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U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(cwf)
FOLDER:	K131447 - 1060 pages
COMPANY:	TERARECON, INC. (TERARECON)
PRODUCT:	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL (LLZ)
SUMMARY:	Product: INTUITION - TDA, TVA, PARAMETRIC MAPPING
DATE REQUESTED:	Oct 9, 2015
DATE PRINTED:	Oct 9, 2015
Note:	Printed

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

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DEC 2 4 2013
K131447

TERARECON

Date of Summary: November 14, 2013

510(k) Summary of Safety and Effectiveness (As required by 21 CFR 807.92(c))	**iNtuition**

Submitter/: Applicant/ Sponsor TeraRecon Inc.
4000 E 3rd Ave, Suite 200
Foster City, CA 94404

Contact Person: Emilly Tojima Nurthen
Regulatory Affairs Manager
Ph: 650.653.4282
Fax: 650.372.1101
Email: emilly@terarecon.com

Establishment: Registration # 2954793

Device Information:

Name of Device:	iNtuition – TDA, TVA, Parametric Mapping
Common Name:	Medical Imaging System
Classification Name:	§ 892.2050, Picture Archiving and Communication System. ProCode: LLZ
Classification Panel:	Radiology
Device Classification:	Class II device

Substantial Equivalence:

iNtuition – TDA, TVA, Parametric Mapping, as addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

- Aquarius Workstation (K011142)
- AquariusAPS Server (K061214)
- LEONARDO syngo Cardiology Workstation (Argus) (K042203)
- LEONARDO (K040970)
- Syngo.CT Cardiac Function (K110366)
- CT Perfusion 4 (K052839)
- Syngo.MR Neurology (K121459)

iNtuition TDA has similar technological characteristics to the Aquarius Workstation, AquariusAPS Server and CT Perfusion 4, with added MR modality support as included in Syngo.MR Neurology.

iNtuition TVA has similar technological characteristics to the Aquarius Workstation, with improvements and additional features. These additional features include MR modality support

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and right ventricle analysis (CT, MR) which are included in the Leonardo, Leonardo Argus and Syngo.CT Cardiac Function (excludes MR).

In comparison to AquariusAPS, iNtuition Parametric Mapping has improved visual appearance and additional color display options.

Indications for Use:

iNtuition-TDA, TVA, and Parametric Mapping are software modules which supports assessment of time-dependent behavior of image intensity, density, dimensions or volume of regions of interest over time, for volumetric or planar dynamic image types such as CT or MR. Parametric mapping tools encode in color various parameters derived from the temporal or spatial characteristics of the planar or volumetric data.

Support is provided for digital image processing to derive metadata or new images from input image sets, for internal use or for forwarding to other devices using the DICOM protocol. Image processing tools are provided to extract metadata to derive parametric images from combinations of multiple input images.

iNtuition-TDA, TVA and Parametric Mapping are iNtution-based software features with dedicated workflows and basic tools and thus support post-processing, displaying and manipulation of reports and medical images from acquisition devices and visualization in 2D, 3D and 4D for single or multiple datasets, or combinations thereof.

iNtuition-TDA, TVA, Parametric Mapping are designed for use by healthcare professionals and are intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions.

Device Description:

iNtuition – TDA, TVA, Parametric Mapping are post-processing modules, part of iNtuition, which is a software device generally used with off-the-shelf hardware, offered in various configurations, with the simplest configuration being a stand-alone workstation capable of image review, communications, archiving, database maintenance, remote review, reporting and basic 3D capabilities. It can also be configured as a server with some, all, or none of its optional features disabled. A fully-configured iNtuition system is capable of various image processing and visualization functions to support the physician in medical image reviewing.

iNtuition – TDA, TVA, Parametric Mapping intended used is to provide solutions to various medical image analysis and viewing problems, which come about as modalities generate more and more images. They also support image distribution over networks, and are DICOM compliant.

iNtuition Time-Dependent Analysis (TDA) and Time-Volume Analysis (TVA) features can obtain quantitative information relating to the evolution of the intensity, density or

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dimensions of certain regions of CT, MR or other images over time. Statistical analysis such as a histogram representation of the image density values in an image is supported, and analysis of changes in volume over time from multi-phase volumetric images; for example, ejection fraction and stroke volume measurement calculation can be performed using the Time-Volume Analysis tools.

iNtuition Parametric Mapping tools encode in color various parameters derived from the temporal or spatial characteristics of the planar or volumetric data.

iNtuition – TDA, TVA and Parametric Mapping are iNtuition-based optional features, and employ all standard features offered by iNtuition, such as convenient tools to support creation of a report, transmitting and storing this report in digital form, and tracking historical information about the studies analyzed with the software.

These three modules can be sold separately or as a part of the bigger iNtuition package.

Technological Characteristics:
iNtuition-TDA, TVA, Parametric Mapping will be marketed as iNtuition-based software only solution for the end-user (with recommended hardware requirements).

Summary of Non-Clinical Performance Tests:
There are no applicable FDA mandated performance standards for this device. However, voluntary standards such as DICOM, various in-house standard operating procedures are in place and utilized in the production of the software.

In all material aspects, iNtuition-TDA, TVA, Parametric Mapping is substantially equivalent to the predicate devices. Performance testing was carried out according to internal company procedures. Software testing and validation were done according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to formalize after ensuring that the software fully satisfies all expected and previously defined system requirements and features. Test results support the conclusion that actual device performance satisfies the design intent and is equivalent to its predicate devices.

Summary of Clinical Performance Tests:
The subject of this traditional 510k notification, iNtuition-TDA, TVA, Parametric Mapping, did not require clinical studies to show safety and effectiveness of the software.

General Safety and Effectiveness Concerns:
The introduction of iNtuition-TDA, TVA, Parametric Mapping has no significant concerns of safety and efficacy. iNtuition-TDA, TVA, Parametric Mapping in comparison with their

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predicate devices are iNtuition-based software modules which have the same intended use and technological characteristics.

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Risk management is ensured via risk analysis, which is used to identify and mitigate potential hazards beginning early in the design cycle and continuing throughout the development of the product. These potential hazards are controlled via software development, verification and validation testing. Furthermore, the operators are healthcare professionals familiar with and responsible for making all final patient management decisions.

Conclusion:

iNtuition-TDA, TVA, Parametric Mapping as described in this premarket notification have the same intended use and similar technical characteristics to the predicate devices listed above. These devices are substantially equivalent in terms of basic design, features and intended use.

In summary, TeraRecon, Inc. is of the opinion that iNtuition-TDA, TVA, Parametric Mapping are iNtuition-based software modules which does not include any new potential safety or effectiveness risks and are substantially equivalent to and perform as well as the predicate devices.

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 24, 2013

TERARECON
EMILLY TOJIMA NURTHEN
REGULATORY AFFAIRS MANAGER
4000 E 3RD AVE STE 200
FOSTER CITY CA 94404

Re: K131447
Trade/Device Name: iNtuition - TDA, TVA, Parametric Mapping
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 29, 2013
Received: December 2, 2013

Dear Ms. Nurthen:

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 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.

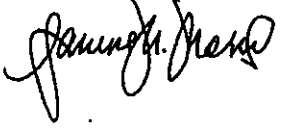
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@FDA.HHS.gov or 301-796-8118

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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. 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,



Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

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

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Indications for Use

510(k) Number: K131447

Device Name: iNtuition-TDA, TVA, Parametric Mapping

Indications for Use:

iNtuition-TDA, TVA, and Parametric Mapping are software modules which supports assessment of time-dependent behavior of image intensity, density, dimensions or volume of regions of interest over time, for volumetric or planar dynamic image types such as CT or MR. Parametric mapping tools encode in color various parameters derived from the temporal or spatial characteristics of the planar or volumetric data.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

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K131447/A001

TERARECON

FDA CDRH DMC
JUN 06 2013
Received

June 4, 2013

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

RE: Change of Contact in 510(k) Notification, K131447
iNtuition-TDA, TVA, Parametric Mapping

Dear Document Control:

This letter is to inform you of the change in contact for 510(k) premarket notification K131447. For all future communication regarding this premarket notification please contact:

Emilly Tojima Nurthen
Regulatory Affairs Manager
TeraRecon, Inc.,
4000 E 3rd Ave, Suite 200,
Foster City, CA 94404

Cell phone: 415-359-6032
Fax: 650-372-1101
Email: emilly@terarecon.com

To comply with ***eCopy Program for Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff***, TeraRecon, Inc. submits this letter in duplicate, both in hard copy and a soft ecopy in accordance with §807.90(c).

The ecopy is an exact duplicate of the paper copy.

Sincerely,

Emilly Tojima Nurthen
Regulatory Affairs Manager
TeraRecon, Inc.

Enclosed: One (1) hard copy and one (1) ecopy.

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

33

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TERARECON

Emilly Tojima Nurthen
Regulatory Affairs Manager

4000 East 3rd Avenue, Suite 200
Foster City, CA 94404
www.terarecon.com
emilly@terarecon.com

[redacted]
Mobile 415.359.6032
Fax 650.372.1101

June 4, 2013

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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December 24, 2013

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EMILLY TOJIMA NURTHEN
REGULATORY AFFAIRS MANAGER
4000 E 3RD AVE STE 200
FOSTER CITY CA 94404

Re: K131447
Trade/Device Name: iNtuition - TDA, TVA, Parametric Mapping
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 29, 2013
Received: December 2, 2013

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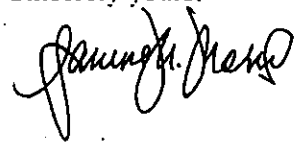

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

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---------REMOVE THIS PAGE WHEN PRINTING OR EMAILING TO SPONSOR---------

510(k) Number: K131447-S001

Digital Signature Concurrence Table	
Reviewer Sign-Off	Sanaz Jansen 12/23/2013
Branch Chief Sign-Off	Robert Ochs December 24, 2013
Division Sign-Off	Janine M. Morris -A 2013.12.24 14:19:29 -05'00'

Template Name: OIR Letter Generator v1.10 - Letter type: SE

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Indications for Use

510(k) Number: K131447

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

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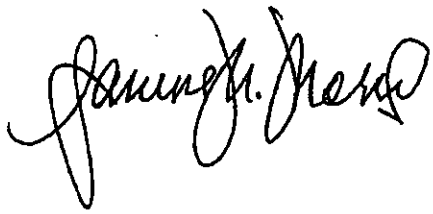
Concurrence of Center for Devices and Radiological Health (CDRH)



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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

K131447

FDA CDRH DMC
MAY 22 2013
Received

510(k) Submission: 20th May, 2013

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

RE: Replacement Ecopy Submission for 510(k) Notification (21 CFR 807.90(e)) – K131447

Trade Name:	iNtuition – TDA, TVA, Parametric Mapping	**Model No:**	4.4
Common Name:	Medical Imaging System	**Establishment Registration #:**	2954793
Submitter/: Applicant/ Sponsor	TeraRecon, Inc. 4000 E 3rd Ave, Suite 200, Foster City, CA 94404	**Contact Person**:	Robert Taylor President/ CEO Ph: (415) 577-9036 Fax: (415) 680-1573

Dear Document Control:

The eCopy submitted on 17th May, 2013 failed the FDA's eCopy validation process. TeraRecon, Inc. herewith submits a replacement eCopy with the eCopy statement mentioned below.

The enclosed 510(k) Premarket Notification is submitted by TeraRecon, Inc. This document provides notice at least ninety days before the date TeraRecon, Inc. intends to introduce the **iNtuition – TDA, TVA, Parametric Mapping** system in question into commercial distribution. This is a traditional 510(k) submission for change in technological characteristics. The administrative details are attached herewith:

Classification Name	§ 892.2050, Picture Archiving and Communication System.
ProCode	LLZ – System, Image Processing, Radiological

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

U2

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Class	II
Predicate Device(s)	Aquarius Workstation – K011142 AquariusAPS Server – K061214 LEONARDO syngo Cardiology Workstation (Argus) (K042203), LEONARDO (K040970) CT Perfusion 4 (K052839), Syngo.MR Neurology (K121459)

The following modules are intended for the same purpose as the previously cleared version of the modules. TeraRecon makes this substantial equivalence application by demonstrating no additional risks/ impact on safety and effectiveness due to changes in technological characteristics.

1. Time-Dependent Analysis (TDA),
2. Time Volume Analysis (TVA),
3. Parametric Mapping

The iNtuition system can be configured with some, all, or none of its optional features disabled. These modules can be sold separately or as a part of the bigger iNtuition (K121916) package with updated proposed labeling.

iNtuition – TDA, TVA, Parametric Mapping is substantially equivalent to existing legally marketed image communication and storage systems manufactured and marketed before May 28, 1976 or to devices legally marketed since that time. We believe the attached Premarket Notification establishes this equivalence.

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

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

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Is the device implanted?		X

The information contained in this document is confidential and proprietary. Knowledge of this project and product line has been restricted to TeraRecon, Inc. employees only. None of this information is public. The complete document should not be released through Freedom of Information Act requests or any other way. We request that TeraRecon, Inc. be notified by FDA if there is an FOI request filed for this document. Selected confidential and/or proprietary information must be deleted before any part of the document is released.

To comply with "eCopy Program for Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff," TeraRecon, Inc. herewith submits one copy of telephone hold request in ecopy (CD) format, which is accompanied with a separate cover letter and the following eCopy statement.

The ecopy submission is an exact duplicate of the paper copy.

TeraRecon, Inc. believes, to the best of its knowledge, that all data and information submitted in this premarket notification is truthful and accurate and that no material/ fact have been omitted. Should you have any questions concerning this submission, please contact me at (415) 577-9036.

Sincerely,

Robert Taylor
President/ CEO

TeraRecon, Inc.,
4000 E 3rd Ave, Suite 200,
Foster City, CA 94404

Tel: 415-577-9036
Fax: 415-680-1573
Email: taylor@terarecon.com

Enclosed: One (1) replacement ecopy.

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

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K131447

FDA CDRH DMC
MAY 20 2013
Received

510(k) Submission: 17th May, 2013

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

RE: 510(k) Notification (21 CFR 807.90(e))

Trade Name:	iNtuition – TDA, TVA, Parametric Mapping	**Model No:**	4.4
Common Name:	Medical Imaging System	**Establishment Registration #:**	2954793
Submitter/: Applicant/ Sponsor	TeraRecon, Inc. 4000 E 3rd Ave, Suite 200, Foster City, CA 94404	**Contact Person**:	Robert Taylor President/ CEO Ph: (415) 577-9036 Fax: (415) 680-1573

Dear Document Control:

The enclosed 510(k) Premarket Notification is submitted by TeraRecon, Inc. This document provides notice at least ninety days before the date TeraRecon, Inc. intends to introduce the **iNtuition – TDA, TVA, Parametric Mapping** system in question into commercial distribution. This is a traditional 510(k) submission for change in technological characteristics. The administrative details are attached herewith:

Classification Name	§ 892.2050, Picture Archiving and Communication System.
ProCode	LLZ – System, Image Processing, Radiological
Class	II
Predicate Device(s)	Aquarius Workstation – K011142 AquariusAPS Server – K061214

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

	LEONARDO syngo Cardiology Workstation (Argus) (K042203), LEONARDO (K040970) CT Perfusion 4 (K052839), Syngo.MR Neurology (K121459)

The following modules are intended for the same purpose as the previously cleared version of the modules. TeraRecon makes this substantial equivalence application by demonstrating no additional risks/ impact on safety and effectiveness due to changes in technological characteristics.

1. Time-Dependent Analysis (TDA),
2. Time Volume Analysis (TVA),
3. Parametric Mapping

The iNtuition system can be configured with some, all, or none of its optional features disabled. These modules can be sold separately or as a part of the bigger iNtuition (K121916) package with updated proposed labeling.

iNtuition – TDA, TVA, Parametric Mapping is substantially equivalent to existing legally marketed image communication and storage systems manufactured and marketed before May 28, 1976 or to devices legally marketed since that time. We believe the attached Premarket Notification establishes this equivalence.

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

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

The information contained in this document is confidential and proprietary. Knowledge of this project and product line has been restricted to TeraRecon, Inc. employees only. None of this information is public. The complete document should not be released through Freedom of Information Act requests or any other way. We request that TeraRecon, Inc. be notified by FDA if there is an FOI request filed for this document. Selected confidential and/or proprietary information must be deleted before any part of the document is released.

To comply with "eCopy Program for Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff," TeraRecon, Inc. herewith submits one copy of telephone hold request in ecopy (CD) format, which is accompanied with a separate cover letter and the following eCopy statement.

The ecopy submission is an exact duplicate of the paper copy.

TeraRecon, Inc. believes, to the best of its knowledge, that all data and information submitted in this premarket notification is truthful and accurate and that no material/ fact have been omitted. Should you have any questions concerning this submission, please contact me at (415) 577-9036.

Sincerely,

Robert Taylor
President/ CEO

TeraRecon, Inc.,
4000 E 3rd Ave, Suite 200,
Foster City, CA 94404

Tel: 415-577-9036
Fax: 415-680-1573
Email: taylor@terarecon.com

Enclosed: One (1) hardcopy and one (1) ecopy.

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. 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)	2. CONTACT NAME
TERARECON INC 4000 East 3rd Avenue Suite 200 Foster City San Mateo CA 94404 US	Robert Taylor 2.1 E-MAIL ADDRESS taylor@terarecon.com 2.2 TELEPHONE NUMBER (include Area code) 415-5779036 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 415-6801573
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4) [redacted]	

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

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

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

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

NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: (b)(4) [redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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

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

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

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

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

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

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

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

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

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

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

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

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

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

$2,480.00 08-May-2013

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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For further support, go to www.adobe.com/support/products/acrreader.html

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

TERARECON

510(k) Submission: 20th May, 2013

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

RE: Replacement Ecopy Submission for 510(k) Notification (21 CFR 807.90(e)) – K131447

Trade Name:	iNtuition – TDA, TVA, Parametric Mapping	**Model No:**	4.4
Common Name:	Medical Imaging System	**Establishment Registration #:**	2954793
Submitter/: Applicant/ Sponsor	TeraRecon, Inc. 4000 E 3rd Ave, Suite 200, Foster City, CA 94404	**Contact Person:**	Robert Taylor President/ CEO Ph: (415) 577-9036 Fax: (415) 680-1573

Dear Document Control:

The eCopy submitted on 17th May, 2013 failed the FDA's eCopy validation process. TeraRecon, Inc. herewith submits a replacement eCopy with the eCopy statement mentioned below.

The enclosed 510(k) Premarket Notification is submitted by TeraRecon, Inc. This document provides notice at least ninety days before the date TeraRecon, Inc. intends to introduce the **iNtuition – TDA, TVA, Parametric Mapping** system in question into commercial distribution. This is a traditional 510(k) submission for change in technological characteristics. The administrative details are attached herewith:

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ProCode	LLZ – System, Image Processing, Radiological

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Class	II
Predicate Device(s)	Aquarius Workstation – K011142 AquariusAPS Server – K061214 LEONARDO syngo Cardiology Workstation (Argus) (K042203), LEONARDO (K040970) CT Perfusion 4 (K052839), Syngo.MR Neurology (K121459)

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Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Is the device implanted?		X

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The ecopy submission is an exact duplicate of the paper copy.

TeraRecon, Inc. believes, to the best of its knowledge, that all data and information submitted in this premarket notification is truthful and accurate and that no material/ fact have been omitted. Should you have any questions concerning this submission, please contact me at (415) 577-9036.

Sincerely,

Robert Taylor
President/ CEO

TeraRecon, Inc.,
4000 E 3rd Ave, Suite 200,
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Tel: 415-577-9036
Fax: 415-680-1573
Email: taylor@terarecon.com

Enclosed: One (1) replacement ecopy.

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Table of Content

Section #	Section Title	Page #
1	Medical Device User Fee Cover Sheet……..	i
2	CDRH Premarket Review Submission Cover Sheet……..	ii
3	510(k) Cover Letter	
	Table of Content ……	iii
	Checklist for Traditional 510(k) submission……..	iv
4	Indications for Use Statement……	4-1
5	510(k) Summary……..	5-1
6	Truth and Accuracy Statement……	6-1
11	Device Description…….	11-1
12	Substantial Equivalence Discussion	
	12.1 SE Matrix……	12-1
	12.2 Predicate Device Labeling……..	12-7
13	Proposed Labeling	
	13.1 User Manual…….....	Appendix A Binder # 1
	13.2 Marketing Material……..	Appendix B Binder # 1
16	Software	
	16.1 Level of Concern……	16.1-1
	16.2 Software Description/ Product Specifications……	16.2-1
	16.3 Device Hazard Analysis……..	16.3-1
	16.4 Software Requirements Specifications (SRS)……	16.4-1
	16.5 Architecture Design Chart……..	16.5-1
	16.6 Software Design Specification (SDS)……	Appendix C Binder # 2
	16.7 Traceability Analysis……..	16.7-1
	16.8 Traceability Analysis……..	16.8-1
	16.9 Verification & Validation documentation……..	Appendix D Binder # 2
	16.10 Revision level history……	16.10-1
	16.11 Unresolved Anomalies (Bugs or Defects)…….	16.11-1
Appendix A	User Manual – iNtuition-TDA, TVA, Parametric Mapping 4.4	Binder # 1
Appendix B	Marketing Material – iNtuition-TDA, TVA, Parametric Mapping Brochure	Binder # 1
Appendix C	Software Design Specifications (SDS)	Binder # 2
Appendix D	Verification and Validation Documentation	Binder # 2
Table 1	SE Matrix Table	12-3

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

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Table 2	SE discussion for safety and effectiveness assessment. iNtuition-Parametric Mapping vs. Primary Predicate Devices	12-3
Table 3	SE discussion for safety and effectiveness assessment. iNtuition-TDA vs. Secondary Predicate Devices	12-4
Table 4	SE discussion for safety and effectiveness assessment. iNtuition-TVA vs. Secondary Predicate Devices	12-5
Table 5	Revision Level History Log for iNtuition-TDA, TVA, Parametric Mapping 4.4	16.10-1
Table 6	Unresolved Anomalies (Bugs or Defects)	16.11-1
Diagram 1	iNtuition Architecture Design Chart	16.5-1

Note: Section # 7, 8, 9, 10, 14, 15, 17, 18, 19, 20 have been removed as are not applicable to TeraRecon, Inc's application.

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

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Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm			
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf			
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm			
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080275.htm			
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm			
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm			
Class III Summary and Certification	Class III Summary and Certification Form http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm			
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf Financial Disclosure by Clinical Investigators http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm			

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

Title	Related Information	Present	Inadequate	N/A
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm FDA Standards program http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm			
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm			
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm			
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm			
Proposed Labeling	Device Advice " Content of a 510(k)" Section H http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm			
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm			
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm			
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm			

Title	Related Information	Present	Inadequate	N/A
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/default.htm See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)			
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm			
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm			
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf			
FORM FDA 3654, *Standards Data Report for 510(k)s - http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf*	**Standards Data Report Form – Form 3654** 1: No standard used - **No Standards Form Required** 2: Declaration of Conformity – **Yes Standards Form Required** 3: Standard but no declaration – **Yes Standards Form Required**			
Kit Certification	Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080213.htm			

Last Updated: 9/3/08 – Brandi Stuart

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

4. Indications for Use Statement

510(k) Number (if known): _____

Device Name: iNtuition-TDA, TVA, Parametric Mapping

Indications for Use:

iNtuition-TDA, TVA, and Parametric Mapping are software modules which supports assessment of time-dependent behavior of image intensity, density, dimensions or volume of regions of interest over time, for volumetric or planar dynamic image types such as CT or MR. Parametric mapping tools encode in color various parameters derived from the temporal or spatial characteristics of the planar or volumetric data.

Support is provided for digital image processing to derive metadata or new images from input image sets, for internal use or for forwarding to other devices using the DICOM protocol. Image processing tools are provided to extract metadata to derive parametric images from combinations of multiple input images.

iNtuition-TDA, TVA and Parametric Mapping are iNtution based software features with dedicated workflows and basic tools and thus support post-processing, displaying and manipulation of reports and medical images from acquisition devices and visualization in 2D, 3D and 4D for single or multiple datasets, or combinations thereof.

iNtuition-TDA, TVA, Parametric Mapping are designed for use by healthcare professionals and are intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions.

Prescription Use ___**X**____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

TERARECON

Date of Summary: 17th May, 2013

510(k) Summary of Safety and Effectiveness (As required by 21 CFR 807.92(c))	**iNtuition**

Submitter/: TeraRecon Inc.
Applicant/ Sponsor 4000 E 3rd Ave, Suite 200
Foster City, CA 94404

Contact Person: Robert Taylor
President/ CEO
Ph: 415-577-9036
Fax: 415-680-1573
Email: taylor@terarecon.com

Establishment: Registration # 2954793

Device Information:

Name of Device:	iNtuition – TDA, TVA, Parametric Mapping
Model No:	4.4
Common Name:	Medical Imaging System
Classification Name:	§ 892.2050, Picture Archiving and Communication System. ProCode: LLZ
Classification Panel:	Radiology
Device Classification:	Class II device

Substantial Equivalence:

iNtuition – TDA, TVA, Parametric Mapping, as addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

Aquarius Workstation (K011142),
AquariusAPS Server (K061214)
LEONARDO syngo Cardiology Workstation (Argus) (K042203),
LEONARDO (K040970),
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iNtuition-TDA, TVA, and Parametric Mapping are software modules which supports assessment of time-dependent behavior of image intensity, density, dimensions or volume of regions of interest over time, for volumetric or planar dynamic image types such as CT or MR. Parametric mapping tools encode in color various parameters derived from the temporal or spatial characteristics of the planar or volumetric data.

Support is provided for digital image processing to derive metadata or new images from input image sets, for internal use or for forwarding to other devices using the DICOM protocol. Image processing tools are provided to extract metadata to derive parametric images from combinations of multiple input images.

iNtuition-TDA, TVA and Parametric Mapping are iNtution-based software features with dedicated workflows and basic tools and thus support post-processing, displaying and manipulation of reports and medical images from acquisition devices and visualization in 2D, 3D and 4D for single or multiple datasets, or combinations thereof.

iNtuition-TDA, TVA, Parametric Mapping are designed for use by healthcare professionals and are intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions.

Device Description:

iNtuition – TDA, TVA, Parametric Mapping are post-processing modules, part of iNtuition, which is a software device generally used with off-the-shelf hardware, offered in various configurations, with the simplest configuration being a stand-alone workstation capable of image review, communications, archiving, database maintenance, remote review, reporting and basic 3D capabilities. It can also be configured as a server with some, all, or none of its optional features disabled. A fully-configured iNtuition system is capable of various image processing and visualization functions to support the physician in medical image reviewing.

iNtuition – TDA, TVA, Parametric Mapping intended used is to provide solutions to various medical image analysis and viewing problems, which come about as modalities generate more and more images. They also support image distribution over networks, and are DICOM compliant.

iNtuition Time-Dependent Analysis (TDA) and Time-Volume Analysis (TVA) features can obtain quantitative information relating to the evolution of the intensity, density or dimensions of certain regions of CT, MR or other images over time. Statistical analysis such as a histogram representation of the image density values in an image is supported, and analysis of changes in volume over time from multi-phase volumetric images; for example, ejection fraction and stroke volume measurement calculation can be performed using the Time-Volume Analysis tools.

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iNtuition Parametric Mapping tools encode in color various parameters derived from the temporal or spatial characteristics of the planar or volumetric data.

iNtuition – TDA, TVA and Parametric Mapping are iNtuition-based optional features, and employ all standard features offered by iNtuition, such as convenient tools to support creation of a report, transmitting and storing this report in digital form, and tracking historical information about the studies analyzed with the software.

These three modules can be sold separately or as a part of the bigger iNtuition package.

Technological Characteristics:
iNtuition-TDA, TVA, Parametric Mapping will be marketed as iNtuition-based software only solution for the end-user (with recommended hardware requirements).

Summary of Non-Clinical Performance Tests:
There are no applicable FDA mandated performance standards for this device. However, voluntary standards such as DICOM, various in-house standard operating procedures are in place and utilized in the production of the software.

In all material aspects, iNtuition-TDA, TVA, Parametric Mapping is substantially equivalent to the predicate devices. Performance testing was carried out according to internal company procedures. Software testing and validation were done according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to formalize after ensuring that the software fully satisfies all expected and previously defined system requirements and features. Test results support the conclusion that actual device performance satisfies the design intent and is equivalent to its predicate devices.

Summary of Clinical Performance Tests:
The subject of this traditional 510k notification, iNtuition-TDA, TVA, Parametric Mapping, did not require clinical studies to show safety and effectiveness of the software.

General Safety and Effectiveness Concerns:
The introduction of iNtuition-TDA, TVA, Parametric Mapping has no significant concerns of safety and efficacy. iNtuition-TDA, TVA, Parametric Mapping in comparison with their predicate devices are iNtuition-based software modules which have the same intended use and technological characteristics.

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

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Risk management is ensured via risk analysis, which is used to identify and mitigate potential hazards beginning early in the design cycle and continuing throughout the development of the product. These potential hazards are controlled via software development, verification and validation testing. Furthermore, the operators are healthcare professionals familiar with and responsible for making all final patient management decisions.

Conclusion:

iNtuition-TDA, TVA, Parametric Mapping as described in this premarket notification have the same intended use and similar technical characteristics to the predicate devices listed above. These devices are substantially equivalent in terms of basic design, features and intended use.

In summary, TeraRecon, Inc. is of the opinion that iNtuition-TDA, TVA, Parametric Mapping are iNtuition-based software modules which does not include any new potential safety or effectiveness risks and are substantially equivalent to and perform as well as the predicate devices.

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

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6. Premarket Notification 510(k)

Truthful and Accuracy Statement

(As required by 21 CFR 807.87(k))

I certify that, in my capacity as President/ CEO of TeraRecon, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification for iNtuition – TDA, TVA, Parametric Mapping is truthful and accurate and that no material fact has been omitted.

(Signature)

5/16/2013

(Date)

Robert Taylor,

President/ CEO

TeraRecon, Inc.

(510(k) Number)

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

11. Device Description

iNtuition – TDA, TVA, Parametric Mapping are post-processing modules, part of iNtuition (K121916), which is a software device generally used with off-the-shelf hardware, offered in various configurations, with the simplest configuration being a stand-alone workstation capable of image review, communications, archiving, database maintenance, remote review, reporting and basic 3D capabilities. It can also be configured as a server with some, all, or none of its optional features disabled. A fully-configured iNtuition system is capable of various image processing and visualization functions to support the physician in medical image reviewing.

iNtuition – TDA, TVA, Parametric Mapping intended used is to provide solutions to various medical image analysis and viewing problems, which come about as modalities generate more and more images. They also support image distribution over networks, and are DICOM compliant.

iNtuition Time-Dependent Analysis (TDA) and Time-Volume Analysis (TVA) features can obtain quantitative information relating to the evolution of the intensity, density or dimensions of certain regions of CT, MR or other images over time. Statistical analysis such as a histogram representation of the image density values in an image is supported, and analysis of changes in volume over time from multi-phase volumetric images; for example, ejection fraction and stroke volume measurement calculation can be performed using the Time-Volume Analysis tools.

iNtuition Parametric Mapping tools encode in color various parameters derived from the temporal or spatial characteristics of the planar or volumetric data.

iNtuition – TDA, TVA and Parametric Mapping are iNtuition based optional features, and employ all standard features offered by iNtuition, such as convenient tools to support creation of a report, transmitting and storing this report in digital form, and tracking historical information about the studies analyzed with the software.

These three modules can be sold separately or as a part of the bigger iNtuition (K121916) package.

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

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12. Substantial Equivalence Discussion

12.1 SE Matrix

iNtuition – TDA, TVA, Parametric Mapping are iNtuition-based software modules working to provide the intended use of solutions to various medical image analysis and viewing problems. They also support image distribution over networks, and are DICOM compliant.

Multiple predicate devices have been used to help demonstrate substantial equivalence and they are cited in the Substantial Equivalence Matrix below.

The predicate devices Aquarius Workstation (K011142), and AquariusAPS Server (K061214) may be considered and identified as the primary predicate devices to which the substantial equivalence claim is being made. These primary predicate devices have the same intended use and similar technological characteristics as iNtuition – TDA, TVA and Parametric Mapping.

Furthermore, other legally marketed predicate devices (secondary predicate devices) - LEONARDO syngo Cardiology Workstation (Argus) (K042203), Leonardo (K040970), CT Perfusion 4 (K052839), Syngo.MR Neurology (K121459), - having the same intended use and similar technological characteristics are used to support substantial equivalence for specific features.

INtuition-based features TVA, TDA and Parametric Mapping have been listed in the SE matrix table below showing both similarities and differences with the applicable predicate device(s). They have the same intended use as the predicate devices listed below. All the above features are compared to primary predicate devices and secondary predicate devices are used only where applicable to enhance substantial equivalence discussion and determination.

Comparison testing on essential features' output has been executed and validated between iNtuition – TDA, TVA, Parametric Mapping features and the predicate devices according to written company procedures and test protocols established before testing was conducted. These comparison tests provide information necessary and sufficient to identify and describe the technological characteristics of the device and its predicates and to permit a substantial equivalence comparison. The comparison testing and performance data attached demonstrate that iNtuition – TDA, TVA and Parametric Mapping have similar technological characteristics as their predicate devices, and that the differences don't raise different questions of safety and effectiveness.

iNtuition – TDA, TVA, Parametric Mapping are substantially equivalent to:
Aquarius Workstation (K011142),
AquariusAPS Server (K061214),
LEONARDO syngo Cardiology Workstation (Argus) (K042203),
LEONARDO (K040970)

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CT Perfusion 4 (K052839),
Syngo.MR Neurology (K121459),

The comparison testing can be located at:

1. Time Dependent Analysis (TDA): Section 16.9 "Validation and Verification Documentation," (refer to ecopy 002_Time Dependent Analysis, page 64).
2. Time Volume Analysis (TVA): Section 16.9 "Validation and Verification Documentation," (refer to ecopy 003_Time Volume Analysis, page 77).
3. Parametric Mapping: Section 16.2 "Software Description," (refer to point 3).

These devices are substantially equivalent in terms of basic design, features, technological characteristics and intended use.

Table 1: SE Matrix Table attached below compares iNtuition-TDA, TVA, Parametric Mapping features:

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

Table 1: SE Matrix Table

Feature	iNtuition – TDA, TVA, Parametric Mapping	Aquarius Workstation	AquariusAPS Server	LEONARDO *syngo* Cardiology Workstation (Argus)	LEONARDO	CT Perfusion 4	Syngo.MR Neurology
510(k) Accession Number	**TBD**	**K011142**	**K061214**	**K042203**	**K040970**	**K052839**	**K121459**
Indications for Use/ Intended Use	**(1)**	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**	**(7)**
TDA - Time Dependent Analysis	Yes	Yes	Yes	-	-	Yes	Yes
TVA - Time Volume Analysis	Yes	No	Yes	Yes	Yes	-	-
Parametric Mapping	Yes	No	Yes	-	-	-	-

Table 2: SE discussion for safety and effectiveness assessment. iNtuition-Parametric Mapping vs. Primary Predicate Devices

Feature	iNtuition – TDA, TVA, Parametric Mapping	Aquarius Workstation	AquariusAPS Server	Explanation of similarities and differences
510(k) Accession Number	**TBD**	**K011142**	**K061214**	**-**
Indications for Use/ Intended Use	**(1)**	**(2)**	**(3)**	-
Parametric Mapping	Yes	No	Yes	(b)(4) [redacted]

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				(b)(4) [redacted]

Table 3: SE discussion for safety and effectiveness assessment. iNtuition-TDA vs. Primary and Secondary Predicate Devices

Feature	iNtuition – TDA, TVA, Parametric Mapping	Aquarius Workstation	AquariusAPS Server	CT Perfusion 4	Syngo.MR Neurology	Explanation of similarities and differences
510(k) Accession Number	**TBD**	**K011142**	**K061214**	**K052839**	**K121459**	-
Indications for Use/ Intended Use	**(1)**	**(2)**	**(3)**	**(6)**	(7)	-
TDA - Time Dependent Analysis	Yes	Yes	Yes	Yes	Yes	(b)(4) [redacted]

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

Table 4: SE discussion for safety and effectiveness assessment. iNtuition-TVA vs. Primary and Secondary Predicate Devices

Feature	iNtuition – TDA, TVA, Parametric Mapping	AquariusAPS Server	LEONARDO syngo Cardiology Workstation (Argus)	LEONARDO	Explanation of similarities and differences
510(k) Accession Number	**TBD**	**K061214**	**K042203**	**K040970**	-
Indications for Use/ Intended Use	**(1)**	**(3)**	**(4)**	**(5)**	-
TVA - Time Volume Analysis	Yes	Yes	Yes	Yes	(b)(4) [redacted]

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

Indications for Use/ Intended Use:

(1) iNtuition-TDA, TVA, and Parametric Mapping are software modules which supports assessment of time-dependent behavior of image intensity, density, dimensions or volume of regions of interest over time, for volumetric or planar dynamic image types such as CT or MR. Parametric mapping tools encode in color various parameters derived from the temporal or spatial characteristics of the planar or volumetric data.

Support is provided for digital image processing to derive metadata or new images from input image sets, for internal use or for forwarding to other devices using the DICOM protocol. Image processing tools are provided to extract metadata to derive parametric images from combinations of multiple input images.

iNtuition-TDA, TVA and Parametric Mapping are iNtution based software features with dedicated workflows and basic tools and thus support post-processing, displaying and manipulation of reports and medical images from acquisition devices and visualization in 2D, 3D and 4D for single or multiple datasets, or combinations thereof.

iNtuition-TDA, TVA, Parametric Mapping are designed for use by healthcare professionals and are intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions.

(2) To acquire, store, transmit, and display medical images from medical scanning devices such as EBT, CT or MRI and patient reports of various types. Teleradiology, image acquisition, distribution, archiving, image manipulation, 3D and 4D visualization are supported. The software supports post-processing based on dynamic CT or MR images continuously acquired to aid in the assessment of time-dependent behavior of the image density or dimensions of certain regions of interest. Calcium Scoring from whole body computed tomography derived measurements, for non-invasive detection and quantification of atherosclerotic plaque. Tools for histogram analysis of the density distribution of certain regions of interest are provided. A database management and report generation tool is included.

(3) The AquariusAPS server receives medical images from medical imaging acquisition devices adhering to the DICOM protocol for image transfer such as EBT, CT, MRI, and other volumetric or planar medical imaging modalities, and performs digital image processing to derive certain information or new images from these image sets. The information or new images thus derived is transmitted using the DICOM protocol to other devices supporting this standard protocol.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

(4) The LEONARDO syngo Cardiology Workstation is a medical diagnostic workstation for viewing, manipulation, communication and storage of medical images and data on exchange media.

The LEONARDO syngo Cardiology Workstation can be configured as a stand-alone diagnostic review and post-processing workstation with a variety of syngo or Windows based software options, which are

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intended to assist the physician in diagnosis or treatment planning. These includes commercially available post-processing techniques.

(5) The LEONARDO is a medical diagnostic workstation for viewing, manipulation, communication, and storage of medical images and data on exchange media.

The LEONARDO can be configured as a satellite console, sharing a database with the main console of a CT, MR, or radiographic/ fluoroscopic imaging system, as well as stand-alone diagnostic review and post-processing workstation.

The LEONARDO can be configured with a variety of syngo or Windows XP-based software options, which are intended to assist the physician in diagnosis or treatment planning. This includes commercially available post-processing techniques.

(6) CT Perfusion 4 is an image analysis software package that allows the user to produce dynamic image data and to generate information with regard to changes in image intensity over time. It supports the analysis of CT perfusion images, obtained by cine imaging (in the head and the body) after the intravenous injection of contrast, in calculation of the various perfusion-related parameters (i.e. regional blood flow, regional blood volume, mean transit time and capillary permeability). The results are displayed in a user-friendly graphic format as parametric images.

This software will aid in the assessment of the extent and type of perfusion, blood volume and capillary permeability changes, which may be related to stroke or tumor angiogenesis and the treatment thereof.

(7) *syngo*.MR Neurology is a software solution to be used for viewing and evaluation for Neuroperfusion MR images for the routine use in MR image viewing.

It is a *syngo*.via based software option with dedicated MR specific workflows and basic MR evaluation tools and thus supports interpretation and evaluation of examinations within healthcare institutions, for e.g. in Radiology, Neuroradiology and Neurosurgery environments.

12.2 Predicate Device Labeling

Attached are the FDA cleared summaries of predicate devices:

Aquarius Workstation (K011142),
AquariusAPS Server (K061214),
LEONARDO syngo Cardiology Workstation (Argus) (K042203),
LEONARDO (K040970)
CT Perfusion 4 (K052839),
Syngo.MR Neurology (K121459),

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

K011142
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MAY - 8 2001

510(k) Premarket Notification Summary of Safety and Effectiveness Information	*Aquarius™ Workstation*

Device Name:
Trade Name: *Aquarius™ Workstation*
Common Name: Image communication and storage system
Classification Name: System, Digital Image Communication Teleradiology System

Establishment Name & Registration Number:
Name: TeraRecon, Inc.
Number: Pending

Classification:
Title 21, Code of Federal Regulations, § 892.2020 & § 892.2050. Now proposed exempt, final rule pending.

ProCode: 90-LMD & 90-LLZ

Equivalent Device(s):
IiVS™ Integrated image Viewing Station (K994329).

Description of the Device:
The Aquarius Workstation is a device offered in various configurations, with the simplest configuration being a workstation capable of image review, communications, archiving, database maintenance, reporting and basic 3D capabilities. The fully configured workstation is also capable of full-color Volume Rendering, Calcium Scoring.

The intended use of the device is to provide solutions to various medical image viewing problems, which come about as modalities generate more and more images. It also supports image distribution over networks, and is DICOM conformant.

Applicant / Sponsor Name / Address:
TeraRecon, Inc.
2955 Campus Drive, Suite 325
San Mateo, CA 94403
650.372.2669

Contact Person:
Mr. Robert Taylor
Executive Vice President
TeraRecon, Inc.
2955 Campus Drive, Suite 325
San Mateo, CA 94403
650.372.2669

Submission Correspondent:
Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 / 925.356.2654 FAX

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

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Manufacturing Facility:
At the present time, the ***Aquarius™ Workstation*** is manufactured by TeraRecon, Inc.

Performance Standards:
There are no applicable FDA mandated performance standards for this device. However, voluntary standards such as DICOM, various in-house Standard Operating Procedures and vendor qualification procedures are in place and utilized in the production of the software.

The software designed to control and manipulate the diagnostic images follows the international standard ISO/IEC 12207: 1995 Information Technology - Software Life Cycle Processes. In accordance with that standard, the level of concern relative to this software has been determined using the decision tree provided in Version 1 of the FDA Software Guidance.

Hardware requirements
The hardware platform for the Aquarius Workstation is an "off-the-shelf" personal computer running Microsoft Windows NT Version 4.0, or Microsoft Windows 2000, or equivalent. The workstation software supports single or multiple processors as supported by the operating system providing they are of the Pentium III class or equivalent. A minimum of 512MB memory is recommended, and a minimum of 18GB hard drive space. A standard Ethernet interface is recommended for network connectivity. A monitor appropriate for the intended use required.

User interface
The user interacts with the system through a standard keyboard and a wheel-mouse.

Data input:
DICOM transfer:
Compliance with DICOM 3.0 C-FIND
Compliance with DICOM 3.0 C-MOVE
Compliance with DICOM 3.0 C-STORE
Compliance with DICOM 3.0 C-PRINT
Import of DICOM files directly from supported media (e.g. Hard Drive or CD)
Maximum dataset size: 512 MB or 1000 slices

Data output:
Data output is user defined and supports one of the following formats:

DICOM file
JPEG image file
BMP file
Microsoft Word Document
Microsoft Excel Document
Microsoft Access Database
Modality supporting DICOM PRINT (optional)
Printer supported by Microsoft Windows (optional)
CD-R Media (optional)
MOD Media (optional)

The Report Function
Provide preset image format for included images. This format has to be easily modified. Overlay of figures and characters on top of the images to annotate findings. Provide for placing the report on a network as DICOM files or BMP or JPEG format. Provide a print function.

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

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Comparison Table:

Feature	Aquarius Workstation	Imatron Ultra Access K972903	TeraRecon IiVS K994329
2D Image Review	Yes	Yes	Yes
Multiplanar reformatting	Yes	Yes	Yes
3D Volume Rendering	Yes	Yes	Yes
Maximum Intensity Projection	Yes	Yes	Yes
Image Archiving	Yes	Yes	Yes
Image Filming	Yes	Yes	Yes
Image Transfer or Network Connectivity	Yes	Yes	Yes
Examination of 2D image data from a calcium scan	Yes	Yes	Yes
Examination of calcium scan as a 3D volume	Yes	Yes	Yes
Semi-automated identification of regions that are considered calcium	Yes	Yes	No
User override of automatically identified regions	Yes	Yes	No
Automatic calculation of calcium score	Yes	Yes	No*
Ability to measure CT numbers on a 2D image	Yes	Yes	Yes
Identification of mistriggered slices	Yes	Yes	No
Saving of calcium data with patient exam data	Yes	Yes	No
Creation of a calcium report	Yes	Yes	No
Comparison of multiple scans	Yes	Yes	Yes
Identification of mistriggered data	Yes	Yes	No
Deselection of a mistriggered image	Yes	Yes	No
Creation of a parametric image	Yes	Yes	No
Indications for use – general medical imaging workstation	Yes	Yes	Yes
Indications for use – calcium	Yes	Yes	Yes**

* = manual calculation previously ** = calculated value previously

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
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2001

TeraRecon, Inc.
% Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
PLEASANT HILL CA 94523-3389

Re: K011142
Aquarius Workstation
Dated: April 11, 2001
Received: April 13, 2001
Regulatory Class: II
21 CFR §892.2050/Procode: 90 LLZ

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

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

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510(k) NUMBER: K011142

DEVICE NAME : AQUARIUS WORKSTATION

INDICATIONS FOR USE:

To acquire, store, transmit, and display medical images from medical scanning devices such as EBT, CT or MRI and patient reports of various types. Teleradiology, image acquisition, distribution, archiving, image manipulation, 3D and 4D visualization are supported. The software supports post-processing based or dynamic CT or MR images continuously acquired to aid in the assessment of time-dependant behavior of the image density or dimension of certain regions of interest. Calcium Scoring from whole body computed tomography derived measurements, for non-invasive detection and quantification of atherosclerotic plaque. Tools for histogram analysis of the density distribution of certain regions of interest are provided. A database management and report generation tool is included.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011142

Prescription Use ✓ (Per 21 CFR 801.109) OR **Over-The-Counter Use** _____ (Optional format 1-2-96)

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

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K061214 Page 1 of 2

510(k) Premarket Notification — AquariusAPS Server

Summary of Safety and Effectiveness Information — **December 16, 2005**

Trade Name: *AquariusAPS Server*
Common/Usual Name: Server for image processing and communication
Classification Name: System, Image Processing

MAY 15 2006

Establishment Name and Registration Number:
Name: TeraRecon, Inc.
Number: 2954793

Classification:
21 CFR § 892.2050, Picture Archiving and Communications System, Class II, proposed exempt, final rule pending.

ProCode: 90-LLZ

Equivalent Device(s):

1. *Aquarius Workstation*-K011142 by TeraRecon Inc.
2. *AquariusNET Server*- K012086 by TeraRecon Inc.
3. *Lung CAR*-K041807 by Medicsight PLC.
4. *Colon CAR*-K042674 by Medicsight PLC.
5. *Fusion 7D*-K020546 by Mirada Solutions, Ltd.

Parts of these devices are substantially equivalent in terms of basic design, features and intended use.

Applicant/Sponsor Name/Address:
TeraRecon Inc.
2955 Campus Drive, Suite 325
San Mateo, CA 94403
Tel: (650) 372-1100
FAX: 650-372.1101

Contact Person:
Emilly Tojima
Quality Assurance and Regulatory Affairs Manager
TeraRecon Inc.
2955 Campus Drive, Suite 325
San Mateo, CA 94403
Tel: (650) 372-1100

Description of the Device:
The AquariusAPS server receives medical images from medical imaging acquisition devices adhering to the DICOM protocol for image transfer such as EBT, CT, MRI, and other volumetric or planar medical imaging modalities, and performs digital image processing to derive certain information or new images from these image sets. The information or new images thus derived is transmitted using the DICOM protocol to other devices supporting this standard protocol. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA."

The intended use of the device is to provide time-saving pre-processing of images to remove the need for an image review system to perform these activities while a user is waiting for processing to complete, to optimize the use of the user's time.

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

K061214 Page 2 of 2

Hardware & Software Information

The AquariusAPS Server utilizes standard "off the shelf" personal computer systems as its hardware platform. The software requires the use of the Windows NT 4.0 or Windows 2000 operating system, and a Pentium III – class processor or equivalent.

The software designed to control and manipulate the diagnostic images are based upon information and guidance found in the list of standards provided in Appendix III. In accordance with TeraRecon's software development procedures, the level of concern relative to this software has been determined through information obtained from the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005).

Feature Comparison Table

Feature	Aquarius APS	Aquarius NET Server	Aquarius Workstation	Lung CAR Medicsight	Colon CAR Medicsight	Fusion 7D Mirada Solutions
2D, 3D Image Review	No	Yes	Yes	No	No	No
Removal of the CT table from a CT examination	Yes	Yes	Yes	No	No	No
Removal of bony structures from a CT examination	Yes	Yes	Yes	No	No	No
Calculation of a centerline through a hollow organ or structure, or vessels, for a CT or MR scan	Yes	Yes	Yes	No	No	No
Isolation of tissue in the vicinity of and including the heart from a CT scan	Yes	No	Yes	No	No	No
Calculation of a parametric color overlay map for time-dependent a MR or CT scan	Yes	No	Yes	No	No	No
Identifying locations of sphere-like structures in a CT scan	Yes	No	Yes (Manual)	Yes	Yes	No
Calculation of a set of images in certain orientations or planes using MPR, MIP, VR or other rending techniques.	Yes	Yes	Yes	No	No	No
Calculation of a transformation to register one set of images to another	Yes	Yes (Manual)	No	No	No	Yes
Calculation of the volume of a certain structure, possibly with time dependence	Yes	No	Yes	No	No	No
Receiving images using DICOM transfer protocols	Yes	Yes	Yes	Yes	Yes	Yes
Sending Images and other data using DICOM transfer protocols	Yes	Yes	Yes	Yes	Yes	Yes
Performing actions based on DICOM tags contained in images received by DICOM	Yes	Yes	No	No	No	No
Administration control through a browser-based interface	Yes	Yes	No	No	No	No
Export of images and image sequences in a variety of formats	Yes	Yes	Yes	Yes	Yes	Yes

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 15 2006

TeraRecon, Inc.
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K061214
Trade/Device Name: AquariusAPS Server
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 1, 2006
Received: May 2, 2006

Dear Mr. Lehtonen:

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

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

Protecting and Promoting Public Health

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

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

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological 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 2014-9975; Released by CDRH on 12/3/2015

510(k) NUMBER (IF KNOWN): K061214

DEVICE NAME: AquariusAPS

INDICATIONS FOR USE:

The AquariusAPS server receives medical images from medical imaging acquisition devices adhering to the DICOM protocol for image transfer such as EBT, CT, MRI, and other volumetric or planar medical imaging modalities, and performs digital image processing to derive certain information or new images from these image sets. The information or new images thus derived is transmitted using the DICOM protocol to other devices supporting this standard protocol.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061214

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

K042203
Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

510(k) Summary

SEP 2 4 2004

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

I. GENERAL INFORMATION

Establishment:

- Address: Siemens Medical Systems, Inc.
  51 Valley Stream Parkway
  Malvern, PA 19355

- Registration Number: 2240869

- Contact Person: Ana Ladino
  Technical Specialist Regulatory Submissions
  Telephone: (610) 448-1785
  Telefax: (610) 448-1787

Device Name:

- Trade Name: LEONARDO *syngo* Cardiology Workstation
- Classification: Picture Archiving and Communications System (PACS)
- Classification Panel: Radiology
- CFR Section: 21 CFR §892.2050
- Device Class: Class II
- Product Code: LLZ

Date of Preparation of Summary: August 5th, 2004

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

- **Device Description and Intended Use:**
  This premarket notification covers Siemens LEONARDO *syngo* Cardiology Workstation *syngo* is a universal imaging platform based on Windows XP. LEONARDO *syngo* Cardiology offers a comprehensive cardiology solution to view, optimize, post-process diagnostic information and aid the doctors in the evaluation of digital cardiological and radiological examinations and patient information.

  Due to special customer requirements based on the modality image type and the clinical focus, the LEONARDO *syngo* Cardiology Workstation can be configured with different combinations of clinical applications. *syngo* applications can be

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

added to the LEONARDO *syngo* Cardiology Workstation either individually or as clinical focus packages.

The LEONARDO *syngo* Cardiology Workstation is a medical diagnostic workstation for viewing, manipulation, communication, and storage of medical images and data on exchange media.

The LEONARDO *syngo* Cardiology Workstation can be configured with a variety of *syngo*- or Windows based software options, which are intended to assist the physician in diagnosis or treatment planning. This includes commercially available post-processing techniques.

- **Technological Characteristics:**
  The LEONARDO *syngo* Cardiology Workstation will be marketed as a software only solution for the end-user (with recommended hardware requirements) or as a complete work station for the end-user (hardware and software package). It will be installed by Siemens service engineers. The LEONARDO *syngo* Cardiology Workstation described supports DICOM formatted images and information. The workstation is based on the Windows XP operating system.

- **General Safety and Effectiveness Concerns:**
  The device labeling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device.

  Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

- **Substantial Equivalence:**
  The LEONARDO *syngo* Cardiology Workstation, addressed in this premarket notification, is substantially equivalent to the following commercially available device:

  LEONARDO (K040970)

  The LEONARDO *syngo* Cardiology Workstation described in this premarket notification has the same intended use and similar technical characteristics as the device listed above.

In summary, Siemens is of the opinion that LEONARDO *syngo* Cardiology Workstation does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device.

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 24 2004

Ms. Ana Ladino
Technical Specialist,
Regulatory Submission
Siemens Medical Systems, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

Re: K042203
Trade/Device Name: LEONARDO *syngo* Cardiology Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 5, 2004
Received: August 16, 2004

Dear Ms. Ladino:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological 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 2014-9975; Released by CDRH on 12/3/2015

Intended Use

510(k) Number (if known): K042203
Device Name: **LEONARDO *syngo* Cardiology Workstation**

Indications for Use

The LEONARDO *syngo* Cardiology Workstation is a medical diagnostic workstation for viewing, manipulation, communication, and storage of medical images and data on exchange media.

The LEONARDO *syngo* Cardiology Workstation can be configured as a stand-alone diagnostic review and post-processing workstation with a variety of *syngo* or Windows based software options, which are intended to assist the physician in diagnosis or treatment planning. This includes commercially available post-processing techniques.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

David R. Segars

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042203

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

510(k) Summary

JUL - 8 2004

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

I. GENERAL INFORMATION

Establishment:

- Address: Siemens AG
  Medical Solutions
  Henkestrasse 127
  D-91052 Erlangen
  Germany
- Registration Number: 2240869
- Contact Person: Ana Ladino
  Technical Specialist Regulatory Submissions
  Telephone: (610) 448-1785
  Telefax: (610) 448-1787

Device Name:

- Trade Name: LEONARDO
- Classification: Picture Archiving and Communications System (PACS)
- Classification Panel: Radiology
- CFR Section: 21 CFR §892.2050
- Device Class: Class II
- Product Code: LLZ

Date of Preparation of Summary: April 9th, 2004

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

- **Device Description and Intended Use:**
  This premarket notification covers Siemens LEONARDO *syngo*-based multi-modality workplace. *syngo* is a universal imaging platform based on Windows XP. Leonardo offers a comprehensive solution to view, optimize, post-process diagnostic information and aid the doctors in the evaluation of digital radiological examinations and patient information.

Questions? Contact FDA/CDRH/OCE/DIS/CDRH-RCSTATUS@FDA.HHS.gov or 301-796-8118

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Due to special customer requirements based on the modality image type and the clinical focus, the LEONARDO can be configured with different combinations of clinical applications. *syngo* applications can be added to the LEONARDO multi-modality workplace either individually or as clinical focus packages.

The LEONARDO is a medical diagnostic workstation for viewing, manipulation, communication, and storage of medical images and data on exchange media.

The LEONARDO can be configured as a satellite console, sharing a database with the main console of a CT, MR, or radiographic/fluoroscopic imaging system, as well as stand-alone diagnostic review and post-processing workstation.

The LEONARDO can be configured with a variety of *syngo*- or Windows XP-based software options, which are intended to assist the physician in diagnosis or treatment planning. This includes commercially available post-processing techniques.

- **Technological Characteristics:**
  The LEONARDO will be marketed as a software only solution for the end-user (with recommended hardware requirements) or as a complete work station for the end-user (hardware and software package). It will be installed by Siemens service engineers. The LEONARDO supports DICOM formatted images and information. The workstation is based on the Windows XP operating system.

- **General Safety and Effectiveness Concerns:**
  The device labeling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device.

  Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

- **Substantial Equivalence:**
  The LEONARDO *syngo* Multimodality Workstation, addressed in this premarket notification, is substantially equivalent to the following commercially available device:

  syngo Multimodality Workstation (K010938)

  The LEONARDO Workplace described in this premarket notification has the same intended use and similar technical characteristics as the device listed above.

  In summary, Siemens is of the opinion that LEONARDO does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device.

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 2004

Ms. Ana Ladino
Technical Specialist,
Regulatory Submissions
Siemens Medical Systems, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

Re: K040970
Trade/Device Name: LEONARDO
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: April 9, 2004
Received: April 14, 2004

Dear Ms. Ladino:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological 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 2014-9975; Released by CDRH on 12/3/2015

Indications for use

510(k) Number (if known): K040970
Device Name: LEONARDO

Indications for Use

The LEONARDO is a medical diagnostic workstation for viewing, manipulation, communication, and storage of medical images and data on exchange media.

The LEONARDO can be configured as a satellite console, sharing a database with the main console of a CT, MR, or radiographic/fluoroscopic imaging system, as well as stand-alone diagnostic review and post-processing workstation.

The LEONARDO can be configured with a variety of *syngo*- or Windows XP-based software options, which are intended to assist the physician in diagnosis or treatment planning. This includes commercially available post-processing techniques.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040970

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

MAR 1 0 2006

GE Healthcare

K052839

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Date Prepared June 27 2005

Submitter

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
Tel: (262) 544-3894
Fax: (262) 544-4768
GE Healthcare W-400
3000 North Grandview Blvd.
Waukesha, WI 53188 USA

PRODUCT IDENTIFICATION

Name: CT Perfusion 4

Classification Name: Accessory to Computed Tomography System

Manufacturer: GE Medical Systems S.C.S
283, rue de la Minière
78533 Buc Cedex, FRANCE

Distributor: General Electric Medical Systems S.C.S, Buc, France.

Marketed Devices: The CT Perfusion 4 is substantially equivalent to the devices listed below:

Model: CT Perfusion 2
Manufacturer: GE Medical Systems S.C.S, Buc, France
510(k) #: K010042

Device Description:

CT Perfusion 4 is an image analysis software package that allows the evaluation of dynamic CT data following an injection of a compact bolus of contrast material, generating information with regards to changes in image intensity over time. It provides a quick and reliable assessment of the type and

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

K052839

extent of perfusion disturbances by providing qualitative and quantitative information on various perfusion related parameters.

The results are displayed in a user-friendly graphic format as parametric images (single image calculated from a set of time course images at a single location).

Indications for Use:

CT perfusion 4 is an image analysis software package that allows the user to produce dynamic image data and to generate information with regard to changes in image intensity over time. It supports the analysis of CT Perfusion images, obtained by cine imaging (in the head and body) after the intravenous injection of contrast, in calculation of the various perfusion-related parameters (i.e. regional blood flow, regional blood volume, mean transit time and capillary permeability). The results are displayed in a user-friendly graphic format as parametric images.
This software will aid in the assessment of the extent and type of perfusion, blood volume and capillary permeability changes, which may be related to stroke or tumor angiogenesis and the treatment thereof.

Comparison with Predicate:

CT Perfusion 4 images as compared with the CT Perfusion 2 device are obtained by CT scanning after an injection of contrast media. CT Perfusion 4 is a software post-processing device and as such does not affect the dosage characteristics or the imaging performance of GEMS CT scanners. The algorithms used to calculate the perfusion parameters are similar to CT Perfusion 2 device. The functional features of the CT Perfusion 4 software package are substantially equivalent to that of the following device:

Device Name	FDA Clearance Number
CT Perfusion 2	K010042

Adverse Effects on Health:

The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

Conclusions:

CT Perfusion 4 does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the CT Perfusion 4 to be equivalent to those of CT Perfusion 2 (K010042).

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2006

GE Healthcare
c/o Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 017190

Re: K052839
Trade/Device Name: CT Perfusion 4
Regulation Number: 21 CFR §892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: February 14, 2006
Received: February 15, 2006

Dear Mr. Lehtonen:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

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

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological 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

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Indications for Use

510(k) Number (if known): K052839

Device Name: CT Perfusion 4

Indications for Use:

CT perfusion 4 is an image analysis software package that allows the user to produce dynamic image data and to generate information with regard to changes in image intensity over time. It supports the analysis of CT Perfusion images, obtained by cine imaging (in the head and body) after the intravenous injection of contrast, in calculation of the various perfusion-related parameters (i.e. regional blood flow, regional blood volume, mean transit time and capillary permeability). The results are displayed in a user-friendly graphic format as parametric images.

This software will aid in the assessment of the extent and type of perfusion, blood volume and capillary permeability changes, which may be related to stroke or tumor angiogenesis and the treatment thereof.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)

Division of [illegible]

and [illegible]

510(k) Number K052839

Page __ of ___

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

JUN 22 2012

K121459

P1/4

510(k) Summary: *syngo*.MR Neurology

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

Date of Summary Preparation: May 15, 2012

I. General Information

Importer/Distributor Siemens Medical Solutions USA, Inc.
51 Valley Stream Pkwy
Mail Code D02
Malvern, PA 19355, USA

Registration Number: **2240869**

Manufacturer Siemens AG Sector Healthcare
Medical Solutions
Henkestrasse 127
D-91052 Erlangen, Germany

Registration Number: **8010024**

Contact Person Michelle Byrne
Regulatory Affairs Technical Specialist
Siemens Medical Solutions USA, Inc.
51 Valley Stream Pkwy
Mail Code D02
Malvern, PA 19355, USA
Phone: (610) 448-4293
Fax: (610) 448-1787
Email: Michelle.L.Byrne@siemens.com

Device Name and Classification

Data	Details
Trade name / Device Proprietary Name:	*syngo*.MR Neurology *syngo*.MR Neurology includes *syngo*.MR Neuro Perfusion Engine and *syngo*.MR Neuro fMRI. *syngo*.MR Neuro Perfusion Engine bundles the applications *syngo*.MR Neuro Perfusion and *syngo*.MR Neuro Perfusion Mismatch. Each application is also sold separately.

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

K121459
P2/4

Data	Details
Classification Name:	Regulation Description: - Picture Archiving and Communication System (PACS)
Classification Panel:	Radiology
Device Classification:	Class II devices
Regulation number:	21 CFR 892.2050
Product Code:	LLZ, LNH

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use

syngo.MR Neurology is a software solution to be used for viewing and evaluation of Neuroperfusion MR images for the routine use in MR image viewing.

It is a *syngo.via* based software option with dedicated MR specific workflows and basic MR specific evaluation tools and thus supports interpretation and evaluation of examinations within healthcare institutions, for example in Radiology, Neuroradiology and Neurosurgery environments.

Device Description

syngo.MR Neurology is a post-processing software/application to be used for viewing and evaluating neurological MR images provided by a magnetic resonance diagnostic device. *syngo*.MR Neurology is a *syngo*.via-based software that enables structured evaluation of MR neurological images.

The medical device *syngo*.MR Neurology comprises *syngo*.MR Neuro fMRI (Neuro functional evaluation) and *syngo*.MR Neuro Perfusion Engine.
syngo.MR Neuro Perfusion Engine comprises *syngo*.MR Neuro Perfusion (Perfusion and Local as well as Global AIF (Arterial Input Function)) and *syngo*.MR Neuro Perfusion Mismatch (Perfusion-Diffusion Mismatch Evaluation). This bundling is done for purchase purposes. Each application can also be purchased separately.

- ***syngo*.MR Neuro Perfusion** enables: processing of brain perfusion datasets acquired with DSC imaging. It provides color display and calculation of perfusion maps based on Arterial Input Function (AIF) (relative Mean Transit Time (relMTT), relative Cerebral Blood Volume (relCBV), and relative Cerebral Blood Flow (relCBF)).

- ***syngo*.MR Neuro Perfusion Mismatch** performs a calculation of the area differences between perfusion-diffusion datasets.

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

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K121459
P3/4

- ***syngo*.MR Neuro fMRI** is a workflow-oriented visualization package for BOLD fMRI.

General Safety and Effectiveness Concerns
Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Risk management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. These potential hazards are controlled via software development, verification and validation testing. To minimize hazards, Siemens adheres to recognized and established industry practices and standards. Furthermore, the operators are healthcare professionals familiar with and responsible for the evaluating and post processing of magnetic resonance images.

syngo.MR Neurology conforms to the applicable FDA recognized and international IEC, ISO, and NEMA standards with regards to performance and safety as recommended by the respective MR FDA Guidance Document.

Substantial Equivalence
syngo.MR Neurology is substantially equivalent to the following predicate devices (see Table 1):

Table 1: Predicate devices for *syngo*.MR Neurology

Predicate Device Name	FDA Clearance Number	FDA Clearance Date
syngo MR D11D for MAGNETOM Aera & MAGNETOM Skyra	K111242	November 23, 2011
syngo.x®[3]	K092519	August 27, 2009

Conclusion as to Substantial Equivalence
syngo.MR Neurology has a similar intended use and the same basic technical characteristics as the predecessor devices *syngo* MR D11D (on MAGNETOM Aera and MAGNETOM Skyra) and *syngo*.x, in regards to the specific neurological functionalities. *syngo*.MR Neurology will be used for post-processing neurological images (viewing, processing and reading). The predicate device, MAGNETOM Aera and MAGNETOM Skyra with software *syngo* MR D11D, is also capable of post-processing neurological images (viewing, processing and reading), in addition to acquiring the MR images. *syngo*.x is used as the basic software platform and is intended for post-processing, for example, viewing, manipulating, communicating and

[3] *syngo*.x® is a registered trademark of Siemens AG.

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

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K121459
P4/4

storing medical images. The differences between the subject device and the predicate devices, which include the aforementioned new software applications, give the subject device greater capabilities than the predicate devices, but have the same technological characteristics as the predicate devices, are similar to the functionalities of the predicate devices, and do not introduce any new issues of safety or effectiveness.

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

JUN 22 2012

Ms. Michelle L. Byrne
Regulatory Affairs Technical Specialist
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway, Mail Code D02
MALVERN PA 19355

Re: K121459
Trade/Device Name: *syngo*.MR Neurology
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 15, 2012
Received: May 17, 2012

Dear Mr. Ms. Byrne:

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

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

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

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medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
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 2014-9975; Released by CDRH on 12/3/2015 K121459

Indications for Use Statement

510(k) Number (if known) _____

Device Name: ***syngo*.MR Neurology**

Indications for Use:

syngo.MR Neurology is a software solution to be used for viewing and evaluation of Neuroperfusion MR images for the routine use in MR image viewing.

It is a *syngo*.via based software option with dedicated MR specific workflows and basic MR specific evaluation tools and thus supports interpretation and evaluation of examinations within healthcare institutions, for example in Radiology, Neuroradiology and Neurosurgery environments.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K121459

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

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13. Proposed Labeling

Please refer to Appendix A for draft iNtuition – TDA, TVA, Parametric Mapping User Manual and,

Please refer to Appendix B for iNtuition – TDA, TVA, Parametric Mapping Brochure

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

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Linkage to User Manual

Note:
Brochure: iNtuition-TDA, TVA, Parametric Mapping modules are part of iNtuition (K121916) product. The entire iNtuition brochure is provided for context and relevant sections are highlighted in red boxes for ease of navigation
User Manual: iNtuition - TDA, TVA, Parametric Mapping modules are part of iNtuition (K121916) product. Only applicable sections associated with TDA, TVA and Parametric Mapping are provided for ease of navigation

Category	Feature/ Module	Brochure Page No	Booklet No	Name	Chapter No	Chapter Name	Page No
Optional Clinical Modules	TDA - Time Dependent Analysis	6,9,11	I	AQi	Chap 7	Time Dependent Analysis	7-1 to 7-16
	TVA - Time Volume Analysis	6,13	I	AQi	Chap 5/ Chap 2	TVA and Cardiac Function/ The 3D Viewer	5-1 to 5-30/ 2-102 to 2-111
	Parametric Mapping	6, 11	II/ III/ IV	AquariusNET Thin Client/ AquariusAPS/ iReview	Chap 10/ Chap 1/ Chap 3	Multiphase Studies/ Introduction to AquariusAPS/ The Viewer	10-5 to 10-7/ 1-4 to 1-4/ 3-19 to 3-22

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

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i*N*tuition - TDA, TVA and Parametric Mapping

Version 4.4

User Manual

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

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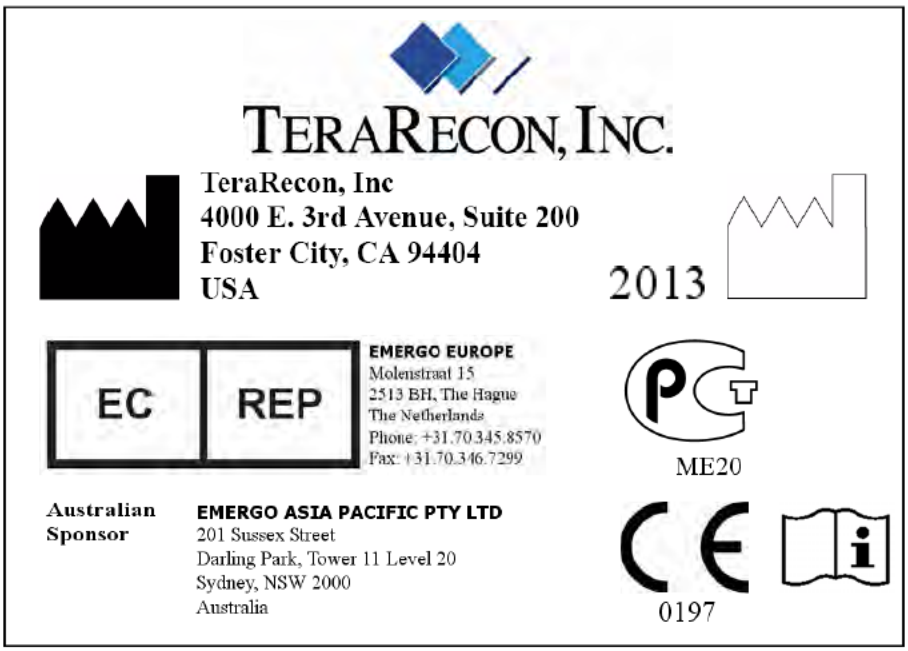

Symbols used in the label:

Symbol	Meaning
	Consult Instructions for Use.
0197	The CE 0197 mark applies to AquariusNET Server, Aquarius Workstation and AquariusAPS software when such software is installed on the computer to which the CE 0197 mark is affixed.
	Manufacturer The name and address of the manufacturer are listed next to this symbol.
	Date of Manufacture The year of manufacture is listed next to this symbol.
EC REP	**Authorized Representative in the European Community** The name and address of TeraRecon's authorized representative in the European Community are listed next to this symbol.
ME20	**GOST-R Mark** Mark of conformity certifying that Russian Federation safety requirements have been met.

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

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This document contains important, helpful, use and precautionary information. Please review carefully all precautionary statements and advisories, whether onscreen or contained herein, as these are essential to the effective and authorized use of the products and applications discussed.

Note: The beta features are not to be used clinically.

Note: The product i*N*tuition described in the manual is also referred to as Aquarius i*N*tuition.

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Indications For Use

iNtuition-TDA, TVA, and Parametric Mapping are software modules which supports assessment of time-dependent behavior of image intensity, density, dimensions or volume of regions of interest over time, for volumetric or planar dynamic image types such as CT or MR. Parametric mapping tools encode in color various parameters derived from the temporal or spatial characteristics of the planar or volumetric data. Support is provided for digital image processing to derive metadata or new images from input image sets, for internal use or for forwarding to other devices using the DICOM protocol. Image processing tools are provided to extract metadata to derive parametric images from combinations of multiple input images.

iNtuition-TDA, TVA and Parametric Mapping are iNtution-based software features with dedicated workflows and basic tools and thus support post-processing, displaying and manipulation of reports and medical images from acquisition devices and visualization in 2D, 3D and 4D for single or multiple datasets, or combinations thereof.

iNtuition-TDA, TVA, Parametric Mapping are designed for use by healthcare professionals and are intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions.

> **NOTE: Interpretation of mammographic images or digitized film screen images is supported only when the software is used without compression and with an FDA-Approved monitor that offers at least 5Mpixel resolution and meets other technical specifications reviewed and accepted by the FDA.**

Safety Concerns

i*N*tuition is intended to be used for review and analysis of volumetric medical imaging data acquired by CT or MR scanners. i*N*tuition is part of a Class II medical device regulated by the Food and Drug Administration.

> **NOTE: U.S. Federal Law restricts use of this device to trained physicians, or other suitably qualified and trained personnel on the order of a physician.**

i*N*tuition is part of a sophisticated medical device, and as such **MUST ONLY BE USED BY QUALIFIED AND TRAINED PERSONNEL**. If you require training, please contact TeraRecon or a suitably qualified trainer. Please keep this documentation readily available near i*N*tuition at all times, and please keep it updated with all corrections/addenda that may be released by TeraRecon from time to time.

Please also be aware that patient information is restricted, private, and extremely confidential, and subject to stringent legal regulations - you should control access to the i*N*tuition or patient data contained therein accordingly.

Devices attached to this product must comply with their own applicable safety standards.

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

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Precautions Relating to General Use

The i*N*tuition software may allow images to be generated in which parts of the original scan data are obscured, removed (including but not limited to, through use of lossy compression), hidden, or modified. Similarly, output images and reports can be produced, saved, and annotated, with elements of the original acquisition omitted, obscured, modified, or hidden. Hence, careful and responsible use of the equipment and its output images requires that the user be aware of, and effectively communicate these important facts to, untrained or uninformed observers or recipients of the processed information. Please ensure that all processing has completed (including completion of any final stage subsequent to an intermediate stage of processing) before formulating a final interpretative decision.

In certain situations, processing takes a brief time, but please ensure that all processing of whatever type has completed (including, for example, completion of any final stage subsequent to an intermediate stage of processing) before seeking to validate, or validating, a final interpretative decision.

Precautions Relating To Display Hardware

Please be aware that i*N*tuition display is limited in acuity and color or grayscale depth to that of the display device used. Display hardware characteristics can vary widely.

The judgment of the medical imaging professional is essential to reaching the appropriate conclusion from the results presented by the i*N*tuition.

Precautions Relating To Interpretation

Please be aware that calculations relating to distances, volumes, centerline creations and other physical properties performed by i*N*tuition are dependent in accuracy upon the correct information being supplied in the input DICOM images. It is the responsibility of the operator to ensure that inputted DICOM images are correctly formatted and to heed any warnings that the software may display during operation relating to potential problems with the information supplied in those DICOM images.

Note further that, in certain instances, even though there may be problems or inconsistencies in the DICOM information, the i*N*tuition will be unable to detect this, and erroneous image display will be unavoidable unless the user properly ensures the correctness of all input data in advance. Potential problems relating to errors in the DICOM information include incorrect dimensional readouts, incorrect orientation markings, and incorrect pixel value calibration. Three-dimensional imaging inherently offers a wide variety of different imaging views of any given dataset; it is an important responsibility of the operator to ensure that a proper visualization is achieved, and that a complete review of the data has been performed before reaching any diagnostic or interpretive conclusion relating to the dataset in question. Limitations present in the original input data (such as those relating to spatial and/ or temporal resolution, pixel size, and slice thickness) remain valid even when i*N*tuition processes the data, and these provisos should be considered when using the equipment for image review.

The image processing and display techniques offered by i*N*tuition are only intended as an adjunct to, and not a substitute for, conventional diagnostic review of medical imaging data. **All results should be validated by qualified physicians trained in the subject matter.**

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

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The Aquarius products provide tools and protocols to quantify metrics and distances relating to structures in the CT, MR scans or images which are based upon the dimensions of the anatomy scanned or imaged at the time the images were originally acquired from the patient, and based on the measurement calibrations provided by the acquiring device. The suitability for any particular purpose, especially monitoring the progression of disease, or the sizing or planning of a device to be implanted in a patient, is dependent upon many factors, including, but not limited to, the accuracy of the original acquisition, the extent to which the images acquired still represent the patient's anatomy, and the way in which the actual device deployment may modify the anatomy into which it is introduced. TeraRecon does not represent that the Aquarius products are suitable for such purposes - all such activities should always be cross-correlated with other techniques to ensure a complete understanding of the patient and contemplated procedure is obtained by the validating physician(s) in charge.

Precautions Relating To Magnetic Resonance Imaging Machines

Components of i*N*tuition, including this document and its packaging or binding, may contain metallic or Ferro-magnetic components. Please ensure that no such component is introduced into the influence of magnetic fields from devices such as Magnetic Resonance Imaging Scanners, since injury or damage to equipment or property could occur.

Precautions Relating To Risk Of Loss Of Data

i*N*tuition is not intended to be used as a primary archive for medical imaging data. This means that a secure copy of any data should be maintained in a location separate from the software, for example, in the scanner, in a PACS archive, or on archive media. Please do not rely on i*N*tuition as your primary archive.

In addition, do not rely on i*N*tuition to convey data from its acquisition point to your primary archive, because in this configuration, a failure in i*N*tuition could compromise your primary archive. Your primary archive should be maintained in a manner independent of, and not relying on, i*N*tuition.

Precautions Relating to Computer Software and Hardware:

NOTE THAT THE INSTALLATION AND USE OF ANY ADDITIONAL SOFTWARE OR HARDWARE COMPONENT WITHOUT THE SPECIFIC DIRECTION AND APPROVAL OF TERARECON MAY IMPAIR THE SAFETY AND EFFECTIVENESS OF THE PRODUCT. HENCE, NO ADDITIONAL SOFTWARE OR HARDWARE COMPONENT SHOULD BE ADDED TO i*N*tuition, NOR SHOULD THE CONFIGURATION BE CHANGED IN ANY WAY, EXCEPT UNDER THE EXPRESS DIRECTION OF TERARECON PERSONNEL. DO NOT USE THE SOFTWARE IF IT IS DAMAGED, COMPROMISED, OR IF YOU IN ANY WAY SUSPECT THAT ITS SAFETY MAY HAVE BEEN COMPROMISED. IN THIS EVENT, CONTACT YOUR CUSTOMER SERVICE REPRESENTATIVE IMMEDIATELY.

