Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(smw)
FOLDER:	K120238 - 1046 pages
COMPANY:	OPTOVUE, INC. (OPTOVUE)
PRODUCT:	OPHTHALMOSCOPE, AC-POWERED (HLI)
SUMMARY:	Product: RTVUE XR OCT
DATE REQUESTED:	Aug 24, 2015
DATE PRINTED:	Aug 24, 2015
Note:	Printed

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2012 K120238

optovue

APR - 3 2012

510(k) Summary
Optovue, Incorporated

This 510(k) summary for the RTVue is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

General Information

Manufacturer:
Optovue, Inc.
45531 Northport Loop West,
Fremont, CA 94538
Phone: (510) 623-8868
Fax: (510) 623-8668
Registration No.: 3005950902

Contact Person:
John J. Talarico
VP Regulatory/Quality Assurance
Optovue, Inc.
Phone: (510)623-8868 x209
e-mail: john_talarico@optovue.com

Device Information

Classification: Class II

Trade Name: RTVue XR

Common Name: Optical Coherence Tomography (OCT)

Classification Name: Ophthalmoscope, a-c powered (21 C.F.R. § 886.1570)

Predicate Devices

510(k) **K101505** RTVue with NDB Optical Coherence Tomography (OCT)

Purpose of the Special 510(k) notice

The RTVue XR OCT is an upgrade to the current cleared device RTVue with NDB (**K101505**) with a new line scan camera for faster image acquisition.

Intended Use

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

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The RTVue XR with Normative Database is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician.
The RTVue XR with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

Technological Characteristics

The RTVue XR is a non-invasive diagnostic device for imaging the cornea, anterior chamber, and retinal tissue structure with micrometer range resolution. The RTVue XR OCT is based on the same Optical Coherence Tomography (OCT) technology used in its predicate device, RTVue with NDB OCT.
The RTVue XR is a computer controlled ophthalmic imaging system. The device scans the patient's eye using a low coherence interferometer to measure the reflectivity of the retinal tissue. The cross sectional retinal tissue structure is composed of a sequence of A-scans. It has a traditional patient and instrument interface like most ophthalmic devices. The computer has a graphic user interface for acquiring and analyzing the image.

RTVue XR offers three scan types: Retina, Glaucoma, and Cornea. For the Cornea scan, a lens must be attached to the front of the device for proper scanning. This lens is called the CAM (Cornea Anterior Module-cleared under K111505)

The upgrade of the line scan camera is designed to **provide faster image acquisition.** The RTVue XR is an updated version of RTVue with NDB that operates at ~70,000 A-lines per second while the RTVue-100 operates at ~27,000 A-lines per second. The RTVue XR machines will be equipped with new line-scan cameras capable of operating at ~70,000 A-lines per second while delivering equivalent imaging results as the older generation RTVue line-scan cameras operating at ~27,000 A-lines per second.

Performance Data

Elliot lab Certification Testing and Report (ref: R64363 Rev.3 and R63863 Rev. 4) in accordance to IEC 60601-1 Amendment 1 and 2 and IEC-60601-1-2. In addition a Bench test was also performed, with the results for comparison of the RTVue XR with the predicate device RTVue with NDB. The RTVue XR meets the safety and stability requirements of IEC 60601-1and IEC-60601-1-2 as well as the bench test requirements results.

Substantial Equivalence

The RTVue XR has the same intended use and similar indications, principles of operation, and technological characteristics as the **RTVue with NDB OCT**. The minor difference in the RTVue XR OCT is **a new line scan camera for faster image acquisition and this upgrade** does not raise any new questions of safety or effectiveness. Performance data demonstrates that the **RTVue XR** is as safe and effective as **RTVue with NDB OCT**. Thus, the **RTVue XR** is substantially equivalent to its predicate devices.

45531 Northport Loop W, Fremont, CA 94538 Phone: (866) 344.8948; (510) 623-8868 Fax: (510) 623.8668

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 Room –WO66-G609
Silver Spring, MD 20993-0002

Optovue, Inc
c/o Mr. John Talarico
VP Regulatory and Clinical Affairs
45531 Northport Loop W.
Fremont, CA 94538

APR - 3 2012

Re: K120238
Trade/Device Name: RTVue XR OCT
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLI
Dated: February 23, 2012
Received: February 27, 2012

Dear Mr. Talarico:

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 device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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

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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,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
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 #2012-3758; Released by CDRH on 09-8-2015

optovue

Indications for Use Statement

510(k) Number (if known): K120238

Device Name: RTVue XR

Indications for Use:

The RTVue XR with Normative Database is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician.
The RTVue XR with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

Prescription Use X
(Per 21 C.F.R. 801.109)

AND/OR

Over-The-Counter Use____
(Per 21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K120238

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 Room –WO66-G609
Silver Spring, MD 20993-0002

Optovue, Inc
c/o Mr. John Talarico
VP Regulatory and Clinical Affairs
45531 Northport Loop W.
Fremont, CA 94538

APR - 3 2012

Re: K120238
Trade/Device Name: RTVue XR OCT
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLI
Dated: February 23, 2012
Received: February 27, 2012

Dear Mr. Talarico:

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.

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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.

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Sincerely yours,

for Kesia Alexander

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

Enclosure

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

optovue

Indications for Use Statement

510(k) Number (if known): K120238

Device Name: RTVue XR

Indications for Use:

The RTVue XR with Normative Database is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician.
The RTVue XR with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

Prescription Use X
(Per 21 C.F.R. 801.109)

AND/OR

Over-The-Counter Use ____
(Per 21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K120238

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8115

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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

February 27, 2012

OPTOVUE, INC.
45531 Northport Loop W
FREMONT, CALIFORNIA 94538
ATTN: JOHN J. TALARICO

510k Number: K120238

Product: RTVUE XR OCT

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Mcdonald, Lisa *

From: Microsoft Outlook
To: 'john_talarico@optovue.com'
Sent: Monday, February 27, 2012 1:51 PM
Subject: Relayed: K120238 AI Letter

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

'john_talarico@optovue.com'

Subject: K120238 AI Letter

Sent by Microsoft Exchange Server 2007

16

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

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

February 15, 2012

OPTOVUE, INC.
45531 Northport Loop W
FREMONT, CALIFORNIA 94538
ATTN: JOHN J. TALARICO

510k Number: K120238
Product: RTVUE XR OCT
On Hold As of 2/14/2012

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 #2010-0758; Released by CDRH on 09-8-2015

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Mcdonald, Lisa *

From: Microsoft Outlook
To: 'john_talarico@optovue.com'
Sent: Wednesday, February 15, 2012 8:11 AM
bject: Relayed: K120238 Hold Letter

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

'john_talarico@optovue.com'

Subject: K120238 Hold Letter

Sent by Microsoft Exchange Server 2007

19

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

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

January 26, 2012

OPTOVUE, INC.
45531 Northport Loop W
FREMONT, CALIFORNIA 94538
ATTN: JOHN J. TALARICO

510k Number: K120238
Received: 1/26/2012
Product: RTVUE XR OCT

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

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

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Grayson, Giovanna *

From: Microsoft Outlook
To: 'john_talarico@optovue.com'
Sent: Thursday, January 26, 2012 2:24 PM
Subject: Relayed: ack letter

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

'john_talarico@optovue.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

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

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Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Thursday, January 26, 2012 2:24 PM
To: 'john_talarico@optovue.com'
Subject: ack letter
Attachments: image002.png

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
January 26, 2012
TALARICO
JOHN
J
OPTOVUE, INC.
45531 Northport Loop W
FREMONT, CALIFORNIA 94538
ATTN: JOHN J. TALARICO

510k Number: K120238
Received: 1/26/2012
Product: RTVUE XR OCT

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

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 Pumas, PMA Supplements, Original Blass 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 Cry'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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
1/26/2012

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

optovue

Special 510(k) Submission

Optovue, Inc.

RTVue XR

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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 #2012-3758; Released by CDRH on 09-8-2015

optovue

To Whom It May Concern:

(Please tape a CD sleeve securely onto this pageand insert the CD-ROM. Label the CD-Rom as"Optovue RTVue XR Special 510(k) Notification")

This CD-ROM contains the protected document format (.pdf) file for the enclosed premarket notification. The .pdf file is searchable in Adobe Reader with bookmark links to the various referenced documents. Thanks in advance for all your efforts on behalf of Optovue

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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 #2012-3758; Released by CDRH on 09-8-2015

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Cover Letter

Special 510(k) Premarket Notification Checklist

Special 510(k) Premarket Notification

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M. Indications for Use Statement
N. Truth and Accuracy Statement

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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 #2012-3758; Released by CDRH on 09-8-2015

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: (b)(4) [redacted]
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)

OPTOVUE INC
45531 NORTHPORT LOOP W
FREMONT CA 94538
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****2608

2. CONTACT NAME
John Talarico

2.1 E-MAIL ADDRESS
John_Talarico@optovue.com

2.2 TELEPHONE NUMBER (include Area code)
510-623-8868 209

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

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

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[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
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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
(b)(4) [redacted]
24-Jan-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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
01/24/2012	(b)(4) [redacted]	

SECTION A — TYPE OF SUBMISSION

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

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

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

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Optovue Inc.	Establishment Registration Number *(if known)*: 3005950902		
Division Name *(if applicable)*:	Phone Number *(including area code)*: 510-623-8868 x209		
Street Address: 45531 Northport Loop W.	FAX Number *(including area code)*: 510-623-8668		
City: Fremont	State / Province: CA	ZIP/Postal Code: 94538	Country: USA
Contact Name: John J. Talarico			
Contact Title: VP Regulatory Affairs and Quality Assurance	Contact E-mail Address: john_talarico@optovue.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name:			
Division Name *(if applicable)*:	Phone Number *(including area code)*:		
Street Address:	FAX Number *(including area code)*:		
City:	State / Province:	ZIP Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

FORM FDA 3514 (12/10)

PSC Publishing Services (301) 443-6740 EF

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

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SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] New Device
- [ ] 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)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

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

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

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

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Response to FDA correspondence:

- [x] Other Reason *(specify)*:

SECTION D2 — 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

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

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

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

- [x] Other Reason *(specify)*:

Replacing Camera in the existing RTVue with NDB OCT system

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] 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 ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	HLI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K101505	1	RTVue OCT with Normative Data Base (NDB)	1	Optovue Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Optical Coherence Tomography

	Trade or Proprietary or Model Name for This Device		Model Number
1	RTVue XR OCT	1	RTVue XR
2		2	
3		3	
4		4	
5		5	

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

1 (K101505)	2 K062552	3 K100861	4 K091297	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
HLI	21 CFR 886.1570	[ ] Class I [x] Class II
Classification Panel: 86		[ ] Class III [ ] Unclassified

Indications *(from labeling)*

The RTVue XR with Normative Database is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician.

The RTVue XR with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

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

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 300595092	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name: Optovue Inc.		Establishment Registration Number: 68717	
Division Name *(if applicable)*		Phone Number *(including area code)*: 510-623-8868 x209	
Street Address: 45531 Northport Loop W.		FAX Number *(including area code)*: 510-623-8668	
City: Fremont		State / Province: CA	ZIP Code: 94538 / Country: USA
Contact Name: John J. Talarico	Contact Title: VP Regulatory Affairs and Quality Assurance	Contact E-mail Address: john_talarico@optovue.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

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

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SECTION I — UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	IEC 60601-2	International Electronic Commission	Medical Electrical Equipment Part 1-2-General Requirements for basic safety and essential performance	3.0	3/30/2007
2	IEC-60601-1	International Electronic Commission	Safety Requirements for Medical Electrical Equipment, Part 1-General requirements for Safety with amendments A1:1993 and A2 1995	2.0	12/14/2000
3					
4					
5					
6					
7					

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

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

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

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.

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

K120238
OP / DONED

optovue

45531 Northport Loop West
Fremont, CA 94538
Phone: (510) 623-8868
Fax: (510) 623-8668

January 23, 2012

By Messenger

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
JAN 26 2012
Received

Re: Special 510(k): RTVue XR

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (" FDC Act"), **Optovue**, Inc. ("**Optovue**" or the "Company"), is submitting the attached Special 510(k) premarket notification ("Special 510(k)") for its **RTVue XR Optical Coherence Tomography** ("Optovue RTVue OCT" or "RTVue OCT") regarding the **replacement of a new technologically updated camera on the RTVue OCT system with normative database.**

Optovue's RTVue OCT is a computer controlled ophthalmic imaging system, commonly known as an optical tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer and optic disk as a tool and aid in the diagnosis and management of retinal disease.

It has a traditional patient and instrument interface like most ophthalmic devices, where the patient rests their heads on the forehead and chin rest while the operator uses a joystick interface to align the device to the patients' eye. The computer has a graphic user interface for acquiring and analyzing the image.

The purpose of this special 510(k) notice is for the **RTVue XR which consists of an** upgrade; a new camera for the original RTVue OCT System (**K101505**) that has already been cleared by the Food and Drug Administration for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disk as a tool and aid in the diagnosis and management of retinal disease.

The RTVue XR is an updated version of RTVue with NDB that will operate at ~70,000 A-lines per second while the original RTVue-100 operated at ~27,000 A-lines per second. The RTVue XR machines will be equipped with *new line-scan cameras* capable of operating at ~70,000 A-lines per second while delivering equivalent imaging results as the older generation RTVue line-scan cameras operating at ~27,000 A-lines per second.

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

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The **RTVue XR** has the same intended use and fundamental scientific technology as the RTVue with NDB OCT.

The **RTVue XR** OCT has the same intended use and same indications, technological characteristics, and principles of operation as the RTVue OCT. As explained in the attached Special 510(k) notice, there is no fundamental change between the **RTVue XR OCT** and the RTVue with Normative Database (NDB) OCT (predicate device) therefore there are no new questions of safety or effectiveness. Testing was conducted on the system according to IEC60601-1 and the results of the **replacement with the new camera (XR) demonstrates that this change to the RTVue XR OCT device is as SAFE AND EFFECTIVE AS THE PREDICATE DEVICE.** Thus, we believe that **RTVue XR OCT** is substantially equivalent.

In accordance with the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), **Optovue** has submitted the appropriate application fee. A copy of the User Fee Cover Sheet is provided with the attached Special 510(k) notice.

We trust that the information provided in the Special 510(k) notice is sufficient for FDA to find the **RTVue XR** OCT is substantially equivalent to its predicate device (RTVue with NDB OCT) for the listed indication. If you have any additional questions regarding the Special 510(k) notice, please contact me at the above number. Upon a finding of substantial equivalence, please fax the substantial equivalence letter to me at (510) 623-8668.

Sincerely,

John J. Talarico

John J. Talarico
VP Regulatory & Quality Assurance
Optovue, Inc.

Attachments

cc: Howard Holstein, esq.

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

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Optovue, Inc.'s

RTVue XR

Special 510(k) PREMARKET NOTIFICATION CHECKLIST

Item	Comment	510k Notice Section/Attachment
1. Device trade or proprietary name	*See* Special 510(k) Notice	Section 1
2. Device common or usual name or classification name	*See* Special 510(k) Notice	Section 3
3. Establishment registration number (only applies if establishment is registered)	*See* Special 510(k) Notice	Section 2
4. Class into which the device is classified	*See* Special 510(k) Notice	Section 3
5. Classification Panel	*See* Special 510(k) Notice	Section 3
6. Action taken to comply with Section 514 of the Act	Not Applicable - no performance standards developed and no applicable special controls	
7. Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use	*See* Attachments	Attachment B
8. A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	*See* Attachments	Attachment L
9. For class III devices only, a class III certification and a class III summary	Not Applicable - This is not a Class III device	
10. Photographs and engineering drawings of the device	*See* Attachments	Attachment C
11. The marketed device(s) to which equivalence is claimed including labeling and description of the device	*See* Special 510(k) Notice	Section 11 & Attachment E
12. Statement of similarities and/or differences with marketed devices(s)	*See* Special 510(k) Notice	Section 7 & Attachment E
13. Data to show consequences and effects of a modified device	Not Applicable	
14. Submitter's name and address	*See* Special 510(k) Notice	Section 16
15. Contact person, telephone number and fax number	*See* Special 510(k) Notice	Section 16
16. Representative/Consultant if applicable	Howard Holstein, Esq.	
17. Table of Contents with pagination	*See* Table of Contents Tab	
18. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	*See* Special 510(k) Notice	Section 2
19. Comparison table of the new device to the marketed device(s)	*See* Attachments	Attachment E

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

20. Action taken to comply with voluntary standards and Standards Data Report Form for 510(k)s	IEC 60601-1 Copy of FDA form 3654 *See* Special 510(k) Notice	Section 4 & Attachments A
21. Performance data		
a. bench testing	*See* Special 510(k) Notice	Section 7.3
b. animal testing	Not Applicable	
c. clinical data	Not Applicable	
d. Certification of Compliance with the Requirements of ClinicalTrials.gov data bank	*See* Attachments	Attachment F
22. Sterilization/shelf information	Not Applicable	
23. Software Information	*See Attachment*	Section 8 & Attachment G
24. Hardware information	Not Applicable	
25. Is this device subject to issues that have been addressed in specific guidance document(s)?	No	
26. Other (specify)		
Biocompatibility Certification/Information	*See* Special 510(k) Notice	Section 10 & Attachment J
27. Declaration of Conformance to Design Control	*See* Special 510(k) Notice	Section 9 & Attachment I

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

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optovue

January 24, 2012

FDA COPY

K3

Special 510(k) Submission:

RTVue XR

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

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The following information is provided as required by 21 C.F.R. § 807.87 (2003) for **OPTOVUE, INC., RTVUE XR** Special 510(k) premarket notification:

1. Name of Device

Trade Name: **RTVue XR**

Common Names: **Optical Coherence Tomography (OCT)**

Classification Name: **Ophthalmoscope, a-c powered (21 C.F.R. § 886.1570)**

2. Establishment Registration Number

Manufacturer: **Optovue, Inc**
45531 Northport Loop W.
Fremont, CA 94538

Manufacturer Registration Number: **3005950902**

3. Device Classification/FDA Reviewing Branch

The **Center for Devices and Radiological Health** has classified the RTVue OCT **Ophthalmoscope** as **Class II** device pursuant to 21 C.F.R. § 886.1570.

4. Performance Standards

We have reviewed the requirements of Sections 513 and 514 of the Act and are not aware of any requirements of either section applicable to this device. No performance standards or special controls have been developed under Section 514 of the FDC Act for the ophthalmoscope. No special controls apply.

Consistent with FDA's guidance document entitled "Use of Standards in Substantial Equivalence Determinations" (March 12, 2002), Optovue has included this statement that the **RTVue XR** complies with IEC 60601-1. This is the same standard with which the cleared RTVue with NDB **(K101505)** complied. Standards Data Report Forms for each listed recognized consensus standard are provided in **Attachment [A].**

5. Proposed Labeling

The Operator's Manual for the **RTVue XR** along with its promotional materials and proposed labeling, is provided in **Attachment [B]** of this submission.

The following modifications have been made to the labeling:

- **Upgrade of the line scan camera to the RTVue OCT System and will be labeled as RTVue XR**

This modification does not affect the device's intended use or fundamental scientific technology.

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

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6. Device Description

The RTVue XR is a non-invasive diagnostic device for imaging and measurement of the retina, retinal nerve fiber layer and optic disk, as a tool and aid in the diagnosis and management of retinal disease.

The RTVue XR is computer controlled ophthalmic imaging system. The device scans the patient's eye using a low coherence interferometer to measure the reflectivity of the retinal tissue. The cross sectional retinal tissue structure is composed of a sequence of A-scans. It has a traditional patient and instrument interface like most ophthalmic devices. The computer has a graphic user interface for acquiring and analyzing the image.

The RTVue XR is based on the same Optical Coherence Tomography (OCT) technology used in its predicate device, RTVue with Normative Database (K101505). A brochure of the RTVue is in the Attachment [D].

The upgrade line scan camera is designed to **provide faster image acquisition for RTVue XR OCT when used under normal operational conditions**. The RTVue XR is an updated version of RTVue with NDB that now operates at ~70,000 A-lines per second while the RTVue-100 operates at ~27,000 A-lines per second. The RTVue XR machines will be equipped with new line-scan cameras capable of operating at ~70,000 A-lines per second while delivering equivalent imaging results as the older generation RTVue line-scan cameras operating at ~27,000 A-lines per second. *See* **Attachment C** for drawings and technical specifications of the **RTVue XR OCT System with the upgraded line scan camera**

7. Substantial Equivalence

The company's **RTVue XR** has an upgraded line scan camera compared to the **RTVue with NDB OCT (K101505)**, which was cleared in **September, 2010**. As explained in more detail below, the **RTVue XR OCT** has the same intended use and indications for use, same principles of operation, and similar technological characteristics as the previously cleared predicate **RTVue with NDB OCT**. *See* **Attachment [D]** for information and promotional materials for the predicate devices. *See* **Attachment [E]** for a substantial equivalence chart comparing the similarities and differences between the RTVue XR and its predicates. Thus, the RTVue XR OCT is substantially equivalent to its predicates.

7.1 Intended Use and Indications

The RTVue XR with Normative Database is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician. The RTVue XR with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

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7.2 Technological Characteristics

The **RTVue XR** has the exact same technological characteristics as the RTVue with NDB OCT System; however the upgraded line scan camera will allow faster image acquisition. The RTVue XR will operate at ~70,000 A-lines per second and delivers equivalent imaging results as the older generation RTVue with NDB line-scan camera (currently operating at ~27,000 A-lines per second).
THE TECHNOLOGICAL CHARACTERISTICS ARE THE SAME.

7.3 Performance Testing

The RTVue XR has been tested to IEC60601-1 and IEC-60601-1-2 and it meets the safety and stability requirements specified in these standards. In addition, bench tests have also been performed indicating equivalent imaging performance between the RTVue and RTVue XR All test results are listed in **Attachment F.**

7.4 Conclusion

In summary, the company's RTVue XR OCT System has the same intended use as the previously cleared RTVue with NDB OCT. The RTVue XR has the exact indications, technological characteristics, and principles of operation as its predicates. There is now atechnologically upgraded line scan camera replacement between the RTVue XR and its predicate device, resulting in the capacity for faster image acquisition; this difference does not raise new questions of safety or efficacy. Thus, the RTVue XR is substantially equivalent.

8. Software Information

RTVue XR was tested and validated via software validation protocols # 200-45762 and 200-46929. All software related documents are attached in the submission. **See Attachment G.**

9. Design Control Information

The risk analysis method used to assess the impact of the modifications was analyzed according to ISO 14971 Medical Devices – Application of Risk Management. The design verification tests that were performed as a result of this risk analysis assessment are listed in Table 1 below. The test methods used are the **same** as those submitted in the submission of RTVue with NDB (K101505)

All harms and hazard identified for RTVue XR were evaluated in RTVue OCT risk analyses report. Identified risks are either in the Broadly Acceptable Category or in the As Low As Reasonable Practicable category. Due to no change in the basic design of the RTVue XR no new no risk was introduced, therefore all the risk identified for RTVue will apply to RTVue XR.
Please see RTVue Risk Analysis Report Doc#: 200-24047 for mitigation factors.

Declaration of conformity with design controls, which is provided in **Attachment [I],** includes:

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1. A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met; and

2. A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

10. Biocompatibility Information

There are no changes to biocompatibility of the device. A copy of the biocompatibility certification is provided in **Attachment [J].**

11. Sterilization / Cleaning / Disinfection / Shelf Life

The RTVue XR is non sterile device. *See* **Attachment K.**

12. Financial Disclosures

Optovue, Inc. is not submitting clinical data in support of this Special 510(k) notice. For this reason, the regulations regarding clinical investigators financial interests in 21 C.F.R. § 54.4 do not apply. Thus, the company is not providing a disclosure or certification to the absence of any financial arrangements.

13. 510(K) Summary

Attachment [L] Of This Submission Contains the Company's 510(K) Summary.

14. Confidentiality

Optovue considers its intent to market the **RTVue XR OCT** as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore, requests FDA not to disclose the existence of this application until such time as final action on the submission is taken.

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

15. Submitter's Name And Address

Optovue, Inc
45531 Northport Loop W
Fremont, CA 94538
Phone: 510-623-8868
Facsimile: 510-623-8668

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

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optovue

16. Contact Person and Telephone/Facsimile Numbers

John J. Talarico
VP Regulatory & Quality Assurance
Phone: 510-623-8868 x 209
Fax: 510-623-8668

17. Indications for Use Statement

The company's Indications for Use Statement for **RTVue XR** OCT is provided in **Attachment [M].**

18. Truth and Accuracy Statement

The company's signed Truth and Accuracy statement is included in **Attachment [N].**

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

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Attachment [A]

Standards are referenced in Data Report Form for Premarket Notifications

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

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Form Approved: OMB No. 0910-0120; 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]

IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirement for basic Safety and essential performance

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 5-53	
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 any 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 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirement for basic Safety and essential performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All sections	IEC-60601-2-Medical Electrical Equipment	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

Classification electrical conformance component

DESCRIPTION

Conformance met

JUSTIFICATION

See attached report # R63864 Rev.4

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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Department of Health and Human Services
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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC-60601-1-1990, Safety Req. for Medical Elect. Equipment, Part 1-General Req. for Safety with amends A1:1993 and A2 1995

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-35	
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 any 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 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC-60601-1-1990, Safety Req. for Medical Elect. Equipment, Part 1-General Req. for Safety with amends A1:1993 and A2 1995

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5-7	5-Classification, 6-Marking Label& documents, 7-Power Input	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Classification of safety conformance component and electrical test

DESCRIPTION
Conformance met

JUSTIFICATION
See attached report # R64363 Rev.3

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
14 & 15	14-Req.related to classification, 15-Limitation of Voltage and/or Energy	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Classification of safety conformance component and electrical test

DESCRIPTION
Conformance met

JUSTIFICATION
See attached report # R64363 Rev.3

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
16, 17,18, 19	16-Enclosures & Protective covers, 17-Separation, 18-Impedence, 19-Leakage	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Classification of safety conformance component and electrical test

DESCRIPTION
Conformance met

JUSTIFICATION
See attached report # R64363 Rev.3

* 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.

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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
20-23	20-Dielectric test, 21-Mechanical Strength, 22-Moving Parts, 23-rough surface	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Classification of safety conformance component and electrical test

DESCRIPTION
Conformance met

JUSTIFICATION
See attached report # R64363 Rev.3

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
24, 28, 42,43, 44	24-Stability, 28-Integrity, 42-Temperature, 43-Fire Prevention, 44-Humudity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Classification of safety conformance component and electrical test

DESCRIPTION
Conformance met

JUSTIFICATION
See attached report # R64363 Rev.3

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
49, 51	49-Interrusption of Power Supply, 51-Protection against hazardous output	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Classification of safety conformance component and electrical test

DESCRIPTION
Conformance met

JUSTIFICATION
See attached report # R64363 Rev.3

* 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.

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STANDARD TITLE
IEC-60601-1-1990, Safety Req. for Medical Elect. Equipment, Part 1-General Req. for Safety with amends A1:1993 and A2 1995

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
20-23	20-Dielectric test, 21-Mechanical Strength, 22-Moving Parts, 23-rough surface	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •
Classification of safety conformance component and electrical test

DESCRIPTION
Conformance met

JUSTIFICATION
See attached report # R64363 Rev.3

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
24, 28, 42,43, 44	24-Stability, 28-Integrity, 42-Temperature, 43-Fire Prevention, 44-Humudity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •
Classification of safety conformance component and electrical test

DESCRIPTION
Conformance met

JUSTIFICATION
See attached report # R64363 Rev.3

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
49, 51	49-Interrusption of Power Supply, 51-Protection against hazardous output	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •
Classification of safety conformance component and electrical test

DESCRIPTION
Conformance met

JUSTIFICATION
See attached report # R64363 Rev.3

* 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:

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

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.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC-60601-1-1990, Safety Req. for Medical Elect. Equipment, Part 1-General Req. for Safety with amends A1:1993 and A2 1995

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
52, 56	52-Abnormal operation & fault Condition, 56-Components & General Assemb	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Classification of safety conformance component and electrical test

DESCRIPTION
Conformance met

JUSTIFICATION
See attached report # R64363 Rev.3

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
57, 58	57-Main parts, components & Layout, protecting earth terminals & conditions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Classification of safety conformance component and electrical test

DESCRIPTION
Conformance met

JUSTIFICATION
See attached report # R64363 Rev.3

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
59	59-Construction and Layout	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Classification of safety conformance component and electrical test

DESCRIPTION
Conformance met

JUSTIFICATION
See attached report # R64363 Rev.3

* 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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Attachment [B]

Proposed Labeling and Instructions for RTVue XR

- Proposed Labeling
- RTVue-XR-User Manual # 580-47497-001

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

REV	ECN	DESCRIPTIONS	DATE	APPROVAL
A		draft		

Notes:

MATERIAL:
.002" Heavy Coat Chrome Mylar.

ADHESIVE:
Heavy Coat Perm

COLOR:
Font/ Artwork: Black
Background: Silver

SIZE:
3.00" X 1.50" 0.06" Corner Radius

optovue
45531 Northport Loop West
Fremont, CA 94538 USA

REF : **RTVue XR Scanner**
Voltage: 120V A.C.
Frequency: 50/60 Hz
Current: 3.1 A
Fuse:
Rating: 4A/250V
Type: Fast Acting
P/N: 500-47498-001 Rev. A

optovue	*Optovue Inc.*	45531 Northport Loop West Fremont, CA 94538 USA	
TITLE:	**Label RTVue XR Scanner**		
ENGINEER: Lee Truong	SIZE: **A**	PART NUMBER	REV
	SHEET NO.	**500-47498-001**	**A**
DATE: 04-15-08	1 OF 1		

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

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REV	ECN	DESCRIPTION	DATE	APPROVAL
A		draft		

Notes:

MATERIAL:
.002" Heavy Coat Chrome Mylar.

ADHESIVE:
Heavy Coat Perm

COLOR:
Font: Black
Background: Silver

SIZE:
3.00" X 2.00" 0.06" Corner Radius

optovue
45531 Northport Loop West
Fremont, CA 94538 USA

REF **RTVue XR**

Voltage: 115/230V A.C.
Frequency: 50/60 Hz
Current: 6.3 A

Tested to comply with FCC standard

P/N: 500-47499-001 Rev.A

optovue	*Optovue Inc.*	45531 Northport Loop West Fremont, CA 94538 USA	
TITLE:	**Label RTVue XR PC**		
ENGINEER: Lee Truong	SIZE: **A**	PART NUMBER	REV
	SHEET NO.	**500-47499-001**	**A**
DATE: 04-15-08	1 OF 1		

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

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REV	ECN	DESCRIPTION	DATE	APPROVAL
A		draft		

Notes:

MATERIAL:
.002" Heavy Coat Chrome Mylar.

ADHESIVE:
Heavy Coat Perm

COLOR:
Font: Black
Background: Silver

SIZE:
3.00" X 2.00" 0.06" Corner Radius

optovue
45531 Northport Loop West
Fremont, CA 94538 USA

REF : RTVue XR 100-1
Voltage: 120 V A.C.
Frequency: 50/60 Hz
Current: 6 A

Tested to comply with
FCC standard

P/N: 500-47500-001 Rev. A

optovue	Optovue Inc.	45531 Northport Loop West Fremont, CA 94538 USA	
TITLE:	Label RTVue XR 100-1		
ENGINEER: Lee Truong	SIZE: A	PART NUMBER	REV
	SHEET NO.	500-47500-001	A
DATE: 04-15-08	1 OF 1		

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

104

REV	ECN	DESCRIPTION	DATE	APPROVAL
A		draft		

Notes:

MATERIAL:
.002" Heavy Coat Chrome Mylar.

ADHESIVE:
Heavy Coat Perm

COLOR:
Font: Black
Background: Silver

SIZE:
3.00" X 2.00" 0.06" Corner Radius

optovue
45531 Northport Loop West
Fremont, CA 94538 USA

REF : RTVue XR 100-2
Voltage: 230 V A.C.
Frequency: 50 Hz
Current: 3 A

CE 0197

FC Tested to comply with FCC standard

P/N: 500-47501-001 Rev. A

optovue	Optovue Inc.	45531 Northport Loop West Fremont, CA 94538 USA	
TITLE:	Label RTVue XR 100-2		
ENGINEER: Lee Truong	SIZE: A	PART NUMBER	REV
	SHEET NO.	500-47501-001	A
DATE: 04-15-08	1 OF 1		

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

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RTVue XR

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- Model - XR-100

Deleted: RT100

User's Manual

Version 6.6

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optovue

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Publishing details

RTVue XR
Version 6.6

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Deleted: 6.2
Deleted: 1.0

Optovue Inc.
Fremont, CA 94538
Phone: 510-623-8868
Fax: 510-623-8668
www.optovue.com

E-mail: info@optovue.com

For Customer Service or Technical Support:
(510)623-8868

Revision Control

Part Number	Rev	Software ver.	Description	Release Date
580-XXXXX-XXX	A	v 6.6	Reference ECR #XXXXX	xx/2012

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License and use of the RTVue XR-100 systems is intended only for trained medical personnel in accordance with the license agreement – all other usage is prohibited – warranty restrictions and possible claim limitations apply.

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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 Safety Notes

General
This instrument has been developed and tested in accordance with Optovue safety standards as well as national and international regulatory guidelines to ensure a high degree of instrument safety. Please observe all safety notes and information in this manual and on the device labels. This device does not produce any waste that needs disposal. Product contains no material which has a chemical hazard concern.

Proper Instrument Use

1. Always enter patient information first.
2. Clean patient contact surface (forehead and chin rest according to the cleaning method in Chapter 7 of this manual).
3. Instantly turn off the power switch of the instrument and disconnect the power cable if uncertain problems arise.
4. Clean ocular lens frequently to ensure good image quality.
5. Adjust power table height properly to ensure patient comfort during the examination.
6. Align the patient's head and eye position to the canthus indicator mark on the chin and forehead rest assembly.
7. Dim the room lights to allow natural dilation of the patients' pupil and to provide a comfortable visualization of the fixation target without glare. Note: Chemically induced pupil dilation is not needed.

Intended Use

The RTVue XR with Normative Database s an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician.

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The RTVue XR with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

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Note: The RTVue XR OCT is not intended to be used as the sole diagnostic aid in disease identification, classification or management. The RTVue XR provides data to be used in conjunction with other information, intended to assist an eye care clinician in determining a diagnosis. A patient diagnosis is the sole domain of a licensed eye care clinician.

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WARNING: THE RTVue XR CANNOT REPLACE CLINICAL JUDGEMENT AND IS INTENDED TO BE USED ONLY IN CONJUCTION OTHER CLINICAL TOOLS CONSIDERED TO BE THE STANDARD OF CARE FOR DIAGNOSIS OF EYE DISEASE.

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Warning: User Changes to Software or Hardware

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The RTVue XR is a medical device. The software and hardware has been designed in accordance with U.S., European and other international medical device design and manufacturing standards. Unauthorized modification of the RTVue XR software or hardware, or any addition or deletion of any

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

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Safety Notes

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application in any way can jeopardize the safety of operators and patients, the performance of the instrument, and the integrity of patient data.

Any changes, additions or deletions to factory installed applications, operating system or modifications to hardware in any manner VOIDS the Warranty completely.

Warning: Phototoxicity

Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures.

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

"While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure to the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography."

Caution: Federal law restricts this device to sale by or on the order of a Physician or Practitioner (CFR 801.109(b)(1)).

Product Compliance

Indicates this equipment contains Type B applied parts.

Electromagnetic Compatibility (EMC) : EN 60601-1-2:2001
The RTVue XR100 device has been tested to comply with the emission and Immunity requirements of EN60601-1-2:2001. The RTVue XR100 is intended for use in an electromagnetic environment where radiated RF disturbances are not beyond the standard defined in EN60601-1-2:2001.
RTVue XR-100 is a Medical Electrical Equipment that need special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Manual.
RTVue XR - 100 is a Medical Electrical Equipment and can be affected during operation by portable and mobile RF communication devices.
RTVue XR-100 is self-contained medical equipment. It should not be used adjacent or stacked with other equipment .

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

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CB Certification: under IEC 60601-1

Guidance and manufacture's declaration – electromagnetic emissions		
The RTVue XR-100 is intended for use in the electromagnetic environment specified below. The customer or user of the RTVue XR100 should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group1	The RTVue XR100 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The RTVue XR100 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The RTVue XR100 is intended for use in the electromagnetic environment specified below. The customer or user of the RTVue XR100 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 2 kV common mode ± 1 kV differential mode	± 2 kV common mode ± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (95% dip in UT) for 5 sec		Mains power quality should be that of a typical commercial or hospital environment. If the user of the RTVue XR100 requires continued operation during power mains interruptions, it is recommended that the RTVue XR100 be powered from an uninterruptible power source.

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

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			Note: UT is the A.C. mains voltage prior to application of the test level.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	150kHz to 80 MHz 3Vrms	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the RTVue XR100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** **d = 1.2 * SQRT(P)** for 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	80MHz -2.5GHz, 3V/m	3V/m	**d = 1.2 * SQRT(P)** for 80 MHz to 800 MHz **d = 2.3 * SQRT(P)** for 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, **a** should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Note 1: At 80 MHz and 800 MHz, the higher frequency applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is			

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affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RTVue XR100 is used exceeds the applicable RF compliance level above, the RTVue XR100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the RTVue XR100.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communication equipment and the RTVue XR - 100

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The RTVue XR100 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RTVue XR100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RTVue XR100 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d = 1.2 SQRT(P)	80 MHz to 800 MHz d = 1.2 SQRT(P)	800 MHz to 2.5 GHz d = 2.3 SQRT (P)
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

During OCT imaging, the essential performance of RTVue XR - 100 consists of the presence of OCT scanning beam and the continual display of at least the background noise in the application software.

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List of major cables

Part number	Specification	Max. Length	Remark
660-42031	USB 2.0	5 feet	
660-42024	Camera Link	6 feet	
700-43184	Power Cord	10 feet	

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Please ask authorized personnel from Optovue Inc. for cable replacement. The use of cables other than those specified by Optovue Inc. may result in increased EMISSIONS or decreased IMMUNITY of the RTVue XR system.

Symbols and Labels

Caution, consult accompanying documents.

Note: There are important Operating and maintenance instructions found in the manual.

Presence of electrical shock hazard.

Note: Indicates risk of electrical shock due to the presence of non-insulated high voltage inside the instrument. Do not remove the instrument cover or parts.

Fuse

Type B Applied parts.

Note: This instrument complies with the specified requirements to provide protection against electrical shock, particularly regarding allowable patient leakage current.

Manufacturer
Optovue Incorporated
45531 & 45395 Northport Loop W.
Fremont, CA 94538

EC REP

Authorized European Community Representative

Medical Device Safety Services (MDSS) GMbH
Schiffgraben 41
30175 Hannover, Germany

SN

Serial number

REF

Catalog number / part number

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Protective Packing Symbols

The protective packing symbols specify the handling requirements and the transport and storage conditions.

Fragile, Handle with care

Keep Dry

This end up

Relative Humidity (10% to 100%, including condensation)

Temperature (-40 to 70 deg. C)

Waste Electrical and Electronic Equipment (WEEE) Recycling Instructions

When determined that the device is ready for disposal, it is to be recycled following the policies and procedures reflecting respective country's requirements. Do not dispose of device as general waste.

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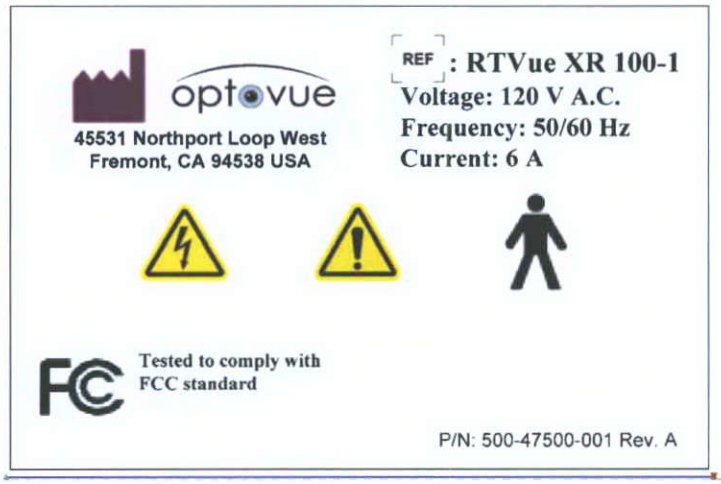
Safety Notes

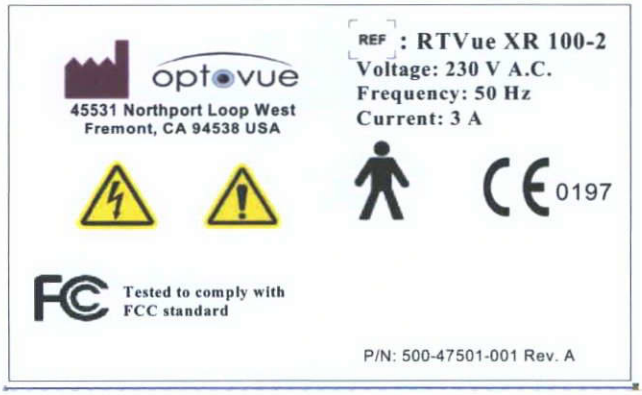
Product Labels:

RTVue XR system labels (Samples Only):

Model: XR100-1 for 120Va.c. input



Model: XR100-2 for 230V A.C. input



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XR Scanner Label: (common for both XR100-1 and XR100-2 models)

optovue
45531 Northport Loop West
Fremont, CA 94538 USA

REF : RTVue XR Scanner
Voltage: 120V A.C.
Frequency: 50/60 Hz
Current: 3.1 A
Fuse:
Rating: 4A/250V
Type: Fast Acting
P/N: 500-47498-001 Rev. A

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Fremont, CA 94538 USA

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System PC Label:

optovue
45531 Northport Loop West
Fremont, CA 94538 USA

REF RTVue XR
Voltage: 115/230V A.C.
Frequency: 50/60 Hz
Current: 6.3 A

Tested to comply with
FCC standard

P/N: 500-47499-001 Rev.A

optovu
45531 Northport Loop W
Fremont, CA 94538 US

Tested to comply w
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Patient Menu

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2 Instrument Description

2.1 RTVue XR System Configuration:

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The RTVue XR system is shipped in one palletized box, which contains the following hardware:

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1. RTVue XR Scanner:
This is the main component of the RTVue XR system. It is used to view and scan the patient's retina, collect the OCT signal, and send it to the computer for processing. It also provides a fixation light target on which the patient can fixate during the scan, as well as a position sensor for automatic detection of whether the left or right eye is aligned for scanning. Communication between the scanner and computer is achieved via a USB cable connection. The RTVue XR uses a medical-grade power supply.

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2. Computer:
The computer is used to control the scanner during the patient examination. The application software provides data analysis, presentation, and data storage and archiving. A relational database is included to organize all patient information and data, as well as to allow for search capability.

3. System Table:
The system table provides power to the RTVue XR scanner, computer, and computer display through a medical-grade isolation transformer to prevent leakage current from main AC power. The table elevation can be adjusted to fit patient height. The telescopic lift that supplies the power of the RTVue XR system is medical grade.

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It is recommended that the user connect the RTVue XR OCT system to a proper electrical source via the use of an Uninterrupted Power Supply (UPS) module connected to the wall outlet.

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4. Monitor (Computer Display):
A 22" wide screen LCD flat panel display for graphical user interface and data presentation.

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5. Keyboard and Mouse

System Configuration:

Model: XR-100-1: 120V AC.
Model: XR-100-2: 230V AC.

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Patient Menu

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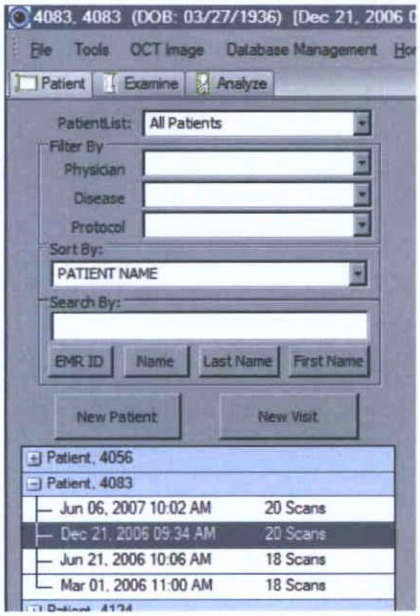
3 Patient Menu

The patient menu contains three components:
1. Patient List
2. Patient Information
3. Visit Information

In the patient menu, the user can search, add, and edit patient information. It is designed to help you schedule a patient's visit in advance, preview today's or this week's scheduled patients, and search for a patient's history.

3.1 *Patient List:*

The patient list displays the results of the user-defined search criteria.



1. All Patients
2. Current Patient
3. This week
4. Today

The patient list display can be filtered by following criteria:
1. Physicians name
2. Disease
3. Scan protocol

You may sort the results by:
1. Patient Name
2. Last Visit Time

You may search for a specific text string
1. EMR ID
2. Name (first or last)
3. Last Name only
4. First Name only

To search:

1. Type the patient's EMR ID, Name, or Last/First Name in the [**Search By**] space and click on the designated button; this will move the searched patient to the top of the list.
2. Clicking on the patient's name will list all the patient's visits and will open the patient's information.
3. Clicking on the visit will open the visit information.

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Patient Menu

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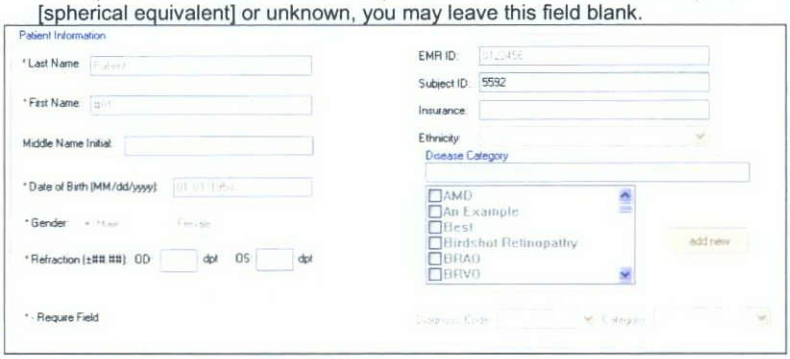
3.2 New Patient and Patient Information:

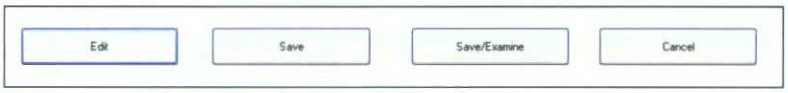
To create a new patient, click the [**New Patient**] button, fill out the information fields (fields marked with a "*" are required – if the Refraction is "0" Diopters [spherical equivalent] or unknown, you may leave this field blank.



Required information fields are marked by an (*).

- First and Last name fields are required. These can be any combination of letters or numbers. Symbols may be used, but may interfere with the capture JPEG function. It is recommended that users follow the office convention for capitalization of names.
- Refraction value (patient's current refraction – Spherical equivalent with Add) when used, sets the initial focus for scanner. The focus (scan beam and video fundus image) can be adjusted or fine-tuned in the Clinical Tab during the scan operation.
- Disease Category is a "user defined" list of diseases. The disease category (multiple choices) can also be used as a filter for the patient list.
- Diseases can be entered one at a time by clicking the [**add new**] button.
- The selected Patient Name, DOB, and EMR ID will be displayed on the title bar of the Report window.
- The "Ethnicity" field (Use or selection if for user reference only.
- If the [**Save**] and [**Save/Examine**] buttons are grayed-out, check to see that all required fields are filled.

If you are adding the list of patients with appointments for OCT scanning that day, then click the [**Save**] button at the bottom.



If you are entering the patient data in just prior to scanning the patient, then use the **[Save/Examine] button at the bottom. This will add the patient, create a new visit with today's date and take you directly to the Examine mode.**

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- If you would like to cancel this operation, then simply click on [**Cancel**] button to exit the **New Patient** screen.

3.3 New Visit

To create a new visit for an existing patient, click the [**New Visit**] button and then click [**Save**]. If you would like to cancel this operation, then simply click the [**cancel**] button to exit the **New Visit** screen.

You can also create a new visit for an existing patient by right clicking on the patient name in the list, and selecting "Add New Visit"

3.4 Select Date of Birth Format

The default format of date of birth can be set in the User Preference:

Note: The RTVue XR computer settings must match the date format specified in RTVue XR. To change the computer date settings, please follow the steps below.

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- Go to "Regional and Language Options" in Control Panel.
- Click the button "Customize" under the "Regional Options" tab.
- Select the proper format in "Short Date Format" under the "Date" tab.

3.5 Editing Patient or Visit Information

- To edit a patient's information, select the patient name from the Patient List and click the [Edit] button.
- To edit a patient's visit information, select a visit date in the list of visit dates for the selected patient, then click the [Edit] button.

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Patient Menu

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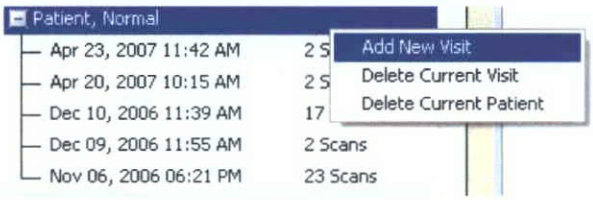
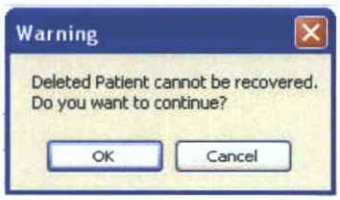
3.6 Patient List Short-cuts

Click on the patient's name to view patient visits. Right click on the patient name or visit date to view options:

- **Add New Visit** – automatically create a new visit using the current date for the selected patient, which takes the system directly to the Examination screen. Visit information is left blank.
- **Delete Current Visit** – Deletes the selected visit (any visit in the patient visit history)



- **Delete Current Patient**. – Permanently deletes the selected patient (a warning message appears first to verify that this is the intended action).



Click [**OK**] to confirm the delete action, or [**Cancel**] to withdraw the operation.

- If the [**Save**] and [Save/Examine] buttons are grayed-out, check to see that all required fields are filled.

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3.7 Correcting visit linked to the wrong patient

The user has the option of moving a visit (complete visit not specific scans) from an incorrect patient association, to the correct patient association. **(Care should always be taken by the user to ensure that the patient being scanned is the specific patient selected in the application to associate the scan data).**

1. Select the Patient > Visit you wish to move
2. Select "**Move a visit to another patient**" from the **Database Management** menu (Figure 3.7A)

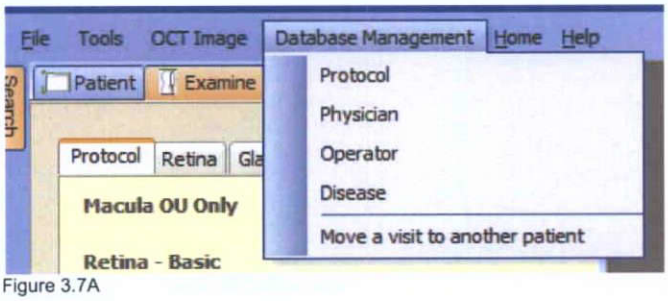

Figure 3.7A

3. Confirm that you wish to move the selected visit (first confirmation request)

Figure 3.7B

4. Select the correct patient you wish to move the visit **TO,** select **OK**

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Patient Menu

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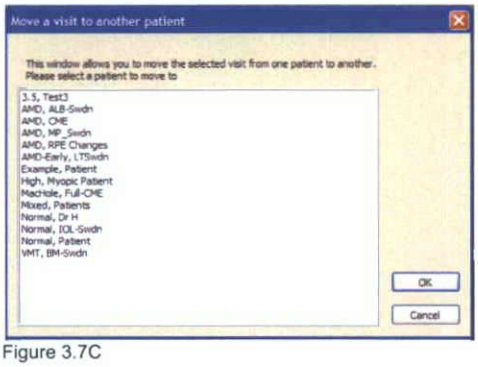

Figure 3.7C

5. Confirmation (second confirmation request) to move the selected visit to the correct patient selected. Click "Yes" to complete the move

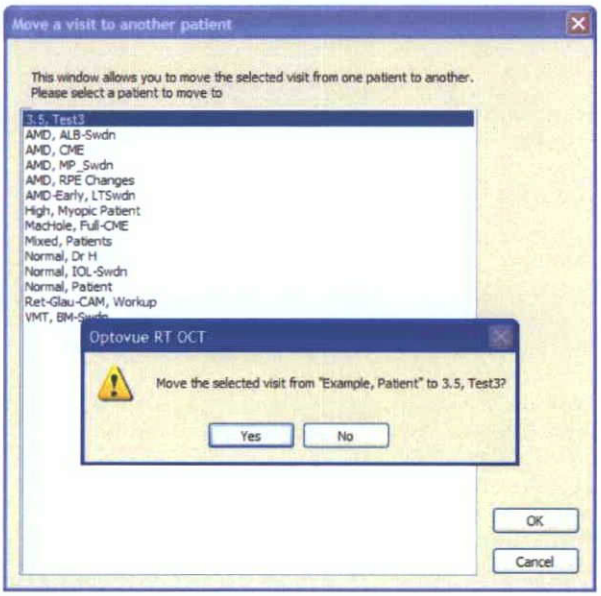

Figure 3.7D

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4 Examine Menu

4.1 Acquiring OCT Images

The following is a general procedure to acquire OCT images:

1. Select an Existing Patient or Create a New Patient.
2. Select today's visit (if it exists already) or create a new visit. Note: new scans cannot be added to visits prior to today's date
3. Click the **Examine** tab (if not automatically directed).
4. Select desired scan protocol or scan patterns (Single click to load into scan menu).
5. To launch, you may do any one of the following to activate the scanning process.
   a. Double click the scan name in the scan list.
   b. Highlight the scan name (single click) then click on the **SCAN** button at bottom center of the screen.
   c. Press the joystick button.
6. Ensure that you have positioned the patient correctly as follows: Patients' chin in the system chin rest with mouth closed, patient forehead against the system forehead rest, patient eye to be scanned aligned vertically with the canthus mark on the system head frame.
   a. Please refer to section 7.1 (Maintenance & Troubleshooting), item #3 on cleaning the chin rest and forehead rest surfaces.
7. Align center of the patient pupil with center of scan (pattern in the live video image on the screen, and move the scan head towards the patient so that the video image passes through patient's pupil.
8. Adjust distance to patient to get best illuminated fundus IR image (view of fundus from edge to edge – *there may be dark areas on either side when imaging the optic disc*).
   a. (Do Not Stop forward movement if a live scan appears in the scan window before you achieve a good IR image of the fundus. Set the working distance first)
9. Hold scanner head still and click on the "Auto All" button if no scan is visible in the scan window. This will optimize the image and should place it in the target area (between the red dashed lines).
   a. Double clicking in the scan window will also activate the "**Auto All**" button and will – in turn – perform the **Auto Z** (Axial length), **Auto F** (Focus) to offset the refractive condition, and **Auto P** (Polarization) to adjust for differences in the device and patient polarizations
   b. If scan is visible somewhere in the window, click once in the scan window and use mouse scroll wheel to bring scan to target area. Then use the **Auto F** and **Auto P** functions to optimize the scan.

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Examine Menu

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10. Adjust scan positioning in the fundus area, visible in the live IR image (if it is not where you wish it to be) by:
    a. Double clicking the mouse cursor in the center of where you want the scan to be done (IR image) OR
    b. Click and hold down on left mouse button with cursor on scan pattern, drag to desired location, and release the left mouse button.
11. Optimize the scan signal strength/ image quality using position (X/Y), Focus or P-Motor. Look for the high GREEN bar on the right side of the live scan window.
12. **For Non – Tracked Scans**
    a. **Capture** scan (by pressing the joystick button) – this is the capture function.
13. **For Tracked Scans**
    a. When acquiring the OCT image with Tracking, start the process as one normally would when scanning with the RTVue. Before starting the scan, the number of averaged scans and scan width can be adjusted in the scanner control Auto tab. The user is also given the option to turn Tracking mode on/off (green dot = on, red dot = off). For more information on the scanner control tab, see section 1.3
    b. Once the scan settings have been specified, make sure the IR image has a clear fundus image. Tracking is tracked by the blood vessels and optic nerve in the IR image, therefore optimizing the IR image is critical, particularly in the nasal region where vessels around the optic disc are most pronounced. It often helps to lower the brightness settings and turn up the contrast in the scanner control ADVANCED tab. There should be good visibility of optic nerve and blood vessels without glare or shadow artifact. The below images give an example of a good and poor IR image.
    c. Once the IR has an acceptable image of the fundus, the capture button will turn green and is ready for capture. When capturing, a small progress bar will indicate tracking progression on the bottom left of the screen, and a crosshair in the IR image will indicate how the current scan location matches with the beginning scan location which will help with monitoring how well the patient is fixating. When the progress bar has finished loading, the capture process will have finished.
    d. If the "checkmark" is GREEN then the system is actively tracking the IR image and you may start the capture process by pressing the joystick button, or clicking on the green checkmark with the mouse cursor.
    e. If the "checkmark" is grayed out, the system is not actively tracking the IR image and the capture function is not available.

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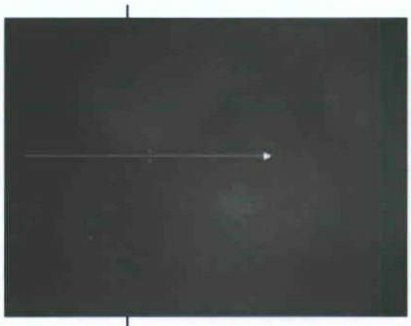
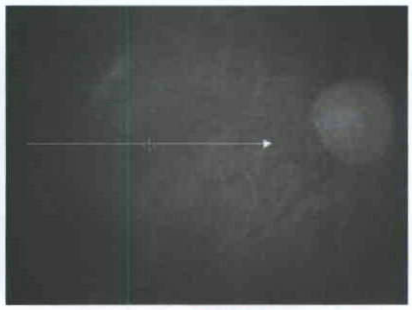
Examine Menu





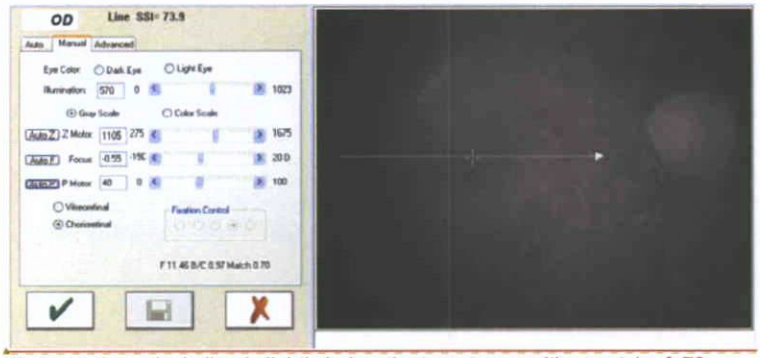
Example of a good IR image *Example of a poor IR image*

14. **Save** the scan.

4.2 Acquiring Scans in Followup Mode

In Follow up Mode, a crosshair will be shown in IR image. Before starting the capture process, the crosshair should be aligned as closely as possible with the scan indicator line as shown in the image below in order to repeat original scan placement.

When aligned within tolerance, the crosshair will turn green and the capture button will also turn green. If the crosshair is not properly aligned with the scan indicator line, the crosshair will be red and the capture button will be grayed out (not available). The patient may not be fixating in the same location as the previous scan and may need to be re-instructed. Alternatively, if a new scan location is desired, then the follow-up mode may be turned off (green dot = ON and red dot = OFF).



1) shows the reticule lined slightly below the target area with a match of .70

4.3 Scan Controls

Button presentation before starting a scan

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Examine Menu

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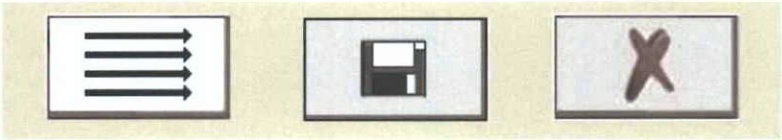
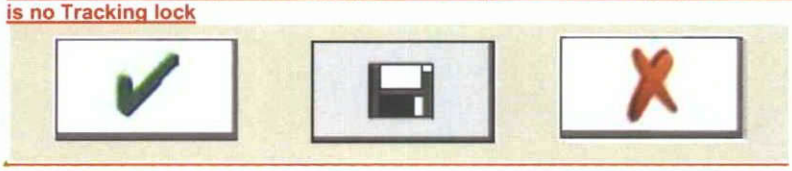


Initiates a scan

Button presentation while in live scanning mode and Tracking lock achieved (on Tracked scans with Tracking option ON only) Checkmark is gray when there is no Tracking lock



Capture/Acquire the data (scan) Cancel/abort scanning

4.4 *Protocols*

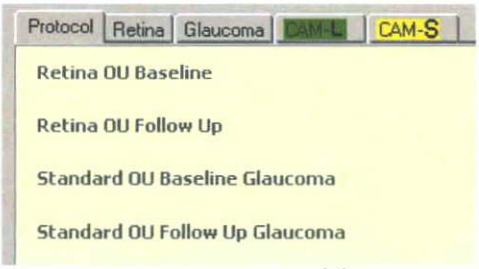
Scan patterns available are organized into two groups based on primary purpose: **Retina** and **Glaucoma**

The **Protocol TAB** is the first TAB (left to right) in the Examine screen. It is recommended that for optimum patient through-put each practice either use the recommended Protocols that are installed with the system, or set up their own protocol based on the practice patient demographics. This will allow a single "selection" for retina or glaucoma patients.

Standard Protocols include OU Baseline and OU Follow-up for both Retina and Glaucoma.

It is recommended that you set up protocols that are based on your patient pathology demographic and practice terminology. For example "Optic disc Analysis", "Retina - First Visit", Glaucoma Follow Up, etc.)

Protocol Tab



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Restart scanning process Save scan¶
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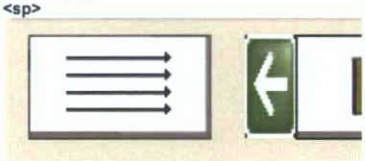

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Button presentation while in live scanning mode ¶
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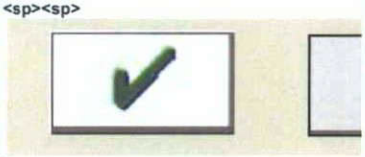

¶
Capture/Acquire the data (scan)
Cancel/abort scanning¶
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Button presentation after acquiring (stopping) scan¶
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Restart scanning process Save scan¶
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Examine Menu

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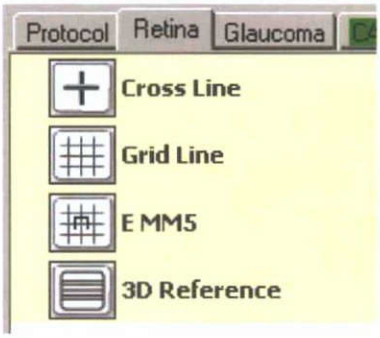
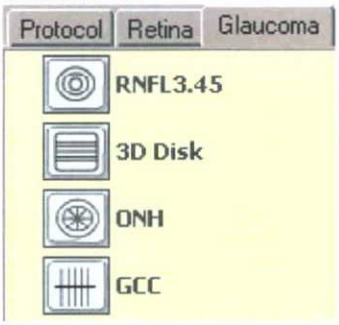
Retina Tab



Glaucoma Tab



NOTE: ONH (Optic Nerve Head) was formerly labeled NHM4

NOTE ON CAM OPTION: If you have the CAM (Cornea-Anterior Module) Option installed on your RTVue XR, you will have additional tabs in the Examine View screen. Please refer to the CAM Option User Manual for detailed explanation of the use of the CAM Option for the RTVue XR system.

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4.5 Selecting a Patient to be examined:

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Examine Menu

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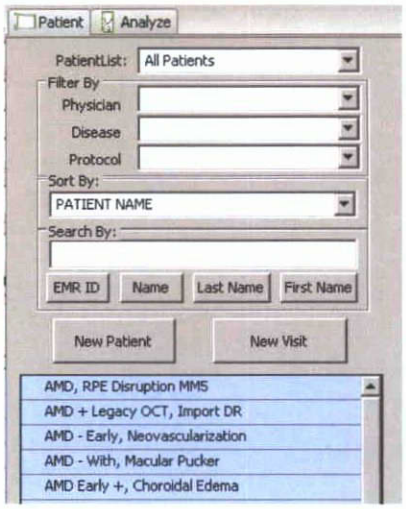
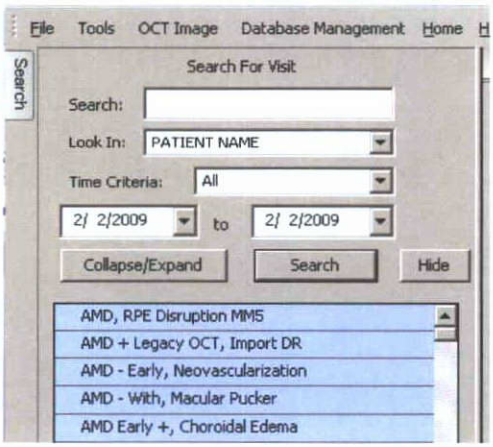
There are two ways to select a patient for examination:

1. Select Patient from Patient Menu using either the [Patient Name] to sort alphabetically, or [Last Visit Date] to display from most recent to oldest visit in database.

2. Use the <Search> tab in the Examine Menu. To exit the Search window, click anywhere outside the window.



Search Window



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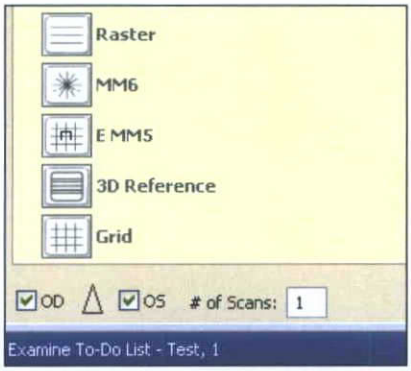
4.6 Scan List:

The scan list shows the scans to be performed in the current visit.

1. Select the scan pattern from the upper window or a scan protocol (click on the <Exam Protocol> tab to bring up the scan protocol window).
   a. A single click on the scan pattern will "load" the scan in the exam list window.
2. OD and OS are checked by default.
3. If you wish to scan any particular pattern more than once, you will need to select how many times each set of scans will be performed first.



1). Select scan pattern with single click to "load" into the "To Do List".

2). Select number of times (if more than one) each scan will be performed BEFORE selecting the specific scan.

OD, OS, checked by default

Examine To-Do List - Test, 1

Scan Type	Eye	Repeat
✔ ◉ Line	OD	1
✔ ◉ Cross Line	OD	1
✔ ◉ E MM5	OD	1
✔ ◉ GCC	OD	1
☐ ○ 3D Disk	OD	1
☐ ○ ONH	OD	1

An empty green circle indicates that the single scan has not been completed. A solid green circle indicates that the scan is complete.

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4.7 Scanner Control Tabs

The default GUI setting will present two tabs during the Examination process (**Auto** and **Manual**).

4.7.1 Auto Tab

The Auto Tab contains only the minimum function buttons to enable automated acquisition of optimized scans with minimum actions from the user.

a. Light & Dark Eye Buttons: Accesses the Brightness and Contrast default settings for each affecting the live IR image

b. Illumination Control Buttons: Reduces or increases the IR illumination for the live IR image viewing.

c. Grayscale / Color live scan Buttons: Select the viewing preference for the live OCT scan in the upper window (if different from default setting). NOTE: Default presentation of color or Grayscale can be set in the [OCT Image>Scan Parameter Setting] window.

d. Auto All: this button initiates the all of the automatic functions of the Auto Z, Auto F and Auto P buttons to optimize the scan.

e. Auto Z: Automatic adjustment for the Axial length

f. Auto F: automatic adjustment for the refractive state

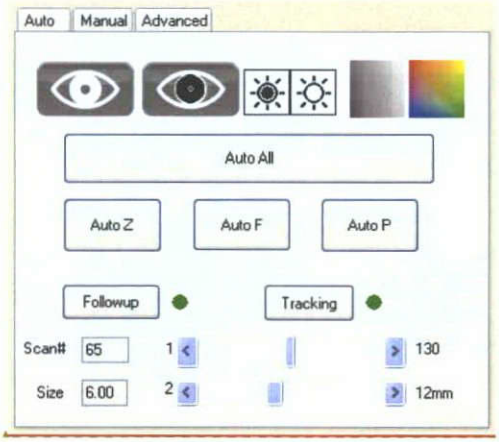
g. Auto P: Automatic adjustment for polarization

h. Followup ON / OFF Button

i. Tracking ON / OFF Button

j. Scan # slider (number of scans to collect for averaging)

k. Size slider (set length of scan line)



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Examine Menu

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4.7.1.1 Use of Auto Tab Controls.

1. Set the number of scans to collect for averaging and the length of scan you want to use.
   a. If this is a follow up scan to a previous tracked scan, the scan length will be grayed out as the value will match the previous line scan for that eye
   b. After aligning on the pupil and moving the scan head forward through the pupil (IR image) to achieve a view of the fundus, Hold scanner head still and if there is no scan visible in the live window click on the "Auto All" button. (You may also Double-click anywhere in any of the live scan windows to activate the "Auto All" function (one to four scan windows appear depending on the scan type).

2. After aligning the pupil and moving the scan head forward to achieve a view of the fundus in the IR image window activate the Auto All function.
   a. NOTE: You only need to use the Auto buttons for the first scan taken on the first visit. After the first scan is optimized and captured, the same settings should be used for all subsequent scan for that visit. The system will store the settings for that patient (each eye) for any follow-up visits.

3. Double clicking in the scan window will also activate the "Auto All" button and will – in turn – perform the Auto Z (Axial length), Auto F (Focus) to offset the refractive condition, and Auto P (Polarization) to adjust for differences in the device and patient polarizations

4. If scan is visible in the window, click once in the scan window and use mouse scroll wheel to bring scan to target area. Then use the Auto F and Auto P functions to optimize the scan.

The **Auto Average** button will appear after the scan is complete – only if the scan pattern is one that uses the Averaging function. The **Manual Average** button will also appear in the **Manual** Tab

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<#>Light & Dark Eye Buttons: Accesses the Brightness and Contrast default settings for each affecting the live IR image¶
<#>Illumination Control Buttons: Reduces or increases the IR illumination for the live IR image viewing.¶
<#>Grayscale / Color live scan Buttons: Select the viewing preference for the live OCT scan in the upper window (if different from default setting). NOTE: Default presentation of color or Grayscale can be set in the [OCT Image>Scan Parameter Setting] window.¶
<#>Auto All: this button initiates the all of the automatic functions of the Auto Z, Auto F and Auto P buttons to optimize the scan.¶
<#>Auto Z: Automatic adjustment for the Axial length¶
<#>Auto F: automatic adjustment for the refractive state¶
<#>Auto P: Automatic adjustment for polarization¶
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4.7.2 Tracking Feature

The RTVue XR has tracking as a standard feature. Tracking consists of moving the scan beam, based on image alignment techniques, to scan approximately the same part of the eye in the event a patient blinks or if their eye moves away from the fixation target. Tracking allows collection of a higher number of usable scans in approximately the same area which may provide sharper images. This allows users to scan patients who have trouble fixating at the fixation target or patients who cannot avoid blinking during the scan capture process. Furthermore, the operators have the ability to turn tracking on or off as deemed necessary. Thus, tracking provides operators with more control in the scan acquisition process.

RTVue also provides a Follow up mode for follow up visits. Follow up mode consists of adjusting the scan beam based on image alignment to begin scanning approximately the same part of the eye that was scanned in the previous visit even in the event the patient does not maintain same fixation

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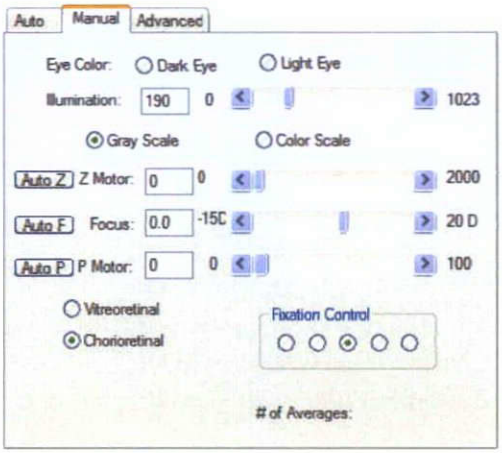
from one visit to next. This feature can be turned on or off as deemed necessary.

Tracking is available for the following scans: **Line, Cross Line, Raster, and Grid Line.** In the tracking software release, the scan acquistion behavior in RTVue is changed. As opposed to clicking the capture button to end the scan, the new software works by clicking the capture button to start the scan. This behavior applies to all scans regardless if Tracking is turned on or off.

4.7.3 Manual Tab

The Manual Tab contains the slider controls to manually adjust the Z, Focus and Polarization directly, as well as manual controls for the other step control buttons on the Auto Tab



4.7.3.1 Use of Manual Tab Controls

1. **Eye Color**: Select dark or light according to patient iris color to optimize the illumination, brightness, and contrast settings for IR image. The individual Brightness and Contract adjustment are in the Advanced Tab.
   a. If neither eye color is selected, then the default settings are the average of the respective values of illumination, brightness, and contrast for the dark and light eye.
2. **Illumination**: Adjusts the IR illumination for the IR video image. Level is set by selecting Eye Color, but may be adjusted separately to attain best image.
3. **Grey Scale /Color Scale:** Toggles live OCT image in gray-scale or color.
4. **Z Motor / Auto:** position adjustment: Click on the OCT image window, then use thumb wheel on the mouse to adjust Z-position. Double clicking

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on the OCT image window will auto-search Z position. This is the same as clicking on the "Auto" button next to the Z Motor.

5. **Focus** adjustment: Use to focus OCT and video image resulting in a sharper image. Use the slider control to fine tune the focus of the IR image and Signal strength of the OCT scan.
6. **P Motor:** Polarization adjustment to optimize the OCT image signal strength resulting in a clearer image.
7. **Vitreoretinal / Chorioretinal:** Setting are programmed based on scan design to enhance either the information above the RPE (Vitreoretinal), or the choroid and overall information (Chorioretinal)
   a. **Vitreoretinal:** This setting puts the highest signal strength at the top of the scan window and results in higher signal strength in the inner retina layers (RPE through ILM and vitreous)
   b. **Chorioretinal:** This setting puts the highest signal strength at the bottom of the screen, resulting in a stronger signal - and better visualization of the choroid.
8. **Fixation Control:** Use to change preferred fixation location (if other than default setting) for patient to focus on. There are five fixation settings.
9. **Process Average:** For the **Line** scan, **Cross Line** scan, **Raster** scan, and **Grid** scan, you have the option of averaging the multiple scans to achieve and final "averaged" image. This process is used to reduce the noise of the OCT image and provide a speckle less B-scan result. Eye or operator motion may limit the number of frames that can be used in this process. Quick eye motion may also smear the OCT image and reduce the quality.

4.8 Advanced Tab Controls: (Recommended for Advanced Users only)

This tab is hidden as the default setting

1. **OCT Image Noise:** Adjusts the noise level of OCT for best visualization of retina tissue. The default value is "3". *This should not be changed other than by an expert user.*
2. **Scan Length:** To adjust the scan length with the center of scan fixed.
3. **Scan Width:** To adjust the width of a raster scan. The number of raster scan lines will be equally spaced in the width of scan pattern selected.
4. **Scan Angle:** To rotate the scan around the center of the scan. Use slider to rotate the scan or click on the scan graphic in the IR window and use the mouse wheel to rotate the scan direction.
5. **Video Brightness:** Controls the brightness of the Video image only (not the OCT scan)
6. **Video Contrast:** Controls the amount of contrast or shading between areas in the Video Image only (not the OCT scan)

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7. **XY Offset:** The arrow keys can be used to move the scan pattern around in the IR image in very small steps. Below are the two most common ways to position the scan in the desired location:
   a. Click and hold down the left mouse button on the scan graphic in the live video image and slowly drag the scan pattern to desired location.
   b. Double click the mouse cursor in the center of ***where you want the scan to be.*** The scan pattern will shift and center on the spot you selected. (Recommended method).

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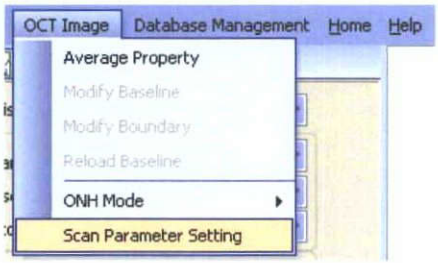
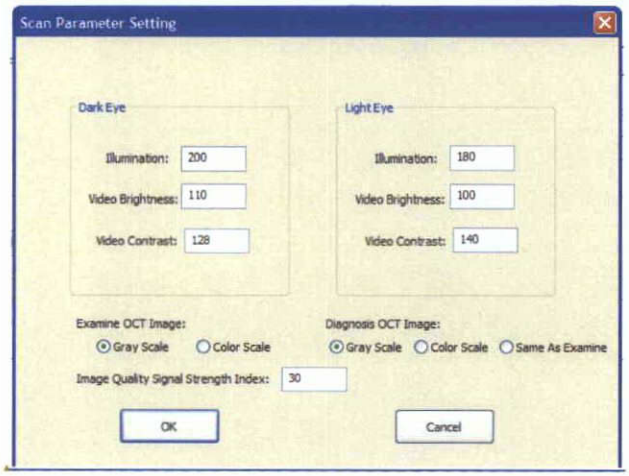
4.9 Setting the Image control default

The Scan Parameter Setting menu can be found by clicking the OCT Image menu.



The user may now set a different default live scan view mode between the Examine and the Review sessions. The view can be individually set for either Grayscale or Color presentation of the live scan. Go to **Scan Parameter Setting** under the **OCT Image** menu



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Examine Menu

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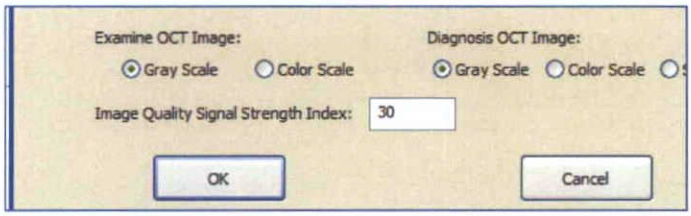


NOTE: Setting for "**Image Quality Signal Strength Index**" should not be changed by other than Research site users with prior approval from Optovue personnel.

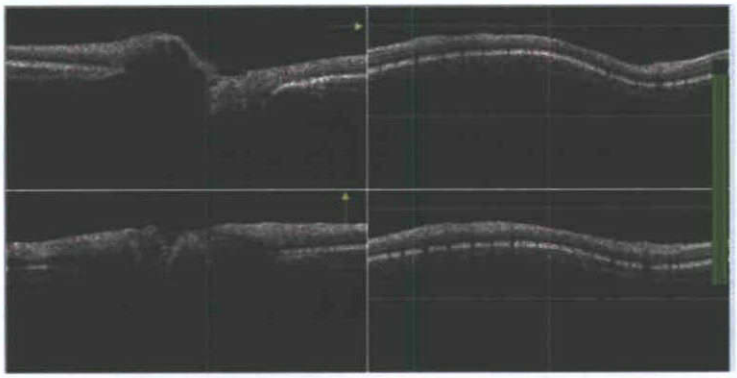
4.10 Correct Alignment of live OCT image

In all scan patterns, you will see one or more pairs of parallel red dashed lines. Some scans may have as many as four "live scan" windows with the target zone parallel lines. In any scan, the optimum placement of the live scan is between the red dashed lines. If the lines are horizontal, the scan should be in the upper part of the target area. (3D disc scan will have some of the scan image fall below the lower line; this is OK)

In the case of vertical red dashed lines (such as in the ONH), the physiology targeted should be between the two parallel lines. (See below)

If you select a different scan mode (Vitreoretinal / Chorioretinal) than the default setting, the location of the red dashed lines will shift to the top or the bottom of the screen, depending on where the default position is.

Below is an example of the correct ONH scan alignment.



1. Place Choroid endpoints (RPE tips) (Red arrow) between two vertical guide lines
2. Place circular scan between two horizontal guide lines

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In this version, a vertical line is provided in the center of "live scan" windows as well to aid centering of the scan.

NOTE: Live scans for all patterns are to be placed between the red dashed "target zone" lines. Target zone may be near the top or the bottom of the live scan window depending upon the **Vitreoretinal** or **Chorioretinal** setting.

4.11 Averaging (Auto and Manual)

Automatic Averaging will take place immediately after capturing a **Line, Cross Line, Raster** or **Grid** scan. This is a noise-reduction function to reduce the amount of speckle noise in the image. A Speckle less B-scan is presented as a result of this noise reduction function.

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¶
To obtain the final averaged image in either the Line or Cross Line scans:¶
<#>Move the rectangle(s) on or over the region of interest ¶
<#>Then click **OK** in the message box.¶
¶
The rectangles may be adjusted to any size in order to encompass the area of primary interest. You may repeat the "Process Average" function as many times as you wish using any of the scans as the averaging basis. ¶
<#>Click on any image from the individual scans at the left side of the screen to see it in the large window. Place the rectangle and click on the **Process Average** button. ¶
¶
NOTE: Larger ROI coverage may sometimes produce better results, however increasing the box size also increases the processing time.¶

4.12 Reviewing Scan Images:

After stopping the scan, the window will automatically bring up a list of thumbnail images. Click on any thumbnail image to display that scan in the working window. The window can be closed with the Microsoft Windows "Close" (X box) icon on the upper right hand corner.

RTVue XR utilizes two 3D scan patterns to produce an SLO type image for registration purposes. Providing vessel registration and optic disc centering for orientation and serial registration, these scans produce the baseline image that enables real change analysis of both retina diseases and glaucoma.

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Higher measurement precision due to registration:
Registration of images increases the repeatability and of measurements between visits. With the new registration feature, the average improvement for vessel registration is 1.2 microns.

For the EMM5, the average full retinal thickness 95% repeatability estimate is 4.5 microns. For the ONH scan, the average RNFL thickness 95% repeatability estimate is 10 microns.

A. 3D Reference (for EMM5 registration – retina diseases)

This scan produces an SLO like reference image of 7mm x 7mm (7,000 x 7,000 microns on the macula). This scan utilizes an "En Face" perspective to produce a high contrast grayscale image of the retina surface detail. This En face image is used as the reference and registration image for the EMM5 macular map (explained later in this section) based on vessel tracing.

Note: This feature is eliminated since it's no longer being used

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Examine Menu

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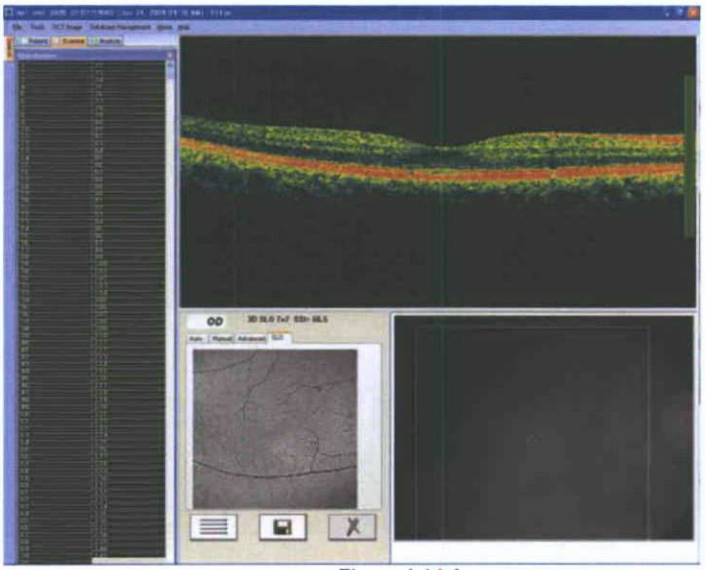

Figure 4.14 A

- Resulting SLO type reference image for EMM5 registration

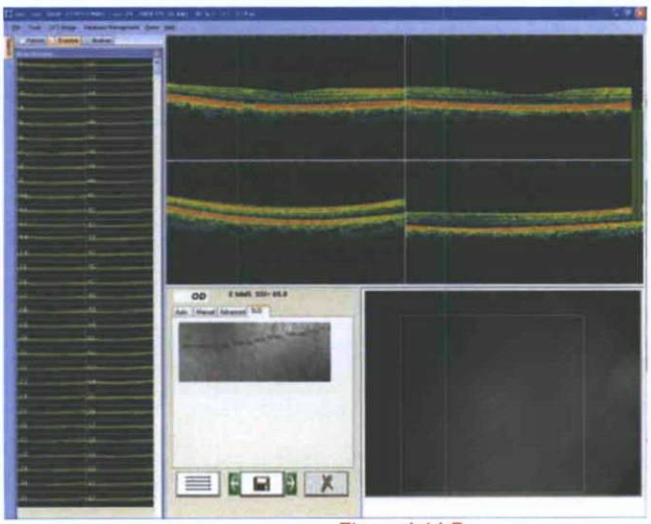

Figure 4.14 B

EMM5 scan pattern contains a sampling raster, offset from the mapping grid in order to capture a vessel tracing for registration purposes.

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Possible instances in which rescanning may be required to establish a new reference and baseline scan:

A new reference image may be desirable in the event of the vessel changing (orientation) or moving, due to disease progression or surgical intervention. EMM5 scans from that point on would use the newer reference image; however the mapping scans that existed prior to the new reference being established will remain registered to the original reference image.

B. ***Reference Image for ONH Map (Glaucoma)***

For serial registration of the ONH (Optic Nerve Head) scan for glaucoma, the 3D Disc scan is used to create a baseline SLO type image. The ONH scan pattern produces vessel tracing patterns that are matched to the vessels in the SLO en face result of the 3D Disc.

Image for vessel registration

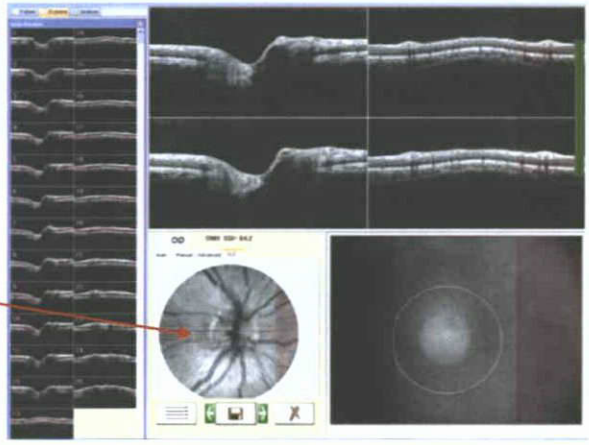

Figure 4.14 C

The 3D Disc scan result also provides the detail for the automatic tracing of the disc boundary (disc margin). This provides the disc margin shape and exact center of the disc, each of which is used along with the vessel tracing for serial registration of data and change analysis.

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Auto-detection of disc margin

Verification of accuracy (Choroid endpoints / RPE Tips)

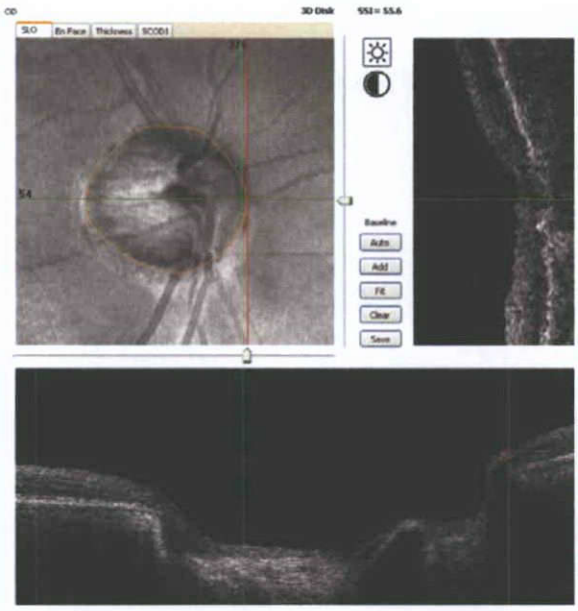

Figure 4.14.D

The option "Auto detect 3D baseline while saving scan" is located in User preference: This can be set to "Yes" (default) or "No". When the selection is "Yes," disk boundary is auto drawn while 3D disk scan is being saved. When "No" is selected however, auto drawing of optic disk is skipped when it is saved. Instead it takes place when 3D disk scan is opened in analysis mode.
When "No" is selected in above option, it is recommended that 3D disk scan is always opened first in analysis mode, during with the auto drawing of disk will take place. Due to this, it may take a few seconds longer to open the 3D disk scan compared to if opened with disk already drawn (during scan save).

If ONH scan is analyzed prior to analyzing 3D disk, following window appears.

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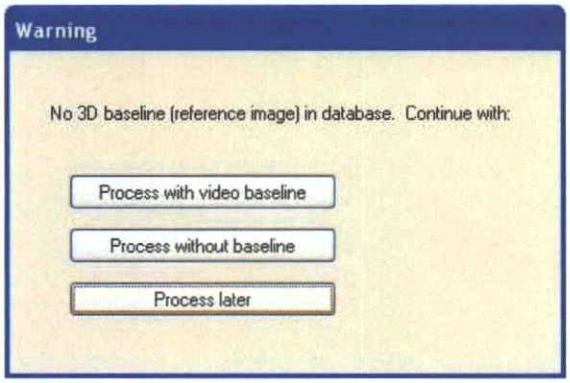

"Process later" option is recommended, which will act as a "cancel" function. Then 3D disk scan should be opened and analyzed. At this point the auto-drawn disk boundary can be modified in needed. "Save" button needs to be clicked to save the boundary if any changes to the auto-drawn boundary are made. If no changes are made, then leaving the 3D disk scan automatically saves the disk boundary.

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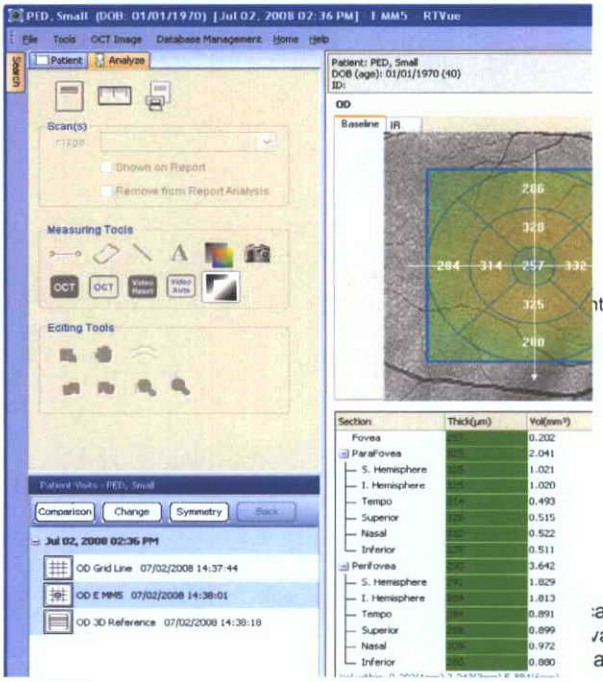
5 Analyze Menu

5.1 Analyze Layout



Report form window (Analyze report)

:ans results list
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Figure 5.1

1. **Report** Form View: The default Analysis Report view (This is also the Print Preview form) with analysis results
2. **Measurement View**: Activates the view and tools for manual measurement on the OCT images and the presentation ratio. (Right Click Options)
3. **Print**: Send the current screen to the printer (any Window's compatible printer)
4. **Measurement Tools/ Image Enhancement:** The measurement tools become available when in Measurement View, including the appropriate tools for the CAM Option (Cornea-Anterior Module). The image enhancement tools for the OCT scan (increase or reduce background noise) and IR image (contracting).
5. **Image viewing tools:** remove tracing lines, zoom, area of interest selection and Undo/Redo
6. **Scan Results List:** All scans performed during the selected visit are listed below the Exam Date
7. All presentations (Analysis and Measurement views) appear in the window to the right of the controls

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Analyze Menu

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5.1.1 Analyze List

After selecting the patient, a list of scan records will appear under the tool window. Click a particular scan pattern to show the results in the report window.

NOTE: Depending on the type of scan, it will sometimes take 5 to 15 seconds for the to the measurement result to appear the first time the scan data is selected. (This is due to calculation time). After the first time, the calculated (processed) data is stored and subsequent viewing will open in less time.

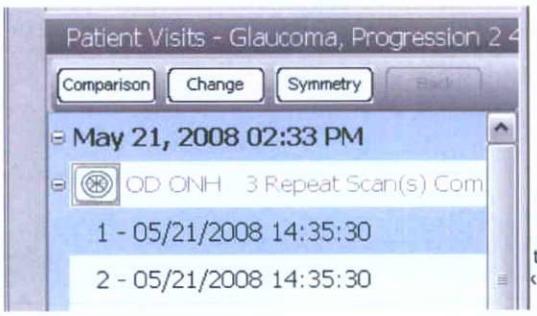
5.1.2 Diagnosis Data Input Field

At the bottom of the Report screen is a textbox labeled "Diagnosis". Any text entered here will be saved automatically when you exit the Analyze menu, whether you move to another window or exit the application entirely. This information is specific to the scan; it will not be displayed in other scans or visits from this patient.

5.1.3 Change / Symmetry / Comparison Analysis

If there are eligible scans available in the patient visit history, the related **Change** and/or **Symmetry and Comparison** options will be available. Click the button to activate the additional analysis.

Click to list scans that may be used in Change overview with the current scan.



to the default report
k "BACK"

Note on Change Analysis: Up to six (6) ONH scans, four (4) GCC scans or four (4) EMM5 Retina scans may be included in the Change report.

If the patient history contains six visits or less, all visits will be automatically selected and the report generated automatically for presentation

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Analyze Menu

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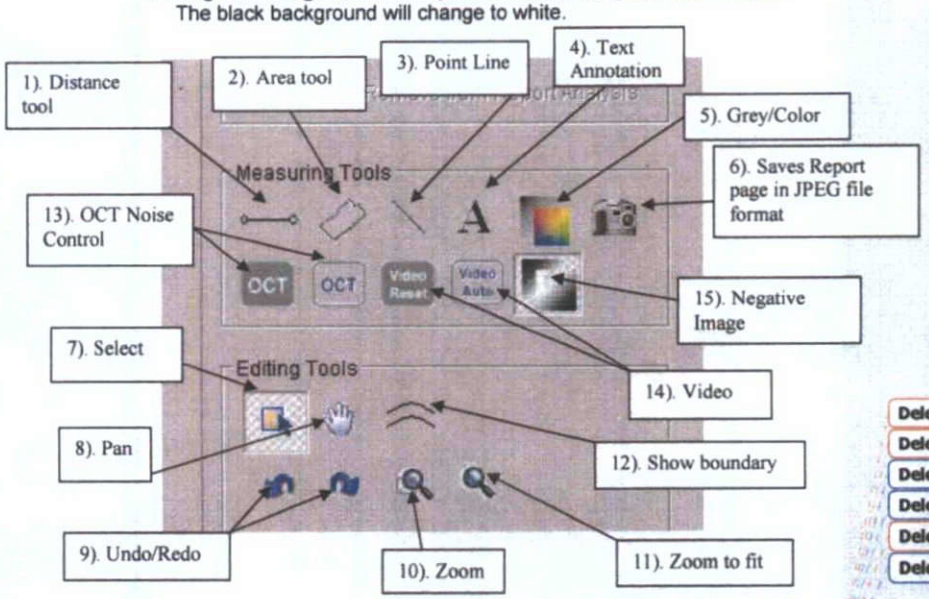
5.2 Measurement

Measurement tools are accessed by clicking the icon.

5.2.1 Tools:

1. **Distance tool**: Measures the distance between two points.
2. **Area tool**: Measures the area of a polygonal area.
3. **Point Line**: Draws a line between two points.
4. **Text Annotation**: Add text to images.
5. **Grey/Color**: Toggles scan display from gray-scale and pseudo-color.
6. **Snapshot**: Saves the Report Page in .jpg format. File name has default but is user editable. User defined destination
7. **Select**: Click to deselect the tool in use.
8. **Pan**: Moves the OCT image around in window.
9. **Undo/Redo**: Return to previous or prior state before/after an action.
10. **Zoom**: Zooms in or out of the OCT image. (No interpolation)
11. **Zoom to fit**: Fits all scans in the scan pattern into the window.
12. **Show boundary**: Display/remove boundary on the OCT image.
13. **OCT noise**: Increase (white) and reduce (gray) OCT noise level.
14. **Video**: Brighten (white) and reset (Grey) video image contrast.
15. **Negative Image**: inverts the presentation of the gray scale images. The black background will change to white.



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5.2.2 *Using Manual Measurement*

To make a manual measurement, first select the tool, and then make the desired measurement on the selected OCT image. Next, select an initial or "anchor" point and then proceed to the second endpoint (linear measurement or arrow) or the next in a series (area measurement).

Right clicking on the measurement will show the properties of the tool.

NOTE:

- You can select the **Snapshot Tool (camera icon)** to export a .jpg of the Measurement report screen.
- You may select the **Print** option to print a copy of the Measurement report screen with the practice and patient information header.

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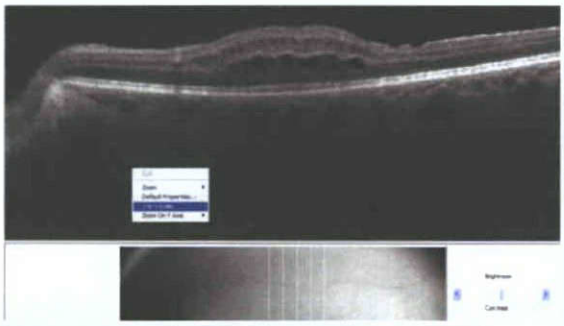
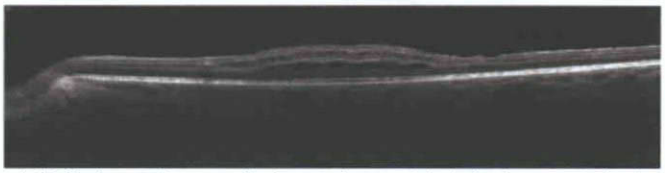
5.2.3 OCT Scan Selection

Above the Measuring Tools, there is a drop-down menu labeled "**Scans**". If the scan pattern performed had more than one image, the *different scan images are available for viewing by selecting from the drop-down menu.*

When evaluating a specific scan in the measurement view, you now have the option of showing the scan in a 1:1 ratio and altering the Y-axis display





1:1 Display option results (scan shown at 1:1 pixel presentation)
Analyze View – Retina Reports

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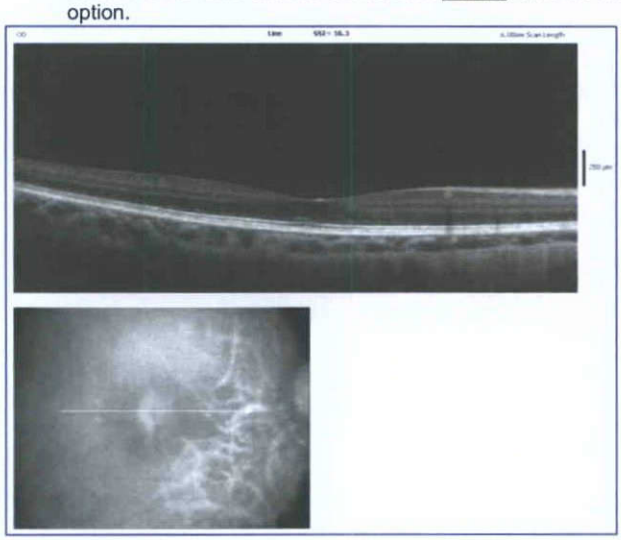
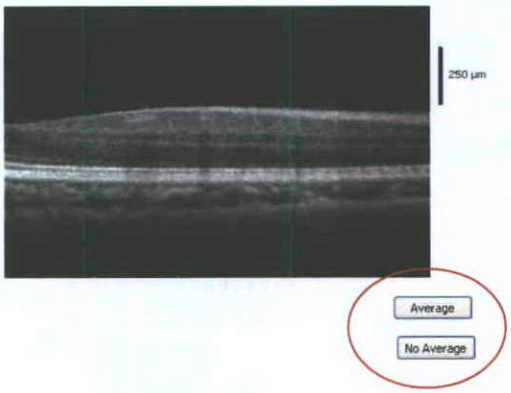
5.2.4 Line

If you used the Averaging option prior to saving the Line (or Cross Line) scan, both the Average and last single B-scan image are saved and available for review in the Analyze view.

Note: The **HD Line** and **HD Cross Line** do not have the average option.



Click on the [**Average**] or [**No Average**] button to select which image will be displayed.



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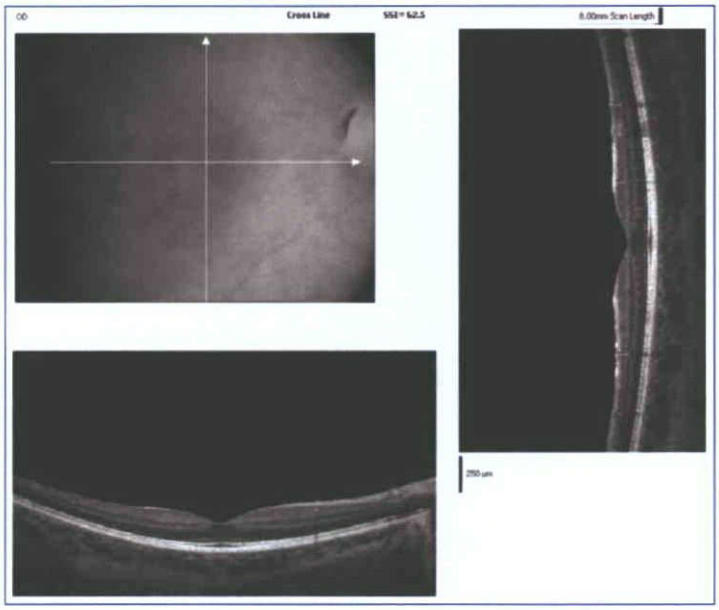
5.2.5 Cross Line



The Cross Line results are shown with the scan orientation aligned to the direction the scan was taken.

Presentation is either with **Average** or **No Average** as with the line scan.

5.2.6 Grid

Grid scan shows the exact scan location of five horizontal and five vertical scans in the grid. When this scan is captured upon capturing a 3D Reference scan, it uses registration from 3D Reference and applies a patch in this scan to show ten grid lines (five horizontal and five vertical) on the reference SLO style image to show the exact location of the scans taken.

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Analyze Menu

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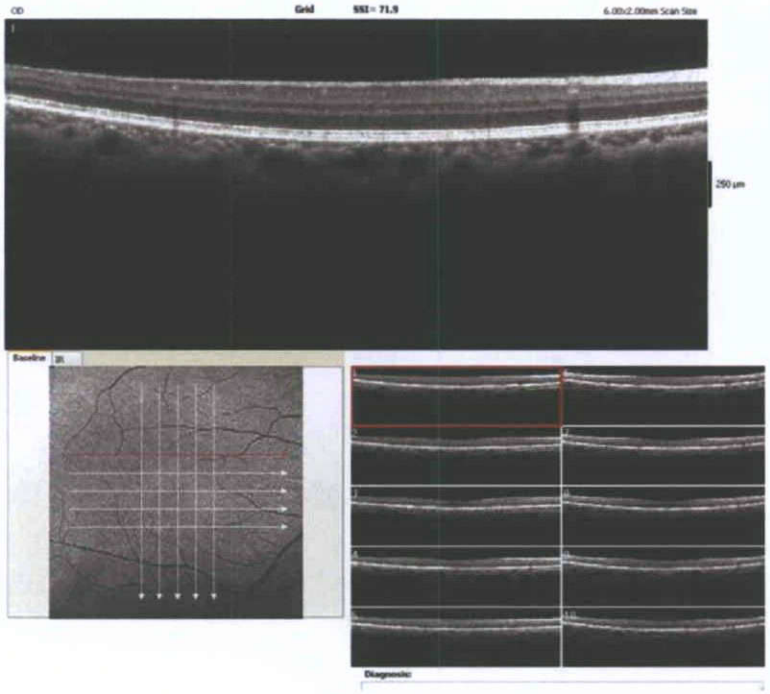

Above image shows the Grid scan in analysis mode. Note the grid lines on the reference SLO style image in Baseline Tab at the bottom left corner of the image. Mouse wheel or arrow keys can be used to scroll through each of ten scans. The red rectangle around the thumbnail of a scan denotes the scan that you're currently looking at in the large window above it. Also the appropriate grid line color changes to red as you're scrolling through the scans.

Right clicking the SLO style image and then selecting "Patch On" allows you to see the patch and how well the vessels in the patch align with vessels seen on the reference SLO style image. While the algorithms do the aligning with a very high success rate, the patch can be moved manually to align vessels on the patch and on the SLO style image. Grid lines will move with the patch giving the exact location of scans taken. See the image below. Proper alignment of the vessels on the patch with those of in the SLO style image are denoted by green color. Any misalignment is denoted by yellow.

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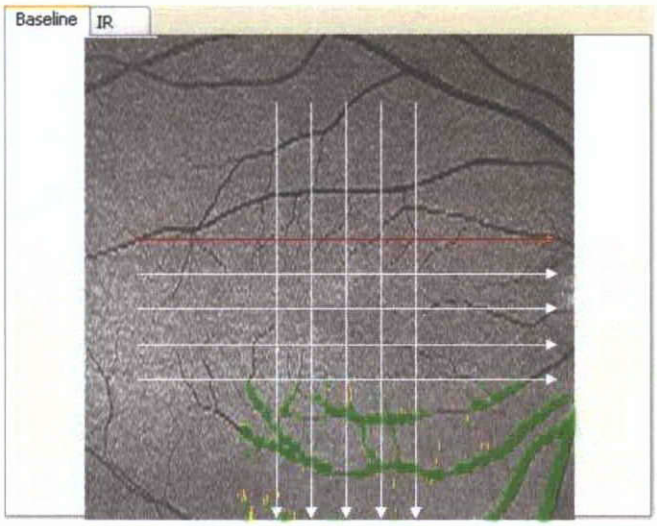

5.2.7 EMM5 Analysis Report

The EMM5 scan is registered to a reference SLO style image created by the new 3D Reference image scan. (3D Reference must exist)

The EMM5 includes a raster sampling that is acquired in the middle of the EMM5 scan (horizontal line scans – raster sample scans – vertical line scans) in an area inferior and nasal from the EMM5 scans.

This allows the sampling to capture the larger vessels lying inferior to the optic disc and use this "vessel tracing" to register to the SLO reference image.

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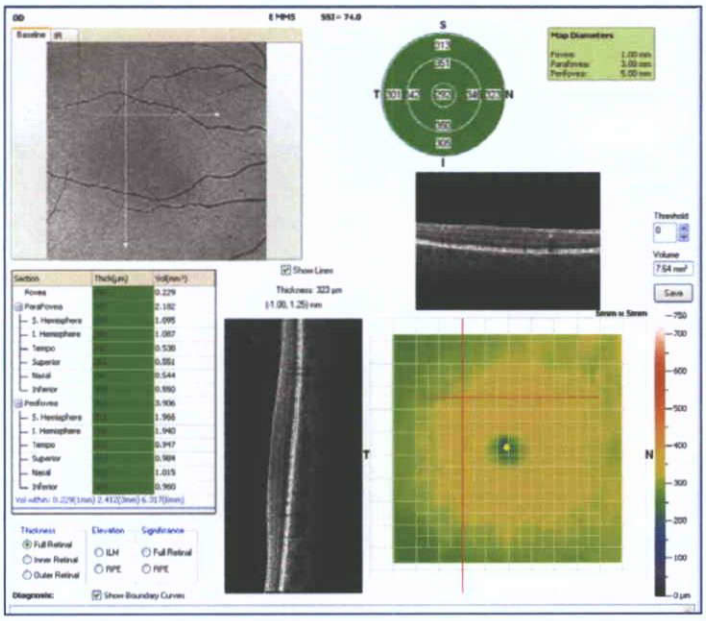

- The scan display control is active when the reference lines are Blue, and Locked when they are Red (single click will change the state from the map only)
- Macular thickness values (red circle), and retinal cross sectional images can be seen by moving the mouse cursor around the macular color-coded map. These will update while the display control is unlocked (lines are blue), and lock when the display controls are locked.
- The grid shows the EMM5 scan pattern (available scans indicated in white). The horizontal and vertical cross section image will be displayed corresponding to the color highlighted scan lines. The thickness and coordinates at the tip of the cursor are displayed in the center area of the page.

The mapping presentations for **Thickness, Elevation** and **Significance** are selectable at the bottom left of the report.

- **Full Retinal** Thickness measured from VRI to RPE layer.
- **Inner Retinal** Thickness measured from VRI to IPL.
- **Outer Retinal** Thickness measured from the RPE layer to the IPL
- **RPE** and **ILM Elevation**: show the height of the RPE or ILM relative to a reference plane. The reference plane is the best elliptical fit to the RPE boundary.

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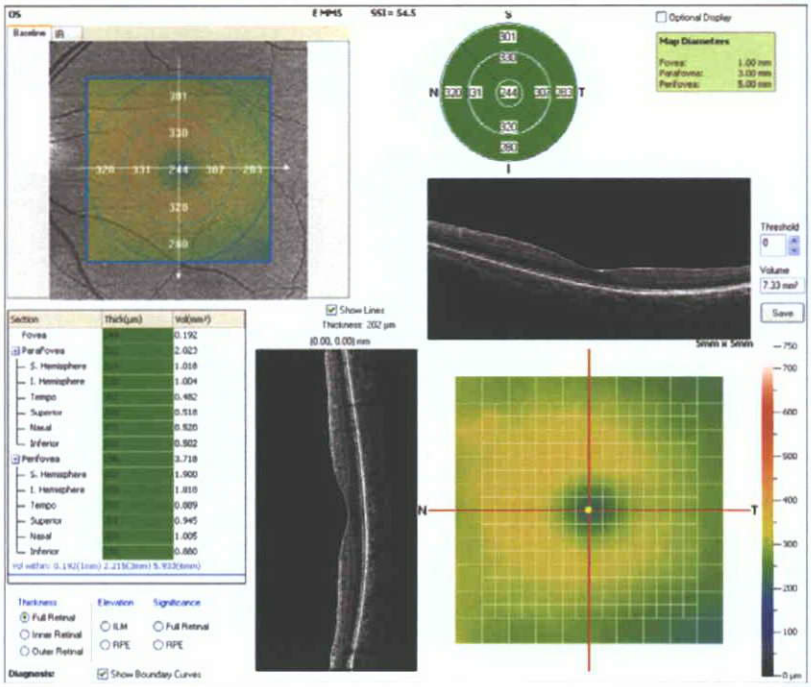

- The thickness map is further organized and presented at the top right in the nine ETDRS-like zones. (Based on the original four macular regions as defined in "***Stereoscopic Altas of Macular Diseases diagnosis and treatment", J. Donald M. Gass, Mosby, 3rd edition, volume 1, P3***.

Factors that can affect the Signal Strength Index (SSI):
EMM5 scan pattern not centered on the fovea: During the EMM5 scan, if the patient does not maintain good fixation, the fovea may not be in the center of the scan pattern. All measurements assume the fovea is in the center of the scan. If it is not, then the measurements will be affected. If the fovea is not in the center of the scan, it can be moved by the user manually. This will ensure the measurements come from the expected locations. The results should not be used if the repositioned fovea causes some measurement areas to be outside the scan pattern.

Check the layer segmentation accuracy of the EMM5 scan: The segmented layers for EMM5 scans are the ILM (Inner Limiting Membrane), IPL (Inner Plexiform Layer), and RPE (Retinal Pigment Epithelium). Check the segmentation lines for accuracy, and make

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adjustments as necessary. The ILM segmentation line should be at the retinal surface at the ILM. The IPL segmentation line should be at the bottom of the IPL layer. The RPE segmentation line should be in the middle of the RPE layer. If the segmentation lines are not accurately placed, the thickness measurements will be affected. If the user performs any manual correction, the results will be valid and the scan can be used.

Overall precision results with the EMM5 scan for normal, retina patients, and glaucoma patients:

EMM5 Full Retina Volume			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	0.63 (0.03)	0.64 (0.07)	103.02 (12.22)
Repeatability SD* (Min, Max)	0.003(0.002, 0.006)	0.004(0.002, 0.010)	2.40(1.78, 2.87)
Reproducibility SD** (Min, Max)	0.005(0.003, 0.015)	0.007(0.003, 0.011)	2.53(1.78, 3.52)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

EMM5 Full Retina Fovea			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	243.61 (26.00)	267.15 (73.32)	246.22 (22.14)
Repeatability SD* (Min, Max)	2.57(1.66, 2.57)	2.96(1.83, 3.15)	3.01(1.95, 3.01)
Reproducibility SD** (Min, Max)	17.72(1.66, 17.72)	13.78(1.83, 13.78)	3.01(2.05, 5.80)

EMM5 Inner Retina TSNI			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	112.83 (9.16)	113.04 (15.05)	103.02 (12.22)
Repeatability SD* (Min, Max)	1.38(0.88, 1.72)	2.52(1.57, 3.12)	2.40(1.78, 2.87)
Reproducibility SD** (Min, Max)	1.70(0.88, 7.09)	3.02(1.57, 6.59)	2.53(1.78, 3.52)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

For details on the clinical study and the clinical precision for RTVue scan measurements (repeatability, reproducibility), study information is available in the Appendix B–RTVue Precision

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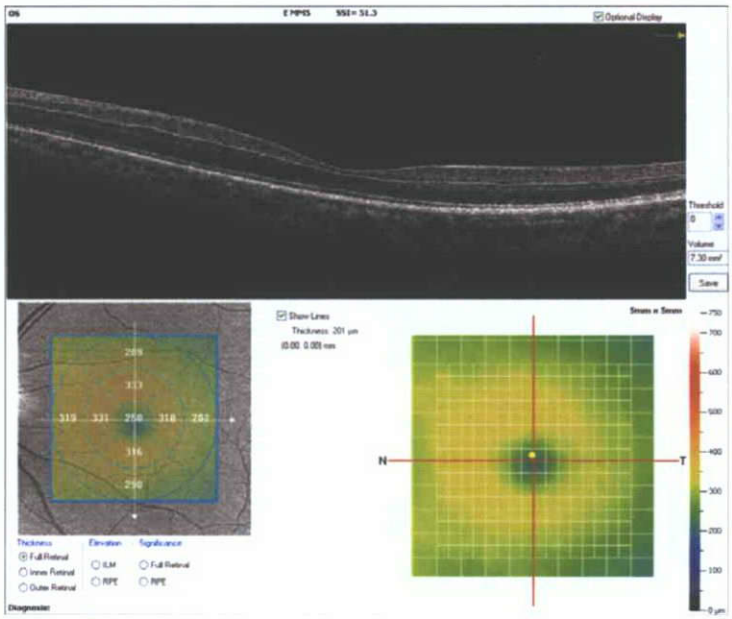
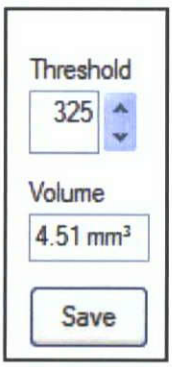
5.2.8 Alternate EMM5 Report / Printout



The check box at the top of the EMM5 report will bring up the alternative presentation of a single large representative scan and the correlating location on both the thickness map and the SLO reference image.

5.3 Volume Contouring and Measurements



- User can define a threshold level (numerical value – microns) for edema or elevated pathologies, and the map will trace a contour around all tissue exceeding the value entered.

- The Total Volume of the tissue exceeding the threshold is displayed real-time in the Volume field.

- This threshold, Volume and segment (Full, Inner or Outer) can be saved by selecting the [Save] button. Information is added to the table at the left of the report display.

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- Total volume exceeding the threshold value is outlined by contour tracing

(EMM5 Thickness Map – Without scan line indicators)

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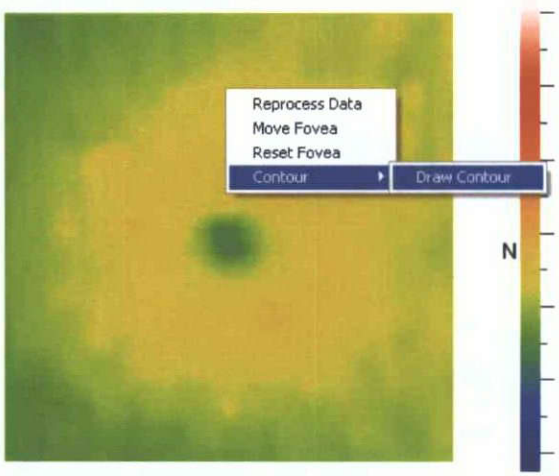
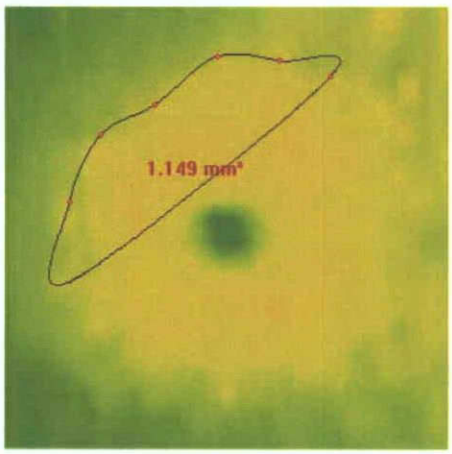
5.4.3.1 Custom Drawn Volume Contouring

You may also freehand draw the outline of a specific area on the map and the resulting volume will be displayed also real-time.

- Right-click on the map and select Contour>Draw contour





- Use the left mouse button to click on points around the area you are interested in.
- Contour line is black and active while drawing. Resulting volume is rendered real-time as you go.
- Double click on the last point to end the drawing and post the final shape and volume. Contour will turn Red to confirm final form.

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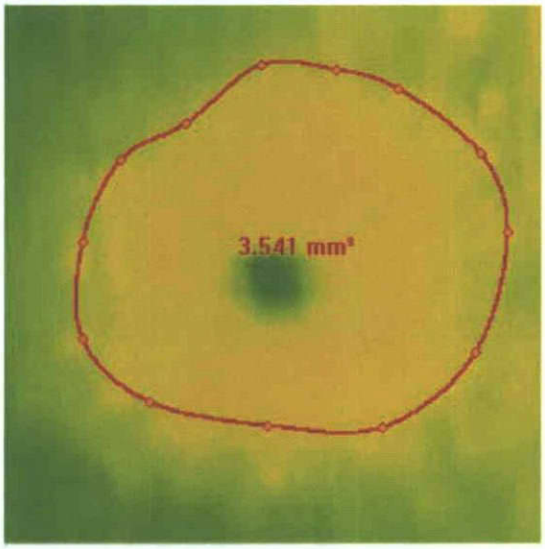

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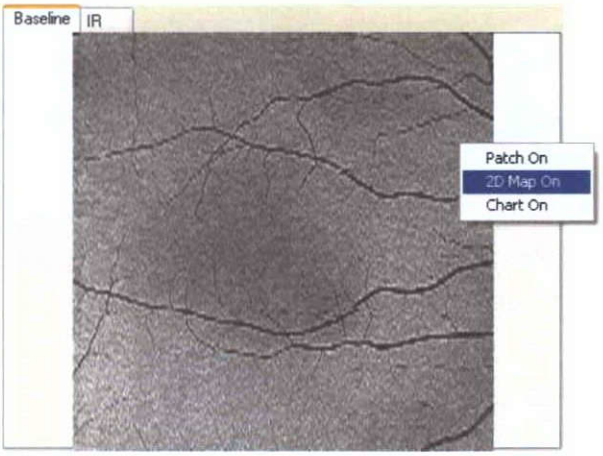
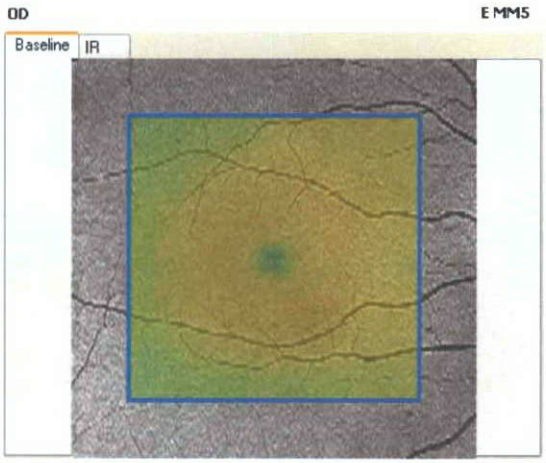
5.4 Overlay Options for Reference Fundus Image

- In the Reference image in the upper left of the EMM5 report screen the user has the option of superimposing the registered map (in the lower right displaying either thickness or elevation) over the image, and/or the ETDRS map/results.
- These options are available by right-clicking on the reference image



- 2D map is placed on the reference image
- Display of map and map on reference image are both updated when selecting the various thickness and elevation option presentations



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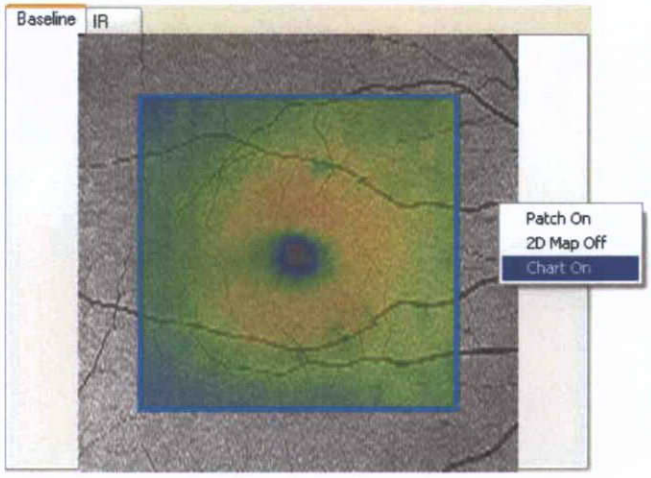
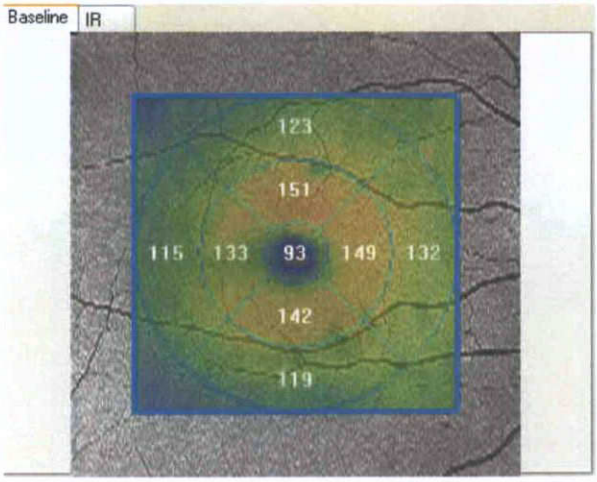
- Both the 2D map and the ETDRS grid and results may be displayed on the reference image at the same time or individually



- The Color reference for the Normative Database comparison is not shown in the overlay of the ETDRS grid when both (ETDRS and 2D map) are in overlay. **NOTE: This is the default presentation of the reference image.**



- The Color reference for the Full Retina thickness is shown when only the ETDRS grid is superimposed.

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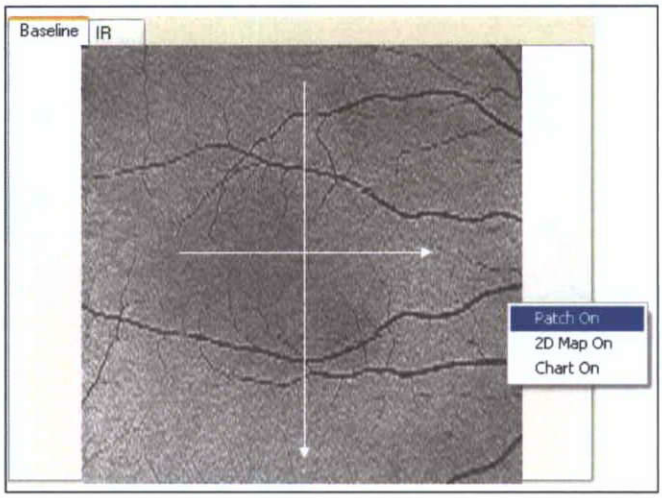
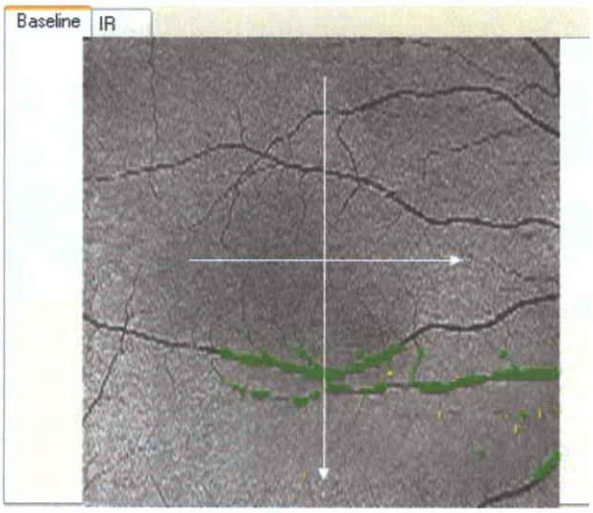
- The **Patch** overlay is the results of the sampling raster taken during the EMM5 scan. This is used to obtain the vessel tracing for the registration to the Reference image. You can see the Patch location using the right-click option.



- When the Patch is displayed, it will show green vessel tracings when aligned (as seen in the image below). If it is moved from its location, the tracings turn yellow indicating a deviation from the vessel match.



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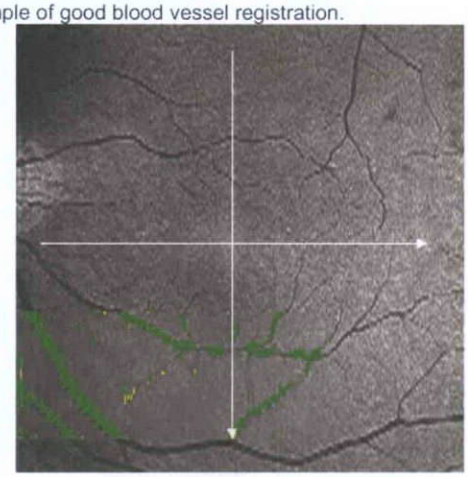
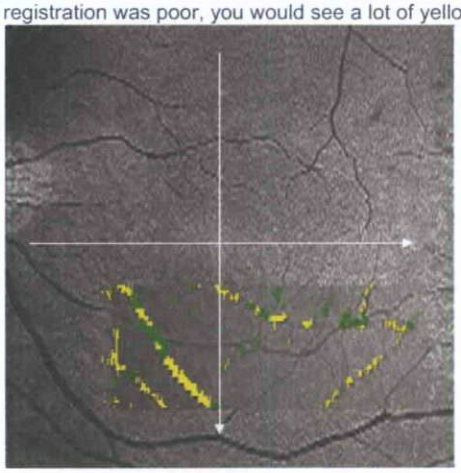
Example of poor blood vessel registration:

Below is an example of good blood vessel registration.



If the blood vessel registration was poor, you would see a lot of yellow in the image.



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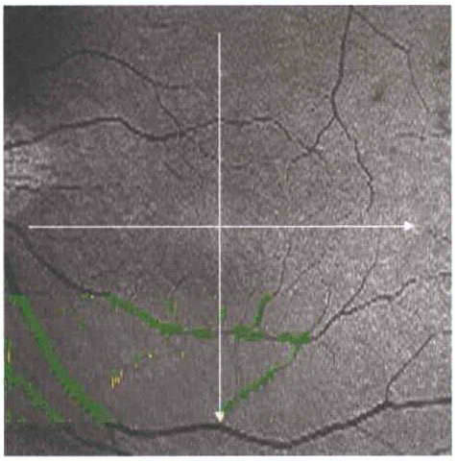
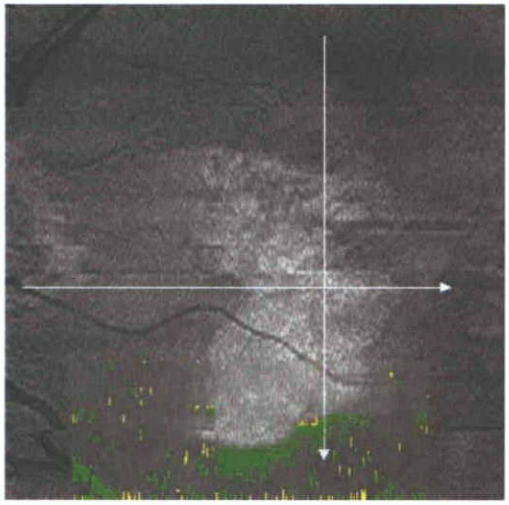
You can then manually move the patch area with your mouse until the blood vessel patterns are matched and you don't see any more yellow.



Examples of eye movement which indicate rescanning may be necessary:

Eye movement can cause poor blood vessel detection. Eye movement is indicated by the break in blood vessels within the scan. It is recommended to retake the scans with patients who displays eye movement during the scan.



Eye movement indicated by the break in the blood vessel pattern

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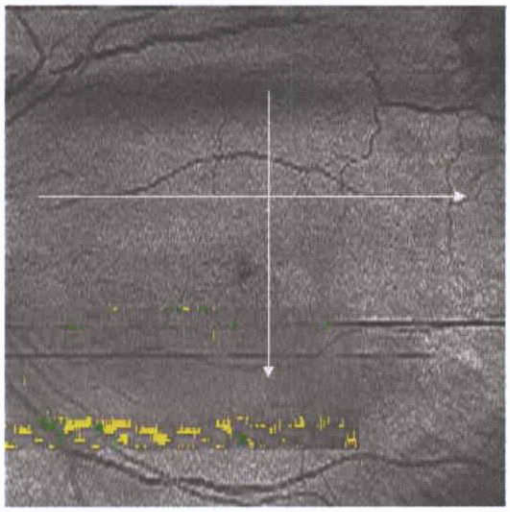
Another example of eye movement causing registration failure and poor blood vessel detection is shown in the image below. Eye movement is indicated by the dark horizontal lines within the scan. The below image is a patient with Diabetic Retinopathy who displays eye movement during the scan. The image also displays no blood vessel detection in the patch area - evident by the yellow patterns. In cases like this, it is also recommended to retake the scans.

Eye movement indicated by dark horizontal lines in the image



Yellow color indicates no match found for blood vessels

5.4.1 EMM5 Change Overview Report

The EMM5 change analysis report shows an overview of up to four individual visit results (A baseline exam and three follow-up exams) for a specific patient eye. (See section 6.1 for detail on Normative change overview report)

The threshold input and the resulting automatic contour drawing are available in this report and apply to all four visits displayed.

- The value inserted causes all of the 2D maps in the top row to delineate the volume of all tissue above the defined threshold value.
- The volume defined by the contour outline is displayed, providing clear reference of the change (positive or negative) of any edema/elevation.
- Value is entered in the **Threshold** field in the upper right

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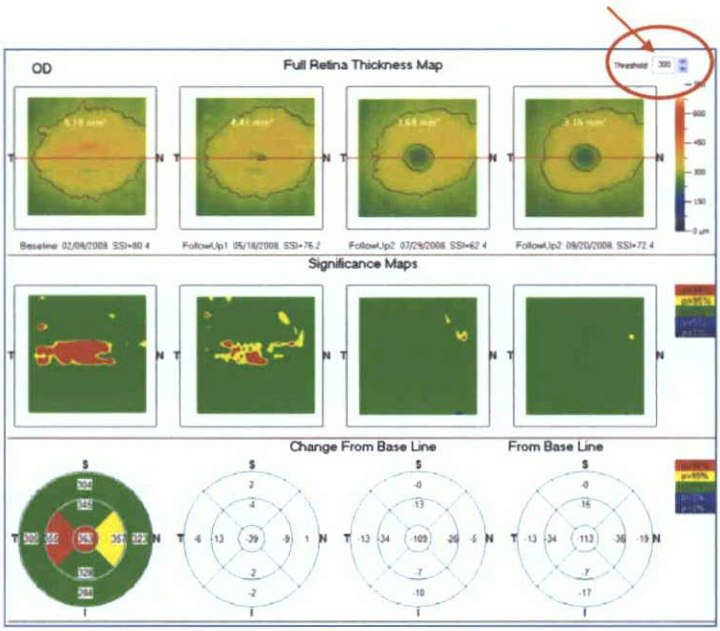

Figure 5.4.5 (Baseline and three follow-up exams)

5.4.2 *Retina Normative Database*

RTVue XR software contains the Normative Database that allows comparison of a patient's retina structure (macula thickness and RPE elevation) with "normal" patients in the same at segment. This comparison to "Normal" provides the clinician with an objective metric to use in the overall diagnosis.

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The EMM5 Normative presentations are:

- Full Thickness Significance – selecting this option displays the significance, of the thickness deviation from normal of the scanned eye. Parameters include within normal for both edema and ischemic conditions.

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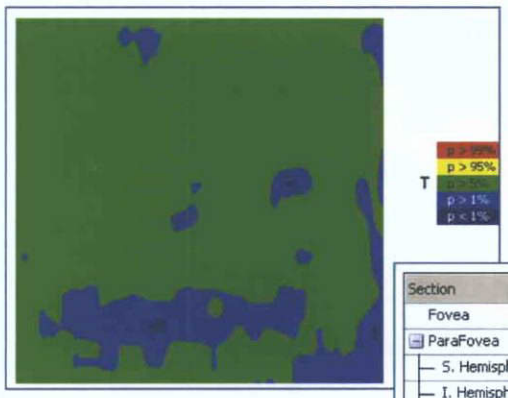
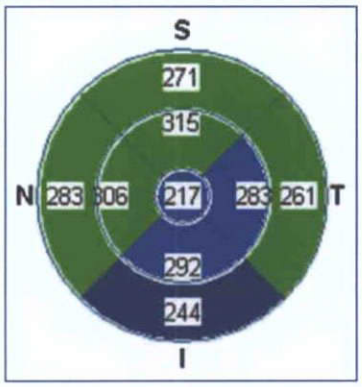


EMM5 Significance Map with Normative segmentation legend



ETDRS Map with average values

Section	Thick(µm)	Vol(mm³)
Fovea	217	0.170
ParaFovea	299	1.880
S. Hemisphere	305	0.959
I. Hemisphere	293	0.921
Tempo	283	0.445
Superior	315	0.494
Nasal	306	0.481
Inferior	292	0.459
Perifovea	265	3.328
S. Hemisphere	274	1.722
I. Hemisphere	256	1.606
Tempo	261	0.820
Superior	271	0.852
Nasal	283	0.890
Inferior	244	0.766
Vol within: 0.170(1mm) 2.050(3mm) 5.378(6mm)		

Normative DB Metrics

- RPE Elevation Map – this option displays the patient's RPE tracing compared to a normalized ellipse fit. Elevation is based on +/- 80% of the RPE (24 microns), and amplitude of +/- 150% of the RPE thickness (45 microns).

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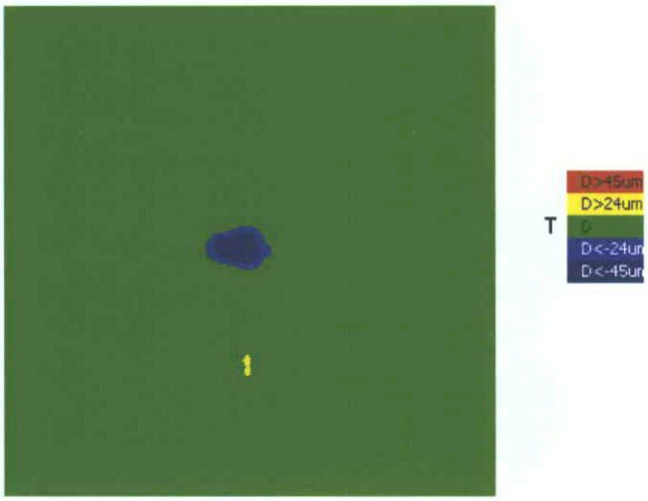

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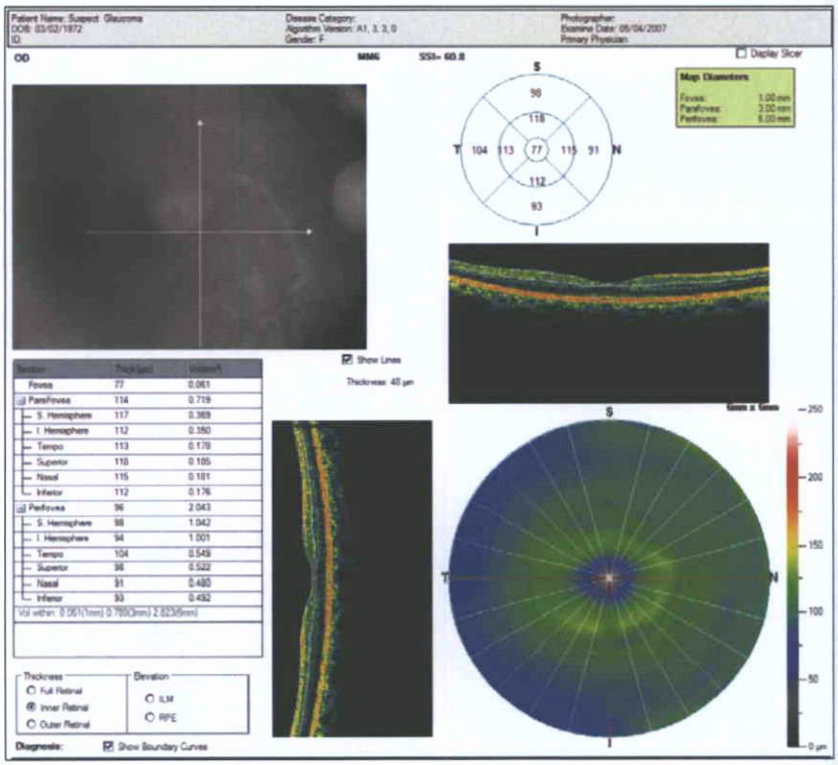
5.4.3 MM6 Analysis Report

The MM6 (12 Radial scans) maps the central macula using a radial scan pattern more familiar to those who have had previous OCT technologies.

Note: The MM6 is not included in the Normative Database collection that is in process.

Display Slicer option: Toggles the display of the MM6 between the standard presentation and as Radial Slicer presentation, including all 12 scans



Show Lines: This option toggles the map display between showing with or without scan reference lines. Map graphic without lines works well for case study presentations

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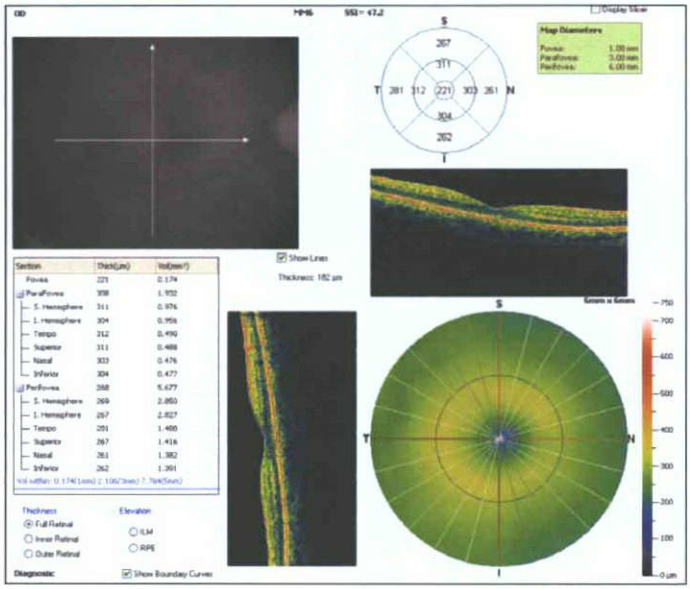
5.4.4 *Missing Scans Due to Blink*

For all map patterns saved which included missing or dropped B-scans (due to blinking, weak signal, eyelash obstruction, iris clipping, etc), the scans not included in the map rendering are indicated in gray instead of white (scan indicator lines).

For missing scans indicated in any map, the raw B-scans not used should be reviewed by the clinician and the map data in this area should be reviewed with caution.



Missing lines indicated in gray. Date in this area is interpolated based on the nearest adjacent complete scan data.

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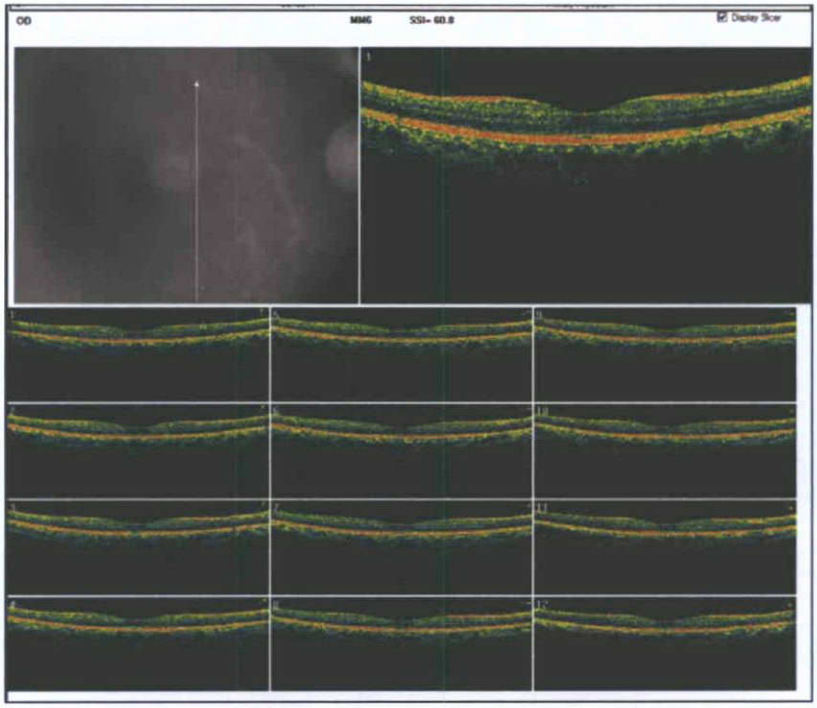
MM6 Slicer (Option) Display



Click once on any scan to display it in the larger window at the top right.

Double click on any scan to go immediately to the measurement mode presentation.

Note: The **Radial Raster** and the **Raster** report displays have two ways of presenting the scans for view and printing. At the top you will find the selection options of One page or Two page (larger scan images) presentations.

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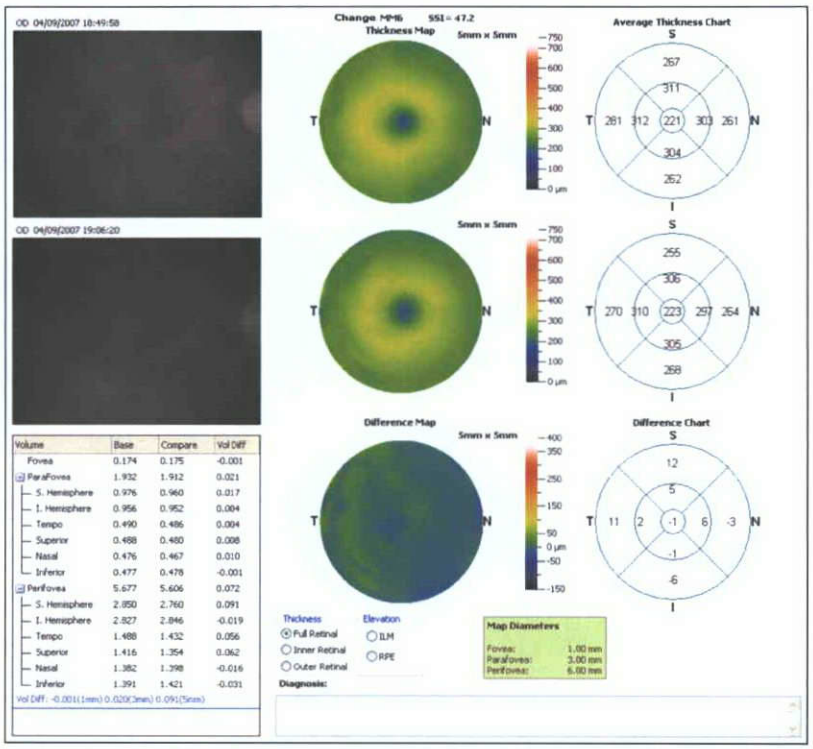
5.4.5 MM6 Change Analysis Report

The MM6 change analysis shows the difference between two MM6 analyses. To speed up the comparison results, it is better to analyze each individual MM6 scan first before making comparisons.



Please Note:
Change analysis is a simple difference map without any statistical adjustments. The values are simple differences and may not be statistically or clinically significant.

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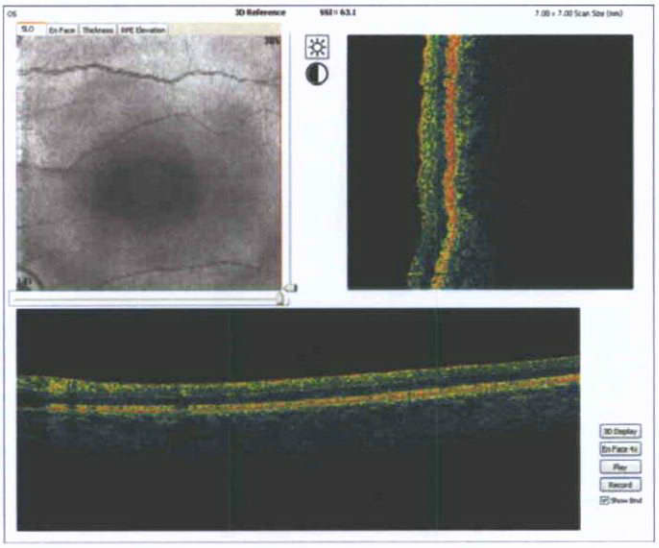
5.5 3D Presentations

The 3D scan presentations are updated considerably from the previous version. The following viewing options are indicated by the tabs SLO, En Face, and so forth.

- **SLO**: This view shows a SLO-style image created by the sum of all the C-scans, producing a high contrast "En face" image.
- **En face**: This view presents the sum of the c-scan planes indicated in the thickness value field.
- **Thickness**: Presents the thickness with log scale of user selectable segmentations for Full, Inner and Outer retina. The 3D Reference and 3D Macular scan displays an ETDRS thickness map in the thickness tab when the scan size surpasses 6.00 x 6.00 mm. The ETDRS map is a traditional ETDRS map consisting of 1mm, 3mm, and 6mm diameter circles. Note that the ETDRS map is always in the center of the window. It may not be centered on the fovea.
- **RPE Elevation**: Presents the elevation of the RPE from a normalized plane. This is available for 3D Macular and 3D Reference scans.

Tab presentation window *Brightness/ Contrast controls for SLO image*



B-scan presentation *Standard controls*

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Analyze Menu

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Standard controls

- **Brightness:** Controls brightness settings for the SLO image

- **Contrast:** Controls contrast settings for the SLO image

3D Display

- **3D Display:** Brings a separate full sized screen for a 3D presentation of the OCT scan.

En Face 4x

- **En Face 4x:** Brings a separate full sized screen displaying 4 En Face views of 4 separate layers of your choosing.

Play

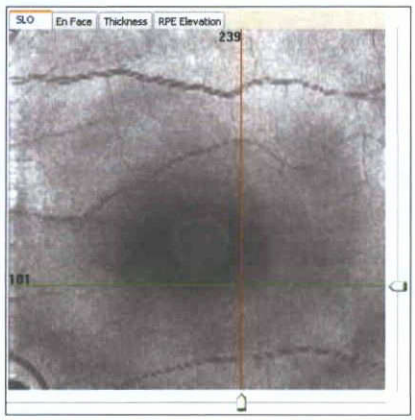
- **Play:** Sequentially plays through the B-scans and 3D display while showing the reference in the SLO-style image.

Record

- **Record:** Clicking 'Record' will prompt a new window to pop up asking for a folder to save in. The file recorded will be saved in an .AVI format. Click 'Stop Recording' to finish recording.

☑ Show Bnd

- **Show Bnd** (boundary): Displays or removes the algorithm tracing



- **Green line:** Position of horizontal B-Scan.
- **Red line:** Position of vertical B-scan
- Clicking anywhere on the window (shown to your left) will automatically show corresponding horizontal and vertical B-scans.
- Note: 3D Volume and 3D Display are memory intensive functions. Frequent usage of these features may slow down the processing of scans.

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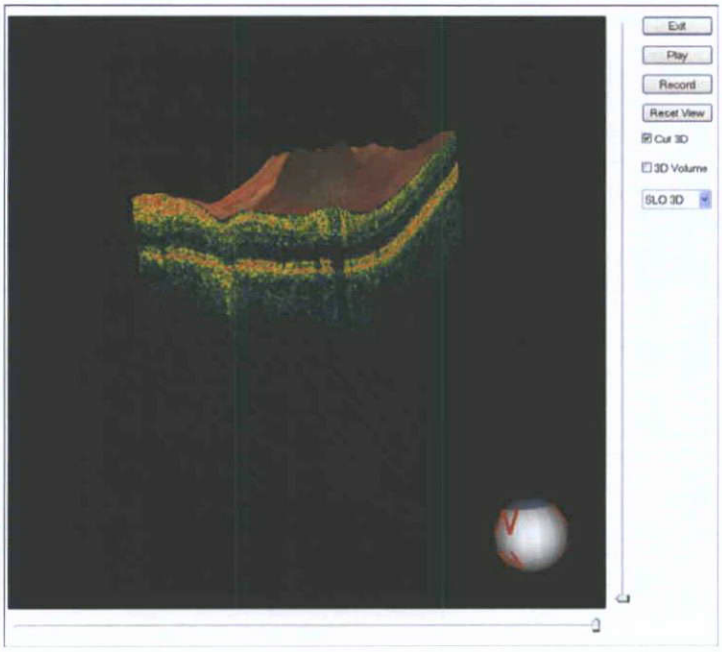
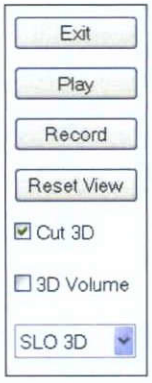
3D Display

The 3D display presentation appears in a separate window to give a more detailed view of the 3D model. The model offers multiple views to choose from: SLO 3D, Full Thickness, Inner Thickness, Outer Thickness, and RPE Elevation (available for 3D Macular and 3D Reference scans). These can be chosen from the drop down menu in the right panel.



- **Orientation Legend:** Shows orientation based on TSNIT.
- **Exit:** Closes the 3D Display window.
- **Play:** Sequentially plays through the B-scans on 3D display.
- **Record:** Clicking 'Record' will prompt a new window to pop up asking for a folder to save in. The file recorded will be saved in an .AVI format. Click 'Stop Recording' to finish recording.
- **Reset View:** Resets the image to a top-down view.
- **Cut 3D:** Option to have 3D image "cut" as the B-scans are reviewed.
- **3D Volume:** This option presents entire data captured in the 3D block including the tissue in the vitreous just above the ILM plane.



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3D Volume

The 3D Volume rendering shows an SLO-style image super imposed to the bottom of the 3D image. The 3D Volume presentation can be accessed by selecting the '3D Volume' option in 3D Display.

PLEASE NOTE: 3D features introduced in this version are intended for the RTVue XR PC system as it applies to the specifications listed in Section 9.1D. PC systems that do not adhere to the specifications may experience less than optimal performance when using 3D features.

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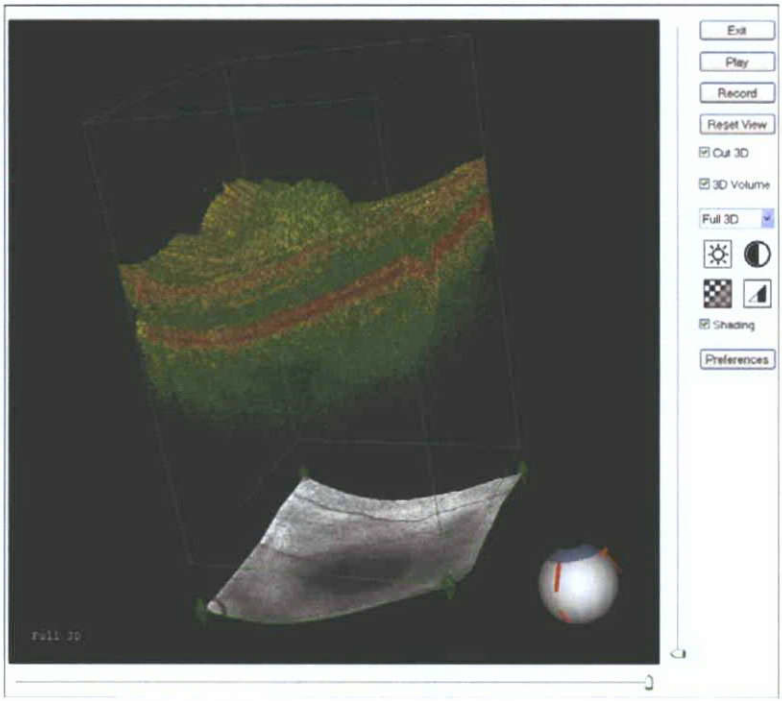

Like the 3D display, the 3D volume has the option of displaying multiple views. The different views can be modified by clicking the 'Preferences' button.

- **3D Transparency:** Changes the transparency of the 3D volume model

- **3D Volume Low Cut Off:** Filters out additional noise in the 3D rendering.

☑ Shading

- **Shading:** Affects the shading of the 3D volume model. Turning off 'Shading' will also disable the SLO mounted on the bottom of the 3D model.

Preferences

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Analyze Menu

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- **Preferences:** Brings up specific options for the 3D Volume selection.
- **Layer Selection:** Choose which view to present in the 3D Volume window. Layers 1-4 are user selectable and can be set in 'Preferences'. Selecting Vitreous gives a vitreous view with a white background.

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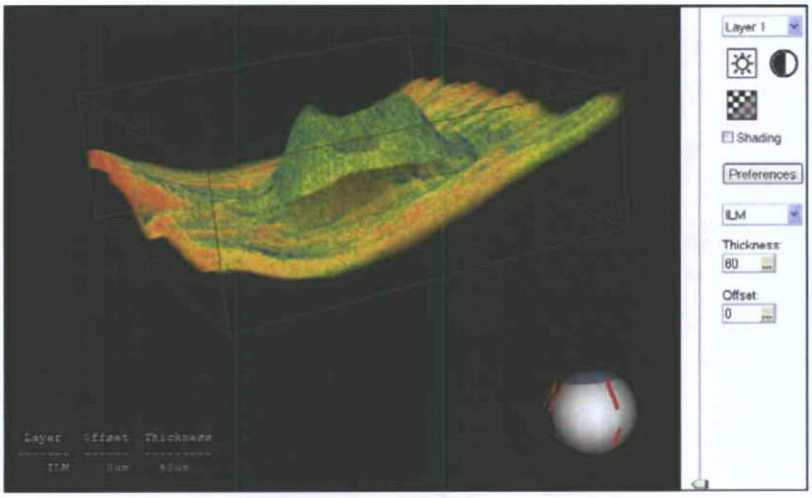

3D Volume view of ILM layer.

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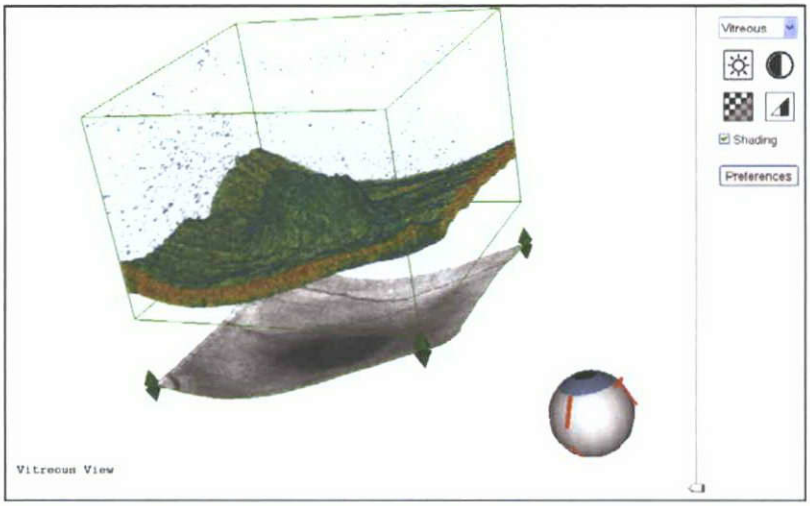
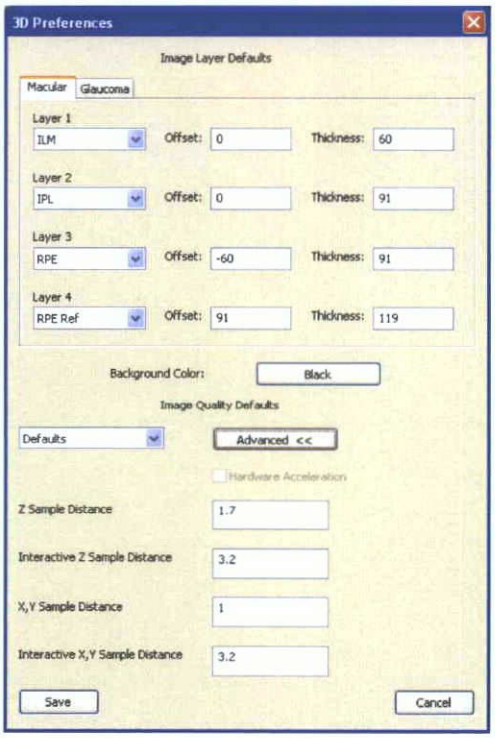


3D Volume view of the Vitreous View. The Vitreous view uses a white background to better view the particles in the vitreous.



- **3D Preferences:** The top half of the 3D Preferences window lets the user select the layer and modify the offset and thickness to be represented in Layers 1-4. The Figure to the left shows the default layers and their respective settings for offset and thickness. These values will correspond with any settings changed in the **En Face 4x** preferences (as seen later in the manual).
- **Background Color:** Change the background color of the 3D model from black, grey, and white.
- **Advanced:** The Advanced options affect the 3D volume rendering when the object is dynamic and static. **The advanced options are intended for advanced clinical research purposes.**

3D Advanced Options

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The advanced options affect how the 3D Volume model is rendered in its 'static' and 'dynamic' state. The dynamic state refers to the state the model is in when it is interactively being manipulated (dragging and rotating views). The static state refers to the 3D model when it is not being manipulated by the user.

The options: "Interactive Z Sample Distance and Interactive X, Y Sample Distance" affect the quality of rendering when the user moves the 3D Model.

The options "Z Sample Distance and X,Y Sample Distance" affect the quality of the rendering of the static 3D Volume model.

The Hardware Acceleration option is available to RTVue XR PC systems that have graphic cards that support hardware acceleration. PC systems without abilities to use the Hardware Acceleration option will have the option gray'ed out. Selecting the Hardware Acceleration option uses the video card's GPU to power the 3D model. If the Hardware Acceleration option is not selected, 3D models will be powered by CPU instead.

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Higher values yield faster processing time but lower resolution 3D Volume models. Lower values take longer to process the 3D models but have increased resolution. The values set as default were found to have the best balance between processing time and rendering quality. The chart below show the possible input values for each selection.

	CPU	GPU (Hardware Acceleration option selected)
Z Sample Distance	1.0 < X < 10	.4 < X < 10
Interactive Z Sample Distance	2.5 < X < 10	.7 < X < 10
X,Y Sample Distance	.7 < X < 10	N/A
Interactive X,Y Sample Distance	2.0 < X < 10	N/A

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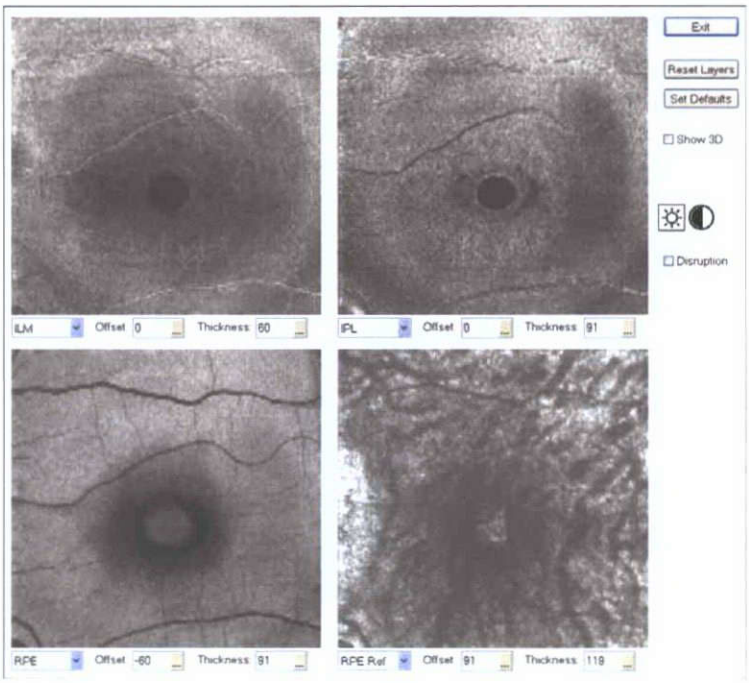
En Face 4x

The En Face 4x presentation provides en face views of four different layers. The default layers shown are ILM, IPL, RPE, and RPE Ref for retinal 3D scans. For 3D Disk, the default layers are ILM, NFL, and RPE. These layers can be changed by going to the respective drop down menu in each en face window. These options also affect the layer selection in the 3D Volume selection.



The offset and thickness values can be modified. Click "Show 3D" on the right hand side, to view the En face layers in 3D.

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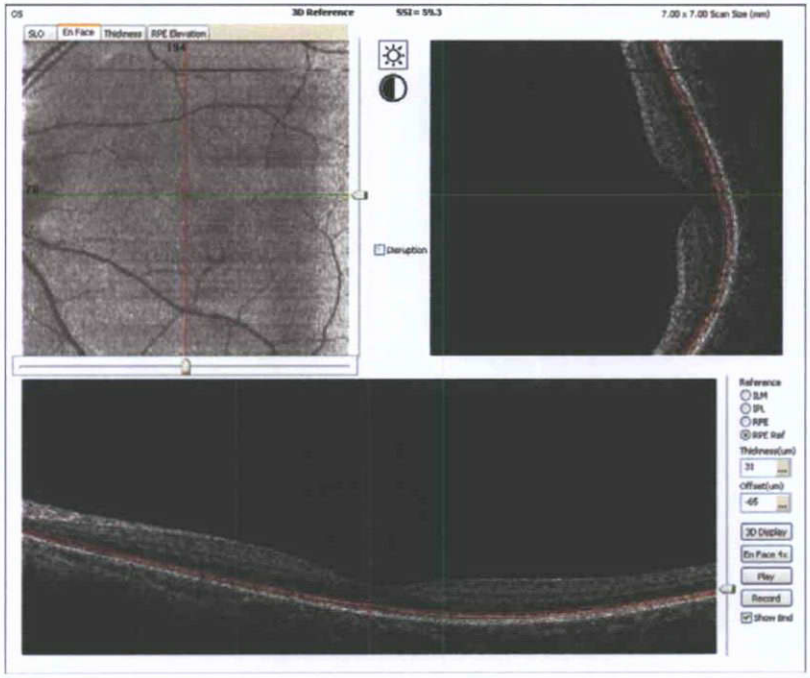
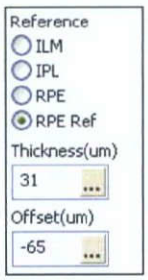
En Face presentation

This view presents the sum of the c-scan planes indicated in the thickness value field





- Options for reference plane contour.
- Thickness (µm): You can select the thickness of the scan plane (slab or Sum) presentation (microns) in the En face window.
- Offset (depth or elevation) from starting plane in microns.

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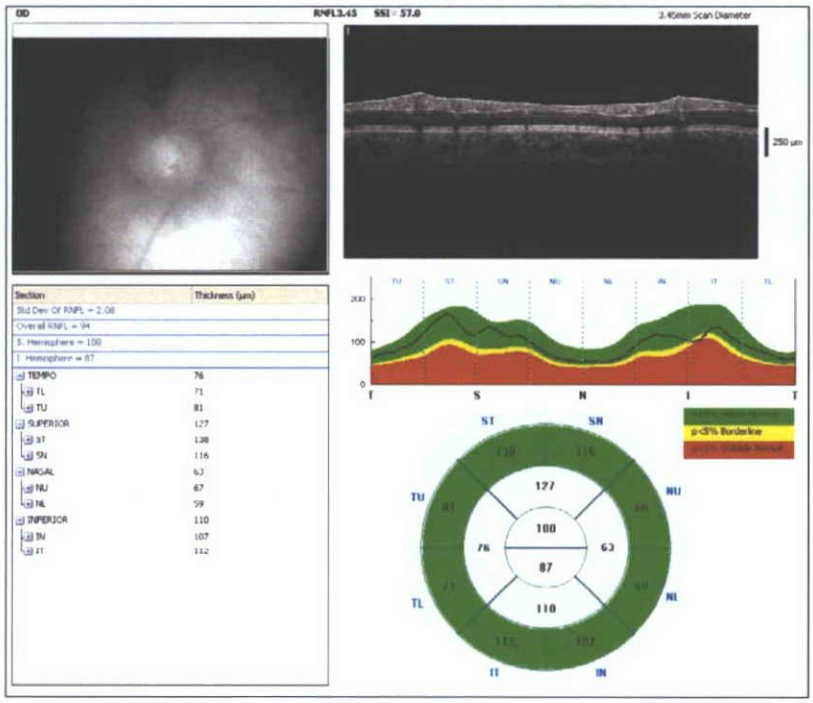
5.6 Analyze Report – Glaucoma Scans

5.6.1 RNFL3.45 Analysis Report

The RNFL scan pattern completes four circular scans in 0.16 seconds at a diameter of 3.45 mm, targeted around the optic nerve head. These scans are averaged and the result is presented within the normative range parameters.

With version 6.1, RNFL average thickness is show in 8 sectors in RNFL 3.45 analysis and change reports.

NOTE: This scan pattern cannot be registered for viewing change over time purposes. For Glaucoma and sequential change analysis, we strongly recommend using the ONH scan pattern (which offers an alignment-corrected RNFL measurement)



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5.6.2 *RNFL 3.45 Change Overview Report*

Up to four exams (baseline and three follow-up visit results) can be selected for the Change overview report.

Each averaged (4 scans) result is plotted against the Normative parameters.

NOTE: This scan pattern is included in the RTVue XR for users wishing some continuity with previous Time-Domain OCT systems. However, just as with the Time-Domain OCT systems sold previously, the scan placement is completely dependent upon the operator. Registration is not possible with this scan pattern.

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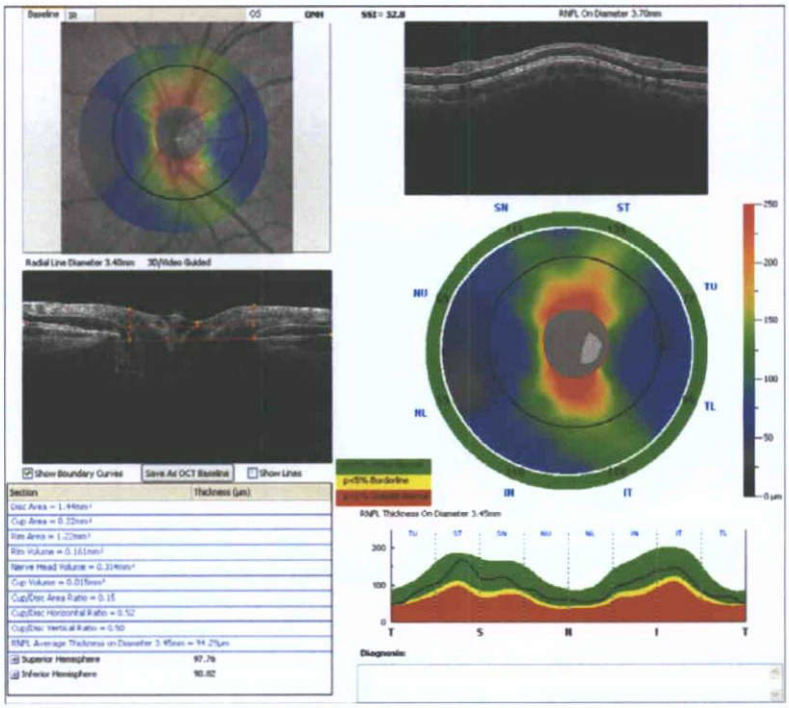
5.6.3 *ONH Analysis Presentation*

The ONH map includes several pieces of important disc morphology information: Disc and Cup Areas, C/D Ratio, RNFL 3.45 and NFL thickness map from disc margin up to 4.93 mm radius from the center of disc.

With version 6.1, RNFL average thickness is show in 8 sectors in ONH analysis and change reports.



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Factors that can affect Scan Signal Index (SSI) for the ONH scan:

Scan not centered on the optic disc:

During the scan, the operator should check to make sure the scan pattern is well centered on the optic disc. If it is not, the operator should move the scan pattern to be centered on the disc. If the operator does not and if the scan pattern is not centered on the disc, the RNFL thickness measurements may be affected. The software can automatically reposition the RNFL TSNIT circle to be centered on the optic disc after the scan, however if the disc is too close to the edge of the scan pattern, some of the data may be missing if the measurement circle falls outside the scan pattern area. In these cases, the scan should be retaken.

Check optic disc drawing and RPE tip placement:

Make sure the optic disc drawing accurately demarcates the edge of the optic disc boundary. Also make sure the RPE tip placements are at the correct positions (end of RPE/choroid complex at the disc margin). Re-draw the optic disc margin drawing if necessary. Adjust the RPE/Choroid tips placement if necessary. If the optic disc drawing or the RPE tip placement is not accurate, the measurements can be affected. Scans should be retaken if the RNFL measurement circle falls outside the scan area after the disc drawing and RPE tip placement are in correct positions. This verification of RPE tips can be done at any time (regardless of setting in the User Preferences) by "right clicking" on the NFL result map.

Check the layer segmentation accuracy of the scan:

The segmented layers are ILM and NFL (Nerve Fiber Layer). If the segmentation lines are not accurate, the user should manually make the necessary corrections. If the segmentation is not accurate and the user does not make the correction, the results will be affected. If the user performs manual correction, the results will be valid and the scan can be used.

Overall precision results with the ONH scan for normal and glaucoma patients:

ONH Average RNFL		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	100.82 (8.11)	86.40 (14.99)
Repeatability SD* (Min, Max)	1.76(1.76, 6.18)	1.56(1.56, 5.86)
Reproducibility SD** (Min, Max)	2.11(2.11, 9.78)	7.87(3.92, 16.33)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning

**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

For details on the clinical study and the clinical precision for RTVue scan measurements (repeatability, reproducibility), study information is available in the Appendix B–RTVue Precision.

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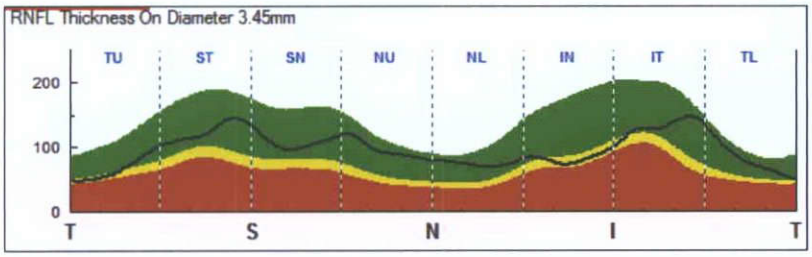
5.6.4 *TSNIT Histogram*

RNFL thickness profile in the ONH is the thickness of RNFL at a *calculated* **3.45mm diameter** around the *center* of the disc. **NOT THE CENTER OF THE SCAN**

*The thickness measurement at 3.45mm is re-sampled relative to the disc center, not the scan beam center, so the de-centering of the disc relative to the scan beam will not affect the measurement.



5.6.5 *Stereometric analysis*

Optic disc analysis results are listed in the spread sheet as follows:

Section	Thickness (µm)
Disc Area = 2.01mm²	
Cup Area = 1.06mm²	
Rim Area = 0.96mm²	
Rim Volume = 0.085mm³	
Nerve Head Volume = 0.164mm³	
Cup Volume = 0.300mm³	
Cup/Disc Area Ratio = 0.53	
Cup/Disc Horizontal Ratio = 0.79	
Cup/Disc Vertical Ratio = 0.70	
RNFL Average Thickness on Diameter 3.45mm = 82.18µm	
⊞ Superior Hemisphere	80.75
⊞ Inferior Hemisphere	83.62

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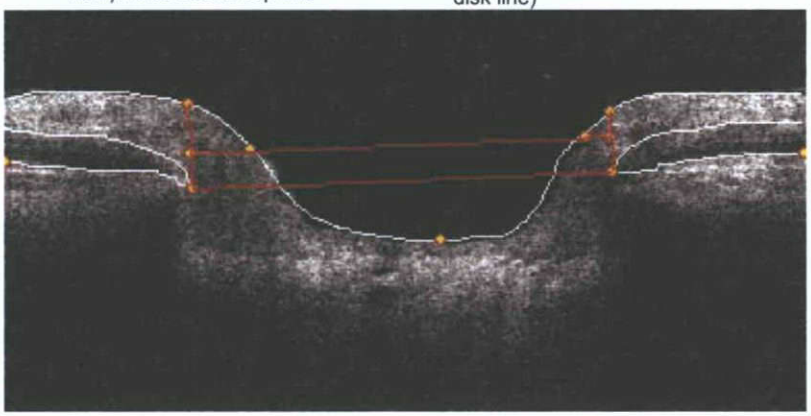
Definitions:

Rim Volume (cross sectional view). Area above cup line

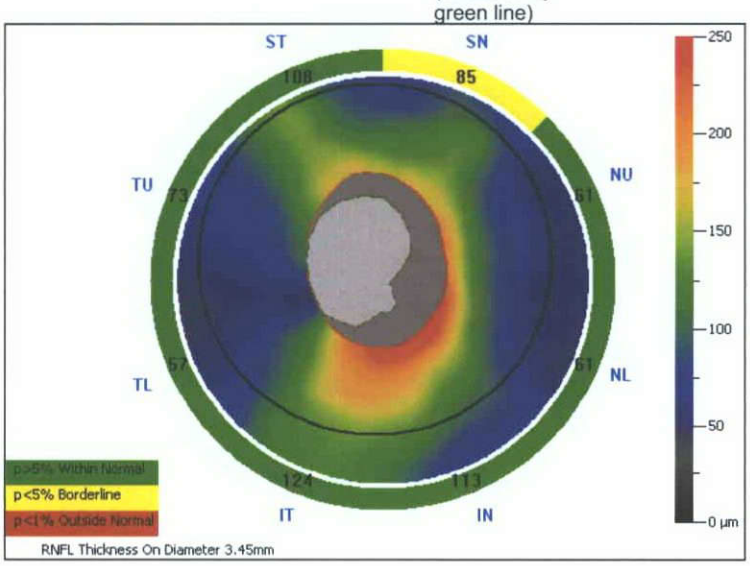
Cup Line (150um above disk line)



Cup area (enclosed by green line)

Average thickness in section and Normative Significance (color code) of section (16 sections total from disc margin to 4mm diameter)

Rim area (enclosed between red and green line)



Normative database legend

Disk margin (indicated by red line)

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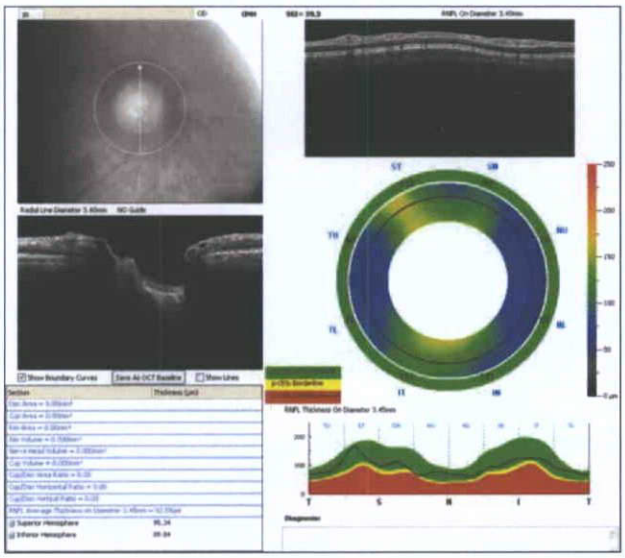
Optic Nerve Head Morphology

The ONH analysis can be performed with either one of four disc border baseline modes:

1. **3D Baseline:** Disc drawing from 3D Optic Disc scan (**Default**)
2. **Video Baseline:** Disc drawing from IR image (ONH)
3. **OCT Baseline *(Advanced GUI only)*:** Uses the manually adjusted RPE endpoints on the radial scans (Available in Advanced GUI only)
4. **No Baseline*** No disc drawing or RPE tip setting is required



*** The "No Baseline" option removes any serial registration capability, and therefore removes the possibility of change analysis. All disk metrics are reported as zeros, since the disk measurements are not calculated.**

Presentation of ONH scan with "No Baseline" option

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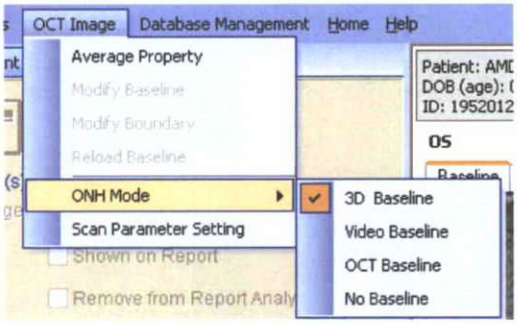
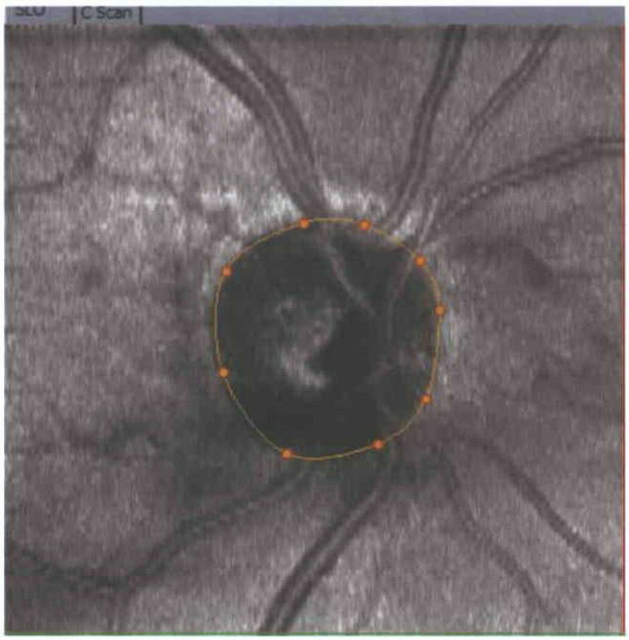


5.7.6.5 The default setting is"3D Baseline" and should not be changed unless there is no possibility of capturing a 3D disc image with any patients.

5.7.6.5 **3D Baseline** is the disc boundary that is automatically drawn using the 3D Disc scan.

To see the boundary automatically drawn, "Right click" the mouse cursor on the SLO image and selecting "Show Disc".



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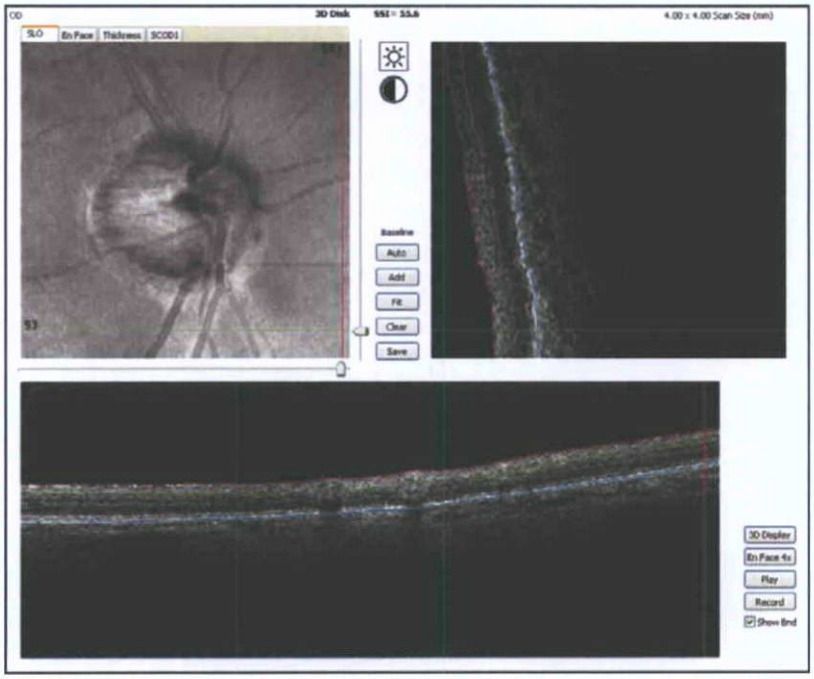
5.7.6.5 You may also use the 3D presentation screens to precisely determine the optic disc boundary, by using the RPE endpoints visualized in the B-Scan (lower left) and A-Scan (upper right).

Brightness and **Contrast** controls for the SLO type en face image presentation



- **Auto** – Draws the disc margin on the En face SLO image.
- **Add** – Adds an anchor point on the image for disc boundary. Click the SLO image to find the correct point (RPE tip) position, then click **Add**.
- **Fit** – Uses anchor points to draw the disc boundary to close contour.
- **Clear** – Clears any currently marked anchor points
- **Save** – Saves the resulting disc drawing as the baseline for the ONH

Note: As you click on any position in the SLO image screen, the three perspective windows also change to reflect the location and cross section within the 3D presentation.

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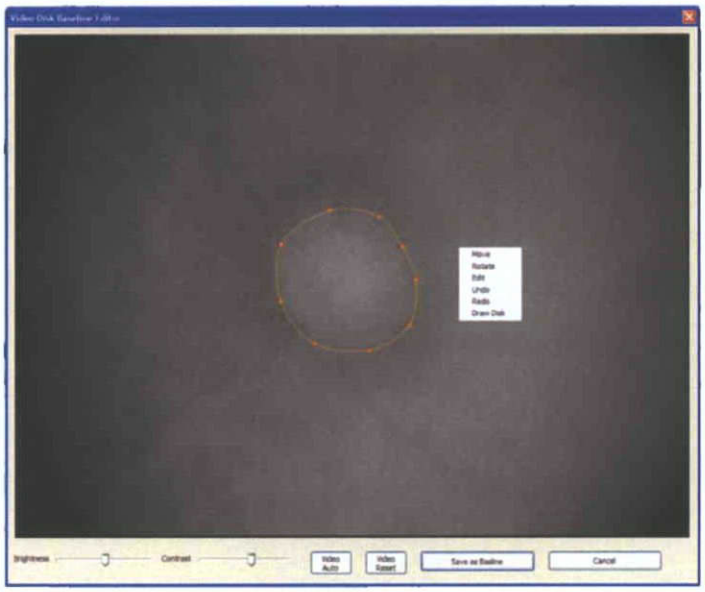
5.7.6.5 **Video Baseline** option should only be used if it is not possible to capture a 3D Disc scan. You may draw the optic disc margin on the IR video image to get the optic nerve head metrics.



5.7.6.5 **OCT Baseline (Advanced GUI only)**

This method is a more complex and user intensive method of adjusting the baseline. This function should not be used by anyone but research technicians. Please call for instructions

NOTE: If no 3D or Video (IR) baseline has been captured (or drawn) at the time of reviewing the ONH scan, you will have the option of rendering "without" a baseline in Analysis view. THIS IS NOT RECOMMENDED as the results are completely dependent upon the skill of the operator to center the scan pattern on the optic disc center.

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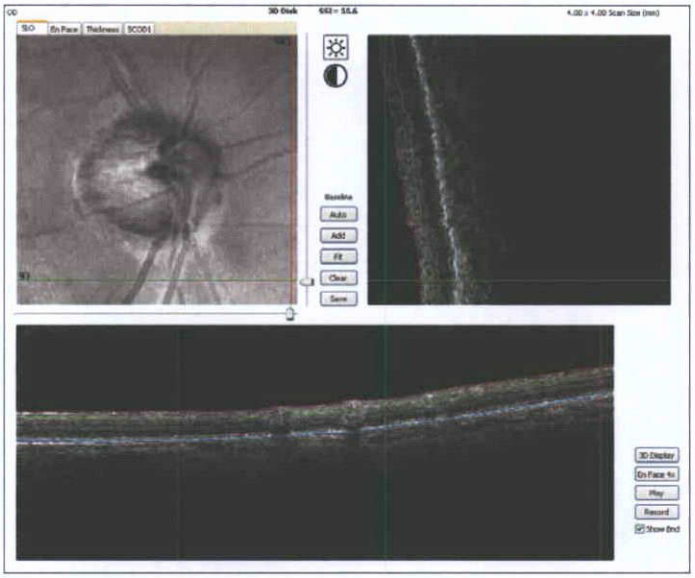
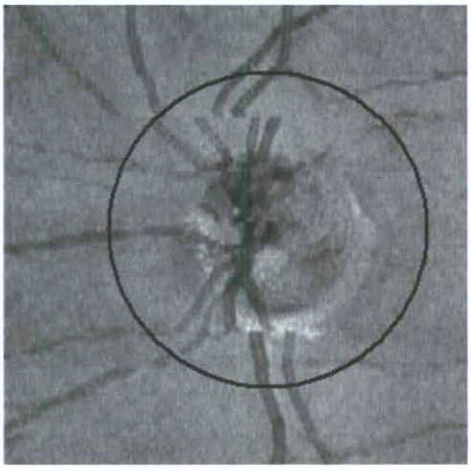
5.6.6 3D Optic Disc Presentation



NOTE: Eye motion can cause image registration to fail and require a scan to be redone. An example of eye motion during the 3-D ONH scan is seen below. The eye movement is evident in the break in the blood vessel pattern. It is recommended if such breaks are seen, the scan should be redone.

Eye movement indicated by the break in the blood vessel pattern



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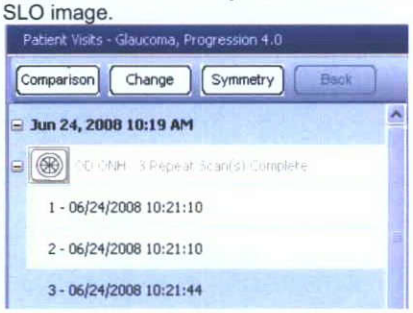
5.6.7 Comparison

Image comparison is a very handy tool used to see the difference of the retina between two visits. This option is available on all scan patterns.

