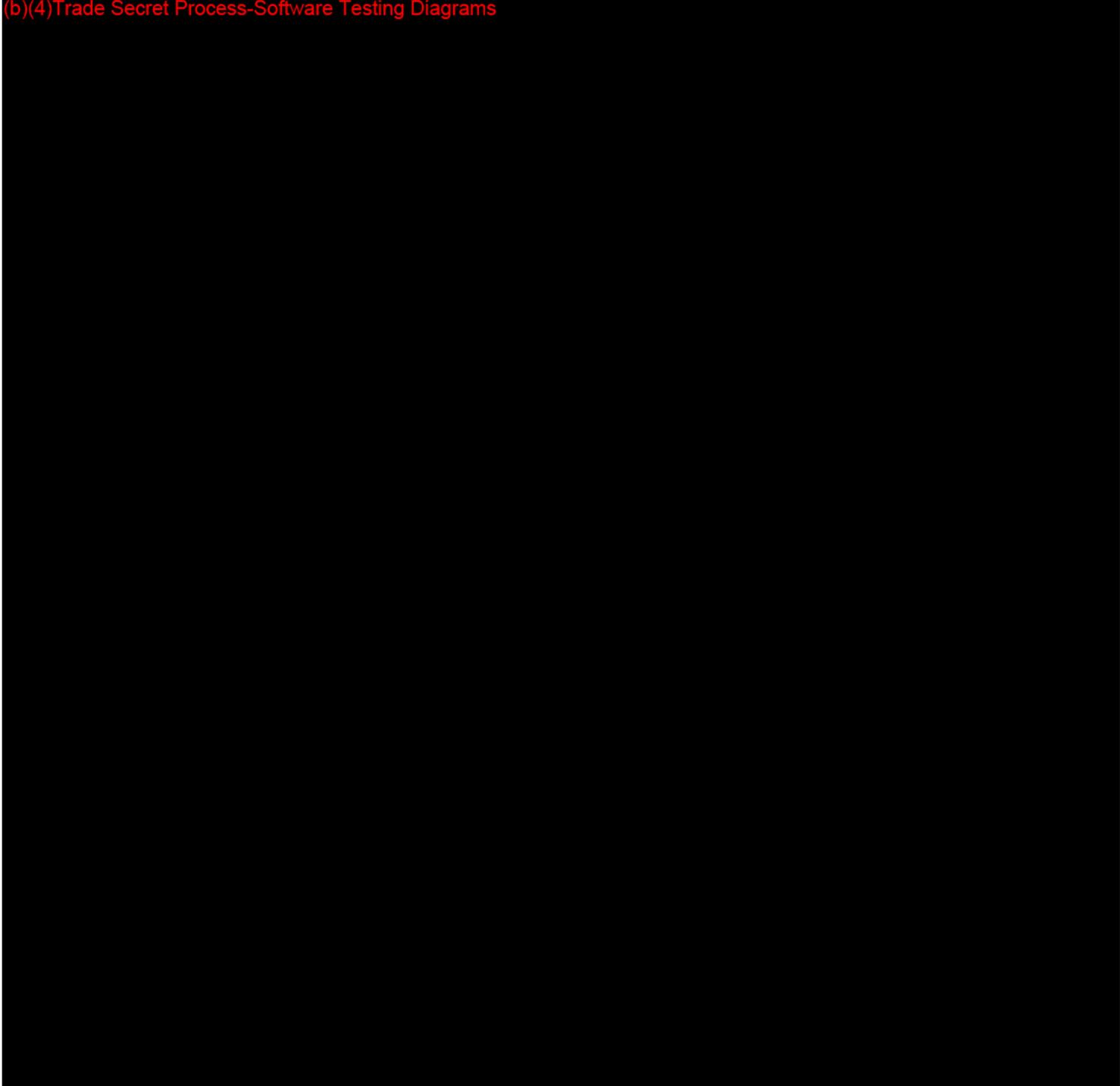
(b)(4)Trade Secret Process-Software Testing Diagrams

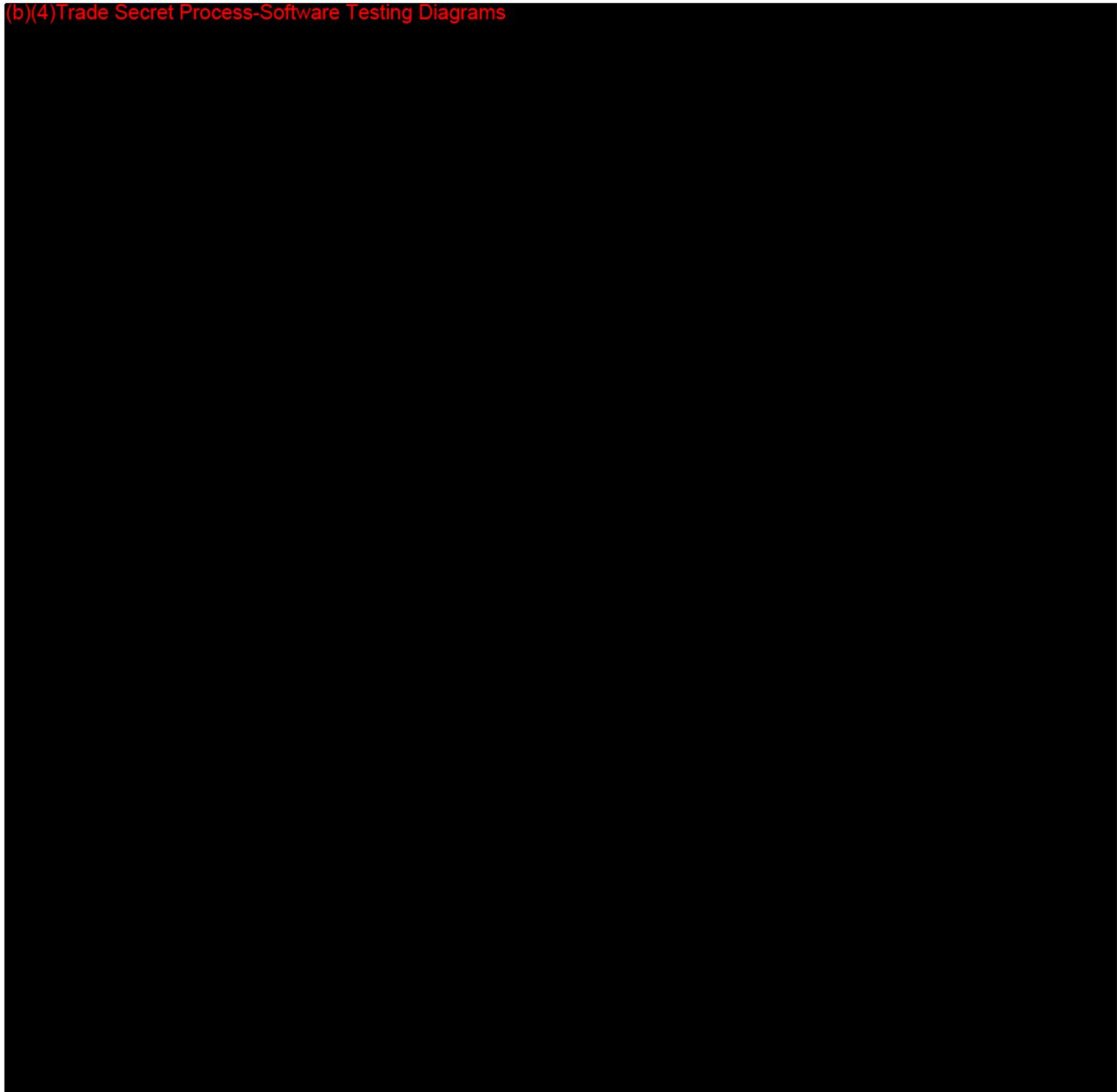


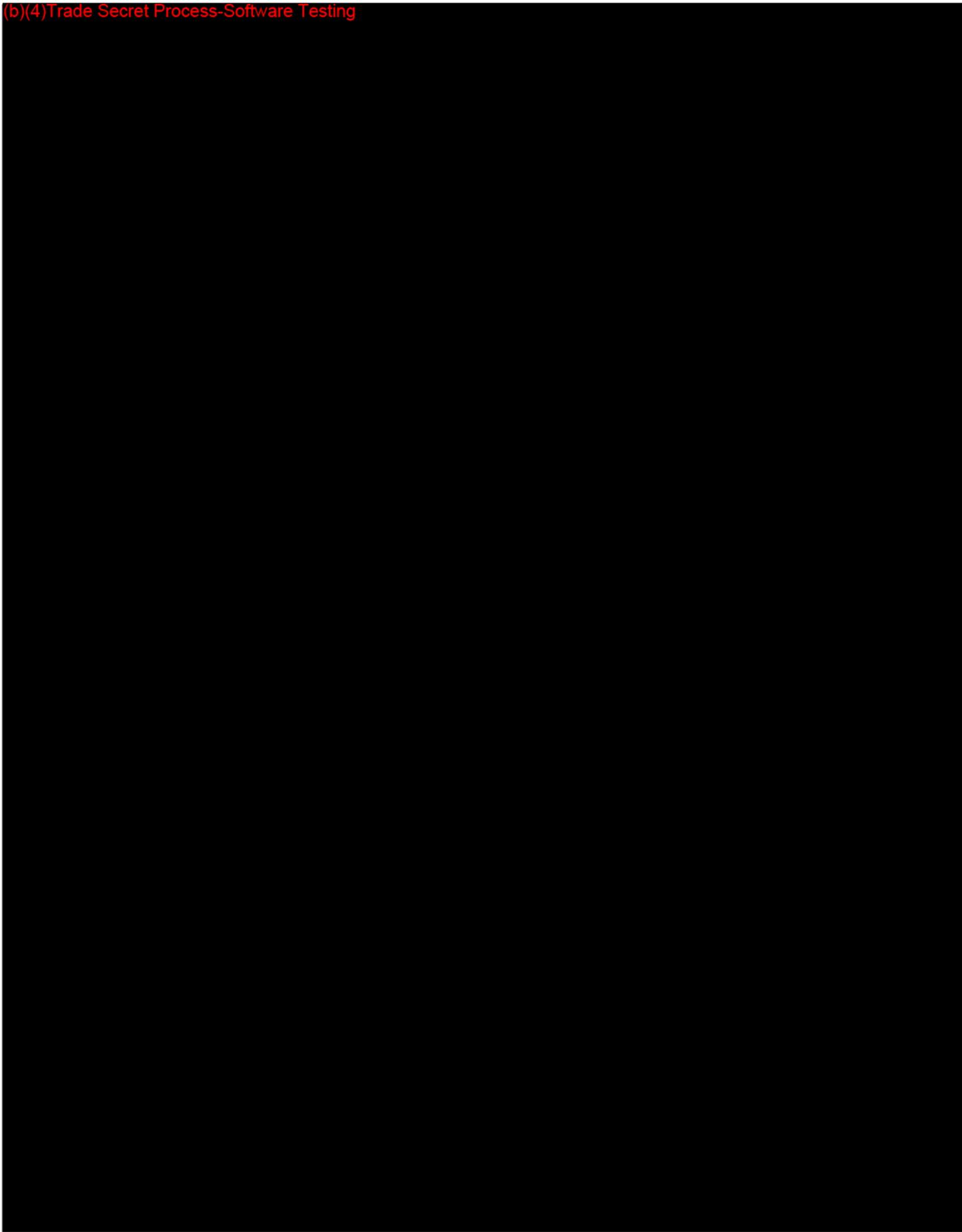
(b)(4)Trade Secret Process-Software Testing Diagrams



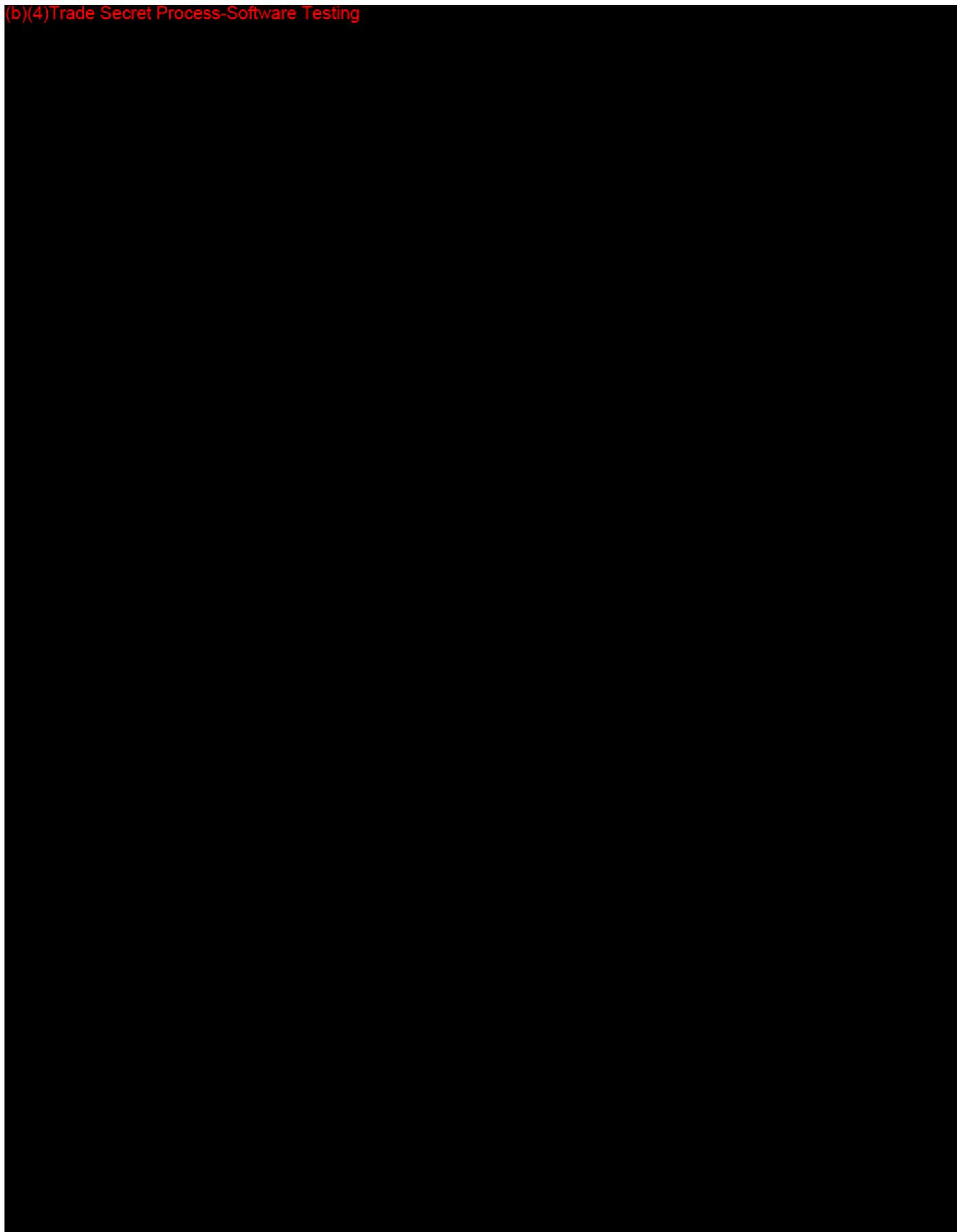
(b)(4) Trade Secret Process-Software Testing Diagrams

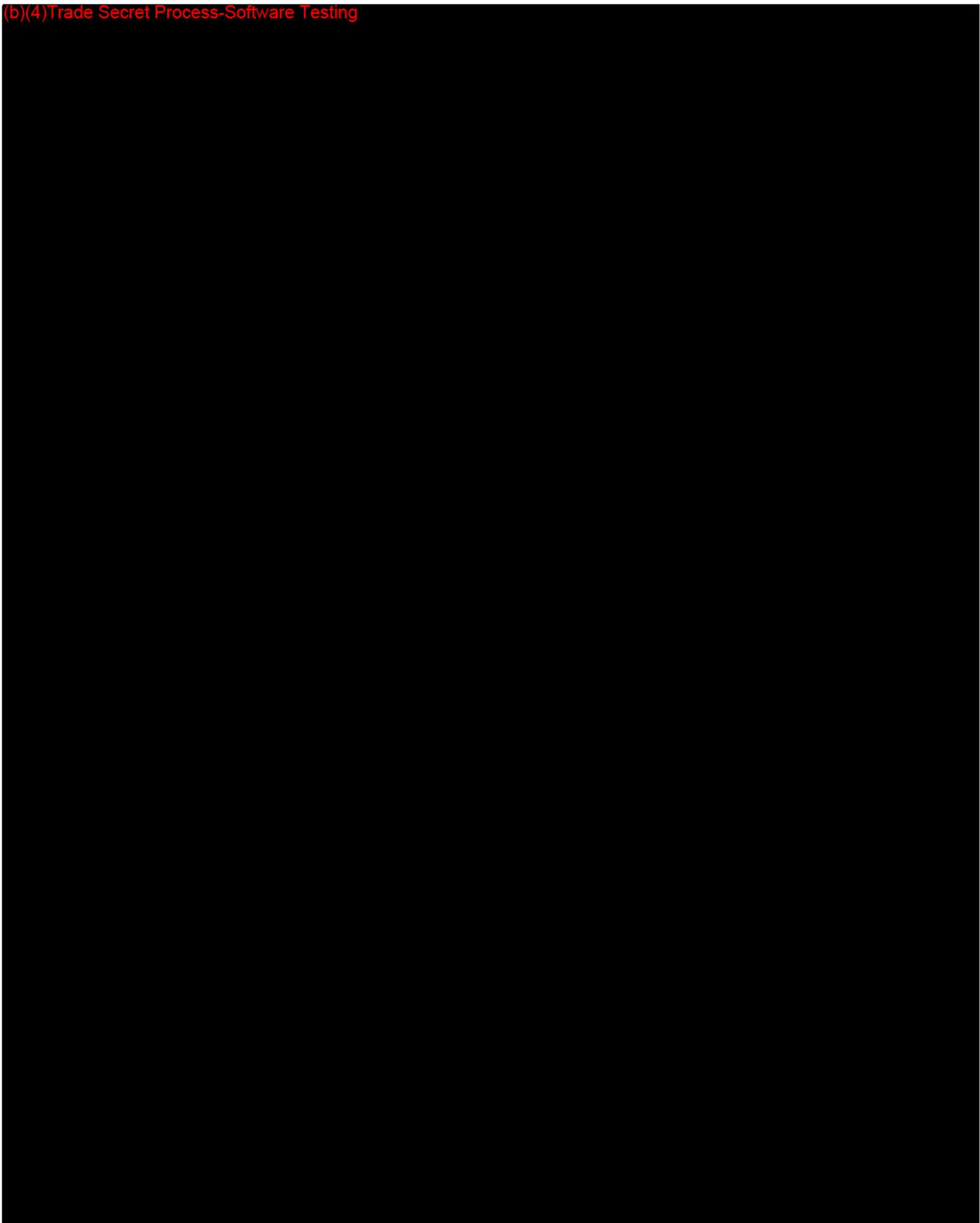




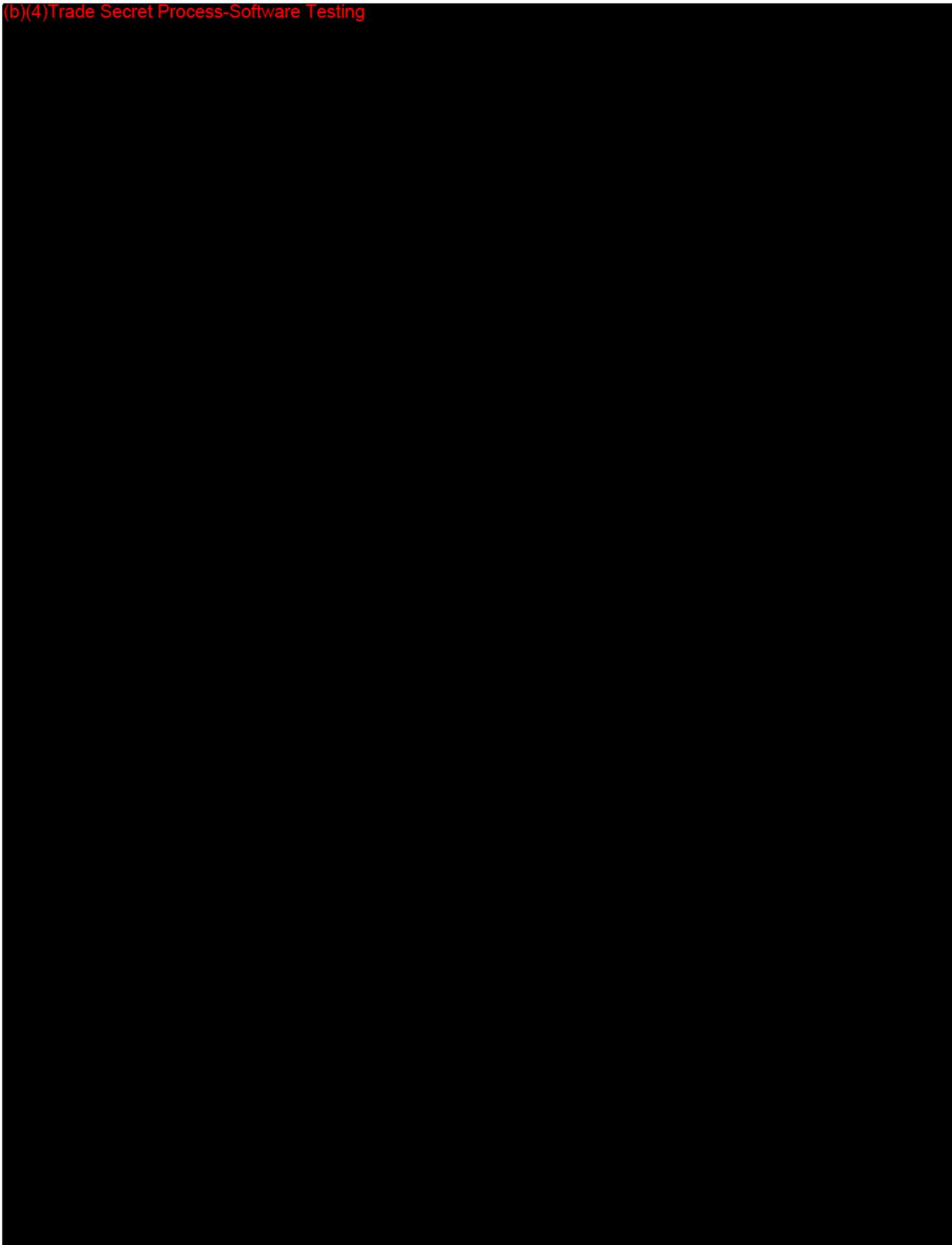


(b)(4)Trade Secret Process-Software Testing

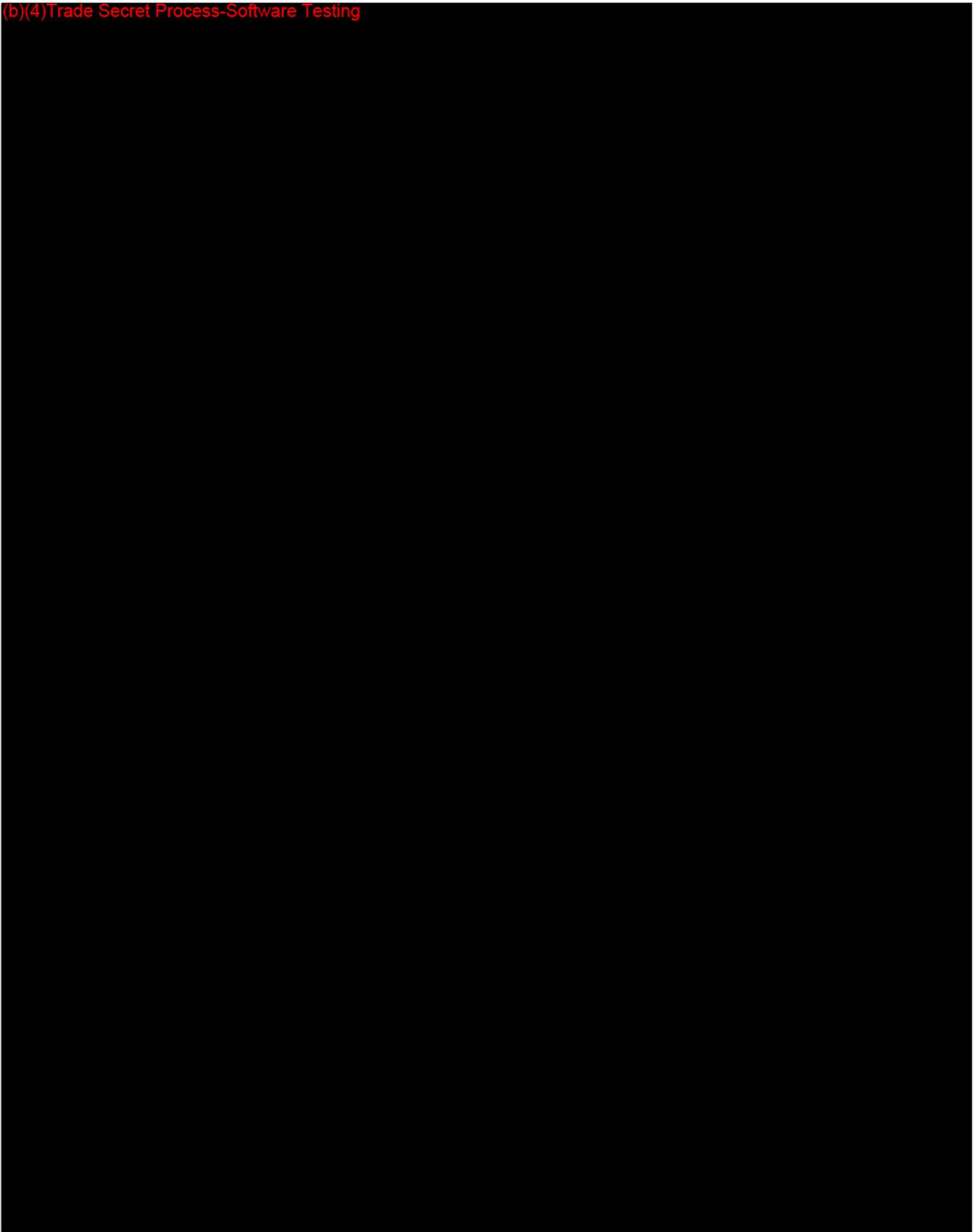




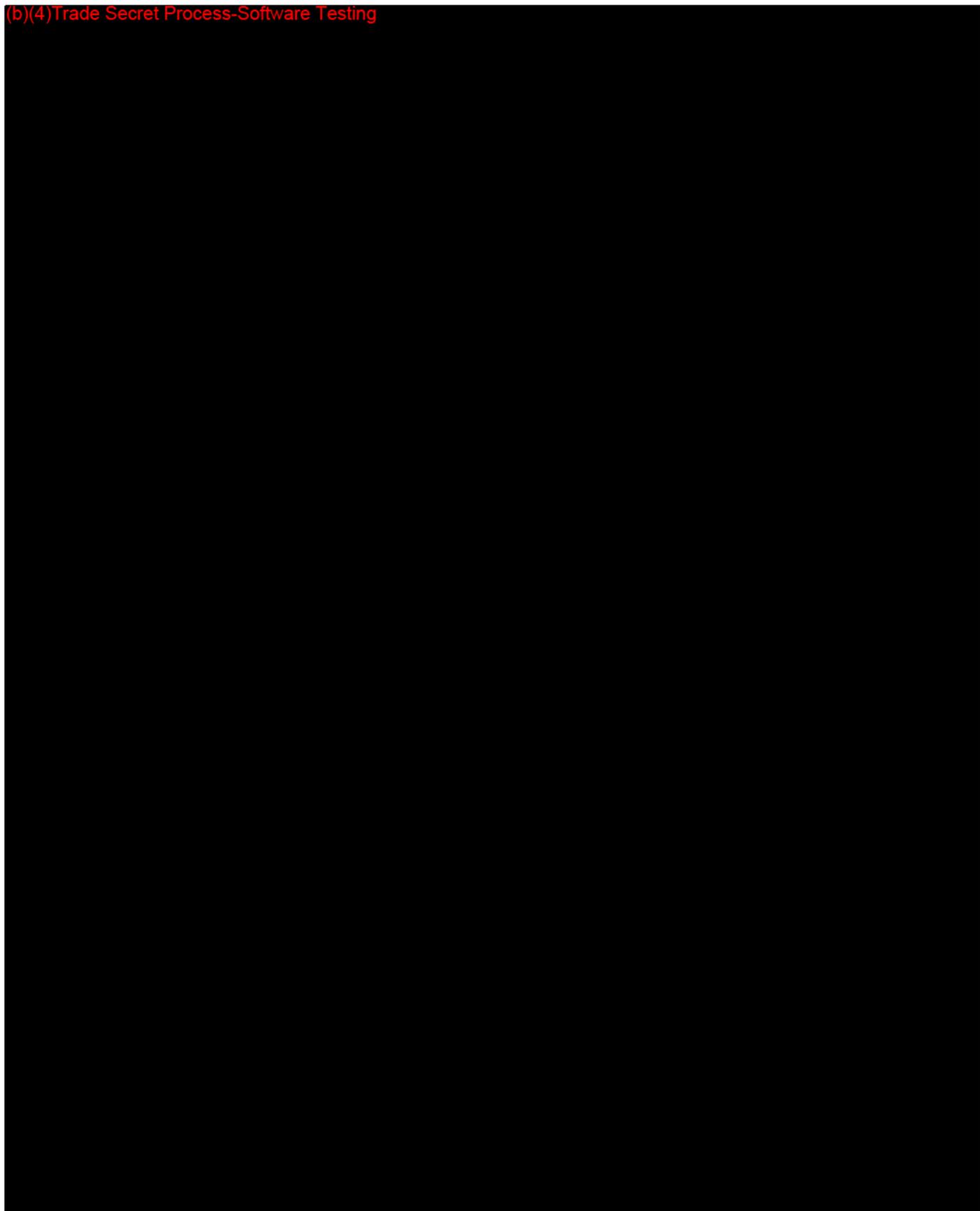
(b)(4)Trade Secret Process-Software Testing