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Patent Information

The product described in this document is protected by the following patents:

US Patents

Real Time PC Based Volume Rendering System - Patent No. 6,008,813.
Volume Rendering Pipelines - Patent No. 6,243,098.
A Method for Rendering Sections of a Volume Data Set - Patent No. 6,262,740.
A Method for Rendering Miniblocks of a Volume Data Set - Patent No. 6,219,061.
Volume Rendering Integrated Circuit - Patent No. 6,512,517.
Parallel Volume Rendering System with a Resampling Module for Parallel & Perspective Projection - Patent No. 6,313,841.
Method and Apparatus for Illuminating Volume Data in a Rendering Pipeline - Patent No. 6,342,885.
Method and Apparatus for Volume Rendering with Multiple Depth Buffers - Patent No. 6,310,620.
Two-Level Mini-Block Storage System for Volume Data Sets - Patent No. 6,266,733.
Incrementally Calculated Cut-Plane Region for Viewing a Portion of a Volume Data Set in Real-Time - Patent No. 6,211,884.
Super-Sampling and Gradient Estimation in a Ray-Casting Volume Rendering System - Patent No. 6,483,507.
Three-Dimensional Cursor for a Real-Time Volume Rendering System - Patent No. 6,297,799.
Method and Apparatus for Mapping Samples in a Rendering Pipeline - Patent No. 6,424,346.
Early Ray Termination in a Parallel Pipelined Volume Rendering System - Patent No. 6,654,012.
Volume Rendering Pipelines - Patent No. 6,532,017 B1.
Rendering a Partitioned Volume Data Set - Patent No. 6,407,737.
Method & Apparatus for Modulating Lighting w/t Gradient Magnitude of Vol Data in Rendering Pipelines - Patent No. 6,356,265.
Method for Modulating Volume Samples with Gradient Magnitude - Patent No. 6,404,429.
Method for Modulating Volume Samples using Gradient Magnitude - Patent No. 6,369,816.
Method and Apparatus for Mapping Reflectance While Illuminated - Patent No. 6,426,749.
Method and Apparatus for Applying Modulated Lighting to Volume Data in a Rendering Pipeline - Patent No. 6,411,296.
Configurable Volume Rendering Pipeline - Patent No. 6,421,057.
Method and Apparatus for Generating a Histogram of a Volume Data set - Patent No. 6,476,810.
Method and Apparatus for Correcting Opacity Values in a Rendering Pipeline - Patent No. 6,614,447.
Methods for Correcting Gradients of Irregular Spaced Graphic Data - Patent No. 6,680,735.
Displaying Three-Dimensional Medical Images - Patent No. 6,826,297.
Three-Dimensional Image Display Device In Network – Patent No. 6,683,933.
Image Based Medical Report System On a Network – Patent No. 7,209,578.
Reporting System In a Networked Environment – Patent No. 7,492,970.
Three-Dimensional Image Display Device Creating Three-Dimensional Image Directly From Projection Data - Patent No. 7,236,558.

Japanese Patents

Real Time PC Based Volume Rendering System – Patent No. 3, 129,701.
Volume Rendering Pipelines – Patent No. 4,158,006.
A Method for Rendering Sections of a Volume Data Set – Patent No. 4,158,007.
A Method for Rendering Miniblocks of a Volume Data Set – Patent No. 4,158,167.
Parallel Volume Rendering System with a Resampling Module for Parallel and Perspective Projection – Patent No. 4,197,203.
Method and Apparatus for Illuminating Volume Data in a Rendering Pipeline – Patent No. 4,420,531.
Method and Appartus for Modulating Lighting with Gradient Magnitude of Volume Data in a Rendering Pipelines – Patent No. 4,435,377.
Volume Rendering in XY-Image Order – Patent No. 4,205,327.

EU Patents

Real Time PC Based Volume Rendering System - Patent No. 0,903,694.
Method and Apparatus for Volume Rendering with Multiple Depth Buffers - Patent No. 1,014,308.

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Welcome

Welcome to the i*N*tuition Manual. This guide is intended for users performing and analyzing different studies using the i*N*tuition application. Please read the chapters sequentially to gain a complete understanding of the i*N*tuition application. You can use the table of contents to navigate to your topics of interest.

Please pay attention to all Notices, whether onscreen, or contained herein, including all precautionary statements and advisories, as these are essential to the effective and authorized use of the products and applications discussed herein.

Conventions

This guide uses the following conventions:

- The text that appears on buttons, menu items, dialog boxes and other elements of the AQi user interface are printed in a bold font. For example, “Click the **Save** button.”
- Screen names are capitalized. For example, Patient List, 3D Viewer.
- The chapters are arranged based on the functions in the i*N*tuition application.
- A NOTE contains supplementary information about a topic.

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Table of Contents

BOOKLET I – AQi

Chapter 2: The 3D Viewer

Opening the 3D Viewer
Elements of the 3D Viewer Screen
Clinical Tools
Dual energy and multiKV applications
Cardiac MR
Finding viewer
Top Bar Tool Buttons
Buttons in the Image Annotations
Mini-Toolbars
Color Templates
3D Settings
Series
Hiding the Right Panel

Chapter 5: TVA and Cardiac Function

Introduction
Starting TVA for CT Studies
TVA of the Left Ventricle (LV)
TVA of the Right Ventricle (RV)
Generating a Report
Cardiac Function Measurements: Inter-Observer Difference, Cross-Product Difference, and Reading Time

Chapter 7: Time Dependent Analysis

Introduction
Starting TDA
Maps and Graphs
Drawing ROI
Manual TDA
Generating a Report

Appendix A: GUI Configuration

Opening Preferences
General
Application Error
Command Line
Patient List
Series List
3D Viewer
Toolbar
Workflow
Mask
Measure/Annotation
Multidata/4D
Capture

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

CPR
CPR Interactive
Calcium
SAT
Batch
Launch Program
Mouse Operation
TDA
TDA Functional Map
TDA Classification Map
TDA Capture
TVA
TVA(LV)
TVA(RV)
Flythrough
Output Panel
Page Format
Measurement Settings
Movie
Patient Annotation

Appendix B: Keyboard Shortcuts

Index

BOOKLET II – Thin Client

Chapter 10: Multiphase Studies

Multiphase study
Opening a Multiphase Study
Viewing Multiphase Data
Creating a 'Wash In-Wash Out' Curve
Viewing a phase in multiplanar views
Multi-phase MR Views
Color Coding in Parametric Map

Appendix A: User Preferences

Links
General (left)
General (bottom left)
General (bottom right)
2D
3D
4D
CPR
Fusion
Measurement
Patient List
Capture
Output (left)
Output (right)

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Server Status
Dashboard
APS

Index

BOOKLET III – AquariusAPS

Chapter 1: Introduction to AquariusAPS

Purpose of this Manual
A Brief Overview of AquariusAPS
Implementations of AquariusAPS
The AquariusAPS Modules

Index

BOOKLET IV – iReview

Chapter 3: The Viewer

Mouse mode and measurement buttons
The Top Tool Bar
Viewing Studies
Clickable Annotations
Right click menu

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DRAFT

Aquarius i*N*tuition Client

Version 4.4

User Manual

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Chapter 2: The 3D Viewer

This chapter describes the graphical user interface (GUI) of the Aquarius *iN*tuition 3D Viewer. The 3D Viewer screen GUI is divided into several areas, and each is described in a different section.

To go to the section you need, click the appropriate link:

Elements of the 3D Viewer
Clinical Tools
Top Bar Tool Buttons
3D Settings
Buttons in the Image Annotation
Mini-Toolbars
Color Templates

Opening the 3D Viewer

Select one or multiple series from the Patient List, and double-click the series, or click on the **Load** button (see Figure 1-1 on page 1-1). The image is loaded into the 3D viewer and displayed as shown in Figure 2-1:

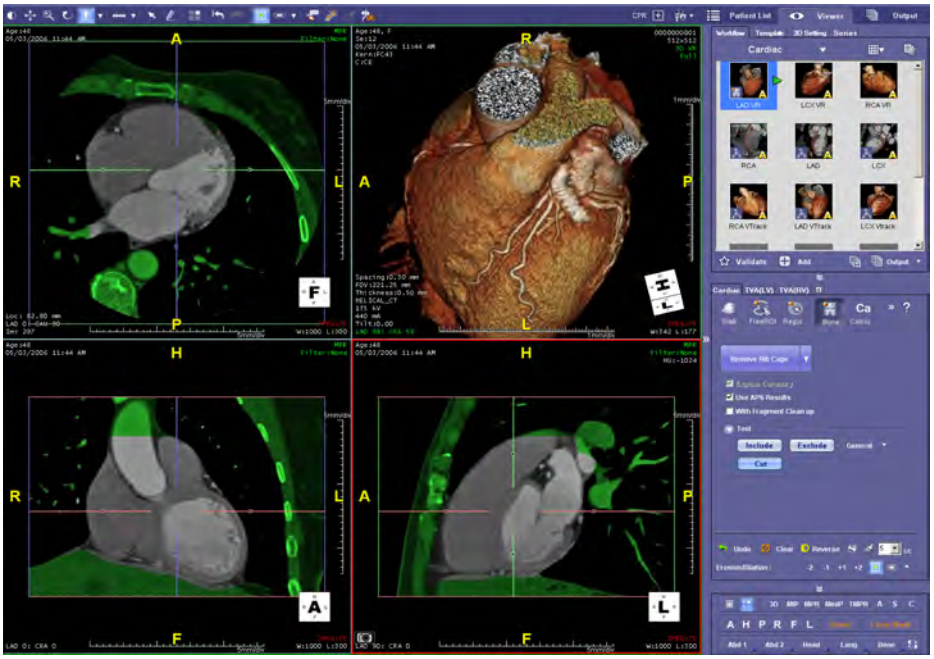

Figure 2-1: 3D Viewer

Elements of the 3D Viewer Screen

The Main Window

The main window contains images rendered from the data that has been loaded:

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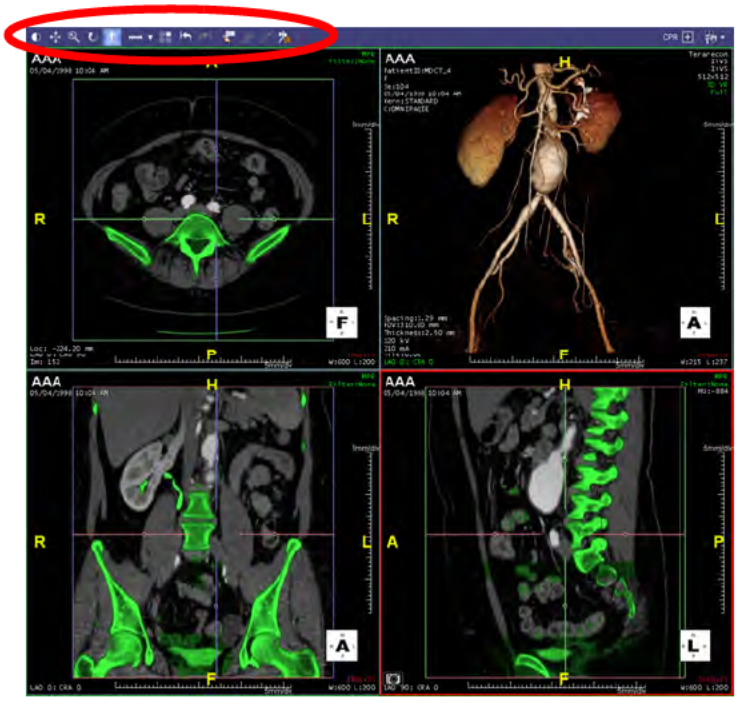

The typical main window display contains at least one 3D image and one or more 2D images. However, there are several different screen layouts, and which one is displayed depends on the chosen image layout, the selected workflow, or the diagnostic tool currently in use. This is explained in greater detail later in this chapter.

There are a number of tools available for manipulating images:

- Clinical tools

  These tools are accessed through the Tool Panel, which is discussed under "Clinical Tools" on page 2-7.

- Top toolbar functions

  The toolbar located directly above the main window (circled in the previous figure) contains several important tools for rotating, zooming (scaling) and panning an image, taking measurements, making notations, and several other functions. These are discussed under "Top Bar Tool Buttons" on page 2-118.

- Right-click menu on the image

  When you right-click on an image, a pull-down menu is displayed showing a number of functions that can be performed on that image. The right-click menu is slightly different for 2D and 3D images. The table below lists each menu item, which type of image the feature is valid for (2D, 3D or both) and a description of the function.

Features	2D/3D	Description/Reference
Capture	**Both**	Capture the selected image.

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Features	2D / 3D	Description / Reference
Capture All	**Both**	Capture all images currently displayed in the viewer, and place each image in a separate cell of the Output Panel.
Capture All in One	**Both**	Capture all images currently displayed in the viewer, and place them all in a single cell of the Output Panel.
Capture to Folder	**Both**	Capture to a folder defined in the Capture preferences.
Batch Wizard	**Both**	See "The Batch Wizard" on page 2-54 for details.
Arrow / Text	**Both**	See "Arrows and Labels" on page 2-135 for details.
Rendering Modes	**Both**	These allow you to change the rendering mode of the image.
CPR	**Both**	Allows you to select a vessel and view it in CPR mode. See "CPR Tool" on page 2-13 for details.
Segmentation	**Both**	Opens a sub-menu from which you can select one of the following segmentation tools: • Dynamic Region Growing on page 2-40 • FreeROI on page 2-36 • Bone Removal on page 2-42
Measurement	**Both**	See "Measurement Tools" on page 2-119 for details.
Mouse Mode	**Both**	See "Mouse Modes" on page 2-119 for details.
Layout	**Both**	See "Window Layout Modes" on page 2-136 for details.
Smooth Surface	**Both**	
Slab	**3D**	Display the 3D image in slab view. This menu item has the same effect as checking the Slab checkbox in the **Slab** tool panel. See "Slab and Cube View Tool" on page 2-8 or "Slab Thickness" on page 2-150.
Cube View	**3D**	Display the 3D image in cube view. This menu item has the same effect as checking the Cube checkbox in the **Slab** tool panel. For more information, see "Slab and Cube View Tool" on page 2-8.
Reset Orientation	**3D**	Reset the orientation of the 3D image to the orientation at load time.
Save Scene	**3D**	Save the 3D image as a scene. For details, see "Saving a Scene" on page 2-147.
Light Setting	**3D**	
Background color	**3D**	Changes the background color of the 3D image (default is black).

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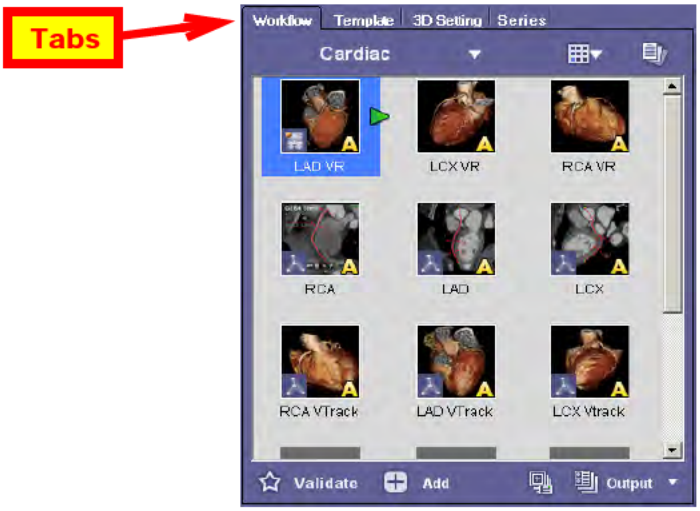
Features	2D/3D	Description/Reference
2D Filter	**2D**	Select one of the following filters to apply to any 2D image: • Median • Gaussian • Blur • Sharpen • iGENTLE Select **Filter Strength** to apply a strength from 1 to 5 on any filter.
Link to 3D	**2D**	When rotating the 3D image, perform the same rotation to the MPR images automatically. This also works in reverse and will rotate the 3D image if one of the MPR images is rotated.
Link the center of rotation	**2D**	All images rotate about the same location as their center.
Reset	**2D**	Reset the orientation to the original.

The Workflow Panel

The workflow panel is in the upper-right section of the 3D Viewer screen. There are four tabs, each of which contains a separate sub-screen: Workflow, Template, 3D Setting and Series.



To view each of the screens located in this area of the 3D Viewer, click the appropriate tab. These screens are described in greater detail in the following sections:

Tab	Where to find more information
Workflow	Chapter 3: "Workflows"
Template	"Workflows and Templates" on page 3-2
3D Settings	"3D Settings" on page 2-159
Series	"Series" on page 2-163

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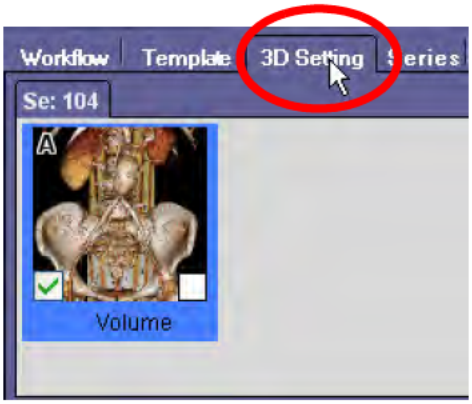
Floating the Workflow Panel

You can detach any of the tabs in the workflow panel so that it can be moved to another part of the 3D Viewer screen. This is called a "floating" panel. This would make it possible to see more than one tab in the workflow panel. When the panel is floating it can also be resized. This is useful when you need more room in the panel.

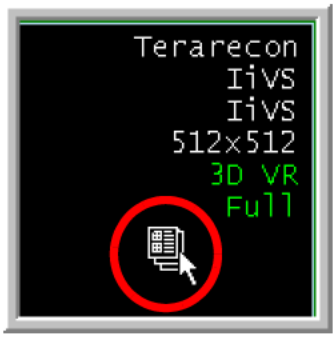
To float a panel, do the following:

1. Click on the tab name and hold down the mouse button.



2. Drag the mouse to another location on the screen. A small panel icon is displayed to indicate that the tab is being moved.

3. Release the mouse. The panel is now separated from its usual location in the upper-right corner.



You can now resize the panel and place it anywhere on the screen.

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To restore the panel to the workflow control panel, click the **X** in the upper-right corner of the floating panel, to close it.

The Tool Panel

The tool panel contains the tools for viewing data and performing diagnostic tasks. It is located on the right side of the 3D Viewer screen, halfway down. The specific functions contained in the tool panel that you see when a study is loaded depend on which workflow was chosen to process the data.

The Tool Panel contains one or more tabs, each of which contains five visible tool icons. The following are two examples of tool panels associated with their respective workflows:

Figure 2-2: Left: Cardiac Tool Panel; Right: General Workflow Tool Panel

In addition to the five visible tools, there are several more in the hidden panel. You can access the hidden tool panel by doing the following:

1. Click the double right arrow located on the right side of the Tool Panel (circled in Figure 2-3). A second panel is opened above the main tab, containing the remaining tools that are not currently visible in the tab.

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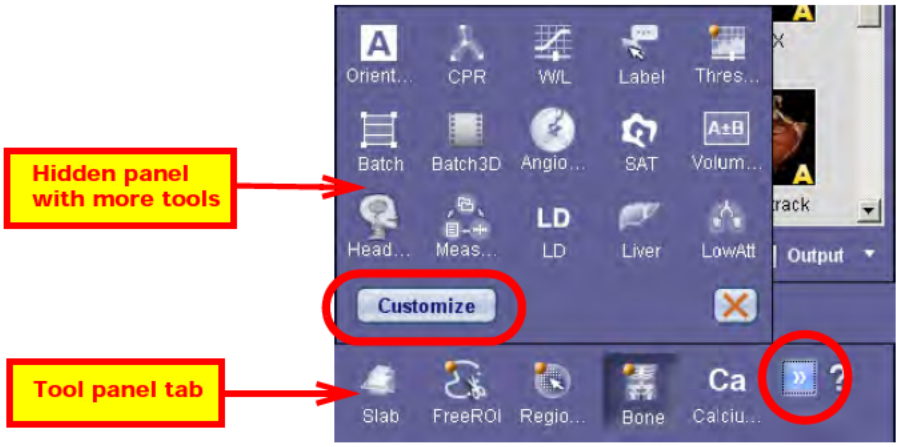

Figure 2-3: Hidden Tools

2. Click the **Customize** button in the lower-left corner of the hidden-function panel (circled in green in the image above).

3. Drag the desired tool from the upper panel and drop it in the tab below.

   Note: The maximum number of tool icons that can be showing at once is five. If you drag a sixth icon to the tab, the right-most icon in the tab is automatically moved up to the hidden panel.

4. Click the double right arrow again when finished to hide the hidden panel.

For information on more ways to customize the Tool Panel, see "Customizing the Tool Panel" on page 2-92.

Clinical Tools

This section describes all the tools used to perform clinical and diagnostic functions in the 3D Viewer.

Use these links to jump to the section describing the tool you want to use:

Slab and Cube View
Orientation
CPR Tool
FreeROI
Dynamic Region Growing
Bone Removal
Head/Neck Bone Removal
Calcium Scoring
Batch
Batch 3D
Customizing the Tool Panel
Window Level
Anatomy List
Mask Threshold
Angio View
SAT
Volume Operation Tool
Measurement Protocols
Lobular Decomposition
Lobular Decomposition 2
Low Attenuation Analysis

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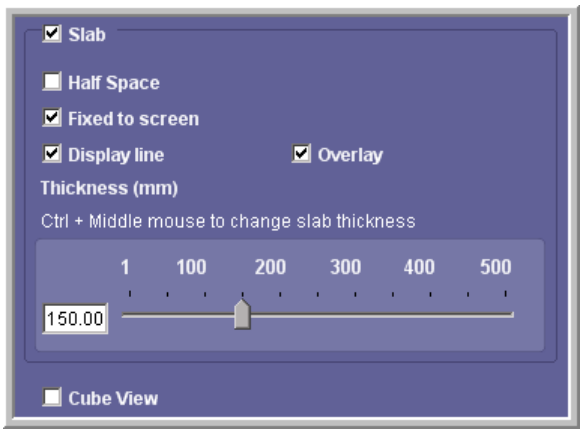
Slab and Cube View Tool

Click the **Slab** button from the tool panel. The Slab tool opens in the tool panel (see figure at right).



Settings

Slab - Check this box to apply slab rendering.

Half Space - Check this box to remove half of the volume on one side of the center of rotation.

Fixed to screen - When this is checked, the cutplane is always parallel to the screen, and the rotations of the 3D image are linked to the rotations of the MPR images. When it is unchecked, the cutplane can be rotated to any orientation and does not necessarily face the screen. Rotations of the 3D image are not reflected in the MPR images. (See "Rotation" on page 2-10 for more information.)

Display line - Show display lines (yellow) on MPR images. These lines delineate the slab boundaries. As you move them closer together (toward the center line), the slab thickness decreases. When the two outer lines are far enough apart that the entire MPR image is between them, the 3D window displays the full volume (see Figure 2-4 on page 2-9). The slider in the tool panel changes as you move the display lines closer or further apart.

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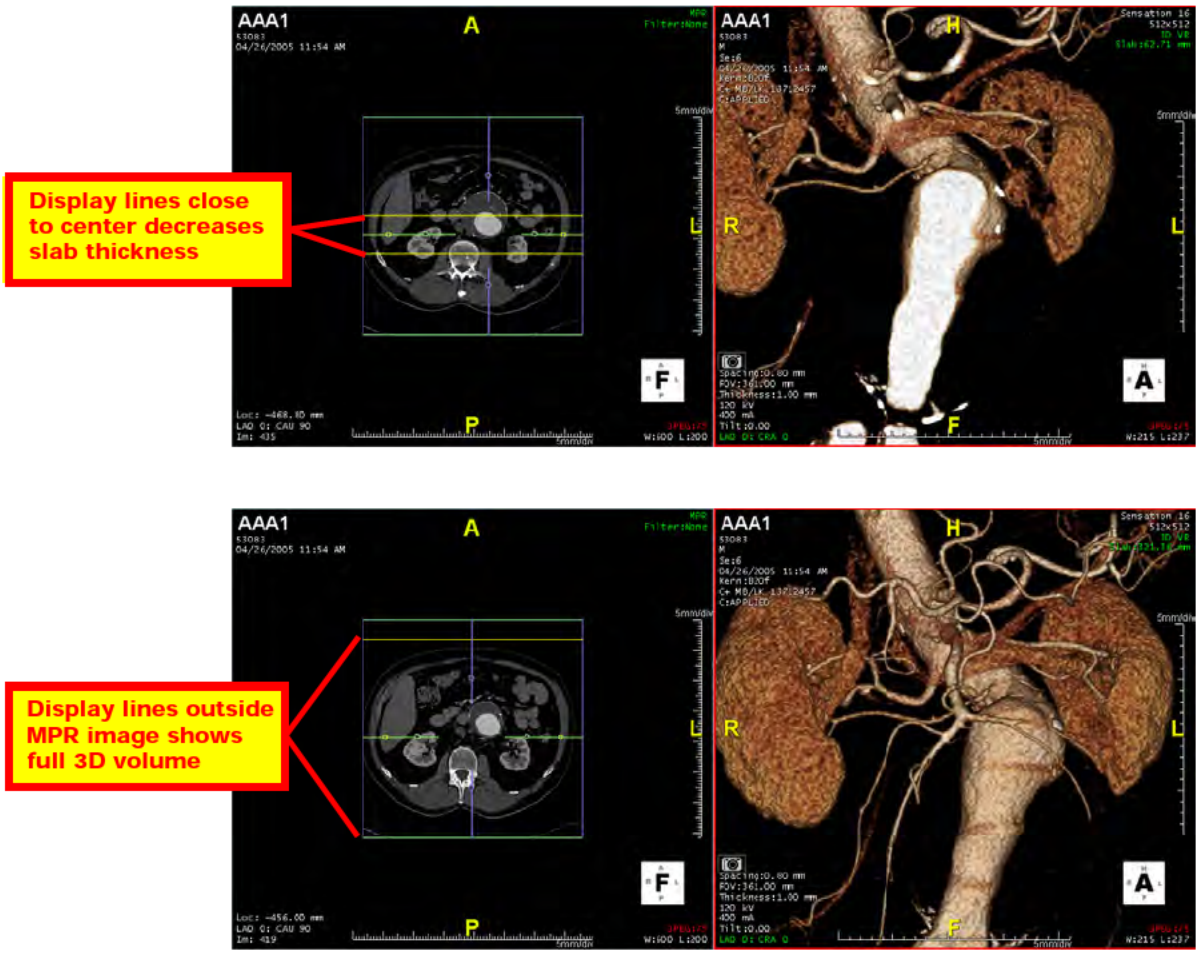
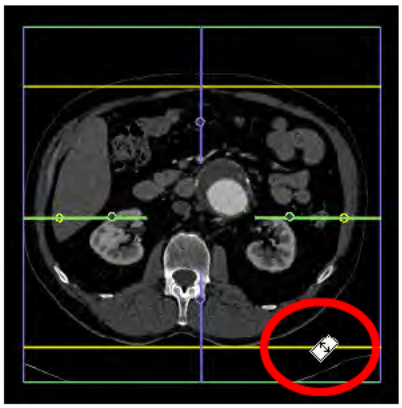


Figure 2-4: Moving Yellow Lines Apart Increases Slab Thickness in 3D Image

To move the display lines apart, click on one of the lines and move it away from the center. The other display line moves away from the center symmetrically. When you move the line toward the center, the other line comes toward the center from the other side. The cursor is circled in the following image:



Overlay - When checked, an overlay is shown on the parts of an image that have been cut out.

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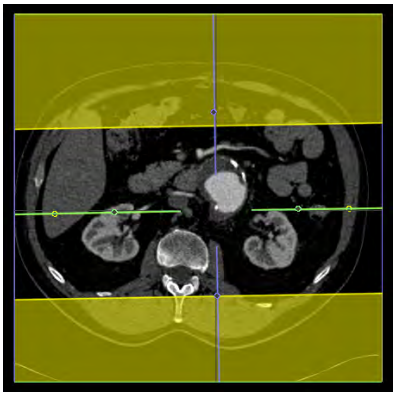

Cube View - Check this box to display the image in cube view. To zoom in or out, hold down **Ctrl** key and the middle mouse button, and then drag the mouse up or down.

The Slider

Note: When Half Space is selected, the slider is inactive.

Adjust the thickness of the slab using the slider in the control box, or by holding down the control (**Ctrl**) key and the middle mouse button, and then dragging the mouse up or down. The slider unit is in millimeters.

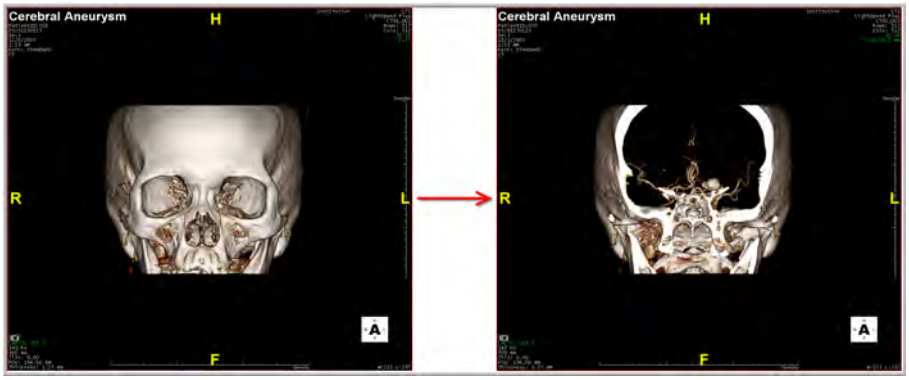

Figure 2-5: Slab rendering

Rotation

You can rotate the slab mask around the 3D image so that the only visible part of the volume is the section intersected by the rotating mask. The mask is rotated by manipulating the display lines in any of the MPR windows.

1. Make sure the **Display Line** box in the tool panel is checked.
2. Hover the mouse near one of the *outer* control points on the middle yellow line until the cursor is displayed as a pointing hand. See the following image:

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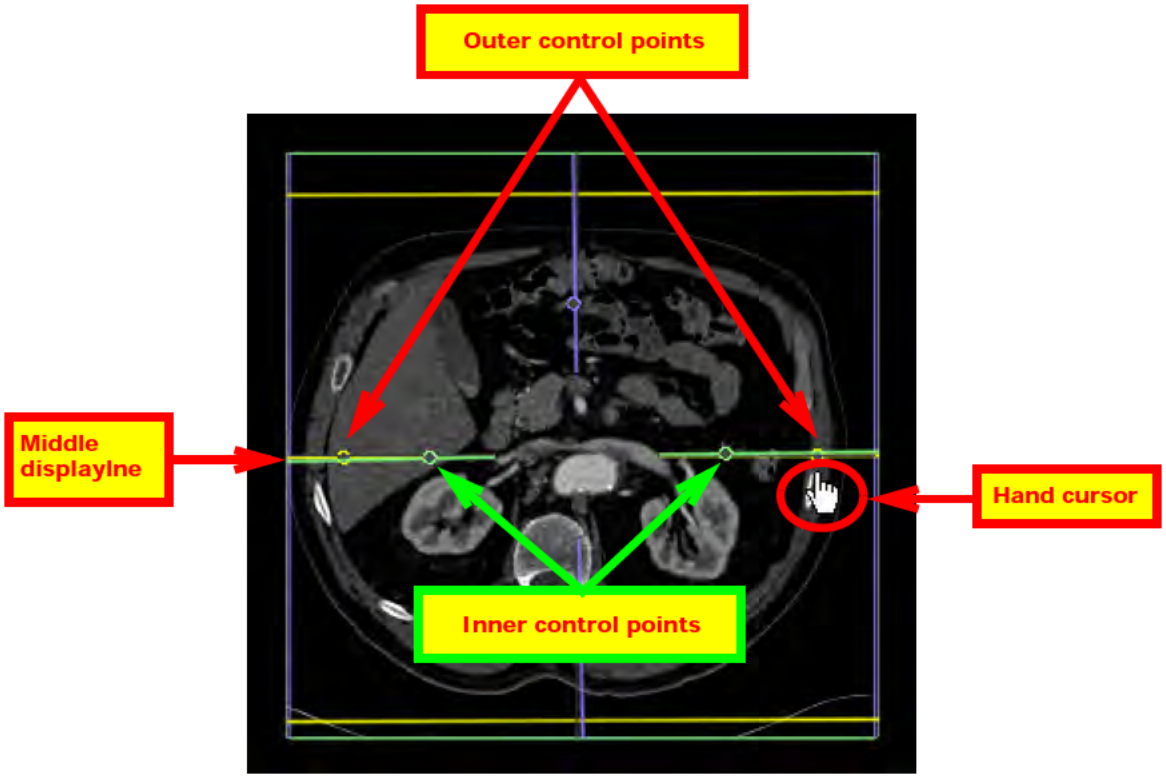
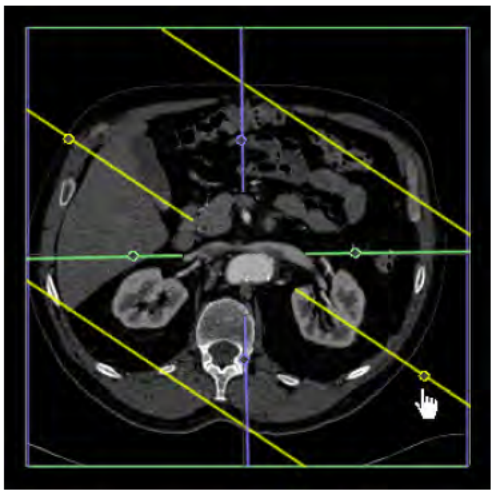


3. When the cursor becomes a hand, left-click and drag the mouse up or down. The three display lines will rotate around the image in parallel.



As the slab region is rotated around the MPR image, a slab volume mask is rotated in the same direction around the 3D image. This is the most obvious when the MPR image being used to move the display lines is in the same orientation as the 3D image (see the following image):

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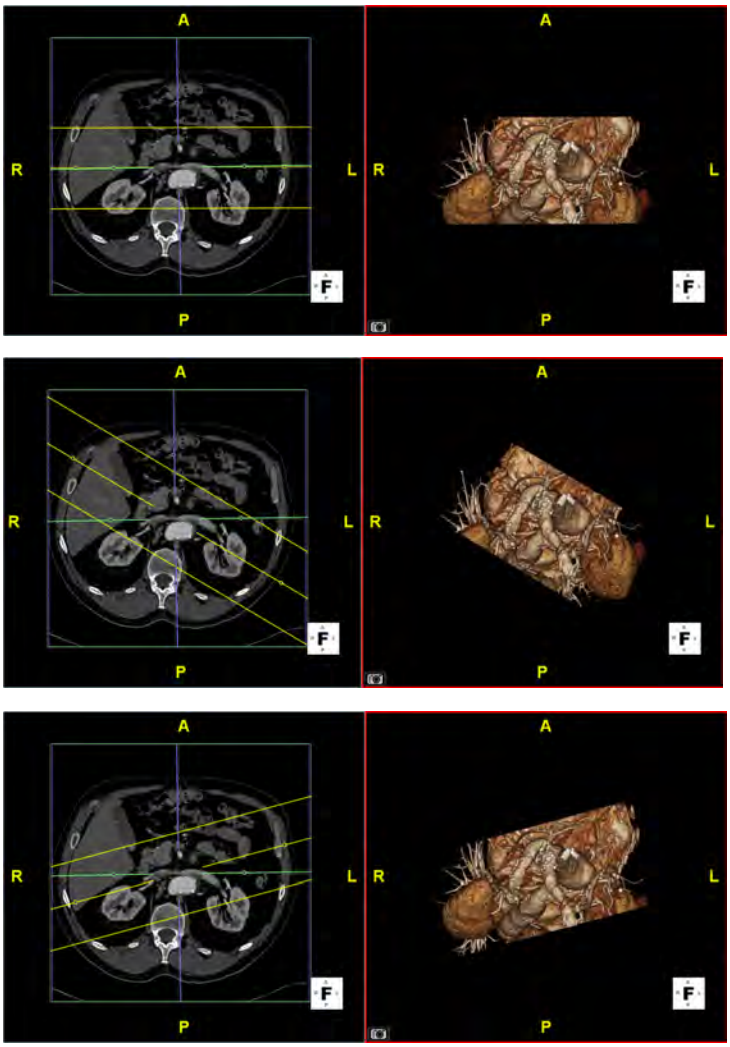

Figure 2-6: Slab mask on 3D image is parallel to display lines on MPR

Note that the 3D image itself is not moving. Only the slab mask, through which the 3D image is shown, is being rotated. If you want the 3D image to rotate as well, check the **Fixed to screen** box in the tool panel.

Orientation Tool

Use the positioning buttons to set the image to preferred viewing positions.

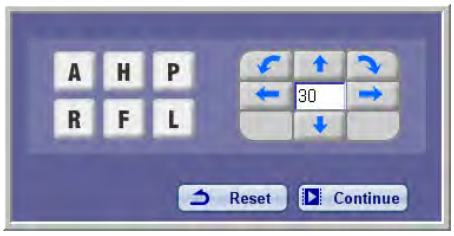

Figure 2-7: Orientation Options

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The six letters A,P,L,R,H,F can be used to switch the 3D view directly to the following orientations:

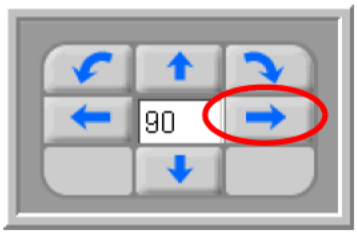
A	Anterior (view from the front, the patient is vertical).
P	Posterior (view from the rear).
L	View from the left.
R	View from the right.
H	View from head towards feet, while the patient is lying on back.
F	View from feet towards head.

The **Reset** button brings you back to the default anterior position.

Continue mode

You may apply animation to the 3D image using the **Continue** button next to the angle setting controls. Click the **Continue** button, specify the angular increment in degrees, and select the direction of rotation by clicking one of the arrows. This moves the object in the direction specified. When you want to stop the cine mode, simply click the **Continue** button again.

For example, the following figure shows a continuous rotation rightward, in 90-degree increments. If you click the Continue button and then click the right arrow, the image rotates to the right in 90-degree increments, continuously.



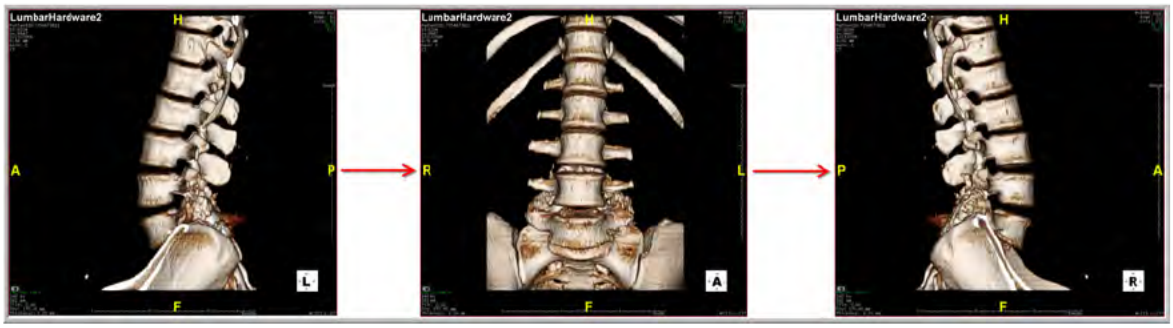


Figure 2-8: Image rotation in 3D cine mode

CPR Tool

Centerlines allow you to view vessel paths. Centerlines can be added automatically by Advanced Processing prior to being pushed to your server. You can also add centerlines manually using this tool, whether or not any Advanced Processing has been performed on the current data being viewed.

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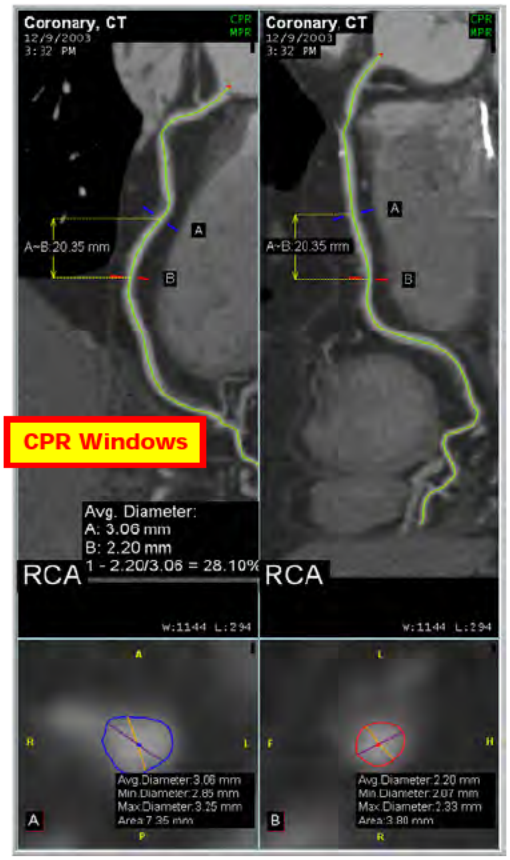
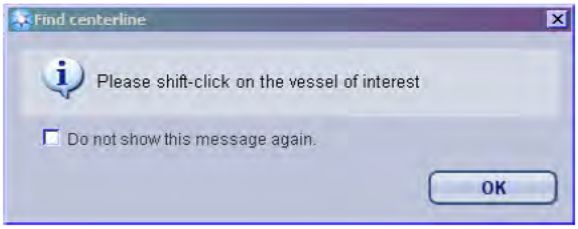
If Advanced Processing has added centerlines to the data, the CPR view is displayed as shown in the figure at right:



The CPR Windows

The CPR Tool displays two perpendicular CPR images and two orthogonal MPR images by default. These windows can be viewed in other formats, which will be discussed further in this section (see "Right-Click Menu on CPR Window" on page 2-20).

If the data being viewed has not had centerlines added by Advanced Processing, the MPR and CPR windows are initially displayed as empty, and a dialog box is posted to notify you that you must draw the centerlines manually, as shown in the following figure:



The CPR Tool Panel

When you click the CPR button, the CPR Tool Panel is displayed below the main Tool Panel.

Figure 2-9CPR Tool Panel

Creating a Centerline Automatically

There are 5 predefined automatic centerline creation modes: Auto, Coronary, Normal, Two Clicks and Tree

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To create a centerline through a vessel automatically, hold down the shift key and left-click on the vessel. This works the same way in the Auto, Coronary and Normal modes.

For tree mode, hold the shift key down and left-click at the root of the vessel.

Creating a Centerline Manually

To create a centerline manually, do the following:

1. Click the **Manual** button.
2. Hold down the shift key.
3. Left-click at the start of the range.
4. Left-click *twice* at the end of the range.

Extracting Centerlines

To extract a centerline, highlight the centerline in the 3D window. You can do this by either clicking on it directly in the 3D window, or by clicking the forward or backward arrows in the toolbar at the bottom of the CPR window, to display each centerline individually. (For details on the CPR toolbar, see "Toolbars" on page 2-18.) Then click the **Extract** button.

Vessel List

You can also create a centerline by choosing from the list of predefined vessels in the Vessel List. Select a vessel from the list and then shift and left-click on the main window to draw a centerline on that vessel.

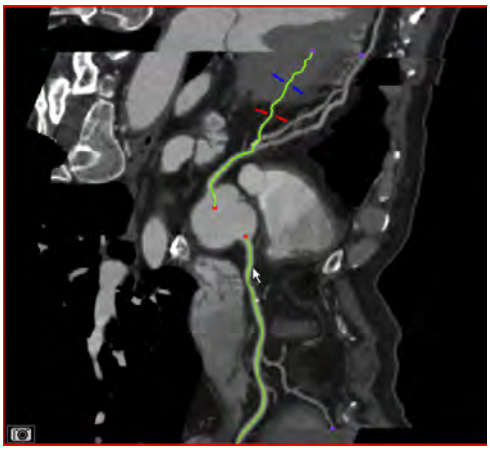
Deleting Centerlines

To delete all centerlines, click the **X** button located just above the vessel list (circled in Figure 2-9).

Once a centerline has been created, the CPR window opens automatically.

Medial Axis Reformation (MAR) View

MAR (Medial Axis Reformation) is an image representation for given centerline trees, which can be regarded as multiple CPRs combined. It can display multiple centerlines on the same image.



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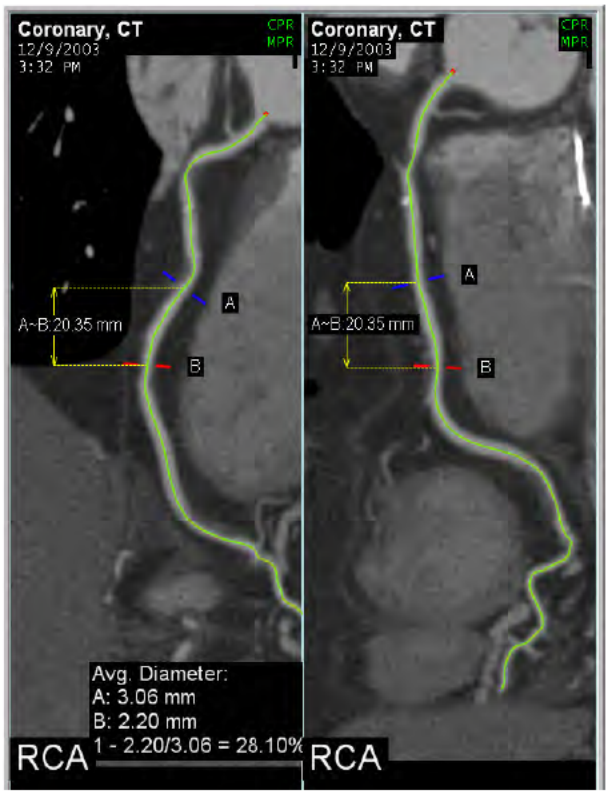
The CPR Windows

The CPR Tool displays two perpendicular images that can be synchronized and rotated around the current stenosis.

You can perform the following operations in the CPR windows:

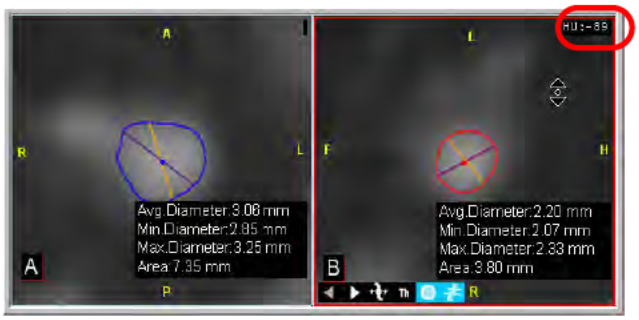
- Edit the centerline, by moving the control points (dots) to change the path
- Show cross section lines and measurements
- Display the vessel in straight view (sMPR)
- Perform measurements - Distance, Ellipse, and Profile measurements are enabled in the CPR window
- Perform stenosis calculations, using either the simple fraction method or QCA

For details about these features see "Toolbars" on page 2-18.



The Cross-Section Windows

The cross-section windows display two MPR images that are orthogonal to the CPR images. They can be synchronized and rotated around the centerline, as shown in the following figure:



You can perform the following operations in the cross-section windows:

- Display the HU value as you move the mouse cursor (circled in the figure above)
- Display the average diameter and area of the cross sections in the CPR windows. These averages change as you move the cross section lines along the vessel

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- Show outline or cross section lines of the vessel, or both
- Ctrl+left-click on the image to rotate the image around the center
- Alt+left-click on the cross-section image to resize or reshape the outline (nudge tool).
- Shift+Click and drag to redraw the outline. Redraws the outer wall and redefines stenosis calculation.

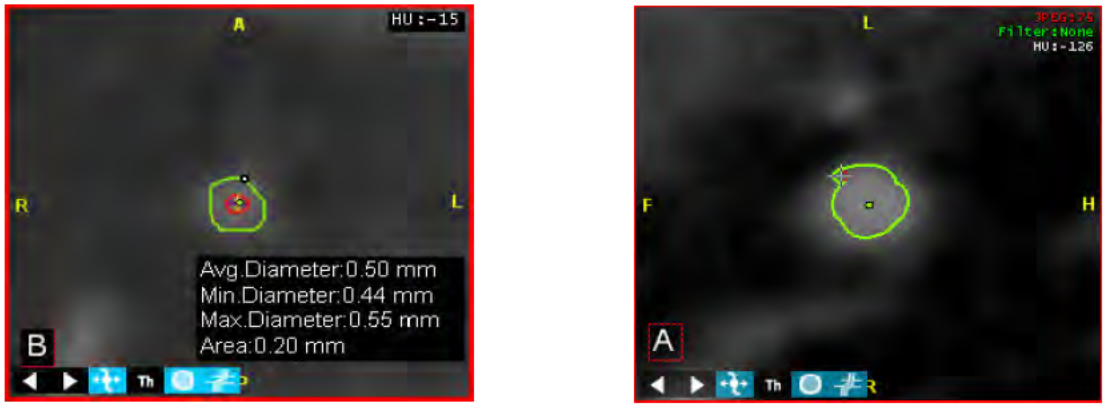
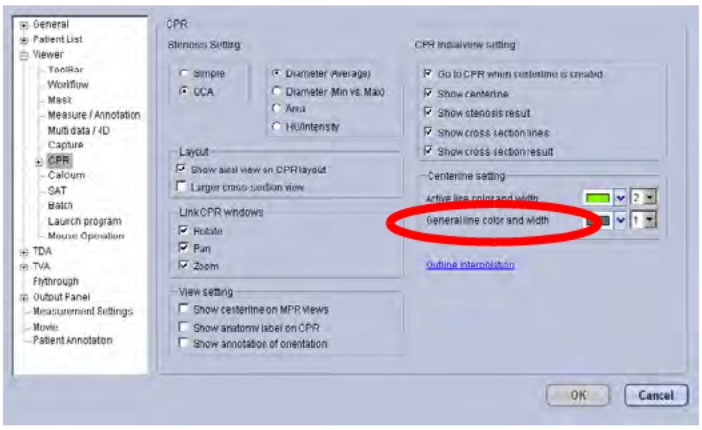


Figure 2-10: Left - Redrawing the outer boundary; Right - Nudge Tool

- Display a larger cross-section view (relative to the rest of the CPR display). To do this, open the Preferences menu by clicking the Preferences button located on the right end of the top toolbar:

Select **CPR** from the navigation section on the left, and checkmark the box labeled **Larger cross-section view**:



The cross-section view windows will be larger relative to the entire CPR display.

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Toolbars

When you move the mouse over any of the CPR or MPR windows, a toolbar appears at the bottom of the window, as shown in the following figures:.

Figure 2-11: Left: CPR Window Toolbar; Right: MPR Window Toolbar

Description of the Toolbar Buttons

The following identifies and describes the buttons in the toolbars, from left to right:

- Previous/Next Vessels (left and right arrows)

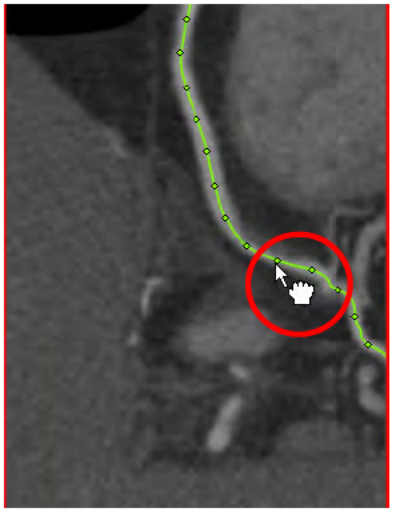
  Click the left and right arrows to show successive vessels from the 3D window. The vessel currently being displayed in the CPR window is highlighted in green in the 3D window.

- Edit Centerline

  When this button is clicked, control points are added to the centerline in the CPR windows so you can edit the centerline. When you place the cursor close to one of the control points on the centerline, the curser turns to a "hand" sign (circled at right), indicating that you can move and stretch the centerline from its current position.

  When you have repositioned that section of the centerline, release the left mouse button and position the cursor on another section you want to change.

  You can also edit the centerline in the MPR window. Click on the centerline in the center of the image and drag it to the desired location. (Because this is a perpendicular view, the centerline appears as a dot.)



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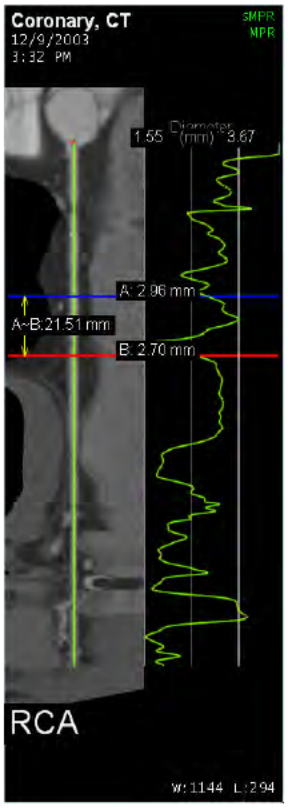
- Straight MPR View - CPR windows only ("sMPR")

  Display the vessel in straight view, as shown at right.



- W/L Threshold - MPR windows only ("Th")

  Changes the W/L based on HU thresholds in the MPR window.

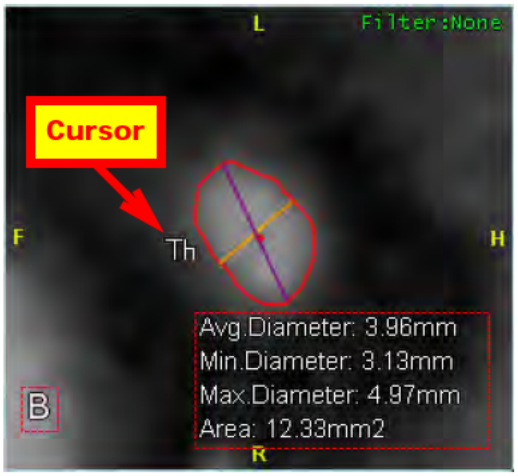


Figure 2-12: W/L Theshold

- Show/Hide Outline and Centerline

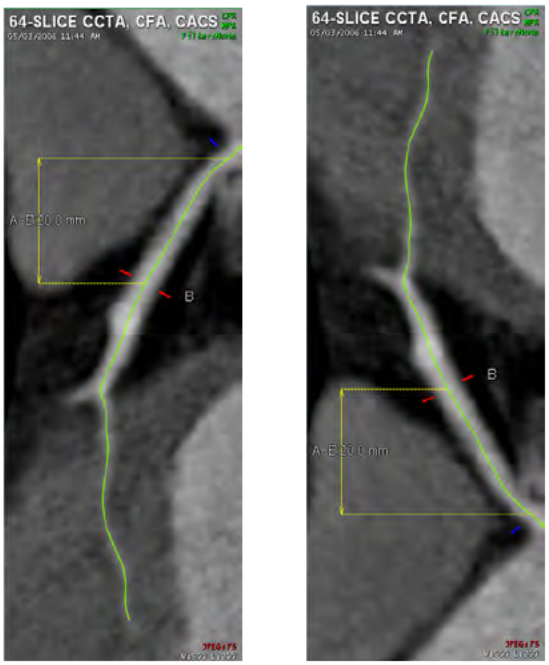
  Toggle on/off display of the centerline in the CPR views, and outline and diameter/area in the MPR views.

- Show/Hide Measurements

  Toggle on/off display of the cross-section lines and measurements in the CPR views. This button has the same function whether it is accessed from a CPR or MPR window.

- Flip Image - CPR windows only

  Flip the image vertically. (See figure at right. Left: original image; Right: flipped image.)



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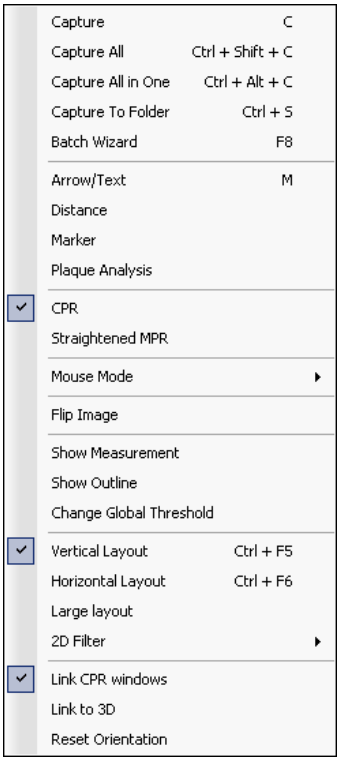
Right-Click Menu on CPR Window



The right-click menu on the CPR window gives you an alternate way to perform functions that have already been discussed.

However, there are a few extra options in this menu:

- Plaque Analysis

  Performs an analysis of plaque along a section of vessel. For a detailed description of this feature, see "Plaque Analysis" on page 2-23.

- Vertical Layout

  Vertical layout shows the two CPR windows in vertical position with the two MPR windows below them. The 3D image and MPR axial view are shown on the right side of the window.

  Vertical layout is the default layout of the CPR window.

- Horizontal Layout

  Horizontal layout shows the two CPR windows in horizontal position, with the two MPR windows below them. The 3D image and MPR axial view are shown on the right side of the window.

- Large Layout

  Large layout eliminates the 3D and axial MPR window so that the entire image display window is available for the CPR view. Both vertical and horizontal views can be displayed in large layout.

- Link CPR Windows

  When this option is selected, operations performed on one CPR window are reflected in the other automatically. For example, if you rotate one CPR window, the other is automatically rotated to the corresponding position. When not selected, the CPR windows are independent of one another.

- Link to 3D

  When this option is selected, operations performed on the 3D window are reflected in the CPR windows.

- Reset Orientation

  Reset the position of the CPR windows to their original orientation.

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Right-Click Menu on the Centerline

This menu allows you to modify a centerline itself. Right-click on any centerline to display this menu.

- Mark Here

  Set a marker on the centerline.

- Delete above (to the Red Dot)

  Remove everything in the selected branch above the selection point (from the selection point to the red dot)

- Delete below

  Remove everything in the selected branch below the selection point

- Delete branch

  Remove the entire branch

- Edit

  This is the same as the Edit Centerline icon in the toolbar at the bottom of the CPR window (see "Edit Centerline" on page 2-18).

- Smooth

  The **Smooth** feature allows you to adjust and then edit the CPR centerline. To use this feature, do the following:

  1. After selecting **Smooth** from the menu, hold down the Control (**Ctrl**) key and click the centerline in an area that needs to be smoothed. A small circle cursor is displayed (see center image below).

  2. Drag the mouse along the rough section of centerline.

  3. When finished, release the mouse. The centerline is now in Edit mode.

  4. Edit the centerline as you normally would (see "Edit Centerline" on page 2-18)

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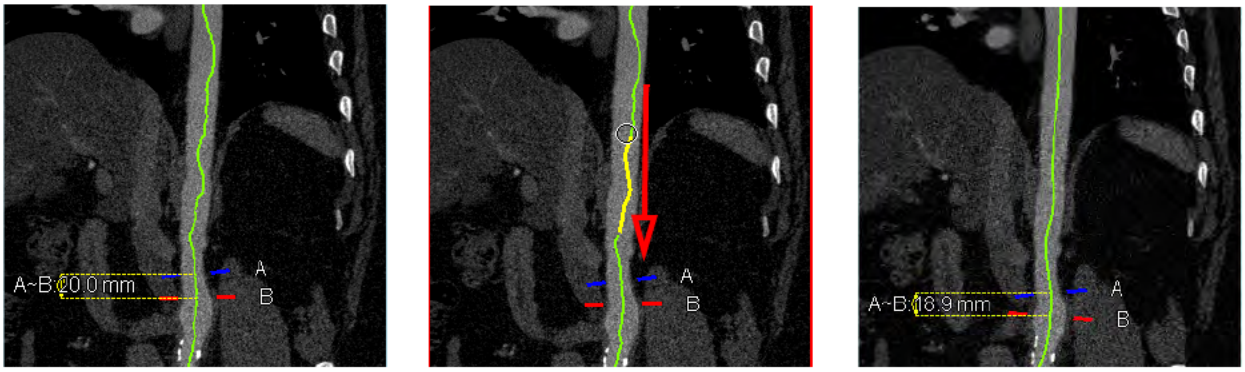


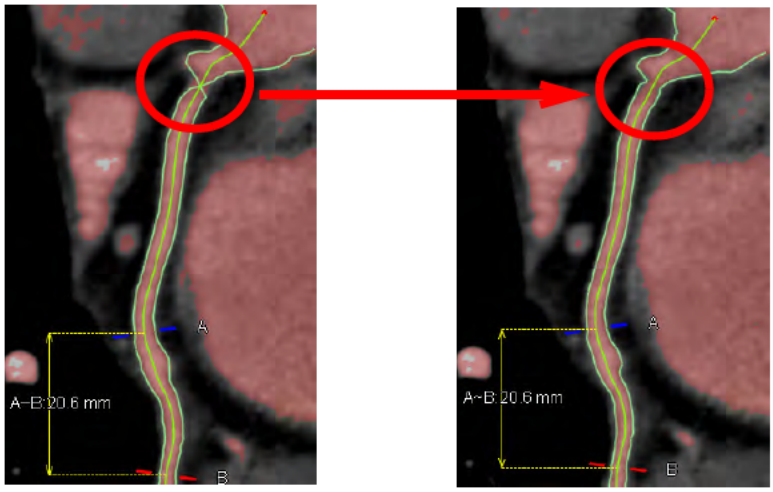
Left: Rough Section of Centerline; Center: Smoothing; Right: Corrected Centerline

- Change root

  The start point of a vessel determines its orientation in the CPR windows. The start point is indicated by a red dot. There is a blue dot at the terminating point of that vessel. When you select this menu item, the start and end points are switched. The CPR windows are updated to reflect the new orientation. You can also see that the start and ending points on the vessel in the 3D window have been switched.

- Change Global Threshold from here

  If you are not satisfied with the outline drawn on the vessel under examination, this feature allows you to change the HU threshold levels along the entire centerline, so that the boundaries of the vessel will be recalculated.



- Export Centerline Data

  Export centerline coordinates to local storage.

  Note: The Enable Centerline Export preference must be enabled for this item to appear in the menu. To enable the option, open Preferences, navigate to the CPR screen, and check the box for Enable Centerline Export. See Appendix A: "CPR" on page A-12 **for more information.**

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Plaque Analysis

Note: You are obligated to define the parameter ranges that are used in this procedure. When first accessed, the user interface for setting these parameters contains generic default values having no particular significance. You must acknowledge this by dismissing a warning message to this effect.

Right-click on one of the CPR windows and select **Plaque Analysis** fromthe menu. Then, by dragging the mouse, draw a line along the centerline, from the start to the end of the area of interest (see Figure 2-13 on page 2-23). When finished, release the mouse.

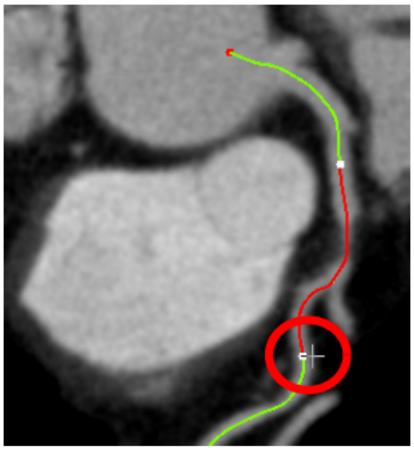

Figure 2-13: Dragging the Mouse Along the Centerline

The plaque analysis is displayed in the CPR window:

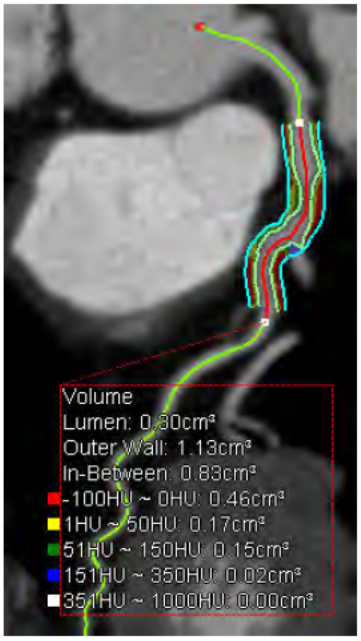

Figure 2-14: Plaque Analysis Results

Color Maps

The cross-section (MPR) windows can be displayed using a color map to show different HU ranges in and around the vessel. To show the color map, right-click on the measurement. The right-click menu is displayed.

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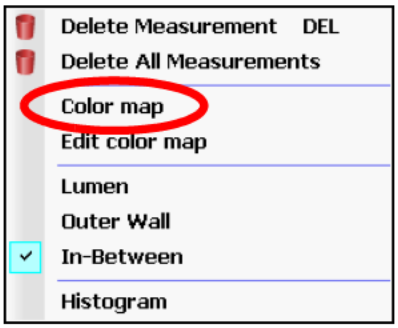

Select **Color map** from the menu.

Color maps are overlaid on the cross-section image to show three different views: lumen, outer wall or in-between (see Figure 2-15). These views are selected from the right-click menu, as shown in the previous image. Each color overlay represents the HU value range of that region, according to the colors shown in the measurement results (see Figure 2-14 on page 2-23).

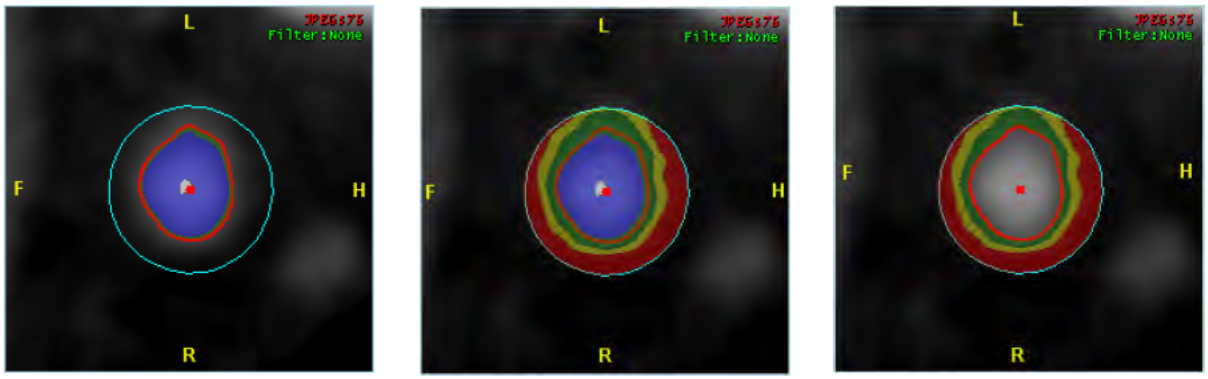

Figure 2-15: Left: Lumen; Middle: Outer Wall; Right: In Between

Cross-section Editing Tools

If needed, you can edit the outer or inner wall by drawing a new circle around the wall, redrawing in freehand, or using the nudge tool.

> **Note: If you would like the outer wall to be interpolated, enter outline edit mode first. (See Figure 2-16.)**

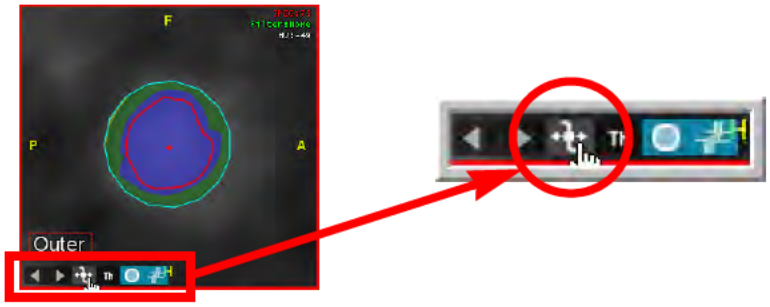

Figure 2-16: Enter Edit Mode

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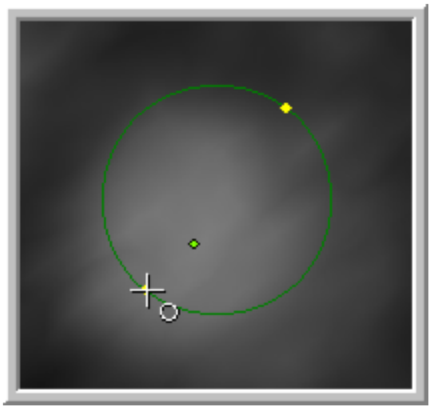
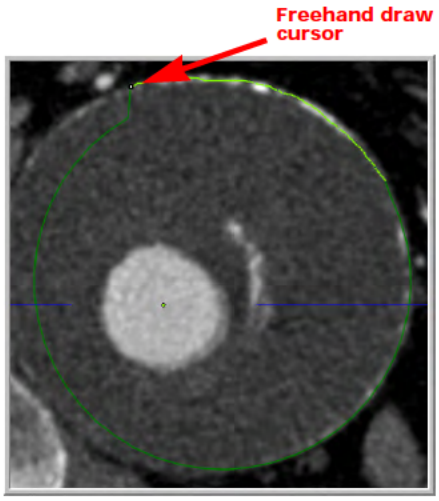
- **Draw Circle**



Use this tool when you need to redraw the outer wall completely. This tool draws a perfect circle, which may need to be corrected using one of the other tools.

1. Press and hold the **Ctrl** key.
2. Click the edge of the outer wall and drag across the cross section image. A new circle is drawn on the image, which increases in diameter as you drag the mouse.
3. When the circle matches the outer wall, release the mouse.

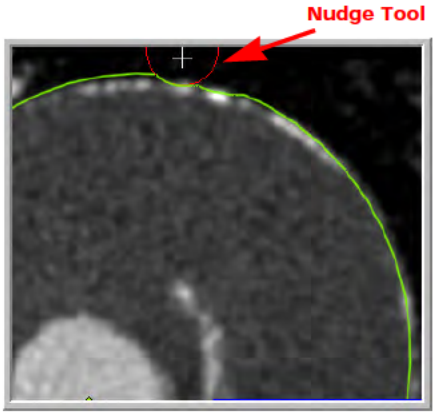
- **Redraw**



Use this tool to redraw the outer wall freehand.

1. Press and hold the **Shift** key.
2. Click on the edge of the outer wall, in an area that needs to be redrawn.
3. Drag the mouse along the correct circumference of the outer wall.

- **Nudge Outer Wall**



Use this tool to correct small areas of the outer wall.

1. Press and hold the **Alt** and **Ctrl** keys together. The nudge tool appears.
2. Click and hold down the mouse.

   Note: When you click a location close to the outer wall, the nudge tool circle is small. The further away from the wall the image is clicked, the larger the circle.

3. Move the mouse along the outer wall to push the outline into the correct place.

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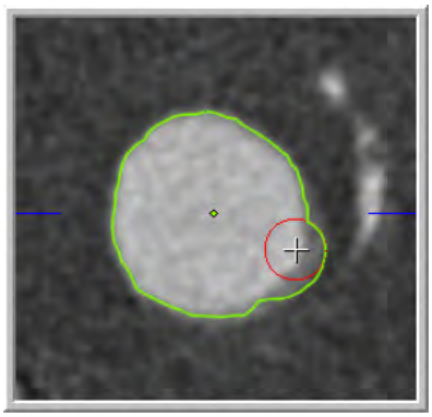
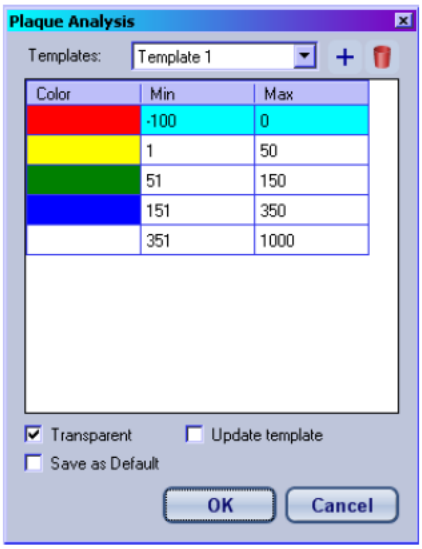
- **Nudge Inner Wall**

  This is the same as the outer wall nudge tool. The only difference is that you press the **Alt** key (instead of **Ctrl**) before clicking on the image.



Color Map Templates



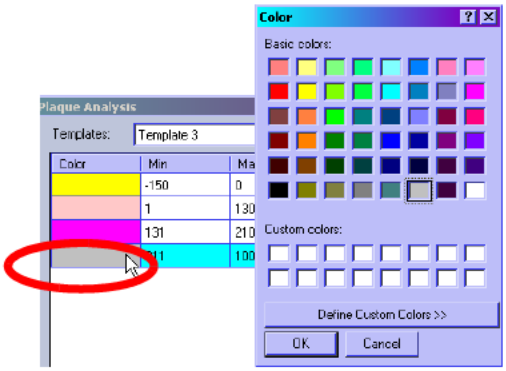
The color map (which associates specific colors to HU value ranges) is defined by a template. When you first display the color map, one of the default templates is in use. You can change to another template, you can modify the default templates and you can also create your own.

To make changes in the color map templates, select **Edit color map** from the right-click menu. The template dialog is displayed:

From this dialog, you can change the colors of the template. modify the HU ranges and create new templates.

To change any of the colors, click on the color. The Windows color palette is opened. You can then select a new color from the palette.

To change any of the HU ranges, highlight the number to be changed and type in the new number.



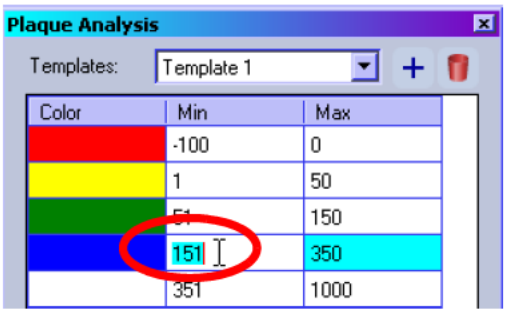


Figure 2-17: Left: Change Color; Right: Change HU Range

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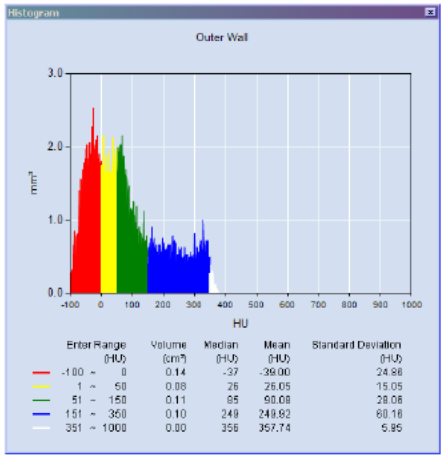
Histograms

Select **Histogram** from the right-click menu. The graph and statistical data displayed on the screen refer to the section of the vessel cross-section selected at the time (lumen, outer wall or in-between).

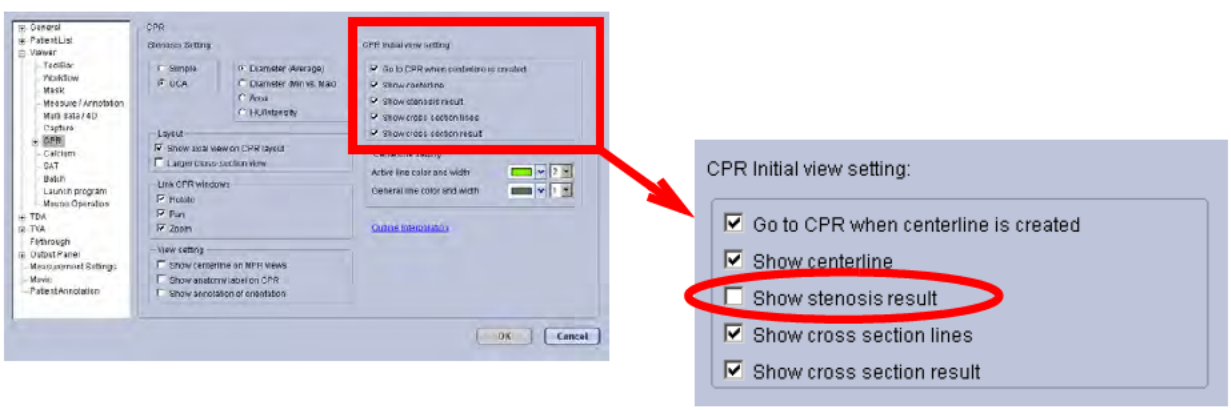


Display Stenosis

The stenosis calculation should be displayed on the CPR image. If it is not, you will need to enable **Show stenosis result** in the Preferences.

1. Open Preferences, and select **CPR** from the navigation panel on the left.

2. In the upper-right section of the CPR Preference screen, there is a list of settings under the heading **CPR Initial view setting**. Make sure the box for **Show stenosis result** is checked.



The result is shown in the CPR window:

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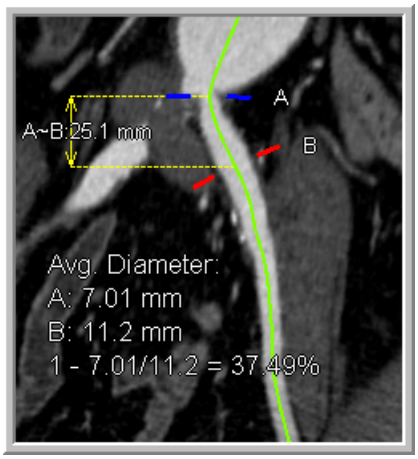
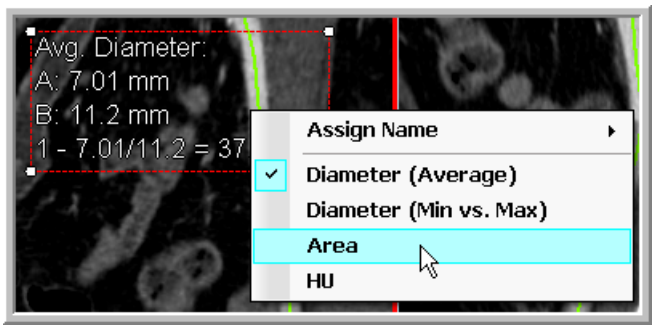


Changing the Stenosis Display

You can select different calculation methods for the display. To do so, right-click on the result and make another selection from the pulldown menu:



Default Stenosis Display

Stenosis results are displayed as the average diameter by default. If you would like to change the default stenosis results, you can do so in the Preferences.

1. Open the Preferences window.

2. Select **CPR** in the navigation panel on the left.

   Settings for the default stenosis display are in the upper-left section of the CPR screen:

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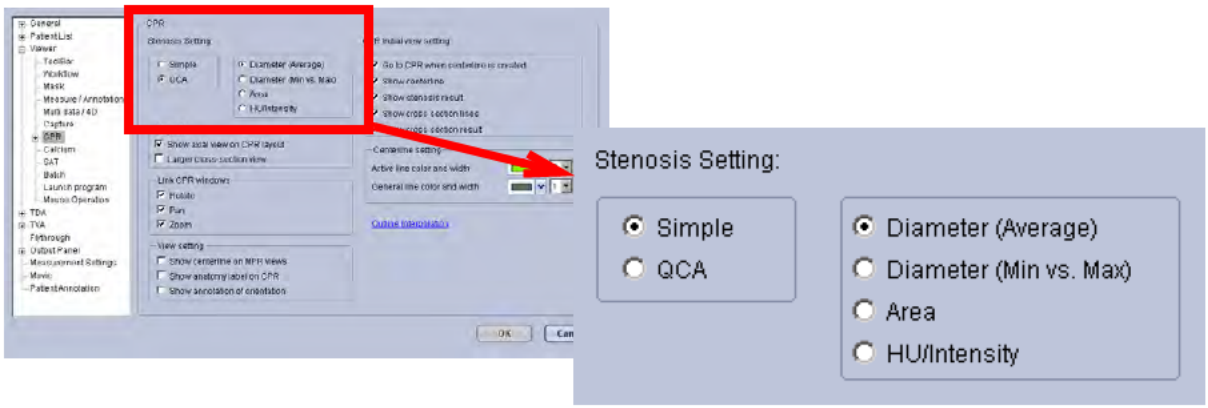


3. To change the default, select the desired type from the right column and click **OK**.

Stenosis Calculation Algorithm

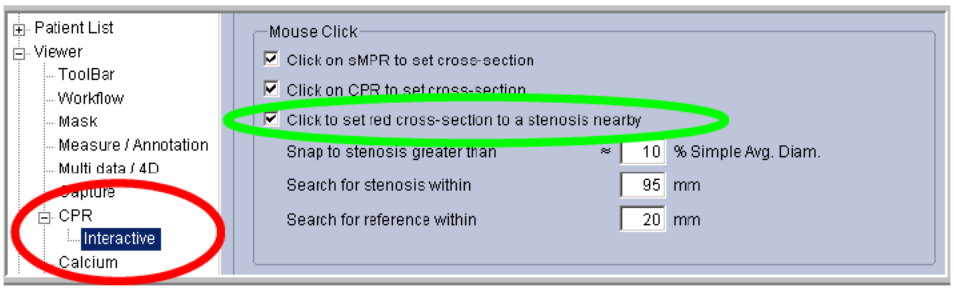
The left column in the **Stenosis Setting** section contains settings for the algorithm used to calculate the results displayed in the CPR window. Select either **Simple** (default) or **QCA** as preferred.