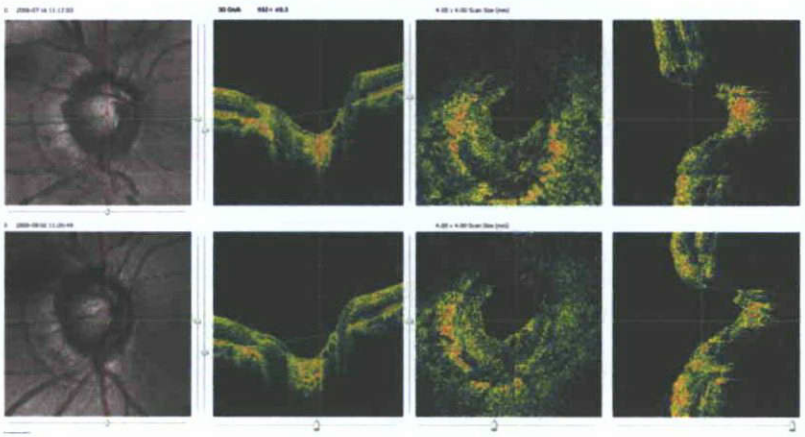
To use image comparison, first select the patient scan in the analyze window. If there are examinations available for comparison, the [**Comparison**] button will be available. This is the same method used to select change and symmetry option.

Two rows of images will appear. You can select which frame image to compare by using the slider on the fundus image (SLO image in 3D scan) to choose the images on each visit. The horizontal and vertical image locations are indicated by horizontal and vertical highlight lines on the SLO image.



Comparison/Change/Symmetry Image Comparison options

Lines to register C-scan plane



Lines to register the horizontal and vertical image frames

Image fly through bars

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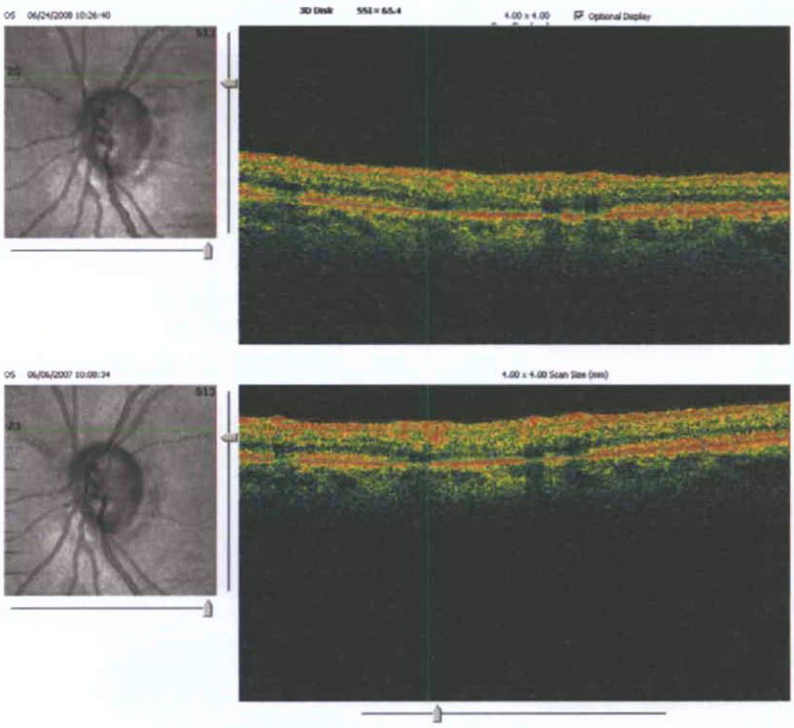
5.6.8 3D Disk Change Analysis

3D Disk change analysis report has been modified for an improved presentation with larger OCT images.



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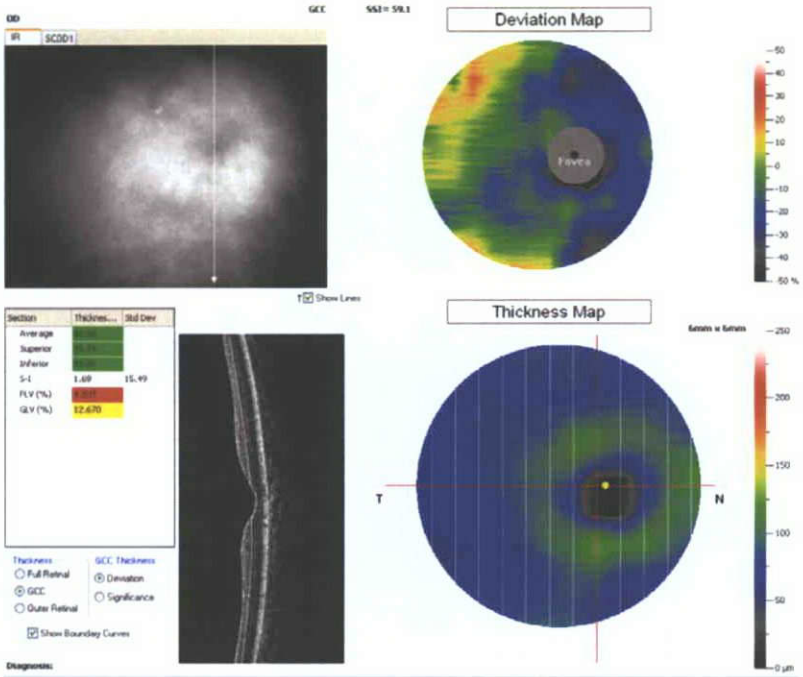
5.6.9 GCC Analysis Presentation



The **GCC** (Ganglion Cell Complex), formerly called the MM7, display the thickness map and deviation from normal of the Inner Retina. These layers make up the complete Ganglion Cell Complex thickness in the macular region. The upper right display will default to the **Deviation Map** (see section 5.8 on the Normative Database). The display may be changed based on user selection in the "Thickness" and "GCC Thickness" display options.

The vertical scan displayed is indicated in Red on the cross sectional scan is displayed on the left side when moving the cursor in the thickness map.

The **Difference** map between superior and inferior hemispheres displayed in previous versions (in the upper right), is now shown as summary values in the table to the left center (red circle).

Focal Loss Volume (FLV) is a parameter that provides a quantitative measure for the amount of significant GCC loss. FLV is the total sum of significant GCC loss (in volume) divided by the map area. As such it provides a percent of significant tissue loss for volume. Early study results have found that FLV is the most accurate parameter to differentiate normal from glaucomatous eyes, being better than the average GCC thickness parameter.

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Analyze Menu

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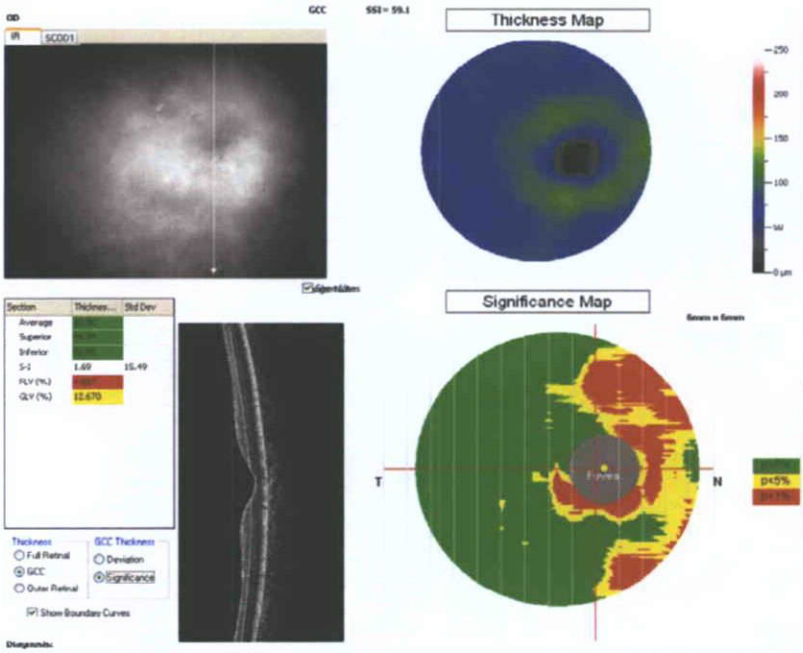
Global Loss Volume (GLV) is the sum of the pixels where the Fractional Deviation map value is < 0, and then divided by the total area to give a percent loss of GCC thickness.



By selecting the "**Significance**" option under **GCC Thickness** display options, the Deviation map is replaced by the **Significance Map** (of the Deviation – see section 5.8 on the Normative Database). Depending upon which display option is selected, the most recent selection (of either option group) is displayed in the lower right and the exiting map moves to the upper right.

Note that fovea is marked by a small dot with the word "Fovea" under it for a clearer presentation of the maps.

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Overall precision results with the GCC scan for normal and glaucoma patients:

GCC Inner Retina Average		
	Normal Patients	Glaucoma Patients
# of Scans	72	71
Overall Mean (Overall SD)	98.28 (9.31)	81.76 (8.90)
Repeatability SD* (Min, Max)	1.86 (1.86, 2.07)	1.18 (1.18, 1.59)
Reproducibility SD** (Min, Max)	7.56 (7.32, 7.92)	2.55 (1.59, 3.36)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

For details on the clinical study and the clinical precision for RTVue scan measurements (repeatability, reproducibility), study information is available in the Appendix B–RTVue Precision.

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5.7 Normative Database

5.7.1 Color Legend for Normative Significance Maps

Both GCC and RNFL Thickness Significance
Legend for TSNIT graph and all parameters

p = 5-95% Within	→ Average
p < 5% Borderline	→ Below average
p < 1% Outside Normal	→ Significantly below average

Retinal Thickness Significance Legend (MM5 and RPE)

p > 99% Outside	→ Significantly above average
p > 95% Borderline	→ Above average
p = 5-95% Within	→ Average
p < 5% Below Normal	→ Below average
p < 1% Outside Normal	→ Significantly below average

Please Note: Normative database comparisons are based on statistical comparisons only and there are possible normal outliers. You should reduce the risk of misclassification by using multiple clinical tools for diagnosis.

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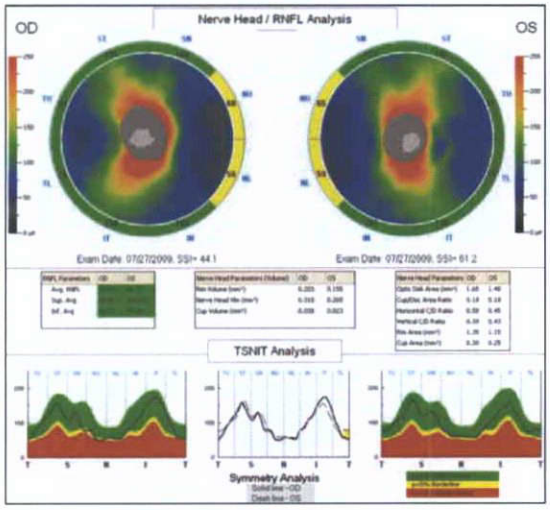
5.7.2 Normative Reports (Samples)

5.7.2.1 ONH Symmetry Report (when no GCC scan exists in Visit)

When "Symmetry" is selected in viewing an ONH report, and **no GCC scans** exist in the same Visit, "Symmetry" analysis option is selected the screen and print report appear as below.



- RNFL Normative Database comparison for 16 sectors

Center Section
- (Left) RNFL average for each eye.
- (Center) Nerve Head volume parameters
- (Right) Optic Nerve Head metrics.

- TSNIT deviation maps

- Bi-lateral TSNIT comparison. (Dashed line is left eye) Red between lines is significant

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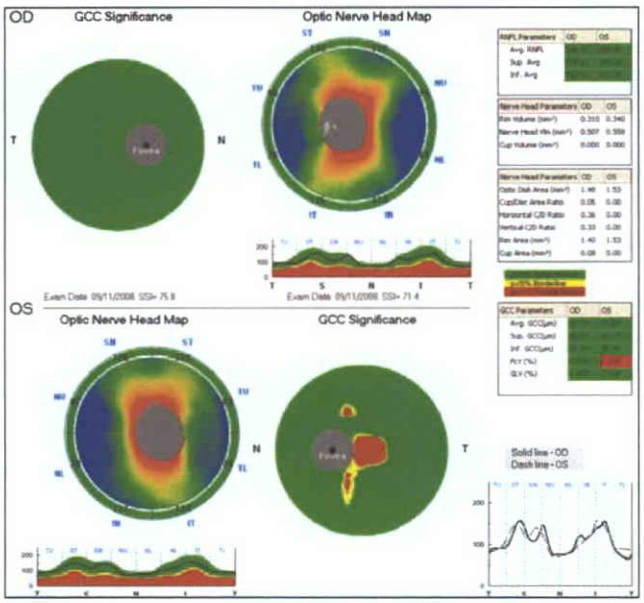
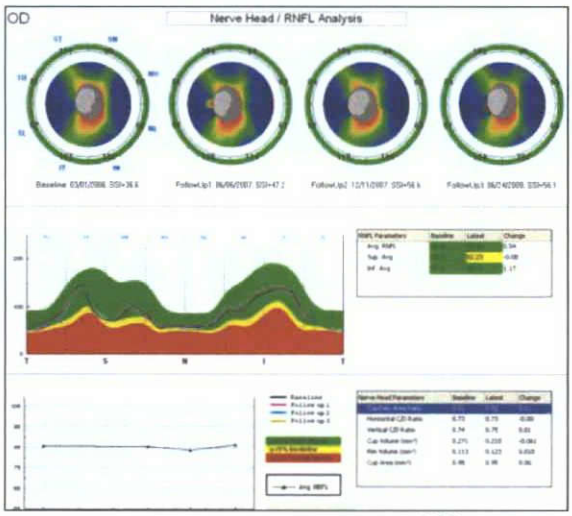
5.7.2.1.1 Symmetry Report (Combined when GCC scan exists in Visit)



A new presentation combining both ONH and GCC scans is provided in order to see the summary of the two in one place. This is available for any visit in which both ONH and GCC scans are acquired.

5.7.2.2 Change Analysis Overview – ONH



- Baseline and three follow-up exam ONH results
- (Left) TSNIT graph of all selected exams
- (Right) RNFL thickness parameters coded for NDB
- (Left) Trend plot of average values for selected exams.
- (Right) Optic Nerve baseline and latest exam metrics

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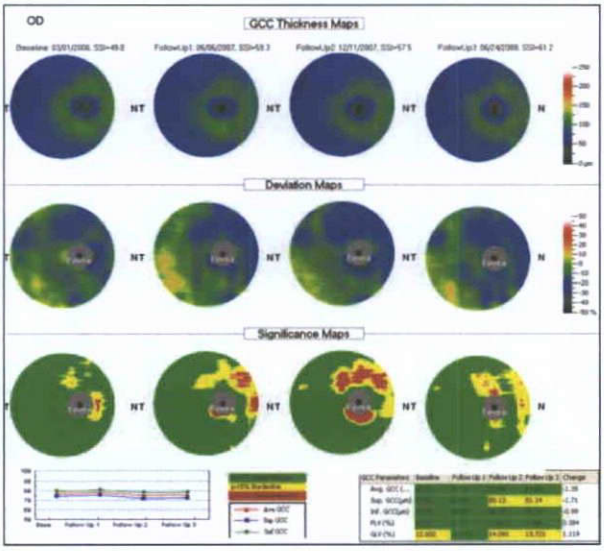
5.7.2.3 Change Analysis Overview – GCC



- GCC Thickness Map of selected exams
- Deviation from Normal map
- Significance (of deviation from normal) Map
- Trend and Average GCC table. Coded for Normative comparison.

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6 Main Menu Bar

The options available in the top level menu bar, and in certain screen presentations, is dependent up on the GUI setting of your RTVue XR. The default setting is the "Clinical" GUI. This GUI setting contains all of the required tools and options for a clinical practice environment. The "Advanced" GUI provides additional options that are useful to a large institution with a dedicated imaging staff or research environment.

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The following is a brief overview of the menu bar options. The options available only in "Advanced" GUI are indicated. These functions should be accessed only be users who have a high level of experience with the RTVue XR FD-OCT system.

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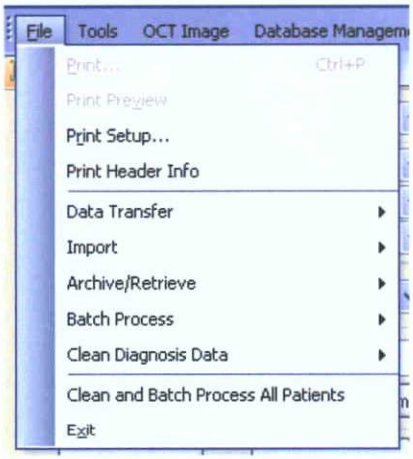
6.1 File Menu



6.1.1 Print

Sends the report visible in the Analysis view screen to the printer (if attached), or whatever print option is installed on the RTVue XR

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6.1.2 Print Setup

Brings up the standard "Windows™" Print Setup window

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Main Menu Bar

6.1.3 *Data Transfer*

This option brings up the "Data Output" function, used in conjunction with ReVue -- the stand-alone review software application. This software product is used for viewing patient data away from the RTVue XR device. Please see the manual for ReVue.

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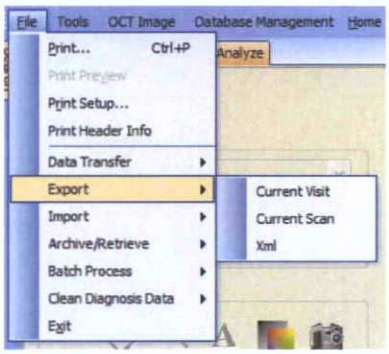
6.1.4 *Export (Advanced GUI only)*

This option brings up the data export options for analysis by 3rd party analysis applications, such are for research purposes. The export format is XML. For a detailed XML specification Guide, please contact the Optovue corporate office at 510-623-8868.



6.1.5 *Import (Images)*

The Import function now includes the ability to bring in previous digital stored (digital printout) results from certain other devices to the patient record.

Along with importing Color, Red Free, FA and ICG images from any digital fundus system, you may import results (image format files only) from other diagnostic devices and scanning systems (Cornea Topography, Visual Fields, Wavefront results, and OCT, SLO, SLP imaging results).

These results must be image based (output to a digital image format file such as .jpg, .bmp, .png etc) to be eligible for importing into the RTVue XR system database.

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This allows the results from previous visits and other devices to be viewed along with the RTVue XR OCT results for the same patient in the current visit.

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First select patient/visit then, click on **File > Import > Import Image**. Select image in the network or from removable media (file types compatible are listed), and click **Open**.

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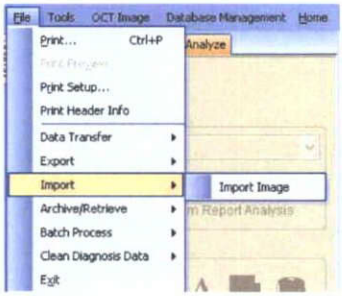
Main Menu Bar

Image will be opened in a window for identification. Select eye [OD/OS], then image type for fundus imaging results, or diagnostic type for test result. Then click on the **Save** button.



The options for importing are:

- Fundus Images (Figure 6A)
  - Color
  - Red Free
  - Fluorescein Angiograms (FA)
  - Indo-cyanide Green (IA)

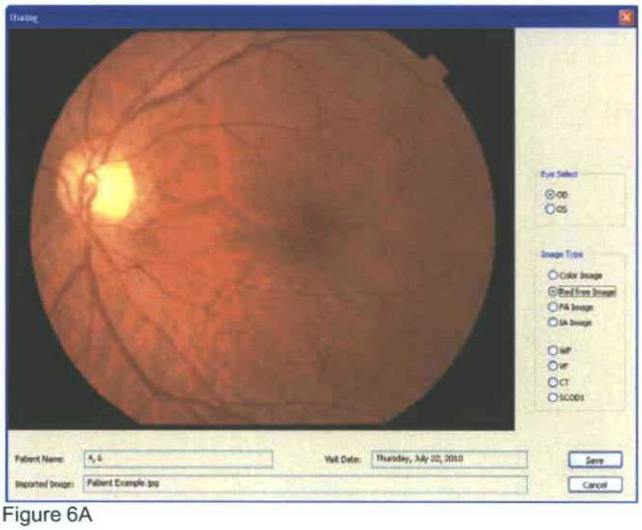


Figure 6A

- Diagnostic Results (Figure 6B)
  - Wavefront (WF)
  - Visual Fields (VF)
  - Corneal Topography (CT)
  - Scanning Computerized Ophthalmic Diagnostic Instruments (SCODI per Medicare nomenclature)

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Main Menu Bar

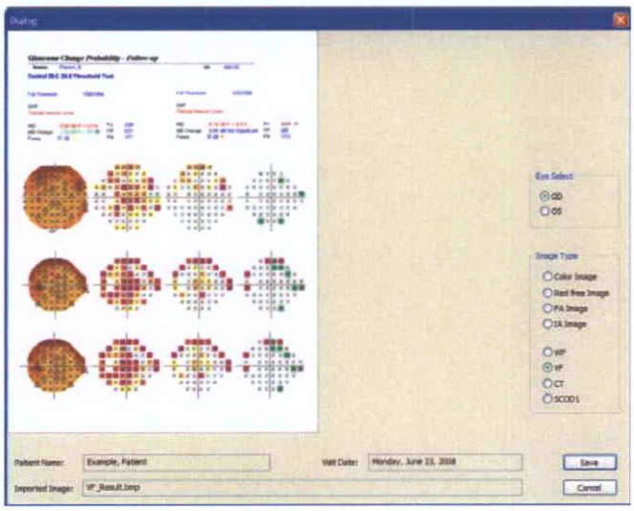

Figure 6B

- Imported data will appear in the upper left of the Review screen with a Tab indicating the type of result. Double-clicking on the image within the Tab will open it up in a larger window. (Figure 6C)

- Sample of imported Visual Field test results, viewed next to the GCC Analysis from the RTVue XR.

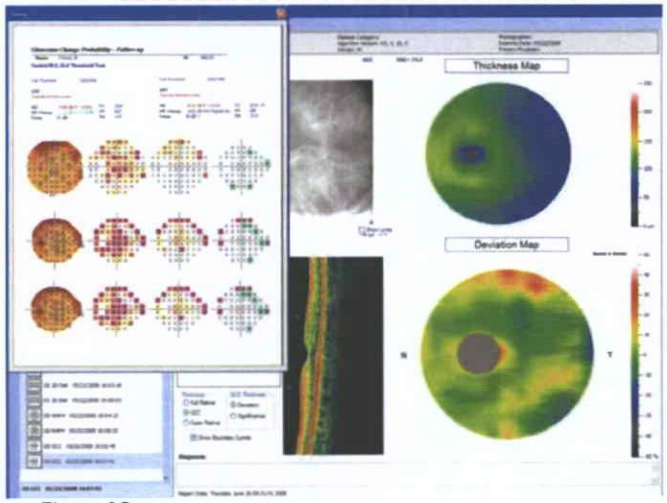

Figure 6C

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Main Menu Bar

6.1.6 *Archive Data*

An **external USB hard drive** or a **network drive** is required to archive data from the RTVue XR. **All archive hard drives are required to support NTFS format**.

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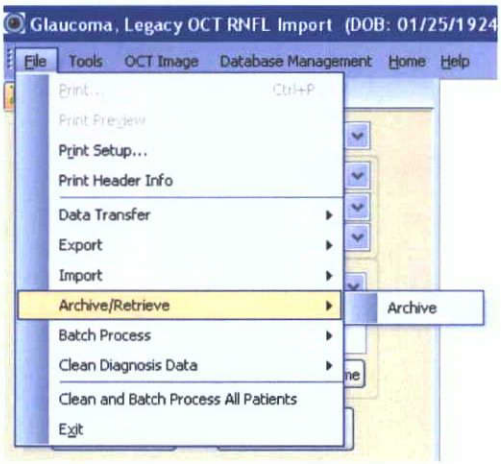
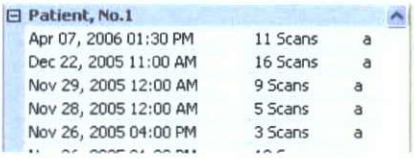
The first step in archive process is to select the archive/retrieve drive by clicking on Tools → User Preference. To archive patient data into the portable/network drive, select the archive destination in the file menu. Archived patients will still appear on the patient list; however, to analyze the patient's data, the same HD must be connected to retrieve the patient's data.



The basic archive unit is the **visit**. Check the visit date on the patient to be archived. Use the sorting functions to help organize the patient list.

After selecting the visits, follow the software instructions to archive the data. The hard drive should be labeled exactly the same as the label name entered in the software. It is advisable to make a backup of the archive drive in the event that the archive drive is accidentally damaged or lost.

Please note that once a visit is archived, it is removed from C and (backup) D drives. It is advisable to backup your archive drive.



The letter "a" appears next to the scan information indicating that the patient visit is archived. However when this data or visit is selected for

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review use, it is automatically retrieved in a few seconds and brought to the screen.

NOTE: This function does require that the Archive media source (network or USB removable drive) is connected to the system at all times during use.

6.1.7 *Note on Backing up Data*

A backup function is done automatically in the background during the normal operation of the system. There are two hard drives supplied in all RTVue XR systems. The application automatically performs a backup routine as you finish each patient examination (capture) session.

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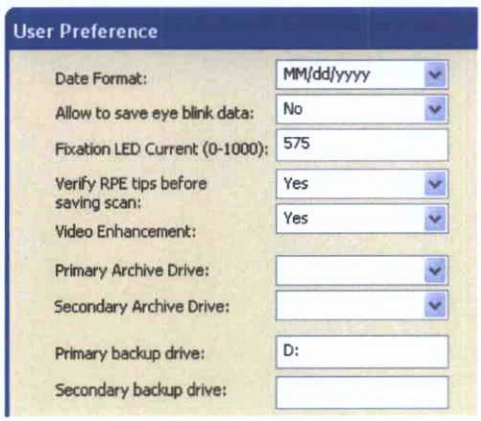
You may add an additional backup target in the form of a USB removable/portable drive or a network address (folder, drive, etc). Simply add the appropriate drive letter (assigned automatically by Window when connected, or determined by your IT person) in the Secondary Backup field in the User Preferences window.



6.1.8 *Batch Process*

This option can be run if you have not opened patient's scans in the Analyze view and wish to pre-process all date. This will reduce the time required when scans are selected in the Analyze view.

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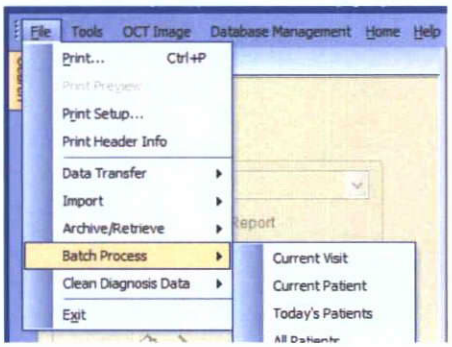
Main Menu Bar



It is best to use the **Batch Process** function whenever the system is not in use. Processing time depends upon the number of patient and scans in the stored data.

6.1.9 Clean Diagnosis Data:

This process removes any previous calculations on the raw data. When opening a patient visit and scan in the Analyze view, the raw data will be processed again. This can also be used prior to reprocessing with updates, if a "reprocessing" requirement is stated. This can also be used when applying custom research site algorithms. NOTE: Please contact Optovue if you wish to apply any algorithms to RAW data other than those supplied with the FDA cleared RTVue XR device application software.

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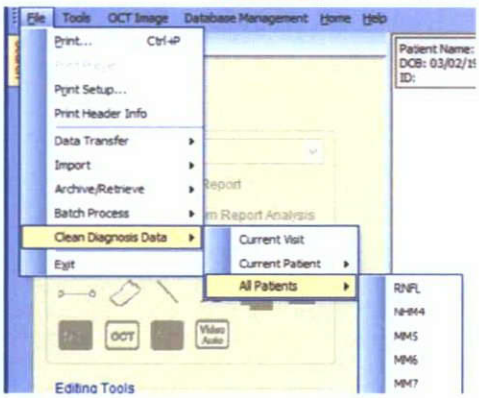

There is an improvement in the processing of ONH and GCC scans. This will only affect the data captured using these scans from the date of installation of the 6.1 upgrade.

PLEASE NOTE: If you wish to use previously captured ONH or GCC scans in a Change Analysis Report with any current data captured *after* the

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installation of version 6.1, the previous data will need to be reprocessed for that patient in order to be included in the Change Analysis. This reprocessing will also affect the previous data single report when opened. The values may or may not be different but the original data is unchanged. This can be done by clicking on File --> Clean Diagnosis Data --> Current Patient --> ONH/GCC. Any Change Analysis Report that does not include data captured and processed with previous version of the RTVue XR application, do not need to be reprocessed.

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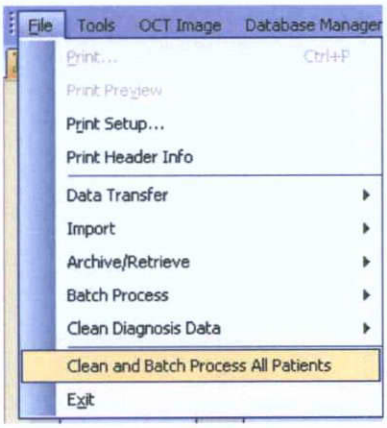
6.1.10 *Clean and Batch Process All Patients:*

This is a one click solution to clean and reprocess all scans for all patients. Depending on the size of the data, this can take several hours. It is recommended that this step is taken after the last patient is scanned for a given day. A progress bar appears showing total number of scans and the number of scans reprocessed.



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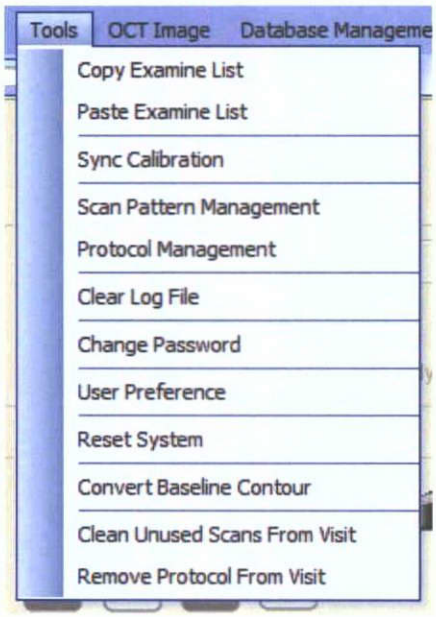
Main Menu Bar

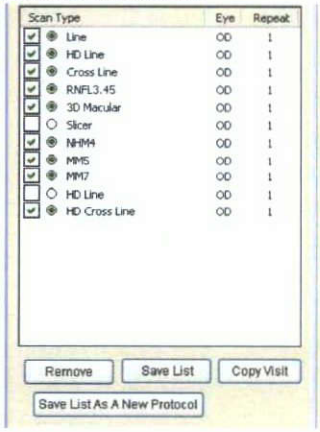
6.2 Tools Menu



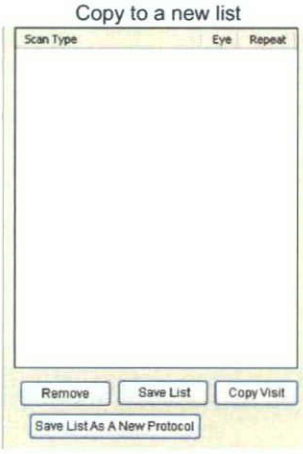
6.2.1 *Copy Examine List: (Advanced GUI only)*

This function allows the user to copy a particular examination list (of scan patterns) in order to paste them into a subsequent visit.

Previous visit scan list



Copy to a new list



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6.2.2 *Paste Examine List: (Advanced GUI only)*

This function pastes or copies the exam list from a previous exam to the current one as desired by the user.

6.2.3 *Sync Calibration: (Technical Support assisted function only)*

This function synchronizes the calibration file between the scanner head and the RTVue XR OCT application.

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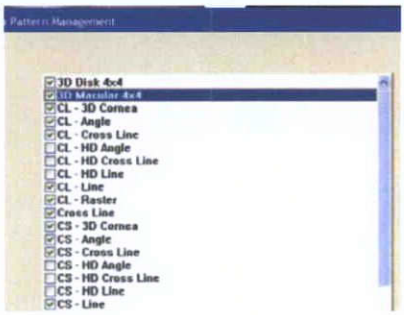
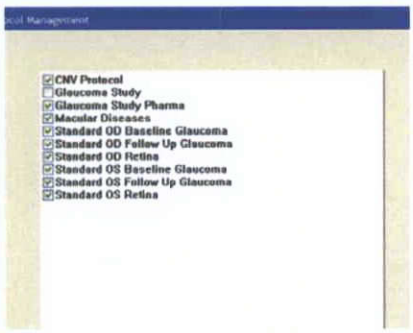
6.2.4 *Scan Pattern Management Screen*

This function allows the user to show or hide any of the scan patterns in the exam list. A clinical site may reduce the number of scan patterns visible to only those that are used in the clinical site. Hidden scans can be made "available" again at any time.



6.2.5 *Protocol Management*

Check the scan protocols (groups of scans) you wish to have available in the Examine View. Allows user to "un-clutter" the protocol list from various trials or studies that are concluded or which no longer apply.



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6.2.6 *Clear Log File*

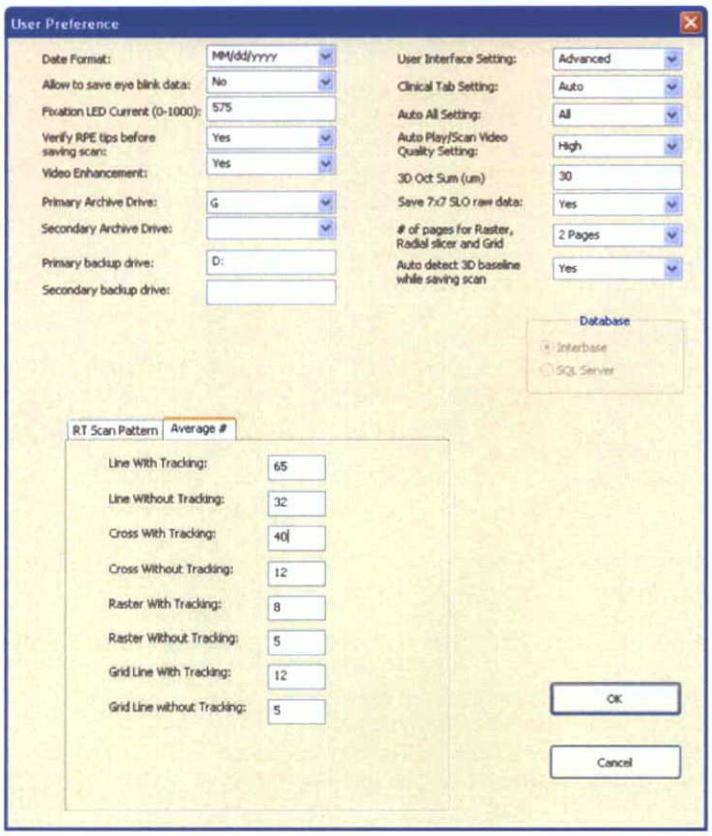
Clears the system event log file. This function should only be selected under the direction of technical support

6.2.7 *Change Password*

Allows administrator of system (log in) to set or change the system password.

6.2.8 *User Preference*

This screen allows the user to modify various default settings for the system. Certain scan parameters and views may be adjusted to user preference.



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Main Menu Bar

User Preferences Fields Defined:

1. **Date Format:** allows you to choose from different date formats.
2. **Allow save eye blink data**: select **YES** to save even if there are blinks, or **NO** to force a rescan when an eye blink is detected.
3. **Fixation LED Current (0-1000)**: adjust the blue LED output by increasing or decreasing the value
4. **Select RPE tips before savings scan**: Select **YES** to set RPE Tips in the **ONH scan** before saving, or select **NO** to draw them during the Analysis viewing.
   i. **WARNING** – if the scan was not placed adequately by the user, and the RPE tips may fall outside the 3.45mm target zone (red dashed lines), the patient should be scanned again. If this option is set to NO, the operator may not identify this problem while the patient is still available for re-scanning
5. **User Interface Setting**: Switches the GUI setting between "Clinical" and "Advanced".
6. **Video Enhancement**: Selecting YES on this option will automatically apply a contrast enhancement to the IR reference image captures with the scan
7. **Primary Archive Drive**: Sets the default drive for archiving function. This may be set to another type of removable media (USB) or a mapped network drive.
8. **Secondary Archive Drive**: Allows a second drive location to be used for archive.
9. **Primary Backup Drive**: Sets primary drive where the system sends a copy of the database, raw data and processed data. (recovery drive)
10. **Secondary Backup Drive**: Allows a second drive location to be used for backup.
11. **TABs (RTVue XR Scan Pattern; Cornea Long; Cornea Short:** These tabs contain the length and width default setting for the various scan patterns.
    i. **NOTE:** The Cornea Long and Cornea Short will only appear if the CAM option is installed on the RTVue XR system
12. **User Interface Setting:** Same as previous options, however "Clinical" is now divided into two Tabs; **Auto** and **Manual**
13. **Clinical Tab Setting**: Sets default presentation to either **Auto** or **Manual**
14. **Auto All setting**: Defines Auto All button and "double-click" in live scan area functions
15. **Auto Play/ Scan Video Quality Settings**: Sets the default level of quality and file size for the AVI file created by recording the animation of the 3D scans
    i. *Range: Low = 25MB (1 loop/cycle) and High = 125MB (1 loop/cycle)*
16. **3D OCT Sum:** Starting value for En Face presentation (microns) in 3D analysis display
17. **Save 7x7 SLO Raw data:** Option to save or discard the Raw data for the SLO style reference image (image is retained regardless of option selected)
18. **# of Pages for Raster, Radial scan and Grid:** User selects the number of pages the printout uses to render the multi-scan presentations.

Click [**OK**] to save user preference changes. If [**Cancel**] is selected, no changes will be saved.

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6.2.9 *Reset System: (Advanced GUI only)*

This option resets the scanner head in the event of a lock up.

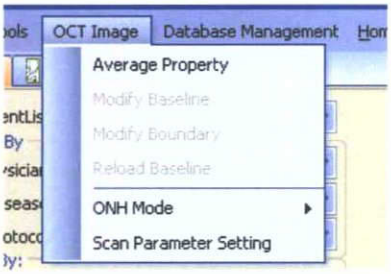
6.2.10 *Clean Unused Scans from Visit*

This option removes the unfinished or unused scans (light gray in scan list) from the list. Use for cleaning up exam with excessive unused scans.

6.2.11 *Remove Protocol from Visit (Advanced GUI only)*

Removes the top level protocol (above the scan list) from the visit. The individual scans will remain, but will not be linked to the protocol for this patient, in this visit only.

6.3 *OCT Image Menu*



6.3.1 *Average Property (Advanced GUI only)*

This is the value used to govern the allowable percentage of variance / match of the individual Line and Cross Line scans that are used for the "averaging" function. (.97 value in field = 97% matching or 3% variance from base image). The default value for this is 0.65.

6.3.2 *Modify Baseline*

Brings up the Video (IR) image and places the disc margin baseline drawing as an overlay for editing purposes. The drawing saved as the baseline may or may not have been drawn on the IR image.

6.3.3 *Reload Baseline*

Places the existing baseline disc margin drawing into the IR image in the upper left corner of the report screen for reference (to edit you must use "Modify Baseline" function (if drawn on the IR image), or the

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3D SLO image of same eye in the baseline 3D scan (if disc margin was drawn using the 3D SLO image).

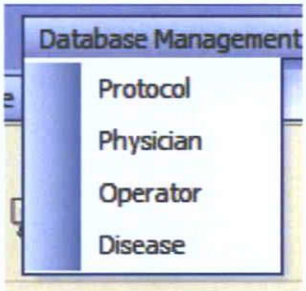
6.3.4 *ONH Mode*

Sets the default location for the disc margin baseline drawing for use with the ONH scan analysis presentation. (see section 6.3.11)

6.3.5 *Scan Parameter Setting*

Set default values for "Dark Eye and "Light Eye" illumination, Grayscale or Color scan display and minimum recommended SSI threshold. (See section 5.12)

6.4 *Database Management Menu*



In the **Database Management** drop-down menu, you may edit and determine the various fields and scans that are displayed in each category.

6.4.1 *Protocol (scan protocol editor):*

These can be created or modified per user preferences.

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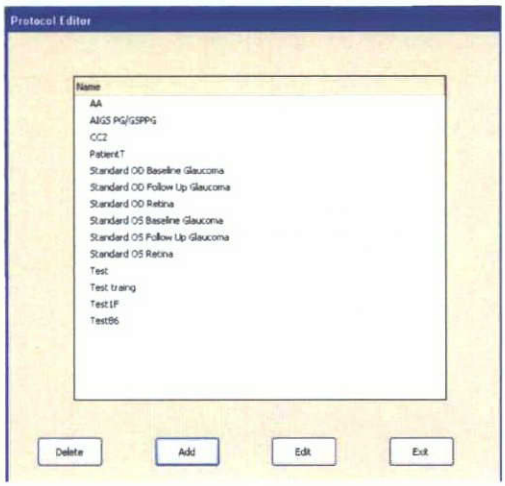
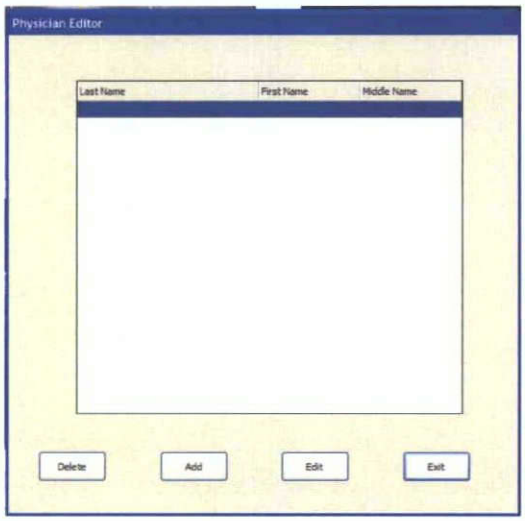
Main Menu Bar



6.4.2 *Physician:*

Add a new physician, edit the name or other information of a current physician or delete a physician if not used by users.



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Main Menu Bar

6.4.3 *Operator:*

Add a new operator, edit the name or other information of a current operator or delete an unused operator who no longer exists.

6.4.4 *Disease:*

Add, delete or edit disease category

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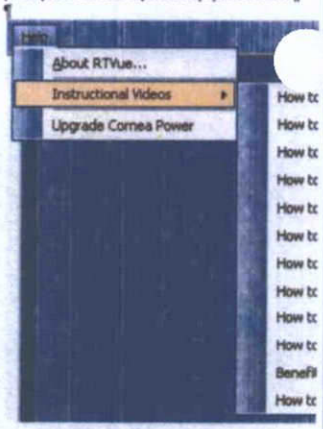
<#>Instructional videos:¶
Instructional videos demonstrating how different scans are acquired are included in the Help menu to serve as a reference. Each time a selection is made under Help → Instructional Videos, a corresponding video will play in Windows Media Player. Use earphones or external computer speakers for sound.¶
¶
Please note that Windows Media Player needs to be setup in order to use this feature. If it were not used prior to playing an instructional video, you may be prompted for a simple setup procedure.¶
¶



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Note: Instructional video's for RTVue XR has not been developed

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7 Maintenance & Troubleshooting

7.1 Routine Care

1. **Dust Prevention:**
   When not using the RTVue XR, make sure the cloth dust cover is placed over the unit.

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2. **Ocular (Front Objective) Lens Cleaning:**
   We recommend that the ocular (front objective) lens of the RTVue XR be cleaned daily. A weak OCT image or blurry video fundus image may be caused by an unclean front lens (eyelash, finger or nose prints, or excessive dust or dirt from the environment).

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   Material required to clean front lens:
   1) Diluted Acetone or Lens cleaning solution
   2) Lens cleaning paper

   Method:
   Wet the lens paper with cleaning solution and wipe the ocular lens with one pass in one direction. Discard the used lens paper. Use a new sheet for each repeat cleaning until the lens is clean.

3. **Head and Chin Rest:**

   For head and chin rest maintenance, it is recommended to clean the surfaces periodically.

   Material required:
   1) Disinfecting agent such as an anti-germicide or isopropyl alcohol; AND
   2) Cloth or cleaning towels
      OR
   3) Wet isopropyl alcohol cleaning paper pad

   Method:
   Soak the cleaning cloth or towel in disinfecting solution or use a wet isopropyl alcohol cleaning paper pad. Wipe the chin-rest cup and head rest pad.

7.2 RTVue XR Computer Boot Sequence

1. Power up the RTVue XR table.
2. Turn on the RTVue XR computer.
3. After Windows™ has fully initialized, double click the RTVue XR icon to launch the application. It may take approximately 1-2 minutes for Windows to fully initialize.

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7.3 RTVue XR Computer Maintenance

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Optovue recommends performing **disk cleanup** and **disk defragment** on a regular basis to keep the RTVue XR PC computer running smoothly. The above functions can be found in system tools.

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8 Scan Pattern Specifications

8.1 Scan Patterns

Summary:

Name	Description	# A-Scan	Adjustability	Default
Scan Pattern				
Line ~(0.015 seconds)	Single line averaging, Tracking Option	1 x 1024 (User selectable # of scans for averaging to single B-scan image presentation) **Divide by 69000**	Transverse: 2-12mm (0.5 mm increment) Angle: 0 to 180° (1° increment)	6mm, 0 degree (from left to right of the monitor screen)
Cross Line ~(0.030 seconds)	Cross line scan with averaging, Tracking Option	2 x 1024 (User selectable # of scans for averaging and two B-scan images presentation)	Transverse: 2-12mm (0.5 mm increment) Angle: 0 to 180° (1° increment)	6mm, 0 degree (from left to right of the monitor screen)
HD Line ~(0.059 seconds)	High definition single line scan	1 x 4096 (4 scans are captured – one is selected for saving)	Transverse: 2-12mm (0.5 mm increment) Angle: 0 to 180° (1° increment)	6mm, 0 degree (from left to right of the monitor screen)
HD Cross Line ~(0.119 seconds)	High definition cross line scan	2 x 4096 *(8192 data points)*	Transverse: 2-12mm (0.5 mm increment) Angle: 0 to 180° (1° increment)	6mm, 0 degree (from left to right of the monitor screen)
RNFL3.45 ~ (0.06 seconds) Glaucoma	Four 3.45mm diameter circular scans center on disc	4 x 1024 *(4 scans are taken and presented. Avg is also presented in TSNIT)*	Fixed	3.45mm diameter. (From Temple to Superior to Nasal to Inferior (**TSNIT** convention)

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Scan Pattern Specifications

3D Macular ~(751 seconds)	101 frames equally spaced B-scans to cover a square volume fixation at center	101x513 *(51,813 data points)*	Transverse: 2-10 mm (0.1 mm increment) Angle: 0 to 180° (1° increment) Width: 1-6 mm (0.1 mm increment)	6mm x 6mm
3D Disc ~(751 seconds)	101 frames equally spaced B-scans to cover a square volume fixation at 20° nasal	101x513 *(51,813 data points)*	Transverse: 2-10 mm (0.1 mm increment) Angle: 0 to 180° (1° increment) Width: 1-6 mm (0.1 mm increment)	6mm x 6mm
3D Reference ~(787 seconds)	141 B-scans equally spaced to cover 7mm x 7mm volume. Center fixation	141 x 385 (54,285 data points)	Fixed	7mm x 7mm
Raster ~(252 seconds)	17 parallel line scans, Tracking Option, (User selectable number of B-scans per line location for averaging)	17 x 1024	2-10 mm in length 1-6 mm in width	L: 6mm W: 4mm
MM6 ~(0178 seconds)	12 radial line scans through a central point	12 x 1024 (12,288 data points)	MM6 = 6mm fixed Radial Slicer = up to 10mm	MM6 / Radial = 6mm diameter circular pattern
Grid Line ~(696 seconds)	5 Vertical raster and 5 Horizontal raster lines Tracking Option (User selectable number of B-scans per line location for averaging)	10 x 5 x 960 (48,000 data points)	2 – 12 mm length and 0 – 12 mm width adjustment	8 mm length x 2 mm width (250 µm separation)

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Scan Pattern Specifications

EMM5 ~(0.43 seconds) Retina	13 horizontal lines with 6mm scan length and 0.5mm interval, + 8 horizontal lines with 4mm scan length and 0.5mm interval, 13 vertical lines with 6mm scan length and 0.5mm interval, + 8 vertical lines with 4mm scan length and 0.5mm interval, all centered at fovea	26x 803 + 16x535 *(29,438 data points)*	Fixed	6 x 6mm outer region. 4 x 4 mm inner region 250 µm interval in central 4mm and 500 µm separation outside 1mm (each side and top/bottom)	Deleted: 1.30
GCC ~(0.21seconds) Glaucoma	1 horizontal line with 7mm scan length, followed by 15 vertical lines with 7mm scan length and 0.5mm interval, centered 1mm temporal to fovea	1 x 933 /Horizontal line. 15 x 933/Vertical line	Fixed	7mm x 7mm	Deleted: 58
ONH ~(0.018 seconds) Glaucoma	12 radial line scans 3.4mm length & 13 concentric rings (1.3 - 4.9mm diameter) All centered on disc	3 x 965/ring (4.9, 4.6, 4.3), 3 x 775/ring (4.0, 3.7, 3.4), 3 x 587 (3.1, 2.8, 2.5), 4 x 425/ring (2.2, 1.9, 1.6, 1.3), 12 x 455/radial line	Fixed	4.9 mm diameter centered on the optic disc	Deleted: 55
Grid ~(0.70 seconds)	5 Vertical raster and 5 Horizontal raster lines captured 5 times each and then averaged	10 x 5 x 960 (48,000 data points)	2 – 12 mm length and 0 – 12 mm width adjustment	6 mm length x 2mm width (250 µm separation)	Deleted: 2.0

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Scan Pattern Specifications

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Technical Specifications

9 Technical Specifications

9.1 System Specification

A. RTVue XR Scanner:

OCT Image Acquisition Rate: ~70 kHz A-scan/second
Frame Rate: 256 to 1024 A-scan/Frame
Optical Resolution: (in tissue)
- Depth: 5µm
- Beam Spot Size: 15µm

Image Sampling Rate:
- Depth: 2.9µm
- Transverse: 8µm (nominal)

Scan Range:
- Depth: 2 to 2.9mm
- Transverse: 2mm to 12mm

Scan Beam Wavelength: λ=840±10nm, Δλ (FWHW) = 50nm
Exposure Power at pupil: 750µW

B. Fundus Imager:

FOV: 32° (H) x 22° (V)
Monochrome CCD Camera: 768 x 498 pixel 1/3" CCD Format
NIR Illumination: 735nm LED

C. Patient Interface:

Working Distance: 22mm
Motorized Focus Range: -15D to +20D
Internal Fixation: Center, ±3.5° (Horizontal), and ±18° (Horizontal)
Motorized Chin-Rest adjustable range: 65mm
Joystick controlled X-Y-Z adjustment: X-100m, Y-85mm, Z-25mm
Lock-mechanism: Electro-magnetic activated

D .Computer Unit:

CPU: 2.66GHz Quad-Core Processor
Hard Disc: 1 TB
Back up Hard Disc: 1 TB
Archive: USB or Network Drive
RAM: 4 GB
DAQ: Camera link frame grabber

E. Display Unit:

19" Flat Panel LCD Monitor

F. Power Table:

Power Input: 110V A.C. (RTVue XR 100-1)
230V A.C. (RTVue XR 100-2)
Current: 1.8AMPS
Frequency: 50/60 Hz
Power Rating: 160W
Maximum Force: 2500N
Motorized adjustment range: 200 mm

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Technical Specifications

G. Circuit Breaker and Fuse:

Thermal circuit breaker (main power entry)

Rating:	6AMPs, 125-250VAC
Dielectric Strength:	2500 VAC/1 minutes
Operating Temp.:	-10 °C to 60 °C

Fuse (Power supply in Scanner)

Rating:	4AMPs/250V
Package:	5mm x20mm
Type:	Fast Acting, Short Time Lag

H: Compliance:

General Medical	EN60601-1
Medical System	EN60601-1-1
EMC of Medical System	EN60601-1-2
ITE (Computer)	EN60950

I: Environment:

Operating Condition: (no condensation)
- Ambient Temperature: +10 to 40 °C
- Relative humidity: 30% to 75%
- Atmospheric pressure: 700 to 1060 mbar

Storage and Transport Condition:
- Ambient Temperature: -40 to 70 °C
- Relative humidity: 10% to 100% (include condensation)
- Atmospheric pressure: 500 to 1060 mbar

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Appendix

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10 Appendix - A

10.1 Printer Installation

WARNING: When powering a USB-interfaced printer to the RTVue XR system, it is recommended to connect the power through the designated power supply outlet in the PC compartment. This outlet is isolated from the wall plug (building power) through RTVue XR's isolation transformer.

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If the printer is powered from somewhere other than the designated power outlet, the printer should be placed at least 1.5 meters away from the patient to avoid electric shock.

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Appendix

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11 Appendix – B

Note: below data is based on clinical study performed on RTVue System (K101505)

11.1 RTVue Precision

Description of Precision Study, Subject Selection Criteria and Pathologies

Instruments:
For the study, 3 RTVues with three different operators and results were compared in normal eyes, and eyes with retina pathology, cornea pathology, and glaucoma.

Scans:
The measurements and parameters calculated from ONH, EMM5 and GCC scans. Both eyes were scanned in each subject.

Precision results are not available for the MM5, MM6 and RNFL 3.45 scan patterns. However, these scan patterns are very similar to other scan patterns where precision results have been presented.

The MM5 scan area is included in the EMM5 since the EMM5 is an enhanced MM5 scan. Precision results of the MM5 scan and the EMM5 scan would be identical.

The MM6 scan pattern is a radial line scan pattern centered on the fovea extending out 3 mm (6 mm total line length with fovea in the middle). The scan pattern shows measurements for full retinal thickness measurements and inner retina thickness measurements. This is very similar to the EMM5 scan pattern. This scan pattern covers a 6 mm by 6 mm square area using a grid scan pattern. It also is centered on the fovea and displays full retinal thickness values and inner retinal thickness values. Because both scan patterns measure retinal thickness, are similar in size and are centered on the fovea, the precision performance is expected to be very similar.

The RNFL 3.45 scan pattern is a circular scan centered on the optic disc. The results are presented as RNFL thickness in the parapapillary region taken from a circle with 3.45 mm diameter. The ONH scan pattern is made up of twelve radial lines and 13 circles centered on the optic disc. The results show RNFL thickness from a circle with 3.45 mm diameter centered on the optic disc. This is the same information presented for the RNFL 3.45 scan pattern. The main difference is the fact the ONH scan pattern has information over a larger area. However the information presented is the same for both, a circular RNFL thickness profile form a 3.45 mm diameter circle. Because of this, we expect the precision results to be nearly identical for the RNFL 3.45 and ONH scan patterns.

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Four types of subjects were enrolled in the study at two clinical sites, namely 1) normal healthy eyes with no ocular pathology, 2) glaucoma patients, 3) retina patients, and 4) cornea patients. Normal subjects were free from ocular pathology as determined by the Principal Investigator (PI) at each clinical site. Glaucoma patients were diagnosed as having glaucoma by the PI at each site. Retina patients included subjects with any type of retina pathology diagnosed by the PI. Retina pathologies included but were not limited to, AMD, DME, and ERM. Cornea patients included subjects with any type of cornea pathology as diagnosed by the PI, or cornea alteration including LASIK. There were 4 normal subjects, 4 cornea patients, 4 retina patients, and 4 glaucoma patients enrolled for each RTVue device. There were 3 RTVue devices at 2 clinical sites. At one site, there were 2 RTVue systems and 2 operators at different times. In total, there were 16 subjects enrolled for each RTVue device; a total of 48 subjects were included in the study.

Cornea precision results are available in the RTVue User Manual – CAM (Cornea Adaptor Module).

Precision Results:
The following tables provide the precision results for the RTVue scans. The data in the table includes the number of scans per subject group, the overall mean, the standard deviation, the repeatability standard deviation (Median value of subfields with the minimum of all related subfield values and the maximum of all related subfield values), and reproducibility standard deviation (Median value of subfields with the minimum of all related subfield values and the maximum of all related subfield values).

i) EMM5 Scan Precision Results (Normal, Retina and Glaucoma Patients)

EMM5 Full Retina Thickness Fovea			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	243.61 (26.00)	267.15 (73.32)	246.22 (22.14)
Repeatability SD* (Min, Max)	2.57(1.66, 2.57)	2.96(1.83, 3.15)	3.01(1.95, 3.01)
Reproducibility SD** (Min, Max)	17.72(1.66, 17.72)	13.78(1.83, 13.78)	3.01(2.05, 5.80)

EMM5 Full Retina Thickness outside Fovea			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	295.05 (16.21)	299.03 (30.70)	282.30 (25.26)
Repeatability SD* (Min, Max)	1.96(1.66, 2.57)	2.69(1.83, 3.15)	2.35(1.95, 3.01)
Reproducibility SD** (Min, Max)	2.01(1.66, 17.72)	2.69(1.83, 13.78)	2.66(2.05, 5.80)

EMM5 Full Retina Thickness Volume			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	0.63 (0.03)	0.64 (0.07)	103.02 (12.22)

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Repeatability SD* (Min, Max)	0.003(0.002, 0.006)	0.004(0.002, 0.010)	2.40(1.78, 2.87)
Reproducibility SD** (Min, Max)	0.005(0.003, 0.015)	0.007(0.003, 0.011)	2.53(1.78, 3.52)

EMM5 Inner Retina Thickness all measurements			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	112.83 (9.16)	113.04 (15.05)	103.02 (12.22)
Repeatability SD* (Min, Max)	1.38(0.88, 1.72)	2.52(1.57, 3.12)	2.40(1.78, 2.87)
Reproducibility SD** (Min, Max)	1.70(0.88, 7.09)	3.02(1.57, 6.59)	2.53(1.78, 3.52)

EMM5 Global RPE/Choroid Disruption			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	5.657 (1.468)	9.797 (3.280)	9.268 (2.552)
Repeatability SD* (Min, Max)	0.207(0.207, 0.207)	0.479(0.479, 0.479)	0.761(0.761, 0.761)
Reproducibility SD** (Min, Max)	0.736(0.736, 0.736)	0.877(0.877, 0.877)	1.611(1.611, 1.611)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

ii) ONH Scan Precision Results (Normal and Glaucoma Patients)

ONH Average RNFL		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	100.82 (8.11)	86.40 (14.99)
Repeatability SD* (Min, Max)	1.76(1.76, 6.18)	1.56(1.56, 5.86)
Reproducibility SD** (Min, Max)	2.11(2.11, 9.78)	7.87(3.92, 16.33)

ONH All Sectors		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	100.82 (14.80)	86.41 (18.55)
Repeatability SD* (Min, Max)	3.92(1.76, 6.18)	4.48(1.56, 5.86)
Reproducibility SD** (Min, Max)	5.40(2.11, 9.78)	7.84(3.92, 16.33)

ONH Horizontal CD Ratio

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	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	1.27 (0.50)	0.79 (0.21)
Repeatability SD* (Min, Max)	0.04 (0.01, 0.04)	0.08(0.05, 0.08)
Reproducibility SD** (Min, Max)	0.04 (0.01, 0.04)	0.08(0.05, 0.08)

ONH Vertical CD Ratio		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	2.15 (0.65)	0.76 (0.23)
Repeatability SD* (Min, Max)	0.01 (0.01, 0.04)	0.05(0.05, 0.08)
Reproducibility SD** (Min, Max)	0.01 (0.01, 0.04)	0.05(0.05, 0.08)

ONH Cup Area		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	0.39 (0.18)	1.04 (0.53)
Repeatability SD* (Min, Max)	0.02 (0.02, 0.03)	0.07(0.07, 0.21)
Reproducibility SD** (Min, Max)	0.02 (0.02, 0.03)	0.07(0.07, 0.21)

ONH Rim Area		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	0.69 (0.17)	0.89 (0.66)
Repeatability SD* (Min, Max)	0.03 (0.02, 0.03)	0.18(0.07, 0.21)
Reproducibility SD** (Min, Max)	0.03 (0.02, 0.03)	0.18(0.07, 0.21)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

iii) GCC Scan Precision Results (Normal and Glaucoma Patients)

GCC Inner Retina Average		
	Normal Patients	Glaucoma Patients
# of Scans	72	71
Overall Mean (Overall SD)	98.28 (9.31)	81.76 (8.90)
Repeatability SD* (Min, Max)	1.86 (1.86, 2.07)	1.18 (1.18, 1.59)
Reproducibility SD** (Min, Max)	7.56 (7.32, 7.92)	2.55 (1.59, 3.36)

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GCC Inner Retina S-I Average		
	Normal Patients	Glaucoma Patients
# of Scans	72	71
Overall Mean (Overall SD)	0.69 (3.51)	1.98 (8.17)
Repeatability SD* (Min, Max)	1.59 (1.59, 1.59)	2.10 (2.10, 2.10)
Reproducibility SD** (Min, Max)	1.91 (1.91, 1.91)	2.10 (2.10, 2.10)

GCC GCC FLV		
	Normal Patients	Glaucoma Patients
# of Scans	72	71
Overall Mean (Overall SD)	0.60 (0.67)	4.30 (3.47)
Repeatability SD* (Min, Max)	0.37 (0.37, 0.37)	0.88 (0.88, 0.88)
Reproducibility SD** (Min, Max)	0.46 (0.46, 0.46)	1.04 (1.04, 1.04)

GCC GCC GLV		
	Normal Patients	Glaucoma Patients
# of Scans	72	71
Overall Mean (Overall SD)	3.99 (3.43)	15.51 (7.81)
Repeatability SD* (Min, Max)	0.83 (0.83, 0.83)	1.03 (1.03, 1.03)
Reproducibility SD** (Min, Max)	2.44 (2.44, 2.44)	1.71 (1.71, 1.71)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

Note: Above data is based on clinical study performed on RTVue System (K101505)

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12 Appendix – C

Note: below data is based on clinical study performed on RTVue System (K101505)

12.1 Signal Strength Index (SSI)

For the RTVue, a Signal Strength Index classification is provided for each scan type in order to help guide the user to determine if the scan quality is acceptable or not. The Signal Strength Index (SSI) is a quantitative measure for judging image quality. It serves as a guide to help the user know if the image quality is generally good or not. It is not the only thing to consider when determining image quality, but it does offer a quantitative assessment of the signal strength in the image which is a major component of image quality. The Signal Strength Index is based on the intensity of the reflected light. The greater the intensity (brightness), the higher the SSI. This is based on a global average over the entire scan pattern. The Signal Strength Index (SSI) is displayed after each scan. In the above scan, the SSI is at the top of the scan. If the SSI is low, it is recommended that the user re-take the scan and try to improve the SSI. The cut-offs recommended for retaking scans are provided in the table below. They are different for each scan pattern due to the fact that different scans require different levels of retinal segmentation. For example, GCC and EMM5 scans require the inner-plexiform layer to be segmented and this layer is generally not the most reflective compared to other retinal layers. The ONH scan is OK at lower SSI levels because the RNFL layer is highly reflective and can be segmented even under less ideal signal strength values. In some cases, the SSI cannot be improved even when retaking the scans due to ocular opacity (e.g., cataract) or other unavoidable causes. In these cases, the scan can still be used even with a low SSI but the results should be interpreted with more caution compared to a scan with a high SSI.

Recommended SSI cut-offs for each scan

Scan Type	Minimum Recommended SSI
EMM5	SSI < 39
ONH	SSI < 28
GCC	SSI < 32

These SSI cut-off values used for RTVue were determined based on an in-house review of a large data set from the RTVue, made up of approximately 100 scans with a wide range of SSI values and including scan types - EMM5, ONH, GCC. MM5, and MM6 patterns are very similar to EMM5, ONH and GCC scan patterns. (see Appendix – RTVue Precision for further explanation on scan similarities) To establish the SSI cut-off, approximately 100 B scans were reviewed for 3 scan types on the RTVue (EMM5, ONH, GCC). The basic criteria for review was whether visualization of the critical retinal layers was possible or not, including the ILM (for all scan types), the RNFL (for glaucoma scans), the IPL (for retina scans), and the RPE (for retina scans). The Un-usable cut off value was determined for each scan pattern to be the SSI value where the various retinal layers could no longer be reliably visualized in the B scans. These scans cannot be

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segmented accurately if there is no ocular structure that can be reliably visualized with low variability. The SSI value associated with this point (where retinal layers cannot be reliably discerned) were used as the recommended cut-off point for the user and are included in the table above.

In order to validate the recommended cut-off between acceptable and not acceptable scans, the repeatability of scans was evaluated at difference SSI levels. For this evaluation, repeat scans were performed on six normal subjects with clear ocular media to establish a baseline level of precision. All 3 scan patterns on the RTVue were evaluated and scans were repeated 3 times in order to calculate repeatability defined as the standard deviation of the thickness values for each measurement. The image quality was manipulated by defocusing the OCT image during scan acquisition. The defocusing and resulting lowering of the image quality mimics the clinical situation which would occur with media opacity and small pupils. All measurements were analyzed and the results are provided in the following tables (numbers are the average standard deviation of the 3 scans averaged across all six subjects). The standard deviation represents the amount of measurement variability present under different image quality classifications; the higher the standard deviation, the greater the measurement variability.

EMM5 scan variability results comparing scans with SSI values above the recommended cut-off and below the recommended cut-off

EMM5			
Measurements		Above Cut-Off	Below Cut-Off
Full Retina	Fovea	9.58	54.57
	Tempo	7.27	62.04
	Superior	10.77	43.42
	Nasal	6.91	52.72
	Inferior	10.90	60.97
	Tempo2	5.33	38.96
	Superior2	2.90	33.91
	Nasal2	5.59	42.38
	Inferior2	9.91	52.25
Average		7.68	49.02

Table 1.

Table 1 shows the standard deviation values of 3 scans averaged over all subjects for each EMM5 thickness parameter. The first column of data is the result when the image quality above the recommended cut-off (equal to or above the ROC cutoff 39) and the scans are deemed acceptable and usable. The second column of data is the result when the image quality is listed as below the recommended cut-off (below the ROC cutoff 39) and the scans are deemed unacceptable and not usable. It can be seen that the standard deviations are very good when the image quality is usable, and then gets much worse when the image quality is unusable. From the high variability in the unusable scans, it is recommended that 'Un-usable' scans not be used for clinical decision making due to their poor quality.

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ONH scan variability results comparing scans with SSI values below the recommended cut-off and scans with SSI values above the recommended cut-off.

ONH		
Measurements	Above Cut-Off	Below Cut-Off
Avg RNFL	2.01	5.88
Sup RNFL	2.56	4.31
Inf RNFL	2.76	8.82
Tempo	6.21	11.52
Superior	3.96	10.46
Nasal	4.55	12.68
Inferior	3.68	8.36
TU	5.68	14.16
ST	5.29	13.37
SN	5.92	15.63
NU	5.82	15.79
NL	4.52	10.99
IN	5.40	14.56
IT	4.29	13.93
TL	7.76	19.08
Average	4.69	11.97

Table 2.

Table 2 shows the standard deviation values of 3 scans averaged over all subjects for each ONH thickness parameter. The first column of data is the result when the image quality is above the recommended cut-off (equal to or above the ROC cutoff 28). The second column of data is the result when the image quality is below the recommended cut-off (below the ROC cutoff 28). It can be seen that the standard deviations are very good when the image quality is above the cut-off, and then gets much worse when the image quality is below the cut off. From the high variability in the unusable scans, it is recommended that these scans not be used for clinical decision making due to their poor quality.

GCC scan variability results comparing scans with SSI values above the recommended cut-off and scans with SSI values below the recommended cut-off.

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GCC		
Measurements	Above Cut-Off	Below Cut-Off
Inner Retina Average	1.88	12.25
Superior Average	2.13	14.06
Inferior Average	3.25	14.02
S-I Average	4.13	12.43
GCC-FLV	0.98	3.59
GCC-GLV	1.47	4.85
Average	2.31	10.20

Table 3.

Table 3 shows the standard deviation values of 3 scans averaged over all subjects for each GCC thickness parameter. The first column of data is the result when the image quality is listed as above the cut-off(equal to or above the ROC cutoff 32) and the scans are deemed acceptable and usable. The second column of data is the result when the image quality is below the cut-off (below the ROC cutoff 32). It can be seen that the standard deviations are very good when the image quality is above the cut-off, and then gets much worse when the image quality is below the cut-off. From the high variability scans below the recommended cut-off, it is recommended that these scans not be used for clinical decision making due to their poor quality.

Note: Above data is based on clinical study performed on RTVue System (K101505)

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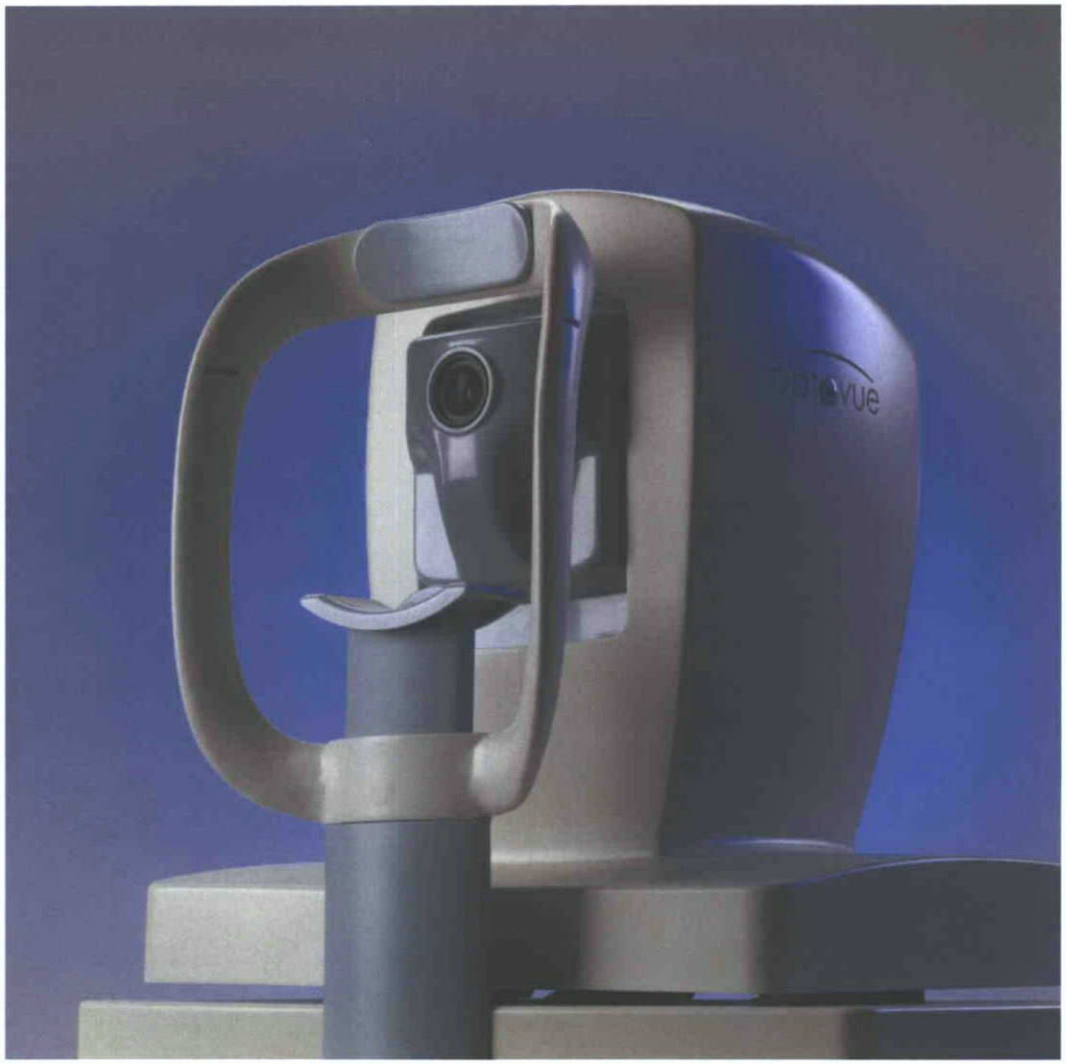
RTVue XR

- Model - XR-100



User's Manual

Version 6.6

optovue

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

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Publishing details

RTVue XR
Version 6.6

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Revision Control

Part Number	Rev	Software ver.	Description	Release Date
580-XXXXX-XXX	A	v 6.6	Reference ECR #XXXXX	xx/2012

License and use of the RTVue XR-100 systems is intended only for trained medical personnel in accordance with the license agreement – all other usage is prohibited – warranty restrictions and possible claim limitations apply.

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

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1 Safety Notes

General
This instrument has been developed and tested in accordance with Optovue safety standards as well as national and international regulatory guidelines to ensure a high degree of instrument safety. Please observe all safety notes and information in this manual and on the device labels. This device does not produce any waste that needs disposal. Product contains no material which has a chemical hazard concern.

Proper Instrument Use

1. Always enter patient information first.
2. Clean patient contact surface (forehead and chin rest according to the cleaning method in Chapter 7 of this manual).
3. Instantly turn off the power switch of the instrument and disconnect the power cable if uncertain problems arise.
4. Clean ocular lens frequently to ensure good image quality.
5. Adjust power table height properly to ensure patient comfort during the examination.
6. Align the patient's head and eye position to the canthus indicator mark on the chin and forehead rest assembly.
7. Dim the room lights to allow natural dilation of the patients' pupil and to provide a comfortable visualization of the fixation target without glare. Note: Chemically induced pupil dilation is not needed.

Intended Use
The RTVue XR with Normative Database s an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician.

The RTVue XR with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

Note: The RTVue XR OCT is not intended to be used as the sole diagnostic aid in disease identification, classification or management. The RTVue XR provides data to be used in conjunction with other information, intended to assist an eye care clinician in determining a diagnosis. A patient diagnosis is the sole domain of a licensed eye care clinician.

WARNING: THE RTVue XR CANNOT REPLACE CLINICAL JUDGEMENT AND IS INTENDED TO BE USED ONLY IN CONJUCTION OTHER CLINICAL TOOLS CONSIDERED TO BE THE STANDARD OF CARE FOR DIAGNOSIS OF EYE DISEASE.

Warning: User Changes to Software or Hardware

The RTVue XR is a medical device. The software and hardware has been designed in accordance with U.S., European and other international medical device design and manufacturing standards. Unauthorized modification of the RTVue XR software or hardware, or any addition or deletion of any

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application in any way can jeopardize the safety of operators and patients, the performance of the instrument, and the integrity of patient data.

Any changes, additions or deletions to factory installed applications, operating system or modifications to hardware in any manner VOIDS the Warranty completely.

Warning: Phototoxicity

Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures.

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

"While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure to the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography."

Caution: Federal law restricts this device to sale by or on the order of a Physician or Practitioner (CFR 801.109(b)(1)).

Product Compliance

Indicates this equipment contains Type B applied parts.

Electromagnetic Compatibility (EMC) : EN 60601-1-2:2001
The RTVue XR100 device has been tested to comply with the emission and Immunity requirements of EN60601-1-2:2001. The RTVue XR100 is intended for use in an electromagnetic environment where radiated RF disturbances are not beyond the standard defined in EN60601-1-2:2001.
RTVue XR-100 is a Medical Electrical Equipment that need special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Manual.
RTVue XR - 100 is a Medical Electrical Equipment and can be affected during operation by portable and mobile RF communication devices.
RTVue XR-100 is self-contained medical equipment. It should not be used adjacent or stacked with other equipment .

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CB Certification: under IEC 60601-1

Guidance and manufacture's declaration – electromagnetic emissions		
The RTVue XR-100 is intended for use in the electromagnetic environment specified below. The customer or user of the RTVue XR100 should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group1	The RTVue XR100 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The RTVue XR100 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The RTVue XR100 is intended for use in the electromagnetic environment specified below. The customer or user of the RTVue XR100 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 2 kV common mode ± 1 kV differential mode	± 2 kV common mode ± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (95% dip in UT) for 5 sec		Mains power quality should be that of a typical commercial or hospital environment. If the user of the RTVue XR100 requires continued operation during power mains interruptions, it is recommended that the RTVue XR100 be powered from an uninterruptible power source.

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			Note: UT is the A.C. mains voltage prior to application of the test level.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	150kHz to 80 MHz 3Vrms	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the RTVue XR100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** **d = 1.2 * SQRT(P)** for 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	80MHz -2.5GHz, 3V/m	3V/m	**d = 1.2 * SQRT(P)** for 80 MHz to 800 MHz **d = 2.3 * SQRT(P)** for 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, **a** should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Note 1: At 80 MHz and 800 MHz, the higher frequency applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is			

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affected by absorption and reflection from structures, objects and people.
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RTVue XR100 is used exceeds the applicable RF compliance level above, the RTVue XR100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the RTVue XR100. **b** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communication equipment and the RTVue XR - 100

The RTVue XR100 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RTVue XR100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RTVue XR100 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d = 1.2 SQRT(P)	80 MHz to 800 MHz d = 1.2 SQRT(P)	800 MHz to 2.5 GHz d = 2.3 SQRT (P)
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture.
Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

During OCT imaging, the essential performance of RTVue XR - 100 consists of the presence of OCT scanning beam and the continual display of at least the background noise in the application software.

List of major cables

Part number	Specification	Max. Length	Remark
660-42031	USB 2.0	5 feet	
660-42024	Camera Link	6 feet	
700-43184	Power Cord	10 feet	

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Please ask authorized personnel from Optovue Inc. for cable replacement. The use of cables other than those specified by Optovue Inc. may result in increased EMISSIONS or decreased IMMUNITY of the RTVue XR system.

Symbols and Labels

Caution, consult accompanying documents.

Note: There are important Operating and maintenance instructions found in the manual.

Presence of electrical shock hazard.

Note: Indicates risk of electrical shock due to the presence of non-insulated high voltage inside the instrument. Do not remove the instrument cover or parts.

Fuse

Type B Applied parts.

Note: This instrument complies with the specified requirements to provide protection against electrical shock, particularly regarding allowable patient leakage current.

Manufacturer
Optovue Incorporated
45531 & 45395 Northport Loop W.
Fremont, CA 94538

Authorized European Community Representative

Medical Device Safety Services (MDSS) GMbH
Schiffgraben 41
30175 Hannover, Germany

Serial number

Catalog number / part number

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

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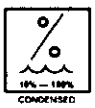
Protective Packing Symbols

The protective packing symbols specify the handling requirements and the transport and storage conditions.

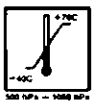
Fragile, Handle with care

Keep Dry

This end up



Relative Humidity (10% to 100%, including condensation)



Temperature (-40 to 70 deg. C)

Waste Electrical and Electronic Equipment (WEEE) Recycling Instructions

When determined that the device is ready for disposal, it is to be recycled following the policies and procedures reflecting respective country's requirements. Do not dispose of device as general waste.

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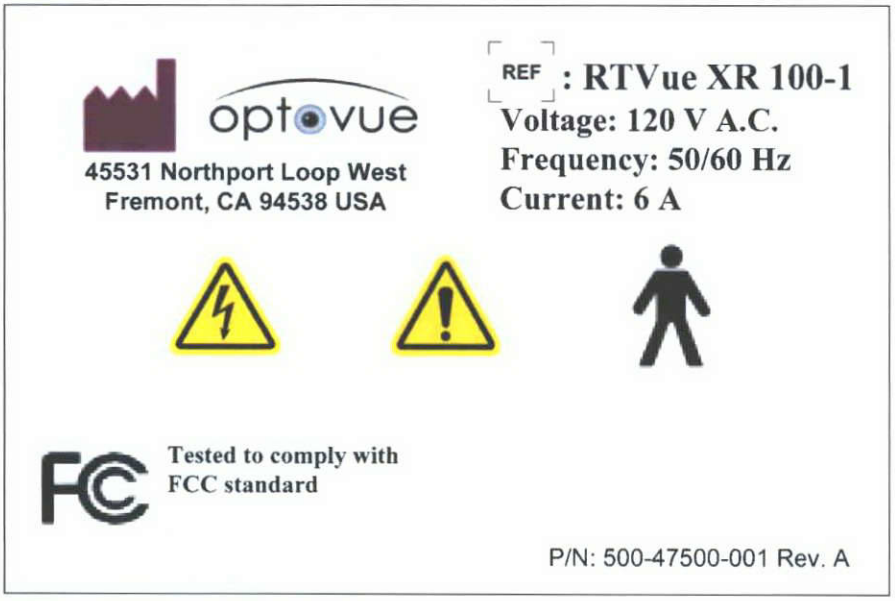
Safety Notes

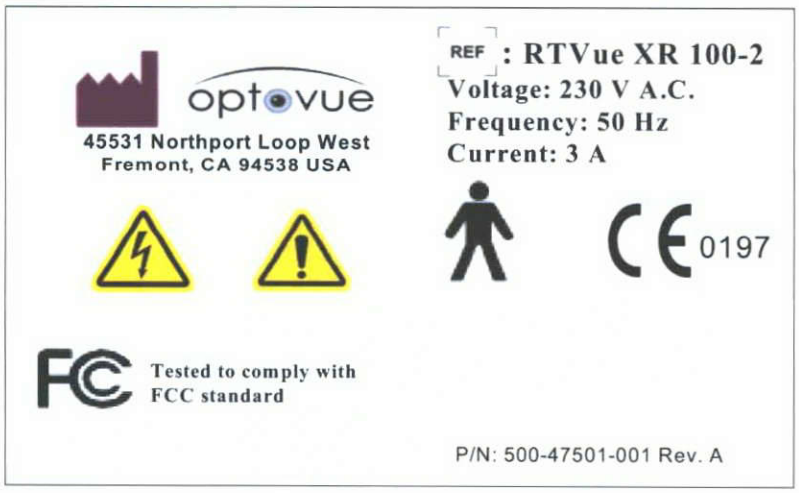
Product Labels:

RTVue XR system labels (Samples Only):

Model: XR100-1 for 120Va.c. input



Model: XR100-2 for 230V A.C. input



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XR Scanner Label: (common for both XR100-1 and XR100-2 models)

optovue

45531 Northport Loop West
Fremont, CA 94538 USA

REF : RTVue XR Scanner

Voltage: 120V A.C.

Frequency: 50/60 Hz

Current: 3.1 A

Fuse:

Rating: 4A/250V

Type: Fast Acting

P/N: 500-47498-001 Rev. A

System PC Label:

optovue

45531 Northport Loop West
Fremont, CA 94538 USA

REF RTVue XR

Voltage: 115/230V A.C.
Frequency: 50/60 Hz
Current: 6.3 A

Tested to comply with
FCC standard

P/N: 500-47499-001 Rev.A

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

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2 Instrument Description

2.1 RTVue XR System Configuration:

The RTVue XR system is shipped in one palletized box, which contains the following hardware:

1. RTVue XR Scanner:
This is the main component of the RTVue XR system. It is used to view and scan the patient's retina, collect the OCT signal, and send it to the computer for processing. It also provides a fixation light target on which the patient can fixate during the scan, as well as a position sensor for automatic detection of whether the left or right eye is aligned for scanning. Communication between the scanner and computer is achieved via a USB cable connection. The RTVue XR uses a medical-grade power supply.

2. Computer:
The computer is used to control the scanner during the patient examination. The application software provides data analysis, presentation, and data storage and archiving. A relational database is included to organize all patient information and data, as well as to allow for search capability.

3. System Table:
The system table provides power to the RTVue XR scanner, computer, and computer display through a medical-grade isolation transformer to prevent leakage current from main AC power. The table elevation can be adjusted to fit patient height. The telescopic lift that supplies the power of the RTVue XR system is medical grade.

It is recommended that the user connect the RTVue XR OCT system to a proper electrical source via the use of an Uninterrupted Power Supply (UPS) module connected to the wall outlet.

4. Monitor (Computer Display):
A 22" wide screen LCD flat panel display for graphical user interface and data presentation.

5. Keyboard and Mouse

System Configuration:

Model: XR-100-1: 120V AC.
Model: XR-100-2: 230V AC.

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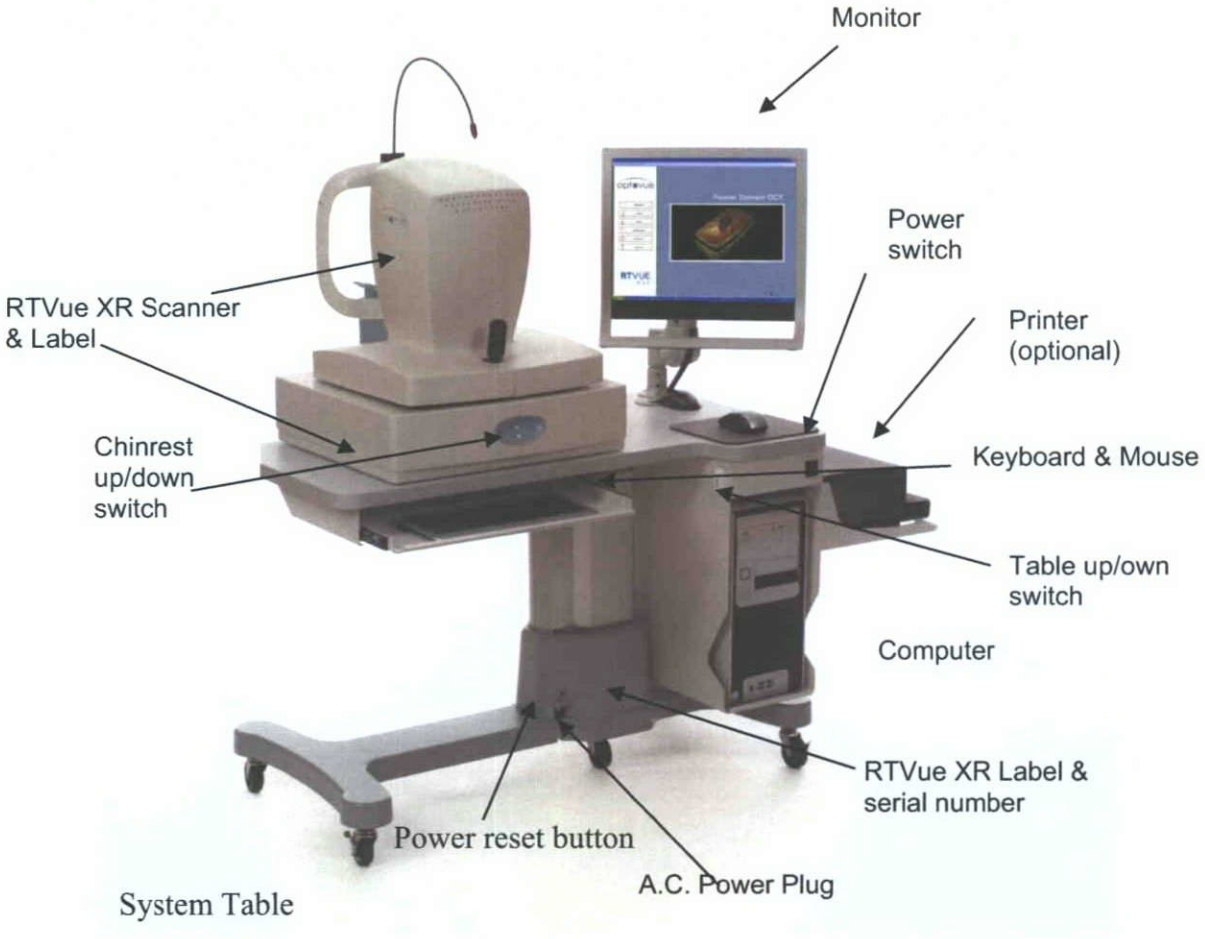
Patient Menu



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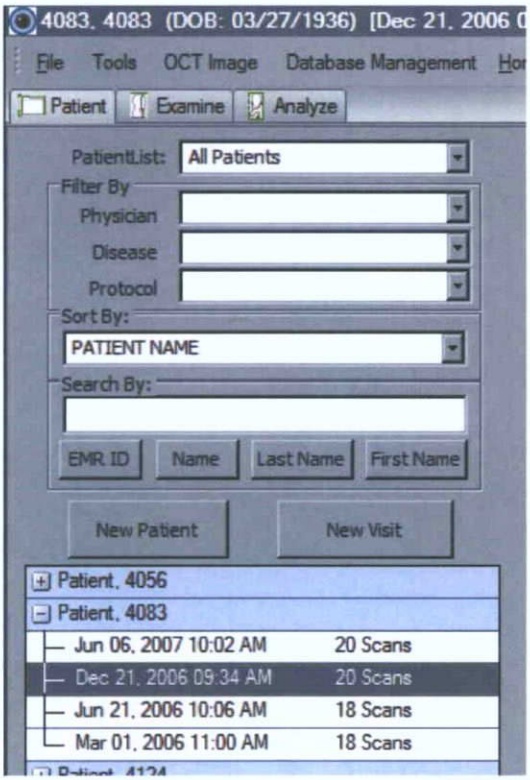
3 Patient Menu

The patient menu contains three components:
1. Patient List
2. Patient Information
3. Visit Information

In the patient menu, the user can search, add, and edit patient information. It is designed to help you schedule a patient's visit in advance, preview today's or this week's scheduled patients, and search for a patient's history.

3.1 *Patient List:*

The patient list displays the results of the user-defined search criteria.



1. All Patients
2. Current Patient
3. This week
4. Today

The patient list display can be filtered by following criteria:

1. Physicians name
2. Disease
3. Scan protocol

You may sort the results by:

1. Patient Name
2. Last Visit Time

You may search for a specific text string

1. EMR ID
2. Name (first or last)
3. Last Name only
4. First Name only

To search:

1. Type the patient's EMR ID, Name, or Last/First Name in the [**Search By**] space and click on the designated button; this will move the searched patient to the top of the list.

2. Clicking on the patient's name will list all the patient's visits and will open the patient's information.

3. Clicking on the visit will open the visit information.

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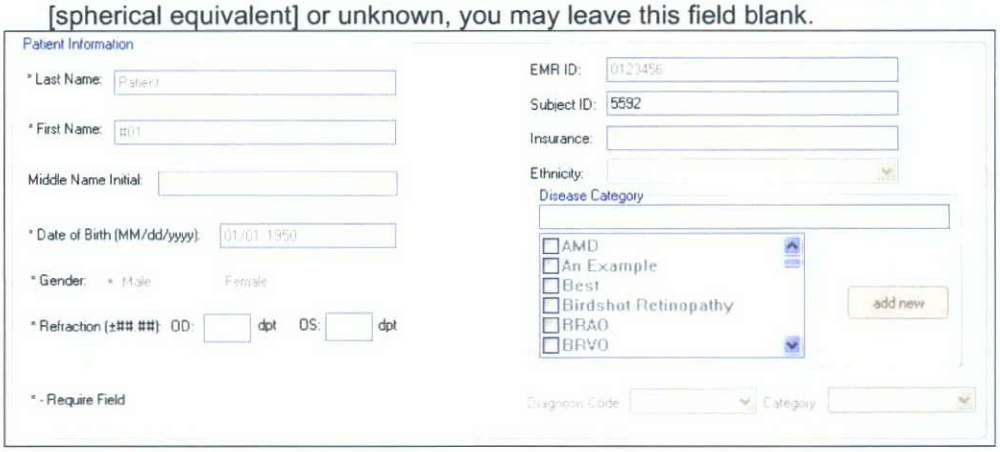
3.2 New Patient and Patient Information:

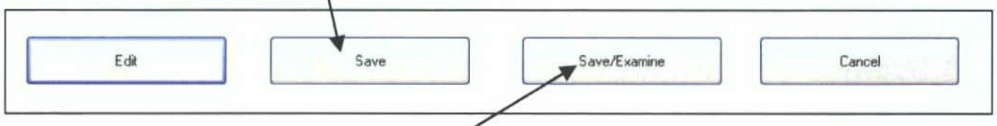
To create a new patient, click the [**New Patient**] button, fill out the information fields (fields marked with a "*" are required – if the Refraction is "0" Diopters [spherical equivalent] or unknown, you may leave this field blank.



Required information fields are marked by an (*).

- First and Last name fields are required. These can be any combination of letters or numbers. Symbols may be used, but may interfere with the capture JPEG function. It is recommended that users follow the office convention for capitalization of names.
- Refraction value (patient's current refraction – Spherical equivalent with Add) when used, sets the initial focus for scanner. The focus (scan beam and video fundus image) can be adjusted or fine-tuned in the Clinical Tab during the scan operation.
- Disease Category is a "user defined" list of diseases. The disease category (multiple choices) can also be used as a filter for the patient list.
- Diseases can be entered one at a time by clicking the [**add new**] button.
- The selected Patient Name, DOB, and EMR ID will be displayed on the title bar of the Report window.
- The "Ethnicity" field (Use or selection if for user reference only.
- If the [**Save**] and [**Save/Examine**] buttons are grayed-out, check to see that all required fields are filled.

If you are adding the list of patients with appointments for OCT scanning that day, then click the [**Save**] button at the bottom.



If you are entering the patient data in just prior to scanning the patient, then use the **[Save/Examine] button at the bottom. This will add the patient, create a new visit with today's date and take you directly to the Examine mode.**

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- If you would like to cancel this operation, then simply click on [**Cancel**] button to exit the **New Patient** screen.

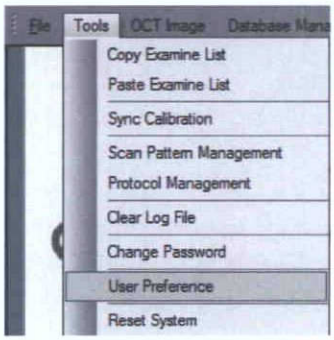
3.3 New Visit

To create a new visit for an existing patient, click the [**New Visit**] button and then click [**Save**]. If you would like to cancel this operation, then simply click the [**cancel**] button to exit the **New Visit** screen.

You can also create a new visit for an existing patient by right clicking on the patient name in the list, and selecting "Add New Visit"

3.4 Select Date of Birth Format

The default format of date of birth can be set in the User Preference:



Note: The RTVue XR computer settings must match the date format specified in RTVue XR. To change the computer date settings, please follow the steps below.

- Go to "Regional and Language Options" in Control Panel.
- Click the button "Customize" under the "Regional Options" tab.
- Select the proper format in "Short Date Format" under the "Date" tab.

3.5 Editing Patient or Visit Information

- To edit a patient's information, select the patient name from the Patient List and click the [Edit] button.
- To edit a patient's visit information, select a visit date in the list of visit dates for the selected patient, then click the [Edit] button.

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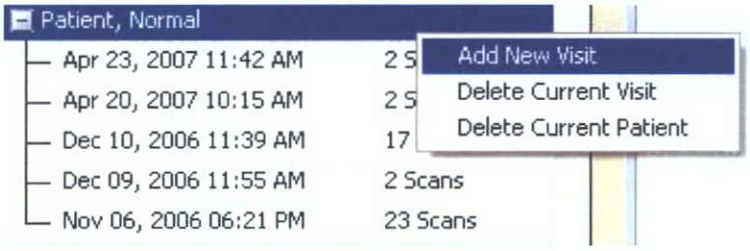
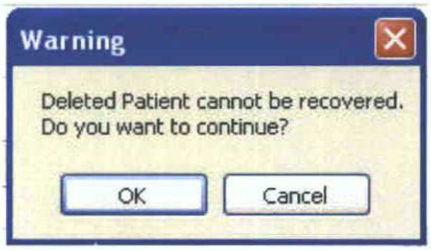
3.6 Patient List Short-cuts

Click on the patient's name to view patient visits. Right click on the patient name or visit date to view options:

- **Add New Visit** – automatically create a new visit using the current date for the selected patient, which takes the system directly to the Examination screen. Visit information is left blank.
- **Delete Current Visit –** Deletes the selected visit (any visit in the patient visit history)



- **Delete Current Patient**. – Permanently deletes the selected patient (a warning message appears first to verify that this is the intended action).



Click [**OK**] to confirm the delete action, or [**Cancel**] to withdraw the operation.

- If the [**Save**] and [Save/Examine] buttons are grayed-out, check to see that all required fields are filled.

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3.7 Correcting visit linked to the wrong patient

The user has the option of moving a visit (complete visit not specific scans) from an incorrect patient association, to the correct patient association. **(Care should always be taken by the user to ensure that the patient being scanned is the specific patient selected in the application to associate the scan data).**

1. Select the Patient > Visit you wish to move
2. Select "**Move a visit to another patient**" from the **Database Management** menu (Figure 3.7A)

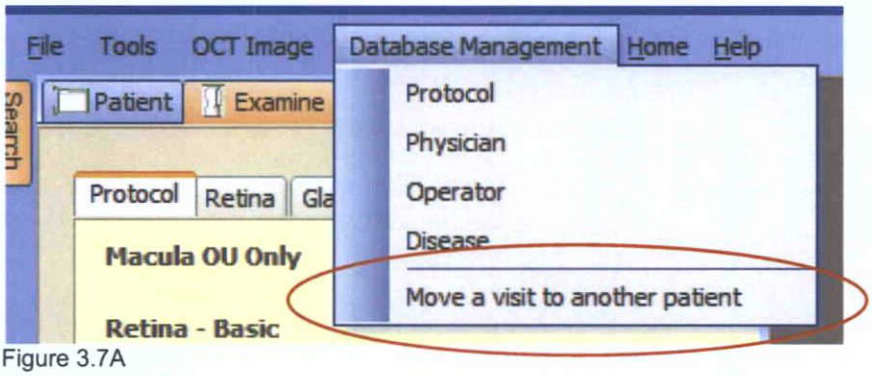

Figure 3.7A

3. Confirm that you wish to move the selected visit (first confirmation request)

Figure 3.7B

4. Select the correct patient you wish to move the visit **TO**, select **OK**

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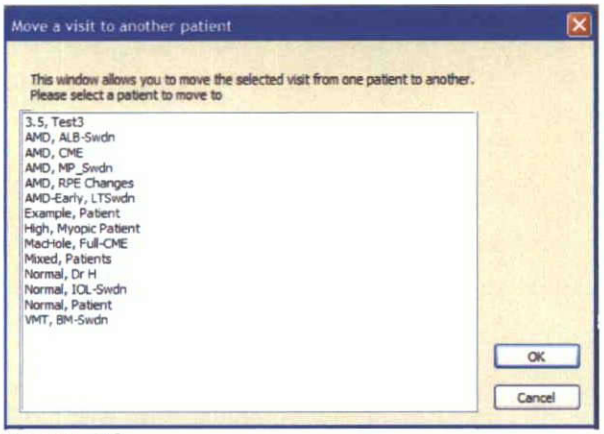

Figure 3.7C

5. Confirmation (second confirmation request) to move the selected visit to the correct patient selected. Click "Yes" to complete the move

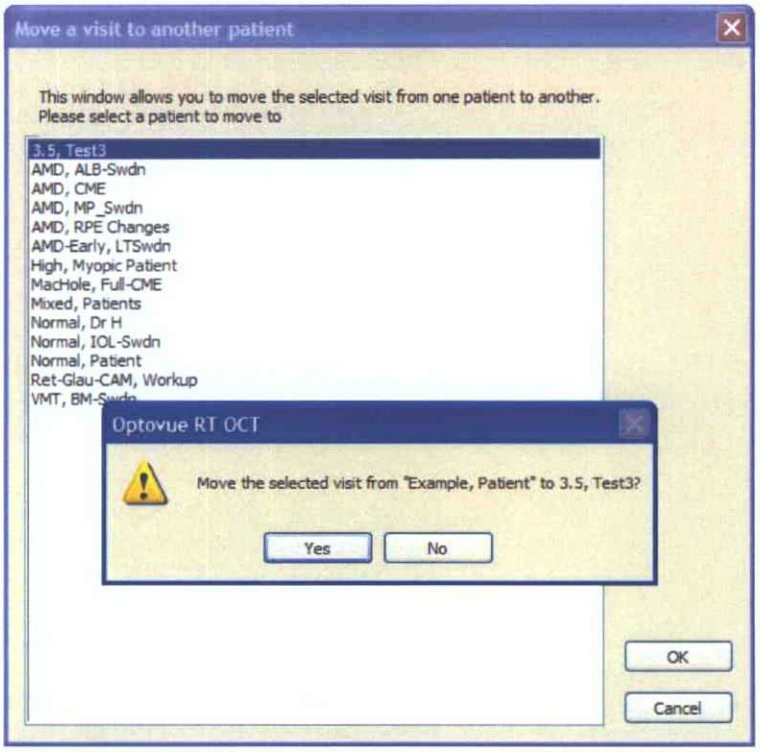

Figure 3.7D

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4 Examine Menu

4.1 Acquiring OCT Images

The following is a general procedure to acquire OCT images:

1. Select an Existing Patient or Create a New Patient.
2. Select today's visit (if it exists already) or create a new visit. Note: new scans cannot be added to visits prior to today's date
3. Click the **Examine** tab (if not automatically directed).
4. Select desired scan protocol or scan patterns (Single click to load into scan menu).
5. To launch, you may do any one of the following to activate the scanning process.
   a. Double click the scan name in the scan list.
   b. Highlight the scan name (single click) then click on the **SCAN** button at bottom center of the screen.
   c. Press the joystick button.
6. Ensure that you have positioned the patient correctly as follows: Patients' chin in the system chin rest with mouth closed, patient forehead against the system forehead rest, patient eye to be scanned aligned vertically with the canthus mark on the system head frame.
   a. Please refer to section 7.1 (Maintenance & Troubleshooting), item #3 on cleaning the chin rest and forehead rest surfaces.
7. Align center of the patient pupil with center of scan (pattern in the live video image on the screen, and move the scan head towards the patient so that the video image passes through patient's pupil.
8. Adjust distance to patient to get best illuminated fundus IR image (view of fundus from edge to edge – *there may be dark areas on either side when imaging the optic disc*).
   a. (Do Not Stop forward movement if a live scan appears in the scan window before you achieve a good IR image of the fundus. Set the working distance first)
9. Hold scanner head still and click on the "Auto All" button if no scan is visible in the scan window. This will optimize the image and should place it in the target area (between the red dashed lines).
   a. Double clicking in the scan window will also activate the "**Auto All**" button and will – in turn – perform the **Auto Z** (Axial length), **Auto F** (Focus) to offset the refractive condition, and **Auto P** (Polarization) to adjust for differences in the device and patient polarizations
   b. If scan is visible somewhere in the window, click once in the scan window and use mouse scroll wheel to bring scan to target area. Then use the **Auto F** and **Auto P** functions to optimize the scan.

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10. Adjust scan positioning in the fundus area, visible in the live IR image (if it is not where you wish it to be) by:
    a. Double clicking the mouse cursor in the center of where you want the scan to be done (IR image) OR
    b. Click and hold down on left mouse button with cursor on scan pattern, drag to desired location, and release the left mouse button.
11. Optimize the scan signal strength/ image quality using position (X/Y), Focus or P-Motor. Look for the high GREEN bar on the right side of the live scan window.
12. **For Non – Tracked Scans**
    a. **Capture** scan (by pressing the joystick button) – this is the capture function.
13. **For Tracked Scans**
    a. When acquiring the OCT image with Tracking, start the process as one normally would when scanning with the RTVue. Before starting the scan, the number of averaged scans and scan width can be adjusted in the scanner control Auto tab. The user is also given the option to turn Tracking mode on/off (green dot = on, red dot = off). For more information on the scanner control tab, see section 1.3
    b. Once the scan settings have been specified, make sure the IR image has a clear fundus image. Tracking is tracked by the blood vessels and optic nerve in the IR image, therefore optimizing the IR image is critical, particularly in the nasal region where vessels around the optic disc are most pronounced. It often helps to lower the brightness settings and turn up the contrast in the scanner control ADVANCED tab. There should be good visibility of optic nerve and blood vessels without glare or shadow artifact. The below images give an example of a good and poor IR image.
    c. Once the IR has an acceptable image of the fundus, the capture button will turn green and is ready for capture. When capturing, a small progress bar will indicate tracking progression on the bottom left of the screen, and a crosshair in the IR image will indicate how the current scan location matches with the beginning scan location which will help with monitoring how well the patient is fixating. When the progress bar has finished loading, the capture process will have finished.
    d. If the "checkmark" is GREEN then the system is actively tracking the IR image and you may start the capture process by pressing the joystick button, or clicking on the green checkmark with the mouse cursor.
    e. If the "checkmark" is grayed out, the system is not actively tracking the IR image and the capture function is not available.

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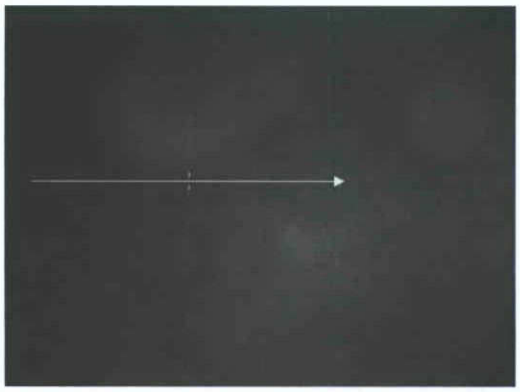
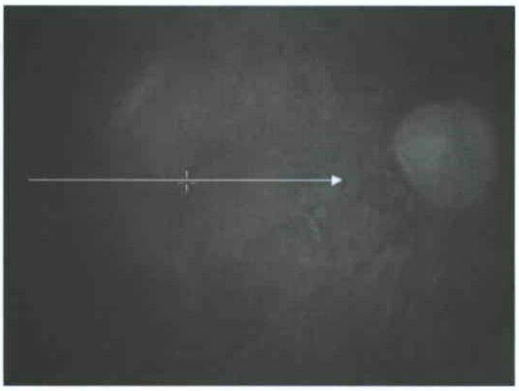


Example of a good IR image



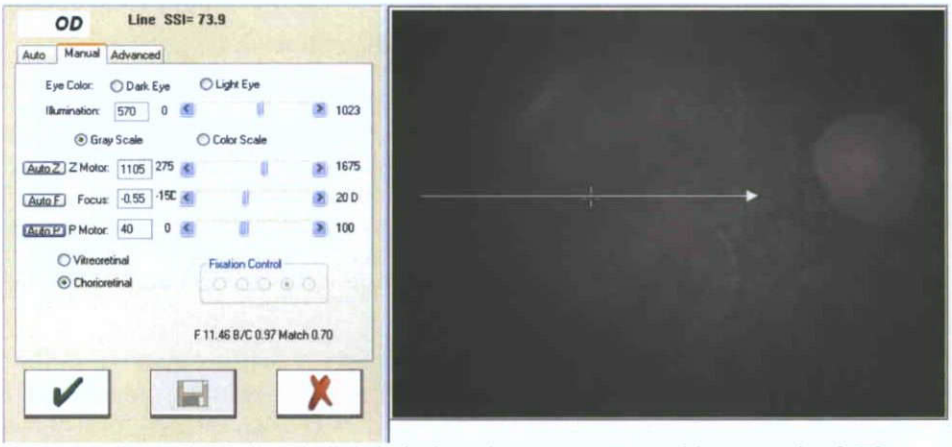
Example of a poor IR image

14. **Save** the scan.

4.2 Acquiring Scans in Followup Mode

In Follow up Mode, a crosshair will be shown in IR image. Before starting the capture process, the crosshair should be aligned as closely as possible with the scan indicator line as shown in the image below in order to repeat original scan placement.

When aligned within tolerance, the crosshair will turn green and the capture button will also turn green. If the crosshair is not properly aligned with the scan indicator line, the crosshair will be red and the capture button will be grayed out (not available). The patient may not be fixating in the same location as the previous scan and may need to be re-instructed. Alternatively, if a new scan location is desired, then the follow-up mode may be turned off (green dot = ON and red dot = OFF).



1) shows the reticule lined slightly below the target area with a match of .70

4.3 Scan Controls

Button presentation before starting a scan

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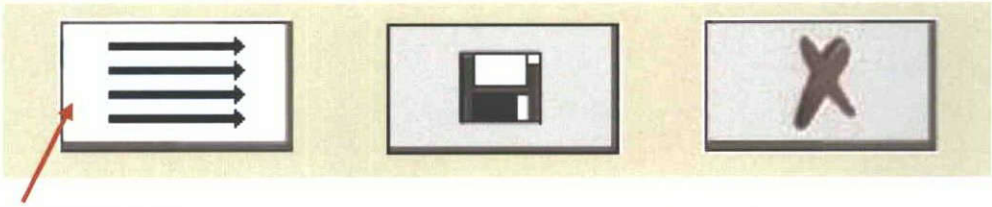
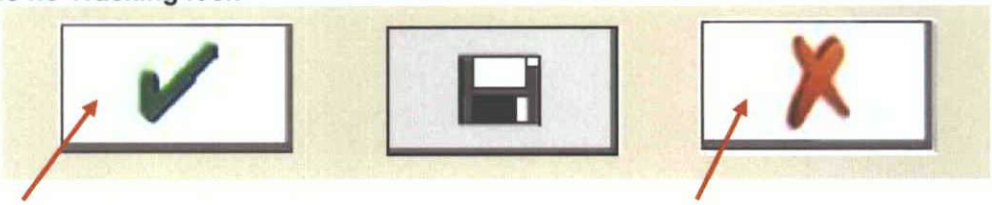


Initiates a scan

Button presentation while in live scanning mode and Tracking lock achieved (on Tracked scans with Tracking option ON only) Checkmark is gray when there is no Tracking lock



Capture/Acquire the data (scan)

Cancel/abort scanning

4.4 *Protocols*

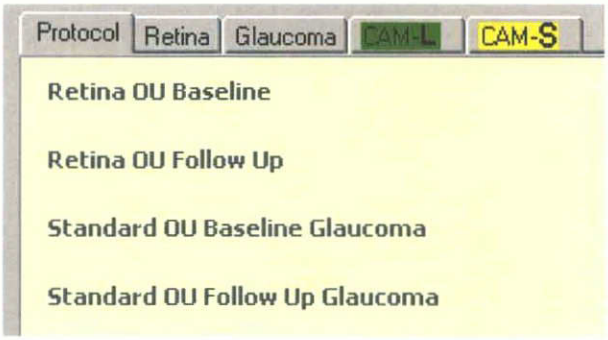
Scan patterns available are organized into two groups based on primary purpose: **Retina** and **Glaucoma**

The **Protocol TAB** is the first TAB (left to right) in the Examine screen. It is recommended that for optimum patient through-put each practice either use the recommended Protocols that are installed with the system, or set up their own protocol based on the practice patient demographics. This will allow a single "selection" for retina or glaucoma patients.

Standard Protocols include OU Baseline and OU Follow-up for both Retina and Glaucoma.

It is recommended that you set up protocols that are based on your patient pathology demographic and practice terminology. For example "Optic disc Analysis", "Retina - First Visit", Glaucoma Follow Up, etc.)

Protocol Tab



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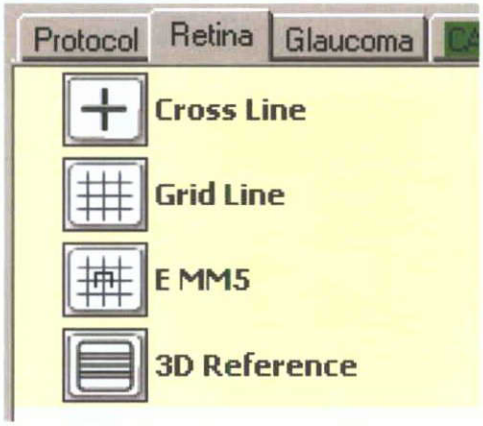
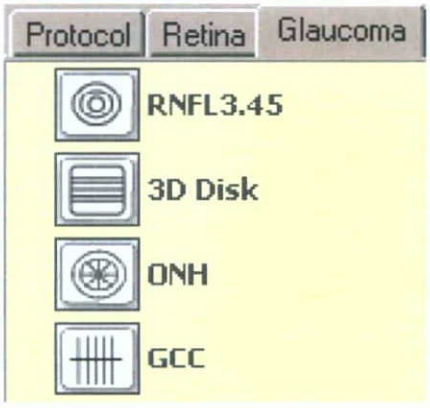
Retina Tab



Glaucoma Tab



NOTE: ONH (Optic Nerve Head) was formerly labeled NHM4

<u>NOTE ON CAM OPTION</u>: If you have the CAM (Cornea-Anterior Module) Option installed on your RTVue XR, you will have additional tabs in the Examine View screen. Please refer to the CAM Option User Manual for detailed explanation of the use of the CAM Option for the RTVue XR system.

4.5 Selecting a Patient to be examined:

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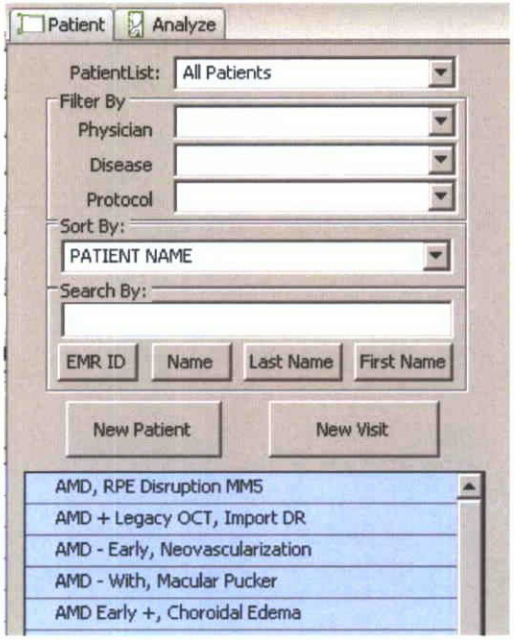
Examine Menu

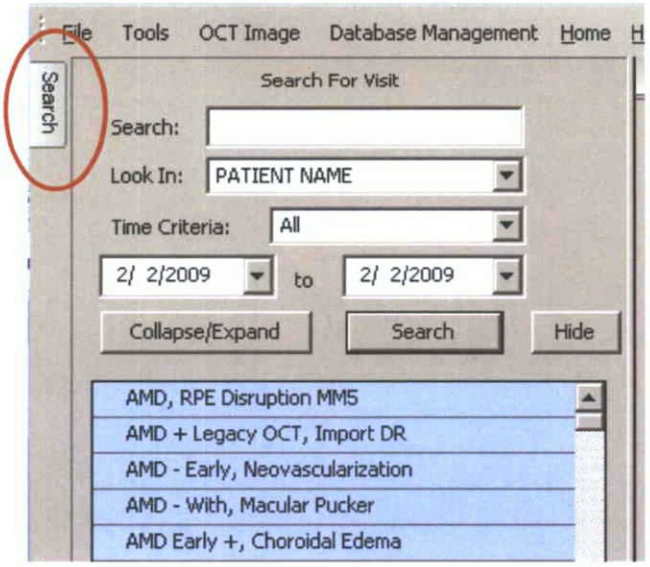
There are two ways to select a patient for examination:

1. Select Patient from Patient Menu using either the [Patient Name] to sort alphabetically, or [Last Visit Date] to display from most recent to oldest visit in database.

2. Use the <Search> tab in the Examine Menu. To exit the Search window, click anywhere outside the window.



Search Window



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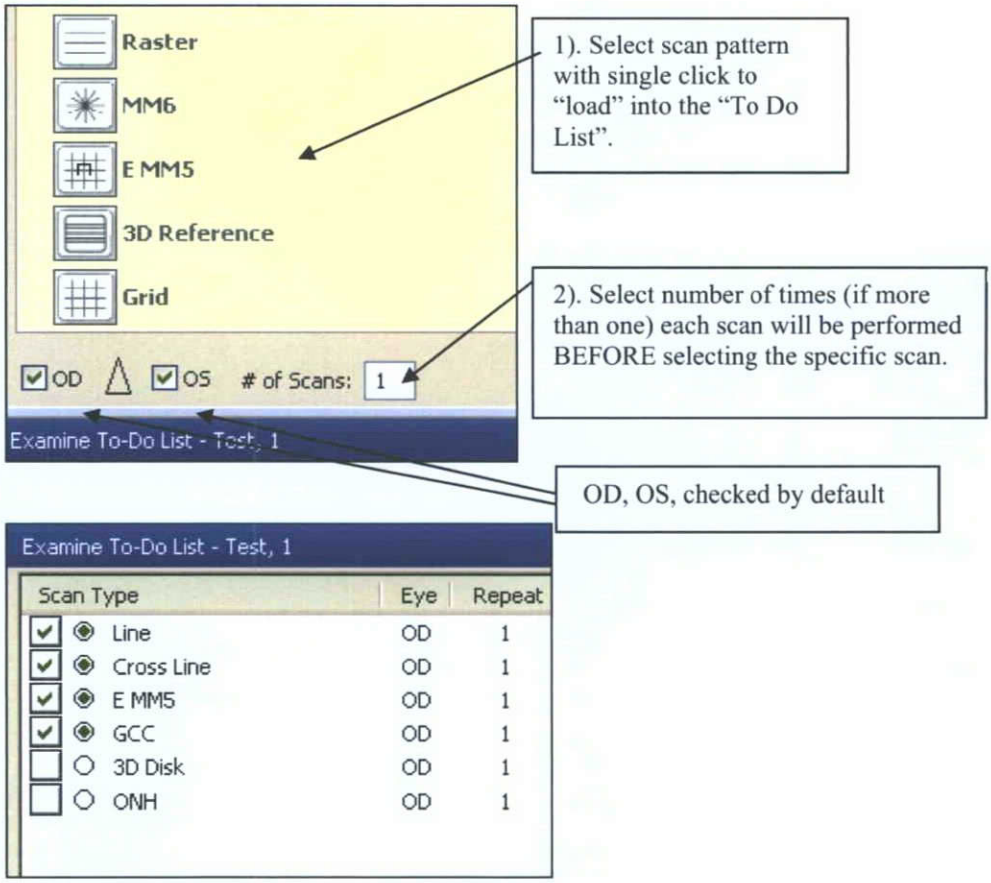
4.6 Scan List:

The scan list shows the scans to be performed in the current visit.

1. Select the scan pattern from the upper window or a scan protocol (click on the <Exam Protocol> tab to bring up the scan protocol window).
   a. A single click on the scan pattern will "load" the scan in the exam list window.
2. OD and OS are checked by default.
3. If you wish to scan any particular pattern more than once, you will need to select how many times each set of scans will be performed first.



An empty green circle indicates that the single scan has not been completed. A solid green circle indicates that the scan is complete.

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4.7 Scanner Control Tabs

The default GUI setting will present two tabs during the Examination process (**Auto** and **Manual**).

4.7.1 Auto Tab

The Auto Tab contains only the minimum function buttons to enable automated acquisition of optimized scans with minimum actions from the user.

a. Light & Dark Eye Buttons: Accesses the Brightness and Contrast default settings for each affecting the live IR image

b. Illumination Control Buttons: Reduces or increases the IR illumination for the live IR image viewing.

c. Grayscale / Color live scan Buttons: Select the viewing preference for the live OCT scan in the upper window (if different from default setting). NOTE: Default presentation of color or Grayscale can be set in the [OCT Image>Scan Parameter Setting] window.

d. Auto All: this button initiates the all of the automatic functions of the Auto Z, Auto F and Auto P buttons to optimize the scan.

e. Auto Z: Automatic adjustment for the Axial length

f. Auto F: automatic adjustment for the refractive state

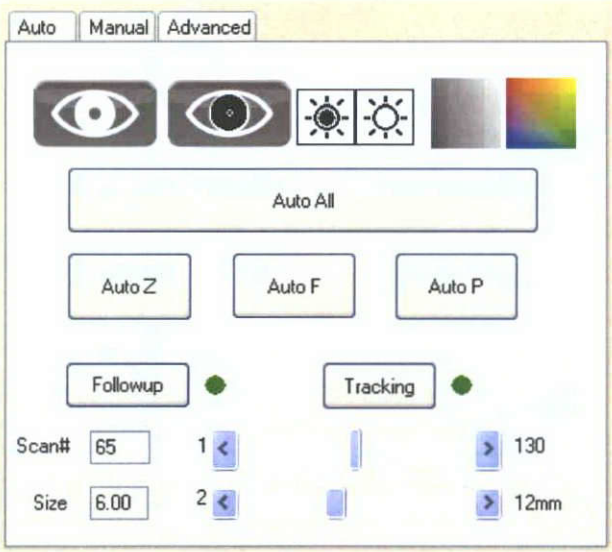
g. Auto P: Automatic adjustment for polarization

h. Followup ON / OFF Button

i. Tracking ON / OFF Button

j. Scan # slider (number of scans to collect for averaging)

k. Size slider (set length of scan line)



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4.7.1.1 Use of Auto Tab Controls.

1. Set the number of scans to collect for averaging and the length of scan you want to use.
    a. If this is a follow up scan to a previous tracked scan, the scan length will be grayed out as the value will match the previous line scan for that eye
    b. After aligning on the pupil and moving the scan head forward through the pupil (IR image) to achieve a view of the fundus, Hold scanner head still and if there is no scan visible in the live window click on the "Auto All" button. (You may also Double-click anywhere in any of the live scan windows to activate the "Auto All" function (one to four scan windows appear depending on the scan type).

2. After aligning the pupil and moving the scan head forward to achieve a view of the fundus in the IR image window activate the Auto All function.
    a. NOTE: You only need to use the Auto buttons for the first scan taken on the first visit. After the first scan is optimized and captured, the same settings should be used for all subsequent scan for that visit. The system will store the settings for that patient (each eye) for any follow-up visits.

3. Double clicking in the scan window will also activate the "Auto All" button and will – in turn – perform the Auto Z (Axial length), Auto F (Focus) to offset the refractive condition, and Auto P (Polarization) to adjust for differences in the device and patient polarizations

4. If scan is visible in the window, click once in the scan window and use mouse scroll wheel to bring scan to target area. Then use the Auto F and Auto P functions to optimize the scan.

. The **Auto Average** button will appear after the scan is complete – only if the scan pattern is one that uses the Averaging function. The **Manual Average** button will also appear in the **Manual** Tab

4.7.2 Tracking Feature

The RTVue XR has tracking as a standard feature. Tracking consists of moving the scan beam, based on image alignment techniques, to scan approximately the same part of the eye in the event a patient blinks or if their eye moves away from the fixation target. Tracking allows collection of a higher number of usable scans in approximately the same area which may provide sharper images. This allows users to scan patients who have trouble fixating at the fixation target or patients who cannot avoid blinking during the scan capture process. Furthermore, the operators have the ability to turn tracking on or off as deemed necessary. Thus, tracking provides operators with more control in the scan acquisition process.

RTVue also provides a Follow up mode for follow up visits. Follow up mode consists of adjusting the scan beam based on image alignment to begin scanning approximately the same part of the eye that was scanned in the previous visit even in the event the patient does not maintain same fixation

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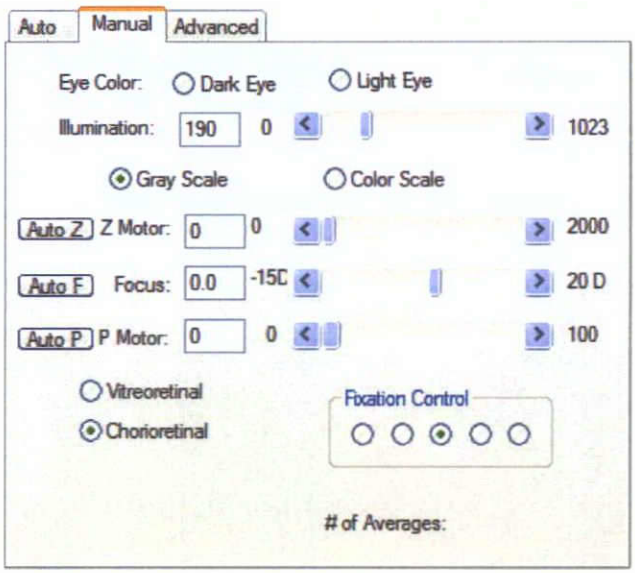
from one visit to next. This feature can be turned on or off as deemed necessary.

Tracking is available for the following scans: **Line, Cross Line, Raster, and Grid Line.** In the tracking software release, the scan acquistion behavior in RTVue is changed. As opposed to clicking the capture button to end the scan, the new software works by clicking the capture button to start the scan. This behavior applies to all scans regardless if Tracking is turned on or off.

4.7.3 Manual Tab

The Manual Tab contains the slider controls to manually adjust the Z, Focus and Polarization directly, as well as manual controls for the other step control buttons on the Auto Tab



4.7.3.1 Use of Manual Tab Controls

1. **Eye Color**: Select dark or light according to patient iris color to optimize the illumination, brightness, and contrast settings for IR image. The individual Brightness and Contract adjustment are in the Advanced Tab.
    a. If neither eye color is selected, then the default settings are the average of the respective values of illumination, brightness, and contrast for the dark and light eye.
2. **Illumination**: Adjusts the IR illumination for the IR video image. Level is set by selecting Eye Color, but may be adjusted separately to attain best image.
3. **Grey Scale /Color Scale:** Toggles live OCT image in gray-scale or color.
4. **Z Motor / Auto:** position adjustment: Click on the OCT image window, then use thumb wheel on the mouse to adjust Z-position. Double clicking

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on the OCT image window will auto-search Z position. This is the same as clicking on the "Auto" button next to the Z Motor.

5. **Focus** adjustment: Use to focus OCT and video image resulting in a sharper image. Use the slider control to fine tune the focus of the IR image and Signal strength of the OCT scan.
6. **P Motor:** Polarization adjustment to optimize the OCT image signal strength resulting in a clearer image.
7. **Vitreoretinal / Chorioretinal:** Setting are programmed based on scan design to enhance either the information above the RPE (Vitreoretinal), or the choroid and overall information (Chorioretinal)
    a. **Vitreoretinal:** This setting puts the highest signal strength at the top of the scan window and results in higher signal strength in the inner retina layers (RPE through ILM and vitreous)
    b. **Chorioretinal:** This setting puts the highest signal strength at the bottom of the screen, resulting in a stronger signal - and better visualization of the choroid.
8. **Fixation Control:** Use to change preferred fixation location (if other than default setting) for patient to focus on. There are five fixation settings.
9. **Process Average:** For the **Line** scan, **Cross Line** scan, **Raster** scan, and **Grid** scan, you have the option of averaging the multiple scans to achieve and final "averaged" image. This process is used to reduce the noise of the OCT image and provide a speckle less B-scan result. Eye or operator motion may limit the number of frames that can be used in this process. Quick eye motion may also smear the OCT image and reduce the quality.

4.8 Advanced Tab Controls: (Recommended for Advanced Users only)

This tab is hidden as the default setting

1. **OCT Image Noise:** Adjusts the noise level of OCT for best visualization of retina tissue. The default value is "3". *This should not be changed other than by an expert user.*
2. **Scan Length:** To adjust the scan length with the center of scan fixed.
3. **Scan Width:** To adjust the width of a raster scan. The number of raster scan lines will be equally spaced in the width of scan pattern selected.
4. **Scan Angle:** To rotate the scan around the center of the scan. Use slider to rotate the scan or click on the scan graphic in the IR window and use the mouse wheel to rotate the scan direction.
5. **Video Brightness:** Controls the brightness of the Video image only (not the OCT scan)
6. **Video Contrast:** Controls the amount of contrast or shading between areas in the Video Image only (not the OCT scan)

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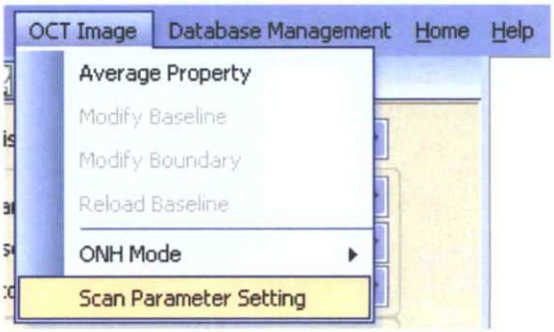
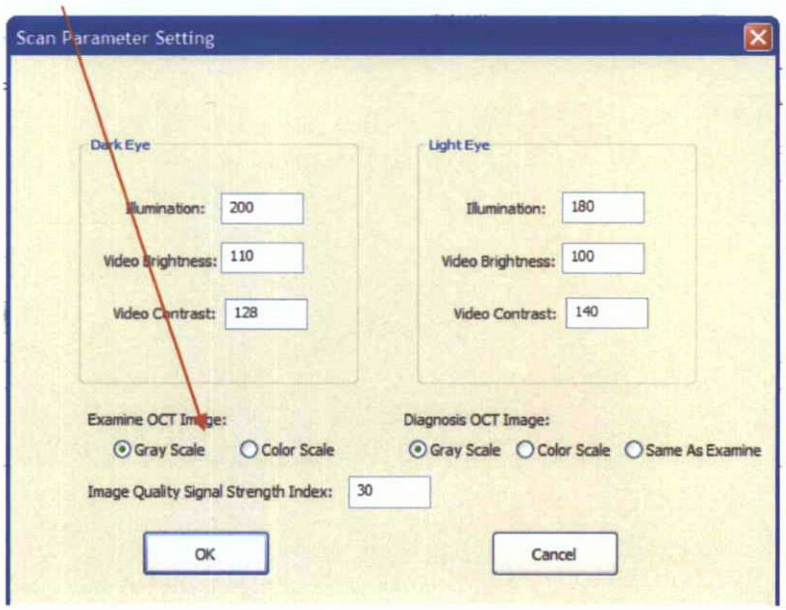
7. **XY Offset:** The arrow keys can be used to move the scan pattern around in the IR image in very small steps. Below are the two most common ways to position the scan in the desired location:
    a. Click and hold down the left mouse button on the scan graphic in the live video image and slowly drag the scan pattern to desired location.
    b. Double click the mouse cursor in the center of ***where you want the scan to be.*** The scan pattern will shift and center on the spot you selected. (Recommended method).

4.9 Setting the Image control default

The Scan Parameter Setting menu can be found by clicking the OCT Image menu.



The user may now set a different default live scan view mode between the Examine and the Review sessions. The view can be individually set for either Grayscale or Color presentation of the live scan. Go to **Scan Parameter Setting** under the **OCT Image** menu



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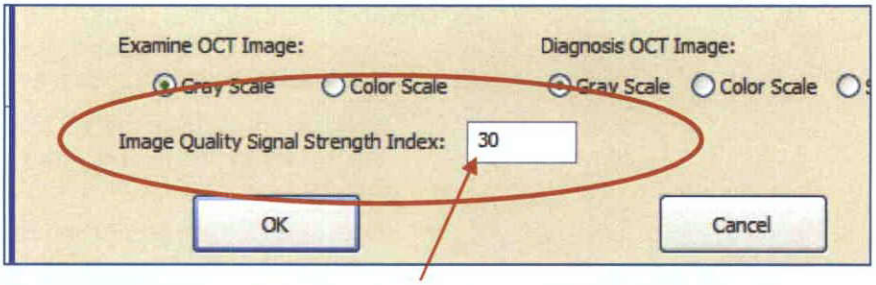


NOTE: Setting for "**Image Quality Signal Strength Index**" should not be changed by other than Research site users with prior approval from Optovue personnel.

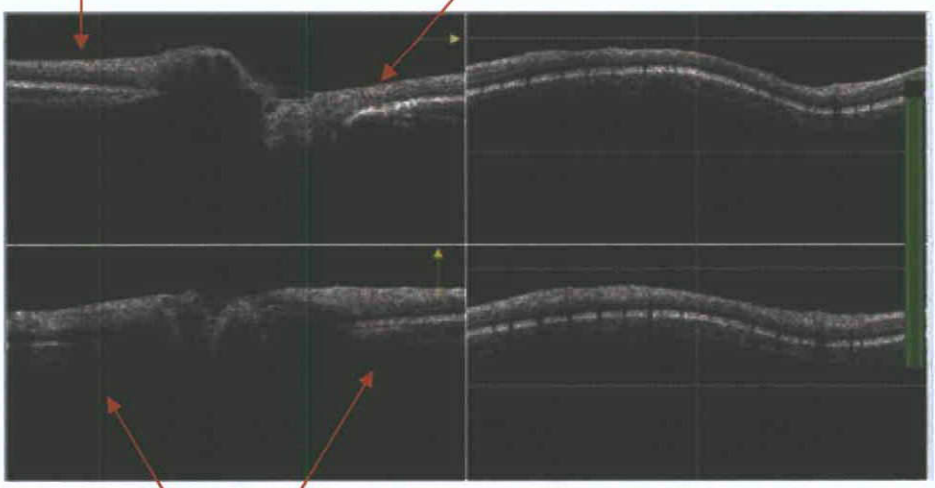
4.10 Correct Alignment of live OCT image

In all scan patterns, you will see one or more pairs of parallel red dashed lines. Some scans may have as many as four "live scan" windows with the target zone parallel lines. In any scan, the optimum placement of the live scan is between the red dashed lines. If the lines are horizontal, the scan should be in the upper part of the target area. (3D disc scan will have some of the scan image fall below the lower line; this is OK)

In the case of vertical red dashed lines (such as in the ONH), the physiology targeted should be between the two parallel lines. (See below)

If you select a different scan mode (Vitreoretinal / Chorioretinal) than the default setting, the location of the red dashed lines will shift to the top or the bottom of the screen, depending on where the default position is.

Below is an example of the correct ONH scan alignment.



1. Place Choroid endpoints (RPE tips) (Red arrow) between two vertical guide lines
2. Place circular scan between two horizontal guide lines

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In this version, a vertical line is provided in the center of "live scan" windows as well to aid centering of the scan.

NOTE: Live scans for all patterns are to be placed between the red dashed "target zone" lines. Target zone may be near the top or the bottom of the live scan window depending upon the **Vitreoretinal** or **Chorioretinal** setting.

4.11 Averaging (Auto and Manual)

Automatic Averaging will take place immediately after capturing a **Line, Cross Line, Raster** or **Grid** scan. This is a noise-reduction function to reduce the amount of speckle noise in the image. A Speckle less B-scan is presented as a result of this noise reduction function.

N

4.12 Reviewing Scan Images:

After stopping the scan, the window will automatically bring up a list of thumbnail images. Click on any thumbnail image to display that scan in the working window. The window can be closed with the Microsoft Windows "Close" (X box) icon on the upper right hand corner.
RTVue XR utilizes two 3D scan patterns to produce an SLO type image for registration purposes. Providing vessel registration and optic disc centering for orientation and serial registration, these scans produce the baseline image that enables real change analysis of both retina diseases and glaucoma.

Higher measurement precision due to registration:
Registration of images increases the repeatability and of measurements between visits. With the new registration feature, the average improvement for vessel registration is 1.2 microns.

For the EMM5, the average full retinal thickness 95% repeatability estimate is 4.5 microns. For the ONH scan, the average RNFL thickness 95% repeatability estimate is 10 microns.

A. 3D Reference (for EMM5 registration – retina diseases)

This scan produces an SLO like reference image of 7mm x 7mm (7,000 x 7,000 microns on the macula). This scan utilizes an "En Face" perspective to produce a high contrast grayscale image of the retina surface detail. This En face image is used as the reference and registration image for the EMM5 macular map (explained later in this section) based on vessel tracing.

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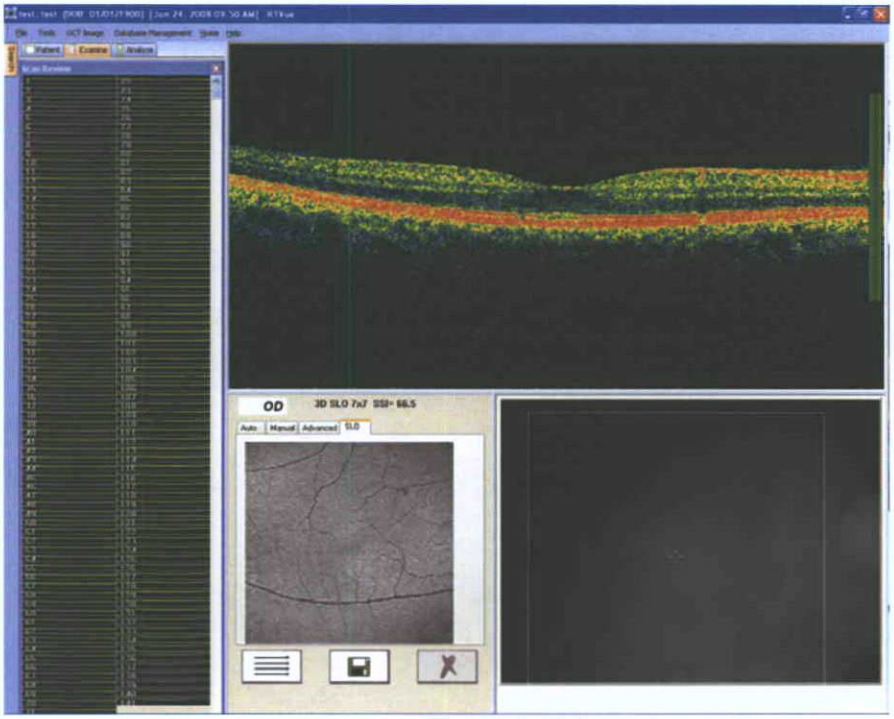

Figure 4.14 A

- Resulting SLO type reference image for EMM5 registration

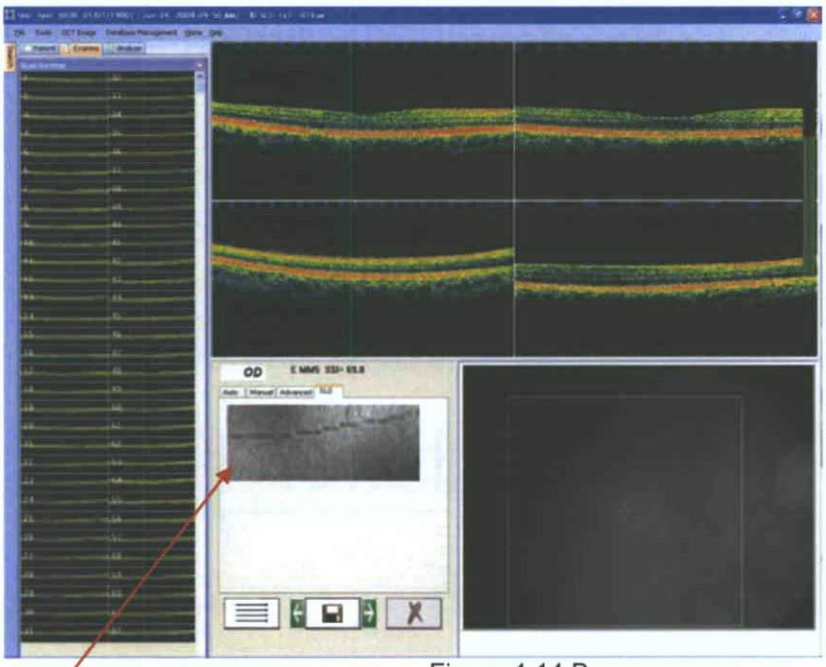

Figure 4.14 B

EMM5 scan pattern contains a sampling raster, offset from the mapping grid in order to capture a vessel tracing for registration purposes.

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Possible instances in which rescanning may be required to establish a new reference and baseline scan:

A new reference image may be desirable in the event of the vessel changing (orientation) or moving, due to disease progression or surgical intervention. EMM5 scans from that point on would use the newer reference image; however the mapping scans that existed prior to the new reference being established will remain registered to the original reference image.

B. ***Reference Image for ONH Map (Glaucoma)***

For serial registration of the ONH (Optic Nerve Head) scan for glaucoma, the 3D Disc scan is used to create a baseline SLO type image. The ONH scan pattern produces vessel tracing patterns that are matched to the vessels in the SLO en face result of the 3D Disc.

Image for vessel registration

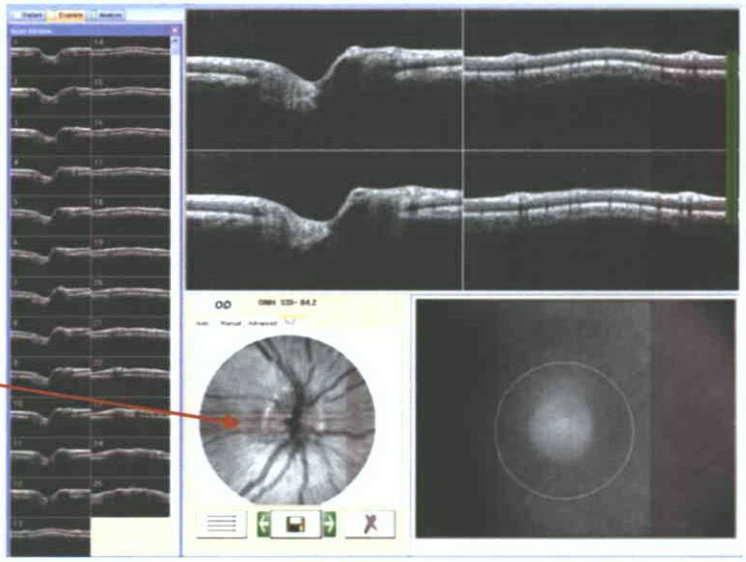

Figure 4.14 C

The 3D Disc scan result also provides the detail for the automatic tracing of the disc boundary (disc margin). This provides the disc margin shape and exact center of the disc, each of which is used along with the vessel tracing for serial registration of data and change analysis.

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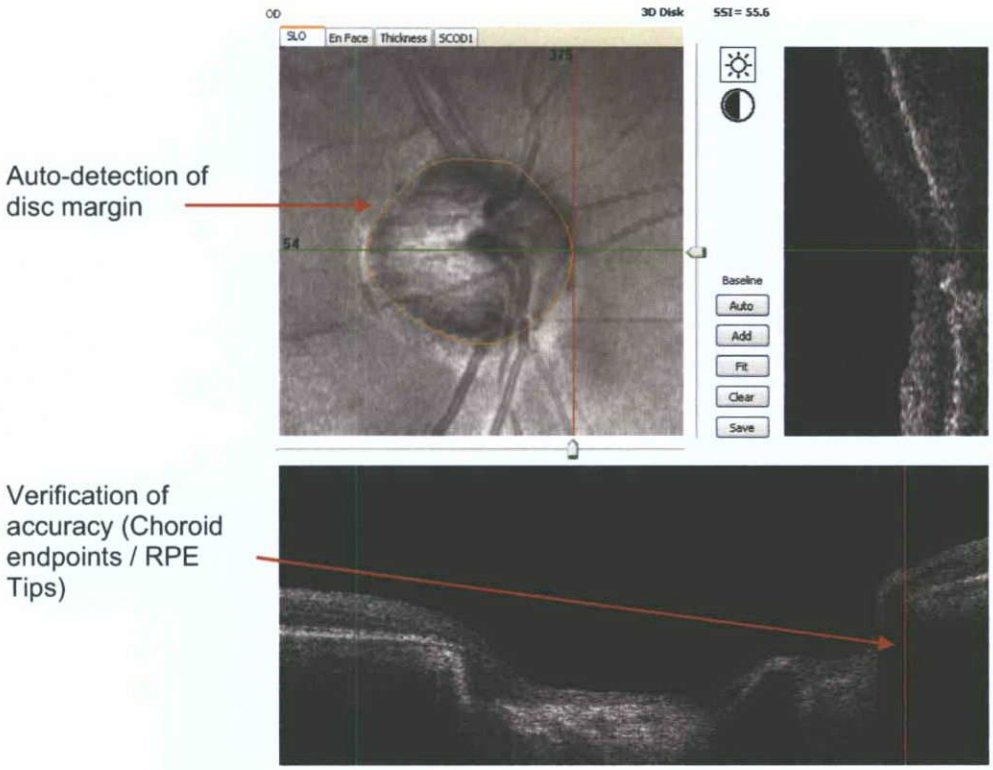

Figure 4.14.D

The option "Auto detect 3D baseline while saving scan" is located in User preference: This can be set to "Yes" (default) or "No". When the selection is "Yes," disk boundary is auto drawn while 3D disk scan is being saved. When "No" is selected however, auto drawing of optic disk is skipped when it is saved. Instead it takes place when 3D disk scan is opened in analysis mode.
When "No" is selected in above option, it is recommended that 3D disk scan is always opened first in analysis mode, during with the auto drawing of disk will take place. Due to this, it may take a few seconds longer to open the 3D disk scan compared to if opened with disk already drawn (during scan save).

If ONH scan is analyzed prior to analyzing 3D disk, following window appears.

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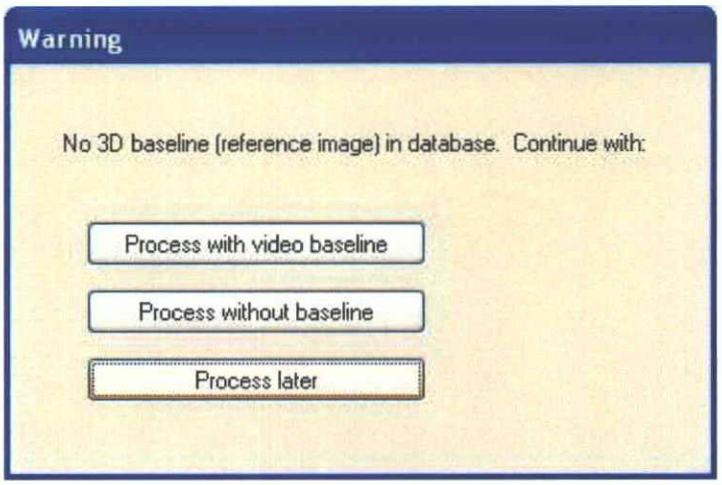

"Process later" option is recommended, which will act as a "cancel" function. Then 3D disk scan should be opened and analyzed. At this point the auto-drawn disk boundary can be modified in needed. "Save" button needs to be clicked to save the boundary if any changes to the auto-drawn boundary are made. If no changes are made, then leaving the 3D disk scan automatically saves the disk boundary.

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5 Analyze Menu

5.1 Analyze Layout

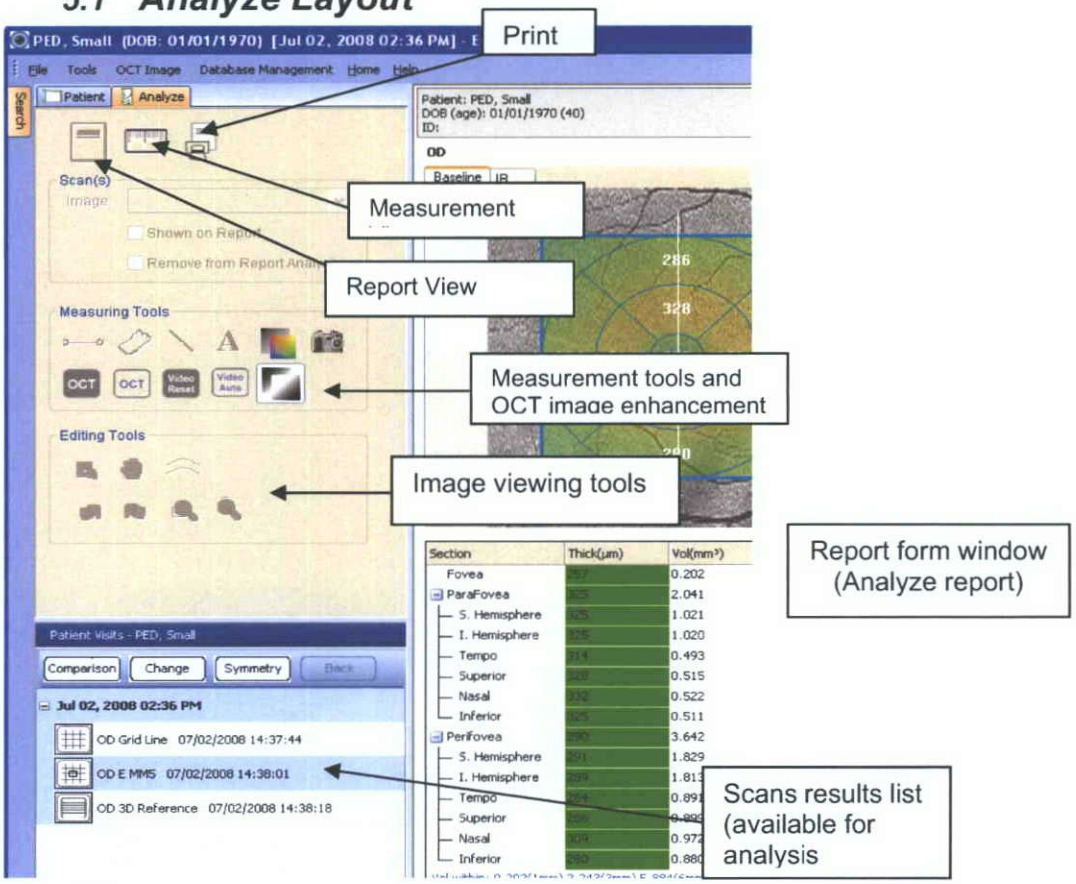

Figure 5.1

1. **Report** Form View: The default Analysis Report view (This is also the Print Preview form) with analysis results
2. **Measurement View**: Activates the view and tools for manual measurement on the OCT images and the presentation ratio. (Right Click Options)
3. **Print**: Send the current screen to the printer (any Window's compatible printer)
4. **Measurement Tools/ Image Enhancement:** The measurement tools become available when in Measurement View, including the appropriate tools for the CAM Option (Cornea-Anterior Module). The image enhancement tools for the OCT scan (increase or reduce background noise) and IR image (contracting).
5. **Image viewing tools:** remove tracing lines, zoom, area of interest selection and Undo/Redo
6. **Scan Results List:** All scans performed during the selected visit are listed below the Exam Date
7. All presentations (Analysis and Measurement views) appear in the window to the right of the controls

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5.1.1 Analyze List

After selecting the patient, a list of scan records will appear under the tool window. Click a particular scan pattern to show the results in the report window.

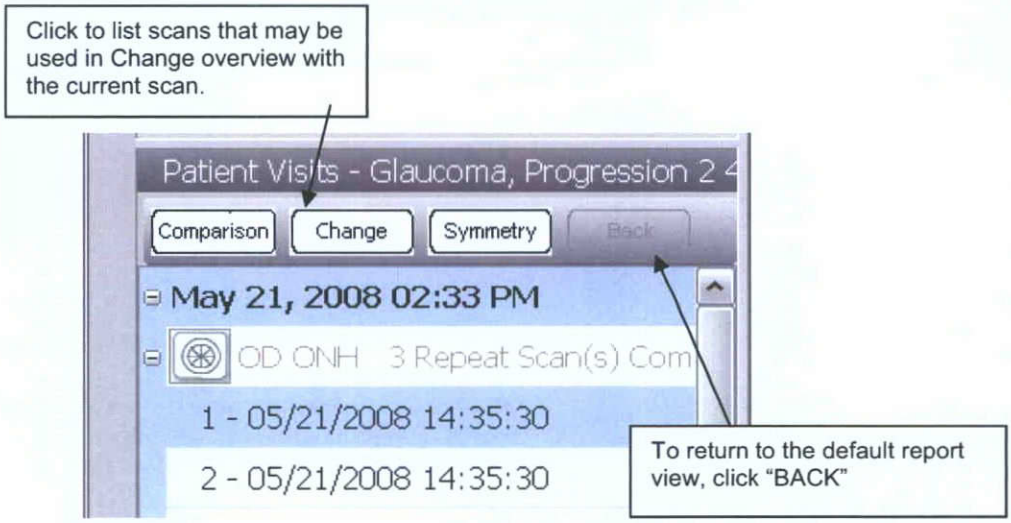
NOTE: Depending on the type of scan, it will sometimes take 5 to 15 seconds for the to the measurement result to appear the first time the scan data is selected. (This is due to calculation time). After the first time, the calculated (processed) data is stored and subsequent viewing will open in less time.

5.1.2 Diagnosis Data Input Field

At the bottom of the Report screen is a textbox labeled "Diagnosis". Any text entered here will be saved automatically when you exit the Analyze menu, whether you move to another window or exit the application entirely. This information is specific to the scan; it will not be displayed in other scans or visits from this patient.

5.1.3 Change / Symmetry / Comparison Analysis

If there are eligible scans available in the patient visit history, the related **Change** and/or **Symmetry and Comparison** options will be available. Click the button to activate the additional analysis.



Note on Change Analysis: Up to six (6) ONH scans, four (4) GCC scans or four (4) EMM5 Retina scans may be included in the Change report.

If the patient history contains six visits or less, all visits will be automatically selected and the report generated automatically for presentation

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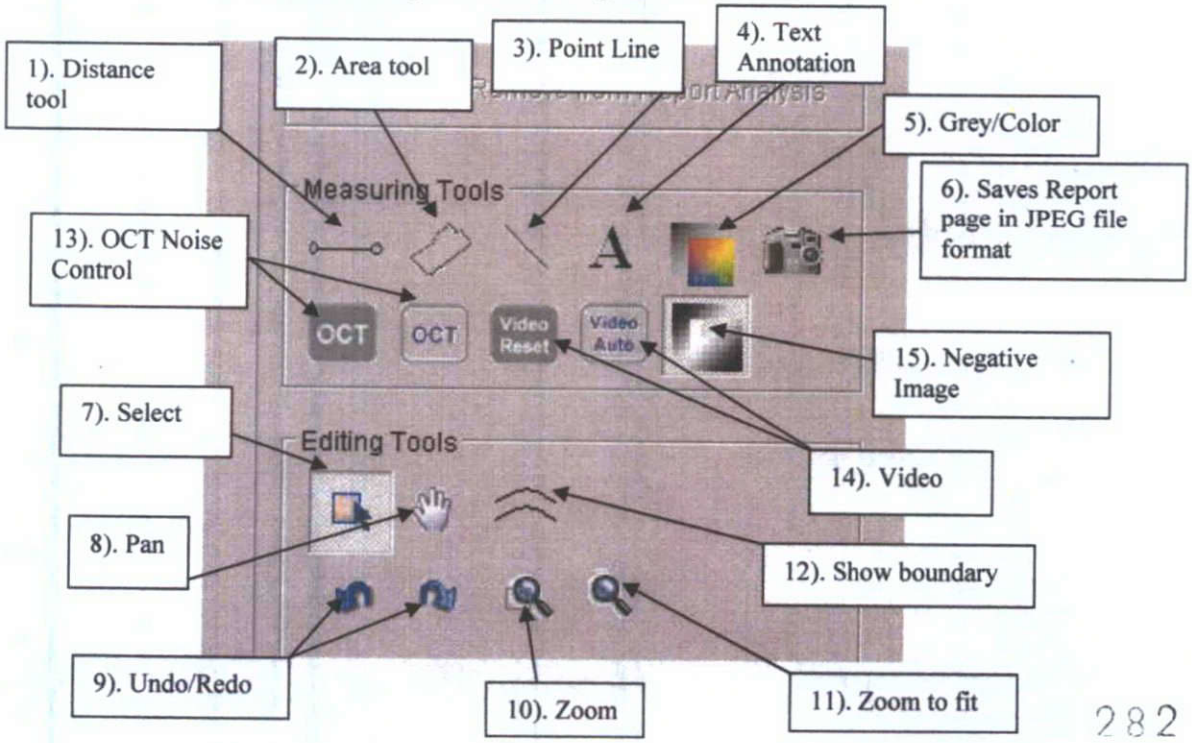
5.2 Measurement

Measurement tools are accessed by clicking the icon.

5.2.1 Tools:

1. **Distance tool**: Measures the distance between two points.
2. **Area tool**: Measures the area of a polygonal area.
3. **Point Line**: Draws a line between two points.
4. **Text Annotation**: Add text to images.
5. **Grey/Color**: Toggles scan display from gray-scale and pseudo-color.
6. **Snapshot**: Saves the Report Page in .jpg format. File name has default but is user editable. User defined destination
7. **Select**: Click to deselect the tool in use.
8. **Pan**: Moves the OCT image around in window.
9. **Undo/Redo**: Return to previous or prior state before/after an action.
10. **Zoom**: Zooms in or out of the OCT image. (No interpolation)
11. **Zoom to fit**: Fits all scans in the scan pattern into the window.
12. **Show boundary**: Display/remove boundary on the OCT image.
13. **OCT noise**: Increase (white) and reduce (gray) OCT noise level.
14. **Video**: Brighten (white) and reset (Grey) video image contrast.
15. **Negative Image**: inverts the presentation of the gray scale images. The black background will change to white.



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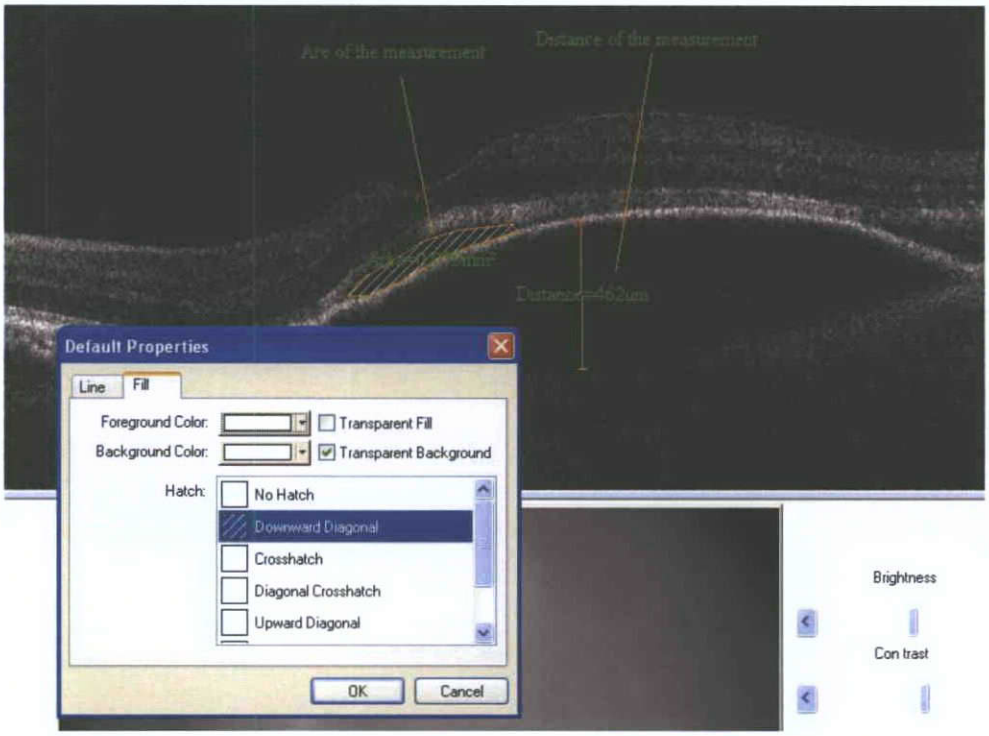
5.2.2 *Using Manual Measurement*

To make a manual measurement, first select the tool, and then make the desired measurement on the selected OCT image. Next, select an initial or "anchor" point and then proceed to the second endpoint (linear measurement or arrow) or the next in a series (area measurement).

Right clicking on the measurement will show the properties of the tool.



NOTE:

- You can select the **Snapshot Tool (camera icon)** to export a .jpg of the Measurement report screen.
- You may select the **Print** option to print a copy of the Measurement report screen with the practice and patient information header.

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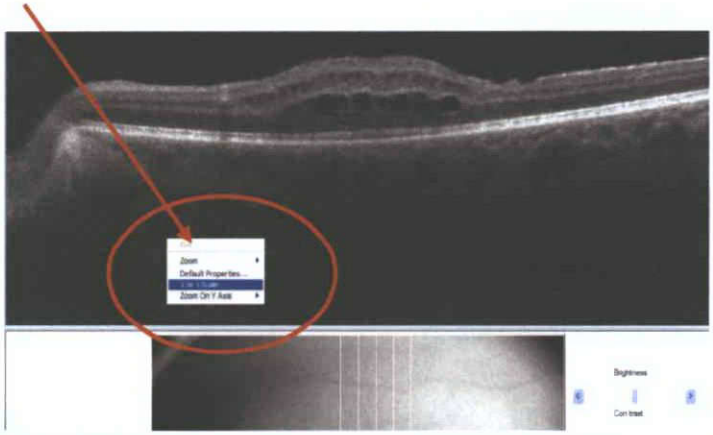
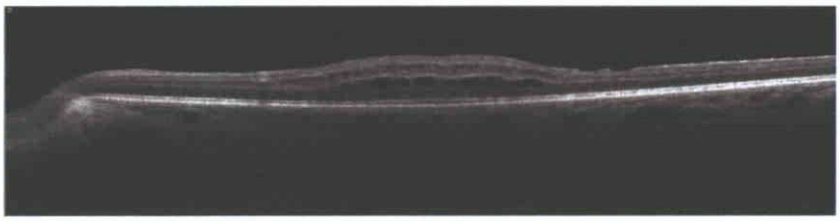
5.2.3 OCT Scan Selection

Above the Measuring Tools, there is a drop-down menu labeled "**Scans**". If the scan pattern performed had more than one image, the *different scan images are available for viewing by selecting from the drop-down menu.*

When evaluating a specific scan in the measurement view, you now have the option of showing the scan in a 1:1 ratio and altering the Y-axis display





1:1 Display option results (scan shown at 1:1 pixel presentation)
Analyze View – Retina Reports

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5.2.4 Line

If you used the Averaging option prior to saving the Line (or Cross Line) scan, both the Average and last single B-scan image are saved and available for review in the Analyze view.

Note: The **HD Line** and **HD Cross Line** **do not** have the average option.

Click on the [**Average**] or [**No Average**] button to select which image will be displayed.

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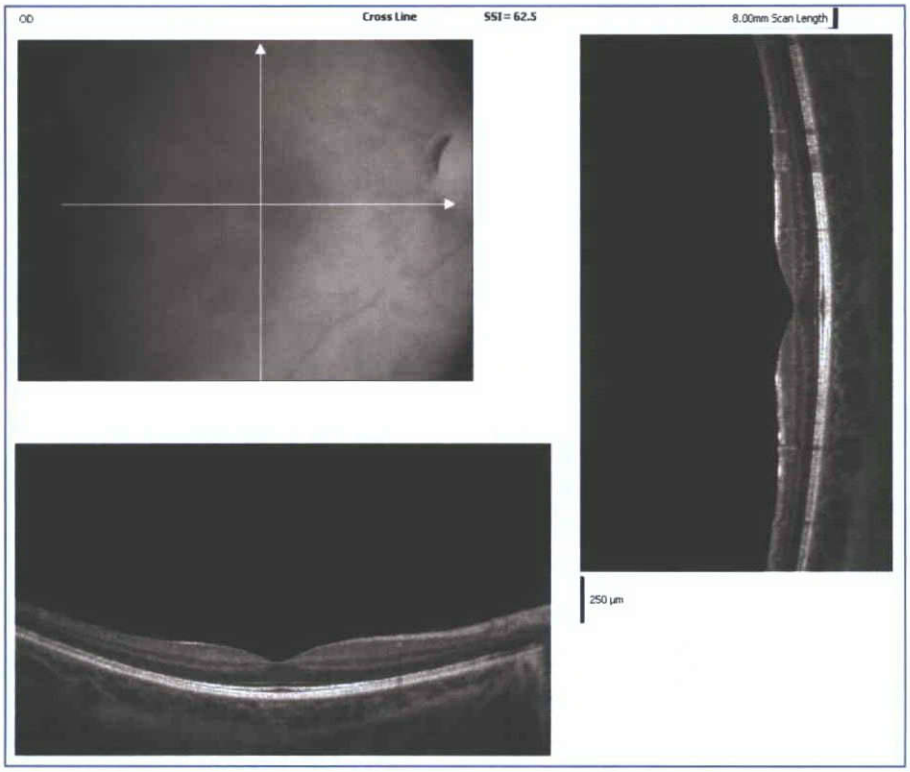
5.2.5 Cross Line



The Cross Line results are shown with the scan orientation aligned to the direction the scan was taken.

Presentation is either with **Average** or **No Average** as with the line scan.

5.2.6 Grid

Grid scan shows the exact scan location of five horizontal and five vertical scans in the grid. When this scan is captured upon capturing a 3D Reference scan, it uses registration from 3D Reference and applies a patch in this scan to show ten grid lines (five horizontal and five vertical) on the reference SLO style image to show the exact location of the scans taken.

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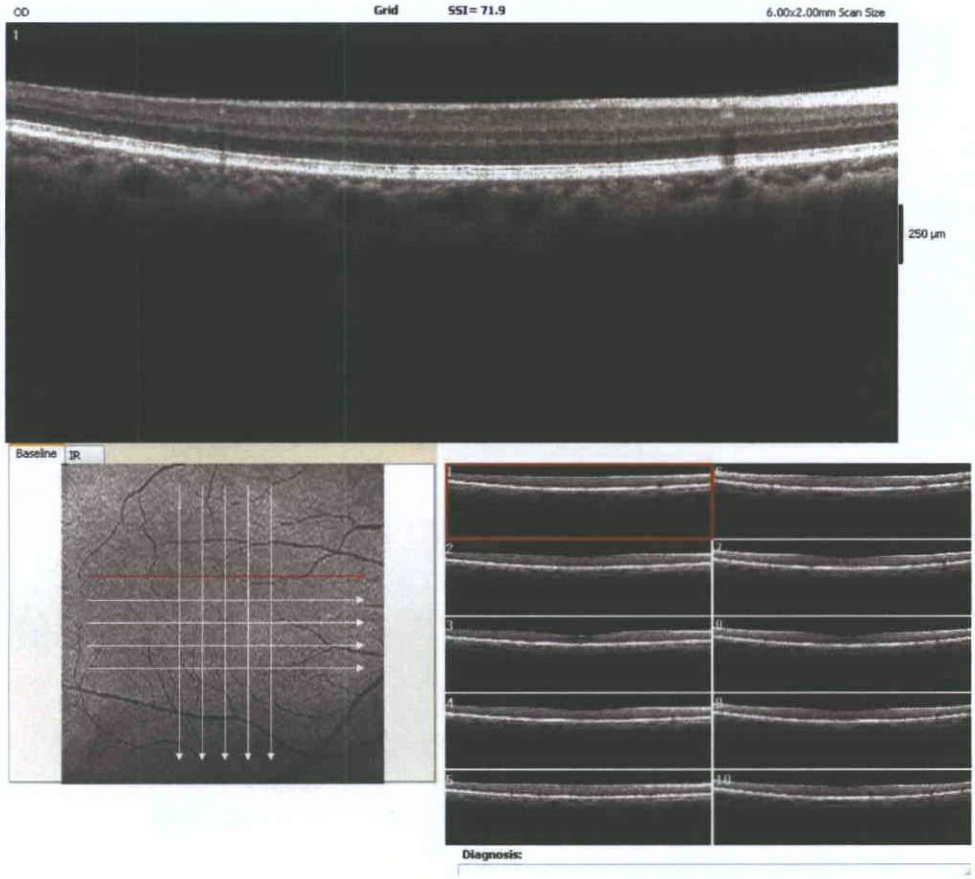
Analyze Menu



Above image shows the Grid scan in analysis mode. Note the grid lines on the reference SLO style image in Baseline Tab at the bottom left corner of the image. Mouse wheel or arrow keys can be used to scroll through each of ten scans. The red rectangle around the thumbnail of a scan denotes the scan that you're currently looking at in the large window above it. Also the appropriate grid line color changes to red as you're scrolling through the scans.

Right clicking the SLO style image and then selecting "Patch On" allows you to see the patch and how well the vessels in the patch align with vessels seen on the reference SLO style image. While the algorithms do the aligning with a very high success rate, the patch can be moved manually to align vessels on the patch and on the SLO style image. Grid lines will move with the patch giving the exact location of scans taken. See the image below. Proper alignment of the vessels on the patch with those of in the SLO style image are denoted by green color. Any misalignment is denoted by yellow.

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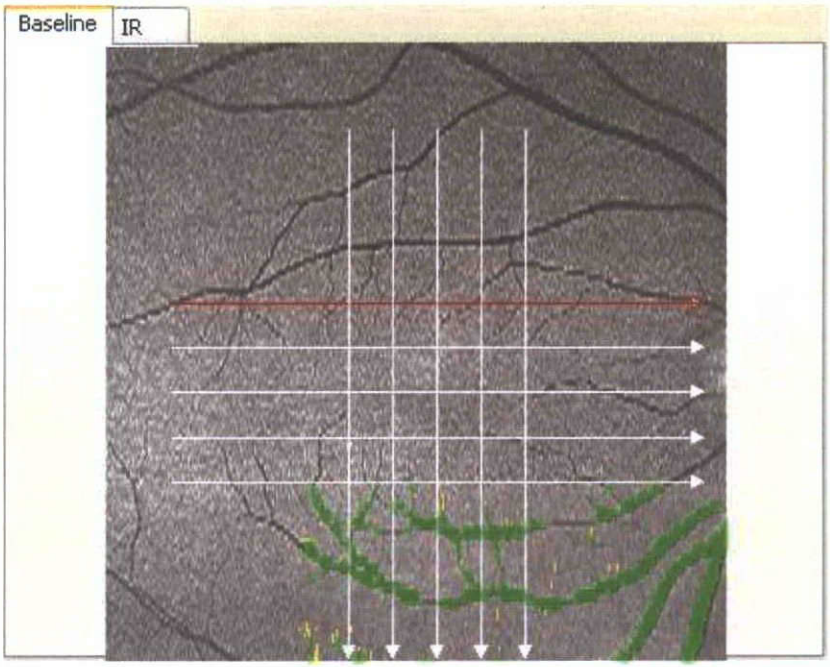

5.2.7 EMM5 Analysis Report

The EMM5 scan is registered to a reference SLO style image created by the new 3D Reference image scan. (3D Reference must exist)

The EMM5 includes a raster sampling that is acquired in the middle of the EMM5 scan (horizontal line scans – raster sample scans – vertical line scans) in an area inferior and nasal from the EMM5 scans.

This allows the sampling to capture the larger vessels lying inferior to the optic disc and use this "vessel tracing" to register to the SLO reference image.

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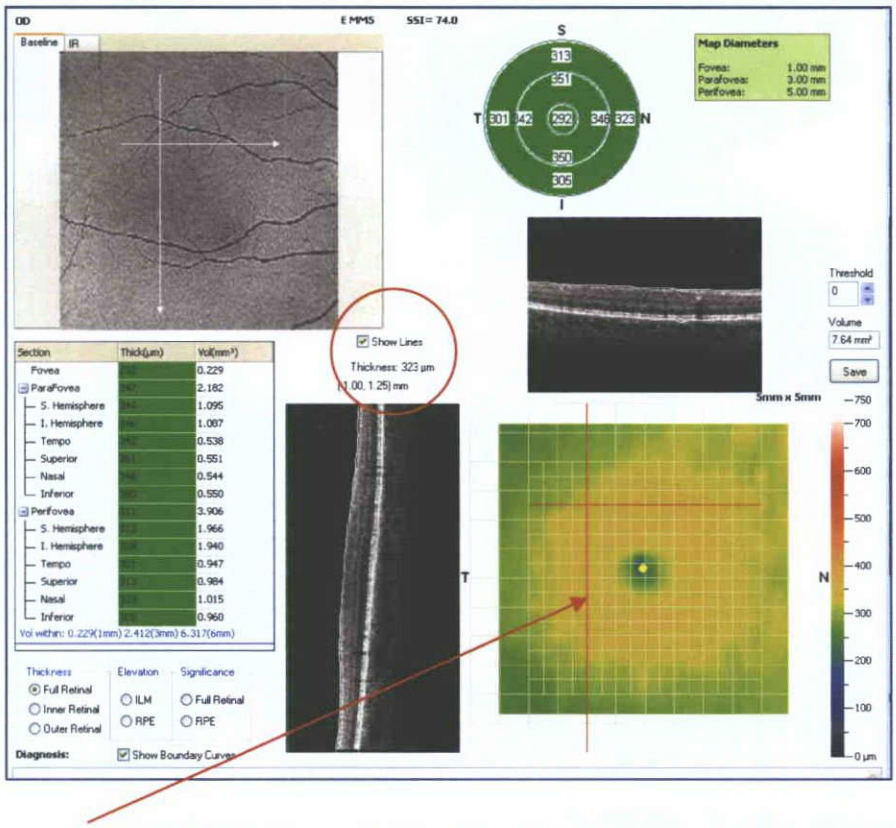
Analyze Menu



- The scan display control is active when the reference lines are Blue, and Locked when they are Red (single click will change the state from the map only)

- Macular thickness values (red circle), and retinal cross sectional images can be seen by moving the mouse cursor around the macular color-coded map. These will update while the display control is unlocked (lines are blue), and lock when the display controls are locked.

- The grid shows the EMM5 scan pattern (available scans indicated in white). The horizontal and vertical cross section image will be displayed corresponding to the color highlighted scan lines. The thickness and coordinates at the tip of the cursor are displayed in the center area of the page.

The mapping presentations for **Thickness, Elevation** and **Significance** are selectable at the bottom left of the report.

- **Full Retinal** Thickness measured from VRI to RPE layer.
- **Inner Retinal** Thickness measured from VRI to IPL.
- **Outer Retinal** Thickness measured from the RPE layer to the IPL
- **RPE** and **ILM Elevation**: show the height of the RPE or ILM relative to a reference plane. The reference plane is the best elliptical fit to the RPE boundary.

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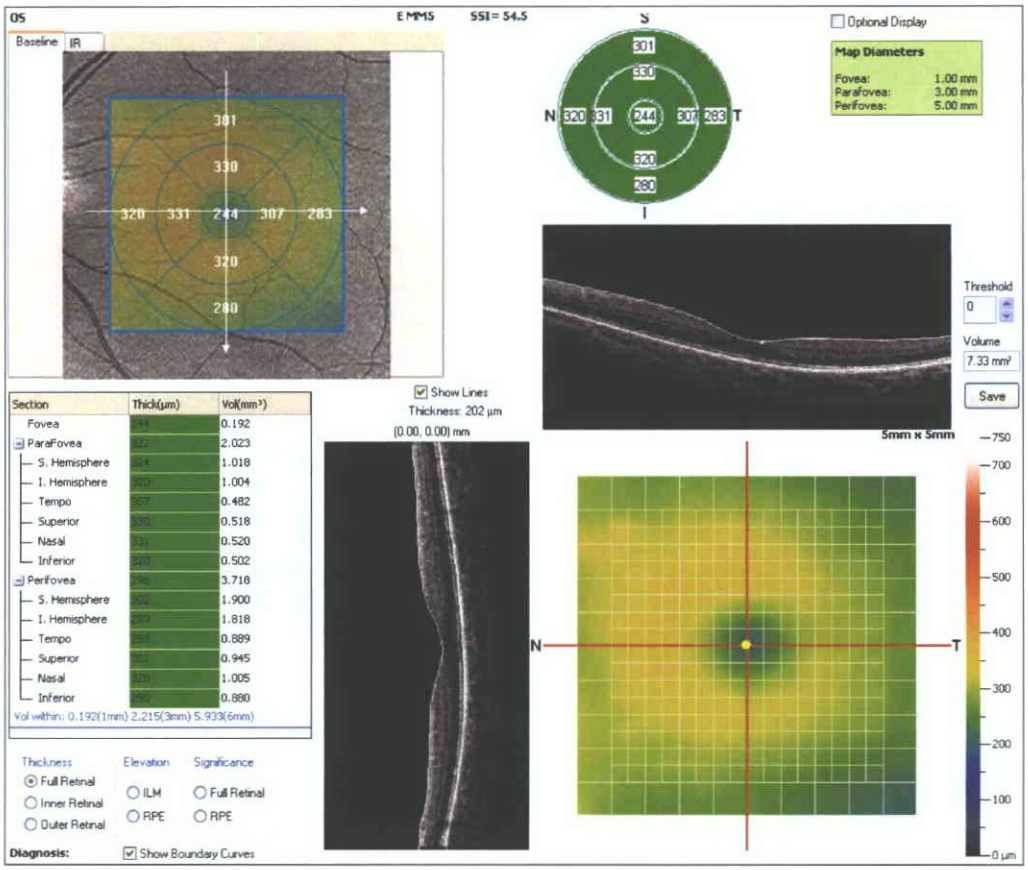

- The thickness map is further organized and presented at the top right in the nine ETDRS-like zones. (Based on the original four macular regions as defined in "***Stereoscopic Altas of Macular Diseases diagnosis and treatment", J. Donald M. Gass, Mosby, 3rd edition, volume 1, P3***.

Factors that can affect the Signal Strength Index (SSI):

<u>EMM5 scan pattern not centered on the fovea:</u> During the EMM5 scan, if the patient does not maintain good fixation, the fovea may not be in the center of the scan pattern. All measurements assume the fovea is in the center of the scan. If it is not, then the measurements will be affected. If the fovea is not in the center of the scan, it can be moved by the user manually. This will ensure the measurements come from the expected locations. The results should not be used if the repositioned fovea causes some measurement areas to be outside the scan pattern.

<u>Check the layer segmentation accuracy of the EMM5 scan:</u> The segmented layers for EMM5 scans are the ILM (Inner Limiting Membrane), IPL (Inner Plexiform Layer), and RPE (Retinal Pigment Epithelium). Check the segmentation lines for accuracy, and make

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adjustments as necessary. The ILM segmentation line should be at the retinal surface at the ILM. The IPL segmentation line should be at the bottom of the IPL layer. The RPE segmentation line should be in the middle of the RPE layer. If the segmentation lines are not accurately placed, the thickness measurements will be affected. If the user performs any manual correction, the results will be valid and the scan can be used.

Overall precision results with the EMM5 scan for normal, retina patients, and glaucoma patients:

EMM5 Full Retina Volume			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	0.63 (0.03)	0.64 (0.07)	103.02 (12.22)
Repeatability SD* (Min, Max)	0.003(0.002, 0.006)	0.004(0.002, 0.010)	2.40(1.78, 2.87)
Reproducibility SD** (Min, Max)	0.005(0.003, 0.015)	0.007(0.003, 0.011)	2.53(1.78, 3.52)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

EMM5 Full Retina Fovea			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	243.61 (26.00)	267.15 (73.32)	246.22 (22.14)
Repeatability SD* (Min, Max)	2.57(1.66, 2.57)	2.96(1.83, 3.15)	3.01(1.95, 3.01)
Reproducibility SD** (Min, Max)	17.72(1.66, 17.72)	13.78(1.83, 13.78)	3.01(2.05, 5.80)

EMM5 Inner Retina TSNI			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	112.83 (9.16)	113.04 (15.05)	103.02 (12.22)
Repeatability SD* (Min, Max)	1.38(0.88, 1.72)	2.52(1.57, 3.12)	2.40(1.78, 2.87)
Reproducibility SD** (Min, Max)	1.70(0.88, 7.09)	3.02(1.57, 6.59)	2.53(1.78, 3.52)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

For details on the clinical study and the clinical precision for RTVue scan measurements (repeatability, reproducibility), study information is available in the Appendix B–RTVue Precision

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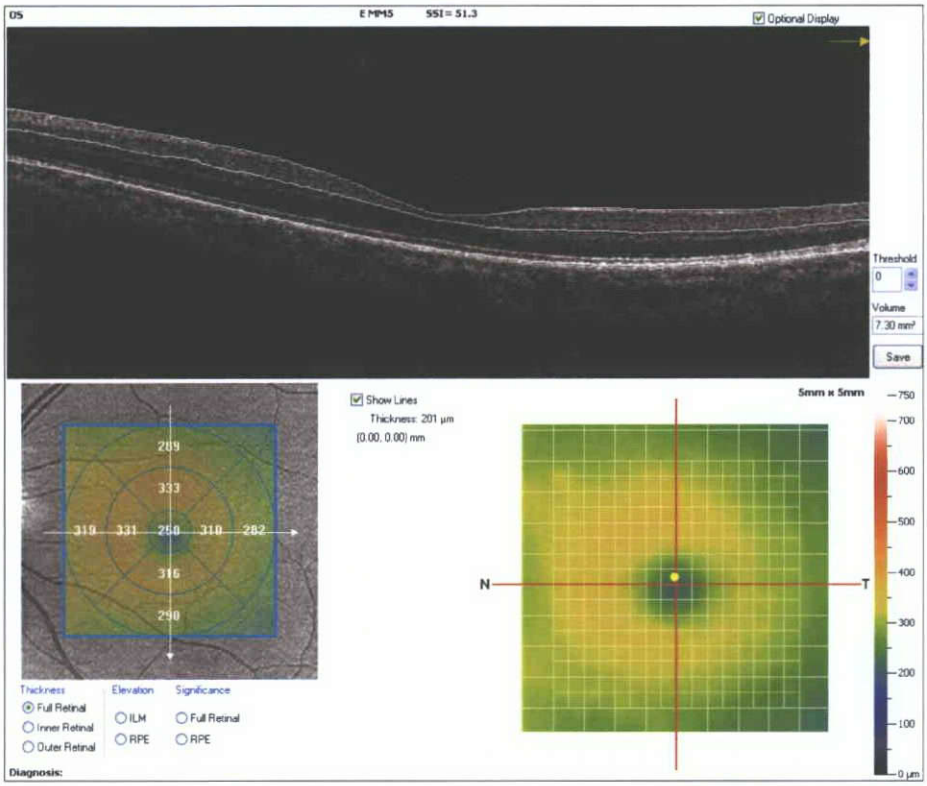
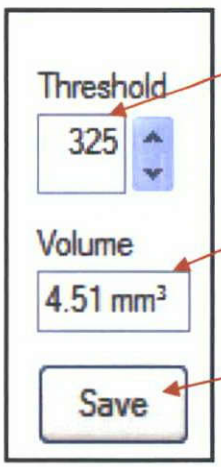
5.2.8 Alternate EMM5 Report / Printout



The check box at the top of the EMM5 report will bring up the alternative presentation of a single large representative scan and the correlating location on both the thickness map and the SLO reference image.

5.3 Volume Contouring and Measurements



- User can define a threshold level (numerical value – microns) for edema or elevated pathologies, and the map will trace a contour around all tissue exceeding the value entered.
- The Total Volume of the tissue exceeding the threshold is displayed real-time in the Volume field.
- This threshold, Volume and segment (Full, Inner or Outer) can be saved by selecting the [Save] button. Information is added to the table at the left of the report display.

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- Total volume exceeding the threshold value is outlined by contour tracing

(EMM5 Thickness Map – Without scan line indicators)

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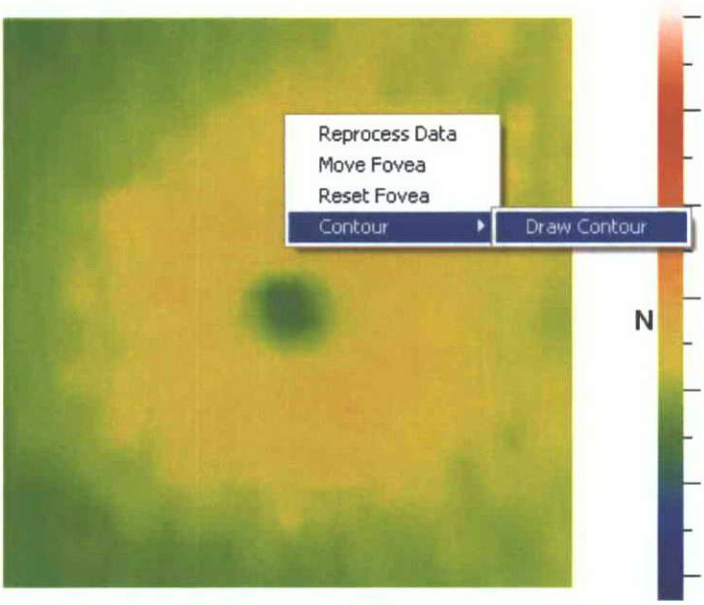
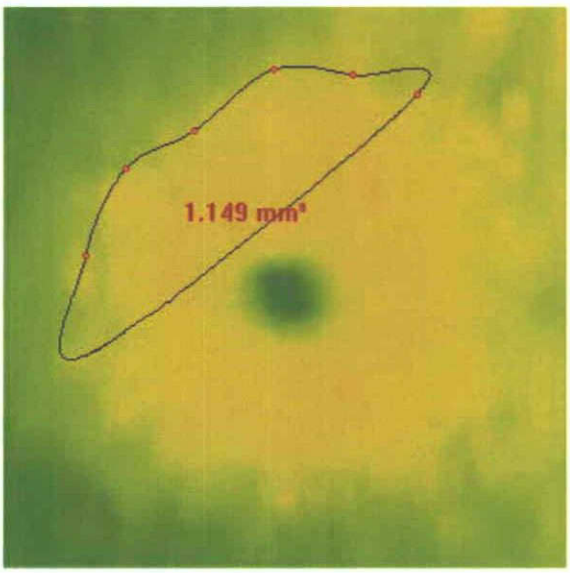
5.4.3.1 Custom Drawn Volume Contouring

You may also freehand draw the outline of a specific area on the map and the resulting volume will be displayed also real-time.

- Right-click on the map and select Contour>Draw contour





- Use the left mouse button to click on points around the area you are interested in.
- Contour line is black and active while drawing. Resulting volume is rendered real-time as you go.
- Double click on the last point to end the drawing and post the final shape and volume. Contour will turn Red to confirm final form.

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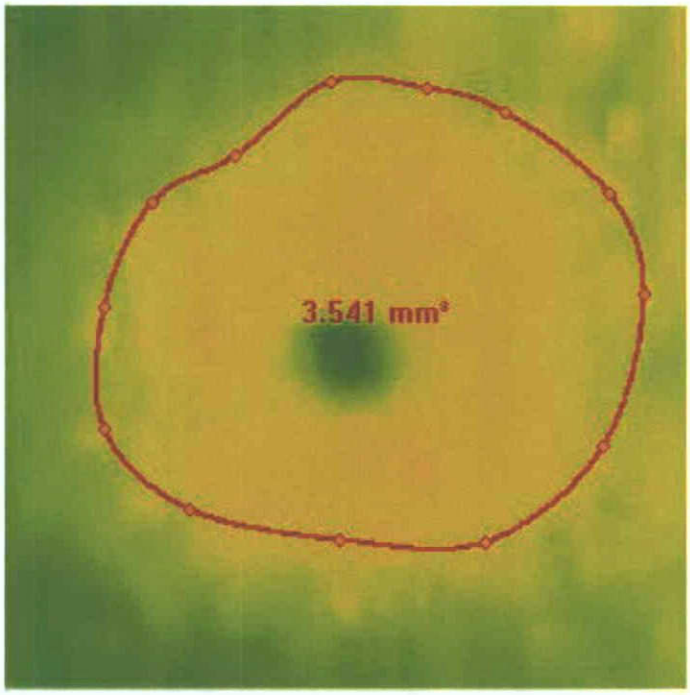

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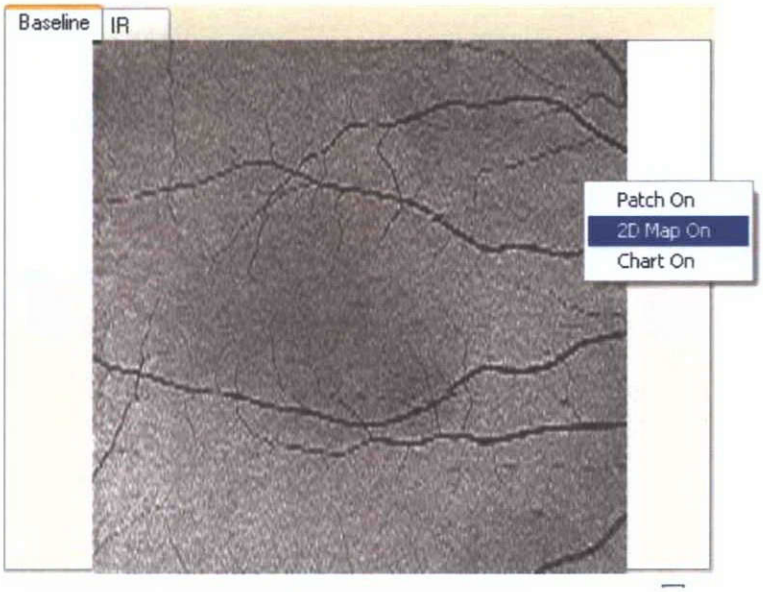
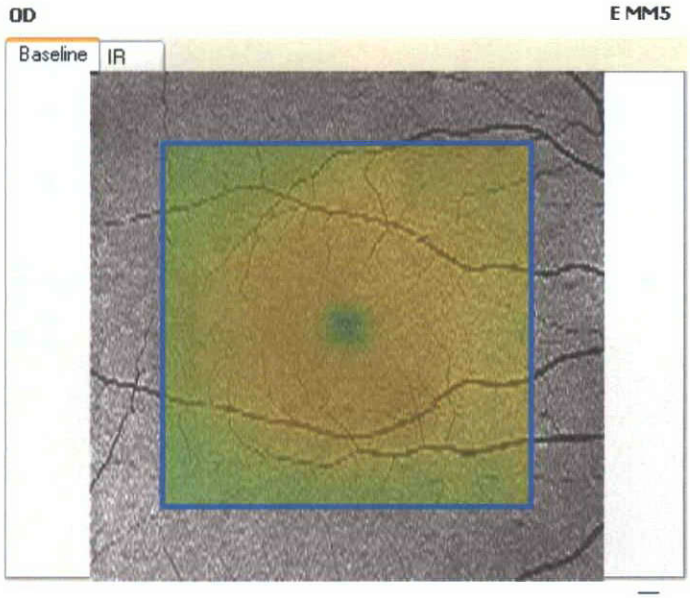
5.4 Overlay Options for Reference Fundus Image

- In the Reference image in the upper left of the EMM5 report screen the user has the option of superimposing the registered map (in the lower right displaying either thickness or elevation) over the image, and/or the ETDRS map/results.