(b)(4)Trade Secret Process-Software Testing



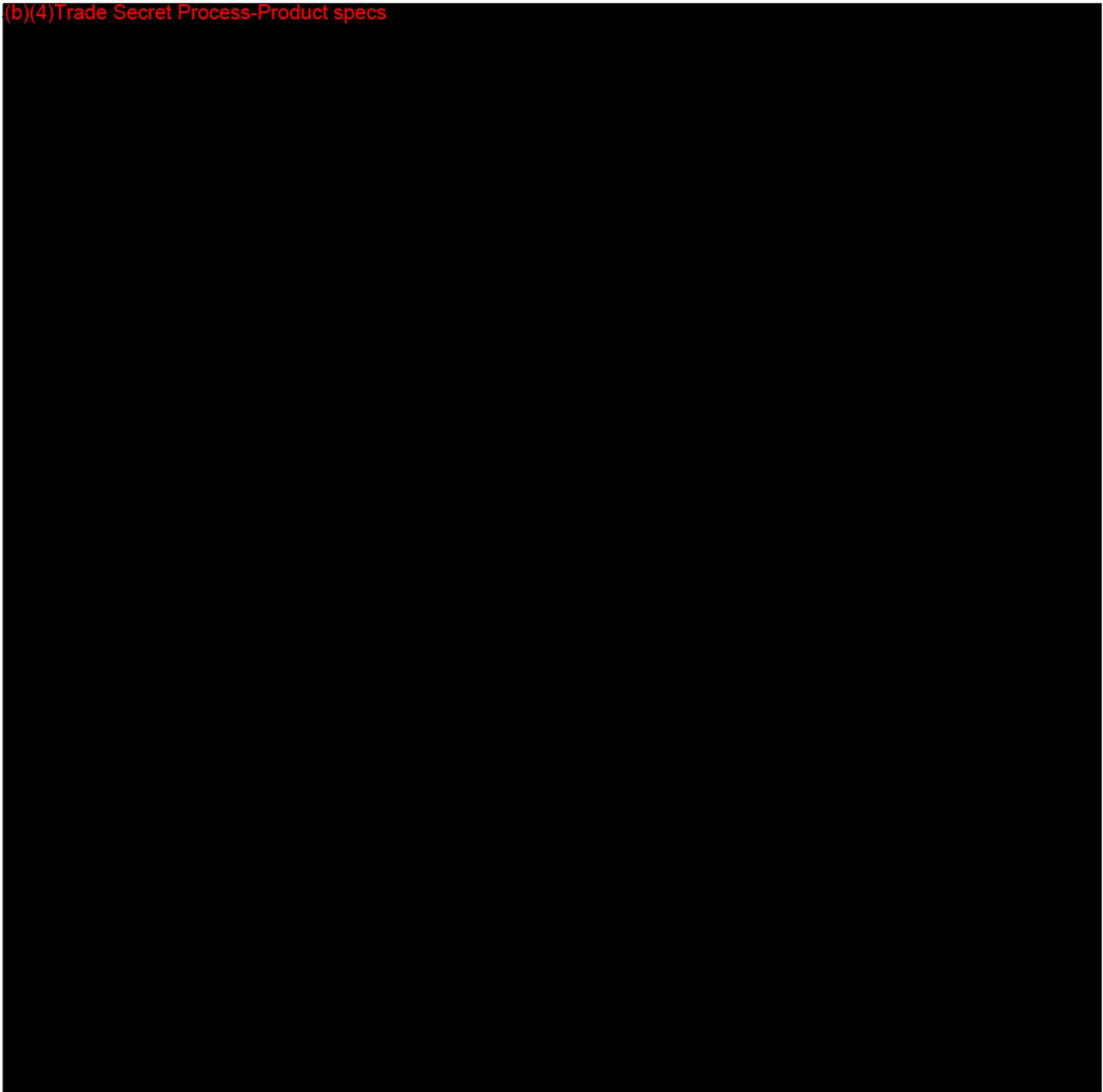
(b)(4)Trade Secret Process-Software Testing



PCP/PC Biocompatibility

Dec. 22, 2010

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





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

December 28, 2010

RNK PRODUCTS, INC.
4195 US HWY 1 SUITE 101
ROCKLEDGE, FLORIDA 32955
UNITED STATES
ATTN: CHARLES R. ABBRUSCATO

510k Number: K102893

Product: PCP/PC STETHOSCOPE

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

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModer nizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 4 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 04, 2010

RNK PRODUCTS, INC.
4195 US HWY 1 SUITE 101
ROCKLEDGE, FLORIDA 32955
UNITED STATES
ATTN: CHARLES R. ABBRUSCATO

510k Number: K102893
Received: 9/30/2010
Product: PCP/PC STETHOSCOPE

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

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

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)Trade 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) RNK PRODUCTS INC 4195 US Hwy 1 Suite 101 Rockledge FL 32955 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****1576	2. CONTACT NAME Charles Abbruscato 2.1 E-MAIL ADDRESS abbruscato@rnkproducts.com 2.2 TELEPHONE NUMBER (include Area code) 321-6267717 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 321-3055983	
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:		
<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)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: SBD108165		
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.		
<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)		24-Sep-2010

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission Sept. 29, 2010	User Fee Payment ID Number (b)(4) Trade Secret Process Software	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 checked="" 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 RNK Products, Inc.	Establishment Registration Number (if known) 3004595287		
Division Name (if applicable)	Phone Number (including area code) 321.626.7717		
Street Address 4195 US Hwy 1, Suite 101	FAX Number (including area code) 321.305.5983		
City Rockledge	State / Province FL	ZIP/Postal Code 32955	Country USA
Contact Name Charles R. Abbruscato			
Contact Title CEO	Contact E-mail Address abbruscato@rnkproducts.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 checked="" type="checkbox"/> New Device <input checked="" 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 checked="" 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 checked="" type="checkbox"/> Process change: <input checked="" type="checkbox"/> Manufacturing <input checked="" 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	D0D	2		3	
5		6		7	
				<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	

Information on devices to which substantial equivalence is claimed (if known)					
	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K030446	1	TR-1 Telephonic Stethoscope	1	RNK Products, Inc.
2	K072026	2	Precordial Stethoscope	2	RNK Products, Inc.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
 Electronic Stethoscope

	Trade or Proprietary or Model Name for This Device		Model Number
1	PCP/PC Stethoscope	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 D0D	C.F.R. Section (if applicable) C.F.R. Section: 21 CFR 870.1875	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 RNK PCP/PC Stethoscope is intended for use as a remote monitoring device, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on a IP connection between the two locations.

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 3004595287	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name RNK Products, Inc.		Establishment Registration Number 3004595287		
Division Name (if applicable)		Phone Number (including area code) 321.626.7717		
Street Address 4195 US Hwy 1, Suite 101		FAX Number (including area code) 321.305.5983		
City Rockledge		State / Province FL	ZIP Code 32955	Country USA
Contact Name Charles R. Abbruscato		Contact Title CEO		Contact E-mail Address abbruscato@rnkproducts.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	EN 60601-1	ISO	Medical Electrical Equipment Part 1: General Requirement for Safety	2nd Edition	01/01/2003
2	EN 60601-1-2	ISO	EMC Immunity Requirements for Medical Electrical Equipment Part 1: General Requirements for Safety, 2. Collateral Standard – Electromagnetic Compatibility Requirements and Tests		01/01/2007
3					
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.

RNK Products

RNK PCP/PC Stethoscope

510(k) Premarket Notification

RNK Products, Inc.
4195 US Hwy 1
Suite 101
Rockledge, FL 32955
(321) 626-7717

K102893

Sept. 29, 2010

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

FDA CDRH DMC

SEP 30 2010

Received K69

Re: Premarket Notification for RNK Products PCP/PC Stethoscope

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act 21 U.S.C. § 351(k), RNK Products, Inc. ("RNK") is submitting the enclosed premarket notification for RNK's PCP/PC Stethoscope, an electronic stethoscope. The RNK PCP/PC Stethoscope is intended for use as a remote monitoring device, whereby a clinician at one location can listen to the auscultation sounds of a patient at a different location, with the signal carried over a data communication channel between the two locations. The RNK PCP/PC Stethoscope is a Class II medical device pursuant to 21 C.F.R. § 870.1875, "Stethoscope."

The RNK PCP/PC Stethoscope is substantially equivalent to other marketed devices that have received premarket clearance, specifically the RNK Products TR-1 Telephonic Stethoscope (K034046) and Precordial Stethoscope (K072026). As explained in greater detail in the attached submission, the RNK PCP/PC Telephonic Stethoscope has the same intended use and principles of operations and technological characteristics as a combination of the predicate TR-1 and Precordial Stethoscopes. The differences of the RNK PCP/PC Stethoscope from the predicates do not raise any new questions of safety or effectiveness.

We trust that the information in the enclosed 510(k) notice will be sufficient to enable the Food and Drug Administration ("FDA") to find that the RNK PCP/PC Telephonic Stethoscope is substantially equivalent to the RNK TR-1 Telephonic Stethoscope and Precordial Stethoscope. Please direct any questions or requests for information concerning this submission to the

undersigned at (321) 626-7717. Upon a finding of substantial equivalence, please send me a copy of the signed substantial equivalence letter by facsimile at (321) 305-5983.

Sincerely,

A handwritten signature in cursive script, appearing to read "Charles R. Abbruscato". The signature is fluid and extends across the width of the line.

Charles R. Abbruscato

Enclosure

510(k) PREMARKET NOTIFICATION CHECKLIST

ITEM	COMMENT
1. Device trade or proprietary name	See 510(k) section II – RNK PCP/PC Stethoscope.
2. Device common or usual name or classification name	See 510(k) section II – Electronic Stethoscope.
3. Establishment registration number (only applies if establishment is registered)	See 510(k) section III. - 3004595287
4. Class into which the device is classified	See 510(k) section IV - This device is a class II device, pursuant to 21 C.F.R. § 870.1875.
5. Classification Panel	See 510(k) section IV - Cardiovascular Panel.
6. Action taken to comply with Section 514 of the Act	See 510(k) section V - Not applicable - no performance standards developed and no applicable special controls.
7. Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use	See Attachments 1 and 2.
8. A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	See Attachment 10.
9. For class III devices only, a class III certification and a class III summary	Not applicable - this device is a class II device.
10. Photographs and engineering drawings of the device	See Attachment 5 for engineering drawings.
11. The marketed device(s) to which equivalence is claimed including labeling and description of the device	See 510(k) section VII; Attachment 3.
12. Statement of similarities and/or differences with marketed devices(s)	See 510(k) section VII.
13. Data to show consequences and effects of a modified device	Not applicable.
14. Submitter's name and address	See 510(k) section XI.
15. Contact person, telephone number and fax number	See 510(k) section XII.

16. Representative/Consultant if applicable	Not applicable.
17. Table of Contents with pagination	See 510(k) notice page ii.
18. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	See 510(k) section III.
19. Comparison table of the new device to the marketed device(s)	See Attachment 4.
20. Action taken to comply with voluntary standards	See 510(k) section VIII.
21. Performance data	--
a. marketed device	--
1. bench testing	n/a
2. animal testing	n/a
3. clinical data	n/a
b. new device	--
1. bench testing	None.
2. animal testing	None.
3. clinical data	None.
22. Sterilization information	Not applicable.
23. Software Information	See Attachment 6.
24. Hardware information	Not applicable.
25. Is this device subject to issues that have been addressed in specific guidance document(s)?	No.
26. Indications for Use Statement	See 510(k) section XIV; Attachment 11.
27. Truthful and Accurate Statement	See 510(k) section XV; Attachment 12.
28. Other (specify)	None.

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LIST OF ATTACHMENTS

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Draft Labeling for the RNK PCP/PC Stethoscope	1
Draft Promotional Material for the RNK PCP/PC Stethoscope	2
Predicate Device Labeling	3
Substantial Equivalence Chart	4
Engineering Drawings	5
Software	6
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I. INTRODUCTION

The purpose of this 510(k) notice is to obtain clearance from the Food and Drug Administration (“FDA”) for RNK Products (“RNK”) PCP/PC Stethoscope.

The RNK PCP/PC Telephonic Stethoscope consists of a Chest Piece assembly that plugs into the Microphone port of a generic PC and a software package called Streaming Stethoscope Over IP (sSOIP) running on the PC. The signal from the PCP/PC chest piece is amplified and digitized at high audio resolution (e.g. 8,000 samples per second) by the PC's audio circuitry. The sSOIP program creates an audio stream in IP communications format and sets up an IP connection to another PC on the IP network. That receive end PC accepts the streaming audio and feeds it to its audio circuitry where it is converted back to analog, amplified and presented to the Headset port. The audio stethoscope sounds can be heard at the Headset output port of the receive end PC.

The RNK PCP/PC Stethoscope is substantially equivalent to the RNK TR-1 Telephonic Stethoscope and Precordial Stethoscope.

II. NAME OF DEVICE

- A. Trade or Proprietary Name: **RNK PCP/PC Stethoscope**
- B. Common Name: **Electronic Stethoscope**
- C. Classification Name: **Stethoscope
(21 C.F.R. § 870.1875)**
- D. Product Code: **DQD**

III. ESTABLISHMENT REGISTRATION NUMBER AND ADDRESS OF MANUFACTURING FACILITY

Establishment Reg. No.: 3004595287

RNK Products
4195 US Hwy 1
Suite 101
Rockledge, FL 32955
Telephone (321) 626-7717
Facsimile: (321) 305-5983

IV. DEVICE CLASSIFICATION/CLASSIFICATION PANEL

Pursuant to 21 C.F.R. §870.1875, FDA has classified electronic stethoscopes as Class II devices. Electronic stethoscopes are reviewed by the Cardiovascular Panel.

V. PERFORMANCE STANDARDS

No performance standards or special controls have been developed under Section 514 of the FDC Act for electronic stethoscopes.

VI. LABELING

Draft labeling for the RNK PCP/PC Stethoscope is provided in **Attachment 1** of this submission. Draft promotional materials for the RNK PCP/PC Stethoscope are provided in **Attachment 2**.

VII. SUBSTANTIAL EQUIVALENCE

The RNK PCP/PC Stethoscope is substantially equivalent to the RNK TR-1 Telephonic Stethoscope (K034046) and Precordial Stethoscope (K072026) which themselves are related. Labeling for the predicate devices is provided in **Attachment 3** of this submission.

The predicate Precordial Stethoscope is comprised of a chest piece assembly and a separate amplifier module. This amplifier is similar to the amplifier inside the TR-1. The Precordial Stethoscope introduced a new chest piece based on a piezo element rather than a microphone as was used in the CP-1 Chest Piece for the TR-1. The PCP/PC chest piece assembly is physically similar to the Precordial Stethoscope chest piece with an identical ABS plastic Bottom piece, piezo element and Silicone cover over the piezo element, and a similar stainless steel Top piece. However, the PCP/PC chest piece has the amplifier of the Precordial Stethoscope embedded within it rather than as a separate module. That is, the printed circuit board with the amplifier in the amplifier module of the Precordial Stethoscope was reduced in size so that it fit inside the PCP/PC chest piece assembly. Thus, The PCP/PC chest piece assembly is functionally equivalent to a consolidation of three pieces of the Precordial Stethoscope: 1) a piezo chest piece assembly 2) plugged into the Chest Piece jack of the amplifier module and 3) an audio cable plugged into the Headset jack the amplifier module.

This is illustrated in the following figure.

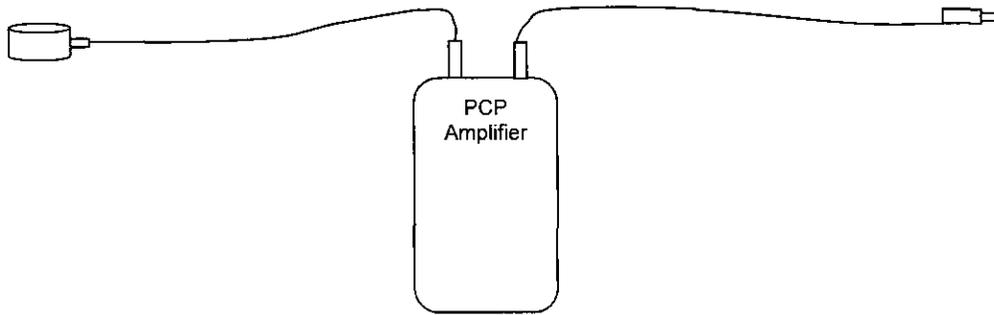


Fig. 1a: Piezo Chest Piece (PCP) and an Audio Cable plugged into an Amplifier Module



Fig. 1b: PCP/PC Chest Piece Assembly with Embedded Amplifier

As part of the predicate TR-1, the CP-1 chest piece has an embedded electret microphone as the sensor which provides some audio gain. A bias voltage (sometimes referred to as a "phantom" voltage) from the TR-1 provides this bias voltage. The PCP/PC chest piece has an embedded piezo element as the sensor and with the embedded amplifier provides some audio gain. Just as the predicate CP-1, the PCP/PC chest piece requires a bias voltage such as that provided by the TR-1. The gain of the PCP/PC amplifier circuit is such that the output level of the PCP/PC chest piece is the same as the output level of the CP-1 chest piece used with the TR-1 Module. Thus, the PCP/PC chest piece is a direct substitute for the CP-1 and can be used with the TR-1.

In addition to obtaining its bias voltage from the TR-1, the PCP/PC chest piece can obtain it from the "phantom" bias voltage present on the Microphone port of a typical PC. With the sSOIP software running on the PC, an IP connection can be made to a remote PC providing a remote auscultation capability. Thus, the PCP/PC Stethoscope can provide remote auscultation as does the TR-1 stethoscope, although the TR-1 does not specify the type of communications channel used.

Since the PCP/PC Stethoscope can obtain its operating voltage (i.e. the phantom bias voltage) from a generic PC, it cannot rely on the use of a medical grade power supply in the PC. A generic ITE grade power supply is assumed for the PC and the necessary isolation from power, ground and signal is provided within the PCP/PC chest piece assembly. This isolation is verified by EN60601-1-1 testing and is shown in **Attachment 7**.

As explained in greater detail below, the RNK PCP/PC Stethoscope has the same intended use and principles of operation and technological characteristics as the predicate devices. **Attachment 4** contains a Substantial Equivalence Chart setting forth the similarities and differences between the RNK PCP/PC Stethoscope and the predicate devices. There are no new questions of safety or effectiveness.

A. Intended Use

The RNK PCP/PC Stethoscope and the TR-1 predicate device are intended for use as remote auscultation monitoring devices, whereby a clinician at one location can listen to the auscultation sounds of a patient at a different location, with the signal carried over a data communication channel between the two locations. While the TR-1 does not specify a specific communication channel, the PCP/PC Stethoscope specifies and encompasses an IP connection between the two locations.

B. Principles of Operation

The principles of operation can be broken down into two categories: the chest piece sensor technology and the remote communications technology.

The PCP/PC chest piece and the predicate Precordial Stethoscope use the same technique and technology to sense auscultation signals in the body and amplify those signals so they can be processed for transmission over a communications channel. The piezo element senses pressure from signals within the body and converts those pressure signals to a very small electrical signal. These signals fall within the audio bandwidth. An amplifier increases the electrical signal to a level that is needed for the communications function to deal with. There are no differences in principles of operation or technology between the Precordial Stethoscope and the PCP/PC chest piece.

The *communications* function converts the analog signal to a digital signal so that it can be processed by the digital signal processing capabilities of a typical PC. The digital signal is formatted into a standard audio format (e.g. WAV), then converted from the word oriented (WAV) file format to a streaming format for communications. The streaming signal is packed into IP packets for transmission over an IP network. The streaming methodology is widely used for sending audio and video over the Internet.

The predicate TR-1 did not specify a communications means and the communications channel fell outside its control. In modern networks, this usually means IP network communications. A typical implementation would have video conferencing system software establishing an IP connection in parallel with the video and audio IP data streams. In comparison, the PCP/PC Stethoscope specifies an IP connection over an IP network and uses sSOIP software controlling standard software functions in a

generic PC to implement it. While the overall principles of operation may be similar if not the same, the PCP/PC Stethoscope has the advantage of directly controlling the communications.

Typical operation of the RNK PCP/PC Stethoscope is as follows:

1. At the patient's location, install the sSOIP software on a PC connected to an IP network (e.g. LAN, Internet, private network) and configure it as a transmit end station. Finish the installation of the transmit end station by plugging the PCP/PC chest piece assembly into the Microphone jack of the PC.
2. At the clinician's location, install the sSOIP software on a PC connected to an IP network (e.g. LAN, Internet, private network) and configure it as a receive end station. Enter the IP address of the transmit end station into the sSOIP address book. Finish the installation of the receive end station by plugging in a headset into the Headset jack.
3. Using the connect command on the sSOIP display an IP connection is established between the receive end and transmit end. The clinician then guides the patient in the placement of the chest piece over the desired locations on the body.
4. The audio level to the headset may be adjusted using the PC's Volume control features.

C. Technological Characteristics

As described above and shown in the substantial equivalence chart at **Attachment 4**, the RNK PCP/PC Stethoscope has the same operational technological characteristics as the predicates Precordial Stethoscope and TR-1 Stethoscope. Specifically, the PCP/PC chest piece and the predicate Precordial Stethoscope use the same technology to sense auscultation signals in the body and amplify those signals so they can be processed for transmission over a communications channel. The piezo element senses pressure from signals within the body and converts those pressure signals to a very small electrical signal. These signals fall within the audio bandwidth. An amplifier increases the electrical signal to a level that is needed for the communications function to deal with. There are no differences in technology between the Precordial Stethoscope and the PCP/PC chest piece.

With the inclusion of the sSOIP software, the PCP/PC has the capability of establishing and managing an IP connection between the transmit and receive end stations. While communications means connecting predicate TR-1 Stethoscopes may have used the same technology, the TR-1 didn't manage the connection and it was not under its control. Handling and resolution of sSOIP software issues are presented in detail in **Attachment 6**.

D. Conclusion

Based on the intended use, principles of operation and technological characteristics, the RNK PCP/PC Stethoscope does not raise any new questions of safety or effectiveness.

VIII CERTIFICATION OF COMPLIANCE WITH STANDARDS

As described at **Attachment 6**, the RNK PCP/PC Stethoscope complies with the appropriate tests/standards and has passed the following tests:

- IEC60601-1:2003/2nd Edition Medical Electrical Equipment Part 1: General Requirement for Safety
- EN60601-1-2, 2007/03, EMC Immunity Requirements for Medical Electrical Equipment Part 1: General Requirements for Safety, 2. Collateral Standard – Electromagnetic Compatibility Requirements and Tests
- EN61000-4-2 Part 2: Electrostatic Discharge Requirements
- EN61000-4-3 Part 3: Radiated Electromagnetic Field Requirements
- EN61000-4-4 Part 4: Electrical Fast Transient/Burst Requirements
- EN61000-4-6 Part 6: Conducted Immunity Requirements
- EN61000-4-8 Part 8: Power Frequency Magnetic Field Requirements

A signed certification of compliance is contained in **Attachment 8**. Charles R. Abbruscato, CEO of RNK Products has signed the certification.

The RNK PCP/PC Stethoscope is comprised of a chest piece assembly and software the runs on a generic PC. Should any function fail whether it be the chest piece assembly, audio hardware on the PC, a software function on the PC, the PC itself or the IP network connecting the transmit end PC to the receive end PC, the RNK PCP/PC Stethoscope could not be used for an auscultation exam. Denial of the use of the RNK PCP/PC Stethoscope is not a hazard. Clinicians are trained in the use of stethoscopes and would recognize the failure of the equipment. There is no hazard potential presented by the RNK PCP/PC Stethoscope.

IX HAZARD ANALYSIS

As shown in the following chart, the PCP/PC Stethoscope presents no residual hazard to patients or clinicians.

Hazard Chart for PCP/PC Stethoscope

Undesirable Effect	Potential Cause	Mode of Control	Minimum Requirements/ Description of Control
Shock	The internal operating voltage shorts to part of the case that the user can touch	Design	By satisfying the safety requirements of EN 60601-1-1, no part that the user can touch will have a hazardous voltage level.
Unauthorized Use	Non-authorized person using the stethoscope	Design	No physical harm can come to someone using the stethoscope.
Misuse by User	Clinician fails to use the stethoscope properly	Clinical Training/ Operation Instructions	Clinicians are trained in auscultation as part of their clinical education. The PCP/PC Stethoscope presents the same auscultation sounds as a traditional acoustic stethoscope, but amplified. The Operation Instructions informs the clinician and patient how to use the PCP/PC Stethoscope.
Adverse Biocompatibility Reaction	Unsafe materials used for the PCP/PC chest piece (the only physical component other than the generic PC)	Design	The PCP/PC chest piece is made from the identical safe materials as the previously cleared Piezo Electronic Stethoscope.
Inability to use device because of hardware or component failure	Failure of a hardware component inside the PCP/PC chest piece or failure of a hardware component in the PC or server running PCP/PC Stethoscope software.	Clinical Training/ Operation Instructions	Clinicians are trained in the use of stethoscopes and would recognize the failure of the equipment. The PCP/PC Stethoscope is intended to be used to listen to auscultation sounds remotely as a supplement to in-person care. Should a clinician not be able to conduct the remote auscultation and feel that an auscultation exam is needed, the clinician would instruct the person to see a clinician in person.
Inability to use device because of software failure	Failure of a PCP/PC Stethoscope software component including: <ul style="list-style-type: none"> • Inability to process analog audio signal at the patient end. • Inability to process digitized audio signals at the patient end. • Inability to transport digitized signals from the patient end location to the clinician end location. • Inability to process digitized audio signals at the patient end. • Inability to process analog audio signal at the patient end. 	Clinical Training/ Operation Instructions	Clinicians are trained in the use of stethoscopes and would recognize the failure of the equipment. The PCP/PC Stethoscope is intended to be used to listen to auscultation sounds remotely as a supplement to in-person care. Should a clinician not be able to conduct the remote auscultation and feel that an auscultation exam is needed, the clinician would instruct the person to see a clinician in person.

X. 510(K) SUMMARY

The 510(k) summary for the RNK PCP/PC Stethoscope is provided in **Attachment 10**.

XI. SUBMITTER'S NAME AND ADDRESS

RNK Products, Inc.
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Facsimile: (321) 303-5983

XII. CONTACT PERSONS AND TELEPHONE/FACSIMILE NUMBERS

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RNK Products, Inc.
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Suite 101
Rockledge, FL 32955
Telephone: (321) 626-7717
Facsimile: (321) 303-5983

XIII. CONFIDENTIALITY

RNK Products, Inc. considers information on the RNK PCP/PC Stethoscope to be confidential commercial information. The company, therefore, requests that FDA not disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application is trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that you consult with the company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

XIV. INDICATIONS FOR USE STATEMENT

The company's Indications for Use Statement for the RNK PCP/PC Stethoscope is provided in **Attachment 11**.

XV. TRUTHFUL AND ACCURATE STATEMENT

A certification of the truthfulness and accuracy of this submission, as required by 21 C.F.R. § 807.87(j), is provided in **Attachment 12**. Charles R. Abbruscato, CEO of RNK Products, Inc. has signed the certification.

ATTACHMENT 1
LABELING
for the
RNK PCP/PC STETHOSCOPE

PCP/PC Stethoscope with sSOIP Installation and Operation Instructions

Rev 1.2
September 11, 2010

This document provides the patient operating instructions for the PCP/PC Stethoscope.



This product meets the safety requirements of EN 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety for Type BF protection using a power source providing 2 - 5 vdc. The device providing power should satisfy IEC 60950.

