Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(smw)
FOLDER:	K121326 - 816 pages
COMPANY:	LANTOS TECHNOLOGIES (LANTTECH)
PRODUCT:	OTOSCOPE (ERA)
SUMMARY:	Product: LANTOS 3D EAR SCANNER
DATE REQUESTED:	Oct 6, 2015
DATE PRINTED:	Oct 6, 2015
Note:	Printed

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

K 121326

LANTOS TECHNOLOGIES
101 Main Street, Suite 1770
Cambridge, MA 02142
+1.617.500.9800
www.lantostechnologies.com

6. 510K Summary

JAN 25 2013

Applicant:

Lantos Technologies
101 Main Street, Suite 1770
Cambridge, MA 02142, USA
Tel: 1-617-500-9800

Date Prepared: January 17, 2013

Contact: Lora Allemeier

Device Identification:

Trade Name – **Lantos 3D Ear Scanner**
Common Name – otoscope
Classification Name – otoscope (21 CFR 874.4770, Product Code ERA)
hearing aid, accessory (21 CFR 874.3300, Product Code ESD)

510(k) Numbers and Product Codes of equivalent devices:

Welch Allyn Video Otoscope (Skaneateles Falls, NY)

Welch Allyn Otoscope; K943916 – SE 08/25/1994

Code: ERA; 874.7440

Device Description

The device consists of a hand held scanner, a single patient use disposable with a silicone conforming membrane, which when in use is filled with an absorbing medium, and a laptop computer. The hand held scanner, when not in use, is placed in a docking stand.

The hand held scanner is tethered to the docking stand with a custom cable. The laptop computer is mounted on the docking stand. The hand held scanner contains LED illumination, optics, a camera, a motor to move the probe tip, and a motor-driven reservoir.

User Interface (UI) software screens are displayed on the laptop and the user interacts with the device via the laptop keyboard and touchpad, and control buttons on the hand held scanner, as guided by the UI screens. Image data from the patient is stored in the laptop, and may be transmitted by the user via a wireless connection. No patient identifiable data is stored in the Lantos device.

A single use disposable, which includes the conforming membrane, is placed over the hand held scanner probe tip, in a manner similar to placing an ear

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speculum over the viewing tip of a conventional otoscope. The disposable includes a clear window over the probe tip. The probe can be used to inspect the ear canal, when inserted into the ear canal no closer than 4-5 mm from the tympanic membrane.

Additionally, the disposable can be filled with an absorbing medium so the membrane conforms to the ear, to enable the 3D scanning functionality of the device. After scanning is complete, the absorbing medium drains from the disposable so that the probe and disposable can be removed from the ear canal. The topographical measurement (scan) of the ear may be transmitted and may be used in the same manner as a desktop scan of a silicone earmold impression.

Indications for Use

The Lantos 3D Ear Scanner is intended for use by a trained hearing professional on patients 18 years of age and older presenting for inspection of the external ear canal.

The Lantos 3D Ear scanner:

- provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for inspection and;
- includes an expanding membrane that can be inserted and conforms to the external ear canal when filled with an absorbing medium which enables the 3D scan and;
- records and presents to the hearing professional in an image file a topology measurement of the external ear canal

Intended Use Population

The Lantos 3D Ear Scanner is indicated for use by trained hearing professionals on patients 18 years of age and older presenting for inspection of the external ear canal.

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Technological Characteristics

The Lantos 3D Ear Scanner is not a change or modification to the predicate device that could significantly affect safety or effectiveness. In other words, there is no change in the intended use (otoscope and hearing aid accessory), design (hand-held with illuminating LED probe tip covered by silicone cover), materials (polymers and silicone), and power source that could raise new issues of safety or effectiveness.

The Lantos 3D Ear Scanner followed ACGIH *American Conference of Governmental Industrial Hygienists Threshold Limit Values for chemical substances and physical agents and Biological Exposure Indices. 2011.* For both intended use and reasonably foreseeable misuse, the Scanner falls within ACGIH Threshold Limit Values for retinal thermal exposure within 10 seconds, blue light exposure within 10000 seconds, actinic ultraviolet radiation within 8 hours of operation and near UV exposure. In addition, the illumination subsystem was evaluated according to ANSI/IESNA *RP-27.3-2007 Recommended Practice for Photobiological Safety for Lamps-Risk Group Classification & Labeling* to provide a photobiological hazard evaluation (including blue light hazard exposure limits). This evaluation resulted in a "Risk Group 1" classification for the blue-violet LED. The exposure time limit for Risk Group 1 was 15 minutes of direct, continuous exposure to the scanner tip without the membrane attached. Package labeling includes a caution: "Do not stare at the scanner tip, or direct scanner tip toward patient's face, while illumination is active. Staring at scanner tip for more than 15 minutes with no membrane attached under fault conditions may exceed photobiological exposure. May be harmful to the eyes."

The output of the Lantos 3D Ear Scanner was validated using two known models (cylindrical and anatomical) with given values and obtaining multiple scans on each using multiple Scanner units. All scans were required to have a mean difference between the model and the scan consistent with manufacturer's requirements for fabrication of devices inserted in the ear.

Performance Standards

The Lantos 3D Ear Scanner meets the following Recognized Performance Standards:

- ISO 10993 Parts 1-13 as applicable

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

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- IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2 – General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-2-18 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- ISO 14971: Medical devices—Application of risk management to medical devices

Conclusion

Based on the comparison of the technological characteristics (including the intended use) and verification tests of the Lantos 3D Ear Scanner, there are no significant new issues of safety and effectiveness that are raised when compared to the predicate device. The Lantos 3D Ear Scanner provides for inspection of the ear canal comparable to the predicate otoscope device and also allows for ear canal measurements, which may be used for the manufacture of hearing devices.

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 25, 2013

Lantos Technologies
% Mr. John Greenbaum
Generic Devices Consulting, Inc.
20310 SW 48th Street
Southwest Ranches, FL 33332

Re: K121326
Trade/Device Name: Lantos 3D Ear Scanner
Regulation Number: 21 CFR 874.4770
Regulation Name: Otoscope
Regulatory Class: Class I
Product Code: ERA, ESD
Dated: December 18, 2012
Received: December 19, 2012

Dear Mr. Greenbaum:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015 K121326

INDICATIONS FOR USE

510(k) Number (If Known): K121326

Device Name: Lantos 3D Ear Scanner

Indications for Use:

The Lantos 3D Ear Scanner is intended for use by a trained hearing professional on patients 18 years of age and older presenting for inspection of the external ear canal.

The Lantos 3D Ear scanner:

- provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for inspection and;
- includes an expanding membrane that can be inserted and conforms to the external ear canal when filled with an absorbing medium which enables the 3D scan and;
- records and presents to the hearing professional in an image file a topology measurement of the external ear canal

Prescription Use__X__ AND/OR Over-the Counter Use____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K121326

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

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

June 26, 2012

LANTOS TECHNOLOGIES
C/O GENERIC DEVICES CONSULTING, INC.
20310 SW 48TH ST
SOUTHWEST RANCHES, FLORIDA 33332
ATTN: JOHN GREENBAUM

510k Number: K121326

Product: LANTOS 3D EAR SCANNER

Extended Until: 09/21/2012

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). 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.

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
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Payne, Melissa T*

From: John Greenbaum [genericd@bellsouth.net]
To: Payne, Melissa T*
Sent: Tuesday, June 26, 2012 8:52 PM
Subject: Read: K121326 FDA Extension Letter

Your message was read on Tuesday, June 26, 2012 8:51:36 PM (GMT-05:00) Eastern Time (US & Canada).

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

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

June 25, 2012

LANTOS TECHNOLOGIES
C/O GENERIC DEVICES CONSULTING, INC.
20310 SW 48TH ST
SOUTHWEST RANCHES, FLORIDA 33332
ATTN: JOHN GREENBAUM

510k Number: K121326
Product: LANTOS 3D EAR SCANNER
On Hold As of 6/22/2012

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/MedicalDeviceProvisionsofFDAModernizationAct/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.

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

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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

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

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* * * COMMUNICATION RESULT REPORT (JUN. 25. 2012 10:06AM) * * *

FAX HEADER 1:
FAX HEADER 2:

T SMITTED/STORED : JUN. 25. 2012 10:05AM

MODE	OPTION	ADDRESS	RESULT	PAGE
6875 MEMORY TX		+1. 954. 653. 1153	OK	2/2

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

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

June 25, 2012

LANTOS TECHNOLOGIES
C/O GENERIC DEVICES CONSULTING, INC.
20310 SW 48TH ST
SOUTHWEST RANCHES, FLORIDA 33332
ATTN: JOHN GREENBAUM

510k Number: K121326
Product: LANTOS 3D EAR SCANNER
On Hold As of 6/22/2012

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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/MedicalDeviceProvisionsofFDAModernizationAct/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.

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

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John Greenbaum
Generic Devices Consulting, Inc.

20310 SW 48th Street
Ft. Lauderdale, FL. 3332

Fax (954) 653-1153
Home Office (954) 680-2548
Mobile (954) 610-0178
Email: genericd@bellsouth.net

FDA CDRH DMC
JUN 26 2012
Received K23

June 22, 2012

US Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: 510K; K121326 Lantos 3D Ear Scanner

RE: Request for additional time to respond.

Dear FDA:

This letter is in response to the request for additional information regarding the subject 510K from Lantos Technologies.

Because the information requested may require additional testing, completion of ongoing clinical studies, etc., we are requesting an additional 60 days to prepare our response; this would be a total of 90 days to respond (September 21, 2012).

Please reply to the undersigned with respect to this request.

Sincerely,

On behalf of
John Greenbaum
Generic Devices Consulting, Inc.

Cc: Doug Johnston, Lantos Technologies

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

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

May 02, 2012

LANTOS TECHNOLOGIES
C/O GENERIC DEVICES CONSULTING, INC.
20310 SW 48TH ST
SOUTHWEST RANCHES, FLORIDA 33332
ATTN: JOHN GREENBAUM

510k Number: K121326

Received: 5/2/2012

Product: LANTOS 3D EAR SCANNER

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

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

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

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

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

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

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

Sincerely,

510(k) Staff

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Mcdonald, Lisa *

From: Microsoft Outlook
To: 'genericd@bellsouth.net'
Sent: Wednesday, May 02, 2012 4:04 PM
Subject: Relayed: K121326 ACK Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'genericd@bellsouth.net'

Subject: K121326 ACK Letter

Sent by Microsoft Exchange Server 2007

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

101

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

K121326
EN|Doned

FDA CDRH DMC

MAY - 2 2012

Received KP

John Greenbaum
Generic Devices Consulting, Inc.

20310 SW 48th Street
Ft. Lauderdale, FL. 33332

Fax (954) 653-1153
Phone (954) 680-2548
Mobile (954) 610-0178
Email: genericd@bellsouth.net

April 30, 2012

US Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - W066-G609
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

RE: Pre-Market Notification, Lantos 3D Ear Scanner

Dear Sir/Madam,

Please find enclosed, one original Pre-market Notification for the Lantos 3D Ear Scanner, an Otoscope (ERA) on behalf of Lantos Technologies and two copies (one hard copy and one e-copy). The e-copy is certified to be identical to the original.

Lantos Technologies (Cambridge, MA) is the primary manufacturer and distributor for the Lantos 3D Ear Scanner.

This is an original 510K; the company has no prior 510k clearance for this device.

Generic Devices Consulting, Inc. (John Greenbaum) is the official correspondent for this pre-market notification. Lantos Technologies has a payment account established and payment for the filing fee for this pre-market notification has been sent prior to the filing by the undersigned correspondent.

Please do not hesitate to call if you have any questions or need additional information.

Sincerely,

On behalf of
John Greenbaum

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

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Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

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

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Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

1. FDA Payment Cover Sheet

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: **MD6060386-956733** 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/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
LANTOS TECHNOLOGIES INC 101 Main St Ste 1706 Cambridge MA 021421519 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****1133	John Greenbaum 2.1 E-MAIL ADDRESS genericd@bellsouth.net 2.2 TELEPHONE NUMBER (include Area code) 954-6100178 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 954-6531153

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

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

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

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

[X] NO, I am not a small business

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

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

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

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

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

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

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

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

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

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

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

$4,049.00 21-Feb-2012

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

2. FDA Pre-Market Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission
30 April 2012

(b) (4) [redacted]

SECTION A — TYPE OF SUBMISSION

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

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

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

SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Lantos Technologies	Establishment Registration Number *(if known)* N/A		
Division Name *(if applicable)*	Phone Number *(including area code)* 1-617-500-9800		
Street Address 101 Main Street, Suite 1760	FAX Number *(including area code)* 1-617-812-5561		
City Cambridge	State / Province MA	ZIP/Postal Code 02142	Country USA
Contact Name Doug Johnston			
Contact Title Vice President	Contact E-mail Address dmj@lantostechnologies.com		

APPLICATION CORRESPONDENT (e.g., consultant, if different from

Company / Institution Name Generic Devices Consulting, Inc.			
Division Name *(if applicable)*	Phone Number *(including area code)* (954) 610-0178		
Street Address 20310 SW 48th Street	FAX Number *(including area code)* (954) 653-1153		
City Southwest Ranches	State / Province FL	ZIP/Postal Code 33332	Country USA
Contact Name John Greenbaum			
Contact Title President	Contact E-mail Address genericd@bellsouth.net		

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

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SECTION D1

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

☐ Change in design, component, or specification:
- ☐ Software / Hardware
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other *(specify below)*

Other *(specify below)*

☐ Location change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager

☐ Process change:
- ☐ Manufacturing
- ☐ Sterilization
- ☐ Packaging
- ☐ Other *(specify below)*

☐ Labeling change:
- ☐ Indications
- ☐ Instructions
- ☐ Performance
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other *(specify below)*

☐ Report Submission:
- ☐ Annual or Periodic
- ☐ Post-approval Study
- ☐ Adverse Reaction
- ☐ Device Defect
- ☐ Amendment

☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

☐ Other Reason *(specify):*

REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

Request for Removal of Applicant Hold

☐ Change in:
- ☐ Correspondent / Applicant
- ☐ Design / Device
- ☐ Informed Consent
- ☐ Manufacturer
- ☐ Manufacturing Process
- ☐ Protocol - Feasibility
- ☐ Protocol - Other
- ☐ Sponsor

☐ Repose to FDA Letter Concerning:
- ☐ Conditional Approval
- ☐ Deemed Approved
- ☐ Deficient Final Report
- ☐ Deficient Progress Report
- ☐ Deficient Investigator Report
- ☐ Disapproval
- ☐ Request Extension of Time to Respond to FDA
- ☐ Request Meeting
- ☐ Request Hearing

Manufacturer

☐ Report submission:
- ☐ Current Investigator
- ☐ Annual Progress Report
- ☐ Site Waiver Report
- ☐ Final

☐ Other Reason *(specify):*

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☐ Other Reason *(specify):*

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

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SECTION E

Product codes of devices to which substantial equivalence is claimed

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

1	ERA	2		3		4	
5		6		7		8	

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K943916	1	Welch Allyn Video Otoscope	1	Welch Allyn, Skaneateles Falls, NY
2		2		2	
3		3		3	
4		4		4	
5		5		5	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Otoscope

	Trade or Proprietary or Model Name for This Device		Model Number
1	Lantos 3D Ear Scanner	1	N/A
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

G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: ERA

C.F.R. Section *(if applicable)*: 874.4770

Classification Panel: ENT

Device Class

☒ Class I ☐ Class II
☐ Class III ☐ Unclassified

Indications *(from labeling)*

The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal.
The Lantos 3D Ear scanner:
provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation and;
includes an expanding conforming membrane which aids observation when inserted in the ear canal and;
records and presents to the hearing professional in an image file a topology measurement of the external ear canal.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

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

(b) (4)

[redacted]

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

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.					
1	Standards No. 60601-1	Standards Organization IEC	Standards Title IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance	Version Third edition	Date 2005-12
2	Standards No. 60601-1-2	Standards Organization IEC	Standards Title IEC 60601-1-2 Medical Electrical Equipment – Part 1-2 – General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and Tests	Version Third edition	Date 2007-03
3	Standards No. 14971	Standards Organization ISO	Standards Title ISO 14971: Medical devices—Application of risk management to medical devices	Version Second edition Corrected	Date 2007-10-01
4	Standards No. ISO 10993-10	Standards Organization ISO	Standards Title Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization	Version N/A	Date 2010
5	Standards No. ISO 10993-5	Standards Organization ISO	Standards Title Biological Evaluation of Medical Devices, Part 5: Cytotoxicity – MEM Elution	Version N/A	Date 2009
6	Standards No. ISO 10993-10	Standards Organization ISO	Standards Title Part 10: Tests for Irritation and Skin Sensitization; Murine Local Lymph node assay	Version N/A	Date 2010
7	Standards No. IEC 60601-2-18	Standards Organization IEC	Standards Title IEC 60601-2-18 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	Version Edition 3.0	Date 2009-08
8	Standards No.	Standards Organization	Standards Title	Version	Date

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

3. Standards Verification Forms

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Form Approved OMB No. 0960-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(k) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971: Medical devices—Application of risk management to medical devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 5-40	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: Q9 – Quality Risk Management

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Form Approved OMB No. 0960-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(k) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-10: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization; Intracutaneous Reactivity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 2-87	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k). – Skin irritation tests – section 5 – see Section 17 Attachment VII; (a)	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510(k)?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'."

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

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TYPE OF 510(k) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-5: Biological Evaluation of Medical Devices, Part 5: Cytotoxicity – MEM Elution

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 023	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. MEM elution – See Section 17; Attachment VII;(b)	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510(k)?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'."

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

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TYPE OF 510(k) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-10: Part 10: Tests for Irritation and Skin Sensitization; Murine Local Lymph node assay

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 2-87	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. Murine Lymph node assay – See Section 17; Attachment VII (c)	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510(k)?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8178

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Form Approved OMB No. 0960-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(k) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-10: Part 10: Tests for Irritation and Skin Sensitization; ISO Skin Irritation

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 2-87	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table. Murine Lymph node assay – See Section 17; Attachment VII (c)	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510(k)?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'."

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

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(k) SUBMISSION

√ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI / ANSI IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	√	☐
FDA Recognition number [3]	# 5-52	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	√
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	√	☐
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	√	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	√	☐
Does this standard include more than one option or selection of tests?	√	☐
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	√
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☐
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	√	☐
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	√
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI / ANSI IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◊
See summary report table attached

DESCRIPTION
Summary report

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

◊ For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(k) SUBMISSION

√ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-2-18: Edition 3.0 2009-08, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	√	☐
FDA Recognition number [3]	# 4-187	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	√
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	√	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	√	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	√	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	√	☐
Were there any deviations or adaptations made in the use of the standard?	☐	√
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there exclusions from the standard? If yes, report these exclusions in the summary report table.	√	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	√
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-2-18: Edition 3.0 2009-08, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◊ See summary report table attached		
DESCRIPTION Summary report		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		

◊ For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

4. Truthful and Accurate Statement

Certification Statement

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 CFR 807.87(j))

I certify, that in my capacity as Vice President, Lantos Technologies, Inc. that I believe to the best of my knowledge, that all data and information submitted on this premarket notification are truthful and accurate and that no material fact has been omitted.

Douglas M Johnston
Vice President Engineering
Lantos Technologies, Inc.

30 APR 2012
Date

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

5. Indications for Use

510(k) Number(if known):_____

Device Name: Lantos 3D Ear Scanner

Indications For Use:

The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal.

The Lantos 3D Ear scanner:

- provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation and;
- includes an expanding conforming membrane which aids observation when inserted in the ear canal and;
- records and presents to the hearing professional in an image file a topology measurement of the external ear canal

Prescription Use_X_ OR Over-The-Counter Use___
(Per 21 CRF 801.109)

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)

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

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5.1. Certification of Conformity to Standards

Certification Statement

PREMARKET NOTIFICATION

CONFORMITY TO APPLICABLE STANDARDS

I certify that in my capacity as Vice President, of Lantos Technologies, Inc., that I believe to the best of my knowledge, that the Lantos 3D Ear Scanner conforms to the requirements of the following standards as applicable:

- Tripartite Guidance – 1987 (G87-1)
- ISO 10993 Parts 1-13 as applicable
- IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2 – General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-2-18 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- ISO 14971: Medical devices—Application of risk management to medical devices

Douglas M Johnston
Vice President Engineering
Lantos Technologias, Inc.

30 APR 2012
Date

Lantos 3D Ear Scanner
510(k) Premarket Notification Title

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

6. 510K Summary

Applicant:

Lantos Technologies
101 Main Street, Suite 1760
Cambridge, MA 02142, USA
Tel: 1-617-500-9800

Contact: Doug Johnston

510(k) Numbers and Product Codes of equivalent devices:

Welch Allyn Video Otoscope (Skaneateles Falls, NY)

Welch Allyn Otoscope; K943916 – SE 08/25/1994

Code: ERA; 874.7440

Indications for Use

The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal.

The Lantos 3D Ear scanner:

- provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation and;
- includes an expanding conforming membrane which aids observation when inserted in the ear canal and;
- records and presents to the hearing professional in an image file a topology measurement of the external ear canal

Intended Use Population

The 3D Ear Scanner may be used in any adult for visual inspection of the external ear, subject to the limitations of the warnings and precautions in the user manual. The 3D Ear Scanner records the external ear topology as an aid for use in the design and manufacturing of devices inserted in the ear.

Device Description

The Device consists of a hand held scanner, a single patient use disposable with a conforming membrane, which when in use is filled with an absorbing medium, and a laptop computer. The hand held scanner, when not in use, is placed in a docking stand.

The hand held scanner is tethered to the docking stand with a custom cable.

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

The docking stand is tied to the laptop computer. The hand held scanner contains illumination, optics, a camera, a motor to move the probe tip, and a motor-driven reservoir.

User Interface (UI) software screens are displayed on the laptop and the user interacts with the device via the laptop keyboard and touchpad, and control buttons on the hand held scanner, as guided by the UI screens. Image data from the patient is stored in the laptop, and may be transmitted by the user via a wireless connection. No patient identifiable data is stored in the Lantos device.

A single use disposable, which includes the conforming membrane, is placed over the hand held scanner probe tip, in a manner similar to placing an ear speculum over the viewing tip of a conventional otoscope. The disposable will contact and reshape the ear canal with mild pressure, to improve the view of the ear canal, and to keep the probe tip from contacting the ear canal, performing the same functions as a speculum.

Performance Standards

The Lantos 3D Ear Scanner meets the following Recognized Performance Standards:

- ISO 10993 Parts 1-13 as applicable
- IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2 – General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-2-18 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- ISO 14971: Medical devices—Application of risk management to medical devices

Predicate Device

The Lantos 3D Ear Scanner is substantially equivalent to the Welch Allyn Otoscope. The predicate device was found SE on August 25, 1994. The Lantos 3D Ear Scanner has similar intended use and target population to the Welch Allyn Otoscope.

Summary of Studies

Table 6-1: Summary of Studies

ISO 10993-10	Tests for Irritation and Skin Sensitization	PASS
ISO 10993-10	Intracutaneous Reactivity	PASS
ISO 10993-5	Cytotoxicity – MEM Elution	PASS
ISO 10993-10	Murine Local Lymph node assay	PASS
Clinical	Direct Scan Earmold Digitization Evaluation	Safety aspect of study completed – interim report demonstrates no adverse events. Non Lantos related aspects of study not yet final.
Clinical	User Preference Evaluation	Study not completed – all safety criteria met

Conclusion

There are more similarities than differences between the predicate device and the Lantos 3D Ear Scanner. The predicate device and Lantos 3D Ear Scanner have the same intended use, warnings and contraindications. When used in accordance with the instructions for use, by qualified personnel, the Lantos 3D Ear Scanner is safe and effective, as indicated, for the intended use.

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7. Device Description

7.1. General Information

7.1. Reason for 510K

This is a new, original pre-market notification. The applicant has no prior devices in interstate commerce, and will commence registration and listing at the time of clearance of this pre-market notification (and in one case after satisfactory completion of the remaining IEC 60601-1-2 pending test). Devices in CFR874.4770 are normally exempt from the requirement of a pre-market notification. However, we believe that the technological differences in the Lantos 3D Ear Scanner are such that the exemption no longer applies and this 510k is submitted herein.

7.2. Device Information:

Trade Name, Proprietary Name:
Lantos 3D Ear Scanner

7.3. Classification Code/Common Name

CFR Number: 874.4770

Code: ERA

Common Name: Otoscope

Classification: Class I

Establishment Registration:
Pending clearance of this pre-market submission. Manufacturer will register with FDA within 30 days of 510k clearance and prior to placing the device into interstate commerce.

7.4. Manufacturing facility:

Lantos Technologies
101 Main Street, Suite 1760
Cambridge, MA 02142
Tel: 1-617-500-9800

7.5. Equivalent Devices:

Welch Allyn Video Otoscope (Skaneateles Falls, NY) – Welch Allyn Otoscope; K943916 – SE 25-AUG-1994

7.6. Standards, Special Controls

Otoscope devices are Class I devices and are not subject to special controls per the requirements of 21CFR874.4770. IEC 60601-2-18 is listed as a recognized consensus standard for this device code. The Lantos Technologies 3D Ear Scanner meets the requirements associated with the special Controls. The Lantos 3D Ear Scanner conforms to the following recognized standards and FDA Guidance Documents.

- 21CFR820; 1996: Quality System Regulation

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

- IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2 – General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-2-18 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- FDA; Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices - May 2005
- ISO 10993; Parts 1-13 Applicable

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

7.7. Design and use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?	*	X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

* Single Patient Use Disposable is for one patient, two ears

7.8. General Device Description

The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal. The 3D Ear Scanner:

- Provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation
- Includes an expanding conforming membrane that aids observation when inserted in the ear canal
- Records and presents to the hearing professional in an image file a topology measurement of the external ear canal

A system illustration is provided in Figure 7-1, below. The Device consists of a hand held scanner as shown in Figure 7-2, below, a single patient use disposable with conforming membrane, which when in use is filled with an absorbing medium, depicted in Figure 7-3, below, and a laptop computer, as shown in Figure 7-4, below. The hand held scanner, when not in use, is placed in a docking stand as depicted in Figure 7-5, below.

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7.9. Depiction of Lantos 3D Ear Scanner

Figure 7-1: System Illustration

Figure 7-2: Hand Held Scanner

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Figure 7-3: Conforming Membrane with Fluid

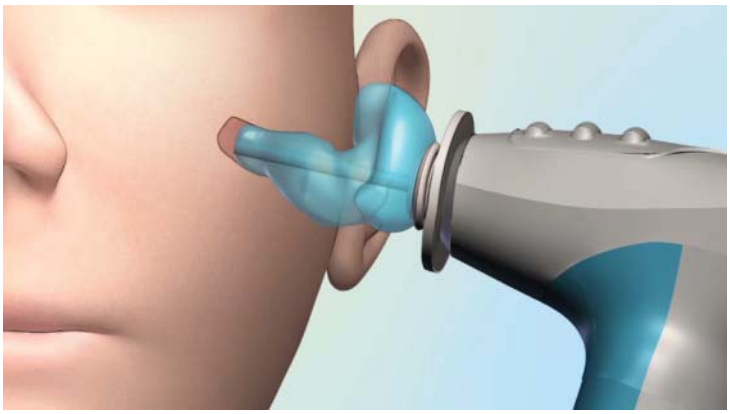

Figure 7-4: Laptop Computer

Figure 7-5: Wand Docking Stand

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7.10. Use Overview

The user starts the device by turning on a switch on the docking stand and the switch on the laptop, and preparing the device in accordance with the instructions for use. The hand held scanner is tethered to the docking stand with a custom cable that provides power and two-way communication. The docking stand is tied to the laptop computer with a USB cable. The hand held scanner contains illumination, optics, a camera, a motor to move the probe, and a motor-driven reservoir with fluid as described in the detailed device description.

User Interface software screens are displayed on the laptop and the user interacts with the device via the laptop keyboard and touchpad, and control buttons on the hand held scanner, as guided by the UI screens. Image data from the patient is stored on the hard disk in the laptop, and may be transmitted by the user via a wireless connection in the laptop. No patient identifiable data is stored in the Lantos device. The user enters a 2 or 3 character alphanumeric code for each scan, which together with the timestamp of the scan, the user identification and the site information, is sufficient to uniquely identify the scan. It is the responsibility of the user to record and transfer the scan identifier for transmission of the image data.

A single patient use disposable which includes the conforming membrane, is placed over the hand held scanner probe tip, in a manner similar to placing an ear speculum over the viewing tip of a conventional otoscope. The disposable will contact and reshape the ear canal with mild pressure, to improve the view of the ear canal, and to keep the probe tip from contacting the ear canal, performing the same functions as a speculum. The disposable may be used up to five times for the single patient before discarding.

The user guides the probe tip visually, looking through a flexible window at the tip of the membrane. The window is circular and similar in size to the opening at the tip of a speculum. The user may inspect the ear canal, and may place the tip to perform a topology measurement of the ear canal. For the topology measurement, a motor in the hand held scanner fills the membrane with liquid absorbing medium, until it expands to conform to the external ear as depicted above in Figure 7-3. (See User Manual- Attachment V, Section 15).

7.11. Contraindications

a. Not for use in pediatric patients

7.12. Warnings & Precautions

a. Take precaution and use clinical judgment for patients with known or suspected ear infections
b. Take precaution and use clinical judgment for patients with known or suspected perforated eardrum(s)
c. Use clinical judgment for patients where the anatomy of the external ear appears to have unsuitable tortuosity
d. Do not use in the presence of flammable anesthetics
e. Do not connect the 3D Ear Scanner to devices other than as expressly described in these Instructions

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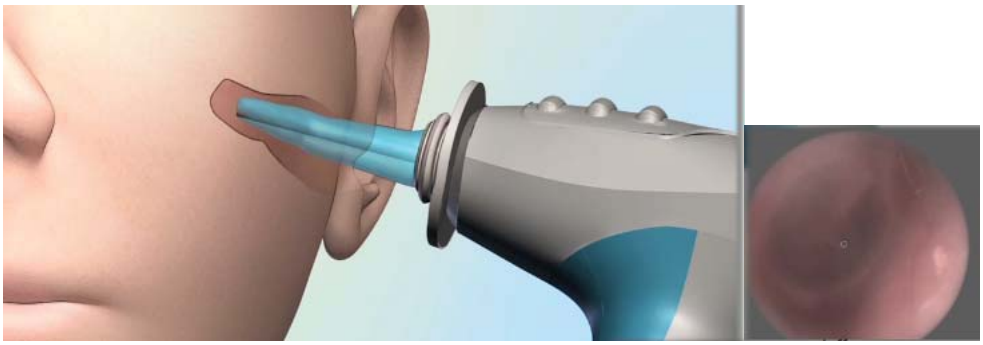
f. Do not use this device for any purpose other than specified in these Instructions
g. Discontinue use of the device is you notice any signs of damage to the components – contact Lantos Technologies support for service – no user serviceable components
h. Disposable is single patient use only

7.13. Detailed Device Description

The Lantos scanner is intended for use by a trained hearing professional (**the user**) in clinical settings on adult patients presenting for inspection of the external ear canal and tympanic membrane. The Lantos scanner displays a magnified visual image of the external ear canal and tympanic membrane to the user on a laptop computer screen. The Lantos scanner incorporates a visible light spectrum source to illuminate the ear canal.

The Lantos scanner has a long thin tip to extend the viewing lens and illumination into the ear canal. The user places a single patient use conforming membrane over the scanner tip. The conforming membrane has a clear window at the distal end. The user may view different portions of external ear canal and tympanic membrane by changing the position and orientation of the scanner, as with a traditional video otoscope. In addition the user may save one or more fixed otoscope images for later use.

Figure 7-6: Video Otoscope Mode



If desired, the user may also record a topology measurement of the external ear canal, and save it as an image file for later use. The user positions the scanner tip visually, according to the desired extent of the topology measurement. When positioned, the user expands the conforming membrane with liquid absorbing medium to match the shape of the external ear canal.

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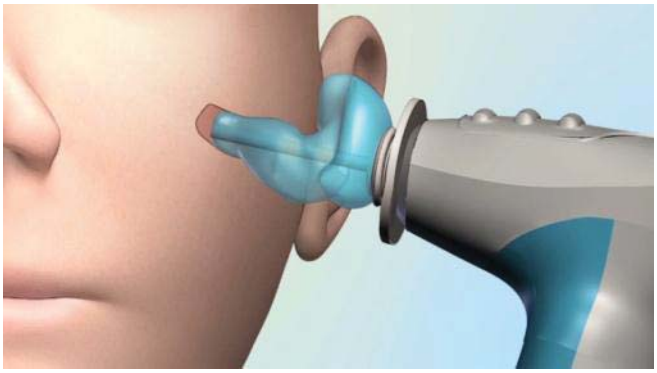
Figure 7-7: Ear Topology Mode – Start



The user holds the scanner in a fixed position relative to head, and retracts the scanner tip into the scanner body; the tip passes through the canal. The scanner captures a series of video images, and transforms the series into an image of the ear topology measurement.

Figure 7-8: Ear Topology Mode – Scan-Retract

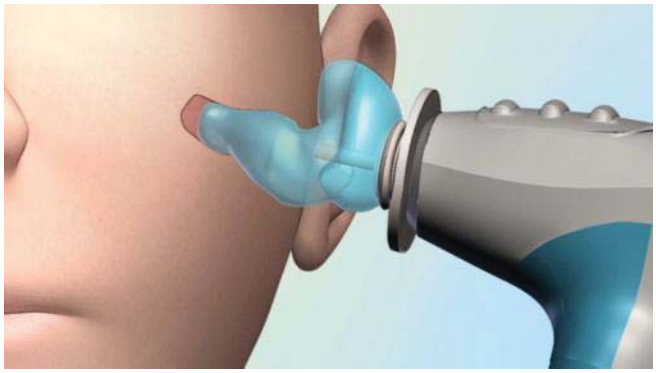
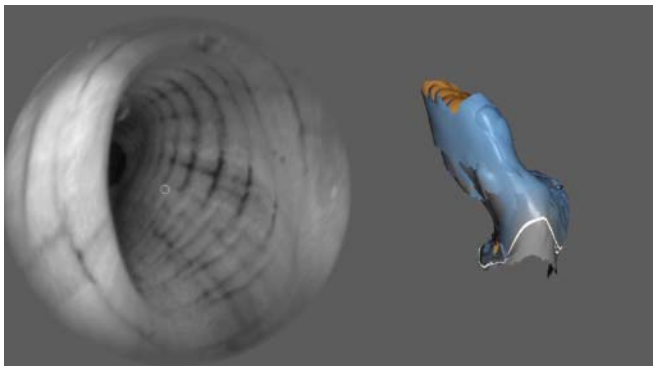


Figure 7-9: Ear Topology Mode – Image Transform



When the desired extent of topology has been captured, the user withdraws the fluid from the conforming membrane and removes the scanner from the ear.

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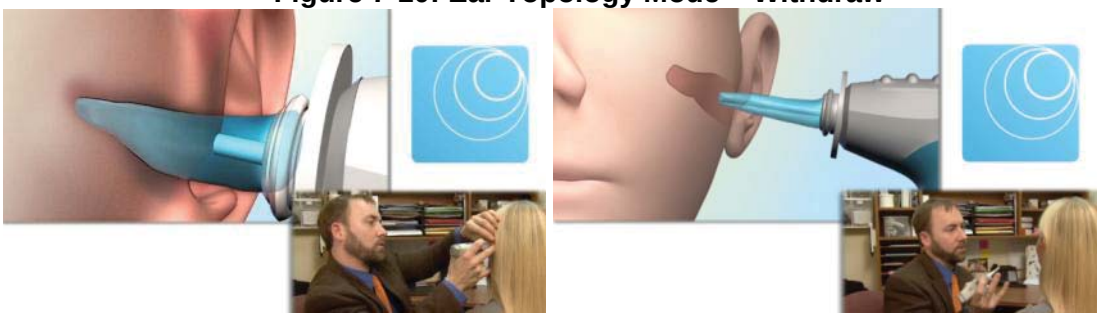
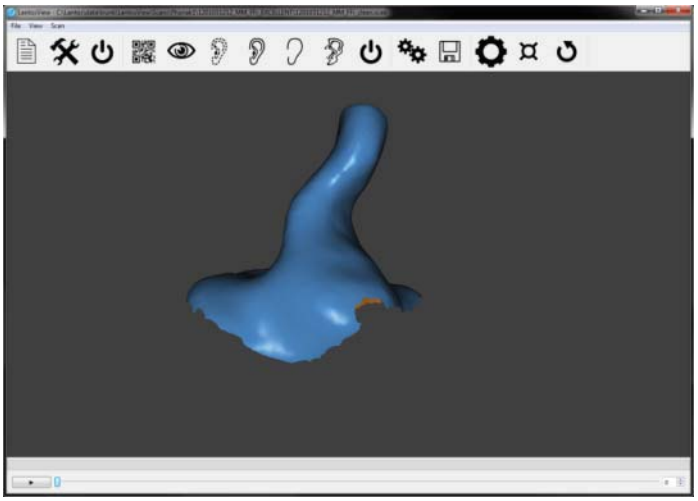
Figure 7-10: Ear Topology Mode – Withdraw



The topology image is visible to the user on the laptop computer screen, and may be saved for later use.

Figure 7-11: Ear Topology Mode – Final Topology Image



If the user desires, the video otoscope inspection and the topology measurement may be repeated on the patient's second ear with the single patient use disposable.

7.14 Components

The Lantos device includes a handheld scanner connected to a laptop computer. Incorporated in the handheld scanner is a single patient use disposable with a conforming membrane and a reservoir for the absorbing medium.

7.14.1 Handheld Scanner with Single Patient Use Disposable

The assembled handheld scanner is depicted in the figure 7-12, below, and includes the subassemblies and components shown in the assembly drawing and table on the first page following (Figure 7-13).

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Figure 7-12: Handheld Scanner with Single Use Disposable

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Figure 7-13: Scanner Assembly

(b)(4)

[redacted]

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Principal functional subassemblies in the handheld scanner include those depicted in the following Figure 7-14 and table below the figure. For additional information see Section 7.16, Theory of Operation.

(b)(4)

[redacted]

The single patient use disposable is depicted in the figure 7-15, below, and includes the subassemblies and components shown in the assembly drawing, Figure 7-16, below and the table which follows.

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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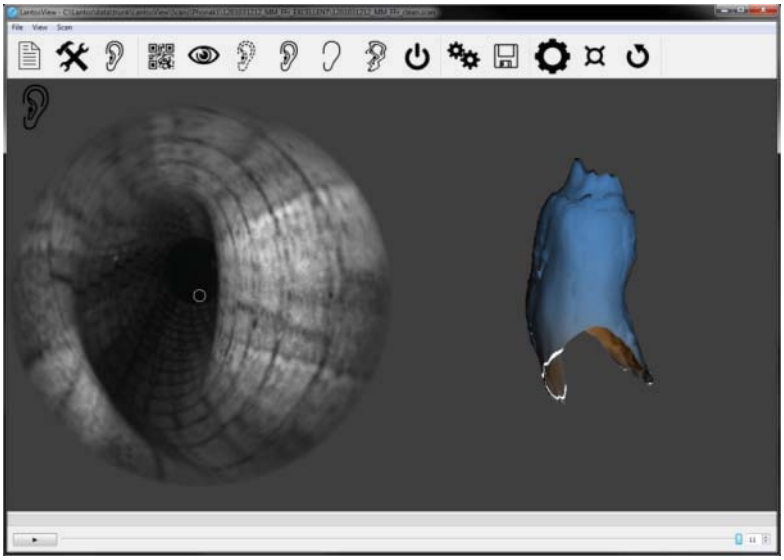
The Docking Stand depicted in following figure, provides a holster for the handheld scanner between scans, provides the interconnect between the tether cable from the scanner and the USB connection on the laptop, and provides power to the scanner.

Figure 7-18: Docking Stand

7.14.3 Software Application

The software application provides live visual feedback to the operator, for inspection of the external ear canal, and to determine the extent of the external ear topology measurement. The software application, if so directed by the hearing professional, saves the inspection images and the topology measurement images for later use. A typical screen image is provided in the following figure. Details of operation and design of the software application are in Section 7-18.

Figure 7-19: Software Application – Scan Screen



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7.15 Materials Used

The components of the Lantos scanner and single use disposable listed in the following table are likely to contact the patient, or contact the hearing professional in the patient vicinity. All component materials were examined during risk analysis, and determined to be safe for such contact, either through test results obtained from the material manufacturers, and reviewed by Lantos, or through biocompatibility tests commissioned by Lantos. Engineering drawings for the components which may contact the patient or user are in Attachment VIII – Section 18.

(b)(4)

[redacted]

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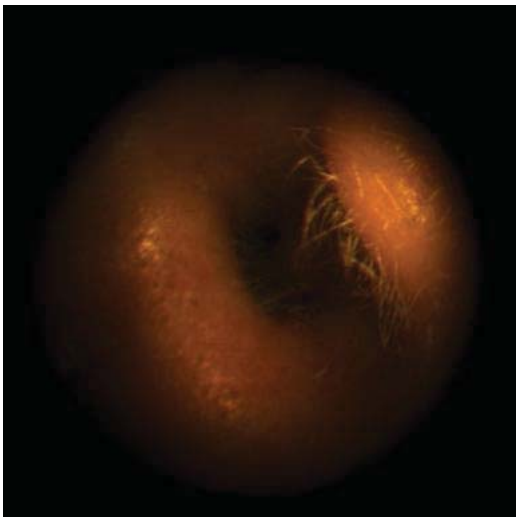
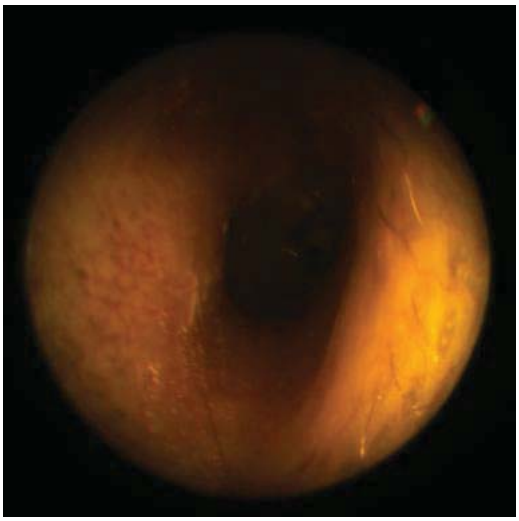
7.16. Theory of Operation

The Lantos 3D Ear Scanner provides a magnified visual image of the external ear canal to the hearing professional on a laptop computer screen. This section provides a step-by-step description of Scanner operation, followed by detailed theories of operation for key subassemblies and algorithms.

Figure 7-20: Lantos 3D Ear Scanner In Use

Figure 7-21 Sample Lantos Ear Scanner Video Otoscope Images





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7.16.1. Step-by-Step Summary – Lantos 3D Ear Scanner Video Otoscope

The Scanner acts as a Video Otoscope, showing high-resolution color images of the ear. To produce the images, the scanner uses the following subassemblies, as described, in functional order from probe tip to laptop screen:

- *Distal Lens* – the lens collects a wide angle view of the ear canal, and passes light in the visible spectrum with high spatial resolution and minimal distortion
- *Illumination Fibers* – glass optical fibers carry visible light to the probe tip; they are positioned in an annular ring surrounding the distal lens, and polished to maximize light throughput
- *Probe Tube* – a thin steel tube contains the distal lens and illumination fibers, and carries the collected light through a series of small relay lenses to the optical sensor – the probe tube effectively extends the view of the sensor into the ear canal
- *Optical Sensor* – a high resolution CMOS optical sensor converts the visible light photons to electrical signals representing signal strength at each pixel
- *Camera Subassembly* – (b)(4) [redacted] the camera subassembly also converts the video images to a high speed serial data stream for effective transmission
- *Illumination Source* – a three color Red/Green/Blue collection of LED die are coupled through an optical taper into the proximal end of the illumination fibers – a microcontroller and associated current control drive circuits create an illumination flash sequence synchronized with the shutter of the optical sensor
- *USB Transmission* – a circuit in the Scanner implements the Universal-Serial-Bus protocol, and communicates via the tether cable over a serial LVDS link to a companion USB circuit in the laptop
- *Laptop CPU and GPU* – Lantos application software directs the laptop processor to monitor the USB channel, to reconstruct the serial data stream back to the series of video images, and directs the graphical processor to display the images on the LCD screen

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7.16.2. Optics Subassembly

The entire Optics Subassembly is mounted within a Lead Screw, to allow advancement and retraction of the Probe Tip within the Scanner. (b)(4) [redacted]

(b)(4) [redacted]

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(b)(4)

[redacted]

Figure 7-24: Probe Advance/Retract Subsystem

(b)(4)

[redacted]

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7.16.4. Illumination / Combo Subassembly

(b)(4)

[redacted]

Figure 7-25: Illumination / Combo Subassembly

(b)(4)

[redacted]

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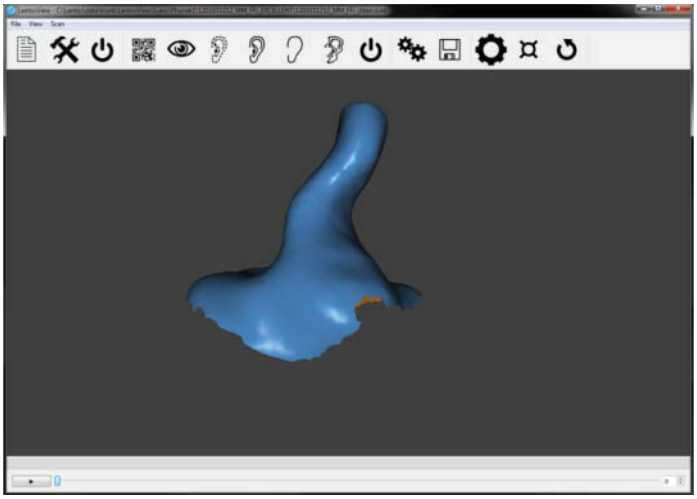
Figure 7-26: 3D Scan Ear Topology Image



7.16.5. Step-by-Step Summary – 3D Scan Ear Topology

The Lantos scanner also provides a measurement of the external ear topology. The same functional sequence described in 7.16.1 is used, with the following additions:

- *Expand Conforming Membrane* – after the user visually positions the probe tip at the appropriate depth in the external ear canal, the user activates a motor driven pump in the scanner to expand the conforming membrane with the liquid absorbing medium – after expansion, the user will see on the screen the illuminated interior surface of the conforming membrane, rather than through the clear window at the membrane tip
- *Reservoir and Fluid Drive* – the reservoir contains (b)(4) [redacted] – under motor driven control directed by the application software, via the microcontroller in the scanner, the fluid is driven into or withdrawn from the conforming membrane, as controlled by the user with +/- keys on the scanner
- *Probe Tip Retract* – for ear topology scanning, the user braces the scanner with the fingers against the patient's head, leaving the other hand free – the user directs the extended probe tube and tip to retract into the braced scanner, collecting a sequence of video images from different positions along the external ear canal
- *Ear Topology Transform* – the application software converts the sequence of video images into a cumulative topology model of the external ear canal, visible to the user – a fluorescent dye embedded in the conforming membrane absorbs visible blue light illumination, and emits in longer wavelengths – an algorithm in the application software parses the emitted wavelengths, and calculates the distance to individual points on the membrane surface – the sequence of point cloud distances is further transformed into the cumulative topology
- *Collapse and Withdraw* – when the topology measurement is complete to the user's satisfaction, the user withdraws the absorbing medium from the membrane back into the reservoir, and removes the scanner probe from the external ear canal

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- *Save and Transmit Images* – the user may save the inspection or topology images for later use, including wireless transmission to other locations at the user's discretion

7.16.6. Fluid Drive Subsystem

(b)(4)

[redacted]

Figure 7-27: Fluid Drive Subsystem

(b)(4)

[redacted]

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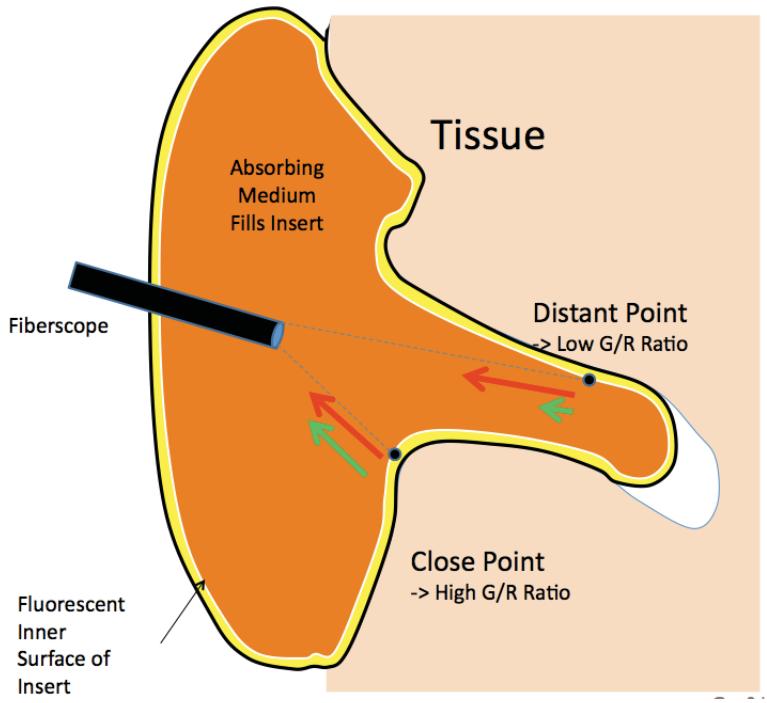
7.16.7. Ear Topology Transform

The LantosView Application software converts the sequence of video images into a cumulative topology model of the external ear canal, visible to the user.

As shown in Figure 7-28 below, a fluorescent dye embedded in the inside surface of the conforming membrane absorbs visible blue light illumination, and emits in longer wavelengths, Red and Green, from each individual point on the membrane surface. The emitted light travels through the absorbing medium, which selectively absorbs the Green emission. The distance to each point on the surface can be calculated from the ratio of Green to Red light detected at that point.

Figure 7-28: 3D Point Collection



The individual points collectively form a point cloud, which is converted by well-known 3D reconstruction techniques to a mesh of triangles, a closed surface. Each raw video image of the membrane interior surface, shown in the left half of Figure 7-29, below, is converted to a 3D mesh surface representing a significant portion of the external ear canal, shown in the right half of Figure 7.29..

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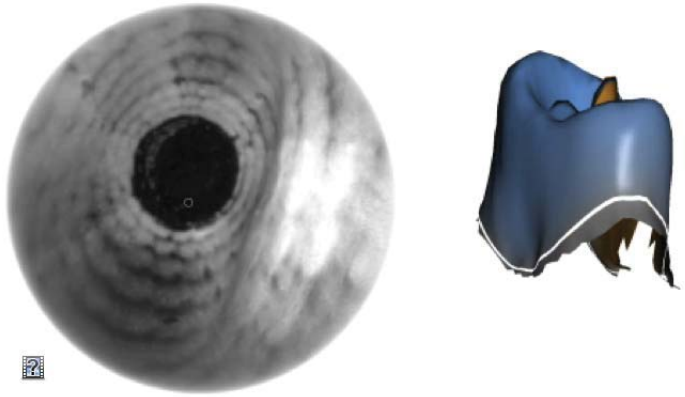
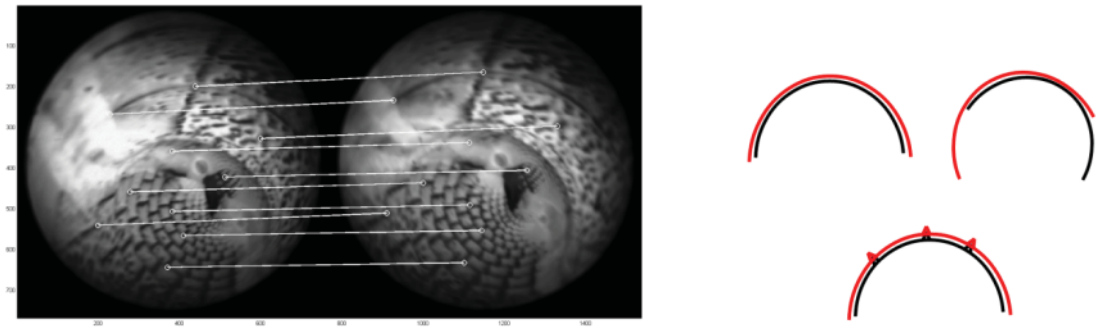
Figure 7-29: 3D Mesh Surface from Single Raw Image



The individual 3D mesh surface fragments are joined together by two methods, with 2D image stitching, identifying and aligning similar features in the sequential raw images, as shown in the left half of Figure 7-30, below, and with 3D surface stitching, identifying similar 3D features in the sequential raw images, as shown in the right half of Figure 7.30. The algorithm intelligently transforms the sequence of meshes into the cumulative topology of the entire external ear.

Figure 7-30: 3D Mesh Surfaces - Stitching



7.16.8. Measurement of Dynamics

For many subjects, the external ear canal moves with jaw or head movement. By extending the methods described immediately above, the Scanner can take a time series of 3D topology measurements, align the measurements, and show an image to the hearing professional of the difference over time. For example in Figure 7-31, below, a cross section through the ear canal shows how the canal shape changes.

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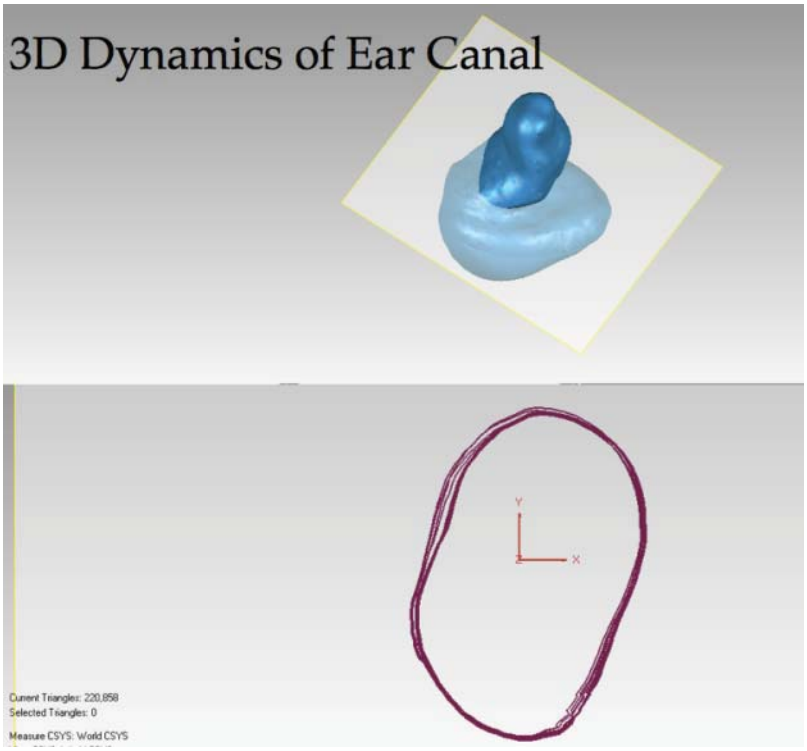
Figure 7-31: Ear Canal Dynamics



7.17. Specifications

The Device System Specification(s) and a full description of the System software functionality can be located in Attachment II, as follows.

The Design Input Requirements for the device are in Attachment II, Section 12.1. The more specific requirements for the optics and the illumination are in the Design Requirements for the Optics and Illumination Subsystem in Attachment II, Section 12.2. The Single Patient Use Disposable Requirements are in Attachment II, Section 12.3.

The Software Requirements Specification is in Attachment II, Section 12.4. Details on the software design are in Attachment II, Section 12.5. The Traceability Matrix for the Software is in Attachment II, Section 12.6.

7.18. Software

7.18.1. Software Overview

7.18.2. Software level of concern

Software controls the operation of the Lantos 3D Ear Scanner. Lantos Technologies has followed the FDA "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices" dated May 11, 2005. The requirements from this guidance are identified below.

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Table 7-2a: Major Level of Concern

	If the answer to any <u>one</u> question below is Yes, the Level of Concern for the Software Device is likely to be Major.
1.	Does the Software Device qualify as Blood Establishment Computer Software? **NO**
2.	Is the Software Device intended to be used in combination with a drug or biologic? **NO**
3.	Is the Software Device an accessory to a medical device that has a Major Level of Concern? **NO**
4.	Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following: **NO**
a.	Does the Software Device control a life supporting or life sustaining function? **NO**
b.	Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators? **NO**
c.	Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury? **NO**
d.	Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death? **NO**
e.	Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary? **NO**

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Table 7-2b Moderate Level of Concern

If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern? **NO**
2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device? **NO**
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury? **NO**

Based on the answers to the questions in Table 7-2, the level of concern for the software is Minor.

In accordance with the FDA Guidance, the following information is included in this pre-market notification.

Table 7-3 : Guidance Based Content of this Pre-Market Notification

SOFTWARE DOCUMENTATION	MINOR CONCERN
Level of Concern	A statement indicating the Level of Concern and a description of the rationale for that level.
Software Description	A summary overview of the features and software operating environment.
Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigations.
Software Requirements Specification (SRS)	Summary of functional requirements from SRS.
Architecture Design Chart	No documentation is necessary in the submission.
Software Design Specification (SDS)	No documentation is necessary in the submission.
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing.
Software Development Environment Description	No documentation is necessary in the submission.
Verification and Validation Documentation	Software functional test plan, pass / fail criteria, and results.
Revision Level History	Revision history log, including release version number and date.
Unresolved Anomalies (Bugs or Defects)	No documentation is necessary in the submission.

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7.19. Detailed Software Description

7.19.1. Programming Language

Application Software - Built with the Microsoft Visual C++ 2010 compiler.

(b)(4)

[redacted]

7.19.6. Software Hazards

7.19.6.1. Overview

The Lantos 3D Ear Scanner generates, provides for view, and stores images of the external ear canal and tympanic membrane. The images are not intended for diagnostic purposes. Failure to generate, show or store the images presents no identified hazards to the patient or the hearing professional.

If the Scanner fails to generate, show, or store images, it will not meet the requirements for intended use, and presents considerable inconvenience to the user and the patient. Risk analysis techniques were applied to mitigate the potential failures to perform as intended.

Potential failures to perform due to the User Interface software identified in the risk analysis included:

- Poor User Interface Design
- Distractions

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- Misinterpretation
- Inadequate Controls
- Loss of Control

Mitigations include extensive evaluation of the UI by experienced practitioners, compliance with UI design standards, and testing by teams with human factors training.

Potential failures to perform due to management of patient data included:

- Data corruption during write, storage, or retrieval
- Data corruption during transmission
- Misleading data presentation

Mitigations include data set protection with indications of corruption (HASH tags), verification upon retrieval and following transmission, and competent clinician interpretation of images.

Full details are in the complete risk analysis provided in Attachment I.

7.19.6.2. Database

The Scanner takes advantage of the file system supplied with the Operating System to store image files to disk, both raw and processed. The files may be later retrieved and viewed by the hearing professional. As determined by the risk analysis, a failure to store or retrieve a particular image file for a subject, while a commercial inconvenience, presents no hazards to the subject or the hearing professional. Verification of the file system database was performed to confirm performance to meet expressed user requirements.

7.19.6.3. Firmware

The Scanner includes firmware which links the LantosView Application software to the image sensor, to the illumination control, to the operation buttons, and to the fluid and probe drive motors. The firmware functions under the direct control of the LantosView Application. Hazards were analyzed and verifications performed at the device system level, recognizing this software architecture.

7.19.7. Software Requirements Specifications

Software specifications were defined by Interview with the processes identified and refined using input screens. Successive interviews refined the processes. A copy of the Traceability Matrix is in Attachment II, Section 12.6.

7.19.8. Software Design Specification

7.19.8.1. Software Subsystems

Application software in the Laptop interacts with firmware in the Scanner to meet the software requirements. The application software controls the device at the system level, provides the user interface, processes raw images, and presents 2D and 3D image visualizations. The firmware controls the device hardware, drives motors, drives LEDs for illumination, and configures and reads the image sensor.

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7.19.8.2. Application Software Workflow

The Application software leads the user through a series of interactions to prepare for the ear exam, and guides the user through the exam and the dimensional measurement.

An introductory screen permits the user to configure the device, to review past history, or to start a new scan.

Figure 7-32 – Introductory Screen

(b)(4)

[redacted]

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Figure 7-33 – Register Disposable

(b)(4)

[redacted]

As directed by the Application, the user inserts the disposable into the scanner until secure, then notifies the device to proceed by pressing *Start Check*. The Application proceeds through a number of steps to assure the device and disposable are ready for use.

Figure 7-34 – Insert and Check Disposable

(b)(4)

[redacted]

When the check passes, the Application prompts for a three character scan ID, which is combined with the date and time, the device serial number, the disposable serial number, and the user ID to form a unique identifier for the scan. This three

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character code helps the user associate scans with patients. The clinical records of the hearing professional must note the code used for the patient, as this is not a function of the Ear Scanner software.

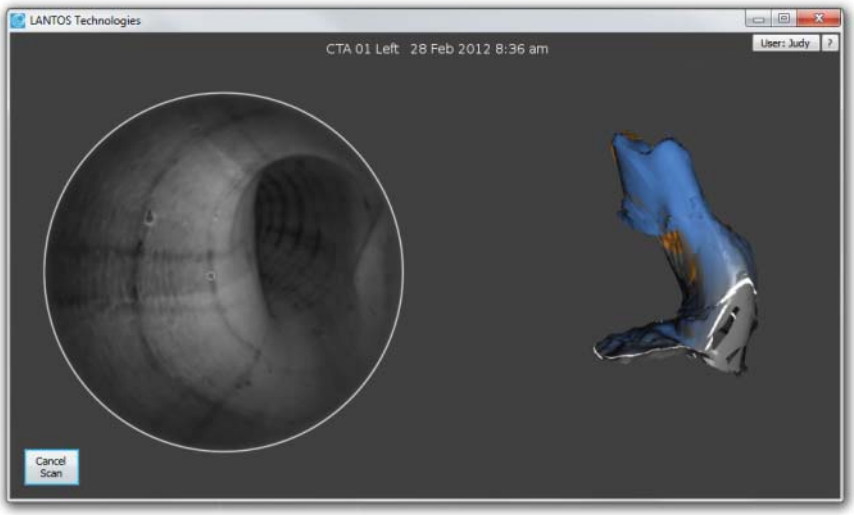
Figure 7-35 – Scan ID Screen

(b)(4)

The user indicates which ear to scan.

The Application shows the Scan screen, which presents the live view through the scope tip in the circle on the left, for both video otoscope exam mode, and for the 3D topology measurement. On the right is the accumulated topology measurement.

Figure 7-36 – Scan Screen



Under various circumstances, the Application presents error indications, to guide the user

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[redacted]

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(b)(4)

[redacted]

7.20. Data Structures

(b)(4)

[redacted]

7.21. Data Integrity

(b)(4)

[redacted]

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(b)(4)

[redacted]

7.22. Memory management

(b)(4)

[redacted]

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7.23. Application Software - Class Hierarchy

Figure 7-40 – Software Class Hierarchy

(b)(4)

[redacted]

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7.24. Application Software - Class View

Figure 7-41 – Software Class View (two pages)

(b)(4)

[redacted]

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[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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8. Device Labeling

The primary device labeling for the Lantos 3D Ear Scanner includes:

1. 3D Ear Scanner Device Kit Label
2. Multi-Pack of Single Use Disposables Label
3. Single Use Disposable Label
4. Scanner Body Label
5. Instructions for Use
6. Promotional Flyer

8.1. Labels Affixed to the Device

Figure 8-1 – 3D Ear Scanner Device Kit Label

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Figure 8-2 – Multi-Pack of Single Use Disposables Label

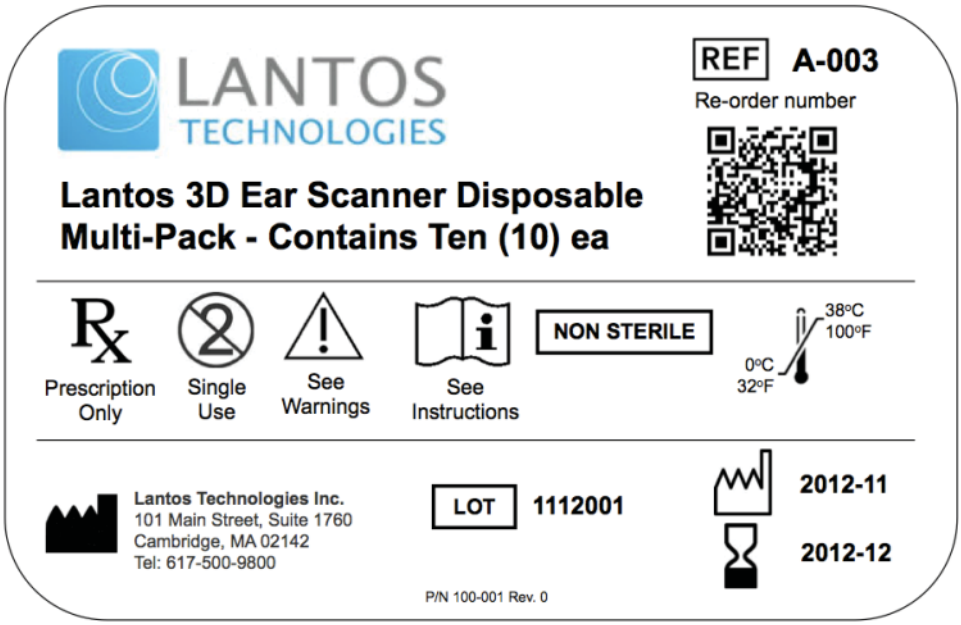

Figure 8-3 – Single Use Disposable Label

Figure 8-4 – Scanner Body Label

Instructions for Use – See Attachment V, section 15.1

Promotional Flyer - See Attachment V, section 15.2

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9. Design Controls (verification and validation)

9.1. Design Controls Process

Lantos Technologies utilizes written procedures which define the Design and Development processes. These processes are defined in Lantos Technologies Design Control Procedures. The activities to develop the Lantos 3D Ear Scanner followed the requirements of the Design Control Procedure. The Company maintains written documentation on each element of the Design Control Plan. This documentation is maintained in the Design History File. Table 9-1, below indicates the major elements of the design documentation which are on file for the Lantos 3D Ear Scanner. Figure 9-1 depicts the design control process used with the development of the Lantos 3D Ear Scanner.

Lantos 3D Ear Scanner System DHF Elements
• Project Plan • Product Requirements Document • Risk & FMECA Analysis • Design Specifications • Review Notes • Verification Plans/Reports/Data • Validation Plans/Reports/Data • Labeling • Design Review/Quality Audit(s) • Reference to Released DCR's

Table 9-1: DHF Elements

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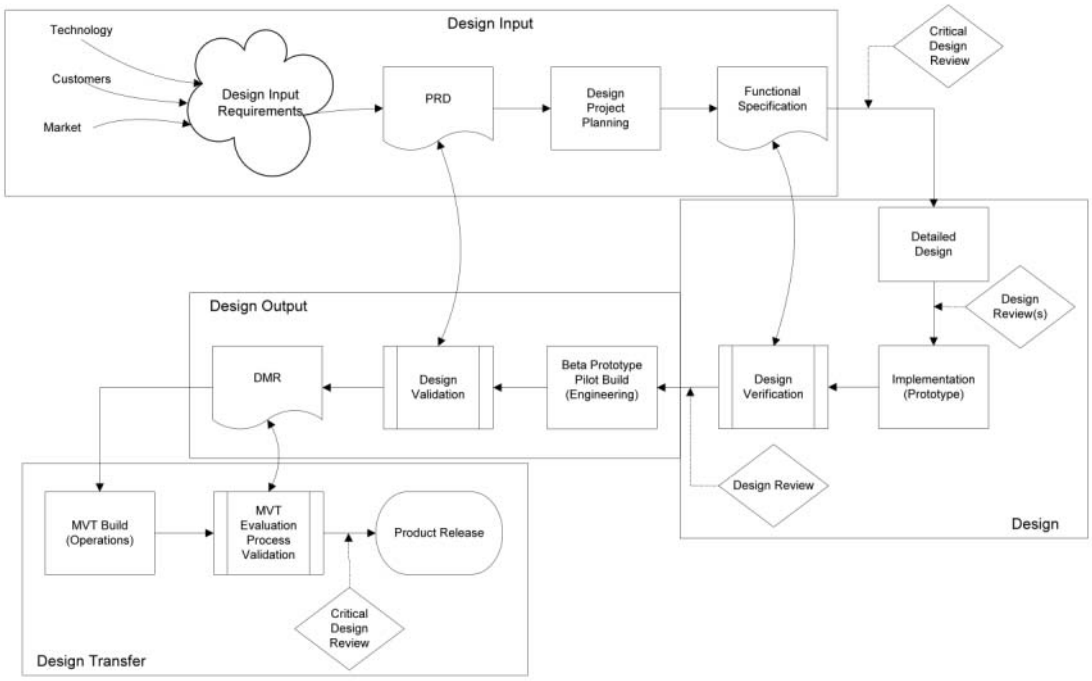
Figure 9-1: Block Diagram – Lantos Design Control Procedure



9.2. Risk Analysis

In the course of product and process development, Lantos conducted a risk analysis for the Lantos 3D Ear Scanner. The risk analysis was performed in accordance with the recognized standard ISO 14971. A copy of the Risk Analysis is provided in Attachment I. The Standards data form in support of the declaration of conformity for ISO 14971 is in Section 3.

9.3. Specific Hazards Analysis

The hazards analysis was conducted in accordance with ISO 14971. All potential hazards associated with the device in both normal and fault conditions were recorded, along with probable causes of the hazards. The record of hazards is included in Attachment I, Section 11.1, as the Risk Management File, Hazard Identification.

The potential hazards were analyzed according to probability and severity. Mitigations were identified and implemented where necessary. The analysis is included in Attachment I, Section 11.2 as the Risk Management File, Hazard Analysis.

9.4. Electrical Safety

The power supply (AC/DC converter) included with the Lantos 3D Ear Scanner, which provides the basis for electrical safety, has been fully tested and certified by a recognized third party laboratory (TUV) for compliance to IEC 60601-1, see Attachment IV, Section 14.6a and 14.7.

Additional safety testing was performed to both the IEC 60601-1 and IEC 60601-2-18 standards on the complete Lantos 3D Ear Scanner, with all components. This testing incorporated the approved (TUV) power supply. The following is a summary of the testing that was performed on the device:

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Standard	Test Clause(s)	Description	Result
IEC 60601-1	4.11	Power Input	Pass
IEC 60601-1	8.7	Leakage Current	Pass
IEC 60601-1	8.8.3	Dielectric Strength	Pass
IEC 60601-1	11.11.1	Excessive Temperature including Applied Parts	Pass
IEC 60601-1	13.2.6	Leakage of liquid (Optical Medium)	Pass
IEC 60601-2-18	201.5.1, 201.6.2, 201.8.3,	Protection Against Electric Shock (Type BF)	Pass
IEC 60601-2-18	201.10.5	Visible Electromagnetic Radiation (from LEDs)	Pass
IEC 60601-2-18	201.11.1	Excessive Temperature including Applied Parts	Pass
IEC 60601-2-18	201.11.6	Leakage of liquid (Optical Medium)	Pass
IEC 60601-2-18	201.15.4.1	Construction of connectors	Pass

Table 9-2: IEC 60601 Safety Testing

IEC 60601 Verification reports are in Attachment IV – Sections 14.6 and 14.8.

Further testing will be conducted prior to commercial distribution to meet the acceptance criteria specified in the applicable voluntary standards AAMI / ANSI IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance and the applicable parts of IEC 60601-2-18: Edition 3.0 2009-08, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment. A recognized third party laboratory will be utilized to perform the testing. Lantos will submit the IEC 60601-1 and IEC 60601-2-18 test reports to the 510(k) file upon completion of the testing.

9.5. Pre-clinical Biocompatibility and In-Vivo Studies

9.5.1 Biocompatibility Studies

The following studies were conducted to assess biocompatibility with materials that would come into contact with the user or patient:

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Standard	Test	Components Tested	Result
ISO 10993-10	**Tests for Irritation and Skin Sensitization**	**Absorbing Medium** (Contained in normal use – may contact skin in event of leak)	**PASS** VII – 17.4
ISO 10993-10	**Intracutaneous Reactivity**	**Conforming Membrane** Valve Cartridge Reservoir	**PASS** VII – 17.1
ISO 10993-5	**Cytotoxicity – MEM Elution**	**Conforming Membrane** Valve Cartridge Reservoir	**PASS** VII – 17.2
ISO 10993-10	**Murine Local Lymph node assay**	**Conforming Membrane** Valve Cartridge Reservoir	**PASS** VII – 17.3

Table 9-3: Summary of Biocompatibility Studies

Please refer to Section 17; Attachment VII for Protocols and reports. FDA Standards Verification Forms have been included in Section 3.0, above.

9.5.2 In-Vivo Studies

There have been two In-vivo studies using the Lantos 3D Ear Scanner. One was done at the Tripler Army Medical Center in Hawaii, the other at South Shore Hearing center in Massachusetts.

The Tripler study was fully designed and funded by the US Army and was intended to serve as a study to evaluate the use of the Lantos Scanner for the end use of custom hearing protection. The endpoints of the study were efficacy related to the specific ear mold technique in use at the TAMC. There were, however safety evaluations. While this study was not designed to provide specific Lantos safety and effectiveness data, it does provide sufficient information to assess device safety and to some degree, effectiveness for the use intended by the Army. The final study report and IRB closure is not completed as of the filing of this 510K, however, an interim report which assessed adverse events is provided in Section 16, Attachment VI. Protocols, IRB approvals, and consents are included along with the interim report. It is our belief, that for a Class I device, normally exempt from 510K, this study provides sufficient data to address any new questions of safety or effectiveness raised by the new technology.

The second study was a user preference study, intended to gather information about the usability, ergonomics, and human factors for the Lantos Scanner. Despite the non-significant risk determination for this type of device and its Class I designation, an IRB approval was required and obtained. Copies of the protocols, consent, and IRB approvals, along with the study report are provided in Section 16 Attachment VI. As the report demonstrated, we obtained valuable feedback from users which have been incorporated into the device design, and in addition we assessed device safety by monitoring adverse events; there were none. It is our belief that for a Class I device, normally exempt from 510K, this study provides sufficient data to address any new questions of safety or effectiveness raised by the new technology.

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10. Predicate Device and Comparative information

10.1 510(k) Numbers and Product Codes of Equivalent Devices

Welch Allyn Video Otoscope VideOtoscope (Skaneateles Falls, NY)
Welch Allyn Otoscope; K943916 – SE 25-AUG-1994
Code: ERA; 874.4770

10.2 510(k) Discussion of similarities and differences between the Lantos 3D Ear Scanner and the Welch Allyn Video Otoscope

10.2.1. Indications for Use

The Lantos 3D Ear Scanner and the Welch Allen Video Otoscope have very similar intended uses.

The Welch Allyn Vide Otoscope is similar to and predicated upon two different Welch Allyn devices already in commercial distribution. The device combines a common otoscope design with the previously 510(k) approved Welch Allyn LCI-200 Illumination and Imaging System (K940270/A) and incorporates a camera attachment in place of the magnifying view window on the otoscope. Additionally the Video Otoscope has the same operating principles and intended use as many competitive video otoscopes already in commercial distribution.

The Video Otoscope's intended use is to non-invasively examine the external ear canal and tympanic membranes in children and adults. The practitioner will use a common ear speculum to cover the otoscope tip; the speculum contacts and reshapes the patient's ear canal when inserted. The image of the ear is picked up by a camera in the otoscope head and then transmitted to a video processor for display on a computer screen.

In addition to visually inspecting the ear, the Video Otoscope has an additional intended use to provide pneumatic otoscopy, which is used to examine the ear canal and tympanic membrane under slight varying applied pressure. The user attaches a pneumatic source to the otoscope, inserts the speculum so it conforms tightly to the ear canal wall, forming a seal, and then inserts and withdraws air, changing the pressure applied to the external ear canal and tympanic membrane, while observing the image.

The Lantos 3D Ear Scanner shares the intended use to non-invasively examine the external ear canal and tympanic membrane. Instead of a common ear speculum, the user covers the Scanner tip with the conforming membrane with view window. The magnification, illumination, and field of view are similar, as are the displayed images on the computer screen.

The primary difference between the predicate device and the Lantos 3D Ear Scanner is the additional intended use. Instead of pneumatic otoscopy, the Scanner uses the conforming membrane to create a topology measurement of the external ear canal. For the topology measurement, the user inserts the probe and conforming membrane into the ear canal, expands the membrane until it conforms tightly to the ear canal wall, while observing the individual 3D images and the cumulative topology image.

The Welch Allyn Video Otoscope also differs in that it is indicated for all age groups. The current intended use of the Lantos 3D Ear Scanner is limited to adult patients. This difference is due to the lack of testing of the Lantos 3D Ear Scanner in pediatric patients. This will be the subject of a later 510k with clinical data on safety.

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10.2.2 Target Population

The primary difference in target population between the welch Allyn Video Otoscope and the Lantos 3D Ear Scanner is the exclusion of the pediatric population. For adult patients, either the common ear speculum, Video Otoscope, or the conforming membrane, Lantos 3D Ear Scanner, will contact the walls of the ear canal. Appropriate clinical judgment and caution is advised with both devices for use in patients with known ear infections or perforated eardrum(s).

10.2.3 Product Labeling

The product labeling for the Welch Allyn Video Otoscope is included in Section 13, Attachment III, the labeling for the Lantos 3D Ear Scanner is provided in Section 15, Attachment V. The differences in the labeling are primarily due to the differences in technological characteristics and different operating principles of the two devices. The end result of both devices is to provide a video image of the external ear.

10.2.4. Performance Characteristics

The Video Otoscope and the Lantos 3D Ear Scanner share many performance characteristics; they also have differences, as follows.

Both devices include a series of lenses in a small tube that can be inserted in the ear canal, with optics designed to collect and project an image onto a camera sensor. Both devices send the resulting digital sensor images over a cable to a video processor in an attached computer, for display to the user. Both devices provide magnified, wide angle, high-resolution views of the ear canal. For both devices, the user must manipulate the device and the patient's outer ear to obtain a composite view of the ear canal.

The Video Otoscope includes a Halogen white light source, coupled through a fiber optic bundle to project a cone of light from the scope tip. The 3D Ear Scanner also couples light through a fiber optic bundle to project a cone of light from the scope tip, but differs in that the white light source is a mixed output of red, green, and blue LED die, and that the resulting color mix varies under software control for different operating modes. Both light sources can be powered either by battery or by wall power.

The Video Otoscope uses both disposable and reusable specula to cover the probe tip, and to reshape the ear canal for viewing. In use, the speculum is intermittently in tight contact with the canal wall, contacting varying surface area depending on placement by the user. The specula are available in various sizes, chosen by the user to accommodate canal size. In contrast the 3D Ear Scanner includes a single patient use disposable with conforming membrane, which expands to conform to the ear canal wall, to shape the canal for viewing, and to provide a known viewing surface. The conforming membrane generally contacts a greater surface area than the speculum, for about the same period of time. The conforming membrane is liquid filled soft silicone. The specula come in many varieties, typically flexible polyethylene for disposable, or polypropylene for reusable. From a viewpoint of substantial equivalence, the conforming membrane (balloon) used in the Lantos Ear Scanner is substantially equivalent to the Specula in the predicate device.

The Video Otoscope requires a closed system with a tight seal for pneumatic otoscopy. The user inserts the scope with covering speculum into the ear canal, compresses the speculum against the canal wall to form the seal, and then squeezes a rubber bulb connected by channel to the distal side of the seal by a flexible tube to increase the air pressure. The 3D Ear scanner uses a closed system for the topology measurement. The user inserts the scope with covering

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conforming membrane into the ear canal, expands the membrane to conform to the ear with liquid from a motor driven reservoir in the scanner, connected by tube to the membrane, then retracts the probe tip to create the topology measurement.

10.2.5. Physical and Technical Characteristics

The illustrations and tables below of this section are used in lieu of text to demonstrate the physical and technical characteristics of the Lantos Ear Scanner, as compared to the Predicate. For example, Figures 10-1 and 10-2, below show the intended use and user interface as nearly identical. The physical and technological characteristics are similar with respect to the capture and display of video images, the differences relate more to the methods by which the images are further processed by the application software, and the fact that the Lantos Ear Scanner provides a 3D image file along with the video image. However, these differences are minor with respect to substantial equivalence as described by regulation and FDA Guidance.

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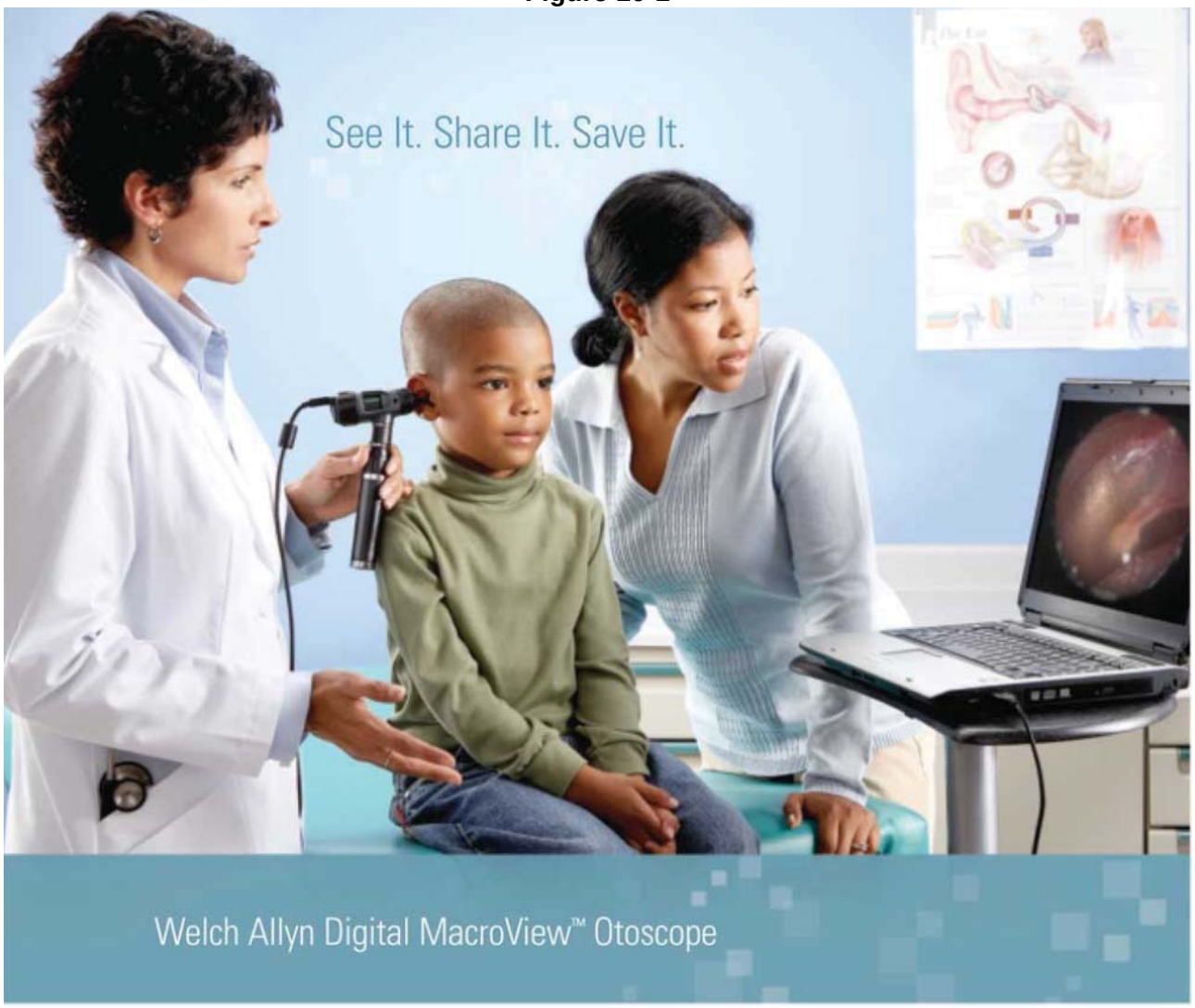
Figure 10-1, below depicts the use of the Welch Allyn VideOtoscope

Figure 10-1



The Welch Allyn Digital MacroView Otoscope is a simple, affordable tool that lets you see, explain, and save digital images of the ear.

Offering you clear, live and still images of the ear canal and tympanic membrane, the Digital MacroView™ Otoscope is a valuable tool in support of the treatment and management of your patients' ears. Easy to learn and use, the Digital MacroView is a plug and play system requiring no additional purchase of software.

Here's how the Welch Allyn Digital MacroView Otoscope can benefit you:

- Improves communication which can lead to better patient compliance
- Allows you to store digital images in patient records for enhanced documentation of exam findings
- Provides you the ability to share images with other providers as visual descriptive reference
- Gives you an excellent training aid for educational purposes
- Offers you the ability to view small details of tubes and hearing aids

Welch Allyn®
Advancing Frontline Care™

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In comparison, Figure 10-2, below depicts the use of the Lantos 3D Ear Scanner. The form factor, components, and clinical use environment are nearly identical to the Predicate..

Figure 10-2: Lantos Ear Scanner in Use

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Both the Lantos 3D Ear Scanner and the Predicate device have very similar Specifications. For comparison, the published specifications for the predicate and the Lantos Ear Scanner are provided below. There are greater similarities than differences in the two specifications.

The following table has the Specifications for the Welch Allyn Video Otoscope.

4 Specifications

Item	Specification
Weight	Approximately 95 g (0.2 lb)
Dimensions (approximate)	Height: 7.0 cm (2.8 inches) Length: 10.2 cm (4.0 inches) Width: 3.7 cm (1.5 inches)
Rating	Lamp: 3.5Vdc, 810 mA USB: 5.0Vdc, 150 mA
Protection against ingress of water	IPXØ
Operating conditions Temperature Relative humidity Altitude	 +10° C to +40° C (+50° F to +104° F) 30% to 75% noncondensing 700 to 1060 hPa
Shipping and storage conditions Temperature Relative humidity	 -20° C to +49° C (-4° F to +120° F) 95% noncondensing max.
Intermittent operation	≤ 2 minutes on, ≥ 10 minutes off between uses
Safety, EMC, and regulatory compliance	CAN/CSA C22.2 No. 601.1-M90, including amendments 1 & 2 EN/IEC 60601-1 EN/IEC 60601-1-2 UL 60601-1
Patents	Patents Pending

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The following table has the Specifications for the Lantos 3D Ear Scanner.

Specifications

Handheld Scanner

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[redacted]

Environment

Operating Conditions
- 10° C to 40° C
- 30% to 85% R.H. noncondensing
- 700 to 1060 hPa Altitude

Shipping and Storage Conditions
- -15° C to 49° C
- 95% R.H. noncondensing max

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10.2.6. Performance Standards

Both the Lantos 3D Ear Scanner and the predicate device meet the same performance standards. FDA has not adopted or published any special controls under 21CFR874.4770, however, all devices in this category are expected to meet the following recognized consensus standards:

- IEC 60601-2-18:1996 Amendment 1
  2000 Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment

- IEC 60601-2-18: Edition 3.0 2009-08 Medical
  electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

10.2.7. Safety Characteristics

The Lantos 3D Ear Scanner and the predicate device have similar safety characteristics. Differences relate to the technological methods used to capture the video image of the ear and the use of the conforming membrane in the Lantos 3D Ear Scanner as compared to the speculum in the predicate. Both the Lantos 3D Ear Scanner and the predicate device use fiber optics to carry visible light illumination to the probe tip.

10.2.8. Comparison Table

The Comparison Table on the following page shows similarities and differences between the Lantos 3D Ear Scanner and the predicate device.

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Comparison Table

	(K943916)	Lantos 3D Ear Scanner (NEW)
Intended use	The VideOtoscope's intended use is to non-invasively examine the external ear canal and tympanic membranes in children and adults. The practitioner will use a common ear speculum to cover the otoscope tip; the speculum contacts and reshapes the patient's ear canal when inserted. The image of the ear is picked up by a camera in the otoscope head and then transmitted to a video processor for display on a computer screen. The VideOtoscope has an additional intended use to provide pneumatic otoscopy, which is used to examine the ear canal and tympanic membrane under slight varying applied pressure.	The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal. The Lantos 3D Ear scanner: provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation and; includes an expanding conforming membrane which aids observation when inserted in the ear canal and; records and presents to the hearing professional in an image file a topology measurement of the external ear canal.
Target population	Patients requiring a visual inspection of the ear.	Patients requiring a visual inspection of the ear. Excludes pediatric patients.
Where used	Independent ear examination clinics, audiologist offices, hearing professional offices, hospital based clinics	Independent ear examination clinics, audiologist offices, hearing professional offices, hospital based clinics
Energy used and/or delivered	SELV DC Volts/Amps White Light	SELV DC Volts/Amps RGB mixed 'White' Light
Human factors	Welch Allyn requires correct positioning of the illumination source and speculum. Human factors are very similar. Use of the computer to see images and store data are similar.	Lantos 3D Ear Scanner requires expansion of a fluid filled membrane to obtain a complete 3D image of the ear. Human factors are very similar. Use of the computer to see images and store data are similar.
Physical Characteristics	[redacted]	

Rec(b)(4)

	Operating 10° C to 40° C 700 to 1060 hPa Altitude	Operating 10° C to 40° C 700 to 1060 hPa Altitude
Performance Characteristics	[redacted]	
Standards	UL 544 (patient vicinity) IEC 60601-1-2 - Medical Electrical Equipment – Part 1-2 – General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and Tests IEC 60601-2-18:1996 Amendment 1 2000 Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment	IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-1-2 Medical Electrical Equipment – Part 1-2 – General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and Tests IEC 60601-2-18: Edition 3.0 2009-08 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment FDA; Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices - May 2005 FDA Guidance; Cyber Security for Networked Medical Devices Containing Off the Shelf Software ISO 14971: Medical devices—Application of risk management to medical devices ISO 10993 Parts 1-13 as Applicable

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

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510k Attachments

11. **Attachment I** - ISO 14971 Risk Assessment
    - 11.1 List of Hazards
    - 11.2 Hazard Analysis

12. **Attachment II** – Specifications
    - 12.1 System Requirements
    - 12.2 Scanner Requirements
    - 12.3 Single Use Disposable Requirements
    - 12.4 Scanner Software Requirements Specification
    - 12.5 Scanner Software Design Specification
    - 12.6 Traceability Matrix

13. **Attachment III** Predicate Device Information
    - 13.1 User Guide (Predicate User manual)
    - 13.2 Website document (predicate)
    - 13.3 Predicate 510(k) K943916

14. **Attachment IV** - Verification & Validation Documents
    - 14.1. System Verification
    - 14.2. Software Verification
    - 14.3. Software Verification Unit
    - 14.4 Single Use Disposable Verification
    - 14.5. Cleaning Validation
    - 14.6. IEC 60601-1
    - 14.7 IEC 60601-2 (statement and certification)
    - 14.8. IEC 60601-2-18
    - 14.9. Software Revision History

15. **Attachment V** – Labeling (Manuals)
    - 15.1. User Manual
    - 15.2. Promotional Flyer
    - 15.3. Training Manual

16. **Attachment VI** - Clinical Studies
    - 16.1 Tripler Army Medical Center Protocol & consent
    - 16.2 Tripler Report
    - 16.3 South Shore Hearing Center Protocol – User Preference Study
    - 16.4 South Shore Hearing Center Report

17. **Attachment VII** – Biocompatibility Reports
    - 17.1 ISO 10993-10: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization – Intracutaneous Reactivity
    - 17.2 ISO 10993-5: Biological Evaluation of Medical Devices, Part 5: Cytotoxicity – MEM Elution
    - 17.3 ISO 10993-10: Part 10: Tests for Irritation and Skin Sensitization; Murine Local Lymph node assay
    - 17.4 ISO 10993-10: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization

18. **Attachment VIII** – Engineering Drawings - Materials

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11. Attachment I - ISO 14971 Risk Assessment

11.1. List of Hazards

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Risk Management File

Identification of Possible Hazards

Team	Ben FrantzDale, Federico Frigerio, Manas Menon, Daniel Vlasic, Doug Johnston, Alban De Brouchoven, Shahid Azim
Date Start / Complete	05-Apr-2012 / 10-Apr-2012 (update of Sep-2011 version)
Product	**Lantos 3D Ear Scanner**
Product Description	The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal. The Lantos 3D Ear Scanner: ▪ provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation ▪ includes an expanding conforming membrane which aids observation when inserted in the ear canal ▪ records and presents to the hearing professional in an image file a topology measurement of the external ear canal
Document Description	This document is part of the Risk Analysis for the device. Questions from Annex C in ISO 14971, and market research, were used to identify possible hazards associated with the device. Identified hazards will be subject to Risk Analysis. The complete Risk Analysis for the device includes: • Identification of Possible Hazards • Risk Analysis • System Risk Assessment

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Medical Device Characteristics that could create Hazards

Question / Characteristic / Possible Hazard	Hazard with Normal Use?	Hazard with Fault?	Not Applicable	Comments
C.2.1 What is the intended use and how is the medical device to be used?				
C.2.1.1 Misleading Video Otoscope Images	No	No		Evaluate image freeze, orientation
C.2.1.2 Incorrect Dimensional Scan Result	No	No		Failure to perform not a Hazard
C.2.2 Is the medical device intended to be implanted?			NA	
C.2.3 Is the medical device intended to be in contact with the patient or other persons?				
C.2.3.1 Contact of Conforming Membrane with intact skin, sensitivity	No	No		Materials biocompatible
C.2.3.2 Release of Absorbing Medium, skin sensitivity	No	No		Materials biocompatible
C.2.3.3 Probe tip sharp edges causes cuts or abrasions, leads to skin or TM puncture	No	YES		
C.2.3.4 Scanner enclosure causes cuts or abrasions to operator	No	YES		
C.2.3.5 Contact of conforming membrane with skin wounds	YES	--		Usage contraindicated
C.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?				
C.2.4.1 Skin sensitivity to Conforming membrane, to Absorbing Medium, to Cartridge, to Reservoir Bulb, to Tubing materials	No	No		Test or evaluate materials for skin sensitivity
C.2.4.2 Enclosure materials incompatible with intact skin	No	No		

Question / Characteristic / Possible Hazard	Hazard with Normal Use?	Hazard with Fault?	Not Applicable	Comments
C.2.5 Is energy delivered to or extracted from the patient?				
C.2.5.1 Excessive Visible Light Energy	No	No		
C.2.5.2 Excessive Pressure from Conforming Membrane expansion	No	No		Operator controlled expansion, limited volume, outer ear overflow relief
C.2.6 Are substances delivered to or extracted from the patient?			NA	
C.2.7 Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?			NA	
C.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?				Consider toxicity, allergenicity, mutagenicity, oncogenicity, carcinogenicity Consider effect of degradation
C.2.8.1 Violating Single Patient Use Control leads to cross contamination	No	YES		
C.2.8.2 Poor Contamination Control, Shelf Life Control of disposable components lead to contamination	No	YES		Packaging must maintain moderate disinfection for contact with intact skin
C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user?				
C.2.9.1 Poor Scanner body disinfection control leads to cross contamination	No	YES		
C.2.10 Is the medical device intended to modify the patient environment?				
C.2.10.1 Excessive Pressure in Ear Canal	--	--		Redundant – see C.2.5.2

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Question / Characteristic / Possible Hazard	Hazard with Normal Use?	Hazard with Fault?	Not Applicable	Comments
C.2.11 Are measurements taken?				
C.2.11.1 Incorrect Dimensional Scan of Ear	No	No		Failure to perform not a Hazard
C.2.12 Is the medical device interpretative?			NA	
C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?				
C.2.13.1 Incorrect sizing of Hearing Aid Shell based on dimensional scan	No	No		Failure to Fit not a Hazard
C.2.14 Are there unwanted outputs of energy or substances?				No ionizing radiation, no pressure vessels, minimal vibration, no acoustic pressure
C.2.14.1 Excessive Leakage current, electrical shock	No	YES		Exposure following damage or fault
C.2.14.2 Excessive Electric or Magnetic Fields, Radiation	No	YES		Exposure following damage or fault
C.2.14.3 Scanner body or probe tip overheats	No	YES		
C.2.14.4 Excessive visible light emission, strobe effect, retinal damage	No	YES		Visible to operator, not patient
C.2.14.5 Leakage, spillage of absorbing medium	No	No		
C.2.14.6 Motor driven optical probe impinges on ear canal wall	No	YES		Probe advances unexpectedly, uncontrolled
C.2.14.7 Motor driven fluid reservoir overfills membrane	No	No		Membrane can accept entire reservoir volume without damage – also C.2.5.2

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Question / Characteristic / Possible Hazard	Hazard with Normal Use?	Hazard with Fault?	Not Applicable	Comments
C.2.15 Is the medical device susceptible to environmental influences?				
C.2.15.1 Electric or Magnetic Fields, Susceptibility - Device operation compromised due to susceptibility after fault	No	No		Failure to perform not a Hazard
C.2.15.2 Operation outside specified Environmental conditions, including loss of power supply	No	No		Failure to perform not a Hazard
C.2.16 Does the medical device influence the environment?				
C.2.16.1 Generation of electromagnetic disturbance	No	YES		
C.2.16.2 Laptop falls from shelf, injuring patient or operator	YES	YES		
C.2.17 Are there essential consumables or accessories associated with the medical device?				
C.2.17.1 Device consumable not available for use	No	No		Failure to perform not a Hazard
C.2.18 Is maintenance or calibration necessary?				
C.2.18.1 Maintenance checks not performed, error results	No	No		Failure to perform not a Hazard
C.2.19 Does the medical device contain software?				
C.2.19.1 Incorrect software installation, operating software corrupted	No	No		Failure to perform not a Hazard
C.2.20 Does the medical device have a restricted shelf-life?				
C.2.20.1 Use of disposable beyond restricted shelf life, poor dimensional scan, degradation of materials leads to sensitivity	No	YES		Possible sensitivity hazard

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Question / Characteristic / Possible Hazard	Hazard with Normal Use?	Hazard with Fault?	Not Applicable	Comments
C.2.21 Are there any delayed or long-term use effects?			NA	
C.2.22 To what mechanical forces will the medical device be subjected?				
C.2.22.1 Inadvertent Physical abuse by user leads to fault – exposing energy nodes or sharp surfaces	No	YES		
C.2.23 What determines the lifetime of the medical device?				
C.2.23.1 Device performance degrades before specified lifetime	No	No		Failure to perform not a Hazard
C.2.24 Is the medical device intended for single use?				
C.2.24.1 Disposable components accidentally reused, leading to erroneous results or cross-contamination				Inadequate indication of prior use
C.2.25 Is safe decommissioning or disposal of the medical device necessary?				
C.2.25.1 Unsafe or wasteful disposal of components	YES	--		
C.2.26 Does installation or use of the medical device require special training or special skills?				
C.2.26.1 Inadequate training leads to misuse, possible injury to patient	YES	--		
C.2.27 How will information for safe use be provided?				
C.2.27.1 Incomplete transfer of IFU to operator	YES	--		
C.2.27.2 Inadequate safe use presentation on UI	YES	--		

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Question / Characteristic / Possible Hazard	Hazard with Normal Use?	Hazard with Fault?	Not Applicable	Comments
C.2.28 Will new manufacturing processes need to be established or introduced?				
C.2.28.1 Insufficient validation of new manufacturing processes	YES	--		
C.2.29 Is successful application of the medical device critically dependent on human factors such as the user interface?				
C.2.29.1 Poor UI Design contributes to user errors – control, indicators, ergonomics, hierarchy of operation, menus	YES	--		
C.2.29.2 Distractions cause user error	YES	--		Including cognitive recall errors
C.2.29.3 Improper insertion of probe into disposable cartridge	YES	--		
C.2.29.4 Misinterpretation of control interface	YES	--		Poor mapping of controls to actions
C.2.29.5 Misinterpretation of displayed information – including image orientation, and undetected frozen image	YES	--		Confusing or conflicting results
C.2.29.6 Misinterpretation of displayed menus, loss of control	YES	--		Confusing menu hierarchy
C.2.29.7 Inadequate controls for users with special needs	YES	--		
C.2.29.8 Loss of control by user, inadvertent mode switch	YES	--		Conflicting modes as compared to existing devices
C.2.30 Does the medical device use an alarm system?				
C.2.30.1 False negative or false positive alarm			NA	Notifications only – no alarms

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Question / Characteristic / Possible Hazard	Hazard with Normal Use?	Hazard with Fault?	Not Applicable	Comments
C.2.31 In what way(s) might the medical device be deliberately misused?				
C.2.31.1 Use as video otoscope without supplied membrane over probe tip, with alternative speculum	YES	--		
C.2.31.2 Use with membrane from non-approved supplier	YES	--		
C.2.31.3 Deliberate reuse of single patient use disposable components	YES	--		
C.2.31.4 Use by untrained, unskilled operator	YES	--		
C.2.32 Does the medical device hold data critical to patient care?				
C.2.32.1 Dimensional data corrupted during write to disk or storage	No	No		Failure to perform not a Hazard
C.2.32.2 Dimensional data corrupted during transmission	No	No		Failure to perform not a Hazard
C.2.33 Is the medical device intended to be mobile or portable?				
C.2.33.1 Probe damaged when transported or dropped; Laptop damaged when transported or dropped – exposing sharp edges or energy nodes	No	Yes		
C.2.34 Does the use of the medical device depend on essential performance?			NA	Competent operator always present during use Failure to perform not a Hazard

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11.2. Hazard Analysis

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Risk Management File – Hazard Analysis

Team	Ben FrantzDale, Federico Frigerio, Manas Menon, Daniel Vlasic, Doug Johnston, Alban De Brouchoven, Shahid Azim
Date Start/ Complete	05-Apr-2012 / 11-Apr-2012 (update of Sep-2011 version)
Product	**Lantos 3D Ear Scanner**
Product Description	The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal. The Lantos 3D Ear Scanner: • provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation • includes an expanding conforming membrane which aids observation when inserted in the ear canal • records and presents to the hearing professional in an image file a topology measurement of the external ear canal
Document Description	This document is part of the Risk Analysis for the device. From the list of possible hazards in ISO 14971, those applicable to the device were selected for further examination The complete Risk Management File for the device includes: • Identification of Possible Hazards • Hazard Analysis • System Risk Assessment

ID	Hazard Description	Severity	Cause	Occur-rence	Risk Index	Mitigation	Type of Mitigation	Mitigated Occur-rence	Mitigated Risk Index	Verific Refer
1	**C.2.1.1 C.2.1.2** **Misleading Image** Incorrectly presented Video Ototscope Image or Scan Image. Operating mistakes and errors in judgment.	Mod	Misinterpretation due to frozen image, image stream interrupted. Misinterpretation due to image orientation, capture or display hardware failure.	Occ	Neg	Software detects loss of real-time image stream, and presents dark screen to user. Image orientation auto-corrected for scanner orientation. Hardware design assures failures unlikely to present corrupt yet coherent images. Operators familiar with ear canal anatomy – unexpected image orientation readily apparent. In-service training for operators.	Design Test Training	Rare	Acc	
2	**C.2.3.3 C.2.3.4 C.2.22.1** **Cut, Skin Abrasion, Puncture** Patient or operator exposed to sharp edges when probe tip or scanner body damaged. Abrasion, cut or puncture from collision in ear canal.	Mod	Probe tip damaged in field, scanner body damaged in field. Scanner unwieldy in use. Inadvertent or intentional physical abuse by user.	Occ	Neg	Probe tip and Scanner enclosure designed with resilient medical grade plastics, coated metals, and medical grade bonding agents. Operator warned and trained to examine probe, scanner before use. Scanner form factor design similar to other tethered devices in common use in ear exams, handling techniques familiar to operators.	Design Labeling	Rare	Acc	
3	**C.2.3.1 C.2.3.2 C.2.3.5 C.2.4.1 C.2.4.2** **Skin Contact** **Skin Sensitivity** Contact of conforming membrane with intact skin with sensitivity to materials. Release of absorbing medium, skin sensitivity. Contact of conforming membrane with open sores, skin wounds. Contact of scanner enclosure with intact skin with sensitivity to materials.	Low	Conforming membrane touches intact skin in normal use. Absorbing medium released if conforming membrane tears or leaks while in ear canal. Operator misses open sore, or intentionally violates contraindication for scanning with open sore or wound. Operator handles Scanner – parts of scanner enclosure touch patient during normal use.	Occ	Acc	Conforming membrane and absorbing medium designed with materials known to be compatible for ear canal skin contact. Membrane from medical grade silicone in wide use for medical devices, including drainage tubes left in ear canals for long periods. Absorbing medium from distilled water and ingestible dye. All Materials verified via ISO-10993 test for compatibility. Contraindication for scan with open sore or wound consistent with long-standing contraindication for silicone impression of ear.	Design Test Labeling	Occ	Acc	

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ID	Hazard Description	Severity	Cause	Occur-rence	Risk Index	Mitigation	Type of Mitigation	Mitigated Occur-rence	Mitigated Risk Index	Verific Refer
4	**C.2.8.1 C.2.8.2 C.2.9.1 Contamination** Violating Single Patient Use Control leads to cross contamination. Poor Contamination Control, Shelf Life Control of disposable components leads to contamination. Poor scanner enclosure disinfection control leads to cross contamination.	Mod	Packaging fails to maintain bioburden safe for contact with intact skin. Mistakes in technique or handling. Single use components intentionally reused. Handling of scanner enclosure fails to maintain bioburden safe for contact with intact skin.	Occ	Neg	Packaging design incorporates standard medical grade materials and processes for controlling bioburden over component life. Packaging and manufacturing process verified via standardized test to control bioburden over time. Packaging form provides clear physical evidence when components have been used. Labeling clearly states single use. Users trained in proper procedure. Users are familiar with single use components from other ear exam procedures. Materials and cleaning procedures for scanner enclosure common in ear exam clinical environment – proven low risk in extended use.	Design Test Labeling	Rare	Acc	
5	**C.2.5.2 C.2.10.1 C.2.14.7 Excessive Pressure** Excessive pressure from Conforming Membrane expansion. Excessive negative pressure from Conforming Membrane removal.	Low	Conforming membrane intended to expand in ear with each use. Material or technique failure produces pressures beyond design limits. Membrane fails to collapse due to blockage or motor failure.	Occ	Acc	[redacted] (b)(4)	Design Test Training	Occ	Acc	

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ID	Hazard Description	Severity	Cause	Occur-rence	Risk Index	Mitigation	Type of Mitigation	Mitigated Occur-rence	Mitigated Risk Index	Verific Refer
6	**C.2.5.1 C.2.14.1** **Excessive Light Energy** **Eye Damage** Patient or operator exposed to non-ionizing radiation – visible light from probe tip. **Seizure** Patient or operator affected by Strobe effects from probe tip.	Low	Scanner emits light for ear canal viewing and for 3D scan. Amount of light may increase under circuit fault conditions. Probe light output pulsed.	Occ	Acc	[redacted] (b)(4)	Design Detection Test Labeling	Occ	Acc	
7	**C.2.14.1 C.2.14.2** **Electrical Shock** **Excessive Leakage Current** **Electrical or Magnetic Fields** Operator or patient exposed to Dangerous voltages or currents after device fault. Device emits excessive Electrical or Magnetic Fields.	High	Scanner has a ground fault. Scanner has an electrical fault.	Occ	Int		Design Test Labeling	Rare	Neg	
8	**C.2.14.3** **Burns** Scanner body or probe tip overheats, leading to burns of patient or operator.	Mod	Circuit failure leading to thermal runaway.	Occ	Neg		Design Detection	Rare	Acc	

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ID	Hazard Description	Severity	Cause	Occur-rence	Risk Index	Mitigation	Type of Mitigation	Mitigated Occur-rence	Mitigated Risk Index	Verific Refer
9	**C.2.14.5 Unwanted Substances** Leakage, spillage of Absorbing Medium. Fluid contacts skin of operator or patient. Fluid compromises electrical safety.	Low	Rupture of Reservoir, tubing or Conforming Membrane leads to release of Absorbing Medium fluid.	Occ	Acc	[redacted] (b)(4)	Design Test	Occ	Acc	
10	**C.2.14.6 Probe abrades wall** Motor driven probe tip touches or scrapes ear canal wall.	Mod	Uncontrolled or unexpected movements of probe tip in ear canal.	Occ	Acc		Design Detection Labeling	Rare	Acc	
11	**C.2.15.1 C.2.16.1 Electromagnetic Compatibility** Device emits radiation, which interferes with other devices, or device operation is affected by EMI from other devices.	Mod	Inadequate design or Electrical fault.	Occ	Neg		Design Test	Rare	Acc	

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ID	Hazard Description	Severity	Cause	Occur-rence	Risk Index	Mitigation	Type of Mitigation	Mitigated Occur-rence	Mitigated Risk Index	Verific Refer
12	**C.2.15.2 Environmental Influence** Operation outside specified Environmental conditions, including loss of power supply – device does not perform.	Low	Device handling, or loss of supply.	Occ	Acc	Failure to perform scans not a hazard, no injury to patient or operator.	Design Labeling	Occ	Acc	
13	**C.2.16.2 Falls** Laptop or scanner or docking stand falls from shelf or table, injuring patient or operator.	Low	Unstable shelf or improper device placement.	Occ	Acc	Laptop weight (< 10 lbs) and form unlikely to cause injury. Form factor familiar to operators.	Design	Occ	Acc	
14	**C.2.17 C.2.18 C.2.19 Availability of Scanner** Device consumable not available. Device maintenance not performed. Incorrect software installation.	Low	Missed process steps, device is unavailable for scan.	Occ	Acc	Failure to perform scans not a hazard, no injury to patient or operator.	Design	Occ	Acc	
15	**C.2.20.1 Restricted Shelf Life** Use of disposable beyond restricted shelf life, poor dimensional scan, degradation of materials leads to sensitivity	Mod	Materials degrade compromising early life sensitivity results.	Occ	Neg	Design with materials with known characteristics for similar exposure. Verification of shelf life via standardized testing.	Design Test	Rare	Acc	
16	**C.2.24.1 C.2.25.1 Single Use Disposable Disposal** Single Use Disposable component accidentally reused. Unsafe or wasteful disposal of device.	Low	Inadequate indication of prior use of disposable component. Improper disposal by user.	Occ	Acc	Foil seal of Single Use Disposable makes prior use apparent – seal cannot be re-attached. Software tracks Disposable use per attached QR code –detect reuse. Materials of disposable similar to other plastics used in clinical settings – proper disposal and recycling process familiar to operator. Materials safe for disposal with common trash. Instructions-for-Use provide disposal guidelines.	Design Labeling	Occ	Acc	

ID	Hazard Description	Severity	Cause	Occur-rence	Risk Index	Mitigation	Type of Mitigation	Mitigated Occur-rence	Mitigated Risk Index	Verific Refer
17	**C.2.26.1 C.2.27.1-2 Training, Installation, Instructions-for-Use** Inadequate training leads to misuse, possible injury to patient. Incomplete transfer of IFU to operator. Inadequate safe use presentation on UI.	Low	Training not provided. IFU not provided.	Occ	Acc	Training usual and customary for similar devices used in ear exams. Training provided by company or by contract with device distributor. IFU delivered with device, also available at point of use as part of UI. Video training provided for safe use.	Design Labeling	Occ	Acc	
18	**C.2.28 New Manufacturing Processes** Inadequate validation of new manufacturing processes lead to devices which fail to meet intended use.	Mod	Failure to fully validate production processes.	Occ	Neg	Company Design Control process specifies and requires proper validation of production processes. Commercial release gate review requires senior management sign off of production process validation.	Process	Rare	Acc	
19	**C.2.29.1-8 User Interface** Poor UI Design Distractions Misinterpretation Inadequate Controls Loss of Control	Mod	Operating mistakes and errors in judgment.	Occ	Neg	UI Design evaluated by experienced users, who recommend and assess Improvements. UI complies with design standards. UI tested by team trained in software QA and human factors. In-service training for operators.	Design Test	Rare	Acc	
20	**C.2.31.1-4 Deliberate Misuse** Use as a video otoscope without supplied membrane, with alternate speculum. Use with membrane from non-approved supplier. Deliberate reuse of single patient use disposable components. Use by untrained, unskilled operator.	Mod	Failure to follow IFU. Deliberate misuse.	Occ	Neg	Clinical settings for ear exams require practitioners licensed by government agencies. Training required upon delivery of device. IFU presented with device, and available on UI. Monitoring of use via data uploads and transmission – reports to designated device users.	Detection Labeling Training	Rare	Acc	

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ID	Hazard Description	Severity	Cause	Occur-rence	Risk Index	Mitigation	Type of Mitigation	Mitigated Occur-rence	Mitigated Risk Index	Verific Refer
21	**C.2.32.1 C.2.32.2 Critical Data** Dimensional data corrupted during write to disk or storage. Dimensional data corrupted during transmission.	Low	Software or hardware failure.	Occ	Acc	Data sets protected with indicators of corruption – used for retransmission or operator notification of failure. Verification of data transmission, ongoing monitoring. Competent clinician intervention at hearing aid fitting, inadequate hearing aid will not be dispensed. Failure to fit does not harm patient.	Design Test Detection	Occ	Acc	

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

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12. Attachment II – Specifications

12.1. System Requirements

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Document Scope

This document states the Design Input Requirements for the Lantos **EarScan3D** device. Requirements are derived from User, Clinical, Market, Regulatory and Technology Research, from Concept Development and Testing, and from subsequent Design Investigations.