- These options are available by right-clicking on the reference image



- 2D map is placed on the reference image
- Display of map and map on reference image are both updated when selecting the various thickness and elevation option presentations



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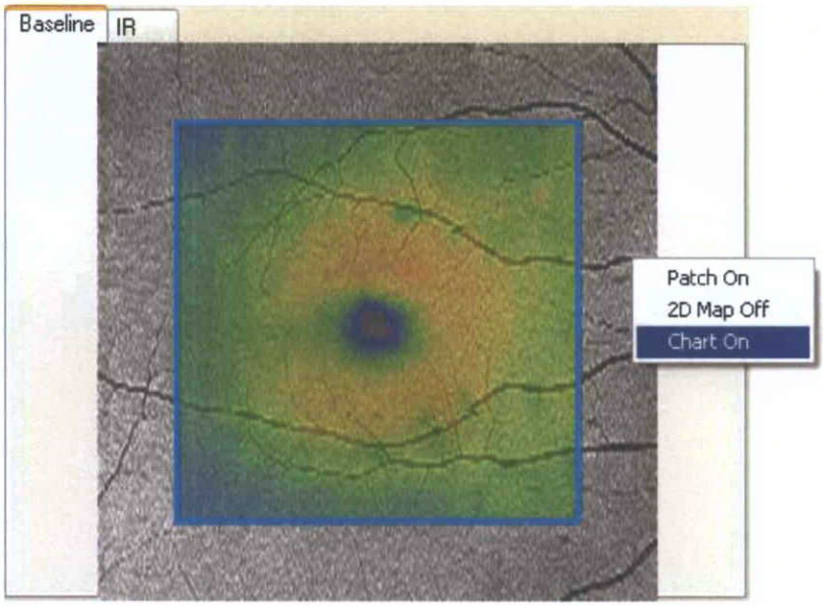
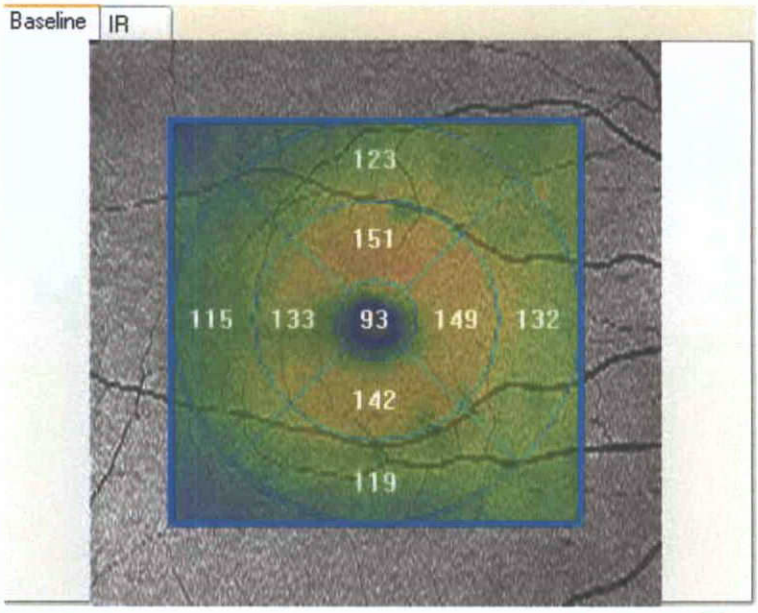
- Both the 2D map and the ETDRS grid and results may be displayed on the reference image at the same time or individually



- The Color reference for the Normative Database comparison is not shown in the overlay of the ETDRS grid when both (ETDRS and 2D map) are in overlay. **NOTE: This is the default presentation of the reference image.**



- The Color reference for the Full Retina thickness is shown when only the ETDRS grid is superimposed.

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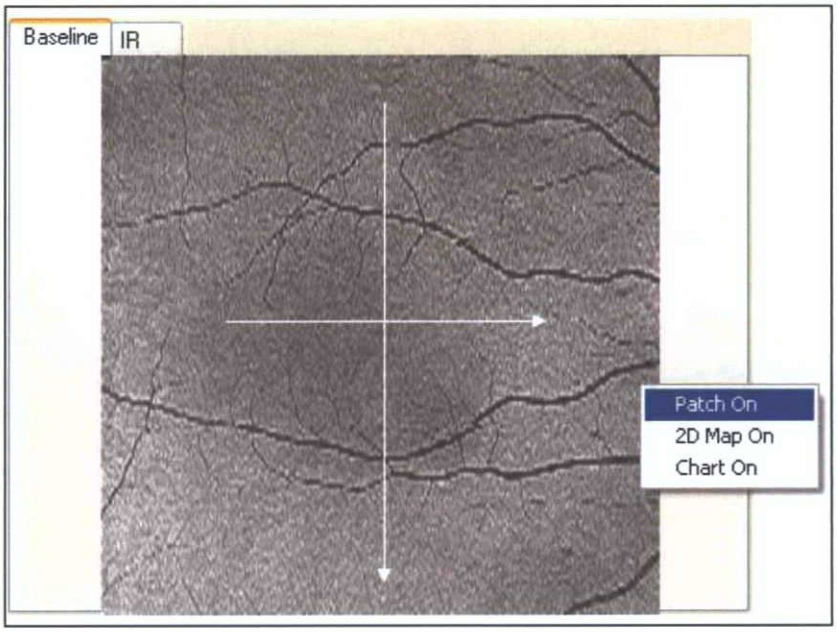
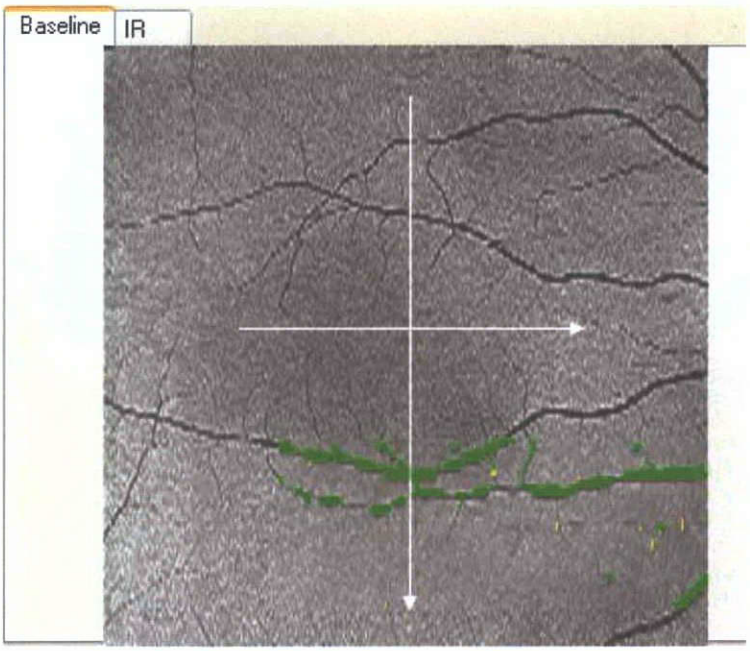
- The **Patch** overlay is the results of the sampling raster taken during the EMM5 scan. This is used to obtain the vessel tracing for the registration to the Reference image. You can see the Patch location using the right-click option.



- When the Patch is displayed, it will show green vessel tracings when aligned (as seen in the image below). If it is moved from its location, the tracings turn yellow indicating a deviation from the vessel match.



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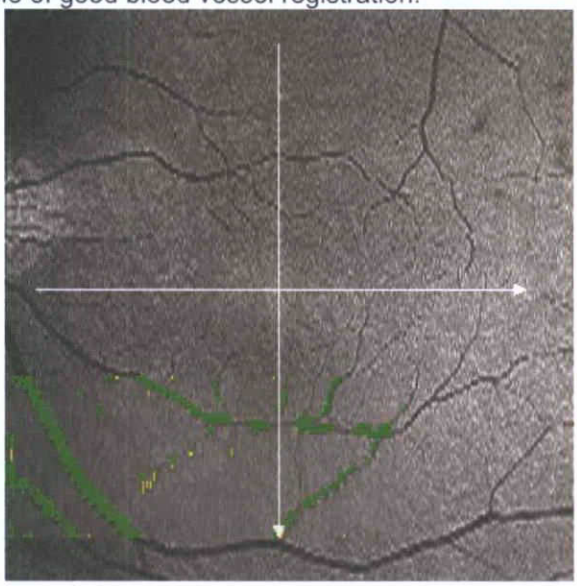
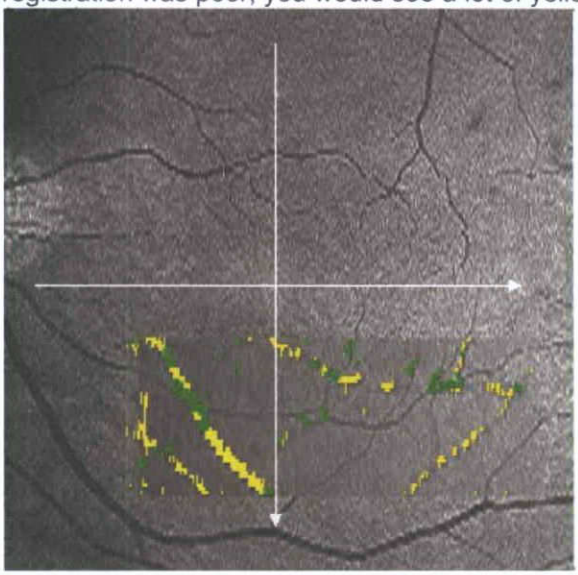
Example of poor blood vessel registration:

Below is an example of good blood vessel registration.



If the blood vessel registration was poor, you would see a lot of yellow in the image.



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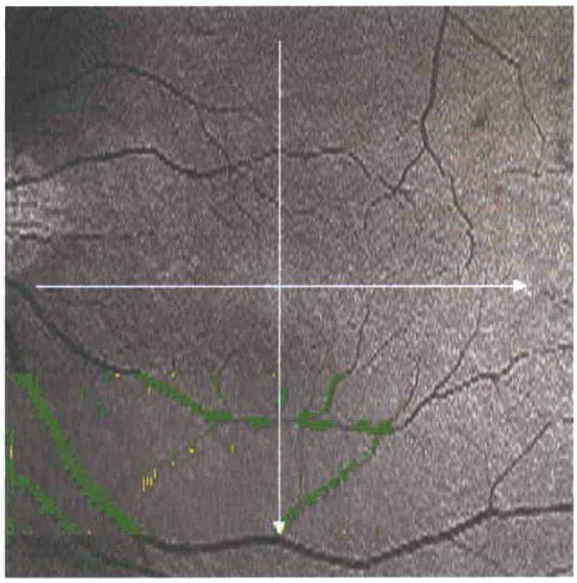
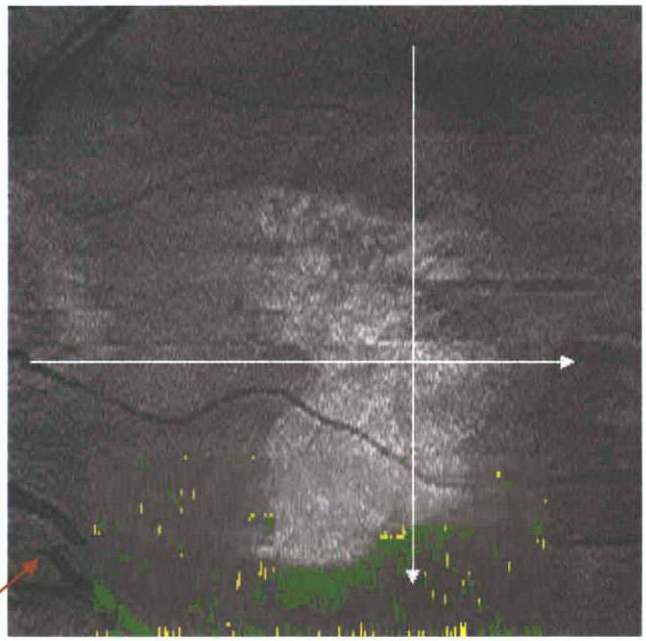
You can then manually move the patch area with your mouse until the blood vessel patterns are matched and you don't see any more yellow.



Examples of eye movement which indicate rescanning may be necessary:

Eye movement can cause poor blood vessel detection. Eye movement is indicated by the break in blood vessels within the scan. It is recommended to retake the scans with patients who displays eye movement during the scan.



Eye movement indicated by the break in the blood vessel pattern

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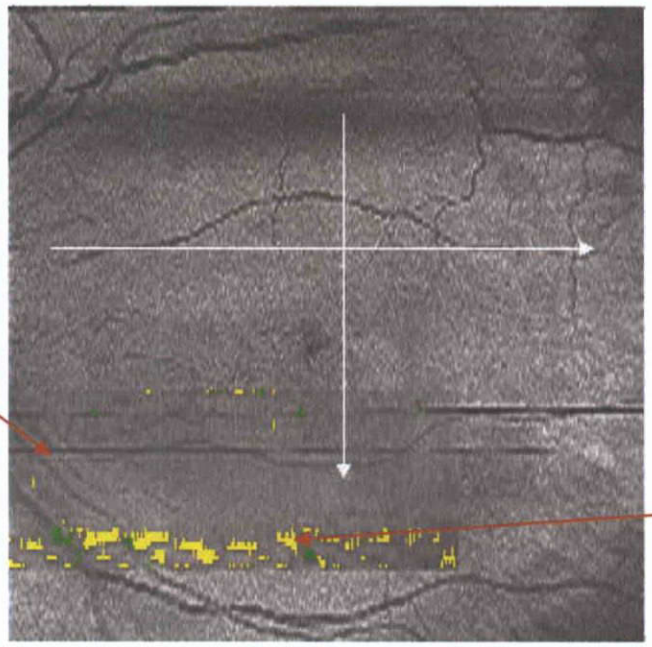
Another example of eye movement causing registration failure and poor blood vessel detection is shown in the image below. Eye movement is indicated by the dark horizontal lines within the scan. The below image is a patient with Diabetic Retinopathy who displays eye movement during the scan. The image also displays no blood vessel detection in the patch area - evident by the yellow patterns. In cases like this, it is also recommended to retake the scans.



5.4.1 EMM5 Change Overview Report

The EMM5 change analysis report shows an overview of up to four individual visit results (A baseline exam and three follow-up exams) for a specific patient eye. (See section 6.1 for detail on Normative change overview report)

The threshold input and the resulting automatic contour drawing are available in this report and apply to all four visits displayed.

- The value inserted causes all of the 2D maps in the top row to delineate the volume of all tissue above the defined threshold value.
- The volume defined by the contour outline is displayed, providing clear reference of the change (positive or negative) of any edema/elevation.
- Value is entered in the **Threshold** field in the upper right

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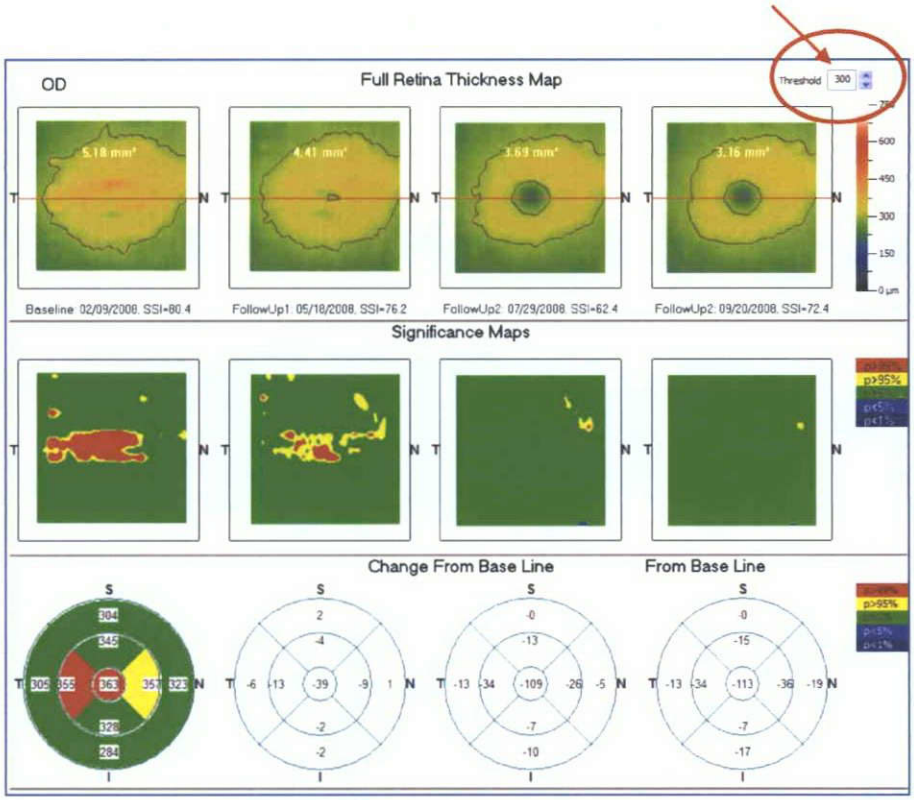
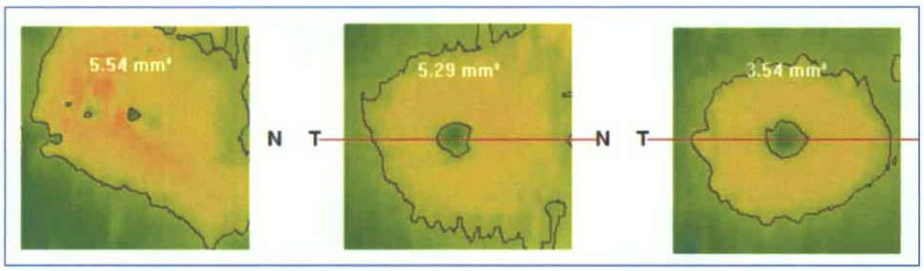


Figure 5.4.5 (Baseline and three follow-up exams)



5.4.2 *Retina Normative Database*

RTVue XR software contains the Normative Database that allows comparison of a patient's retina structure (macula thickness and RPE elevation) with "normal" patients in the same at segment. This comparison to "Normal" provides the clinician with an objective metric to use in the overall diagnosis.

The EMM5 Normative presentations are:

- Full Thickness Significance – selecting this option displays the significance, of the thickness deviation from normal of the scanned eye. Parameters include within normal for both edema and ischemic conditions.

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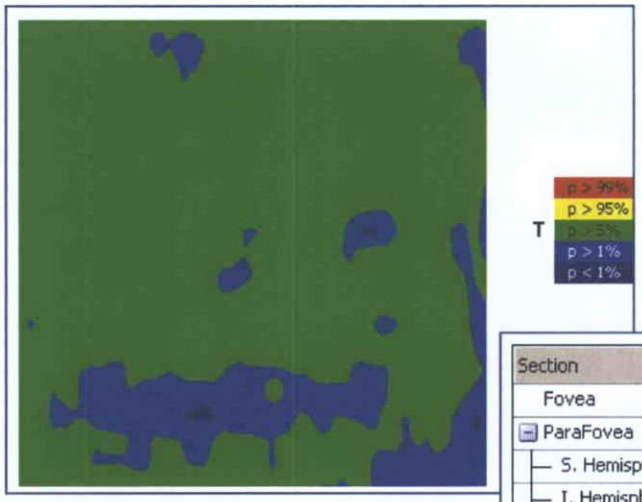
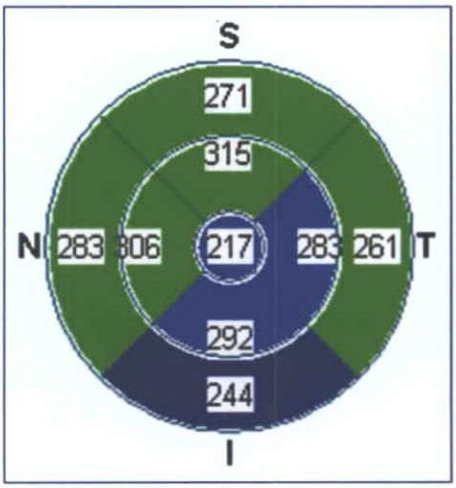


EMM5 Significance Map with Normative segmentation legend



ETDRS Map with average values

Section	Thick(µm)	Vol(mm³)
Fovea	217	0.170
ParaFovea	299	1.880
S. Hemisphere	305	0.959
I. Hemisphere	293	0.921
Tempo	283	0.445
Superior	315	0.494
Nasal	306	0.481
Inferior	292	0.459
Perifovea	265	3.328
S. Hemisphere	274	1.722
I. Hemisphere	256	1.606
Tempo	261	0.820
Superior	271	0.852
Nasal	283	0.890
Inferior	244	0.766
Vol within: 0.170(1mm) 2.050(3mm) 5.378(6mm)		

Normative DB Metrics

- RPE Elevation Map – this option displays the patient's RPE tracing compared to a normalized ellipse fit. Elevation is based on +/- 80% of the RPE (24 microns), and amplitude of +/- 150% of the RPE thickness (45 microns).

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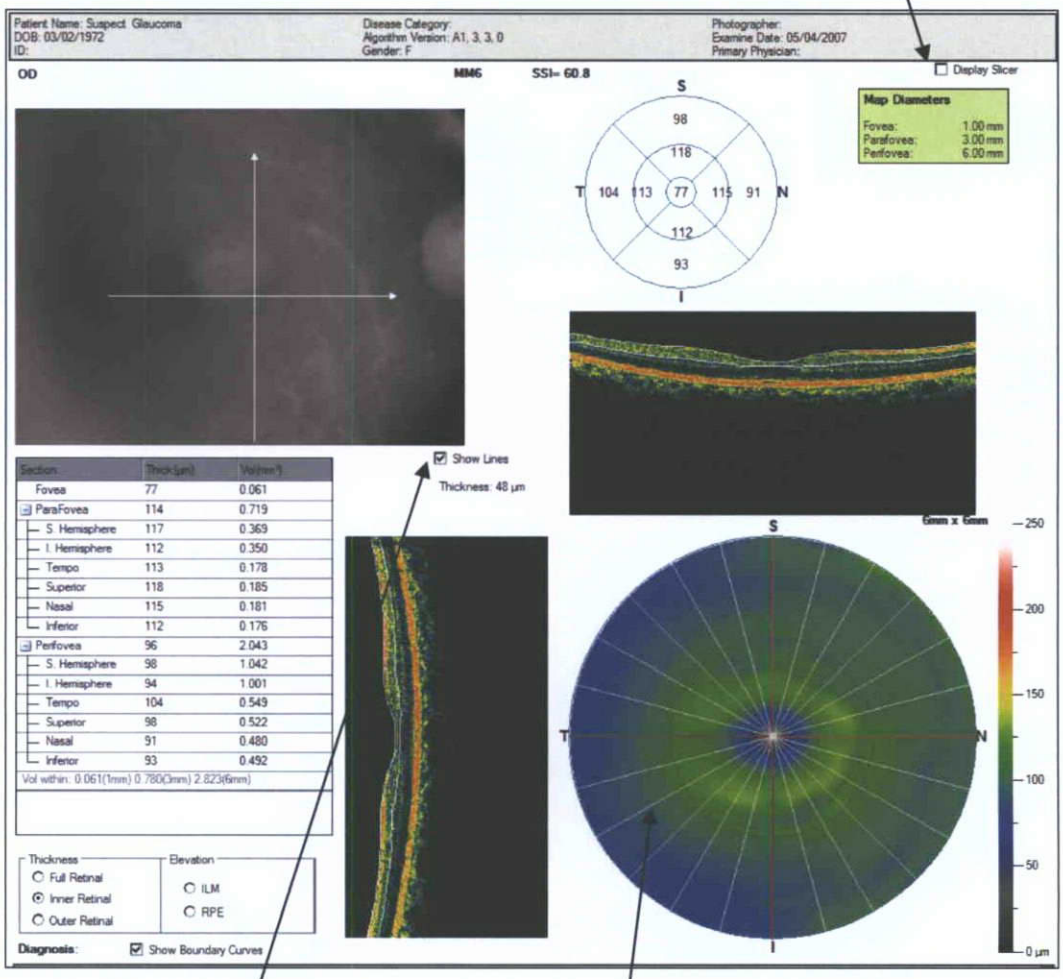
5.4.3 MM6 Analysis Report

The MM6 (12 Radial scans) maps the central macula using a radial scan pattern more familiar to those who have had previous OCT technologies.

Note: The MM6 is not included in the Normative Database collection that is in process.

Display Slicer option: Toggles the display of the MM6 between the standard presentation and as Radial Slicer presentation, including all 12 scans



Show Lines: This option toggles the map display between showing with or without scan reference lines. Map graphic without lines works well for case study presentations

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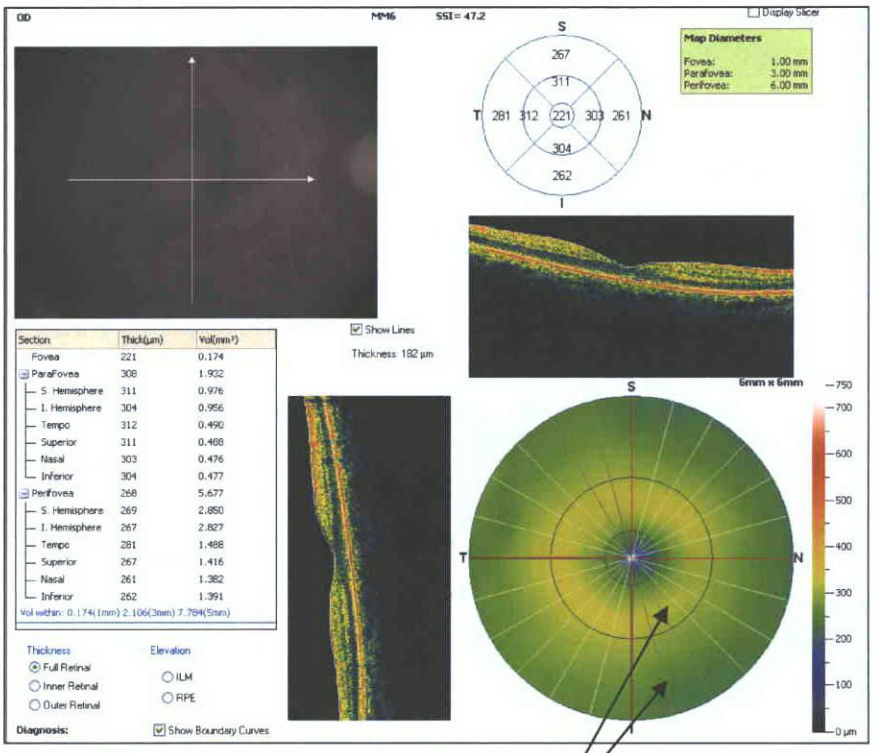
5.4.4 Missing Scans Due to Blink

For all map patterns saved which included missing or dropped B-scans (due to blinking, weak signal, eyelash obstruction, iris clipping, etc), the scans not included in the map rendering are indicated in gray instead of white (scan indicator lines).

For missing scans indicated in any map, the raw B-scans not used should be reviewed by the clinician and the map data in this area should be reviewed with caution.



Missing lines indicated in gray. Date in this area is interpolated based on the nearest adjacent complete scan data.

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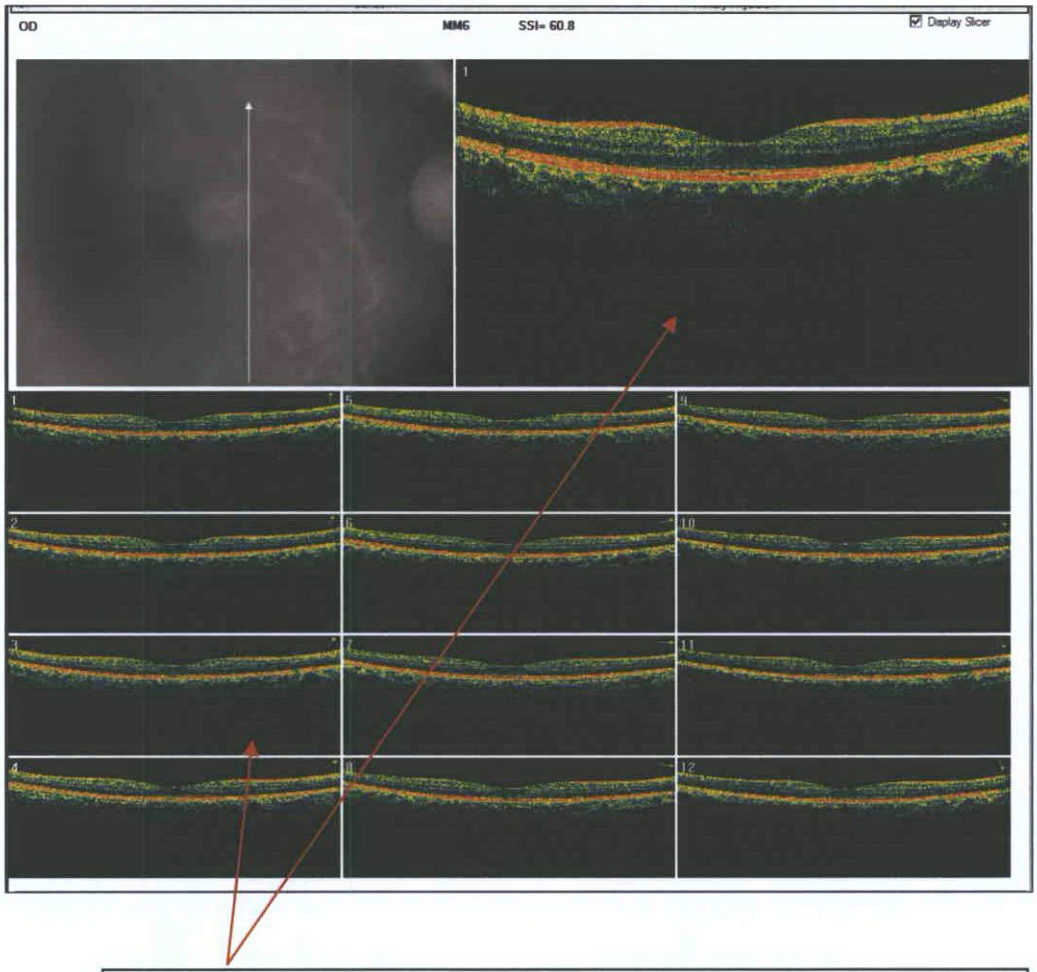
MM6 Slicer (Option) Display



Click once on any scan to display it in the larger window at the top right.

Double click on any scan to go immediately to the measurement mode presentation.

Note: The **Radial Raster** and the **Raster** report displays have two ways of presenting the scans for view and printing. At the top you will find the selection options of One page or Two page (larger scan images) presentations.

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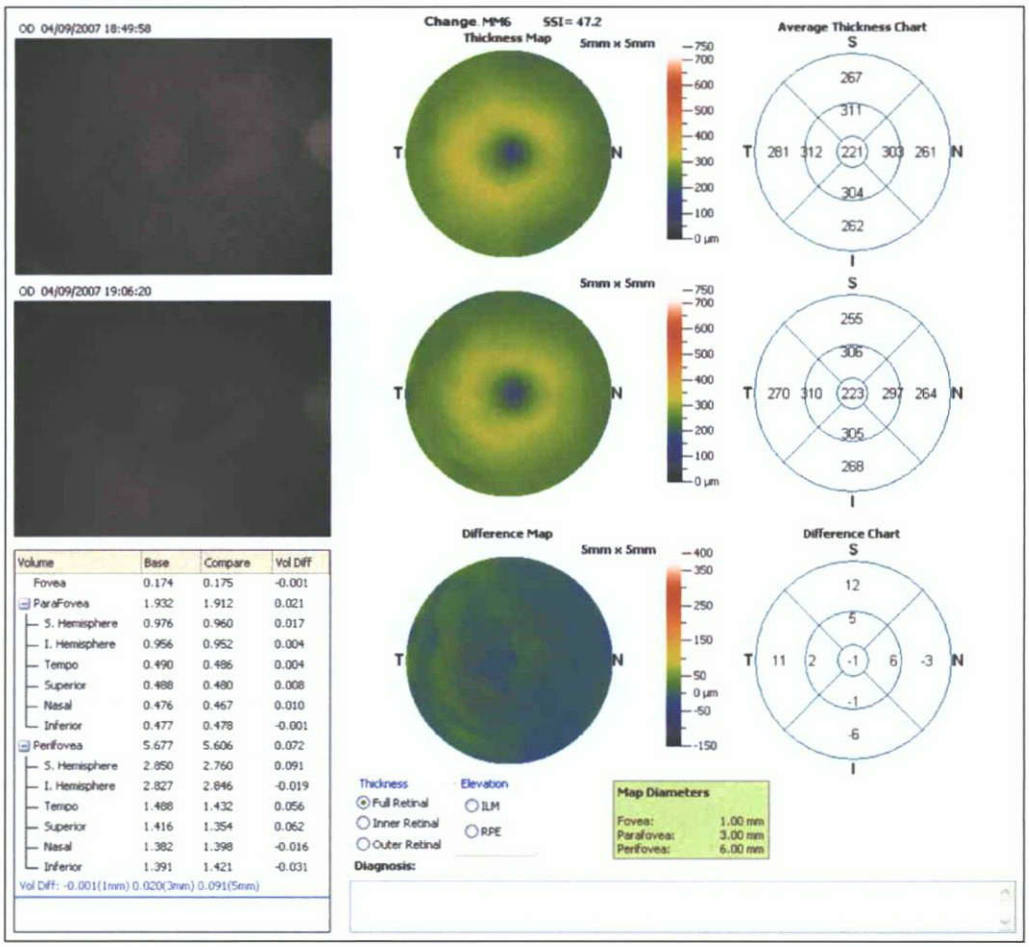
5.4.5 *MM6 Change Analysis Report*

The MM6 change analysis shows the difference between two MM6 analyses. To speed up the comparison results, it is better to analyze each individual MM6 scan first before making comparisons.



Please Note:
Change analysis is a simple difference map without any statistical adjustments. The values are simple differences and may not be statistically or clinically significant.

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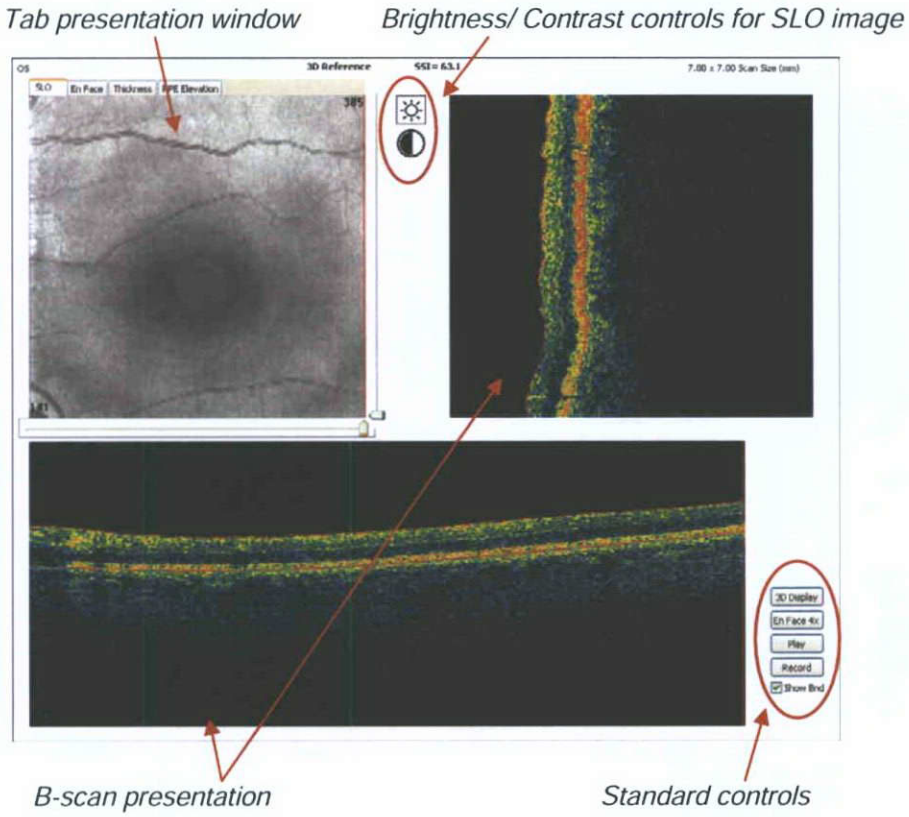
5.5 3D Presentations

The 3D scan presentations are updated considerably from the previous version. The following viewing options are indicated by the tabs SLO, En Face, and so forth.

- **SLO**: This view shows a SLO-style image created by the sum of all the C-scans, producing a high contrast "En face" image.
- **En face**: This view presents the sum of the c-scan planes indicated in the thickness value field.
- **Thickness**: Presents the thickness with log scale of user selectable segmentations for Full, Inner and Outer retina. The 3D Reference and 3D Macular scan displays an ETDRS thickness map in the thickness tab when the scan size surpasses 6.00 x 6.00 mm. The ETDRS map is a traditional ETDRS map consisting of 1mm, 3mm, and 6mm diameter circles. Note that the ETDRS map is always in the center of the window. It may not be centered on the fovea.
- **RPE Elevation**: Presents the elevation of the RPE from a normalized plane. This is available for 3D Macular and 3D Reference scans.



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Analyze Menu

Standard controls

- **Brightness:** Controls brightness settings for the SLO image

- **Contrast:** Controls contrast settings for the SLO image

3D Display

- **3D Display:** Brings a separate full sized screen for a 3D presentation of the OCT scan.

En Face 4x

- **En Face 4x:** Brings a separate full sized screen displaying 4 En Face views of 4 separate layers of your choosing.

Play

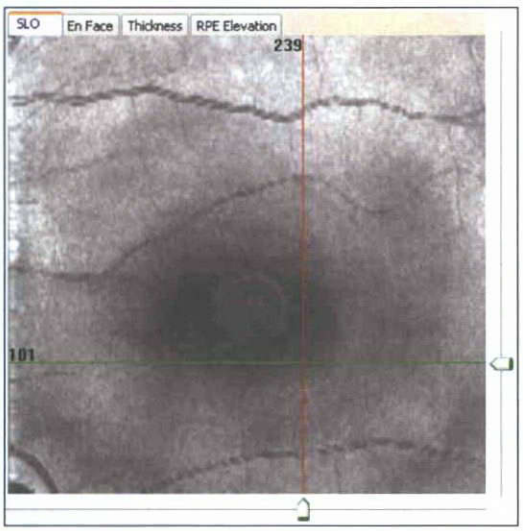
- **Play:** Sequentially plays through the B-scans and 3D display while showing the reference in the SLO-style image.

Record

- **Record:** Clicking 'Record' will prompt a new window to pop up asking for a folder to save in. The file recorded will be saved in an .AVI format. Click 'Stop Recording' to finish recording.

☑ Show Bnd

- **Show Bnd** (boundary)**:** Displays or removes the algorithm tracing



- **Green line:** Position of horizontal B-Scan.
- **Red line:** Position of vertical B-scan
- Clicking anywhere on the window (shown to your left) will automatically show corresponding horizontal and vertical B-scans.
- Note: 3D Volume and 3D Display are memory intensive functions. Frequent usage of these features may slow down the processing of scans.

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

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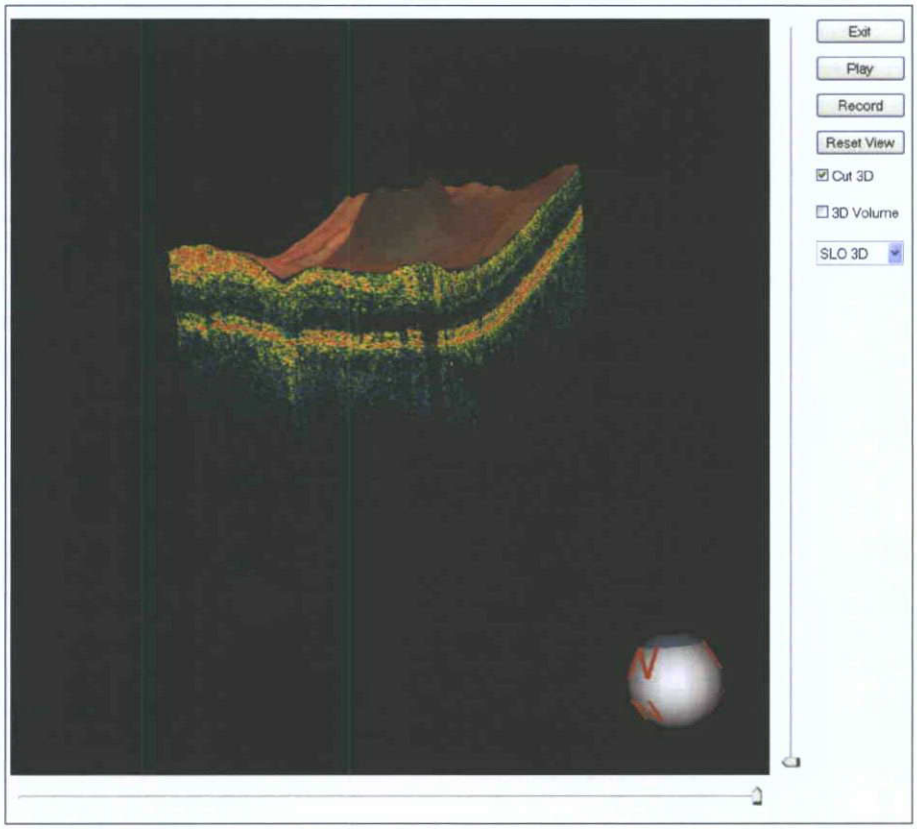
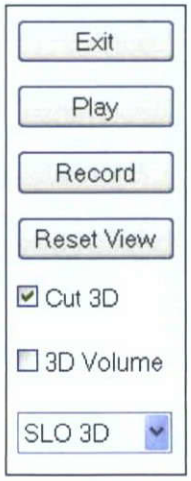
3D Display

The 3D display presentation appears in a separate window to give a more detailed view of the 3D model. The model offers multiple views to choose from: SLO 3D, Full Thickness, Inner Thickness, Outer Thickness, and RPE Elevation (available for 3D Macular and 3D Reference scans). These can be chosen from the drop down menu in the right panel.





- **Orientation Legend:** Shows orientation based on TSNIT.
- **Exit:** Closes the 3D Display window.
- **Play:** Sequentially plays through the B-scans on 3D display.
- **Record:** Clicking 'Record' will prompt a new window to pop up asking for a folder to save in. The file recorded will be saved in an .AVI format. Click 'Stop Recording' to finish recording.
- **Reset View:** Resets the image to a top-down view.
- **Cut 3D:** Option to have 3D image "cut" as the B-scans are reviewed.
- **3D Volume:** This option presents entire data captured in the 3D block including the tissue in the vitreous just above the ILM plane.

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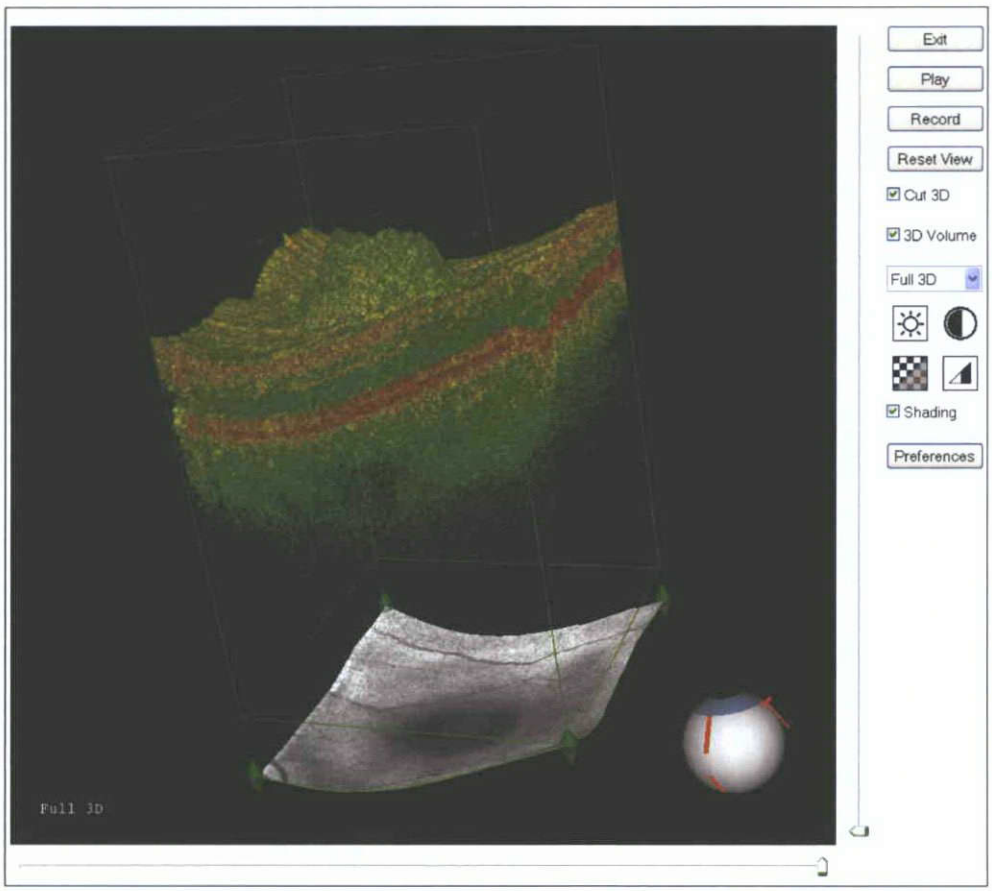
3D Volume

The 3D Volume rendering shows an SLO-style image super imposed to the bottom of the 3D image. The 3D Volume presentation can be accessed by selecting the '3D Volume' option in 3D Display.

PLEASE NOTE: 3D features introduced in this version are intended for the RTVue XR PC system as it applies to the specifications listed in Section 9.1D. PC systems that do not adhere to the specifications may experience less than optimal performance when using 3D features.



Like the 3D display, the 3D volume has the option of displaying multiple views. The different views can be modified by clicking the 'Preferences' button.

- **3D Transparency:** Changes the transparency of the 3D volume model

- **3D Volume Low Cut Off:** Filters out additional noise in the 3D rendering.

- **Shading:** Affects the shading of the 3D volume model. Turning off 'Shading' will also disable the SLO mounted on the bottom of the 3D model.

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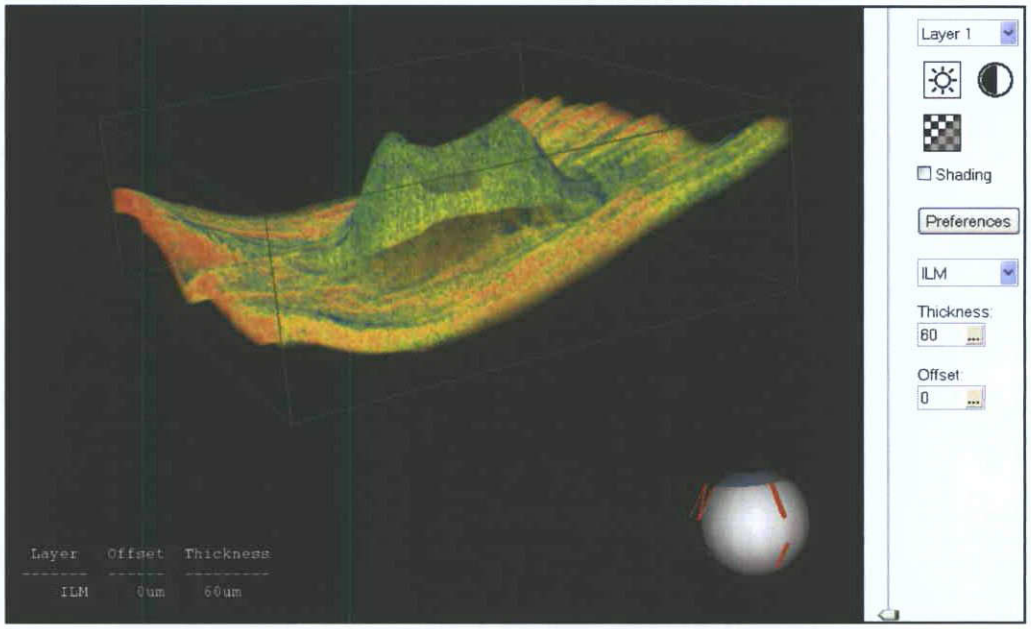
Analyze Menu

- **Preferences:** Brings up specific options for the 3D Volume selection.
- **Layer Selection:** Choose which view to present in the 3D Volume window. Layers 1-4 are user selectable and can be set in 'Preferences'. Selecting Vitreous gives a vitreous view with a white background.



3D Volume view of ILM layer.

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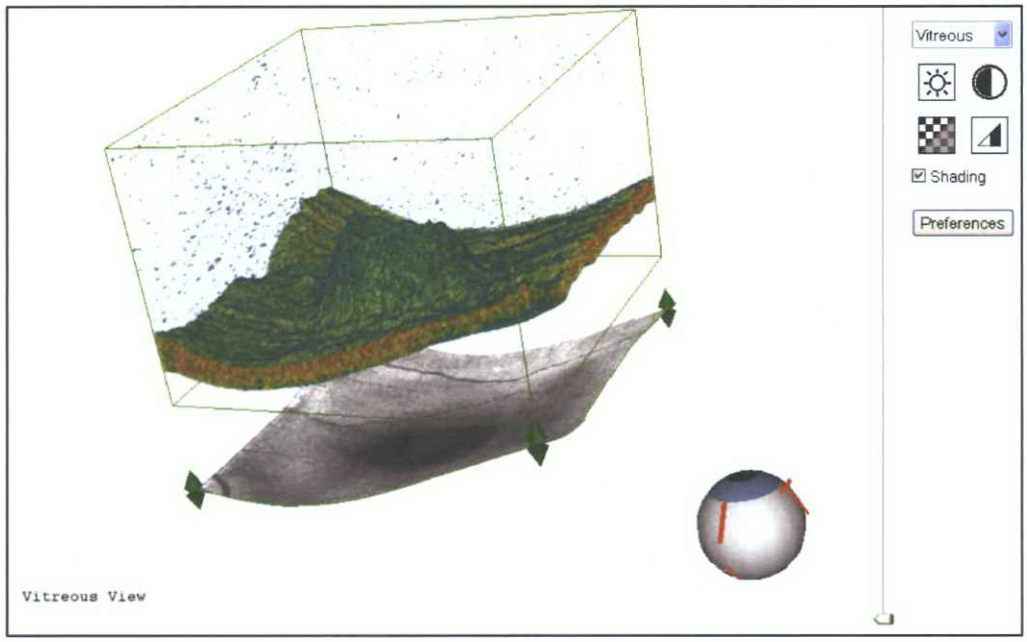
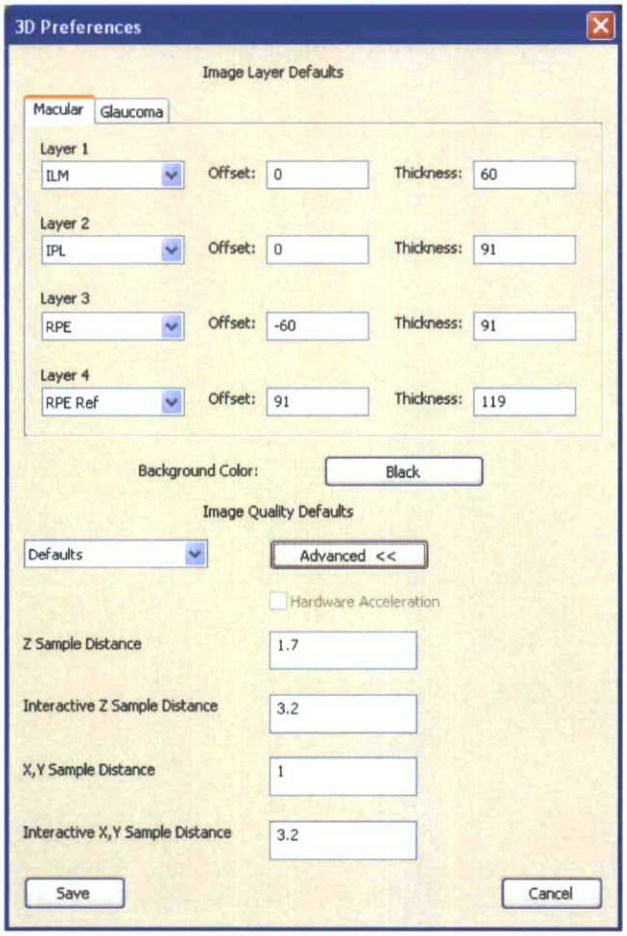


3D Volume view of the Vitreous View. The Vitreous view uses a white background to better view the particles in the vitreous.



- **3D Preferences:** The top half of the 3D Preferences window lets the user select the layer and modify the offset and thickness to be represented in Layers 1-4. The Figure to the left shows the default layers and their respective settings for offset and thickness. These values will correspond with any settings changed in the **En Face 4x** preferences (as seen later in the manual).
- **Background Color:** Change the background color of the 3D model from black, grey, and white.
- **Advanced:** The Advanced options affect the 3D volume rendering when the object is dynamic and static. **The advanced options are intended for advanced clinical research purposes.**

3D Advanced Options

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The advanced options affect how the 3D Volume model is rendered in its 'static' and 'dynamic' state. The dynamic state refers to the state the model is in when it is interactively being manipulated (dragging and rotating views). The static state refers to the 3D model when it is not being manipulated by the user.

The options: "Interactive Z Sample Distance and Interactive X, Y Sample Distance" affect the quality of rendering when the user moves the 3D Model.

The options "Z Sample Distance and X,Y Sample Distance" affect the quality of the rendering of the static 3D Volume model.

The Hardware Acceleration option is available to RTVue XR PC systems that have graphic cards that support hardware acceleration. PC systems without abilities to use the Hardware Acceleration option will have the option gray'ed out. Selecting the Hardware Acceleration option uses the video card's GPU to power the 3D model. If the Hardware Acceleration option is not selected, 3D models will be powered by CPU instead.

Higher values yield faster processing time but lower resolution 3D Volume models. Lower values take longer to process the 3D models but have increased resolution. The values set as default were found to have the best balance between processing time and rendering quality. The chart below show the possible input values for each selection.

	CPU	GPU (Hardware Acceleration option selected)
Z Sample Distance	1.0 < X < 10	.4 < X < 10
Interactive Z Sample Distance	2.5 < X < 10	.7 < X < 10
X,Y Sample Distance	.7 < X < 10	N/A
Interactive X,Y Sample Distance	2.0 < X < 10	N/A

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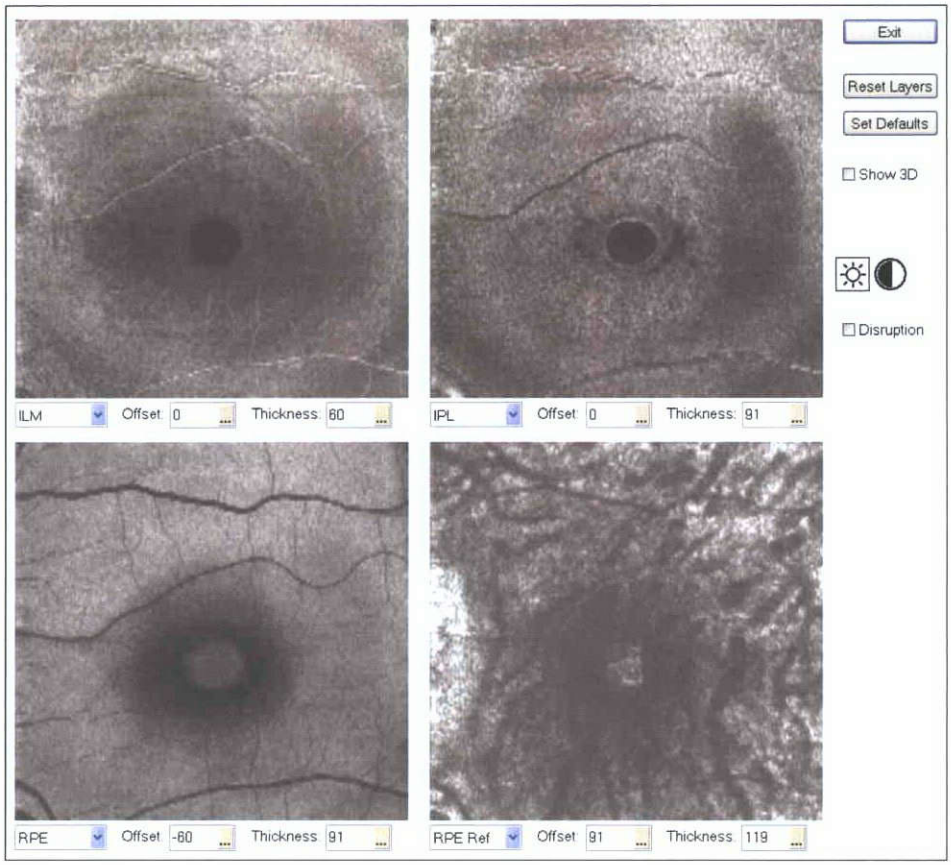
En Face 4x

The En Face 4x presentation provides en face views of four different layers. The default layers shown are ILM, IPL, RPE, and RPE Ref for retinal 3D scans. For 3D Disk, the default layers are ILM, NFL, and RPE. These layers can be changed by going to the respective drop down menu in each en face window. These options also affect the layer selection in the 3D Volume selection.



The offset and thickness values can be modified. Click "Show 3D" on the right hand side, to view the En face layers in 3D.

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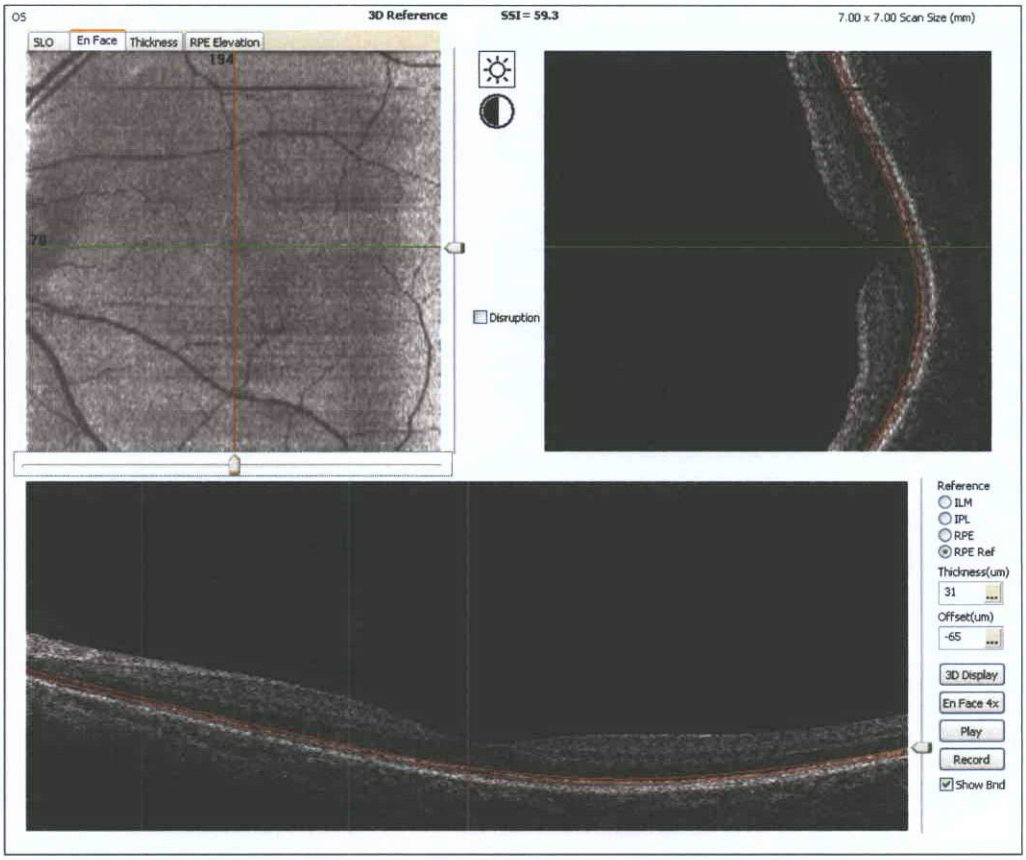
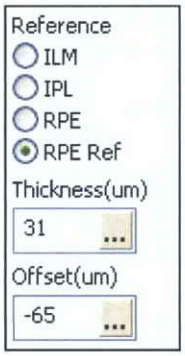
En Face presentation

This view presents the sum of the c-scan planes indicated in the thickness value field





- Options for reference plane contour.
- Thickness (µm): You can select the thickness of the scan plane (slab or Sum) presentation (microns) in the En face window.
- Offset (depth or elevation) from starting plane in microns.

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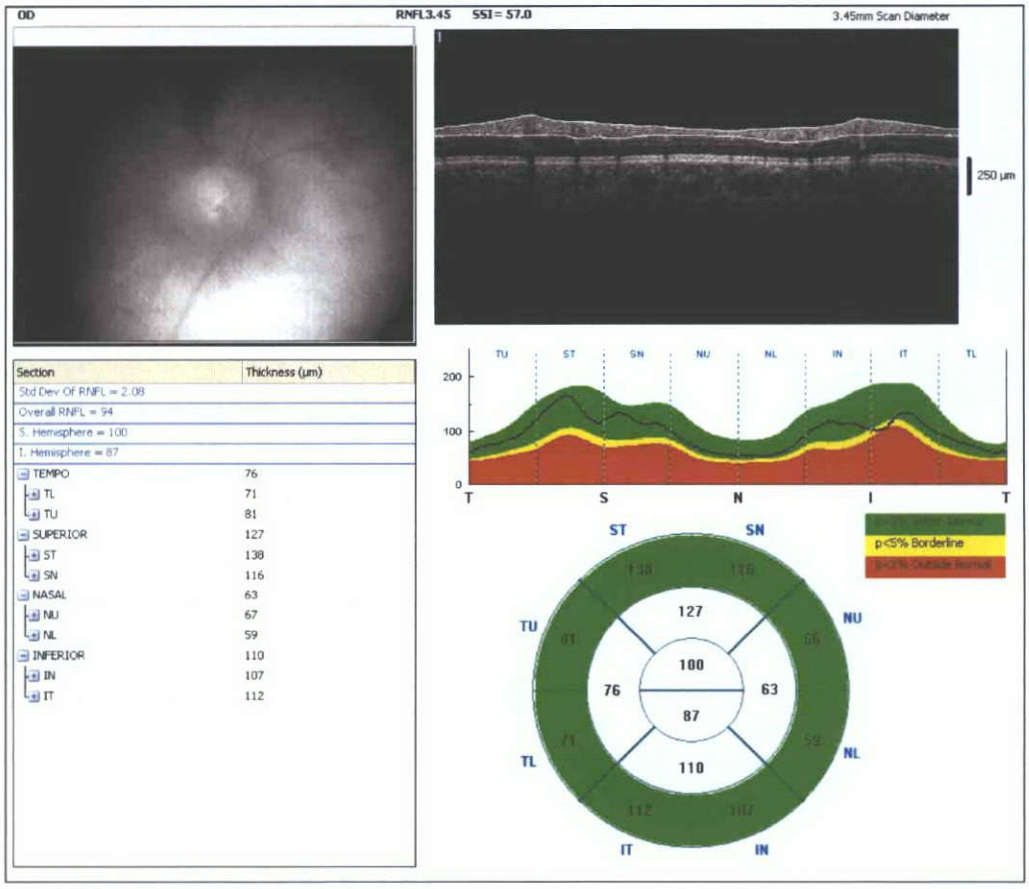
5.6 Analyze Report – Glaucoma Scans

5.6.1 RNFL3.45 Analysis Report

The RNFL scan pattern completes four circular scans in 0.16 seconds at a diameter of 3.45 mm, targeted around the optic nerve head. These scans are averaged and the result is presented within the normative range parameters.

With version 6.1, RNFL average thickness is show in 8 sectors in RNFL 3.45 analysis and change reports.

NOTE: This scan pattern cannot be registered for viewing change over time purposes. For Glaucoma and sequential change analysis, we strongly recommend using the ONH scan pattern (which offers an alignment-corrected RNFL measurement)



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

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5.6.2 *RNFL 3.45 Change Overview Report*

Up to four exams (baseline and three follow-up visit results) can be selected for the Change overview report.

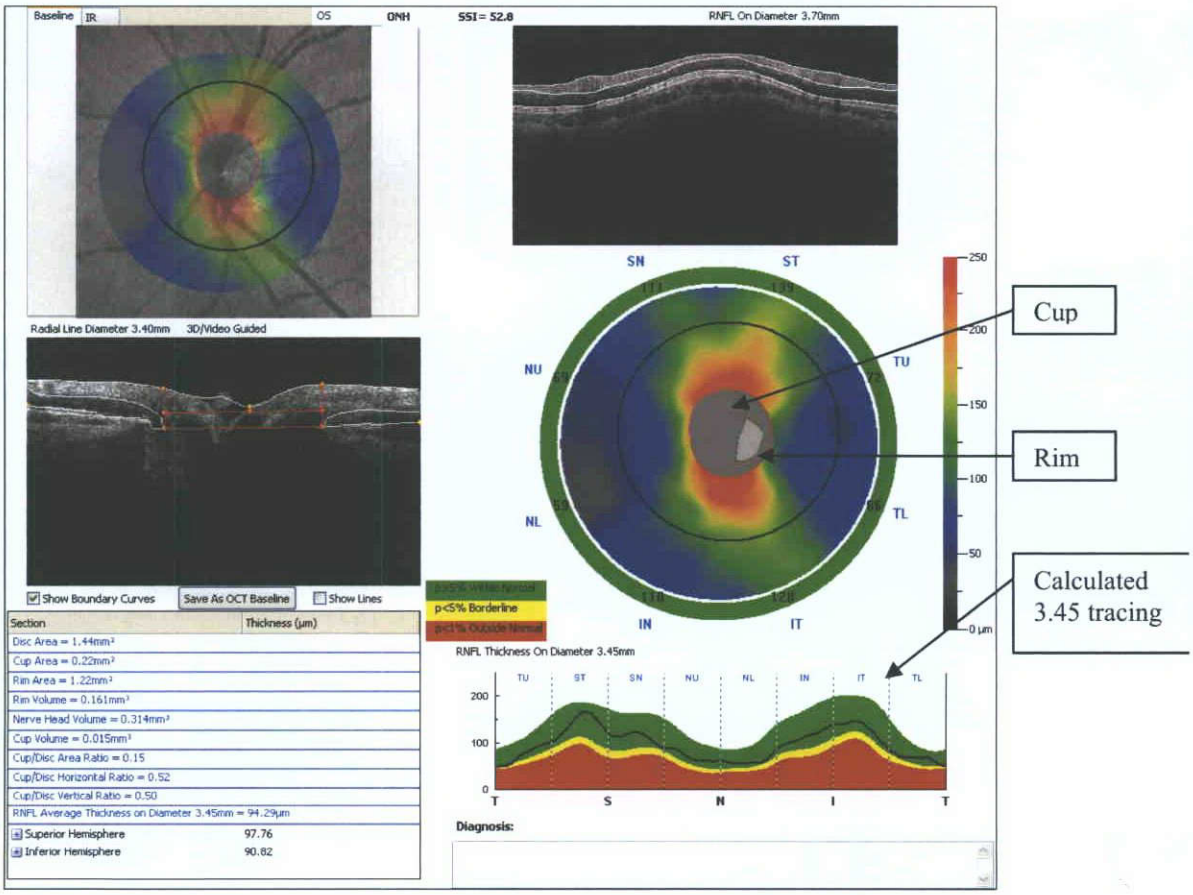
Each averaged (4 scans) result is plotted against the Normative parameters.

NOTE: This scan pattern is included in the RTVue XR for users wishing some continuity with previous Time-Domain OCT systems. However, just as with the Time-Domain OCT systems sold previously, the scan placement is completely dependent upon the operator. Registration is not possible with this scan pattern.

5.6.3 *ONH Analysis Presentation*

The ONH map includes several pieces of important disc morphology information: Disc and Cup Areas, C/D Ratio, RNFL 3.45 and NFL thickness map from disc margin up to 4.93 mm radius from the center of disc.

With version 6.1, RNFL average thickness is show in 8 sectors in ONH analysis and change reports.



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Factors that can affect Scan Signal Index (SSI) for the ONH scan:

Scan not centered on the optic disc:

During the scan, the operator should check to make sure the scan pattern is well centered on the optic disc. If it is not, the operator should move the scan pattern to be centered on the disc. If the operator does not and if the scan pattern is not centered on the disc, the RNFL thickness measurements may be affected. The software can automatically reposition the RNFL TSNIT circle to be centered on the optic disc after the scan, however if the disc is too close to the edge of the scan pattern, some of the data may be missing if the measurement circle falls outside the scan pattern area. In these cases, the scan should be retaken.

Check optic disc drawing and RPE tip placement:

Make sure the optic disc drawing accurately demarcates the edge of the optic disc boundary. Also make sure the RPE tip placements are at the correct positions (end of RPE/choroid complex at the disc margin). Re-draw the optic disc margin drawing if necessary. Adjust the RPE/Choroid tips placement if necessary. If the optic disc drawing or the RPE tip placement is not accurate, the measurements can be affected. Scans should be retaken if the RNFL measurement circle falls outside the scan area after the disc drawing and RPE tip placement are in correct positions. This verification of RPE tips can be done at any time (regardless of setting in the User Preferences) by "right clicking" on the NFL result map.

Check the layer segmentation accuracy of the scan:

The segmented layers are ILM and NFL (Nerve Fiber Layer). If the segmentation lines are not accurate, the user should manually make the necessary corrections. If the segmentation is not accurate and the user does not make the correction, the results will be affected. If the user performs manual correction, the results will be valid and the scan can be used.

Overall precision results with the ONH scan for normal and glaucoma patients:

ONH Average RNFL		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	100.82 (8.11)	86.40 (14.99)
Repeatability SD* (Min, Max)	1.76(1.76, 6.18)	1.56(1.56, 5.86)
Reproducibility SD** (Min, Max)	2.11(2.11, 9.78)	7.87(3.92, 16.33)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning

**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

For details on the clinical study and the clinical precision for RTVue scan measurements (repeatability, reproducibility), study information is available in the Appendix B–RTVue Precision.

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

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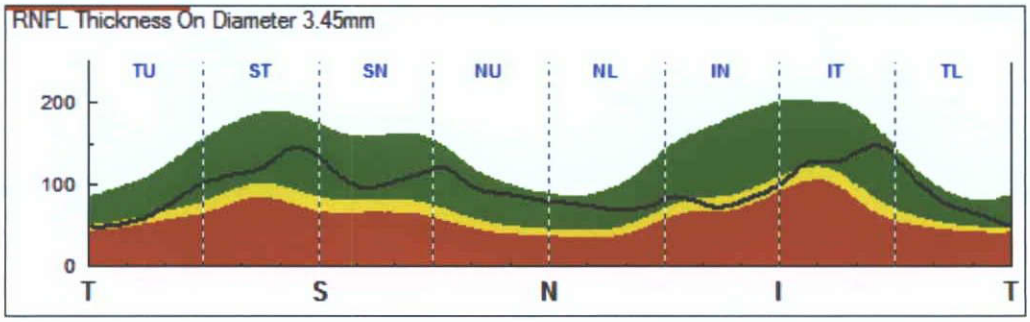
5.6.4 *TSNIT Histogram*

RNFL thickness profile in the ONH is the thickness of RNFL at a *calculated* **3.45mm diameter** around the *center* of the disc. **NOT THE CENTER OF THE SCAN**

*The thickness measurement at 3.45mm is re-sampled relative to the disc center, not the scan beam center, so the de-centering of the disc relative to the scan beam will not affect the measurement.



5.6.5 *Stereometric analysis*

Optic disc analysis results are listed in the spread sheet as follows:

Section	Thickness (µm)
Disc Area = 2.01mm²	
Cup Area = 1.06mm²	
Rim Area = 0.96mm²	
Rim Volume = 0.085mm³	
Nerve Head Volume = 0.164mm³	
Cup Volume = 0.300mm³	
Cup/Disc Area Ratio = 0.53	
Cup/Disc Horizontal Ratio = 0.79	
Cup/Disc Vertical Ratio = 0.70	
RNFL Average Thickness on Diameter 3.45mm = 82.18µm	
⊞ Superior Hemisphere	80.75
⊞ Inferior Hemisphere	83.62

Click on "+" to expand the list

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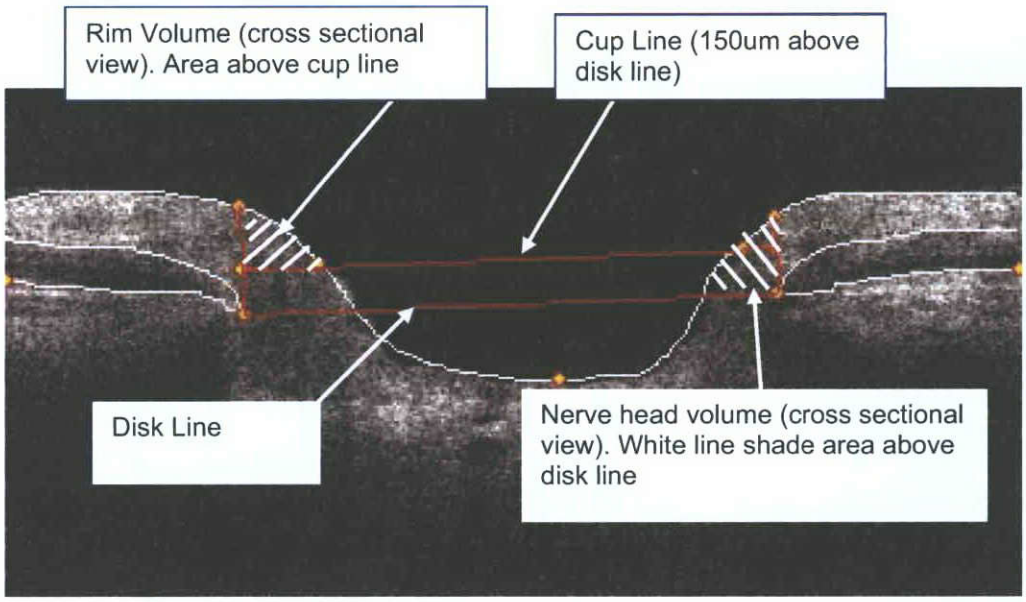
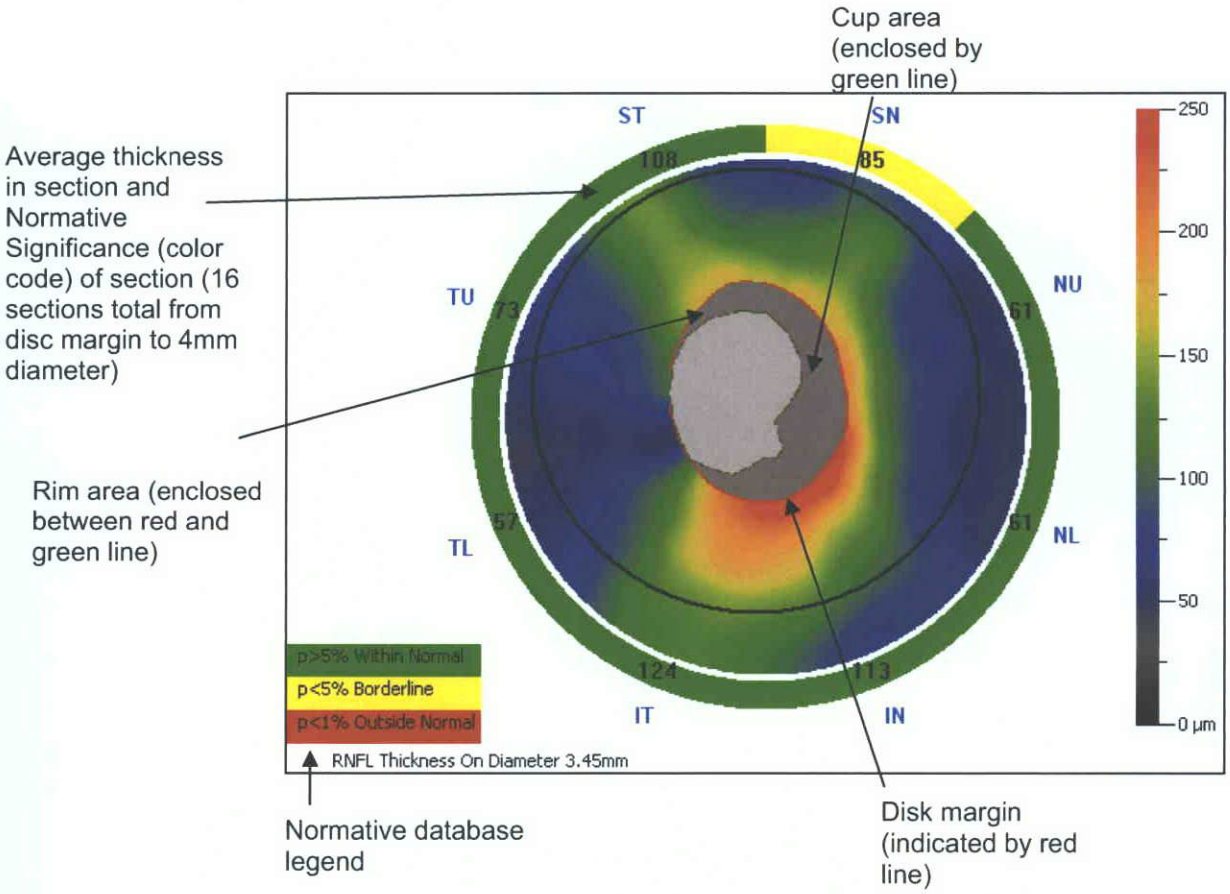
Definitions:





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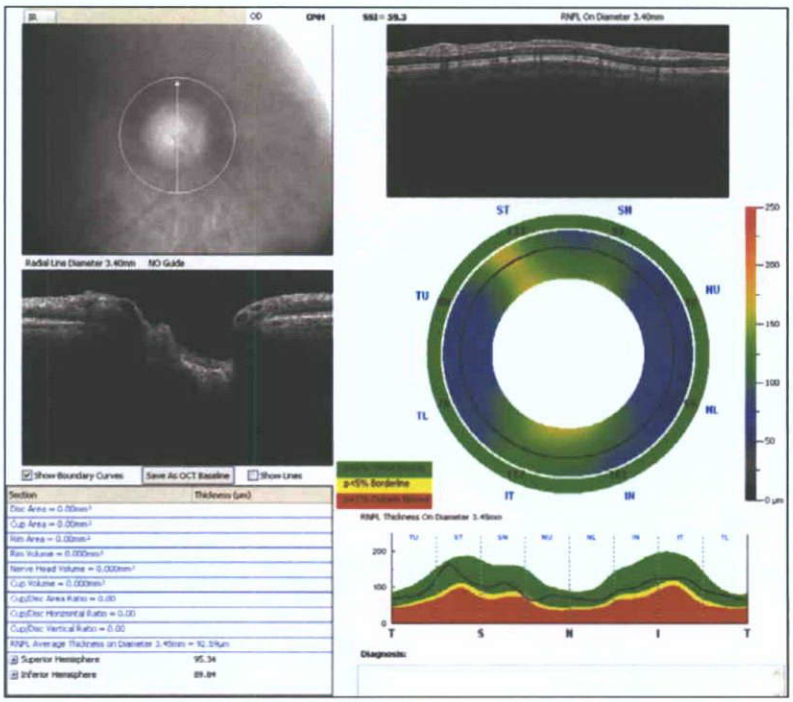
Optic Nerve Head Morphology

The ONH analysis can be performed with either one of four disc border baseline modes:

1. **3D Baseline:** Disc drawing from 3D Optic Disc scan (**Default**)
2. **Video Baseline:** Disc drawing from IR image (ONH)
3. **OCT Baseline *(Advanced GUI only)*:** Uses the manually adjusted RPE endpoints on the radial scans (Available in Advanced GUI only)
4. **No Baseline*** No disc drawing or RPE tip setting is required



*** The "No Baseline" option removes any serial registration capability, and therefore removes the possibility of change analysis. All disk metrics are reported as zeros, since the disk measurements are not calculated.**

Presentation of ONH scan with "No Baseline" option

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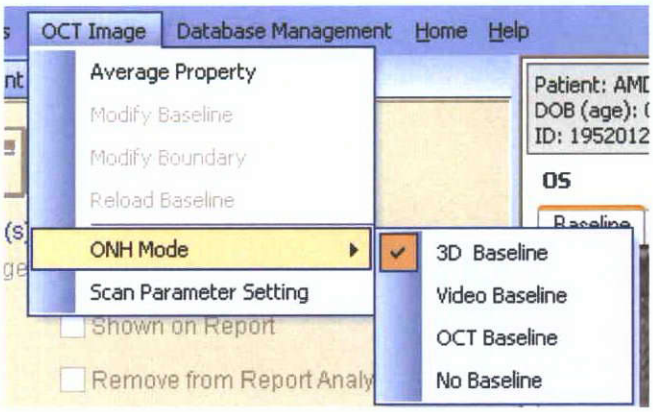
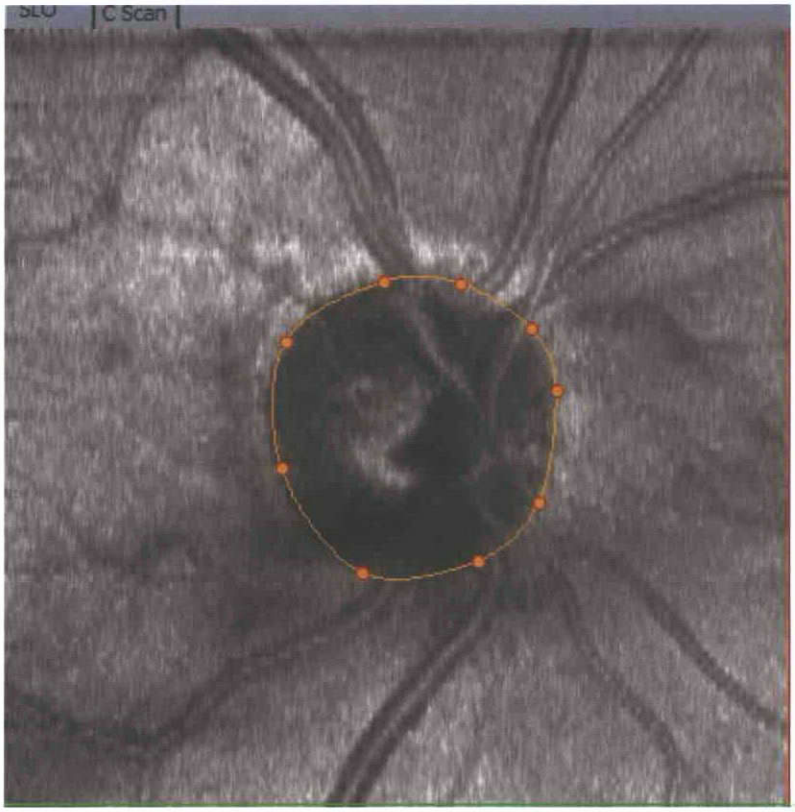


5.7.6.5 The default setting is"3D Baseline" and should not be changed unless there is no possibility of capturing a 3D disc image with any patients.

5.7.6.5 **3D Baseline** is the disc boundary that is automatically drawn using the 3D Disc scan.

To see the boundary automatically drawn, "Right click" the mouse cursor on the SLO image and selecting "Show Disc".



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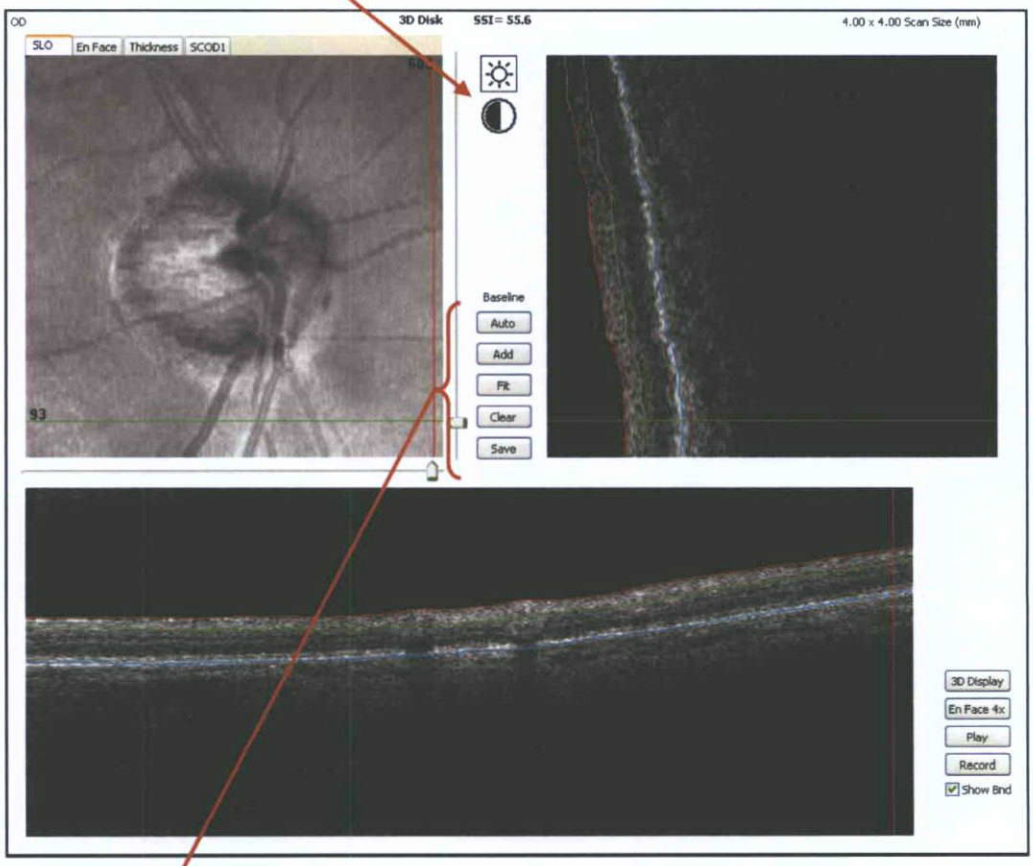
5.7.6.5 You may also use the 3D presentation screens to precisely determine the optic disc boundary, by using the RPE endpoints visualized in the B-Scan (lower left) and A-Scan (upper right).

Brightness and **Contrast** controls for the SLO type en face image presentation



- **Auto** – Draws the disc margin on the En face SLO image.
- **Add** – Adds an anchor point on the image for disc boundary. Click the SLO image to find the correct point (RPE tip) position, then click **Add**.
- **Fit** – Uses anchor points to draw the disc boundary to close contour.
- **Clear** – Clears any currently marked anchor points
- **Save** – Saves the resulting disc drawing as the baseline for the ONH

Note: As you click on any position in the SLO image screen, the three perspective windows also change to reflect the location and cross section within the 3D presentation.

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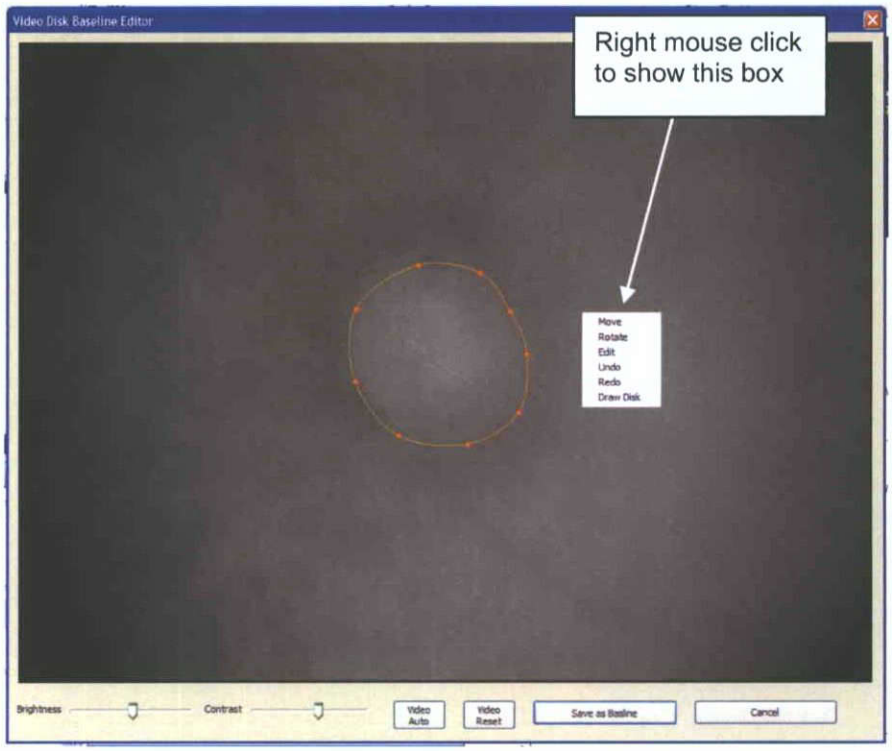
5.7.6.5 **Video Baseline** option should only be used if it is not possible to capture a 3D Disc scan. You may draw the optic disc margin on the IR video image to get the optic nerve head metrics.



5.7.6.5 **OCT Baseline (Advanced GUI only)**

This method is a more complex and user intensive method of adjusting the baseline. This function should not be used by anyone but research technicians. Please call for instructions

NOTE: If no 3D or Video (IR) baseline has been captured (or drawn) at the time of reviewing the ONH scan, you will have the option of rendering "without" a baseline in Analysis view. THIS IS NOT RECOMMENDED as the results are completely dependent upon the skill of the operator to center the scan pattern on the optic disc center.

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

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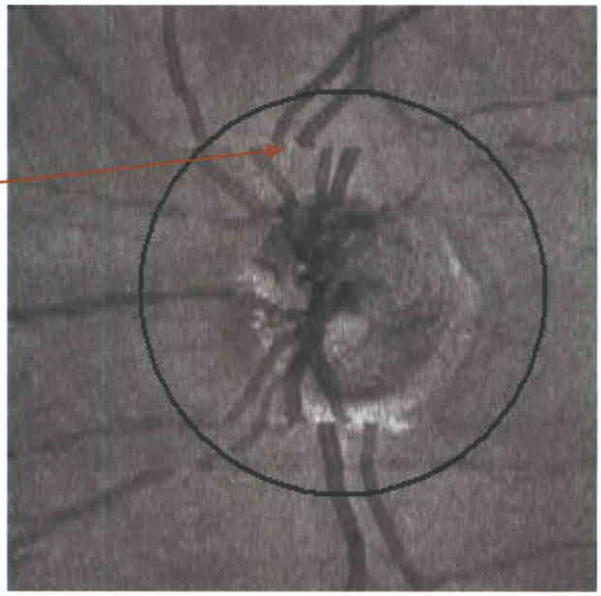
5.6.6 3D Optic Disc Presentation

NOTE: Eye motion can cause image registration to fail and require a scan to be redone. An example of eye motion during the 3-D ONH scan is seen below. The eye movement is evident in the break in the blood vessel pattern. It is recommended if such breaks are seen, the scan should be redone.

Eye movement indicated by the break in the blood vessel pattern



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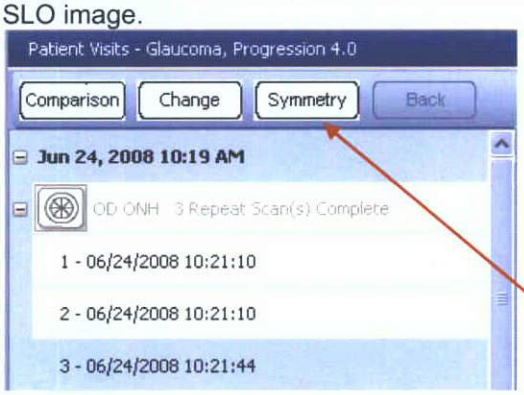
5.6.7 Comparison

Image comparison is a very handy tool used to see the difference of the retina between two visits. This option is available on all scan patterns.

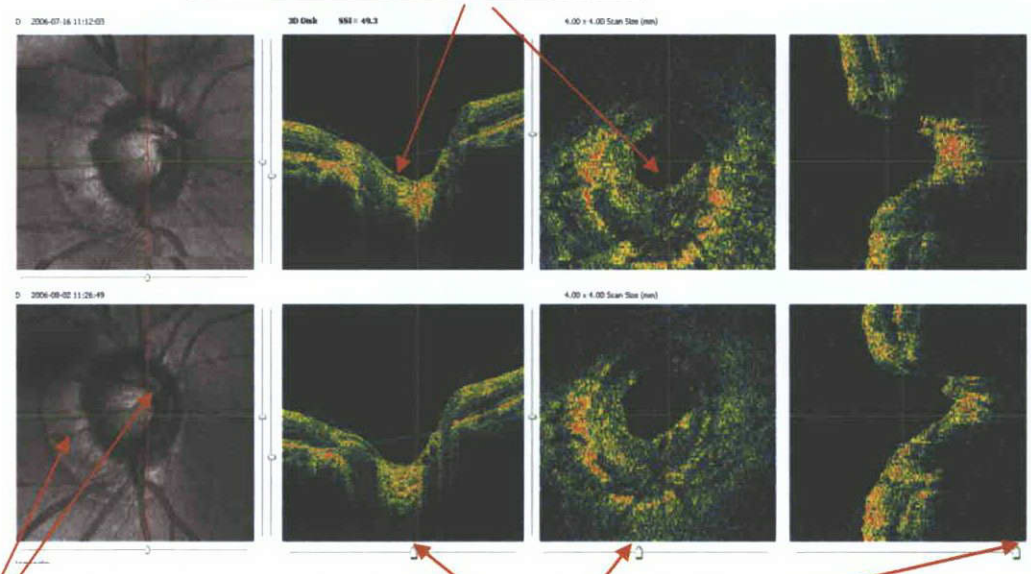
To use image comparison, first select the patient scan in the analyze window. If there are examinations available for comparison, the [**Comparison**] button will be available. This is the same method used to select change and symmetry option.

Two rows of images will appear. You can select which frame image to compare by using the slider on the fundus image (SLO image in 3D scan) to choose the images on each visit. The horizontal and vertical image locations are indicated by horizontal and vertical highlight lines on the SLO image.



Comparison/Change/Symmetry Image Comparison options

Lines to register C-scan plane



Lines to register the horizontal and vertical image frames

Image fly through bars

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

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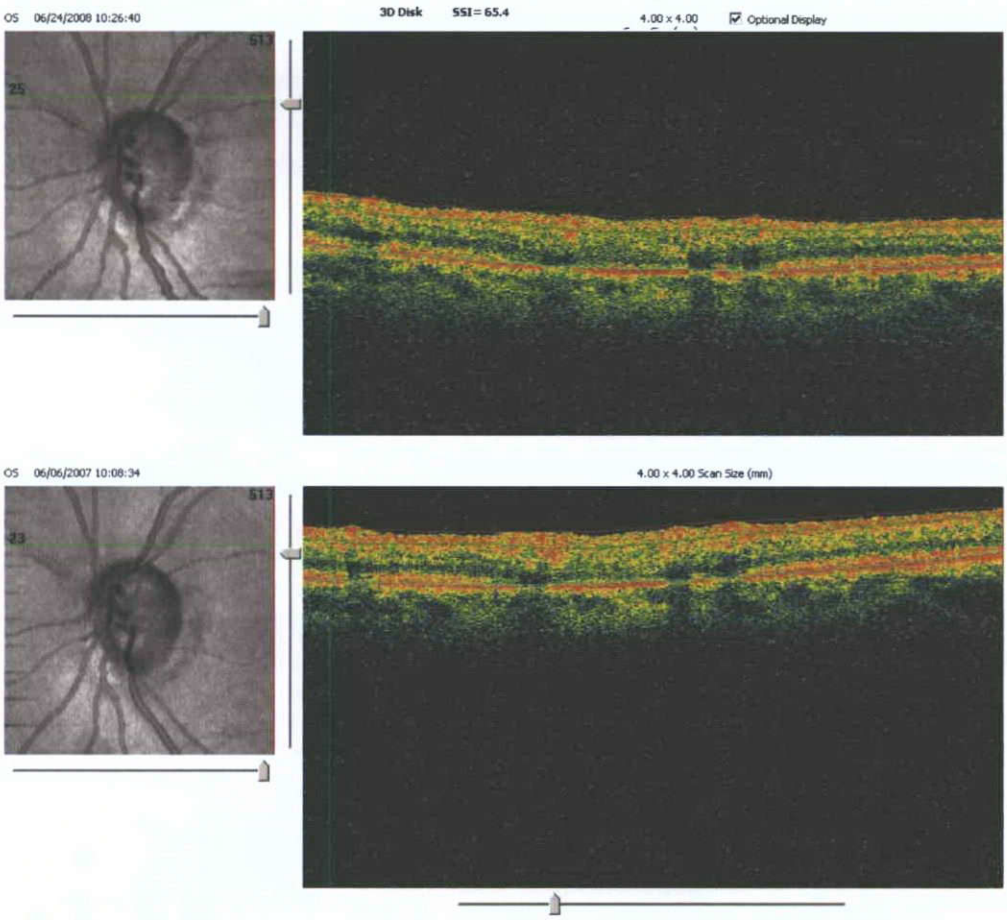
5.6.8 3D Disk Change Analysis

3D Disk change analysis report has been modified for an improved presentation with larger OCT images.



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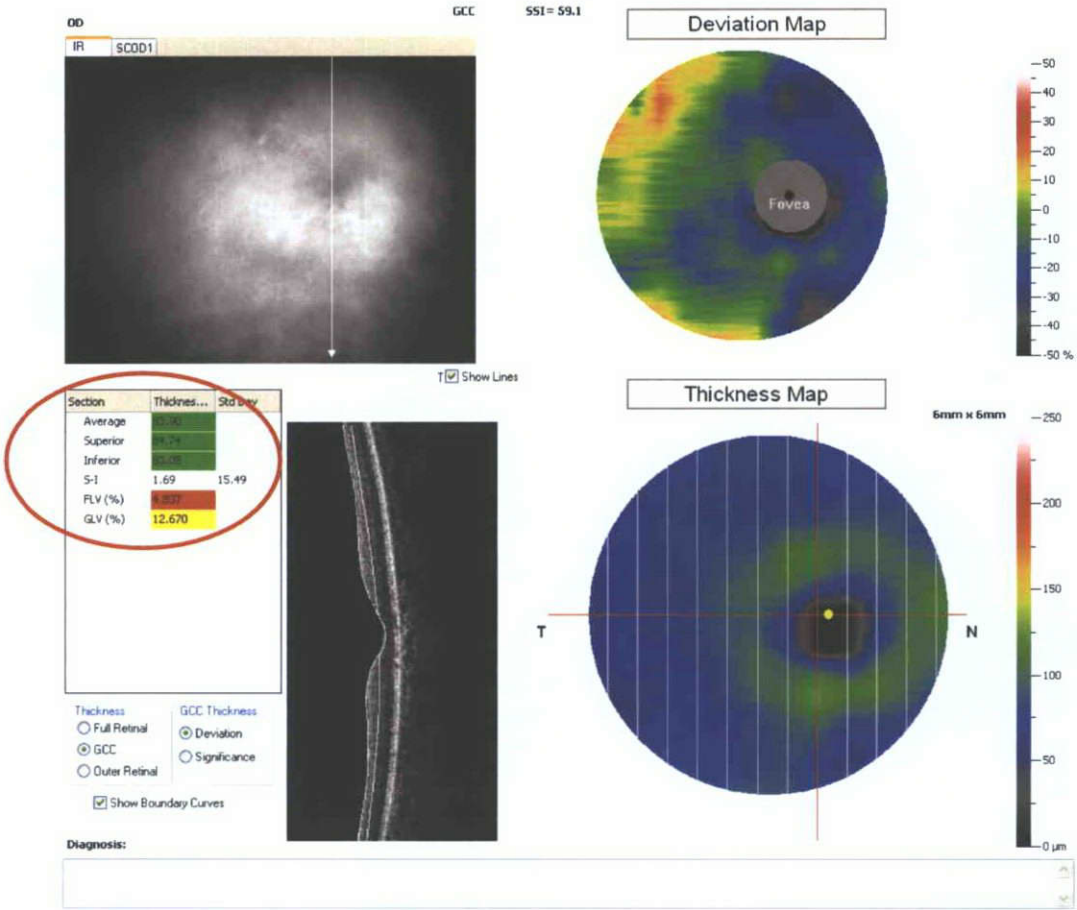
5.6.9 GCC Analysis Presentation



The **GCC** (Ganglion Cell Complex), formerly called the MM7, display the thickness map and deviation from normal of the Inner Retina. These layers make up the complete Ganglion Cell Complex thickness in the macular region. The upper right display will default to the **Deviation Map** (see section 5.8 on the Normative Database). The display may be changed based on user selection in the "Thickness" and "GCC Thickness" display options.

The vertical scan displayed is indicated in Red on the cross sectional scan is displayed on the left side when moving the cursor in the thickness map.

The **Difference** map between superior and inferior hemispheres displayed in previous versions (in the upper right), is now shown as summary values in the table to the left center (red circle).

Focal Loss Volume (FLV) is a parameter that provides a quantitative measure for the amount of significant GCC loss. FLV is the total sum of significant GCC loss (in volume) divided by the map area. As such it provides a percent of significant tissue loss for volume. Early study results have found that FLV is the most accurate parameter to differentiate normal from glaucomatous eyes, being better than the average GCC thickness parameter.

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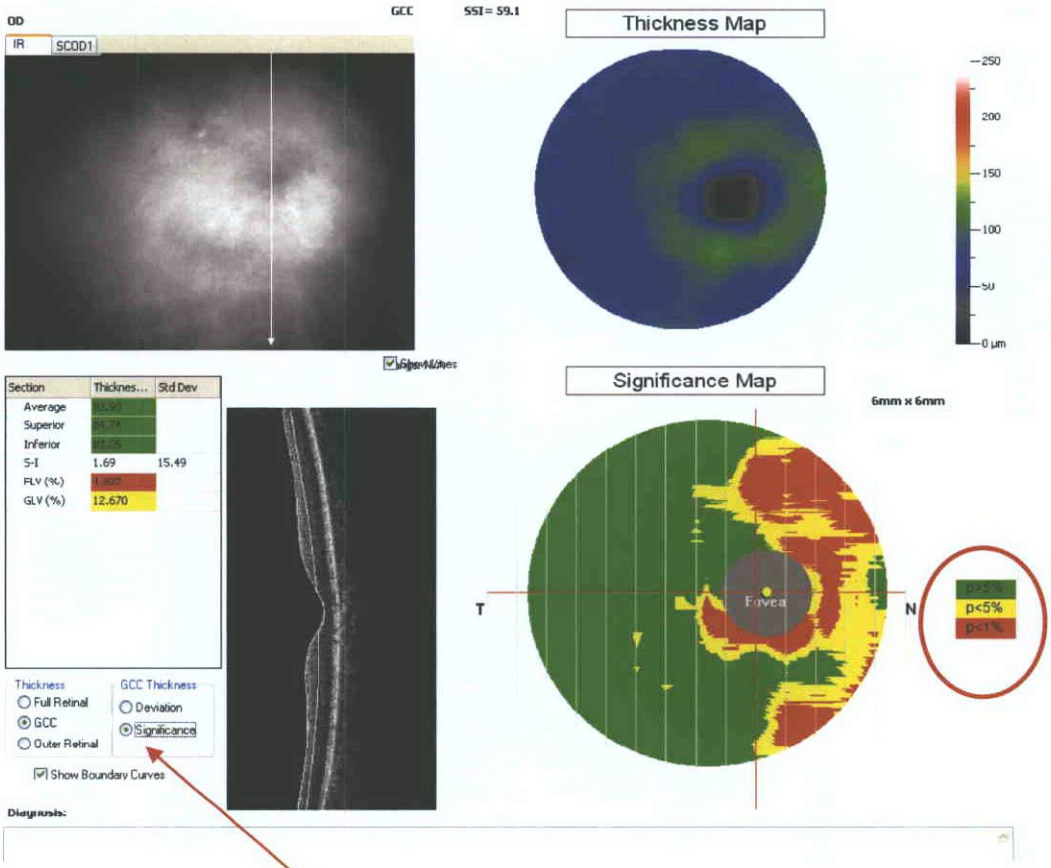
Global Loss Volume (GLV) is the sum of the pixels where the Fractional Deviation map value is < 0, and then divided by the total area to give a percent loss of GCC thickness.



By selecting the "**Significance**" option under **GCC Thickness** display options, the Deviation map is replaced by the **Significance Map** (of the Deviation – see section 5.8 on the Normative Database). Depending upon which display option is selected, the most recent selection (of either option group) is displayed in the lower right and the exiting map moves to the upper right.

Note that fovea is marked by a small dot with the word "Fovea" under it for a clearer presentation of the maps.

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Overall precision results with the GCC scan for normal and glaucoma patients:

GCC Inner Retina Average		
	Normal Patients	Glaucoma Patients
# of Scans	72	71
Overall Mean (Overall SD)	98.28 (9.31)	81.76 (8.90)
Repeatability SD* (Min, Max)	1.86 (1.86, 2.07)	1.18 (1.18, 1.59)
Reproducibility SD** (Min, Max)	7.56 (7.32, 7.92)	2.55 (1.59, 3.36)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

For details on the clinical study and the clinical precision for RTVue scan measurements (repeatability, reproducibility), study information is available in the Appendix B–RTVue Precision.

5.7 *Normative Database*

5.7.1 Color Legend for Normative Significance Maps

Both GCC and RNFL Thickness Significance
Legend for TSNIT graph and all parameters

p = 5-95% Within	→ Average
p < 5% Borderline	→ Below average
p < 1% Outside Normal	→ Significantly below average

Retinal Thickness Significance Legend (MM5 and RPE)

p > 99% Outside	→ Significantly above average
p > 95% Borderline	→ Above average
p = 5-95% Within	→ Average
p < 5% Below Normal	→ Below average
p < 1% Outside Normal	→ Significantly below average

Please Note: Normative database comparisons are based on statistical comparisons only and there are possible normal outliers. You should reduce the risk of misclassification by using multiple clinical tools for diagnosis.

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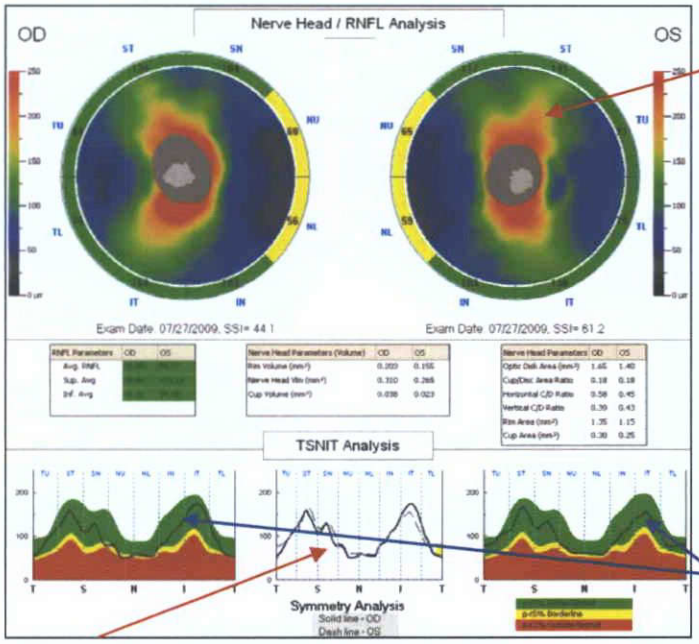
5.7.2 Normative Reports (Samples)

5.7.2.1 ONH Symmetry Report (when no GCC scan exists in Visit)

When "Symmetry" is selected in viewing an ONH report, and **no GCC scans** exist in the same Visit, "Symmetry" analysis option is selected the screen and print report appear as below.



- RNFL Normative Database comparison for 16 sectors

Center Section

- (Left) RNFL average for each eye.
- (Center) Nerve Head volume parameters
- (Right) Optic Nerve Head metrics.

- TSNIT deviation maps

- Bi-lateral TSNIT comparison. (Dashed line is left eye) Red between lines is significant

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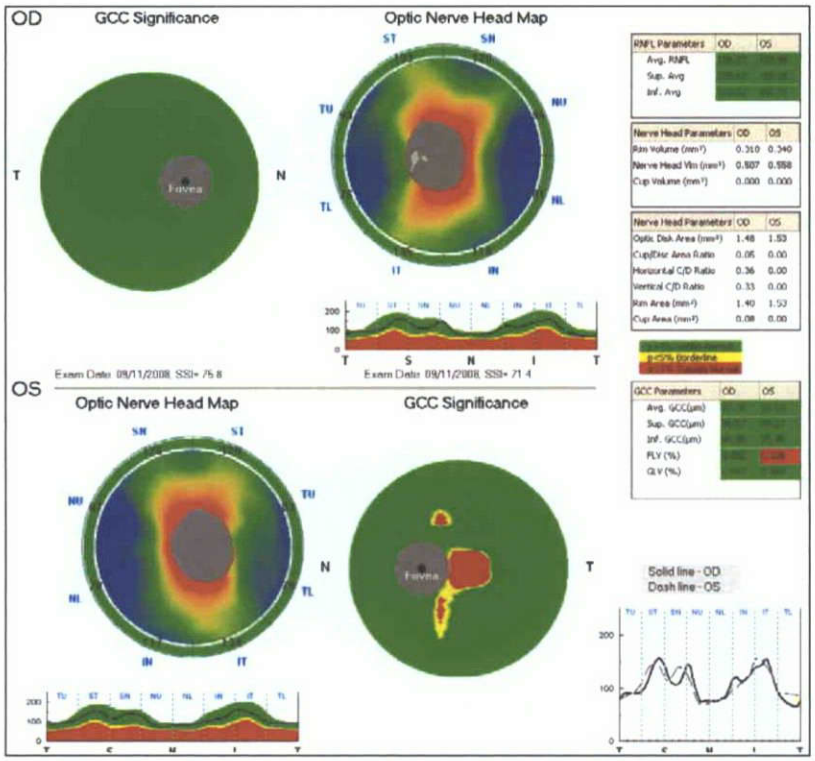
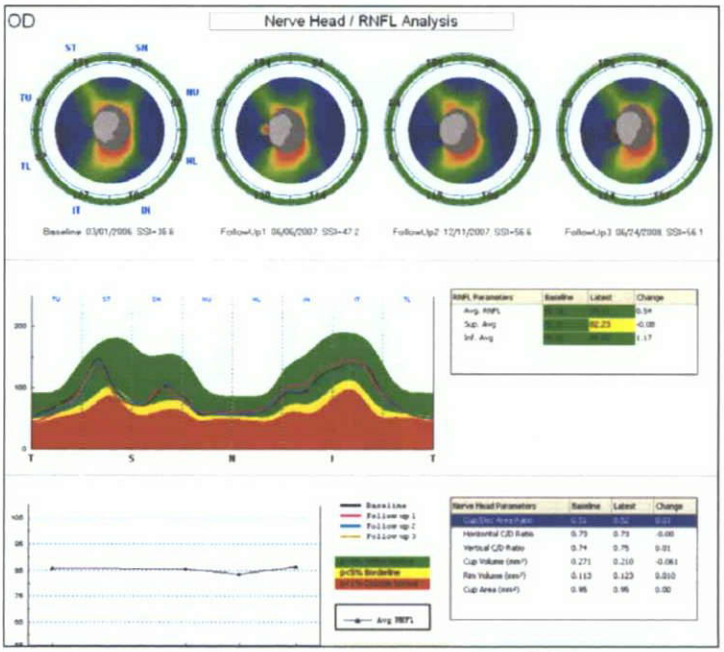
5.7.2.1.1 Symmetry Report (Combined when GCC scan exists in Visit)



A new presentation combining both ONH and GCC scans is provided in order to see the summary of the two in one place. This is available for any visit in which both ONH and GCC scans are acquired.

5.7.2.2 Change Analysis Overview – ONH



- Baseline and three follow-up exam ONH results
- (Left) TSNIT graph of all selected exams
- (Right) RNFL thickness parameters coded for NDB
- (Left) Trend plot of average values for selected exams.
- (Right) Optic Nerve baseline and latest exam metrics

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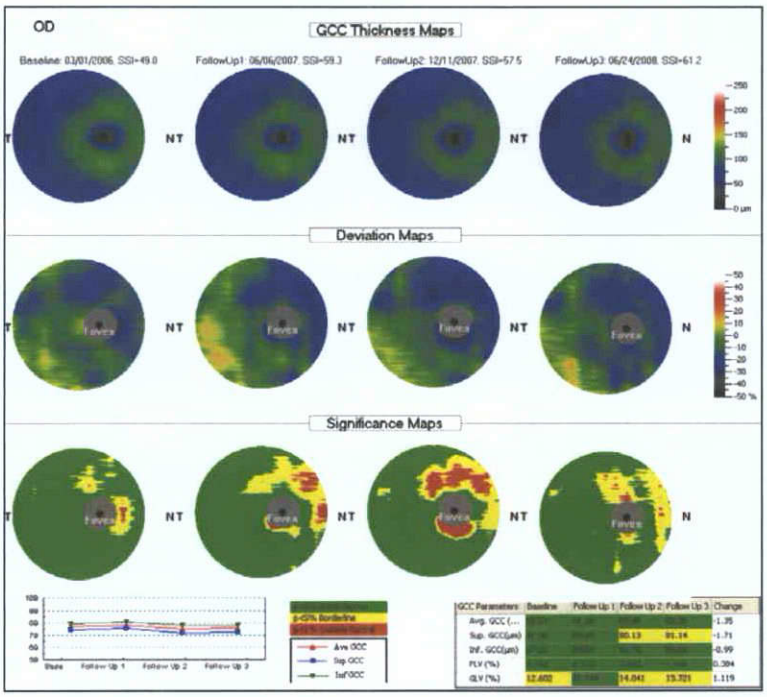
5.7.2.3 Change Analysis Overview – GCC



- GCC Thickness Map of selected exams
- Deviation from Normal map
- Significance (of deviation from normal) Map
- Trend and Average GCC table. Coded for Normative comparison.

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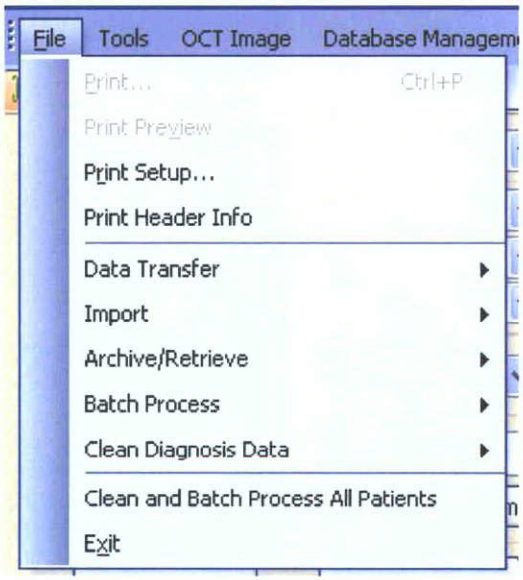
6 Main Menu Bar

The options available in the top level menu bar, and in certain screen presentations, is dependent up on the GUI setting of your RTVue XR. The default setting is the "Clinical" GUI. This GUI setting contains all of the required tools and options for a clinical practice environment. The "Advanced" GUI provides additional options that are useful to a large institution with a dedicated imaging staff or research environment.

The following is a brief overview of the menu bar options. The options available only in "Advanced" GUI are indicated. These functions should be accessed only be users who have a high level of experience with the RTVue XR FD-OCT system.

6.1 File Menu



6.1.1 Print

Sends the report visible in the Analysis view screen to the printer (if attached), or whatever print option is installed on the RTVue XR

6.1.2 Print Setup

Brings up the standard "Windows™" Print Setup window

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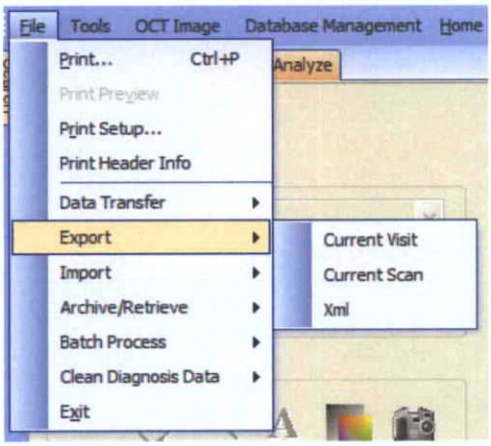
6.1.3 *Data Transfer*

This option brings up the "Data Output" function, used in conjunction with ReVue -- the stand-alone review software application. This software product is used for viewing patient data away from the RTVue XR device. Please see the manual for ReVue.

6.1.4 *Export (Advanced GUI only)*

This option brings up the data export options for analysis by 3rd party analysis applications, such are for research purposes. The export format is XML. For a detailed XML specification Guide, please contact the Optovue corporate office at 510-623-8868.



6.1.5 *Import (Images)*

The Import function now includes the ability to bring in previous digital stored (digital printout) results from certain other devices to the patient record.

Along with importing Color, Red Free, FA and ICG images from any digital fundus system, you may import results (image format files only) from other diagnostic devices and scanning systems (Cornea Topography, Visual Fields, Wavefront results, and OCT, SLO, SLP imaging results).

These results must be image based (output to a digital image format file such as .jpg, .bmp, .png etc) to be eligible for importing into the RTVue XR system database.

This allows the results from previous visits and other devices to be viewed along with the RTVue XR OCT results for the same patient in the current visit.

First select patient/visit then, click on **File > Import > Import Image**. Select image in the network or from removable media (file types compatible are listed), and click **Open**.

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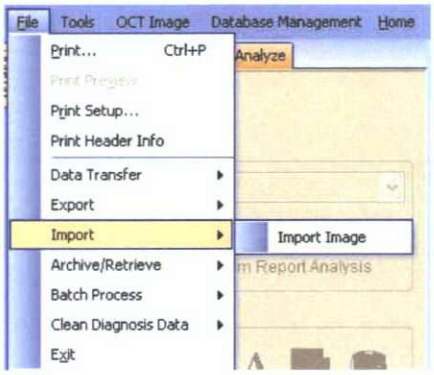
Image will be opened in a window for identification. Select eye [OD/OS], then image type for fundus imaging results, or diagnostic type for test result. Then click on the **Save** button.



The options for importing are:

- Fundus Images (Figure 6A)
  - Color
  - Red Free
  - Fluorescein Angiograms (FA)
  - Indo-cyanide Green (IA)

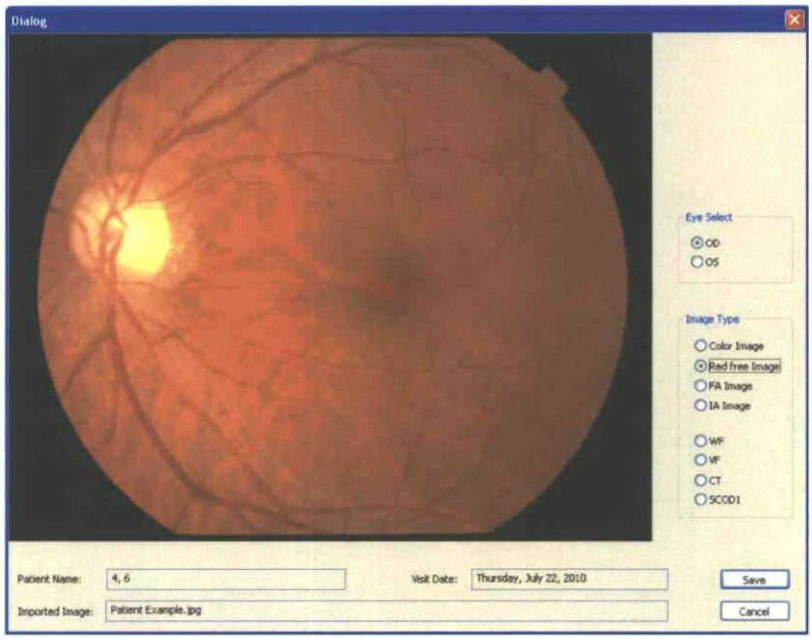


Figure 6A

- Diagnostic Results (Figure 6B)
  - Wavefront (WF)
  - Visual Fields (VF)
  - Corneal Topography (CT)
  - Scanning Computerized Ophthalmic Diagnostic Instruments (SCODI per Medicare nomenclature)

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Figure 6B

- Imported data will appear in the upper left of the Review screen with a Tab indicating the type of result. Double-clicking on the image within the Tab will open it up in a larger window. (Figure 6C)

- Sample of imported Visual Field test results, viewed next to the GCC Analysis from the RTVue XR.

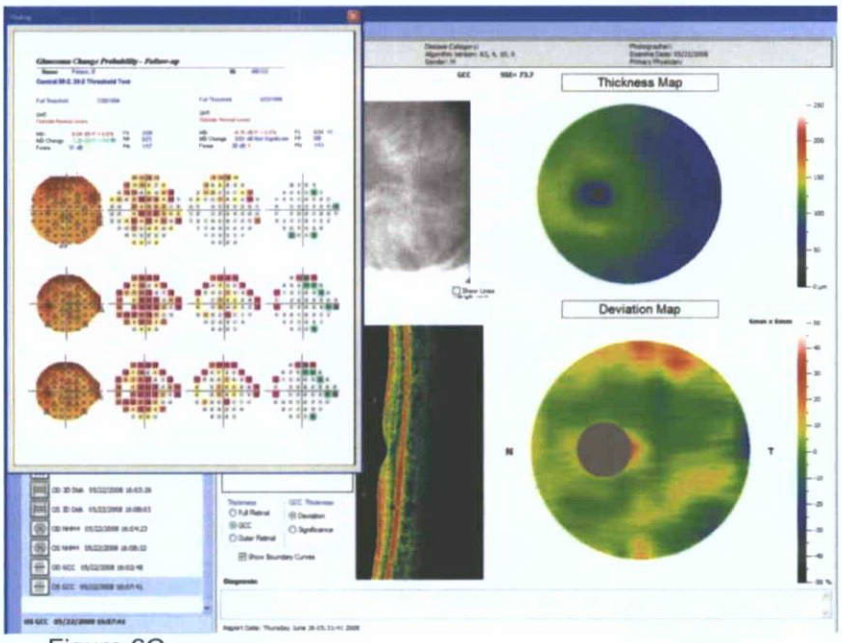

Figure 6C

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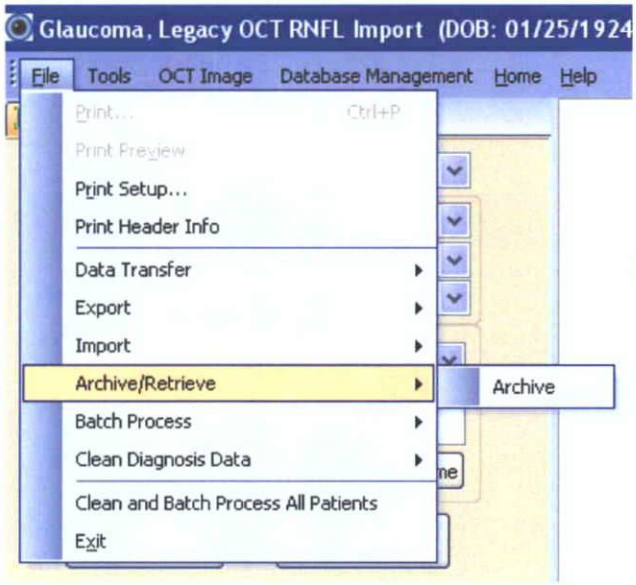
6.1.6 *Archive Data*

An **external USB hard drive** or a **network drive** is required to archive data from the RTVue XR. **All archive hard drives are required to support NTFS format**.

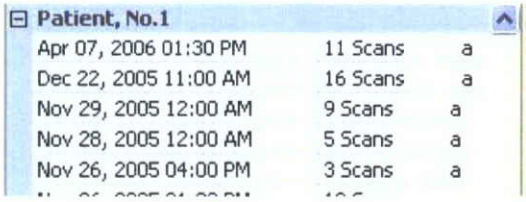
The first step in archive process is to select the archive/retrieve drive by clicking on Tools → User Preference. To archive patient data into the portable/network drive, select the archive destination in the file menu. Archived patients will still appear on the patient list; however, to analyze the patient's data, the same HD must be connected to retrieve the patient's data.



The basic archive unit is the **visit**. Check the visit date on the patient to be archived. Use the sorting functions to help organize the patient list.

After selecting the visits, follow the software instructions to archive the data. The hard drive should be labeled exactly the same as the label name entered in the software. It is advisable to make a backup of the archive drive in the event that the archive drive is accidentally damaged or lost.

Please note that once a visit is archived, it is removed from C and (backup) D drives. It is advisable to backup your archive drive.



The letter "**a**" appears next to the scan information indicating that the patient visit is archived. However when this data or visit is selected for

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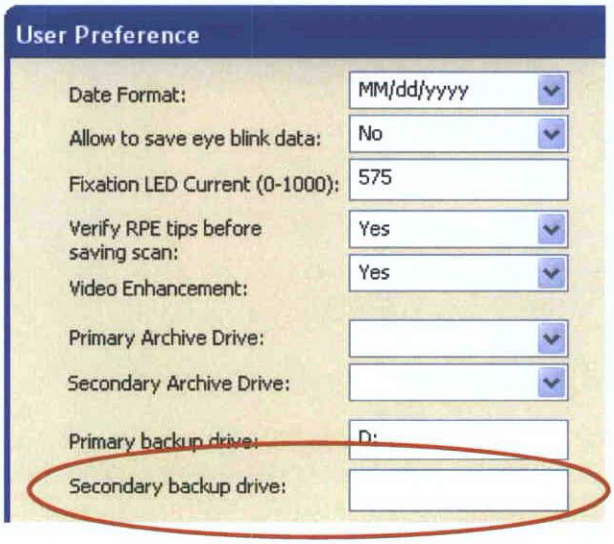
review use, it is automatically retrieved in a few seconds and brought to the screen.

NOTE: This function does require that the Archive media source (network or USB removable drive) is connected to the system at all times during use.

6.1.7 *Note on Backing up Data*

A backup function is done automatically in the background during the normal operation of the system. There are two hard drives supplied in all RTVue XR systems. The application automatically performs a backup routine as you finish each patient examination (capture) session.

You may add an additional backup target in the form of a USB removable/portable drive or a network address (folder, drive, etc). Simply add the appropriate drive letter (assigned automatically by Window when connected, or determined by your IT person) in the Secondary Backup field in the User Preferences window.



6.1.8 *Batch Process*

This option can be run if you have not opened patient's scans in the Analyze view and wish to pre-process all date. This will reduce the time required when scans are selected in the Analyze view.

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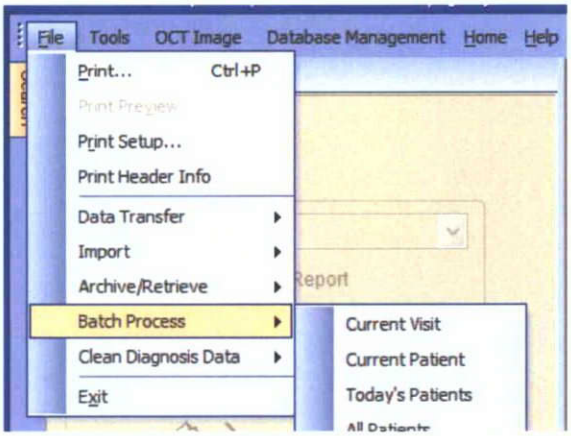
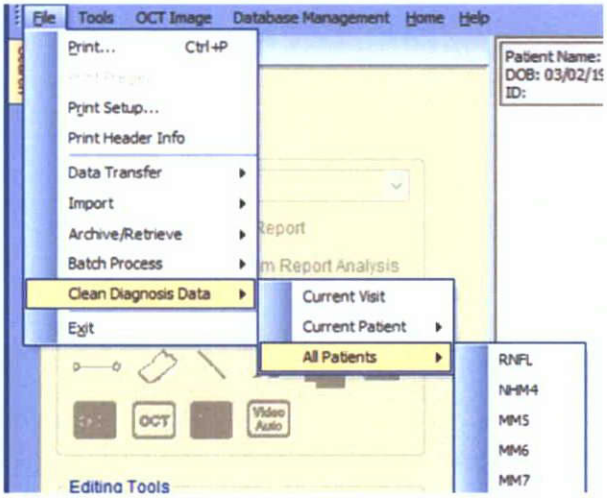


It is best to use the **Batch Process** function whenever the system is not in use. Processing time depends upon the number of patient and scans in the stored data.

6.1.9 Clean Diagnosis Data:

This process removes any previous calculations on the raw data. When opening a patient visit and scan in the Analyze view, the raw data will be processed again. This can also be used prior to reprocessing with updates, if a "reprocessing" requirement is stated. This can also be used when applying custom research site algorithms. NOTE: Please contact Optovue if you wish to apply any algorithms to RAW data other than those supplied with the FDA cleared RTVue XR device application software.



There is an improvement in the processing of ONH and GCC scans. This will only affect the data captured using these scans from the date of installation of the 6.1 upgrade.

PLEASE NOTE: If you wish to use previously captured ONH or GCC scans in a Change Analysis Report with any current data captured *after* the

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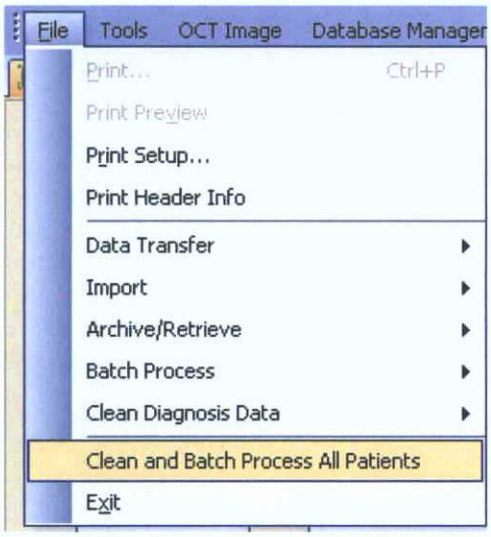
installation of version 6.1, the previous data will need to be reprocessed for that patient in order to be included in the Change Analysis. This reprocessing will also affect the previous data single report when opened. The values may or may not be different but the original data is unchanged. This can be done by clicking on File --> Clean Diagnosis Data --> Current Patient --> ONH/GCC. Any Change Analysis Report that does not include data captured and processed with previous version of the RTVue XR application, do not need to be reprocessed.

6.1.10 Clean and Batch Process All Patients:

This is a one click solution to clean and reprocess all scans for all patients. Depending on the size of the data, this can take several hours. It is recommended that this step is taken after the last patient is scanned for a given day. A progress bar appears showing total number of scans and the number of scans reprocessed.



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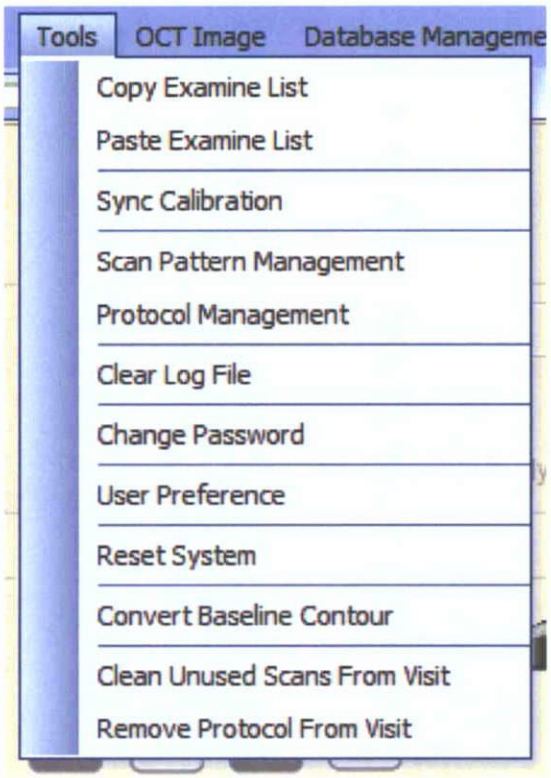
6.2 Tools Menu

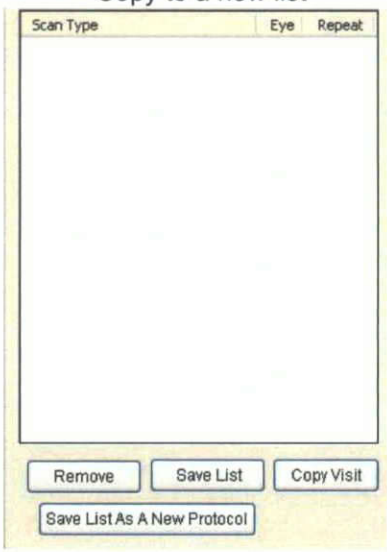


6.2.1 Copy Examine List: (Advanced GUI only)

This function allows the user to copy a particular examination list (of scan patterns) in order to paste them into a subsequent visit.

Previous visit scan list

Copy to a new list



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6.2.2 *Paste Examine List: (Advanced GUI only)*

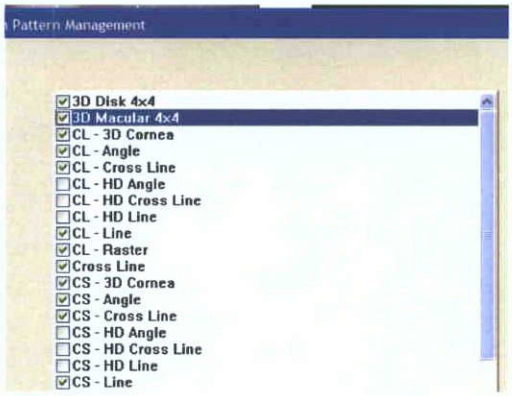
This function pastes or copies the exam list from a previous exam to the current one as desired by the user.

6.2.3 *Sync Calibration: (Technical Support assisted function only)*

This function synchronizes the calibration file between the scanner head and the RTVue XR OCT application.

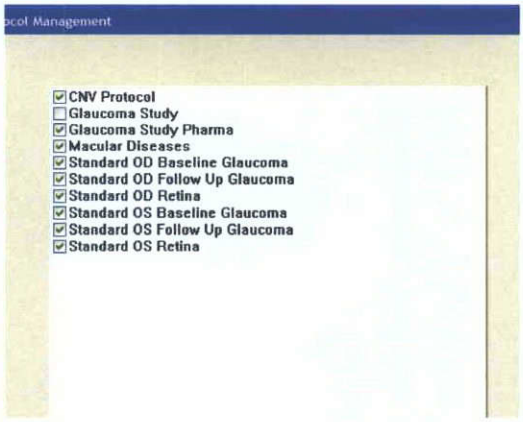
6.2.4 *Scan Pattern Management Screen*

This function allows the user to show or hide any of the scan patterns in the exam list. A clinical site may reduce the number of scan patterns visible to only those that are used in the clinical site. Hidden scans can be made "available" again at any time.



6.2.5 *Protocol Management*

Check the scan protocols (groups of scans) you wish to have available in the Examine View. Allows user to "un-clutter" the protocol list from various trials or studies that are concluded or which no longer apply.



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6.2.6 Clear Log File

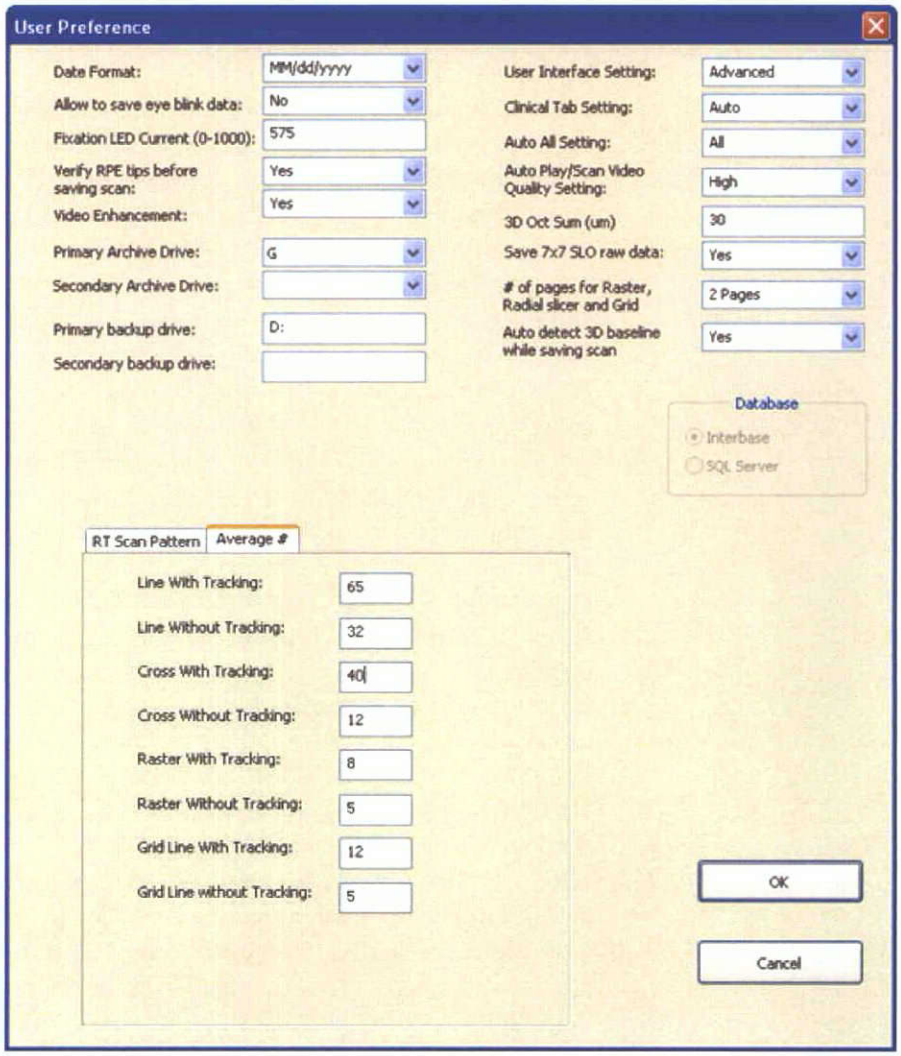
Clears the system event log file. This function should only be selected under the direction of technical support

6.2.7 Change Password

Allows administrator of system (log in) to set or change the system password.

6.2.8 User Preference

This screen allows the user to modify various default settings for the system. Certain scan parameters and views may be adjusted to user preference.



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User Preferences Fields Defined:

1. **Date Format:** allows you to choose from different date formats.
2. **Allow save eye blink data**: select **YES** to save even if there are blinks, or **NO** to force a rescan when an eye blink is detected.
3. **Fixation LED Current (0-1000)**: adjust the blue LED output by increasing or decreasing the value
4. **Select RPE tips before savings scan**: Select **YES** to set RPE Tips in the **ONH scan** before saving, or select **NO** to draw them during the Analysis viewing.
   i. **WARNING** – if the scan was not placed adequately by the user, and the RPE tips may fall outside the 3.45mm target zone (red dashed lines), the patient should be scanned again. If this option is set to NO, the operator may not identify this problem while the patient is still available for re-scanning
5. **User Interface Setting**: Switches the GUI setting between "Clinical" and "Advanced".
6. **Video Enhancement**: Selecting YES on this option will automatically apply a contrast enhancement to the IR reference image captures with the scan
7. **Primary Archive Drive**: Sets the default drive for archiving function. This may be set to another type of removable media (USB) or a mapped network drive.
8. **Secondary Archive Drive**: Allows a second drive location to be used for archive.
9. **Primary Backup Drive**: Sets primary drive where the system sends a copy of the database, raw data and processed data. (recovery drive)
10. **Secondary Backup Drive**: Allows a second drive location to be used for backup.
11. **TABs (RTVue XR Scan Pattern; Cornea Long; Cornea Short:** These tabs contain the length and width default setting for the various scan patterns.
    i. **NOTE:** The Cornea Long and Cornea Short will only appear if the CAM option is installed on the RTVue XR system
12. **User Interface Setting:** Same as previous options, however "Clinical" is now divided into two Tabs; **Auto** and **Manual**
13. **Clinical Tab Setting**: Sets default presentation to either **Auto** or **Manual**
14. **Auto All setting**: Defines Auto All button and "double-click" in live scan area functions
15. **Auto Play/ Scan Video Quality Settings**: Sets the default level of quality and file size for the AVI file created by recording the animation of the 3D scans
    i. Range: Low = 25MB (1 loop/cycle) and High = 125MB (1 loop/cycle)
16. **3D OCT Sum:** Starting value for En Face presentation (microns) in 3D analysis display
17. **Save 7x7 SLO Raw data:** Option to save or discard the Raw data for the SLO style reference image (image is retained regardless of option selected)
18. **# of Pages for Raster, Radial scan and Grid:** User selects the number of pages the printout uses to render the multi-scan presentations.

Click [**OK**] to save user preference changes. If [**Cancel**] is selected, no changes will be saved.

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6.2.9 *Reset System: (Advanced GUI only)*

This option resets the scanner head in the event of a lock up.

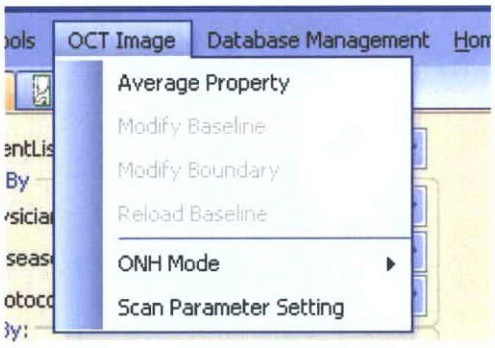
6.2.10 *Clean Unused Scans from Visit*

This option removes the unfinished or unused scans (light gray in scan list) from the list. Use for cleaning up exam with excessive unused scans.

6.2.11 *Remove Protocol from Visit (Advanced GUI only)*

Removes the top level protocol (above the scan list) from the visit. The individual scans will remain, but will not be linked to the protocol for this patient, in this visit only.

6.3 *OCT Image Menu*



6.3.1 *Average Property (Advanced GUI only)*

This is the value used to govern the allowable percentage of variance / match of the individual Line and Cross Line scans that are used for the "averaging" function. (.97 value in field = 97% matching or 3% variance from base image). The default value for this is 0.65.

6.3.2 *Modify Baseline*

Brings up the Video (IR) image and places the disc margin baseline drawing as an overlay for editing purposes. The drawing saved as the baseline may or may not have been drawn on the IR image.

6.3.3 *Reload Baseline*

Places the existing baseline disc margin drawing into the IR image in the upper left corner of the report screen for reference (to edit you must use "Modify Baseline" function (if drawn on the IR image), or the

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3D SLO image of same eye in the baseline 3D scan (if disc margin was drawn using the 3D SLO image).

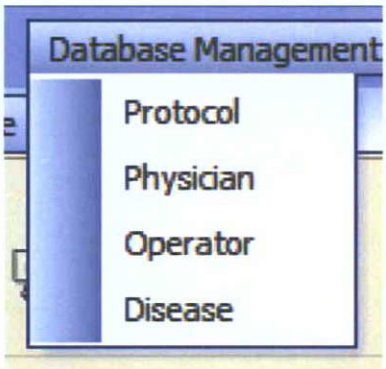
6.3.4 *ONH Mode*

Sets the default location for the disc margin baseline drawing for use with the ONH scan analysis presentation. (see section 6.3.11)

6.3.5 *Scan Parameter Setting*

Set default values for "Dark Eye and "Light Eye" illumination, Grayscale or Color scan display and minimum recommended SSI threshold. (See section 5.12)

6.4 *Database Management Menu*



In the **Database Management** drop-down menu, you may edit and determine the various fields and scans that are displayed in each category.

6.4.1 *Protocol (scan protocol editor):*

These can be created or modified per user preferences.

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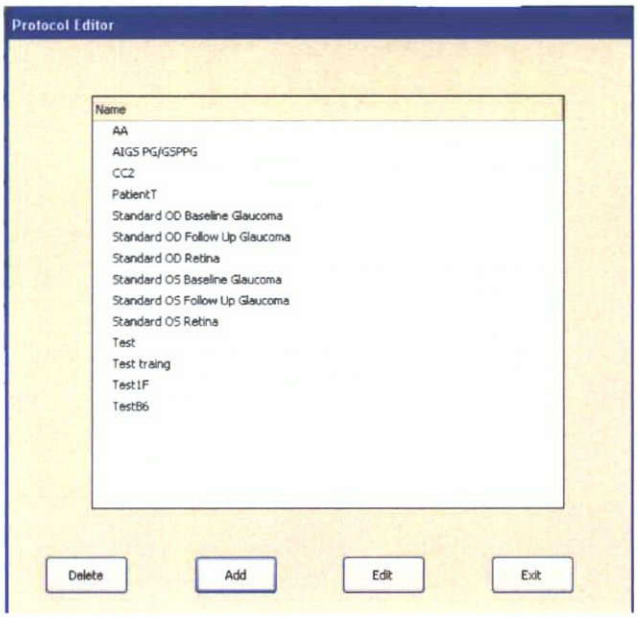
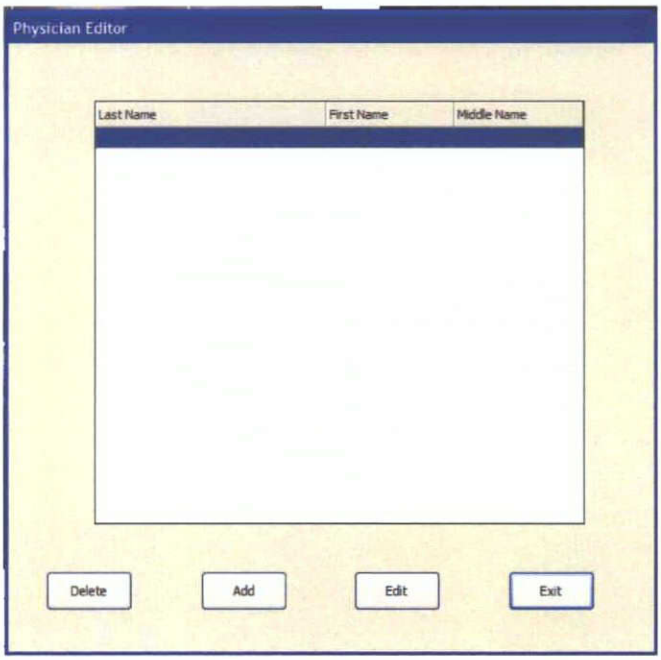


6.4.2 *Physician:*

Add a new physician, edit the name or other information of a current physician or delete a physician if not used by users.



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6.4.3 Operator:

Add a new operator, edit the name or other information of a current operator or delete an unused operator who no longer exists.

6.4.4 Disease:

Add, delete or edit disease category

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7 Maintenance & Troubleshooting

7.1 Routine Care

1. **Dust Prevention:**
   When not using the RTVue XR, make sure the cloth dust cover is placed over the unit.

2. **Ocular (Front Objective) Lens Cleaning:**
   We recommend that the ocular (front objective) lens of the RTVue XR be cleaned daily. A weak OCT image or blurry video fundus image may be caused by an unclean front lens (eyelash, finger or nose prints, or excessive dust or dirt from the environment).

   Material required to clean front lens:
   1) Diluted Acetone or Lens cleaning solution
   2) Lens cleaning paper

   Method:
   Wet the lens paper with cleaning solution and wipe the ocular lens with one pass in one direction. Discard the used lens paper. Use a new sheet for each repeat cleaning until the lens is clean.

3. **Head and Chin Rest:**

   For head and chin rest maintenance, it is recommended to clean the surfaces periodically.

   Material required:
   1) Disinfecting agent such as an anti-germicide or isopropyl alcohol; AND
   2) Cloth or cleaning towels
      OR
   3) Wet isopropyl alcohol cleaning paper pad

   Method:
   Soak the cleaning cloth or towel in disinfecting solution or use a wet isopropyl alcohol cleaning paper pad. Wipe the chin-rest cup and head rest pad.

7.2 RTVue XR Computer Boot Sequence

1. Power up the RTVue XR table.
2. Turn on the RTVue XR computer.
3. After Windows™ has fully initialized, double click the RTVue XR icon to launch the application. It may take approximately 1-2 minutes for Windows to fully initialize.

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7.3 RTVue XR Computer Maintenance

Optovue recommends performing **disk cleanup** and **disk defragment** on a regular basis to keep the RTVue XR PC computer running smoothly. The above functions can be found in system tools.

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8 Scan Pattern Specifications

8.1 Scan Patterns

Summary:

Name	Description	# A-Scan	Adjustability	Default
Scan Pattern				
Line ~(0.015 seconds)	Single line averaging. Tracking Option	1 x 1024 (User selectable # of scans for averaging to single B-scan image presentation) **Divide by 69000**	Transverse: 2-12mm (0.5 mm increment) Angle: 0 to 180° (1° increment)	6mm, 0 degree (from left to right of the monitor screen)
Cross Line ~(0.030 seconds)	Cross line scan with averaging. Tracking Option	2 x 1024 (User selectable # of scans for averaging and two B-scan images presentation)	Transverse: 2-12mm (0.5 mm increment) Angle: 0 to 180° (1° increment)	6mm, 0 degree (from left to right of the monitor screen)
HD Line ~(0.059 seconds)	High definition single line scan	1 x 4096 (4 scans are captured – one is selected for saving)	Transverse: 2-12mm (0.5 mm increment) Angle: 0 to 180° (1° increment)	6mm, 0 degree (from left to right of the monitor screen)
HD Cross Line ~(0.119 seconds)	High definition cross line scan	2 x 4096 *(8192 data points)*	Transverse: 2-12mm (0.5 mm increment) Angle: 0 to 180° (1° increment)	6mm, 0 degree (from left to right of the monitor screen)
RNFL3.45 ~ (0.06 seconds) Glaucoma	Four 3.45mm diameter circular scans center on disc	4 x 1024 *(4 scans are taken and presented. Avg is also presented in TSNIT)*	Fixed	3.45mm diameter. (From **T**emple to **S**uperior to **N**asal to **I**nferior (**TSNIT** convention)

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Scan Pattern Specifications

3D Macular ~(.751 seconds)	101 frames equally spaced B-scans to cover a square volume fixation at center	101x513 *(51,813 data points)*	Transverse: 2-10 mm (0.1 mm increment) Angle: 0 to 180° (1° increment) Width: 1-6 mm (0.1 mm increment)	6mm x 6mm
3D Disc ~(.751 seconds)	101 frames equally spaced B-scans to cover a square volume fixation at 20° nasal	101x513 *(51,813 data points)*	Transverse: 2-10 mm (0.1 mm increment) Angle: 0 to 180° (1° increment) Width: 1-6 mm (0.1 mm increment)	6mm x 6mm
3D Reference ~(.787 seconds)	141 B-scans equally spaced to cover 7mm x 7mm volume. Center fixation	141 x 385 (54,285 data points)	Fixed	7mm x 7mm
Raster ~(.252 seconds)	17 parallel line scans, Tracking Option, (User selectable number of B-scans per line location for averaging)	17 x 1024	2-10 mm in length 1-6 mm in width	L: 6mm W: 4mm
MM6 ~(0.178 seconds)	12 radial line scans through a central point	12 x 1024 (12,288 data points)	MM6 = 6mm fixed Radial Slicer = up to 10mm	MM6 / Radial = 6mm diameter circular pattern
Grid Line ~(.696 seconds)	5 Vertical raster and 5 Horizontal raster lines Tracking Option (User selectable number of B-scans per line location for averaging)	10 x 5 x 960 (48,000 data points)	2 – 12 mm length and 0 – 12 mm width adjustment	8 mm length x 2 mm width (250 µm separation)

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Scan Pattern Specifications

EMM5 ~ (0.43 seconds) Retina	13 horizontal lines with 6mm scan length and 0.5mm interval, + 8 horizontal lines with 4mm scan length and 0.5mm interval, 13 vertical lines with 6mm scan length and 0.5mm interval, + 8 vertical lines with 4mm scan length and 0.5mm interval, all centered at fovea	26x 803 + 16x535 *(29,438 data points)*	Fixed	6 x 6mm outer region. 4 x 4 mm inner region 250 µm interval in central 4mm and 500 µm separation outside 1mm (each side and top/bottom)
GCC ~(0.21seconds) Glaucoma	1 horizontal line with 7mm scan length, followed by 15 vertical lines with 7mm scan length and 0.5mm interval, centered 1mm temporal to fovea	1 x 933 /Horizontal line. 15 x 933/Vertical line	Fixed	7mm x 7mm
ONH ~ (0.018 seconds) Glaucoma	12 radial line scans 3.4mm length & 13 concentric rings (1.3 - 4.9mm diameter) All centered on disc	3 x 965/ring (4.9, 4.6, 4.3), 3 x 775/ring (4.0, 3.7, 3.4), 3 x 587 (3.1, 2.8. 2.5), 4 x 425/ring (2.2, 1.9, 1.6, 1.3), 12 x 455/radial line	Fixed	4.9 mm diameter centered on the optic disc
Grid ~ (0.70 seconds)	5 Vertical raster and 5 Horizontal raster lines captured 5 times each and then averaged	10 x 5 x 960 (48,000 data points)	2 – 12 mm length and 0 – 12 mm width adjustment	6 mm length x 2mm width (250 µm separation)

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9 Technical Specifications

9.1 System Specification

A. RTVue XR Scanner:

OCT Image Acquisition Rate: ~ 70 kHz A-scan/second
Frame Rate: 256 to 1024 A-scan/Frame
Optical Resolution: (in tissue)
- Depth: 5µm
- Beam Spot Size: 15µm

Image Sampling Rate:
- Depth: 2.9µm
- Transverse: 8µm (nominal)

Scan Range:
- Depth: 2 to 2.9mm
- Transverse: 2mm to 12mm

Scan Beam Wavelength: λ=840±10nm, $\Delta\lambda$ (FWHW) = 50nm
Exposure Power at pupil: 750µW

B. Fundus Imager:

FOV: 32° (H) x 22° (V)
Monochrome CCD Camera: 768 x 498 pixel 1/3" CCD Format
NIR Illumination: 735nm LED

C. Patient Interface:

Working Distance: 22mm
Motorized Focus Range: -15D to +20D
Internal Fixation: Center, ±3.5° (Horizontal), and ±18° (Horizontal)
Motorized Chin-Rest adjustable range: 65mm
Joystick controlled X-Y-Z adjustment: X-100m, Y-85mm, Z-25mm
Lock-mechanism: Electro-magnetic activated

D .Computer Unit:

CPU: 2.66GHz Quad-Core Processor
Hard Disc: 1 TB
Back up Hard Disc: 1 TB
Archive: USB or Network Drive
RAM: 4 GB
DAQ: Camera link frame grabber

E. Display Unit:

19" Flat Panel LCD Monitor

F. Power Table:

Power Input: 110V A.C. (RTVue XR 100-1)
230V A.C. (RTVue XR 100-2)
Current: 1.8AMPS
Frequency: 50/60 Hz
Power Rating: 160W
Maximum Force: 2500N
Motorized adjustment range: 200 mm

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G. Circuit Breaker and Fuse:

Thermal circuit breaker (main power entry)

Rating:	6AMPs, 125-250VAC
Dielectric Strength:	2500 VAC/1 minutes
Operating Temp.:	-10 °C to 60 °C

Fuse (Power supply in Scanner)

Rating:	4AMPs/250V
Package:	5mm x20mm
Type:	Fast Acting, Short Time Lag

H: Compliance:

General Medical	EN60601-1
Medical System	EN60601-1-1
EMC of Medical System	EN60601-1-2
ITE (Computer)	EN60950

I: Environment:

Operating Condition: (no condensation)
- Ambient Temperature: +10 to 40 °C
- Relative humidity: 30% to 75%
- Atmospheric pressure: 700 to 1060 mbar

Storage and Transport Condition:
- Ambient Temperature: -40 to 70 °C
- Relative humidity: 10% to 100% (include condensation)
- Atmospheric pressure: 500 to 1060 mbar

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10 Appendix - A

10.1 Printer Installation

WARNING: When powering a USB-interfaced printer to the RTVue XR system, it is recommended to connect the power through the designated power supply outlet in the PC compartment. This outlet is isolated from the wall plug (building power) through RTVue XR's isolation transformer.

If the printer is powered from somewhere other than the designated power outlet, the printer should be placed at least 1.5 meters away from the patient to avoid electric shock.

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11 Appendix – B

Note: below data is based on clinical study performed on RTVue System (K101505)

11.1 RTVue Precision

Description of Precision Study, Subject Selection Criteria and Pathologies

Instruments:
For the study, 3 RTVues with three different operators and results were compared in normal eyes, and eyes with retina pathology, cornea pathology, and glaucoma.

Scans:
The measurements and parameters calculated from ONH, EMM5 and GCC scans. Both eyes were scanned in each subject.

Precision results are not available for the MM5, MM6 and RNFL 3.45 scan patterns. However, these scan patterns are very similar to other scan patterns where precision results have been presented.

The MM5 scan area is included in the EMM5 since the EMM5 is an enhanced MM5 scan. Precision results of the MM5 scan and the EMM5 scan would be identical.

The MM6 scan pattern is a radial line scan pattern centered on the fovea extending out 3 mm (6 mm total line length with fovea in the middle). The scan pattern shows measurements for full retinal thickness measurements and inner retina thickness measurements. This is very similar to the EMM5 scan pattern. This scan pattern covers a 6 mm by 6 mm square area using a grid scan pattern. It also is centered on the fovea and displays full retinal thickness values and inner retinal thickness values. Because both scan patterns measure retinal thickness, are similar in size and are centered on the fovea, the precision performance is expected to be very similar.

The RNFL 3.45 scan pattern is a circular scan centered on the optic disc. The results are presented as RNFL thickness in the parapapillary region taken from a circle with 3.45 mm diameter. The ONH scan pattern is made up of twelve radial lines and 13 circles centered on the optic disc. The results show RNFL thickness from a circle with 3.45 mm diameter centered on the optic disc. This is the same information presented for the RNFL 3.45 scan pattern. The main difference is the fact the ONH scan pattern has information over a larger area. However the information presented is the same for both, a circular RNFL thickness profile form a 3.45 mm diameter circle. Because of this, we expect the precision results to be nearly identical for the RNFL 3.45 and ONH scan patterns.

Subjects:

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

Appendix

Four types of subjects were enrolled in the study at two clinical sites, namely 1) normal healthy eyes with no ocular pathology, 2) glaucoma patients, 3) retina patients, and 4) cornea patients. Normal subjects were free from ocular pathology as determined by the Principal Investigator (PI) at each clinical site. Glaucoma patients were diagnosed as having glaucoma by the PI at each site. Retina patients included subjects with any type of retina pathology diagnosed by the PI. Retina pathologies included but were not limited to, AMD, DME, and ERM. Cornea patients included subjects with any type of cornea pathology as diagnosed by the PI, or cornea alteration including LASIK. There were 4 normal subjects, 4 cornea patients, 4 retina patients, and 4 glaucoma patients enrolled for each RTVue device. There were 3 RTVue devices at 2 clinical sites. At one site, there were 2 RTVue systems and 2 operators at different times. In total, there were 16 subjects enrolled for each RTVue device; a total of 48 subjects were included in the study.

Cornea precision results are available in the RTVue User Manual – CAM (Cornea Adaptor Module).

Precision Results:
The following tables provide the precision results for the RTVue scans. The data in the table includes the number of scans per subject group, the overall mean, the standard deviation, the repeatability standard deviation (Median value of subfields with the minimum of all related subfield values and the maximum of all related subfield values), and reproducibility standard deviation (Median value of subfields with the minimum of all related subfield values and the maximum of all related subfield values).

i) EMM5 Scan Precision Results (Normal, Retina and Glaucoma Patients)

EMM5 Full Retina Thickness Fovea			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	243.61 (26.00)	267.15 (73.32)	246.22 (22.14)
Repeatability SD* (Min, Max)	2.57(1.66, 2.57)	2.96(1.83, 3.15)	3.01(1.95, 3.01)
Reproducibility SD** (Min, Max)	17.72(1.66, 17.72)	13.78(1.83, 13.78)	3.01(2.05, 5.80)

EMM5 Full Retina Thickness outside Fovea			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	295.05 (16.21)	299.03 (30.70)	282.30 (25.26)
Repeatability SD* (Min, Max)	1.96(1.66, 2.57)	2.69(1.83, 3.15)	2.35(1.95, 3.01)
Reproducibility SD** (Min, Max)	2.01(1.66, 17.72)	2.69(1.83, 13.78)	2.66(2.05, 5.80)

EMM5 Full Retina Thickness Volume			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	0.63 (0.03)	0.64 (0.07)	103.02 (12.22)

Repeatability SD* (Min, Max)	0.003(0.002, 0.006)	0.004(0.002, 0.010)	2.40(1.78, 2.87)
Reproducibility SD** (Min, Max)	0.005(0.003, 0.015)	0.007(0.003, 0.011)	2.53(1.78, 3.52)

EMM5 Inner Retina Thickness all measurements			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	112.83 (9.16)	113.04 (15.05)	103.02 (12.22)
Repeatability SD* (Min, Max)	1.38(0.88, 1.72)	2.52(1.57, 3.12)	2.40(1.78, 2.87)
Reproducibility SD** (Min, Max)	1.70(0.88, 7.09)	3.02(1.57, 6.59)	2.53(1.78, 3.52)

EMM5 Global RPE/Choroid Disruption			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	5.657 (1.468)	9.797 (3.280)	9.268 (2.552)
Repeatability SD* (Min, Max)	0.207(0.207, 0.207)	0.479(0.479, 0.479)	0.761(0.761, 0.761)
Reproducibility SD** (Min, Max)	0.736(0.736, 0.736)	0.877(0.877, 0.877)	1.611(1.611, 1.611)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

ii) ONH Scan Precision Results (Normal and Glaucoma Patients)

ONH Average RNFL		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	100.82 (8.11)	86.40 (14.99)
Repeatability SD* (Min, Max)	1.76(1.76, 6.18)	1.56(1.56, 5.86)
Reproducibility SD** (Min, Max)	2.11(2.11, 9.78)	7.87(3.92, 16.33)

ONH All Sectors		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	100.82 (14.80)	86.41 (18.55)
Repeatability SD* (Min, Max)	3.92(1.76, 6.18)	4.48(1.56, 5.86)
Reproducibility SD** (Min, Max)	5.40(2.11, 9.78)	7.84(3.92, 16.33)

ONH Horizontal CD Ratio

	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	1.27 (0.50)	0.79 (0.21)
Repeatability SD* (Min, Max)	0.04 (0.01, 0.04)	0.08(0.05, 0.08)
Reproducibility SD** (Min, Max)	0.04 (0.01, 0.04)	0.08(0.05, 0.08)

ONH Vertical CD Ratio		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	2.15 (0.65)	0.76 (0.23)
Repeatability SD* (Min, Max)	0.01 (0.01, 0.04)	0.05(0.05, 0.08)
Reproducibility SD** (Min, Max)	0.01 (0.01, 0.04)	0.05(0.05, 0.08)

ONH Cup Area		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	0.39 (0.18)	1.04 (0.53)
Repeatability SD* (Min, Max)	0.02 (0.02, 0.03)	0.07(0.07, 0.21)
Reproducibility SD** (Min, Max)	0.02 (0.02, 0.03)	0.07(0.07, 0.21)

ONH Rim Area		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	0.69 (0.17)	0.89 (0.66)
Repeatability SD* (Min, Max)	0.03 (0.02, 0.03)	0.18(0.07, 0.21)
Reproducibility SD** (Min, Max)	0.03 (0.02, 0.03)	0.18(0.07, 0.21)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

iii) GCC Scan Precision Results (Normal and Glaucoma Patients)

GCC Inner Retina Average		
	Normal Patients	Glaucoma Patients
# of Scans	72	71
Overall Mean (Overall SD)	98.28 (9.31)	81.76 (8.90)
Repeatability SD* (Min, Max)	1.86 (1.86, 2.07)	1.18 (1.18, 1.59)
Reproducibility SD** (Min, Max)	7.56 (7.32, 7.92)	2.55 (1.59, 3.36)

Appendix

GCC Inner Retina S-I Average		
	Normal Patients	Glaucoma Patients
# of Scans	72	71
Overall Mean (Overall SD)	0.69 (3.51)	1.98 (8.17)
Repeatability SD* (Min, Max)	1.59 (1.59, 1.59)	2.10 (2.10, 2.10)
Reproducibility SD** (Min, Max)	1.91 (1.91, 1.91)	2.10 (2.10, 2.10)

GCC GCC FLV		
	Normal Patients	Glaucoma Patients
# of Scans	72	71
Overall Mean (Overall SD)	0.60 (0.67)	4.30 (3.47)
Repeatability SD* (Min, Max)	0.37 (0.37, 0.37)	0.88 (0.88, 0.88)
Reproducibility SD** (Min, Max)	0.46 (0.46, 0.46)	1.04 (1.04, 1.04)

GCC GCC GLV		
	Normal Patients	Glaucoma Patients
# of Scans	72	71
Overall Mean (Overall SD)	3.99 (3.43)	15.51 (7.81)
Repeatability SD* (Min, Max)	0.83 (0.83, 0.83)	1.03 (1.03, 1.03)
Reproducibility SD** (Min, Max)	2.44 (2.44, 2.44)	1.71 (1.71, 1.71)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

Note: Above data is based on clinical study performed on RTVue System (K101505)

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12 Appendix – C

Note: below data is based on clinical study performed on RTVue System (K101505)

12.1 *Signal Strength Index (SSI)*

For the RTVue, a Signal Strength Index classification is provided for each scan type in order to help guide the user to determine if the scan quality is acceptable or not. The Signal Strength Index (SSI) is a quantitative measure for judging image quality. It serves as a guide to help the user know if the image quality is generally good or not. It is not the only thing to consider when determining image quality, but it does offer a quantitative assessment of the signal strength in the image which is a major component of image quality. The Signal Strength Index is based on the intensity of the reflected light. The greater the intensity (brightness), the higher the SSI. This is based on a global average over the entire scan pattern. The Signal Strength Index (SSI) is displayed after each scan. In the above scan, the SSI is at the top of the scan. If the SSI is low, it is recommended that the user re-take the scan and try to improve the SSI. The cut-offs recommended for retaking scans are provided in the table below. They are different for each scan pattern due to the fact that different scans require different levels of retinal segmentation. For example, GCC and EMM5 scans require the inner-plexiform layer to be segmented and this layer is generally not the most reflective compared to other retinal layers. The ONH scan is OK at lower SSI levels because the RNFL layer is highly reflective and can be segmented even under less ideal signal strength values. In some cases, the SSI cannot be improved even when retaking the scans due to ocular opacity (e.g., cataract) or other unavoidable causes. In these cases, the scan can still be used even with a low SSI but the results should be interpreted with more caution compared to a scan with a high SSI.

Recommended SSI cut-offs for each scan

Scan Type	Minimum Recommended SSI
EMM5	SSI < 39
ONH	SSI < 28
GCC	SSI < 32

These SSI cut-off values used for RTVue were determined based on an in-house review of a large data set from the RTVue, made up of approximately 100 scans with a wide range of SSI values and including scan types - EMM5, ONH, GCC. MM5, and MM6 patterns are very similar to EMM5, ONH and GCC scan patterns. (see Appendix – RTVue Precision for further explanation on scan similarities) To establish the SSI cut-off, approximately 100 B scans were reviewed for 3 scan types on the RTVue (EMM5, ONH, GCC). The basic criteria for review was whether visualization of the critical retinal layers was possible or not, including the ILM (for all scan types), the RNFL (for glaucoma scans), the IPL (for retina scans), and the RPE (for retina scans). The Un-usable cut off value was determined for each scan pattern to be the SSI value where the various retinal layers could no longer be reliably visualized in the B scans. These scans cannot be

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segmented accurately if there is no ocular structure that can be reliably visualized with low variability. The SSI value associated with this point (where retinal layers cannot be reliably discerned) were used as the recommended cut-off point for the user and are included in the table above.

In order to validate the recommended cut-off between acceptable and not acceptable scans, the repeatability of scans was evaluated at difference SSI levels. For this evaluation, repeat scans were performed on six normal subjects with clear ocular media to establish a baseline level of precision. All 3 scan patterns on the RTVue were evaluated and scans were repeated 3 times in order to calculate repeatability defined as the standard deviation of the thickness values for each measurement. The image quality was manipulated by defocusing the OCT image during scan acquisition. The defocusing and resulting lowering of the image quality mimics the clinical situation which would occur with media opacity and small pupils. All measurements were analyzed and the results are provided in the following tables (numbers are the average standard deviation of the 3 scans averaged across all six subjects). The standard deviation represents the amount of measurement variability present under different image quality classifications; the higher the standard deviation, the greater the measurement variability.

EMM5 scan variability results comparing scans with SSI values above the recommended cut-off and below the recommended cut-off

EMM5			
Measurements		Above Cut-Off	Below Cut-Off
Full Retina	Fovea	9.58	54.57
	Tempo	7.27	62.04
	Superior	10.77	43.42
	Nasal	6.91	52.72
	Inferior	10.90	60.97
	Tempo2	5.33	38.96
	Superior2	2.90	33.91
	Nasal2	5.59	42.38
	Inferior2	9.91	52.25
Average		7.68	49.02

Table 1.

Table 1 shows the standard deviation values of 3 scans averaged over all subjects for each EMM5 thickness parameter. The first column of data is the result when the image quality above the recommended cut-off (equal to or above the ROC cutoff 39) and the scans are deemed acceptable and usable. The second column of data is the result when the image quality is listed as below the recommended cut-off (below the ROC cutoff 39) and the scans are deemed unacceptable and not usable. It can be seen that the standard deviations are very good when the image quality is usable, and then gets much worse when the image quality is unusable. From the high variability in the unusable scans, it is recommended that 'Un-usable' scans not be used for clinical decision making due to their poor quality.

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ONH scan variability results comparing scans with SSI values below the recommended cut-off and scans with SSI values above the recommended cut-off.

ONH		
Measurements	Above Cut-Off	Below Cut-Off
Avg RNFL	2.01	5.88
Sup RNFL	2.56	4.31
Inf RNFL	2.76	8.82
Tempo	6.21	11.52
Superior	3.96	10.46
Nasal	4.55	12.68
Inferior	3.68	8.36
TU	5.68	14.16
ST	5.29	13.37
SN	5.92	15.63
NU	5.82	15.79
NL	4.52	10.99
IN	5.40	14.56
IT	4.29	13.93
TL	7.76	19.08
Average	4.69	11.97

Table 2.

Table 2 shows the standard deviation values of 3 scans averaged over all subjects for each ONH thickness parameter. The first column of data is the result when the image quality is above the recommended cut-off (equal to or above the ROC cutoff 28). The second column of data is the result when the image quality is below the recommended cut-off (below the ROC cutoff 28). It can be seen that the standard deviations are very good when the image quality is above the cut-off, and then gets much worse when the image quality is below the cut off. From the high variability in the unusable scans, it is recommended that these scans not be used for clinical decision making due to their poor quality.

GCC scan variability results comparing scans with SSI values above the recommended cut-off and scans with SSI values below the recommended cut-off.

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GCC		
Measurements	Above Cut-Off	Below Cut-Off
Inner Retina Average	1.88	12.25
Superior Average	2.13	14.06
Inferior Average	3.25	14.02
S-I Average	4.13	12.43
GCC-FLV	0.98	3.59
GCC-GLV	1.47	4.85
Average	2.31	10.20

Table 3.

Table 3 shows the standard deviation values of 3 scans averaged over all subjects for each GCC thickness parameter. The first column of data is the result when the image quality is listed as above the cut-off(equal to or above the ROC cutoff 32) and the scans are deemed acceptable and usable. The second column of data is the result when the image quality is below the cut-off (below the ROC cutoff 32). It can be seen that the standard deviations are very good when the image quality is above the cut-off, and then gets much worse when the image quality is below the cut-off. From the high variability scans below the recommended cut-off, it is recommended that these scans not be used for clinical decision making due to their poor quality.

Note: Above data is based on clinical study performed on RTVue System (K101505)

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RTVueXR

Specifications:

RTVue Scanner:
- OCT Image: ~~26,000~~ ~70,000 A-scan/second
- Frame Rate: 256 to 1024 A-scan/Frame
- Depth Resolution (in tissue) : 5.0 µm
- Transverse Resolution: 8µm (nominal)

Scan Beam Wavelength:
- λ=840±10nm

Exposure Power at pupil:
- 750µW

Patient Interface:
- Working Distance: 22mm
- Motorized Focus Range: -15D to +20D

Computer:
- CPU: 2.66 GHz Quad-Core Processor
- RAM: 4GB
- Hard Disk: 1 TB
- Back Up Hard Disk: 1 TB

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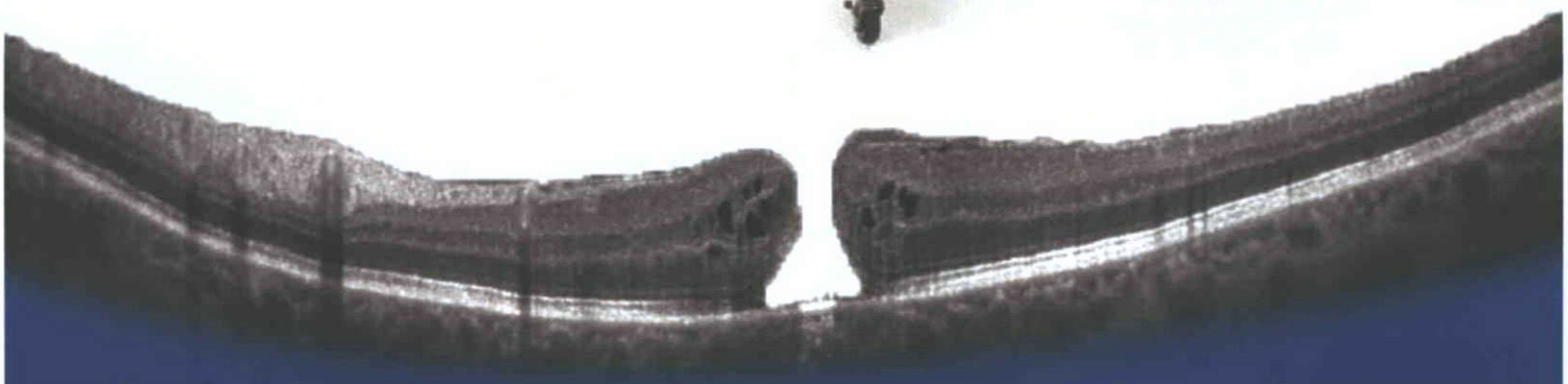

optovue

DEFINING THE OCT REVOLUTION

P/N 300-47510 Rev.A

OPTOVUE, INCORPORATED | 15531 NORTHPORT LOOP WEST, FREMONT, CA 94538 USA | PH: +1 510.623.8868 | FX: +1 510.623.8668

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

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Attachment [C]

- (b)(4) [redacted]
- RTVue-XR-Marketing Requirements (b)(4) [redacted]

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(b)(4) Specification

(b)(4) Specification

(b)(4) Specification

(b)(4) Specification

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Revision History

Rev	ECR #	Date	Description of Change	Initiated by
X1	n/a	12/1/2011	Initial draft	V. Pandya
A		12/16/2011	Added part number	V. Pandya

Approved By:			
Department	**Name**	**Signature**	**Date**
Marketing			
Engineering			
QA			
Regulatory			

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Market Requirements for RTVue XR

The following are the additional features to be added to features and functions of the RTVue system (requirements based on (b) (4) [redacted]. These features are the result of feedback from the market relative to enhancements to the current marketed RTVue system and those that clinical, marketing and customer feedback has determined are competitively desirable to maintain advantage over the other systems now being marketed world-wide.

RTVue with the features below, but not limited to, may be marketed as RTVue XR.

The core focus of this version of RTVue is to be able to increase the number of a-scans the RTVue can capture per second. Increasing the ability to capture higher number of a-scans may facilitate ability to capture more data in less amount of time, which may be found beneficial by the clinician in multiple ways. For example: shorter scan capture time may increase the possibility of avoiding blinks. Furthermore, the patient is more likely to be able to fixate in the same location due to a faster scan capture time.

Features:

1. Enhance the ability to of the RTVue to capture 70,000 a-scans/sec

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Attachment [D]

Labeling for the Predicate Device

- **RTVue User Manual # 580-45044-005 Rev. A**
- **Brochure # 300-42876 Rev. A**

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RTVue

- Model - RT100

User's Manual

Version 6.2

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Publishing details

RTVue
Version 6.2

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(510)623-8868

Revision Control

Part Number	Rev	Software ver.	Description	Release Date
580-45044-005	A	v 6.2	Reference ECR #00608	9/2011

License and use of the RTVue-100 systems is intended only for trained medical personnel in accordance with the license agreement – all other usage is prohibited – warranty restrictions and possible claim limitations apply.

PLEASE NOTE: 3D features introduced in this version are intended for the RTVue PC system as it applies to the specifications listed in Section 9.1D.

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1 Safety Notes

General
This instrument has been developed and tested in accordance with Optovue safety standards as well as national and international regulatory guidelines to ensure a high degree of instrument safety. Please observe all safety notes and information in this manual and on the device labels. This device does not produce any waste that needs disposal. Product contains no material which has a chemical hazard concern.

Proper Instrument Use

1. Always enter patient information first.
2. Clean patient contact surface (forehead and chin rest according to the cleaning method in Chapter 7 of this manual).
3. Instantly turn off the power switch of the instrument and disconnect the power cable if uncertain problems arise.
4. Clean ocular lens frequently to ensure good image quality.
5. Adjust power table height properly to ensure patient comfort during the examination.
6. Align the patient's head and eye position to the canthus indicator mark on the chin and forehead rest assembly.
7. Dim the room lights to allow natural dilation of the patients' pupil and to provide a comfortable visualization of the fixation target without glare. Note: Chemically induced pupil dilation is not needed.

Intended Use
The RTVue is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician.

The RTVue with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

☞ **Note: The RTVue OCT is not intended to be used as the sole diagnostic aid in disease identification, classification or management. The RTVue provides data to be used in conjunction with other information, intended to assist an eye care clinician in determining a diagnosis. A patient diagnosis is the sole domain of a licensed eye care clinician.**

⚠ **WARNING: THE RTVue CANNOT REPLACE CLINICAL JUDGEMENT AND IS INTENDED TO BE USED ONLY IN CONJUCTION OTHER CLINICAL TOOLS CONSIDERED TO BE THE STANDARD OF CARE FOR DIAGNOSIS OF EYE DISEASE.**

⚠ **Warning: User Changes to Software or Hardware**

The RTVue is a medical device. The software and hardware has been designed in accordance with U.S., European and other international medical device design and manufacturing standards. Unauthorized modification of the RTVue software or hardware, or any addition or deletion of any application in

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any way can jeopardize the safety of operators and patients, the performance of the instrument, and the integrity of patient data.

Any changes, additions or deletions to factory installed applications, operating system or modifications to hardware in any manner VOIDS the Warranty completely.

Warning: Phototoxicity

Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures.

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

"While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure to the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography."

Caution: Federal law restricts this device to sale by or on the order of a Physician or Practitioner (CFR 801.109(b)(1)).

Product Compliance

Indicates this equipment contains Type B applied parts.

Electromagnetic Compatibility (EMC) : EN 60601-1-2:2001
The RTVue100 device has been tested to comply with the emission and Immunity requirements of EN60601-1-2:2001. The RTVue100 is intended for use in an electromagnetic environment where radiated RF disturbances are not beyond the standard defined in EN60601-1-2:2001.

CB Certification: under IEC 60601-1

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Safety Notes

Symbols and Labels

Caution, consult accompanying documents.

Note: There are important Operating and maintenance instructions found in the manual.

Presence of electrical shock hazard.

Note: Indicates risk of electrical shock due to the presence of non-insulated high voltage inside the instrument. Do not remove the instrument cover or parts.

Fuse

Type B Applied parts.

Note: This instrument complies with the specified requirements to provide protection against electrical shock, particularly regarding allowable patient leakage current.

Manufacturer
Optovue Incorporated
45531 & 45395 Northport Loop W.
Fremont, CA 94538

Authorized European Community Representative

Medical Device Safety Services (MDSS) GMbH
Schiffgraben 41
30175 Hannover, Germany

Serial number

Catalog number / part number

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Safety Notes

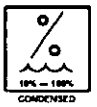
Protective Packing Symbols

The protective packing symbols specify the handling requirements and the transport and storage conditions.

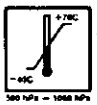
Fragile, Handle with care

Keep Dry

This end up



Relative Humidity (10% to 100%, including condensation)



Temperature (-40 to 70 deg. C)

Waste Electrical and Electronic Equipment (WEEE) Recycling Instructions

When determined that the device is ready for disposal, it is to be recycled following the policies and procedures reflecting respective country's requirements. Do not dispose of device as general waste.

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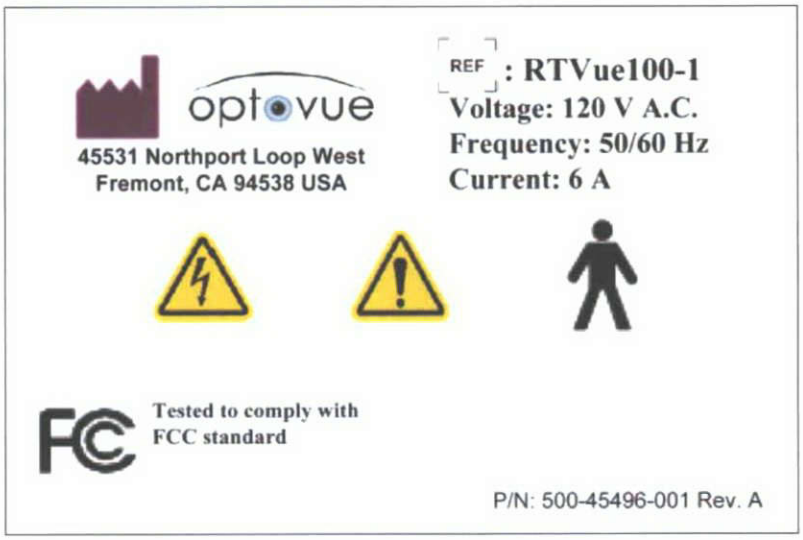
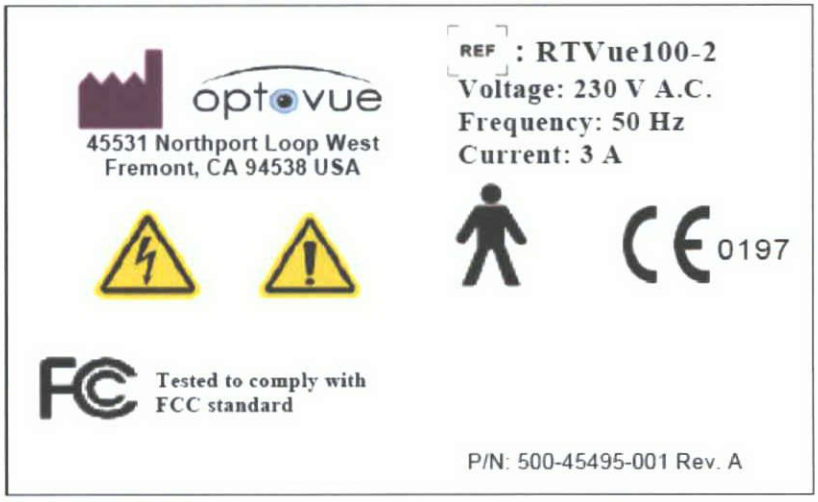
Product Labels:

RTVue system labels (Samples Only):

Model: RT100-1 for 120Va.c. input



Model: RT100-2 for 230V A.C. input



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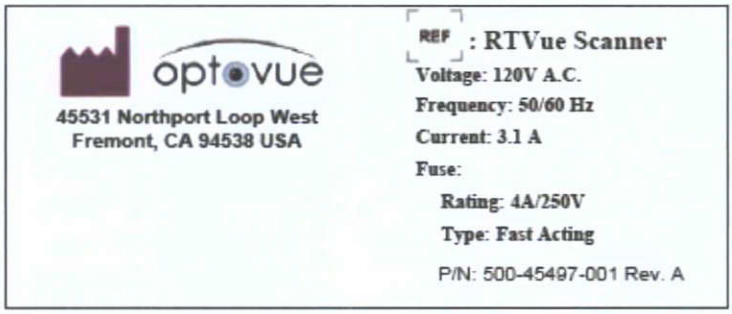
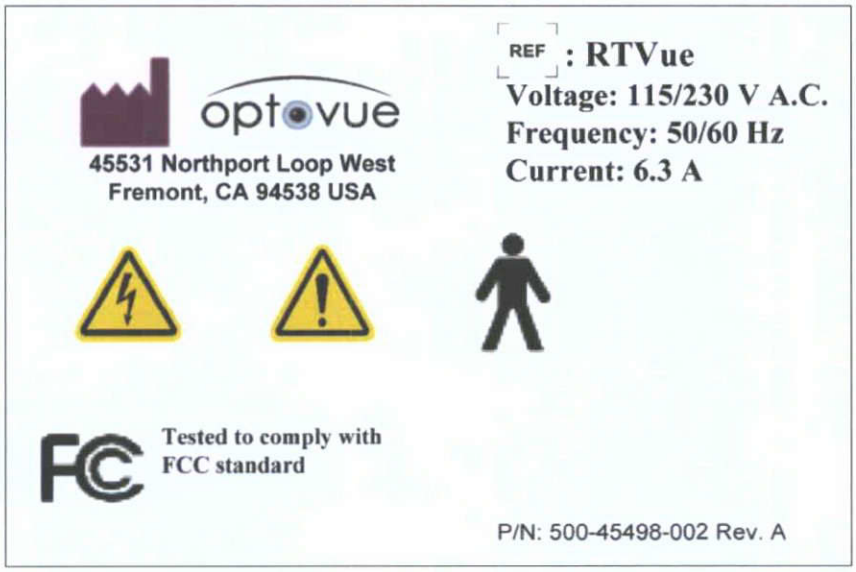
Safety Notes

RT Scanner Label: (common for both RT100-1 and RT100-2 models)



System PC Label:



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2 Instrument Description

2.1 RTVue System Configuration:

The RTVue system is shipped in one palletized box, which contains the following hardware:

1. RTVue Scanner:
This is the main component of the RTVue system. It is used to view and scan the patient's retina, collect the OCT signal, and send it to the computer for processing. It also provides a fixation light target on which the patient can fixate during the scan, as well as a position sensor for automatic detection of whether the left or right eye is aligned for scanning. Communication between the scanner and computer is achieved via a USB cable connection. The RTVue uses a medical-grade power supply.