Snap-to-Stenosis

The Snap-to-Stenosis feature requires that you enable a Preference setting first.

1. Open Preferences.

2. In the navigation panel, expand the **CPR** list, and then click **Interactive** (see the following image).



3. Under **Mouse Click**, check the box labeled "Click to set red cross-section to a stenosis nearby".

4. Modify the three parameters underneath as needed:

Parameter	Description
Snap to stenosis greater than	Minimum ratio of stenosis to reference diameter and area (expressed as a percentage).
Search for stenosis within	Maximum distance between the current position of the red cross-section and the nearest stenosis.

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Parameter	Description
Search for reference within	Maximum distance between the red and blue cross-sections.

5. Click **OK** to close the Preference window.

6. Click on one of the CPR images or on the 3D view near a stenosis. The red marker will snap to the stenosis. A confirmation message is displayed. The blue marker is placed at a near-optimal distance (defined by your preferences) from the red marker.

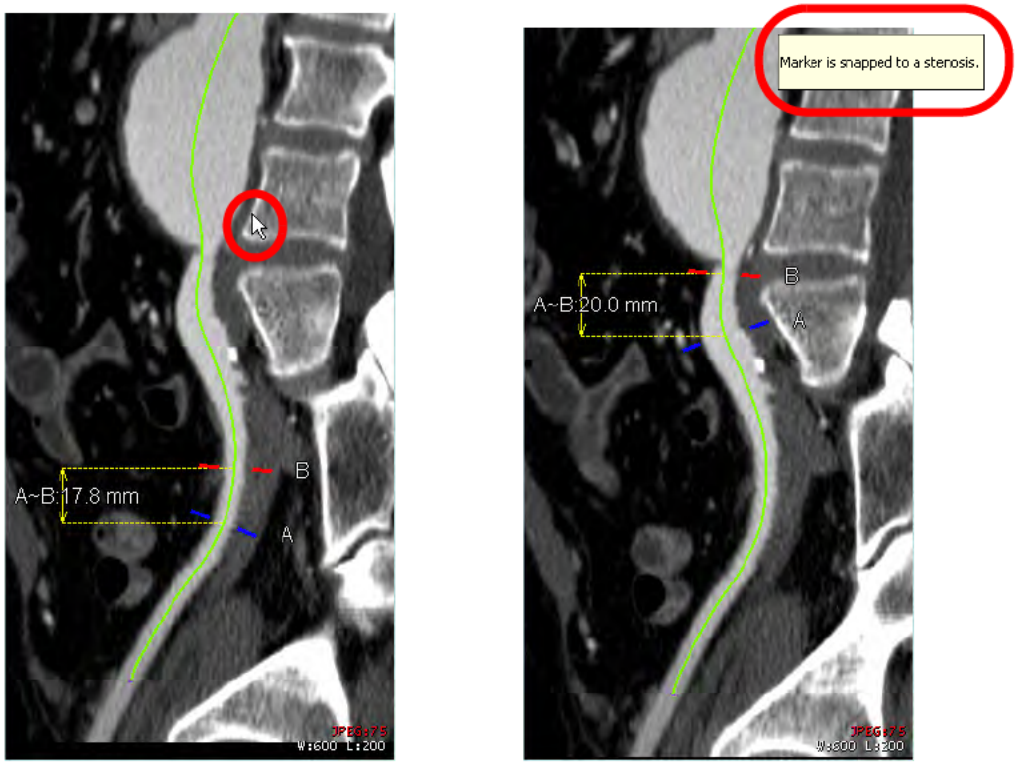

Figure 2-18: Left: Clicking on CPR near stenosis; Right: Red marker snapped to stenosis Upper right: confirmation message

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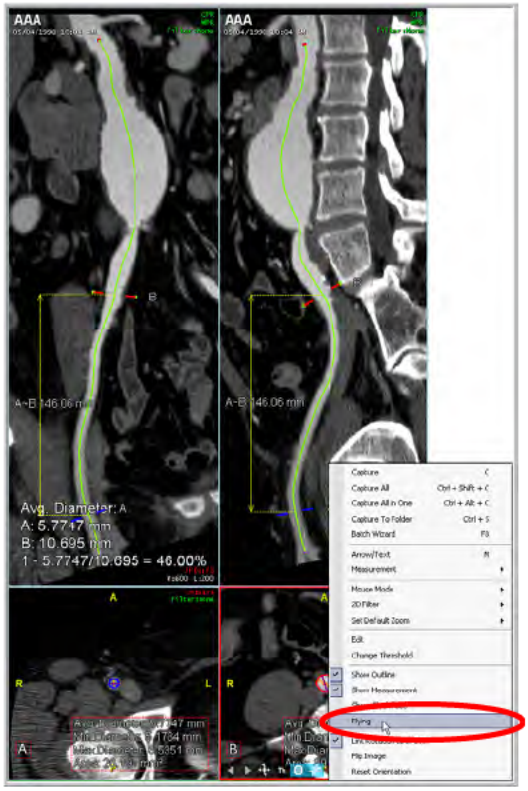
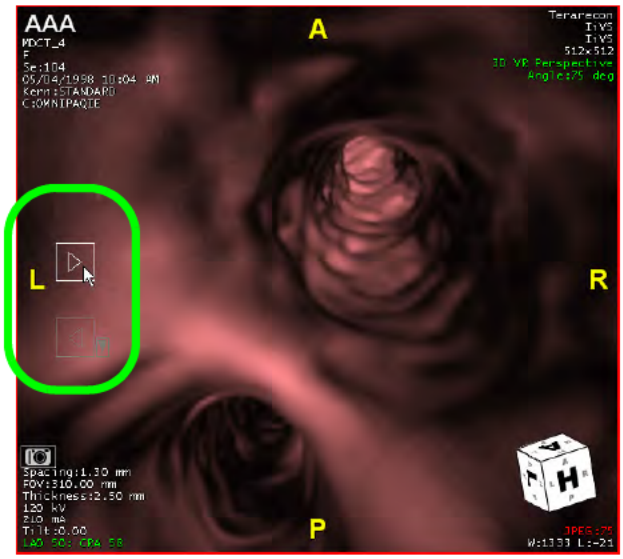
Vessel Flythrough



Flythrough functions can be used to view the inside of a vessel. Before you can initiate the flythrough, you must already have a vessel study open in CPR view. To open the flythrough main window, right-click on either of the cross-section views and select **Flying** from the menu (see image at right).

> **Note: The flythrough always begins wherever the red marker is situated, regardless of which cross-section view is used.**

The main window loads the 3D perspective view of the inside of the vessel (see the following image):



To begin flying, do the following:

1. Hover the mouse near the left edge of the flythrough window (circled in the image above). This causes the cine buttons (directional arrows) to become visible.

2. Click the right arrow to start forward motion.

Navigating the Flight

Direction and Speed

There are two ways to control the direction and speed of the flythrough.

- <u>Cine Buttons</u>

  The right arrow begins a forward flight, and the left arrow begins a backward flight.

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- Mouse movements

  Drag the mouse upward on the image to increase the speed. Drag the mouse downward to slow the flight. As you move downward, the flight will eventually come to a stop and then reverse direction.

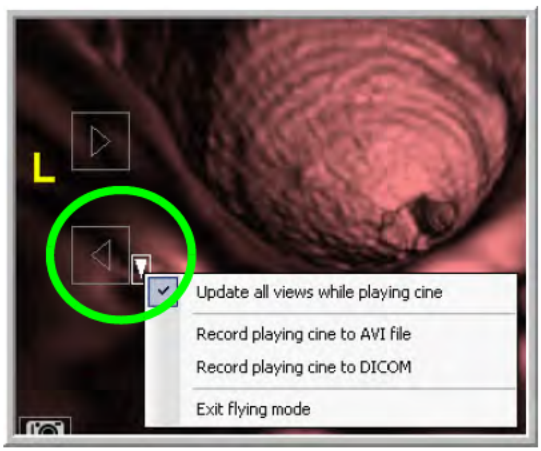
Starting and Stopping

- Directional arrows begin a flight in the appropriate direction (right arrow begins a forward flight, left arrow begins a backward flight).

- A mouse click on the perspective window stops a flight in progress, but does not initiate or resume a stopped flight.

Other Tools

When the two directional arrows are showing, you can also see a small down-arrow just below the left arrow. Click on the down arrow to display a menu containing more tools.



- Update all views while playing cine

  When this is enabled, the two cross-section views and the axial view are automatically paged through the slices as the flight passes through the corresponding position.

- Record playing cine to AVI file

  When you select this option, a Windows navigation window opens so that you can create the AVI file that will contain the images from the flythrough, and specify the folder where that file will be stored. The flythrough then goes into recording mode (indicated by the down arrow turning red). You will not be able to select any other items in this menu until you stop the recording.

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- Record playing cine to DICOM

  This records the flythrough. When you complete the flythough and stop the recording, a dialog opens where you can select a DICOM server to send the recording to.

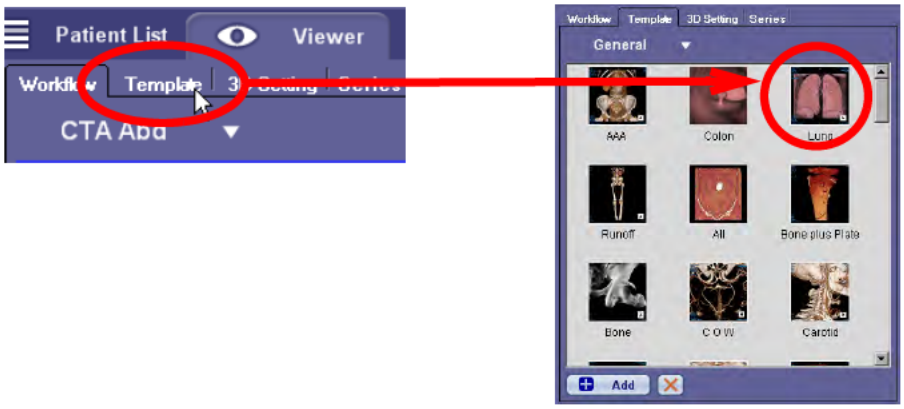
- Exit flying mode

  Upon exiting flying mode, the 3D viewer returns to the CPR view.

Airway CPR

You can use the CPR tool to create centerlines in the airway of a lung study, and view it in CPR mode.

1. To begin airway CPR, open a lung study. To view it properly, use the lung template. The template panel is located in the upper-right area of the iNtuition Viewer. Click the **Template** tab to show the template panel. Then click the **Lung** template.



The lungs are made visible in the 3D image window (see the following figure).

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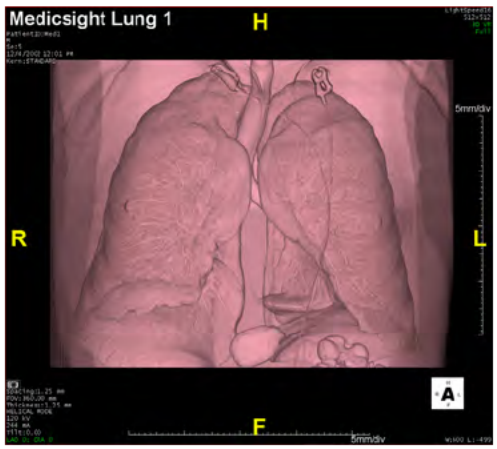
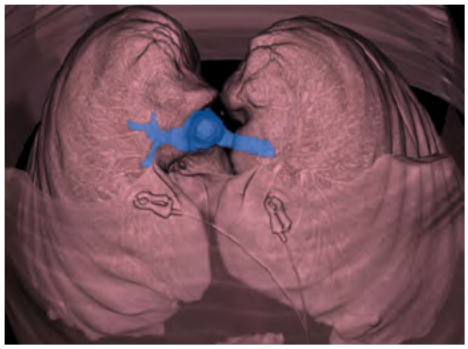


2. To isolate the airway, use the **Region Grow** tool in the Tool Panel.

3. To grow a region inside the airway, rotate the image to the Head orientation so that the opening is visible (see figure below). Then position the mouse right over the airway opening to begin the region grow. Otherwise, you will grow the region on the surface of the lungs, rather than inside the airway.

4. Hold down the **Shift** key and click. The masked area is displayed:



5. If too much of the lung has been masked, you can decrease the masked area by doing the following:

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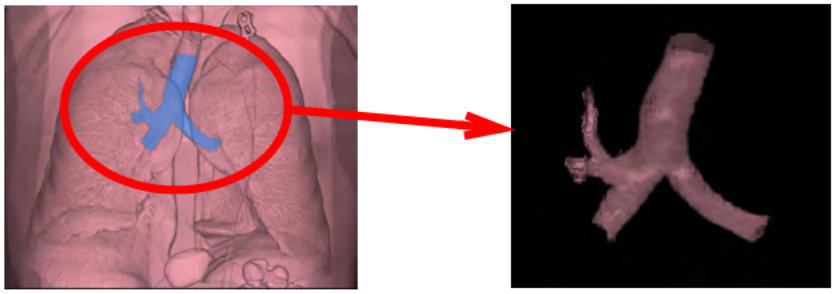
a. Position the mouse over the area you want to remove.
b. Roll the middle mouse button back (toward you).
c. Continue doing this until only the area under examination is masked.

6. Click the **Add/Select** button in the Tool Panel (see the following figure).

Only the masked airway is displayed:



7. Now click the **CPR** button in the Tool Panel.

8. To create centerlines, hold down the **Shift** key and click on sections of the airway where you want to draw centerlines. The centerline is automatically drawn, and the image is displayed in 2x2 CPR Vertical mode (see the following figure).

You can perform all of the same operations that are available for vessel CPR, such as centerline edits, viewing cross section lines , performing measurements and displaying the airway in straightened view (sMPR). See "CPR Tool" on page 2-13 for details on CPR mode.

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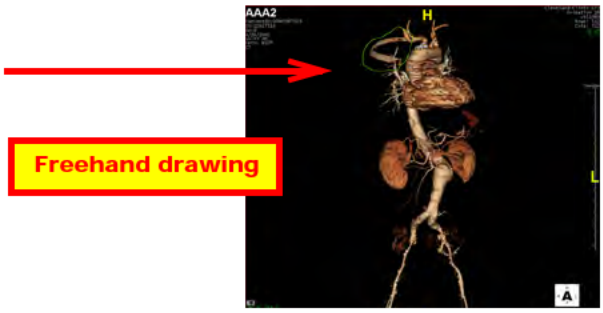
FreeROI

This tool allows you to define a Region of Interest within an image, using the hand drawing tool. You can then choose either to remove that area from the image, or to remove everything except that area.

Removing a Region of Interest

To remove a Region of Interest on an image, do the following:

1. Hold down the Shift key and click on the area where you want to begin drawing.
2. Draw a circle around the ROI. Continue holding down the shift key as you do this.



3. When you have finished drawing the circle, release the mouse. The area you have circled is removed from the image (see Figure 2-19).

Adding In a Region of Interest

To add back a previously removed area, perform the above three steps, drawing with the *right* mouse button (shift + right-draw).

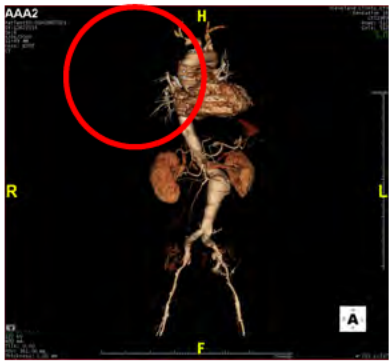


Figure 2-19: Region of Interest Removed (circled)

Drawing an ROI Using Multi-Clicks

You can also draw a ROI using multiple clicks.

1. Hold down the shift key and click along the edge of the ROI. Each click produces a green dot on the image in that spot.

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2. When enough dots have been placed to define an area, the 3D Viewer draws a line from the most recent click to the first click. You can continue clicking and the Viewer will redraw the final line.

3. When you have defined the ROI, release the mouse.

4. The FreeROI Tool Panel is enabled and contains buttons allowing you to remove, retain, and add in the Region of Interest (see Figure 2-20).

Figure 2-20: FreeROI Tool

The tool buttons have the following functions:

- Include - adds back the previously removed area, defined by the ROI
- Exclude - removes only the area defined by the ROI
- Select - removes everything except the area defined by the ROI
- Clear ROI - removes the most recent ROI outline that was drawn from the image. To remove previous ROIs, continue to click this button.

When the data loaded in the 3D Viewer is a multi-phase 4D series, you can process the changes performed on one phase to all phases by clicking the **Process all 4D phases** box.

Erosion / Dilation Dialog

This is a dialog that is displayed when Select, Include, Exclude or Add/Select is performed. See "Erosion/Dilation Dialog" on page 2-42 for more details.

Auto Detection

The FreeROI function can automatically detect the edges of a region and draw an outline around it.

To use auto detection, click the **Advanced** arrow in the tool panel.

Note: Auto detection can only be performed on 2D images.

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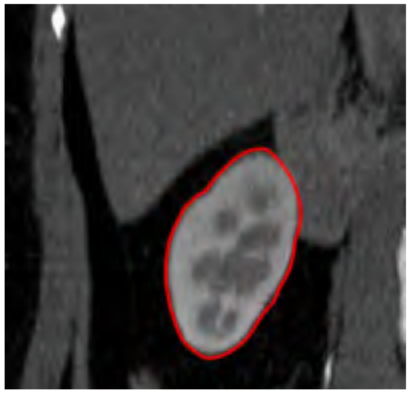
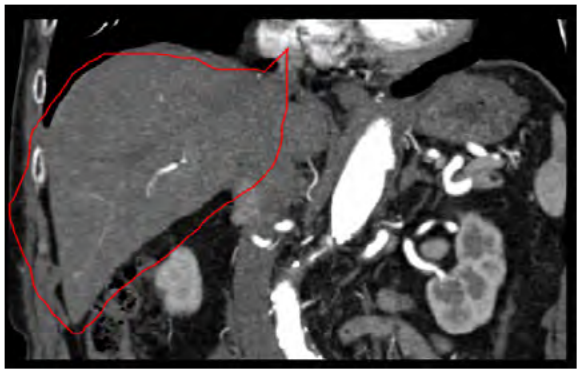
Edge detection can be determined using the HU threshold or by gradient. Select the preferred algorithm by clicking the corresponding radio button. Then hold down the CTRL key and click on the ROI.



Redrawing a Contour

To fix a poorly drawn contour, hold down the shift key and begin drawing along the edge where the problem exists. The contour will change shape according to the new outline drawn (see the following images).



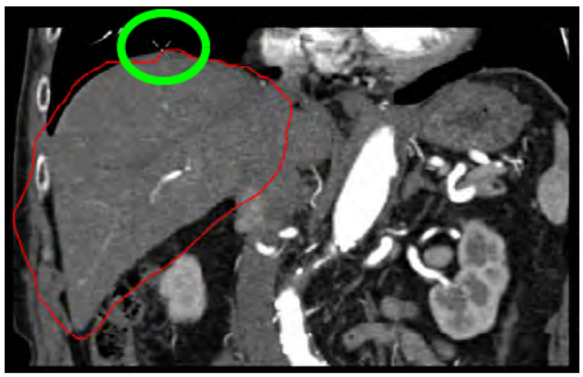


Figure 2-21: Left: Original Contour; Right: Redrawing Contour

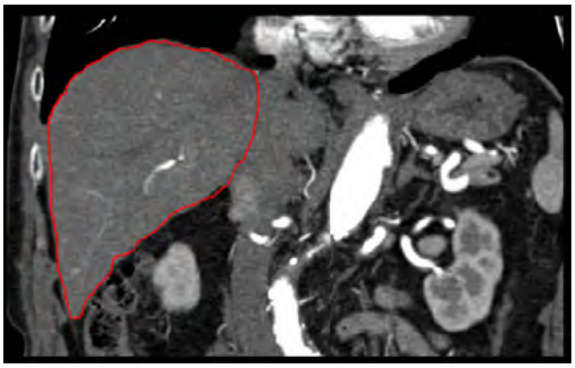


Figure 2-22: Redrawn Contour

Sphere and Circle Drawing

The FreeROI tool can be used to isolate a spherical object such as a femur head.

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1. In the Sagittal image, page to a slice showing the femur head clearly.

2. Select the sphere mode for drawing a region.

3. On the image, place the mouse on the edge of the circular ROI, and then drag the mouse across the area. A circle is automatically drawn on the image. As you drag the mouse across the area, the circle becomes larger.

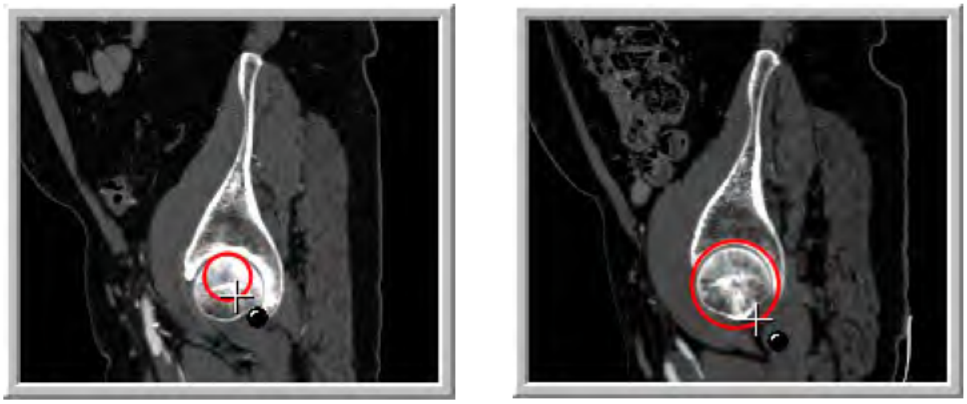
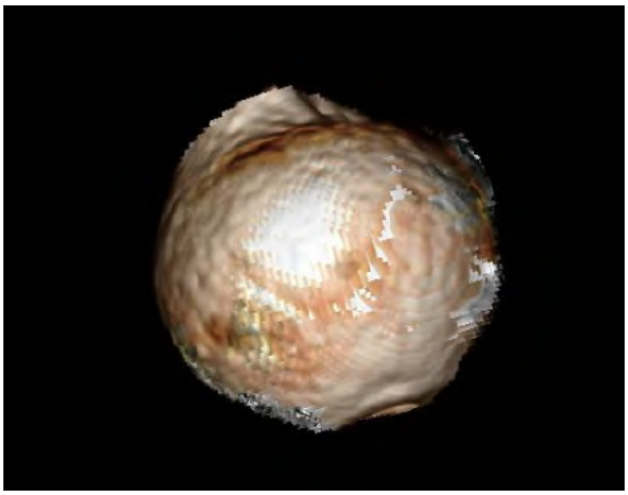


Figure 2-23: Left: Drawing Spherical Contour; Right: Spherical Contour Completed

Click the **Select** button in the Tool Panel to segment the femur head. The segmented section is displayed in the 3D window:



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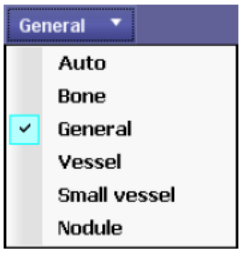
Dynamic Region Growing

Perform mask operations on the region you want to examine by doing the following:

Masking a Region

1. Click on the **Region** button for mask operations.
2. Click the down-arrow to the right of the word **General** (circled in red in the previous image). The pull-down menu containing region grow modes is displayed (see the image at right).



3. Select the region grow mode that best suits the body part.
4. Choose the level of sensitivity or constraint you want for region growth, by selecting the appropriate value from the **Connectivity** scale (circled in green in the figure above), ranging from 1/5 to 5/5.

   - **1/5** - This level grows the most slowly and is recommended for very fine vessels.
   - **5/5** - This level grows the most quickly and is recommended for objects such as large vessels, bone, and other tissue.

   The levels in between these two ends allow you to adjust the growth level more finely.

5. Hold down the **Shift** key, and then click and hold the mouse on the vessel you want to grow.
6. When you have masked the region you want to grow, release the mouse.

Functions

- Include - Adds back some of the tissue that was previously removed, such as with bone removal.
- Exclude - Shows everything except the masked area.
- Select - Shows only the masked area.

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- Clear Region - Removes all masking from the image (does not change the image).

Add / Select

There is also a function called **Add / Select**. Add/Select performs the functions of both **Include** and **Select** together. This feature is not shown in the **Region Grow** tool panel by default. To display it in the tool panel, open the Preference screen and select **Mask** from the navigation panel on the left. Check the box for "Same button for Add/Select". When you close the Preference screen, the Region Grow tool panel is displayed as shown in the following image:

Example

1. Load an image into the i*N*tuition 3D Viewer, and click the **Region** button in the Tool Panel.

2. Mask the area of interest, following the instructions under "Masking a Region" on page 2-40.

3. Click the **Add / Select** button.

4. Select the **1x2 Bone Edit** window mode. (For information about window modes, see "Window Layout Modes" on page 2-136.) The right panel of the window shows the included region, and the left panel shows all parts of the original image that were not included (the "Excluded" region).

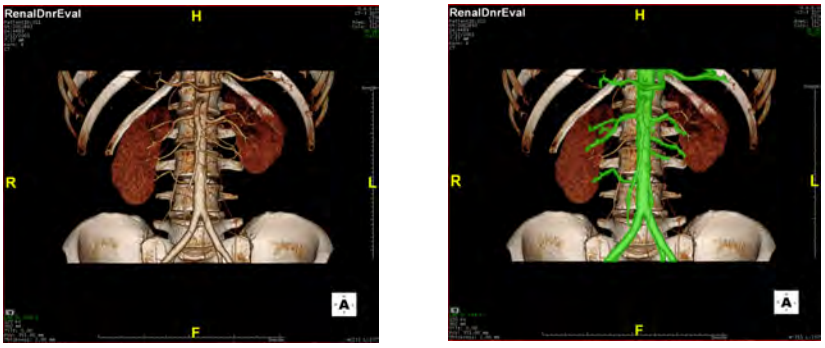

Figure 2-24Left: Original Image; Right: Masked Region

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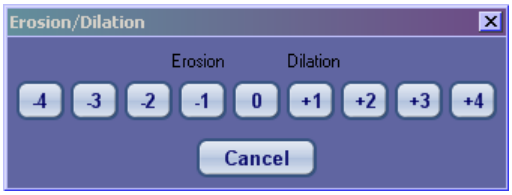
Left: Included Region; Right: Image in 1x2 Bone Edit Layout

Erosion / Dilation Dialog

This is a dialog that is displayed when Select, Include, Exclude or Add/Select is performed. It allows you to choose the connectivity level (see "Masking a Region" on page 2-40), which allows you to fine-tune the amount that is added or removed:



This dialog is not displayed by default, but must be enabled through the Preference screen. For details, see "Mask" on page A-8.

Single Click

You can mask a region with a single click by enabling it in the Preferences. When single-click region-grow is enabled, place the mouse over the area you want to grow, hold down the shift key, and click once. The entire structure (vessel, etc) is masked.

For information on how to change the single-click Preference option, see "Mask" on page A-8.

Bone Removal

When you click the **Bone Removal** icon, bone removal is performed automatically. You can use the bone removal tools to fine-tune the process.

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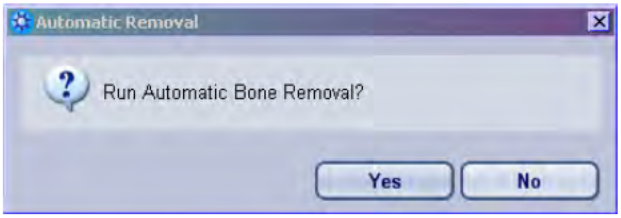
Figure 2-25: Bone Removal Tool Panel

- Fragment Cleanup - This removes any remaining bits of bone or other undesirable material from the image.

Head/Neck Bone Removal

Click the **Head/Neck** button in the Tool Panel to display the Head/Neck bone removal tools. If the Head/Neck function is not already set for automatic bone removal, a dialog box is displayed first asking if you want the Aquarius iNtuition Client to remove the bone:



Click **Yes** to remove the bone, find centerlines, and extract the centerlines. The Head/Neck tool is displayed in the Tool Panel (see Figure 2-26) as bone removal is being performed.

Figure 2-26: Head/Neck Bone Removal Tool Panel

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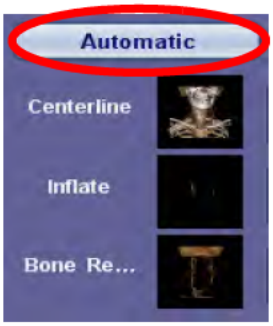
As each function is performed, a small ("thumbnail") image is displayed underneath the **Automatic** button:



Each thumbnail image corresponds with views of the centerlines, the vessels extracted and the anatomy with bones removed. Click any of the thumbnail images to display that image in the main window.

Use the camera icons (circled in green in Figure 2-26) to capture the corresponding image to the Output Panel.

Vessel Tools

The **Head/Neck** tool allows you to to analyze vessels using the **CPR** tool, to do region growing on the image using the **Region Grow** tool and to cut out or add in sections of the image using the **FreeRoi** tool. These are accessed by clicking on the **CPR**, **Region Grow** and **FreeROI** tabs located in the lower portion of the tool panel.

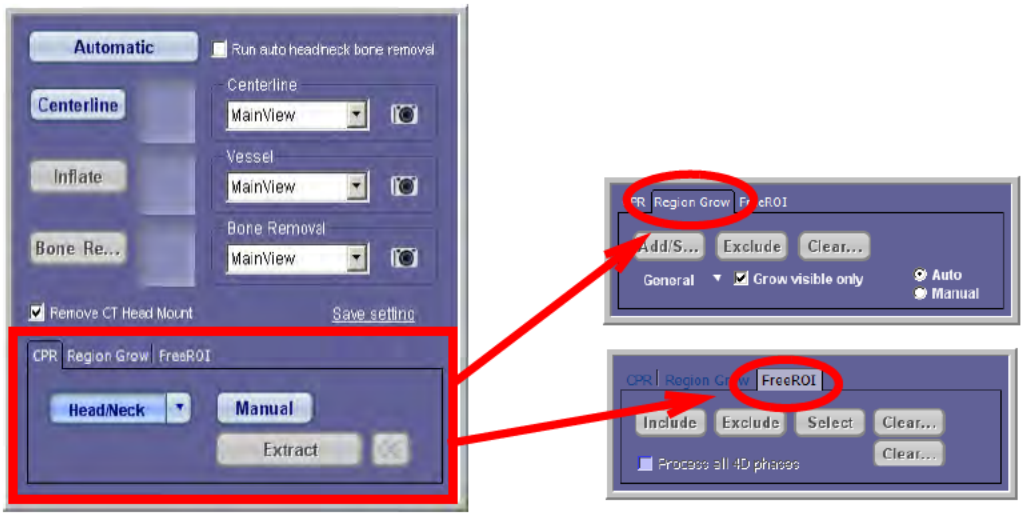


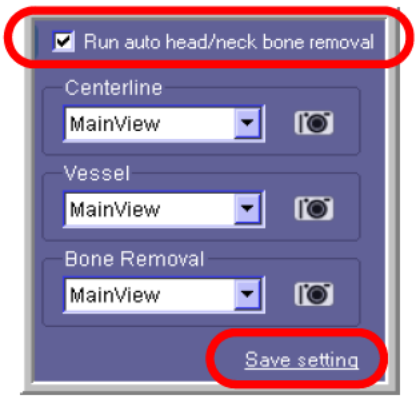
Figure 2-27: Vessel Tools

For instructions on using these tools, see the following sections:

- CPR: "CPR Tool" on page 2-13
- Region Grow: "Dynamic Region Growing" on page 2-40
- FreeROI: "FreeROI" on page 2-36

Saving Settings

You can set an option to specify that the **Head/Neck** tool always removes the bone, finds centerlines and extracts the centerlines automatically, whenver the **Head/Neck** tool button is clicked. The checkbox for this option is located above the window pull-down menus. Check this checkbox, and then click the **Save Setting** link, located just below the camera icons (see figure at right).



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Calcium Score

When you click on the Calcium Score button in the Workflow, a window containing the series list for this study is opened. Click on the appropriate series and then click OK, opening the Classic Calcium module. For a detailed description of the Calcium module, see Chapter 8: "Calcium Scoring".

Batch Tool

The Batch function allows you to display a series of consecutive images, taken from a defined area on an image. These can be 2D slices in MPR, MIP and other 2D rendering modes (Parallel mode), or they can be a succession of rotating 3D images (Radial).
To begin Batch mode, click the **Batch** button in the Tool Panel.

Figure 2-28: Batch Tool Panel

Parallel Batch

To make sure the batch mode is parallel, select **Parallel** from the pull-down menu labeled **Type** in the Tool Panel (see Figure 2-28).

1. Click on the image in the main window, and drag the mouse down along the image. A grid is drawn as you drag the mouse, defining the batch area from the first slice to the last.

   Alternately, you can define the batch area by entering the batch parameters manually. In the **Batch** tool panel (see Figure 2-28), enter the rendering mode, number of images, spacing and field of view (FOV). To enter the FOV, do the following:

   a. Click the double right arrow to the right of the **FOV** field.
   b. Enter the width in the text box that appears.

   When you change the value of FOV, the width of the grid changes in the main viewer.

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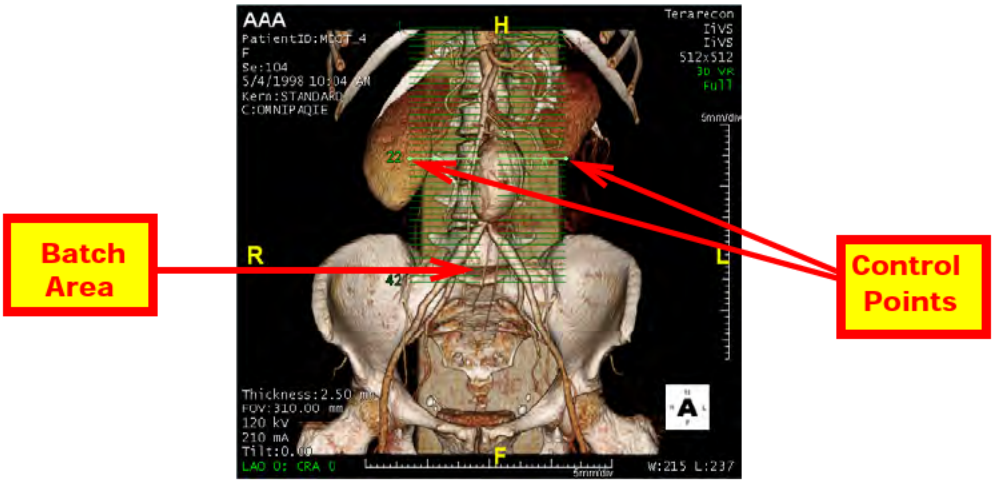
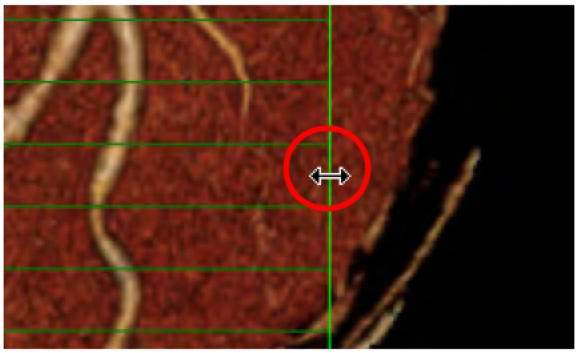


Figure 2-29: Defining the Batch Area (parallel mode) on a 3D Image

2. To adjust the size, location and rotation of the batch grid, note the circular dots in the corners and along the top and bottom edges of the grid. These are the *control points*, which allow you to change the size of the grid or to rotate it.

   - **To adjust the height of the grid**, click on one of the dots in the center of the top or bottom edge, and drag it up or down.
   - **To adjust the width of the grid**, place the mouse over the right or left edge of the grid. The cursor becomes a horizontal double-arrow (see the figure below). Click on the edge and drag the mouse right or left.
   - **To rotate the grid**, click any one of the dots in the four corners of the grid.
   - **To move the entire grid across the image**, click on any space inside the grid that is not part of the actual grid. Hold the mouse down and drag the grid to the desired location.



3. To play a cine of the slices, click the **Preview** button in the Tool Panel. The cine is played in the top-left MPR window in the 2x2 layout.

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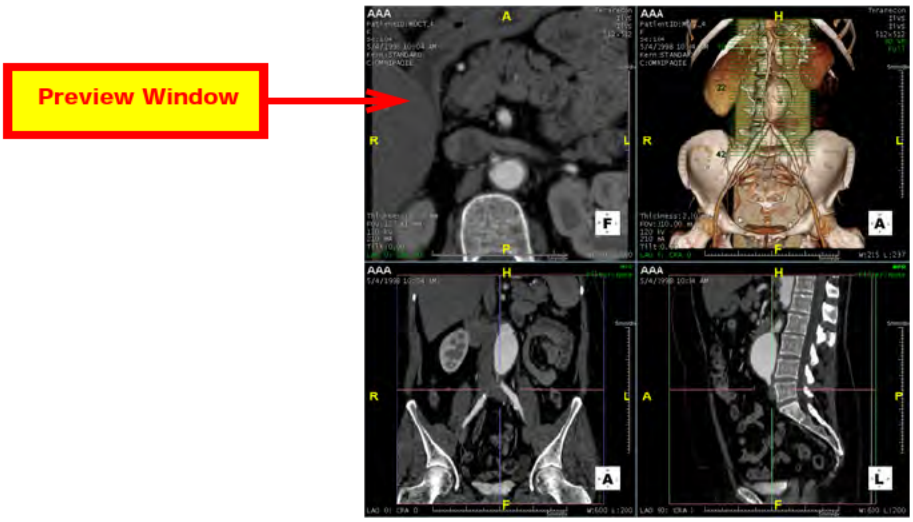


Figure 2-30: Preview Window

4. To send the images to the Output Panel, click the **Output** button.

Fix to Axial

When this is selected, the parallel grid is automatically drawn perpendicular to the axial view. The grid can not be rotated.

Output Scout Image

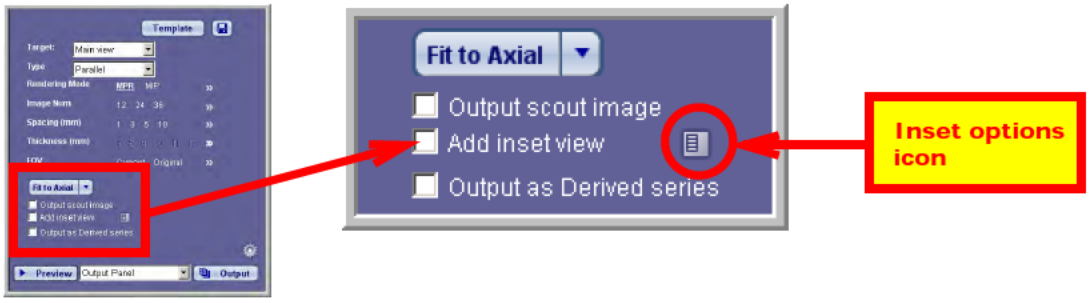
When this is checked, a scout image (the 3D image where the grid has been drawn) is captured to the Output Panel first, with the 2D slice images following.

Add inset view

This feature allows you to place the scout image on each slice image captured in the batch process. The inset can be positioned and sized within the slice images.To add an inset view, do the following:

1. Check the **Add inset view** checkbox.

2. Click the inset options icon.



The options icon dialog is displayed:

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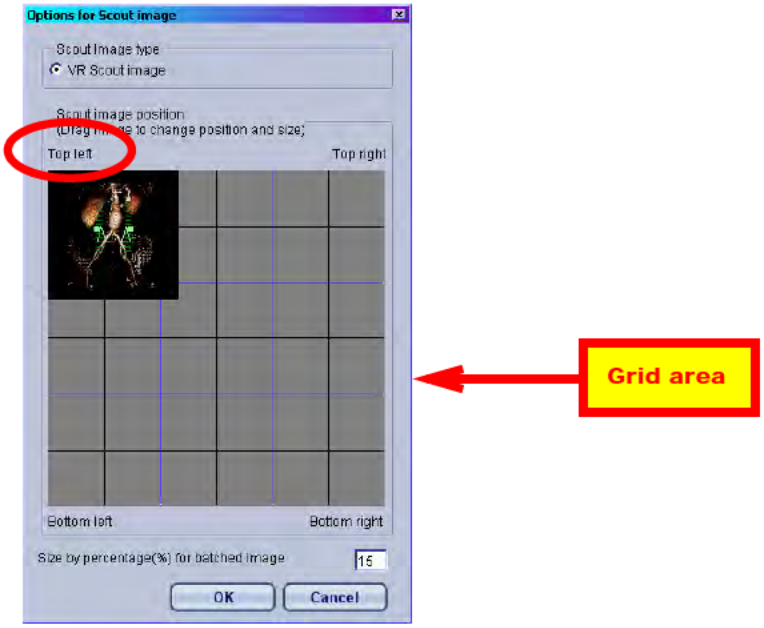

The grid area represents the slice image.

3. Click the **Top left** link (circled in the image above).

4. Click in the upper left corner of the grid and drag the mouse. The inset image appears on the grid.

5. Drag the inset image to where you want to place the inset, and then release the mouse button.

6. Resize the inset by clicking the bottom right corner of the inset image and dragging the mouse.

7. Click **OK** when finished.

When the slice images are sent to the Output Panel, they will appear as follows (inset image circled in each slice below):

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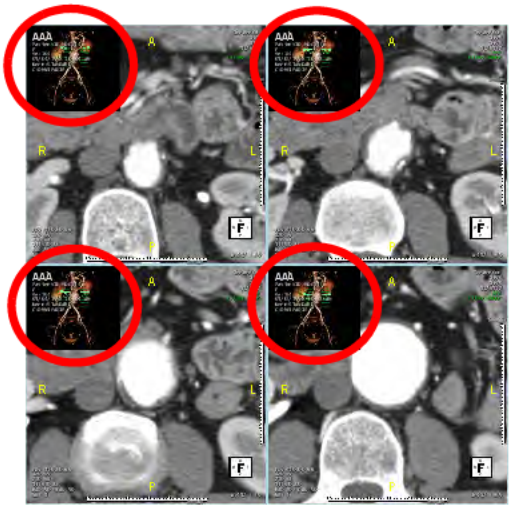

Output as Derived Series

It is possible to created a derived series by outputting batched slices to the Patient List.

To output the batched slices as a series, do the following:

1. Select either **Patient List** or **Output Panel and Patient List** from the output pull-down menu between the **Preview** and **Output** buttons.

2. Enter the name of the new series in the **Description** input field.

3. If you want to capture annotations into the slices, check the **Show annotations** box.

4. When finished, click the **Output** button.

5. To verify that the derived series has been created, go back to the Patient List and look for the series in the Series List.

In the above example, the derived series had "Batch Jan 13" in the **Description** field. A series having this descripton should now appear in the Series List.

> **Note: Click another study in the study list and then click the current study again to refresh the Series List.**

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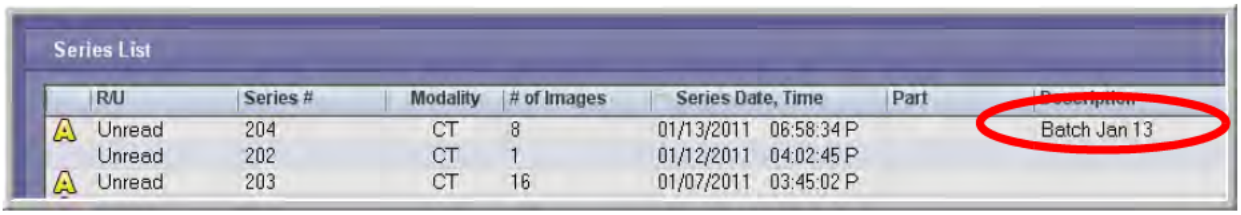
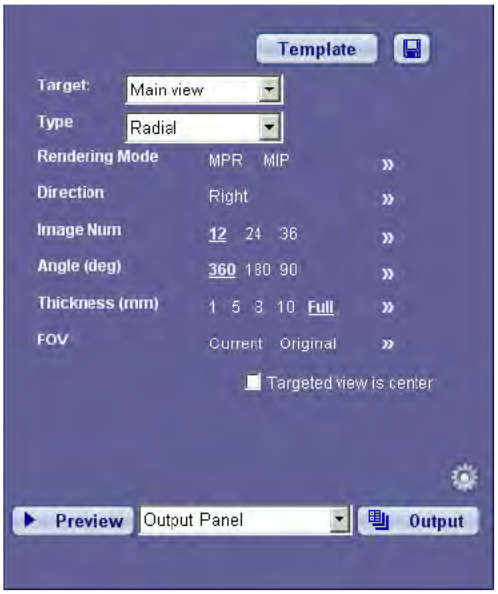


Radial Batch



Radial batch mode shows the image rotating around a central line. The image can be rotated to the left or right around the vertical center, and can be rotated up or down around the horizontal center.

To change to radial mode, select **Radial** from the pull-down menu labeled **Type** in the Tool Panel (see Figure 2-28 on page 2-45).

Parameters must be entered manually in the Tool Panel for radial batch mode.

1. Enter the Rendering Mode, Number of Images, Thickness and FOV as with Parallel Batch mode. All rendering modes are valid. Slab thickness applies only to 3D rendering mode.
2. Enter the rotation **Direction** (right, left, up or down).
3. Enter the **Angle**, which defines the *total* angle of rotation. The total angle size will be divided by the number of images, to obtain the angle of rotation for *each* image.
4. Click the **Preview** button to see the batch movie.

CPR Batch

2D Batch can also be performed on CPR windows.

CPR Perpendicular

Perpendicular allows you to view perpendicular slices along the centerline of a CPR image.

To begin perpendicular batch, open the CPR view of a vessel and then do the following:

1. Click the **Batch** tool button. The **Batch** tool panel is opened, with **CPR View** as the target.
2. From the **Type** menu, select **Perpendicular**:

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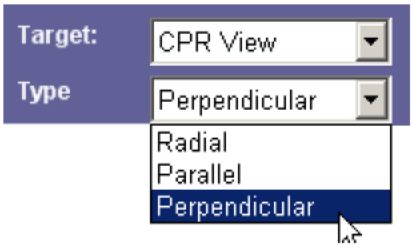
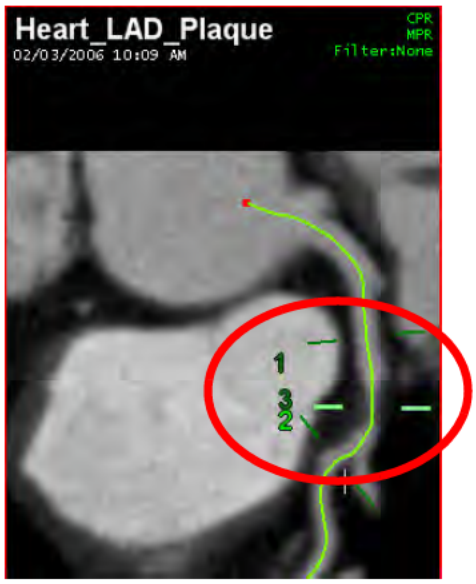


3. Click and then drag the mouse in the CPR window. The batch area is drawn along the centerline:



4. In the tool panel, select the rendering mode, number of images, and other values, as you would in parallel batch mode.

CPR Parallel Batch

In parallel batch mode on a CPR window, the view of the slices is perpendicular to the centerline. To perform parallel batching on a CPR image, you first need to open the CPR view of a vessel. Then do the following:

1. Select the **Batch** tool panel. The **Target** menu will already display "CPR View".

2. Select "Parallel" from the **Type** menu.

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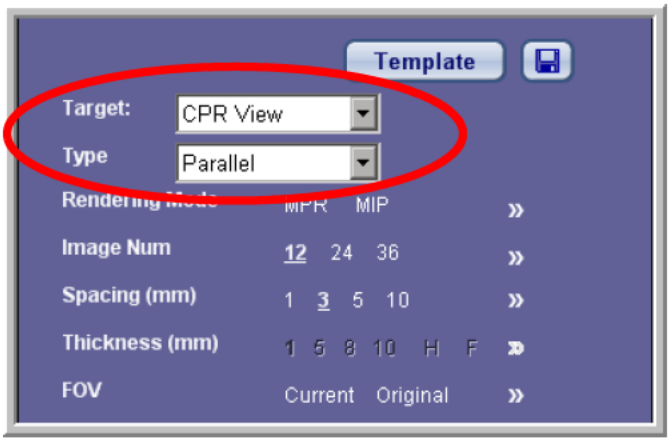
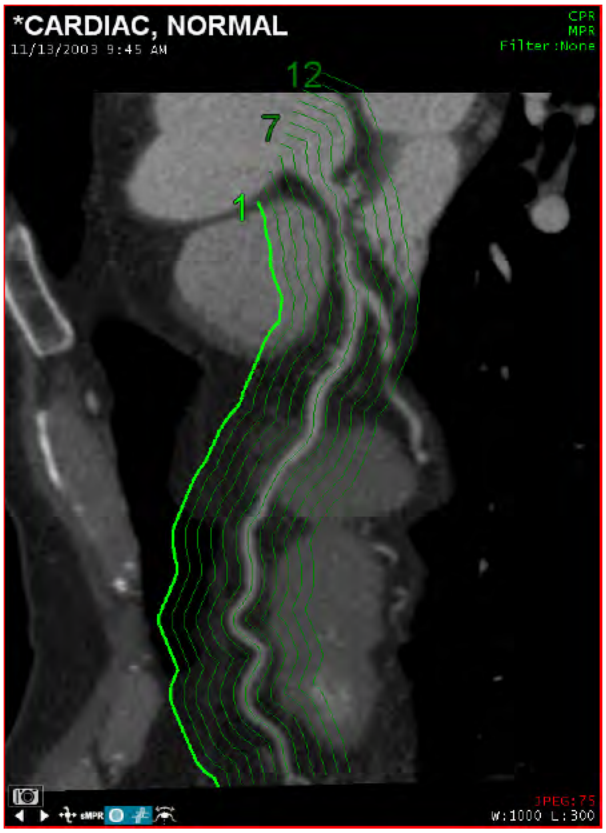


The parallel batch grid is displayed on one of the CPR windows as follows:



As with batch operations on a 3D window, you can change the grid using the Tool Panel. You can set the rendering mode, the number of images and the distance between each slice.

Slice output is viewed in the other CPR window.

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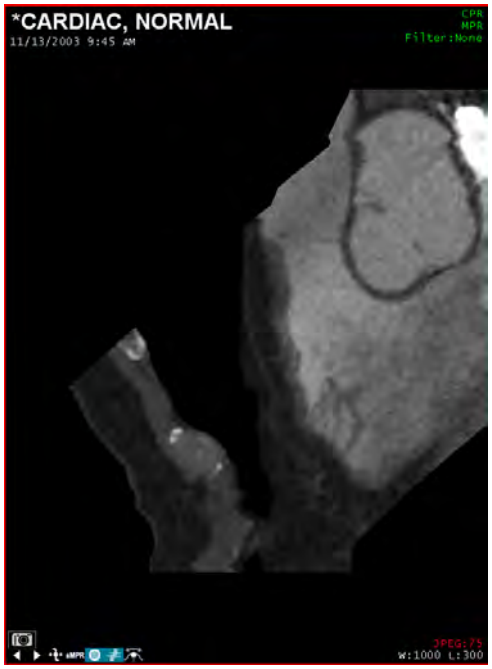
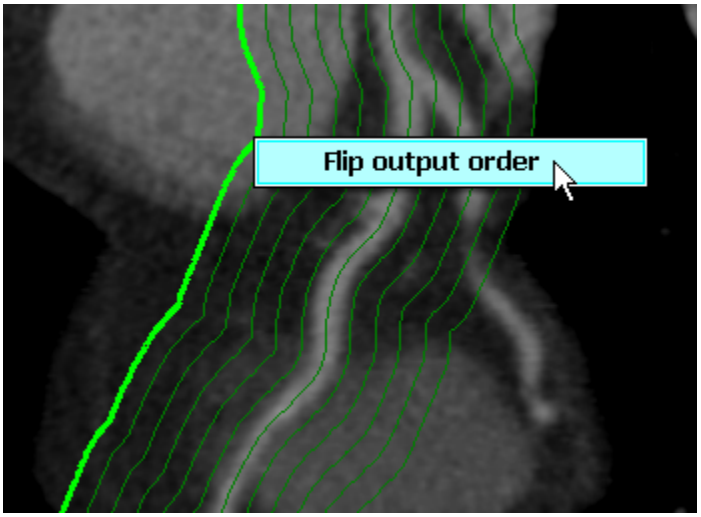


You can also change the output direction of the batch. To do so, right-click on any of the grid lines of the batch window, and select **Flip Output Order**.



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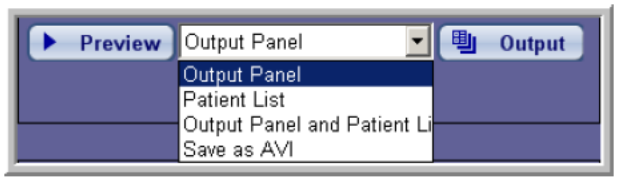
Templates

Templates allow you to save and then use the same batch parameters at different times or for different data. If you perform many similar batch operations on different studies, you can specify the spacing, number of images, angle, and so on, and can then use that same specification later for another study.

Outputting Images

You can send batch images to the Output Panel, the Patient List, both, or as an AVI file. Use the pull-down menu between the **Preview** and **Output** buttons to select one of these four choices. Then click the **Output** button to send the images.

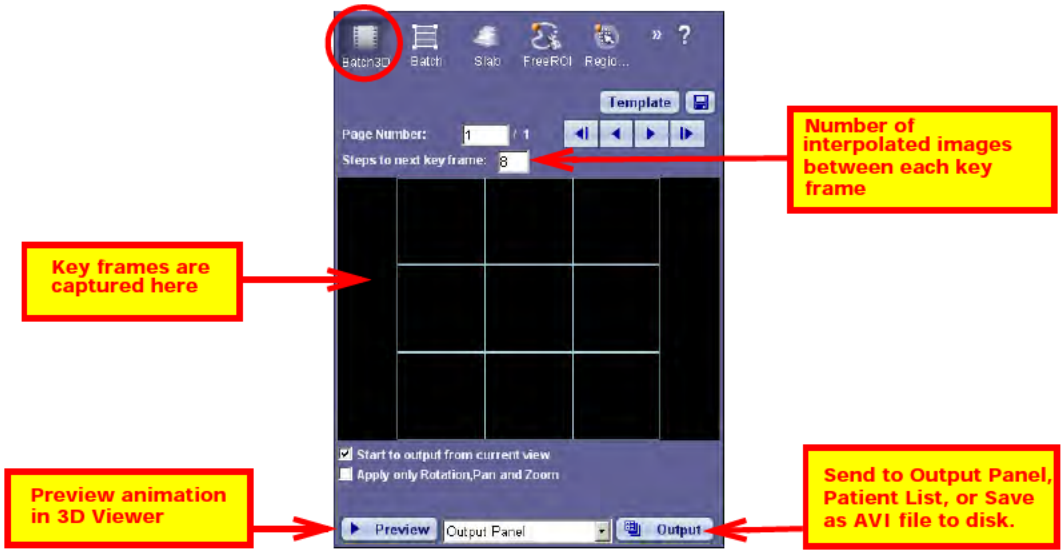


The Batch Wizard

If you need to use the entire screen to display the main image, you can open the Batch Wizard by pressing the **F8** function key on your keyboard. The Batch Wizard is the same Tool Panel as the one in the right panel, but it is displayed on the bottom of the image area. You can then hide the right panel to obtain maximum space for the image.

Batch3D

Click the **Batch3D** button in the Tool Panel. The Batch3D tools are displayed:



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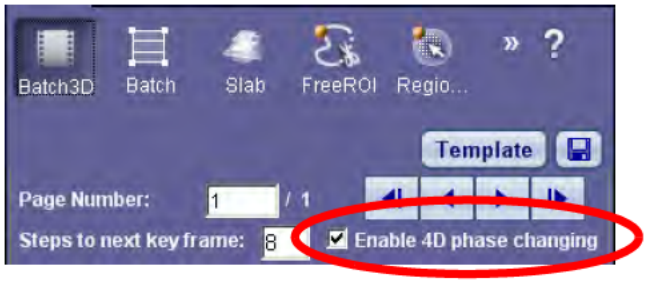
Batch3D works by taking snapshots that you have captured from the 3D window (known as *key frames*) and creating an animation of the image. The animation begins with the first key frame, ends with the final key frame, and passes through each of the intermediary key frames you have captured. In addition, the software inserts interpolated images between each key frame to produce a smoother transition.

The following example uses a multi-phase series to create a 4D batch of a beating heart. For 4D moving images, the **Enable 4D phase changing** checkbox must be checked:



Note: This option does not appear for non-phased series.

1. Orient the 3D image to the starting point, and capture the image by clicking the camera icon in the lower left corner of the image (see the following figure).

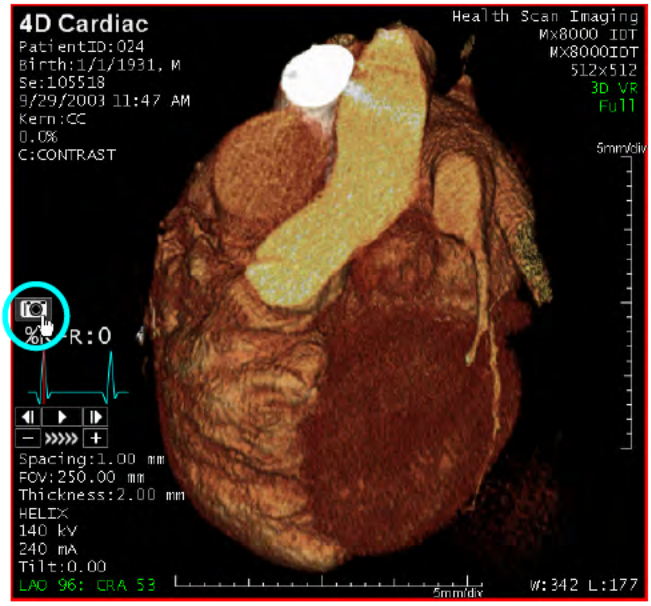


Figure 2-31: Capturing Image For Batch

The first key frame appears in the first (upper-left) square of the Batch3D tool panel.

2. Modify the image as you wish (pan, zoom, rotate, change the rendering mode, or click to the next phase in the 3D window) and click the camera icon again to add the next key frame to the tool panel.

Note: If you are performing several operations on the image, but only want to see rotation, zoom and pan operations in the batch animation, click the "Apply only Pan, Rotation and Zoom" checkbox.

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3. Repeat step 2 for all views you want to capture.

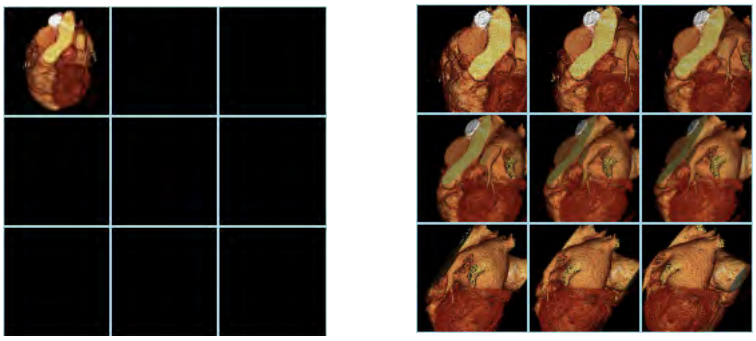
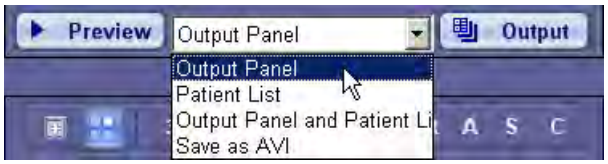


Figure 2-32: Left: First Key Frame; Right: Multiple Key Frames

4. Enter the number of images between each key frame in the input box labeled **Steps to next key frame**. This determines how many interpolated images will be inserted between each key frame. A higher number will produce a smoother transition as the image moves, but will also create more batch data.

5. If desired, preview the batch by clicking the **Preview** button. This does not output any images, but simply plays the animation in the main window.

6. Select the output destination from the pull-down menu located between the **Preview** and **Output** buttons.



7. Click **Output**. If you have selected **Save as AVI** as the output destination, a Windows **Save As** dialog is opened so that you can name the file and navigate to the folder where you want to save it.

   The AVI movie can be viewed in any video-playing software that supports the AVI format. Windows Media Player (standard with the Windows operating system) is one option.

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Figure 2-33: 3D Batch Movie Playing in Windows Media Player

Common Mask Controls

Figure 2-34: Common Mask Controls

This control panel is used to fine-tune mask functions in each of the following tools:

- FreeROI
- Dynamic Region Growing
- Bone Removal
- Mask Threshold
- Angio View

The Common Mask Control Panel appears at the bottom of the Tool Panel for each of the above tools.

Description

- Undo - Undoes the most recent action.

- Clear - Undoes *all* functions that have been performed during this session.

- Reverse - Most useful for the FreeROI tool, and is best seen in 1x2 layout (see "1x2 Bone Edit" on page 2-137). The left panel shows everything that has been removed, and the right panel shows everything that remains in the image. The Reverse button switches the two images.

- Bone Edit Mode - Opens 1x2 Bone Edit layout mode.

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- Fragment Cleanup

- Begins fragment cleanup. You can specify the level in the pulldown menu.

- Erosion/Dilation

- Adds or subtracts pixels of data to/from the image.

- Turn Overlay On/Off - Toggles the green overlay on the MPR views, showing the masked area that has been removed.

- Show/Hide Mask Outline - Allows you to see the outline of bone mask on an image that has had bone removed. Click on the down-arrow on the right to display a slider. Moving the slider to the right shows more bone outline.

Window Level Tool

Adjust the window width/level from this tool panel. Use any of the preset buttons, or enter appropriate values in text boxes.

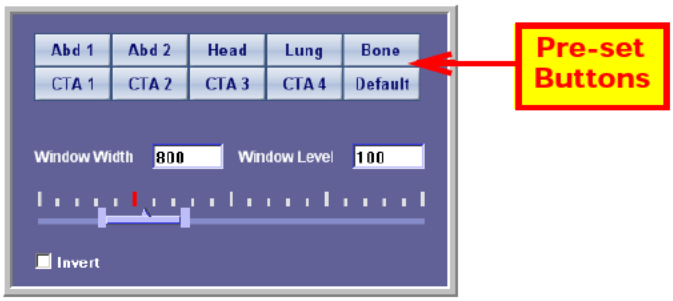

Figure 2-35: Window/Level Tool

If you select **W/L** as the mouse mode, you can also adjust the W/L of the image by left-click and drag.

Changing a Preset W/L

To change an existing preset W/L to a new level, right-click on the preset icon. The following dialog box is displayed:

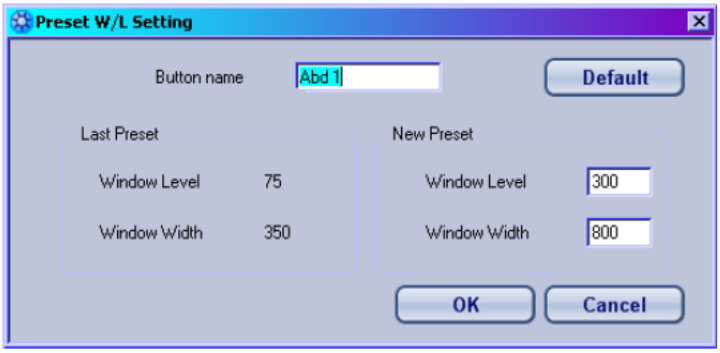

Figure 2-36: Change Preset W/L Dialog

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The values on the left side, under “Last Preset”, show the current values for this preset button. The input boxes are on the right, where you can enter new values.

You can also rename the preset button by entering the new name in the “Button name” input box at the top of the dialog.

Clicking the **Default** button will restore the reset button to its original default values.

Invert W/L

Invert W/L reverses the black and white values of the image. Click the **Invert** checkbox, in the bottom-left corner of the tool panel, to display the image in reverse.

Anatomy List

WARNING: The labels displayed by this function are suggestions resulting from an automated algorithm, and are not necessarily 100% accurate. The labels must be verified by a qualified person before being used.

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Anatomy labels allow you to identify vessels or other body parts so that they can be found easily. Labels can be added automatically by Advanced Processing prior to being pushed to your server. You can also add labels manually using this tool, whether or not Advanced Processing has previously added labels.

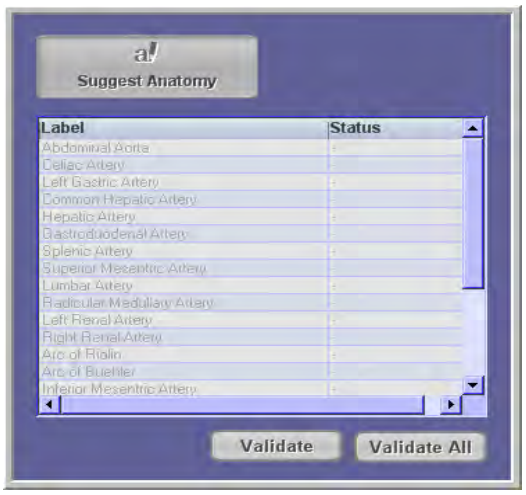
If labels have been added by Advanced Processing, the list of vessels in the Anatomy List is displayed in regular text, as in the figure at right.

If labels have not been added to this data by Advanced Processing, the anatomy list initially appears in light-weight (grayed-out) text, as shown in the following figure. Grayed-out text indicates that a label has not been added to the data for that vessel or body part.

This feature allows you to examine each label in the image and validate it (if desired), to move the label to the correct place, to delete the label if that is appropriate, and to add new labels manually.

Finding a Vessel

When you click on a vessel name in the anatomy list (shown in the figure at right), the image is automatically panned so that the vessel having this label is centered in the screen, making it easier to find.



Note that the name must be in regular type, showing that the vessel has already been labeled. If the type is grayed out, this means that the corresponding vessel does not have a label. You can label it manually. See "Adding New Labels" on page 2-61 for instructions on adding labels.

Validating a Label

To validate a label, select the desired vessel from the list and click the **Validate** button.

Moving a Label

There are two ways to move a label to another location on the image. The first is as follows:

1. Hold down the shift key.
2. Click on the label and drag the label to the new location.
3. Release the mouse.

The second way to move a label is as follows:

1. Hold down the shift key and right-click on the label. The Anatomy List menu is displayed:

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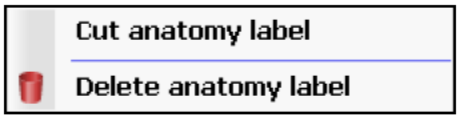

2. Select **Cut anatomy label**.
3. Move the mouse so that the cursor points to the appropriate place for the label.
4. Shift and right-click again.
5. Select **Paste anatomy label**.

Deleting a Label

To delete a label, do the following:

1. Hold down the shift key and right-click on the label. The Anatomy List menu is displayed.
2. Select **Delete anatomy label**.

Adding New Labels

You can also add labels to vessels that were not identified by the Advanced Processing module, or in the case where no Advanced Processing was done.

1. Scroll down the Anatomy List to the lower section of the list, where the text is displayed as grayed-out (see Figure 2-37). These are the unidentified (unlabeled) vessels.

   Note: If there has been no Advanced Processing on this data, all vessels in the list are unidentified and are displayed as grayed-out.

2. Click on the name of the unidentified vessel that you would like to add a label to.

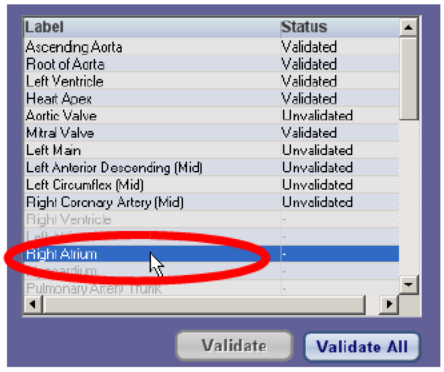

Figure 2-37: Selecting an Unidentified Vessel

3. Right-click on the vessel where you are adding a label. The following menu is displayed:

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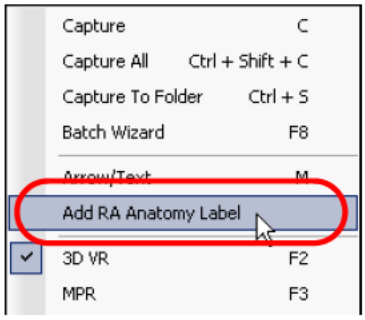


Figure 2-38: Right-click Menu on Vessel

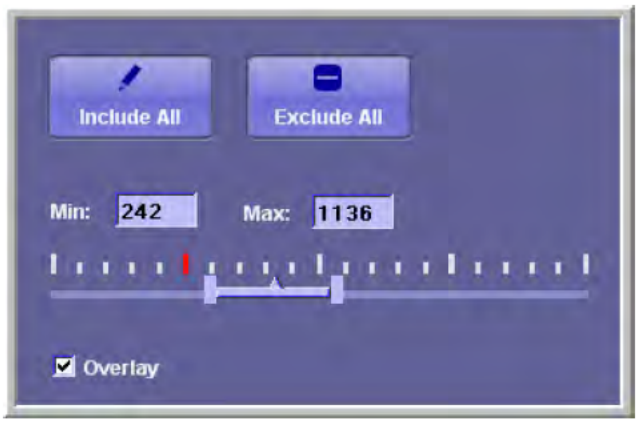
4. Select **Add [Selected Label]Anatomy Label**.

   Note: The name of this menu item changes depending on which label was selected in the unidentified vessels list. In this example, the Right Atrium has been selected, so the item displays as "Add RA Anatomy Label".

   The new label is added to the image and is automatically validated.

Mask Threshold

Set the mask threshold to display all points of an image whose HU values are between the numbers specified in the tool (see figure at right).



1. Set the minimum and maximum HU values, either by entering them manually in the text boxes, or by using the sliders. (The values are reflected in the text boxes as the sliders are moved.)

2. To display all points of the image that fall within the threshold, click **Include All**.

3. To display all points that fall *outside* the threshold, click **Exclude All**.

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Angio View

Angio View allows you to display a MIP view of an image, with the focus on the vessels. To generate the angio view automatically, click the **Auto Angio View** button located at the top of the toolbar. The tool panel displays results as shown in the figure at right.

Each small ("thumbnail") image along the upper-left side of the tool panel corresponds with views of the heart, coronary arteries and ventricle. Click any of the thumbnail images to display that image in the main window.

Use the camera icons to capture the corresponding image to the Output Panel.

The Angio View tool panel allows you to do region growing on the image to show more vessel tissue, and to cut out or add in sections of the image using the FreeRoi tool. These are accessed by clicking on the **Region Grow** and **FreeROI** tabs located in the lower half of the tool panel.

- For instructions on Region Growing, see "Dynamic Region Growing" on page 2-40.
- For instructions on using the FreeROI tool, see "FreeROI" on page 2-36.

SAT

The Segmentation, Analysis and Tracking (SAT) module is started when you click the **SAT** Tool Panel button.

To perform SAT on a study, do the following:

1. Load a lung study or series into the 3D Viewer.
2. Click the **SAT** button in the Tool Panel.

For a detailed description of the SAT module, please see Chapter 6, "Segmentation, Analysis and Tracking".

Volume Operation Tool

Registration

In order to view an accurate overlay study, the series images have to be properly aligned or matched. This process is called *Registration*.

To register images, do the following:

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1. Load two series from the same study.

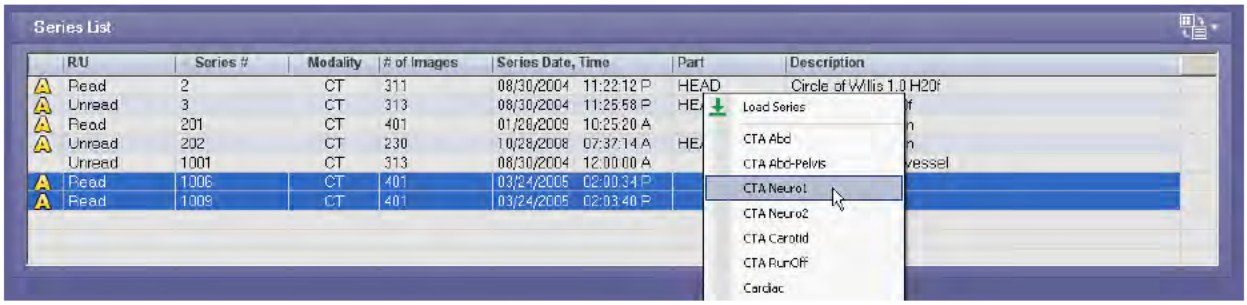


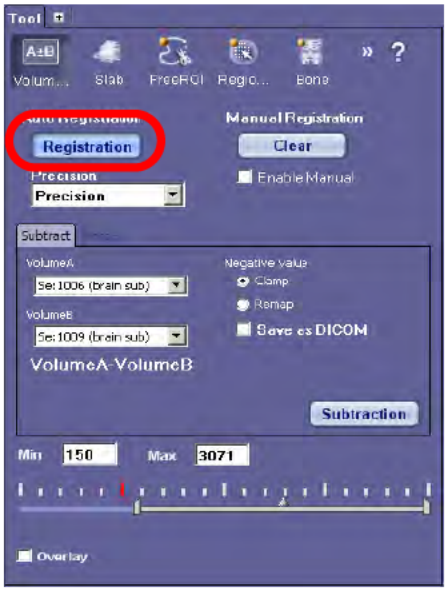
Figure 2-39: Loading Two Series

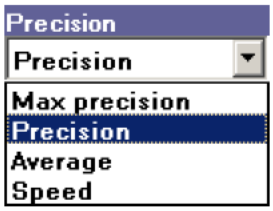
2. Click the **Volume Operation** icon in the Tool Panel to open the Volume Operation Tool.

Note: If the Volume Operation icon does not appear in the Tool Panel, click the double right-arrow on the right to open the hidden functions (see "Customizing the Tool Panel" on page 2-92 for details).

3. Click the **Registration** button in the Tool Panel (circled in red in the figure at right). The images are automatically registered so that they are aligned properly.

   You can choose a level of precision vs. speed for the registration process, from among several levels. "Max precision" is the most precise, and "Speed" is the fastest.





4. If you are not satisfied with the automatic registration, you can use the Manual registration option.

Subtraction

The Subtraction function performs a combination or superimposition of two series, which demonstrates the difference between them. Using this process, you can take a non-contrast image and subtract a contrasted image to result in a subtracted 3D image of the contrasted area of interest.

Note: You are obligated to define the parameter ranges that are used in this procedure. When first accessed, the user interface for setting

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these parameters contains generic default values having no particular significance. You must acknowledge this by dismissing a warning message to this effect.

To perform Subtraction, do the following:

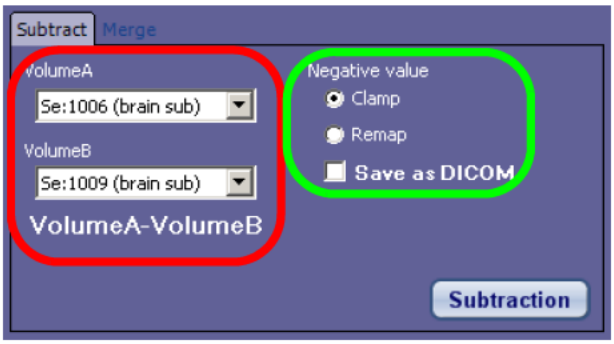


Figure 2-40: The Subtraction Tool

1. You first must decide which series is Volume A and which is Volume B. This is because the automatic Subtraction function in Aquarius iNtuition always calculates the result as Volume A - Volume B. Use the Volume pull-down menus to assign the volumes (circled in red in the figure above).

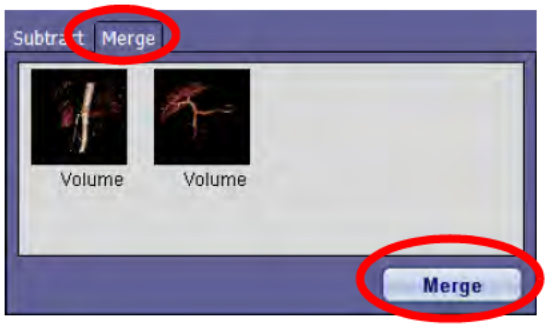
2. If the resulting values fall outside the specified range, select the **Clamp** option (circled in green). Data outside the value will be discarded.

   If you select the **Remap** option, all values will be re-scaled to fit within the range. Data will not be lost but re-scaled.

   To save the subtracted images as DICOM files, select the checkbox labeled **Save as DICOM**.

Merge

To merge the two volumes, click the **Merge** tab:



Click the **Merge** button to merge the two volumes. A third column is displayed in the main window, showing the result of merging the volumes in the first two columns:

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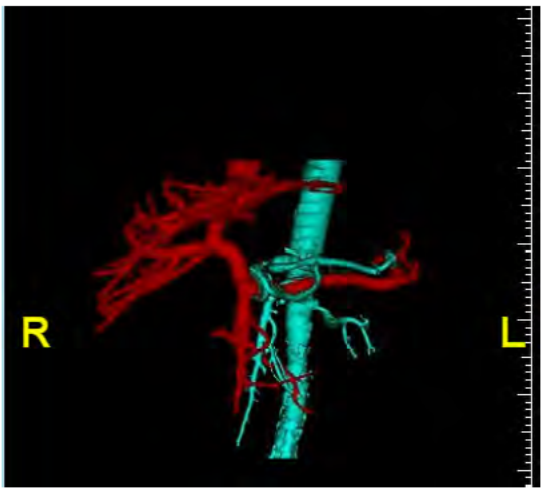
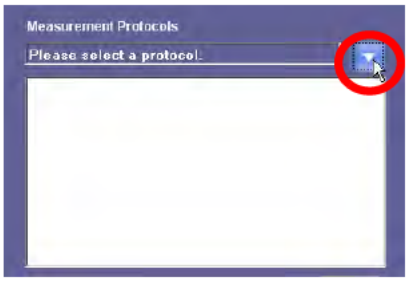


Measurement Protocols

The Measurement Protocols tool allows you to obtain the measurements required for a procedure or device, such as a stent.



1. To begin, click the down-arrow located in the upper-right corner of the Tool Panel:

   The Measurement Protocols Dialog Box is displayed:

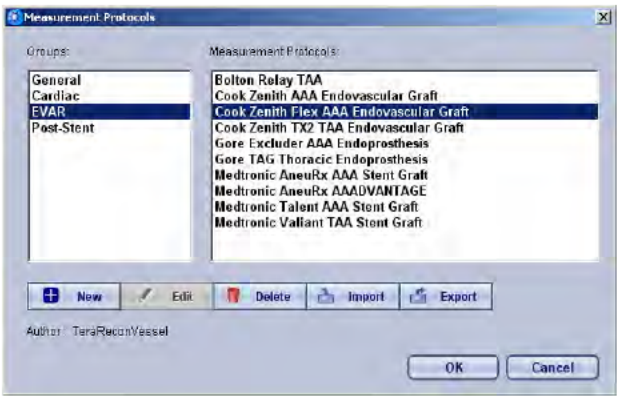


Figure 2-41: Measurement Protocols Dialog

2. Select a group from the left window, and then select a measurement protocol from the right window. The measurement protocol is displayed in the Tool Panel.