Following design and development, verification against these Requirements, and validation with user experience tests will confirm that the Lantos **EarScan3D** is fit for its intended use.

Related Documents and Standards

- Audiologist Interviews – Design Concepts
  - **110913_lantos_directionalTesting1_review.pdf**
  - **111103_Lantos_DirectionalTesting2.pdf**
- Clinical / Market Research Summary
  - **Lantos_SC_Final_Readout_28Apr2011_vf.pdf**
- User Preference Testing
  - **LantosEarScanProtocol-2011.1rev2.pdf**
- Independent Risk Assessment
  - **Opinion letter for NEIRB 091011.docx**
- Biocompatibility
  - **ISO-10993**
- Electrical Safety and Electromagnetic Compatibility
  - **IEC-60601-1 and IEC-60601-1-2**
- Endoscope Standard
  - **IEC-60601-2-18**
- Alpha Device Testing Results

Intended Use

The **Lantos EarScan3D** provides a dimensional scan of the ear canal and outer ear, and provides a video otoscope view of the ear canal during insertion. The device is for use by qualified audiologists and hearing aid dispensers with adult patients. The device:

- provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation
- includes an expanding conforming membrane which aids observation when inserted in the ear canal
- records and presents to the hearing professional in an image file a topology measurement of the external ear canal

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8178

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Description

Lantos EarScan3D – Subsystem Description

The following subsystems comprise the EarScan3D device:

- Laptop Computer
- Handheld Scanner
- Conforming Membrane and Valve Cassette
- Fluid Reservoir and Absorbing Medium
- Algorithm and Software

Laptop Computer

Description and Use:
The operator interacts with the EarScan3D using the keyboard and touchpad; the LCD panel presents a series of User Interface screens. A battery subsystem supplies DC Power to the Laptop and the Scanner.

Key Components:

- Motherboard with CPU and Memory and GPU
- LCD Panel with LED Backlight
- Hard Disk Drive
- Keyboard and Touchpad
- Power Supply and Li-ion Battery
- USB Interface to Scanner

Lantos Technologies 3D Ear Scanner Proprietary and Confidential Page 108 of 535
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Handheld Scanner

Description and Use:
The operator places a conforming membrane and valve cassette over the extended tip of the Scanner, and then inserts the combination in the ear with a video otoscope view through a clear window in the tip of the conforming membrane. After expanding the membrane with fluid (following section) the operator presses a control to retract the

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[redacted]

Key Components:

- Endoscope probe – exposed section (b)(4) [redacted]
- Visible light illumination source with coupling to probe tip
- Sensor and Camera Electronics – conversion to FireWire images
- Motor, gears, chassis for automated retraction of probe
- Motor, gears, chassis for absorbing medium displacement
- Fluid Pressure Sensor
- Enclosure and USB / Power cable

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Conforming Membrane and Valve Cassette

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[redacted]

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Materials and Design Details:

The cassette body is standard medical polycarbonate. The encased valve is medical grade silicone. The conforming membrane contains several types of medical grade silicone, combined and formed with pressure molding techniques common for medical bladders. The clear window is also silicone.

The dye used for the inner coating of the membrane is a commercial fluorescent pigment. Dye particles are encapsulated in silicone to render the particles water insoluble. The outer portion of the membrane is cured first and then the dye mixture is applied to the inner wall of the solidified membrane. The pigment will not migrate during the curing process. The outer surface of the membrane forms a medical grade silicone barrier between the pigment and the skin that is (b)(4) [redacted] The dye particles have a stronger affinity for silicone than water. If a particle on the surface of the inner coating is exposed to the aqueous agent when the membrane is inflated, that particle will adhere to the silicone and should not migrate into the aqueous agent.

The failure mode of the silicone membranes is generally graceful. When partially expanded (to fill the ear canal) a puncture causes a stable, non-propagating pinhole leak. When fully expanded (to fill the canal and outer ear) a puncture causes a membrane tear, but not fragmentation. The maximum pressure within the membrane when fully expanded is less than (b)(4) [redacted]

Design Details

- Optimize Insert Shape - for conformance, peristaltic expansion, air expulsion
- Insert Tip Design - incorporate clear window and steering, centering 'donut' feature
  - Mating of Probe Tip to Insert Tip - retention and release
- Final Dye Selection – Final Absorbing Medium Selection
- Include pattern markings on conforming membrane inner surface

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Fluid Reservoir and Absorbing Medium

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[redacted]

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Algorithm and Software

Key Elements

- (b)(4) [redacted] ure
- [redacted] o
- (b)(4) [redacted]
-
    - Scan Metadata
    - 3D Model Data
    - Dynamics Data

Lantos Technologies 3D Ear Scanner Proprietary and Confidential Page 118 of 535
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Use Cases - Scanning

Scanning Procedure Overview

- Preparation
- Scanning
- Removal

Preparation

1. Push scanner probe all the way into the disposable until seated
2. Align clear window at tip of CM with tip of probe – confirm visually
3. Apply OtoEase (or equivalent) to sides of CM, avoiding clear window
4. Warm membrane to reduce fogging (if necessary)

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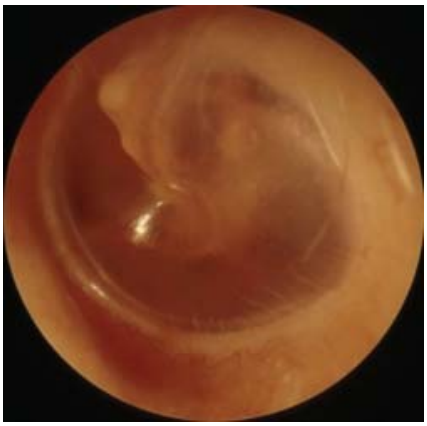
Scanning

1. Insert probe to desired scan depth, based on view of ear anatomy. The following image shows a representative tympanic membrane at a distance of approximately 5 mm, as seen through the Scanner in Otoscope mode.



2. Activate fluid drive until conformal membrane inflation is externally visible in the concha.

3. Activate Scanner probe retraction and Scan ear canal by guiding probe tip near centerline of canal. Pause probe retraction as needed to complete scan coverage. When canal scan is complete and probe is fully retracted, scan concha bowl by manipulating CM and aiming probe tip at sections of the concha until desired coverage is obtained.

Removal

1. Activate fluid withdraw until CM has collapsed.
2. Remove CM and probe from ear.

Typically, as required, repeat the Preparation, Scanning, and Removal process for the patient's other ear. Disposable components are single patient use.

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Use Cases – Detailed

Use Case – Standard Scan

- Insert Probe through concha pressure cup - fit Probe tip to conforming membrane window
- Position Scanner against outer ear – video otoscope mode – press *Mode* to start video capture and view – perform ear exam
- (b)(4) [redacted] (b)(4) [redacted]
- Activate fluid drive to expand conforming membrane until membrane visibly fills [redacted] fe limit
- (b)(4) [redacted]
- [redacted] be retracted, manipulate Scanner and concha pressure cup to view regions of concha bowl – 3D data frames appear on UI and are stitched together to complete model
- (b)(4) [redacted]
- Activate fluid drive to withdraw absorbing medium from conforming membrane – extract probe from ear, then extract collapsed membrane

Use Case – Addendums

- Ear Canal Dynamics measurement – following probe retract to entrance of ear canal – maintain steady view of canal from entrance to second bend – have patient move jaw, clench teeth, established pattern – capture motion of ear canal
- Scan completion, Hole-filling – Visualization of 'holes' in the surface reconstruction – re-insert Probe to capture more images – provide guidance for where to point Probe to obtain missing data
- For any re-insertion, extension of probe tip should take place outside the ear

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System Specifications

Environment

Operating Conditions
10° C to 40° C
30% to 80% R.H.
500hPa to 1060hPa Altitude

Internally powered device when in use.
Laptop charger AC 100-240V 50/60 Hz

IEC 60601-1 IEC 60601-1-2
Applied Part, Probe Tip – Type BF

Patient Skin Contact Components – Biocompatible ISO-10993 compliant

Ingress Protection Rating – IP22 for Handheld Scanner
as received for OEM Laptop

Cleaning and Storage

The EarScan3D Scanner and Laptop can be cleaned with a cloth dampened with warm water or a non-staining disinfectant. Avoid liquid pooling or dripping – neither the Scanner nor the Laptop is watertight.

Store device components in a dry, temperature controlled environment. Avoid extremes in temperature or humidity.

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

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Requirements Tables

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12.2. Scanner Requirements

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

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[redacted]

Document Scope

This document states the Design Requirements for the Optics and Illumination Subsystems of the Lantos **EarScan3D** device. The Design Input Requirements for the **EarScan3D** are detailed in the document:

Lantos EarScan3D – Design Input Requirements

That document also provides Use Cases and Instructions for Use, and provides context for the Requirements herein. The Optics and Illumination Requirements are derived from the system requirements, to be consistent with related subsystems.

Following design and development, verification tests will confirm that the Optics and Illumination Subsystems have met Design Requirements.

Related Documents

- Lantos EarScan3D – Design Input Requirements
- Lantos EarScan3D – Design Requirements – Subsystem Conformable Membrane

Summary Description

The optics subsystem shall include probe with a wide-angle objective lens group, an endoscope-like relay group, and a back-end lens group to form an image on a sensor. An illumination fiber optic bundle surrounding the optical tube will carry broad-spectrum visible light to the probe tip. The proximal end of the illumination bundle will be gathered in a ferrule for efficient coupling to a mixing taper which collects the light output from multiple chip-on-board LED die.

Lantos Technologies 3D Ear Scanner Proprietary and Confidential Page 12 of 535
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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

(b)(4)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

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

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12.3. Single Use Disposable Requirements

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

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Document Scope

This document states the Design Requirements for the Single Use Disposable with Conforming Membrane, which is part of the Lantos **EarScan3D** device. The Design Input Requirements for the EarScan3D are detailed in the document:

Lantos EarScan3D - Design Input Requirements

This document also provides context information for the requirements herein. The Disposable requirements are derived from the system requirements, to be consistent with related subsystems.

Following design and development, verification tests will confirm that the Disposable has met design requirements.

Related Documents and Standards

- Lantos EarScan3D - Design Input Requirements
- Lantos EarScan3D – Design Requirements – Subsystem Optics / Illumination

Summary Description

Four subsystems comprise the Single Use Disposable, as described in the sections that follow:

- Conforming Membrane
- Valve Cassette
- Fluid Reservoir
- Absorbing Medium

Lantos Technologies 3D Ear Scanner Proprietary and Confidential Page 126 of 535
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8178

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Requirements Tables

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Requirements Tables

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12.4. Scanner Software Requirements Specification

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

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Document Scope

This document lists the **Software Requirements Specification** for the **Lantos EarScan3D** device. Software requirements are derived from the Design Input Requirements.

Following design and development, verification against these Requirements, and validation with user experience tests will confirm that the Lantos **EarScan3D** is fit for its intended use.

Related Documents

LantosEarScan3D-DesignInputRequirements-Beta

Description

The **EarScan3D** provides a dimensional scan of the ear canal and outer ear, and provides a video otoscope view of the ear canal during insertion. The device is for use by qualified audiologists and hearing aid dispensers with adult patients.

Two components of the **EarScan3D** incorporate software, the Scanner and the Laptop computer, see following section.

Lantos Technologies 3D Ear Scanner Proprietary and Confidential Page 134 of 535
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Lantos EarScan3D – Subsystem Description

EarScan3D Subsystems incorporating software.

Laptop Computer

The operator interacts with the EarScan3D using the keyboard and touchpad; the LCD panel presents a series of User Interface screens. A battery subsystem supplies DC Power to the Laptop and the Scanner.

Scanner

The operator places a conforming membrane and valve cassette over the extended tip of the Scanner, and then inserts the combination in the ear with a video otoscope view through a clear window in the tip of the conforming membrane. After expanding the membrane with fluid the operator presses a control to retract the extended tip, and manipulates the Scanner to obtain a 3D image of the ear canal.

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Lantos EarScan3D – Algorithm and Software

Key Elements

- apture

(b)(4) [redacted]

-

(b)(4) [redacted]

-
  - Patient / Scan Metadata
  - 3D Model Data

Software Subsystems

Application software in the Laptop interacts with firmware in the Scanner to meet the software requirements. The application software controls the device at the system level, provides the user interface, processes raw images, and presents 2D and 3D image visualizations. The firmware controls the device hardware, drives motors, drives LEDs for illumination, and configures and reads the image sensor.

Software Development Tools

(b)(4) [redacted]

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

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Software Details

Processing Pipeline

While scanning, the algorithm comprised of a pipeline of steps: it takes images in, processes those images to create 3D surfaces, then assembles those surfaces into the full 3D model. The processing pipeline includes the following key elements:

(b)(4) [redacted]

Data Structures

(b)(4) [redacted]

Memory management

All memory is managed automatically. (b)(4) [redacted] Resources are deleted automatically.

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(b)(4)

[redacted]

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12.5. Scanner Software Design Specification

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Document Scope

This document provides the Software Design Specification for the **Lantos 3D Ear Scanner**. Software requirements are derived from the Design Input Requirements, and from the Software Requirements Specification (SRS).

Following design and development, verification against these Requirements, and validation with user experience tests, will confirm that the Lantos device is fit for its intended use.

Related Documents

LantosEarScan3D-DesignInputRequirements-Beta
LantosEarScan3D-SRS-Beta

Description

The 3D Ear Scanner provides a dimensional scan of the ear canal and outer ear, and provides a video otoscope view of the ear canal during insertion. The device is for use by qualified audiologists and hearing aid dispensers with adult patients.

Two components of the device incorporate software, the Handheld Scanner and the Laptop computer, see following section.

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

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Lantos Scanner – Subsystem Description

Laptop Computer

The operator interacts with the EarScan3D using the keyboard and touchpad; the LCD panel presents a series of User Interface screens.

Handheld Scanner

The operator places a conforming membrane and valve cassette over the extended tip of the Scanner, and then inserts the combination in the ear with a video otoscope view through a clear window in the tip of the conforming membrane. After expanding the membrane with fluid, the operator presses a control to retract the extended tip, and manipulates the Scanner to obtain a 3D image of the ear canal.

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Lantos 3D Ear Scanner – Algorithm and Software

Software Subsystems

Application software in the Laptop interacts with firmware in the Scanner to meet the software requirements. The application software controls the device at the system level, provides the user interface, processes raw images, and presents 2D and 3D image visualizations. The firmware controls the device hardware, drives motors, drives LEDs for illumination, and configures and reads the image sensor.

Software Development Tools

(b)(4)

[redacted]

Laptop Operating System

(b)(4)

[redacted]

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Software Details

Key Elements

- pture

(b)(4) [redacted]

-
-

(b)(4) [redacted]

-
  - Scan Images / Scan Metadata
  - 3D Model Data

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

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Processing Pipeline

For 3D image scans, the processing pipeline takes images in, processes those images to create 3D surfaces, then assembles those surfaces into the full 3D image.

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12.6. Traceability Matrix

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

Risk Management File – Software Hazard Trace Matrix

ID	Hazard Description	Cause	Software Mitigation	Software Test Reference
1	**C.2.1.1 C.2.1.2** **Misleading Image** Incorrectly presented Video Ototscope Image or Scan Image. Operating mistakes and errors in judgment.	Misinterpretation due to frozen image, image stream interrupted. Misinterpretation due to image orientation, capture or display hardware failure.	[redacted] (b) (4)	VerificationReport-LantosSoftwareSystem.2012.03.24 RESULTS_Section-6_Test-1 Appendix 1 RESULTS_Section-6_Test-3 Appendix 3
17	**C.2.26.1 C.2.27.1-2** **Training, Installation, Instructions-for-Use** Inadequate training leads to misuse, possible injury to patient. Incomplete transfer of IFU to operator. Inadequate safe use presentation on UI.	Training not provided. IFU not provided.		Lantos3DEarScanner-IFU-Ver04b Electronic Version in Application Lantos Training Video Electronic Version in Application
19	**C.2.29.1-8** **User Interface** Poor UI Design Distractions Misinterpretation Inadequate Controls Loss of Control	Operating mistakes and errors in judgment.		VerificationReport-LantosSoftwareSystem.2012.03.24 RESULTS_Section-6_Test-5 Appendix 5
21	**C.2.32.1 C.2.32.2** **Critical Data** Dimensional data corrupted during write to disk or storage. Dimensional data corrupted during transmission.	Software or hardware failure.		VerificationReport-LantosSoftwareSystem.2012.03.24 RESULTS_Section-6_Test-2 Appendix 2 RESULTS_Section-6_Test-3 Appendix 3 RESULTS_Section-6_Test-4 Appendix 4

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13. Attachment III – Predicate Device Information

13.1. User Guide (Predicate User Manual)

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Digital MacroView™ Otoscope

Directions for Use

Welch Allyn®
Advancing Frontline Care™

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

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Caution: Federal law restricts this device to sale by or on the order of a licensed professional trained in otoscopy.

Welch Allyn assumes no responsibility for any injury, or for any illegal or improper use of the product, that may result from failure to use this product in accordance with the instructions, cautions, warnings, or indications for use published in this manual.

Welch Allyn is a registered trademark of Welch Allyn, Inc. Digital Macroview is a trademark of Welch Allyn, Inc.

Software in this product is copyright Welch Allyn or its vendors. All rights are reserved. The software is protected by United States of America copyright laws and international treaty provisions applicable worldwide. Under such laws, the licensee is entitled to use the copy of the software incorporated with this instrument as intended in the operation of the product in which it is embedded. The software may not be copied, decompiled, reverse-engineered, disassembled or otherwise reduced to human-perceivable form. This is not a sale of the software or any copy of the software; all right, title, and ownership of the software remain with Welch Allyn or its vendors.

Caution: Changes or modifications not expressly approved by Welch Allyn could void the purchaser's authority to operate the equipment.

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For information about any Welch Allyn product, call Welch Allyn Technical Support:

USA	+ 1 315 685 4560 800 535 6663	Australia	+ 61 29 638 3000
Canada	800 561 8797	China	+ 86 216 327 9631
European Call Center	+ 353 46 906 7790	France	+ 331 6009 3366
Germany	+ 49 747 792 7186	Japan	+ 81 33 219 0071
Latin America	+ 1 305 669 9003	Netherlands	+ 31 15 750 5000
Singapore	+ 65 6419 8100	South Africa	+ 27 11 777 7555
United Kingdom	+ 44 207 365 6780	Sweden	+ 46 85 853 6551

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Welch Allyn
4341 State Street Road,
PO Box 220
Skaneateles Falls, NY
13153-0220
www.welchallyn.com

EC REP

European Regulatory Manager
Welch Allyn Ltd.
Navan Business Park
Dublin Road
Navan, County Meath,
Republic of Ireland
Tel.: +353 46 90 67700
Fax: +353 46 90 67755

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1 Introduction

The Digital MacroView System consists of a digital otoscope head and a USB Video Cable. A 3.5 volt Welch Allyn power source and a computer are necessary to use the Digital MacroView System.

The Digital MacroView System is designed for "Plug and Play" operation - all adjustments including illumination and white balance are pre-set at the factory.

System Requirements

The Digital MacroView requires a user device running Windows XP Service Pack 2 or later operating system, a viewing screen, and a USB 2.0 port.

Intended use

The otoscope is intended to allow inspection of the external ear, ear canal, and tympanic membrane under magnification. A secondary use of the otoscope may be for general illumination of the throat and/or nasal cavities or assessing flexibility of the tympanic membrane (pneumatic otoscopy).

User Profile

The Digital MacroView is intended for licensed professionals trained in otoscopy.

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Symbols

Safety Symbols

	WARNING		Caution
	Caution: Consult accompanying documentation	IPXØ	Not protected from the ingress of water
	Type BF		Temperature limits
	USB		Relative humidity limit

Recycle the product separate from other disposables. See "Recycling the system components" on page 17.

Button Symbols

Capture Image

Zoom

Agency Symbols

C US
166292

CERTIFIED TO:
CAN/CSA STD C22.2 NO. 601.1

CONFORMS TO:
UL STD 60601-1

IEC 60601-1

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The CE mark on this product indicates that it has been tested to and conforms with the provisions noted within the 93/42/EEC Medical Device Directive.

European Regulatory Manager
Welch Allyn Ltd.
Navan Business Park • Dublin Road • Navan, County Meath,
Republic of Ireland
Tel.: +353 46 90 67700 • Fax: +353 46 90 67755

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Warnings and cautions

Familiarize all operating personnel with the general safety information in this summary. Specific warnings and cautions are also found throughout this manual. Such specific warnings and cautions may not appear here in this summary.

Warnings

A warning statement in this manual identifies a condition or practice, which if not corrected or discontinued immediately, could lead to injury, illness, or death.

WARNING Do not use in the presence of flammable anesthetics.

WARNING This product has no user serviceable/ replaceable parts except for the lamp. Please refer all other service to authorized service personnel.

WARNING This instrument is not intended to be used in the eye.

WARNING This product generates and records reference images from inputs obtained from the Welch Allyn Digital Macroview. These reference images are not intended for diagnostic purposes.

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Cautions

A caution statement in this manual identifies a condition or practice, which if not corrected or discontinued immediately, could lead to equipment failure, equipment damage, or data loss.

Caution In order to obtain optimum performance and ensure patient safety, thoroughly read this booklet.

Caution The Digital MacroView System is designed expressly for use with an approved Welch Allyn 3.5v power source. Damage to the system will occur if alternate power sources are attached to the video head.

Caution Do not use the Digital MacroView if you notice any signs of damage to the components of the system. Contact Customer Service Department for immediate assistance.

Caution Do not attempt to disinfect the Digital MacroView System using glutaraldehyde products, ethylene oxide gas, steam or any other liquid or gas disinfectant.

Caution The signal output (USB Port) connector is intended for connection of only devices complying with IEC 60601-1, or other IEC standards (for example, IEC 60950), as appropriate to the device. Connecting additional devices to the Digital MacroView System is configuring a medical system and you are responsible for verifying that the system complies with the requirements of the system standard IEC 60601-1-1.

Caution This product complies with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using this device in close proximity to other equipment.

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Caution To minimize external otoscope housing temperatures, on-time should not exceed 2 minutes and off-time a minimum of 10 minutes.

Caution Only accepts Welch Allyn specula.

Caution Use only Welch Allyn approved lamps.

Caution Do not apply alcohol, chemicals, or water to the lenses. Solution entering the optical assembly could damage internal components.

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

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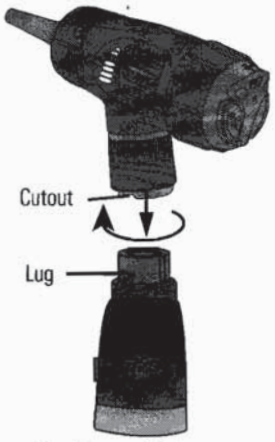
2 Operation

Using the otoscope head

Align the cutouts in the otoscope head base with power source lugs. Push down slightly and turn 90° clockwise. To remove, reverse this procedure. The otoscope head fits all 3.5v Welch Allyn power sources.



Caution Only accepts Welch Allyn specula.

Attach: Twist the specula clockwise until it clicks into the locked position.
Remove: Turn the TipGrip or twist the specula counterclockwise.

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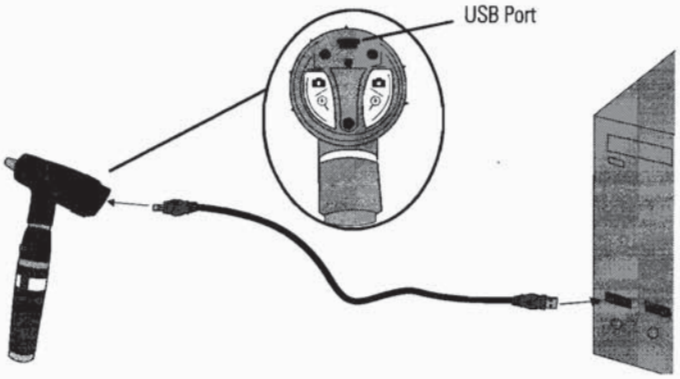
Setup

Prior to using the Digital MacroView for the first time, install the Welch Allyn Viewer Utility following the instructions provided with the Viewer CD.

Using the Digital MacroView System

1. Verify the power source is off and attach the Welch Allyn Digital MacroView head to the power source (see page 7).
2. Connect the USB cable to the port on the back of the Digital MacroView head and to the computer USB port. The computer gives an audible signal that the connection is complete.



3. Double-click the Welch Allyn Viewer icon on your computer desktop.

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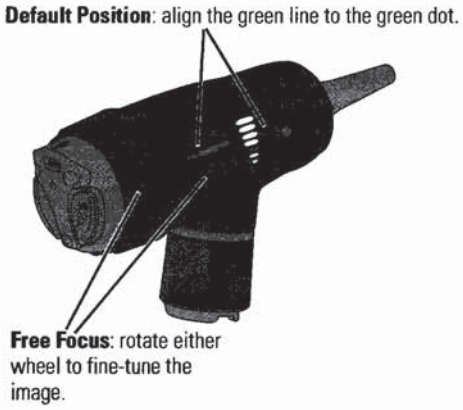
4. Turn the power source to FULL ON position to achieve optimum performance. The computer displays an image. Digital MacroView automatically optimizes the image brightness.

   If necessary, adjust the color and brightness controls on the computer monitor for picture quality.

Using focus



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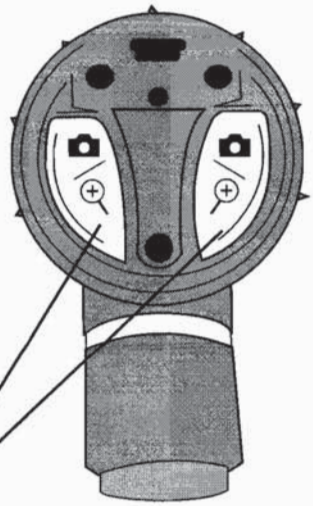
Using the controls



Capture: Press and hold ***either*** function button for approximately 1 second. Upon *release* of the function button the *image freezes* as a thumbnail on the screen. If the image is rotated (see below) then the captured image is rotated.
Zoom: Press and hold ***either*** function button for approximately 2 seconds. Zoom is for on-screen viewing purposes only. Capturing an image while in zoom mode produces a standard thumbnail. Press and hold ***either*** function button again to zoom out.
Rotate: Press and hold ***both*** buttons for approximately 4 seconds. Image rotates 180° on screen. Press and hold again to return the image to its original position.

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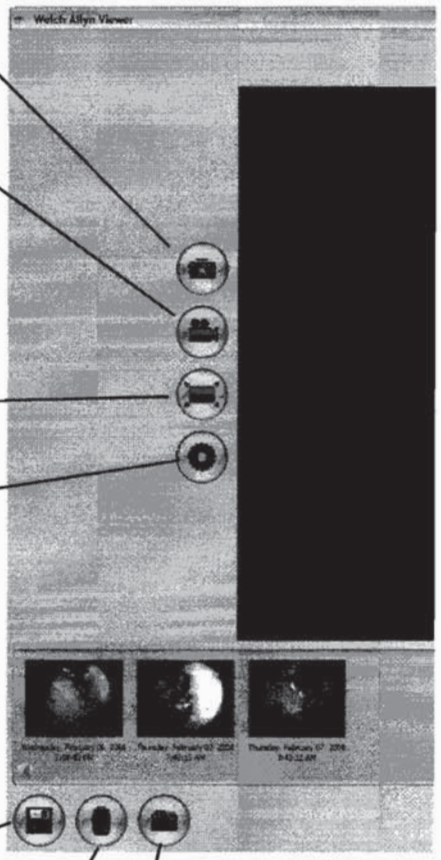
Reviewing images

Snapshot: Click to take a snapshot from the viewer. Image displays as a thumbnail on the screen.

Record Video Clip: Click to start recording (green icon); click again to stop recording (blue icon). Video clip displays as a thumbnail on the screen and marked as Video.
NOTE: You must have a video recorder such as Windows Movie Maker or Windows Media Player installed on your computer.

View Full Screen: Click to view full screen.
Press ESC to return to the normal view.

Settings:
Default Directory: Click Browse and select the file path where you want to save your images.
Video Clip Length: Select Video Capture Limit and select an option. Two minutes is the maximum allowable length of a recorded video.
Default File Format: Select an available file type for your graphics.



Save All Images/Videos: Select Yes.
To save a single image/video:
Right-click the thumbnail and select Clear. Answer Yes.

View Saved Images/Videos:
Window displays default directory for storage. Select the file or select another diretory or folder to locate the desired file. Double-click on the file name to view the image.

Clear All Images/Videos: Select Yes.
To clear a single image/video:
Right-click the thumbnail and select Clear. Answer Yes.

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

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Standby Mode

The Digital MacroView shuts down the active viewing window after approximately 12 hours of continuous connection to the active viewing window and computer.

To restart the Digital MacroView:

1. Press either function button and re-open Windows Explorer.
2. Open Windows Explorer and click **My Computer** in the left pane. Double-click the **USB Video Device**.

   Or double-click the **My Computer** icon on your computer desktop and double-click the **USB Video Device**.

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Using the throat illuminator

The Welch Allyn Digital MacroView can transform into a throat illuminator. While using the throat illuminator there are no images available on screen or for capture.

WARNING It is important to note that while the throat illuminator section provides an excellent source of general illumination, avoid more than momentary direct skin contact due to possible heat build up.

1. Grasp the otoscope section with the left hand.
2. Grasp the throat illuminator's collar at (under the silver ring).
3. Hold the throat illuminator collar stationary, twist the otoscope section counterclockwise until the otoscope head is removed.

   To replace otoscope section, align the otoscope section with the top of the throat illuminator and turn clockwise.

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3 Maintenance and service

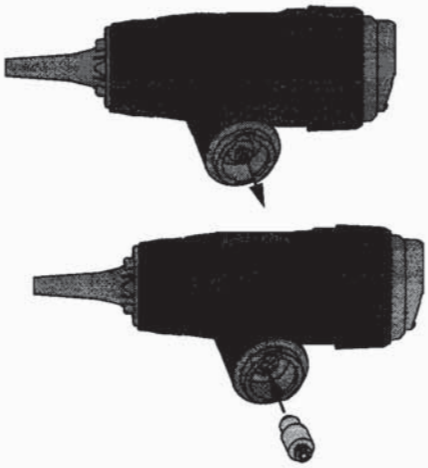
Replacing the lamp

Caution Halogen lamps are pressurized to provide maximum efficiency and illumination. Mistreatment may cause shattering. Protect lamp surface against abrasions and scratches. Use protective eyeglasses when handling. Dispose of lamp with care.

Caution Only use Welch Allyn lamp REF 06500-U.

Caution Lamps may be hot. Allow the lamps to cool before removing.

Caution Avoid removing the lamp for reasons other than replacement.



It is necessary to re-calibrate the white balance on the Digital MacroView after replacing the lamp.

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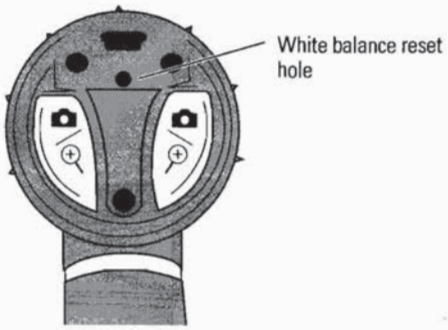
To recalibrate the white balance:

Use a fully-charged 3.5v power source.

1. Connect the head to the computer and turn the power to the full on position see "Using the Digital MacroView System" on page 8.
2. Shine the light on a piece of white paper approximately 3.2 cm (1.25") away.
3. Unfold a standard paperclip and insert it into the white balance reset hole. Push slightly to activate the white balance reset button.

   The image becomes blue on the computer screen. A live image returns to the computer screen when calibrated.

   If the screen is red then repeat steps 1 through 3 above.



Cleaning recommendation

Caution Do not apply alcohol, chemicals, or water to the lenses. Solution entering the optical assembly could damage internal components.

Use a dry cloth to clean the Digital MacroView System monthly.

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

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Recycling the system components

Within the EU

Do not dispose of this product as unsorted municipal waste. Prepare it for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE).

If this product is contaminated, this directive does not apply.

For more specific disposal information, see www.welchallyn:com/weee, or contact Welch Allyn Customer Service.

Outside the EU

When the product and its components reach end of life, recycle it locally according to national, state, and local regulations, or return it to Welch Allyn.

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

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Accessories

REF	Description
23900-10	Replacement USB cable, 10 ft length
23804	Insufflator bulb for MacroView
23857	3.5v Throat Illuminator section only
24302-U	Universal Poly Reusable Speculum 2.5mm
24303-U	Universal Poly Reusable Speculum 3mm
24304-U	Universal Poly Reusable Speculum 4mm
24305-U	Universal Poly Reusable Speculum 5mm
24400-U	Set of 4 Universal Reusable Speculum
52432-U	2.75mm Disposable Ear Specula
52434-U	4.25mm Disposable Ear Specula
24320	SofSeal Small, Disposable Sealing Tip
24330	SofSeal Medium, Disposable Sealing Tip
06500-U	Lamp
23920MAN/ 23960MAN	Directions for Use - CD
23920-QSG	Quick Start Guide

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Service policy

All repairs on products under warranty must be performed or approved by Welch Allyn. Unauthorized repairs will void the warranty. In addition, whether or not covered under warranty, any product repair shall exclusively be performed by Welch Allyn certified service personnel.

If the product fails to function properly — or if you need assistance, service, or spare parts — contact Welch Allyn.

Before contacting Welch Allyn, try to duplicate the problem, and check all accessories to ensure that they are not causing the problem. When calling, please be prepared to provide:

- Product name and model number and complete description of the problem.
- Serial number of your product (if applicable).
- Complete name, address and phone number of your facility.
- For out-of-warranty repairs or spare parts orders, a purchase order (or credit card) number.
- For parts orders, the required spare or replacement part numbers.

If your product requires warranty, extended warranty, or non-warranty repair service, please call Welch Allyn. A representative will assist you troubleshooting the problem and will make every effort to solve it over the phone, avoiding potential unnecessary returns. In case a return cannot be avoided, the representative will record all necessary information and will provide a Service Notification number, as well as the appropriate return address. The Service Notification number must be obtained prior to any return.

If you have to return goods for service, follow these recommended packing instructions:

- Remove all hoses, cables, sensors, power cords, and ancillary products (as appropriate) before packing, unless you suspect they are associated with the problem.
- Wherever possible use the original shipping carton and packing materials.
- Include a packing list and the Welch Allyn Service Notification number.

It is recommended that all returned goods be insured. Claims for loss or damage to the product must be initiated by the sender.

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

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4 Specifications

Item	Specification
Weight	Approximately 95 g (0.2 lb)
Dimensions (approximate)	Height: 7.0 cm (2.8 inches) Length: 10.2 cm (4.0 inches) Width: 3.7 cm (1.5 inches)
Rating	Lamp: 3.5Vdc, 810 mA USB: 5.0Vdc, 150 mA
Protection against ingress of water	IPXØ
Operating conditions Temperature Relative humidity Altitude	 +10° C to +40° C (+50° F to +104° F) 30% to 75% noncondensing 700 to 1060 hPa
Shipping and storage conditions Temperature Relative humidity	 -20° C to +49° C (-4° F to +120° F) 95% noncondensing max.
Intermittent operation	≤ 2 minutes on, ≥ 10 minutes off between uses
Safety, EMC, and regulatory compliance	CAN/CSA C22.2 No. 601.1-M90, including amendments 1 & 2 EN/IEC 60601-1 EN/IEC 60601-1-2 UL 60601-1
Patents	Patents Pending

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

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Limited Warranty

Welch Allyn warrants that the Digital MacroView products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within one year after the date of purchase. Neither the lamp or specula have an explicit warranty beyond out of box failures.

The date of purchase is: 1) the date specified in our records if you purchased the Product directly from us, 2) the date specified in the warranty registration card that we ask you to send to us, or 3) the date of purchase of product from the authorized Welch Allyn distributor as documented from a receipt from said distributor.

This warranty does not cover damage caused by: 1) handling during shipping, 2) use or maintenance contrary to labeled instructions, 3) alteration or repair by anyone not authorized by Welch Allyn, and 4) accidents.

If a Product or accessory covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period described above, Welch Allyn will, at its discretion, repair or replace the defective Product or accessory free of charge.

You must obtain a service notification number from Welch Allyn to return your Product before you send it to Welch Allyn's designated service center for repair. Contact Welch Allyn Technical Support.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. WELCH ALLYN'S OBLIGATION UNDER THIS WARRANTY IS LIMITED TO REPAIR OR REPLACEMENT OF PRODUCTS CONTAINING A DEFECT. WELCH ALLYN IS NOT RESPONSIBLE FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM A PRODUCT DEFECT COVERED BY THE WARRANTY.

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

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13.2. Predicate Website Documents

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Welch Allyn Digital MacroView Video Otoscope

The new Welch Allyn Digital MacroView Video Otoscope used in conjunction with your computer makes an incredibly functional and easy to use video otoscope at an incredible introductory price. If you have a computer with a USB port, all you need is the MacroView Video Otoscope, the Welch Allyn power handle of your choice, and you are ready to start doing video otoscopy with all of the features of the most expensive video otoscopes at your fingertips.

Click here to download a Welch Allyn products price list.

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Welch Allyn Digital MacroView™ Otoscope

The Welch Allyn Digital MacroView Otoscope is a simple, affordable tool that lets you see, explain, and save digital images of the ear.

Offering you clear, live and still images of the ear canal and tympanic membrane, the Digital MacroView™ Otoscope is a valuable tool in support of the treatment and management of your patients' ears. Easy to learn and use, the Digital MacroView is a plug and play system requiring no additional purchase of software.

*handle sold separately

Here's how the Welch Allyn Digital MacroView Otoscope can benefit you:

- Improves communication which can lead to better patient compliance
- Allows you to store digital images in patient records for enhanced documentation of exam findings
- Provides you the ability to share images with other providers as visual descriptive reference
- Gives you an excellent training aid for educational purposes
- Offers you the ability to view small details of tubes and hearing aids

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The Welch Allyn Digital MacroView™ Otoscope

Features you expect from an otoscope and more:

USING THE DIGITAL MACROVIEW OTOSCOPE IS EASY AS 1 – 2 – 3

1 Plug In.
Plug the otoscope into your computer using the USB cable.

2 Power On.
Put on ear specula and turn on light.

3 Play.
View live picture or capture image.

Ordering Information

23920 Digital MacroView Otoscope with 10 ft USB cable and set of four reusable ear specula

Accessories

23804	Insufflator Bulb
24400-U	Additional set of four Reusable Specula
24302-U	2.5 mm Universal Poly Reusable Speculum
24303-U	3.0 mm Universal Poly Reusable Speculum
23404-U	4.0 mm Universal Poly Reusable Speculum
23405-U	5.0 mm Universal Poly Reusable Speculum
24320	SofSeal Small, Disposable Sealing Tip
24330	SofSeal Medium, Disposable Sealing Tip
52432-U	2.75 mm Single use Ear Specula
52434-U	4.25 mm Single use Ear Specula
06500-U	Lamp
23900-10	Replacement USB Cable, 10 ft
71000-A	NiCad Rechargeable Handle (Plug-in)
71000-C	NiCad/Convertible Rechargeable Handle (Plug-in)
71670	NiCad Rechargeable Handle for Universal Charger
71900	Lithium Ion Rechargeable Handle with AC Charging Module
71910	Lithium Ion Rechargeable Handle for Universal Charger

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13.3. Predicate 510K Summary

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SW 19580

K943916

AUG 25 1994

510(k) SUMMARY
Summary of Safety and Effectiveness

Submitter's Name & Address: Welch Allyn, Inc.
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220

Contact Person & Telephone: Scott Giacciardi
315/685-4470

Date Summary Prepared: August 3, 1994

Device Name: Classification Name - Otoscope
Common/Usual Name - Video Otoscope
Proprietary Name - Welch Allyn VideOtoscope

Predicate Device: Welch Allyn model Otoscope &
Welch Allyn model LCI-200 Illumination and Imaging System

Device Principles, Description & Intended Use:

The VideOtoscope is similar to and predicated upon two different Welch Allyn devices already in commercial distribution. The device combines a common otoscope design with the previously 510(k) approved Welch Allyn model LCI-200 Illumination and Imaging System (ref. 510(k) #K940270/A) and incorporates a camera attachment in place of the magnifying view window on the otoscope. Additionally, the VideOtoscope has the same operating principles and intended use as many competitive video otoscopes already in commercial distribution.

Instructions for Use:

The Video Otoscope's intended use is to non-invasively examine the external ear canal and tympanic membrane in children and adults. The practitioner will use a common ear speculum on the otoscope for patient comfort and safety. The instrument will be used by the practitioner in the same manner as a traditional otoscope; however, instead of looking through the otoscope manually, the image will be picked up by a camera in the otoscope head and then transmitted to a video processor.

When performing otoscopy the practitioner places the otoscope approximately 4mm into the ear canal. This procedure is safe, performed routinely, and does not cause discomfort to the patient. To perform a visual otoscopic examination one would do the following:

1. Inspect the entrance to the ear canal for debris or pus which might interfere with further examination.

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2. Choose the largest speculum which can comfortably be inserted into the ear canal. Straightening of the outer ear canal makes insertion of the speculum easier. With adults this is accomplished by retracting the pinna up and back. With children this is accomplished by retracting the pinna horizontally back.

3. The otoscope should be held like a pencil, between the thumb and forefinger, with the ulnar aspect of the hand resting firmly but gently against the patients cheek.

4. Because of the limited field of vision through even the largest of speculum, it may be necessary for the practitioner to adjust the position of the speculum to view completely the entire ear canal and all areas of the tympanic membrane.

In addition to visually inspecting the ear, one can perform another exam with the otoscope called pneumatic otoscopy. Pneumatic otoscopy provides practitioners with a simple method for determining tympanic membrane mobility and helps them recognize many middle ear disorders. Pneumatic otoscopy is performed in the following manner:

1. One attaches a pneumatic device to the otoscope. The pneumatic device is a short piece of rubber tubing with a small rubber bulb attached to the end.

2. One must use a speculum sufficiently large enough to fit snugly into the ear canal in order to establish an airtight chamber between the canal and the interior of the otoscope head.

3. Gently squeezing the rubber bulb of the pneumatic attachment produces small changes in the air pressure of the ear canal. By observing the relative movements of the tympanic membrane in response to the induced changes in pressure, the physician can obtain valuable diagnostic data about the mobility of the tympanic membrane. When fluid is present in the middle ear, for example, movement of the tympanic membrane is generally diminished or absent.

Summary of Safety:

Numerous safety areas were investigated and reviewed to ensure that the Welch Allyn VideOtoscope was as safe or safer than existing similar devices already in commercial distribution. The device under review is considered very safe for both practitioner and patient (Class I). No significant energy is delivered into the body and the procedure and technique is low risk and requires very limited skill and effort. The specific safety areas considered were as follows:

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Electrical (Shock)	-	Not a hazard; product is being designed to meet and approval is being sought to the standards UL 544 (patient vicinity), CSA 601-1, and IEC 601-1.
Corrosion	-	Device is non-corrosive.
Explosion	-	Highly unlikely; manufactured of non-explosive materials.
Fire Hazard	-	Probability extremely low. Fuses have been built in to the electrical subsystems to prevent such occurrences. Enclosures meet flammability requirements.
Mechanical (Sharp Edges)	-	All contact surfaces have been rounded and textured. No injury will result from any of the edges or surfaces of the device.
Surface Temperature	-	Not a hazard; all surfaces remain well within UL 544 limits for patient and practitioner contact.

The only patient contact with the device is the ear specula. The device will utilize either a disposable or re-usable polypropolene specula. This certifies that the specula is of the same material and formulation as is used on the current/equivalent device(s).

Summary of Effectiveness

The determination of device effectiveness was coordinated in the following manner:

The Marketing Dept. of Welch Allyn, Inc. conducted on-site evaluations of the device with practicing physicians in an effort to determine if the VideOtoscope met all of the practitioner's needs in viewing the external ear canal and tympanic membrane of their patients. The evaluating practitioners were also users of either an existing Welch Allyn model otoscope or some other Video Otoscope (all have the same intended use). The results of the evaluations indicated that the Welch Allyn VideOtoscope serves the needs of the diagnostic procedure in an equivalent or better manner of effectiveness.

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14. Attachment IV – Verification and Validation Documents

14.1. System Verification

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PURPOSE

This Protocol details the system level test for the Lantos 3D Ear Scanner device. The system level tests are executed on a specific set of hardware. For each execution of the protocol, a report will be generated which incorporates this protocol. This protocol, in conjunction with the software system test, comprises the in-vitro verification test for the system, providing evidence that the 3D Ear Scanner is fit for its intended us.

REPORT: Test of Lantos 3D Ear Scanner – Laptop Dell E6520 SN F8N2BS1

Handheld Beta00, Beta01, Beta04 as recorded in Results section

1. SCOPE

Applies to the Lantos 3D Ear Scanner as a system, including the Lantos Laptop, the Handheld Scanner, and power distribution and all connecting cables.

2. REFERENCE DOCUMENTS:

PROTOCOL: LANTOSVIEW Software System

3. DEFINITIONS:

None.

4. MATERIALS AND EQUIPMENT:

4.1. Materials. Test single use disposables and inorganic test objects.

4.2. Equipment. Laptop and Handheld Scanner. Device hardware shall be identified in the verification report. Lab test equipment as indicated.

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5. TEST PROCEDURES AND ACCEPTANCE CRITERIA:

Test	Summary / Description / Procedure	Acceptance Criteria
Button Test	Assure that activation buttons on the handheld scanner and on the laptop computer perform as expected. Navigate to screen icons with the laptop touchpad, activate and assure appropriate response. Procedure: • Press each button in context and sequence – assure appropriate actions by the application software • Scan button – Fill / Empty (+/-) buttons – Extend button • Laptop touchpad and touchpad activation	No detected activation or sequence errors; no duplication errors.
Reservoir Motor Test	Assure that motor driving fluid reservoir performs as expected. Assure that motor limit protections function as expected. Procedure: • Select three single use disposables – drive the reservoir motor to fully empty and fully refill the reservoir three times each • Monitor supply current to motors – assure that current does not exceed safe operating limit for motor – 200mA at 12V • Record Pass/Fail for each test sequence	Motor and coupling successfully drives 3 disposables x 3 cycles to full empty and refill. Motor current does not exceed 200mA limit.
Optics Motor Test	Assure that motor driving optics and probe performs as expected. Assure that motor limit protections function as expected. Procedure: • Select two handheld scanners – drive optics and probe to full extend and full retract three times each • Monitor supply current to motors – assure that current does not exceed safe operating limit for motor – 200mA at 12V • Record Pass/Fail for each test sequence	Motor and coupling successfully drives 2 devices x 3 cycles to full extension and retraction. Motor current does not exceed 200mA limit.

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Accelerometer and Gyro Test	Assure that accelerometer and gyro built into handheld scanner works as expected for image orientation correction, and handheld orientation detection. Procedure: (b) (4) [redacted]	Image orientation remains within 10° of upright as scanner is rotated around the probe axis. Extend button is active only when probe tip is pointed within 20° of straight down.
In-Vitro Test Objects Scan Tests	Assure that the device consistently recreates in-vitro test objects. Procedure: • Inflate conforming membrane into CheckCap – scan CheckCap – repeat • Inflate conforming membrane into Lantos test cylinder – scan cylinder - repeat • Inflate conforming membrane into Lantos test-step object – scan test-step object - repeat • Record results for 2x tests of 3x objects	Selected dimensional compares as follows: CheckCap – Median Error < 0.35mm Test-Step Object Median Error < 0.35mm Test Cylinder Median Error < 0.35mm Dimension selections and known values for each test object recorded in DHF.

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6. RESULTS:

Results of the verification tests as follows. Devices, test dates, test personnel recorded.

Test	Summary / Description / Procedure	Acceptance Criteria
Button Test	Assure that activation buttons on the handheld scanner and on the laptop computer perform as expected. Navigate to screen icons with the laptop touchpad, activate and assure appropriate response.	No detected activation or sequence errors; no duplication errors. Beta00, Beta04 Laptop F8N2BS1 05-Apr-2012, 06-Apr-2012 FF, BF PASS
Reservoir Motor Test	Assure that motor driving fluid reservoir performs as expected. Assure that motor limit protections function as expected.	Motor and coupling successfully drives 3 disposables x 3 cycles to full empty and refill. Motor current does not exceed 200mA limit. Beta00 Laptop F8N2BS1 Disposable Lot Beta-01 06-Apr-2012 MM PASS
Optics Motor Test	Assure that motor driving optics and probe performs as expected. Assure that motor limit protections function as expected. Procedure: • Select two handheld scanners – drive optics and probe to full extend and full retract three times each • Monitor supply current to motors – assure that current does not exceed safe operating limit for motor – 200mA at 12V • Record Pass/Fail for each test sequence	Motor and coupling successfully drives 2 devices x 3 cycles to full extension and retraction. Motor current does not exceed 200mA limit. Beta00, Beta01 Laptop F8N2BS1 05-Apr-2012 BF PASS

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Accelerometer and Gyro Test	Assure that accelerometer and gyro built into handheld scanner works as expected for image orientation correction, and handheld orientation detection.	Image orientation remains within 10° of upright as scanner is rotated around the probe axis. Extend button is active only when probe tip is pointed within 20° of straight down. Beta00 Laptop F8N2BS1 06-Apr-2012 BF PASS Appendix A
In-Vitro Test Objects Scan Tests	Assure that the device consistently recreates in-vitro test objects.	Selected dimensional compares as follows: CheckCap – Median Error < 0.35mm Result: 0.30mm Test-Step Object Median Error < 0.35mm Result: 0.25mm Test Cylinder Median Error < 0.35mm Result: 0.26mm Beta04 Laptop F8N2BS1 06-Apr-2012 AB PASS Appendix B

7. CONCLUSIONS / DEVIATIONS:

All device system tests passed on devices as recorded. Acceptance criteria were met. No deviations found.

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Appendix A

(b)(4)

[redacted]

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Appendix B

(b)(4)

[redacted]

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(b)(4)

[redacted]

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14.2. Software Verification

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PURPOSE

This Protocol details the system level test for the Lantos 3D Ear Scanner LANTOSVIEW Application software. The system level tests are executed on a specific hardware version. For each execution of the protocol, a report will be generated which incorporates this protocol.

REPORT: Test of LantosView rev993 AAApre12 release 16-Mar-2012

1. SCOPE

Applies to the LANTOSVIEW Application software. This protocol, in conjunction with the software unit testing protocol, comprises the verification test for the software.

2. REFERENCE DOCUMENTS:

PROTOCOL: LANTOSVIEW Software Unit Test.

3. DEFINITIONS:

None.

4. MATERIALS AND EQUIPMENT:

4.1. Version. The protocol is applied to a specific version of the LANTOSVIEW Application software, maintained by the Lantos software configuration management process. The software version shall be identified in the verification report.

4.2. Equipment. The protocol is applied to a specific instantiation of the Lantos device hardware. Device hardware shall be identified in the verification report.

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5. ACCEPTANCE CRITERIA:

Test	Summary / Description / Procedure	Acceptance Criteria
Scan Data Collection and Transmission	Assure that raw images from the image sensor are processed and transmitted without error from the handheld Scanner to the LANTOSVIEW software. Assure no images are missed, and no images are corrupted. Procedure: • configure image sensor to create known sequence of test images • write test code to read sequence in LANTOSVIEW software and compare with expected sequence – image by image • (b)(4) [redacted] • Record Pass/Fail for each test sequence	No detected sequence errors or individual image corruption.
Scan Data Disk Save and Recall	Assure that raw images can be saved to and recalled from hard disk without error. Procedure: • Select five full real ear scan sequences of varying length, from at least three different subjects • write test code to bring each sequence into memory, and write out to disk under different name minimum 10x • reread minimum 10x versions of 5x scan sequences, and assure all images are identical to selected source • Record Pass/Fail for each test sequence	No detected sequence errors or individual image corruption.

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Scan Data – 3D Image Recreation Integrity	Assure that raw image sequence repeatedly and deterministically recreates identical 3D image files. Procedure: • Select five full real ear scan sequences of varying length, from at least three different subjects • write test code to bring each sequence into memory, and transform to 3D topology measurement of external ear – repeat process 3x for each scan sequence • compare result to original 3D measurement for 3x repeats of 5x test scans • Record Pass/Fail for each test sequence	Recreated 3D topology measurement image files are identical.
Scan Database Management Integrity	Assure that sizable database of raw images and processed scan images can be created, accessed, and managed without errors. Procedure: • Start with database of minimum 40 real ear scans from different subjects, both raw images and processed 3D image files • write test code to bring each scan into memory, make 5x slight but measureable modification of raw images – reprocess raw image stream to produce 3D image files – and write modified raw images and processed scan images to disk • write test code to access and reread minimum 6x versions of 40x scan sequences, and assure all raw and processed mages are identical to expected – change order of retrieval 3x and repeat • Record Pass/Fail for each test sequence	No detected database access or image data corruption errors.

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Scan Control Interaction Integrity	Assure that the user control of the Scan sequence is robust and defect-free. Test the User Interface mode control sequence, and button function. Procedure: • Setup the Scanner and Laptop with the conforming membrane and probe inserted in the CheckCap – prepare test object of known shape, which can be qualitatively compared to 3D image • Repeat the Scan sequence – setup / view / scan / review – intentionally alter the timing and sequence of button pushes – observe and record any anomalies from the expected screen sequence and behavior	No software halts, freezes, or crashes. No screen behavior inconsistent with software design specification, or with Instructions-for-Use. Button response time and control response time consistent with requirements.
In-Vitro Test Objects Scan Tests	Assure that the software consistently recreates test objects. NOTE: For software system test, dimensional compare limits are set to confirm software function, not to determine device system accuracy. Separate test protocols have been developed to verify device system accuracy. Procedure: • Inflate conforming membrane into CheckCap – scan CheckCap – repeat • Inflate conforming membrane into Lantos test cylinder – scan cylinder - repeat • Inflate conforming membrane into Lantos test-step object – scan test-step object - repeat • Record results for 2x tests of 3x objects	Selected dimensional compares +-10% of known test object dimensions. Dimension selections and known values for each test object recorded in DHF.

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6. RESULTS:

Tests performed 18-23 Mar 2012 – AB, BF, DV – test logs see appendices.

Test	Summary / Description / Procedure	Acceptance Criteria
Scan Data Collection and Transmission	Assure that raw images from the image sensor are processed and transmitted without error from the handheld Scanner to the LANTOSVIEW software. Assure no images are missed, and no images are corrupted.	No detected sequence errors or individual image corruption. PASS Appendix 1
Scan Data Disk Save and Recall	Assure that raw images can be saved to and recalled from hard disk without error.	No detected sequence errors or individual image corruption. PASS Appendix 2
Scan Data – 3D Image Recreation Integrity	Assure that raw image sequence repeatedly and deterministically recreates identical 3D image files.	Recreated 3D topology measurement image files are identical. PASS Appendix 3
Scan Database Management Integrity	Assure that sizable database of raw images and processed scan images can be created, accessed, and managed without errors.	No detected database access or image data corruption errors. PASS Appendix 4
Scan Control Interaction Integrity	Assure that the user control of the Scan sequence is robust and defect-free. Test the User Interface mode control sequence, and button function.	No software halts, freezes, or crashes. No screen behavior inconsistent with software design specification, or with Instructions-for-Use. Button response time and control response time consistent with requirements. PASS Appendix 5
In-Vitro Test Objects Scan Tests	Assure that the software consistently recreates test objects.	Selected dimensional compares +-10% of known test object dimensions. Dimension selections and known values for each test object recorded in DHF. PASS Appendix 6

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7. CONCLUSIONS / DEVIATIONS:

All system tests passed on LantosView rev993 software. Acceptance criteria were met. No deviations found.

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APPENDIX 1

Also: http://lantosatlassian:8085/bamboo/browse/LVIEW-UTESTS-506

Build Result Summary

Details

Trigger	Code has been updated by Albandb.
Revision	993
Completed	16 Mar 2012, 3:08:16 PM – 5 days ago
Duration	7 minutes
Successful since	#498 (13 hours before)
Labels	None

Shared Artifacts

See all Artifacts

UnitTests.exe (19 MB)
log.xml (100 KB)
report.xml (248 bytes)

1 more Shared Artifacts...

Test Summary

70 tests in total

0	0	0
New Failures	Existing Failures	Fixed

BetaScanner.verifyAptinaTestFrame_log_svn_rev_993.txt
252K View Download

Log file excerpt (full file saved in DHF): 3752 rows total

```
stripe: 3 0 100 at 0     # bad: 0 total 0 with 0 duplicates
stripe: 3 0 101 at 15.1515     # bad: 0 total 2 with 0 duplicates
stripe: 3 0 102 at 15.625      # bad: 0 total 4 with 0 duplicates
stripe: 3 0 103 at 15.873      # bad: 0 total 6 with 0 duplicates
stripe: 3 0 104 at 15.9681     # bad: 0 total 8 with 0 duplicates
stripe: 3 0 105 at 16.0514     # bad: 0 total 10 with 0 duplicates
stripe: 3 0 106 at 16.1074     # bad: 0 total 12 with 0 duplicates
stripe: 3 0 107 at 16.1476     # bad: 0 total 14 with 0 duplicates
...
stripe: 11 49 111 at 16.3385   # bad: 0 total 7492 with 0 duplicates
stripe: 11 49 112 at 16.3385   # bad: 0 total 7494 with 0 duplicates
stripe: 11 49 113 at 16.3385   # bad: 0 total 7496 with 0 duplicates
stripe: 11 49 114 at 16.3385   # bad: 0 total 7498 with 0 duplicates
Did 7500 at  16.3388
SUCCESS
```

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APPENDIX 2

Log file excerpt (full file saved in DHF):

Verif-SystemsSoftware-Protocol 2.txt 136609 rows total
PROTOCOL TEST 2

Load, Reprocess and Save

Original Filename : C:/Lantos/data/LantosView/Scans/1111011600_DF_0r/1111011600_DF_0r.txt
Load original image :1 time(s) Succeeded!
Raw images reprocessed: Succeeded!
Computation of 3D data: Succeeded!
Save data to: C:/Lantos/data/LantosView/Scans/Protocol_2_3_1203191025/1111011600_DF_0r_120319102550 Succeeded!
Load original image :2 time(s) Succeeded!
Raw images reprocessed: Succeeded!
Computation of 3D data: Succeeded!
Save data to: C:/Lantos/data/LantosView/Scans/Protocol_2_3_1203191025/1111011600_DF_0r_120319102805 Succeeded!
Load original image :3 time(s) Succeeded!
Raw images reprocessed: Succeeded!
Computation of 3D data: Succeeded!
…

Reload and compare

Original Scan ID 1111011600_DF_0r
Actual Scan ID 1111011600_DF_0r_120319102550
load image [686] succeeded!
image comparison [686] : succeeded!
load image [309] succeeded!
image comparison [309] : succeeded!
...

load image [994] succeeded!
image comparison [994] : succeeded!
load image [36] succeeded!
image comparison [36] : succeeded!
load image [1030] succeeded!
image comparison [1030] : succeeded!
load image [137] succeeded!
image comparison [137] : succeeded!
PROTOCOL 2 Succeeded!
END OF PROTOCOL 2

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APPENDIX 3

Log file excerpt (full file saved in DHF):

Verif-SystemsSoftware-Protocol 3.txt 319 rows total

PROTOCOL TEST 3

Load, Reprocess and Save

```
  Original Filename : C:/Lantos/data/LantosView/Scans/1111011600_DF_0r/1111011600_DF_0r.txt
    Load original image :1 time(s) Succeeded!
        Raw images reprocessed: Succeeded!
        Computation of 3D data: Succeeded!
Save data to: C:/Lantos/data/LantosView/Scans/Protocol_2_3_1203191025/1111011600_DF_0r_120319102550
Succeeded!
    Load original image :2 time(s) Succeeded!
        Raw images reprocessed: Succeeded!
        Computation of 3D data: Succeeded!
Save data to: C:/Lantos/data/LantosView/Scans/Protocol_2_3_1203191025/1111011600_DF_0r_120319102805
Succeeded!
    Load original image :3 time(s) Succeeded!
        Raw images reprocessed: Succeeded!
        Computation of 3D data: Succeeded!
…
```

Reload and compare

```
Original Scan ID 1111011600_DF_0r
    Actual Scan ID 1111011600_DF_0r_120319102550
        3D comparison surface_1203191027.obj with surface_1202062205.obj succeeded!
    Actual Scan ID 1111011600_DF_0r_120319102805
        3D comparison surface_1203191029.obj with surface_1202062205.obj succeeded!
    Actual Scan ID 1111011600_DF_0r_120319102952
        3D comparison surface_1203191031.obj with surface_1202062205.obj succeeded!
    Actual Scan ID 1111011600_DF_0r_120319103139
        3D comparison surface_1203191033.obj with surface_1202062205.obj succeeded!

…

    Actual Scan ID 1111011709_LP_0r_120319115602
        3D comparison surface_1203191157.obj with surface_1202062224.obj succeeded!
    Actual Scan ID 1111011709_LP_0r_120319115723
        3D comparison surface_1203191158.obj with surface_1202062224.obj succeeded!
    Actual Scan ID 1111011709_LP_0r_120319115843
        3D comparison surface_1203191200.obj with surface_1202062224.obj succeeded!
PROTOCOL 3 Succeeded!
END OF PROTOCOL 3
```

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APPENDIX 4

Log file excerpt (full file saved in DHF):

Verif-SystemsSoftware-Protocol 4.txt 1533809 lines total

PROTOCOL TEST 4

Load, Reprocess and Save

```
  Original Filename : C:/Lantos/data/LantosView/Scans/1111011600_DF_0r/1111011600_DF_0r.txt
    Load modified image set number :1 Succeeded!
        Raw images reprocessed: Succeeded!
        Computation of 3D data: Succeeded!
Save data to: C:/Lantos/data/LantosView/Scans/Protocol_4_1203171347/1111011600_DF_0r_120317153802
Succeeded!
    Load modified image set number :2 Succeeded!
        Raw images reprocessed: Succeeded!
        Computation of 3D data: Succeeded!
Save data to: C:/Lantos/data/LantosView/Scans/Protocol_4_1203171347/1111011600_DF_0r_120317153957
Succeeded!
    Load modified image set number :3 Succeeded!
        Raw images reprocessed: Succeeded!
        Computation of 3D data: Succeeded!
…
```

Reload and compare

```
Original Scan ID 1111011600_DF_0r
    Actual Scan ID 1111011600_DF_0r_120317153802
        Change Order Of Retrieval Number: 1
            load image [35] succeeded!
            image comparison [35] : succeeded!
            load image [718] succeeded!
            image comparison [718] : succeeded!
            load image [995] succeeded!
            image comparison [995] : succeeded!

…

            image comparison [68] : succeeded!
            load image [117] succeeded!
            image comparison [117] : succeeded!
            load image [98] succeeded!
            image comparison [98] : succeeded!
            load image [523] succeeded!
            image comparison [523] : succeeded!
            load image [267] succeeded!
            image comparison [267] : succeeded!
PROTOCOL 4 Succeeded!
END OF PROTOCOL 4
```

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APPENDIX 5

Log file (file saved in DHF):

Verif-SystemsSoftware-Protocol 5.txt

Scan processed 1203161403_MM_FFr Succeeded!
Scan processed 1203161359_MM_FFr Succeeded!
Scan processed 1203131842_MM_ADr Succeeded!
Scan processed 1203071239_MM_ADBr Succeeded!
Scan processed 1203051653_MM_DVr Succeeded!
Scan processed 1203051646_MM_DVl Succeeded!
Scan processed 1203051639_MM_ADBl Succeeded!
Scan processed 1203051633_MM_ADBr Succeeded!
Scan processed 1203050941_MM_FFr Succeeded!
Scan processed 1203050934_MM_FFr Succeeded!

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APPENDIX 6

(b)(4)

[redacted]

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(b)(4)

[redacted]

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14.3. Software Verification – Unit Test

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

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PURPOSE

This Protocol details the Unit and Functional Testing for the LantosView application software used in the Lantos 3D Ear Scanner. For each execution of the protocol, a report will be generated which incorporates this protocol.

REPORT: Test of LantosView rev904 AAApre26 release 02-Mar-2012

1. SCOPE

Applies to the LantosView software, all released versions.

2. REFERENCE DOCUMENTS:

Atlassian Bamboo – Documentation for Automated Software Test

http://confluence.atlassian.com/display/ALLDOC/Bamboo+Documentation+Directory

3. DEFINITIONS:

None.

4. MATERIALS AND EQUIPMENT:

4.1. Unit Tests. Create sequence of Unit Tests for classes and methods of LantosView software. Identify acceptance criteria for all Unit Tests. Maintain Unit Tests under Subversion SVN revision control, per the Lantos software configuration management process, and update this protocol document periodically as tests are added to the sequence.

4.2. Equipment. Unit tests run on a Windows 7 based desktop computer, where software tools have been properly installed. Refer to Atlassian Bamboo documentation for latest versions of tools and installation procedure.

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4.3. Example Test.

Coded Test Case and expected Result. See documentation for details.

```
-- coded test case
#include "LantosQuaternionT.hpp"

#include <boost/test/unit_test.hpp>

BOOST_AUTO_TEST_CASE(LantosQuaternionTest) {
  using Lantos::math::QuaternionT;
  typedef QuaternionT<double> Q;
  Q q;
  //Eigen::Matrix<double>;
  typedef Eigen::Matrix<double, 3, 3, Eigen::ColMajor> Mat;
  Mat R = q.matrix3x3();
  BOOST_REQUIRE(R == Mat::Identity());
  R = Mat::Identity();
  R(0,0) =  0; R(0,1) = 1;
  R(1,0) = -1; R(1,1) = 0;
  q = Q(R);
}

-- test case result
<testcase classname="Master Test Suite.src/LantosQuaternionT_test" name="LantosQuaternionTest"
time="0"><system-out>
[Info] - check R == Mat::Identity() passed  == [File] - src/LantosQuaternionT_test.cpp  == [Line] - 12
</system-out></testcase>

-- more complete test case result
<testcase classname="Master Test Suite.src/LantosMinDisk_test" name="LantosMinDiskTest_Disk"
time="0"><system-out>
[Info] - absolute value of (Vector2(0,0) - D1.center).norm() - D1.radius{0} doesn't exceed 9.9999999999999995e-008
 == [File] - src/LantosMinDisk_test.cpp  == [Line] - 21
[Info] - absolute value of (Vector2(0,0) - D2.center).norm() - D2.radius{0} doesn't exceed 9.9999999999999995e-008
 == [File] - src/LantosMinDisk_test.cpp  == [Line] - 23
[Info] - absolute value of (Vector2(2,0) - D2.center).norm() - D2.radius{0} doesn't exceed 9.9999999999999995e-008
 == [File] - src/LantosMinDisk_test.cpp  == [Line] - 24
[Info] - absolute value of (Vector2(0,0) - D3.center).norm() - D3.radius{0} doesn't exceed 9.9999999999999995e-008
 == [File] - src/LantosMinDisk_test.cpp  == [Line] - 26
[Info] - absolute value of (Vector2(1,1) - D3.center).norm() - D3.radius{0} doesn't exceed 9.9999999999999995e-008
 == [File] - src/LantosMinDisk_test.cpp  == [Line] - 27
[Info] - absolute value of (Vector2(2,0) - D3.center).norm() - D3.radius{0} doesn't exceed 9.9999999999999995e-008
 == [File] - src/LantosMinDisk_test.cpp  == [Line] - 28
[Info] - absolute value of (Vector2(0,0) - D4.center).norm() - D4.radius{0} doesn't exceed 9.9999999999999995e-008
 == [File] - src/LantosMinDisk_test.cpp  == [Line] - 30
[Info] - absolute value of (Vector2(1,2) - D4.center).norm() - D4.radius{0} doesn't exceed 9.9999999999999995e-008
 == [File] - src/LantosMinDisk_test.cpp  == [Line] - 31
[Info] - absolute value of (Vector2(2,0) - D4.center).norm() - D4.radius{0} doesn't exceed 9.9999999999999995e-008
 == [File] - src/LantosMinDisk_test.cpp  == [Line] - 32
</system-out></testcase>
```

5. ACCEPTANCE CRITERIA:

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A version of the LantosView software passes this Unit Test Protocol when the results of all Unit Test sshow no errors, no failures, and no tests skipped. As of this protocol release date and revision, there are 60 Units Tests as listed.

```
-- Test List – Full Suite of Unit Tests
<testsuite tests="60" errors="0" failures="0" name="Master Test Suite" skipped="0">

<testcase classname="LantosCalibrationSuite.src/LantosCalibration_test"
        name="LantosCalibration_test_projection_unprojection0" time="0.24"></testcase>
<testcase classname="LantosCalibrationSuite.src/LantosCalibration_test"
        name="LantosCalibration_test_projection_unprojection1" time="0.223"></testcase>
<testcase classname="LantosCalibrationSuite.src/LantosCalibration_test"
        name="LantosCalibration_test_projection_unprojection_sign_of_offset" time="0.204"></testcase>
<testcase classname="LantosCalibrationSuite.src/LantosCalibration_test"
        name="LantosCalibration_test_sign_of_□_tip" time="0.22"></testcase>
<testcase classname="LantosCalibrationSuite.src/LantosCalibration_test"
         name="LantosCalibration_test_imagespace_distortion" time="0.178"></testcase>
<testcase classname="Master Test Suite.src/LantosConcurrent_test"
        name="LantosConcurrent_test_□ipe" time="0.005"></testcase>
<testcase classname="Master Test Suite.src/Lantos□arbageCollector_test"
        name="Lantos□arbageCollectorTest" time="0.025"></testcase>
<testcase classname="Master Test Suite.D:/Atlassian/ Data/Bamboo/xml-data/…test/impl/results_collector"
        name="LantosImageCorrelation_test0" time="2.759"></testcase>
<testcase classname="Master Test Suite.src/Lantos□eometryAlgorithm_test"
        name="□□□_Lantos□eometryAlgorithm_test_alignRigid□oint□oint" time="0.167"></testcase>
<testcase classname="Master Test Suite.src/Lantos□eometryAlgorithm_test"
        name="□□□_Lantos□eometryAlgorithm_test_alignRigid□oint□lane" time="0.091"></testcase>
<testcase classname="Master Test Suite.src/Lantos□eometryAlgorithm_test"
        name="Lantos□eometryAlgorithm_test_alignRigid□oint□laneRA□SAC" time="0.004"></testcase>
<testcase classname="Master Test Suite.src/Lantos□eometryAlgorithm_test"
        name="Lantos□eometryAlgorithm_test_alignRigid□oint□lane_nearly_flat" time="0.001"></testcase>
<testcase classname="Master Test Suite.src/Lantos□eometryAlgorithm_test"
        name="Lantos□eometryAlgorithm_test_example" time="0"></testcase>
<testcase classname="Master Test Suite.src/Lantos□eometryAlgorithm_test"
        name="□eometryAlgorithm_recover_motion" time="0.013"></testcase>
<testcase classname="Master Test Suite.src/Lantos□omography2D_test"
        name="Lantos□omographyTest1" time="0"></testcase>
<testcase classname="Master Test Suite.src/Lantos□omography2D_test"
        name="Lantos□omographyTest2_□eighted" time="0"></testcase>
<testcase classname="Master Test Suite.src/Lantos□omography2D_test"
        name="Lantos□omography2D_Robust" time="0.002"></testcase>
<testcase classname="Master Test Suite.src/LantosImage□rocessing_test"
        name="Image□rocessing" time="0.001"></testcase>
<testcase classname="Master Test Suite.src/LantosImageT_test"
        name="LantosImageT_test_interpolation" time="0"></testcase>
<testcase classname="Master Test Suite.src/LantosImageT_test"
        name="LantosImageT_test_scalar_mult" time="0"></testcase>
<testcase classname="Master Test Suite.src/LantosImageT_test"
        name="LantosImageT_test_comparison" time="0"></testcase>
<testcase classname="Master Test Suite.src/Lantos□ey□ordMap_test"
        name="□ey□ordMap" time="0.016"></testcase>
<testcase classname="Master Test Suite.src/LantosMath_test"
        name="Lantos□anTest" time="0.001"></testcase>
<testcase classname="Master Test Suite.src/LantosMath_test"
        name="LantosMathTest" time="0"></testcase>
<testcase classname="Master Test Suite.src/LantosMinDisk_test"
        name="LantosMinDiskTest_Disk" time="0"></testcase>
```

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```
<testcase classname="Master Test Suite.src/LantosMinDisk_test"
        name="LantosMinDiskTest_MinDisk" time="0.001"></testcase>
<testcase classname="Master Test Suite.D:/Atlassian/Data/Bamboo/xml-data/…/test/impl/results_collector"
        name="Lantos□oisyTransform_test" time="0"></testcase>
<testcase classname="Master Test Suite.src/LantosQuaternionT_test"
        name="LantosQuaternionTest" time="0"></testcase>
<testcase classname="Master Test Suite.D:/Atlassian/Data/Bamboo/xml-data/…/test/impl/results_collector"
        name="LantosRA□SACTest" time="0"></testcase>
<testcase classname="Master Test Suite.src/LantosRA□SAC_test"
        name="LantosRA□SAC□omographyTest" time="0.004"></testcase>
<testcase classname="Master Test Suite.src/LantosRA□SAC_test"
        name="LantosRA□SAC3D□ointFitTest" time="0.005"></testcase>
<testcase classname="Master Test Suite.src/LantosRA□SAC_test"
        name="LantosRA□SAC3D□ointRecovery" time="0"></testcase>
<testcase classname="Master Test Suite.src/LantosResource□ool_test"
        name="LantosResource□oolTest" time="0.001"></testcase>
<testcase classname="Master Test Suite.src/LantosScan_test"
        name="LantosScan_test1" time="1.056"></testcase>
<testcase classname="Master Test Suite.src/LantosScan_test"
        name="LantosScan_test0" time="0.412"></testcase>
<testcase classname="Master Test Suite.src/LantosScan_test"
        name="LantosScan_compute□ose_test" time="0.183"></testcase>
<testcase classname="Master Test Suite.D:/Atlassian/Data/Bamboo/xml-data/…/test/impl/results_collector"
        name="LantosStitchTest0" time="0"></testcase>
<testcase classname="Master Test Suite.src/LantosSTL_test"
        name="LantosSTLTest" time="0"></testcase>
<testcase classname="Master Test Suite.src/LantosVectorT_test"
        name="VectorConstruction" time="0"></testcase>
<testcase classname="Master Test Suite.src/LantosVie□Types_test"
        name="LantosVie□TypesTest" time="0"></testcase>
<testcase classname="Master Test Suite.src/LantosVL_test"
        name="LantosVLTest_xpmat" time="0.001"></testcase>
<testcase classname="Master Test Suite.src/LantosVL_test"
        name="LantosVLTestSqrtm" time="0"></testcase>
<testcase classname="Master Test Suite.src/LantosVL_test"
        name="LantosVLTestExpSE3" time="0"></testcase>
<testcase classname="Master Test Suite.src/LantosVL_test"
        name="LantosVLTest_solveSym" time="0.002"></testcase>
<testcase classname="Master Test Suite.src/LantosVL_test"
        name="LantosVLTest_solveUnsym" time="0"></testcase>
<testcase classname="Master Test Suite.src/LantosVL_test"
        name="LantosVLTest_Solve" time="0.103"></testcase>
<testcase classname="Master Test Suite.src/Motion□raphTest"
        name="Motion□raphTests" time="0.022"></testcase>
<testcase classname="Master Test Suite.src/Motion□raphTest"
        name="Motion□raphMetricTests" time="0"></testcase>
<testcase classname="Master Test Suite.src/□oseOptimi□ation_test"
        name="SparseIdentityTest0" time="0"></testcase>
<testcase classname="Master Test Suite.src/□oseOptimi□ation_test"
        name="SparseIdentityTest1" time="0"></testcase>
<testcase classname="Master Test Suite.src/□oseOptimi□ation_test"
        name="ExtractBlockTest" time="0"></testcase>
<testcase classname="Master Test Suite.src/□oseOptimi□ation_test"
        name="□oseOptimi□ationTest_three_joint_example" time="0.001"></testcase>
<testcase classname="Master Test Suite.src/□oseOptimi□ation_test"
        name="□oseOptimi□ationTest_three_joint_example_2" time="0.001"></testcase>
<testcase classname="Master Test Suite.src/□oseOptimi□ation_test"
        name="Test_buildID2SequentialIndexMap" time="0"></testcase>
```


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```
<testcase classname="Master Test Suite.src/□oseOptimi□ation_test"
        name="□oseOptimi□ationTest" time="0.001"></testcase>
<testcase classname="Master Test Suite.src/□oseOptimi□ation_test"
        name="asdfasdfsdf" time="0"></testcase>
<testcase classname="Master Test Suite.src/□oseOptimi□ation_test"
        name="LantosVie□ModuleCompute□osesTest" time="0.004"></testcase>
<testcase classname="Master Test Suite.src/□oseOptimi□ation_test"
        name="□oseOptimi□ationTest_vs_neighbors" time="0"></testcase>
<testcase classname="Master Test Suite.src/□oseOptimi□ation_test"
        name="Compute□ose_test" time="0.541"></testcase>
<testcase classname="Master Test Suite.src/□oseOptimi□ation_test"
        name="Compute□oses_test" time="0.004"></testcase>

</testsuite>
```


6. RESULTS:

Run tests and examine results; capture automated output of test suite. BF – 02-Mar-2012.

Unit Test rev904

---------- Forwarded message ----------
From: **Bamboo** <atlassian@lantostechnologies.com>
Date: Fri, Mar 2, 2012 at 4:13 PM
Subject: [Bamboo] LantosView > UnitTests > #431 was SUCCESSFUL (with 60 tests).

LantosView > **UnitTests** > **#431** was successful.
Code has been updated by DanielVlasic.
All **5** jobs passed with **60** tests in total.

Conclusion / Deviations

All Unit Tests passed on LantosView rev904 software. Acceptance criteria were met. No deviations noted.

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14.4. Single Use Disposable Verification

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PURPOSE

This is the test report for the Bench Testing for the Lantos 3D Ear Scanner single-patient-use Disposable component, per the referenced protocol.

REPORT: Test of Disposable Lot 28 on 02-Mar-2012, 13-Mar-2012 – results Section 7

1. SCOPE

Applies to the Lantos single-patient-use Disposable, Alpha version.

2. REFERENCE DOCUMENTS:

VerificationProtocol-LantosDisposableBenchRevA

3. DEFINITIONS:

None.

4. MATERIALS AND EQUIPMENT:

4.1. Samples. Test samples shall be manufactured using a manufacturing process that is equivalent to the final manufacturing process for the Alpha device. Appendix A of the report for this protocol shall include lot history records and other data that describes how, when and by whom these devices were manufactured.

4.2. Equipment. All equipment used (including Lantos scanners) shall be identified in the protocol report.

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5. ACCEPTANCE CRITERIA:

Test	Summary / Description / Procedure	Acceptance Criteria
Window Clarity Test	(b)(4) [redacted]	90% confidence that 90% of manufactured devices will pass this attribute test.
Leak Test	[redacted]	90% confidence that 90% of manufactured devices will pass this attribute test.

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Peristaltic Inflation Test	The conformable membrane has been constructed to permit inflation in a peristaltic manner, that is, the tip should inflate first with inflation continuing proximal to the tip. Membranes are filled slowly, with air, to ensure that they possess this property. Procedure: • Inflate membrane. • Observe location of initial inflation. • Pass: inflation starts at tip (distal end) instead of body (proximal end). • Record pass/fail for each cartridge.	90% confidence that 90% of manufactured devices will pass this attribute test.
Max Pressure Test	The membranes should not rupture when exposed to anticipated inflation pressures. At the conclusion of the peristaltic inflation test, membranes are inflated to ensure that they maintain their physical integrity despite exposure to maximum pressure. Procedure: • Inflate membrane (b)(4) [redacted]. • Ensure membrane does not rupture. • Pass: membrane remains leak free after pressure test. • Record pass/fail for each cartridge.	90% confidence that 90% of manufactured devices will pass this attribute test.
Scan Test	Fully assembled disposables are attached to a scanner, and a scan is made of a measured cylindrical cavity. Procedure: • Inflate membrane into packaging cap. • Scan inside of membrane. • Pass: scan results in a conical geometry representative of interior of packaging cap per acceptance criteria.	90% confidence that 90% of the devices will achieve within +/- 10% scanning accuracy.

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6. DISCUSSION

Bench testing was performed to ensure that the Lantos scanner meets each of its product function related Design Input Requirements. A test protocol was prepared in advance, which included the acceptance criteria described in this report. Testing was performed on production equivalent devices. The following tests were performed:

Window Clarity Test. The user guides the device location visually, using the image on the laptop screen. This image must be captured by the scanning probe through the optically transparent window at the end of the disposable. Each test sample was evaluated by viewing a sample image (a 2-dimensional bar code image) through the window and ensuring that the test software could discern the message encoded in the bar code.

Leak Test. The device's conforming membrane is inflated with absorbing dye solution. To ensure proper functionality and patient comfort, the membrane must not leak. Test sample membranes were filled with air, and then submerged in a solution of 90% distilled water and 10% Isopropyl alcohol. Absence of bubbles indicates that the device is leak free.

Peristaltic Inflation Test. The conforming membrane preferred inflation commences from the tip of the device (in the ear canal) and proceeds outwardly towards the outside of the ear. This reduces the likelihood that air is trapped between the membrane and the wall of the ear canal. Test samples were inflated and inflation was observed to ensure that that the needed inflation pattern was observed.

Maximum Pressure Test. To ensure that the conforming membranes would not be damaged during use, conforming membranes were inflated and inflation pressure was monitored. Test samples were pressurized to the maximum specified pressure for the device, and observed to ensure that they inflated properly and were not damaged.

Scan Test. The scan test integrates all of the product's required bench test functionality. Fully assembled, production disposables were loaded into the scanner hand piece. The devices were powered-up and placed visually into a cone of known dimensions, representing the typical dimensions of an adult ear. A scan was taken, and the results assessed to determine the devices ability to reproduce the geometry of the known dimensions to within +/- 10%.

Sample Size and Statistical Rationale. A sample size of 52 scans using 52 separate disposables was chosen in order to meet the requirements of a standard hypothesis test of a binomial proportion and allow for a small number of failed units. The test statistic for the null hypothesis of the binomial proportion test is:

H0: P=P0
Z0 = (X - nP0)/sqrt(nP0(1-P0))

The null hypothesis is rejected in favor of the alternative hypothesis:

H1: P<P0
when Z0 < -Zalpha

The acceptance criteria require that the percent defective is P0=10% or less with 90% confidence (thus alpha=0.05). The acceptance criteria are met when 47 trials are conducted with 3 or fewer failures. Given that

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multiple evaluations are being performed on each disposable trial, it is possible that a failure of one criterion on a sample would render that sample unusable for the other criteria. Therefore, an additional 5 samples have been budgeted (for a total of 52 samples) to guard against undesirable censoring of data.

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7. RESULTS

Test Lot 28 – 52 Disposables

4% / 6% Black – 2.5% Pad Print v7 delivered 01-Mar-2012

Tests performed, results recorded MM, ADB 02-Mar-2012 13-Mar-2012 see Appendix B

Alpha Four Scanner – used for Scan Test

Test articles were selected randomly from a lot of production equivalent disposables. These were assembled using disposable sub-assemblies fabricated at Lantos' contract manufacturing partner; and conforming membrane sub-assemblies fabricated at a supplier. A final assembly protocol that incorporates attaching conforming membranes to disposable sub-assemblies, and filling them with absorbing dye was followed. Conforming membranes sub-assemblies were subjected to an incoming inspection test that included a 100% leak test.

The data sheet for the testing performed is provided in Appendix B.

Test	Requirement	Acceptance Criteria	Result
1. Window Clarity Test	The window at distal tip must be clear enough to permit proper placement of the device.	A minimum of 47 samples tested with 3 or fewer failures.	Pass
2. Leak Test	The conformable membrane portion of the disposable must be able to be inflated without leaking.	A minimum of 47 samples tested with 3 or fewer failures.	Pass
3. Peristaltic Inflation Test	The conformable membrane has been constructed to permit inflation in a peristaltic manner, that is, the tip should inflate first with inflation continuing proximal to the tip.	A minimum of 47 samples tested with 3 or fewer failures.	Pass
4. Max Pressure Test	The membranes should not rupture when exposed to anticipated inflation pressures.	A minimum of 47 samples tested with 3 or fewer failures.	Pass
5. Scan Test	Fully assembled disposables are attached to a scanner, and a scan is made of a measured cylindrical cavity.	A minimum of 47 samples tested with 3 or fewer failures.	Pass

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8. CONCLUSIONS / DEVIATIONS

Lot 28 was acceptable for Window Clarity, Leak, Peristaltic Inflation, Max Pressure and Scan tests. There were no deviations from the Protocol. We conclude that the Alpha disposable meets the bench test requirements as outlined in the testing protocol.

Subsequent lots with improved processes will be fabricated and tested per this Disposable Bench Testing Protocol, and documented in the Design History File, prior to commercial release of the Lantos 3D Ear Scanner.

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APPENDIX A

(b)(4)

[redacted]

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APPENDIX B - Raw Data Results

(b)(4)

[redacted]

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14.5. Cleaning Validation

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PURPOSE

This Protocol details the tests to verify the cleaning procedures for the Lantos 3D Ear Scanner handheld scanner, as specified in the Instructions-for-Use. For each execution of the protocol, a report will be generated which incorporates this protocol.

REPORT – Lantos 3D Ear Scanner – Handheld Cleaning per IFU
Scanner BetaD1

1. SCOPE

Applies to the handheld scanner of the Lantos 3D Ear Scanner, and the scanner tether cable.

2. REFERENCE DOCUMENTS:

Lantos3DEarScanner-IFU-Ver04b.docx

3. DEFINITIONS:

None.

4. MATERIALS AND EQUIPMENT:

4.1. Lantos 3D Ear Scanner handheld scanner and tether cable.

4.2. Cleaning materials as specified in the Instructions-for-Use – and inspection equipment as required.

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5. ACCEPTANCE CRITERIA:

Follow all the recommended cleaning procedures in the Instructions-for-Use – excerpted below for reference. Repeat each procedure three times. Confirm that all surfaces of the handheld scanner, and the connectors and sheath of the tether cable, withstand the cleaning with no detectible deterioration.

Cleaning Procedures

After each patient, cleaning the body of the Handheld Scanner and the tether cord with water and/or a non-staining disinfectant is recommended.
You do not need to shut down the Scanner while cleaning its surfaces. The following agents can be used for cleaning:

- BIREX®se (by Biotrol) or equivalent
- Warm water and a mild, non-abrasive detergent: Fantastic®, Lysol
- Do not use ammonia-based cleaners

Follow these steps:

- Apply the cleaning agent to a soft, non-abrasive cloth – wring out the cloth until damp
- Wipe down the surfaces with the damp cloth
- Rinse the cloth in clean water – wipe down the surfaces a second time
- Dry the surfaces with a clean, soft, non-abrasive cloth
- Do not spray or pour liquids on the surfaces – avoid liquid pooling or dripping – never submerge the Handheld Scanner – neither the Scanner nor the Laptop is watertight

Store device components in a dry, temperature controlled environment. Avoid extremes in temperature or humidity.

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Test	Summary / Description / Procedure	Acceptance Criteria
BIREX Cleaning Prodedure	Follow specified steps in IFU • Apply cleaning agent • Wipe Down • Rinse • Dry Repeat process 3x on handheld scanner and tether Inspect all surfaces	No detectible deterioration of surfaces of handheld scanner or tether cable.
Detergent Cleaning Procedure	Follow specified steps in IFU • Apply cleaning agent • Wipe Down • Rinse • Dry Repeat process 3x on handheld scanner and tether Inspect all surfaces	No detectible deterioration of surfaces of handheld scanner or tether cable.

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6. RESULTS:

Test	Summary / Description / Procedure	Acceptance Criteria
BIREX Cleaning Prodedure	Follow specified steps in IFU Repeat 3x	No detectible deterioration of surfaces of handheld scanner or tether cable. PASS – Appendix A
Detergent Cleaning Procedure	Follow specified steps in IFU Repeat 3x	No detectible deterioration of surfaces of handheld scanner or tether cable. PASS – Appendix A

7. CONCLUSIONS / DEVIATIONS:

The enclosure and exposed surfaces of the Lantos 3D Ear Scanner device BetaD1 were unaffected by repeated cleaning procedures as specified in the Instructions-for-Use . Acceptance criteria were met. No deviations found.

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Appendix A – Handheld Cleaning Test Results – BetaD1

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BOSTONDEVICE DEVELOPMENT

MEMORANDUM

Date	18 April 2012
To	Lantos Team
From	Jay Zignego
Subject	Test Report: Device Cleaning with LYSOL and BIREX
cc	
Version	1

Purpose

In order to verify the sterilization procedure does not visually impact the components in the Beta device, we conducted the following tests.

Test Methods

Testing was conducted in accordance with the Lantos Device Cleaning Protocol (Rev A).

Test 1: Effects of LYSOL on Beta Device

Lysol (non-aerosol) was sprayed on a clean paper towel and allowed to settle to ensure no foam was present. The Beta Device was then thoroughly wiped down with this towel, followed by a paper towel with clean water and then dried. This process was repeated three times.

Test 2: Effects of BIREX on Beta Device

After cleaning with LYSOL, the BIREX solution was tested on the same Beta Device. The BIREX solution was prepared in accordance to the BIREX specifications (1 QT room temperature water mixed with one concentrate packet and mixed in a spray bottle). The contents were then sprayed on a paper towel and allowed to settle to ensure no foam was present. The Beta Device was thoroughly wiped down followed by a paper towel with clean water and then dried. This process was repeated three times.

Results/Data

Test 1/II: Cleaning Solutions on Beta Device

Cleaning Solution Test		
Housing Material	**LYSOL Solution**	**BIREX Solution**
Urethane Casting (Rigid)	Unaffected	Unaffected
Urethane Grip (Flexible)	Unaffected	Unaffected
Aluminum Heat Sink	Unaffected	Unaffected
Painted Urethane Buttons (Rigid)	Unaffected	Unaffected

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Figure 1: BIREX Pre and Post wipe on Urethane Housing and Grip.

Figure 2: Images of all components post wipe with LYSOL followed by BIREX.

Observations

- Upon visual inspection, there were no changes to any of the materials on the Beta Device. This includes, but is not limited to, the rigid urethane housing, the flexible grip material, the anodized aluminum components, the ODU receptacle, the painted rigid urethane buttons along with dry transfers, the silk screen Lantos logo on the anodized button bezel etc.

Conclusions

The visual analysis conducted would suggest either cleaning solution may be used in conjunction with the Beta Device following the Device Cleaning Protocol (Rev A) with no deleterious effects.

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14.6. IEC 60601-1

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1. PURPOSE

This report details the system level test for the Lantos 3D Ear Scanner device per

INTERNATIONAL STANDARD – IEC 60601-1 Third edition 2005-12

Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

A subset of the full protocol, specific to electrical safety of the Scanner, was performed. Additional sections of the standard were evaluated for applicability to the Scanner.

Test requirements, setup, and equipment are specified in detail in the standard, and were adhered to in the tests. The tests were executed on a specific set of hardware, as listed herein. This protocol is part of the in-vitro verification test for the system, providing evidence that the 3D Ear Scanner is fit for its intended use.

REPORT: Test of Lantos 3D Ear Scanner – IEC-60601-1 Electrical Safety

2. SCOPE

Applies to the Lantos 3D Ear Scanner as a system, including the Lantos Laptop, the Handheld Scanner, the Docking Stand, and power distribution and all connecting cables.

3. REFERENCE DOCUMENTS:

INTERNATIONAL STANDARD – IEC 60601-1

4. DEFINITIONS:

None.

5. MATERIALS AND EQUIPMENT:

5.1. Materials. Device Enclosures. Single Use Disposable.

5.2. Equipment. Laptop and Handheld Scanner and Docking Stand. Device hardware identified in the verification report. Lab test equipment as indicated in the section to follow.

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Lantos Device Components

- Laptop Dell E6520 – S/N F8N2BS1
- Handheld Scanner – S/N Beta00
- Docking Stand – S/N A02

Laboratory Test Equipment

- Continental Resources – Quadcheck Model 65545A HiPot Tester – S/N 940128
- Agilent Model U1251A – Digital Multimeter – S/N TW47260011
- Hewlett:Packard Model 1146A AC/DC Current Probe – S/N 12HH9990
- Model DM6802A Type-K Thermometer 2-Channel – S/N VC278831
- R-C test circuit – 1kohm // 0.015uF

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Test Setup – Laptop, Handheld Scanner, Docking Stand, Power Distribution

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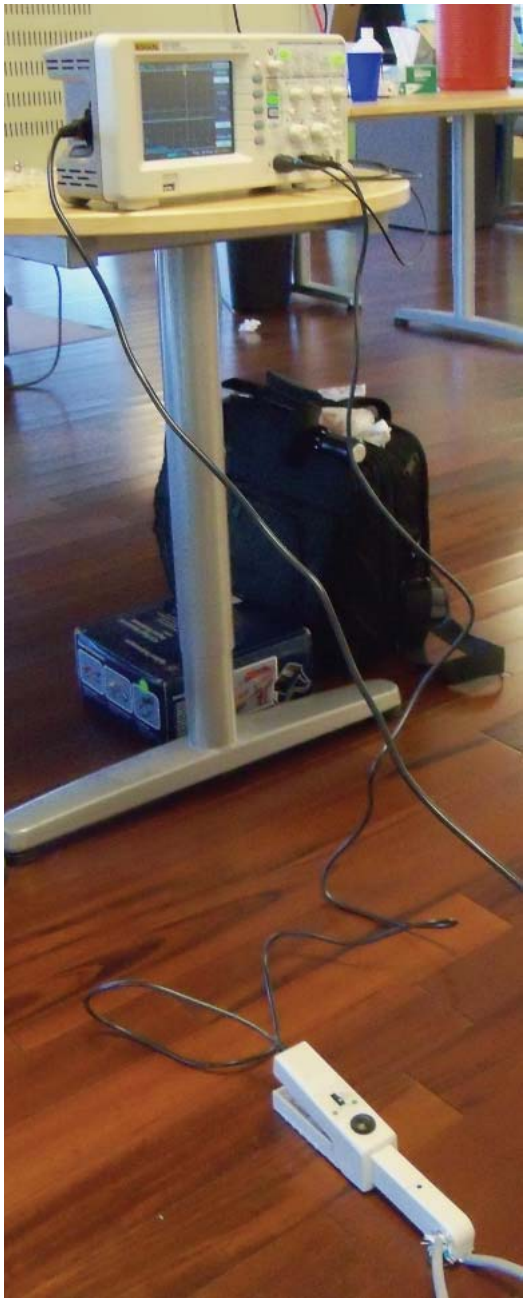
Test Setup – Input Power Measurement - Hewlett:Packard Model 1146A



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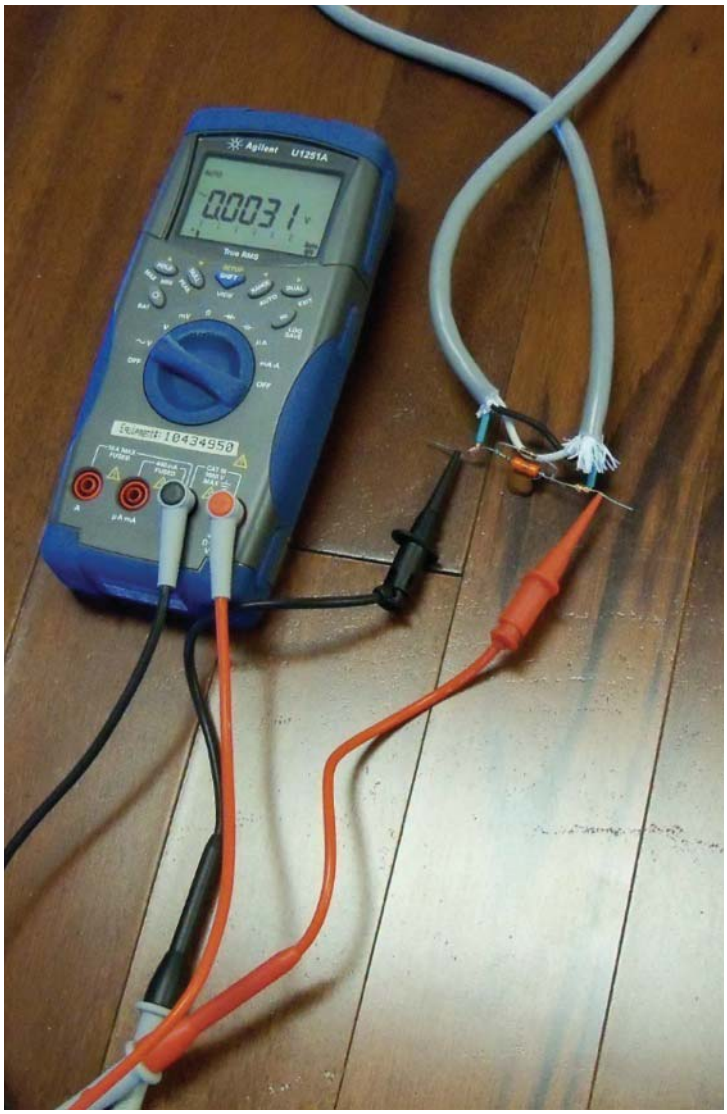
Test Setup – Line Leakage Current Measurement - Agilent Model U1251A and R-C Circuit



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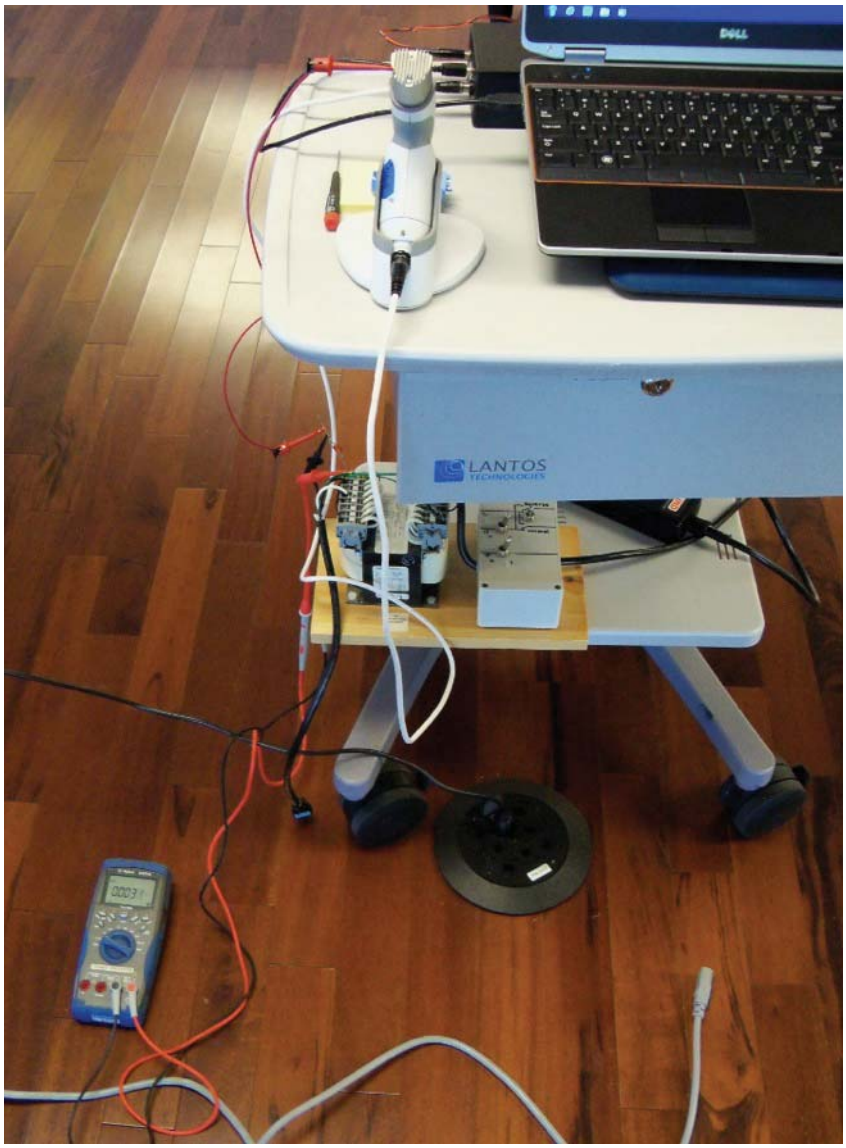
Test Setup – Enclosure Leakage Current Measurement - Agilent Model U1251A and R-C Circuit



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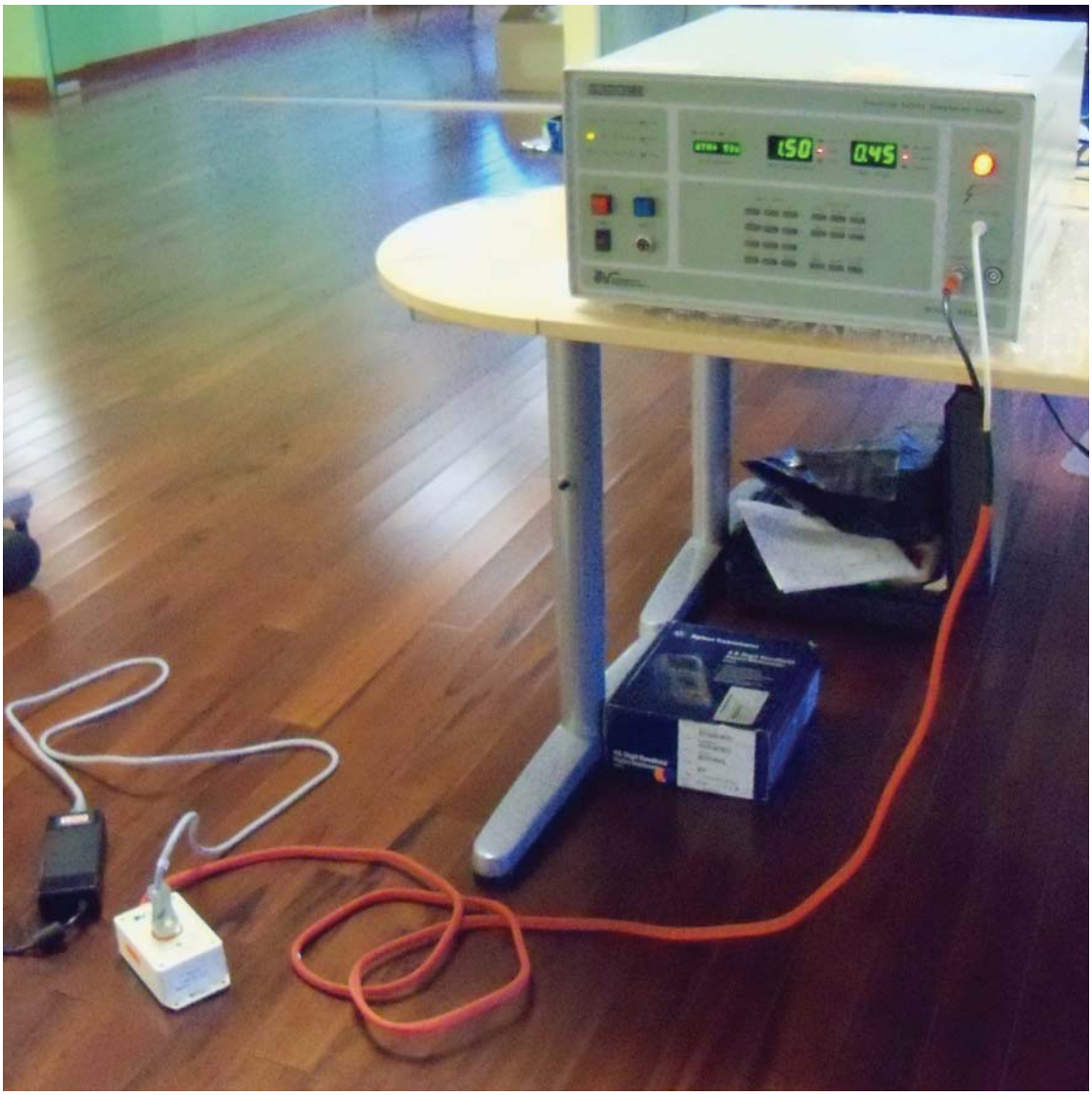
Test Setup – Dielectric Strength Testing - Quadcheck Model 65545A



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Test Setup – Leakage of Liquid – Single Use Disposable with Leak – Drive Syringe

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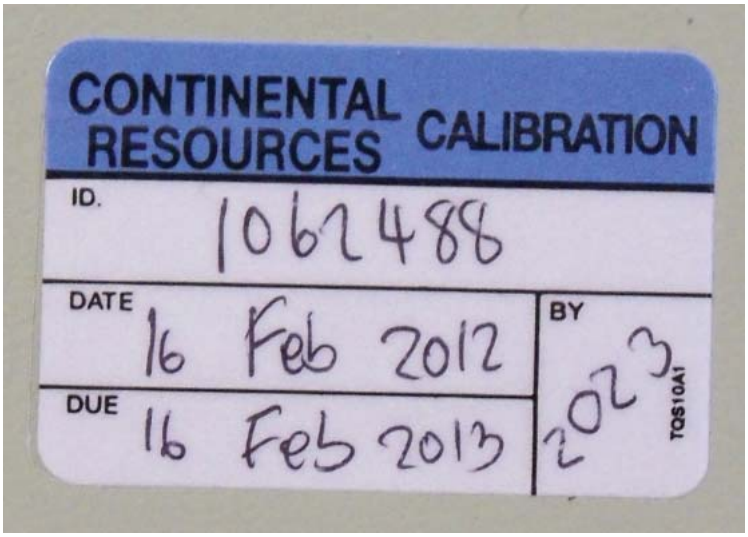
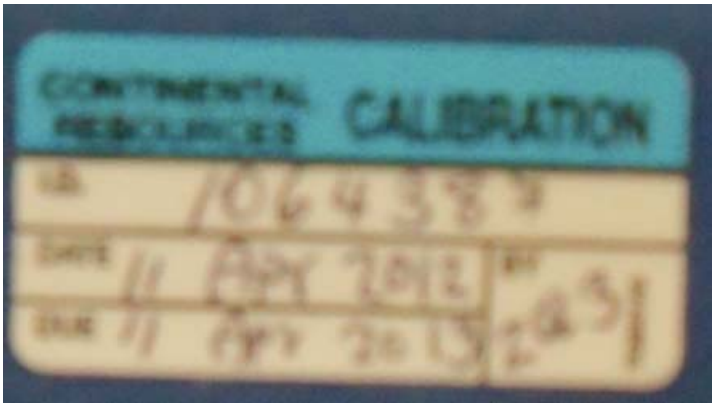
Calibration: Quadcheck Model 65545A



Calibration: Agilent Model U1251A



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6. TESTS PERFORMED AND ACCEPTANCE CRITERIA - RESULTS

Section	Acceptance Criteria	Result
4.11 Power Input	The steady-state measured input of the ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in the instructions for use shall not exceed the marked rating by more than 10 % (see 7.2.7).	PASS Appendix A – page 01
8.7 Leakage Currents	a) The electrical isolation providing protection against electric shock shall be of such quality that currents flowing through it are limited to the values specified in 8.7.3. b) The specified values of the EARTH LEAKAGE CURRENT, the TOUCH CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT apply in any combination of the following conditions	PASS Appendix A – page 02
8.8.3 Dielectric Strength	The dielectric strength of solid electrical insulation of ME EQUIPMENT shall be capable of withstanding the test voltages as specified in Table 6. Only insulation with a safety function need be subject to testing (see 8.8.1).	PASS Appendix A– page 04
11.1.1 Excessive Temperatures	**Maximum temperature during NORMAL USE** When ME EQUIPMENT is operated in worst-case NORMAL USE including the maximum ambient operating temperature specified in the technical description (see 7.9.3.1): – ME EQUIPMENT parts shall not reach temperatures exceeding the values given in Table 22 and Table 23;	PASS Appendix A – page 05
13.2.6 Leakage of Liquid	ME EQUIPMENT shall be so constructed that liquid that might escape in a SINGLE FAULT CONDITION does not result in an unacceptable RISK.	PASS Appendix A – page 07
Other	Assess other sections relevant to 3D Ear Scanner – mark as N/A if tests do not apply	See Appendix

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7. CONCLUSIONS / DEVIATIONS:

All device tests per the standard passed as recorded. Acceptance criteria were met. No deviations found. Additional evaluation and testing is planned per IEC-60601 prior to commercial release of the Lantos 3D Ear Scanner.