2. Computer:
The computer is used to control the scanner during the patient examination. The application software provides data analysis, presentation, and data storage and archiving. A relational database is included to organize all patient information and data, as well as to allow for search capability.

3. System Table:
The system table provides power to the RTVue scanner, computer, and computer display through a medical-grade isolation transformer to prevent leakage current from main AC power. The table elevation can be adjusted to fit patient height. The telescopic lift that supplies the power of the RTVue system is medical grade.

It is recommended that the user connect the RTVue OCT system to a proper electrical source via the use of an Uninterrupted Power Supply (UPS) module connected to the wall outlet.

4. Monitor (Computer Display):
A 19" LCD flat panel display for graphical user interface and data presentation.

5. Keyboard and Mouse

System Configuration:

Model: RT100-1: 120V AC.
Model: RT100-2: 230V AC.

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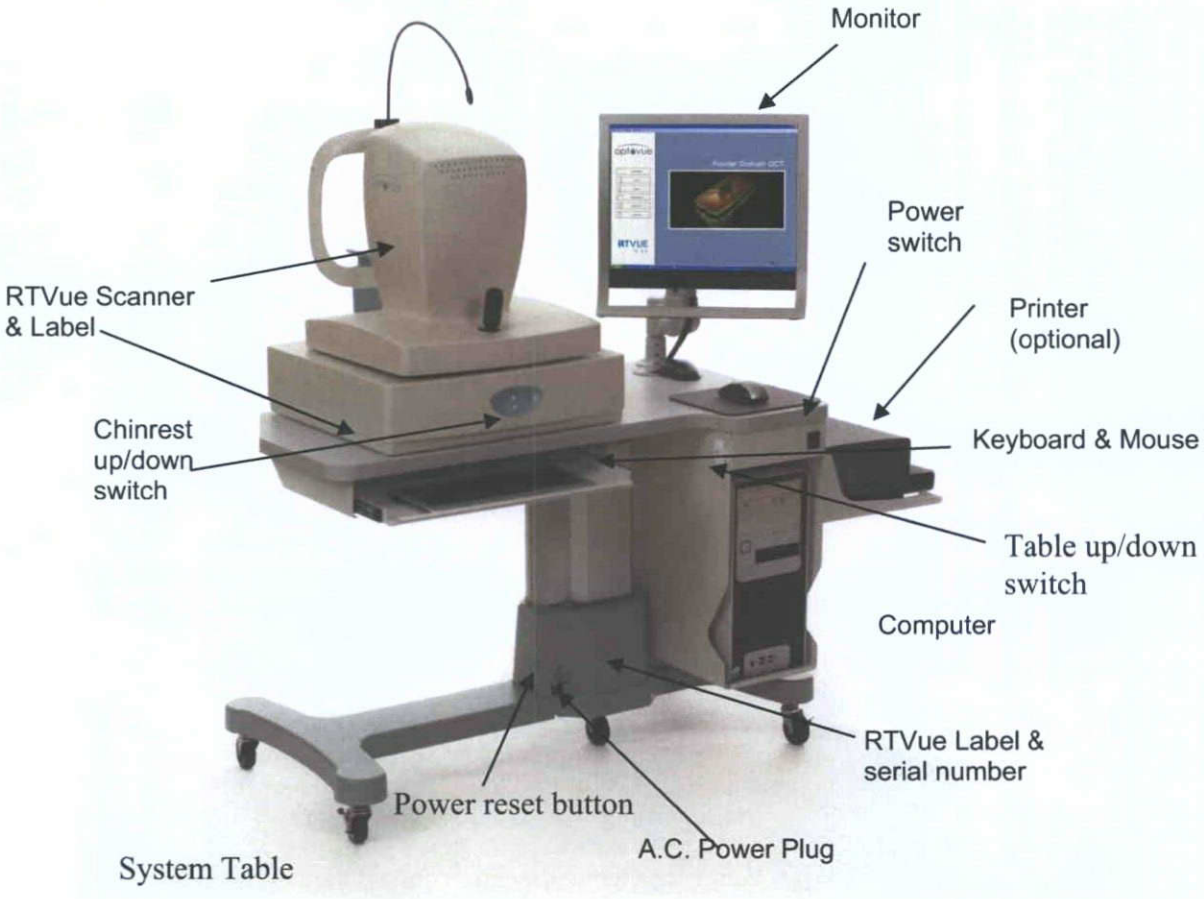
Instrument Description



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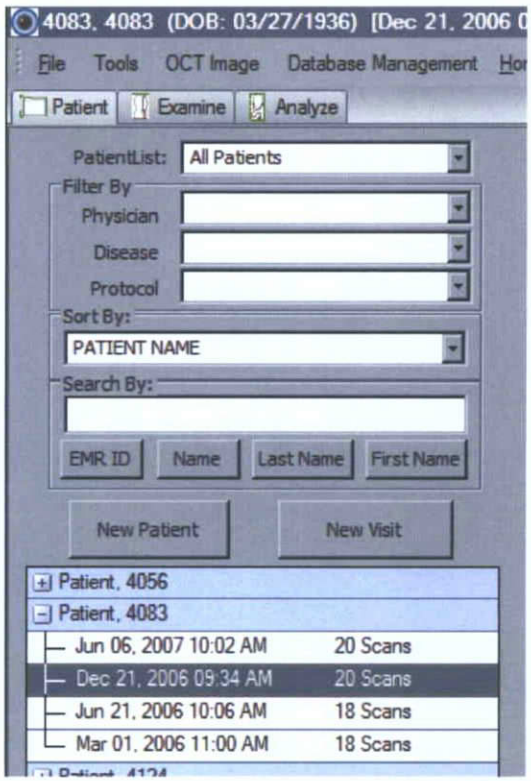
3 Patient Menu

The patient menu contains three components:
1. Patient List
2. Patient Information
3. Visit Information

In the patient menu, the user can search, add, and edit patient information. It is designed to help you schedule a patient's visit in advance, preview today's or this week's scheduled patients, and search for a patient's history.

3.1 *Patient List:*

The patient list displays the results of the user-defined search criteria.



1. All Patients
2. Current Patient
3. This week
4. Today

The patient list display can be filtered by following criteria:

1. Physicians name
2. Disease
3. Scan protocol

You may sort the results by:

1. Patient Name
2. Last Visit Time

You may search for a specific text string

1. EMR ID
2. Name (first or last)
3. Last Name only
4. First Name only

To search:

1. Type the patient's EMR ID, Name, or Last/First Name in the [**Search By**] space and click on the designated button; this will move the searched patient to the top of the list.

2. Clicking on the patient's name will list all the patient's visits and will open the patient's information.

3. Clicking on the visit will open the visit information.

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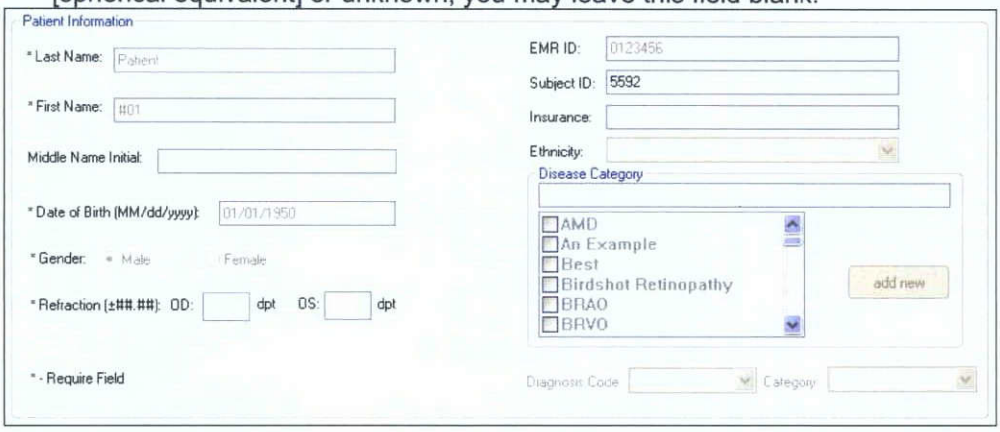
3.2 New Patient and Patient Information:

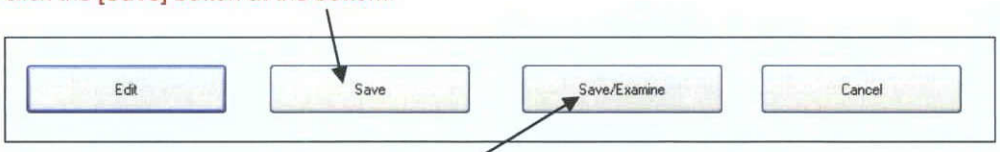
To create a new patient, click the [**New Patient**] button, fill out the information fields (fields marked with a "*" are required – if the Refraction is "0" Diopters [spherical equivalent] or unknown, you may leave this field blank.



Required information fields are marked by an (*).

- First and Last name fields are required. These can be any combination of letters or numbers. Symbols may be used, but may interfere with the capture JPEG function. It is recommended that users follow the office convention for capitalization of names.
- Refraction value (patient's current refraction – Spherical equivalent with Add) when used, sets the initial focus for scanner. The focus (scan beam and video fundus image) can be adjusted or fine-tuned in the Clinical Tab during the scan operation.
- Disease Category is a "user defined" list of diseases. The disease category (multiple choices) can also be used as a filter for the patient list.
- Diseases can be entered one at a time by clicking the [**add new**] button.
- The selected Patient Name, DOB, and EMR ID will be displayed on the title bar of the Report window.
- The "Ethnicity" field (Use or selection if for user reference only.
- If the [**Save**] and [**Save/Examine**] buttons are grayed-out, check to see that all required fields are filled.

If you are adding the list of patients with appointments for OCT scanning that day, then click the [**Save**] button at the bottom.



If you are entering the patient data in just prior to scanning the patient, then use the **[Save/Examine] button at the bottom. This will add the patient, create a new visit with today's date and take you directly to the Examine mode.**

- If you would like to cancel this operation, then simply click on [**Cancel**] button to exit the **New Patient** screen.

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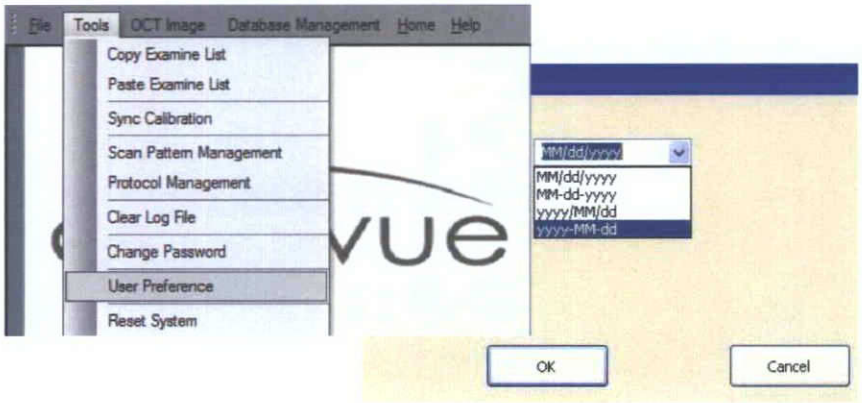
3.3 New Visit

To create a new visit for an existing patient, click the [**New Visit**] button and then click [**Save**]. If you would like to cancel this operation, then simply click the [**cancel**] button to exit the **New Visit** screen.

You can also create a new visit for an existing patient by right clicking on the patient name in the list, and selecting "Add New Visit"

3.4 Select Date of Birth Format

The default format of date of birth can be set in the User Preference:



Note: The RTVue computer settings must match the date format specified in RTVue. To change the computer date settings, please follow the steps below.

- Go to "Regional and Language Options" in Control Panel.
- Click the button "Customize" under the "Regional Options" tab.
- Select the proper format in "Short Date Format" under the "Date" tab.

3.5 Editing Patient or Visit Information

- To edit a patient's information, select the patient name from the Patient List and click the [Edit] button.
- To edit a patient's visit information, select a visit date in the list of visit dates for the selected patient, then click the [Edit] button.

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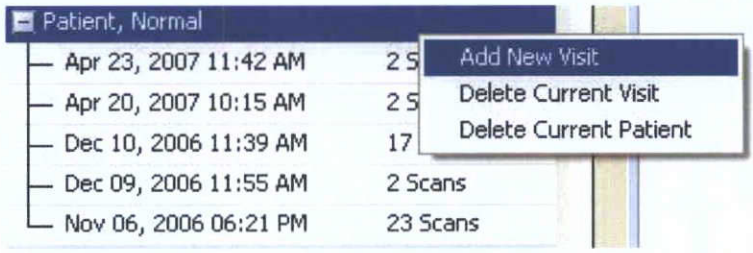
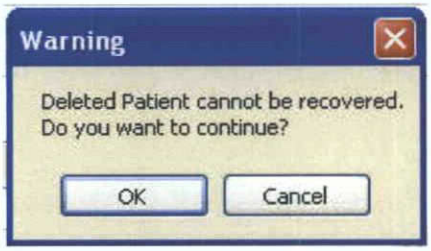
3.6 Patient List Short-cuts

Click on the patient's name to view patient visits. Right click on the patient name or visit date to view options:

- **Add New Visit** – automatically create a new visit using the current date for the selected patient, which takes the system directly to the Examination screen. Visit information is left blank.
- **Delete Current Visit –** Deletes the selected visit (any visit in the patient visit history)



- **Delete Current Patient**. – Permanently deletes the selected patient (a warning message appears first to verify that this is the intended action).



Click [**OK**] to confirm the delete action, or [**Cancel**] to withdraw the operation.

- If the [**Save**] and [Save/Examine] buttons are grayed-out, check to see that all required fields are filled.

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3.7 Correcting visit linked to the wrong patient

The user has the option of moving a visit (complete visit not specific scans) from an incorrect patient association, to the correct patient association. **(Care should always be taken by the user to ensure that the patient being scanned is the specific patient selected in the application to associate the scan data).**

1. Select the Patient > Visit you wish to move
2. Select "**Move a visit to another patient**" from the **Database Management** menu (Figure 3.7A)

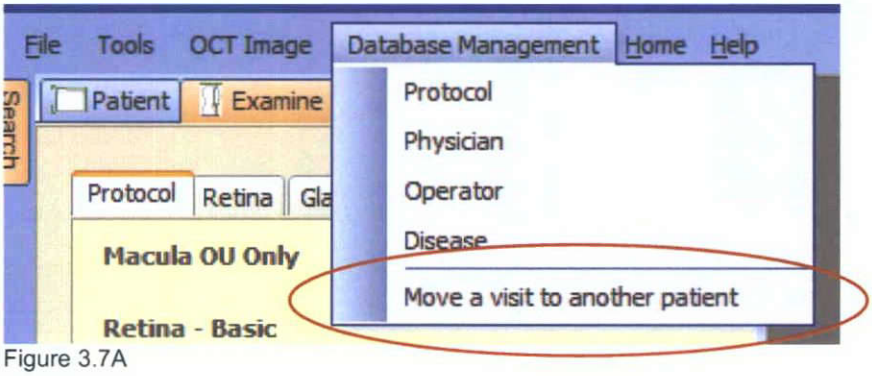

Figure 3.7A

3. Confirm that you wish to move the selected visit (first confirmation request)

Figure 3.7B

4. Select the correct patient you wish to move the visit **TO**, select **OK**

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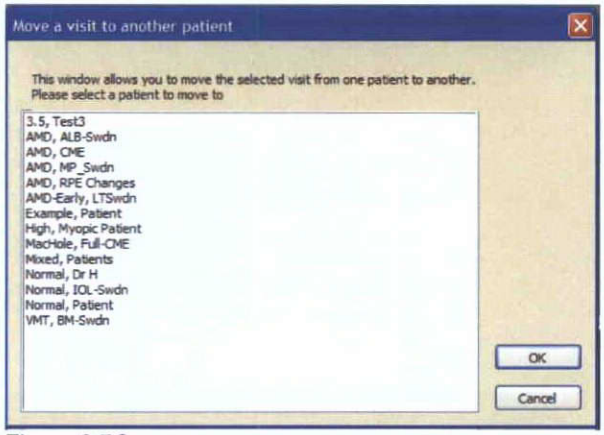

Figure 3.7C

5. Confirmation (second confirmation request) to move the selected visit to the correct patient selected. Click "Yes" to complete the move

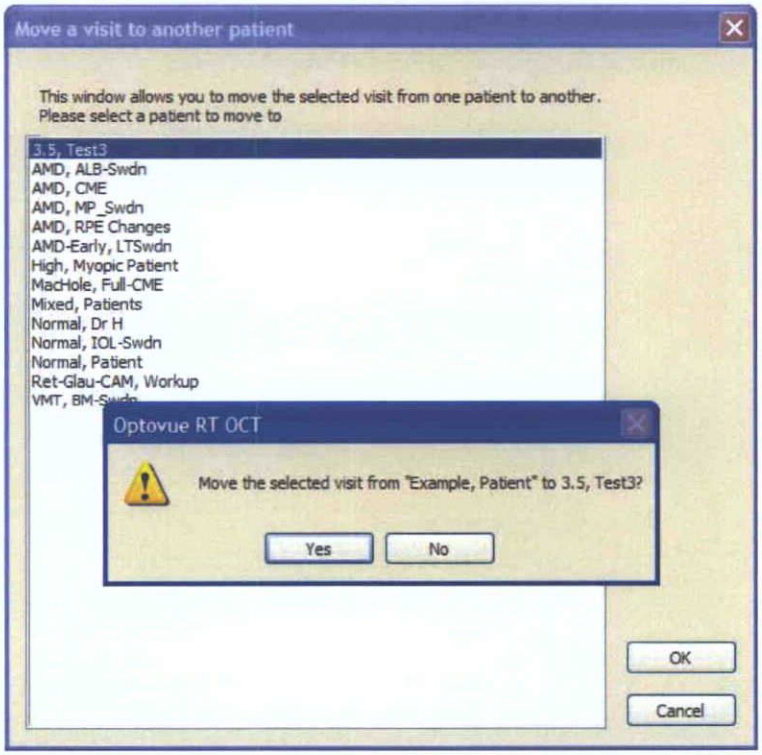

Figure 3.7D

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4 Examine Menu

4.1 Acquiring OCT Images (Quick Guide)

The following is a general procedure to acquire OCT images:

1. Select an Existing Patient or Create a New Patient.
2. Select today's visit (if it exists already) or create a new visit. Note: new scans cannot be added to visits prior to today's date
3. Click the **Examine** tab (if not automatically directed).
4. Select desired scan protocol or scan patterns (Single click to load into scan menu).
5. To launch, you may do any one of the following to activate the scanning process.
   a. Double click the scan name in the scan list.
   b. Highlight the scan name (single click) then click on the **SCAN** button at bottom center of the screen.
   c. Press the joystick button.
6. Ensure that you have positioned the patient correctly as follows: Patients' chin in the system chin rest with mouth closed, patient forehead against the system forehead rest, patient eye to be scanned aligned vertically with the canthus mark on the system head frame.
   a. Please refer to section 7.1 (Maintenance & Troubleshooting), item #3 on cleaning the chin rest and forehead rest surfaces.
7. Align center of the patient pupil with center of scan (pattern in the live video image on the screen, and move the scan head towards the patient so that the video image passes through patient's pupil.
8. Adjust distance to patient to get best illuminated fundus IR image (view of fundus from edge to edge – *there may be dark areas on either side when imaging the optic disc*).
   a. (Do Not Stop forward movement if a live scan appears in the scan window before you achieve a good IR image of the fundus. Set the working distance first)
9. Hold scanner head still and click on the "Auto All" button if no scan is visible in the scan window. This will optimize the image and should place it in the target area (between the red dashed lines).
   a. Double clicking in the scan window will also activate the "**Auto All**" button and will – in turn – perform the **Auto Z** (Axial length), **Auto F** (Focus) to offset the refractive condition, and **Auto P** (Polarization) to adjust for differences in the device and patient polarizations
   b. If scan is visible somewhere in the window, click once in the scan window and use mouse scroll wheel to bring scan to target area. Then use the **Auto F** and **Auto P** functions to optimize the scan.

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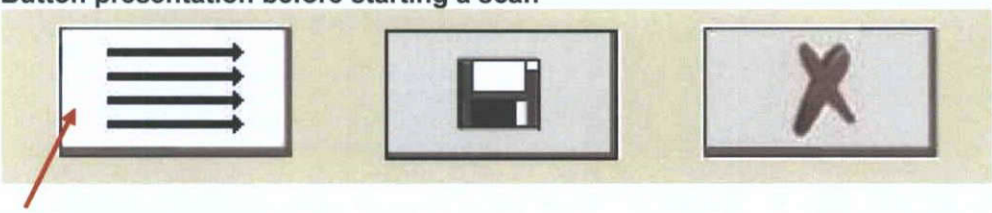
10. Adjust scan positioning in the fundus area, visible in the live IR image (if it is not where you wish it to be) by:
    a. Double clicking the mouse cursor in the center of where you want the scan to be done (IR image) OR
    b. Click and hold down on left mouse button with cursor on scan pattern, drag to desired location, and release the left mouse button.
11. Optimize the scan signal strength/ image quality using position (X/Y), Focus or P-Motor. Look for the high GREEN bar on the right side of the live scan window.
12. **Capture** scan (by pressing the joystick button) – this is the capture function.
13. **Save** the scan.

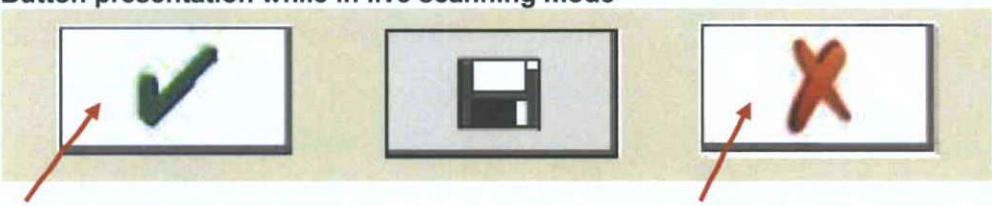
4.2 Scan Controls

Button presentation before starting a scan



Initiates a scan

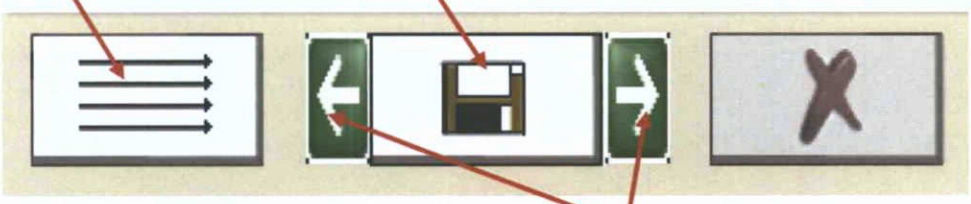
Button presentation while in live scanning mode



Capture/Acquire the data (scan) Cancel/abort scanning

Button presentation after acquiring (stopping) scan

Restart scanning process Save scan



Scan Patterns with multiple captures: Use the Arrows to scroll through other captured scan sets (scans with multiple captures)

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1. For scan patterns with possible multiple capture sets (EMM5 = 2 sets; Grid = 5 sets; ONH = 1-3 sets; GCC = 1-3 sets), **arrow** buttons on either side of the **Save** button will appear to allow the user to review the other data sets.

2. Please note that on the **EMM5**, one of two sets will be saved. On the **Grid** scan the best 3 of 5 sets are averaged to provide speckle-free (noise reduction) results for each of the 10 final scans.

3. For the **Grid**, if you scroll through the other sets of scans after the Auto Average function, the Averaged results are lost and you must click on the "**Auto Average**" button at the bottom of the **Auto** or **Manual** Tab

4.3 Scan Patterns and Protocols

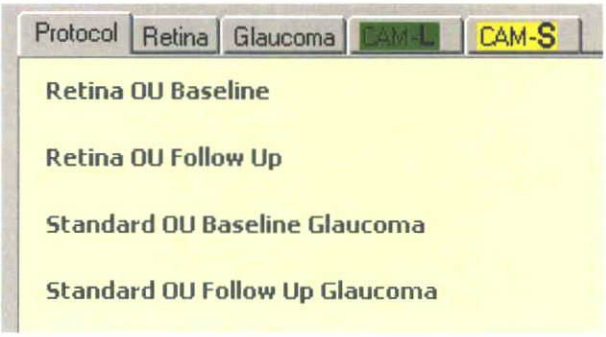
Scan patterns available are organized into two groups based on primary purpose: **Retina** and **Glaucoma**

The **Protocol TAB** is the first TAB (left to right) in the Examine screen. It is recommended that for optimum patient through-put each practice either use the recommended Protocols that are installed with the system, or set up their own protocol based on the practice patient demographics. This will allow a single "selection" for retina or glaucoma patients.

Standard Protocols include OU Baseline and OU Follow-up for both Retina and Glaucoma.

It is recommended that you set up protocols that are based on your patient pathology demographic and practice terminology. For example "Optic disc Analysis", "Retina - First Visit", Glaucoma Follow Up, etc.)

Protocol Tab



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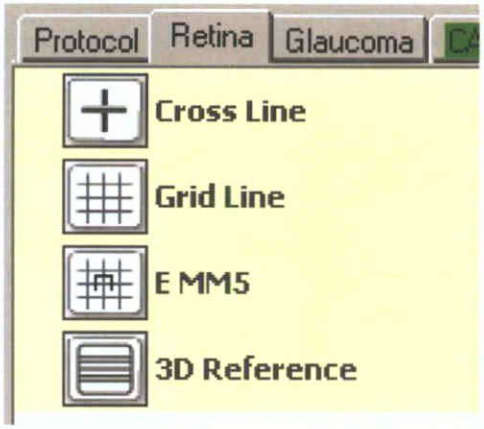
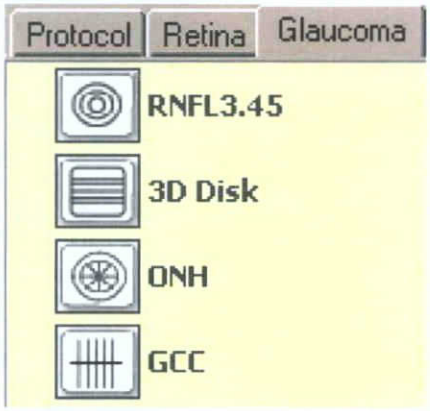
Examine Menu

Retina Tab



Glaucoma Tab



NOTE: ONH (Optic Nerve Head) was formerly labeled NHM4

<u>NOTE ON CAM OPTION</u>: If you have the CAM (Cornea-Anterior Module) Option installed on your RTVue, you will have additional tabs in the Examine View screen. Please refer to the CAM Option User Manual for detailed explanation of the use of the CAM Option for the RTVue system.

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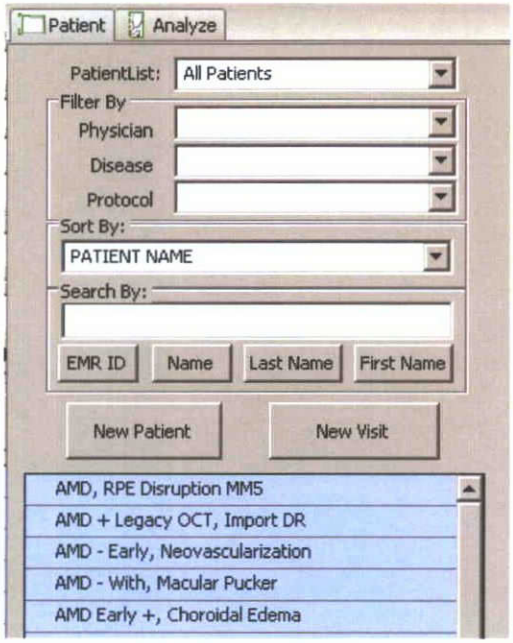
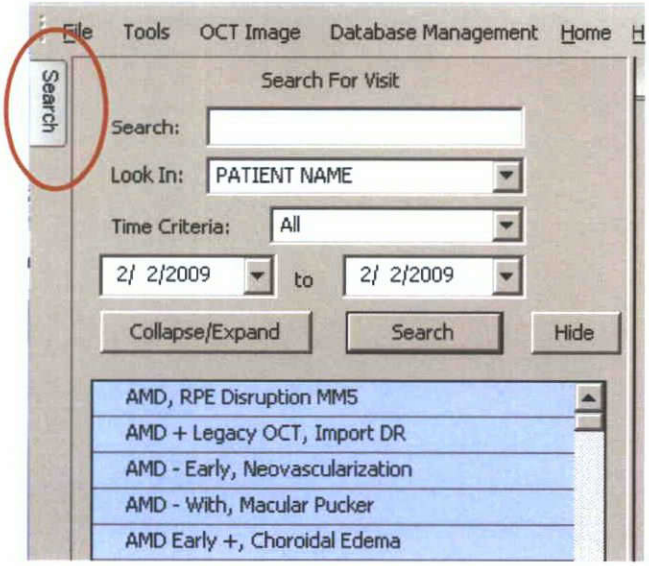
4.4 Selecting a Patient to be examined:

There are two ways to select a patient for examination:

1. Select Patient from Patient Menu using either the [Patient Name] to sort alphabetically, or [Last Visit Date] to display from most recent to oldest visit in database.
2. Use the <Search> tab in the Examine Menu. To exit the Search window, click anywhere outside the window.



Search Window



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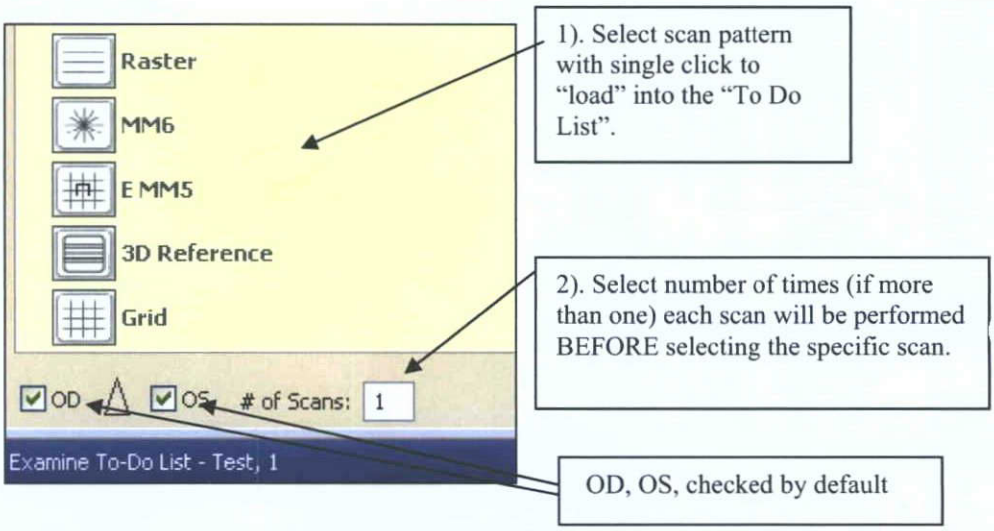
4.5 Scan List:

The scan list shows the scans to be performed in the current visit.

1. Select the scan pattern from the upper window or a scan protocol (click on the <Exam Protocol> tab to bring up the scan protocol window).
   a. A single click on the scan pattern will "load" the scan in the exam list window.
2. OD and OS are checked by default.
3. If you wish to scan any particular pattern more than once, you will need to select how many times each set of scans will be performed first.



Examine To-Do List - Test, 1

Scan Type	Eye	Repeat
✓ Line	OD	1
✓ Cross Line	OD	1
✓ E MM5	OD	1
✓ GCC	OD	1
○ 3D Disk	OD	1
○ ONH	OD	1

An empty green circle indicates that the single scan has not been completed. A solid green circle indicates that the scan is complete.

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4.6 Scanner Control Tabs

The default GUI setting will present two tabs during the Examination process (**Auto** and **Manual**).

4.6.1 Auto Tab

The Auto Tab contains only the minimum function buttons to enable automated acquisition of optimized scans with minimum actions from the user.

a. Light & Dark Eye Buttons: Accesses the Brightness and Contrast default settings for each affecting the live IR image

b. Illumination Control Buttons: Reduces or increases the IR illumination for the live IR image viewing.

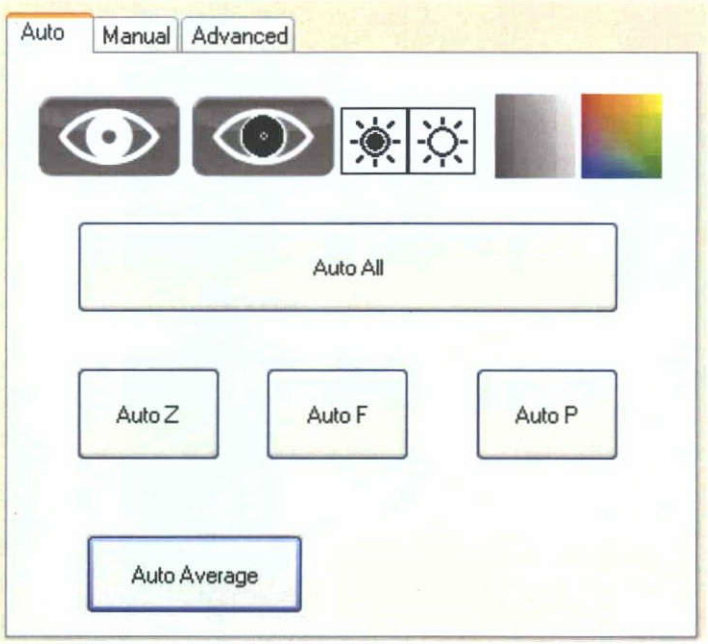
c. Grayscale / Color live scan Buttons: Select the viewing preference for the live OCT scan in the upper window (if different from default setting). NOTE: Default presentation of color or Grayscale can be set in the [OCT Image>Scan Parameter Setting] window.

d. Auto All: this button initiates the all of the automatic functions of the Auto Z, Auto F and Auto P buttons to optimize the scan.

e. Auto Z: Automatic adjustment for the Axial length

f. Auto F: automatic adjustment for the refractive state

g. Auto P: Automatic adjustment for polarization



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4.6.1.1 Use of Auto Tab Controls.

1. After aligning on the pupil and moving the scan head forward through the pupil (IR image) to achieve a view of the fundus, Hold scanner head still and if there is no scan visible in the live window click on the "Auto All" button. (You may also Double-click anywhere in any of the live scan windows to activate the "Auto All" function (one to four scan windows appear depending on the scan type).

2. NOTE: You only need to use the Auto buttons for the first scan taken on the first visit. After the first scan is optimized and captured, the same settings should be used for all subsequent scan for that visit. The system will store the settings for that patient (each eye) for any follow-up visits.

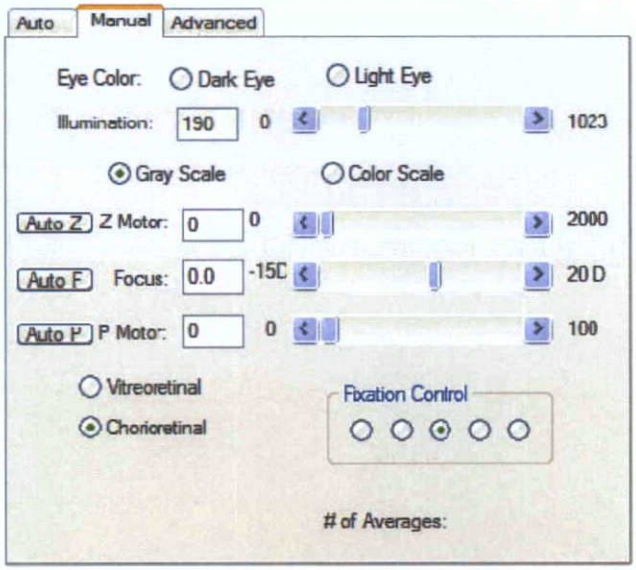
3. Double clicking in the scan window will also activate the "Auto All" button and will – in turn – perform the Auto Z (Axial length), Auto F (Focus) to offset the refractive condition, and Auto P (Polarization) to adjust for differences in the device and patient polarizations

4. If scan is visible in the window, click once in the scan window and use mouse scroll wheel to bring scan to target area. Then use the Auto F and Auto P functions to optimize the scan.

5. The **Auto Average** button will appear after the scan is complete – only if the scan pattern is one that uses the Averaging function. The **Manual Average** button will also appear in the **Manual** Tab

4.6.2 Manual Tab

The Manual Tab contains the slider controls to manually adjust the Z, Focus and Polarization directly, as well as manual controls for the other step control buttons on the Auto Tab



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4.6.2.1 Use of Manual Tab Controls

1. **Eye Color**: Select dark or light according to patient iris color to optimize the illumination, brightness, and contrast settings for IR image. The individual Brightness and Contract adjustment are in the Advanced Tab.
    a. If neither eye color is selected, then the default settings are the average of the respective values of illumination, brightness, and contrast for the dark and light eye.
2. **Illumination**: Adjusts the IR illumination for the IR video image. Level is set by selecting Eye Color, but may be adjusted separately to attain best image.
3. **Grey Scale /Color Scale:** Toggles live OCT image in gray-scale or color.
4. **Z Motor / Auto:** position adjustment: Click on the OCT image window, then use thumb wheel on the mouse to adjust Z-position. Double clicking on the OCT image window will auto-search Z position. This is the same as clicking on the "Auto" button next to the Z Motor.
5. **Focus** adjustment: Use to focus OCT and video image resulting in a sharper image. Use the slider control to fine tune the focus of the IR image and Signal strength of the OCT scan.
6. **P Motor:** Polarization adjustment to optimize the OCT image signal strength resulting in a clearer image.
7. **Vitreoretinal / Chorioretinal:** Setting are programmed based on scan design to enhance either the information above the RPE (Vitreoretinal), or the choroid and overall information (Chorioretinal)
    a. **Vitreoretinal:** This setting puts the highest signal strength at the top of the scan window and results in higher signal strength in the inner retina layers (RPE through ILM and vitreous)
    b. **Chorioretinal:** This setting puts the highest signal strength at the bottom of the screen, resulting in a stronger signal - and better visualization of the choroid.
8. **Fixation Control:** Use to change preferred fixation location (if other than default setting) for patient to focus on. There are five fixation settings.
9. **Process Average:** For the **Line** scan, **Cross Line** scan and **Grid** scan, you have the option of averaging the multiple scans to achieve and final "averaged" image. This process is used to reduce the noise of the OCT image and provide a speckleless B-scan result. Eye or operator motion may limit the number of frames that can be used in this process. Quick eye motion may also smear the OCT image and reduce the quality.

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4.7 Advanced Tab Controls: (Recommended for Advanced Users only)

This tab is hidden as the default setting

1. **OCT Image Noise:** Adjusts the noise level of OCT for best visualization of retina tissue. The default value is "3". *This should not be changed other than by an expert user.*
2. **Scan Length:** To adjust the scan length with the center of scan fixed.
3. **Scan Width:** To adjust the width of a raster scan. The number of raster scan lines will be equally spaced in the width of scan pattern selected.
4. **Scan Angle:** To rotate the scan around the center of the scan. Use slider to rotate the scan or click on the scan graphic in the IR window and use the mouse wheel to rotate the scan direction.
5. **Video Brightness:** Controls the brightness of the Video image only (not the OCT scan)
6. **Video Contrast:** Controls the amount of contrast or shading between areas in the Video Image only (not the OCT scan)
7. **XY Offset:** The arrow keys can be used to move the scan pattern around in the IR image in very small steps. Below are the two most common ways to position the scan in the desired location:
    a. Click and hold down the left mouse button on the scan graphic in the live video image and slowly drag the scan pattern to desired location.
    b. Double click the mouse cursor in the center of ***where you want the scan to be.*** The scan pattern will shift and center on the spot you selected. (Recommended method).

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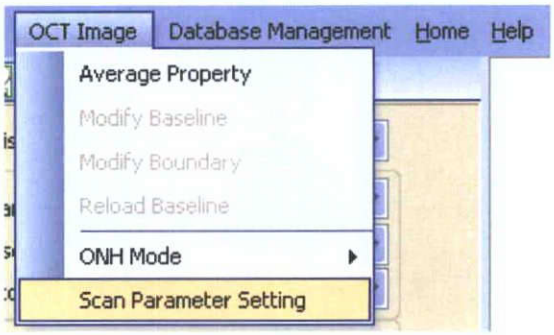
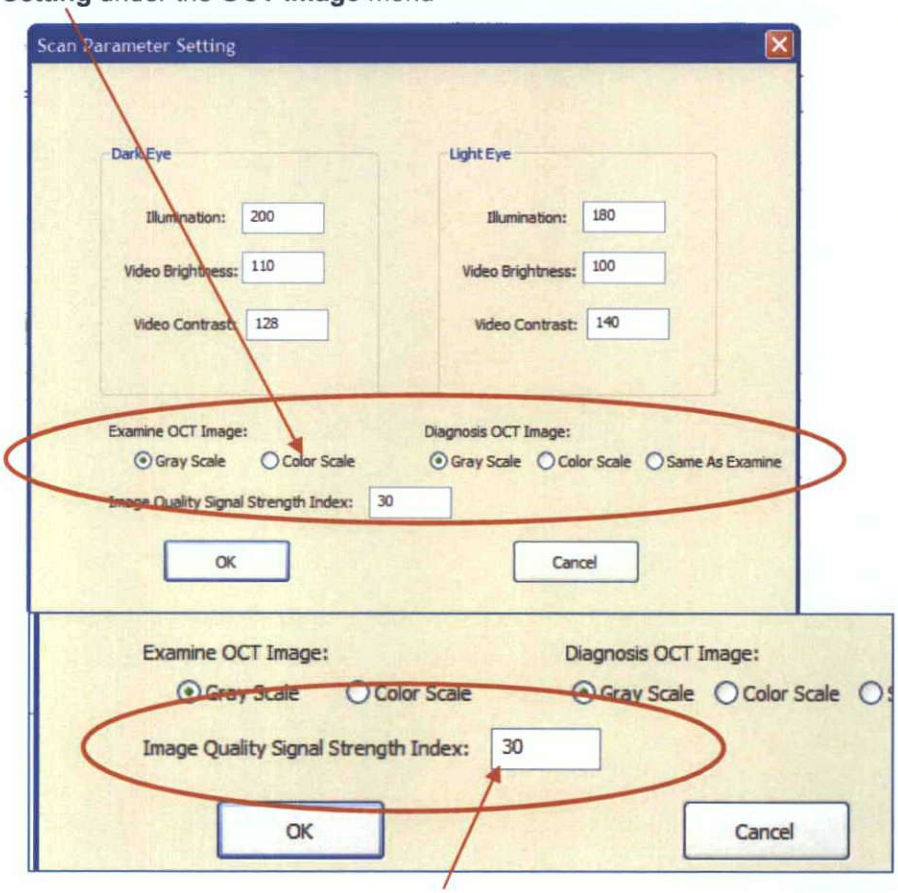
4.8 Setting the Image control default

The Scan Parameter Setting menu can be found by clicking the OCT Image menu.



The user may now set a different default live scan view mode between the Examine and the Review sessions. The view can be individually set for either Grayscale or Color presentation of the live scan. Go to **Scan Parameter Setting** under the **OCT Image** menu



NOTE: Setting for "**Image Quality Signal Strength Index**" should not be changed by other than Research site users with prior approval from Optovue personnel.

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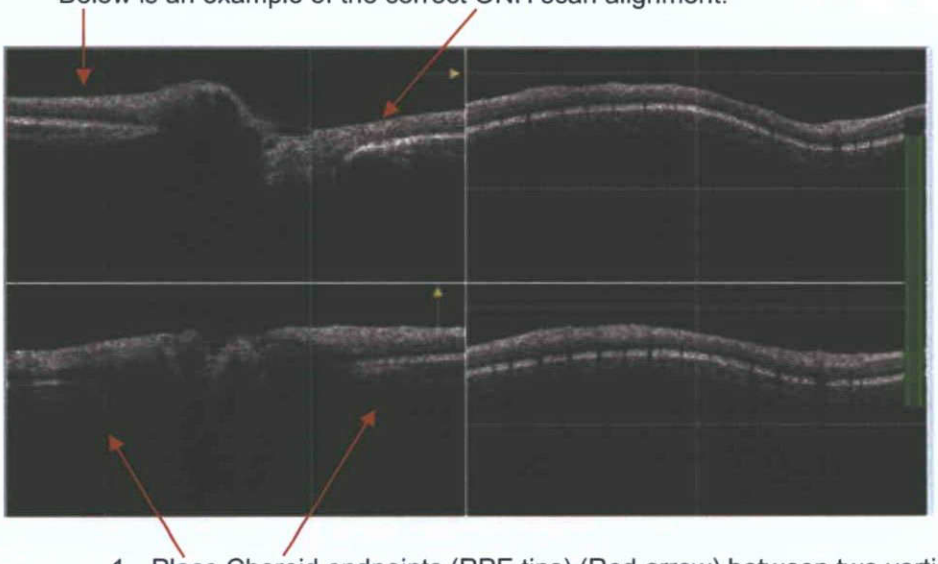
4.9 Correct Alignment of live OCT image

In all scan patterns, you will see one or more pairs of parallel red dashed lines. Some scans may have as many as four "live scan" windows with the target zone parallel lines. In any scan, the optimum placement of the live scan is between the red dashed lines. If the lines are horizontal, the scan should be in the upper part of the target area. (3D disc scan will have some of the scan image fall below the lower line; this is OK)

In the case of vertical red dashed lines (such as in the ONH), the physiology targeted should be between the two parallel lines. (See below)

If you select a different scan mode (Vitreoretinal / Chorioretinal) than the default setting, the location of the red dashed lines will shift to the top or the bottom of the screen, depending on where the default position is.

Below is an example of the correct ONH scan alignment.



1. Place Choroid endpoints (RPE tips) (Red arrow) between two vertical guide lines
2. Place circular scan between two horizontal guide lines

In this version, a vertical line is provided in the center of "live scan" windows as well to aid centering of the scan.

NOTE: Live scans for all patterns are to be placed between the red dashed "target zone" lines. Target zone may be near the top or the bottom of the live scan window depending upon the **Vitreoretinal** or **Chorioretinal** setting.

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4.10 Averaging (Auto and Manual)

Automatic Averaging will take place immediately after capturing a **Line, Cross Line** or **Grid** scan. This is a noise-reduction function to reduce the amount of speckle noise in the image. A Speckleless B-scan is presented as a result of this noise reduction function.

If you are not satisfied with the results of the **Auto Averaging** results (recommended), you may either select the **Auto Average** button again, or select the **Manual Average** option.

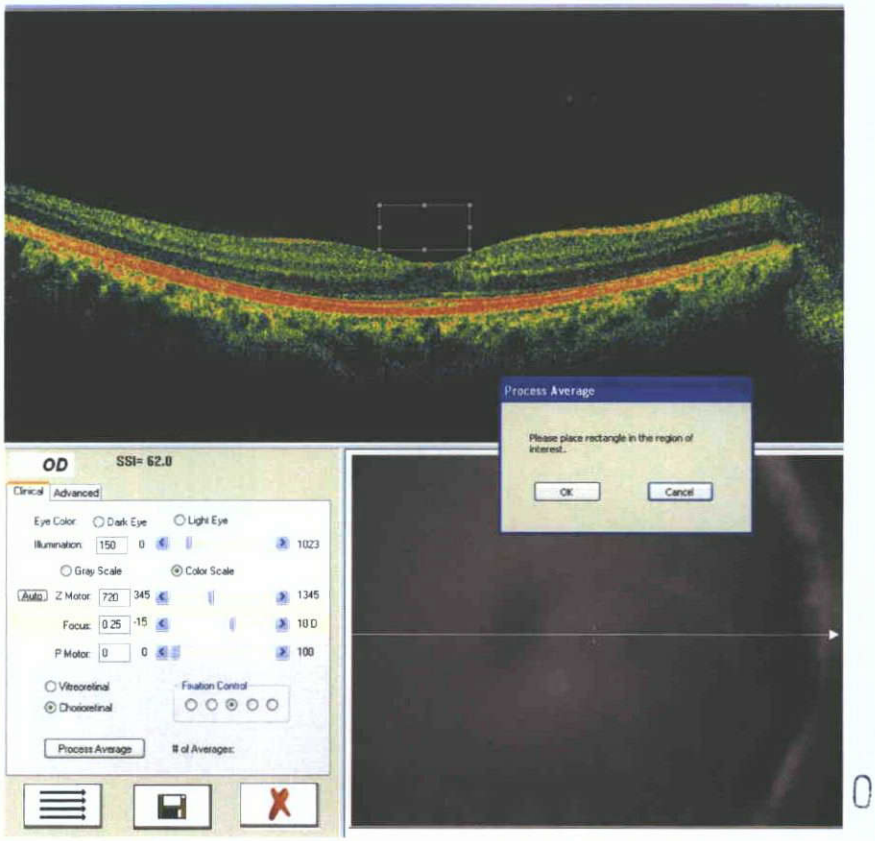
To obtain the final averaged image in either the Line or Cross Line scans:

1. Move the rectangle(s) on or over the region of interest
2. Then click **OK** in the message box.

The rectangles may be adjusted to any size in order to encompass the area of primary interest. You may repeat the "Process Average" function as many times as you wish using any of the scans as the averaging basis.

1. Click on any image from the individual scans at the left side of the screen to see it in the large window. Place the rectangle and click on the **Process Average** button.

NOTE: Larger ROI coverage may sometimes produce better results, however increasing the box size also increases the processing time.



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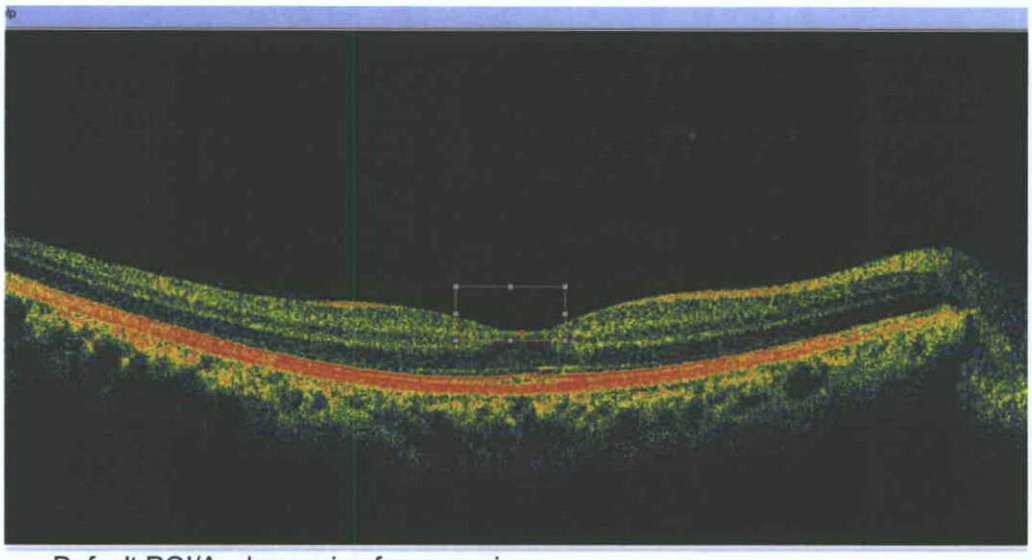
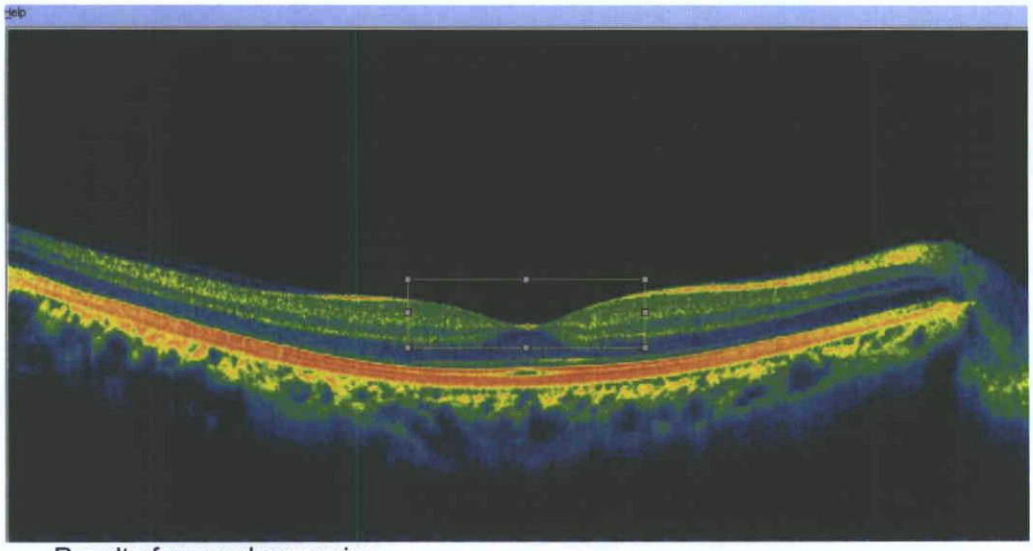


Default ROI/Anchor region for averaging



Result of manual averaging

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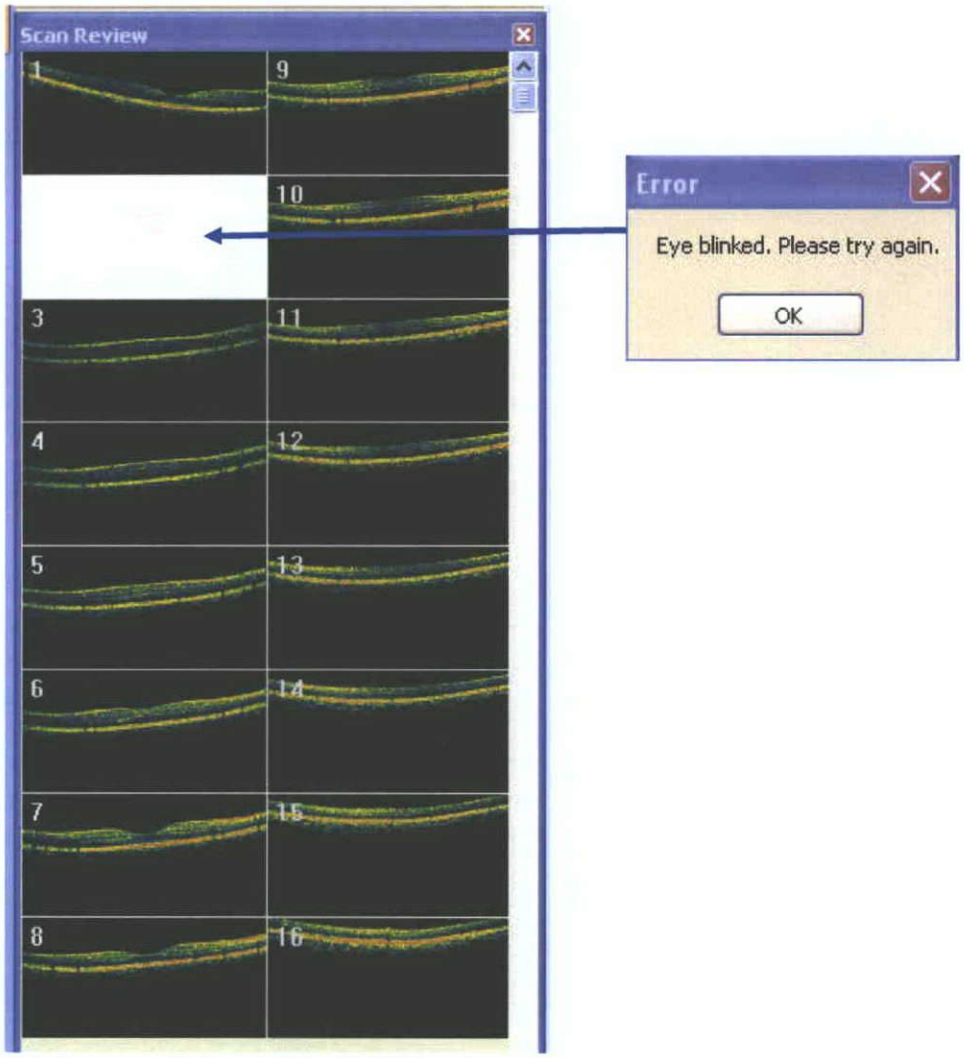
4.11 Reviewing Scan Images:

After stopping the scan, the window will automatically bring up a list of thumbnail images. Click on any thumbnail image to display that scan in the working window. The window can be closed with the Microsoft Windows "Close" (X box) icon on the upper right hand corner.



4.12 Saving Scan Images:

After reviewing the image, pressing the [Save] (disc icon) button will save the images. Pressing the scan button again without saving will discard the current scan images and will restart the same scan.

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4.13 Reference and Baseline Scans (for Registration)

The RTVue utilizes two 3D scan patterns to produce an SLO type image for registration purposes. Providing vessel registration and optic disc centering for orientation and serial registration, these scans produce the baseline image that enables real change analysis of both retina diseases and glaucoma.

Higher measurement precision due to registration:
Registration of images increases the repeatability and of measurements between visits. With the new registration feature, the average improvement for vessel registration is 1.2 microns.

For the EMM5, the average full retinal thickness 95% repeatability estimate is 4.5 microns. For the ONH scan, the average RNFL thickness 95% repeatability estimate is 10 microns.

A. 3D Reference (for EMM5 registration – retina diseases)

This scan produces an SLO like reference image of 7mm x 7mm (7,000 x 7,000 microns on the macula). This scan utilizes an "En Face" perspective to produce a high contrast grayscale image of the retina surface detail. This En face image is used as the reference and registration image for the EMM5 macular map (explained later in this section) based on vessel tracing.

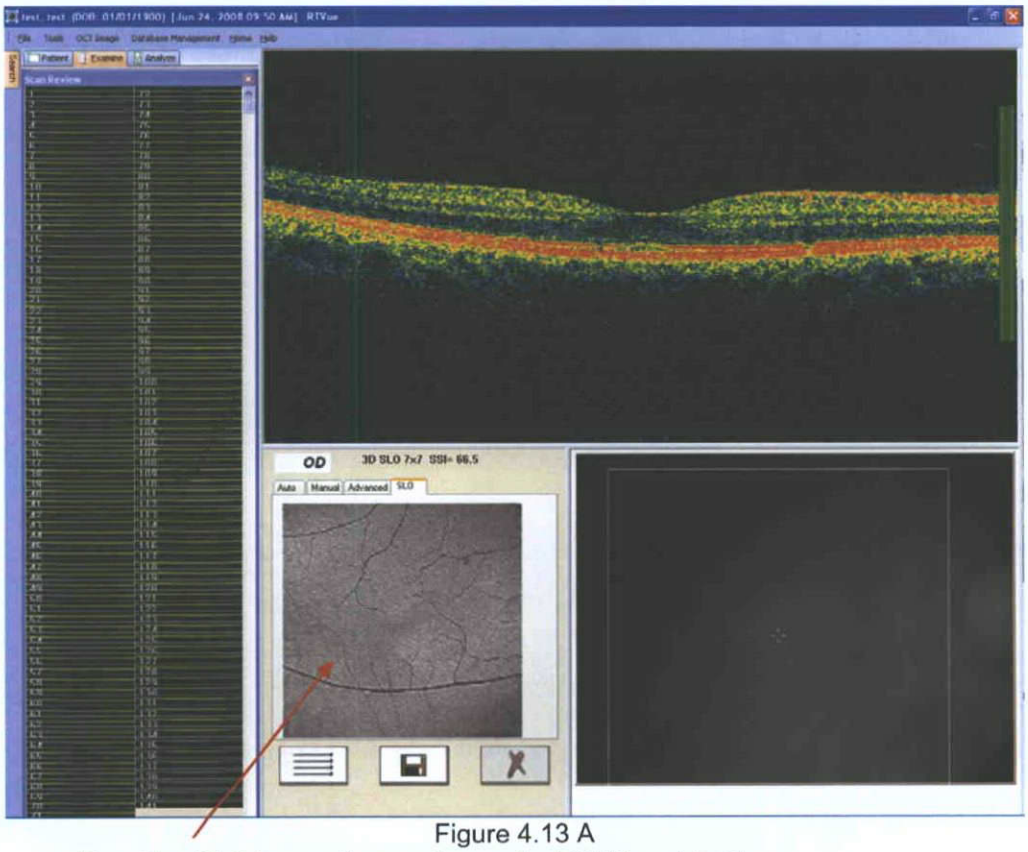

Figure 4.13 A

- Resulting SLO type reference image for EMM5 registration

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EMM5 scan pattern contains a sampling raster, offset from the mapping grid in order to capture a vessel tracing for registration purposes.

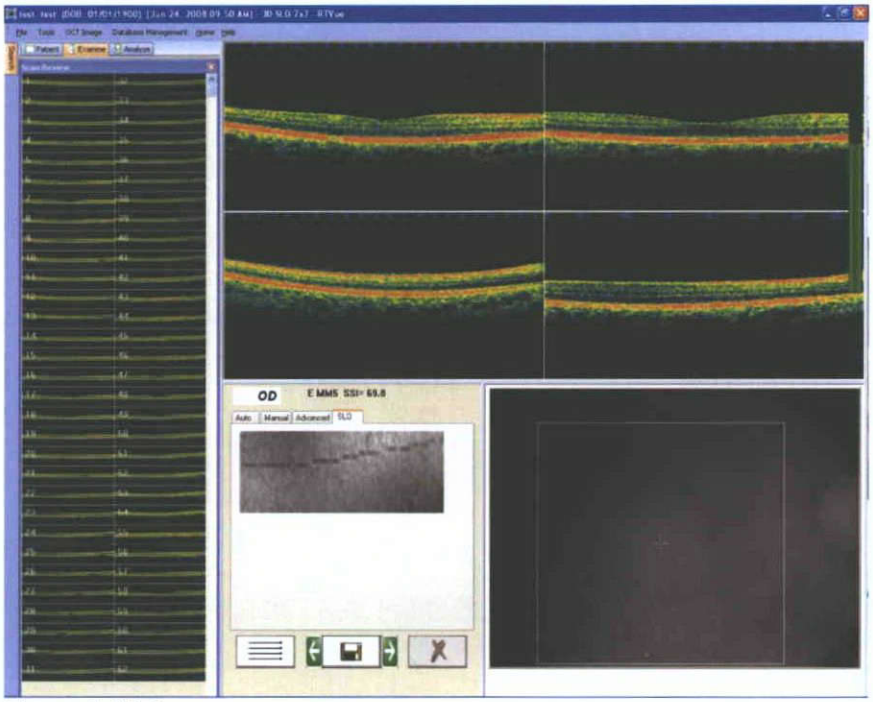

Figure 4.13 C

Possible instances in which rescanning may be required to establish a new reference and baseline scan:

A new reference image may be desirable in the event of the vessel changing (orientation) or moving, due to disease progression or surgical intervention. EMM5 scans from that point on would use the newer reference image; however the mapping scans that existed prior to the new reference being established will remain registered to the original reference image.

B. *Reference Image for ONH Map (Glaucoma)*

For serial registration of the ONH (Optic Nerve Head) scan for glaucoma, the 3D Disc scan is used to create a baseline SLO type image. The ONH scan pattern produces vessel tracing patterns that are matched to the vessels in the SLO en face result of the 3D Disc.

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Image for vessel registration

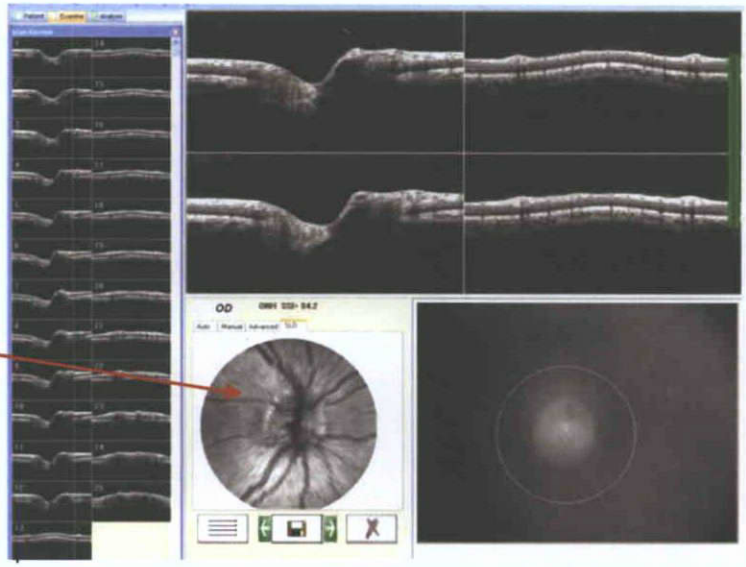

Figure 4.13 D

The 3D Disc scan result also provides the detail for the automatic tracing of the disc boundary (disc margin). This provides the disc margin shape and exact center of the disc, each of which is used along with the vessel tracing for serial registration of data and change analysis.

Auto-detection of disc margin

Verification of accuracy (Choroid endpoints / RPE Tips)

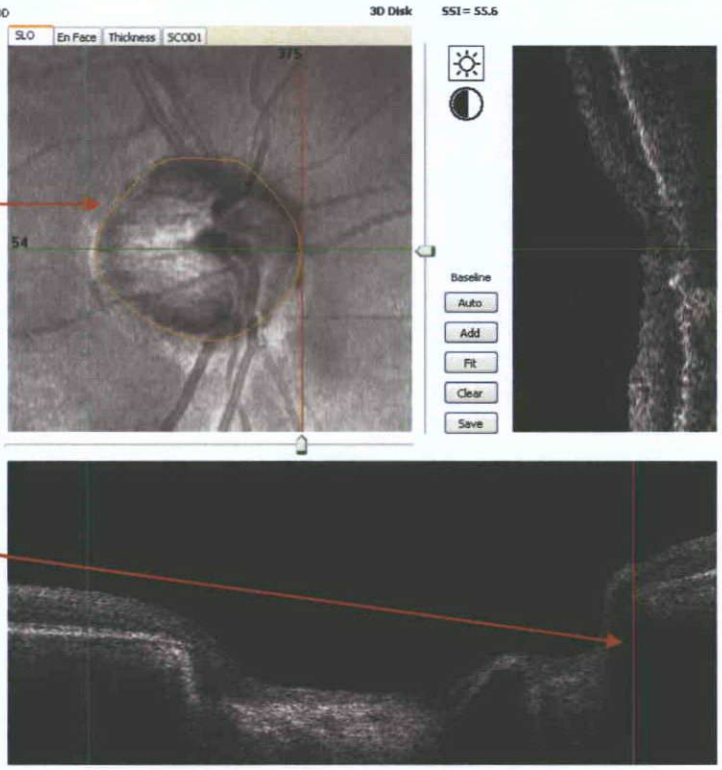

Figure 4.13.E

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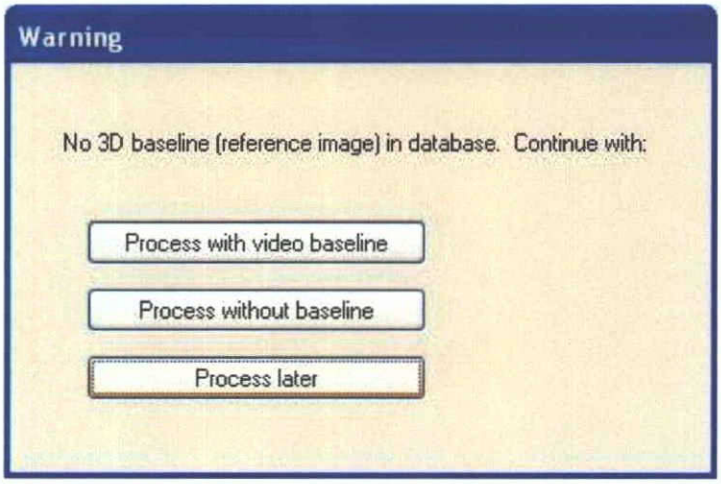
The option "Auto detect 3D baseline while saving scan" is located in User preference: This can be set to "Yes" (default) or "No". When the selection is "Yes," disk boundary is auto drawn while 3D disk scan is being saved. When "No" is selected however, auto drawing of optic disk is skipped when it is saved. Instead it takes place when 3D disk scan is opened in analysis mode.
When "No" is selected in above option, it is recommended that 3D disk scan is always opened first in analysis mode, during with the auto drawing of disk will take place. Due to this, it may take a few seconds longer to open the 3D disk scan compared to if opened with disk already drawn (during scan save).

If ONH scan is analyzed prior to analyzing 3D disk, following window appears.



"Process later" option is recommended, which will act as a "cancel" function. Then 3D disk scan should be opened and analyzed. At this point the auto-drawn disk boundary can be modified in needed. "Save" button needs to be clicked to save the boundary if any changes to the auto-drawn boundary are made. If no changes are made, then leaving the 3D disk scan automatically saves the disk boundary.

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5 Analyze Menu

5.1 Analyze Layout

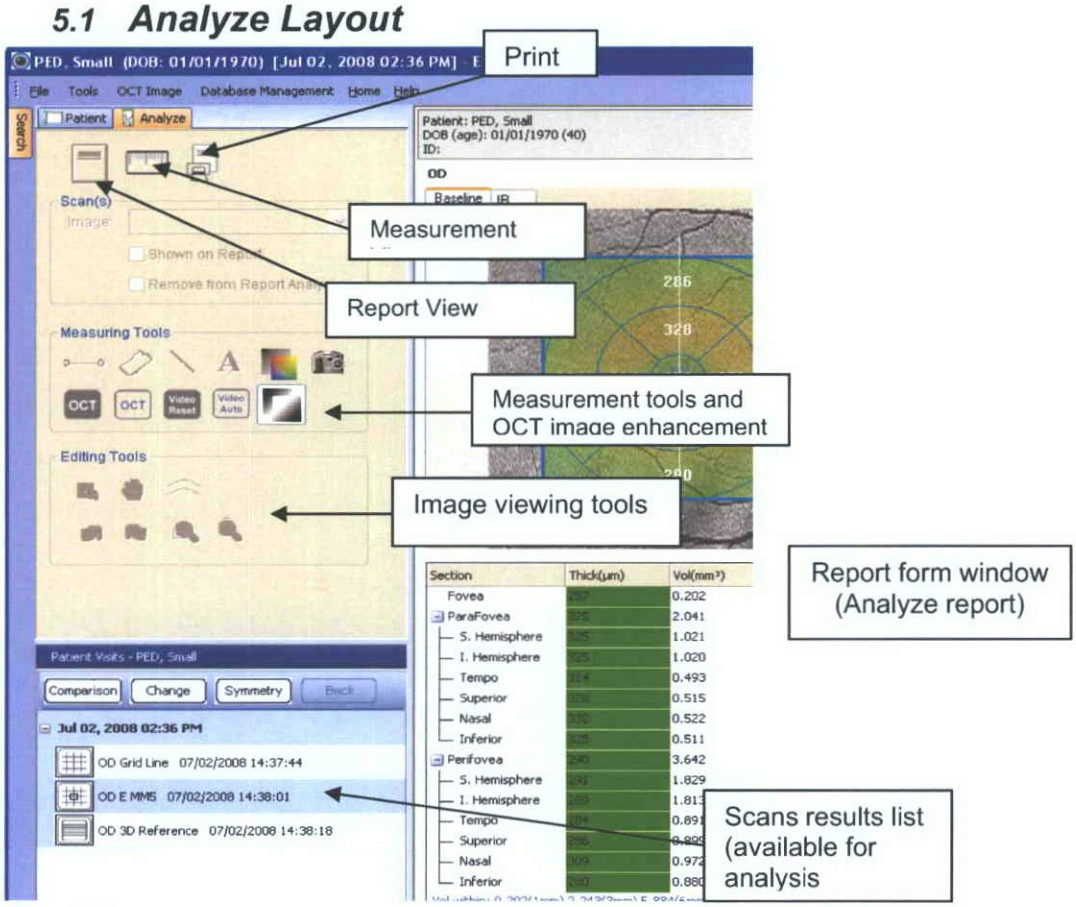

Figure 5.1

1. **Report** Form View: The default Analysis Report view (This is also the Print Preview form) with analysis results
2. **Measurement View**: Activates the view and tools for manual measurement on the OCT images and the presentation ratio. (Right Click Options)
3. **Print**: Send the current screen to the printer (any Window's compatible printer)
4. **Measurement Tools/ Image Enhancement:** The measurement tools become available when in Measurement View, including the appropriate tools for the CAM Option (Cornea-Anterior Module). The image enhancement tools for the OCT scan (increase or reduce background noise) and IR image (contracting).
5. **Image viewing tools:** remove tracing lines, zoom, area of interest selection and Undo/Redo
6. **Scan Results List:** All scans performed during the selected visit are listed below the Exam Date
7. All presentations (Analysis and Measurement views) appear in the window to the right of the controls

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5.1.1 Analyze List

After selecting the patient, a list of scan records will appear under the tool window. Click a particular scan pattern to show the results in the report window.

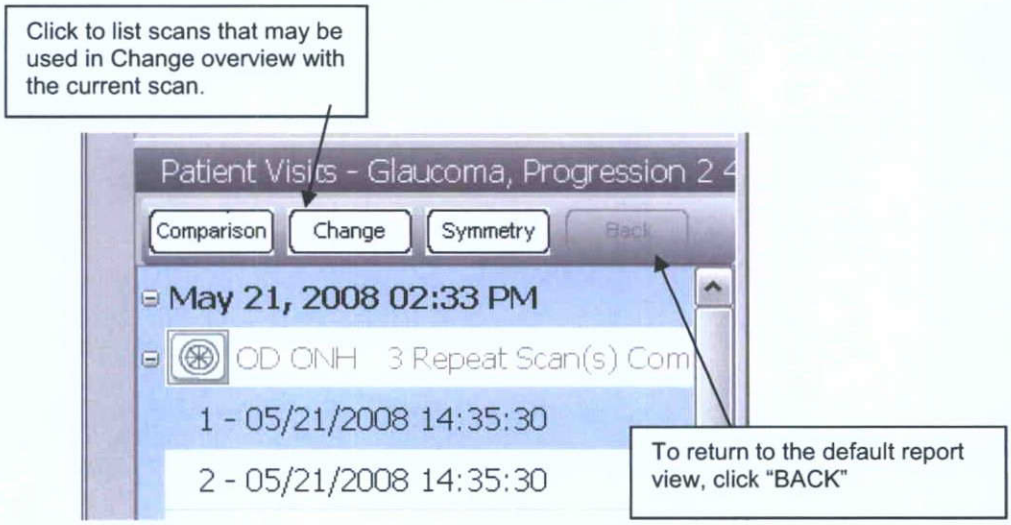
NOTE: Depending on the type of scan, it will sometimes take 5 to 15 seconds for the to the measurement result to appear the first time the scan data is selected. (This is due to calculation time). After the first time, the calculated (processed) data is stored and subsequent viewing will open in less time.

5.1.2 Diagnosis Data Input Field

At the bottom of the Report screen is a textbox labeled "Diagnosis". Any text entered here will be saved automatically when you exit the Analyze menu, whether you move to another window or exit the application entirely. This information is specific to the scan; it will not be displayed in other scans or visits from this patient.

5.1.3 Change / Symmetry / Comparison Analysis

If there are eligible scans available in the patient visit history, the related **Change** and/or **Symmetry and Comparison** options will be available. Click the button to activate the additional analysis.



Note on Change Analysis: Up to six (6) ONH scans, four (4) GCC scans or four (4) EMM5 Retina scans may be included in the Change report.

If the patient history contains six visits or less, all visits will be automatically selected and the report generated automatically for presentation

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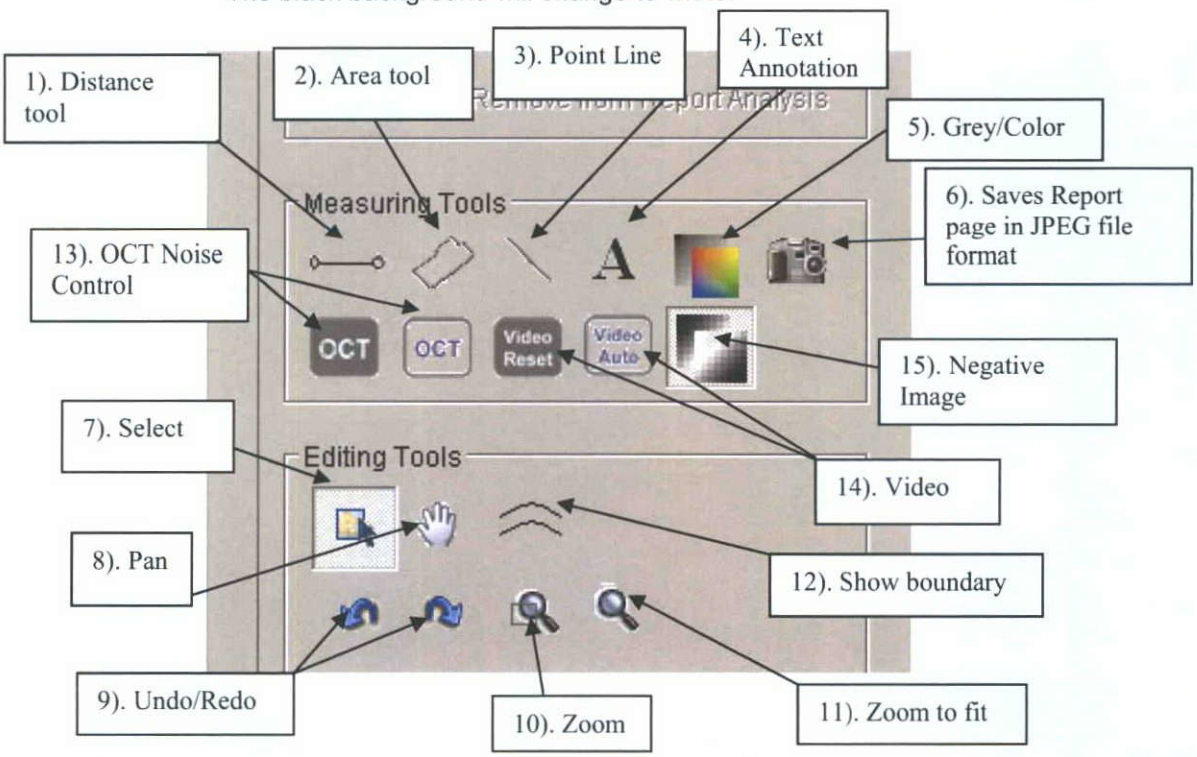
5.2 Measurement

Measurement tools are accessed by clicking the icon.

5.2.1 Tools:

1. **Distance tool**: Measures the distance between two points.
2. **Area tool**: Measures the area of a polygonal area.
3. **Point Line**: Draws a line between two points.
4. **Text Annotation**: Add text to images.
5. **Grey/Color**: Toggles scan display from gray-scale and pseudo-color.
6. **Snapshot**: Saves the Report Page in .jpg format. File name has default but is user editable. User defined destination
7. **Select**: Click to deselect the tool in use.
8. **Pan**: Moves the OCT image around in window.
9. **Undo/Redo**: Return to previous or prior state before/after an action.
10. **Zoom**: Zooms in or out of the OCT image. (No interpolation)
11. **Zoom to fit**: Fits all scans in the scan pattern into the window.
12. **Show boundary**: Display/remove boundary on the OCT image.
13. **OCT noise**: Increase (white) and reduce (gray) OCT noise level.
14. **Video**: Brighten (white) and reset (Grey) video image contrast.
15. **Negative Image**: inverts the presentation of the gray scale images. The black background will change to white.



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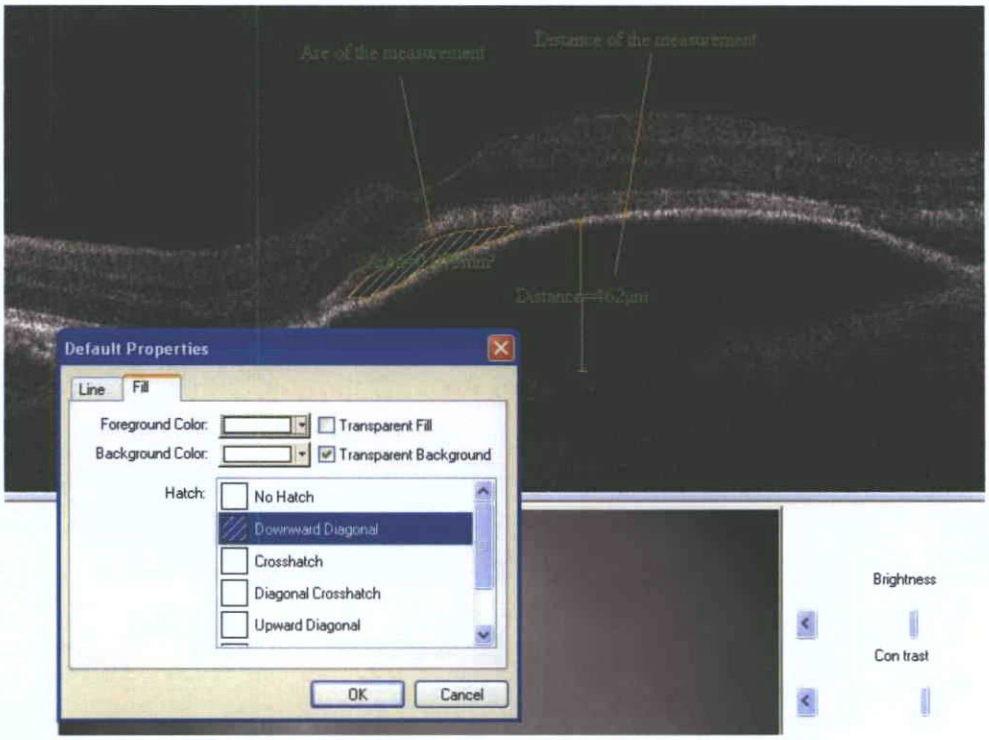
5.2.2 *Using Manual Measurement*

To make a manual measurement, first select the tool, and then make the desired measurement on the selected OCT image. Next, select an initial or "anchor" point and then proceed to the second endpoint (linear measurement or arrow) or the next in a series (area measurement).

Right clicking on the measurement will show the properties of the tool.



NOTE:

- You can select the **Snapshot Tool (camera icon)** to export a .jpg of the Measurement report screen.
- You may select the **Print** option to print a copy of the Measurement report screen with the practice and patient information header.

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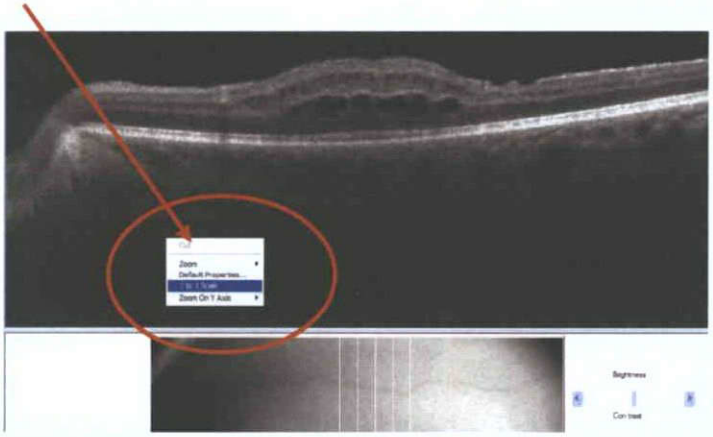
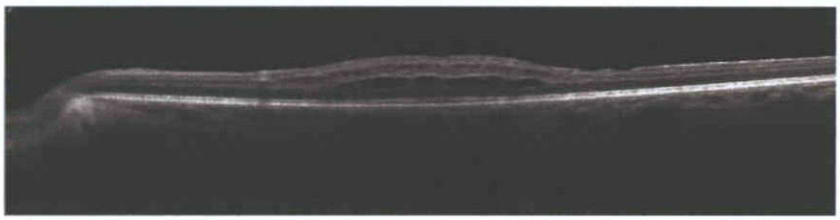
5.2.3 OCT Scan Selection

Above the Measuring Tools, there is a drop-down menu labeled "**Scans**". If the scan pattern performed had more than one image, the *different scan images are available for viewing by selecting from the drop-down menu.*

When evaluating a specific scan in the measurement view, you now have the option of showing the scan in a 1:1 ratio and altering the Y-axis display





1:1 Display option results (scan shown at 1:1 pixel presentation)

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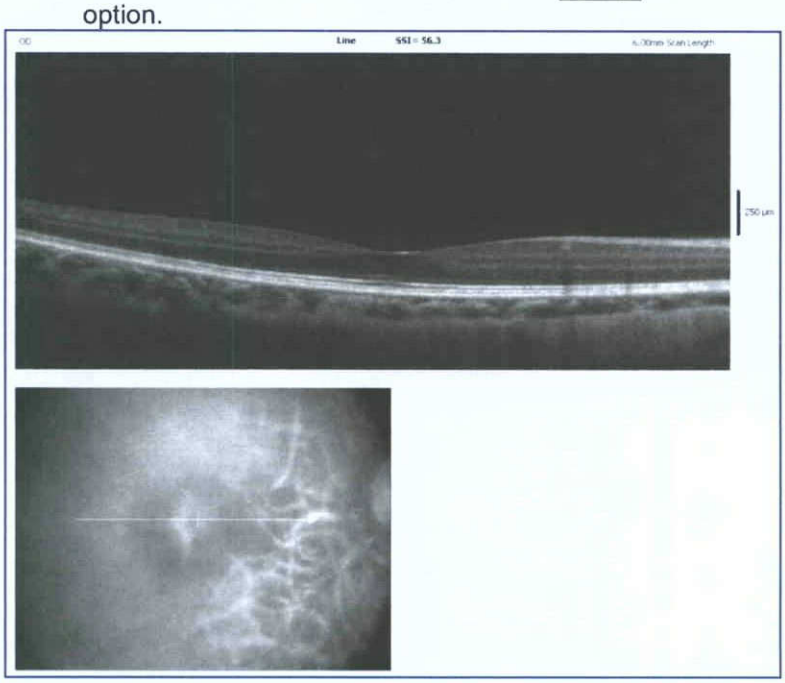
5.3 Analyze View – Retina Reports

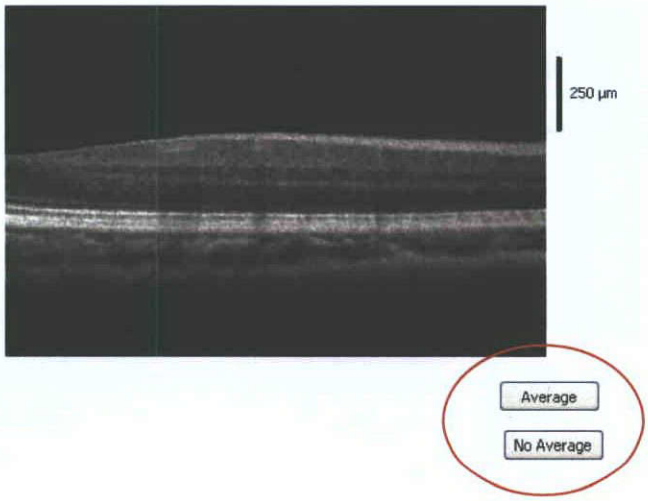
5.3.1 Line

If you used the Averaging option prior to saving the Line (or Cross Line) scan, both the Average and last single B-scan image are saved and available for review in the Analyze view.

Note: The **HD Line** and **HD Cross Line** **do not** have the average option.



Click on the [**Average**] or [**No Average**] button to select which image will be displayed.



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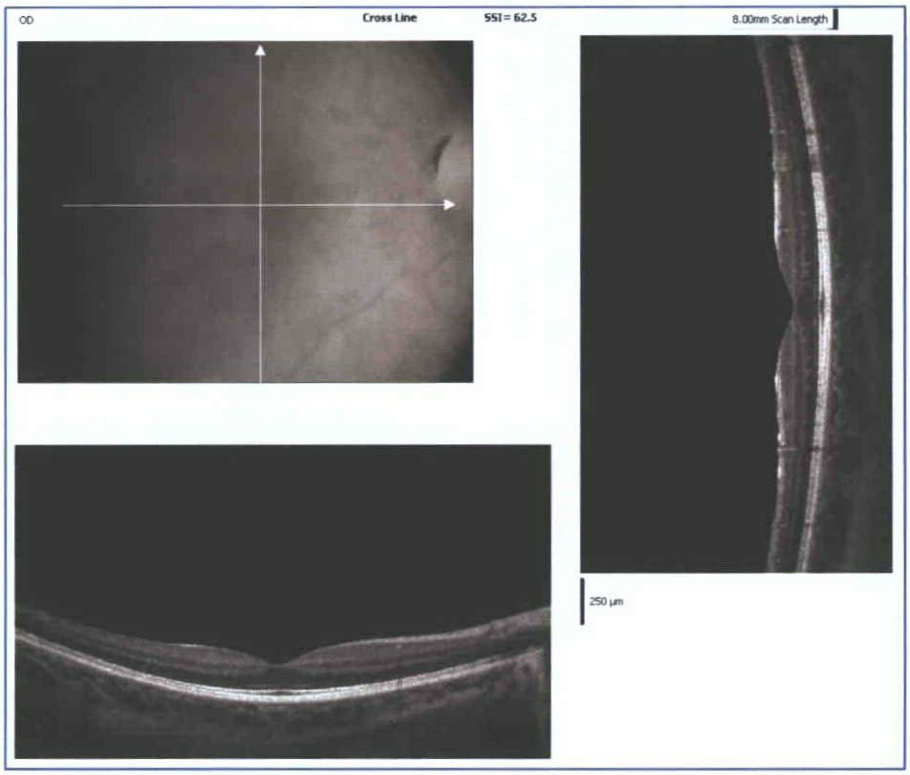
5.3.2 Cross Line



The Cross Line results are shown with the scan orientation aligned to the direction the scan was taken.

Presentation is either with **Average** or **No Average** as with the line scan.

5.3.3 Grid

Grid scan shows the exact scan location of five horizontal and five vertical scans in the grid. When this scan is captured upon capturing a 3D Reference scan, it uses registration from 3D Reference and applies a patch in this scan to show ten grid lines (five horizontal and five vertical) on the reference SLO style image to show the exact location of the scans taken.

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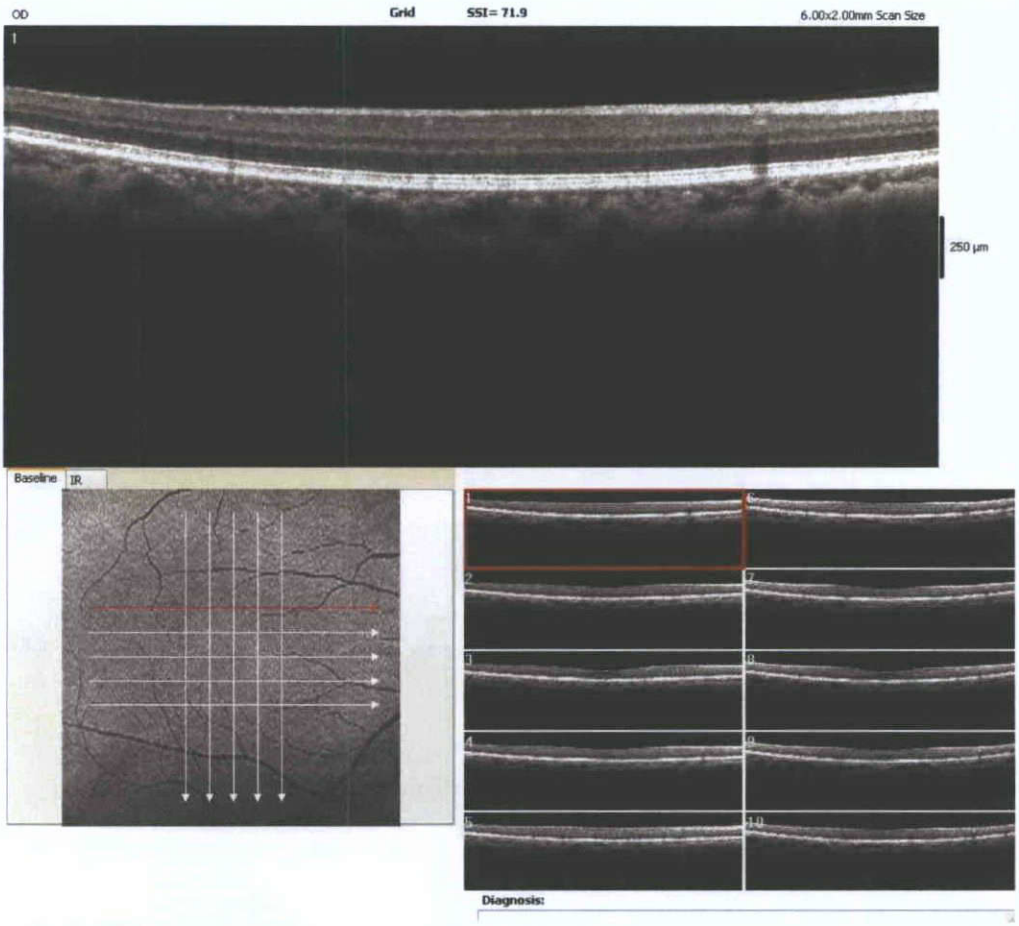
Analyze Menu



Above image shows the Grid scan in analysis mode. Note the grid lines on the reference SLO style image in Baseline Tab at the bottom left corner of the image. Mouse wheel or arrow keys can be used to scroll through each of ten scans. The red rectangle around the thumbnail of a scan denotes the scan that you're currently looking at in the large window above it. Also the appropriate grid line color changes to red as you're scrolling through the scans.

Right clicking the SLO style image and then selecting "Patch On" allows you to see the patch and how well the vessels in the patch align with vessels seen on the reference SLO style image. While the algorithms do the aligning with a very high success rate, the patch can be moved manually to align vessels on the patch and on the SLO style image. Grid lines will move with the patch giving the exact location of scans taken. See the image below. Proper alignment of the vessels on the patch with those of in the SLO style image are denoted by green color. Any misalignment is denoted by yellow.

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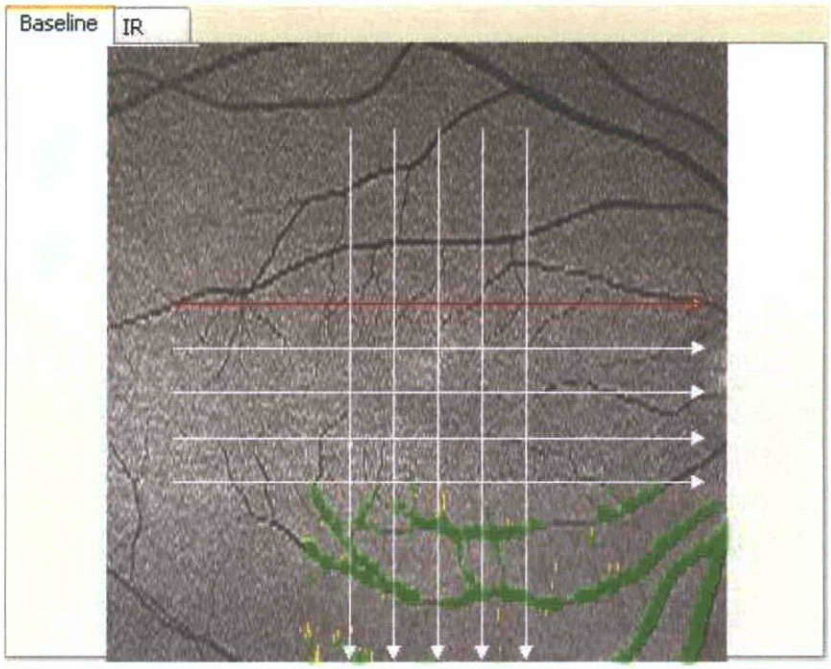

5.3.4 EMM5 Analysis Report

The EMM5 scan is registered to a reference SLO style image created by the new 3D Reference image scan. (3D Reference must exist)

The EMM5 includes a raster sampling that is acquired in the middle of the EMM5 scan (horizontal line scans – raster sample scans – vertical line scans) in an area inferior and nasal from the EMM5 scans.

This allows the sampling to capture the larger vessels lying inferior to the optic disc and use this "vessel tracing" to register to the SLO reference image.

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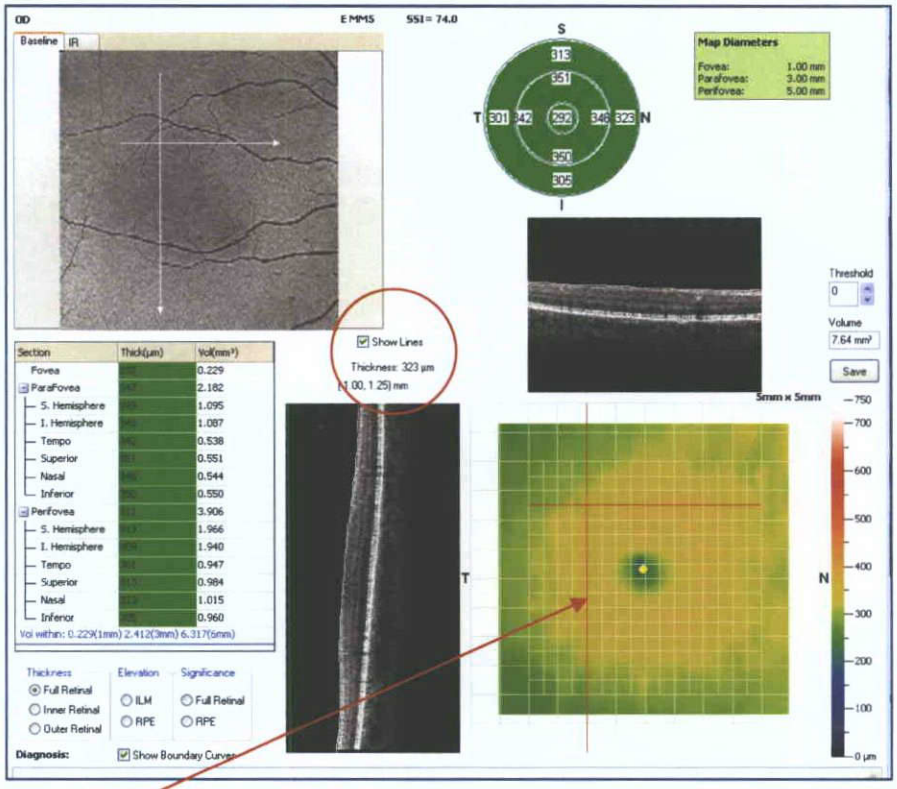
Analyze Menu



- The scan display control is active when the reference lines are Blue, and Locked when they are Red (single click will change the state from the map only)

- Macular thickness values (red circle), and retinal cross sectional images can be seen by moving the mouse cursor around the macular color-coded map. These will update while the display control is unlocked (lines are blue), and lock when the display controls are locked.

- The grid shows the EMM5 scan pattern (available scans indicated in white). The horizontal and vertical cross section image will be displayed corresponding to the color highlighted scan lines. The thickness and coordinates at the tip of the cursor are displayed in the center area of the page.

The mapping presentations for **Thickness, Elevation** and **Significance** are selectable at the bottom left of the report.

- **Full Retinal** Thickness measured from VRI to RPE layer.
- **Inner Retinal** Thickness measured from VRI to IPL.
- **Outer Retinal** Thickness measured from the RPE layer to the IPL
- **RPE** and **ILM Elevation**: show the height of the RPE or ILM relative to a reference plane. The reference plane is the best elliptical fit to the RPE boundary.

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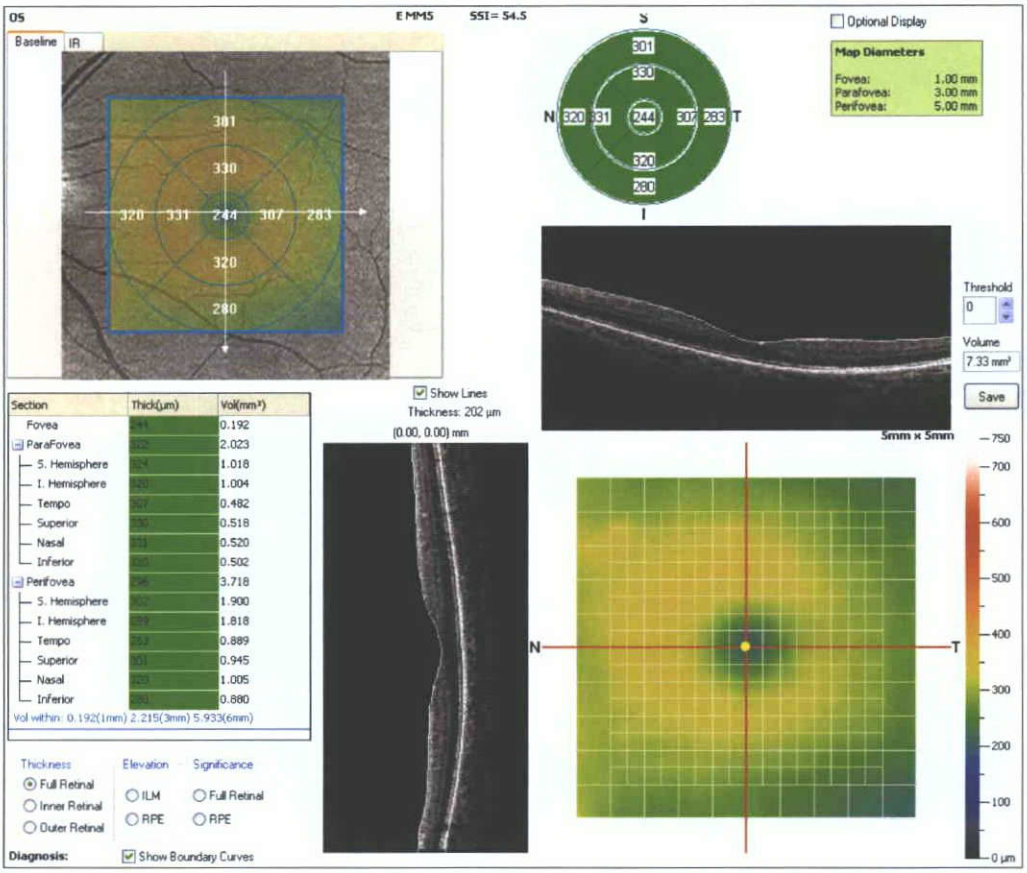

- The thickness map is further organized and presented at the top right in the nine ETDRS-like zones. (Based on the original four macular regions as defined in "***Stereoscopic Altas of Macular Diseases diagnosis and treatment", J. Donald M. Gass, Mosby, 3rd edition, volume 1, P3***.

Factors that can affect the Signal Strength Index (SSI):
EMM5 scan pattern not centered on the fovea: During the EMM5 scan, if the patient does not maintain good fixation, the fovea may not be in the center of the scan pattern. All measurements assume the fovea is in the center of the scan. If it is not, then the measurements will be affected. If the fovea is not in the center of the scan, it can be moved by the user manually. This will ensure the measurements come from the expected locations. The results should not be used if the repositioned fovea causes some measurement areas to be outside the scan pattern.

Check the layer segmentation accuracy of the EMM5 scan: The segmented layers for EMM5 scans are the ILM (Inner Limiting Membrane), IPL (Inner Plexiform Layer), and RPE (Retinal Pigment Epithelium). Check the segmentation lines for accuracy, and make adjustments as necessary. The ILM segmentation line should be at the retinal

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surface at the ILM. The IPL segmentation line should be at the bottom of the IPL layer. The RPE segmentation line should be in the middle of the RPE layer. If the segmentation lines are not accurately placed, the thickness measurements will be affected. If the user performs any manual correction, the results will be valid and the scan can be used.

Overall precision results with the EMM5 scan for normal, retina patients, and glaucoma patients:

EMM5 Full Retina Volume			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	0.63 (0.03)	0.64 (0.07)	103.02 (12.22)
Repeatability SD* (Min, Max)	0.003(0.002, 0.006)	0.004(0.002, 0.010)	2.40(1.78, 2.87)
Reproducibility SD** (Min, Max)	0.005(0.003, 0.015)	0.007(0.003, 0.011)	2.53(1.78, 3.52)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

EMM5 Full Retina Fovea			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	243.61 (26.00)	267.15 (73.32)	246.22 (22.14)
Repeatability SD* (Min, Max)	2.57(1.66, 2.57)	2.96(1.83, 3.15)	3.01(1.95, 3.01)
Reproducibility SD** (Min, Max)	17.72(1.66, 17.72)	13.78(1.83, 13.78)	3.01(2.05, 5.80)

EMM5 Inner Retina TSNI			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	112.83 (9.16)	113.04 (15.05)	103.02 (12.22)
Repeatability SD* (Min, Max)	1.38(0.88, 1.72)	2.52(1.57, 3.12)	2.40(1.78, 2.87)
Reproducibility SD** (Min, Max)	1.70(0.88, 7.09)	3.02(1.57, 6.59)	2.53(1.78, 3.52)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

For details on the clinical study and the clinical precision for RTVue scan measurements (repeatability, reproducibility), study information is available in the Appendix –RTVue Precision

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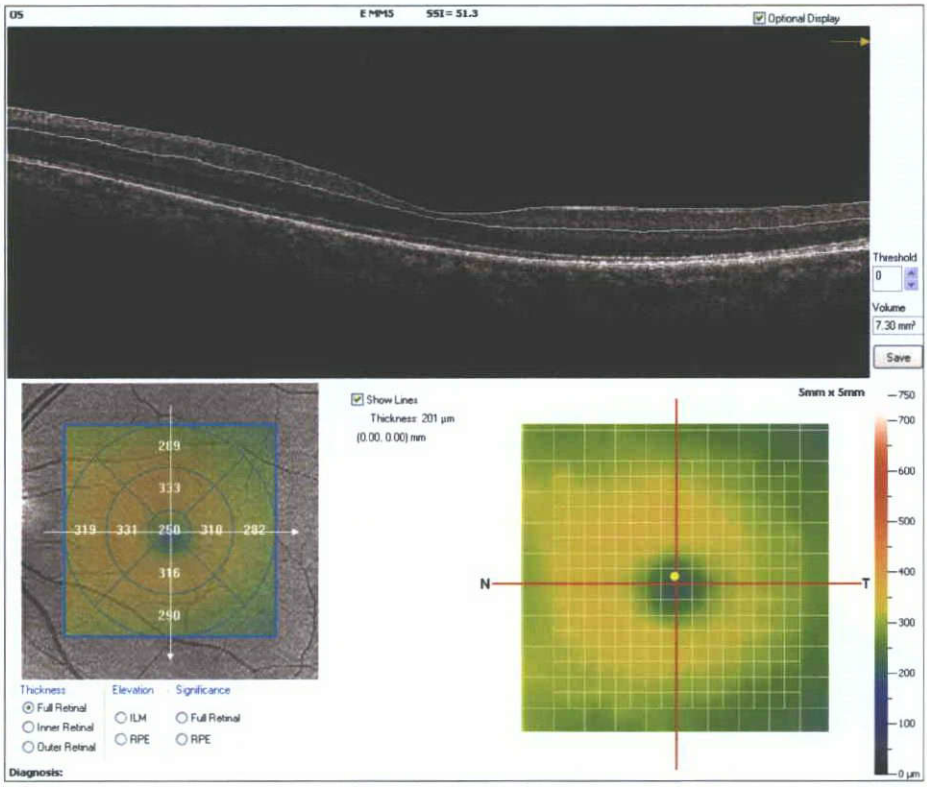
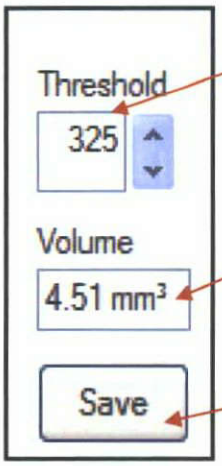
5.3.5 Alternate EMM5 Report / Printout



The check box at the top of the EMM5 report will bring up the alternative presentation of a single large representative scan and the correlating location on both the thickness map and the SLO reference image.

5.4 Volume Contouring and Measurements



User can define a threshold level (numerical value – microns) for edema or elevated pathologies, and the map will trace a contour around all tissue exceeding the value entered.

The Total Volume of the tissue exceeding the threshold is displayed real-time in the Volume field.

This threshold, Volume and segment (Full, Inner or Outer) can be saved by selecting the [Save] button. Information is added to the table at the left of the report display.

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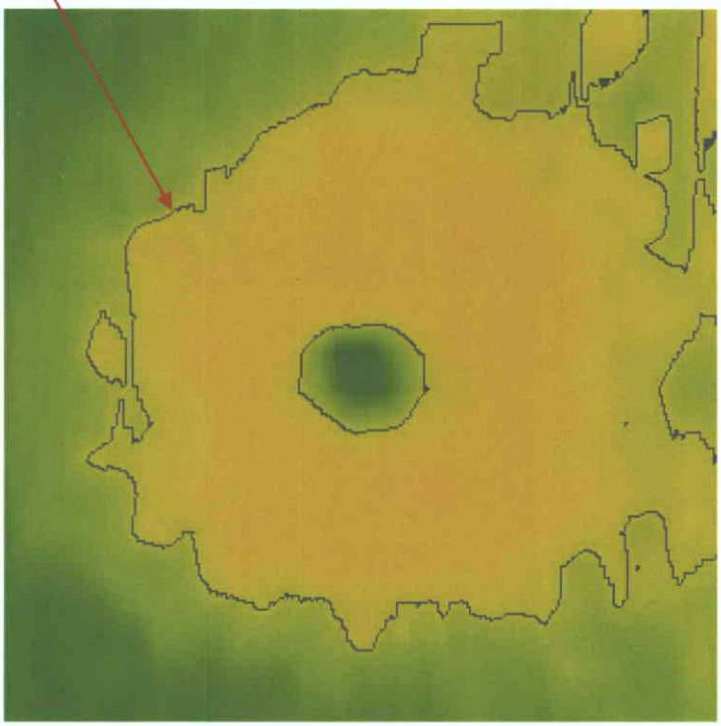
- Total volume exceeding the threshold value is outlined by contour tracing



(EMM5 Thickness Map – Without scan line indicators)

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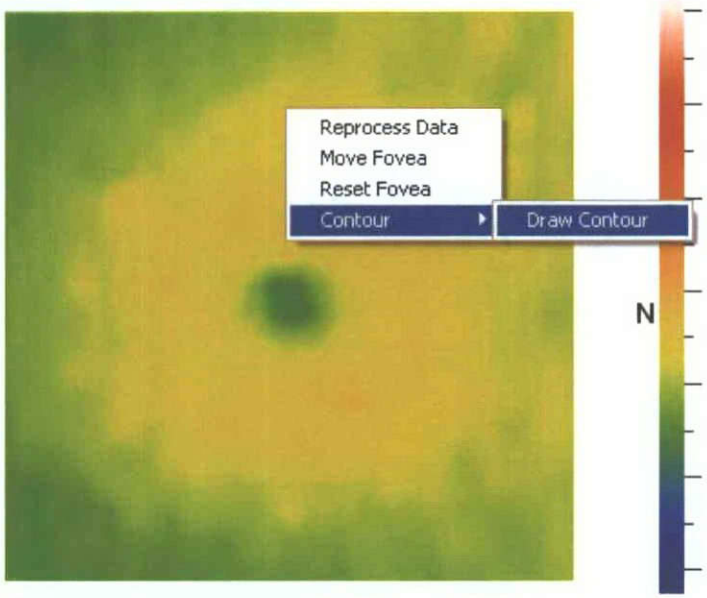
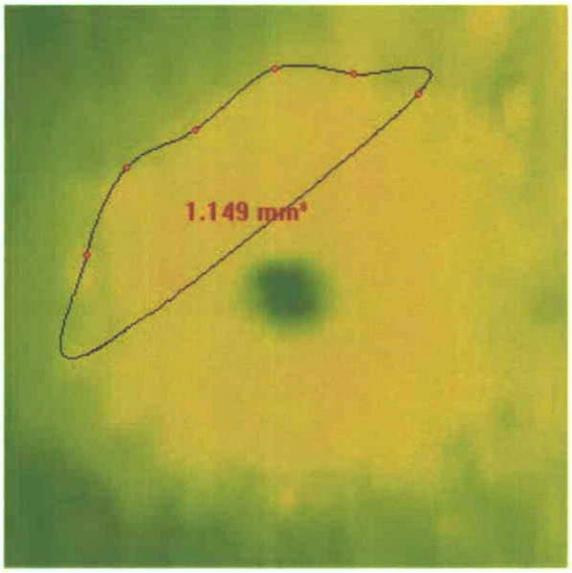
5.4.3.1 Custom Drawn Volume Contouring

You may also freehand draw the outline of a specific area on the map and the resulting volume will be displayed also real-time.

- Right-click on the map and select Contour>Draw contour





- Use the left mouse button to click on points around the area you are interested in.
- Contour line is black and active while drawing. Resulting volume is rendered real-time as you go.
- Double click on the last point to end the drawing and post the final shape and volume. Contour will turn Red to confirm final form.

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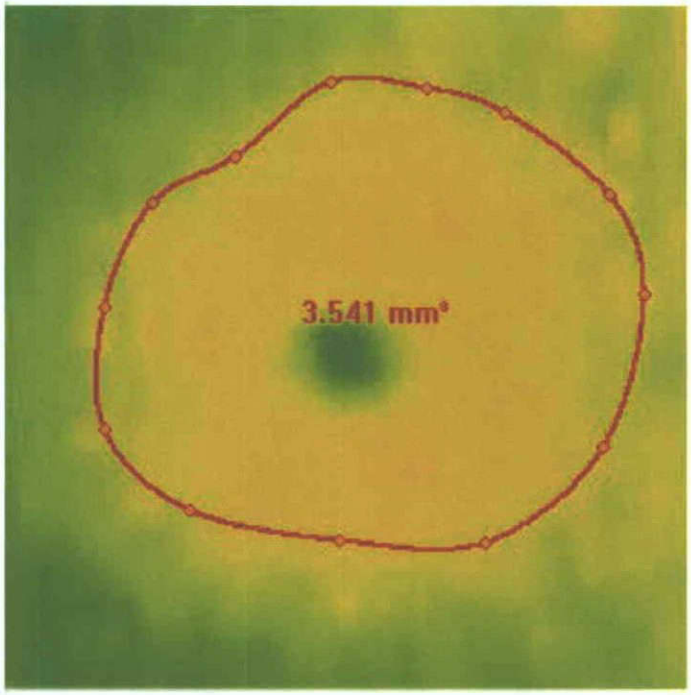

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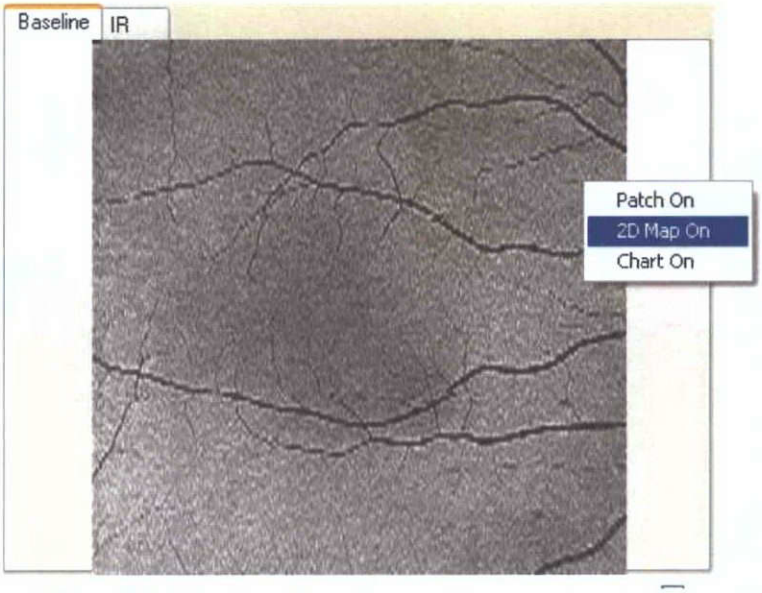
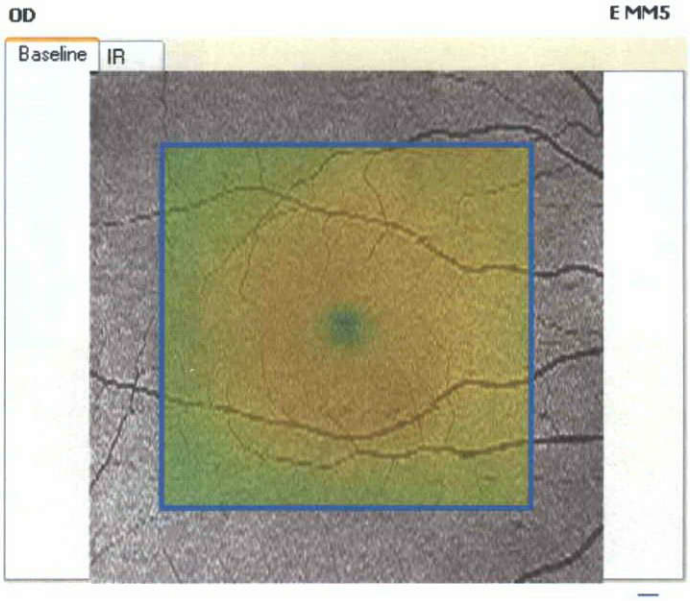
5.5 Overlay Options for Reference Fundus Image

- In the Reference image in the upper left of the EMM5 report screen the user has the option of superimposing the registered map (in the lower right displaying either thickness or elevation) over the image, and/or the ETDRS map/results.

- These options are available by right-clicking on the reference image



- 2D map is placed on the reference image
- Display of map and map on reference image are both updated when selecting the various thickness and elevation option presentations



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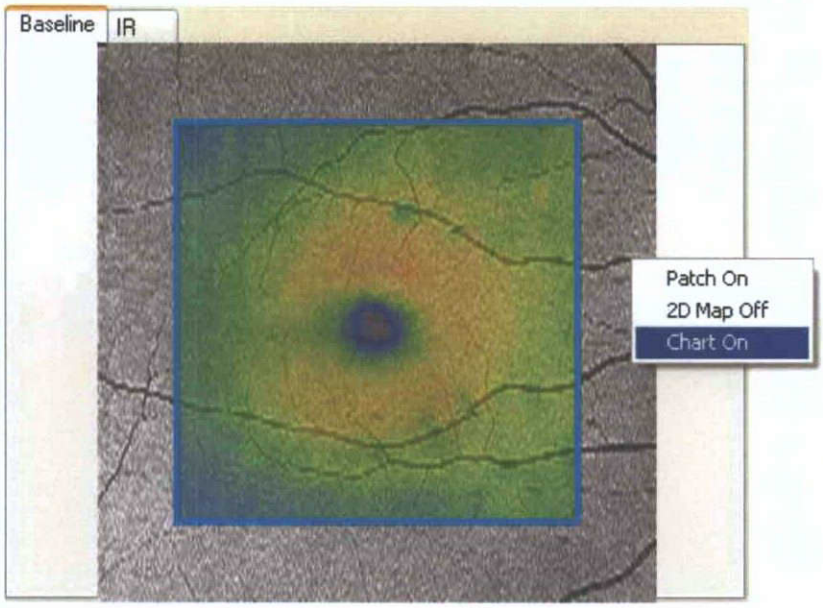
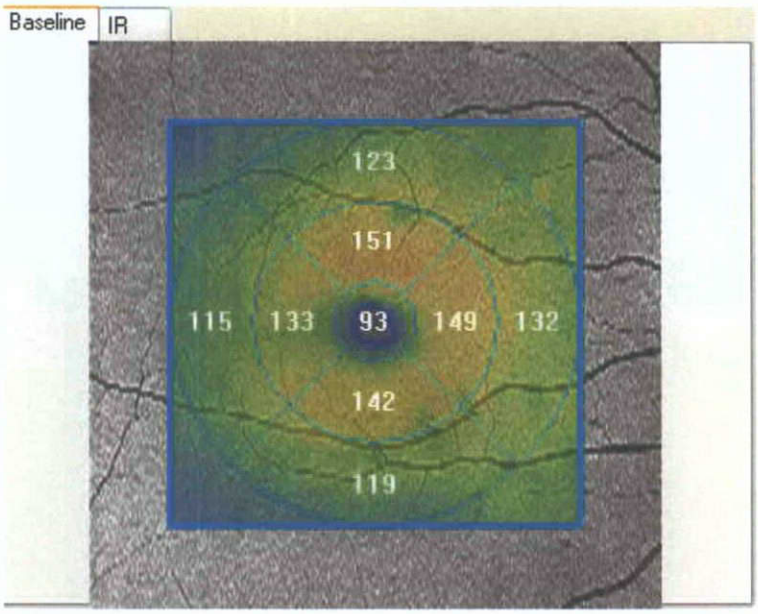
- Both the 2D map and the ETDRS grid and results may be displayed on the reference image at the same time or individually



- The Color reference for the Normative Database comparison is not shown in the overlay of the ETDRS grid when both (ETDRS and 2D map) are in overlay. **NOTE: This is the default presentation of the reference image.**



- The Color reference for the Full Retina thickness is shown when only the ETDRS grid is superimposed.

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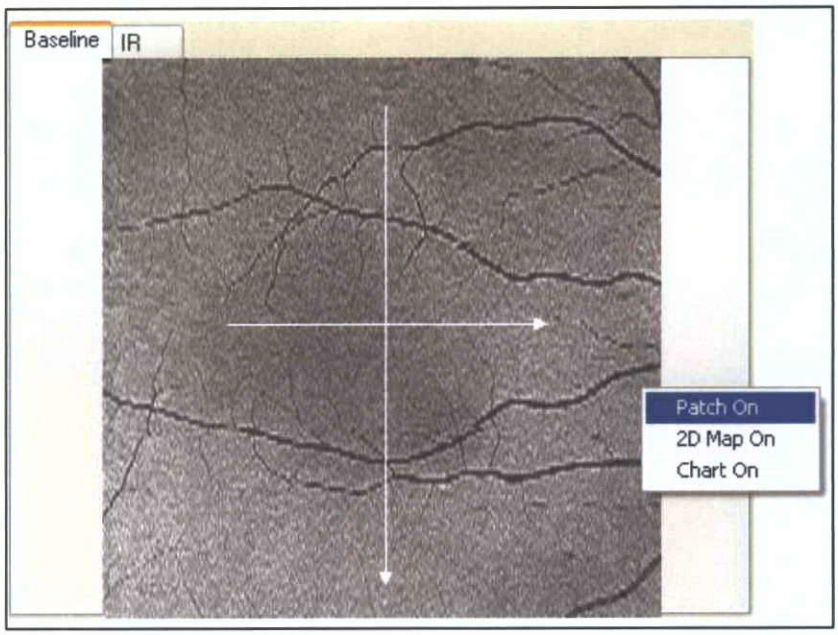
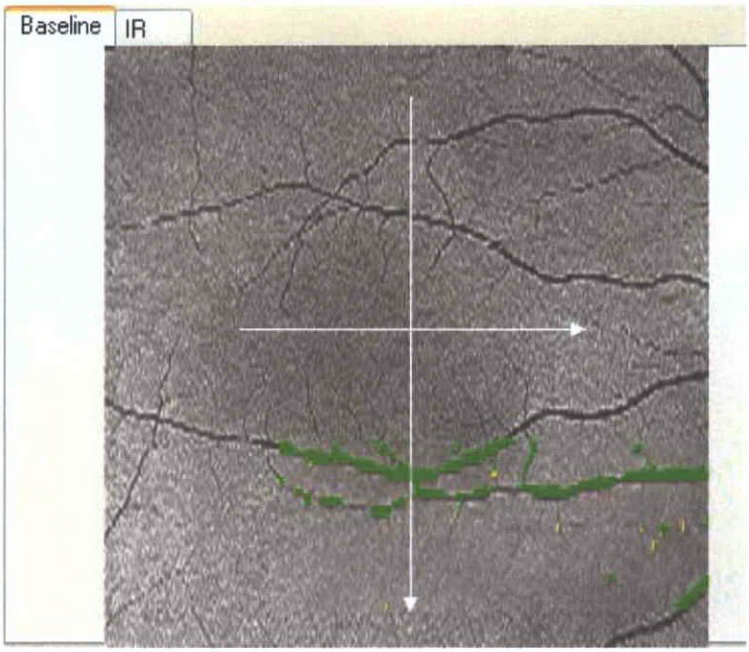
- The **Patch** overlay is the results of the sampling raster taken during the EMM5 scan. This is used to obtain the vessel tracing for the registration to the Reference image. You can see the Patch location using the right-click option.



- When the Patch is displayed, it will show green vessel tracings when aligned (as seen in the image below). If it is moved from its location, the tracings turn yellow indicating a deviation from the vessel match.



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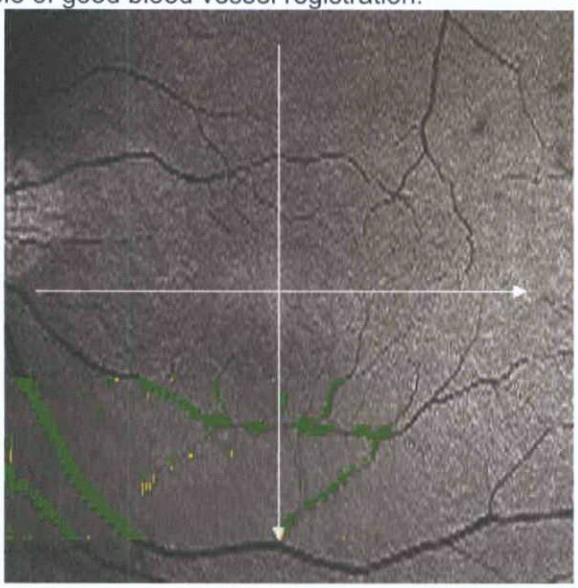
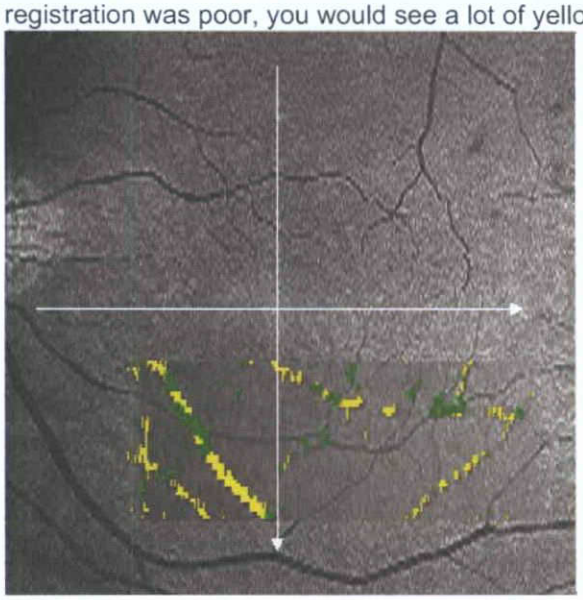
Example of poor blood vessel registration:

Below is an example of good blood vessel registration.



If the blood vessel registration was poor, you would see a lot of yellow in the image.



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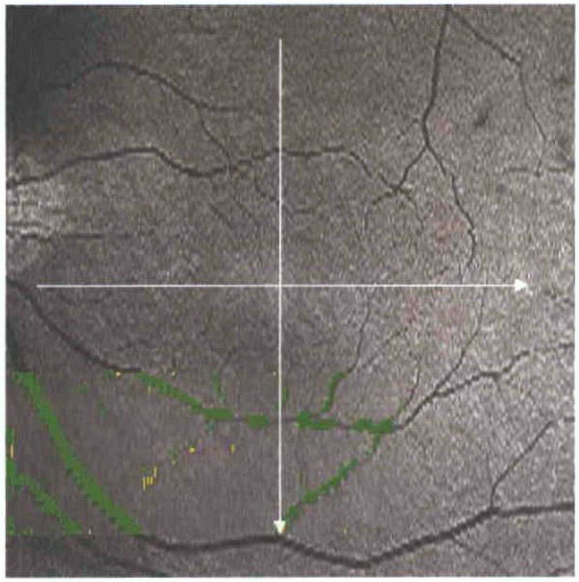
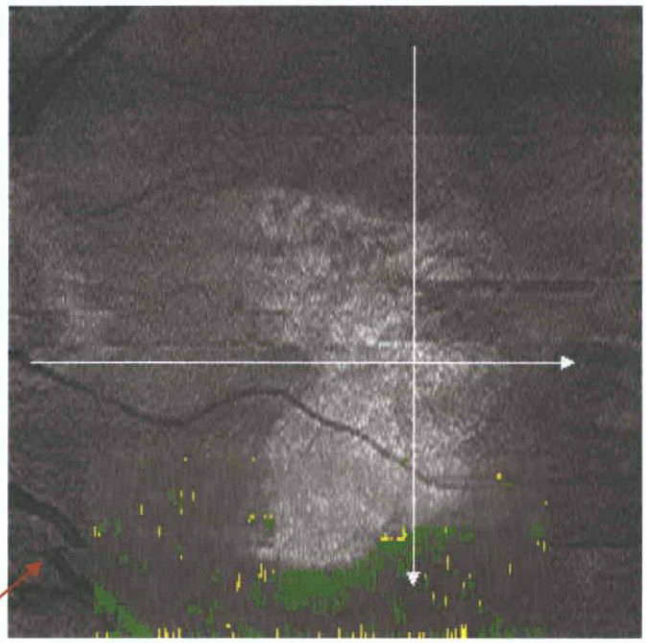
You can then manually move the patch area with your mouse until the blood vessel patterns are matched and you don't see any more yellow.



Examples of eye movement which indicate rescanning may be necessary:

Eye movement can cause poor blood vessel detection. Eye movement is indicated by the break in blood vessels within the scan. It is recommended to retake the scans with patients who displays eye movement during the scan.



Eye movement indicated by the break in the blood vessel pattern

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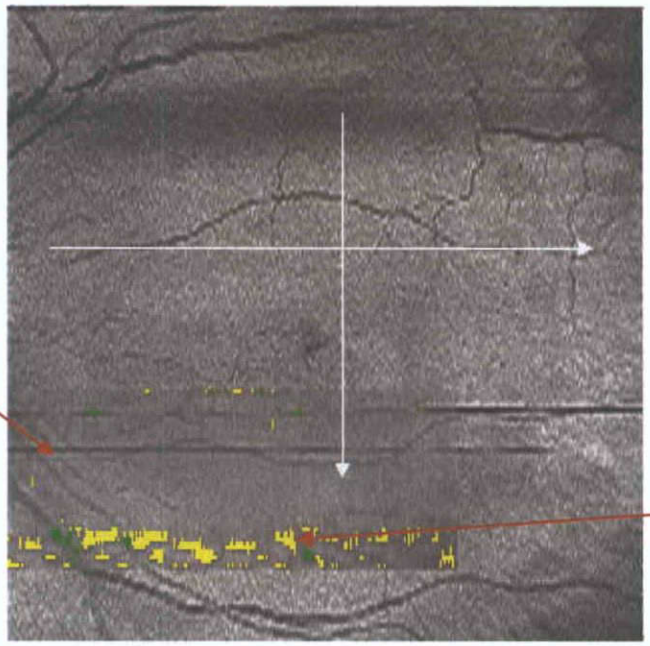
Another example of eye movement causing registration failure and poor blood vessel detection is shown in the image below. Eye movement is indicated by the dark horizontal lines within the scan. The below image is a patient with Diabetic Retinopathy who displays eye movement during the scan. The image also displays no blood vessel detection in the patch area - evident by the yellow patterns. In cases like this, it is also recommended to retake the scans.



5.5.1 EMM5 Change Overview Report

The EMM5 change analysis report shows an overview of up to four individual visit results (A baseline exam and three follow-up exams) for a specific patient eye. (See section 6.1 for detail on Normative change overview report)

The threshold input and the resulting automatic contour drawing are available in this report and apply to all four visits displayed.

- The value inserted causes all of the 2D maps in the top row to delineate the volume of all tissue above the defined threshold value.
- The volume defined by the contour outline is displayed, providing clear reference of the change (positive or negative) of any edema/elevation.

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- Value is entered in the **Threshold** field in the upper right

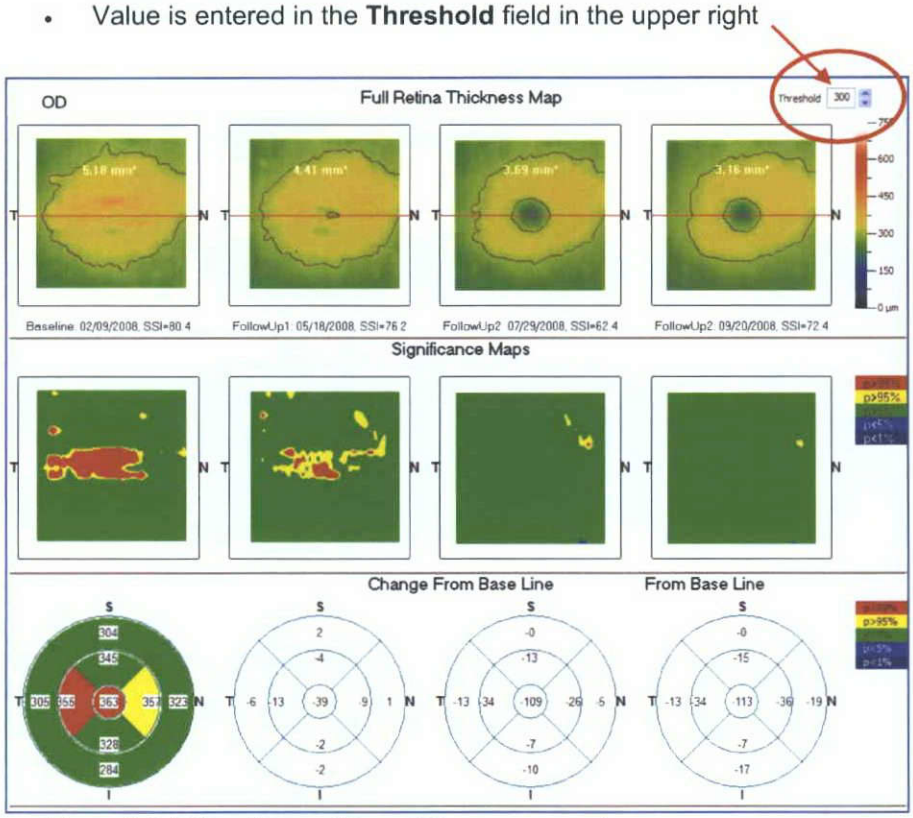
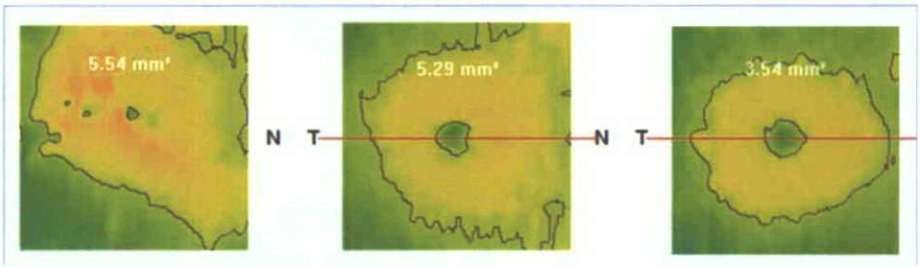


Figure 5.4.5 (Baseline and three follow-up exams)



5.5.2 *Retina Normative Database*

RTVue software contains the Normative Database that allows comparison of a patient's retina structure (macula thickness and RPE elevation) with "normal" patients in the same at segment. This comparison to "Normal" provides the clinician with an objective metric to use in the overall diagnosis.

The EMM5 Normative presentations are:

- Full Thickness Significance – selecting this option displays the significance, of the thickness deviation from normal of the scanned eye. Parameters include within normal for both edema and ischemic conditions.

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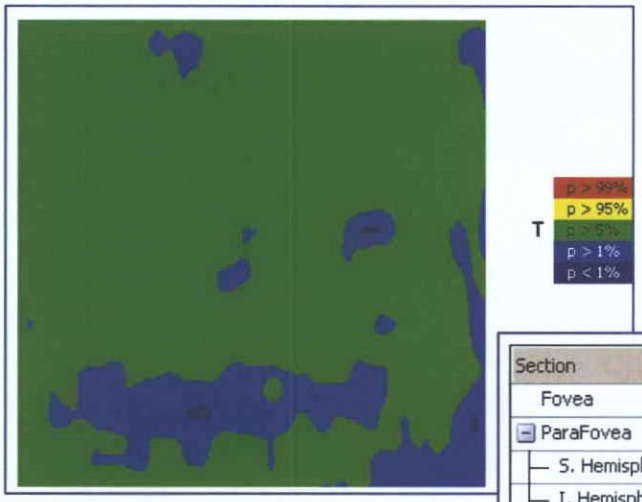
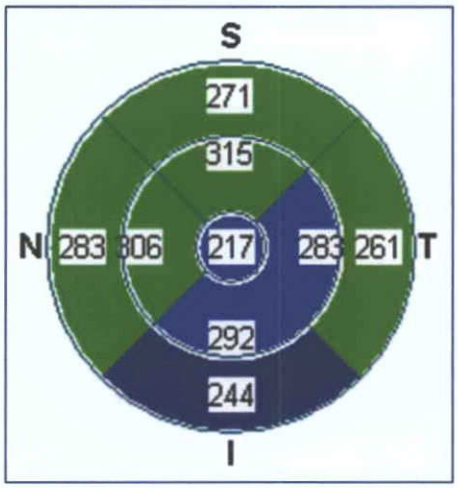


EMM5 Significance Map with Normative segmentation legend

Section	Thick(µm)	Vol(mm³)
Fovea	217	0.170
ParaFovea	299	1.880
S. Hemisphere	305	0.959
I. Hemisphere	293	0.921
Tempo	283	0.445
Superior	315	0.494
Nasal	306	0.481
Inferior	292	0.459
Perifovea	265	3.328
S. Hemisphere	274	1.722
I. Hemisphere	256	1.606
Tempo	261	0.820
Superior	271	0.852
Nasal	283	0.890
Inferior	244	0.766
Vol within: 0.170(1mm) 2.050(3mm) 5.378(6mm)		

Normative DB Metrics



ETDRS Map with average values

- RPE Elevation Map – this option displays the patient's RPE tracing compared to a normalized ellipse fit. Elevation is based on +/- 80% of the RPE (24 microns), and amplitude of +/- 150% of the RPE thickness (45 microns).

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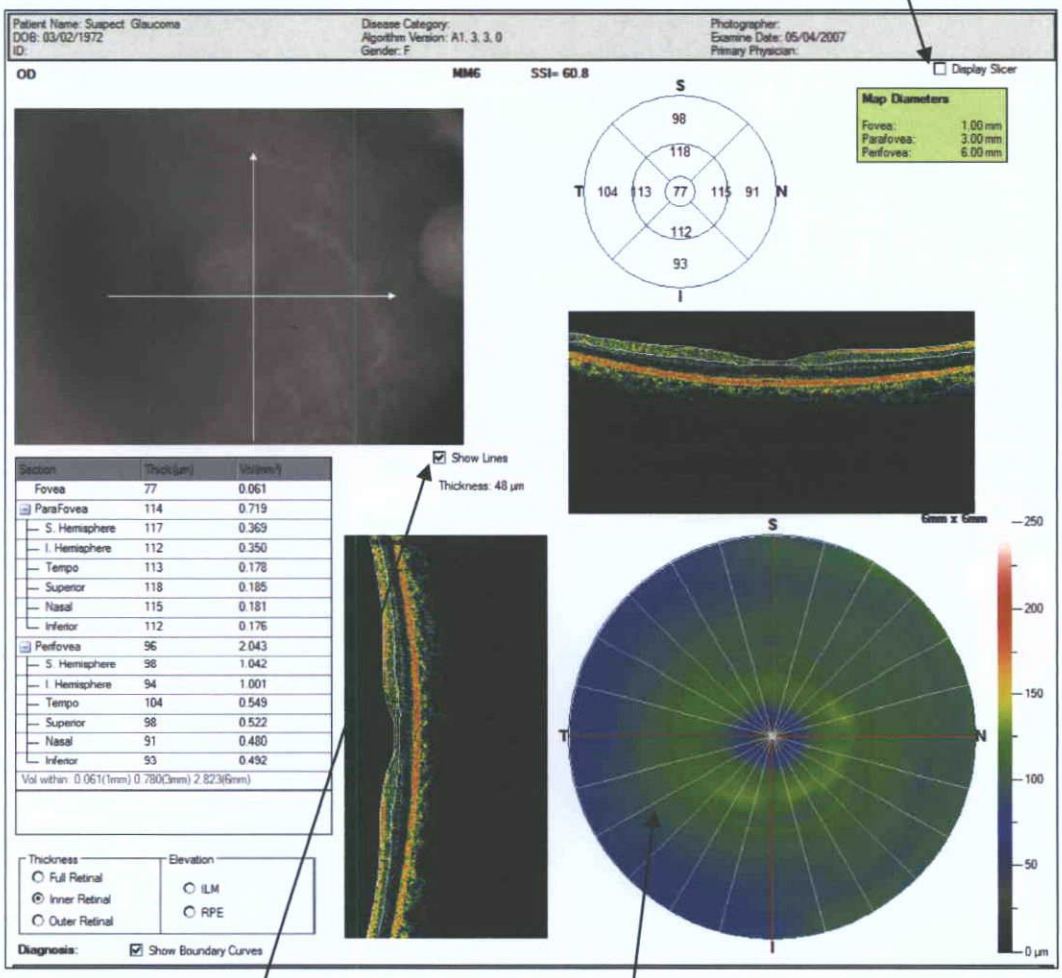
5.5.3 MM6 Analysis Report

The MM6 (12 Radial scans) maps the central macula using a radial scan pattern more familiar to those who have had previous OCT technologies.

Note: The MM6 is not included in the Normative Database collection that is in process.

Display Slicer option: Toggles the display of the MM6 between the standard presentation and as Radial Slicer presentation, including all 12 scans



Show Lines: This option toggles the map display between showing with or without scan reference lines. Map graphic without lines works well for case study presentations

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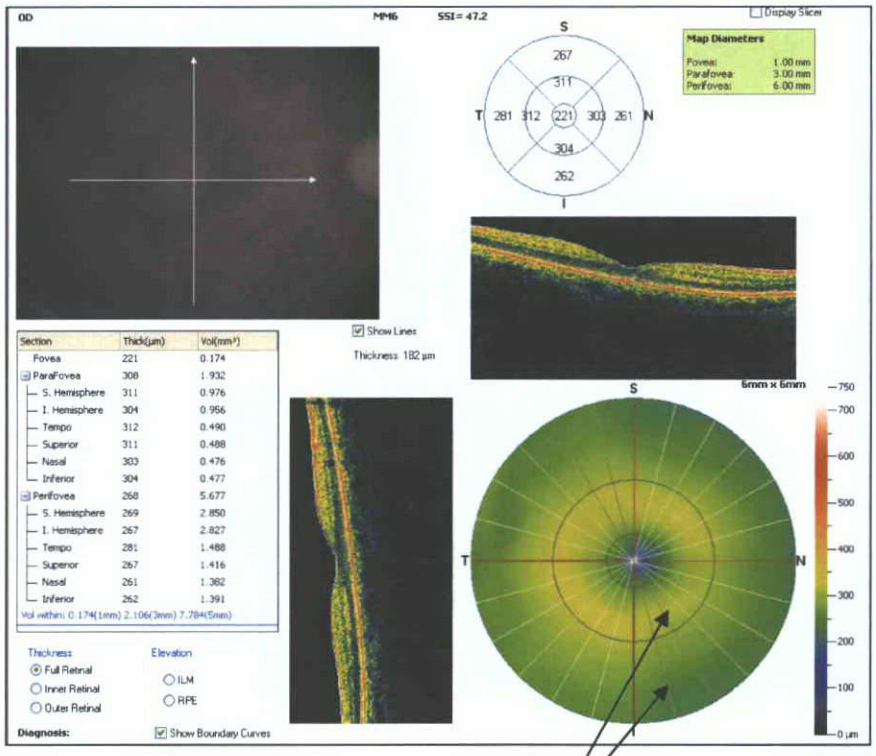
5.5.4 Missing Scans Due to Blink

For all map patterns saved which included missing or dropped B-scans (due to blinking, weak signal, eyelash obstruction, iris clipping, etc), the scans not included in the map rendering are indicated in gray instead of white (scan indicator lines).

For missing scans indicated in any map, the raw B-scans not used should be reviewed by the clinician and the map data in this area should be reviewed with caution.



Missing lines indicated in gray. Date in this area is interpolated based on the nearest adjacent complete scan data.

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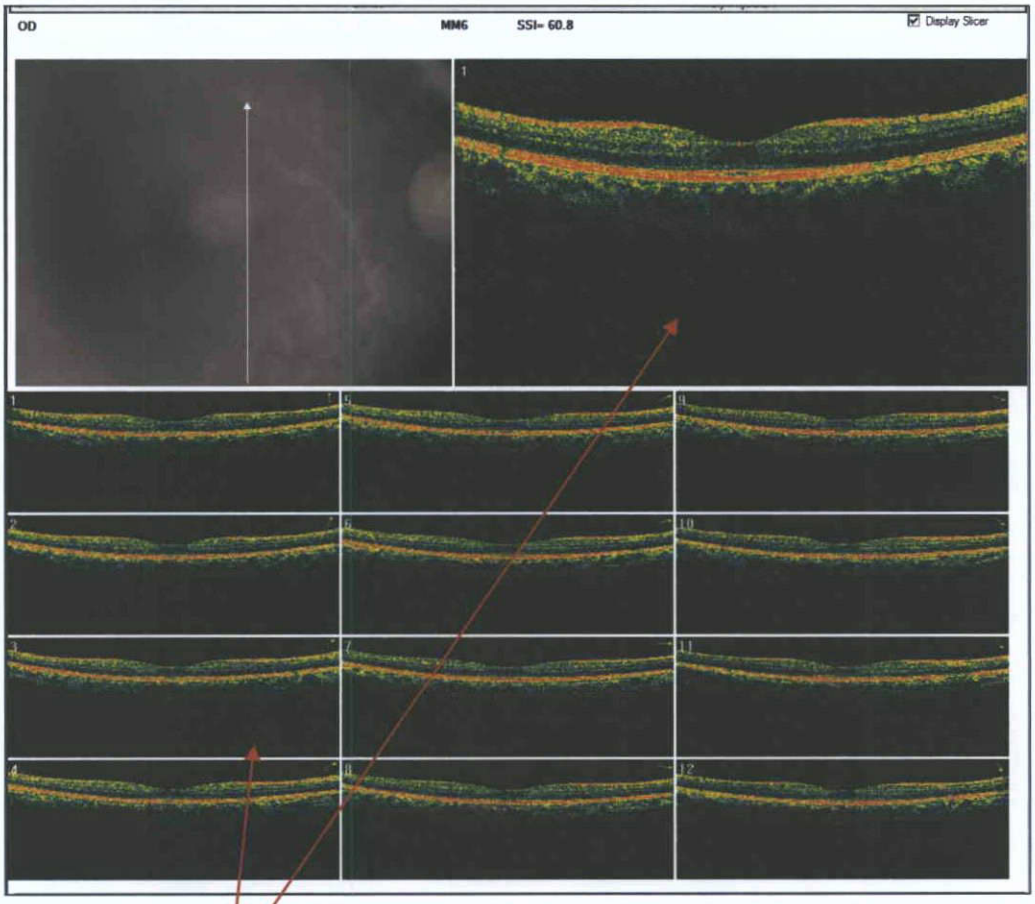
MM6 Slicer (Option) Display



Click once on any scan to display it in the larger window at the top right.

Double click on any scan to go immediately to the measurement mode presentation.

Note: The **Radial Raster** and the **Raster** report displays have two ways of presenting the scans for view and printing. At the top you will find the selection options of One page or Two page (larger scan images) presentations.

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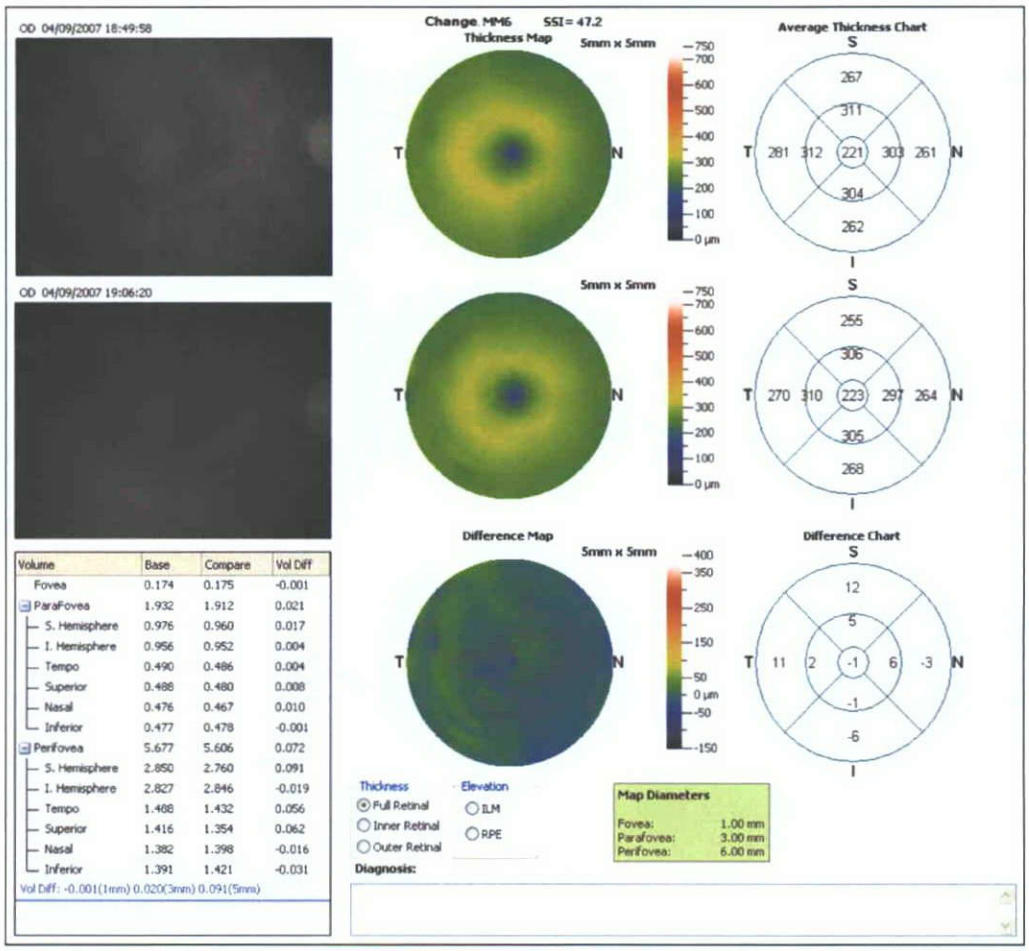
5.5.5 *MM6 Change Analysis Report*

The MM6 change analysis shows the difference between two MM6 analyses. To speed up the comparison results, it is better to analyze each individual MM6 scan first before making comparisons.



Please Note:
Change analysis is a simple difference map without any statistical adjustments. The values are simple differences and may not be statistically or clinically significant.

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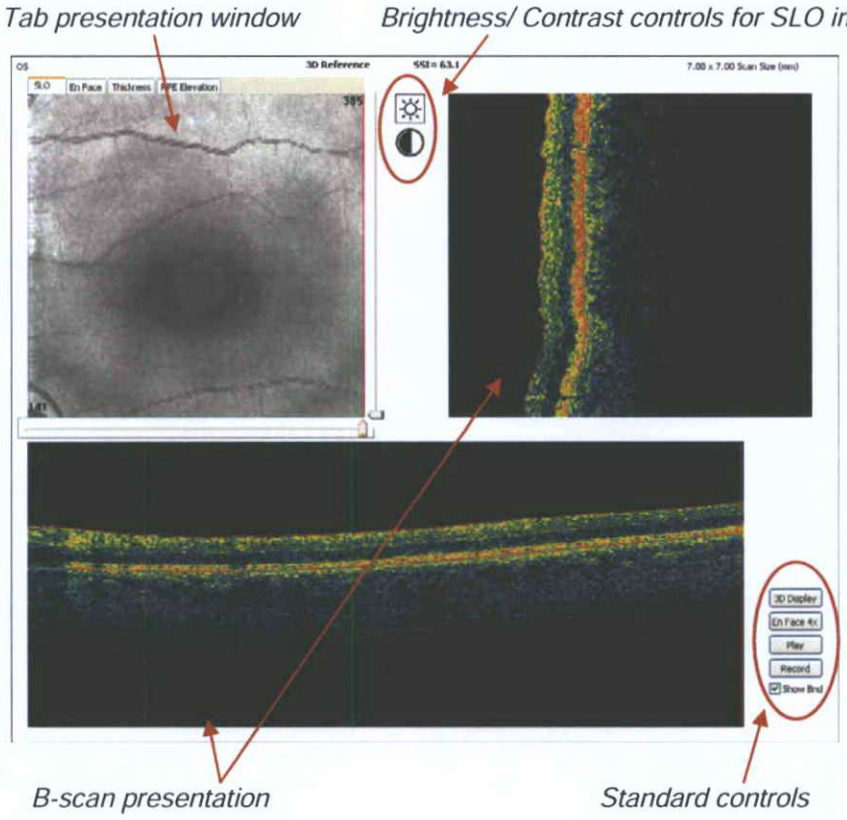
5.6 3D Presentations

The 3D scan presentations are updated considerably from the previous version. The following viewing options are indicated by the tabs SLO, En Face, and so forth.

- **SLO**: This view shows a SLO-style image created by the sum of all the C-scans, producing a high contrast "En face" image.
- **En face**: This view presents the sum of the c-scan planes indicated in the thickness value field.
- **Thickness**: Presents the thickness with log scale of user selectable segmentations for Full, Inner and Outer retina. The 3D Reference and 3D Macular scan displays an ETDRS thickness map in the thickness tab when the scan size surpasses 6.00 x 6.00 mm. The ETDRS map is a traditional ETDRS map consisting of 1mm, 3mm, and 6mm diameter circles. Note that the ETDRS map is always in the center of the window. It may not be centered on the fovea.
- **RPE Elevation**: Presents the elevation of the RPE from a normalized plane. This is available for 3D Macular and 3D Reference scans.



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Analyze Menu

Standard controls

- **Brightness:** Controls brightness settings for the SLO image

- **Contrast:** Controls contrast settings for the SLO image

3D Display

- **3D Display:** Brings a separate full sized screen for a 3D presentation of the OCT scan.

En Face 4x

- **En Face 4x:** Brings a separate full sized screen displaying 4 En Face views of 4 separate layers of your choosing.

Play

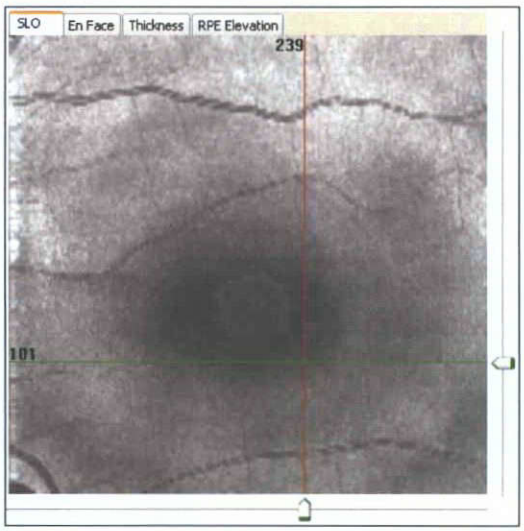
- **Play:** Sequentially plays through the B-scans and 3D display while showing the reference in the SLO-style image.

Record

- **Record:** Clicking 'Record' will prompt a new window to pop up asking for a folder to save in. The file recorded will be saved in an .AVI format. Click 'Stop Recording' to finish recording.

Show Bnd

- **Show Bnd** (boundary)**:** Displays or removes the algorithm tracing



- **Green line:** Position of horizontal B-Scan.
- **Red line:** Position of vertical B-scan
- Clicking anywhere on the window (shown to your left) will automatically show corresponding horizontal and vertical B-scans.
- Note: 3D Volume and 3D Display are memory intensive functions. Frequent usage of these features may slow down the processing of scans.

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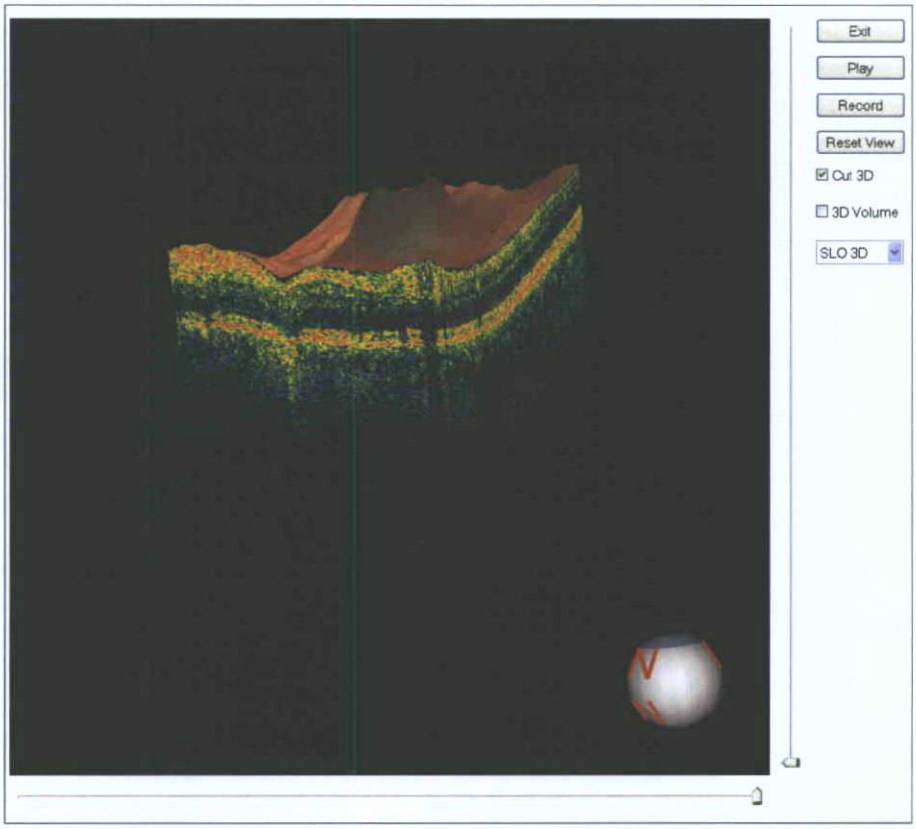
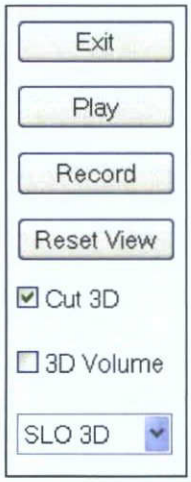
3D Display

The 3D display presentation appears in a separate window to give a more detailed view of the 3D model. The model offers multiple views to choose from: SLO 3D, Full Thickness, Inner Thickness, Outer Thickness, and RPE Elevation (available for 3D Macular and 3D Reference scans). These can be chosen from the drop down menu in the right panel.





- **Orientation Legend:** Shows orientation based on TSNIT.
- **Exit:** Closes the 3D Display window.
- **Play:** Sequentially plays through the B-scans on 3D display.
- **Record:** Clicking 'Record' will prompt a new window to pop up asking for a folder to save in. The file recorded will be saved in an .AVI format. Click 'Stop Recording' to finish recording.
- **Reset View:** Resets the image to a top-down view.
- **Cut 3D:** Option to have 3D image "cut" as the B-scans are reviewed.
- **3D Volume:** This option presents entire data captured in the 3D block including the tissue in the vitreous just above the ILM plane.

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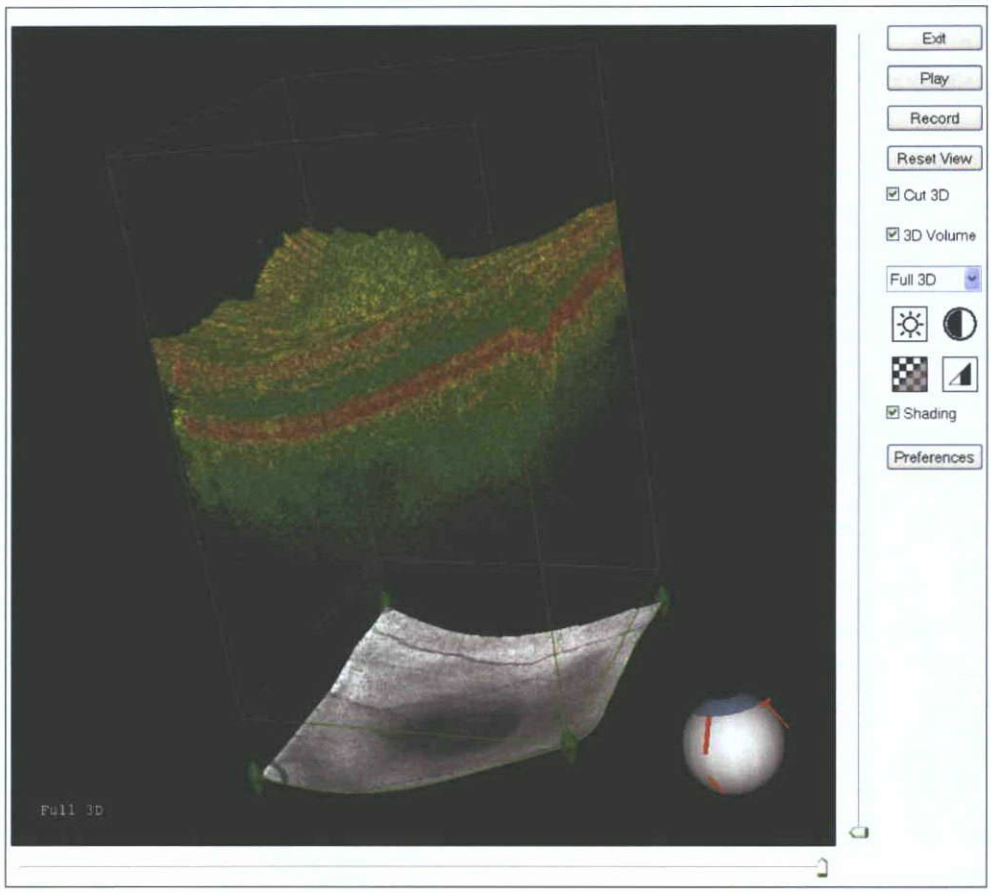
3D Volume

The 3D Volume rendering shows an SLO-style image super imposed to the bottom of the 3D image. The 3D Volume presentation can be accessed by selecting the '3D Volume' option in 3D Display.

PLEASE NOTE: 3D features introduced in this version are intended for the RTVue PC system as it applies to the specifications listed in Section 9.1D. PC systems that do not adhere to the specifications may experience less than optimal performance when using 3D features.



Like the 3D display, the 3D volume has the option of displaying multiple views. The different views can be modified by clicking the 'Preferences' button.

- **3D Transparency:** Changes the transparency of the 3D volume model

- **3D Volume Low Cut Off:** Filters out additional noise in the 3D rendering.

- **Shading:** Affects the shading of the 3D volume model. Turning off 'Shading' will also disable the SLO mounted on the bottom of the 3D model.

- **Preferences:** Brings up specific options for the 3D Volume

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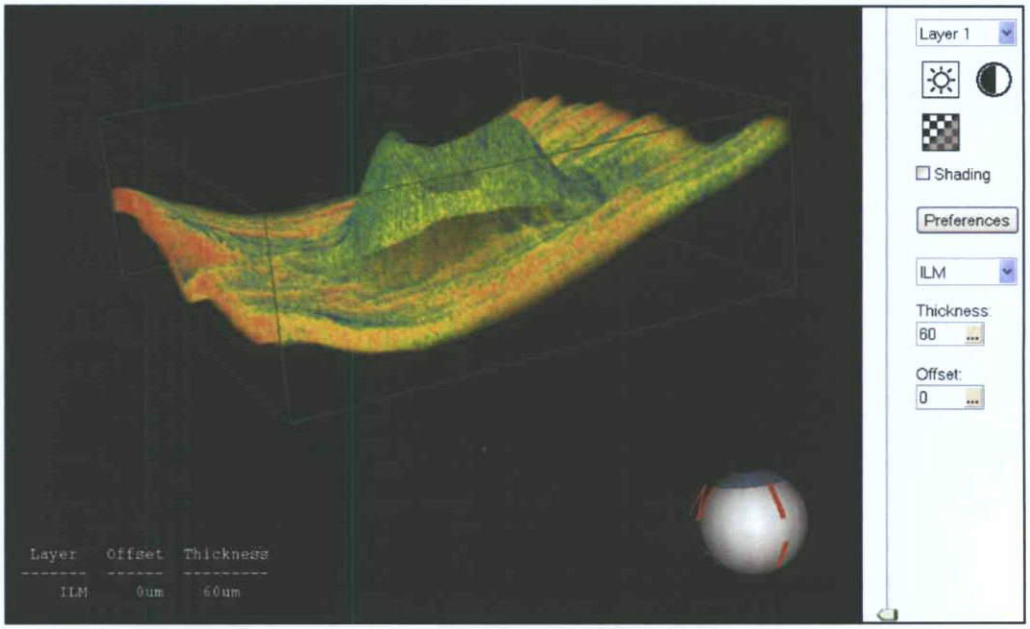
selection.

- **Layer Selection:** Choose which view to present in the 3D Volume window. Layers 1-4 are user selectable and can be set in 'Preferences'. Selecting Vitreous gives a vitreous view with a white background.



3D Volume view of ILM layer.

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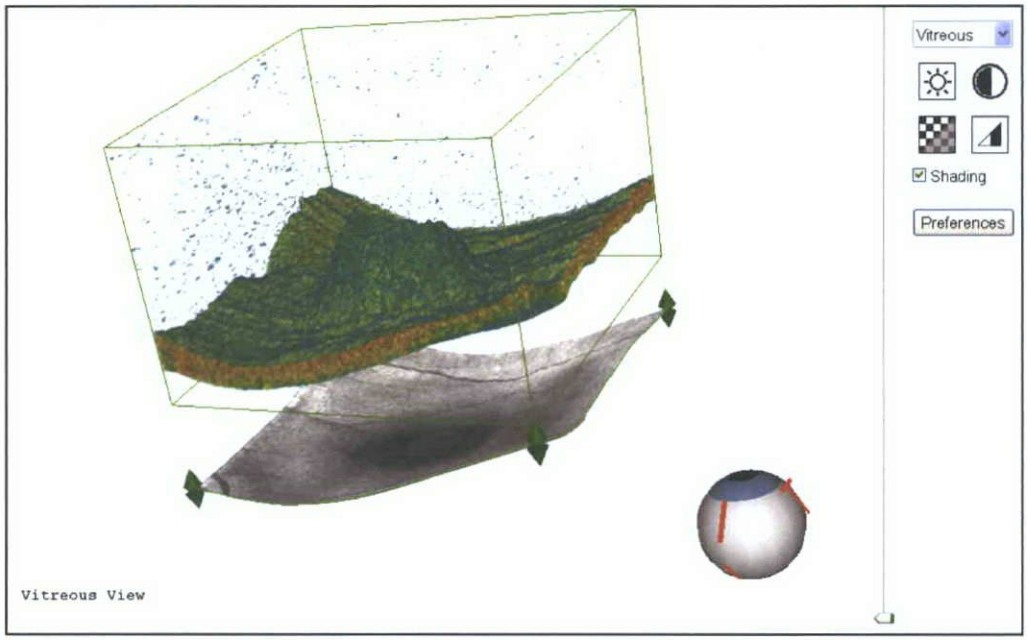
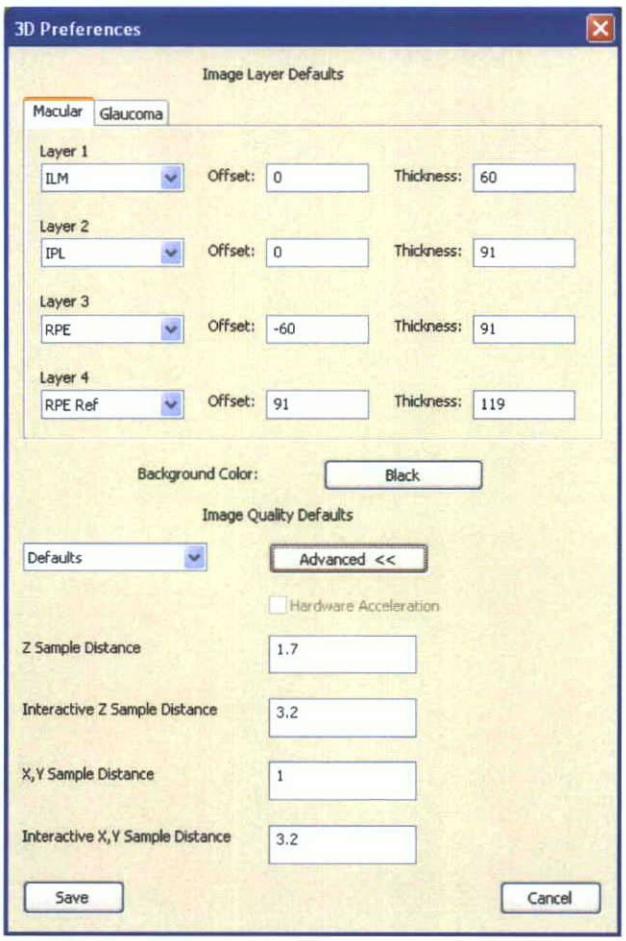


3D Volume view of the Vitreous View. The Vitreous view uses a white background to better view the particles in the vitreous.



- **3D Preferences:** The top half of the 3D Preferences window lets the user select the layer and modify the offset and thickness to be represented in Layers 1-4. The Figure to the left shows the default layers and their respective settings for offset and thickness. These values will correspond with any settings changed in the **En Face 4x** preferences (as seen later in the manual).
- **Background Color:** Change the background color of the 3D model from black, grey, and white.
- **Advanced:** The Advanced options affect the 3D volume rendering when the object is dynamic and static. **The advanced options are intended for advanced clinical research purposes.**

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3D Advanced Options

The advanced options affect how the 3D Volume model is rendered in its 'static' and 'dynamic' state. The dynamic state refers to the state the model is in when it is interactively being manipulated (dragging and rotating views). The static state refers to the 3D model when it is not being manipulated by the user.

The options: "Interactive Z Sample Distance and Interactive X, Y Sample Distance" affect the quality of rendering when the user moves the 3D Model.

The options "Z Sample Distance and X,Y Sample Distance" affect the quality of the rendering of the static 3D Volume model.

The Hardware Acceleration option is available to RTVue PC systems that have graphic cards that support hardware acceleration. PC systems without abilities to use the Hardware Acceleration option will have the option gray'ed out. Selecting the Hardware Acceleration option uses the video card's GPU to power the 3D model. If the Hardware Acceleration option is not selected, 3D models will be powered by CPU instead.

Higher values yield faster processing time but lower resolution 3D Volume models. Lower values take longer to process the 3D models but have increased resolution. The values set as default were found to have the best balance between processing time and rendering quality. The chart below show the possible input values for each selection.

	CPU	GPU (Hardware Acceleration option selected)
Z Sample Distance	1.0 < X < 10	.4 < X < 10
Interactive Z Sample Distance	2.5 < X < 10	.7 < X < 10
X,Y Sample Distance	.7 < X < 10	N/A
Interactive X,Y Sample Distance	2.0 < X < 10	N/A

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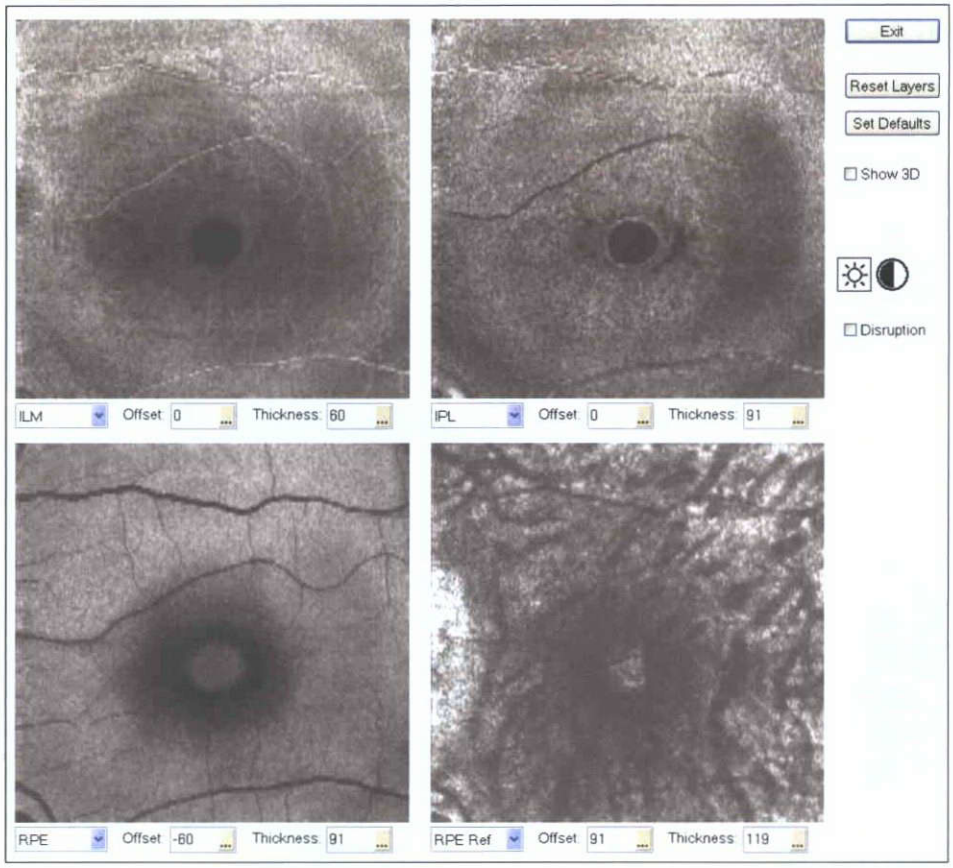
En Face 4x

The En Face 4x presentation provides en face views of four different layers. The default layers shown are ILM, IPL, RPE, and RPE Ref for retinal 3D scans. For 3D Disk, the default layers are ILM, NFL, and RPE. These layers can be changed by going to the respective drop down menu in each en face window. These options also affect the layer selection in the 3D Volume selection.



The offset and thickness values can be modified. Click "Show 3D" on the right hand side, to view the En face layers in 3D.

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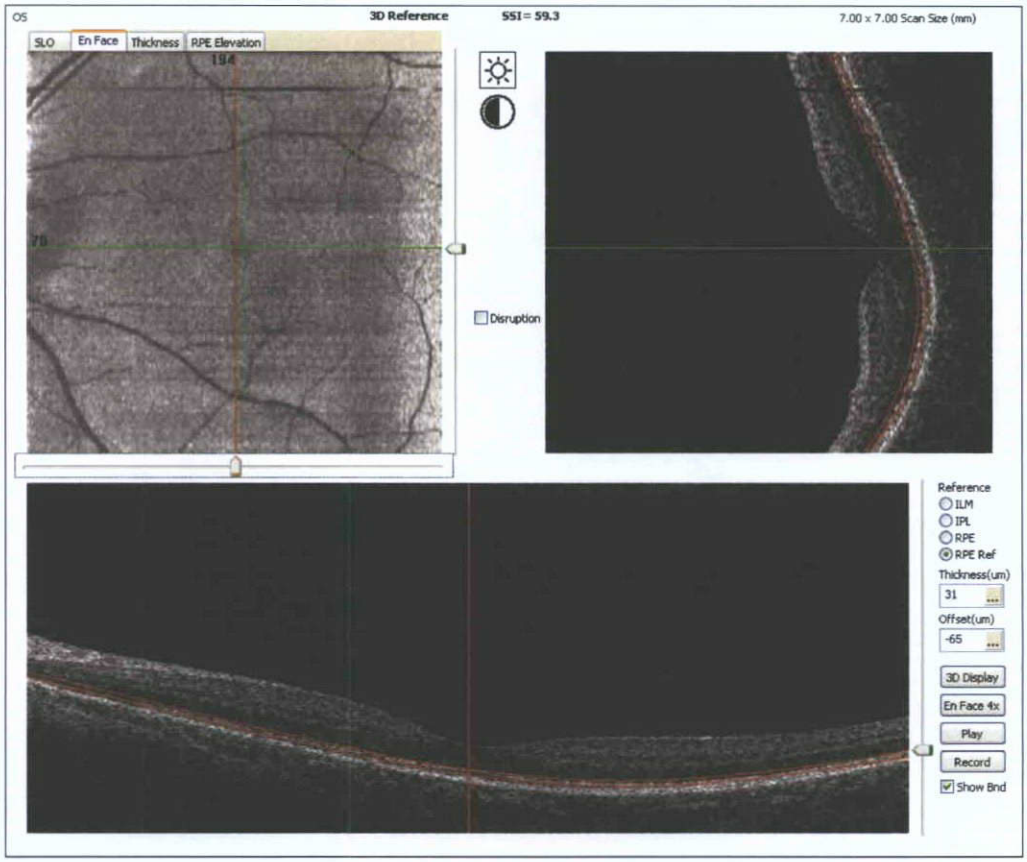
En Face presentation

This view presents the sum of the c-scan planes indicated in the thickness value field



- Options for reference plane contour.
- Thickness (µm): You can select the thickness of the scan plane (slab or Sum) presentation (microns) in the En face window.
- Offset (depth or elevation) from starting plane in microns.

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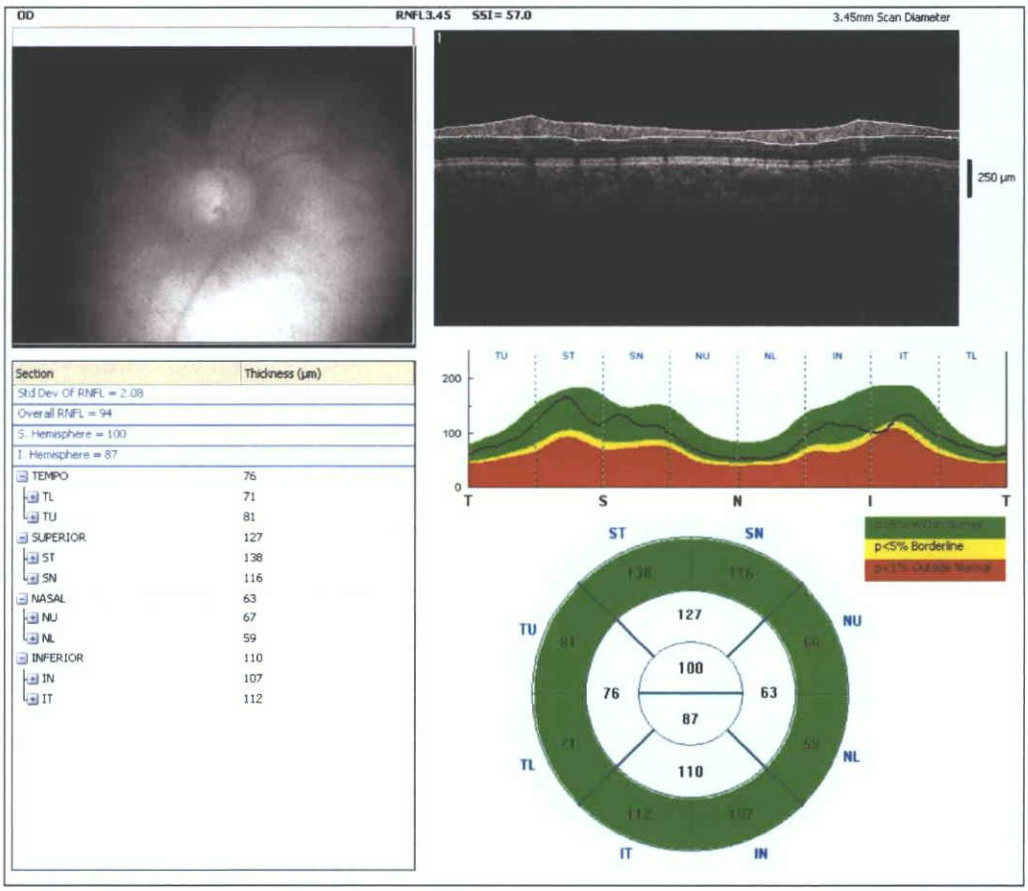
5.7 Analyze Report – Glaucoma Scans

5.7.1 RNFL3.45 Analysis Report

The RNFL scan pattern completes four circular scans in 0.16 seconds at a diameter of 3.45 mm, targeted around the optic nerve head. These scans are averaged and the result is presented within the normative range parameters.

With version 6.1, RNFL average thickness is show in 8 sectors in RNFL 3.45 analysis and change reports.

NOTE: This scan pattern cannot be registered for viewing change over time purposes. For Glaucoma and sequential change analysis, we strongly recommend using the ONH scan pattern (which offers an alignment-corrected RNFL measurement)



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5.7.2 *RNFL 3.45 Change Overview Report*

Up to four exams (baseline and three follow-up visit results) can be selected for the Change overview report.

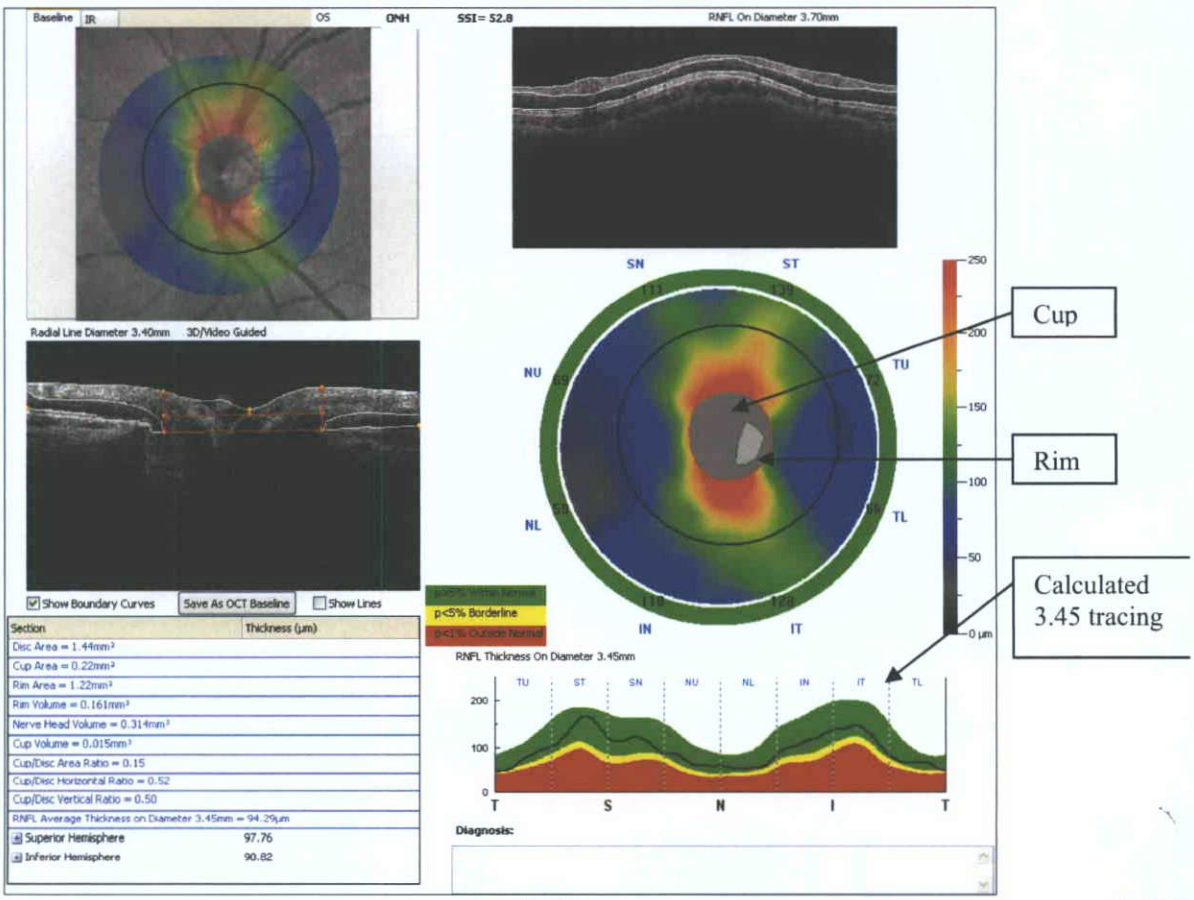
Each averaged (4 scans) result is plotted against the Normative parameters.

NOTE: This scan pattern is included in the RTVue for users wishing some continuity with previous Time-Domain OCT systems. However, just as with the Time-Domain OCT systems sold previously, the scan placement is completely dependent upon the operator. Registration is not possible with this scan pattern.

5.7.3 *ONH Analysis Presentation*

The ONH map includes several pieces of important disc morphology information: Disc and Cup Areas, C/D Ratio, RNFL 3.45 and NFL thickness map from disc margin up to 4.93 mm radius from the center of disc.

With version 6.1, RNFL average thickness is show in 8 sectors in ONH analysis and change reports.



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Factors that can affect Scan Signal Index (SSI) for the ONH scan:

Scan not centered on the optic disc:

During the scan, the operator should check to make sure the scan pattern is well centered on the optic disc. If it is not, the operator should move the scan pattern to be centered on the disc. If the operator does not and if the scan pattern is not centered on the disc, the RNFL thickness measurements may be affected. The software can automatically reposition the RNFL TSNIT circle to be centered on the optic disc after the scan, however if the disc is too close to the edge of the scan pattern, some of the data may be missing if the measurement circle falls outside the scan pattern area. In these cases, the scan should be retaken.