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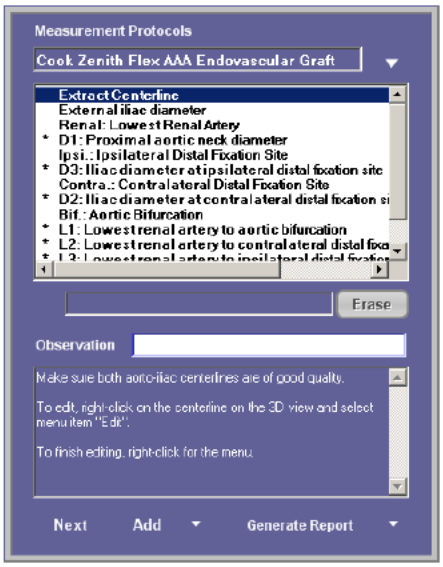


Figure 2-42: Measurement Protocols Tool

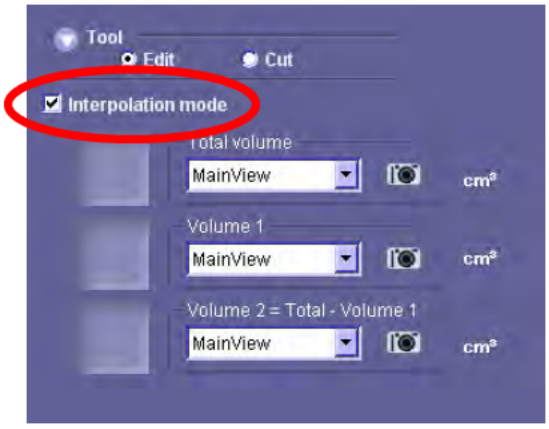
Each measurement protocol contains detailed instructions for obtaining the required measurements.

For more information, see Chapter 10: "Measurement Protocols".

Lobular Decomposition (LD)

Lobular Decomposition allows you to measure the volume of each lobe of the liver. First you need to obtain the volume of the entire liver, and then the volume of the right lobe. The tool then calculates the volume of the left lobe. (Total volume - lobe 1 volume = lobe 2 volume).

To begin using the LD tool, open a liver study, and then click the **LD** icon. This icon is located in the hidden tools area (see Figure 2-3 on page 2-7). The tool panel is opened, as shown in the next image:



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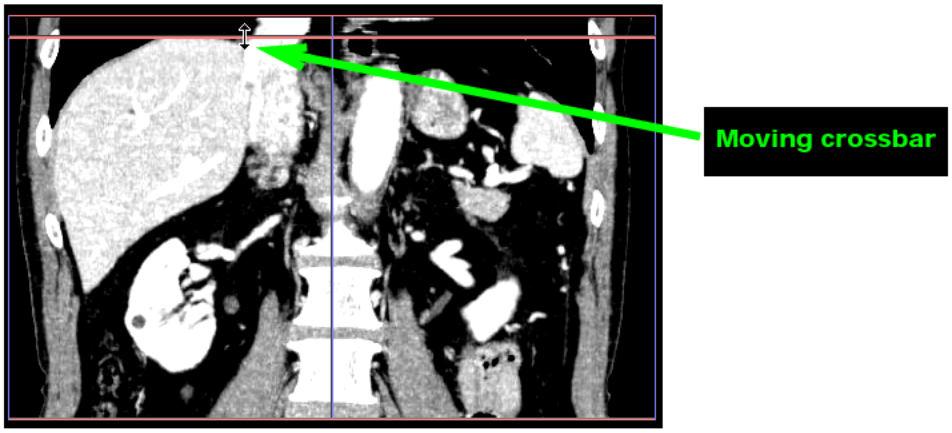
Step 1: Measuring the Total Volume

To get the volume measurement of the liver, first draw the outline of the whole liver on several slices throughout the entire volume, including the very top and very bottom of the structure. The LD tool will interpolate the area of the liver on each slice that comes between the ones where you have drawn outlines.

Note: The Interpolation mode must be enabled by checking the box, as shown above (circled).

1. In the coronal MPR, position the crossbar at the very top of the liver.



2. In the axial image, draw an outline of the entire liver, as seen in that slice. To draw, hold down the **Shift** key and trace the outline with the mouse.

3. When you have completed the outline, release the mouse. The outline appears as shown in the following image:

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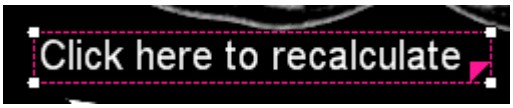
4. Page through the slices on the axial image (or move the crossbar down a short way on the coronal image).

   Choose the next slice where you will draw an outline of the liver. There is no specific number of slices to advance between; however, the closer together the slices are, the more accurate the interpolation will be.

5. Continue through the entire volume, drawing the area of the liver at selected slices. Be sure to draw the final slice in the volume.

6. When you are finished, calculate the volume by clicking the text on the image that reads **Click here to recalculate**.



   The volume is automatically calculated, and is displayed on the image:

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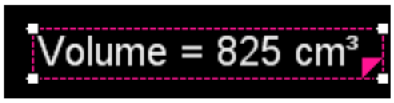
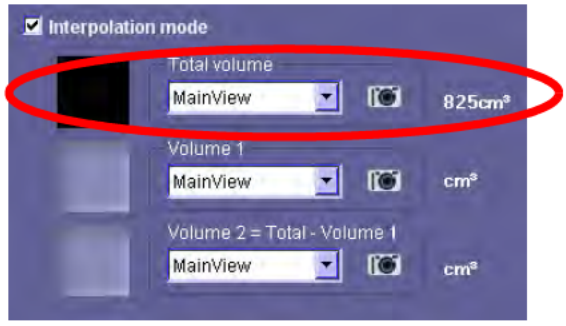


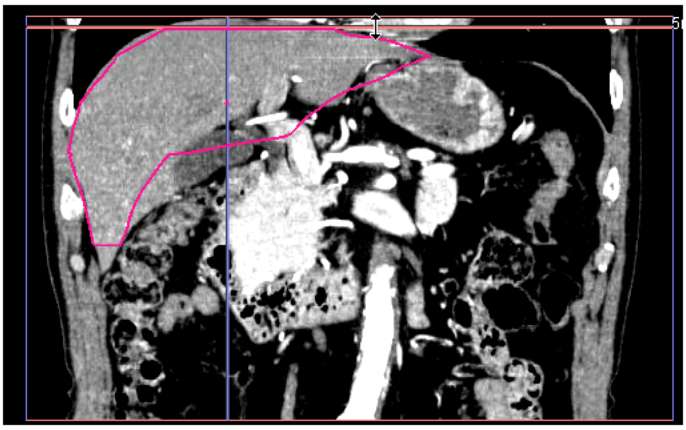
7. To capture this volume in the LD tool, go to the tool panel, and click the camera icon in the first row of volumes, **Total volume**. The volume is displayed on the tool panel.



Step 2: Edit - Measuring the Right Lobe Volume

Measuring the right lobe's volume requires the same steps performed in measuring the total volume. However, you can modify the outlines already drawn around the entire volume so that only the area of the right lobe will be considered in the next calculation.

1. Reposition the crossbar in the coronal image back at the top of the liver.



2. In the axial image, slowly scroll through the slices in the vicinity of the top until you find the first (topmost) slice having an outline.

Note: the interpolation that was done in the whole-volume calculation added an outline to every slice in the volume, so you need to begin at the topmost slice.

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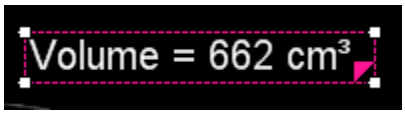
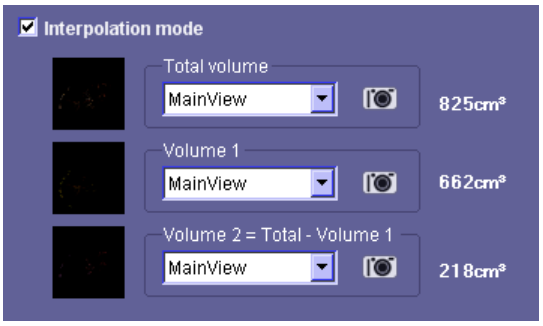
3. Continue paging through the volume, stopping at intervals of your choosing to modify the outline to include only the right lobe. Hold down the **Shift** key and draw along the edge of the area. When you reach the point on the perimeter where the outline of the right lobe follows a different direction from what was previously drawn, follow the new outline. The shape of the area will automatically change to follow the new outline.

   Note that the final slice for the right lobe is the same as that for the total volume, so you do not need to change that slice.

4. When finished, click the **Click here to recalculate** text. The volume of the right lobe is displayed in the tool panel:



5. Click the camera icon in the second row of the tool panel to capture the volume of the large lobe. At this time, the volume of the small lobe is automatically calculated and displayed, along with the thumbnail image of the subtraction.



The volume of the left lobe, along with the RECIST and WHO values, is displayed on the axial image:

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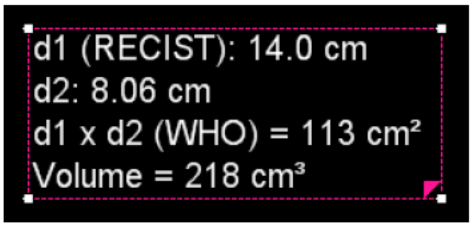
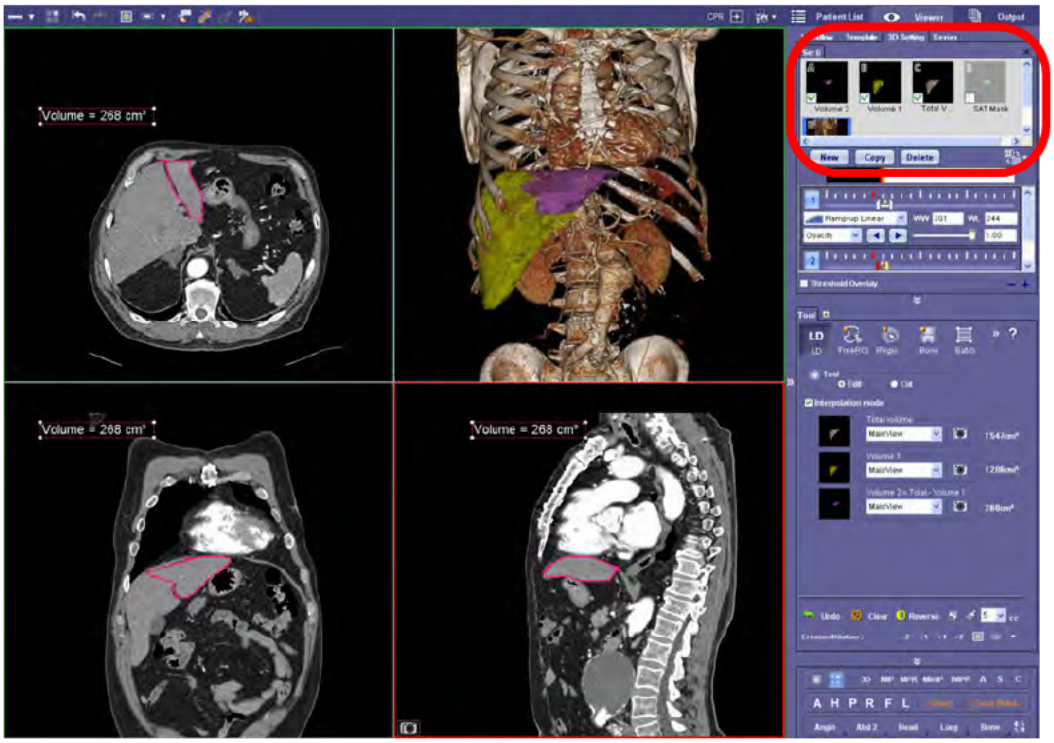


3D Imaging

To isolate the liver in the 3D view, click the 3D settings tab to show the image mask thumbnails.



Select or deselect the thumbnails as desired.

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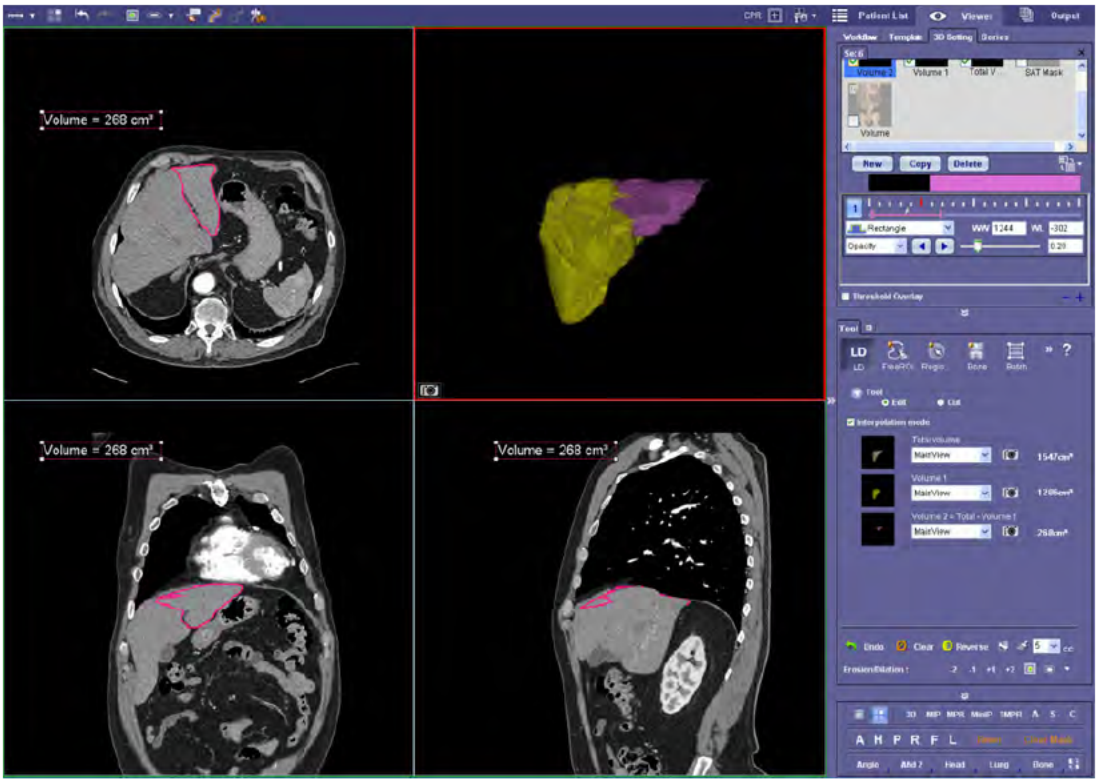
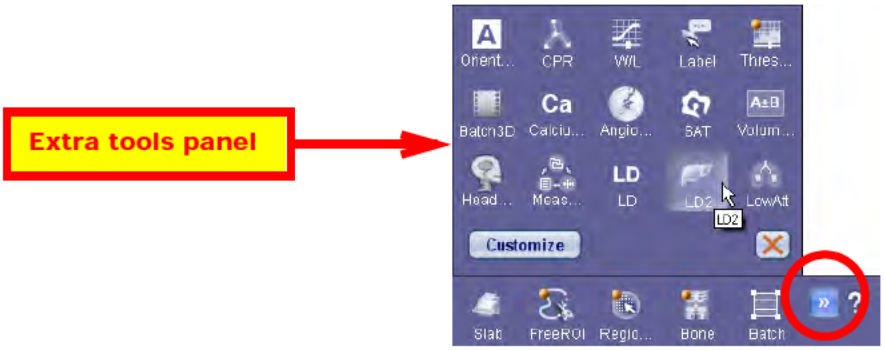


For more details about 3D settings, see "3D Settings" on page 2-159.

Lobular Decomposition 2 (LD2)

Load a liver study and open the LD2 tool panel. The LD2 button is located in the extra tools panel. Click the double right arrow to display the window.



The LD2 tool panel is displayed:

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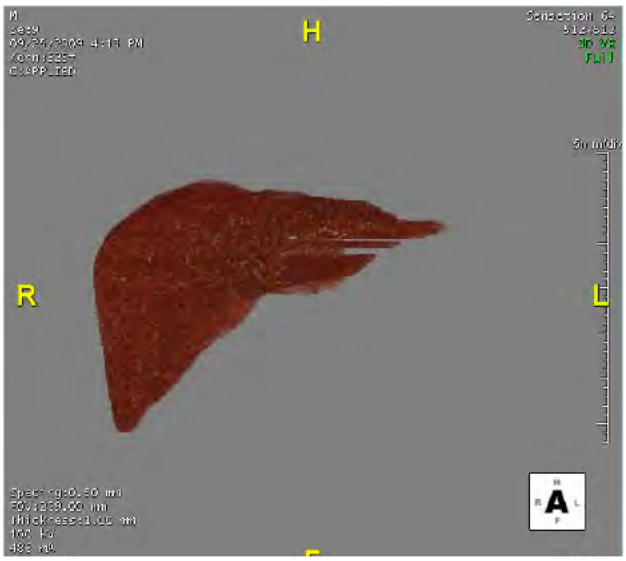
Figure 2-43: The LD2 Tool Panel

Segmenting the Liver

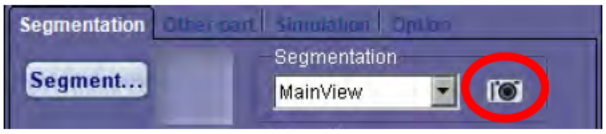
1. Click the **Segmentation** tab to bring the segmentation tool to the front.

2. Before beginning the liver segmentation, adjust the window/level in the 3D image so that the liver is visible and dark.

3. Click the **Segment** button. The segmented liver is displayed in the main window:



4. If the segmentation is acceptable, capture the image by clicking the camera icon on the same row as the **Segment** button.



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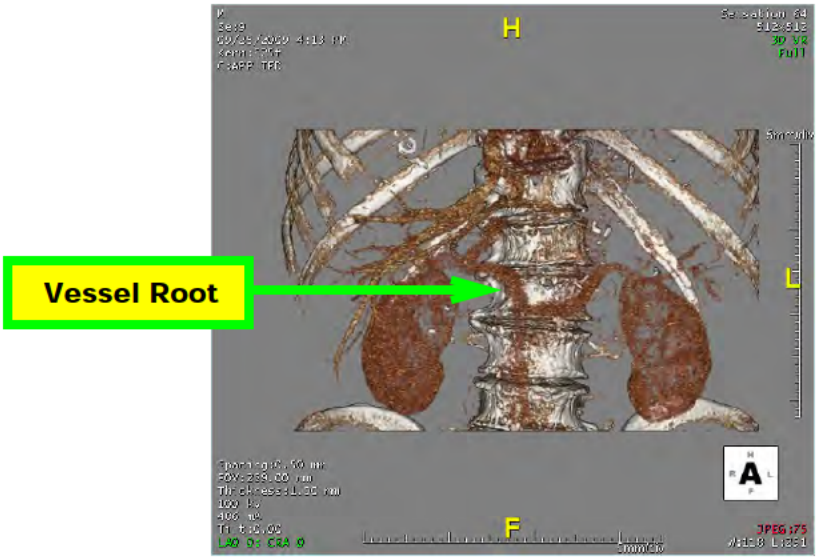
A thumbnail image of the segmented liver is shown in the small window (to the right of the **Segment** button), indicating that it has been captured.

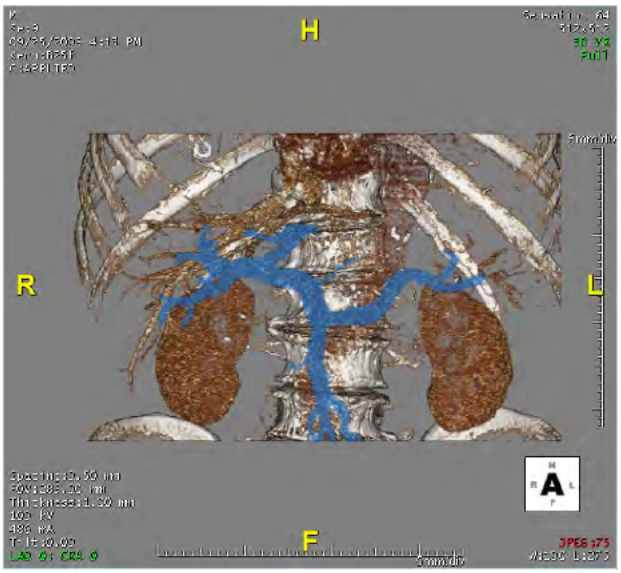
Segmenting Vessels

Use W/L to make the image very light so that the Region Grow function works properly.

1. While holding down the shift key, click on the vessel root.



The entire vessel tree is masked (see the following image).



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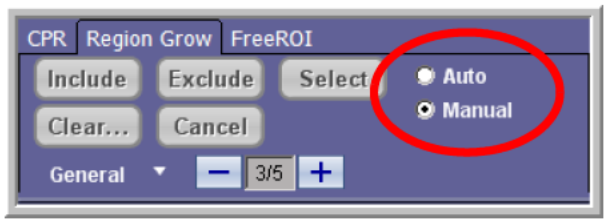
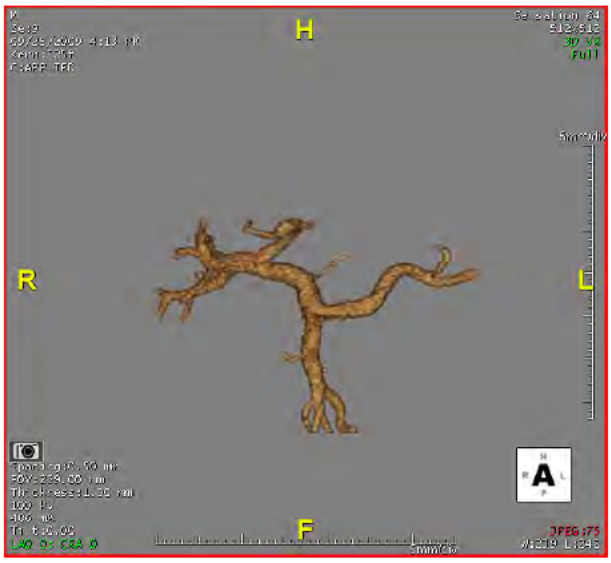
Note: If the Region Grow operation does not fully mask the desired area, you might get better results using Manual Region Grow rather than Auto. Click the Manual button (see the following image) to switch to Manual Region Grow.



2. Click **Select** to segment the masked area. The vessel is displayed in the main window.



3. Capture the vessel by clicking the camera icon in the same row of the Tool Panel.

Note: The camera icon in the lower-left corner of the image captures images to the Output Panel and does not serve the same purpose as the camera icon in the Tool Panel (see Figure 2-43 on page 2-74**).**

Before the image is captured, you will be prompted to shift-click on the segmented vessel so that the software can find all the centerlines for the vessel tree. When that is complete, the thumbnail image of the vessel is displayed in the tool panel.

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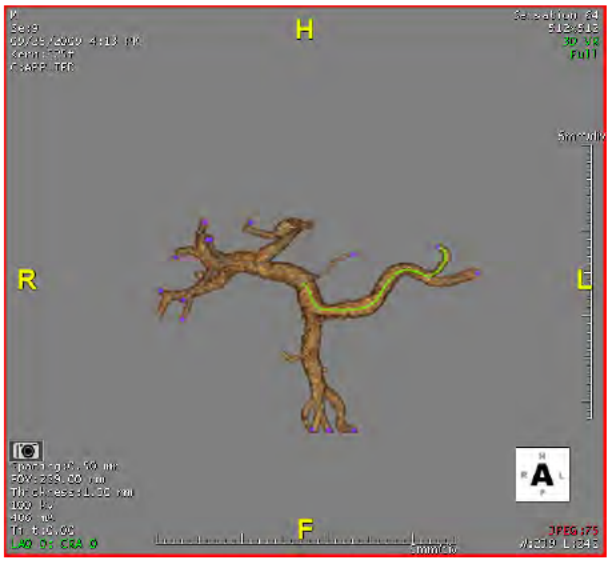
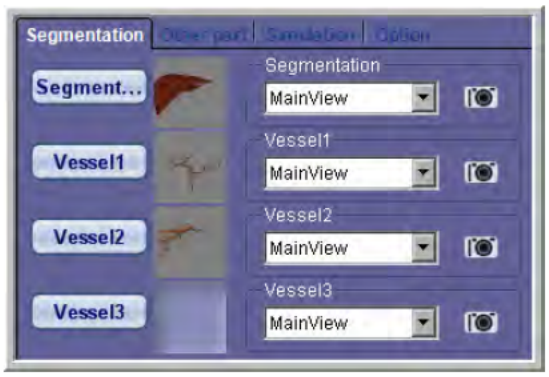


4. If needed, click on one or more other vessels and follow steps 1-3 for each vessel.

   At the end of the segmentation step, the tool panel should look like this:



Other Parts

This step allows you to segment and select other parts of the liver to be identified and measured separately. One example of this would be pathological tissue found in the the liver, such as a tumor.

1. Use one of the MPR images to find and identify the tumor in the liver. On the axial, coronal or sagittal MPR, scroll through slices until you can see the tumor.

2. Select **FreeROI** in the Tool Panel to draw a boundary around the tumor. In this example, the Volume ROI icon is used (see the following image).

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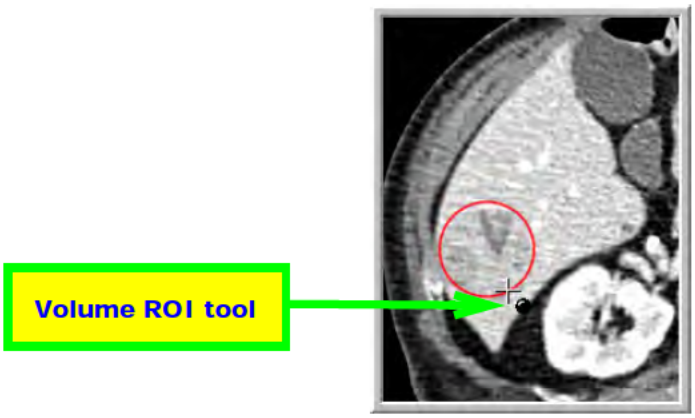
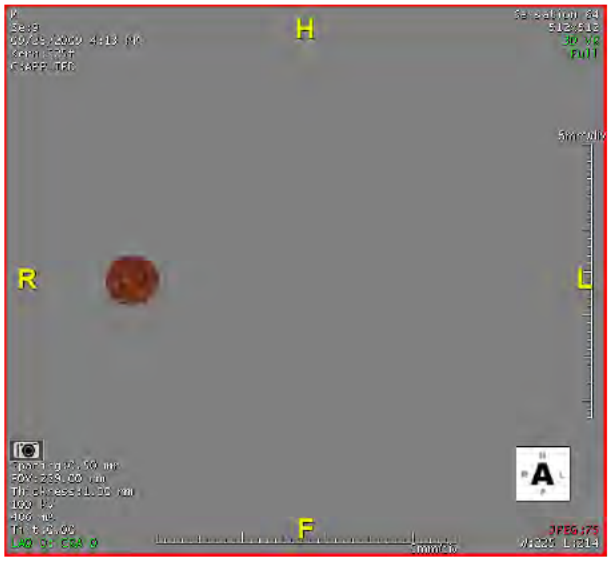
3. Press the shift key and drag the mouse across the tumor, so that a circle is drawn around the tumor:



4. Click **Select**. If the tumor segmentation does not appear in the 3D window, use W/L to darken the image.



5. Click the camera icon in the Tool Panel to capture the image. If desired, type in a name to capture in the input field before capturing.

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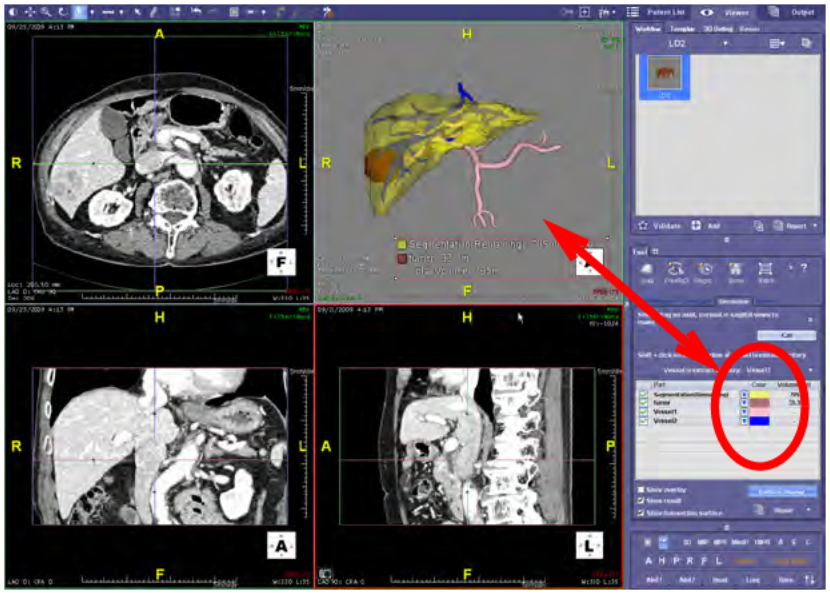
Simulation

Click the **Simulation** tab. The segmentation result image is displayed, along with a table in the tool panel, containing the name of each segmented part, the color mapping for each part and the volume of each.



Making a Cut

To make a cut, hold down the **Shift** key, and use the mouse to draw a line along the axial MPR image, so that the liver is divided into two parts: the cut part, which contains the pathology, and the remaining part.

Make sure that the line extends well beyond the boundaries of the liver, so that the cut will be made through the entire organ. It can be difficult to see where the boundaries are when looking at only one slice. The cut section should contain all of the diseased tissue.

The *transection surface*, a plane that cuts through the organ, is displayed in the 3D image. In Figure 2-44 on page 2-80, the smooth green side of the plane faces the part to be cut away, whereas the white mesh side faces the section that will remain.

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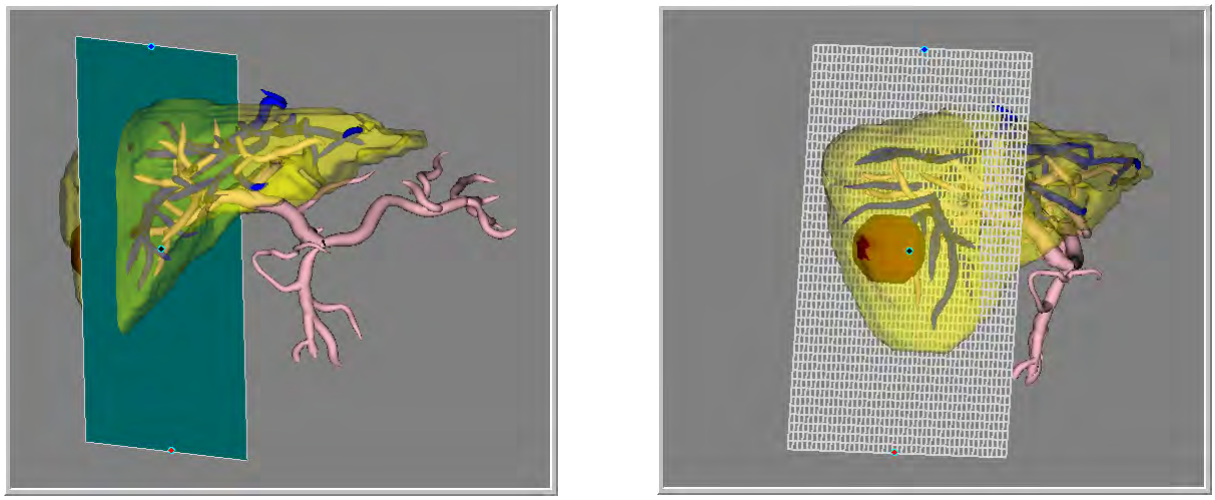

Figure 2-44: Transection Surface. Left: Cut Side; Right: Remaining Side

Note: Make sure the Show transection surface box in the tool panel is checked. (See "Other display options" on page 2-85 for more information.)

Manipulating the Transection Surface / Cut Line

There are several tools available for manipulation of the transection surface (in the 3D image) or cut line on the axial image.

Note: The transection surface is the 3D representation of the two-dimensional cut line drawn on the axial MPR. Any function performed on the transection surface is automatically applied, two-dimensionally, to the cut line, and vice versa.

- Changing the direction of the transection surface

  Observe that, in Figure 2-44, the cut side (smooth green) of the transection surface is facing away from the tumor. When this happens, you can reverse the transection surface so that it is oriented correctly.

  1. Right-click on one of the control points (dots located at the top, middle and bottom of the transection surface) of the transection surface to display a menu.

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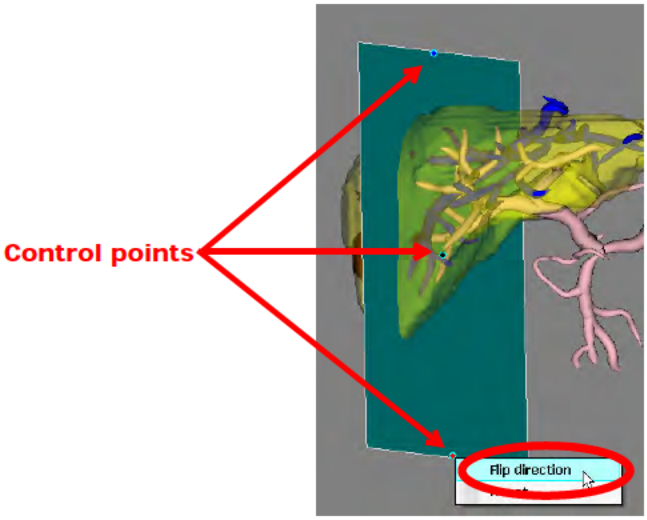

2. Select **Flip direction** from the menu.

You can also flip the direction of the transection surface from the axial MPR image. In the middle of the cut line, a short perpendicular line is displayed on the image, pointing toward the portion of the organ that is assumed by AQi to be *removed*. If this is incorrect, you can change the direction.

As with the 3D image, right-click on one of the end points or the middle point, and select **Flip direction** from the menu. Verify that the perpendicular line is now pointing in the correct direction.

- <u>Rotating the transection surface/cut line</u>

To rotate the cut line, click one of the end points. The cursor changes to a horizontal double arrow. Drag the mouse clockwise or counterclockwise to rotate it.

As the cut line is rotated, the transection surface is also rotated. You can rotate the three-dimensional surface around different axes by rotating the cut lines in the sagittal and coronal MPR images.

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- Panning the transection surface/cut line

  To pan the cut line, click the center control point (circled in the previous image). The cursor changes to a cross shape (see Figure 2-45 on page 2-82). You can then drag the cut line to the desired location.

  To pan the transection surface, click the control point in the very center of the plane, and then drag the surface to the desired location.

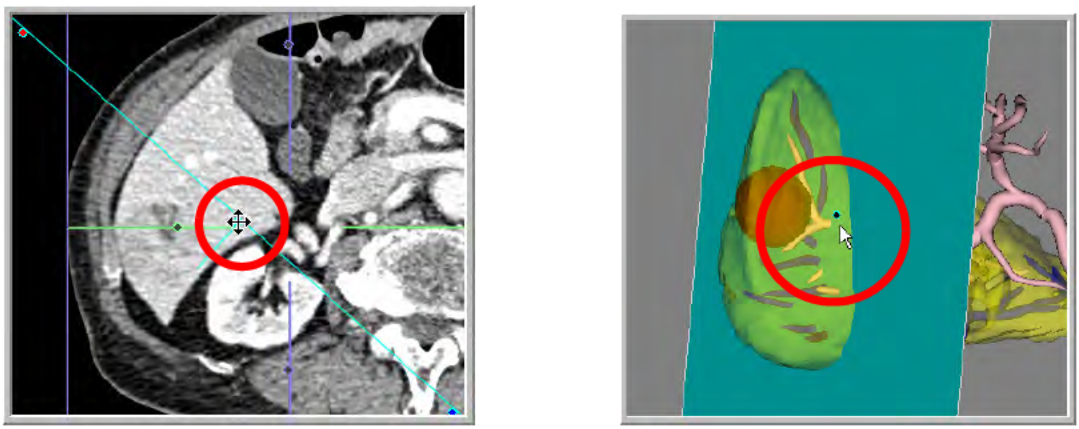
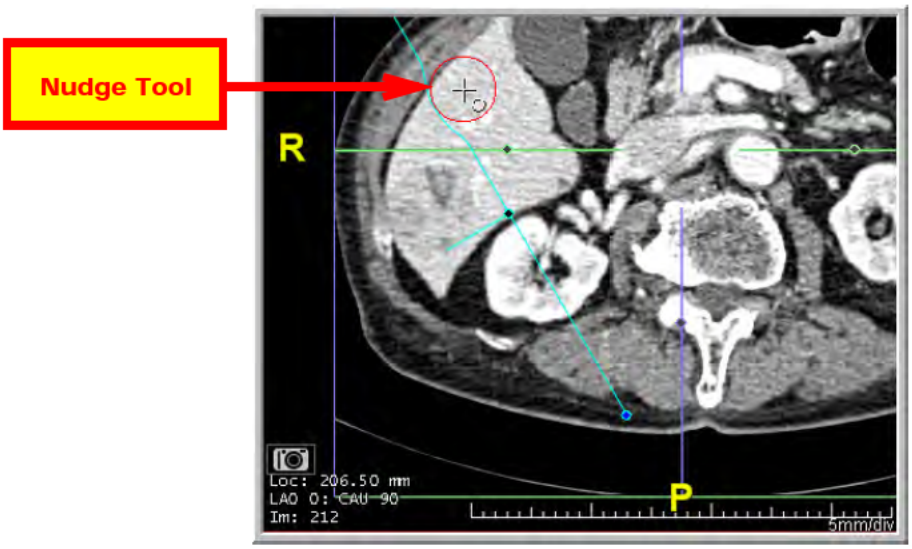


Figure 2-45: Left: Panning the Cut Line; Right: Panning the Transection Surface

- Editing the shape of the cut line and transection surface

  If desired, you can use the nudge tool to edit the cut line, and give it a curved shape more closely fitted to the diseased tissue. To do so, follow these steps:

  1. Hold down the **Alt** key and click on the image. A circle appears on the image (see the following figure).



  2. As you move the circle closer to the cut line, the cut line will bend in that place. Push the line toward the tumor.

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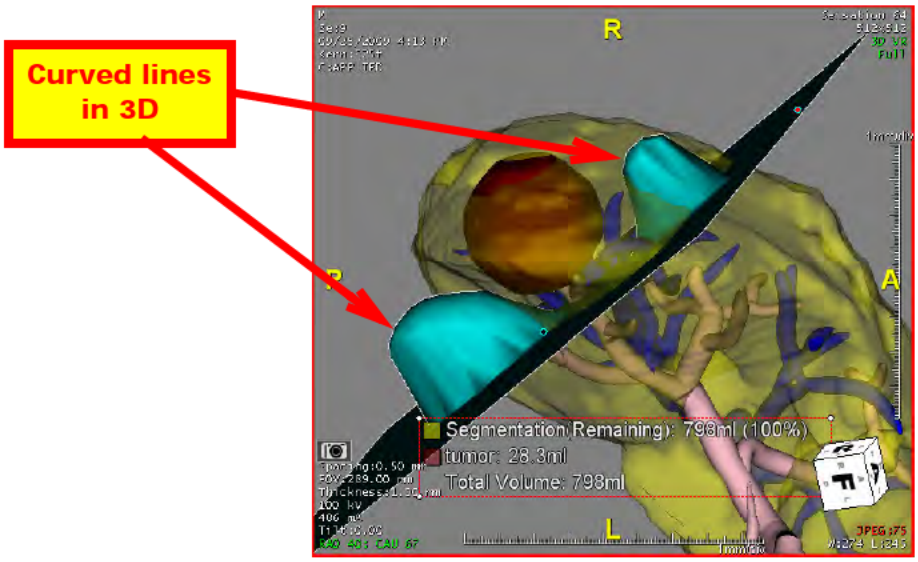
Note that when you click on the image close to the cut line, the circle is relatively small. The further away from the cut line you start, the larger the circle.

Curved lines on the axial MPR are represented in 3D as follows:



- <u>Deleting the cut line and transection surface</u>

  To delete the cut line, right-click on one of the control points and select **Reset** in the pulldown menu. This removes the cut line, the transection surface, and all work that has been done with them. You can then draw a new cut line.

Completing the Cut

Click the **Cut** button when finished.

The **Cut1** part is added to the colormap table in the Tool Panel. The default color is light blue. In the 3D image, the section of the liver that has been cut is overlaid with the same color. The volume of (See Figure 2-46 on page 2-84.)

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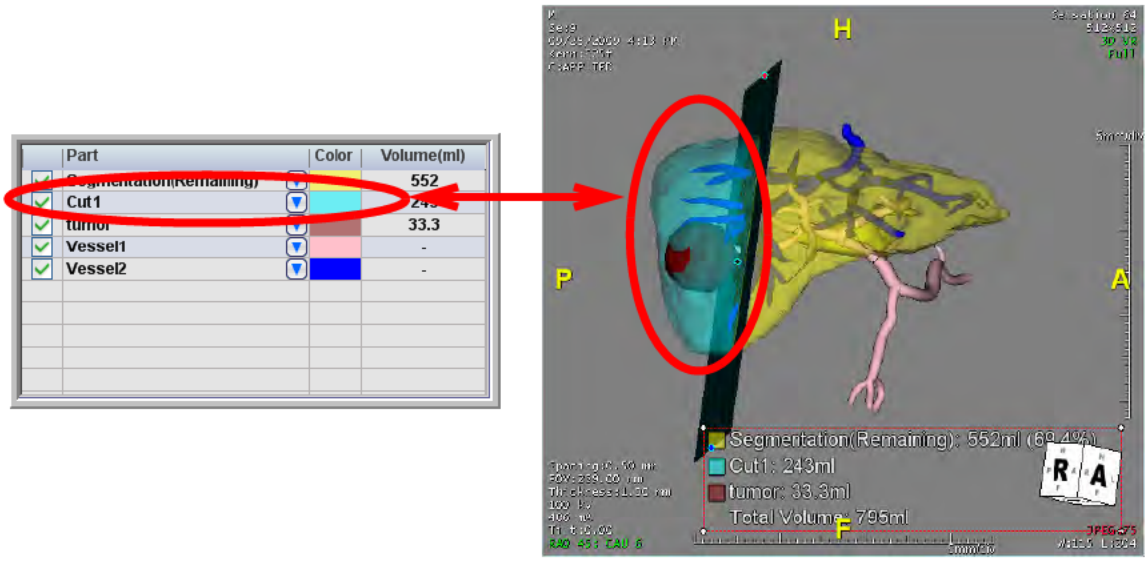


Figure 2-46: Color of Cut Region is Colormapped to Cut1 Color in Tool Panel

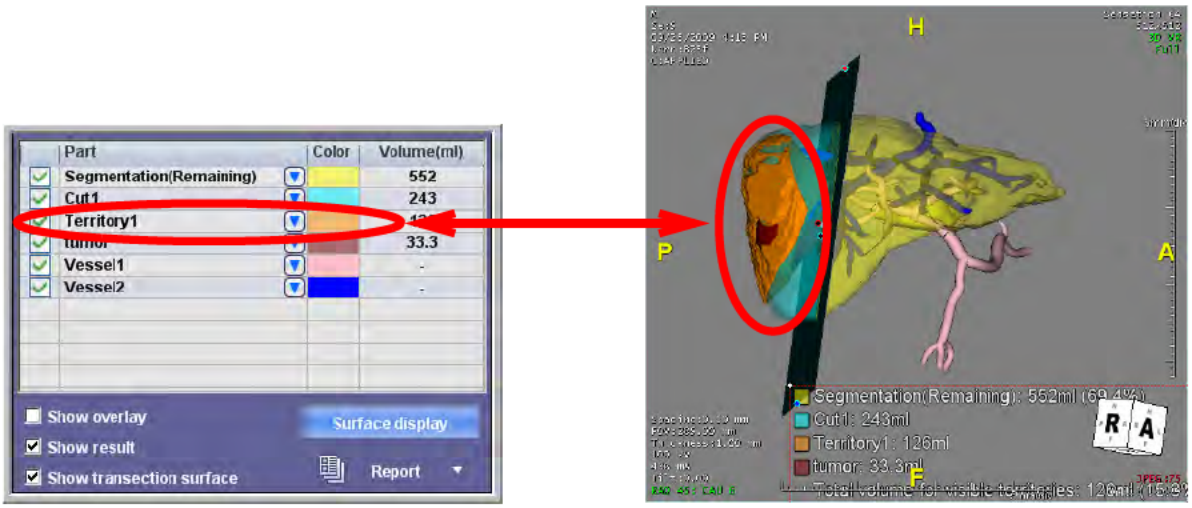
Vessel Territories

You can use the Territory mask to see which sections of tissue within the cut area would be affected by vessels that extend across the cut line and into the cut area.

To find the territory related to a vessel, do the following:

1. Press the shift key to make the vessel centerlines visible.

2. Click the centerline of any vessel that crosses the cut line. The territory of that vessel is masked in a color corresponding to the **Territory1** color in the color table.



3. Repeat this process for all vessels that cross into the cut area. Each new territory will be masked in a different color, and will have a separate entry in the segmented parts table.

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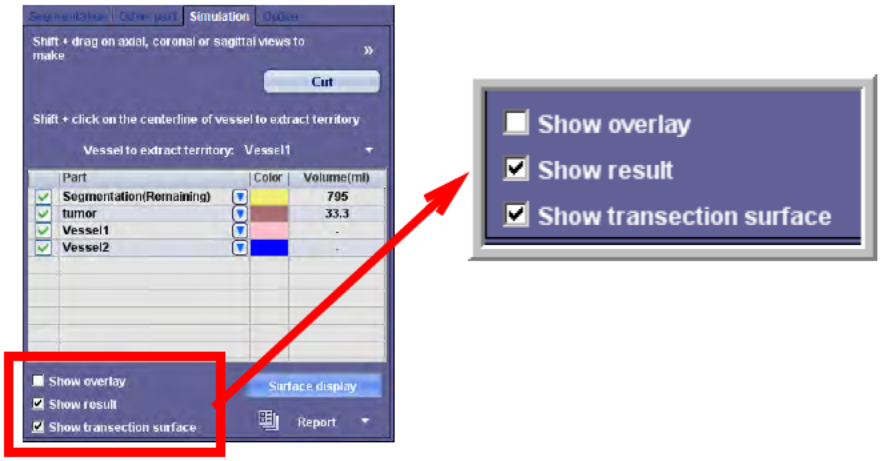
Other display options

In the bottom-left corner of the tool panel there are three options for displaying more information on the screen.



- **Show overlay** - Shows an overlay on the 2D images, whose colors are mapped to the segmentation list in the tool panel.
- **Show result** - Shows the volume information on the 3D image.
- **Show transection surface** - Shows the plane that cuts through the organ.

The Option Dialog

The Option dialog allows you to set parameters for part segmentation. You can do the following:

- Create Mask

  When you check the **Create Mask** box for a specific part, a mask is created in the 3D Settings tab from the segmentation of that part.

- Operate Mask

  Select **Operate mask** when you want the mask in the 3D window to change after a specific segmentation. You can then choose between:

  - **Clear**, which clears the mask that had been created for the segmentation
  - **Reverse**, which reverses the mask in the 3D window to show everything except the segemented part

- Mask Color

  Select a color and opacity value for each segmented part of the organ.

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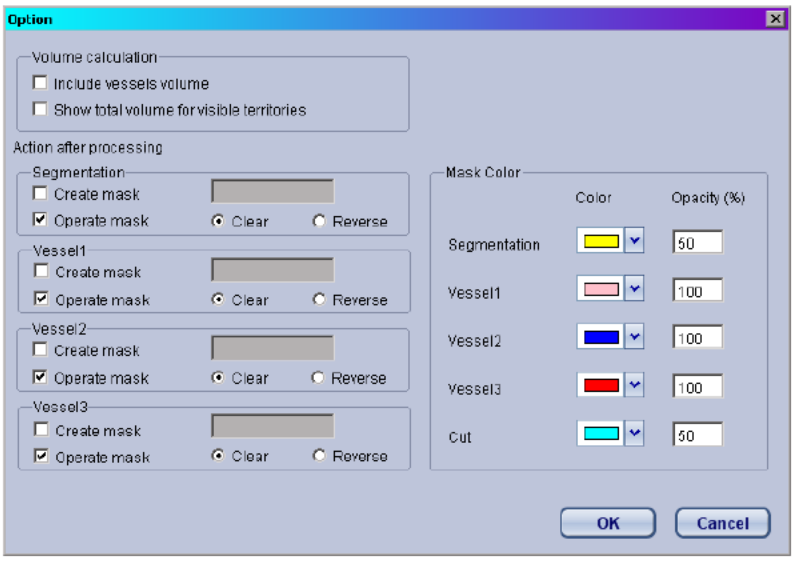


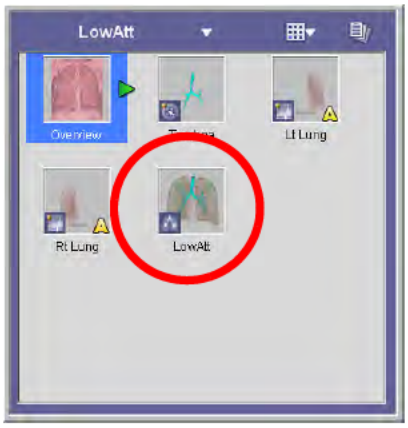
Low Attenuation Analysis

Automatic Segmentation

1. To begin Low Attenuation Analysis, open a low-attenuation study in the **LowAtt** workflow.

The study is loaded into the 3D Viewer using the **LowAtt** workflow

2. Click the final Workflow element (circled in the image at right). The **LowAtt** Tool Panel is automatically opened.



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3. Click the **Auto Run** button in the Tool Panel (circled in red, in the image at right).

   The LowAtt tool performs all the segmentation and captures. The volume of each segmented part is then calculated, and a segmented 3D image of the lung is built from the segmented parts.

   To see the volume results, make sure the *Show Result* button is active (circled in green at right).

The volume results are displayed on the 3D image:

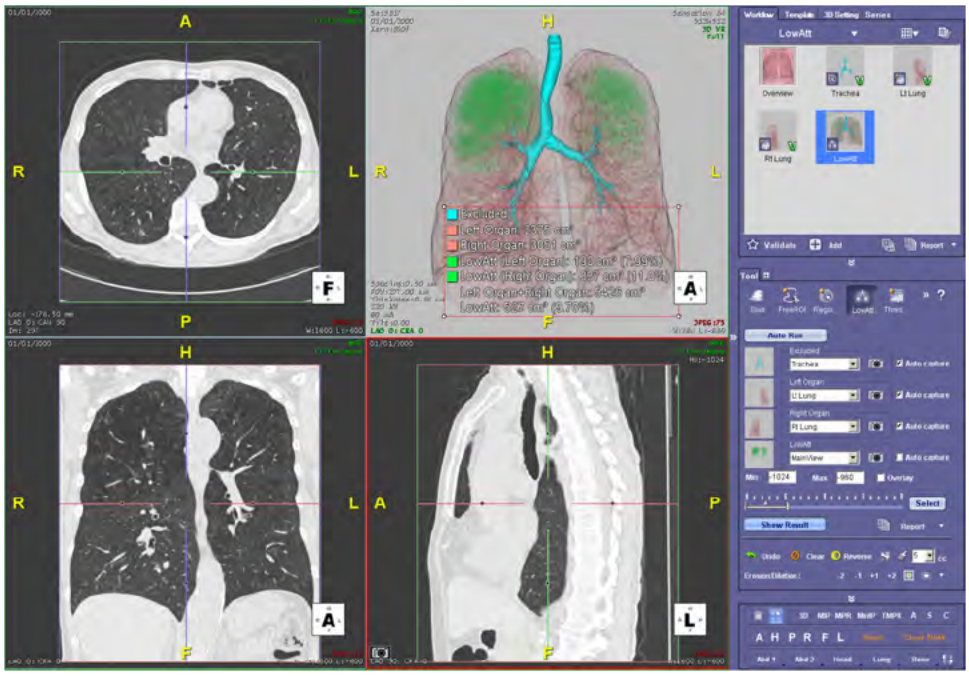

Figure 2-47: Completed Workflow

4. Check each segmentation and the final result. If they are satisfactory, the analysis is complete.

If there are any errors in the segmentations or if the results don't look right, you can do them over manually. For each part that contains an error, do the following:

1. Click the **Clear Mask** button to restore the original 3D image (see the following figure).

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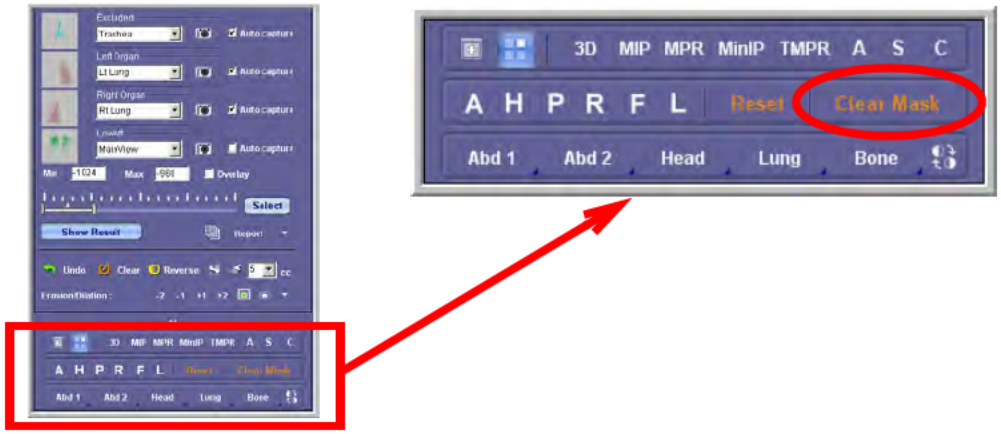
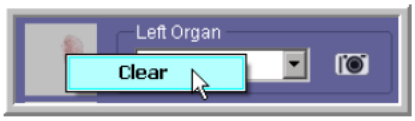


2. Using the **FreeROI** and **Dynamic Region Grow** tools as needed to isolate the part. (See "FreeROI" on page 2-36 and "Dynamic Region Growing" on page 2-40 for instructions on using each of these tools, respectively.)

3. When the part is displayed as a segmented image in the 3D window, click the **LowAtt** Tool Panel button.

4. Right-click on the thumbnail window of the part to be replaced, and select **Clear** from the menu.

5. Click the camera icon to capture the new image.



When finished correcting the segmentations, click **Auto Run** to recalculate the end result. When the dialog asking you whether you want to replace the thumbnail images, click **No**.

Manual Segmentation

Open a low-attenuation study in the **LowAtt** workflow. When the study has been loaded, click the **LowAtt** button in the Tool Panel to open the tool.

1. Validate the **Overview** workflow element. AQi automatically moves to the **Trachea** element.

2. Segment the trachea.

   - If there is an APS file of the segmented trachea, the image is automatically loaded.
   - If there is no trachea mask from APS, or if the APS segmentation was incorrect, segment the trachea manually:

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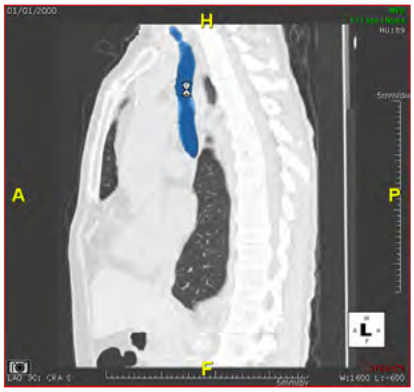
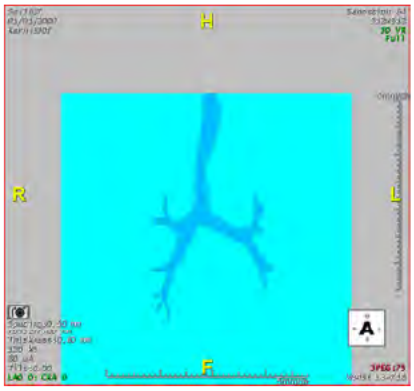
a. Click the **Region Grow** tool in the Tool Panel.

b. In the sagittal image, click and hold the left mouse on the trachea until the trachea is fully masked.





c. Click the **Select** button in the Tool Panel. The segmented trachea is displayed in the 3D window.

3. In the Tool Panel, click the camera icon on the first line to capture the segmented trachea image as a thumbnail (see the image at right).

4. Validate the **Trachea** Workflow element.

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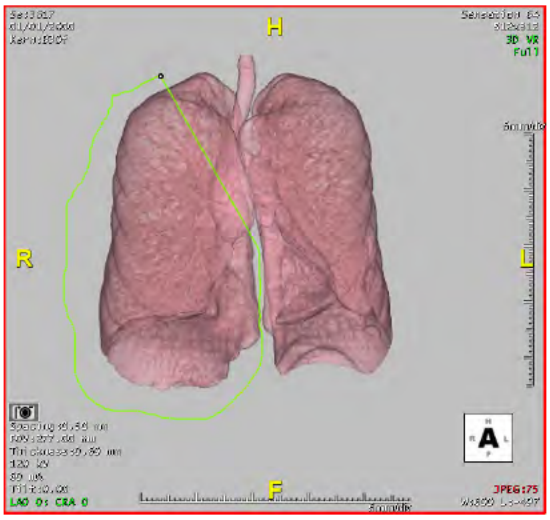
5. Segment the left lung.

   - If there is an APS mask of the segmented left lung, the image is automatically loaded.
   - If there is no left lung mask from APS, or if the APS segmentation was incorrect, segment the left lung manually, using the **FreeROI** and **Region Grow** tools as needed to remove the right lung. (See "FreeROI" on page 2-36 and "Dynamic Region Growing" on page 2-40 for more information.)



6. Capture the segmented left lung to a thumbnail in the Tool Panel (see the image at right).

7. Validate the **Lt Lung** workflow element.

8. Repeat steps 5-7 for the right lung.

9. When all three parts have been segmented and captured, click **Auto Run** (circled in red at right) to calculate the volume of each segmented part, and build a segmented 3D image of the lung. The volume results are displayed on the 3D image.

   Note: To see the volume results, make sure the *Show Result* button is active (circled in green).

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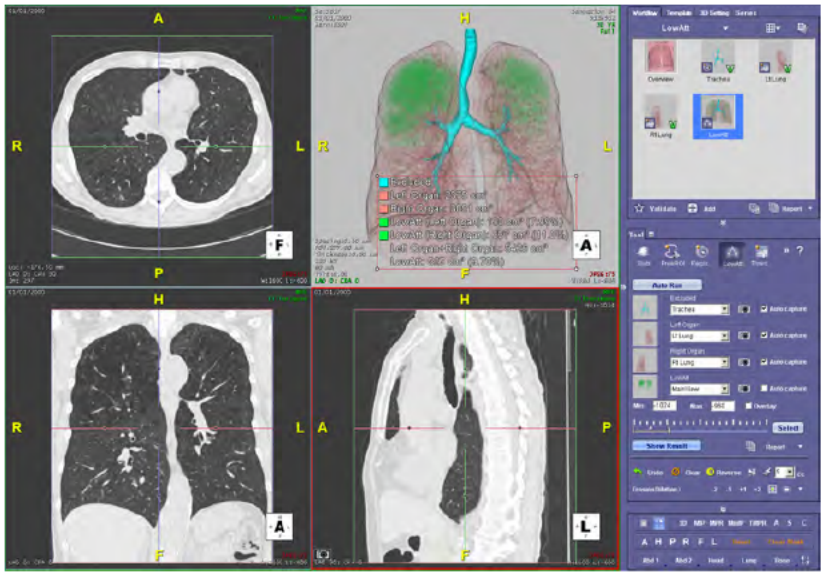


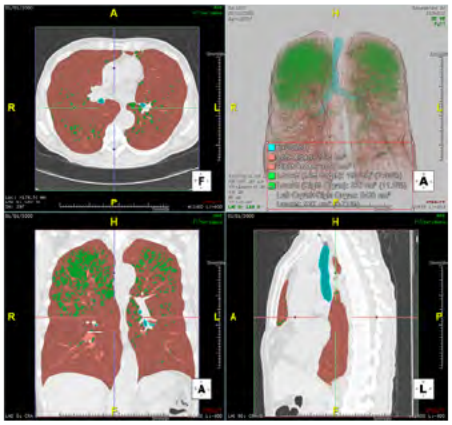
Figure 2-48: Completed Workflow

Other Features

- Click the mask overlay icon to see color overlay on the 2D images.

Note: The *mask overlay* icon is not the same as the checkbox labeled Overlay in the Tool Panel. The latter is used only to display a threshold overlay.

The Low Attenuation color overlay is shown on the 2D images:



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- Click the color squares in the volume results to show or hide the corresponding segmented parts in the 3D image. When a part is hidden, the corresponding color box is hollow.

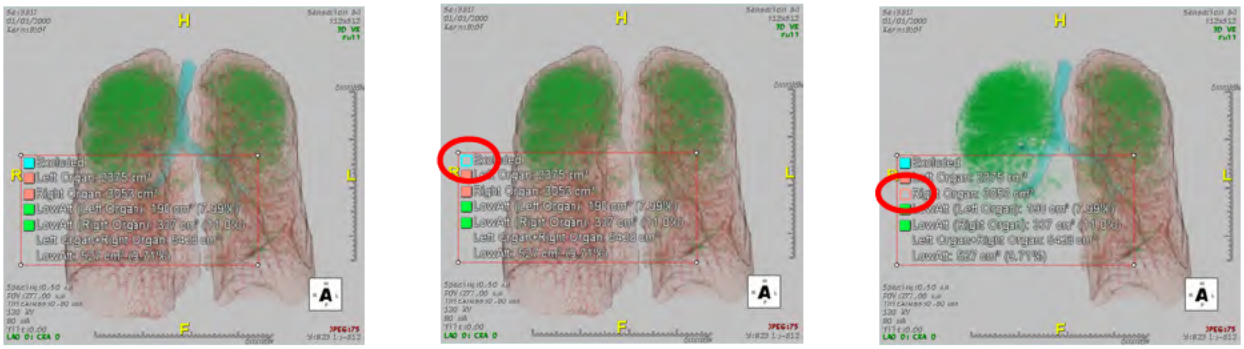


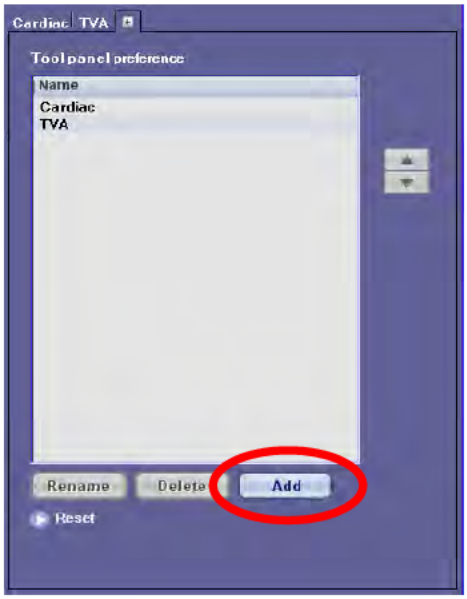
Figure 2-49: Left: All Parts Showing; Middle: Trachea Hidden; Right: Left Lung Hidden

Customizing the Tool Panel

You can create your own Tool Panels that each contain the tools used most frequently in different types of studies or workflows. To create a new tool panel, do the following:

1. Click the plus sign ('+') tab, located to the right of other tool panel tabs such as the Cardiac tool panel.

The Tool Panel Preference panel is displayed, as shown in the following figure:



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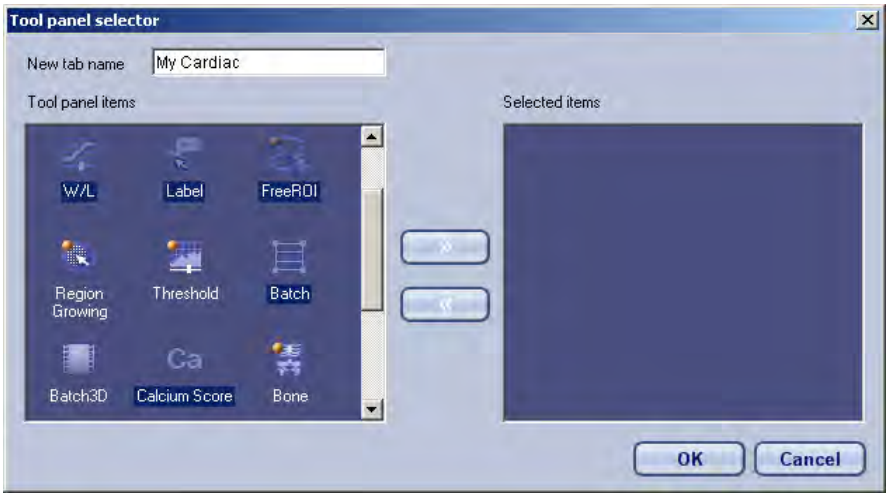
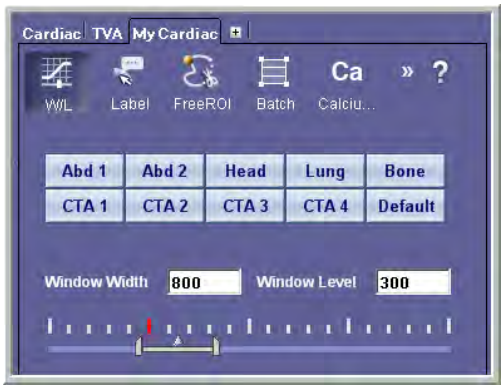
2. Click the **Add** button. The Tool Panel Selector dialog is displayed.



3. Type in a name for the new Tool Panel tab in the **New tab name** field.

4. Select up to five tools to be displayed in the tab.

5. Close the Tool Panel Selector by selecting another tab.



Note: All custom-created tool panels remain permanently in the Aquarius i*N*tuition 3DViewer, unless they are deleted.

Other Customizing Tools

Other functions of the Customizing tool include:

- Rename - Rename the selected tool panel. Select a tool panel from the list and click the Rename button at the bottom of the tool panel. (You can also rename by double-clicking the tool panel name slowly.)

- Delete - Delete by selecting a tool panel and clicking the Delete button at the bottom of the tool panel.

- Change Position - Move the position of a tab by selecting the name and then moving it up or down in the list with the up and down arrows located to the right of the list.

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- Reset - Reset the tool panel to an earlier state, either to what it was at the time of the most recent login, or to the default state of the 3D Viewer. Click the Reset button at the bottom of the tool panel.

Floating Tool Panel

The tool panel can be detached from the right panel of the screen so that you can move it to a more convenient location.

To float the tool panel, click on the the active tab in the tool panel and drag it in any direction.

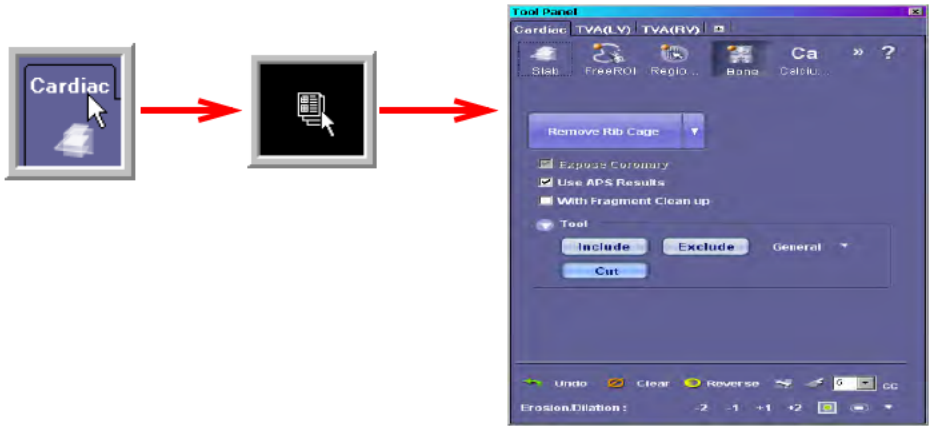

Figure 2-50: Click on Tab; Drag in Any Direction; Floating Tool Panel

To return the tool panel to its original position, click the **X** in the upper-right corner to close it.

Dual energy and multiKV applications

VEn(Siemens)(Workspace)

Right click on the study list to load Siemens dual energy data (140KV series and 80KV series) to VEn(Siemens)(workspace).

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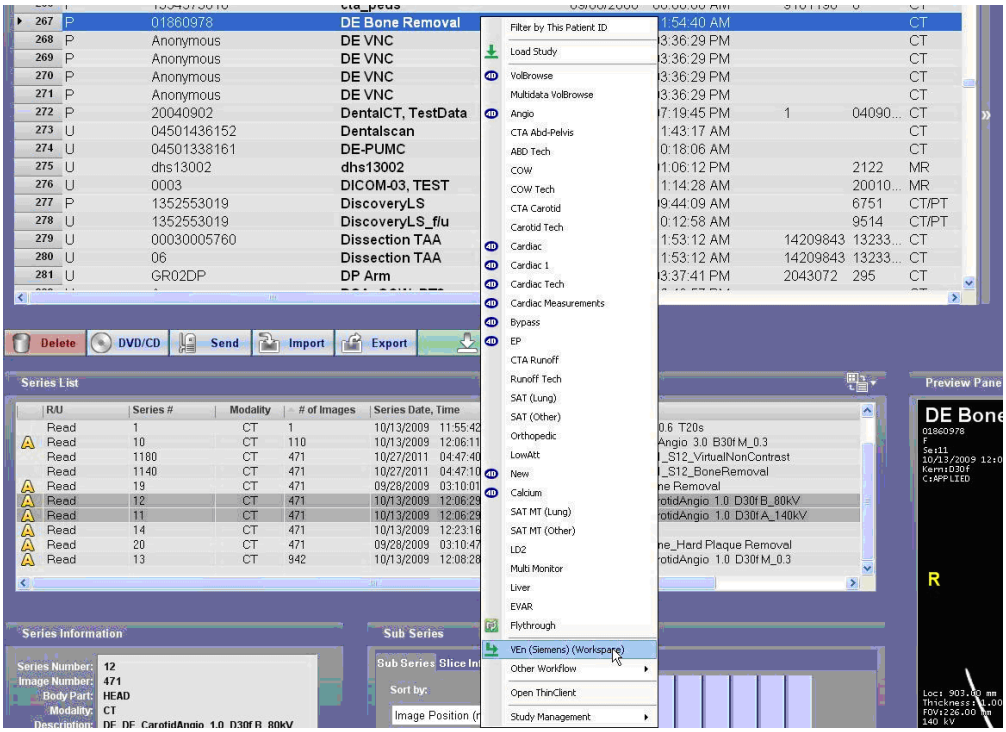

By default, the images show up in 3X1 layout with 80KV, 140KV and blended image from left to right.

Drag the slider bar on the control panel to change the display image to different blended percentage image in third column. The displayed image will change in real time when dragging the slider bar. The whole volume set will be changed to that percentage image when the mouse is released from slider bar.

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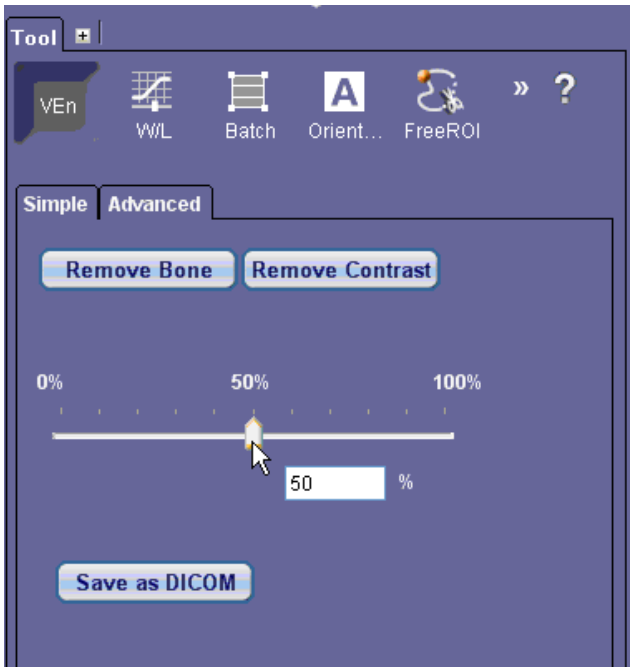

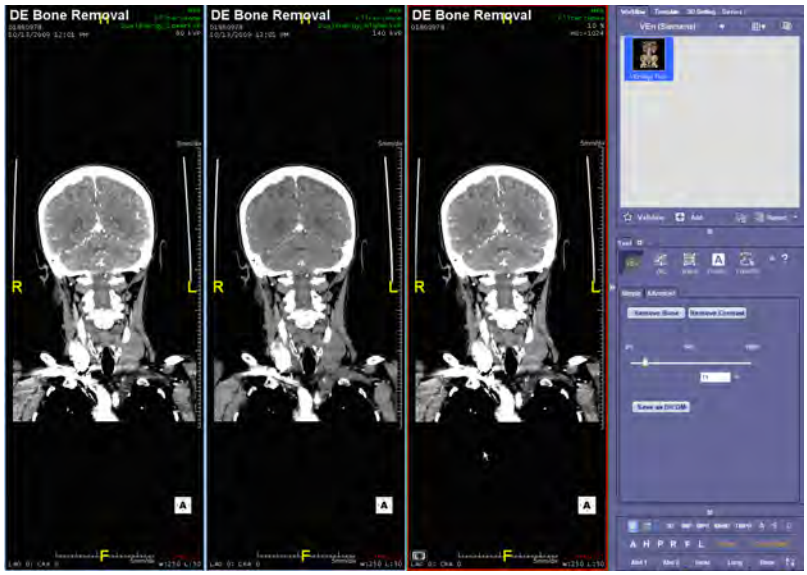

Click on 'Save as DICOM' to save the newly created volume set back to server as a new series.
Click on 'Remove Bone' to create the bone removal volume
Click on 'Remove contrast' to create the virtual non-contrast volume

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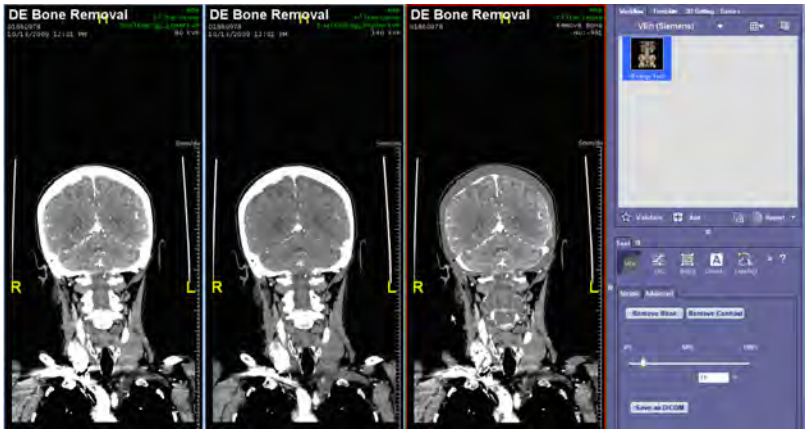
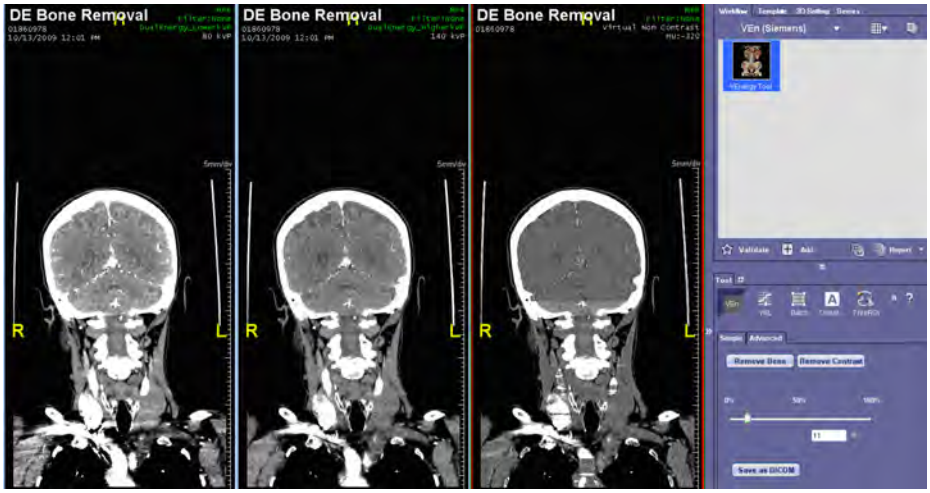
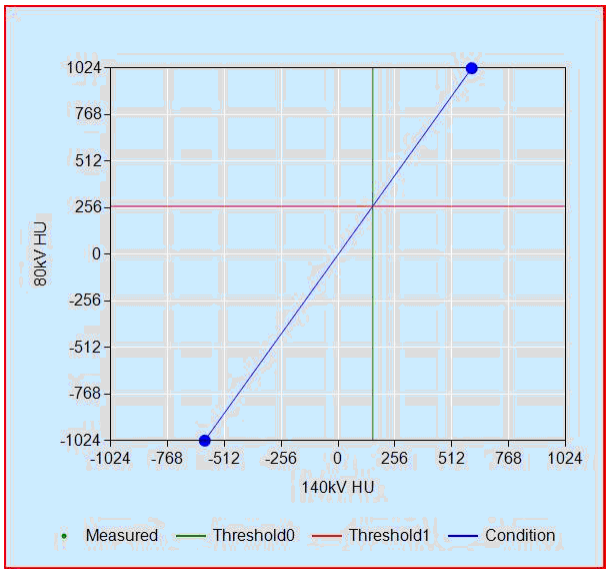




Click on 'Advanced' button to perform advance features for dual energy data.
Adjust the blue slider bar to separate tissues with different HU features based on different KVP scan.



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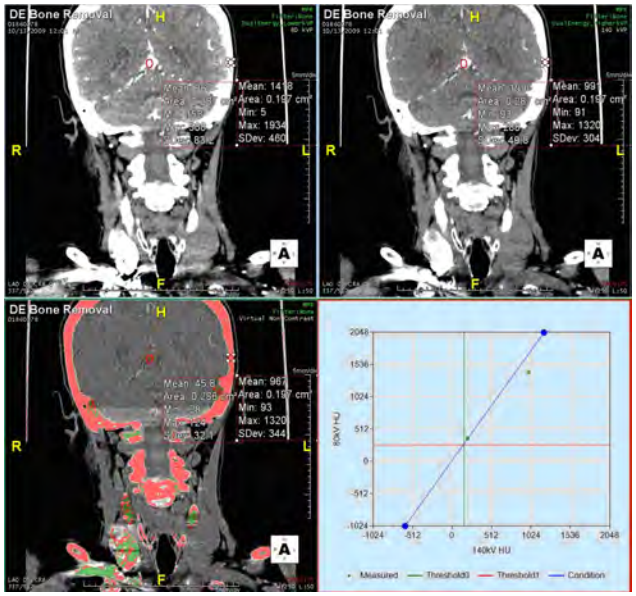
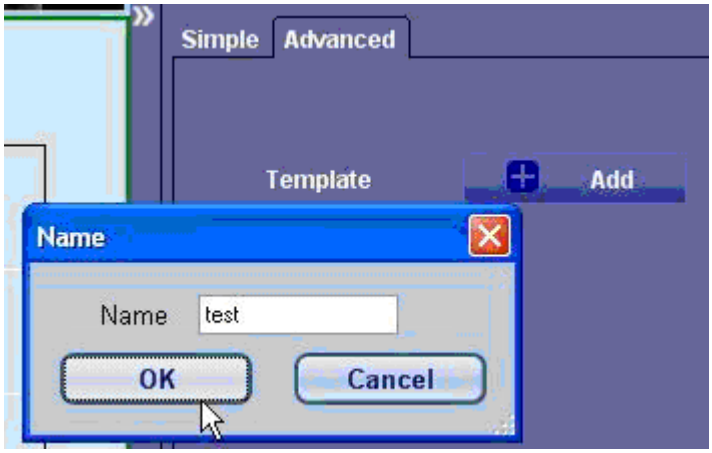
Click on measurement->ellipse (virtual energy) to draw ROIs on one of the image, measurements will show up on individual image. The reference image will show green and red color associated with the blue slider bar. The associated ROIs will also show up on the graph in small circles.



To save current graph as a template, click on 'add' button and give a name to the template.



To load a existing template, click on 'template' button then click on the template name. The reference image and graph will change accordingly.