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Appendix A – IEC-60601-1 Test Results

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.9	RM RESULTS TABLE: Use of components with high-integrity characteristics		
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

4.11	TABLE: Power Input				Pass
Operating Conditions / Ratings	Voltage (V)	Frequency (Hz)	Current (A)	Power (W or VA)	Power factor (cos φ)
Video Otoscope Mode	261	60	380 mA		
Video Otoscope Mode	121	60	460 mA		
Supplementary Information:					

5.1	RM RESULTS TABLE: Type Tests		
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			

5.4 a)	RM RESULTS TABLE: Other Conditions		
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			

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(b)(4)

[redacted]

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IEC 60601-1				
Clause	Requirement + Test		Result - Remark	Verdict
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 uA Type CF: N/A
				N/A
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current): 100 uA NC; 500 uA SFC (a.c.) ; Type CF AP: 10 uA NC;50 uA SFC (d.c. or a.c. current)
				N/A
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC; 1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
				N/A
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC;1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
				N/A
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000uA Type CF: 100 uA
				N/A

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IEC 60601-1				
Clause	Requirement + Test		Result - Remark	Verdict
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 uA Type CF: N/A

Supplementary information:

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7
Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).

ER - Earth leakage current
TC – Touch current
P - Patient leakage current
PA – Patient auxiliary current
TP – Total Patient current
PM - Patient leakage current with mains on the applied parts
MD - Measuring device

A - After humidity conditioning
B - Before humidity conditioning
1 - Switch closed or set to normal polarity
0 - Switch open or set to reversed polarity
NC - Normal condition
SFC - Single fault condition

8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)				Pass
Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s[1]	Dielectric breakdown after 1 minute Yes/No[2]
		PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
Power Supply L & N to GND	1 MOOP	240		1500	No

Supplementary information:

[1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.
[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				Pass
Model No. ..... :					
Test ambient (°C) ..... :	25				
Test supply voltage/frequency (V/Hz)[4] .. :	121/60				

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
		Tip		26	Pass
		Heat Sink		31	Pass
		Power Supply Case		33	Pass
		Dell Exhaust Vent		43	Pass – Not patient applied part

Supplementary information:

[1] Maximum allowable temperature on surfaces of test corner is 90 °C

[2] Max temperature determined in accordance with 11.1.3e)

[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.

[4] Supply voltage:

- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

13.1.2	TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances	

Power dissipated less than (W)..... :	15
Energy dissipated less than (J)..... :	900

Part or component tested	Measured power dissipated (W)	Calculated energy dissipated (J)	SINGLE FAULT CONDITIONS waived (Yes/No)	Remarks

Supplementary information:

13.2	TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive	

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.2	Electrical SINGLE FAULT CONDITIONS per Clause 8.1:	—	—
			N/A
13.2.3	Overheating of transformers per Clause 15.5:	—	—
	Dell Power Supply TUV Approved		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.4	Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—
			N/A
13.2.5	Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—
			N/A
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	—	—
	Optical Medium Handpiece Leakage Test	Leakage Current 4.0 uA Patient Applied Part (Tip to GND)	PASS
13.2.7	Impairment of cooling that could result in a HAZARD using test method of 11.1:	—	—
	Single ventilation fans locked consecutively		N/A
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls		
	Simulated blocking of filters		
	Flow of a cooling agent interrupted		
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	—	—
			N/A
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10	—	—
		V measured =	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
		V measured =	
13.2.10	Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:	—	—
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or at the upper limit of RATED voltage range for specified time:		N/A
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices		
	Temperatures measured as specified in 11.1.3 d)		
	Temperatures did not exceed limits of Table 26		
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:	—	—
			N/A
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	—	—
			N/A

Supplementary information:
Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.

13.2.6	RM RESULTS TABLE: Leakage of liquid		
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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14.6a IEC 60601-1 Certification for Power Supply

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Industrial Services, Mobility and Transport, Product Safety and Quality, Education and Consulting, IT Services and Innovation

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Superior Product Consulting, Inc.
Mr. Frank Hsu, President
-
3F, No. 10, Alley 6
Lane 235, Pao Chiao Rd.
Hsin Tien, Taipei Hsien 231
Taiwan

Date : 11.03.2011
Our ref. : SCL ZTW1
Your ref.: 8548200498/CL/SPC

Ref : TA License

Type of Equipment : AC/DC Adapter
Model Designation : See Certificate
Certificate No. : TA 50199353 0004
Report No. : 10028820 001

Dear Mr. Frank Hsu,

Enclosed please find above certification documents.
Please forward these originals to the certificate holder.

If you contact our office, please quote our reference above.

We thank you for your cooperation.

The certificate holder is: FSP Group Inc.

With kind regards,

Certification Body

Dipl.-Ing. W. Hsu

Enclosure

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11F., No. 758, Sec. 4, Bade Rd.,
Songshan Dist., Taipei City 105,
Taiwan (R. O. C.)
Tel. (02) 2172-7000
Fax (02) 2578-9125 / 2578-9126
http: //www.twn.tuv.com

TAICHUNG BRANCH:
No. 9, Lane 36 , Sec. 3, Minsheng Rd.,
Daya Township, Taichung County 428,
Taiwan R.O.C.
Tel. (04) 2566-3598
Fax (04) 2566-3598

KAOHSIUNG BRANCH:
33F-3, No. 80, Min Tzu 1st Rd.,
Kaohsiung 807, Taiwan, R.O.C.
Tel. (07) 380-1722
Fax (07) 380-1748

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FSP Technology Inc., Kaohsiung Branch
Mr. Caiter Lee
R & D Dept.
2-3, East 3rd Street
N.E.P.Z., Kaohsiung 811
Taiwan

Date : 11.03.2011
Our ref. : SCL ZTW1
Your ref.: 8548200498/CL/SPC

Ref : TA License

Type of Equipment : AC/DC Adapter
Model Designation : See Certificate
Certificate No. : TA 50199353 0004
Report No. : 10028820 001

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With kind regards,

Certification Body

Dipl.-Ing. W. Hsu

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http: //www.twn.tuv.com

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No. 9, Lane 36 , Sec. 3, Minsheng Rd.,
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33F-3, No. 80, Min Tzu 1st Rd.,
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Tel. (07) 380-1722

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FSP Group Inc.
Mr. Mike Lin, Manager
R & D 6 Dept.
No. 22, Jianguo E. Road
Taoyuan 330
Taiwan

Date : 11.03.2011
Our ref. : SCL ZTW1
Your ref.: 8548200498/CL/SPC

Ref : TA License

Type of Equipment : AC/DC Adapter
Model Designation : See Certificate
Certificate No. : TA 50199353 0004
Report No. : 10028820 001

Dear Mr. Mike Lin,

The above specified technical equipment has been tested and found to be in accordance with the relevant requirements.

Enclosed you will find the certificate of approval.

If cancellation of the certificate is submitted by November 15 in a given year, no fee will be charged for the following year.

We appreciate your kind support and would like to offer our assistance and continuous services in the future.

Please contact our office for approval of your new products.

With kind regards,

Certification Body

W. Hu

Dipl.-Ing. W. Hsu

CC: FSP Technology Inc., Kaohsiung Bran

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Songshan Dist., Taipei City 105,
Taiwan (R. O. C.)
Tel. (02) 2172-7000
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http: //www.twn.tuv.com

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Taiwan R.O.C.
Tel. (04) 2566-3598
Fax (04) 2566-3598

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Certificate

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Certificate no. TA 50199353 01

License Holder:
FSP Group Inc.
No. 22, Jianguo E. Road
Taoyuan 330
Taiwan

Manufacturing Plant:
FSP Technology Inc., Kaohsiung Branch
2-3, East 3rd Street
N.E.P.Z., Kaohsiung 811
Taiwan

Test report no.: ZTW1-SCL 10028820 001 **Client Reference:** 8548200498/CL/SPC

Tested to: IEC 60601-1:2005
EN 60601-1:2006

Certified Product: (AC/DC Adapter) **License Fee - Units**

Type Designation	: FSP135-KxM1 (FSP)	10
x stands for	: HA, GA, DA, CA, AA, KA, LA, EA or FA	1
Rated Voltage	: AC 100-240V, 47-63Hz	
Rated Current	: 1.6-0.8A	
Output Voltage	: see constructional dataform	
Output Current	: see constructional dataform	
max. Power Output	: see constructional dataform	
max. Ambient Temperature	: 1) 40°C (for full output load)	
	2) 60°C (for half output load)	
Protection Class	: I	

This certificate is valid for maximum 5 years.

11

Appendix: 1

Licensed Test mark:

www.tuv.com TÜV ID:0000000001 — EN 60601-1, IEC 60601-1

TÜVRheinland Taiwan Ltd.
Signature

Quality Assurance Product TÜVRheinland Approved

W. Hsu

Dipl.-Ing. W. Hsu

Date of Issue (day/mo/yr)
11/03/2011

TÜV Rheinland Taiwan Ltd., 11fl., No. 758, Sec. 4, Bade Road, Songshan Dist., Taipei City 105, Taiwan, R.O.C.- Tel (02) 2172-7000 - Fax (02) 2528-0018

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

10/020 04.08 TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Certificate

TÜVRheinland®

Certificate no. TA 50199353 02

License Holder:
FSP Group Inc.
No. 22, Jianguo E. Road
Taoyuan 330
Taiwan

Manufacturing Plant:
FSP Technology Inc., Kaohsiung Branch
2-3, East 3rd Street
N.E.P.Z., Kaohsiung 811
Taiwan

Test report no.: ZTW1-SCL 10028820 001 **Client Reference:** 8548200498/CL/SPC

Tested to: IEC 60601-1:2005
EN 60601-1:2006

Certified Product: (AC/DC Adapter) **License Fee - Units**

as page 01

Addition

Type Designation :	PMP135-xyyyy (PROTEK POWER)	1
x stands for :	12, 12-1, 13, 13-1, 13-3, 14, 15, 16, 17, 18	1
y stands for :	0-9, A-Z, hyphen or blank	1

This certificate is valid for maximum 5 years.

3

Appendix: 1

Licensed Test mark:

www.tuv.com TÜV ID:0000000001 — EN 60601-1 IEC 60601-1

TÜV Rheinland Taiwan Ltd.
Signature

Product Quality Assurance TÜVRheinland Approved

Dipl.-Ing. W. Hsu

Date of Issue (day/mo/yr)
11/03/2011

TÜV Rheinland Taiwan Ltd., 11fl., No. 758, Sec. 4, Bade Road, Songshan Dist., Taipei City 105, Taiwan, R.O.C.- Tel (02) 2172-7000 - Fax (02) 2528-0018

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Certificate

TÜVRheinland®

Certificate no. TA 50199353 03

License Holder:
FSP Group Inc.
No. 22, Jianguo E. Road
Taoyuan 330
Taiwan

Manufacturing Plant:
Protek Electronics (China) Corp.
North Area, Tianmei Ind. Zone
Huangjiang Town
Dongguan City, Guangdong Province
P.R. China

Test report no.: ZTW1-SCL 10028820 001
Client Reference: 8548200498/CL/SPC
Tested to: IEC 60601-1:2005
EN 60601-1:2006

Certified Product: (AC/DC Adapter)
License Fee - Units

as page 01

Addition

Factory : see above

This certificate is valid for maximum 5 years.

Appendix: 1

Licensed Test mark:

www.tuv.com TÜV ID:0000000001
EN 60601-1
IEC 60601-1

TÜV Rheinland Taiwan Ltd.
Signature

Product Quality Assurance TÜVRheinland Approved

W. Hsu
Dipl.-Ing. W. Hsu

Date of Issue (day/mo/yr)
11/03/2011

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Certificate

TÜVRheinland®

Certificate no. TA 50199353 04

License Holder:
FSP Group Inc.
No. 22, Jianguo E. Road
Taoyuan 330
Taiwan

Manufacturing Plant:
ZhongHan Electronics (ShenZhen)
Co., Ltd.
JuYuan Industrial Zone
TangWei Village, FuYong Town
BaoAn District, ShenZhen City 518103
P.R. China

Test report no.: ZTW1-SCL 10028820 001

Client Reference: 8548200498/CL/SPC

Tested to: IEC 60601-1:2005
EN 60601-1:2006

Certified Product: (AC/DC Adapter)

License Fee - Units

as page 01

Addition

Factory : see above

This certificate is valid for maximum 5 years.

Appendix: 1

Licensed Test mark:

www.tuv.com TÜV ID:0000000001 — EN 60601-1, IEC 60601-1

TÜV Rheinland Taiwan Ltd.
Signature

Product Quality Assurance TÜVRheinland Approved

Dipl.-Ing. W. Hsu

Date of Issue (day/mo/yr)
11/03/2011

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14.7. IEC 60601-1-2

The testing to confirm compliance to the electromagnetic compatibility aspects of IEC 60601-1-2, are underway but not yet completed. Preliminary tests suggest that the device performs per standards, however an independent test lab will confirm this with a written report.

The power supply used has been certified to meet the requirements of IEC 60601-1-2 in all relevant aspects. Copies of the evidence to support this is provided below.

The Applicant certifies that the device will not be placed into interstate commerce until these tests have been satisfactorily completed.

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

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CE

VERIFICATION OF COMPLIANCE

This Verification of Compliance is hereby issued to the product designated below.

Product	**Switching Power Supply**
Model	**PMP135x-y (x=Blank or F, y=12,12-1,13,13-1,13-3, 14, 15,16,17 and 18)** **FSP135-1KxM1(FSP), x=20, 21, 30, 31, 33, 40, 50, 60, 70 and 80**
Brand Name	**FSP and PROTEK POWER**
Applicant	**FSP Group Inc.** 2-3, East 3rd Street N.E.P.Z., Kaohsiung, Taiwan.
Manufacturer	**(1) FSP Technology Inc., Kaohsiung Branch.** 2-3, East 3rd Street N.E.P.Z., Kaohsiung, Taiwan. **(2) Protek Electronics China Corp.** North Area, Tianmei Industrial Zone, Huangjiang Town, Dongguan City, Guangdong Province, China.
Applicable Standard(s)	**EN 60601-1-2:2007** **EN 55011:2007 Group 1, Class B** EN 61000-3-2:2006 ; EN 61000-3-3:1995+A1:2001+A2:2005 IEC 61000-4-2:1995+A1:1998+ A2:2000 IEC 61000-4-3:2006 ; IEC 61000-4-4:2004 IEC 61000-4-5:2005 : IEC 61000-4-6:2007 IEC 61000-4-8:1993+A1:2000 ; IEC 61000-4-11:2004
Reference No.	T100402403-E
Test Laboratory	**Compliance Certification Services Inc. (Tainan Lab.)** No. 8, Jiu Cheng Ling, Jiaokeng Village,Sinhua Township, Tainan Hsien 712, Taiwan R.O.C.

This device has been tested and found to comply with the stated standard(s), which is(are) required by the Council Directive of 2004/108/EC. The test results are indicated in the test report and are applicable only to the tested sample identified in the report.

Jeter Wu / Section Manager
Tainan Lab.
Data: April 16, 2010

CCS Compliance Certification Services Inc.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

CE EMC
TEST REPORT

for

Switching Power Supply

Trade Mark : FSP and PROTEK POWER

Model : PMP135x-y (x=Blank or F, y=12,12-1,13,13-1,13-3, 14, 15,16,17 and 18)

FSP135-1KxM1(FSP), x=20, 21, 30, 31, 33, 40, 50, 60, 70 and 80

Test Report Number:

T100402403-E

Issued for

FSP Group Inc.

2-3, East 3rd Street N.E.P.Z., P.O. Box 35-25,
Kaohsiung Taiwan, R.O.C.

Issued By:
Compliance Certification Services Inc.
Tainan Laboratory
No. 8, Jiu Cheng Ling, Jiaokeng Village, Sinhua
Township, Tainan Hsien 712, Taiwan R.O.C.
TEL: 886-6-580-2201
FAX: 886-6-580-2202

Issued Date: April 16, 2010

Testing Laboratory 1109

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14.8. IEC 60601-2-18

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1. PURPOSE

This report details the evaluation of the Lantos 3D Ear Scanner device per

INTERNATIONAL STANDARD – IEC 60601-2-18 Edition 3.0 2009-08

Medical electrical equipment –
Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

The features and performance characteristics of the Scanner were assessed to assure compliance with the particular requirements of the standard. The assessment log is included as Appendix A. Adherence to the standard provides evidence that the 3D Ear Scanner is fit for its intended use.

REPORT: Test of Lantos 3D Ear Scanner – IEC-60601-2-18

2. SCOPE

Applies to the Lantos 3D Ear Scanner as a system, including the Lantos Laptop, the Handheld Scanner, the Docking Stand, and power distribution and all connecting cables.

3. REFERENCE DOCUMENTS:

INTERNATIONAL STANDARD – IEC 60601-2-18

4. DEFINITIONS:

None.

5. MATERIALS AND EQUIPMENT:

5.1. Materials. Device Enclosures. Single Use Disposable.

5.2. Equipment. Laptop and Handheld Scanner and Docking Stand. Device hardware identified in the verification report.

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Lantos Device Components

- Laptop Dell E6520 – S/N F8N2BS1
- Handheld Scanner – S/N Beta00
- Docking Stand – S/N A02

Evaluation Setup – Laptop, Handheld Scanner, Docking Stand, Power Distribution

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6. CONCLUSIONS:

As shown in the report log included as Appendix A, the Lantos 3D Ear Scanner device meets the particular requirements for the basic safety and essential performance of endoscopic equipment. Required tests were performed where dictated. Electromagnetic compatibility testing per IEC-60601-1-2 will be completed prior to the commercial launch of the Scanner.

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Appendix A – IEC-60601-2-18 Assessment and Test Results

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IEC 60601-2-18			
Clause	Requirement + Test	Result - Remark	Verdict
201.4	**General requirements**		
201.4.1.101	Energized endotherapy devices		
	Where requirements for ENDOTHERAPY DEVICES given in other applicable particular standards conflict with the requirements for INTERCONNECTION CONDITIONS of this particular standard, the requirements of this particular standard shall take precedence		
201.4.1.102	Ultrasonic diagnostic equipment		
	For the ultrasonic safety aspects of ENDOSCOPIC EQUIPMENT which is also ULTRASONIC DIAGNOSTIC EQUIPMENT, that part which is intended for ultrasonic diagnosis shall comply with the requirements of IEC 60601-2-37 and the other parts shall comply with the requirements of this particular standard.		
201.4.1.103	SUPPLY UNITS		
	SUPPLY UNITS providing a plurality of functions where different particular standards apply, the appropriate parts of these shall comply with the requirements of the relevant particular standards.		
201.4.3.101	Additional ESSENTIAL PERFORMANCE requirements		
	Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses 201.12.4.4 and 201.13.1.101		
201.4.6	ME EQUIPMENT or ME SYSTEM PARTS that contact the PATIENT		
	Addition: Light guide cables are treated as ME SYSTEM parts that CONTACT the PATIENT for the purposes of this particular standard, unless the RISK MANAGEMENT FILE indicates otherwise for specific configurations.		
201.4.7	SINGLE FAULT CONDITION for ME EQUIPMENT		
	To be SINGLE FAULT SAFE, the INTERCONNECTION CONDITIONS and INTERFACE CONDITIONS as defined by the MANUFACTURER shall be taken into account as part of the RISK MANAGEMENT process.		

201.5	**General requirements for testing of ME EQUIPMENT**		
201.5.1	TYPE TESTS		
	the required F-TYPE APPLIED part isolation is provided in the SUPPLY UNIT	Type BF	Pass

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IEC 60601-2-18			
Clause	Requirement + Test	Result - Remark	Verdict
201.5.7	Humidity preconditioning treatment		
	ACCESS COVERS which can be opened without the use of a TOOL, but which inactivate the EQUIPMENT (e.g. by an interlock) once opened, may remain closed and/or attached during humidity preconditioning unless otherwise stated in RISK MANAGEMENT process		
	ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES which are subject to disinfection and/or sterilization processes prior to use are excluded from humidity preconditioning treatment, but shall instead be subjected to subclauses 11.6.6 and/or 11.6.7 of the general standard		
201.6	**Classification of ME EQUIPMENT and ME SYSTEMS**		
201.6.2	Protection against electric shock		
	Replacement of final paragraph: APPLIED PARTS of ENDOSCOPIC EQUIPMENT shall be classified as TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS	Type BF	Pass
	APPLIED PARTS may be classified as DEFIBRILLATION-PROOF APPLIED PARTS		N/A
201.7	**ME EQUIPMENT identification, marking and documents**		
201.7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		
201.7.2.1	Minimum requirements for marking on ME EQUIPMENT and interchangeable parts		
	Replacement: If the size of the ME EQUIPMENT, an ME EQUIPMENT part or an ACCESSORY, or the nature of its ENCLOSURE, does not allow affixation of all markings specified in 7.2.2 to 7.2.20, at least the markings as indicated in 7.2.2, 7.2.5, 7.2.6 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 7.2.10 and 7.2.13 (if applicable) shall be affixed		
	The remaining markings shall be recorded in full in the ACCOMPANYING DOCUMENTS or may be affixed to the individual packaging		

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IEC 60601-2-18			
Clause	Requirement + Test	Result - Remark	Verdict
	m) That before each use, the compatibility of the ENDOSCOPIC Equipment with any ACCESSORIES and/or ENERGIZED ENDOTHERAPY DEVICES should be checked according to any criteria for safe use defined in the instructions for use……:		
	n) That before each use, the outer surface of the portions of any ENERGIZED ENDOTHERAPY DEVICES which are intended to be inserted into a PATIENT should be checked to ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM……:		
	- Warning and safety notices regarding INTERFACE CONDITIONS:		
	o) Advice when ENDOSCOPIC EQUIPMENT is used with ACCESSORIES, other ME EQUIPMENT and/or non-ME EQUIPMENT within a CONFIGURATION FOR ENDOSCOPIC APPLICATION, on the avoidance of RISKS caused by their use together (see also 16.2 of the general standard and 201.15.4.1 of this particular standard):		
201.7.9.2.12	Cleaning, disinfection and sterilization		
	If the ACCOMPANYING DOCUMENTS provide instructions for visual and/or other inspection by the OPERATOR or the RESPONSIBLE ORGANIZATION to enable checking the suitability for reuse prior to each use, then the number of cycles the ENDOSCOPIC EQUIPMENT parts or ACCESSORIES can tolerate need not be given…:		
201.7.9.2.14	ACCESSORIES, supplementary equipment, used material		
	When ENERGIZED ENDOTHERAPY DEVICES are used with HF SURGICAL EQUIPMENT, advice concerning their safe use shall be given in the instructions for use in accordance with the relevant requirements of IEC 60601-2-2.		

201.8	**Protection against electrical HAZARDS from ME EQUIPMENT**		
201.8.3	Classification of APPLIED PARTS		
	Replacement: c) An APPLIED PART of ENDOSCOPIC EQUIPMENT shall be a TYPE BF APPLIED PART or TYPE CF APPLIED PART	Type BF	Pass

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IEC 60601-2-18			
Clause	Requirement + Test	Result - Remark	Verdict
	Replacement: h) The minimum number of cycles of operation shall be RATED in accordance with the EXPECTED SERVICE LIFE of the pressure-relief device, taking into account the environmental conditions and resultant RISKS should the pressure-relief valve not operate as expected.		
	For one-time use devices, such as bursting disks, the environmental conditions and resultant RISKS should the pressure-relief valve not operate as expected shall be taken into account.		
201.9.8	HAZARDS associated with support systems		
	This subclause does not apply to ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES.		

201.10	**Protection against unwanted and excessive radiation HAZARDS**		
201.10.4	Lasers and light emitting diodes (LED's)		
	This subclause does not apply to light emitting diodes (LEDs) which are intended to provide illumination for an internal view or image generated by ENDOSCOPIC EQUIPMENT, requirements for which are included in clauses 201.10.5, 201.10.6 and 201.10.7 of this particular standard.	LEDs used for illumination	N/A
201.10.5	Other visible electromagnetic radiation		
	Replacement: When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT process the RISKS associated with visible electromagnetic radiation, including LED's intended to provide illumination for an internal view or image generated by ENDOSCOPIC EQUIPMENT.	Yes – See Risk Analysis	Pass
201.10.6	Infrared radiation		
	Replacement: When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT process the RISKS associated with infrared radiation, including LED's intended to provide illumination for an internal view or image generated by ENDOSCOPIC EQUIPMENT.	N/A	N/A
201.10.7	Ultraviolet radiation		N/A

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IEC 60601-2-18			
Clause	Requirement + Test	Result - Remark	Verdict
	Replacement: When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT process the RISKS associated with ultraviolet radiation, including LED's intended to provide illumination for an internal view or image generated by ENDOSCOPIC EQUIPMENT.		N/A
201.11	**Protection against excessive temperatures and other HAZARDS**		
201.11.1	Excessive temperatures in ME EQUIPMENT		Pass – See IEC 60601-1 Test Report
201.11.1.2	Temperature of APPLIED PARTS		Pass – See IEC 60601-1 Test Report
201.11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT		Pass – See IEC 60601-1 Test Report
	The maximum temperature need not be disclosed in the instructions for use when:		N/A
	– the surface temperature of the insertion portion of an ENDOSCOPE exceeds 41 °C as a result of its use with an ENERGIZED ENDOTHERAPY DEVICE;		N/A
	– the LIGHT EMMISSION PART of an ENDOSCOPE exceeds 41 °C;		N/A
	– light guide connectors connecting to either a SUPPLY UNIT or an ENDOSCOPE exceed 41 °C.		N/A
	The instructions for use shall give appropriate warnings and advice on measures that should be taken to avoid unacceptable RISK to the PATIENT.		N/A
	These warnings shall include a description of the potential clinical consequences of high surface temperatures, for instance permanent tissue damage or coagulation.		N/A
201.11.1.4	GUARDS		N/A
	Illumination lamps of SUPPLY UNITS may be accessible without the aid of a TOOL, but there shall be marking on or near the ACCESS COVER provided for lamp replacement and a caution shall be included in the instructions for use.		N/A

Pluas 4/12/12

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IEC 60601-2-18			
Clause	Requirement + Test	Result - Remark	Verdict
	Symbol of IEC 60417-5041 (2002-10) may be used.		N/A
201.11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT		Pass – See IEC 60601-1 Test Report
201.11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		
	ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES intended to be cleaned, disinfected and/or sterilized are excluded from this requirement but shall meet the requirements of 11.6.6 and/or 11.6.7 of the general standard, as appropriate.		N/A
201.11.101	INTERCONNECTION CONDITIONS		N/A
201.11.101.1	Thermal and other HAZARDS from INTERCONNECTION CONDITIONS with LASERS		N/A
	The MANUFACTURER'S RISK MANAGEMENT process shall address the possibility of thermal and other RISKS to the PATIENT or OPERATOR from the use of laser equipment with ENERGIZED ENDOSCOPES and/or ENERGIZED ENDOTHERAPY DEVICES, including, under NORMAL USE and SINGLE FAULT conditions:		N/A
	– thermal damage (including ignition) to the ENDOSCOPE from reflected laser energy;		N/A
	– potential eye damage from reflected laser energy.		N/A
201.11.101.2	Thermal and other HAZARDS from INTERCONNECTION CONDITIONS with HF SURGICAL EQUIPMENT		N/A
	a) The MANUFACTURER'S RISK MANAGEMENT process shall address the possibility of thermal and other RISKS to the PATIENT or OPERATOR from the use of HF SURGICAL EQUIPMENT with ENERGIZED ENDOSCOPES and/or ENERGIZED ENDOTHERAPY DEVICES, including, under NORMAL USE and SINGLE FAULT CONDITION:		N/A
	1) thermal damage to the ENDOSCOPE caused by electrical discharge or CAPACITIVELY COUPLED HF CURRENT;		N/A
	2) image interference on video screens from HF electromagnetic energy.		N/A

Bluas 4/12/12

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IEC 60601-2-18			
Clause	Requirement + Test	Result - Remark	Verdict
	b) Sufficient dielectric strength shall be provided on ENERGIZED ENDOTHERAPY DEVICES which are APPLIED PARTS of HF SURGICAL EQUIPMENT to protect the PATIENT and/or OPERATOR from unacceptable RISK.		
	c) Conductive parts of an ENERGIZED ENDOSCOPE accessible to touch in NORMAL USE intended for use with ENERGIZED ENDOTHERAPY DEVICES, which are the APPLIED PARTS of HF SURGICAL EQUIPMENT, shall be isolated in order to protect the OPERATOR from the thermal effects of CAPACITIVELY COUPLED HF CURRENT.		
	Non-conducting coatings, such as lacquer and the like, which cannot provide durable isolation, shall not be used.		
201.12	**Accuracy of controls and instruments and protection against hazardous outputs**		
201.12.2	USABILITY		
	If the RISK MANAGEMENT process concludes there is no unacceptable RISK in relation to USABILITY, this subclause does not apply.		
201.12.3	Alarm systems		
	This particular standard does not specify an ALARM CONDITION priority.		
	An INFORMATION SIGNAL is any signal that is not an ALARM SIGNAL or a REMINDER SIGNAL.		
201.12.4	Protection against hazardous output		
201.12.4.4	Incorrect output		
	A significant error in or the lack of the provision of a particular spectral output or frequency necessary to provide accurate diagnosis or therapy which is not identifiable by a trained OPERATOR shall be addressed in the RISK MANAGEMENT process.		
201.13	**HAZARDOUS SITUATIONS and fault conditions**		
201.13.1	Specific HAZARDOUS SITUATIONS		Pass
201.13.1.101	Image observation		Pass

4/12/12

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IEC 60601-2-18			
Clause	Requirement + Test	Result - Remark	Verdict
	The possibility of an OPERATOR (intentionally or unintentionally) viewing a recorded image rather than the live image during an endoscopic procedure shall be addressed in the RISK MANAGEMENT process.	Yes – See Risk Analysis	Pass
201.15	**Construction of ME EQUIPMENT**		
201.15.3	Mechanical strength		N/A – Dell Power Supply TUV Approved
201.15.3.1	General		N/A
	Subclauses 15.3.1 to 15.3.7 of the general standard do not apply to ENERGIZED ENDOSCOPES and ENERGIZED ENDOTHERAPY DEVICES.		N/A
201.15.3.5	Rough handling test		N/A
	Subclause 15.3.5 of the general standard does not apply to MOBILE ME SYSTEMS installed on a workstation ('stack') intended for use within the CONFIGURATION FOR ENDOSCOPIC APPLICATION.		N/A
201.15.4	ME EQUIPMENT components and general assembly		Pass
201.15.4.1	Construction of connectors		Pass
	b) The MANUFACTURER of ENDOSCOPIC EQUIPMENT and ENDOTHERAPY DEVICES shall carry out a RISK MANAGEMENT process to consider the probability of misconnection of medical devices intended for connection to ENDOSCOPES or ENDOTHERAPY DEVICES to non-endoscopic PATIENT CONNECTIONS (e.g. intravenous applications).	Yes – See Risk Analysis	Pass
	For applications where the INTENDED USE of connectors includes more than one application, the design used shall be that most unlikely to be misconnected according to its specific intended use, as identified by the RISK MANAGEMENT process.	Yes – See Risk Analysis	Pass
202	**Electromagnetic compatibility – Requirements and tests**		
202.6.2	IMMUNITY		
202.6.2.1	General		

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14.9. Software Revision History

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LantosView Application Software – Software Revision History
Verification Release Versions

Revision	Date	Revision Title	Purpose
rev552	27-Oct-2011	TAMC Test	Clinical Trial at Tripler Army Medical Center
rev713	03-Jan-2012	Starkey Expo	User demonstrations – Starkey Exposition User Preference Testing
rev904	02-Mar-2012	AAApre26	Software Unit Test – Disposable Bench Test
rev993	16-Mar-2012	AAApre12	Software System Test – System Verification Testing – User demonstrations - AudiologyNOW

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15. Attachment V – Labeling (Manuals)

15.1. Lantos User Manual

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Lantos 3D Ear Scanner

Instructions for Use

The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal.
The Lantos 3D Ear Scanner:

- provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation
- includes an expanding conforming membrane which aids observation when inserted in the ear canal
- records and presents to the hearing professional in an image file a topology measurement of the external ear canal

Lantos Technologies 3D Ear Scanner Proprietary and Confidential Page 312 of 535
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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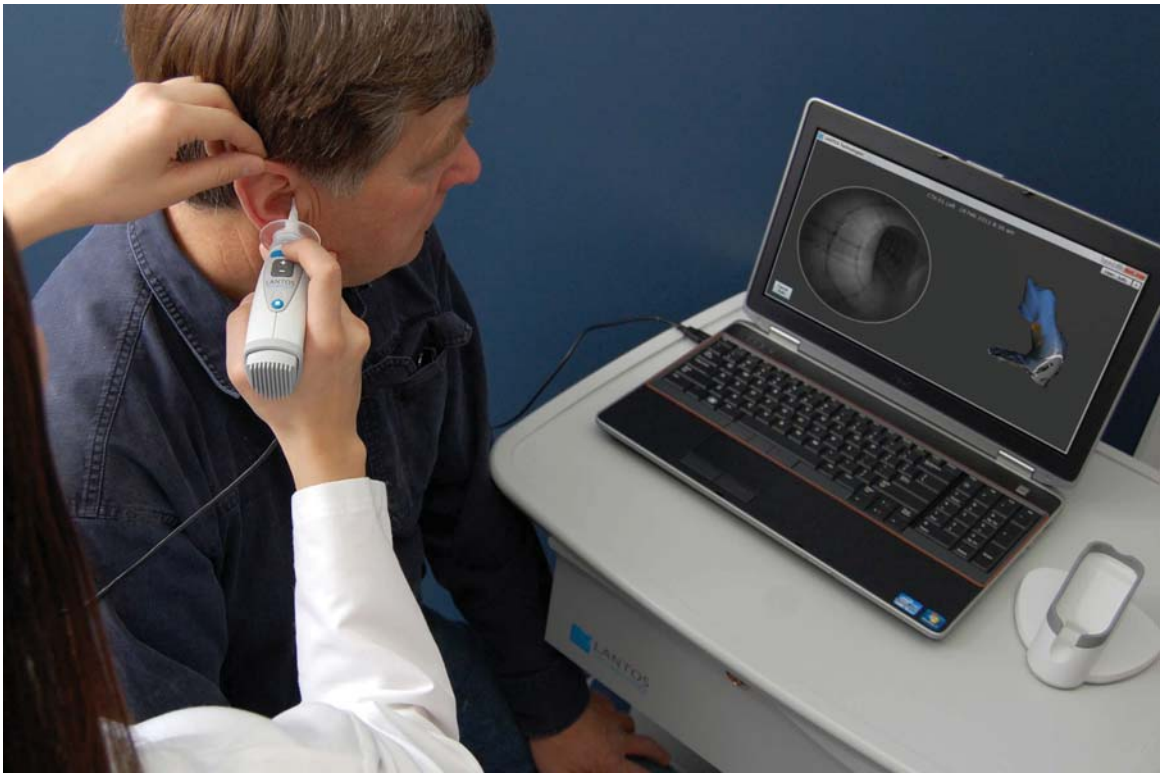
Please read these Instructions for Use thoroughly before using the **Lantos 3D Ear Scanner**. Take particular note of precautions and warnings.

FOLLOW INSTRUCTIONS FOR USE P/N 100-001 Rev. 0

If you have questions please contact your Lantos Technologies support representative.

<support@lantostechnologies.com>
Lantos Technologies
101 Main St Suite 1760
Cambridge, MA 02142
+1 (617) 500-9800

Every effort has been made to assure these instructions are complete and accurate. Lantos makes no warranty of applicability for use, or guarantee of accuracy. Contents of these instructions are subject to change without notice.



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Warnings: Electrical and Fire Hazards

WARNING: DO NOT CONNECT THE LANTOS 3D EAR SCANNER TO DEVICES OTHER THAN AS EXPRESSLY DESCRIBED IN THESE INSTRUCTIONS

WARNING: PLUG THE SCANNER INTO A PROPERLY GROUNDED POWER OUTLET TO MAINTAIN PATIENT AND USER SAFETY WHEN OPERATING FROM A/C POWER SOURCE

WARNING: DISCONNECT THE SCANNER FROM A/C POWER SOURCE IF IT GETS WET, IF CABLES ARE DAMAGED, OR IF COMPONENTS ARE DROPPED

WARNING: DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS

Cautions

CAUTION: THE MEMBRANE, CARTRIDGE, RESERVOIR AND MEDIUM ARE FOR SINGLE PATIENT USE

CAUTION: DO NOT USE THE SCANNER FOR ANY PURPOSES OTHER THAN THOSE DESCRIBED IN THESE INSTRUCTIONS

CAUTION: DISCONTINUE USE OF THE DEVICE IF YOU NOTICE ANY SIGNS OF DAMAGE TO THE COMPONENTS – CONTACT LANTOS FOR SERVICE – NO USER SERVICEABLE COMPONENTS

CAUTION: THE HANDHELD SCANNER IS A HIGHLY PRECISE OPTICAL INSTRUMENT – IMPROPER HANDLING, SUCH AS DROPPING OR BUMPING THE TIP, MAY CAUSE THE SCANNER TO BREAK OR MALFUNCTION

CAUTION: DO NOT ADVANCE THE PROBE TIP IN THE PATIENT'S EAR – TO HELP PREVENT INADVERTENT EXTENSION, THE PROBE TIP WILL ONLY ADVANCE WHEN THE SCANNER IS POINTED DOWN

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

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TYPE BF PATIENT APPLIED PART

Foreign body and moisture intrusion rating per IEC/EN60529.

Handheld Scanner

IP22 Protection against solid bodies: objects greater than 12mm.
Protection against liquids: 75° – 90° dripping water, with Scanner upright

Laptop and Docking Stand

IPXØ Protection against solid bodies: not rated.
Protection against liquids: not protected.

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EMI, FCC and Safety Standards

This device has been tested and conforms to EMI, FCC and safety standards.

IEC 60601-1

Troisième édition
Third edition
2005-12

Medical electrical equipment –

Part 1:
General requirements for basic safety and essential performance

U.S. Federal Communications Commission (FCC) Requirements

This device was tested and complies with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. This equipment generates, uses, and can radiate radiofrequency energy, and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

There is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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

To comply with the limits for an FCC Class A computing device, always use the power and signal cables supplied with this unit. The FCC warns that changes or modification of the unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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

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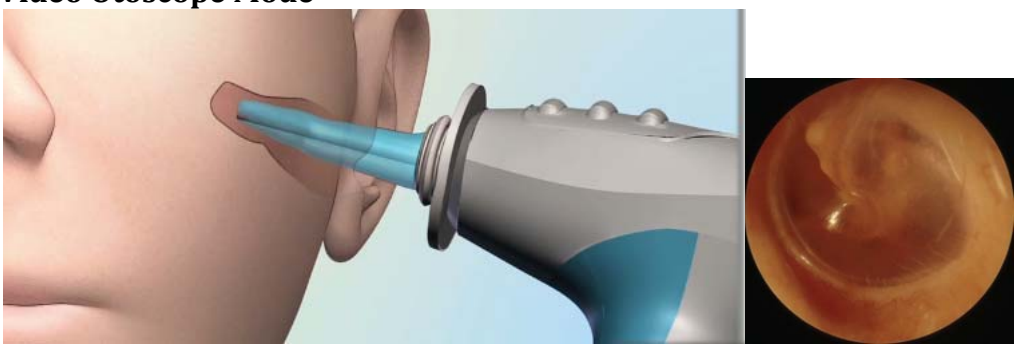
Introduction and Overview

The **Lantos 3D Ear Scanner** is intended for use by a trained hearing professional (the **user**) in clinical settings on adult patients presenting for inspection of the external ear canal and tympanic membrane. The Scanner displays a magnified visual image of the external ear canal and tympanic membrane to the user on a laptop computer screen. The Scanner incorporates a visible light spectrum source to illuminate the ear canal.

The Scanner should not be used for other purposes.

The Scanner has a long thin tip to extend the viewing lens and illumination into the ear canal. The user places a single patient use conforming membrane over the Scanner tip. The conforming membrane has a clear flexible window at the distal end. The user may view different portions of external ear canal and tympanic membrane by changing the position and orientation of the Scanner, as with a traditional video otoscope. In addition the user may save one or more fixed otoscope images for later use.

Video Otoscope Mode



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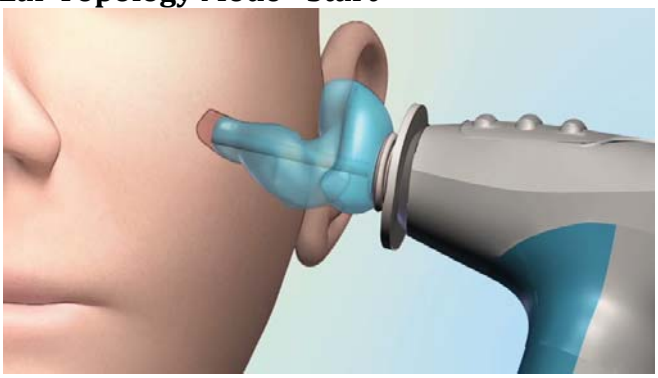
If desired, the user may also record a topology measurement of the external ear canal, and save it as an image file for later use. The user positions the Scanner tip visually, according to the desired extent of the topology measurement. When positioned, the user expands the conforming membrane with liquid absorbing medium to match the shape of the external ear canal.

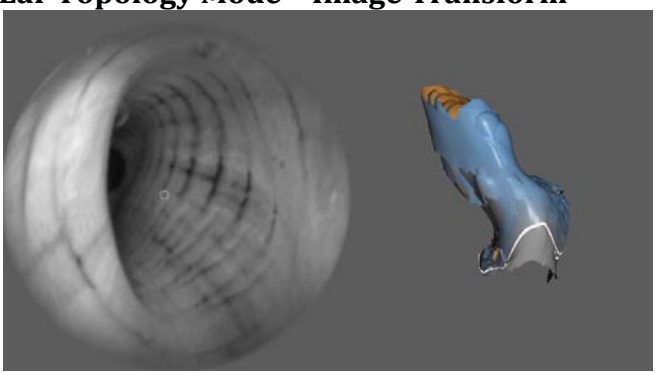
Ear Topology Mode - Start



The user holds the Scanner in a fixed position relative to the head, and retracts the Scanner tip into the Scanner body; the tip passes through the canal. The Scanner captures a series of video images, and transforms the series into an image of the ear topology measurement.

Ear Topology Mode – Scan-Retract

Ear Topology Mode – Image Transform



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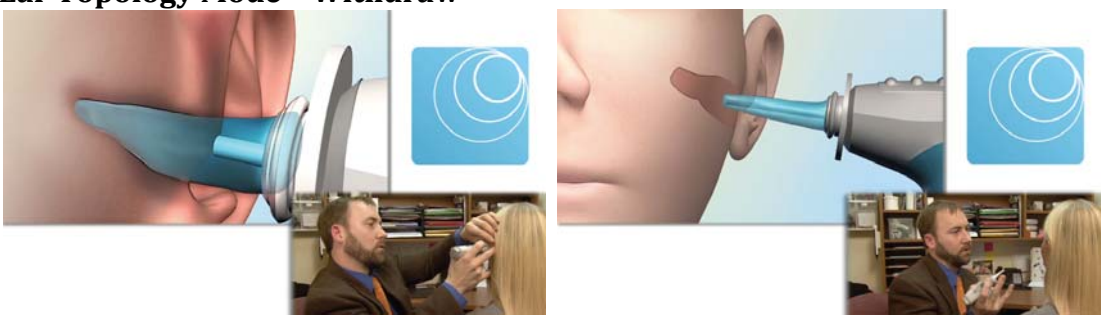
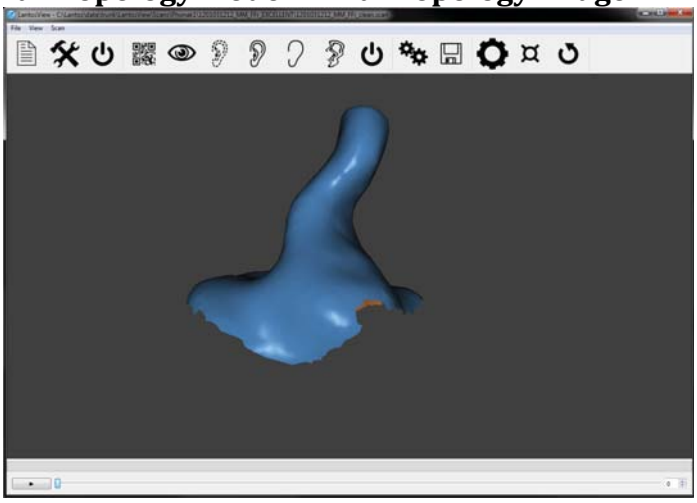
When the desired extent of topology has been captured, the user withdraws the liquid absorbing medium from the conforming membrane and removes the Scanner from the ear.

Ear Topology Mode – Withdraw



The topology image is visible to the user on the laptop computer screen, and may be saved for later use.

Ear Topology Mode – Final Topology Image



If the user desires, the video otoscope inspection and the topology measurement may be repeated on the patient's second ear with the single patient use disposable.

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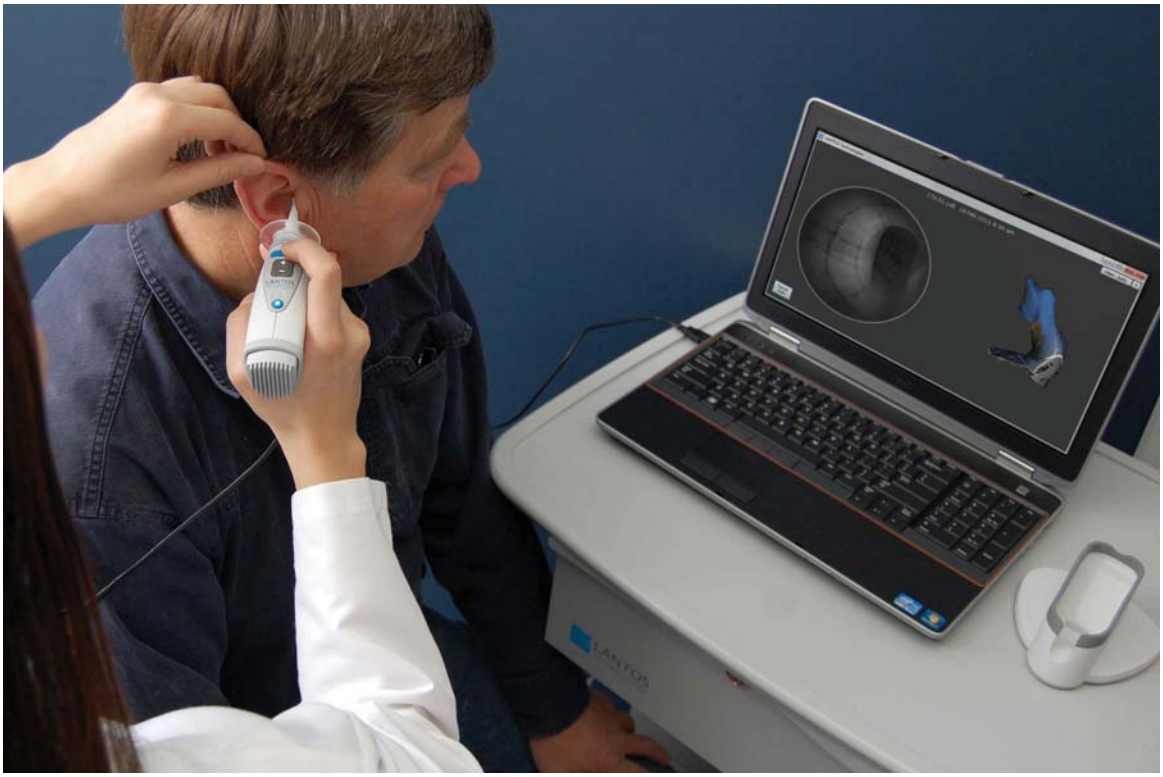
Components of the 3D Ear Scanner

- Lantos Laptop – with case and Docking Stand
- Handheld Scanner
- Single Patient Use Disposable
    - Conforming Membrane and Valve Cartridge
    - Reservoir and Absorbing Medium
- Device Application Software



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Lantos Laptop and Docking Stand

Description and Use:

The Laptop is packaged with a Docking Stand (holster) for the Scanner. A custom cable connects the Scanner with the Stand; other cables connect the Stand with the Laptop and with a power supply. A battery subsystem supplies power to the Laptop, and a power brick supplies power to charge the laptop battery, and to power and charge the Scanner.

The user interacts with the Scanner using the Laptop keyboard and touchpad; the Laptop LCD panel presents a series of User Interface screens, including ear canal images.

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Handheld Scanner

Description and Use:

The user snaps the Single Patient Use Disposable (following section) over the extended probe tip of the Handheld Scanner, into the mating receptacle on the Scanner. The user guides the covered probe tip into the ear canal with a video otoscope view through a clear flexible window in the tip of the conforming membrane.

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Single Patient Use Disposable - Conforming Membrane and Valve Cartridge

Description and Use:

The Conforming Membrane covers the Scanner probe tip, and expands to conform to the inner surface of the ear canal and outer ear. The tip of the Membrane has a flexible window of the same approximate size at the probe tip, providing a clear video otoscope view of the ear canal and tympanic membrane.

The extended probe tip pushes through the Valve Cartridge into the Membrane, which is held in a fixed attachment to the Cartridge. The valves seal the liquid inside and maintain the liquid pressure during expansion. The inside surface of the membrane contains a dye that returns an image when illuminated with visible blue light.

Single Patient Use Disposable - Reservoir and Absorbing Medium

Description and Use:

The Absorbing Medium contains a dilute amount of an ingestible coloring dye in distilled water, with a small amount of preservative. The Absorbing Medium is held in the Reservoir, and in the Membrane. When the user signals to expand the Membrane, a plunger in the Reservoir is driven by a motor in the Scanner to drive the Medium through the connecting tube to the Membrane. When the user signals withdrawal, the Medium returns to the Reservoir, allowing easy extraction of the collapsed membrane from the ear.

⚠ CAUTION: THE MEMBRANE, CARTRIDGE, RESERVOIR AND MEDIUM ARE FOR SINGLE PATIENT USE

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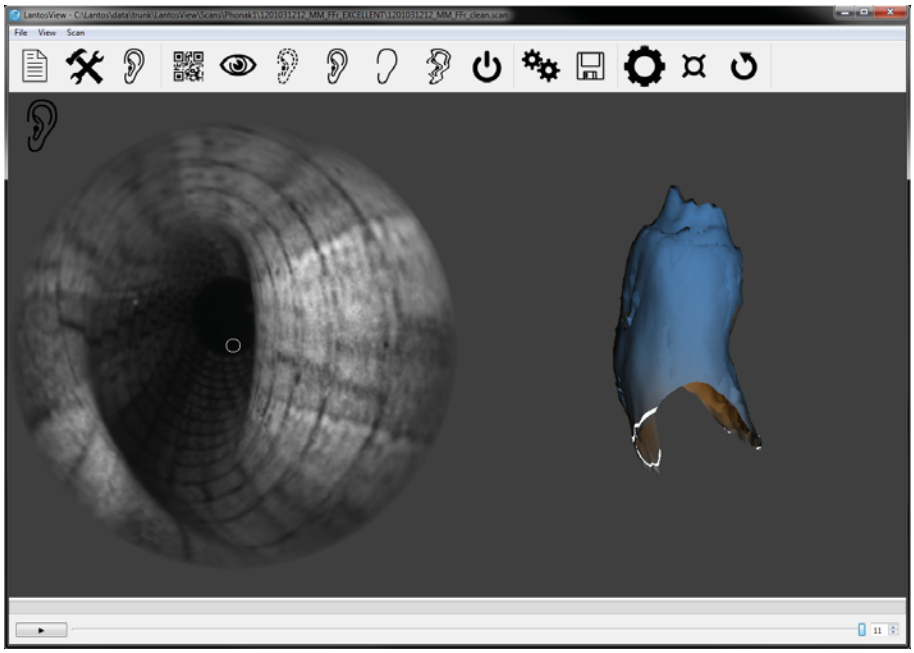
Device Application Software

The Application software provides live visual feedback to the user, for inspection of the external ear canal, and to determine the extent of the external ear topology measurement. The Application software leads the user through a series of interactions to prepare for the ear exam, and guides the user through the exam and the dimensional measurement. The Application software saves the inspection images and the topology measurement images for later review.



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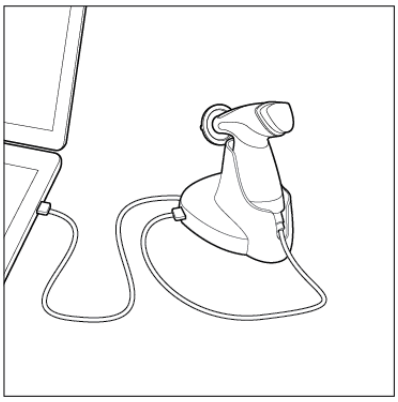
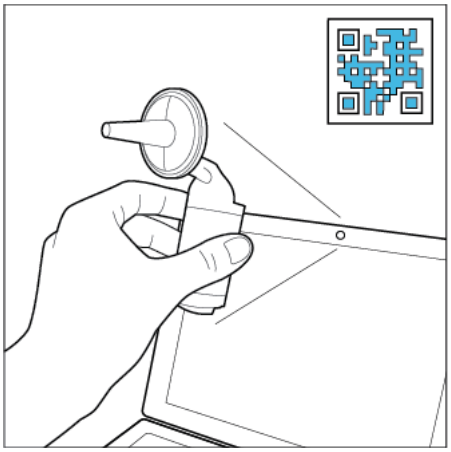
Instructions for use - Setup

- Charge the Laptop and Docking Stand before use – or assure AC power is available and the device is plugged in – check all power connections
- Assure the Scanner is connected to the Stand, and the Stand to the Laptop



- Turn on the Laptop, the **Lantos 3D Ear Scanner** Application software will start
- Turn on the power switch on the Docking Stand
- A new Single Patient Use Disposable is required for each patient
- Remove a Disposable from packaging – hold the back side of the Disposable (with code label) near the Laptop camera to register the Disposable



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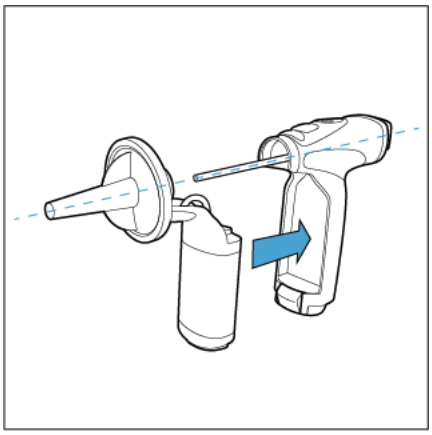
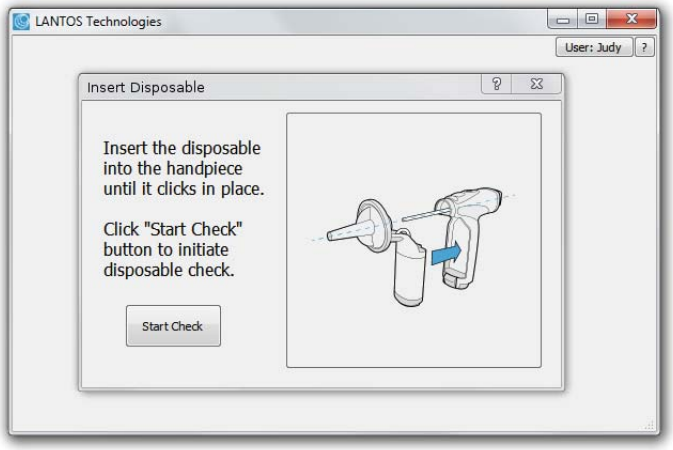
- Place the Membrane over the extended tip of the Scanner, and insert the Reservoir into the receptacle on the Scanner until it snaps in place



- Once inserted, follow the instructions on the screen to activate the device check – the device will perform a series of actions to assure the device and Disposable are ready for use – you may notice fluid movement and illumination



- When the check is complete, remove and discard the Check Cap and its retaining ring

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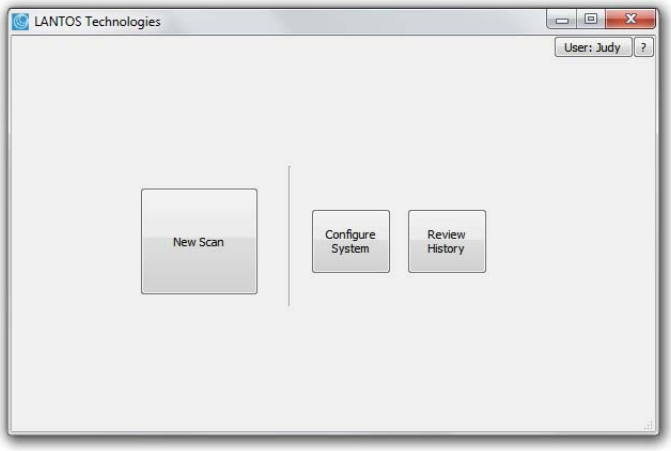
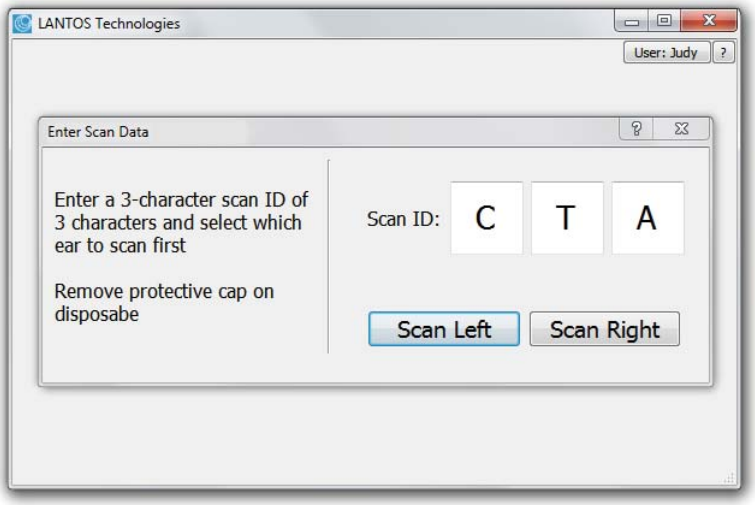
- Select from the introductory screen to configure the device, to review past history, or to start a new scan.



- Enter a two or three character scan ID, which will be combined with the date and time, the device serial number, the disposable serial number, and the user ID to form a unique identifier for the scan
- Select which ear to scan first



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- Under various circumstances, the Application software presents error indications – for example, if the software determines that the Scanner is not responding, it prompts the user to check the tether cable

- Select Review History to recall recent and past images to view – past images are ordered by date for selection – selected video Otoscope images and 3D topology images are saved

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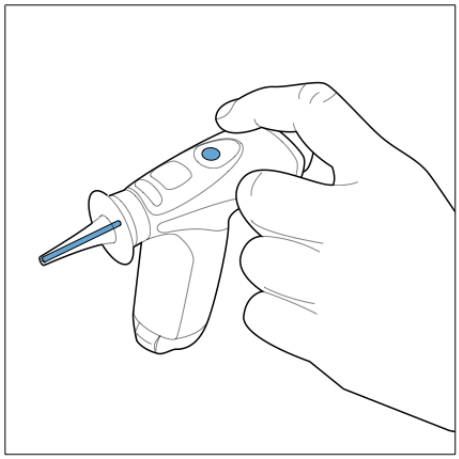
Instructions for use - Scanning

Preparation

- With scanner clear of patient, point the Scanner probe tip down and push the Advance '■' button until probe tip is at full extension



CAUTION: DO NOT ADVANCE THE PROBE TIP IN THE PATIENT'S EAR – TO HELP PREVENT INADVERTENT EXTENSION, THE PROBE TIP WILL ONLY ADVANCE WHEN THE SCANNER IS POINTED DOWN

- Align clear window at tip of Conforming Membrane with probe tip – confirm visually by pointing tip toward a known target

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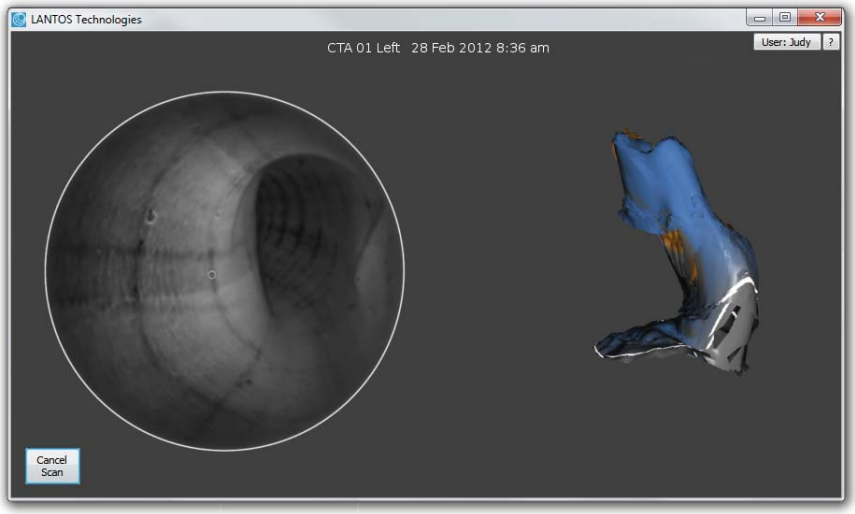
- The Application software shows the Scan screen, which presents the live view through the scope tip in the circle on the left, for both video Otoscope exam mode, and for the 3D topology measurement. On the right is the accumulated topology measurement.



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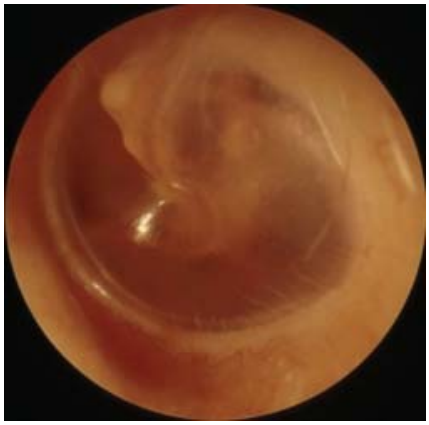
Video Otoscope View

- Secure patient and the Handheld Scanner – select Otoscope view mode
- If necessary to reduce tip window fogging, before entering the ear canal, stir membrane in warm water for five seconds
- Insert probe to desired viewing depth – navigate in external ear canal to view features – the following image shows a representative tympanic membrane at a distance of approximately 5 mm, as seen through the Scanner



Ear Topology Measurement

- Visually navigate the probe tip to set the desired depth of the 3D topology measurement
- Secure the patient and the Handheld Scanner, and use '+/-' buttons on Scanner to expand the Conforming Membrane until it fills the concha, constrained by the Pressure Cup
- The Membrane window will release from the probe tip, and the view will change to that of the inside of the Membrane, conforming with the external ear
- Brace the patient, and use the Scan '○' button to retract the probe tip along the external ear canal – stop and restart retraction at any time by releasing and pressing the Scan '○' button
- When the probe tip is fully retracted, manipulate the Scanner to collect 3D data from sections of the concha bowl

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

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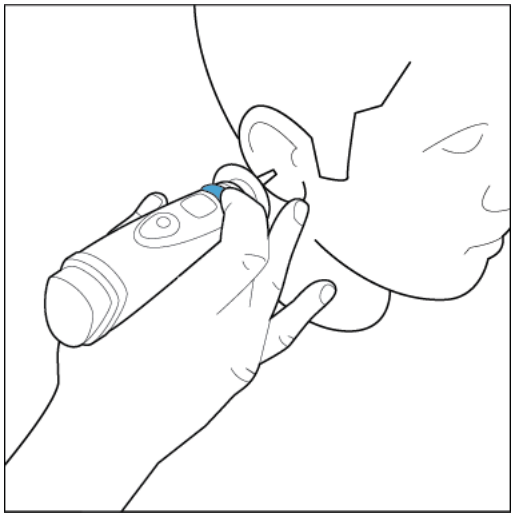

- Navigate while retracting to view all parts of the external ear – the Application software will show parts captured and yet to capture, until desired coverage is obtained

Removal

- When finished scanning, press the '– ' button to withdraw the Absorbing Medium from the Conforming Membrane, the Membrane will collapse
- Remove the Membrane and the probe tip from the ear

If desired, repeat the Preparation, Scanning, and Removal process for the patient's other ear.

When finished with the patient, discard the Single Use Disposable, including the membrane, cartridge, reservoir and medium.

CAUTION: THE MEMBRANE, CARTRIDGE, RESERVOIR AND MEDIUM ARE FOR SINGLE PATIENT USE

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

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Care, Maintenance, and Handling of the Device

Follow these guidelines when using the device:

- The device is intended for use by qualified operators who have been trained in proper use
- Store and use the device within prescribed temperature, humidity, and altitude limits (refer to Environment: Operating Conditions)
- Do not alter any existing connections in the device, excepting the tether cable between the Handheld Scanner and the Docking Stand which can be separated at either or both ends for transport and storage
- Exercise care when using the Handheld Scanner – return it to the holster on the Docking Stand when not in use – do not submerge the Scanner in water

CAUTION: DISCONTINUE USE OF THE DEVICE IF YOU NOTICE ANY SIGNS OF DAMAGE TO THE COMPONENTS – CONTACT LANTOS FOR SERVICE – NO USER SERVICEABLE COMPONENTS

CAUTION: THE HANDHELD SCANNER IS A HIGHLY PRECISE OPTICAL INSTRUMENT – IMPROPER HANDLING, SUCH AS DROPPING OR BUMPING THE TIP, MAY CAUSE THE SCANNER TO BREAK OR MALFUNCTION

Cleaning Procedures

After each patient, cleaning the body of the Handheld Scanner and the tether cord with water and/or a non-staining disinfectant is recommended.
You do not need to shut down the Scanner while cleaning its surfaces. The following agents can be used for cleaning:

- BIREX®se (by Biotrol) or equivalent
- Warm water and a mild, non-abrasive detergent: Fantastic®, Lysol
- Do not use ammonia-based cleaners

Follow these steps:

- Apply the cleaning agent to a soft, non-abrasive cloth – wring out the cloth until damp
- Wipe down the surfaces with the damp cloth
- Rinse the cloth in clean water – wipe down the surfaces a second time
- Dry the surfaces with a clean, soft, non-abrasive cloth
- Do not spray or pour liquids on the surfaces – avoid liquid pooling or dripping – never submerge the Handheld Scanner – neither the Scanner nor the Laptop is watertight

Store device components in a dry, temperature controlled environment. Avoid extremes in temperature or humidity.

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

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Specifications

Handheld Scanner

Dimensions	~160mm L x 130mm H x 40mm W
Weight	~230g without tether cable
Field of View	>120° Cone in Air – Video Otoscope View
	>90° Cone in Water – Topology Measurement
Direction of View	0° aligned with probe axis
Working Depth	4mm to >15mm from tip
Illumination	Red / Green / Blue Visible Light
Video Capture Rate	≥15 frames/sec
Tether Cable	~2m

Lantos Laptop

Dimensions	~384mm W x 28-34mm H x 258mm D	
Weight	~2.5kg including battery	
Display	~396 mm diagonal	
Power Supply and Charger	135W AC Adapter 100-240V 47-63Hz	for Laptop and Scanner

Single Use Disposable

Dimensions	~95mm L x 120mm H x 35mm W including CheckCap
Weight	~40g with Absorbing Medium

Environment

Operating Conditions
- 10° C to 40° C
- 30% to 85% R.H. noncondensing
- 700 to 1060 hPa Altitude

Shipping and Storage Conditions
- -15° C to 49° C
- 95% R.H. noncondensing max

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

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Replacement

Contact Lantos Technologies support for replacement parts or additional disposable parts.

<support@lantostechnologies.com>

Lantos Technologies
101 Main Street Suite 1760
Cambridge, MA 02142
+1 (617) 500-9800

Warranty

Lantos warrants this product will be free from defects in material and manufacture. Lantos MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and Lantos' sole obligation shall be repair or replacement of the product.

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

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15.2. Draft Brochure Lantos 3D Ear Scanner

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

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LANTOS TECHNOLOGIES

Introducing the Lantos Ear Canal Scanner

Our all-in-one device combines a state-of-the-art digital otoscope with cutting-edge 3D digital scanning capabilities. The audiology world has been waiting for years for a device like the Lantos Ear Canal Scanner. Now it's here. We're ready to help you go direct with breakthrough technology that lets you inspect, navigate, and measure the ear canal—directly, quickly, and digitally.

Go Digital with Direct 3D Scanning

Measuring the ear canal accurately via the traditional earmold impressions is a familiar process, but is also time-consuming, inefficient, frustrating, messy, and uncomfortable. And ultimately, the results can be inaccurate. Hearing professionals and manufacturers have long anticipated a solution that directly captures ear canal shape in a digital image, and makes it available immediately, anywhere.

NOW THE TECHNOLOGY YOU'VE BEEN WAITING FOR IS HERE

Based on breakthrough 3D scanning technology that originated in the labs of the Massachusetts Institute of Technology, Lantos Technologies has created a complete, digital solution for inspecting and imaging the ear canal. At the heart of our solution is the Lantos Ear Canal Scanner—a small, portable, handheld device that enables inspection and scanning of the shape of the ear canal in sixty seconds or less.

Get Powerful Benefits

The Lantos Ear Canal Scanner delivers many critical benefits:

- **DIRECT DIGITAL OBSERVATION AND IMAGING**
  Convenient and fast, direct digital ear canal measurements provide critical information about the unique details of each ear canal—while improving the patient experience. Now audiologists can annotate digital images with notes and provide additional information to the manufacturers seamlessly.

- **SAFETY AND COMFORT**
  For the patient, the inspection and scanning process is fast, safe, and comfortable. The scanner can be used with confidence in cases where traditional impression material might require extended preparation.

- **FASTER RESULTS AND COMMUNICATION**
  The entire process takes a minute or less. All 3D scan files and other information can be made anywhere almost instantly.

- **NEW POTENTIAL**
  By capturing canal dynamics, the changing shape of the ear canal, the Lantos system provides opportunities to drive innovation in hearing devices.

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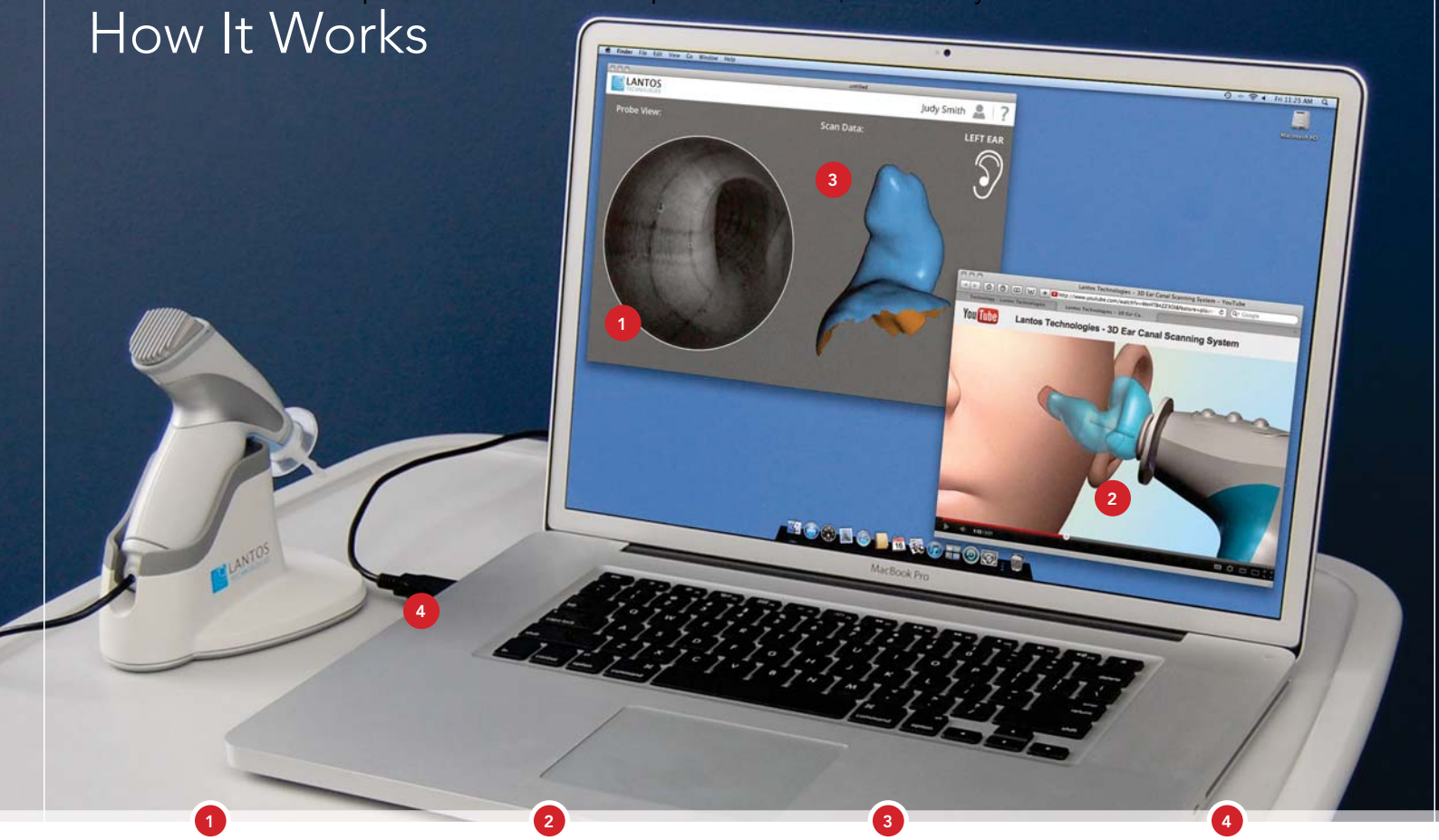
How It Works



1. The Lantos Ear Canal Scanner enables audiologists to inspect the ear canal with a state-of-the-art otoscope with integrated lighting, enabling exceptional visualization of the ear canal.

2. For advanced, 3D scanning, a disposable membrane expands to conform to the ear canal anatomy.

3. A 3D digital scan captures the ear canal, including dynamic structures and areas deep within the canal.

4. The scanner connects to a laptop, providing convenient access to data and seamless integration with the way today's hearing professionals work.

LANTOS TECHNOLOGIES

About Lantos Technologies

Our company includes a team of technologists and proven entrepreneurs backed by leading venture capital groups. We are dedicated to bringing new technology to bear on the challenges of audiology—creating advanced solutions that meet the needs of today's audiology marketplace. And we are committed to an open data approach, one that enables the broadest group of device manufacturers, hearing professionals, and patients to benefit from direct digital ear canal scanning.

Explore the Potential

To find out more about Lantos Technologies, go to www.lantostechnologies.com or contact us at (617) 500-9800.

MIT DESHPANDE CENTER FOR TECHNOLOGICAL INNOVATION

Ignition Grant 2008
Innovation Grant 2009

FROST & SULLIVAN
2011 BEST PRACTICES AWARD
NORTH AMERICAN 3D EAR SCANNING ENABLING TECHNOLOGY AWARD

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

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15.3. Training Manual

Note; A DVD/CD is provided in the 510k package with a video training film.

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

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16. Attachment VI - Clinical Studies

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: August 31, 2012

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		
	Denby Fukuda, AUD., CCC-A	Leslie J. Peters, Ph.D., CCC-A/SP
	David Citron, III, Ph.D., FAAA	

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Douglas M. Johnston	VP Engineering
FIRM/ORGANIZATION	
Lantos Technologies	
SIGNATURE	DATE *(mm/dd/yyyy)*
Doug M Johnston	03/12/2012

Paperwork Reduction Act Statement

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. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

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16.1 Tripler Army Medical Center Protocol

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LANTOS TECHNOLOGIES

APPLICATION FOR CLINICAL INVESTIGATION PROJECT INVOLVING HUMAN SUBJECTS

SUMMARY PAGE

1. PROTOCOL TITLE: Direct Scan Earmold Digitization Evaluation

2. VERSION OF THE PROTOCOL: Version 3, 29 September 2011

3. SPONSOR: Department of Defense

4. PRINCIPAL INVESTIGATOR: Denby Fukuda, AUD., CCC-A, Chief, Audiology Section, Otolaryngology Service, Department of Surgery, Tripler Regional Medical Center, 1 Jarrett White Rd., TAMC, Honolulu 96859. 808-433-3198, Fax 808-433-7115, Denby.Fukuda@ Amedd.Army.Mil; CV located in Appendix 2.

4.1 ASSOCIATE INVESTIGATOR:
Leslie J. Peters, Ph.D., CCC-A/SP. Contract Audiologist, Tripler Regional Medical Center; Telephone: 808-433-3195; Fax: 808-433-7115. Leslie.Peters@Amedd.Army.Mil; CV located in Appendix 2.

5 MOST RECENT RESEARCH TRAINING:
The dates and documentation of CITI training for all investigators are located in Appendix 3.

6. MEDICAL MONITOR: N/A

7. LOCATION OF STUDY: Tripler Regional Medical Center, 1 Jarrett White Rd, Honolulu, HI. 96859. POC: Leslie J. Peters, Ph.D. Contract Audiologist; 808-433-3195, Fax: 808-433-7115.

8. LABORATORIES: MIT Mechanical Engineering Department.

9. TOTAL STUDY DURATION: 10 Months

A. Anticipated start date: August 2011

B. Anticipated completion date: June 2012

10. RECRUITMENT SUMMARY:

Number and type of study subjects: 40 normally healthy and normal hearing subjects, evenly divided male and female, ranging in age from 18 to 60 years of age.

B. Anticipated number of subjects to be enrolled per month: 40

C. Anticipated number of subjects to be enrolled per year: 40.

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11. REVIEWING IRB: TAMC; Human Use Committee / Institutional Review Board; ATTN: MCHK-CI; 1 Jarrett White Road; Tripler AMC, HI 96859-5000; telephone: 808-433-6709; Fax: 808-433-9246.

12. SOURCE OF FUNDING:

A. Funding source: Telemedicine Advanced Research Project Office (AAMTI).

B. Total cost of the project: $89,170.00

13. LITERATURE SEARCH FOR DUPLICATION:

A. Literature sources: performed by Mabel Trafford, TAMC; sources included but not limited to – Medline, CINAHL, DTIC, EMBASE, CAB abstracts CRISP, FEDRIP, Biomedical Research Database.

B. Date and search number : December 2010; TG 817799429

C. Key words of search: Ear canal measurement, computer aided design, direct scan of ear canal.

D. Results of search : 59 hits of related material. 1 hit relating to the subject matter, no hits for a human factors evaluation of ear canal measurement techniques.

14. INFORMATION MANAGEMENT APPROVAL LETTER: N/A. No access to a network computer is required.

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

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PROTOCOL

1. **ABSTRACT:**

A. Hearing loss continues as one of the most commonly occurring occupational injuries in the Department of Defense. Many sudden hearing losses and hearing loss due to blast injury become permanent due to a lack of adequate hearing protection in a highly mobile battlefield. Even in peacetime the second most frequent occupational injury for the Armed Services continues to be hearing loss. Earplugs are the basic method of personal protection from hearing loss due to noise damage.

The purpose of this proposal is to determine whether Computer Aided Design (CAD) manufactured custom earplugs from direct digitization of an ear canal can produce an earplug with similar attenuation as a custom CAD earplug manufactured using direct earmold scanning. A prior study, Tripler Protocol #24H07, demonstrated that a digitized ear impression could be used to build a custom earplug with similar attenuation as the traditional "lost wax" method. The ability to capture, store, and later manufacture a custom earplug will serve to reduce hearing loss in the Army.

B. To accomplish this goal, a repeated measures design which has been counter balanced and randomized will be used to conduct multiple attenuation measures for this comparative study. It is expected that no attenuation differences will be found between the manufacture procedures.

C. The methodology of the study will require that 40 normal hearing (defined as h-1 Army profiling standards) with no known pathology be evaluated using the two types of custom earplugs. The specific frequency of hearing threshold results will be compared against similar results using each set of manufactured earplugs.

D. There are no major safety concerns. These procedures are non-invasive and pose a minimal risk for human subjects.

2. **HYPOTHESIS:**

The hypothesis to be tested is that the attenuation found with custom earplugs manufactured from direct ear canal digitization will not differ significantly from custom earplugs manufactured using visible light imagery of an ear mold from the same ear.

3. **OBJECTIVES:**

Task 1. Obtain budgeted equipment to allow direct digitization of ear canals and manufacture of CAD design custom earplugs.
Task 2. Train on utilization of direct digitization process

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Task 3. Manufacture of custom earplugs using visible light imagery data of the ear canal and manufacture of custom earplugs from data collected from earmolds.

Task 4. Conduct attenuation testing between direct data collection and earmold data earplugs (to include volume measurements).

Task 5. Complete a final report describing descriptive results and analytical trends between the two types of earplugs.

4. **SIGNIFICANCE:**

Currently available earplugs are either the standard pre-formed single or triple flanged variety, foam, or custom made earplugs. In real world studies, the most comfort and attenuation is achieved through the use of custom earplugs. However the cost and availability of such earplugs are limiting factors. All other varieties of pre-formed plugs do no provide acceptable attenuation for individuals with twisted ear canals or extremely small or extremely large ear canals.

The best hearing protection is the one that is worn. Custom earplugs, which can be stored on a computer and manufactured when and where needed, provide an improvement to the current practice of centrally stock piling standard pre-formed earplugs which may not be available to a highly mobile soldier in a dynamic situation. Whereas, available hearing protection will result in reduced hearing loss due to noise exposure.

5. **BACKGROUND**

5.1 **INTRODUCTION:** It is well documented that repeated or prolonged exposure to hazardous noise will cause temporary or permanent hearing loss. To prevent hearing loss, hearing protection devices have been provided in many styles. The "one size fits most" ear plugs are the most readily available, but hearing attenuation can be variable, and for many, they are uncomfortable. The only method of insuring maximum comfort and attenuation is a custom earplug. This customized manufacturing process is traditionally a manual process creating low reproducibility and the quality is very operator skill dependent. Turn around time for this procedure at TAMC is approximately thirty days and The cost involved in manufacturing using the standard method (lost wax) is approximately 75 dollars per pair. In order to overcome these disadvantages, we propose to combine a variety of available techniques to rapidly produce an inexpensive custom-fit ear plug.

Computer Aided Design and Manufacturing (CAD/CAM) has become available which faithfully produces a three dimensional (3D), digital model of the internal surface of the ear and ear canal. This 3D model has been used create shells for in jewelry manufacture . A number of manufacturing processes have been developed to take this digitized CAD data and produce in-ear hearing aid shells. This process, computer aided design and manufacturing (CAD/CAM) method, has been adopted to produce custom fit, digital earplugs instead of creating a hollow shell for in-ear hearing aids. The process by which this is accomplished is called printing. During this process, a chamber is prepared by either introducing a thin film across a flat pan surface or very fine microscopic particles (print material) are used to coat the pan. With each

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pass of film or particles, a group of lasers is used to "cook" the print material at intersecting precise points. Multiple passes lead to the creation of a 3 dimensional model (the scanned image) (4).

There are many advantages of having a data model of the ear canal. Digital data can be stored and retrieved at any time, obviating the need for return visits by the patient every time a replacement ear plug is required. Uniformed quality of the manufactured ear plug is ensured. Data is constantly being transmitted over the internet. Digitized data of the ear canal can be transmitted either as it is obtained or right thereafter for evaluation at the manufacturing facility. This significantly reduces turnaround time and transportation costs. Medics at an aid station with access to the web will be able to submit requests for custom earplugs at any time. These earplugs will be created and shipped within hours of receipt of the digitized impression data. Once a hardwired system is demonstrated, this proposed manufacturing method will allow for custom earplugs to be the norm rather than the exception.

5.2 **MILITARY RELEVANCE**: The military of today faces the problem of the mobile battlefield. Hearing loss continues as the second most common occupational injury (1).

The proposed research would allow the production of custom-fit in-ear earplugs anywhere, anytime. Digitized data sets of individual ear surfaces and ear canals would be available for transmission over the worldwide web to any certified earplug manufacturer. Turn-around time, cost, and most importantly ready availability of earplugs for soldiers deployed anywhere around the world is the goal of this research.

6. **PROTOCOL DESIGN:**

6.1. **OVERVIEW:** Using custom earplugs manufactured from digital images created by two specific techniques: direct digitization of an ear mold and direct digitization of an ear canal using visible light . The purpose is to establish whether a significant difference in attenuation can be found from custom earplugs created from these two techniques. Subjects will be volunteers from a military unit. Prior to manufacture, the volume of each earplug data sample will be measured. Next, the subjects will be fitted with earmold digitized earplugs and with earplugs made using direct digitization of the ear canal. Both sets of earplugs will have been CAD/CAM manufactured. A basic puretone audiometric test will be collected for each subject without earplugs at the beginning and end of the test sequence. Then two counterbalanced basic puretone audiometric tests will be conducted (ascending and descending, the results will be averaged for each audiometric frequency) for each set of earplugs. Therefore each subject will complete 6 audiometric tests.

6.2 **INSTITUTIONS/GROUPS RESPONSIBILITIES:** Tripler Regional Medical Center will be responsible for conducting the research effort, compiling, analyzing, and maintaining the

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collected data. Tripler Regional Medical Center will be responsible for initial draft and coordinating the final report. Appendix 2 delineates specific investigator responsibilities.

6.3 **ENDPOINTS:** The first two tasks: obtaining equipment and training on equipment are preliminary tasks required for the conduct of the study. Task three: making scans and ultimately the custom earmolds are part of the study tasks. Task four: data collection will be accomplished by evaluating audiometric thresholds at the following frequencies: 250, 500, 1000, 2000, 3000, 4000 and 6000Hz. These scores will be collected in sound field and will represent a basic audiometric test. This test will be repeated twice for each type of custom earplug and the data will be averaged. Pre and post audiometric testing will be completed and compared to insure that no significant difference has occurred. The end point for task four will be when all audiometric testing has been completed for all forty subjects.

6.4 **SAMPLE SIZE:** This study will require 40 subjects to achieve a .05 level of significance. This value was derived from the work of Cohen (3). This study will be conducted as a prospective analysis using paired observations of audiometric threshold data using Cohen's Kappa. The degree of agreement among these scores will determine significance. Per Cohen (3), a median effect size with a .05 level of confidence will require 30 subjects. Forty subjects will be recruited to meet the number required and account for subject attrition.

6.5 **STUDY GROUP DESCRIPTION AND DETERMINANTS OF STUDY GROUP DESIGN:** This is Multi-observational study without control group. Each subject acts as his or her own control.

6.6 **POPULATION TO BE STUDIED:** Adult male and female subjects from the respective military population. Each participant must be a native English speaker and must have no other major health concern except for hearing loss.

6.7 **AGE RANGE:** 21 to 60 years of age.

6.8 **GENDER:** Both male and female voluteers will be utilized. The number of each sex recruited will be equivalent and subject testing will be counter-balanced for time of day. In this way no one sex will always be tested at the same time.

6.9 **DESCRIPTION OF TEST ARTICLE OR DEVICES:** A computer based clinical audiometer, calibrated to ANSI standards will be used with sound field speakers to collect the attenuation data. These tests are well established and are administered in an established presentation format.

6.10 **DATA AND SPECIMEN COLLECTION:** Data will be stored in a computer based audiometer by subject number. These results will be collected by the assistant PI and kept under lock.

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6.11 **MONITORING:** Each subject will be observed by an onsite monitor (assistant PI). No safety issues are expected as this study will be conducted as a standard audiometric test procedure. Audiometric testing is non-invasive.

If Subject # is	Right ear			Left ear		
Odd	Baseline	Direct scan	Earmold scan	Earmold scan	Direct scan	Baseline
Even	Baseline	Earmold scan	Direct scan	Direct scan	Earmold scan	Baseline

7.1 **METHODS:** Tasks 1 & 2 – Obtain and train on equipment: Consultants from LANTOS INC. will be hired to provide both the required scanning equipment and training necessary to complete the manufacture of the custom earplugs (task 3). The impression scanned custom earplugs will be manufactured by Unitron industries (currently standard of care for custom earplugs). Task 4- the comparison of audiometric attenuation data will be completed at Tripler once all earplugs have been produced. Each subject will receive a pre audiometric hearing test. Then each subject will receive (in counterbalanced order) two audiometric hearing tests using both type of custom earplugs. These threshold puretone audiometric tests use the standard audiometric frequencies of 250, 500, 1000, 2000, 3000, 4000, and 6000 hz. Data will be scored as levels of agreement in 5dB steps from the standard baseline (average of pre and post test results) for each frequency. Both descriptive and correlation data will be produced for the final report. Task 5, write a final report: A final report will be written within the 12 month timeframe.

7.1a **PROCEEDURAL MILESTONES:** All milestones are set post IRB approval with a start date within 30 days (funding in on site)

	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
IRB approval	x									
start date		x								
task 1		x								
task 2			x	x	x					
task 3					x	x				
task 4						x	x	x	x	x
task 5										x

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

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7.2 **SOURCE OF RESEARCH MATERIAL:** The data collected will be locked. ***A master key will be initiated at the time of enrollment. The master key will link the patient with a patient number. At the second session, only the patient number will appear on the data collection sheet will be stored in a secure location. The master key will be stored in a locked file cabinet in the office or will be stored in a password protected computer file, and it will be promptly destroyed as soon as data collection is completed. The data collection sheet will be stored in a secure location.***

7.3 RECRUITMENT OF STUDY VOLUNTEERS: The PI or her representative will identify potential subject volunteers from the population of adult English speaking, normally healthy military volunteers. The volunteer subject order of recruitment will be considered a random presentation.

7.4 **INFORMED CONSENT:** The PI or her representative will conduct the consent interview. This interview will take place just prior to enrollment in the study and scanning of the earcanals. Privacy will be maintained by providing each test subject with a subject number in place of their name. No study procedure will occur without prior subject consent. As these procedures represent standard of care, the only limiting factor will be whether a subject has the time (2 hours total) to complete the study.

7.5 **SCREENING PROCEDURES:** No screening procedures will be used except for subjective information on age, fluent english speaking ability and relative health.

7.6 **DETERMINATION OF ELIGIBILITY:** Subjects will be 40 normal hearing men and women (20 of each) as defined by the Army H-1 profiling criteria with no known medical pathology.

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7.6.1 **INCLUSION CRITERIA:** Must be an adult between the age of 18 and 60 years of age.

7.6.2 **EXCLUSION CRITERIA:** Subject is not between the age of 18 and 60, is not a fluent English speaker, and has medical problems in addition to hearing loss.

7.7 **RANDOMIZATION AND SUBJECT ASSIGNMENT:** Patient presentation at the Tripler Audiology Clinic will be considered a sufficient random order. Half the subjects will be male and half the subjects will be female. The earplugs will be counterbalanced as will the test presentation. Appendix 6 provides clinic test order for counter-balanced test presentation.

7.8 **BLINDING: N/A**

7.9 ADMINISTRATION OF THE RESEARCH INTERVENTION: N/A

7.10 CONCOMITANT MEDICATION: N/A

7.11 SPECIMEN COLLECTION AND TESING: N/A

7.12 **CLINICAL ASSESSMENTS:** All testing will be complete at time of evaluation. Results will be presented in the form of a standard report based on the on-site evaluation.

7.13.3 **DATA MANAGEMENT and COMPILATION:** Data will be collected for each frequency. The test will be conducted twice for each type of custom earplug and the data will be averaged. The pre and post puretone audiometric test will be evaluated and any significant difference on two frequencies will require a re-test of the subject. The conduct of the experiment will control for time of day. Each subject will receive (in counterbalanced order) two puretone hearing tests using both type of custom earplugs. puretone audiometric testing uses the standard audiometric frequencies 250, 500, 1000, 2000, 3000, 4000, 60000, and 8000 Hz (average pre and post test results). Data will be transcribed from the test serial audiogram to an excel spreadsheet with subjects represented by subject number. The proposed spreadsheet would be as follows, with the cells to be filled in with the threshold intensity (decibels, dB) determined from incremental increases of 5 dB.

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Table 3. A sample of mock data.

Subject #	Ear	Site	250 Hz	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz	8000 Hz
1	L	Baseline	0	5	0	5	5	0	5	5
1	L	Lost Wax	20	25	30	25	25	35	35	20
1	L	CAD-design	25	20	25	25	25	30	30	30
1	R	Baseline	0	5	0	5	5	0	5	5
1	R	Lost Wax	20	25	25	25	30	35	35	25
1	R	CAD-design	25	20	25	25	30	30	30	30

The data from this spreadsheet will be used to produce a set of attenuation scores for each condition in the following manner: The corresponding baseline score will be subtracted from each ear plug condition (e.g., Subject 1's Baseline for 250 Hz in the left ear will be subtracted from the direct scan threshold for the same ear and frequency. Similarly the same Baseline will be subtracted from the earmold digitized threshold for the left ear at 250 Hz.) The resulting attenuation data are shown in the following spreadsheet for the mock data listed in the table above.

Table 4. Attenuation Scores Using Mock Data

Subject #	Ear	EarPlug	250 Hz	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz	8000 Hz
1	L	DS	20	20	30	20	20	35	30	15
1	L	ES	25	15	25	20	20	30	25	25
1	R	DS	20	20	25	20	25	35	30	20
1	R	ES	25	15	25	20	25	30	25	25

DS- Direct Scan
ES- Earmold Scan

7.14 **SERIOUS AND UNEXPECTED ADVERSE EVENTS**: We do not anticipate any adverse effects as this is standard of care

7.14.1 **ADVERSE EVENT:** N/A

7.14.2 **SERIOUS ADVERSE EVENT:** N/A

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7.14.3 **UNEXPECTED ADVERSE EVENTS: N/A**
7.14.4 **EXPECTED ADVERSE EVENTS: N/A**

7.14.5 COLLECTING ADVERSE EVENTS: N/A

7.14.6 DOCUMENTING ADVERSE EVENTS: N/A

7.14.7 FOLLOW-UP OF ADVERSE EVENTS: N/A

7.14.8 REPORTING ADVERSE EVENTS: N/A (All adverse events will be reported)

7.14.9 **WITHDRAWAL CRITERIA:** Volunteers will be allowed to withdraw from the study at any time without penalty of any type.

7.14.10 **CRITERIA FOR STUDY TERMINATION:** Subject request for any reason.

7.14.11 **QUALITY CONTROL AND QUALITY ASSURABCE:** Standard of care as specified in clinic SOP and as specified by the American Speech Language and Hearing Association.

7.15 **SPECIAL MEDICAL OR NURSING CARE OR EQUIPMENT: N/A**

8. DATA ANALYSIS: The data from two audiograms collected for each subject while wearing no earplugs will be averaged and set as the baseline audiogram for that subject. There will be a baseline threshold for each subject, each ear, each of the eight frequencies.

The methodology describes the mixed factors design used in this study. The two presentation orders is the between subjects variable. The ears (sound field), the frequencies (8 levels), and the type of earplugs (2) are the three repeated measures.

An analysis of variance for the mixed factors design will be conducted. The significiance of the following comparisons will be determined:

1. Is there a difference in the attenuation effect of the two types of earplugs?
2. Is there a difference in the attenuation effect at different frequencies?
3. Is there an interaction between the attenuation effect for these two variables?

Only the main effect and the interactions involving the frequencies will require follow on tests to determine which of the differences is showing the significant effect.

From the spreadsheet and derived datasheet described in section 7.13.3, the total disagreement and specific directional deviations will be obtained. From these data a Cohen's Kappa value (Cohen 1960) will be determined and a Cronbach's alpha value determined from the binomially distributed data (agree or disagree). A high degree of agreement as determined by the Kappa statistic or by Cronbach's alpha is considered to produce a value in either statistic of .8 or

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greater. This indicates that with forty sujects you will have 80% probability (power) of detecting a difference of 9% or greater at the $p < 0.05$ level of probability. Both are measures of correlation for binomial data. We will also be able to determine if there is a significant tendency for the disagreement to be in one direction by comparison to an expected distribution of 50:50 if the disagreements were caused by completely random interference by a binomial probability test. Also, a binomial probability test can be used to detect a "significant" degree of disagreement. That is, by comparing the % disagreement observed, to 0. These binomial procedures are particularly useful in determining a significant occurrence of disagreement when data the data disagree in a random fashion, i.e. equally up and down. In such cases there may be no differences in overall means. Also, a commonly used binomial test for comparisons of a response of the same individual in paired fashion, is the McNemar's test. However, if the disagreement is equally distributed between increases and decreases, no significant difference is determined, despite great discrepancies in overall agreement. Therefore, we will not depend on the McNemar's analysis, but will incorporate it in the analysis.

Data will be analyzed within 30 days of the completion of all data collection. Due to the nature of the study missing data are not possible. Data analysis and final report are the responsibility of Leslie J. Peters, Ph.D. TAMC.

9. ETHICAL CONSIDERATIONS:

9.1 **INFORMED CONSENT:** See section 7.4 and Informed Consent Document (Appendix 10).

9.2 **VOLUNTEER IDENTIFICATION AND CONFIDENTIALITY:** Data will be extracted from the standard of care audiometric report and identified only by subject number.

9.3 **RISK TO VOLUNTEERS AND PRECAUTIONS TO MINIMIZE RISK:** There are no known risks associated with routine audiometric testing. As stated in section 7.14, the risks of remote audiometric testing are extremely low but not zero.

9.4 **ALTERNATIVES TO TEST ARTICLE, RESEARCH TREATMENT OR RESEARCH INTERVENTION**: Standard of care. A patient who chooses to not participate will still be provided the requested audiometric evaluation.

9.5 **BENEFITS TO VOLUNTEERS**: Subjects participating in this study will receive two pair of custom earplugs.

9.6 **RISKS TO STUDY PERSONNEL AND PRECAUTIONS TO MINIMIZE RISK:** There are no known risks to audiometric test procedures.

9.7 **RISKS TO THE ENVIRONMENT:** N/A

9.8 **FINANCIAL INCENTIVES TO VOLUNTEERS:** N/A

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9.9 **MEDICAL CARE FOR INJURY OR ILLNESS:** N/A . There is no known adverse effect associated with pure tone audiometric testing.

10. **ADMINISTRATIVE PROCEDURES:**

10.1 **TEST ARTICLE ACCOUNTABILITY:** Audiometric data will be identified by subject number. This data will be transcribed from the audiometric report and placed in an excel spread sheet and imported electronically into a data base maintained at Tripler Army Medical Center. Privacy and confidentially issues are not applicable here as transmitted data will identify subjects only by number.

10.2 **DISPOSITION OF DATA:** Data will be maintained in an electronic format at Tripler Army Medical Center. Subject informed consent forms will be maintained at the respective test site. All data will be maintained for a period of three years.

10.3 **ACCESS TO SOURCE DATA/DOCUMENTS:** The investigators, a medical monitor, members of the TAMC HUC, representatives of the U.S. Army, representatives of the HHS, and other government agencies may have access to the study data as part of their duties and part of their responsibility to protect human subjects in research.

10.4 **CERTIFICATION OF TRANSLATION:** N/A

10.5 **PROTOCOL AMENDMENTS**: Any change or amendment to the protocol affecting study volunteers, study objectives, study design, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendment will be submitted to the HUC for review and approval and then forwarded to CIRO.

The Informed Consent Form must be revised to concur with any significant amendment that directly affects volunteers, and must also be reviewed and approved with the amendment. New volunteers enrolled in the study will be consented with the most recent approved consent form. Volunteers already enrolled in the study will be informed about the revision and, depending on the impact of the amendment, may be asked to reconsent. This may be accomplished by repeating the consent process with the revised consent form with attention given to the changes, or it may be done using an appendix that states the revision or new information. The new document must be signed, placed in the study record, and a copy given to the volunteer.

Administrative changes to the protocol are corrections and/or clarifications that have no effect on the way the study is to be conducted. Such administrative changes will be submitted to the HUC for review and approval prior to implementation.

10.6 **PROTOCOL DEVIATIONS:** N/A

10.7 **PUBLICATION POLICY:** Results of this study will be presented in scientific forums orally and in written publications in scientific journals. No identifying information for any of

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the volunteers in the study will be included in any presentation of data or photographs. Publications will be submitted as per Command review policy.

10.8 **RESPONSIBILITIES OF LISTED STUDY PERSONNEL:** Paragrah 10.11 describes the duties of researcher personnel.

10.9 **RESPONSIBILITIES OF THE MEDICAL MONITOR:** N/A

10.10 **COMPLIANCE WITH LAWS AND REGULATIONS:** The undersigned Principal and Associated Investigators have reviewed this protocol and will conduct the study in full compliance with current Good Clinical Practice Guidelines, HHS regulations, FDA regulations, and Army regulations.

10.11 **INVESTIGATOR'S STATEMENT**
PRINCIPAL INVESTIGATOR: Denby K. Fukuda, Au.D.

I agree to prepare a protocol and conduct this study as written IAW the policies and procedures set forth in AR 40-38, paragraph 2-10c, current Good Clinical Practices (cGCP) guidelines, and Department of Health and Human Services, OHRP policies as listed below:

- Design, and implement ethical research, consistent with three ethical principles delineated in the Belmont Report.
- Comply with all applicable Federal Regulations impacting the protection of human subjects: 45 CFR 46 (subpart B,C and D), Federal Policy for the protection of human subjects – "The Common Rule" June 18 1991, Food and Drug Administration (IRB – 21 CFR 56 and Informed Consent – 21 CFR 50).
- Comply with all applicable Tripler Army Medical Center Research Program.
- Implement research as approved only and obtain prior Scientific Review Committee (SRC)/Human Use Committee (HUC) approval for changes. (See Dept of Clinical Investigation (DCI) for assistance).
- Prepare progress reports, including annual reports (Clinical Investigation Program, RSC MED-300 (R1), as determined by the approving authority and regulatory agencies.
- Promptly notify the SRC of deviations to the protocol.
- Report serious and unexpected adverse experiences involving execution of your protocol.
- Ensure that the clinical investigation has been approved by the proper review committee(s) before starting, changing, or extending the investigation.
- Ensure that a new principal investigator (PI) is appointed if the current PI cannot complete the protocol for reasons such as permanent change of station, deployment, or retirement.
- Apprise the SRC/HUC of any investigator's noncompliance with the protocol.
- Notify DCI of any changes in the Investigators participating in the protocol.
- Ensure that studies involving attitude or opinion surveys are approved in accordance with AR 600 46.

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I acknowledge that I have read the above information, understand the requirements, and accept the responsibilities listed. I assure that the protected health information used in this research study will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by 45 CFR 164.

Note: Research at Tripler Army Medical Center is a privilege. Failure to comply with or to fulfill any of these responsibilities may result in study suspension and corrective actions will be taken.

11. **SIGNATURES**: Signatures indicate review, concurrence, sponsorship responsibilities and ability to support protocol.