Check optic disc drawing and RPE tip placement:

Make sure the optic disc drawing accurately demarcates the edge of the optic disc boundary. Also make sure the RPE tip placements are at the correct positions (end of RPE/choroid complex at the disc margin). Re-draw the optic disc margin drawing if necessary. Adjust the RPE/Choroid tips placement if necessary. If the optic disc drawing or the RPE tip placement is not accurate, the measurements can be affected. Scans should be retaken if the RNFL measurement circle falls outside the scan area after the disc drawing and RPE tip placement are in correct positions. This verification of RPE tips can be done at any time (regardless of setting in the User Preferences) by "right clicking" on the NFL result map.

Check the layer segmentation accuracy of the scan:

The segmented layers are ILM and NFL (Nerve Fiber Layer). If the segmentation lines are not accurate, the user should manually make the necessary corrections. If the segmentation is not accurate and the user does not make the correction, the results will be affected. If the user performs manual correction, the results will be valid and the scan can be used.

Overall precision results with the ONH scan for normal and glaucoma patients:

ONH Average RNFL		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	100.82 (8.11)	86.40 (14.99)
Repeatability SD* (Min, Max)	1.76(1.76, 6.18)	1.56(1.56, 5.86)
Reproducibility SD** (Min, Max)	2.11(2.11, 9.78)	7.87(3.92, 16.33)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning

**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

For details on the clinical study and the clinical precision for RTVue scan measurements (repeatability, reproducibility), study information is available in the Appendix –RTVue Precision.

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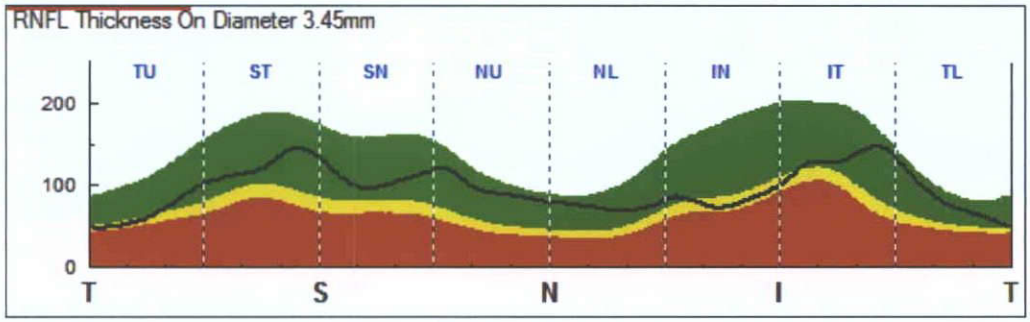
5.7.4 *TSNIT Histogram*

RNFL thickness profile in the ONH is the thickness of RNFL at a *calculated* **3.45mm diameter** around the *center* of the disc. **NOT THE CENTER OF THE SCAN**

*The thickness measurement at 3.45mm is re-sampled relative to the disc center, not the scan beam center, so the de-centering of the disc relative to the scan beam will not affect the measurement.



5.7.5 *Stereometric analysis*

Optic disc analysis results are listed in the spread sheet as follows:

Section	Thickness (µm)
Disc Area = 2.01mm²	
Cup Area = 1.06mm²	
Rim Area = 0.96mm²	
Rim Volume = 0.085mm³	
Nerve Head Volume = 0.164mm³	
Cup Volume = 0.300mm³	
Cup/Disc Area Ratio = 0.53	
Cup/Disc Horizontal Ratio = 0.79	
Cup/Disc Vertical Ratio = 0.70	
RNFL Average Thickness on Diameter 3.45mm = 82.18µm	
⊞ Superior Hemisphere	80.75
⊞ Inferior Hemisphere	83.62

Click on "+" to expand the list

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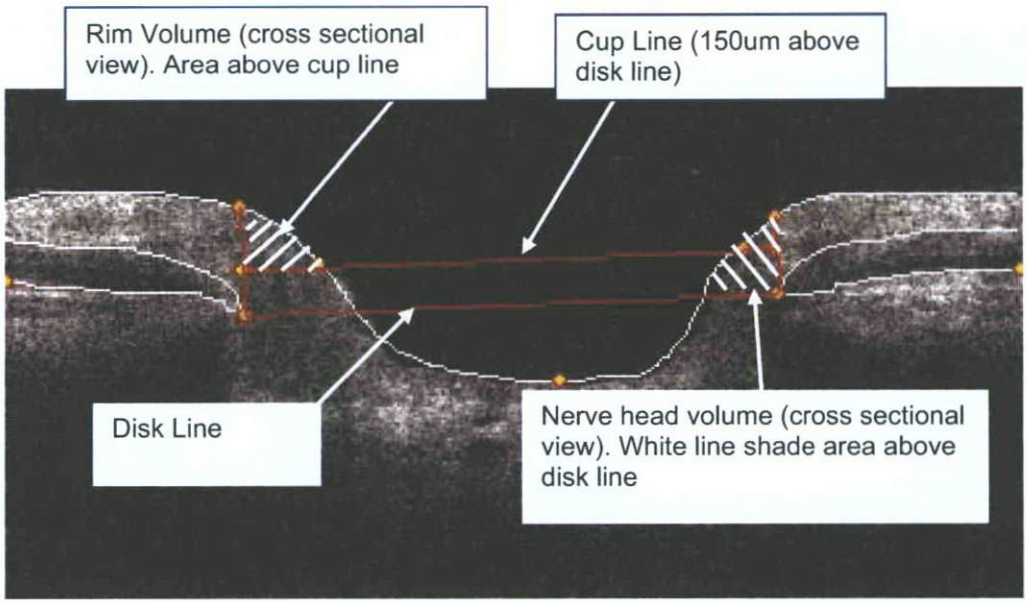
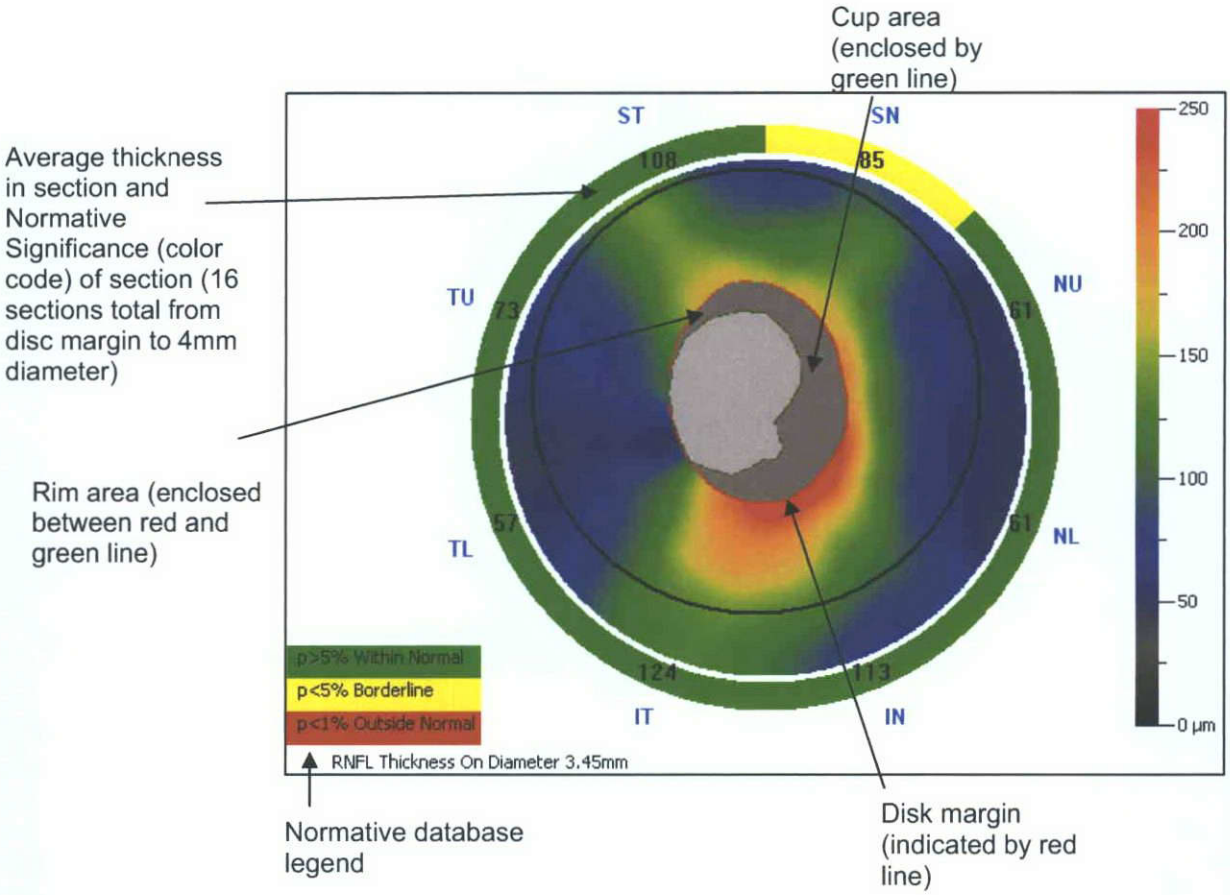
Definitions:





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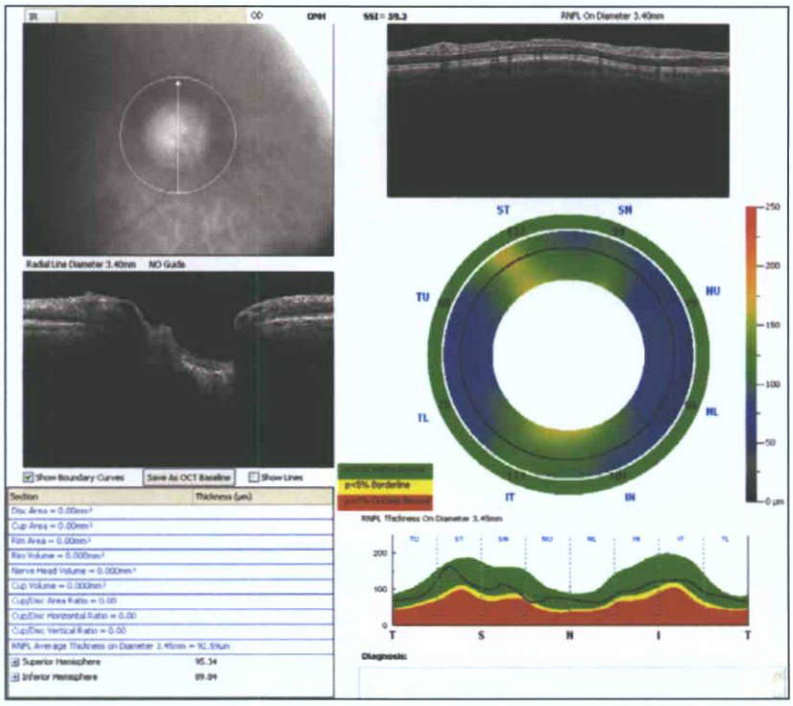
Optic Nerve Head Morphology

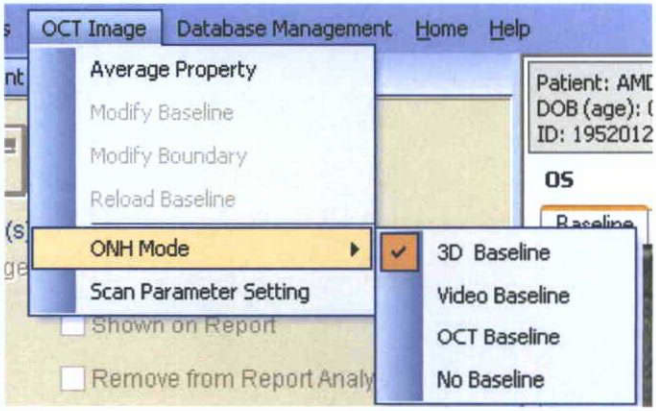
The ONH analysis can be performed with either one of four disc border baseline modes:

1. **3D Baseline:** Disc drawing from 3D Optic Disc scan (**Default**)
2. **Video Baseline:** Disc drawing from IR image (ONH)
3. **OCT Baseline *(Advanced GUI only)*:** Uses the manually adjusted RPE endpoints on the radial scans (Available in Advanced GUI only)
4. **No Baseline*** No disc drawing or RPE tip setting is required



*** The "No Baseline" option removes any serial registration capability, and therefore removes the possibility of change analysis. All disk metrics are reported as zeros, since the disk measurements are not calculated.**

Presentation of ONH scan with "No Baseline" option



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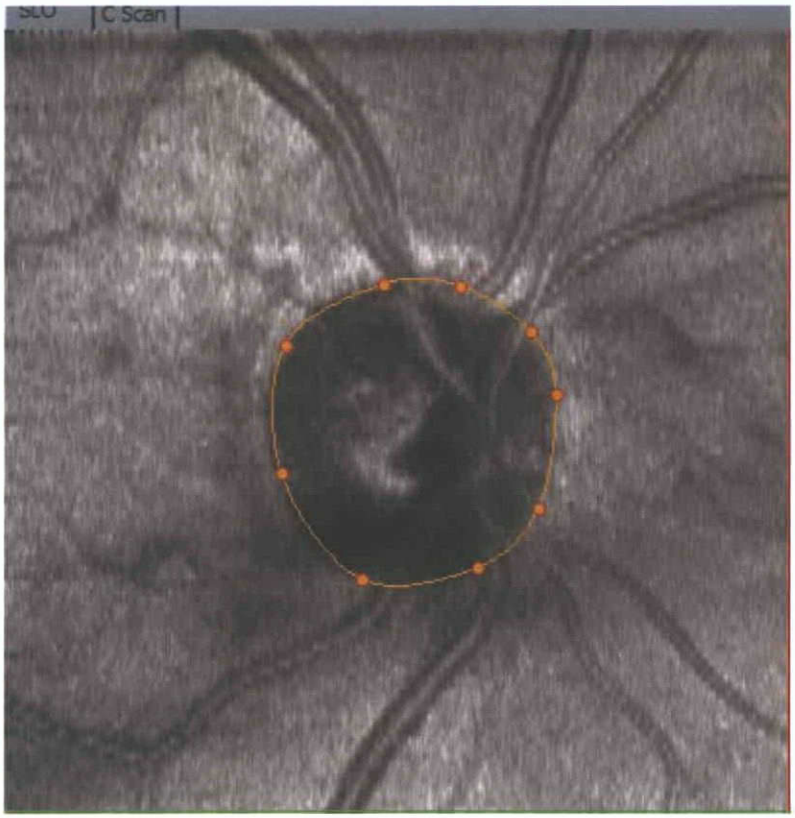
5.7.6.5 The default setting is"3D Baseline" and should not be changed unless there is no possibility of capturing a 3D disc image with any patients.

5.7.6.5 **3D Baseline** is the disc boundary that is automatically drawn using the 3D Disc scan.

To see the boundary automatically drawn, "Right click" the mouse cursor on the SLO image and selecting "Show Disc".



5.7.6.5 You may also use the 3D presentation screens to precisely determine the optic disc boundary, by using the RPE endpoints visualized in the B-Scan (lower left) and A-Scan (upper right).

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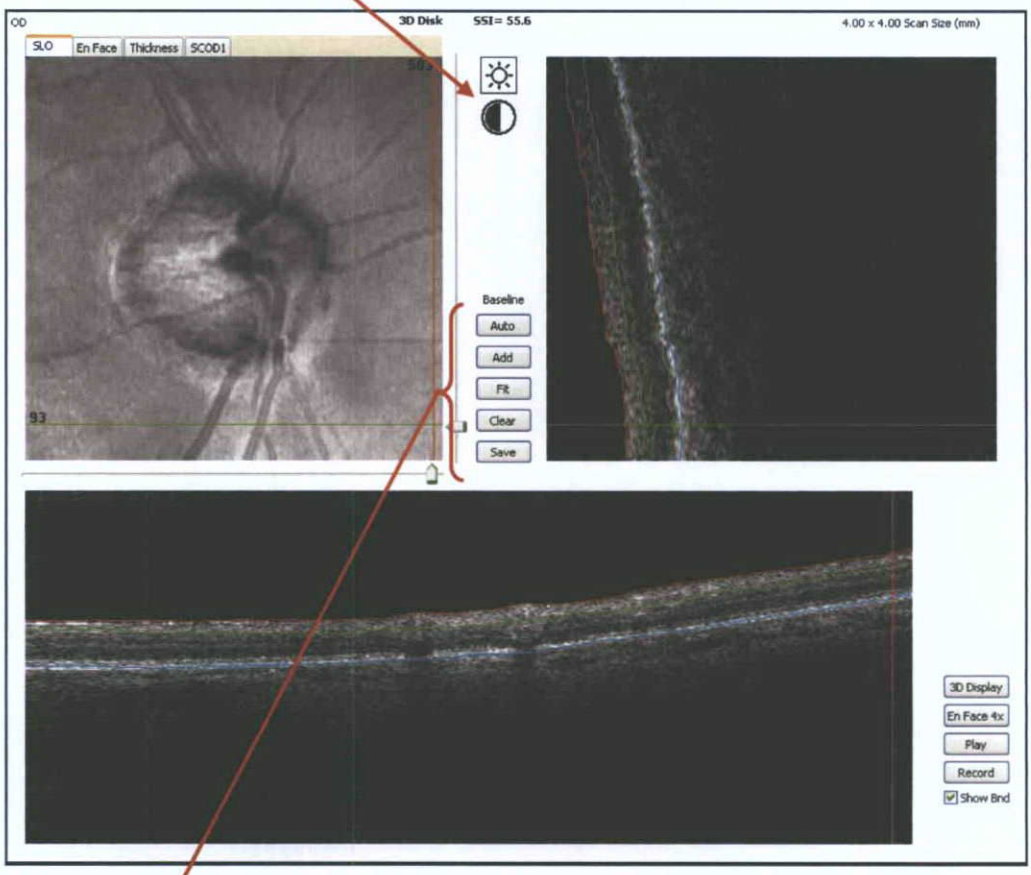
Analyze Menu

Brightness and **Contrast** controls for the SLO type en face image presentation



- **Auto** – Draws the disc margin on the En face SLO image.
- **Add** – Adds an anchor point on the image for disc boundary. Click the SLO image to find the correct point (RPE tip) position, then click **Add**.
- **Fit** – Uses anchor points to draw the disc boundary to close contour.
- **Clear** – Clears any currently marked anchor points
- **Save** – Saves the resulting disc drawing as the baseline for the ONH

Note: As you click on any position in the SLO image screen, the three perspective windows also change to reflect the location and cross section within the 3D presentation.

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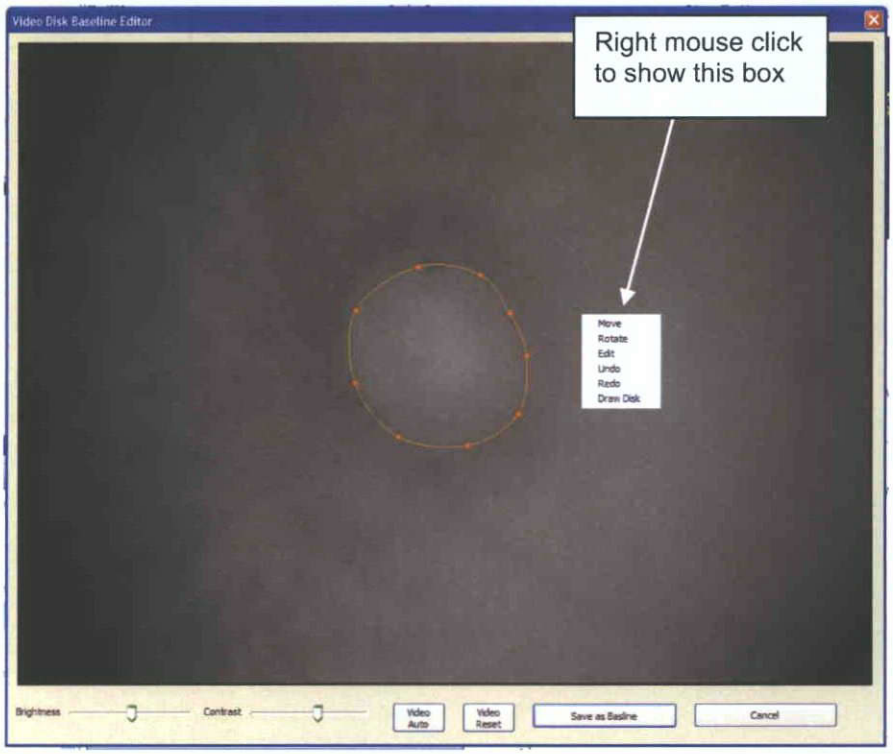
5.7.6.5 **Video Baseline** option should only be used if it is not possible to capture a 3D Disc scan. You may draw the optic disc margin on the IR video image to get the optic nerve head metrics.



5.7.6.5 **OCT Baseline (Advanced GUI only)**

This method is a more complex and user intensive method of adjusting the baseline. This function should not be used by anyone but research technicians. Please call for instructions

NOTE: If no 3D or Video (IR) baseline has been captured (or drawn) at the time of reviewing the ONH scan, you will have the option of rendering "without" a baseline in Analysis view. THIS IS NOT RECOMMENDED as the results are completely dependent upon the skill of the operator to center the scan pattern on the optic disc center.

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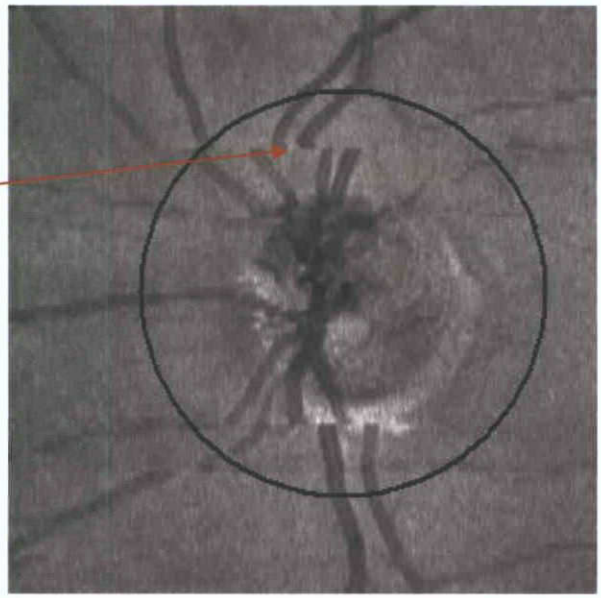
5.7.6 3D Optic Disc Presentation

NOTE: Eye motion can cause image registration to fail and require a scan to be redone. An example of eye motion during the 3-D ONH scan is seen below. The eye movement is evident in the break in the blood vessel pattern. It is recommended if such breaks are seen, the scan should be redone.

Eye movement indicated by the break in the blood vessel pattern



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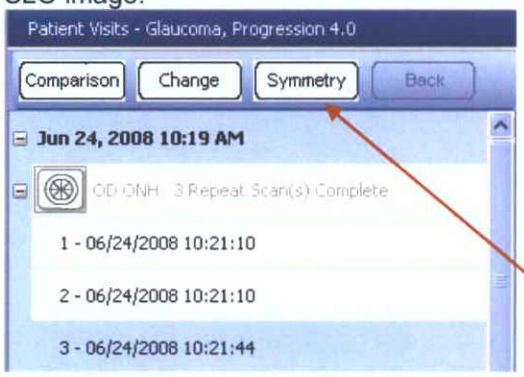
5.7.7 Comparison

Image comparison is a very handy tool used to see the difference of the retina between two visits. This option is available on all scan patterns.

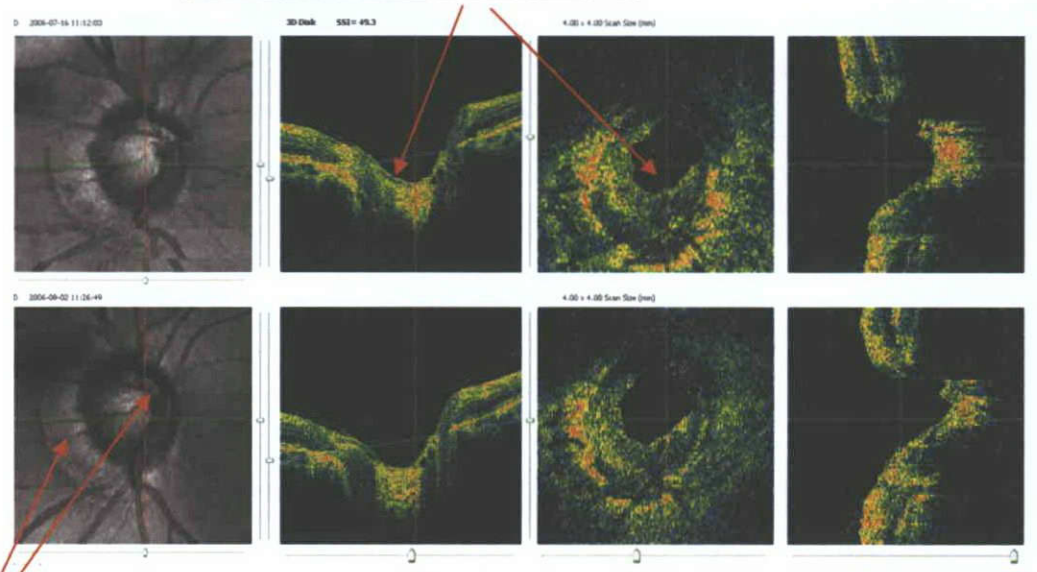
To use image comparison, first select the patient scan in the analyze window. If there are examinations available for comparison, the [**Comparison**] button will be available. This is the same method used to select change and symmetry option.

Two rows of images will appear. You can select which frame image to compare by using the slider on the fundus image (SLO image in 3D scan) to choose the images on each visit. The horizontal and vertical image locations are indicated by horizontal and vertical highlight lines on the SLO image.



Comparison/Change/Symmetry Image Comparison options

Lines to register C-scan plane



Lines to register the horizontal and vertical image frames

Image fly through bars

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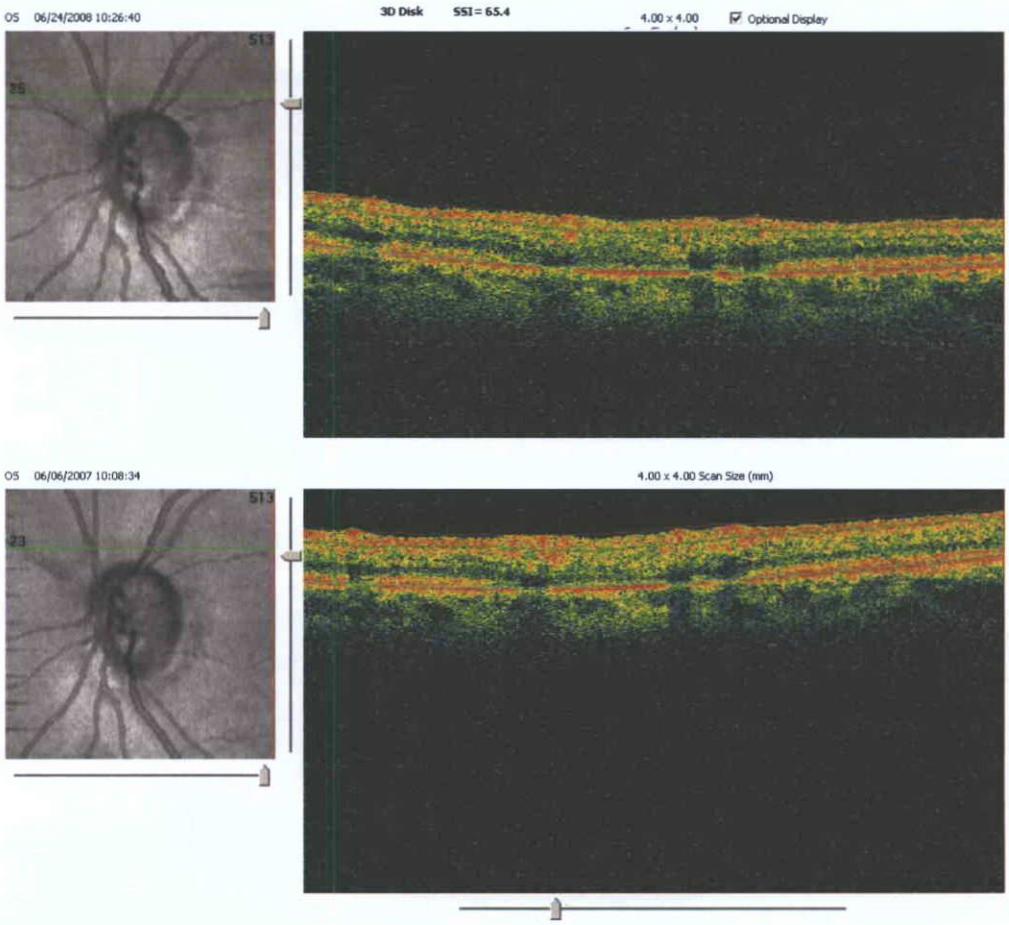
5.7.8 3D Disk Change Analysis

3D Disk change analysis report has been modified for an improved presentation with larger OCT images.



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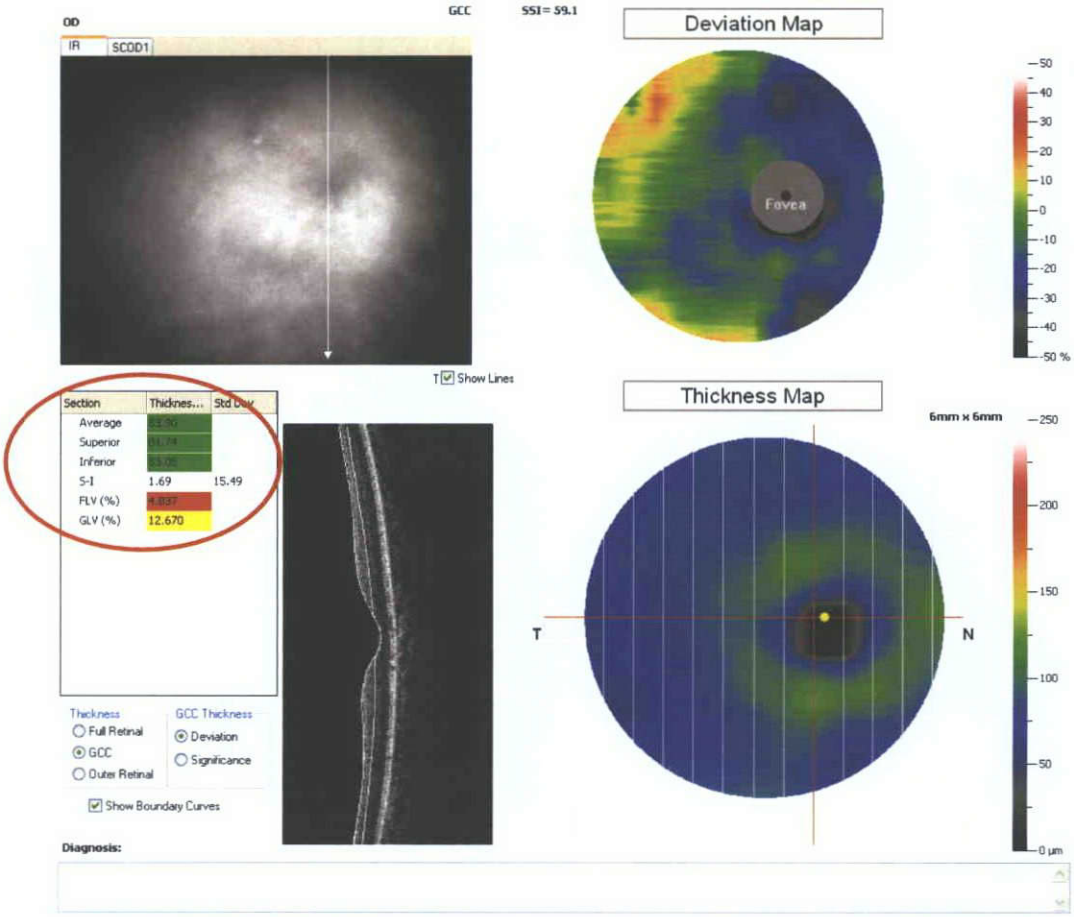
5.7.9 GCC Analysis Presentation



The **GCC** (Ganglion Cell Complex), formerly called the MM7, display the thickness map and deviation from normal of the Inner Retina. These layers make up the complete Ganglion Cell Complex thickness in the macular region. The upper right display will default to the **Deviation Map** (see section 5.8 on the Normative Database). The display may be changed based on user selection in the "Thickness" and "GCC Thickness" display options.

The vertical scan displayed is indicated in Red on the cross sectional scan is displayed on the left side when moving the cursor in the thickness map.

The **Difference** map between superior and inferior hemispheres displayed in previous versions (in the upper right), is now shown as summary values in the table to the left center (red circle).

Focal Loss Volume (FLV) is a parameter that provides a quantitative measure for the amount of significant GCC loss. FLV is the total sum of significant GCC loss (in volume) divided by the map area. As such it provides a percent of significant tissue loss for volume. Early study results have found that FLV is the most accurate parameter to differentiate normal from glaucomatous eyes, being better than the average GCC thickness parameter.

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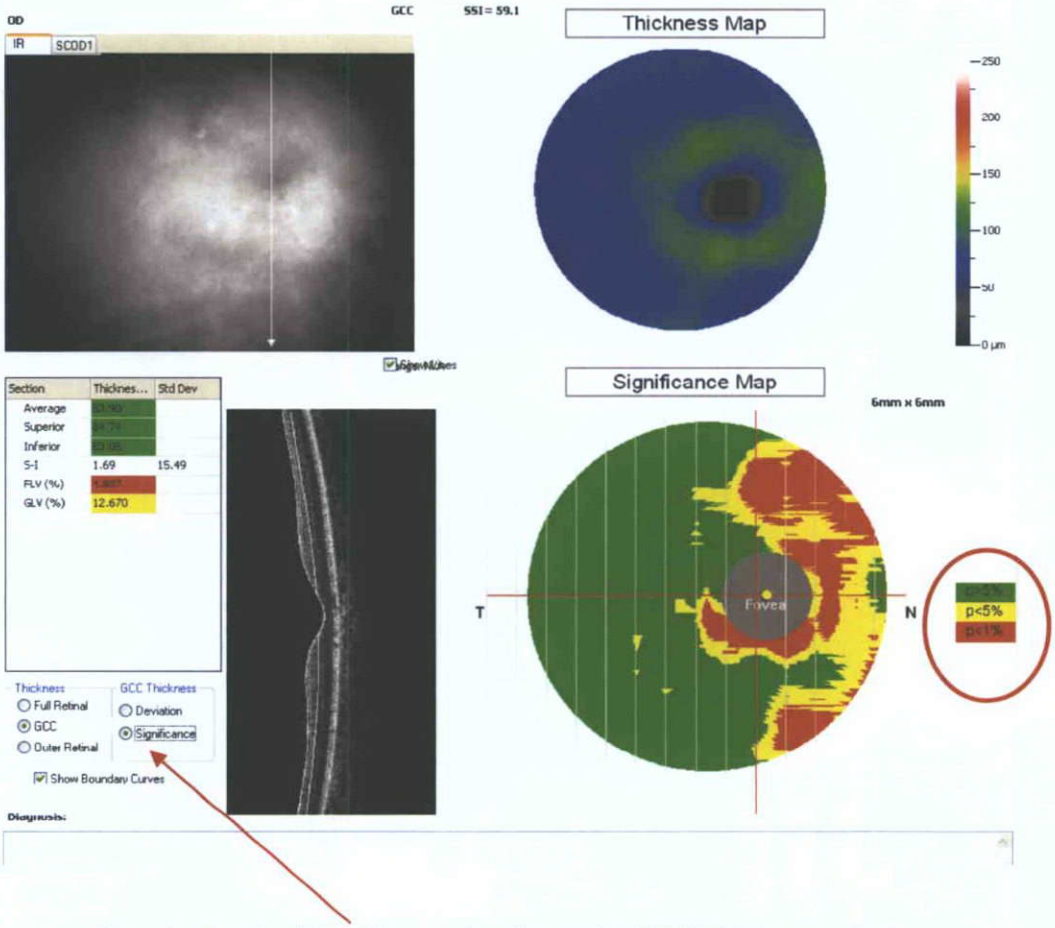
Global Loss Volume (GLV) is the sum of the pixels where the Fractional Deviation map value is < 0, and then divided by the total area to give a percent loss of GCC thickness.



By selecting the "**Significance**" option under **GCC Thickness** display options, the Deviation map is replaced by the **Significance Map** (of the Deviation – see section 5.8 on the Normative Database). Depending upon which display option is selected, the most recent selection (of either option group) is displayed in the lower right and the exiting map moves to the upper right.

Note that fovea is marked by a small dot with the word "Fovea" under it for a clearer presentation of the maps.

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Overall precision results with the GCC scan for normal and glaucoma patients:

GCC Inner Retina Average		
	Normal Patients	Glaucoma Patients
# of Scans	72	71
Overall Mean (Overall SD)	98.28 (9.31)	81.76 (8.90)
Repeatability SD* (Min, Max)	1.86 (1.86, 2.07)	1.18 (1.18, 1.59)
Reproducibility SD** (Min, Max)	7.56 (7.32, 7.92)	2.55 (1.59, 3.36)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

For details on the clinical study and the clinical precision for RTVue scan measurements (repeatability, reproducibility), study information is available in the Appendix –RTVue Precision.

5.8 Normative Database

5.8.1 Color Legend for Normative Significance Maps

Both GCC and RNFL Thickness Significance
Legend for TSNIT graph and all parameters

p = 5-95% Within	→ Average
p < 5% Borderline	→ Below average
p < 1% Outside Normal	→ Significantly below average

Retinal Thickness Significance Legend (MM5 and RPE)

p > 99% Outside	→ Significantly above average
p > 95% Borderline	→ Above average
p = 5-95% Within	→ Average
p < 5% Below Normal	→ Below average
p < 1% Outside Normal	→ Significantly below average

Please Note: Normative database comparisons are based on statistical comparisons only and there are possible normal outliers. You should reduce the risk of misclassification by using multiple clinical tools for diagnosis.

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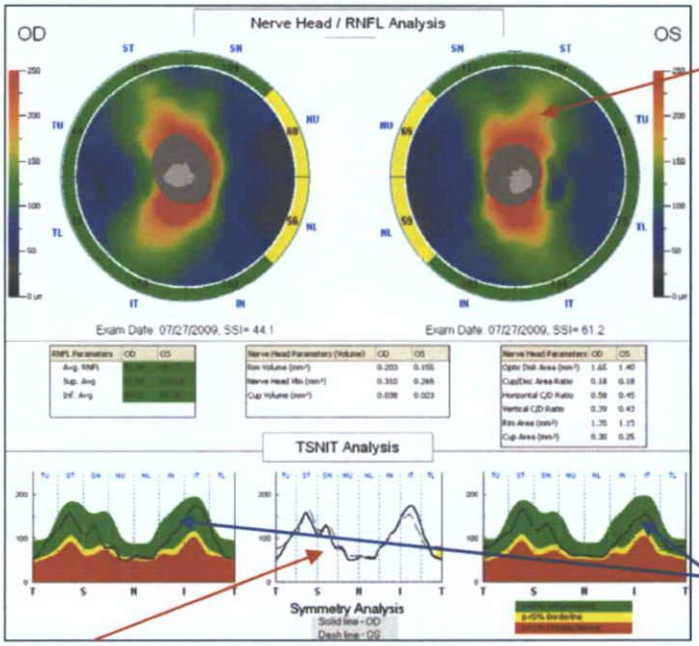
5.8.2 Normative Reports (Samples)

5.8.2.1 ONH Symmetry Report (when no GCC scan exists in Visit)

When "Symmetry" is selected in viewing an ONH report, and **no GCC scans** exist in the same Visit, "Symmetry" analysis option is selected the screen and print report appear as below.



- RNFL Normative Database comparison for 16 sectors

Center Section
- (Left) RNFL average for each eye.
- (Center) Nerve Head volume parameters
- (Right) Optic Nerve Head metrics.

- TSNIT deviation maps

- Bi-lateral TSNIT comparison. (Dashed line is left eye) Red between lines is significant

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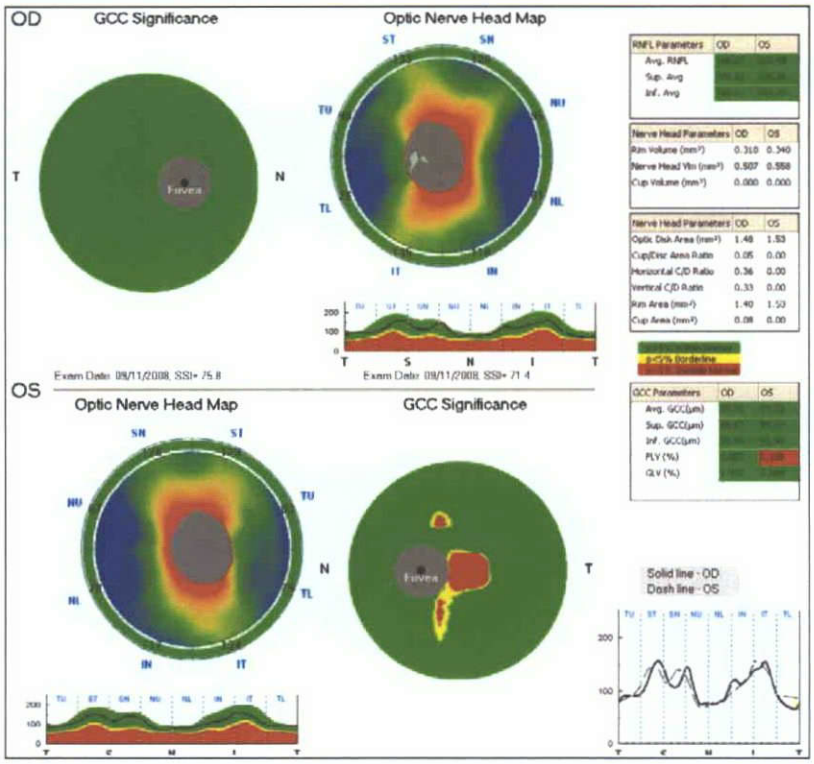
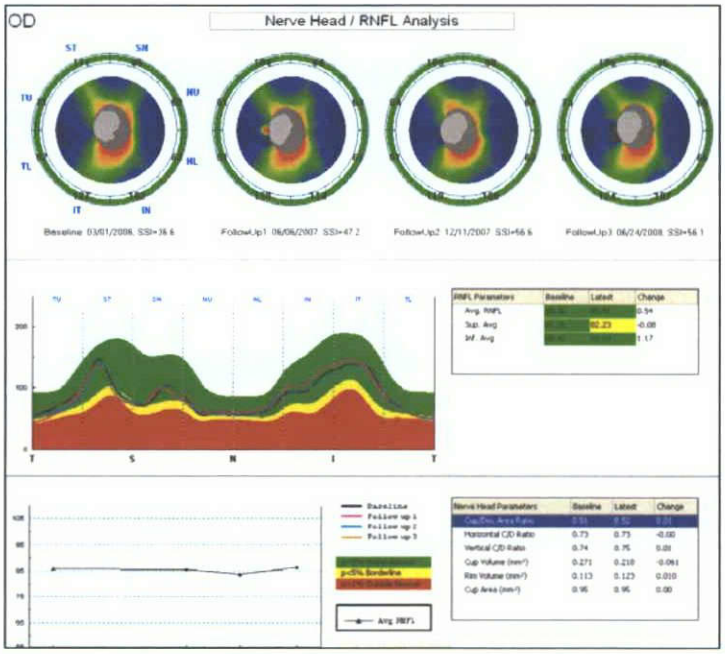
5.8.2.1.1 Symmetry Report (Combined when GCC scan exists in Visit)



A new presentation combining both ONH and GCC scans is provided in order to see the summary of the two in one place. This is available for any visit in which both ONH and GCC scans are acquired.

5.8.2.2 Change Analysis Overview – ONH



- Baseline and three follow-up exam ONH results
- (Left) TSNIT graph of all selected exams
- (Right) RNFL thickness parameters coded for NDB
- (Left) Trend plot of average values for selected exams.
- (Right) Optic Nerve baseline and latest exam metrics

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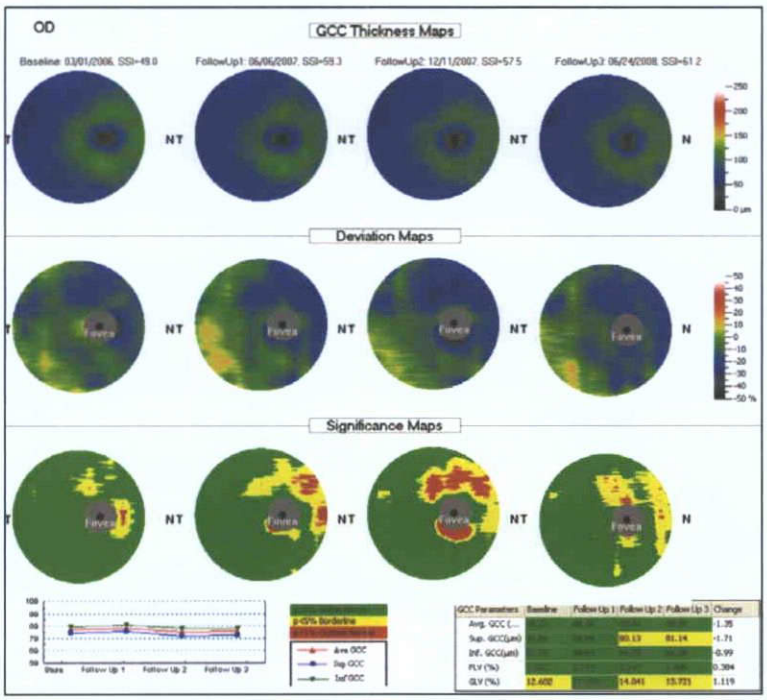
5.8.2.3 Change Analysis Overview – GCC



- GCC Thickness Map of selected exams
- Deviation from Normal map
- Significance (of deviation from normal) Map
- Trend and Average GCC table. Coded for Normative comparison.

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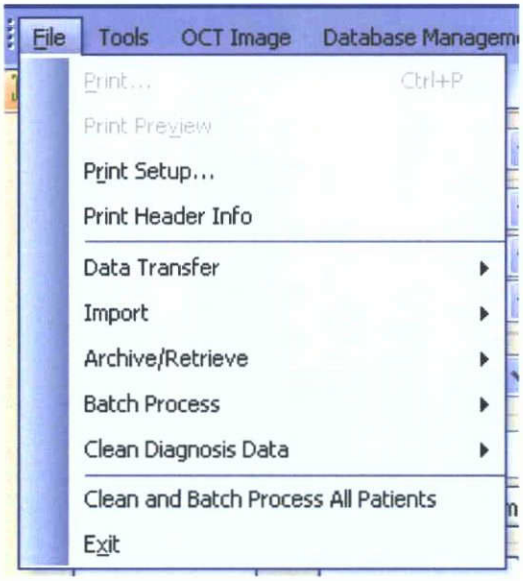
6 Main Menu Bar

The options available in the top level menu bar, and in certain screen presentations, is dependent up on the GUI setting of your RTVue. The default setting is the "Clinical" GUI. This GUI setting contains all of the required tools and options for a clinical practice environment. The "Advanced" GUI provides additional options that are useful to a large institution with a dedicated imaging staff or research environment.

The following is a brief overview of the menu bar options. The options available only in "Advanced" GUI are indicated. These functions should be accessed only be users who have a high level of experience with the RTVue FD-OCT system.

6.1 File Menu



6.1.1 Print

Sends the report visible in the Analysis view screen to the printer (if attached), or whatever print option is installed on the RTVue

6.1.2 Print Setup

Brings up the standard "Windows™" Print Setup window

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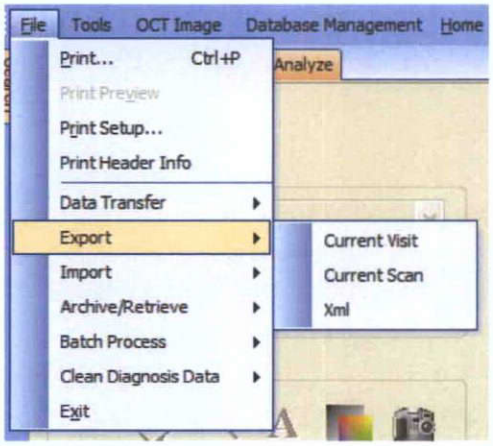
6.1.3 *Data Transfer*

This option brings up the "Data Output" function, used in conjunction with ReVue -- the stand-alone review software application. This software product is used for viewing patient data away from the RTVue device. Please see the manual for ReVue.

6.1.4 *Export (Advanced GUI only)*

This option brings up the data export options for analysis by 3rd party analysis applications, such are for research purposes. The export format is XML. For a detailed XML specification Guide, please contact the Optovue corporate office at 510-623-8868.



6.1.5 *Import (Images)*

The Import function now includes the ability to bring in previous digital stored (digital printout) results from certain other devices to the patient record.

Along with importing Color, Red Free, FA and ICG images from any digital fundus system, you may import results (image format files only) from other diagnostic devices and scanning systems (Cornea Topography, Visual Fields, Wavefront results, and OCT, SLO, SLP imaging results).

These results must be image based (output to a digital image format file such as .jpg, .bmp, .png etc) to be eligible for importing into the RTVue system database.

This allows the results from previous visits and other devices to be viewed along with the RTVue OCT results for the same patient in the current visit.

First select patient/visit then, click on **File > Import > Import Image**. Select image in the network or from removable media (file types compatible are listed), and click **Open**.

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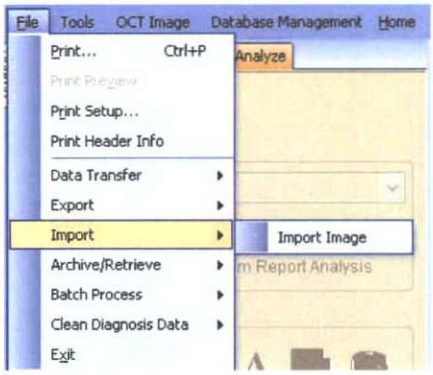
Image will be opened in a window for identification. Select eye [OD/OS], then image type for fundus imaging results, or diagnostic type for test result. Then click on the **Save** button.



The options for importing are:

- Fundus Images (Figure 6A)
  - Color
  - Red Free
  - Fluorescein Angiograms (FA)
  - Indo-cyanide Green (IA)

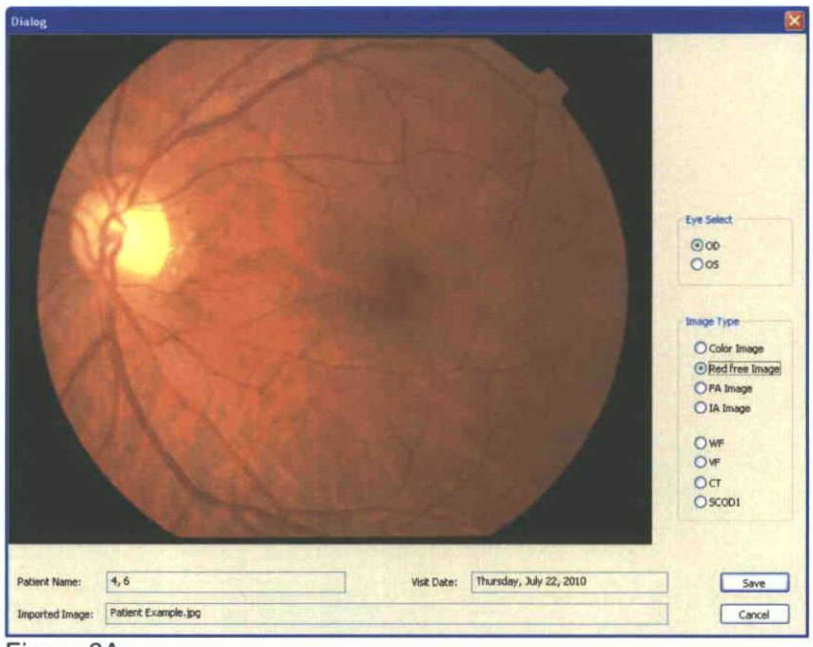


Figure 6A

- Diagnostic Results (Figure 6B)
  - Wavefront (WF)
  - Visual Fields (VF)
  - Corneal Topography (CT)
  - Scanning Computerized Ophthalmic Diagnostic Instruments (SCODI per Medicare nomenclature)

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Figure 6B

- Imported data will appear in the upper left of the Review screen with a Tab indicating the type of result. Double-clicking on the image within the Tab will open it up in a larger window. (Figure 6C)

- Sample of imported Visual Field test results, viewed next to the GCC Analysis from the RTVue.

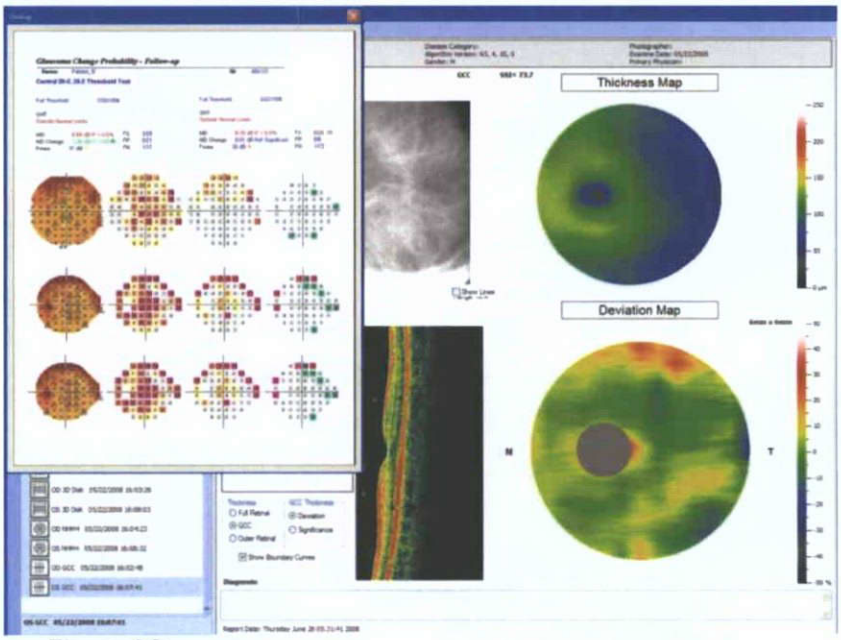

Figure 6C

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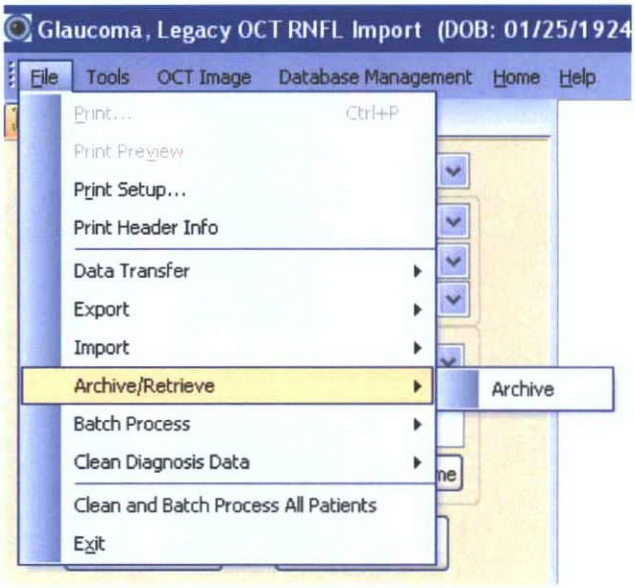
6.1.6 *Archive Data*

An **external USB hard drive** or a **network drive** is required to archive data from the RTVue. **All archive hard drives are required to support NTFS format**.

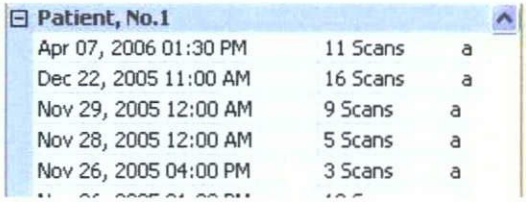
The first step in archive process is to select the archive/retrieve drive by clicking on Tools → User Preference. To archive patient data into the portable/network drive, select the archive destination in the file menu. Archived patients will still appear on the patient list; however, to analyze the patient's data, the same HD must be connected to retrieve the patient's data.



The basic archive unit is the **visit**. Check the visit date on the patient to be archived. Use the sorting functions to help organize the patient list.

After selecting the visits, follow the software instructions to archive the data. The hard drive should be labeled exactly the same as the label name entered in the software. It is advisable to make a backup of the archive drive in the event that the archive drive is accidentally damaged or lost.

Please note that once a visit is archived, it is removed from C and (backup) D drives. It is advisable to backup your archive drive.



The letter "**a**" appears next to the scan information indicating that the patient visit is archived. However when this data or visit is selected for

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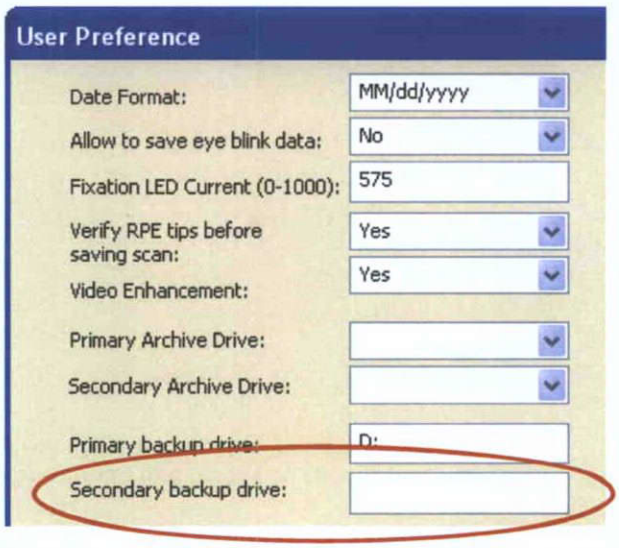
review use, it is automatically retrieved in a few seconds and brought to the screen.

NOTE: This function does require that the Archive media source (network or USB removable drive) is connected to the system at all times during use.

6.1.7 *Note on Backing up Data*

A backup function is done automatically in the background during the normal operation of the system. There are two hard drives supplied in all RTVue systems. The application automatically performs a backup routine as you finish each patient examination (capture) session.

You may add an additional backup target in the form of a USB removable/portable drive or a network address (folder, drive, etc). Simply add the appropriate drive letter (assigned automatically by Window when connected, or determined by your IT person) in the Secondary Backup field in the User Preferences window.



6.1.8 *Batch Process*

This option can be run if you have not opened patient's scans in the Analyze view and wish to pre-process all date. This will reduce the time required when scans are selected in the Analyze view.

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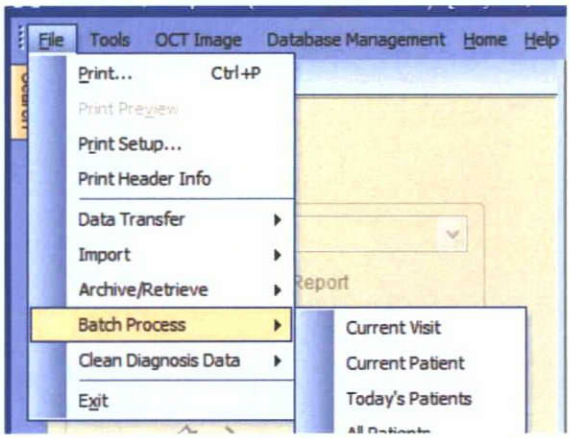
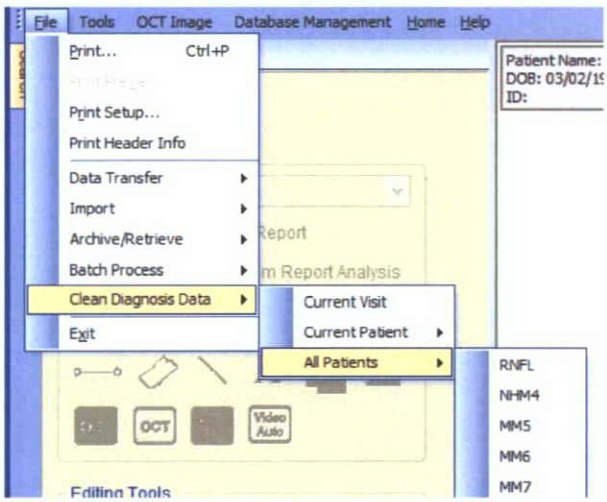


It is best to use the **Batch Process** function whenever the system is not in use. Processing time depends upon the number of patient and scans in the stored data.

6.1.9 Clean Diagnosis Data:

This process removes any previous calculations on the raw data. When opening a patient visit and scan in the Analyze view, the raw data will be processed again. This can also be used prior to reprocessing with updates, if a "reprocessing" requirement is stated. This can also be used when applying custom research site algorithms. NOTE: Please contact Optovue if you wish to apply any algorithms to RAW data other than those supplied with the FDA cleared RTVue device application software.



There is an improvement in the processing of ONH and GCC scans. This will only affect the data captured using these scans from the date of installation of the 6.1 upgrade.

PLEASE NOTE: If you wish to use previously captured ONH or GCC scans in a Change Analysis Report with any current data captured *after* the installation of version 6.1, the previous data will need to be reprocessed for

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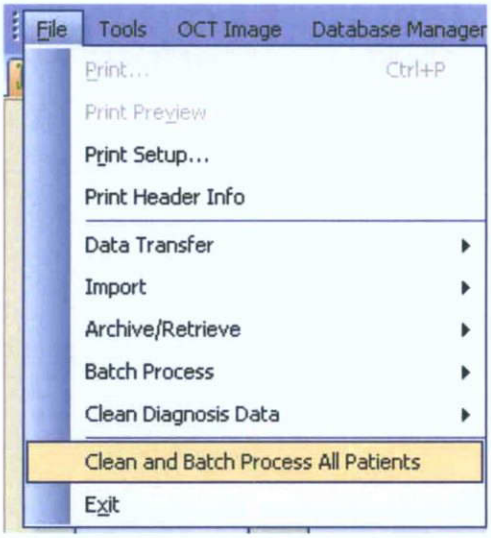
that patient in order to be included in the Change Analysis. This reprocessing will also affect the previous data single report when opened. The values may or may not be different but the original data is unchanged. This can be done by clicking on File --> Clean Diagnosis Data --> Current Patient --> ONH/GCC. Any Change Analysis Report that does not include data captured and processed with previous version of the RTVue application, do not need to be reprocessed.

6.1.10 Clean and Batch Process All Patients:

This is a one click solution to clean and reprocess all scans for all patients. Depending on the size of the data, this can take several hours. It is recommended that this step is taken after the last patient is scanned for a given day. A progress bar appears showing total number of scans and the number of scans reprocessed.



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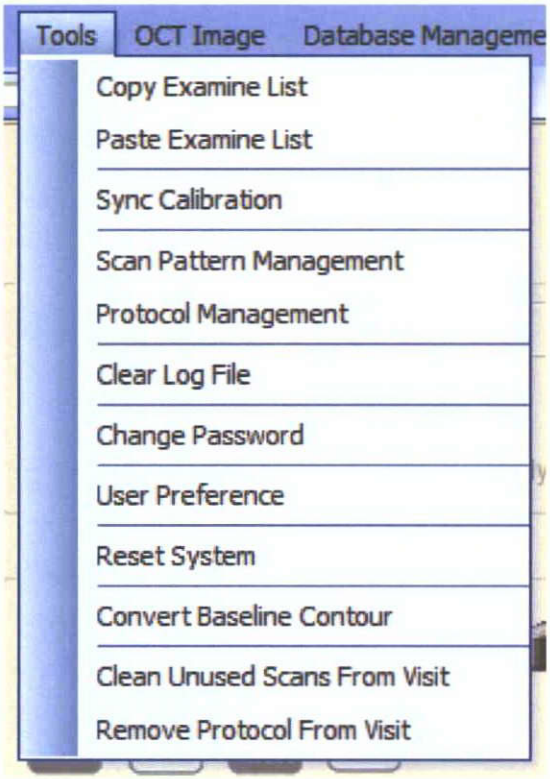
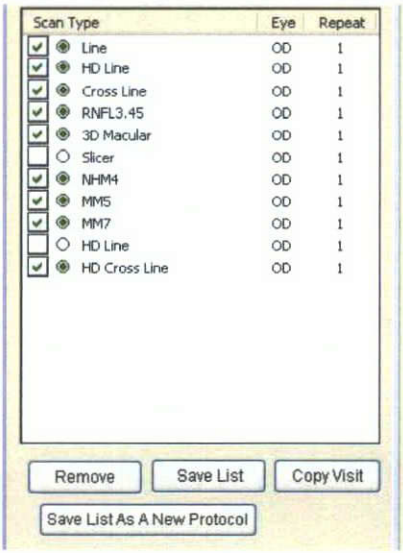
6.2 Tools Menu



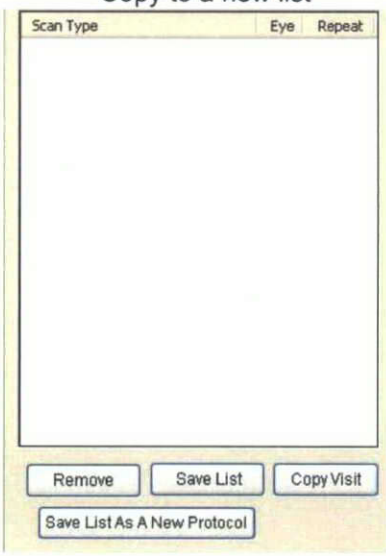
6.2.1 *Copy Examine List: (Advanced GUI only)*

This function allows the user to copy a particular examination list (of scan patterns) in order to paste them into a subsequent visit.

Previous visit scan list



Copy to a new list



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6.2.2 *Paste Examine List: (Advanced GUI only)*

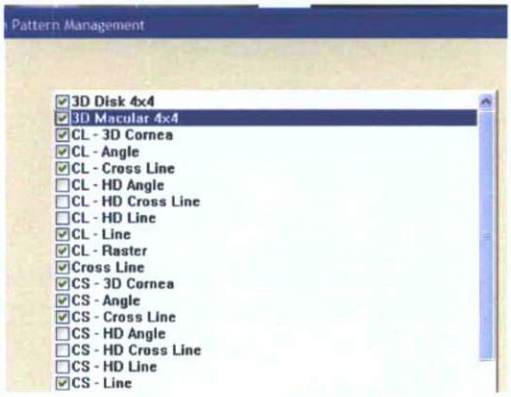
This function pastes or copies the exam list from a previous exam to the current one as desired by the user.

6.2.3 *Sync Calibration: (Technical Support assisted function only)*

This function synchronizes the calibration file between the scanner head and the RTVue OCT application.

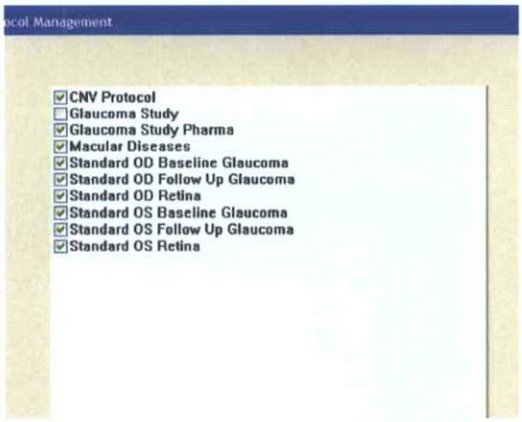
6.2.4 *Scan Pattern Management Screen*

This function allows the user to show or hide any of the scan patterns in the exam list. A clinical site may reduce the number of scan patterns visible to only those that are used in the clinical site. Hidden scans can be made "available" again at any time.



6.2.5 *Protocol Management*

Check the scan protocols (groups of scans) you wish to have available in the Examine View. Allows user to "un-clutter" the protocol list from various trials or studies that are concluded or which no longer apply.



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6.2.6 *Clear Log File*

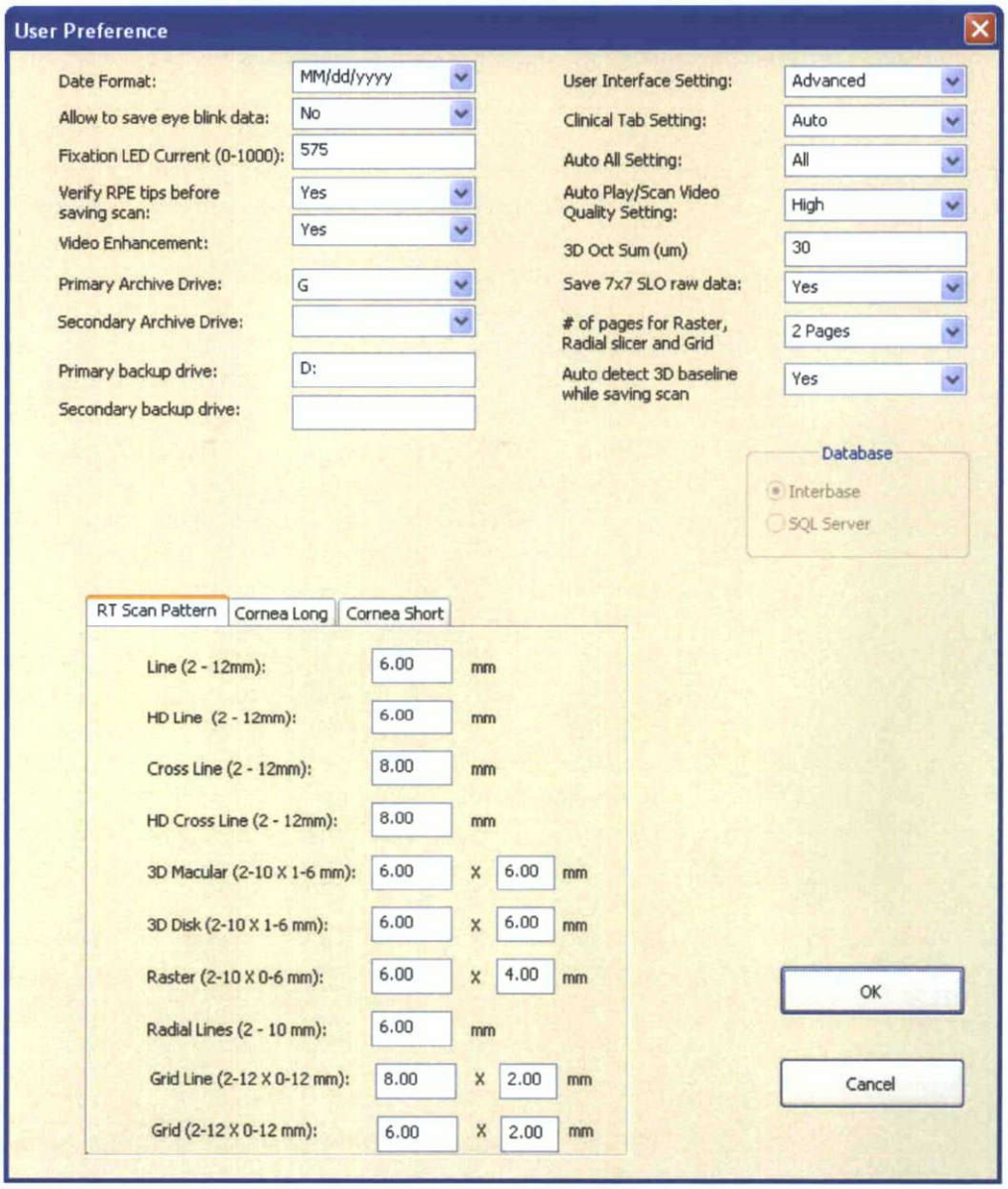
Clears the system event log file. This function should only be selected under the direction of technical support

6.2.7 *Change Password*

Allows administrator of system (log in) to set or change the system password.

6.2.8 *User Preference*

This screen allows the user to modify various default settings for the system. Certain scan parameters and views may be adjusted to user preference.



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User Preferences Fields Defined:

1. **Date Format:** allows you to choose from different date formats.
2. **Allow save eye blink data**: select **YES** to save even if there are blinks, or **NO** to force a rescan when an eye blink is detected.
3. **Fixation LED Current (0-1000)**: adjust the blue LED output by increasing or decreasing the value
4. **Select RPE tips before savings scan**: Select **YES** to set RPE Tips in the **ONH scan** before saving, or select **NO** to draw them during the Analysis viewing.
   i. **WARNING** – if the scan was not placed adequately by the user, and the RPE tips may fall outside the 3.45mm target zone (red dashed lines), the patient should be scanned again. If this option is set to NO, the operator may not identify this problem while the patient is still available for re-scanning
5. **User Interface Setting**: Switches the GUI setting between "Clinical" and "Advanced".
6. **Video Enhancement**: Selecting YES on this option will automatically apply a contrast enhancement to the IR reference image captures with the scan
7. **Primary Archive Drive**: Sets the default drive for archiving function (factory default is the 35GB ZIP removable media). This may be set to another type of removable media (USB) or a mapped network drive.
8. **Secondary Archive Drive**: Allows a second drive location to be used for archive.
9. **Primary Backup Drive**: Sets primary drive where the system sends a copy of the database, raw data and processed data. (recovery drive)
10. **Secondary Backup Drive**: Allows a second drive location to be used for backup.
11. **TABs (RTVue Scan Pattern; Cornea Long; Cornea Short:** These tabs contain the length and width default setting for the various scan patterns.
    i. **NOTE:** The Cornea Long and Cornea Short will only appear if the CAM option is installed on the RTVue system
12. **User Interface Setting:** Same as previous options, however "Clinical" is now divided into two Tabs; **Auto** and **Manual**
13. **Clinical Tab Setting**: Sets default presentation to either **Auto** or **Manual**
14. **Auto All setting**: Defines Auto All button and "double-click" in live scan area functions
15. **Auto Play/ Scan Video Quality Settings**: Sets the default level of quality and file size for the AVI file created by recording the animation of the 3D scans
    i. Range: Low = 25MB (1 loop/cycle) and High = 125MB (1 loop/cycle)
16. **3D OCT Sum:** Starting value for En Face presentation (microns) in 3D analysis display
17. **Save 7x7 SLO Raw data:** Option to save or discard the Raw data for the SLO style reference image (image is retained regardless of option selected)
18. **# of Pages for Raster, Radial scan and Grid:** User selects the number of pages the printout uses to render the multi-scan presentations.

Click [**OK**] to save user preference changes. If [**Cancel**] is selected, no changes will be saved.

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6.2.9 *Reset System: (Advanced GUI only)*

This option resets the scanner head in the event of a lock up.

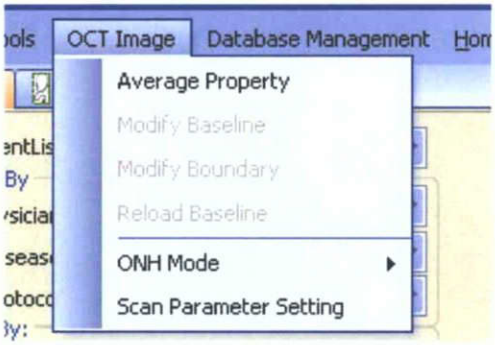
6.2.10 *Clean Unused Scans from Visit*

This option removes the unfinished or unused scans (light gray in scan list) from the list. Use for cleaning up exam with excessive unused scans.

6.2.11 *Remove Protocol from Visit (Advanced GUI only)*

Removes the top level protocol (above the scan list) from the visit. The individual scans will remain, but will not be linked to the protocol for this patient, in this visit only.

6.3 *OCT Image Menu*



6.3.1 *Average Property (Advanced GUI only)*

This is the value used to govern the allowable percentage of variance / match of the individual Line and Cross Line scans that are used for the "averaging" function. (.97 value in field = 97% matching or 3% variance from base image). The default value for this is 0.65.

6.3.2 *Modify Baseline*

Brings up the Video (IR) image and places the disc margin baseline drawing as an overlay for editing purposes. The drawing saved as the baseline may or may not have been drawn on the IR image.

6.3.3 *Reload Baseline*

Places the existing baseline disc margin drawing into the IR image in the upper left corner of the report screen for reference (to edit you must use "Modify Baseline" function (if drawn on the IR image), or the

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3D SLO image of same eye in the baseline 3D scan (if disc margin was drawn using the 3D SLO image).

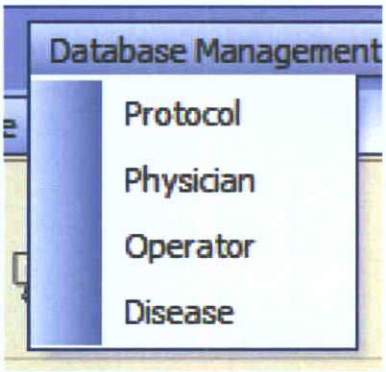
6.3.4 *ONH Mode*

Sets the default location for the disc margin baseline drawing for use with the ONH scan analysis presentation. (see section 6.3.11)

6.3.5 *Scan Parameter Setting*

Set default values for "Dark Eye and "Light Eye" illumination, Grayscale or Color scan display and minimum recommended SSI threshold. (See section 5.12)

6.4 *Database Management Menu*



In the **Database Management** drop-down menu, you may edit and determine the various fields and scans that are displayed in each category.

6.4.1 *Protocol (scan protocol editor):*

These can be created or modified per user preferences.

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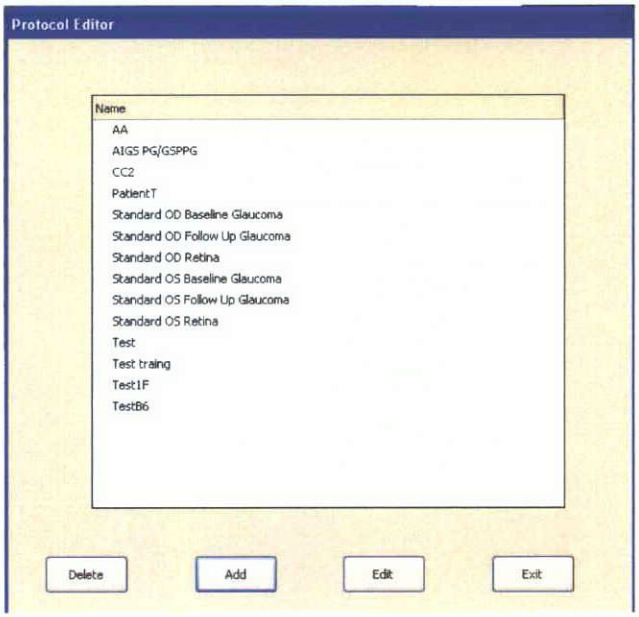
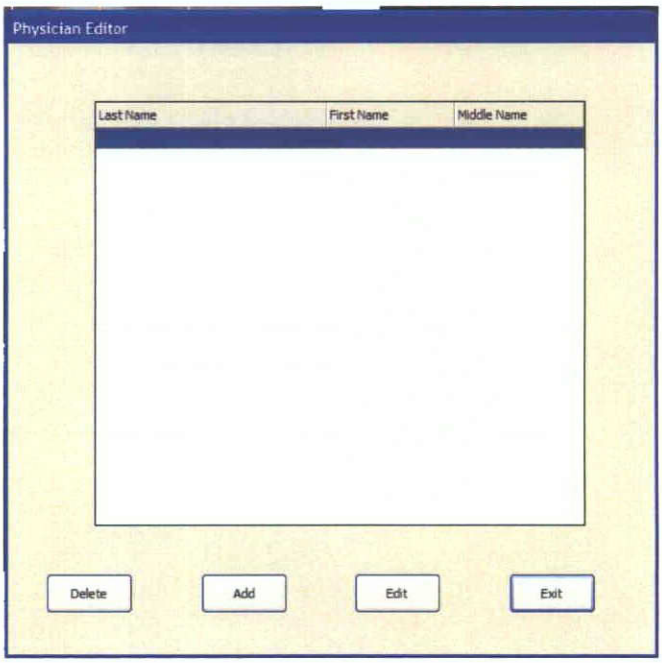


6.4.2 *Physician:*

Add a new physician, edit the name or other information of a current physician or delete a physician if not used by users.



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6.4.3 *Operator:*

Add a new operator, edit the name or other information of a current operator or delete an unused operator who no longer exists.

6.4.4 *Disease:*

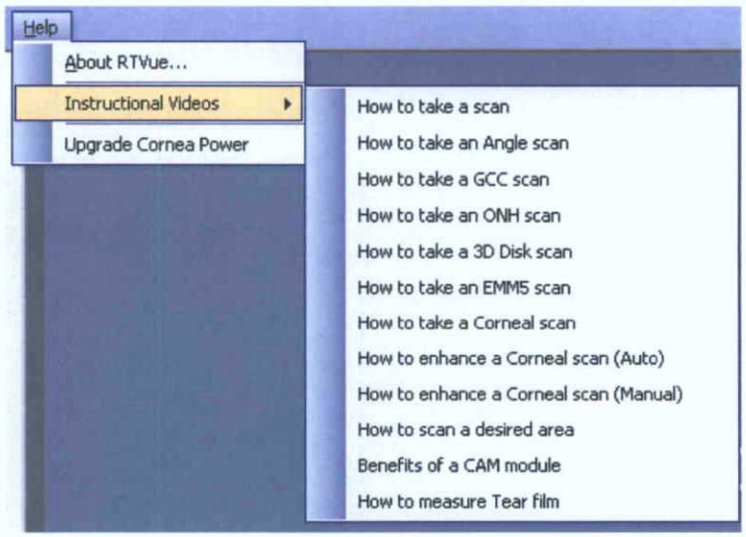
Add, delete or edit disease category

6.5 *Help Menu*

6.5.1 *Instructional videos:*

Instructional videos demonstrating how different scans are acquired are included in the Help menu to serve as a reference. Each time a selection is made under Help → Instructional Videos, a corresponding video will play in Windows Media Player. Use earphones or external computer speakers for sound.

Please note that Windows Media Player needs to be setup in order to use this feature. If it were not used prior to playing an instructional video, you may be prompted for a simple setup procedure.



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7 Maintenance & Troubleshooting

7.1 Routine Care

1. **Dust Prevention:**
   When not using the RTVue, make sure the cloth dust cover is placed over the unit.

2. **Ocular (Front Objective) Lens Cleaning:**
   We recommend that the ocular (front objective) lens of the RTVue be cleaned daily. A weak OCT image or blurry video fundus image may be caused by an unclean front lens (eyelash, finger or nose prints, or excessive dust or dirt from the environment).

   Material required to clean front lens:
   1) Diluted Acetone or Lens cleaning solution
   2) Lens cleaning paper

   Method:
   Wet the lens paper with cleaning solution and wipe the ocular lens with one pass in one direction. Discard the used lens paper. Use a new sheet for each repeat cleaning until the lens is clean.

3. **Head and Chin Rest:**

   For head and chin rest maintenance, it is recommended to clean the surfaces periodically.

   Material required:
   1) Disinfecting agent such as an anti-germicide or isopropyl alcohol; AND
   2) Cloth or cleaning towels
      OR
   3) Wet isopropyl alcohol cleaning paper pad

   Method:
   Soak the cleaning cloth or towel in disinfecting solution or use a wet isopropyl alcohol cleaning paper pad. Wipe the chin-rest cup and head rest pad.

7.2 RTVue Computer Boot Sequence

1. Power up the RTVue table.
2. Turn on the RTVue computer.
3. After Windows™ has fully initialized, double click the RTVue icon to launch the application. It may take approximately 1-2 minutes for Windows to fully intilalize.

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7.3 RTVue Computer Maintenance

Optovue recommends performing **disk cleanup** and **disk defragment** on a regular basis to keep the RTVue PC computer running smoothly. The above functions can be found in system tools.

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8 Scan Pattern Specifications

8.1 Scan Patterns

Summary:

Name	Description	# A-Scan	Adjustability	Default
Scan Pattern				
Line (0.039 seconds)	Single line scan with speckle elimination process option	1 x 1024 (32 scans for 16,384 total data points averaged to single scan image)	Transverse: 2-12mm (0.5 mm increment) Angle: 0 to 180° (1° increment)	6mm, 0 degree (from left to right of the monitor screen)
Cross Line (0.156 seconds)	Cross line scan with speckle elimination process option	2 x 1024 (16 scans in each direction are then averaged)	Transverse: 2-12mm (0.5 mm increment) Angle: 0 to 180° (1° increment)	6mm, 0 degree (from left to right of the monitor screen)
HD Line (0.156 seconds)	High definition single line scan	1 x 4096 (4 scans are captured – one is selected for saving)	Transverse: 2-12mm (0.5 mm increment) Angle: 0 to 180° (1° increment)	6mm, 0 degree (from left to right of the monitor screen)
HD Cross Line (0.312 seconds)	High definition cross line scan	2 x 4096 *(8192 data points)*	Transverse: 2-12mm (0.5 mm increment) Angle: 0 to 180° (1° increment)	6mm, 0 degree (from left to right of the monitor screen)
RNFL3.45 (0.15 seconds) Glaucoma	Four 3.45mm diameter circular scans center on disc	4 x 1024 *(4 scans are taken and presented. Avg is also presented in TSNIT)*	Fixed	3.45mm diameter. (From **T**emple to **S**uperior to **N**asal to **I**nferior (**TSNIT** convention)

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Scan Pattern Specifications

3D Macular (2.2 seconds)	101 frames equally spaced B-scans to cover a square volume fixation at center	101x513 *(51,813 data points)*	Transverse: 2-10 mm (0.1 mm increment) Angle: 0 to 180° (1° increment) Width: 1-6 mm (0.1 mm increment)	6mm x 6mm
3D Disc (2.2 seconds)	101 frames equally spaced B-scans to cover a square volume fixation at 20° nasal	101x513 *(51,813 data points)*	Transverse: 2-10 mm (0.1 mm increment) Angle: 0 to 180° (1° increment) Width: 1-6 mm (0.1 mm increment)	6mm x 6mm
3D Reference (2.4 seconds)	141 B-scans equally spaced to cover 7mm x 7mm volume. Center fixation	141 x 385 (54,285 data points)	Fixed	7mm x 7mm
Raster (0.64 seconds)	17 parallel line scans	17 x 1024 *(17,408 data points)*	2-10 mm in length 1-6 mm in width	L: 6mm W: 4mm
MM6 (0.45 seconds)	12 radial line scans through a central point	12 x 1024 (12,288 data points)	MM6 = 6mm fixed Radial Slicer = up to 10mm	MM6 / Radial = 6mm diameter circular pattern
Grid Line (1.8 seconds)	5 Vertical raster and 5 Horizontal raster lines captured 5 times each and then averaged	10 x 5 x 960 (48,000 data points)	2 – 12 mm length and 0 – 12 mm width adjustment	8 mm length x 2 mm width (250 µm separation)

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Scan Pattern Specifications

EMM5 (1.30 seconds) Retina	13 horizontal lines with 6mm scan length and 0.5mm interval, + 8 horizontal lines with 4mm scan length and 0.5mm interval, 13 vertical lines with 6mm scan length and 0.5mm interval, + 8 vertical lines with 4mm scan length and 0.5mm interval, all centered at fovea	26x 803 + 16x535 *(29,438 data points)*	Fixed	6 x 6mm outer region. 4 x 4 mm inner region 250 µm interval in central 4mm and 500 µm separation outside 1mm (each side and top/bottom)
GCC (0.58 seconds) Glaucoma	1 horizontal line with 7mm scan length, followed by 15 vertical lines with 7mm scan length and 0.5mm interval, centered 1mm temporal to fovea	1 x 933 /Horizontal line. 15 x 933/Vertical line	Fixed	7mm x 7mm
ONH (0.55 seconds) Glaucoma	12 radial line scans 3.4mm length & 13 concentric rings (1.3 - 4.9mm diameter) All centered on disc	3 x 965/ring (4.9, 4.6, 4.3), 3 x 775/ring (4.0, 3.7, 3.4), 3 x 587 (3.1, 2.8. 2.5), 4 x 425/ring (2.2, 1.9, 1.6, 1.3), 12 x 455/radial line	Fixed	4.9 mm diameter centered on the optic disc
Grid (2.0 seconds)	5 Vertical raster and 5 Horizontal raster lines captured 5 times each and then averaged	10 x 5 x 960 (48,000 data points)	2 – 12 mm length and 0 – 12 mm width adjustment	6 mm length x 2mm width (250 µm separation)

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9 Technical Specifications

9.1 System Specification

A. RTVue Scanner:

OCT Image Acquisition Rate: 26,000 A-scan/second
Frame Rate: 256 to 1024 A-scan/Frame
Optical Resolution: (in tissue)
- Depth: 5µm
- Beam Spot Size: 15µm

Image Sampling Rate:
- Depth: 2.9µm
- Transverse: 8µm (nominal)

Scan Range:
- Depth: 2 or 2.3mm
- Transverse: 2mm to 12mm

Scan Beam Wavelength: λ=840±10nm, $\Delta\lambda$ (FWHW) = 50nm
Exposure Power at pupil: 750µW

B. Fundus Imager:

FOV: 32° (H) x 22° (V)
Monochrome CCD Camera: 768 x 498 pixel 1/3" CCD Format
NIR Illumination: 735nm LED

C. Patient Interface:

Working Distance: 22mm
Motorized Focus Range: -15D to +20D
Internal Fixation: Center, ±3.5° (Horizontal), and ±18° (Horizontal)
Motorized Chin-Rest adjustable range: 65mm
Joystick controlled X-Y-Z adjustment: X-100m, Y-85mm, Z-25mm
Lock-mechanism: Electro-magnetic activated

D .Computer Unit:

CPU: 2.66 GHz Quad-Core Processor
Hard Disc: 1 TB
Back up Hard Disc: 1 TB
Archive: USB or Network Drive
RAM: 4 GB
DAQ: Camera link frame grabber

E. Display Unit:

19" Flat Panel LCD Monitor

F. Power Table:

Power Input: 110V A.C. (RTVue RT100-1)
230V A.C. (RTVue RT-100-2)
Current: 1.8AMPS
Frequency: 50/60 Hz
Power Rating: 160W
Maximum Force: 2500N
Motorized adjustment range: 200 mm

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G. Circuit Breaker and Fuse:

Thermal circuit breaker (main power entry)

Rating:	6AMPs, 125-250VAC
Dielectric Strength:	2500 VAC/1 minutes
Operating Temp.:	-10 °C to 60 °C

Fuse (Power supply in Scanner)

Rating:	4AMPs/250V
Package:	5mm x20mm
Type:	Fast Acting, Short Time Lag

H: Compliance:

General Medical	EN60601-1
Medical System	EN60601-1-1
EMC of Medical System	EN60601-1-2
ITE (Computer)	EN60950

I: Environment:

Operating Condition: (no condensation)
- Ambient Temperature: +10 to 40 °C
- Relative humidity: 30% to 75%
- Atmospheric pressure: 700 to 1060 mbar

Storage and Transport Condition:
- Ambient Temperature: -40 to 70 °C
- Relative humidity: 10% to 100% (include condensation)
- Atmospheric pressure: 500 to 1060 mbar

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10 Appendix - A

10.1 Printer Installation

WARNING: When powering a USB-interfaced printer to the RTVue system, it is recommended to connect the power through the designated power supply outlet in the PC compartment. This outlet is isolated from the wall plug (building power) through RTVue's isolation transformer.

If the printer is powered from somewhere other than the designated power outlet, the printer should be placed at least 1.5 meters away from the patient to avoid electric shock.

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11 Appendix - B

11.1 RTVue Precision

Description of Precision Study, Subject Selection Criteria and Pathologies

Instruments:
For the study, 3 RTVues with three different operators and results were compared in normal eyes, and eyes with retina pathology, cornea pathology, and glaucoma.

Scans:
The measurements and parameters calculated from ONH, EMM5 and GCC scans. Both eyes were scanned in each subject.

Precision results are not available for the MM5, MM6 and RNFL 3.45 scan patterns. However, these scan patterns are very similar to other scan patterns where precision results have been presented.

The MM5 scan area is included in the EMM5 since the EMM5 is an enhanced MM5 scan. Precision results of the MM5 scan and the EMM5 scan would be identical.

The MM6 scan pattern is a radial line scan pattern centered on the fovea extending out 3 mm (6 mm total line length with fovea in the middle). The scan pattern shows measurements for full retinal thickness measurements and inner retina thickness measurements. This is very similar to the EMM5 scan pattern. This scan pattern covers a 6 mm by 6 mm square area using a grid scan pattern. It also is centered on the fovea and displays full retinal thickness values and inner retinal thickness values. Because both scan patterns measure retinal thickness, are similar in size and are centered on the fovea, the precision performance is expected to be very similar.

The RNFL 3.45 scan pattern is a circular scan centered on the optic disc. The results are presented as RNFL thickness in the parapapillary region taken from a circle with 3.45 mm diameter. The ONH scan pattern is made up of twelve radial lines and 13 circles centered on the optic disc. The results show RNFL thickness from a circle with 3.45 mm diameter centered on the optic disc. This is the same information presented for the RNFL 3.45 scan pattern. The main difference is the fact the ONH scan pattern has information over a larger area. However the information presented is the same for both, a circular RNFL thickness profile form a 3.45 mm diameter circle. Because of this, we expect the precision results to be nearly identical for the RNFL 3.45 and ONH scan patterns.

Subjects:
Four types of subjects were enrolled in the study at two clinical sites, namely 1) normal healthy eyes with no ocular pathology, 2) glaucoma patients, 3) retina patients, and 4) cornea patients. Normal subjects were free from ocular pathology as determined by the Principal Investigator (PI)

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at each clinical site. Glaucoma patients were diagnosed as having glaucoma by the PI at each site. Retina patients included subjects with any type of retina pathology diagnosed by the PI. Retina pathologies included but were not limited to, AMD, DME, and ERM. Cornea patients included subjects with any type of cornea pathology as diagnosed by the PI, or cornea alteration including LASIK. There were 4 normal subjects, 4 cornea patients, 4 retina patients, and 4 glaucoma patients enrolled for each RTVue device. There were 3 RTVue devices at 2 clinical sites. At one site, there were 2 RTVue systems and 2 operators at different times. In total, there were 16 subjects enrolled for each RTVue device; a total of 48 subjects were included in the study.

Cornea precision results are available in the RTVue User Manual – CAM (Cornea Adaptor Module).

Precision Results:
The following tables provide the precision results for the RTVue scans. The data in the table includes the number of scans per subject group, the overall mean, the standard deviation, the repeatability standard deviation (Median value of subfields with the minimum of all related subfield values and the maximum of all related subfield values), and reproducibility standard deviation (Median value of subfields with the minimum of all related subfield values and the maximum of all related subfield values).

i) EMM5 Scan Precision Results (Normal, Retina and Glaucoma Patients)

EMM5 Full Retina Thickness Fovea			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	243.61 (26.00)	267.15 (73.32)	246.22 (22.14)
Repeatability SD* (Min, Max)	2.57(1.66, 2.57)	2.96(1.83, 3.15)	3.01(1.95, 3.01)
Reproducibility SD** (Min, Max)	17.72(1.66, 17.72)	13.78(1.83, 13.78)	3.01(2.05, 5.80)

EMM5 Full Retina Thickness outside Fovea			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	295.05 (16.21)	299.03 (30.70)	282.30 (25.26)
Repeatability SD* (Min, Max)	1.96(1.66, 2.57)	2.69(1.83, 3.15)	2.35(1.95, 3.01)
Reproducibility SD** (Min, Max)	2.01(1.66, 17.72)	2.69(1.83, 13.78)	2.66(2.05, 5.80)

EMM5 Full Retina Thickness Volume			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	0.63 (0.03)	0.64 (0.07)	103.02 (12.22)
Repeatability SD* (Min, Max)	0.003(0.002, 0.006)	0.004(0.002, 0.010)	2.40(1.78, 2.87)
Reproducibility SD** (Min, Max)	0.005(0.003, 0.015)	0.007(0.003, 0.011)	2.53(1.78, 3.52)

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EMM5 Inner Retina Thickness all measurements			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	112.83 (9.16)	113.04 (15.05)	103.02 (12.22)
Repeatability SD* (Min, Max)	1.38(0.88, 1.72)	2.52(1.57, 3.12)	2.40(1.78, 2.87)
Reproducibility SD** (Min, Max)	1.70(0.88, 7.09)	3.02(1.57, 6.59)	2.53(1.78, 3.52)

EMM5 Global RPE/Choroid Disruption			
	Normal Patients	Retina Patients	Glaucoma Patients
# of Scans	71	71	71
Overall Mean (Overall SD)	5.657 (1.468)	9.797 (3.280)	9.268 (2.552)
Repeatability SD* (Min, Max)	0.207(0.207, 0.207)	0.479(0.479, 0.479)	0.761(0.761, 0.761)
Reproducibility SD** (Min, Max)	0.736(0.736, 0.736)	0.877(0.877, 0.877)	1.611(1.611, 1.611)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

ii) ONH Scan Precision Results (Normal and Glaucoma Patients)

ONH Average RNFL		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	100.82 (8.11)	86.40 (14.99)
Repeatability SD* (Min, Max)	1.76(1.76, 6.18)	1.56(1.56, 5.86)
Reproducibility SD** (Min, Max)	2.11(2.11, 9.78)	7.87(3.92, 16.33)

ONH All Sectors		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	100.82 (14.80)	86.41 (18.55)
Repeatability SD* (Min, Max)	3.92(1.76, 6.18)	4.48(1.56, 5.86)
Reproducibility SD** (Min, Max)	5.40(2.11, 9.78)	7.84(3.92, 16.33)

ONH Horizontal CD Ratio		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	1.27 (0.50)	0.79 (0.21)
Repeatability SD* (Min, Max)	0.04 (0.01, 0.04)	0.08(0.05, 0.08)

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Reproducibility SD** (Min, Max)	0.04 (0.01, 0.04)	0.08(0.05, 0.08)

ONH Vertical CD Ratio		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	2.15 (0.65)	0.76 (0.23)
Repeatability SD* (Min, Max)	0.01 (0.01, 0.04)	0.05(0.05, 0.08)
Reproducibility SD** (Min, Max)	0.01 (0.01, 0.04)	0.05(0.05, 0.08)

ONH Cup Area		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	0.39 (0.18)	1.04 (0.53)
Repeatability SD* (Min, Max)	0.02 (0.02, 0.03)	0.07(0.07, 0.21)
Reproducibility SD** (Min, Max)	0.02 (0.02, 0.03)	0.07(0.07, 0.21)

ONH Rim Area		
	Normal Patients	Glaucoma Patients
# of Scans	72	72
Overall Mean (Overall SD)	0.69 (0.17)	0.89 (0.66)
Repeatability SD* (Min, Max)	0.03 (0.02, 0.03)	0.18(0.07, 0.21)
Reproducibility SD** (Min, Max)	0.03 (0.02, 0.03)	0.18(0.07, 0.21)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

iii) GCC Scan Precision Results (Normal and Glaucoma Patients)

GCC Inner Retina Average		
	Normal Patients	Glaucoma Patients
# of Scans	72	71
Overall Mean (Overall SD)	98.28 (9.31)	81.76 (8.90)
Repeatability SD* (Min, Max)	1.86 (1.86, 2.07)	1.18 (1.18, 1.59)
Reproducibility SD** (Min, Max)	7.56 (7.32, 7.92)	2.55 (1.59, 3.36)

GCC Inner Retina S-I Average		
	Normal Patients	Glaucoma Patients
# of Scans	72	71

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Overall Mean (Overall SD)	0.69 (3.51)	1.98 (8.17)
Repeatability SD* (Min, Max)	1.59 (1.59, 1.59)	2.10 (2.10, 2.10)
Reproducibility SD** (Min, Max)	1.91 (1.91, 1.91)	2.10 (2.10, 2.10)

GCC GCC FLV		
	Normal Patients	Glaucoma Patients
# of Scans	72	71
Overall Mean (Overall SD)	0.60 (0.67)	4.30 (3.47)
Repeatability SD* (Min, Max)	0.37 (0.37, 0.37)	0.88 (0.88, 0.88)
Reproducibility SD** (Min, Max)	0.46 (0.46, 0.46)	1.04 (1.04, 1.04)

GCC GCC GLV		
	Normal Patients	Glaucoma Patients
# of Scans	72	71
Overall Mean (Overall SD)	3.99 (3.43)	15.51 (7.81)
Repeatability SD* (Min, Max)	0.83 (0.83, 0.83)	1.03 (1.03, 1.03)
Reproducibility SD** (Min, Max)	2.44 (2.44, 2.44)	1.71 (1.71, 1.71)

*estimate of the standard deviation among measurements taken on the same subject using the same operator and device in the same testing session with repositioning
**estimate of the standard deviation among measurements taken on different subjects using different operators and devices, including repeatability; in some cases the reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

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

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12 Appendix - C

12.1 Signal Strength Index (SSI)

For the RTVue, a Signal Strength Index classification is provided for each scan type in order to help guide the user to determine if the scan quality is acceptable or not. The Signal Strength Index (SSI) is a quantitative measure for judging image quality. It serves as a guide to help the user know if the image quality is generally good or not. It is not the only thing to consider when determining image quality, but it does offer a quantitative assessment of the signal strength in the image which is a major component of image quality. The Signal Strength Index is based on the intensity of the reflected light. The greater the intensity (brightness), the higher the SSI. This is based on a global average over the entire scan pattern. The Signal Strength Index (SSI) is displayed after each scan. In the above scan, the SSI is at the top of the scan. If the SSI is low, it is recommended that the user re-take the scan and try to improve the SSI. The cut-offs recommended for retaking scans are provided in the table below. They are different for each scan pattern due to the fact that different scans require different levels of retinal segmentation. For example, GCC and EMM5 scans require the inner-plexiform layer to be segmented and this layer is generally not the most reflective compared to other retinal layers. The ONH scan is OK at lower SSI levels because the RNFL layer is highly reflective and can be segmented even under less ideal signal strength values. In some cases, the SSI cannot be improved even when retaking the scans due to ocular opacity (e.g., cataract) or other unavoidable causes. In these cases, the scan can still be used even with a low SSI but the results should be interpreted with more caution compared to a scan with a high SSI.

Recommended SSI cut-offs for each scan

Scan Type	Minimum Recommended SSI
EMM5	SSI < 39
ONH	SSI < 28
GCC	SSI < 32

These SSI cut-off values used for RTVue were determined based on an in-house review of a large data set from the RTVue, made up of approximately 100 scans with a wide range of SSI values and including scan types - EMM5, ONH, GCC. MM5, MM6 and RNFL 3.45 scan patterns are very similar to EMM5, ONH and GCC scan patterns. (see Appendix – RTVue Precision for further explanation on scan similarities) To establish the SSI cut-off, approximately 100 B scans were reviewed for 3 scan types on the RTVue (EMM5, ONH, GCC). The basic criteria for review was whether visualization of the critical retinal layers was possible or not, including the ILM (for all scan types), the RNFL (for glaucoma scans), the IPL (for retina scans), and the RPE (for retina scans). The Un-usable cut off value was determined for each scan pattern to be the SSI value where the various retinal layers could no longer be reliably visualized in the B scans. These scans cannot be segmented accurately if there is no ocular structure that can be reliably visualized with low variability. The SSI value associated with this point (where retinal layers cannot be reliably

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discerned) were used as the recommended cut-off point for the user and are included in the table above.

In order to validate the recommended cut-off between acceptable and not acceptable scans, the repeatability of scans was evaluated at difference SSI levels. For this evaluation, repeat scans were performed on six normal subjects with clear ocular media to establish a baseline level of precision. All 3 scan patterns on the RTVue were evaluated and scans were repeated 3 times in order to calculate repeatability defined as the standard deviation of the thickness values for each measurement. The image quality was manipulated by defocusing the OCT image during scan acquisition. The defocusing and resulting lowering of the image quality mimics the clinical situation which would occur with media opacity and small pupils. All measurements were analyzed and the results are provided in the following tables (numbers are the average standard deviation of the 3 scans averaged across all six subjects). The standard deviation represents the amount of measurement variability present under different image quality classifications; the higher the standard deviation, the greater the measurement variability.

EMM5 scan variability results comparing scans with SSI values above the recommended cut-off and below the recommended cut-off

EMM5			
Measurements		Above Cut-Off	Below Cut-Off
Full Retina	Fovea	9.58	54.57
	Tempo	7.27	62.04
	Superior	10.77	43.42
	Nasal	6.91	52.72
	Inferior	10.90	60.97
	Tempo2	5.33	38.96
	Superior2	2.90	33.91
	Nasal2	5.59	42.38
	Inferior2	9.91	52.25
Average		7.68	49.02

Table 1.

Table 1 shows the standard deviation values of 3 scans averaged over all subjects for each EMM5 thickness parameter. The first column of data is the result when the image quality above the recommended cut-off(equal to or above the ROC cutoff 39) and the scans are deemed acceptable and usable. The second column of data is the result when the image quality is listed as below the recommended cut-off (below the ROC cutoff 39) and the scans are deemed unacceptable and not usable. It can be seen that the standard deviations are very good when the image quality is usable, and then gets much worse when the image quality is unusable. From the high variability in the unusable scans, it is recommended that 'Un-usable' scans not be used for clinical decision making due to their poor quality.

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ONH scan variability results comparing scans with SSI values below the recommended cut-off and scans with SSI values above the recommended cut-off.

ONH		
Measurements	Above Cut-Off	Below Cut-Off
Avg RNFL	2.01	5.88
Sup RNFL	2.56	4.31
Inf RNFL	2.76	8.82
Tempo	6.21	11.52
Superior	3.96	10.46
Nasal	4.55	12.68
Inferior	3.68	8.36
TU	5.68	14.16
ST	5.29	13.37
SN	5.92	15.63
NU	5.82	15.79
NL	4.52	10.99
IN	5.40	14.56
IT	4.29	13.93
TL	7.76	19.08
Average	4.69	11.97

Table 2.

Table 2 shows the standard deviation values of 3 scans averaged over all subjects for each ONH thickness parameter. The first column of data is the result when the image quality is above the recommended cut-off (equal to or above the ROC cutoff 28). The second column of data is the result when the image quality is below the recommended cut-off (below the ROC cutoff 28). It can be seen that the standard deviations are very good when the image quality is above the cut-off, and then gets much worse when the image quality is below the cut off. From the high variability in the unusable scans, it is recommended that these scans not be used for clinical decision making due to their poor quality.

GCC scan variability results comparing scans with SSI values above the recommended cut-off and scans with SSI values below the recommended cut-off.

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GCC		
Measurements	Above Cut-Off	Below Cut-Off
Inner Retina Average	1.88	12.25
Superior Average	2.13	14.06
Inferior Average	3.25	14.02
S-I Average	4.13	12.43
GCC-FLV	0.98	3.59
GCC-GLV	1.47	4.85
Average	2.31	10.20

Table 3.

Table 3 shows the standard deviation values of 3 scans averaged over all subjects for each GCC thickness parameter. The first column of data is the result when the image quality is listed as above the cut-off(equal to or above the ROC cutoff 32) and the scans are deemed acceptable and usable. The second column of data is the result when the image quality is below the cut-off (below the ROC cutoff 32). It can be seen that the standard deviations are very good when the image quality is above the cut-off, and then gets much worse when the image quality is below the cut-off. From the high variability scans below the recommended cut-off, it is recommended that these scans not be used for clinical decision making due to their poor quality.

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

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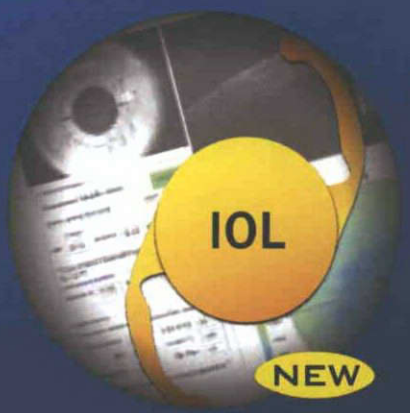
optovue

EFINING THE OCT REVOLUTION

RTVue®

Power for
your practice.

Tracking



Corneal Power

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

Optovue Inc.

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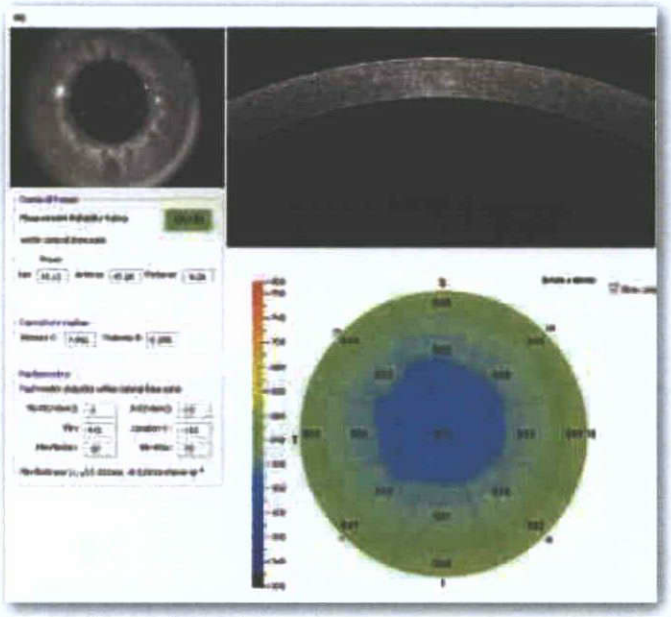
Cornea / Anterior Segment

for non-contact Anterior Segment Assessment

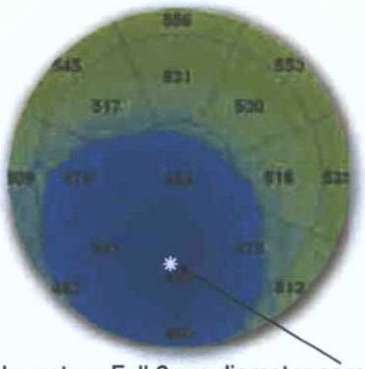
Cornea Power

The Cornea Power Upgrade allows evaluation of patients with prior refractive procedures. Standard topography only calculates the front curvature and then extrapolates posterior curvature. Using the Cornea Power Upgrade, both the anterior and posterior curvatures are measured directly to obtain cornea powers.



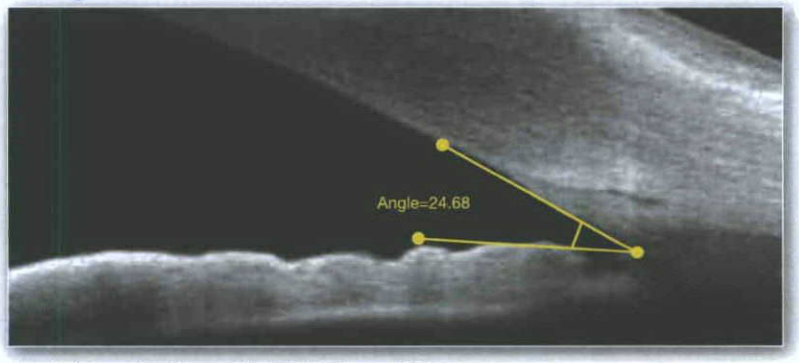
Corneal Power Report

Pachymetry



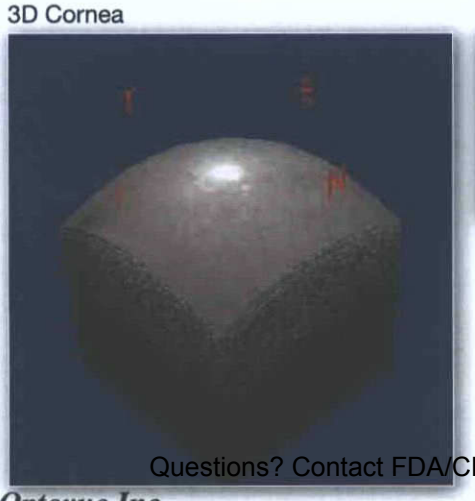
Pachymetry - Full 6mm diameter corneal thickness mapping with minimum thickness indicator (example of Keratoconus)

Angles



Angle Visualization with FDA Cleared Measurement

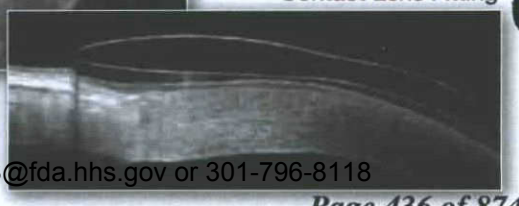
3D Cornea



Lasik Flap

Tear Film

Contact Lens Fitting



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Retina

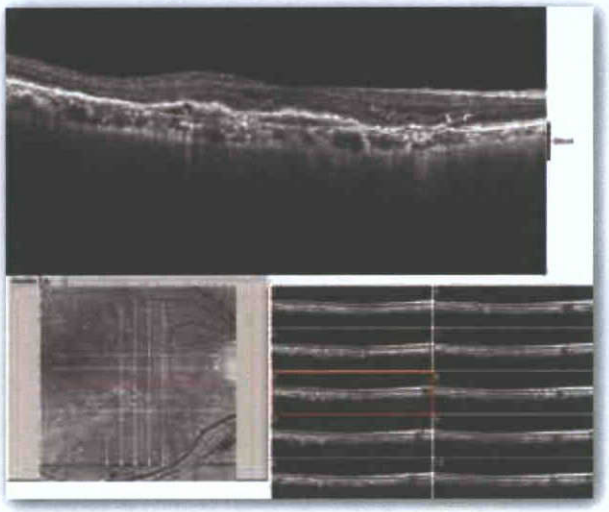
for detecting & tracking disease progression

Tracking

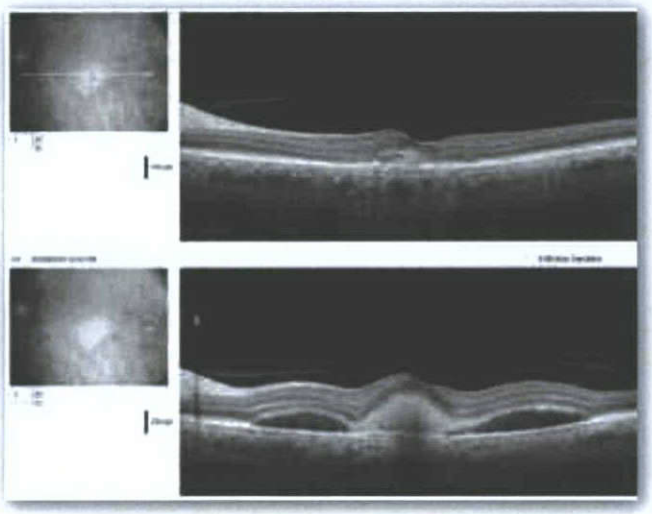
Tracked B-scan with Choroidal Measurements

-18D Myope

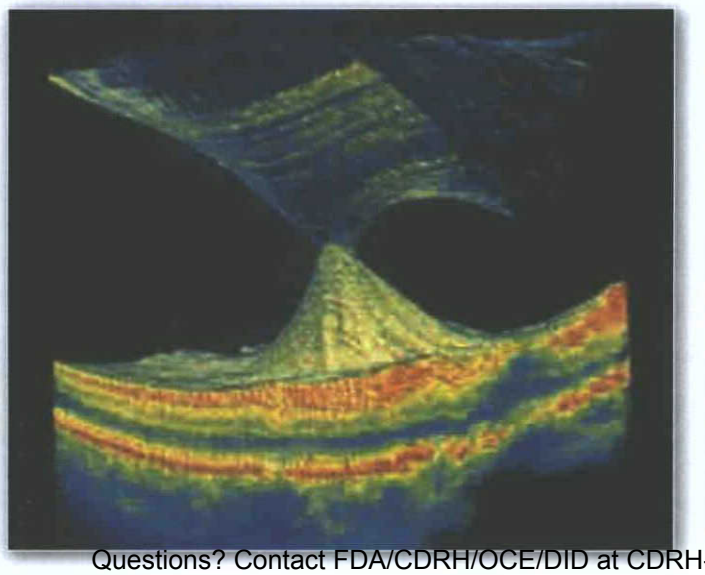
Scroll Through Hi-Resolution Raster B-scans



Compare Hi-Resolution B-scans for Change



3D Retina Volume



Epiretinal Membrane from En Face Analysis

511

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Glaucoma

for early detection and management

The Original GCC®

The power of the GCC Scan can identify ganglion cell loss which may be an early indication of glaucoma. GCC loss precedes RNFL loss based on The Glaucoma Continuum.*

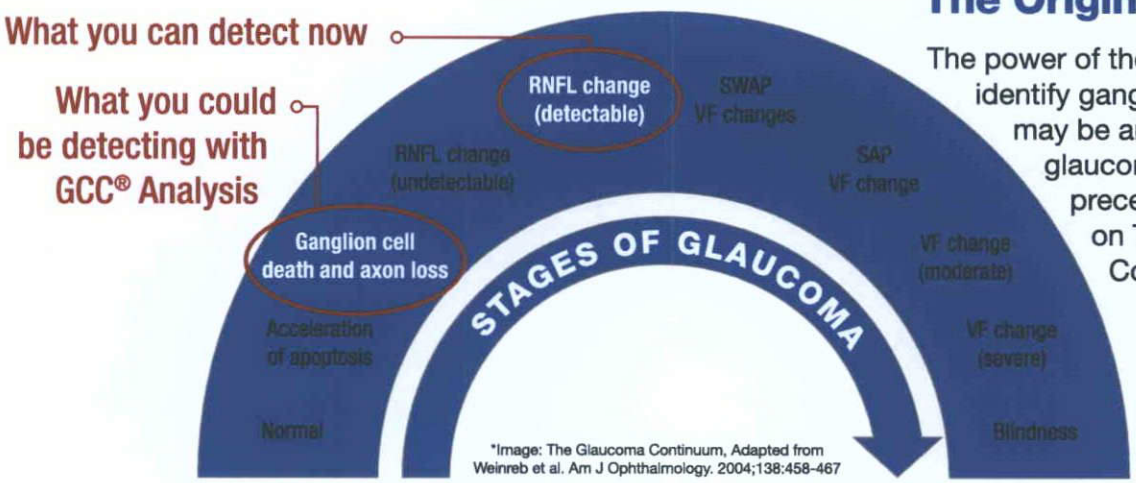
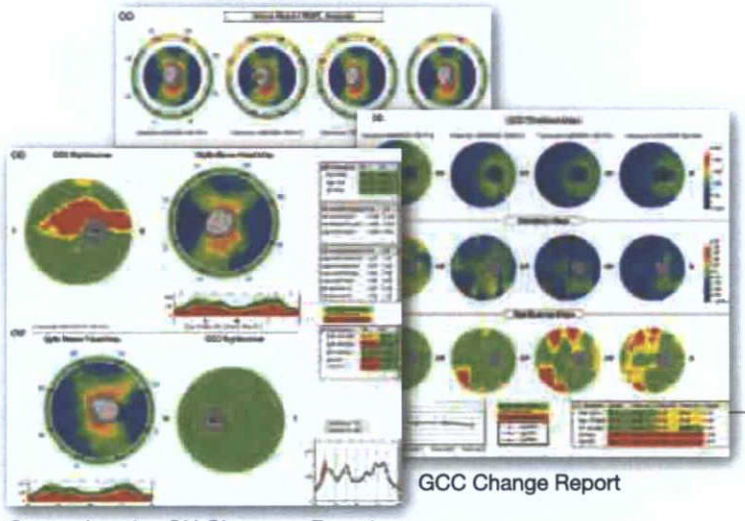


*Image: The Glaucoma Continuum, Adapted from Weinreb et al. Am J Ophthalmology. 2004;138:458-467

Sym-metrix™ & Change

ONH Change Report



GCC Change Report

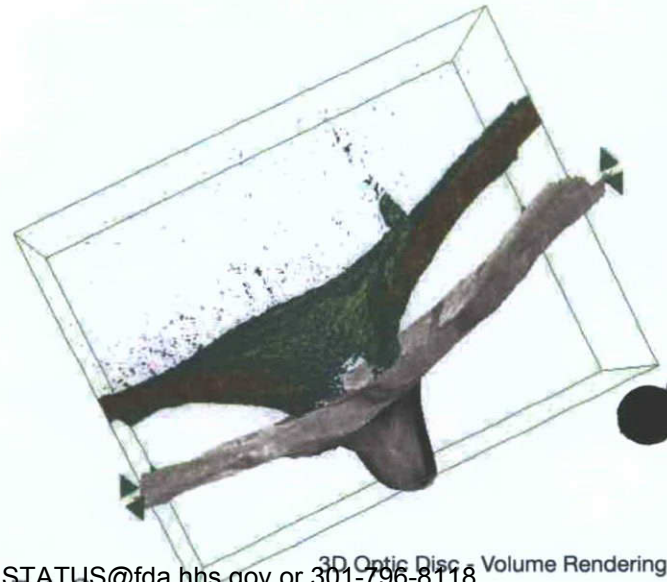
Comprehensive OU Glaucoma Report

GCC { Global Loss Volume (GLV) / Focal Loss Volume (FLV)

GLV and FLV metrics are designed to detect patterns of loss. GLV detects diffuse (global) loss and FLV detects localized (focal) loss over the **Ganglion Cell Complex** map with color-coding based on the comparison to the Normative Database.

The Consummate Glaucoma Package

- GCC with FLV/GLV & Normative Database comparison
- RNFL with Normative Database comparison
- Largest FDA Cleared Normative Database with 656 eyes. Adjusts for:
  - o Age
  - o Optic Disc Size (for ONH scan) – only Optovue does this to date
  - o Scan Signal Strength – only Optovue does this to date
- Optic Disc Metrics
- Angle Measurement (FDA Cleared)
- Full Pachymetry Mapping – 6mm diameter, color coded
- 3D Optic Disc



3D Optic Disc - Volume Rendering

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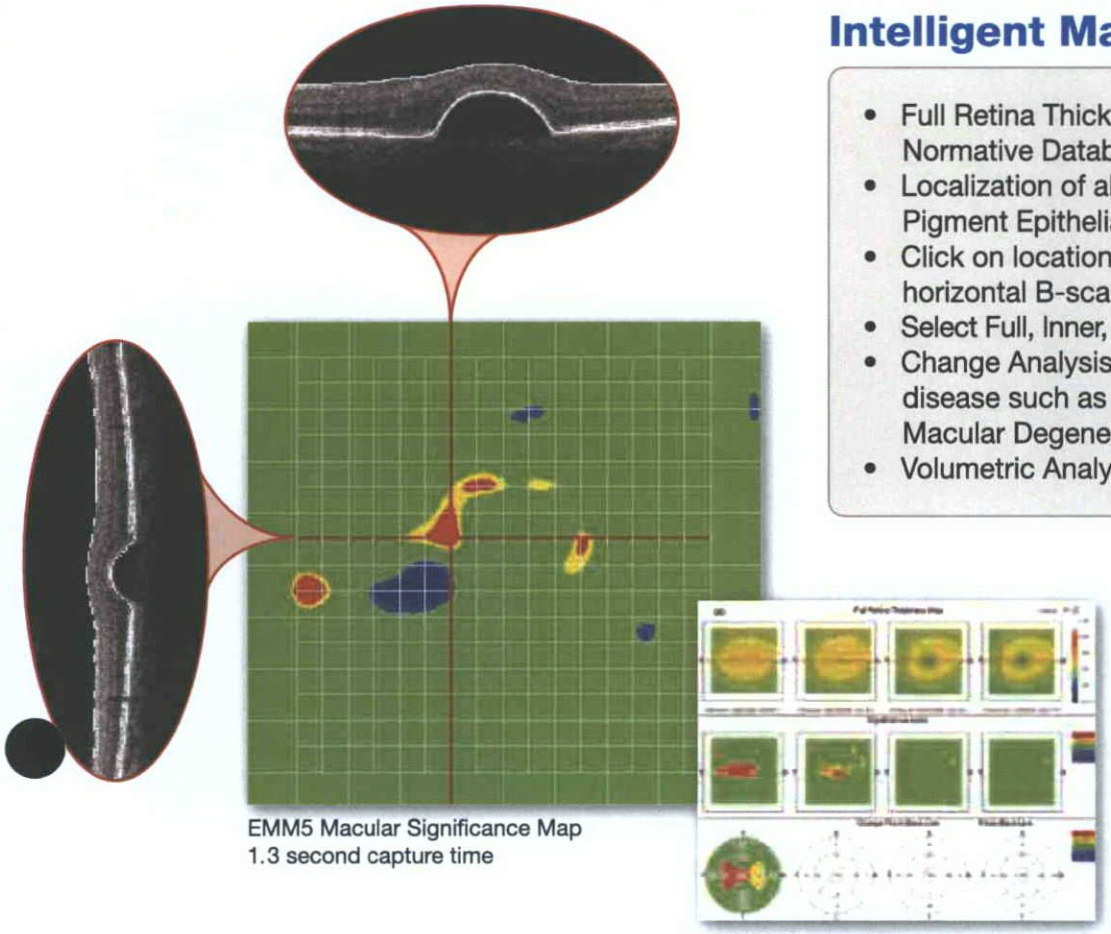
Retina

for detecting & tracking disease progression



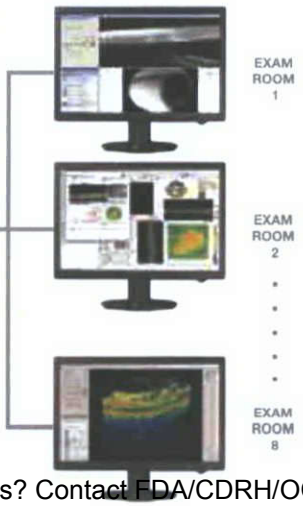
EMM5 Macular Significance Map
1.3 second capture time

EMM5 Change Report

Intelligent Macular Mapping

- Full Retina Thickness comparison to the Normative Database
- Localization of abnormalities (i.e. Pigment Epithelial Detachment on left)
- Click on location to present vertical and horizontal B-scans
- Select Full, Inner, Outer and RPE layer mapping
- Change Analysis to monitor retinal disease such as Diabetic Retinopathy, Macular Degeneration, etc.
- Volumetric Analysis

Networking



With Optovue's networking software, you will be able to:

- **Enhance practice efficiency**
- **Provide patient education**
- **Integrate with EMR software**
- **Eliminate printing costs**

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

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RTVue®

Specifications:

RTVue Scanner:
- OCT Image: 26,000 A-scan/second
- Frame Rate: 256 to 1024 A-scan/Frame
- Depth Resolution (in tissue) : 5.0 µm
- Transverse Resolution: 8µm (nominal)

Scan Range:
- Depth: 2 - 2.3mm (retina)

Scan Beam Wavelength:
- $\lambda = 840 \pm 10$nm

Exposure Power at pupil:
- 750µW

OCT Fundus Image (En Face):
- FOV: 32°(H) x 22°(V)
- Minimum Pupil diameter: 2.5mm

External Image (Live IR)
- FOV: 13mm x 9mm

Patient Interface:
- Working Distance: 22mm
- Motorized Focus Range: -15D to +20D

Computer:
- CPU: 2.66 GHz Quad-Core Processor
- RAM: 4GB
- Hard Disk: 1 TB
- Back Up Hard Disk: 1 TB

514

RTVue® Innovation

Cataract ▸ Cornea Power
Glaucoma ▸ The Original Ganglion Cell Complex (GCC®) Analysis
Retina ▸ Tracking, Deep Choroidal Imaging & Measurement

optovue

Defining the OCT Revolution

P/N 300[illegible]6 Rev.A

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Optovue, Europe GmbH | Gerhart-Hauptmann-Str. 38, 69221 Dossenheim, Germany | PH: +49 6221 5860 661 | FX: +49 6221 5860 664

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

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Attachment [E]

Substantial Equivalence Chart

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8488

Substantial Equivalence Comparison Table

	RTVue with Normative Database	RTVue XR	Comparison Comments
510K No.	K101505		
Decision Date			
Intended Use	The RTVue with Normative Database is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disk as a tool and aid in the diagnosis and management of retinal disease. The RTVue with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.	The RTVue XR with Normative Database is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disk as a tool and aid in the diagnosis and management of retinal disease. The RTVue XR with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.	Exactly the same
Where Used	Hospital/Dr.'s examine room	Hospital/Dr.'s examine room	Exactly the same
Technology Principle	Optical Coherence Tomography (Fourier-Domain)	Optical Coherence Tomography (Fourier-Domain)	Exactly the same
Signal Type	Optical Scattering from Tissue	Optical Scattering from Tissue	Exactly the same
Energy Source	SLD	SLD	Exactly the same
Light Power Level	0.75mW (at cornea)	0.75mW (at cornea)	Exactly the same
Performance			
Axial Resolution (in tissue)	≤6μm	≤6μm	Exactly the same

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8181

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Scan Rate	0.037 mSec/A-Scan	0.014mSec/A-Scan	RTVue XR is faster
Scan Patterns	Line, Circle, Concentric Rings, Radial lines	Line, Circle, Concentric Rings, Radial lines	Exactly the same
Tracking	Averaging and image alignment techniques *(Memo To File for software V6.6)* Move the scan beam to scan the same part of the eye using image alignment algorithm and higher number of averaging	Averaging and image alignment techniques Move the scan beam to scan the same part of the eye using image alignment algorithm and higher number of averaging	Exactly the same. Tracking may provide a sharper scan image even when a patient is not able to fixate on the target or blinks during the scan capture process (clinician has ability to turn tracking off). Existing averaging techniques are utilized.
Follow-up mode	Image alignment techniques *(Memo To File for software V 6.6)* Adjust the scan beam based on image alignment to begin scanning approximately the same part of the eye that was scanned in the previous visit	Image alignment techniques Adjust the scan beam based on image alignment to begin scanning approximately the same part of the eye that was scanned in the previous visit	Exactly the same. Provides ability to scan approximately the same part of the eye even in the event patient does not maintain same fixation from visit to visit. Existing image alignment techniques were utilized (clinician has ability to turn off)
Retinal	**Scan Pattern used:** MM5/EMM5 Scan pattern is a grid scan pattern **Measurements provided from the scan pattern:** 1. Full retinal thickness 2. GCC thickness 3. Outer retinal thickness 4. ILM Height 5. RPE Height	**Scan Pattern used:** MM5/EMM5 Scan pattern is a grid scan pattern **Measurements provided from the scan pattern:** 1. Full retinal thickness 2. GCC thickness 3. Outer retinal thickness 4. ILM Height 5. RPE Height	Exactly the same.

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	NDB Comparison for: 1. Full retinal thickness **Color code for Cutoff Thresholds on all retina thickness:** 1. <1%: black 2. 1% to 5%: blue 3. 5% to 95%: Green 4. 95% to 99%: yellow 5. >99%: red	**NDB Comparison for:** 1. Full retinal thickness **Color code for Cutoff Thresholds on all retina thickness:** 1. <1%: black 2. 1% to 5%: blue 3. 5% to 95%: Green 4. 95% to 99%: yellow 5. >99%: red	
GCC (Glaucoma)	**Scan Pattern used:** MM7/GCC Scan pattern is a raster scan pattern **Measurement provides from the scan pattern:** 1. GCC thickness 2. Focal Loss Volume 3. Global Loss Volume **NDB Comparison for:** 1. GCC thickness **Color code for Cutoff Thresholds on GCC:** 1. <1%: red 2. 1% to 5%: yellow 3. >5% : green	**Scan Pattern used:** MM7/GCC Scan pattern is a raster scan pattern **Measurement provides from the scan pattern:** 1. GCC thickness 2. Focal Loss Volume 3. Global Loss Volume **NDB Comparison for:** 2. GCC thickness **Color code for Cutoff Thresholds on GCC:** 1. <1%: red 2. 1% to 5%: yellow 3. >5% : green	Exactly the same
RNFL and optic disk (Glaucoma)	**Scan Pattern used:** NHM4/ONH Scan pattern composed of concentric rings and radial lines **Measurements provided from the scan pattern:** 1. RNFL thickness 2. Disk Size 3. Rim Size	**Scan Pattern used:** NHM4/ONH Scan pattern composed of concentric rings and radial lines **Measurements provided from the scan pattern:** 1. RNFL thickness 2. Disk Size 3. Rim Size	Exactly the same.

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	4. Cup size 5. C/D ratio **NDB Comparison for:** 1. RNFL thickness **Color code for Cutoff Thresholds for :** **RNFL thickness and Rim area:** 1. <1%: red 2. 1% to 5%: yellow 3. > 5%: Green **Cup area:** 1 >99%: Red 2 95% to 99%: yellow 3 < 95%: Green **C/D ratio:** 1. >99%: Red 2. 95% to 99%: yellow 3. < 95%: Green	4. Cup size 5. C/D ratio **NDB Comparison for:** 1. RNFL thickness **Color code for Cutoff Thresholds for :** **RNFL thickness and Rim area:** 1. <1%: red 2. 1% to 5%: yellow 3. 5%: Green **Cup area:** 1. >99%: Red 2. 95% to 99%: yellow 3. < 95%: Green **C/D ratio:** 1. >99%: Red 2. 95% to 99%: yellow 3. < 95%: Green	

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Attachment [F]

Performance Data and Certification of Compliance, under 42 U.S.C. § 282(j) (5) (B)

- IEC-60601-1 Safety Test Report # R64363 Rev.3
- IEC-60601-1-2 EMC-Report #R63864 Rev.4
- RTVue XR Bench Test Report
- FDA Form # 3674

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CE Safety Component Compliance Report
For
Optovue Inc.

**Models: RTVue100-1, RTVue100-2 and RTVue XR*

In accordance with
EN 60601-1: 1990, Safety requirements for Medical Electrical Equipment, Part 1 General Requirements for safety
With amendments A1: 1993 and A2 1995

MANUFACTURER:	Optovue, Inc. 45531 Northport Loop West Fremont, CA 94538 U.S.A.
PRODUCT TYPE:	High Speed Tomographic Device
REPORT DATE:	August 15, 2006
REISSUE DATE:	December 20, 2011
COMPLIANCE ENGINEER:	Jim Leng, Product Safety Engineer
REPORT REVISED BY:	Noel Lovato, Product Safety Engineer
REVIEWED BY:	Gary Izard, Quality Assurance Representative

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REVISION SUMMARY

The following is a list of revisions that have been made to the report.

Revision	Issue Date	Description Of Modifications	Revised By
	August 15, 2006	Initial Release	
1	August 31, 2006	Changed contact name from Chang to Chen	Jim Leng
2	October 31, 2006	Changed model and computer holder rear panel	Jim Leng
3	December 20, 2011	Added RTVue XR model, updated computer and monitor	Noel Lovato

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Manufacturer's General Information

Declaration Holder/Manufacturer: Optovue, Inc.
45531 Northport Loop West
Fremont, CA 94538
U.S.A.

510-623-8898 (Telephone)

Manufacturer's Representative:
Email: (b)(4) [redacted]

Report Objective

*Optovue, Inc., models RTVue100-1, RTVue100-2 and RTVue XR have been evaluated and tested in accordance with the following standards: EN 60601-1:1990, Safety requirements for Medical Electrical Equipment, Part 1: General Requirements.

*Optovue, Inc., models RTVue100-1, RTVue100-2 and RTVue XR have been found to comply with the above standard. Certain features are considered to be incomplete in construction and the products acceptability is based on its acceptance in the end use Standard. The clauses referenced in Section 3 of this Report are applicable to the subject product. Comments pertaining to the clauses are for clarification or support of compliance to the clause. If clauses are not referenced, they are either non-applicable or narrative in nature.

Product Function:

*The RTVue100-1, RTVue100-2 and RTVue XR are a high resolution and high-speed tomographic device for the viewing and axial cross sectional imaging of posterior ocular structures. It is used for in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disk. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases, including but not limited to macular edema, central serous retinopathy, and glaucoma.

EU Declaration of Conformity:

The above Standard has been identified as the harmonized standard that needs to be met before declaring conformity with the Medical (93/42/EEC) Directive. This Report per the above Standard can serve as part of the documentation to be placed in the product Technical File. The existence of a Technical File is required to support the EU Declaration of Conformity for this product.

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Manufacturer's Documentation:

The manufacturer must keep the following documents on file and readily available if requested by the competent authorities.

1. Declaration of Conformity.

2. Copy of this Report.

3. Copies of Component Licenses.

4. Production Test records.

5. Material such as design specification, schematics, drawings, BOMs, operators' guides, and other supporting documentation in the Technical File. This File must be kept for 10 years after the last unit is produced and marketed in order to meet European Union requirements in effect at the publishing date of this Report.

Generic Construction Criteria:

Wiring: All internal wiring is UL, CSA, Harmonized (HAR) or equivalent rated for the temperature, voltage, and current in which it is exposed.

Tubing/Sleeving: All tubing/sleeving used for compliance with the standards are UL, CSA, HAR or equivalent, rated for the temperature, voltage and current in which it is exposed.

Printed Circuit Boards: All printed circuit boards and including flexible circuit boards are UL Recognized, with a minimum flame rating of 94 V-1 or better and a temperature rating of at least 105 °C.

Internal Plastics: All internal plastics (excluding small electrical components, i.e., capacitors, chips & etc.) have a minimum flammability rating of V-2.

Dimensions: All dimensions are approximate unless otherwise specified.

Wire Fixings: Hazardous wiring connections have a redundant means of securement.

Securement of Components: All components that may create a safety hazard are secured by screws or provided with such means as integral tabs on the component.

Miscellaneous Components: Components not specifically described in the product description portion of this report are not deemed critical to safety. However, they should comply with the *Generic Construction Criteria.*

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Product Description:

Section 1, General Product Information:

Product Type:	High Speed Tomographic Device
*Models:	RTVue100-1, RTVue100-2 and RTVue XR
Electrical Ratings:	120V, 50/60 Hz, 5A.
Connection to Supply:	Via power cord
Pollution Degree:	2
Installation Category:	II
Max. Tmra:	40 ° C
Serial Number (test sample):	Prototype

Section 2, Components:

Components that bear approval by a certification agency are denoted with the following abbreviations:

(VDE) - Verband Deutscher Electrotechniker
(TÜV Rh) -Technische Uberwachungs-Verein - Rheinland
(TÜV PS)-Technische Uberwachungs-Verein - Product Service
(CSA) - Canadian Standards Association
(UL) - Underwriters Laboratories
(HAR) - Harmonized, approved component to a European Harmonized standard
** Indicates the component has a Certificate or License to an EN or IEC standard.
@@ Indicates compliance to a standard with equivalent requirements of EN 61010-1

The term "or equiv." is used in the report to denote components for which an equivalent manufacturer or part number may be used without affecting compliance with the applicable safety standards. Components *not* specified with an "or equiv." should be evaluated for continued compliance with the standards.

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(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

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Condition of Acceptability:

1. The equipment has not been investigated for the protection against hazards of explosions in medically used rooms.
2. The main supply cord set provided with the equipment must be an approved type acceptable to the authorities in the country where the equipment is sold.
3. The user replaceable mains (line) fuse must be an approved type acceptable to the authorities where the equipment is sold.
4. Evaluated to IEC/EN 60601-1 Amendment 2 excluding requirements for Electromagnetic compatibility (Clause 36), Biocompatibility (Clause 48) and Programmable Electronic Systems (Clause 52.1).
5. Markings as described in the report shall appear on each unit.
6. The protective earthing conductor shall be green/yellow.
7. The equipment shall be marked with a fixed warning notice stating that transport may be undertaken only in a certain position, which is clearly described in the instructions for use or illustrated by inscription on the equipment.
8. A correctly rated fuse link shall be fitted in each supply.
9. Insulated conductors of the primary circuit and safety extra low voltage circuits shall be secured and separated.
10. There shall be no indicator lights that are red in colour except to indicate a warning of danger or need for urgent action.
11. The shipping package shall be marked with the allowable environmental conditions such as humidity range, atmospheric pressure range and temperature range. This shall also be listed in the manual.
12. Following Production-Line Test shall be conducted 100% on the products covered by this report. Production Line Di-electric Voltage Withstand Test and Ground continuity test.

    -Di-electric test needs to be performed for basic insulation from input electrical inlet. The test voltage is 1000V AC or 1414V DC.

    -Ground Continuity test, the indicating device can be as ohmmeter, battery and buzzer combination or the like may be used to determine compliance. The continuity shall be determined between the grounding conductor of the attachment plug cap, and /or the designated main grounding point, and accessible dead-metal parts of the product using the test equipment.

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Compliance per the applicable clauses of EN 60601-1:1990

5	CLASSIFICATION		Verdict
5.1	Class I equipment, Classw II equipment or internally powered equipment	Class I equipment	P
5.2	Type B applied part, Type Type BF applied part, Type CF applied part, Not classified	Type B applied part.	P
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1)	For in door use only IPX0	P
5.4	Method(s) of sterilization or disinfection	Clearing method stated in the user manual	P
5.5	Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide	Not intended for use with anaesthetic material condition.	P
	Anaesthetic proof AP	See above	N
	Anaesthetic proof category G (APG)	See above	N
5.6	Mode of operation:		
	Continuous operation	This is a continuous operation with intermittent loading, which is an optomologist diagnostic device.	P
	short-time operation, specified operation; rest period	See above	N
	intermittent operation, specified operation; rest period	See above	N
	continuous operation with short-time, stated permissible loading time:	See above	N
	Continuous operation with intermittent, stated permissible loading/rest time:	See above	N

6	IDENTIFICATION, MARKING AND DOCUMENTS		
6.1	Marking on the outside of equipment or equipment parts		
	a) Mains operated equipment		
	b) Marking on the major part of equipment	Marking on the base of the equipment	P
	c) Markings of the specific power supply are affixed	No external power supply provided	N
	e) Name and/or trademark of the manufacturer or supplier	Label provided such information	P
	f) Model or type reference	Provided with label	P
	g) Rated supply voltages or voltage ranges, number of phases, type of current	Stated in the manual and labeled on the device	P
	h) Rated frequency or rated frequency ranges in Hz	See above	P
	j) Rated power input (VA, W or A) :	See above and maximum current are for input 120V AC / 5A	P
	k) Power output of auxiliary mains socket-outlets	The auxiliary mains socket outlets is for internal connection only	N
	l) Class II symbol	It's class I equipment	N
	Symbol for degree of protection provided:		
	drip-proof equipment (IPx1)	IPX0	P
	splash-proof equipment IPx4)	See above	N
	watertight equipment (IPx7)	See above	N
	Symbol for protection against electric shock:		
	type B	Provide in the user manual and on the label	P
	type BF or CF :	See above	N

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	Symbol for protection of defibrillation-proof applied parts :	No such applied part	N
	m) Mode of operation (if no marking, suitable for continuous operation	Continuous operation with intermittent loads.	P
	n) Types and rating of external accessible fuses	Label adjacent to fuse holder	P
	p) Rated output voltage and current or power output frequency (where applicable)	Provided in the user manual and on the label	P
	q) Symbol for physiological effect(s):		
	attention, consult accompanying documents	No readiations	N
	non-ionizing radiation, or symbols as adopted by ISO or IEC 417	See above	N
	r) Anaesthetic-proof symbol:		
	type AP	No such device	N
	type APG	No such device	N
	s) Dangerous voltage symbol	No accessible to high voltage and no such device	N
	t) Special cooling requirements	No such device and requirement	N
	u) Limited mechanical stability	Tested for 10 degree tilted	P
	v) Protective packing requirement(s)	Provided Fragile, Keep dry and this end up symbols	P
	Marking(s) for unpacking safety hazard(s)	No such material provided	N
	Equipment or accessories supplied sterile, marked as sterile	No such device provided	N
	y) Potential equalization terminal	Not provided	N
	Functional earth terminal	Not provided	N
	z) Removable protective means	No user removable parts	N
	Durability of markings	Use UL recognized label	P
6.2	Marking on the inside of equipment or equipment parts		
	a) Nominal voltage of permanently installed equipment	Evaluated under isolation transformer and internal power supplies	P
	b) Maximum power loading for heating elements or holders for heating lamps	No such parts	N
	c) Dangerous voltage parts	No such part accessible to the operator or patient	P
	d) Type of battery and mode of insertion	No user replaceable battery provided. Cell battery for computer main board is a cell lithium battery, which is not intended as replaceable battery	N
	Battery not intended to be changed by the operator	See above	P
	e) Fuse type and rating or reference	No user replaceable fuse	N
	f) Protective earth terminal		P
	g) Functional earth terminal	Not provided	N
	h) Supply neutral conductor in permanently installed equipment (N)	Not a permanently installed equipment	N
	j) Markings required in 6.2 f), h), k) ,and l) shall not be affixed to parts which have to be removed and remain visible after connection	No removable part contains marking.	P
	k) The supply connections are clearly marked adjacent to the terminals or in accompanying documents (for small equipment)	Not a permanently installed equipment	N
	l) Statement for suitable wiring materials (at temperatures over 75°C) located at or near the point of the supply connections (see also Cl 42)	See above	N

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	Statement is clearly discernible	See above	N
	n) Capacitors and/or circuit parts are marked as required in 15 c)	Use medical graded isolation transformer and internal power supply	N
6.3	Marking of controls and instruments		
	a) Mains switch clearly identified	Provided and consider acceptable	P
	ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light or other unambiguous means	Provided ON and OFF symbols on the switch	P
	b) Indications of controls and other switches	Monitor and Computer have they are own switches and consider adequate.	P
	c) Indication of the direction of setting devices	General statement	N
	f) Functions of operator controls and indicators are identified	Provided in the user manual	P
	g) Numeric indications of parameters are according to ISO 1000	Consider adequate	P
6.4	Symbols		
	Symbols used comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	Symbol of number 1,6,14, 15 and 16 are provided from table DI. Symbol of number 1 and 6 are provided from DII	P
6.5	Colours of insulation of conductors		
	a) Protective earth conductor has green/yellow insulation	Green and yellow insulation provided	P
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations	Consider acceptable	P
	c) Only protective earth or potential equalization conductors are green/yellow	Consider adequate	P
	d) Colour of neutral conductor :	Within approved power supply and medical graded power cord	P
	Colours of phase conductors :	Within approved power supply	N
	e) Compliance with IEC 227 and IEC 245	No applicable	N
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors	See above	N
6.6	Medical gas cylinders and connections		N
	a) In accordance with ISO/R 32	No such part	N
	b) Identification of connection point	No such part	N
6.7	Indicator lights and push-buttons		N
	a) On indicator lights the colour red is used exclusively to indicate a warning of danger and/or a need for urgent action	No such red indicator	N
	b) Colour red is used only for push-buttons by which a function is interrupted in case of emergency	No red indicator	N
6.8	Accompanying documents		P
6.8.1	Equipment is accompanied at least by:		P
	- instructions for use	Provide and consider adequate	P
	- technical description	Provide	P
	- an address to which the user can refer	Provide in the user manual	P
	All classifications specified in Cl. 5 are included in both the instructions for use and the technical description if separable	Provide in the user manual and consider adequate	P

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	Warning statements and explanations of warning symbols are provided in accompanying documents	Provide in the user manual	P
	Language of accompanying documents :	English	P
	All markings specified in 6.1 shall be included in full in the accompanying documents if they have not been permanently affixed to equipment	Consider adequate	P
6.8.2	Instructions for use		P
	General information	General statement	P
	Instructions for use shall:		P
	- state the function and intended application of the equipment	Provide in the user manual	P
	- include an explanation of: the function of controls, displays and signals	See above	p
	- the sequence of operation	See above	P
	- the connection and disconnection of detachable parts and accessories	See above	P
	- the replacement of material which is consumed during operation	No such material	N
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	No such material or part	N
	- provide the user or operator with information regarding potential electromagnetic or other interference	General statement in the user manual	P
	- instructions for user or operator concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	Provide in the user manual	P
	The instructions shall:		
	- provide information for the safe performance or routine maintenance	Provide in the user manual	P
	- identify the parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	No such part requires maintenance	N
	- explanation of figures, symbols, warning statements and abbreviations on the equipment	Provide in the user manual	P
	Signal output and signal input parts	All ports are defined except port with personnel computer such as USB ports, audio port and earphone port	P
	Signal output or signal input parts intended only for connection to specified equipment	Defined in the user manual except USB ports	P
	Cleaning, disinfection and sterilization of parts in contact with the patient	Needs cleaning instruction	P
	Details about cleaning or disinfection or sterilization methods that may be used for the equipment parts which come into contact with the patient in normal use	Needs cleaning instruction	P
	Mains operated equipment with additional power source	No such power source	N
	A warning statement referring to the necessity for periodical checking or replacement of an additional power source	See above	N
	If Class I equipment a statement saying that where the integrity of the external protective conductor in the installation or its arrangement is in doubt, equipment is operated from its internal electrical power source	No such function or statement for the device	N

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	Removal of primary batteries	No user replaceable battery	N
	A warning to remove batteries if equipment is not likely to be used for some time, unless there is no risk of a safety hazard arising	See above	N
	Rechargeable batteries	See above	N
	Instructions to ensure safe use and adequate maintenance	See above	N
	Equipment with a specified power supply or battery charger	Not applicable	N
	Identification of power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	See above	P
	Environmental protection	Not applicable	N
	Instructions for use shall:		
	- identify any risks associated with the disposal or waste products, residues, etc., and of the equipment accessories of the end of their useful lives	Not applicable	N
	- provide advice in minimizing these risks	See above	N
6.8.3	Technical description		
	General	General Statement	P
	All data, which is essential for safe operation including:		P
	- data mentioned in 6.1	Considered adequate	P
	- all characteristics of the equipment, including ranges, accuracy, and precision of the displayed values	Provided in the user manual and consider adequate	P
	A statement whether particular measures or particular conditions are to be observed for installing equipment and bringing equipment into use	Operation condition has been provided	P
	Replacement of fuses and other parts	No user replaceable fuse	N
	Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment	See above	N
	Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	No such parts	N
	Circuit diagrams, component part lists, etc.	No user serviceable parts	N
	A statement that the supplier will make available on request circuit diagrams, component part lists, descriptions, calibration instructions etc.	See above	N
	d) Environmental conditions for transport and storage	Provide in the user manual	P
	A specification of the permissible environmental conditions for transport and storage	Defined in the user manual and consider adequate. Label on the shipping box also indicate shipping environmental conditions	P

7	POWER INPUT		
	Power input	(See appended table)	
7.1	Rated steady state input power (W, VA, A) :	Within approved isolation transformer and power supply	P

14	REQUIREMENTS RELATED TO CLASSIFICATION		
14.1	Class I equipment		N
	a) Parts with double insulation	Evaluated under isolation transformer and power supplies. DC/DC converter, passed dielectric test in lore of meeting double insulation	N

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	Parts with reinforced insulation	See above	N
	Parts with SEL voltage	See above	N
	Parts with protective impedance	See above	N
	b) If the mains part of equipment specified for an external DC power source is isolated from accessible metal parts by basic insulation only, a separate protective earth conductor is provided	No DC input	N
14.2	Class II equipment		
	a) Class II equipment is one of the following types:		
	insulation-enclosed	Its class I device	N
	metal-enclosed	Not applicable	N
	combination of insulation and metal-enclosed	Not applicable	N
	b) If equipment is fitted with a device for changing over from Class I to Class II protection, the following requirements are fulfilled:		
	the change-over device indicates the selected class clearly	Not applicable	N
	a tool for change-over is necessary	See above	N
	the equipment complies with all requirements for the selected class at any time given	See above	N
	Class II position: the device interrupts the connection of protective earth conductor to equipment or changes it into a functional earth conductor (compliance with 18.2)	See above	N
14.4	Class I and Class II equipment		
	a) Equipment is provided with additional protection according to the rules of Class I or Class II	Class I device	N
	b) No safety hazard shall develop, when a connection with the wrong polarity is made in equipment specified for power supply from an external DC power source (e.g. in mobile equipment)	No external DC source required	N
14.5	Internally powered equipment		
	b) For connection to a supply mains the equipment complies with the requirements for Class I or II equipment	Not internally power device	N
14.6	Types B, BF and CF applied parts		
	c) Applied parts which are specified in the accompanying documents as suitable for direct cardiac application are of type CF	No applied parts	N

15	LIMITATION OF VOLTAGE AND/OR ENERGY		
	b) Interference suppression capacitors	Evaluated under isolation transformer and power supplies	N
	Capacitance between each line & protective earth	With approved power supply	N
	Measured value (pF) :	See above	—
	Capacitance between lines	Within approved power supply	N
	Measured value (pF) :	See above	—
	Maximum residual voltage in the mains plug 1 s after disconnection (measured in the least favourable position of the ON/OFF switch, if any):		N
	Remark: pins 1 and 2 are line and neutral supply pins		
	c) Residual voltage or energy in capacitors	(See appended table)	P
	Means of discharging capacitors:		
	- automatic	Within approved power supply	N
	- non-automatic (included and marked)	Not applicable	N

16	ENCLOSURES AND PROTECTIVE COVERS		

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	a) Protection against accidental contact; location of opening; test result (finger, pin, hook):	On the side, there are 39 holds measured 3.5mm diameter and internal are SELV	P
	b) Openings in top covers (test rod)	See above	N
	c) Conductive parts of actuating mechanism of electrical controls after the removal of handles, knobs, levers etc. have either resistance to the protective earth terminal 0,2 or the separation from live parts comply with Cl. 17g)	No such handle can be removed	N
	d) Protection of internal parts of the equipment with a circuit voltage exceeding 25V AC or 60V DC which cannot be disconnected from the supply by external means	Detachable power cord used	P
	e) Protective enclosures are removable only with the aid of tool or an automatic device shall make these parts not live, when the enclosure is opened or removed	Use of tool to remove screws	P
	f) Basic insulation or live parts or parts not protectively earthed and separated from the mains by basic insulation only are inaccessible to the test rod trough openings for adjustment of pre-set controls	Tested by test rod.	P

17	SEPARATION		P
	a) Separation method of the applied part from live parts:		
	1) Basic insulation: applied part earthed	Apply part is not earthed	N
	2) by protectively earthed conductive part (e.g. screen)	See above	N
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure	Plastic chassis used.	P
	4) by double or reinforced insulation	See above	N
	5) by protective impedances limiting current to applied part	See above	N
	c) There is no conductive connection between applied parts and accessible conductive parts, which are not protectively earthed	Plastic material in contact with client.	P
	d) Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)	Not applicable	N
	g) Separation method of accessible parts other than applied parts from live parts:		N
	1) basic insulation: accessible part earthed	See above	N
	2) by protectively earthed conductive part (e.g. screen)	See above	N
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure	Plastic chassis used.	P
	4) by double or reinforced insulation	See above	N
	5) by protective impedances limiting current to accessible part	See above	P
	h) Arrangements used to isolate defibrillation-proof applied parts are so designed that:		N
	- no hazardous electrical energies do appear during a discharge of a cardiac defibrillator	Not defibrillator	N
	- after exposure to the defibrillation voltage, the equipment shall continue to perform its intended function	See above	N

18	PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION		
	a) Accessible parts of Class I equipment separated from live parts by basic insulation only are connected by sufficiently low impedance to the protective earth terminal	Tested, see clause 18, f.	P

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	b) The protective earth terminal is suitable for the protective conductor in the installation either by a protective earth conductor in a power supply cord and by suitable plug or by a fixed and permanently installed protective earth conductor	Provide with power cord	P
	e) Potential equalization	No such part	N
	Equipment provided with connection of a potential equalization conductor	See above	N
	This connection complies with following requirements:		
	- readily accessible	See above	N
	- no possibility to accidental disconnection in normal use	See above	N
	- conductor is detachable without the use of a tool	See above	N
	- power supply cord does not include potential equalization conductor	See above	N
	- connection is marked with symbol	See above	N
	f) Impedance of protective earthing system:		
	measured between any protectively earthed accessible metal part and protective earth terminal (PE): requirement R < 0,1 :	Not applicable	N
	measured between any protectively earthed accessible metal part and protective earth contact in appliance inlet: requirement R < 0,1 :	See test result	P
	measured between any protectively earthed accessible metal part and protective earth pin in mains plug: requirement R < 0,2 :	Not applicable	N
	g) If the impedance of protective earth connections other than in Cl. 18 f) exceeds 0,1, the allowable value of the enclosure leakage current is not exceeded in single fault condition	Not applicable	N
	k) Functional earth terminals are not used to provide protective earthing	No such terminal	N
	l) For Class II equipment with isolated internal screens and with a power supply cord		
	- the third cord is used only as functional earth of these screens and is coloured green/yellow	This is class I device	N
	- insulation of such screens and all internal wiring connected to them is double insulation or reinforced insulation (see also 20.3)	See above	N
	- insulations meet dielectric strength requirements (see also 20.3)	See above	N
	- marking of functional earth terminal is distinguished from protective earth terminal and is noted in accompanying documents	See above	N

19	CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS		
	Continuous leakage currents and patient auxiliary currents; before moisture treatment	(See appended table)	P
	Continuous leakage currents and patient auxiliary currents; after moisture treatment	(See appended table)	P

20	DIELECTRIC STRENGTH AT OPERATING TEMPERATURE		
	Dielectric strength at operating temperature	(See appended table)	P
	Overall compliance with Cl. 20		P
	Dielectric strength after humidity preconditioning treatment	(See appended table)	P
	Overall compliance with Cl. 20		P

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21	MECHANICAL STRENGTH		
	a) Rigidity of enclosure; test force 45 N	Tested	P
	b) Strength of enclosure part and any component ' there on (impact hammer test)	0.5J forced impact tested on scanner plastic enclosure	P
	c) On portable equipment carrying handles or grips withstand the requirements of the loading test	Not portable device	N
	Test force (N) (four times the weight of equipment):	No such part	N
21.3	No damage to parts of patient support and/or immobilization system after the loading test; tests at force 1350 N and 2700 N	No such part	N
21.5	Hand-held equipment or equipment parts are safe after drop test (dropping height 1 m)	Not hand held device	N
21.6	Portable and mobile equipment is able to withstand rough handling:		
	a) PORTABLE EQUIPMENT	Not portable device	
	drop height (cm) :		
	dropping three times :	Not applicable	N
	b) MOBILE EQUIPMENT		
	Propelled at 0.4 m/s or max self powered velocity over a step 20 mm high.	Not applicable	N
	Performed 20 times :	Not applicable	N

22	MOVING PARTS		
22.2	a) Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment	Not transportable device	N
	b) Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation	Device can be moved up and down ward by slower step motor and no moving hazards are exposed. Thus, consider adequate.	P
22.3	Cords (ropes), chains and bands are provide with guides to prevent them from running off or from jumping out of their guiding devices	No such parts and not applicable	N
	Guides or other safeguards are removable only with a tool	See above	N
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the control of operator	Movable scanner head is blocked by bottom of chin resting plastic housing and human head guide. There is between 15mm to 20mm spacing between patient eye to the scanner lance.	P
22.6	Parts of equipment subject to mechanical wear are accessible for inspection	No required parts	N
22.7	To remove an unexpected safety hazard caused by an electrically produced mechanical movement, there are means for emergency switching of a relevant part	Not applicable	N
	The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard	Not applicable	N
	Current breaking capability	See above	N
	Means for stopping of movements operate as a result of one single action	See above	N

23	SURFACES, CORNERS AND EDGES		
	There are no rough surfaces, sharp corners, flange or frame edges and burrs in the equipment	Consider adequate	P

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24	STABILITY IN NORMAL USE		
24.1	Equipment does not overbalance, when tilted trough an angle of 10	Tested	P
24.3	If equipment overbalances when tilted 10 :		
	- it does not overbalance when tilted through an angle of 5 in any position of normal use, excluding transport	No applicable. See above	N
	- the equipment carries a warning notice for transport	Device is shipped without fully assembled. Scanner and PC can be easily removed and assembled	N
	- it does not overbalance when tilted through an angle of 10 in the condition specified for transport	No applicable	N
24.6	a) Equipment or its parts with a mass of more than 20kg is provided with:		
	- suitable handling devices (grips etc.), or	Consider acceptable	N
	- instructions for lifting and handling during assembly	Provided in the user manual	P
	b) On portable equipment with a mass of more than 20kg carrying handles are so situated that equipment may be carried by 2 or more persons	Not a portable device	N

25	EXPELLED PARTS		
25.1	Protective means are provided where expelled parts of the equipment could be a hazard	No such part	N
25.2	Display vacuum tubes with a face dimension of 16cm or larger are intrinsically safe with respect to effects of implosion of tubes and to mechanical impact, or the enclosure of the equipment is provided with adequate protection against implosion	No such part	N
	A non-intrinsically safe tube is provided with an effective protective screen which cannot be removed without the use of a tool	See above	N
	Certificate of the test provided	See above	N

28	SUSPENDED MASSES		
28.3	Where the integrity of the system is in doubt, a safety device shall be provided, unless excess travel in the event of breakdown is limited :		—
	Suspension systems include a safety device with adequate safety factors to protect user or patient from hazards	No such parts	N
	If after activation of a safety device the equipment can still be used, the activation of the device, e.g. a secondary rope, becomes obvious to operator	See above	N
28.4	If a safety device is not provided the construction shall comply with the following:		
	1) the total load does not exceed the safe working load	Computer holder and keyboard are secured to the metal structure	P
	2) where it is unlikely that supporting characteristics will be impaired by wear, corrosion, material fatigue or ageing, the safety factor of all supporting parts is not less than 4	See above	N
	3) where impairment by wear, corrosion, material fatigue or ageing is expected, the safety factor is not less than 8	Not likely due to operating environment is in hospital or optomologist office.	N
	4) where metal having a specific elongation at break of less than 5% is used in supporting components, the safety factor is not less than 1,5 times those given in 2) and 3)	See above	N

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	5) sheaves, sprockets, bandwheels and guides are so designed that the safety factors of this subclause shall be maintained for a specified minimum life till replacement of the ropes, chains and bands	Not applicable	N
29	X-RADIATION		
	For equipment not intended to produce X-radiation for diagnostic and therapeutic purposes, ionizing radiation emitted by vacuum tubes excited by voltages exceeding 5kV does not produce an exposure exceeding 130nC/kg (0,5 mR)	Not applicable	N
37	COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT		
	Requirements for category AP and APG equipment (Cl. 37 - 41)	Not AP or APG device	N
42	EXCESSIVE TEMPERATURES		
42.1	Determination of the temperature rise of copper windings by the resistance method:	(See appended table) Thermocouple	P
42.2	Results of measuring	(See appended table)	P
42.3	Surface temperatures of applied parts not intended to supply heat to a patient do not exceed 41°C	Consider adequate	P
42.5	Guards for preventing contact with hot accessible surfaces are removable only with the aid of a tool	No such part required	N
43	FIRE PREVENTION		
	Strength and rigidity of the equipment are sufficient to avoid fire hazards (see Cl. 21)	Consider adequate	P
44	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION, DISINFECTION AND COMPATIBILITY		
44.2	Overflow		
	If equipment contains a liquid reservoir:		
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min	No such liquid chamber	N
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15 in the least favourable directions (if necessary with refilling)	See above	N
44.3	Spillage		
	Electrical properties of the equipment do not change in connection of spillage test performed by the method mentioned in the standard (200 ml of water)	No such device	N
44.4	Leakage		
	Electrical properties of the equipment do not change in connection of leakage test performed by the method mentioned in the standard (drops of water)	See above	N
44.5	Humidity		
	Checked by the preconditioning treatment and tests (see 4.10)	Tested	P
44.6	Ingress of liquids (see IEC 529)		
	Artificial rainfall test (drip-proof) IPx1	In door use only	N
	Spray and splash test (splash-proof) IPx4	No applicable	N
	Immersion test (watertight) IPx7	See above	N
44.7	Cleaning sterilization and disinfections		
	Method specified by the manufacturer :	Described in the user manual	P
	Default method of IEC 601-1 :		N
	No signs of damage and/or deterioration	No damage observed	P
	Pass dielectric strength test	No applicable	N

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45	PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE		
45.2	Pressure vessel covered by a National Standard:	No such device	—
	If No, default hydraulic pressure test is required	See above	N
	Hydraulic test pressure: required(kPa); measured(kPa):	See above	—
45.3	The maximum pressure to the part does not exceed the maximum permissible working pressure of the part	See above	N
	The used maximum pressure is the highest of the following:		
	a) marked maximum supply pressure from external source	See above	N
	b) pressure setting of a pressure relief device provided as a part of the assembly	See above	N
	c) maximum that can be developed by an air compressor included in the assembly	See above	N
45.7	Pressure-relief device :	Yes / No	—
	If yes, it complies with the following requirements:		
	a) connected as close as possible to the pressure vessel or parts of system that it is intended to protect	See above	N
	b) readily accessible for inspection, maintenance and repair	See above	N
	c) not capable of being adjusted or rendered inoperative without a tool	See above	N
	d) its discharge opening located and directed so, that released material is not directed towards any person	See above	N
	e) operation of device does not deposit material on parts, causing a possible safety hazard	See above	N
	f) to ensure the pressure not exceeding the maximum permissible working pressure by more than 10%, if a failure occurs in the control of the supply pressure	See above	N
	g) no shut-off valve between the pressure-relief device and the parts that it is intended to protect	See above	N
	h) minimum number of cycles of operation is 100 000	See above	N

49	INTERRUPTION OF THE POWER SUPPLY		
49.1	If automatically resetting thermal cut-outs and over-current releases are used, they give a safe condition by such resetting	No such device	N
49.2	Interruption and restoration of the power supply do not result in safety hazards other than interruption of intended function	Only function will be affected shall the power supply is interrupted.	P
49.3	Means are provided for removal of mechanical constraints on patients in case of a supply mains failure	No mechanical constraint for patient	N

51	PROTECTION AGAINST HAZARDOUS OUTPUT		
51.4	In multi-purpose equipment providing both low and high intensity outputs for different treatments means are provided to minimize the possibility of the accidental selection of high output	No applicable. All measurements and functions are preprogrammed at factory	N

52	ABNORMAL OPERATION AND FAULT CONDITIONS		
52.1	Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13)	Evaluated and tested. For primary circuitry, the evaluation is under power supply approval	P
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4	Software does not affect function of the device except it is only for data processing	N
52.5.2	Failure of thermostats		N
52.5.3	Short-circuiting one part of a double insulation	Evaluated under power supply	P

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52.5.5	Impairment of cooling	Tested for covering the openings	P
52.5.6	Locking of moving parts (see also 52.5.8)		N
52.5.7	Interruption and short-circuiting of motor capacitors (see also (52.5.8)	Lock motor was tested for motor controls chin holder up and down. Chin holder was set for upward and locked. No hazards were observed.	P
	Duration of test (min) :	3 hours	—
	Voltage (V) :	12V DC	—
	Loading :	Lock motor	—
	Final temperature (C) of winding :	63°C	—
	Open circuited or short-circuited capacitors	No such capacitor	N
52.5.8	Additional tests for motor operated equipment	No applicable	N
	Duration of operating time :	See above	N
52.5.9	Failure of components	See above	N
52.5.10	Overload		
	a) Equipment with heating element:		N
	1) thermostats (see 52.5.10 c) and d)) :	Not such parts	—
	2) equipment with heating elements with short-time rating (see 52.5.10 c) and d)) :	See above	—
	3) other equipment (see 52.5.10 c)) :	See above	—
	b) Equipment having motors, which are a part of equipment (see 52.5.5 - 52.5.8 and 52.5.10 f) - h))	Lock rooter tested.	P

56	COMPONENTS AND GENERAL ASSEMBLY		
	List of critical components	(See appended table)	P
56.1	Marking of components		
	Component markings are in accordance with conditions of use	Consider adequate	P
56.3	a) Connections		
	Incorrect interconnection of accessible connectors removable without the use of a tool, is prevented where a hazard may be caused	SELV only	P
	Accessible parts are separated from live parts (see Cl. 17 g))	Minimum basic insulation is provided.	P
	Plugs for connection of patient circuit cannot be connected to other outlets	Not applicable. The only patient contact is head guard and chin support plastic holder from scanner unit.	P
	Medical gas connections are not interchangeable	No such connection	N
	b) Accessible conductive parts are prevented from becoming live when connection between different parts of the equipment, by means of detachable flexible cords, is loosened or broken	All connections are covered by metal cover and requires tool access	P
	c) Any connector in a lead having a conductive connection to a patient is constructed in such a manner that no conductive connection of that part can contact earth or possibly hazardous voltage	Consider acceptable	P
56.4	Capacitors		
	Capacitors not connected between live parts and non-protectively earthed accessible parts	Evaluated under power supply	N
	Capacitors between the mains part and protectively earthed accessible metal parts, comply with IEC 384-14 or equivalent	See above	N

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	The enclosure of capacitors connected to the mains part and provided with only basic insulation is not secured directly to non-protectively earthed accessible metal parts	See above	N
	Capacitors or other spark suppression devices are not connected between the contacts of thermal cut-outs	See above	N
56.5	Protective devices		
	Protective devices which operate by producing a short-circuit which results in operation of an overcurrent protection device in supply mains system not used	Evaluate under power supply approval	N
56.6	Temperature and overload control devices		
	a) Thermal cut-outs which require a soldering operation to reset are not used	No such device	N
	Thermal safety devices are provided to prevent temperatures exceeding limits as specified	Evaluated under medical graded isolation transformer	N
	An independent non-self-resetting thermal cut-out is provided where the failure of a thermostat may cause a hazard	See above	N
	The operating temperature of the above thermal cut-out is between the upper limit of the first thermostat and the safe limit for the function	See above	N
	There is an audible alarm where loss of function due to operation of thermal cut-out could present a safety hazard	No such device	N
	Test of thermal cut-outs and overcurrent releases	Short circuit test was applied to medical grade isolation transformer	P
	Heated liquid containers are protected against dangerous overheating when containers are empty	No such device	N
	b) The adjustment range of thermostat is not greater than required for equipment function	No such device	N
	The temperature setting is clearly indicated	See above	N
	The operating temperature of cutouts is clearly indicated	See above	N
56.7	Batteries		
	a) Battery compartments are:		
	1) adequately ventilated	No user replaceable battery, Lithium cell battery for memory chips only in the computer. Computer provides larger openings at rear	P
	2) accidentally short-circuiting is prevented (obs! lithium batteries)	See above. Evaluated under PC motherboard	N
	b) Incorrect polarity of connection prevented (obs! lithium batteries)	See above	N
56.8	Indicators		
	Unless indication is provided by other means, from the normal operation position, indicator lights are used (colours see 6.7):		
	- to indicate that equipment is energized	Green LED provide	P
	- to indicate the operation of non-luminous heaters if a safety hazard could result	No such part	N
	- to indicate when output exists if a safety hazard could result	See above	N
	- charging mode indicator is provided	No such function	N
56.10	Actuating parts of controls		
	b) Actuating parts are adequately secured to prevent them for working loose during normal use	Actuator is UL and CE approved device	N
	Controls are secured to prevent the movement relative to scale marking (safety related only)	Symbol up and down is marked on the actuator's switch. On and off is marked on power switch	P

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	Detachable indicating devices are prevented from incorrect connection without the use of a tool	Manufacture installation part only	P
	Rotating controls:		
	gripping diameter (mm) of the knob :	No such parts	N
	torque test; torque (Nm) :	See above	N
	Pull controls:		
	axial pull, pull (N) :	See above	N
	test force (Nm) :	See above	N
	c) Stops are provided on rotating controls:		
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard	No such control	N
	- to prevent damage to wiring	See above	N
56.11	Cord connected hand-held and foot-operated control devices		
	a) Voltage on cord connected control devices do not exceed 25V AC or 60V DC	No such parts	N
	Measured voltage (V) :		—
	The means of isolation from mains part :		—
	b) Hand-held devices: no safety hazard as a result of a free fall test	Not a hand held device	N
	Foot-operated control devices: an actuating force of 1350 N does not damage	Not applicable	N
	c) No change of control setting when inadvertent operation placed in an abnormal position	See above	N
	d) IP classification of foot-operated control device:		
	At least IPx4 according to IEC 529 :	Not applicable	—
	Specified for use in operating rooms :	See above	—
	Watertight :	See above	—
	e) Provided with adequate means of anchoring supply cords (see test of 57.4)	In door use only	N
	Displacement (mm) :	See above	N

57	MAINS PARTS, COMPONENTS AND LAYOUT		
57.1	Isolation from supply mains		
	a) Means of isolation:		P
	incorporated in equipment :	Isolation transformer is used	—
	external :	Not applicable	—
	The equipment has a means for simultaneous disconnection of all supply poles	Evaluate under power supply	N
	Means of external isolation are specified in accompanying documents	See above	N
	d) Creepage distances and air clearances (IEC 328)	Evaluated under power supply. For AC power supply installed in the scanner 1.6 mm minimum clearance is required and measured 5mm. Maximum 5V DC input of DC/DC converter passed 3000V AC di-electric between primary and secondary in lure of meeting the spacing requirement.	P
	f) Mains switches are not incorporated in flexible leads	No such part	N
	g) The directions of movement of their actuators (IEC447)	Consider acceptable	P
	h) If there is a suitable plug device to isolate the non-permanently installed equipment from the supply mains, it is considered as a means complying with 57.1 a)	See above	P

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	m) Fuses and semiconductor devices are not used as isolating devices	Medical graded isolation trans-former is used as isolating device	P
57.2	Mains connectors and appliance inlets		
	e) Auxiliary mains socket-outlets:		
	- cannot accept a mains plug (only applied to non-permanently installed equipment)	There is an internal auxiliary mains socket outlets, which is only for system use. It is not visible from outside of the equipment.	P
	- are properly marked	Not required due to consider as internal connection.	N
	g) Except where a functional earth needs to be provided, Class I appliance inlets are not used in Class II equipment	Not class II equipment	N
57.3	Power supply cords		
	a) There is only one connection to a particular supply mains	One appliance inlet provided	P
	Alternative connections to a different supply system do not cause safety hazards when more than one connection is made simultaneously	No such connection	N
	The mains plug has only one power supply cord	Consider adequate	P
	Equipment, not intended to be permanently connected to fixed wiring, is provided with power supply cord, or appliance inlet	One appliance inlet provided	P
	b) Supply cables are sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53	Medical graded power cord will provided with the system	P
	Temperature of metal parts of equipment exceeding 75 C: PVC-cords not used	No such metal part	N
	c) Nominal cross-sectional area (mm² Cu) of supply conductors (see Table XV) :	Evaluated under medical graded power cord	N
	d) Stranded conductors fixed by any clamping means or screws are not soldered	No such part	N
57.4	Connection of power supply cords		
	a) Cord anchorages:		
	the equipment or its mains connectors incorporate a cable anchoring device to relieve strain on conductors and prevent abrasion of covering (no knots etc.)	Evaluate under medical graded power cord approval	N
	the construction and materials of the cord anchorages are made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation, or	See above	N
	having an insulating lining fixed to the cord anchorage if a total insulation failure of the power supply cord could make accessible conductive parts not protectively earthed live	See above	N
	clamping screws do not bear directly on the cord insulation	See above	N
	screws associated with cable replacement are not used to secure other components	See above	N
	conductors of the power supply cord are so arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals	See above	N
	cable displacement (mm) with force indicated in Table XVIII :	See above	N
	b) For other than stationary equipment, the power supply cord is adequately protected against excessive bending		
	Bending test :	See above	N

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	If a cord guard is not fitted, the entrance for the cord is suitably shaped		
	Flexing test :	See above	N
	Percent (%) of broken conductor strands :	See above	N
	c) There is sufficient space inside the equipment to allow the supply cable conductors to be introduced and connected	See above	N
	Any covers can be fitted without risk of damage to conductors or their insulation	See above	N
	It is possible to check that conductors are correctly connected before the cover is fitted	See above	N
57.5	Mains terminal devices and wiring of mains part		
	a) Mains connected equipment other than those with a detachable supply cord is provided with mains terminals, where connections are made with screws, nuts or equally effective methods	Detachable power cord is used	N
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced	See above	N
	They are not used to fix any other component (other than internal conductors unlikely to be displaced)	See above	N
	b) Equipment with rewirable cords and terminals including any protective earth terminal are closely grouped to allow easy connection	No such wire	N
	Protective earth conductor (see Cl. 58)	Not applicable	N
	Marking of mains terminals (see 6.2)	Not applicable	N
	Mains terminal devices are inaccessible without the use of a tool	See above	N
	Mains terminal devices are so located or shielded that there is no risk of accidental contact between live parts and accessible conductive parts and for Class II equipment between live parts and conductive parts if wire should escape	See above	N
	Single strand of wire (8 mm) :	See above	N
	c) When means for clamping the conductors are tightened and loosened, the internal wiring is not subjected to stress	See above	N
	Creepage distances and air clearances not reduced below values specified in 57.10	See above	N
	Cross-sectional area (mm²) of conductor used in test:	See above	N
	d) Effective connection to mains terminals shall not require special preparation of cables	See above	N
	Conductors are not damaged or displaced when tightening or loosening of the clamping screws or nuts	See above	N
	e) Fixing of wiring (see 56.1 f))	See above	N
57.6	Mains fuses and overcurrent releases		
	Current rating of fuses etc. is:		
	- sufficient (see table in Cl. 56)	Evaluate under power supply. Additional external fuse also provided for scanner	N
	- not greater than rating of mains components	See above	N
	There are fuses or overcurrent releases in each supply lead for Class I equipment and for Class II equipment having a functional earth according to Cl. 18 l))	Multiple fuses provided: one in table base appliance inlet assembling, one provided in scanner appliance inlet housing, one provided in medical graded power supply inside scanner, and one in personal computer power supply	P

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	There is at least one mains fuse for other single phase Class II equipment	Class I device	N
	A protective earth conductor is not fused	No fuse is employed on protective earthing.	P
	No fuse is fitted in neutral conductor of permanently installed equipment	See above	N
57.8	Wiring of mains part		
	a) Is insulation of all individual conductors at least equivalent to that required by IEC 227 or IEC 245. If not, specify conductors to be considered as bare :	Safety approved wires are used.	P
	b) The cross-sectional area (mm² Cu) of wiring between the mains terminal and fuse; measured cross-sectional area (mm² Cu) (see 57.3 c)) :	18 AWG wired used. Measured 1.024 mm in diameter.	P
	The cross-sectional area of other wiring in the mains part and sizes of tracks on printed wiring circuits are sufficient to prevent any fire hazard in case of possible fault currents	Evaluated under power supply	N
57.9	Mains supply transformers		
	Transformers	Medical graded isolation transformer is used.	P
57.9.1	Overheating		
	Overheating tests	Evaluate under isolation transformer	N
	a) short circuit test	Tested	P
	b) Overload	Evaluate under isolation transformer	N
	External protective devices are connected in such a way that failure of any component cannot render the protective devices inoperative	See above, thermal fuse is used and short circuit test is applied.	N
57.9.2	Dielectric strength		
	The electrical insulation between primary winding and other windings, screens and the core of the transformers have been investigated by the tests performed as described in Cl. 20	Evaluated under isolation transformer. And tested after short circuit	P
	Insulation between turns and layers, test performed according to 57.9.2	See above	N
	Voltage used in test; test voltage (V) :	4000V AC between primary and secondary windings.	—
	Frequency used in test; test frequency (Hz) :	60Hz.	—
57.9.4	Construction		
	a) One of the following methods is used to separate primary from secondary windings having a conductive connection to applied parts or to accessible metal parts not protectively earthed:		
	- separate bobbins or formers	Evaluate under isolation transformer approval	N
	- one bobbin or former with imperforate insulation partition	See above	N
	- one bobbin or former with concentric windings and having an imperforate protective copper screen with thickness of not less than 0,13 mm	See above	N
	- one bobbin with concentric windings separated by double or reinforced insulation	See above	N
	c) Means are provided to prevent displacement of end turns	See above	N
	d) An earthed screen has a minimum overlap of 3mm and with at least equal to the axial length of the primary winding	See above	N

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	e) The double or reinforced insulation between the primary and secondary winding:		N
	number of insulation layers; number (mm) :	See above	—
	total thickness (mm) :		—
	voltage test :		—
	f) The creepage distances (mm) between the primary and secondary windings at location :	See above	N
	g) For toroidal transformers:		
	- the exit of wires from internal windings is provided with double sleeving complying with requirements for double insulation	See above	N
	- its total thickness is at least 0,3mm extending at least 20mm outside the winding; measured thickness (mm):	See above	N
57.10	Creepage distances and air clearances		
	a) Values	(See appended table)	
	Creepage distances and air clearances comply at least with specified values	Consider adequate	P
	Creepage distances for slot insulation of motors are at least 50% of the specified values with a minimum of 2mm at 250V	12V DC motor is used and test was waived.	N
	Creepage distances and air clearances between defibrillator-proof applied parts and other parts are not less than 4mm	Not defibrillator	N

58	PROTECTIVE EARTHING TERMINALS AND CONNECTIONS		
58.1	The protective earth terminal clamping means of rewirable non-detachable supply cables comply with the following requirements (see 57.5 c)):		N
	not accessible without the aid of a tool	Not user accessible and it is evaluated under power supply	N
	Tightening or loosening of clamping means does not:		
	- subject internal wiring to stress	See above	N
	- creepage distances and air clearances not reduced below allowed limits	See above	N
	Screws for internal earth connections are covered or protected against loosening from outside	See above	N
58.7	Where an appliance inlet is used for the supply connection, its earth pin is regarded as the protective earth terminal	Evaluate under power supply	N
58.8	The protective earth terminal is not used for connection between different parts or fixing of any component not related to protective or functional earthing	See above	N
58.9	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting	See above	N

59	CONSTRUCTION AND LAYOUT		
59.1	Internal wiring		
	a) Internal cables and wiring:		
	- are protected against contact with moving parts or friction with sharp edges or corners	Consider adequate	P
	- are protected by additional fixed sleeving, if there is movement relative to metal parts where it is in direct contact with them, and	Some of the cables have additional sleeving to provide protection from movement	P
	- components are not likely to be damaged by opening or assembling the equipment	Minimum assembling may be required. All wires are not likely to be damaged during the assembling due each component is a complete unit and industrial standard plugs are used.	P

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	b) Guiding rollers or movable leads are such that the leads are not bent around a radius of less than five times the outer diameter of the lead	Consider acceptable for scanner internal wires.	P
	c) Insulation:		
	- insulating sleeving can only be removed by breaking or cutting or is secured at both ends	Consider acceptable	P
	- if the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245	Not applicable	N
	- insulated conductors, which are subjected to temperatures greater than 70°C, have an insulation of heat-resistant material, if compliance with this standard is likely to be impaired by deterioration of the insulation	Type minimum 75°C wires are used.	P
	d) Aluminums wires of less than 16mm² cross-section shall not be used	No such part	N
59.2	Insulation		
	b) Resistance to moisture test (see Cl. 44)	Use safety approved wires	N
	Dielectric strength test (see Cl. 20)	See above	P
	Mechanical strength test (see Cl. 21)	See above	P
	Ball-pressure test	See above	P
	c) Insulation is not likely to be impaired by deposition of dirt or dust resulting from wear of parts within the equipment	See above	N
	Ceramic materials specified in this subclause are not used as supplementary or reinforced insulation	See above	N
	Rubber materials used as supplementary insulation in Class II equipment are resistant to aging (oxygen test)	See above	N
	Creepage distances are not reduced below the values specified in 57.10 whatever cracks may occur	See above	N
	Insulating materials in which heating elements are embedded are not used as reinforced insulation	No such part	N
59.3	Excessive current and voltage protection		
	An Internal Electrical power source in equipment shall be provided with an appropriately rated device for protection against fire hazard caused by excessive currents if the cross-sectional area and layout of the internal wiring or the rating of connected components may give rise to the occurrence of a fire hazard in case of a short circuit	Not internally powered device	N
	Fuse elements replaceable without opening the enclosure are fully enclosed in a fuse-holder	Fuse holder are provide as appliance inlet assembling in the scanner	P
	Live parts of fuse-holders are shielded to prevent electric shock when replacing fuses (if replaceable without the use of a tool)	Tool access only for replace fuse	P
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500V r.m.s.	Evaluate under medical graded isolation transformer and power supply	N
59.4	Oil containers		
	Oil containers in portable equipment are adequately sealed to prevent oil loss in any position and the oil container design allows for the expansion of oil	No oil container	N
	Oil containers in mobile equipment are sealed to prevent loss of oil during transport	See above	N
	An oil level indicator is provided on partially sealed oil-filled equipment or parts	See above	N

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Test Data:

6.1	TABLE: marking durability	X

marking tested	Remarks

Comments: Safety agency approved label are use. (Bay Area Label), Thus tests is waived.

7.	TABLE: power input, Room temp. 16.9 °C	X

Operating Condition	Voltage	Frequency	Current	Power	Remarks
Input 120V AC Version					
Normal, camera on, scan on, computer on	100Vac	60	2.82	276	
Normal, camera on, scan on, computer on	108Vac	60	2.61	271	
Normal, camera on, scan on, computer on	120Vac	60	2.31	267	
Standby, camera off, scan off. Computer on	132Vac	60	2.11	262	

Comments: For 120 connection, isolation transformer is rated at 4.17A.

15. b)	TABLE: residual voltage in attachment plugs	X

Voltage Measured Between:	Measurements (ms)										Remarks
	1	2	3	4	5	6	7	8	9	10	
Line to neutral (120V AC)	16.1										Peak voltage to 0
Line to ground (120V AC)	50.4										Peak voltage to 0
Neutral to ground (120V AC)	9.6										Peak voltage to 0

Comments:
(a) Pins 1 and 2 are line and neutral supply pins.
(b) Measured/Calculated capacitance between each line and P.E. = _____ pF. *(WAIVE test if < 3000 pF.)*
(c) Measured/Calculated capacitance between lines = _____ µF. *(WAIVE test if < 0.1 µF.)*

Note: measurement was done from the peak voltage

18.	TABLE: protective earthing	X

Test Location	Test current (A)	Measured voltage (V)	Resistance (Ω)	Remarks
Metal rear side of the computer (Re-test for 120V AC version)	40A/2mins.		69.4 mΩ	Pass

Comments:

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21.	TABLE: mechanical strength	
Part under test	**Test (impact, drop, force, handle, rough handling, mobile)**	**Remarks**
Top part cover	There are four impact one on each corner, three of them plastic has shartered and finger probe are not able to reach Power supply or any internal hazards.	Pass
Bottom base part	After impact, there is no damage observed	Pass
Comments:		

24.	TABLE: stability. Tilted test 10 °	x
Part under test	**Test condition**	**Remarks**
RTVue Model RT100, Panel monitor, computer and printer	Facing to patient	Pass
Same as above	Facing to doctor with keyboard	Pass
	Left side	Pass
	Right side	Pass
Comments:		

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42.	TABLE: normal temperature		
	supply voltage	207V AC	-
	ambient temperature °C	23.2 °C	-
	test condition	Fully operational printer is no without printing	-

Measuring Location	Measured Temperature (°C)	Remarks
Power supply		
1. T3 coil	45	
2. T2 coil	43	
3. Q1	42	
4. C5	46	
5. CR8	41	
6. CR7	47	
7. C20	38	
8. U6	45	
Analog control board P/N 014-X2		
9. U 17	45	
USB control board		
10. U 13	37	
Computer		
Power supply		
11. T1	50	
12. Q6	Bad	
13. C3	44	
14. D16	53	
15. C33	41	
16. CPU	40	
17. Hard drive adjacent to enclosure	49	
18.	36	
19. VR!	65	
20 PCB card PN-109-A31900	52	
21. C100	36	
22. DC/DC converter	27	
23. Camera body	29	
24. Chin holder	25	
25. Ambient	23.9	
Duration:	2hrs.	