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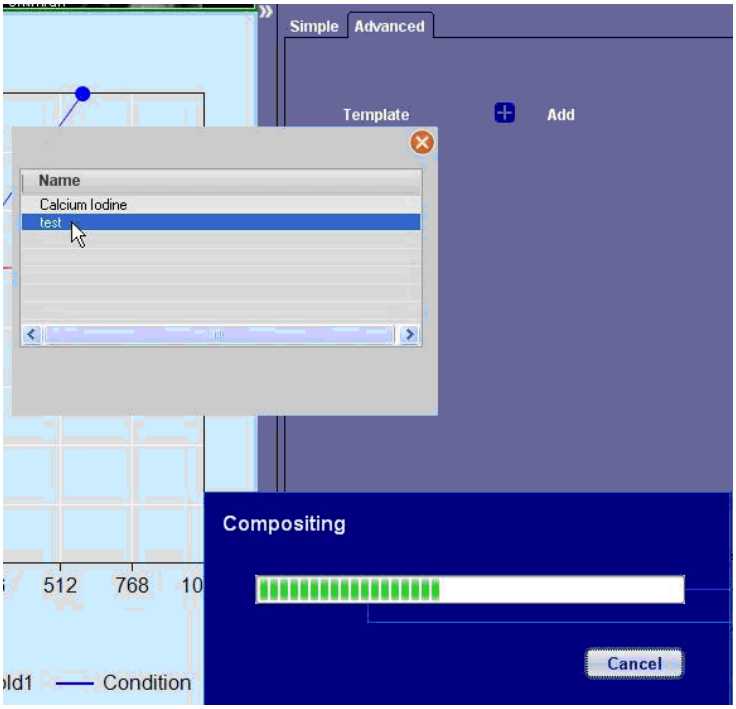

VEn(GE)(Workspace)

Right click on the study list to load GE MultiKV data (Dual energy(portal) series, APS Water Density series and APS Iodine Density series) to VEn(GE)(workspace).

Please note that the original data from GE does not have water density series and iodine density series. The data has to be sent to APS server to get these two series results in order to use this multiKV feature on AQi viewer.

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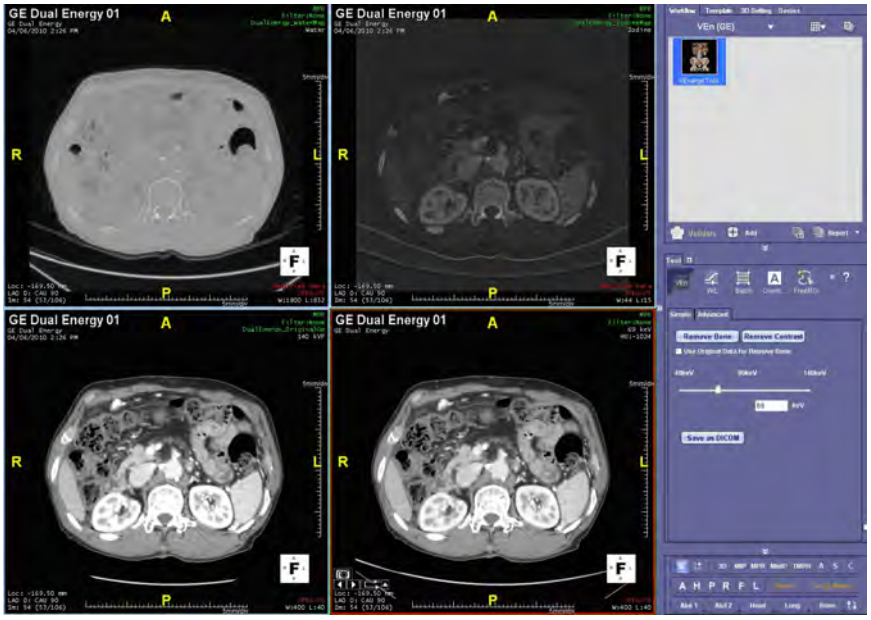
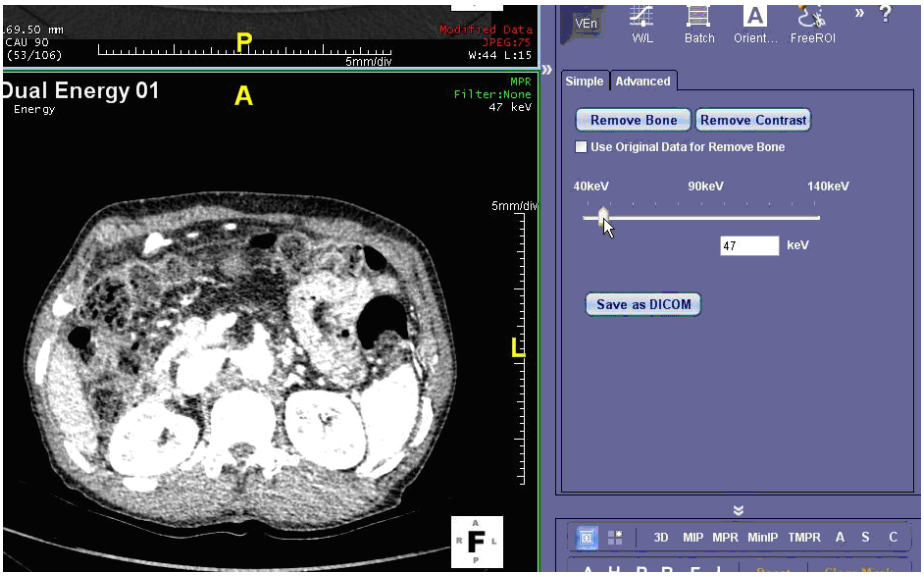
The images show up in 2X2 layout by default. Water map and iodine map are on the top and original image and mono energy image are on the bottom.





Drag the slider bar on control panel to change the mono energy image in real time. The whole volume will be changed to that energy scan after the mouse is released from the slider bar. Click on 'Save as DICOM' to save newly created mono energy images as a new series back to the server.

Click on 'Remove Bone' to create the bone removal volume
Click on 'Remove contrast' to create the virtual non-contrast volume. Check 'Use Original Date for Remove Bone' will use original data instead of water and iodine map for bone removal processing.

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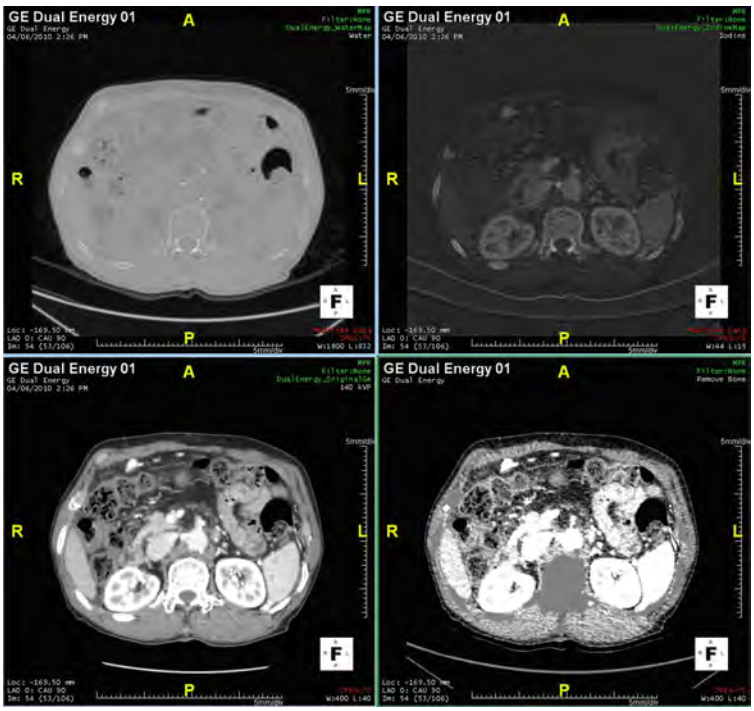

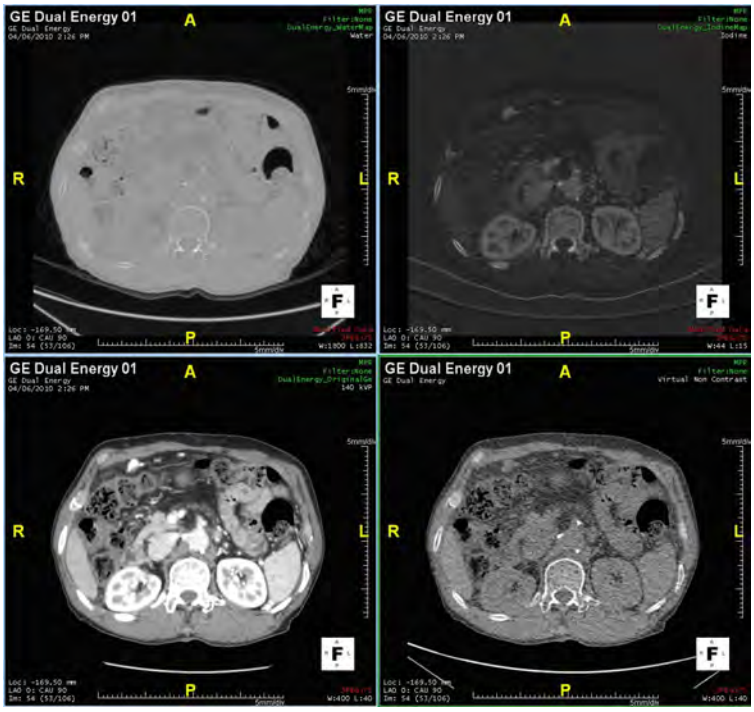

Click on 'advance' button. Bottom right image will change to blank graph.
Click on measure->ellipse(virtual energy) to do ROI measurements.
ROIs will show up on all three loaded images. a graph will show up indicate the HU different on different mono energy scans for the tissue within the ROI.

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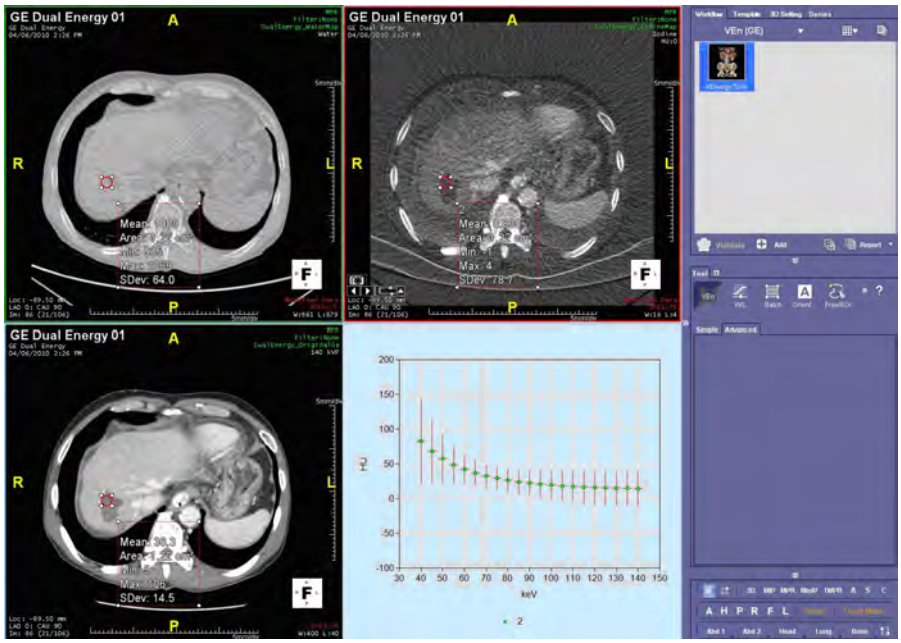
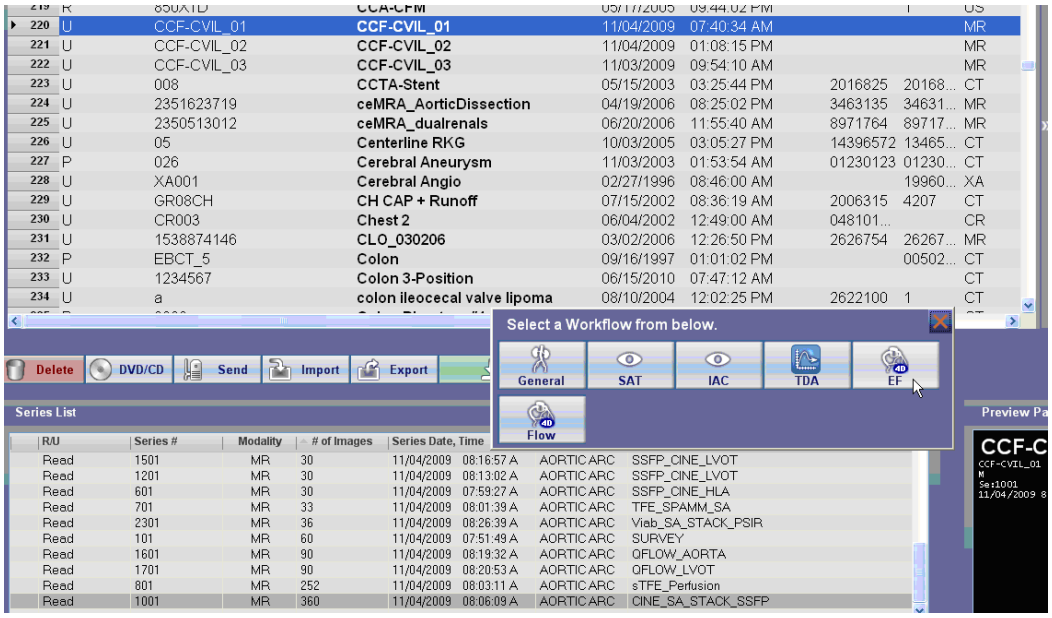


Cardiac MR

TVA(LV)

Highlight the cine series in cardiac MR data, click on 'load' then 'EF' button.



Default layouts show all slices images from the same phase. Adjust the threshold as needed. Click on 'play' button under 'Slice' to view different slice image. Click on 'play' button under '4D' to view the cardiac motion from different phases.

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

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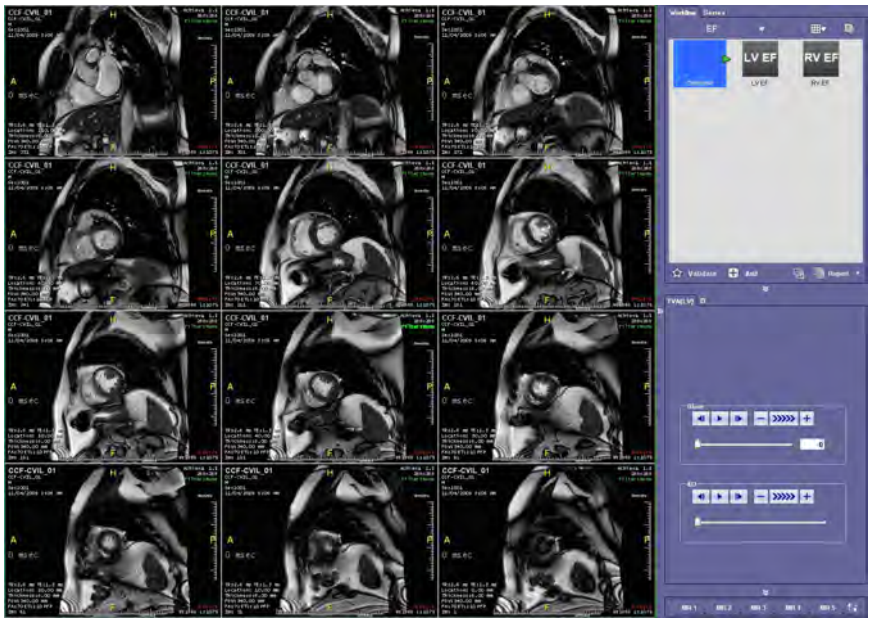
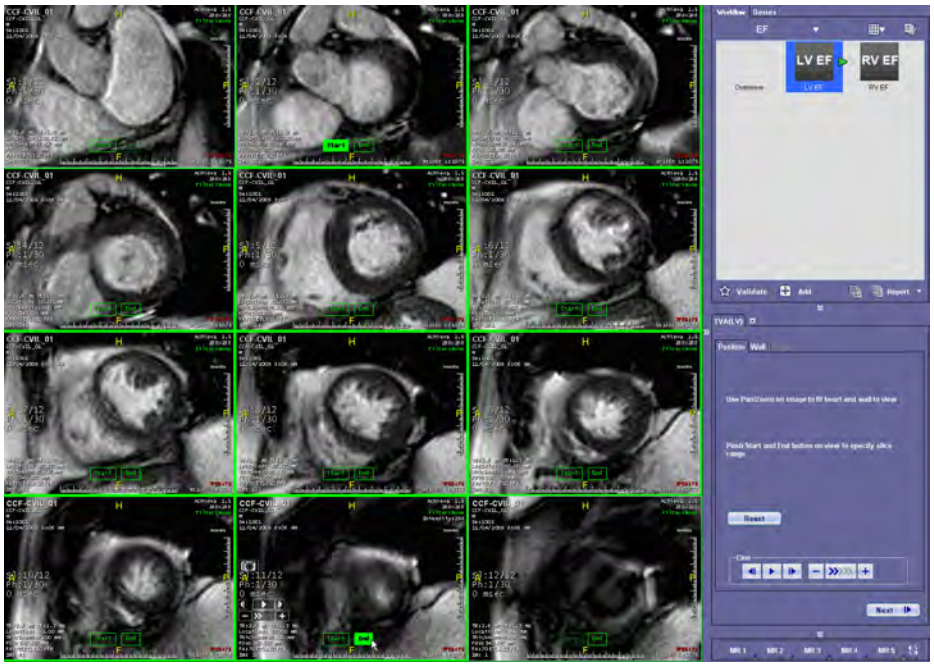


Click on 'LVEF' workflow element. Follow the instructions on the control panel to start EF processing.



Click on 'Play' button under 'Cine' to preview the images. Click on 'Next' button to continue EF processing.

Reselect 'End-Diastole' or 'End-systole' phase if the software did not select them correctly.

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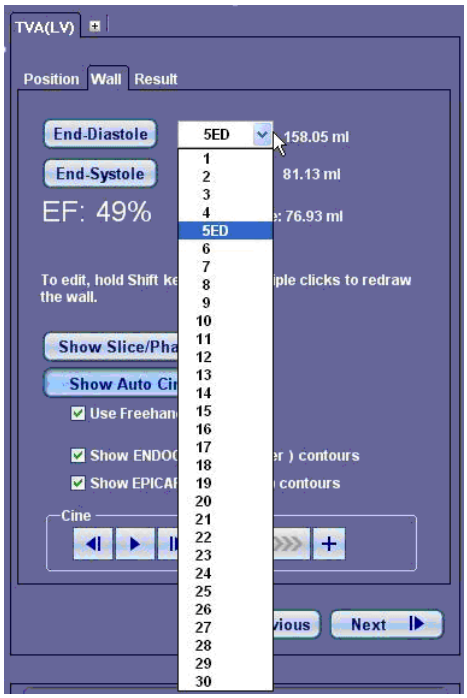

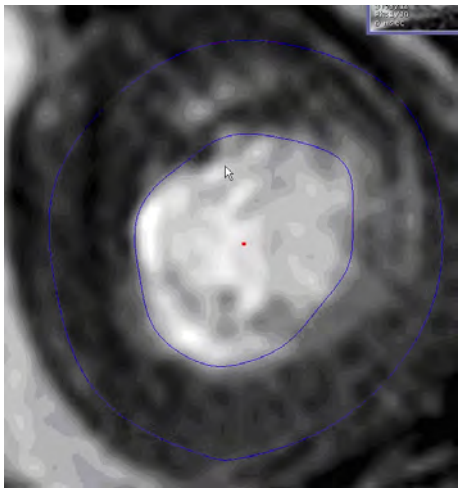

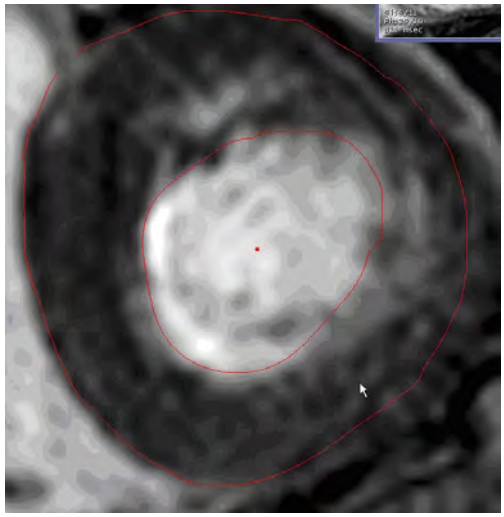

Hold shift key to edit the inner or outer contour as needed. Check 'Use Freehand Editing' will change the edit mode from dots to free hand. After editing, the contour color will change from blue to red.

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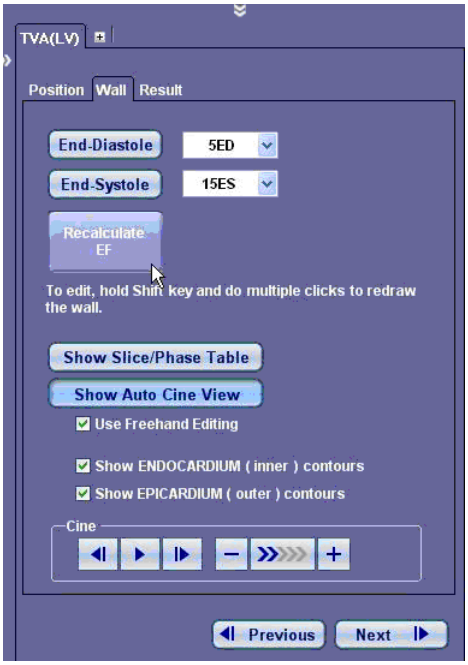
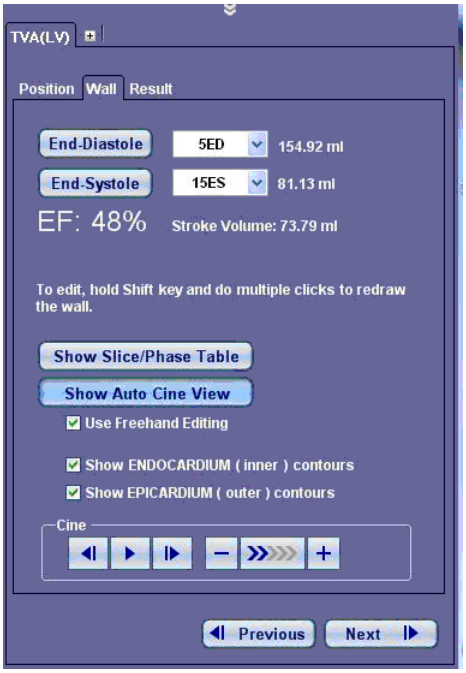
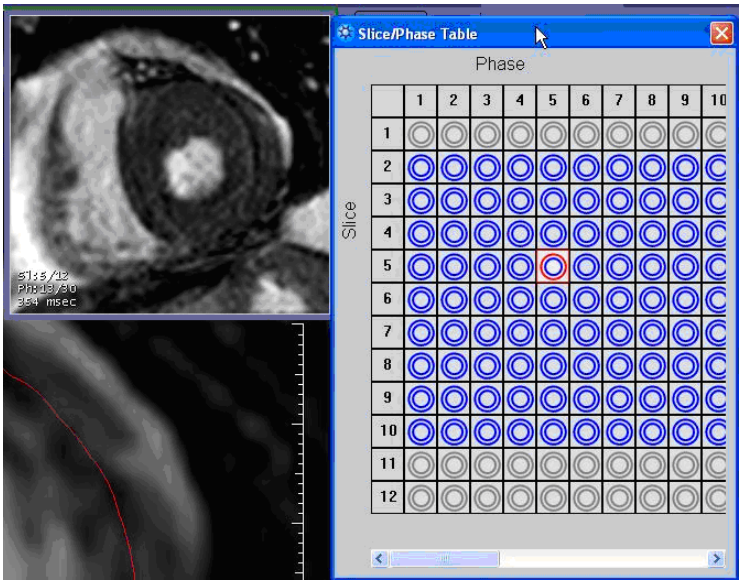




Click on Recalculate EF after editing, the EF will be updated.

Click on 'Show Auto Cine View' to see the Cine image on top right of the main window.
Click on 'Show Slice/Phase Table' to see the current image definition in the whole volume.



Click on 'Next' button to show the result images and result table. Input Height, Weight and heart Rate and click on 'update' to get more parameters displayed.

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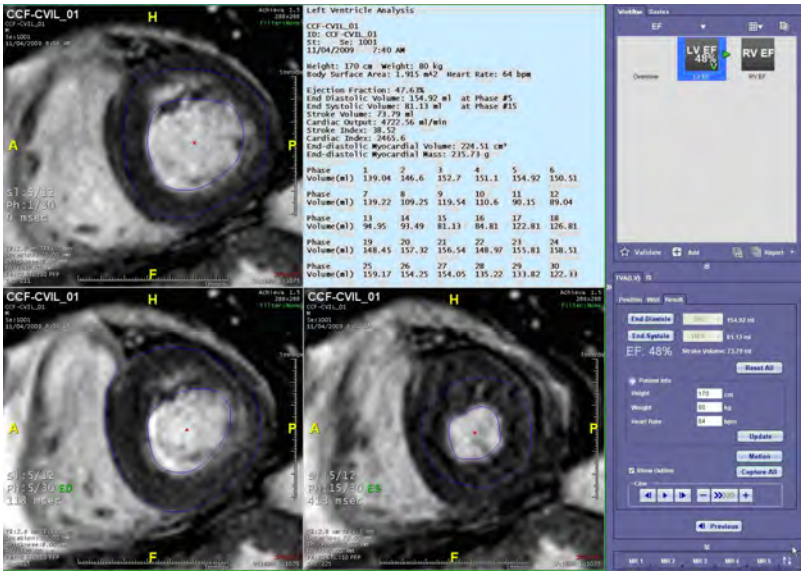
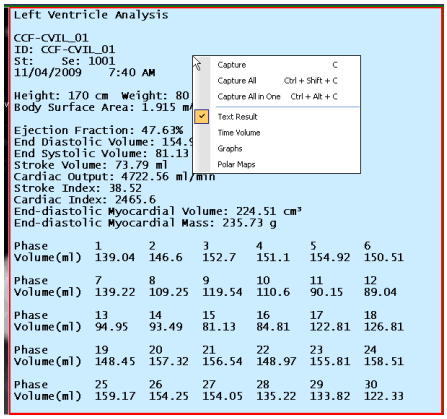
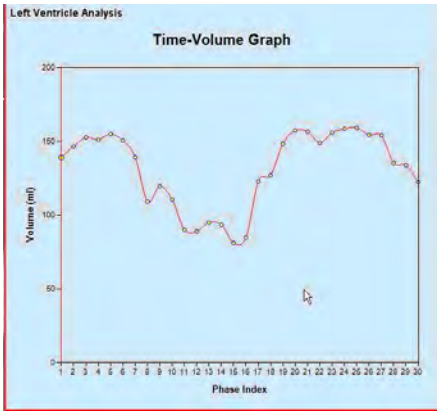
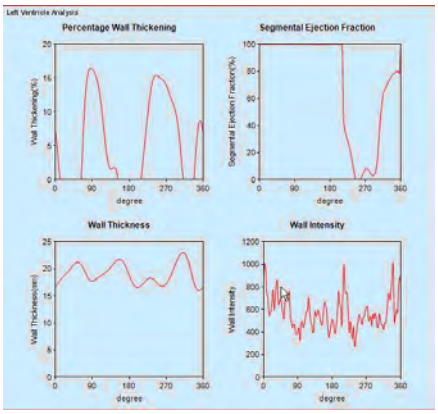
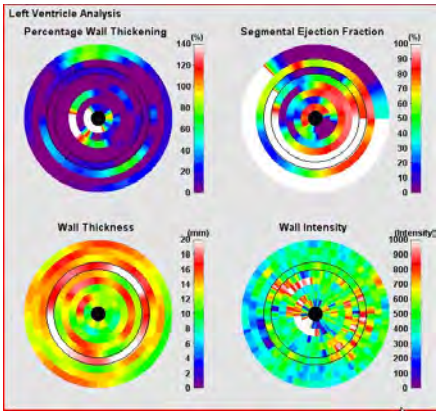


Right click on the result image to change to other displays similar to CT data.









Click on Motion to see motion images in systolic and diastolic phase.

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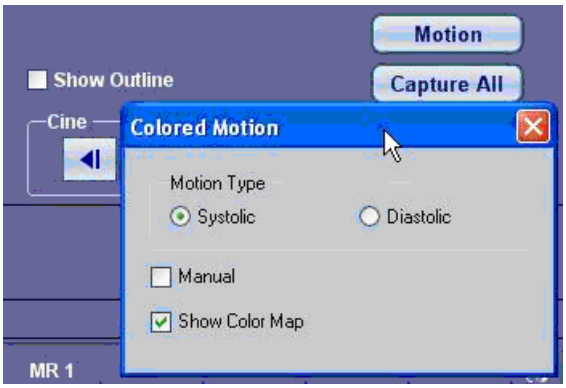

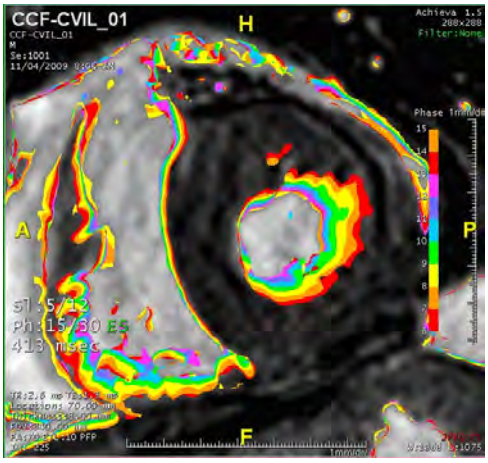

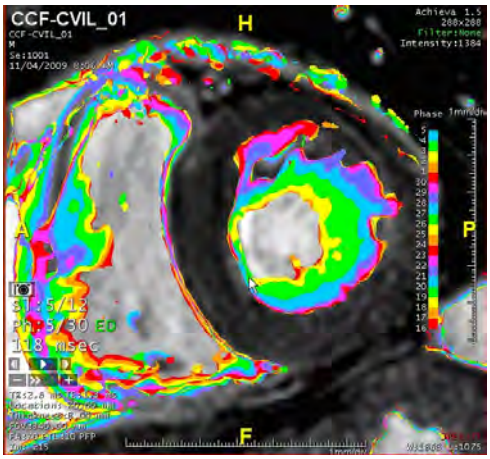

TVA(RV)

Click on 'RV EF' workflow element. If you have done the LVEF, when you click on RVEF, the software will detect RV contour for you automatically. If the contour does not look good to you, click on 'position' tab to start over. Follow the instructions on the control panel to manipulate the images then click on 'next'.

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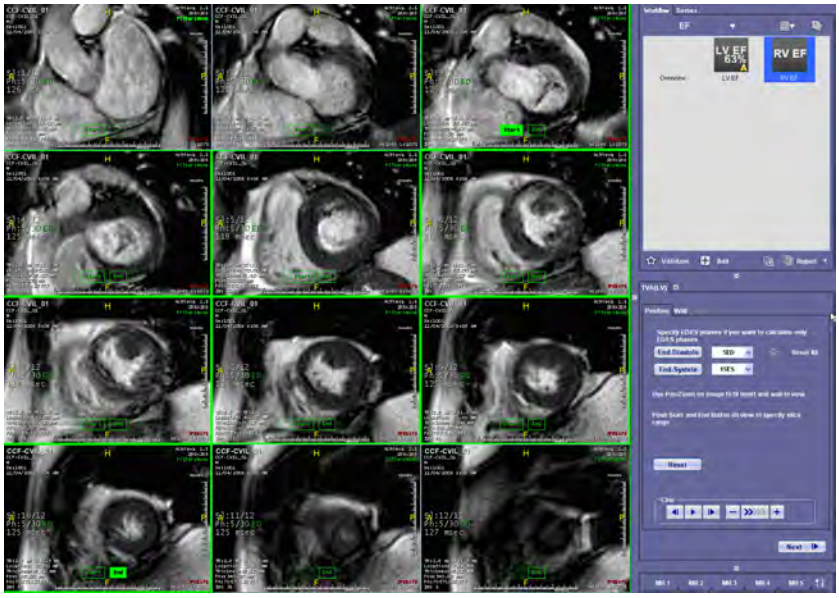
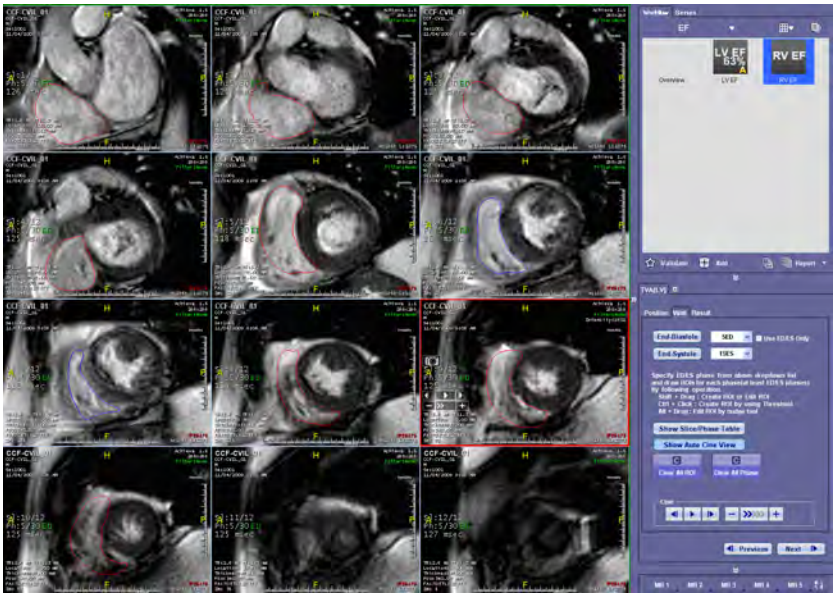


If the ROIs are not good, edit the ROIs as needed follow the instructions on control panel. Click on 'Next' when finish.



Input patient information to get more parameters. use Motion features the same as LVEF.

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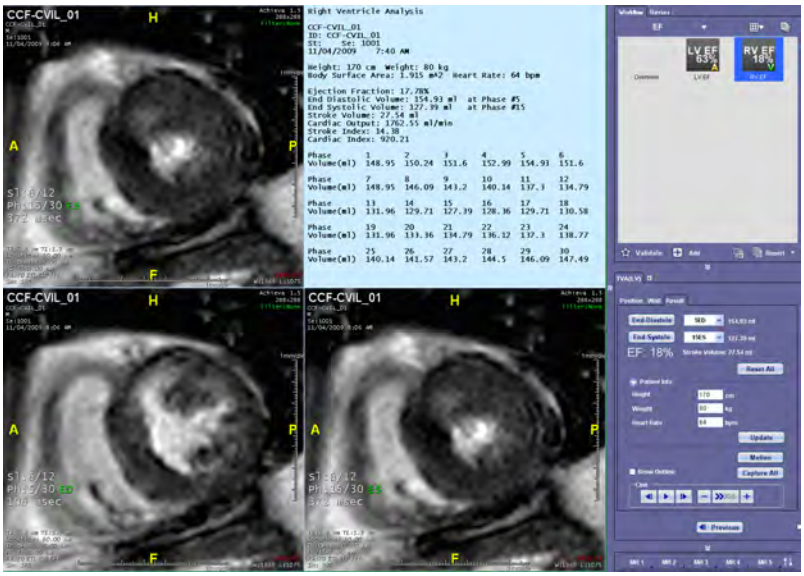

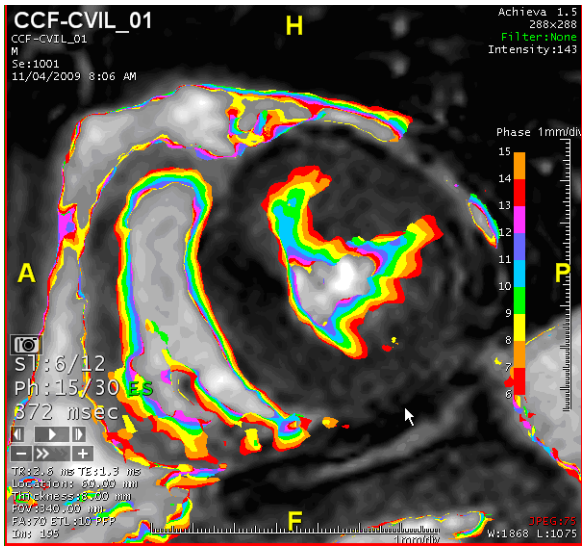

Flow

Highlight the flow series from the cardiac MR data then click on load->Flow.

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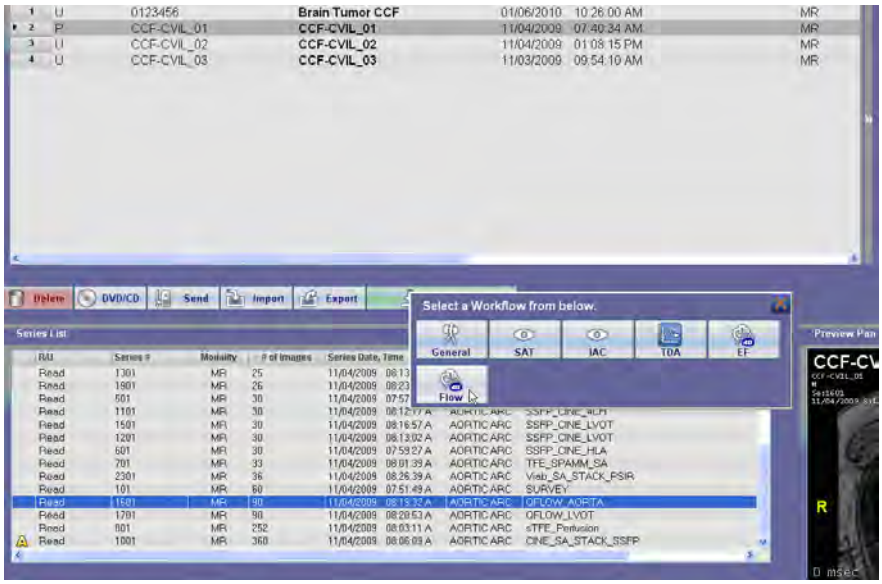
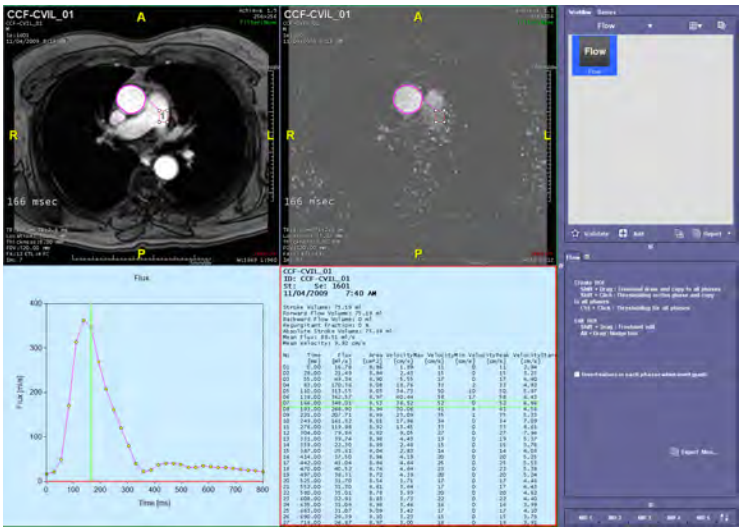


Draw ROI on the anatomic data follow the instructions on control panel. Edit the ROI as needed. The measurements will be displayed instantly.



Right click on the graph to reverse it.

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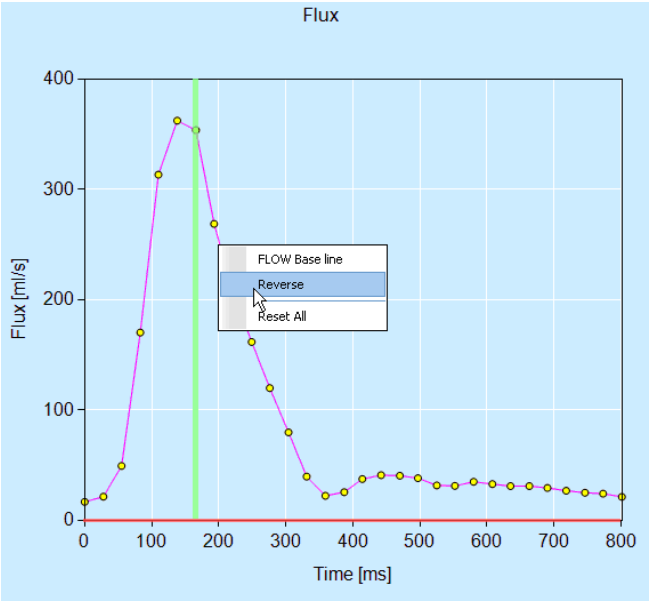

Finding viewer

Select baseline data and click on load->SAT MT(Other).

The data loaded in 1X2 layout with axial image on top and coronal image on bottom.

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

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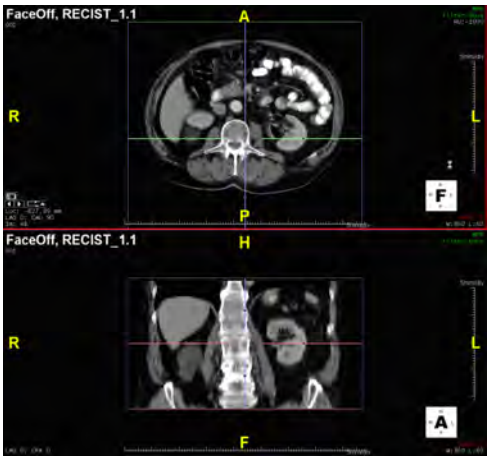
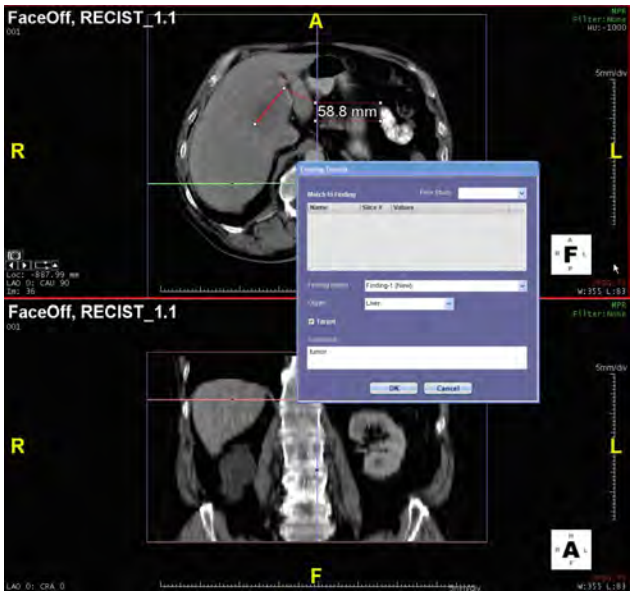


Slice through the data and find the lesion. Do distance measurement , 'finding details' window pops up. Input organ name and comment etc then 'OK'.



Click on finding viewer icon to open the finding viewer. You could see the finding just created.

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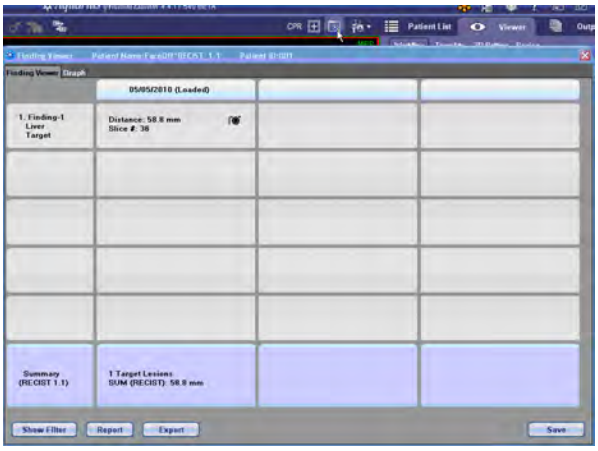
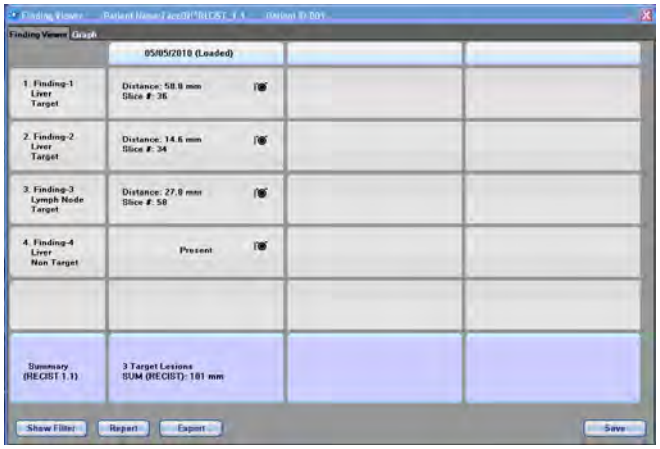


Do a few other measurements. They should all appear in the finding list.



Click on Save to save the measurement back to the database and save scene at the same time.
Go back to patient list and load the follow up study to the same workflow. Slice through to the first lesion position. Open the finding viewer and mouse hovers over the blank column next to the prior finding, you could see 'perform measurement' and 'mark as absent'. Click on perform measurement. Do a distance measurement, the 'finding detail' window pops up with suggested matched finding highlighted. If not correct, highlight different one then click on OK.

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If not sure which lesion it is, click on the camera icon next to the prior finding could bring up the image where the previous measurement wad performed.

Open 'finding viewer', you could see the new measurement is matched to the baseline study.

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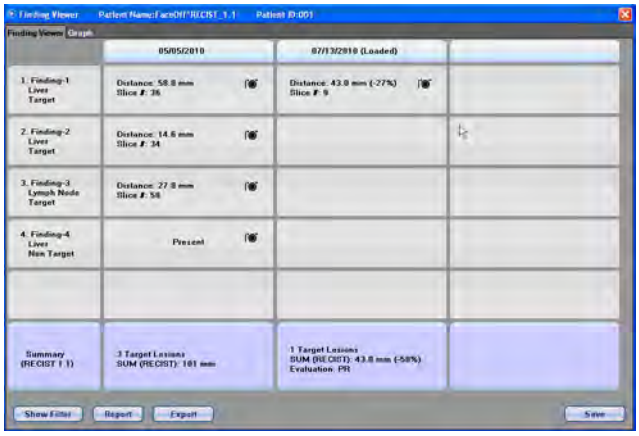
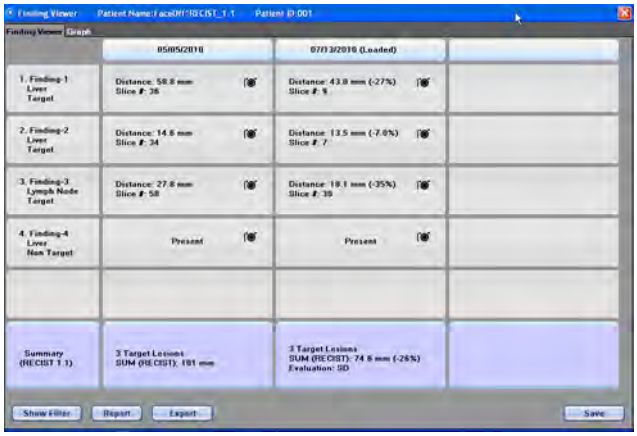


Continue with other measurements.



Click on 'Save' to save measurements and scene. Click on 'Report' to open the report.

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Report
AnyScan Medical Imaging Center
1234 Road Street
South Medical Plaza, AB 13240
Tel: 663-132-0231

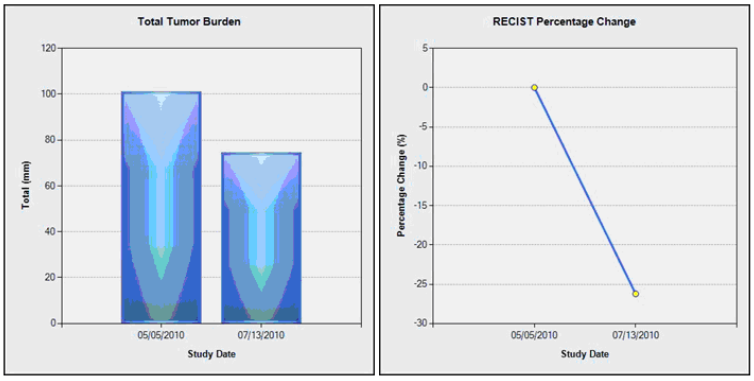
TERARECON, INC.

Patient Name:	[BETA] FaceOff^RECIST_1.1		
Patient Age:	81	Referring MD:	MIGPM3
Patient Gender:	M	Scan Date:	07/13/2010
Date of Birth:	01/01/1929	Patient ID:	[BETA] 001

Findings:

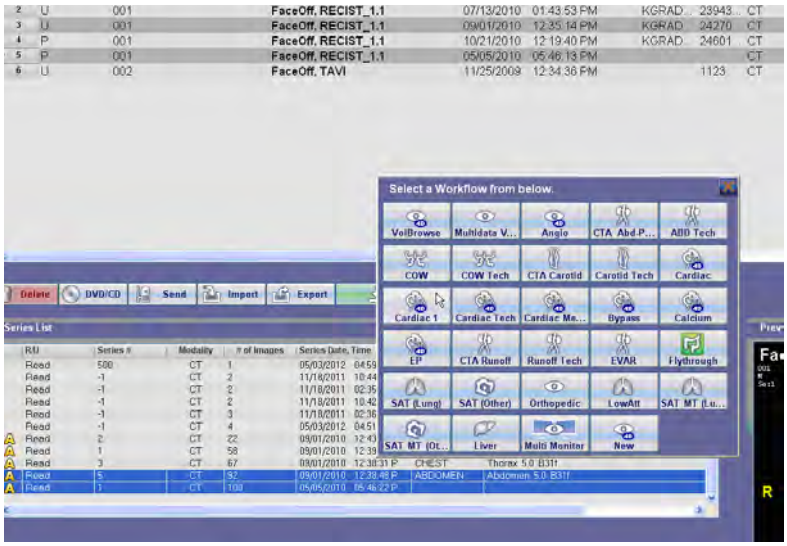
Name	05/05/2010	07/13/2010
Finding-1 (Target)	D: 58.8 mm (0%) Slice #: 36	D: 43.0 mm (-27%) Slice #: 9
Finding-2 (Target)	D: 14.6 mm (0%) Slice #: 34	D: 13.5 mm (-7.0%) Slice #: 7
Finding-3 (Target)	D: 27.8 mm (0%) Slice #: 58	D: 18.1 mm (-35%) Slice #: 30
Finding-4 (NonTarget)	D: 7.03 mm (0%) Slice #: 38	D: 6.61 mm (-6.0%) Slice #: 12
(Target)		
Summary	3 Target Lesions SUM (RECIST): 101 mm	3 Target Lesions SUM (RECIST): 74.6 mm (-26%) Evaluation: SD

Graphs:



Click on 'Export' to export the results to AIM file. Click on 'Show Filter' to filter the display with Criteria and type of measurements. Click on 'Graph' to see graph as above.

if user load baseline and follow up study together.



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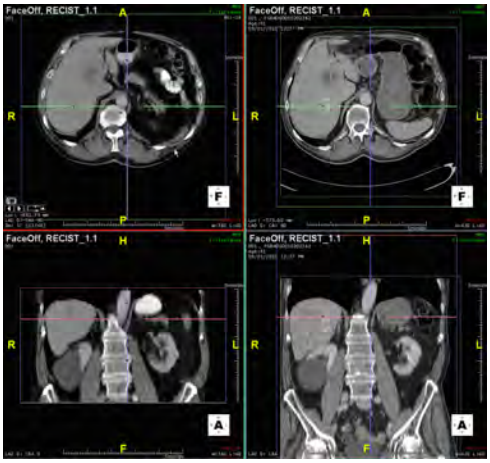
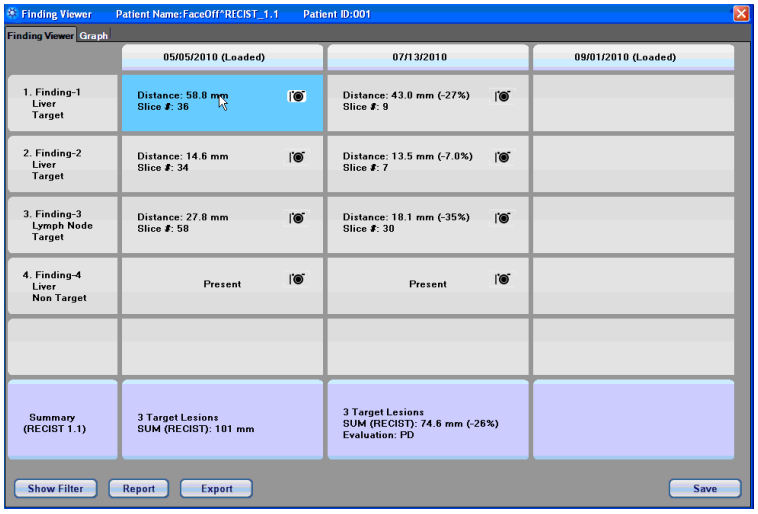
The images will show up side by side.



Open 'finding viewer' then double click on prior scan, both baseline image and current scan image will be switched to that measurement position.



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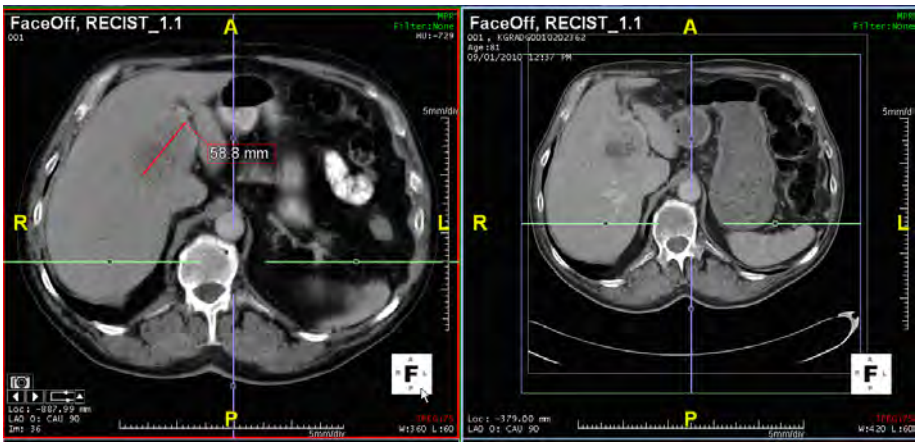
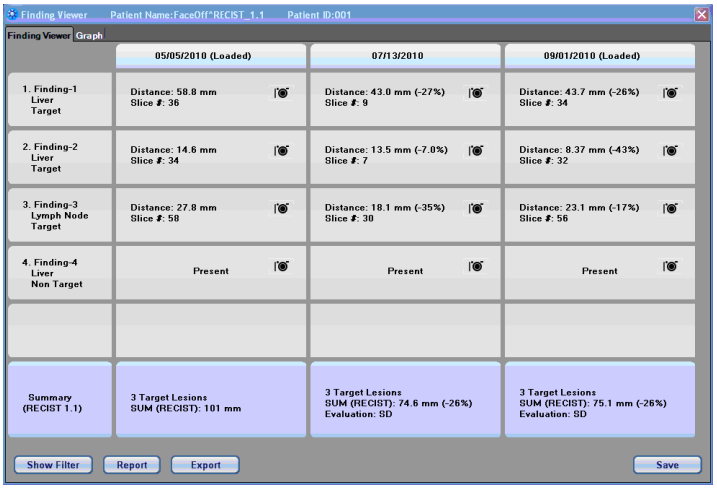


Slice through the current data if it is not on the right slice then do the measurement as previous stated. The 'finding viewer 'will be updated.



Click on the 'Save' button.

Top Bar Tool Buttons

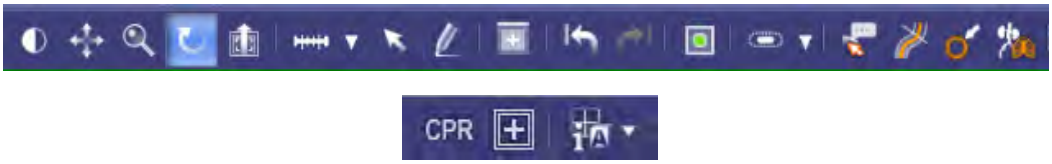


Figure 2-51: Top Bar Tool Buttons (Top: Left End; Bottom: Right End)

The Top Bar (located above the main 3D Viewer window) contains the following tool buttons:

Mouse Modes

Show or Hide Mask Outline

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Measurement Tools
Arrows and Labels
Window Layout Modes
Undo and Redo
Advanced Processing Functions
CPR
Save Scene
Display Annotations

Mouse Modes

The four main mouse functions are rotation, panning, zooming and window/level changes. To perform these functions, do the following:

- Rotate Image - hold down left mouse button and drag mouse
- Pan Image - hold down right mouse button and drag mouse
- Zoom In or Out - hold down middle mouse button and drag mouse up or down
- Window/Level - hold down left and right button together and drag mouse

If you use one of these functions more frequently than the others, you can change the function of the left mouse button by clicking one of the following buttons on the top tool bar:

In order from left to right, the buttons change the function mode of the left mouse button:

- Window/level
- Pan
- Zoom
- Rotate

Note: If you change the left mouse button to something other than rotation, the rotation function will not be available unless you change the left mouse button back.

Measurement Tools

The measurement tool button is at the very left of the bar. Click the down-arrow located to the right of the button to display the pull-down menu, as shown in the following image:

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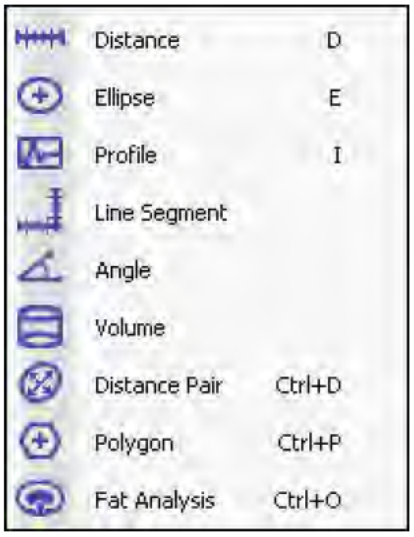
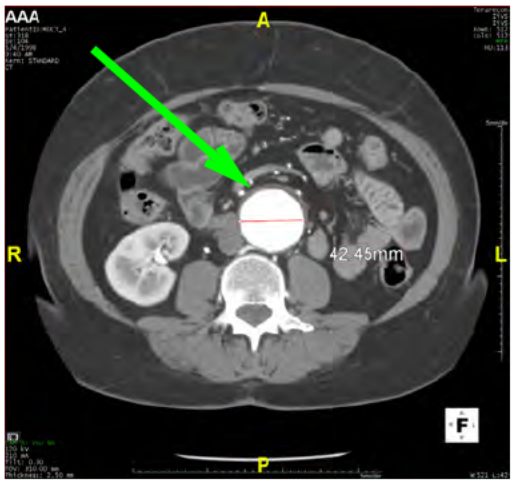
Links to Tools:

Distance
Ellipse
Profile
Line Segment
Angle
Volume
Volume Histogram
Distance Pair
Polygon
Fat Analysis



Other Measurement Features

- **Distance**



This tool can be used on MPR, MIP, MinIP and ThickMPR in any window.

This feature calculates the distance of a line drawn on the image (see the figure at right).

To draw a line, do the following:

1. Click on any point in the image.
2. Drag the mouse across the image.
3. Release the mouse to finish drawing.

Ratio Tool

The Ratio tool allows you to make two measurements, A and B, and then display the percentage calculated using this formula:

(100 x (1-(A/B))), where B is the greater of the two.

This is typically used by operators for estimating stenosis, for example.

1. Make two Distance measurements on the image.

2. Right-click on the second measurement result and select **Show Stenosis Comparison** from the menu. The percentage is displayed under the measurement.

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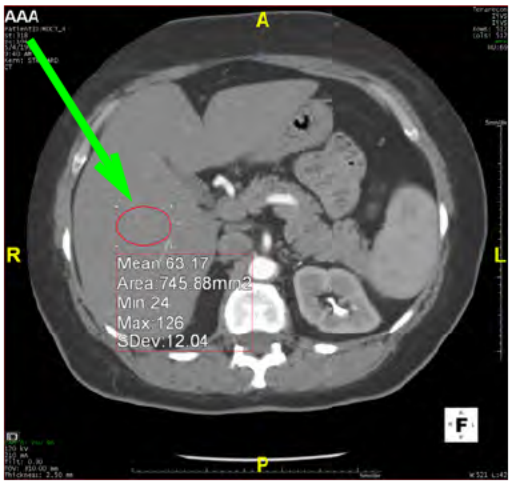
- **Ellipse**



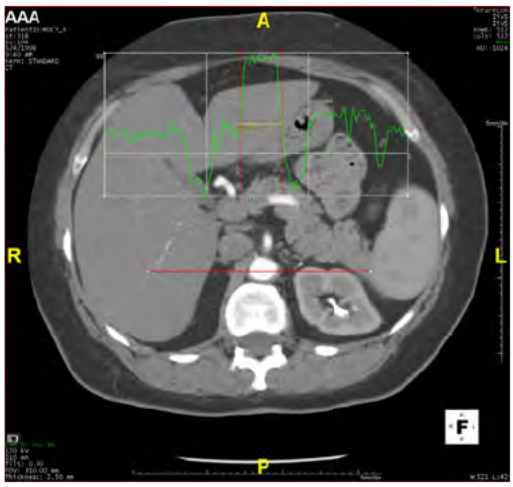
This tool can be used only on MPR images in the active (upper right) window.

This feature calculates the average HU value within an area, defined by the ellipse drawn on the image (see the figure at right).

To draw an ellipse, do the following:

1. Click on any point in the image.
2. Drag the mouse across the image.
3. Release the mouse to finish drawing.

- **Profile**



This tool can be used on MPR images in any window.

This displays a graph showing an image's HU values, along the line drawn on the image (see the figure at right).

To draw a line, do the following:

1. Click on any point in the image.
2. Drag the mouse across the image.
3. Release the mouse to finish drawing.

Exporting a Profile

A profile can be exported to a text file and saved on your computer. To do so:

1. Right-click on the profile graph.
2. Select **Export Measurement**. A Windows **Save As** dialog is displayed.
3. Navigate to the appropriate folder and save.

The profile data is saved as a text file.

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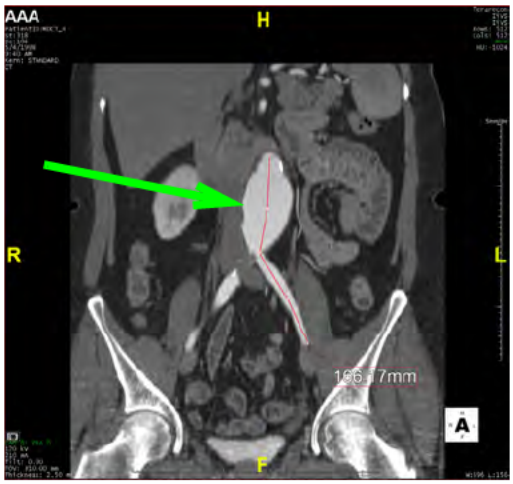
- **Line Segment**



In the active (upper right) window, this tool can be used only on MPR images. In the inactive windows, this tool can be used in MPR, MIP, MinIP and ThickMPR images.

This allows you to draw a series of connected line segments by clicking on the image, dragging the mouse along the image, and then repeating those actions as many times as required. The measurement given is the sum of the lengths of all line segments on the image (see the figure at right).

To place a **Line Segment** measuring tool onto an image, do the following:

1. Click on any point in the image.
2. Drag the mouse across the image.
3. Release the mouse to finish drawing line segment.
4. Repeat steps 1-3 to draw a new line segment, as many times as needed.
5. Double-click to finish drawing.

- **Angle**

This tool can be used on MPR, MIP, MinIP and ThickMPR images, in any window.

The angle measurement tool displays the degree of the angle between two lines drawn on an image. The lines do not need to be connected.

To measure an angle, do the following:

1. Click on any point along one line of the angle.
2. Drag the mouse along the line to the vertex of the angle.
3. Release the mouse to finish drawing the first line.
4. Click on any point along the other line of the angle. This may be right at the vertex of the angle, or it may be a disconnected line.
5. Drag the mouse along the second line, and then release to finish creating the angle. The angle measurement appears on the screen, with an input text box so that you can add information about the angle being measured.
6. Input text if desired.
7. Press the return button to finish.

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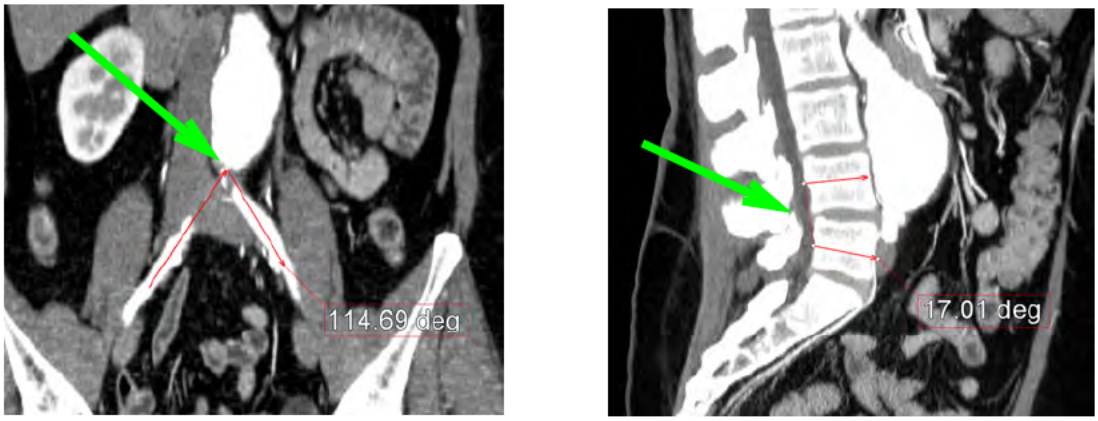
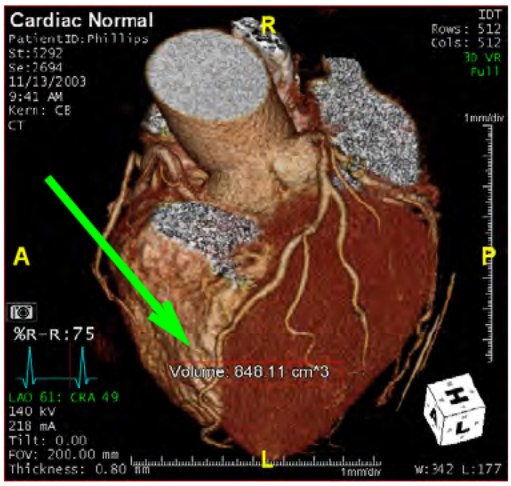


Figure 2-52: Angle Measurements: Left - Connected lines; Right - Unconnected Lines

- **Volume**

The Volume measurement finds the total volume (in cubic centimeters) of everything that is visible in the main window. For example, if you measure the volume, then remove bone, or cut out parts of the image using the FreeROI tool or slab rendering, and then measure the volume again, the amount displayed is less than the amount of the first calculation.



To measure the volume, select **Volume** from the measurement menu. The volume is displayed on the 3D image, as shown in the figure at right:

Volume Classification

You can classify volumetric data into sub-volumes. The opaque and transparent portions of the volume reflect the visible and hidden segments of the 3D image, and can therefore be affected by any operation, such as masking or segmentation, that changes what is visible in the main window.

Note: Supported in CT data only.

Opaque/Transparent Volumes

To show the volume of the transparent and opaque portions of the data, right-click on the the measurement and select **Show Opaque/Transparent** from the pull-down menu:

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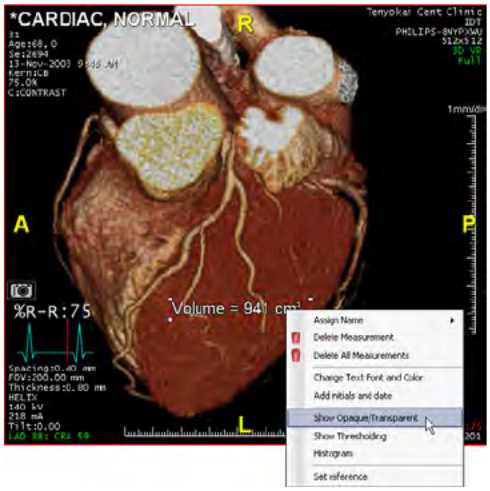
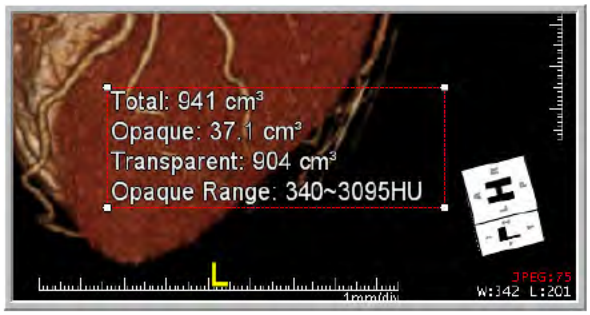
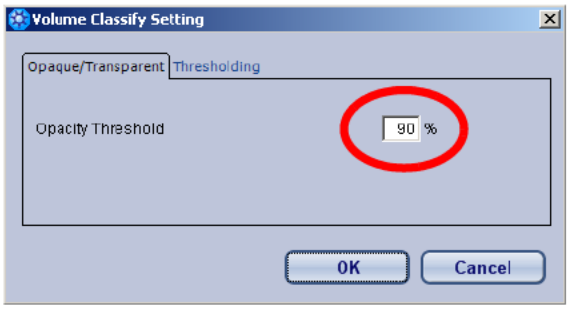


The transparent/opaque values are displayed in the measurement:



These values can also be determined by the opacity threshold. In this case, the default threshold has been used. To adjust the opacity threshold, right-click the measurement and select **Settings** from the menu. The **Volume Classify Setting** dialog is displayed:



Enter a new threshold value in the input box and click **OK**. The opaque and transparent values shown in the measurement are recalculated and redisplayed.

HU Threshold Volumes

To set the HU threshold, click the **Thresholding** tab in the settings dialog. In the **Threshold** input box, enter a threshold value that will be used to separate the volume into sub-volumes of data having HU values above (or equal to) the threshold, or below the threshold.

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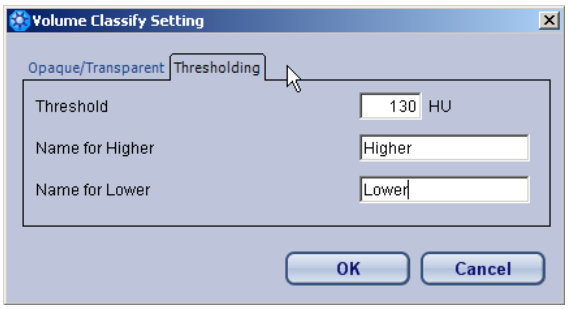
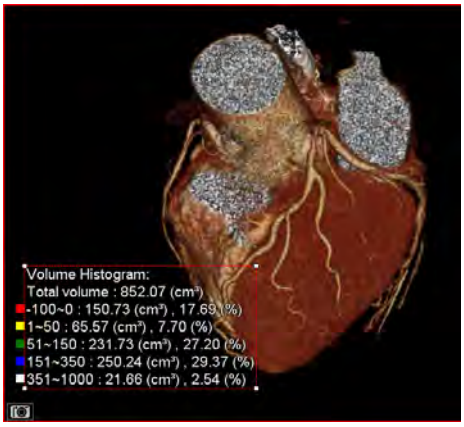
Optionally, you can enter names for the higher and lower HU volumes, which will be displayed on the measurement. Click **OK** when done.



The HU threshold values:

- **Volume Histogram**

  Note: You are obligated to define the parameter ranges that are used in this procedure. When first accessed, the user interface for setting these parameters contains generic default values having no particular significance. You must acknowledge this by dismissing a warning message to this effect.



Volume Histogram calculates the same overall volume that the Volume tool does, but in addition, the total volume is broken down into HU value ranges. The volume and percentage of the total volume are displayed for each.

In the image at right, the HU values are partitioned into five ranges. For each range, the volume of all data having HU values within that range is displayed, followed by that volume's percentage of the total volume.

In this example, the volume of data having HU values between -100 and 0 comes to 150.73 cubic centimeters, which is 17.69 percent of the total (852.07).

Each HU range is associated with a color. These colors are used more extensively in the histogram graph. To see the graph, right-click on the measurement and select **Histogram**. The graph and color key are displayed as follows:

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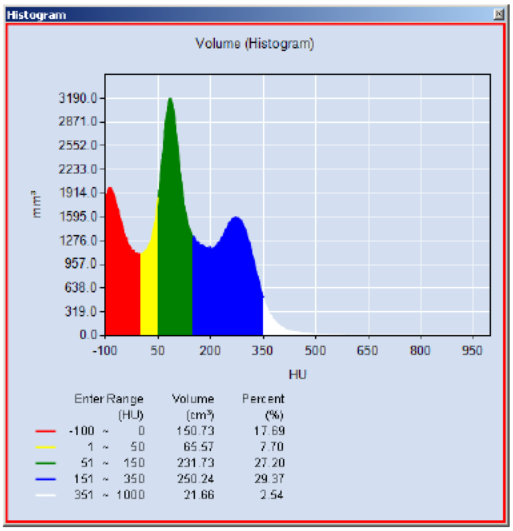
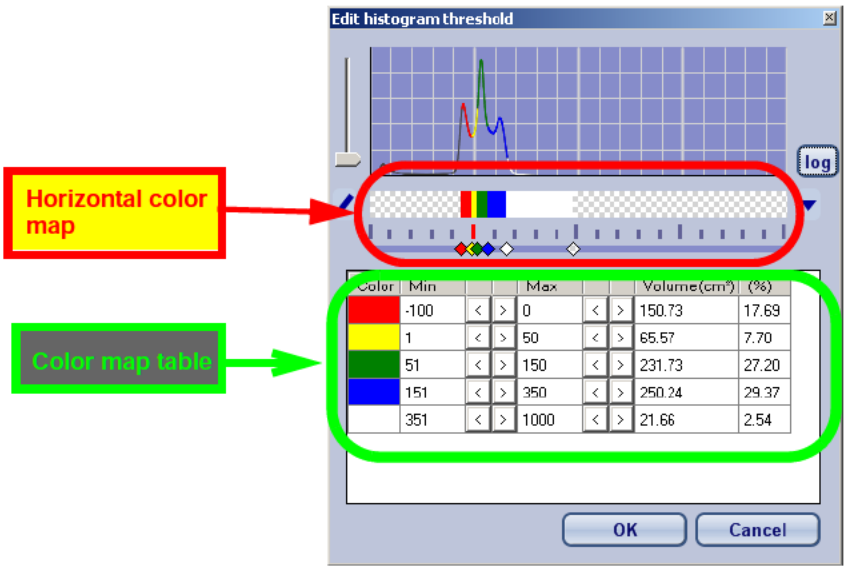


Editing the Histogram Threshold and Color Map

You can modify the threshold of an HU range and the color map in the **Edit histogram threshold** dialog. To open the dialog, right-click on the measurement and select **Edit color map**. The dialog is displayed as follows:



The thresholds and color maps can be changed in two ways:

- Horizontal color map - Add, delete, move, and change the color associated with the diamond markers below the horizontal color map.
- Color map table - Click the left or right arrows in the table at the bottom of the dialog to change thresholds; click a color (left column) to change it.

Set Reference Volume

1. Create or select a volume mask, and apply it to the volume.

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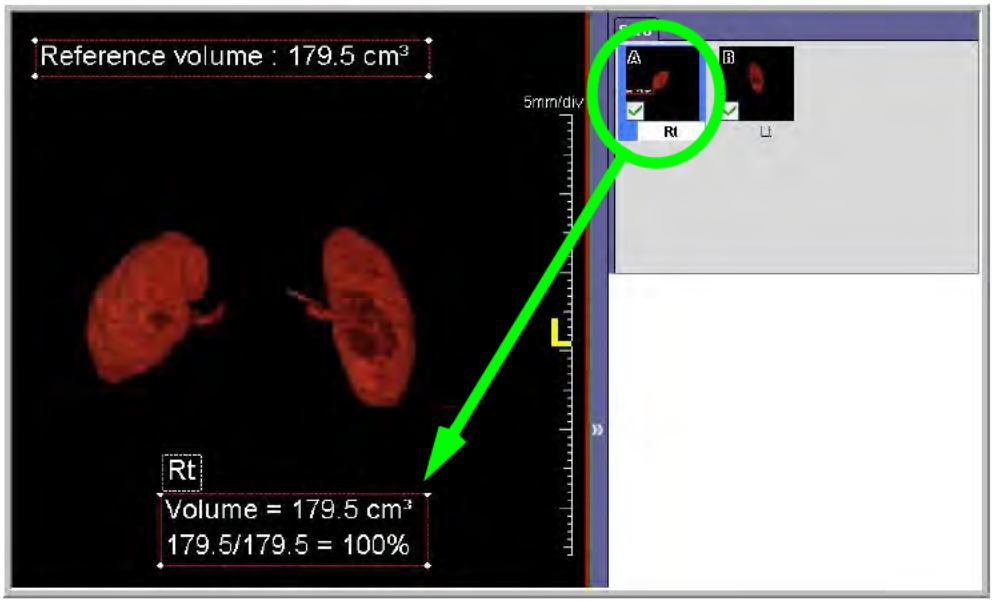
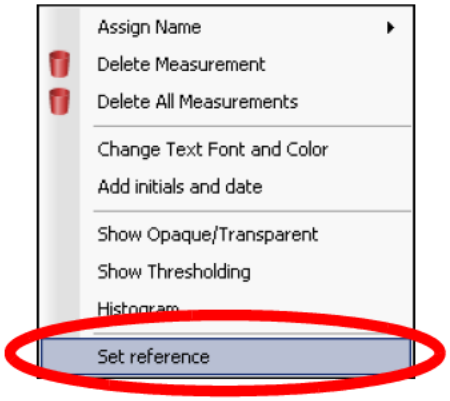
2. Obtain the volume measurement.



3. To designate the measurement as the *reference volume,* right-click the measurement and select **Set Reference**.



4. Create or select a different volume mask, and apply that mask to the same volume.

5. Obtain a new volume measurement. The measurement results will display the ratio of the new measurement to the reference volume.

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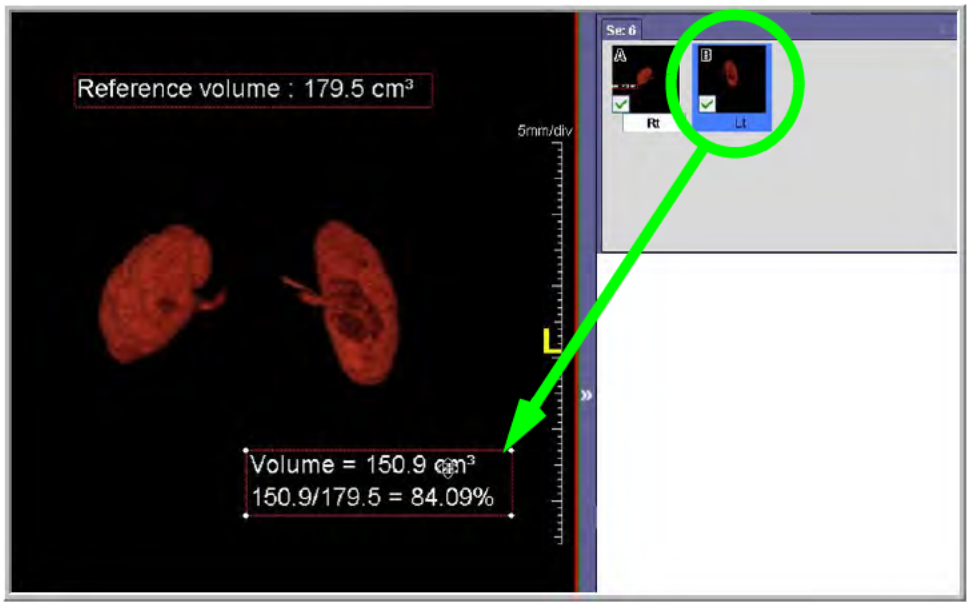
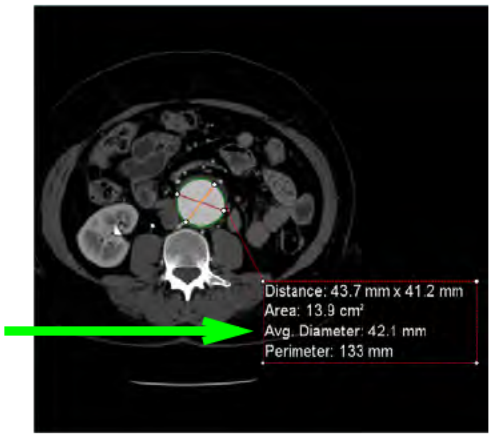


- **Distance Pair**

  This tool can be used on MPR, MIP and ThickMPR images.