_____ _____

Joseph Sniezek, LTC (P) Date
Chief Otolaryngology Service
Tripler Army Medical Center

_____ _____

Denby Fukuda, AUD. Date
Chief, Audiology Section
Otolaryngology Service
Tripler Army Medical Center
Principal Investigator

_____ _____

Leslie J. Peters, Ph.D. Date
Consulting Audiologist
Otolaryngology Service, Audiology Section
Tripler Army Medical Center

12. ATTACHMENTS:

Appendix 1: References
Appendix 2: CV:
Dr. Denby Fukuda
Dr. Leslie J. Peters
Appendix 3: CITI Certification
Dr. Denby Fukuda
Dr. Leslie J. Peters
Appendix 4: Budget
Appendix 5: Informed Consent Document

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8178

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Appendix 1: References

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

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LANTOS TECHNOLOGIES

REFERENCES

1. Dr. Tom Helpher. Personal correspondence, May 2007
2. Dr. Leslie Peters. Personal correspondence, April 2007.
3. Cohen J. A coefficient of agreement for nominal scales. Educ Psychol Meas, 1960; 20:37-46.
4. Trine, Tim, Ph.D., Starkey Laboratory, Minneapolis, Minn., Personal correspondence, April 2007

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

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Appendix 3: CITI Certification

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

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CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report
Printed on 2/25/2010

Learner: Denby Fukuda (username: denbyf)
Institution: Tripler Army Medical Center
Contact Information Department: Surgery-Audiology
Phone: 8084333194
Email: denby.fukuda@us.army.mil

Group 1. Biomedical Research Investigators and Staff:

Stage 1. Basic Course Passed on 02/25/10 (Ref # 3789562)

Required Modules	Date Completed	
Introduction	11/25/09	no quiz
History and Ethical Principles	11/25/09	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process	11/25/09	5/5 (100%)
Informed Consent	02/25/10	4/4 (100%)
Social and Behavioral Research for Biomedical Researchers	02/25/10	4/4 (100%)
Records-Based Research	02/25/10	2/2 (100%)
Genetic Research in Human Populations	02/25/10	2/2 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	02/25/10	4/4 (100%)
Vulnerable Subjects - Research Involving Minors	02/25/10	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero	02/25/10	3/3 (100%)
International Research	02/25/10	1/1 (100%)
Group Harms: Research With Culturally or Medically Vulnerable Groups	02/25/10	3/3 (100%)
FDA-Regulated Research	02/25/10	5/5 (100%)
Human Subjects Research at the VA	02/25/10	3/3 (100%)
HIPAA and Human Subjects Research	02/25/10	2/2 (100%)
Conflicts of Interest in Research Involving Human Subjects	02/25/10	2/2 (100%)
Tripler Army Medical Center.	02/25/10	11/12 (92%)

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

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

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LANTOS TECHNOLOGIES

CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report
Printed on 4/12/2011

Learner: Leslie Peters (username: lpete967)
Institution: Tripler Army Medical Center
Contact Information
Department: Department of Army
Phone: 808-433-3195
Email: lpete967@aol.com

Group 1. Biomedical Research Investigators and Staff:

Stage 4. Refresher Course Passed on 02/07/11 (Ref # 4863438)

Required Modules	Date Completed	
Refresher Course 200 Introduction	02/01/11	no quiz
History and Ethical Principles.	02/01/11	no quiz
Regulations and Process, Part 1	02/01/11	1/1 (100%)
Regulations and Process, Part 2	02/01/11	1/1 (100%)
Informed Consent.	02/01/11	1/1 (100%)
Social & Behavioral Research (SBR)	02/01/11	2/2 (100%)
Genetics Research, Part 1	02/01/11	1/1 (100%)
Genetics Research, Part 2	02/01/11	1/1 (100%)
Records-Based Research, Part 1	02/01/11	1/1 (100%)
Records-Based Research, Part 2	02/01/11	1/1 (100%)
Records-Based Research, Part 3	02/01/11	1/1 (100%)
Research with Protected Populations - Vulnerable Subjects: A Definition.	02/04/11	1/1 (100%)
Studies With Minors, Part 1	02/04/11	1/1 (100%)
Studies With Minors, Part 2	02/04/11	1/1 (100%)
Studies With Minors, Part 3	02/04/11	1/1 (100%)
Studies with Pregnant Women and Fetuses, Part 1	02/04/11	0/1 (0%)

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

Studies with Pregnant Women and Fetuses, Part 2	02/04/11	1/1 (100%)
Group Harms: Research with Culturally or Medically Vulnerable Groups.	02/04/11	3/3 (100%)
FDA-Regulated Research, Part 1	02/04/11	1/1 (100%)
FDA-Regulated Research, Part 2	02/04/11	1/2 (50%)
Human Subjects Protections at the VA, Part 1	02/04/11	0/1 (0%)
Human Subjects Protections at the VA, Part 2	02/07/11	1/1 (100%)
HIPAA and Human Subjects Research.	02/07/11	2/2 (100%)
Conflicts of Interest in Research Involving Human Subjects.	02/07/11	2/2 (100%)
How to Complete the CITI Refresher Course and Receive a Completion Report	02/07/11	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

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

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Appendix 4: Budget

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

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EE Principal Investigator/Program Director (Last, First, Middle): Fukuda, Denby, K.

BUDGET FOR ENTIRE PROPSED PERIOD OF SUPPORT
DIRECT COST ONLY

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD *(FROM Form DD)*	ADDITIONALYEARS OF SUPPORT REQUESTED 2nd	3rd	4th	5th
PERSONNEL: *Salary and fringe benefits*	20000.00				
CONSULTANT COST	20722.00				
EQUIPMENT	36258.10				
SUPPLIES	2000.00				
TRAVEL	5989.90				
PATIENT CARE COSTS TIENT					
PATIENT					
ALTERATIONS AND RENOVATIONS					
OTHER EXPENSES	1200.00				
SUBTOTAL DIRECT COSTS	86170.00				
CONSORTIUM/ CONTRACTUAL COSTS					
T	3000.00				
TOTAL DIRECT COSTS	89170.00				
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT				**$89170.00**	

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation sheets as needed.

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

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Appendix 5: Informed Consent Document

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

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LANTOS TECHNOLOGIES

VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 70-25 or AR 40-38, the proponent agency is OTSG

PRIVACY ACT OF 1974

Authority: 10 USC 3013, 44 USC 3101, and 10 USC 1071-1087.

Principle Purpose: To document voluntary participation in the Clinical Investigation and Research Program. Home address will be used for identification and locating purposes.

Routine Uses: The home address will be used for identification and locating purposes. Information derived from the study will be used to document the study; implementation of medical programs; adjudication of claims; and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State and local agencies.

Disclosure: The furnishing of your home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this investigational study.

PART A(1) - VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for injury or disease
which is the proximate result of their participation in such studies.

I, _____,

having full capacity to consent and having attained my _____ birthday, do hereby volunteer/give consent as legal

representative for _____ to participate in an investigational study entitled
Direct Scan Earmold Digitization Evaluation
(Research Study)
under the direction of
conducted at Dr. Denby Fukuda, Aud.
(Name of Institution)
Tripler Regional Medical Center

The implications of my voluntary participation/consent as legal representative; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

_____

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights/the rights of the person I represent on study related injury, I may contact

the Center Judge Advocate

at Tripler Army Medical Center, Tripler AMC, HI 96859-5000 (808) 433-5311
(Name, Address and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my consent and withdraw/have the person I represent withdrawn from the study without further penalty or loss of benefits; however, I/the person I represent may be required (military volunteer) or requested (civilian volunteer) to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my/the person I represent's health and well-being. My/the person I represent's refusal to participate will involve no penalty or loss of benefits to which I am/the person I represent is otherwise entitled.

PART A(2) - ASSENT VOLUNTEER AFFIDAVIT *(MINOR CHILD)*

I, _____,

having full capacity to assent and having attained my _____ birthday, do hereby volunteer for

_____ to participate in an investigational study entitled

_____
(Research Study)

_____

under the direction of _____

conducted at _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8178

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(Name of Institution)

(Continue on Reverse)

DA FORM 5303-R, MAY 89 PREVIOUS EDITIONS ARE OBSOLETE

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

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PART A(2) - ASSENT VOLUNTEER AFFIDAVIT *(MINOR CHILD) (Cont'd.)*

The implications of my voluntary participation; the nature, duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

_____

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights I may contact

_____

_____

(Name, Address, and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my assent and withdraw from the study without further penalty or loss of benefits; however, I may be requested to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

PART B - TO BE COMPLETED BY INVESTIGATOR

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT**:** *(Provide a detailed explanation in accordance with Appendix C, AR 40-38 or AR 70-25.)*

PARTICIPATION INFORMATION: You have been invited to participate in a clinical investigational/research study conducted at Tripler Army Medical Center. It is very important that you read and understand the following general principles that apply to all participants in our studies: (a) your participation is entirely voluntary; (b) you may withdraw from participation in this study or any part of the study at any time; refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled; (c) after you read the explanation, please feel free to ask any questions that will allow you to clearly understand the nature of the study.

NATURE OF STUDY: The purpose of this study is to determine whether computer aided design (CAD) earplugs created from a digitized data cloud of an earmold (created using visible light imaging) will provide equivalent attenuation to CAD earplugs created from a digitized data cloud using visible light directly from the ear canal.

EXPECTED DURATION OF SUBJECT'S PARTICIPATION: 2 hours over two visits.

WHAT WILL BE DONE: Earmold impressions will be taken of each ear and a digitized image of both ears will be completed using a visible light source. Time for this visit is about 1 hour. At a later time (approximately 5 weeks later) you will be asked to complete two sets of audiometric tests wearing both sets of custom earplugs. Total time for this visit will be 1 hour

INCLUSION AND EXCLUSION CRITERIA: You must be an adult between the ages of 18 and 60 and be fluent in English.

REASONABLY FORESEEABLE RISKS OR DISCOMFORTS: None

COMPENSATION FOR INJURY: Should you be injured as a direct result of participating in this research project, you will be provided medical care at TAMC, at no cost to you, for that injury. You will not receive any injury compensation, only medical care. This is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

BENEFIT(S) TO THE SUBJECT OR TO OTHERS: You will receive 2 pair of custom earplugs.

ALTERNATIVE PROCEDURES OR COURSES OF TREATMENT: None

CONFIDENTIALITY: Information gained because of your participation in this study may be publicized in the medical literature, discussed as an educational model, and used generally in the furtherance of medical science. Information from this study may be used as part of a scientific publication in medical or professional journals, but you will in no way be personally identified. Complete confidentiality cannot be promised because information bearing on your health may be required to be reported to appropriate medical or command authorities.

Your medical records relating to this study may be reviewed by the Institutional Review Board (IRB) at Tripler Army Medical Center, Clinical Investigation Regulatory Office at Fort Detrick, Maryland and other government agencies as part of their normal duties in protecting human research subjects, and results of the study will be reported to them. The recipients will treat this information confidentially, and in the event of publication regarding this study, your identity will not be disclosed.

Your medical records relating to this study may be reviewed by the United States Food and Drug Administration (FDA), (name of drug sponsor/manufacturer) and the Institutional Review Board (IRB) at Tripler Army Medical Center, Clinical Investigation Regulatory Office at Fort Detrick, Maryland and other government agencies as part of their normal duties in protecting human research subjects, and results of the study will be reported to them. The recipients will treat this information confidentially, and in the event of publication regarding this study, your identity will not be disclosed.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA). A HIPAA Authorization form for this study will be provided to you separately, and you will be asked to sign that form.

PRECAUTIONS TO BE OBSERVED BY SUBJECT BEFORE AND FOLLOWING THE STUDY: None

CIRCUMSTANCES UNDER WHICH YOUR PARTICIPATION MAY BE TERMINATED WITHOUT YOUR CONSENT: (a) Health conditions or other conditions that might occur which may be dangerous or detrimental to you or your health; (b) if military contingency requires it; (c) if you become ineligible for military care as authorized by Army regulation; (d) if the safety monitor determines that continued treatment under this study may be harmful to you.

COSTS TO SUBJECT THAT MAY RESULT FROM PARTICIPATION IN STUDY: In accordance with AR 40-38, paragraph 3-3(j)(2), daily charges for inpatient care will be waived while the volunteer is in the hospital if the volunteer would not normally enter the hospital for treatment but is requested to do so as part of a research study or as a result of adverse reaction to the drug(s) or procedure(s) used in this study. This also applies to the volunteer's extension of time in a hospital for a research study when the volunteer is already in the hospital.

SIGNIFICANT NEW FINDINGS: Any significant new findings developed during the course of this study that could affect your willingness to continue participation will be made available to you. The results of

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

the research will be made available to you if you so desire. In some cases complete results may not be known for several years.

APPROXIMATE NUMBER OF SUBJECTS INVOLVED IN THE STUDY: 40

DOMICILIARY CARE STATEMENT: The extent of medical care provided, should it become necessary, is limited and will be within the scope authorized for Department of Defense (DOD) health care beneficiaries. Necessary medical care does not include domiciliary (home or nursing home) care.

FOR FURTHER INFORMATION: For questions about the study, contact the principal investigator:

Denby Fukuda, AUD, C, Audiology Section
Otolaryngology Service
Tripler Army Medical Center
808-433-3198

For questions about your rights as a research participant, contact the Tripler Army Medical Center's Institutional Review Board (which is a group of people who review the research to protect your rights) at (808) 433-6709.

For questions about research related injury, contact the Center Judge Advocate at Tripler Army Medical Center at (808) 433-5311.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

IF THERE IS ANY PORTION OF THIS EXPLANATION THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. A COPY OF THE VOLUNTEER AGREEMENT AFFIDAVIT WILL BE PROVIDED TO YOU.

******

I have read the above explanation and agree to participate in the investigational study described.

I do [ ] do not [ ] (check one & initial) consent to the inclusion of this form in my outpatient medical treatment record

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (if volunteer is a minor)
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS	
	SIGNATURE OF WITNESS	DATE

(Date)

(Printed Name of Individual Obtaining Consent)

(Signature of Individual Obtaining Consent)

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Appendix 6: HIPAA Statement

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

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LANTOS TECHNOLOGIES

HIPAA Statement

By signing this form, you are authorizing Tripler Army Medical Center, including the Principal Investigator **[Denby Fukuda, AUD]**, and other members of the research staff, to use and disclose your health information as needed for the research study, **[Direct Scan Earmold Digitization Evaluation]**. Only information that is relevant to this study will be used or disclosed.

Your medical records relating to this study may be reviewed by the Institutional Review Board (IRB) at Tripler Army Medical Center and other government agencies as part of their normal duties, and results of the study will be reported to them. Representatives of the U.S. Army Medical Research and Material Command are authorized to review research records as part of their responsibility to protect human research volunteers. Research records will be stored in a confidential manner so as to protect the confidentiality of your information.

If you decide not to sign this authorization, you will not be allowed to participate in this research study.

You have the right to revoke this authorization at any time by sending a written letter to the Principal Investigator at **Department of Surgery, Tripler Army Medical Center, 1 Jarrett White Road, Tripler AMC, HI 96859-5000**. If you revoke this authorization, the research staff may only use and disclose your health information already collected before you withdrew your permission and you will not be allowed to continue to participate in the research study. Beginning on the date you withdraw your permission, new protected health information about you will no longer be collected or used for research unless the information is needed to maintain the scientific integrity of our study or if there is an adverse event (a bad side effect) related to the study. If an adverse event occurs, we may need to review your entire medical record.

Once your health information has been disclosed to anyone outside this research study, there is a possibility that it may be redisclosed by the recipient and no longer be protected by the privacy regulation, such as a result of a court order.

The research investigators agree to protect your health information by using and disclosing it only as permitted in this Authorization.

This Authorization does not have an expiration date.

****
I authorize the Principal Investigator and the research staff to use and disclose my health information for the purpose of conducting this research study.

_____ _____
Signature of research subject or legal representative Date

_____ _____
Printed name of research subject or legal representative Date

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

If a legal representative signs, explain the representative's authority to act on behalf of the research subject.

_____

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

ATTACHMENT II

IRB Approval

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

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LANTOS TECHNOLOGIES

MCHK-CI 06 October 2011

MEMORANDUM FOR Denby K. Fukuda, AUD, CCC-A, Department of Surgery, Otolaryngology Service (ATTN: MCHK-DS), Tripler AMC, HI

SUBJECT: Approval to Initiate No Greater Than Minimal Risk Study

1. Your clinical investigation protocol entitled "**TAMC 45H11: Direct Scan Earmold Digitization Evaluation**," was reviewed and approved as No Greater Than Minimal Risk by the Institutional Review Board (IRB) at Tripler Army Medical Center (TAMC) on 30 August 2011. On 05 October 2011 the IRB received your modifications and these have been reviewed and found to comply with all applicable human subjects' protection regulations. The protocol may now be initiated.

2. The protocol is approved for a period of ***one year*** and must be re-approved for continuation no later than **04 October 2012**. You will be notified to submit a Continuing Review Report for your study using the Detailed Summary Sheet.

3. You are approved to enroll **40** subjects into the study. You may not exceed this number without ***prior*** approval. Subjects that enroll but withdraw from participation are considered in the total number of subjects. The official informed consent document for use in this study is enclosed and affixed with the TAMC IRB stamp dated 05 October 2011 with the expiration date of 04 October 2012 for duplication and enrollment of study subjects.

4. You must ***promptly*** notify the IRB through the medical monitor of any serious or unexpected adverse reactions caused by the clinical investigations. 21 CFR 312.32 define a serious adverse reaction as one that results in: (a) death, (b) persistent or significant disability or incapacity, (c) life-threatening situation, (d) inpatient or prolonged hospitalization, or (e) congenital anomaly/birth defect in an offspring, or (f) an important medical event that, based upon appropriate medical judgment may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed above.

5. Approval is granted with the understanding that no further changes or additions will be made to the procedures followed, investigators involved, or to the informed consent document(s) used without the knowledge and approval of the IRB. Changes include, but not limited to, modifications in study design, recruitment process and number of subjects.

You should retain this letter as part of this protocol's record.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8178

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

LANTOS TECHNOLOGIES

MCHK-CI
SUBJECT: Approval to Initiate Greater Than Minimal Risk Study

6. You are required to keep all signed subject informed consent documents in a permanent file in an area designated for that purpose that is accessible to your chain of command and inspectors of official audit agencies. Your study and its documentation, including the executed informed consent documents, are subject to inspection at any time. You must maintain your records to facilitate such inspections. Upon completion of the study, you should report this to the Department of Clinical Investigation.

7. Please note that this is ***not*** an approval to receive extramural resources (i.e., personnel, drugs, supplies, equipment, money, and gifts from any source outside of TAMC) nor an indication of guaranteed funding from the Department of Clinical Investigation. You must coordinate extramural resource approvals with the Department of Clinical Investigation, Bldg. 40, 433-6709. If any extramural resources are received without DA or MEDCOM approval, the individual who receives them may be found in ethics violation and prosecuted for criminal misconduct.

8. All manuscripts, abstracts, or publicly-released information related to research conducted at or sponsored by TAMC must be submitted for approval as stated in TAMC Pamphlet 40-31 ***prior*** to submission for public release or publication. This includes oral presentations or posters, manuscripts, review articles, abstracts and interviews.

9. Your research study has been determined to be of potential importance to the academic and professional program of Tripler AMC. You are to give all possible priority to its completion. Should any problem arise that jeopardizes the success of your research, please notify the undersigned at 433-6709.

Enc

KEVIN M. LIN-HURTUBISE, MD
Chair, Institutional Review Board

You should retain this letter as part of this protocol's record.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

ATTACHMENT III

IRB APPROVED CONSENT

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 70-25 or AR 40-38, the proponent agency is OTSG

PRIVACY ACT OF 1974

Authority: 10 USC 3013, 44 USC 3101, and 10 USC 1071-1087.

Principle Purpose: To document voluntary participation in the Clinical Investigation and Research Program. Home address will be used for identification and locating purposes.

Routine Uses: The home address will be used for identification and locating purposes. Information derived from the study will be used to document the study; implementation of medical programs; adjudication of claims; and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State and local agencies.

Disclosure: The furnishing of your home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this investigational study.

PART A(1) - VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

I, _____

having full capacity to consent and having attained my _____ birthday, do hereby volunteer/give consent as legal representative for _____ to participate in an investigational study entitled

Direct Scan Earmold Digitization Evaluation

(Research Study)

under the direction of Dr. Denby Fukuda, Aud.

conducted at Tripler Regional Medical Center

(Name of Institution)

The implications of my voluntary participation/consent as legal representative; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights/the rights of the person I represent on study related injury, I may contact

the Center Judge Advocate

at Tripler Army Medical Center, Tripler AMC, HI 96859-5000 (808) 433-5311

(Name, Address and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my consent and withdraw/have the person I represent withdrawn from the study without further penalty or loss of benefits; however, I/the person I represent may be required (military volunteer) or requested (civilian volunteer) to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my/the person I represent's health and well-being. My/the person I represent's refusal to participate will involve no penalty or loss of benefits to which I am/the person I represent is otherwise entitled.

PART A(2) - ASSENT VOLUNTEER AFFIDAVIT *(MINOR CHILD)*

I, _____

having full capacity to assent and having attained my _____ birthday, do hereby volunteer for _____ to participate in an investigational study entitled

(Research Study)

under the direction of _____

conducted at _____

(Name of Institution)

NOT APPLICABLE

(Continue on Reverse)

DA FORM 5303-R, MAY 89 PREVIOUS EDITIONS ARE OBSOLETE

HUC APPROVED 05OCT11
CONSENT FORM EXPIRES 04OCT12

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

PART A(2) - ASSENT VOLUNTEER AFFIDAVIT *(MINOR CHILD) (Cont'd.)*

The implications of my voluntary participation; the nature, duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

I have been given an opportunity to ask questions concerning this investigation or study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights I may contact

at

(Name, Address, and Phone Number of Hospital (Include Area Code))

I understand that my participation in the course of this study, revoke my assent and withdraw from the study without further penalty or loss of benefits; however, I may be requested to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

NOT APPLICABLE

PART B - TO BE COMPLETED BY INVESTIGATOR

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT: *(Provide a detailed explanation in accordance with Appendix C, AR 40-38 or AR 70-25.)*

PARTICIPATION INFORMATION: You have been invited to participate in a clinical investigational/research study conducted at Tripler Army Medical Center. It is very important that you read and understand the following general principles that apply to all participants in our studies: (a) your participation is entirely voluntary; (b) you may withdraw from participation in this study or any part of the study at any time; refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled; (c) after you read the explanation, please feel free to ask any questions that will allow you to clearly understand the nature of the study.

NATURE OF STUDY: The purpose of this study is to determine whether computer aided design (CAD) earplugs created from a digitized data cloud of an earmold (created using visible light imaging) will provide equivalent attenuation to CAD earplugs created from a digitized data cloud using visible light directly from the ear canal.

EXPECTED DURATION OF SUBJECT'S PARTICIPATION: 2 hours over two visits.

WHAT WILL BE DONE: Earmold impressions will be taken of each ear and a digitized image of both ears will be completed using a visible light source. Time for this visit is about 1 hour. At a later time (approximately 5 weeks later) you will be asked to complete two sets of audiometric tests wearing both sets of custom earplugs. Total time for this visit will be 1 hour

INCLUSION AND EXCLUSION CRITERIA: You must be an adult between the ages of 18 and 60 and be fluent in English.

REASONABLY FORESEEABLE RISKS OR DISCOMFORTS: None

COMPENSATION FOR INJURY: Should you be injured as a direct result of participating in this research project, you will be provided medical care at TAMC, at no cost to you, for that injury. You will not receive any injury compensation, only medical care. This is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

HUC APPROVED 05OCT11
CONSENT FORM EXPIRES 04OCT12

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

BENEFIT(S) TO THE SUBJECT OR TO OTHERS: You will receive 2 pair of custom earplugs.

ALTERNATIVE PROCEDURES OR COURSES OF TREATMENT: None

CONFIDENTIALITY: Information gained because of your participation in this study may be publicized in the medical literature, discussed as an educational model, and used generally in the furtherance of medical science. Information from this study may be used as part of a scientific publication in medical or professional journals, but you will in no way be personally identified. Complete confidentiality cannot be promised because information bearing on your health may be required to be reported to appropriate medical or command authorities.

Your medical records relating to this study may be reviewed by the Institutional Review Board (IRB) at Tripler Army Medical Center, Clinical Investigation Regulatory Office at Fort Detrick, Maryland and other government agencies as part of their normal duties in protecting human research subjects, and results of the study will be reported to them. The recipients will treat this information confidentially, and in the event of publication regarding this study, your identity will not be disclosed.

Your medical records relating to this study may be reviewed by the United States Food and Drug Administration (FDA), the Institutional Review Board (IRB) at Tripler Army Medical Center, Clinical Investigation Regulatory Office at Fort Detrick, Maryland and other government agencies as part of their normal duties in protecting human research subjects, and results of the study will be reported to them. The recipients will treat this information confidentially, and in the event of publication regarding this study, your identity will not be disclosed.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA). A HIPAA Authorization form for this study will be provided to you separately, and you will be asked to sign that form.

PRECAUTIONS TO BE OBSERVED BY SUBJECT BEFORE AND FOLLOWING THE STUDY: None

CIRCUMSTANCES UNDER WHICH YOUR PARTICIPATION MAY BE TERMINATED WITHOUT YOUR CONSENT: (a) Health conditions or other conditions that might occur which may be dangerous or detrimental to you or your health; (b) if military contingency requires it; (c) if you become ineligible for military care as authorized by Army regulation; (d) if the safety monitor determines that continued treatment under this study may be harmful to you.

COSTS TO SUBJECT THAT MAY RESULT FROM PARTICIPATION IN STUDY: In accordance with AR 40-38, paragraph 3-3(j)(2), daily charges for inpatient care will be waived while the volunteer is in the hospital if the volunteer would not normally enter the hospital for treatment but is requested to do so as part of a research study or as a result of adverse reaction to

HUC APPROVED 05OCT11
CONSENT FORM EXPIRES 04OCT12
HUC-Approved Form

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

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the drug(s) or procedure(s) used in this study. This also applies to the volunteer's extension of time in a hospital for a research study when the volunteer is already in the hospital.

SIGNIFICANT NEW FINDINGS: Any significant new findings developed during the course of this study that could affect your willingness to continue participation will be made available to you. The results of the research will be made available to you if you so desire. In some cases complete results may not be known for several years.

APPROXIMATE NUMBER OF SUBJECTS INVOLVED IN THE STUDY: 40

DOMICILIARY CARE STATEMENT: The extent of medical care provided, should it become necessary, is limited and will be within the scope authorized for Department of Defense (DOD) health care beneficiaries. Necessary medical care does not include domiciliary (home or nursing home) care.

FOR FURTHER INFORMATION: For questions about the study, contact the principal investigator:

Denby Fukuda, AUD, C, Audiology Section
Otolaryngology Service
Tripler Army Medical Center
808-433-3198

For questions about your rights as a research participant, contact the Tripler Army Medical Center's Institutional Review Board (which is a group of people who review the research to protect your rights) at (808) 433-6709.

For questions about research related injury, contact the Center Judge Advocate at Tripler Army Medical Center at (808) 433-5311.

HUC APPROVED 05OCT11
CONSENT FORM EXPIRES 04OCT12
HUC Approved Form

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

IF THERE IS ANY PORTION OF THIS EXPLANATION THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. A COPY OF THE VOLUNTEER AGREEMENT AFFIDAVIT WILL BE PROVIDED TO YOU.

******

I have read the above explanation and agree to participate in the investigational study described.

I do [ ] do not [ ] (check one & initial) consent to the inclusion of this form in my outpatient medical treatment record

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (if volunteer is a minor)

PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS	
	SIGNATURE OF WITNESS	DATE

NOT APPLICABLE

(Date) (Printed Name of Individual Obtaining Consent)

(Signature of Individual Obtaining Consent)

Page 5 of DA Form 5303-R, "Direct Scan Earmold Digitization Evaluation"

HUC APPROVED 05OCT11
CONSENT FORM EXPIRES 04OCT12

HUC Approved form

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

16.2 Tripler Report

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

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LANTOS TECHNOLOGIES

Lantos 3D Ear Scanner

Direct Scan Earmold Digitization Evaluation

Interim Clinical Report

Tripler Army Medical Center
1 Jarrett White Rd., TAMC
Honolulu 96859

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

LANTOS TECHNOLOGIES

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

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1.0 Study Information

Indication:	The Lantos 3D Ear Scanner is intended for use by trained hearing professional in a clinical setting on adult patients presenting for inspection of the external ear canal. The Lantos Ear Scanner: • Provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation and; • Includes an expanding conforming membrane which aids observation when inserted in the ear canal and; • Records and presents to the hearing professional in an image file a topology measurement of the external ear canal.
Methods:	A prospective (non-inferiority) 40 patient study.
Sponsor name and address:	Lantos Technologies 101 Main Street, Suite 1760 Cambridge, MA 02142
Regulatory status:	IDE exempt
Study initiation date:	October 31, 2011
Study completion date:	On-going
Investigators:	Principal Investigator Denby Fukuda, Au.D., CCC-A, Chief, Audiology Section Associate Investigator: Leslie J. Peters, PhD., CCC-A/SP. (Contract Audiologist)
Compliance statement:	This study was performed in compliance with Good Clinical Practices (GCP).
Date of report:	March 27, 2012

2.0 Study Synopsis

Title:	Direct Scan Earmold Digitization Evaluation
Investigators:	Principal Investigator Denby Fukuda, Au.D., CCC-A, Chief, Audiology Section

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

	Associate Investigator: Leslie J. Peters, PhD., CCC-A/SP. (Contract Audiologist)
Study Center(s):	Tripler Regional Medical Center 1 Jarrett White Rd., TAMC Honolulu 96859 Tel: (808) 433-3198 Fax: (808) 433-7115
Publication (reference):	None
Study Period:	Study is on-going
Date of First Enrollment:	November 1, 2011
Regulatory Status:	IDE exempt, IRB approved October 6, 2011
Primary Objective	The attenuation found with custom earplugs manufactured from direct ear canal digitization will not differ significantly from custom earplugs manufactured using visible light (Lantos ED Ear Scanner) imagery of an ear mold from the same ear.
Secondary Objective:	Safety – no serious, device related adverse events
Methodology	A prospective (non-inferiority) 40 patient study
Number of Patients	40
Diagnosis and Main Criteria for Inclusion	The study will require 40 normal hearing subjects with no known pathology be evaluated using the two types of custom earplugs. The specific frequency of hearing threshold results will be compared against similar results using each set of manufactured earplugs. Inclusion Criteria : Subject between the ages of 18-60 Subject is fluent in English Subject had satisfactory ear exam
Device Serial Number(s):	One scanner was utilized throughout the study: Alpha Four 40 disposable expanding membranes were used during the study and all were from lot 23.
Criteria for Evaluation:	Efficacy for noise protection devices Safety- absence of device related adverse events
Statistical Methods:	This study will require 40 subjects to achieve a .05 level of significance. This value was derived from the work of Cohen (3). This study will be conducted as a prospective analysis using paired observations of audiometric threshold data using Cohen's Kappa. The degree of agreement among these scores will determine significance. Per Cohen (3), a median effect size with a .05 level of confidence will require 30 subjects. Forty subjects

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	will be recruited to meet the number required and account for subject attrition.
Summary/Conclusions:	Safety endpoint is met, efficacy evaluation is ongoing

3.0 Ethics

3.1. Institutional Review Board

This study was performed in accordance with the principals of the Declaration of Helsinki and in accordance with 21 CFR 50 Protection of Human Patients and 21 CFR 56 Institutional Review Boards.

Prior to initiating this study, the protocol and Informed Consent Form were reviewed and approved by a properly constituted Institutional Review Board (IRB). The Principal Investigator at each site submitted an application to that site's IRB. The Principal Investigator at the site bore complete responsibility for the conduct of the study at that site.

The opinions of the IRB were dated and given in writing. A list of those present at the committee meeting (names and positions) was attached whenever possible.

3.2. Ethical Review

The Investigator was responsible for informing the IRB of any serious adverse events, amendments to the protocol as well as notification of the termination/completion of the study as per local requirements. All correspondence with the committee was maintained by the Investigator.

3.3. Ethical Conduct of the Study

The conduct of the study was audited by the Sponsor for conformance with the GCP guidance E6 released by FDA in April 1996.

4.0 Investigators and Study Administrative Structure

4.1. Investigators

The study was conducted by one Principal investigator and one Associate Investigator at one Investigational Site.

- Principal Investigator: Denby Fukuda, AUD., CCC-A, Chief

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- Associate Investigator: Leslie J. Peters, PhD., CCC-A/SP. Contract Audiologist

4.2. Sponsors Study Personnel

The study was sponsored by the US Department of Defense with the assistance of Lantos Technologies, Inc.

5.0 Introduction

5.1. Device Information

The Lantos 3D Ear Scanner provides a dimensional scan of the ear canal and outer ear, and provides a video otoscope view of the ear canal during insertion. The device is for use by qualified audiologist and hearing aid dispensers with adult patients.

The Ear Mold Impression material was obtained by (b)(4) [redacted] and is made of silicone. The silicone material is intended to obtain a mold of the inner ear for the purposes of developing an ear plug.

5.2. Background

Hearing loss continues as one of the most commonly occurring occupational injuries in the Department of Defense. Many sudden hearing losses and hearing loss due to blast injury become permanent due to a lack of adequate hearing protection in a highly mobile battlefield. Even in peacetime the second most frequent occupational injury for the Armed Services continues to be hearing loss. Earplugs are the basic method of personal protection from hearing loss due to noise damage.

It is well documented that repeated or prolonged exposure to hazardous noise will cause temporary or permanent hearing loss. To prevent hearing loss, hearing protection devices have been provided in many styles. The "one size fits most" ear plugs are the most readily available, but hearing attenuation can be variable, and for many, they are uncomfortable. The only method of insuring maximum comfort and attenuation is a custom earplug. This customized manufacturing process is traditionally a manual process creating low reproducibility and the quality is very operator skill dependent. (b)(4) [redacted] In order to overcome these disadvantages, we propose to combine a variety of available techniques to rapidly produce an inexpensive custom-fit ear plug.

Computer Aided Design and Manufacturing (CAD/CAM) has become available which faithfully produces a three dimensional (3D), digital model of the internal surface of the

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ear and ear canal. (b)(4) [redacted] The process by which this is accomplished is called printing. During this process, a chamber is prepared by either introducing a thin film across a flat pan surface or very fine microscopic particles (print material) are used to coat the pan. With each pass of film or particles, a group of lasers is used to "cook" the print material at intersecting precise points. Multiple passes lead to the creation of a 3 dimensional model (the scanned image) (4).

There are many advantages of having a data model of the ear canal. Digital data can be stored and retrieved at any time, obviating the need for return visits by the patient every time a replacement ear plug is required. Uniformed quality of the manufactured ear plug is ensured.

Data is constantly being transmitted over the internet. Digitized data of the ear canal can be transmitted either as it is obtained or right thereafter for evaluation at the manufacturing facility. This significantly reduces turnaround time and transportation costs. Medics at an aid station with access to the web will be able to submit requests for custom earplugs at any time. These earplugs will be created and shipped within hours of receipt of the digitized impression data. Once a hardwired system is demonstrated, this proposed manufacturing method will allow for custom earplugs to be the norm rather than the exception.

5.3. Prior Studies

There have been no prior studies conducted using the EarScan 3D.

5.4. Trial Design

Using custom earplugs manufactured from digital images created by two specific techniques: direct digitization of an ear mold and direct digitization of an ear canal using visible light (Lantos 3D Ear Scanner). The purpose is to establish whether a significant difference in attenuation can be found from custom earplugs created from these two techniques. Subjects will be volunteers from a military unit. Prior to manufacture, the volume of each earplug data sample will be measured. Next, the subjects will be fitted with earmold digitized earplugs and with earplugs made using direct digitization of the ear canal. Both sets of earplugs will have been CAD/CAM manufactured. A basic puretone audiometric test will be collected for each subject without earplugs at the beginning and end of the test sequence. Then two counterbalanced basic puretone audiometric tests will be conducted (ascending and

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descending, the results will be averaged for each audiometric frequency) for each set of earplugs. Therefore each subject will complete 6 audiometric tests; Baseline Audiometric test (right and left ear), Post Scan Audiometric test (right and left ear) and Efficacy Audiometric test (right and left ear).

5.5. Primary Objective

The attenuation found with custom earplugs manufactured from direct ear canal digitization will not differ significantly from custom earplugs manufactured using visible light imagery of an ear mold from the same ear.

5.6. Secondary Objective

Absence of any device related serious adverse events

5.7. Safety Objectives

The Incidence of Adverse Events will assessed during the direct scan with the Lantos 3D Ear Scanner. Adverse Events will be reviewed during the study in order to analyze the occurrence of complications.

6.0 Study Objectives

The Study objective is to establish whether a significant difference in attenuation can be found from custom earplugs manufactured from digital images created by two specific techniques: traditional ear mold and the Lantos 3D Ear Scanner direct digitization of an ear canal using visible light. Subjects will be volunteers from a military unit. Prior to manufacture, the volume of each earplug data sample will be measured. Next, the subjects will be fitted with earmold digitized earplugs and with earplugs made using direct digitization of the ear canal. Both sets of earplugs will have been CAD/CAM manufactured. A basic puretone audiometric test will be collected for each subject without earplugs at the beginning and end of the test sequence. Then two counterbalanced basic puretone audiometric tests will be conducted (ascending and descending, the results will be averaged for each audiometric frequency) for each set of earplugs. Therefore each subject will complete 6 audiometric tests.

7.0 Study Population

7.1. Inclusion Criteria

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The Inclusion Criteria for the study is listed below:

- Subject between the ages of 18-60
- Subject is fluent in English
- Subject had satisfactory ear exam

7.2. Exclusion Criteria

The Exclusion Criteria for the study is listed below:

- Subject has Ear Infection
- Subject has evidence of a perforated ear drum
- Subject has cognitive delay
- Subject has stenotic ear canal
- Subject has irregular ear canal
- Subject has Osteomas in the ear canal
- Subject is under medication for treatment for the ear

8.0 Study Procedures

8.1. Follow-up

The subjects are required to return to TAMC once the two types of ear plugs have been manufactured. The two types of ear plugs are based on the traditional earmold impression and the EarScan 3D mold.

8.2. Termination

The Subjects participation in this study will be completed when two sets of ear plugs have been manufactured from the EarScan 3D and the traditional Ear mold Impression with audiometric testing performed for each ear plug.

8.3. Withdrawal Criteria

If a patient was withdrawn from the study for any reason, then that patient was assessed up to the time of withdrawal. The reason for early termination was recorded on the patient withdrawal case report form. A patient was withdrawn from the study for any of the following reasons:

- Lost to follow-up
- Patient voluntarily withdrew
- Investigator's withdrew patient

8.4. Data Quality Assurance

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Monitoring of patient enrollment data will be performed as part of the Direct Scan Earmold Digitization Evaluation

8.5. Statistical Methods and Determination of Sample Size

This study will require 40 subjects to achieve a .05 level of significance. This value was derived from the work of Cohen (3). This study will be conducted as a prospective analysis using paired observations of audiometric threshold data using Cohen's Kappa. The degree of agreement among these scores will determine significance. Per Cohen (3), a median effect size with a .05 level of confidence will require 30 subjects. Forty subjects will be recruited to meet the number required and account for subject attrition.

8.6. Changes in the Conduct of the Study or Planned Analysis

An "Ad-Hoc' safety analysis was performed.

9.0 Study Patients

10.0 Protocol Deviations

There were a total of three protocol deviations related to the study protocol and affected all patients. These deviations are listed below:

- The protocol states an equal number of males and females were to be enrolled into the clinical study. There were 28 males and 12 females enrolled into the study. TAMC audiologist determined there would not be a statistical difference audiometrically therefore enrolled subjects as they were presented into the clinic meeting the inclusion/exclusion criteria.
- The protocol indicates subjects will be randomized as defined in the table below:

If Subject # is	Right ear			Left ear		
Odd	Baseline	Direct scan	Earmold scan	Earmold scan	Direct scan	Baseline
Even	Baseline	Earmold scan	Direct scan	Direct scan	Earmold scan	Baseline

The audiologist determined potential clinical implications for subjects receiving earmold impression scans prior to the EarMold 3D Direct scans of the ear canal. The earmold impressions were likely to cause ear canal irritation and/or a hematoma as a result of the pressure formed during the extraction of the earmold impression. In addition, if subjects experienced ear canal irritation

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and/or a hematoma within the ear this would prevent the subject from completing the study using the EarScan 3D.

- The protocol indicates the audiometric frequencies to be tested are 250Hz, 500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz, 6000Hz and 8000Hz. The audiometric frequencies 250Hz and 8000Hz were not done during the course to the study. The standard of care at TAMC does not utilize 250Hz and 8000HZ audiometric frequencies. In addition, the audiologist determined these frequencies are unreliable for testing and re-testing purposes due to the directionality of the 8000Hz and subjects respond to 250Hz as a vibro-tactile even when not heard. Therefore, both of these audiometric frequencies were determined to provide inaccurate data. Lastly, these audiometric frequencies were mistakenly included in the final protocol.

11.0 Efficacy Evaluation

11.1. Data Sets Analyzed

The tables below provide interim analysis of the audio metric data conducted pre and post scans for both the left and right ear.

	BASELINE LEFT EAR					
Patient Number	500	1000	2000	3000	4000	6000
(b) (6) [redacted]	15	15	5	0	5	25
	10	0	5	5	0	25
	0	0	0	5	10	15
	5	10	5	5	5	15
	5	15	20	15	10	35
	10	5	0	0	10	10
	10	15	10	0	20	15
	5	10	10	5	15	10
	10	5	10	15	10	10
	0	5	0	5	5	20
	5	0	0	0	0	10
	0	10	5	5	5	0
	5	5	10	15	15	30
	5	5	15	15	20	5
	25	15	5	15	15	25
	10	10	5	0	15	0
	10	15	10	5	0	10
	0	0	0	0	0	10

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	BASELINE LEFT EAR					
Patient Number	500	1000	2000	3000	4000	6000
(b)(4) [redacted]	5	10	15	10	20	25
	15	10	10	5	0	0
	5	0	5	5	20	20
	0	0	0	0	0	15
	10	0	0	0	10	40
	20	10	10	20	25	30
	5	5	0	0	0	0
	10	5	10	10	10	10
	10	5	5	0	0	0
	10	10	10	5	5	5
	10	10	5	10	10	0
	20	20	15	20	20	10
	0	5	0	0	5	5
	10	15	20	20	20	15
	15	15	15	10	0	0
	5	5	10	10	10	5
	10	5	5	0	0	5
	5	10	15	25	20	20
	15	15	25	20	40	25
	15	10	15	15	15	15
	10	5	0	0	5	10
	5	5	5	15	0	15
Average	8.5	7.875	7.75	7.75	9.875	13.5
Std Dev	5.905235	5.416913	6.499507	7.420519	9.09265	10.45135
Median	10	7.5	5	5	10	10
Min	0	0	0	0	0	0
Max	25	20	25	25	40	40

Table 12-1: Pre-Audiometric Data Left Ear

	BASELINE RIGHT EAR					
Patient Number	500	1000	2000	3000	4000	6000
(b)(4) [redacted]	15	10	5	0	5	20
	5	0	10	5	0	25
	0	5	0	5	5	5
	0	0	5	10	10	5

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	BASELINE RIGHT EAR					
Patient Number	500	1000	2000	3000	4000	6000
(b)(4) [redacted]	5	5	10	10	5	35
	15	5	10	5	5	20
	5	10	10	5	35	15
	5	5	5	0	15	50
	5	15	10	10	5	10
	0	0	0	0	5	15
	5	5	0	0	5	5
	5	10	20	10	5	5
	5	10	5	10	5	30
	10	10	20	30	15	15
	20	15	10	15	15	10
	10	5	5	0	0	10
	10	5	0	0	5	0
	0	0	0	5	20	10
	5	10	10	5	15	10
	20	10	15	0	5	5
	5	0	0	10	15	10
	5	0	10	0	0	35
	5	5	0	5	0	10
	15	10	10	10	15	5
	5	5	5	5	5	5
	10	5	10	10	5	10
	10	10	5	0	0	0
	10	10	5	0	5	10
	10	10	5	10	10	0
	15	15	15	15	10	15
	10	0	5	5	5	0
	15	10	10	15	10	5
	15	15	15	10	5	0
	5	5	5	5	5	5
	10	5	0	5	10	10
	5	0	5	10	15	15
	15	15	10	20	25	30
	15	10	5	10	40	20
	10	0	0	0	0	10
	5	5	10	15	5	10

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	BASELINE RIGHT EAR					
Patient Number	**500**	**1000**	**2000**	**3000**	**4000**	**6000**
Average	8.5	6.75	7	7.125	9.125	12.625
Std Dev	5.334936	4.876684	5.406549	6.49334	8.835208	11.03535
Median	7.5	5	5	5	5	10
Min	0	0	0	0	0	0
Max	20	15	20	30	40	50

Table 12-2: Pre Audiometric Data Right Ear

	POST LEFT EAR					
Patient Number	**500**	**1000**	**2000**	**3000**	**4000**	**6000**
(b)(4) [redacted]	15	15	0	0	0	25
	10	5	10	10	0	0
	0	0	5	0	15	20
	5	10	5	10	5	15
	0	10	20	5	15	20
	15	0	5	10	10	20
	5	10	5	0	20	15
	5	5	5	0	15	10
	5	5	5	10	5	5
	0	0	0	10	5	15
	0	0	0	0	0	20
	0	5	0	5	5	0
	0	5	10	15	20	25
	10	5	10	15	10	10
	25	15	5	15	20	25
	5	0	0	0	0	0
	5	10	5	0	0	5
	0	0	0	0	0	10
	5	5	10	10	5	10
	10	10	10	5	0	0
	5	5	5	10	15	15
	0	0	5	0	0	15
	10	10	5	5	5	0
	15	15	10	15	15	25
	5	5	5	0	0	0
	5	5	0	0	5	5
	5	5	5	0	0	0

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LANTOS TECHNOLOGIES

	POST LEFT EAR					
Patient Number	500	1000	2000	3000	4000	6000
(b)(4) [redacted]	10	10	10	5	5	10
	5	5	5	10	10	0
	20	20	15	15	20	10
	0	0	0	0	5	5
	10	15	20	15	20	10
	15	15	15	10	5	5
	5	5	10	10	10	5
	5	0	0	0	5	15
	5	5	15	25	20	10
	15	10	20	20	30	25
	15	10	10	15	15	10
	10	10	0	0	0	10
	5	0	5	10	5	5
Average	7.125	6.625	6.75	7.125	8.5	10.75
Std Dev	6.08566	5.357418	5.834249	6.783039	7.942098	8.208032
Median	5	5	5	7.5	5	10
Min	0	0	0	0	0	0
Max	25	20	20	25	30	25

Table 12-3: Post EarScan 3D and Ear Mold Impression Audiometric Left Ear

	POST RIGHT EAR					
Patient Number	500	1000	2000	3000	4000	6000
(b)(4) [redacted]	10	15	0	0	0	15
	10	5	10	10	5	0
	0	0	0	0	10	10
	5	5	5	10	5	0
	5	10	0	10	15	30
	15	5	10	0	10	20
	10	5	15	10	25	20
	5	5	5	5	25	40
	5	5	5	5	5	10
	0	0	0	0	5	10
	10	5	0	0	0	5
	10	5	30	10	5	5

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	POST RIGHT EAR					
Patient Number	500	1000	2000	3000	4000	6000
(b)(4) [redacted]	5	10	0	5	10	20
	10	5	20	30	15	5
	15	15	5	15	10	5
	5	5	5	0	0	5
	5	5	0	0	0	5
	0	0	0	5	20	10
	5	5	10	10	10	10
	15	10	5	0	0	0
	5	0	0	10	5	10
	0	0	5	0	0	20
	10	10	5	5	10	10
	15	15	5	10	10	0
	0	0	5	0	5	5
	5	0	0	10	5	20
	0	0	0	0	0	5
	10	10	10	5	5	10
	5	10	5	10	10	0
	15	15	15	15	10	15
	5	0	5	5	5	0
	10	10	10	10	10	0
	10	10	15	15	5	5
	5	5	5	5	5	5
	0	0	0	0	0	15
	5	0	10	10	15	5
	10	10	15	20	35	30
	10	10	10	10	10	5
	10	0	5	10	0	10
	5	0	5	10	10	5
Average	7	5.625	6.375	7.125	8.25	10
Std Dev	4.640955	4.959774	6.503204	6.49334	7.72525	9.198662
Median	5	5	5	7.5	5	7.5
Min	0	0	0	0	0	0
Max	15	15	30	30	35	40

Table 12-4: Post EarScan 3D and Ear Mold Impression Audiometric Right Ear

11.2. Demographic and Other Baseline Characteristics

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The Table 12-1 below presents demographic for during the Direct Scan EarMold Evaluation Study.

	Patients (N=40)
Age (years)	
N	40
Mean	33.5
Median	31
Standard Deviation	40
Min	22
Max	59
Sex	
Male	28
Female	12

Table 12-5: Demographics

12.0 Overall Discussion and Conclusion

This is an interim report of the secondary endpoint for the study. No adverse events were noted in either arm of the study, thus the secondary safety endpoint was met.

Audiometric results showed no significant differences in pre-and post data, however the analysis of the audiometric tests is pending final follow up and testing. This data will be presented in the final report.

It is concluded in this interim report that as no adverse events were noted, the device (Lantos 3D Ear Scanner) may be considered as safe when used in accordance with the manufacturer's instructions and the requirements of the protocol.

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16.3 South Shore Hearing Center Protocol – User Preference Study

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Lantos EarScan 3D User Preference Study

Date Issued: November 26, 2011

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PROTOCOL SYNOPSIS	
Title	**Lantos EarScan 3D User Preference Study Protocol**
Objectives	The objective of this clinical study is to assess the Lantos Digital EarScan 3D device features, device operation, and operator experience.
Study Sponsor	Lantos Technologies 101 Main Street, Suite 1760 Cambridge, MA 02142
Protocol number	**2011.1 Revision 3**
Study Device	The Lantos EarScan 3D provides a dimensional scan of the ear canal and outer ear, and provides a video otoscope view of the ear canal during insertion.
Primary Endpoint	• With training, operators are able to complete digital scans in the same or less time than traditional silicone earmold impressions. • Operators rate the digital scan experience equal or better than that for earmold impressions.
Secondary Endpoint	• Observations and records of use, which may lead to device improvements.
Study Design	Single-Center, prospective, non-randomized user preference study.
Study Center:	South Shore Hearing Center David Citron, III, Ph.D., FAAA dcitron@sshc.com Stetson Medical Center 541 Main Street, Suite 418 South Weymouth, Massachusetts, 02190 Phone: (781) 337-6860
Number of Patients	Up to 25 patients will be enrolled
Eligibility Criteria	*Inclusion:* • Patient presenting for silicone earmold impression • Satisfactory ear exam prior to use of Lantos EarScan 3D • Patient must be 21 – 95 years of age *Exclusion:* • Patients under the age of 21 • Patients with cognitive delay

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	• Patients with existing ear infection • Patients with evidence of perforation of ear drum • Patients with a stenotic ear canal • Patients with an irregular ear canal (e.g. exostoses) • Patients with osteomas in the ear canal • Any patient on medication for a condition of the ear.
Study Protocol	The purpose of this study is to assist the company designing a novel digital scanning method intended to replace and enhance the traditional silicone earmold impression. Device features, device operation, and operator experience will be evaluated to improve the design of the device prior to production and marketing.

Data Evaluation	For the purposes of this study, the final interpretation of each scan will be expressed as follows:
	• Perform qualitative assessments of scan data, including
	  o Extent of scanned surface and
	  o Length of scan time
	• Obtain qualitative answers to interview questions regarding scan experience from operator, including
	  o Comparisons to traditional silicone earmold impressions.
	  o Record suggestions for improvement of device or process.

Data Analysis	Data analysis will be completed with a compilation of the inputs from the questionnaire at the end of the protocol. A table of results will be complied and used for design input for further product improvements.
Acceptance Criteria	N/A – this is a usability study in a non-significant risk device
Reporting	Results comparing the Lantos EarScan 3D scan experience versus taking Silicone earmold impressions will be presented.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

1.0 Introduction and Background

This study is being conducted on late stage device prototypes, which have been subject to the manufacturer's in house testing. Materials used are known to be biocompatible. Safety of materials and instrument operation have been assessed by physicians and independent persons.

2.0 Study Device

Please refer to the Instructions for Use, Attachment B.

3.0 Ethical and Legal Considerations

3.1. Informed Consent

Patient's informed consent (Attachment A) will be obtained and documented according to the principles of informed consent in the current version of the 21CFR50 (Protection of Human Subjects), Declaration of Helsinki and the International Conference on Harmonization Guideline for Good Clinical Practice (ICH-GCP).

Prior to obtaining informed consent, information will be given in a language and at a level of complexity understandable to the subject in both oral and written form by the investigator or designee. Patients should not be coerced, persuaded, or unduly influenced to participate or remain in the trial. A patient must be given ample time and opportunity to inquire about details of the trial and all questions about the trial should be answered to the satisfaction of the patient.

Prior to the participation in the trial, the written informed consent form should be signed and personally dated by the patient, and by the person who conducted the informed consent discussion (investigator or designee). If the patient is unable to read the consent form, a witness should be present during the entire informed consent discussion. After the informed consent form is read to the patient and signed by the subject, the witness should also sign the consent form, attesting the patient freely gave that informed consent.

All patients should be informed of the side effects and risks of the procedure before undergoing any study related assessments or procedures. The background of the proposed study, and the risks and benefits of the procedures and study will be explained to the patient.

The patient must sign the consent form prior to screening. This form or a modification based on local Ethics Committee recommendations must be completed by all screened patients and signed by the investigator. All patients who agree to participate must sign the informed consent form before undergoing any study related procedures.

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3.2. Notification/Submission to Regulatory Authority(ies)

The investigator will assure that an appropriately constituted Institutional Review Board (IRB) complies with the requirements of the International Conference on Harmonization Guidelines. Prior to initiation of the study, the investigator will forward copies of the protocol, informed consent form and all other appendices to be used for the study to the IRB for its review and approval. A copy of the approval from the IRB plus other regulatory documents must be forwarded to the sponsor or their designee, before any investigational supplies can be shipped to the investigator.

3.3. Local Regulations and Declaration of Helsinki

The investigator will ensure that this study is conducted in full conformance with 21CFR50 (Protection of Human Subjects), the principles of the "Declaration of Helsinki" (as amended in Japan, Italy, Hong Kong, South Africa, Scotland, USA and Japan 2004) or with the laws and regulations of the country in which the research is conducted, whichever affords the greater protection to the individual. The study must fully adhere to all applicable local regulatory requirements.

3.4. Patient Privacy – Confidentiality – Data Security

The investigator will assure that subjects' anonymity will be maintained and that their identities are protected from unauthorized parties.

The purpose of the study is to seek opinions from clinicians about the usability of the device and its accessories. The data collected will be that in the Study Questionnaire included as Appendix C. No subject identifying information or protected health information will be included in or linked to the data collected. Access to the data collected will be limited to the investigators and research staff. Data security awareness is promoted through training and education, supplemented by policies and procedures.

The Principal Investigator and the site investigator will collect Informed Consent Forms from the subjects. Those Forms will not be seen by the sponsor or research staff, and will not be linked to the data collected via the Study Questionnaires.

3.5. Data Monitoring

Prior to beginning the study, a monitor will contact the investigator to discuss the investigational plan and review the data requirements in detail. A clinical study monitor will visit the investigator periodically during the study to monitor progress, to assist in gathering the required data and answer any questions. Clinical monitors will ensure auditing of the investigational site. During these visits, the program monitor may review the predicate device records to verify that records from the Investigational Device and files are correct, and to assure compliance with all requirements of the protocol and FDA regulations. The investigator will make the predicate device and study records available to the clinical monitor for periodic inspection.

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3.6. Study Quality Assurance

The Sponsor has a Quality Assurance designee for this study. The Quality Assurance designee will provide assurance that all regulatory requirements have been met.

4.0 Study Objectives

The Study objective is to evaluate the hearing healthcare clinician's satisfaction with the Lantos EarScan 3D. Lantos representatives will describe the intended use and technical characteristics of the Lantos EarScan 3D device and provide training as to device use. Lantos representatives will observe and record use by trained operators when scanning patients in clinical settings, and will perform qualitative assessments of scan data, including extent of scanned surface and scan time. Users will provide qualitative answers to interview questions regarding scan experience, including comparisons to traditional silicone earmold impressions, and will document suggestions for improvement of the device or process.

5.0 Study Design

This is a single center, open labeled, prospective, non-randomized clinical trial designed to assess the Lantos EarScan 3D.

5.1. Primary Endpoint

The primary endpoint will be:

- With training, operators are able to complete digital scans in the same or less time than taking traditional silicone earmold impressions.
- Operators rate the digital scan experience equal or better than that for earmold impressions.

5.2. Secondary Endpoints

The secondary endpoint will be:

- Observations and records of use, which may lead to device improvements.

6.0 Study Population

6.1. Number of Patients

Up to 25 patients will be enrolled at a single center.

6.2. Inclusion criteria

- Patient presenting for silicone earmold impression
- Satisfactory ear exam prior to use of Lantos EarScan 3D
- Patient must be 21 – 95 years of age

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6.3. Exclusion criteria

- Patients under the age of 21
- Patients with cognitive delay
- Patients with existing ear infection
- Patients with evidence of perforation of ear drum
- Patients with a stenotic ear canal
- Patients with an irregular ear canal (e.g. exostoses)
- Patients with osteomas in the ear canal
- Any patient on medication for a condition of the ear.

7.0 Study Procedures and Methodology

For each subject presenting for a silicone ear mold impression for assessment and fit of a hearing aid or other ear-level device, the audiologist will examine the ear canals to assure they are healthy enough for the traditional silicone impression process. The audiologist will insert a probe covered by a flexible silicone membrane into the subject's ear canal, visually guided by a camera with a lens at the probe tip that provides a wide view of the canal. When the probe is properly situated, the audiologist will expand the membrane with a liquid absorbing fluid (water with a trace colorant) until it touches the walls of the subject's ear canal. The mild pressure applied to the ear canal by the membrane will be less than 40 cmH2O. The audiologist will withdraw the probe through the canal, and then direct the probe tip around the concha bowl of the outer ear, to collect the digital scan data. The audiologist will withdraw the fluid, the membrane will collapse, and the probe and membrane will be pulled from the ear. During the insertion and scanning steps, the inside of the membrane will be illuminated with visible light of varying wavelength; small amounts of light may be visible through the membrane.

For each subject, at the audiologist's discretion, the digital scan process may be repeated for the subject's other ear.

Prior to or following the digital scan(s), the audiologist may take one or more traditional silicone ear mold impressions of the subject's ears, which may be used to design and shape the hearing aid or other ear-level device. The silicone ear mold impression is not a part of this study and will be performed using the appropriate standard of care.

8.0 Risks

8.1. Risks Associated with Investigational Device

Properly following this protocol and the inclusion/exclusion criteria are essential to mitigate risks associated with the Investigational Device. The device and accessories are comprised of medical grade materials, commonly approved for use in contact with skin. In vitro testing by the materials suppliers provides reasonable assurance of biocompatibility in humans.

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The risks associated with the use of the investigational device are similar to those using silicone ear mold impression material. These include possible abrasion and irritation, and exacerbation of any pre-existing condition such as an already infected ear, perforated eardrum, stenotic ear canal, exostoses, or osteomas. These are exclusion criteria in this protocol, but could be overlooked in the pre-procedure ear exam. None of these conditions or risks would be reasonably expected to result in a permanent injury and would be reversible via standard treatment for such conditions.

Additional risks are related to any possible failure of the device membrane; in the event of failure fluid could leak into the outer ear. There are no anticipated adverse effects associated with such leakage, provided a proper ear exam is performed and all of the inclusion and exclusion criteria are met. In the event of leakage with an already infected ear, perforated eardrum, stenotic ear canal, exostoses, or osteomas, there is a risk of inflammation or similar immune response. None of the anticipated risks would reasonably be expected to be irreversible and can be treated in the same manner as if they occurred with a silicone ear mold material, using conventional treatment methods.

The rates of occurrence of these risks are not well documented in the clinical literature, but are generally known to clinical professionals and to the investigator in this study.

Other risks related to the investigational device relate to misuse, failure to follow the instructions for use, (e.g. excessive pressure, misplacement, excessive force in use) which can result in an exacerbation of an existing condition, and/or create an inflammatory response, minor bleeding, and if untreated, infection.

9.0 Adverse Events & Safety Monitoring

All adverse events (AE) must be recorded regardless of casual relationship. All AEs must be followed until resolved or otherwise explained by the principal investigator.

To allow a standardized safety evaluation across centers and studies, assessment of the seriousness, intensity, outcome and causality of the AEs, should be undertaken by the Investigator using the CTCAE v3.0 criteria.

10.0 Study Termination

Any unexpected, serious adverse event using the device will be a cause for early study termination.

11.0 Patient Withdrawal

Patients may be withdrawn from the study by the investigator or terminate their participation prematurely based on the following:

- Post-consent determination of ineligibility based on safety or eligibility criteria
- Clinician's judgment following an Adverse Event
- Termination by the sponsor or a regulatory authority
- Any other reason for withdrawal that the study clinician or patient indicates is in the overall best interest of the patient

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Patients who withdraw consent prior to receiving any therapy will be withdrawn from the study and no follow-up safety surveillance is required.

Patients who voluntarily withhold consent or who are withdrawn by the study clinician for any reason after being scanned will be followed-up for at least 7 days. The purpose of this follow-up is to capture all adverse events and document any serious, procedure related adverse events.

12.0 Study Completion

The study will be considered completed when:

- Patients have completed the Lantos EarScan 3D scan.

13.0 Data Analysis and Statistical Considerations

Not applicable, this is a user preference study.

14.0 Populations for Analysis

Healthy Adult subjects meeting all inclusion and exclusion criteria.

15.0 Patient Demographics/Other Baseline Characteristics

N/A

16.0 Treatments (study treatments and concomitant medications)

N/A

17.0 Efficacy Analysis

N/A

18.0 Primary Endpoint

Primary endpoint will be assessed by a qualitative review of all questionnaires. Standard statistical methods will be used to compare responses.

19.0 Secondary Efficacy Endpoints

Secondary endpoint will be assessed by a qualitative review of all questionnaires. Standard statistical methods will be used to compare responses by different users.

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Attachment A – Informed Consent – Subject

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

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Informed Consent Statement

Study Name: Lantos EarScan 3D User Preference Study

Study Sponsor: Lantos Technologies

Principal Investigator: David Citron III, Ph.D. FAAA

South Shore Hearing Center
Stetson Medical Center
541 Main Street, Suite 418
South Weymouth, Massachusetts, 02190
Phone: (781) 337-6860 <dcitron@sshc.com>

Study Purpose:

You are being asked to participate in this research study to compare the Lantos EarScan 3D and the silicone earmold Impression. Both are intended to assess the shape of your ear canal, however the Lantos EarScan 3D has not been cleared by the US Food and Drug Administration. The study will assess the Lantos EarScan 3D device features, device operation, and operator experience. Use of the silicone earmold impression is not a part of this study.

Study Procedures:

Your ear canals will be examined to assure they are healthy enough for a traditional silicone earmold impression, and that there are no infections or other conditions that would make you ineligible for the study. The study doctor will insert a probe covered by a membrane into your ear canal, visually guided by a camera with a lens at the probe tip that provides a wide view of the canal. When the probe is properly situated, the study doctor will expand the membrane with water until it touches the walls of your ear canal. The pressure you will feel will be less than that you would experience lowering your head one foot below the surface of a swimming pool. The study doctor will withdraw the probe through the canal, and then direct the probe tip around the concha bowl of your outer ear, to collect the digital scan data. The water will be withdrawn, the membrane will collapse, and the probe and membrane will be pulled from your ear. During the insertion and scanning steps, the inside of the membrane will be illuminated with visible light of varying wavelength; small amounts of light may be visible through the membrane. If the study doctor chooses, the digital scan process may be repeated in your second ear.

Before or after the digital scans, the study doctor may take a traditional silicone earmold impression, which may be used to design and shape your hearing aid or other ear-level device. The silicone earmold impression is not a part of this study and would be performed using the appropriate standard of care.

The expected time added to your visit for the research study will be approximately fifteen minutes. A representative of the study sponsor may be present during this time to observe the device use.

What is Experimental:

The measurement of the shape of the ear canal by the Lantos EarScan 3D is experimental, including the guided insertion, the membrane expansion, the scan, and the withdrawal.

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

Risks:

The risks associated with the use of the investigational device are similar to the risks from using silicone ear mold impression material. These include possible abrasion and irritation, irritation from fluid leakage in the outer ear, and exacerbation of pre-existing conditions such as an already infected ear, perforated eardrum, stenotic ear canal, exostoses, or osteomas.

The study doctor will examine your ear for any of these conditions, and exclude you from the study if any are found. You must inform the study doctor if you have any problems with your ears or are taking any medications. None of these risks would be reasonably expected to result in a permanent injury and would be reversible via standard treatment for such conditions.

Benefits:

There is no benefit to you in your treatment for participating in this study.

Alternatives:

There are no alternative procedures. Any measurements made for fitting a hearing aid or other ear-level device will not be a part of this study and will be done using standard methods by your clinician.

Voluntary Participation:

Taking part in this study is entirely voluntary. If you decide not to participate in this research study, the decision will not affect your medical care. You can still have the silicone earmold Impression and not be a part of this study.

The Investigator, Sponsor, New England IRB or the FDA can stop this study at any time.

Confidentiality:

If you participate, only the Investigator, the research coordinator and the employees of the organizations listed below will have access to the information collected in this study. Personal information that could identify you will not be released without your written consent. Every effort will be made to keep your personal information confidential. The results of this research may be presented at scientific, medical meetings or published in scientific journals. In this case, your identity will not be made known.

Qualified representative of the following organizations will have access to information collected in this study for data analysis and quality assurance:

- South Shore Hearing Center
- New England Institutional Review Board (IRB) may review your medical records relating to this study as part of their normal duties in protecting human research subjects, and results of the study will be reported to them. The recipients will treat this information confidentially, and in the event of publication regarding this study, your identity will not be disclosed.
- This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA). A HIPAA Release Authorization form for this study will be provided to you separately, and you will be asked to sign that form.
- Lantos Technologies: The manufacturer of the Lantos EarScan 3D device and the study sponsor
- US Food and Drug Administration (FDA): Office of Human Research Protection (OHRP) or other regulatory agencies as necessary.

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Financial Information

You or your insurance company will be responsible for payment for the silicone earmold impression, and all other medical care that would normally be part of the treatment of your condition. The study sponsor will pay costs for tests that are specific to the study and not part of your routine care; this includes the Lantos EarScan 3D scan.

In the case of illness or injury resulting from this study, medical treatment will be made available to you at your own or your insurer's expense. You will not receive injury compensation.

Compensation

You will receive $200.00 for participation in this study.

Subject's Rights:

Your participation in this study is voluntary and you are free to withdraw at any time. Choosing not to participate or withdrawing from this study will not affect your present or future medical treatment to which you are otherwise entitled. You will be told in a timely manner about new information that may affect your health, welfare, or willingness to stay in this study.

Contact person:

If you have any questions about this study, or you suffer a research-related injury, you may talk to:

Dr. David Citron
South Shore Hearing Center
Stetson Medical Center
541 Main Street, Suite 418
South Weymouth, MA 02190
781-337-6860

In case of emergency, Dr. Citron can be reached through Tel: 617-216-6860.

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

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VOLUNTEER'S STATEMENT:

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. I may contact David Citron if I have any more questions about taking part in this study. The study doctor is not being paid by the sponsor for this study.

I understand that my participation in this research project is voluntary. I know that I may quit the study at any time without harming my future medical care or losing any benefits to which I might be entitled. I also understand that the investigator in charge of this study may decide at any time that I should no longer participate in this study.

If I have any questions about my rights as a research subject in this study I may contact:

New England Institutional Review Board
Telephone: 1-800-232-9570

By signing this form, I have not waived any of my legal rights.

I have read and understand the above information. I agree to participate in this study. I understand that I will be given a copy of this signed and dated form for my own records.

_____ _____
Study Participant (signature) Date

_____
Print Participant's Name

_____ _____
Person who explained this study (signature) Date

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

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Attachment B – Instructions for Use

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

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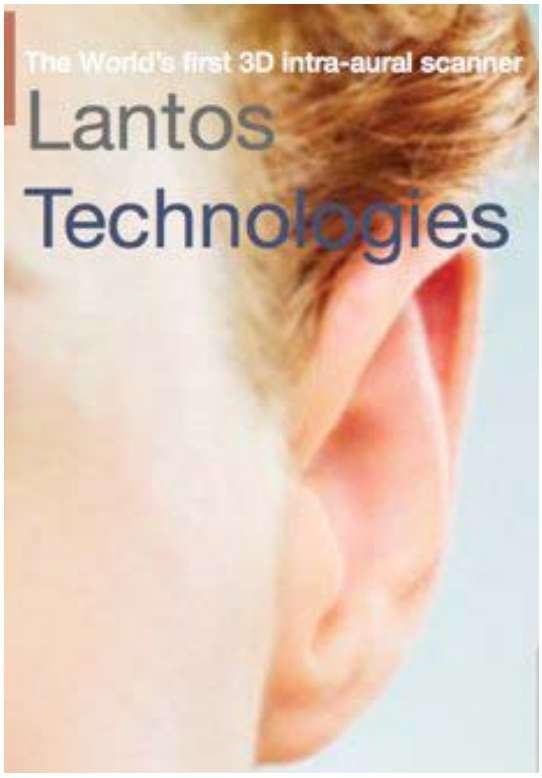
Lantos EarScan 3D

Instructions for Use

--- PRELIMINARY ---



Indications for Use include:

- the EarScan 3D provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation
- the EarScan 3D includes an expanding conforming membrane which aids observation when inserted in the ear canal
- the EarScan 3D records the ear topology for use in the design and manufacturing of devices inserted in the ear, including hearing aid shells

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

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Please read these Instructions for Use thoroughly before using the **Lantos EarScan 3D**. If you have questions please contact your Lantos Technologies support representative.
<support@lantostechnologies.com>

Pending Qualifications:

ETL listed:
UL2601-1, CSA C22.2 No. 601.1,
IEC 60601-1, AS 3200.1.
IEC 60601-1-2

Symbols

Consult operator's manual for important information

Type BF

IPXØ Not protected against the ingress of water

Safety & Warnings

DO NOT USE IN THE PRESENCE OF FLAMABLE ANESTHETICS

- Do not connect the EarScan 3D to devices other than as expressly described in these Instructions
- Do not use this device for any purpose other than specified in these Instructions
- Discontinue use of the device is you notice any signs of damage to the components – contact Lantos Technologies support for service – no user serviceable components

DISCONNECT THE LAPTOP COMPUTER POWER SUPPLY BEFORE SCANNING

THE MEMBRANE, CASSETTE, RESERVOIR AND MEDIUM ARE FOR SINGLE PATIENT USE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

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Setup

1. Charge the Laptop computer – disconnect the Laptop power supply
2. Connect the Scanner to the Laptop computer at the FireWire port – start up the Laptop
3. Start the **EarScan 3D** software by clicking on the icon

Introduction

The **Lantos EarScan 3D** provides a dimensional scan of the ear canal and outer ear, and provides a video otoscope view of the ear canal during insertion. The device is for use by qualified audiologists and hearing aid dispensers with adult patients.

Usage includes:

- Examination of the visual anatomy of the ear canal and tympanic membrane
- Obtaining a dimensional scan of the ear for design of a close-fitting hearing aid shell
- Obtaining a dimensional scan of the ear for design of a hearing protection device or custom earbud

The **EarScan 3D** should not be used for other purposes.

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

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Parts of the EarScan 3D

- Laptop
- Scanner
- Conforming Membrane and Valve Cassette
- Fluid Reservoir and Absorbing Medium

Laptop Computer

Description and Use:

The operator interacts with the EarScan 3D using the keyboard and touchpad; the LCD panel presents a series of User Interface screens. A battery subsystem supplies DC Power to the Laptop and the Scanner.

Scanner

Description and Use:

The operator places a conforming membrane and valve cassette over the extended tip of the Scanner, and then inserts the combination in the ear with a video otoscope view through a clear window in the tip of the conforming membrane. After expanding the membrane with fluid (following section) the operator pulls back on the Scanner to obtain a 3D image of the ear canal.

Proprietary and Confidential
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

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Conforming Membrane and Valve Cassette

Description and Use:

The Conforming Membrane (CM) covers the Scanner probe tip, and expands to conform to the inner surface of the ear canal and outer ear. The inside of the membrane contains a dye that returns an image when illuminated with visible violet light. The tip of the conforming membrane has a clear window of the same approximate size at the probe tip. Through the window the operator can see the ear canal during insertion – a mode of operation equivalent to currently marketed video otoscopes with clear patient isolation sheaths.

The extended probe tip pushes through the valve cassette into the conforming membrane, which is held in a fixed attachment to the cassette. The valves seal the liquid inside and maintain the liquid pressure during expansion.

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

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Fluid Reservoir and Absorbing Medium

Description and Use:

The absorbing medium contains a dilute amount of approved ingestible coloring in distilled water. A reservoir of the medium is held in a compressible bulb behind a releasable one-way valve, connected via a small silicone tube to the valve cassette. When the operator compresses the reservoir bulb, the absorbing medium flows into the conforming membrane, pressing the membrane against the ear canal wall. When the operator releases the one-way valve, the medium returns to the reservoir, allowing easy extraction of the collapsed membrane from the ear.

THE MEMBRANE, CASSETTE, RESERVOIR AND MEDIUM ARE FOR SINGLE PATIENT USE

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

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Instructions for use - Scanning

Scanning procedure overview

- Preparation
- Scanning
- Removal

Preparation

1. Push scanner probe all the way into the disposable until seated
2. Align clear window at tip of CM with tip of probe – confirm visually
3. Apply OtoEase (or equivalent) to sides of CM, avoiding clear window.

4. Turn on scanner, dip tip of device into distilled water to clear visual field

⚠ DISCONNECT THE LAPTOP COMPUTER POWER SUPPLY BEFORE SCANNING

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

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Scanning

1. Insert probe to desired scan depth. The following image shows a representative tympanic membrane at a distance of approximately 5 mm, as seen through the Scanner in Otoscope mode.

2. Squeeze fluid reservoir bulb until conformal membrane inflation is externally visible.

3. Scan ear canal scan by slowly extracting Scanner probe tip along centerline of canal – Scan concha bowl by manipulating CM and aiming probe tip at sections of the concha until desired coverage is obtained. Refer to Lantos Technologies training aids.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

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Removal

1. Squeeze bulb neck to release fluid from CM.

2. Remove CM and probe from ear.

If desired, repeat the Preparation, Scanning, and Removal process for the patient's other ear.

⚠ THE MEMBRANE, CASSETTE, RESERVOIR AND MEDIUM ARE FOR SINGLE PATIENT USE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8178

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Specifications

Environment

Operating Conditions
10° C to 40° C
30% to 80% R.H.
500hPa to 1060hPa Altitude

Internally powered device when in use.
Laptop charger AC 100-240V 50/60 Hz

Cleaning and Storage

The EarScan 3D Scanner and Laptop can be cleaned with a cloth dampened with warm water or a non-staining disinfectant. Avoid liquid pooling or dripping – neither the Scanner nor the Laptop is watertight.

Store device components in a dry, temperature controlled environment. Avoid extremes in temperature or humidity.

Replacement

Contact Lantos Technologies support for replacement parts or additional disposable parts.

<support@lantostechnologies.com>

Lantos Technologies

101 Rogers St, Suite 213
Cambridge, MA 02142

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

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Attachment C – Study Questionnaire

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

User ID				**Date Completed**	
EarScan 3D Serial Number			**User Guide Version Preliminary (23 Aug 2011)**		

Instructions: After completing the training required to participate in this study please complete the questionnaire by answering the questions with a circle or check mark in the following sections based on your experience with the Lantos EarScan 3D.

Record the length of time in Video Otoscope Mode (Insertion Time - minutes)	Data obtained from device software: _____
Record length of time in scan mode (minutes)	Data obtained from device software: _____

Assess the ease of setup of the instrument	**Very Difficult**	**Difficult**	**No Opinion**	**Easy**	**Very Easy**
Assess the ease of use of the instrument	**Very Difficult**	**Difficult**	**No Opinion**	**Easy**	**Very Easy**
Assess the time to complete a digital scan as compared to your taking a conventional silicone ear mold.	**Much Slower**	**Slower**	**About the Same**	**Faster**	**Much Faster**
Assess your experience taking digital scan as compared to taking a conventional silicone ear impression	**Much Worse**	**Worse**	**About the Same**	**Better**	**Much Better**
Assess the patient experience undergoing a digital scan as compared to a conventional silicone ear impressions	**Much Worse**	**Worse**	**About the Same**	**Better**	**Much Better**
Assess the video otoscope images provided by the EarScan 3D with the image quality of other otcoscopes you have used, either video or conventional	**Much Worse**	**Worse**	**About the Same**	**Better**	**Much Better**
Assess your ease or difficulty obtaining a complete scan of the ear canal and outer ear with the digital scan process	**Very Difficult**	**Difficult**	**No Opinion**	**Easy**	**Very Easy**

What three things would you change about the device or the process to improve your experience, the patient experience, or results?	**1.**
	2.
	3.

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

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Were there any adverse events or outcomes in your use of the device?	**Yes** ☐	**No** ☐

If you experienced an Adverse Event or other outcomes in your use of the device complete the following section:

List the Event	**Intensity/ SWOG Grade** 1=Mild 2=Moderate 3=Severe 4=Life-Threatening	**Treatment** 1=None 2=Began Medication 3=Hospitalization/ 4=Other	**Outcome** 1=Completely recovered 2=Not yet completely recovered, condition improved 3=Deterioration 4=Permanent Damage 5=Death 6=Ongoing 7=Unknown	**Date of Outcome (mm/dd/yy)**	**Related To Study Device** 1=Not Assessable 2=Not Related 3=Unlikely 4=Possible 5=Probable 6=Highly probable
1.					
2.					
3.					
Please provide any additional comments about your experience with the EarScan 3D:					

User Signature Date

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

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NEIRB
New England Institutional Review Board

December 1, 2011

Douglas Johnston
Lantos Technologies, Inc.
101 Main Street Suite 1760
Cambridge, MA 02412

RE: **NEIRB** #11-333: 2011.1 Revision 3: "Lantos EarScan 3D User Preference Study Protocol" dated November 26, 2011

Dear Mr. Johnston:

This is to inform you that New England Institutional Review Board (NEIRB), via expedited review (Thursday Board) has reviewed the above-referenced research protocol and informed consents.

Investigators intending to submit to NEIRB must submit a study submission package to NEIRB and receive approval prior to initiating any protocol procedures.

The approval period will begin upon approval of the first investigative site and will end on 10/24/2012. Your study number is 11-333. Please be sure to reference this number in any correspondence with NEIRB.

Approval will be conditional upon your compliance with the following requirements:

- A copy of the **Investigator Informed Consent,** NEIRB version 1.0, approved on 12/1/2011 is enclosed. Only NEIRB-approved informed consent documents should be used.
- A copy of the **Subject Informed Consent Template** is enclosed.
- The following must be promptly reported to NEIRB: changes to the study site and all unanticipated problems that may involve risks or affect the safety or welfare of subjects or others, or that may affect the integrity of the research.
- Approval is valid for enrollment of the number of subjects indicated on your submission form. If you anticipate enrolling more than this number of subjects, NEIRB approval must be obtained prior to exceeding the approved enrollment number.
- All protocol amendments and changes to approved research must be submitted to the IRB and not be implemented until approved by the IRB except where necessary to eliminate apparent immediate hazards to the study subjects.
- Compliance with all federal and state laws pertaining to this research, and with NEIRB's SOPs.
- Advertisements, letters, internet postings, and any other media for subject recruitment must be submitted to NEIRB and approved prior to use. Please refer to *NEIRB Guidelines for Recruitment and Advertising*, available at www.neirb.com.
- All deaths, life-threatening problems, or serious or unexpected adverse events, *whether related to the study article or not*, must be reported to the IRB. The Serious Adverse Event Form is available at www.neirb.com.
- Any and all necessary FDA approvals must be received prior to your initiation of the trial. If this study is being conducted under an IDE, a copy of the FDA IDE approval letter must be submitted to NEIRB.

Association for the Accreditation of Human Research Protection Programs, Inc. Full Accreditation

85 Wells Avenue · Suite 107 · Newton, MA 02459 Phone: 617-243-3924 · Fax: 617-969-1310 www.neirb.com

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

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NEIRB
New England Institutional Review Board

- The study cannot continue after 10/24/2012 until re-approved by NEIRB. A Study Renewal Report must be completed and returned to NEIRB prior to the expiration of the approval period.

Please call me if you have any questions about the terms of this approval.

Katie Goldberg

Katie Goldberg, CIP, CIM
Senior Administrator

Copy: NEIRB Chair

85 Wells Avenue · Suite 107 · Newton, MA 02459 Phone: 617-243-3924 · Fax: 617-969-1310 www.neirb.com

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

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16.4 South Shore Hearing Center Interim Report

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

LANTOS TECHNOLOGIES

Lantos 3D Ear Scanner User Preference Study

Interim Study Report

South Shore Hearing Center
Stetson medical Center
541 Main Street, Suite 418
South Weymouth, Massachusetts, 02190

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

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

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1.0 Study Information

Indication:	The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal. The Lantos 3D Ear scanner: • provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation and; • includes an expanding conforming membrane which aids observation when inserted in the ear canal and; • records and presents to the hearing professional in an image file a topology measurement of the external ear canal
Methods:	Single-Center, prospective, non-Randomized user preference study.
Sponsor name and address:	Lantos Technologies 101 Main Street, Suite 1760 Cambridge, MA 02142
Regulatory status:	IDE Exempt
Study initiation date:	December 1, 2011
Study completion date:	On-going
Investigators:	Principal Investigator David Citron, III, Ph.D., FAAA
Compliance statement:	This study was performed in compliance with Good Clinical Practices (GCP).
Date of report:	March 27, 2012

2.0 Study Synopsis

Title:	Lantos 3D Ear Scanner User Preference Study
Investigators:	Principal Investigator David Citron, III, Ph. D., FAAA
Study Center(s):	South Shore Hearing Center (SHCC) Stetson medical Center

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8178

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

	541 Main Street, Suite 418 South Weymouth, MA 02190 Phone: (781) 337-6860
Publication (reference):	None
Study Period:	Preference Study is on-going
Date of First Enrollment:	December 21, 2012
Regulatory Status:	IDE Exempt, IRB Approved December 1, 2011
Primary Objective	The objective of this clinical study is to assess the Lantos 3D Ear Scanner device features, device operation, and operator experience. • With training, operators are able to complete digital scans in the same or less time than traditional silicone earmold impressions • Operators rate the digital scan experience equal or better than that for earmold impressions.
Secondary Objective:	Observations and records of use, which may lead to device improvements.
Methodology	Single-Center, prospective, non-randomized user preference study.
Number of Patients	Up to 25 subjects.
Diagnosis and Main Criteria for Inclusion	The study will require up to 25 subjects with no known pathology be evaluated using the Lantos 3D Ear Scanner. Inclusion Criteria : • Patient presenting for silicone earmold impression • Satisfactory ear exam prior to use of the Lanots EarScan 3D • Subject must be 21-95 years of age
Device Serial Number(s):	Alpha 4
Criteria for Evaluation:	**Safety:** absences of adverse events
Statistical Methods:	Data analysis will be completed with a compilation of the inputs from the questionnaire at the end of the protocol.
Summary/Conclusions:	The user preference study is on-going.

3.0 Ethics

3.1. Institutional Review Board

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

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This study was performed in accordance with the principals of the Declaration of Helsinki and in accordance with 21 CFR 50 Protection of Human Patients and 21 CFR 56 Institutional Review Boards.

Prior to initiating this study, the protocol and Informed Consent Form were reviewed and approved by a properly constituted Institutional Review Board (IRB). The Principal Investigator submitted an application to that site's IRB. The Principal Investigator at the site bore complete responsibility for the conduct of the study at that site.

The opinions of the IRB were dated and given in writing. A list of those present at the committee meeting (names and positions) was attached whenever possible.

3.2. Ethical Review

The Investigator was responsible for informing the IRB of any serious adverse events, amendments to the protocol as well as notification of the termination/completion of the study as per local requirements. All correspondence with the committee was maintained by the Investigator.

4.0 Investigators and Study Administrative Structure

4.1. Investigators

The study was conducted by one Principal Investigator at one Investigational Site.

- David Citron, III, Ph.D, FAAA

4.2. Sponsors Study Personnel

Lantos Technologies served as the sole sponsor of this study and South Shore Hearing Center was the sole investigational center for this study.

5.0 Introduction

5.1. Device Information

The Lantos 3D Ear Scanner provides a dimensional scan of the ear canal and outer ear, and provides a video otoscope view of the ear canal during insertion. The device is for use by qualified audiologist and hearing aid dispensers with adult patients.

5.2. Background

Hearing loss continues as one of the most commonly occurring occupational injuries in

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the manufacturing industry. Many sudden hearing losses and hearing loss due to sudden noise, chronic loud noise, trauma, and injury become permanent due to a lack of adequate hearing protection in the workplace environment. Earplugs are the basic method of personal protection from hearing loss due to noise damage.

The purpose of this proposal is to determine whether Computer Aided Design (CAD) manufactured custom earplugs from direct digitization using the Lantos 3D EarScan meet the expectations of the audiologist in a clinical setting. In addition, even though this was a non-significant risk study, and IRB approved, adverse event data was collected to assure the safety of the design.

5.3. Trial Design

A single-center, non-randomized, open labeled prospective clinical trail designed to assess the Lantos 3D Ear Scanner.

5.4. Primary Objective

The primary objectives:

- With training, operators able to complete digital scans in the same or less time than taking traditional silicone earmold impressions.
- Operators rate the digital scan experience equal or better than that for earmold impressions.

5.5. Secondary Objective

The secondary endpoint:

- Observations and records of use, which may lead to device improvements.

5.6. Safety Objectives

All adverse events will be recorded regardless of casual relationship. All AE's will be followed until resolved or otherwise explained by the principal investigator.

There are no AE's associated with this study to date.

6.0 Study Objectives

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

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The study objective was to evaluate the hearing healthcare clinician's satisfaction with the Lantos 3D Ear Scanner. Lantos representatives described the intended use and technical characteristics of the Lantos 3D Ear Scanner device and provided training for the device. Lantos representatives observed and recorded use by trained operators when patients were scanned in clinical settings, and performed qualitative assessments of scan data, including extent for scanned surface and scan time. Users provided qualitative answers to interview questions regarding scan experience, including comparison to traditional silicone ear mold impressions, and documented suggestions for improvement of the device or process.

7.0 Study Population

7.1. Number of Subjects

Up to 25 subjects will be enrolled at a single center. This interim report includes data from 10 subjects.

7.2. Inclusion Criteria

The Inclusion Criteria for the study is listed below:

- Patient presenting for silicone earmold impression
- Satisfactory ear exam prior to use of Lantos 3D Ear Scanner
- Subject must be 21-95 years of age

7.3. Exclusion Criteria

The Exclusion Criteria for the study is listed below:

- Subject under the age of 21
- Subject with cognitive delay
- Subject with existing ear infection
- Subject with evidence of perforation of ear drum
- Subjects with a stenotic ear canal
- Subjects with an irregular ear canal (e.g., exotoses)
- Subjects with osteomas in the ear canal
- Any subject on medication for a condition of the ear.

8.0 Study Procedures

For each subject presenting for a silicone ear mold impression for assessment and fit of a hearing aid or other ear-level device, the audiologist examined the ear canals to assure they are healthy enough for the traditional silicone impression process. The audiologist inserted a probe covered by a flexible silicone membrane into the subjects ear canal, visually guided by a camera with alerts at the probe tip that provided a wide

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

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view of the canal. When the probe was properly situated, the audiologist expanded the membrane with a liquid absorbing fluid (water with a trace of colorant) until it touched the walls of the subjects canal. The mild pressure applied to the ear canal by the membrane was less than 40cmH20. The audiologist withdrew the probe through the canal, and then directed the probe tip around the concha bowl of the outer ear, to collect the digital scan data. The audiologist withdrew the fluid, the membrane then collapsed, and the membrane was illuminated with visible light of varying wavelength; small amounts of light may be visible through the membrane.

For each subject, at the audiologist's discretion, the digital scan process may have been repeated for the subject's other ear.

Prior to or following the digital scan(s), the audiologist could have taken one or more traditional ear mold impressions of the subjects ears, which may be used to design and shape the hearing aid or other ear-level device. The silicone ear mold impressions were not a part of this study and were performed using the appropriate standard of care.

8.1. Termination

The Subjects participation in this study will be completed after the audiologists completes the digital scanning with the Lantos 3D Ear Scanner.

Any unexpected, serious adverse event using the device will be cause for early study termination.

8.2. Withdrawal Criteria

If a patient was withdrawn from the study for any reason, then that patient was assessed up to the time of withdrawal. The reason for early termination was recorded on the patient withdrawal case report form. A patient was withdrawn from the study for any of the following reasons:

- Post-consent determination of ineligibility based on safety or eligibility criteria
- Clinicians judgments following an Adverse Event
- Termination by the sponsor or a regulatory authority
- Any other reason for withdrawal that the study clinician or patient indicates is in the overall best interest of the patient.

8.3. Data Quality Assurance

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

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Monitoring of patient enrollment data will be performed as part of the Lantos 3D Ear Scanner user preference study.

8.4. Statistical Methods and Determination of Sample Size

This is not applicable; this is a user preference study.

8.5. Changes in the Conduct of the Study or Planned Analysis

An "Ad-Hoc" Safety Analysis was performed.

9.0 Study Patients

10.0 Protocol Violations

There has been no protocol deviations associated with this study to date.

11.0 User Evaluation

11.1. Data Sets Analyzed

The data below identifies data analyzed from the user input questionnaire:

Table 11-1 identifies the length of time (seconds) in video otoscope mode and in scan mode.

User ID	Length of time in Video otoscope mode	Length of time in scan mode
001	14	49
002	15	50
003	14	55
004	20	77
005	24	50
006	26	47
007	12	96

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

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LANTOS TECHNOLOGIES

User ID	Length of time in Video otoscope mode	Length of time in scan mode
008	33	44
009	25	36
010	25	82
Average	20.8	58.6
Std Dev	6.876691711	19.42621368
Median	22	50
Min	12	36
Max	33	96

Table 11-1: Length of Time in seconds (Otoscope Mode and Scan Time)

The Table 11-2 below identifies the total number of responses to the user input questionnaire. The responses are based on an N=10.

Questions	Very Difficult	Difficult	No Opinion	Easy	Very Easy
Assess the ease of setup of the instrument	0	0	0	10	0
Assess the ease of use of the instrument	0	0	0	10	0
	Much Slower	**Slower**	**About the Same**	**Faster**	**Much Faster**
Assess the time to complete a digital scan as compared to your taking a conventional silicone ear mold	0	0	1	9	0
	Much Worse	**Worse**	**About the Same**	**Better**	**Much Better**
Assess your experience taking digital scan as compared to taking a conventional silicone ear impression	0	0	5	4	1
Assess the patient experience undergoing a digital scan as compared to a conventional silicone ear impressions	0	0	0	3	7
Assess the video otoscope	0	3	7	0	0

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

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images provided by the EarScan 3D with the image quality of other otoscopes you have used, either video or conventional					
	Very Difficult	**Difficult**	**No Opinion**	**Easy**	**Very Easy**
Assess your ease or difficult in obtained a complete scan of the ear canal and outer ear with the digital scan process	0	3	0	7	0

Table 11-2 Input Questionnaire Responds (N=10)

The user input questionnaire asked to identify three changes the user wanted to make to the device, or the process, patient experience or results from the device. The table below identifies the user responses:

User ID	What three things would you change about the device or the process to improve your experience, the patient experience or results (1)	What three things would you change about the device or the process to improve your experience, the patient experience or results (2)	What three things would you change about the device or the process to improve your experience, the patient experience or results (3)
001	Prompt for ear canal depth length	Beta version	Gaps in Scanning (errors)
002	Prompt for ear canal depth length	Beta version	Gaps in Scanning (errors)
003	Prompt for ear canal depth length	Beta version	Gaps in Scanning (errors)
004	Identification of depth of proper insertion	easier inflation/insertion process	ID of errors in scan
005	Know there is a beta two (illegible word)	Prompt/ID of depth (canal length)	Sensitivity to ID area not scanned
006	Know there is a beta two (illegible word)	Prompt/ID of depth (canal length)	Sensitivity to ID area not scanned
007	Know there is a beta two (illegible word)	Prompt/ID of depth (canal length)	Sensitivity to ID area not scanned
008	Balloon Sticking	Camera Fogging	Depth of probe insertion to assure adequate
009	Balloon Sticking	Camera Fogging	Depth of probe insertion to assure adequate

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

User ID	What three things would you change about the device or the process to improve your experience, the patient experience or results (1)	What three things would you change about the device or the process to improve your experience, the patient experience or results (2)	What three things would you change about the device or the process to improve your experience, the patient experience or results (3)
010	Balloon Sticking	Camera Fogging	Depth of probe insertion to assure adequate

Table 11-3: User Input, Device Comments

11.2. Safety Data

The user input questionnaire documented if any adverse events occurred during the Lantos 3D Ear Scanner process. Based on the user input questionnaire there were no adverse events noted in this study.

12.0 Overall Discussion and Conclusion

This is an interim report of the Lantos 3D Ear Scanner User Preference Study. No adverse events were noted during the study.

It is concluded in this interim report that as no adverse events were noted, the device (Lantos 3D Ear Scanner) may be considered as safe when used in accordance with the manufacturer's instructions and the requirements of the protocol.

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

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17. Attachment VII – Biocompatibility Reports

17.1. ISO 10993-10: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization & Intracutaneous Reactivity

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

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NELSON LABORATORIES

Sponsor:
Manas Menon
Lantos Technologies
101 Main St., Ste. 1760
Cambridge MA 02142

ISO Intracutaneous Reactivity Test

Summary: Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

Test Article:	Parts 1-27 P/N: 2011-10-1-3 (NS) P/N: 2011-10-1-4(CSO) Lot # 1
Nelson Laboratory Number:	607197
Testing Lab:	WuXi AppTec, Inc.

Results: The requirements of the ISO Intracutaneous Reactivity Test **have been met** by the test article.

If you have any questions, please feel free to call or email any of our Subcontracting personnel at 801-290-7500 or subcontracting@nelsonlabs.com. Thank you for testing with Nelson Laboratories, Inc.

Subcontracting Coordinator Jennifer Shaw, B.S.

14 Feb 2012
Date

P.O. Box 571830 | Murray, UT 84157-1830 U.S.A. • 6280 South Redwood Road | Salt Lake City, UT 84123-6600 U.S.A.
www.nelsonlabs.com • Telephone 801 290 7500 • Fax 801 290 7998 • sales@nelsonlabs.com

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

These results relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NLI terms and conditions at www.nelsonlabs.com

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FINAL STUDY REPORT

STUDY TITLE:	**ISO Intracutaneous Reactivity Test**
PROTOCOL NUMBER:	9107015-2
TEST ARTICLE IDENTIFICATION:	Parts 1-27 P/N: 2011-10-1-3 (NS) P/N: 2011-10-1-4 (CSO) Lot # 1
PERFORMING LABORATORY:	WuXi AppTec, Inc. 2540 Executive Drive St. Paul, MN 55120
SPONSOR:	Nelson Laboratories, Inc. 6280 South Redwood Road Salt Lake City, UT 84123
STUDY NUMBER:	161562
CLIENT MNEMONIC:	NEL05
NLI#:	607197
RESULT SUMMARY:	The requirements of the ISO Intracutaneous Reactivity Test **have been met** by the test article.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

QUALITY ASSURANCE UNIT SUMMARY

The objective of the Quality Assurance Unit is to monitor the conduct and reporting of nonclinical laboratory studies. This study has been performed under Good Laboratory Practices regulations (FDA, 21 CFR, Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies) and in accordance to standard operating procedures and a standard protocol. The Quality Assurance Unit maintains copies of study protocols and standard operating procedures and has inspected this study on the dates listed below. Studies are inspected at time intervals to assure the quality and integrity of the study.

Phase Inspected	Date	Study Director	Management
Dosing	01/12/12	01/13/12	01/30/12
Final Report	01/27/12	01/30/12	01/30/12

The findings of these inspections have been reported to management and the Study Director.

Quality Assurance Auditor: _____ Date: 1/30/12
Amy Uren

GOOD LABORATORY PRACTICES STATEMENT

The study referenced in this report was conducted in compliance with U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR part 58.

The studies not performed by or under the direction of WuXi AppTec, Inc., are exempt from this Good Laboratory Practice Statement and include characterization and stability of the test compound(s)/test article.

Study Director: _____ Date: 1/30/12
Ryan Koslofsky

Professional Personnel Involved:

Teri Tanquist, BS	Vice President of Process Improvement and Operations
Christine Olson, BS	Study Operations Director
Roxanne Miller, AA, CVT	Associate Director, In-Life Studies
Ryan Koslofsky, MS	Study Director
Jean Mesarich, AA	Client Relations Manager

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-5118

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PURPOSE

The purpose of this test was to determine if any chemicals that may leach or be extracted from the test article were capable of causing local irritation in the dermal tissues of rabbits.

TEST FACILITY: WuXi AppTec, Inc.
2540 Executive Drive
St. Paul, MN 55120

DATE SAMPLE RECEIVED: 11/14/11
STUDY INITIATION DATE: 11/15/11
STUDY COMPLETION DATE: 01/30/12

TEST ARTICLE IDENTIFICATION :

Test Article Name:	Parts 1-27 P/N: 2011-10-1-3 (NS) P/N: 2011-10-1-4 (CSO)
Lot/Batch #:	1
NLI#:	607197
Sterilization Method:	Non-Sterile
Physical State:	Insoluble Material
Expiration Date:	Not Applicable
Storage Conditions:	Room Temperature
Intended Use/Application:	Unknown

CHARACTERIZATION

The Sponsor was responsible for all test article characterization data as specified in the GLP regulations. The identity, strength, stability, purity, and chemical composition of the test article were solely the responsibility of the Sponsor. The Sponsor was responsible for supplying to the testing laboratory results of these determinations and any others that may have directly impacted the testing performed by the testing laboratory, prior to initiation of testing. Furthermore, it was the responsibility of the Sponsor to ensure that the test article submitted for testing was representative of the final product that was subjected to materials characterization. Any special requirements for handling or storage were arranged in advance of receipt and the test article was received in good condition.

SAMPLE STORAGE

Upon receipt by the Sample Receiving Department, the test samples were placed in a designated, controlled access storage area ensuring proper temperature conditions. Test and control article storage areas are designed to preclude the possibility of mix-ups, contamination, deterioration or damage. The samples remained in the storage area until retrieved by the technician for sample preparation and/or testing.

SAFETY

Appropriate routine safety procedures were followed in handling the test article, unless more cautious procedures were specified by the Sponsor. All applicable WuXi AppTec safety policies and procedures were observed during the performance of the test.

EXPERIMENTAL DESIGN

Experimental Summary

The study was conducted in accordance with ISO 10993-10: 2010 Standard, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization, Pages 11-14. Each rabbit received five sequential 0.2 mL intracutaneous injections along either side of the dorsal mid-line with the test article extract on one side and the concurrent vehicle control on the other. The irritation reaction of the test extracts were compared to vehicle controls and recorded over a 72-hour period according to the standard ISO irritation scoring system.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-5118

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Justification For Selection Of The Test System
This test method and species have historically been used to assess the potential of the material under test to produce intradermal irritation to help determine biocompatibility of materials used in medical devices. The animal species, number and route of test article administration will be as recommended in ISO 10993-10.

Institutional Animal Care and Use Committee (IACUC)
The protocol and any amendments or procedures involving the care or use of animals on this study were reviewed and approved by WuXi AppTec's IACUC prior to the initiation of such procedures.

IACUC Protocol / Effective Date: 07-122B / June, 2010

AMENDMENTS: The study directorship was reassigned from M. Dietzel to R. Koslofsky. This amendment was needed for study completion and does not impact the study interpretation.

DEVIATIONS: None.

TEST SYSTEM

Species/Strain: Albino rabbits (*Oryctolagus cuniculus*) / New Zealand White strain

Source: Bakkom Rabbitry

Sex: Female. Females used were nulliparous and non-pregnant.

Weight Range: Animals weighed between 2.9 – 3.1 kg at the experimental start of the study.

Age: The rabbits were young adults.

Number: A total of three animals were used for this study.

Animal Identification: Individual animals were identified per WuXi AppTec SOP: ILS-0112.

HUSBANDRY

Receipt: Animals were received on 01/03/12 according to WuXi AppTec SOP: ILS-0092. The animals were acclimated for a minimum of 5 days under the same conditions as the actual test.

Housing: Animals were individually housed in stainless steel caging. Housing dimensions complied with NIH and AAALAC International guidelines for this species.

Environment: The environmental conditions in the animal rooms were maintained according to WuXi AppTec SOP: ILS-0018. The temperature and photo-period were set to meet the AAALAC International recommendations for these species. The laboratory and animal rooms were maintained as limited-access facilities.

Diet: Animals were supplied with certified commercial feed, *ad libitum*. There were no known contaminants present in the feed expected to interfere with the test results. Feed analysis results are available and archived by WuXi AppTec.

Water: Potable water was supplied from the St. Paul municipal water supply, *ad libitum*. There were no known contaminants present in the water expected to interfere with the test results. Periodic analysis of the water is conducted and the results are archived by WuXi AppTec.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

TEST AND CONTROL MATERIAL PREPARATION

According to the Sponsor, the test article consisted of clear tubing with pink liquid attached to clear hub with blue and yellow o-rings and black rubber tip, white zip tie. The test article remained intact, placed into test tubes and prepared at a ratio of 60 cm^2 to 20 mL of extraction vehicle.

TABLE 1: TEST ARTICLE RECORD

EXTRACT VEHICLE	TEST ARTICLE AREA (CM^2)	VEHICLE AMOUNT (mL)	NUMBER OF TEST ARTICLE DEVICES USED PER EXTRACT
0.9% Normal Saline (NS)	51.6	17.2	1
Cottonseed Oil (CSO)	51.6	17.2	1

Test Article Extraction: The extraction mixtures and corresponding control blanks were incubated for 72 ± 2 hours at 50 ± 2 °C. At the start of the extraction, the solutions appeared clear and free of particulates. The extracts were agitated during the course of the extraction period. At the end of the extraction period, the vessels were shaken well and the liquid aseptically decanted into a sterile glass vessel. The test article was observed after all extractions to be intact with no macroscopically observable degradation and the NS extract was clear and free of particulate. The CSO extract was turbid and free of particulate. After decanting, the extracts were not filtered prior to use. The extracts were maintained at room temperature and used within 24 hours of preparation. See Tables 1-3.

TABLE 2: EXTRACTION RECORD

VEHICLE	EXTRACTION TEMPERATURE (IN)	DATE/TIME OF EXTRACTION START	EXTRACTION TEMPERATURE (OUT)	DATE/TIME OF EXTRACTION END
NS	50.2 °C	01/09/12 10:20 am	50.2 °C	01/12/12 8:28 am
CSO	50.2 °C	01/09/12 10:20 am	50.2 °C	01/12/12 8:28 am

TABLE 3: VEHICLE RECORD

VEHICLE IDENTIFICATION:	LOT #	SUPPLIED BY:	EXPIRATION
NS	J1E609	Braun	11/2013
CSO	ZN1009	Spectrum	06/15/12

SELECTION OF ANIMALS

Animals were randomly placed in cages upon receipt, and were placed on study as available. Any animals considered unsuitable due to poor health, abraded skin or outlying body weight were excluded from the study.

ANIMAL PREPARATION

Each animal was weighed and the weight recorded prior to test injection. The fur of the animals was clipped on both sides of the spinal column to expose a sufficient sized area for injection.

TEST ARTICLE ADMINISTRATION

The two test article extracts and the two vehicle controls were each injected into three rabbits. Each rabbit received five sequential 0.2 mL intracutaneous injections of the test article extract on the right side of the vertebral column and similarly the control vehicle on the left side. The second test and control extract injections were parallel and distal to the first injection sites. (See Figure 1.)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-5718

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

FIGURE 1: INJECTION SITES ON RABBITS

	CONTROL		HEAD	TEST		
	Control Vehicle #2	Control Vehicle #1	|	Test Extract #1	Test Extract #2	
0.2 mL Control Vehicle Injected	1	1	|	1	1	0.2 mL Test Article Extract Injected
	2	2	|	2	2	
	3	3	|	3	3	
	4	4	|	4	4	
	5	5	|	5	5	
			TAIL			

OBSERVATIONS AND SCORING

The animals were observed daily for abnormal clinical signs. The appearance of each injection site was noted at 24 ± 2, 48 ± 2 and 72 ± 2 hours post injection. The tissue reactions were rated for gross evidence of erythema and edema. The skin was lightly swabbed with dilute alcohol to enhance the appearance of any erythema or edema. The intradermal injection of CSO frequently elicits an inflammatory response. CSO erythema scores ≤ 2 are considered normal. A well-defined positive response is characterized by a score greater than 2. Table 4 was used to score the reactions.

TABLE 4: DERMAL OBSERVATION SCORING

ERYTHEMA	EDEMA
0 = No erythema	0 = No edema
1 = Very slight erythema (barely perceptible)	1 = Very slight edema (barely perceptible)
2 = Well defined erythema	2 = Well defined edema (edges of area well-defined by definite raising)
3 = Moderate to severe erythema	3 = Moderate edema (raised ~1 mm)
4 = Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4 = Severe edema (raised > 1 mm and extending beyond area)

TERMINATION

All animals were euthanized according to WuXi AppTec SOP: ILS-0230 with a sodium pentobarbital based solution after the 72-hour observations were recorded.

EVALUATION CRITERIA

According to ISO 10993:10 test criteria, if the difference between the average scores for the extract of the test article and the vehicle control is less than or equal to 1.0, the test article is considered non-irritating.

ASSAY VALIDITY

Final evaluation of the validity of the assay and test article results was based upon scientific judgment.

METHOD FOR CONTROL OF BIAS: Not applicable.

DATA ANALYSIS: See calculations section.

STATISTICAL METHODS: None used.

RECORD RETENTION: An exact copy of the original final report and all raw data pertinent to this study will be stored by WuXi AppTec, Inc. It was the responsibility of the Sponsor to retain a sample of the test article.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-5118

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

COMPLIANCE

Animal Welfare

WuXi AppTec, Inc. maintains the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International accreditation. All applicable portions of the study will also conform to the following regulations and guidelines regarding animal care and welfare:

- NIH guidelines as reported in the "Guide for the Care and Use of Laboratory Animals," National Research Council of the National Academies, eighth edition, 2011;
- (OPRR), "Public Health Service Policy on Humane Care and Use of Laboratory Animals," Health Research Extension Act of 1985 (Public Law 99-158), Revised 1986.
- USDA, Department of Agriculture, Animal and Plant Health Inspection Service, 9 CFR, Parts 1, 2, and 3, Animal Welfare, Final Rule 1989.
- WuXi AppTec Policy on Humane Care.

The study was also performed in compliance with the following International Standards:

ISO 10993-10: 2010 Standard, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization, Pages 11-14.

ISO 10993-12:2007 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials.

TEST ARTICLE DISPOSITION: Unused test samples remain in the storage area until all testing is completed. Once completed, the remaining samples were discarded or returned as requested by the Sponsor.

RESULTS

Clinical Observations

None of the animals on study showed abnormal clinical signs during the 72 hour test period.

Dermal Observations

There were no significant dermal reactions observed at the injected test and control sites on the rabbits at the 24, 48 and 72 hour observation periods.