Vdc: 

Type BF applied part:



Class II protection
against electrical shock:



This product meets the EMC Emissions and Immunity requirements of EN 60601-1-2 Medical Electrical Equipment Part 2 Collateral Standard: Electromagnetic Compatibility Requirements and Tests:

EN61000-4-2	Part 2: Electrostatic Discharge Requirements
EN61000-4-3	Part 3: Radiated Electromagnetic Field Requirements
EN61000-4-4	Part 4: Electrical Fast Transients/Bursts Requirements
EN61000-4-6	Part 6: Conducted Immunity Requirements
EN61000-4-8	Part 8: Power Frequency Magnetic Field Requirements

This product may be used in continuous operation.

This product is not a defibrillation-proof applied part. This product is not suitable for use in the presence of a flammable anesthetic mixture with air or with continuous oxygen or nitrous oxide.

Normal use for this product is at an ambient temperature range of +10° to +40°C, a relative humidity range of 30% to 75%, an atmospheric pressure range of 700 hPa to 1,065 hPa. It may be transported and stored at temperatures from 0°C to 50°C and relative humidity of 10% to 95%.

The device contains electronic components and disposal of it should in accordance with all federal and local laws.

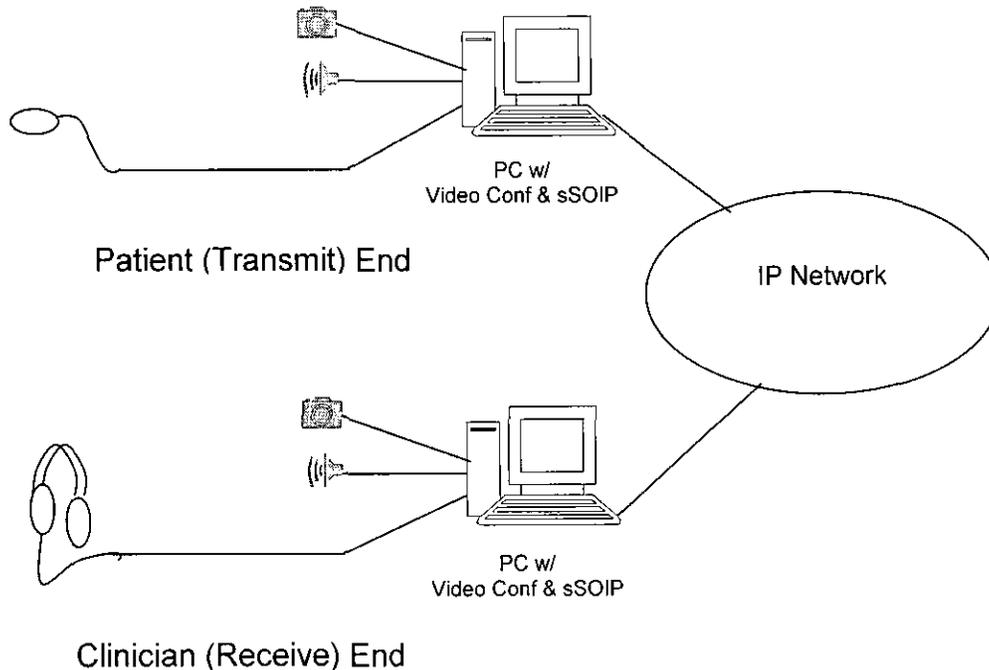
Local laws may take priority over the above requirements. If in doubt, consult your local representative or the technical service department.

For questions or comments, contact RNK Products, Inc., 4195 US Hwy 1, Suite 101, Rockledge, FL 32955

I. Introduction

The PCP/PC Stethoscope Patient Station is comprised of a PCP/PC Chest Piece plugged into a generic PC on an IP network (e.g. the Internet) and the streaming Stethoscope Over IP (sSOIP) software application running on the PC. It provides remote auscultation between a patient at one location and a clinician at another location.

The typical application for a telephonic stethoscope is in conjunction with a video conference session for telemedicine. With the video conference over IP, the stethoscope sounds will go over a separate socket from the video conferencing data.



The clinician at the receive end is in control of the connection and will Start or Stop the stethoscope exam from the receive end PC. When the clinician clicks on Connect, the IP connection between the two PCs will be completed. When Disconnect is clicked, the exam stops and the connection breaks at the transmit end so that no stethoscope data is sent over the IP network.

The SOIP program also provides the capability for recording stethoscope sound data into special files, saving those files and playing them back.

II. Installation

Before the PCP/PC Stethoscope can be used, the PCP/PC sSOIP application must be installed on the target PC, which must be on an IP network such as the Internet. Once the application software is installed, the PCP/PC Stethoscope must be configured (section III).

Insert the PCP/PC Stethoscope Patient Station CD into the PC and run the sSOIP Setup.exe installation program. This will start the installation process. Click on Next and continue to click on Next for subsequent screens unless you want to install the SOIP program into special folders of your choosing.

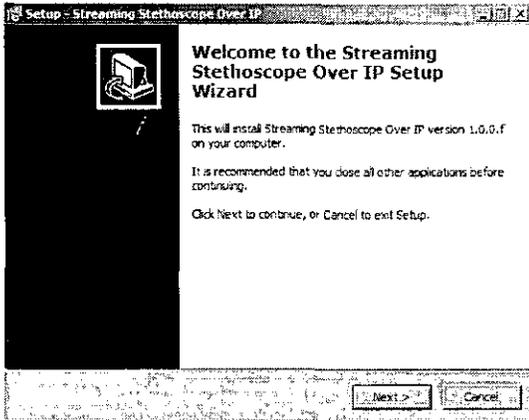


Figure 1: Installation Wizard

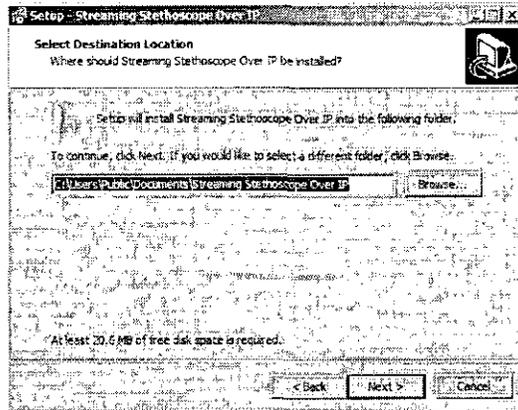


Figure 2: Select Destination Folder

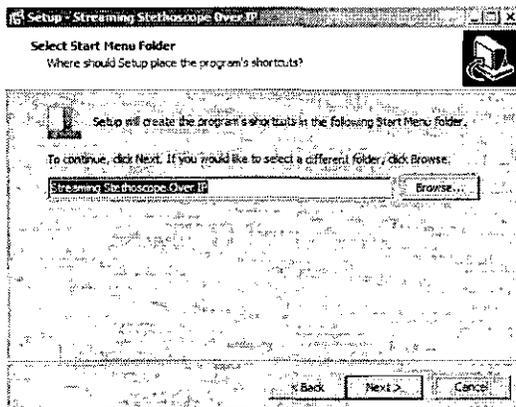


Figure 3: Select Start Menu Folder

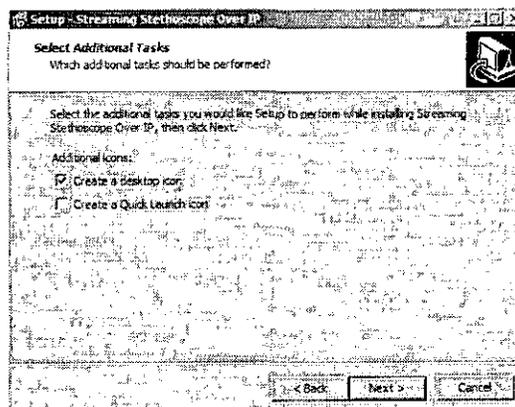


Figure 4: Create a Desktop Icon

Next in Figure 5 click on Install.

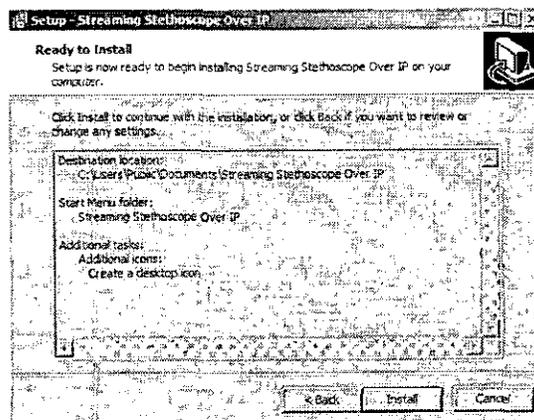


Figure 5: Install the Program

This will bring up Figure 6 asking if you want to delete the precious installation. Click on Yes.

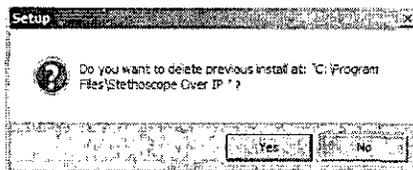


Figure 6: Delete Previous Installation

When the completion screen comes up, click on Finish.

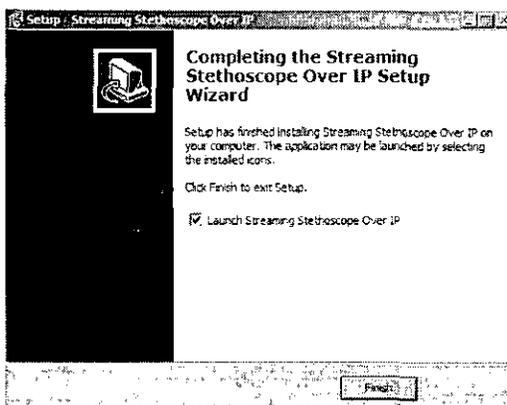


Figure 7: Installation Complete

III. Setup

A. Transmit Mode

Open the SOIP program using the desktop icon or the C:\Program Files\Stethoscope Over IP\SOIP.exe file. Whatever mode the program was in when it was last closed will be the mode that the program goes into when opened next. For example, if the SOIP program was configured for Transmit mode last time it was opened, then the Main screen shown in Figure 8 will display when the program is reopened.

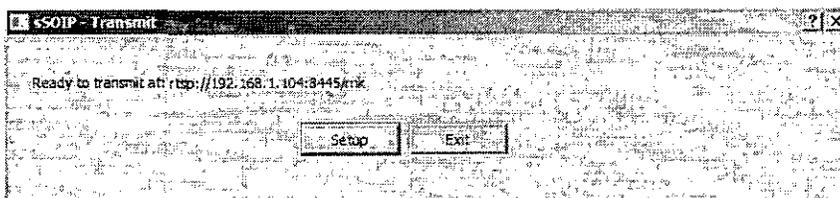


Figure 8: Main Screen – Ready to Transmit

Clicking on the Setup button brings up the screen for selecting the telephonic stethoscope model, the operating mode, the port assignments and the IP Address Book for entering IP addresses of remote site telephonic stethoscopes. Since the system would be in Transmit mode from Figure 8, the setup screen would show Transmit mode as shown in Figure 9.

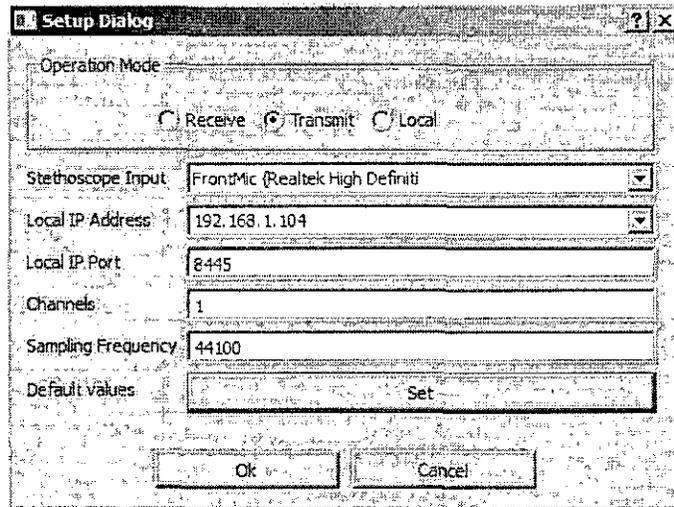


Figure 9: Setup Screen – Transmit Mode

The sSOIP program will detect the PCP/PC Chest Piece and display the audio port. It will also check for local IP addresses and display them. The default local IP port is 8445. If that is changed, then the Receive end sSOIP must select that same IP to be able to connect to this sSOIP station.

B. Receive Mode

Clicking on Receive Mode brings up the screen in Figure 10.

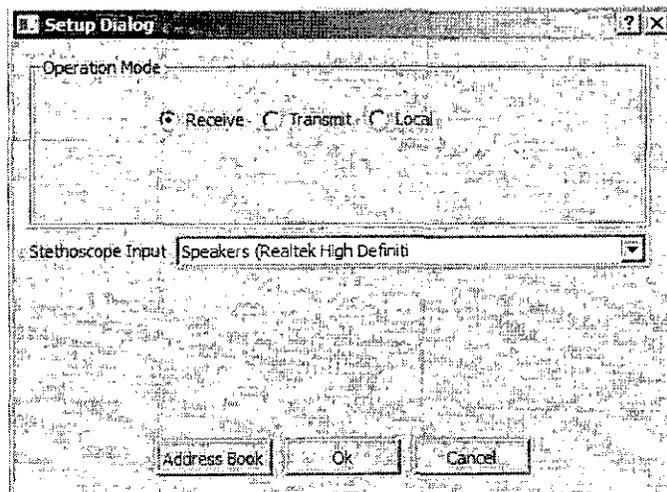


Figure 10: Setup Screen – Receive Mode

The audio output port is automatically detected and shown. Also a button for the IP Address Book is presented.

C. IP Address Book

Since the receive end initiates all connections, it is necessary to know the IP address of the transmit end. Multiple transmit end locations are handled through the IP Address Book, which allows the creation and storing of a list of IP addresses where the transmit end PCP/PC Stethoscope stations are located. Open the IP Address Book by clicking on the IP Address Book button.

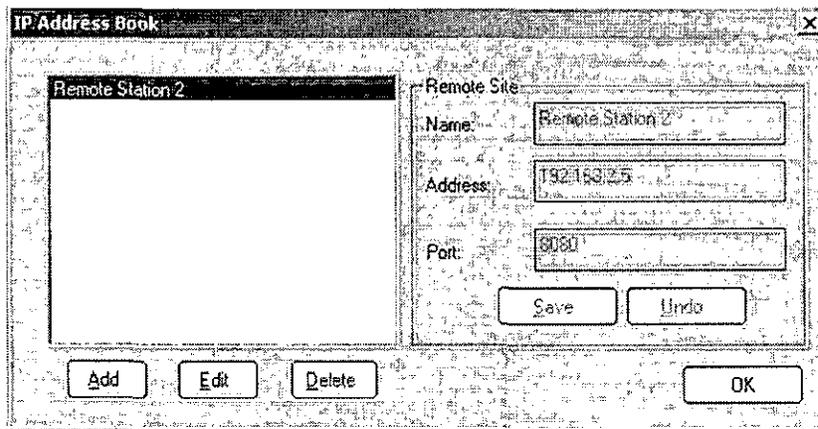


Figure 11: IP Address Book

To add a new location, click on Add, then enter the user friendly name you want to give for that location, the IP address and the port number. You can then either Save the address information or Undo it. Figure 11 shows Remote Station 2 in the IP Address Book.

An IP address can be edited by clicking on the name in the box on the left to highlight it, then clicking on Edit. Changes can be saved with Save or cancelled with Undo.

IV. Operation Mode

The sSOIP program has three modes of operation:

- Transmit mode is used at the patient end.
- Receive mode is used at the clinician end.
- Local is used for playing back recorded stethoscope files.

A. Transmit Mode

To set up for Transmit mode, from the Main screen, click on Setup. When the Setup window opens as shown in Figure 9, click on the Transmit radio button to enable Transmit Mode, then click on OK to get back to the Main screen as shown in Figure 8.

When the Status is Ready to Transmit, then the sSOIP program is waiting for a connection to be made from the far-end station, which would be in Receive mode. Once an IP connection is established, the Status will change to Transmitting Data.

B. Receive Mode

To set up for Receive mode, from the Main screen, click on Setup, then select the Receive radio button to display the screen shown in Figure 10. Then click the OK button to get to the Received end main screen as shown in Figure 12.

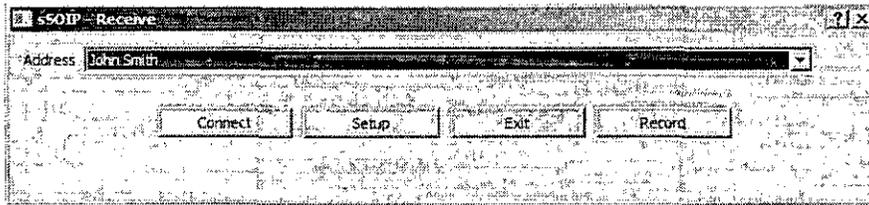


Figure 12: Main Screen in Receive Mode

In Receive mode, the program needs to know the IP address of the transmit end to which it wants to connect. The operator can create and access a list of IP addresses where the transmit end TR-x units are located. This is done in the Address Book as described in Section III C above.

Connections are initiated from the receive end where the consulting clinician is located. With sSOIP in Receive mode, select a patient (transmit end) location by clicking on the down arrow in the Address list box, then selecting the desired patient location. (If the desired patient location is not on the list, then go back to the Setup screen and use the IP Address Book to enter the information for the desired patient.) After selecting the patient location, click on the Connect button to initiate the IP connection. Once the connection is made, the Status will change from Ready to Receiving Data as shown in Figure 13. If a connection cannot be made, the connection attempt will time out and Status will return to Ready.

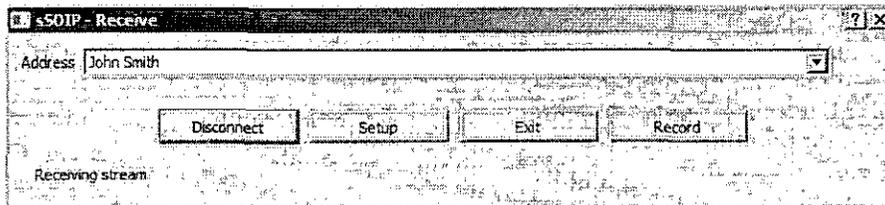


Figure 13: Main Screen while Receiving Data

C. Recording Stethoscope Sounds

With sSOIP receiving stethoscope data, click on Record to start recording. While recording the Record button changes to Stop Recording.

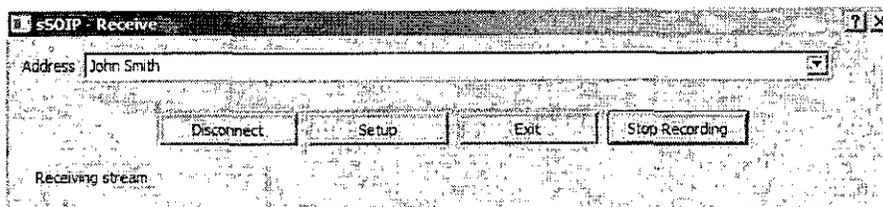


Figure 14: Main Screen while Recording Data

To stop recording, Click on the Stop Recording button. A new screen will pop up to allow the recording to be saved. Figure 15 shows the screen with Play Time and Creation Date entered automatically by sSOIP.

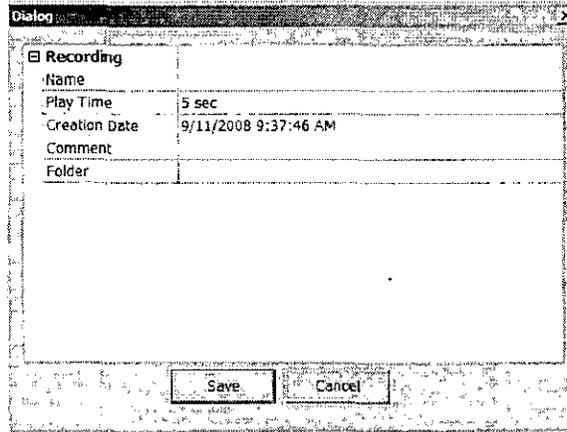


Figure 15: Adding a New Stethoscope File

Click on the fields next to Name and Comment to enter the patient’s name and a comment, respectively. Click on the field next to Folder, then click on the down arrow to display the list of folders available. Figure 16 shows an example where “John Smith” was entered in the Name field and “Heart sounds after walking up stairs” was entered in the Comment field. In his example, a folder for John Smith was already created (see Local Mode below).

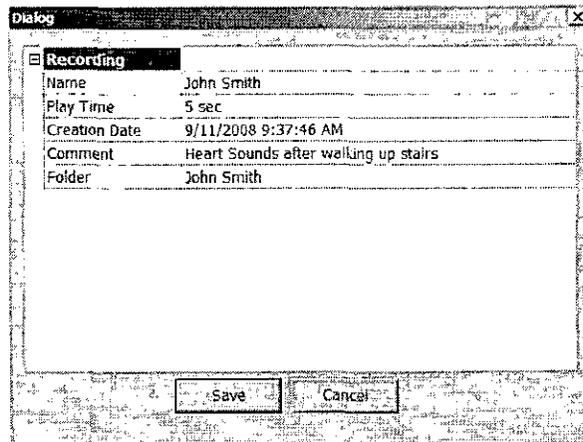


Figure 16: Example of New Stethoscope File

Clicking on the Save button saves the file, closes the window and goes back to the Main window in Receive mode. When the stethoscope session is over, click on Disconnect to terminate the connection.

D. Local Mode

The sSOIP program provides the capability for recording stethoscope sound data into special files, saving those files and playing them back. While recording may be done in either Receive or Local mode, playback can only be performed while in Local mode. All file management functions are done in Local Mode.

To get into Local mode, start from the Main screen and click on Setup to bring up the Setup screen shown in Figure 17.

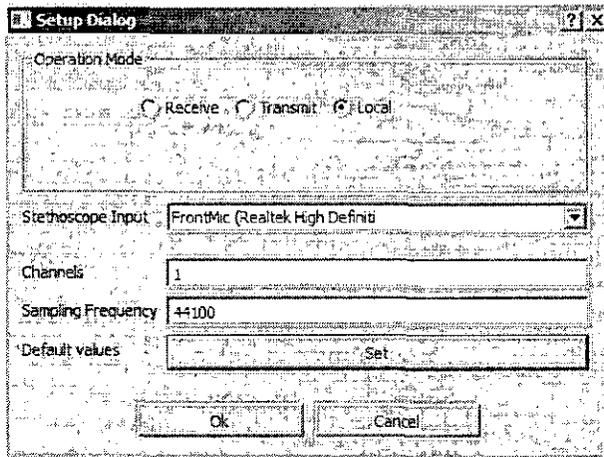


Figure 17: Setup Screen Selecting Local Mode

Click the radio button for Local then click on the OK button. That will go back to the Main screen in Local mode as shown in Figure 18.

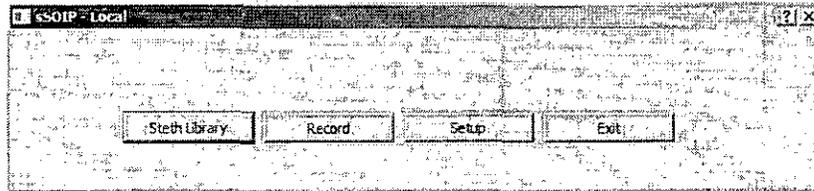


Figure 18: Main Screen in Local Mode

To access the file management functions or to playback a file, click on Steth Library. Figure 19 shows a blank Steth Files window.

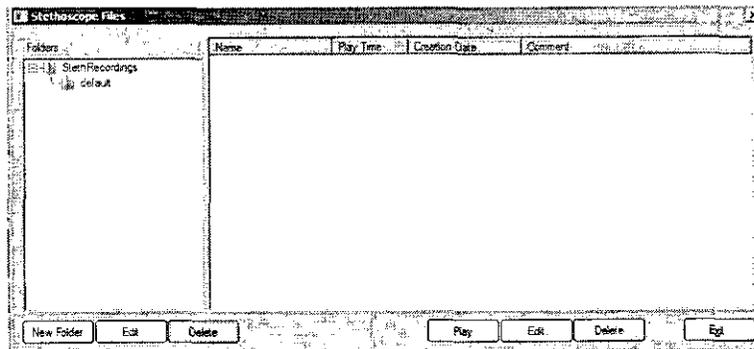


Figure 19: Steth Files Window

To add a new folder for a patient, click on the *New Folder* button, then next to Name and Description fields enter appropriate information on that patient. Figure 20 shows an example where a new Folder for John Smith was created.

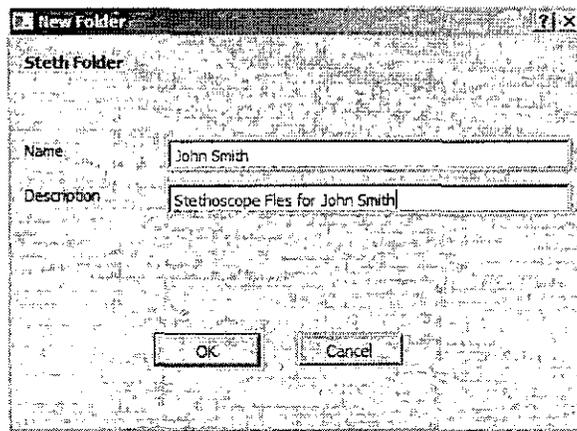


Figure 20: Create New Patient Folder

Click on OK to finish the creation of the folder. A folder can be edited by clicking on the folder to highlight it, then clicking on Edit. That brings up the Steth Folder window again. Make the desired changes then click on OK. To delete a folder, click on the folder to highlight it, then click on Delete. A window will pop up to confirm that you want to delete the folder. If you are sure, click on Yes, otherwise click on No.

In the previous section, an example stethoscope sound file was saved for John Smith. The files for this patient example can be accessed by clicking on the folder name on the right side of the Steth Files window. In this example, the window in Figure 21 would show.

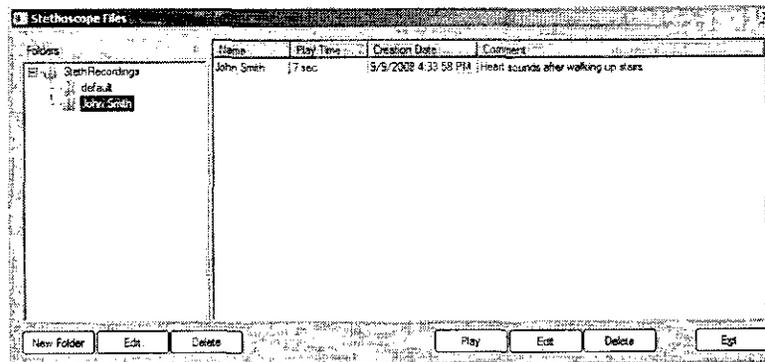


Figure 21: Steth Files Screen Showing Files

To play back a saved file, click on the desired file to highlight it, then click on Play. The stethoscope sound file will playback through the attached Headset. Clicking on Stop stops the playback.

The information for a stethoscope file can be edited by selecting the file to highlight it, then clicking on the Edit button. Make the desired changes to either the Name or Comment field, then click on Save. A file can be deleted by selecting the file to highlight it, then clicking on the Delete button. A window will pop up to confirm that you want to delete the file. If you are sure, click on Yes, otherwise click on No.

E. Auscultation Session Connection Overview

The transmit end locations (where the patients will be) should be in Transmit Mode with their Main screens open and status at Ready to Transmit.

At the receive end, the clinician can choose which patient location to connect to by using the Address drop down list box. Clicking on the down arrow pulls down the list box showing all the patient location choices previously entered. The clinician selects one by clicking on it. That brings back the Main screen with that location showing in the Location field.

The clinician then clicks on Connect to complete the connection to the PCP/PC Stethoscope at that location. The Connect button changes to Disconnect. To terminate the auscultation session the clinician clicks on the Disconnect button.

To close the sSOIP program, click on Exit.

V. Cleaning, Preventive Inspection, Maintenance and Calibration

The PCP/PC Stethoscope requires no preventive inspection, no preventive or routine maintenance, and it does not have to be calibrated.

The PCP/PC Stethoscope is not a sterile device and does not require sterilization or disinfection. It can be cleaned, as required, by wiping with a moist cloth, alcohol or a sanitizing towelette.

VI. Trouble Shooting

Failure to operate: If an IP connection cannot be established to the transmit end station, service personnel from the company that provided the PCP/PC should check the following:

- Insure the transmit end sSOIP application is open and ready to transmit.
- Insure the transmit end PC is connected to the Internet and can access the Internet.
- Insure the assigned IP address of the transmit end is properly entered into the received end sSOIP application.
- Insure the receive end PC is connected to the Internet and can access the Internet.
- Check for a failed PCP/PC Chest Piece by substituting it with a replacement PCP/PC Chest Piece. (Note that the date of manufacture of the PCP/PC Chest Piece is a two hexadecimal (0, 1, 2, 3, 4, 5, 6, 7, 8, 9, A, B, C, D, E, and F) character code where the first character is the number of the month and the second character is the last two digits of the year. For example, August 2010 is 8A.)
- Check for an improperly operating sSOIP by reloading sSOIP.