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COR - indicates measurements taken using change-of-resistance method

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42.	TABLE: normal temperature		
	supply voltage	207Vac	-
	ambient temperature °C	23.2 °C	-
	test condition	Stop fan and block rear side of computer.	-

Measuring Location	Measured Temperature (°C)	Remarks
Power supply		
1. T3 coil	57	
2. T2 coil	49	
3. Q1	48	
4. C5	56	
5. CR8	56	
6. CR7	61	
7. C20	54	
8. U6	57	
Analog control board P/N 014-X2		
9. U 17	45	
USB control board		
10. U 13	37	
Computer		
Power supply		
11. T1	49	
12. Q6	Bad	
13. C3	44	
14. D16	51	
15. C33	41	
16. CPU	39	
17. Hard drive adjacent to enclosure	48	
18.	37	
19. VR!	69	
20 PCB card PN-109-A31900	54	
21. C100	37	
22. DC/DC converter	29	
23. Camera body	39	
24. Chin holder	25	
25. Ambient	22.9	
Duration	2hrs.	
COR - indicates measurements taken using change-of-resistance method		

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42.	TABLE: normal temperature		x
	supply voltage	254V AC	-
	ambient temperature °C	23.2 °C	-
	test condition	Fully operational printer is no without printing.	-

Measuring Location	Measured Temperature (°C)	Remarks
Power supply		
1. T3 coil	47	
2. T2 coil	41	
3. Q1	42	
4. C5	47	
5. CR8	41	
6. CR7	47	
7. C20	38	
8. U6	45	
Analog control board P/N 014-X2		
9. U 17	45	
USB control board		
10. U 13	36	
Computer		
Power supply		
11. T1	51	
12. Q6	Bad	
13. C3	44	
14. D16	53	
15. C33	41	
16. CPU	39	
17. Hard drive adjacent to enclosure	48	
18.	36	
19. VR!	65	
20 PCB card PN-109-A31900	53	
21. C100	35	
22. DC/DC converter	27	
23. Camera body	28	
24. Chin holder	25	
25. Ambient	23.3	
Duration	14hrs.	
COR - indicates measurements taken using change-of-resistance method		

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42.	TABLE: normal temperature		x
	supply voltage ..... :	132Vac	-
	ambient temperature °C ..... :	22.5 °C	-
	test condition ..... :	Normal operation	-

Measuring Location	Measured Temperature (°C)	Remarks
Power supply		
1. T3 coil	44	
2. T2 coil	28	
3. Q1	41	
4. C5	45	
5. CR8	39	
6. CR7	44	
7. C20	36	
8. U6	46	
Analog control board P/N 014-X2		
9. U 17	44	
USB control board		
10. U 13	35	
Computer		
Power supply		
11. T1	46	
12. Q6	Bad	
13. C3	39	
14. D16	49	
15. C33	39	
16. CPU	37	
17. Hard drive adjacent to enclosure	46	
18.	32	
19. VR!	66	
20 PCB card PN-109-A31900	51	
21. C100	33	
22. DC/DC converter	25	
23. Camera body	26	
24. Chin holder	23	
25. Ambient	21.6	
Duration	20hrs.	
COR - indicates measurements taken using change-of-resistance method		

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42.	TABLE: normal temperature		x
	supply voltage ..... :	90Vac	-
	ambient temperature °C ..... :	23.9 °C	-
	test condition ..... :	Normal operation	-

Measuring Location	Measured Temperature (°C)	Remarks
Power supply		
1. T3 coil	45	
2. T2 coil	43	
3. Q1	42	
4. C5	44	
5. CR8	40	
6. CR7	46	
7. C20	38	
8. U6	44	
Analog control board P/N 014-X2		
9. U 17	45	
USB control board		
10. U 13	37	
Computer		
Power supply		
11. T1	46	
12. Q6	Bad	
13. C3	41	
14. D16	49	
15. C33	39	
16. CPU	38	
17. Hard drive adjacent to enclosure	48	
18.	33	
19. VR!	63	
20 PCB card PN-109-A31900	52	
21. C100	36	
22. DC/DC converter	38	
23. Camera body	29	
24. Chin holder	25	
25. Ambient	23.9	
Duration	4hrs.	
COR - indicates measurements taken using change-of-resistance method		

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42.	TABLE: normal temperature		x
	supply voltage	90V AC	-
	ambient temperature °C	23.9 °C	-
	test condition	Abnormal operation. Block rear of computer opening and Scanner top openings.	-

Measuring Location	Measured Temperature (°C)	Remarks
Power supply		
1. T3 coil	45	
2. T2 coil	42	
3. Q1	42	
4. C5	44	
5. CR8	40	
6. CR7	46	
7. C20	38	
8. U6	44	
Analog control board P/N 014-X2		
9. U 17	45	
USB control board		
10. U 13	38	
Computer		
Power supply		
11. T1	48	
12. Q6	Bad	
13. C3	43	
14. D16	50	
15. C33	41	
16. CPU	38	
17. Hard drive adjacent to enclosure	49	
18.	38	
19. VR!	69	
20 PCB card PN-109-A31900	56	
21. C100	36	
22. DC/DC converter	28	
23. Camera body	29	
24. Chin holder	25	
25. Ambient	24	
Duration	2hrs.	
COR - indicates measurements taken using change-of-resistance method		

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42.	TABLE: normal temperature		x
	supply voltage	132V AC	-
	ambient temperature °C	23.6 °C	-
	test condition	Abnormal operation. Block front of computer opening and stop Scanner's fan.	-

Measuring Location	Measured Temperature (°C)	Remarks
Power supply		
1. T3 coil	64	
2. T2 coil	50	
3. Q1	55	
4. C5	61	
5. CR8	61	
6. CR7	66	
7. C20	58	
8. U6	62	
Analog control board P/N 014-X2		
9. U 17	46	
USB control board		
10. U 13	38	
Computer		
Power supply		
11. T1	53	
12. Q6	Bad	
13. C3	47	
14. D16	55	
15. C33	43	
16. CPU	44	
17. Hard drive adjacent to enclosure	47	
18.	39	
19. VR!	63	
20 PCB card PN-109-A31900	53	
21. C100	35	
22. DC/DC converter	22	
23. Camera body	33	
24. Chin holder	25	
25. Ambient	24.1	
Duration	2hrs.	
COR - indicates measurements taken using change-of-resistance method		

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52.	TABLE: abnormal operation	x

Test type, condition and clause reference	Observed results	Remarks
52.5.6 Lock motor test	12V DC P/N 415A882 motor: Temperature reached 63 °C. No smoke or fire has observed. After remove the lock, motor start turning again.	Pass.
	Jammed chin holder and keep up bottun lock for upward position. No hazards was observed	Pass
Comments: Tested for 3hrs.		

57.9.1a)	Sub- TABLE: short circuit test: P/N TIS500/ST-1120 ***Rise of Resistance Measurements & Calculation***	

Winding	Initial R1 (ohms)	t1 (deg C) Room Ambient		Final R2 (ohms)	t2 (deg C) Room Ambient	Final Temp. Rise = dt	Final Temperature dt + 25C	Max. Allowed (deg C)	Remarks
120Vac						---	---		(a), (b)
Prim. #1	1.0000	24.5		Fuse opened		187.50	212.50		
Prim. #2	1.1000	24.5		Fuse opened		187.50	212.50		
Sec.#3	1.1000	24.5		1.1000		---	---		
						---	---		
						---	---		
						---	---		
						---	---		

57.9.2	TABLE: transformer dielectric strength	*X*

Transformer under test	Test voltage applied to	Test voltage	Test frequency	Remarks
120V AC connection	Primary to ground	2121	60Hz	After short circuit test, Pass
	Primary to secondary	4000	60Hz	After short circuit test. Pass

	TABLE: additional tests		
Clause	Test type and condition	Remarks and observed results	Verdict
59.2 b) 1)	Enclosure Ball Pressure	75 °C for 1hrs. measured 1.9mm	Pass
UL2601, 55 refers to UL 746 C	Mould Stress Relief Test	Plastic had few bubbles but no deformation can expose any hazards. .	Pass
Comments:			

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LEAKAGE CURRENT DETAILED RESULTS

LEAKAGE TEST FORM # 1

The following leakage current tables follow the guidelines listed below.

Explanation:
N.C. = normal condition
S.F.C. = single fault condition
1 = switch closed
0 = switch open

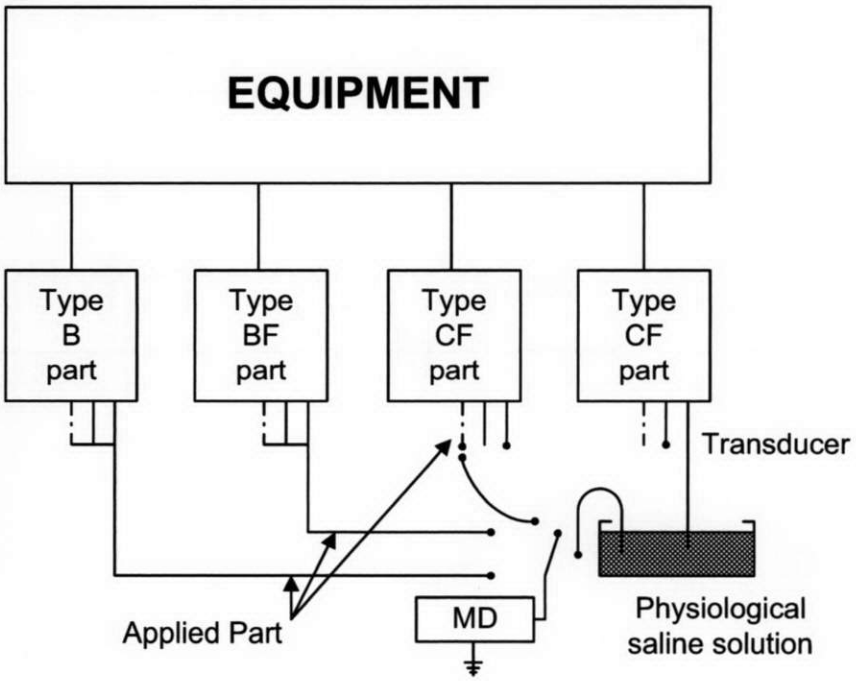
The equipment is tested using the following method unless otherwise specified.

V = _120____ (Volts)
U = _132____ (Volts) __60__ (Hz)

Environmental conditions during testing at operating temperatures: ____ °C room ambient temperature; ____% relative humidity;
___ hPa atmospheric pressure.

Environmental conditions during testing after humidity conditioning: ____°C room ambient temperature; ____% relative humidity;
___ hPa atmospheric pressure.

Type B product



Applied Part:

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(b)(4) Test Report

[redacted]

Conditions: At Operating Temperature / **After Moisture Preconditioning

s5	s10	s12	N.C. S1 = 1 max. measured value (µA)		S.F.C. s1 = 0 max. measured value (µA)		Other S.F.C. s1 = 1 due to Sub-Clause 17a max. measured value (µA)	
Condition				**		**		**
1			6	13	71	43	[redacted]	[redacted]
1							[redacted]	[redacted]
1							[redacted]	[redacted]
1							[redacted]	[redacted]
0			17	20	71	43	[redacted]	[redacted]
0							[redacted]	[redacted]
0							[redacted]	[redacted]
0							[redacted]	[redacted]

Description of additional S.F.C.:

Notes:

Room temp 23.6
Humidity 44%
Pressure: 1010 Hpa.

Isolation transformer is added to the measurement.

After humidity test, June 14, 2006

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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 #2012-3758; Released by CDRH on 09-8-2015

(b)(4) Test Report

[redacted]

Conditions: At Operating Temperature / **After Moisture Preconditioning

s5	s10	s11	s12	N.C. s1, s2, s3, s8 = 1 measured (µA)				S.F.C. s1, s2, s3 = 1 s8 = 0 (power supply protectively earthed) measured (µA)		S.F.C. s1 = 0 s2, s3, s8 = 1 measured (µA)				S.F.C. s1 = 1 s2 = 0 s3 = 1 s8 = 1				S.F.C. s1 = 1 s2 = 1 s3 = 0 s8 = 1			
				MD1		MD2		MD2		MD1		MD2		MD1		MD2		MD1		MD2	
Condition					**		**		**		**		**		**		**		**		**
1	1	1	1																		
1	1	1	0																		
1	1	0	1																		
1	1	0	0																		
1	0	1	1																		
1	0	1	0																		
1	0	0	1																		
1	0	0	0																		
0	1	1	1																		
0	1	1	0																		
0	1	0	1																		
0	1	0	0																		
0	0	1	1																		
0	0	1	0																		
0	0	0	1																		
0	0	0	0																		

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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 #2012-3758; Released by CDRH on 09-8-2015

(b)(4) Test Report

[redacted]

Conditions: At Operating Temperature/**After Moisture Preconditioning

s5	s10	s12	N.C. s1 = 1 s7 = 1 measured (µA)				S.F.C. s1 = 0 s7 = 1 measured (µA)				S.F.C. S1 = 1 s7 = 0 measured (µA)				Other S.F.C. s1 = 1 s7 = 1 measured (µA)			
			MD1		MD2		MD1		MD2		MD1		MD2		MD1		MD2	
Condition				**		**		**		**		**		**		**		**
1			1	1	0	0	1	1	0	0	0	0	0	0				
1																		
1																		
1																		
0			1	1	0	0	1		0	0	0	0	0	0				
0																		
0																		
0																		

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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 #2012-3758; Released by CDRH on 09-8-2015

(b)(4) Test Report

[redacted]

Conditions: At Operating Temperature/**After Moisture Preconditioning

s5	s10	s12	s1 = 1 s7 = 1 s9 = 1 measured (µA)				s1 = 1 s7 = 1 s9 = 0 measured (µA)			
			MD1		MD2		MD1		MD2	
				**		**		**		**
1			14.3	15.9			14.3	15.9		
1										
1										
1										
0			14.3	15.9			14.3	15.9		
0										
0										
0										

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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 #2012-3758; Released by CDRH on 09-8-2015

(b)(4) Test Report

[redacted]

Conditions: At Operating Temperature/**After Moisture Preconditioning

s5	s10	s12	s1 = 1 s7 = 1 s9 = 1 measured (µA)				s1 = 1 s7 = 1 s9 = 0 measured (µA)			
			MD1		MD2		MD1		MD2	
				**		**		**		**
1			15.1	15.9			15.1	15.9		
1										
1										
1										
0			15.0	15.9			15.1	15.9		
0										
0										
0										

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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 #2012-3758; Released by CDRH on 09-8-2015

(b)(4) Test Report

[redacted]

Conditions: At Operating Temperature/**After Moisture Preconditioning

s5	s10	s12	s1 = 1 s7 = 1 s9 = 1 measured (µA)				s1 = 1 s7 = 1 s9 = 0 measured (µA)			
			MD1		MD2		MD1		MD2	
				**		**		**		**
1			14.7	15.9			14.7	15.9		
1										
1										
1										
0			14.7	15.9			14.7	15.9		
0										
0										
0										

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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 #2012-3758; Released by CDRH on 09-8-2015

(b)(4) Test Report

[redacted]

Conditions: At Operating Temperature/**After Moisture Preconditioning

s5	s10	s12	s1 = 1 s7 = 1 s9 = 1 measured (µA)				s1 = 1 s7 = 1 s9 = 0 measured (µA)			
			MD1		MD2		MD1		MD2	
				**		**		**		**
1			14.3	15.9			14.6	15.9		
1										
1										
1										
0			14.3	15.9			14.6	15.9		
0										
0										
0										

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8418

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

(b)(4) Test Report

[redacted]

Conditions: At Operating Temperature/**After Moisture Preconditioning

s5	s10	s12	s1 = 1 s7 = 1 s9 = 1 measured (µA)				s1 = 1 s7 = 1 s9 = 0 measured (µA)			
			MD1		MD2		MD1		MD2	
				**		**		**		**
1			15.5	23.3			15.4	23.3		
1										
1										
1										
0			15.5	23.3			15.5	23.3		
0										
0										
0										

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-5648

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

(b)(4) Test Report

[redacted]

Conditions: At Operating Temperature/**After Moisture Preconditioning

s5	s10	s12	s1 = 1 s7 = 1 s9 = 1 measured (µA)				s1 = 1 s7 = 1 s9 = 0 measured (µA)			
			MD1		MD2		MD1		MD2	
				**		**		**		**
1			14.5	5.2			14.7	5.3		
1										
1										
1										
0			14.5	5.2			14.7	5.3		
0										
0										
0										

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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 #2012-3758; Released by CDRH on 09-8-2015

(b)(4) Test Report

[redacted]

Conditions: At Operating Temperature/**After Moisture Preconditioning

s5	s10	s12	s1 = 1 s7 = 1 s9 = 1 measured (μA)				s1 = 1 s7 = 1 s9 = 0 measured (μA)			
			MD1		MD2		MD1		MD2	
				**		**		**		**
1			18.2	10.9			18.2	10.9		
1										
1										
1										
0			18.2	10.9			18.2	10.9		
0										
0										
0										

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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 #2012-3758; Released by CDRH on 09-8-2015

(b)(4) Test Report

[redacted]

Enclosure Leakage Current for Equipment with a Specified Power Supply *[Figure 19, Clause 19.4g)4)& 19.2c)] (see figure on previous page)*

Conditions: At Operating Temperature / ** After Moisture Preconditioning

s5	s11	N.C. s1 = 1 s7 = 1 s8 = 1 measured (µA)				S.F.C. s1 = 0 S7 = 1 s8 = 1 measured (µA)				S.F.C. s1 = 1 s7 = 0 s8 = 1 measured (µA)				Other S.F.C. s1 = 1 s7 = 1 s8 = 1 measured max. (µA)			
		MD1		MD2		MD1		MD2		MD1		MD2		MD1		MD2	
Condition			**		**		**		**		**		**		**		**
1	1																
1	0																
0	1																
0	0																

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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 #2012-3758; Released by CDRH on 09-8-2015

Enclosure Leakage Current for Equipment with a Specified Power Supply *(see figure on previous page)*

s5	s10	s11	s12	N.C. s1, s2, s3, s7, s8 = 1 measured (µA)				S.F.C. s1, s3, s7, s8 = 1, s2 = 0 measured (µA)				S.F.C. s1, s2, s7, s8 = 1, s3 = 0 measured (µA)			
				MD3		MD4		MD3		MD4		MD3		MD4	
Condition					**		**		**		**		**		**
1	1	1	1												
1	1	1	0												
1	1	0	1												
1	1	0	0												
1	0	1	1												
1	0	1	0												
1	0	0	1												
1	0	0	0												
0	1	1	1												
0	1	1	0												
0	1	0	1												
0	1	0	0												
0	0	1	1												
0	0	1	0												
0	0	0	1												
0	0	0	0												

s5	s10	s11	s12	S.F.C. s2, s3, s7, s8 = 1, s1 = 0 measured (µA)				S.F.C. s1, s2, s3, s8 = 1, s7 = 0 measured (µA)				S.F.C. s1, s2, s3, s7 = 1, s8 = 0 measured (µA)			
				MD3		MD4		MD3		MD4		MD3		MD4	
Condition					**		**		**		**		**		**
1	1	1	1												
1	1	1	0												
1	1	0	1												
1	1	0	0												
1	0	1	1												
1	0	1	0												
1	0	0	1												
1	0	0	0												
0	1	1	1												
0	1	1	0												
0	1	0	1												
0	1	0	0												
0	0	1	1												
0	0	1	0												
0	0	0	1												
0	0	0	0												

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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 #2012-3758; Released by CDRH on 09-8-2015

(b)(4) Test Report

[redacted]

s5	s10	s13	N.C. s1, s7 = 1 measured (μA)		S.F.C. s1 = 0 s7 = 1 measured (μA)		S.F.C. s1 = 1 s7 = 0 measured (μA)		Other S.F.C. s1, s7 = 1 measured max (μA)	
Condition				**		**		**		**
1		1	18.2	15.8	18.2	15.8	18.2	17.4		
1		0	18.2	15.8	18.2	15.8	18.2	17.4		
1										
1										
0		1	18.2	15.8	18.2	15.8	18.2	17.8		
0		0	18.2	15.8	18.2	15.8	18.2	17.8		
0										
0										

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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 #2012-3758; Released by CDRH on 09-8-2015

Patient Leakage Current via a **Type B** Applied Part Caused by an external voltage on any **Accessible Metal Parts** not protectively earthed *[Refer to Clause 19.2b) 3rd Dash]*

(b)(4) Test Report

[redacted]

Conditions: At operating temperature / ** After moisture preconditioning

s5	s9	s10	s1, s7 = 1 s9 = 0 measured (µA)		s1, s7, s9 = 1 measured (µA)	
Condition				**		**
1	1		7	7.1	7	7.2
1	1					
1	0		7	7.1	7	7.2
1	0					
0	1		7	7.1	7	7.2
0	1					
0	0		7	7.1	7	7.2
0	0					

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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 #2012-3758; Released by CDRH on 09-8-2015

Patient Leakage Current via a **Type B** Applied Part Caused by an external voltage on the Signal Input or Signal Output Part
[Figure 22, Clause 19.4h)3) & 19.2b 1st Dash]

(**S.F.C.** for TYPE B if inspection of the circuits and physical arrangements shows there may be a safety hazard)

Conditions: At operating temperature /** After moisture preconditioning
For Class II equipment the protective earth connection and s7 are not used.

s5	s9	s10	s13	S.F.C. s1, s7 = 1 measured (µA)	S.F.C. s1, s7 = 1 measured (µA)
Condition					**
1	1		1	7	7.2
1	1		0	7	7.2
1	1		1		
1	1		0		
1	0		1	7	7.2
1	0		0	7	7.2
1	0		1		
1	0		0		
0	1		1	7	7.2
0	1		0	7	7.2
0	1		1		
0	1		0		
0	0		1	7	7.2
0	0		0	7	7.2
0	0		1		
0	0		0		

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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 #2012-3758; Released by CDRH on 09-8-2015

Patient Leakage Current via a **Type B** Applied Part Caused by an external voltage on the Signal Input or Signal Output Part

(b)(4) Test Report

[redacted]

Conditions: At operating temperature /** After moisture preconditioning
For Class II equipment the protective earth connection and s7 are not used.

s5	s9	s10	s13	S.F.C. s1, s7 = 1 measured (µA)	S.F.C. s1, s7 = 1 measured (µA)
Condition					**
1	1		1	3.5	3.6
1	1		0	3.6	3.6
1	1		1		
1	1		0		
1	0		1	3.7	3.7
1	0		0	4.4	3.7
1	0		1		
1	0		0		
0	1		1	4.3	3.7
0	1		0	4.2	3.7
0	1		1		
0	1		0		
0	0		1	3.7	3.7
0	0		0	3.9	3.7
0	0		1		
0	0		0		

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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 #2012-3758; Released by CDRH on 09-8-2015

Patient Leakage Current via a **Type B** Applied Part Caused by an external voltage on the Signal Input or Signal

(b)(4) Test Report

[redacted]

Conditions: At operating temperature /** After moisture preconditioning
For Class II equipment the protective earth connection and s7 are not used.

s5	s9	s10	s13	S.F.C. s1, s7 = 1 measured (µA)	S.F.C. s1, s7 = 1 measured (µA)
Condition					**
1	1		1	3.8	6.1
1	1		0	3.7	6.1
1	1		1		
1	1		0		
1	0		1	4.4	6.1
1	0		0	4.3	6.1
1	0		1		
1	0		0		
0	1		1	3.4	6.0
0	1		0	3.6	6.0
0	1		1		
0	1		0		
0	0		1	4.2	6.0
0	0		0	3.6	6.0
0	0		1		
0	0		0		

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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 #2012-3758; Released by CDRH on 09-8-2015

Patient Leakage Current via a **Type B** Applied Part Caused by an external voltage on the Signal Input or Signal Output Part

(b)(4) Test Report

[redacted]

Conditions: At operating temperature /** After moisture preconditioning
For Class II equipment the protective earth connection and s7 are not used.

s5	s9	s10	s13	S.F.C. s1, s7 = 1 measured (µA)	S.F.C. s1, s7 = 1 measured (µA)
Condition					**
1	1		1	4.0	5.9
1	1		0	4.1	5.9
1	1		1		
1	1		0		
1	0		1	2.5	5.8
1	0		0	2.5	5.8
1	0		1		
1	0		0		
0	1		1	4.1	5.9
0	1		0	4.0	5.9
0	1		1		
0	1		0		
0	0		1	4.1	5.9
0	0		0	4.0	5.9
0	0		1		
0	0		0		

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8488

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Patient Leakage Current *[Figure 23, Clause 19.4h)6)]*

Patient Leakage Current via a **Type B** Applied Part Caused by an external voltage on the Signal Input or Signal Output Part
[Figure 22, Clause 19.4h)3) & 19.2b 1st Dash]

(b)(4) Test Report

[redacted]

Conditions: At operating temperature /** After moisture preconditioning
For Class II equipment the protective earth connection and s7 are not used.

s5	s9	s10	s13	S.F.C. s1, s7 = 1 measured (µA)	S.F.C. s1, s7 = 1 measured (µA)
Condition					**
1	1		1	3.4	4.1
1	1		0	3.4	4.1
1	1		1		
1	1		0		
1	0		1	2.5	4.2
1	0		0	2.5	4.2
1	0		1		
1	0		0		
0	1		1	3.5	4.2
0	1		0	3.7	4.3
0	1		1		
0	1		0		
0	0		1	2.5	4.1
0	0		0	2.5	4.2
0	0		1		
0	0		0		

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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 #2012-3758; Released by CDRH on 09-8-2015

Patient Leakage Current via a **Type B** Applied Part Caused by an external voltage on the Signal Input or Signal Output Part
[Figure 22, Clause 19.4h)3) & 19.2b 1st Dash]

(b)(4) Test Report

[redacted]

Conditions: At operating temperature /** After moisture preconditioning
For Class II equipment the protective earth connection and s7 are not used.

s5	s9	s10	s13	S.F.C. s1, s7 = 1 measured (µA)	S.F.C. s1, s7 = 1 measured (µA)
Condition					**
1	1		1	4.1	4.1
1	1		0	4.2	4.3
1	1		1		
1	1		0		
1	0		1	2.5	4.1
1	0		0	2.5	4.2
1	0		1		
1	0		0		
0	1		1	3.6	4.3
0	1		0	3.7	4.3
0	1		1		
0	1		0		
0	0		1	4.0	4.1
0	0		0	4.0	4.1
0	0		1		
0	0		0		

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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 #2012-3758; Released by CDRH on 09-8-2015

Patient Leakage Current via a **Type B** Applied Part Caused by an external voltage on the Signal Input or Signal Output Part

(b)(4) Test Report

[redacted]

Conditions: At operating temperature /** After moisture preconditioning
For Class II equipment the protective earth connection and s7 are not used

s5	s9	s10	s13	S.F.C. s1, s7 = 1 measured (µA)	S.F.C. s1, s7 = 1 measured (µA)
Condition					**
1	1		1	4.2	4.2
1	1		0	4.2	4.2
1	1		1		
1	1		0		
1	0		1	3.6	4.1
1	0		0	3.6	4.1
1	0		1		
1	0		0		
0	1		1	3.6	4.1
0	1		0	3.6	4.3
0	1		1		
0	1		0		
0	0		1	2.4	4.2
0	0		0	2.4	4.1
0	0		1		
0	0		0		

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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 #2012-3758; Released by CDRH on 09-8-2015

Before Humidity conditioning

Input 120V AC

6	TABLE: Protection against electric shock -							Form A.5	
Pollution degree:			Measurement category (overvoltage category)						
Location or description	Insulation type (NOTE 1)	Maximum working voltage (NOTE 2)	CREEPAGE DISTANCE(NOTE 3)				CLEARANCE (NOTE 3) mm	Test voltage (NOTE 2) V	Comments
			PWB mm	CTI	Other mm	CTI			Before Humidity conditioning
A (A-f)	B	120			4			1000V AC	Waived,using standard 320 plug
B (A-a1)	B	120			4			1414V DC	Between primary to ground. **Pass**
C (A-e)	D	120			8			4242V DC	Primary to scanner plastic enclosure. **Pass**
C1	B	120			4			1414V DC	Grounded SIP/SOP Primary to Pin on top of chin holder **Pass**
D ((A-e)	B	120			4			1414V DC	Primary to computer chassis **Pass**
E	D	120			8			4242V DC	Primary to monitor enclosure.**Pass**
F	D	120			8			4242V DC	Primary to printer enclosure. **Pass**
G	D	120			8			4242V DC	Primary to Keyboard.**Pass**
H(A-a2)	D	120			4			770	Computer metal enclosure to scanner. **Pass**
I (A-a2)	D	120			4			770	Computer metal enclosure to Monitor. **Pass**
J (A-a2)	D	120			4			770	Computer metal enclosure to Printer. **Pass**
K (A-a2)	D	120			4			770V DC	Computer metal Keyboard. **Pass**
L (A-b)	B	Input 12V output 300V			Potted DC converter in lieu of creepage			3000V AC	Between input and output EMCO DC/DC converter. **Pass**
M (B-a)	D	120			8			4242V DC	Primary to computer USB 1. **Pass**
M1(B-a)	D	120			8			4242V DC	Primary to computer USB 2. **Pass**
M2 (B-a)	D	120			8			4242V DC	Primary to computer USB 3. **Pass**
M3 (B-a)	D	120			8			4242V DC	Primary to computer USB 4. **Pass**
M3 (B-a)	D	120			8			4242V DC	Primary to computer USB 5. **Pass**
M4 (B-a)	D	120			8			4242V DC	Primary to computer ear phone. **Pass**
M5 (B-a)	D	120			8			4242V DC	Primary to computer speaker phone. **Pass**

NOTE 1 – Type of insulation:	NOTE 2 - Types of voltage	NOTE 3 - INSTALLATION CATEGORIES
BI = BASIC INSULATION DI = DOUBLE INSULATION PI = PROTECTIVE IMPEDANCE RI = Reinforced INSULATION SI = Supplementary INSULATION	Peak impulse test voltage (pulse) r.m.s. DC peak	(OVERVOLTAGE CATEGORIES) or POLLUTION DEGREES which differ from these should be shown under "Comments"

Supplementary Information: Input rated voltage is 120V AC

Voltage limiting devices was removed during the di-electric tests..

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After Humidity conditioning

Input 120V AC

6	TABLE: Protection against electric shock - Block diagram of system							Form A.5	
Pollution degree.....			Measurement category (overvoltage category).....:						
Location or description	Insulation type (NOTE 1)	Maximum working voltage (NOTE 2)	CREEPAGE DISTANCE(NOTE 3)				CLEARANCE (NOTE 3) mm	Test voltage (NOTE 2) V	Comments
			PWB mm	CTI	Other mm	CTI			After Humidity Conditioning
A (A-f)	B	120			4			1000V AC	Waived,using standard 320 plug
B (A-a1)	B	120			4			1414V DC	Between primary to ground.**Pass**
C (A-e)	D	120			8			4242V DC	Primary to scanner plastic enclosure. **Pass**
C1	B	120			4			1414V DC	Grounded SIP/SOP, Primary to Pin on top of chin holder **Pass**
D ((A-e)	B	120			4			1414V DC	Primary to computer chassis, **Pass**
E	D	120			8			4242V DC	Primary to monitor enclosure. **Pass**
F	D	120			8			4242V DC	Primary to printer enclosure. **Pass**
G	D	120			8			4242V DC	Primary to Keyboard. **Pass**
H(A-a2)	D	120			4			770	Computer metal enclosure to Scanner. **Pass**
I (A-a2)	D	120			4			770	Computer metal enclosure to Monitor. **Pass**
J (A-a2)	D	120			4			770	Computer metal enclosure to Printer. **Pass**
K (A-a2)	D	120			4			770V DC	Computer metal keyboard. **Pass**
L (A-b)	B	Input 12V output 300V			Potted DC converter in lieu of creepage			3000V AC	Between input and output EMCO DC/DC converter. **Pass**
M (B-a)	D	120			8			4242V DC	Primary to computer USB 1.**Pass**
M1(B-a)	D	120			8			4242V DC	Primary to computer USB 2.**Pass**
M2 (B-a)	D	120			8			4242V DC	Primary to computer USB 3.**Pass**
M3 (B-a)	D	120			8			4242V DC	Primary to computer USB 4.**Pass**
M3 (B-a)	D	120			8			4242V DC	Primary to computer USB 5.**Pass**
M4 (B-a)	D	120			8			4242V DC	Primary to computer ear phone. **Pass**
M5 (B-a)	D	120			8			4242V DC	Primary to computer speaker phone. **Pass**

NOTE 1 – Type of insulation:	NOTE 2 - Types of voltage	NOTE 3 - INSTALLATION CATEGORIES
BI = BASIC INSULATION DI = DOUBLE INSULATION PI = PROTECTIVE IMPEDANCE RI = Reinforced INSULATION SI = Supplementary INSULATION	Peak impulse test voltage (pulse) r.m.s. DC peak	(OVERVOLTAGE CATEGORIES) or POLLUTION DEGREES which differ from these should be shown under "Comments".

Supplementary Information: Input rated voltage is 120V AC

After humidity, repeat above tests and all tests are pass.

Voltage limiting devices was removed during the di-electric tests..

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Product Photos

Over view

(Note: Printer in the photo is not part of the evaluation)

Doctor side

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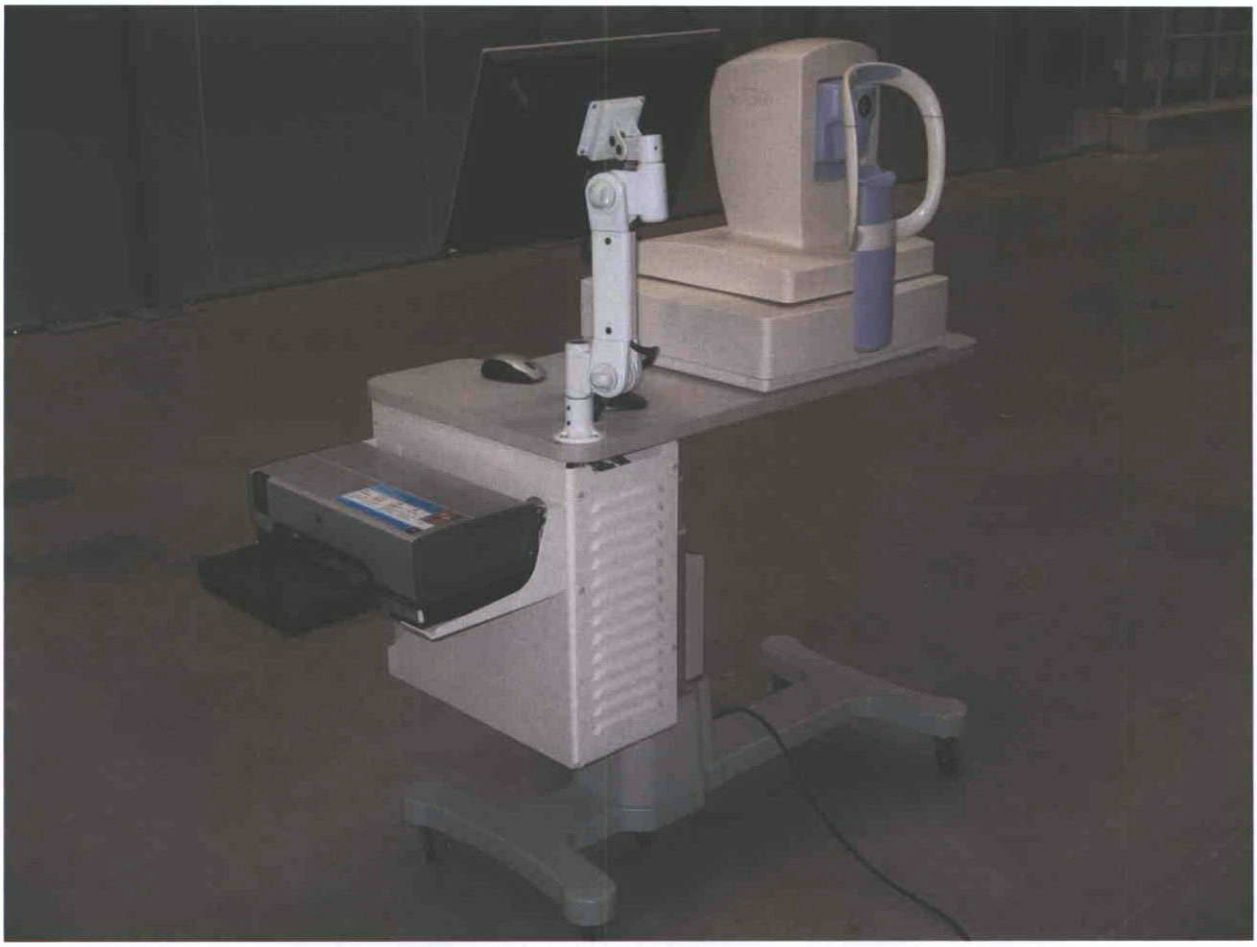
Patient side view



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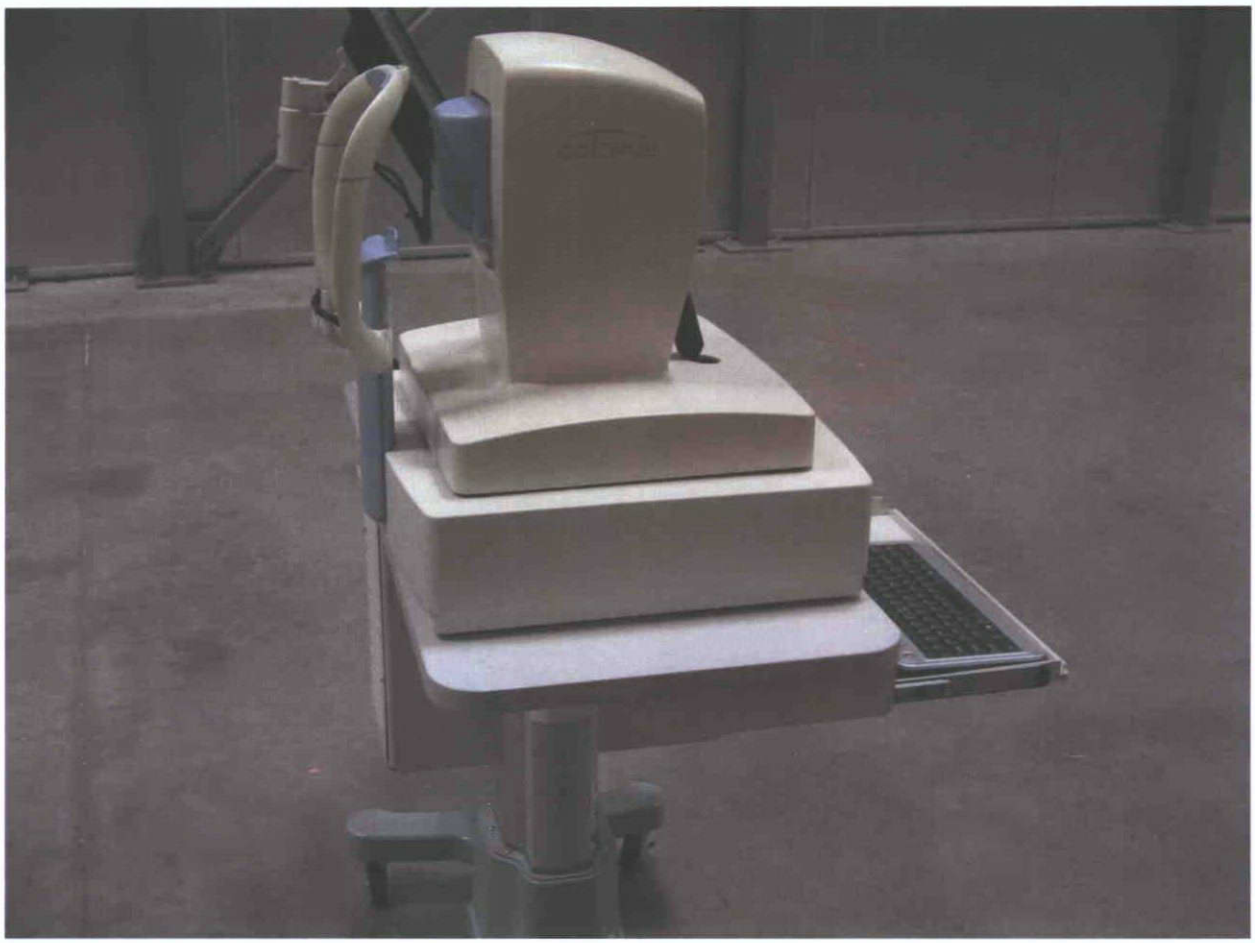
Side view



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Scanner

Doctor side view

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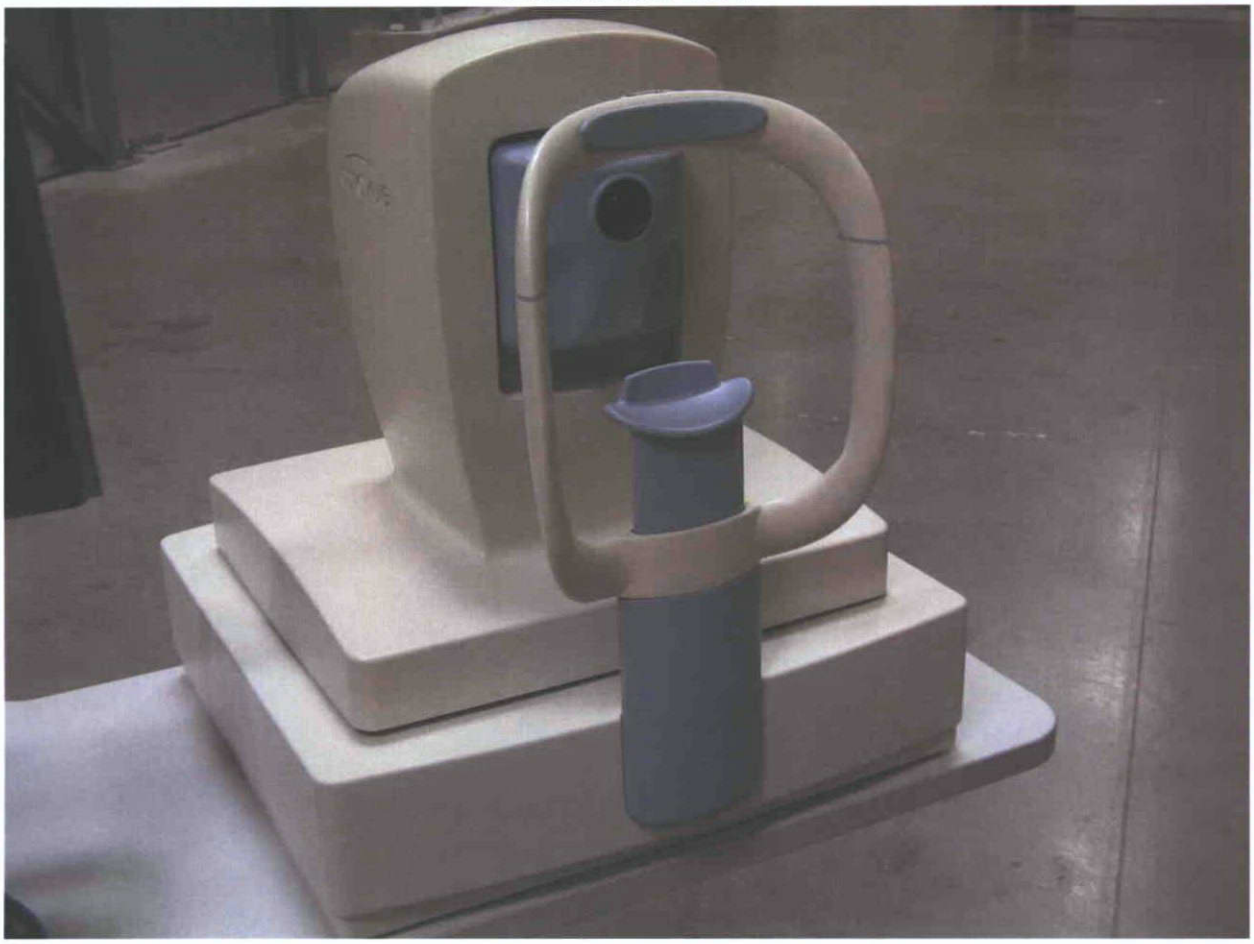
Patient side view



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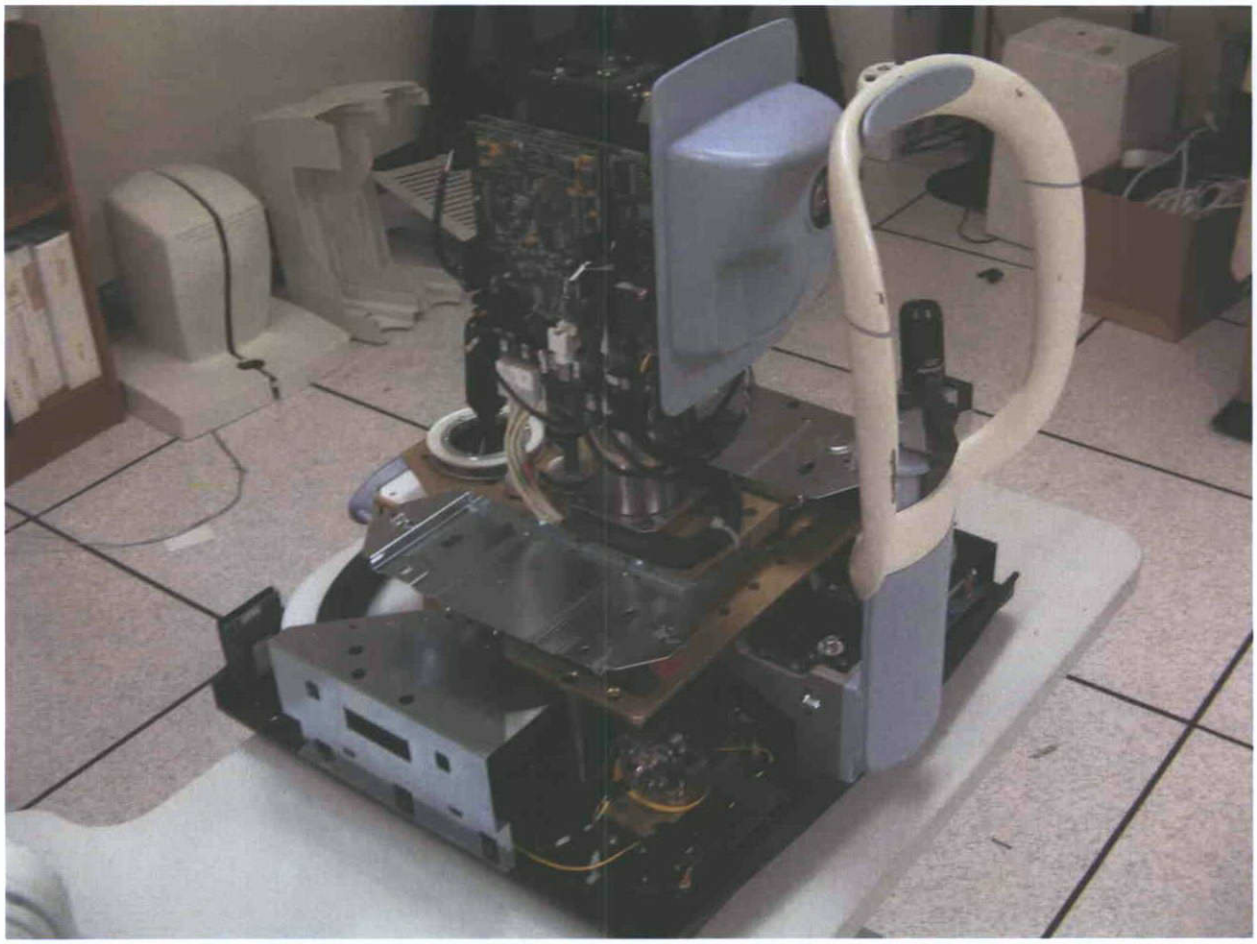
Scanner internal view



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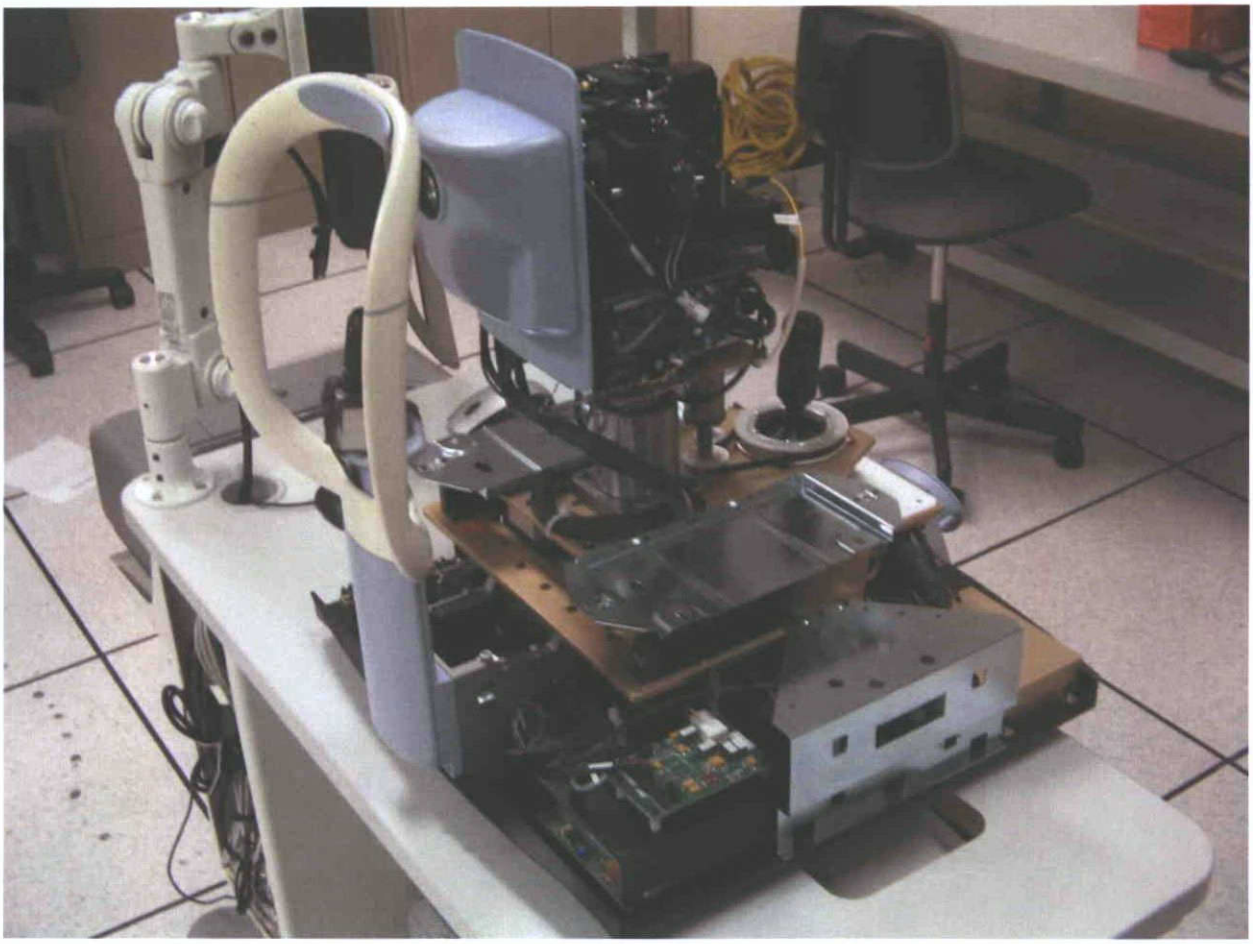

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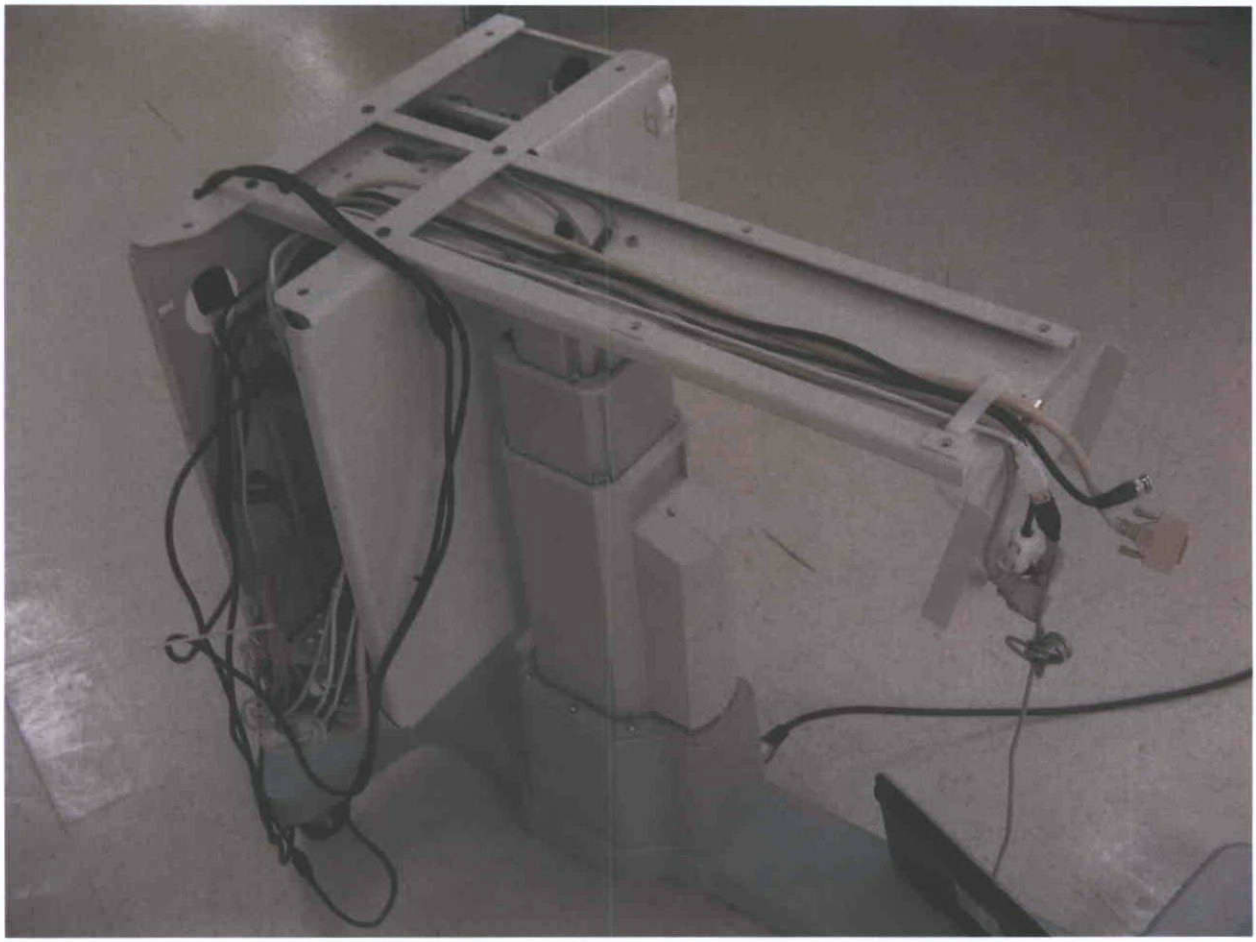
Internal wiring path



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Isolation tranformer:

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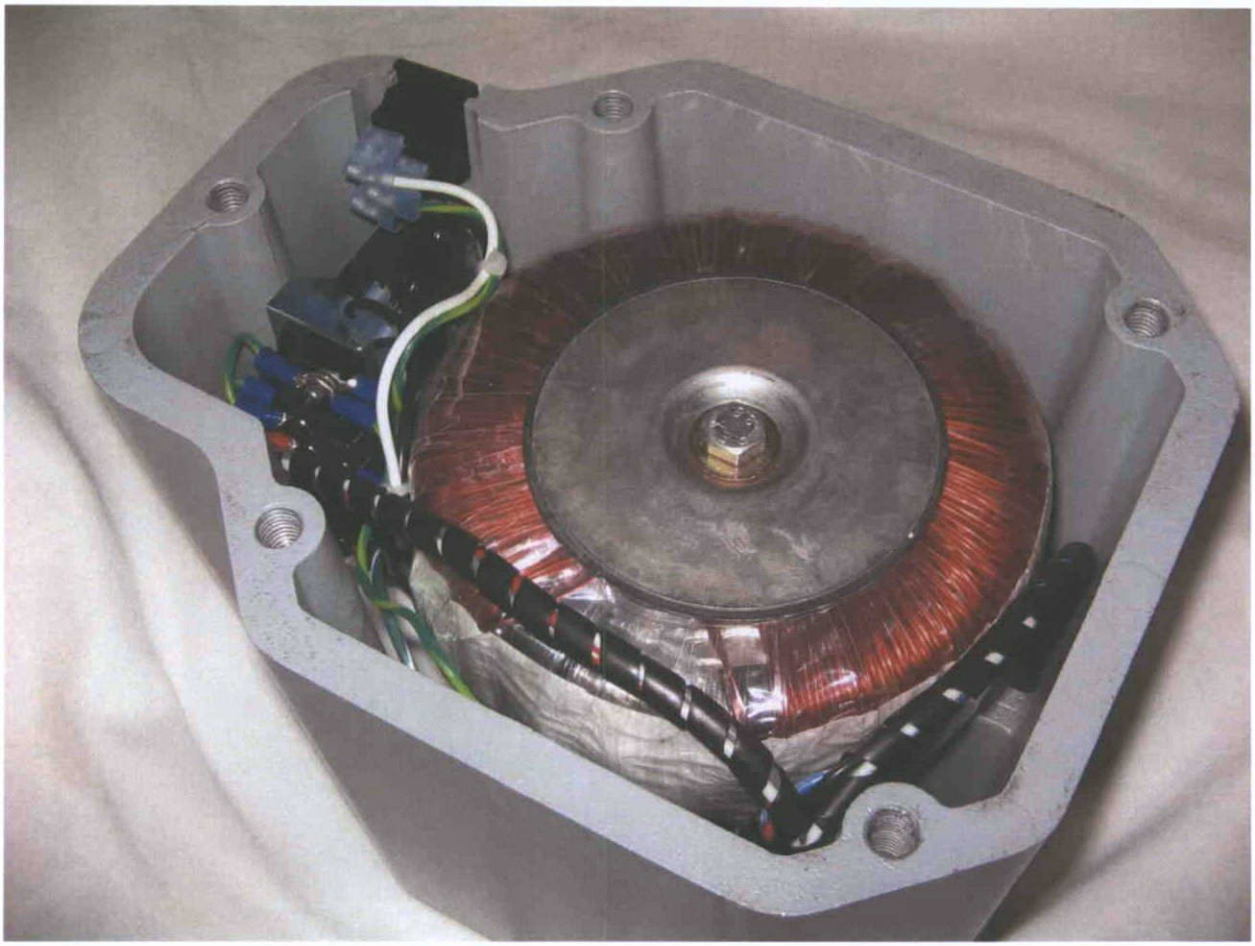

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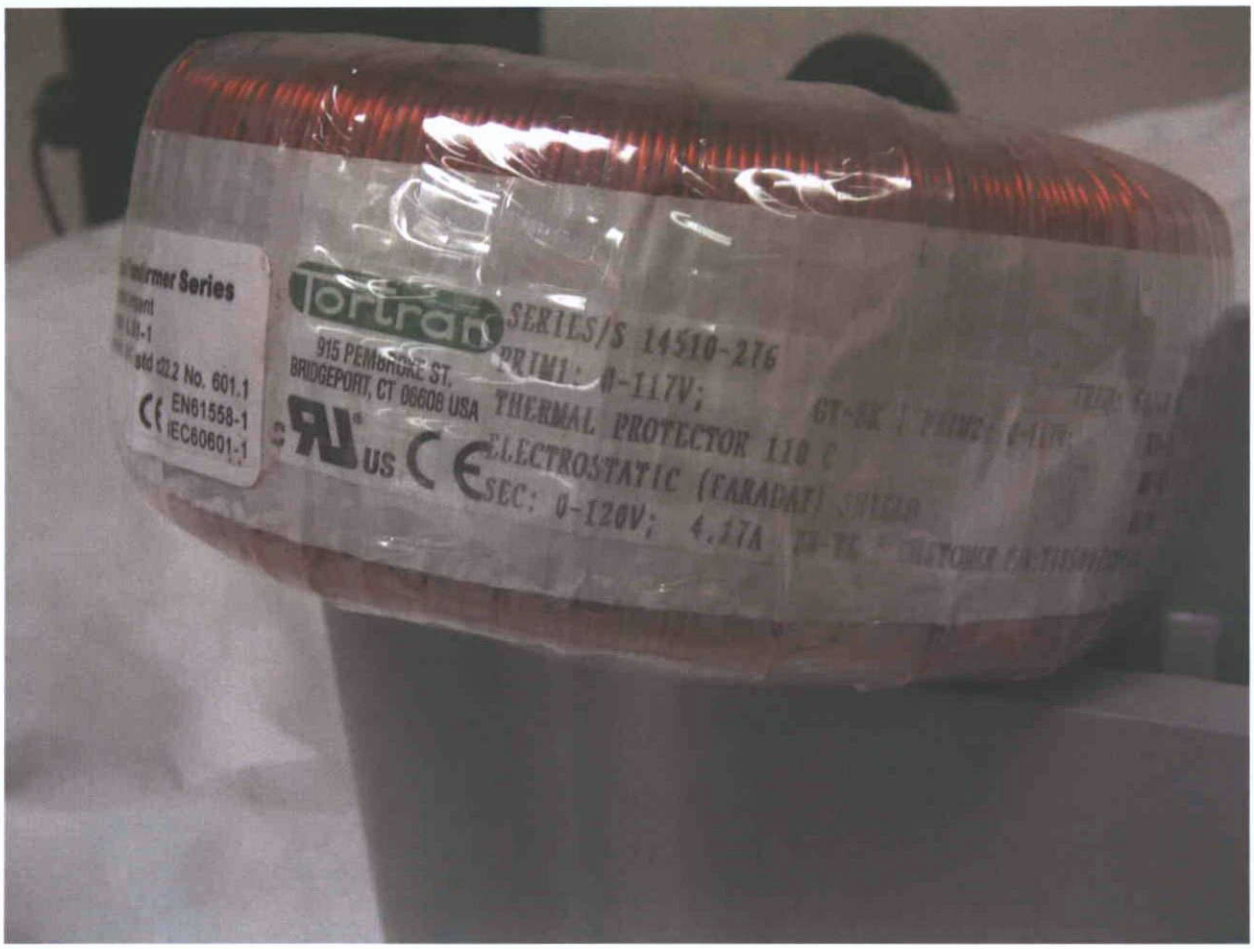

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END OF REPORT

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Elliott
An NTS company

Test Certificate

A sample of the following product received on April 11, 2006 and tested on April 11, 17, 18, 19, 20, 24, 25 and May 15, 2006 and received on November 23, 2011 and tested on November 23, 27 and 28, 2011 complied with the requirements of:

- **EN 60601-1-2:2007 "Medical electrical equipment - Part 1-2: General requirements for safety - Collateral Standard: Electromagnetic compatibility - Requirements and tests"**
- **IEC 60601-1-2:2007, "Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests"**

for a class A product given the measurement uncertainties as detailed in Elliott report R63864 Rev 4. Compliance with Clause 5 of EC/IEC 60601-1-2 standard has been included in this evaluation and reported separately.

Optovue
Models RTVue 100 and RTVue XR

David W. Bare
Chief Engineer

Optovue

TONY KO
Printed Name

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Electromagnetic Compatibility Test Report for Medical Electrical Equipment per EN 60601-1-2:2007 and IEC 60601-1-2:2007 Specifications on the Optovue Models: RTVue 100 and RTVue XR

MANUFACTURER:	Optovue 45531 Northport Loop West Fremont, CA. 94538
TEST SITE:	Elliott Laboratories, Inc. 684 W. Maude Ave Sunnyvale, CA 94086
TEST SITE:	Elliott Laboratories, Inc. 41039 Boyce Road. Fremont, CA. 94538-2435
REPORT DATE:	Insert Report Date
FINAL TEST DATES:	April 11, 17, 18, 19, 20, 24 and 25, 2006 and May 15, 2006
AND:	November 23, 27 and 28, 2011
TOTAL NUMBER OF PAGES:	154

TECHNICAL REVIEWER:

David W. Bare
Chief Engineer

QUALITY ASSURANCE DELEGATE / FINAL REPORT PREPARER:

David Guidotti
Senior Technical Writer

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REVISION HISTORY

Revision #	Date	Comments	Modified By
1	May 15, 2006	Initial Release	David Guidotti
2	December 19, 2006	Changed the model name from RTVue Device to RTVue100	David Guidotti
3	December 22, 2010	Updated test log emissions & immunity standards	David Guidotti
4	January 16, 2012	Added new test data taken due to PCB modifications and internal component (line camera) change Updated standard to 2007 version. Updated A2LA certificate number (previous testing performed under certificate # 2016.01)	David Guidotti

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SCOPE

The European Committee for Electrotechnical Standardization (CENELEC) publishes standards regarding the electromagnetic compatibility of medical electrical equipment. Electromagnetic emissions and immunity testing has been performed on the Optovue models RTVue 100 and RTVue XR to establish compliance with one of these standards.

Electromagnetic emissions data has been taken and immunity tests performed pursuant to the relevant requirements of the following standards. Conducted and radiated emissions data has been collected, reduced, and analyzed and immunity tests have been performed as described in this report in accordance with the appropriate specifications, test procedures, and measurement guidelines as outlined in Elliott Laboratories test procedures.

Standard	Title	Standard Date
EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral Standard: Electromagnetic compatibility - Requirements and tests	2007
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	2007

The test results recorded herein are based on a single type test of the Optovue models RTVue 100 and RTVue XR and therefore apply only to the tested samples. The samples were selected and prepared by David Chen of Optovue.

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OBJECTIVE

The primary objective of the manufacturer is to verify compliance with the General Requirements listed in clause 4 of EN 60601-1-2 and IEC 60601-1-2 for the operation of medical electrical equipment. Compliance may be presumed by applying the protection requirements of clause 6 of EN60601-1-2:2007 and IEC 60601-1-2:2007.
For emissions, the standards reference the provisions of the latest editions of:

- CISPR 11 "Limits and Methods of Measurements of Radio Disturbance Characteristics of Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment"
- IEC 61000-3-2 "Electromagnetic compatibility (EMC) – Part 3: Limits – Section 2: Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)"
- IEC 61000-3-3 "Electromagnetic compatibility (EMC) – Part 3: Limits – Section 3: Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current ≤ 16 A"

In this case, the Group-1, Class-A limits of CISPR 11 and the Class-A limits of IEC 61000-3-2 were utilized based on the manufacturer's statement of intended use.

For immunity, the standards reference the provisions of the latest editions of:

- IEC 61000-4-2 "Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 2: Electrostatic discharge immunity test – Basic EMC publication"
- IEC 61000-4-3 "Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test"
- IEC 61000-4-4 "Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 4: Electrical fast transient/burst immunity test – Basic EMC publication"
- IEC 61000-4-5 "Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 5: Surge immunity test"
- IEC 61000-4-6 "Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 6: Immunity to conducted disturbances, induced by radio-frequency fields"
- IEC 61000-4-8 "Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 8: Power frequency magnetic field immunity test – Basic EMC publication"
- IEC 61000-4-11 "Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 11: Voltage dips, short interruptions and voltage variations immunity tests."

Verification is a procedure where the manufacturer or a contracted laboratory makes measurements and takes necessary steps to ensure that the equipment complies with the appropriate technical standards. The manufacturer may use this report, along with the other necessary documentation, to declare conformity to the European Union's medical device directive (93/42/EEC).

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STATEMENT OF COMPLIANCE

The tested samples of Optovue model RTVue 100 complied with the emission and susceptibility requirements of:

Standard/Regulation	Standard Date
EN 60601-1-2	2007
IEC 60601-1-2	2007

Compliance with Clause 5 of EC/IEC 60601-1-2 standard has been included in this evaluation and reported separately.

Maintenance of compliance is the responsibility of the manufacturer. Any modification of the product that could result in increased emissions should be checked to ensure compliance has been maintained (i.e., printed circuit board layout changes, different enclosure, different line filter or power supply, harnessing and/or interface cable changes, etc.).

DEVIATIONS FROM THE STANDARDS

No deviations were made from the requirements in EN 60601-1-2:2007 or IEC 60601-1-2:2007

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EMISSION TEST RESULTS

The following emissions tests were performed on the Optovue models RTVue 100 and RTVue XR. The actual test results are contained in an appendix of this report.

CONDUCTED EMISSIONS (AC POWER PORT)

2006 (RTVue 100)

Test	Standard/Section	Requirement	Measurement	Result	Compliance Status
CE, 0.15-30 MHz, 230V, 50Hz	CISPR 11, Section 5, Table 2a	0.15-0.5 MHz, 79 dBµV QP 0.5-30 MHz, 73 dBµV QP 0.15-0.5 MHz, 66 dBµV Av 0.5-30 MHz, 60 dBµV Av	54.157.91dBµV @ 10.157MHz	-5.9dB	Complied
CE, 0.15-30 MHz, 120V, 60Hz			46.550.32dBµV @ 11.062MHz	-13.5dB	Complied
Harmonics	IEC 61000-3-2	Refer to Standard	0.091	15.22%	Complied
Voltage Fluctuations	IEC 61000-3-3	Refer to Standard	Plt	0.027	Complied

2011 (RTVue XR)

Test	Standard/Section	Requirement	Measurement	Result	Compliance Status
CE, 0.15-30 MHz, 120V, 60Hz	CISPR 11, Section 5, Table 2a	0.15-0.5 MHz, 79 dBµV QP 0.5-30 MHz, 73 dBµV QP 0.15-0.5 MHz, 66 dBµV Av 0.5-30 MHz, 60 dBµV Av	36.2dBµV @ 0.996MHz	-23.8dB	Complied
Harmonics	IEC 61000-3-2	Refer to Standard	0.178	44.6%	Complied
Voltage Fluctuations	IEC 61000-3-3	Refer to Standard	Plt	0.040	Complied

RADIATED EMISSIONS

2006 (RTVue 100)

Test	Standard/Section	Requirement	Measurement	Result	Compliance Status
RE, 30-1000 MHz	CISPR 11, Section 5, Table 3	30 – 230, 40 dBµV/m 230 – 1000, 47 dBµV/m	37.1dBµV/m @218.753 MHz	-2.9dB	Complied

2011 (RTVue XR)

Test	Standard/Section	Requirement	Measurement	Result	Compliance Status
RE, 30-1000 MHz	CISPR 11, Section 5, Table 3	30 – 230, 40 dBµV/m 230 – 1000, 47 dBµV/m	42.8dBµV/m @816.03 MHz	-4.2dB	Complied

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IMMUNITY TEST RESULTS

The following tests were performed on the Optovue models RTVue 100 and RTVue XR. The results are based upon performance criterion defined by the manufacturer. The actual test results and associated performance criteria are contained within an appendix of this report.

2006 (RTVue 100)

Test	Basic Standard	Level Required	Level Tested	Criterion Met?	Compliance Status
ESD	IEC 61000-4-2	6 kV CD, 8 kV AD	6 kV CD, 8 kV AD	Yes	Complied
RF EM Field, AM	IEC 61000-4-3	80-2500 MHz, 3 V/m, 80% 1 kHz AM	3 V/m	Yes	Complied
EFT, AC Power Port	IEC 61000-4-4	2 kV	2 kV	Yes	Complied
EFT, DC Power Port	IEC 61000-4-4	N/A – Note 1			
EFT, Signal Ports	IEC 61000-4-4	1 kV	1 kV	Yes	Complied
Surge, AC Power Port	IEC 61000-4-5	1 kV DM, 2 kV CM 1.2/50 µs	1 kV DM, 2 kV CM 1.2/50 µs	Yes	Complied
RF, Conducted Disturbances AC Power Port	IEC 61000-4-6	0.15-80 MHz, 3 Vrms, 80% 1 KHz AM	0.15-80 MHz, 3 Vrms	Yes	Complied
RF, Conducted Disturbances DC Power Port	IEC 61000-4-6	N/A – Note 1			
RF, Conducted Disturbances Signal Ports	IEC 61000-4-6	0.15-80 MHz, 3 Vrms, 80% 1 KHz AM	0.15-80 MHz, 3 Vrms	Yes	Complied
Power Frequency Magnetic Field	IEC 61000-4-8	3 A/m	3 A/m	Yes	Complied
Voltage Dips and Interrupts	IEC 61000-4-11	>95%, 0.5 cycles 60%, 5 cycles 30%, 25 cycles >95%, 250 cycles	>95%, 0.5 cycles 60%, 5 cycles 30%, 25 cycles >95%, 250 cycles	Yes	Complied

Note 1 – The EUT does not have a DC power port.
Note 2 – The manufacturer stated that the EUT's interface cables will not exceed 3 meters in length.

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2011 (RTVue XR)

Test	Basic Standard	Level Required	Level Tested	Criterion Met?	Compliance Status
ESD	IEC 61000-4-2	6 kV CD, 8 kV AD	6 kV CD, 8 kV AD	Yes	Complied
RF EM Field, AM	IEC 61000-4-3	80-2500 MHz, 3 V/m, 80% 1 kHz AM	3 V/m	Yes	Complied
EFT, AC Power Port	IEC 61000-4-4	2 kV	2 kV	Yes	Complied
EFT, DC Power Port	IEC 61000-4-4	N/A – Note 1			
EFT, Signal Ports	IEC 61000-4-4	N/A – Note 2			
Surge, AC Power Port	IEC 61000-4-5	1 kV DM, 2 kV CM 1.2/50 µs	1 kV DM, 2 kV CM 1.2/50 µs	Yes	Complied
RF, Conducted Disturbances AC Power Port	IEC 61000-4-6	0.15-80 MHz, 3 Vrms, 80% 1 KHz AM	0.15-80 MHz, 3 Vrms	Yes	Complied
RF, Conducted Disturbances DC Power Port	IEC 61000-4-6	N/A – Note 1			
RF, Conducted Disturbances Signal Ports	IEC 61000-4-6	N/A – Note 2			
Power Frequency Magnetic Field	IEC 61000-4-8	3 A/m	3 A/m	Yes	Complied
Voltage Dips and Interrupts	IEC 61000-4-11	>95%, 0.5 cycles 60%, 5 cycles 30%, 25 cycles >95%, 250 cycles	>95%, 0.5 cycles 60%, 5 cycles 30%, 25 cycles >95%, 250 cycles	Yes	Complied

Note 1 – The EUT does not have a DC power port.
Note 2 – The manufacturer stated that the EUT's interface cables will not exceed 3 meters in length.

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MEASUREMENT UNCERTAINTIES

ISO Guide 17025 requires that an estimate of the measurement uncertainties associated with the test results be included in the report. The measurement uncertainties given below are based on a standard uncertainty multiplied by a coverage factor of k=2, providing a 95% confidence level and were calculated in accordance with NAMAS document LAB 34. For emissions tests, the uncertainties were calculated using the approach described in CISPR 16-4-2:2003 and the levels were found to be below levels of Ucispr and therefore no adjustment of the data for measurement uncertainty is required

Measurement Type	Measurement Unit	Frequency Range	Expanded Uncertainty
Conducted Emissions	dBuV	0.15 to 30 MHz	± 2.4 dB
Radiated Emissions	dBuV/m	30 to 1000 MHz	± 3.6 dB
AC Current Harmonics	Amps	50 to 2,000 Hz	± 0.12 %
AC Voltage Flicker	Voltage	N/A	± 0.12 %
	Pst, Plt	N/A	± 3.46 %
Radiated Immunity	V/m	80 – 1000 MHz	- 26.3%, + 29.97%
ESD	KV	N/A	± 8.6%
Fast Transients	Voltage	N/A	± 5.98 %
	Timing	N/A	± 8.60 %
Surge	Voltage	N/A	± 4.92 %
RF Common Mode (CDN method)	Vrms	N/A	-12.64 %, +13.33 %
RF Common Mode (BCI method)	Vrms	N/A	-13.45 %, +15.32 %
Magnetic Field	Arms	50-60 Hz	± 2.83 %
Voltage Dips	Voltage	N/A	± 2.32 %
	Timing	N/A	± 0.08mS

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EQUIPMENT UNDER TEST (EUT) DETAILS

GENERAL

The Optovue Systems model RTVue 100k or RTVue XR is a retina scanner used by a medical professional to capture images of the retina for diagnosis. The system is on a free-standing cart and consists of a PC, monitor, mouse, keyboard and patient unit. It has one external connection (10/100 Ethernet). The electrical rating of the EUT is 230V/ 50 Hz, 1.5 Amps and 120V/ 60Hz.

The RTVue 100 sample was received on April 11, 2006 and tested on April 11, 17, 18, 19, 20, 24, 25 and May 15, 2006. The EUT consisted of the following component(s):

Manufacturer	Model	Description	Serial Number	FCC ID
Optovue	RTVue 100	retina scanner	-	-
Magnetic	TFG50	Riser / Table	-	-
AMAX	Custom Built for Optovue	PC	-	-
HP	Deskjet 6940	Printer	MY5BF5Q0BG	-
SONY	SDM-HS75P	TFT LCD Computer Display	6307779	-
BTC	6100C	USB Keyboard	-	E5XKB6100C
Logitech	-	Wireless Mouse	-	-
Logitech	C-BN4	Fast RF Cordless Mouse Receiver	-	-

The RTVue XR sample was received on November 23, 2011 and tested on November 23, 27 and 28, 2011. The electrical rating of the EUT is 100 - 120VAC, 50/60 Hz, 120VAC 6 Amps. The EUT consisted of the following component(s):

Manufacturer	Model	Description	Serial Number	FCC ID
Optovue	RTVue XR	Eye Scanner	N/A	N/A

OTHER EUT DETAILS

Per customer the retina scanner, PC, printer, monitor, mouse and keyboard are considered as a system. The PC doesn't have model or serial number because it is custom made for Optovue. There are two units 1st unit 230V/ 50Hz and 2nd unit 120V/ 60Hz.

ENCLOSURE

The EUT enclosure is primarily constructed of plastic. The retina scanner, PC, printer, monitor, mouse and keyboard are considered as a complete system.

MODIFICATIONS

The EUT required the following modifications in order to comply with the specifications.

Mod. #	Test	Date	Modification
1	RE	4/11/2006	Added Steward Ferrite Part # 28A0640-0A0 on USB Port at scanner end.

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SUPPORT EQUIPMENT

No local support equipment was used during testing.

The following equipment was used as remote support equipment during testing performed in 2006:

Manufacturer	Model	Description	Serial Number
Linksys	EZXS55W	5 Port 10/100 Work group switch	-

No support equipment was used during testing performed in 2011.

EUT INTERFACE PORTS

The I/O cabling configuration during testing performed in 2006 was as follows:

Port	Connected To	Cable(s)		
		Description	Shielded or Unshielded	Length(m)
Ethernet on PC	5 Port 10/100 Work group switch	CAT-5 RJ45	Unshielded	10.0
AC Power	AC Mains	AC Power Cord	Unshielded	2.0

Note: The USB, microphone and speaker ports were not connected during testing. The manufacturer stated that these are not intended for use and therefore would not normally be connected.

The I/O cabling configuration during testing performed in 2011 was as follows:

Port	Connected To	Cable(s)		
		Description	Shielded or Unshielded	Length(m)
AC Power (Entire System is connected to a internal power strip)	AC Mains	3 Wire	Unshielded	2
PC DVI	DVI Monitor	Multi Cable	Shielded	2
PC Audio	Audio Monitor	Multi Cable	Shielded	2
PC USB	RTVue USB	USB	Shielded	2
PC Camera Link	RTVue Camera Link	Multi Cable	Shielded	2
PC Line Sync	RTVue Line Sync	Multi Cable	Shielded	2
PC USB	Keyboard	USB	Shielded	2
PC USB	Mouse	USB	Shielded	1

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EUT OPERATION

2006:
During emissions testing the EUT was exercising RTVue application software.
During immunity testing the EUT was exercised by the RTVue software application. The EUT was continuously scanned and displayed an OCT image of an eye scan. Due to system limitations it was necessary to restart the software approximately every 7 or 8 minutes.

2011
During emissions testing the EUT was scanning in retina mode.
During immunity testing the EUT was scanning in retina mode.
Normal operation is indicated by a continuous video stream of the retina scan. When warning/error messages pops up this is acceptable as long as the system can be restarted and continue to perform retina scans.

Performance Criteria used:
Normal operation of a continuous video stream of the retina scan maybe interrupted. The video stream may freze up requiring a system restart to reset the system. Warning/error messages are acceptable as long as the system can be restarted.

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EMISSIONS TEST SITE

GENERAL INFORMATION

Final test measurements were taken at the Elliott Laboratories Anechoic Chambers and Open Area Test Site(s) listed below. The test sites contain separate areas for radiated and conducted emissions testing. The sites conform to the requirements of ANSI C63.4: 2003 American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz and CISPR 16-1:1999 - Specification for radio disturbance and immunity measuring apparatus and methods Part 1: Radio disturbance and immunity measuring apparatus. They are registered with the VCCI and are on file with the FCC.
In the case of Open Area Test Sites, ambient levels are at least 6 dB below the specification limits with the exception of predictable local TV, radio, and mobile communications traffic.
Considerable engineering effort has been expended to ensure that the facilities conform to all pertinent requirements.

	Site	Location
■	Chamber 3	41039 Boyce Road
■	Chamber 4	Fremont, CA 94538-2435

CONDUCTED EMISSIONS CONSIDERATIONS

Conducted emissions tests are performed in conformance with CISPR 11. Measurements are made with the EUT connected to the public power network or a motor generator set through a nominal, standardized RF impedance, which is provided by a line impedance stabilization network, known as a LISN. A LISN is inserted in series with each current-carrying conductor of the EUT power cord.

RADIATED EMISSIONS CONSIDERATIONS

CENELEC has determined that radiated measurements made in non-anechoic shielded enclosures are not suitable for determining levels of radiated emissions. Radiated measurements are performed in an Open Area Test Site or anechoic chamber, as defined in CISPR 16-1-4. The test site is maintained free of conductive objects within the defined elliptical area.

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EMISSIONS MEASUREMENT INSTRUMENTATION

RECEIVER SYSTEM

An EMI receiver as specified in CISPR 16-1-1:2006 is used for emissions measurements. The receivers used can measure over the frequency range of 9 kHz up to 7 GHz. These receivers allow both ease of measurement and high accuracy to be achieved. The receivers have Peak, Average, and CISPR (Quasi-peak) detectors built into their design so no external adapters are necessary. The receiver automatically sets the required bandwidth for the CISPR detector used during measurements.

INSTRUMENT CONTROL COMPUTER

The receivers utilize either a Rohde & Schwarz EZM Spectrum Monitor/Controller or contain an internal Spectrum Monitor/Controller to view and convert the receiver measurements to the field strength at an antenna or voltage developed at the LISN measurement port, which is then compared directly with the appropriate specification limit. This provides faster, more accurate readings by performing the conversions described under Sample Calculations within the Test Procedures section of this report. Results are printed in a graphic and/or tabular format, as appropriate. A personal computer is used to record all measurements made with the receivers.

The Spectrum Monitor provides a visual display of the signal being measured. In addition, the controller or a personal computer run automated data collection programs which control the receivers. This provides added accuracy since all site correction factors, such as cable loss and antenna factors are added automatically.

LINE IMPEDANCE STABILIZATION NETWORK (LISN)

Line conducted measurements utilize a fifty micro-Henry Line Impedance Stabilization Network as the monitoring point. The LISN used also contains a 250-μH CISPR adapter. This network provides for calibrated radio-frequency noise measurements by the design of the internal low-pass and high-pass filters on the EUT and measurement ports, respectively.

FILTERS/ATTENUATORS

External filters and precision attenuators are often connected between the receiving antenna or LISN and the receiver. This eliminates saturation effects and non-linear operation due to high-amplitude transient events.

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ANTENNAS

A biconical antenna is used to cover the range from 30 MHz to 300 MHz and a log periodic antenna is utilized from 300 MHz to 1000 MHz. Narrowband tuned dipole antennas are used over the entire 30 to 1000 MHz range for precision measurements of field strength. The antenna calibration factors are included in site factors which are programmed into the test receivers

ANTENNA MAST AND EQUIPMENT TURNTABLE

The antennas used to measure the radiated electric field strength are mounted on a non-conductive antenna mast equipped with a motor drive to vary the antenna height.

CISPR 11 specifies that the test height above ground for table-mounted devices shall be 80 centimeters. Floor-mounted equipment shall be placed on the ground plane if the device is normally used on a conductive floor or separated from the ground plane by insulating material up to 12-mm thick if the device is normally used on a non-conductive floor. During radiated measurements, the EUT is positioned on a motorized turntable in conformance with this requirement.

INSTRUMENT CALIBRATION

All test equipment is regularly checked to ensure that performance is maintained in accordance with the manufacturer's specifications. All antennas are calibrated at regular intervals with respect to tuned half-wave dipoles. An appendix of this report contains the list of test equipment used and calibration information.

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EMISSIONS TEST PROCEDURES

EUT AND CABLE PLACEMENT

CISPR 11 requires that interconnecting cables are connected to the available ports of the unit and that the placement of the unit and the attached cables simulate the worst-case orientation that can be expected from a typical installation, so far as practicable. To this end, the position of the unit and associated cabling is varied, and the worst-case orientation is used for final measurements.

CONDUCTED EMISSIONS

Conducted emissions are measured at the plug end of the power cord supplied with the EUT. Excess power cord length is wrapped in a bundle between 30 and 40 centimeters in length near the center of the cord. Preliminary measurements are made to determine the highest-amplitude emission relative to the specification limit for all the modes of operation. Placement of system components and varying of cable positions are performed in each mode. A final peak-mode scan is then performed in the position and mode for which the highest emission was noted on all current carrying conductors of the power cord. Emissions having peak values close to the specification limit are also measured in the quasi-peak and average detection modes to determine compliance except when the amplitude of the emission when measured with the quasi-peak detector is more than 10 dB below the specification limit for average measurements. In this case only quasi-peak measurements are performed.

RADIATED EMISSIONS

Radiated emissions measurements are performed in two phases as well. A preliminary scan of emissions is conducted in which all significant EUT frequencies are identified with the system in a nominal configuration. At least two scans are performed from 30 to 1000 MHz. One or more of these is with the antenna polarized vertically while the one or more of these are with the antenna polarized horizontally. During the preliminary scans, the EUT is rotated through 360°, the antenna height is varied and cable positions are varied to determine the highest emission relative to the limit.

A speaker is provided in the receiver to aid in discriminating between EUT and ambient emissions. Other methods used during the preliminary scan for EUT emissions involve scanning with near-field magnetic loops, monitoring I/O cables with RF current clamps, and cycling power to the EUT.

Final maximization is a phase in which the highest-amplitude emissions identified in the spectral search are viewed while the EUT azimuth angle is varied from 0 to 360 degrees relative to the receiving antenna. The azimuth resulting in the highest emission is then maintained while varying the antenna height from one to four meters. The result is the identification of the highest amplitude for each of the highest peaks. Each recorded level is corrected in the receiver using appropriate factors for cables, connectors, antennas, and preamplifier gain. Emissions having values close to the specification limit may also be measured with a tuned dipole antenna to determine compliance.

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SAMPLE CALCULATIONS - EMISSIONS

SAMPLE CALCULATIONS - CONDUCTED EMISSIONS

Receiver readings are compared directly to the conducted emissions specification limit (decibel form). The calculation is as follows:

$$R_r - S = M$$

where:

R_r = Receiver Reading in dBuV

S = Specification Limit in dBuV

M = Margin to Specification in +/- dB

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SAMPLE CALCULATIONS - RADIATED EMISSIONS

Receiver readings are compared directly to the specification limit (decibel form). The receiver internally corrects for cable loss, preamplifier gain, and antenna factor. The calculations are in the reverse direction of the actual signal flow, thus cable loss is added and the amplifier gain is subtracted. The Antenna Factor converts the voltage at the antenna coaxial connector to the field strength at the antenna elements. A distance factor, when used for electric field measurements, is calculated by using the following formula:

$$F_d = 20*LOG_{10}(D_m/D_s)$$

where:

F_d = Distance Factor in dB

D_m = Measurement Distance in meters

D_s = Specification Distance in meters

Measurement Distance is the distance at which the measurements were taken and Specification Distance is the distance at which the specification limits are based. The Antenna Factor converts the voltage at the antenna coaxial connector to the field strength at the antenna elements.

The margin of a given emission peak relative to the limit is calculated as follows:

$$R_c = R_r + F_d$$

and

$$M = R_c - L_s$$

where:

R_r = Receiver Reading in dBuV/m

F_d = Distance Factor in dB

R_c = Corrected Reading in dBuV/m

L_s = Specification Limit in dBuV/m

M = Margin in dB Relative to Spec

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IMMUNITY TEST SITE

GENERAL INFORMATION

Final tests were performed at the Elliott Laboratories test site located at 41039 Boyce Road, Fremont, California. Considerable engineering effort has been expended to ensure that the facilities conform to all pertinent CENELEC standards.

IMMUNITY MEASUREMENT INSTRUMENTATION

ELECTROSTATIC DISCHARGE TEST SYSTEM

An ESD generator is used for all testing. It is capable of applying electrostatic discharges in both contact discharge mode to 8 kV and air discharge mode to 16.5 kV in both positive and negative polarities in accordance with the IEC 61000-4-2 basic EMC publication.

ELECTROMAGNETIC FIELD TEST SYSTEM

A signal generator and power amplifiers are used to provide a signal at the appropriate power and frequency to an antenna to obtain the required electromagnetic field at the position of the EUT in accordance with the IEC 61000-4-3 basic EMC publication.

ELECTRICAL FAST TRANSIENT/BURST TEST SYSTEM

An electrical fast transient/burst generator is used for all testing. It is capable of applying the required fast transient immunity test levels to the mains at any phase angle with respect to the mains voltage waveform and to attached cables via a capacitive coupling clamp in accordance with the IEC 61000-4-4 basic EMC publication.

SURGE TEST SYSTEM

A surge generator is used for all testing. It is capable of providing the required surge immunity test levels to the mains port at any phase angle with respect to the mains line voltage waveform or to the signal port in accordance with the IEC 61000-4-5 basic EMC publication.

CONDUCTED INTERFERENCE TEST SYSTEM

A signal generator and power amplifier are used to provide a signal at the appropriate power and frequency through a coupling network to obtain the required electromagnetic signal on the power cord and attached cables of the EUT in accordance with the IEC 61000-4-6 basic immunity standard.

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MAGNETIC FIELD TEST SYSTEM

A signal generator and power amplifier are used to provide a signal at the appropriate power and frequency to a loop antenna to obtain the required magnetic field around the EUT in accordance with the IEC 61000-4-8 basic immunity standard.

VOLTAGE VARIATION TEST SYSTEM

A powerline disturbance simulator and variable transformer are used for all testing. These two units are, when used together, capable of simulating mains voltage variations between 0 and 100% for periods up to 100 seconds in duration in accordance with the IEC 61000-4-11 basic EMC standard.

INSTRUMENT CALIBRATION

All test equipment is regularly checked to ensure that performance is maintained in accordance with the manufacturer's specifications. An appendix of this report contains the list of test equipment used and calibration information.

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

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EQUIPMENT TEST TABLE

IEC 61000-4-2 specifies that the EUT shall be placed above a ground reference plane. For tabletop equipment, the standard specifies that a 1.6-by-0.8 meter metal sheet, connected to the reference ground plane via a metal strap with two 470-kΩ resistors in series, shall be placed on a 0.8 m high, non-conductive table. The EUT and attached cables are isolated from this metal sheet by 0.5 millimeter thick insulating material. EN 61000-4-2 states that floor-mounted equipment shall be placed on insulating supports so that the equipment and associated interface cables are 10 centimeters above the reference ground plane. During the tests, the EUT was positioned over a ground reference plane in conformance with these requirements.

IEC 61000-4-3 specifies that the test be performed in a shielded chamber meeting the field-uniformity requirements described in this basic EMC publication. Tabletop EUTs are to be placed on an 80 cm high, non-conducting table and floor-mounted equipment shall be positioned 10 cm above the floor of the chamber. During the IEC 61000-4-3 test, the EUT was positioned in a shielded, anechoic test chamber in conformance with this requirement.

IEC 61000-4-4 specifies that the EUT and attached cables be placed on an insulating support 10 centimeters above a ground reference plane. During the tests, the EUT was positioned on a table with a ground reference plane or on the floor in conformance with this requirement.

IEC 61000-4-5 does not specify positioning of the EUT. The EUT was therefore placed on a non-conductive table or on an insulating support in the same manner as during the IEC 61000-4-4 tests.

IEC 61000-4-6 specifies that the EUT be placed on an insulating support 10 centimeters above a ground reference plane and that the attached cables be maintained between 30 and 50 millimeters above this plane where possible. During the tests, the EUT was positioned on a table with a ground reference plane or on the floor in conformance with this requirement.

IEC 61000-4-8 specifies that the EUT be placed on an insulating support above a ground reference plane. During the tests, the EUT was positioned on a table with a ground reference plane or on the floor in conformance with this requirement.

IEC 61000-4-11 does not specify positioning of the EUT. The EUT was therefore placed on a non-conductive table or on an insulating support in the same manner as during the IEC 61000-4-4 tests.

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IMMUNITY TEST PROCEDURES

EUT AND CABLE PLACEMENT

The EUT and any peripherals are located at the center of the table for tabletop devices and in the center of the ground plane with the insulating support for floor-standing devices. The standards require that interconnecting cables be connected to the available ports of the unit and that the placement of the unit and the attached cables simulate a typical installation, so far as practicable.

APPLICATION OF ELECTROSTATIC DISCHARGES

The points of application of the test discharges directly to the EUT are determined after consideration of the parts of the EUT that are accessible to the operator during normal operation. Contact and air discharges are applied to the EUT. Contact discharges are also applied to the coupling planes to simulate nearby ESD events.

APPLICATION OF ELECTROMAGNETIC FIELD

The electromagnetic field is established at the front edge of the EUT.

The frequency range is swept from 80 to 2500 MHz using a power level necessary to obtain the required field strength at the EUT. The field is amplitude modulated using a 1kHz sine wave to a depth of 80% for the swept frequency test in accordance with IEC 61000-4-3.

The test is repeated with each of the four sides of the EUT facing the field-generating antenna. For small, portable products the test is also performed with the top and bottom sides of the EUT facing the antenna.

APPLICATION OF ELECTRICAL FAST TRANSIENTS

The application of the test voltage to the EUT is made through the power cable and through a capacitive coupling clamp in the case of cables attached to the unit.

APPLICATION OF SURGES

The application of the surge to the EUT is made through the power cable attached to the unit or in the case of signal ports directly to the cable or chassis of the EUT.

APPLICATION OF CONDUCTED INTERFERENCE

The application of the test voltage to the EUT is made through either a coupling-decoupling network (CDN), by direct injection, or through an inductive coupling clamp as appropriate to the cable being tested. The frequency range is swept from 0.15 to 80 MHz using a power level necessary to obtain the specified interference voltage.

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APPLICATION OF POWER FREQUENCY MAGNETIC FIELD

The application of the magnetic field to the EUT is made using an induction coil. The test level is gradually increased from 0 A/m to the specified test level, maintained at the specified test level for a period of not less than 1 minute, and then reduced gradually back to 0 A/m. If the cycle time of the EUT exceeds one minute then the test field is maintained at the required level for the cycle time of the EUT. The test is performed with the EUT oriented in each of the three orthogonal axes. If the dimensions of the sides of the EUT exceed 50% of the shortest side of the loop then the induction coil is placed at different positions along the sides of the EUT in order to test the entire volume of the EUT.

APPLICATION OF VOLTAGE VARIATIONS

The applications of the variations in AC mains voltage to the EUT are made through the AC power cable attached to the unit.

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Appendix A Test Equipment Calibration Data

T63585

Radiated Emissions, 30 - 1,000 MHz, 11-Apr-06

Manufacturer	Description	Model	Asset #	Cal Due
Com-Power Corp.	Pre Amplifier, 30-1000MHz	PA-103	1543	11/4/2006
Sunol Sciences	Biconilog, 30-3000MHz	JB3	1657	3/21/2007
Rohde & Schwarz	EMI Test Receiver, 20Hz-7GHz	ESIB7	1756	8/29/2006

, 17-Apr-06

Manufacturer	Description	Model	Asset #	Cal Due
EMCO	LISN, 10kHz-100MHz	3825/2	1293	7/7/2006
Sunol Sciences	Biconilog, 30-3000MHz	JB3	1549	4/26/2006
Rohde & Schwarz	EMI Test Receiver, 20Hz-7GHz	ESIB7	1630	12/28/2006
Com-Power Corp.	Pre Amplifier , 30-1000MHz	PA-103	1632	6/7/2006

Harmonics and Flicker, 18-Apr-06

Manufacturer	Description	Model	Asset #	Cal Due
California Instruments	Harmonics & Flicker test System	5001ix , AC Power Source	1221	9/9/2006
California Instruments	Harmonics & Flicker Power Unit	CTS-LR1-PCI (PACS-1)	1222	9/13/2006

Conducted Immunity, 18-Apr-06

Manufacturer	Description	Model	Asset #	Cal Due
Rohde & Schwarz	Power Meter, Single Channel	NRVS	1422	10/14/2006
Rohde & Schwarz	Signal Generator, 9 kHz-1.04 GHz	SMY01	1450	10/29/2006
Instruments for Industry	Wideband Solid State Amplifier, 0.01-230MHz	M75	1531	12/16/2006
Rohde & Schwarz	Power Sensor 100uW - 10 Watts	NRV-Z53	1555	9/28/2006
Fischer Custom Comm.	EM Clamp 10 KHz - 1 GHz	F-203I-32MM	1566	4/21/2006
Fischer Custom Comm.	Decoupling Network, 100KHz - 1GHz	F-203I-DCN	1567	N/A
Bird Electronics Corp.	6dB, 100W Attenuator	100-A-FFN-06	1596	5/11/2006

VDI and EFT, 19-Apr-06

Manufacturer	Description	Model	Asset #	Cal Due
Amplifier Research	VDI Transformer	VDI, V4070	1584	7/18/2006
EM Test AG	VDI aznd EFT Generator	UCS 500 M6	1585	7/18/2006
Amplifier Research	EFT/B Capacitive Coupling clamp	EM Test / C ClampHFK	1583	N/A

Surge, 21-Apr-06

Manufacturer	Description	Model	Asset #	Cal Due
EM Test AG	Surge Generator	UCS 500 M6	1585	7/18/2006

ESD , 24-Apr-06

Manufacturer	Description	Model	Asset #	Cal Due
Schaffner	ESD Gun, 100pF - 1500 ohm & 150pF -330 ohm tips	NSG-438	1424	9/22/2006

Radiated Immunity, 80 - 1000 MHz, 24-Apr-06

Manufacturer	Description	Model	Asset #	Cal Due
Rohde & Schwarz	Signal Generator, 100kHz-4320MHz	SMHU	1478	10/25/2006

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

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Werlatone	Coupler, 0.1-1000 MHz, 40dB, 500w	C6021	1533	N/A
ETS Lindgren	Biconlilog Antenna 26 MHz - 3 GHz, Radiated Immunity Only	3140B	1775	N/A
Rohde & Schwarz	Power Meter, Dual Channel	NRVD	1787	1/31/2007
Rohde & Schwarz	Power Sensor, 1uW-100mW, DC-18 GHz, 50ohm	NRV-Z51	1797	1/31/2007
Amplifier Research	Amplifier, 250W, 1000 Amps	250W1000A	1809	N/A

Radiated Immunity, 1000 - 25000 MHz, Horn Attena 1242, 25-Apr-06

Manufacturer	Description	Model	Asset #	Cal Due
Fischer Custom Comm.	150-50 ohm adapter, 1/2	FCC-801-150-50	872	1/10/2007
Hewlett Packard	Signal Generator (sweep) 0.01 - 26.5 GHz	8340A	1244	N/A
Agilent Technologies	Function/Arbitrary waveform generator 15 MHz	33120A	1262	N/A
Werlatone	Coupler, 800-2800 MHz, 30dB, 100w	C6529	1402	N/A
Amplifier Research	Amplifier, 0.8-4.2GHz, 50Watts	50S1G4A	1493	N/A

Power Frequency, Magnetic Fields, 15-May-06

Manufacturer	Description	Model	Asset #	Cal Due
F.W. Bell	100 Amp. Current Clamp	CG-100A	373	6/16/2006
Fluke	True RMS Multimeter	111	1480	12/6/2006

T85575

Radiated Emissions, 30 - 1,000 MHz, 23-Nov-11

Manufacturer	Description	Model	Asset #	Cal Due
Rohde & Schwarz	EMI Test Receiver, 20 Hz-7 GHz	ESIB7	1630	4/13/2012
Sunol Sciences	Biconilog, 30-3000 MHz	JB3	2237	7/14/2012
Com-Power Corp.	Preamplifier, 30-1000 MHz	PAM-103	2380	4/13/2012

Conducted Emissions - AC Power Ports, 23-Nov-11

Manufacturer	Description	Model	Asset #	Cal Due
EMCO	LISN, 10 kHz-100 MHz	3825/2	1293	3/1/2012
Rohde & Schwarz	Pulse Limiter	ESH3 Z2	1401	4/21/2012
Rohde & Schwarz	EMI Test Receiver, 20 Hz-7 GHz	ESIB7	1630	4/13/2012

Harmonics and Flicker, 23-Nov-11

Manufacturer	Description	Model	Asset #	Cal Due
California Instruments	Harmonics & Flicker test System	5001ix , AC Power Source	2157	7/13/2012
California Instruments	Harmonics & Flicker Power Unit	PACS-1	2158	7/13/2012

EFT, VDI and ESD, 23-Nov-11

Manufacturer	Description	Model	Asset #	Cal Due
Schaffner	ESD Gun, 100pF-1500 ohm & 150pF-330 ohm tips	NSG-438	1424	9/28/2012
EM Test AG	EFT Generator	UCS 500 M6	1585	7/22/2012
EM Test AG	VDI Generator	UCS 500 M6	1585	7/19/2012
Elliott Laboratories	ESD, Vertical Plane, 19-3/4 x 19-3/4	ESD, VP, 19-3/4 x 19-3/4	1664	N/A

Radiated Immunity, 80 - 1,000 MHz, 27-Nov-11

Manufacturer	Description	Model	Asset #	Cal Due
Rohde & Schwarz	Power Sensor, 1 uW-100 mW,	NRV-Z51	1070	5/25/2012

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	DC-18 GHz, 50ohms			
Amplifier Research	Field Probe, RF, 0.5 MHz-5 GHz	FP4036	1496	5/18/2012
Werlatone	Directional Coupler, 0.1-1000 MHz, 40dB, 500w	C6021	1533	N/A
Instruments For Industry	IFI Amplifier 80 - 1000 MHz (200W CW)	CMC-200	1546	N/A
ETS Lindgren	Biconilog Antenna 26 MHz - 3 GHz, Radiated Immunity Only	3140B	1775	N/A
Rohde & Schwarz	Power Meter, Dual Channel, DC to 40 GHz, 100 pW to 30 W, 9 kHz to 3 GHz, 200µV to 1000V	NRVD	1786	2/28/2012
Agilent	PSG, Performance Signal Generator, (installed options, HEH, HEC, 602, 420)	E8267C	2200	5/11/2012

Radiated Immunity, 1,000 - 2,500 MHz, 27-Nov-11

Manufacturer	Description	Model	Asset #	Cal Due
Rohde & Schwarz	Power Sensor, 1 uW-100 mW, DC-18 GHz, 50ohms	NRV-Z51	1070	5/25/2012
Werlatone	Directional Coupler, 800-2800 MHz, 30dB, 100w	C6529	1402	N/A
Amplifier Research	Field Probe, RF, 0.5 MHz-5 GHz	FP4036	1496	5/18/2012
EMCO	Antenna, Horn, 1-18 GHz (SA40-Purple)	3115	1779	3/31/2012
Rohde & Schwarz	Power Meter, Dual Channel, DC to 40 GHz, 100 pW to 30 W, 9 kHz to 3 GHz, 200µV to 1000V	NRVD	1786	2/28/2012
Amplifier Research	Amplifier, 25w, 0.8-4.2GHz	25S1G4AM3	1805	N/A
Agilent	PSG, Performance Signal Generator, (installed options, HEH, HEC, 602, 420)	E8267C	2200	5/11/2012

Magnetic Immunity , 27-Nov-11

Manufacturer	Description	Model	Asset #	Cal Due
Elliott Laboratories	Magnetic Immunity Power Source	None	1996	10/5/2012

Conducted Immunity and Surge, 28-Nov-11

Manufacturer	Description	Model	Asset #	Cal Due
Rohde & Schwarz	Signal Generator, 9 kHz-1.04 GHz	SMY01	168	11/4/2012
Instruments For Industry	Amplifier, Wideband, 0.01-230MHz	M75	1295	7/1/2012
Rohde & Schwarz	Power Meter, Single Channel, +1795+1796	NRVS	1534	5/17/2012
Fischer Custom Comm.	M3 Network, 150 kHz-230 MHz	FCC-801-M3-25A	1579	5/13/2012
EM Test AG	Surge Generator	UCS 500 M6	1585	7/22/2012
Bird Electronics Corp.	6 dB, 100 W Attenuator	100-A-FFN-06	1596	6/27/2012
Fischer Custom Comm.	150-50 ohm adapter, 1/2, 0.15 to 80 MHz	FCC-801-150-50	1600	5/13/2012
Fischer Custom Comm.	150-50 ohm adapter, 1/2, 0.15 to 80 MHz	FCC-801-150-50	1601	5/13/2012
Rohde & Schwarz	Pwr Sensor 300 uW - 30 Watts (+ 25dB pad)	NRV-Z54	1788	7/29/2012
Rohde & Schwarz	Attenuator, 25 dB, 30W, DC-18 GHz	25dB, 30W, Type N	1794	7/29/2012

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

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Appendix B Test Data Log Sheets

AC current harmonics test data and voltage fluctuations test data are contained in separate appendices of this report.

T63585 Pages 31 - 95
T85575 Pages 96 - 135

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	Test-Log Number:	T63585
		Project Manager:	Nesha Lambert
Contact:	David Chen		
Emissions Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

EMC Test Data

For The

Optovue

Model

RTVue

Date of Last Test: 5/16/2006

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Radiated Emissions

(Elliott Laboratories Fremont Facility, Semi-Anechoic Chamber)

Test Specifics

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 4/11/2006
Test Engineer: rmomand
Test Location: Fremont Chamber #3

Config. Used: 1
Config Change: None
EUT Voltage: 230V/50Hz

General Test Configuration

The EUT and any local support equipment were located on the turntable for radiated emissions testing. Any remote support equipment was located outside the semi-anechoic chamber. Any cables running to remote support equipment where routed through metal conduit and when possible passed through a ferrite clamp upon exiting the chamber.

Unless otherwise specified, the measurement antenna was located 10 meters from the EUT for the measurement range 30 - 1000 MHz.

Note, **preliminary** testing indicates that the emissions were maximized by orientation of the EUT and elevation of the

Ambient Conditions:

Temperature: 23 °C
Rel. Humidity: 38 %

Summary of Results

Run #	Test Performed	Limit	Result	Margin
-	RE, 30 - 1000 MHz, Preliminary Scan	EN55011 Group 1 Class A	Pass	Refer to individual runs
13	RE, 30 - 1000 MHz, Maximized Emissions	EN55011 Group 1 Class A	Pass	-2.9

Modifications Made During Testing

Modifications are detailed under each run description.

Deviations From The Standard

No deviations were made from the requirements of the standard.

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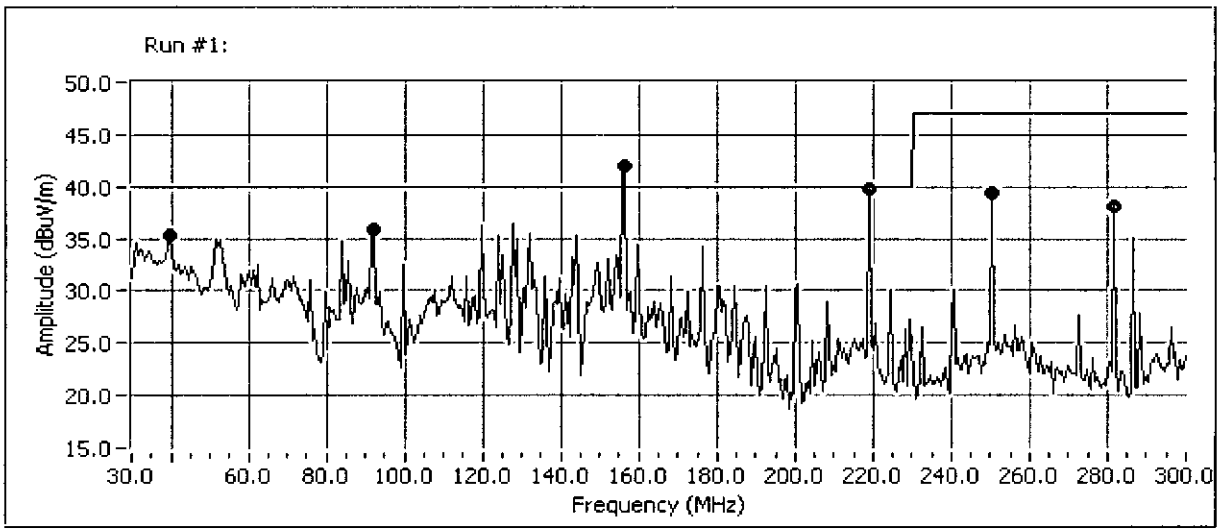
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

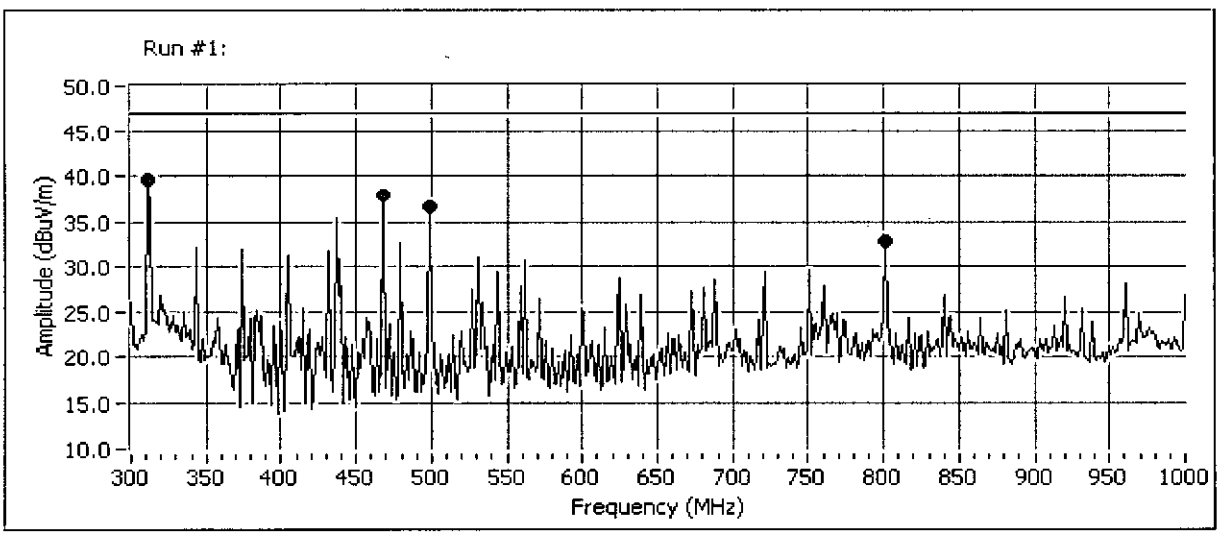
Elliott — EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run #1: Preliminary Radiated Emissions, 30 - 1000 MHz
Steward Ferrite Part # 28 A0640-0A0 on USB Port at the Scanner end Unit Running from 230V / 50HZ AC.

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	10	10	0.0





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Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run #1: Preliminary Radiated Emissions, 30 - 1000 MHz

Preliminary peak readings captured during pre-scan

Frequency	Level	Pol	EN55011 Group 1 Class A		Detector	Azimuth	Height	Comments
MHz	dBμV/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
468.751	37.8	H	47.0	-9.2	Peak	8	2.0	
92.000	35.9	V	40.0	-4.1	Peak	36	1.5	
218.753	39.8	H	40.0	-0.2	Peak	38	3.5	
218.753	39.8	H	40.0	-0.2	Peak	38	3.5	
500.010	36.6	V	47.0	-10.4	Peak	41	3.0	
250.002	39.4	V	47.0	-7.6	Peak	65	1.0	
156.244	41.9	V	40.0	1.9	Peak	114	1.0	
281.249	38.0	V	47.0	-9.0	Peak	151	1.0	
312.505	39.5	V	47.0	-7.5	Peak	157	1.0	
800.802	32.9	V	47.0	-14.2	Peak	192	2.5	
39.999	35.2	V	40.0	-4.8	Peak	238	1.5	

Preliminary quasi-peak readings (no manipulation of EUT interface cables)

Frequency	Level	Pol	EN55011 Group 1		Detector	Azimuth	Height	Comments
MHz	dBμV/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
156.244	41.5	V	40.0	1.5	QP	114	1.0	
218.753	36.4	H	40.0	-3.6	QP	38	3.5	
92.000	33.3	V	40.0	-6.7	QP	36	1.5	
312.505	38.7	V	47.0	-8.3	QP	158	1.0	
250.002	38.5	V	47.0	-8.5	QP	65	1.0	
281.249	38.2	V	47.0	-8.8	QP	151	1.0	
468.751	37.7	H	47.0	-9.3	QP	8	2.0	
500.010	36.5	V	47.0	-10.5	QP	41	3.0	
39.999	28.7	V	40.0	-11.3	QP	238	1.5	

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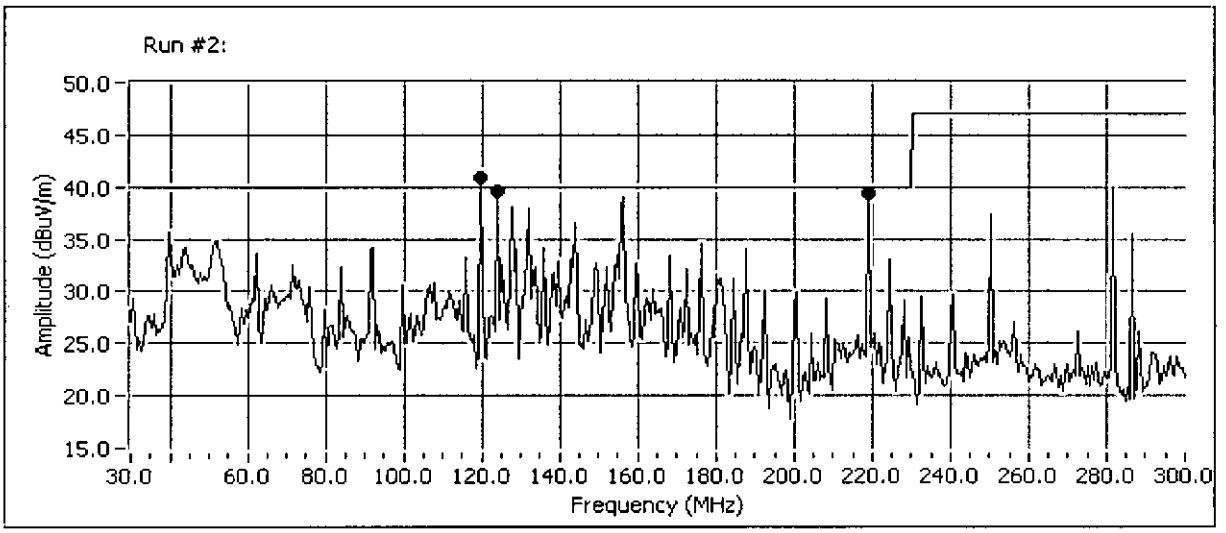
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott — EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run #2: Preliminary Radiated Emissions, 30 - 1000 MHz
Steward Ferrite Part# 28 A0640-0A0 on USB Port and Card board covering the metal cover at the Scanner end.
Unit Running from 230V / 50HZ AC.

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 300 MHz	10	10	0.0



Preliminary peak readings captured during pre-scan

Frequency	Level	Pol	EN55011 Group1 Class A		Detector	Azimuth	Height	Comments
MHz	dBµV/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
120.001	40.9	V	40.0	0.9	Peak	57	1.0	
124.148	39.5	V	40.0	-0.5	Peak	155	1.0	
218.838	39.4	V	40.0	-0.6	Peak	155	1.0	

Preliminary quasi-peak readings (no manipulation of EUT interface cables)

Frequency	Level	Pol	EN55011 Group1 Class A		Detector	Azimuth	Height	Comments
MHz	dBµV/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
120.001	40.5	V	40.0	0.5	QP	57	1.0	

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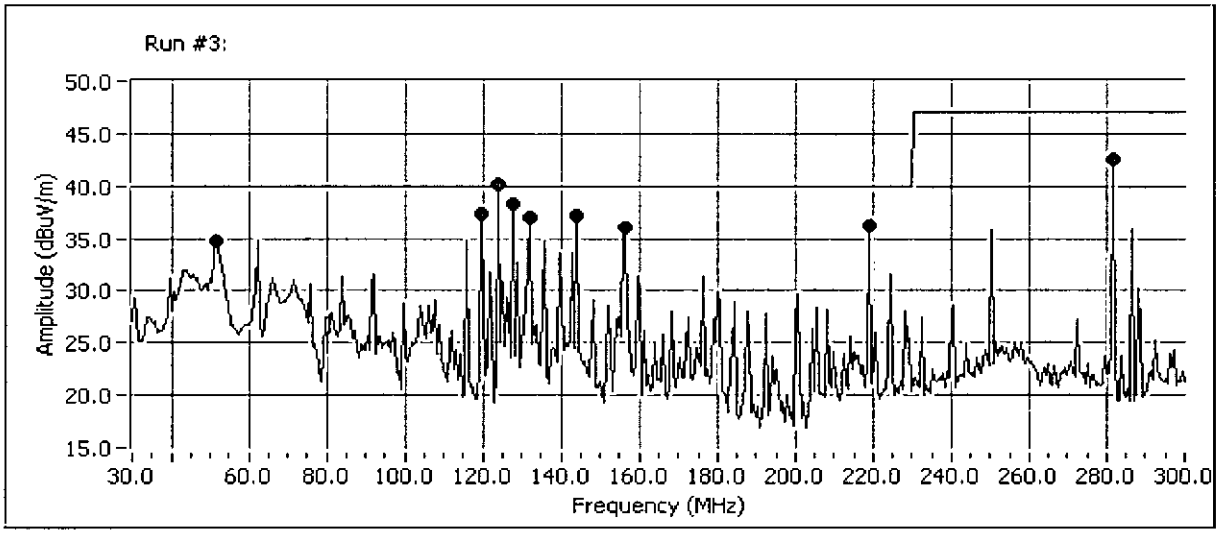
Elliott — EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run # 3: Preliminary Radiated Emissions, 30 - 1000 MHz
Steward Ferrite P/N:28 A0640-0A0 on USB Port and the metal cover at the Scanner end removed.
Unit Running from 230V / 50HZ AC.

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	10	10	0.0



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Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run # 3: Preliminary Radiated Emissions, 30 - 1000 MHz
Preliminary peak readings captured during pre-scan

Frequency	Level	Pol	EN55011 Group1 Class A		Detector	Azimuth	Height	Comments
MHz	dBµV/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
281.249	42.5	V	47.0	-4.5	Peak	50	1.0	
119.999	37.3	V	40.0	-2.7	Peak	115	1.0	
156.255	36.0	V	40.0	-4.0	Peak	121	1.0	
218.758	36.2	V	40.0	-3.8	Peak	125	1.0	
123.999	40.2	V	40.0	0.2	Peak	158	1.0	
128.001	38.3	V	40.0	-1.7	Peak	167	1.0	
132.265	37.0	V	40.0	-3.0	Peak	177	1.0	
144.168	37.1	V	40.0	-2.9	Peak	204	1.5	
51.643	34.7	V	40.0	-5.3	Peak	301	1.0	

Preliminary quasi-peak readings (no manipulation of EUT interface cables)

Frequency	Level	Pol	EN55011 Group1 Class A		Detector	Azimuth	Height	Comments
MHz	dBµV/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
281.249	42.4	V	47.0	-4.6	QP	50	1.0	
119.999	38.8	V	40.0	-1.3	Peak	115	1.0	
156.255	35.7	V	40.0	-4.3	QP	120	1.0	
218.758	36.0	V	40.0	-4.1	QP	126	1.0	
123.999	41.8	V	40.0	1.8	QP	158	1.0	
128.001	38.6	V	40.0	-1.4	QP	167	1.0	

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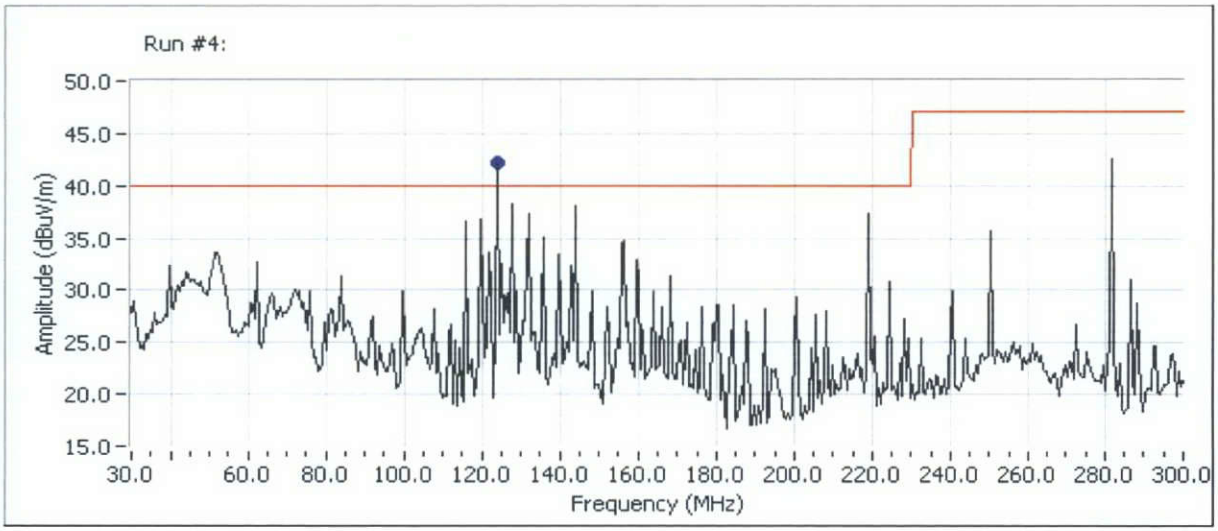
Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run # 4: Preliminary Radiated Emissions, 30 - 1000 MHz
USB Cables not connected and the metal cover at the Scanner end removed.
Unit Running from 230V / 50HZ AC.

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	10	10	0.0



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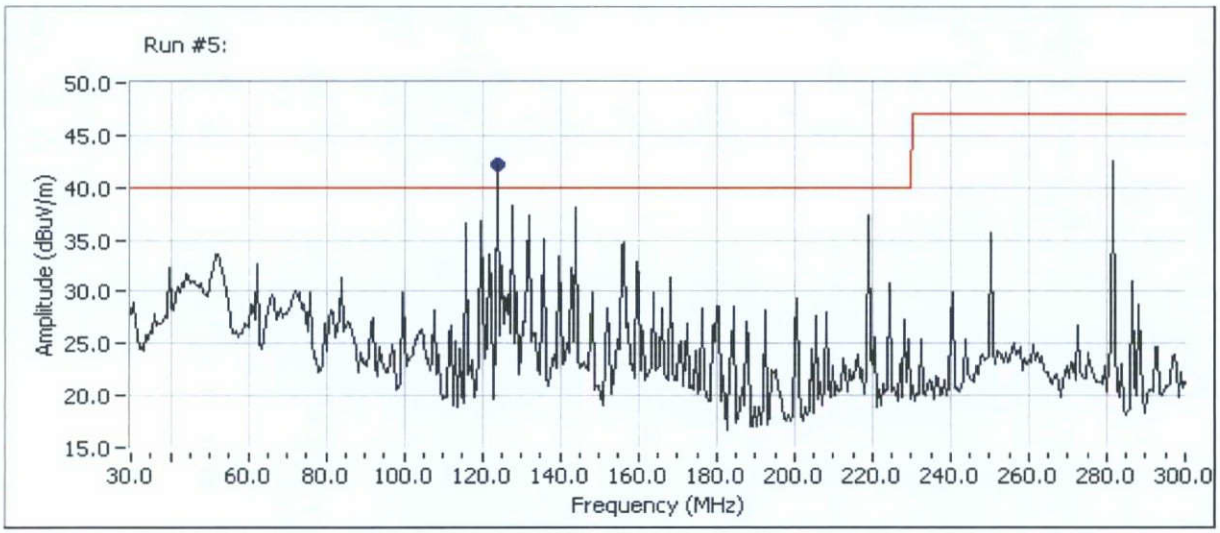
Elliott — EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run # 5: Preliminary Radiated Emissions, 30 - 1000 MHz
USB Cables not connected on both sides and the metal cover at the Scanner end removed.
Unit Running from 230V / 50HZ AC.

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	10	10	0.0



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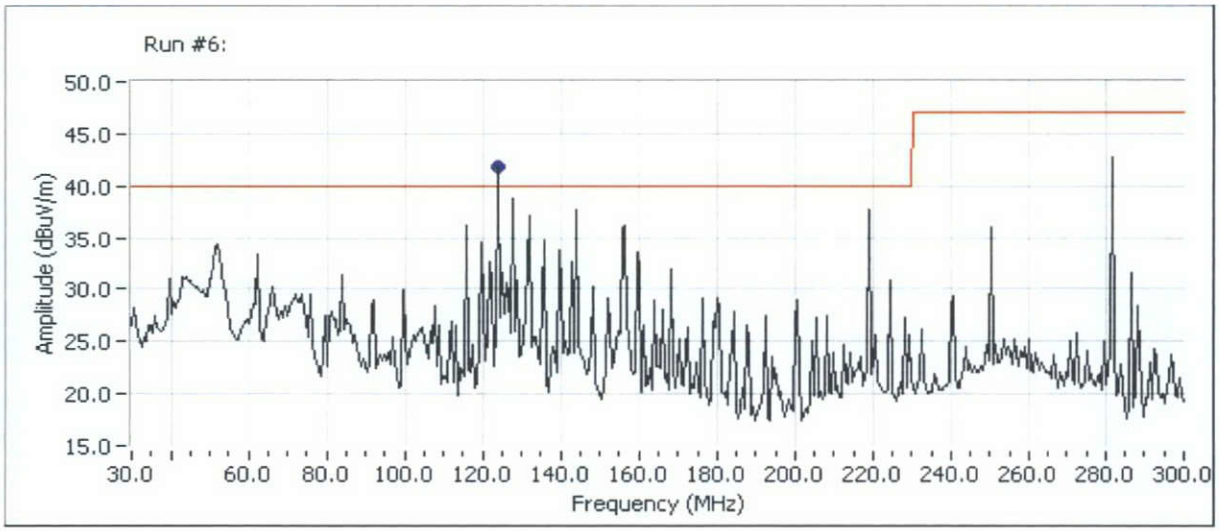
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott — EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run # 6: Preliminary Radiated Emissions, 30 - 1000 MHz
Removed USB Cable to keyboard and USB to scanner and the metal cover at the Scanner end removed.
Unit Running from 230V / 50HZ AC.

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	10	10	0.0



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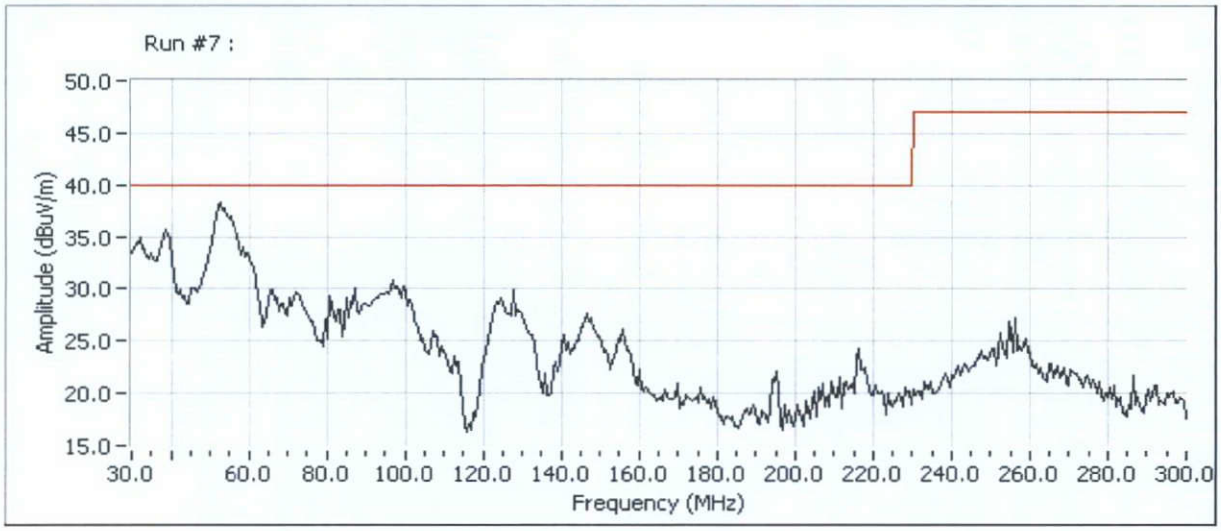
Elliott — EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run # 7: Preliminary Radiated Emissions, 30 - 1000 MHz
Turn OFF the Scanner only PC, Monitor and Printer ON.

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	10	10	0.0



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Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

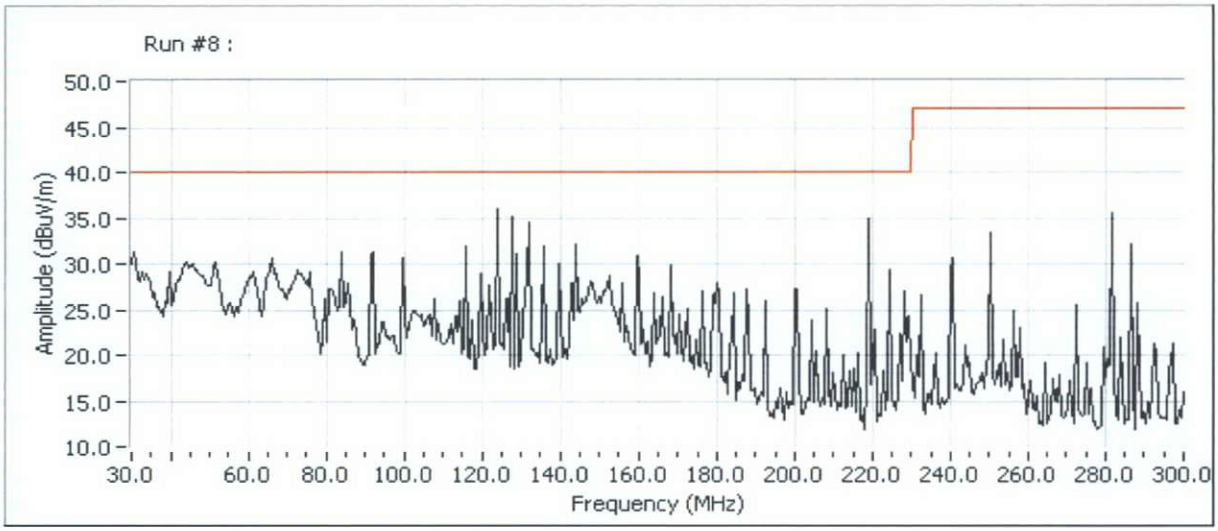
Elliott — EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run # 8: Preliminary Radiated Emissions, 30 - 1000 MHz

Scanner, PC, Printer and Monitor ON, no cable connection between and Scanner and PC.

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	10	10	0.0



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

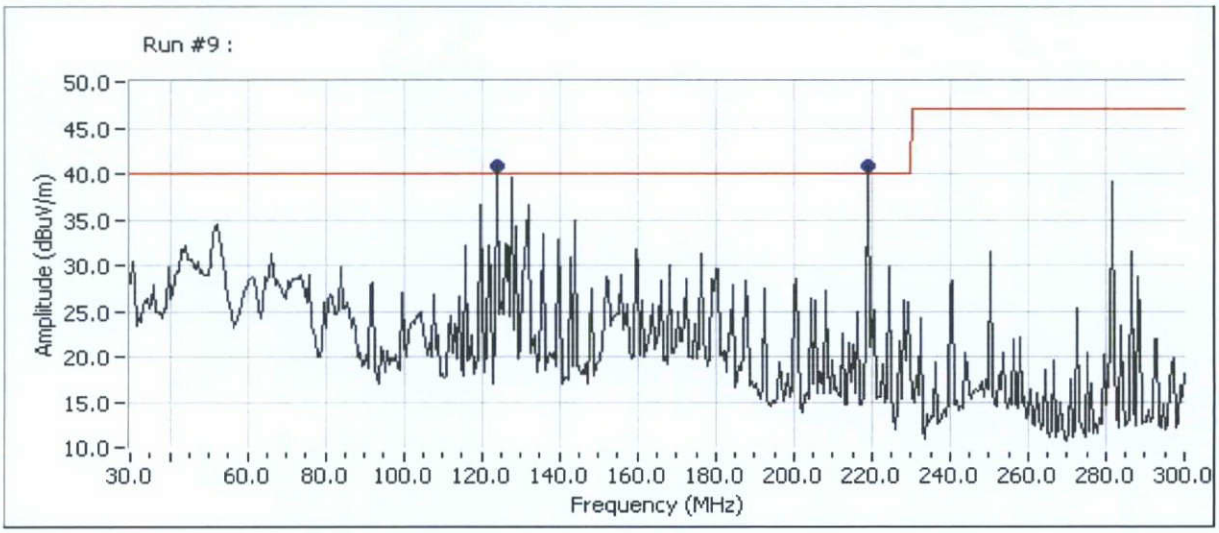
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott — EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run # 9: Preliminary Radiated Emissions, 30 - 1000 MHz
Connect two USB Cables between the Scanner and PC.

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	10	10	0.0



638

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

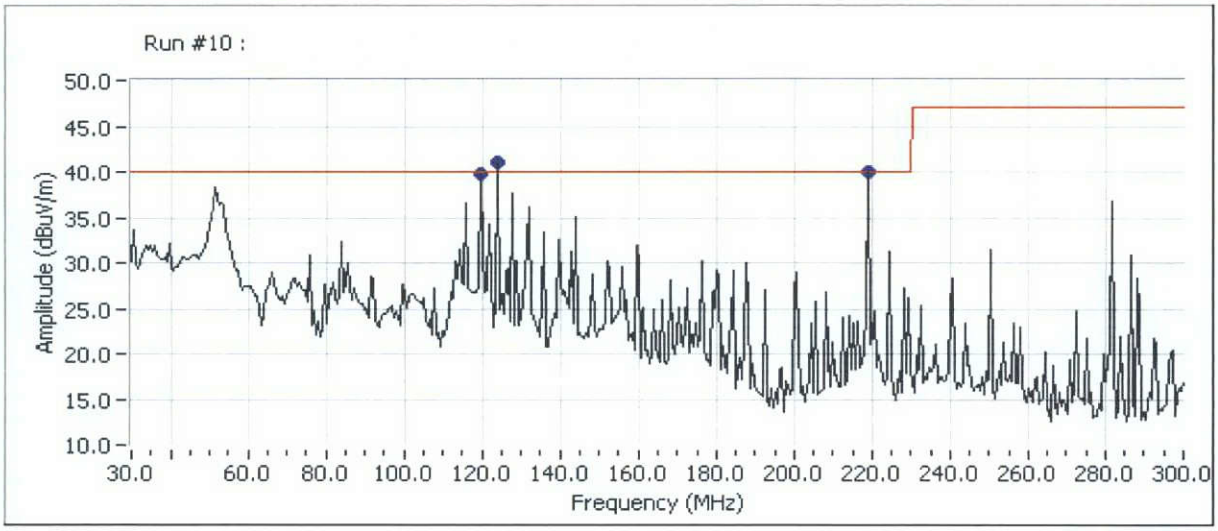
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott — EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run # 10: Preliminary Radiated Emissions, 30 - 1000 MHz
All the cables connected except Camera Link.

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	10	10	0.0



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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

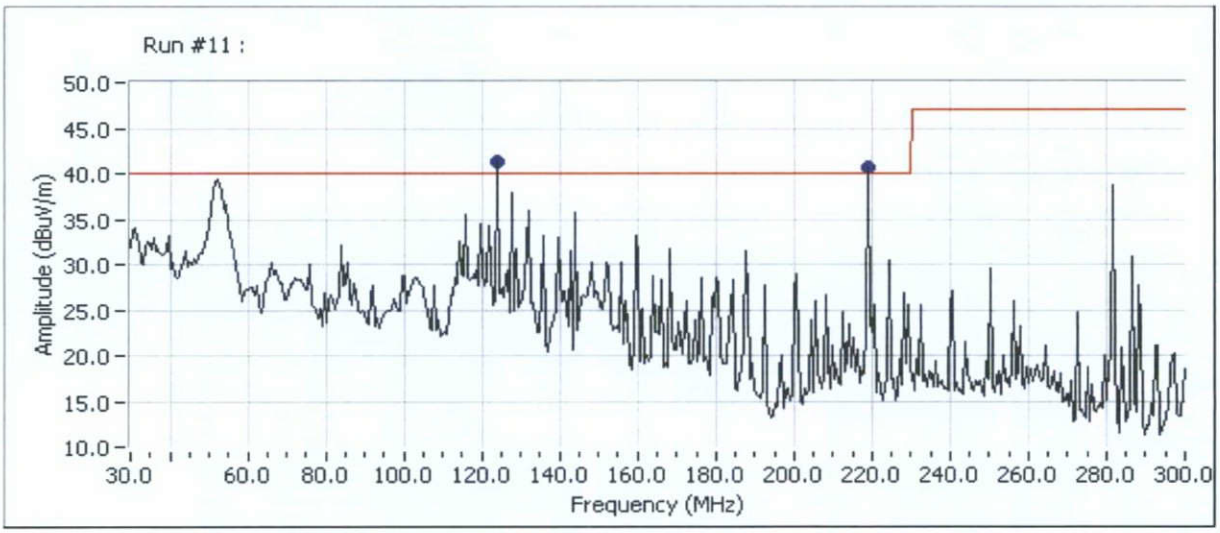
EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run # 11: Preliminary Radiated Emissions, 30 - 1000 MHz

All the cables not connected except DB-9.

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	10	10	0.0



640

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

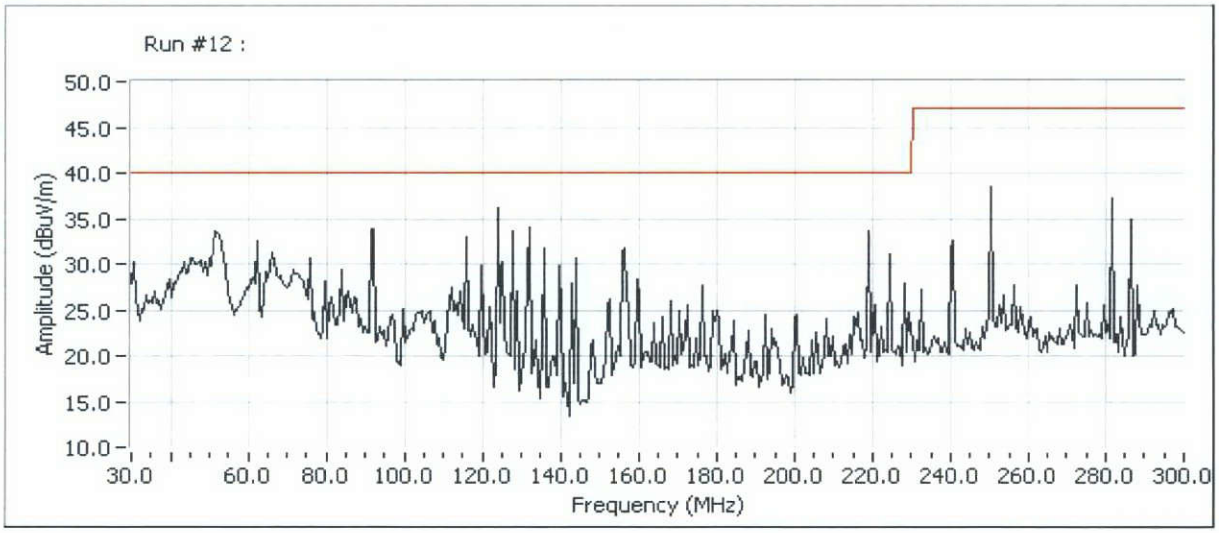
Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run # 12: Preliminary Radiated Emissions, 30 - 1000 MHz
Re-connect power socket, Unit fully running with no Cover.

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	10	10	0.0



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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

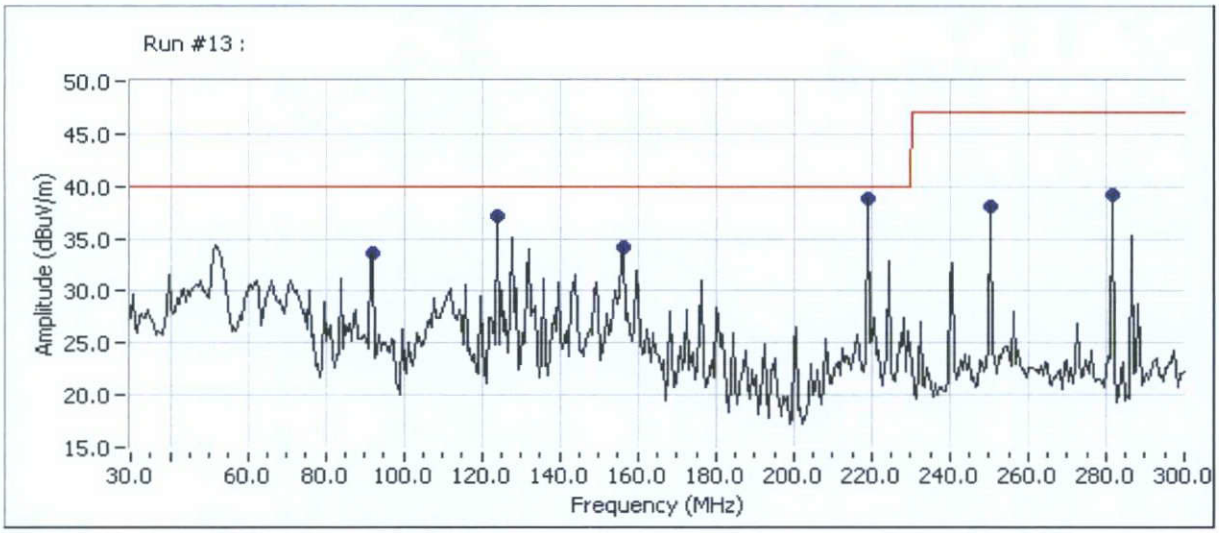
EMC Test Data

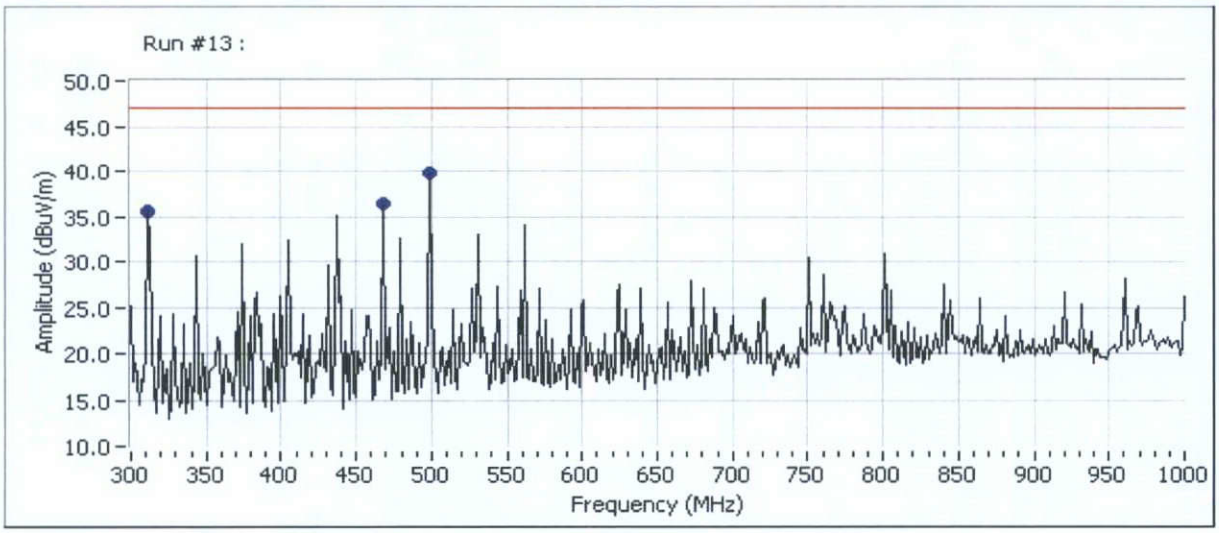
Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

FINAL RUN

Run # 13: Preliminary Radiated Emissions, 30 - 1000 MHz
Re-connect power socket, Unit fully running with Cables cover on scanner end.
Steward Ferrite Part # 28A0640-0A0 on USB Port at scanner end.

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	10	10	0.0





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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run #13: Preliminary Radiated Emissions, 30 - 1000 MHz

Preliminary peak readings captured during pre-scan

Frequency	Level	Pol	EN55011 Group1 Class A		Detector	Azimuth	Height	Comments
MHz	dBμV/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
92.000	33.6	V	40.0	-6.4	Peak	17	1.5	
250.004	38.2	V	47.0	-8.8	Peak	53	1.0	
156.259	34.1	V	40.0	-5.9	Peak	102	1.0	
281.249	39.3	V	47.0	-7.7	Peak	161	1.0	
123.999	37.2	V	40.0	-2.8	Peak	180	1.5	
218.753	38.8	V	40.0	-1.2	Peak	254	1.0	
499.999	39.8	H	47.0	-7.2	Peak	195	1.5	
312.494	35.6	H	47.0	-11.4	Peak	18	2.0	
468.757	36.4	H	47.0	-10.7	Peak	324	2.5	

Preliminary quasi-peak readings (no manipulation of EUT interface cables)

Frequency	Level	Pol	EN55011 Group1 Class A		Detector	Azimuth	Height	Comments
MHz	dBμV/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
218.753	37.1	V	40.0	**-2.9**	QP	254	1.0	
123.999	34.2	V	40.0	-5.9	QP	179	1.5	
92.000	34.1	V	40.0	-5.9	QP	17	1.3	
250.004	38.4	V	47.0	-8.6	QP	53	1.0	
499.999	38.0	H	47.0	-9.0	QP	195	1.5	
281.249	37.7	V	47.0	-9.3	QP	161	1.0	
156.253	29.9	V	40.0	-10.1	QP	102	1.0	
312.494	36.3	H	47.0	-10.7	Peak	17	2.0	
468.757	34.1	H	47.0	-12.9	Peak	324	2.5	

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott — EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run #13: Maximized Readings From Run #13
Maximized quasi-peak readings (includes manipulation of EUT interface cables)

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	10	10	0.0

Frequency	Level	Pol	EN55011 Group1 Class A		Detector	Azimuth	Height	Comments
MHz	dBµV/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
218.753	37.1	V	40.0	**-2.9**	QP	254	1.0	
123.999	36.5	V	40.0	-3.5	QP	179	1.5	
92.000	34.6	V	40.0	-5.4	QP	17	1.5	
250.004	38.4	V	47.0	-8.6	QP	53	1.0	
499.999	38.0	H	47.0	-9.0	QP	195	1.5	

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Test Configuration Photograph #1
(Radiated Emissions)

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Test Configuration Photograph #2
(Radiated Emissions)

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Radiated Emissions

(Elliott Laboratories Fremont Facility, Semi-Anechoic Chamber)

Test Specifics

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 4/17/2006
Test Engineer: Ivo Tankov
Test Location: Fremont Chamber # 4

Config. Used: 1
Config Change: None
EUT Voltage: 120V/60Hz

General Test Configuration

The EUT and any local support equipment were located on the turntable for radiated emissions testing. Any remote support equipment was located outside the semi-anechoic chamber. Any cables running to remote support equipment where routed through metal conduit and when possible passed through a ferrite clamp upon exiting the chamber.

Unless otherwise specified, the measurement antenna was located 10 meters from the EUT for the measurement range 30 - 1000 MHz and 3m from the EUT for the frequency range 1 - 10 GHz.

Note, **preliminary** testing indicates that the emissions were maximized by orientation of the EUT and elevation of the measurement antenna. **Maximized** testing indicated that the emissions were maximized by orientation of the EUT, elevation of the measurement antenna, and manipulation of the EUT's interface cables.

Ambient Conditions:

Temperature: 19 °C
Rel. Humidity: 45 %

Summary of Results

Run #	Test Performed	Limit	Result	Margin
1	RE, 30 - 1000 MHz, Preliminary Scan	EN 55011 Class A	Pass	Refer to individual runs
2	RE, 30 - 1000 MHz, Maximized Emissions	EN 55011 Class A	Pass	37.3dBµV/m @ 119.999MHz(-2.7dB)

Modifications Made During Testing

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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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 #2012-3758; Released by CDRH on 09-8-2015

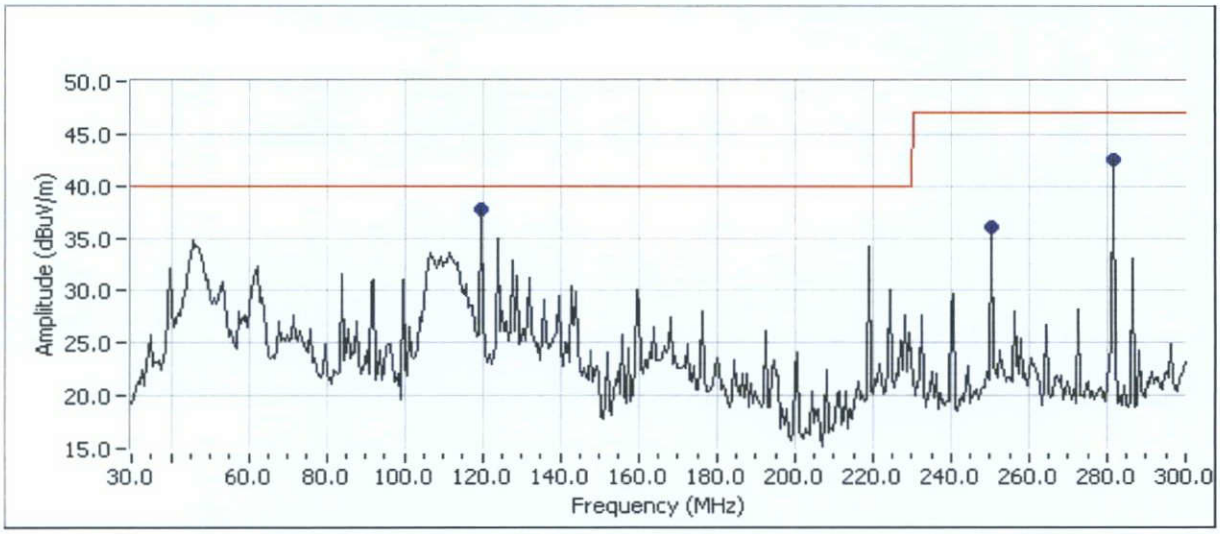
Elliott

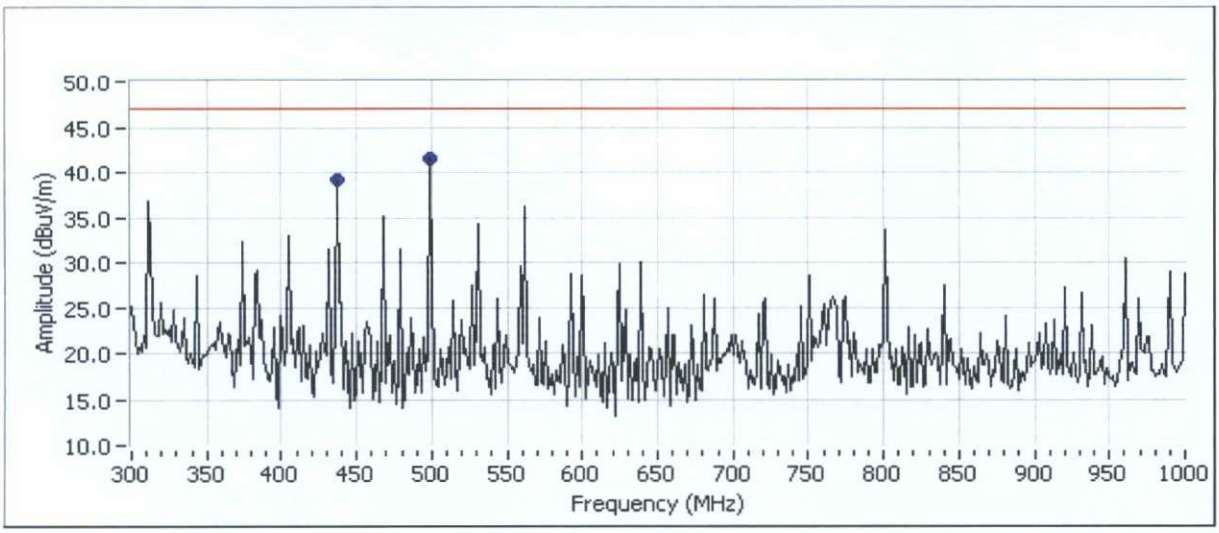
EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run #1: Preliminary Radiated Emissions, 30 - 1000 MHz

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	5	10	-6.0





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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run #1: Continued

Preliminary peak readings captured during pre-scan

Frequency	Level	Pol	EN 55011 Class A		Detector	Azimuth	Height	Comments
MHz	dBµV/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
119.999	37.8	V	40.0	-2.2	Peak	222	1.0	
250.002	36.1	V	47.0	-11.0	Peak	6	1.0	
281.247	42.6	H	47.0	-4.4	Peak	282	1.5	
437.503	39.2	H	47.0	-7.8	Peak	273	1.0	
499.977	41.5	V	47.0	-5.5	Peak	199	1.5	

Run #2: Maximized Readings From Run #1

Preliminary quasi-peak readings (no manipulation of EUT interface cables)

Frequency	Level	Pol	EN 55011 Class A		Detector	Azimuth	Height	Comments
MHz	dBµV/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
119.999	37.3	V	40.0	**-2.7**	QP	222	1.0	
281.247	42.6	H	47.0	-4.4	QP	282	1.5	
250.002	36.0	V	47.0	-11.0	QP	5	1.0	
437.503	38.9	H	47.0	-8.1	QP	273	1.0	
499.977	40.7	V	47.0	-6.3	QP	198	1.5	

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Conducted Emissions

(Elliott Laboratories Fremont Facility, Semi-Anechoic Chamber)

Test Specifics

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 4/17/2006
Test Engineer: Ivo Tankov
Test Location: FTCH #4

Config. Used: 1
Config Change: None
EUT Voltage: 120V/60Hz

General Test Configuration

For floor-standing equipment, the EUT was located above a ground plane inside the semi-anechoic chamber, 80 cm from the LISN.

Ambient Conditions:

Temperature: 19 °C
Rel. Humidity: 43 %

Summary of Results

Run #	Test Performed	Limit	Result	Margin
1	CE, AC Power, 230V/50Hz	EN 55022 Class A	Pass	54.157.91 @ 10.157 (-5.9dB)
2	CE, AC Power,120V/60Hz	EN 55022 Class A	Pass	46.550.32 @ 11.062 (-13.5dB)

Modifications Made During Testing:

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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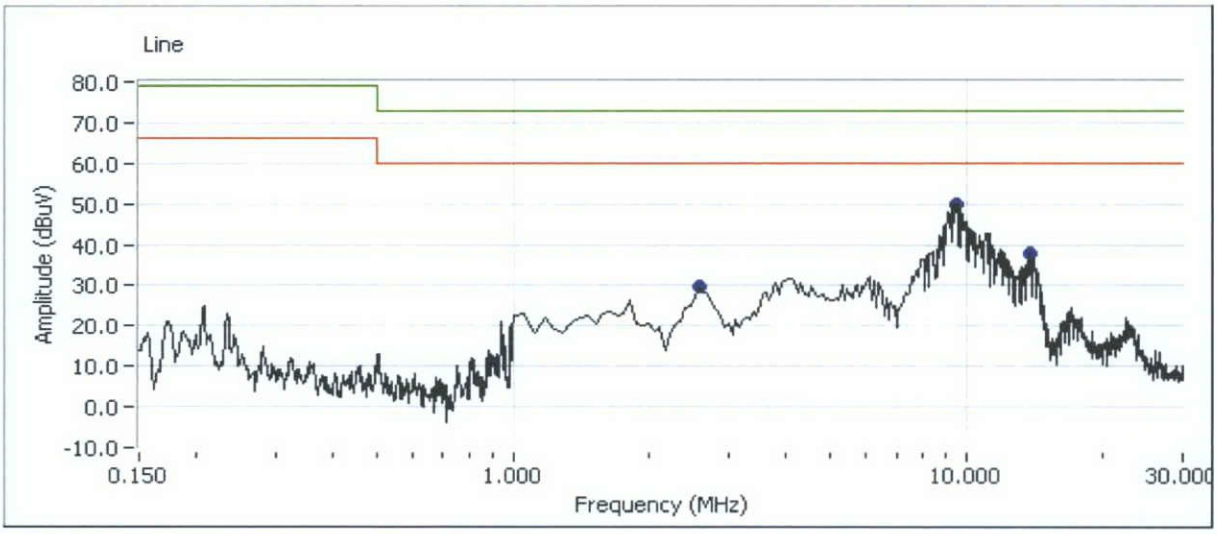
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

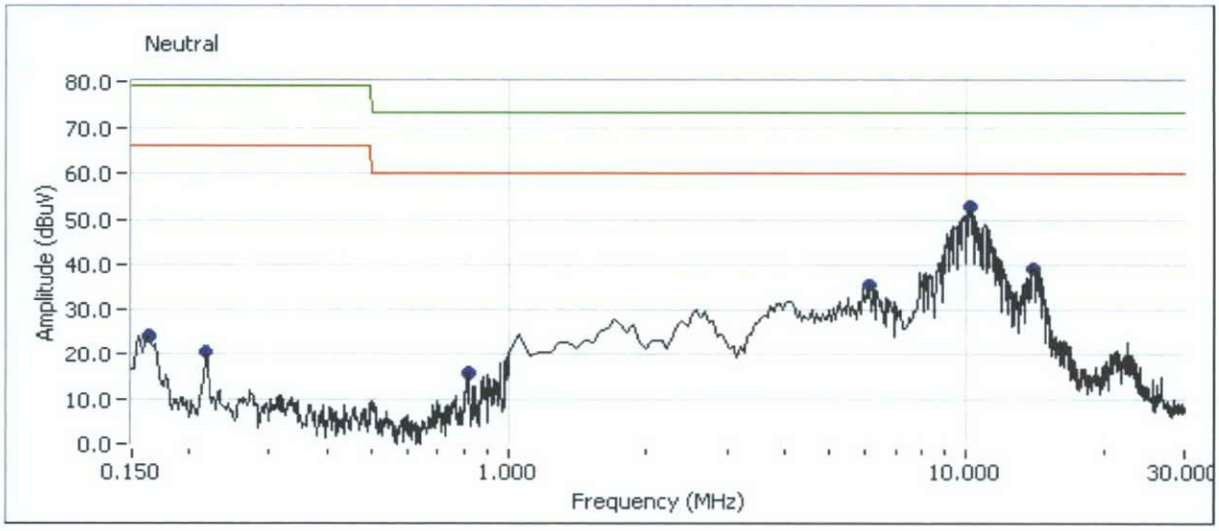
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott — EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run #1: AC Power Port Conducted Emissions, 0.15 - 30MHz, 230V/50Hz





Note:	Conducted Emissions graph is 10 dB lower

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run #1: Continued

Preliminary peak readings captured during pre-scan (peak readings vs. average limit)

Frequency MHz	Level dBμV	AC Line	EN55022 Class A Limit	Margin	Detector QP/Ave	Comments
0.173	31.2	Line 1	66.0	-34.8	Peak	
0.208	34.8	Line 1	66.0	-31.2	Peak	
0.235	32.9	Line 1	66.0	-33.1	Peak	
2.580	39.9	Line 1	60.0	-20.1	Peak	
9.458	59.9	Line 1	60.0	-0.1	Peak	
13.788	47.7	Line 1	60.0	-12.3	Peak	
0.163	33.9	Neutral	66.0	-32.1	Peak	
0.218	30.6	Neutral	66.0	-35.4	Peak	
0.816	25.9	Neutral	60.0	-34.1	Peak	
6.134	45.2	Neutral	60.0	-14.8	Peak	
10.157	62.6	Neutral	60.0	2.6	Peak	
13.982	49.1	Neutral	60.0	-10.9	Peak	

Final quasi-peak and average readings

Frequency MHz	Level dBμV	AC Line	EN55022 Class A Limit	Margin	Detector QP/Ave	Comments
10.157	54.1	Neutral	60.0	**-5.9**	AVG	
9.458	50.2	Line 1	60.0	-9.8	AVG	
10.157	57.9	Neutral	73.0	-15.1	QP	
13.982	42.5	Neutral	60.0	-17.5	AVG	
9.458	54.3	Line 1	73.0	-18.7	QP	
13.788	38.0	Line 1	60.0	-22.0	AVG	
6.134	35.8	Neutral	60.0	-24.2	AVG	
13.982	47.0	Neutral	73.0	-26.0	QP	
2.580	29.4	Line 1	60.0	-30.6	AVG	
13.788	41.9	Line 1	73.0	-31.1	QP	
6.134	41.5	Neutral	73.0	-31.5	QP	
2.580	34.1	Line 1	73.0	-39.0	QP	
0.816	12.5	Neutral	60.0	-47.5	AVG	
0.235	30.3	Line 1	79.0	-48.7	QP	
0.208	27.6	Line 1	79.0	-51.4	QP	
0.235	14.1	Line 1	66.0	-51.9	AVG	
0.208	14.0	Line 1	66.0	-52.0	AVG	
0.218	26.5	Neutral	79.0	-52.5	QP	
0.173	12.8	Line 1	66.0	-53.2	AVG	
0.218	12.5	Neutral	66.0	-53.5	AVG	
0.163	12.5	Neutral	66.0	-53.5	AVG	
0.173	25.0	Line 1	79.0	-54.0	QP	
0.816	17.5	Neutral	73.0	-55.5	QP	
0.163	22.7	Neutral	79.0	-56.3	QP	

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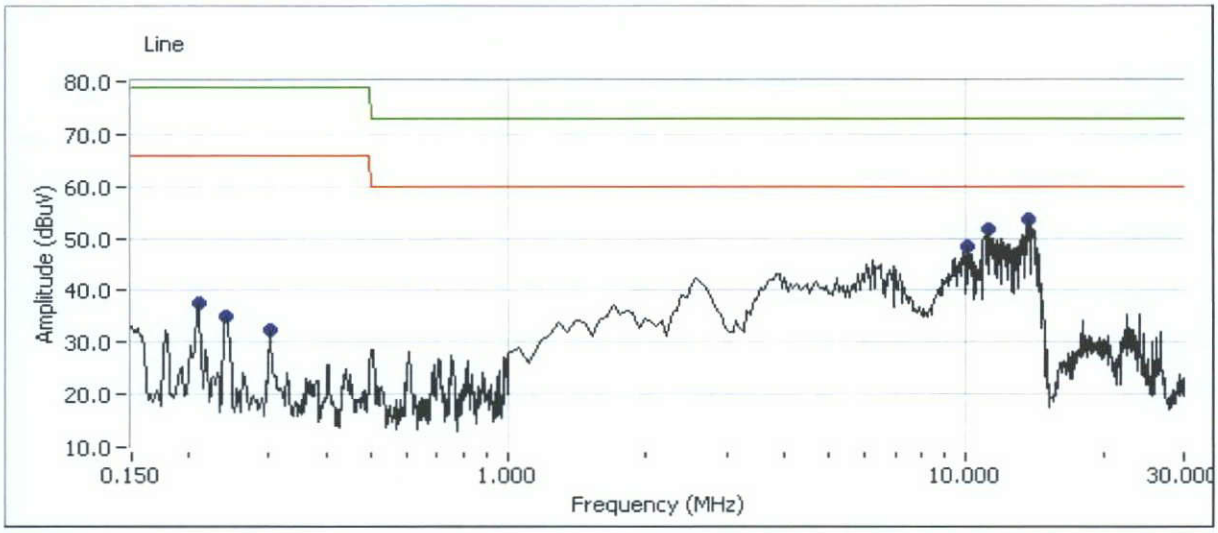
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

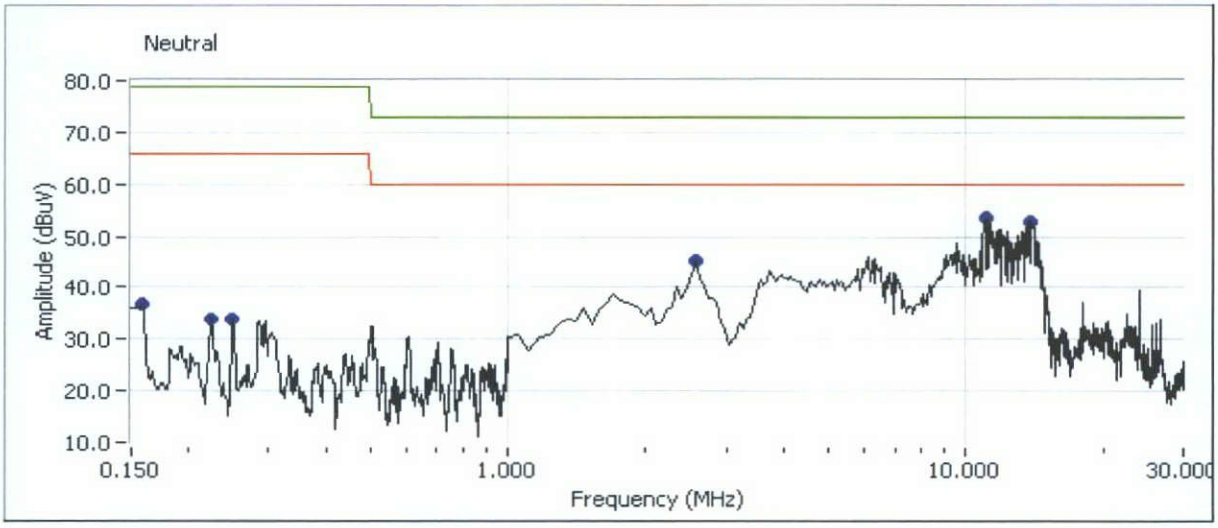
Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run #2: AC Power Port Conducted Emissions, 0.15 - 30MHz, 120V/60Hz





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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott — EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Run #2: AC Power Port Conducted Emissions, 0.15 - 30MHz, 120V/60Hz
Preliminary peak readings captured during pre-scan (peak readings vs. average limit)

Frequency MHz	Level dBμV	AC Line	EN55022 Class A Limit	Margin	Detector QP/Ave	Comments
0.208	37.4	Line 1	66.0	-28.6	Peak	
0.242	34.9	Line 1	66.0	-31.1	Peak	
0.303	32.3	Line 1	66.0	-33.7	Peak	
10.063	48.5	Line 1	60.0	-11.5	Peak	
11.164	51.7	Line 1	60.0	-8.4	Peak	
13.684	53.5	Line 1	60.0	-6.5	Peak	
0.159	36.7	Neutral	66.0	-29.3	Peak	
0.223	33.7	Neutral	66.0	-32.3	Peak	
0.249	33.7	Neutral	66.0	-32.3	Peak	
2.582	45.5	Neutral	60.0	-14.5	Peak	
11.062	53.7	Neutral	60.0	-6.3	Peak	
13.882	52.9	Neutral	60.0	-7.1	Peak	

Final quasi-peak and average readings

Frequency MHz	Level dBμV	AC Line	EN55022 Class A Limit	Margin	Detector QP/Ave	Comments
11.062	46.5	Neutral	60.0	**-13.5**	AVG	
13.882	46.1	Neutral	60.0	-13.9	AVG	
11.164	45.5	Line 1	60.0	-14.5	AVG	
13.684	45.4	Line 1	60.0	-14.6	AVG	
10.063	39.8	Line 1	60.0	-20.2	AVG	
2.582	38.1	Neutral	60.0	-21.9	AVG	
11.062	50.3	Neutral	73.0	-22.7	QP	
13.882	50.1	Neutral	73.0	-22.9	QP	
13.684	49.4	Line 1	73.0	-23.6	QP	
11.164	49.1	Line 1	73.0	-23.9	QP	
10.063	43.7	Line 1	73.0	-29.3	QP	
2.582	41.4	Neutral	73.0	-31.6	QP	
0.159	23.8	Neutral	66.0	-42.2	AVG	
0.223	36.5	Neutral	79.0	-42.5	QP	
0.242	35.3	Line 1	79.0	-43.7	QP	
0.249	34.9	Neutral	79.0	-44.1	QP	
0.223	20.8	Neutral	66.0	-45.3	AVG	
0.208	32.7	Line 1	79.0	-46.3	QP	
0.159	32.4	Neutral	79.0	-46.6	QP	
0.303	17.6	Line 1	66.0	-48.4	AVG	
0.249	16.7	Neutral	66.0	-49.3	AVG	
0.242	16.6	Line 1	66.0	-49.4	AVG	
0.208	16.0	Line 1	66.0	-50.0	AVG	
0.303	24.4	Line 1	79.0	-54.6	QP	

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

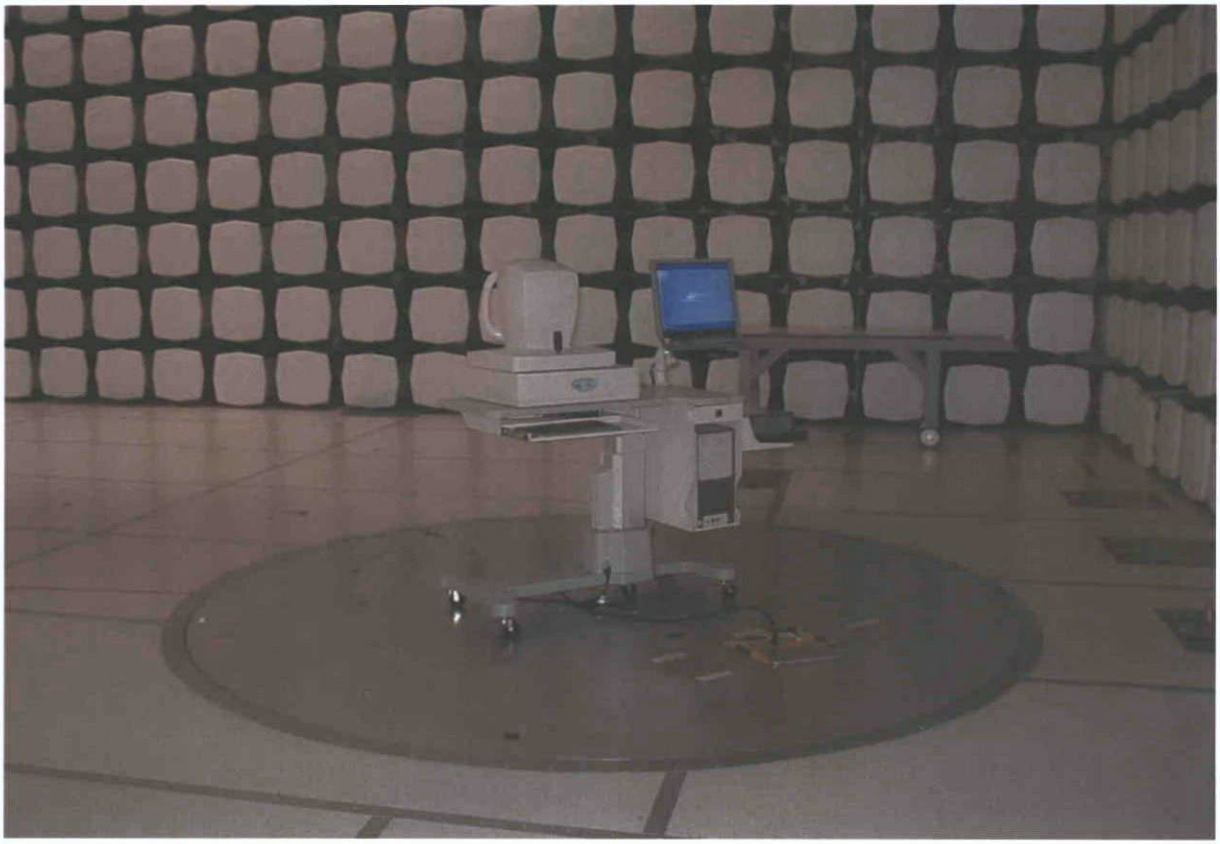
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Test Configuration Photograph #1
(Conducted Emissions - Power Port)



655

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Spec:	EN 55011 Group 1 & EN 60601-1-2 Ed. 2	Class:	A

Test Configuration Photograph #2
(Conducted Emissions - Power Port)

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

ElectroStatic Discharge (EN 61000-4-2)

Test Specifics

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 4/20/2006
Test Engineer: rmomand
Test Location: Fremont EMC Lab

Config. Used: 1
Config Change: None
EUT Voltage: 230V/50Hz

General Test Configuration

For floor-standing equipment, the EUT and the host system were located 10 cm above a ground reference plane.

Ten discharges at each voltage, and polarity, were applied to each test point listed. Contact discharges were applied to coupling planes and conductive surfaces of the EUT and host system. Air discharges were applied to any non-conductive surfaces of the EUT and host system. The VCP was located 80cm above the ground plane for floor standing equipment.

The determination as to the test point being a part of a conductive or non-conductive surface was based on the manufacturer's declaration.

Ambient Conditions:

Temperature: 22 °C
Rel. Humidity: 48 %
Pressure: 1011 mb

Summary of Results

Run #	Test Performed	Level	Criteria/Result	Comments
1	ESD - Enclosure	Refer to Run	Pass	-

Modifications Made During Testing:

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Run #1: Electrostatic Discharge

Indirect Discharges (To Coupling Planes)	Positive Polarity (kV)				Negative Polarity (kV)			
Contact Mode	Level 1 2	Level 2 4	Level 3 6	Level 4 8	Level 1 2	Level 2 4	Level 3 6	Level 4 8
Vertical Coupling Plane (VCP)	x	x	x		x	x	x	
VCP located 10cm from the front, rear, left and right sides of the EUT	x	x	x		x	x	x	

Direct Discharges (To the EUT)	Positive Polarity (kV)				Negative Polarity (kV)			
Contact Mode	Level 1 2	Level 2 4	Level 3 6	Level 4 8	Level 1 2	Level 2 4	Level 3 6	Level 4 8
PC Front	x	x	x		x	x	x	
Front Screws of the system	x	x	x		x	x	x	
Front of the System	x	x	x		x	x	x	
PC USB Ports on Front	x	x	x		x	x	x	
PC Fire Wire Port on Front	x	x	x		x	x	x	
PC Audio Ports on Front	x	x	x		x	x	x	
Printerr tray	x	x	x		x	x	x	
Keyboard Tray	x	x	x		x	x	x	
Keyboard and Printer Tray Screws	x	x	x		x	x	x	
Scanner Front Panel Power indicator LED	x	x	x		x	x	x	
Left side of the Computer Tray	x	x	x		x	x	x	
Monitor Stand	x	x	x		x	x	x	
Monitor Stand Screws	x	x	x		x	x	x	
Base	x	x	x		x	x	x	
Raiser	x	x	x		x	x	x	
Wheels	x	x	x		x	x	x	
Scan Unit	x	x	x		x	x	x	
Screws on Scan Unit	x	x	x		x	x	x	
Cables Conduit Under table	x	x	x		x	x	x	
Cables Conduit Screws	x	x	x		x	x	x	
Power Box	x	x	x		x	x	x	
(Back panel holding the PC)Assembly holding PC Inside	x	x	x		x	x	x	
Scan Unit Chin rest assembly	x	x	Note 1		x	x	Note 1	
Scan Unit Handel	x	x	Note 1		x	x	Note 1	
Scan Unit metal arround the Lense	x	x	x		x	x	x	

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Run #1:Continued

Air Discharge	Level 1	Level 2	Level 3	Level 4	Level 1	Level 2	Level 3	Level 4
Mode	2	4	8	15	2	4	8	15
Scan Unit Base Front	ND	ND	x		ND	ND	x	
PC Front	ND	ND	ND		ND	ND	ND	

Note:	An "X" indicates that the unit continued to operate as intended.
Note:	ND: No discharge was possible due to the lack of a discharge path to ground from the test point. HCP: Horizontal Coupling Plane. VCP: Vertical Coupling Plane
Note 1:	There was a contineous small noise coming from the Scan Unit everything else was normal.
Note 2:	Per Customer the back, left and right of the PC will not be tested for ESD because they are not accessable to the user and need special tool to open the back panel holding the PC. Mouse, keyboard, printer and monitor according to the customer are CE certified so no need to test for ESD.

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

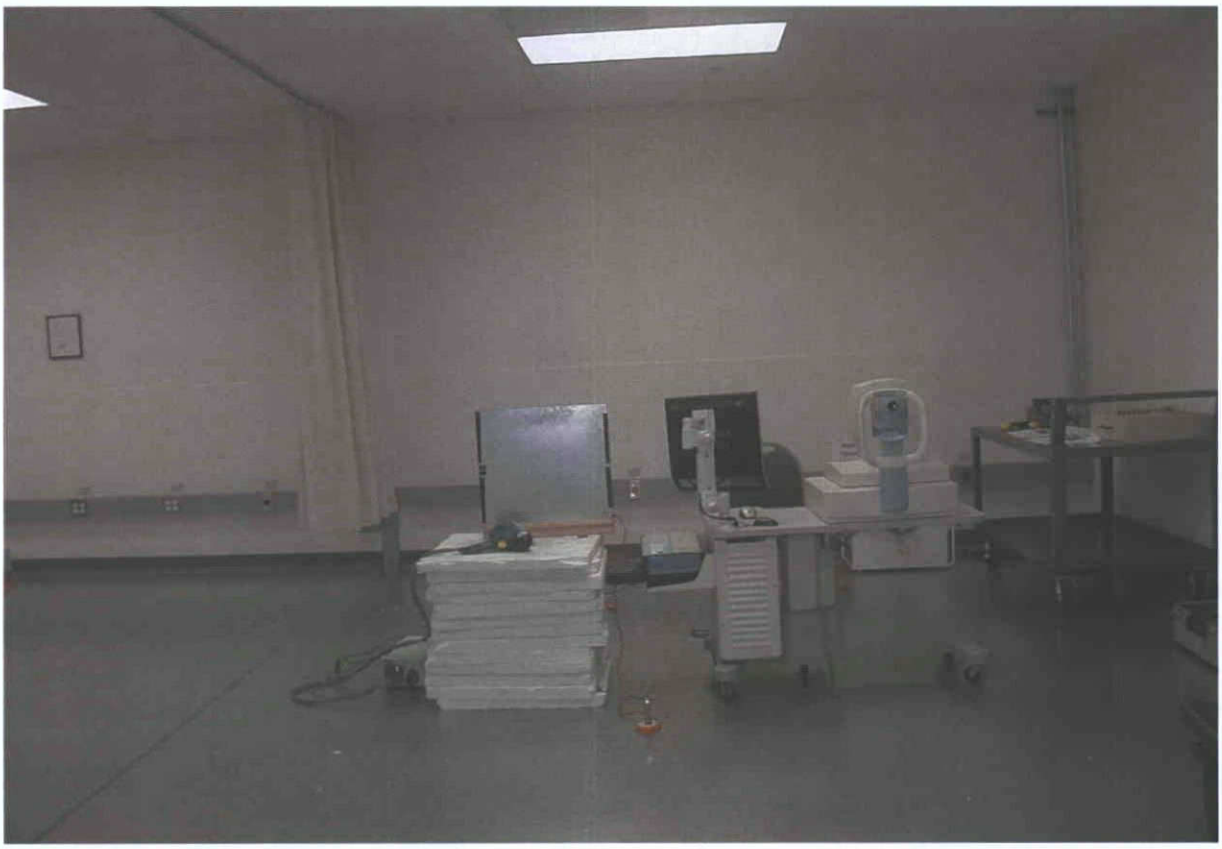
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Test Configuration Photograph #1
(Electrostatic Discharge, EN 61000-4-2)



660

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

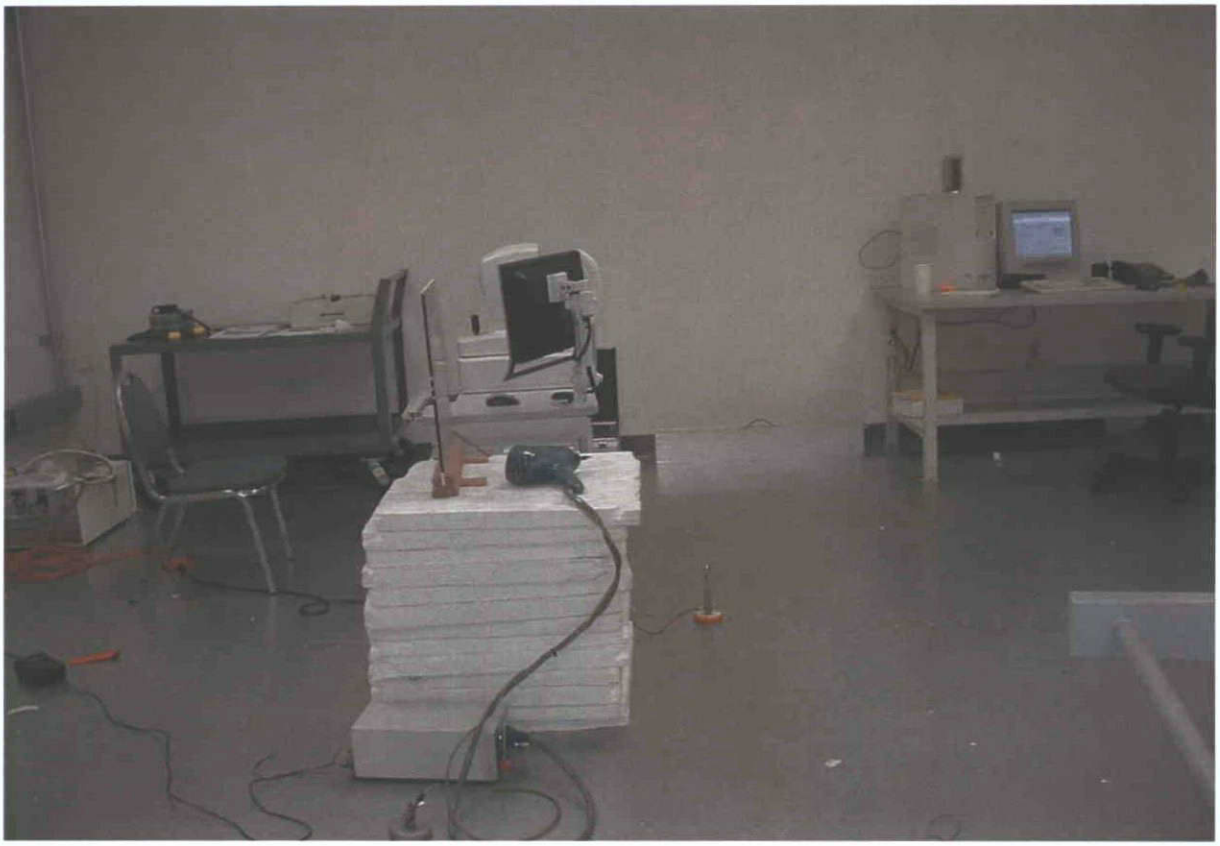
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Test Configuration Photograph #2
(Electrostatic Discharge, EN 61000-4-2)



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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Radiated Immunity (EN 61000-4-3)

Test Specifics

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 4/25/2006
Test Engineer: Joe What
Test Location: Chamber #1

Config. Used: 1
Config Change: None
EUT Voltage: 230V/50Hz

General Test Configuration

The EUT and all local support equipment were located on a turntable in an anechoic chamber. All remote support equipment was located outside the chamber. Interface cabling to the remote support equipment was routed along the floor and, where possible, passed through ferrite clamps at the exit point from the chamber.

The transmitting antenna was located 3 meters from the EUT, unless otherwise noted.

Ambient Conditions:

Temperature: 19 °C
Rel. Humidity: 46 %

Summary of Results

Run #	Test Performed	Level	Criteria/Result	Comments
1	RI 1000 - 2500 MHz, 1kHz 80% AM	3 V/m	Pass	The unit continued to operate as intended.

Modifications Made During Testing:

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Run #1: Radiated Immunity, 1000 - 2500 MHz (EN61000-4-3)

Test Level:	3 V/m
Step Size:	1 %
Dwell time:	2874 ms
Uniformity:	1 point

Modulation Details	
Modulating Frequency:	1kHz
Modulation:	AM
Depth / Deviation:	80%

Frequency Range MHz	Front		Left Side		Rear		Right		Top		Bottom	
	Vert.	Horiz.	Vert.	Horiz.	Vert.	Horiz.	Vert.	Horiz.	Vert.	Horiz.	Vert.	Horiz.
1000 - 2500	X	X	X	X	X	X	X	x	N/A	N/A	N/A	N.A

Test files used for this run:

Position B, 1.4m 1000MHz - 2500MHz V 3Vm

Position B, 1.4m 1000MHz - 2500MHz H 3Vm

Note 1:	An "X" indicates that the unit continued to operate as intended. Monitored RTVue application software. There were no data errors reported by the monitoring software.
Note 2:	For the frequency range above 1GHz the field uniformity is for a single-point grid.