CALCULATIONS

After the 72 ± 2 hour observation period, all erythema grades plus edema grades 24 ± 2, 48 ± 2, and 72 ± 2 hour were totaled separately for each test sample or control for each individual animal. To calculate the score of a test sample or control on each individual animal, each of the totals was divided by 15 (three scoring time points x five test or control sample injection sites). To determine the overall mean score for each test sample and each corresponding control, the scores were added for the three animals and divided by three. The final test sample score was obtained by subtracting the score of the control from the test sample score. The results are presented in Tables 5 and 6.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

TABLE 5: DERMAL OBSERVATIONS – 0.9% NORMAL SALINE

Rabbit # 24611	Control Scores						Test Scores					
	24 Hour		48 Hour		72 Hour		24 Hour		48 Hour		72 Hour	
	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
Site 1	0	0	0	0	0	0	0	0	0	0	0	0
Site 2	0	0	0	0	0	0	0	0	0	0	0	0
Site 3	0	0	0	0	0	0	0	0	0	0	0	0
Site 4	0	0	0	0	0	0	0	0	0	0	0	0
Site 5	0	0	0	0	0	0	0	0	0	0	0	0
Total	0		0		0		0		0		0	
Rabbit # 24609	**Control Scores**						**Test Scores**					
	24 Hour		48 Hour		72 Hour		24 Hour		48 Hour		72 Hour	
	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
Site 1	0	0	0	0	0	0	0	0	0	0	0	0
Site 2	0	0	0	0	0	0	0	0	0	0	0	0
Site 3	0	0	0	0	0	0	0	0	0	0	0	0
Site 4	0	0	0	0	0	0	0	0	0	0	0	0
Site 5	0	0	0	0	0	0	0	0	0	0	0	0
Total	0		0		0		0		0		0	
Rabbit # 24610	**Control Scores**						**Test Scores**					
	24 Hour		48 Hour		72 Hour		24 Hour		48 Hour		72 Hour	
	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
Site 1	0	0	0	0	0	0	0	0	0	0	0	0
Site 2	0	0	0	0	0	0	0	0	0	0	0	0
Site 3	0	0	0	0	0	0	0	0	0	0	0	0
Site 4	0	0	0	0	0	0	0	0	0	0	0	0
Site 5	0	0	0	0	0	0	0	0	0	0	0	0
Total	0		0		0		0		0		0	
Rabbit	**Control scores (Total ER & ED)**						**Test scores (Total ER & ED)**					
24611	0		0		0		0		0		0	
24609	0		0		0		0		0		0	
24610	0		0		0		0		0		0	
Rabbit	**Total / 15**						**Total /15**					
24611	0						0					
24609	0						0					
24610	0						0					
Average (Total/3)	0/3 = 0						0/3 = 0					
Comparative Results (Average Test – Average Control)	0 – 0 = **0**											

ER=Erythema ED=Edema

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIA-STATUS@fda.hhs.gov or 301-796-5118

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

TABLE 6: DERMAL OBSERVATIONS – COTTONSEED OIL

Rabbit # 24611	Control Scores						Test Scores					
	24 Hour		48 Hour		72 Hour		24 Hour		48 Hour		72 Hour	
	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
Site 1	1	0	1	0	1	0	1	0	1	0	1	0
Site 2	1	0	1	0	1	0	1	0	1	0	1	0
Site 3	1	0	1	0	1	0	1	0	1	0	1	1
Site 4	1	0	1	0	1	0	1	0	1	0	1	1
Site 5	1	0	1	0	1	0	1	0	1	0	1	1
Total	5		5		5		5		5		8	
Rabbit # 24609	**Control Scores**						**Test Scores**					
	24 Hour		48 Hour		72 Hour		24 Hour		48 Hour		72 Hour	
	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
Site 1	1	0	1	0	1	0	1	0	1	0	1	0
Site 2	1	0	1	0	1	0	1	0	1	0	1	0
Site 3	1	0	1	0	1	0	1	0	1	0	1	0
Site 4	1	0	1	0	1	0	1	0	1	0	1	0
Site 5	1	0	1	0	1	0	1	0	1	0	1	0
Total	5		5		5		5		5		5	
Rabbit # 24610	**Control Scores**						**Test Scores**					
	24 Hour		48 Hour		72 Hour		24 Hour		48 Hour		72 Hour	
	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
Site 1	1	0	1	0	1	0	1	0	1	0	1	0
Site 2	1	0	1	0	1	0	1	0	1	0	1	0
Site 3	1	0	1	0	1	0	1	0	1	0	1	1
Site 4	1	0	1	0	1	0	1	0	1	0	1	1
Site 5	1	0	1	0	1	0	1	0	1	0	1	1
Total	5		5		5		5		5		8	
Rabbit	**Control scores (Total ER & ED)**						**Test scores (Total ER & ED)**					
24611	5		5		5		5		5		8	
24609	5		5		5		5		5		5	
24610	5		5		5		5		5		8	
Rabbit	**Total / 15**						**Total /15**					
24611	1.0						1.2					
24609	1.0						1.0					
24610	1.0						1.2					
Average (Total/3)	3/3 = 1.0						3.4/3 = 1.1					
Comparative Results (Average Test – Average Control)	1.1 – 1.0 = **0.1**											

ER=Erythema ED=Edema

ANALYSIS AND CONCLUSION

The test was considered valid based upon scientific judgment. The differences in the mean test and control scores of the extract dermal observations were **less than 1.0**, indicating that the requirements of the ISO Intracutaneous Reactivity Test **have been met** by the test article.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-5718

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

REFERENCES

U.S. Pharmacopeia, Section 88, current revision.

WuXi AppTec SOP: ALS-0260, Sample Extraction Procedures

WuXi AppTec Reference Library Contents, Form ALS-4650-1

WuXi AppTec SOP: ILS-0018, Environmental Conditions in the Animal Facility

WuXi AppTec SOP: ILS-0092, Receiving Shipments of Animals

WuXi AppTec SOP: ILS-0100, ISO/USP/Japanese Intracutaneous Reactivity Test

WuXi AppTec SOP: ILS-0112, Animal Identification

WuXi AppTec SOP: ILS-0230, Euthanasia Procedures

WuXi AppTec SOP: ILS-0233, Proper Handling of Sick and Moribund Animals

WuXi AppTec SOP: TRG-0300, Preparation of Biomaterials for Extraction

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-5118

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17.2. ISO 10993-5: Biological Evaluation of Medical Devices, Part 5: Cytotoxicity – MEM Elution

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

NELSON LABORATORIES

Sponsor:
Manas Menon
Lantos Technologies
101 Main St., Ste. 1760
Cambridge MA 02142

MEM Elution GLP Report

Test Article: Lot #1 Part 1-2
Laboratory Number: 607196
Study Received Date: 07 Nov 2011
Test Procedure(s): Standard Test Protocol (STP) Number: STP0032 Rev 07
Protocol Detail Sheet (PDS) Number: 201104121 Rev 01

Summary: The Minimal Essential Media (MEM) Elution test was designed to determine the cytotoxicity of extractable substances. An extract of the test article was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction. All test method acceptance criteria were met.

Results:

Test Article:

Results Pass/Fail	Scores				Extraction Ratio	Amount Tested / Extraction Solvent Amount	Post Extraction Appearance
	#1	#2	#3	Average			
Pass	0	0	0	0	3 cm^2/mL	51.6 cm^2 / 17.2 mL	Clear; Particulate Free

Controls:

Identification	Scores				Extraction Ratio	Amount Tested / Extraction Solvent Amount	Post Extraction Appearance
	#1	#2	#3	Average			
Negative Control - Polypropylene Pellets	0	0	0	0	0.2 g/mL	4 g / 20 mL	Clear; Particulate Free
Media Control	0	0	0	0	N/A	20 mL	Clear; Particulate Free
Positive Control - Latex Natural Rubber	4	4	4	4	0.2 g/mL	4 g / 20 mL	Clear; Particulate Free

Acceptance Criteria: The United States Pharmacopeia & National Formulary (USP 87) states that the test article meets the requirements, or receives a passing score (**Pass**) if the reactivity grade is not greater than grade 2 or a mild reactivity. The ANSI/AAMI/ISO 10993-5 standard states that the achievement of a numerical grade greater than 2 is considered a cytotoxic effect, or a failing score (**Fail**).

ACLASS ACCREDITED TESTING

Study Director — Christine Jensen

16 Nov 2011
Study Completion Date

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

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Protocol, Test Request Form, and Amendments

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

WuXi AppTec

(For Laboratory Use Only)

WuXi AppTec Study # 1615e2

WuXi AppTec

PROTOCOL TITLE: **ISO INTRACUTANEOUS REACTIVITY TEST**

TEST CODE: 9107015

PERFORMING LABORATORY: WuXi AppTec, Inc.
2540 Executive Drive
St. Paul, MN 55120

EFFECTIVE DATE: 06 MAY 2011

GLP PROTOCOL: 9107015-2

Quality Assurance has reviewed this protocol for compliance with applicable regulatory requirements and internal procedures.

PROPRIETARY INFORMATION

This document is provided with the understanding that the recipient shall recognize it contains WuXi AppTec proprietary information, that it shall be kept confidential by the person and/or company to whom it is addressed, and that it shall be used for no other purpose than assessing and approving the described services to be performed by WuXi AppTec or for the purpose of regulatory submission.

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Lantha Technologies 2540 Executive Drive St. Paul, MN 55120 Phone: 651-675-2000 Fax: 651-675-2005 Page 1 of 535
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Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

1.0 PURPOSE

The purpose of this test is to determine if chemicals that may leach or be extracted from the test material are capable of causing local irritation in the dermal tissues of the rabbit.

2.0 TEST FACILITY: WuXi AppTec, Inc.
2540 Executive Drive
St. Paul, MN 55120

3.0 SCHEDULING AND DISCLAIMER

3.1 Test protocol initiation is generally within 10 working days after receipt of the test article, a signed protocol/Client Approval form, and a signed test request form. The Client Approval form and the test request form serve as addenda to this protocol. Written notification of the proposed initiation and completion dates will be provided at the time the test article and signed protocol are received by the laboratory. The estimated testing time is 3 - 7 days. Verbal results will be available from the Study Director upon completion of the study with the written report to follow approximately 10 working days after completion of the study.

3.2 Testing is performed in strict adherence to WuXi AppTec standard operating procedures (SOPs) which have been constructed to cover all aspects of the work including, but not limited to, receipt, identification, log-in and tracking of test article(s). Additionally, each test is assigned a unique Project Number. This number is used for identification during the course of the test.

3.3 If a test, or a portion of it, must be repeated due to failure by WuXi AppTec to adhere to specified procedures, it will be repeated free of charge. If a test, or a portion of it, must be repeated due to failure of internal controls or failure to meet assay validity requirements, it will be repeated free of charge. "Methods Development" fees shall be assessed, however, if the test article and test system require modifications due to complexity and difficulty of testing.

3.4 If the Sponsor requests a repeat test, they will be charged for an additional test.

3.5 The Sponsor is responsible for any rejection of the final report by the regulatory agency concerning report format, pagination, etc. To prevent rejection, the Sponsor should carefully review the WuXi AppTec final report and notify WuXi AppTec of any perceived deficiencies in these areas before submission of the report to the regulatory agency. WuXi AppTec will make reasonable changes deemed necessary by the Sponsor, without altering the technical data.

3.6 Neither the name of WuXi AppTec nor any of its employees are to be used in advertising or other promotion without written consent from WuXi AppTec.

4.0 TEST ARTICLE IDENTIFICATION

Test article information to be included in the final report will be provided solely by the Sponsor on the WuXi AppTec test request form attached to this protocol.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

5.0 TEST ARTICLE CHARACTERIZATION

The Sponsor is responsible for all test article characterization data as specified in the Good Laboratory Practices (GLP) regulations. The identity, strength, stability, purity, and chemical composition of the test article is solely the responsibility of the Sponsor. The Sponsor is responsible for supplying to the testing laboratory results of these determinations and any others that may directly impact the testing performed by the testing laboratory, prior to initiation of testing. Furthermore, it is the responsibility of the Sponsor to ensure that the test article submitted for testing is representative of the final product that will be subjected to materials characterization. Any special requirements for handling or storage must be arranged in advance of receipt and the test article must be received in good condition.

6.0 SAFETY

Appropriate routine safety procedures will be followed in handling the test article, unless more cautious procedures are specified by the Sponsor. All applicable WuXi AppTec safety policies and procedures will be observed during the performance of the test.

7.0 EXPERIMENTAL DESIGN

7.1 Experimental Overview

For safety evaluation of a biomaterial sample, rabbits will be injected intracutaneously (Dose = 0.2 mL x 5 sites) with extracts of the test article and associated vehicle controls. Injection sites will be examined and scored immediately following administration and at 24 ± 2, 48 ± 2, and 72 ± 2 hours after treatment for signs of skin reactions. If the difference between the average scores for the extract of a test article and the control is less than or equal to 1.0, the test article meets the requirements of the test.

Each rabbit will receive five sequential 0.2 mL intracutaneous injections along either side of the dorsal mid-line with the test article extract on one side and the concurrent vehicle control on the other. The vehicles to be used are listed on the test request form attached to this protocol.

According to ISO 10993:10 test criteria, if the difference between the average scores for the extract of a test article and the control is less than or equal to 1.0, the test article meets the requirements of the test and will be considered non-irritating.

7.2 Justification For Selection Of The Test System

This test method and species have historically been used to assess the potential of the material under test to produce intradermal irritation to help determine biocompatibility of materials used in medical devices. The animal species, number and route of test article administration will be as recommended in ISO 10993-10.

7.3 Institutional Animal Care and Use Committee (IACUC)

The protocol and any amendments or procedures involving the care or use of animals on this study will be reviewed and approved by WuXi AppTec's IACUC prior to the initiation of such procedures.

IACUC Protocol / Effective Date: 07-122B / June, 2010

It has been determined that no sedation, analgesia, or anesthesia is necessary in this procedure. In the unlikely event that an animal should become sick or injured, euthanasia or veterinary care will be conducted according to WuXi AppTec SOP: ILS-0233 and current veterinary medical practices. The objectives of the study will be given full consideration prior to any decisions and the study Sponsor will be advised.

Lanto Technologies, Inc. 2540 Executive Drive • St. Paul, MN 55120 • 888.794.0077 • 651.675.2000 • Fax: 651.675.2005 Page 3 of 9 535

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

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7.4 **Amendments/Deviations**
If it becomes necessary to make changes in the approved protocol, the revisions and reasons for changes will be documented, signed by the Study Director, dated, maintained with the protocol and reported to the Sponsor. If an event occurs which may have an effect on the validity of the study, the Sponsor will be notified as soon as is practical. If the Study Director is unable to complete the study, an alternate Study Director with full responsibility and authority regarding the study will be assigned.

8.0 IDENTIFICATION OF THE TEST SYSTEM

8.1 **Species/Strain:** Albino rabbits (*Oryctolagus cuniculus*) / New Zealand White strain

8.2 **Source:** Rabbits will be obtained from certified commercial vendors.

8.3 **Sex:** Either males or females may be used for this study. Females, if used, will be nulliparous and non-pregnant.

8.4 **Weight Range:** Each rabbit will weigh at least 2.0 kg.

8.5 **Age:** The rabbits will be young adults, but no particular age is required, however vendor practice assures consistency in the age of the animals.

8.6 **Number:** A total of three animals per extract or pair of extracts will be used for this study to evaluate the test material.

If a retest is indicated three additional rabbits will be used unless a well-defined positive response [score greater than '2' for either erythema or edema (see Table 1) is observed], in which case, a minimum of two additional animals will be used for the retest.

8.7 **Animal Identification:** Individual animals will be identified per WuXi AppTec SOP: ILS-0112.

8.8 **Husbandry**

8.8.1 **Receipt And Acclimation**
Receipt will be according to WuXi AppTec SOP: ILS-0092. The animals will be acclimated for a minimum of 5 days under the same conditions as the actual test.

8.8.2 **Housing**
Animals will be individually housed in stainless steel caging. Housing dimensions will comply with NIH and AAALAC International guidelines for this species.

8.8.3 **Environment**
The environmental conditions in the animal rooms will be maintained according to WuXi AppTec SOP: ILS-0018. The temperature and photo-period will be set to meet the AAALAC International recommendations for these species. The laboratory and animal rooms will be maintained as limited-access facilities.

8.8.4 **Diet**
Animals will be supplied with certified commercial feed, *ad libitum*. There are no known contaminants present in the feed expected to interfere with the test results. Feed analysis results are available and archived by WuXi AppTec.

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8.8.5 **Water**
Potable water will be supplied from the St. Paul municipal water supply, *ad libitum*. There are no known contaminants present in the water expected to interfere with the test results. Periodic analysis of the water is conducted and the results are archived by WuXi AppTec.

9.0 TEST METHOD

9.1 Test and Control Article Preparation

The Sponsor-submitted test article will be prepared and extracted as indicated on the WuXi AppTec test request form attached to this protocol per ISO 10993:12, Sample Preparation and Reference Materials, and according to WuXi AppTec SOPs: TRG-0300 and ALS-0260. The extractions will be stored at room temperature and used within 24 hours of preparation. The pH of the extractants will be tested by litmus paper and if the pH is less than or equal to 2 or greater than or equal to 11.5, the material will be considered an irritant and no further testing will be required unless it is properly justified and documented.

9.2 Selection Of Animals

Animals will be selected at random from a larger pool of animals. Selection criteria will be based on the required weight range of this study and the condition and suitability of the animal skin, as observed after shaving. Each animal is observed for any signs of clinical disease prior to introduction into the study.

9.3 Test Article Administration

9.3.1 The fur on the animal's back will be closely clipped 4 - 18 hours before the test to expose a sufficient area on either side of the spinal column to allow for injections and observations to be made. Mechanical irritation and trauma to the skin will be avoided during clipping.

9.3.2 At five sites on the right side of the spinal column on three rabbits, 0.2 mL of the test article extract will be injected intracutaneously. At five sites on the left side of the spinal column on three rabbits, 0.2 mL of the corresponding vehicle control will be injected intracutaneously. If a second extract is used, it will be injected as the first extract on sites parallel and distal to the test and control injections. (see Figure 1).

HEAD			
CONTROL		TEST	
Vehicle #2	Vehicle #1	Extract #1	Extract #2
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
TAIL			

FIGURE 1: INJECTION SITES ON RABBITS

9.4 Observations

9.4.1 The appearance of each site will be observed immediately post-injection and at 24 ± 2, 48 ± 2, and 72 ± 2 hours post injection.

9.4.2 The tissue reactions will be evaluated according to Table 1 for gross evidence of erythema, edema, and necrosis. The animals' skin will be lightly swabbed with diluted alcohol to facilitate scoring.

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TABLE 1: DERMAL OBSERVATION SCORING

ERYTHEMA	EDEMA
0 = No erythema	0 = No edema
1 = Very slight erythema (barely perceptible)	1 = Very slight edema (barely perceptible)
2 = Well defined erythema	2 = Well defined edema (edges of area well-defined by definite raising)
3 = Moderate to severe erythema	3 = Moderate edema (raised ~1 mm)
4 = Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4 = Severe edema (raised > 1 mm and extending beyond area)

Note: Other adverse changes at the injections sites shall be noted and reported.

9.5 Termination
All animals will be euthanized according to WuXi AppTec SOP: ILS-0230 by lethal injection with a sodium pentobarbital based solution after the 72-hour observations are recorded.

10.0 TEST EVALUATION

10.1 Positive Response
If the difference between the test and control mean scores is greater than 1.0, the requirements of the test are not met.

10.2 Negative Response
The study is considered meeting the requirements of the test if the difference between the overall mean test and control score is 1.0 or less.

10.3 Repeat Assays
Using the above method of computation, if at any observation period the average reaction to the test sample is questionably greater than the average reaction to the control vehicle, the test should be repeated using three additional rabbits. If a well-defined response is observed, the repeat test will be performed in two animals. On the repeat of the test, the requirements of the test are met if the difference between the test sample and the control vehicle overall mean score is 1.0 or less.

11.0 ASSAY VALIDITY

Final evaluation of the validity of the assay and test article results will be based upon scientific judgment.

If a study, or portion of, is deemed invalid based on negative control scores, then the study can be repeated in three additional rabbits.

12.0 METHOD FOR CONTROL OF BIAS: Not applicable.

13.0 DATA ANALYSIS

After the 72 ± 2 hour observation period, all erythema grades plus edema grades 24 ± 2, 48 ± 2, and 72 ± 2 hour are totaled separately for each test sample or control for each individual animal. To calculate the score of a test sample or control on each individual animal, each of the totals is divided by 15 (3 scoring time points x 5 test or control sample injection sites). To determine the overall mean score for each test sample and each corresponding control, the scores will be added for the three animals and divided by three. The final test sample score is obtained by subtracting the score of the control from the test sample score.

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14.0 STATISTICAL METHODS: None used.

15.0 FINAL REPORT

The final report will include but will not be limited to: the date of the study initiation and completion, the purpose as stated in the approved protocol, changes in the approved protocol, identification of the test system, a description of the methods used, results, and conclusion as it relates to the test.

16.0 RECORD RETENTION

16.1 Study Specific Documents

All of the original raw data developed exclusively for this study shall be retained according to WuXi AppTec, Inc.'s standard operating procedures for archival. These original data include, but are not limited to the following:

16.1.1 All handwritten and equipment generated raw data for control(s) and test article(s).
16.1.2 Any protocol amendments/deviation notifications.
16.1.3 Memoranda, specifications, and other study specific correspondence relating to interpretation and evaluation of data, other than those documents contained in the final study report.
16.1.4 Original signed protocol.
16.1.5 Certified copy of final study report.
16.1.6 Study-specific SOP deviations made during the study.
16.1.7 QA reports for each QA inspection with comments.

16.2 Facility Specific Documents

The following records shall also be retained according to WuXi AppTec, Inc.'s standard operating procedures for archival. These documents include, but are not limited to, the following:

16.2.1 SOPs which pertain to the study conducted.
16.2.2 Non study-specific SOP deviations made during the course of this study which may affect the results obtained during this study.
16.2.3 Methods which were used or referenced in the study conducted.
16.2.4 Facility Records: Temperature Logs (ambient, incubator, etc.), Instrument Logs, Calibration and Maintenance Records.
16.2.5 Current job descriptions and summary of experience and training for all personnel involved in the study.

17.0 COMPLIANCE

17.1 Animal Welfare

WuXi AppTec, Inc. maintains the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International accreditation. All applicable portions of the study will also conform to the following regulations and guidelines regarding animal care and welfare:

17.1.1 NIH guidelines as reported in the "Guide for the Care and Use of Laboratory Animals," National Research Council of the National Academies, eighth edition, 2011;

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17.1.2 (OPRR), "Public Health Service Policy on Humane Care and Use of Laboratory Animals," Health Research Extension Act of 1985 (Public Law 99-158), Revised 1986;

17.1.3 USDA, Department of Agriculture, Animal and Plant Health Inspection Service, 9 CFR, Parts 1, 2, and 3, *Animal Welfare*, Final Rule 1989; and

17.1.4 WuXi AppTec Policy on Humane Care.

17.2 USDA Animal Welfare Act

In order to satisfy the USDA Animal Welfare Act, the Sponsor agrees that this test is required for the submitted test article to satisfy a state or federal regulatory requirement or is scientifically necessary and such testing is not an unnecessary duplication of a previous test submission by the Sponsor. In addition, the duration of testing is determined by the cited regulatory guidelines and will not exceed the time limits contained therein. This protocol was reviewed and approved by WuXi AppTec's Institutional Animal Care and Use Committee (IACUC) in compliance with the Animal Welfare Act.

17.3 GLP Status

The study will be conducted under GLP compliance (FDA, 21 CFR, Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies). The study will be inspected during at least one phase and the final report will be audited by the WuXi AppTec Quality Assurance unit.

17.4 International Standards

17.4.1 ISO 10993-10: 2010 Standard, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization, Pages 11-14.

17.4.2 ISO 10993-12:2007 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials.

18.0 TEST ARTICLE DISPOSITION

It is the responsibility of the Sponsor to retain a sample of the test material. All unused test material will be discarded following study completion unless otherwise requested by the Sponsor.

19.0 REFERENCES

19.1 U.S. Pharmacopeia, Section 88, current revision.

19.2 WuXi AppTec SOP: ALS-0260, Sample Extraction Procedures

19.3 WuXi AppTec Reference Library Contents, Form ALS-4650-1

19.4 WuXi AppTec SOP: ILS-0018, Environmental Conditions in the Animal Facility

19.5 WuXi AppTec SOP: ILS-0092, Receiving Shipments of Animals

19.6 WuXi AppTec SOP: ILS-0100, ISO/USP/Japanese Intracutaneous Reactivity Test

19.7 WuXi AppTec SOP: ILS-0112, Animal Identification

19.8 WuXi AppTec SOP: ILS-0230, Euthanasia Procedures

19.9 WuXi AppTec SOP: ILS-0233, Proper Handling of Sick and Moribund Animals

19.10 WuXi AppTec SOP: TRG-0300, Preparation of Biomaterials for Extraction

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20.0 VERSION CHANGE SUMMARY

20.1 Section 9.1 was edited for clarity.

20.2 Section 9.2, Table 1 was updated to match ISO reference.

20.3. Sections 7.1 and 9.4.1 were updated to included observations to be made immediately post-dosing.

20.4 Section 17.0 Compliance was updated for clarity.

20.5 ISO standards were moved from the reference section to the compliance section for clarity concerning compliance of this assay.

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

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WuXi AppTec

CLIENT PROTOCOL APPROVAL FORM

PLEASE NOTE THAT TESTING CANNOT BE INITIATED UNTIL THIS FORM IS COMPLETED WITH AN AUTHORIZED SIGNATURE AND THE ORIGINAL IS RETURNED TO WUXI APPTEC.

SPONSOR:

Ms. Jennifer Shaw
Nelson Laboratories, Inc.
6280 South Redwood Road
Salt Lake City, UT 84123 USA

NEL05
Phone #: 801-290-7540
Facsimile: 801-963-2630
E-mail: jshaw@nelsonlabs.com

Primary Approval Statement

I have read WuXi AppTec, Inc.'s client protocol, **9107015-2 -** ISO Intracutaneous Reactivity Test. I accept the test method described. I understand that my approval will be valid until one or both of the following occur:

1. The protocol is revised and a new version letter is issued.
2. The Primary Approver's position with the Sponsor company is terminated or changes, whichever may occur first.

NAME: Jennifer Shaw TITLE: Subcontracting

SIGNATURE: Jennifer Shaw DATE: 09 May 2011

Associate(s) Approval Statement

The Primary Approver (above) has authorized the following Associate(s) to accept the responsibility for submitting samples for testing under this protocol. Each associate understands that their authorization for submission will be valid until one or more of the following has occurred:

1. The protocol has been revised and new version letter has been issued.
2. The primary Approver's position with the Sponsor company is terminated or changes, whichever may occur first.
3. Any of the Associate's positions with the Sponsor company are terminated or change, whichever may occur first.
4. The Primary Approver has removed any Associate's authorization by sending a signed and dated letter to WuXi AppTec, ATTN: Client Services.

☐ I do not wish to have an Associate(s) authorized to initiate testing of samples under this protocol.

☒ I do wish to have the following Associate(s) authorized to initiate testing of samples under this protocol.

Thor Rollins
Name of Associate (please print)

Scott Dimond
Name of Associate (please print)

Tarika Onishi
Name of Associate (please print)

Mindy Schwanevelt
Name of Associate (please print)

WUXI APPTEC, INC.:

NAME: Michelle Dietzel
Study Director

SIGNATURE: Michelle Dietzel
Study Director

DATE: 11/15/11

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

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WuXi AppTec

Wuxi AppTec, Inc.

GLP COMPLIANT TEST PROTOCOL AMENDMENT

1.0 **Amendment Number:** 1

2.0 **Effective Date:** December 23, 2011

3.0 **Amendment Date:** December 23, 2011

4.0 **Sponsor:** Nelson Laboratories Inc.
6280 South Redwood Road
Salt Lake City, UT 84123

5.0 **Test Facility:** WuXi AppTec, Inc.
2540 Executive Drive
St. Paul, MN 55120

6.0 **WuXi AppTec Protocol Number:** ~~NA~~ NA RK 1/30/12
9107015-2

7.0 **WuXi AppTec Project Number:** 161562

8.0 **Modification to Protocol, Section :** The study directorship was reassigned from M Dietzel to R. Koslofsky.

9.0 **Reason for Change:** Sponsor requested a change to the test article identification. ①

10.0 **Impact to Protocol Interpretation:** This amendment was needed for study completion. ②

11.0 **Review**
Signatures below represent authorization of the amendment (e.g. authorize change to the SOP and protocol).

NA — Sponsor (if applicable) — Date: NA

[signature] — Study Director — Date: 12/23/11

NA — QA (Applicable only to OECD GLP Studies) — Date: NA

Check applicable box as task is completed:

NA
☐ ☒ Amendment attached to protocol
☒ ☐ Annotation made in protocol
☒ ☐ Special Instructions Worksheet/Study Worksheets Updated
☒ ☐ IACUC Protocol Amended/Updated
☒ ☐ Project Schedules updated
☒ ☐ Project Folder Annotations/Stamps updated
☒ ☐ Critical Phase Audited Re-scheduled
☒ ☐ Cage Card Termination Date updated

Updates Complete:

[signature] — Study Director or Manager — Date: 12/23/11

① WL should read "This amendment was needed for study completion" RK 1/30/12
② WL Should read "This amendment will not impact the study interpretation" RK 1/30/12

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8718

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Nelson Laboratories acceptance criteria was based upon the negative and media controls receiving "0" reactivity grades and positive controls receiving a 3-4 reactivity grades (moderate to severe). The test was considered valid as the control results were within acceptable parameters.

The cell monolayers were examined microscopically. The wells were scored as to the degree of discernable morphological cytotoxicity on a relative scale of 0 to 4:

Conditions of All Cultures	Reactivity	Grade
No cell lysis, intracytoplasmic granules.	None	0
Not more than 20% rounding, occasional lysed cells.	Slight	1
Not more than 50% rounding, no extensive cell lysis.	Mild	2
Not more than 70% rounding and lysed cells.	Moderate	3
Nearly complete cell destruction.	Severe	4

The results from the three wells were averaged to give a final cytotoxicity score.

Procedure: The amount of test material extracted was based on ANSI/AAMI/ISO and USP surface area or weight recommendations. Test articles and controls were extracted in 1X Minimal Essential Media with 5% bovine serum for 24-25 hours at 37 ± 1°C. Multiple well cell culture plates were seeded with a verified quantity of industry standard L-929 cells (ATCC CCL-1) and incubated until approximately 80% confluent. The test extracts were added to the cell monolayers in triplicate. The cells were incubated at 37 ± 1°C with 5 ± 1% CO_2 for 72 ± 3 hours.

Lantos Technologies 3D Fax Service Proprietary and Confidential Page 118 of 535
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NELSON LABORATORIES

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Part 58) Regulations.

Activity	Date
Study Initiation	09 Nov 2011
Audit Performed by Quality Assurance	11 Nov 2011
Audit Results Reported to Study Director	16 Nov 2011
Audit Results Reported to Management	14 Nov 2011

Scientists	Title
Chad Summers	Supervisor
Christine Jensen	Study Director

Data Disposition: The raw data and final report from this study are archived at NLI or an approved off-site location.

Danielle Shoost
Quality Assurance

16 Nov 2011
Date

Lantos Technologies 3 ID Eye Stamped PDF Delivery CDRH Court Order ST
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8178

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NELSON LABORATORIES

FORM TITLE: BIOCOMPATIBILITY PDS / SUBCONTRACTING APPROVAL FORM

PDS NUMBER: 201104121

PDS REVISION: 1

PREPARED FOR SPONSOR		LABORATORY / CONTRACTOR
CONTACT:	Manas Menon	Nelson Laboratories, Inc. P.O. Box 17577 SALT LAKE CITY, UT. 84117-0557 6280 SOUTH REDWOOD ROAD SALT LAKE CITY, UT. 84123-6600 Tel: 801-290-7500 Fax: 801-290-7998 Web Site: www.nelsonlabs.com
COMPANY:	Lantos Technologies	
EMAIL:	~~momenon~~@lantostechnologies.com mcmenon	
PHONE:	617-500-9800	
FAX:		

PROTOCOL SPECIFICATIONS			
PDS INITIATION DATE:	07-Nov-2011	EXPIRATION DATE:	07-Nov-2013
SECTION:	Biocompatibility / Subcontracting		
SAMPLE ID:	Lot # 1 Parts 1-7, 9-11		

TESTS BEING REQUESTED

- ☐ STP0031 Agar Overlay Rev 7
- ☑ STP0032 MEM Elution Rev 7
- ☐ SCX120 Sensitization: Local Lymph Node Assay, per extract
- ☐ SCX240 Irritation: Primary Skin, each
- ☐ N/A
- ☐ N/A

IN VIVO TESTING SUBCONTRACTED TO: WuXi AppTec, Inc.

JUSTIFICATION:

No changes to the Standard Testing Protocols

PROTOCOL SPECIFICATIONS:

Test according to Standard Test Protocols
10 parts total. Please do not use parts that are leaking (this is a part that was damaged during shipping).

The sponsor is responsible for test/control article characterization.
This includes, but is not limited to, identity, strength, purity, and stability.

****PLEASE SIGN, DATE, & RETURN TO NELSON LABORATORIES****

SPONSOR APPROVAL:

SIGNATURE[1]: Manas Menon

DATE: 11/8/2011

PRINT NAME: Manas Menon

☑ **NLI STUDY DIRECTOR:**
☐ **COORDINATOR APPROVAL:**

SIGNATURE: Christine Jensen

DATE: 09 Nov 2011

PRINT NAME: Christine Jensen

[1]SIGNING THIS DOCUMENT SIGNIFIES AN ACCEPTANCE OF THE NELSON LABORATORIES TESTING TERMS AND CONDITIONS ASK ATTACHED OR AS LISTED AT WWW.NELSONLABS.COM/PROTOCOLCONDITIONS.JSP.

FOR OFFICE USE ONLY	See sample submission form	☑ FDA GLP	☐ NON-GLP

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17.3. ISO 10993-10: Part 10: Tests for Irritation and Skin Sensitization; Murine Local Lymph node assay

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

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NELSON LABORATORIES

Sponsor:
Manas Menon
Lantos Technologies
101 Main St., Ste. 1760
Cambridge MA 02142

Murine Local Lymph Node Assay (LLNA)

Summary: Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

Test Article:	Parts 1-3, 1-6, 1-11, 1-27 Lot#1
Nelson Laboratory Number:	607198
Testing Lab:	WuXi AppTec, Inc.

Results: Test article **was not** a potential sensitizer. The test article is considered **negative** for evidence of dermal sensitization.

If you have any questions, please feel free to call or email any of our Subcontracting personnel at 801-290-7500 or subcontracting@nelsonlabs.com. Thank you for testing with Nelson Laboratories, Inc.

Subcontracting Coordinator Jennifer Shaw, B.S. — Date: 01 Feb 2012

P.O. Box 571830 | Murray, UT 84157-1830 U.S.A. • 6280 South Redwood Road | Salt Lake City, UT 84123-6600 U.S.A.
www.nelsonlabs.com • Telephone 801 290 7500 • Fax 801 290 7998 • sales@nelsonlabs.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118
Lantos Technologies 3D Ent Feb 04 PDD Dietary CDRH-FOIA-2014-5942 1-796-8118-535
These results relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NLI terms and conditions at www.nelsonlabs.com

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FINAL STUDY REPORT

STUDY TITLE:	**Murine Local Lymph Node Assay (LLNA)**
PROTOCOL NUMBER:	190856-14
TEST ARTICLE IDENTIFICATION:	Parts 1-3, 1-6, 1-11, 1-27 Lot #1
PERFORMING LABORATORY:	WuXi AppTec, Inc. 2540 Executive Drive St. Paul, MN 55120
SPONSOR:	Nelson Laboratories, Inc. 6280 South Redwood Road Salt Lake City, UT 84123
STUDY NUMBER:	161563
CLIENT MNEMONIC:	NEL05
NLI#:	607198
RESULT SUMMARY:	Test article **was not** a potential sensitizer. The test article is considered **negative** for evidence of dermal sensitization.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

QUALITY ASSURANCE UNIT SUMMARY

The objective of the Quality Assurance Unit is to monitor the conduct and reporting of nonclinical laboratory studies. This study has been performed under Good Laboratory Practices regulations (FDA, 21 CFR, Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies) and in accordance to standard operating procedures and a standard protocol. The Quality Assurance Unit maintains copies of study protocols and standard operating procedures and has inspected this study on the dates listed below. Studies are inspected at time intervals to assure the quality and integrity of the study.

Phase Inspected	Date	Study Director	Management
Injection of Thymidine	01/16/12	01/17/12	01/30/12
Final Report	01/30/12	01/30/12	01/30/12

The findings of these inspections have been reported to management and the Study Director.

Quality Assurance Auditor: Melissa Eilers Date: 1/30/12
Melissa Eilers

GOOD LABORATORY PRACTICES STATEMENT

The study referenced in this report was conducted in compliance with U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR part 58.

The studies not performed by or under the direction of WuXi AppTec, Inc., are exempt from this Good Laboratory Practice Statement and include characterization and stability of the test compound(s)/test article.

Study Director: Date: 1/30/12
Peter Kratz

Professional Personnel Involved:

Teri Tanquist, BS	Vice President of Process Improvement and Operations
Christine Olson, BS	Director of Study Operations
Roxanne Miller, AA, CVT	Associate Director, In-Life Studies
Peter Kratz, MS	Study Director
Jean Mesarich, AA	Client Relations Manager

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

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PURPOSE: The intent of this procedure is to assess the dermal sensitization potential of a test article using the Murine Local Lymph Node Assay (LLNA).

TEST FACILITY: WuXi AppTec, Inc.
2540 Executive Drive
St. Paul, MN 55120

DATE SAMPLE RECEIVED: 11/14/11, 12/22/11
STUDY INITIATION DATE: 11/14/11
STUDY COMPLETION DATE: 01/30/12

TEST ARTICLE IDENTIFICATION

Test Article Name:	Parts 1-3, 1-6, 1-11, 1-27
Lot/Batch #:	1
NLI#:	607198
Sterilization Method:	Non-Sterile
Physical State:	Insoluble Material
Expiration Date:	Not Applicable
Storage Conditions:	Room Temperature
Intended Use/Application:	Unknown

TEST ARTICLE CHARACTERIZATION
The Sponsor was responsible for all test article characterization data as specified in the GLP regulations. The identity, strength, stability, purity, and chemical composition of the test article were solely the responsibility of the Sponsor. The Sponsor was responsible for supplying to the testing laboratory results of these determinations and any others that may have directly impacted the testing performed by the testing laboratory, prior to initiation of testing. Furthermore, it was the responsibility of the Sponsor to ensure that the test article submitted for testing was representative of the final product that was subjected to materials characterization. Any special requirements for handling or storage were arranged in advance of receipt and the test article was received in good condition.

SAMPLE STORAGE
Upon receipt by the Sample Receiving Department, the test samples were placed in a designated, controlled access storage area ensuring proper temperature conditions. Test and control article storage areas are designed to preclude the possibility of mix-ups, contamination, deterioration or damage. The samples remained in the storage area until retrieved by the technician for sample preparation and/or testing.

SAFETY
Appropriate routine safety procedures were followed in handling the test article, unless more cautious procedures were specified by the Sponsor. All applicable WuXi AppTec safety policies and procedures were observed during the performance of the test.

EXPERIMENTAL DESIGN

Experimental Summary
This study was designed to evaluate the skin sensitization potential of a test article by administering an extract of the test article to the skin of mice and measuring the proliferation of cells in lymph nodes draining the exposure site.

The test article extract, vehicle control solution, and a known sensitizer (either 2,4-dinitrobenzenesulfonic acid (DNBS) or 2,4-dinitrochlorobenzene (DNCB)) were applied to the dorsal surface of the ears of mice daily for three days. On Day 5 following initiation of treatment, the animals were administered [*methyl*-^{3}H]thymidine ([^{3}H]TdR) by tail vein injection. Approximately five hours later, the mice were sacrificed, and the radioactivity incorporation into lymphocytes was determined as a measure of cell proliferation.

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

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TABLE 1: TIME COURSE OF ASSAY

DAY 0	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6
T	T	T	-	-	^{3}H	C

T = Topical application of test substance/vehicle.
- = No treatment
^{3}H = 0 hrs – Administration of approximately 20 µCi of [^{3}H]TdR.
+ 5 hrs – Sacrifice and harvest, lymph node cell preparation.
C = Determination of [^{3}H]TdR incorporation into lymph node cells.

Justification For Selection Of The Test System
Preparation and testing of extracts is recognized as an acceptable method for evaluating the sensitization of potential leachables from solid materials. The Sponsor may choose to test an aqueous extract, a non-aqueous extract, or both. The guinea pig maximization sensitization assay has been used historically as the preferred animal assay model.

The LLNA has been reviewed by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the American Society for Testing and Materials (ASTM) and is considered an acceptable alternative assay. WuXi AppTec has validated the assay using aqueous and non-aqueous extracts so that the assay can be applied to devices.

The use of mice in place of guinea pigs is a refinement, since it requires fewer animals of a less sentient species, and it causes less distress and pain in the experimental subject. Female CBA/J mice are preferred for use in the murine local lymph node assay for evaluating dermal sensitization.

Institutional Animal Care and Use Committee (IACUC)
The protocol and any amendments or procedures involving the care or use of animals on this study were reviewed and approved by WuXi AppTec's IACUC prior to the initiation of such procedures.

IACUC Protocol / Effective Date: 07-131B / July, 2010

DEVIATIONS/AMENDMENTS: None.

IDENTIFICATION OF THE TEST SYSTEM

Species/Strain: Swiss mice (*Mus musculus*), CBA/J

Source: Jackson Laboratory

Sex: Female; all animals were nulliparous and not pregnant.

Body Weight Range: There is no required body weight range; weight data are gathered as a general measure of animal health (Table 7). Animals weighed between 19.5 and 25.3g at the start of testing.

Age: All mice were within 8-12 weeks of age at the start of the study. All animals were age-matched to within approximately seven days.

Number: This assay used 15 mice per extract; five test mice, five negative control mice, and five positive control mice.

TABLE 2: ANIMAL NUMBERS AND TREATMENT GROUPS

AQUEOUS DOSE GROUP	CAGE NUMBER	# DOSED	ANIMAL ID NUMBERS
Negative Control	1	5	1 - 5
Positive Control (20% DNBS)	2	5	11 - 15
Test Article	3	5	21 - 25

NON-AQUEOUS DOSE GROUP	CAGE NUMBER	# DOSED	ANIMAL ID NUMBERS
Negative Control	4	5	1 - 5
Positive Control (0.5% DNCB)	5	5	11 - 15
Test Article	6	5	21 - 25

Questions? Contact FDA/CDRH/OCE/DIDEA CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

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Animal Identification: Cage cards were labeled and individual animals were identified according to WuXi AppTec SOP ILS-0112.

HUSBANDRY

Receipt: Animals were received on 12/20/11 according to WuXi AppTec SOP: # ILS-0092. The animals were acclimated for a minimum of 5 days within the designated animal room. Each animal was examined for signs of disease and injury prior to entry into the research area.

Housing: Animals were individually housed in suspended stainless steel cages. Housing dimensions complied with AAALAC International recommendations and NIH guidelines for this species.

Environment: The environmental conditions in the animal rooms were maintained according to WuXi AppTec SOP: # ILS-0018. The laboratory and animal rooms were maintained as limited-access facilities.

Diet: Animals were supplied with certified commercial rodent chow. No known contaminants present in the feed were expected to interfere with the test results.

Water: The animals were given free access to water obtained from the St. Paul municipal water supply. No known contaminants present in the water were expected to interfere with the results.

TEST MATERIAL PREPARATION

The Sponsor-submitted test device was prepared and extracted as requested by the Sponsor and according to WuXi AppTec SOP ALS-0260. A pretest to determine solvent compatibility indicated that the dimethyl sulfoxide (DMSO) turned the extract solution cloudy, but all components were stable to polyethylene glycol (PEG), so PEG was selected as the non-aqueous extraction vehicle.

According to the Sponsor, the test article consisted of clear tubing with pink liquid attached to a clear hub with blue and yellow O-rings, a black rubber tip, and a white zip tie. The test article was extracted intact, placed into test tubes and prepared at a ratio of 60 cm^2 to 20 mL of extraction vehicle. Per Sponsor provided instructions the test article was not used if the device was leaking fluid.

TABLE 3: TEST ARTICLE RECORD

TEST DOSE AND VEHICLE	TEST ARTICLE AREA (cm^2)	VEHICLE AMOUNT (mL)	NUMBER OF TEST ARTICLE DEVICES USED
Dose 1 - 0.9% Normal Saline (NS)	51.6	17.2	1
Dose 2 and 3 - 0.9% Normal Saline (NS)	51.6	17.2	1
Dose 1 - Polyethylene glycol (PEG)	51.6	17.2	1
Dose 2 and 3 - Polyethylene glycol (PEG)	51.6	17.2	1

TEST ARTICLE EXTRACTION

The extraction mixtures and corresponding control blanks were incubated for 72 ± 2 hours at 50 ± 2 °C. At the start of the extraction, the solutions appeared clear and free of particulates. The extracts were agitated during the course of the extraction period. At the end of the extraction period, the vessels were shaken well and the liquid aseptically decanted into a sterile glass vessel. The test article was observed after all extractions to be intact with no macroscopically observable degradation. The extracts were not filtered prior to use, were maintained at room temperature and used within 24 hours of preparation. See Tables 2-4. To facilitate dispersion and dermal exposure the aqueous extract was mixed 5:1 with a 6% aqueous solution of a detergent, Pluronic-L92. The non-aqueous extract (PEG) was dosed neat.

Questions? Contact FDA/CDRH/OCE/DIDT at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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TABLE 4: EXTRACTION RECORD

TEST PHASE AND VEHICLE	EXTRACTION TEMPERATURE (IN)	DATE/TIME OF EXTRACTION START	EXTRACTION TEMPERATURE (OUT)	DATE/TIME OF EXTRACTION END
Dose 1 - NS	50.2 °C	01/08/12 7:38 am	50.2 °C	01/11/12 6:30 am
Dose 2 and 3 - NS	50.0 °C	01/09/12 10:20 am	50.2 °C	01/12/12 8:28 am
Dose 1 –PEG	50.2 °C	01/08/12 7:38 am	50.2 °C	01/11/12 6:30 am
Dose 2 and 3 -PEG	50.0 °C	01/09/12 10:20 am	50.2 °C	01/12/12 8:28 am

TABLE 5: VEHICLE RECORD

VEHICLE IDENTIFICATION:	TEST PHASE	LOT #	SUPPLIED BY:	EXPIRATION
0.9% Normal Saline (NS)	Dose 1, 2, & 3	J1E609	Braun	11/2013
Polyethylene glycol (PEG)	Dose 1, 2, & 3	111839	Fisher	01/03/14

TABLE 6: ADDITIONAL TEST REAGENT RECORD

ADDITIONAL TEST REAGENTS:	LOT #	SUPPLIED BY:	EXPIRATION
Pluronic L-92	WPHE543C	BASF	01/15/12
DNBS	MKAA2164V	Aldrich	01/15/12
Normal Saline (NS) Positive Control	J0S679	Braun	06/2013
DNCB	A0296107	Acros	01/29/12
Polyethylene glycol (PEG) Positive Control	103186	Fisher	07/01/14

SELECTION OF ANIMALS: Animals were randomly placed in cages upon receipt and were placed on study as available. Animals considered unsuitable due to poor health were excluded from the study.

TEST AND CONTROL ARTICLE ADMINISTRATION

Five test mice were administered a 25-µL dose of test article extract applied to the dorsum of each ear daily for three days. Five negative control mice received the same volume of vehicle administered in the same way, and five positive control mice received a known sensitizer, either 20% 2,4-dinitrobenzenesulfonic acid in normal saline (20% DNBS) or 0.5% dinitrochlorobenzene in PEG (0.5% DNCB).

HEALTH OBSERVATIONS

Each animal was observed daily for general health and clinical signs of toxicity. Animal weights were recorded on Day 0 and Day 5 (Table 7). Attention was paid to the ears for gross evidence of irritation (inflammation).

Questions? Contact FDA/CDRH/OCE/DIDSI/CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

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TABLE 7: BODY WEIGHT CHANGES

DOSE GROUP	ANIMAL NUMBER	AQUEOUS		
		DAY 0 (g)	DAY 5 (g)	CHANGE (g)
Negative Control	1	23.4	24.2	0.8
	2	22.6	22.7	0.1
	3	21.9	22.6	0.7
	4	21.9	23.2	1.3
	5	23.2	23.1	-0.1
Positive Control (20% DNBS)	11	25.3	24.5	-0.8
	12	22.0	22.1	0.1
	13	21.4	21.6	0.2
	14	20.4	20.9	0.5
	15	19.5	20.6	1.1
Test Article	21	24.4	24.1	-0.3
	22	22.8	22.5	-0.3
	23	21.5	22.1	0.6
	24	21.0	21.6	0.6
	25	21.3	21.9	0.6
DOSE GROUP	ANIMAL NUMBER	NON-AQUEOUS		
		DAY 0 (g)	DAY 5 (g)	CHANGE (g)
Negative Control	1	23.0	24.1	1.1
	2	20.9	23.4	2.5
	3	23.7	24.2	0.5
	4	21.7	21.9	0.2
	5	20.5	23.5	3.0
Positive Control (0.5% DNCB)	11	22.4	23.7	1.3
	12	23.4	23.1	-0.3
	13	21.6	22.4	0.8
	14	22.1	22.6	0.5
	15	21.9	20.2	-1.7
Test Article	21	21.5	21.7	0.2
	22	22.4	22.8	0.4
	23	23.7	23.4	-0.3
	24	22.5	21.4	-1.1
	25	24.5	23.5	-1.0

ASSESSMENT OF CELL PROLIFERATION

On the fifth day following initiation of dosing with test or control article each animal was injected with approximately 20 µCi of [^{3}H]TdR via tail vein. This radioisotope is rapidly incorporated into mitotically active cells (dividing lymphocytes). The isotope injection is a critical phase and intravenous delivery was monitored by the inclusion of 0.1% Evans Blue dye. The auricular lymph nodes were then dissected bilaterally, isolated lymph node cells prepared, and radioactivity incorporation measured. The lymph nodes from each mouse were pooled but individual animal data were collected and remained separate from the other animals on test.

TERMINATION

Approximately five hours following administration of [^{3}H]TdR the mice were sacrificed by CO_2 gas asphyxiation.

TEST EVALUATION

Positive Response

The test article may be considered a potential skin sensitizer if its stimulation index (SI) is greater than or equal to 3.0. Values at or very near 3.0 (3.01-3.30) may justify additional testing to verify results. Overall evaluation encompassed the SI, statistical analysis, toxicity, vehicle consistency, and the controls.

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

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Equivocal Response
Any equivocal response was clarified by considering statistical analyses, structural relationships, available toxicity information, and dose selection and may necessitate additional testing to confirm.

ASSAY VALIDITY
The assay is considered valid if the stimulation index for the positive control was greater than 3.0 and there was good delivery of radioisotope to all animals. Insufficient delivery of isotope may necessitate exclusion of that animal as invalid. Sound scientific judgment was applied to all data for final conclusions.

METHOD FOR CONTROL OF BIAS
Animals selected for the study were from a larger pool of animals and were examined to ensure that the were within the required age range and were not exhibiting abnormal clinical signs at entry into the study. Selected animals were identified and weighed to the nearest 0.1 gram before being randomly assigned to test and control groups.

DATA ANALYSIS
The radioactivity in the lymph nodes harvested from each mouse in its respective group was measured as disintegrations per minute (DPM). The average DPM was calculated for each group and compared to the average DPM of the control group (Tables 8 and 9).

The stimulation index (SI), is calculated as follows:

$$SI = \frac{\text{Average Radioactivity(test)}}{\text{Average Radioactivity(negative control)}}$$

A stimulation index greater than or equal to 3.0 indicates the test material may be a sensitizer.

STATISTICAL METHODS
Statistical analyses were conducted using a one way analysis of variance (ANOVA) to compare the treatment groups (Test vs. Control). Probability (p) values of 0.05 or less were considered significant (Table 10).

RECORD RETENTION: A certified copy of the original final report and all raw data pertinent to this study will be stored at WuXi AppTec, Inc., 2540 Executive Drive, St. Paul, MN 55120. It was the responsibility of the Sponsor to retain a sample of the test article.

COMPLIANCE

Animal Welfare
WuXi AppTec, Inc. maintains the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International accreditation. All applicable portions of the study will also conform to the following regulations and guidelines regarding animal care and welfare:

- NIH guidelines as reported in the "Guide for the Care and Use of Laboratory Animals," National Research Council of the National Academies, eighth edition, 2011;
- (OPRR), "Public Health Service Policy on Humane Care and Use of Laboratory Animals," Health Research Extension Act of 1985 (Public Law 99-158), Revised 1986;
- USDA, Department of Agriculture, Animal and Plant Health Inspection Service, 9 CFR, Parts 1, 2, and 3, *Animal Welfare*, Final Rule 1989; and
- WuXi AppTec Policy on Humane Care.

International Standard
ISO 10993-10:2010 Standard, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization, Pages 16-18.

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

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TEST ARTICLE DISPOSITION: Unused test samples remain in the storage area until all testing is completed. Once completed, the remaining samples were discarded or returned as requested by the Sponsor.

RESULTS

All of the animals on study were in good health and most gained weight over the course of the study. The Stimulation Index was 3.83 for the aqueous NS positive control and 4.55 for the non-aqueous PEG positive control. These results indicate a valid assay.

TABLE 8: RADIOISOTOPE UPTAKE AND STIMULATION INDEX – AQUEOUS NS

TREATMENT & ANIMAL ID	[^{3}H]-THYMIDINE UPTAKE (DPM)	MEAN DPM (± σ)	STIMULATION INDEX
Negative Control; 1	306.7	303.1 ± 67.6	1.00
Negative Control; 2	191.4		
Negative Control; 3	362.3		
Negative Control; 4	304.0		
Negative Control; 5	350.9		
Positive Control; 11	958.0	1,160.8 ± 168.3	3.83
Positive Control; 12	1,293.9		
Positive Control; 13	1,060.4		
Positive Control; 14	1,123.7		
Positive Control; 15	1,368.2		
Test Article Extract; 21	490.9	746.6 ± 220.0	2.46
Test Article Extract; 22	771.6		
Test Article Extract; 23	585.6		
Test Article Extract; 24	1,054.3		
Test Article Extract; 25	830.5		

TABLE 9: RADIOISOTOPE UPTAKE AND STIMULATION INDEX – NON-AQUEOUS PEG

TREATMENT & ANIMAL ID	[^{3}H]-THYMIDINE UPTAKE (DPM)	MEAN DPM (± σ)	STIMULATION INDEX
Negative Control; 1	758.5	697.3 ± 320.6	1.00
Negative Control; 2	446.6		
Negative Control; 3	1,226.0		
Negative Control; 4	467.2		
Negative Control; 5	588.2		
Positive Control; 11	5,198.7	3,172.6 ± 1146.5	4.55
Positive Control; 12	2,580.7		
Positive Control; 13	2,742.8		
Positive Control; 14	2,432.9		
Positive Control; 15	2,907.7		
Test Article Extract; 21	588.5	900.0 ± 244.8	1.29
Test Article Extract; 22	840.5		
Test Article Extract; 23	999.0		
Test Article Extract; 24	1,250.9		
Test Article Extract; 25	821.0		

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

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TABLE 10: STATISTICAL COMPARISONS

GROUP	TEST		NEGATIVE CONTROL		STATISTICALLY SIGNIFICANT?
	MEAN DPM	σ	MEAN DPM	σ	
AQUEOUS (NS) EXTRACT	746.6	220.0	303.1	67.6	YES (p = 0.003)
AQUEOUS POSITIVE CONTROL (DNBS)	1160.8	168.3	303.1	67.6	YES (p = 0.000)
NON–AQUEOUS (PEG) EXTRACT	900.0	244.8	697.3	320.6	NO (p = 0.294)
NON–AQUEOUS POSITIVE CONTROL (DNCB)	3172.6	1146.5	697.3	320.6	YES (p = 0.002)

ANALYSIS AND CONCLUSION

Statistical comparisons show no significant differences between the non-aqueous test extract and the non-aqueous negative controls (Table 10). There was a statistically significant difference between aqueous test extract and the aqueous negative control. Despite the statistically significant difference between the aqueous test article and the aqueous negative control the test article SI was below 3.0, indicating no sensitizing reaction from the aqueous test article. The NS test article extract gave a stimulation index of 2.46. The PEG test article extract gave a stimulation index of 1.29. Based on these findings, the test article was not a potential sensitizer. This indicates that the requirements of the Murine Local Lymph Node Assay have been met by the test article. The test article is considered **negative** for evidence of dermal sensitization.

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

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REFERENCES

American Society for Testing and Materials (ASTM) Designation: F619-08. "Standard Practice for Extraction of Medical Plastics" (2008).

American Society for Testing and Materials (ASTM) Designation: F2148-07. "Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA)" (2007).

Dearman, Rebecca J.; Wright, Zoë M.; Basketter, David A.; Ryan, Cindy A.; Gerberick, G. Frank; and Kimber, Ian. "The Suitability of Hexyl Cinnamic Aldehyde as a Calibrant for the Murine Local Lymph Node Assay," Contact Dermatitis 44: pp. 357-361 (2001).

Gerberick, G. Frank; Ryan, Cindy A.; Kimber, Ian; Dearman, Rebecca J.; Lea, Linda J.; and Basketter, David A.. "Local Lymph Node Assay: Validation Assessment for Regulatory Purposes," American Journal of Contact Dermatitis 11: pp. 3-18 (2000).

ICCVAM Immunotoxicology Working Group Recommended Protocol for the Murine Local Lymph Node Assay (LLNA): Testing of Chemicals for Contact Sensitizing (Allergic Contact Dermatitis [ACD]) Potential, January 2001.

ISO 10933-12:2007 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Material.

Organisation for Economic Co-operation and Development, OECD Guidelines for Testing Chemicals, Guideline 429: Skin Sensitisation: Local Lymph Node Assay, adopted April 24, 2002.

Ryan, C. A., Cruse, L. W.; Skinner, R. A.; Dearman, R. J.; Kimber, I.; and Gerberick, G.F. "Examination of a Vehicle for Use with Water Soluble Materials in the Murine Local Lymph Node Assay," Food and Chemical Toxicology 40: pp. 1719-1725 (2002).

United States Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances, Health Effects Test Guidelines. "OPPTS 870.2600 Skin Sensitization" (2003).

WuXi AppTec Reference Library Contents, Form ALS-4650-1

WuXi AppTec SOP: ALS-0260, Sample Extraction Procedures

WuXi AppTec SOP: ILS-0018, Environmental Conditions in the Animal Facility

WuXi AppTec SOP: ILS-0092, Receiving Shipments of Animals

WuXi AppTec SOP: ILS-0112, Animal Identification

WuXi AppTec SOP: ILS-0155, ISO Guinea Pig Maximization Sensitization Test

WuXi AppTec SOP: ILS-0233, Proper Handling of Sick, Injured, and/or Moribund Animals

WuXi AppTec SOP: ILS-0810, Murine Local Lymph Node Assay

WuXi AppTec SOP: TRG-0300, Preparation of Biomaterials for Extraction

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

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WuXi AppTec

Protocol and Test Request Form

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

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WuXi AppTec

(For Laboratory Use Only)

WuXi AppTec Study # 101503

WuXi AppTec

PROTOCOL TITLE: MURINE LOCAL LYMPH NODE ASSAY (LLNA)

TEST CODE: 190856

PERFORMING LABORATORY: WuXi AppTec, Inc.
2540 Executive Drive
St. Paul, MN 55120

EFFECTIVE DATE: 8 August 2011

GLP PROTOCOL: 190856-14

Quality Assurance has reviewed this protocol for compliance with applicable regulatory requirements and internal procedures.

PROPRIETARY INFORMATION

This document is provided with the understanding that the recipient shall recognize it contains WuXi AppTec proprietary information, that it shall be kept confidential by the person and/or company to whom it is addressed, and that it shall be used for no other purpose than assessing and approving the described services to be performed by WuXi AppTec or for the purpose of regulatory submission.

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1.0 **PURPOSE**
The intent of this procedure is to assess the dermal sensitization potential of a test article using the Murine Local Lymph Node Assay (LLNA).

2.0 **TEST FACILITY:** WuXi AppTec, Inc.
2540 Executive Drive
St. Paul, MN 55120

3.0 **SCHEDULING AND DISCLAIMER**

3.1 Test protocol initiation is generally within 10 working days after receipt of the test article, a signed protocol/Client Approval form, and a signed test request form. The Client Approval form and the test request form serve as addenda to this protocol. Written notification of the proposed initiation and completion dates will be provided at the time the test article and signed protocol are received by the laboratory. The estimated testing time is 16 days. Verbal results will be available from the Study Director upon completion of the study with the written report to follow approximately 10 working days after completion of the study.

3.2 Testing is performed in strict adherence to WuXi AppTec standard operating procedures (SOPs) which have been constructed to cover all aspects of the work including, but not limited to, receipt, identification, log-in and tracking of test article(s). Additionally, each test is assigned a unique Project Number. This number is used for identification during the course of the test.

3.3 If a test, or a portion of it, must be repeated due to failure by WuXi AppTec to adhere to specified procedures, it will be repeated free of charge. If a test, or a portion of it, must be repeated due to failure of internal controls or failure to meet assay validity requirements, it will be repeated free of charge. "Methods Development" fees shall be assessed, however, if the test article and test system require modifications due to complexity and difficulty of testing.

3.4 If the Sponsor requests a repeat test, they will be charged for an additional test.

3.5 The Sponsor is responsible for any rejection of the final report by the regulatory agency concerning report format, pagination, etc. To prevent rejection, the Sponsor should carefully review the WuXi AppTec final report and notify WuXi AppTec of any perceived deficiencies in these areas before submission of the report to the regulatory agency. WuXi AppTec will make reasonable changes deemed necessary by the Sponsor, without altering the technical data.

3.6 Neither the name of WuXi AppTec nor any of its employees are to be used in advertising or other promotion without written consent from WuXi AppTec.

4.0 **TEST ARTICLE IDENTIFICATION**
Test article information to be included in the final report will be provided solely by the Sponsor on the WuXi AppTec test request form attached to this protocol.

5.0 **TEST ARTICLE CHARACTERIZATION**
The Sponsor is responsible for all test article characterization data as specified in the Good Laboratory Practice (GLP) regulations. The identity, strength, stability, purity, and chemical composition of the test article is solely the responsibility of the Sponsor. The Sponsor is responsible for supplying to the testing laboratory results of these determinations and any others that may directly impact the testing performed by the testing laboratory, prior to initiation of testing.

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

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Furthermore, it is the responsibility of the Sponsor to ensure that the test article submitted for testing is representative of the final product that will be subjected to materials characterization. Any special requirements for handling or storage must be arranged in advance of receipt and the test article must be received in good condition.

6.0 SAFETY

Appropriate routine safety procedures will be followed in handling the test article, unless more cautious procedures are specified by the Sponsor. All applicable WuXi AppTec safety policies and procedures will be observed during the performance of the test.

7.0 EXPERIMENTAL DESIGN

7.1 Experimental Overview

This study was designed to evaluate the skin sensitization potential of a test article by administering an extract of the test article to the skin of mice and measuring the proliferation of cells in lymph nodes draining the exposure site.

This study is designed to evaluate the skin sensitization potential of a test article by administering topically to the ears of mice and measuring the proliferation of cells in lymph nodes draining the exposure site. The test article may be an extract (aqueous and / or non-aqueous) or a dissolved solid. Aqueous extracts will be performed using sterile normal saline (NS). Non-aqueous extracts will be performed using dimethyl sulfoxide (DMSO), or, if the test article is incompatible with DMSO, polyethylene glycol (PEG).

The test article (extracts or solution), vehicle control solution in extract solvents, or the known sensitizer 2,4-dinitrobenzenesulfonic acid (DNBS) or dinitrochlorobenzene (DNCB) will be applied bilaterally to the dorsal surface of the ears of mice daily for three consecutive days. This will be followed by two days of no treatment. On Day 5, the animals will be administered [*methyl*-^{3}H]thymidine ([^{3}H]TdR) by tail vein injection. Approximately five hours later the mice will be sacrificed, their auricular lymph nodes collected, and the radioactivity incorporation into the lymph node cells will be determined as a measure of cell proliferation.

TABLE 1 – TIME COURSE OF ASSAY

DAY 0	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6
T	T	T	-	-	^{3}H	C

T = Topical application of test substance/vehicle.
- = No treatment
^{3}H = 0 hrs – Administration of approximately 20 µCi of [^{3}H]TdR.
+ 5 hrs – Sacrifice and harvest, lymph node cell preparation.
C = Determination of [^{3}H]TdR incorporation into lymph node cells.

TABLE 2 – TREATMENT GROUP DISTRIBUTION

DOSE GROUP	AQUEOUS EXTRACT	NON-AQUEOUS EXTRACT
Negative Control [vehicle]	5 mice	5 mice
Positive Control (20% DNBS) aqueous	5 mice	NA
Positive Control (0.5% DNCB) non-aqueous	NA	5 mice
Test Article	5 mice	5 mice

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

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7.2 **Justification For Selection Of The Test System**
Preparation and testing of extracts is recognized as an acceptable method for evaluating the sensitization potential of potential leachables from solid materials. The Sponsor may choose to test an aqueous extract, a nonaqueous extract, or both. The Guinea Pig Maximization Sensitization Assay has been used historically as the preferred animal assay model. The LLNA has been reviewed by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), International Organization for Standardization (ISO), and the American Society for Testing and Materials (ASTM) and is considered an acceptable alternative assay.

WuXi AppTec has validated the assay using aqueous and nonaqueous extracts so that the assay can be applied to devices. The use of mice in place of guinea pigs is a refinement, since it requires fewer animals of a less sentient species, and it causes less distress and pain in the experimental subject. Female CBA/J mice are preferred for use in the Murine Local Lymph Node Assay for evaluating dermal sensitization.

7.3 **Institutional Animal Care and Use Committee (IACUC)**
The protocol and any amendments or procedures involving the care or use of animals on this study will be reviewed and approved by WuXi AppTec's IACUC prior to the initiation of such procedures.

IACUC Protocol/Effective Date: 07-131B/July, 2010

It has been determined that no sedation, analgesia, or anesthesia is necessary in this procedure. In the unlikely event that an animal should become sick or injured, euthanasia or veterinary care will be conducted according to WuXi AppTec SOP: ILS-0233 and current veterinary medical practices. The objectives of the study will be given full consideration prior to any decisions and the study Sponsor will be advised.

7.4 **Amendments / Deviations**
If it becomes necessary to make changes in the approved protocol, the revisions and reasons for changes will be documented, signed by the Study Director, dated, maintained with the protocol and reported to the Sponsor. If an event occurs which may have an effect on the validity of the study, the Sponsor will be notified as soon as is practical. If the Study Director is unable to complete the study, an alternate Study Director with full responsibility and authority regarding the study will be assigned.

8.0 IDENTIFICATION OF THE TEST SYSTEM

8.1 **Species / Strain:** Swiss mice (*Mus musculus*), CBA/J

8.2 **Source:** The animal source is a registered commercial breeding laboratory.

8.3 **Sex:** Females. All animals used shall be nulliparous and non-pregnant

8.4 **Body Weight Range:** There is no required body weight range at the experimental start of the study.

8.5 **Age:** All mice will be within 8-12 weeks of age. All animals will be age-matched to within seven days.

8.6 **Number:** This standard assay uses 15 mice per extract vehicle; five test mice, five negative control mice, and five positive control mice.

8.7 **Animal Identification:** Cage cards will be labeled and individual animals will be identified according to WuXi AppTec SOP ILS-0112.

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

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8.8 **Husbandry**

8.8.1 **Receipt And Acclimation Period**
Receipt will be according to WuXi AppTec SOP ILS-0092. The animals will be acclimated for a minimum of 5 days under the same conditions as the actual test.

8.8.2 **Housing**
Mice will be group housed according to treatment group, five animals per group, in polycarbonate cages with contact bedding. Housing density will comply with the NIH and AAALAC International guidelines for this species.

8.8.3 **Environment**
The environmental conditions in the animal rooms will be maintained according to WuXi AppTec SOP ILS-0018. The temperature, humidity, air handling and photoperiod will meet the AAALAC International recommendations for this species. The laboratory and animal rooms will be maintained as limited-access facilities.

8.8.4 **Diet**
Animals will be supplied with certified commercial feed, *ad libitum*. There are no known contaminants present in the feed expected to interfere with the test results.

8.8.5 **Water**
Animals will be supplied with potable water, *ad libitum*, from the St. Paul municipal water supply. There are no known contaminants present in the water expected to interfere with the test results.

9.0 **TEST METHOD**

9.1 **Test Article Preparation**
The Sponsor-submitted test article will be prepared and extracted as indicated on the test request form attached to this protocol and according to ASTM F619 or ISO 10993-12 and WuXi AppTec SOPs TRG-0300 and ALS-0260. Routinely, only two vehicles are utilized by WuXi AppTec; sterile normal saline (NS) and dimethylsulfoxide (DMSO). To facilitate dispersion and dermal exposure the aqueous extracts are mixed 5:1 with a detergent, Pluronic-L92. The non-aqueous extracts (DMSO) are dosed neat. The extracts will be stored at room temperature and used within 24 hours of preparation.

Solid test substances will be dissolved in Sponsor-designated appropriate solvents or vehicles at a ratio of 4 g to 20 mL and dosed neat. Non-aqueous liquid test substances may be dosed directly. Aqueous liquids received for testing must be mixed with Pluronic-L92 in a 5:1 ratio before dosing.

A test article that degrades in DMSO requires the use of an alternate non-aqueous vehicle, polyethylene glycol (PEG). Although an acetone/olive oil (AOO) solution is specified as a suitable nonpolar solvent by ASTM F 2148-07 and ISO 10993-10:2010, PEG has been validated and is more suited to higher temperature extraction conditions.

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9.2 **Test And Control Article Administration**
Five test mice will be administered a 25-µL dose of test article extract applied to the dorsum of each ear daily for three days. The applications will be performed at intervals of 24 ± 2 hours. Five negative control mice will receive the same volume of vehicle administered in the same way, and five positive control mice will receive a known sensitizer, either 20% 2,4-dinitrobenzenesulfonic acid in normal saline (20% DNBS) or 0.5% dinitrochlorobenzene in DMSO or PEG (0.5% DNCB).

9.3 **Health Observations**
Each animal will be observed daily for general health and clinical signs of toxicity. Animal weights will be recorded on Days 0 and 5. Attention will be paid to the ears for gross evidence of irritation (inflammation).

9.4 **Assessment Of Cell Proliferation**
On the fifth day following initiation of dosing with test or control article (72 ± 2 hours after the last ear dosing), each animal will be injected with approximately 20 µCi of [^{3}H]TdR via tail vein. This radioisotope is rapidly incorporated into mitotically active cells (dividing lymphocytes). The isotope injection is a critical phase and intravenous (IV) delivery is monitored by the inclusion of 0.1% Evans Blue dye. If two attempts at IV injection are unsuccessful, the [^{3}H]TdR solution will be delivered via intraperitoneal (IP) injection.

9.5 **Termination**
Approximately 5 hours following administration of [^{3}H]TdR, the mice will be sacrificed by CO_2 gas asphyxiation. The auricular lymph nodes will be dissected bilaterally, isolated lymph node cells prepared, and radioactivity incorporation measured. Each mouse will have pooled lymph nodes, but individual animal data will be collected.

10.0 TEST EVALUATION

10.1 **Positive Response**
The test article may be considered a potential skin sensitizer if its stimulation index is greater than or equal to 3.0. Values at or very near 3.0 (3.01-3.30) may justify additional testing to verify results. Overall evaluation should encompass the SI, statistical analysis, toxicity, vehicle consistency, and the controls.

10.2 **Equivocal Response**
Any equivocal responses should be clarified by considering statistical analyses, structural relationships, available toxicity information, and dose selection and may necessitate additional testing to confirm.

11.0 ASSAY VALIDITY

The assay is considered valid if the stimulation index for the positive control(s) is greater than or equal to 3.0 and there was good delivery of radioisotope to all animals. Insufficient delivery of isotope may necessitate exclusion of that animal as an outlier. A stimulation index of less than 3.0 for the positive control(s), can result in the need for a retest. Sound scientific judgment will be applied to all data for final conclusions.

12.0 METHOD FOR CONTROL OF BIAS

Animals selected for the study will be from a larger pool of animals and will be examined to ensure that they are within age range and are not exhibiting abnormal clinical signs at entry into study. Selected animals will be identified and weighed to the nearest 0.1 gram. The animals will be randomly assigned to test and control groups.

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13.0 DATA ANALYSIS

The radioactivity in the lymph nodes harvested from each mouse in their respective groups will be measured as disintegrations per minute (DPM). The average DPM is calculated for each group and compared to the average DPM of the negative control group.

The stimulation index (SI), will be calculated as follows:

$$SI = \frac{\text{Average Radioactivity(test)}}{\text{Average Radioactivity(negative control)}}$$

A stimulation index greater than or equal to 3.0 indicates the test material may be a sensitizer in the LLNA. A small increase in SI may also be induced by agents that are irritants.

Group means of individual animal body weights will be compared between test and control groups.

14.0 STATISTICAL METHODS

Statistical analysis will be conducted comparing the treatment groups (test or positive control versus negative control). The statistical method used for the data will be a one way Analysis of Variance (ANOVA) or two-sample t-test assuming equal variances. Probability (p) values of 0.05 or less will be considered significant. Other descriptive statistics may be applied, as appropriate, to verify statistically significant differences in DPM and subsequent SI between groups.

15.0 FINAL REPORT

The final report will include but will not be limited to: the test substance, controls and vehicles, the date of the study initiation and completion, the purpose as stated in the approved protocol, changes in the approved protocol, identification of the test system, a description of the methods used, results, and conclusion as it relates to the test.

16.0 RECORD RETENTION

16.1 Study Specific Documents

All of the original raw data developed exclusively for this study shall be retained according to WuXi AppTec, Inc.'s standard operating procedures for archival. These original data include, but are not limited to the following:

16.1.1 All handwritten and equipment generated raw data for control and test substances.
16.1.2 Any protocol amendments/deviation notifications.
16.1.3 Memoranda, specifications, and other study specific correspondence relating to interpretation and evaluation of data, other than those documents contained in the final study report.
16.1.4 Original signed protocol.
16.1.5 Certified copy of final study report.
16.1.6 Study-specific SOP deviations made during the study.
16.1.7 QA reports for each QA inspection with comments, if conducted under GLP guidelines.

16.2 Facility Specific Documents

The following records shall also be retained according to WuXi AppTec, Inc.'s standard operating procedures for archival. These documents include, but are not limited to, the following:

16.2.1 SOPs which pertain to the study conducted.
16.2.2 Non study-specific SOP deviations made during the course of this study which may affect the results obtained during this study.

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16.2.3 Methods which were used or referenced in the study conducted.
16.2.4 Facility Records: Temperature Logs (ambient, incubator, etc.), Instrument Logs, Calibration and Maintenance Records.
16.2.5 Current job descriptions and summary of experience and training for all personnel involved in the study.

17.0 COMPLIANCE

17.1 Animal Welfare

WuXi AppTec, Inc. maintains the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International accreditation. All applicable portions of the study will also conform to the following regulations and guidelines regarding animal care and welfare:

17.1.1 NIH guidelines as reported in the "Guide for the Care and Use of Laboratory Animals," National Research Council of the National Academies, eighth edition, 2011;

17.1.2 (OPRR), "Public Health Service Policy on Humane Care and Use of Laboratory Animals," Health Research Extension Act of 1985 (Public Law 99-158), Revised 1986;

17.1.3 USDA, Department of Agriculture, Animal and Plant Health Inspection Service, 9 CFR, Parts 1, 2, and 3, *Animal Welfare*, Final Rule 1989; and

17.1.4 WuXi AppTec Policy on Humane Care.

17.2 USDA Animal Welfare Act

In order to satisfy the USDA Animal Welfare Act, the Sponsor agrees that this test is required for the submitted test article to satisfy a state or federal regulatory requirement or is scientifically necessary and such testing is not an unnecessary duplication of a previous test submission by the Sponsor. In addition, the duration of testing is determined by the cited regulatory guidelines and will not exceed the time limits contained therein. This protocol was reviewed and approved by WuXi AppTec's Institutional Animal Care and Use Committee (IACUC) in compliance with the Animal Welfare Act.

17.3 GLP Status

The study will be conducted under GLP compliance (FDA, 21 CFR, Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies). The study will be inspected during at least one phase and the final report will be audited by the WuXi AppTec Quality Assurance unit.

17.4 International Standard

ISO 10993-10: 2010 Standard, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization, Pages 16-18.

18.0 TEST ARTICLE DISPOSITION

It is the responsibility of the Sponsor to retain a sample of the test material. All unused test material will be discarded following study completion unless otherwise requested by the Sponsor.

Langis Technologies 2540 Executive Drive St. Paul, MN 55120 Phone: 651-675-2000 Fax: 651-675-2005 Page 497 of 535
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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19.0 REFERENCES

19.1 American Society for Testing and Materials (ASTM) Designation: F619-08. "Standard Practice for Extraction of Medical Plastics" (2008).

19.2 American Society for Testing and Materials (ASTM) Designation: F2148-07. "Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA)" (2007).

19.3 Dearman, Rebecca J.; Wright, Zoë M.; Basketter, David A.; Ryan, Cindy A.; Gerberick, G. Frank; and Kimber, Ian. "The Suitability of Hexyl Cinnamic Aldehyde as a Calibrant for the Murine Local Lymph Node Assay," Contact Dermatitis 44: pp. 357-361 (2001).

19.4 Gerberick, G. Frank; Ryan, Cindy A.; Kimber, Ian; Dearman, Rebecca J.; Lea, Linda J.; and Basketter, David A.. "Local Lymph Node Assay: Validation Assessment for Regulatory Purposes," American Journal of Contact Dermatitis 11: pp. 3-18 (2000).

19.5 ICCVAM Immunotoxicology Working Group Recommended Protocol for the Murine Local Lymph Node Assay (LLNA): Testing of Chemicals for Contact Sensitizing (Allergic Contact Dermatitis [ACD]) Potential, January 2001.

19.6 ISO 10993-12:2007 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials.

19.7 Ryan, C. A., Cruse, L. W.; Skinner, R. A.; Dearman, R. J.; Kimber, I.; and Gerberick, G.F. "Examination of a Vehicle for Use with Water Soluble Materials in the Murine Local Lymph Node Assay," Food and Chemical Toxicology 40: pp. 1719-1725 (2002).

19.8 United States Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances, Health Effects Test Guidelines. "OPPTS 870.2600 Skin Sensitization" (2003).

19.9 Organisation for Economic Co-operation and Development, OECD Guidelines for Testing Chemicals, Guideline 429: Skin Sensitisation: Local Lymph Node Assay, adopted April 24, 2002.

19.10 WuXi AppTec Reference Library Contents, Form ALS-4650-1

19.11 WuXi AppTec SOP: ALS-0260, Sample Extraction Procedures

19.12 WuXi AppTec SOP: ILS-0018, Environmental Conditions in the Animal Facility

19.13 WuXi AppTec SOP: ILS-0092, Receiving Shipments of Animals

19.14 WuXi AppTec SOP: ILS-0112, Animal Identification

19.15 WuXi AppTec SOP: ILS-0155, ISO Guinea Pig Maximization Sensitization Test

19.16 WuXi AppTec SOP: ILS-0233, Proper Handling of Sick, Injured, and/or Moribund Animals

19.17 WuXi AppTec SOP: ILS-0810, Murine Local Lymph Node Assay

19.18 WuXi AppTec SOP: TRG-0300, Preparation of Biomaterials for Extraction

20.0 VERSION CHANGE SUMMARY – from Version 190856-13 to 190856-14

Section 9.4 – assessment of cell proliferation: Incubation time from last dosing to tritium injection updated to 72 ± 2 hours per ISO guidelines.

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APPENDIX

Adaptations To The Murine Local Lymph Node Assay For The Use With Medical Devices

1.) **Justification For The Use Of Polyethylene Glycol (PEG)**

A pretest is performed (unless otherwise noted), to determine the stability of the test article in dimethyl sulfoxide (DMSO) (this is the preferred extractant for the LLNA). If it is determined that the test article is not stable to DMSO, an extractant vehicle with less solvency will be used to perform the extract. Traditionally, the LLNA uses acetone olive oil (AOO) as the alternative to DMSO for substrates/chemicals, but we have had problems in the past with AOO degrading medical devices. We have been conducting the LLNA using polyethylene glycol (PEG) as the extractant vehicle since 2004.

In subsection 7.4 of Preparation of Positive Controls, ASTM F2148 refers to dimethyl sulfoxide (DMSO) and acetone olive oil (AOO) as recommended, but other permissible extractants are listed in the ICCVAM document following the procedures described in F 619 (PEG is listed in F 619). The ICCVAM document provides additional extractants (N,N-dimethylformamide (DMF), methyl ethyl ketone (MEK), and propylene glycol (PG)) and states that others may be used.

ISO 10993-10:2010 subsection 7.2.2 mentions the use of AOO, DMSO, and DMF as commonly used vehicles for extraction used in the LLNA, but other extract vehicles can be used. In July of 2004, we conducted an internal study to compare AOO and PEG using two known test articles that degraded in DMSO. Our results indicated the use of AOO severely degraded both test articles after an extraction period of 3 days at 37 °C. The PEG extract had no visible effect at the end of the extraction. Both AOO and PEG negative controls did not elicit any substantive lymph node proliferation response. PEG was validated for the use of the Murine Local Lymph Node Assay on August 23, 2004.

2.) **Justification For The Use Of 6.0% Pluronic L92**

Our procedure utilizes 6.0% Pluronic L92 as the surfactant for the aqueous ear dosing. The ASTM F2148 recommends hydroxyethyl cellulose, and ISO 10993-10:2010 subsection 7.2.2, mentions the use of agents like carboxy methyl cellulose or hydroxyethyl cellulose (0.5 % w/v). The surfactant Pluronic L92 was chosen because of its dispersal abilities, low irritation potential, and low acute toxicity profile. Pluronic L92 has been tested in concentrations up to 50% and has shown not to induce positive responses in the LLNA (Ryan *et al.*, 2002).

3.) **Justification For The Use Of 20% 2, 4-Dinitrobenzenesulfonic Acid (DNBS)**

The use of 20% 2, 4-dinitrobenzenesulfonic acid (DNBS) solution as the aqueous positive control, ASTM F2148 suggests the use of neutral buffered formalin. ISO 10993-10:2010 subsection 7.2.4 states the criteria for the positive control should be a well-known weak to moderate contact allergen and suggests the use of mercaptobenzothiazole, hexyl cinnamic aldehyde, and benzocaine. The examples given in ISO 10993-10:2010 might not be suitable for all extraction vehicles and other positive controls maybe selected. DNBS and formaldehyde both have demonstrated to be good skin sensitizers for the use in the LLNA (Ryan *et al.*, 2002). Our in-house testing during the LLNA procedure development stage indicated that the 20% DNBS generated a higher mean Stimulation Index (SI) than formaldehyde.

4.) **Justification For The Use Of PBS / 0.1 % Evans Blue Dye**

The final adaptation is the use of PBS/0.1 % Evans Blue Dye during the tritium injection phase. ASTM F2148 highlights the use of Evans Blue Dye for practice animals in the identification of the lymph nodes. Our purpose is to ensure proper IV delivery of the tritium solution.

All differences noted above have been validation of the Murine Local Lymph Node Assay. Our method has produced consistent results since 2004.

Lantos Testimonial Request #2014-8535
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIA-STATUS@fda.hhs.gov or 301-796-8118

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WuXi AppTec

CLIENT PROTOCOL APPROVAL FORM

PLEASE NOTE THAT TESTING CANNOT BE INITIATED UNTIL THIS FORM IS COMPLETED WITH AN AUTHORIZED SIGNATURE AND THE ORIGINAL IS RETURNED TO WUXI APPTEC.

SPONSOR:

Ms. Jennifer Shaw
Nelson Laboratories, Inc.
6280 South Redwood Road
Salt Lake City, UT 84123 USA

NEL05
Phone #: 801-290-7540
Facsimile: 801-963-2630
E-mail: jshaw@nelsonlabs.com

Primary Approval Statement

I have read WuXi AppTec, Inc.'s client protocol, **190856-14** - Murine Local Lymph Node Assay (LLNA). I accept the test method described. I understand that my approval will be valid until one or both of the following occur:

1. The protocol is revised and a new version letter is issued.
2. The Primary Approver's position with the Sponsor company is terminated or changes, whichever may occur first.

NAME: Tarika Onishi TITLE: Subcontractor

SIGNATURE: [signature] DATE: 19 Aug 2011

Associate(s) Approval Statement

The Primary Approver (above) has authorized the following Associate(s) to accept the responsibility for submitting samples for testing under this protocol. Each associate understands that their authorization for submission will be valid until one or more of the following has occurred:

1. The protocol has been revised and new version letter has been issued.
2. The primary Approver's position with the Sponsor company is terminated or changes, whichever may occur first.
3. Any of the Associate's positions with the Sponsor company are terminated or change, whichever may occur first.
4. The Primary Approver has removed any Associate's authorization by sending a signed and dated letter to WuXi AppTec, ATTN: Client Services.

☐ I do not wish to have an Associate(s) authorized to initiate testing of samples under this protocol.

☒ I do wish to have the following Associate(s) authorized to initiate testing of samples under this protocol.

Jennifer Shaw
Name of Associate (please print)

Mindy Schvaneveldt
Name of Associate (please print)

Scott Dirrand
Name of Associate (please print)

Thor Rollins
Name of Associate (please print)

WUXI APPTEC, INC.:

NAME: Peter Kratz
Study Director

SIGNATURE: [signature]
Study Director

DATE: 11/14/11 ①

① LE, verified by ILS-0970-2A, PK 11/18/11

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

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17.4. ISO 10993-10: Part 10: Tests for Irritation and Skin Sensitization; ISO Rabbit Skin Irritation

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

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GLP REPORT

TEST FACILITY

NAMSA
6750 Wales Road
Northwood, OH 43619
419.666.9455

SPONSOR

Manas Menon
Lantos Technologies
101 Main Street #1760
Cambridge, MA 02115

CONFIDENTIAL

STUDY TITLE

ISO Skin Irritation Study in Rabbits

TEST ARTICLE NAME

Lantos Optical Medium

TEST ARTICLE IDENTIFICATION

Batch 1

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

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Summary

The test article, Lantos Optical Medium, was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization. Two 0.5 mL portions of the test article and control article were topically applied to the skin of each of three rabbits and left in place for 4 hours. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single sample application.

There was no erythema and no edema observed on the skin of the animals treated with the test article. The Primary Irritation Index for the test article was calculated to be 0.0. The response of the test article was categorized as negligible.

Supervisory Personnel:

Colleen M. Stevenson, A.A.
Supervisor, Toxicology

Lisa A. Severhof, B.A.
Assistant Manager, Toxicology

Approved by:

Elizabeth G. Fesl, B.S., M.S., L.A.T.G.
Study Director

3-16-12
Date Completed

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

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

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Statement of GLP Compliance

There were no deviations to the provisions of the FDA Good Laboratory Practice (GLP) Regulations (21 CFR, Part 58) noted during the course of the study.

Study Director: Elizabeth G. Fesl, B.S., M.S., L.A.T.G. 3-16-12 Date

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

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1. Introduction

Purpose
The purpose of this study was to evaluate the test article for the potential to cause skin irritation in the rabbit.

Testing Guidelines
This study was conducted based on the International Organization for Standardization 10993-10, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization.

Dates

Test Article Received:	February 15, 2012
Treatment Started:	March 9, 2012
Observations Concluded:	March 12, 2012

GLP Compliance
The study initiated by protocol signature on February 17, 2012 was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58. A Statement of Quality Assurance Activities was issued with this report.

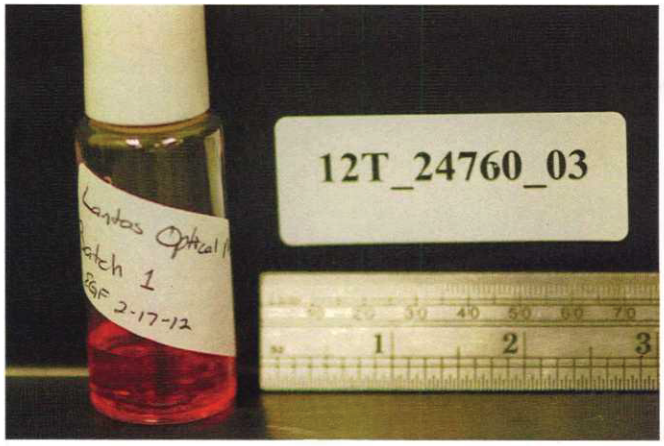
Duplication of Experimental Work
By signature on the protocol, the sponsor confirmed that the conduct of this study did not unnecessarily duplicate previous experiments.

2. Materials

The test article provided by the sponsor was identified and handled as follows:

Test Article Name:	Lantos Optical Medium
Identification:	Batch 1
Stability Testing:	In progress (per sponsor)
Expiration Date:	Stable for duration of intended testing (per sponsor)
Strength, Purity and Composition:	Strength: not applicable because no active ingredients are used to formulate a concentration; Purity: not applicable because the test article does not contain an active ingredient; Composition: water, food safe colorant; isopropyl alcohol
Physical Description of the Test Article:	Red liquid
Storage Conditions:	Room Temperature

Test Article



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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Control Article:	Four-ply gauze supplied by the test facility, was cut into 25 mm x 25 mm sections, moistened with 0.5 mL of saline per section and backed with polyethylene plastic.
Stability Testing:	Marketed product, stability characterized by its labeling
Strength, Purity, Composition or Other Characteristics:	Purity: FDA Quality System Requirements (QSR) as stipulated in 21 CFR Part 820; Composition: 20% rayon, 80% polyester blend
Preparation:	The test article was divided into 0.5 mL portions. The test article was backed with four-ply gauze and polyethylene plastic, and applied to the skin of the rabbit.

3. Test System

Test System

Species:	Rabbit (*Oryctolagus cuniculus*)
Breed:	New Zealand White
Source:	Covance
Sex:	Two male, one female
Body Weight Range:	2.9 kg to 3.1 kg at selection
Age:	Young adult
Acclimation Period:	Minimum 5 days
Number of Animals:	Three
Identification Method:	Ear tag

Justification of Test System

The rabbit (animal) is specified as an appropriate animal model for evaluating potential skin irritants by the current ANSI/AAMI/ISO testing standards. The rabbit is widely used for this purpose and relative ranking of irritant scores can be determined.

4. Animal Management

Husbandry:	Conditions conformed to NAMSA Standard Operating Procedures that are based on the "*Guide for the Care and Use of Laboratory Animals*."
Food:	A commercially available rabbit feed, PROLAB Hi-Fiber Rabbit - 5P25, was provided daily.
Water:	Potable water was provided *ad libitum* through species appropriate water containers or delivered through an automatic watering system.
Contaminants:	Contaminants reasonably expected in feed or water supplies were not believed to have influenced the outcome of this test.
Housing:	Animals were individually housed in stainless steel or plastic suspended cages identified by a card indicating the lab number, animal number, test code, sex, and date dosed.
Environment:	The animal housing room temperature and relative humidity were monitored daily. The temperature for the room was set to 61-72°F and the relative humidity was set to 30-70%. There were no significant temperature or relative humidity excursions that adversely affected the health of the animals. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).
Accreditation:	NAMSA is an AAALAC International accredited facility and is registered with the United States Department of Agriculture. Additionally, NAMSA maintains an approved Animal Welfare Assurance on file with the National Institutes of Health, Office for Laboratory Animal Welfare.
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy, previously unused, animals free from irritation or other dermatological lesions that could interfere with the test were selected.
Veterinary Care:	Standard veterinary medical care was provided in this study.
IACUC:	This procedure has been approved by NAMSA Institutional Animal Care and Use Committees (IACUC), and is reviewed at least annually by the same committees.

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

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5. Method

The animals were weighed and the fur on the back of each animal was clipped with an electric clipper 4 to 24 hours prior to treatment. On the day of treatment, four sites, two on each side of the back and positioned cranially and caudally, were designated on each animal. The sites were free of blemishes that could interfere with the interpretation of results.

A 0.5 mL portion of the test article was applied to one cranial site and one caudal site (two sites per animal) by introduction under a 4 ply gauze layer to an area of skin approximately 25 mm x 25 mm square. The patches were backed with plastic and covered with a nonreactive tape. The control was moistened with 0.5 mL of saline and similarly applied to the opposite cranial and caudal sites. The trunk of each animal was wrapped with an elastic binder to maintain the test patches in position. Animals were returned to their cages after treatment.

After a 4 hour exposure, the binders, tape, and patches were removed. The sites were gently wiped with a gauze sponge dampened with deionized water in an attempt to remove any remaining residue.

Laboratory Observations

1. Animals were observed daily for general health.
2. Body weights were recorded for each animal at pretreatment.
3. Dermal observations for erythema and edema were recorded at 1, 24, 48 and 72 hours after patch removal in accordance with the criteria in Appendix 1.

All times and temperatures reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or NAMSA standard operating procedures.

6. Evaluation and Statistical Analysis

The Primary Irritation Index of the test was calculated following test completion for each animal. The erythema and edema scores obtained at the 24, 48 and 72 hour intervals were added together and divided by the total number of observations. This calculation was conducted separately for the test and control article for each animal. The score for the control was subtracted from the score for the test article to obtain the Primary Irritation Score. The Primary Irritation Score for each animal was added together and divided by the number of animals to obtain the Primary Irritation Index. The Primary Irritation Index was characterized based on the definitions outlined in Appendix 1.

7. Results

All animals were clinically normal throughout the study. Individual results of dermal scoring appear in Appendix 2. No irritation was observed on the skin of the animals. The Primary Irritation Index of the test article was calculated to be 0.0. The irritation calculations are shown below:

Animal Number	Test Score Average	-	Control Score Average	Individual Primary Irritation Score	Combined Primary Irritation Score (CPIS)	Primary Irritation Index (CPIS ÷ 3)	Response Category
81697	0.0	-	0.0	0.0	0.0	0.0	Negligible
81698	0.0	-	0.0	0.0			
81715	0.0	-	0.0	0.0			

8. Conclusion

There was no erythema and no edema observed on the skin of the animals treated with the test article. The Primary Irritation Index for the test article was calculated to be 0.0. The response of the test article was categorized as negligible.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

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9. Quality Assurance

Inspections were conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report was reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Statement of Quality Assurance Activities was issued with the report.

10. Records

All raw data pertaining to this study and a copy of the final report are retained in designated NAMSA archive files.

11. ISO Compliance

All procedures were certified to ISO 13485:2003 and accredited to ISO 17025:2005.

12. References

Code of Federal Regulations (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

Code of Federal Regulations (CFR), Title 16, Part 1500, Federal Hazardous Substances Act (FHSA) Regulations (2008).

Code of Federal Regulations (CFR), Title 9, Parts 1-4, Animal Welfare Act.

National Research Council, *Guide for the Care and Use of Laboratory Animals*, Washington, DC: National Academy Press, 2011.

Office of Laboratory Animal Welfare (OLAW), Public Health Service Policy on Humane Care and Use of Laboratory Animals.

International Organization for Standardization (ISO) 10993-1, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process (2009).

International Organization for Standardization (ISO) 10993-2, Biological Evaluation of Medical Devices - Part 2: Animal Welfare Requirements (2008).

International Organization for Standardization (ISO) 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization (2010).

International Organization for Standardization (ISO) 10993-12, Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials (2007).

International Organization for Standardization (ISO) 13485, Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes (2003).

International Organization for Standardization (ISO) 17025, General Requirements for the Competence of Testing and Calibration Laboratories (2005).

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

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Appendix 1 - Classification System For Skin Reaction

Reaction	Numerical Grading
Erythema and Eschar Formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Edema Formation	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond exposure area)	4
Total possible score for irritation	8

NOTE: Other adverse changes at the skin sites shall be recorded and reported

Irritation Response Categories in the Rabbit

Response Category	Mean Score
Negligible	0.0 to 0.4
Slight	0.5 to 1.9
Moderate	2.0 to 4.9
Severe	5.0 to 8.0

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Appendix 2 - Dermal Observations

Animal Number/ Sex	Weight (kg)	Group	Observation	Interval (hours)							
				1*		24†		48		72	
				Left	Right	Left	Right	Left	Right	Left	Right
81697 Male	3.1	Test	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
		Control	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
81698 Male	2.9	Test	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
		Control	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
81715 Female	3.0	Test	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
		Control	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0

*Animals 81698 and 81715 had pink discoloring on the test sites.
†Slight discoloration at test sites.

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Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Statement of Quality Assurance Activities

Phase Inspected	Date Inspected	Date Reported to Study Director	Date Reported to Management
Scoring	March 12, 2012	March 12, 2012	March 12, 2012
Study Data Review	March 13, 2012	March 13, 2012	March 13, 2012
Final Report Review	March 16, 2012	March 16, 2012	March 16, 2012

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: Lauren Michaels 3-16-12

Lauren M. Michaels, B.S.P.S.
Auditor, Quality Assurance

Date

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

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18. Attachment VIII – Engineering Drawings - Materials

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

(b)(4) Engineering Drawings and Materials

(b)(4) Engineering Drawings and Materials

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name LCDR Andrew Yang

Subject: 510(k) Number K121326

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/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 (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

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 X	
Is this a combination product? (Please specify category _____, 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)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			X

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
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)		X	
Child (2 years -< 12 years old)		X	
Adolescent (12 years -< 18 years old)		X	
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.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		X	
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	**Class***	**Product Code**
874.4770	I	ERA

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

Additional Product Codes:_____

Review:_____
(Branch Chief) (Branch Code) (Date)

Final Review:_____
(Division Director) (Date)

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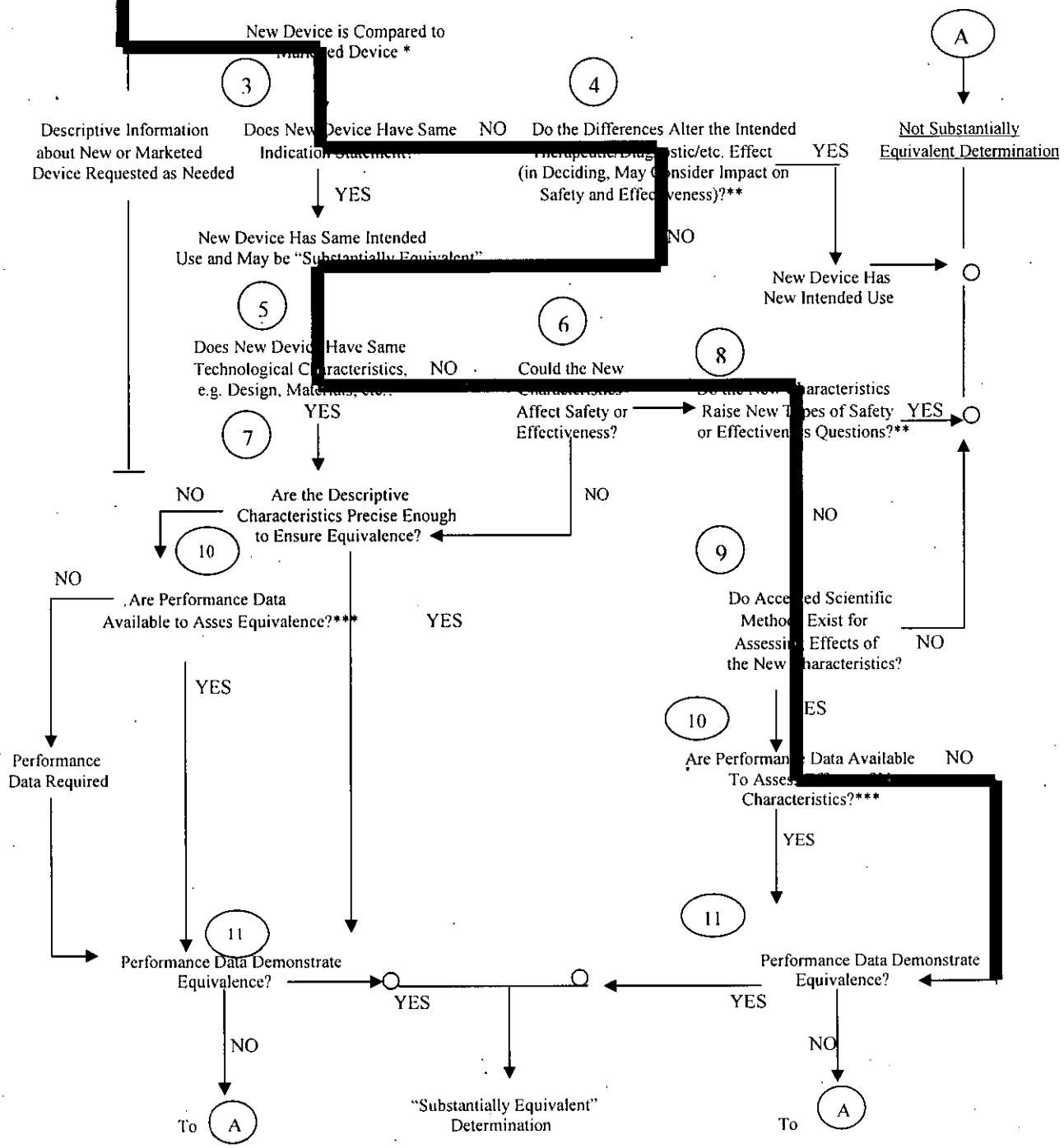
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 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.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Yang, Andrew

From: Yang, Andrew
Sent: Thursday, June 21, 2012 5:57 PM
To: 'genericd@bellsouth.net'
Subject: K121326 Lantos 3D Ear Scanner
Attachments: K121326 TH attachment.pdf

Dear Mr. Greenbaum:

We cannot determine whether the device is substantially equivalent to your chosen legally marketed predicate device. Please see the attached file.

This email is sent in lieu of a formal written letter.

Please feel free to contact me if you have any questions.

LCDR Andrew Yang, BE, ME, EIT
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health
301-796-6860

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Lantos Technologies
% Mr. John Greenbaum
Generic Devices Consulting, Inc.
20310 SW 48th St
Southwest Ranches, FL 33332

Re: K121326
Trade Name: Lantos 3D Ear Scanner
Dated: April 30, 2012
Received: May 2, 2012

Dear Mr. Greenbaum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following:

(b)(4) Deficiencies

[redacted]

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

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(b)(4) Deficiencies

[redacted]

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Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

(b)(4) Deficiencies

[redacted]

The deficiencies identified above 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 (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

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 additional information 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. .

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact LT Andrew Yang at (301) 796 - 6860. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

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(b)(4) Deficiencies

[redacted]

The deficiencies identified above 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 (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification

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

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(510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

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 additional information 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. .

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact LT Andrew Yang at (301) 796 - 6860. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

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

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		**YES**	**NO**
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			X
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			X
3. Does this device type require a PMA by regulation? (Please see management.)			X
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)			X
5. a. Did the firm request expedited review? (See management.)□			X
b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)			
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:		X
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		X
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			X

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Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s
http://www.fda.gov/cdrh/ode/guidance/1567.html

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html	X		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf	X		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/cdrh/ode/guidance/1567.html	X		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6	X		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7	X		
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9	X		
Class III Summary and Certification	Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html			X
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html.		X	
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html. FDA Standards program www.fda.gov/cdrh/stdsprog.html. Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/reqrecstand.html			X

Rev. 5/30/07

Title	Related Information	Present	Inadequate	N/A
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), www.fda.gov/cdrh/k863.html	X		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H www.fda.gov/cdrh/devadvice/314312.html#link_10	X		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) www.fda.gov/cdrh/ode/guidance/361.html For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices www.fda.gov/cdrh/ode/guidance/1216.html			X
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" www.fda.gov/cdrh/g951.html	X		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices www.fda.gov/cdrh/ode/software.html	X		
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program www.fda.gov/cdrh/emc See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)	X		
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			X
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf	X		

Title	Related Information	Present	Inadequate	N/A
FORM FDA 3654, *Standards Data Report for 510(k)s - http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf*	**Standards Data Report Form – Form 3654** 1: No standard used - **No Standards Form Required** 2: Declaration of Conformity – **Yes Standards Form Required** 3: Standard but no declaration – **Yes Standards Form Required**			X
Kit Certification	Device Advice http://www.fda.gov/cdrh/ode/odecl874.html			

Last Updated: 9/3/08 – Brandi Stuart

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DEPARTMENT OF HEALTH AND HUMAN SERVICES M E M O R A N D U M

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

Premarket Notification 510(k) Review
Traditional
K121326

Date: June 19, 2012
To: The Record
From: Andrew Yang

Office: ODE
Division: DONED

510(k) Holder: Lantos Technologies
Device Name: Lantos 3D Ear Scanner
Contact: John Greenbaum
Phone: (954) 610-0178
Fax: (954) 653-1153
Email: genericd@bellsouth.net

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the Lantos 3D Ear Scanner into interstate commerce.

II. Administrative Requirements

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

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	

The Device consists of a hand held scanner, a single patient use disposable with a conforming membrane, which when in use is filled with an absorbing medium, and a laptop computer. The hand held scanner, when not in use, is placed in a docking stand.

The hand held scanner is tethered to the docking stand with a custom cable. The docking stand is tied to the laptop computer. The hand held scanner contains illumination, optics, a camera, a motor to move the probe tip, and a motor-driven reservoir.

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

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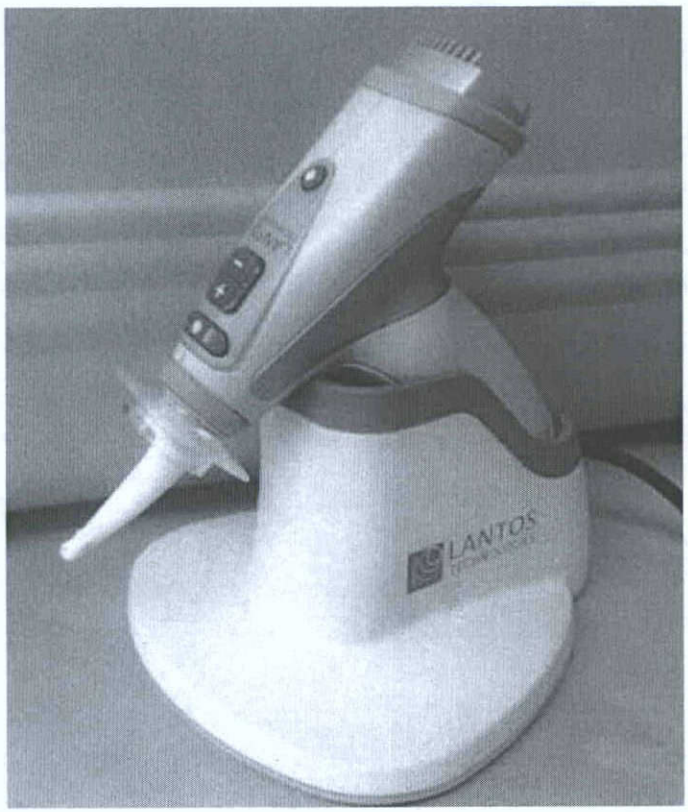
User Interface (UI) software screens are displayed on the laptop and the user interacts with the device via the laptop keyboard and touchpad, and control buttons on the hand held scanner, as guided by the UI screens. Image data from the patient is stored in the laptop, and may be transmitted by the user via a wireless connection. No patient identifiable data is stored in the Lantos device.

A single use disposable, which includes the conforming membrane, is placed over the hand held scanner probe tip, in a manner similar to placing an ear speculum over the viewing tip of a conventional otoscope. The disposable will contact and reshape the ear canal with mild pressure, to improve the view of the ear canal, and to keep the probe tip from contacting the ear canal, performing the same functions as a speculum.



Comment: The device description is inadequate. Some key elements of its operation were unclear. The sponsor references a training video that was lost at the DMC. I found videos on Youtube showing the device in use. This resolved some questions regarding how it is anchored against the head while scanning takes place. The software allows for a certain degree of movement. The engineering drawings are incomplete: at the very least, the pump assembly and power source are absent.. A live demonstration or video, such as the training video, would be very helpful. *Deficiency*

IV. Indications for Use

The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal.

The Lantos 3D Ear scanner:

- provides a magnified visual image for inspection of the external ear canal and tympanic membrane,

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

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and provides illumination of the ear canal for observation and;

- includes an expanding conforming membrane which aids observation when inserted in the ear canal and;
- records and presents to the hearing professional in an image file a topology measurement of the external ear canal

Comment: Contraindicated for pediatric patients, but no ages specified. *Deficiency*

V. Predicate Device Comparison

	(K943916)	Lantos 3D Ear Scanner (NEW)
Intended use	The VideOtoscope's intended use is to non-invasively examine the external ear canal and tympanic membranes in children and adults. The practitioner will use a common ear speculum to cover the otoscope tip; the speculum contacts and reshapes the patient's ear canal when inserted. The image of the ear is picked up by a camera in the otoscope head and then transmitted to a video processor for display on a computer screen. The VideOtoscope has an additional intended use to provide pneumatic otoscopy, which is used to examine the ear canal and tympanic membrane under slight varying applied pressure.	The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal. The Lantos 3D Ear scanner: provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation and; includes an expanding conforming membrane which aids observation when inserted in the ear canal and; records and presents to the hearing professional in an image file a topology measurement of the external ear canal.
Target population	Patients requiring a visual inspection of the ear.	Patients requiring a visual inspection of the ear. Excludes pediatric patients.
Where used	Independent ear examination clinics, audiologist offices, hearing professional offices, hospital based clinics	Independent ear examination clinics, audiologist offices, hearing professional offices, hospital based clinics
Energy used and/or delivered	SELV DC Volts/Amps White Light	SELV DC Volts/Amps RGB mixed 'White' Light
Human factors	Welch Allyn requires correct positioning of the illumination source and speculum. Human factors are very similar. Use of the computer to see images and store data are similar.	Lantos 3D Ear Scanner requires expansion of a fluid filled membrane to obtain a complete 3D image of the ear. Human factors are very similar. Use of the computer to see images and store data are similar.
Physical Characteristics	Scanner Dimensions ~70mm L x 102mmH x 37mmW Weight ~95g without cable Laptop Commercial 15in Laptop Operating 10° C to 40° C 700 to 1060 hPa Altitude	Scanner Dimensions ~160mm L x 130mmH x 40mmW Weight ~230g without tether cable Laptop Commercial 15in Laptop Operating 10° C to 40° C 700 to 1060 hPa Altitude
Performance Characteristics	Field of View >100° Cone in Air – Video Otoscope View Direction of View 0° aligned with probe axis Illumination Halogen Source 'White' Light via fiber bundle	Field of View >120° Cone in Air – Video Otoscope View Direction of View 0° aligned with probe axis Illumination Red / Green / Blue 'White' Light via fiber bundle
Standards	UL 544 (patient vicinity) IEC 60601-1-2 - Medical Electrical Equipment – Part 1-2 –General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and Tests IEC 60601-2-18:1996 Amendment 1 2000 Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment	IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-1-2 Medical Electrical Equipment – Part 1-2 –General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and Tests IEC 60601-2-18: Edition 3.0 2009-08 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential

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

		performance of endoscopic equipment FDA; Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices - May 2005 FDA Guidance; Cyber Security for Networked Medical Devices Containing Off the Shelf Software ISO 14971: Medical devices—Application of risk management to medical devices ISO 10993 Parts 1-13 as Applicable

Comment: The table focuses on the similarities between the otoscope functions. The new technology, 3D scanning, has no cleared precedent. The closest technology is a physical ear mold (generally silicone) that is scanned 3-dimensionally and uploaded to a computer.