If taking the above steps does not remedy the problem, contact your provider of the PCP/PC Stethoscope for assistance and product resolution.

Interference: This product is classified as medical electronic equipment and thus needs special precautions regarding EMC and needs to be installed in accordance with the instructions in this Manual. Portable and mobile RF communications equipment can affect medical electrical equipment.

If interference from other equipment is heard from the PCP/PC during a stethoscope session, the problem may be resolved by relocating other equipment so that it is farther from the PCP/PC. The

provider of the PCP/PC Stethoscope will assist in resolving any interference problems. If the interference problems cannot be resolved and the interference does not permit auscultation sounds from being heard, then the PCP/PC should not be used in that location.

Label for PCP/PC Chest Piece

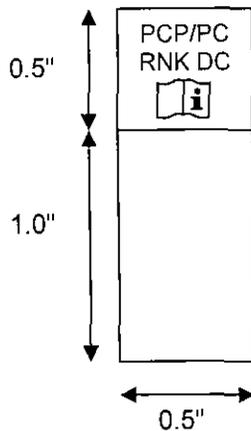
August 7, 2010

Rev 1.0

The PCP/PC Chest Piece is a chest piece with a permanently attached cable. There is no convenient surface on the PCP/PC Chest Piece to apply a label. This is a similar situation as the PCP Chest Piece and the CP-1 Chest Piece. For those products, a small waterproof label is wrapped around the cable to identify the product. Other pertinent information is in the Operator's Manual.

Label Spec

SLL4LU Label from Sharpmark



This portion of the label has a white background and contains text.

This portion of the label is clear. It wraps around the text portion to protect the part with the text.

PCP/PC is the product name.

RNK denotes RNK Products, Inc.

DC is the two character hexadecimal date code denoting month and year of manufacture.

ATTACHMENT 2

PROMOTIONAL MATERIAL

for the

RNK PCP/PC STETHOSCOPE

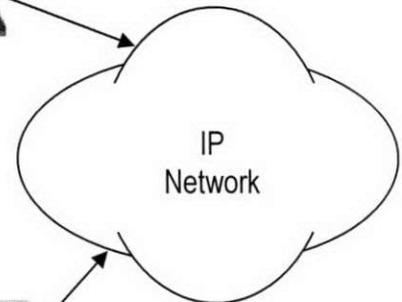
PCP/PC Stethoscope Over IP Networks

PCP/PC Chest Piece and sSOIP Software Running on Generic PC

PCP/PC
Chest Piece



PC with sSOIP



IP
Network



PC with sSOIP



Transmit End:

- Connect the PCP/PC Chest Piece to Microphone port of PC.
- Run sSOIP software program on PC.
- PC connected to IP network.

***Clinician initiates
connection to patient.
Patient end PC
automatically answers.***

Receive End:

- PC connected to IP network.
- PC runs sSOIP software program.
- Use sSOIP to select patient (transmit end) location.
- Use headset to listen to heart and lung sounds.

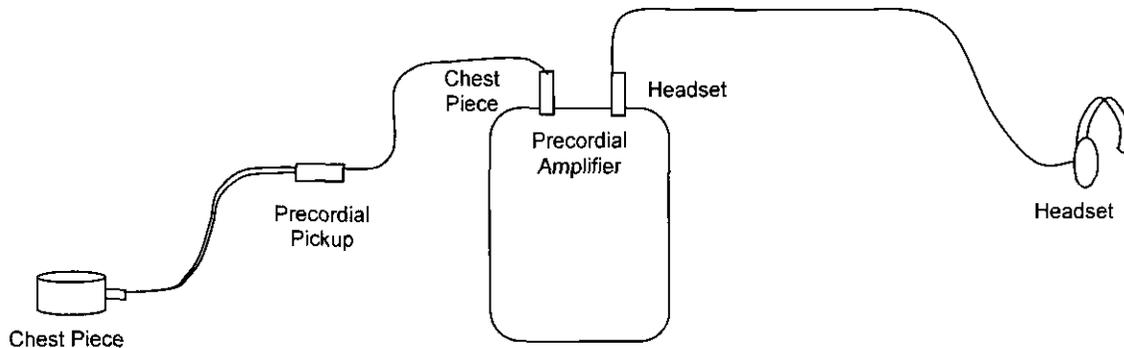
ATTACHMENT 3
PREDICATE DEVICE LABELING

Precordial Stethoscope Precordial Pickup and Amplifier

Rev. 1.1

1. Introduction

The Precordial Pickup cable assembly and the Precordial Amplifier can be use with a common precordial chest piece to provide amplified auscultation sounds to a set of headphones.



2. Operation

Slip the tubing of the Precordial Pickup over the nipple on the side of the precordial chest piece.

Plug the other end of the Precordial Pickup cable into the **Chest Piece** jack of the Precordial Amplifier. The Precordial Amplifier detects the insertion of the plug and uses its internal battery to turn ON the audio amplifier.

When not in use, unplug the Precordial Pickup cable from the Precordial Amplifier to conserve the batteries.

Plug the Headset into the **Headset** jack of the Precordial Amplifier. While holding the Chest Piece during an auscultation exam, minimize finger movement to avoid finger noise.

3. Battery Replacement

Slide back the battery cover on the backside of the Precordial Amplifier to expose the two AAA batteries. Remove the old batteries and put two new AAA batteries in their place being careful to align the polarity of the batteries as shown in the diagram in the battery compartment. Put the battery cover back in place sliding it shut.

4. Cleaning

Clean the Precordial Pickup, Chest Piece and the Precordial Amplifier by wiping them with a moist cloth, alcohol or a sanitizing towelette.

5. Specifications

Frequency Range is 20 Hz – 2,000 Hz.

Normal use for this product is at an ambient temperature range of +10° to +40°C, a relative humidity range of 30% to 75%, an atmospheric pressure range of 700 hPa to 1,065 hPa. It may be transported and stored at temperatures from 0°C to 50°C.

For questions or comments, contact RNK Products, Inc., 4195 US Hwy 1, Suite 101, Rockledge, FL 32955.

RNK Products, Inc.

TR-1
Telephonic Stethoscope
Installation and Operation Manual

TR-1 Telephonic Stethoscope Installation and Operation Manual
March 3, 2004
Revision 1.2

Table of Contents:

I. Introduction and Overview	3
II. Installation.....	3
A. Power	3
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C. Mode Selection	5
III. Operation.....	5
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B. RX Mode.....	6
IV. Maintenance and Calibration.....	6
V. Trouble Shooting	6

This product meets the safety requirements of IEC 60601-1-1 for Type BF protection using a medical grade power supply providing 9 vdc - 12 vdc at a maximum of 600 mA (GlobTek GMT341-12-600 or equivalent).

Vdc: 

Type BF applied part:



This product may be used in continuous operation.

This product is not suitable for use in the presence of a flammable anesthetic mixture with air or with continuous oxygen or nitrous oxide.

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

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

Normal use for this product is at an ambient temperature range of +10° to +40°C, a relative humidity range of 30% to 75%, an atmospheric pressure range of 700 hPa to 1,065 hPa. It may be transported and stored at temperatures from 0°C to 50°C.

For questions or comments, contact RNK Products, Inc., 12700 Diamond Drive, Burnsville, MN 55337

I. Introduction and Overview

The TR-1 Telephonic Stethoscope provides high quality remote auscultation with a number of valuable and unique features.

- Low bandwidth while achieving quality auscultation. The TR-1 connects to the system Data Channel via an RS232 interface operating at 9.6 Kb/s.
- Same model can be configured for Transmit operation or Receive operation.
- Plugging in the Chest Piece Assembly automatically puts the unit into Transmit Mode and illuminates the TX Mode light.
- In Transmit Mode, the same auscultation sounds that are sent to the remote TR-1 unit are also presented at the Headset jack for local monitoring.
- Leaving the Chest Piece input jack empty automatically puts the unit into Receive Mode and illuminates the RX light.
- Volume control for adjusting the sound level delivered to the Headset jack. The Volume control works in Receive Mode for sounds received from a remote TR-1 unit or in Transmit Mode for monitoring sounds generated from the Chest Piece Assembly plugged into that local unit.
- B/D Switch for an enhanced Bell/Diaphragm selection. The Diaphragm (D) position selects the full bandwidth of 20 Hz to 700 Hz. The Bell (B) position cuts off the high end at 250 Hz and boosts the low frequencies down below 20 Hz for enhanced heart auscultation. The B/D Switch works in Receive Mode for sounds received from a remote TR-1 unit or in Transmit Mode for monitoring sounds generated from the Chest Piece Assembly plugged into that local unit.

The TR-1 Telephonic Stethoscope is for prescription use by medical care professionals.

II. Installation

Installing the TR-1 Telephonic Stethoscope is as easy as applying power and connecting the unit to a functional Data Channel.

A. Power

Power is provided to the TR-1 unit from a small, wall mount Power Supply. Plug the Power Supply into a 115 vac wall outlet and insert the plug at the end of the power cable into the jack at the left rear of the TR-1 unit.

If there is no Chest Piece Assembly plugged into the unit, the RX Mode light will be lit and the TX Mode light will be OFF. If a Chest Piece Assembly is plugged into the unit, then the TX Mode light will be lit and the RX Mode light will be OFF.

B. Data Communications Channel

The TR-1 Telephonic Stethoscope data interface is in asynchronous format with:

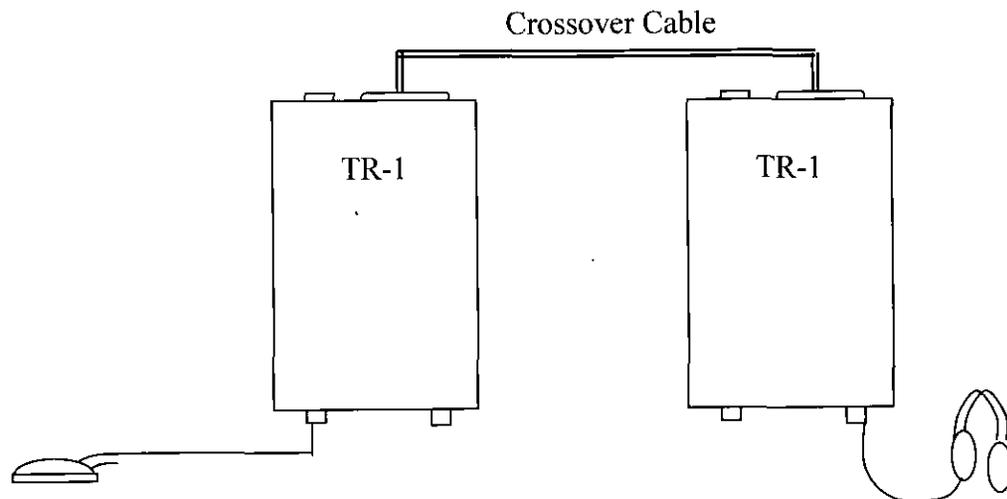
- RS232 electrical voltage levels
- 9.6 Kb/s data rate.
- 8-bits per character.
- No Parity.
- One Stop bit.

The Data Communication Channel interface must be set up to match this specification.

The TR-1 Telephonic Stethoscope functions as a DTE in terms of data communications. If the Data Channel linking the transmitting TR-1 unit to the receiving TR-1 unit is to be a modem, multiplexer or other similar DCE, then (probably) a straight-through cable should be used to connect the TR-1 units to the Data Channel interface. The TR-1 unit has a male DB-9 connector at the rear of the unit. Typically, DCE equipment will have a female DB-9 connector for its data communications interface. In that case, a female DB-9 to male DB-9 straight through cable should be used. Sometimes DCE equipment will have a DB-25 connector for its interface. In that case a DB-9 to DB-25 adapter may be used, or a cable with a female DB-9 connector at one end and a male DB-25 connector at the other end.

If a PC is used for the Data Channel interface, then it is important to know that the Serial Port (COM Port) of a PC is a DTE interface. In that case (or any situation where the Data Channel equipment interface is DTE), a cross-over (or null modem) cable is needed with a female DB-9 at both ends of the cable.

Before connecting the TR-1 units to the Data Channel (or if data communications problems arise), it is a good idea to test the TR-1 units back-to-back to verify that they are working properly by themselves. Apply power to both TR-1 units and interconnect them with a male DB-9 to male DB-9 cross-over cable as shown below.



If sounds from the Chest Piece are heard at the headset, then the TR-1 units are working properly and if problems arise in connecting the unit to the Data Channel, it is appropriate to the concentrate on getting the signal through the Data Communications Channel.

C. Mode Selection

If there is no Chest Piece Assembly plugged into the Chest Piece jack of the unit, then the unit will be in Receive Mode and the RX Mode light will be illuminated. The TX Mode light will be OFF.

If a Chest Piece Assembly is plugged into the Chest Piece jack of the unit, then the unit will be in Transmit Mode and the TX Mode light will be illuminated. The RX Mode light will be OFF.

III. Operation

For a normal remote auscultation exam, the TR-1 unit located with the patient is in Transmit Mode and the TR-1 unit with the clinician is in the Receive Mode.

A. TX Mode

To operate as an auscultation transmitting unit the TR-1 must have a Chest Piece Assembly plugged into the Chest Piece jack. That will put the unit into Transmit Mode and illuminate the TX Mode light located just over the Chest Piece jack. Sounds from the Chest Piece will be converted to digital signals and sent out over the RS232 data interface.

In addition to transmitting the digital signals, the auscultation sounds from the Chest Piece are looped back and presented at the local Headset jack. Thus, with an optional Headset, the local user can listen to the same auscultation sounds that the listener at the remote TR-1 (in Receive Mode) would hear.

Volume to the Headset can be increased by turning the Volume control clockwise. Increasing the volume too high can cause distortion in the Headset and will also increase the background noise.

The B/D Switch can be used in an auscultation exam similarly to a traditional stethoscope. The Diaphragm (D) position selects the full bandwidth of 20 Hz to 700 Hz and is best for listening to lung or bowel sounds. The Bell (B) position cuts off the high end at 250 Hz and boosts the low frequencies down below 20 Hz for enhanced heart auscultation.

Adjusting the Volume or changing the B/D Switch only affects what the local listener hears and does not affect what the remote TR-1 listener would hear. The remote TR-1 listener has independent Volume and B/D Switch controls.

B. RX Mode

Without a Chest Piece Assembly plugged into the Chest Piece jack of the TR-1, the unit is automatically in the Receive Mode. With the Data Communications Channel established and a Headset plugged into the Headset jack of the unit, the clinician is set up to hear the stethoscope sounds from the remote TR-1 (in Transmit Mode).

Volume to the Headset can be increased by turning the Volume control clockwise. Increasing the volume too high can cause distortion in the Headset and will also increase the background noise.

The B/D Switch can be used in an auscultation exam similarly to a traditional stethoscope. The Diaphragm (D) position selects the full bandwidth of 20 Hz to 700 Hz and is best for listening to lung or bowel sounds. The Bell (B) position cuts off the high end at 250 Hz and boosts the low frequencies down below 20 Hz for enhanced heart auscultation.

IV. Maintenance and Calibration

There is no scheduled maintenance required for the TR-1 Telephonic Stethoscope.

There is no calibration required for the TR-1 Telephonic Stethoscope.

If problems should arise with the TR-1 Telephonic Stethoscope, the table in the following section may be used to trouble shoot the problem. Any failed units should be returned for repair.

The TR-1 Telephonic Stethoscope may be cleaned with a damp cloth.

V. Trouble Shooting

Following is a chart to assist in trouble shooting problems which may arise during installation or operation.

Symptoms	Possible Causes and Solutions
Neither TX Mode nor RX Mode lights come ON	Power plug not inserted all the way into the jack. <i>Make sure the power plug is fully seated.</i> No power at the wall outlet. <i>Try a lamp or other electrical item at that wall outlet to determine if there is power.</i> <i>If there is no power, fins a power outlet that does provide the proper 115 vac.</i> If there is power at the wall outlet,

	<p><i>Try another TR-1 Power Supply.</i></p> <p><i>If the TR-1 works, return the Power Supply for repair/replacement.</i></p> <p><i>If the TR-1 unit still does not work, return the TR-1 unit for repair/replacement.</i></p>
<p>Chest Piece is plugged in, but the RX Mode light stays ON and the TX Mode light is OFF.</p>	<p>The Chest Piece Assembly is not plugged in all the way.</p> <p><i>Make sure Chest Piece Assembly plug is fully seated.</i></p> <p>The TR-1 unit has failed.</p> <p><i>Return the TR-1 unit for repair/replacement.</i></p>
<p>Nothing is plugged into Chest Piece jack, but the TX Mode light is ON and the RX Mode light is OFF</p>	<p>The TR-1 unit has failed.</p> <p><i>Return the TR-1 unit for repair/replacement.</i></p>
<p>The Chest Piece is plugged in, the TX Mode light is lit, but there is no sound heard in the local Headset.</p>	<p>The Chest Piece Assembly is not plugged in all the way.</p> <p><i>Make sure Chest Piece Assembly plug is fully seated.</i></p> <p>The Headset is not plugged in all the way.</p> <p><i>Make sure Headset plug is fully seated.</i></p> <p>The Chest Piece Assembly and Headset are plugged into the wrong jacks.</p> <p><i>Make sure Chest Piece Assembly and Headset are plugged into the proper jacks and are fully seated.</i></p>
<p>The Chest Piece is plugged in, the TX Mode light is lit, sounds can be heard in the local Headset, but there is no sounds heard in the Headset of the remote TR-1.</p>	<p>The remote TR-1 unit is not in Receive Mode.</p> <p><i>Make sure that on the remote unit, the Headset is fully seated in the Headset jack and nothing is plugged into the Chest Piece jack. The RX Mode light should be ON.</i></p> <p>Test the TR-1 units back-to-back with a cross-over cable.</p> <p><i>If that test fails, then one of the two TR-1 units or the cable is bad. Test with a third unit and new cable to determine which has failed.</i></p> <p><i>Return the failed unit for repair/replacement.</i></p> <p>If the TR-1 units test good back-to-back, trouble shoot the Data Communications Channel.</p> <p><i>See Section II. B. for proper Data Communication Channel setup.</i></p>

ATTACHMENT 4
SUBSTANTIAL EQUIVALENCE CHART
for the
RNK PCP/PC STETHOSCOPE

Substantial Equivalence Chart for PCP/PC Stethoscope

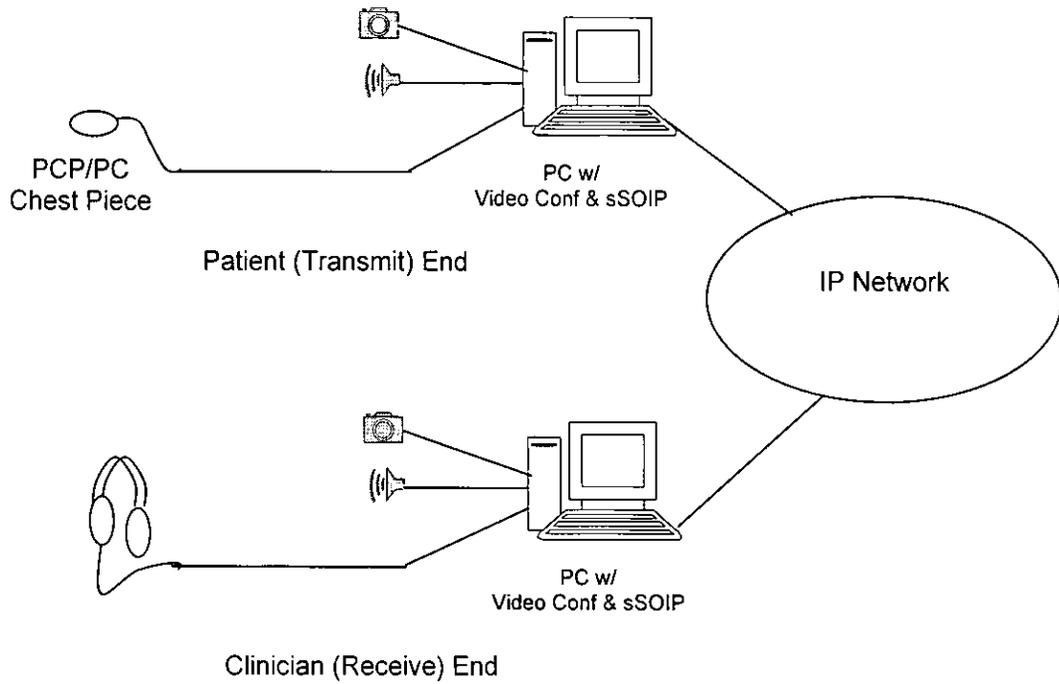
	RNK PCP/PC Stethoscope	RNK TR-1 Telephonic Stethoscope	RNK Precordial Stethoscope
Intended use:	Remote monitoring device, whereby a clinician at one location can listen to the auscultation sounds of a patient at a different location with the signal carried over a data communication channel between the two locations.	Remote monitoring device, whereby a clinician at one location can listen to the auscultation sounds of a patient at a different location with the signal carried over a data communication channel between the two locations. (Note: Same as PCP/PC Stethoscope).	Detecting and amplifying heart, lung and other body sounds. (Note: Auscultation at one location.)
Components:	<ul style="list-style-type: none"> • Detachable Chest Piece • Detachable Headset • Chest Piece and Headset connect to generic PC • Audio handling control and communications software on PC 	<ul style="list-style-type: none"> • Detachable Chest Piece • Detachable Headset • Electronics Module – 4 ½”L x 2 ½”W x 1”H <p>Same Module can be used for Transmitting or for Receiving</p>	<ul style="list-style-type: none"> • Detachable Chest Piece • Detachable Headset • Electronics Module – 3.9”L x 1.9”W x 0.9”H
Technical Characteristics - Chest Piece	PCP/PC Chest Piece converts body auscultation signals to analog signal	CP-1 Chest Piece converts body auscultation signals to analog signal	Piezo Chest Piece converts body auscultation signals to analog signal.
Technical Characteristics – Audio/Digital processing	<p>Analog signal from Chest Piece amplified in PC</p> <p>Analog signal is converted and encoded to a digital signal, then put into IP data format in the PC</p> <p>At receive end, PC accepts IP data stream, decodes the digital signal converting it back to analog then amplifies the analog signal and presents it to Headset port</p>	<p>Analog signal from Chest Piece amplified in TR-1 Module</p> <p>Analog signal converted to digital signal, encodes signal and puts into asynchronous format.</p> <p>At receive end, decodes digital signal, converts it back to analog then amplifies it to Headset port</p>	<p>Analog signal from Chest Piece amplified in Amplifier Module and presented at Headset port</p>

Technical Characteristics - Data Communications:	PC software puts signal into IP format Destination IP addresses are entered into PC PC transmits IP data to network At receive end, PC accepts IP data stream	TR-1 Module sends signal in asynchronous data protocol over an RS232 Interface Communications transport handled in separate networking devices	No data communications
Power Source	2 -5 vdc provided from the PC. Safety isolation is provided within the PCP/PC Chest Piece.	Ac-to-dc wall mount Power Adapter converts 120 vac to 9 – 12 vdc. Internal regulator converts that to 5vdc to power the circuitry.	Battery powered
Auscultation Bandwidth:	20 Hz to 2,000 Hz	20 Hz to 700 Hz	20 Hz to 2,000 Hz
Controls:	<ul style="list-style-type: none"> No controls on PCP/PC Chest Piece Volume Control to Headset using PC audio controls 	<ul style="list-style-type: none"> Volume Control to Headset on TR-1 D/B Switch to select Bandwidth to Headset 	<ul style="list-style-type: none"> No controls on Precordial Chest Piece or Amplifier Module

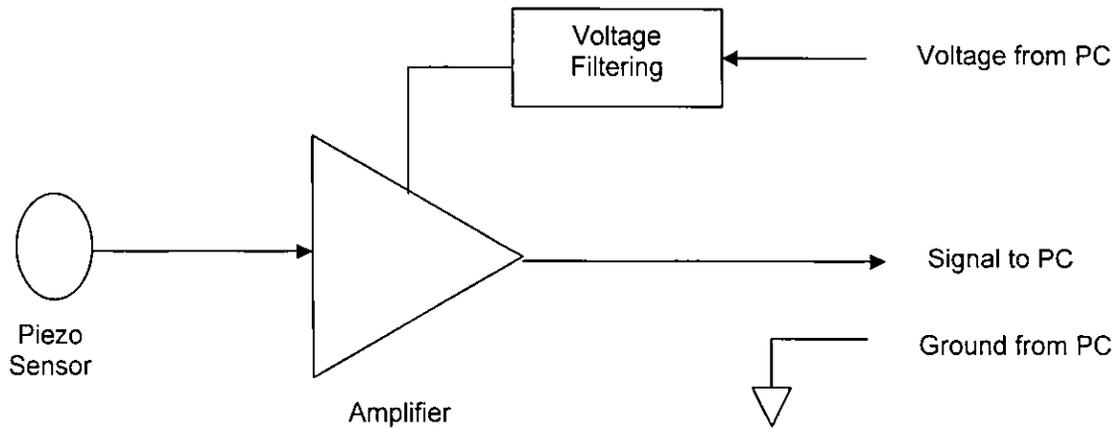
ATTACHMENT 5
ENGINEERING DRAWINGS
for the
RNK PCP/PC STETHOSCOPE

PCP/PC Stethoscope Block Diagram

System Diagram

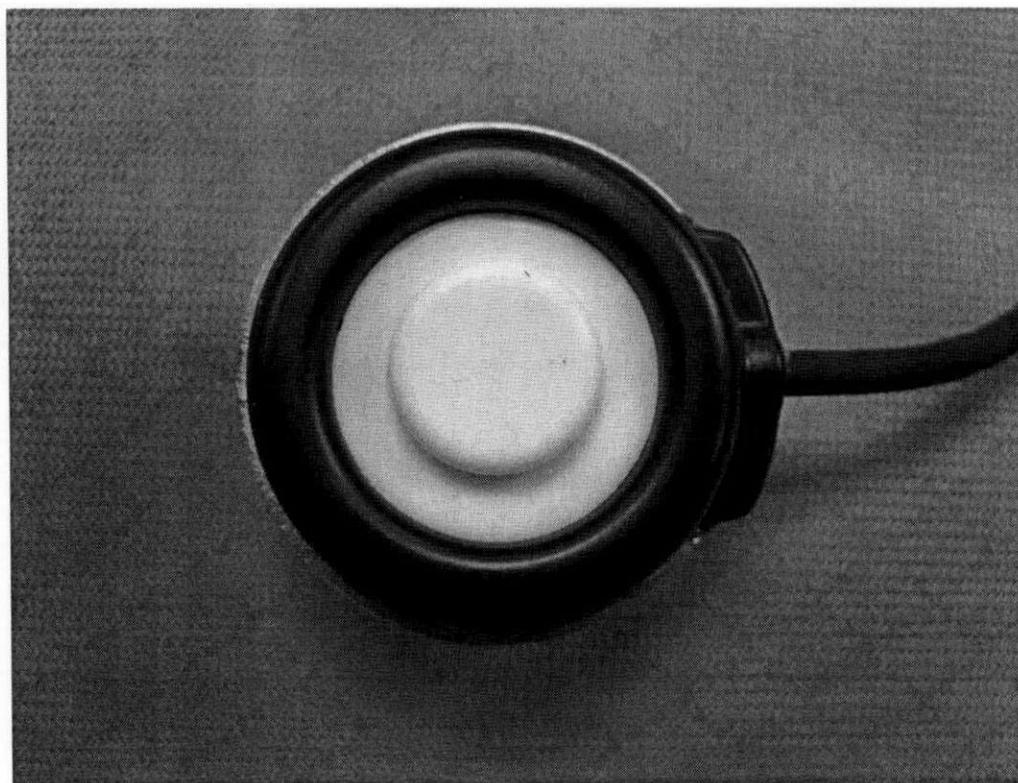


PCP/PC Chest Piece Block Diagram





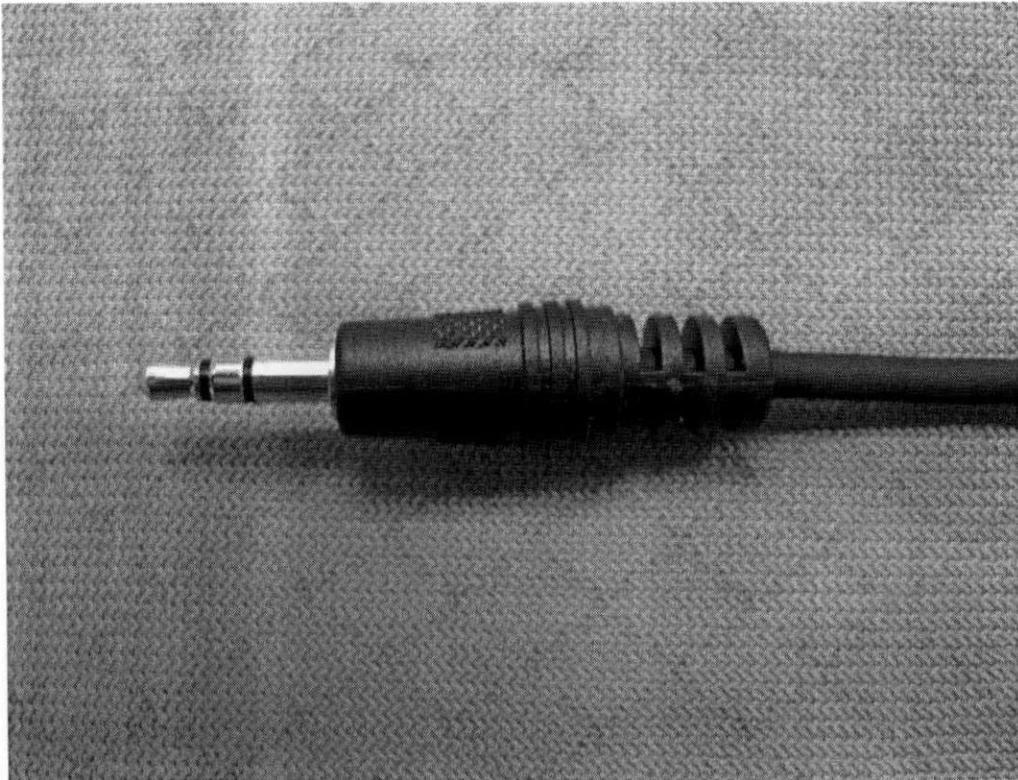
PCP/PC Chest Piece – Top View



PCP/PC Chest Piece – Bottom View



PCP/PC Chest Piece and cable assembly – Top View



Connection end – plugs into Host PC microphone port

ATTACHMENT 6
for the
RNK PCP/PC STETHOSCOPE

PCP/PC Stethoscope with sSOIP Software

PCP/PC Stethoscope Overview

The purpose of the PCP/PC Stethoscope is to provide remote auscultation services between a patient at a location with a PC connected to an IP network (i.e. Transmit End station) and a clinician at another location also with a PC connected to the IP network (i.e. Receive End station).