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

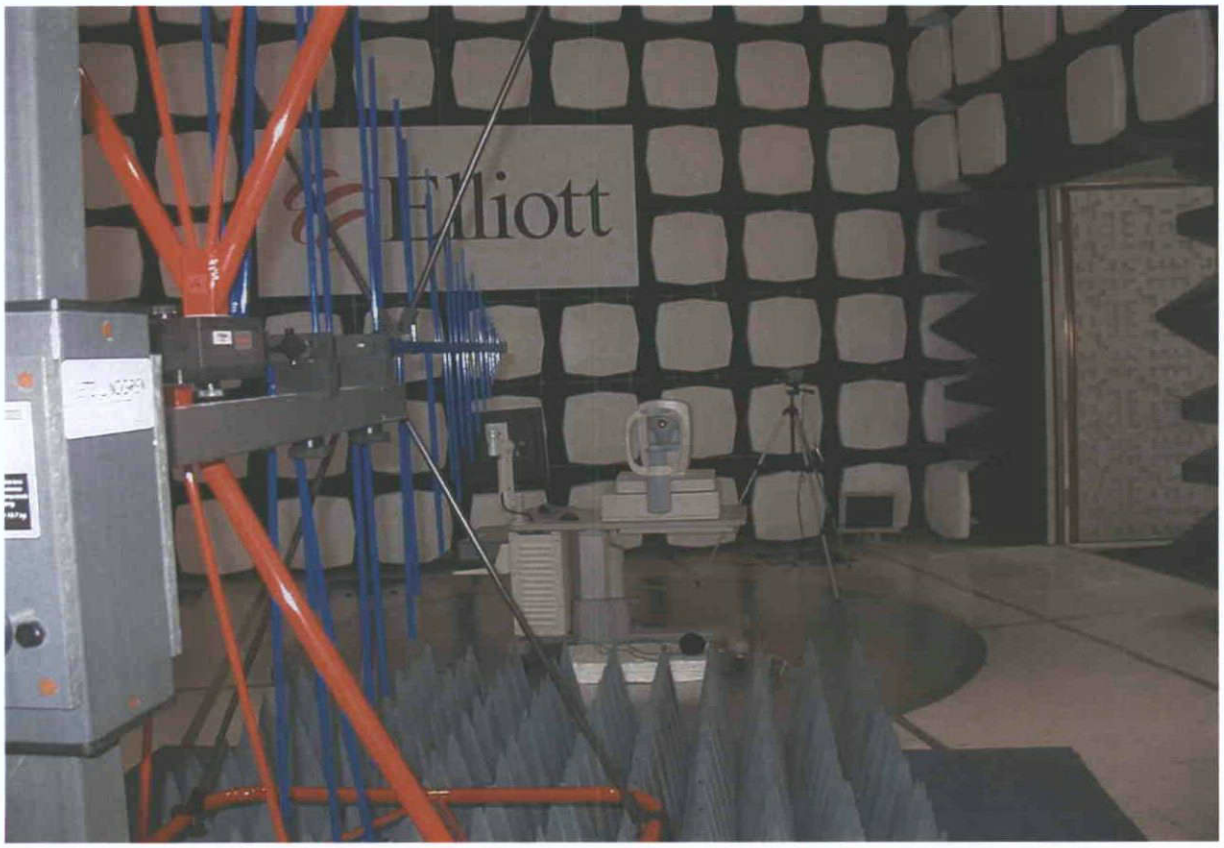
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Test Configuration Photograph #1
(Radiated Immunity, EN 61000-4-3)



664

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Radiated Immunity (EN 61000-4-3)

Test Specifics

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 4/24/2006
Test Engineer: rmomand
Test Location: Fremont Chamber #5
Config. Used: 1
Config Change: None
EUT Voltage: 230V/50Hz

General Test Configuration

The EUT and all local support equipment were located on a turntable in an anechoic chamber. All remote support equipment was located outside the chamber. Interface cabling to the remote support equipment was routed along the floor and, where possible, passed through ferrite clamps at the exit point from the chamber.

The transmitting antenna was located 3 meters from the EUT, unless otherwise noted.

Ambient Conditions:

Temperature: 24 °C
Rel. Humidity: 50 %

Summary of Results

Run #	Test Performed	Level	Criteria/Result	Comments
1	RI 80 - 1000 MHz, 1kHz 80% AM	3V/m	Pass	-

Modifications Made During Testing:

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Run #1: Radiated Immunity, 80 - 1000 MHz (EN61000-4-3)

Test Level:	3 V/m
Step Size:	1 %
Dwell time:	2874 ms
Uniformity:	16 point

Modulation Details	
Modulating Frequency:	1kHz
Modulation:	AM
Depth / Deviation:	80%

Frequency Range MHz	Front		Left Side		Rear		Right		Top		Bottom	
	Vert.	Horiz.	Vert.	Horiz.	Vert.	Horiz.	Vert.	Horiz.	Vert.	Horiz.	Vert.	Horiz.
80 - 1000	x	Note 1	x		Note 1	x	Note 1	Note 1	N/A	N/A	N/A	N.A

The following calibration files from O:\EMC Stuff\Radiated Immunity Cal Files\Chamber #5\Chamber #5 - August 31, 2005 Cal (With new ETS antenna)\03 Vm\ were used:

1.48m high, tip of ETS antenna 2.45m from uniform area 80 MHz - 1000 MHz V 3Vm.crf
1.55m high, tip of ETS antenna 2.45m from uniform area 80 MHz - 1000 MHz H 3Vm.crf

Note:	An "X" indicates that the unit continued to operate as intended.
Note 1:	There was some background noise observed at several frequencies (106MHz, 109MHz, 111MHz and 980MHz to 995Mhz), otherwise everything else was normal. The OCT Image and the imaged object did not change during the test and each layer could be properly identified during test. The EUT met Performance Criteria A.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Test Configuration Photograph #1
(Radiated Immunity, EN 61000-4-3)

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Electrical Fast Transient/Burst (EFT/B) (EN 61000-4-4)

Test Specifics

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 4/19/2006
Test Engineer: Ed Pavlu
Test Location: Fremont EMC Lab #2

Config. Used: 1
Config Change: None
EUT Voltage: 230V/50Hz / 120V/60Hz

General Test Configuration

The EUT system was located 10 cm above a ground reference plane. A 0.5m long power cord was used between the EUT's power port and the coupling/decoupling network. Interference was coupled onto the cables connected to the ports identified in the test data tables using the capacitive trench, with a maximum length of 0.5m of cable between the interface port and the trench.

Ambient Conditions:

Temperature: 21 °C
Rel. Humidity: 41 %

Summary of Results

Run #	Test Performed	Level	Criteria/Result	Comments
1	EFT AC power port	+/-2kV	Pass	120V/60Hz
1	EFT I/O Port	+/-1kV	Pass	120V/60Hz
2	EFT AC power port	+/-2kV	Pass	230V/50Hz
2	EFT I/O Port	+/-1kV	Pass	230V/50Hz

Modifications Made During Testing:

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Run #1: EFT/B Testing, 120V/60Hz

Test Parameters	
Waveshape: 5 ns / 50 ns	Burst Period: 300 ms
Repetition Frequency: 5 kHz (2.5 kHz @ 4 kV)	Burst Width: 15 ms

Applied Location	Positive Polarity (kV)				Negative Polarity (kV)			
Power	Level 1	Level 2	Level 3	Level 4	Level 1	Level 2	Level 3	Level 4
Line	0.5	1.0	2.0	4.0	0.5	1.0	2.0	4.0
Line	X	X	X		X	X	X	
Neutral	X	X	X		X	X	X	
Protective Earth	X	X	X		X	X	X	
I/O	Level 1	Level 2	Level 3	Level 4	Level 1	Level 2	Level 3	Level 4
Port	0.25	0.5	1.0	2.0	0.25	0.5	1.0	2.0
Ethernet	X	X	X		X	X	X	

Note:	An "X" indicates that the unit continued to operate as intended. The EUT was being exercised by the RTVue software application. Normal operation is indicated by operating software continuously scanning and shall be monitored by RTVue application software. Loss of function is allowed provided that normal operation can be restored by operator intervention.
Note 1:	The interface cable for the I/O port tested was routed through the capacitive trench and tested.

The following interface ports were not tested:

Port(s)	Reason
USB, Microphone, and Speaker	The ports are not intended to be connected during normal operation.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Run #2: EFT/B Testing, 230V/50Hz

Test Parameters	
Waveshape: 5 ns / 50 ns	Burst Period: 300 ms
Repetition Frequency: 5 kHz (2.5 kHz @ 4 kV)	Burst Width: 15 ms

Applied Location	Positive Polarity (kV)				Negative Polarity (kV)			
Power Line	Level 1 0.5	Level 2 1.0	Level 3 2.0	Level 4 4.0	Level 1 0.5	Level 2 1.0	Level 3 2.0	Level 4 4.0
Line	X	X	X		X	X	X	
Neutral	X	X	X		X	X	X	
Protective Earth	X	X	X		X	X	X	
I/O Port	Level 1 0.25	Level 2 0.5	Level 3 1.0	Level 4 2.0	Level 1 0.25	Level 2 0.5	Level 3 1.0	Level 4 2.0
Ethernet	X	X	X		X	X	X	

Note:	An "X" indicates that the unit continued to operate as intended. The EUT was being exercised by the RTVue software application. Normal operation is indicated by operating software continuously scanning and shall be monitored by RTVue application software. Loss of function is allowed provided that normal operation can be restored by operator intervention.
Note 1:	The interface cable for the I/O port tested was routed through the capacitive trench and tested.

The following interface ports were not tested:

Port(s)	Reason
USB, Microphone, and Speaker	The ports are not intended to be connected during normal operation.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Test Configuration Photograph #1
(Electrical Fast Transient/Burst, EN 61000-4-4)

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

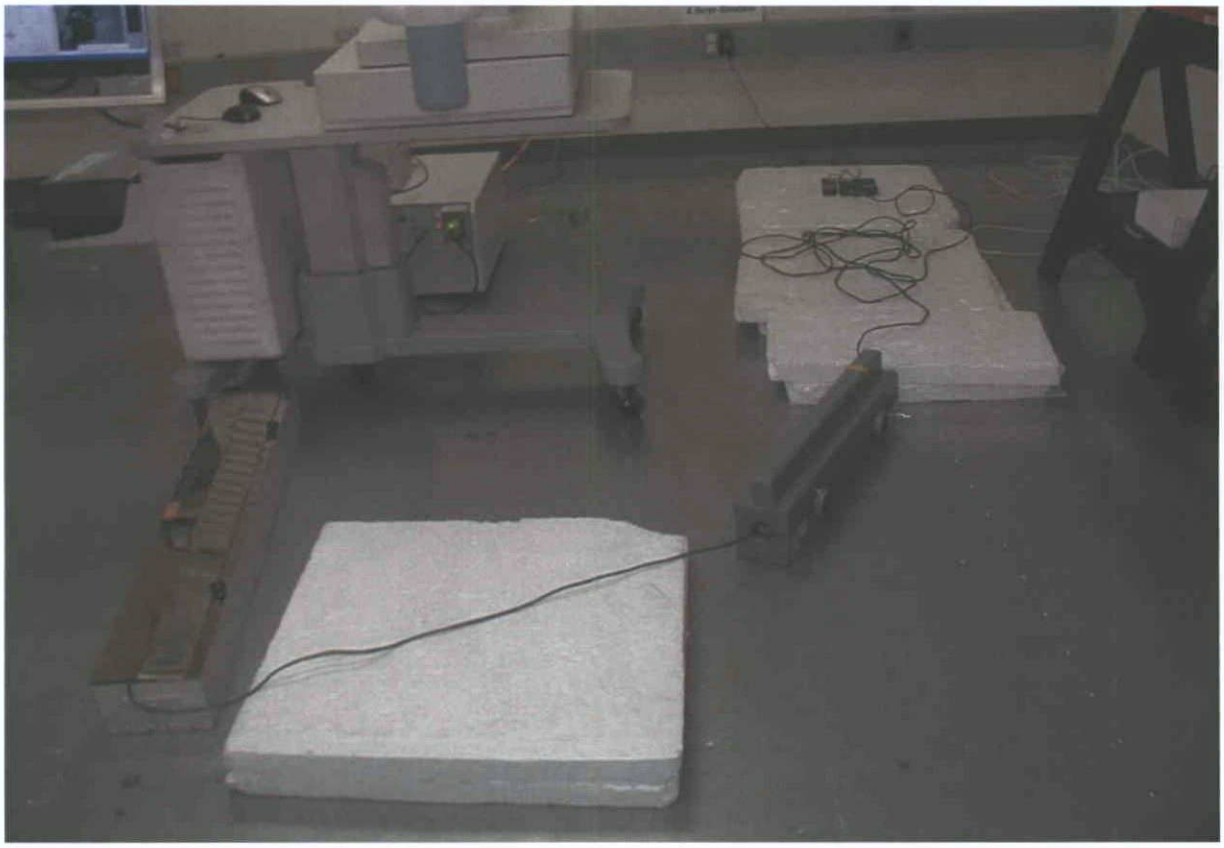
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Test Configuration Photograph #2
(Electrical Fast Transient/Burst, EN 61000-4-4)



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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Surge (EN 61000-4-5)

Test Specifics

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 4/21/2006
Test Engineer: Chris Groat/Vishal
Test Location: Fremont EMC Lab

Config. Used: 1
Config Change: none
EUT Voltage: 230V/50Hz and 120V/60Hz

General Test Configuration

The EUT and all local support equipment were located on a non-conductive bench.

Ambient Conditions:

Temperature: 21 °C
Rel. Humidity: 34 %

Summary of Results

Run #	Test Performed	Level	Criteria/Result	Comments
1	AC power port surges	+/- 2kv Common +/- 1kv Differential	A / Pass	See Individual Run
2	AC power port surges	+/- 2kv Common +/- 1kv Differential	A / Pass	See Individual Run

Modifications Made During Testing:

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

673

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Run #1: Surge Immunity, Power Line 230VAC/50Hz

Test Parameters
Waveshape: 1.2/50µS
Impedance: 12 Ohms (Common Mode), 2 Ohms (Differential Mode)

Applied Location	Positive Polarity (kV)				Negative Polarity (kV)			
Power Line	Level 1 0.5	Level 2 1.0	Level 3 2.0	Level 4 4.0	Level 1 0.5	Level 2 1.0	Level 3 2.0	Level 4 4.0
Line to Line (Differential Mode)								
0°	X	X			X	X		
90°	X	X			X	X		
180°	X	X			X	X		
270°	X	X			X	X		
Line to PE (Common Mode)								
0°	X	X	X		X	X	X	
90°	X	X	X		X	X	X	
180°	X	X	X		X	X	X	
270°	X	X	X		X	X	X	
Neutral to PE (Common Mode)								
0°	X	X	X		X	X	X	
90°	X	X	X		X	X	X	
180°	X	X	X		X	X	X	
270°	X	X	X		X	X	X	

Note: An "X" indicates that the unit continued to operate as intended. The EUT was being exercised by the RTVue software application. Normal operation is indicated by operating software continuously scanning and shall be monitored by RTVue application software. Loss of function is allowed provided that normal operation can be restored by operator intervention.

674

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Run #2: Surge Immunity, Power Line 120VAC/60Hz

Test Parameters
Waveshape: 1.2/50µS
Impedance: 12 Ohms (Common Mode), 2 Ohms (Differential Mode)

Applied Location	Positive Polarity (kV)				Negative Polarity (kV)			
Power Line	Level 1 0.5	Level 2 1.0	Level 3 2.0	Level 4 4.0	Level 1 0.5	Level 2 1.0	Level 3 2.0	Level 4 4.0
Line to Line (Differential Mode)								
0°	X	X			X	X		
90°	X	X			X	X		
180°	X	X			X	X		
270°	X	X			X	X		
Line to PE (Common Mode)								
0°	X	X	X		X	X	X	
90°	X	X	X		X	X	X	
180°	X	X	X		X	X	X	
270°	X	X	X		X	X	X	
Neutral to PE (Common Mode)								
0°	X	X	X		X	X	X	
90°	X	X	X		X	X	X	
180°	X	X	X		X	X	X	
270°	X	X	X		X	X	X	

Note: An "X" indicates that the unit continued to operate as intended. The EUT was being exercised by the RTVue software application. Normal operation is indicated by operating software continuously scanning and shall be monitored by RTVue application software.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Test Configuration Photograph #1
(Surge, EN 61000-4-5)

676

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

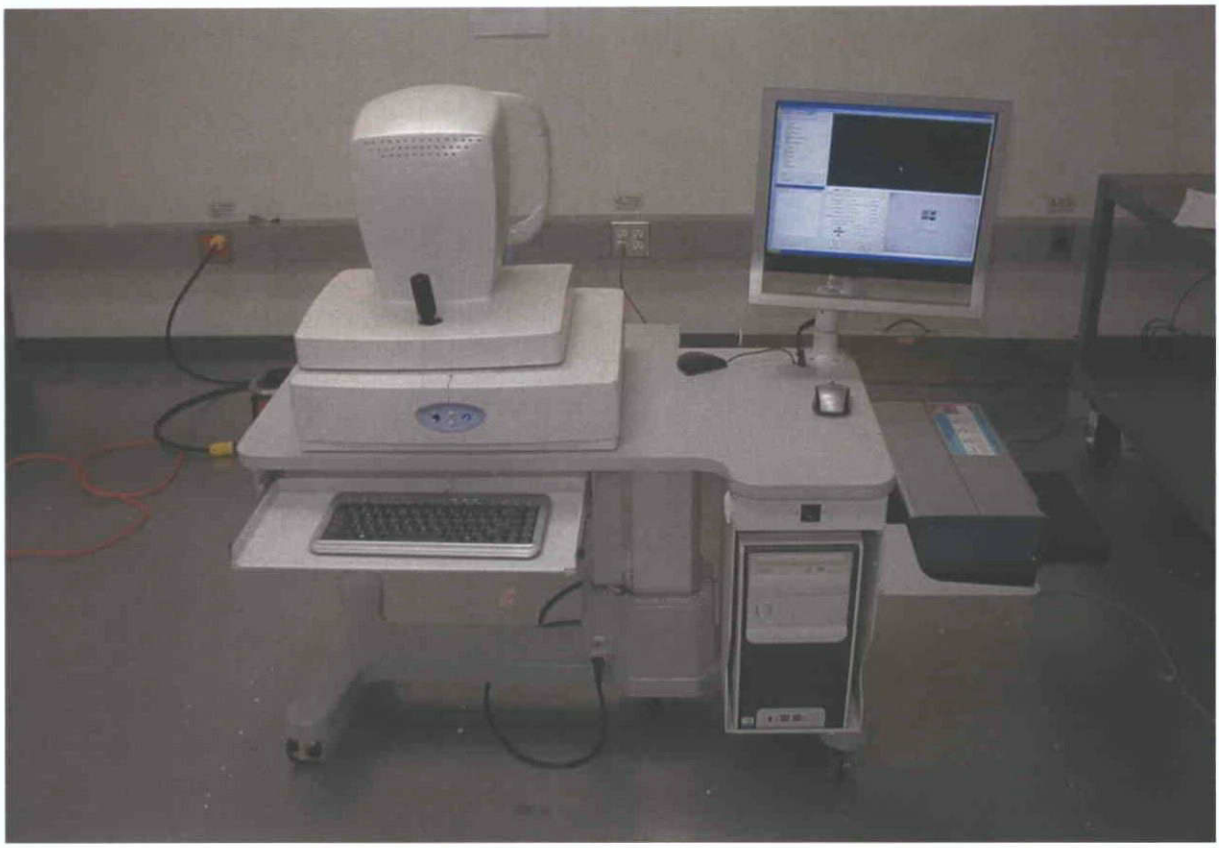
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Test Configuration Photograph #2
(Surge, EN 61000-4-5)



677

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Conducted Immunity (EN 61000-4-6)

Test Specifics

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 4/18/2006
Test Engineer: Chris Groat
Test Location: Fremont EMC Lab

Config. Used: 1
Config Change: none
EUT Voltage: 230V/50Hz

General Test Configuration

The EUT and all local support equipment were located 10cm above a ground plane. All interface cabling between the equipment and the CDN or decoupling network was located 5 cm above the ground plane.

Ambient Conditions:

Temperature: 25 °C
Rel. Humidity: 34 %

Summary of Results

Run #	Test Performed	Level	Criteria/Result	Comments
1	CI - 0.15 - 80 MHz 80% AM w/2Hz, AC and I/O ports	3 Vrms	A / Pass	Refer to Individual Run

Modifications Made During Testing:

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Run #1: Conducted Susceptibility (EN61000-4-6)

Test Level:	3 Vrms
Step Size:	1 %
Dwell time:	2874 ms

Modulation Details	
Modulating Frequency:	2Hz
Modulation:	AM
Depth / Deviation:	80%

Frequency Range MHz	Port Under Test	Injection Method	Comments
0.15 - 80	AC Power	M3 CDN	The unit continued to operate as intended. Monitored RTVue application software. There were no data errors reported by the monitoring software.
0.15 - 80	10/100 Ethernet	EM Clamp	The unit continued to operate as intended. Monitored RTVue application software. There were no data errors reported by the monitoring software.

Note:	During Conducted Immunity testing the EUT will be exercised by RTVue software application. Normal operation is indicated by operating software continuously scanning and shall be monitored by RTVue application software.

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

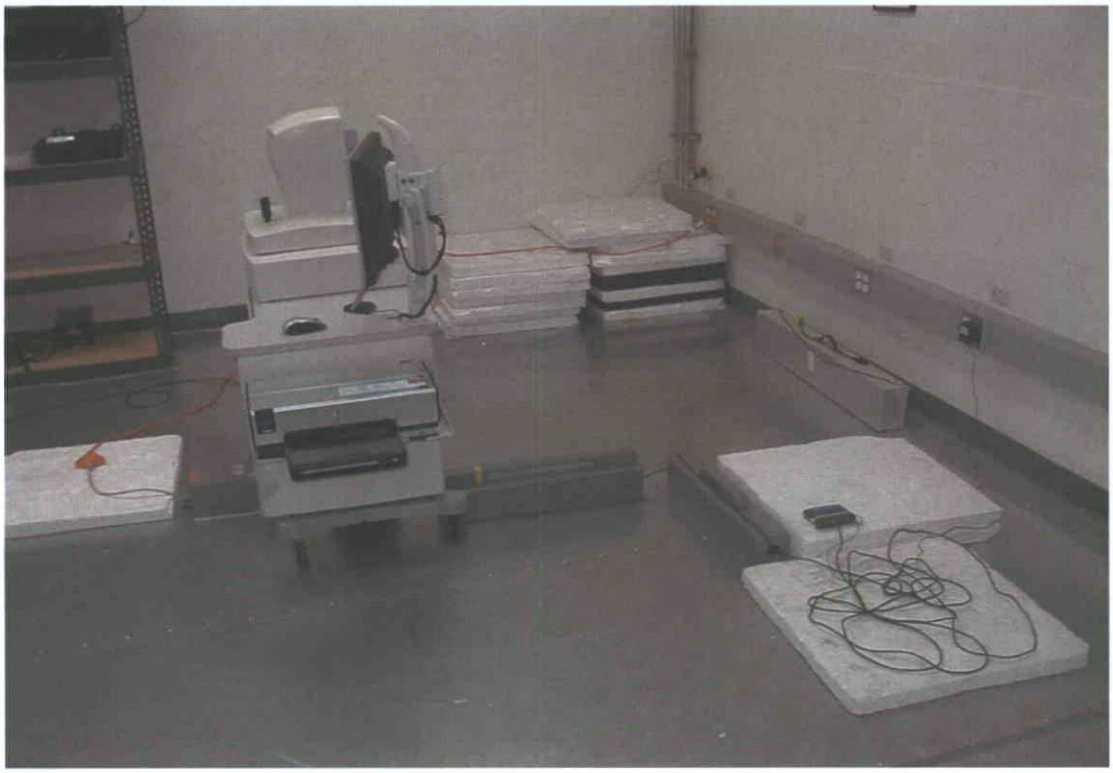
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Test Configuration Photograph #1
(Conducted Immunity, EN 61000-4-6)



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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Test Configuration Photograph #2
(Conducted Immunity, EN 61000-4-6)

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Power Frequency Magnetic Field (EN 61000-4-8)

Test Specifics

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 5/15/2006
Test Engineer: Joe What
Test Location: 3m Lab

Config. Used: 1
Config Change: None
EUT Voltage: 230V/50Hz

General Test Configuration

The EUT and all local support equipment were located above a conductive ground plane. The EUT was positioned inside the 1m field-generating loop during the test.

Ambient Conditions

Temperature: 23 °C
Rel. Humidity: 46 %

Summary of Results

Run #	Test Performed	Level	Results	Comments
1	Power Frequency Magnetic Field (50Hz)	3 A/m	Pass	The unit continued to operate as intended.
2	Power Frequency Magnetic Field (60Hz)	3 A/m	Pass	The unit continued to operate as intended.

Modifications Made During Testing:

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Run #1: Power Frequency Magnetic Field Immunity (EN61000-4-8)

Frequency (Hz)	Level A/m	EUT Orientation X	Y	Z
50	3.0	Pass	Pass	Pass
60	3.0	Pass	Pass	Pass

Note 1:	The unit continued to operate as intended. The displayed eye ball image was displayed and monitored. No distortion or loss of image was observed. The unit continued to operate as intended.

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Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Test Configuration Photograph #1
(Power Frequency Magnetic Immunity, EN 61000-4-8)

684

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

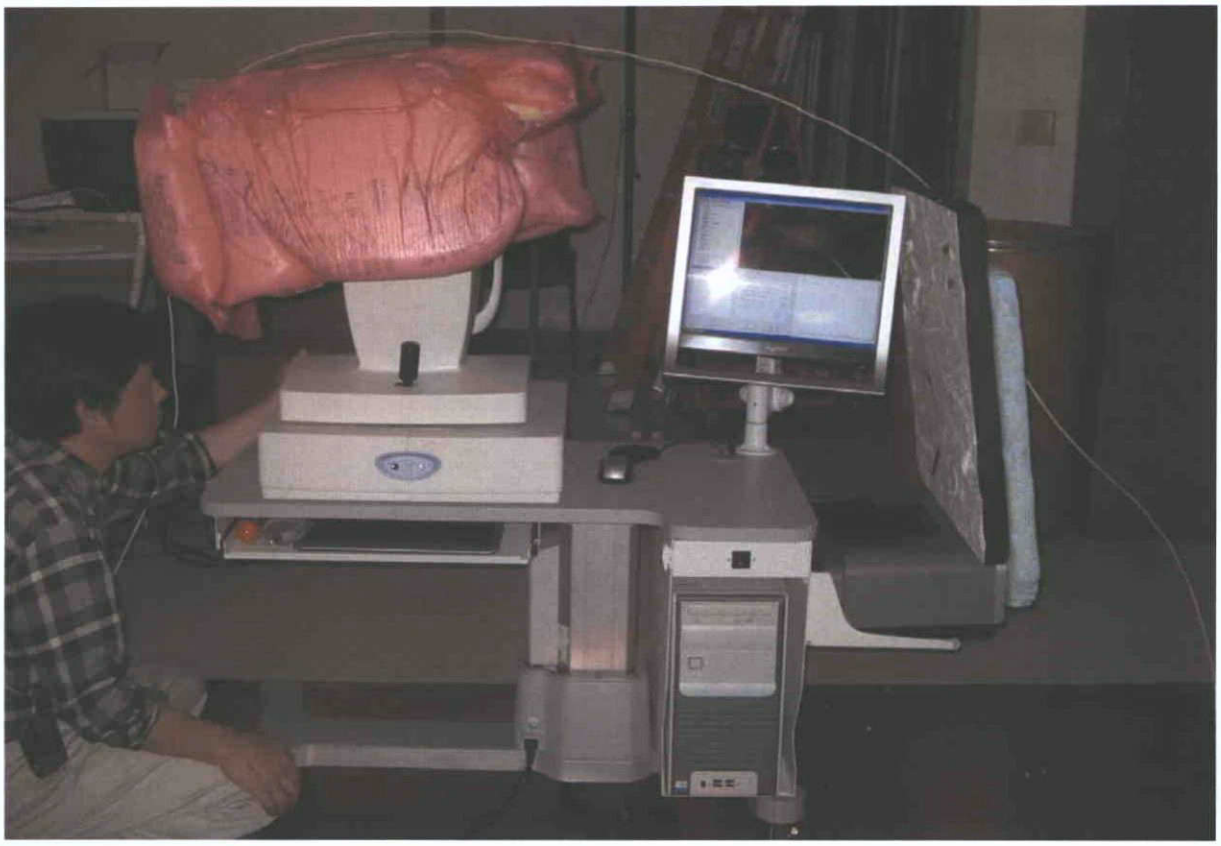
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Test Configuration Photograph #2
(Power Frequency Magnetic Immunity, EN 61000-4-8)



685

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Voltage Dips and Interrupts (EN 61000-4-11)

Test Specifics

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 4/19/2006
Test Engineer: Ed Pavlu
Test Location: Fremont EMC Lab #2

Config. Used: 1
Config Change: None
EUT Voltage: 230V/50Hz / 120V/60Hz

General Test Configuration

The EUT and all local support equipment were located on a non-conductive bench.

Ambient Conditions:

Temperature: 18 °C
Rel. Humidity: 47 %

Summary of Results

Run #	Test Performed	Level	Criteria/Result	Comments
1	VDI on AC port #1	>95% ½ period 30% 25 periods 60% 5 periods >95% 250periods	Pass Pass Pass Pass	230Vac
2	VDI on AC port #1	>95% ½ period 30% 25 periods 60% 5 periods >95% 250periods	Pass Pass Pass Pass	120Vac

Modifications Made During Testing:

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Run #1: Voltage Dips and Interrupts

Nominal Operating Voltage of EUT:	230 Volts	50 Hz

Voltage Dips/Time % / ms or % / periods	Port Under Test	Interrupt Voltage dropped to:	Comments
>95% ½ period	AC Power	>11.5Vac	Pass see Note 1
30% 25 periods		161Vac	Pass see Note 1
60% 5 periods		92Vac	Pass see Note 1
>95% 250periods		>11.5Vac	Pass see Note 1

Note 1:	The unit continued to operate as intended. The EUT was being exercised by the RTVue software application. Normal operation is indicated by operating software continuously scanning and shall be monitored by RTVue application software. Loss of function is allowed provided that normal operation can be restored by operator intervention.

687

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Run #2: Voltage Dips and Interrupts

Nominal Operating Voltage of EUT:	120 Volts	60 Hz

Voltage Dips/Time % / ms or % / periods	Port Under Test	Interrupt Voltage dropped to:	Comments
>95% ½ period	AC Power	>6Vac	Pass see Note 1
30% 25 periods		84Vac	Pass see Note 1
60% 5 periods		48Vac	Pass see Note 1
>95% 250periods		>6Vac	Pass see Note 1

Note 1:	The unit continued to operate as intended. The EUT was being exercised by the RTVue software application. Normal operation is indicated by operating software continuously scanning and shall be monitored by RTVue application software. Loss of function is allowed provided that normal operation can be restored by operator intervention.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Test Configuration Photograph #1
(Voltage Dips and Interrupts, EN 61000-4-11)

689

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott

EMC Test Data

Client:	Optovue	Job Number:	J63556
Model:	RTVue	T-Log Number:	T63585
		Account Manager:	Nesha Lambert
Contact:	David Chen		
Immunity Spec:	EN 60601-1-2 Ed. 2	Environment:	Medical

Test Configuration Photograph #2
(Voltage Dips and Interrupts, EN 61000-4-11)

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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 #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Emissions Standard(s):	EN 60601-1-2:2007	Class:	A

EMC Test Data

For The

Optovue

Model

RTVue XR

Date of Last Test: 11/28/2011

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Standard:	EN 60601-1-2:2007	Class:	A

Radiated Emissions

(Elliott Laboratories Fremont Facility, Semi-Anechoic Chamber)

Test Specific Details

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 11/23/2011
Test Engineer: Chris Groat
Test Location: Fremont Chamber #3

Config. Used: 1
Config Change: none
EUT Voltage: 120V/60Hz

General Test Configuration

The EUT and any local support equipment were located on the turntable for radiated emissions testing. Any remote support equipment was located outside the semi-anechoic chamber. Any cables running to remote support equipment where routed through metal conduit and when possible passed through a ferrite clamp upon exiting the chamber.

The test distance and extrapolation factor (if applicable) are detailed under each run description.

Note, preliminary testing indicates that the emissions were maximized by orientation of the EUT and elevation of the measurement antenna. Maximized testing indicated that the emissions were maximized by orientation of the EUT, elevation of the measurement antenna, and manipulation of the EUT's interface cables.

Ambient Conditions:

Temperature: 21 °C
Rel. Humidity: 45 %

Summary of Results

Run #	Test Performed	Limit	Result	Margin
1	Radiated Emissions 30 - 1000 MHz, Preliminary	Class A	EVAL	Refer to individual runs
2	Radiated Emissions 30 - 1000 MHz, Maximized	Class A	Pass	42.8dBμV/m @ 816.03MHz (-4.2dB)

Modifications Made During Testing

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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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 #2012-3758; Released by CDRH on 09-8-2015

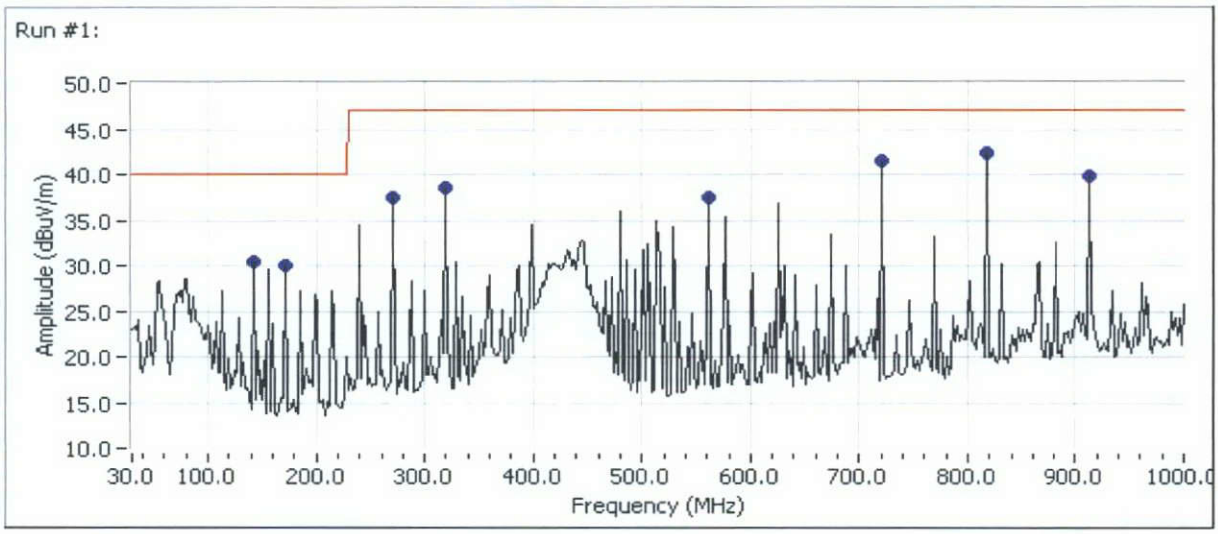
Elliott
An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Standard:	EN 60601-1-2:2007	Class:	A

Run #1: Preliminary Radiated Emissions, 30 - 1000 MHz

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	10	10	0.0



Preliminary peak readings captured during pre-scan

Frequency	Level	Pol	EN55011 A		Detector	Azimuth	Height	Comments
MHz	dBµV/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
816.027	42.3	H	47.0	-4.7	Peak	222	1.0	
720.029	41.5	H	47.0	-5.5	Peak	98	1.0	
912.031	39.8	H	47.0	-7.2	Peak	194	1.0	
320.001	38.6	H	47.0	-8.4	Peak	360	3.0	
272.041	37.5	V	47.0	-9.5	Peak	149	1.0	
560.001	37.5	H	47.0	-9.5	Peak	214	1.5	
143.177	30.4	V	40.0	-9.6	Peak	145	1.0	
171.815	30.0	V	40.0	-10.0	Peak	140	1.0	

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott An NAS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Standard:	EN 60601-1-2:2007	Class:	A

Run #1: Preliminary Radiated Emissions, 30 - 1000 MHz

Preliminary quasi-peak readings (no manipulation of EUT interface cables)

Frequency	Level	Pol	EN55011 A		Detector	Azimuth	Height	Comments
MHz	dBμV/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
816.027	42.8	H	47.0	-4.2	QP	223	1.0	QP (1.00s)
720.029	42.1	H	47.0	-4.9	QP	96	1.0	QP (1.00s)
912.031	39.9	H	47.0	-7.1	QP	193	1.0	QP (1.00s)
320.001	39.6	H	47.0	-7.4	QP	360	3.0	QP (1.00s)
272.041	37.7	V	47.0	-9.3	QP	150	1.0	QP (1.00s)
560.001	37.6	H	47.0	-9.4	QP	212	1.5	QP (1.00s)
171.815	30.2	V	40.0	-9.8	QP	139	1.0	QP (1.00s)
143.177	29.7	V	40.0	-10.3	QP	144	1.0	QP (1.00s)

Run #2: Maximized Readings From Run #1
Maximized quasi-peak readings (includes manipulation of EUT interface cables)

Frequency Range	Test Distance	Limit Distance	Extrapolation Factor
30 - 1000 MHz	10	10	0.0

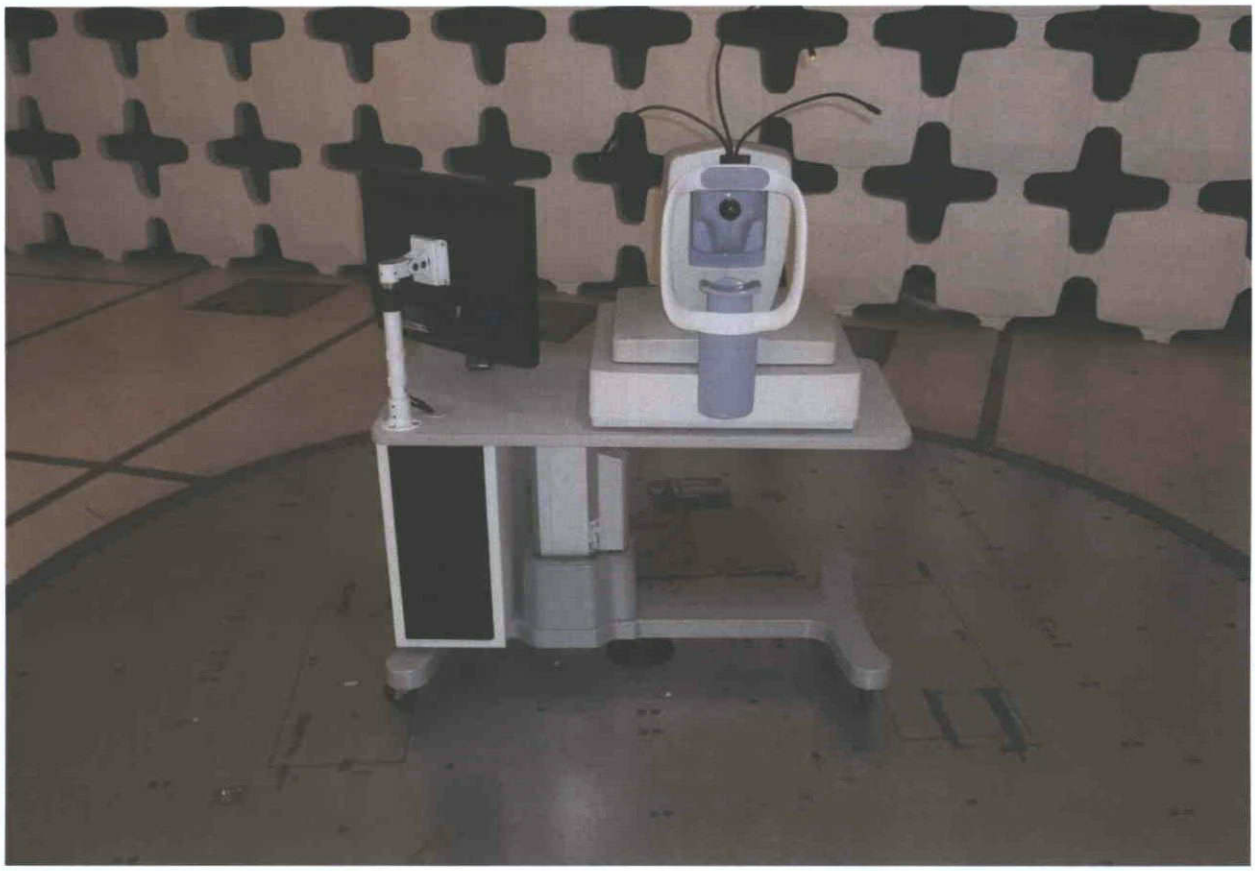
Frequency	Level	Pol	EN55011 A		Detector	Azimuth	Height	Comments
MHz	dBμV/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
816.027	42.8	H	47.0	-4.2	QP	223	1.0	QP (1.00s)
720.029	42.1	H	47.0	-4.9	QP	96	1.0	QP (1.00s)
912.031	39.9	H	47.0	-7.1	QP	193	1.0	QP (1.00s)
320.001	39.6	H	47.0	-7.4	QP	360	3.0	QP (1.00s)
272.041	37.7	V	47.0	-9.3	QP	150	1.0	QP (1.00s)
560.001	37.6	H	47.0	-9.4	QP	212	1.5	QP (1.00s)

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Standard:	EN 60601-1-2:2007	Class:	A

Test Configuration Photograph #1
(Radiated Emissions)



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

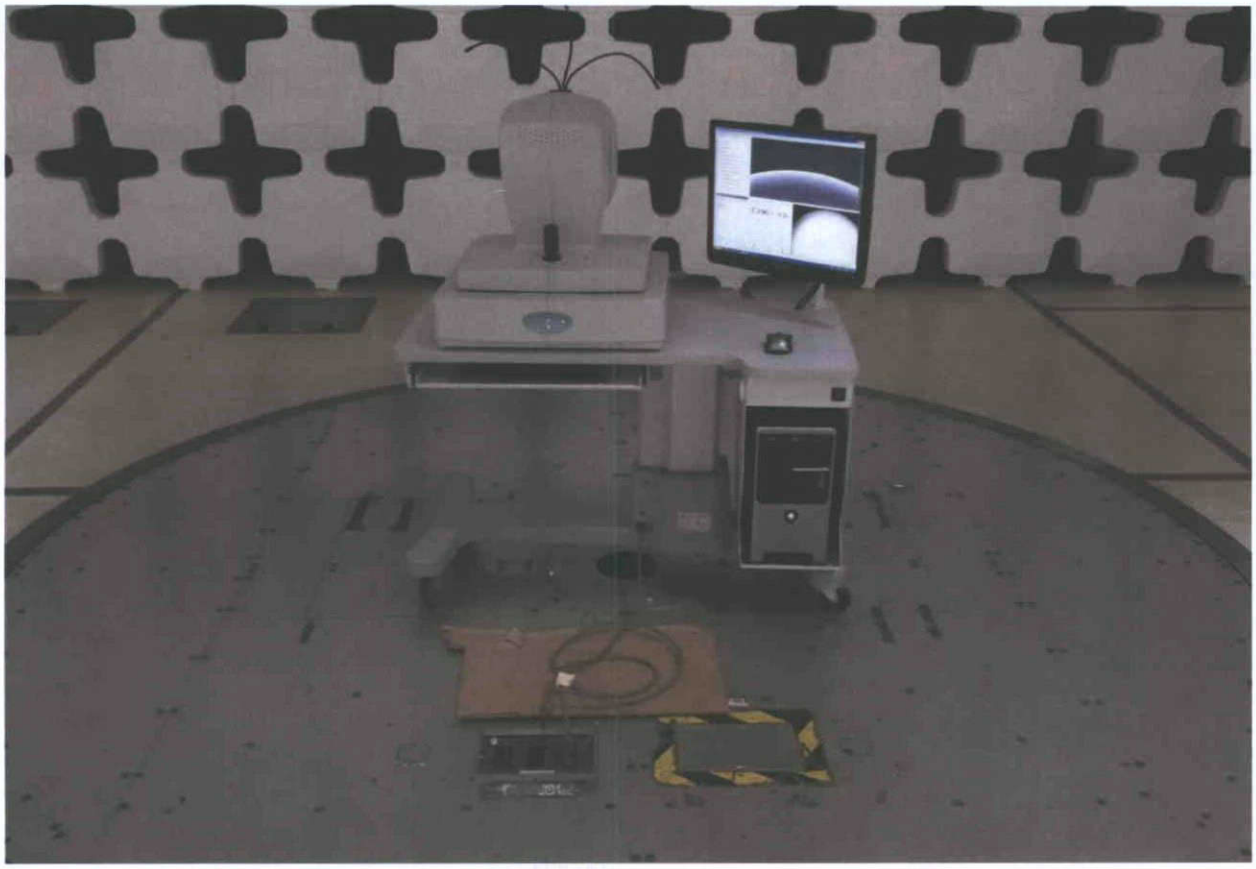
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NAT company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Standard:	EN 60601-1-2:2007	Class:	A

Test Configuration Photograph #2
(Radiated Emissions)



696

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Standard:	EN 60601-1-2:2007	Class:	A

Conducted Emissions

(Elliott Laboratories Fremont Facility, Semi-Anechoic Chamber)

Test Specific Details

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 11/23/2011
Test Engineer: Chris Groat
Test Location: Fremont Chamber #3

Config. Used: 1
Config Change: none
EUT Voltage: 120V/60Hz

General Test Configuration

For tabletop equipment, the EUT was located on a fiberglass table inside the semi-anechoic chamber, 40 cm from a vertical coupling plane and 80cm from the LISN. A second LISN was used for all local support equipment. Remote support equipment was located outside of the semi-anechoic chamber. Any cables running to remote support equipment where routed through metal conduit and when possible passed through a ferrite clamp upon exiting the chamber.

Ambient Conditions:

Temperature: 21 °C
Rel. Humidity: 34 %

Summary of Results

Run #	Test Performed	Limit	Result	Margin
1	CE, AC Power,120V/60Hz	Class A	Pass	36.2dBµV @ 0.996MHz (-23.8dB)

Modifications Made During Testing

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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

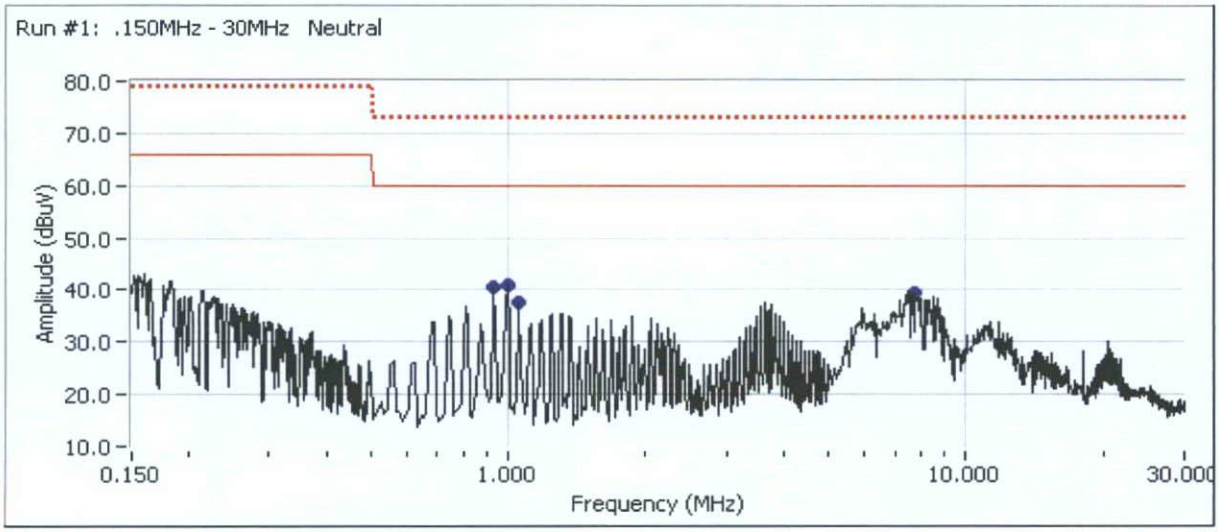
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

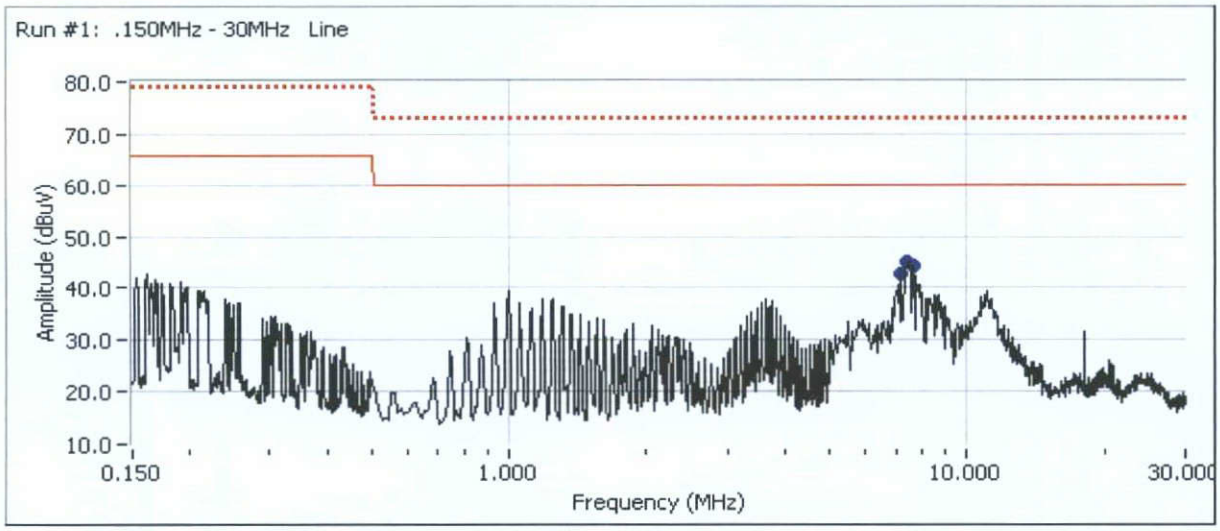
Elliott An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Standard:	EN 60601-1-2:2007	Class:	A

Run #1: AC Power Port Conducted Emissions, 0.15 - 30MHz, 120V/60Hz





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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Standard:	EN 60601-1-2:2007	Class:	A

Run #1: AC Power Port Conducted Emissions, 0.15 - 30MHz, 120V/60Hz

Preliminary peak readings captured during pre-scan (peak readings vs. average limit)

Frequency MHz	Level dBµV	AC Line	Class A Limit	Class A Margin	Detector QP/Ave	Comments
7.397	45.0	Line 1	60.0	-15.0	Peak	
7.666	44.3	Line 1	60.0	-15.7	Peak	
7.217	42.7	Line 1	60.0	-17.3	Peak	
0.996	40.8	Neutral	60.0	-19.2	Peak	
0.934	40.5	Neutral	60.0	-19.5	Peak	
7.750	39.5	Neutral	60.0	-20.5	Peak	
1.058	37.4	Neutral	60.0	-22.6	Peak	

Final quasi-peak and average readings

Frequency MHz	Level dBµV	AC Line	Class A Limit	Class A Margin	Detector QP/Ave	Comments
0.996	36.2	Neutral	60.0	-23.8	AVG	AVG (0.10s)
0.934	35.0	Neutral	60.0	-25.0	AVG	AVG (0.10s)
1.058	33.6	Neutral	60.0	-26.4	AVG	AVG (0.10s)
7.397	32.8	Line 1	60.0	-27.2	AVG	AVG (0.10s)
7.217	30.9	Line 1	60.0	-29.1	AVG	AVG (0.10s)
7.666	30.7	Line 1	60.0	-29.3	AVG	AVG (0.10s)
7.397	43.3	Line 1	73.0	-29.7	QP	QP (1.00s)
7.666	41.3	Line 1	73.0	-31.7	QP	QP (1.00s)
7.217	40.6	Line 1	73.0	-32.4	QP	QP (1.00s)
0.996	40.5	Neutral	73.0	-32.5	QP	QP (1.00s)
0.934	40.4	Neutral	73.0	-32.6	QP	QP (1.00s)
7.750	26.7	Neutral	60.0	-33.3	AVG	AVG (0.10s)
1.058	38.5	Neutral	73.0	-34.5	QP	QP (1.00s)
7.750	37.0	Neutral	73.0	-36.0	QP	QP (1.00s)

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

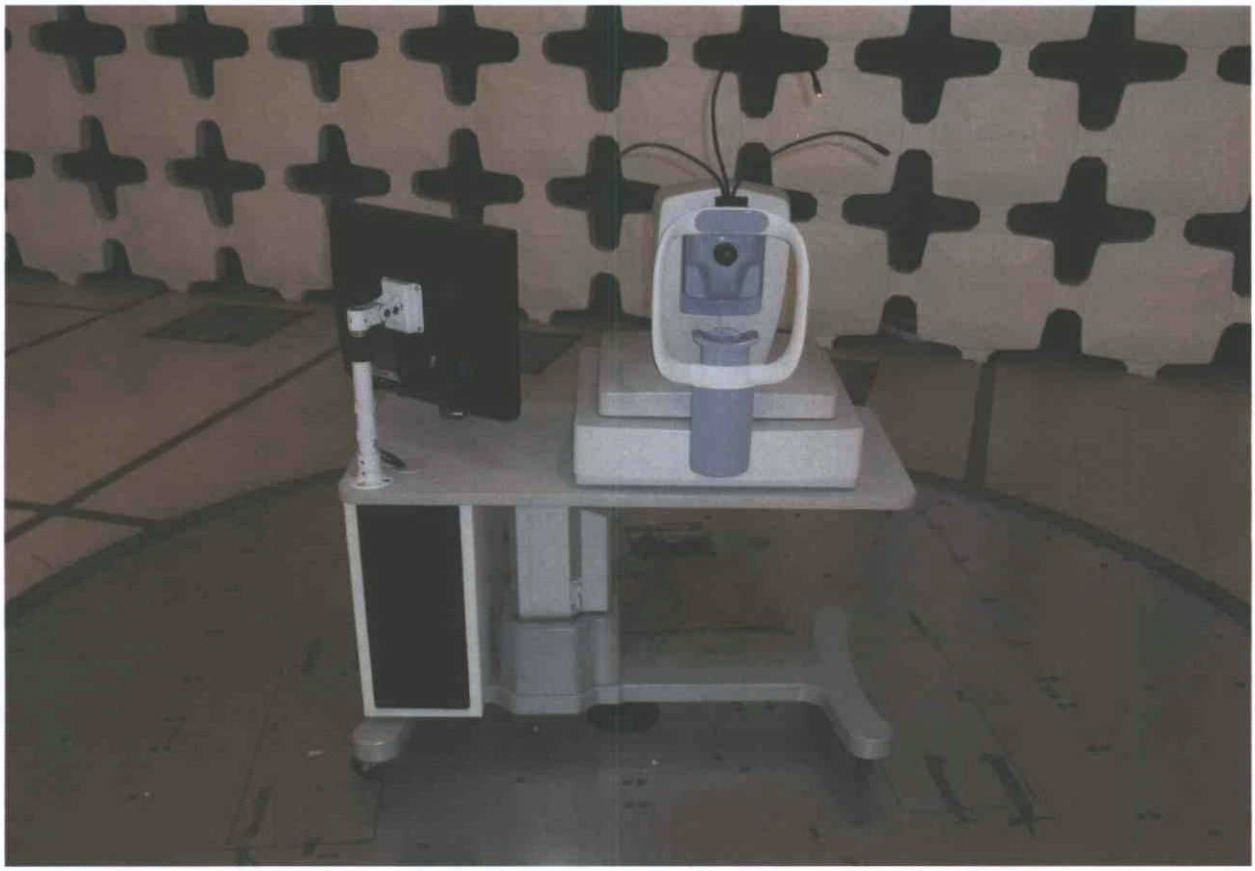
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Standard:	EN 60601-1-2:2007	Class:	A

Test Configuration Photograph #1
(Conducted Emissions - Power Port)



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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 #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Standard:	EN 60601-1-2:2007	Class:	A

Test Configuration Photograph #2
(Conducted Emissions - Power Port)

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Electrostatic Discharge (EN 61000-4-2)

Test Specific Details

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 11/23/2011 17:23
Test Engineer: Vishal Narayan\
Test Location: Fremont EMC Lab #1

Config. Used: 1
Config Change: None
EUT Voltage: 120V/60Hz

General Test Configuration

For table-top equipment, the EUT and all local support equipment were located on a 0.5-mm thick insulating layer above a horizontal coupling plane, 80 cm above a ground reference plane.

Unless otherwise stated, ten discharges at each voltage, and polarity, were applied to each test point listed. Contact discharges were applied to coupling planes and conductive surfaces of the EUT. Air discharges were applied to any non-conductive surfaces of the EUT. The VCP was located on the table top for table top devices and 80cm above the ground plane for floor standing equipment.

The determination as to the test point being a part of a conductive or non-conductive surface was based on the manufacturer's declaration.

Ambient Conditions:

Temperature: 22 °C
Relative Humidity: 33 %
Pressure: 1014 mb

Summary of Results - Electrostatic Discharges

Run #	Port	Test Level		Performance Criteria		Comments
		Required	Applied	Required	Met / Result	
1	Enclosure	6kV CD 8kV AD	6kV CD 8kV AD	A	A / Pass	

Modifications Made During Testing

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Run #1: Electrostatic Discharge

Indirect Discharges (To Coupling Planes)	Positive Polarity (kV)				Negative Polarity (kV)			
Contact Mode	Level 1 2	Level 2 4	Level 3 6	Level 4 8	Level 1 2	Level 2 4	Level 3 6	Level 4 8
Vertical Coupling Plane (VCP) located 10cm from the front, rear, left and right sides of the EUT	X	X	X		X	X	X	
Horizontal Coupling Plane (HCP) located 10cm from the front, rear, left and right sides of the EUT	X	X	X		X	X	X	

Direct Discharges (To the EUT)	Positive Polarity (kV)				Negative Polarity (kV)			
Contact Mode	Level 1 2	Level 2 4	Level 3 6	Level 4 8	Level 1 2	Level 2 4	Level 3 6	Level 4 8
Tested the actual table, Desktop PC, Monitor, Keyboard and the Eye Scanner as a system								
All Sides	X	X	X		X	X	X	
All Conductive Surfaces	X	X	X		X	X	X	
All Connector Shields	X	X	Note 1		X	X	X	
Latches	X	X	X		X	X	X	
Screws	X	X	X		X	X	X	
Buttons, switches and latches	X	X	X		X	X	X	
Joystick	X	X	X		X	X	X	

Air Discharge Mode	Level 1 2	Level 2 4	Level 3 8	Level 4 15	Level 1 2	Level 2 4	Level 3 8	Level 4 15
Tested the actual table, Desktop PC, Monitor, Keyboard and the Eye Scanner as a system								
All Sides	X	X	X		X	X	X	
All Seams	X	X	X		X	X	X	
All Non-Conductive Surfaces	X	X	X		X	X	X	
Display	X	X	X		X	X	X	
LED's	X	X	X		X	X	X	
Buttons, Switches and Knobs	X	X	X		X	X	X	
Keyboard	X	X	X		X	X	X	
Joystick	X	X	X		X	X	X	
Cables	X	X	X		X	X	X	

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Continuation of Run #1

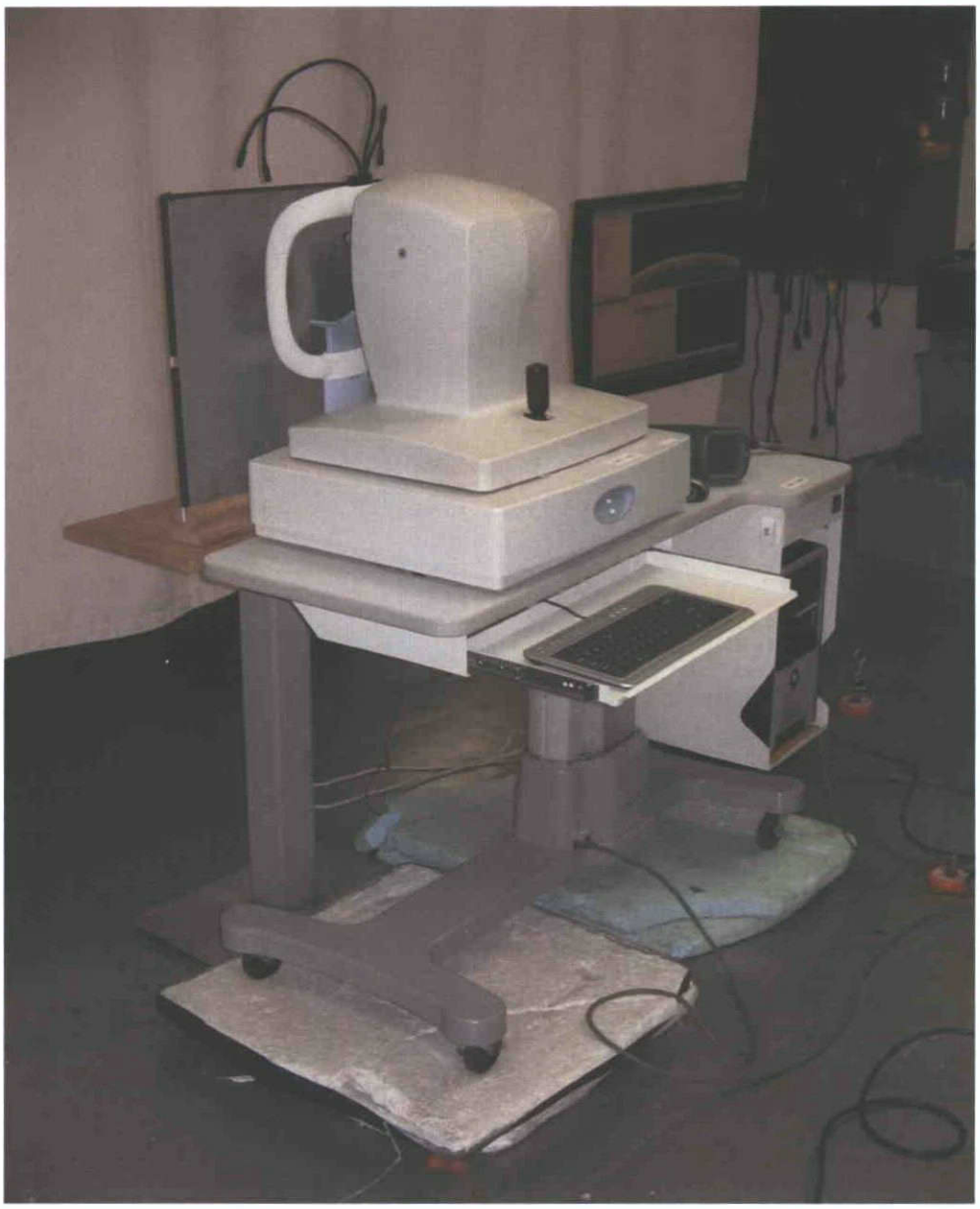
Note:	An "X" indicates that the unit continued to operate as intended. The EUT had a continuous video stream of the retina scan. There were no errors reported.
Note:	ND: No discharge was possible due to the lack of a discharge path to ground from the test point. HCP: Horizontal Coupling Plane. VCP: Vertical Coupling Plane
Note 1:	When discharge was applied to the connector shield of the front firewire, USB and Audio Ports the PC froze up. The mouse and the keyboard were not responding. The video stream of the retina scan seemed to be frozen up. The PC had to be restarted. Retested and the error was repeatable.

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Test Configuration Photograph #1
(Electrostatic Discharge, EN 61000-4-2)



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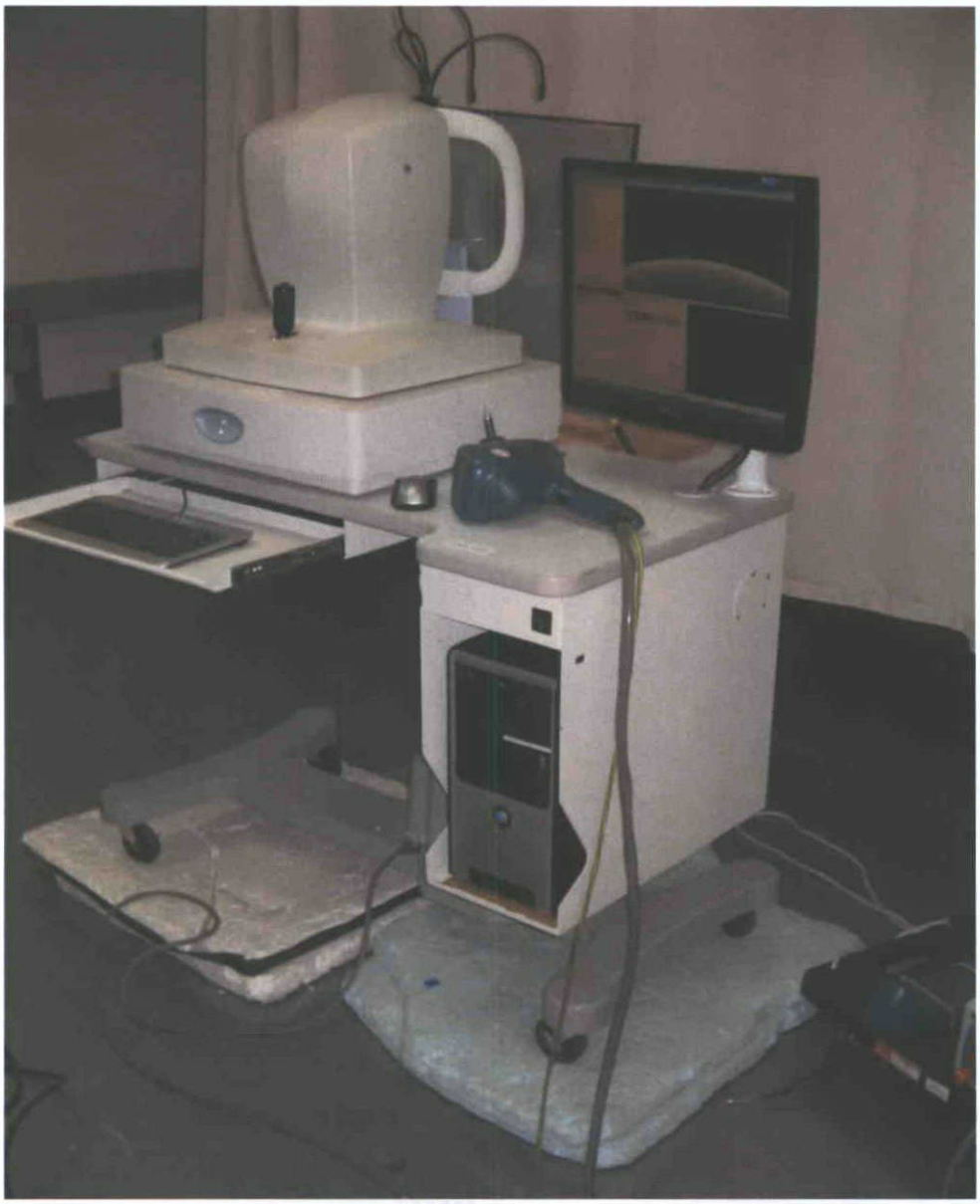
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Test Configuration Photograph #2
(Electrostatic Discharge, EN 61000-4-2)



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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NAS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Radiated Immunity (EN 61000-4-3)

Test Specific Details

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 11/27/2011 9:52
Test Engineer: Chris Groat
Test Location: Fremont Chamber #6
Config. Used: 1
Config Change: none
EUT Voltage: 120V/60Hz

General Test Configuration

The EUT and all local support equipment were located on a turntable in an anechoic chamber. All remote support equipment was located outside the chamber. Interface cabling to the remote support equipment was routed along the floor and, where possible, passed through ferrite clamps at the exit point from the chamber.

Ambient Conditions:

Temperature: 21 °C
Rel. Humidity: 42 %

Summary of Results-Radiated Immunity

Run #	Port	Test Level		Performance Criteria		Comments
		Required	Applied	Required	Met / Result	
EN 60601-1-2:2007						
1	Enclosure	80-2500 MHz 1kHz 80% AM 3 V/m	80-2500 MHz 1kHz 80% AM 3 V/m	A	A / Pass	Refer to Individual Run

Modifications Made During Testing

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NAT company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Run #1: Radiated Immunity, 80-2500 MHz (EN61000-4-3)

Frequency:	80-1000 MHz	1-2.5 GHz
Step Size:	1 %	1 %
Dwell time:	2874 ms	2874 ms
Field Uniformity:	1.5m x 1.5m	1.0m x 1.0m
Test Distance:	2 meters	2 meters

Modulation Details	
Modulating Frequency:	1 kHz
Modulation:	AM
Depth / Deviation:	80%

Frequency Range (MHz)	Level V/m	Front		Left Side		Rear		Right		Top		Bottom	
		Vert.	Horiz.	Vert.	Horiz.	Vert.	Horiz.	Vert.	Horiz.	Vert.	Horiz.	Vert.	Horiz.
80-1000	3	X	X	X	X	X	X	X	X	N/A	N/A	N/A	N/A
1000-2500	3	X	X	X	X	X	X	X	X	N/A	N/A	N/A	N/A
EN 55024 Select Frequencies (Note 1)	3	X	X	X	X	X	X	X	X	N/A	N/A	N/A	N/A

Test files used for this run:
The following calibration files from U:\EMC Stuff\RI Playback Files FT\CH6\Current\80-1000 MHz (April 2010)\03 Vm\ were used:
Position A 1.55m 80 MHz - 1000 MHz H 3Vm.crf
Position A 1.55m 80 MHz - 1000 MHz V 3Vm.crf
The following calibration files from U:\EMC Stuff\RI Playback Files FT\CH6\Current\1-2.7 GHz (April 2010)\3 Vm\ were used:
Position B 1.3m High 1000 MHz - 2700 MHz H 3Vm.crf
Position B 1.3m High 1000 MHz - 2700 MHz V 3Vm.crf

Note:	An "X" indicates that the unit continued to operate as intended. The EUT had a continuous video stream of the retina scan. Normal operation is indicated by a continuous video stream of the retina scan. When warning/error messages pops up this is acceptable as long as the system can be restarted. Then continue to perform imaging on the computer screen which shall be monitored by the PC Monitor. There were no errors reported.
Note 1:	As the EUT was telecommunications terminal equipment, functional checks of the system were made at the selected frequencies detailed in EN 55024 in accordance with Annex A of the standard. The selected frequencies are 80, 120, 160, 230, 434, 460, 600, 863 and 900 MHz.

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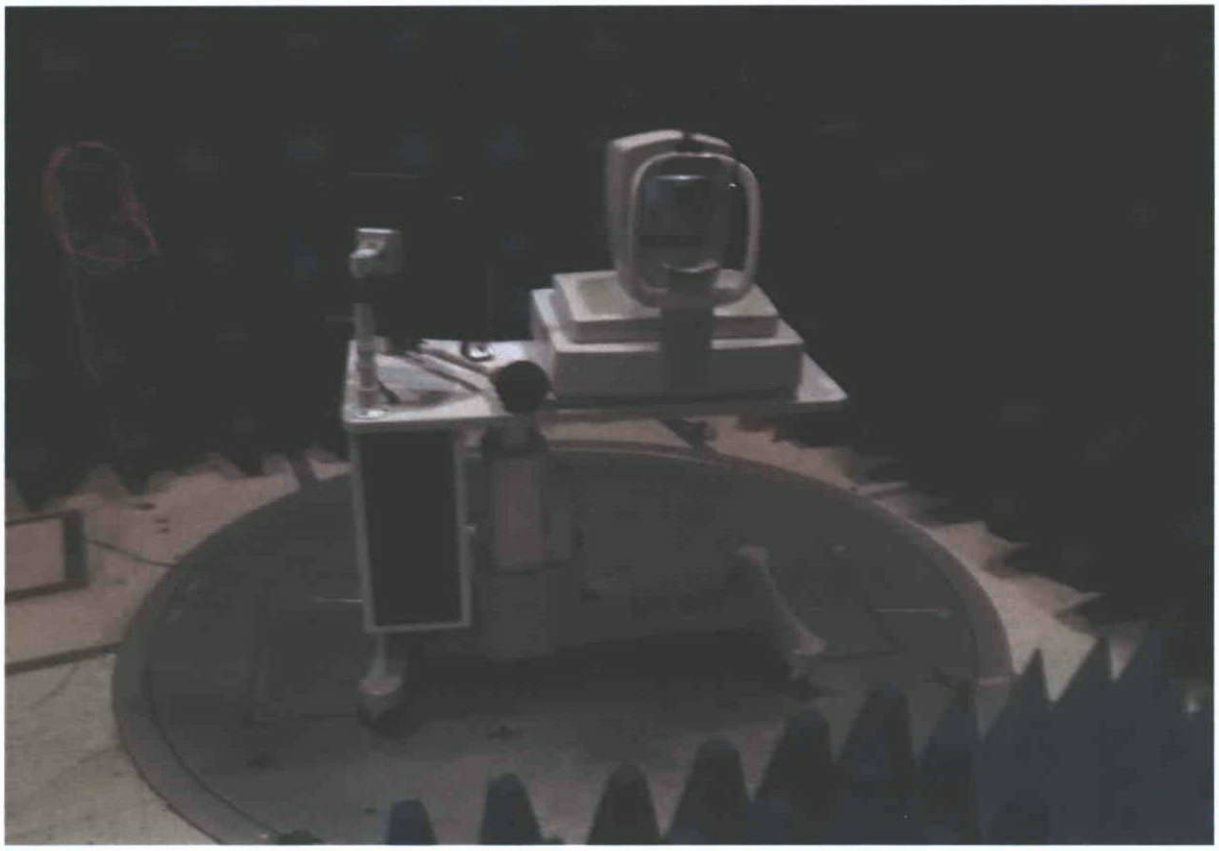
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Test Configuration Photograph #1
(Radiated Immunity, EN 61000-4-3)



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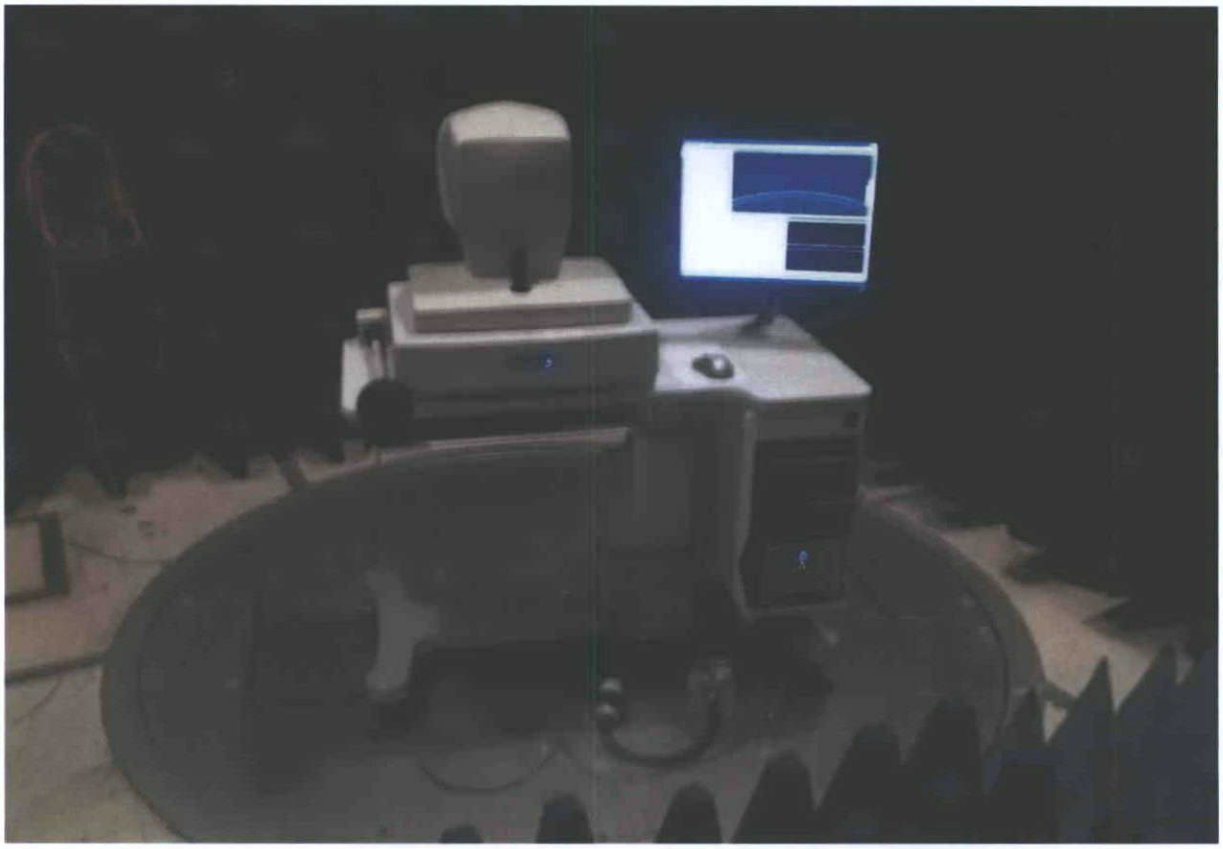
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Test Configuration Photograph #2
(Radiated Immunity, EN 61000-4-3)



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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott
An MTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Electrical Fast Transient/Burst (EFT/B) (EN 61000-4-4)

Test Specific Details

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 11/23/2011 17:23
Test Engineer: Vishal Narayan
Test Location: Fremont EMC Lab #1
Config. Used: 1
Config Change: None
EUT Voltage: 120V/60Hz

General Test Configuration

The EUT system was located 10 cm above a ground reference plane. A 0.5m long power cord was used between the EUT's power port and the coupling/decoupling network. Interference was coupled onto the cables connected to the ports identified in the test data tables using the capacitive trench, with a maximum length of 0.5m of cable between the interface port and the trench.

Ambient Conditions:

Temperature: 20 °C
Rel. Humidity: 41 %

Summary of Results

Run #	Port	Test Level		Performance Criteria		Comments
		Required	Applied	Required	Met / Result	
1	AC Power	± 2 kV	± 2 kV	A	A / Pass	

Modifications Made During Testing

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Run #1: EFT/B Testing

Test Parameters	
Waveform: 5 ns / 50 ns	Burst Period: 300 ms
Repetition Frequency: 5 kHz (2.5 kHz @ 4 kV)	Burst Width: 15 ms

Applied Location	Positive Polarity (kV)				Negative Polarity (kV)			
Power Line AC Power Port(s)	Level 1 0.5	Level 2 1.0	Level 3 2.0	Level 4 4.0	Level 1 0.5	Level 2 1.0	Level 3 2.0	Level 4 4.0
Line + Neutral + Protective Earth *(3-Wire AC Power Port)*	X	X	X		X	X	X	

Note:	An "X" indicates that the unit continued to operate as intended. The EUT had a continuous video stream of the retina scan. There were no errors reported.
Note 1:	The interface cables for the I/O ports tested were routed through the capacitive trench and tested simultaneously.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Test Configuration Photograph #1
(Electrical Fast Transient/Burst, EN 61000-4-4)

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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 #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Test Configuration Photograph #2
(Electrical Fast Transient/Burst, EN 61000-4-4)

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Surge (EN 61000-4-5)

Test Specific Details

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 11/28/2011 18:01
Test Engineer: Vishal Narayan
Test Location: Fremont EMC Lab #2

Config. Used: 1
Config Change: None
EUT Voltage: 120V/60Hz

General Test Configuration

The EUT and all local support equipment were located on a non-conductive bench.

Ambient Conditions:

Temperature: 20 °C
Rel. Humidity: 41 %

Summary of Results

Run #	Port	Test Level		Performance Criteria		Comments
		Required	Applied	Required	Met / Result	
1	AC Power	± 2 kV CM ± 1 kV DM	± 2 kV CM ± 1 kV DM	A	A / Pass	

Modifications Made During Testing

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NAS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Run #1: Surge Immunity, Power Line
AC Power Port

Test Parameters
Waveform: 1.2/50µS
Impedance: 12 Ohms (Common Mode), 2 Ohms (Differential Mode)

Applied Location	Positive Polarity (kV)				Negative Polarity (kV)			
Power Line	Level 1 0.5	Level 2 1.0	Level 3 2.0	Level 4 4.0	Level 1 0.5	Level 2 1.0	Level 3 2.0	Level 4 4.0
Line to Line (Differential Mode)								
0°	X	X			X	X		
90°	X	X			X	X		
180°	X	X			X	X		
270°	X	X			X	X		
Line to PE (Common Mode)								
0°	X	X	X		X	X	X	
90°	X	X	X		X	X	X	
180°	X	X	X		X	X	X	
270°	X	X	X		X	X	X	
Neutral to PE (Common Mode)								
0°	X	X	X		X	X	X	
90°	X	X	X		X	X	X	
180°	X	X	X		X	X	X	
270°	X	X	X		X	X	X	

Note: The EUT had a continuous video stream of the retina scan. There were no errors reported.

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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 #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Test Configuration Photograph #1
(Surge, EN 61000-4-5)

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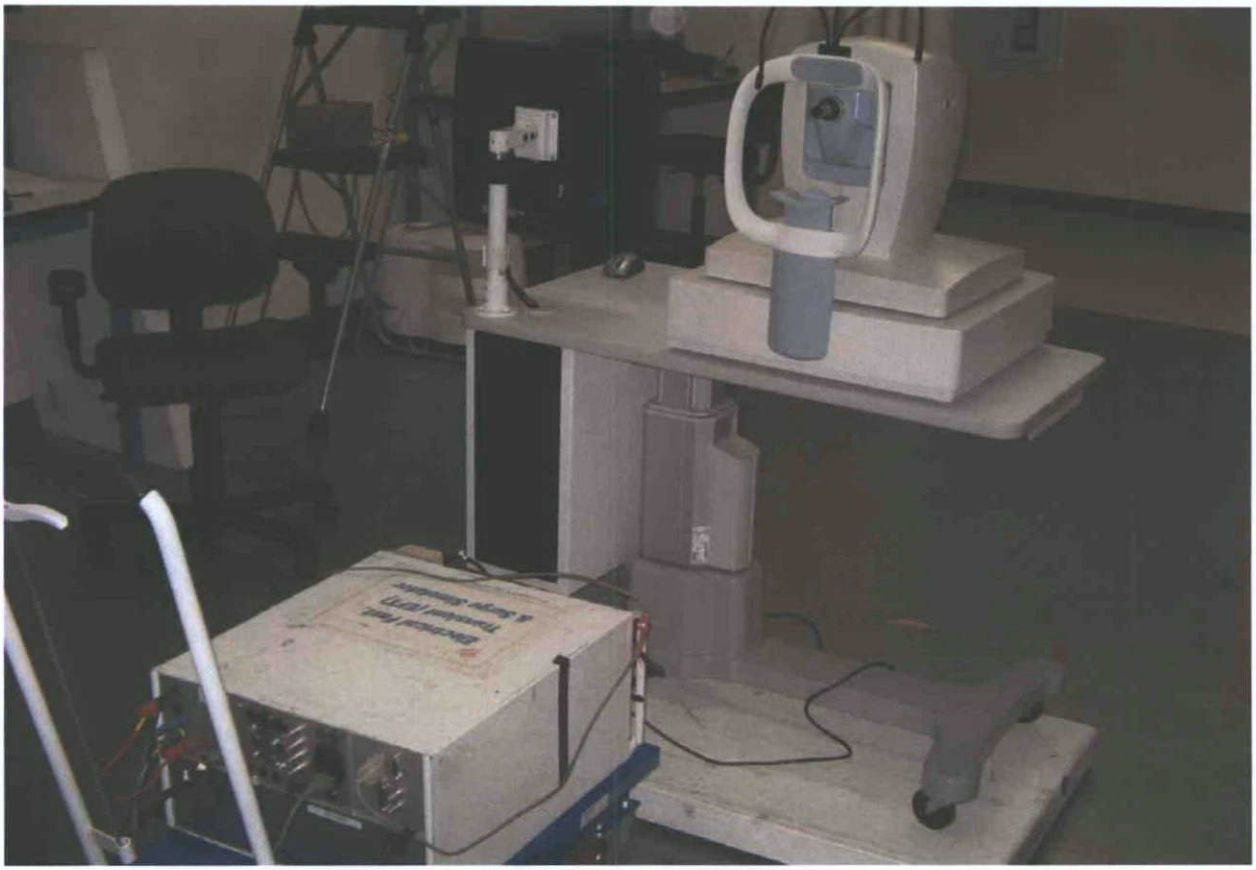
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Test Configuration Photograph #2
(Surge, EN 61000-4-5)



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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Conducted Immunity (EN 61000-4-6)

Test Specific Details

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 11/28/2011 19:00
Test Engineer: Vishal Narayan
Test Location: Fremont EMC Lab #2
Config. Used: 1
Config Change: None
EUT Voltage: 120V/60Hz

General Test Configuration

The EUT and all local support equipment were placed on an insulating support 10 cm above a ground reference plane. All interface cables between parts of the EUT (for equipment comprising several units) and to local support equipment were also placed on the insulating support. All interface cabling between the EUT and the coupling and decoupling network(s) were located 3 to 5 cm above the ground reference plane.

Ambient Conditions:

Temperature: 20 °C
Rel. Humidity: 41 %

Summary of Results - Conducted Immunity

Run #	Port	Test Level		Performance Criteria		Comments
		Required	Applied	Required	Met / Result	
1	AC power	0.15-80MHz 1kHz 80% AM 3 Vrms	0.15-80MHz 1kHz 80% AM 3 Vrms	A	A / Pass	

Modifications Made During Testing

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Run #1: Conducted Susceptibility (EN61000-4-6)

Test Level:	3 Vrms
Step Size:	1 %
Dwell time:	2874 ms

Modulation Details	
Modulating Frequency:	1 kHz
Modulation:	AM
Depth / Deviation:	80%

Frequency Range MHz	Port Under Test	Injection Method	Comments
0.15 - 80	Power Supply	M3	Note 1

Note 1: The EUT had a continuous video stream of the retina scan. There were no errors reported.

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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 #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Test Configuration Photograph #1
(Conducted Immunity, EN 61000-4-6)

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

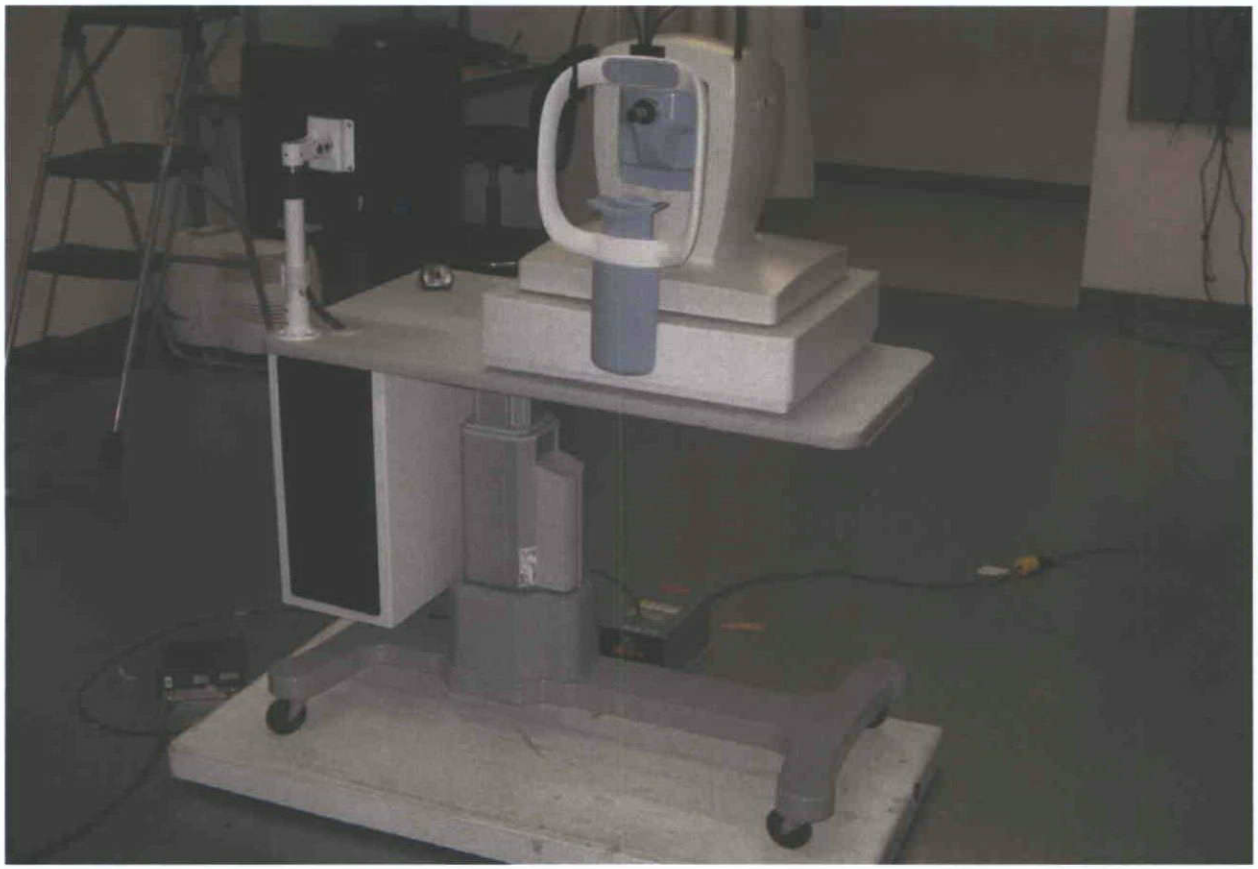
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NAS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Test Configuration Photograph #2
(Conducted Immunity, EN 61000-4-6)



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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott
An MAS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Power Frequency Magnetic Field (EN 61000-4-8)

Test Specific Details

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 11/27/2011 9:52
Test Engineer: Chris Groat
Test Location: Fremont EMC Lab #5

Config. Used: 1
Config Change: none
EUT Voltage: 120V/50/60Hz

General Test Configuration

The EUT and all local support equipment were located above a conductive ground plane. The EUT was positioned inside the 1m field-generating loop during the test.

Ambient Conditions

Temperature: 21 °C
Rel. Humidity: 42 %

Summary of Results

Run #	Port	Test Level		Performance Criteria		Comments
		Required	Applied	Required	Met / Result	
1	Enclosure	3 A/m 50Hz / 60Hz	3 A/m 50Hz / 60Hz	A	A / Pass	Refer to Individual Run

Modifications Made During Testing

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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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 #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Run #1: Power Frequency Magnetic Field Immunity (EN61000-4-8)

Frequency (Hz)	Level A/m	EUT Orientation		
		"X" Axis	"Y" Axis	"Z" Axis
50	1.0	X	X	X
50	3.0	X	X	X

Frequency (Hz)	Level A/m	EUT Orientation		
		"X" Axis	"Y" Axis	"Z" Axis
60	1.0	X	X	X
60	3.0	X	X	X

Notes:	
Note 1:	An "X" indicates that the unit continued to operate as intended. The EUT had a continuous video stream of the retina scan. Normal operation is indicated by a continuous video stream of the retina scan. When warning/error messages pops up this is acceptable as long as the system can be restarted. Then continue to perform imaging on the computer screen which shall be monitored by the PC Monitor. There were no errors reported.

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Test Configuration Photograph #1
(Power Frequency Magnetic Immunity, EN 61000-4-8)

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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 #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Test Configuration Photograph #2
(Power Frequency Magnetic Immunity, EN 61000-4-8)

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Voltage Dips and Interrupts (EN 61000-4-11)

Test Specific Details

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 11/23/2011 17:23
Test Engineer: Vishal Narayan
Test Location: Fremont EMC Lab #1

Config. Used: 1
Config Change: None
EUT Voltage: 120V/60Hz

General Test Configuration

The EUT and all local support equipment were located on a non-conductive bench.

Ambient Conditions:

Temperature: 21 °C
Rel. Humidity: 33 %

Summary of Results

Run #	Port	Test Level Required	Test Level Applied	Performance Criteria Required	Performance Criteria Met / Result	Comments
EN 60601-1-2 (Test required at both MIN and MAX operating voltages, always tested at MIN operating frequency)						
1	AC power	>95% 0.5 periods	>95% 0.5 periods	A	A / Pass	
1	AC power	60% 5 periods	60% 5 periods	A	A / Pass	Refer to Note 3
1	AC power	30% 25 periods	30% 25 periods	A	A / Pass	
1	AC power	>95% 5 seconds	>95% 5 seconds	A	A / Pass	Refer to Note 3

Modifications Made During Testing

No modifications were made to the EUT during testing

Deviations From The Standard

No deviations were made from the requirements of the standard.

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Elliott
An NTS company

EMC Test Data

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Run #1: Voltage Dips and Interrupts

Nominal Operating Voltage of EUT:	120 Volts	60 Hz

Voltage Dips/Time % / ms or % / periods	Port Under Test	Interrupt Voltage	Comments
>95% 0.5 periods	AC Power	0V	Note 1
60% 5 periods	AC Power	48V	Note 2
30% 25 periods	AC Power	84V	Note 1
>95% 5 seconds	AC Power	0V	Note 3

Note 1:	The EUT had a continuous video stream of the retina scan. There were no errors reported.
Note 2:	The Monitor turned off for 5 periods and then turned back ON. When the monitor turned back ON the display a continuous video stream of the retina scan proving that the scanner and the PC never turned OFF.
Note 3:	The whole system turned OFF and had to be restarted.

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Test Configuration Photograph #1
(Voltage Dips and Interrupts, EN 61000-4-11)

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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 #2012-3758; Released by CDRH on 09-8-2015

Client:	Optovue	Job Number:	J85563
Model:	RTVue XR	T-Log Number:	T85575
		Account Manager:	Sheareen Washington
Contact:	David Chen		
Immunity Standard(s):	EN 60601-1-2:2007	Environment:	Medical

Test Configuration Photograph #2
(Voltage Dips and Interrupts, EN 61000-4-11)

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

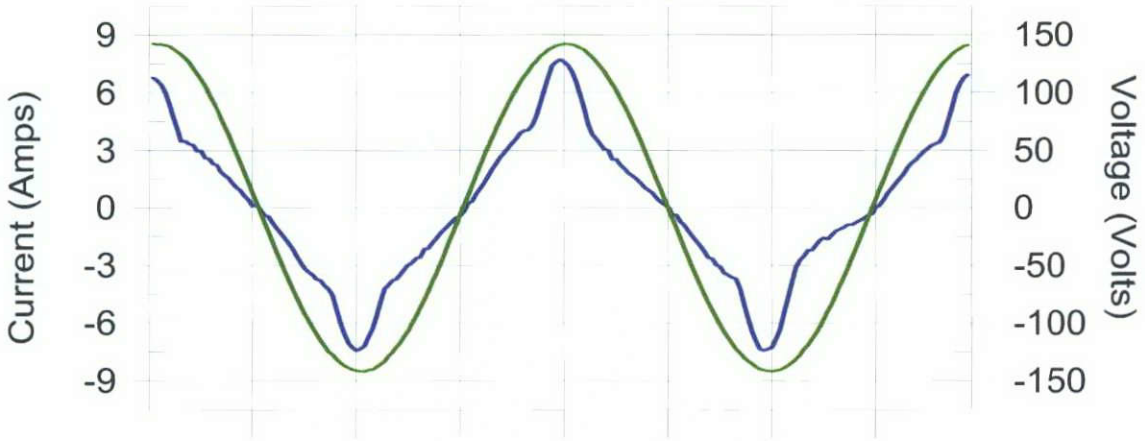
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Appendix C Current Harmonics Test Data (EN 61000-3-2)
Harmonics – Class-A per A-14(Run time)

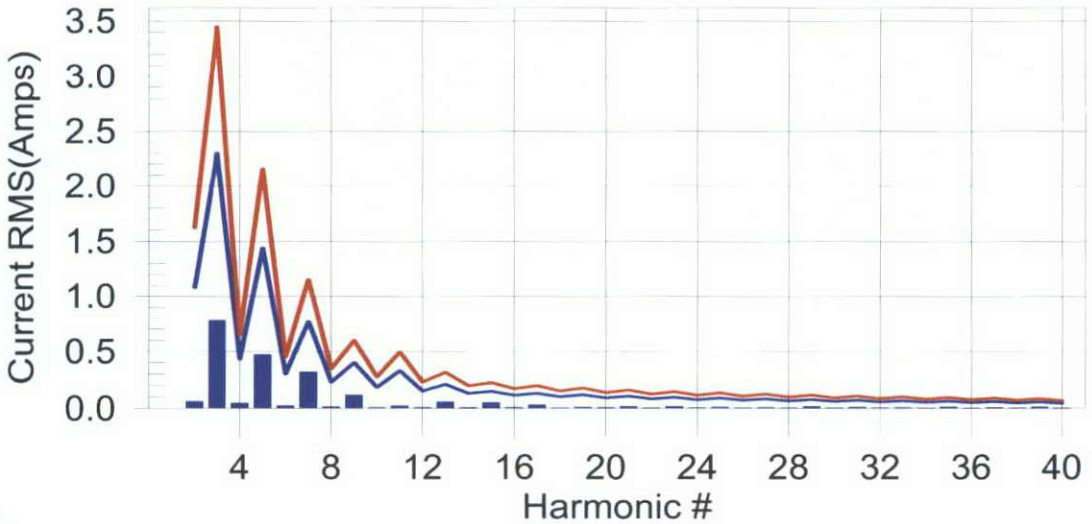
EUT: RTVue **Tested by: Chris Groat**
Test category: Class-A per A-14 (European limits) **Test Margin: 100**
Test date: 4/18/2006 **Start time: 11:33:47 AM** **End time: 11:43:57 AM**
Test duration (min): 10 **Data file name: H-000751.cts_data**
Comment: J63556/T63585
Customer: Optovue

Test Result: Pass **Source qualification: Normal**

Current & voltage waveforms



Harmonics and Class A limit line **European Limits**



Test result: Pass **Worst harmonic was #7 with 27.42 % of the limit.**

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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 #2012-3758; Released by CDRH on 09-8-2015

Current Test Result Summary (Run time)

EUT: RTVue **Tested by: Chris Groat**
Test category: Class-A per A-14 (European limits) **Test Margin: 100**
Test date: 4/18/2006 **Start time: 11:33:47 AM** **End time: 11:43:57 AM**
Test duration (min): 10 **Data file name: H-000751.cts_data**
Comment: J63556/T63585
Customer: Optovue

Test Result: Pass **Source qualification: Normal**

Highest parameter values during test:

V_RMS (Volts):	100.38		
I_Peak (Amps):	7.720	I_RMS (Amps):	3.539
I_Fund (Amps):	3.402	Crest Factor:	2.609
Power (Watts):	343	Power Factor:	0.966

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.051	1.080	4.7	0.058	1.620	3.56	Pass
3	0.733	2.300	31.9	0.779	3.450	22.58	Pass
4	0.040	0.430	9.3	0.043	0.645	6.61	Pass
5	0.457	1.440	31.7	0.471	2.160	21.81	Pass
6	0.017	0.300	5.7	0.019	0.450	4.23	Pass
7	0.307	0.770	39.8	0.317	1.155	27.42	Pass
8	0.011	0.230	4.9	0.013	0.345	3.64	Pass
9	0.114	0.400	28.4	0.117	0.600	19.48	Pass
10	0.005	0.184	2.8	0.007	0.276	2.46	Pass
11	0.016	0.330	4.8	0.021	0.495	4.33	Pass
12	0.004	0.153	2.9	0.006	0.230	2.67	Pass
13	0.049	0.210	23.2	0.055	0.315	17.30	Pass
14	0.004	0.131	2.8	0.005	0.197	2.65	Pass
15	0.045	0.150	30.0	0.048	0.225	21.35	Pass
16	0.004	0.115	3.2	0.005	0.173	3.03	Pass
17	0.026	0.132	19.4	0.028	0.199	14.11	Pass
18	0.004	0.102	3.6	0.005	0.153	3.24	Pass
19	0.009	0.118	7.3	0.010	0.178	5.82	Pass
20	0.004	0.092	4.1	0.005	0.138	3.80	Pass
21	0.014	0.107	13.0	0.016	0.161	9.68	Pass
22	0.004	0.084	4.3	0.005	0.125	3.99	Pass
23	0.015	0.098	15.3	0.016	0.147	11.22	Pass
24	0.004	0.077	4.6	0.005	0.115	4.22	Pass
25	0.009	0.090	10.2	0.010	0.135	7.58	Pass
26	0.003	0.071	4.8	0.005	0.106	4.63	Pass
27	0.005	0.083	6.4	0.006	0.125	4.88	Pass
28	0.003	0.066	5.1	0.005	0.099	4.69	Pass
29	0.015	0.078	18.7	0.016	0.116	13.79	Pass
30	0.003	0.061	5.5	0.005	0.092	5.10	Pass
31	0.006	0.073	8.1	0.008	0.109	6.99	Pass
32	0.003	0.058	5.7	0.005	0.086	5.30	Pass
33	0.004	0.068	6.1	0.005	0.102	5.17	Pass
34	0.003	0.054	6.1	0.005	0.081	5.81	Pass
35	0.011	0.064	16.4	0.013	0.096	13.90	Pass
36	0.003	0.051	6.5	0.005	0.077	6.15	Pass
37	0.005	0.061	7.7	0.006	0.091	7.06	Pass
38	0.003	0.048	6.9	0.005	0.073	6.66	Pass
39	0.008	0.058	14.1	0.011	0.087	12.30	Pass
40	0.003	0.046	5.6	0.004	0.069	5.50	Pass

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Voltage Source Verification Data (Run time)

EUT: RTVue **Tested by: Chris Groat**
Test category: Class-A per A-14 (European limits) **Test Margin: 100**
Test date: 4/18/2006 **Start time: 11:33:47 AM** **End time: 11:43:57 AM**
Test duration (min): 10 **Data file name: H-000751.cts_data**
Comment: J63556/T63585
Customer: Optovue

Test Result: Pass **Source qualification: Normal**

Highest parameter values during test:

Voltage (Vrms):	100.38		
I_Peak (Amps):	7.720	I_RMS (Amps):	3.539
I_Fund (Amps):	3.402	Crest Factor:	2.609
Power (Watts):	343	Power Factor:	0.966

Harm#	Harmonics V-rms	Limit V-rms	% of Limit	Status
2	0.029	0.201	14.62	OK
3	0.209	0.903	23.19	OK
4	0.016	0.201	7.95	OK
5	0.076	0.401	18.87	OK
6	0.024	0.201	11.78	OK
7	0.070	0.301	23.25	OK
8	0.014	0.201	6.82	OK
9	0.025	0.201	12.41	OK
10	0.009	0.201	4.68	OK
11	0.009	0.100	9.30	OK
12	0.002	0.100	2.11	OK
13	0.006	0.100	5.51	OK
14	0.001	0.100	1.34	OK
15	0.006	0.100	5.87	OK
16	0.003	0.100	3.28	OK
17	0.003	0.100	3.27	OK
18	0.003	0.100	3.18	OK
19	0.001	0.100	1.47	OK
20	0.024	0.100	23.80	OK
21	0.016	0.100	15.47	OK
22	0.011	0.100	10.70	OK
23	0.010	0.100	10.29	OK
24	0.011	0.100	10.56	OK
25	0.001	0.100	1.49	OK
26	0.011	0.100	11.21	OK
27	0.001	0.100	1.30	OK
28	0.011	0.100	11.43	OK
29	0.023	0.100	23.35	OK
30	0.010	0.100	10.35	OK
31	0.013	0.100	13.09	OK
32	0.010	0.100	9.87	OK
33	0.005	0.100	4.62	OK
34	0.010	0.100	9.75	OK
35	0.021	0.100	21.07	OK
36	0.015	0.100	15.38	OK
37	0.019	0.100	18.52	OK
38	0.016	0.100	15.78	OK
39	0.018	0.100	18.26	OK
40	0.028	0.100	27.57	OK

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

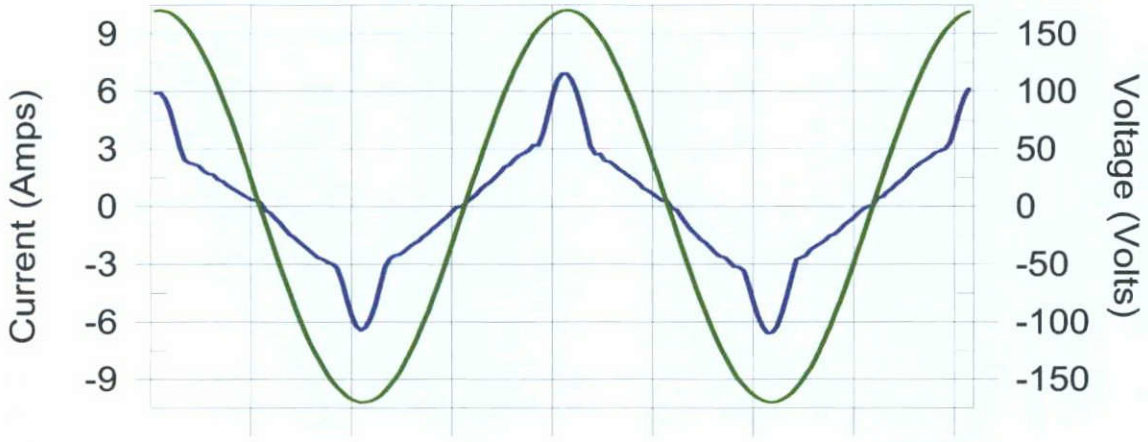
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Harmonics – Class-A per A-14(Run time)

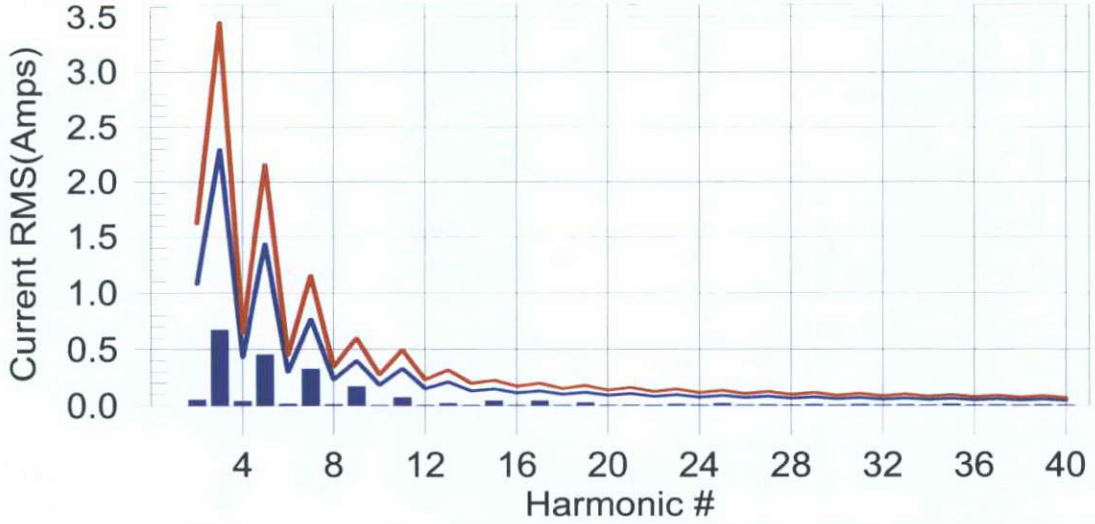
EUT: RTVue **Tested by: Chris Groat**
Test category: Class-A per A-14 (European limits) **Test Margin: 100**
Test date: 4/18/2006 **Start time: 1:38:08 PM** **End time: 1:48:18 PM**
Test duration (min): 10 **Data file name: H-000753.cts_data**
Comment: J63556/T63585
Customer: Optovue

Test Result: Pass **Source qualification: Normal**

Current & voltage waveforms



Harmonics and Class A limit line **European Limits**



Test result: Pass **Worst harmonic was #7 with 28.10 % of the limit.**

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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 #2012-3758; Released by CDRH on 09-8-2015

Current Test Result Summary (Run time)

EUT: RTVue **Tested by: Chris Groat**
Test category: Class-A per A-14 (European limits) **Test Margin: 100**
Test date: 4/18/2006 **Start time: 1:38:08 PM** **End time: 1:48:18 PM**
Test duration (min): 10 **Data file name: H-000753.cts_data**
Comment: J63556/T63585
Customer: Optovue

Test Result: Pass **Source qualification: Normal**

Highest parameter values during test:

V_RMS (Volts):	120.50		
I_Peak (Amps):	6.916	I_RMS (Amps):	2.930
I_Fund (Amps):	2.784	Crest Factor:	2.598
Power (Watts):	338	Power Factor:	0.958

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.043	1.080	4.0	0.051	1.620	3.13	Pass
3	0.656	2.300	28.5	0.671	3.450	19.44	Pass
4	0.034	0.430	7.8	0.038	0.645	5.88	Pass
5	0.443	1.440	30.8	0.452	2.160	20.94	Pass
6	0.014	0.300	4.8	0.017	0.450	3.71	Pass
7	0.320	0.770	41.6	0.325	1.155	28.10	Pass
8	0.010	0.230	4.3	0.011	0.345	3.25	Pass
9	0.162	0.400	40.6	0.168	0.600	28.02	Pass
10	0.004	0.184	2.4	0.005	0.276	1.90	Pass
11	0.067	0.330	20.2	0.072	0.495	14.53	Pass
12	0.004	0.153	2.6	0.005	0.230	2.07	Pass
13	0.017	0.210	8.2	0.020	0.315	6.28	Pass
14	0.004	0.131	2.8	0.004	0.197	2.18	Pass
15	0.039	0.150	25.8	0.041	0.225	18.40	Pass
16	0.004	0.115	3.2	0.004	0.173	2.53	Pass
17	0.041	0.132	31.1	0.043	0.199	21.67	Pass
18	0.004	0.102	3.4	0.004	0.153	2.73	Pass
19	0.024	0.118	19.9	0.026	0.178	14.50	Pass
20	0.003	0.092	3.8	0.004	0.138	3.08	Pass
21	0.005	0.107	4.2	0.006	0.161	3.68	Pass
22	0.003	0.084	4.1	0.004	0.125	3.38	Pass
23	0.010	0.098	10.4	0.012	0.147	8.08	Pass
24	0.003	0.077	4.4	0.004	0.115	3.54	Pass
25	0.017	0.090	19.0	0.018	0.135	13.41	Pass
26	0.003	0.071	4.7	0.004	0.106	3.84	Pass
27	0.005	0.083	6.1	0.006	0.125	5.07	Pass
28	0.003	0.066	5.0	0.004	0.099	4.12	Pass
29	0.009	0.078	11.6	0.011	0.116	9.78	Pass
30	0.003	0.061	5.4	0.004	0.092	4.36	Pass
31	0.009	0.073	13.1	0.011	0.109	9.70	Pass
32	0.003	0.058	5.8	0.004	0.086	4.69	Pass
33	0.006	0.068	9.4	0.008	0.102	7.42	Pass
34	0.003	0.054	6.1	0.004	0.081	4.97	Pass
35	0.011	0.064	17.0	0.012	0.096	12.64	Pass
36	0.003	0.051	6.5	0.004	0.077	5.21	Pass
37	0.006	0.061	9.3	0.007	0.091	7.83	Pass
38	0.003	0.048	6.9	0.004	0.073	5.64	Pass
39	0.007	0.058	12.9	0.009	0.087	9.97	Pass
40	0.002	0.046	5.4	0.003	0.069	4.53	Pass

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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 #2012-3758; Released by CDRH on 09-8-2015

Voltage Source Verification Data (Run time)

EUT: RTVue **Tested by: Chris Groat**
Test category: Class-A per A-14 (European limits) **Test Margin: 100**
Test date: 4/18/2006 **Start time: 1:38:08 PM** **End time: 1:48:18 PM**
Test duration (min): 10 **Data file name: H-000753.cts_data**
Comment: J63556/T63585
Customer: Optovue

Test Result: Pass **Source qualification: Normal**

Highest parameter values during test:

Voltage (Vrms):	120.50		
I_Peak (Amps):	6.916	I_RMS (Amps):	2.930
I_Fund (Amps):	2.784	Crest Factor:	2.598
Power (Watts):	338	Power Factor:	0.958

Harm#	Harmonics V-rms	Limit V-rms	% of Limit	Status
2	0.204	0.241	84.79	OK
3	0.341	1.084	31.43	OK
4	0.033	0.241	13.85	OK
5	0.122	0.482	25.26	OK
6	0.012	0.241	5.13	OK
7	0.107	0.361	29.58	OK
8	0.027	0.241	11.14	OK
9	0.054	0.241	22.22	OK
10	0.015	0.241	6.32	OK
11	0.012	0.120	10.15	OK
12	0.001	0.120	0.58	OK
13	0.002	0.120	1.96	OK
14	0.002	0.120	1.61	OK
15	0.004	0.120	3.57	OK
16	0.006	0.120	4.67	OK
17	0.006	0.120	4.83	OK
18	0.012	0.120	9.84	OK
19	0.002	0.120	1.64	OK
20	0.011	0.120	9.04	OK
21	0.001	0.120	1.18	OK
22	0.010	0.120	8.03	OK
23	0.010	0.120	8.52	OK
24	0.010	0.120	7.92	OK
25	0.013	0.120	10.92	OK
26	0.010	0.120	8.47	OK
27	0.002	0.120	1.36	OK
28	0.010	0.120	8.50	OK
29	0.008	0.120	6.31	OK
30	0.015	0.120	12.12	OK
31	0.023	0.120	19.14	OK
32	0.014	0.120	11.48	OK
33	0.017	0.120	13.71	OK
34	0.012	0.120	9.62	OK
35	0.023	0.120	19.02	OK
36	0.011	0.120	9.08	OK
37	0.019	0.120	15.85	OK
38	0.012	0.120	9.75	OK
39	0.018	0.120	15.09	OK
40	0.011	0.120	9.35	OK

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

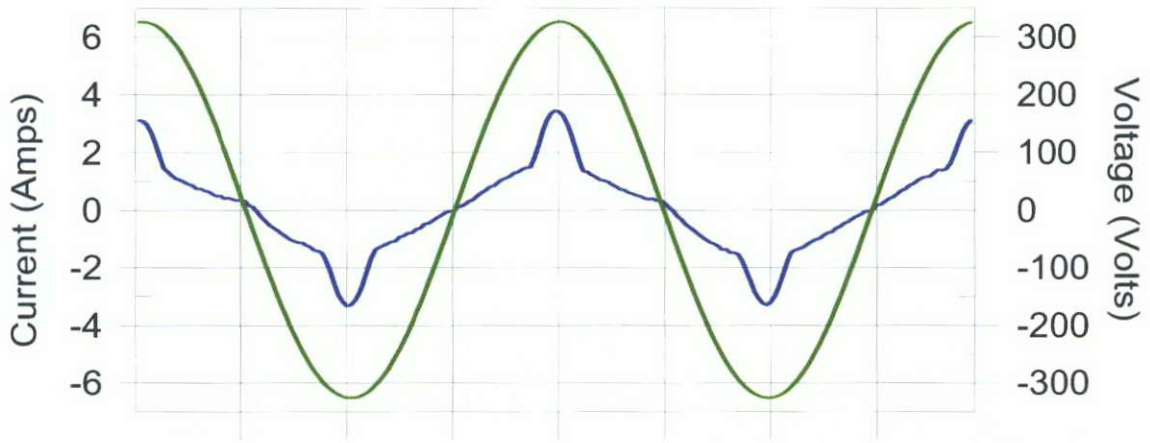
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Harmonics – Class-A per A-14(Run time)

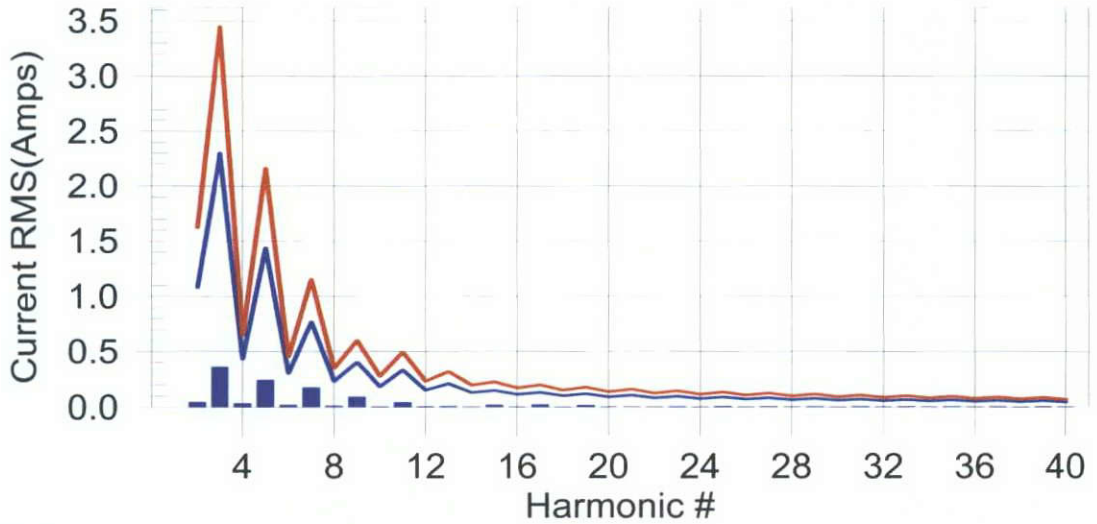
EUT: RTVue **Tested by: Chris Groat**
Test category: Class-A per A-14 (European limits) **Test Margin: 100**
Test date: 4/18/2006 **Start time: 2:58:21 PM** **End time: 3:08:31 PM**
Test duration (min): 10 **Data file name: H-000755.cts_data**
Comment: J63556/T63585
Customer: Optovue

Test Result: Pass **Source qualification: Normal**

Current & voltage waveforms



Harmonics and Class A limit line **European Limits**



Test result: Pass **Worst harmonic was #9 with 15.22 % of the limit.**

737

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Current Test Result Summary (Run time)

EUT: RTVue **Tested by: Chris Groat**
Test category: Class-A per A-14 (European limits) **Test Margin: 100**
Test date: 4/18/2006 **Start time: 2:58:21 PM** **End time: 3:08:31 PM**
Test duration (min): 10 **Data file name: H-000755.cts_data**
Comment: J63556/T63585
Customer: Optovue

Test Result: Pass **Source qualification: Normal**

Highest parameter values during test:

V_RMS (Volts):	230.89		
I_Peak (Amps):	3.445	I_RMS (Amps):	1.509
I_Fund (Amps):	1.429	Crest Factor:	2.623
Power (Watts):	332	Power Factor:	0.954

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.041	1.080	3.8	0.044	1.620	2.70	Pass
3	0.352	2.300	15.3	0.358	3.450	10.37	Pass
4	0.031	0.430	7.2	0.032	0.645	5.01	Pass
5	0.237	1.440	16.5	0.240	2.160	11.12	Pass
6	0.018	0.300	6.0	0.019	0.450	4.17	Pass
7	0.172	0.770	22.4	0.174	1.155	15.05	Pass
8	0.010	0.230	4.4	0.011	0.345	3.13	Pass
9	0.089	0.400	22.2	0.091	0.600	15.22	Pass
10	0.005	0.184	2.9	0.006	0.276	2.07	Pass
11	0.040	0.330	12.1	0.041	0.495	8.36	Pass
12	0.003	0.153	1.8	0.003	0.230	1.38	Pass
13	0.008	0.210	3.7	0.008	0.315	2.61	Pass
14	0.002	0.131	1.6	0.002	0.197	1.22	Pass
15	0.019	0.150	12.5	0.020	0.225	8.94	Pass
16	0.002	0.115	1.4	0.002	0.173	1.13	Pass
17	0.023	0.132	17.5	0.024	0.199	11.91	Pass
18	0.001	0.102	1.4	0.002	0.153	1.15	Pass
19	0.014	0.118	11.7	0.015	0.178	8.57	Pass
20	0.001	0.092	1.6	0.002	0.138	1.28	Pass
21	0.003	0.107	2.4	0.003	0.161	1.74	Pass
22	0.001	0.084	1.7	0.002	0.125	1.41	Pass
23	0.005	0.098	5.5	0.006	0.147	3.96	Pass
24	0.001	0.077	1.9	0.002	0.115	1.50	Pass
25	0.008	0.090	8.9	0.009	0.135	6.34	Pass
26	0.001	0.071	2.0	0.002	0.106	1.66	Pass
27	0.005	0.083	5.7	0.005	0.125	4.09	Pass
28	0.001	0.066	2.2	0.002	0.099	1.81	Pass
29	0.004	0.078	5.8	0.005	0.116	4.70	Pass
30	0.001	0.061	2.4	0.002	0.092	1.90	Pass
31	0.003	0.073	4.4	0.004	0.109	3.25	Pass
32	0.002	0.058	2.6	0.002	0.086	2.17	Pass
33	0.005	0.068	7.8	0.006	0.102	5.62	Pass
34	0.002	0.054	2.8	0.002	0.081	2.37	Pass
35	0.004	0.064	6.8	0.005	0.096	5.11	Pass
36	0.002	0.051	3.1	0.002	0.077	2.43	Pass
37	0.003	0.061	4.3	0.003	0.091	3.44	Pass
38	0.002	0.048	3.3	0.002	0.073	2.72	Pass
39	0.005	0.058	7.9	0.005	0.087	5.92	Pass
40	0.001	0.046	2.7	0.002	0.069	2.26	Pass

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Voltage Source Verification Data (Run time)

EUT: RTVue **Tested by: Chris Groat**
Test category: Class-A per A-14 (European limits) **Test Margin: 100**
Test date: 4/18/2006 **Start time: 2:58:21 PM** **End time: 3:08:31 PM**
Test duration (min): 10 **Data file name: H-000755.cts_data**
Comment: J63556/T63585
Customer: Optovue

Test Result: Pass **Source qualification: Normal**

Highest parameter values during test:

Voltage (Vrms):	230.89		
I_Peak (Amps):	3.445	I_RMS (Amps):	1.509
I_Fund (Amps):	1.429	Crest Factor:	2.623
Power (Watts):	332	Power Factor:	0.954

Harm#	Harmonics V-rms	Limit V-rms	% of Limit	Status
2	0.024	0.462	5.23	OK
3	0.393	2.078	18.90	OK
4	0.023	0.462	5.08	OK
5	0.079	0.923	8.56	OK
6	0.018	0.462	3.90	OK
7	0.088	0.693	12.66	OK
8	0.029	0.462	6.31	OK
9	0.039	0.462	8.45	OK
10	0.014	0.462	3.05	OK
11	0.022	0.231	9.49	OK
12	0.001	0.231	0.57	OK
13	0.003	0.231	1.30	OK
14	0.002	0.231	0.75	OK
15	0.003	0.231	1.39	OK
16	0.011	0.231	4.66	OK
17	0.004	0.231	1.86	OK
18	0.014	0.231	6.08	OK
19	0.003	0.231	1.27	OK
20	0.027	0.231	11.49	OK
21	0.002	0.231	0.66	OK
22	0.008	0.231	3.60	OK
23	0.010	0.231	4.17	OK
24	0.006	0.231	2.60	OK
25	0.001	0.231	0.45	OK
26	0.008	0.231	3.66	OK
27	0.003	0.231	1.37	OK
28	0.006	0.231	2.63	OK
29	0.016	0.231	6.85	OK
30	0.008	0.231	3.57	OK
31	0.012	0.231	5.24	OK
32	0.014	0.231	6.00	OK
33	0.015	0.231	6.45	OK
34	0.012	0.231	5.28	OK
35	0.012	0.231	5.00	OK
36	0.012	0.231	5.25	OK
37	0.011	0.231	4.94	OK
38	0.013	0.231	5.46	OK
39	0.016	0.231	6.84	OK
40	0.025	0.231	10.65	OK

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

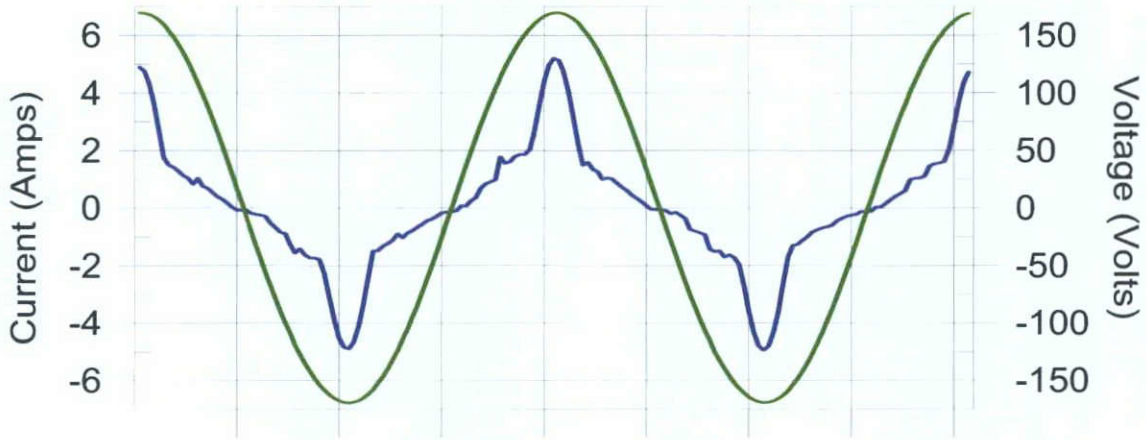
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Harmonics
(per EN 61000-3-2:2006 + A1:2009 + A2:2009)
– Class-A per Ed. 3.2 (2009)(Run time) incl. inter-harmonics

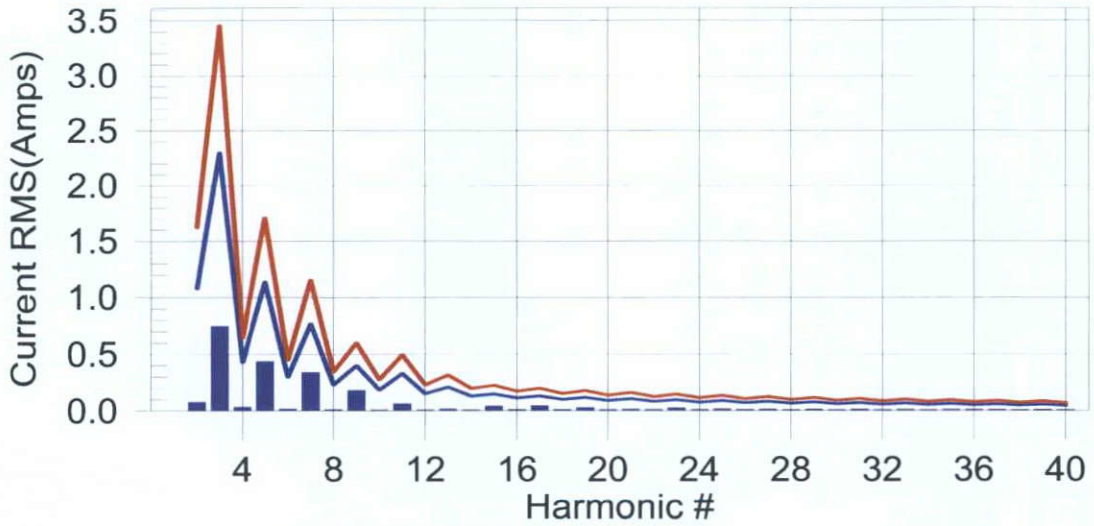
EUT: RTVue XR **Tested by: Chris Groat**
Test category: Class-A per Ed. 3.2 (2009) (European limits) **Test Margin: 100**
Test date: 11/23/2011 **Start time: 1:11:34 PM** **End time: 1:27:16 PM**
Test duration (min): 15 **Data file name: H-000190.cts_data**
Comment: J85563/T85575
Customer: Optovue

Test Result: Pass **Source qualification: Normal**

Current & voltage waveforms



Harmonics and Class A limit line **European Limits**



Test result: Pass **Worst harmonic was #9 with 44.56% of the limit.**

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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 #2012-3758; Released by CDRH on 09-8-2015

Current Test Result Summary (Run time)

EUT: RTVue XR **Tested by: Chris Groat**
Test category: Class-A per Ed. 3.2 (2009) (European limits) **Test Margin: 100**
Test date: 11/23/2011 **Start time: 1:11:34 PM** **End time: 1:27:16 PM**
Test duration (min): 15 **Data file name: H-000190.cts_data**
Comment: J85563/T85575
Customer: Optovue

Test Result: Pass **Source qualification: Normal**
THC(A): 0.94 **I-THD(%): 57.46** **POHC(A): 0.028** **POHC Limit(A): 0.295**
Highest parameter values during test:

V_RMS (Volts):	119.92	Frequency(Hz):	60.00
I_Peak (Amps):	5.206	I_RMS (Amps):	1.990
I_Fund (Amps):	1.658	Crest Factor:	2.795
Power (Watts):	198.6	Power Factor:	0.881

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.062	1.080	5.7	0.077	1.620	4.73	Pass
3	0.735	2.300	32.0	0.747	3.450	21.64	Pass
4	0.026	0.430	6.1	0.032	0.645	5.02	Pass
5	0.434	1.140	38.1	0.437	1.710	25.54	Pass
6	0.013	0.300	4.2	0.015	0.450	3.41	Pass
7	0.333	0.770	43.2	0.339	1.155	29.31	Pass
8	0.007	0.230	0.0	0.010	0.345	2.82	Pass
9	0.178	0.400	44.6	0.180	0.600	30.03	Pass
10	0.006	0.184	0.0	0.007	0.276	2.60	Pass
11	0.060	0.330	18.0	0.062	0.495	12.45	Pass
12	0.006	0.153	0.0	0.007	0.230	2.83	Pass
13	0.013	0.210	6.3	0.015	0.315	4.62	Pass
14	0.006	0.131	0.0	0.007	0.197	3.51	Pass
15	0.037	0.150	24.8	0.040	0.225	17.91	Pass
16	0.007	0.115	0.0	0.008	0.173	4.52	Pass
17	0.042	0.132	31.6	0.043	0.199	21.84	Pass
18	0.008	0.102	0.0	0.009	0.153	5.73	Pass
19	0.025	0.118	21.2	0.026	0.178	14.63	Pass
20	0.008	0.092	0.0	0.009	0.138	6.57	Pass
21	0.011	0.107	10.4	0.013	0.161	7.98	Pass
22	0.007	0.084	0.0	0.009	0.125	7.42	Pass
23	0.022	0.098	22.0	0.024	0.147	16.47	Pass
24	0.007	0.077	0.0	0.009	0.115	7.43	Pass
25	0.013	0.090	14.3	0.014	0.135	10.61	Pass
26	0.006	0.071	0.0	0.007	0.106	6.92	Pass
27	0.012	0.083	13.9	0.013	0.125	10.48	Pass
28	0.006	0.066	0.0	0.007	0.099	6.86	Pass
29	0.010	0.078	13.7	0.012	0.116	10.19	Pass
30	0.005	0.061	0.0	0.007	0.092	7.48	Pass
31	0.010	0.073	14.3	0.011	0.109	10.44	Pass
32	0.005	0.058	0.0	0.006	0.086	7.35	Pass
33	0.010	0.068	0.0	0.010	0.102	10.10	Pass
34	0.006	0.054	0.0	0.007	0.081	8.45	Pass
35	0.008	0.064	0.0	0.009	0.096	9.64	Pass
36	0.006	0.051	0.0	0.007	0.077	9.63	Pass
37	0.007	0.061	0.0	0.009	0.091	9.49	Pass
38	0.006	0.048	0.0	0.007	0.073	9.86	Pass
39	0.008	0.058	0.0	0.010	0.087	11.19	Pass
40	0.005	0.046	0.0	0.006	0.069	8.51	Pass

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Voltage Source Verification Data (Run time)

EUT: RTVue XR **Tested by: Chris Groat**
Test category: Class-A per Ed. 3.2 (2009) (European limits) **Test Margin: 100**
Test date: 11/23/2011 **Start time: 1:11:34 PM** **End time: 1:27:16 PM**
Test duration (min): 15 **Data file name: H-000190.cts_data**
Comment: J85563/T85575
Customer: Optovue

Test Result: Pass **Source qualification: Normal**

Highest parameter values during test:

Voltage (Vrms):	119.92	Frequency(Hz):	60.00
I_Peak (Amps):	5.206	I_RMS (Amps):	1.990
I_Fund (Amps):	1.658	Crest Factor:	2.795
Power (Watts):	198.6	Power Factor:	0.881

Harm#	Harmonics V-rms	Limit V-rms	% of Limit	Status
2	0.079	0.240	32.77	OK
3	0.404	1.079	37.47	OK
4	0.033	0.240	13.87	OK
5	0.089	0.480	18.62	OK
6	0.011	0.240	4.72	OK
7	0.113	0.360	31.30	OK
8	0.019	0.240	8.13	OK
9	0.050	0.240	20.98	OK
10	0.010	0.240	4.24	OK
11	0.024	0.120	20.37	OK
12	0.005	0.120	4.47	OK
13	0.028	0.120	23.40	OK
14	0.007	0.120	6.12	OK
15	0.044	0.120	36.53	OK
16	0.008	0.120	6.42	OK
17	0.042	0.120	35.44	OK
18	0.007	0.120	5.75	OK
19	0.020	0.120	16.90	OK
20	0.006	0.120	4.66	OK
21	0.010	0.120	8.59	OK
22	0.005	0.120	4.09	OK
23	0.026	0.120	21.36	OK
24	0.005	0.120	3.87	OK
25	0.023	0.120	18.93	OK
26	0.005	0.120	4.27	OK
27	0.017	0.120	14.43	OK
28	0.004	0.120	3.63	OK
29	0.013	0.120	11.20	OK
30	0.004	0.120	3.71	OK
31	0.017	0.120	13.87	OK
32	0.005	0.120	3.87	OK
33	0.019	0.120	15.60	OK
34	0.005	0.120	4.10	OK
35	0.014	0.120	12.05	OK
36	0.005	0.120	4.32	OK
37	0.011	0.120	8.83	OK
38	0.006	0.120	4.94	OK
39	0.014	0.120	11.63	OK
40	0.006	0.120	5.19	OK

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

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Appendix D Voltage Fluctuations Test Data
Flicker Test Summary (Run time)

EUT: RTVue **Tested by: Chris Groat**
Test category: All parameters (European limits) **Test Margin: 100**
Test date: 4/18/2006 **Start time: 11:50:50 AM** **End time: 12:17:49 PM**
Test duration (min): 120 **Data file name: F-000752.cts_data**
Comment: J63556/T63585
Customer: Optovue

Test Result: Pass **Status: Test Aborted**

Pst_i and limit line **European Limits**

Time is too short for Plt plot

Parameter values recorded during the test:

Vrms at the end of test (Volt):	**99.51**			
Highest dt (%):	**0.36**	**Test limit (%):**	**3.30**	**Pass**
Highest dc (%):	**0.34**	**Test limit (%):**	**3.30**	**Pass**
Highest dmax (%):	**-0.51**	**Test limit (%):**	**4.00**	**Pass**
Highest Pst (10 min. period):	**0.230**	**Test limit:**	**1.000**	**Pass**
Highest Plt (2 hr. period):	**0.126**	**Test limit:**	**0.650**	**Pass**

Not evaluated. Over two observation periods the value of Pst was less than 0.1, indicating that the device under test did not produce significant voltage fluctuations. As Pst was less than 0.1, Plt would also be less than 0.1.

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

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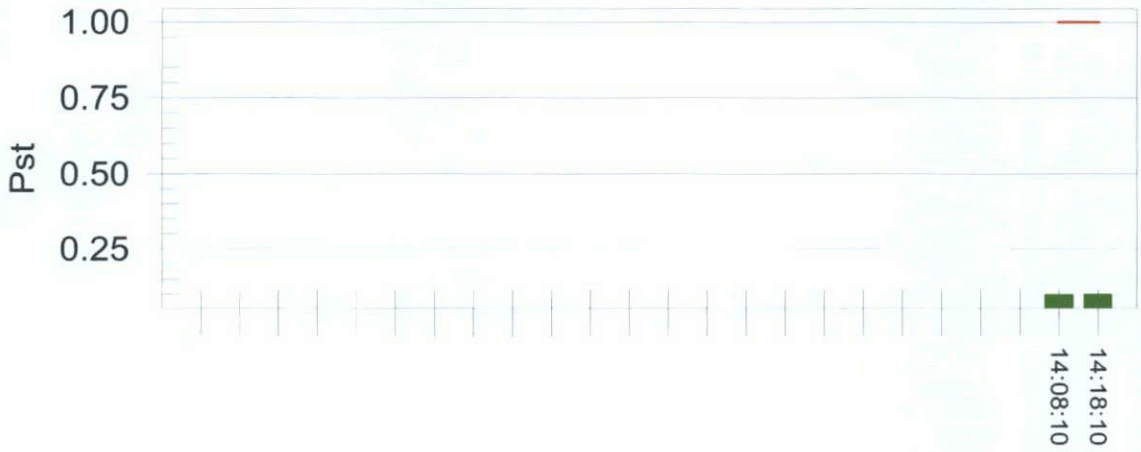
Flicker Test Summary (Run time)

EUT: RTVue **Tested by: Chris Groat**
Test category: All parameters (European limits) **Test Margin: 100**
Test date: 4/18/2006 **Start time: 1:57:58 PM** **End time: 2:19:36 PM**
Test duration (min): 120 **Data file name: F-000754.cts_data**
Comment: J63556/T63585
Customer: Optovue

Test Result: Pass **Status: Test Aborted**

Pst_i and limit line **European Limits**



Time is too short for Plt plot

Parameter values recorded during the test:

Vrms at the end of test (Volt):	119.81			
Highest dt (%):	-0.27	Test limit (%):	3.30	Pass
Highest dc (%):	0.23	Test limit (%):	3.30	Pass
Highest dmax (%):	-0.38	Test limit (%):	4.00	Pass
Highest Pst (10 min. period):	0.100	Test limit:	1.000	Pass
Highest Plt (2 hr. period):	0.055	Test limit:	0.650	Pass

Not evaluated. Over two observation periods the value of Pst was less than 0.1, indicating that the device under test did not produce significant voltage fluctuations. As Pst was less than 0.1, Plt would also be less than 0.1.

744

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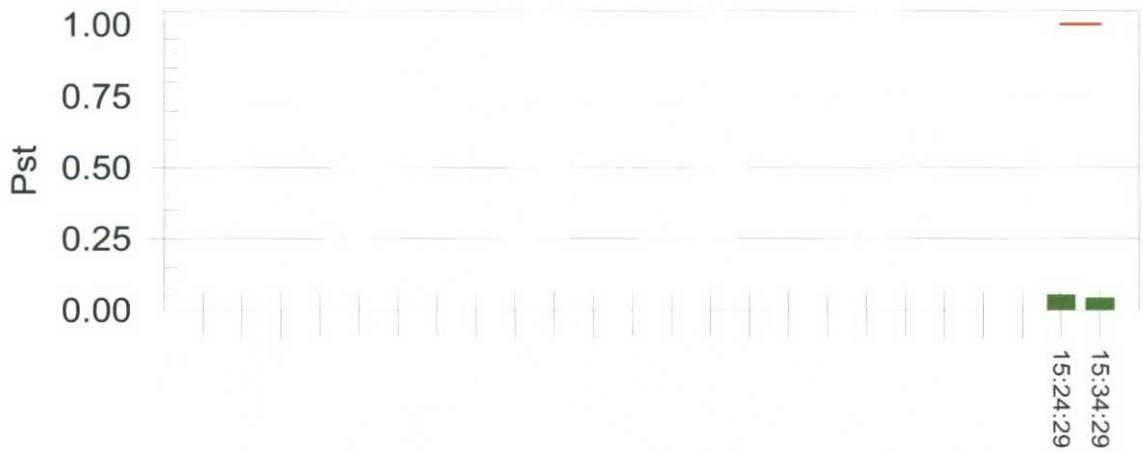
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Flicker Test Summary (Run time)

EUT: RTVue **Tested by: Chris Groat**
Test category: All parameters (European limits) **Test Margin: 100**
Test date: 4/18/2006 **Start time: 3:14:17 PM** **End time: 3:35:35 PM**
Test duration (min): 120 **Data file name: F-000756.cts_data**
Comment: J63556/T63585
Customer: Optovue

Test Result: Pass **Status: Test Aborted**

Pst_i and limit line **European Limits**



Time is too short for Plt plot

Parameter values recorded during the test:

Vrms at the end of test (Volt):	230.35			
Highest dt (%):	-0.17	Test limit (%):	3.30	Pass
Highest dc (%):	0.00	Test limit (%):	3.30	Pass
Highest dmax (%):	-0.18	Test limit (%):	4.00	Pass
Highest Pst (10 min. period):	0.054	Test limit:	1.000	Pass
Highest Plt (2 hr. period):	0.027	Test limit:	0.650	Pass

Not evaluated. Over two observation periods the value of Pst was less than 0.1, indicating that the device under test did not produce significant voltage fluctuations. As Pst was less than 0.1, Plt would also be less than 0.1.

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

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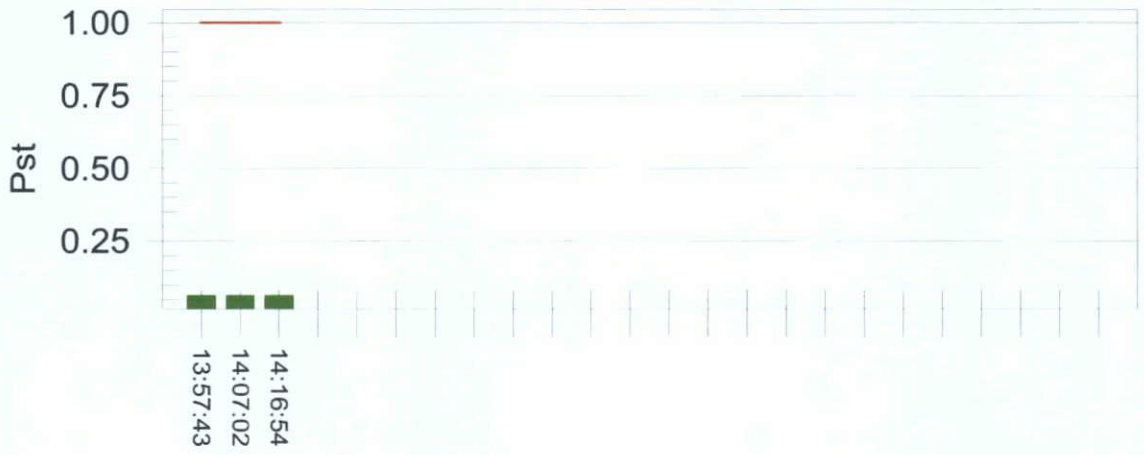
Flicker Test Summary
(EN(Run time) 61000-3-2:2006 +A1:2009 +A2:2009)

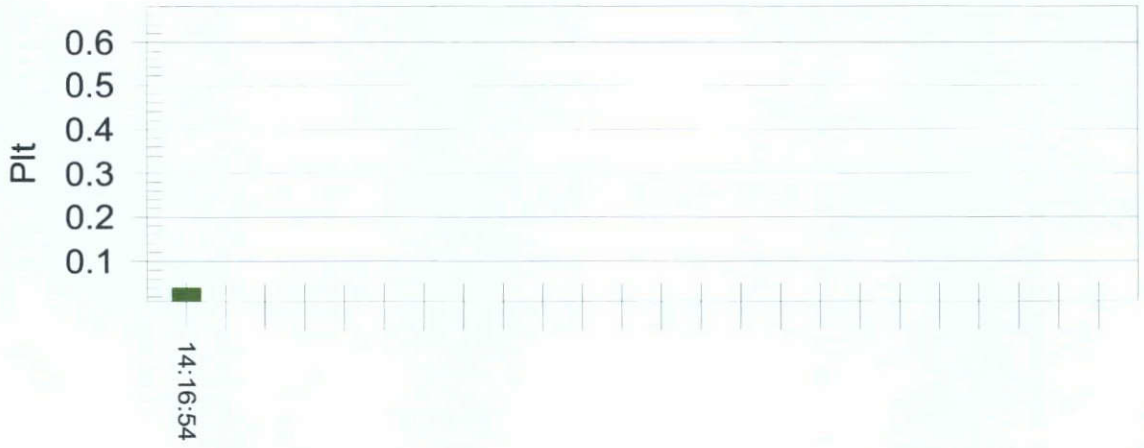
EUT: RTVue XR **Tested by: Chris Groat**
Test category: All parameters (European limits) **Test Margin: 100**
Test date: 11/23/2011 **Start time: 1:47:03 PM** **End time: 2:22:55 PM**
Test duration (min): 120 **Data file name: F-000191.cts_data**
Comment: J85563/T85575
Customer: Optovue

Test Result: Pass **Status: Test Aborted**

Pst and limit line **European Limits**



Plt and limit line



Parameter values recorded during the test:

Vrms at the end of test (Volt):	**119.94**			
Highest dt (%):	**0.00**	**Test limit (%):**	**3.30**	**Pass**
Time(mS) > dt:	**0.0**	**Test limit (mS):**	**500.0**	**Pass**
Highest dc (%):	**0.00**	**Test limit (%):**	**3.30**	**Pass**
Highest dmax (%):	**0.00**	**Test limit (%):**	**4.00**	**Pass**
Highest Pst (10 min. period):	**0.064**	**Test limit:**	**1.000**	**Pass**
Highest Plt (2 hr. period):	**0.040**	**Test limit:**	**0.650**	**Pass**

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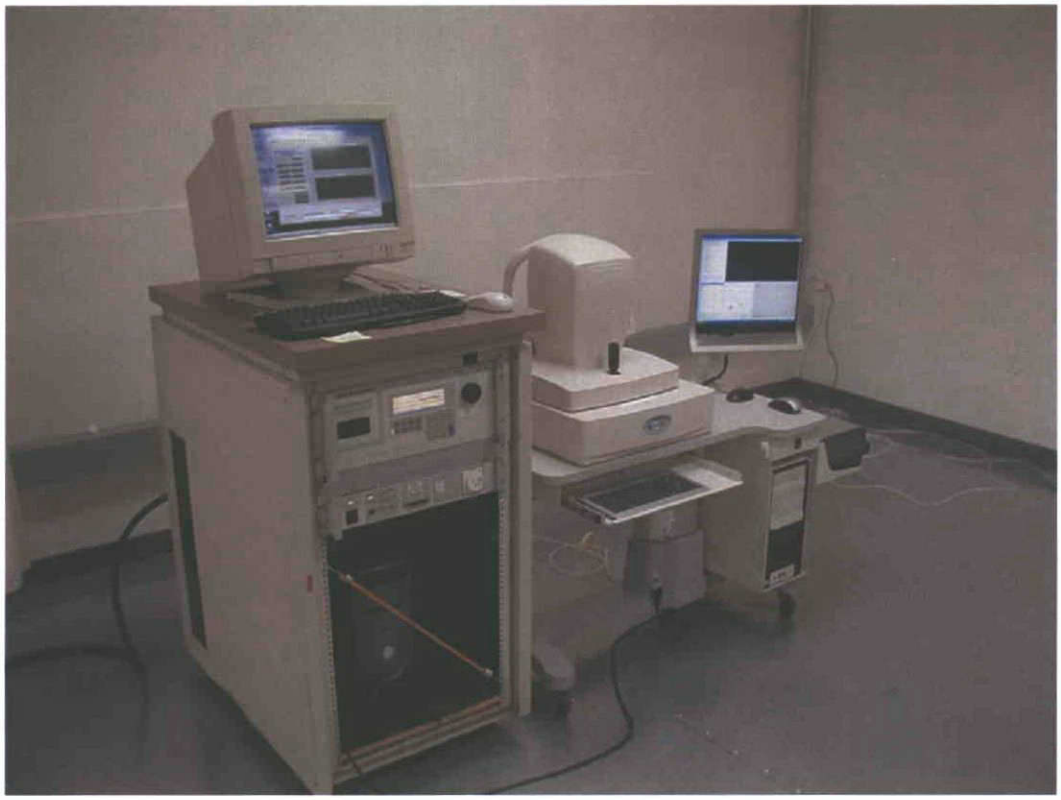
Appendix E AC Current Harmonics and Voltage Fluctuations Test Configuration Photographs

System tested in 2006



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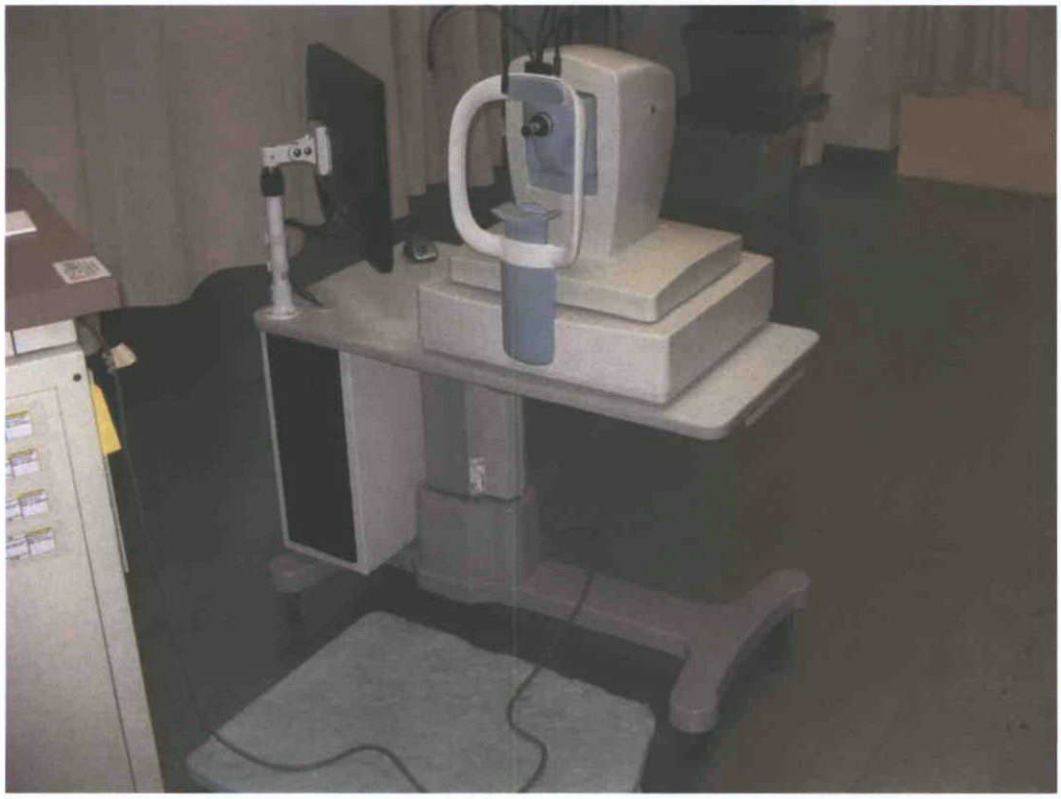
System tested in 2011



748

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End of Report

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marks the last page of this test report.

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RTVue XR Bench Test Report

Overview

The RTVue XR is an updated version of RTVue-100 that operates at ~70,000 A-lines per second (RTVue XR System Design Specifications, 200-24002-CX1,) while the RTVue-100 operating at ~27,000 A-lines per second (RTVue100 System Design Specification, 200-24002-C,). The RTVue XR machines are equipped with new line-scan cameras (b) (4) [redacted] capable of operating at ~70,000 A-lines per second while delivering equivalent imaging results as the older generation RTVue line-scan cameras (b) (4) [redacted] operating at ~27,000 A-lines per second.

This bench test report compares the OCT imaging performance of RTVue XR with RTVue-100. Measurements were taken from three RTVue XR machines (SN 10488, 11969, 12002) and compared to measurements taken from three RTVue-100 machines (SN 10438, 10439, 10709). Measurements taken include system speed, signal intensity, axial resolution, as well as phantom target imaging and tracking performance.

References

No.	Description	Part Number / Source
1	RTVue XR System Design Specifications	(b) (4) [redacted]
2	RTVue-100 System Design Specification	
3	RTVue Final Test Report	
4	Software Requirement Specification (RTVue)	
5	Software Requirement Specification (RTVue Tracking)	

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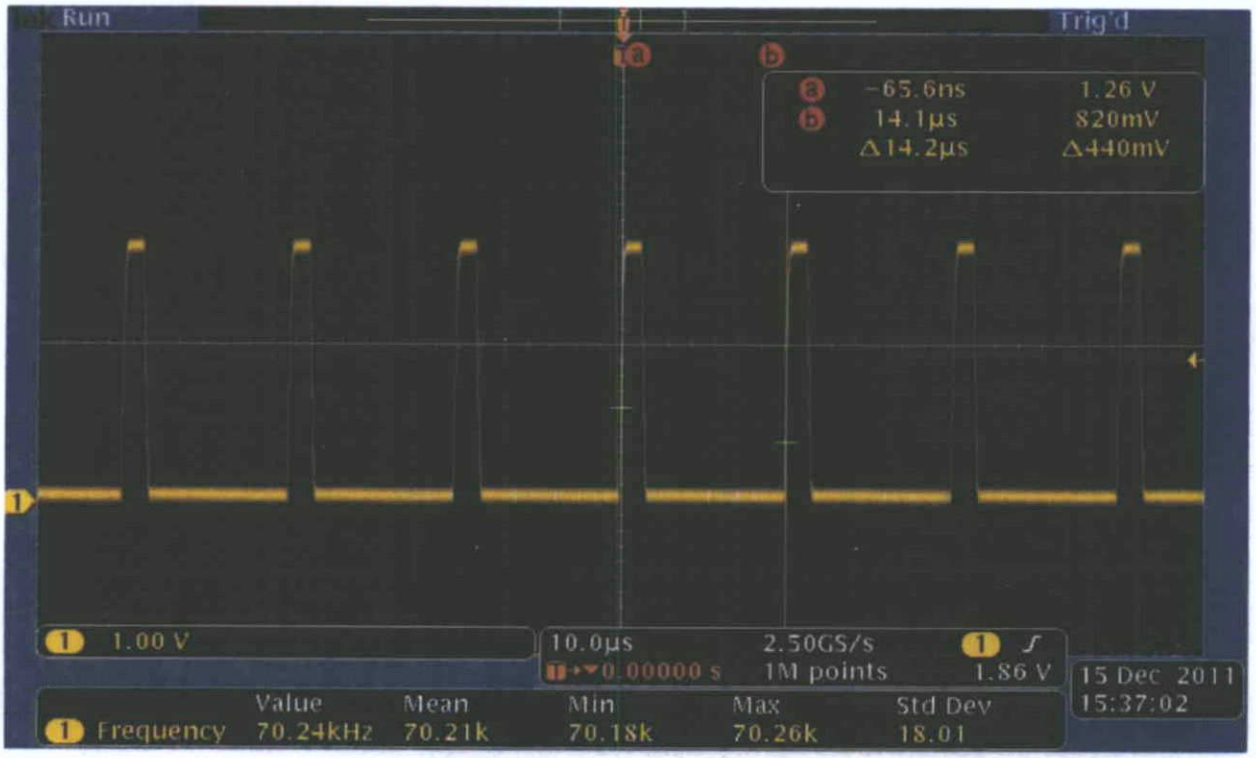
RTVue XR System #1 (SN 10488)

Operating speed is ~70,000 A-lines per second

The operating speed of the line-scan camera and therefore the RTVue XR system can be measured by probing the line sync trigger signal. The following oscilloscope screen capture indicates the operating speed of RTVue XR SN 10488 is aproximatly 70,000 A-lines per second (A-scan time period is ~14.2 microseconds).



OCT signal intensity is equivalent to RTVue-100

The RTVue-100 Manufacturing Process Instructions and Final Test Report (F-OPR-45366-H, RTVue Final Test Report) indicates that the difference in OCT Signal with tool on and without tool on, in a particular calibration step, needs to be above 18. The following screen captures show that, in this calibration step, RTVue XR SN 10488 has an OCT Signal difference of 19 (64 minus 45; reference the relevant OCT Signal readings in red circles) which meets the manufacturing requirement of RTVue-100.

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(b) (4)

[redacted]

752

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(b) (4)

[redacted]

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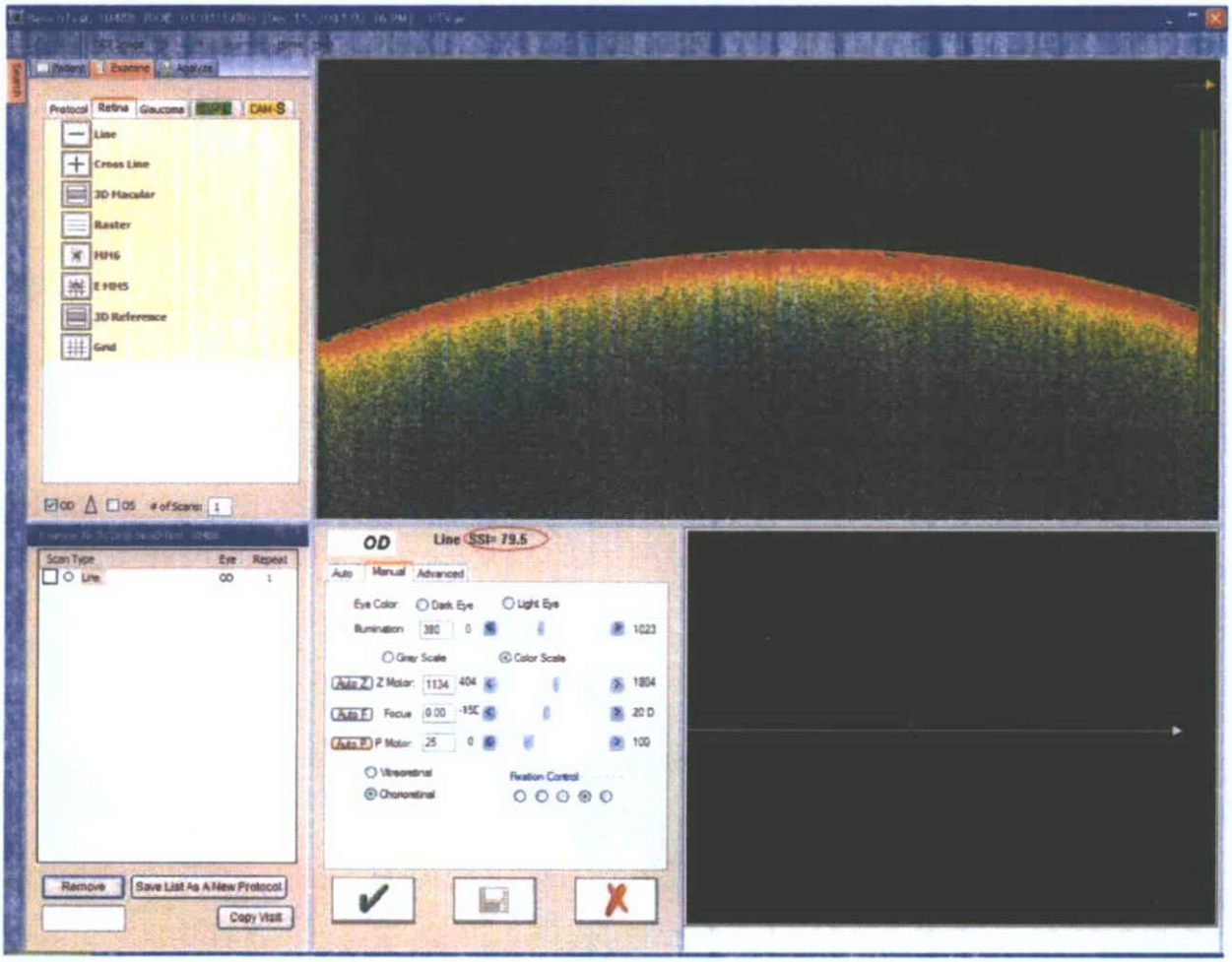
optovue

Phantom imaging performance

Since the different line-scan cameras are the only main difference between RTVue XR and RTVue -100, the same RTVue application software can be used to run the RTVue XR (200-24052-F, Software Requirement Specification for RTVue). Using the RTVue application software (version 6.6.0.82), an OCT image of a standard phantom target is obtained using RTVue XR SN 10488. The signal intensity and image quality of this OCT image is equivalent to that taken with a standard RTVue-100 systems. For this type of phantom imaging target, a Signal Strength Index (SSI) of 79.5 (reference the SSI reading in the red circle) is similar to the values acquired with RTVue-100.



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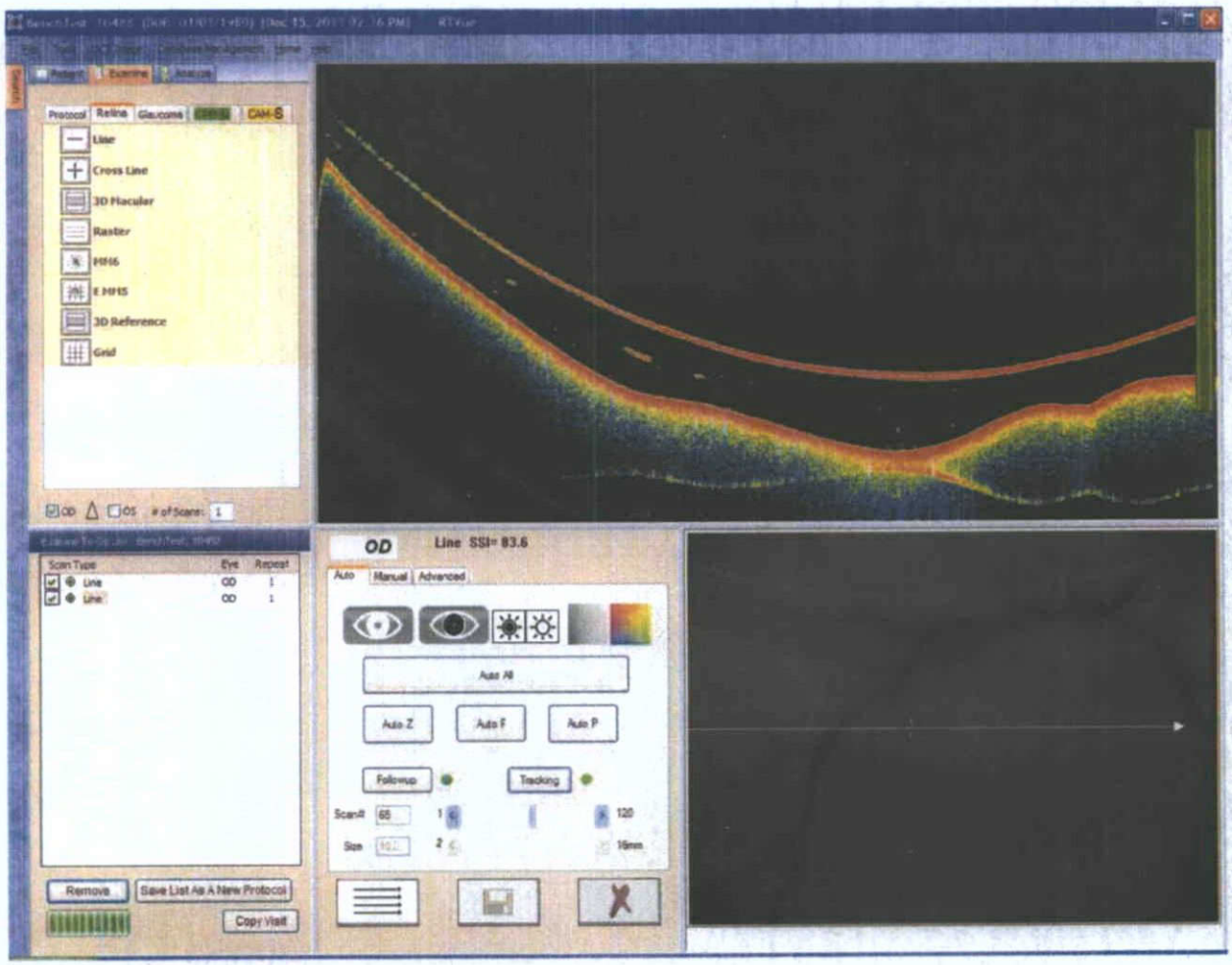
Phantom tracking performance

Using the RTVue appliaction software (version 6.6.0.82), the OCT image of a phantom eye target is acquired using the tracking protocol (200-47145-A, Software Requirement Specification for RTVue Tracking). During image acquisition, motion is simulated by moving the phantom target in relation to the RTVue XR SN 10488 scan head and eye blinking is simulated by covering up the phantom eye target. Tracking OCT can successfully handle the simulated eye blink and motion in order to complete the image acquisition and generate the resulting OCT image.



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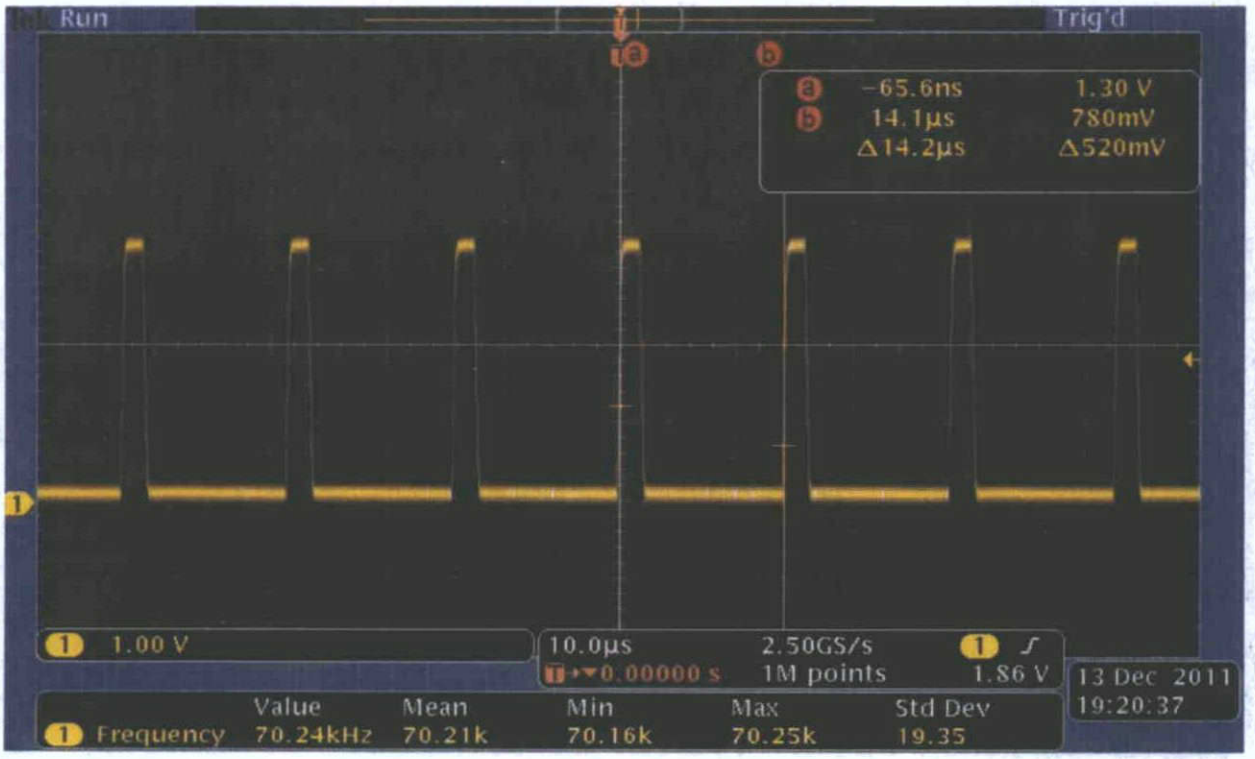
RTVue XR System #2 (SN 11969)

Operating speed is ~70,000 A-lines per second

The operating speed of the line-scan camera and therefore the RTVue XR system can be measured by probing the line sync trigger signal. The following oscilloscope screen capture indicates the operating speed of RTVue XR SN 11969 is aproximatly 70,000 A-lines per second (A-scan time period is ~14.2 microseconds).



OCT signal intensity is equivalent to RTVue-100

The RTVue-100 Manufacturing Process Instructions and Final Test Report (F-OPR-45366-H, RTVue Final Test Report) indicates that the difference in OCT Signal with tool on and without tool on, in a particular calibration step, needs to be above 18. The following screen captures show that, in this calibration step, RTVue XR SN 11969 has an OCT Signal difference of 20 (65 minus 45; reference the relevant OCT Signal readings in red circles) which meets the manufacturing requirement of RTVue-100.

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

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(b) (4)

[redacted]

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(b)(4)

[redacted]

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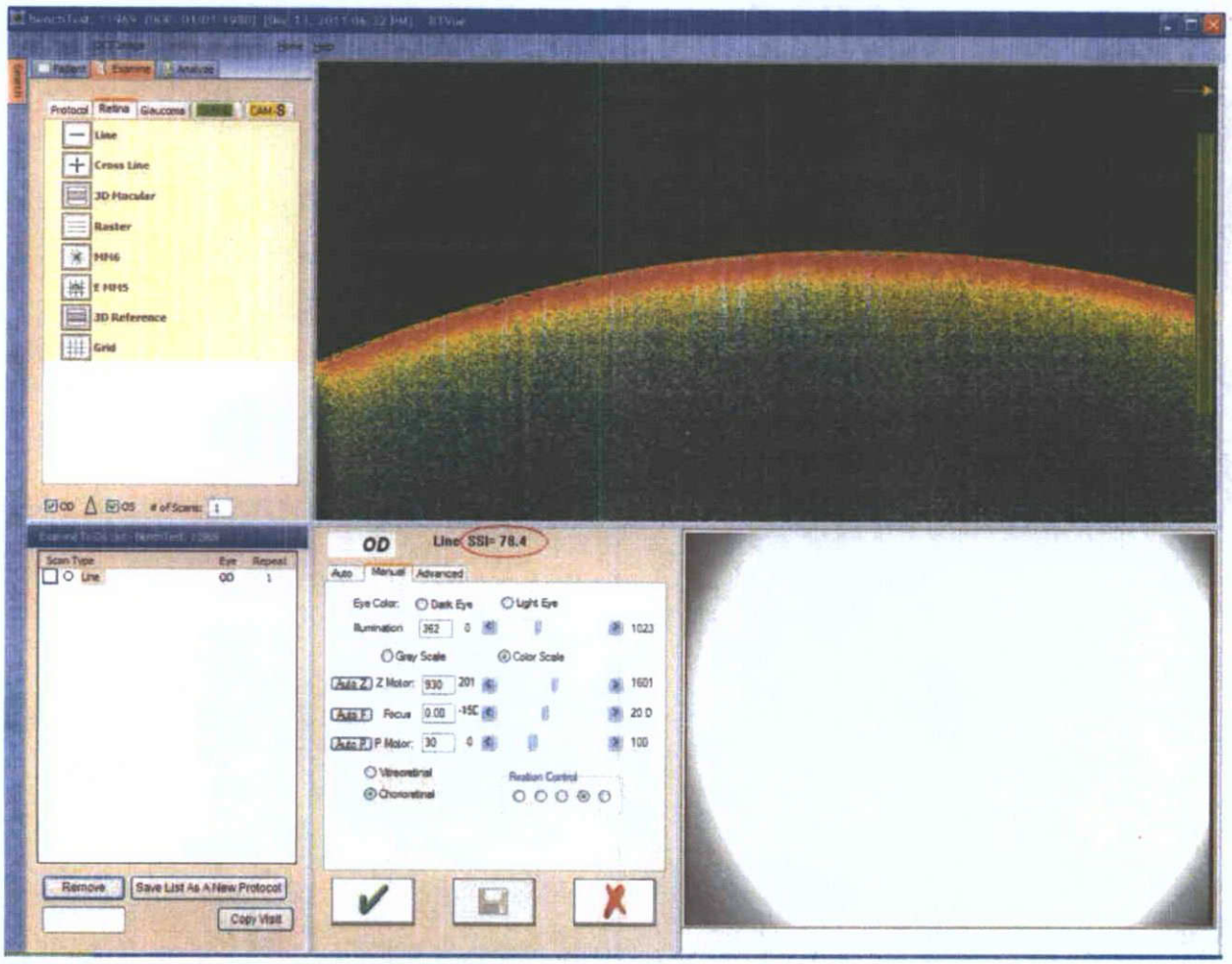
optovue

Phantom imaging performance

Since the different line-scan cameras are the only main difference between RTVue XR and RTVue -100, the same RTVue application software can be used to run the RTVue XR (200-24052-F, Software Requirement Specification for RTVue). Using the RTVue application software (version 6.6.0.82), an OCT image of a standard phantom target is obtained using RTVue XR SN 11969. The signal intensity and image quality of this OCT image is equivalent to that taken with a standard RTVue-100 systems. For this type of phantom imaging target, a Signal Strength Index (SSI) of 78.4 (reference the SSI reading in the red circle) is similar to the values acquired with RTVue-100.



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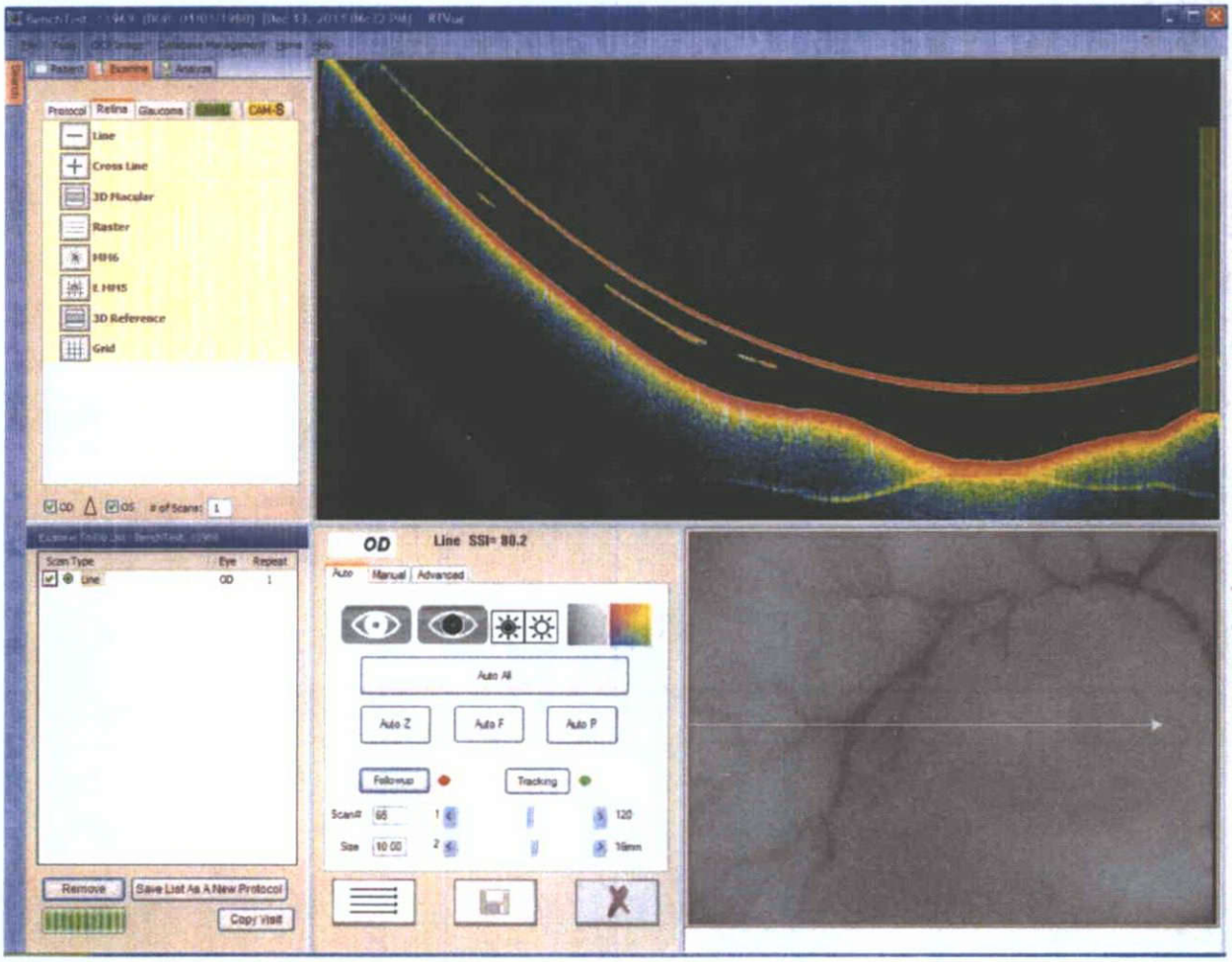
optovue

Phantom tracking performance

Using the RTVue appliaction software (version 6.6.0.82), the OCT image of a phantom eye target is acquired using the tracking protocol (200-47145-A, Software Requirement Specification for RTVue Tracking). During image acquisition, motion is simulated by moving the phantom target in relation to the RTVue XR SN 11969 scan head and eye blinking is simulated by covering up the phantom eye target. Tracking OCT can successfully handle the simulated eye blink and motion in order to complete the image acquisition and generate the resulting OCT image.



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

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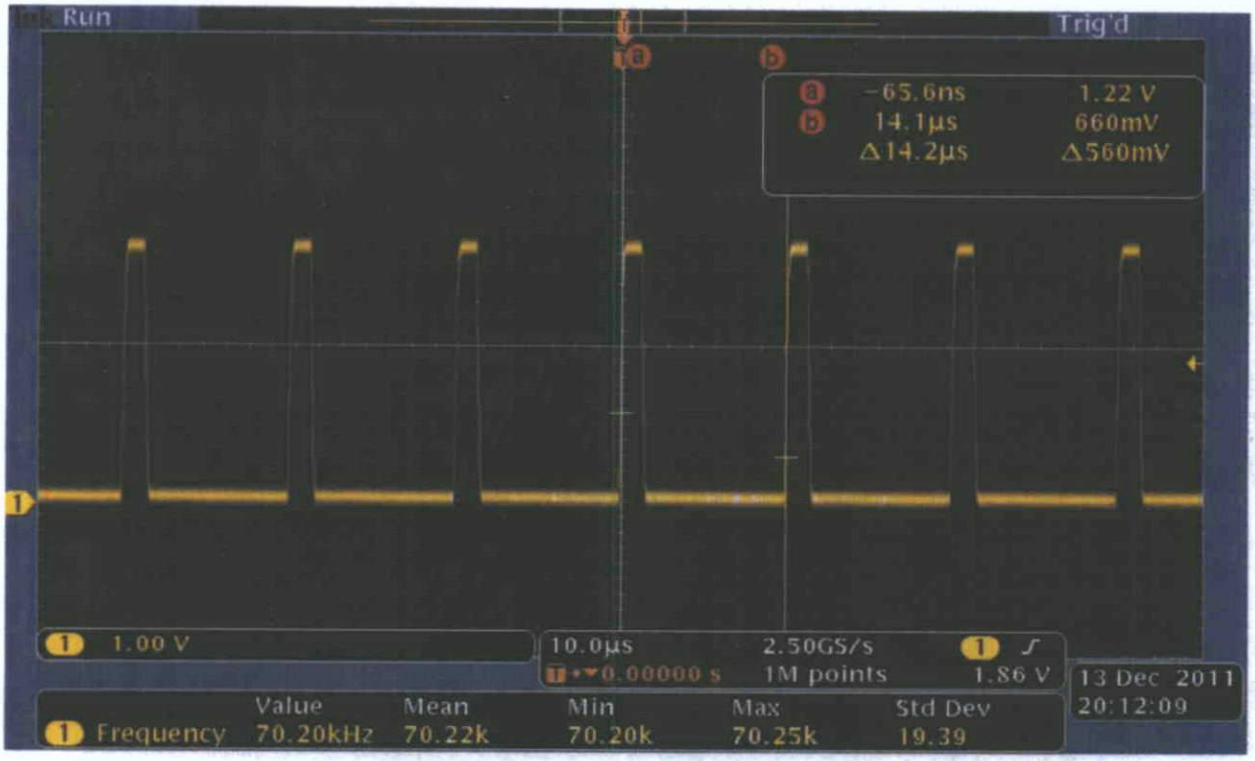
optovue

RTVue XR System #3 (SN 12002)

Operating speed is ~70,000 A-lines per second

The operating speed of the line-scan camera and therefore the RTVue XR system can be measured by probing the line sync trigger signal. The following oscilloscope screen capture indicates the operating speed of RTVue XR SN 12002 is aproximatly 70,000 A-lines per second (A-scan time period is ~14.2 microseconds).



OCT signal intensity is equivalent to RTVue-100

The RTVue-100 Manufacturing Process Instructions and Final Test Report (F-OPR-45366-H, RTVue Final Test Report) indicates that the difference in OCT Signal with tool on and without tool on, in a particular calibration step, needs to be above 18. The following screen captures show that, in this calibration step, RTVue XR SN 12002 has an OCT Signal difference of 20.5 (63.5 minus 43; reference the relevant OCT Signal readings in red circles) which meets the manufacturing requirement of RTVue-100.

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

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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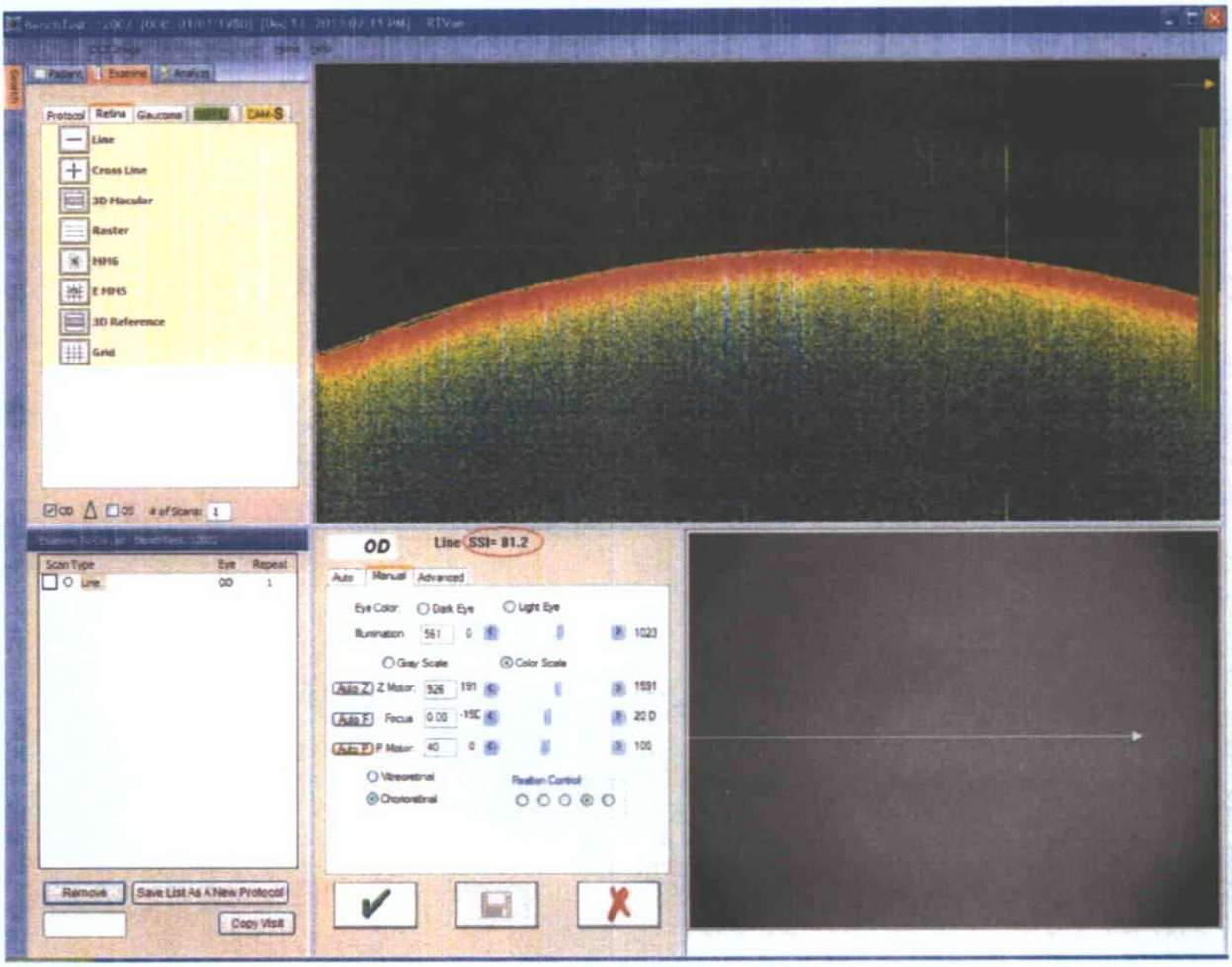
optovue

Phantom imaging performance

Since the different line-scan cameras are the only main difference between RTVue XR and RTVue -100, the same RTVue application software can be used to run the RTVue XR (200-24052-F, Software Requirement Specification for RTVue). Using the RTVue application software (version 6.6.0.82), an OCT image of a standard phantom target is obtained using RTVue XR SN 12002. The signal intensity and image quality of this OCT image is equivalent to that taken with a standard RTVue-100 systems. For this type of phantom imaging target, a Signal Strength Index (SSI) of 81.2 (reference the SSI reading in the red circle) is similar to the values acquired with RTVue-100.



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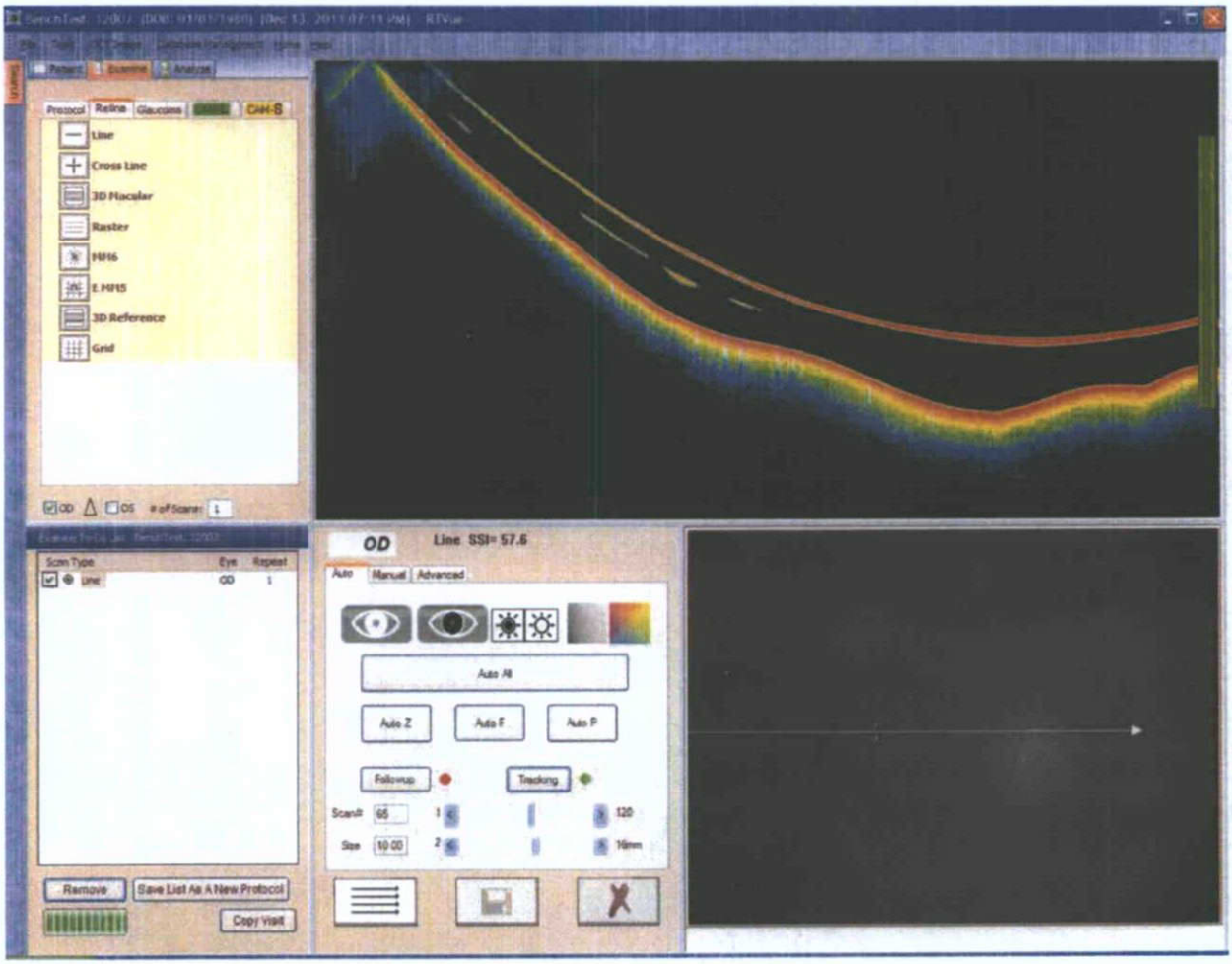
optovue

Phantom tracking performance

Using the RTVue appliaction software (version 6.6.0.82), the OCT image of a phantom eye target is acquired using the tracking protocol (200-47145-A, Software Requirement Specification for RTVue Tracking). During image acquisition, motion is simulated by moving the phantom target in relation to the RTVue XR SN 12002 scan head and eye blinking is simulated by covering up the phantom eye target. Tracking OCT can successfully handle the simulated eye blink and motion in order to complete the image acquisition and generate the resulting OCT image.