  This feature calculates the maximum and minimum distances of an object, as well as its area.

  Click on an enclosed object (such as a vessel). The following items are calculated and displayed:



  - An outline around the object
  - The maximum and minimum diameters
  - The area
  - The average diameter
  - The perimeter length

  See the previous figure.

- **Polygon**

  This tool can be used on any 2D image.

  Polygon is a free-hand ROI tool, allowing you to draw an outline around the region of interest, as you would do using the FreeROI tool. On most types of images, this feature calculates the area enclosed by the outline you have drawn. On MPR images, the average HU value within the area is also calculated and displayed.

  To measure the region of interest, do the following:

  1. Hold down the mouse and draw an outline around the region of interest.

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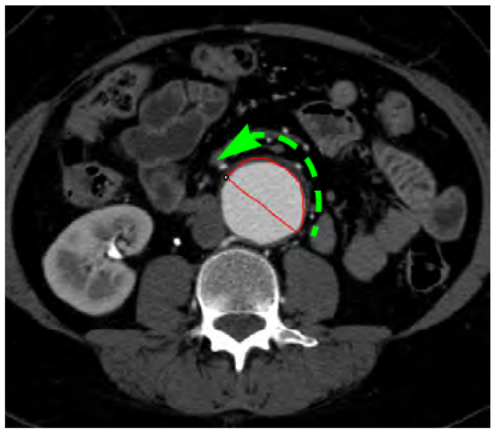
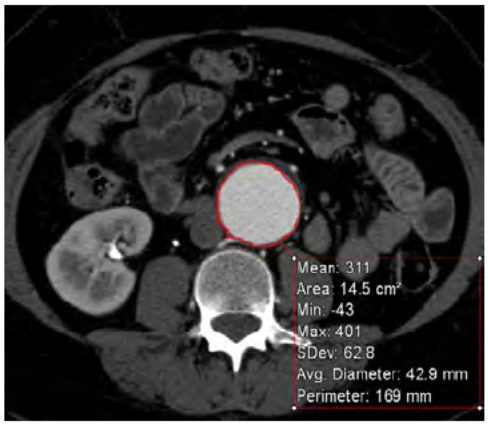
2. When you are finished drawing, release the mouse. The area, mean, min and max, standard deviation, average diameter and perimeter length are displayed.

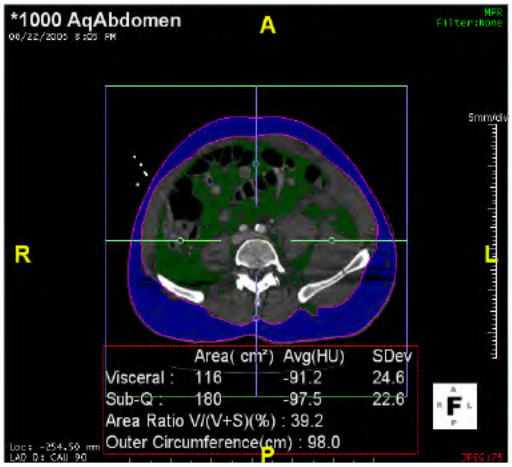




- **Fat Analysis**

This tool can be used on axial MPR images only.

To obtain a fat analysis, select **Fat Analysis** from the measurement menu. The result is displayed on the axial MPR image, as shown in the figure at right:



Options

To see fat analysis options, right-click on the measurement annotation and select Option from the menu. The options dialog is displayed.

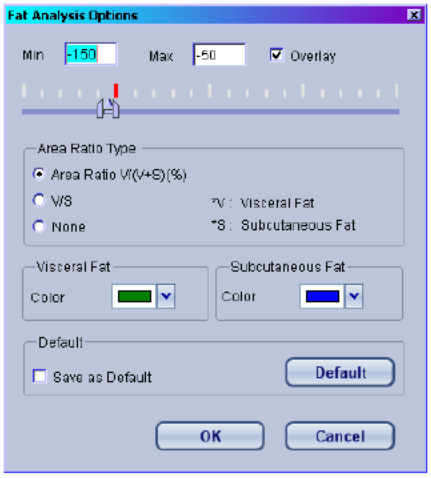


Figure 2-53: Fat Analysis Options

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HU Range

You can adjust the HU range used to detect fat in the region of interest. Use the slider to change the minimum or maximum ends of the range, or enter the desired values in the input boxes. To display the overlay colors, check the **Overlay** box.

Area Ratio Type

You can calculate the area ratio (V/[V+S]%), the visceral/subcutaneous fat ratio or neither. The selected ratio is displayed in the measurement annotation.

Color Map

The green and blue colors shown in Figure 2-53 are the default colors and can be changed. To change the color, click the down arrow to the right of the color you want to change. The color palette is displayed.

Select a new color from either the **Theme colors** or **Standard colors** group. To see the Windows palette, click **More colors**.

Default

- To make the new color map the default, click the **Save as Default** box.
- To reset the color map to the current default, click the **Default** button.

Other Measurement Features

These features apply to some or all of the measurement tools.

Modifying Measurement Annotations

These options allow you some flexibility in the naming and manipulation of the measurement annotation. When you right-click on a measurement annotation, the following menu is displayed:

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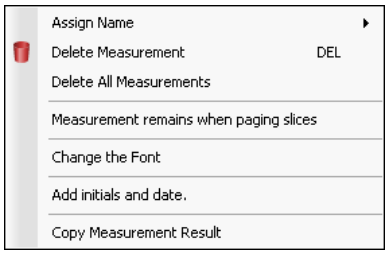


- **Assign Name**

  Allows you to insert a name in the annotation text.

- **Delete**

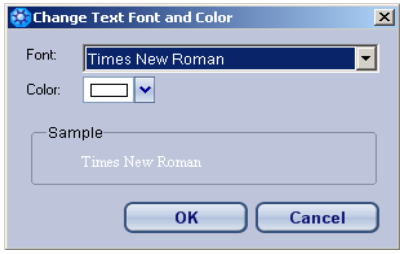
  - Delete Measurement - Deletes the measurement that you right-clicked on.
  - Delete All Measurements - Deletes all measurements from the series.

- **Change The Font or Color**

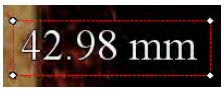
  You can change both the font and the color of the annotations on any of the measurements described in this section.

  To change the font or the color, do the following:

  1. Right-click on the annotation you want to change.
  2. From the right-click menu, select **Change Text Font and Color**.
  3. From the **Font** pull-down menu, select the desired font.
  4. Select a color from the **Color** menu



  5. Click **OK** to change the font or color:



- **Change the Size**

  To change the size, click on one of the corners of the box surrounding the annotation, and drag the corner to change the size of the box. The text will change size correspondingly.

- **Add initials and date**

  Opens a text-input box where you can enter a set of initials or a name. The initials and the current date are then added to the annotation.

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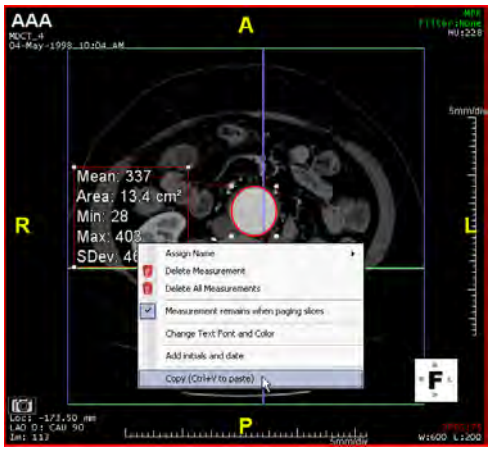
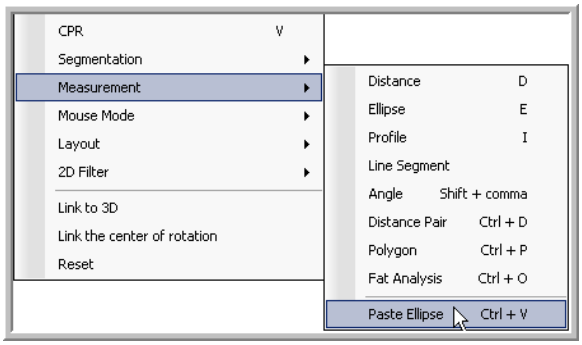
Copy Measurement Result

Copies the measurement to the clipboard, which can then be pasted to another application.

1. Right-click a measurement and select **Copy** from the pull-down menu.



2. On the window where you want to place the copy, right-click and select **Measurement ->Paste (*Function*)**, where *Function* is the type of measurement copied (Distance, Ellipse, and others). Alternatively, you can select the window where the copy will be placed and type **Ctrl+V**.



The measurement is pasted on the second window. The area is the same as it is in the original image, but the Min, Max and Mean values depend on the HU values of the area encompassed by the measurement.

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Significant Digits

You can set the number of digits with which to display a measurement annotation, to a value between 1 and 5. Regardless of the number chosen, the most significant digit(s) of the number will always be displayed. To change the number of digits shown, click the Preferences button and select Measure/Annotation from the navigation list on the left. For more information, see Appendix A: "Measure/Annotation" on page A-9.

Removing Measurement Endpoints

When a measurement is made on an image, the dots that mark the end points or anchors remain visible. You can remove these dots for a clearer view of the exact end points of the measurement, or any part of the image obscured by the dots.

To remove the dots, click once on the image.

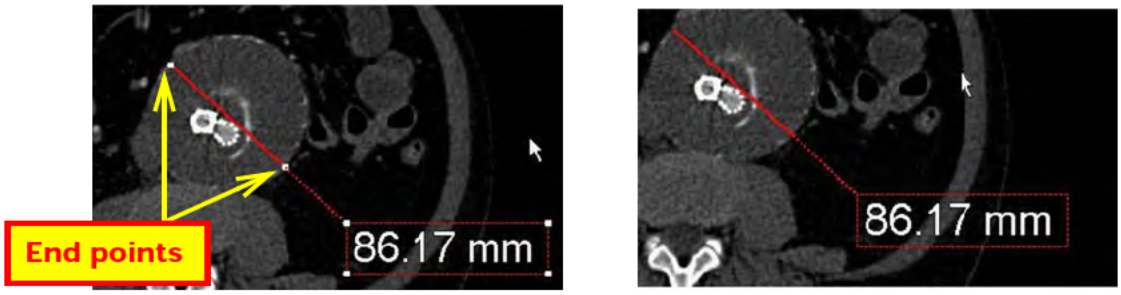

Figure 2-54: Left - End points visible; Right - End points removed.

Synchronized Measurements on Multidata

When two or more datasets are loaded and synchronized, some measurements performed on one are applied to both. Ellipse, Polygon, Angle and Distance pair are supported.

1. Click the **Synchronize** button.
2. Click the **Registration** button so the two studies will be aligned.

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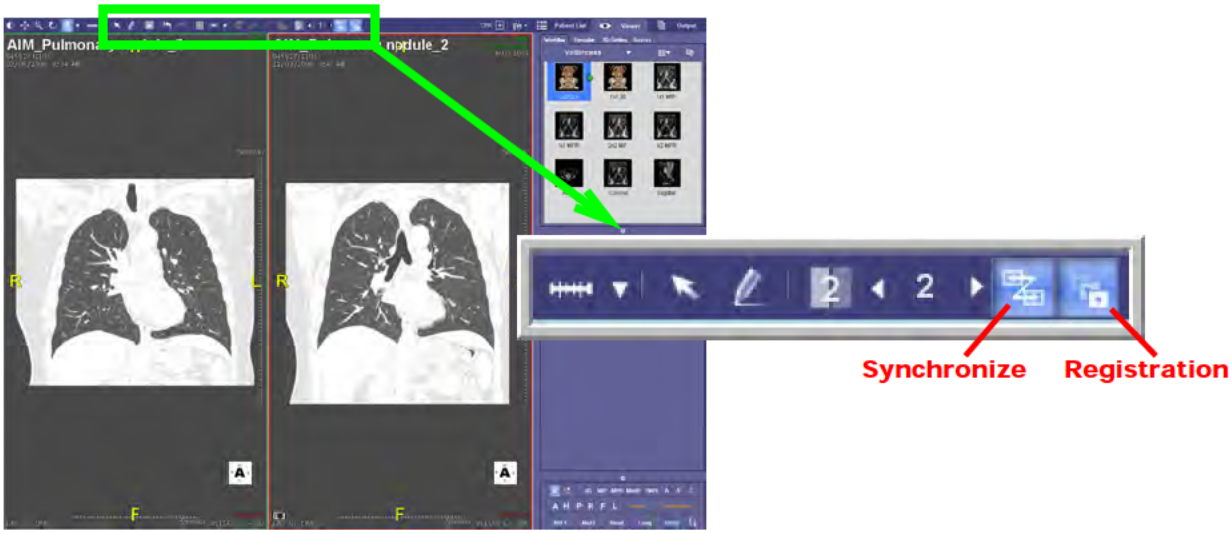
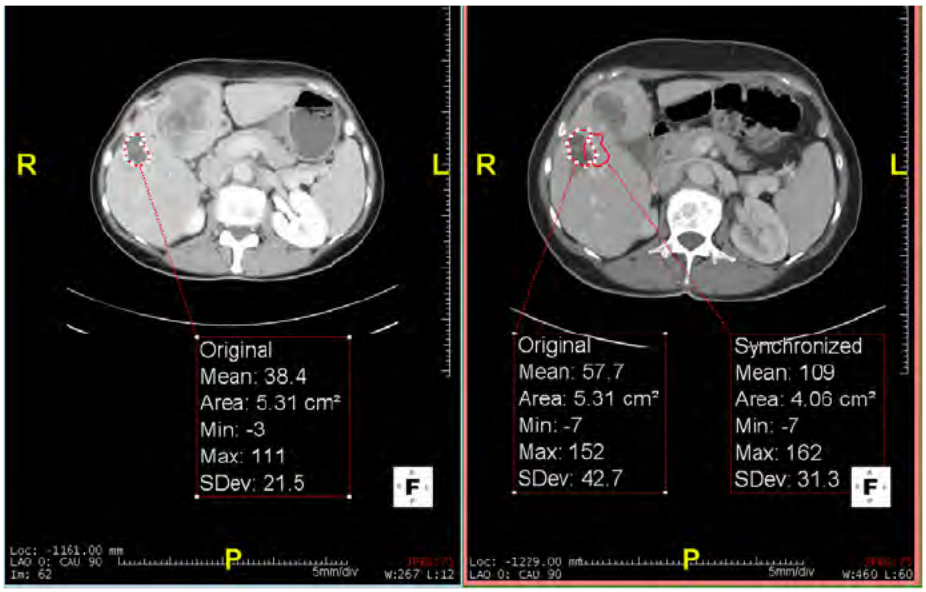


3. Obtain a measurement on one of the studies. The same measurement appears on the other study, but the results may be different because of differences in the two scans.

Compare synchronized measurements with a cut-and-pasted measurement from one study to the other, while the datasets are not synchronized:



In the image on the left, a measurement is taken while the two studies are in sychronization. This measurement is reflected in the measurement at right, labeled "Synchronized". The measurement labeled "Original" in the right-hand image was cut and pasted from the left-hand image. The cut and pasted measurement is identical to the original, even appearing in the exact same place on the image.

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Arrows and Labels

Adding Text

You can annotate the images in the main viewer. To do this, click the **Label** button in the top tool bar, or right-click on the image and select **Arrow / Text**. A text window opens on the image, where you can type in the annotation you want to add (see Figure 2-55).

If you have previously entered annotations beginning with the same letter or letters you type as you input the text, the previous annotations appear in a drop-down list below the text input box. If you want to reuse an annotation, select it from the drop-down list.

When you are finished typing the text, press the **Enter** key to complete the annotation.

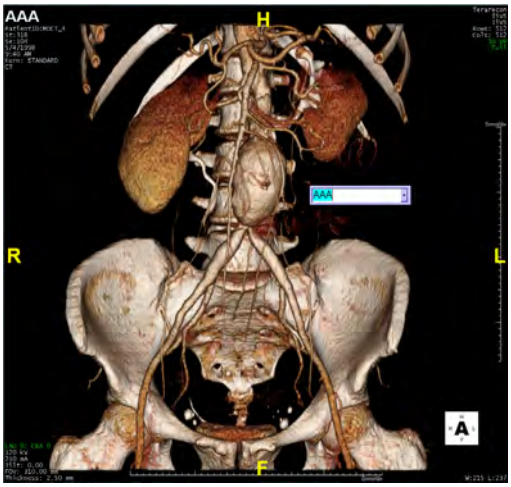

Figure 2-55: Entering User Annotation

Adding an Arrow and Text

You can add an arrow with text to an image by clicking the **Arrow** button in the top tool bar, or by right-clicking on the image and selecting **Arrow / Text** from the menu. The cursor appears on the image as a plus sign ('**+**'). To add the arrow and text, place the cursor over the area you are pointing to, and drag the cursor away from it. The arrow and text box appear (see Figure 2-56 on page 2-136), and you can input your text in the box as above.

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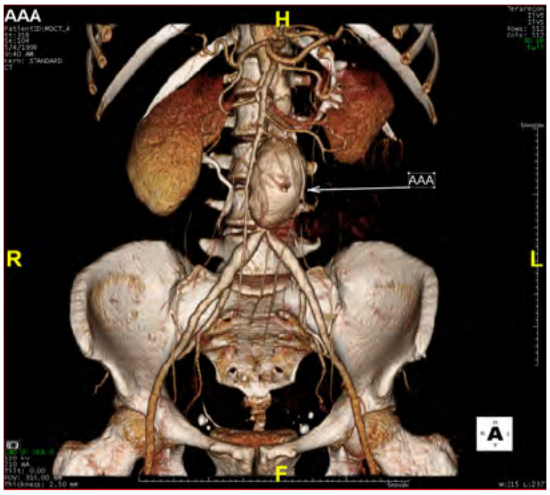


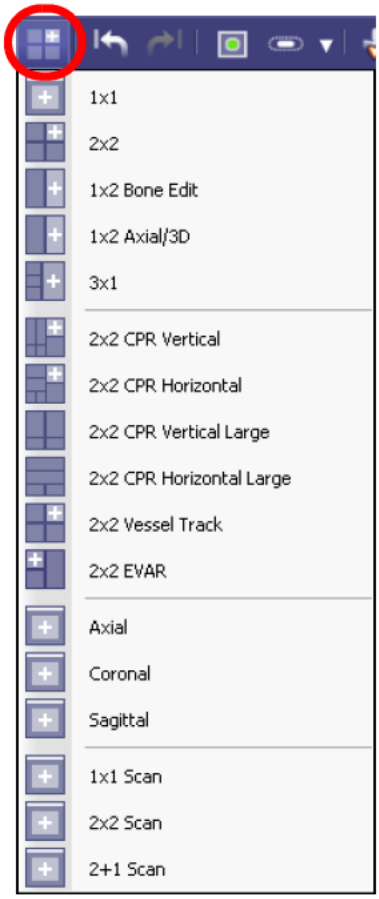
Figure 2-56: Entering a Label and Arrow

Changing the Font and Color of Label Text

You can change the font and text size of the label text. For instructions, see "Change The Font or Color" on page 2-131.

Window Layout Modes

Window layout is controlled with the Layout button at the top of the screen. Click the down arrow to the right of the button to see the pull-down menu of layout choices, as shown at right.



The following table describes the default positioning and content of each screen layout.

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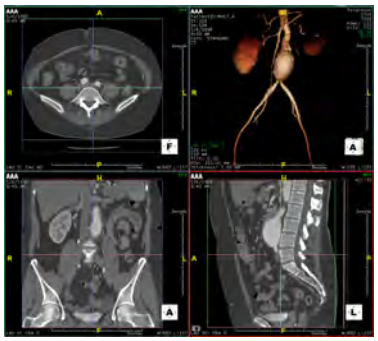
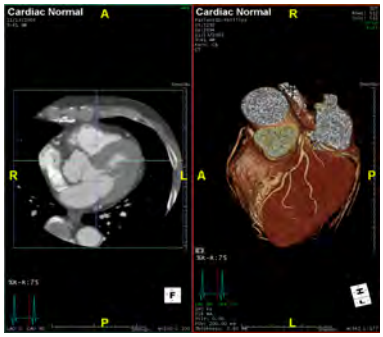
Layout	Description	Image
1x1	The 3D image fills the entire screen in this layout.	
2x2	The default 2x2 layout shows a 3D image in the upper-right panel, with MPR images in the other 3 panels, seen from different orientations.	
1x2 Bone Edit	This layout shows the 3D image in the right panel. The left panel displays any part of the 3D image that has been removed, such as in bone removal, or any section taken out using the FreeROI function). Sections from the left panel can be selected and put back into the 3D image on the right.	
1x2 Axial 3D	This layout shows the 3D image in the right panel. The left panel displays the Axial image in MPR format.	

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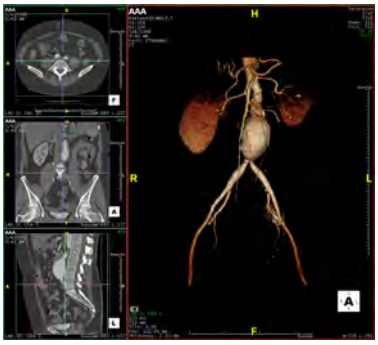
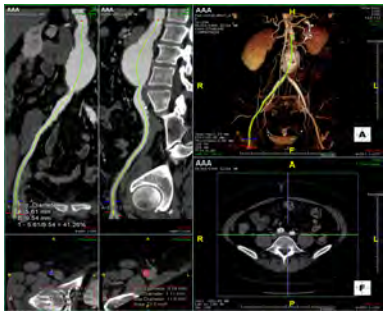
Layout	Description	Image
3x1	This is similar to the 2x2 in that it shows the image in 3D and 3 MPR views, but the 3D image is much larger in relation to the others.	
2x2 CPR Vertical	The right side of the screen contains the 3D image on top, and the axial MPR view in the panel below it. On the left side are CPR and MPR views of selected vessels. Nothing is shown in these windows until a centerline has been drawn and the vessel has been selected. This view is best for examining vertical vessels.	
2x2 CPR Horizontal	This view is best for examining horizontal vessels.	
2x2 CPR Vertical Large	Similar to 2x2 CPR Vertical, but without the 3D or axial images, which give maximum space to the CPR view.	

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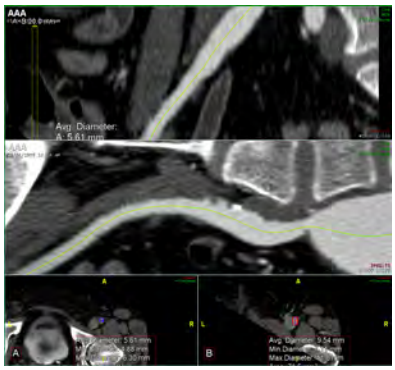
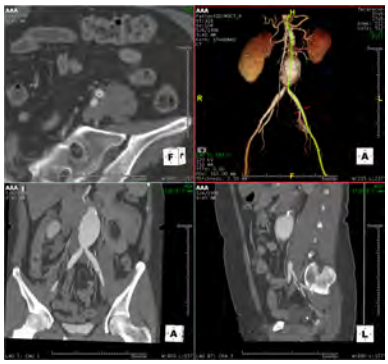
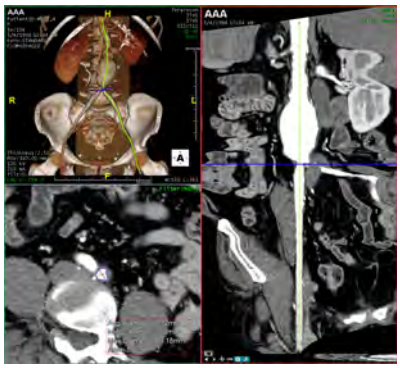
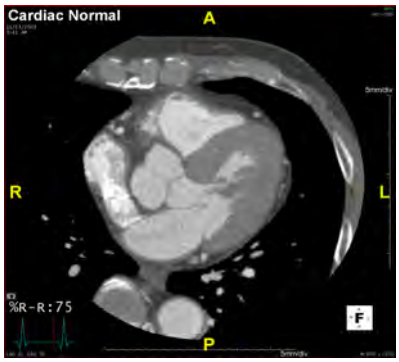
Layout	Description	Image
2x2 CPR Horizontal Large	Similar to 2x2 CPR Horizontal, but without the 3D or axial images, which give maximum space to the CPR view.	
2x2 Vessel Track	This view displays the image in MIP mode.	
2X2 EVAR	3D image (upper left), MPR cross-section view (lower left) and straightened MPR view (right), used for taking measurements for a stent.	
Axial	MPR view of the image in the foot orientation.	

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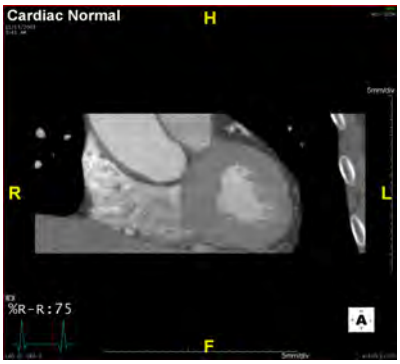
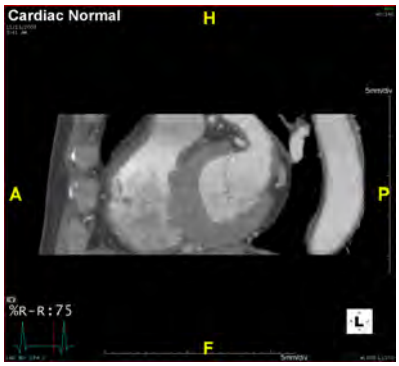
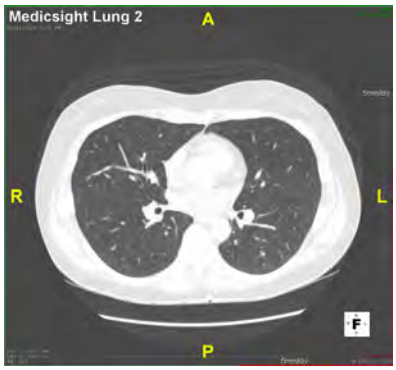
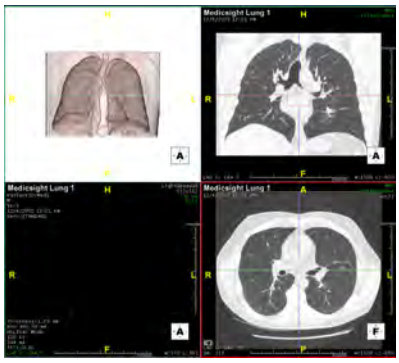
Layout	Description	Image
Coronal	MPR view of the image in the anterior orientation.	
Sagittal	MPR view of the image in the left orientation.	
1x1 Scan	Used for SAT.	
2X2 Scan	Used for SAT.	

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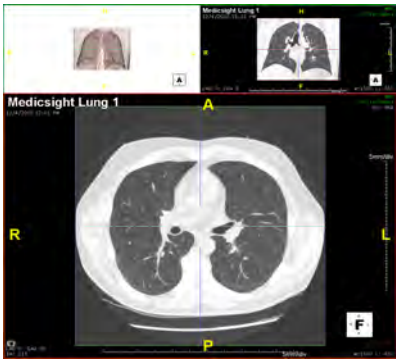
Layout	Description	Image
2+1 Scan	Used for SAT.	

Undo and Redo

Undo the last operation. Redo the last operation to be undone.

Show or Hide Overlay

Toggles the green overlay on the MPR views, showing the masked area that has been removed

Show or Hide Mask Outline

Allows you to see the outline of bone mask on an image that has had bone removed. Click on the down-arrow on the right to display a slider. Moving the slider to the right shows more bone outline.

Advanced Processing Functions

If you have AquariusAPS (Advanced Processing), the next group of tools can be very useful and time-saving.

Advanced Processing is performed on incoming data before it is available on your AquariusNET server.

The tool icons in the figure above, from left to right, perform the following functions, respectively: Label, Centerline, Find Candidates and Mask. To display the image with AquariusAPS results, click the desired processor from the toolbar shown in the previous figure.

Label

Display the labels that have been identified by Advanced Processing.

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WARNING: The labels displayed by this function are suggestions resulting from an automated algorithm, and are not necessarily 100% accurate. The labels must be verified by a qualified person before being used.

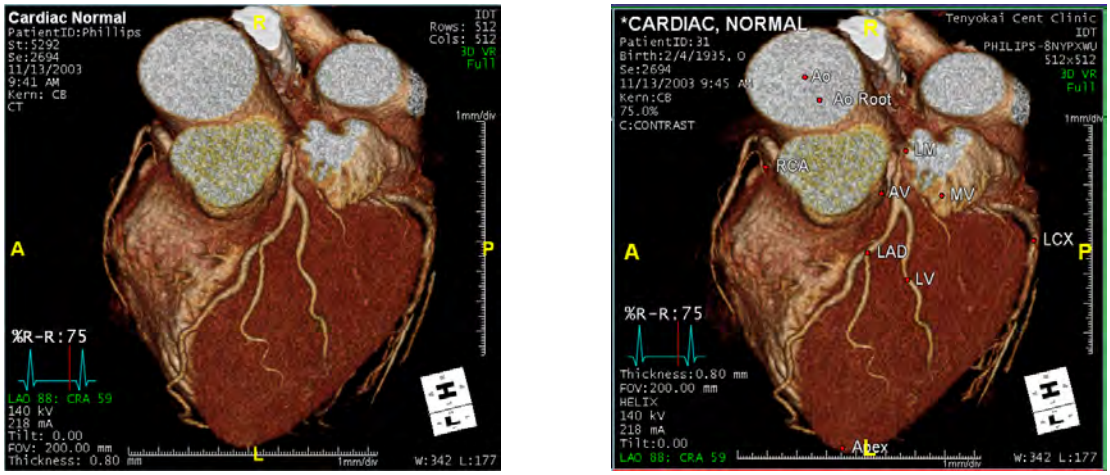

Figure 2-57: Without AquariusAPS (left); Labels Identified by AquariusAPS (right)

Centerline

Display centerlines that were created by Advanced Processing.

- To highlight a specific vessel, move the cursor over it.
- To open a CPR window displaying that vessel, click on the vessel.

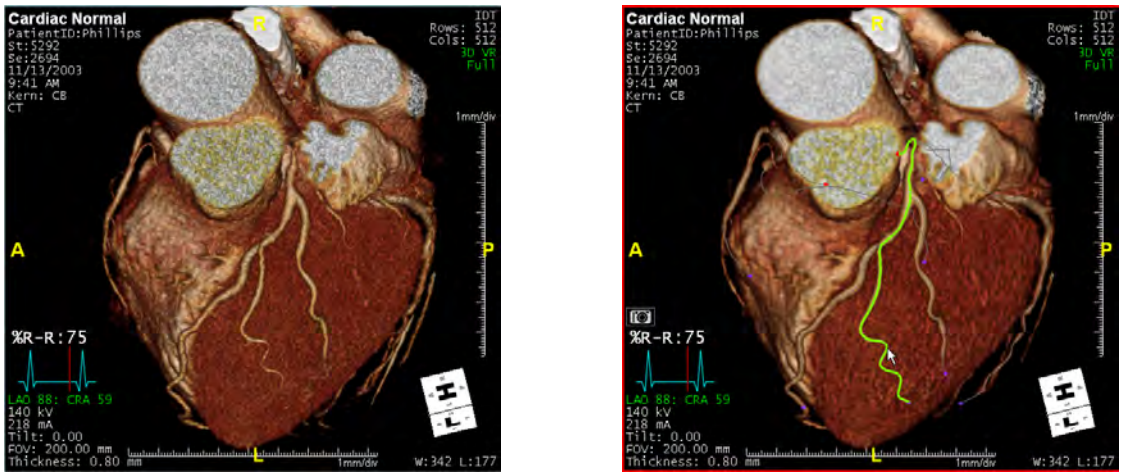

Figure 2-58: Without AquariusAPS (left); Centerlines Created by AquariusAPS (right)

Candidate Marker

Display candidates for spherical nodules that were found in Advanced Processing. AquariusAPS places a small red dot at the location of the candidate.

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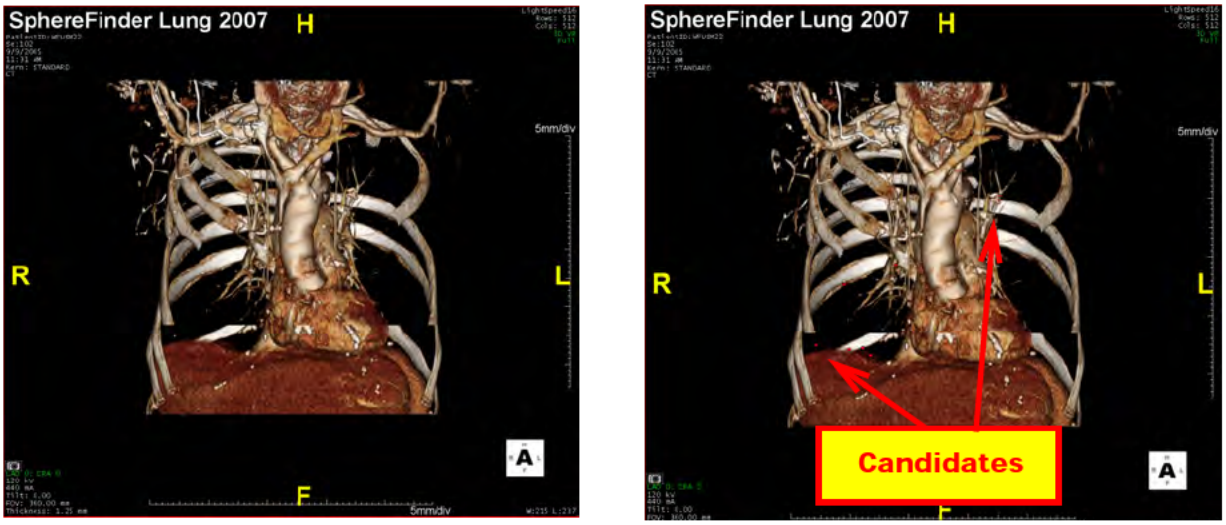

Figure 2-59: Without AquariusAPS (left); Candidates Identified by AquariusAPS (right)

Masks

Add, subtract or isolate vessels or other areas that have had masks created in Advanced Processing.

For example, suppose you want to isolate the aortic root, lad/lcx and rca vessels, to examine them more closely. You can do the following:

1. Click the **APS Mask** button. The Mask pull-down menu is displayed this study.

   Note: The items in the pull-down menu depend on which APS operations were applied to the loaded study. Another study with Advanced Processing might show more, fewer, or different vessels in the list.

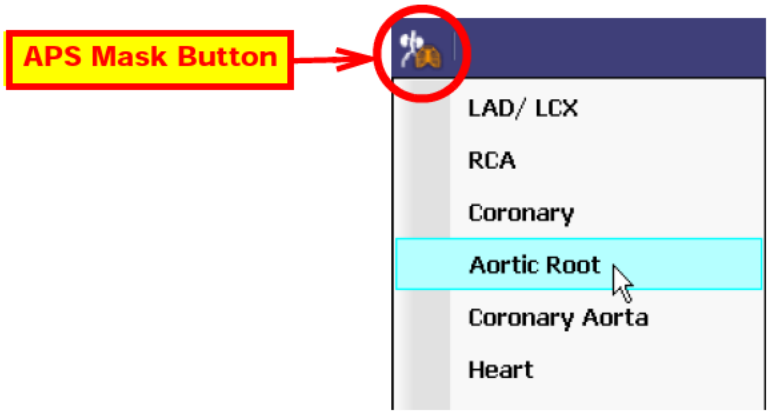

Figure 2-60: Mask Pull-down Menu

2. Select **Aortic Root** to apply the mask for the aortic root. The **Load Mask** dialog is displayed.

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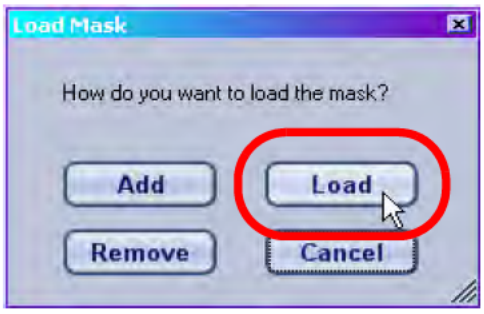

Figure 2-61: Load Mask Dialog

3. Select **Load** to load the *masked area only*, which is the aortic root. The aortic root is displayed in the main window (see Figure 2-62).

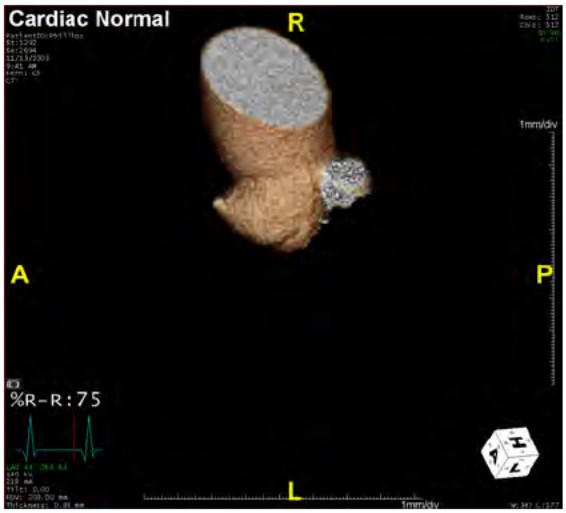

Figure 2-62: Aortic Root Loaded

4. Click the **APS Mask** button again to display the mask menu.

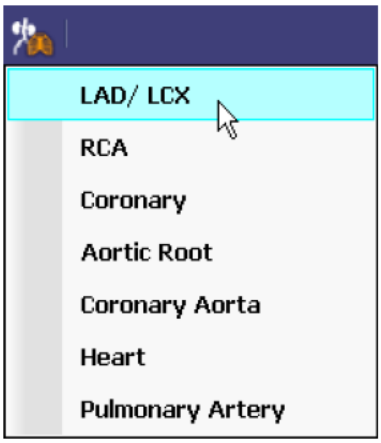

Figure 2-63: Apply LAD/LCX Mask

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5. Select LAD/LCX to apply the LAD/LCX mask.The Load Mask dialog is displayed again.

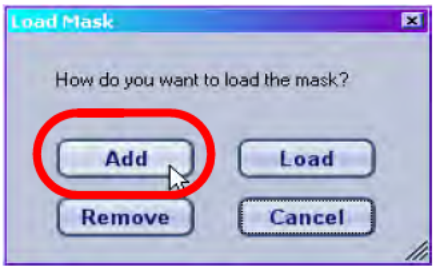


Figure 2-64: Add Additional Masks

6. Click **Add** this time, to add the LAD/LCX vessel to the aortic root image. The LAD/LCX vessel is added so that both are displayed together.

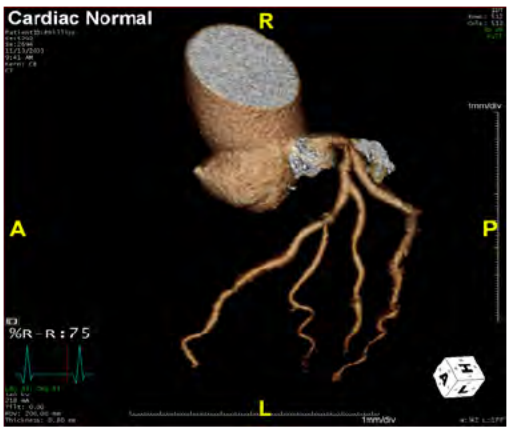
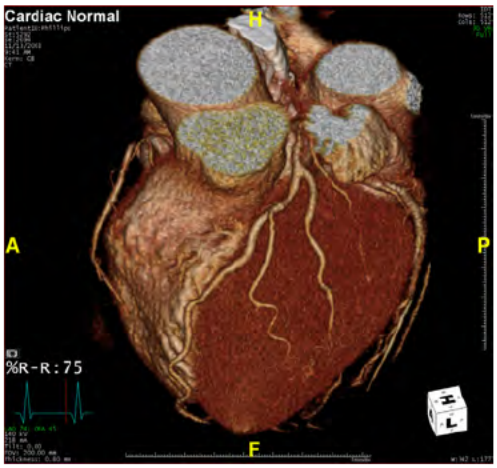


Figure 2-65: LAD/LCX Added to Image

7. Click the APS Mask button again, and select RCA from the menu.

8. In the Load Mask dialog, click Add. The RCA vessel is added to the image.

9. Rotate the image as needed for the best view.



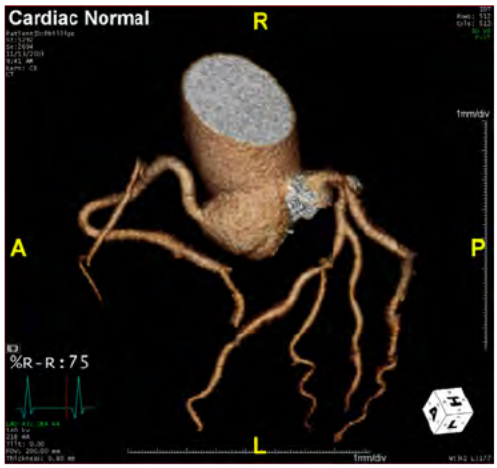


Figure 2-66: Without AquariusAPS (left) and Isolated Vessels (right)

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Bone Removal

Remove bone or CT table automatically.

To remove bone, click the mask button and select Remove Bone from the pull-down menu. To remove the CT table, select CT Table from the menu.

Figure 2-67: Mask Function Menu

The result of each operation is shown in Figure 2-68.

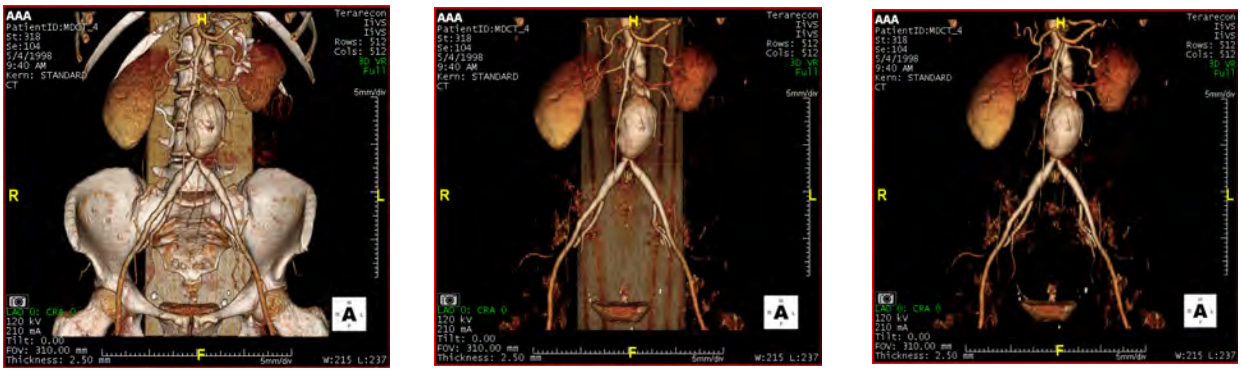

Figure 2-68: Without AqauriusAPS (left); Bone removed (middle); CT table removed (right)

Applying APS Masks Using Drag-and-drop Icons

As an alternative to the pull-down menus described above, you can apply masks generated by advanced processing using a set of APS result icons that represent each mask. This feature is enabled through a preference setting, “Enable to apply APS by drag and drop”. See "Toolbar" on page A-7 for details on setting the preference.

When you click on the mask icon in the top toolbar, a set of APS result icons is displayed on the screen:

To apply a mask to an image, right-click the desired mask and drag it onto the image. The **Load Mask** dialog is displayed, asking whether to Load, Add or Remove a mask (see Figure 2-61 on page 2-144). This works the same way as it works with the pull-down menu.

The previous image shows a sample icon for each of the masks. These are generic images. You can also display the APS Result icons using real images from the currently loaded study. This feature is disabled by default. To enable it, click the checkbox for the preference setting,

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

"Do not use sample icon". See "Toolbar" on page A-7 for details. When this feature is enabled, the APS Result icons are displayed as follows:

If You Do Not Have AquariusAPS

If you do not have AquariusAPS, the Advanced Processing tool icons in the upper bar are displayed as grayed-out.

You can still perform some of the functions, such as labeling, masking, and creating centerlines, but you will need to perform them manually.

Note: The remaining Top Bar Tool Buttons are located on the right end of the bar.

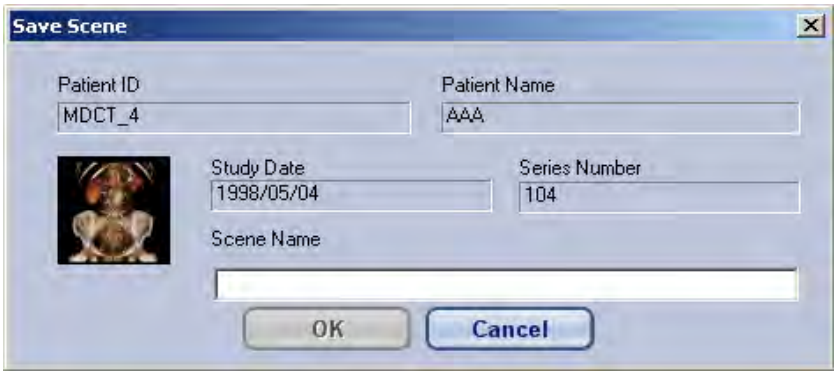
CPR

The CPR button allows you to select a vessel in the image to open a CPR view of the vessel. It is the same as using the **CPR** tool in the Tool Panel. (See "CPR Tool" on page 2-13, in The Tool Panel section for more information.)

Saving a Scene

To save an image as a scene, do the following:

1. Click the **Scene** button (shown above). This opens the **Save Scene** dialog (see below).
2. Change the name of the scene if desired, and click **OK**. The scene is saved in the Series List, and can be loaded directly from there.



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Display Annotations Menu

The Display Annotations menu allows you to choose which information will be superimposed on the images in the 3D Viewer. You can display one or any combination of annotations.

The annotations are as follows:

- Scale Bar - Calibrated lines at the bottom and right sides of each image, showing the proportions of the image (labeled in Figure 2-69).
- Orientation - The white cube in the bottom right corner, showing the orientation of the image. Also, the letters on the sides and top, indication orientation (A, P, L, R, H, F) (circled in green).
- Annotation Text - The text describing the image, plus links and buttons. The white text provides information about the study. Green text items are function buttons that you can click on to change the image (circled in red).
- Cross Cursor and Overlay - Cross cursor allows you to place an area of a 2D image into the center of the window. Overlays show mask areas where bone or other tissue has been removed (see the right-hand image below). You can also set a preference so that a single click on the 2D image will move the cross cursor to the clicked location. The preference is located on the **Mouse Operation** screen. (See Appendix A: "GUI Configuration" for a description of preferences.)

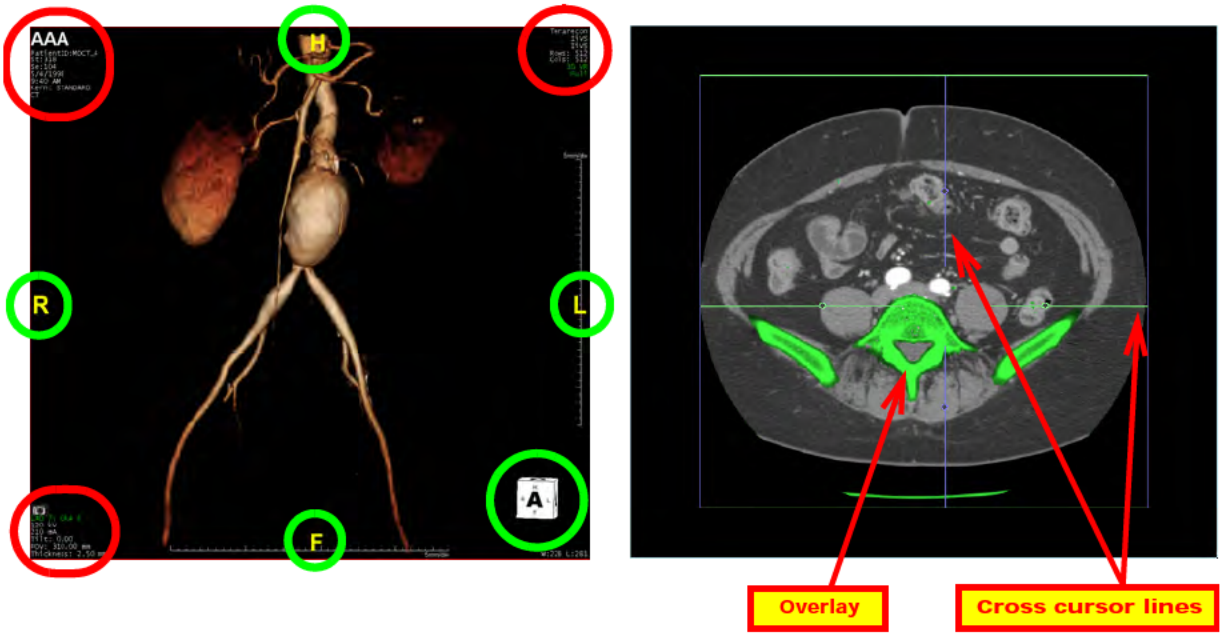

Figure 2-69: Annotations

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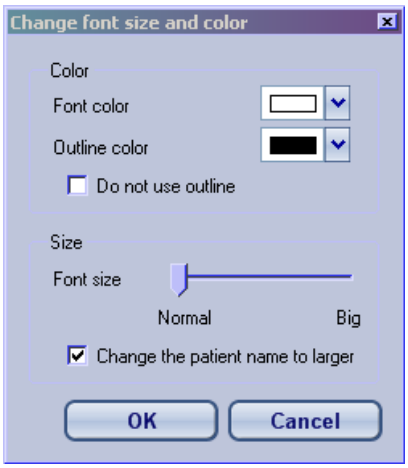
Changing the Size and Color of Patient Annotation

You can change the patient annotation's color and size from the default values. To do so, right-click on the patient annotation to display a small menu:

Select **Change font size and color**. The following dialog is displayed:



To change the color, select a new color from the **Font color** pulldown menu. You can select a contrasting color for a the text outline so the text will be visible on any background. The default outline color is black. If you do not want an outline on the text, check the box labeled **Do not use outline**.

To change the font size, use the slider. If you want to display the patient name in a larger size, check the box labeled **Change the patient name to larger**.

Show / Hide Annotations

If you want annotations displayed on images, select **Show All Annotations** from this menu. If you would prefer not to see annotations, select **Hide All Annotations**. The image is displayed as shown in the right-hand image in Figure 2-69.

Hide Patient Information

You can also choose to hide patient information even when showing all other annotations. To do this, select **Hide Patient Information**.

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Buttons in the Image Annotations

Some of the annotations on an image are displayed in bright green. This indicates that it is an active button allowing you to change that image attribute. The three attributes that allow changes in this manner are the rendering mode (all images), the slab thickness (3D images only) and the heart angle (main image only).

Rendering Mode

The rendering mode button is located in the upper-right corner of each image panel. In a 3D image, this annotation is displayed as "3D VR"; in an MPR image, it is displayed as "MPR", and so on.

To change the rendering mode in this panel, point the cursor directly on the annotation and left-click. A pull-down menu of other rendering mode options is displayed (see Figure 2-70).

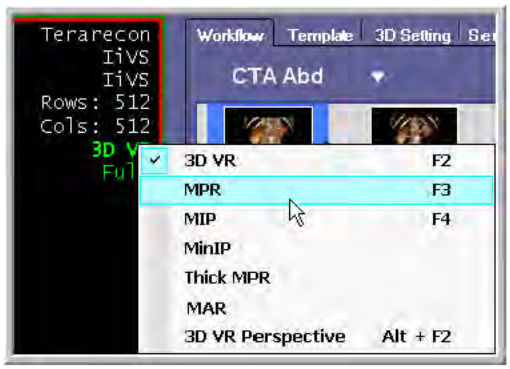

Figure 2-70: View Mode Pull-Down Menu

Slab Thickness

The slab thickness annotation is located just below the rendering mode annotation. This is active only in a 3D image. If the image is not 3D, the annotation is displayed in white text and does not activate a pull-down menu.

To change the slab thickness, click on the green annotation to display the pull-down menu, and then select a new thickness (see Figure 2-71).

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

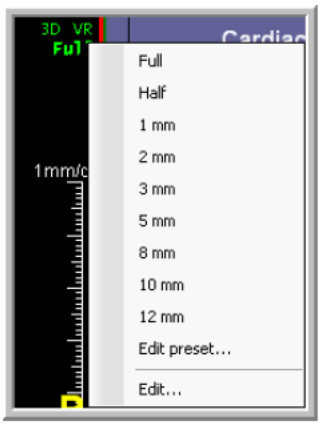
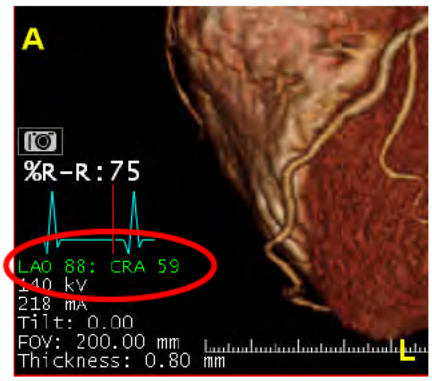


Figure 2-71: Slab Thickness Pull-down Menu

Heart Angle Setting



This annotation is located in the lower-left corner of the image. It is active only in the main window.

When you click this annotation, the Angle Setting dialog box (see Figure 2-72) is displayed. Enter the desired angles and click **OK** to change the setting.

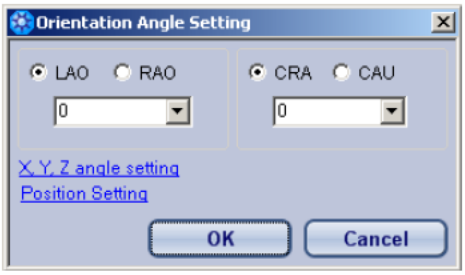
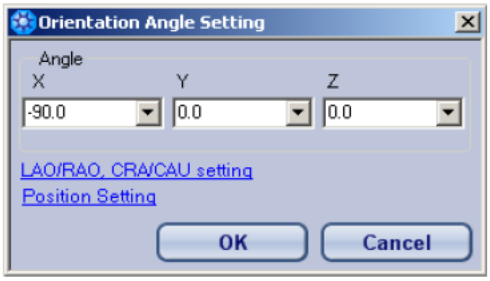


Figure 2-72: Heart Angle Settings

XYZ Angle Setting

The XYZ angle setting dialog allows you to change the viewing angle of the heart in one dimension at a time, or more than one at once. To use XYZ settings, click the **X, Y, Z angle setting** link (see Figure 2-72). The XYZ dialog is displayed:



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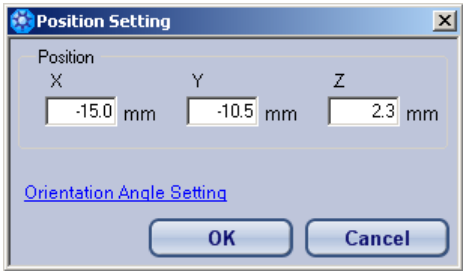
Using this dialog, you can change the heart's viewing angle in the horizontal, vertical, and/or depth direction. Click the **LAO/RAO, CRA/CAU setting** link to display the original dialog.

Position Edit

This dialog allows you to change the position of the image in the main window along the X, Y or Z-axis.

To access the Position Setting dialog, click the **Position Setting** link on the **Orientation Angle Setting** dialog. The Position Setting dialog is displayed as follows:

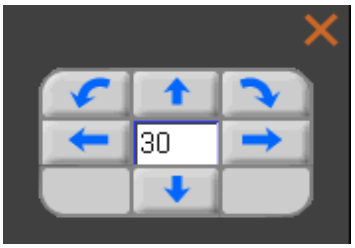


The direction an image will move for each axis depends on the initial orientation. When the 3D image is in the axial (Foot) orientation, the X-axis runs from left to right, the Y-axis runs from top to bottom and the Z-axis runs forward to back. However, changes to values in the Z box will not result in a visible change on the screen. In order to see positional changes on the Z-axis, rotate the image 90 degrees to the left or right.

When the initial orientation is rotated from the axial position, the position setting tool works the same way, except that the axes have also been rotated the same amount and direction. Therefore, the image will move left, right, up, down, back and forward in relation to the *rotated* axes.

Image Rotation Form

The image rotation form allows you to rotate an image by a specified number of degrees:



To display the rotation form, click the Orientation cube in the bottom-right corner of the 3D image:

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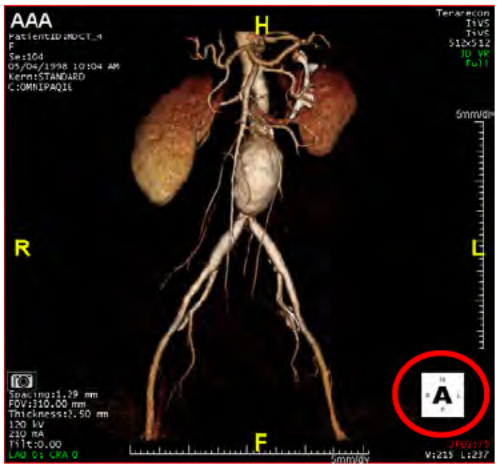

The rotation form works similarly to the way it works in the Orientation tool (see "Orientation Tool" on page 2-12). You can specify an angle of rotation, and then click one of six directions in which to rotate the image.

Mini-Toolbars

These tools are located in the lower-right corner of the 3D Viewer screen. They provide different ways to change the appearance of the images on the screen.

Rendering Mode Mini-Toolbar

These features change the rendering or viewing mode of the main window.

Figure 2-73: Rendering Mode Mini-Toolbar

- Layout buttons - These select 1x1 and 2x2 layout, respectively
- 3D - Shows the 3D Volume Rendering image
- MIP - Shows the image in MIP mode
- MPR - Shows the image in MPR mode
- MinIP - Shows the image in MinIP mode
- TMPR - Shows the image in ThickMPR mode
- A, S, C - Shows the image in axial, sagittal and coronal view, respectively

Orienatation Mini-Toolbar

Figure 2-74: Orientation Mini-Toolbar

A, H, P, R, F, L

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These are the Orientation buttons. When you click one, the selected image is redisplayed from the point of view of the corresponding orientation (Anterior, Head, Posterior, Right, Feet, Left).

Reset

This button redisplays the image in the original orientation, prior to any edits done in the 3D Viewer.

Clear Mask

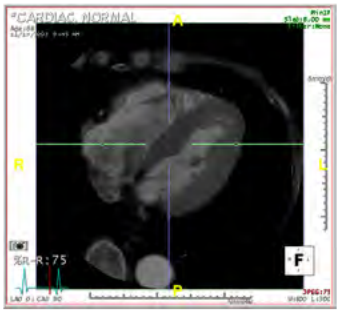
Restores all parts of the image that have been masked out.

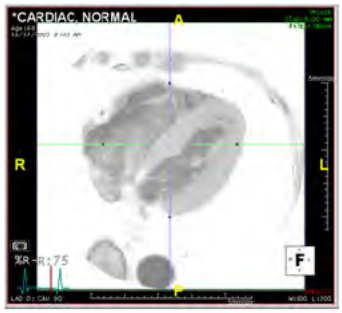
Window/Level Mini-Toolbar

These are preset window/levels that are best for viewing different types of studies. These settings can be changed if desired. See "Changing a Preset W/L" on page 2-58 for instructions.

Invert W/L

The rightmost button in the Mini-Toolbar (circled in the figure above) allows you to invert the W/L values of the currently loaded 2D images. Click the Invert button (circled in the previous figure). The results (left: original 2D image; right: inverted image are as shown below:





Color Templates

Aquarius iNtuition provides a set of templates containing color and window level information that can be applied to the currently loaded study data. They modify the 3D image display so that it is easier to see and examine the relevant ROI. You can access templates by clicking on the **Template** tab at the top of the upper-right panel (circled in the image at right).

For example, if you have loaded a lung study into the 3D Viewer, you will see that the lung tissue is not visible. The lung template changes the color and window level settings so that the lungs

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become visible. To apply the template to the data, click the **Lung** template icon in the **Template** panel.

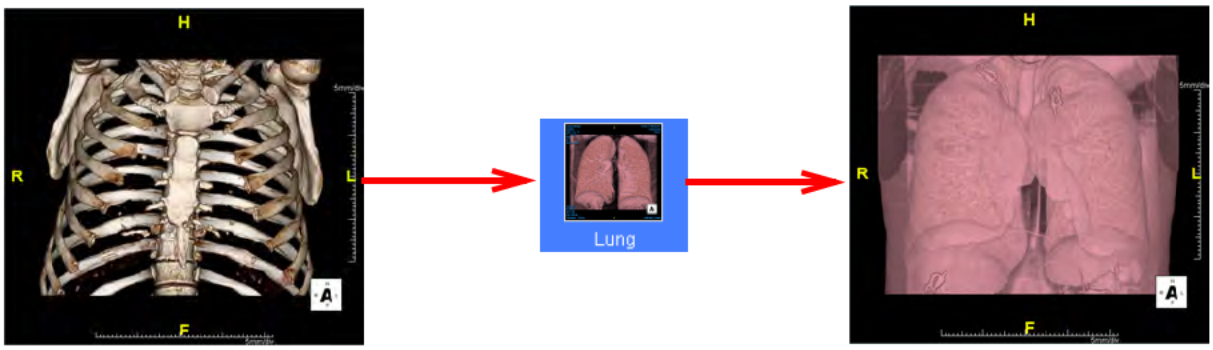

Figure 2-75: Left: Lung Data as Loaded; Center: Lung Template; Right: Template Applied

Adding a Template

You can create templates and add them to existing categories.

1. Click the **Add** button, which is located at the bottom of the template panel (see Figure 2-77). A dialog is opened.

2. Enter a name for the template in the dialog and click **OK**.

Any changes in the color settings or window/level made prior to creating the template are saved in the template. Those changes can then be applied to any 3D image.

The new template is added to the category that is currently showing, referred to as the **current category**. (Template categories are discussed in the next section.)

Deleting a Template

To delete a template, first make sure it is selected (see the following figure) and then click the **X** button next to the **Add** button.

Figure 2-76: Left - Template Not Selected; Right - Template Selected

For details on changing the 3D color settings, see 3D Settings.

Template Categories

Template categories are groupings of templates that have a related function. For example, one of the the default categories is Flythrough. All of the templates in this category are designed to show images of the colon in the most effective way:

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Figure 2-77: Flythrough Template Category

Selecting a Category

To select another category, To do so, click the category button located at the top of the template panel (circled in Figure 2-78). A pulldown menu is displayed:

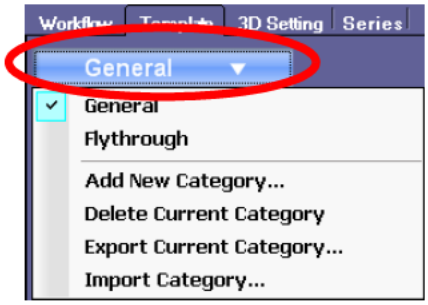
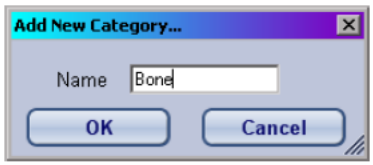


Figure 2-78: Template Category Menu

Category selections are listed in the top portion of the menu, above the horizontal line.

Creating a New Template Category

You can also create your own template categories, tailored to your specific needs. To add a category, select **Add New Category** from the menu (see Figure 2-78). This opens a dialog box where you can enter the name of the category:



The empty category is shown in the template panel:

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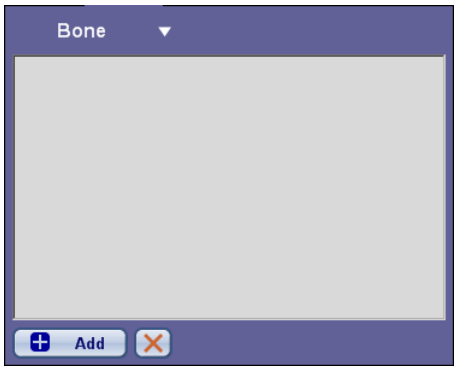
DRAFT



You can now add templates to the category, as described in Adding a Template.

To delete a category (including any of the default categories provided by TeraRecon), select **Delete Current Category** from the menu, and click **OK** in the confirmation dialog.

> **Caution: When you delete a category, all templates belonging to that category are also permanently deleted.**

Importing and Exporting Template Categories

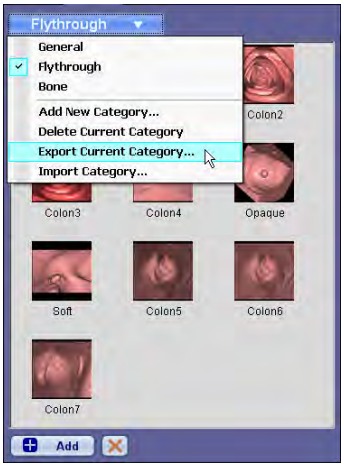
Use the Export function to save template categories on the local hard drive, or on any storage device that is accessible to the Windows file system. The Import function allows you to add a template category stored on a computer storage device to the Template panel.

Export Current Category

The Export function saves the current category and all of its templates in a single folder. To export a template, do the following:

1. Click the category name at the top of the Template panel to display the pulldown menu (see Figure 2-78 on page 2-156).

2. Select **Export Current Category** from the menu. A Windows navigation dialog is opened.



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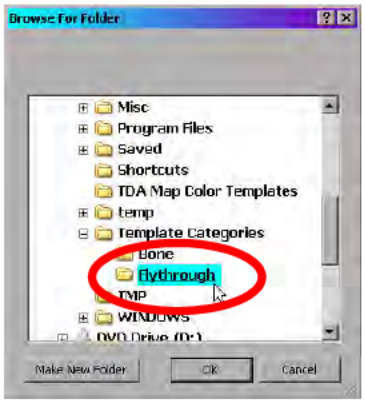
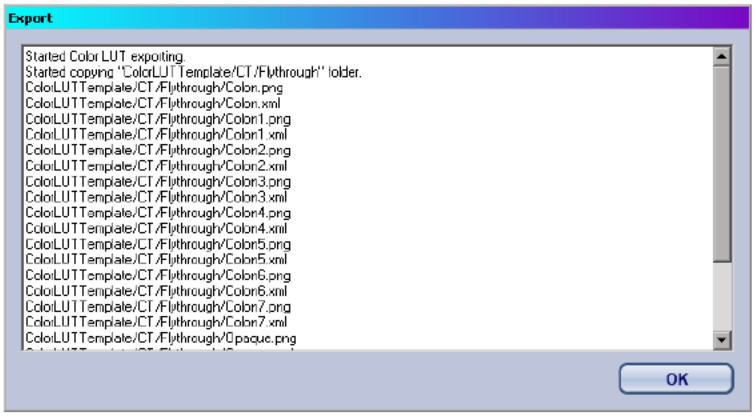
3. Navigate to the folder where you want to store the templates.

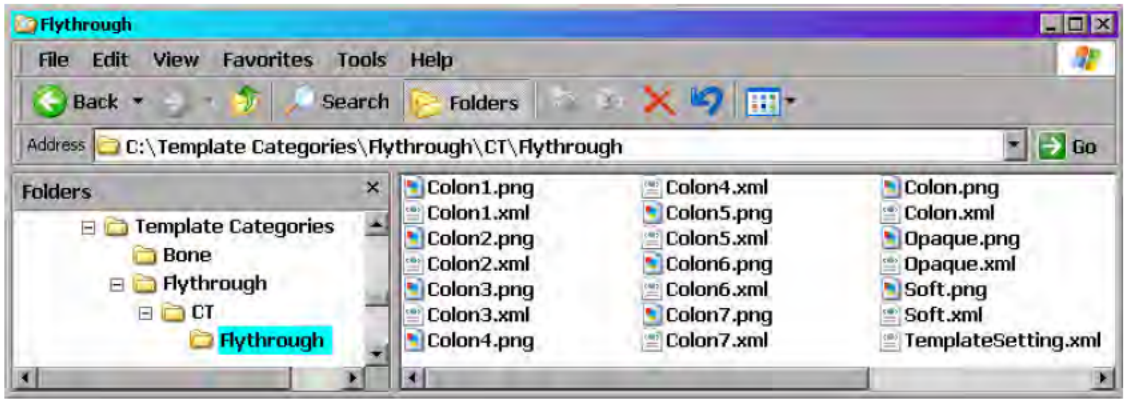
Note: This folder must be empty. Only one category can be stored in a folder at one time. To export two or more categories, you will need to create folders for each of them.



4. Click **OK**. The **Export** status window shows a list of the files that were exported. Click OK again to close the status window.



The template files are stored as XML documents, along with the icon images for each template. The category structure can be seen in the Folders panel on the left.



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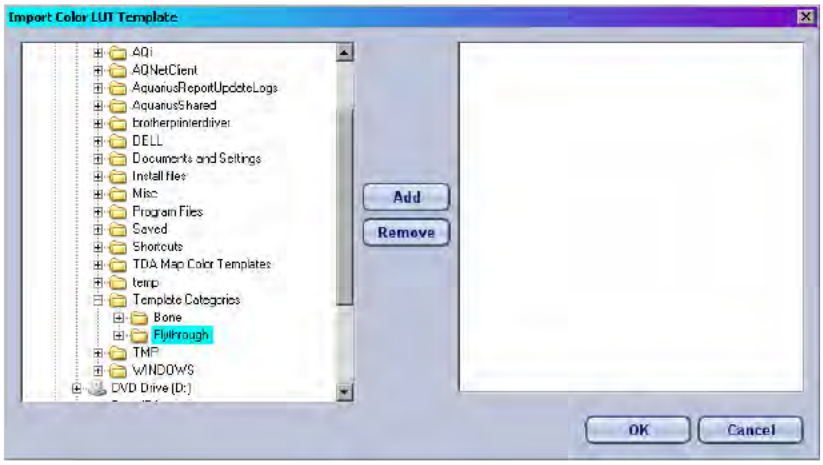
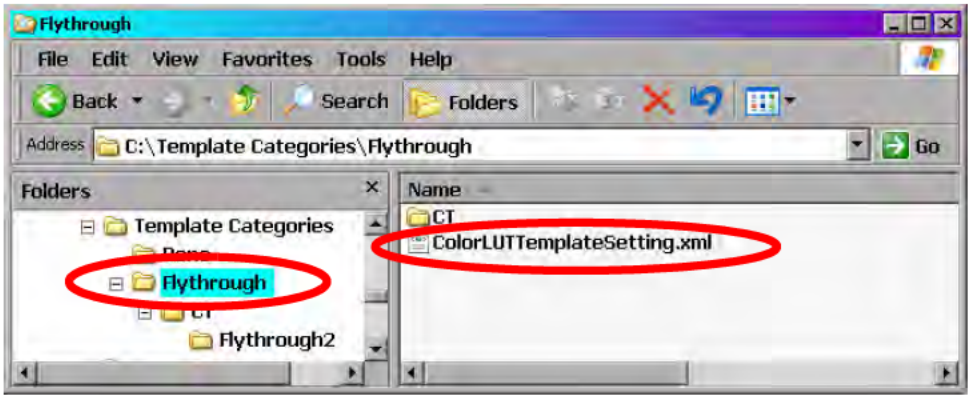
Import Category

To import a category that is stored on your computer or other local storage, select **Import Category** from the pulldown menu. A dialog is opened so that you can navigate to the folder where the category is stored.



Navigate to the folder that contains the file `ColorLUTTemplateSetting.xml`. This is not the folder that contains the template files, but is actually two levels above in the file structure.

Please see the following screenshot, of the Windows folder where template categories are stored. In this image, the **Flythrough2** folder contains the templates, but the **Flythrough** folder (highlighted in the image) is the one you need to navigate to. All template categories are similarly structured.



Click **Add** in the Import Color LUT Template dialog. The pathname of the folder is shown in the right panel. You can import multiple template category folders at the same time.

Click **OK** when you are ready to import.

3D Settings

The **3D Setting** tab, located in the upper-right corner (next to Workflow), allows you to adjust a 3D image for better viewing of critical sections under examination. You can adjust the opacity, window level, window width and rendering algorithm of the image. (See Figure 2-79.)

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Objects represent different segments of the image, depending on whether mask operations have been performed.

For example, if bone has been removed from the 3D image, two objects are displayed in the 3D Setting area. One represents the main image in its current state (having the bone removed). The second object represents just the bone that has been removed.

If you then remove the CT table from the image, a third object is displayed. The first object represents the main 3D image in its current state (having neither bone nor CT table included), the second object represents the bone that has been removed, and the third represents the CT table that has been removed.

When you click on one of these objects, the image corresponding to it is displayed in the 3D window. If you check the box next to any object, the image in the 3D window shows pixels from both objects, superimposed. This way, you can temporarily re-display bone, if necessary, without needing to add and then remove it from the image. If you wanted to see only bone, for example, you would uncheck all the objects except the "Bone" object.

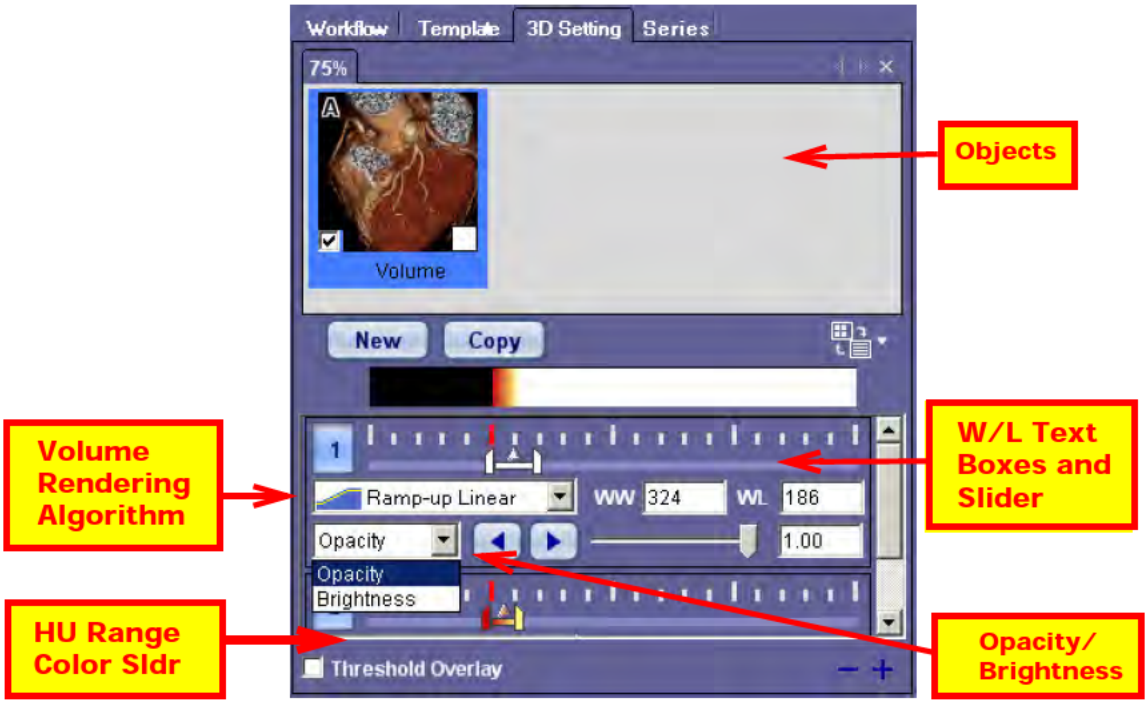

Figure 2-79: 3D Settings on Image Having Bone and CT Table Removed

Configuring 3D settings

Icon	Function
W/L Slider	Slide this bar to set the new HU value or drag either end of this bar to adjust the HU range.
W/L Input Boxes	Enter the value directly to set the desired HU value.
VR Pull-down Menu	Select the volume-rendering algorithm for optimal 3D visualization.

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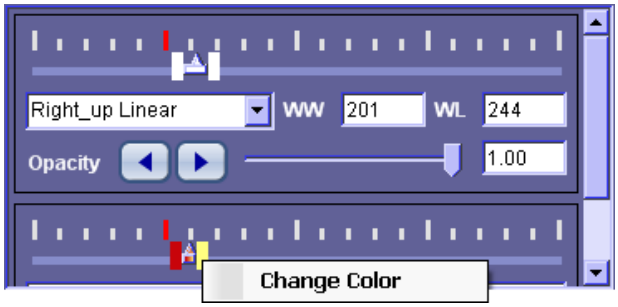
Icon	Function
Opacity Slider	Slide the slider bar to adjust the level of opacity of the object.
Opacity Input Box	Enter the direct value to adjust the level of opacity of the object.
Brightness Slider	Slide the slider bar to adjust the level of brightness of the object.
Brightness Input Box	Enter the direct value to adjust the level of brightness of the object.
HU Range Color Slider	Slide the slider bar to display portions of the image within different HU ranges.

Changing the Color

To change the color, perform the following:

1. In the color slider bar, right-click one of the sliders. A pull-down menu is displayed:



2. Select **Change Color**. This opens the color palette (see image at right).

3. Select a color from the color palette. You can also define a custom color. Click **OK** when done.

   The colors on the image now reflect the new range of colors, as you slide the slider back and forth to display parts of the image having different HU values.

Exporting a 3D Mask as a Mesh

You can output any 3D mask to local storage as a mesh, using any of several file formats for the output file.

1. To start the exporting process, right-click on the desired 3D mask and select **Export as Mesh**.

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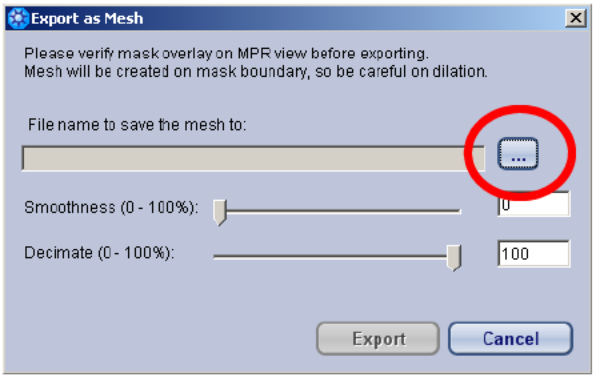
The **Export as Mesh** dialog is opened:

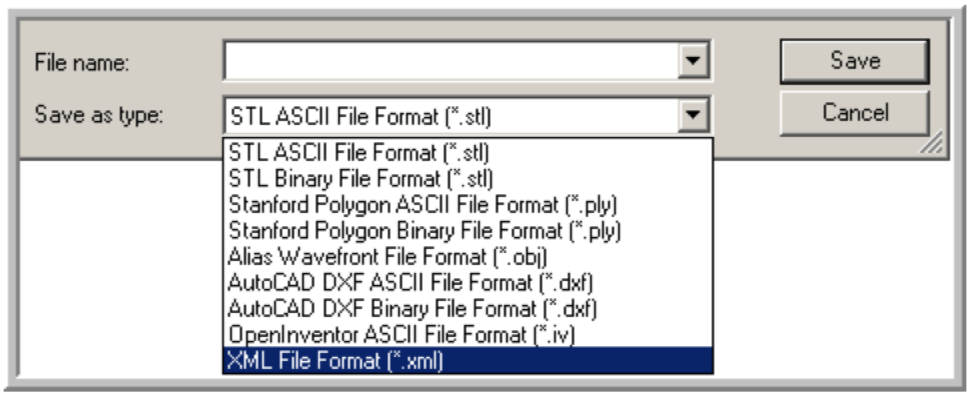


2. Click the browse button (circled in the previous image) to open a Windows navigation dialog.

3. Navigate to the desired folder.

4. Enter the name of the output file.

5. Select a file format (for example, XML, as shown below) from the **Save as type** list.



6. Click **Save** to begin the file export.

When the file export is completed, the output file will reside in the designated folder.