The PCP/PC Stethoscope Transmit End station has a PCP/PC Chest Piece connected to the Microphone audio port of the PC. The Streaming Stethoscope Over IP (sSOIP) software on the PC directs the capture and digitization of the audio signal, converts it into a streaming format then directs it to the preloaded IP address of the Receive End station. At the PCP/PC Receive End station it is converted back to file format and then converted to an audio signal at the speaker output port of the PC. A clinician can listen to the received audio signal and save it if desired.

Contents of Attachment 6 for Software

The following documentation items are addressed in the sections shown:

Topic	Document	Section
Level of Concern	Level of Concern	Attachment 6.A.
Software Description	PCP/PC Stethoscope with sSOIP Requirements	Attachment 6.B. - Section III.
Device Hazard Analysis	Hazard Chart for PCP/PC Stethoscope	Attachment 6.C.
	Risk Analysis - PCP/PC Stethoscope	Attachment 6.D.
Software Requirements Specification	PCP/PC Stethoscope with sSOIP Requirements	Attachment 6.B. - Section III.
Architecture Design Chart	PCP/PC Stethoscope Software Design Specification	Attachment 6.E. - Section <i>Appendix A</i>
Software Design Specification	PCP/PC Stethoscope Software Design Specification	Attachment 6.E.
Traceability Analysis	Performance at all stages are compared back to PCP/PC Stethoscope Requirements	
Software Development Environment Description	PCP/PC Stethoscope Software Design Specification	Attachment 6.E. - Section <i>II</i> .
Verification and Validation Documentation	PCP/PC Stethoscope Alpha Test PCP/PC Stethoscope Clinical Test	Attachment 9

Revision Level History	MRI	Attachment 6.F.
Unresolved Anomalies (Bugs or Defects)	No know software anomalies that prevent the product from satisfying requirement or that adversely affect safety or effectiveness.	

Level of Concern – PCP/PC Stethoscope with sSOIP Software

Sept. 3, 2010

I. Overview

The purpose of the PCP/PC Stethoscope is to provide remote auscultation services between a patient at a location with a PC connected to an IP network (i.e. Transmit End station) and a clinician at another location also with a PC connected to the IP network (i.e. Receive End station). The Streaming Stethoscope Over IP (sSOIP) software running on the PCs is used to create the IP connection between the two stations and to transmit the stethoscope data over that connection.

In general, telemedicine provides certain clinical services over distance using telecommunications facilities such as POTS (Plain Old Telephone Service) and increasingly over the Internet. The sSOIP software is intended to send data from a PCP/PC chest piece over an IP network to implement a remote stethoscope function for telemedicine applications. Typically, services such as the Internet do not offer guaranteed service. (*Guaranteed communications services are specially provisioned and are explicit about the guarantees provided. They are outside the scope of the telemedicine devices and are the responsibility of the systems provider of a communications service providing guaranteed services.*) Thus, unless otherwise stated, telemedicine offerings accept that outages may occur.

The intended usage of the PCP/PC Stethoscope with the sSOIP software is for telemedicine applications that can tolerate unexpected service interruptions. As explained below, the level of concern is minor.

II. Analysis

The PCP/PC Stethoscope with sSOIP software:

- Is not intended to be used in combination with a drug or biologic.
- Is not intended to be used as an accessory that has a Major or Moderate Level of Concern.
- Does not control a life support or life sustaining function, nor monitoring of alarms in which medical intervention is necessary.
- Does not control the delivery of potentially harmful energy.
- Does not control the delivery of treatment or therapy such that an error or malfunction could result in death, serious injury or minor injury.
- In general, does not cause injury should it or the communications link malfunction.

III. Level of Concern

Based on the above analysis, the PCP/PC Stethoscope with sSOIP software presents a Minor Level of Concern.

Hazard Chart for PCP/PC Stethoscope

Undesirable Effect	Potential Cause	Mode of Control	Minimum Requirements/ Description of Control
Electrical Safety	The internal operating voltage shorts to part of the case that the user can touch	Design	By satisfying the safety requirements of EN 60601-1-1, no part that the user can touch will have a hazardous voltage level.
Electrical EMI and EMC	Electro-magnetic interference to the device or by the device	Design	By satisfying the EMI and EMC requirements of EN 60601-1-2, such risks are negligible.
Adverse Biocompatibility Reaction	Unsafe materials used for the PCP/PC chest piece (the only physical component other than the generic PC)	Design	The PCP/PC chest piece is made from the identical safe materials as the previously cleared Piezo Electronic Stethoscope.
Inability to use device because of hardware or component failure	Failure of a hardware component inside the PCP/PC chest piece or failure of a hardware component in the PC or server running PCP/PC Stethoscope software.	Clinical Training/ Operation Instructions	<p>Clinicians are trained in the use of stethoscopes and would recognize the failure of the equipment.</p> <p>The PCP/PC Stethoscope is intended to be used to listen to auscultation sounds remotely as a supplement to in-person care. Should a clinician not be able to conduct the remote auscultation and feel that an auscultation exam is needed, the clinician would instruct the person to see a clinician in person.</p>
Inability to use device because of software failure	<p>Failure of a PCP/PC Stethoscope software component including:</p> <ul style="list-style-type: none"> • Inability to process analog audio signal at the patient end. • Inability to process digitized audio signals at the patient end. • Inability to transport digitized signals from the patient end location to the clinician end location. • Inability to process digitized audio signals at the patient end. • Inability to process analog audio signal at the patient end. 	Clinical Training/ Operation Instructions	<p>Clinicians are trained in the use of stethoscopes and would recognize the failure of the equipment.</p> <p>The PCP/PC Stethoscope is intended to be used to listen to auscultation sounds remotely as a supplement to in-person care. Should a clinician not be able to conduct the remote auscultation and feel that an auscultation exam is needed, the clinician would instruct the person to see a clinician in person.</p>
Unauthorized Use	Non-authorized person using the stethoscope	Design	No physical harm can come to someone using the stethoscope.
Misuse by User	Clinician fails to use the stethoscope properly	Clinical Training/ Operation Instructions	<p>Clinicians are trained in auscultation as part of their clinical education. The PCP/PC Stethoscope presents the same auscultation sounds as a traditional acoustic stethoscope, but amplified.</p> <p>The Operation Instructions informs the clinician and patient how to use the PCP/PC Stethoscope.</p>

Risk Analysis – PCP/PC Stethoscope

Rev. 1.0

August 19, 2010

I. Scope

This Risk Analysis applies to the PCP/PC Stethoscope Chest Piece Assembly and software that resides on the PC to which the PCP/PC Chest Piece attaches.

II. Responsibilities

As part of his role as head of engineering and head of operations, C. R. Abbruscato conducted this Risk Analysis for the PCP/PC Stethoscope.

III. Intended Use and Identification of Characteristics Related to Safety

The PCP/PC Stethoscope is intended to be used for remote auscultation where a clinician at one location can hear the heart and lung sounds of a patient at another location. The patient or a care giver with the patient holds the PCP/PC chest piece to the part of the body as requested by the clinician and the clinician listens to the sounds via the headset.

The PCP/PC Chest Piece plugs into the Microphone port of a generic PC and derives its power from the approximately 2 vdc -5 vdc provided on the Tip and Ring leads of the Microphone jack.

A stethoscope is a tool used by clinicians who are trained in the use of a stethoscope for auscultation. Some clinicians are better at it than others. The PCP/PC Stethoscope is subject to misuse by a clinician without adequate skills in stethoscope use.

IV. Identification of Hazards

Hazards for the PCP/PC Chest Piece are:

1. Electrical safety associated with the dc power.
2. Other potential safety issues.
3. Electromagnetic interference (EMI).
4. Electromagnetic compatibility (EMC).
5. Biocompatibility.
6. Component failure.
7. Misuse by the clinician due to improper labeling.
8. Misuse by the clinician due to lack of skills.

Hardware hazards within the PC to which the PCP/PC Chest Piece is connected are:

1. Failure of the PC's internal power supply.
2. Microphone or headset circuitry failure.
3. Any other internal failure which causes the PC to stop performing.

Software hazards within the PC to which the PCP/PC Chest Piece is connected are:

- Failure of software in the PC or within the communications network can occur at many points – control of microphone function, control of headset function, digitization of the stethoscope signal, formatting of the stethoscope signal, and network connection and control anywhere along the path of the connection from the patient site to the clinician site.

V. Estimation of Risks for Each Hazardous Situation

Following is an estimation of each PCP/PC Chest Piece hazard:

1. Electrical safety and energy hazards are addressed and verified through the pertinent testing specified in IEC 60601-1 Medical electrical equipment - Part 1 General Requirements for Safety. If the tests are successfully performed, then the covered risks are negligible.
2. There are three issues with potential safety ramifications raised in IEC 60601-1. First is that the connector for the applied part (Chest Piece) is the same style as the connector for the Headset – a stereo audio jack. The Chest Piece function provides a signal to the unit and the Headset accepts a signal from the unit. If the PCP/PC Chest Piece is plugged into the wrong port or if the Headset is plugged into the wrong jack, the stethoscope will not work properly until the user puts them in the correct jack. There is no risk to the user or to the equipment if the user inadvertently uses the wrong jacks. The second potential issue is that the PCP/PC Chest Piece must have adequate isolation from power, ground and signal from the PC to provide adequate protection to the user per EN 60601-1 Medical electrical equipment - Part 1 General Requirements for Safety. The design of the PCP/PC Chest Piece addresses these requirements and is explained in PCP/PC Creepage Analysis 5/24/2010. The third potential issue is if a component inside the PCP/PC shorted the voltage source to ground. The bias voltage on the Microphone port is provided through a resistor typically in the range of 1k - 2K ohm from 5vdc. The PC circuit design is such that it is expected that the Microphone leads may be short to ground. For example, if someone plugs in a mono device into the Microphone jack, the Ring lead is shorted to ground. However, because the bias voltage is provided through a resistor, only milliamps or less of current is drawn. Even assuming a fault in the PC where that resistor somehow shorts, the worst effect would be that the power supply of the PC could fail (or not be able to provide enough power to the PC). That would deny use of the PC (as would other faults in the PC) but would not present a safety hazard.
3. Electromagnetic interference (EMI) is addressed and verified through the pertinent testing specified in EN 60601-1-2 Medical Electrical Equipment - Collateral Standard; Electromagnetic Compatibility Requirements and Tests. If the tests are successfully performed, then the covered risks are negligible and remote in frequency of occurrence.
4. Electromagnetic compatibility (EMC) is addressed and verified through the pertinent testing specified in EN 60601-1-2 Medical Electrical Equipment - Collateral Standard; Electromagnetic Compatibility Requirements and Tests. If the tests are successfully performed, then the covered risks are negligible and remote in frequency of occurrence.
5. Biocompatibility hazards have been addressed through the use of safe materials for those parts of the PCP/PC Stethoscope that can be touched by the patient or clinician. The Bottom part of the PCP/PC Chest Piece enclosure is made from Tairilac ABS AG15A1

plastic and Materials Testing reports are available with copies retained in the DHF. The Top part of the PCP/PC Chest Piece is made from inert SUS304 Stainless Steel. There is a covering that goes over the piezo element in the PCP/PC Chest Piece that is made of inert Silicone. The coverings on the cables of the Headset and Chest Piece Assembly are PVC. The Headset is an off-the-shelf consumer product and biocompatibility has been addressed by the manufacturer. All these materials are the same as used in the previously FDA cleared Piezo Precordial Stethoscope.

6. Failure of an electrical component within the PCP/PC Chest Piece can result in the unavailability of the PCP/PC Stethoscope to perform its normal functions. Such a failure inherently causes no harm. Since the stethoscopes are used for monitoring purposes, the net effect is an inconvenience and infrequent in frequency of occurrence.
7. Misuse by the clinician due to improper labeling are addressed and verified through the pertinent testing specified in IEC 60601-1 Medical electrical equipment - Part 1 General Requirements for Safety. If the tests are successfully performed, then the covered risks are negligible and remote in frequency of occurrence.
8. Misuse or the PCP/PC Stethoscope or any stethoscope by the clinician due to lack of skills is a possibility. It is expected that clinicians will receive the necessary training in auscultation to perform their jobs. If they don't that is roughly equivalent to not having the stethoscope available for use. Such unavailability inherently causes no harm. Since the stethoscopes are used for monitoring purposes, the net effect is an inconvenience and infrequent in frequency of occurrence.

Following is an estimation of each PC hardware hazard:

1. Failure of the power supply in the PC is a possibility. PCs to which the PCP/PC Chest Piece is connected use ITE power supplies conforming to IEC 60950-1. Per IEC 60601-1 Medical electrical equipment - Part 1 General Requirements for Safety, the design of the PCP/PC Chest Piece provides adequate protection for any specified failures of the PC's power supply.
2. Failure of the microphone or headset circuitry in the PC results in the unavailability of the stethoscope. Such unavailability inherently causes no harm. Since the stethoscopes are used for monitoring purposes, the net effect is an inconvenience and infrequent in frequency of occurrence.
3. Failure of any other hardware component with the PC results in the unavailability of the stethoscope. Such unavailability inherently causes no harm. Since the stethoscopes are used for monitoring purposes, the net effect is an inconvenience and infrequent in frequency of occurrence.

Following is an estimation of PC software hazards:

1. Failure of software in the PC or within the communications network can occur at many points – control of microphone function, control of headset function, digitization of the stethoscope signal, formatting of the stethoscope signal, and network connection and control anywhere along the path of the connection from the patient site to the clinician site.

VI. Risk Evaluation

The risk estimation meets the risk criteria described in the Risk Management Plan – PCP/PC Stethoscope. Therefore, no risk reduction is required and there is no residual risk.

VII. Risk Controls Required

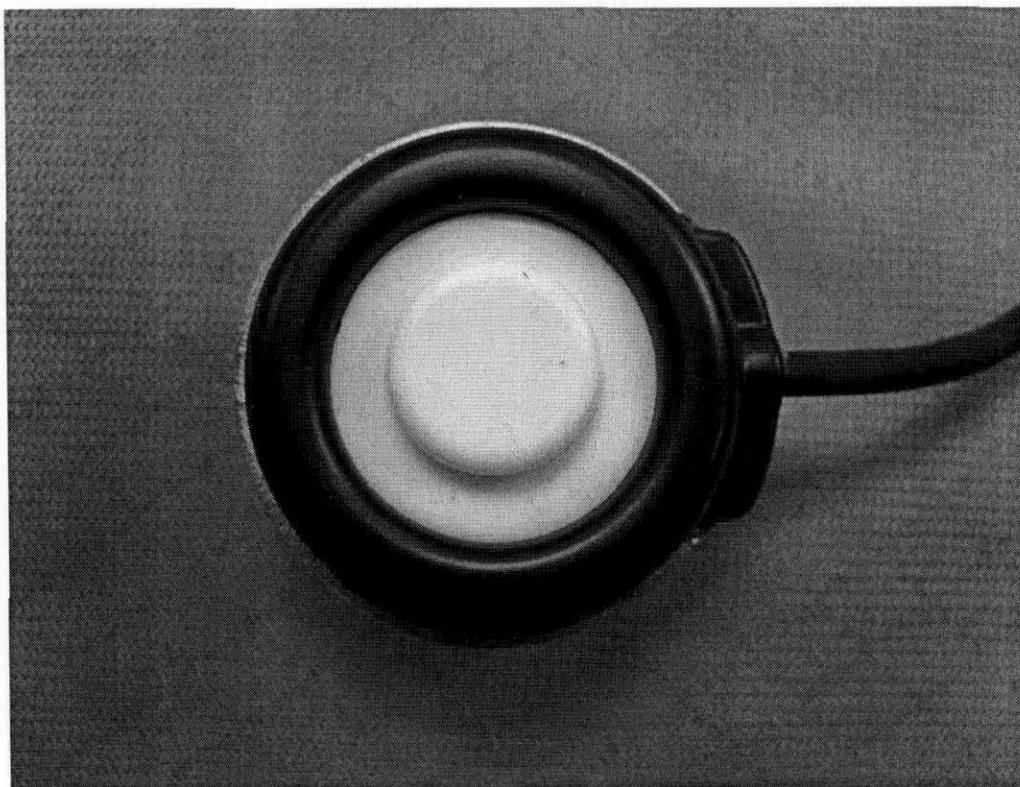
No risk controls are required.

VIII. Conclusions

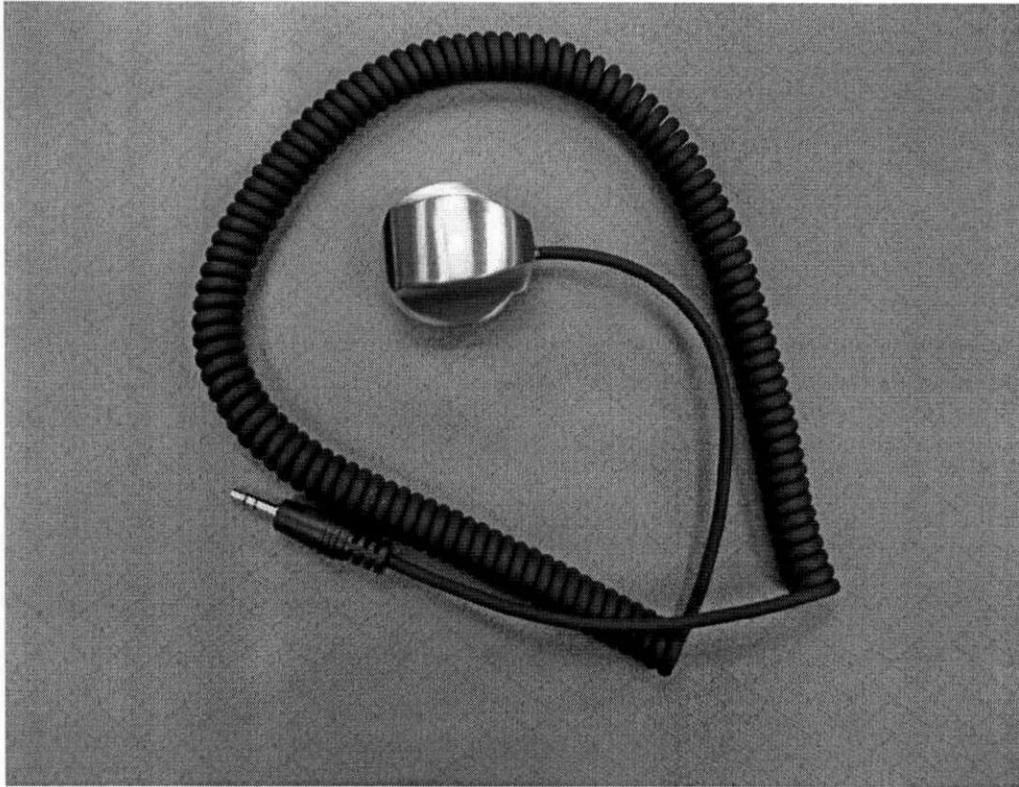
All the hazards for the PCP/PC Stethoscope have been identified and the evaluation for those hazards shows that the risk criteria described in the Risk Management Plan – PCP/PC Stethoscope are satisfied. No risk reduction is required, no risk controls are required and there is no residual risk.



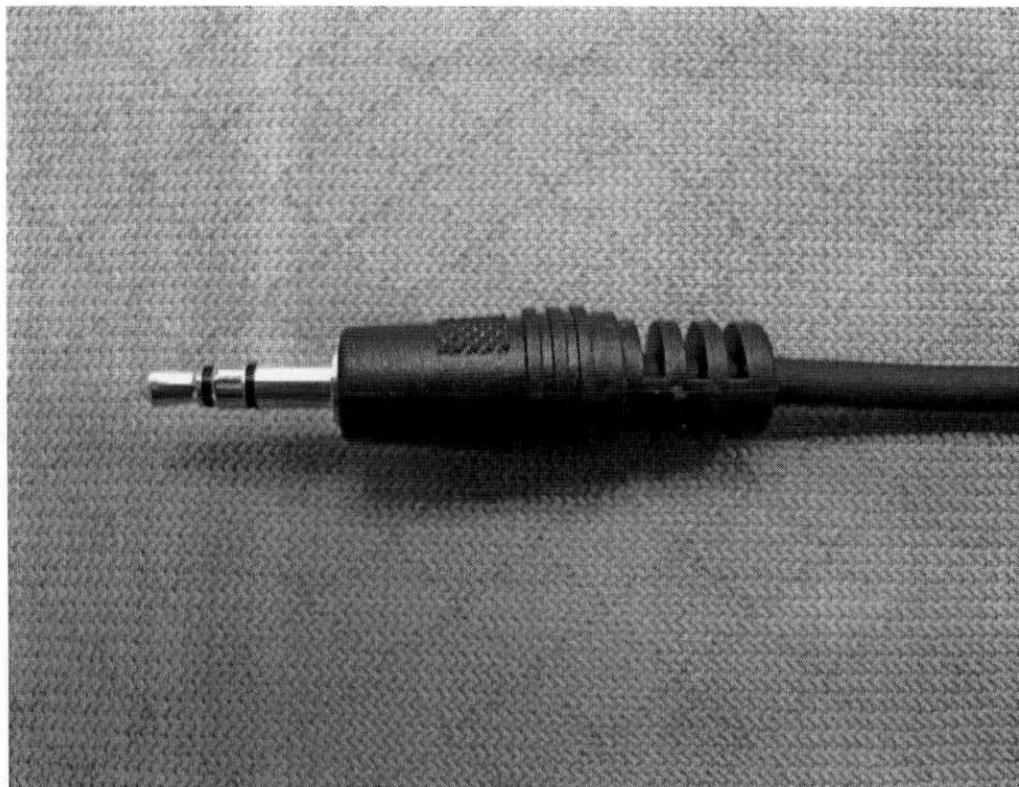
PCP/PC Chest Piece – Top View



PCP/PC Chest Piece – Bottom View



PCP/PC Chest Piece and cable assembly – Top View



Connection end – plugs into Host PC microphone port

ATTACHMENT 8

CERTIFICATION OF COMPLIANCE WITH STANDARDS

for the

RNK PCP/PC STETHOSCOPE

**CERTIFICATION OF COMPLIANCE WITH STANDARDS
BY RNK PRODUCTS INC. PCP/PC STETHOSCOPE**

I certify that RNK Products, Inc. PCP/PC Stethoscope complies with appropriate tests/standards:

- IEC60601-1:2003/2nd Edition Medical Electrical Equipment Part 1: General Requirement for Safety
- EN60601-1-2, 2007/03, EMC Immunity Requirements for Medical Electrical Equipment Part 1: General Requirements for Safety, 2. Collateral Standard – Electromagnetic Compatibility Requirements and Tests
- EN61000-4-2 Part 2: Electrostatic Discharge Requirements
- EN61000-4-3 Part 3: Radiated Electromagnetic Field Requirements
- EN61000-4-4 Part 4: Electrical Fast Transient/Burst Requirements
- EN61000-4-6 Part 6: Conducted Immunity Requirements
- EN61000-4-8 Part 8: Power Frequency Magnetic Field Requirements


Signature

Charles R. Abbruscato
Typed Name

CEO
Title

RNK Products, Inc.
Company

Sept. 29, 2018
Date

ATTACHMENT 9
VERIFICATION AND VALIDATION
for the
RNK PCP/PC STETHOSCOPE

Verification and Validation

The final verification and validation of the RNK PCP/PC Stethoscope was conducted in-house with an Alpha Test and by a clinical user with a Clinical Test.

Test Results

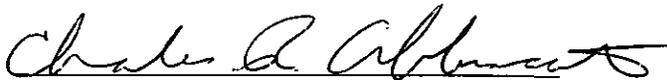
The test results from the Alpha Test were recorded and are included at the end of this section. The PCP/PC Stethoscope performed per its technical specifications.

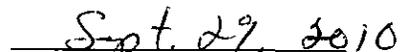
The test results from the Clinical Test were recorded and are included at the end of this section. The PCP/PC Stethoscope performed per its user specifications

Certification

The Company certifies that it developed the RNK PCP/PC Stethoscope following its Design Procedures as part of its Quality System.

The company certifies that it used an adequate test plan to verify and validate the RNK PCP/PC Stethoscope. The testing demonstrated that the functional requirements and specifications were met.


Signature


Date

Charles R. Abbruscato
Name

CEO
Title

RNK Products

PCP/PC Stethoscope

Alpha Test

Rev 0.0

July 15, 2010

Tested By:

C. Q. Abbascato

Signature:

C. Q. Abbascato

Date:

July 22, 2010

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER RNK Products, Inc.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES Sept. 29, 2010
3. ADDRESS (Number, Street, State, and ZIP Code) 4195 US Hwy 1 Suite 101 Rockledge, FL 32955	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 321.626.7717 (Fax) 321.305.5983

PRODUCT INFORMATION

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
 FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
 (Attach extra pages as necessary)

PCP/PC Stethoscope, Class II Electronic Stethoscope

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

IND
 NDA
 ANDA
 BLA
 PMA
 HDE
 510(k)
 PDP
 Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.
 B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.
 C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Charles R. Abbruscato (Title) CEO	
3. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 4195 US Hwy 1, Suite 101 Rockledge, FL 32955	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 321.626.7717 (Fax) 321.305.5983	15. DATE OF CERTIFICATION Sept. 29, 2010

RNK Products

2

PCP/PC Stethoscope
Clinical Test

Rev 0.0
July 15, 2010

Tested By: *Dr KEVIN FRIEDMAN DO*

Signature: *Kevin Friedman*

Date: *Sep 29, 2010*

ATTACHMENT 10
510(K) SUMMARY
for the
RNK PCP/PC STETHOSCOPE

510(k) SUMMARY
RNK Products
PCP/PC Stethoscope

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

Submitter Information

Submitter: RNK Products
4195 US Hwy 1
Suite 101
Rockledge, FL 32955
Telephone: (321) 626-7717
Facsimile: (321) 305-5983

Contact Person: Charles R. Abbruscato
RNK Products
Telephone: (321) 626-7717
Facsimile: (321) 305-5983

Date Prepared: Sept. 3, 2010

Device Information

Name of Device RNK PCP/PC Stethoscope

Common or Usual Name Electronic Stethoscope

Classification Name Electronic Stethoscope

Predicate Devices RNK Products TR-1 Telephonic Stethoscope (034046)
RNK Products Precordial Stethoscope (K072026)

Device Description

The PCP/PC Stethoscope is comprised of a PCP/PC Chest Piece that plugs into a generic PC on an IP network (e.g. the Internet) and the streaming Stethoscope Over IP (sSOIP) software application running on the PC. It provides remote auscultation between a patient at one location and a clinician at another location.

The PCP/PC Chest Piece derives operating voltage from the bias voltage on the Microphone port of the PC. PCP/PC Chest Piece contains an embedded amplifier which amplifies the auscultation signal from the piezo sensor and presents it as an analog signal to the Microphone input of the PC.

Under direction of the sSOIP program, the analog signal is digitized in the PC, formatted and converted to IP packets for transport. At the receive end PC, the sSOIP program directs the acceptance of the IP packets, conversion of the signal back to analog and presentation of the analog signal to the Headset port of the PC.

Intended Use

The RNK PCP/PC Stethoscope is intended for use as a remote monitoring device, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations.