VI. Labeling

The primary device labeling for the Lantos 3D Ear Scanner includes:

1. 3D Ear Scanner Device Kit Label
2. Multi-Pack of Single Use Disposables Label
3. Single Use Disposable Label
4. Scanner Body Label
5. Instructions for Use
6. Promotional Flyer

Figure 8-1 – 3D Ear Scanner Device Kit Label

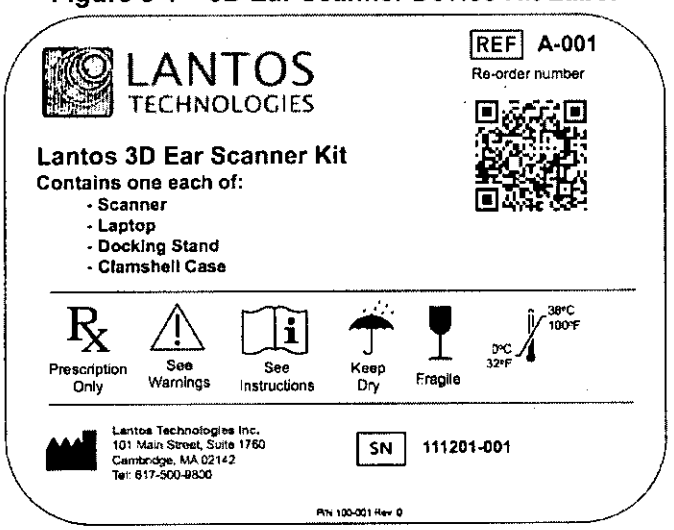


Figure 8-2 – Multi-Pack of Single Use Disposables Label

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

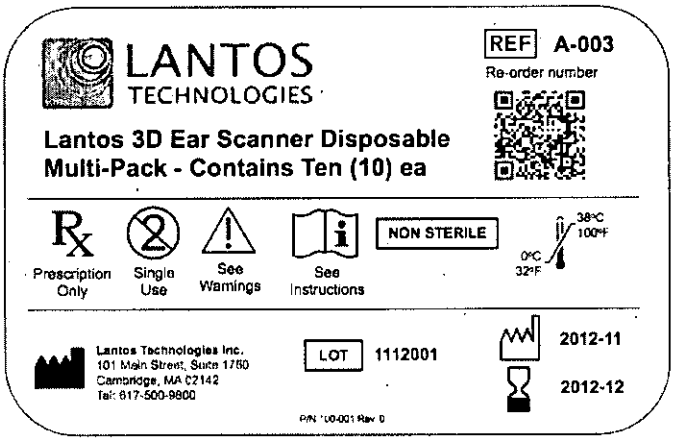


Figure 8-3 – Single Use Disposable Label

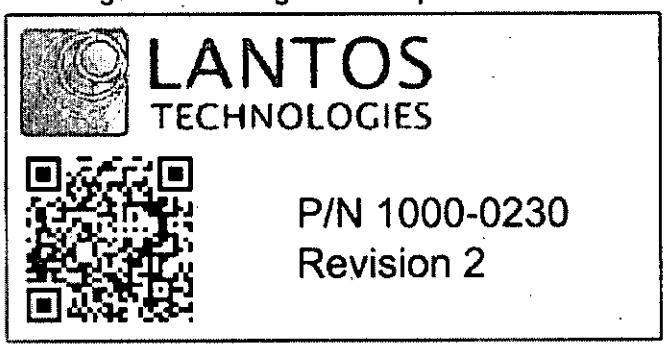
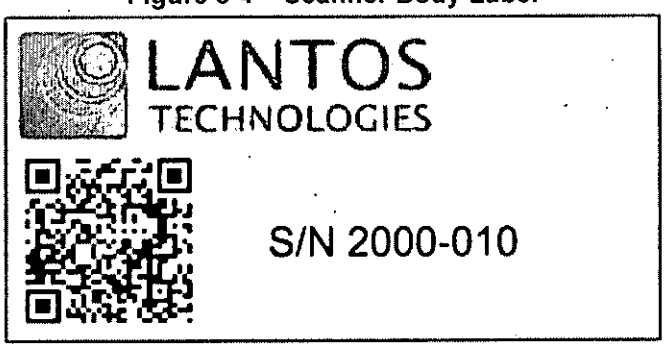


Figure 8-4 – Scanner Body Label



Comment: The symbols are defined. There was nothing out of the ordinary in the promotional flyer and instructions for use. The labeling is acceptable.

VII. Sterilization/Shelf Life/Reuse

Comment: Sponsor provides cleaning instructions and validation. The validation confirms the integrity of the device after cleaning. It does not address the microbiological effect. No component is sterile, not even the disposable parts. However, the risk analysis mentions a shelf-life for the disposable components. This should be clarified. Deficiency

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

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VIII. Biocompatibility

The components of the Lantos scanner and single use disposable listed in the following table are likely to contact the patient, or contact the hearing professional in the patient vicinity. All component materials were examined during risk analysis, and determined to be safe for such contact, either through test results obtained from the material manufacturers, and reviewed by Lantos, or through biocompatibility tests commissioned by Lantos. Engineering drawings for the components which may contact the patient or user are in Attachment VIII – Section 18.

Table 7-1: Materials

(b) (4)

[redacted]

Comment: Vasant Malshet, PhD, DABT reviewed the toxicology and found it to be acceptable (see review).

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

IX. Software

Quality Review Element	Explanation of Quality Review Issues
1. Level of concern: Did the submission identify the level of concern and provide a reasonable rationale for that level?	Adequate
2. Software description: Did the submission provide a summary overview of the features and software operating environment? Did the submission address: the role of software in the operation of the device; critical operations performed by software or checked by software; and how the software is related to the clinical use of the device?	Adequate
3. Hazard analysis: Did the submission address: completeness of the hazard analysis and whether hazards were appropriately identified; appropriate mitigations, traceability, and acceptability criteria for identified hazards; and a review of hazards and safety requirements as clinically appropriate by device expert?	Adequate
4. Software requirements specifications (SRS): Did the submission assess the adequacy of the SRS? Were safety requirements explicitly listed? (Was SRS broken down at the module, feature, and functional levels? Were mitigations of hazards identified?)	Adequate
5. Architecture design chart: Did the submission discuss the existence of a detailed description of functional units and software modules?	n/a
6. Software design specification (SDS): Did the submission provide an adequate SDS?	n/a
7. Traceability analysis: Did the submission provide an adequate traceability analysis?	
8. Software development environment description: Did the submission address the development environment? Did the submission indicate that a summary of software life cycle was included?	n/a
9. Verification and validation (V&V) documentation: Did the submission adequately present V&V documentation and testing? Did the submission address validation by user testing?	Adequate
10. Revision level history: Did the submission assess the adequacy of the revision level history? Did the submission indicate that an iterative process was performed?	Adequate
11. Unresolved anomalies: Did the submission adequately address issues of unresolved anomalies? Did the submission address clinical impact of unresolved anomalies?	n/a
12. Off-The-Shelf (OTS) Software: If the device contained OTS software, did the submission indicate that the following steps were taken by the sponsor: a. identifying OTS software, including version number; b. identifying all hazards associated with the OTS software; and c. indicating that appropriate steps were taken to adequately mitigate each hazard?	n/a
13. Standards: Did the submission document any use of software standards?	n/a
14. Connectivity: Were connectivity, communication, and/or security software issues addressed in the submission? If so, how were they evaluated?	n/a

Comment: LCDR Andrew Yang reviewed the software (see review). The sponsor claims a minor level of concern, which I do no disagree with. Therefore, only some of the review elements are necessary. All elements were acceptable.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The power supply (AC/DC converter) included with the Lantos 3D Ear Scanner, which provides the basis for electrical safety, has been fully tested and certified by a recognized third party laboratory (TUV) for compliance to IEC 60601-1, see Attachment IV, Section 14.6a and 14.7.

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

Additional safety testing was performed to both the IEC 60601-1 and IEC 60601-2-18 standards on the complete Lantos 3D Ear Scanner, with all components. This testing incorporated the approved (TUV) power supply. The following is a summary of the testing that was performed on the device:

Standard	Test Clause(s)	Description	Result
IEC 60601-1	4.11	Power Input	Pass
IEC 60601-1	8.7	Leakage Current	Pass
IEC 60601-1	8.8.3	Dielectric Strength	Pass
IEC 60601-1	11.11.1	Excessive Temperature including Applied Parts	Pass
IEC 60601-1	13.2.6	Leakage of liquid (Optical Medium)	Pass
IEC 60601-2-18	201.5.1, 201.6.2, 201.8.3,	Protection Against Electric Shock (Type BF)	Pass
IEC 60601-2-18	201.10.5	Visible Electromagnetic Radiation (from LEDs)	Pass
IEC 60601-2-18	201.11.1	Excessive Temperature including Applied Parts	Pass
IEC 60601-2-18	201.11.6	Leakage of liquid (Optical Medium)	Pass
IEC 60601-2-18	201.15.4.1	Construction of connectors	Pass

Table 9-2: IEC 60601 Safety Testing

IEC 60601 Verification reports are in Attachment IV – Sections 14.6 and 14.8.

Further testing will be conducted prior to commercial distribution to meet the acceptance criteria specified in the applicable voluntary standards AAMI / ANSI IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance and the applicable parts of IEC 60601-2-18: Edition 3.0 2009-08, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment. A recognized third party laboratory will be utilized to perform the testing. Lantos will submit the IEC 60601-1 and IEC 60601-2-18 test reports to the 510(k) file upon completion of the testing.

Comment: LCDR Andrew Yang reviewed the EMC and electrical safety (see review). The testing demonstrates adequate safety. Mechanical safety was confirmed under the Risk Analysis which listed successful mitigations to potential mechanical injury, namely, over extending and striking the tympanic membrane, injuring the ear canal walls, and over-pressurizing the expanding membrane of the disposable tip. All mitigations are reasonable and lowers the risks to ALARP.

XI. Performance Testing – Bench

n/a

XII. Performance Testing – Animal

n/a

XIII. Performance Testing – Clinical

Comment: Cherish Giusto, Au.D., CCC-A reviewed the clinical and audiology information (see review). This information was scattered throughout the submission. She identified a few deficiencies.

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

XIV. Substantial Equivalence Discussion

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

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
The IFU resembles a typical video otoscope IFU, but includes language for 3D ear modeling, which is new technology

2. Explain why there is or is not a new effect or safety or effectiveness issue:
n/a

3. Describe the new technological characteristics:
3D ear modeling is accomplished without a physical mold. Rather, a camera collects a series of red and green images to create a 3D model in the software.

4. Explain how new characteristics could or could not affect safety or effectiveness:
This is a first-of-its-kind device and there are a lot of unknowns regarding its safety and effectiveness.

5. Explain how descriptive characteristics are not precise enough:
n/a

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
These are not new concerns. There has always been a potential for harm to the ear canal or tympanic membrane with respect to otoscopes.

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7. Explain why existing scientific methods can not be used:
These safety concerns can be studies and mitigated with existing scientific methods.

8. Explain what performance data is needed:
See deficiencies.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
n/a

XV. Deficiencies

Indications for Use

1. In the Indications for Use (page 24 of 535), you state that your device is indicated for use "by a trained hearing professional in clinical settings on adult patients..." Please clarify the following issues and also update the Instructions for Use (User's Manual) accordingly:

   a. Please be more specific about which trained hearing professionals you are referring to, as well as what type of training, if any, recommended for using this device.

   b. Please define "adult patients" by providing the age criteria (e.g., adult patients 18 years and older).

Device Description

2. For otoscopy and the topography measurements, correct use of the device is essential for generating a safe and accurate image of the ear canal. It is important to minimize the risk of user error that could result in an inaccurate ear canal measurement or damage to a patient's ear. Please address the following issues in your device description and update your Instructions for Use as appropriate:

   a. Please provide a recommended maximum insertion depth of the probe into the ear canal (e.g., 3mm from the TM).

   b. Please indicate if the conforming membrane expands medially from the probe tip. If so, please explain how the user should avoid the possibility of the membrane contacting the tympanic membrane.

   c. Since your disposable comes with a reservoir of 15cc of fluid, this suggests that the user will need to judge how much fluid is necessary to generate the appropriate topography measure. Please indicate how the user should avoid using too much or too little of the fluid to fill the conforming membrane and generate an accurate measure.

   d. Please clarify if it is possible to displace the cartilaginous portion of the ear canal with pressure from the conforming membrane and fluid and to what extent. Also, please

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indicate why you do not expect this to have an impact on the accuracy of the topography measure.

e. Please indicate the length of your probe tip and how this compares to a standard speculum on a traditional otoscope. Also, please indicate if you have included any mechanisms for minimizing the risk of the probe tip making contact with the tympanic membrane during use.

3. In section 7.10 (Use Overview, page 37 of 535), you state "The disposable will contact and reshape the ear canal with mild pressure..." Please indicate if this amount of mild pressure has been judged to be acceptable in terms of comfort by the majority of patients on whom the device has been used.

4. You provide a list of contraindications, warnings, and precautions (Sections 7.11 & 7.12, page 34 of 535). This list is lacking some detail to effectively guide users' clinical judgment. Please address the following issues and be sure to include all of these contraindications, warnings, and precautions in your Instructions for Use (User's Manual):

   a. You specify that the device is not for use in the pediatric population. Please provide the specific age range for who the device is contraindicated.

   b. In Warnings & Precautions, bullet 'c', you state "Use clinical judgment for patients where the anatomy of the external ear appears to have unsuitable tortuosity." Please clarify what is meant by "unsuitable tortuosity" and provide examples of tortuous ear canals that are unsuitable for your device. Also, please explain why your device should not be used in these patients, since this is a population who have difficulty with traditional ear impressions and could greatly benefit from 3D scanning technology.

   c. You do not provide any guidance on the use of your device with respect to the presence of cerumen in the ear canal. Please indicate if the ear canal should be completely clear of cerumen prior to use of the otoscopic and/or topography functions of your device.

   d. Please indicate if your device may be used in patients with exotoses or osteomas, and if so, what precautions should be taken.

   e. Please indicate what precautions should be taken for the use of your device in immuno-compromised patients, such as persons with diabetes or HIV.

5. You provide engineering drawing in Attachment 8. However, it appears that some components are missing. We have identified 2 missing components: pump assembly, power source. Please provide these drawings and any others that were not previously included.

6. On page 46 of 535, Device Description, you state that the illumination source of your device is "a three color Red/Green/Blue collection of LED die are coupled through an optical taper into the proximal end of the illumination fibers – a microcontroller and associated current

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control drive circuits create an illumination flash sequence synchronized with the shutter of the optical sensor."

However, you do not provide the technical characteristics of these LEDs (e.g., wavelength (spectrum distribution), maximum and normal operating output power). Please provide these parameters which are the essential information for evaluating your risk analysis.

Clinical Testing

7. You provide an interim report for the Direct Scan Earmold Digitization Evaluation which demonstrates no adverse events for the Lantos related aspects of the study. However, this interim report includes only the secondary endpoint results for safety; it does not include the primary endpoint effectiveness data demonstrating the comparison between the current standard of care for ear impressions and custom earplug manufacturing (earmold scan) and your device's direct scan method. Because your intended population use and labeling include claims about using the topography measures to manufacture custom ear pieces and hearing aids, these effectiveness data are important to support a pre-market clearance of your device. Please provide the final results from this clinical investigation that include both the safety and effectiveness endpoints.

   Similarly, you provide an interim clinical report for your User Preference Study which includes a partial data set and no analyses. Please provide the final results from this clinical investigation in support of the safety and effectiveness of your device for its intended use.

8. You state that custom earplugs were manufactured for your Direct Scan Earmold Digitization Evaluation, but a description of the earplug style/features cannot be easily located. Please provide further details about the earplug features, including if the custom earplugs were full shell style or canal style plugs.

9. Please indicate how you intend to evaluate the accuracy/effectiveness of the 3D ear scan for the concha and helix regions of the topography measurements obtained with your 3D Ear Scanner device.

10. In the Methods section of the Direct Scan Earmold Digitization Evaluation protocol (section 7.6, Determination of Eligibility, page 350 of 355), you state "subjects will be 40 normal hearing mean and women...with no known medical pathology." However, your subjects included persons with hearing loss, and this was not reported as a protocol deviation. Please indicate why you included subjects with hearing loss in this study and any expected impact on your study results.

11. You measure the amount of attenuation provided by the custom earplugs in each ear separately in the Direct Scan Earmold Digitization Evaluation. Given that your audiometric measures were performed in the sound field, please explain how you were able to isolate each ear for the attenuation measures.

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Also, please indicate if your subjects and investigators were blinded as to which custom earplugs were derived from which scanning method. If not, please indicate how you will control for this potential bias, particularly with respect to the investigators' blinding.

12. You describe the protocol deviations (section 10.0, page 395 of 535) in the Direct Scan Earmold Digitization Evaluation. However, further details are needed to explain the impact of these deviations. Please address the following issues:

    a. The second bullet states "the audiologist determined potential clinical implications for subjects receiving earmold impression scans prior to the EarMold 3D Direct scans of the ear canal" and explains those implications. However, it is unclear exactly how the protocol was modified and what impact the modification could have on the results. Please provide these details.

    b. Under the third bullet, you state "In addition, the audiologist determined these frequencies are unreliable for testing and re-testing purposes due to the directionality of the 8000Hz and subjects respond to 250 Hz as a vibro-tactile even when not heard." Please clarify what is meant by "the directionality of the 8000 Hz." Also, please clarify why you would expect subjects to have a vibro-tactile response to a 250 Hz tone presented via loud speaker in the sound field at levels of 40 dB HL and below.

13. In your User Preference Study, 10 out of 10 clinicians rated the video otoscope images from this device the same or more difficult relative to the quality of images from other conventional or video otoscopes. Furthermore, in Figure 7-21(page 48 of 538) you provide images from the video otoscope where there appears to be limited visibility of the tympanic membrane. This suggests that the images from the video otoscopy of your device may not yield "exceptional visualization of the ear canal" as claimed in your Draft Brochure, or that visualization of the tympanic membrane may be limited. Please provide images and performance data to support your claims about the quality of images from the video otoscopy with your device.

14. In your User Preference Study, most of your clinician subjects indicated that they would like a prompt or an identification of insertion depth or ear canal length. Please indicate how you plan to address this issue.

Labeling

15. In section 15.3 (Training Manual, page 342 of 538), you state "Note; A DVD/CD is provided in the 510k package with a video training film." However, this DVD/CD with the Training Manual cannot be located in the submission package. Please include this in your next submission.

16. In the Draft Brochure (page 337 of 535), under Safety and Comfort, you state "The scanner can be used with confidence in cases where traditional impression material might require extended preparation." This statement implies that the Lantos 3D Ear Scanner is a better

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option in difficult cases. Please clarify is meant by this statement by indicating what cases this is referring to and providing data or a rationale to support this statement.

17. You provide descriptions of the steps for using the Lantos 3D Ear Scanner to perform video otoscopy and topography measurements in the Instructions for Use. You may consider including additional diagrams and/or photographs of the device in use in order to provide references for the user. Examples of additional images that may be helpful for the Instructions for use include the button controls on the device, the check cap, the protective cap, how to brace the device while retracting the probe tip during topography, etc.

18. Please include the updated contraindications and precautions in the Instructions for Use.

19. You provide copies of your labeling. One of the labels is for the Lantos 3D Ear Scanner Disposable Multi-Pack – Contains Ten (10) ea which bears the manufacturing month and the expiration month. Please explain how you arrived at this 1 month shelf-life and provide supporting documentation. Furthermore, in Attachment 1, you provide a list of hazards, among which are potential consequences of not heeding the expiration date. This suggests that the disposable components may become unsafe within 1 month of manufacturing. You do not provide a description of the packaging. Combined with the short shelf-life and dangers of expired product, the packaging is paramount. Please describe how all components are packaged, which includes the individual packaging for each component, individual cartons, shipping containers, etc.

Phototoxicity

20. The eye is the organs most susceptible to damage by optical radiation. It is not clear that whether the LEDs are turned on before or after the probe is inserted into ear. If the LEDs are turned on before inserting, there is the potential optical radiation hazard to the eye because of the proximity to the eyes. If Lantos 3D Ear Scanner is designed to be used in this condition, your device may pose the following types of hazards:

    - Retinal photochemical aphakic light hazard (305 -700 nm)
    - Retinal visible and infrared radiation thermal hazard (400 -700 nm)
    - There's more evidence that blue light (400 – 500nm) can damage eyes, with people who have had cataracts removed being particularly vulnerable.

    We believe an evaluation of phototoxicity to the eyes for use of your device is necessary. For phototoxicity analysis including classification, labeling, and informational requirements for the device, we recommend reference to the following standards:

    - American Conference of Governmental Industrial Hygienists (ACGIH): Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices (2011)

    - ANSI/IESNA RP-27.2-2000 Recommended Practice for Photobiological Safety for Lamps & Lamp Systems - Measurement Techniques

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- ANSI/IESNA RP-27.3-2007 Recommended Practice for Photobiological Safety for Lamps - Risk Group Classification & Labeling

Please provide a phototoxicity evaluation, including (may not limited to) the following information:

a. Irradiance measurement at a default distance of 20cm and at the worst case (shortest) of distance form nose.

b. Risk group assessment: This assessment results in either an Exempt Group or one of three Risk Group classification: Risk Group 1 ((Low-Risk)), Risk Group 2 (Moderate Risk)) and Risk Group 3 (High Risk).

c. Appropriate protection should be used when the risk group classification is not "Exempt". Please describe whether there is any mitigation that will be effective to prevent the potential harm to the eyes to insure user safety when operating the device under the condition of intended use.

The following labeling issues are for your consideration:

We recommend follow excerpt from ANSI/IESNA RP-27.3 -07 Section 6.2. to provide Caution labels to inform and instruct end user regarding pertinent safety related information that should be provided if the lamp is classified as Risk Groups 1, 2, or 3. For example:

i. A statement of the potential hazard, if any. This should simply advise as to what might expected to occur (i.e., skin irritation, or eye injury).

ii A list of what precautions could or should be taken to avoid the risk (e.g., "Do not shine the device directly in eyes…", "Appropriate eye protection should be used when daily exposure at short distance (XX cm) is greater than XX minutes.")

21. The ear skin is also vulnerable to damage by optical radiation. The type of effect, injury thresholds, and damage mechanisms vary significantly with wavelength. There are different types of damage to the skin may be caused by optical radiation, for example:

- Thermal damage (burns) of the skin with visible and infrared radiation.

- Photosensitized damage of the skin: It is generally far more typical of UVR wavelengths (less than 380 nm). However, such photosensitized reactions can extend to approximately 700 nm, possibly as a side-effect of certain medications.

You do not include an evaluation of optical radiation hazard to the skin. We recommend you evaluate skin safety for use of your device by performing an optical radiation hazard

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evaluation to demonstrate your device meets the safety guideline specified in ACGIH [1] and ICNIRP [2] or an equivalent method. Please provide this information.

[1] ACGIH American Conference of Governmental Industrial Hygienists Threshold Limit Values for chemical substances and physical agents and Biological Exposure Indices. 2011.

[2]. International Commission on Non-Ionizing Radiation Protection (ICNIRP). Guidelines on limits of exposure to broad-band incoherent optical radiation (0.38-3um). Health Phys. 73: 37 539-554; 1997.

You may choose alternate approaches as long as above concern related to optical radiation safety can be addressed.

XVI. Advisory

n/a

XVII. Recommendation
Regulation Number: 874.4770
Regulation Name: Otoscope
Regulatory Class: Class I
Product Code: ERA

TH – Telephone Hold

Reviewer

6/19/12
Date

Branch Chief

Date

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

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REVIEW OF TOXICOLOGY DATA

Date : June 11, 2012
From: : Vasant G. Malshet, Ph.D., DABT **Division/Branch:** DONED/ENTB
To : Lt. Andrew Yang, ME **Division/Branch:** DONED/ENTB
Trade Name: LANTOS 3D EAR SCANNER
510(k)# : K121326
Applicant : LANTOS TECHNOLOGIES (LANTTECH)

Checklist: Biocompatibility Evaluation of Medical Devices

Indications for Use: The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal.

The Lantos 3D Ear scanner:

- provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation
- and;
- includes an expanding conforming membrane which aids observation when inserted in the ear canal and;
- records and presents to the hearing professional in an image file a topology measurement of the external ear canal

Brief Device Description: The Device consists of a hand held scanner, a single patient use disposable with a conforming membrane, which when in use is filled with an absorbing medium, and a laptop computer. The hand held scanner, when not in use, is placed in a docking stand. The hand held scanner is tethered to the docking stand with a custom cable.

The docking stand is tied to the laptop computer. The hand held scanner contains illumination, optics, a camera, a motor to move the probe tip, and a motor-driven reservoir.

User Interface (UI) software screens are displayed on the laptop and the user interacts with the device via the laptop keyboard and touchpad, and control buttons on the hand held scanner, as guided by the UI screens. Image data from the patient is stored in the laptop, and may be transmitted by the user via a wireless connection. No patient identifiable data is stored in the Lantos device.

A single use disposable, which includes the conforming membrane, is placed over the hand held scanner probe tip, in a manner similar to placing an ear speculum over the viewing tip of a conventional otoscope. The disposable will contact and reshape the

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Type of Tissue Contact: (check one)

__x__ Surface device: skin
____ Surface device: mucosal membrane
____ Surface device: breached or compromised surfaces
____ External communicating device: blood path, indirect
____ External communicating device: tissue/bone/dentin
____ External communicating device: circulating blood
____ Implant device: tissue/bone
____ Implant device: blood

Duration of Contact: (check one)

_x___ < 24 hours
____ > 24 hours, but less than 30 days
____ > 30 days
____ potential for repeat exposure (If so, please explain)

Table 2. Biocompatibility Testing Submitted

Biocompatibility Test	Recommended (will plan to add links to tests)	Provided	Need to provide
Cytotoxicity	x	x	
Sensitization	x	x	
Irritation or intracutaneous reactivity	x	x	
Acute systemic toxicity and material mediated pyrogenicity			
Sub-chronic toxicity			
Genotoxicity			
Gene mutations in bacteria			
Gene mutations in mammalian cells			
Clastogenicity in mammalian cells			
Implantation			
Hemocompatibility			
Hemolysis			
Complement activation			
Thrombogenicity			
Chronic toxicity			

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Conclusions: The submission contains adequate information to show that the patient contacting materials are biocompatible during intended use of this device.

Vasant G. Malshet, Ph. D., DABT
Expert Toxicologist

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

Memorandum

Software, EMC, Electrical Safety, Mechanical Engineering Review

Date: June 15, 2012

To: The Record

From:

Andrew Yang
Biomedical Engineer
Intraocular and Corneal Implants Branch
Division of Ophthalmic and Ear, Nose and Throat Devices

Subject: K121326

Device: Lantos 3D Ear Scanner

Recommendation: **TH – Telephone Hold**

INDICATIONS FOR USE

The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal.

The Lantos 3D Ear scanner:

- provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation and;
- includes an expanding conforming membrane which aids observation when inserted in the ear canal and;
- records and presents to the hearing professional in an image file a topology measurement of the external ear canal

DEVICE DESCRIPTION

The Device consists of a hand held scanner, a single patient use disposable with a conforming membrane, which when in use is filled with an absorbing medium, and a laptop computer. The hand held scanner, when not in use, is placed in a docking stand.

The hand held scanner is tethered to the docking stand with a custom cable. The docking stand is tied to the laptop computer. The hand held scanner contains illumination, optics, a camera, a motor to move the probe tip, and a motor-driven reservoir.

User Interface (UI) software screens are displayed on the laptop and the user interacts with the device via the laptop keyboard and touchpad, and control buttons on the hand held scanner, as guided by the UI screens. Image data from the patient is stored in the laptop, and may be transmitted by the user via a wireless connection. No patient identifiable data is stored in the Lantos device.

A single use disposable, which includes the conforming membrane, is placed over the hand held scanner

Note:
Arial font indicates sponsor language
Times New Roman font indicates reviewer language

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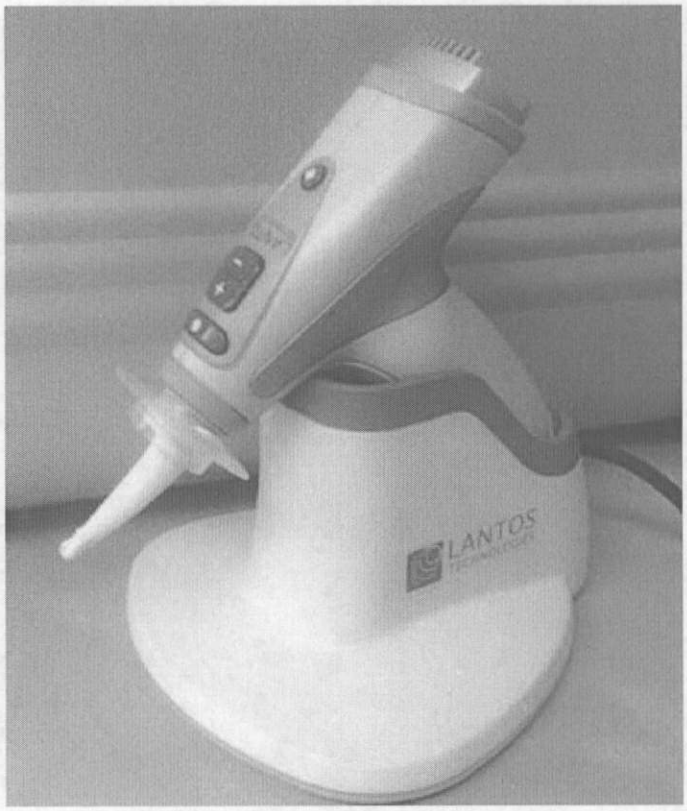
probe tip, in a manner similar to placing an ear speculum over the viewing tip of a conventional otoscope. The disposable will contact and reshape the ear canal with mild pressure, to improve the view of the ear canal, and to keep the probe tip from contacting the ear canal, performing the same functions as a speculum.



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

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SOFTWARE

Software controls the operation of the Lantos 3D Ear Scanner. Lantos Technologies has followed the FDA "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices" dated May 11, 2005. The requirements from this guidance are identified below.

Level of Concern (LOC)

Table 7-2a: Major Level of Concern

If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.
1. Does the Software Device qualify as Blood Establishment Computer Software? **NO**
2. Is the Software Device intended to be used in combination with a drug or biologic? **NO**
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern? **NO**
4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following: **NO**
a. Does the Software Device control a life supporting or life sustaining function? **NO**
b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators? **NO**
c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury? **NO**
d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death? **NO**
e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary? **NO**

Table 7-2b Moderate Level of Concern

If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern? **NO**
2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device? **NO**
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury? **NO**

Based on the answers to the questions in Table 7-2, the level of concern for the software is Minor.

In accordance with the FDA Guidance, the following information is included in this pre-market notification.

Comment: The gray area here is the "prior to mitigation" clause. I interpret this to mean software mitigation, not mechanical or design safety features intended to prevent injury. Therefore, I agree that prior to software mitigation, there is no risk of injury and therefore agree that the LOC is minor.

Software Description

(b)(4) Reveiw

[redacted]

Windows 7 ® operating system in a componentized form to create advanced commercial devices with strict control of applications and drivers.

7.19.4. Firmware

(b)(4) Reveiw

[redacted]

Comment: The description is adequate.

Device Hazard Analysis

7.19.6.1. Overview

The Lantos 3D Ear Scanner generates, provides for view, and stores images of the external ear canal and tympanic membrane. The images are not intended for diagnostic purposes. Failure to generate, show or store the images presents no identified hazards to the patient or the hearing professional.

If the Scanner fails to generate, show, or store images, it will not meet the requirements for intended use, and presents considerable inconvenience to the user and the patient. Risk analysis techniques were applied to mitigate the potential failures to perform as intended.

Potential failures to perform due to the User Interface software identified in the risk analysis included:

- Poor User Interface Design
- Distractions
- Misinterpretation
- Inadequate Controls
- Loss of Control

Mitigations include extensive evaluation of the UI by experienced practitioners, compliance with UI design standards, and testing by teams with human factors training.

Potential failures to perform due to management of patient data included:

- Data corruption during write, storage, or retrieval
- Data corruption during transmission
- Misleading data presentation

Mitigations include data set protection with indications of corruption (HASH tags), verification upon retrieval and following transmission, and competent clinician interpretation of images.

Full details are in the complete risk analysis provided in Attachment I.

7.19.6.2. Database

The Scanner takes advantage of the file system supplied with the Operating System to store image files to disk, both raw and processed. The files may be later retrieved and viewed by the hearing professional. As determined by the risk analysis, a failure to store or retrieve a particular image file for a subject, while a commercial inconvenience, presents no hazards to the subject or the hearing professional. Verification of the file system database was performed to confirm performance to meet expressed user requirements.

7.19.6.3. Firmware

The Scanner includes firmware which links the LantosView Application software to the image sensor, to the illumination control, to the operation buttons, and to the fluid and probe drive motors. The firmware functions under the direct control of the LantosView Application. Hazards were analyzed and verifications performed at the device system level, recognizing this software architecture.

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Comment: Again, if the scope of the review is limited to the software, the hazard analysis is complete. They have adequately met this requirement.

Software Requirements Specifications (SRS)
12.4. Scanner Software Requirements Specification

Comment: The SRS was adequate.

Architecture Design Chart

n/a

Software Design Specifications
12.5. Scanner Software Design Specification

Comment: Not necessary for Minor LOC, but the information provided is adequate.

Traceability Analysis/Matrix

ID	Hazard Description	Cause	Software Mitigation	Software Test Reference
1	**C.2.1.1 C.2.1.2 Misleading Image** Incorrectly presented Video Ototscope Image or Scan Image. Operating mistakes and errors in judgment.	Misinterpretation due to frozen image, image stream interrupted. Misinterpretation due to image orientation, capture or display hardware failure.	Software detects loss of real-time image stream, and presents dark screen to user. Image orientation auto-corrected for scanner orientation. Hardware design assures failures unlikely to present corrupt yet coherent images.	VerificationReport-LantosSoftwareSystem.2012.03.24 RESULTS_Section-6_Test-1 Appendix 1 RESULTS_Section-6_Test-3 Appendix 3
17	**C2.26.1 C2.27.1-2 Training, Installation, Instructions-for-Use** Inadequate training leads to misuse, possible injury to patient. Incomplete transfer of IFU to operator. Inadequate safe use presentation on UI.	Training not provided. IFU not provided.	Training usual and customary for similar devices used in ear exams. Training provided by company or by contract with device distributor. IFU delivered with device, also available at point of use as part of UI. Video training provided for safe use.	Lantos3DEarScanner-IFU-Ver04b Electronic Version in Application Lantos Training Video Electronic Version in Application
19	**C.2.29.1-8 User Interface** Poor UI Design Distractions Misinterpretation Inadequate Controls Loss of Control	Operating mistakes and errors in judgment.	UI Design evaluated by experienced users, who recommend and assess Improvements. UI complies with design standards. UI tested by team trained in software QA and human factors. In-service training for operators.	VerificationReport-LantosSoftwareSystem.2012.03.24 RESULTS_Section-6_Test-5 Appendix 5

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21	**C2.32.1 C2.32.2 Critical Data** Dimensional data corrupted during write to disk or storage. Dimensional data corrupted during transmission.	Software or hardware failure.	Data sets protected with indicators of corruption – used for retransmission or operator notification of failure. Verification of data transmission, ongoing monitoring. Competent clinician intervention at hearing aid fitting, inadequate hearing aid will not be dispensed. Failure to fit does not harm patient.	VerificationReport-LantosSoftwareSystem.2012.03.24 RESULTS_Section-6_Test-2 Appendix 2 RESULTS_Section-6_Test-3 Appendix 3 RESULTS_Section-6_Test-4 Appendix 4

Comment: The traceability matrix appears to be complete.

Development Environment

Configuration Management / Version Control – Apache Subversion (SVN) CollabNet, Inc Apache Software Foundation http://www.apache.org/
TortoiseSVN Client – Windows Shell Extension, Windows Explorer integration

See also 7.19.1 through 7.19.4

Comment: Not necessary for Minor LOC.

Verification & Validation Testing

Lantos Technologies utilizes written procedures which define the Design and Development processes. These processes are defined in Lantos Technologies Design Control Procedures. The activities to develop the Lantos 3D Ear Scanner followed the requirements of the Design Control Procedure. The Company maintains written documentation on each element of the Design Control Plan. This documentation is maintained in the Design History File. Table 9-1, below indicates the major elements of the design documentation which are on file for the Lantos 3D Ear Scanner. Figure 9-1 depicts the design control process used with the development of the Lantos 3D Ear Scanner.

Lantos 3D Ear Scanner System DHF Elements
• Project Plan • Product Requirements Document • Risk & FMECA Analysis • Design Specifications • Review Notes • Verification Plans/Reports/Data • Validation Plans/Reports/Data • Labeling • Design Review/Quality Audit(s) • Reference to Released DCR's

Table 9-1: DHF Elements

Comment: The actual V&V was performed in-vitro and is found in Attachment IV Section 14. They passed all tests within a safe margin. This is acceptable,

Revision level history

Comment: This information was no provided, but I see no reason to request it.

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

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Anomalies

n/a

Quality Review Element	Explanation of Quality Review Issues
1. Level of concern: Did the submission identify the level of concern and provide a reasonable rationale for that level?	Adequate
2. Software description: Did the submission provide a summary overview of the features and software operating environment? Did the submission address: the role of software in the operation of the device; critical operations performed by software or checked by software; and how the software is related to the clinical use of the device?	Adequate
3. Hazard analysis: Did the submission address: completeness of the hazard analysis and whether hazards were appropriately identified; appropriate mitigations, traceability, and acceptability criteria for identified hazards; and a review of hazards and safety requirements as clinically appropriate by device expert?	Adequate
4. Software requirements specifications (SRS): Did the submission assess the adequacy of the SRS? Were safety requirements explicitly listed? (Was SRS broken down at the module, feature, and functional levels? Were mitigations of hazards identified?)	Adequate
5. Architecture design chart: Did the submission discuss the existence of a detailed description of functional units and software modules?	n/a
6. Software design specification (SDS): Did the submission provide an adequate SDS?	n/a
7. Traceability analysis: Did the submission provide an adequate traceability analysis?	
8. Software development environment description: Did the submission address the development environment? Did the submission indicate that a summary of software life cycle was included?	n/a
9. Verification and validation (V&V) documentation: Did the submission adequately present V&V documentation and testing? Did the submission address validation by user testing?	Adequate
10. Revision level history: Did the submission assess the adequacy of the revision level history? Did the submission indicate that an iterative process was performed?	Adequate
11. Unresolved anomalies: Did the submission adequately address issues of unresolved anomalies? Did the submission address clinical impact of unresolved anomalies?	n/a
12. Off-The-Shelf (OTS) Software: If the device contained OTS software, did the submission indicate that the following steps were taken by the sponsor: a. identifying OTS software, including version number; b. identifying all hazards associated with the OTS software; and c. indicating that appropriate steps were taken to adequately mitigate each hazard?	n/a
13. Standards: Did the submission document any use of software standards?	n/a
14. Connectivity: Were connectivity, communication, and/or security software issues addressed in the submission? If so, how were they evaluated?	n/a

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

EMC & ELECTRICAL SAFETY

The power supply (AC/DC converter) included with the Lantos 3D Ear Scanner, which provides the basis for electrical safety, has been fully tested and certified by a recognized third party laboratory (TUV) for compliance to IEC 60601-1, see Attachment IV, Section 14.6a and 14.7.

Additional safety testing was performed to both the IEC 60601-1 and IEC 60601-2-18 standards on the complete Lantos 3D Ear Scanner, with all components. This testing incorporated the approved (TUV) power supply. The following is a summary of the testing that was performed on the device:

Standard	Test Clause(s)	Description	Result
IEC 60601-1	4.11	Power Input	Pass
IEC 60601-1	8.7	Leakage Current	Pass
IEC 60601-1	8.8.3	Dielectric Strength	Pass
IEC 60601-1	11.11.1	Excessive Temperature including Applied Parts	Pass
IEC 60601-1	13.2.6	Leakage of liquid (Optical Medium)	Pass
IEC 60601-2-18	201.5.1, 201.6.2, 201.8.3,	Protection Against Electric Shock (Type BF)	Pass
IEC 60601-2-18	201.10.5	Visible Electromagnetic Radiation (from LEDs)	Pass
IEC 60601-2-18	201.11.1	Excessive Temperature including Applied Parts	Pass
IEC 60601-2-18	201.11.6	Leakage of liquid (Optical Medium)	Pass
IEC 60601-2-18	201.15.4.1	Construction of connectors	Pass

Table 9-2: IEC 60601 Safety Testing

IEC 60601 Verification reports are in Attachment IV – Sections 14.6 and 14.8.

Further testing will be conducted prior to commercial distribution to meet the acceptance criteria specified in the applicable voluntary standards AAMI / ANSI IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance and the applicable parts of IEC 60601-2-18: Edition 3.0 2009-08, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment. A recognized third party laboratory will be utilized to perform the testing. Lantos will submit the IEC 60601-1 and IEC 60601-2-18 test reports to the 510(k) file upon completion of the testing.

Comment: The battery of tests is comprehensive and the Ear Scanner passed all tests. Reports are provided in 14.6. Testing was performed by TUV Rheinland, which is a reputable firm. This is acceptable.

RECOMMENDATION

None of these tests were intended to compare itself to its predicate. Rather, the sponsor set acceptable goals and achieved them, demonstrating safety and effectiveness. The device is relatively well-understood and appears to function as intended with an acceptable degree of safety, but is not completely understood and a video or live demonstration would complete my understanding.

TH – Telephone Hold

DEFICIENCIES

1. You provide engineering drawing in Attachment 8. However, it appears that some components are missing. We have identified 2 missing components: pump assembly, power source. Please provide these drawings and any others that were not previously included.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Date:	06/14/2012
To:	LCDR Andrew Yang, BE, ME, EIT, Team Leader, DONED/ENTB
From:	Dexiu Shi, Ph. D., Physicist, DONED/ONDB
510(k)	K121326
Device:	Lantos 3D Ear Scanner
Applicant:	Lantos Technologies
Subject:	Phototoxicity Review - ocular and ear/skin safety

SUMMARY OF REVIEW

This review is limited to review of potential optical radiation hazard for use of Lantos 3D Ear Scanner.

A. Proposed Indications for Use/Intended Use:

The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal. The Lantos 3D Ear scanner:

- provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation and;
- includes an expanding conforming membrane which aids observation when inserted in the ear canal and;
- records and presents to the hearing professional in an image file a topology

B. Device Description

Components

The Device consists of a hand held scanner, a single patient use disposable with a conforming membrane, which when in use is filled with an absorbing medium, and a laptop computer. The hand held scanner, when not in use, is placed in a docking stand.

The hand held scanner is tethered to the docking stand with a custom cable.

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The docking stand is tied to the laptop computer. The hand held scanner contains illumination, optics, a camera, a motor to move the probe tip, and a motor-driven reservoir.
User Interface (UI) software screens are displayed on the laptop and the user interacts with the device via the laptop keyboard and touchpad, and control buttons on the hand held scanner, as guided by the UI screens. Image data from the patient is stored in the laptop, and may be transmitted by the user via a wireless connection. No patient identifiable data is stored in the Lantos device.

A single use disposable, which includes the conforming membrane, is placed over the hand held scanner probe tip, in a manner similar to placing an ear speculum over the viewing tip of a conventional otoscope. The disposable will contact and reshape the ear canal with mild pressure, to improve the view of the ear canal, and to keep the probe tip from contacting the ear canal, performing the same functions as a speculum.

Figure 7-1: System Illustration

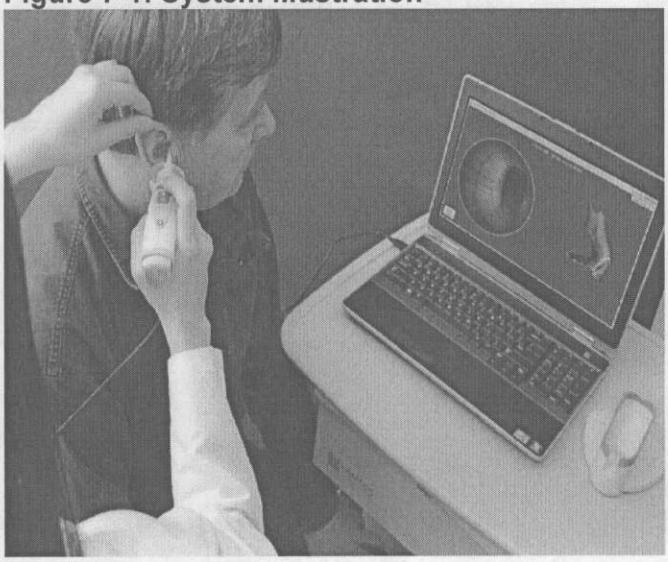

Figure 7-2: Hand Held Scanner

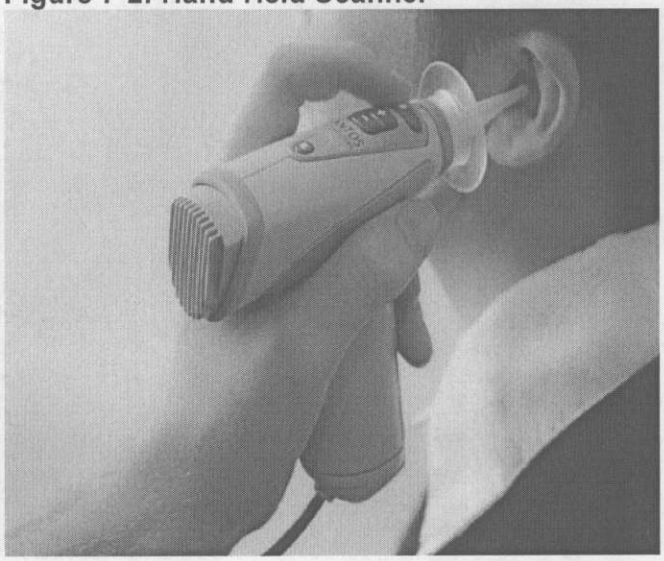

Figure 7-3: Conforming Membrane with Fluid

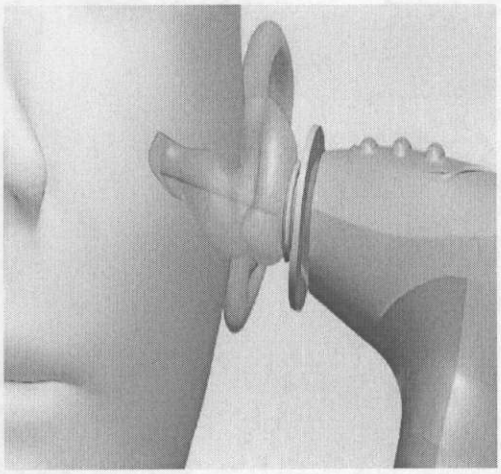

Figure 7-5: Wand Docking Stand

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(b)(4) Reveiw

[redacted]

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

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Theory of Operation

The Lantos 3D Ear Scanner provides a magnified visual image of the external ear canal to the hearing professional on a laptop computer screen. The sponsor provides a step-by-step description of Scanner operation, followed by detailed theories of operation for key subassemblies and algorithms.

The Scanner acts as a Video Otoscope, showing high-resolution color images of the ear. To produce the images, the scanner uses the following subassemblies, as described, in functional order from probe tip to laptop screen:

- *Distal Lens* – the lens collects a wide angle view of the ear canal, and passes light in the visible spectrum with high spatial resolution and minimal distortion.

- *Illumination Fibers* – glass optical fibers carry visible light to the probe tip; they are positioned in an annular ring surrounding the distal lens, and polished to maximize light throughput.

- *Probe Tube* – a thin steel tube contains the distal lens and illumination fibers, and carries the collected light through a series of small relay lenses to the optical sensor – the probe tube effectively extends the view of the sensor into the ear canal.

- *Optical Sensor* – a high resolution CMOS optical sensor converts the visible light photons to electrical signals representing signal strength at each pixel.

- *Camera Subassembly* – (b)(4) Reveiw [redacted]

- *Illumination Source* – a three color Red/Green/Blue collection of LED die are coupled through an optical taper into the proximal end of the illumination fibers – a microcontroller and associated current control drive circuits create an illumination flash sequence synchronized with the shutter of the optical sensor.

- *USB Transmission* – a circuit in the Scanner implements the Universal-Serial-Bus protocol, and communicates via the tether cable over a serial LVDS link to a companion USB circuit in the laptop.

- *Laptop CPU and GPU* – Lantos application software directs the laptop processor to monitor the USB channel, to reconstruct the serial data stream back to the series of video images, and directs the graphical processor to display the images on the LCD screen.

Illumination / Combo Subassembly

Four visible-light LED die are mounted on a metal core circuit board, and wire-bonded

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via pads to a connector. The metal core board also includes a thermistor to detect over-temperature. LED drive circuits on a mating board control the power and timing of current through the LED die to provide continuously variable scene lighting for the Scanner. Altera FPGA and CPLD circuits on a Combo board synchronize the LED pulses with the image sensor.

An optical glass Taper-Coupler collects the LED light output and guides it to a cylindrical ferrule that contains the glass optical fibers, which in turn carry the illumination to the probe tip. The Combo Subassembly also contains Flex Cables which join the electronic subassemblies in the Scanner.

(b)(4) Reveiw

[redacted]

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

<u>Reviewer Comments:</u> The sponsor states the a three color Red/Green/Blue collection of LED die are coupled through an optical taper into the proximal end of the illumination fibers creating an illumination flash sequence synchronized with the shutter of the optical sensor. However, they do not provide the technical characteristics of the LEDs (e.g., wavelength, maximum output power). This basic information is necessary for the review of the device safety. The sponsor should provide this information.

C. Risk Analysis (§9.2 and Attachment I))

The sponsor states that "Specific Hazards Analysis The hazards analysis was conducted in accordance with ISO 14971. All potential hazards associated with the device in both normal and fault conditions were recorded, along with probable causes of the hazards.

The record of hazards is included in Attachment I, Section 11.1, as the Risk Management File, Hazard Identification. The potential hazards were analyzed according to probability and severity. Mitigations were identified and implemented where necessary. The analysis is included in Attachment I, Section 11.2 as the Risk Management File, Hazard Analysis."

<u>Reviewer Comment:</u> Among the listed hazards, the following two items related to potential optical radiation damage to the eye and ear under device fault conditions (cited from Attachment I):

- **Excessive Light Energy Eye Damage**

ID	Hazard Description	Severity	Cause	Occur-rence	Risk Index	Mitigation	Type of Mitigation
6	C.2.5.1 C.2.14.1 **Excessive Light Energy Eye Damage** Patient or operator exposed to non-ionizing radiation – visible light from probe tip. **Seizure** Patient or operator affected by Strobe effects from probe tip.	Low	Scanner emits light for ear canal viewing and for 3D scan. Amount of light may increase under circuit fault conditions. Probe light output pulsed.	Occ	Acc	Emitted light confined to narrow angle. Wavelength of light tightly confined to visible range by design. Detection and control circuits to shut down light output if faults detected. By design, blink rate remains low until target detected in close range, within 30mm. Operator warned and trained to turn on light only when probe tip in ear canal; no risk to patient, and reflected light to operator much less intense. Conforming Membrane blocks light.	Design Detection Test Labelling

- **Burns: Scanner body or probe tip overheats, leading to burns of patient or operator.**

8	C.2.14.3 **Burns** Scanner body or probe tip overheats, leading to burns of patient or operator.	Mod	Circuit failure leading to thermal runaway.	Occ	Neg	By design, potential thermal energy sources in scanner have low thermal conductivity to probe tip. Probe tip components metal, glass and plastic, and transmit light energy only. Thermal energy sources in scanner shielded from operator by plastic enclosure, or shell with limited thermal conductivity. Hardware monitoring of likely heat sources during fault, with shutdown.	Design Detection

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However, the sponsor does not evaluate/analysis the optical radiation safety under normal use condition (i.e.., under the proposed indications for use).

Deficiency:

The sponsor should address the following concerns which are relative to the potential optical radiation hazard issue.

Device Description

1. On page 46 of 535, Device Description, you state that the illumination source of your device is "a three color Red/Green/Blue collection of LED die are coupled through an optical taper into the proximal end of the illumination fibers – a microcontroller and associated current control drive circuits create an illumination flash sequence synchronized with the shutter of the optical sensor."

   However, you do not provide the technical characteristics of these LEDs (e.g., wavelength (spectrum distribution), maximum and normal operating output power). Please provide these parameters which are the essential information for evaluating your risk analysis.

Eye Safety

2. The eye is the organs most susceptible to damage by optical radiation. It is not clear that whether the LEDs are turned on before or after the probe is inserted into ear. If the LEDs are turned on before inserting, there is the potential optical radiation hazard to the eye because of the proximity to the eyes. If Lantos 3D Ear Scanner is designed to be used in this condition, your device may pose the following types of hazards:

   - Retinal photochemical aphakic light hazard (305 -700 nm)
   - Retinal visible and infrared radiation thermal hazard (400 -700 nm)
   - There's more evidence that blue light (400 – 500nm) can damage eyes, with people who have had cataracts removed being particularly vulnerable.

   We believe an evaluation of phototoxicity to the eyes for use of your device is necessary. For phototoxicity analysis including classification, labeling, and informational requirements for the device, we recommend reference to the following standards:

   - American Conference of Governmental Industrial Hygienists (ACGIH): Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices (2011)

   - ANSI/IESNA RP-27.2-2000 Recommended Practice for Photobiological Safety for Lamps & Lamp Systems - Measurement Techniques

   - ANSI/IESNA RP-27.3-2007 Recommended Practice for Photobiological Safety for Lamps - Risk Group Classification & Labeling

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

Please provide a phototoxicity evaluation, including (may not limited to) the following information:

a. Irradiance measurement at a default distance of 20cm and at the worst case (shortest) of distance form nose.

b. Risk group assessment: This assessment results in either an Exempt Group or one of three Risk Group classification: Risk Group 1 ((Low-Risk)), Risk Group 2 (Moderate Risk)) and Risk Group 3 (High Risk).

c. Appropriate protection should be used when the risk group classification is not "Exempt". Please describe whether there is any mitigation that will be effective to prevent the potential harm to the eyes to insure user safety when operating the device under the condition of intended use.

The following labeling issues are for your consideration:

We recommend follow excerpt from ANSI/IESNA RP-27.3 -07 Section 6.2. to provide Caution labels to inform and instruct end user regarding pertinent safety related information that should be provided if the lamp is classified as Risk Groups 1, 2, or 3. For example:

i. A statement of the potential hazard, if any. This should simply advise as to what might expected to occur (i.e., skin irritation, or eye injury).

ii A list of what precautions could or should be taken to avoid the risk (e.g., "Do not shine the device directly in eyes…", "Appropriate eye protection should be used when daily exposure at short distance (XX cm) is greater than XX minutes.")

Ear/Skin Safety

3. The ear skin is also vulnerable to damage by optical radiation. The type of effect, injury thresholds, and damage mechanisms vary significantly with wavelength. There are different types of damage to the skin may be caused by optical radiation, for example:

- Thermal damage (burns) of the skin with visible and infrared radiation.

- Photosensitized damage of the skin: It is generally far more typical of UVR wavelengths (less than 380 nm). However, such photosensitized reactions can extend to approximately 700 nm, possibly as a side-effect of certain medications.

You do not include an evaluation of optical radiation hazard to the skin. We recommend you evaluate skin safety for use of your device by performing an optical radiation hazard evaluation to demonstrate your device meets the safety guideline specified in ACGIH [1] and ICNIRP [2] or an equivalent method. Please provide this information.

[1] ACGIH American Conference of Governmental Industrial Hygienists Threshold Limit Values for chemical substances and physical agents and Biological Exposure Indices. 2011.

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[2]. International Commission on Non-Ionizing Radiation Protection (ICNIRP). Guidelines on limits of exposure to broad-band incoherent optical radiation (0.38-3um). Health Phys. 73: 37 539-554; 1997.

You may choose alternate approaches as long as above concern related to optical radiation safety can be addressed.

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

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
510(k) AUDIOLOGY REVIEW MEMO

From: Cherish Giusto, Au.D., CCC-A, ENTB/DONED/ODE Cherish Giusto 6/14/12

To: Andrew Yang, ENTB/DONED/ODE

CC: Nandu Nandkumar, Ph.D., Branch Chief, ENTB/DONED

Subject: K121326: Lantos 3D Ear Scanner

Date: June 14, 2012

RECOMMENDATION: TELEPHONE HOLD

Per your request, I have completed the audiology review of this K121326 submission regarding the Lantos 3D Ear Scanner. I have reviewed the Indications for Use, Device Description and Predicate Comparison, Clinical Performance Data, and Labeling from the clinical audiology perspective. I will defer review of the bench testing and risk analysis to the engineering reviewer. I have identified a number of questions for the sponsor to address before a determination of substantial equivalence can be made. My deficiencies are located in the Conclusion & Recommendations section, and I recommended that the submission be placed on telephone hold and the deficiencies be forwarded to the sponsor. Please refer to the remainder of this review memo for details.

INDICATIONS FOR USE

The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal.

The Lantos 3D Ear scanner:

- ☐ provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation and;
- ☐ includes an expanding conforming membrane which aids observation when inserted in the ear canal and;
- ☐ records and presents to the hearing professional in an image file a topology measurement of the external ear canal

Intended Use Population

The 3D Ear Scanner may be used in any adult for visual inspection of the external ear, subject to the limitations of the warnings and precautions in the user manual. The 3D Ear Scanner records the external ear topology as an aid for use in the design and manufacturing of devices inserted in the ear.

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

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Reviewer's Comments: The sponsor states in the 510(k) Summary that they believe this device is a Class I Otoscope (21CFR874.4770) that trips the exemption because of new technology. I agree that this device introduces new technology and requires a 510(k) submission. Specifically, traditional otoscopes simply provide a means to visually inspect the ear canal and tympanic membrane as viewed through the external auditory meatus. Video otoscopes, such as the predicate Welch Allyn device, also display a digital video image of what is seen through the speculum. This device takes the technology even a step further by producing a 3D topographic representation of the ear canal. Therefore, this device not only provides a means of magnifying and visualizing the ear canal for otoscopic inspection, but also generates a digital ear impression. It is important to recognize that this device is not simply being utilized as a video otoscope, but will also for making a digital ear impression from which custom ear pieces (e.g. Bluetooth, custom earphones, etc.), custom ear plugs, and hearing aids can be manufactured.

The first bullet of the IFU is a standard, traditional video otoscope indication that is equivalent to the predicate device. The second and third bullets of the IFU represent a change in technology and indications for use for this type of device (otoscope), as well as the Intended Use Population statement "records the external ear topology as an aid for use in the design and manufacturing of devices inserted in the ear." These reflect the changes in technology and IFU that warrant a 510(k) pre-market review.

The sponsor states that this device currently is only indicated for adults, not for pediatric use. I agree with this indication; further performance data would be warranted for a pediatric indication at this time.

I have the following comment for the sponsor:

1. ***In the Indications for Use (page 24 of 535), you state that your device is indicated for use "by a trained hearing professional in clinical settings on adult patients..." Please clarify the following issues and also update the Instructions for Use (User's Manual) accordingly:***
    a. ***Please be more specific about which trained hearing professionals you are referring to, as well as what type of training, if any, recommended for using this device.***
    b. ***Please define adult patients by providing the age criteria (e.g., adult patients 18 years and older).***

DEVICE DESCRIPTION

The Device consists of a hand held scanner, a single patient use disposable with a conforming membrane, which when in use is filled with an absorbing medium, and a laptop computer. The hand held scanner, when not in use, is placed in a docking stand.

The hand held scanner is tethered to the docking stand with a custom cable. The docking stand is tied to the laptop computer. The hand held scanner contains illumination, optics, a camera, a motor to move the probe tip, and a motor-driven reservoir.

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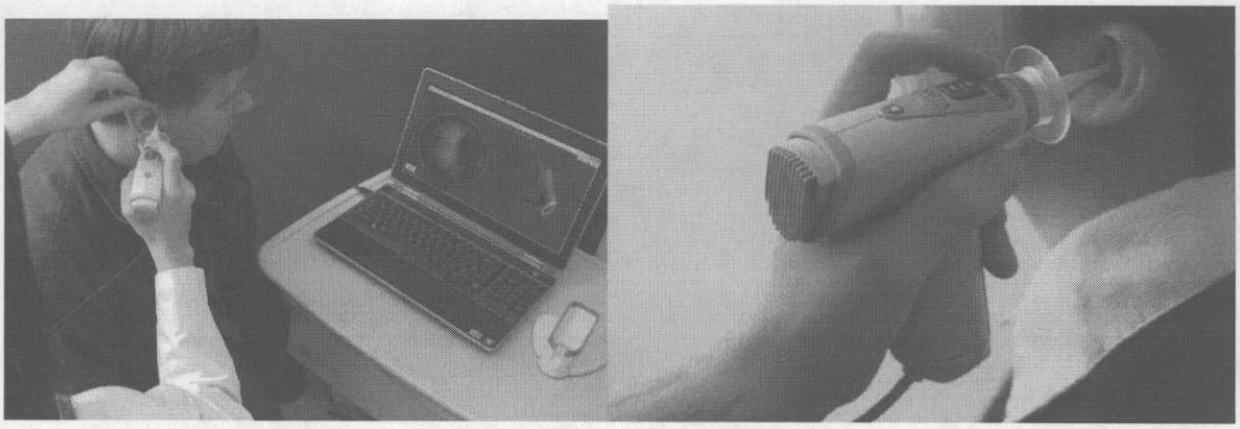
A system illustration is provided below:



The user starts the device by turning on a switch on the docking stand and the switch on the laptop, and preparing the device in accordance with the instructions for use. The hand held scanner is tethered to the docking stand with a custom cable that provides power and two-way communication. The docking stand is tied to the laptop computer with a USB cable. The hand held scanner contains illumination, optics, a camera, a motor to move the probe, and a motor-driven reservoir with fluid as described in the detailed device description.

User Interface software screens are displayed on the laptop and the user interacts with the device via the laptop keyboard and touchpad, and control buttons on the hand held scanner, as guided by the UI screens. Image data from the patient is stored on the hard disk in the laptop, and may be transmitted by the user via a wireless connection in the laptop. No patient identifiable data is stored in the Lantos device. The user enters a 2 or 3 character alphanumeric code for each scan, which together with the timestamp of the scan, the user identification and the site information, is sufficient to uniquely identify the scan. It is the responsibility of the user to record and transfer the scan identifier for transmission of the image data.

A single patient use disposable which includes the conforming membrane, is placed over the hand held scanner probe tip, in a manner similar to placing an ear speculum over the viewing tip of a conventional otoscope. The disposable will contact and reshape the ear canal with mild pressure, to improve the view of the ear canal, and to keep the probe tip from contacting the ear canal, performing the same functions as a speculum. The disposable may be used up to five times for the single patient before discarding.

The Lantos scanner is intended for use by a trained hearing professional (**the user**) in clinical settings on adult patients presenting for inspection of the external ear canal and tympanic membrane. The user guides the probe tip visually, looking through a flexible window at the tip of the membrane. The window is circular and similar in size to the opening at the tip of a speculum. The Lantos scanner displays a magnified visual image of the external ear canal and tympanic membrane to the user on a laptop computer screen. The Lantos scanner incorporates a visible light spectrum source to illuminate the ear canal.

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

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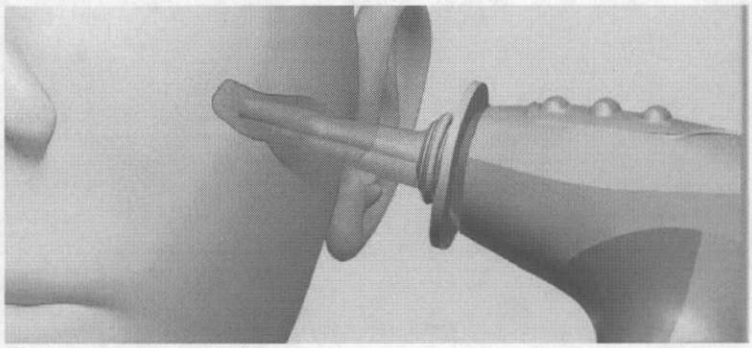
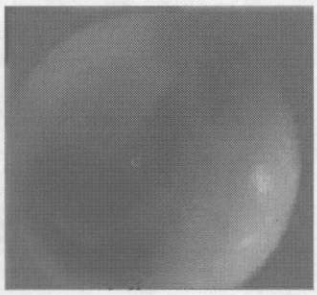
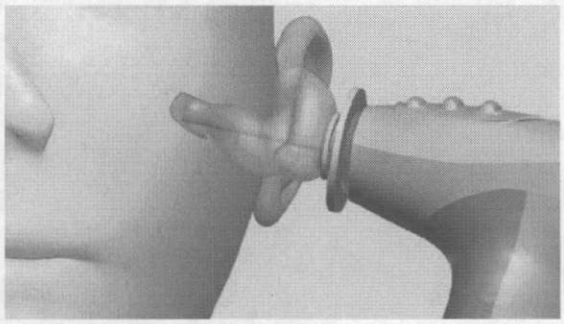
The Lantos scanner has a long thin tip to extend the viewing lens and illumination into the ear canal. The user places a single patient use conforming membrane over the scanner tip. The conforming membrane has a clear window at the distal end. The user may view different portions of external ear canal and tympanic membrane by changing the position and orientation of the scanner, as with a traditional video otoscope. In addition the user may save one or more fixed otoscope images for later use.

Video Otoscope Mode

If desired, the user may also record a topology measurement of the external ear canal, and save it as an image file for later use. The user positions the scanner tip visually, according to the desired extent of the topology measurement. When positioned, the user expands the conforming membrane with liquid absorbing medium to match the shape of the external ear canal as depicted below:



Ear Topology Mode – Start

The user holds the scanner in a fixed position relative to head, and retracts the scanner tip into the scanner body; the tip passes through the canal. The scanner captures a series of video images, and transforms the series into an image of the ear topology measurement. When the desired extent of topology has been captured, the user withdraws the fluid from the conforming membrane and removes the scanner from the ear. The topology image is visible to the user on the laptop computer screen, and may be saved for later use.

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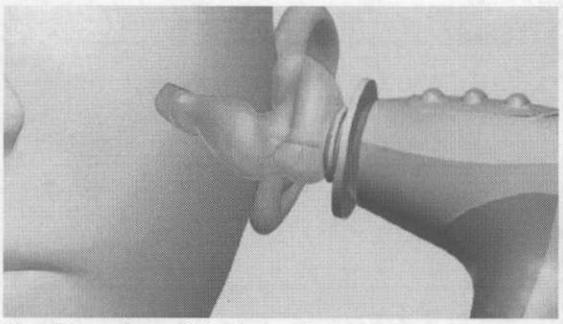
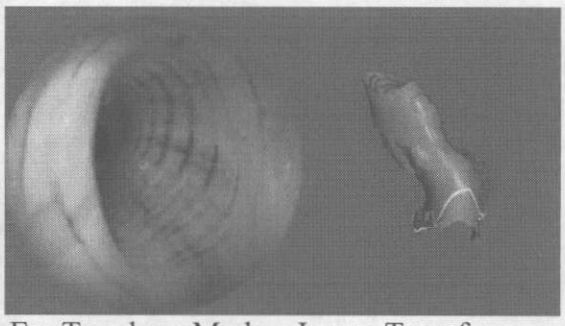
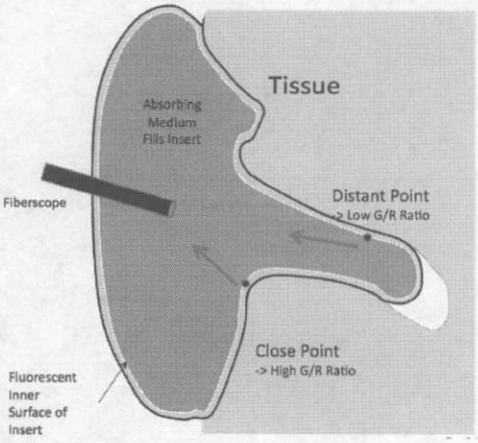

Ear Topology Mode – Scan-Retract


Ear Topology Mode – Image Transform

Ear Topology Mode – Final Topology Image

Ear Topology Transform

The LantosView Application software converts the sequence of video images into a cumulative topology model of the external ear canal, visible to the user. As shown below, a fluorescent dye embedded in the inside surface of the conforming membrane absorbs visible blue light illumination, and emits in longer wavelengths, Red and Green, from each individual point on the membrane surface. The emitted light travels through the absorbing medium, which selectively absorbs the Green emission. The distance to each point on the surface can be calculated from the ratio of Green to Red light detected at that point.



3D Point Collection

The individual points collectively form a point cloud, which is converted by well-known 3D reconstruction techniques to a mesh of triangles, a closed surface. Each raw video image of the

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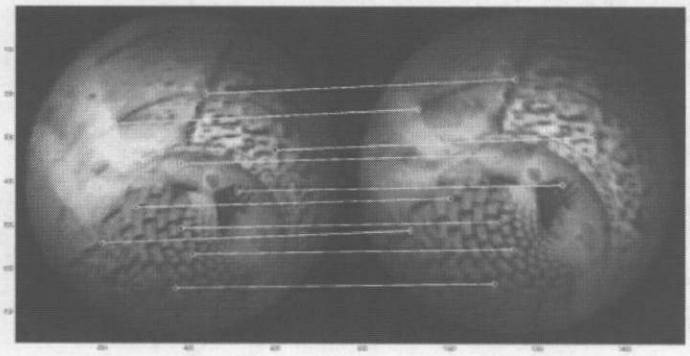
membrane interior surface is converted to a 3D mesh surface representing a significant portion of the external ear canal.

The individual 3D mesh surface fragments are joined together by two methods, with 2D image stitching, identifying and aligning similar features in the sequential raw images, as shown in the left half of the figure below, and with 3D surface stitching, identifying similar 3D features in the sequential raw images, as shown in the right half of the figure below. The algorithm intelligently transforms the sequence of meshes into the cumulative topology of the entire external ear.



Measurement of Dynamics

For many subjects, the external ear canal moves with jaw or head movement. By extending the methods described immediately above, the Scanner can take a time series of 3D topology measurements, align the measurements, and show an image to the hearing professional of the difference over time. For example in Figure 7-31, below, a cross section through the ear canal shows how the canal shape changes.

Contraindications, Warnings, & Precautions (page 34 of 535)

7.11. Contraindications

a. Not for use in pediatric patients

7.12. Warnings & Precautions

a. Take precaution and use clinical judgment for patients with known or suspected ear infections
b. Take precaution and use clinical judgment for patients with known or suspected perforated eardrum(s)
c. Use clinical judgment for patients where the anatomy of the external ear appears to have unsuitable tortuosity
d. Do not use in the presence of flammable anesthetics
e. Do not connect the 3D Ear Scanner to devices other than as expressly described in these Instructions
f. Do not use this device for any purpose other than specified in these Instructions
g. Discontinue use of the device is you notice any signs of damage to the components – contact Lantos Technologies support for service – no user serviceable components
h. Disposable is single patient use only

Reviewer's Comments: After reviewing the device description, there are some remaining questions and concerns about how the device functions. It may be useful to request a sample or a demonstration of the device from the sponsor. I viewed a video about the device located at

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http://www.youtube.com/watch?v=WeHTB4ZZ3OI&feature=plcp. This did not provide much information in addition to what is in the submission. I have the following comments for the sponsor:

1. *For otoscopy and the topography measurements, correct use of the device is essential for generating a safe and accurate image of the ear canal. It is important to minimize the risk of user error that could result in an inaccurate ear canal measurement or damage to a patient's ear. Please address the following issues in your device description and update your Instructions for Use as appropriate:*

    a. *Please provide a recommended maximum insertion depth of the probe into the ear canal (e.g., 3mm from the TM).*
    b. *Please indicate if the conforming membrane expands medially from the probe tip. If so, please explain how the user should avoid the possibility of the membrane contacting the tympanic membrane.*
    c. *Since your disposable comes with a reservoir of 15cc of fluid, this suggests that the user will need to judge how much fluid is necessary to generate the appropriate topography measure. Please indicate how the user should avoid using too much or too little of the fluid to fill the conforming membrane and generate an accurate measure.*
    d. *Please clarify if it is possible to displace the cartilaginous portion of the ear canal with pressure from the conforming membrane and fluid, and indicate if why you do not expect this to have an impact on the accuracy of the topography measure.*
    e. *Please indicate the length of your probe tip and how this compares to a standard speculum on a traditional otoscope. Also, please indicate if you have included any mechanisms for minimizing the risk of the probe tip making contact with the tympanic membrane during use.*

2. *In section 7.10 (Use Overview, page 37 of 535), you state "The disposable will contact and reshape the ear canal with mild pressure…" Please indicate if this amount of mild pressure has been judged to be acceptable by the majority of patients on whom the device has been used.*

3. *You provide a list of contraindications, warnings, and precautions (Sections 7.11 & 7.12, page 34 of 535). This list is lacking some detail to effectively guide users' clinical judgment. Please address the following issues and be sure to include all of these contraindications, warnings, and precautions in your Instructions for Use (User's Manual):*

    a. *You specify that the device is not for use in the pediatric population. Please provide the specific age range for whom the device is contraindicated.*
    b. *In Warnings & Precautions, bullet 'c', you state "Use clinical judgment for patients where the anatomy of the external ear appears to have unsuitable tortuosity." Please clarify what is meant by "unsuitable tortuosity" and provide examples of tortuous ear canals that are unsuitable for your device. Also, please explain why your device should not be used in these patients, since this is a population for whom traditional ear impression techniques are difficult*

and could greatly benefit from 3D scanning technology.

c. ***You do not provide any guidance on the use of your device with respect to the presence of cerumen in the ear canal. Please indicate if the ear canal should be completely cleaned of cerumen prior to use of the otoscopic and/or topography functions of your device.***
d. ***Please indicate if your device may be used in patients with exotoses or osteomas, and if so, what precautions should be taken.***
e. ***Please indicate what precautions should be taken for the use of your device in immuno-compromised patients, such as persons with diabetes or HIV.***

PREDICATE COMPARISONS

The Sponsor identifies the Welch Allyn Video Otoscope (K943916; ERA; 21CFR874.7440) as the predicate device for the 3D Ear Scanner, and provides the following predicate comparison discussion:

Indications for Use
The Lantos 3D Ear Scanner and the Welch Allen Video Otoscope have very similar intended uses. The Welch Allyn Vide Otoscope is similar to and predicated upon two different Welch Allyn devices already in commercial distribution. The device combines a common otoscope design with the previously 510(k) approved Welch Allyn LCI-200 Illumination and Imaging System (K940270/A) and incorporates a camera attachment in place of the magnifying view window on the otoscope. Additionally the Video Otoscope has the same operating principles and intended use as many competitive video otoscopes already in commercial distribution.

The Video Otoscope's intended use is to non-invasively examine the external ear canal and tympanic membranes in children and adults. The practitioner will use a common ear speculum to cover the otoscope tip; the speculum contacts and reshapes the patient's ear canal when inserted. The image of the ear is picked up by a camera in the otoscope head and then transmitted to a video processor for display on a computer screen.

In addition to visually inspecting the ear, the Video Otoscope has an additional intended use to provide pneumatic otoscopy, which is used to examine the ear canal and tympanic membrane under slight varying applied pressure. The user attaches a pneumatic source to the otoscope, inserts the speculum so it conforms tightly to the ear canal wall, forming a seal, and then inserts and withdraws air, changing the pressure applied to the external ear canal and tympanic membrane, while observing the image.

The Lantos 3D Ear Scanner shares the intended use to non-invasively examine the external ear canal and tympanic membrane. Instead of a common ear speculum, the user covers the Scanner tip with the conforming membrane with view window. The magnification, illumination, and field of view are similar, as are the displayed images on the computer screen.

The primary difference between the predicate device and the Lantos 3D Ear Scanner is the additional intended use. Instead of pneumatic otoscopy, the Scanner uses the conforming membrane to create a topology measurement of the external ear canal. For the topology

measurement, the user inserts the probe and conforming membrane into the ear canal, expands the membrane until it conforms tightly to the ear canal wall, while observing the individual 3D images and the cumulative topology image.

The Welch Allyn Video Otoscope also differs in that it is indicated for all age groups. The current intended use of the Lantos 3D Ear Scanner is limited to adult patients. This difference is due to the lack of testing of the Lantos 3D Ear Scanner in pediatric patients. This will be the subject of a later 510k with clinical data on safety.

Target Population

The primary difference in target population between the welch Allyn Video Otoscope and the Lantos 3D Ear Scanner is the exclusion of the pediatric population. For adult patients, either the common ear speculum, Video Otoscope, or the conforming membrane, Lantos 3D Ear Scanner, will contact the walls of the ear canal. Appropriate clinical judgment and caution is advised with both devices for use in patients with known ear infections or perforated eardrum(s).

Product Labeling

The product labeling for the Welch Allyn Video Otoscope is included in Section 13, Attachment III, the labeling for the Lantos 3D Ear Scanner is provided in Section 15, Attachment V. The differences in the labeling are primarily due to the differences in technological characteristics and different operating principles of the two devices. The end result of both devices is to provide a video image of the external ear.

Performance Characteristics

The Video Otoscope and the Lantos 3D Ear Scanner share many performance characteristics; they also have differences, as follows.

Both devices include a series of lenses in a small tube that can be inserted in the ear canal, with optics designed to collect and project an image onto a camera sensor. Both devices send the resulting digital sensor images over a cable to a video processor in an attached computer, for display to the user. Both devices provide magnified, wide angle, high-resolution views of the ear canal. For both devices, the user must manipulate the device and the patient's outer ear to obtain a composite view of the ear canal.

The Video Otoscope includes a Halogen white light source, coupled through a fiber optic bundle to project a cone of light from the scope tip. The 3D Ear Scanner also couples light through a fiber optic bundle to project a cone of light from the scope tip, but differs in that the white light source is a mixed output of red, green, and blue LED die, and that the resulting color mix varies under software control for different operating modes. Both light sources can be powered either by battery or by wall power.

The Video Otoscope uses both disposable and reusable specula to cover the probe tip, and to reshape the ear canal for viewing. In use, the speculum is intermittently in tight contact with the canal wall, contacting varying surface area depending on placement by the user. The specula are available in various sizes, chosen by the user to accommodate canal size. In contrast the 3D Ear Scanner includes a single patient use disposable with conforming membrane, which expands to conform to the ear canal wall, to shape the canal for viewing, and to provide a known viewing

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surface. The conforming membrane generally contacts a greater surface area than the speculum, for about the same period of time. The conforming membrane is liquid filled soft silicone. The specula come in many varieties, typically flexible polyethylene for disposable, or polypropylene for reusable. From a viewpoint of substantial equivalence, the conforming membrane (balloon) used in the Lantos Ear Scanner is substantially equivalent to the Specula in the predicate device.

The Video Otoscope requires a closed system with a tight seal for pneumatic otoscopy. The user inserts the scope with covering speculum into the ear canal, compresses the speculum against the canal wall to form the seal, and then squeezes a rubber bulb connected by channel to the distal side of the seal by a flexible tube to increase the air pressure. The 3D Ear scanner uses a closed system for the topology measurement. The user inserts the scope with covering conforming membrane into the ear canal, expands the membrane to conform to the ear with liquid from a motor driven reservoir in the scanner, connected by tube to the membrane, then retracts the probe tip to create the topology measurement.

Physical and Technical Characteristics
The physical and technological characteristics are similar with respect to the capture and display of video images, the differences relate more to the methods by which the images are further processed by the application software, and the fact that the Lantos Ear Scanner provides a 3D image file along with the video image. However, these differences are minor with respect to substantial equivalence as described by regulation and FDA Guidance.

Reviewer's Comments: I agree that this device shares many similarities with the predicate device. The sponsor makes a good point about the pneumatic otoscopy function on legally marketed video otoscopes. This additional indication/function is analogous to the additional topography indication/function of the Lantos 3D Ear Scanner. None-the-less, the topography feature is a new indication for this device.

CLINICAL PERFORMANCE TESTING

The sponsor provides a summary of two clinical investigations of the Lantos 3D Ear Scanner.

Clinical Evaluation #1: Direct Scan Earmold Digitization Evaluation:
The first investigation, titled Direct Scan Earmold Digitization Evaluation took place at Tripler Regional Medical Center. This study evaluated the custom earplugs manufactured from the Lantos 3D Ear Scanner (direct scan) compared to custom earplugs manufactured from the current practice of digital scanning of a traditional ear impression (from silicone material). The study will compare the attenuation capabilities of the two sets of custom earplugs. A study synopsis is provided below (from Tripler Report, Section 16.2, page 388 of 535):

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Title:	Direct Scan Earmold Digitization Evaluation
Investigators:	Principal Investigator Denby Fukuda, Au.D., CCC-A, Chief, Audiology Section
	Associate Investigator: Leslie J. Peters, PhD., CCC-A/SP. (Contract Audiologist)
Study Center(s):	Tripler Regional Medical Center 1 Jarrett White Rd., TAMC Honolulu 96859 Tel: (808) 433-3198 Fax: (808) 433-7115
Publication (reference):	None
Study Period:	Study is on-going
Date of First Enrollment:	November 1, 2011
Regulatory Status:	IDE exempt, IRB approved October 6, 2011
Primary Objective	The attenuation found with custom earplugs manufactured from direct ear canal digitization will not differ significantly from custom earplugs manufactured using visible light (Lantos ED Ear Scanner) imagery of an ear mold from the same ear.
Secondary Objective:	Safety – no serious, device related adverse events
Methodology	A prospective (non-inferiority) 40 patient study
Number of Patients	40
Diagnosis and Main Criteria for Inclusion	The study will require 40 normal hearing subjects with no known pathology be evaluated using the two types of custom earplugs. The specific frequency of hearing threshold results will be compared against similar results using each set of manufactured earplugs. Inclusion Criteria : Subject between the ages of 18-60 Subject is fluent in English Subject had satisfactory ear exam
Device Serial Number(s):	One scanner was utilized throughout the study: Alpha Four 40 disposable expanding membranes were used during the study and all were from lot 23.
Criteria for Evaluation:	Efficacy for noise protection devices Safety- absence of device related adverse events
Statistical Methods:	This study will require 40 subjects to achieve a .05 level of significance. This value was derived from the work of Cohen (3). This study will be conducted as a prospective analysis using paired observations of audiometric threshold data using Cohen's Kappa. The degree of agreement among these scores will determine significance. Per Cohen (3), a median effect size with a .05 level of confidence will require 30 subjects. Forty subjects
	will be recruited to meet the number required and account for subject attrition.
Summary/Conclusions:	Safety endpoint is met, efficacy evaluation is ongoing

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Clinical Evaluation #2: Lantos EarScan 3D User Preference Study:

The second investigation, titled Lantos EarScan 3D User Preference Study, was conducted to assess the device features, device operation, and operator experience. This investigation appears to serve as a human factors study. A study synopsis is provided below (from South Shore Hearing Interim Report, Section 16.4, page 437 of 535):

Title:	Lantos 3D Ear Scanner User Preference Study
Investigators:	Principal Investigator David Citron, III, Ph. D., FAAA
Study Center(s):	South Shore Hearing Center (SHCC) Stetson medical Center
	541 Main Street, Suite 418 South Weymouth, MA 02190 Phone: (781) 337-6860
Publication (reference):	None
Study Period:	Preference Study is on-going
Date of First Enrollment:	December 21, 2012
Regulatory Status:	IDE Exempt, IRB Approved December 1, 2011
Primary Objective	The objective of this clinical study is to assess the Lantos 3D Ear Scanner device features, device operation, and operator experience. • With training, operators are able to complete digital scans in the same or less time than traditional silicone earmold impressions • Operators rate the digital scan experience equal or better than that for earmold impressions.
Secondary Objective:	Observations and records of use, which may lead to device improvements.
Methodology	Single-Center, prospective, non-randomized user preference study.
Number of Patients	Up to 25 subjects.
Diagnosis and Main Criteria for Inclusion	The study will require up to 25 subjects with no known pathology be evaluated using the Lantos 3D Ear Scanner. Inclusion Criteria : • Patient presenting for silicone earmold impression • Satisfactory ear exam prior to use of the Lanots EarScan 3D • Subject must be 21-95 years of age
Device Serial Number(s):	Alpha 4
Criteria for Evaluation:	Safety: absences of adverse events
Statistical Methods:	Data analysis will be completed with a compilation of the inputs from the questionnaire at the end of the protocol.
Summary/Conclusions:	The user preference study is on-going.

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The sponsor submits interim reports for both of these investigations, which include only very limited information on the results. They state that the safety objectives have been met as no adverse events were reported with the use of the Lantos 3D Ear Scanner.

Reviewer's Comments: The main issue with the clinical investigations is that they were both still in progress at the time of the submission. The interim data were submitted primarily to demonstrate that no adverse events have been reported, suggesting that the topography functionality is safe. I do not have any issues with this in the context of the clinical investigations. However, I do have further questions about mitigating the risk of adverse events and labeling (see above).

I do have concern about a lack of effectiveness data for the topography functionality of the device. Because this device has new technological features in the topography measures, and this will be the primary marketed aspect of the device, effectiveness, or accuracy of the measurement should be demonstrated in this submission. There are also some questions regarding the study designs and results. I have the following comments for the sponsor:

1. ***You provide an interim report for the Direct Scan Earmold Digitization Evaluation which demonstrates no adverse events for the Lantos related aspects of the study. However, this interim report includes only the secondary endpoint results; it does not include the primary endpoint effectiveness data demonstrating the comparison between the current standard of care for ear impressions and custom earplug manufacturing (earmold scan) and your device's direct scan method. Because your intended population use and labeling include claims about using the topography measures to manufacture custom ear pieces and hearing aids, these effectiveness data are important to support a pre-market clearance of your device. Please provide the results from this clinical investigation that include both the safety and effectiveness endpoints.***

   Similarly, you provide an interim clinical report for your User Preference Study which includes a partial data set and no analyses. Please provide the final results from this clinical investigation in support of the safety and effectiveness of your device for its intended use.

2. ***You state that custom earplugs were manufactured for your Direct Scan Earmold Digitization Evaluation, but a description of the earplug style/features cannot be located. Please provide further details about the earplug features, including if the custom earplugs were full shell style or canal style plugs.***

3. ***Please indicate how you intend to evaluate the accuracy/effectiveness of the 3D ear scan for the concha and helix regions of the topography measurements obtained with your device.***

4. ***In the Methods section of the Direct Scan Earmold Digitization Evaluation protocol (section 7.6 Determination of Eligibility, page 350 of 355), you state "subjects will be 40 normal hearing mean and women…with no known medical pathology." However, your subjects included persons with hearing loss, and this***

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was not reported as a protocol deviation. Please indicate why you included subjects with hearing loss in this study.

5. *You measure the amount of attenuation provided by the custom earplugs in each ear separately in the Direct Scan Earmold Digitization Evaluation. Given that your audiometric measures were performed in the sound field, please explain how you were able to isolate each ear for the attenuation measures.*

   Also, please indicate if your subjects and investigators were blinded as to which custom earplugs were derived from which scanning method. If not, please indicate how you will control for this potential bias, particularly with respect to the investigators' blinding.

6. *You describe the protocol deviations (section 10.0, page 395 of 535) in the Direct Scan Earmold Digitization Evaluation. However, further details are needed to explain the impact of these deviations. Please address the following issues:*

   a. *The second bullet states "the audiologist determined potential clinical implications for subjects receiving earmold impression scans prior to the EarMold 3D Direct scans of the ear canal" and explains those implications. However, it is unclear exactly how the protocol was modified and what impact the modification could have on the results.*
   b. *Under the third bullet, you state "In addition, the audiologist detemined these frequencies are unreliable for testing and re-testing purposes due to the directionality of the 8000Hz and subjects respond to 250 Hz as a vibro-tactile even when not heard." Please clarify what is meant by "the directionality of the 8000 Hz." Also, please clarify why you would expect subjects to have a vibro-tactile response to a 250 Hz tone presented via loud speaker in the sound field at levels of 40 dB HL and below.*

7. *In your User Preference Study, 10 out of 10 clinicians rated the video otoscope images from this device the same or more difficult relative to the quality of images from other conventional or video otoscopes. Furthermore, in Figure 7-21(page 48 of 538) you provide images from the video otoscope where there appears to be limited visibility of the tympanic membrane. This suggests that the images from the video otoscopy of your device may not yield "exceptional visualization of the ear canal" as claimed in your draft brochure, or that visualization of the tympanic membrane may be limited. Please provide images and performance data to support your claims about the quality of images from the video otoscopy with your device.*

8. *In your User Preference Study, most of your clinician subjects indicated that they would like a prompt or an identification of insertion depth or ear canal length. Please indicate how you plan to address this issue.*

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LABELING

The sponsor provides drafts of the following labeling in Sections 8.1 – 8.4 and Attachment V, section 15.1, 15.2, & 15.3:

1. 3D Ear Scanner Device Kit Label
2. Multi-Pack of Single Use Disposables Label
3. Single Use Disposable Label
4. Scanner Body Label
5. Instructions for Use
6. Promotional Flyer
7. Training Manual (on a separate CD included in the submission)

The labeling information has been reviewed from the perspective of clinical audiology, with particular focus on the Instructions for Use and the Promotional Flyer.

Reviewer's Comments: In the absence of a training video, the Instructions for Use provide reasonable guidance for a trained hearing healthcare professional to use the Lantos 3D Ear Scanner. However, I have the following comments for the sponsor:

1. ***In section 15.3 (Training Manual, page 342 of 538), you state "Note; A DVD/CD is provided in the 510k package with a video training film." However, this DVD/CD with the Training Manual cannot be located in the submission package. Please include this in your next submission.***

2. ***You provide descriptions of the steps for using the Lantos 3D Ear Scanner to perform video otoscopy and topography measurements in the Instructions for Use. You may consider including additional diagrams and/or photographs of the device in use in order to provide references for the user. Examples of additional images that may be helpful for the Instructions for use include the button controls on the device, the check cap, the protective cap, how to brace the device while retracting the probe tip during topography, etc.***

3. ***In the Draft Brochure (page 337 of 535), under Safety and Comfort, you state "The scanner can be used with confidence in cases where traditional impression material might require extended preparation. Please clarify what is meant by this statement.***

4. ***Please be sure to include the updated contraindications and precautions in the Instructions for Use.***

CONCLUSION & RECOMMENDATION

I have completed the clinical audiology review on this submission, K121326 (Lantos 3D Ear Scanner). The addition of topography measures to the video otoscopy function of the Lantos 3D Ear Scanner constitutes a change in the indications for use and technological characteristic of this type of device. Therefore, I concur that this device meets the limitations of exemption, and a

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510(k) submission with clinical data is warranted. The concerns identified are as follow; please forward them to the sponsor.

Indications for Use

1. In the Indications for Use (page 24 of 535), you state that your device is indicated for use "by a trained hearing professional in clinical settings on adult patients…" Please clarify the following issues and also update the Instructions for Use (User's Manual) accordingly:

    a. Please be more specific about which trained hearing professionals you are referring to, as well as what type of training, if any, recommended for using this device.

    b. Please define "adult patients" by providing the age criteria (e.g., adult patients 18 years and older).

Device Description

2. For otoscopy and the topography measurements, correct use of the device is essential for generating a safe and accurate image of the ear canal. It is important to minimize the risk of user error that could result in an inaccurate ear canal measurement or damage to a patient's ear. Please address the following issues in your device description and update your Instructions for Use as appropriate:

    a. Please provide a recommended maximum insertion depth of the probe into the ear canal (e.g., 3mm from the TM).

    b. Please indicate if the conforming membrane expands medially from the probe tip. If so, please explain how the user should avoid the possibility of the membrane contacting the tympanic membrane.

    c. Since your disposable comes with a reservoir of 15cc of fluid, this suggests that the user will need to judge how much fluid is necessary to generate the appropriate topography measure. Please indicate how the user should avoid using too much or too little of the fluid to fill the conforming membrane and generate an accurate measure.

    d. Please clarify if it is possible to displace the cartilaginous portion of the ear canal with pressure from the conforming membrane and fluid and to what extent. Also, please indicate why you do not expect this to have an impact on the accuracy of the topography measure.

    e. Please indicate the length of your probe tip and how this compares to a standard speculum on a traditional otoscope. Also, please indicate if you have included any mechanisms for minimizing the risk of the probe tip making contact with the tympanic membrane during use.

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3. In section 7.10 (Use Overview, page 37 of 535), you state "The disposable will contact and reshape the ear canal with mild pressure..." Please indicate if this amount of mild pressure has been judged to be acceptable in terms of comfort by the majority of patients on whom the device has been used.

4. You provide a list of contraindications, warnings, and precautions (Sections 7.11 & 7.12, page 34 of 535). This list is lacking some detail to effectively guide users' clinical judgment. Please address the following issues and be sure to include all of these contraindications, warnings, and precautions in your Instructions for Use (User's Manual):

    a. You specify that the device is not for use in the pediatric population. Please provide the specific age range for who the device is contraindicated.

    b. In Warnings & Precautions, bullet 'c', you state "Use clinical judgment for patients where the anatomy of the external ear appears to have unsuitable tortuosity." Please clarify what is meant by "unsuitable tortuosity" and provide examples of tortuous ear canals that are unsuitable for your device. Also, please explain why your device should not be used in these patients, since this is a population who have difficulty with traditional ear impressions and could greatly benefit from 3D scanning technology.

    c. You do not provide any guidance on the use of your device with respect to the presence of cerumen in the ear canal. Please indicate if the ear canal should be completely clear of cerumen prior to use of the otoscopic and/or topography functions of your device.

    d. Please indicate if your device may be used in patients with exotoses or osteomas, and if so, what precautions should be taken.

    e. Please indicate what precautions should be taken for the use of your device in immuno-compromised patients, such as persons with diabetes or HIV.

Clinical Testing

5. You provide an interim report for the Direct Scan Earmold Digitization Evaluation which demonstrates no adverse events for the Lantos related aspects of the study. However, this interim report includes only the secondary endpoint results for safety; it does not include the primary endpoint effectiveness data demonstrating the comparison between the current standard of care for ear impressions and custom earplug manufacturing (earmold scan) and your device's direct scan method. Because your intended population use and labeling include claims about using the topography measures to manufacture custom ear pieces and hearing aids, these effectiveness data are important to support a pre-market clearance of your device. Please provide the final results from this clinical investigation that include both the safety and effectiveness endpoints.

Similarly, you provide an interim clinical report for your User Preference Study which includes a partial data set and no analyses. Please provide the final results from this clinical investigation in support of the safety and effectiveness of your device for its intended use.

6. You state that custom earplugs were manufactured for your Direct Scan Earmold Digitization Evaluation, but a description of the earplug style/features cannot be easily located. Please provide further details about the earplug features, including if the custom earplugs were full shell style or canal style plugs.

7. Please indicate how you intend to evaluate the accuracy/effectiveness of the 3D ear scan for the concha and helix regions of the topography measurements obtained with your 3D Ear Scanner device.

8. In the Methods section of the Direct Scan Earmold Digitization Evaluation protocol (section 7.6, Determination of Eligibility, page 350 of 355), you state "subjects will be 40 normal hearing mean and women...with no known medical pathology." However, your subjects included persons with hearing loss, and this was not reported as a protocol deviation. Please indicate why you included subjects with hearing loss in this study and any expected impact on your study results.

9. You measure the amount of attenuation provided by the custom earplugs in each ear separately in the Direct Scan Earmold Digitization Evaluation. Given that your audiometric measures were performed in the sound field, please explain how you were able to isolate each ear for the attenuation measures.

   Also, please indicate if your subjects and investigators were blinded as to which custom earplugs were derived from which scanning method. If not, please indicate how you will control for this potential bias, particularly with respect to the investigators' blinding.

10. You describe the protocol deviations (section 10.0, page 395 of 535) in the Direct Scan Earmold Digitization Evaluation. However, further details are needed to explain the impact of these deviations. Please address the following issues:

    a. The second bullet states "the audiologist determined potential clinical implications for subjects receiving earmold impression scans prior to the EarMold 3D Direct scans of the ear canal" and explains those implications. However, it is unclear exactly how the protocol was modified and what impact the modification could have on the results. Please provide these details.

    b. Under the third bullet, you state "In addition, the audiologist determined these frequencies are unreliable for testing and re-testing purposes due to the directionality of the 8000Hz and subjects respond to 250 Hz as a vibro-tactile even when not heard." Please clarify what is meant by "the directionality of the 8000 Hz." Also, please clarify why you would expect subjects to have a vibro-tactile response to a 250 Hz tone presented via loud speaker in the sound field at levels of 40 dB HL and below.

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11. In your User Preference Study, 10 out of 10 clinicians rated the video otoscope images from this device the same or more difficult relative to the quality of images from other conventional or video otoscopes. Furthermore, in Figure 7-21(page 48 of 538) you provide images from the video otoscope where there appears to be limited visibility of the tympanic membrane. This suggests that the images from the video otoscopy of your device may not yield "exceptional visualization of the ear canal" as claimed in your Draft Brochure, or that visualization of the tympanic membrane may be limited. Please provide images and performance data to support your claims about the quality of images from the video otoscopy with your device.

12. In your User Preference Study, most of your clinician subjects indicated that they would like a prompt or an identification of insertion depth or ear canal length. Please indicate how you plan to address this issue.

Labeling

13. In section 15.3 (Training Manual, page 342 of 538), you state "Note; A DVD/CD is provided in the 510k package with a video training film." However, this DVD/CD with the Training Manual cannot be located in the submission package. Please include this in your next submission.

14. In the Draft Brochure (page 337 of 535), under Safety and Comfort, you state "The scanner can be used with confidence in cases where traditional impression material might require extended preparation." This statement implies that the Lantos 3D Ear Scanner is a better option in difficult cases. Please clarify is meant by this statement by indicating what cases this is referring to and providing data or a rationale to support this statement.

15. You provide descriptions of the steps for using the Lantos 3D Ear Scanner to perform video otoscopy and topography measurements in the Instructions for Use. You may consider including additional diagrams and/or photographs of the device in use in order to provide references for the user. Examples of additional images that may be helpful for the Instructions for use include the button controls on the device, the check cap, the protective cap, how to brace the device while retracting the probe tip during topography, etc.

16. Please include the updated contraindications and precautions in the Instructions for Use.

Feel free to let me know if you have any questions about this review memo.

Cherish Giusto

Reviewed by Cherish Giusto, Au.D., CCC-A
Clinical Reviewer in Audiology

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

98

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

K121326/S1 V.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

January 25, 2013

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

Lantos Technologies
% Mr. John Greenbaum
Generic Devices Consulting, Inc.
20310 SW 48th Street
Southwest Ranches, FL 33332

Re: K121326
Trade/Device Name: Lantos 3D Ear Scanner
Regulation Number: 21 CFR 874.4770
Regulation Name: Otoscope
Regulatory Class: Class I
Product Code: ERA, ESD
Dated: December 18, 2012
Received: December 19, 2012

Dear Mr. Greenbaum:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K121326/S1

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off	Srinivas Nandkumar 2013.01.25 12:37:45 -05'00'
Division Sign-Off	Eric A. Mann 2013.01.25 12:47:10 -05'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

K121326

INDICATIONS FOR USE

510(k) Number (If Known): K121326

Device Name: Lantos 3D Ear Scanner

Indications for Use:

The Lantos 3D Ear Scanner is intended for use by a trained hearing professional on patients 18 years of age and older presenting for inspection of the external ear canal.

The Lantos 3D Ear scanner:

- provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for inspection and;
- includes an expanding membrane that can be inserted and conforms to the external ear canal when filled with an absorbing medium which enables the 3D scan and;
- records and presents to the hearing professional in an image file a topology measurement of the external ear canal

Prescription Use__X__ AND/OR Over-the Counter Use____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K121326

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

* * * COMMUNICATION RESULT REPORT (JAN. 28. 2013 1:27PM) * * *

FAX HEADER 1:
FAX HEADER 2:

SMITTED/STORED : JAN. 28. 2013 1:27PM

F... MODE	OPTION	ADDRESS	RESULT	PAGE
2772 MEMORY TX		+1. 954. 653. 1153	OK	3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

January 25, 2013

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

Lantos Technologies
% Mr. John Greenbaum
Generic Devices Consulting, Inc.
20310 SW 48th Street
Southwest Ranches, FL 33332

Re: K121326
Trade/Device Name: Lantos 3D Ear Scanner
Regulation Number: 21 CFR 874.4770
Regulation Name: Otoscope
Regulatory Class: Class I
Product Code: ERA, ESD
Dated: December 18, 2012
Received: December 19, 2012

Dear Mr. Greenbaum:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name LCDR Andrew Yang

Subject: 510(k) Number K121326/S001

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 (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

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?			X
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards?		X	
(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 _____, 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)?			X
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

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conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)		
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)	X	
Child (2 years -< 12 years old)	X	
Adolescent (12 years -< 18 years old)	X	
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.)		X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	X	
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	Class*	Product Code
874.4770	I	ERA

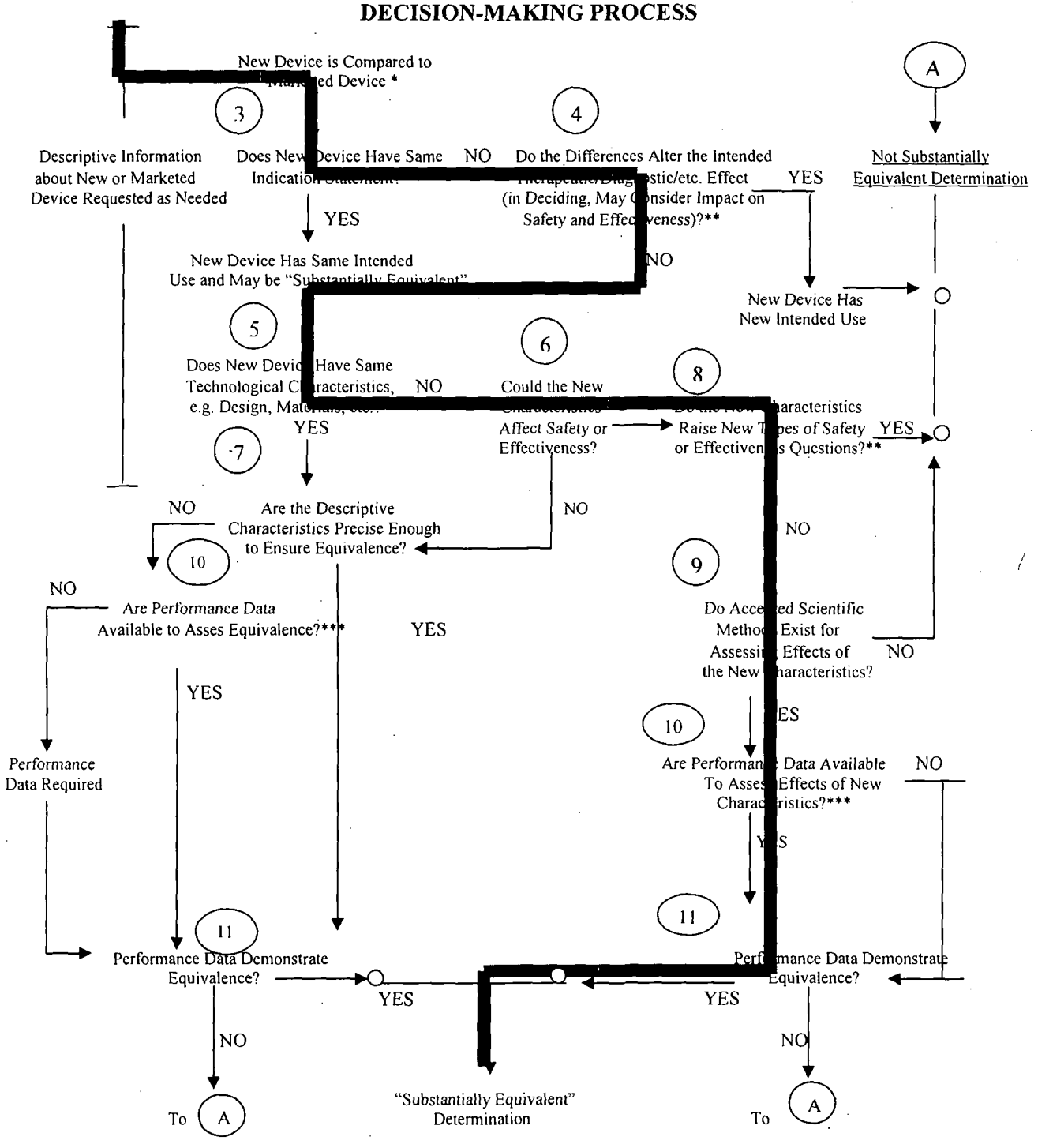
(*If unclassified, see 510(k) Staff)

Additional Product Codes:_____ESD_____

Branch Chief Sign-Off:	Srinivas Nandkumar 2013.01.25 12:12:18 -05'00'
Division Sign-Off:	Eric A. Mann 2013.01.25 13:17:55 -05'00'

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

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.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES M E M O R A N D U M

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

Premarket Notification 510(k) Review
Traditional
K121326/S001

Date: January 14, 2012
To: The Record
From: Andrew Yang

Office: ODE
Division: DONED

510(k) Holder: Lantos Technologies
Device Name: Lantos 3D Ear Scanner
Contact: John Greenbaum
Phone: (954) 610-0178
Fax: (954) 653-1153
Email: genericd@bellsouth.net

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the Lantos 3D Ear Scanner into interstate commerce.

II. Administrative Requirements

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

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	

The Device consists of a hand held scanner, a single patient use disposable with a conforming membrane, which when in use is filled with an absorbing medium, and a laptop computer. The hand held scanner, when not in use, is placed in a docking stand.

The hand held scanner is tethered to the docking stand with a custom cable. The docking stand is tied to the laptop computer. The hand held scanner contains illumination, optics, a camera, a motor to move the probe tip, and a motor-driven reservoir.

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

User Interface (UI) software screens are displayed on the laptop and the user interacts with the device via the laptop keyboard and touchpad, and control buttons on the hand held scanner, as guided by the UI screens. Image data from the patient is stored in the laptop, and may be transmitted by the user via a wireless connection. No patient identifiable data is stored in the Lantos device.

A single use disposable, which includes the conforming membrane, is placed over the hand held scanner probe tip, in a manner similar to placing an ear speculum over the viewing tip of a conventional otoscope. The disposable will contact and reshape the ear canal with mild pressure, to improve the view of the ear canal, and to keep the probe tip from contacting the ear canal, performing the same functions as a speculum.

Comment: The device description is inadequate. Some key elements of its operation were unclear. The sponsor references a training video that was lost at the DMC. I found videos on Youtube showing the device in use. This resolved some questions regarding how it is anchored against the head while scanning takes place. The software allows for a certain degree of movement. The engineering drawings are incomplete: at the very least, the pump assembly and power source are absent. A live demonstration or video, such as the training video, would be very helpful.

IV. Indications for Use

The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal.