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Series

The **Series** tab is located in the Workflow panel, to the right of the **3D Settings** tab.

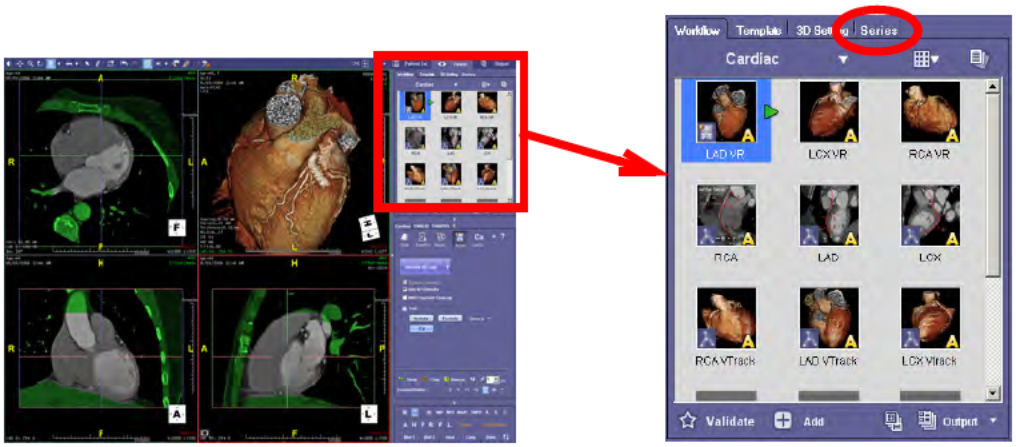
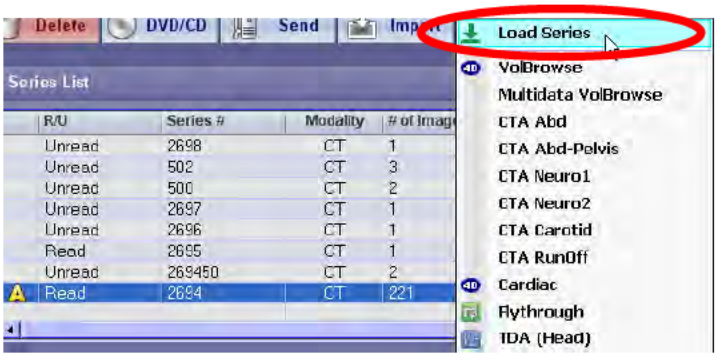


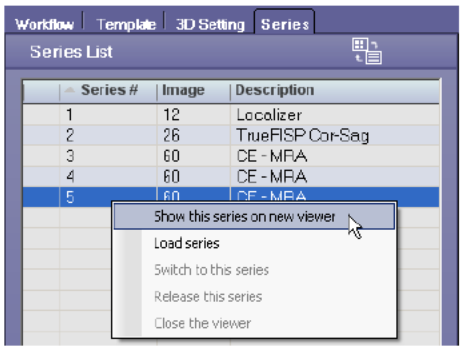
Figure 2-80: Series Tab in Workflow Panel

If a study has more than one series, or if you select multiple studies, the **Series** tab allows you to load and view several series at one time, from within the 3D Viewer.

For example, suppose you load only one series out of several that are part of a study:



The **Series** tab allows you to load and view other series at the same time from the viewer, without any need to go back to the Patient List (see figure below):



A new viewer opens in a second column, displaying the second series:

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Left: One series loaded; Right: Multiple series loaded

You can see which series is loaded in which column by scrolling the Series tab to the right, to see the **Loaded/Reviewing** column:

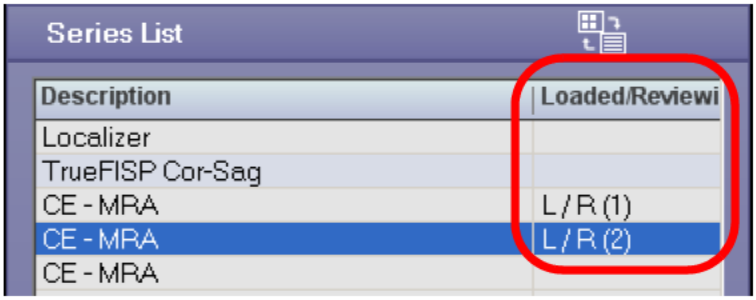

Figure 2-81: Loaded/Reviewing Column

Right-Click Menu Options

When you right-click on any series listed in the Series tab, a pull-down menu is displayed, offering you other options.

- Show this series on new viewer - Opens a new viewing column in the main window to display the selected series.
- Load series - If the series has not been loaded, this item is activated so you can load it into the viewer.
- Switch to this series - Displays this series in the selected viewer column.
- Release this series - Unloads the series.
- Close the viewer - Closes the viewing column.

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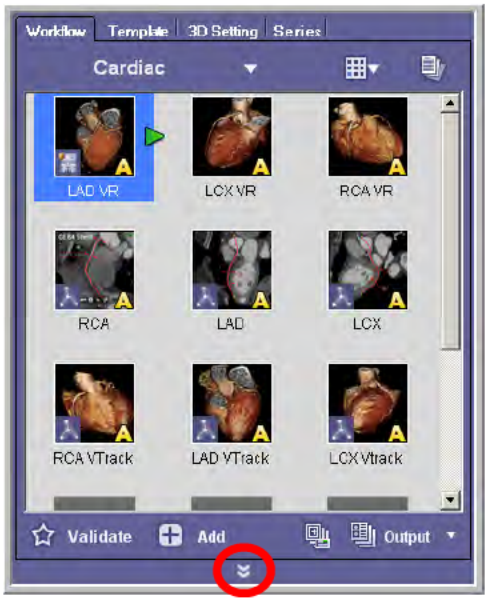
Hiding the Right Panel

To hide the right panel (and widen the Patient List), click the double right arrows that appear along the left edge of the tool panel, about halfway down the screen (see image below) . This closes the Search, Scenes, Reports, Aux File, and DICOM sections that are available from this panel, and devotes the entire screen to the loaded study. To display the right panel again, click the double left arrows on the far right of the screen.

Hiding the Tool Panel

If you need more space for the Workflow area, you can hide the Tool Panel. To do this, click the double down-arrow located just below the Workflow area (circled in the image at right).

The Tool Panel is hidden and the Workflow area (or Template, 3D Setting, or Series area) is lengthened to replace it. To display the Tool Panel again, click the double down-arrow, which is now located just above the mini-toolbars, in the bottom-right corner of the screen.



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Chapter 5: TVA and Cardiac Function

Introduction

The **Time-Volume Analysis** (TVA) optional module calculates time-dependent behavior of volumes in multi-phase studies from CT. An example of a time-dependent behavior is the change in the volume of the left ventricle of the heart.

Starting TVA for CT Studies

To load a study for TVA, do the following:

1. From the Patient List, select an appropriate CT study comprised of multiple series or subseries.

2. Highlight multiple series/subseries in the Series (or Subseries) List by clicking the desired series or subseries with the left mouse button, while holding down the **Ctrl** key.

   NOTE: Each series that you select should have the same number of images.

3. Load the series/subseries into the Cardiac Workflow by doing one of the following:

   - Right-click and select **Cardiac** from the pulldown menu.

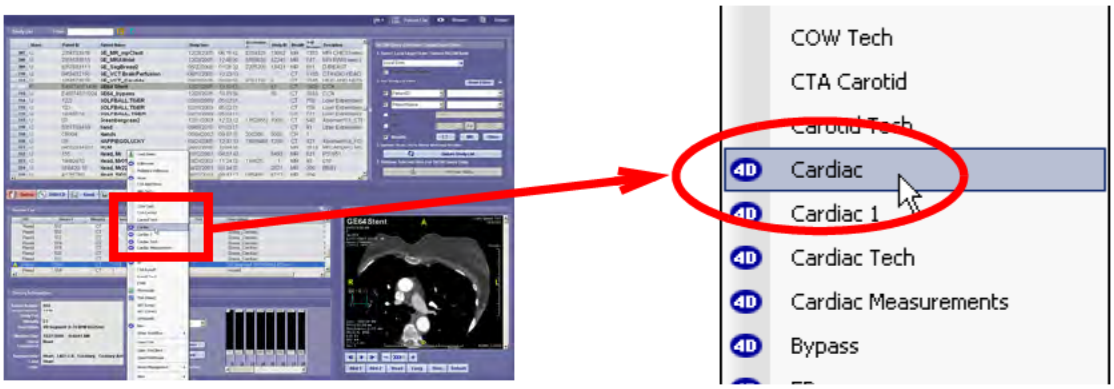

Figure 5-1: Right-Click on Series List and Select Cardiac Workflow

   - Click **Load** in the Data Management Tool Buttons (located in the middle-left of the screen), and then click **Cardiac** from the workflow buttons.

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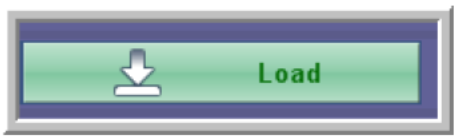

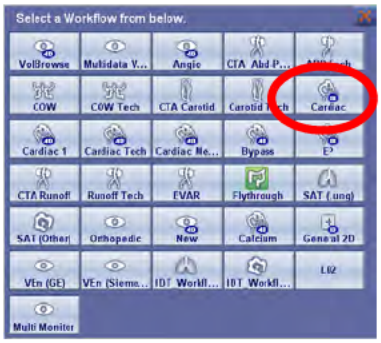

TVA of the Left Ventricle (LV)

Click either the **TVA(LV)** tab in the Tool Panel or the **LV EF** Workflow element:

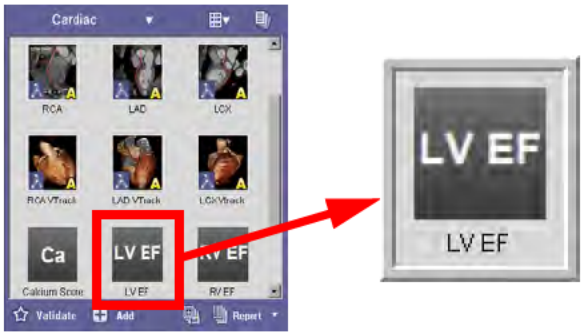

Figure 5-2: Left: TVA(LV) Tab in Tool Panel; Right: LV Ejection Fraction Workflow Element

Automatic vs. Manual EF

Ejection fraction on the left ventricle is calculated automatically by default. The measurements are verified to be accurate with artificial digital phantom data. However, clinical data is more complex. The user is responsible for verifying that the automatic segmentation (overlay and outlines) is correct on both the end-systolic and end-diastolic phases. If any part of the calculation is incorrect, TVA(LV) should be redone manually. The results are accurate if the segmentation is correct.

If in general you prefer to perform TVA(LV) manually, you can set a preference so that manual TVA(LV) is started by default. To set the preference, do the following:

1. Click the preference button in the top bar on the right.

2. The Preference window is displayed. Click on **TVA** in the navigation list and then **LV** in the sub-list to display the TVA(LV) preferences.

3. Check either the Manual, Automatic or Automatic (All Phases) checkbox. (Each selection is explained in the preference screen.)

The change will take effect the next time you start TVA(LV). For more details about TVA(LV) preferences, see "TVA(LV)" on page A-20

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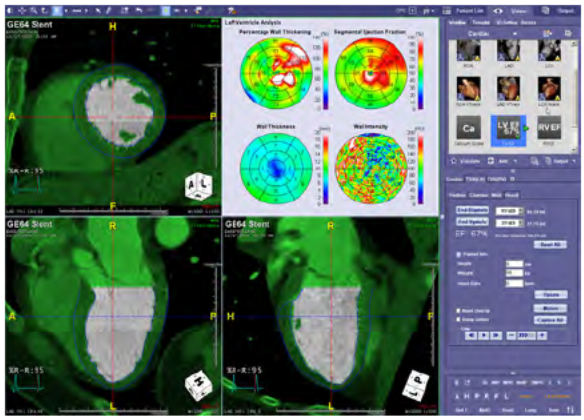
In automatic TVA(LV), the LV EF value is shown on the **LV EF** Workflow element when the calculation is completed, as shown below:



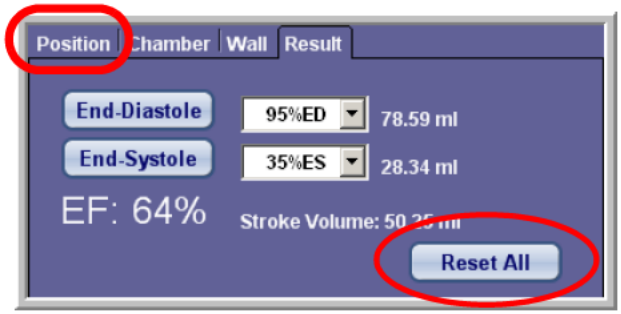
Performing Manual TVA(LV)

The Ejection Fraction on the left ventricle is calculated automatically when the module is invoked. However, you might prefer to perform TVA manually so that you can supply the positioning, threshold and segmentation data yourself.

Manual TVA(LV) is comprised of the following steps:

1. Positioning the images and defining the threshold.
2. Segmenting the volume of interest.
3. Making sure that the wall of the structure under analysis is correctly marked.
4. Viewing and interpreting the results.

To begin manual TVA(LV), click the **Position** tab or the **Reset All** button at the top of the Tool Panel (see image at right).



The Manual TVA(LV) window is displayed:

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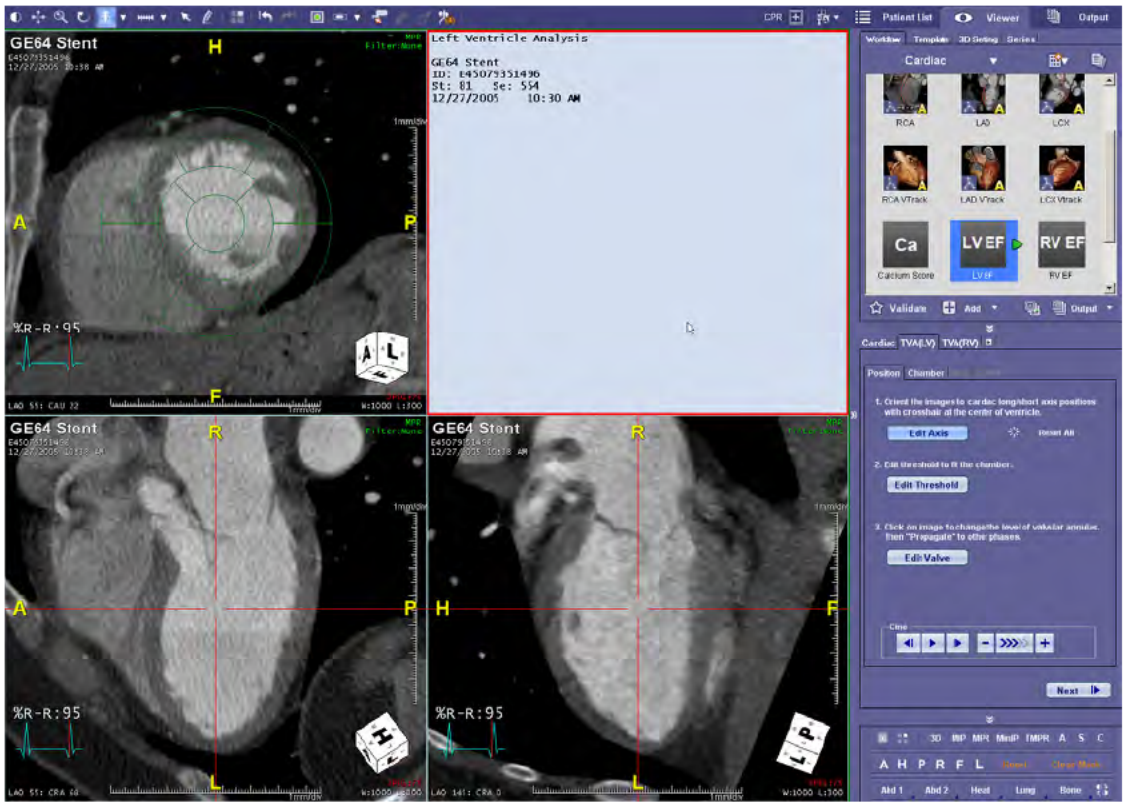


Figure 5-3: Manual TVA(LV) Window

Step 1 - Positioning and Threshold

The **Position** tab allows you to do the following:

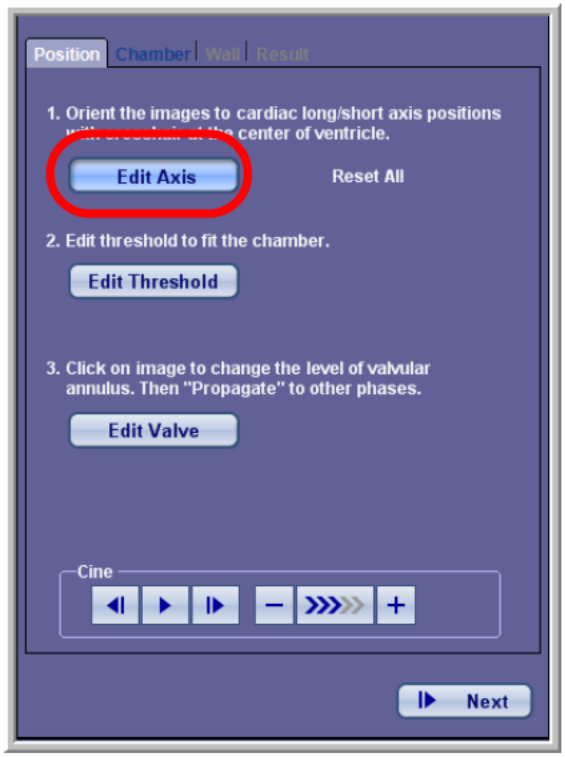
- Position the axis
- Edit the threshold of the contrast area
- Position the valvular annulus

Positioning the Axis

1. Click the **Edit Axis** button in the Tool Panel.

2. Move the mouse over one of the two long-axis views. The cursor changes to a rotation icon to indicate that you can now rotate the image.

3. Rotate the image so that the long-axis image displays the standard position, with the crosshairs at the center of the left ventricle (see Figure 5-4 on page 5-5).



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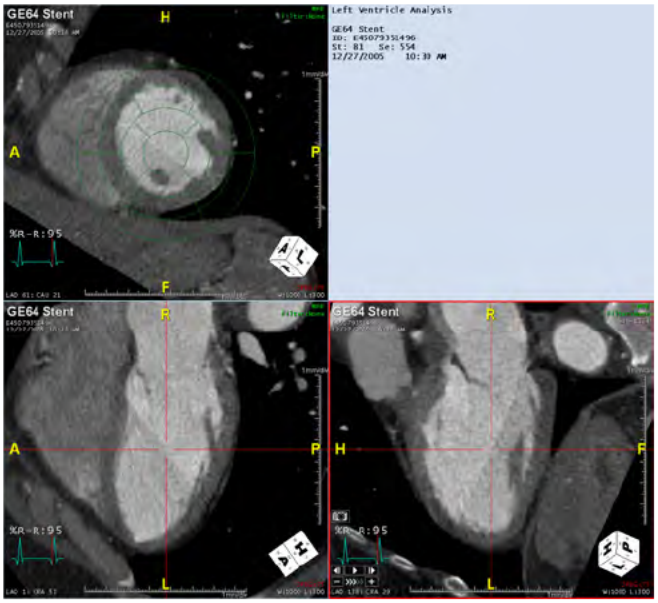

Figure 5-4: Edit Axis Screen

4. When you are satisfied with the positioning, click the **Edit Threshold** Button.

Editing the Threshold

The Aquarius *iN*tuition Client automatically applies the threshold to all the frames. Examine the threshold to make sure it is applied properly, and that the mask best fits the chamber.

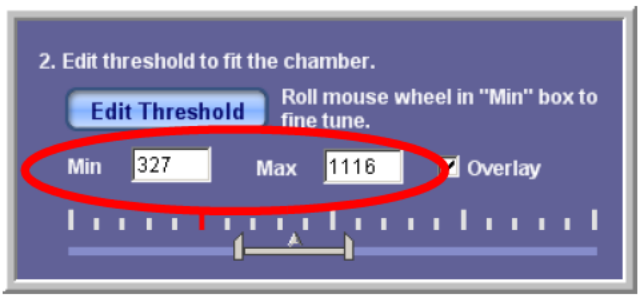

Figure 5-5: The Threshold

1. To adjust the level of overlay, click in the box labeled **Min**, and use the mouse wheel to change the value.

   In Figure 5-6 on page 5-6, the threshold has been properly adjusted:

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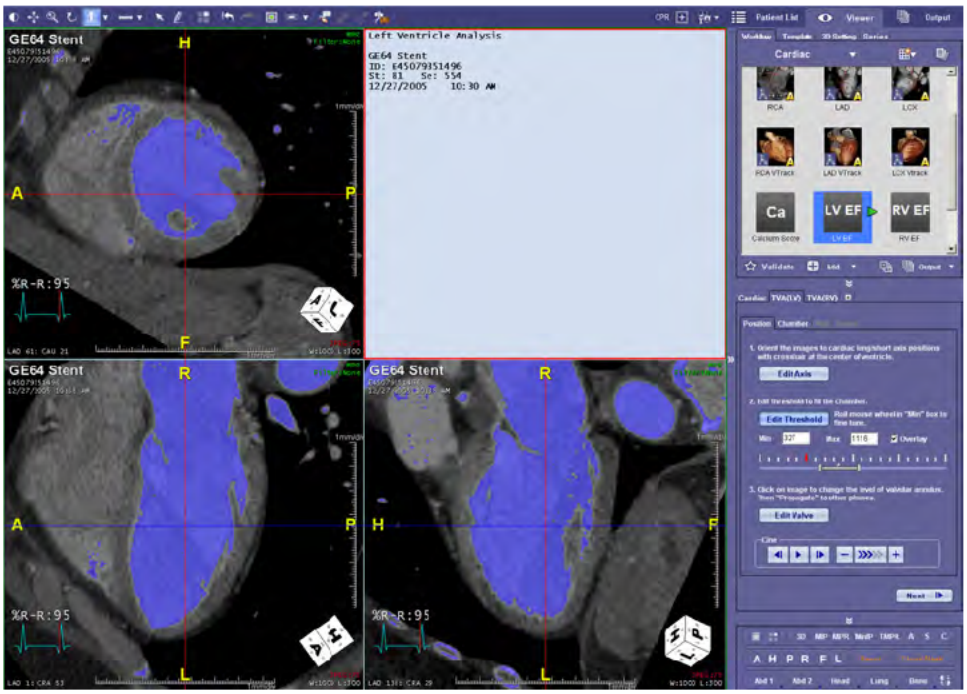

Figure 5-6: Threshold Correctly Adjusted

2. When the threshold has been properly adjusted, click the **Edit Valve** button.

Positioning the Valvular Annulus

The position of the valvular annulus is calculated internally, and is then displayed on the long-axis views with a horizontal green bar.

1. Examine the position of this bar in every phase to verify that it is correct.

2. If any is incorrect, adjust the level of valvular annulus by moving the mouse over the long-axis view that contains the error, and clicking on the place where the bar should be (see Figure 5-7 on page 5-6). The bar moves automatically to the selected position.

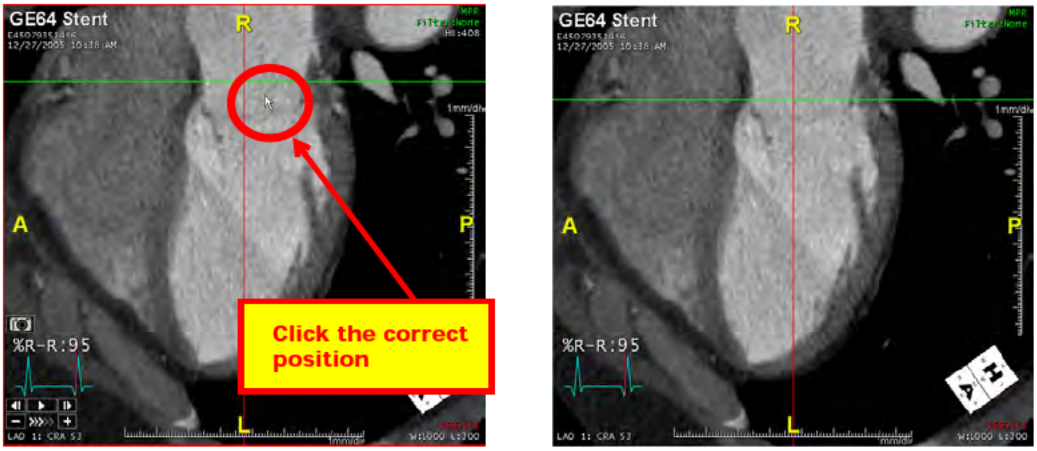

Figure 5-7: Adjusting the Valvular Annulus (Left: Incorrect; Right: Corrected)

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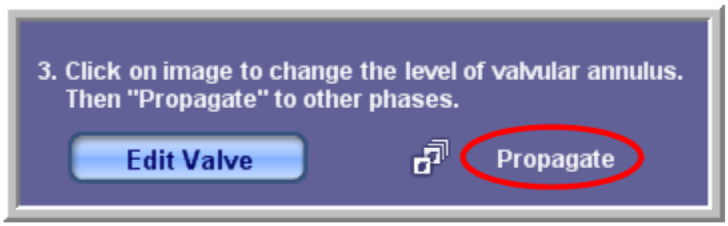
Click the **Propagate** button if you want the valvular annulus to be adjusted automatically in all phases.

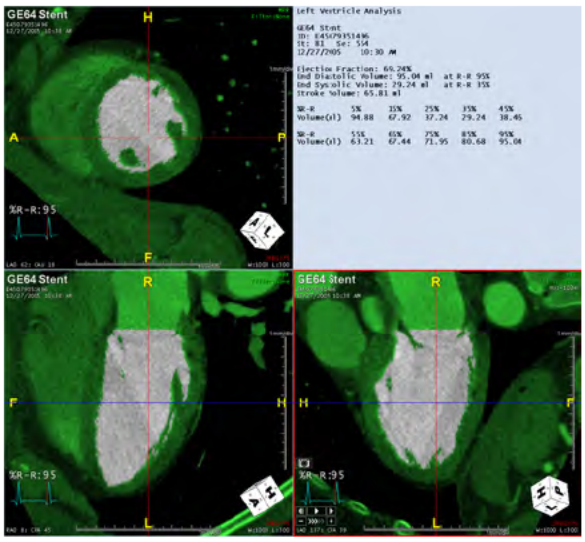


3. When you are ready, click the **Next** button located at the bottom of the Tool Panel, to advance to the **Chamber** tab.

Step 2 - Chamber Segmentation

The **End-Diastole** and **End-Systole** phases have been identified automatically and are displayed at the top of the tool panel (see figure at right). The Ejection Fraction value has also been calculated and is displayed just beneath.

The images are displayed in the main window, as shown below:



By default, the green overlay shows areas that have been removed by previous functions. If you would prefer to see the overlay on the areas inside the chambers, you can change that in the Preferences menu.

1. Click the **Preferences** button in the top bar (see page 5-2).
2. When the Preferences window opens, click **Viewer**, which opens a sub-menu underneath.
3. Click **Mask** in the sub-menu.
4. In the Mask preference window, *uncheck* the box that says **Overlay on Removed Area**.
5. Click OK.

For more information about TVA(LV) preferences, see "TVA(LV)" on page A-20.

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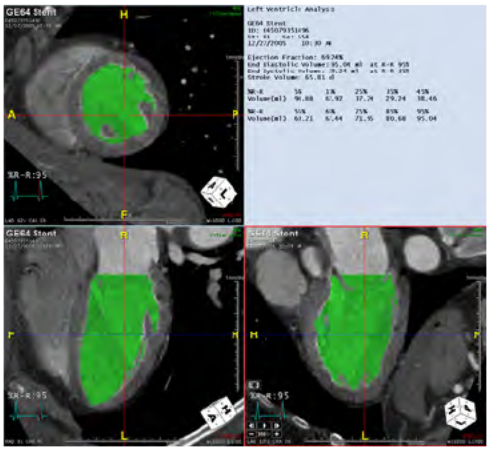
When this box is unchecked, the overlay displays only on the remaining area, after segmentation, as shown in the following figure:



1. Check each phase of the series to verify that the segmentation was performed correctly.

2. If you are not satisfied with the automatic segmentation on any phase, you can recalculate it by adjusting the valvular annulus again on that phase. Do this by clicking the **Previous** button at the bottom of the tool panel. The Position window is displayed.

3. Adjust the valvular annulus on any phase that was not correctly segmented, and click **Next** to come back to the Chamber window.

4. If the segmentation included any part of the heart that should not be considered part of the chamber, you can cut it out manually by doing the following:

   a. Hold down the shift key and click on the image.

   b. Draw a line along the image so that it separates the part you want to keep from the part you are cutting out.

   c. Release the mouse to begin the cut.

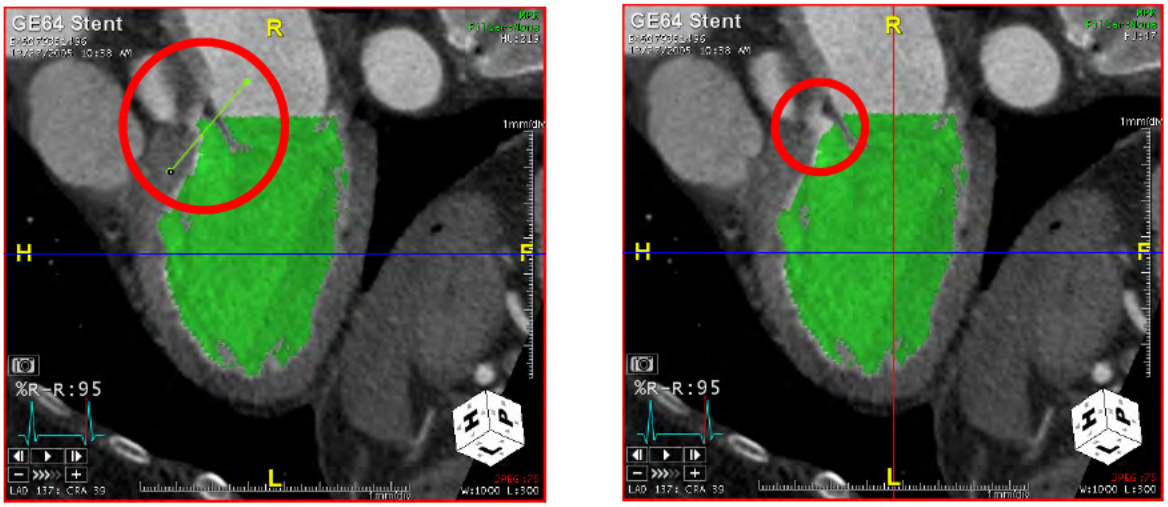


Figure 5-8: Left: Drawing Cut Line; Right: After Cut

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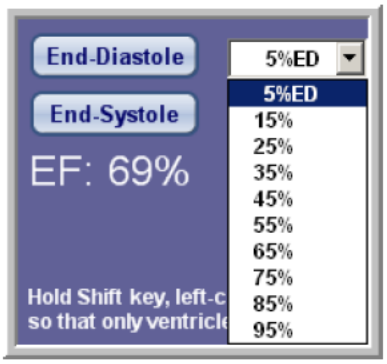
5. Check each phase of the series to verify that the end-diastole and end-systole are correctly identified. If they are not, you can change them by selecting the correct value from the pull-down menu beside the current value (see image at right).



6. When you are ready, click **Next**.

Step 3 - Wall Correction

The LV chamber from the Chamber stage has been wrapped and smoothed to generate the inner surface. The papillary muscles have been filled out in order to calculate the myocardial thickness. The software automatically expands the inner surface to fit the next contrast change, and the result is the outer surface. It may be incorrect when there isn't enough contrast, in which case it needs to be corrected manually.

In this step, perform any corrections necessary to ensure that the ventricle wall has been properly segmented. You need do this only for the End-Diastole and End-Systole phases, as those are the only phases needed for calculations that are done from this point on.

In addition, corrections made in this step affect the wall thickness/thickening and the myocardial volume only. Ventricular volumes and ejection fraction have already been determined in the previous step.

To perform corrections in the wall, do the following:

1. Use the End-Diastole and End-Systole buttons to display these phases.

2. Rotate the image to examine the wall, to verify that it was correctly drawn. If some portions are not correct, you can redraw this sections manually.

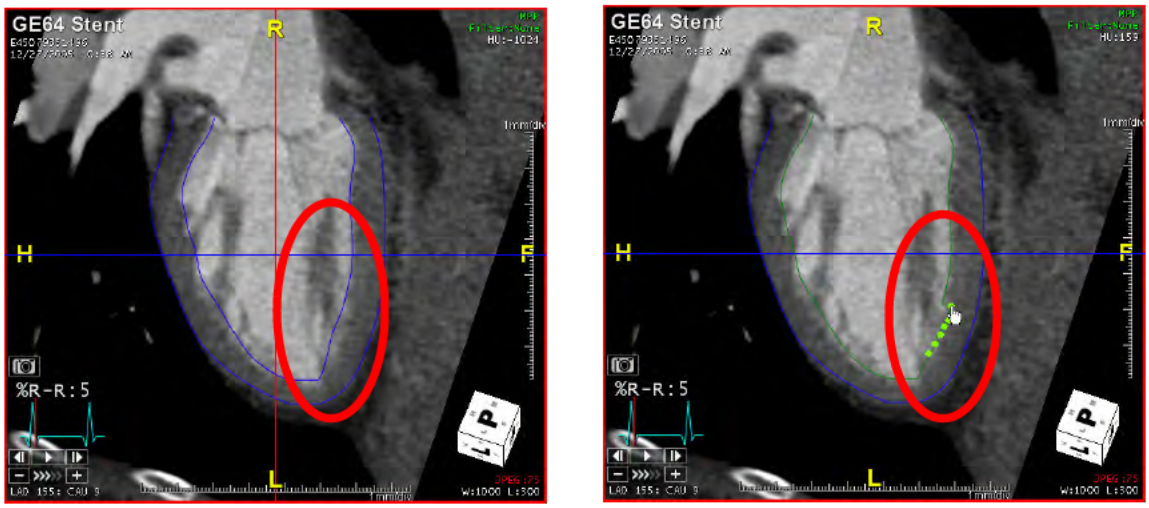


Figure 5-9: Left: Boundary Lines Not Correct; Right: Redrawing Wall

3. Hold the **Shift** key and do multiple clicks along the edges of the wall to redraw the wall in the correct place (see the image on right in Figure 5-9).

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4. When you have finished placing correction dots along the incorrect section of wall, release the shift key to trigger the automatic redraw.

Note: You might need to do this several times to get the boundary lines in the exact place you need it to be.

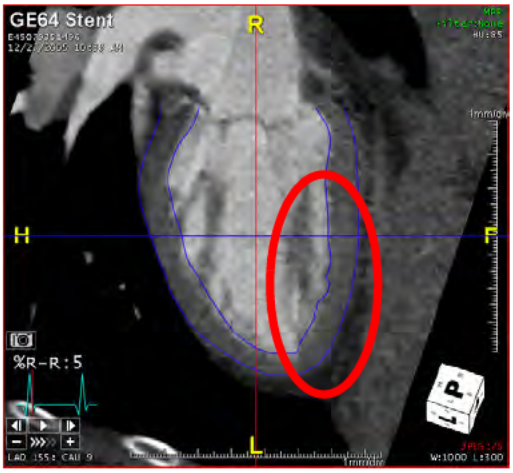

Figure 5-10: Boundary Line Corrected

5. Click **Next** to proceed to the final step.

Step 4 - Calculation and Result

In this step, the cardiac function is calculated and the results are displayed by the software (see the following figure).

Figure 5-11: Manual TVA(LV) Results (Tool Panel)

Presentation of TVA(LV) Results

You can now view tables, graphs, and polar maps of the segmental ejection fraction, wall thickness, and other parameters.

1. To generate these displays, first enter the patient's height, weight, and heart rate into the Patient Info fields.

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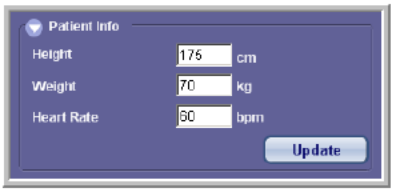
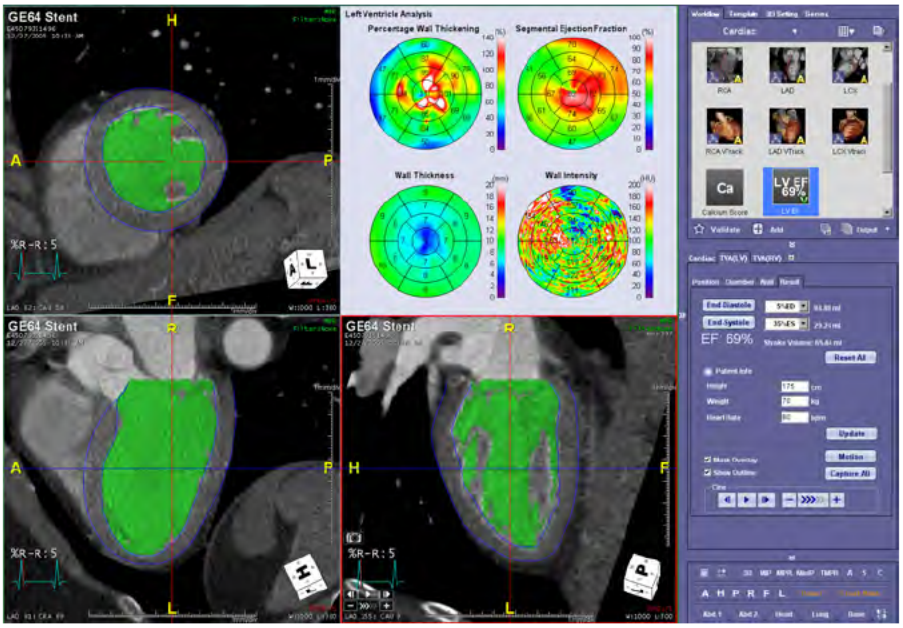
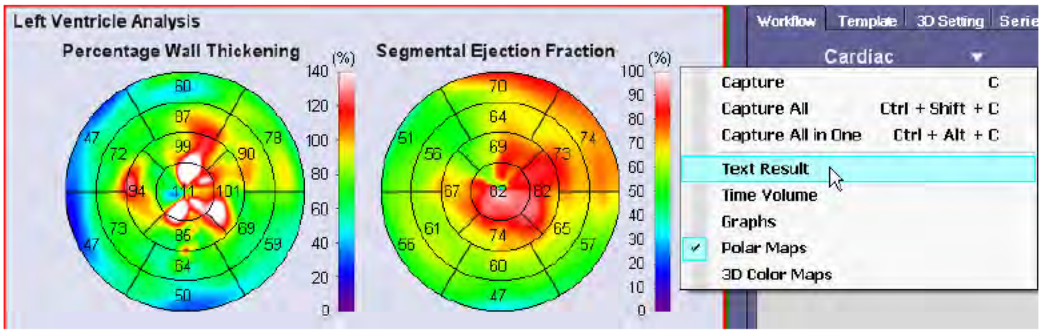


2. Click the **Update** button. The manual TVA(LV) result window is displayed:



You can review different TVA(LV) results in different formats, inclucding text, as a time-volume curve, as a graph, or as a polar map. To change the format for displaying data, do the following:

1. Right-click on the polar map, displayed in the upper-right corner of the main window (see the following figure). This displays a pull-down menu.



2. Select a display format from the menu.

NOTE: The results vary for each frame. Click on each frame using the Cine buttons to view the corresponding data.

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Polar Maps

A polar map shows the distribution of an index on the surface of the left ventricle. The middle corresponds to the apex and the border corresponds to the base. Orientation is the same as the short axis image. Only slices containing myocardium in all 360° are selected. The polar map is divided into 17 segments and an averaged value is labeled on each segment. The segmentation of the polar map conforms to AHA's standard. See the following article for details:

AHA Scientific Statement: Standardized Myocardial Segmentation and Nomenclature for Tomographic Imaging of the Heart (Circulation 2002;105:539-542).
http://circ.ahajournals.org/cgi/content/full/105/4/539

The following are views of different TVA(LV) results in polar maps.

Wall Thickness and Wall Thickening

With the ventricular wall segmented, the wall thickness can be measured automatically, anywhere on the wall. The percentage wall thickening is calculated from the end-systolic wall thickness (Ws) and end-diastolic wall thickness (Wd), as follows:

```
Percentage wall thickening (%) = (Ws - Wd) / Wd  X 100
```

This formula is valid anywhere on the wall.

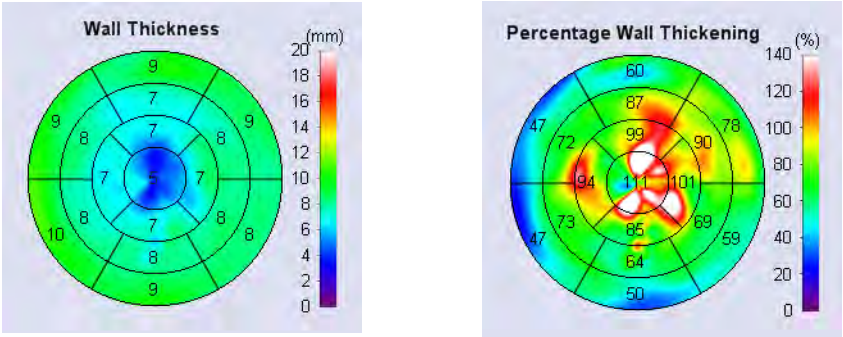

Figure 5-12: Left: Wall Thickness; Right: Wall Thickening

Segmental Ejection Fraction and Wall Intensity

On the short-axis image, the chamber is divided into many sectors in which segmental ejection fraction is calculated. Compared with global ejection fraction, segmental ejection fraction is a regional property that reveals how much blood under a piece of muscle is pumped out.

The wall intensity is sampled at the middle layer between the inner wall and the outer wall. Voxels away from the middle are not sampled because they are subject to partial volume effect and don't reflect the true intensity of the myocardium.

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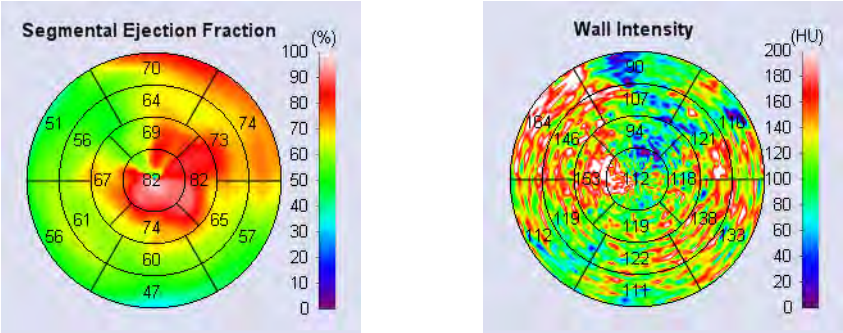
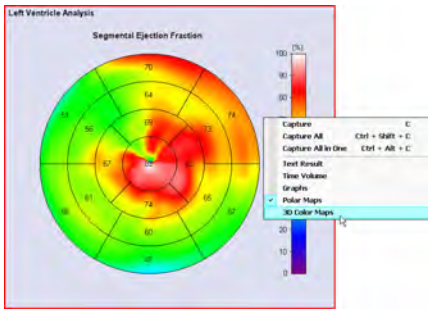


Figure 5-13: Left - Segmental Ejection Fraction; Right - Wall Intensity

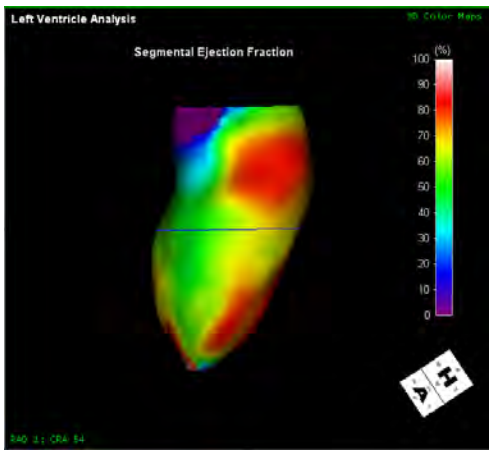
Note: Double-click on the Polar Map display to toggle between single-image view (1x1) and 4-in-1 view.

3D Polar Maps

To view any of the polar maps in 3D, right-click on the desired map and select **3D Color Maps**.



The polar map is displayed in 3D (see the following figure).



To return to the 2D polar maps, right-click and select **Polar Maps**.

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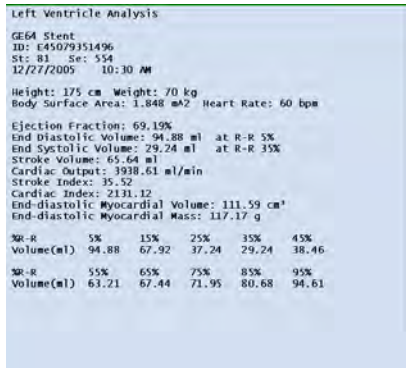
Other Formats

Text



```
Left Ventricle Analysis

GE64 Stent
ID: E450/9351496
St: 81   Se: 554
12/27/2005     10:30 AM

Height: 175 cm  Weight: 70 kg
Body Surface Area: 1.848 m^2  Heart Rate: 60 bpm

Ejection Fraction: 69.19%
End Diastolic Volume: 94.88 ml  at R-R 5%
End Systolic Volume: 29.24 ml   at R-R 35%
Stroke Volume: 65.64 ml
Cardiac Output: 3938.61 ml/min
Stroke Index: 35.52
Cardiac Index: 2131.12
End-diastolic Myocardial Volume: 111.59 cm³
End-diastolic Myocardial Mass: 117.17 g

%R-R        5%      15%     25%     35%     45%
Volume(ml)  94.88   67.92   37.24   29.24   38.46

%R-R        55%     65%     75%     85%     95%
Volume(ml)  63.21   67.44   71.95   80.68   94.61
```

Figure 5-14: Text of TVA(LV) Values

Graphs

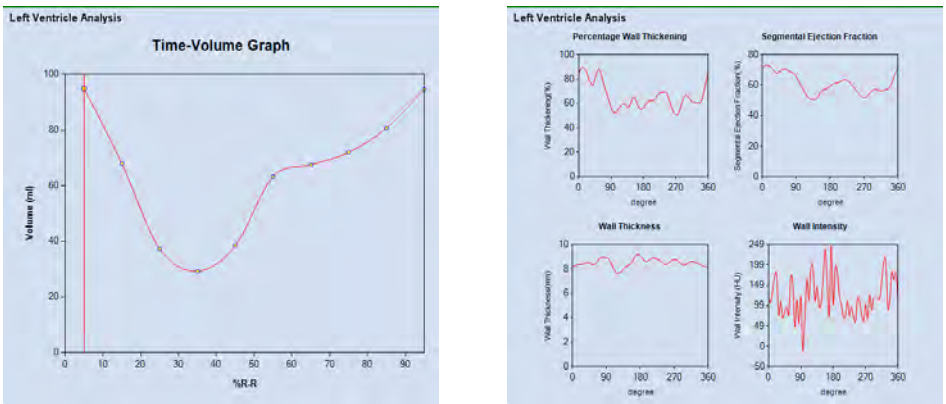


Figure 5-15: Left: Time-Volume Graph; Right: The four graphs in TVA(LV)

Calculation Algorithms

The values calculated are defined as follows:

Left Ventricular Volume: The Left Ventricular chamber is segmented using the threshold, the level of valvular annulus, and the cutting. Next, the Left Ventricular volume is calculated by multiplying the number of voxels in the chamber with the volume of a single voxel.

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Formulas for Other TVA(LV) Values

Value	Formula
Left Ventricular Stroke Volume	LV End Diastolic Volume - LV End Systolic Volume
Left Ventricular Stroke Index	(Stroke Volume) / (BSA)
Left Ventricular Cardiac Output	(Stroke Volume x Heart Rate) / (1000)
Left Ventricular Cardiac Index	(Cardiac Output) / (BSA)
Ejection Fraction	((LV End Diastolic Volume - LV End Systolic Volume) * 100) / LV End Diastolic Volume

Myocardial Volume - The myocardial volume is calculated at the end diastolic phase using the total volume from the outer surface minus the ventricle volume (by threshold and cutting).

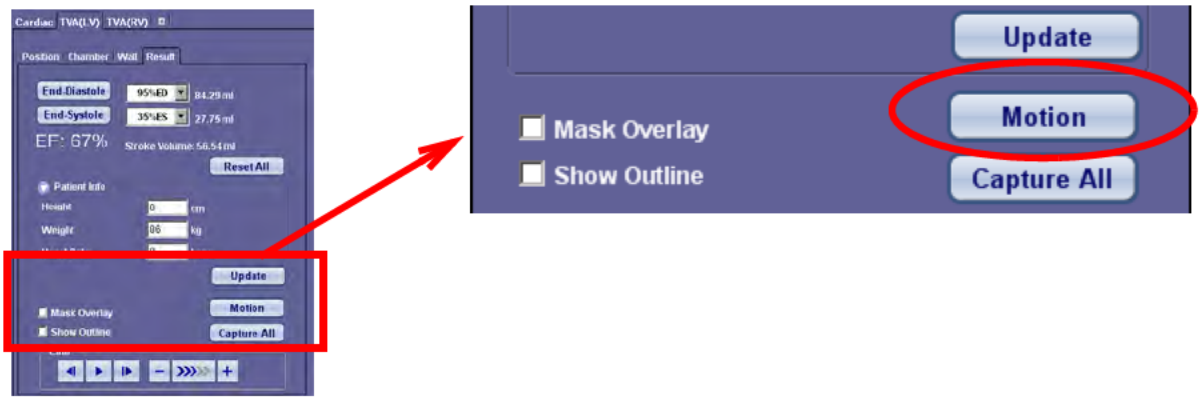
To perform wall analysis, open the **TVA(LV)** Preferences window and check the box labeled **Perform Wall Analysis (for myocardial mass, wall thickening, etc.)**. You can also enter the Myocardial Density in a text-input box in the same window. (For instructions on how to open the TVA(LV) Preference window, see "TVA(LV)" on page A-20.)

Colored Motion Maps

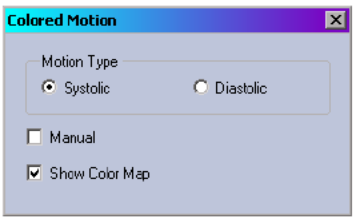
Colored motion maps show the motion of blood at the systolic and diastolic phases. This feature is most useful for capturing images to send to a colleage who does not have access to a 4D cine of the study.

Note: This feature should be applied after TDA (either manual or automatic) has been performed.

1. To show colored motion, click the **Motion** button in the Tool Panel:



The **Colored Motion** dialog box is displayed, as shown at right.



Systolic motion is selected by default. The cine is played automatically, stepping through each phase of the study until the end-systole phase is reached. At that point, the cine stops and the color is overlaid.

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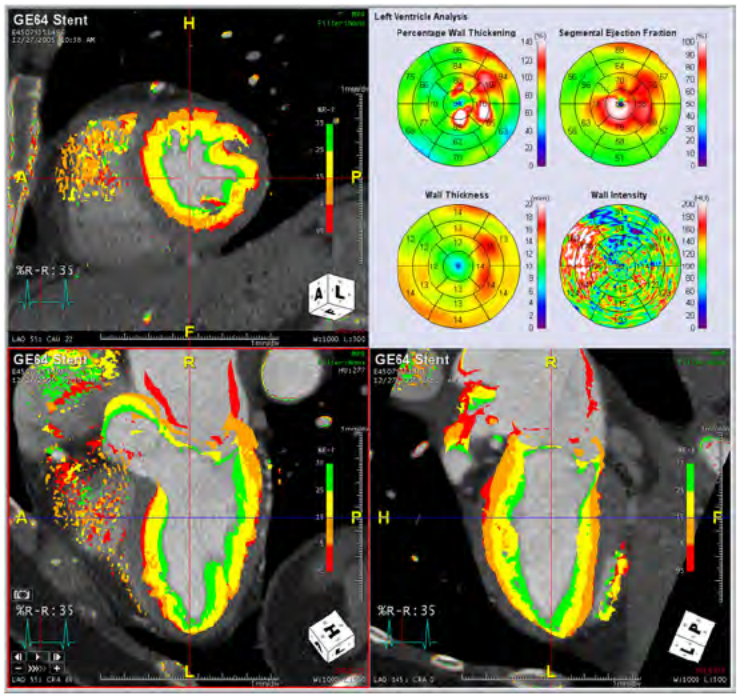

2. Before capturing images to the Output Panel, verify that colored motion overlays are included with captured images.

   1. Open the Preferences tool.
   2. Click **Output Panel** in the navigation panel on the left.
   3. Click the down arrow just to the right of the text reading **Capture image including Color Overlay**.
   4. Check the **Colored Motion** box, if it is not already checked.
   5. Click **OK** to exit Preferences.

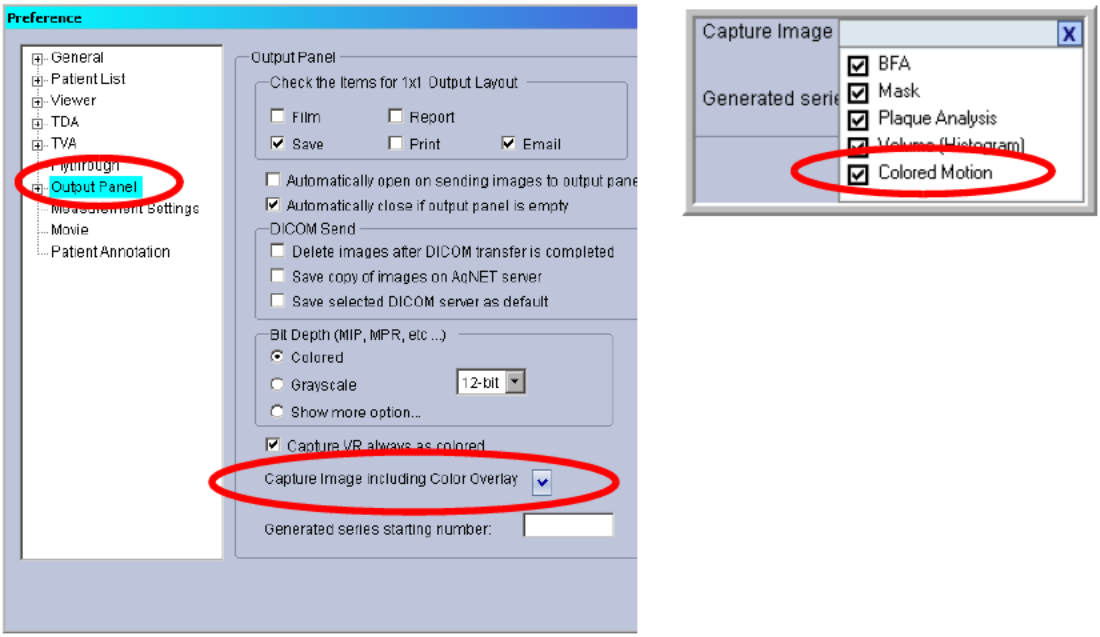

Figure 5-16: Left: Output Panel Preference Screen; Right: Colored Motion Checkbox

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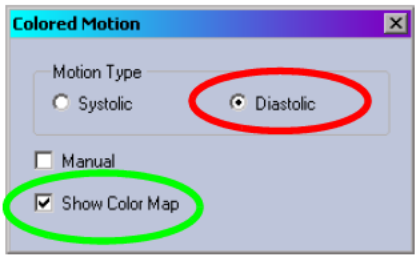
6. Capture images to the Output Panel.

You can show the colored motion overlay for the end-diastole phase by clicking **Diastolic** in the **Colored Motion** dialog.



To hide the color overlay, uncheck **Show Color Map** in the **Colored Motion** dialog (circled in green, above).

TVA of the Right Ventricle (RV)

A different procedure is needed to analyze the volume change of the heart's right ventricle.

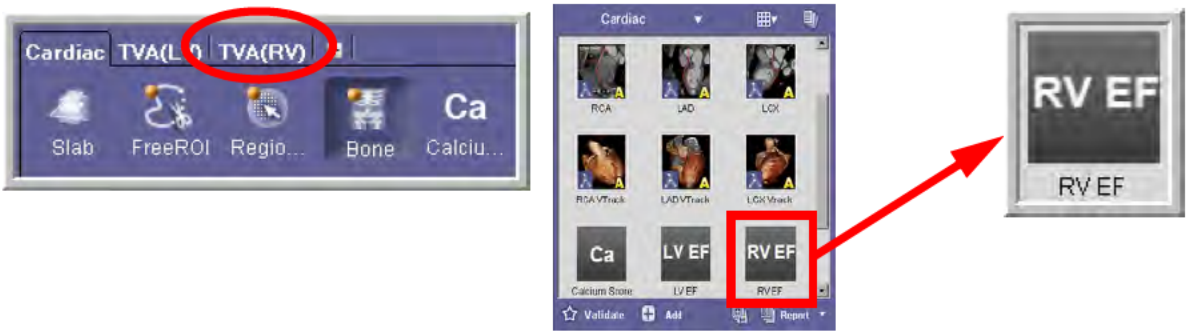
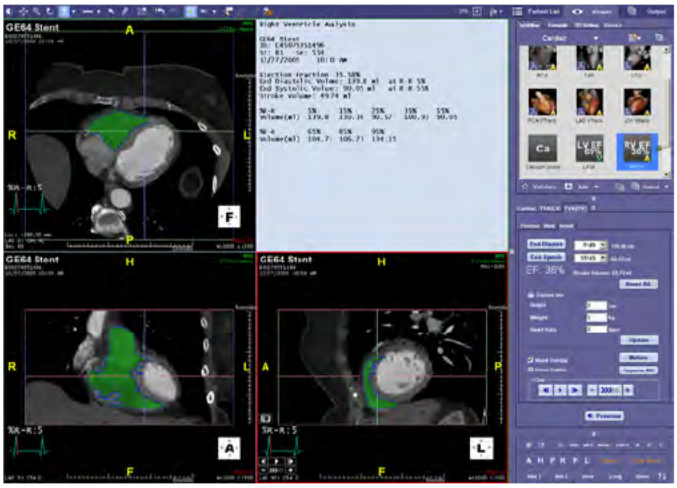


Figure 5-17: Left: TVA (RV) Tab in Tool Panel; Right: RV Ejection Fraction Workflow Element

The right-ventricle ejection fraction is calculated automatically when the RV EF or TVA(RV) module is invoked.



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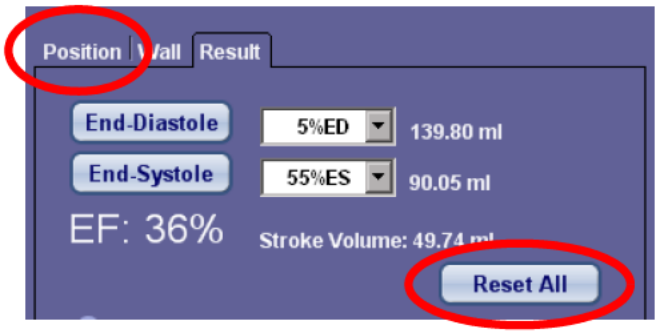
Performing Manual TVA(RV)

In some cases, you might prefer to perform TVA(RV) manually so that you can supply the positioning, threshold and segmentation data yourself.

Manual TVA(RV) is comprised of the following steps:

1. Positioning the images and defining the threshold.
2. Segmenting the volume of interest.
3. Making sure that the wall of the structure under analysis is correctly marked.
4. Viewing and interpreting the results.

To begin manual TVA(RV), click the **Position** tab or the **Reset All** button in the tool panel (see the following image).



The Manual TVA(RV) window is displayed:

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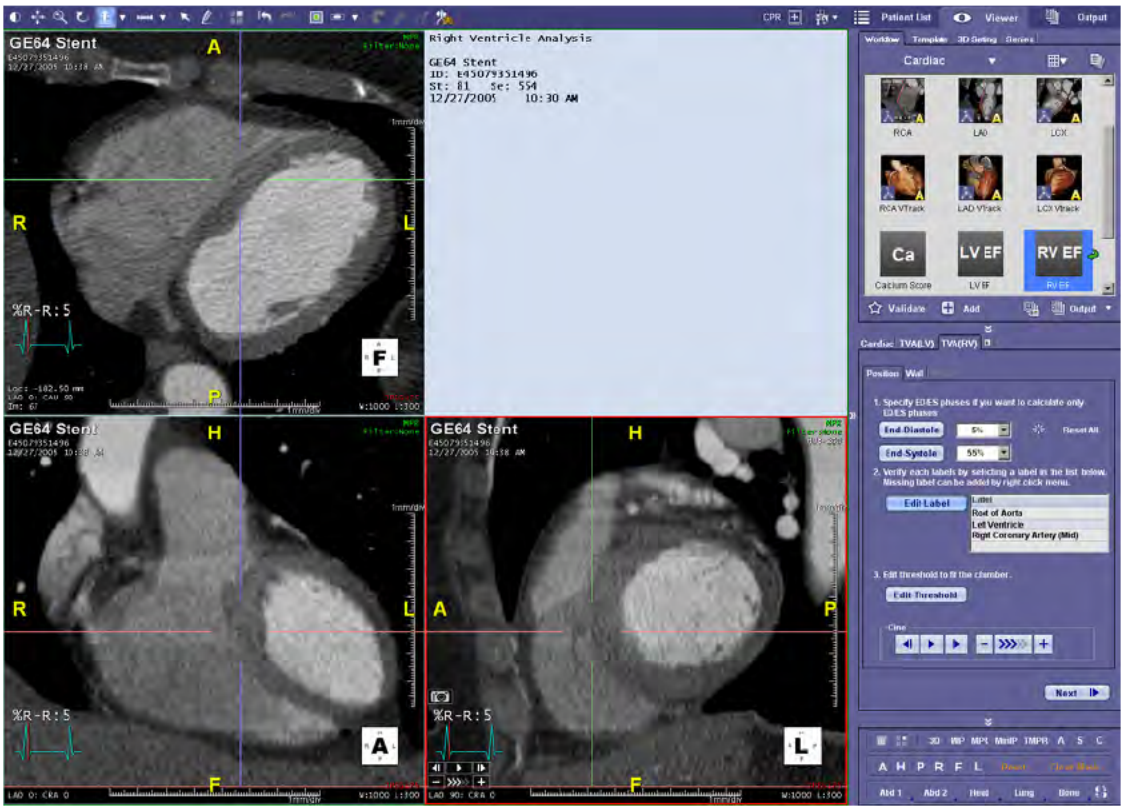
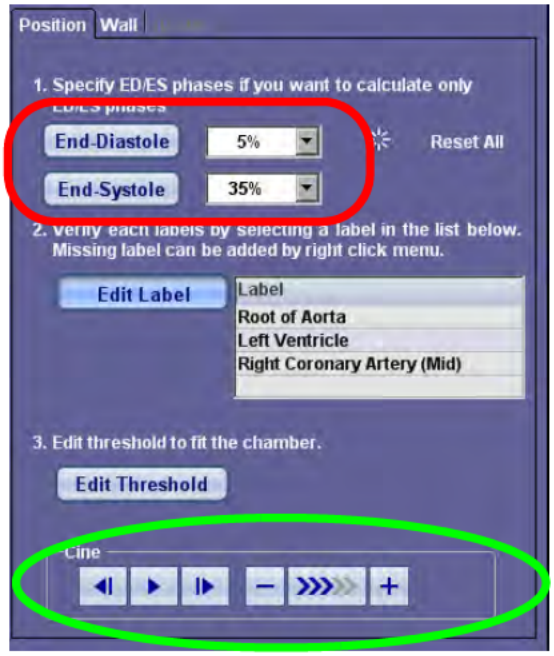


Figure 5-18: Manual TVA(RV) Window

Step 1 - Positioning and Threshold

The **Position** tab allows you to do the following:

- Select the best phases to mark as end-diastole and end-systole.
- Mark the positions of the aortic root, the left ventricle and the proximal RCA.
- Edit the threshold of the contrast area.



Selecting End-Diastole and End-Systole

1. Choose an MPR image that has the best view of the chamber wall and hover the mouse over that image so that the cine buttons are showing. (Alternatively, you can use the cine buttons in the tool panel, circled in green in the image at right.)

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2. Using the step-forward cine button, examine the chamber wall in each phase to determine which one is largest (the most full). This should be the end-diastolic phase. (See the following image.)

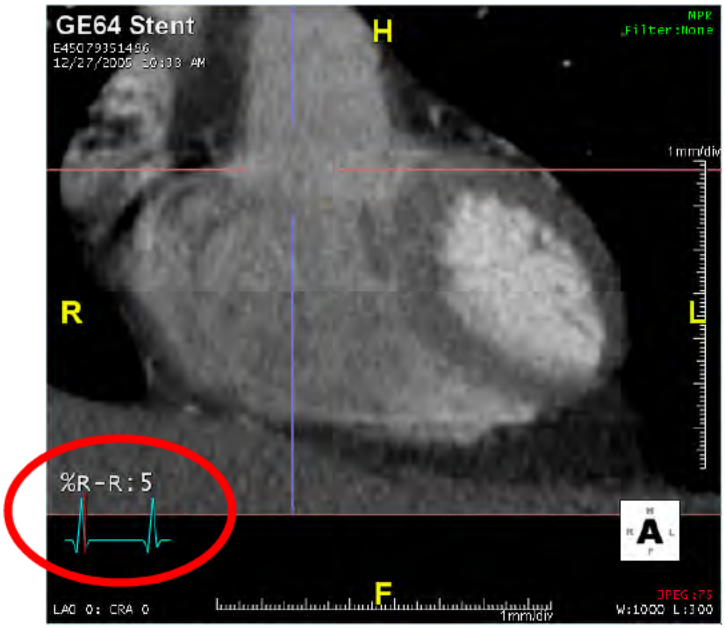

Figure 5-19: End Diastole

3. If the phase designated as **End-Diastole** in the tool panel (see buttons circled in red in the image above) is different from the phase you have determined to be end-diastole, select the correct value from the pulldown menu beside the **End-Diastole** button (see the following image).

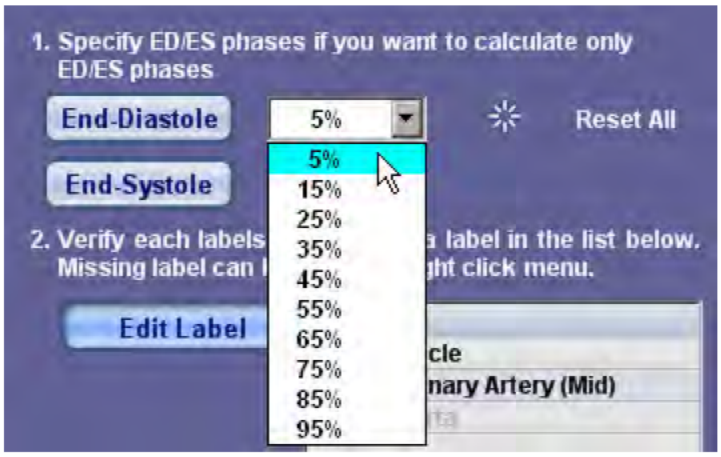

Figure 5-20: Reset End Diastole

4. Repeat steps (2.) and (3.) to verify the end-systole phase.

5. When you are satisfied with the positioning, click the **Edit Label** Button.

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Editing Labels

This section allows you to verify that the labels placed on the images are correct. If they are not, you can move them to the right place.

For example, to verify the RCA label and, if necessary, move it, do the following:

1. Click the **Right Coronary Artery (Mid)** item in the **Label** list (see the following image).

2. The right coronary artery is labeled **RCA** on the lower-left MPR image. If it is correct, you are finished with this step.

3. If the RCA is incorrectly labeled, move it by doing the following:

   a. Hold down the **Shift** key

   b. Click on the label and drag it to the right location.

Figure 5-21: Left: Label in Incorrect Place; Right: Label Corrected

4. Repeat the previous three steps for the **Left Ventricle** and **Aortic Root** labels.

Editing the Threshold

The Aquarius i*N*tuition Client automatically applies the threshold to all frames. Examine the threshold to make sure it is applied properly, and that the mask best fits the chamber.

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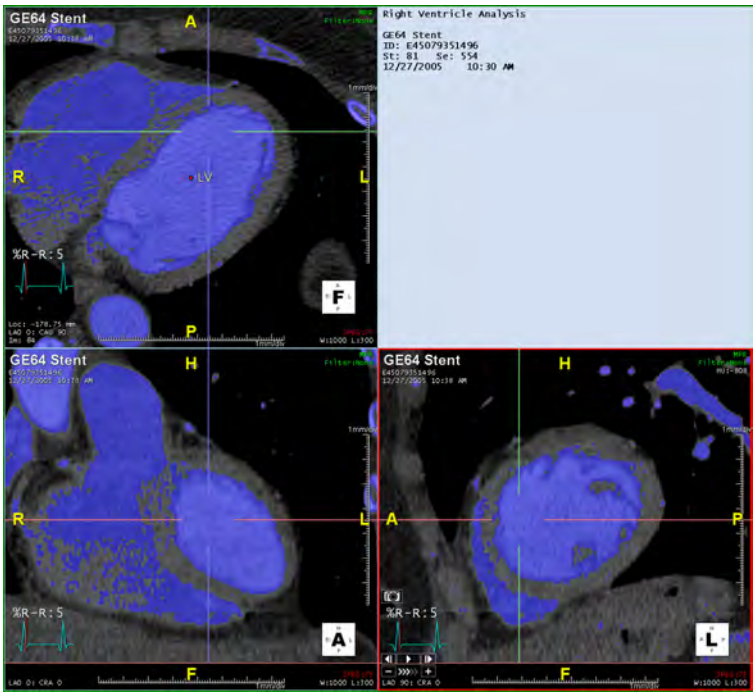
Click the **Edit Threshold** button. To show the overlay, check the **Overlay** box. Use the slider to change the mask area on the images. You can also enter minimum and maximum HU values in the **Min** and **Max** input boxes.

In the following figure, the threshold has been properly adjusted:



When you are satisfied with the threshold coverage, click the **Next** button in the tool panel.

Step 2 - Wall

If there is insufficient contrast, the segmentation may be incorrect. If so, you will need to make corrections manually.

You can make corrections in every phase, but only the end-diastole and end-systole phases are required for the ejection fraction calculations. However, for each phase in which you do make corrections, you must correct **every slice** that has segmentation boundaries drawn. The right ventricle is too irregular for slice interpolation.

To perform wall corrections in the end-diastole and end-systole phases, do the following:

1. Click the **End-Diastole** button to display that phase in the MPR windows.

2. Find the first slice in the phase that has a segmentation boundary drawn on the image.

3. Correct each slice in that phase by doing the following:

   a. Hold down the **Shift** key and, using the mouse, redraw the wall along the correct boundary (see the image on right in Figure 5-9).

      You can make as many corrections as needed on a single slice. Release both the mouse and the **Shift** key between each line you redraw.

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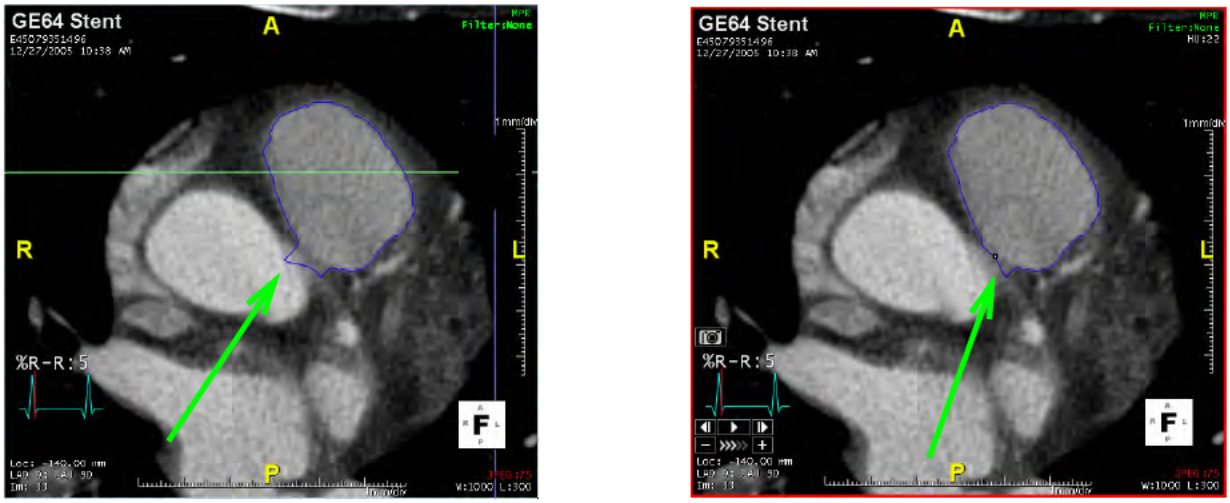

Figure 5-22: Left: Boundary Line Not Correct; Right: Redrawing Wall

b. When you have finished redrawing the slice, use the middle mouse button to advance to the next slice.

c. Repeat steps (a.) and (b.) until all slices in the phase have been corrected.

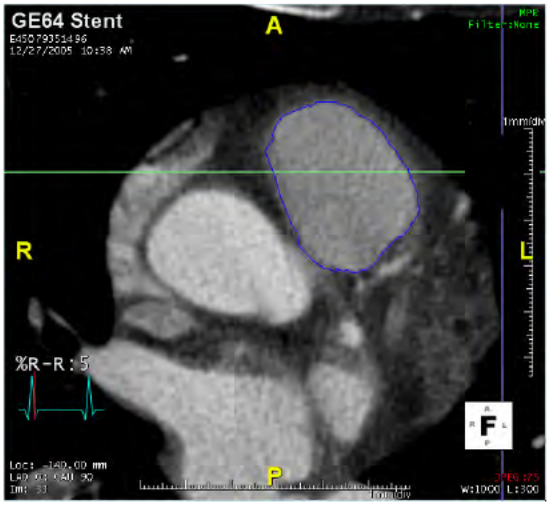

Figure 5-23: Boundary Line Corrected

4. Click the **End-Systole** button, and repeat steps (2.) and (3.) to correct all the slices in the end-systole phase.

> **Note: If you choose to correct the wall boundary in every phase, you will need to step through the phases using the cine buttons in either the tool panel or in lower-left corner of the image window (see Figure 5-23).**

When finished with all corrections, click **Next** to proceed to the final step.

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Step 3 - Calculation and Result

In this step, the cardiac function is calculated and the results are displayed in the tool panel (see the following figure).

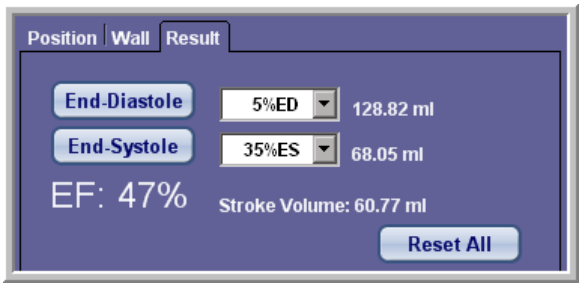
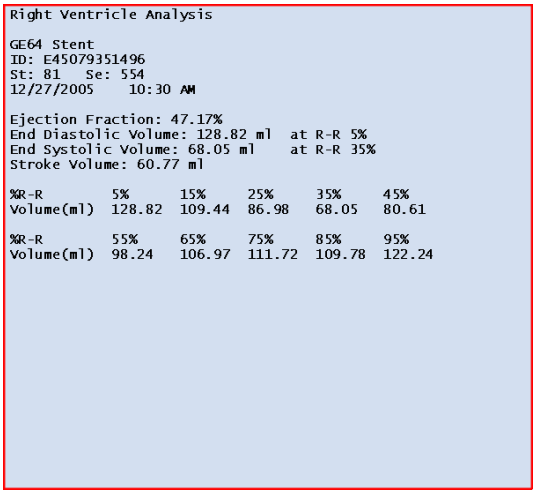


Figure 5-24: Manual TVA(RV) Results (Tool Panel)

More detailed results are displayed in the upper-right portion of the main window:

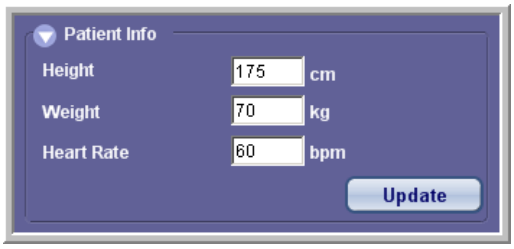


```
Right Ventricle Analysis

GE64 Stent
ID: E45079351496
St: 81   Se: 554
12/27/2005    10:30 AM

Ejection Fraction: 47.17%
End Diastolic Volume: 128.82 ml  at R-R 5%
End Systolic Volume: 68.05 ml    at R-R 35%
Stroke Volume: 60.77 ml

%R-R        5%      15%     25%     35%     45%
Volume(ml)  128.82  109.44  86.98   68.05   80.61

%R-R        55%     65%     75%     85%     95%
Volume(ml)  98.24   106.97  111.72  109.78  122.24
```

Presentation of the TVA(RV) Results

You can now view a more complete table and a graph of the segmental ejection fraction, wall thickness, and other parameters.