Substantial Equivalence

The RNK PCP/PC Stethoscope uses a similar amplifier and chest piece sensor technology as the predicates. The RNK PCP/PC Stethoscope is substantially equivalent to the RNK Products, Inc. Telephonic Stethoscope Model TR-1 and Precordial Stethoscope. Bench testing and clinical testing was performed to verify specification and performance.

The RNK PCP/PC Stethoscope has the same intended use, principles of operation and technological characteristics as the predicate devices. There are no new questions of safety or effectiveness.

ATTACHMENT 11

INDICATIONS FOR USE STATEMENT

for the

RNK PCP/PC STETHOSCOPE

510(k) Number (if known): _____

Device Name: PCP/PC Stethoscope

Indications for Use:

The RNK PCP/PC Stethoscope is intended for use as a remote monitoring device, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations.

Prescription Use: X
(Part 21 CRF 801 Subpart D)

OR

Over-the-Counter Use _____
(Part 21 CRF 801 Subpart C)

(Please Do Not Write Below This Line – Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 1-2-96)

ATTACHMENT 12
TRUTHFUL AND ACCURATE STATEMENT
for the
RNK PCP/PC STETHOSCOPE

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 C.F.R. § 807.87(j))**

I certify that, in my capacity as CEO of RNK Products, Inc. I believe, to the best of my knowledge, that all data and information submitted in this premarket notification for the RNK PCP/PC Stethoscope is truthful and accurate and that no material fact has been omitted.

Charles R. Abbruscato
Signature

Sept. 29, 2010
Date

Charles R. Abbruscato
Name

CEO
Title



COVER SHEET MEMORANDUM

From: Reviewer Name Sabina Reilly
 Subject: 510(k) Number K102893/51
 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/eRoomReg/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	X	
510(k) Summary /510(k) Statement	Attach Summary	X	
Truthful and Accurate Statement:	Must be present for a Final Decision	X	
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
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)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		X	
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.)			X
Does this device include an Animal Tissue Source?			X
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		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	X

Regulation Number: 870.1875 Class*: Class II (two) Product Code: DQD
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: [Signature] CE7B 1/20/11
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 1/20/2011
(Division Director) (Date)



Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification 510(k) Review
Traditional

K102893/S1

Date: January 14, 2011

To: The Record

From: Sabina Reilly

Office: ODE

Division/Branch: DCD/CEMB

510(k) Holder: RNK Products, Inc.
4195 US Hwy 1
Suite 101
Rockledge, FL 32955

Device Name: RNK PCP/PC Telephonic Stethoscope
Contact: Charles R. Abbruscato
Phone: 321-626-7717
Fax: 321-305-5983
Email: abbruscato@rnkproducts.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the RNK PCP/PC Telephonic Stethoscope into interstate commerce. The sponsor has indicated that the device has the following classification:

21 CFR 870.1875 - DQD- Class II - Stethoscope

The sponsor has cited the following predicate device:

K034046: RNK TR-1 Telephonic Stethoscope
K072026: RNK Precordial Stethoscope

II. Administrative Requirements

Table with 4 columns: Requirement, Yes, No, N/A. Rows include: Indications for Use page (Indicate if: Prescription or OTC) - Prescription, Truthful and Accuracy Statement, 510(k) Summary or Statement, Standards Form - See attachment 8.

III. Device Description

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

The device is a telephonic stethoscope consisting of a chest piece assembly that plugs into the microphone port of a generic PC and a software package called Streaming Stethoscope Over IP (sSOIP) running on the PC. The signal from the PCP/PC chest piece is amplified and digitized at high audio resolution by the PC's audio circuitry. The sSOIP program creates an audio stream in IP communications format and sets up an IP connection to another PC on the IP network. That receiving end PC accepts the streaming audio and feeds it to its audio circuitry where it is converted back to analog, amplified and presented to the Headset port. The audio stethoscope sounds can be heard at the headset output port of the receive end PC.

IV. Indications for Use

From the sponsor:

"The RNK PCP/PC Stethoscope is intended for use as a remote monitoring device, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations."

V. Predicate Device Comparison/Substantial Equivalence Discussion

The sponsor cited the following predicate devices:

510(k) number Device name Manufacturer	Subject Device RNK PCP/PC Stethoscope RNK Products, Inc.	K034046 RNK TR-1 Telephonic Stethoscope RNK Products, Inc.	K072026 RNK Precordial Stethoscope RNK Products, Inc.
Indications for Use	Remote monitoring device, whereby a clinician at one location can listen to the auscultation sounds of a patient at a different location with the signal carried over a data communication channel between the two locations.	Remote monitoring device, whereby a clinician at one location can listen to the auscultation sounds of a patient at a different location with the signal carried over a data communication channel between the two locations. SAME	Detecting and amplifying heart, lung and other body sounds.
Design			
Components	<ul style="list-style-type: none"> • Detachable Chest Piece • Detachable headset • Chest Piece and headset connect to generic PC • Audio handling control and communications 	<ul style="list-style-type: none"> • Detachable Chest Piece • Detachable headset • Electronic module- 4 ½"L x 2 ½"W x 1" 	<ul style="list-style-type: none"> • Detachable Chest Piece • Detachable headset • Electronic module- 3.9"L x 1.9"W x

	software on PC	H Same Module can be used for Transmitting or for Receiving	0.9" H
Technical Characteristics of Chest Piece	PCP/PC chest piece converts body auscultation signals to analog signal	CP-1 chest piece converts body auscultation signals to analog signal	Piezo chest piece converts body auscultation signals to analog signal
Technical Characteristics- Audio/Digital processing	Analog signal from Chest Piece amplified in PC Analog signal is converted and encoded to a digital signal, then put into IP data format in the PC At the receive end, PC accepts IP data stream, decodes the digital signal converting it back to analog then amplifies the analog signal and presents it to the headset port	Analog signal from Chest Piece amplified in TR-1 Module Analog signal is converted to digital signal, encodes signal and puts into asynchronous format. At the receive end, decodes digital signal, converts it back to analog then amplifies it to headset port.	Analog signal from Chest Piece amplified in Amplifier Module and presented at Headset port.
Technical Characteristic- Data Communications:	PC software puts signal into IP format. Destination IP addresses are entered into PC. PC transmits IP data to network. At receive end, PC accepts IP data stream.	TR-1 Module sends signal in asynchronous data protocol over RS232 Interface. Communications transport handled in separate networking devices.	No data communications
Power Source	2-5 vdc provided from the PC. Safety isolation is provided within the PCP/PC Chest Pieced.	Ac to dc wall mount Power Adapter converts 120 vac to 9-12 vdc. Internal regulator converts that to 5vdc to power the circuitry.	Battery powered.
Auscultation Bandwidth	20 Hz to 2,000 Hz	20 Hz to 700 Hz	20 Hz to 2,000 Hz
Controls	No controls on PCP/PC Chest Piece. Volume control to Headset using PC audio controls	Volume control to headset on TR-1. D/B Switch to select bandwidth to headset.	No controls on Precordial chest piece or amplifier module.

VI. Labeling

(b) (4)



VII. Sterilization/Shelf Life/Reuse

(b) (4)

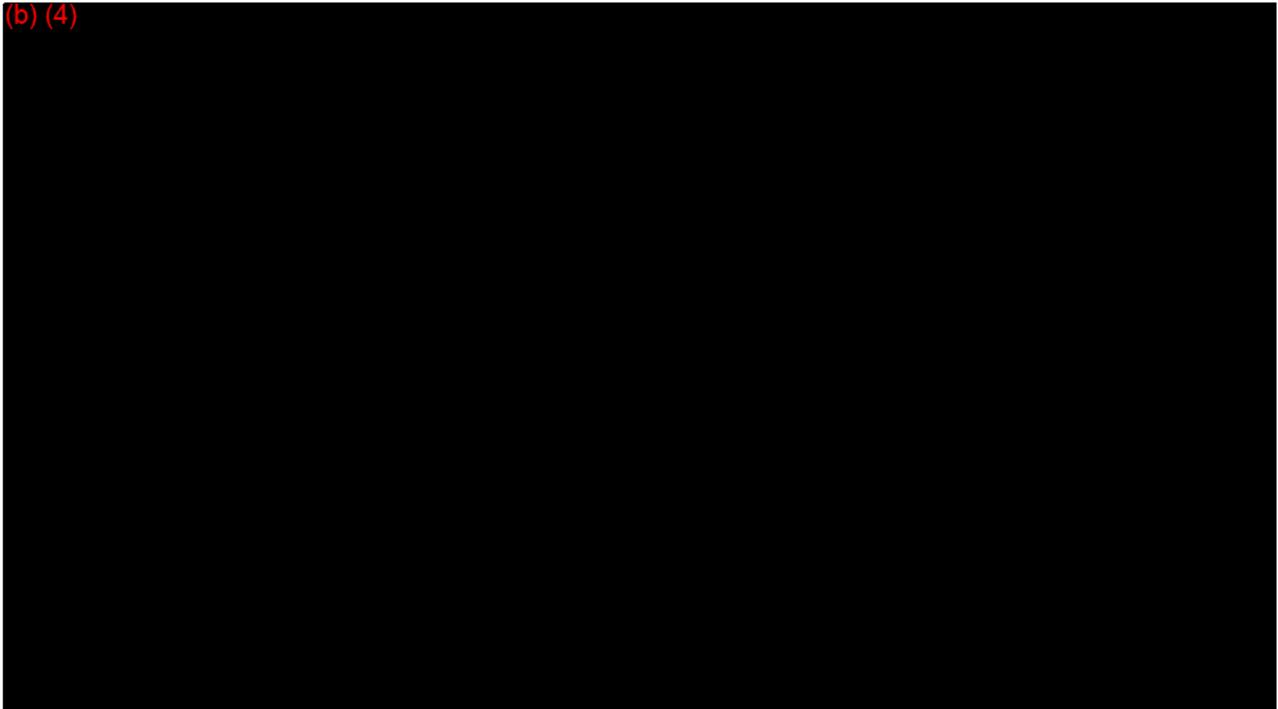
1. Sterilant:	YES	NO
a. Sterilization method description (e.g., Steam (moist heat), EO, Radiation):	N/A	
b. Dose , for radiation (e.g., 25 – 50 kGy):	N/A	
Sterilant residuals remaining on the device:	N/A	
2. A description of the Validation Method for the sterilization cycle (not data):	N/A	
3. Sterility assurance level (SAL):	N/A	
4. Is it labeled "Pyrogen Free"?	N/A	
If so, a description of the method: (e.g., LAL (<i>Limulus</i> Amebocyte Lysate test))	N/A	
5. A description of the packaging (not including package integrity test data):	N/A	

VIII. Biocompatibility

IX. Software

(b) (4)

(b) (4)

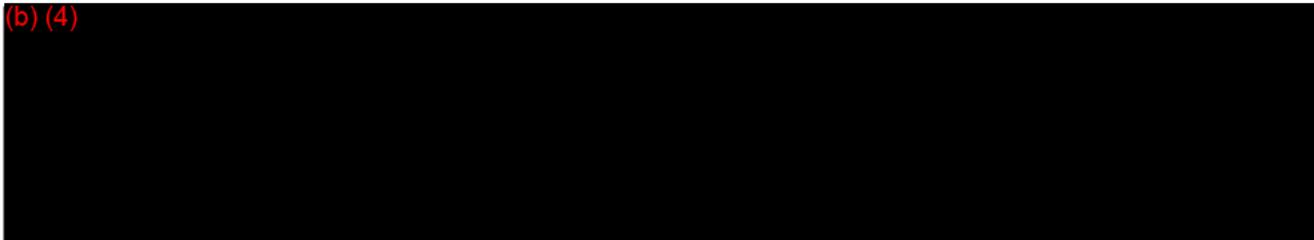


Performance Testing – Bench

The firm provided a certification of compliance with standards for safety testing of their device to indicate that the device complies with the following standards:

- IEC60601-1:2003/2nd Edition Medical Electrical Equipment, Part 1: General Requirements for Safety.
- IEC60601-1-2:2007/03 Immunity Requirements for Medical Electrical Equipment, Part 1: General Requirements for Safety, Part 2: Collateral standard, Electromagnetic Compatibility Requirements & Tests
- EN 61000-4-2 Electrostatic discharge
- EN 61000-4-3 Radiated electromagnetic field requirements
- EN 61000-4-4 Electrical fast transient burst requirements
- EN 61000-4-6 Conducted immunity
- EN 61000-4-8 Power frequency magnetic field requirements

(b) (4)



Performance Testing – Animal

N/A - Animal testing was not performed and was not necessary.

Performance Testing – Clinical

N/A - Clinical testing was not performed and was not necessary.

Substantial Equivalence Flow Chart

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

Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%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.

5. How are the characteristics not descriptive enough? The sponsor has not provided the appropriate level of software documentation for their device.

510(k) SUMMARY REQUIREMENTS CHECKLIST				
21 CFR 807.92				
		Y	N	N/A
All 510(k) summaries shall contain the following information:				
1	The submitter's name, address, telephone number, a contact person, and the date the summary was prepared	✓		
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name	✓		
3	An identification of the legally marketed device(s) to which the submitter claims equivalence.	✓		
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)	✓		
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.			
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.	✓		
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			✓
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.)			✓
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.			✓

Contact History

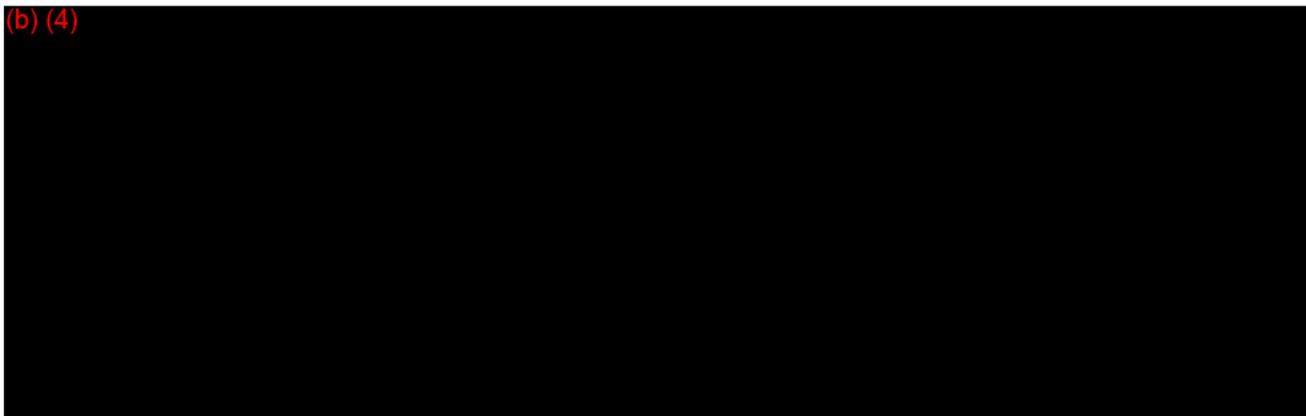
The sponsor was sent a list of deficiencies on Dec 21, 2010 and the file was placed on 'Telephone Hold'.

Additional Discussion

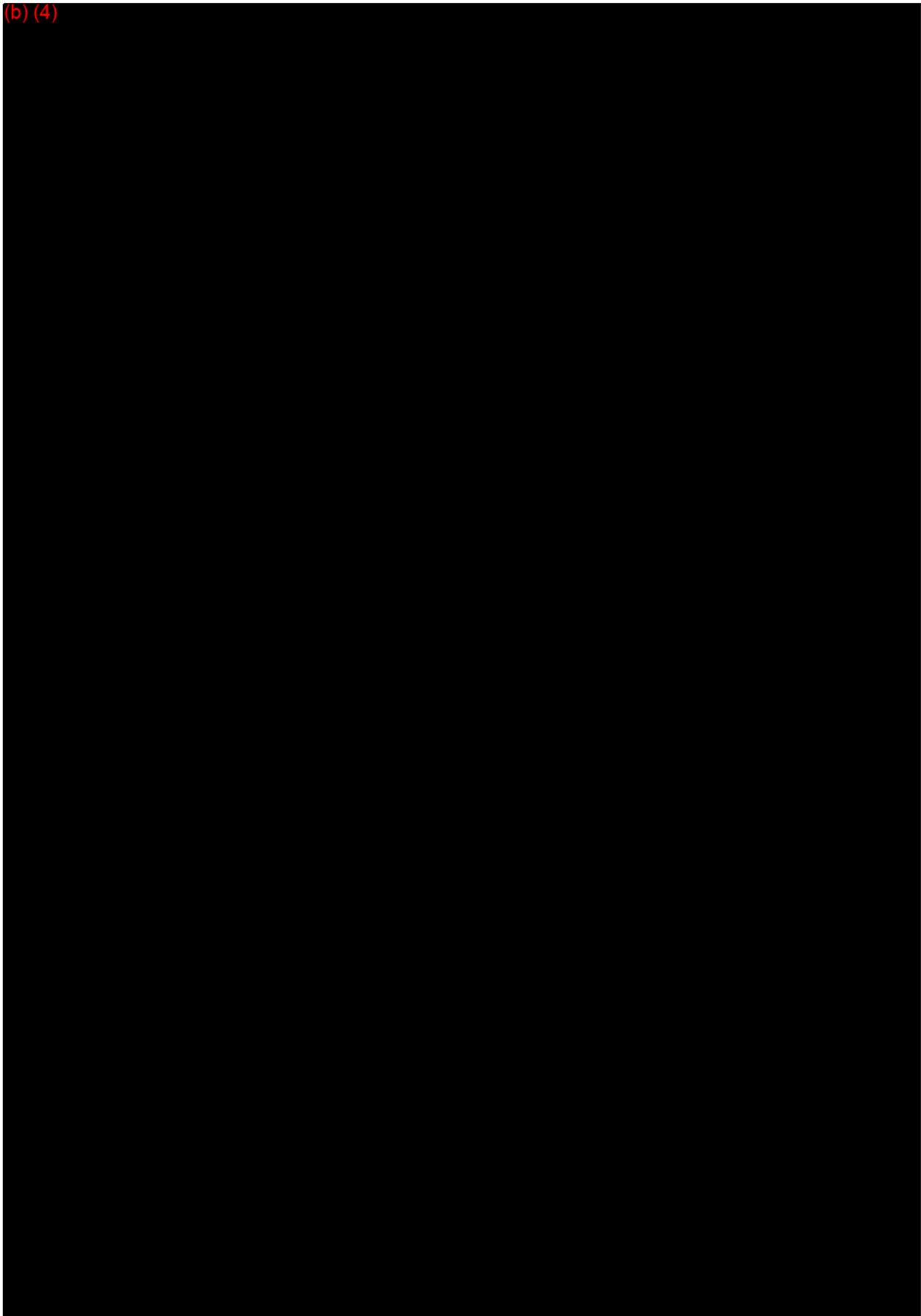
I have attached numerous emails to this file detailing the reviewers inability to access Image 2000 in order to complete this review. As the system was not functioning for over a month time period and the reviewer could not access the system to confirm the predicate device information, the MDUFMA time lines may not be met for this file.

Deficiencies from original review of the submission

(b) (4)



(b) (4)



(b) (4)

Recommendation

I recommend that the proposed device be found **substantially equivalent** to legally marketed stethoscopes, classified as follows:

- Class II
- 21 CFR § 870.1875
- 74 DQD

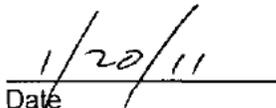


Reviewer



Branch Chief

January 20, 2011 _____
Date



Date

Reilly, Sabina

From: Rich Abbruscato [abbruscato@rnkproducts.com]
Sent: Friday, January 14, 2011 12:19 PM
To: Reilly, Sabina
Subject: RE: K102893 - RNK PCP/PC Stethoscope
Attachments: PCP-PC sSOIP Installation and Operation Instructions.pdf

Sabrina,

I changed the statement on the bottom of the first page in the Manual to use the exact wording. Is this OK?

Regards,

Rich

From: Reilly, Sabina [mailto:Sabina.Reilly@fda.hhs.gov]
Sent: Friday, January 14, 2011 12:09 PM
To: Rich Abbruscato
Subject: RE: K102893 - RNK PCP/PC Stethoscope

Mr. Abbruscato-

I am currently reviewing the response to the deficiencies that you had emailed me. (b) (4)

Best regards,
Sabina Reilly

From: Rich Abbruscato [mailto:abbruscato@rnkproducts.com]
Sent: Wednesday, January 12, 2011 2:20 PM
To: Reilly, Sabina
Subject: RE: K102893 - RNK PCP/PC Stethoscope

Sabrina,

Attached is the additional information you requested. We will send hard copies of all documents immediately.

Regards,

Rich

16

1/20/2011

C. R. (Rich) Abbruscato

RNK Products, Inc.

4195 US Hwy 1

Suite 101

Rockledge, FL 32955

321.626.7717

abbruscato@rnkproducts.com

www.telehealthtechnologies.com

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From: Reilly, Sabina [mailto:Sabina.Reilly@fda.hhs.gov]

Sent: Tuesday, December 21, 2010 4:11 PM

To: Rich Abbruscato

Subject: K102893 - RNK PCP/PC Stethoscope

EMAIL REQUEST FOR ADDITIONAL INFORMATION

FROM:

Sabina Reilly

Reviewer

Office of Device Evaluation

Center for Devices and Radiological Health

FDA

10903 New Hampshire Ave

WO66, Rm 1252

Silver Spring, MD 20993

(301) 796-6324

Email: sabina.reilly@fda.hhs.gov

TO:

RNK Products, Inc.

C/O Charles R. Abbruscato

4195 US Hwy 1

Suite 101

Rockledge, FL 32955

321-626-7717(tel)

321-305-5983(fax)

RE: K102893

RNK PCP/PC Stethoscope

December 21, 2010

Dear Mr. Abbruscato,

We have reviewed your Section 510(k) notification of intent to market the device referenced above. To complete the review of your submission, we require a response to the following deficiencies:

(b) (4)



17

(b) (4)

[Redacted]

Labeling

(b)(4)Trade Secret Process-Testing

[Redacted]

Software

(b)(4)Trade Secret Process-Testing

[Redacted]

Biocompatibility

(b)(4)Trade Secret Process-Testing

[Redacted]

[Redacted]

Your file will be placed on administrative hold until we receive the requested information. Please respond by email (sabina.reilly@fda.hhs.gov) **followed by a hardcopy** to the Document Mail Center. Please reference the 510(k) number on the cover letter to any correspondence submitted to the Agency. Please contact me if you have any questions.

Best regards,
Sabina Reilly
Biomedical Engineer
Center for Devices & Radiological Health
Division of Cardiovascular Devices
10903 New Hampshire Ave
WO66, Rm 1252
Silver Spring, MD 20993
(301) 796-6324

The opinions expressed in this message represent the best judgment of the sender and do not necessarily represent the formal position of the FDA under 21 CFR §10.85

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify Sabina Reilly by return e-mail or telephone at 301-796-6324.

PCP/PC Stethoscope with sSOIP Installation and Operation Instructions

Rev 1.5
January 14, 2011

This document provides the patient operating instructions for the PCP/PC Stethoscope.



This product meets the safety requirements of EN 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety for Type BF protection using a power source providing 2 - 5 vdc. The device providing power should satisfy IEC 60950.

Vdc:

Type BF applied part:



Class II protection
against electrical shock:



This product meets the EMC Emissions and Immunity requirements of EN 60601-1-2 Medical Electrical Equipment Part 2 Collateral Standard: Electromagnetic Compatibility Requirements and Tests:

EN61000-4-2	Part 2: Electrostatic Discharge Requirements
EN61000-4-3	Part 3: Radiated Electromagnetic Field Requirements
EN61000-4-4	Part 4: Electrical Fast Transients/Bursts Requirements
EN61000-4-6	Part 6: Conducted Immunity Requirements
EN61000-4-8	Part 8: Power Frequency Magnetic Field Requirements

This product may be used in continuous operation.

This product is not a defibrillation-proof applied part. This product is not suitable for use in the presence of a flammable anesthetic mixture with air or with continuous oxygen or nitrous oxide.

Normal use for this product is at an ambient temperature range of +10° to +40°C, a relative humidity range of 30% to 75%, an atmospheric pressure range of 700 hPa to 1,065 hPa. It may be transported and stored at temperatures from 0°C to 50°C and relative humidity of 10% to 95%.

The device contains electronic components and disposal of it should in accordance with all federal and local laws.

Local laws may take priority over the above requirements. If in doubt, consult your local representative or the technical service department.

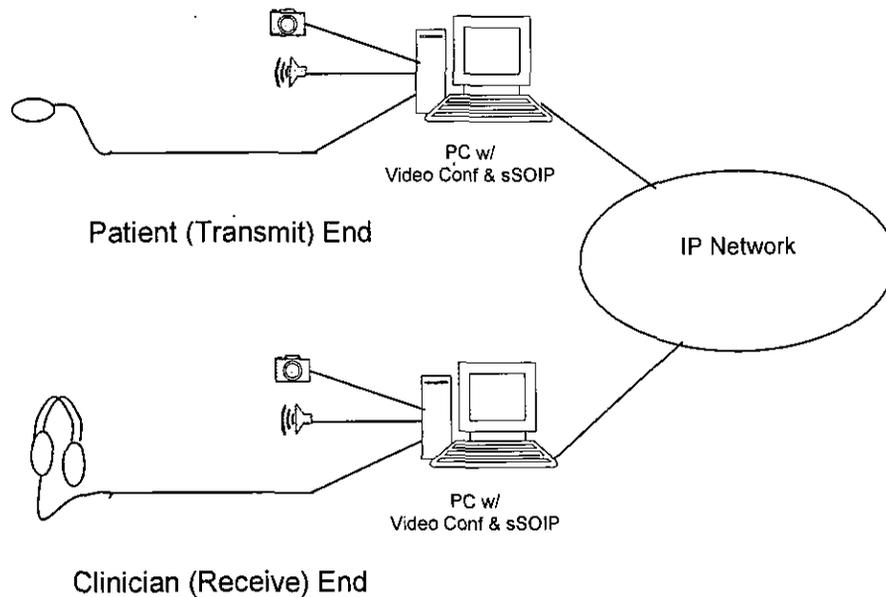
Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner).

For questions or comments, contact RNK Products, Inc., 4195 US Hwy 1, Suite 101, Rockledge, FL 32955

I. Introduction

The PCP/PC Stethoscope Patient Station is comprised of a PCP/PC Chest Piece plugged into a generic PC on an IP network (e.g. the Internet) and the streaming Stethoscope Over IP (sSOIP) software application running on the PC. It provides remote auscultation between a patient at one location and a clinician at another location.

The typical application for a telephonic stethoscope is in conjunction with a video conference session for telemedicine. With the video conference over IP, the stethoscope sounds will go over a separate socket from the video conferencing data.



The clinician at the receive end is in control of the connection and will Start or Stop the stethoscope exam from the receive end PC. When the clinician clicks on Connect, the IP connection between the two PCs will be completed. When Disconnect is clicked, the exam stops and the connection breaks at the transmit end so that no stethoscope data is sent over the IP network.

The SOIP program also provides the capability for recording stethoscope sound data into special files, saving those files and playing them back.

II. Installation

Before the PCP/PC Stethoscope can be used, the PCP/PC sSOIP application must be installed on the target PC, which must be on an IP network such as the Internet. Once the application software is installed, the PCP/PC Stethoscope must be configured (section III).

Insert the PCP/PC Stethoscope Patient Station CD into the PC and run the sSOIP Setup.exe installation program. This will start the installation process. Click on Next and continue to click on Next for subsequent screens unless you want to install the SOIP program into special folders of your choosing.

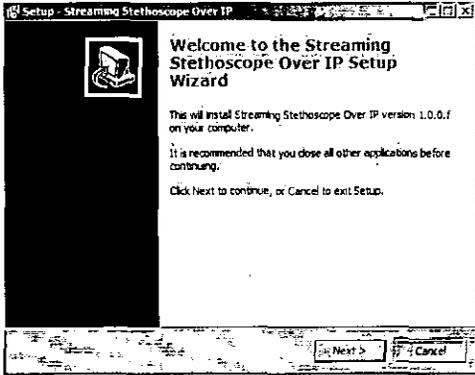


Figure 1: Installation Wizard

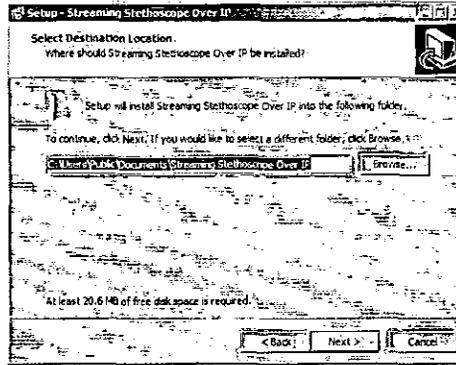


Figure 2: Select Destination Folder

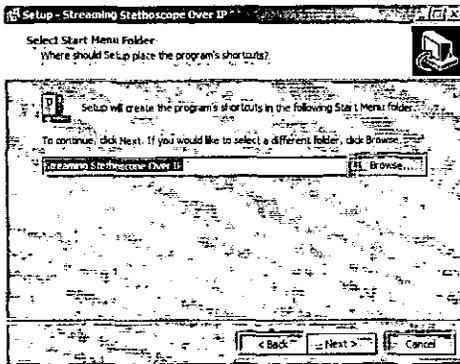


Figure 3: Select Start Menu Folder

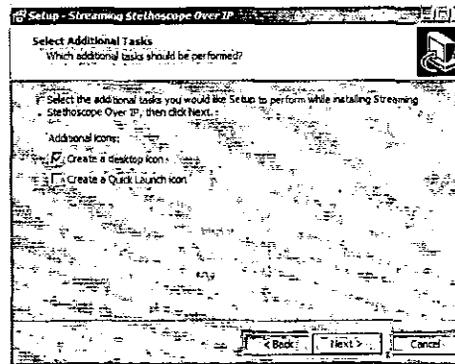


Figure 4: Create a Desktop Icon

Next in Figure 5 click on Install.