The Lantos 3D Ear scanner:

- provides a magnified visual image for inspection of the external ear canal and tympanic membrane,

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and provides illumination of the ear canal for observation and;

- *includes an expanding conforming membrane which aids observation when inserted in the ear canal* and;
- records and presents to the hearing professional in an image file a topology measurement of the *external ear canal*

Comment: Contraindicated for pediatric patients, but no ages specified. Deficiency

V. Predicate Device Comparison

	(K943916)	Lantos 3D Ear Scanner (NEW)
Intended use	The VideOtoscope's intended use is to non-invasively examine the external ear canal and tympanic membranes in children and adults. The practitioner will use a common ear speculum to cover the otoscope tip; the speculum contacts and *reshapes the patient's ear canal when inserted.* The image of the ear is picked up by a camera in the otoscope head and then transmitted to a video processor for display on a computer screen. The VideOtoscope has an additional intended use to provide pneumatic otoscopy, which is used to examine the ear canal and tympanic membrane under slight varying applied pressure.	The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal. *The Lantos 3D Ear scanner:* provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation and; includes an expanding conforming membrane which aids observation when inserted in the ear canal and; records and presents to the hearing professional in an image file a topology measurement of the external ear canal.
Target population	Patients requiring a visual inspection of the ear.	Patients requiring a visual inspection of the ear. Excludes pediatric patients.
Where used	Independent ear examination clinics, audiologist offices, hearing professional offices, hospital based clinics	Independent ear examination clinics, audiologist offices, hearing professional offices, hospital based clinics
Energy used and/or delivered	SELV DC Volts/Amps White Light	SELV DC Volts/Amps RGB mixed 'White' Light
Human factors	Welch Allyn requires correct positioning of the illumination source and speculum. Human factors are very similar. Use of the computer to see images and store data are similar.	Lantos 3D Ear Scanner requires expansion of a fluid filled membrane to obtain a complete 3D image of the ear. Human factors are very similar. Use of the computer to see images and store data are similar.
Physical Characteristics	Scanner Dimensions ~70mm L x 102mmH x 37mmW Weight ~95g without cable *Laptop Commercial 15in Laptop* Operating 10° C to 40° C *700 to 1060 hPa Altitude*	Scanner Dimensions ~160mm L x 130mmH x 40mmW Weight ~230g without tether cable *Laptop Commercial 15in Laptop* Operating 10° C to 40° C *700 to 1060 hPa Altitude*
Performance Characteristics	Field of View >100° Cone in Air – Video Otoscope View Direction of View 0° aligned with probe axis Illumination Halogen Source 'White' Light via fiber bundle	Field of View >120° Cone in Air – Video Otoscope View Direction of View 0° aligned with probe axis Illumination Red / Green / Blue 'White' Light via fiber bundle
Standards	UL 544 (patient vicinity) IEC 60601-1-2 - Medical Electrical Equipment – Part 1-2 –General requirements for basic safety and essential performance – Collateral standard: *Electromagnetic Compatibility – Requirements and* Tests IEC 60601-2-18:1996 Amendment 1 2000 Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment	IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-1-2 Medical Electrical Equipment – Part 1-2 –*General requirements for basic safety and* essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and Tests IEC 60601-2-18: Edition 3.0 2009-08 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential

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

		performance of endoscopic equipment FDA; Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices - May 2005 FDA Guidance; Cyber Security for Networked Medical Devices Containing Off the Shelf Software ISO 14971: Medical devices—Application of risk management to medical devices ISO 10993 Parts 1-13 as Applicable

Comment: The table focuses on the similarities between the otoscope functions. The new technology, 3D scanning, has no cleared precedent. The closest technology is a physical ear mold (generally silicone) that is scanned 3-dimensionally and uploaded to a computer.

VI. Labeling

The primary device labeling for the Lantos 3D Ear Scanner includes:

1. 3D Ear Scanner Device Kit Label
2. Multi-Pack of Single Use Disposables Label
3. Single Use Disposable Label
4. Scanner Body Label
5. Instructions for Use
6. Promotional Flyer

Figure 8-1 – 3D Ear Scanner Device Kit Label

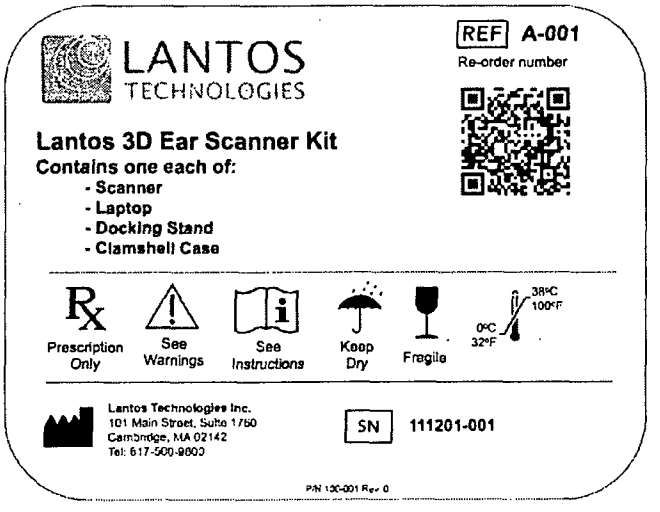

Figure 8-2 – Multi-Pack of Single Use Disposables Label

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

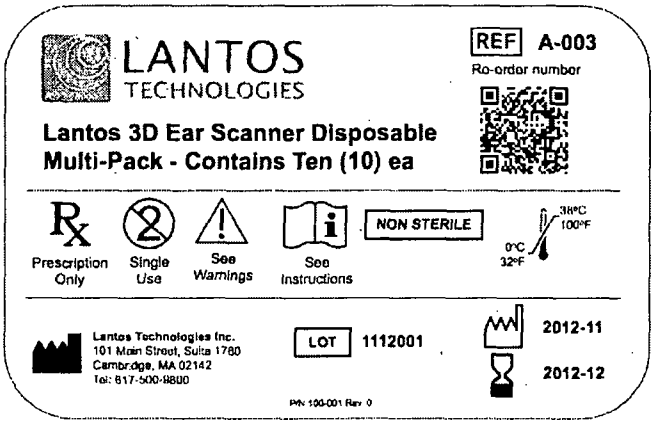

Figure 8-3 – Single Use Disposable Label

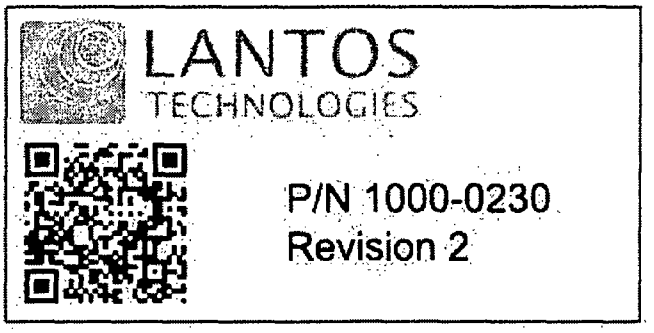

Figure 8-4 – Scanner Body Label

Comment: Cherish Giusto, Au.D., CCC-A reviewed the labeling and found the following: (1)They make a claim of superiority without support, (2) insuffient illustrations in the instructions, (3) outdated instructions that do not feature the latest contraindications and precautions, (4) a 1 month shelf-life that was not validated. Deficiency

VII. Sterilization/Shelf Life/Reuse

Comment: Sponsor provided cleaning instructions and validation. The validation confirmed the integrity of the device after cleaning. It does not address the microbiological effect. No component is sterile, not even the disposable parts. However, the risk analysis mentions a shelf-life for the disposable components. These contradictions required clarification. The sponsor

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responded by removing the shelf-life, explaining that they misunderstood our definition of shelf-life.

VIII. Biocompatibility

The components of the Lantos scanner and single use disposable listed in the following table are likely to contact the patient, or contact the hearing professional in the patient vicinity. All component materials were examined during risk analysis, and determined to be safe for such contact, either through test results obtained from the material manufacturers, and reviewed by Lantos, or through biocompatibility tests commissioned by Lantos. Engineering drawings for the components which may contact the patient or user are in Attachment VIII – Section 18.

Table 7-1: Materials

(b)(4) Reveiw

[redacted]

Comment: Vasant Malshet, PhD, DABT reviewed the toxicology in the original submission and found it to be acceptable.

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IX. Software

Quality Review Element	Explanation of Quality Review Issues
1. Level of concern: Did the submission identify the level of concern and provide a reasonable rationale for that level?	Adequate
2. Software description: Did the submission provide a summary overview of the features and software operating environment? Did the submission address: the role of software in the operation of the device; critical operations performed by software or checked by software; and how the software is related to the clinical use of the device?	Adequate
3. Hazard analysis: Did the submission address: completeness of the hazard analysis and whether hazards were appropriately identified; appropriate mitigations, traceability, and acceptability criteria for identified hazards; and a review of hazards and safety requirements as clinically appropriate by device expert?	Adequate
4. Software requirements specifications (SRS): Did the submission assess the adequacy of the SRS? Were safety requirements explicitly listed? (Was SRS broken down at the module, feature, and functional levels? Were mitigations of hazards identified?)	Adequate
5. Architecture design chart: Did the submission discuss the existence of a detailed description of functional units and software modules?	n/a
6. Software design specification (SDS): Did the submission provide an adequate SDS?	n/a
7. Traceability analysis: Did the submission provide an adequate traceability analysis?	
8. Software development environment description: Did the submission address the development environment? Did the submission indicate that a summary of software life cycle was included?	n/a
9. Verification and validation (V&V) documentation: Did the submission adequately present V&V documentation and testing? Did the submission address validation by user testing?	Adequate
10. Revision level history: Did the submission assess the adequacy of the revision level history? Did the submission indicate that an iterative process was performed?	Adequate
11. Unresolved anomalies: Did the submission adequately address issues of unresolved anomalies? Did the submission address clinical impact of unresolved anomalies?	n/a
12. Off-The-Shelf (OTS) Software: If the device contained OTS software, did the submission indicate that the following steps were taken by the sponsor: a. identifying OTS software, including version number; b. identifying all hazards associated with the OTS software; and c. indicating that appropriate steps were taken to adequately mitigate each hazard?	n/a
13. Standards: Did the submission document any use of software standards?	n/a
14. Connectivity: Were connectivity, communication, and/or security software issues addressed in the submission? If so, how were they evaluated?	n/a

Comment: LCDR Andrew Yang reviewed the software (see review). The sponsor claims a minor level of concern, which I do no disagree with. Therefore, only some of the review elements are necessary. All elements were acceptable.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The power supply (AC/DC converter) included with the Lantos 3D Ear Scanner, which provides the basis for electrical safety, has been fully tested and certified by a recognized third party laboratory (TUV) for compliance to IEC 60601-1, see Attachment IV, Section 14.6a and 14.7.

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Additional safety testing was performed to both the IEC 60601-1 and IEC 60601-2-18 standards on the complete Lantos 3D Ear Scanner, with all components. This testing incorporated the approved (TUV) power supply. The following is a summary of the testing that was performed on the device:

Standard	Test Clause(s)	Description	Result
IEC 60601-1	4.11	Power Input	Pass
IEC 60601-1	8.7	Leakage Current	Pass
IEC 60601-1	8.8.3	Dielectric Strength	Pass
IEC 60601-1	11.11.1	Excessive Temperature including Applied Parts	Pass
IEC 60601-1	13.2.6	Leakage of liquid (Optical Medium)	Pass
IEC 60601-2-18	201.5.1, 201.6.2, 201.8.3,	Protection Against Electric Shock (Type BF)	Pass
IEC 60601-2-18	201.10.5	Visible Electromagnetic Radiation (from LEDs)	Pass
IEC 60601-2-18	201.11.1	Excessive Temperature including Applied Parts	Pass
IEC 60601-2-18	201.11.6	Leakage of liquid (Optical Medium)	Pass
IEC 60601-2-18	201.15.4.1	Construction of connectors	Pass

Table 9-2: IEC 60601 Safety Testing

IEC 60601 Verification reports are in Attachment IV – Sections 14.6 and 14.8.

Further testing will be conducted prior to commercial distribution to meet the acceptance criteria specified in the applicable voluntary standards AAMI / ANSI IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance and the applicable parts of IEC 60601-2-18: Edition 3.0 2009-08, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment. A recognized third party laboratory will be utilized to perform the testing. Lantos will submit the IEC 60601-1 and IEC 60601-2-18 test reports to the 510(k) file upon completion of the testing.

Comment: LCDR Andrew Yang reviewed the EMC and electrical safety in the original submission. The testing demonstrated adequate safety. Mechanical safety was confirmed under the Risk Analysis which listed successful mitigations to potential mechanical injury, namely, over extending and striking the tympanic membrane, injuring the ear canal walls, and over-pressurizing the expanding membrane of the disposable tip. All mitigations were reasonable and lowered the risks to ALARP.

Comment: Dexiu Shi, Ph. D., reviewed the phototoxicity of the light source (see review).

XI. Performance Testing – Bench

n/a

XII. Performance Testing – Animal

n/a

XIII. Performance Testing – Clinical

Comment: Cherish Giusto, Au.D., CCC-A reviewed the clinical and audiology information (see review). This information was scattered throughout the submission. She identified a few deficiencies.

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XIV. Substantial Equivalence Discussion

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

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
The IFU resembles a typical video otoscope IFU, but includes language for 3D ear modeling, which is new technology

2. Explain why there is or is not a new effect or safety or effectiveness issue:
n/a

3. Describe the new technological characteristics:
3D ear modeling is accomplished without a physical mold. Rather, a camera collects a series of red and green images to create a 3D model in the software.

4. Explain how new characteristics could or could not affect safety or effectiveness:
This is a first-of-its-kind device and there are a lot of unknowns regarding its safety and effectiveness.

5. Explain how descriptive characteristics are not precise enough:
n/a

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
These are not new concerns. There has always been a potential for harm to the ear canal or tympanic membrane with respect to otoscopes.

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7. Explain why existing scientific methods can not be used:
These safety concerns can be studies and mitigated with existing scientific methods.

8. Explain what performance data is needed:
See deficiencies.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
n/a

XV. Deficiencies

Indications for Use

1. In the Indications for Use (page 24 of 535), you state that your device is indicated for use "by a trained hearing professional in clinical settings on adult patients..." Please clarify the following issues and also update the Instructions for Use (User's Manual) accordingly:

   a. Please be more specific about which trained hearing professionals you are referring to, as well as what type of training, if any, recommended for using this device.

   b. Please define "adult patients" by providing the age criteria (e.g., adult patients 18 years and older).

Device Description

2. For otoscopy and the topography measurements, correct use of the device is essential for generating a safe and accurate image of the ear canal. It is important to minimize the risk of user error that could result in an inaccurate ear canal measurement or damage to a patient's ear. Please address the following issues in your device description and update your Instructions for Use as appropriate:

   a. Please provide a recommended maximum insertion depth of the probe into the ear canal (e.g., 3mm from the TM).

   b. Please indicate if the conforming membrane expands medially from the probe tip. If so, please explain how the user should avoid the possibility of the membrane contacting the tympanic membrane.

   c. Since your disposable comes with a reservoir of 15cc of fluid, this suggests that the user will need to judge how much fluid is necessary to generate the appropriate topography measure. Please indicate how the user should avoid using too much or too little of the fluid to fill the conforming membrane and generate an accurate measure.

   d. Please clarify if it is possible to displace the cartilaginous portion of the ear canal with pressure from the conforming membrane and fluid and to what extent. Also, please

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indicate why you do not expect this to have an impact on the accuracy of the topography measure.

e. Please indicate the length of your probe tip and how this compares to a standard speculum on a traditional otoscope. Also, please indicate if you have included any mechanisms for minimizing the risk of the probe tip making contact with the tympanic membrane during use.

3. In section 7.10 (Use Overview, page 37 of 535), you state "The disposable will contact and reshape the ear canal with mild pressure..." Please indicate if this amount of mild pressure has been judged to be acceptable in terms of comfort by the majority of patients on whom the device has been used.

4. You provide a list of contraindications, warnings, and precautions (Sections 7.11 & 7.12, page 34 of 535). This list is lacking some detail to effectively guide users' clinical judgment. Please address the following issues and be sure to include all of these contraindications, warnings, and precautions in your Instructions for Use (User's Manual):

   a. You specify that the device is not for use in the pediatric population. Please provide the specific age range for who the device is contraindicated.

   b. In Warnings & Precautions, bullet 'c', you state "Use clinical judgment for patients where the anatomy of the external ear appears to have unsuitable tortuosity." Please clarify what is meant by "unsuitable tortuosity" and provide examples of tortuous ear canals that are unsuitable for your device. Also, please explain why your device should not be used in these patients, since this is a population who have difficulty with traditional ear impressions and could greatly benefit from 3D scanning technology.

   c. You do not provide any guidance on the use of your device with respect to the presence of cerumen in the ear canal. Please indicate if the ear canal should be completely clear of cerumen prior to use of the otoscopic and/or topography functions of your device.

   d. Please indicate if your device may be used in patients with exotoses or osteomas, and if so, what precautions should be taken.

   e. Please indicate what precautions should be taken for the use of your device in immuno-compromised patients, such as persons with diabetes or HIV.

5. You provide engineering drawing in Attachment 8. However, it appears that some components are missing. We have identified 2 missing components: pump assembly, power source. Please provide these drawings and any others that were not previously included.

6. On page 46 of 535, Device Description, you state that the illumination source of your device is "a three color Red/Green/Blue collection of LED die are coupled through an optical taper into the proximal end of the illumination fibers – a microcontroller and associated current

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control drive circuits create an illumination flash sequence synchronized with the shutter of the optical sensor."

However, you do not provide the technical characteristics of these LEDs (e.g., wavelength (spectrum distribution), maximum and normal operating output power). Please provide these parameters which are the essential information for evaluating your risk analysis.

Clinical Testing

7. You provide an interim report for the Direct Scan Earmold Digitization Evaluation which demonstrates no adverse events for the Lantos related aspects of the study. However, this interim report includes only the secondary endpoint results for safety; it does not include the primary endpoint effectiveness data demonstrating the comparison between the current standard of care for ear impressions and custom earplug manufacturing (earmold scan) and your device's direct scan method. Because your intended population use and labeling include claims about using the topography measures to manufacture custom ear pieces and hearing aids, these effectiveness data are important to support a pre-market clearance of your device. Please provide the final results from this clinical investigation that include both the safety and effectiveness endpoints.

   Similarly, you provide an interim clinical report for your User Preference Study which includes a partial data set and no analyses. Please provide the final results from this clinical investigation in support of the safety and effectiveness of your device for its intended use.

8. You state that custom earplugs were manufactured for your Direct Scan Earmold Digitization Evaluation, but a description of the earplug style/features cannot be easily located. Please provide further details about the earplug features, including if the custom earplugs were full shell style or canal style plugs.

9. Please indicate how you intend to evaluate the accuracy/effectiveness of the 3D ear scan for the concha and helix regions of the topography measurements obtained with your 3D Ear Scanner device.

10. In the Methods section of the Direct Scan Earmold Digitization Evaluation protocol (section 7.6, Determination of Eligibility, page 350 of 355), you state "subjects will be 40 normal hearing mean and women...with no known medical pathology." However, your subjects included persons with hearing loss, and this was not reported as a protocol deviation. Please indicate why you included subjects with hearing loss in this study and any expected impact on your study results.

11. You measure the amount of attenuation provided by the custom earplugs in each ear separately in the Direct Scan Earmold Digitization Evaluation. Given that your audiometric measures were performed in the sound field, please explain how you were able to isolate each ear for the attenuation measures.

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Also, please indicate if your subjects and investigators were blinded as to which custom earplugs were derived from which scanning method. If not, please indicate how you will control for this potential bias, particularly with respect to the investigators' blinding.

12. You describe the protocol deviations (section 10.0, page 395 of 535) in the Direct Scan Earmold Digitization Evaluation. However, further details are needed to explain the impact of these deviations. Please address the following issues:

    a. The second bullet states "the audiologist determined potential clinical implications for subjects receiving earmold impression scans prior to the EarMold 3D Direct scans of the ear canal" and explains those implications. However, it is unclear exactly how the protocol was modified and what impact the modification could have on the results. Please provide these details.

    b. Under the third bullet, you state "In addition, the audiologist determined these frequencies are unreliable for testing and re-testing purposes due to the directionality of the 8000Hz and subjects respond to 250 Hz as a vibro-tactile even when not heard." Please clarify what is meant by "the directionality of the 8000 Hz." Also, please clarify why you would expect subjects to have a vibro-tactile response to a 250 Hz tone presented via loud speaker in the sound field at levels of 40 dB HL and below.

13. In your User Preference Study, 10 out of 10 clinicians rated the video otoscope images from this device the same or more difficult relative to the quality of images from other conventional or video otoscopes. Furthermore, in Figure 7-21(page 48 of 538) you provide images from the video otoscope where there appears to be limited visibility of the tympanic membrane. This suggests that the images from the video otoscopy of your device may not yield "exceptional visualization of the ear canal" as claimed in your Draft Brochure, or that visualization of the tympanic membrane may be limited. Please provide images and performance data to support your claims about the quality of images from the video otoscopy with your device.

14. In your User Preference Study, most of your clinician subjects indicated that they would like a prompt or an identification of insertion depth or ear canal length. Please indicate how you plan to address this issue.

Labeling

15. In section 15.3 (Training Manual, page 342 of 538), you state "Note; A DVD/CD is provided in the 510k package with a video training film." However, this DVD/CD with the Training Manual cannot be located in the submission package. Please include this in your next submission.

16. In the Draft Brochure (page 337 of 535), under Safety and Comfort, you state "The scanner can be used with confidence in cases where traditional impression material might require extended preparation." This statement implies that the Lantos 3D Ear Scanner is a better

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option in difficult cases. Please clarify is meant by this statement by indicating what cases this is referring to and providing data or a rationale to support this statement.

17. You provide descriptions of the steps for using the Lantos 3D Ear Scanner to perform video otoscopy and topography measurements in the Instructions for Use. You may consider including additional diagrams and/or photographs of the device in use in order to provide references for the user. Examples of additional images that may be helpful for the Instructions for use include the button controls on the device, the check cap, the protective cap, how to brace the device while retracting the probe tip during topography, etc.

18. Please include the updated contraindications and precautions in the Instructions for Use.

19. You provide copies of your labeling. One of the labels is for the Lantos 3D Ear Scanner Disposable Multi-Pack – Contains Ten (10) ea which bears the manufacturing month and the expiration month. Please explain how you arrived at this 1 month shelf-life and provide supporting documentation. Furthermore, in Attachment 1, you provide a list of hazards, among which are potential consequences of not heeding the expiration date. This suggests that the disposable components may become unsafe within 1 month of manufacturing. You do not provide a description of the packaging. Combined with the short shelf-life and dangers of expired product, the packaging is paramount. Please describe how all components are packaged, which includes the individual packaging for each component, individual cartons, shipping containers, etc.

Branch Chief Comment:
Sponsor response to all deficiencies were reviewed and accepted in attached consulting review memos. The lead reviewer is a USPHS officer and has been deployed. I as Branch Chief wrapped up his lead review memo.

XVI. Advisory

n/a

XVII. Recommendation

Regulation Number: 874.4770
Regulation Name: Otoscope
Regulatory Class: Class I
Product Code: ERA Additional Product code: ESD (hearing aid accessory)

SE

Branch Chief Sign-Off:	Srinivas Nandkumar 2013.01.25 12:24:22 -05'00'

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
510(k) AUDIOLOGY REVIEW MEMO

From: Shu-Chen Peng, Ph.D., CCC-A
ENTB/DOED/ODE

Shuchen Peng

Digitally signed by Shuchen Peng
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Shuchen Peng, 0.9.2342.19200300.100.1.1=1300399622
Date: 2013.01.25 12:37:43 -05'00'

To: Andrew Yang, ENTB/DOED/ODE

CC: Nandu Nandkumar, Branch Chief, ENTB/DOED/ODE

Subject: **K121326/S001**
Response to AI Request – 510(k) K121326
Lantos Technologies

Date: January 25, 2013

Per your request, I have completed the review on the sponsor's response to FDA Questions 1 – 4 and 7 – 18 that Dr. Cherish's Giusto identified in her review of K121326. During this review, the sponsor submitted additional information, including the revised Indications for Use (IFU) statement and the 510k summary submitted as per this reviewer and Dr. Nandkumar's request following the teleconference with the the sponsor representative, Deb Arthur on January 16, 2013 (see email dated January 18, 2013 with its attached files). This review of the sponsor's response and the additional information submitted on January 18 does not reveal any additional concerns or questions from the perspective of clinical audiology. Thus, "substantially equivalent" (SE) is recommended for the Lantos 3D Ear Scanner. Please refer to the remainder of this review memo for my question, followed by the sponsor's response, as well as my comment on the response.

FDA Question 1 (Indications For Use): In the Indications for Use (Page 24 of 535), you state that your device is indicated for use "by a trained hearing professional clinical settings on adult patients…" Please clarify the following issues and also update the Instructions for Use (User's Manual) accordingly:
a. Please be more specific about which trained hearing professionals you are referring to, as well as what type of training, if any, recommended for using this device.
b. Please define "adult patients" by providing the age criteria (e.g., adult patients 22 years and older).

Sponsor's Response:
a. The Lantos 3D Ear Scanner is indicated for use by the same population of hearing professionals who use video otoscopes, the predicate device. This population generally includes audiologists, physicians, and other licensed hearing healthcare professionals. These individuals

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by training, experience and licensure are knowledgeable in external ear canal anatomy as it relates to inspection of the canal with the intent of making an impression to be used for device earmolds, hearing aids, etc. They have experience with otoscopes whether video or stationary. Recommended training for use of the Lantos 3D Scanner is found in Attachment 3 (Instructions for Use). Additionally, company personnel will be available in the field and/or at Lantos's site to answer questions.

b. The appropriate revised language follows and can be found in the updated labeling within Attachment 3 on page 5. *The Lantos 3D Scanner is indicated for use on individuals 18 years of age and older…*

Reviewer's Comment: The sponsor has specified the professional training requirements and modified the cutoff age for the "adult patients" in the revised IFU and Instructions for Use. This response is judged as adequate.

FDA Question 2: For otoscopy and the topography measurements, correct use of the device is essential for generating a safe and accurate image of the ear canal. It is important to minimize the risk of user error that could result in an inaccurate ear canal measurement or damage to a patient's ear. Please address the following issues in your device description and update your Instructions for Use as appropriate:

a. Please provide a recommended maximum insertion depth of the probe into the ear canal (e.g. 3 mm from the TM)

b. Please indicate if the conforming membrane expands medially from the probe tip. If so, please explain how the user should avoid the possibility of the membrane contacting the tympanic membrane.

c. Since your disposable component comes with a reservoir of 15cc of fluid, this suggests that the user will need to judge how much fluid is necessary to generate the appropriate topography measure. Please indicate how the user should avoid using too much or too little of the fluid to fill the conforming membrane and generate an accurate measurement.

d. Please clarify if it is possible to displace the cartilaginous portion of the ear canal with pressure from the conforming membrane and fluid and to what extent. Also, please indicate why you do not expect this to have an impact on the accuracy of the topography measure.

e. Please indicate the length of your probe tip and how this compares to a standard speculum on a traditional otoscope. Also, please indicate if you have included any mechanisms for minimizing the risk of the probe tip making contact with the tympanic membrane during use.

Sponsor's Response: Risk of user error has been mitigated through design and labeling of the Scanner. Specifically, items 2a through 2e below have been answered and that response

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incorporated into the Instructions for Use to improve clarity and consistency. The modifications to labeling referenced below are located in Attachment 3 with their specific pages described.

a. Lantos recommends using the video otoscope image stream to adjust the position and insertion depth of the scanner tip (probe) into the ear canal. As can be seen in Figures 2a and 2b below, the scanner tip should be inserted no deeper than the point where the image of the tympanic membrane's perimeter reaches the edge of the viewing circle. This recommendation for maximum insertion depth insures that the scanner tip will be at least 4-5mm away from the tympanic membrane.

b. The conforming membrane is designed to expand radially with minimal medial expansion. Medial expansion as measured in anatomical models was 0.3 mm to 1.6 mm. As long as the user follows the recommended guidelines for insertion depth (see 2a above) by visually monitoring the positioning of the TM perimeter in the otoscope's visual stream, there is minimal risk of the conforming membrane contacting the tympanic membrane.

c. The user should fill the conforming membrane with fluid (see Figure 3) until the proximal part of the membrane has expanded and has filled the concha bowl (see Figure 4). Since the proximal end of the membrane is clearly visible it is reasonable for the user to judge when the concha bowl has been filled. This process is not unlike the conventional silicone injection methods used by hearing healthcare professionals when making ear impressions today. By design, the conforming membrane's radial expansion starts at the distal tip and continues out of the canal and into the concha. This design feature order ensures that the distal part of the membrane has already expanded and conformed to the geometry of the canal when the visible proximal end of the membrane starts to expand in the concha. While it is not necessary to empty the reservoir of all fluid to achieve a successful topology measurement, testing indicates that the total volume of fluid in the reservoir will fit in the conforming membrane with minimal risk of rupture. Testing also confirms that if all the fluid is injected into the membrane, canal wall pressure measurements are still less than the maximum pressure generated by silicone impressions.

Furthermore, the pressure and topology measurements are relatively insensitive to the amount of fluid in the membrane because the proximal section of the membrane remains unconstrained.

d. The Lantos conforming membrane has been designed to exert pressure on the canal wall that falls within the range of pressure exerted by current silicone impression processes. Silicone impressions are known to apply pressure to the ear canal wall, and displace the cartilaginous portion of the canal. This pressure and displacement can vary significantly depending on technique and factors such as silicone viscosity or jaw position (Pirzanski and Berge, 20052). Figure 5 below shows the measured range of wall pressure exerted on a model ear canal by multiple silicone impressions and Lantos 3D scans. It can be seen that the wall pressure measurements of the Lantos 3D scans fall within the range of pressure exerted by the silicone impressions.

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e. The Scanner (probe) tip length is 1mm when retracted and 36mm when fully extended; the diameter of the scanner tip is 3.3mm along its entire length. Video otoscope specula vary widely in size and shape, standard sizes vary in length from 15 to 30mm, tips vary from 2.5 to 9mm, and the shape is typically conical, increasing from distal to proximal. A description of the method of use (intended to minimize risk of the scanner tip contacting the TM) is found above in response to question 2a.

Reviewer's Comment: The sponsor has revised the labeling to address items 2a through 2e. This response is judged as adequate.

FDA Question 3: In section 7.10 (Use Overview, page 37 of 535), you state "The disposable will contact and reshape the ear canal with mild pressure..." Please indicate if this amount of mild pressure has been judged to be acceptable in terms of comfort by the majority of the patients on whom the device has been used.

Sponsor's Response: Lantos realizes that the description on the referenced page for the process of visualizing the external ear canal with the 3D Scanner is misleading. Actually, the disposable will contact the ear canal in the same manner as the predicate device. It may be moved laterally and superior/inferiorly to improve visualization through the scanner tip in the same manner as a video otoscope or a standard otoscope with speculum. There is no 'pressure' or 'reshaping' in the process of visualization.

With regard to the process of scanning the ear canal utilizing the Lantos scanner with conformal membrane, that process and a comparison to the conventional method of 'injection of silicone impression' material into the ear canal are addressed in the response to question 2d above.

Reviewer's Comment: The sponsor has clarified the description as requested. This response is judged as adequate.

FDA Question 4: You provide a list of contraindications, warning, and precautions (Sections 7.11 & 7.12, page 34 of 535). This list is lacking some detail to effectively guide users' clinical judgment. Please address the following issues and be sure to include all of these contraindications, warnings and precautions in your Instructions for Use (User's Manual):

a. You specify that the device is not for use in the pediatric population. Please provide the specific age range for who the device is contraindicated.

b. In Warnings & Precautions, bullet 'c', you state "Use clinical judgment for patients where the anatomy of the external ear appears to have unsuitable tortuosity." Please clarify what is meant by "unsuitable tortuosity" and provide examples of tortuous ear canals that are unsuitable for your device. Also, please explain why your device should not be used in these patients, since this

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is a population who have difficulty with traditional ear impressions and could greatly benefit from 3D scanning technology.

c. You do not provide any guidance on the use of your device with respect to the presence of cerumen in the ear canal. Please indicate if the ear canal should be completely clear of cerumen prior to use of the otoscopic and/or topography functions of your device.

d. Please indicate if your device may be used in patients with exotoses or osteomas, and if so, what precautions should be taken.

e. Please indicate what precautions should be taken for the use of your device in immuno-compromised patients, such as persons with diabetes or HIV.

Sponsor's Response: Lantos has addressed the Agency's concerns in questions 4a-e and has updated the Instruction for Use (Attachment 3) for clarity and consistency.
a. The Lantos 3D Scanner is contraindicated for use with individuals below 18 years of age.

b. Upon review of the referenced 'Warning & Precaution' and discussion with consulting audiologists, Lantos is removing this statement. As with standard and video otoscopes, if the scanner tip can be inserted and the ear canal and TM visualized, then it is likely that a successful scan can be obtained.

c. Precautions for the presence of cerumen in the ear canal are no different with the scanner than with conventional silicone EM impressions. Modest or thin deposits of cerumen will create commensurately small differences in the topology measurement, and the conforming membrane will compress deposits of soft cerumen similar to the conventional silicone impression. There is no limitation to the use of the scanner in otoscope mode in the presence of cerumen.

d. The use of the scanner in visualizing the external auditory meatus (EAM) of individuals experiencing exotoses or osteama would not be different than with a standard or video otoscope. The determination should be made by the trained hearing professional.

e. As with other methods of visualization and inspection of the EAM, the hearing clinician should always use standard precautions, i.e. use of disposable gloves with an additional protection offered by the single-use, disposable intent of the conforming membrane.

Reviewer's Comment: The sponsor has revised the information related to the contra-indications, warnings and precautions in the IFU. This response is judged as acceptable.

FDA Question 7: You provide an interim report for the Direct Scan Earmold Digitization Evaluation which demonstrates no adverse events for the Lantos related aspects of the study. However, this interim report includes only the secondary endpoint results for safety; it does not

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include the primary endpoint effectiveness data demonstrating the comparison between the current standard of care for ear impressions and custom earplug manufacturing (earmold scan) and your device's direct scan method. Because your intended population use and labeling include claims about using the topography measures to manufacture custom ear pieces and hearing aids, these effectiveness data are important to support a pre-market clearance of your device. Please provide the final results from this clinical investigation that include both the safety and effectiveness endpoints.

Similarly, you provide an interim clinical report for your User Preference Study which includes a partial data set and no analyses. Please provide the final results from this clinical investigation in support of the safety and effectiveness of your device for its intended use.

Sponsor's Response:
The use of this interim clinical report in the original 510(k) submission (April 2012) should have been clarified within the original submission. The intent, execution, and analysis of the study came from the ENT Department at Tripler Army Medical Center. While the information is certainly of interest to Lantos Technologies and they did provide a 3D Scanner and software for use, the study was not designed by Lantos nor intended to be a protocol to prove the safety and effectiveness of the Lantos 3D Scanner for Lantos' stated intended use.

In an attempt to ensure full disclosure, the manufacturer shared the study details in a manner that may have inferred it was provided as 'proof' of safety and efficacy of the 3D Scanner in the 510(k) submission (K121326). Lantos would like to apologize for any confusion and clarify its intent for inclusion in the original submission.

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Lantos Technologies felt the study data gathered by the time (April 2012) of 510(k) submission was *supportive* of the device's safety only; the efficacy parameters were not intended to be data interpreted as the *proof* of efficacy. The data cited in support of safety (absence of adverse events) were certainly expected and consistent with the manufacturer's risk profile. The remaining data are interesting but Lantos does not believe the study design was valid for the determination of efficacy, nor is the protocol design, study conduct and data management and analysis under the purview of Lantos as they are not the sponsor of the study.

In fact, in discussions with the FDA's ENT Branch Chief in November 2012, it was shared that Lantos had determined that bench verification was a more appropriate method to assess efficacy of the 3D Scanner for the intended use. The outcome of this verification is described below. As discussed, it is evident that the scanner is comparable to that of the 'lost wax' method for the making of ear canal impressions. Future post-marketing studies conducted by Lantos and others may be intended to determine its effectiveness in the development of a noise attenuating device or hearing aids compared to the current 'standard of care', but that is not the claim at this time.

The device is intended to provide illumination and visualization of the ear canal and to allow an alternate technique (i.e. lost wax or silicone injection methods) to capture ear canal topography (digital scanning) using a single device, consistent with the intent to seek premarket clearance for the Lantos 3D Scanner under 21 CFR Part 874.4770 as an *otoscope* and an accessory to a hearing aid (21 CFR Part 874.3300).

Reviewer's Comment: The sponsor provides the rationale for the adequacy with the submitted bench performance data to support SE, in addition to submitting a summary of results verifying the 3D scanner accuracy. The reference for the acceptance criterion (0.4mm) adopted is also provided in the sponsor's response. This response is judged as acceptable after discussing with Dr. Nandkumar, followed by a teleconference on January 16, 2013 with the sponsor representative, Deb Arthur for clarification.

FDA Question 8: You state that custom earplugs were manufactured for your Direct Scan Earmold Digitization Evaluation, but a description of the earplug style/features cannot be easily located. Please provide further details about the earplug features, including if the custom earplugs were full shell style or canal style plugs.

Sponsor's Response: As indicated above in response to question 7, the study provided is not intended to prove efficacy of the 3D scanner.

Reviewer's Comment: The sponsor clarifies that it is not their intention to prove the efficacy of the 3D scanner. This is consistent with the revised IFU, where no specific claims are made for earmodes or custom earplugs. This response is acceptable.

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FDA Question 9: Please indicate how you intend to evaluate the accuracy/effectiveness of the 3D ear scan for the concha and helix regions of the topography measurements obtained with your 3D Ear Scanner device.

Sponsor's Response: The evaluation of accuracy and effectiveness of the 3D scan for the concha and helix regions is found above in the Question 7 response as *Verification of 3D Scanner Accuracy*. The verification included the concha and helix regions.

Reviewer's Comment: The sponsor clarifies that the verification included the concha and helix regions for bench performance data. This response is acceptable.

FDA Question 10: In the Methods section of the Direct Scan Earmold Digitization Evaluation protocol (section 7.6, Determination of Eligibility, page 350 of 355), you state "subjects will be 40 normal hearing mean and women...with no known medical pathology." However, your subjects included persons with hearing loss, and this was not reported as a protocol deviation. Please indicate why you included subjects with hearing loss in this study and any expected impact on your study results.

Sponsor's Response: As indicated above in response to question 7, the study provided is not intended to prove efficacy of the 3D scanner.

Reviewer's Comment: See this reviewer's comment for Questions 7 and 8. This response is judged as acceptable.

FDA Question 11: You measure the amount of attenuation provided by the custom earplugs in each ear separately in the Direct Scan Earmold Digitization Evaluation. Given that your audiometric measures were performed in the sound field, please explain how you were able to isolate each ear for the attenuation measures.

Also, please indicate if your subjects and investigators were blinded as to which custom earplugs were derived from which scanning method. If not, please indicate how you will control for this potential bias, particularly with respect to the investigators' blinding.

Sponsor's Response: As indicated above in response to question 7, the study provided is not intended to prove efficacy of the 3D scanner.

Reviewer's Comment: See this reviewer's comment for Questions 7 and 8. This response is judged as acceptable.

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

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FDA Question 12: You describe the protocol deviations (section 10.0, page 395 of 535) in the Direct Scan Earmold Digitization Evaluation. However, further details are needed to explain the impact of these deviations. Please address the following issues:

a. The second bullet states "the audiologist determined potential clinical implications for subjects receiving earmold impression scans prior to the EarMold 3D Direct scans of the ear canal" and explains those implications. However, it is unclear exactly how the protocol was modified and what impact the modification could have on the results. Please provide these details.

b. Under the third bullet, you state "In addition, the audiologist determined these frequencies are unreliable for testing and re-testing purposes due to the directionality of the 8000Hz and subjects respond to 250 Hz as a vibro-tactile even when not heard." Please clarify what is meant by "the directionality of the 8000 Hz." Also, please clarify why you would expect subjects to have a vibro-tactile response to a 250 Hz tone presented via loud speaker in the sound field at levels of 40 dB HL and below.

Sponsor's Response: As indicated above in response to question 7, the study provided is not intended to prove efficacy of the 3D scanner.

Reviewer's Comment: See this reviewer's comment for Questions 7 and 8. This response is judged as acceptable.

FDA Question 13: In your User Preference Study, 10 out of 10 clinicians rated the video otoscope images from this device the same or more difficult relative to the quality of images from other conventional or video otoscopes. Furthermore, in Figure 7-21(page 48 of 538) you provide images from the video otoscope where there appears to be limited visibility of the tympanic membrane. This suggests that the images from the video otoscopy of your device may not yield "exceptional visualization of the ear canal" as claimed in your Draft Brochure, or that visualization of the tympanic membrane may be limited. Please provide images and performance data to support your claims about the quality of images from the video otoscopy with your device.

Sponsor's Response: Lantos has determined that further development and investment at this time in the referenced marketing Brochure are ill-advised and consumes unnecessary resources prior to commercialization of the device. Lantos plans on updating/modifying the Brochure upon FDA issuance of clearance for the premarket notification (K121326). At that time, developed marketing materials will reflect the intended use of the Lantos 3D Scanner and any associated features/functionalities supportive of its determination of safety and effectiveness. Additionally, Lantos is withdrawing statements of 'exceptional visualization' of the ear canal or TM at this time from its labeling.

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With respect to the stated concern regarding the quality of the visual image from the Lantos 3D Scanner, Lantos apologizes for the quality of the images included as Figure 7-21 (page 48 of 538) which was the result of compression of the image for the digital file. In addition, Lantos has modified settings such as exposure time, illumination, gamma correction and gain, which can impact image quality. As we have gained experience with the scanner, we have tuned these parameters to improve our image quality. Please see Figure 12 below which reflects the quality of the video otoscope mode of the Lantos 3D Scan.

Reviewer's Comment: To address the concerns raised in this question, the sponsor has withdrawn the claims regarding 'exceptional visualization' of the ear canal or TM at this time from its labeling. Similarly, the sponsor has chosen to modify the statements about image quality. This response is judged as acceptable.

FDA Question 14: In your User Preference Study, most of your clinician subjects indicated that they would like a prompt or an identification of insertion depth or ear canal length. Please indicate how you plan to address this issue.

Sponsor's Response: As described in the responses to questions 2a-e, the clinicians are provided a description of the ear canal and TM visualization with applicable photographs indicating how to approximate when 4-5 mm back from the TM (the recommended depth for initiation of the topography measurement).

Reviewer's Comment: The sponsor has made the clarification as requested. This response is judged as acceptable.

FDA Question 15: In the Draft Brochure (page 337 of 535), under Safety and Comfort, you state "The scanner can be used with confidence in cases where traditional impression material might require extended preparation." This statement implies that the Lantos 3D Ear Scanner is a better option in difficult cases. Please clarify is meant by this statement by indicating what cases this is referring to and providing data or a rationale to support this statement.

Sponsor's Response: Upon review, Lantos is withdrawing that statement/claim. At this time, Lantos is making no statement that the 3D Scanner is a better alternative than the use of traditional impression material methods.

As stated in response to Question 13, Lantos has terminated development of all marketing materials (i.e. Draft Brochure) until premarket clearance is obtained with final safety and efficacy of the device approved.

Reviewer's Comment: The sponsor indicates that this statement/claim is withdrawn. This question is thus no longer applicable.

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FDA Question 16: You provide descriptions of the steps for using the Lantos 3D Ear Scanner to perform video otoscopy and topography measurements in the Instructions for Use. You may consider including additional diagrams and/or photographs of the device in use in order to provide references for the user. Examples of additional images that may be helpful for the Instructions for Use include the button controls on the device, the check cap, the protective cap, how to brace the device while retracting the probe tip during topography, etc.

Sponsor's Response: Lantos has incorporated additional diagrams and photos to its modified Instructions for Use (Attachment 3). The original Introduction section has been shortened and much of the information consolidated into the Operation section of the IFU. Updated details and figures have been included in the current version of the IFU and are summarized in the table below:

PAGE	CHANGE
1	Updated product image on cover
2	Added a copyright page
4	Added a table of contents
5	Consolidated Introduction into portions of the Operation section, added System Requirements, Intended Use and User Profile
7	Added cautions to reflect 1) need for good clinical judgment 2) distance from TM and 3) illumination and eye caution
11	Changed to an updated photo of the system
12	Updated photo of docking stand
13	Updated photo of scanner
14	Updated photo of consumable
16	Updated user interface image
18	Updated to new log in screen
19	Updated image of check cap of consumable
21	Added two photos depicting position of user in relation to patient and hand placement of the user during scanning
23	Used terms "data capture" and "scanning mode" in lieu of "ear topology mode"
24	Added updated image of application software as visualized during the scanning process
27	Added updated image of user interface
31	Updated specifications to reflect new consumable, scanner, and docking stand

Reviewer's Comment: The sponsor has incorporated additional diagrams ***and photos to its modified Instructions for Use (Attachment 3) as requested. This response is judged as acceptable.***

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FDA Question 17. Please include the updated contraindications and precautions in the Instructions for Use.

Sponsor's Response: Please see Instructions for Use (Attachment 3 on pages 6 and 7) for the updated contraindications and precautions within the Instructions for Use. For your convenience, Lantos is restating as follows:

Contraindications

- Individuals less than 18 years of age6

Warnings & Precautions

Warnings:

- Do not connect the Lantos 3D Ear Scanner to devices other than as expressly described in these instructions
- Plug the scanner into a properly grounded power outlet to maintain patient and user safety when operating from an A/C power
- Disconnect the scanner from A/C power source if it gets wet, if cables are damaged, or if components are dropped
- Do not use in the presence of flammable anesthetics

Precautions:

- The membrane, reservoir and medium are for single patient use
- Do not user the scanner for any purposes other than those described in these instructions
- Discontinue user of the device if you notice any signs of damage to the components. Contact Lantos for service. No user serviceable components.
- The handheld scanner is a highly precise optical instrument. Improper handling, such as dropping or bumping the tip, may cause the scanner to break or malfunction.
- Use good clinical judgment and inspect the ear canal prior to membrane inflation. Do not use on patients with excess cerumen in the ear canal, patients with an infection in the external or middle ear, patients with drainage or blood in the ear, or patients with a foreign body in the ear canal.
- Use good clinical judgment when approaching the tympanic membrane (TM) and do not touch the TM
- Do not stare at scanner tip or direct scanner tip toward patient's face, while illumination is active.
- May be harmful to the eyes

Reviewer's Comment: The sponsor has updated contraindications and precautions in the Instructions for Use as requested. This response is judged as adequate.

FDA Question 18. You provide copies of your labeling. One of the labels is for the Lantos 3D Ear Scanner Disposable Multi-Pack—Contains Ten (10) ea which bears the manufacturing month and the expiration month. Please explain how you arrived at this 1 month shelf-life and provide the suporting documentation. Furthermore, in Attachment 1, you provide a list of hazards that the disposable components may become unsafe within 1 month of

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manufacturing. You do not provide a description of the packaging. Combined with the short shelf-life and dangers of expired product, the packaging is paramount. Please describe how all components are packaged, which includes the individual packaging for each component, individual cartons, shipping containers, etc.

Sponsor's Response: Upon review and discussion with outside consultants, it became clear to Lantos that its interpretation of the definition/requirements for stipulating 'shelf life' was erroneous. The Hazards Analysis was updated to reflect that this is a non-sterile, packaged device with the materials used in the patient-contacting, disposable portion (Membrane and Pressure Cup components) of the Lantos Single Use Disposable consisting of implantable-grade silicone rubber and thermoplastic elastomer. These materials are well characterized and known for their stability in medical device use, and have had biocompatibility testing per ISO-10993 for Cytotoxicity, Irritation and Skin Sensitization, and Intracutaneous Reactivity.

The Lantos Disposable is individually-packaged in a foil pouch. Based on the established use of the materials in these components, there is no reason to be concerned about material or packaging stability over time. Per your request, the following is a drawing of the component outer pouch. Lantos respectfully believes that its earlier stated concerns on shelf-life were a misunderstanding of the existing standards and guidelines.

Reviewer's Comment: The sponsor has clarified the issues related to shelf life. This response is judged as acceptable.

CONCLUSION & RECOMMENDATION

This review focuses on the sponsor's responses to FDA Questions 1 – 4 and 7 – 18, along with the revised materials sent via the sponsor's January 18, 2013 email. All responses and the revised IFU and 510k Statement are judged as acceptable. There are no outstanding questions or concerns from the perspective of clinical audiology, and thus "substantially equivalent" (SE) is recommended. Please indicate to this reviewer if any questions arise.

Reviewed by Shu-Chen Peng, Ph.D. CCC-A
Scientific Reviewer in Audiology

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

Memorandum

Software, EMC, Electrical Safety, Mechanical Engineering Review

Date: January 15, 2012

To: The Record

From: Andrew Yang

Digitally signed by Andrew Yang
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Andrew Yang, 0.9.2342.19200300.100.1.1=1300396773
Date: 2013.01.16 14:53:56 -05'00'

Andrew Yang
Biomedical Engineer
Intraocular and Corneal Implants Branch
Division of Ophthalmic and Ear, Nose and Throat Devices

Subject: K121326/S001

Device: Lantos 3D Ear Scanner

Recommendation: **SE – Substantially Equivalent**

INDICATIONS FOR USE

The Lantos 3D Ear Scanner is intended for use by a trained hearing professional in clinical settings on adult patients presenting for inspection of the external ear canal.

The Lantos 3D Ear scanner:

- provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for observation and;
- includes an expanding conforming membrane which aids observation when inserted in the ear canal and;
- records and presents to the hearing professional in an image file a topology measurement of the external ear canal

DEVICE DESCRIPTION

The Device consists of a hand held scanner, a single patient use disposable with a conforming membrane, which when in use is filled with an absorbing medium, and a laptop computer. The hand held scanner, when not in use, is placed in a docking stand.

The hand held scanner is tethered to the docking stand with a custom cable. The docking stand is tied to the laptop computer. The hand held scanner contains illumination, optics, a camera, a motor to move the probe tip, and a motor-driven reservoir.

User Interface (UI) software screens are displayed on the laptop and the user interacts with the device via the laptop keyboard and touchpad, and control buttons on the hand held scanner, as guided by the UI screens. Image data from the patient is stored in the laptop, and may be transmitted by the user via a wireless connection. No patient identifiable data is stored in the Lantos device.

A single use disposable, which includes the conforming membrane, is placed over the hand held scanner

Note:
Arial font indicates sponsor language
Times New Roman font indicates reviewer language

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probe tip, in a manner similar to placing an ear speculum over the viewing tip of a conventional otoscope. The disposable will contact and reshape the ear canal with mild pressure, to improve the view of the ear canal, and to keep the probe tip from contacting the ear canal, performing the same functions as a speculum.

PREVIOUS DEFICIENCIES & RESPONSES

You provide engineering drawing in Attachment 8. However, it appears that some components are missing. We have identified 2 missing components: pump assembly, power source. Please provide these drawings and any others that were not previously included.

Lantos reviewed the provided drawings in Attachment 8 (K121326) and has added the ten drawings found in Attachment 2 to address the FDA's concerns regarding missing drawings (i.e. pump assembly and power source). Lantos would like to clarify that there are not component drawings with those specific identifiers, but the drawings provided in Attachment 2 include the components that comprise the pump assembly (Attachment 2, Figures 1---5) and power source (Attachment 2, Figures 6---10).

Comment: Upon reviewing Attachment 2, I see that they have changed the design quite a bit. These unsolicited changes were the product of "Design-for-Manufacturing improvement phase, to reduce the cost of the Disposable prior to full production". They claim the "performance characteristics were confirmed by repeating design verification testing", but did not provide this data. The sponsor was contacted January 11, 2013 via email to provide that testing (see attached). The sponsor responded via email January 14, 2013 via email (see attached). The email attachment was a whole-system validation that confirms the functionality of the redesigned device. The new device demonstrates equivalent accuracy to the original design. This is sufficient.

RECOMMENDATION

None of these tests were intended to compare itself to its predicate. Rather, the sponsor set acceptable goals and achieved them, demonstrating safety and effectiveness. The device is relatively well-understood and appears to function as intended with an acceptable degree of safety and accuracy.

SE – Substantially Equivalent

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Date:	01/18/2013
To:	LT Andrew Yang, BE, ME, EIT, Team Leader, DOED/ENTB
From:	Dexiu Shi, Ph. D., Physicist, DOED/DSDB Dexiu Shi 2013.01.18 20:32:52 -05'00'
510(k)	K121326/S1
Device:	Lantos 3D Ear Scanner
Applicant:	Lantos Technologies
Subject:	Review of sponsor's response to FDA June 11, 2012 Deficiencies regarding phototoxicity - ocular and ear/skin safety

SUMMARY OF REVIEW

Per Team Leader's request, I reviewed sponsor's response to deficiencies 6, 19-20 (regarding phototoxicity - ocular and ear/skin safety) from our AI letter of June 11, 2012. The sponsor has adequately addressed these three deficiencies. SE is recommended.

Each deficiency is copied below and followed by the sponsor's response and reviewer's comments.

Device Description

6. **On page 46 of 535, Device Description, you state that the illumination source of your device is "a three color Red/Green/Blue collection of LED die are coupled through an optical taper into the proximal end of the illumination fibers – a microcontroller and associated current control drive circuits create an illumination flash sequence synchronized with the shutter of the optical sensor."**

   However, you do not provide the technical characteristics of these LEDs (e.g., wavelength (spectrum distribution), maximum and normal operating output power). Please provide these parameters which are the essential information for evaluating your risk analysis.

   Response:

   The Lantos Scanner includes three LED sources. Two LED sources, Red and Green, are used for illumination in video otoscope mode. One LED source, Blue-Violet, is used to illuminate the inside surface of the Conforming Membrane for the topology measurement of the external ear canal. Attachment 4 includes a full summary.

   The following table and figures show the technical characteristics of the LEDs.

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(b)(4) Reveiw

[redacted]

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(b)(4) Reveiw

[redacted]

Reviewer Comment: **The responses are acceptable.**

The sponsor has adequately addressed this deficiency. They provided a detailed description for all light sources used in the device. This information gives us a clear understanding the device and is very helpful to assist us in interpretation of their optical radiation safety analyses.

Phototoxicity

19. The eye is a sensitive organ highly susceptible to damage by optical radiation. It is not clear that whether the LEDs are turned on before or after the probe is inserted into ear. If the LEDs are turned on before inserting, there is the potential optical radiation hazard to the eye because of the proximity to the eyes. If Lantos 3D Ear Scanner is designed to be used in this condition, your device may pose the following types of hazards:

- **Retinal photochemical aphakic light hazard (305 -700 nm)**
- **Retinal visible and infrared radiation thermal hazard (400 -700 nm)**
- **There's more evidence that blue light (400 – 500nm) can damage eyes, with people who have had cataracts removed being particularly vulnerable.**

We believe an evaluation of phototoxicity to the eyes for use of your device is necessary. For phototoxicity analysis including classification, labeling, and informational requirements for the device, we recommend reference to the following standards:

- **American Conference of Governmental Industrial Hygienists (ACGIH): Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices (2011)**

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- **ANSI/IESNA RP-27.2-2000 Recommended Practice for Photobiological Safety for Lamps & Lamp Systems - Measurement Techniques**
- **ANSI/IESNA RP-27.3-2007 Recommended Practice for Photobiological Safety for Lamps - Risk Group Classification & Labeling**

Please provide a phototoxicity evaluation, including (may not limited to) the following information:

a. **Irradiance measurement at a default distance of 20cm and at the worst case (shortest) of distance form nose.**
b. **Risk group assessment: This assessment results in either an Exempt Group or one of three Risk Group classification: Risk Group 1 ((Low-Risk)), Risk Group 2 (Moderate Risk)) and Risk Group 3 (High Risk).**
c. **Appropriate protection should be used when the risk group classification is not "Exempt".**
   Please describe whether there is any mitigation that will be effective to prevent the potential harm to the eyes to insure user safety when operating the device under the condition of intended use.

   The following labeling issues are for your consideration:

   We recommend follow excerpt from ANSI/IESNA RP-27.3 -07 Section 6.2. to provide Caution labels to inform and instruct end user regarding pertinent safety related information that should be provided if the lamp is classified as Risk Groups 1, 2, or 3. For example:

   i. **A statement of the potential hazard, if any. This should simply advise as to what might expected to occur (i.e., skin irritation, or eye injury).**
   ii **A list of what precautions could or should be taken to avoid the risk (e.g., "Do not shine the device directly in eyes...", "Appropriate eye protection should be used when daily exposure at short distance (XX cm) is greater than XX minutes.")**

Response:

When the Lantos Scanner is used as intended, illumination is turned on just as the scanner tip approaches the outer ear. When used for inspection in video otoscope mode, mixed Red and Green LEDs illuminate the external ear canal through the window in the conforming membrane.

When used for the topology measurement of the external ear canal, the scanner tip is covered by the conforming membrane. Mixed Red and Green LEDs illuminate the ear canal through the clear window at the tip of the membrane, to guide insertion of the scanner tip. The Blue-Violet LED illuminates the interior surface of the membrane while the scanner tip is retracted and manipulated to capture the topology.

When used as intended, the Lantos Scanner meets the criteria for the Exempt Risk Group Classification as described in ANSI/IESNA RP-27.3-07. The data supporting this classification is provided in Section 4 of Attachment 4.

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

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During Risk Analysis while developing the Scanner, rare but credible examples of operator error or reasonably foreseeable misuse were identified. Even with misuse, the testing shows the Scanner remains in the Exempt Risk Group. As further described in Attachment 4 Section 4.2, and summarized immediately below, Lantos tested these reasonably foreseeable misuse examples according to:

ANSI/IESNA RP-27.1-05 Recommended Practice for Photobiological Safety for Lamps and Lamp Systems—General Requirements

ANSI/IESNA RP-27.1-05 incorporates the ACGIH Threshold Limit Values. ANSI/IESNA RP- 27.2-00 was used as required to define measurement techniques. An appropriate caution for the Exempt Classification was added to the Instructions-for-Use.

Reviewer Comment:

The sponsor states "When the Lantos Scanner is used as intended, illumination is turned on just as the scanner tip approaches the outer ear. When used for inspection in video otoscope mode, mixed Red and Green LEDs illuminate the external ear canal through the window in the conforming membrane." In this use condition, there is the potential optical radiation hazard to the eye because of the proximity to the eyes, thus evaluation of phototoxicity to the eyes for use of this device is necessary. Accordingly, the sponsor provided the phototoxicity analysis. Please see my detailed comment on sponsor's response (Attachment 4) to specific question 19 a-c.

Specific to question 19 a-c above:

a. **Irradiance measurement at a default distance of 20 cm and at the worst case (shortest) of distance from nose**

   At a distance of 20cm, with the uncovered scanner tip pointed directly at a 9 mm (pupil-sized) opening in a collecting integrating sphere, the captured irradiance measures 9 uW, 11 uW and 90 uW respectively for the Red, Green, and Blue-Violet LEDs, at maximum drive current and duty cycle. Since the scanner tip is small, the shortest distance could include the extreme case where the entire light output of the scanner tip entered the pupil, with the probe <5 mm distant from the cornea. In that case, the irradiance would be 2 mW, 2 mW and 58 mW as shown in the reply to Question 6, and in Section 4.1 of Attachment 4.

b. **Risk group assessment: This assessment results in either an Exempt Group or one of the three Risk Group classification: Risk Group 1 (Low-Risk), Risk Group 2(Moderate Risk) and Risk Group 3 (High Risk).**

   When used as intended, or with reasonably foreseeable misuse, the Lantos Scanner meets the criteria for the Exempt Risk Group Classification as described in ANSI/IESNA RP-27.3-07. The data supporting this classification is provided in Section 4 of Attachment 4.

c. **Appropriate protection should be used when the risk group classification is not "Exempt." Please describe whether there is any mitigation that will be effective to prevent the potential harm to the eyes to insure user safety when operating the device under the condition of intended use.**

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

The Risk Group is Exempt – nevertheless the Lantos risk management team identified and implemented the mitigation described in Attachment 4 Section 4.3.
c. i./ii. The Lantos risk management team added the following caution to the Instructions- for-Use, following the recommended language of ANSI/IESNA RP-27.3-97 Section 6.2.

Caution - Do not stare at scanner tip, or direct scanner tip toward patient's face, while illumination is active. May be harmful to the eyes.

Reviewer Comment: The sponsor provided a detailed Assessment of Photobiological Safety in Attachment 4. The states "The Lantos 3D Ear Scanner was tested for Phototoxicity to assure operator and patient safety under intended use conditions, and reasonably foreseeable misuse, using the ANSI, ICNIRP, and ACGIH standards for exposure to UV, visible, and infrared light." They claim that "The illumination subsystem of the Lantos 3D Ear Scanner is classified as "Exempt" per: Section 4.3 Lamp Classifications of ANSI/IESNA RP-27.3-07.

- The tests for optical radiation hazard to the eye were performed. Test results are summarized as follows:

  - **<u>Retinal Thermal Hazard</u>**

    The sponsor states:

    The three LED sources were examined per section 4.3.1 of ANSI/IESNA RP-27.3-07. for the Maximum Hazard scenarios of Section 4.2., the results indicate that "the burn hazard weighted radiance of the illumination source, for each of the LEDs, remained well below the 10 second exposure limits where thermal injury is dominant.

    Thermal injury limits

    (b)(4) Reveiw

    [redacted]

    Technical characteristics of the LEDs

    (b)(4) Reveiw

    [redacted]

Reviewer Comment: Based on the compare the maximum output of LEDs to the thermal limits, the sponsor's conclusion that "LEDs, remained well below the 10 second exposure limits where thermal injury is dominant" is acceptable.

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

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- **UV Light Hazard**

(b)(4) Reveiw

[redacted]

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

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(b)(4) Reveiw

[redacted]

On page 83/91, Attachment 4 - Assessment of Photobiological Safety, you provided the following table shows the technical characteristics of the LEDs:

LED	Nominal Center Wavelength	Nominal Bandwidth (FWHM)	Normal Operating Output Power*	Maximum Output Power*
Red	620 nm	± 10 nm	2 mW	15 mW
Green	530 nm	± 20 nm	2 mW	10 mW
Blue-Violet	405 nm	± 10 nm	58 mW	120 mW

*Note: Output Power is total emitted from the distal end of the illumination fibers at the probe tip

On page 88/91, you state that:

> When the probe tip is less than 30cm from the eye, it should be evaluated per ANSI Section 4.3.2. The integrated spectral radiance of the source weighted with the blue-light hazard function, at the maximum output of the LED source is:
>
> L_B = 0.00395 W / (cm²– sr)
>
> The radiance is less than the 0.01 limit of Equation (5b); therefore the safe exposure time is greater than 10000 seconds.

However, it is not clear that how the "L_B" was calculated/determined. Please provide this information. While calculating, please reference "Appendix A - Calculations of diode emission characteristics of ICNIRP (International Commission on Non-Ionizing Radiation Protection) Statement on Light-Emitting Diodes (LEDs) and Laser Diodes: Implications for Hazard Assessment (Health Physics, June 2000, Vol 78, No 6)". The formulae used in the calculations are as follows:

- Effective emitting area of the source (A_{src}):

$$A_{src} = l \times w,$$

where l is the length and w the width of the source in cm, and A is in cm²;

- Mean effective "dimension" of the source (S_{eff}):

$$S_{eff} = \sqrt{A_{src}};$$

- Angular subtense of the source (α_{src}):

$$\alpha_{src} = \sin^{-1}(S_{eff}/10\text{ cm})$$

(= angular subtense at 10 cm);

- Mean emission angle of the source (Θ_{src}):

$$\Theta_{src} = (\theta_{\parallel} \times \theta_{\perp})^{1/2},$$

where $\theta_{\parallel}$ and $\theta_{\perp}$ are the emission half-angles in two principle planes in sr;

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- Solid angle of source emission (Ω):

$$\Omega = 2\pi[1 - \cos\Theta],$$

where Ω and Θ are in sr.

- Radiance of the source (L_{src}):

$$L_{src} = P_o/(A_{src} \times \Omega),$$

where P_o is the output power in W, A_{src} is in cm^2, and L_{src} is in W cm^{-2} sr^{-1}; and

- Effective radiance (L_{eff}) averaged over 11 mrad:

$$L_{eff} = L_{src} \times (\alpha_{src}/0.011 \text{ rad})^2,$$

where L_{eff} and L_{src} are in W cm^{-2} sr^{-1}, and α_{src} is in rad.

Please use above formulae in your calculations of L_B, and provide calculation result step-by-step. This information will assist us in us in evaluation of your phototoxicity assessment.

The sponsor provided the following response, by email of Jan 16, 2013:

Our measured data was a spectrum taken using a NIST-traceable integrating sphere and radiometer. This provides samples from below 280 nm to above 1000 nm in μW cm^{-2} nm^{-1}. Multiplying by the area of the aperture of the integrating sphere and by our maximum duty cycle and converting μW to W gives our effective spectral power density in W/nm.

Our other inputs are the extent of the illumination source and the solid angle of emission. The width and height of our source are both 3.048 mm. The emission angle is limited by the optical fibers, which are NA = 0.87 and so the emission half-angle is 1.06 rad.

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We next follow the steps from "Calculations of diode emission characteristics of ICNIRP (International Commission on Non-Ionizing Radiation Protection) Statement on Light-Emitting Diodes (LEDs) and Laser Diodes: Implications for Hazard Assessment (Health Physics, June 2000, Vol 78, No 6)".

A_src= 9.29e-02 cm^2 = 3.048 mm × 3.048 mm
S_eff = 0.305 cm
alpha_src = 3.05e-02 rad at 10 cm
theta_|| = theta_perp = 1.06 rad (as constrained by the 0.87 NA fiber)
Theta_src = 1.06 rad =(||)1/2
Omega = 3.19 sr = 2*pi*(1-cos(Theta_src))
P_o = 0.1158 W = sum(L_lambda * D_lambda)
L_src= 0.3915 W cm^{-2} sr^{-1} = P_o * (A_src * Omega)
L_eff = 3.0065 W cm^{-2} sr^{-1} = L_src * (alpha_src / 0.011 rad)^2

To compute the sum for section 4.3.2, we resample the hazard function (given in Appendix A) from samples every 5 nm to samples corresponding to our source data (samples taken between every 0.36 nm and every 0.47 nm). Finally we compute L_B as follows (where `A_src_cm2` and Omega are A_src and Omega from above respectively and `l` is the sample locations in nm and `Dl` is the sample width):

```
violet_W_per_cm2_per_sr_per_nm = violet_W_per_nm / (A_src_cm2 * Omega)
only_300nm_to_700nm = logical_and(300 <= l, l <= 700)
L_B = (violet_W_per_cm2_per_sr_per_nm * B * Dl)[only_300nm_to_700nm].sum(
```

This gives L_B = 0.1058, which is more than the 0.01 threshold of (5b). Referring to (5a) and solving for time gives an acceptable exposure time of 944.9 seconds (15.7 minutes). The Lantos risk management team did not consider as reasonably foreseeable or even credible misuse the case where the probe was pointed directly and steadily at the for this length of time, as it would require both intent to harm and precision.
This analysis also affects our response to sections 4.3.1 and 4.3.3.

Recomputing section 4.3.1 yields:
L_R r = 0.050 L_R g = 0.0346 L_R b = 0.0993
These numbers are larger but still significantly below the thresholds

Recomputing section 4.3.3 showing the steps: When the angle subtended by the source is 0.011 rad the solid angle subtended is 0.000121 sr. Multiplying L_lambda by 0.000121 sr gives E_lambda in units of W $cm^{-2}nm^{-1}$. Plugging this into (7b) gives E_B = 1.2806e-05, which is less than 10^{-4}so we refer to (7a) and solve for t = 0.01 / E_B which gives t = 781 seconds (13.0 minutes).

Thus our conclusions for sections 4.3.1 and 4.3.3 remain unchanged.

Reviewer Comment: The sponsor states that "…we uncovered an error in our initial calculation wherein we misinterpreted the correction factor for the integrating sphere measurement…" Their re-calculation gives the following larger L-B value:

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This gives L_B = 0.1058, which is more than the 0.01 threshold of (5b). Referring to (5a) and solving for time gives an acceptable exposure time of 944.9 seconds (15.7 minutes). The Lantos risk management team did not consider as reasonably foreseeable or even credible misuse the case where the probe was pointed directly and steadily at the for this length of time, as it would require both intent to harm and precision.

This analysis also affects our response to sections 4.3.1 and 4.3.3.

Recomputing section 4.3.1 yields:
L_R r = 0.050 L_R g = 0.0346 L_R b = 0.0993
These numbers are larger but still significantly below the thresholds

Recomputing section 4.3.3 showing the steps: When the angle subtended by the source is 0.011 rad the solid angle subtended is 0.000121 sr. Multiplying L_lambda by 0.000121 sr gives E_lambda in units of W $cm^{-2}nm^{-1}$. Plugging this into (7b) gives E_B = 1.2806e-05, which is less than 10^{-4} so we refer to (7a) and solve for t = 0.01 / E_B which gives t = 781 seconds (13.0 minutes).

Thus our conclusions for sections 4.3.1 and 4.3.3 remain unchanged.

However, per Section 4.3 Lamp Classifications of ANSI/IESNA RP-27.3-07, a lamp that exceeds the limits for the Exempt Group but that does not pose a blue-light hazard (L_B) within 100 seconds is in Rick Group 1. Therefore, the sponsor's determination of Exempt Group for Blue LED is incorrect. They should make correction. This issue has been solved via interactive review, by email. See the details in the following pages.

- On Jan 16, 2013, this review sent the sponsor the following question, by email:

  According to your new calculation results, the blue LED used in your device does not meet classification of Exempt group, and should be classified as Risk Group 1 (Low Risk) (i.e., safe viewing time between 100 and 10,000 seconds). You should make this correction throughout your application. Please include the corrected LEDs classification in the 510(k) Summary and labeling. For Risk Group 1 blue LED, the acceptable maximum exposure time should be provided to the user. Please provide your revised 510(k) and Labeling ASAP. Please highlight the corresponding modifications.

- On Jan 17, 2013, this review sent the following additional question, by email:

  Referring ANSI/IESNA RP-27.3-2007, ANSI/IESNA RP-27.3-2007 Recommended Practice for Photobiological Safety for Lamps-Risk Group Classification & Labeling, we recommend provide the technical characteristics (including Risk Group) of LEDs in Lantos 3D Scanner along with the Caution (required for Risk Group 1 LED) in 510(k) Summary and Labeling. For example:

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

(b)(4) Reveiw

[redacted]

- On Jan 17, 2013, the sponsor provided, by email, the following responses:

  Thank you again for your help interpreting the Photobiological Safety standards, and the warnings required. Lantos is comfortable strengthening the Caution that we provide to include an exposure time of fifteen minutes, as you recommended.

  However, we do not feel the additional table information and Risk Group reclassification is warranted, in either the 510(k) summary or the Instructions for Use. For the Retinal Blue Light Exposure to exceed the value for the Exempt Risk Classification requires BOTH:

  1. operator misuse which the Lantos risk management team does not consider reasonably foreseeable or even credible - i.e. pointing the uncovered probe tip precisely at the eye of the patient or operator for an extended period, with no protective reaction by the patient or operator

  AND

  2. a simultaneous device fault wherein the software fail-safe which detects the membrane in-place and in-range and minimizes the blue light illumination when no membrane is detected

  Further to point one, as is typical with any illumination source, intensity falls off with angle. The L_B calculation we provided, which led to the 15 minute maximum exposure, is the intensity a maximum illumination at the illumination zenith. Less than precise alignment of the probe axis and the pupil-retina, as would be typical in any real world example, leads to rapid fall-off of exposure. In addition, the exposure assumes no blink or aversion reaction to the light source by the person exposed for minutes. Please note that this same argument was made in Section 4.5 in Attachment IV on page 88 of K121326/S001 - Retinal Blue Light Hazard - Small Source.

  Further to point two, please refer to Section 4.3 in Attachment IV on page 86 of K121326/S001 - Intended Use Scenarios. The Lantos risk management and design teams identified light exposure as a hazard, and identified the design mitigation **described therein, where the Scanner continually detects whether the membrane required for 3D scanning is in place and in range, and reduces the blue light power to one tenth or less of its maximum when the probe tip is uncovered. Alternatively with the membrane, which is nearly**

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opaque except for the small window at the tip, in place as intended, the blue light is contained.

We apologize if our evaluation approach of combining all worst cases was misleading to your interpretation. As you know, before the calculation correction engendered by your review, we believed we were exempt despite the combined worst case. We now argue that our scanner remains in the Exempt Risk Classification, certainly for Intended Use scenarios, and we believe for Reasonably Foreseeable Misuse scenarios when the scanner is functioning normally.

- On Jan 17, 2013, this reviewer communicated with ENT Branch Chief, Dr. Srinivas Nandkumar explanting that:

  The suggested technical characteristics (including Risk Group) of LEDs in Lantos 3D Scanner is the essential information to the user per Score of ANSI/IESNA RP-27.3-2007 Recommended Practice for Photobiological Safety for Lamps-Risk Group Classification & Labeling:

2.0 SCOPE

This standard covers the classification, labeling and informational requirements for lamps that emit optical radiation in the wavelength range from 200 nm to 3000 nm except for light emitting diodes used in optical fiber communication systems and for lasers which are covered in a separate series of ANSI standards (Series Z136). Federal mandatory requirements for lamps subject to specific Federal Regulations take precedence over requirements included in this consensus standard.

Note 1: Units of wavelength in this document are exclusively in nanometers (nm).

Note 2: Subtended angles are denoted by the full included angle, not the half angle.

Dr. Srinivas Nandkumar conveyed above information to the user.

- On Jan 18, 2013, the sponsor provided the revised 510(k) Summary and Labeling.

  The following information is added into 510(k) Summary

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Technological Characteristics

The Lantos 3D Ear Scanner is not a change or modification to the predicate device that could significantly affect safety or effectiveness. In other words, there is no change in the intended use (otoscope and hearing aid accessory), design (hand-held with illuminating LED probe tip covered by silicone cover), materials (polymers and silicone), and power source that could raise new issues of safety or effectiveness.

The Lantos 3D Ear Scanner followed ACGIH *American Conference of Governmental Industrial Hygienists Threshold Limit Values for chemical substances and physical agents and Biological Exposure Indices. 2011.* For both intended use and reasonably foreseeable misuse, the Scanner falls within ACGIH Threshold Limit Values for retinal thermal exposure within 10 seconds, blue light exposure within 10000 seconds, actinic ultraviolet radiation within 8 hours of operation and near UV exposure. In addition, the illumination subsystem was evaluated according to ANSI/IESNA *RP-27.3-2007 Recommended Practice for Photobiological Safety for Lamps-Risk Group Classification & Labeling* to provide a photobiological hazard evaluation (including blue light hazard exposure limits). This evaluation resulted in a "Risk Group 1" classification for the blue-violet LED. The exposure time limit for Risk Group 1 was 15 minutes of direct, continuous exposure to the scanner tip without the membrane attached. Package labeling includes a caution: "Do not stare at the scanner tip, or direct scanner tip toward patient's face, while illumination is active. Staring at scanner tip for more than 15 minutes with no membrane attached under fault conditions may exceed photobiological exposure. May be harmful to the eyes."

The following information is added into Instruction for Use:

ANSI/IESNA RP-27.3-2007 Recommended Practice for Photobiological Safety for Lamps-Risk Group Classification & Labeling

This device was evaluated according to ANSI/IESNA *RP-27.3-2007 Recommended Practice for Photobiological Safety for Lamps-Risk Group Classification & Labeling* to provide a photobiological hazard evaluation (including blue light hazard exposure limits). This evaluation resulted in a "Risk Group 1" classification for the blue-violet LED. The exposure time limit for Risk Group 1 was 15 minutes of direct, continuous exposure to the scanner tip without the membrane attached.

Reviewer Comment: The additional information added in 510(k) Summary and Labeling provides user the appropriate Blue light hazard information.

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

20. The ear skin is also vulnerable to damage by optical radiation. The type of effect, injury thresholds, and damage mechanisms vary significantly with wavelength. There are different types of damage to the skin may be caused by optical radiation, for example:

- **Thermal damage (burns) of the skin with visible and infrared radiation.**
- **Photosensitized damage of the skin: It is generally far more typical of UVR wavelengths (less than 380 nm). However, such photosensitized reactions can extend to approximately 700 nm, possibly as a side-effect of certain medications.**

You do not include an evaluation of optical radiation hazard to the skin. We recommend you evaluate skin safety for use of your device by performing an optical radiation hazard evaluation to demonstrate your device meets the safety guideline specified in ACGIH [1] and ICNIRP [2] or an equivalent method. Please provide this information.

[1] ACGIH American Conference of Governmental Industrial Hygienists Threshold Limit Values for chemical substances and physical agents and Biological Exposure Indices. 2011.

[2]. International Commission on Non-Ionizing Radiation Protection (ICNIRP). Guidelines on limits of exposure to broad-band incoherent optical radiation (0.38-3um). Health Phys. 73: 37 539-554; 1997.

You may choose alternate approaches as long as above concern related to optical radiation safety can be addressed.

Response:

The Lantos Scanner was evaluated or tested according to the recommended ICNIRP and ACGIH Guidelines for Thermal Damage and Photosensitized Damage to the Skin.

For short thermal damage exposures, the Lantos Scanner remained within ICNIRP Guidelines even in the extreme misuse case where the scanner tip was pressed hard against the skin of the external ear canal for 10 seconds. For long thermal exposures, heat stress as indicated in ACGIH Guidelines was negligible. Results for Thermal Damage are in Section 4.8 of Attachment 4.

For Photosensitized Damage, evaluation results are shown in Section 4.9 of Attachment 4. Per ACGIH Guidelines, the only skin exposure at the energy levels produced by the Scanner was in the UVA band. Even in the extreme misuse case where the scanner tip is directed at a small patch of skin, and held in place, 45 to 66 minutes of exposure would be safe.

Reviewer Comment: The information provided in Attachment 4 demonstrates the Lantos Scanner was properly evaluated or tested according to the recommended ICNIRP and ACGIH Guidelines for Thermal Damage and Photosensitized Damage to the Skin. The test results indicate the subject device will be safe to the skin under the proposed Indications for Use.

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

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RECOMMEDATION: SE

The sponsor has adequately addressed deficiencies 6, 19-20 (regarding phototoxicity - ocular and ear/skin safety) from our AI letter of June 11, 2012. The newly added information about Blue light Hazard the latest revision of 510(k) Summary and the Instruction for Use is acceptable. I recommend this device to be SE in perspective of phototoxicity.

RECORD OF EMAIL

From: Shi, Dexiu
Sent: Friday, January 18, 2013 3:08 PM
To: Peng, Shu-Chen
Cc: Nandkumar, Srinivas
Subject: RE: K121325/S001 revised Indications for Use page, IFU, and 510(k) summary

I have reviewed the latest revision of 510(k) Summary and the Instruction for Use. The newly added information about Blue light Hazard is acceptable. I have no more questions in perspective of phototoxicity.

However, I do not understand why they are not willing to provide the technical characteristics of the LEDs used in the device. I rely on your branch to make final decision.

I will provide my review soon.

Dexiu

From: Peng, Shu-Chen
Sent: Friday, January 18, 2013 2:26 PM
To: Shi, Dexiu
Cc: Nandkumar, Srinivas
Subject: RE: K121325/S001 revised Indications for Use page, IFU, and 510(k) summary

Hi Dexiu,

Does this version of revision reflects what you requested for the device description in the 510k summary?

If not, you may want to let Nandu know. I will be reviewing the materials from my perspective.

Thanks,

Shu-Chen

From: Nandkumar, Srinivas
Sent: Friday, January 18, 2013 1:38 PM
To: Peng, Shu-Chen; Shi, Dexiu
Subject: Fw: K121325/S001 revised Indications for Use page, IFU, and 510(k) summary

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

I am off today and periodically checking email on BB. I have not opened these attached files but I am hoping they addressed our concerns.

From: Lora Allemeier [mailto:lora@lantostechnologies.com]
Sent: Friday, January 18, 2013 10:19 AM
To: Nandkumar, Srinivas; Yang, Andrew
Cc: DArthur Consulting <deborahartthur@darthurconsulting.com>; Jen Rossi <JRossi@lantostechnologies.com>
Subject: K121325/S001 revised Indications for Use page, IFU, and 510(k) summary

Please find attached revisions to the IFU and 510(k) summary in both redlined and clean copy to address Risk Group 1 photobiological exposure labeling, application of the photobiological standard to the device and inclusion in product summary, In addition, LED as the illumination source was added to both documents. A revised Indications for Use page is also attached. Please do not hesitate to contact me or Deb Arthur today if questions or additional updates are requested.

Best regards,

Lora Allemeier

From: Shi, Dexiu
Sent: Thursday, January 17, 2013 5:05 PM
To: Nandkumar, Srinivas; Yang, Andrew; Peng, Shu-Chen
Subject: FW: K121326/S001 Revised IFU and 510 (k) Summary

Hi:

I refer my following concern to you:

I do not think their revised 510(k) Summery and labeling is acceptable. There is a lack of basic information in Device Description. I did not ask questions on device description during my review of original submission, since I was not the engineering reviewer. However, I DID ask them to provide the technical information of the three LEDs used in the device (see my question and their response below). I just found the company does disclose any information that three LEDs are used in the device.

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

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(b)(4) Reveiw

[redacted]

From: Lora Allemeier [mailto:lora@lantostechnologies.com]
Sent: Thursday, January 17, 2013 4:40 PM
To: Nandkumar, Srinivas; Shi, Dexiu; Yang, Andrew
Cc: DArthur Consulting; Jen Rossi
Subject: K121326/S001 Revised IFU and 510 (k) Summary

Thank you for your review and follow up related to questions associated with the Lantos 3D Ear Scanner, K121326/S001

Please find attached the revised IFU and 510(k) summary for K121326/S001 in redline and clean copy, as requested. We have modified as requested to the best of our understanding both documents.

Please note that revisions to the Risk Group Classification in accordance to photobiological standards has not been included, due to an ongoing interaction with Dr. Shi, related to further work by the Lantos engineering team. We have updated the Caution to include a time duration

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for light exposure with the membrane removed, which is included in the Instructions For Use.

If there are further questions or clarifications, please do not hesitate to contact me.

Best regards,

Lora Allemeier
--
Lantos Technologies, Inc.
Lora Allemeier
Vice President Product Strategy and Regulatory

101 Main Street, Suite 1760, Cambridge, MA 02142, USA
Office: +1-617-500-9800 x 15
Cell: +1-978-621-4461

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From: Shi, Dexiu
Sent: Thursday, January 17, 2013 4:36 PM
To: Nandkumar, Srinivas
Subject: Scope of ANSI/IESNA RP-27.3-2007

ANSI/IESNA RP-27.3-2007 Recommended Practice for Photobiological Safety for Lamps-Risk Group Classification & Labeling

2.0 SCOPE

This standard covers the classification, labeling and informational requirements for lamps that emit optical radiation in the wavelength range from 200 nm to 3000 nm except for light emitting diodes used in optical fiber communication systems and for lasers which are covered in a separate series of ANSI standards (Series Z136). Federal mandatory requirements for lamps subject to specific Federal Regulations take precedence over requirements included in this consensus standard.

Note 1: Units of wavelength in this document are exclusively in nanometers (nm).

Note 2: Subtended angles are denoted by the full included angle, not the half angle.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

From: Lora Allemeier [mailto:lora@lantostechnologies.com]
Sent: Thursday, January 17, 2013 2:11 PM
To: Shi, Dexiu
Cc: DArthur Consulting; Nandkumar, Srinivas; Jen Rossi; Ben FrantzDale
Subject: Re: FW: K121326/S001 - Question on your response of Jan 16, 2013

Dr. Shi:

Thank you again for your help interpreting the Photobiological Safety standards, and the warnings required. Lantos is comfortable strengthening the Caution that we provide to include an exposure time of fifteen minutes, as you recommended.

However, we do not feel the additional table information and Risk Group reclassification is warranted, in either the 510(k) summary or the Instructions for Use. For the Retinal Blue Light Exposure to exceed the value for the Exempt Risk Classification requires BOTH:

1. operator misuse which the Lantos risk management team does not consider reasonably foreseeable or even credible - i.e. pointing the uncovered probe tip precisely at the eye of the patient or operator for an extended period, with no protective reaction by the patient or operator

AND

2. a simultaneous device fault wherein the software fail-safe which detects the membrane in-place and in-range and minimizes the blue light illumination when no membrane is detected

Further to point one, as is typical with any illumination source, intensity falls off with angle. The L_B calculation we provided, which led to the 15 minute maximum exposure, is the intensity a maximum illumination at the illumination zenith. Less than precise alignment of the probe axis and the pupil-retina, as would be typical in any real world example, leads to rapid fall-off of exposure. In addition, the exposure assumes no blink or aversion reaction to the light source by the person exposed for minutes. Please note that this same argument was made in Section 4.5 in Attachment IV on page 88 of of K121326/S001 - Retinal Blue Light Hazard - Small Source.

Further to point two, please refer to Section 4.3 in Attachment IV on page 86 of K121326/S001 - Intended Use Scenarios. The Lantos risk management and design teams identified light exposure as a hazard, and identified the design mitigation described therein, where the Scanner continually detects whether the membrane required for 3D scanning is in place and in range, and reduces the blue light power to one tenth or less of its maximum when the probe tip is uncovered. Alternatively with the membrane, which is nearly opaque except for the small window at the tip, in place as intended, the blue light is contained.

We apologize if our evaluation approach of combining all worst cases was misleading to your interpretation. As you know, before the calculation correction engendered by your review, we believed we were exempt despite the combined worst case. We now argue that our scanner remains in the Exempt Risk Classification, certainly for Intended Use scenarios, and we believe for Reasonably Foreseeable Misuse scenarios when the scanner is functioning normally.

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

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An updated IFU with the revised Caution will be forwarded prior to close of business today.

Thank you for your further consideration.

Best regards,

Lora Allemeier

From: Shi, Dexiu
Sent: Thursday, January 17, 2013 11:33 AM
To: 'Lora Allemeier'
Cc: DArthur Consulting; Nandkumar, Srinivas; Jen Rossi
Subject: RE: FW: K121326/S001 - Question on your response of Jan 16, 2013
Importance: High

Hi Lora:

(b)(4) Reveiw

[redacted]

Please provide your revised 510(k) Summary and modified page of Labeling accordingly.

Thank you,

Dexiu Shi

From: Lora Allemeier [mailto:lora@lantostechnologies.com]
Sent: Thursday, January 17, 2013 10:51 AM
To: Shi, Dexiu

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Cc: DArthur Consulting; Nandkumar, Srinivas; Jen Rossi
Subject: Re: FW: K121326/S001 - Question on your response of Jan 16, 2013

Hi Dexiu,

We have received the email and are working the request.

We have searched for examples of how the labelling and 510(k) summary may be modified for the Risk Group 1, and, have not found a good example.

We are proposing to modify our existing caution to be reworded as follows with modification in red:

CAUTION: DO NOT STARE AT SCANNER TIP, OR DIRECT SCANNER TIP TOWARD PATIENT'S FACE, WHILE ILLUMINATION IS ACTIVE. STARING AT MEMBRANE FOR MORE THAN 15 MINUTES WITH NO MEMBRANE ATTACHED UNDER FAULT CONDITIONS MAY EXCEED PHOTOBIOLOGICAL EXPOSURE. MAY BE HARMFUL TO THE EYES

Can you advise whether this is consistent with your expectation?

Best regards,

Lora Allemeier

From: Shi, Dexiu
Sent: Wednesday, January 16, 2013 5:26 PM
To: 'Lora Allemeier'
Cc: Nandkumar, Srinivas; Yang, Andrew; Shi, Dexiu
Subject: RE: K121326/S001 - FDA question on your response to Phototoxicity questions
Importance: High

Lora:

Thank you for your response.

According to your new calculation results, the blue LED used in your device does not meet classification of Exempt group, and should be classified as Risk Group 1 (Low Risk) (i.e., safe viewing time between 100 and 10,000 seconds). You should make this correction throughout your application. Please include the corrected LEDs classification in the 510(k) Summary and labeling. For Risk Group 1 blue LED, the acceptable maximum exposure time should be provided to the user. Please provide your revised 510(k) and Labeling ASAP. Please highlight the corresponding modifications.

Dexiu Shi

From: Lora Allemeier [mailto:lora@lantostechnologies.com]
Sent: Wednesday, January 16, 2013 4:51 PM

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

To: Shi, Dexiu
Cc: Nandkumar, Srinivas; DArthur Consulting; Ben FrantzDale
Subject: Re: K121326/S001 - FDA question on your response to Phototoxicity questions

Dear Dr. Shi,

Please find attached Lantos response to your requested dated 1/14/13. Please let me know if you have any follow up questions or concerns after the review.

Best regards,

Lora Allemeier

From: Shi, Dexiu
Sent: Monday, January 14, 2013 4:01 PM
To: 'Lora Allemeier'
Cc: Yang, Andrew; Shi, Dexiu
Subject: K121326/S001 - FDA question on your response to Phototoxicity questions

Dear Lora:

I am the Phototoxicity reviewer for your 510(K). I have a question on your response to Question 19 from our June 11, 2012 AI letter. Please check the attached the PDF document for the question, and provide your response by COB Wed, 1/16/13.

Regards,

Dexiu

Dexiu Shi, Ph.D., Senior Scientific and Regulatory Reviewer
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
FDA/CDRH/ODE
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
Phone: 301-796-6470
Fax: 301-847-8127
dexiu.shi@fda.hhs.gov

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. This e- mail message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at dexiu.shi@fda.hhs.gov or call (310) 796-6470.

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

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

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

December 19, 2012

LANTOS TECHNOLOGIES
C/O GENERIC DEVICES CONSULTING, INC.
20310 SW 48TH ST
SOUTHWEST RANCHES, FLORIDA 33332
ATTN: JOHN GREENBAUM

510k Number: K121326

Product: LANTOS 3D EAR SCANNER

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center 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

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

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EXPLANATION FOR ECOPY ATTACHMENT

You provided an eCopy along with the required number of paper copies. Your eCopy did not pass our validation software. The specific reasons for this failure are identified in the attachment.

Because eCopies are currently voluntary and because you already provided the necessary number of paper copies, you do NOT need to provide a replacement eCopy to FDA.

Instead, FDA is providing you with this information so that you can understand the reasons why your eCopy failed in order to better assure that an eCopy that you submit for another submission will not have similar issues.

As additional resources:

- Refer to our eCopy guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf. The eCopy program is not implemented (i.e., eCopy remain voluntary) at this time; however, the technical specifications/standards in Attachment 1 of the guidance are already in place.

- We strongly encourage you to take advantage of our free new eSubmitter-eCopies tool at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm317334.htm, which will help create an eCopy that passes the new technical specifications/standards.

Please keep in mind that once we implement the new eCopy program, most submissions types will go on eCopy hold until a valid eCopy is received.

If you have any questions about the eCopy program or the technical specifications/standards, please contact Ms. Samie Allen at samie.allen@fda.hhs.gov or at 301-796-6055.

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

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Attachment

Attachment for Submission Number(s):

K121326/S001

The list below identifies the reason(s) why your eCopy failed FDA's eCopy validation process. All of these items need to be addressed or your eCopy will not pass the validation process.

1. **The cover letter did not include an adequate eCopy statement.**

   26.pdf

2. **The following PDF file(s) have an invalid naming convention (e.g., numbering scheme incorrect, no underscore between number and descriptive name, descriptive name includes prohibited special characteristics):**

   Cover letter FINAL.pdf

   Lantos K121326 AI Response 12_18_2012 FINAL.pdf

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Jones, Ashlee *

From: Jones, Ashlee *
ent: Wednesday, December 19, 2012 1:57 PM
To: 'GENERICD@BELLSOUTH.NET'
Cc: 'lora@lantostechnologies.com'; 'deborahartur@darthurconsulting.com'
Subject: K121326 AI Letter, Explanation for eCopy Attachment, eCopy Attachment

Attachments: K121326 AI Letter, Explanation for eCopy Attachment, eCopy Attachment.pdf

K121326 AI Letter, Explanation...

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

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K121326 / S001

LANTOS TECHNOLOGIES
101 Main Street, Suite 1760
Cambridge, MA 02142
+1.617.500.9800
www.lantostechnologies.com

December 18, 2012

FDA CDRH DMC
DEC 19 2012
Received

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

Re: K121326: Lantos 3D Ear Scanner
Response to June 11, 2012 Deficiency Questions

To Whom It May Concern:

The attached documentation is in response to the FDA's request for Additional Information as part of the review of Premarket Notification K121326. Lantos Technologies appreciates the multiple opportunities to interact with Agency staff reviewers during the response preparation cycle. Further, the manufacturer believes this submission provides adequate evidence to support the safety and effectiveness of the Lantos 3D Scanner as presented in K121326. For ease of review, Lantos has restated each Agency question in bold type followed by the company's response. A copy of the FDA's request for Additional Information (dated June 22, 2012) is included as Attachment 1.

Lantos has also incorporated a summary of minor changes made to the 3D Scanner as part of its manufacturing process improvements. The described changes were implemented to allow for commercial manufacturing of the components at the required scale. Following its design control process, Lantos determined that the modifications had no impact on the safety or effectiveness of the device. For the Agency's convenience, the summary of modifications/process improvements may be found in Attachment 2.

Should there be questions, please do not hesitate to contact me or regulatory consultant Deborah Arthur via the information provided below.

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

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Lora Allemeier (lora@lantostechnologies.com)

(617) 500-9800 ext 15 (Office)

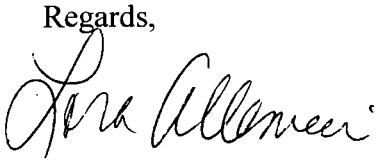
(978) 621-4461 (Mobile)

Deborah Arthur (Deboraharthur@Darthurconsulting.com)

(980) 219-8858 (Office)

(303) 915-2790 (Mobile)

Regards,



Lora Allemeier
Vice President Product Strategy and Regulatory
Lantos Technologies

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

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LANTOS TECHNOLOGIES

Lantos 3D Ear Scanner

Response to AI Request – 510(k) K121326

In the sections that follow are the Additional Information Requests from the lead FDA reviewer Lt Commander Andrew Yang, received June 22, 2012. Lantos Technologies respectfully submits the following responses.

Indications for Use

1. **In the Indications for Use (Page 24 of 535), you state that your device is indicated for use "by a trained hearing professional clinical settings on adult patients..." Please clarify the following issues and also update the Instructions for Use (User's Manual) accordingly:**
    a. **Please be more specific about which trained hearing professionals you are referring to, as well as what type of training, if any, recommended for using this device**

The Lantos 3D Ear Scanner is indicated for use by the same population of hearing professionals who use video otoscopes, the predicate device. This population generally includes audiologists, physicians, and other licensed hearing healthcare professionals. These individuals by training, experience and licensure are knowledgeable in external ear canal anatomy as it relates to inspection of the canal with the intent of making an impression to be used for device earmolds, hearing aids, etc. They have experience with otoscopes whether video or stationary.

Recommended training for use of the Lantos 3D Scanner is found in Attachment 3 (Instructions for Use). Additionally, company personnel will be available in the field and/or at Lantos's site to answer questions.

    b. **Please define "adult patients" by providing the age criteria (e.g., adult patients 22 years and older).**

The appropriate revised language follows and can be found in the updated labeling within Attachment 3 on page 5.

The Lantos 3D Scanner is indicated for use on individuals 18 years of age and older...

Device description

2. **For otoscopy and the topography measurements, correct use of the device is essential for generating a safe and accurate image of the ear canal. It is important to minimize the risk of user error that could result in an inaccurate ear canal measurement or damage to a patient's ear. Please address the following issues in your device description and update your Instructions for Use as appropriate:**

Risk of user error has been mitigated through design and labeling of the Scanner. Specifically, items 2a through 2e below have been answered and that response incorporated into the Instructions for Use to

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

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improve clarity and consistency. The modifications to labeling referenced below are located in Attachment 3 with their specific pages described.

a. Please provide a recommended maximum insertion depth of the probe into the ear canal (e.g. 3 mm from the TM)

Lantos recommends using the video otoscope image stream to adjust the position and insertion depth of the scanner tip (probe) into the ear canal. As can be seen in Figures 2a and 2b below, the scanner tip should be inserted no deeper than the point where the image of the tympanic membrane's perimeter reaches the edge of the viewing circle. This recommendation for maximum insertion depth insures that the scanner tip will be at (b)(4) Reveiw [redacted].

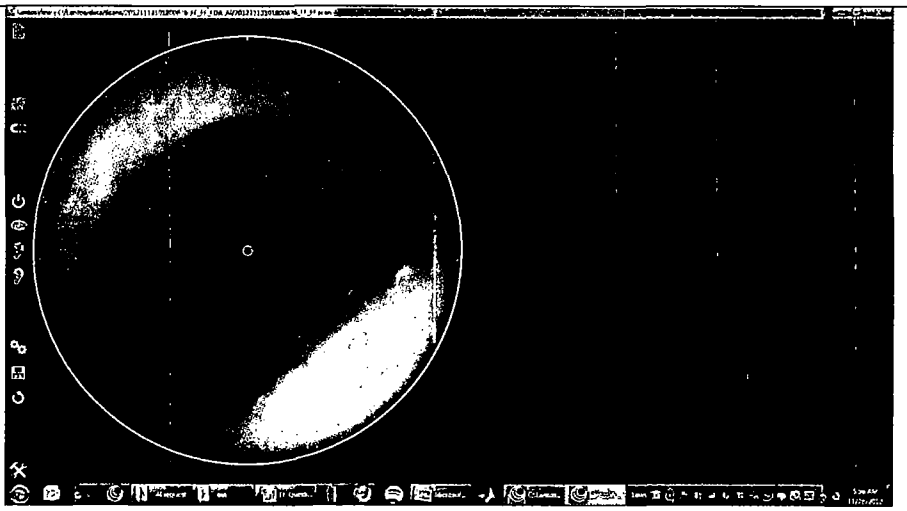

Figure 2a: Video otoscope images with tympanic membrane perimeter (a) extending out approximately 2/3 of the screen. Full perimeter is visible but tympanic membrane does not fill the screen – scanner tip can be inserted deeper if desired.

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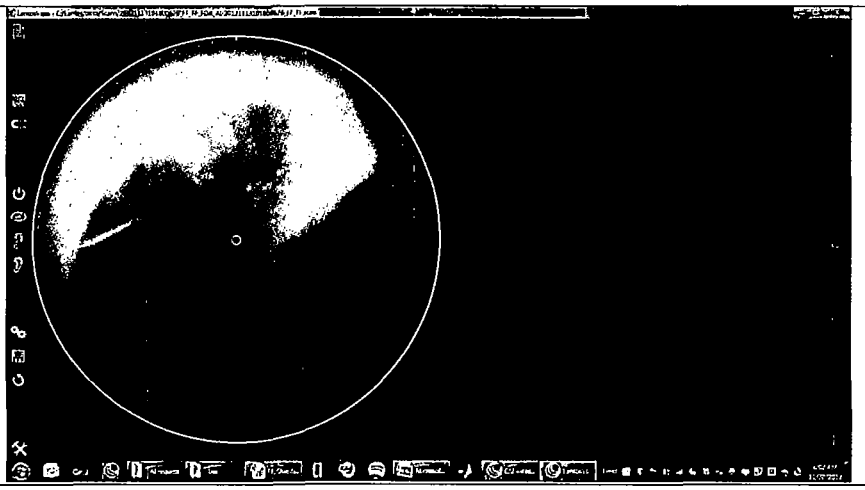

Figure 2b: Full perimeter is visible and tympanic membrane fills the screen - maximum recommended insertion depth has been reached (b)(4) Reveiw [redacted]

b. Please indicate if the conforming membrane expands medially from the probe tip. If so, please explain how the user should avoid the possibility of the membrane contacting the tympanic membrane.

The conforming membrane is designed to expand radially with minimal medial expansion. (b)(4) Reveiw [redacted] As long as the user follows the recommended guidelines for insertion depth (see 2a above) by visually monitoring the positioning of the TM perimeter in the otoscope's visual stream, there is minimal risk of the conforming membrane contacting the tympanic membrane[1].

c. Since your disposable component comes with a reservoir of 15cc of fluid, this suggests that the user will need to judge how much fluid is necessary to generate the appropriate topography measure. Please indicate how the user should avoid using too much or too little of the fluid to fill the conforming membrane and generate an accurate measurement.

The user should fill the conforming membrane with fluid (see Figure 3) until the proximal part of the membrane has expanded and has filled the concha bowl (see Figure 4). Since the proximal end of the membrane is clearly visible it is reasonable for the user to judge when the concha bowl has been filled. This process is not unlike the conventional silicone injection methods used by hearing healthcare professionals when making ear impressions today. By design, the conforming membrane's radial expansion starts at the distal tip and continues out of the canal and into the concha. This design feature

[1] In 84 ears that were scanned in the DOD sponsored study (Attachment VI, Sections 16.1 and 16.2) in K121326 original filing) using the Lantos 3D Scanner, there were no reports of contact with tympanic membranes. All topographical scans were conducted by site audiologists trained by Lantos staff using the information as provided in the attached Instruction for Use (IFU).

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order ensures that the distal part of the membrane has already expanded and conformed to the geometry of the canal when the visible proximal end of the membrane starts to expand in the concha. While it is not necessary to empty the reservoir of all fluid to achieve a successful topology measurement, testing indicates that the total volume of fluid in the reservoir will fit in the conforming membrane with minimal risk of rupture. Testing also confirms that if all the fluid is injected into the membrane, canal wall pressure measurements are still less than the maximum pressure generated by silicone impressions. Furthermore, the pressure and topology measurements are relatively insensitive to the amount of fluid in the membrane because the proximal section of the membrane remains unconstrained.

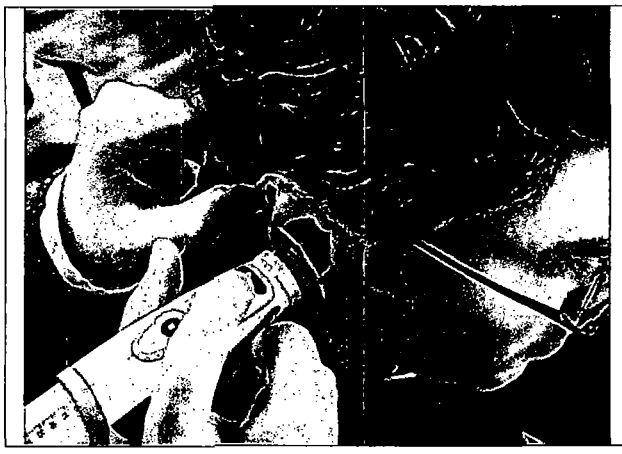

Figure 3

Figure 4

d. Please clarify if it is possible to displace the cartilaginous portion of the ear canal with pressure from the conforming membrane and fluid and to what extent. Also, please indicate why you do not expect this to have an impact on the accuracy of the topography measure.

The Lantos conforming membrane has been designed to exert pressure on the canal wall that falls within the range of pressure exerted by current silicone impression processes. Silicone impressions are known to apply pressure to the ear canal wall, and displace the cartilaginous portion of the canal. This pressure and displacement can vary significantly depending on technique and factors such as silicone viscosity or jaw position (Pirzanski and Berge, 2005[2]). Figure 5 below shows the measured range of wall pressure exerted on a model ear canal by multiple silicone impressions and Lantos 3D scans. It can be seen that the wall pressure measurements of the Lantos 3D scans fall within the range of pressure exerted by the silicone impressions.

[2] Pirzanski, C. and Berge, B. *Ear Canal Dynamics: Fact versus Perception.* The Hearing Journal 2005; 58(10): 50-58

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8418

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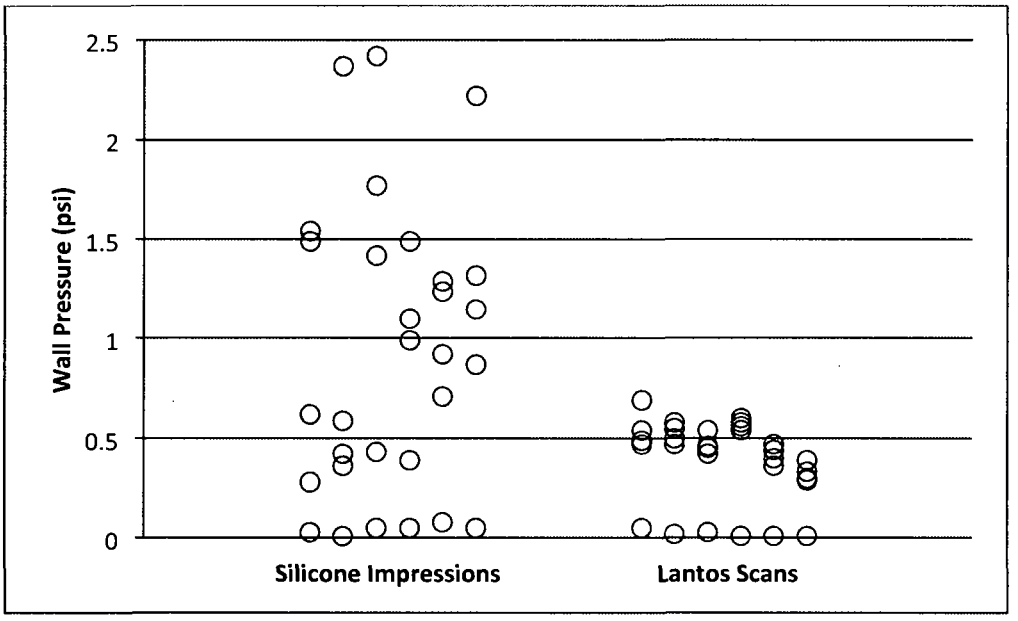

Figure 5: Wall pressures for multiple silicone impressions and Lantos 3D scans. Five evenly spaced measurements were taken during each scan and each impression.

e. **Please indicate the length of your probe tip and how this compares to a standard speculum on a traditional otoscope. Also, please indicate if you have included any mechanisms for minimizing the risk of the probe tip making contact with the tympanic membrane during use.**

The Scanner (probe) tip length is 1mm when retracted and 36mm when fully extended; the diameter of the scanner tip is 3.3mm along its entire length. Video otoscope specula vary widely in size and shape, standard sizes vary in length from 15 to 30mm, tips vary from 2.5 to 9mm, and the shape is typically conical, increasing from distal to proximal.

A description of the method of use (intended to minimize risk of the scanner tip contacting the TM) is found above in response to question 2a.

Questions? Contact FDA/CDRH/OCE/DID at CDRHFOISTATUS@fda.hhs.gov or 301-796-8418

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3. In section 7.10 (Use Overview, page 37 of 535), you state "The disposable will contact and reshape the ear canal with mild pressure..." Please indicate if this amount of mild pressure has been judged to be acceptable in terms of comfort by the majority of the patients on whom the device has been used.

Lantos realizes that the description on the referenced page for the process of visualizing the external ear canal with the 3D Scanner is misleading. Actually, the disposable will contact the ear canal in the same manner as the predicate device. It may be moved laterally and superior/inferiorly to improve visualization through the scanner tip in the same manner as a video otoscope or a standard otoscope with speculum. There is no 'pressure' or 'reshaping' in the process of visualization.

With regard to the process of scanning the ear canal utilizing the Lantos scanner with conformal membrane, that process and a comparison to the conventional method of 'injection of silicone impression' material into the ear canal are addressed in the response to question 2d above.

4. You provide a list of contraindications, warning, and precautions (Sections 7.11 & 7.12, page 34 of 535). This list is lacking some detail to effectively guide users' clinical judgment. Please address the following issues and be sure to include all of these contraindications, warnings and precautions in your Instructions for Use (User's Manual):

Lantos has addressed the Agency's concerns in questions 4a-e and has updated the Instruction for Use (Attachment 3) for clarity and consistency.

a. You specify that the device is not for use in the pediatric population. Please provide the specific age range for who the device is contraindicated.

The Lantos 3D Scanner is contraindicated for use with individuals below 18 years of age.[3]

b. In Warnings & Precautions, bullet 'c', you state "Use clinical judgment for patients where the anatomy of the external ear appears to have unsuitable tortuosity." Please clarify what is meant by "unsuitable tortuosity" and provide examples of tortuous ear canals that are unsuitable for your device. Also, please explain why your device should not be used in these patients, since this is a population who have difficulty with traditional ear impressions and could greatly benefit from 3D scanning technology.

[3] Contraindication for less than 18 years of age only due to lack of clinical experience with individuals less than 18 years of age. There is considered minimal risk in use of the device in individuals less than 18 years of age. In an abundance of caution, Lantos has contraindicated the use of the product until clinical experience in pediatric populations is collected.

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

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Upon review of the referenced 'Warning & Precaution' and discussion with consulting audiologists, Lantos is removing this statement. As with standard and video otoscopes, if the scanner tip can be inserted and the ear canal and TM visualized, then it is likely that a successful scan can be obtained.

c. **You do not provide any guidance on the use of your device with respect to the presence of cerumen in the ear canal. Please indicate if the ear canal should be completely clear of cerumen prior to use of the otoscopic and/or topography functions of your device.**

Precautions for the presence of cerumen in the ear canal are no different with the scanner than with conventional silicone EM impressions. Modest or thin deposits of cerumen will create commensurately small differences in the topology measurement, and the conforming membrane will compress deposits of soft cerumen similar to the conventional silicone impression. There is no limitation to the use of the scanner in otoscope mode in the presence of cerumen.

d. **Please indicate if your device may be used in patients with exotoses or osteomas, and if so, what precaution should be taken.**

The use of the scanner in visualizing the external auditory meatus (EAM) of individuals experiencing exotoses or osteama would not be different than with a standard or video otoscope. The determination should be made by the trained hearing professional.

e. **Please indicate what precautions should be taken for the use of your device in immuno-compromised patients, such as persons with diabetes or HIV.**

As with other methods of visualization and inspection of the EAM, the hearing clinician should always use standard precautions, i.e. use of disposable gloves with an additional protection offered by the single-use, disposable intent of the conforming membrane.