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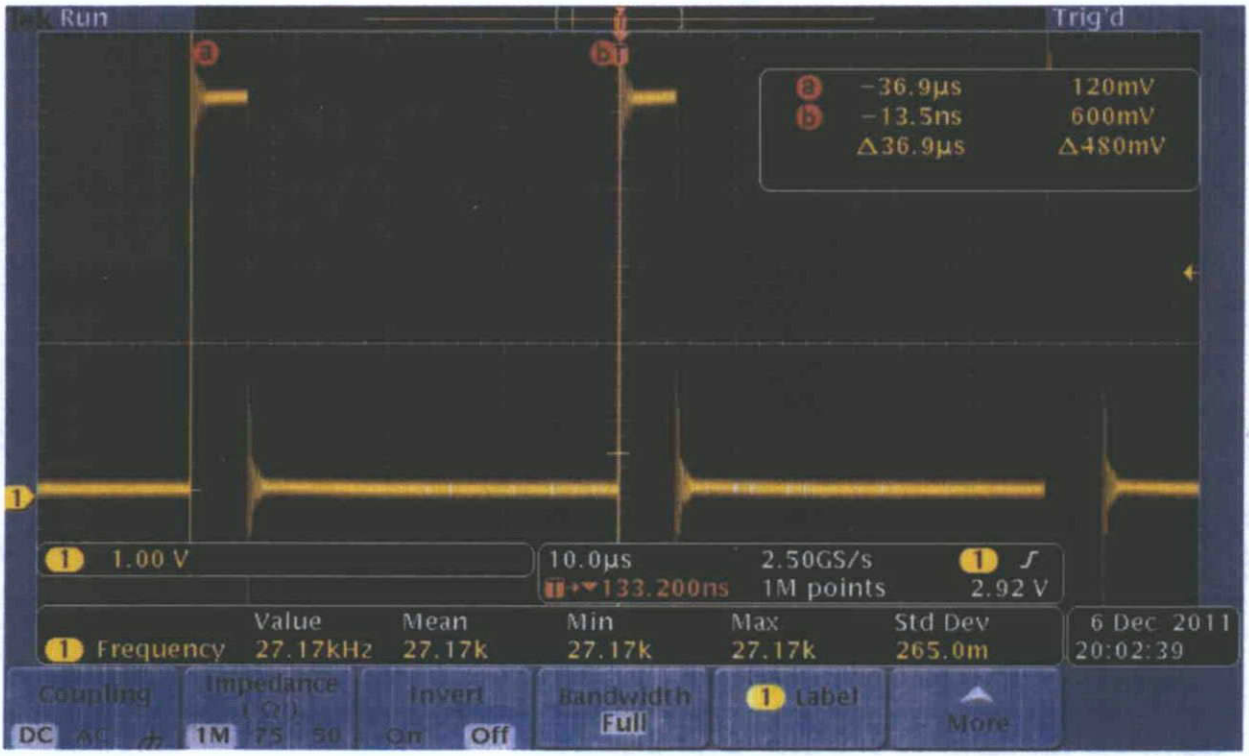
optovue

RTVue-100 System #1 (SN 10438)

Operating speed is ~27,000 A-lines per second

The operating speed of the line-scan camera and therefore the RTVue-100 system can be measured by probing the line sync trigger signal. The following oscilloscope screen capture indicates the operating speed of RTVue-100 SN 10438 is aproximatly 27,000 A-lines per second (A-scan time period is ~36.9 microseconds).



OCT signal intensity is as expected for RTVue-100

The RTVue-100 Manufacturing Process Instructions and Final Test Report (F-OPR-45366-H, RTVue Final Test Report) indicates that the difference in OCT Signal with tool on and without tool on, in a particular calibration step, needs to be above 18. The following screen captures show that, in this calibration step, RTVue-100 SN 10438 has an OCT Signal difference of 20 (67 minus 47; reference the relevant OCT Signal readings in red circles) which meets the manufacturing requirement of RTVue-100.

766

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

optovue

(b)(4)

[redacted]

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

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[redacted]

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

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optovue

(b)(4)

[redacted]

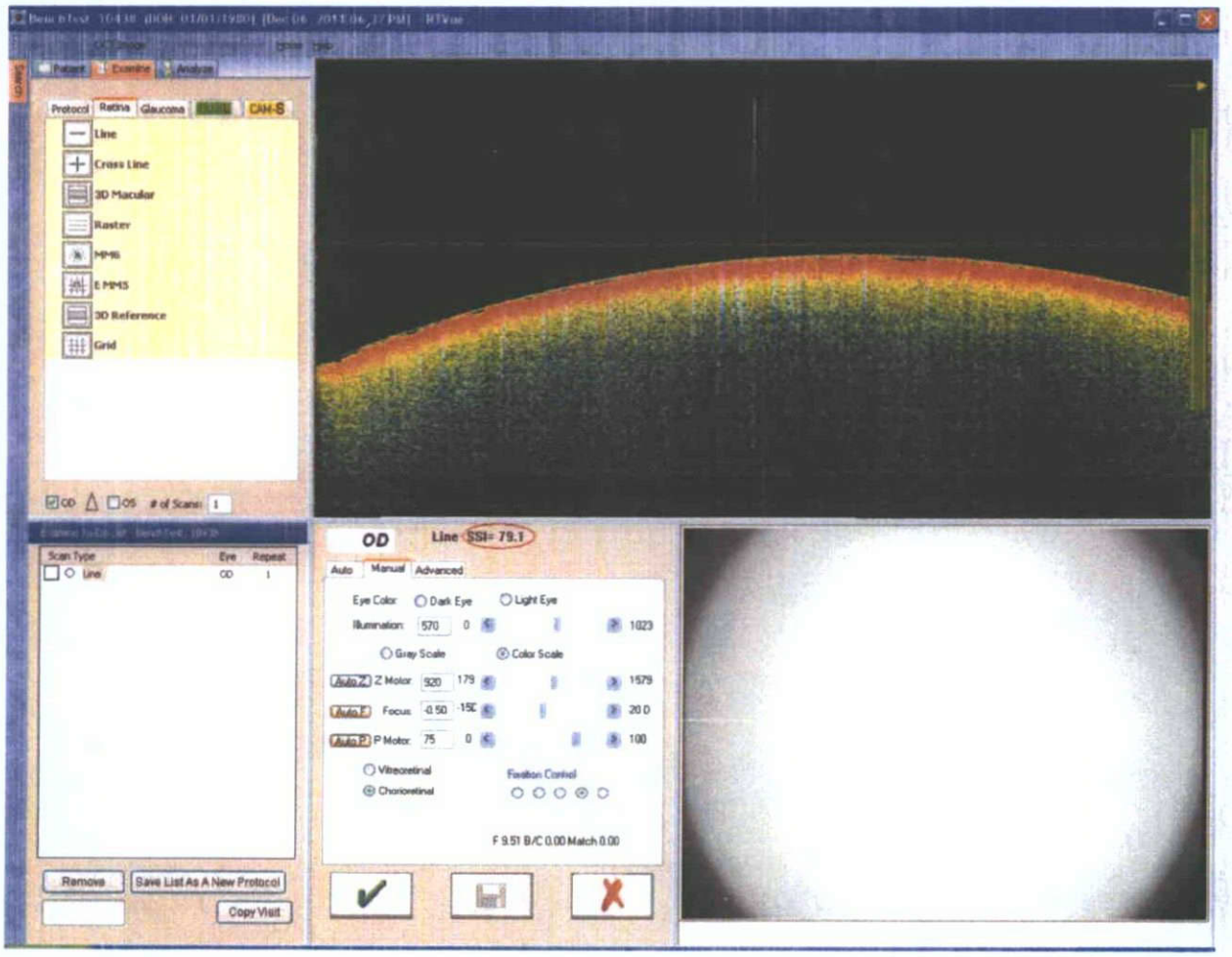
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

optovue

Phantom imaging performance

Using the RTVue appliaction software (version 6.6.0.82), an OCT image of a standard phantom target is obtained using RTVue-100 SN 10438 (200-24052-F, Software Requirement Specification for RTVue). For this type of phantom imaging target, a Signal Strength Index (SSI) of 79.1 (reference the SSI reading in the red circle) is typical of values acquired with the RTVue-100.



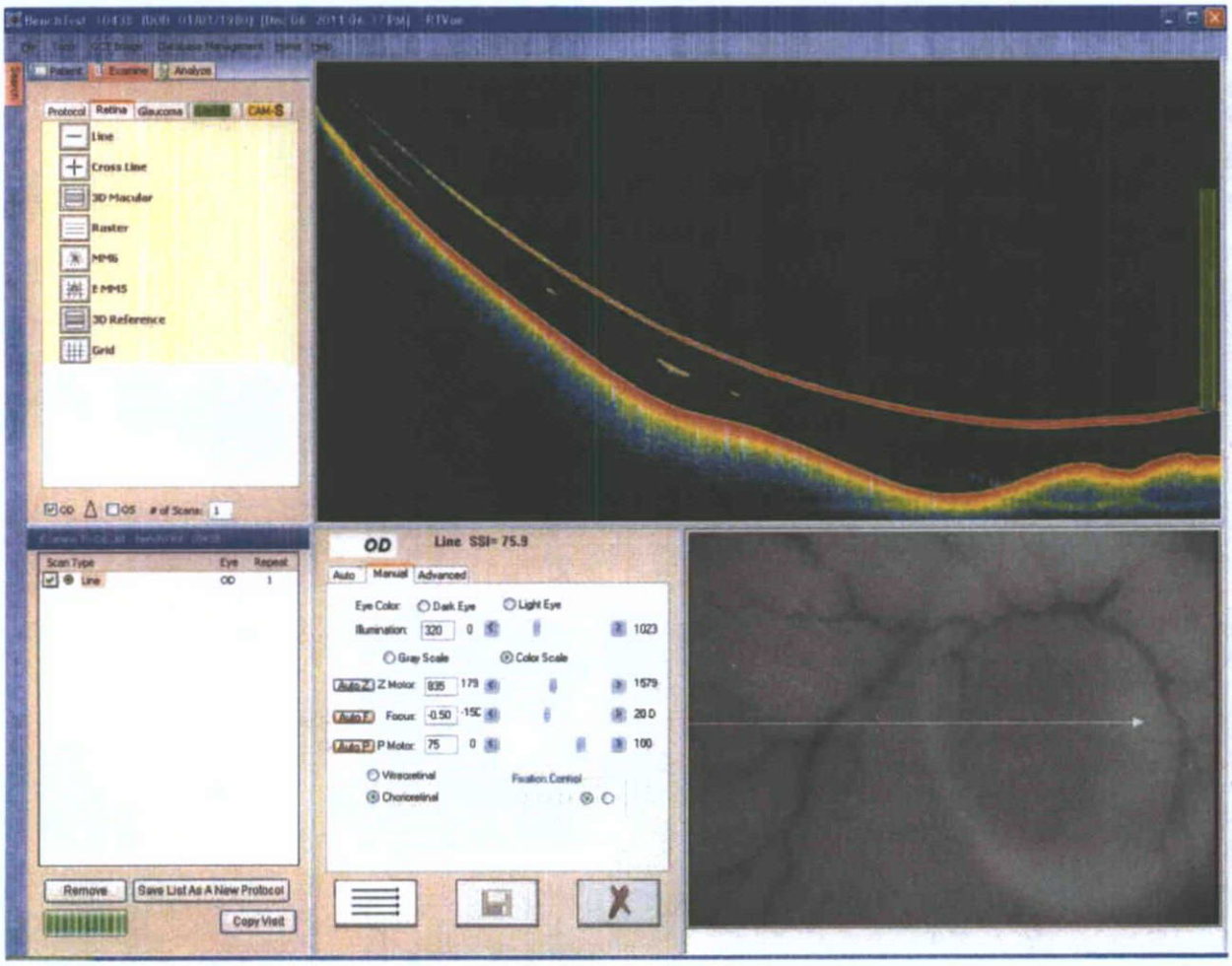
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

optovue

Phantom tracking performance

Using the RTVue appliaction software (version 6.6.0.82), the OCT image of a phantom eye target is acquired using the tracking protocol (200-47145-A, Software Requirement Specification for RTVue Tracking). During image acquisition, motion is simulated by moving the phantom target in relation to the RTVue-100 SN 10438 scan head and eye blinking is simulated by covering up the phantom eye target. Tracking OCT can successfully handle the simulated eye blink and motion in order to complete the image acquisition and generate the resulting OCT image.



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

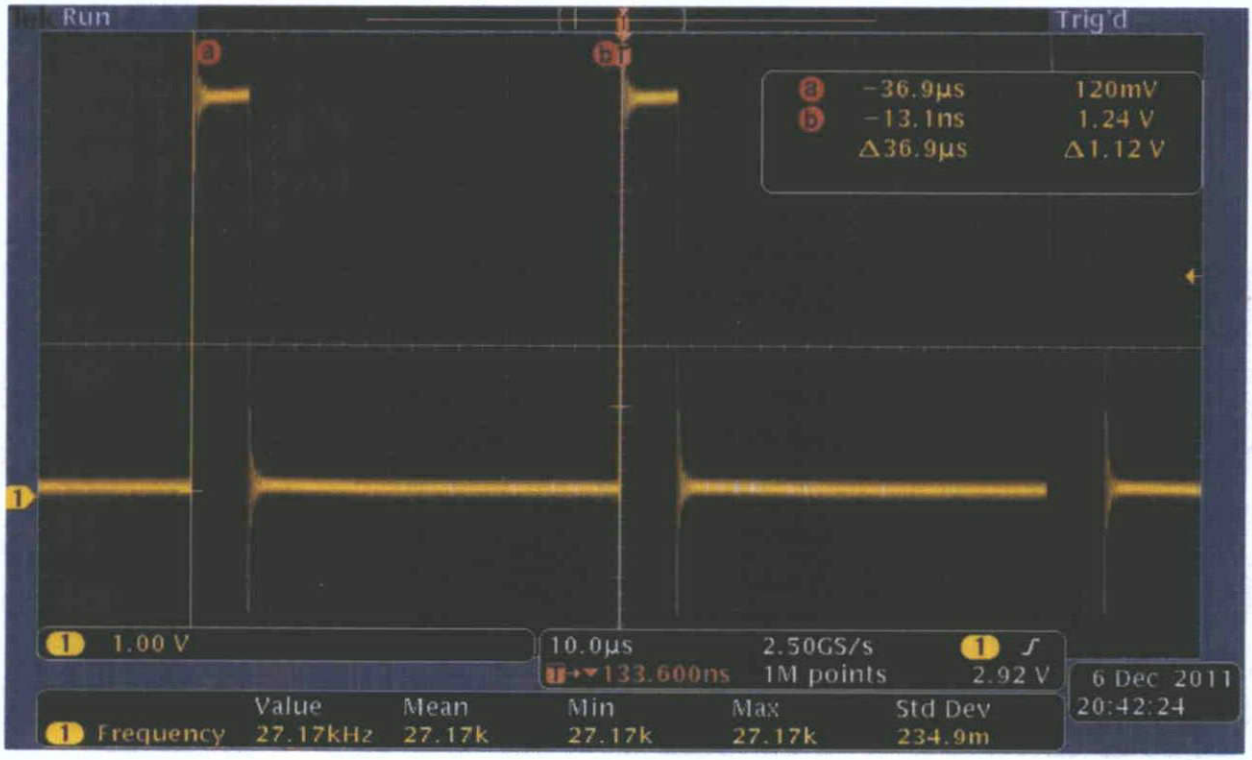
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

optovue

RTVue-100 System #2 (SN 10439)

Operating speed is ~27,000 A-lines per second

The operating speed of the line-scan camera and therefore the RTVue-100 system can be measured by probing the line sync trigger signal. The following oscilloscope screen capture indicates the operating speed of RTVue-100 SN 10439 is aproximatly 27,000 A-lines per second (A-scan time period is ~36.9 microseconds).



OCT signal intensity is as expected for RTVue-100

The RTVue-100 Manufacturing Process Instructions and Final Test Report (F-OPR-45366-H, RTVue Final Test Report) indicates that the difference in OCT Signal with tool on and without tool on, in a particular calibration step, needs to be above 18. The following screen captures show that, in this calibration step, RTVue-100 SN 10439 has an OCT Signal difference of 20 (66 minus 46; reference the relevant OCT Signal readings in red circles) which meets the manufacturing requirement of RTVue-100.

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

optovue

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[redacted]

773

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

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(b)(4)

[redacted]

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

optovue

(b)(4)

[redacted]

775

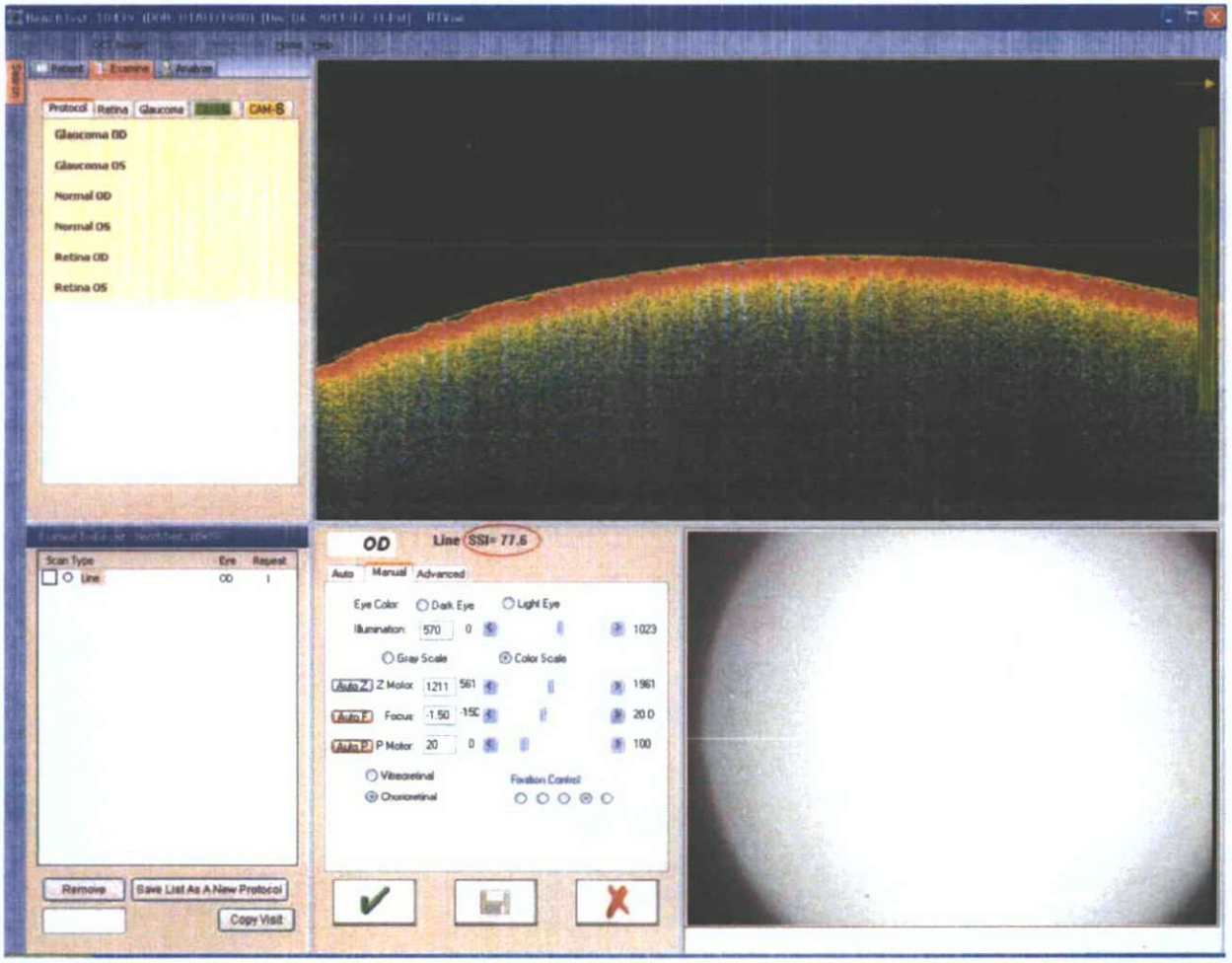
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

optovue

Phantom imaging performance

Using the RTVue appliaction software (version 6.6.0.82), an OCT image of a standard phantom target is obtained using RTVue-100 SN 10439 (200-24052-F, Software Requirement Specification for RTVue). For this type of phantom imaging target, a Signal Strength Index (SSI) of 77.6 (reference the SSI reading in the red circle) is typical of values acquired with the RTVue-100.



776

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

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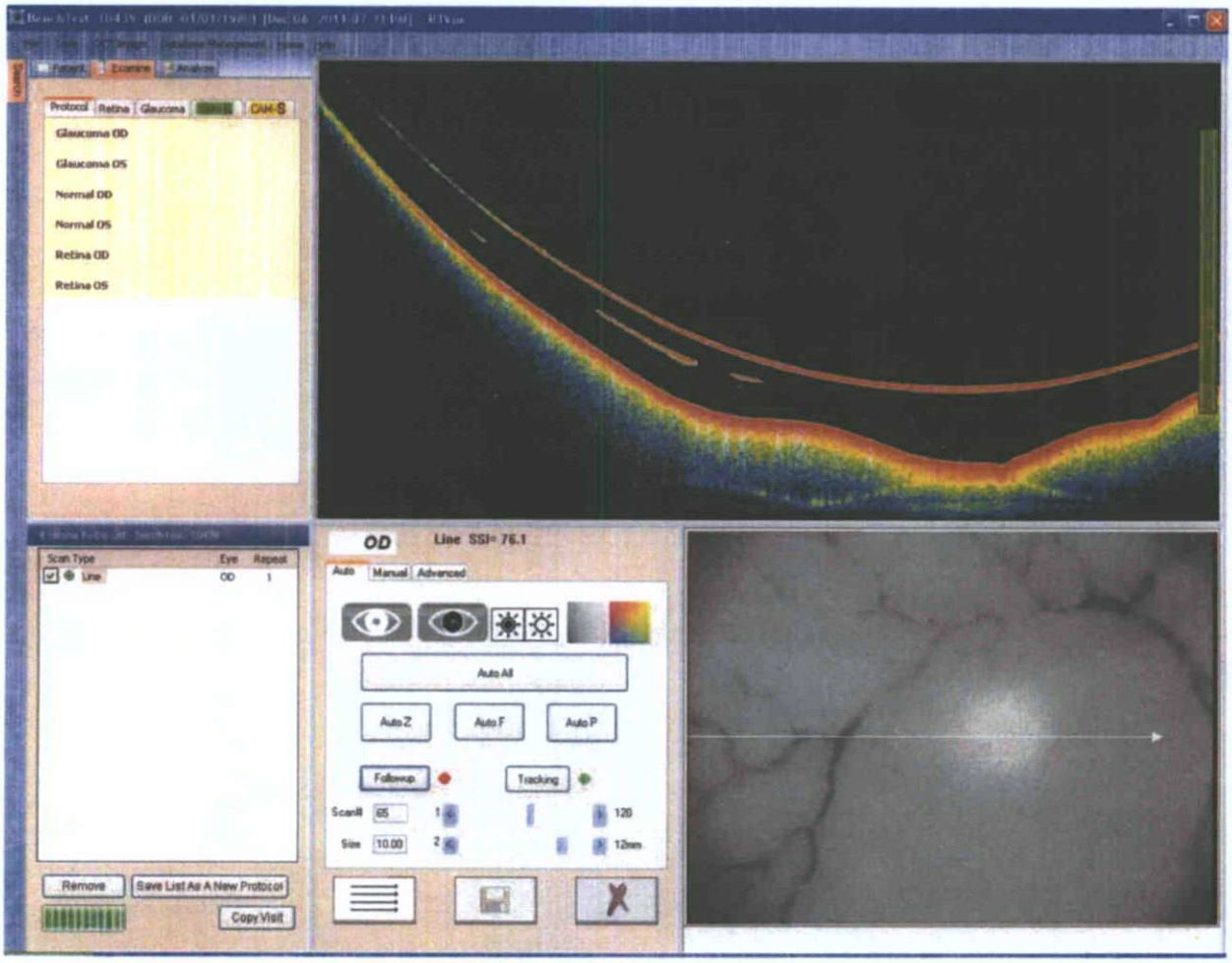
Phantom tracking performance

Using the RTVue appliaction software (version 6.6.0.82), the OCT image of a phantom eye target is acquired using the tracking protocol (200-47145-A, Software Requirement Specification for RTVue Tracking). During image acquisition, motion is simulated by moving the phantom target in relation to the RTVue-100 SN 10439 scan head and eye blinking is simulated by covering up the phantom eye target. Tracking OCT can successfully handle the simulated eye blink and motion in order to complete the image acquisition and generate the resulting OCT image.



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

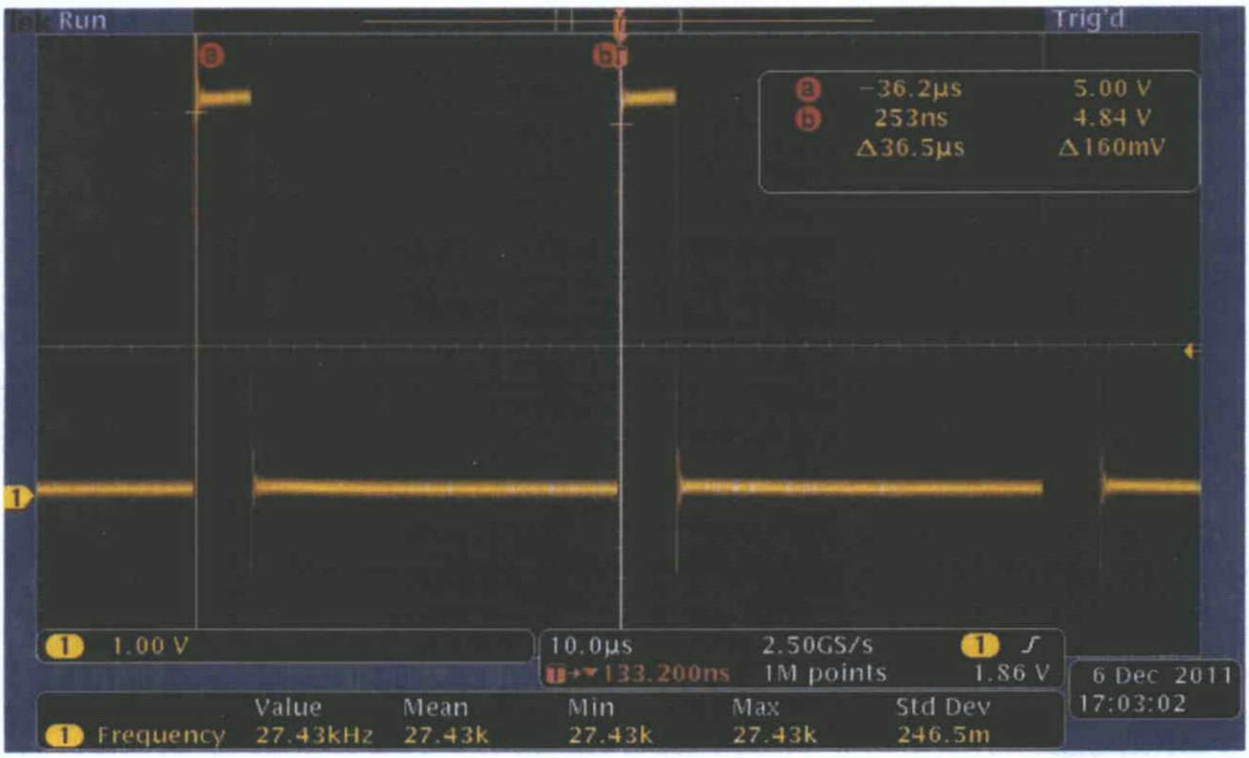
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

optovue

RTVue-100 System #3 (SN 10709)

Operating speed is ~27,000 A-lines per second

The operating speed of the line-scan camera and therefore the RTVue-100 system can be measured by probing the line sync trigger signal. The following oscilloscope screen capture indicates the operating speed of RTVue-100 SN 10709 is aproximatly 27,000 A-lines per second (A-scan time period is ~36.5 microseconds).



OCT signal intensity is as expected for RTVue-100

The RTVue-100 Manufacturing Process Instructions and Final Test Report (F-OPR-45366-H, RTVue Final Test Report) indicates that the difference in OCT Signal with tool on and without tool on, in a particular calibration step, needs to be above 18. The following screen captures show that, in this calibration step, RTVue-100 SN 10709 has an OCT Signal difference of 22 (66.5 minus 44.5; reference the relevant OCT Signal readings in red circles) which meets the manufacturing requirement of RTVue-100.

778

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

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[redacted]

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

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[redacted]

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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Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

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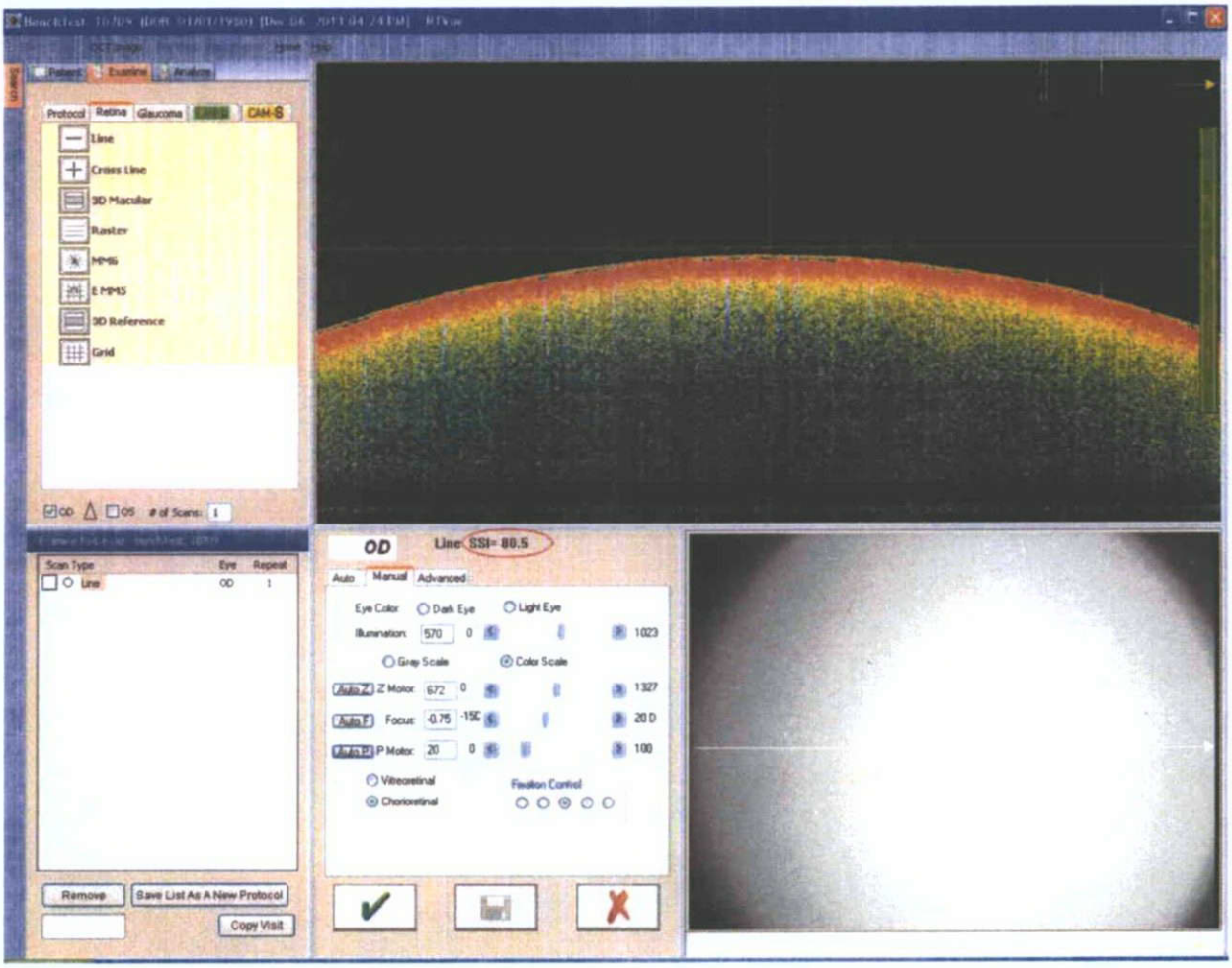
Phantom imaging performance

Using the RTVue appliaction software (version 6.6.0.82), an OCT image of a standard phantom target is obtained using RTVue-100 SN 10709 (200-24052-F, Software Requirement Specification for RTVue). For this type of phantom imaging target, a Signal Strength Index (SSI) of 80.5 (reference the SSI reading in the red circle) is typical of values acquired with the RTVue-100.



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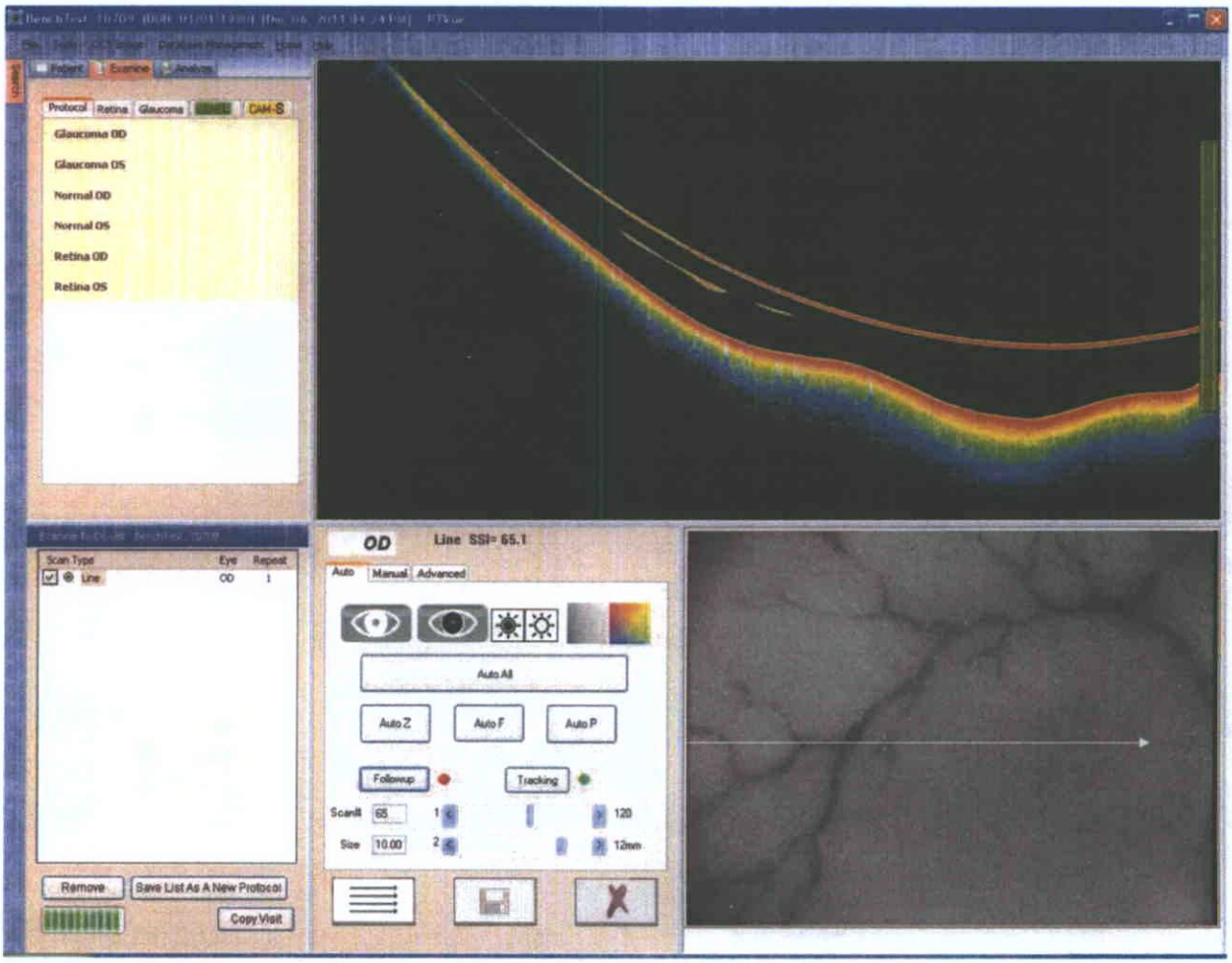
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

optovue

Phantom tracking performance

Using the RTVue appliaction software (version 6.6.0.82), the OCT image of a phantom eye target is acquired using the tracking protocol (200-47145-A, Software Requirement Specification for RTVue Tracking). During image acquisition, motion is simulated by moving the phantom target in relation to the RTVue-100 SN 10709 scan head and eye blinking is simulated by covering up the phantom eye target. Tracking OCT can successfully handle the simulated eye blink and motion in order to complete the image acquisition and generate the resulting OCT image.



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

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Conclusion

The RTVue XR is an updated version of RTVue-100 that can operate at ~70,000 A-lines per second while delivering equivalent imaging performance as the RTVue-100 operating at ~27,000 A-lines per second. This bench test report compares the imaging performance of three RTVue XR machines (SN 10488, 11969, 12002) with that of three RTVue-100 machines (SN 10438, 10439, 10709).

The OCT signal intensity of the RTVue XR is equivalent to that of the RTVue-100, and it also surpasses the manufacturing requirement of the RTVue-100. The axial resolution of the RTVue XR is equivalent to that of the RTVue-100 machines. This is as expected since the RTVue XR and RTVue-100 share the identical spectrometer design and optics.

In performing OCT imaging with RTVue appliaction software (version 6.6.0.82), the RTVue XR delivered similar results as the RTVue-100 in terms of imaging performance (Signal Strength Index of a standard phantom target) and tracking performance (ability to perform OCT imaging in the presence of simulated motion and blinking).

The Signal Strength Index (SSI) of a standard phantom target obtained with the RTVue XR are 78.4, 79.5, and 81.2 (mean ± sd = 79.7 ± 1.4). The Signal Strength Index (SSI) of a standard phantom target obtained with the RTVue-100 are 77.6, 79.1, and 80.5 (mean ± sd = 79.1 ± 1.5). The Signal Strength Index can differ between machines due to the within tolerance variation of the underlying optical components as well as the line-scan camera sensors. The mean and standard deviation values from the SSI imaging results indicate that the RTVue XR and RTVue-100 deliver equivalent performance in imaging the standard phantom target.

Prepared By: Tony Ko
Director of Advanced Development

Signature: Tony Ko
Date: 1/18/2012

Reviewed By:			
Title	**Name**	**Signature**	**Date**
CTO	**Tom Zhao**		1/17/12
Regulatory	**John Talarico**	John Talarico	1/17/2012

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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 #2012-3758; Released by CDRH on 09-8-2015

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

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

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
   Optovue, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   Dec 27, 2011

3. ADDRESS *(Number, Street, State, and ZIP Code)*
   45531 Northport Loop W.
   Fremont, CA 94538

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
   (Tel.) 510-623-8868
   (Fax) 510-623-8668

PRODUCT INFORMATION

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

   RTVue XR

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

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

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

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

CERTIFICATION STATEMENT / INFORMATION

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

   ☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

   ☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

   ☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

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

    NCT Number(s):

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

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
    John Talarico

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
    (Name) John Talarico
    (Title) VP of Regulatory/Quality Assurance

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
    45531 Northport Loop W.
    Fremont, CA 94538

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
    (Tel.) 510-623-8868 Ext. 209
    (Fax) 510-623-8668

15. DATE OF CERTIFICATION
    Dec 27, 2011

PSC Publishing Services (301) 443-6740 EF

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Attachment [G]

Software Documentation

List of Documents Attached:

- Software Requirement Specification (b)(4) [redacted]
- Software Requirement Specification for Tracking (b)(4) [redacted]
- Software Traceability Analyses (b)(4) [redacted]
- Software Traceability Matrix (b)(4) [redacted]
- V&V for Basic Functionality Test Report (b)(4) [redacted]
- V&V Tracking Report (b)(4) [redacted]

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

(b)(4) Software Documentation

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(b)(4) Software Documentation

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Attachment [H]

Financial Disclosure [AND/OR] Financial Certification

[Not APPLICABLE]

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

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Attachment [I]

- Declaration of Conformity with Design Controls
- RTVue Risk Analyses Report # 200-24047 Rev. J

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

optovue

Declaration of Conformity to Design Controls

To the best of my knowledge, the verification activities for optional **RTVue XR OCT** as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Tom Zhao
CTO
Optovue, Inc.

1/19/12
[Date]

Manufacturing Facility
The manufacturing facility, **Optovue, Inc.** is in conformance with the design control requirements as specified in 21 C.F.R. § 820. 30 and the records are available for review.

Joe Sharpe
VP of Operations
Optovue, Inc.

1/19/12
[Date]

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

(b)(4) Risk Analysis Report

(b)(4) Risk Analysis Report

(b)(4) Risk Analysis Report

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

For Device: RTVue Model 100

Summary:

All harms and hazards identified have been evaluated and are either in the Broadly Acceptable Category or in the As Low as Reasonably Practicable category. Where applicable this document lists the tests and/or procedures where the identified mitigation is performed.

1 INTRODUCTION

1.1 Product Description

The RTVue is a Fourier Domain OCT system which can non-invasively image retinal tissue in-vivo, with high acquisition speed and high-resolution scans.

The first generation OCT system developed in early 1990s was a Time-Domain system, which relied on the mechanical scan method to get the tissue depth signal. The scan speed is limited to 400 A-scan per second in conventional time-domain OCT due to the mechanic motion barrier. The RTVue uses a camera to acquire the A-scan signals simultaneously without mechanical motion. The RTVue system's scan speed is 26,000+ A-scan per second, or 65 times faster than the conventional OCT system. Due to the increase in scan rate, artifacts in OCT images caused by eye motion are eliminated in most* scan designs. (*3D scans with nearly 52,000 A-scans take 2 seconds to acquire. Motion artifacts may be present)

The RTVue system also employs a high bandwidth light source; the tissue resolution is approximately 4 - 5 micrometer; double that of a conventional OCT system.

With the speed and resolution improvement, RTVue provides a much more reliable and detailed retinal and nerve head map, with metrics in a much shorter period of time.

1.2 Intended Use of the Product

The RTVue is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disk as an aid in the diagnosis and management of retinal disease. The RTVue is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

The Cornea Anterior Module (CAM) can be attached to the RTVue as an auxiliary lens used in conjunction with the RTVue to view and scan the patient's cornea and anterior segment.Corneal thickness and central corneal refractive power are computed from the corneal scans.

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

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1.3 RTVue System Configuration:

The RTVue system is shipped in one paletted box, which contains the following hardware:

a. RTVue Scanner:
This is the main component of the RTVue system. It is used to view and scan the patient's retina, collect the OCT signal, and send it to the computer for processing. It also provides a fixation light target for patient to fixate on during the scan and position sensor for automatic detection of whether the left or right eye is aligned for scanning. The communication between the scanner and computer is via a USB cable connection. The RTVue uses a medical grade power supply.

b. RTVue CAM module (high magnification and low magnification (optional)):
The CAM is an auxiliary lens used in conjuction with the RTVue to view and scan the patient's cornea. By adding the CAM lens to the front of the RTVue ocular lens, the CAM lens changes the image plane from retina to cornea, by changing the focal length.

c. Computer:
The computer is used to control the scanner during the patient examination. The application software provides data analysis, presentation, and data storage and archive. A relational database is included to organize all patient information and data, as well as allow for search capability.

d. System Table:
The system table provides power to the RTVue scanner, computer, and computer display through a medical grade isolation transformer to prevent leakage current from main AC power. The table elevation can be adjusted to fit patient height. The telescopic raiser which supplies the power of the RTVue system is medical grade.

e. Monitor (Computer Display):
An LCD flat panel display for graphic user interface and data presentation.

f. Keyboard and Mouse

System Configuration:
Model: RT100-1: 110V AC.
Model: RT100-2: 230V AC.

1.4 Risk Evaluation

1.4.1 Operator contact

Operator contact is to the computer keyboard and system.

1.4.2 Materials in contact with patient

The following materials are in contact with the patient:
Chinrest and headrest

1.4.3 CAM module shortens working distance,

The addition of the auxiliary CAM lens shortens the working distance from 22mm to 10mm. However 10mm is still compatible with other FDA cleared devices, e.g. Stratus OCT by Carl Zeiss Meditec. All electrical safety, mechanical safety, energy safety, biocompatibility, misdiagnosis and ergonomic risks remain the same as RTVue without CAM attached.

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

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1.4.4 CAM module scan length increased

The software change to increase the scan length of the cornea scan does not present new risk since the scan method remains the same (user could achieve the same results with the old software by scanning twice) and the working distance is not changed.

1.4.5 Cleaning and Disinfection

Dust Prevention:
When not using the RTVue, make sure the cloth dust cover is placed over the unit.
You can "Shut down" the PC at the end of each day.
Ocular (Front Objective) Lens Cleaning:
We recommend the ocular (front objective) lens of the RTVue is cleaned daily. A weak OCT image or blurry video image may be caused by an unclean front lens (eyelash, finger or nose prints, excessive dust or dirt from the environment).

Material required to clean front lens:
1) Diluted Acetone or Lens cleaning solution
2) Lens cleaning paper

Method:
Wet the lens paper with cleaning solution and wipe the ocular lens with one pass in one direction. Discard the used lens paper. Use a new sheet for each repeat cleaning until all lens area has been cleaned.

Head and Chin Rest Cleaning:
The headrest pad and chin rest cup should be cleaned before every patient visit.

1. Material required: Disinfecting agent such as an anti-germicide or isopropyl alcohol.
2. Cloth or cleaning towels.
3. Wet isopropyl alcohol cleaning paper pad.

Method:
Soak the cleaning cloth or towel in disinfecting solution or use a wet isopropyl alcohol cleaning paper pad. Wipe the chin-rest cup and head rest pad.

Biocompatibility:
Materials used for the chin rest and head rest are biocompatible and ISO 10993 compliant.

2 ANALYSIS METHODOLOGY

(b)(4) Risk Analysis Report

[redacted]

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

(b)(4) Risk Analysis Report

[redacted]

2.1.3 Risk Region Values

Each possible combination of Severity and Likelihood resides within one of the following Risk Region:

- Intolerable Region (IR)
- ALARP (As Low As Reasonably Practicable) Region (AR)
- Broadly Acceptable Region (BR)

Risk Region assignment for the Severity/ Likelihood combinations is as follows

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(b)(4) Risk Analysis Report

[redacted]

3 ANALYSIS FINDINGS

This section presents the findings of the risk analysis. It describes the potential hazards associated with the use of the RTVue, RTVue software and CAM. It also describes the possible failures that could cause those hazards and the controls in place required to mitigate the risk by reducing the likelihood of the failures. The analysis findings are itemized in Table 2.

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

(b)(4) Risk Analysis Report

(b)(4) Risk Analysis Report

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(b)(4) Risk Analysis Report

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Attachment [J]

- **Biocompatibility**
  This submission is only for the component change (Camera) to the RTVue system (K101505), therefore biocompatibility is the same. The previous biocompatibility documentation for RTVue system in included in this section

- **Certification**
  See attachment

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

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Certification of the Biocompatibility of the Optovue, Inc.'s RTVue with Normative Database

I certify that the only components of Optovue, Inc.'s RTVue with Normative Database that contact the patient are the same as the patient contacting components included in the previously cleared RTVue device (K062552). I also certify that no design modifications have been made to the previously cleared RTVue device (K062552). Thus, the biocompatibility of the Optovue, Inc.'s RTVue with Normative Database components has been demonstrated by the premarket clearance of the RTVue (K062552).

Signature

Jay Wei / CEO
(Typed Name and Title)

4/30/2009
(Date)

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

(b)(4) Material Data

(b)(4) Material Data

(b)(4) Material Data

(b)(4) Material Data

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Attachment [K]

Sterilization Information

Not applicable, the RTVue XR does not require sterilization nor is intended to be sterilized

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

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Attachment [L]

510(k) Summary

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

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510(k) Summary
Optovue, Incorporated

This 510(k) summary for the RTVue is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

General Information

Manufacturer:

Optovue, Inc.
45531 Northport Loop West,
Fremont, CA 94538
Phone: (510) 623-8868
Fax: (510) 623-8668
Registration No.: 3005950902

Contact Person:

John J. Talarico
VP Regulatory/Quality Assurance
Optovue, Inc.
Phone: (510)623-8868 x209
e-mail: john_talarico@optovue.com

Device Information

Classification: Class II

Trade Name: RTVue XR

Common Name: Optical Coherence Tomography (OCT)

Classification Name: Ophthalmoscope, a-c powered (21 C.F.R. § 886.1570)

Predicate Devices

510(k) **K101505** RTVue with NDB Optical Coherence Tomography (OCT)

Purpose of the Special 510(k) notice

The RTVue XR OCT is an upgrade to the current cleared device RTVue with NDB **(K101505)** with a new line scan camera for faster image acquisition.

Intended Use

The RTVue XR with Normative Database is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician.
The RTVue XR with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

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

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Technological Characteristics

The RTVue XR is a non-invasive diagnostic device for imaging the cornea, anterior chamber, and retinal tissue structure with micrometer range resolution. The RTVue XR OCT is based on the same Optical Coherence Tomography (OCT) technology used in its predicate device, RTVue with NDB OCT. A brochure of the RTVue with NDB is in the **Attachment [D]**.

The RTVue XR is a computer controlled ophthalmic imaging system. The device scans the patient's eye using a low coherence interferometer to measure the reflectivity of the retinal tissue. The cross sectional retinal tissue structure is composed of a sequence of A-scans. It has a traditional patient and instrument interface like most ophthalmic devices. The computer has a graphic user interface for acquiring and analyzing the image.

RTVue XR offers three scan types: Retina, Glaucoma, and Cornea. For the Cornea scan, a lens must be attached to the front of the device for proper scanning. This lens is called the CAM (Cornea Anterior Module-cleared under K111505)

The upgrade of the line scan camera is designed to **provide faster image acquisition.** The RTVue XR is an updated version of RTVue with NDB that operates at ~70,000 A-lines per second while the RTVue-100 operates at ~27,000 A-lines per second. The RTVue XR machines will be equipped with new line-scan cameras capable of operating at ~70,000 A-lines per second while delivering equivalent imaging results as the older generation RTVue line-scan cameras operating at ~27,000 A-lines per second. *See* **Attachment C** for drawings and specification of the line scan camera

Performance Data

Elliot lab Certification Testing and Report (ref: R64363 Rev.3 and R63863 Rev. 4) in accordance to IEC 60601-1 Amendment 1 and 2 and IEC-60601-1-2. In addition a Bench test was also performed, with the results for comparison of the RTVue XR with the predicate device RTVue with NDB. The RTVue XR meets the safety and stability requirements of IEC 60601-1and IEC-60601-1-2 as well as the bench test requirements results. **See Attachment F**

Substantial Equivalence

The RTVue XR has the same intended use and similar indications, principles of operation, and technological characteristics as the **RTVue with NDB OCT**. The minor difference in the RTVue XR OCT is **a new line scan camera for faster image acquisition and this upgrade** does not raise any new questions of safety or effectiveness. Performance data demonstrates that the **RTVue XR** is as safe and effective as **RTVue with NDB OCT**. Thus, the **RTVue XR** is substantially equivalent to its predicate devices.

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

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Attachment [M]

Indications for Use Statement

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

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Indications for Use Statement

510(k) Number (if known):_____

Device Name: RTVue XR

Indications for Use:

The RTVue XR with Normative Database is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician.
The RTVue XR with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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Attachment [N]
Truth and Accuracy Statement

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

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PREMARKET NOTIFICATION
TRUTH AND ACCURACY STATEMENT
(As required by 21 C.F.R. § 807.87(j))

I certify that, in my capacity as Vice President Regulatory & Clinical Affairs of Optovue Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification for the RTVue XR are truthful and accurate and that no material fact has been omitted.

(Signature)

John J. Talarico Vice President Regulatory and Quality Assurance
(Typed Name and Title)

Optovue, Inc.
(Company)

1/19/2012
(Date)

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Alex Baylin

Subject: 510(k) Number K132238/S1

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
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement	*Must be present for a Final Decision*	✓	
Is the device Class III?	*Must be present for a Final Decision*		✓
If yes, does firm include Class III Summary?			
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category ✓, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓
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 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?			✓

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

ıate/Newborn (Birth to 28 days)		✓
Infant (29 days -< 2 years old)		✓
Child (2 years -< 12 years old)		✓
Adolescent (12 years -< 18 years old)		✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		✓
Nanotechnology		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*	✓

Regulation Number 886.1570 **Class*** 2 **Product Code** HLI

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

Additional Product Codes:

Review: (Branch Chief) ONDB (Branch Code) 3/29/12 (Date)

Final Review: Lenia Alexander (Division Director) 4/3/12 (Date)

for

Records processed under FOIA request F-2012-[illegible] on 09-8-2015

SPECIAL 510(k): Device Modification

ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER **K120238/S1**

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

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

   This change was for the new line camera used in the spectrometer of the OCT.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, **are acceptable. The additional comparison information is included in follow-up emails, attached to the original submission.**

   _____

5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

In supplement 1 the sponsor provided additional design control activities document. Their revised Risk Analysis was performed following the guidelines set forth by EN ISO 14971 :2009 "Medical Device - Application of Risk Management to Medical Devices." Specifically, Failure Mode and Effect Analysis (FMEA) and Fault Tree Analysis (FTA) are performed to assess the impact of the modification on the device and its components." The results of analyses are documented in the "RTVue XR Bench Test Report" that contains the test methods used for the risk mitigation activities and the acceptance criteria that was applied.

6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the

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

design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

(Reviewer's Signature) 3/27/12 (Date)

Comments

revised:8/1/03

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	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?		X	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:

2. Explain why there is or is not a new effect or safety or effectiveness issue:
In the new device RTVue XR the sponsor replaced spectrometer camera. The line camera used in the predicate OCT RTVue 100 (Basler L104k) was replaced with a new faster e2v AVIIVA2 EM4 camera. The camera has different performance characteristics, such as responsively, spectral sensitivity, bit depth, SNR, pixel size, etc. These differences may affect the performance of the spectrometer, and ultimately affect the performance of the new OCT device. In addition, for the new RTVue XR device the sponsor is planning to use the normative data base (NBD) collected with a predicate RTVue 100 device. The changes of image quality and measurements in the new device may affect usability of the NDB.

3. Describe the new technological characteristics:
The following differences between the new and old cameras are important:

	RTVue 100 (based on Basler L104k line camera)	RTVue XR (based on e2v AVIIVA2 EM4)	Comments
Pixel size	10x10 microns	10x180 microns	Different pixels size may affect dynamic range
Bit depth	10 bits	12 bits	Dynamic range difference, more gray levels are visible
Dynamic range	<60 dB	68 dB	
Responsivity	7.5 LSB/(nJ/cm^2)	82 LSB/(nJ/cm^2)	Different spectral sensitivity and quantum efficiency may affect A-scans
Exposure time for a single A-scan	34 µS	12 µS	May affect image quality
Measured System Signal-to-Noise Ratio	SSI = 79.1	SSI = 79.7	May affect image quaity

4. Explain how new characteristics could or could not affect safety or effectiveness:

Based on the analysis of the AVIIVA2 EM4 camera characteristics, it is unlikely that the image quality would be different than images, collected with a predicate device. The main factor is similarity of the spectral sensitivity curve (see follow-up communication with the sponsor) and same size of the pixel, which define the A scans.

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
The new spectrometer camera seems to be the only hardware change in the RTVue XR device. Both devices are based on the same fundamental technology. No new type of S&E concerns are raised.

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

The sponsor conducted Risk Analysis following the guidelines set forth by EN ISO 14971 :2009 "Medical Device - Application of Risk Management to Medical Devices." Specifically, they conducted Failure Mode and Effect Analysis (FMEA) and Fault Tree Analysis (FTA) are performed to assess the impact of the modification on the device and its components." In Attachment 1 of the Suppplement 1 the sponsor documented the results of analyses in the "RTVue XR Bench Test Report" that contains the test methods used for the risk mitigation activities and the acceptance criteria that was applied. Based on the risk, an identification of the verification and/or validation activities required, including methods or tests used and the acceptance criteria applied (report # 200-24047)

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

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K120238

Standard Operating Procedures for 510(k) Summaries

1) If a 510(k) submitter decides to submit a 510(k) summary, as per 21 CFR 807.87(h), they need to follow the content requirements as per 21 CFR 807.92.
2) If during the review of the 510(k), the submitter decides to switch to a 510(k) statement, as per 21 CFR 807.87(h), they may do so while the 510(k) is under review. They must follow 21 CFR 807.93 for a 510(k) statement.
3) The 510(k) summary is written by the 510(k) submitter, but FDA will agree with the content prior to clearing any 510(k).
4) The 510(k) summary needs to agree with the final classification decision of FDA, e.g., the predicate classification needs to match the FDA classification decision. The submitter may need to revise the summary while the 510(k) is under review. In other words, the 510(k) summary will need to reflect the predicate(s) and decision made by FDA. The submitter will then need to revise the summary while the 510(k) is under review.
5) The IFU provided in the 510(k) summary needs to match the IFU statement that is determined to be substantially equivalent
6) The 510(k) summary should reflect all the testing done by the 510(k) submitter to demonstrate substantial equivalence. This may include testing that FDA did/would not require to demonstrate substantial equivalence, but would include all testing that FDA does/would require to demonstrate substantial equivalence.
7) If the 510(k) summary is deficient, the deficiency(ies) may be put in an AI letter or handled through interactive review.
8) The 510(k) may not be found to be substantially equivalent until the 510(k) summary meets the regulatory requirements of 21 CFR 807.92.
9) If, after interactions, a 510(k) submitter does not revise the 510(k) summary as requested and we disagree with their rationale, the 510(k) may be found not substantially equivalent for lack of required data/information.
10) Neither the 510(k) summary, nor 510(k) statement, are needed if the decision is other than SE.
11) The 510(k) summary will go on FDA's website approximately the 5th of the month following any SE decision.

510(k) SUMMARY REQUIREMENTS CHECKLIST
21 CFR 807.92

	All 510(k) summaries shall contain the following information:	Y	N	N/A
1	The submitter's name, address, telephone number, a contact person, and the	✓		

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

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

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Beylin, Alexander

From: Azimun Jamal [azimun_jamal@optovue.com]
Sent: Monday, April 02, 2012 3:15 PM
To: Beylin, Alexander
Cc: Cunningham, Bradley; John Talarico
Subject: RE: K120238
Attachments: Additional Request-510K summary revised.pdf

Dear Dr. Beylin,

Attached is the revised 510 summary per your request.
Please do let me know if you have any additional requests.

I will look forward to your response.

Have a wonderful day!!

Best Regards,

Azimun Jamal
Director of Quality Assurance
optovue
Optovue Inc.
45531 Northport Loop West
Fremont Ca 94538
Phone: (510) 623-8868 Ext. 188
Fax : (510) 623-8668
www.Optovue.com

From: Beylin, Alexander [mailto:Alexander.Beylin@fda.hhs.gov]
Sent: Monday, April 02, 2012 11:32 AM
To: 'Azimun Jamal'; 'John Talarico'
Cc: Cunningham, Bradley
Subject: RE: K120238

Dear Ms. Jamal,

In your K120238 510(k) Summary you reference Attachments D, C, and F.

After your device is cleared, only two sections of your submission, namely your 510(k) Summary and Indication for Use, will be posted on FDA's website and available for the public access. All other information including all your attachments is considered confidential and not available to the public. Therefore, you can not reference your confidential information in publicly-available documents.

With your permission, I can remove these references to the attachments from your 510(k) summary. Alternatively, please send me the revised 510(k) summary.

...anks
Alex

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

From: Azimun Jamal [mailto:azimun_jamal@optovue.com]
ıt: Sunday, April 01, 2012 10:02 PM
.o: Beylin, Alexander
Subject: RE: K120238

Dear Dr. Beylin,
Thank you very much for your prompt response.
I will look forward to the determination letter.

Kind Regards,
Azimun

From: Beylin, Alexander [mailto:Alexander.Beylin@fda.hhs.gov]
Sent: Thursday, March 29, 2012 12:19 PM
To: 'Azimun Jamal'
Subject: RE: K120238

Dear Ms. Jamal,

We have completed review of your Optovue XR OCT device. You will get our formal determination letter shortly. I'm sure, you will like it ☺

Alex

ım: Azimun Jamal [mailto:azimun_jamal@optovue.com]
Sent: Wednesday, March 28, 2012 8:08 PM
To: Beylin, Alexander
Subject: RE: K120238

Dear Dr. Beylin,

Hope this email finds you doing well.

I was just wondering if you have any update on this submission K120238/S1.
Sorry to bother you.

Regards

Azimun Jamal
Director of Quality Assurance
optovue
Optovue Inc.
45531 Northport Loop West
Fremont Ca 94538
Phone: (510) 623-8868 Ext. 188
Fax : (510) 623-8668
www.Optovue.com

..om: Beylin, Alexander [mailto:Alexander.Beylin@fda.hhs.gov]
Sent: Monday, March 19, 2012 6:51 AM
To: 'Azimun Jamal'

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Subject: RE: K120338

lo Ms. Jamal,

Our review of the K120238/S1 (not K120338 referenced in your email) submission will be completed before 3/28/2012.

Thanks,
Alex

From: Azimun Jamal [mailto:azimun_jamal@optovue.com]
Sent: Thursday, March 15, 2012 11:19 AM
To: Beylin, Alexander
Subject: RE: K120338

Dear Dr. Beylin,

Hope this email finds you doing well.

I am just following up on the submission for K120338. Can you please provide us an update on this review.

Your response would be very much appreciated.

Have a wonderful day!!

.t Regards,

Azimun Jamal
Director of Quality Assurance
optovue
Optovue Inc.
45531 Northport Loop West
Fremont Ca 94538
Phone: (510) 623-8868 Ext. 188
Fax : (510) 623-8668
www.Optovue.com

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Alexander Beylin, Ph.D

Subject: 510(k) Number K120238

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
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	
Is clinical data necessary to support the review of this 510(k)?			✓
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 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?			✓
All Pediatric Patients age <= 21			

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

Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			✓
Nanotechnology			✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number	Class*	Product Code
886.1570	2	HLI

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

Additional Product Codes: _____

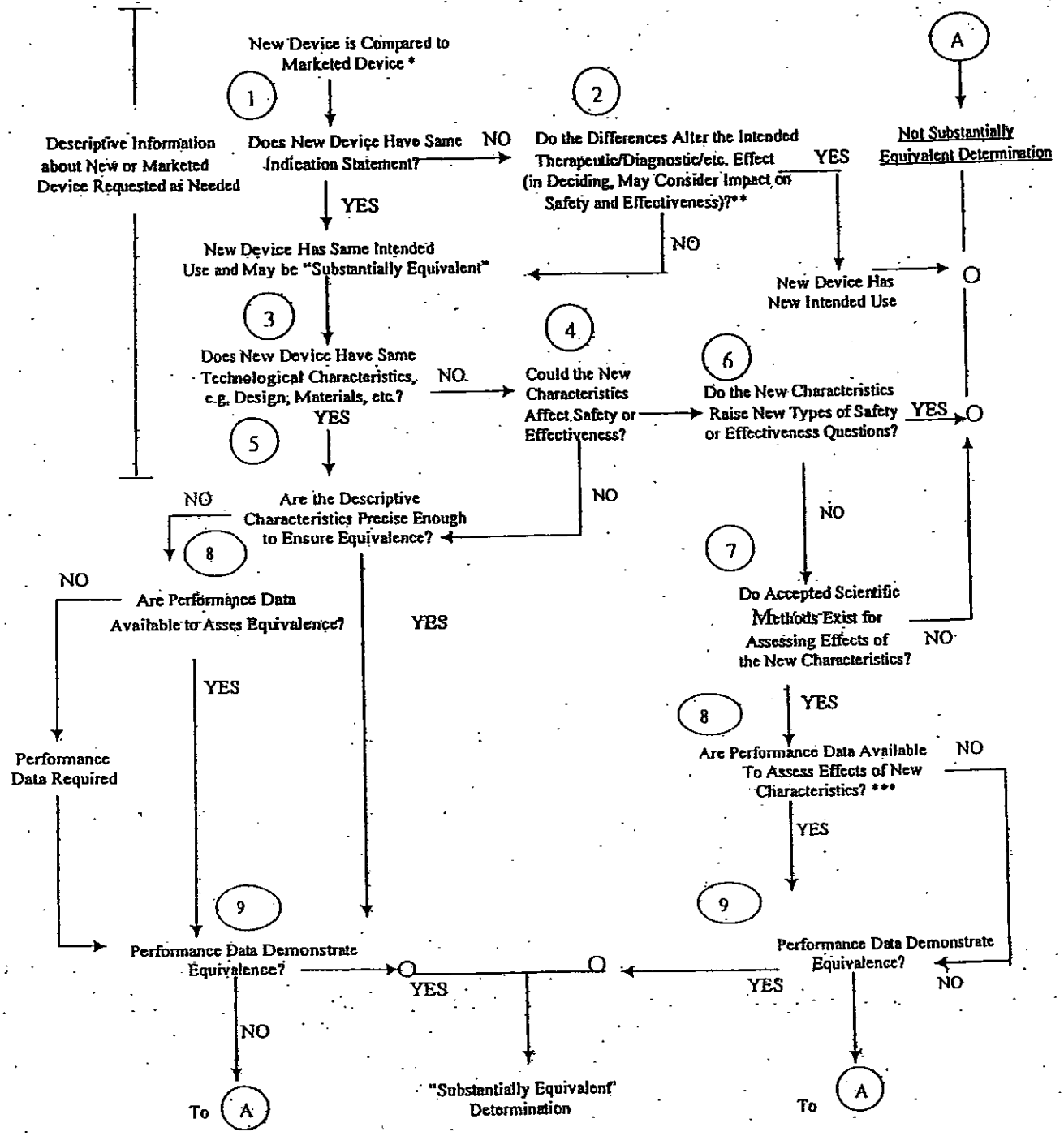
Review: _____ (Branch Chief) (Branch Code) (Date)

Final Review: _____ (Division Director) (Date)

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

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 #2012-3758; Released by CDRH on 09-8-2015

Beylin, Alexander

From: Beylin, Alexander
Sent: Tuesday, February 14, 2012 3:13 PM
To: John Talarico
Cc: 'Azimun Jamal'; Cunningham, Bradley
Subject: K120338

Attachments: K120238 special 510(k) TH memo.pdf

Dear Mr. Talarico,

Our Telephone Hold memo regarding you special 510 (k) Submission for RTVue XR OCT device is attached.

Please let me know if you have any questions.

Best Regards,

K120238 special 510(k) TH memo...

Alexander Beylin, Ph.D.
Biomedical Engineer - Scientific Reviewer
FDA/CDRH/ODE/DONED/ONDB
WO66 Rm. 2244
10903 New Hampshire Ave.,
Silver Spring, MD 20993
(301) 796-6463

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

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

February 14, 2011

To: Mr. John Talarico
Vice President Regulatory and Quality Assurance
Optovue, Inc
45531 Northport Loop W.,
Fremont, CA 94538

Subject: K120238
Trade Name: RTVue XR
Dated: January 23, 2012
Received: January 26 2012

Dear Mr. Talarico:

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 additional information:

In Attachment I you provide Risk Analysis Report for the device RTVue Model 100, which is identified as a predicate for the subject device of your Special 510(k) submission (RTVue XR). To justify this, on page 16 of the submission of you state the following:

> "Due to no change in the basic design of the RTVue XR no new no risk was introduced, therefore all the risk identified for RTVue [Model 100] will apply to RTVue XR."

The risk analysis of the predicate device does not substitute the risk analysis of the modified device, as it does not meet the criteria stated in 21 CFR 807.87(g). Please note that the design control activities should include the risk analysis report of the subject device [i.e., RTVue XR] to assess the impact of the modification on the device and its components on safety and effectiveness. Furthermore, based on the Risk Analysis, please clearly identify the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied. To address this concern, please provide a concise summary of the design control activities, which includes the following missing documents:

- An identification of the Risk Analysis methods used to assess the impact of the modification on the device and its components as well as the results of the analysis;

- Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and the acceptance criteria applied;

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

This information is important for better understanding the impact of the modifications on safety and effectiveness of your device and your validation and verification activities, described in your Attachment F, Performance data.

This letter reflects the current progress of our review of your application. Please be advised that further substantive review of your application or any response to this letter may result in additional deficiencies.

The deficiency identified above represents the issue that we believe needs to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiency, 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.

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, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at www.fda.gov/cdrh/ode/guidance/1655.html.

If you do 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 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-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Alexander Beylin, Ph.D. at (301) 796-6620. 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.html.

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

SCREENING CHECKLIST FOR SPECIAL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: __K120238_

Section 1: Required Elements for a SPECIAL 510(k) submission:

	Present or Adequate	Missing or Inadequate
Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html	X p.4	
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 p.10	
Table of Contents	X p.3	
Truthful and Accurate Statement Device Advice - www.fda.gov/cdrh/devadvice/314312.html#link_9	X p.874	
Form FDA 3654 - Standards Data Report for 510(k)s – http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf 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 pp.20-26	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	X p. 14	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	X p. 14	
Proposed Labeling - Device Advice www.fda.gov/cdrh/devadvice/314312.html#link_10	X pp. 305-440	
Indications for Use Statement Device Advice - www.fda.gov/cdrh/devadvice/314312.html#link_6	X p.872	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	X p.442-445	
510(k) Summary or 510(k) Statement Device Advice - www.fda.gov/cdrh/devadvice/314312.html#link_7	X p.868	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	X pp.297-303	
Identification of legally marketed predicate device. *	X p.442	

Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	X pp. 446-712	
Class III Certification and Summary. ** Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html	n/a	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. 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.	n/a	
Kit Certification: Device Advice http://www.fda.gov/cdrh/ode/odecl874.html	n/a	

*- May not be applicable for Special 510(k)s.
**- Required for Class III devices, only.

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present or Adequate	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	X pp.442	
A description of the modified device and a comparison to the sponsor's predicate device.	X pp.446-712	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	X p. 442	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		X
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	pp.854-860	
c. A Declaration of Conformity with design controls that includes the following statements:	X p.838	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met.? This statement is signed by the individual responsible for those particular activities.	X p.838	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	X p.838	

Items with checks in the Present or Adequate column do not require additional information from the sponsor. Items with checks in the Missing or Inadequate column must be submitted before substantive review of the document.

Passed Screening __ __Yes ___ X __No - Reviewer:__Alexander Beylin, Ph.D._____
Concurrence by Review Branch:_____ Date:_____

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 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

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

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/cdrh/modact/leastburdensome.html

Records processed under FOIA Request 2015-3059, Released Date 09-8-2015

SPECIAL 510(k): Device Modification

ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER **K120238**

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

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

   This change was for the new line camera used in the spectrometer of the OCT.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, **are acceptable. The additional comparison information is included in follow-up emails (attached).**

   _____.

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

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

(Reviewer's Signature) 2/14/12 (Date)

Comments 2/14/12

Due to inadequate design control activity information (namely, Risk analysis data), I recommend placing submission On Hold pending adequate response to one deficiency.

revised:8/1/03

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	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?		X	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:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

(b) (4)

[redacted]

3. Describe the new technological characteristics:

(b) (4)

[redacted]

(b)(4)

[redacted]

4. Explain how new characteristics could or could not affect safety or effectiveness:

(b)(4)

[redacted]

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
The new spectrometer camera seems to be the only hardware change in the RTVue XR device. Both devices are based on the same fundamental technology. No new type of S&E concerns are raised.

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

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Beylin, Alexander

From: Azimun Jamal [azimun_jamal@optovue.com]
Sent: Thursday, February 09, 2012 2:28 PM
To: Beylin, Alexander
Cc: Cunningham, Bradley; Agrawal, Anant; John Talarico
Subject: RE: K120238 RTVue XR
Attachments: Additional Request-Camera noise level.pdf

Dear Dr. Beylin,

Hope all is going well.

Attached is the information that you requested.

Please let me know if you have additional questions or requests.

Best Regards,

Azimun Jamal
Director of Quality Assurance
optovue
ptovue Inc.
+5531 Northport Loop West
Fremont Ca 94538
Phone: (510) 623-8868 Ext. 188
Fax : (510) 623-8668
www.Optovue.com

From: Beylin, Alexander [mailto:Alexander.Beylin@fda.hhs.gov]
Sent: Wednesday, February 08, 2012 5:48 AM
To: 'Azimun Jamal'
Cc: Cunningham, Bradley; Agrawal, Anant
Subject: RE: K120238 RTVue XR

Dear Ms. Jamal,

(b)(4)

[redacted]

Please provide this data before February 13, 2012

Thank you,
Alex

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

From: Azimun Jamal [mailto:azimun_jamal@optovue.com]
Sent: Monday, February 06, 2012 1:32 PM
To: Beylin, Alexander
Cc: John Talarico; Agrawal, Anant; Cunningham, Bradley
Subject: RE: K120238 RTVue XR

Dear Dr. Beylin,

Thank you so much for your prompt response

Attached is the response regarding the camera pixel size.

Best Regards,

Azimun Jamal
Director of Quality Assurance
optovue
Optovue Inc.
45531 Northport Loop West
Fremont Ca 94538
Phone: (510) 623-8868 Ext. 188
Fax : (510) 623-8668
www.Optovue.com

From: Beylin, Alexander [mailto:Alexander.Beylin@fda.hhs.gov]
Sent: Monday, February 06, 2012 7:52 AM
To: 'Azimun Jamal'
Cc: John Talarico; Agrawal, Anant; Cunningham, Bradley
Subject: RE: K120238 RTVue XR

Dear Ms. Jamal,

(b)(4)

[redacted]

Thanks
Alex

From: Azimun Jamal [mailto:azimun_jamal@optovue.com]
Sent: Monday, February 06, 2012 12:33 AM
To: Beylin, Alexander
Cc: John Talarico
Subject: RE: K120238 RTVue XR

Dear Dr. Beylin,

Hope you had a great weekend

Attached is the information you requested.

Please let me know if you have any additional requests.

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Regards,
Azimun Jamal

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Beylin, Alexander

From: Agrawal, Anant
Sent: Thursday, February 09, 2012 3:01 PM
To: Beylin, Alexander
Subject: RE: K120238 RTVue XR

Yes, I see they have a shorter exposure time. But the phantom images we looked at and the SNR calculation both indicate equivalent (or better) performance compared to the new camera. This may be because the new camera apparently has higher responsivity and lower noise level, so the shorter exposure time is ok.

From: Beylin, Alexander
Sent: Thursday, February 09, 2012 2:55 PM
To: Agrawal, Anant
Subject: RE: K120238 RTVue XR

It is possible... Or they evacuate the charge way before the well filles up. Please note that they are using a short a exposure time.....

From: Agrawal, Anant
Sent: Thursday, February 09, 2012 2:52 PM
To: Beylin, Alexander
ubject: RE: K120238 RTVue XR

(b)(4)

[redacted]

From: Beylin, Alexander
Sent: Thursday, February 09, 2012 2:32 PM
To: Agrawal, Anant
Subject: RE: K120238 RTVue XR

(b)(4)

[redacted]

From: Agrawal, Anant
Sent: Thursday, February 09, 2012 2:26 PM
To: Beylin, Alexander
Subject: RE: K120238 RTVue XR

Sounds good, thanks.

From: Beylin, Alexander
Sent: Thursday, February 09, 2012 2:23 PM
To: Agrawal, Anant
Subject: RE: K120238 RTVue XR

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Anant,
Thank you for the reminder. I extended CTS for a week, Optovue should send me their response by COB Monday, so hopefully we will close the submission bu Tuesday.

From: Agrawal, Anant
Sent: Thursday, February 09, 2012 11:56 AM
To: Beylin, Alexander
Subject: RE: K120238 RTVue XR

Alex,
My consult for you is due today. Should I mark it as complete, or do you want to extend the due date by one week to allow for their response?

Thanks,
Anant

From: Beylin, Alexander
Sent: Wednesday, February 08, 2012 8:48 AM
To: 'Azimun Jamal'
Cc: Cunningham, Bradley; Agrawal, Anant
Subject: RE: K120238 RTVue XR

Dear Ms. Jamal,

(b)(4)

[redacted]

Thank you,
Alex

From: Azimun Jamal [mailto:azimun_jamal@optovue.com]
Sent: Monday, February 06, 2012 1:32 PM
To: Beylin, Alexander
Cc: John Talarico; Agrawal, Anant; Cunningham, Bradley
Subject: RE: K120238 RTVue XR

Dear Dr. Beylin,

Thank you so much for your prompt response

Attached is the response regarding the camera pixel size.

Best Regards,

Azimun Jamal
Director of Quality Assurance

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

optovue
Optovue Inc.
3531 Northport Loop West
Fremont Ca 94538
Phone: (510) 623-8868 Ext. 188
Fax : (510) 623-8668
www.Optovue.com

From: Beylin, Alexander [mailto:Alexander.Beylin@fda.hhs.gov]
Sent: Monday, February 06, 2012 7:52 AM
To: 'Azimun Jamal'
Cc: John Talarico; Agrawal, Anant; Cunningham, Bradley
Subject: RE: K120238 RTVue XR

Dear Ms. Jamal,

(b)(4)
[redacted]

Thanks
Alex

From: Azimun Jamal [mailto:azimun_jamal@optovue.com]
Sent: Monday, February 06, 2012 12:33 AM
To: Beylin, Alexander
Cc: John Talarico
Subject: RE: K120238 RTVue XR

Dear Dr. Beylin,

Hope you had a great weekend

Attached is the information you requested.

Please let me know if you have any additional requests.

Regards,
Azimun Jamal

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Beylin, Alexander

From: Azimun Jamal [azimun_jamal@optovue.com]
Sent: Wednesday, February 08, 2012 12:50 PM
To: Beylin, Alexander
Cc: Cunningham, Bradley; Agrawal, Anant; John Talarico
Subject: RE: K120238 RTVue XR

Dear Dr. Beylin,

You are very welcome!!

We are looking into your request and we will provide a response on or before the request date.

Best Regards,

Azimun Jamal
Director of Quality Assurance
optovue
Optovue Inc.
45531 Northport Loop West
Fremont Ca 94538
Phone: (510) 623-8868 Ext. 188
ax : (510) 623-8668
www.Optovue.com

From: Beylin, Alexander [mailto:Alexander.Beylin@fda.hhs.gov]
Sent: Wednesday, February 08, 2012 5:48 AM
To: 'Azimun Jamal'
Cc: Cunningham, Bradley; Agrawal, Anant
Subject: RE: K120238 RTVue XR

Dear Ms. Jamal,

(b)(4)

[redacted]

Please provide this data before February 13, 2012

Thank you,
Alex

---

rom: Azimun Jamal [mailto:azimun_jamal@optovue.com]
Sent: Monday, February 06, 2012 1:32 PM
To: Beylin, Alexander
Cc: John Talarico; Agrawal, Anant; Cunningham, Bradley

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Subject: RE: K120238 RTVue XR

ear Dr. Beylin,

Thank you so much for your prompt response

(b)(4)
[redacted]

Best Regards,

Azimun Jamal
Director of Quality Assurance

optovue

Optovue Inc.
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From: Beylin, Alexander [mailto:Alexander.Beylin@fda.hhs.gov]
Sent: Monday, February 06, 2012 7:52 AM
To: 'Azimun Jamal'
Cc: John Talarico; Agrawal, Anant; Cunningham, Bradley
Subject: RE: K120238 RTVue XR

Dear Ms. Jamal,

(b)(4)
[redacted]

Thanks
Alex

From: Azimun Jamal [mailto:azimun_jamal@optovue.com]
Sent: Monday, February 06, 2012 12:33 AM
To: Beylin, Alexander
Cc: John Talarico
Subject: RE: K120238 RTVue XR

Dear Dr. Beylin,

Hope you had a great weekend

Attached is the information you requested.

Please let me know if you have any additional requests.

egards,
Azimun Jamal

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Beylin, Alexander

From: Azimun Jamal [azimun_jamal@optovue.com]
Sent: Monday, February 06, 2012 1:32 PM
To: Beylin, Alexander
Cc: John Talarico; Agrawal, Anant; Cunningham, Bradley
Subject: RE: K120238 RTVue XR
Attachments: Response for Pixel size.pdf

Dear Dr. Beylin,

Thank you so much for your prompt response

Attached is the response regarding the camera pixel size.

Best Regards,

Azimun Jamal
Director of Quality Assurance
optovue
Optovue Inc.
45531 Northport Loop West
Fremont Ca 94538
Phone: (510) 623-8868 Ext. 188
Fax : (510) 623-8668
www.Optovue.com

From: Beylin, Alexander [mailto:Alexander.Beylin@fda.hhs.gov]
Sent: Monday, February 06, 2012 7:52 AM
To: 'Azimun Jamal'
Cc: John Talarico; Agrawal, Anant; Cunningham, Bradley
Subject: RE: K120238 RTVue XR

Dear Ms. Jamal,

(b)(4)
[redacted]

Thanks
Alex

From: Azimun Jamal [mailto:azimun_jamal@optovue.com]
Sent: Monday, February 06, 2012 12:33 AM
To: Beylin, Alexander
Cc: John Talarico
Subject: RE: K120238 RTVue XR

Dear Dr. Beylin,

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Hope you had a great weekend

'tached is the information you requested.

Please let me know if you have any additional requests.

Regards,
Azimun Jamal

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Beylin, Alexander

From: Azimun Jamal [azimun_jamal@optovue.com]
Sent: Thursday, February 02, 2012 4:11 PM
To: Beylin, Alexander
Cc: John Talarico
Subject: RE: K120238 RTVue XR

Dear Dr. Beylin,

Good to hear from you. Hope all is going well.

Here is the link for the documents:

(b)(4)
[redacted]

Regards,

Azimun Jamal
Director of Quality Assurance
optovue
Optovue Inc.
45531 Northport Loop West
Fremont Ca 94538
Phone: (510) 623-8868 Ext. 188
Fax : (510) 623-8668
www.Optovue.com

From: John Talarico [mailto:john_talarico@optovue.com]
Sent: Thursday, February 02, 2012 11:47 AM
To: Azimun Jamal
Subject: FW: K120238 RTVue XR

From: Beylin, Alexander [mailto:Alexander.Beylin@fda.hhs.gov]
Sent: Thursday, February 02, 2012 11:41 AM
To: John Talarico
Cc: Cunningham, Bradley
Subject: K120238 RTVue XR

Dear Mr. Talarico,

We are currently reviewing your 510(k) submission K120238 for RTVue XR OCT. To expedite review process, please email me an electronic copy of your submission.
hank you.

Best Regards

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

Alexander Beylin, Ph.D.
Biomedical Engineer - Scientific Reviewer
DA/CDRH/ODE/DONED/ONDB
WO66 Rm. 2244
10903 New Hampshire Ave.,
Silver Spring, MD 20993
(301) 796-6463

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optovue

February 6, 2012

FDA question:

(b)(4)

[redacted]

Optovue Response:

(b)(4)

[redacted]

45531 Northport Loop W, Fremont, CA 94538 Phone: (866) 344.8948; (510) 623-8868 Fax: (510) 623.8668

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

(b)(4) Materials

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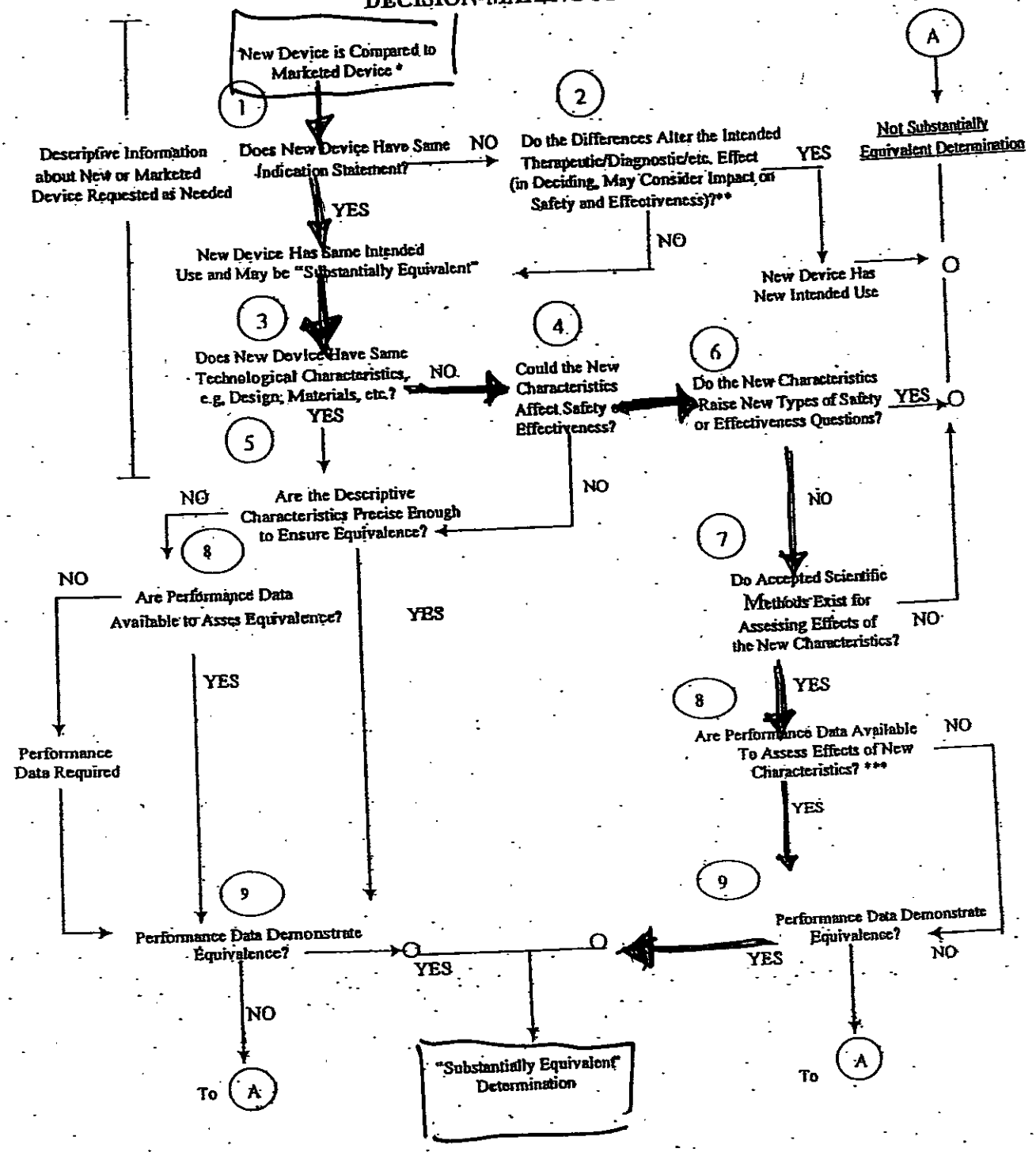
Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

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.

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

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optovue

01/DOMED K120238S1

45531 Northport Loop West
Fremont, CA 94538
Phone: (510) 623-8868
Fax: (510) 623-8668

February 23, 2012

Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FD DMC
FE 2
Rece

Re: K120238-RTVue-XR

Dear Dr. Beylin:

This letter is in response to the request for additional information for the letter dated February, 14, 2012

Agency Question 1

- Please provided an identification of the Risk Analysis methods used to assess the impact of the modification on the device and its components as well as the results of the analyses

Optovue's Response:

- The Risk Analysis was performed following the guidelines set forth by EN ISO 14971:2009 "Medical Device – Application of Risk Management to Medical Devices." Specifically, Failure Mode and Effect Analysis (FMEA) and Fault Tree Analysis (FTA) are performed to assess the impact of the modification on the device and its components."

  The results of analyses are documented in the "RTVue XR Bench Test Report" that contains the test methods used for the risk mitigation activities and the acceptance criteria that was applied. (Attachment 1)

Agency Question 2

- Based on the risk, an identification of the verification and/or validation activities required, including methods or tests used and the acceptance criteria applied;

Optovue's Response:

- The risk identified for this change is verified and mitigated in the attached Risk analyses report # 200-24047 re-formatted specifically for the RTVue XR. (Red Lined-Attachment 2 & final copy-Attachment 3 and Dr. Sliney's Report-Attachment 4)

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

12-22

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

optovue

We trust that the information provided in this letter is sufficient for FDA to find the **RTVue XR** OCT substantially equivalent for the listed indication. If you have any additional questions regarding this response please contact me at (510) 623-8668.

Sincerely,

John J. Talarico
VP Regulatory & Quality Assurance
Optovue, Inc.

Attachments

cc: Gerald Prud'homme, Esq.
cc: Azimun Jamal

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

Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

45531 Northport Loop West
Fremont, CA 94538
Phone: (510) 623-8868
Fax: (510) 623-8668

February 23, 2012

Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K120238-RTVue-XR

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Agency Question 1

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Sincerely,

John J. Talarico
VP Regulatory & Quality Assurance
Optovue, Inc.

Attachments

cc: Gerald Prud'homme, Esq.
cc: Azimun Jamal

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

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Attachment 1

RTVue XR Bench Test Report

(Reference Only)

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

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optovue

RTVue XR Bench Test Report

Overview

The RTVue XR is an updated version of RTVue-100 that operates at ~70,000 A-lines per second (RTVue XR System Design Specifications, 200-24002-CX1,) while the RTVue-100 operating at ~27,000 A-lines per second (RTVue100 System Design Specification, 200-24002-C,). The RTVue XR machines are equipped with new line-scan cameras (b)(4) [redacted] capable of operating at ~70,000 A-lines per second while delivering equivalent imaging results as the older generation RTVue line-scan cameras (b)(4) [redacted] operating at ~27,000 A-lines per second.

This bench test report compares the OCT imaging performance of RTVue XR with RTVue-100. Measurements were taken from three RTVue XR machines (SN 10488, 11969, 12002) and compared to measurements taken from three RTVue-100 machines (SN 10438, 10439, 10709). Measurements taken include system speed, signal intensity, axial resolution, as well as phantom target imaging and tracking performance.

References

No.	Description	Part Number / Source
1	RTVue XR System Design Specifications	200-24002-CX1
2	RTVue-100 System Design Specification	200-24002-C
3	RTVue Final Test Report	F-OPR-45366-H
4	Software Requirement Specification (RTVue)	200-24052-F
5	Software Requirement Specification (RTVue Tracking)	200-47145-A

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

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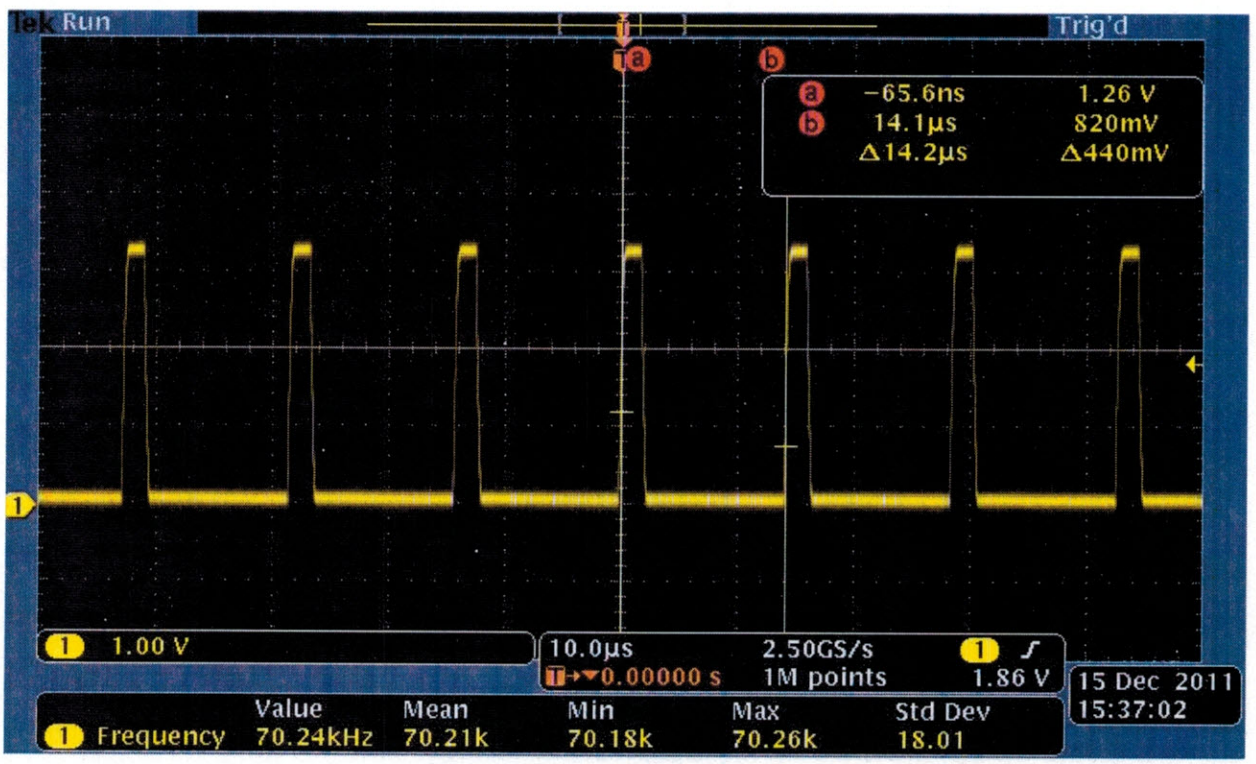
optovue

RTVue XR System #1 (SN 10488)

Operating speed is ~70,000 A-lines per second

The operating speed of the line-scan camera and therefore the RTVue XR system can be measured by probing the line sync trigger signal. The following oscilloscope screen capture indicates the operating speed of RTVue XR SN 10488 is aproximatly 70,000 A-lines per second (A-scan time period is ~14.2 microseconds).



OCT signal intensity is equivalent to RTVue-100

The RTVue-100 Manufacturing Process Instructions and Final Test Report (F-OPR-45366-H, RTVue Final Test Report) indicates that the difference in OCT Signal with tool on and without tool on, in a particular calibration step, needs to be above 18. The following screen captures show that, in this calibration step, RTVue XR SN 10488 has an OCT Signal difference of 19 (64 minus 45; reference the relevant OCT Signal readings in red circles) which meets the manufacturing requirement of RTVue-100.

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

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optovue

(b)(4)

[redacted]

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

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optovue

(b)(4)

[redacted]

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

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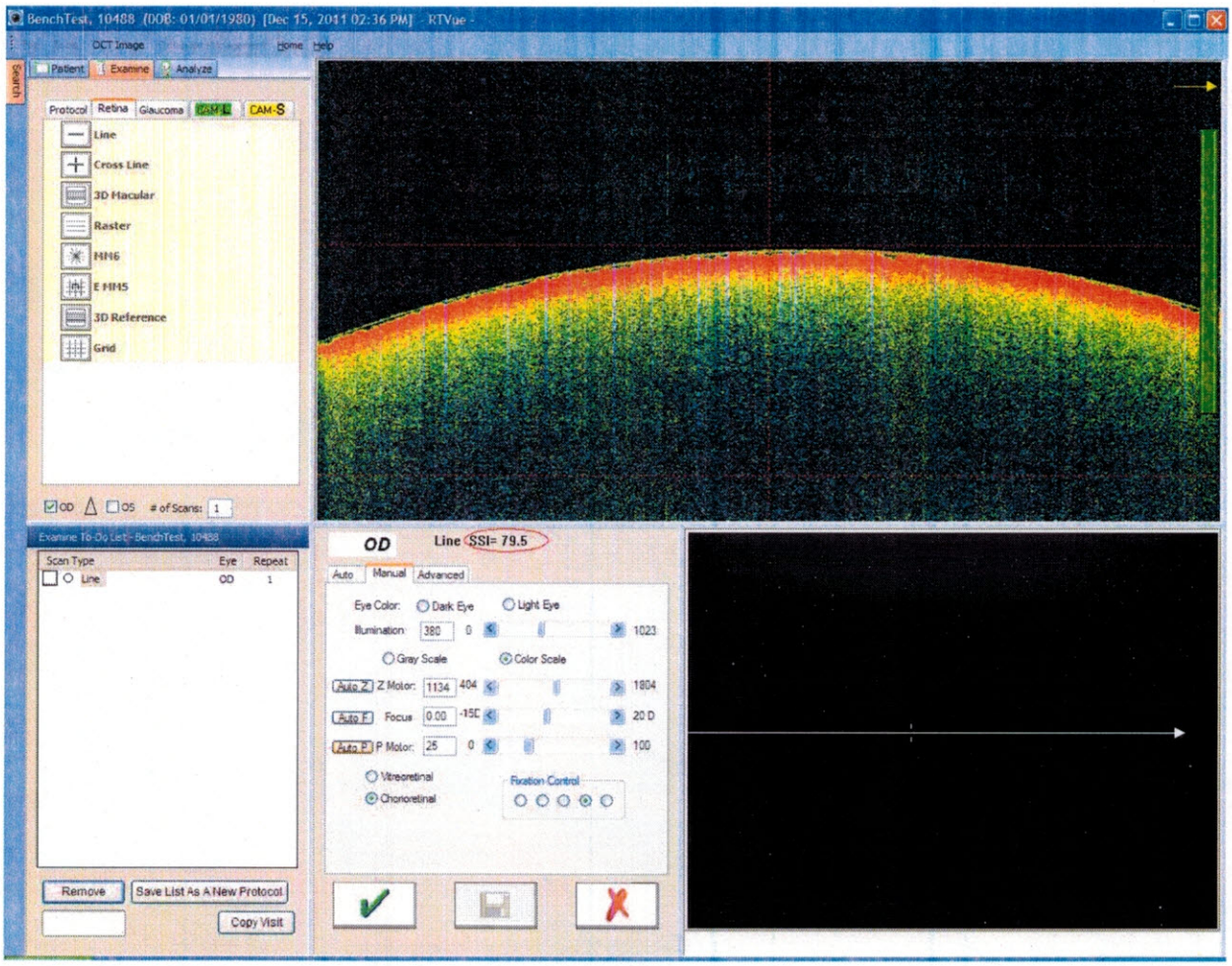
optovue

Phantom imaging performance

Since the different line-scan cameras are the only main difference between RTVue XR and RTVue -100, the same RTVue application software can be used to run the RTVue XR (200-24052-F, Software Requirement Specification for RTVue). Using the RTVue application software (version 6.6.0.82), an OCT image of a standard phantom target is obtained using RTVue XR SN 10488. The signal intensity and image quality of this OCT image is equivalent to that taken with a standard RTVue-100 systems. For this type of phantom imaging target, a Signal Strength Index (SSI) of 79.5 (reference the SSI reading in the red circle) is similar to the values acquired with RTVue-100.



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

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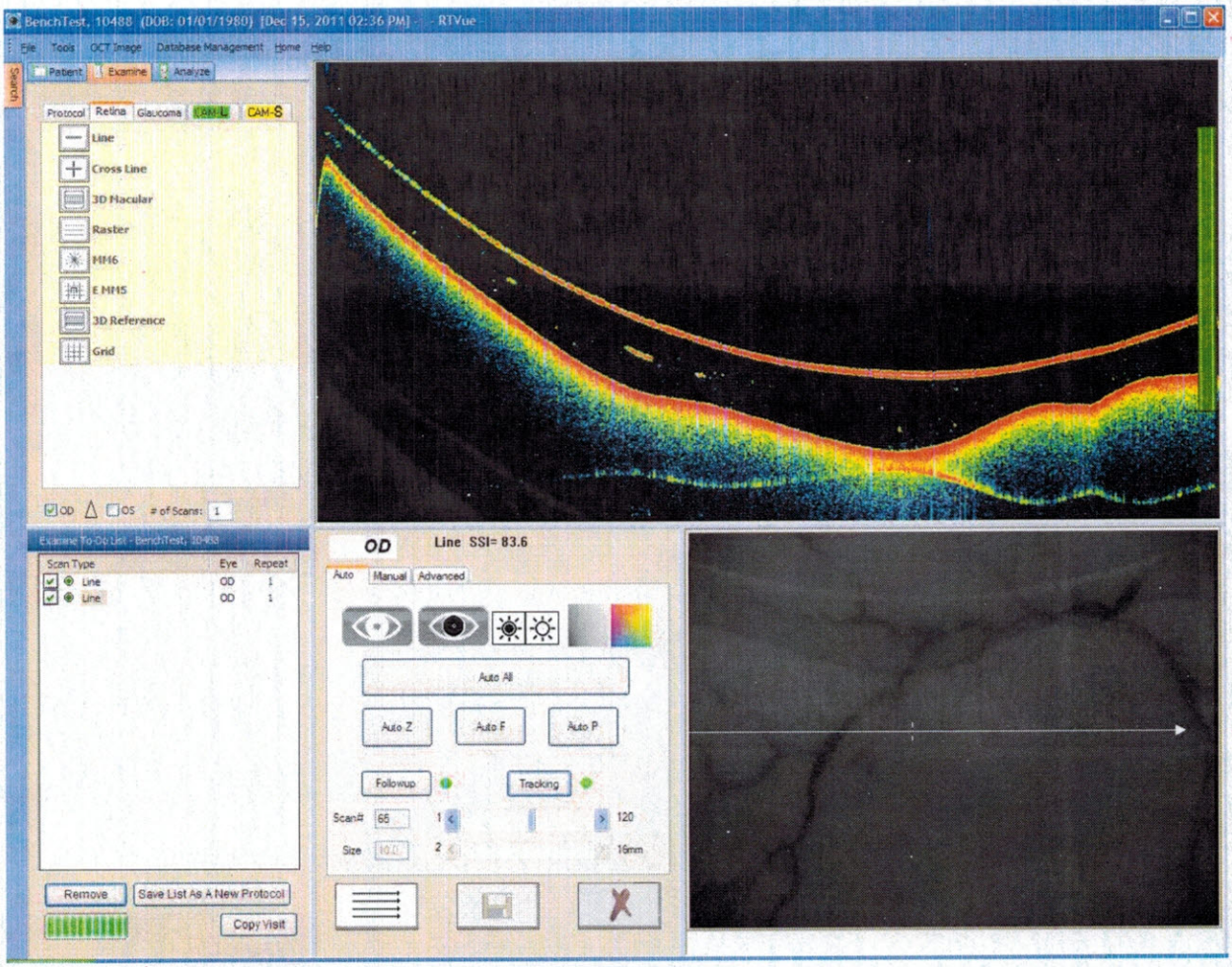
optovue

Phantom tracking performance

Using the RTVue appliaction software (version 6.6.0.82), the OCT image of a phantom eye target is acquired using the tracking protocol (200-47145-A, Software Requirement Specification for RTVue Tracking). During image acquisition, motion is simulated by moving the phantom target in relation to the RTVue XR SN 10488 scan head and eye blinking is simulated by covering up the phantom eye target. Tracking OCT can successfully handle the simulated eye blink and motion in order to complete the image acquisition and generate the resulting OCT image.



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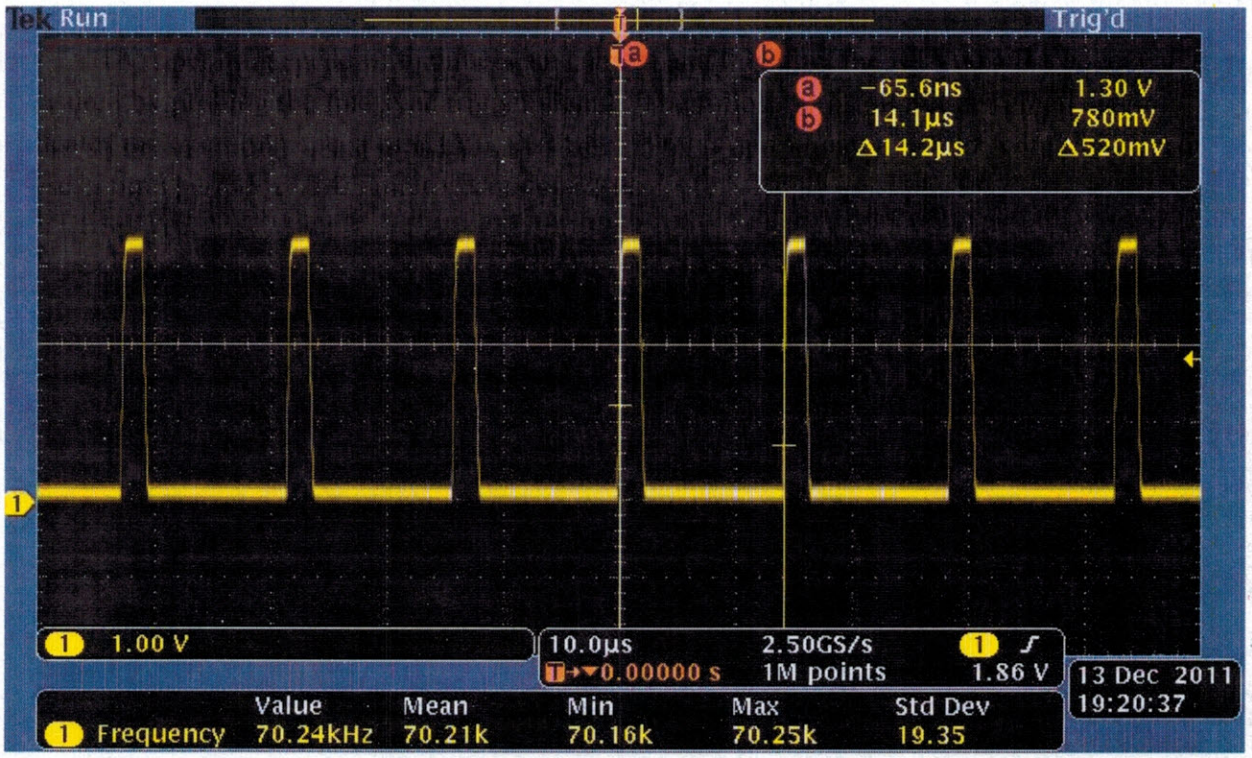
RTVue XR System #2 (SN 11969)

Operating speed is ~70,000 A-lines per second

The operating speed of the line-scan camera and therefore the RTVue XR system can be measured by probing the line sync trigger signal. The following oscilloscope screen capture indicates the operating speed of RTVue XR SN 11969 is aproximatly 70,000 A-lines per second (A-scan time period is ~14.2 microseconds).



OCT signal intensity is equivalent to RTVue-100

The RTVue-100 Manufacturing Process Instructions and Final Test Report (F-OPR-45366-H, RTVue Final Test Report) indicates that the difference in OCT Signal with tool on and without tool on, in a particular calibration step, needs to be above 18. The following screen captures show that, in this calibration step, RTVue XR SN 11969 has an OCT Signal difference of 20 (65 minus 45; reference the relevant OCT Signal readings in red circles) which meets the manufacturing requirement of RTVue-100.

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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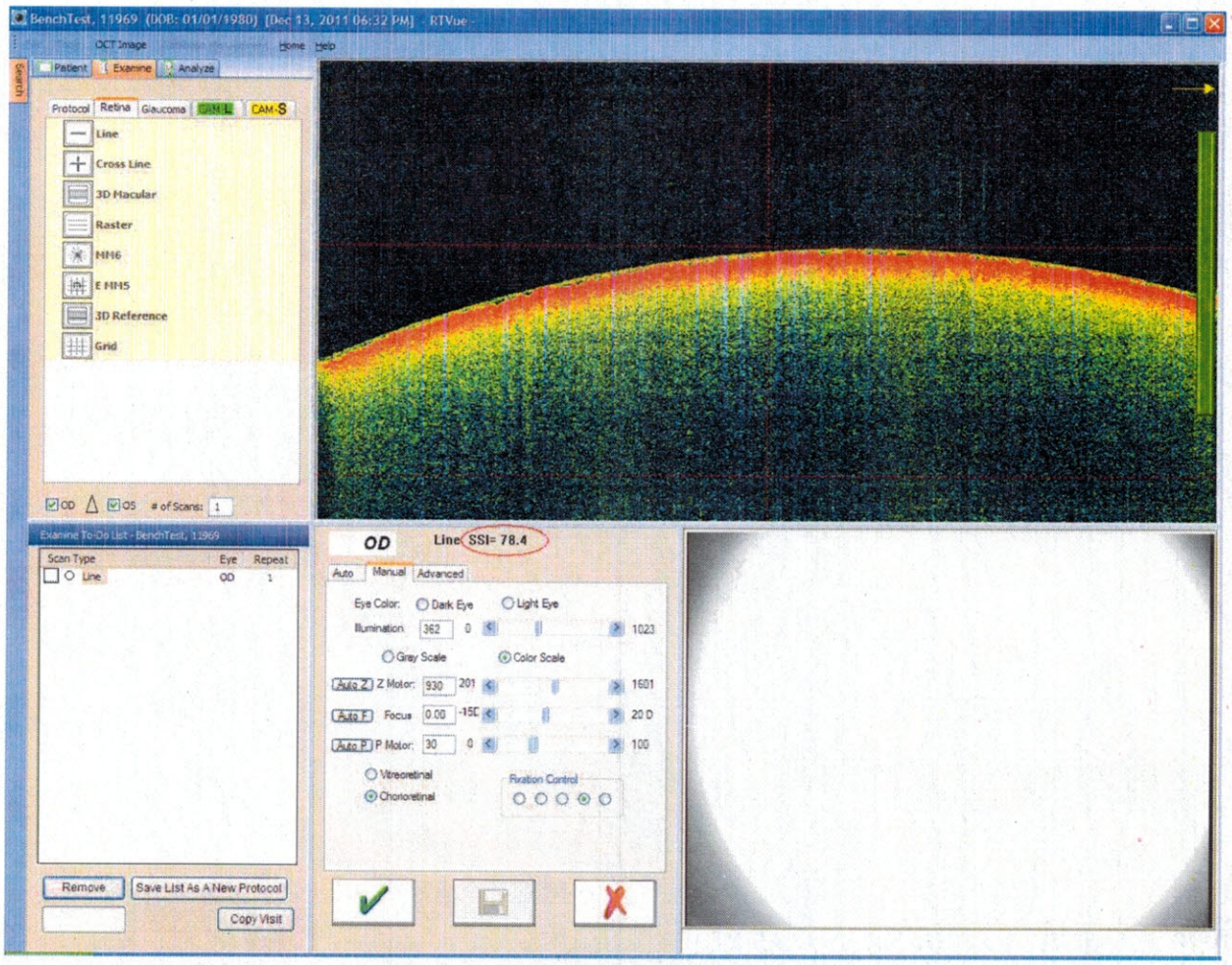
Phantom imaging performance

Since the different line-scan cameras are the only main difference between RTVue XR and RTVue -100, the same RTVue application software can be used to run the RTVue XR (200-24052-F, Software Requirement Specification for RTVue). Using the RTVue application software (version 6.6.0.82), an OCT image of a standard phantom target is obtained using RTVue XR SN 11969. The signal intensity and image quality of this OCT image is equivalent to that taken with a standard RTVue-100 systems. For this type of phantom imaging target, a Signal Strength Index (SSI) of 78.4 (reference the SSI reading in the red circle) is similar to the values acquired with RTVue-100.



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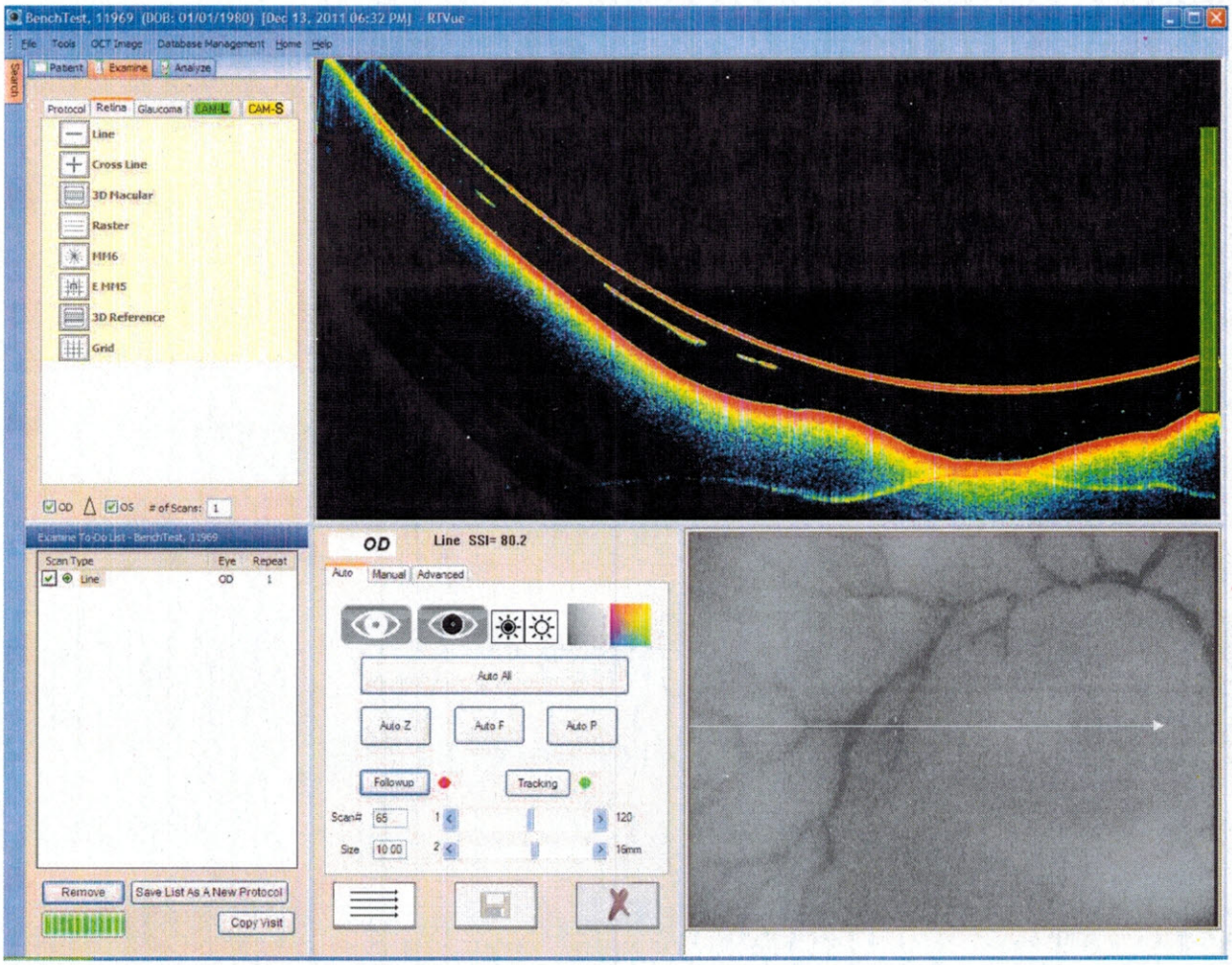
Phantom tracking performance

Using the RTVue appliaction software (version 6.6.0.82), the OCT image of a phantom eye target is acquired using the tracking protocol (200-47145-A, Software Requirement Specification for RTVue Tracking). During image acquisition, motion is simulated by moving the phantom target in relation to the RTVue XR SN 11969 scan head and eye blinking is simulated by covering up the phantom eye target. Tracking OCT can successfully handle the simulated eye blink and motion in order to complete the image acquisition and generate the resulting OCT image.



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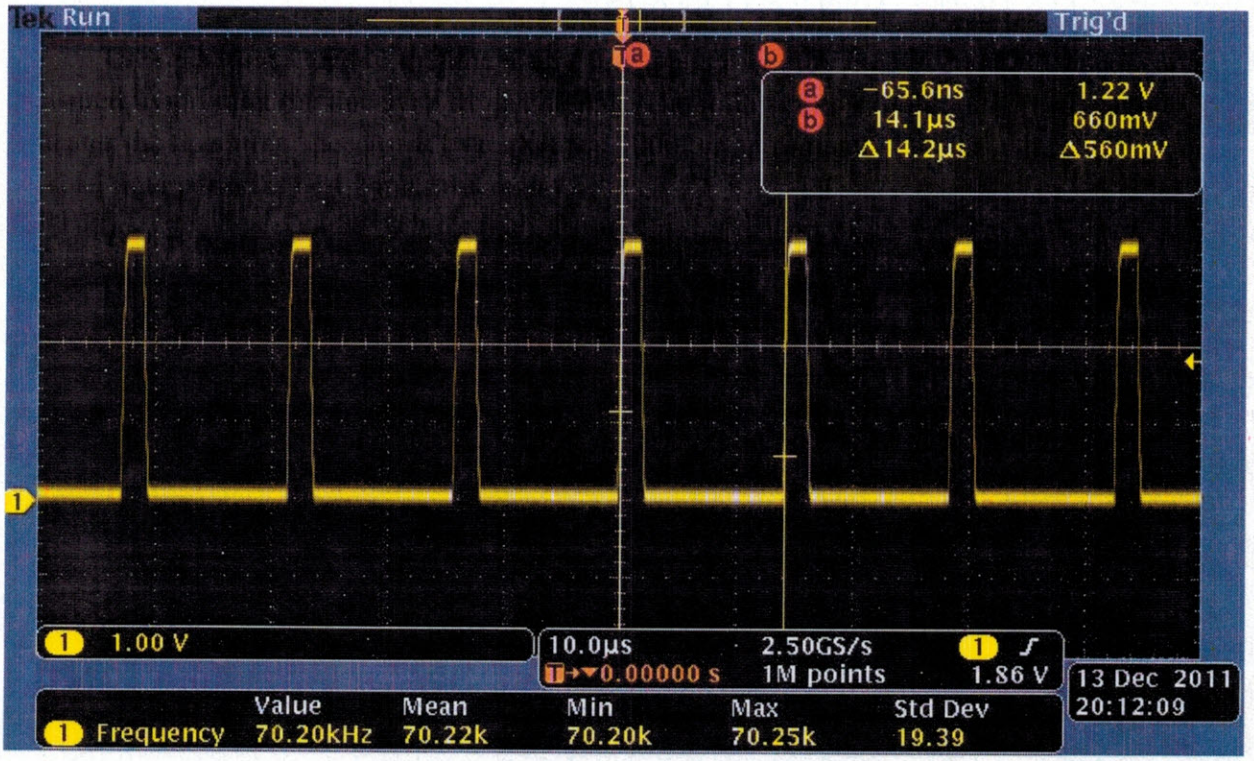
RTVue XR System #3 (SN 12002)

Operating speed is ~70,000 A-lines per second

The operating speed of the line-scan camera and therefore the RTVue XR system can be measured by probing the line sync trigger signal. The following oscilloscope screen capture indicates the operating speed of RTVue XR SN 12002 is aproximatly 70,000 A-lines per second (A-scan time period is ~14.2 microseconds).



OCT signal intensity is equivalent to RTVue-100

The RTVue-100 Manufacturing Process Instructions and Final Test Report (F-OPR-45366-H, RTVue Final Test Report) indicates that the difference in OCT Signal with tool on and without tool on, in a particular calibration step, needs to be above 18. The following screen captures show that, in this calibration step, RTVue XR SN 12002 has an OCT Signal difference of 20.5 (63.5 minus 43; reference the relevant OCT Signal readings in red circles) which meets the manufacturing requirement of RTVue-100.

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

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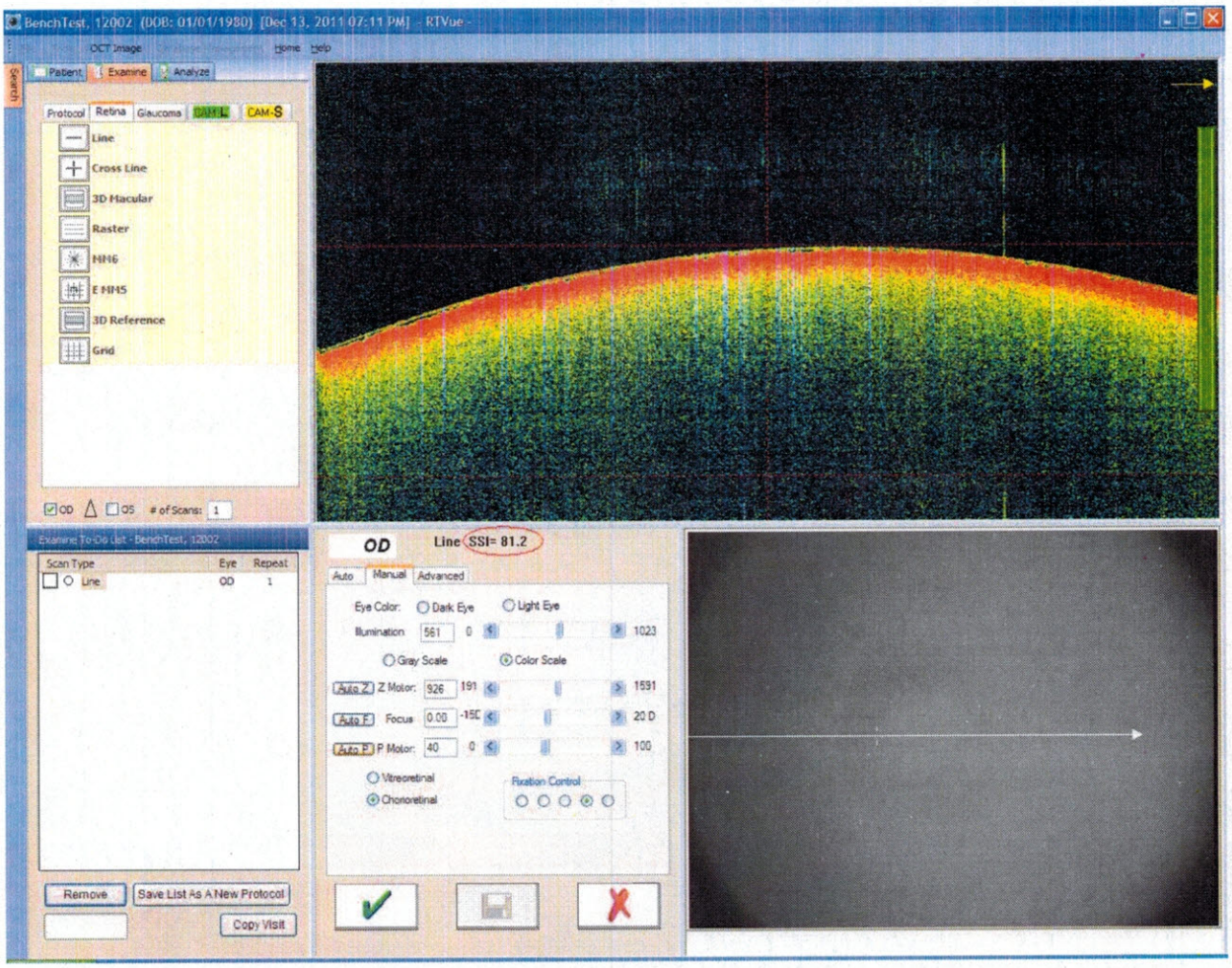
Phantom imaging performance

Since the different line-scan cameras are the only main difference between RTVue XR and RTVue -100, the same RTVue application software can be used to run the RTVue XR (200-24052-F, Software Requirement Specification for RTVue). Using the RTVue application software (version 6.6.0.82), an OCT image of a standard phantom target is obtained using RTVue XR SN 12002. The signal intensity and image quality of this OCT image is equivalent to that taken with a standard RTVue-100 systems. For this type of phantom imaging target, a Signal Strength Index (SSI) of 81.2 (reference the SSI reading in the red circle) is similar to the values acquired with RTVue-100.



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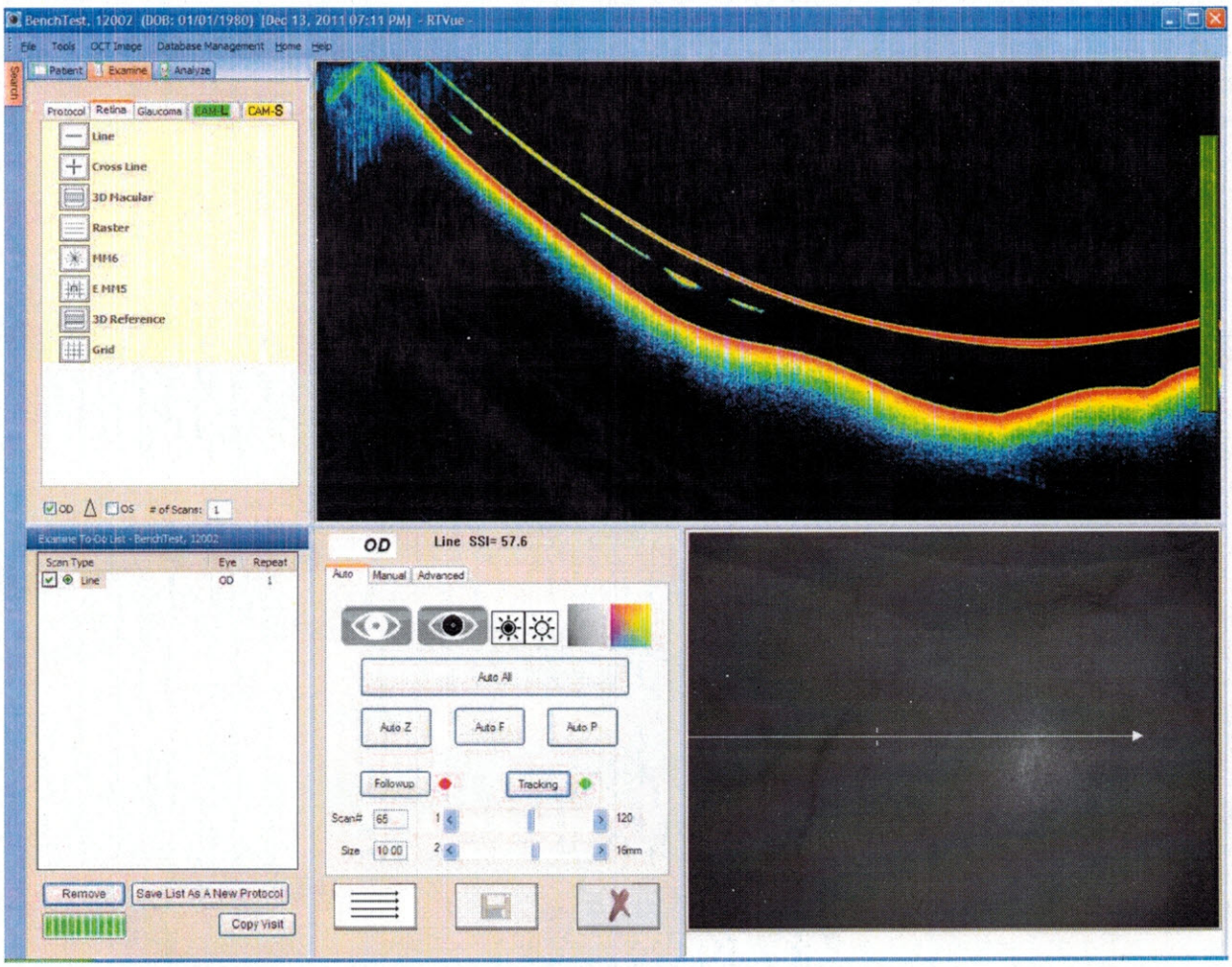
Phantom tracking performance

Using the RTVue appliaction software (version 6.6.0.82), the OCT image of a phantom eye target is acquired using the tracking protocol (200-47145-A, Software Requirement Specification for RTVue Tracking). During image acquisition, motion is simulated by moving the phantom target in relation to the RTVue XR SN 12002 scan head and eye blinking is simulated by covering up the phantom eye target. Tracking OCT can successfully handle the simulated eye blink and motion in order to complete the image acquisition and generate the resulting OCT image.



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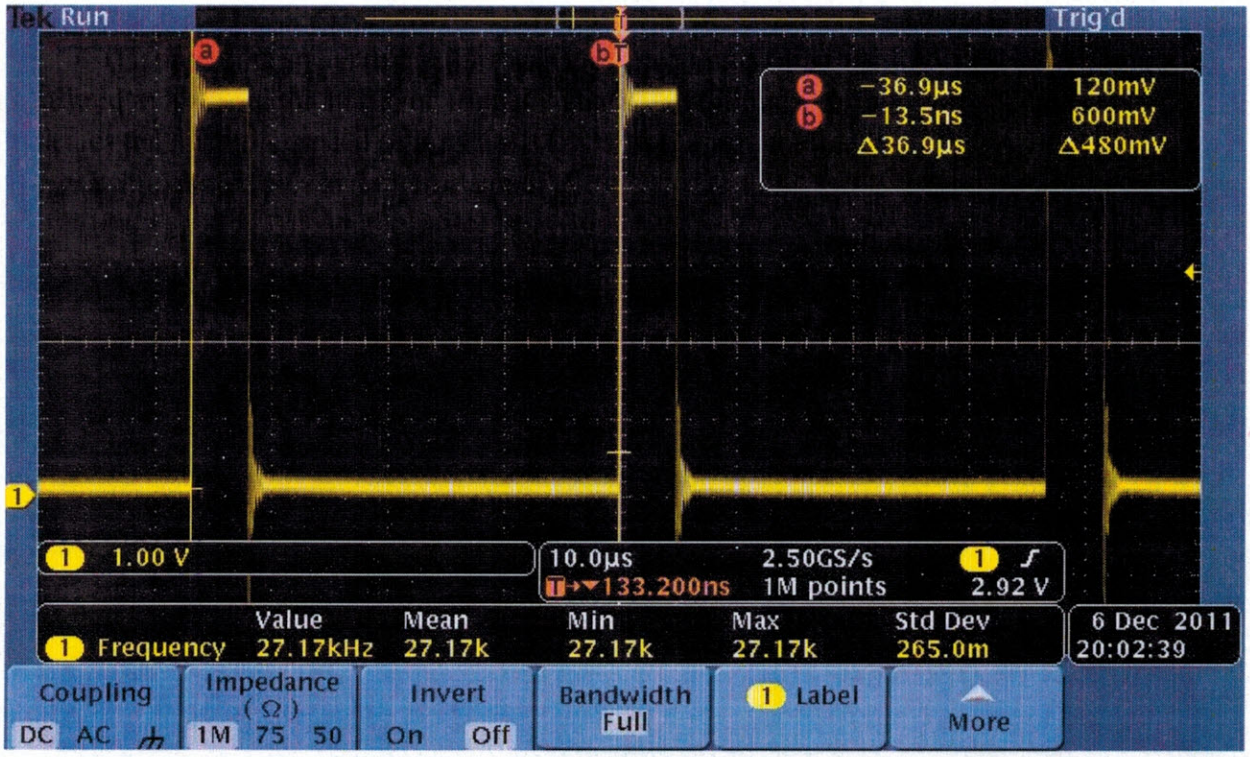
RTVue-100 System #1 (SN 10438)

Operating speed is ~27,000 A-lines per second

The operating speed of the line-scan camera and therefore the RTVue-100 system can be measured by probing the line sync trigger signal. The following oscilloscope screen capture indicates the operating speed of RTVue-100 SN 10438 is aproximatly 27,000 A-lines per second (A-scan time period is ~36.9 microseconds).



OCT signal intensity is as expected for RTVue-100

The RTVue-100 Manufacturing Process Instructions and Final Test Report (F-OPR-45366-H, RTVue Final Test Report) indicates that the difference in OCT Signal with tool on and without tool on, in a particular calibration step, needs to be above 18. The following screen captures show that, in this calibration step, RTVue-100 SN 10438 has an OCT Signal difference of 20 (67 minus 47; reference the relevant OCT Signal readings in red circles) which meets the manufacturing requirement of RTVue-100.

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

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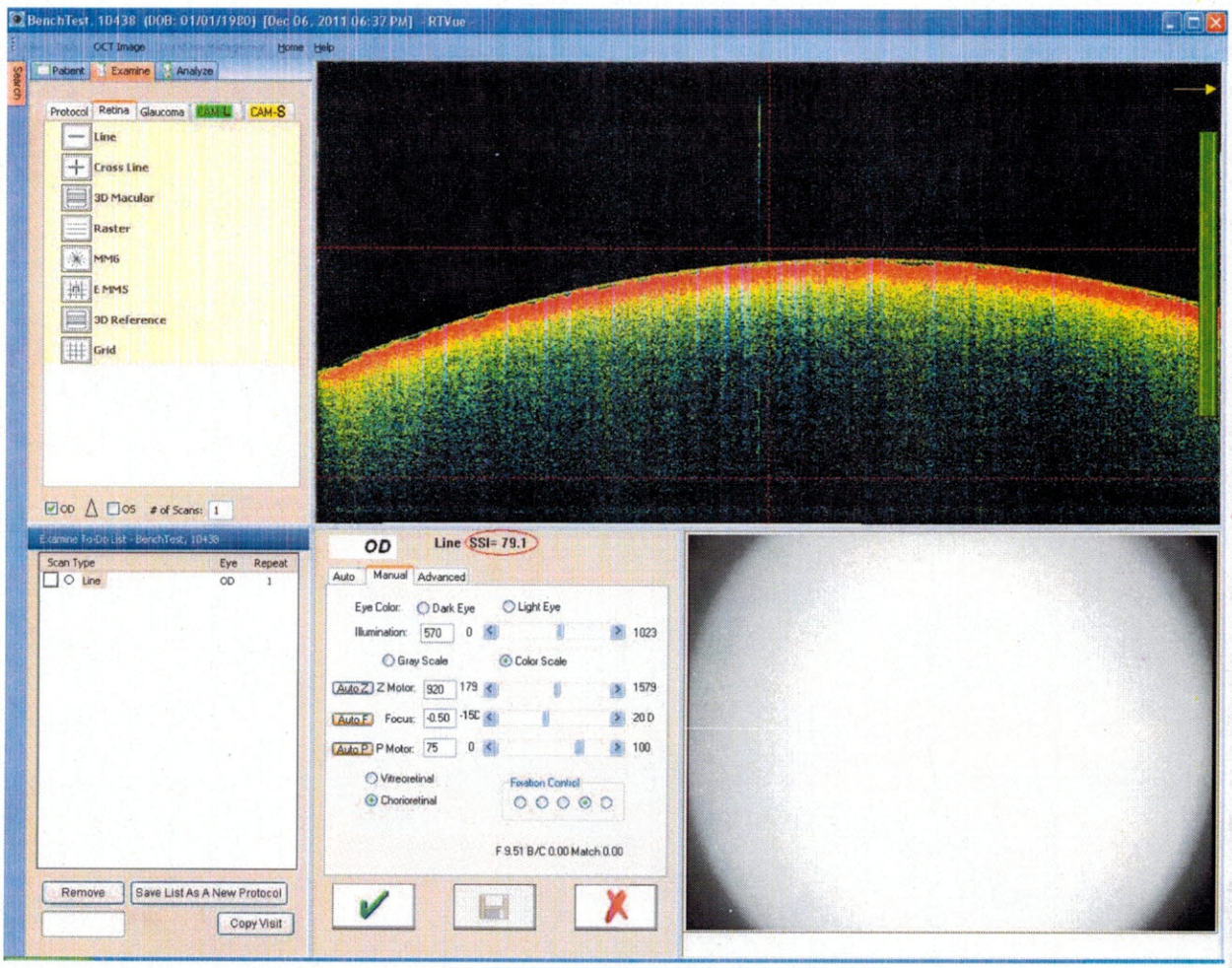
Phantom imaging performance

Using the RTVue appliaction software (version 6.6.0.82), an OCT image of a standard phantom target is obtained using RTVue-100 SN 10438 (200-24052-F, Software Requirement Specification for RTVue). For this type of phantom imaging target, a Signal Strength Index (SSI) of 79.1 (reference the SSI reading in the red circle) is typical of values acquired with the RTVue-100.



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

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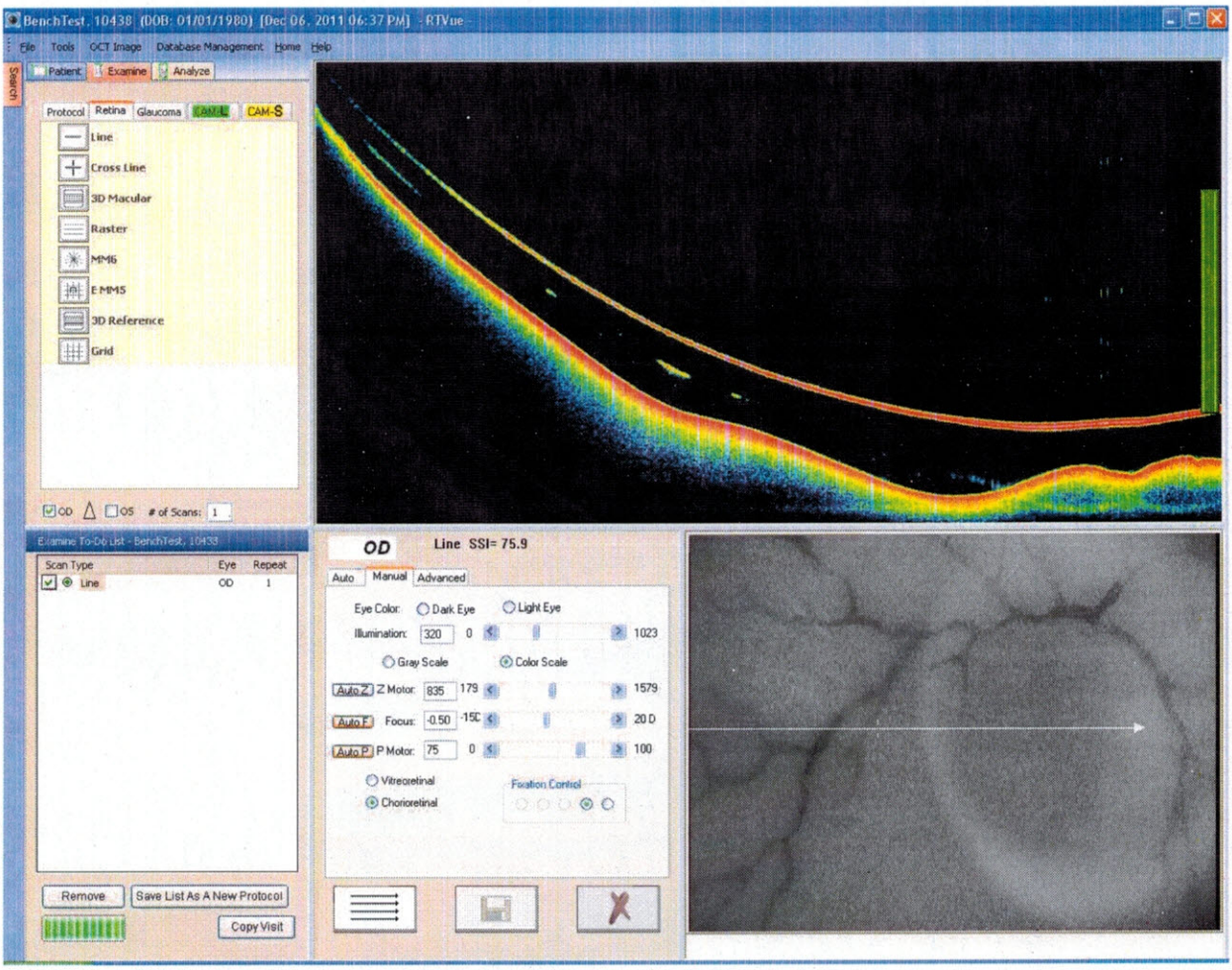
Phantom tracking performance

Using the RTVue appliaction software (version 6.6.0.82), the OCT image of a phantom eye target is acquired using the tracking protocol (200-47145-A, Software Requirement Specification for RTVue Tracking). During image acquisition, motion is simulated by moving the phantom target in relation to the RTVue-100 SN 10438 scan head and eye blinking is simulated by covering up the phantom eye target. Tracking OCT can successfully handle the simulated eye blink and motion in order to complete the image acquisition and generate the resulting OCT image.



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

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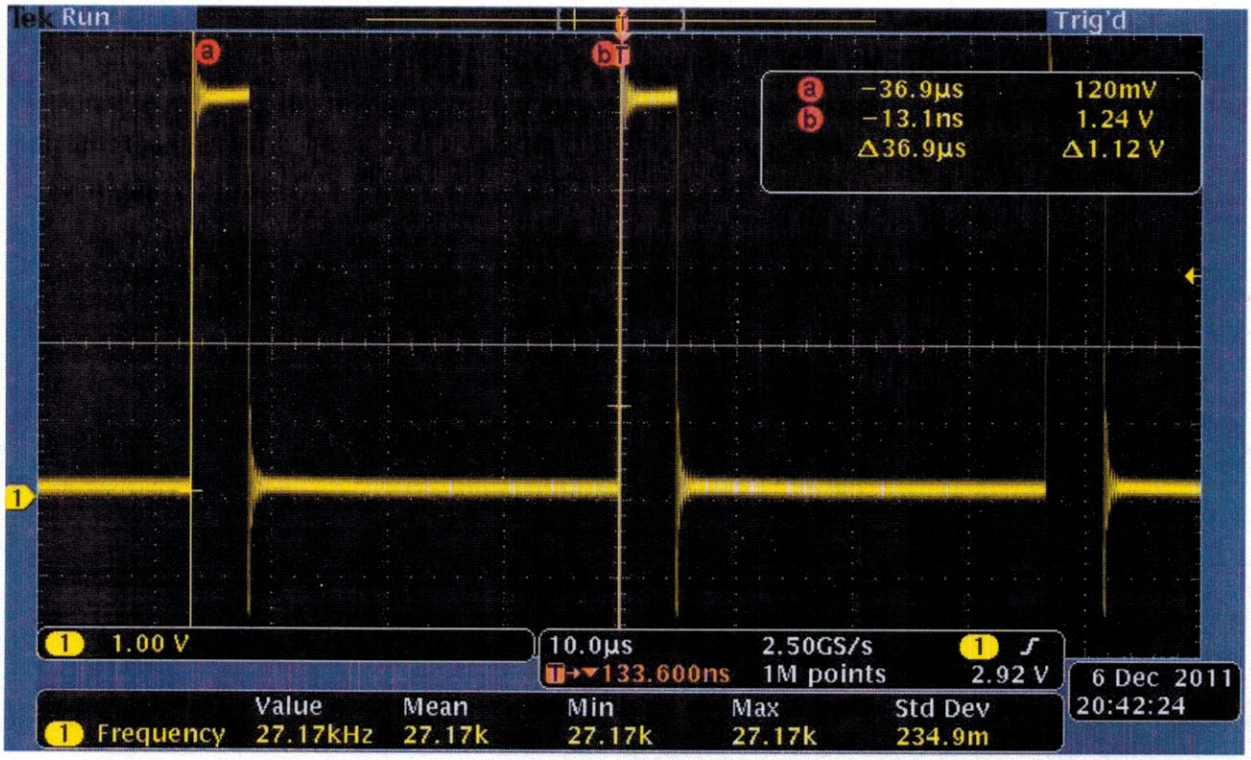
RTVue-100 System #2 (SN 10439)

Operating speed is ~27,000 A-lines per second

The operating speed of the line-scan camera and therefore the RTVue-100 system can be measured by probing the line sync trigger signal. The following oscilloscope screen capture indicates the operating speed of RTVue-100 SN 10439 is aproximatly 27,000 A-lines per second (A-scan time period is ~36.9 microseconds).



OCT signal intensity is as expected for RTVue-100

The RTVue-100 Manufacturing Process Instructions and Final Test Report (F-OPR-45366-H, RTVue Final Test Report) indicates that the difference in OCT Signal with tool on and without tool on, in a particular calibration step, needs to be above 18. The following screen captures show that, in this calibration step, RTVue-100 SN 10439 has an OCT Signal difference of 20 (66 minus 46; reference the relevant OCT Signal readings in red circles) which meets the manufacturing requirement of RTVue-100.

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

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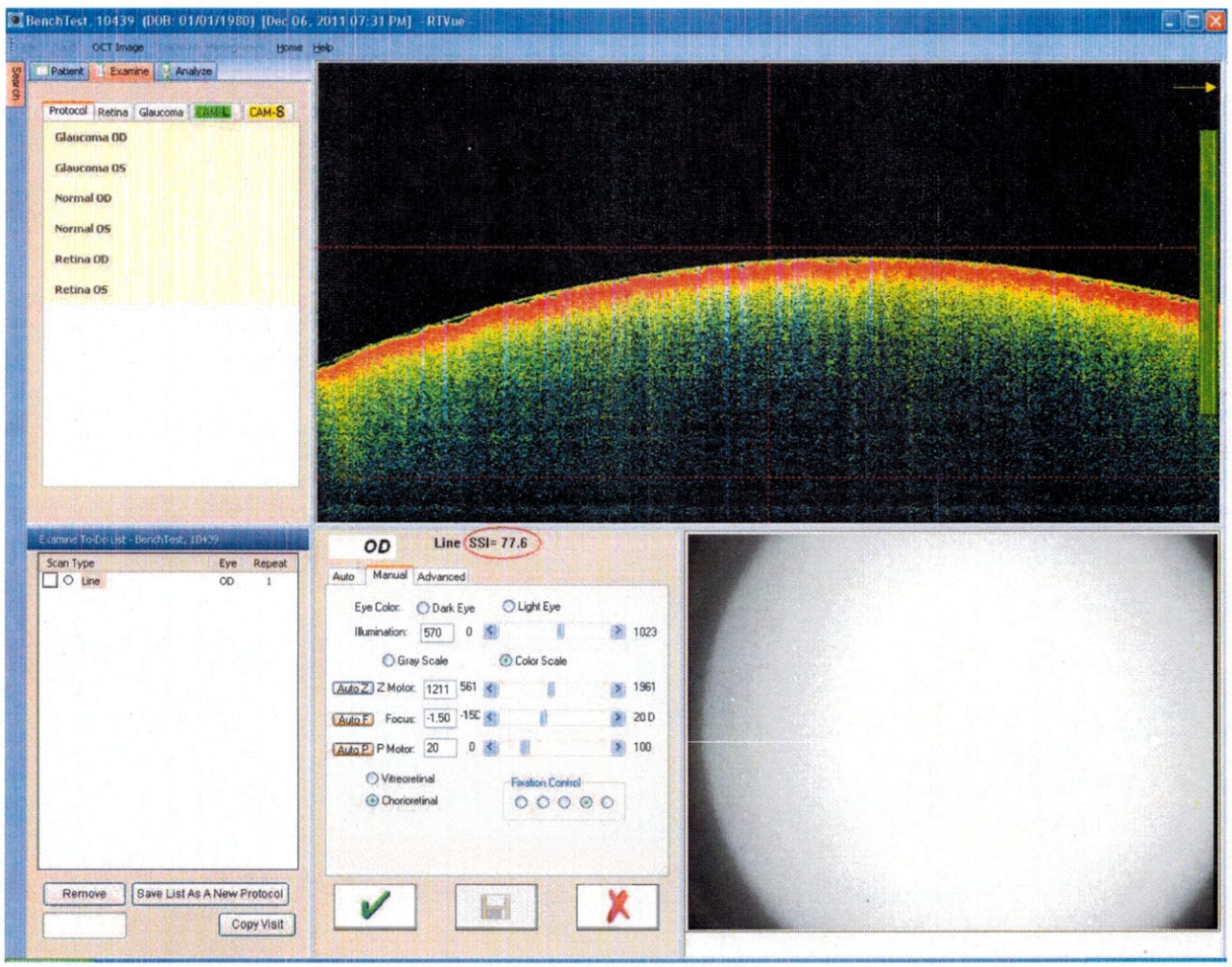
Phantom imaging performance

Using the RTVue appliaction software (version 6.6.0.82), an OCT image of a standard phantom target is obtained using RTVue-100 SN 10439 (200-24052-F, Software Requirement Specification for RTVue). For this type of phantom imaging target, a Signal Strength Index (SSI) of 77.6 (reference the SSI reading in the red circle) is typical of values acquired with the RTVue-100.



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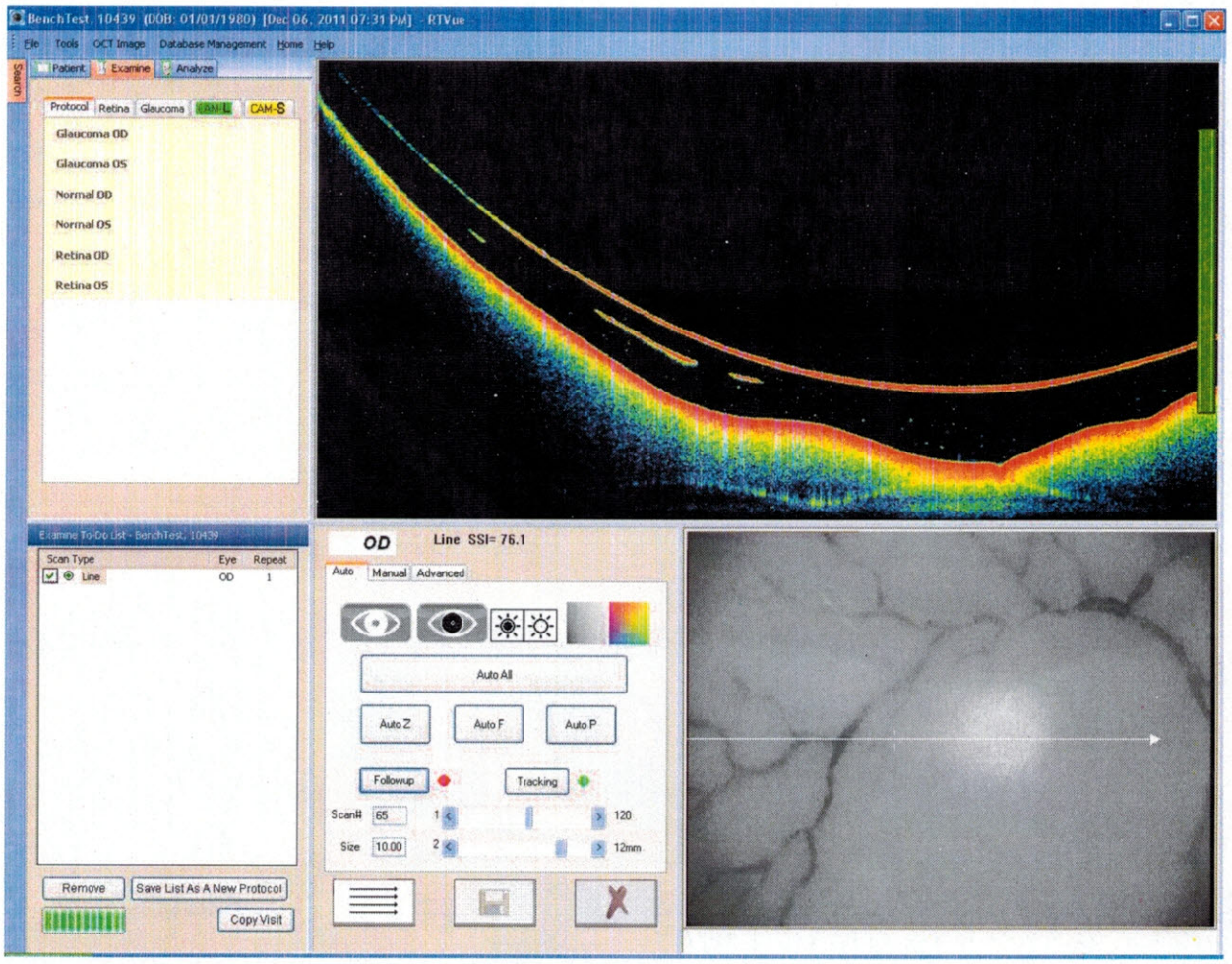
Phantom tracking performance

Using the RTVue appliaction software (version 6.6.0.82), the OCT image of a phantom eye target is acquired using the tracking protocol (200-47145-A, Software Requirement Specification for RTVue Tracking). During image acquisition, motion is simulated by moving the phantom target in relation to the RTVue-100 SN 10439 scan head and eye blinking is simulated by covering up the phantom eye target. Tracking OCT can successfully handle the simulated eye blink and motion in order to complete the image acquisition and generate the resulting OCT image.



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

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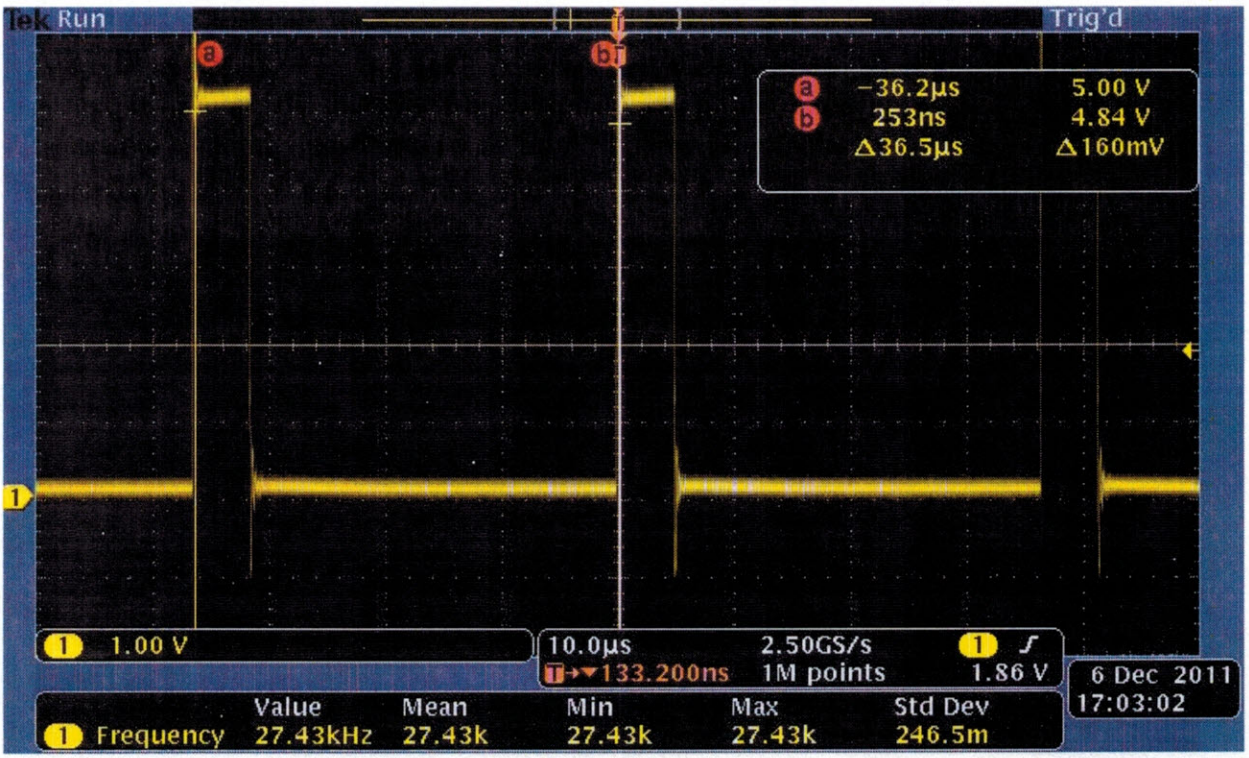
RTVue-100 System #3 (SN 10709)

Operating speed is ~27,000 A-lines per second

The operating speed of the line-scan camera and therefore the RTVue-100 system can be measured by probing the line sync trigger signal. The following oscilloscope screen capture indicates the operating speed of RTVue-100 SN 10709 is aproximatly 27,000 A-lines per second (A-scan time period is ~36.5 microseconds).



OCT signal intensity is as expected for RTVue-100

The RTVue-100 Manufacturing Process Instructions and Final Test Report (F-OPR-45366-H, RTVue Final Test Report) indicates that the difference in OCT Signal with tool on and without tool on, in a particular calibration step, needs to be above 18. The following screen captures show that, in this calibration step, RTVue-100 SN 10709 has an OCT Signal difference of 22 (66.5 minus 44.5; reference the relevant OCT Signal readings in red circles) which meets the manufacturing requirement of RTVue-100.

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

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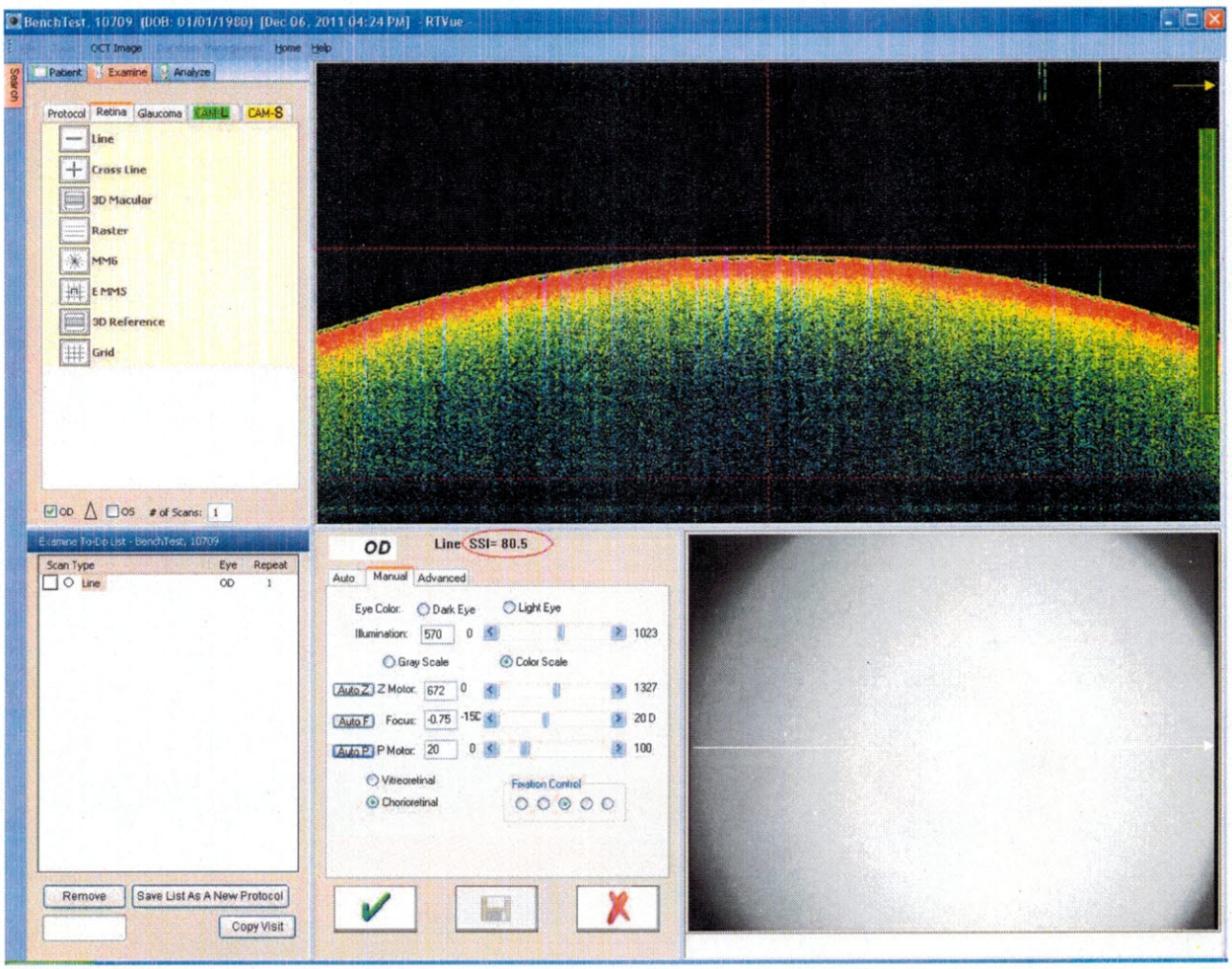
Phantom imaging performance

Using the RTVue appliaction software (version 6.6.0.82), an OCT image of a standard phantom target is obtained using RTVue-100 SN 10709 (200-24052-F, Software Requirement Specification for RTVue). For this type of phantom imaging target, a Signal Strength Index (SSI) of 80.5 (reference the SSI reading in the red circle) is typical of values acquired with the RTVue-100.



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Records processed under FOIA Request #2012-3758; Released by CDRH on 09-8-2015

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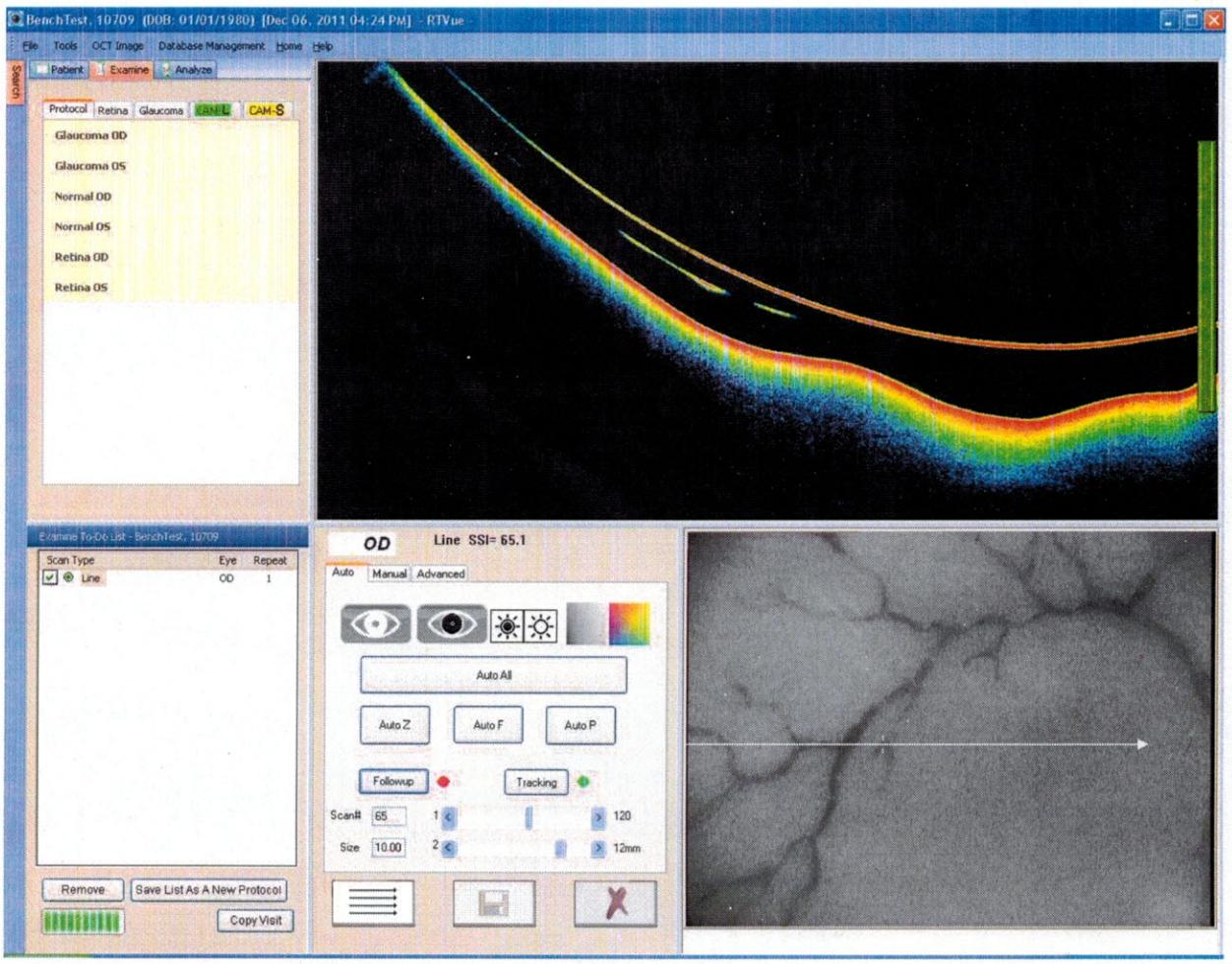
Phantom tracking performance

Using the RTVue appliaction software (version 6.6.0.82), the OCT image of a phantom eye target is acquired using the tracking protocol (200-47145-A, Software Requirement Specification for RTVue Tracking). During image acquisition, motion is simulated by moving the phantom target in relation to the RTVue-100 SN 10709 scan head and eye blinking is simulated by covering up the phantom eye target. Tracking OCT can successfully handle the simulated eye blink and motion in order to complete the image acquisition and generate the resulting OCT image.



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Conclusion

The RTVue XR is an updated version of RTVue-100 that can operate at ~70,000 A-lines per second while delivering equivalent imaging performance as the RTVue-100 operating at ~27,000 A-lines per second. This bench test report compares the imaging performance of three RTVue XR machines (SN 10488, 11969, 12002) with that of three RTVue-100 machines (SN 10438, 10439, 10709).

The OCT signal intensity of the RTVue XR is equivalent to that of the RTVue-100, and it also surpasses the manufacturing requirement of the RTVue-100. The axial resolution of the RTVue XR is equivalent to that of the RTVue-100 machines. This is as expected since the RTVue XR and RTVue-100 share the identical spectrometer design and optics.

In performing OCT imaging with RTVue appliaction software (version 6.6.0.82), the RTVue XR delivered similar results as the RTVue-100 in terms of imaging performance (Signal Strength Index of a standard phantom target) and tracking performance (ability to perform OCT imaging in the presence of simulated motion and blinking).

The Signal Strength Index (SSI) of a standard phantom target obtained with the RTVue XR are 78.4, 79.5, and 81.2 (mean ± sd = 79.7 ± 1.4). The Signal Strength Index (SSI) of a standard phantom target obtained with the RTVue-100 are 77.6, 79.1, and 80.5 (mean ± sd = 79.1 ± 1.5). The Signal Strength Index can differ between machines due to the within tolerance variation of the underlying optical components as well as the line-scan camera sensors. The mean and standard deviation values from the SSI imaging results indicate that the RTVue XR and RTVue-100 deliver equivalent performance in imaging the standard phantom target.

Prepared By: Tony Ko
Director of Advanced Development

Signature: Tony Ko
Date: 1/18/2012

Reviewed By:			
Title	**Name**	**Signature**	**Date**
CTO	**Tom Zhao**		1/17/12
Regulatory	**John Talarico**	John Talarico	1/19/2012

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

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Attachment 2

- RTVue-XR Risk Analyses Report (redlined copy)

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

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REFERENCE DOCUMENT: EN ISO 14971:2009 "Medical Device – Application of Risk Management to Medical Devices

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

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Approved By:			
(b)(4) [redacted]	Name	Signature	Date

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

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For Device: RTVue XR Model

Deleted: 100

Summary:

All harms and hazards identified have been evaluated and are either in the Broadly Acceptable Category or in the As Low as Reasonably Practicable category. Where applicable this document lists the tests and/or procedures where the identified mitigation is performed.

1 INTRODUCTION

1.1 Product Description

The RTVue XR is a Fourier Domain OCT system which can non-invasively image retinal tissue in-vivo, with high acquisition speed and high-resolution scans.

The first generation OCT system developed in early 1990s was a Time-Domain system, which relied on the mechanical scan method to get the tissue depth signal. The scan speed is limited to 400 A-scan per second in conventional time-domain OCT due to the mechanic motion barrier. The RTVue uses a camera to acquire the A-scan signals simultaneously without mechanical motion. The RTVue system's scan speed is 26,000+ A-scan per second, or 65 times faster than the conventional OCT system. Due to the increase in scan rate, artifacts in OCT images caused by eye motion are eliminated in most* scan designs. (*3D scans with nearly 52,000 A-scans take 2 seconds to acquire. Motion artifacts may be present) Recent advances in line scan camera technology has enabled the RTVue XR to operate at ~70,000 A-lines per second while delivering equivalent imaging results as the older generation RTVue line scan cameras operating at ~27,000 A-lines per second.

The RTVue XR system employs the same high bandwidth light source as the RTVue; the tissue resolution is approximately 4 - 5 micrometer; double that of a conventional OCT system.

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With the speed and resolution improvement, RTVue XR provides a much more reliable and detailed retinal and nerve head map, with metrics in a much shorter period of time.

1.2 Intended Use of the Product

The RTVue XR is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disk as an aid in the diagnosis and management of retinal disease. The RTVue XR is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

The Cornea Anterior Module (CAM) can be attached to the RTVue XR as an auxiliary lens used in conjunction with the RTVue XR to view and scan the patient's cornea and anterior segment.Corneal thickness and central corneal refractive power are computed from the corneal scans.

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1.3 RTVue XR System Configuration:

The RTVue XR system is shipped in one paletted box, which contains the following hardware:

a. RTVue XR Scanner:
This is the main component of the RTVue XR system. It is used to view and scan the patient's retina, collect the OCT signal, and send it to the computer for processing. It also provides a fixation light target for patient to fixate on during the scan and position sensor for automatic detection of whether the left or right eye is aligned for scanning. The communication between the scanner and computer is via a USB cable connection. The RTVue XR uses a medical grade power supply.

b. RTVue XR CAM module (high magnification and low magnification (optional)):
The CAM is an auxiliary lens used in conjuction with the RTVue XR to view and scan the patient's cornea. By adding the CAM lens to the front of the RTVue XR ocular lens, the CAM lens changes the image plane from retina to cornea, by changing the focal length.

c. Computer:
The computer is used to control the scanner during the patient examination. The application software provides data analysis, presentation, and data storage and archive. A relational database is included to organize all patient information and data, as well as allow for search capability.

d. System Table:
The system table provides power to the RTVue XR scanner, computer, and computer display through a medical grade isolation transformer to prevent leakage current from main AC power. The table elevation can be adjusted to fit patient height. The telescopic raiser which supplies the power of the RTVue XR system is medical grade.

e. Monitor (Computer Display):
An LCD flat panel display for graphic user interface and data presentation.

f. Keyboard and Mouse

System Configuration:
Model: RTVue XR 100-1: 110V AC.
Model: RTVue XR 100-2: 230V AC.

1.4 Risk Evaluation

1.4.1 Operator contact

Operator contact is to the computer keyboard and system.

1.4.2 Materials in contact with patient

The following materials are in contact with the patient:
Chinrest and headrest

1.4.3 CAM module shortens working distance,

The addition of the auxiliary CAM lens shortens the working distance from 22mm to 10mm. However 10mm is still compatible with other FDA cleared devices, e.g. Stratus OCT by Carl Zeiss Meditec. All electrical safety, mechanical safety, energy safety, biocompatibility, misdiagnosis and ergonomic risks remain the same as RTVue XR without CAM attached.

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1.4.4 CAM module scan length increased

The software change to increase the scan length of the cornea scan does not present new risk since the scan method remains the same (user could achieve the same results with the old software by scanning twice) and the working distance is not changed.

1.4.5 Cleaning and Disinfection

Dust Prevention:
When not using the RTVue XR, make sure the cloth dust cover is placed over the unit. You can "Shut down" the PC at the end of each day.
Ocular (Front Objective) Lens Cleaning:
We recommend the ocular (front objective) lens of the RTVue XR is cleaned daily. A weak OCT image or blurry video image may be caused by an unclean front lens (eyelash, finger or nose prints, excessive dust or dirt from the environment).

Material required to clean front lens:
1) Diluted Acetone or Lens cleaning solution
2) Lens cleaning paper

Method:
Wet the lens paper with cleaning solution and wipe the ocular lens with one pass in one direction. Discard the used lens paper. Use a new sheet for each repeat cleaning until all lens area has been cleaned.

Head and Chin Rest Cleaning:
The headrest pad and chin rest cup should be cleaned before every patient visit.

1. Material required: Disinfecting agent such as an anti-germicide or isopropyl alcohol.
2. Cloth or cleaning towels.
3. Wet isopropyl alcohol cleaning paper pad.

Method:
Soak the cleaning cloth or towel in disinfecting solution or use a wet isopropyl alcohol cleaning paper pad. Wipe the chin-rest cup and head rest pad.

Biocompatibility:
Materials used for the chin rest and head rest are biocompatible and ISO 10993 compliant.

2 ANALYSIS METHODOLOGY

2.1 Risk Function Employed

The risk function used for this analysis was derived from EN ISO 14971:2009 "Medical Device – Application of Risk Management to Medical Devices" as shown in Table 1. Risk is specified as a function of Severity (S) and Likelihood (L).

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2.1.1 Severity Values

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2.1.3 Risk Region Values

Each possible combination of Severity and Likelihood resides within one of the following Risk Region:

- Intolerable Region (IR)
- ALARP (As Low As Reasonably Practicable) Region (AR)
- Broadly Acceptable Region (BR)

Risk Region assignment for the Severity/ Likelihood combinations is as follows

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3 ANALYSIS FINDINGS

This section presents the findings of the risk analysis. It describes the potential hazards associated with the use of the RTVue XR, RTVue XR software and CAM. It also describes the possible failures that could cause those hazards and the controls in place required to mitigate the risk by reducing the likelihood of the failures. The analysis findings are itemized in Table 2.

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CONCLUSIONS

Referring to Table 2 all of the identified risks are in the ALARP category. These risks require mitigation steps but do not require any redesign.

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Attachment 3

- RTVue-XR Risk Analyses Report (final copy)

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Approved By:			
(b)(4) Risk Analysis Report [redacted]	Name	Signature	Date

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For Device: RTVue XR Model

Summary:

All harms and hazards identified have been evaluated and are either in the Broadly Acceptable Category or in the As Low as Reasonably Practicable category. Where applicable this document lists the tests and/or procedures where the identified mitigation is performed.

1 INTRODUCTION

1.1 Product Description

The RTVue XR is a Fourier Domain OCT system which can non-invasively image retinal tissue in-vivo, with high acquisition speed and high-resolution scans.

The first generation OCT system developed in early 1990s was a Time-Domain system, which relied on the mechanical scan method to get the tissue depth signal. The scan speed is limited to 400 A-scan per second in conventional time-domain OCT due to the mechanic motion barrier. The RTVue uses a camera to acquire the A-scan signals simultaneously without mechanical motion. The RTVue system's scan speed is 26,000+ A-scan per second, or 65 times faster than the conventional OCT system. Due to the increase in scan rate, artifacts in OCT images caused by eye motion are eliminated in most* scan designs. (*3D scans with nearly 52,000 A-scans take 2 seconds to acquire. Motion artifacts may be present) Recent advances in line scan camera technology has enabled the RTVue XR to operate at ~70,000 A-lines per second while delivering equivalent imaging results as the older generation RTVue line scan cameras operating at ~27,000 A-lines per second.

The RTVue XR system employs the same high bandwidth light source as the RTVue; the tissue resolution is approximately 4 - 5 micrometer; double that of a conventional OCT system.

With the speed and resolution improvement, RTVue XR provides a much more reliable and detailed retinal and nerve head map, with metrics in a much shorter period of time.

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The RTVue XR is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disk as an aid in the diagnosis and management of retinal disease. The RTVue XR is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

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1.3 RTVue XR System Configuration:

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b. RTVue XR CAM module (high magnification and low magnification (optional)):
The CAM is an auxiliary lens used in conjuction with the RTVue XR to view and scan the patient's cornea. By adding the CAM lens to the front of the RTVue XR ocular lens, the CAM lens changes the image plane from retina to cornea, by changing the focal length.

c. Computer:
The computer is used to control the scanner during the patient examination. The application software provides data analysis, presentation, and data storage and archive. A relational database is included to organize all patient information and data, as well as allow for search capability.

d. System Table:
The system table provides power to the RTVue XR scanner, computer, and computer display through a medical grade isolation transformer to prevent leakage current from main AC power. The table elevation can be adjusted to fit patient height. The telescopic raiser which supplies the power of the RTVue XR system is medical grade.

e. Monitor (Computer Display):
An LCD flat panel display for graphic user interface and data presentation.

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Model: RTVue XR 100-1: 110V AC.
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The software change to increase the scan length of the cornea scan does not present new risk since the scan method remains the same (user could achieve the same results with the old software by scanning twice) and the working distance is not changed.

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Dust Prevention:
When not using the RTVue XR, make sure the cloth dust cover is placed over the unit. You can "Shut down" the PC at the end of each day.
Ocular (Front Objective) Lens Cleaning:
We recommend the ocular (front objective) lens of the RTVue XR is cleaned daily. A weak OCT image or blurry video image may be caused by an unclean front lens (eyelash, finger or nose prints, excessive dust or dirt from the environment).

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2) Lens cleaning paper

Method:
Wet the lens paper with cleaning solution and wipe the ocular lens with one pass in one direction. Discard the used lens paper. Use a new sheet for each repeat cleaning until all lens area has been cleaned.

Head and Chin Rest Cleaning:
The headrest pad and chin rest cup should be cleaned before every patient visit.

1. Material required: Disinfecting agent such as an anti-germicide or isopropyl alcohol.
2. Cloth or cleaning towels.
3. Wet isopropyl alcohol cleaning paper pad.

Method:
Soak the cleaning cloth or towel in disinfecting solution or use a wet isopropyl alcohol cleaning paper pad. Wipe the chin-rest cup and head rest pad.

Biocompatibility:
Materials used for the chin rest and head rest are biocompatible and ISO 10993 compliant.

2 ANALYSIS METHODOLOGY

2.1 Risk Function Employed

The risk function used for this analysis was derived from EN ISO 14971:2009 "Medical Device – Application of Risk Management to Medical Devices" as shown in Table 1. Risk is specified as a function of Severity (S) and Likelihood (L).

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Attachment 4

Dr. Sliney Optical Radiation Safety Report for RTVue- June 15, 2005)

(Reference Only)

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15 June 2005

Optical Radiation Hazard Analysis

OPTOVUE
OPTICAL COHERENCE TOMOGRAPHY (OCT) RETINAL SCANNER

INTRODUCTION

Optovue, Inc. (Fremont, CA) has developed a high-speed OCT Retinal Scanner instrument for the examination of retinal structures. The Retinal OCT instrument consists of a fiber-optic interferometer that uses a super-luminescent diode (SLD) for the optical source. The OCT system produces a cross-sectional image of the retina in depth by low-coherence reflectometry. Optical coherent tomography (OCT) of the eye was first described in 1991.[1] A super-luminescent diode is used because of its much smaller coherence length compared to a laser (i.e., of the order of 10 μm). Although not a diode laser, the most appropriate safety guidelines and standards to apply to an SLD are those that relate to laser safety. The reason is that the SLD has a relatively narrow spectral bandwidth of 60 nm (FWHM) centered at approximately 830 nm. The very high radiance of the SLD permits imaging in only a very small retinal image. Indeed, there exists a movement in the laser safety standards community to treat SLDs as equivalent to lasers of the same wavelength.

RETINAL EXPOSURES

The beam entering the eye is 1.4 mm in diameter and scans a line pattern on the retina of at least 2 mm length. Along the 2-mm scan, the beam focus is scanned axially at approximately 1024 points along the scan, i.e., at 2-μm intervals for this worst-case, minimal line length. Since the total scan with 1024 axial scans takes approximately 35.3 ms, the beam's axial sampling duration at each retinal location is approximately 0.0345 ms (34.5 μs). For the minimal line length, the beam skips about 2 μm to another spot, scans axially, and then goes on. The SLD optical beam is not diffraction-limited, but the retinal focal zone is designed to be of the order of 22 μm in diameter. Therefore, each retinal "point" (~22 μm) image exposure from the SLD is about eleven (22/2) repetitive exposures. The SLD retinal focal zone of the order of 22 μm in diameter is actually less than the 25.5-μm image corresponding to a visual angle α referred to as the minimal angular subtense α_{min} of 1.5 milliradian as used in laser safety standards. The OCT operator would not dwell on the same retinal line and generally will perform a series or even raster scan over a much larger area. A maximum dwell time of up to 4 s over the same retinal line or a slightly different scan pattern to chose the best image would represent an extremely

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worst-case, maximal-dwell duration. Because of normal eye movements, it would be highly unlikely that multiple exposures would be superimposed so precisely. The typical power entering the eye--for clear ocular media--is approximately 0.7 mW. The absolute maximum power that can be emitted from the device is 0.75 mW, which would only be used in a poor (scattering) lens; however, in such an eye, the likelihood of the beam scanning over the exact same path is extremely remote; hence, the probability of multiple exposures, or a substantial fraction of the original power reaching the same retina retinal area 22 μm by 2000 μm is very low. The scanning beam can never scan over a line length of less than 2 mm, since there are both hardware and software system safety features to prevent this.

APPLICABLE EXPOSURE LIMITS

A number of national and international groups have recommended human exposure limits (ELs) for laser exposure and for non-coherent optical radiation [i.e., ultraviolet (UV), light and infrared (IR) radiant energy]. The earliest group to recommend the modern system of exposure limits is well known in the field of occupational health--the American Conference of Governmental Hygienists (ACGIH). The ACGIH refers to its exposure limits as "Threshold Limit Values," or TLVs and these are issued yearly, so there is an opportunity for a yearly revision[2-4]. The current ACGIH TLV's for infrared radiation refer to wavelengths of 760 nm to 3 μm[3-4]. The TLVs are based in large part on ocular injury data from animal studies and from data from human retinal injuries resulting from laser accidents and from viewing the sun and welding arcs. The TLVs also have an underlying assumption that outdoor environmental exposures to visible radiant energy are normally not hazardous to the eye except in very unusual environments such as snow fields and deserts. The ACGIH laser TLVs are the generally same as those recommended by the American National Standards Institute (ANSI) standard Z136.1-2000, but at this time, the ANSI maximum permissible exposure (MPE) limits are more current at this time for exposure durations longer than 10 seconds.[5]

On the international scene there are currently limits for optical radiation exposure as well as for the special case of laser irradiation. The International Commission on Non-Ionizing Radiation Protection (ICNIRP) publishes “Guidelines on Limits of Exposure to Non-Broad-Band Incoherent Optical Radiation (0.38 to 3 μm),” which most recently was updated in 1997[6]. The ICNIRP also publishes “Guidelines on Limits of Exposure to Laser Radiation,” with the most recent revision published in 2000[7]. ICNIRP guidelines are developed through collaboration with the World Health Organization (WHO) by jointly publishing criteria documents, which provide the scientific base for the exposure limits[8]. The ICNIRP guidelines for exposure to non-coherent optical radiation are basically those also recommended by ACGIH. In 2000 ICNIRP published a statement on LEDs, which recommended that LEDs should be treated as lamps and not lasers for the purpose of hazard evaluation, although it did note that SLDs might also be evaluated by laser exposure limits.[9] However, the 1993 edition of the International Electrotechnical Commission (IEC) standard 825-1 (later 60825-1) for the first time included LEDs in the laser safety standard, thus the OCT source is now covered by that standard, and the same laser safety exposure limits would apply. This IEC standard[10] is also published as a European Norm EN 60825-1, which under the “Low-Voltage Directive” of the European Community, it has some regulatory stature. However, the IEC Technical Committee TC76 that is responsible for this standard voted in the

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fall of 2004 to remove diode emitters from the scope of the basic standard. The ICNIRP, IEC and ANSI limits for this type of laser exposure are the same (IEC, 2001; ANSI, 2000). It should be noted here that the US Federal Regulation that applies to laser products,[11] does not apply to LEDs. However, laser products classified under IEC 60825-1 can follow most of the IEC standard for US Federal compliance certification.[12] For the US, the retinal OCT is *not* considered a laser, and does not require certification as meeting the Federal Laser Product Performance Standard.

To protect the retina against thermal injury from a near-infrared laser exposure, all of the aforementioned groups recommend a maximum permissible exposure (MPE) *for a single-pulse exposure* expressed as a radiant exposure for energy arriving within an angular subtense α_{min} of 1.5 mrad (corresponding to a circular retinal area of 25 μm on the retina.

$$MPE = 1.8\ C_A t^{3/4}\ mJ/cm^2 \qquad [1]$$

where t is the exposure duration in s and C_A is a spectral correction factor which has a value of:

$$C_A = 10^{[0.002\ (\lambda\ -\ 700nm)]} \qquad [2]$$

$$= 1.82 \text{ at } \lambda = 830 \text{ nm}$$

In addition to the above time-dependent MPE for 830-nm, "point-source" laser exposure, the ACGIH and ICNRIP recommend an incoherent irradiance limit for corneal exposure (to protect against damage to the cornea and lens. This limit (Threshold Limit Value, or TLV) is:

$$TLV = 1.8 t^{-3/4}\ W/cm^2 \text{ (for } t < 1{,}000 \text{ s)} \qquad [3]$$

$$= 1.8\ W/cm^2 \text{ for a 1-s exposure}$$

$$= 1.07\ W/cm^2 \text{ for a 2-s exposure}$$

$$= 0.64\ W/cm^2 \text{ for a 4-s exposure}$$

The ACGIH also has a limit to protect against retinal hazards for lengthy staring into an incoherent near infrared (770-1400-nm) continuous sources, but this is normally not applied to a minimal image size condition. The criterion is that for a source subtending an angle α, the radiance in this spectral band L_{NIR} is limited to:

$$L_{NIR} = 0.6/\alpha \qquad [4]$$

which for a source subtending an angle of 11 milliradians (mrad) or less, the angle α is fixed at 0.011 radian, and the limit reduces to 54.5 W/(cm^2?sr). Since a linear angle of 11 mrad corresponds to 9.6 sr, this radiance reduces to an irradiance of 5.2 mW/cm^2. For a 7-mm pupil, this average power entering the eye would be 2 mW. This criterion would only be relevant to a lengthy CW exposure from this device under study.

(b) (4)

[redacted]

(b) (4)

[redacted]

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(b) (4)

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exposures were used, a large number of pulses would have to be placed in the same retinal (25 μm) region to exceed the laser limit.

CONCLUSION

The Optovue Retinal OCT system emits near-infrared radiation from an SLD that is below all of the applicable exposure limits—including the guidelines for ophthalmic instrument exposure.

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