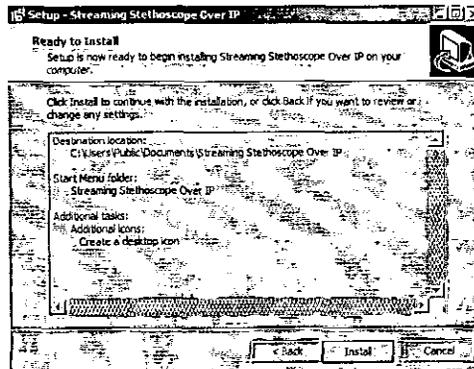


Figure 5: Install the Program

This will bring up Figure 6 asking if you want to delete the previous installation. Click on Yes.

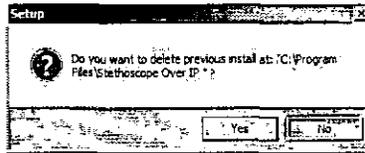


Figure 6: Delete Previous Installation

When the completion screen comes up, click on Finish.



Figure 7: Installation Complete

III. Setup

A. Transmit Mode

Open the SOIP program using the desktop icon or the C:\Program Files\Stethoscope Over IP\SOIP.exe file. Whatever mode the program was in when it was last closed will be the mode that the program goes into when opened next. For example, if the SOIP program was configured for Transmit mode last time it was opened, then the Main screen shown in Figure 8 will display when the program is reopened.

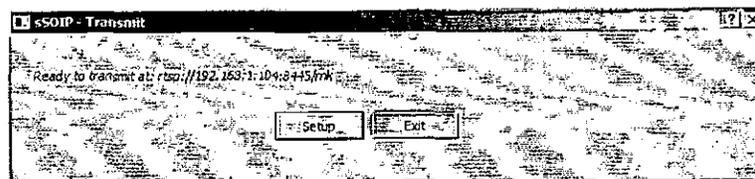


Figure 8: Main Screen – Ready to Transmit

Clicking on the Setup button brings up the screen for selecting the telephonic stethoscope model, the operating mode, the port assignments and the IP Address Book for entering IP addresses of remote site telephonic stethoscopes. Since the system would be in Transmit mode from Figure 8, the setup screen would show Transmit mode as shown in Figure 9.

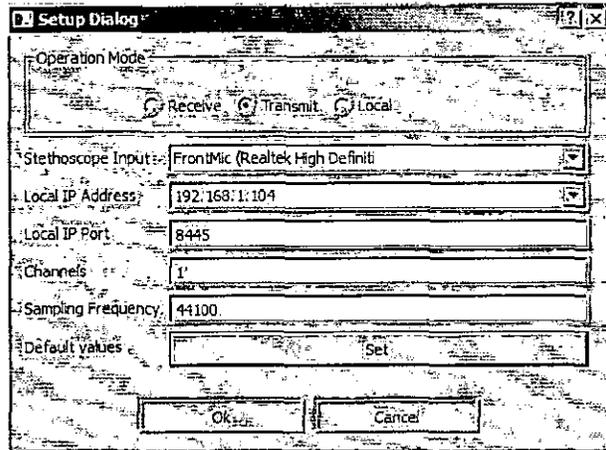


Figure 9: Setup Screen – Transmit Mode

The sSOIP program will detect the PCP/PC Chest Piece and display the audio port. It will also check for local IP addresses and display them. The default local IP port is 8445. If that is changed, then the Receive end sSOIP must select that same IP to be able to connect to this sSOIP station.

B. Receive Mode

Clicking on Receive Mode brings up the screen in Figure 10.

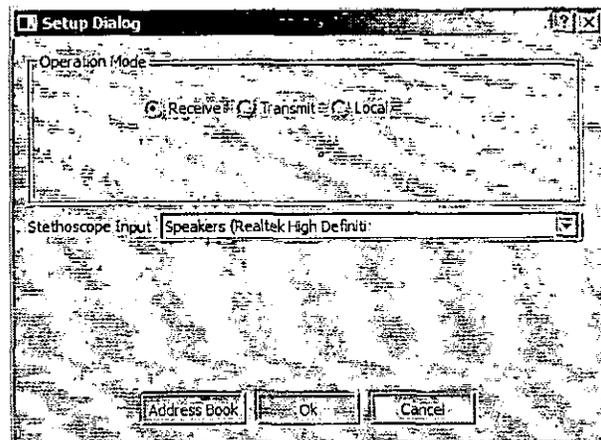


Figure 10: Setup Screen – Receive Mode

The audio output port is automatically detected and shown. Also a button for the IP Address Book is presented.

C. IP Address Book

Since the receive end initiates all connections, it is necessary to know the IP address of the transmit end. Multiple transmit end locations are handled through the IP Address Book, which allows the creation and storing of a list of IP addresses where the transmit end PCP/PC Stethoscope stations are located. Open the IP Address Book by clicking on the IP Address Book button.

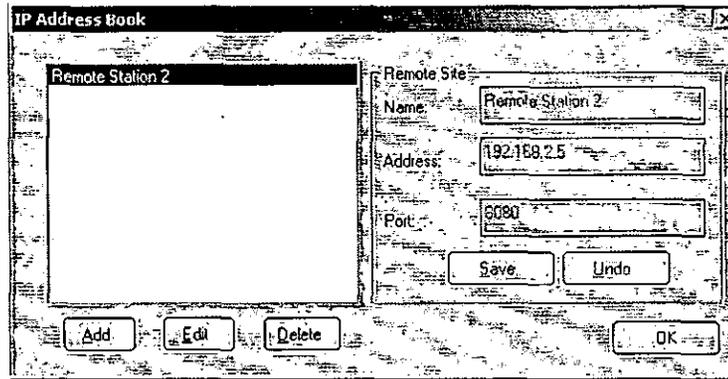


Figure 11: IP Address Book

To add a new location, click on Add, then enter the user friendly name you want to give for that location, the IP address and the port number. You can then either Save the address information or Undo it. Figure 11 shows Remote Station 2 in the IP Address Book.

An IP address can be edited by clicking on the name in the box on the left to highlight it, then clicking on Edit. Changes can be saved with Save or cancelled with Undo.

IV. Operation Mode

The sSOIP program has three modes of operation:

- Transmit mode is used at the patient end.
- Receive mode is used at the clinician end.
- Local is used for playing back recorded stethoscope files.

A. Transmit Mode

To set up for Transmit mode, from the Main screen, click on Setup. When the Setup window opens as shown in Figure 9, click on the Transmit radio button to enable Transmit Mode, then click on OK to get back to the Main screen as shown in Figure 8.

When the Status is Ready to Transmit, then the sSOIP program is waiting for a connection to be made from the far-end station, which would be in Receive mode. Once an IP connection is established, the Status will change to Transmitting Data.

B. Receive Mode

To set up for Receive mode, from the Main screen, click on Setup, then select the Receive radio button to display the screen shown in Figure 10. Then click the OK button to get to the Received end main screen as shown in Figure 12.

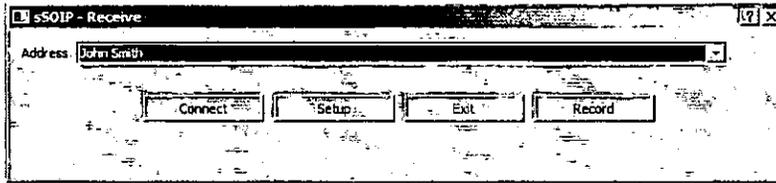


Figure 12: Main Screen in Receive Mode

In Receive mode, the program needs to know the IP address of the transmit end to which it wants to connect. The operator can create and access a list of IP addresses where the transmit end TR-x units are located. This is done in the Address Book as described in Section III C above.

Connections are initiated from the receive end where the consulting clinician is located. With sSOIP in Receive mode, select a patient (transmit end) location by clicking on the down arrow in the Address list box, then selecting the desired patient location. (If the desired patient location is not on the list, then go back to the Setup screen and use the IP Address Book to enter the information for the desired patient.) After selecting the patient location, click on the Connect button to initiate the IP connection. Once the connection is made, the Status will change from Ready to Receiving Data as shown in Figure 13. If a connection cannot be made, the connection attempt will time out and Status will return to Ready.

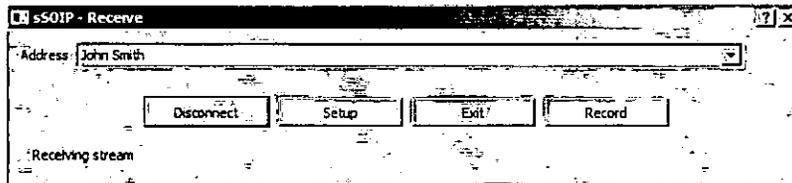


Figure 13: Main Screen while Receiving Data

C. Recording Stethoscope Sounds

With sSOIP receiving stethoscope data, click on Record to start recording. While recording the Record button changes to Stop Recording.

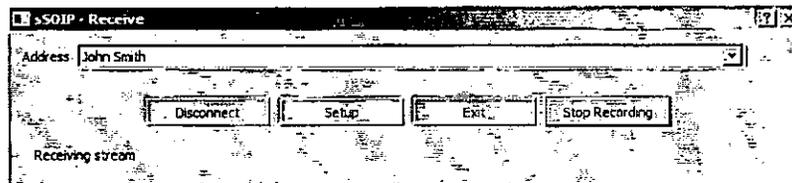


Figure 14: Main Screen while Recording Data

To stop recording, Click on the Stop Recording button. A new screen will pop up to allow the recording to be saved. Figure 15 shows the screen with Play Time and Creation Date entered automatically by sSOIP.

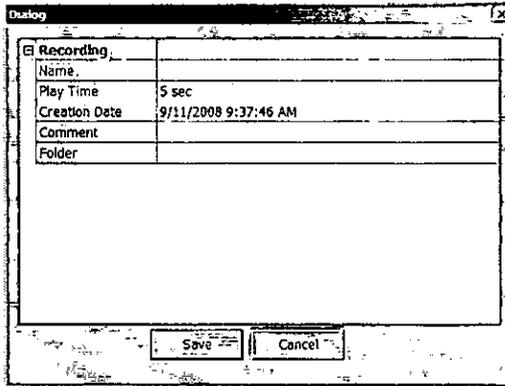


Figure 15: Adding a New Stethoscope File

Click on the fields next to Name and Comment to enter the patient’s name and a comment, respectively. Click on the field next to Folder, then click on the down arrow to display the list of folders available. Figure 16 shows an example where “John Smith” was entered in the Name field and “Heart sounds after walking up stairs” was entered in the Comment field. In his example, a folder for John Smith was already created (see Local Mode below).

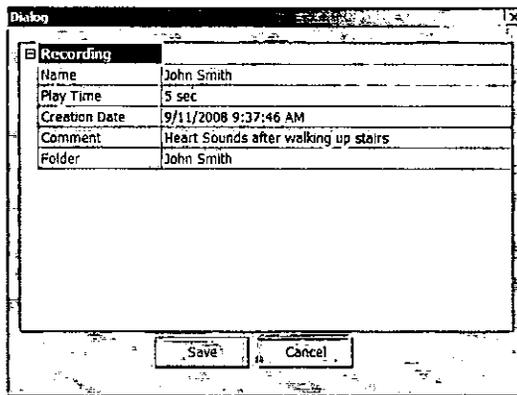


Figure 16: Example of New Stethoscope File

Clicking on the Save button saves the file, closes the window and goes back to the Main window in Receive mode. When the stethoscope session is over, click on Disconnect to terminate the connection.

D. Local Mode

The sSOIP program provides the capability for recording stethoscope sound data into special files, saving those files and playing them back. While recording may be done in either Receive or Local mode, playback can only be performed while in Local mode. All file management functions are done in Local Mode.

To get into Local mode, start from the Main screen and click on Setup to bring up the Setup screen shown in Figure 17.

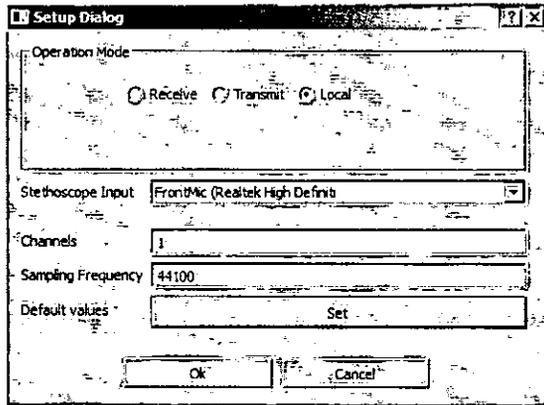


Figure 17: Setup Screen Selecting Local Mode

Click the radio button for Local then click on the OK button. That will go back to the Main screen in Local mode as shown in Figure 18.

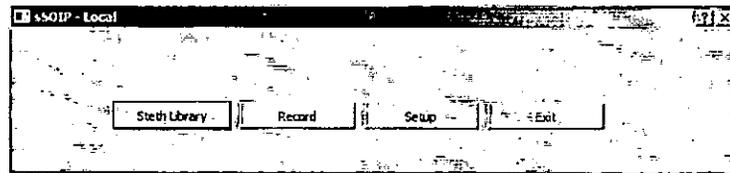


Figure 18: Main Screen in Local Mode

To access the file management functions or to playback a file, click on Steth Library. Figure 19 shows a blank Steth Files window.

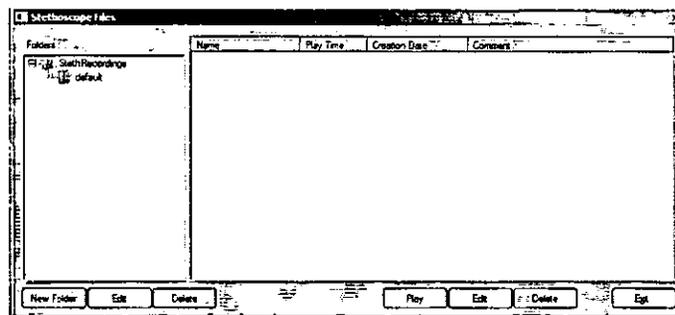


Figure 19: Steth Files Window

To add a new folder for a patient, click on the New Folder button, then next to Name and Description fields enter appropriate information on that patient. Figure 20 shows an example where a new Folder for John Smith was created.

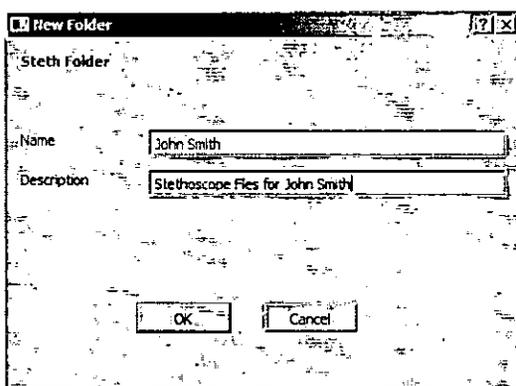


Figure 20: Create New Patient Folder

Click on OK to finish the creation of the folder. A folder can be edited by clicking on the folder to highlight it, then clicking on Edit. That brings up the Steth Folder window again. Make the desired changes then click on OK. To delete a folder, click on the folder to highlight it, then click on Delete. A window will pop up to confirm that you want to delete the folder. If you are sure, click on Yes, otherwise click on No.

In the previous section, an example stethoscope sound file was saved for John Smith. The files for this patient example can be accessed by clicking on the folder name on the right side of the Steth Files window. In this example, the window in Figure 21 would show.

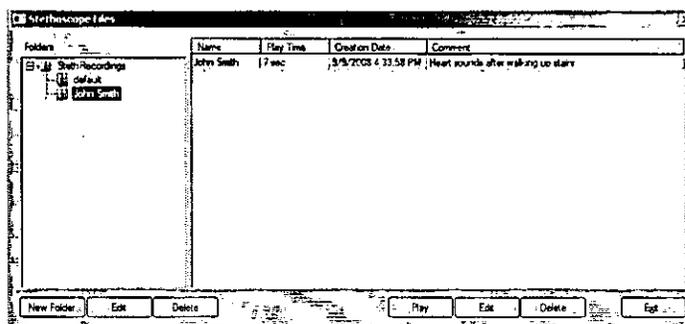


Figure 21: Steth Files Screen Showing Files

To play back a saved file, click on the desired file to highlight it, then click on Play. The stethoscope sound file will playback through the attached Headset. Clicking on Stop stops the playback.

The information for a stethoscope file can be edited by selecting the file to highlight it, then clicking on the Edit button. Make the desired changes to either the Name or Comment field, then click on Save. A file can be deleted by selecting the file to highlight it, then clicking on the Delete button. A window will pop up to confirm that you want to delete the file. If you are sure, click on Yes, otherwise click on No.

E. Auscultation Session Connection Overview

The transmit end locations (where the patients will be) should be in Transmit Mode with their Main screens open and status at Ready to Transmit.

At the receive end, the clinician can choose which patient location to connect to by using the Address drop down list box. Clicking on the down arrow pulls down the list box showing all the patient location choices previously entered. The clinician selects one by clicking on it. That brings back the Main screen with that location showing in the Location field.

The clinician then clicks on Connect to complete the connection to the PCP/PC Stethoscope at that location. The Connect button changes to Disconnect. To terminate the auscultation session the clinician clicks on the Disconnect button.

To close the sSOIP program, click on Exit.

V. Cleaning, Preventive Inspection, Maintenance and Calibration

The PCP/PC Stethoscope requires no preventive inspection, no preventive or routine maintenance, and it does not have to be calibrated.

The PCP/PC Stethoscope is not a sterile device and does not require sterilization or disinfection. It can be cleaned, as required, by wiping with a moist cloth, alcohol or a sanitizing towelette.

VI. Trouble Shooting

Failure to operate: If an IP connection cannot be established to the transmit end station, service personnel from the company that provided the PCP/PC should check the following:

- Insure the transmit end sSOIP application is open and ready to transmit.
- Insure the transmit end PC is connected to the Internet and can access the Internet.
- Insure the assigned IP address of the transmit end is properly entered into the received end sSOIP application.
- Insure the receive end PC is connected to the Internet and can access the Internet.
- Check for a failed PCP/PC Chest Piece by substituting it with a replacement PCP/PC Chest Piece. (Note that the date of manufacture of the PCP/PC Chest Piece is a two hexadecimal (0, 1, 2, 3, 4, 5, 6, 7, 8, 9, A, B, C, D, E, and F) character code where the first character is the number of the month and the second character is the last two digits of the year. For example, August 2010 is 8A.)
- Check for an improperly operating sSOIP by reloading sSOIP.

If taking the above steps does not remedy the problem, contact your provider of the PCP/PC Stethoscope for assistance and product resolution.

Interference: This product is classified as medical electronic equipment and thus needs special precautions regarding EMC and needs to be installed in accordance with the instructions in this Manual. Portable and mobile RF communications equipment can affect medical electrical equipment.

If interference from other equipment is heard from the PCP/PC during a stethoscope session, the problem may be resolved by relocating other equipment so that it is farther from the PCP/PC. The

provider of the PCP/PC Stethoscope will assist in resolving any interference problems. If the interference problems cannot be resolved and the interference does not permit auscultation sounds from being heard, then the PCP/PC should not be used in that location.



COVER SHEET MEMORANDUM

From: Reviewer Name Sabrina Reilly
Subject: 510(k) Number K102893
To: The Record

TH

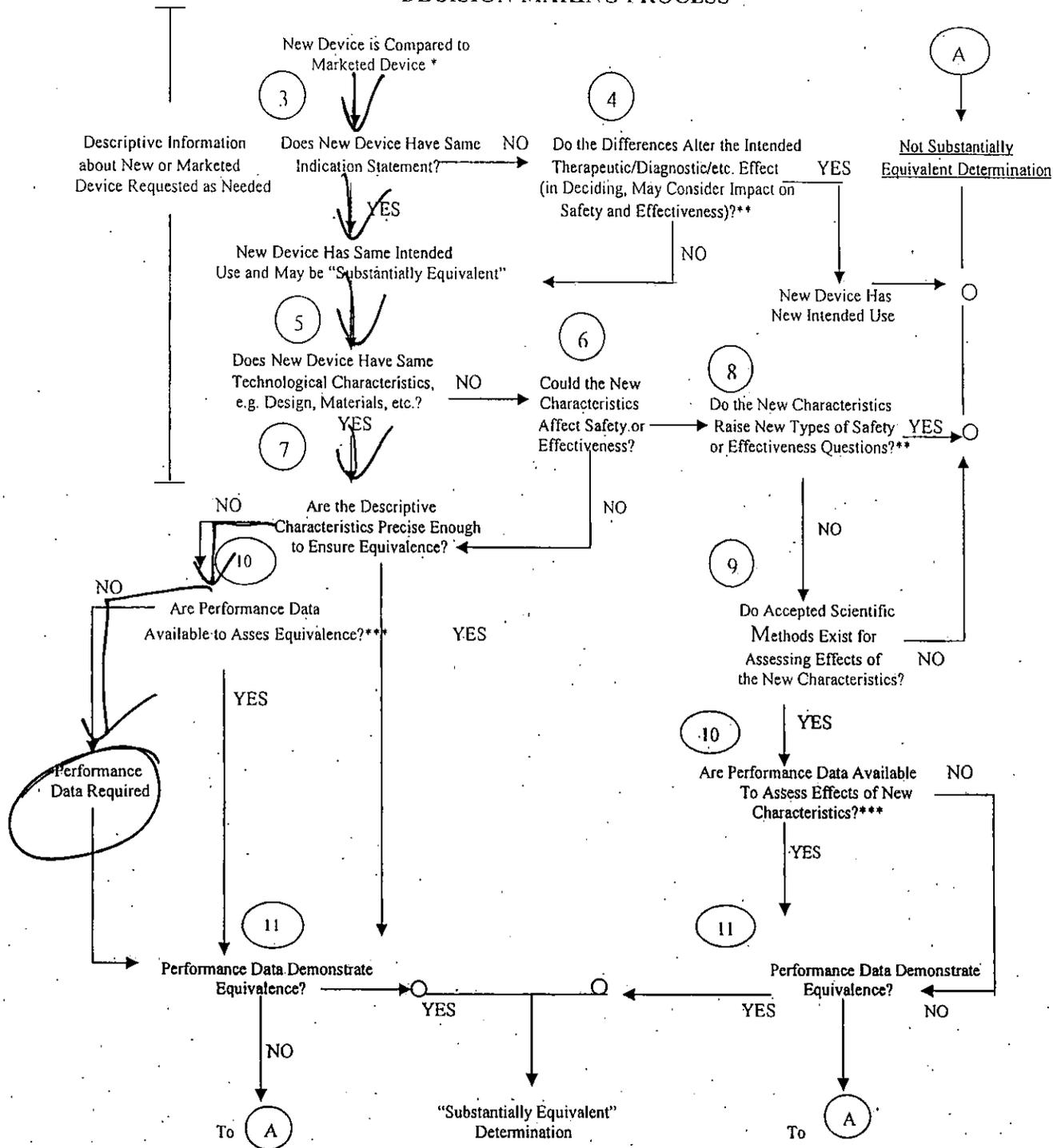
TH on 12/21

Please list CTS decision code

- 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	X	
510(k) Summary /510(k) Statement	Attach Summary	X	
Truthful and Accurate Statement.	Must be present for a Final Decision	X	
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
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)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		X	
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.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age <=21			X
Neonate/Newborn (Birth to 28 days)			X
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.)			

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.



Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification 510(k) Review
Traditional

K102893

Date: December 20, 2010
To: The Record
From: Sabina Reilly

Office: ODE
Division/Branch: DCD/CEMB

510(k) Holder: RNK Products, Inc.
4195 US Hwy 1
Suite 101
Rockledge, FL 32955

Device Name: RNK PCP/PC Telephonic Stethoscope
Contact: Charles R. Abbruscato
Phone: 321-626-7717
Fax: 321-305-5983
Email: abbruscato@rnkproducts.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the RNK PCP/PC Telephonic Stethoscope into interstate commerce. The sponsor has indicated that the device has the following classification:

21 CFR 870.1875 - DQD- Class II - Stethoscope

The sponsor has sited the following predicate device:

K034046: RNK TR-1 Telephonic Stethoscope
K072026: RNK Precordial Stethoscope

II. Administrative Requirements

Table with 4 columns: Requirement, Yes, No, N/A. Rows include: Indications for Use page (Indicate if: Prescription or OTC) - Prescription, Truthful and Accuracy Statement, 510(k) Summary or Statement, Standards Form - See attachment 8.

III. Device Description

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

The device is a telephonic stethoscope consisting of a chest piece assembly that plugs into the microphone port of a generic PC and a software package called Streaming Stethoscope Over IP (sSOIP) running on the PC. The signal from the PCP/PC chest piece is amplified and digitized at high audio resolution by the PC's audio circuitry. The sSOIP program creates an audio stream in IP communications format and sets up an IP connection to another PC on the IP network. That receiving end PC accepts the streaming audio and feeds it to its audio circuitry where it is converted back to analog, amplified and presented to the Headset port. The audio stethoscope sounds can be heard at the headset output port of the receive end PC.

IV. Indications for Use

From the sponsor:

"The RNK PCP/PC Stethoscope is intended for use as a remote monitoring device, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations."

V. Predicate Device Comparison/Substantial Equivalence Discussion

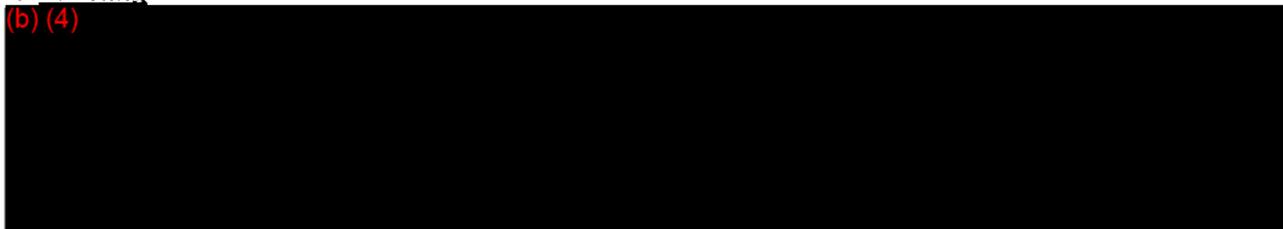
The sponsor cited the following predicate devices:

510(k) number Device name Manufacturer	Subject Device RNK PCP/PC Stethoscope RNK Products, Inc.	K034046 RNK TR-1 Telephonic Stethoscope RNK Products, Inc.	K072026 RNK Precordial Stethoscope RNK Products, Inc.
Indications for Use	Remote monitoring device, whereby a clinician at one location can listen to the auscultation sounds of a patient at a different location with the signal carried over a data communication channel between the two locations.	Remote monitoring device, whereby a clinician at one location can listen to the auscultation sounds of a patient at a different location with the signal carried over a data communication channel between the two locations. SAME	Detecting and amplifying heart, lung and other body sounds.
Design			
Components	<ul style="list-style-type: none"> • Detachable Chest Piece • Detachable headset • Chest Piece and headset connect to generic PC • Audio handling control and communications 	<ul style="list-style-type: none"> • Detachable Chest Piece • Detachable headset • Electronic module- 4 ½"L x 2 ½"W x 1" 	<ul style="list-style-type: none"> • Detachable Chest Piece • Detachable headset • Electronic module- 3.9"L x 1.9"W x

	software on PC	H Same Module can be used for Transmitting or for Receiving	0.9" H
Technical Characteristics of Chest Piece	PCP/PC chest piece converts body auscultation signals to analog signal	CP-1 chest piece converts body auscultation signals to analog signal	Piezo chest piece converts body auscultation signals to analog signal
Technical Characteristics- Audio/Digital processing	Analog signal from Chest Piece amplified in PC Analog signal is converted and encoded to a digital signal, then put into IP data format in the PC At the receive end, PC accepts IP data stream, decodes the digital signal converting it back to analog then amplifies the analog signal and presents it to the headset port	Analog signal from Chest Piece amplified in TR-1 Module Analog signal is converted to digital signal, encodes signal and puts into asynchronous format. At the receive end, decodes digital signal, converts it back to analog then amplifies it to headset port.	Analog signal from Chest Piece amplified in Amplifier Module and presented at Headset port.
Technical Characteristic- Data Communications:	PC software puts signal into IP format. Destination IP addresses are entered into PC. PC transmits IP data to network. At receive end, PC accepts IP data stream.	TR-1 Module sends signal in asynchronous data protocol over RS232 Interface. Communications transport handled in separate networking devices.	No data communications
Power Source	2-5 vdc provided from the PC. Safety isolation is provided within the PCP/PC Chest Pieced.	Ac to dc wall mount Power Adapter converts 120 vac to 9-12 vdc. Internal regulator converts that to 5vdc to power the circuitry.	Battery powered.
Auscultation Bandwidth	20 Hz to 2,000 Hz	20 Hz to 700 Hz	20 Hz to 2,000 Hz
Controls	No controls on PCP/PC Chest Piece. Volume control to Headset using PC audio controls	Volume control to headset on TR-1. D/B Switch to select bandwidth to headset.	No controls on Precordial chest piece or amplifier module.