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5. **You provide engineering drawings in Attachment 8. However, it appears that some components are missing. We have identified 2 missing components: pump assembly, power source. Please provide these drawings and any others that were not previously included.**

Lantos reviewed the provided drawings in Attachment 8 (K121326) and has added the ten drawings found in Attachment 2 to address the FDA's concerns regarding missing drawings (i.e. pump assembly and power source). Lantos would like to clarify that there are not component drawings with those specific identifiers, but the drawings provided in Attachment 2 include the components that comprise the pump assembly (Attachment 2, Figures 1-5) and power source (Attachment 2, Figures 6-10).

6. **On page 46 of 535, Device Description, you state that the illumination source of your device is "a three color Red/Green/Blue collection of LED die are coupled through an optical taper into the proximal end of the illumination fibers—a microcontroller and associated current control drive circuits create an illumination flash sequence synchronized with the shutter of the optical sensor."**

   However, you do not provide the technical characteristics of these LEDs (e.g., wavelength (spectrum distribution), maximum and normal operating output power). Please provide these parameters which are the essential information for evaluating our risk analysis.

The Lantos Scanner includes three LED sources. Two LED sources, Red and Green, are used for illumination in video otoscope mode. One LED source, Blue-Violet, is used to illuminate the inside surface of the Conforming Membrane for the topology measurement of the external ear canal. Attachment 4 includes a full summary.

The following table and figures show the technical characteristics of the LEDs.

(b)(4) Reveiw

[redacted]

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(b)(4) Reveiw

[redacted]

Clinical Testing

7. **You provide an interim report for the Direct Scan Earmold Digitization Evaluation which demonstrates no adverse events for the Lantos related aspects of the study. However, this interim report includes only the secondary endpoint results for safety; it does not include the primary endpoint effectiveness data demonstrating the comparison between the current standard of care for ear impressions and custom earplug manufacturing (earmold scan) and your device's direct scan method. Because your intended population use and labeling include claims about using the topography measures to manufacture custom ear pieces and hearing aids, these effectiveness data are important to support a pre-market clearance of your device. Please provide the final results from this clinical investigation that include both the safety and effectiveness endpoints.**

   Similarly, you provide an interim clinical report for your User Preference Study which includes a partial data set and no analyses. Please provide the final results from this clinical investigation in support of the safety and effectiveness of your device for its intended use.

The use of this interim clinical report in the original 510(k) submission (April 2012) should have been clarified within the original submission. The intent, execution, and analysis of the study came from the ENT Department at Tripler Army Medical Center. While the information is certainly of interest to Lantos Technologies and they did provide a 3D Scanner and software for use, the study was not designed by Lantos nor intended to be a protocol to prove the safety and effectiveness of the Lantos 3D Scanner for Lantos' stated intended use.

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In an attempt to ensure full disclosure, the manufacturer shared the study details in a manner that may have inferred it was provided as 'proof' of safety and efficacy of the 3D Scanner in the 510(k) submission (K121326). Lantos would like to apologize for any confusion and clarify its intent for inclusion in the original submission.

Lantos Technologies felt the study data gathered by the time (April 2012) of 510(k) submission was *supportive* of the device's safety only; the efficacy parameters were not intended to be data interpreted as the *proof* of efficacy. The data cited in support of safety (absence of adverse events) were certainly expected and consistent with the manufacturer's risk profile. The remaining data are interesting but Lantos does not believe the study design was valid for the determination of efficacy, nor is the protocol design, study conduct and data management and analysis under the purview of Lantos as they are not the sponsor of the study.

In fact, in discussions with the FDA's ENT Branch Chief in November 2012, it was shared that Lantos had determined that bench verification was a more appropriate method to assess efficacy of the 3D Scanner for the intended use. The outcome of this verification is described below. As discussed, it is evident that the scanner is comparable to that of the 'lost wax' method for the making of ear canal impressions. Future post-marketing studies conducted by Lantos and others may be intended to determine its effectiveness in the development of a noise attenuating device or hearing aids compared to the current 'standard of care', but that is not the claim at this time.

The device is intended to provide illumination and visualization of the ear canal and to allow an alternate technique (i.e. lost wax or silicone injection methods) to capture ear canal topography (digital scanning) using a single device, consistent with the intent to seek premarket clearance for the Lantos 3D Scanner under 21 CFR Part 874.4770 as an *otoscope* and an accessory to a hearing aid (21 CFR Part 874.3300).

The summary of the verification is included as follows:

Verification of 3D Scanner Accuracy:
A bench top verification study was designed to determine the accuracy and repeatability of the scanner. The study was conducted using two different models of known dimensions, cylindrical and anatomical.

(a) Cylandrical Accuracy Model

A 9 mm diameter x 51 mm long cylindrical model (Figure 9) machined out of Delrin plastic to a tolerance of ± 0.002 in (± 50 μm) (Incodema, Ithaca, NY). The 9 mm diameter dimension is based on caliper measurements of 20 silicone ear impressions at the aperture. The 9 mm is also in the range of the ear canal diameter at the aperture of 9.3 ± 0.9 mm (Staab and Martin, 1994[4]).

[4] Staab, W. J. and Martin, R. L. Taking Ear Impressions for Deep Canal Hearing Aid Fittings. The Hearing Journal 1994; 47(11): 19-28

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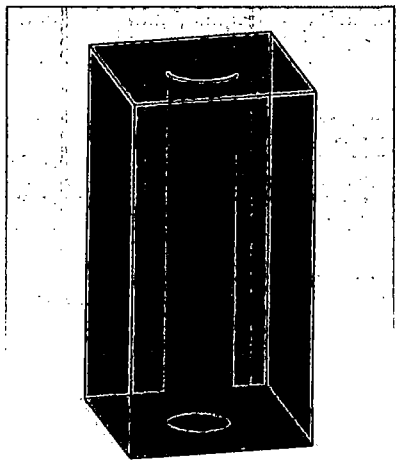

Figure 9: A transparent view of the cylindrical accuracy model

(b) Anatomical Accuracy Model.

A 36 x 36 x 36 mm cube with an internal cavity (Figure 10) was based on a silicone impression of an actual ear. The model was manufactured using stereolithography, a 3D printing technology to a tolerance of ± 0.005 in (± 125 μm) (Spectrum Plastics Group, Westminster, CO).

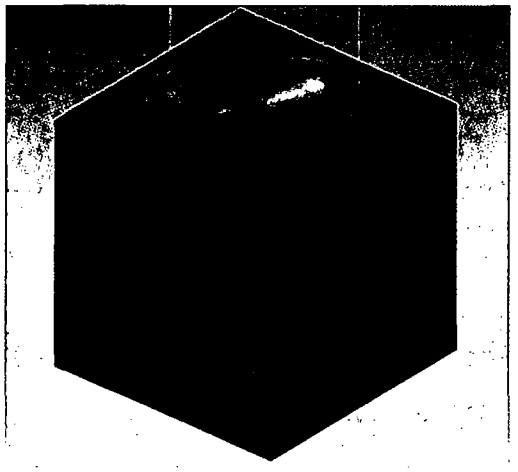

Figure 10. A transparent view of anatomical accuracy model, which was based on a silicone impression of an actual ear.

Each model was scanned six times, each time using a different disposable. After data alignment with model reference surfaces (using a manual registration function in an analytical quality software), the average error (mean difference) between the model reference and the scans had to be below 400 μm (0.4mm) in order to meet the verification acceptance criteria. The acceptance criteria was based on the known variability in ear canal diameter caused by

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jaw motion which is greater than 0.5 mm for approximately 45% of the population (Pirzanski and Berge, 2005[5]). All scans met the criteria with no protocol deviations. The following Figure 11 is a visual comparison of the Lantos scan and the reference surface of the anatomical model.

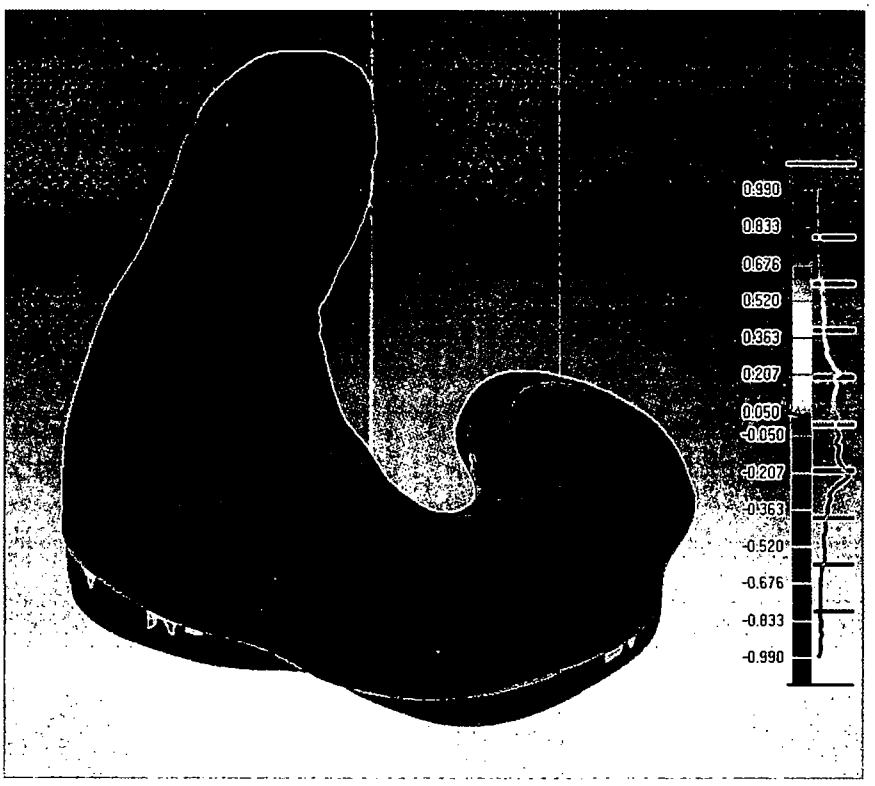

Figure 11: A visualization of the scan (color) aligned with the model reference (gray). Units are in mm.

[5] Pirzanski, C. and Berge, B. Ear Canal Dynamics: Fact versus Perception. The Hearing Journal 2005; 58(10): 50-58

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The summary of results is found below (Table 2).

Trial Number	Model Type	Mean Difference (µm)	Result
1	Anatomical - D	266	PASS
2	Cylinder	232	PASS
4	Cylinder	333	PASS
5	Anatomical – D	330	PASS
6	Cylinder	213	PASS
7	Anatomical – D	268	PASS
8	Cylinder	379	PASS
10	Cylinder	246	PASS
11	Anatomical – D	265	PASS
12	Cylinder	373	PASS
13	Anatomical – D	347	PASS
14	Anatomical - D	293	PASS

Table 2: Summary of results Verification of 3D Scanner Accuracy

User preference study:
A review of the study protocol and interim report by company and external personnel determined that the methodology employed (single audiology user, 10 ears) and the data gathered (forced responses even when non-applicable) *did not accurately represent the primary and secondary objectives of this study.* While feedback was in some cases informative, the design of the study was inadequate to achieve the objectives as stated. Lantos respectfully wishes to withdraw the User Preference Study and any earlier associated claims-based statements.

8. You state that custom earplugs were manufactured for your Direct Scan Earmold Digitization Evaluation, but a description of the earplug style/features cannot be easily located. Please provide further details about the earplug features, including if the custom earplugs were full-shell style or canal-style plugs.

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As indicated above in response to question 7, the study provided is not intended to prove efficacy of the 3D scanner.

9. Please indicate how you intend to evaluate the accuracy/effectiveness of the 3D ear scan for the concha and helix regions of the topography measurements obtained with your 3D ear scanner device.

The evaluation of accuracy and effectiveness of the 3D scan for the concha and helix regions is found above in the Question 7 response as *Verification of 3D Scanner Accuracy*. The verification included the concha and helix regions.

10. In the Methods section of the Direct Scan Earmold Digitization Evaluation protocol (section 7.6, Determination of Eligibility, page 350 of 355), you state "subjects will be 40 normal hearing men and women...with no known medical pathology." However, your subjects included persons with hearing loss, and this was not reported as a protocol deviation. Please indicate why you included subjects with hearing loss in this study and any expected impact on your study results.

As indicated above in response to question 7, the study provided is not intended to prove efficacy of the 3D scanner.

11. You measure the amount of attenuation provided by the custom earplugs in each ear separately in the Direct Scan Earmold Digitization Evaluation. Given that your audiometric measures were performed in the sound field, please explain how you were able to isolate each ear for the attenuation measures.

Also, please indicate if our subjects and investigators were blinded as to which custom earplugs were derived from which scanning method. If not, please indicate how you will control for this potential bias, particularly with respect to the investigators' blinding.

As indicated above in response to question 7, the study provided is not intended to prove efficacy of the 3D scanner.

12. You describe the protocol deviations (section 10.0, page 395 of 535) in the Direct Scan Earmold Digitization Evaluation. However, further details are needed to explain the impact of these deviations. Please address the following issues:

a. The second bullet states "the audiologist determined potential clinical implications for subjects receiving earmold impression scans prior to the EarMold 3D Direct scans of the ear canal" and explains those implications. However, it is unclear exactly how the protocol was modified and what impact the modification could have on results. Please provide these details.

b. Under the third bullet, you state "In addition, the audiologist determined these frequencies are unreliable for testing and retesting purposes due to the

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directionality of the 8000 Hz and subjects respond to 250 Hz as a vibro-tactile response to a 250 Hz tone presented via loud speaker in the sound field of 40 dB HL and below.

As indicated above in response to question 7, the study provided is not intended to prove efficacy of the 3D scanner.

13. Following your User Preference Study, 10/19 clinicians rated the video otoscope images from this device as the same or more difficult relative to the quality of images from other conventional or video otoscopes. Furthermore, in Figure 7-21 (page 48 of 538) you provide images from the video otoscope where there appears to be limited visibility of the tympanic membrane. This suggests that the images from the video otoscopy of your device may not yield "exceptional visualization of the ear canal" as claimed in your Draft Brochure, or that visualization of the tympanic membrane may be limited. Please provide images and performance data to support your claims about the quality of images from the video otoscopy with your device.

Lantos has determined that further development and investment at this time in the referenced marketing Brochure are ill-advised and consumes unnecessary resources prior to commercialization of the device. Lantos plans on updating/modifying the Brochure upon FDA issuance of clearance for the premarket notification (K121326). At that time, developed marketing materials will reflect the intended use of the Lantos 3D Scanner and any associated features/functionalities supportive of its determination of safety and effectiveness. Additionally, Lantos is withdrawing statements of 'exceptional visualization' of the ear canal or TM at this time from its labeling.

With respect to the stated concern regarding the quality of the visual image from the Lantos 3D Scanner, Lantos apologizes for the quality of the images included as Figure 7-21 (page 48 of 538) which was the result of compression of the image for the digital file. In addition, Lantos has modified settings such as exposure time, illumination, gamma correction and gain, which can impact image quality. As we have gained experience with the scanner, we have tuned these parameters to improve our image quality. Please see Figure 12 below which reflects the quality of the video otoscope mode of the Lantos 3D Scan.

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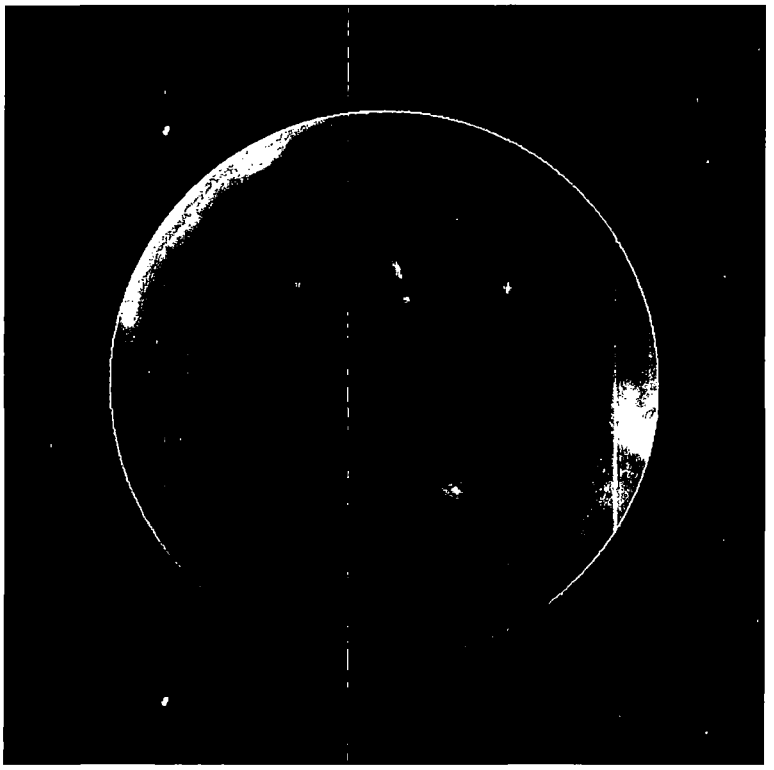

Figure 12: Visualization of the tympanic membrane, manubrium of the umbo, through the Lantos 3D scanner with conforming membrane in video otoscope mode

14. In your User Preference Study, most of your clinician subjects indicate that they would like a prompt or an identification of insertion depth or ear canal length. Please indicate how you plan to address this issue.

As described in the responses to questions 2a-e, the clinicians are provided a description of the ear canal and TM visualization with applicable photographs indicating how to approximate when 4-5 mm back from the TM (the recommended depth for initiation of the topography measurement).

Labeling

15. In the Draft Brochure (page 337 of 535), under Safety and Comfort, you state "The scanner can be used with confidence in cases where traditional impression material might require extended preparation." This statement implies that the Lantos 3D Ear Scanner is a better option in difficult cases. Please clarify this statement by indicating what cases you are referring to and providing data or a rationale to support your statement.

Upon review, Lantos is withdrawing that statement/claim. At this time, Lantos is making no statement that the 3D Scanner is a better alternative than the use of traditional impression material methods.

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As stated in response to Question 13, Lantos has terminated development of all marketing materials (i.e. Draft Brochure) until premarket clearance is obtained with final safety and efficacy of the device approved.

16. You provide descriptions of the steps for using the Lantos 3D Ear Scanner to perform video otoscopy and topography measurements in the Instructions for Use. You may consider including additional diagrams and/or photographs of the device in use in order to provide references for the user. Examples of additional images that may be helpful for the Instructions for Use include the button controls on the device, the check cap, the protective cap, how to brace the device while retracting the probe tip during topography, etc.

Lantos has incorporate additional diagrams and photos to its modified Instructions for Use (Attachment 3). The original **Introduction** section has been shortened and much of the information consolidated into the **Operation** section of the IFU. Updated details and figures have been included in the current version of the IFU and are summarized in the table below:

PAGE	CHANGE
1	Updated product image on cover
2	Added a copyright page
4	Added a table of contents
5	Consolidated Introduction into portions of the Operation section, added System Requirements, Intended Use and User Profile
7	Added cautions to reflect 1) need for good clinical judgment 2) distance from TM and 3) illumination and eye caution
11	Changed to an updated photo of the system
12	Updated photo of docking stand
13	Updated photo of scanner
14	Updated photo of consumable
16	Updated user interface image
18	Updated to new log in screen
19	Updated image of check cap of consumable
21	Added two photos depicting position of user in relation to patient and hand placement of the user during scanning
23	Used terms "data capture" and "scanning mode" in lieu of "ear topology mode"
24	Added updated image of application software as visualized during the scanning process
27	Added updated image of user interface
31	Updated specifications to reflect new consumable, scanner, and docking stand

17. Please include the updated contraindications and precautions in the Instructions for Use.

Please see Instructions for Use (Attachment 3 on pages 6 and 7) for the updated contraindications and precautions within the Instructions for Use. For your convenience, Lantos is restating as follows:

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Contraindications

- Individuals less than 18 years of age[6]

Warnings & Precautions

Warnings:

- Do not connect the Lantos 3D Ear Scanner to devices other than as expressly described in these instructions
- Plug the scanner into a properly grounded power outlet to maintain patient and user safety when operating from an A/C power
- Disconnect the scanner from A/C power source if it gets wet, if cables are damaged, or if components are dropped
- Do not use in the presence of flammable anesthetics

Precautions:

- The membrane, reservoir and medium are for single patient use
- Do not user the scanner for any purposes other than those described in these instructions
- Discontinue user of the device if you notice any signs of damage to the components. Contact Lantos for service. No user serviceable components.
- The handheld scanner is a higly precise optical instrument. Improper handling, such as dropping or bumping the tip, may cause the scanner to break or malfunction.
- Use good clinical judgment and inspect the ear canal prior to membrane inflation. Do not use on patients with excess cerumen in the ear canal, patients with an infection in the external or middle ear, patients with drainage or blood in the ear, or patients with a foreign body in the ear canal.
- Use good clinical judgment when approaching the tympanic membrane (TM) and do not touch the TM
- Do not stare at scanner tip or direct scanner tip toward patient's face, while illumination is active. May be harmful to the eyes

18. You provide copies of your labeling. One of the labels is for the Lantos 3D Ear Scanner Disposable Multi-Pack—Contains Ten (10) ea which bears the manufacturing month and the expiration month. Please explain how you arrived at this 1 month shelf-life and provide the suporting documentation. Furthermore, in Attachment 1, you provide a list of hazards that the disposable components may become unsafe within 1 month of manufacturing. You do not provide a description of the packaging. Combined with the short shelf-life and dangers of expired product, the packaging is paramount. Please describe how all components are packaged, which includes the individual packaging for each component, individual cartons, shipping containers, etc.

---

[6] Contraindication for less than 18 years of age only due to lack of clinical experience with individuals less than 18 years of age. There is considered minimal risk in use of the device in individuals less than 18 years of age. In an abundance of caution, Lantos has contraindicated the use of the product until clinical experience in pediatric populations is collected.

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Upon review and discussion with outside consultants, it became clear to Lantos that its interpretation of the definition/requirements for stipulating 'shelf life' was erroneous. The Hazards Analysis was updated to reflect that this is a non-sterile, packaged device with the materials used in the patient-contacting, disposable portion (Membrane and Pressure Cup components) of the Lantos Single Use Disposable consisting of implantable-grade silicone rubber and thermoplastic elastomer. These materials are well-characterized and known for their stability in medical device use, and have had biocompatibility testing per ISO-10993 for Cytotoxicity, Irritation and Skin Sensitization, and Intracutaneous Reactivity.

The Lantos Disposable is individually-packaged in a foil pouch. Based on the established use of the materials in these components, there is no reason to be concerned about material or packaging stability over time. Per your request, the following is a drawing of the component outer pouch. Lantos respectfully believes that its earlier stated concerns on shelf-life were a misunderstanding of the existing standards and guidelines.

(b)(4) Reveiw

[redacted]

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Phototoxicity

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[redacted]

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(b)(4) Reveiw

[redacted]

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(b)(4) Reveiw

[redacted]

20. The ear skin is also vulnerable to damage by optical radiation. The type of effect, injury thresholds, and damage mechanisms vary significantly with wavelength. There are different types of damage to the skin may be caused by optical radiation, for example:

- **Thermal damage (burns) of the skin with visible and infrared radiation.**
- **Photosensitized damage of the skin: It is generally far more typical of UVR wavelengths (less than 380 nm). However, such photosensitized reactions can extend to approximately 700 nm, possibly as a side-effect of certain medications.**

You do not include an evaluation of optical radiation hazard to the skin. We recommend you evaluate skin safety for use of your device by performing an optical radiation hazard evaluation to demonstrate your device meets the safety guideline specified in ACGIH[1] and ICNIRP [2] or an equivalent method. Please provide this information

[1] ACGIH American Conference of Governmental Industrial Hygienists Threshold Limit Values for chemical substances and physical agents and Biological Exposure Indices. 2011.

[2] International Commission on Non-Ionizing Radiation Protection (ICNIRP). Guidelines on limits of exposure to broadband incoherent optical radiation (0.38 – 3 um_. Health Phys. 73: 37 539-554; 1997

The Lantos Scanner was evaluated or tested according to the recommended ICNIRP and ACGIH Guidelines for Thermal Damage and Photosensitized Damage to the Skin.

For short thermal damage exposures, the Lantos Scanner remained within ICNIRP Guidelines even in the extreme misuse case where the scanner tip was pressed hard against the skin of the external ear canal for 10 seconds. For long thermal exposures, heat stress as indicated in ACGIH Guidelines was negligible. Results for Thermal Damage are in Section 4.8 of Attachment 4.

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For Photosensitized Damage, evaluation results are shown in Section 4.9 of Attachment 4. Per ACGIH Guidelines, the only skin exposure at the energy levels produced by the Scanner was in the UV-A band. Even in the extreme misuse case where the scanner tip is directed at a small patch of skin, and held in place, 45 to 66 minutes of exposure would be safe.

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

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Attachment 1:

Additional Information Request Re: K121326 Received June 22, 2012

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

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

Lantos Technologies
% Mr. John Greenbaum
Generic Devices Consulting, Inc.
20310 SW 48th St
Southwest Ranches, FL 33332

Re: K121326
Trade Name: Lantos 3D Ear Scanner
Dated: April 30, 2012
Received: May 2, 2012

Dear Mr. Greenbaum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following:

Indications for Use

1. In the Indications for Use (page 24 of 535), you state that your device is indicated for use "by a trained hearing professional in clinical settings on adult patients..." Please clarify the following issues and also update the Instructions for Use (User's Manual) accordingly:

    a. Please be more specific about which trained hearing professionals you are referring to, as well as what type of training, if any, recommended for using this device.

    b. Please define "adult patients" by providing the age criteria (e.g., adult patients 22 years and older).

Device Description

2. For otoscopy and the topography measurements, correct use of the device is essential for generating a safe and accurate image of the ear canal. It is important to minimize the risk of user error that could result in an inaccurate ear canal measurement or damage to a patient's ear. Please address the following issues in your device description and update your Instructions for Use as appropriate:

    a. Please provide a recommended maximum insertion depth of the probe into the ear canal (e.g., 3mm from the TM).

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b. Please indicate if the conforming membrane expands medially from the probe tip. If so, please explain how the user should avoid the possibility of the membrane contacting the tympanic membrane.

c. Since your disposable component comes with a reservoir of 15cc of fluid, this suggests that the user will need to judge how much fluid is necessary to generate the appropriate topography measure. Please indicate how the user should avoid using too much or too little of the fluid to fill the conforming membrane and generate an accurate measure.

d. Please clarify if it is possible to displace the cartilaginous portion of the ear canal with pressure from the conforming membrane and fluid and to what extent. Also, please indicate why you do not expect this to have an impact on the accuracy of the topography measure.

e. Please indicate the length of your probe tip and how this compares to a standard speculum on a traditional otoscope. Also, please indicate if you have included any mechanisms for minimizing the risk of the probe tip making contact with the tympanic membrane during use.

3. In section 7.10 (Use Overview, page 37 of 535), you state "The disposable will contact and reshape the ear canal with mild pressure…" Please indicate if this amount of mild pressure has been judged to be acceptable in terms of comfort by the majority of patients on whom the device has been used.

4. You provide a list of contraindications, warnings, and precautions (Sections 7.11 & 7.12, page 34 of 535). This list is lacking some detail to effectively guide users' clinical judgment. Please address the following issues and be sure to include all of these contraindications, warnings, and precautions in your Instructions for Use (User's Manual):

   a. You specify that the device is not for use in the pediatric population. Please provide the specific age range for who the device is contraindicated.

   b. In Warnings & Precautions, bullet 'c', you state "Use clinical judgment for patients where the anatomy of the external ear appears to have unsuitable tortuosity." Please clarify what is meant by "unsuitable tortuosity" and provide examples of tortuous ear canals that are unsuitable for your device. Also, please explain why your device should not be used in these patients, since this is a population who have difficulty with traditional ear impressions and could greatly benefit from 3D scanning technology.

   c. You do not provide any guidance on the use of your device with respect to the presence of cerumen in the ear canal. Please indicate if the ear canal should be completely clear of cerumen prior to use of the otoscopic and/or topography functions of your device.

   d. Please indicate if your device may be used in patients with exotoses or osteomas, and if so, what precautions should be taken.

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e. Please indicate what precautions should be taken for the use of your device in immuno-compromised patients, such as persons with diabetes or HIV.

5. You provide engineering drawing in Attachment 8. However, it appears that some components are missing. We have identified 2 missing components: pump assembly, power source. Please provide these drawings and any others that were not previously included.

6. On page 46 of 535, Device Description, you state that the illumination source of your device is "a three color Red/Green/Blue collection of LED die are coupled through an optical taper into the proximal end of the illumination fibers – a microcontroller and associated current control drive circuits create an illumination flash sequence synchronized with the shutter of the optical sensor."

   However, you do not provide the technical characteristics of these LEDs (e.g., wavelength (spectrum distribution), maximum and normal operating output power). Please provide these parameters which are the essential information for evaluating your risk analysis.

Clinical Testing

7. You provide an interim report for the Direct Scan Earmold Digitization Evaluation which demonstrates no adverse events for the Lantos related aspects of the study. However, this interim report includes only the secondary endpoint results for safety; it does not include the primary endpoint effectiveness data demonstrating the comparison between the current standard of care for ear impressions and custom earplug manufacturing (earmold scan) and your device's direct scan method. Because your intended population use and labeling include claims about using the topography measures to manufacture custom ear pieces and hearing aids, these effectiveness data are important to support a pre-market clearance of your device. Please provide the final results from this clinical investigation that include both the safety and effectiveness endpoints.

   Similarly, you provide an interim clinical report for your User Preference Study which includes a partial data set and no analyses. Please provide the final results from this clinical investigation in support of the safety and effectiveness of your device for its intended use.

8. You state that custom earplugs were manufactured for your Direct Scan Earmold Digitization Evaluation, but a description of the earplug style/features cannot be easily located. Please provide further details about the earplug features, including if the custom earplugs were full shell style or canal style plugs.

9. Please indicate how you intend to evaluate the accuracy/effectiveness of the 3D ear scan for the concha and helix regions of the topography measurements obtained with your 3D Ear Scanner device.

10. In the Methods section of the Direct Scan Earmold Digitization Evaluation protocol (section 7.6, Determination of Eligibility, page 350 of 355), you state "subjects will be 40 normal hearing mean and women…with no known medical pathology." However, your subjects

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included persons with hearing loss, and this was not reported as a protocol deviation. Please indicate why you included subjects with hearing loss in this study and any expected impact on your study results.

11. You measure the amount of attenuation provided by the custom earplugs in each ear separately in the Direct Scan Earmold Digitization Evaluation. Given that your audiometric measures were performed in the sound field, please explain how you were able to isolate each ear for the attenuation measures.

    Also, please indicate if your subjects and investigators were blinded as to which custom earplugs were derived from which scanning method. If not, please indicate how you will control for this potential bias, particularly with respect to the investigators' blinding.

12. You describe the protocol deviations (section 10.0, page 395 of 535) in the Direct Scan Earmold Digitization Evaluation. However, further details are needed to explain the impact of these deviations. Please address the following issues:

    a. The second bullet states "the audiologist determined potential clinical implications for subjects receiving earmold impression scans prior to the EarMold 3D Direct scans of the ear canal" and explains those implications. However, it is unclear exactly how the protocol was modified and what impact the modification could have on the results. Please provide these details.

    b. Under the third bullet, you state "In addition, the audiologist determined these frequencies are unreliable for testing and re-testing purposes due to the directionality of the 8000Hz and subjects respond to 250 Hz as a vibro-tactile even when not heard." Please clarify what is meant by "the directionality of the 8000 Hz." Also, please clarify why you would expect subjects to have a vibro-tactile response to a 250 Hz tone presented via loud speaker in the sound field at levels of 40 dB HL and below.

13. In your User Preference Study, 10 out of 10 clinicians rated the video otoscope images from this device the same or more difficult relative to the quality of images from other conventional or video otoscopes. Furthermore, in Figure 7-21(page 48 of 538) you provide images from the video otoscope where there appears to be limited visibility of the tympanic membrane. This suggests that the images from the video otoscopy of your device may not yield "exceptional visualization of the ear canal" as claimed in your Draft Brochure, or that visualization of the tympanic membrane may be limited. Please provide images and performance data to support your claims about the quality of images from the video otoscopy with your device.

14. In your User Preference Study, most of your clinician subjects indicated that they would like a prompt or an identification of insertion depth or ear canal length. Please indicate how you plan to address this issue.

Labeling

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15. In the Draft Brochure (page 337 of 535), under Safety and Comfort, you state "The scanner can be used with confidence in cases where traditional impression material might require extended preparation." This statement implies that the Lantos 3D Ear Scanner is a better option in difficult cases. Please clarify this statement by indicating what cases you are referring to and providing data or a rationale to support your statement.

16. You provide descriptions of the steps for using the Lantos 3D Ear Scanner to perform video otoscopy and topography measurements in the Instructions for Use. You may consider including additional diagrams and/or photographs of the device in use in order to provide references for the user. Examples of additional images that may be helpful for the Instructions for use include the button controls on the device, the check cap, the protective cap, how to brace the device while retracting the probe tip during topography, etc.

17. Please include the updated contraindications and precautions in the Instructions for Use.

18. You provide copies of your labeling. One of the labels is for the Lantos 3D Ear Scanner Disposable Multi-Pack – Contains Ten (10) ea which bears the manufacturing month and the expiration month. Please explain how you arrived at this 1 month shelf-life and provide supporting documentation. Furthermore, in Attachment 1, you provide a list of hazards, among which are potential consequences of not heeding the expiration date. This suggests that the disposable components may become unsafe within 1 month of manufacturing. You do not provide a description of the packaging. Combined with the short shelf-life and dangers of expired product, the packaging is paramount. Please describe how all components are packaged, which includes the individual packaging for each component, individual cartons, shipping containers, etc.

Phototoxicity

19. The eye is a sensitive organ highly susceptible to damage by optical radiation. It is not clear whether the LEDs are turned on before or after the probe is inserted into ear. If the LEDs are turned on before inserting, there is the potential optical radiation hazard to the eye because of the proximity to the eyes. If Lantos 3D Ear Scanner is designed to be used in this condition, your device may pose the following types of hazards:

    - Retinal photochemical aphakic light hazard (305 -700 nm)
    - Retinal visible and infrared radiation thermal hazard (400 -700 nm)
    - There's more evidence that blue light (400 – 500nm) can damage eyes, with people who have had cataracts removed being particularly vulnerable.

    We believe an evaluation of phototoxicity to the eyes for use of your device is necessary. For phototoxicity analysis including classification, labeling, and informational requirements for the device, we recommend reference to the following standards:

    - American Conference of Governmental Industrial Hygienists (ACGIH): Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices (2011)

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- ANSI/IESNA RP-27.2-2000 Recommended Practice for Photobiological Safety for Lamps & Lamp Systems - Measurement Techniques

- ANSI/IESNA RP-27.3-2007 Recommended Practice for Photobiological Safety for Lamps - Risk Group Classification & Labeling

Please provide a phototoxicity evaluation, including (but not limited to) the following information:

a. Irradiance measurement at a default distance of 20cm and at the worst case (shortest) of distance form nose.

b. Risk group assessment: This assessment results in either an Exempt Group or one of three Risk Group classification: Risk Group 1 ((Low-Risk)), Risk Group 2 (Moderate Risk)) and Risk Group 3 (High Risk).

c. Appropriate protection should be used when the risk group classification is not "Exempt". Please describe whether there is any mitigation that will be effective to prevent the potential harm to the eyes to insure user safety when operating the device under the condition of intended use.

   The following labeling issues are for your consideration:

   We recommend following ANSI/IESNA RP-27.3 -07 Section 6.2. to provide Caution labels to inform and instruct end user regarding pertinent safety related information that should be provided if the lamp is classified as Risk Groups 1, 2, or 3. For example:

   i. A statement of the potential hazard, if any. This should simply advise as to what might be expected to occur (i.e., skin irritation, or eye injury).

   ii A list of what precautions could or should be taken to avoid the risk (e.g., "Do not shine the device directly in eyes…", "Appropriate eye protection should be used when daily exposure at short distance (XX cm) is greater than XX minutes.")

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20. The ear skin is also vulnerable to damage by optical radiation. The type of effect, injury thresholds, and damage mechanisms vary significantly with wavelength. There are different types of damage to the skin may be caused by optical radiation, for example:

    - Thermal damage (burns) of the skin with visible and infrared radiation.

    - Photosensitized damage of the skin: It is generally far more typical of UVR wavelengths (less than 380 nm). However, such photosensitized reactions can extend to approximately 700 nm, possibly as a side-effect of certain medications.

    You do not include an evaluation of optical radiation hazard to the skin. We recommend you evaluate skin safety for use of your device by performing an optical radiation hazard evaluation to demonstrate your device meets the safety guideline specified in ACGIH [1] and ICNIRP [2] or an equivalent method. Please provide this information.

    [1] ACGIH American Conference of Governmental Industrial Hygienists Threshold Limit Values for chemical substances and physical agents and Biological Exposure Indices. 2011.

    [2]. International Commission on Non-Ionizing Radiation Protection (ICNIRP). Guidelines on limits of exposure to broad-band incoherent optical radiation (0.38-3um). Health Phys. 73: 37 539-554; 1997.

    You may choose alternate approaches as long as you can adequately address the above concern related to optical radiation safety.

The deficiencies identified above 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 (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification

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(510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

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 additional information 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. .

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact LT Andrew Yang at (301) 796 - 6860. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

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Attachment 2:

Device Description—Comparison of current product to Section 7 of Premarket Application

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Attachment 2:

Description

As compared to the device described in Section 7 of the Pre-Market Application, Lantos has updated the Single Use Disposable, and the fluid drive subsystem of the Scanner. The update was the result of a Design-for-Manufacturing improvement phase, to reduce the cost of the Disposable prior to full production. The update has no effect on the intended use and does not alter the technical performance or safety characteristics as compared to the predicate device or the Lantos device as submitted. The performance characteristics were confirmed by repeating design verification testing. The safety characteristics were confirmed by detailed review by the Lantos risk management team.

The update is described in the sections that follow, with detailed comparisons for those components or subassemblies that have changed.

Comparison of Current Lantos Scanner Design Embodiment to that Previously Submitted

1) The Disposable fluid reservoir in the previous design had been a rigid container containing the Absorbing Medium with an internal lead screw and plunger platform. The current design specifies a flexible bag reservoir, with the lead screw and lifter platform externalized as part of the Handheld Scanner pump chamber. The current Disposable is loaded into the pump chamber by the user, and a rigid door built into the Handheld Scanner is secured to close the pump chamber. Upon activation by the user, the lead screw lifts the lifter platform, compressing the flexible reservoir and filling the Disposable Membrane as required. The rate and control of infusion in the current embodiment is equivalent to the previous version.

2) The design of the remaining Handheld Scanner systems (Optics Drive, Illumination Source, and Camera) is the same as the previous version, with minor modifications for manufacturability.

3) The Disposable Valve Housing, Valves, Pressure Cup, Check Cap, and Conforming Membrane components, as well as the Absorbing Medium, are the same as the previous version, with minor modifications for manufacturability.

4) The materials used in the patient-contacting portion (Membrane and Pressure Cup and Valve Housing components) of the Single Use Disposable have not changed. The Membrane is made from implantable-grade silicone rubbers, with black and fluorescent dyes for the topology measurement. The Pressure Cup is made from Thermoplastic Elastomer. The Valve Housing is made from Polycarbonate. These materials have passed Biocompatibility Testing per ISO-10993 for Cytotoxicity, Irritation and Skin Sensitization, and Intracutaneous Reactivity which is consistent with required testing for short-term skin contact.

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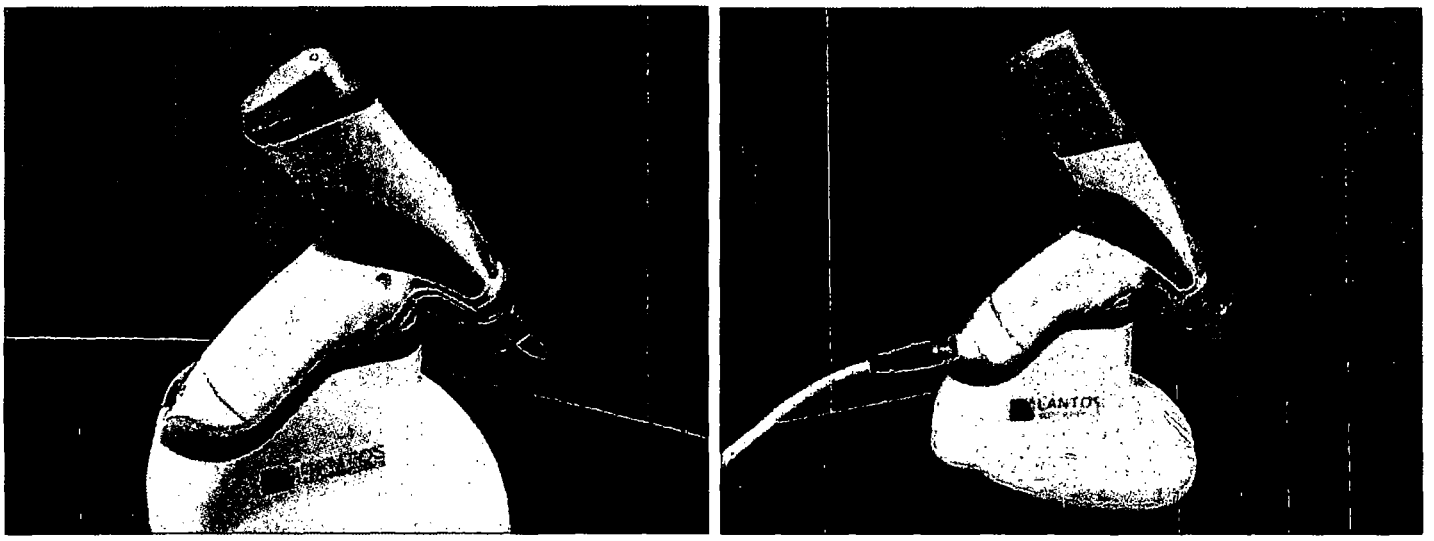

Figure 1. Handheld Scanner with Single Use Disposable

(Left - Previous Version, Right – Current Version).

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Attachment 2:

(b)(4) Reveiw

[redacted]

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Attachment 2:

(b)(4) Reveiw

[redacted]

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Attachment 2:

(b)(4) Reveiw

[redacted]

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Attachment 2:

The single patient use disposable is depicted in Figure 4 below, and includes the subassemblies and components shown in the assembly drawing, Figure 5 below, and the tables which follow.

(b)(4) Reveiw

[redacted]

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Attachment 2:

(b)(4) Reveiw

[redacted]

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Attachment 2:

Component Design Changes

(b)(4) Reveiw

[redacted]

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Lantos 3D Ear Scanner - Power Source and Power Distribution

AC / DC Conversion – a IEC-60601-1 medical grade power brick converts AC Wall Power to:

Nominal 20V DC (Range 19-21V) @ 6.75A

The Bulk of the 20V DC current supplies the charge circuit on the Lantos Dell Laptop.

*All dangerous AC voltages are confined within the power brick. By design, only **Safety Extra-Low Voltages** (SELV) are present elsewhere in the Docking Stand, the Laptop, and the Handheld Scanner.*

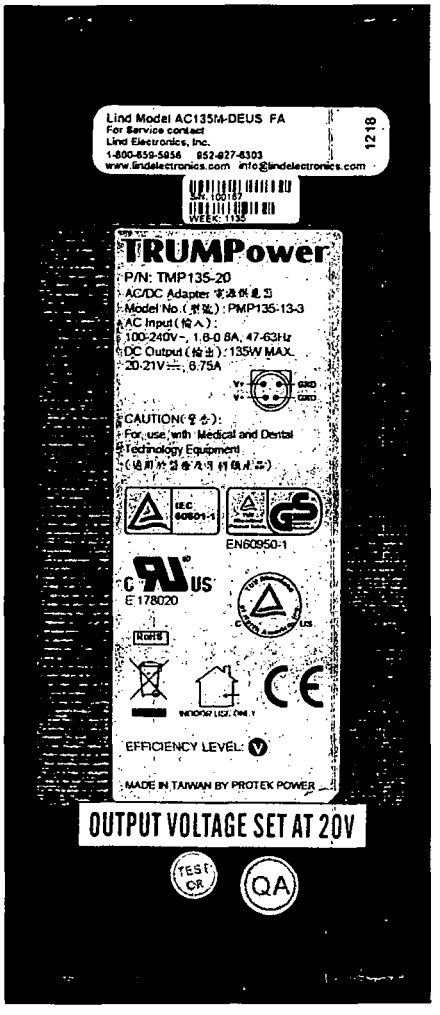

Figure 6. AC/DC converter.

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Attachment 2:

(b)(4) Reveiw

[redacted]

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Attachment 2:

(b)(4) Reveiw

[redacted]

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Attachment 2:

(b)(4) Reveiw

[redacted]

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Attachment 3:

Instructions for Use

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Attachment 3

Changes to Instructions for Use

The Instructions for use for the Lantos 3D Ear Scanner have been update from the time of submission of K12136 in April 2012. The original **Introduction** section has shortened and much of the information consolidated into the **Operation** section of the IFU. Updated details and figures have been included in the current version of the IFU and are summarized in the table below:

PAGE	CHANGE
1	Updated product image on cover
2	Added a copyright page
4	Added a table of contents
5	Consolidated Introduction into portions of the Operation section, added System Requirements, Intended Use and User Profile
7	Added cautions to reflect 1) need for good clinical judgment 2) distance from TM and 3) illumination and eye caution
11	Changed to an updated photo of the system
12	Updated photo of docking stand
13	Updated photo of scanner
14	Updated photo of consumable
16	Updated user interface image
18	Updated to new log in screen
19	Updated image of check cap of consumable
21	Added two photos depicting position of user in relation to patient and hand placement of the user during scanning
23	Used terms "data capture" and "scanning mode" in lieu of "ear topology mode"
24	Added updated image of application software as visualized during the scanning process
27	Added updated image of user interface
31	Updated specifications to reflect new consumable, scanner, and docking stand

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

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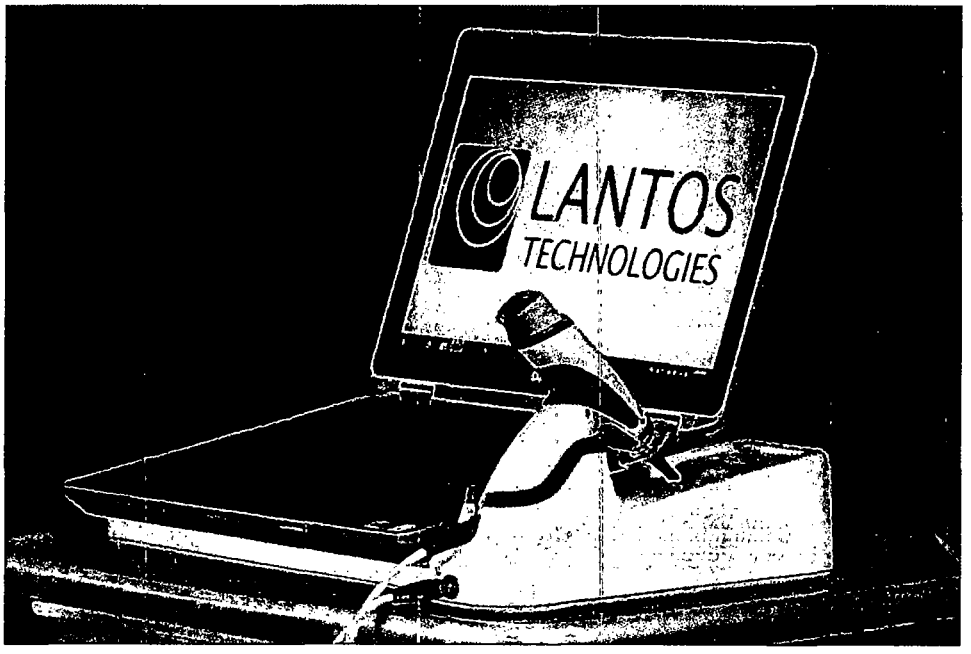
LANTOS TECHNOLOGIES

FDA Premarket Clearance Pending

Lantos 3D Ear Scanner

Instructions for Use



19 December 2012

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8218

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Please read these Instructions for Use thoroughly before using the **Lantos 3D Ear Scanner**. Take particular note of precautions and warnings.

FOLLOW INSTRUCTIONS FOR USE P/N 100-001 Rev. 0

If you have questions please contact your Lantos Technologies support representative.

<support@lantostechnologies.com>
Lantos Technologies
101 Main St Suite 1760
Cambridge, MA 02142
+1 (617) 500-9800

Every effort has been made to assure these instructions are complete and accurate. Lantos makes no warranty of applicability for use, or guarantee of accuracy. Contents of these instructions are subject to change without notice.

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

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1. Introduction

Overview

The Lantos 3D Ear Scanner is a digital solution for inspecting and imaging the ear canal. The all-in-one device is a video otoscope and 3D scanning system that provides an image of the topology measurements of the external ear canal.

System Requirements

The System requires standard power access for charging. A closed system, it requires that no other devices or software are connected or added to the system. Addition of software or non-supported Lantos devices to the system invalidates the service policy.

Intended Use

The Lantos 3D Ear Scanner is indicated for use by trained hearing professionals on individuals 18 years of age and older presenting for inspection of the external ear canal. The Lantos 3D Ear Scanner and its components should not be used for other purposes.

User Profile

The Lantos 3D Ear Scanner is indicated for use by the same population of hearing professionals who use video otoscopes. This population generally includes audiologists, physicians, and other licensed hearing healthcare professionals. These individuals by training, experience and licensure are knowledgeable in external ear canal anatomy as it relates to inspection of the canal with the intent of making an impression to be used for device earmolds, hearing aids, etc. They have experience with otoscopes whether video or stationary.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-6418

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Warnings: Electrical and Fire Hazards

WARNING: DO NOT CONNECT THE LANTOS 3D EAR SCANNER TO DEVICES OTHER THAN AS EXPRESSLY DESCRIBED IN THESE INSTRUCTIONS

WARNING: PLUG THE SCANNER INTO A PROPERLY GROUNDED POWER OUTLET TO MAINTAIN PATIENT AND USER SAFETY WHEN OPERATING FROM A/C POWER SOURCE

WARNING: DISCONNECT THE SCANNER FROM A/C POWER SOURCE IF IT GETS WET, IF CABLES ARE DAMAGED, OR IF COMPONENTS ARE DROPPED

WARNING: DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8418

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Cautions

⚠ CAUTION: THE MEMBRANE, RESERVOIR AND MEDIUM ARE FOR SINGLE PATIENT USE

⚠ CAUTION: DO NOT USE THE SCANNER FOR ANY PURPOSES OTHER THAN THOSE DESCRIBED IN THESE INSTRUCTIONS

⚠ CAUTION: DISCONTINUE USE OF THE DEVICE IF YOU NOTICE ANY SIGNS OF DAMAGE TO THE COMPONENTS – CONTACT LANTOS FOR SERVICE – NO USER SERVICEABLE COMPONENTS

⚠ CAUTION: THE HANDHELD SCANNER IS A HIGHLY PRECISE OPTICAL INSTRUMENT – IMPROPER HANDLING, SUCH AS DROPPING OR BUMPING THE TIP, MAY CAUSE THE SCANNER TO BREAK OR MALFUNCTION

⚠ CAUTION: USE GOOD CLINICAL JUDGEMENT; INSPECT THE EAR CANAL PRIOR TO MEMBRANCE INFLACTION. DO NOT USE ON PATIENTS WITH EXCESS CERUMEN IN THE EAR CANAL, PATIENTS WITH AN INFECTION IN THE EXTERNAL OR MIDDLE EAR, PATIENTS WITH DRAINAGE OR BLOOD IN THE EAR OR PATIENTS WITH A FOREIGN BODY IN THE EAR CANAL

⚠ CAUTION: USE GOOD CLINICAL JUDGEMENT WHEN APPROACHING THE TYPMAPNIC MEMBRANE (TM) AND DO NOT TOUCH THE TM

⚠ CAUTION: DO NOT STARE AT SCANNER TIP, OR DIRECT SCANNER TIP TOWARD PATIENT'S FACE, WHILE ILLUMINATION IS ACTIVE. MAY BE HARMFUL TO THE EYES

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

TYPE BF PATIENT APPLIED PART

Foreign body and moisture intrusion rating per IEC/EN60529.

Handheld Scanner

IP22 Protection against solid bodies: objects greater than 12mm.
Protection against liquids: 75° – 90° dripping water, with Scanner upright

Laptop and Docking Stand

IPXØ Protection against solid bodies: not rated.
Protection against liquids: not protected.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8418

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

EMI, FCC and Safety Standards

This device has been tested and conforms to EMI, FCC and safety standards.

IEC 60601-1

Troisième édition
Third edition
2005-12

Medical electrical equipment –

Part 1:
General requirements for basic safety and essential performance

U.S. Federal Communications Commission (FCC) Requirements

This device was tested and complies with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. This equipment generates, uses, and can radiate radiofrequency energy, and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

There is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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

To comply with the limits for an FCC Class A computing device, always use the power and signal cables supplied with this unit. The FCC warns that changes or modification of the unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8418

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

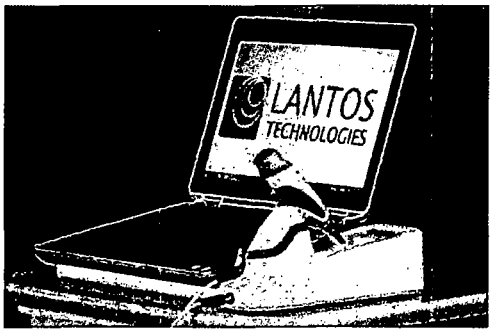
2. Operation

Operation Overview

The Scanner displays a magnified visual image of the external ear canal and tympanic membrane to the user on a laptop computer screen. The Scanner incorporates a visible light spectrum source to illuminate the ear canal and has a long thin tip to extend the viewing lens and illumination into the ear canal. The user may view different portions of external ear canal and tympanic membrane by changing the position and orientation of the Scanner, as with a traditional video otoscope. The user places a Single Patient Use Disposable which includes the Conforming Membrane over the Scanner tip. The conforming membrane has a clear flexible window at the distal end. The user then inserts the Scanner tip into the patient's ear canal and inflates the membrane with the Absorbing Medium in the Single Patient Use Disposable. Once the membrane is properly inflated, the user begins to scan the topology of the canal. When the scan is complete, the user reviews the scans and may upload them to Lantos.

System Components

- Lantos Laptop – with Docking Stand
- Handheld Scanner
- Single Patient Use Disposable
  - Conforming Membrane
  - Reservoir and Absorbing Medium
- Device Application Software



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8418

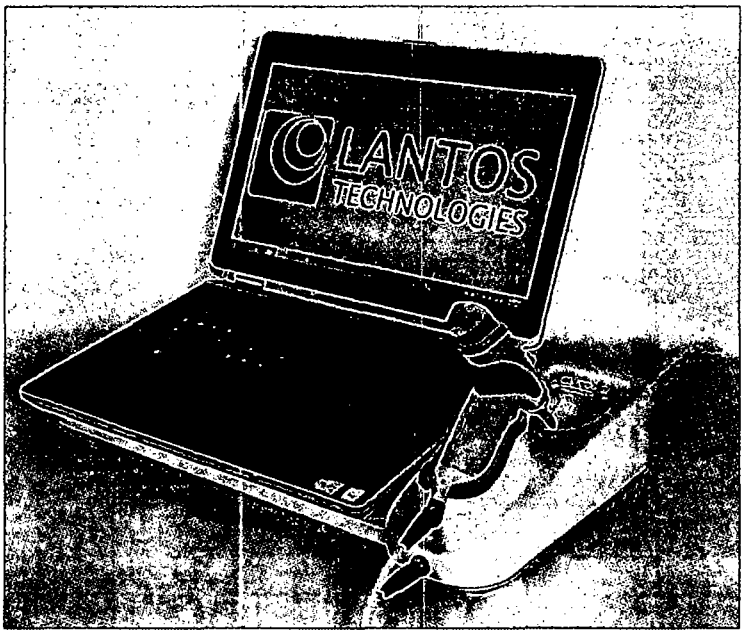
Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Lantos Laptop and Docking Stand

Description and Use:

The laptop is fitted to a Docking Stand including a holster for the Scanner. A custom cable connects the Scanner with the Stand; other cables connect the Stand with the laptop and with a power supply. A battery subsystem supplies power to the laptop, and a power brick supplies power to charge the laptop battery, and to power and charge the Scanner.

The user interacts with the Scanner using the Scanner buttons, laptop keyboard and touchpad; the laptop LCD panel presents a series of user interface screens, including ear canal images.



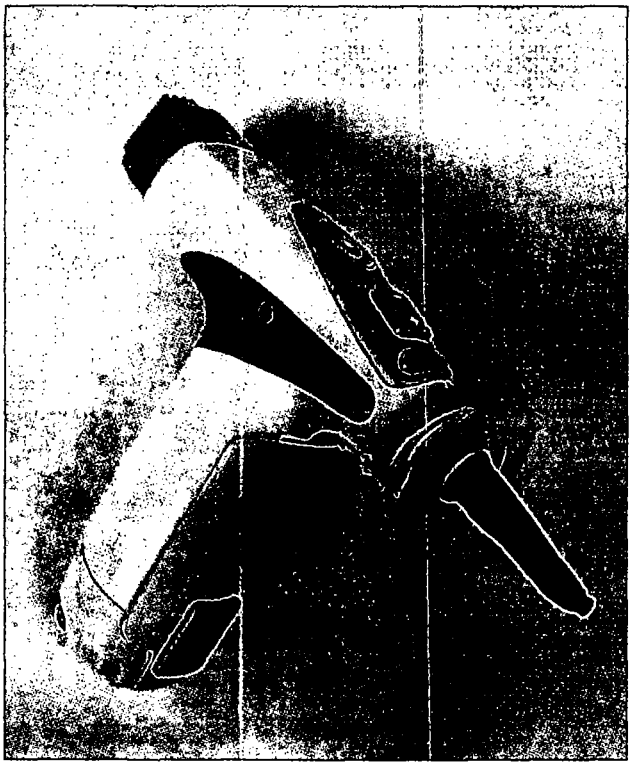
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-6418

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Handheld Scanner

Description and Use:

The Handheld scanner has a set of buttons positioned for ease of use. The user places the membrane of the Single Patient Use Disposable (following section) over the extended tip of the Handheld Scanner, and slides the reservoir bag into the handle. The user guides the covered Scanner tip into the ear canal in video otoscope view; the canal is visible through a clear flexible window in the tip of the conforming membrane.



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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Single Patient Use Disposable - Conforming Membrane and Reservoir

Description and Use:

The Conforming Membrane covers the Scanner tip, and expands to conform to the inner surface of the ear canal and outer ear. The tip of the Membrane has a flexible window of the same approximate size at the Scanner tip, providing a video otoscope view of the ear canal and tympanic membrane.

The extended Scanner tip pushes into the Membrane, which is connected to a Reservoir stored in the scanner handle. The valves seal the liquid inside and maintain the liquid pressure during expansion. The inside surface of the membrane contains a dye that returns an image when illuminated with visible blue light.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Single Patient Use Disposable - Reservoir and Absorbing Medium

Description and Use:

The Absorbing Medium contains a dilute amount of an ingestible coloring dye in distilled water with a small amount of preservative. The Absorbing Medium is held in the Reservoir and in the Membrane. When the user signals to expand the Membrane, the elevator in the handle of the Scanner is driven by a motor and pushes Medium through the connecting tube to the Membrane. When the user signals withdrawal, the Medium returns to the Reservoir, allowing extraction of the collapsed membrane from the ear.

⚠ CAUTION: THE MEMBRANE, RESERVOIR AND MEDIUM ARE FOR SINGLE PATIENT USE

Questions? Contact FDA/CDRH/OCE/DIDP at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8418

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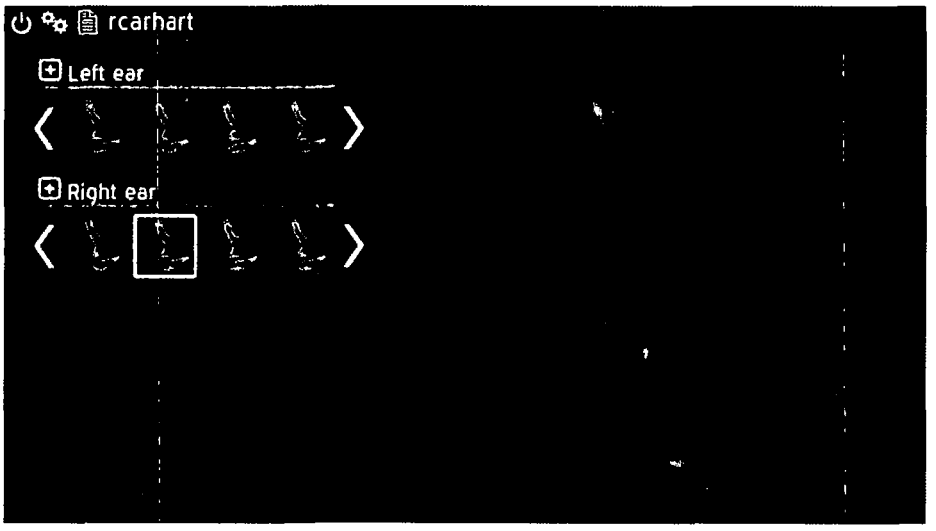
Device Application Software

The Application software provides live visual feedback to the user for inspection of the external ear canal and to determine the extent of the external ear topology measurement. The Application software leads the user through a series of interactions to prepare for the ear exam and guides the user through the exam and the dimensional measurement. The Application software saves the inspection images and the topology measurement images for later review and submission.



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

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System Setup

- *Your system has already been configured with a unique account ID which was provided to you at installation.*

- Charge the laptop and Docking Stand before use or ensure that AC power is available.
  - If using AC power, plug in the device and check all power connections.

- Check that the Scanner is connected to the stand and the stand to the laptop.

- Turn on the laptop, which will initiate the **Lantos 3D Ear Scanner** Application software

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8146

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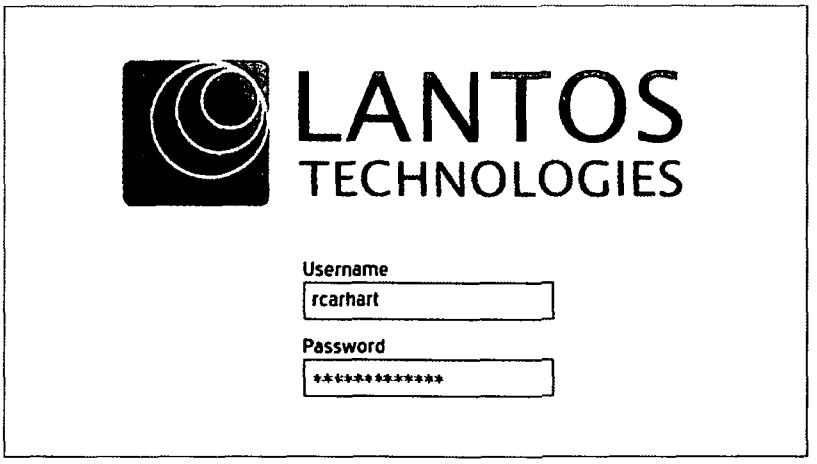
- Log in with your unique user name and password.



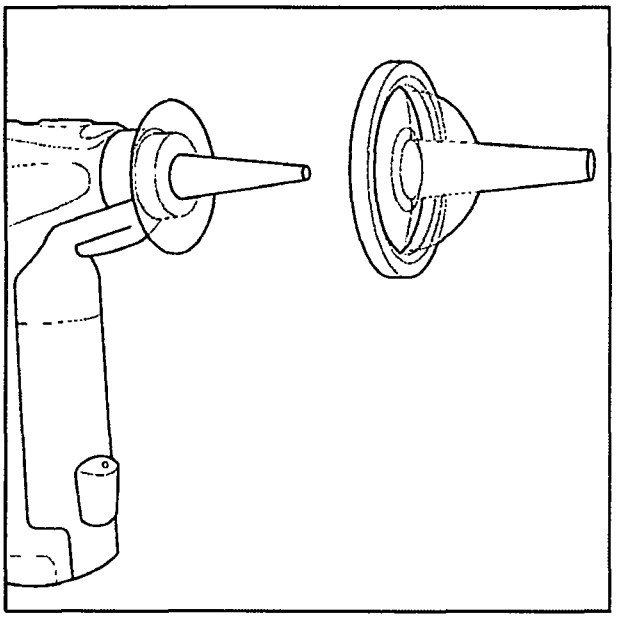
- From user interface, select new scan (left or right ear).
- Remove disposable from foil packaging.
- Enter the membrane ID from the Single Patient Use Disposable package.
- Open the door of the Scanner handle.
- Place the Membrane over the extended tip of the Scanner. Insert the Reservoir into the handle on the Scanner until it is secure.
- Close the door of the Scanner handle.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

- Once inserted, follow the instructions on the screen to activate the device check. The device will perform a series of actions to assure the Scanner and Single Patient Use Disposable is ready for use. You may notice fluid movement and/or illumination.

- When the check is complete, remove and discard the Check Cap.



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

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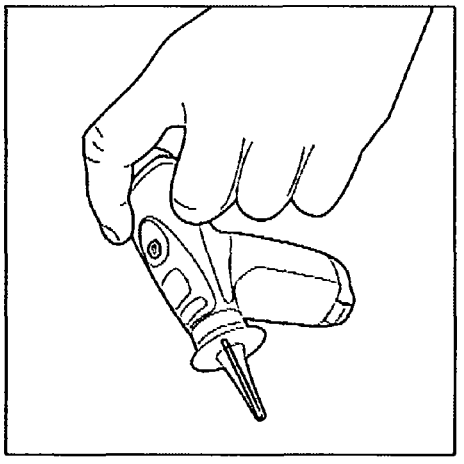
Scanner Preparation

- With Scanner clear of patient, point the Scanner tip down and push the Advance '**O**'button until tip is at full extension



- Align clear window at tip of Conforming Membrane with tip. Confirm visually by pointing tip toward a known target.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8418

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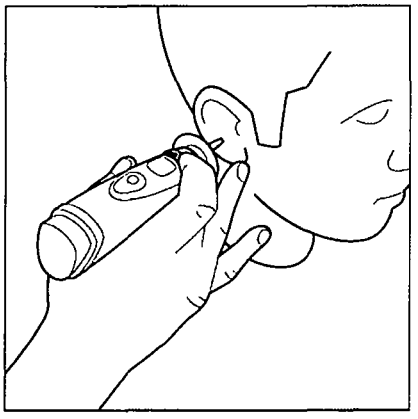
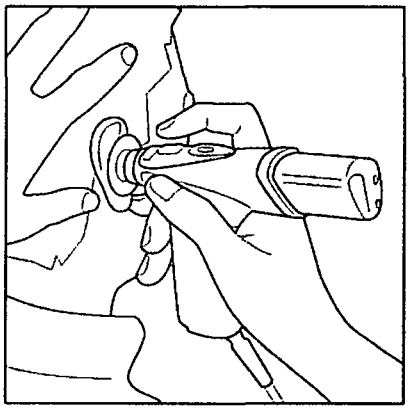
Obtaining a Lantos Scan

Scanner Insertion in video otoscope mode

- Secure patient and the Handheld Scanner
- If necessary to reduce tip window fogging, before entering the ear canal, stir membrane in warm water for five seconds.

  ⚠ CAUTION: DO NOT STARE AT SCANNER TIP, OR DIRECT SCANNER TIP TOWARD PATIENT'S FACE, WHILE ILLUMINATION IS ACTIVE. MAY BE HARMFUL TO THE EYES
- Insert Scanner tip into patient's ear – using fingers to secure against patient's head.
- Precautions for the presence of cerumen in the ear canal are no different with the Scanner than with conventional silicone earmold impressions. Modest or thin deposits of cerumen will create commensurately small differences in the topology measurement, and the conforming membrane will compress deposits of soft cerumen similar to the conventional silicone impression. There is no limitation to the use of the scanner in otoscope mode in the presence of cerumen.
- During insertion the laptop will display real-time video as the Scanner tip reaches the desired depth.





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-9118

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- Navigate in external ear canal to view features – the following image shows a representative tympanic membrane at a distance of approximately 5 mm, as seen through the Scanner. When the field of view shows the complete margins of the TM periphery, this is the proper placement; do not insert further.

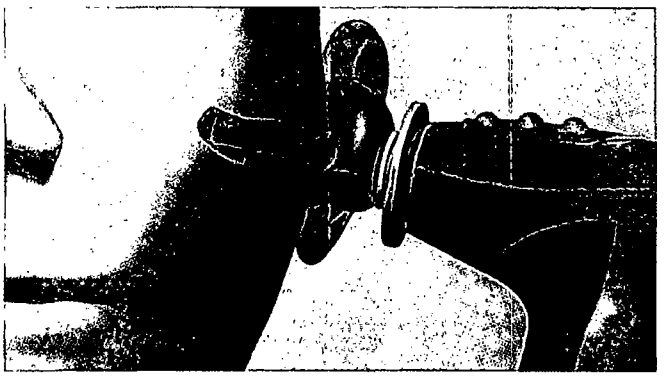
⚠ CAUTION: USE GOOD CLINICAL JUDGEMENT WHEN APPROACTING THE TYPMAPNIC MEMBRANE (TM) AND DO NOT TOUCH THE TM.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

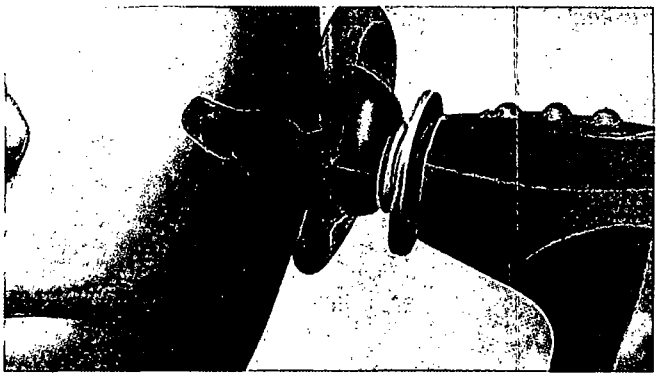
Data Capture – scanning mode

- Press the '**O**' button on the Scanner to expand the Conforming Membrane until it fills the canal and concha.



- Upon proper expansion, the view will change to that of the inside of the Membrane, conforming to the external ear canal wall. To adjust the Absorbing Medium in the Conforming Membrane, use the '**+/-**' buttons.

- Use the Scanner button '**O**'to retract the scanner tip along the external ear canal – stop and restart at any time by releasing and pressing the button.

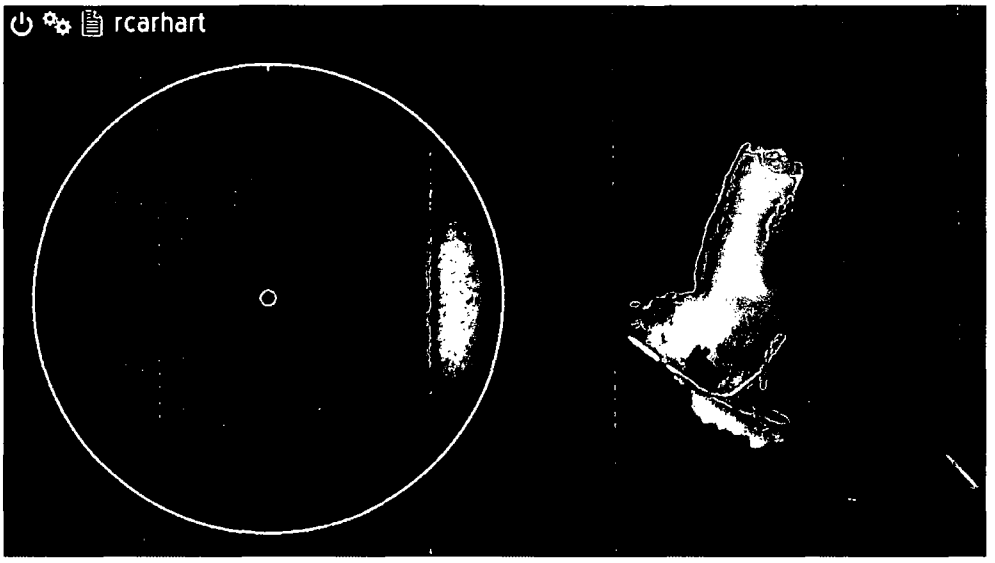


Questions? Contact FDA/CDRH/OCE/DDI at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8418

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

- While the conforming membrane is inflated, a series of images of the patients ear canal are being captured

- The Application software shows the Scan screen, which presents the live view through the scope tip and the accumulated 3D representation of the ear canal.



- When the Scanner tip is fully retracted, manipulate the Scanner to collect 3D data from sections of the concha bowl.

System Checks

- The software monitors the system for any issues that could impair the scanning process and notifies the user.

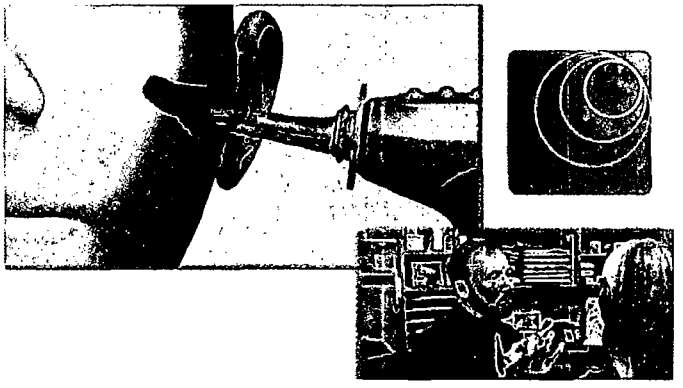
Questions? Contact FDA/CDRH/OCE/DD at CDRHFOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Removal

- When finished scanning, press the end scan'■' button to retract the Scanner tip fully (if necessary) and to withdraw the Absorbing Medium from the Conforming Membrane, the Membrane will collapse.

- Remove the Membrane and the Scanner tip from the ear.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8418

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- **If desired, repeat the Preparation, Scanning, and Removal process on the same ear or for the patient's other ear.**

- When finished with the patient, discard the Single Patient Use Disposable, including the Membrane, Reservoir and Medium. No special handling procedures are necessary; dispose of as you would specula. The Single Patient Use Disposable may only be used for one patient and one session.

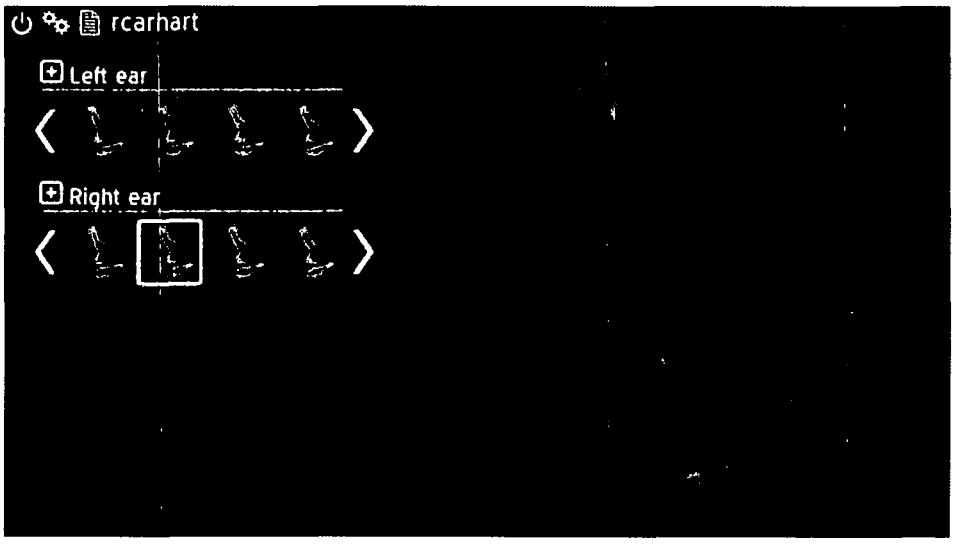
⚠ CAUTION: THE MEMBRANE, RESERVOIR AND MEDIUM ARE FOR SINGLE PATIENT USE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8518

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Reviewing and uploading scans

- Review right and left patient scans by clicking on the appropriate icon in the user interface.



- Select ONE right and ONE left ear scan for upload to Lantos.
- The session is now complete.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8618

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

3. MAINTENANCE

Care, Maintenance, and Handling of the Device

Follow these guidelines when using the device:

- The device is intended for use by qualified operators who have been trained in proper use
- Store and use the device within prescribed temperature, humidity, and altitude limits (refer to Environment: Operating Conditions)
- Do not alter any existing connections in the device, excepting the tether cable between the Handheld Scanner and the Docking Stand which can be separated at either or both ends for transport and storage
- Exercise care when using the Handheld Scanner. Return it to the holster on the Docking Stand when not in use
- Do not submerge the Scanner in water

⚠ CAUTION: DISCONTINUE USE OF THE DEVICE IF YOU NOTICE ANY SIGNS OF DAMAGE TO THE COMPONENTS. CONTACT LANTOS FOR SERVICE. NO USER SERVICEABLE COMPONENTS

⚠ CAUTION: THE HANDHELD SCANNER IS A HIGHLY PRECISE OPTICAL INSTRUMENT – IMPROPER HANDLING, SUCH AS DROPPING OR BUMPING THE TIP, MAY CAUSE THE SCANNER TO BREAK OR MALFUNCTION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-9118

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Cleaning Procedures

After each patient, cleaning the body of the Handheld Scanner and the tether cord with water and/or a non-staining disinfectant is recommended.
You do not need to shut down the Scanner while cleaning its surfaces. The following agents can be used for cleaning:

- BIREX®se (by Biotrol) or equivalent
- Warm water and a mild, non-abrasive detergent: Fantastic®, Lysol
- Do not use ammonia-based cleaners

Follow these steps:

- Apply the cleaning agent to a soft, non-abrasive cloth until damp
- Wipe down the surfaces with the damp cloth
- Rinse the cloth in clean water – wipe down the surfaces a second time
- Dry the surfaces with a clean, soft, non-abrasive cloth
- Do not spray or pour liquids on the surfaces – avoid liquid pooling or dripping – never submerge the Handheld Scanner – neither the Scanner nor the Laptop is watertight

Store device components in a dry, temperature controlled environment. Avoid extremes in temperature or humidity.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8418

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Replacement

Contact Lantos Technologies support for replacement parts or additional disposable parts.

<support@lantostechnologies.com>

Lantos Technologies
101 Main Street Suite 1760
Cambridge, MA 02142
+1 (617) 500-9800

Warranty

Lantos warrants this product will be free from defects in material and manufacture. Lantos MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and Lantos' sole obligation shall be repair or replacement of the product.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-9618

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4. System Specifications

Handheld Scanner

Dimensions	~160mm L x 130mm H x 40mm W
Weight	~272g without tether cable
Field of View	>120° Cone in Air – Video Otoscope View
	>90° Cone in Water – Topology Measurement
Direction of View	0° aligned with probe axis
Working Depth	4mm to >15mm from tip
Illumination	Red / Green / Blue Visible Light
Video Capture Rate	≥15 frames/sec
Tether Cable	~2m

Lantos Laptop & Docking Stand

Dimensions	~430mm L x 70mm H x 245mm W
Weight	~7.9kg including battery
Display	~396mm diagonal
Power Supply for Laptop, Scanner and Charger	135W AC Adapter 100-240V 47-63Hz

Single Patient Use Disposable

Dimensions	~87mm L x 61mm H x 30mm W including Check Cap
Weight	~29g with Absorbing Medium

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Environment

Operating Conditions
- 10° C to 40° C
- 30% to 85% R.H. noncondensing
- 700 to 1060 hPa Altitude

Shipping and Storage Conditions
- -15° C to 49° C
- 95% R.H. noncondensing max

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8518

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Attachment 4:
Assessment of Photobiological Safety

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-5518

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Attachment 4:
Assessment of Photobiological Safety

Lantos 3D Ear Scanner – Response to AI Request – 510(k) K121326

1. PURPOSE

The Lantos 3D Ear Scanner was tested for Phototoxicity to assure operator and patient safety under intended use conditions, and reasonably foreseeable misuse, using the ANSI, ICNIRP, and ACGIH standards for exposure to UV, visible, and infrared light. This attachment provides a summary of the full report.

2. REFERENCES

ANSI/IESNA RP-27.1-05 Recommended Practice for Photobiological Safety for Lamps and Lamp Systems—General Requirements

ANSI/IESNA RP-27.2-00 Recommended Practice for Photobiological Safety for Lamps & Lamp Systems—Measurement Techniques

ANSI/IESNA RP-27.3-07 Recommended Practice for Photobiological Safety for Lamps—Risk Group Classification and Labeling

International Commission on Non-Ionizing Radiation Protection – Guidelines on Limits of Exposure to Broadband Incoherent Optical Radiation (0.38 to 3 μ M)

ACGIH American Conference of Governmental Industrial Hygienists Threshold Limit Values for chemical substances and physical agents and Biological Exposure Indices. 2011.

3. SUMMARY RESULTS AND CLASSIFICATION

The illumination subsystem of the Lantos 3D Ear Scanner is classified as "**Exempt**" per:
Section 4.3 Lamp Classifications of ANSI/IESNA RP-27.3-07

The Exempt classification is demonstrated in the sections that follow. For both intended use and reasonably foreseeable misuse, the Scanner falls within ACGIH Threshold Limit Values for:

- Retinal thermal exposure within 10s
- Blue Light exposure within 10000s
- Actinic Ultraviolet radiation within 8 hours of operation
- Near UV exposure
- IR cornea/lens

In addition, the Scanner was tested for skin exposure, thermal damage and photosensitized damage, and was deemed safe when used as intended, and for reasonably foreseeable misuse.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8418

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

Although not required due to the Exempt classification, Lantos added the following caution to the Instructions-for-Use:

> *Caution - Do not stare at probe tip, or direct probe tip toward patient's face, while illumination is active. May be harmful to the eyes.*

4. EMISSION BANDS AND EXPOSURE LIMITS - DETAILS

The Lantos 3D Ear Scanner has an LED based illumination subsystem, which emits in three narrow bands in the visible spectrum. Assessments in the sections that follow were based on the maximum output power in the worst-case usage scenarios as determined by the risk analysis.

4.1. ILLUMINATION SUBSYSTEM

(b)(4) Reveiw

[redacted]

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

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(b)(4) Reveiw

[redacted]

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4.2. MAXIMUM HAZARD SCENARIOS

During risk analysis for the Scanner, two rare but credible cases of reasonably foreseeable misuse were identified, during which the operator or patient might be exposed for brief periods to the full output power of the illumination subsystem. In both cases, the uncovered probe tip might be directed toward the face and eyes. The exposure remains below Threshold Limit Values for long periods of exposure, while clearly the operator or patient would be likely to avert their eyes or redirect the probe tip to correct the misuse quickly.

Foreseeable misuse – illumination turned on or left on when examining patient

Foreseeable misuse – illumination triggered when installing disposable

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

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4.3. INTENDED USE SCENARIOS

Alternatively, when used as intended, the Scanner exposes the operator and patient to far lower visible radiant energy than in the misuse scenarios described in Section 4.2. The operator sees some diffused, reflected white light from the external ear canal, similar to numerous predicate devices. During the topology measurement, the probe tip is covered by the conforming membrane, which blocks a high percentage of the emitted light. To further reduce possible hazard, the following mitigation was identified during the risk analysis, and implemented in the device software.

> The Lantos Scanner uses the visible Blue-Violet LED light source to illuminate the inside surface of the Conforming Membrane to capture the topology measurement of the external ear canal. When the measurement is requested by the operator, the Scanner continually detects whether the Membrane surface is present and within scanning range, and reduces power and slows the flash rate of the light source when either condition is not met. This helps protect the operator and patient from operator error.

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4.4. RETINAL THERMAL HAZARD

The three LED sources were examined per section 4.3.1 of ANSI/IESNA RP-27.1-05 for the Maximum Hazard scenarios of Section 4.2.

4.3.1 Retinal Thermal Hazard Exposure Limit

To protect against retinal thermal injury, the integrated spectral radiance of the light source, L_R, weighted by the burn hazard weighting function, $R(\lambda)$, (from Table 3), should not exceed the levels defined by:

$$L_R = \sum_{400}^{1400} L_\lambda \cdot R(\lambda) \cdot \Delta\lambda \leq \frac{5}{\alpha t^{0.25}} \qquad (4)$$

As shown in the following table – the burn hazard weighted radiance of the illumination source, for each of the LEDs, remained well below the 10-second exposure limits where thermal injury is dominant.

Burn Hazard Weighted Radiance W / (cm^2 – sr)	10s Limit at 30cm Probe Tip to Face	10s Limit at 10cm Probe Tip to Face
L_R r = 0.0150799	281	94
L_R g = 0.0103328	281	94
L_R b = 0.0159497	281	94

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4.5. RETINAL BLUE-LIGHT HAZARD

The Blue-Violet LED source was examined per section 4.3.2 and 4.3.3 of ANSI/IESNA RP-27.1-05 for the Maximum Hazard scenarios of Section 4.2.

4.3.2 Retinal Blue Light Hazard Exposure Limit

To protect against retinal photochemical injury from chronic blue-light exposure, the integrated spectral radiance of the light source weighted against the blue-light hazard function B(λ) (from **Table 3**) should not exceed the levels defined by:

$$(L_B \cdot t) = \sum_{300}^{700} L_\lambda \cdot B(\lambda) \cdot t \cdot \Delta\lambda \leq 100 \text{ (for } t \leq 10^4) \quad (5a)$$

$$L_B = \sum_{300}^{700} L_\lambda \cdot B(\lambda) \cdot \Delta\lambda \leq 0.01 \text{ (for } t > 10^4) \quad (5b)$$

When the probe tip is less than 30cm from the eye, it should be evaluated per ANSI Section 4.3.2. The integrated spectral radiance of the source weighted with the blue-light hazard function, at the maximum output of the LED source is:

L_B = 0.00395 W / (cm^2– sr)

The radiance is less than the 0.01 limit of Equation (5b); therefore the safe exposure time is greater than 10000 seconds.

4.3.3 Retinal Blue Light Hazard Exposure Limit - Small Source

For a light source subtending an angle less than 0.011 radian (11 milliradian), the limits of **Section 4.3.2** are relaxed such that the spectral irradiance at the eye E_λ weighted against the blue-light hazard function B(λ) should not exceed the levels defined by:

$$(E_B \cdot t) = \sum_{300}^{700} E_\lambda \cdot t\, B(\lambda) \cdot \Delta\lambda \leq 0.01 \text{ (for } t \leq 10^4)^* \quad (7a)$$

$$E_B = \sum_{300}^{700} E_\lambda \cdot B(\lambda) \cdot \Delta\lambda \leq 10^{-6} \text{ (for } t > 10^4)^* \quad (7b)$$

$$t(\max) \leq \frac{0.01}{E_B} \text{ (for } t \leq 10^4) \quad (8)$$

When the probe tip is 30cm or more from the eye, it subtends an angle less than 11 milliradian, and should be evaluated per ANSI Section 4.3.3. The integrated spectral radiance of the source weighted with the blue-light hazard function, at the maximum output of the LED source is:

E_B = 0.00004345 W / (cm^2– sr)

The radiance exceeds the 1 uW limit of Equation (7b), and was evaluated per Equation (8). Maximum permissible exposure duration is 230 seconds. The Lantos risk management team did not consider as reasonably foreseeable or even credible misuse the case where the probe was pointed directly and steadily at the eye from more than 30 cm distance for this length of time, as it would require both intent to harm and precision, and a failure of the membrane detect failsafe described in Section 4.3. Therefore the Blue Light Hazard exposure limit was set per ANSI Section 4.3.2.

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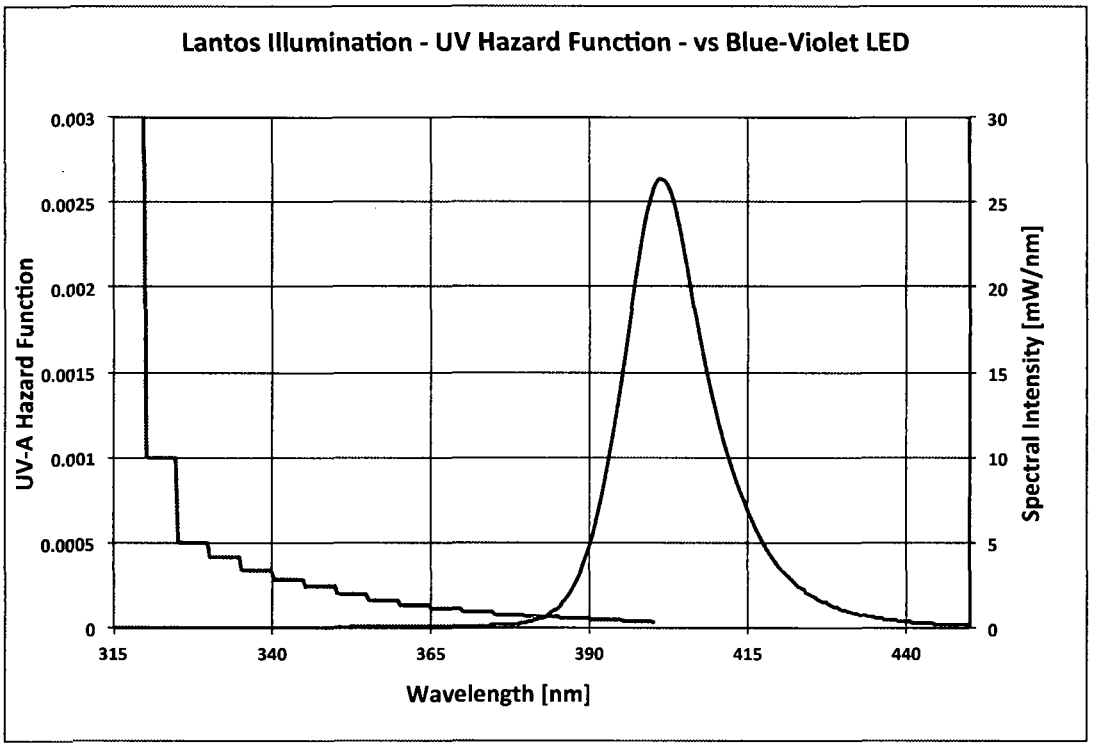
4.6. UV LIGHT HAZARD

The Blue-Violet LED emits limited energy in the UV band, as shown in the figure below, which shows the LED emission spectrum and the UV-A Hazard Weighting function from ANSI/IESNA RP-27.1-05. Of the maximum output power of 120mW from the Blue-Violet LED, only 1.8uW remains when weighted for UV-A Hazard. Operator or patient exposure is negligible.



According to ACGIH guidelines, Section 2, Broadband UV-A Sources, for the extreme case of shining the probe tip directly in the patient's eye at 1 cm from the cornea, the UV exposure limit of 1000 mJ/cm^2 allows an exposure time of 24.4 seconds. The Lantos risk management team did not consider this extreme case a credible misuse scenario. For all credible misuse scenarios, where the probe is more than 10 cm from the eye, hours of exposure would be safe.

4.7. IR LIGHT HAZARD

The Scanner illumination system emits no energy in the IR band, as can be seen from inspection of the spectra in Section 4.1.

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

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4.8. THERMAL DAMAGE OF THE SKIN

Using the ICNIRP Guidelines, the Lantos Scanner was tested according the Equation 14 in the section "Visible and infrared thermal injury to the skin."

> To protect the skin from thermal injury, the radiant exposure for durations less than 10 s should be limited to:
>
> H = 20,000 t^(1/4) J m^-2 (14)

When the Scanner is operating in video otoscope mode, if the uncovered probe tip were to be pressed against the skin, so the entire illumination energy were concentrated in a spot of ~3 mm diameter for the entire 10 seconds, the spot of skin would receive:

11,841 J / (m^2) which is less than the 20,000 J / (m^2) limit.

The Lantos risk management team concluded that pressing the probe tip against the skin of the external ear canal for short periods was a credible misuse example. When the Scanner is used as intended, there is no risk of thermal damage to the skin.

Much longer exposure durations are dominated by concerns of heat stress, which are covered in the ACGIH guidelines, in the section on heat stress, which says:

> The goal of this TLV is to maintain body core temperature within +1C of normal (37C).

The maximum luminous power output of the Lantos Scanner is under 200 mW (Section 4.1). A scan would rarely exceed 10 minutes. Human tissue has a specific heat capacity of roughly 3.5 J/(g*K). Therefore:

(((0.2 W) * 10 minutes) / ((3.5 J) / (g * K))) / (1 K) = 34 grams

If the entire light output of the Scanner were absorbed as heat, it could raise only 34 grams of tissue by 1°C. Effect on core body temperature and heat stress would be negligible.

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4.9. PHOTOSENSITIZED DAMAGE OF THE SKIN

The Lantos Scanner was evaluated or tested according to the ACGIH Guideline sections covering Light and Near-Infrared Radiation and Ultraviolet Radiation.

For radiation in the visible 'Light' band, the ACGIH flowchart leads to evaluation of the Retinal Thermal TLV (Section 4.4 above) and the Retinal Blue Light (Photochemical) TLV (Section 4.5 above).

The Lantos Scanner emits no energy in the 'Near-Infrared' band.

As shown in Section 4.6 above, of the maximum output power of 120mW from the Blue-Violet LED, only 1.8uW remains when weighted for UV-A Hazard. The spectral tail of the LED in the 390 to 400 nm band might be loosely construed as a 'Narrowband' source per the Guideline. Under that interpretation, with the unlikely but credible misuse condition where the uncovered probe tip was directed at a 1 cm^2 patch of skin, the Guidelines allow more than 45 minutes per day of exposure. If the probe is instead considered a 'Broadband' source per the Guideline, with the same misuse condition, the maximum exposure per day is 66 minutes per Equation 1. The combinations of misuse and exposure time were not considered credible misuse scenarios by the Lantos risk management team.

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

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

September 17, 2012

LANTOS TECHNOLOGIES
C/O GENERIC DEVICES CONSULTING, INC.
20310 SW 48TH ST
SOUTHWEST RANCHES, FLORIDA 33332
ATTN: JOHN GREENBAUM

510k Number: K121326

Product: LANTOS 3D EAR SCANNER

Extended Until: 12/19/2012

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). 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.

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
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

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Mcdonald, Lisa *

From: Microsoft Outlook
To: GENERICD@BELLSOUTH.NET
Sent: Monday, September 17, 2012 7:47 AM
Subject: Relayed: K121326 Ext Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

GENERICD@BELLSOUTH.NET (GENERICD@BELLSOUTH.NET)

Subject: K121326 Ext Letter

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

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John Greenbaum
Generic Devices Consulting, Inc.

20310 SW 48th Street
Ft. Lauderdale, FL. 3332

Fax (954) 653-1153
Home Office (954) 680-2548
Mobile (954) 610-0178
Email: genericd@bellsouth.net

September 11, 2012

US Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH
SEP 14 2012
Received

SUBJECT: 510K; K121326 Lantos 3D Ear Scanner

RE: Request for additional time to respond.

Dear FDA:

This letter is in response to the FDA request for additional information regarding the subject 510K.

The additional information requested required additional testing, completion of ongoing clinical studies, etc.. It is taking longer than expected to prepare our response.

The original AI letter was undated (see attached) and sent via email. The AI letter hold letter which followed (copy attached) indicated a hold date of June 22, 2012. We requested an additional 60 days for the response, which was granted. We are now modifying our extension request for the entire 180 days allowed. This would place the due date of our response on or before December 19, 2012.

Please respond to the undersigned with respect to this request.

Sincerely,

John Greenbaum
Generic Devices Consulting, Inc.

Cc: Doug Johnston

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Lantos Technologies
% Mr. John Greenbaum
Generic Devices Consulting, Inc.
20310 SW 48th St
Southwest Ranches, FL 33332

Re: K121326
Trade Name: Lantos 3D Ear Scanner
Dated: April 30, 2012
Received: May 2, 2012

Dear Mr. Greenbaum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following:

Indications for Use

1. In the Indications for Use (page 24 of 535), you state that your device is indicated for use "by a trained hearing professional in clinical settings on adult patients..." Please clarify the following issues and also update the Instructions for Use (User's Manual) accordingly:

   a. Please be more specific about which trained hearing professionals you are referring to, as well as what type of training, if any, recommended for using this device.

   b. Please define "adult patients" by providing the age criteria (e.g., adult patients 22 years and older).

Device Description

2. For otoscopy and the topography measurements, correct use of the device is essential for generating a safe and accurate image of the ear canal. It is important to minimize the risk of user error that could result in an inaccurate ear canal measurement or damage to a patient's ear. Please address the following issues in your device description and update your Instructions for Use as appropriate:

   a. Please provide a recommended maximum insertion depth of the probe into the ear canal (e.g., 3mm from the TM).

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b. Please indicate if the conforming membrane expands medially from the probe tip. If so, please explain how the user should avoid the possibility of the membrane contacting the tympanic membrane.

c. Since your disposable component comes with a reservoir of 15cc of fluid, this suggests that the user will need to judge how much fluid is necessary to generate the appropriate topography measure. Please indicate how the user should avoid using too much or too little of the fluid to fill the conforming membrane and generate an accurate measure.

d. Please clarify if it is possible to displace the cartilaginous portion of the ear canal with pressure from the conforming membrane and fluid and to what extent. Also, please indicate why you do not expect this to have an impact on the accuracy of the topography measure.

e. Please indicate the length of your probe tip and how this compares to a standard speculum on a traditional otoscope. Also, please indicate if you have included any mechanisms for minimizing the risk of the probe tip making contact with the tympanic membrane during use.

3. In section 7.10 (Use Overview, page 37 of 535), you state "The disposable will contact and reshape the ear canal with mild pressure..." Please indicate if this amount of mild pressure has been judged to be acceptable in terms of comfort by the majority of patients on whom the device has been used.

4. You provide a list of contraindications, warnings, and precautions (Sections 7.11 & 7.12, page 34 of 535). This list is lacking some detail to effectively guide users' clinical judgment. Please address the following issues and be sure to include all of these contraindications, warnings, and precautions in your Instructions for Use (User's Manual):

   a. You specify that the device is not for use in the pediatric population. Please provide the specific age range for who the device is contraindicated.

   b. In Warnings & Precautions, bullet 'c', you state "Use clinical judgment for patients where the anatomy of the external ear appears to have unsuitable tortuosity." Please clarify what is meant by "unsuitable tortuosity" and provide examples of tortuous ear canals that are unsuitable for your device. Also, please explain why your device should not be used in these patients, since this is a population who have difficulty with traditional ear impressions and could greatly benefit from 3D scanning technology.

   c. You do not provide any guidance on the use of your device with respect to the presence of cerumen in the ear canal. Please indicate if the ear canal should be completely clear of cerumen prior to use of the otoscopic and/or topography functions of your device.

   d. Please indicate if your device may be used in patients with exotoses or osteomas, and if so, what precautions should be taken.

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e. Please indicate what precautions should be taken for the use of your device in immuno-compromised patients, such as persons with diabetes or HIV.

5. You provide engineering drawing in Attachment 8. However, it appears that some components are missing. We have identified 2 missing components: pump assembly, power source. Please provide these drawings and any others that were not previously included.

6. On page 46 of 535, Device Description, you state that the illumination source of your device is "a three color Red/Green/Blue collection of LED die are coupled through an optical taper into the proximal end of the illumination fibers – a microcontroller and associated current control drive circuits create an illumination flash sequence synchronized with the shutter of the optical sensor."

   However, you do not provide the technical characteristics of these LEDs (e.g., wavelength (spectrum distribution), maximum and normal operating output power). Please provide these parameters which are the essential information for evaluating your risk analysis.

Clinical Testing

7. You provide an interim report for the Direct Scan Earmold Digitization Evaluation which demonstrates no adverse events for the Lantos related aspects of the study. However, this interim report includes only the secondary endpoint results for safety; it does not include the primary endpoint effectiveness data demonstrating the comparison between the current standard of care for ear impressions and custom earplug manufacturing (earmold scan) and your device's direct scan method. Because your intended population use and labeling include claims about using the topography measures to manufacture custom ear pieces and hearing aids, these effectiveness data are important to support a pre-market clearance of your device. Please provide the final results from this clinical investigation that include both the safety and effectiveness endpoints.

   Similarly, you provide an interim clinical report for your User Preference Study which includes a partial data set and no analyses. Please provide the final results from this clinical investigation in support of the safety and effectiveness of your device for its intended use.

8. You state that custom earplugs were manufactured for your Direct Scan Earmold Digitization Evaluation, but a description of the earplug style/features cannot be easily located. Please provide further details about the earplug features, including if the custom earplugs were full shell style or canal style plugs.

9. Please indicate how you intend to evaluate the accuracy/effectiveness of the 3D ear scan for the concha and helix regions of the topography measurements obtained with your 3D Ear Scanner device.

10. In the Methods section of the Direct Scan Earmold Digitization Evaluation protocol (section 7.6, Determination of Eligibility, page 350 of 355), you state "subjects will be 40 normal hearing mean and women…with no known medical pathology." However, your subjects

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included persons with hearing loss, and this was not reported as a protocol deviation. Please indicate why you included subjects with hearing loss in this study and any expected impact on your study results.

11. You measure the amount of attenuation provided by the custom earplugs in each ear separately in the Direct Scan Earmold Digitization Evaluation. Given that your audiometric measures were performed in the sound field, please explain how you were able to isolate each ear for the attenuation measures.

    Also, please indicate if your subjects and investigators were blinded as to which custom earplugs were derived from which scanning method. If not, please indicate how you will control for this potential bias, particularly with respect to the investigators' blinding.

12. You describe the protocol deviations (section 10.0, page 395 of 535) in the Direct Scan Earmold Digitization Evaluation. However, further details are needed to explain the impact of these deviations. Please address the following issues:

    a. The second bullet states "the audiologist determined potential clinical implications for subjects receiving earmold impression scans prior to the EarMold 3D Direct scans of the ear canal" and explains those implications. However, it is unclear exactly how the protocol was modified and what impact the modification could have on the results. Please provide these details.

    b. Under the third bullet, you state "In addition, the audiologist determined these frequencies are unreliable for testing and re-testing purposes due to the directionality of the 8000Hz and subjects respond to 250 Hz as a vibro-tactile even when not heard." Please clarify what is meant by "the directionality of the 8000 Hz." Also, please clarify why you would expect subjects to have a vibro-tactile response to a 250 Hz tone presented via loud speaker in the sound field at levels of 40 dB HL and below.

13. In your User Preference Study, 10 out of 10 clinicians rated the video otoscope images from this device the same or more difficult relative to the quality of images from other conventional or video otoscopes. Furthermore, in Figure 7-21(page 48 of 538) you provide images from the video otoscope where there appears to be limited visibility of the tympanic membrane. This suggests that the images from the video otoscopy of your device may not yield "exceptional visualization of the ear canal" as claimed in your Draft Brochure, or that visualization of the tympanic membrane may be limited. Please provide images and performance data to support your claims about the quality of images from the video otoscopy with your device.

14. In your User Preference Study, most of your clinician subjects indicated that they would like a prompt or an identification of insertion depth or ear canal length. Please indicate how you plan to address this issue.

Labeling

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15. In the Draft Brochure (page 337 of 535), under Safety and Comfort, you state "The scanner can be used with confidence in cases where traditional impression material might require extended preparation." This statement implies that the Lantos 3D Ear Scanner is a better option in difficult cases. Please clarify this statement by indicating what cases you are referring to and providing data or a rationale to support your statement.

16. You provide descriptions of the steps for using the Lantos 3D Ear Scanner to perform video otoscopy and topography measurements in the Instructions for Use. You may consider including additional diagrams and/or photographs of the device in use in order to provide references for the user. Examples of additional images that may be helpful for the Instructions for use include the button controls on the device, the check cap, the protective cap, how to brace the device while retracting the probe tip during topography, etc.

17. Please include the updated contraindications and precautions in the Instructions for Use.

18. You provide copies of your labeling. One of the labels is for the Lantos 3D Ear Scanner Disposable Multi-Pack – Contains Ten (10) ea which bears the manufacturing month and the expiration month. Please explain how you arrived at this 1 month shelf-life and provide supporting documentation. Furthermore, in Attachment 1, you provide a list of hazards, among which are potential consequences of not heeding the expiration date. This suggests that the disposable components may become unsafe within 1 month of manufacturing. You do not provide a description of the packaging. Combined with the short shelf-life and dangers of expired product, the packaging is paramount. Please describe how all components are packaged, which includes the individual packaging for each component, individual cartons, shipping containers, etc.

Phototoxicity

19. The eye is a sensitive organ highly susceptible to damage by optical radiation. It is not clear whether the LEDs are turned on before or after the probe is inserted into ear. If the LEDs are turned on before inserting, there is the potential optical radiation hazard to the eye because of the proximity to the eyes. If Lantos 3D Ear Scanner is designed to be used in this condition, your device may pose the following types of hazards:

    - Retinal photochemical aphakic light hazard (305 -700 nm)
    - Retinal visible and infrared radiation thermal hazard (400 -700 nm)
    - There's more evidence that blue light (400 – 500nm) can damage eyes, with people who have had cataracts removed being particularly vulnerable.

    We believe an evaluation of phototoxicity to the eyes for use of your device is necessary. For phototoxicity analysis including classification, labeling, and informational requirements for the device, we recommend reference to the following standards:

    - American Conference of Governmental Industrial Hygienists (ACGIH): Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices (2011)

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- ANSI/IESNA RP-27.2-2000 Recommended Practice for Photobiological Safety for Lamps & Lamp Systems - Measurement Techniques

- ANSI/IESNA RP-27.3-2007 Recommended Practice for Photobiological Safety for Lamps - Risk Group Classification & Labeling

Please provide a phototoxicity evaluation, including (but not limited to) the following information:

a. Irradiance measurement at a default distance of 20cm and at the worst case (shortest) of distance form nose.

b. Risk group assessment: This assessment results in either an Exempt Group or one of three Risk Group classification: Risk Group 1 ((Low-Risk)), Risk Group 2 (Moderate Risk)) and Risk Group 3 (High Risk).

c. Appropriate protection should be used when the risk group classification is not "Exempt". Please describe whether there is any mitigation that will be effective to prevent the potential harm to the eyes to insure user safety when operating the device under the condition of intended use.

The following labeling issues are for your consideration:

We recommend following ANSI/IESNA RP-27.3 -07 Section 6.2. to provide Caution labels to inform and instruct end user regarding pertinent safety related information that should be provided if the lamp is classified as Risk Groups 1, 2, or 3. For example:

i. A statement of the potential hazard, if any. This should simply advise as to what might be expected to occur (i.e., skin irritation, or eye injury).

ii A list of what precautions could or should be taken to avoid the risk (e.g., "Do not shine the device directly in eyes…", "Appropriate eye protection should be used when daily exposure at short distance (XX cm) is greater than XX minutes.")

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20. The ear skin is also vulnerable to damage by optical radiation. The type of effect, injury thresholds, and damage mechanisms vary significantly with wavelength. There are different types of damage to the skin may be caused by optical radiation, for example:

    - Thermal damage (burns) of the skin with visible and infrared radiation.

    - Photosensitized damage of the skin: It is generally far more typical of UVR wavelengths (less than 380 nm). However, such photosensitized reactions can extend to approximately 700 nm, possibly as a side-effect of certain medications.

    You do not include an evaluation of optical radiation hazard to the skin. We recommend you evaluate skin safety for use of your device by performing an optical radiation hazard evaluation to demonstrate your device meets the safety guideline specified in ACGIH [1] and ICNIRP [2] or an equivalent method. Please provide this information.

    [1] ACGIH American Conference of Governmental Industrial Hygienists Threshold Limit Values for chemical substances and physical agents and Biological Exposure Indices. 2011.

    [2]. International Commission on Non-Ionizing Radiation Protection (ICNIRP). Guidelines on limits of exposure to broad-band incoherent optical radiation (0.38-3um). Health Phys. 73: 37 539-554; 1997.

    You may choose alternate approaches as long as you can adequately address the above concern related to optical radiation safety.

The deficiencies identified above 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 (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification

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

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(510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

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 additional information 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. .

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact LT Andrew Yang at (301) 796 - 6860. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

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

June 25, 2012

LANTOS TECHNOLOGIES
C/O GENERIC DEVICES CONSULTING, INC.
20310 SW 48TH ST
SOUTHWEST RANCHES, FLORIDA 33332
ATTN: JOHN GREENBAUM

510k Number: K121326
Product: LANTOS 3D EAR SCANNER
On Hold As of 6/22/2012

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/MedicalDeviceProvisionsofFDAModernizationAct/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.

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

Records processed under FOIA Request #2014-5942; Released by CDRH on 12-8-2015

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

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