VI. Labeling

(b) (4)



VII. Sterilization/Shelf Life/Reuse

(b)(4)Trade Secret Process-Testing

1. Sterilant:	YES	NO
a. Sterilization method description (e.g., Steam (moist heat), EO, Radiation):	N/A	
b. Dose , for radiation (e.g., 25 – 50 kGy):	N/A	
Sterilant residuals remaining on the device:	N/A	
2. A description of the Validation Method for the sterilization cycle (not data):	N/A	
3. Sterility assurance level (SAL):	N/A	
4. Is it labeled "Pyrogen Free"? If so, a description of the method: (e.g., LAL (<i>Limulus</i> Amebocyte Lysate test))	N/A N/A	
5. A description of the packaging (not including package integrity test data):	N/A	

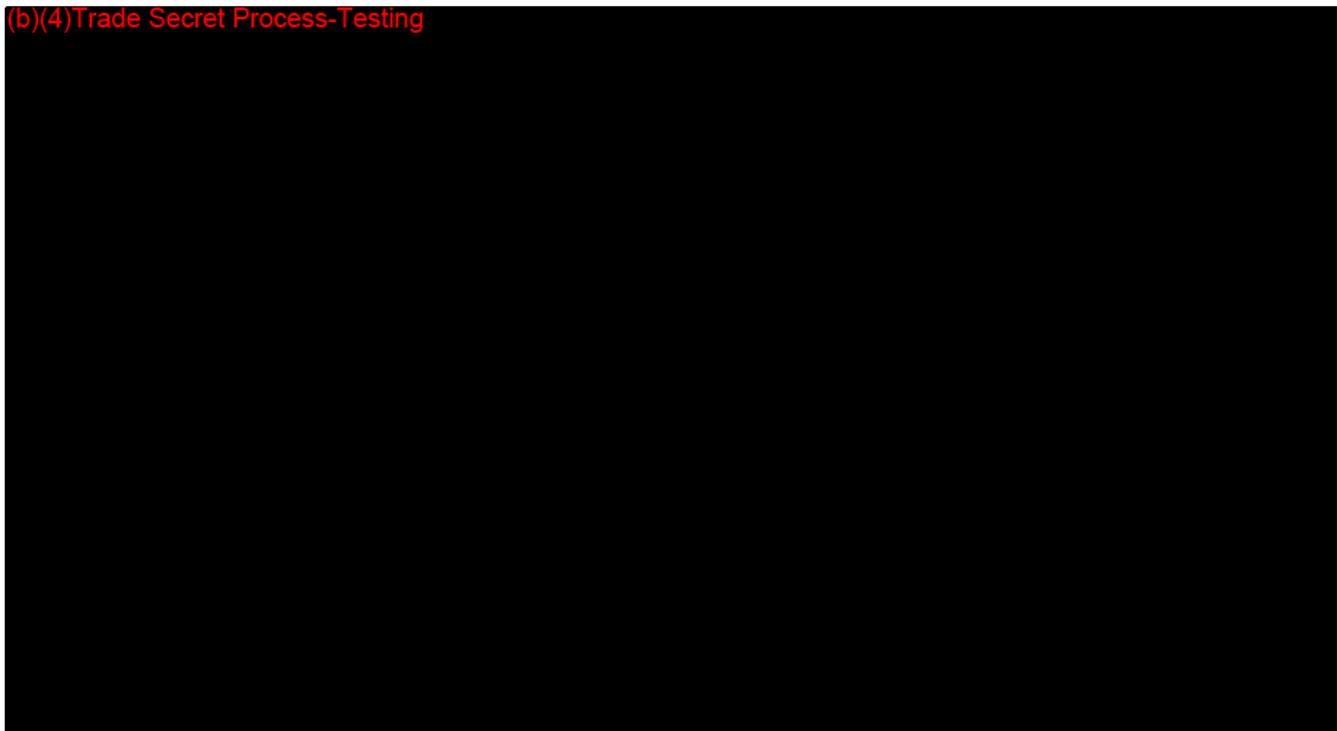
VIII. Biocompatibility

(b)(4)Trade Secret Process-Testing

IX. Software

(b)(4)Trade Secret Process-Testing

(b)(4)Trade Secret Process-Testing

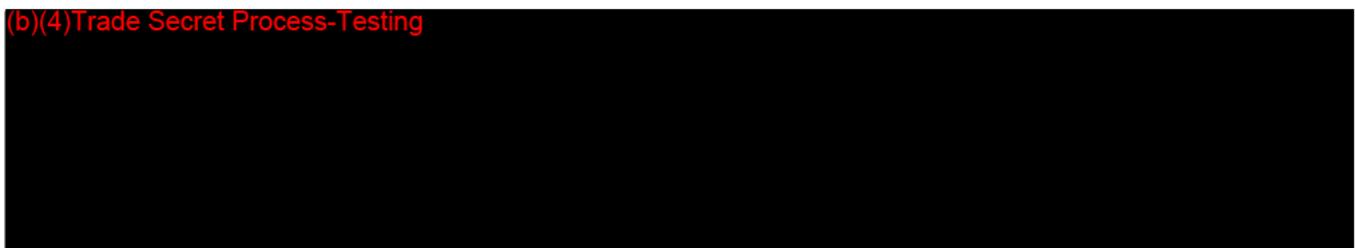


Performance Testing – Bench

The firm provided a certification of compliance with standards for safety testing of their device to indicate that the device complies with the following standards:

- IEC60601-1:2003/2nd Edition Medical Electrical Equipment, Part 1: General Requirements for Safety.
- IEC60601-1-2:2007/03 Immunity Requirements for Medical Electrical Equipment, Part 1: General Requirements for Safety, Part 2: Collateral standard, Electromagnetic Compatibility Requirements & Tests
- EN 61000-4-2 Electrostatic discharge
- EN 61000-4-3 Radiated electromagnetic field requirements
- EN 61000-4-4 Electrical fast transient burst requirements
- EN 61000-4-6 Conducted immunity
- EN 61000-4-8 Power frequency magnetic field requirements

(b)(4)Trade Secret Process-Testing



Performance Testing – Animal

N/A - Animal testing was not performed and was not necessary.

Performance Testing – Clinical

N/A - Clinical testing was not performed and was not necessary.

Substantial Equivalence Flow Chart

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

Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCART%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.

5. How are the characteristics not descriptive enough? The sponsor has not provided the appropriate level of software documentation for their device.

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	✓		
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name	✓		
3	An identification of the legally marketed device(s) to which the submitter claims equivalence.	✓		
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)	✓		
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.			
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.	✓		
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			✓
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.)			✓
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.			✓

Contact History

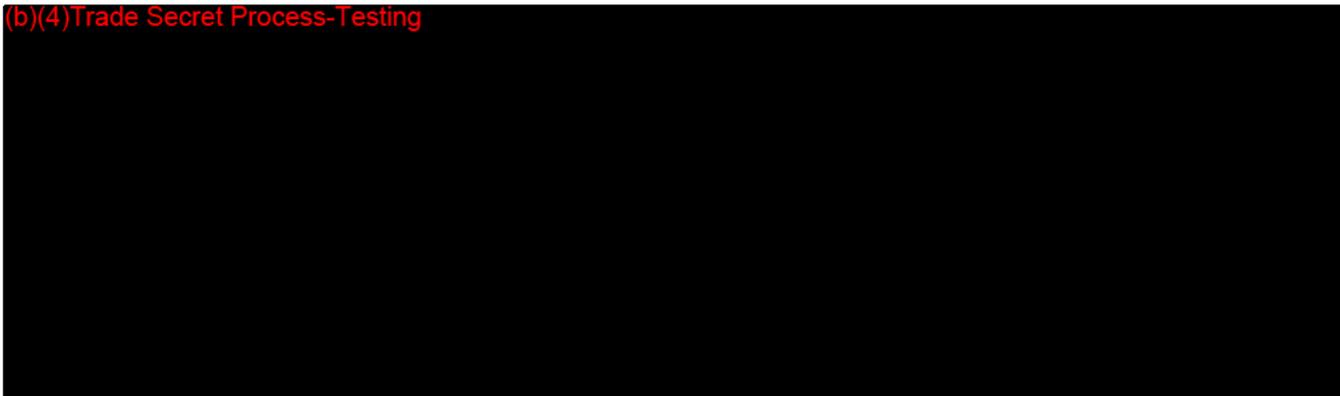
The sponsor was sent a list of deficiencies on Dec 21, 2010 and the file was placed on 'Telephone Hold'.

Additional Discussion

I have attached numerous emails to this file detailing the reviewers inability to access Image 2000 in order to complete this review. As the system was not functioning for over a month time period and the reviewer could not access the system to confirm the predicate device information, the MDUFMA time lines may not be met for this file.

Deficiencies

(b)(4)Trade Secret Process-Testing



Labeling

(b)(4) Trade Secret Process-Testing

Software

(b)(4) Trade Secret Process-Testing

Biocompatibility

(b)(4) Trade Secret Process-Testing

Recommendation

I recommend that the proposed device be placed on telephone hold, via email, requesting the **additional information** described in the deficiencies listed above. I have attached that email to this review memo.

Sabrina Pail
Reviewer

12/21/10
Date

W. M. F. For
Branch Chief
F. Aguel

12/21/2010
Date

Reilly, Sabina

From: Reilly, Sabina
Sent: Tuesday, December 21, 2010 4:11 PM
To: 'abbruscato@mkproducts.com'
Subject: K102893 - RNK PCP/PC Stethoscope

EMAIL REQUEST FOR ADDITIONAL INFORMATION

FROM:
Sabina Reilly
Reviewer
Office of Device Evaluation
Center for Devices and Radiological Health
FDA
10903 New Hampshire Ave
WO66, Rm 1252
Silver Spring, MD 20993
(301) 796-6324
Email: sabina.reilly@fda.hhs.gov

TO:
RNK Products, Inc.
C/O Charles R. Abbruscato
4195 US Hwy 1
Suite 101
Rockledge, FL 32955
321-626-7717(tel)
321-305-5983(fax)

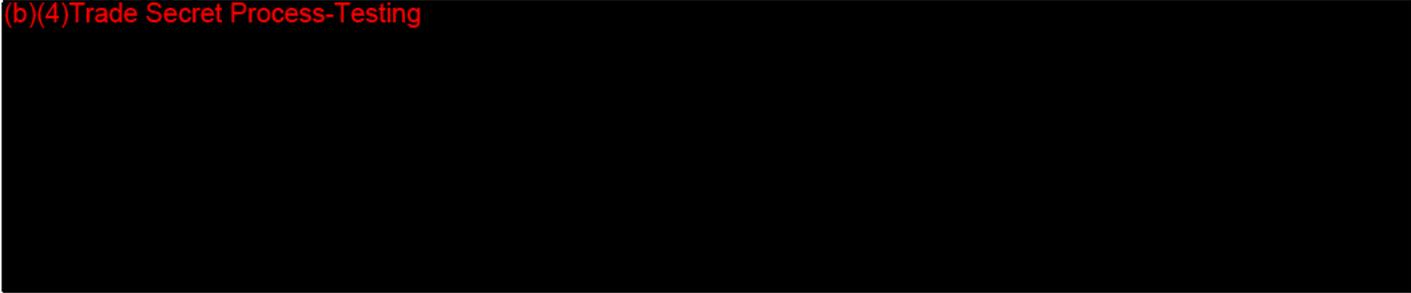
RE: K102893
RNK PCP/PC Stethoscope

December 21, 2010

Dear Mr. Abbruscato,
We have reviewed your Section 510(k) notification of intent to market the device referenced above. To complete the review of your submission, we require a response to the following deficiencies:

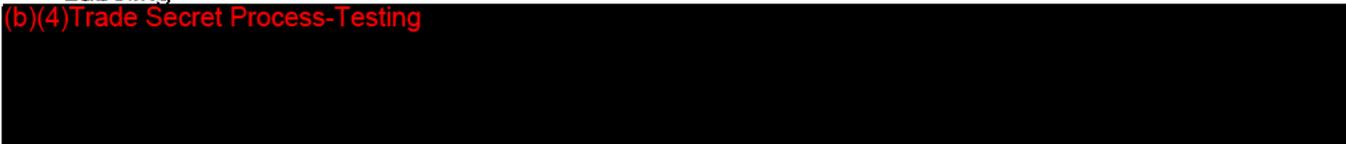
Regulatory

(b)(4)Trade Secret Process-Testing



Labeling

(b)(4)Trade Secret Process-Testing



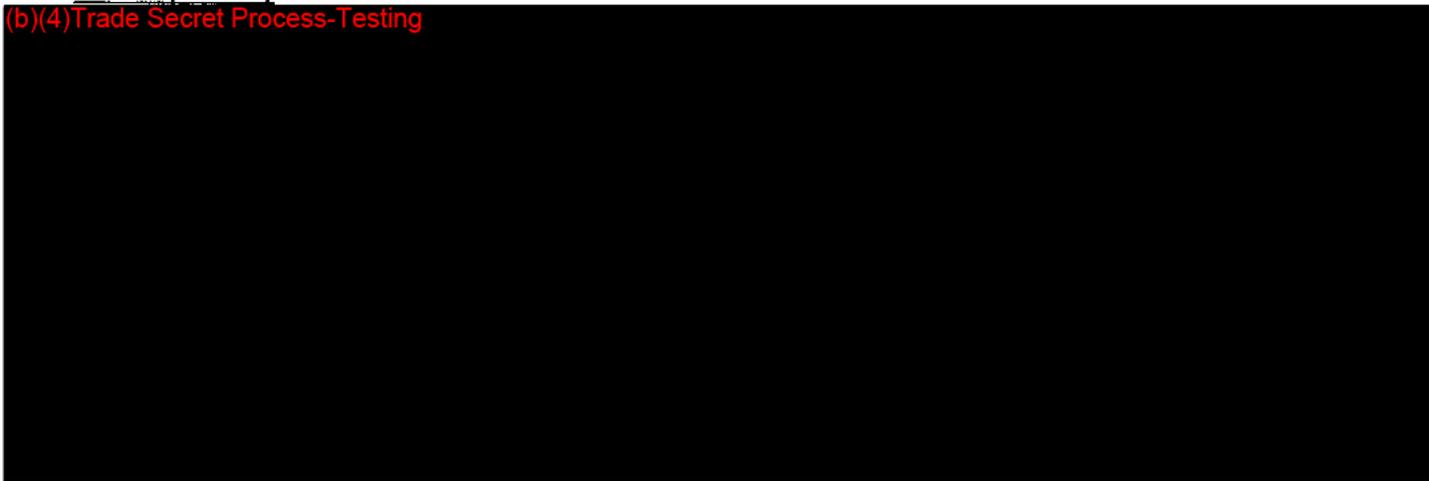
Software

(b)(4)Trade Secret Process-Testing

A large black rectangular redaction box covers the majority of the page content under the 'Software' heading.

Biocompatibility

(b)(4)Trade Secret Process-Testing

A large black rectangular redaction box covers the majority of the page content under the 'Biocompatibility' heading.

Your file will be placed on administrative hold until we receive the requested information. Please respond by email (sabina.reilly@fda.hhs.gov) **followed by a hardcopy** to the Document Mail Center. Please reference the 510(k) number on the cover letter to any correspondence submitted to the Agency. Please contact me if you have any questions.

Best regards,

Sabina Reilly

Biomedical Engineer
Center for Devices & Radiological Health
Division of Cardiovascular Devices
10903 New Hampshire Ave
WO66, Rm 1252
Silver Spring, MD 20993
(301) 796-6324

The opinions expressed in this message represent the best judgment of the sender and do not necessarily represent the formal position of the FDA under 21 CFR §10.85

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify Sabina Reilly by return e-mail or telephone at 301-796-6324.

Reilly, Sabina

From: Office of Information Management Flash
Sent: Wednesday, December 01, 2010 4:21 PM
To: FDA-Wide
Cc: IT Call Center
Subject: White Oak Data Center Remediation

Importance: High

**Office of Information Management
White Oak Data Center Remediation
December 1, 2010**

The White Oak Data Center (WODC) has been experiencing instability and performance issues over the past several weeks. A root cause analysis has been completed and the cause has been isolated to vendor implementation errors in the WODC Storage Area Network environment. In an effort to expedite stabilization in the WODC, complete the necessary remediation, and minimize risks, upcoming migrations to the WODC will be placed on hold until remediation work has been completed and environmental stability is proven. This work is expected to take several weeks to complete, with the WODC environment becoming more stable as the remediation activities progress.

The Office of Information Management (OIM) will continue to provide updates regarding the status of this remediation plan.

Planned migrations to the FDA's primary production application facility, the Contractor Hosted Data Center (CHDC), are unaffected by this work.

Thank you for your continued patience during this migration effort.

Stephen Veneruso, Acting Director
Division of Infrastructure, OIM

For more information contact:

Employee Resource & Information Center (ERIC)
301.827.ERIC (3742)
866.807.ERIC (3742)
TTY 301.480.0434

<http://inside.fda.gov>

Reilly, Sabina

From: Office of Information Management Flash
Sent: Wednesday, November 24, 2010 5:13 PM
To: FDA-Wide
Subject: White Oak Data Center Outage Update

Office of Information Management
White Oak Data Center Outage Update
November 24, 2010

The White Oak Data Center is experiencing intermittent database connectivity issues. Testing for a solution is underway in the development environment and if successful, will be applied to production, development and test systems as soon as possible. An update will be provided once the solution timeframe has been determined.

Thank you for your patience as we work to resolve this issue.

Lori Davis, CIO
OIM

For more information contact:

Employee Resource & Information Center (ERIC)

301.827.ERIC (3742)

866.807.ERIC (3742)

TTY 301.480.0434

<http://inside.fda.gov>

DO NOT RESPOND TO THIS EMAIL, IT IS A SEND-ONLY ACCOUNT

Reilly, Sabina

From: CDRH Electronic Submissions
Sent: Wednesday, November 24, 2010 10:15 AM
To: Reilly, Sabina
Cc: Moy, Timothy J*; CDRH Electronic Submissions
Subject: IM1257097 [Severity 4 / Priority 4] - Group Assignment of ERIC Service Request

Hi Sabina,

Many users are experiencing a problem when they are logging into Image2000, <http://image2000.fda.gov/>, and i2kPlus, <http://i2kplus.fda.gov>. However, a few users have had success logging onto i2kplus when they are not able to access Image 2000. We are currently working on resolving this issue as quickly as possible.

Please let us know if you have any questions.

Regards,

Albert Cheng
CDRH Electronic Submissions Support
cdresub@fda.hhs.gov

From: Office of Information Management Flash
Sent: Tuesday, November 23, 2010 1:57 PM
To: FDA-CDRH-wide
Subject: CDRH Image 2000 unavailable to some users

Office of Information Management

CDRH Image 2000 unavailable to some users

November 23, 2010

It has been reported that the CDRH Image2000 is unavailable to some users. Technicians have been alerted and are working to resolve the problem as quickly as possible. Please use Image 2000 +, this application utilizes the same document repository as Image 2000. <http://i2kplus.fda.gov>.

We regret any inconvenience this outage may cause.

Jim Shugars, Acting Director
Division of Systems, OIM

For more information contact:
Employee Resource & Information Center (ERIC)
301.827.ERIC (3742)
866.807.ERIC (3742)
TTY 301.480.0434

<http://inside.fda.gov>

DO NOT RESPOND TO THIS EMAIL, IT IS A SEND-ONLY ACCOUNT.

ServiceCenter Operator: DMINOR

The ERIC has referred Incident Record IM1257097 [Severity 4/ Priority 4] to the Assignment Group: CDRH-IMAGE&IMAGE2000.

Assigned on: 11/24/10 08:31:31
Customer: REILLY, SABINA
Center: CDRH

Location: WHITE OAK BUILDING 66

Room: 1252

Phone: 3017966324

Extension: 149

The customer has reported the following issue:

User states that she is unable to log into image 2000. error cannot verify password combination. User is working from home 240-447-1764

Please log into ServiceCenter or visit <http://fdaress17:8080/sc/frames.do> to view, update, and resolve this incident record.

Best Regards,

The Employee Resource and Information Center

PLEASE DO NOT REPLY TO THIS SYSTEM GENERATED EMAIL(message320)

Reilly, Sabina

From: Zimmerman, Barbara C.
Sent: Monday, November 29, 2010 6:02 PM
To: CDRH-ODE-Group; CDRH-OIVD-Group
Subject: Image 2000 plus

FYI

From: Chu, Jonathan*
Sent: Monday, November 29, 2010 5:13 PM
To: Zimmerman, Barbara C.
Subject: RE: Maintenance of Production Documentum Servers at CHDC

Hi Barbara,

Please see the email from Swati Kulkarni (FDA Documentum team lead) below. The search being down is directly related to the Documentum migration to the ICT-21 data center a couple weeks back. The Documentum team is estimating that the reindexing of the document in Image 2000+ will be completed by the end of the week.

When this is completed, the Image 2000+ full-text search functionality will be back up and running.

This was a known issue that was communicated via the outage message below going into the migration since the migration to new hardware required the reindexing. However, it looks like it's taking longer than anticipated.

Jonathan

From: Kulkarni, Swati P.
Sent: Monday, November 29, 2010 4:33 PM
To: Chu, Jonathan*; Crasta, Belinda*; Humphrey, Kerry*
Cc: Broderick, Brianna; Clayton, Jeff; Williams, Angela L; Cook, Nicholas*; 'Vittetoe, Tom'; Pant, Vikram*
Subject: Documentum Search Capabilities Update - CDRH/CVM/CTP
Importance: High

Hi,

We had estimated to get Documentum indexing completed by today 11/29. But, it is progressing slower than expected. Documentum team has added resources to speed up the indexing and the team is monitoring the progress closely. As of now we are hoping to have indexing done by end of the week. We will keep you posted about its progress.

Please reach out to your centers respective business users.

Thanks

Swati Kulkarni

*eContent Project Manager, COTS Applications Team
OC/OIM/DOS
Food and Drug Administration
2094 Gaither Road, Room 349
Rockville, MD 20850
Office: 301-796-7825
Email: Swati.Kulkarni@fda.hhs.gov*

Office of Information Management

November 19th – November 21st Multiple System Outages Due to Migration to the New FDA

Data Center

November 17, 2010

On Friday, November 19th starting at 5PM EDT, the following systems will not be available due to migration tasks being performed to move systems operations to the new FDA datacenter. The data center migration is a project to move all applications, file shares, print servers and data to new FDA data centers in White Oak and Ashburn, VA.

CDRH

Documentum for eReference , Postmarket 522, RadHealth Assembler, eService, i2K+, Closeout, iReview, eLoader, Image2000

CTP

Documentum for CTP Loader, CTP Image Service

CVM

Documentum for CDMS

Newly migrated systems will be available starting Monday, November 21st, at 6AM EDT. However, Documentum search capability will not be available until all indexing is completed at approximately 8:00 AM on Monday November 29th. If any issues arise during the migration process, additional outages may be necessary during the week in order to complete the migration process. If needed, work would be performed between 6PM EDT and 6AM EDT. Notifications will be sent to impacted users if weeknight migration work is required.

Thank you for your continued patience during this migration effort.

Jim Shugars, Acting Director
Division of Systems, OIM

For more information contact:
Employee Resource & Information Center (ERIC)
301.827.ERIC (3742)
866.807.ERIC (3742)
TTY 301.480.0434

<http://inside.fda.gov>

DO NOT RESPOND TO THIS EMAIL, IT IS A SEND-ONLY ACCOUNT.

From: Zimmerman, Barbara C.
Sent: Monday, November 29, 2010 5:03 PM
To: Chu, Jonathan*
Subject: FW: Maintenance of Production Documentum Servers at CHDC

Hi Jonathan,
A few people have indicated to me that the search engine in Image 2000 plus is not working. They can pull up files by number but can not do any key word searches. Do you know when this will be fixed?

Barb

From: Office of Information Management News
Sent: Monday, November 29, 2010 5:00 PM
To: FDA-CDRH-wide; FDA-CVM-wide; FDA-CTP-Wide; OIM-DS
Subject: Maintenance of Production Documentum Servers at CHDC

**Office of Information Management
Maintenance of Production Documentum Servers at CHDC
November 29, 2010**

For 1 hour on Thursday, December 2, 2010 from 10:00 PM through 11:00 PM Eastern Standard Time, HP will be applying critical patches to the CHDC Documentum Production servers. This will impact CDRH, CVM and CTP Documentum applications.

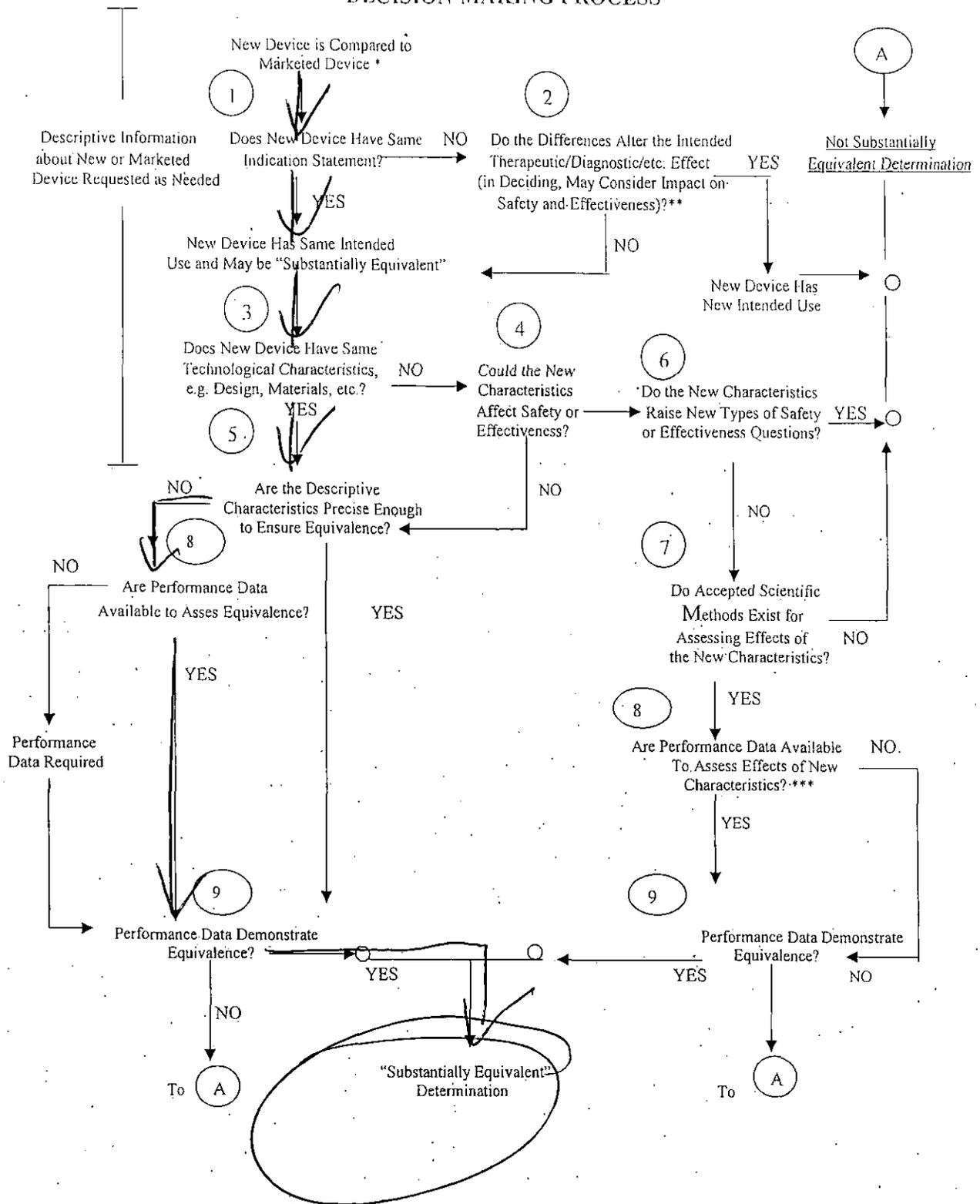
We apologize for any inconvenience that this may cause.

Stephen Veneruso, Director (Acting)
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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.