1. To generate these displays, first enter the patient's height, weight, and heart rate into the Patient Info fields.



2. Click the **Update** button. The manual TVA(RV) result window is displayed:

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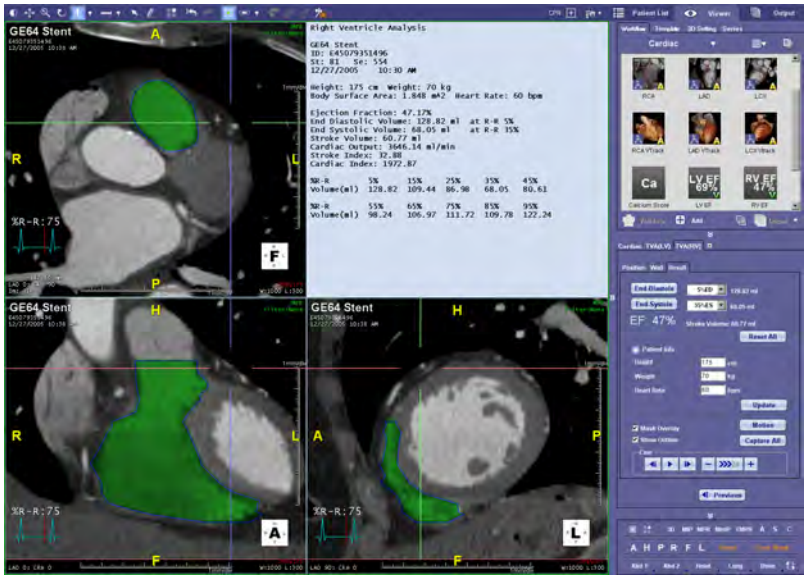
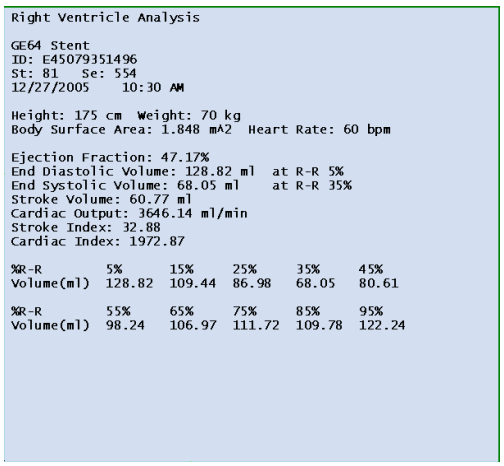
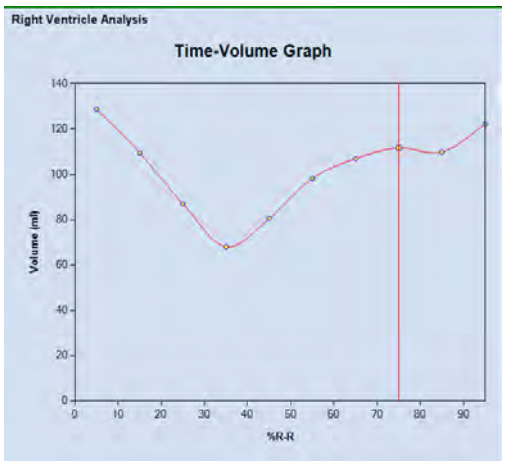


Formats for Reviewing Results

Results can be viewed in two formats, text and a time-volume graph.



```
Right Ventricle Analysis

GE64 Stent
ID: E45079351496
St: 81   Se: 554
12/27/2005     10:30 AM

Height: 175 cm  Weight: 70 kg
Body Surface Area: 1.848 mA2  Heart Rate: 60 bpm

Ejection Fraction: 47.17%
End Diastolic Volume: 128.82 ml   at R-R 5%
End Systolic Volume: 68.05 ml     at R-R 35%
Stroke Volume: 60.77 ml
Cardiac Output: 3646.14 ml/min
Stroke Index: 32.88
Cardiac Index: 1972.87

%R-R        5%      15%     25%     35%     45%
Volume(ml)  128.82  109.44  86.98   68.05   80.61

%R-R        55%     65%     75%     85%     95%
Volume(ml)  98.24   106.97  111.72  109.78  122.24
```



Generating a Report

You can generate a cardiac report, which will include the TVA results.

To generate a TVA calculation report, capture the images that you require, and click the **Generate Report** button. In this case, the report is directly generated without going through the Output Panel. Following is an example of a TVA report, including analyses on both the left and right ventricles:

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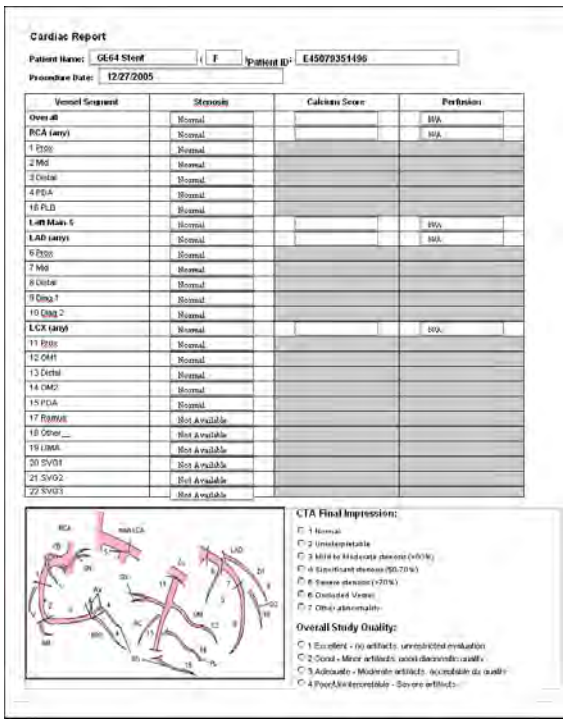

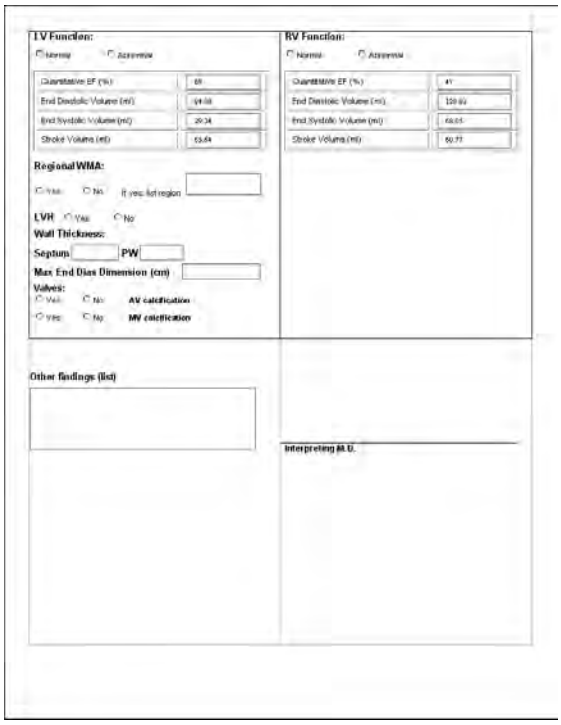

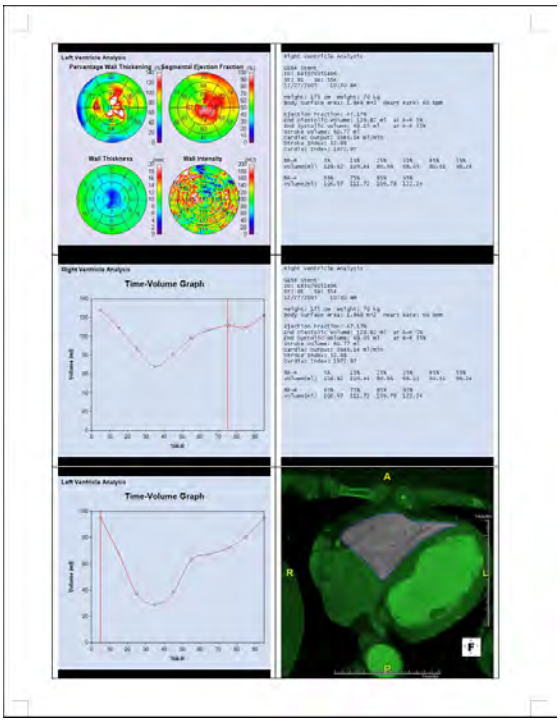

Figure 5-25: Cardiac Report with TVA Results

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Cardiac Function Measurements: Inter-Observer Difference, Cross-Product Difference, and Reading Time

This section describes testing that was done to compare results among the automatic TVA module included in the Aquarius i*N*tution (AQi) Client, manual TVA in the AQi Client, and the Classic Workstation's TVA module.

Objective

TeraRecon's Time-Volume Analysis (TVA) module has been widely used to measure cardiac function from 4D cardiac CT data on the Classic Aquarius Workstation for many years. The AQi-TVA documented in this chapter has added a fully automatic mode in order to speed up reading, while still allowing the user to switch to manual mode when automatic TVA does not meet requirements. The Classic TVA has manual mode only.

The objective of this test is to compare the cardiac function measurements made on AQi-TVA to those made on Classic TVA, to see if the difference is significant. We are also testing to determine whether AQi-TVA cuts down reading time.

Material and Method

Twenty Cardiac CT datasets were randomly chosen from a hospital. The acquisition was using the ordinary protocol that served the reading in the department of radiology.

Two experienced technicians (both having 6 or more years' experience processing cardiac CT data) processed the data using classic TVA and AQi-TVA. For each dataset being processed, the entire chamber analysis and wall analysis were performed. Values of the End-Diastolic (ED) phase, End-Systolic (ES) phase, ED volume, ES volume, Ejection Fraction (EF), and myocardial volume were captured. The time was measured from the beginning, when the patient data was selected, to the display of the results.

Linear regression (from Microsoft Excel) was used to process the measured values, for the purposes of comparison. The values from user A and user B, using classic TVA, were compared for the inter-observer difference. The values from user A using AQi-TVA manual mode were compared with the values from user A using classic TVA for the cross-product difference. And the values from user A using AQi-TVA automatic mode were compared with the values from user A using classic TVA for the cross-product difference.

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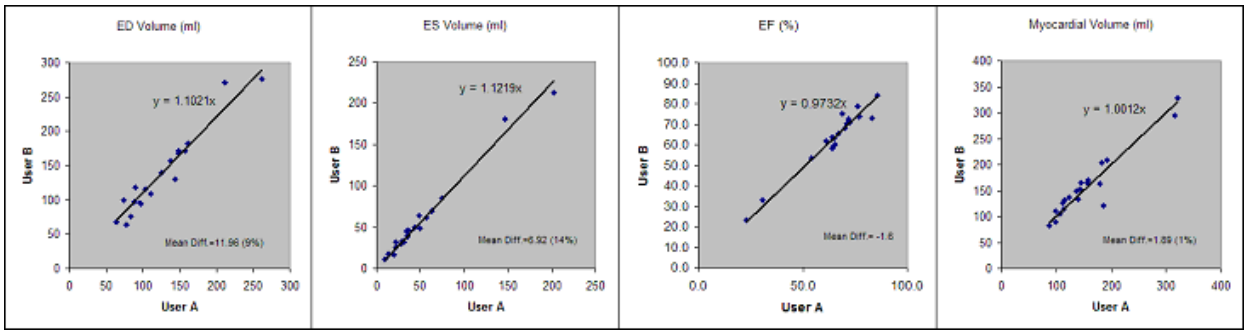
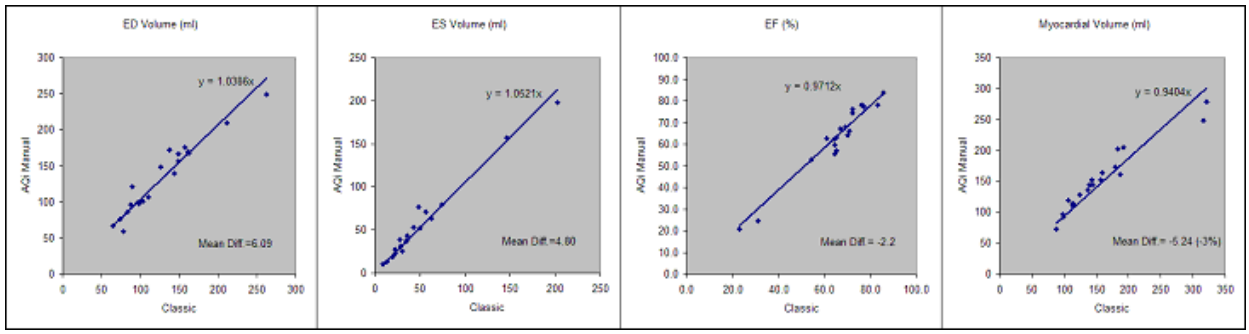
Results

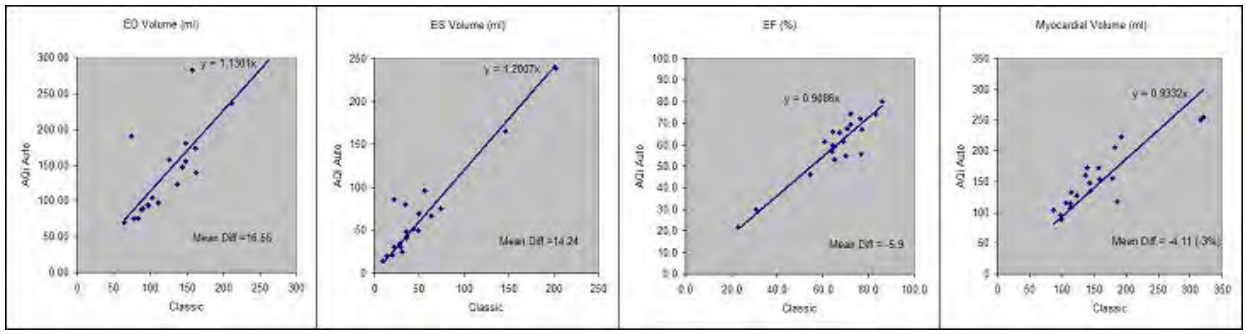
Classic TVA Inter-Observer



AQi-TVA Manual Mode vs. Classic TVA



AQi-TVA Automatic Mode vs. Classic TVA



Time Spent

The average time spent in Classic TVA for each case was 3.8 minutes for user A, and 6.4 minutes for user B. The average time spent in AQi-TVA manual mode for each case was 5.2 minutes for user A. The automatic mode in AQi-TVA took 1 minute for every case (mostly on loading the data).

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Conclusion

For the measurements of ED volume, ES volume, EF, and myocardial volume, there is no significant difference between AQi-TVA manual mode and classic TVA. The difference is comparable to the inter-observer difference with classic TVA itself. AQi-TVA manual mode can replace classic TVA in these measurements.

For these measurements, AQi-TVA automatic mode has a significantly larger difference than AQi-TVA manual mode when compared to Classic TVA. AQi-TVA automatic mode can not replace Classic TVA or manual mode.

The time spent in automatic mode is significantly shorter than manual mode or Classic TVA.

Discussion

There were two cases where the automatic mode showed a very large difference in ED volume. These datasets were noisy, and noise in data affects automatic processing more.

If a site consistently has low-noise high-contrast data, we recommend using automatic mode in AQi-TVA by default. Be sure to follow the instructions to check the overlay for the segmentation result on both ED and ES phases. If any of them is wrong, go back to edit them manually.

If a site consistently has high-noise data, or is experiencing errors too frequently in automatic mode, we recommend changing the default to use manual mode.

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Chapter 7: Time Dependent Analysis

Introduction

Time Dependent Analysis (TDA) studies blood flow through a structure after the patient is injected with a contrast dye. The study provides a time-dependent curve, for the CT number of an arbitrary region-of-interest (ROI). The study also creates several kinds of functional maps - Blood Volume (BV), Blood Flow (BF), Mean Transit Time (MTT), Time-To-Peak, Temporal Maximum Intensity Projection (MIP) and error maps.

> **Note: You are obligated to define the parameter ranges that are used in this procedure. When first accessed, the user interface for setting these parameters contains generic default values having no particular significance. You must acknowledge this by dismissing a warning message to this effect.**

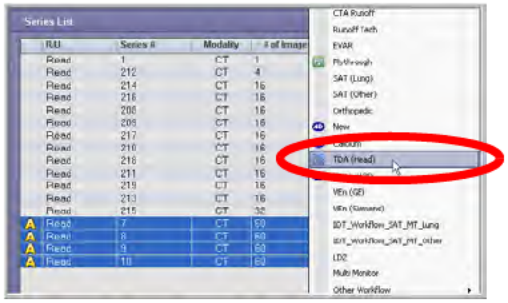
Starting TDA

To start Time Dependent Analysis, select a relevant a study from the patient list, and then select multiple series from the series list.

> **Note: To perform TDA, select only dynamic studies from the Series List.**

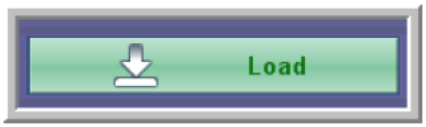
Then do one of the following:

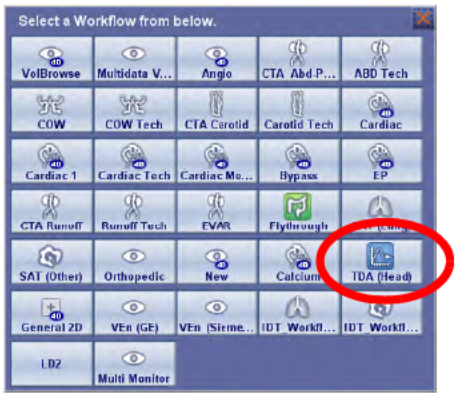
- Right-click and select **TDA (Head)** from the menu (circled in the figure shown at right):



- OR -

1. Click the **Load** button in the **Data Management Tools** bar. The Workflow menu is displayed (see figures below).





2. Click the **TDA (Head)** button in the Workflow Menu.

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The software calculates the TDA, applies motion correction, and displays the results:

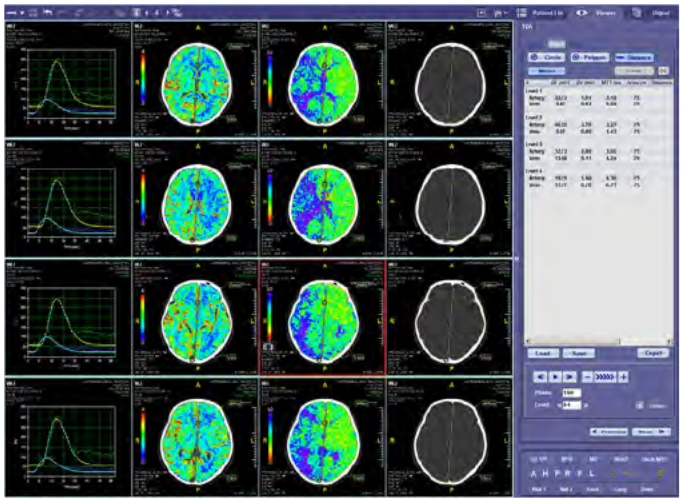
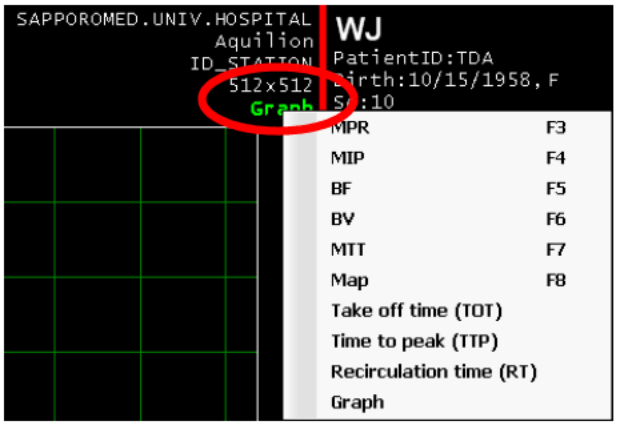


Figure 7-1: Automatic TDA Results

Maps and Graphs

The TDA calculation generates a set of image maps as shown in Figure 7-1 above. Only four maps can be displayed for each level at any one time. The default images displayed are a profile graph, the blood volume image, the mean time transit image and the MPR image.

However, there are several other displays that contain valuable information. To access these, click the green text in the upper-right corner of any image in the main window. A menu is displayed, as shown in the image shown at right:



Any image can be displayed in both MPR and MIP rendering modes. In addition, the following table describes the other maps and graphs that can be displayed:

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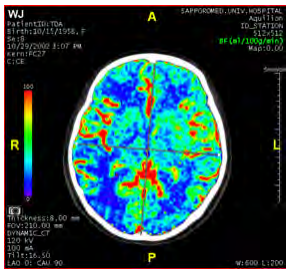
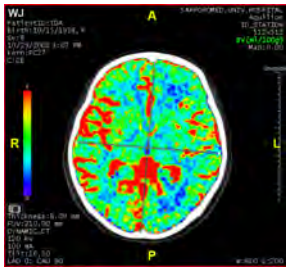
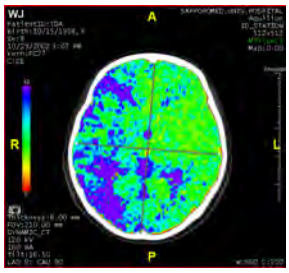
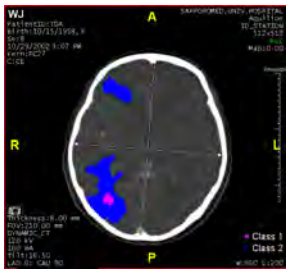
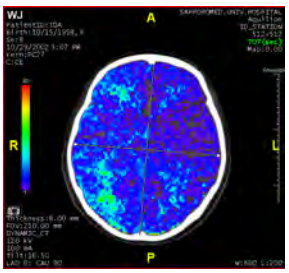
Function	Definition	Image
Blood Flow (BF)	The volume of blood flowing through the specified ROI per unit time.	
Blood Volume (BV)	The amount or fraction of blood in a given volume of the structure under analysis.	
Mean Transit Time (MTT)	The average time taken by the contrast to reside in a volume of the ROI.	
Map		
Take off Time (TOT)	The time at which the contrast begins to flow into the system.	

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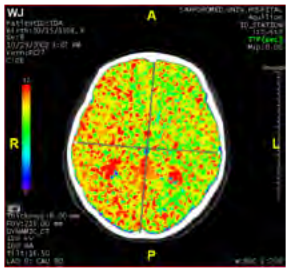
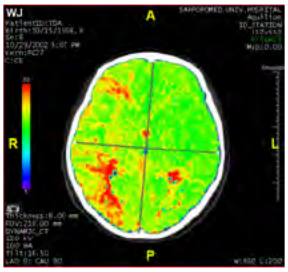
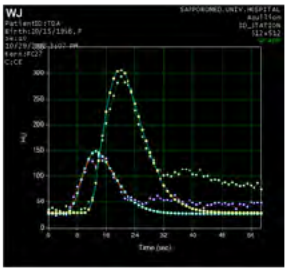
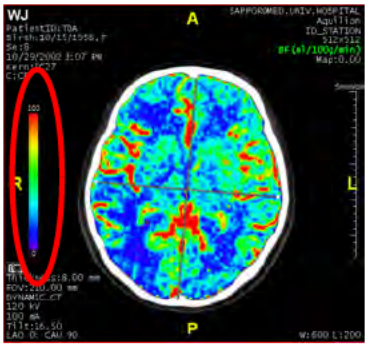
Function	Definition	Image
Time to peak (TTP)	The time taken for the intensity to peak.	
Recirculation time (RT)	The time taken by the contrast to recirculate to the structure.	
Graph	Profile graph of HU values over time. • The red line depicts the pixel at the center of ROI of artery. • The yellow line removes the effect of recirculation. • The blue line is the fitting curve. • The green line depicts the pixel at the center of ROI of vein. • Hover the mouse over a dot on any curve to see the exact HU value.	

Editing the Color Map



Each map is displayed with a color scheme that can be configured. The color map is accessed through the vertical color bar on the left side of each map image.

Display Range

The display range refers to the range of calculated functional values that are currently displayed in the map. This range is capped by the upper and lower values shown just above and below the vertical color bar. You can edit these upper and lower limits to show a greater or lesser range of colors.

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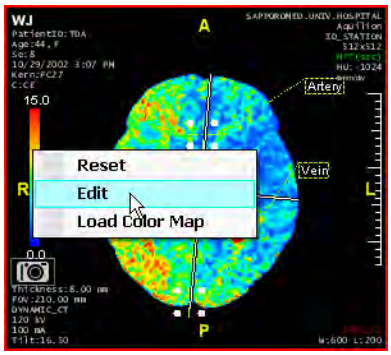
There are two ways to edit the display range:

- Right-click the vertical color bar and select **Edit**.



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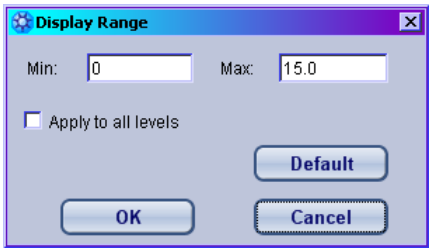
The **Display Range** dialog is displayed (see the following image).



Enter new **Min** or **Max** values and click OK when finished.

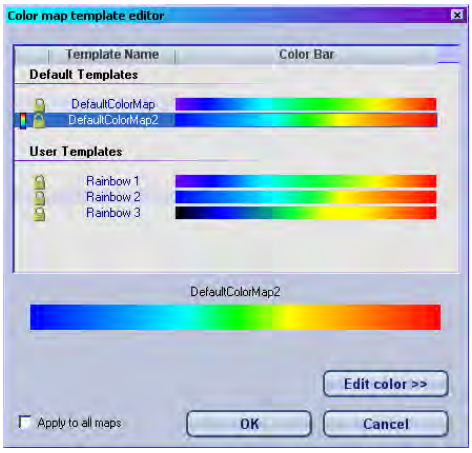
You can also edit the display range by dragging the mouse up or down along the vertical color bar. The numbers shown at the top and bottom change as you move the mouse, and the colors displayed on the map change accordingly.

Changing Color Maps

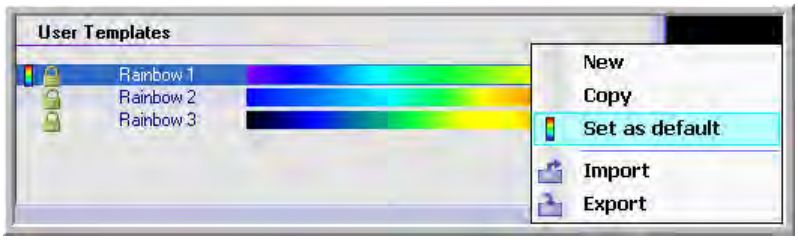
The color map template currently in use determines which colors represent functional values in each function map. You can select a different color template or create a new one.

To access the color maps, right-click the color bar and select **Load Color Map**.

The Color Map Template Editor is displayed:



From here you can select a different template. To do so, right-click on the desired template and select **Set as default** from the menu.



Click **OK** to close the template editor. The map is now displayed using the new template.

Creating Color Map Templates

To create a new color map template, do the following.

1. Click the **Edit color** button. The edit panel is displayed in the template editor.

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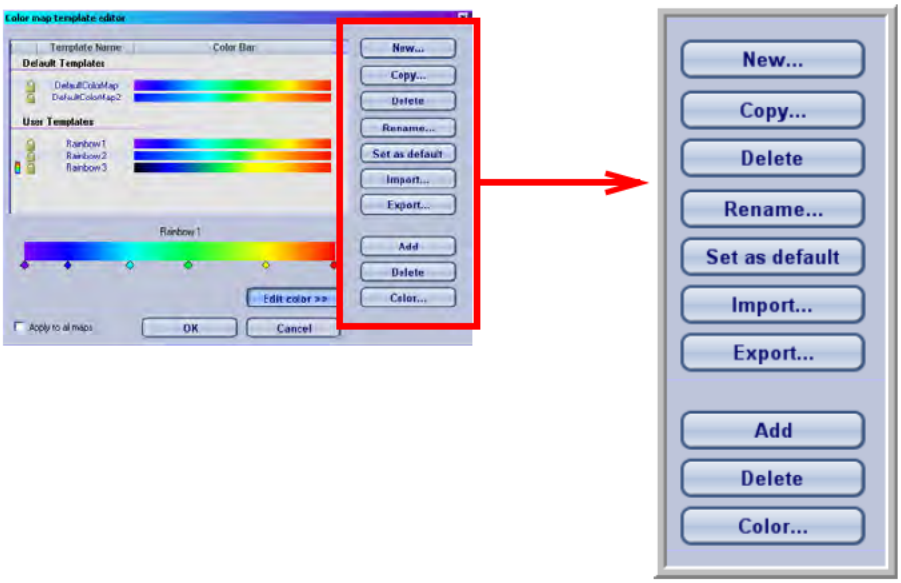
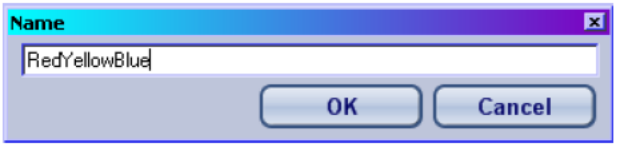


2. At the top of the edit panel, click New.

3. Enter a name for the new template in the dialog that is displayed, and click OK.



A new template is created, and can be viewed and edited in the bottom half of the template editor:

You can now add colors to the template. Just under the color bar, there are small diamond-shaped markers. Each of these markers points to the new color threshold.

In this example, a three-color template is being created. Therefore, three diamond markers are needed. The template is created automatically with two markers, one at each end. To add the third marker, click the **Add** button. A third marker is added halfway between the first two:

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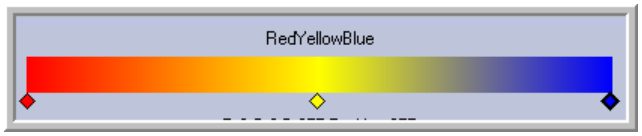
1. Click on the leftmost marker and then click the **Color** button. The Windows color palette is displayed:

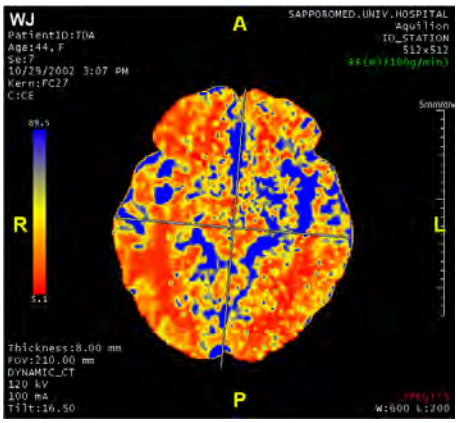
2. Select the desired color and click **OK**. That color is now added to the left end of the bar:

3. Click the middle marker and when the Windows color palette is displayed, select another color. Do the same for the rightmost marker. The new template is now complete.



4. Click **OK** to exit the template editor.

The function map is now displayed using the new color template.



Other features

In addition to the above, you can use the color map template to do the following:

- **Copy a template** - You can create a new template this way, first by copying an existing template and then renaming the copy.
- **Delete** - Deletes the selected template.
- **Rename** - Renames the selected template.
- **Import** - If you have a TDA color template on your local hard disk (or other storage medium accessible to the Windows file system), you can import it to the AQi TDA module.

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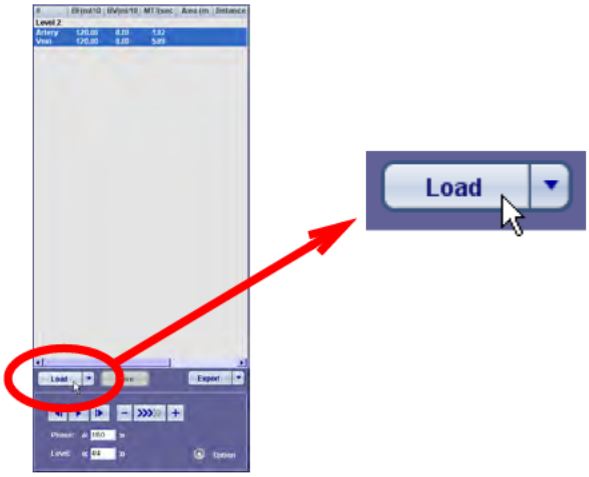
- **Export** - Save the selected template on your local hard drive. You can navigate to any folder first.
- **Apply to all maps** (checkbox in the lower left corner) - Anything you select, create or change will be applied to all maps in the module.

ROI Templates

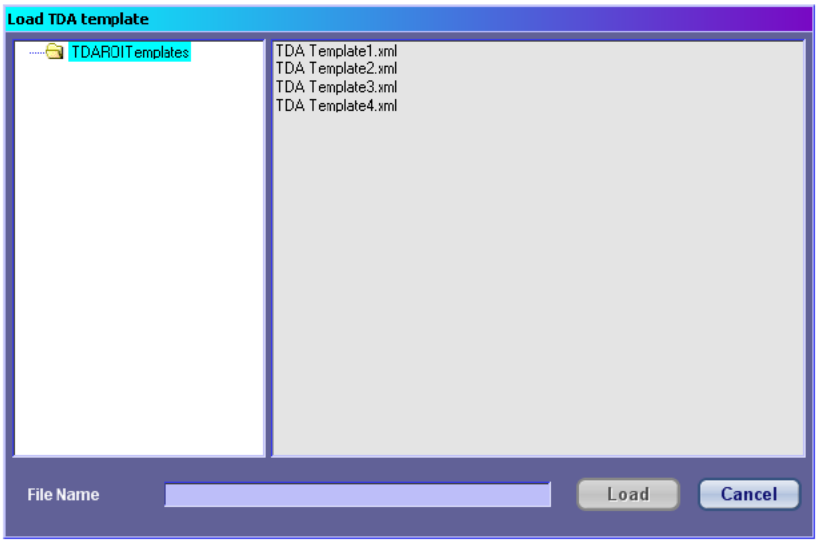
You can load, modify and create ROI templates, which determine where the ROIs to be examined are placed on each image. This determines the output values shown on the Result panel.

Loading ROI Templates

1. To load one of the default templates, click the **Load** button at the bottom of the Result panel.



The template window is opened.



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2. Select a template and click **Load**. The resulting values are displayed on the Result panel (see the figure at right).

#	BF(ml/10	BV(ml/10	MTT(sec	Area (m	Distance
Level 2					
Artery	120.00	8.00	1.92		
Vein	120.00	8.00	5.89		
Level 4					
1	48.53	2.97	4.31	401	
2	54.54	3.87	5.04	469	
%Diff	-11.02%	-23.18%	-14.35%		
3	51.19	3.46	4.64	425	
4	30.86	3.66	8.07	388	
%Diff	65.86%	-5.62%	-42.48%		
5	51.10	2.87	4.00	935	
6	38.56	4.23	7.75	865	
%Diff	32.50%	-32.15%	-48.39%		
7	40.41	2.60	4.58	652	
8	23.08	3.39	9.14	650	
%Diff	75.07%	-23.35%	-49.91%		
9	42.22	3.33	5.57	953	
10	39.68	3.87	6.95	922	
%Diff	6.39%	-13.93%	-19.92%		
3,5,7	47.65	2.91	4.32	2013	
4,6,8	31.71	3.83	8.29	1904	
%Diff	50.29%	-24.07%	-47.86%		

Creating ROI Templates

To create a new ROI template, you first must perform a manual TDA on the study (see "Manual TDA" on page 7-12 for instructions). When you reach the Result panel, the results based on the ROIs you placed manually are displayed. You can save this template by clicking the **Save** button at the bottom of the panel. The **Save TDA Templates** window is opened, where you can name the file and also add folders if desired.

Viewing Graph Curves

The TDA graph shows the changing HU value of a selected point (either the artery or vein) over time, as blood circulates in the brain. Two curves are plotted, one for the artery (red) and one for the vein (green). Together the two curves are referred to as the *profile*.

The graph contains two different kinds of profiles: the raw profile and the fitted profile. The raw profile shows the actual HU values, which may be affected by artifact or other noise. The fitted profile is calculated by the TDA module to reflect the expected values based on the data. The two profiles should have similar contours. If they are noticeably different, this might indicate an incorrectly selected artery or vein point.

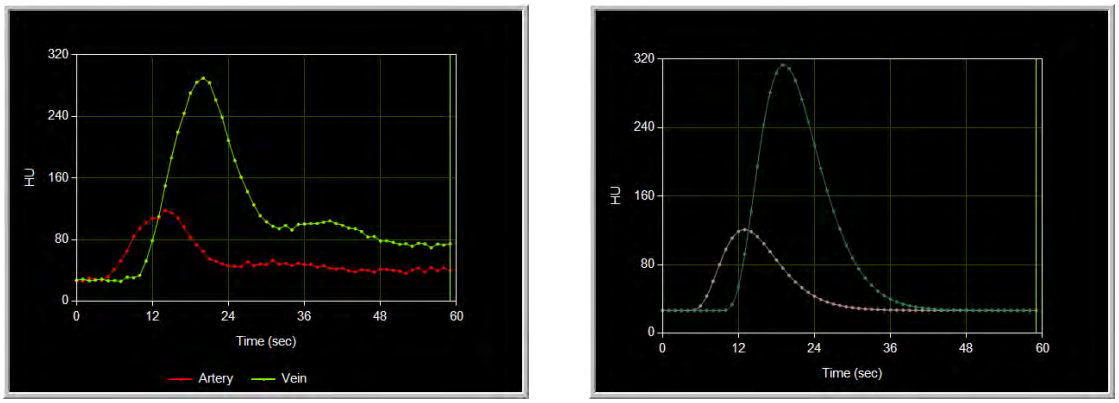

Figure 7-2: Left: Raw Profile; Right: Fitted Profile

You can choose to hide either profile in order to see the other profile more clearly. To do this, right-click in the window where the graph is displayed, and select either **Hide Raw Profile** or **Hide Fitted Profile** from the pull-down menu, as desired.

Drawing ROI

You can draw Regions Of Interest (ROI) in a symmetrical structure to calculate various parameters pertaining to the time-dependent behavior of the underlying tissue. The Aquarius

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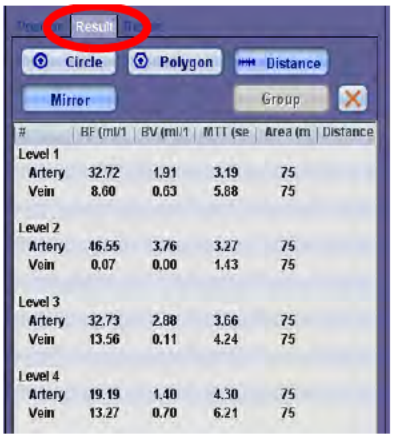
i*N*tuition TDA module provide several tools for defining Regions of Interest and comparing them.

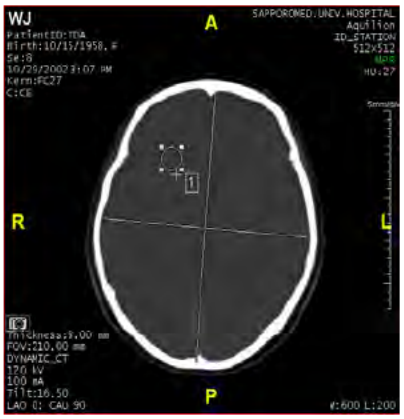
The Result Panel



If you have calculated Time Dependent Analysis on the loaded data, the **Result** tab is currently displayed in the Tool Panel (see image at right). The top of the panel contains tool buttons which allow you to define ROI on data images (using either a circle or a polygon shape), measure distances on the data image, and automatically mirror the ROI on the opposite hemisphere, symmetrical to the center.

To draw a ROI, perform the following:

1. Select either **Circle** or **Polygon** from the top toolbar.
2. Click and drag the left mouse button across the area, until the desired size of ROI has been reached (see image at right).
3. Click the **Mirror** button to have the ROI copied automatically to the other half of the symmetrical structure under analysis (see image below).



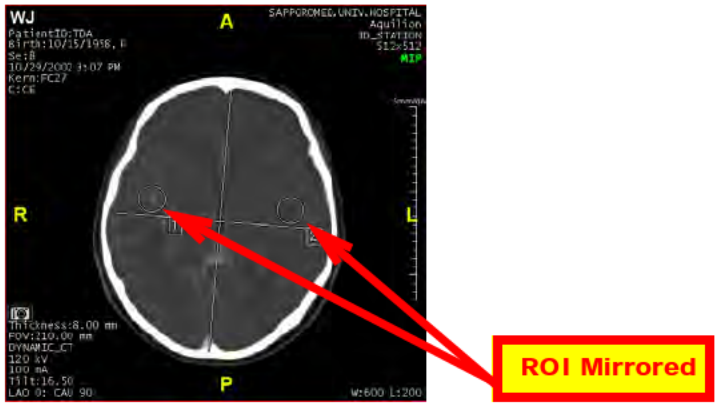


Figure 7-3: ROI Mirrored

This analysis is also reflected in the results list in the Tool Panel:

#	BF(ml/10	BV(ml/10	MTT(sec	Area (m	Distance
Level 1					
1	68.18	5.51	5.68	281	
2	52.13	3.42	4.01	281	
%Diff	30.79%	61.33%	41.48%		
Level 2					
Artery	87.45	5.75	3.83	75	
Vein	80.71	6.21	7.47	75	

Under Level 1, listed in the figure above, the two ROIs numbered 1 and 2 correspond to the numbered circles in Figure 7-3 on page 7-11. The differences between each ROI are calculated and displayed for each pair of ROIs you add to the image.

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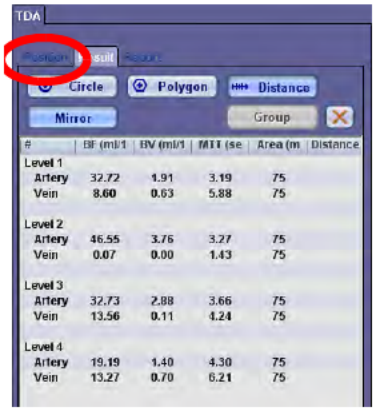
Note: This analysis is not automatically propagated to the other levels. You must perform it for each level separately.

Distance Measurements

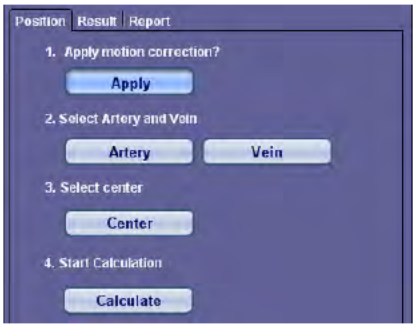
To calculate a distance between two points in the image, click the **Distance** button in the Tool Panel, and then left-click and drag the mouse from the initial point to the final point. The distance is subsequently displayed in the result list in the Tool Panel, in the **Distance** column.

Manual TDA



If you would prefer to calculate the TDA manually, you can begin the process by clicking the Position tab, located at the top of the tool panel (see image at right).

The positioning tool panel is displayed:



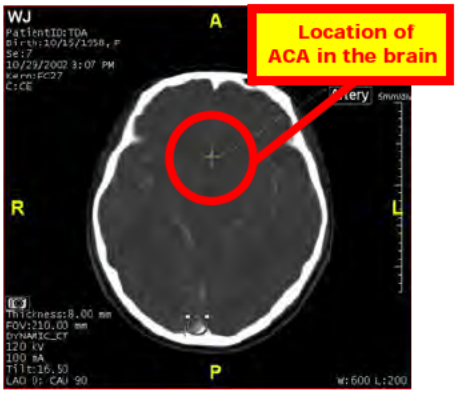
Step 1 - Apply Motion Correction

To apply motion correction, simply click the **Apply** button located under **1. Apply motion correction?** in the tool panel.

Step 2 - Select Artery and Vein

To select an artery, perform the following:

1. Click the **Artery** button under **2. Select Artery and Vein** in the tool panel.
2. Left-click on the center of the region of interest (ROI) For brain perfusion studies, the anterior cerebral artery or ACA is recommended. The ACA is located at the position shown in the figure on the right. Repeat this step for each phase in the series.
3. Drag the mouse to draw a circle around the artery of interest.



NOTE: iNtuition automatically selects an ROI that has the maximum change throughout the acquired images.

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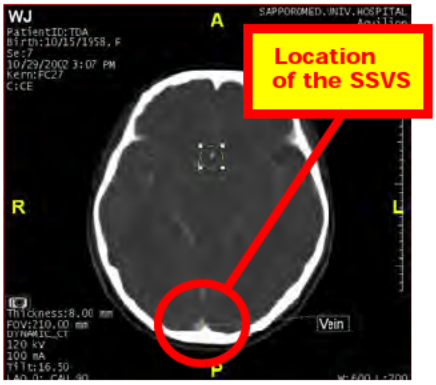
Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

To select a vein, perform the following:

1. Click the **Vein** button under **2. Select Artery and Vein** in the tool panel.

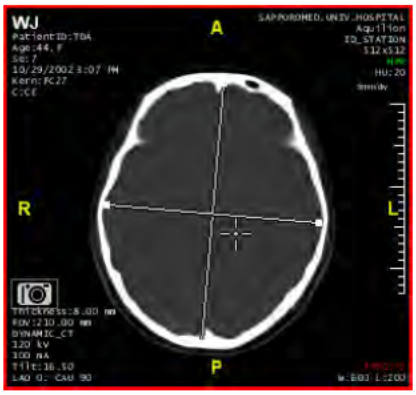
2. To select ROI for a vein, click and draw around the center of an appropriate vein. For example, if you are performing a brain perfusion study, the superior sagittal venus sinus or SSVS is a good selection. Repeat this step for each phase in the series.

The following figure shows the location of SSVS in the brain:



Step 3 - Select Center

Click the **Center** button to redraw the crosshair lines.

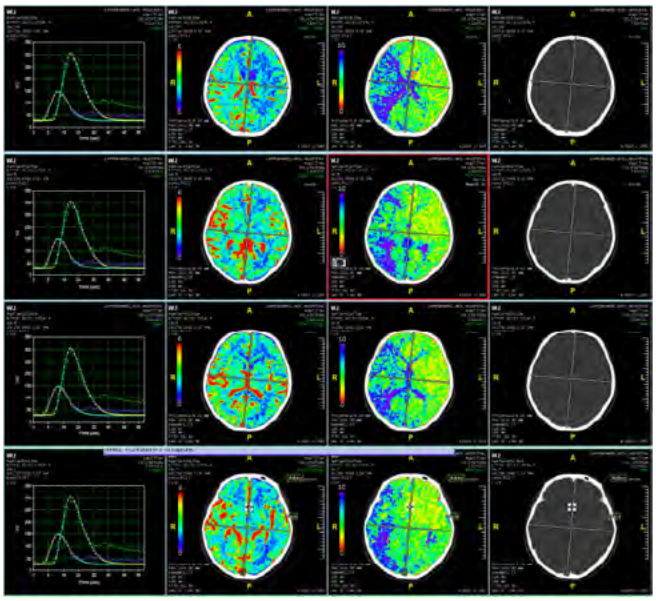


Step 4 - Start Calculation

Click the **Calculate** button under **4. Start Calculation** in the tool panel.

As calculation progresses, functional maps are updated. The application displays a progress bar for the duration of the calculation.

When the calculation is complete, the screen is displayed as shown at left:



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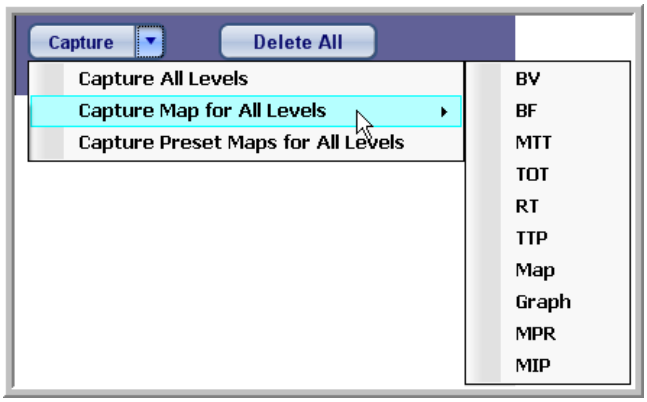
Generating a Report

Once all necessary analysis is performed, you can generate a report. To generate a report, perform the following:

1. Click the **Report** tab in the tool panel.

2. Capture images in one of the following ways:



   - **Capture all visible images**

     If all levels are visible in the main window, click the **Capture** button.

     If all levels are not visible in the main window, click the down-arrow next to the **Capture** button, and then select **Capture All Levels** from the pull-down menu.

   - **Capture a single map for all levels**

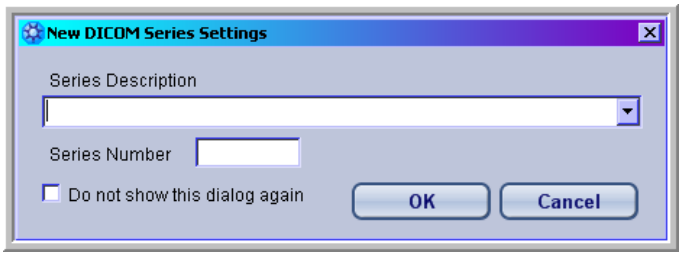
     Click the down-arrow next to the **Capture** button, select **Capture Map for All Levels** from the pull-down menu, and then select the desired map from the sub-menu (see the following image).

   - **Capture preset maps**

     This option captures maps that have been preset in the TDA Capture Preferences screen. Only the selected (preset) maps are captured, but are captured in all levels. (To set options in the TDA Capture preferences screen, see "TDA Capture" on page A-19.)

NOTE: All images are also captured in the Output Panel.

3. A dialog is displayed, asking whether you want to save the capture as a DICOM series:



   If you want to save the capture as a series, enter a name and series number in the dialog and click **OK**. If not, click **Cancel**. The capture will proceed either way.

4. Click **Generate Report** to create a report.

5. In the next window, select your name and click **Proceed** to sign electronically.

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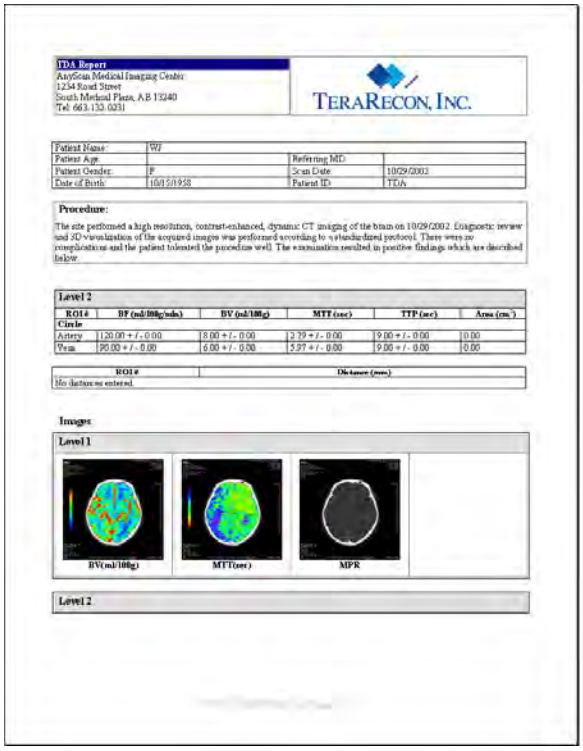
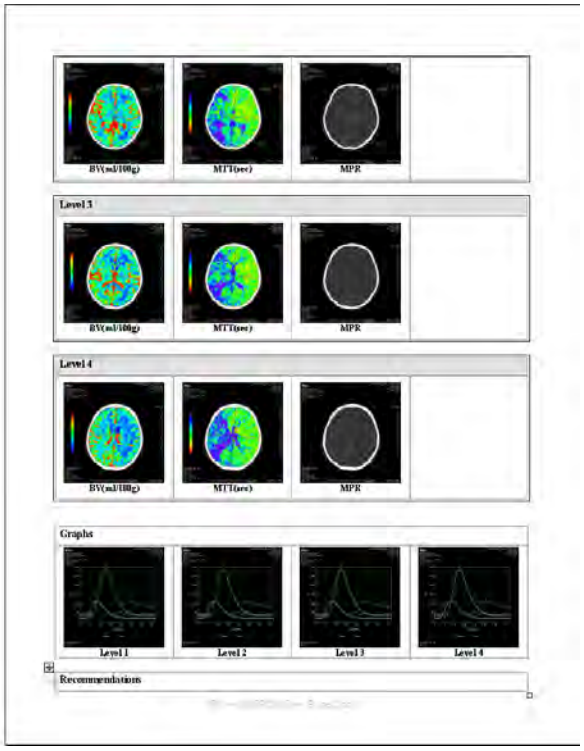
6. The system generates a MS Word report. The sample report shows the values from each measurement, as well as captured images in the 4 x 4 mode.

7. You can save the report in your computer and attach it to emails to send it to other physicians.





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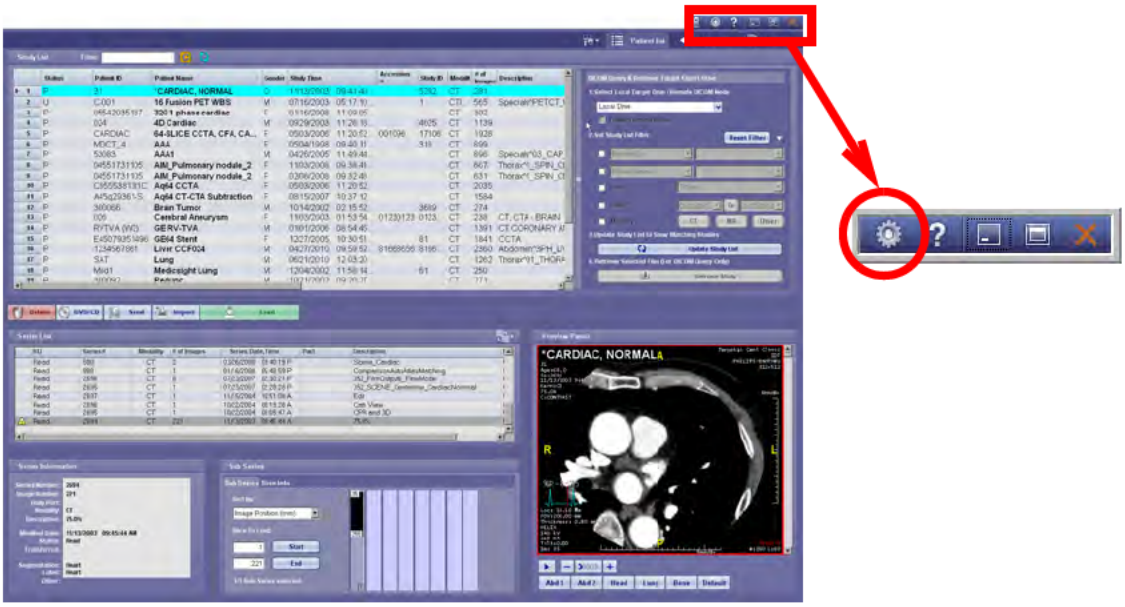
Appendix A: GUI Configuration

The Preference windows allow you to configure the appearance and function of the AQi user interface so that it suits your particular needs. Preference windows are provided for the following modules and tools. Click on any of these to jump to the corresponding page.

General
Application Error
Command Line
Patient List
Series List
3D Viewer
Toolbar
TVA(LV)
Workflow
Mask
Measure/Annotation
Page Format
Measurement Settings
CPR Interactive
Calcium
SAT
Batch
Mouse Operation
TDA
TDA Function Map
TDA Classification Map
TDA Capture
TVA
TVA(RV)
Flythrough
Output Panel
Multidata
Capture
CPR
Movie
Patient Annotation

Opening Preferences

To open Preferences, click the **Preferences** button, located in the top-right corner of the Aquarius i*N*tuition Client screen.



The Preferences window is displayed:

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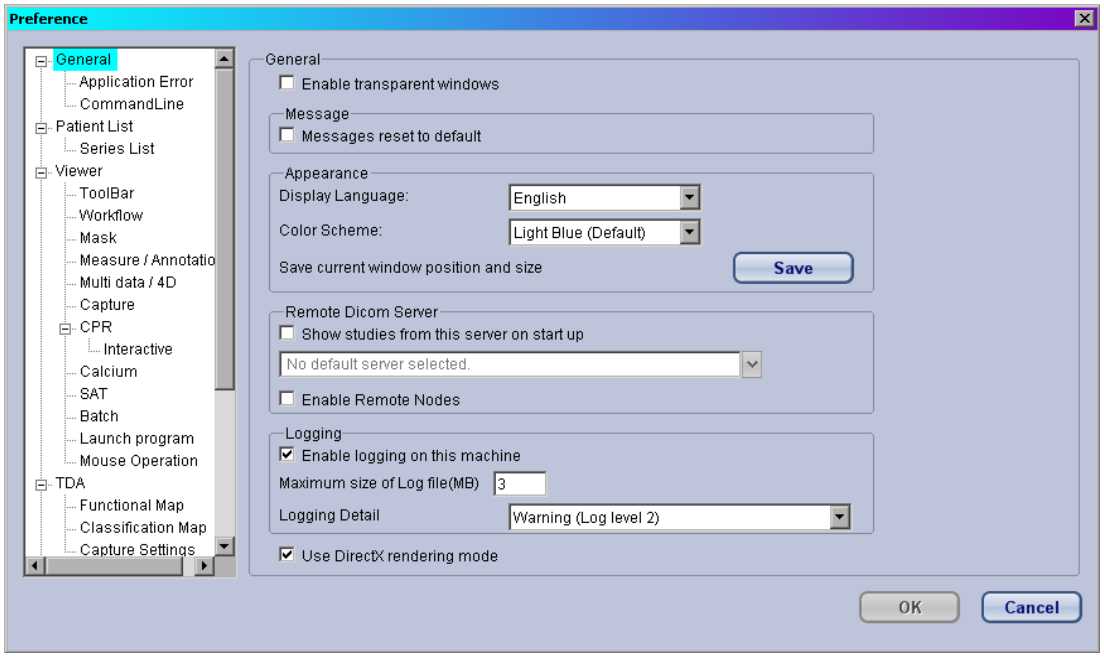

Note: Some preferences require the AQi Client to be closed and then restarted before the change takes place. This is indicated by "(Requires restart)" in the Description column.

General

The **General Preferences** dialog is displayed initially. These settings pertain to the overall look or feel of the Aquarius *iN*tuition Viewer application.

Option	Values (Default value bolded)	Description
Enable transparent windows	Enabled/**Disabled**	Allow transparent dialog boxes and progress bars to be displayed on images.
Messages reset to default	Enabled/**Disabled**	Resets all messages so that a dialog box is displayed saying "Do not show this message again".
Display Language	• **English** • Spanish • French • Japanese • Portuguese • Chinese (PRC)	Language used for the AQi Graphical User Interface (GUI)
Color scheme	• **Light Blue** • Medium Blue • Dark Blue	Background color of the AQi Viewer GUI
Save current window position and size	N/A	Allows you to save the size you have chosen for your current window (click the **Save** button to enable).

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Option	Values (Default value bolded)	Description
Show studies from this server on startup	Enabled/**Disabled**	When enabled, studies from the default remote DICOM server are displayed.
Enable Remote Nodes	Enabled/**Disabled**	Allow data from remote nodes to be displayed in the Patient List.
Enable logging on this machine	Enabled/**Disabled**	When enabled, events occurring on the AQi Client are logged.
Maximum size of Log file (MB)	Range: 1-100 MB **Default: 3 MB**	Maximum file size of log files.
Logging Detail	• Verbose (4) • Information (3) • **Warning (2)** • Error (1) • Critical (0)	Severity level of information to be logged, from Verbose (all errors, major and minor) to Critical errors only.
Use DirectX rendering mode	**Enabled**/Disabled	

Application Error

Application Error Preferences allow you to configure which actions to take in the event of a system crash.

Option	Values (Default value bolded)	Description
Log information to be sent to server	• **Basic** • Detailed	Basic information is fast, but detailed information provides better clues to cause.
Dialog/Restart	• **Show Dialog** • No Dialog, Auto Restart • No Dialog, No Restart	Choose whether to display a dialog box and/ or automatically restart the system after a system crash
Save crash information to the server	**Enabled**/Disabled	Save a copy of the crash log on the AqNET server.
Restore User Setting	Click **Restore** button	Restore the most recent valid user settings.
Initialize User Setting	Click **Set to Default** button	When clicked, sets all user settings back to factory default

Command Line

Option	Values (Default value bolded)	Description
Warn about images in the Output Panel on Clean/ClearAll comma nd	**Enabled**/Disabled	Ask whether to save or delete images in the Output Panel before proceeding.

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Patient List

The Patient List preferences allow you to configure options for the Patient List.

Option	Values (Default value bolded)	Description
Patient List columns	**Status, Patient ID, Patient Name,** Gender, DOB, **Study Time, Accession #, Study ID, Modality, # of Images, Description, Referring Phys Name, AE Name, AE Title, Publish State,** Age, Institution Name, Patient Other ID	Items checked in this list appear as columns in the Patient List.
Display warning when getting patient list without search filter	**Enabled**/Disabled	Show dialog when AQi is first started and the Patient List is displayed without any search filter.
Launch Classic 3D Viewer when double-clicked	Enabled/**Disabled**	Launch Classic 3D viewer when double-clicking
Enable color schema for remote server.	**Enabled**/Disabled	Allow options for color display on remote server.
Fore color	Blue	Select a foreground color for remote server datasets. Click the color square to display the Windows color palette, to select another color.
Update study list after retrieve	**Enabled**/Disabled	Refresh the display of the Study List so that the newly retrieved data is shown.
Automatically update patient list when external nodes change	Enabled/**Disabled**	
Show hidden patient data	Enabled/**Disabled**	Allows you to display all hidden studies. This allows you to unhide the study, if desired.

Series List

Option	Values (Default value bolded)	Description
Available Series List columns	**R/U, Series #, Modality, # of Images, Series Date, Time, Part, Description,** Days To Keep**, Publish State**	Items checked in this list appear as columns in the Series List.
Default Setting of the Subseries Sort	• Image Number • **Image Position** • Image Time • Every N Slices • Preview	Default mode for sorting sub-series data.

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Always use AqNET account authentication (for Web link)	Enabled/**Disabled**	When enabled, a password is automatically generated during Email Series URL. The recipient will be required to enter a username and password. When disabled, the sender can either set a password or not, when sending a link.
Launch email/Copy to Clipboard	• **Launch email** • Copy to Clipboard	Select whether to copy the series URL to the Microsoft Office clipboard, or send it in an email.
Expiration date	Pulldown menu	Determines how long a Web link is valid.
Series List Display mode	• Icons • **Details**	Show Series List as either a detailed list or a set of icons.
Display Series Information	**Enabled**/Disabled	Display the Series information and Sub-series panels by default.
Auto Show/Hide Series Information	Enabled/**Disabled**	Series information is automatically displayed when the study contains subseries. Otherwise, the series information is hidden.
Display Preview	**Enabled**/Disabled	Display the Preview Panel in the patient list, which contains the axial images of the currently selected series. When disabled, this window is not shown. **(Requires restart.)**
Turn off overlay for secondary capture image.	**Enabled**/Disabled	When enabled, the annotations on the Preview panel are not displayed if the image is not part of the original scan.
Preview uses recommended W/L for each image	Enabled/**Disabled**	Preview window uses the Window/ Level values found in the DICOM header of the data.
Automatically select a series on study selection	**Enabled**/Disabled	When you click on a study, AQi also selects the main series.
Display Scene list	Enabled/**Disabled**	When enabled, any scenes in the series list are displayed in a separate display box.
Query Level	• **Series** • Study	If Study is checked, the query searches for studies only. If Series is checked, the query checks for both studies and series.
Text color for Nearline and Offline Series	Pulldown menu containing color palette	Allows you to select a different color for Nearline/Offline series so that they will be easier to distinguish in the series list.

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3D Viewer

The Viewer preferences allow you to configure options for the 3D Viewer.

Option	Values (Default value bolded)	Description
Always display crosshair on main view	Enabled/**Disabled**	When enabled, a crosshair is always displayed on the 3D image.
Link the center of rotation	**Enabled**/Disabled	When enabled, all currently loaded images have the same center of rotation.
Always synchronize	Enabled/**Disabled**	When enabled, two studies loaded together are automatically synchronized.
Display tilted data	**Enabled**/Disabled	When enabled, data is displayed using patient coordinates. When disabled, data is displayed using scan coordinates.
Enable color table correction	Enabled/**Disabled**	When enabled, this feature helps the 3D Viewer to display clearer edges, especially on vessels.
Show magnification factor on the view	Enabled/**Disabled**	When enabled, the magnification factor is displayed in the main image's annotations. This value changes when the image is zoomed in or out.
Use Max/Min instead of WW/WL	Enabled/**Disabled**	In the W/L tool panel, show the text entry fields as Min and Max values rather than Window Width and Window Level.
Enable Fast Loading Cache	**Enabled**/Disabled	Cache study data for faster loading.
Compression image	• **On** • Auto • Off	When **On** is checked, compress the image (defined by the quality in the Quality Slider).
Quality slider (if compression is on)	**75**	100 equals no compression, 1 is the lowest quality image. (**Requires restart.**)
Apply slab for MIP/MinIP/ ThickMPR by default	**CT**/MR	Slab is applied by default to 2D images for whichever modality is enabled (either or both).
3DVR default thickness	**150mm**	Default thickness for the 3D image when the Slab function is applied.
MIP/MinIP/ThickMPR default thickness	**8mm**	Default thickness for 2D images when the Slab function is applied.
VR fine mode will render with full resolution	Enabled/**Disabled**	Renders 3D VR images in fine mode with full resolution. Warning: this may be slow.
Draw slabs with fine mode	Enabled/**Disabled**	Renders slab images in fine mode. Warning: this may be slow.
Maximum thickness	**10 mm**	Maximum thickness allowed for slabs.
Snap to slab	Enabled/**Disabled**	
Rendering Mode	Draft/**Draft-Fine**/Fine	Quality of VR image from Draft (lowest quality/fastest-loading) to Fine (highest quality, slowest-loading)

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Toolbar

Toolbar preferences allow you to configure which buttons appear, and in which order, at the *top* of the 3D Viewer screen. Choose which buttons are to be displayed by checking the box to the left. Position each button on the toolbar by using the Up and Down buttons to the right of the list.

Option	Values (Default value bolded)	Description
Mouse Control	**Enabled**/Disabled	Show W/L, Pan, Zoom and Rotate buttons
Measurement	**Enabled**/Disabled	Show measurement pull-down menu button
Arrow and Text	**Enabled**/Disabled	Show arrow and label buttons
Layout	**Enabled**/Disabled	Show layout mode pull-down menu button
Undo/Redo	**Enabled**/Disabled	Show undo and re-do buttons
Overlay	**Enabled**/Disabled	Show outline of bone mask on an image that has had bone removed.
APS Result	**Enabled**/Disabled	Shows Label, Centerline, Candidate and Mask APS buttons
Enable the apply of APS result by drag and drop	Enabled/**Disabled**	A set of icons representing each mask applied by APS is displayed when the APS mask icon in the top toolbar is clicked. When one of the mask icons is dragged to the main window, that mask is applied to the image in that window.
Do not use sample icon	Enabled/**Disabled**	Use actual images from the study in the individual mask images, rather than the sample icons.
Display all measurement tools	Enabled/**Disabled**	When enabled, all measurement tools are displayed horizontally along the toolbar. When disabled, the measurement tools can be accessed from a pull-down menu on the toolbar.
Continuously use same measurement	Enabled/**Disabled**	Stay in measurement mode (using the same selected tool) after obtaining a measurement. When disabled, the viewer goes back to the currently selected mouse mode.

Workflow

Option	Values (Default value bolded)	Description
Automatically step to next activity after validation	**Enabled**/Disabled	Apply the next Workflow element when a Workflow element is validated.

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Option	Values (Default value bolded)	Description
Enable display of preview by hovering mouse	Enabled/**Disabled**	Show what the image looks like when a Workflow element is applied, by hovering over that element with the mouse.
Use Workflow Template from	• **Private** • Group	If Private is selected, only workflows (or color templates) from your own user account can be used. If Groups, you can use workflows or color templates that have been saved under your default user group.
Use Color Template from	• **Private** • Group	
Include validated workflow images in cardiac report	**Enabled**/Disabled	
Automatically name workflow scene	**Enabled**/Disabled	A name is automatically generated for any workflow scene created. When this is disabled, you must provide a scene name.
Send to DICOM after save workflow scene	Enabled/**Disabled**	Upon save, a dialog is automatically displayed asking you to choose a remote DICOM server to send it to.
Automatically input name when image is added by validation mode (scene number)	Enabled/Disabled	When this feature is disabled, an input box is displayed when you click **Add**, allowing you to enter a name for the scene. When enabled, a new scene is automatically named “Scene”, with a number appended when needed.
Save only validated workflow scene	**Enabled**/Disabled	When feature is disabled, you can save new workflow scenes whether or not they are validated.

Mask

Configure the mask functions used in region growing after bone removal (3D Viewer).

Option	Values (Default value bolded)	Description
Dilation	-2, -1, +1, **+2**	Amount added automatically after selecting the **Include** or **Add** options.
Erosion	-2, -1, +1, **+2**	Amount automatically removed after selecting the **Exclude** option.
Enable adjusting growing distance by zoom	**Enabled**/Disabled	Growing distance increases when the image is zoomed.
Show overlay when region is clicked in bone removal	Enabled/**Disabled**	Show green highlighting on area that has been removed when clicked.
Show erosion/dilation dialog when applying the region	Enabled/**Disabled**	Display erosion/dilation dialog when applying Region Grow, FreeROI or Threshold mask operations, to obtain level to add or remove.

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Option	Values (Default value bolded)	Description
Apply mask slab MIP/MinIP/ ThickMPR	Enabled/**Disabled**	An option to toggle on/off mask on MIP, MinIP and ThickMPR images. (Masks are not added to images with slab by default.)
Overlay on removed area	**Enabled**/Disabled	Show green highlighting on area that has been removed.
Turn on Mask overlay automatically	Enabled/**Disabled**	If enabled, overlay is displayed to show portions of an image removed by a mask operation. If disabled, the overlay is not displayed.
Same button for Add/Select	Enabled/**Disabled**	When enabled, the Add/Select function replaces both the Include and Select functions. Applies only to Region Grow.
Enable one-click mode	Enabled/**Disabled**	When enabled, dynamic region growing can be completed with one click.
Fast static growing by click (undo is disabled)	**Enabled**/Disabled	A single-click in Region Grow causes the mask to grow as far as it can, ignoring the mouse button release. Only available when one-click mode is enabled.
Click detection time	Slider - default is on **Fast**	Speed at which AQi determines whether to grow via click-and-hold (which stops on mouse release) or single-click (which ignores mouse release). Only available when one-click mode is enabled.

Measure / Annotation

Option	Values (Default value bolded)	Description
Copy measurement result to clipboard	**Enabled**/Disabled	When enabled, measurement results are automatically copied to the clipboard. They can then be pasted into other documents, such as reports.
By default, measurement remains when paging slices	Enabled/**Disabled**	Measurement annotations remain on 2D image while paging through slices.
Use scan date for initial	Enabled/**Disabled**	When enabled, the date annotated on the measurement is the date of the scan; otherwise it is the date the measurement is taken.
Measurement annotation default font	**Arial Medium.** **Color: White**	Pull-down menus allow you to select a default font, size and color for measurement text
Digit of significant figures for real measurement result	1-5 (default: **3**)	Total number of significant digits in measurement result, including both left and right sides of the decimal point (floating point).
Plaque volume unit	• **cm3** • mm3	Allows selection of plaque volume units in either cubic centimeters or cubic millimeters.

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Option	Values (Default value bolded)	Description
Automatically attach text to arrow (user annotation)	**Enabled**/Disabled	When enabled, a text box is automatically opened when arrow is selected from the top tool bar.
Delete arrow/text when rotate	**Enabled**/Disabled	When an arrow or text is added to the image, it will be deleted when the image is rotated.
User annotation default font	**Arial Medium. Color: White**	Pull-down menus allow you to select a default font, size and color for user annotation text

Multidata / 4D

Option	Values (Default value bolded)	Description
Enable synchronize option when two datasets are loaded	Enabled/**Disabled**	Setting this option enables syncronization of operations among two or more studies loaded as multidata.
Auto Registration	Enabled/**Disabled**	When enabled, two images from different studies are automatically lined up spatially, so that corresponding places in each study are in the same place on the screen.
Registration type	• **Translation only** • Translation and rotation	Correct for just translation (images are in different positions, but have the same orientation), or both translation and rotation (one image is rotated relative to the other).
Start Series number for Multi-data	No default value	You can specify a starting number for multidata series.
Synchronize images in 4D cine mode	**Enabled**/Disabled	Allows all four screens in a 2x2 layout to be synchronized in a 4D cine.
Show msec if available	Enabled/**Disabled**	Show milliseconds on the annotations, if information is available.
First phase to display when loading 4D (%RR)	**75**	Sets which phase to display first when loading a multi-data study.

Capture

Set options for image capture in the 3D Viewer, to be sent to the Output Panel.

Option	Values (Default value bolded)	Description
User Capture Path	Default is **C:\Documents and Settings\Administration\My Documents**.	Where to store images that have been captured to the Output Panel. Use the browse button to the right to change folder

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Option	Values (Default value bolded)	Description
Format	• JPG • **BMP**	Default image format of captured images
Play sound at the time of capture	**Enabled**/Disabled	Play “camera click” sound at the time of capture
Add pixel spacing in DICOM header for Secondary capture	**Enabled**/Disabled	Pixel spacing command (0028, 0030) is added to the DICOM header of the captured image.
Show original DICOM FOV value annotation for capture image	**Enabled**/Disabled	When enabled, the FOV value showing in the annotation of the captured image is the same as what is displayed in the original image.
Capture area option	• **Expand image to fill frame** • Capture as displayed • Maintain zoom (of captured area)	First option: The dimensions of the captured image (and amount of image captured) fills the entire display box in the Output Panel. Second option: An image captured to the Output Panel will have the same dimensions it has in the Viewer or module. Third option: When enabled, captured image is zoomed to the same level as the original.
Select saving option for capture image	• **512x512** • 1024x1024	High speed or high quality
Select location where an image will be sent after capture	• Output Panel • Patient List • **Output Panel and Patient List**	Send captured images to either the Output Panel, the Patient List (as new files) or to both.
Show new DICOM series setting dialog	**Enabled**/Disabled	When capturing to the Patient List, you can set the series starting number and a description.
Draw cross cursor on captured image	Enabled/**Disabled**	When this is enabled, a cross cursor is added to captures of 2D images.
Capture annotation option	• **With full annotations** • Annotations as-is	First option: Image is captured with full annotation, whether or not they are showing. Second option: Image is captured with whatever annotions are showing at the time.

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

CPR

Set defaults for CPR views in the 3D Viewer.

WARNING: The orientation annotation on the CPR windows is only an estimation. It should be verified by a qualified professional.

Option	Values (Default value bolded)	Description
Stenosis algorithm	• **Simple** • QCA	Use either the Simple or the QCA algorithm to calculate stenosis
Area or diameter stenosis	• **Diameter (Average)** • Diameter (Min vs Max) • Area • HU/Intensity	Calculate stenosis using either the average diameter, the min and max diameters, the area, the HU value or intensity.
Show axial view on CPR layout	**Enabled**/Disabled	CPR layout adds window to display the axial view of the study.
Larger cross-section view	Enabled/**Disabled**	Display the cross-section views in a larger window. **(Requires restart.)**
Link CPR windows	Rotate: **Enabled**/Disabled	CPR windows are rotated when main window is rotated
	Pan: **Enabled**/Disabled	CPR windows are panned when main window is panned
	Zoom: **Enabled**/Disabled	CPR windows are zoomed in/out when main window is zoomed in/out
View setting	Centerline on MPR: Enabled/**Disabled**	MPR window displays the centerline under review.
	Anatomy label on CPR: Enabled/**Disabled**	If there are anatomy labels, the relevant ones are displayed on the CPR windows.
	Annotation of orientation: Enabled/**Disabled**	Displays orientation annotation on CPR windows. (**See warning at end of this table.**)
CPR initial view setting	Go to CPR when centerline is created **Enabled**/Disabled	CPR layout is automatically loaded when a centerline is created. (When the setting is not enabled, CPR layout will not load until the centerline is cilcked.)
	Show centerline on MPR: **Enabled**/Disabled	Automatically show centerline in MPR windows
	Show stenosis result: **Enabled**/Disabled	Show stenosis annotation
	Show cross section lines: **Enabled**/Disabled	Show the cross section lines
	Show cross section result: **Enabled**/Disabled	Show cross section result
Active centerline color and width	Color palette available. Default is green. Valid widths are from 1 to 6. The default is 2.	Set the color and width of the active centerline in the 3D image. The centerlines in the MPR views will automatically change to the same color.

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Option	Values (Default value bolded)	Description
General line color and width	Color palette available. Default is grey. Valid widths are from 1 to 6. The default is 1.	Set the color and width of inactive centerlines in the 3D image.
Outline Interpolation	Inner wall: Enabled/**Disabled** Outer wall: **Enabled**/Disabled	
Enable centerline export	Enabled/**Disabled**	Allow export of centerline data in CPR mode, or grid data from the sMPR in EVAR.

CPR Interactive

Option	Values (Default value bolded)	Description
Click on sMPR to set cross-section	**Enabled**/Disabled	Click anywhere on the sMPR view to move the red cross-section to that vertical position.
Click on CPR to set cross-section	**Enabled**/Disabled	Click on the centerline in the CPR view to move the red cross-section to that spot.
Click to set red cross-section to a stenosis nearby	Enabled/**Disabled**	Click near a stenosis to move the red cross-section to the nearest stenosis that satifies the following three parameters.
Snap to stenosis greater than (% simple average diameter)	**30**	Minimum ratio of stenosis to reference diameter and area (percentage).
Search for stenosis within (mm)	**5**	Maximum distance between current position of red cross-section and the nearest stenosis.
Search for reference within (mm)	**20**	Maximum distance between the red and blue cross-section lines.
Update Axial view when cross-section is moved	Enabled/**Disabled**	The axial view displays the slice that corresponds to where the red cross-section is positioned.
Link center of 3D view	**Enabled**/Disabled (active only when previous preference is enabled)	3D view is centered on the red cross-section line when that line is moved on the CPR image.
Update cross-section view when measuring path	**Enabled**/Disabled	The red cross-section line follows the cursor while a distance along the centerline is measured. When the mouse is released, the cross-section line remains at the final position of the measurement.
Snap to other measurement	Enabled/**Disabled**	When enabled, the end point of a distance measurement is automatically snapped to a nearby marker or measurement. To release the “magnetic” effect temporarily, hold the **Alt** key before clicking.

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Calcium

Option	Values (Default value bolded)	Description
Minimum number of images for Calcium Series	10	Minimum number of slice images required to run the Calcium module.
Maximum number of images for Calcium Series	200	Maximum number of slice images allowed to load into the Calcium module.
Default Calcium Percentile Database	• **J Hoff et al** • MESA • Raggi • BOCA Radiology	Select a default database from which to get percentile rankings.

SAT

Option	Values (Default value bolded)	Description
Display “WHO” and “RECIST” label into measurement results	**Enabled**/Disabled	Display lesion measurements as follows: d1 (RECIST): xx.xx cm d2: xx.xx cm d1 x d2 (WHO) = xx.xx cm2 Volume = xx.xx cm3
Always update the SAT mask	Enabled/**Disabled**	This must be set when displaying a mask in SAT.
Overlay/current mask	• **Overlay** • Current mask	Mask of a segmented lesion can be seen in the cube view window (select 2x2 scan window layout to display this window).
Jump to the center point when measurement is created	**Enabled**/Disabled	When a measurement is created, segmentation is performed. When this setting is enabled, the window displays the center of the lesion.
Jump to the center point when measurement is edited	Enabled/**Disabled**	When a measurement is edited, the segmentation is performed again. When this setting is enabled, the window displays the center of the lesion. When disabled, the lesion is displayed from where the edit was done.

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Batch

Option	Values (Default value bolded)	Description
Save scout image and results as one series	**Enabled**/Disabled	Save the 3D image containing the batch grid along with the 2D batch images.
Save CPR results and sMPR results as one series	Enabled/**Disabled**	When enabled, CPR batch series includes SMPR images.
Batch2D by Server	Enabled/**Disabled**	Perform the batch operation on the AqNET server rather than on the client side. This speeds up the process over a slow network.
Batch Image Quality	• Draft • Fine (Speed) • **Fine (Quality)**	**Draft** is fastest, but of lowest quality. **Fine (Speed)** is of better quality, but is slower. **Fine (Quality)** produces the best quality, but is slowest.
Show centerline/outline on batch image	Enabled/**Disabled**	If the main image has a centerline overlay, batched images also show the overlay when this is enabled.
Show measurement on batch image	Enabled/**Disabled**	If the main image has a measurement overlay, batched images also show the overlay when this is enabled.
Parallel batch - Fix the Begin/End point	**Enabled**/Disabled	When enabled, the beginning and end slices of a parallel batch stay fixed, even when the number of slices or interval size has changed.
Parallel batch - Show batched spacing value annotation	Enabled/**Disabled**	Spacing between slices in batched images. When enabled, this annotation is displayed in the lower-left corner of all batched images.
Parallel batch - Show batched thickenss value annotation	Enabled/**Disabled**	Thickness of slices in batched images. When enabled, this annotation is displayed in the lower-left corner of all batched images.
Generated series starting number	User defined	You can specify a starting number for a generated batch series.

Launch Program

Option	Values (Default value bolded)	Description
Export measurements to text file	Enabled/**Disabled**	When enabled, export measurements to a text file.
Path for text program	C:\WINDOWS\system32\NOTEPAD.EXE	Launch notepad to export measurements to a text file
Export measurements to CSV file	Enabled/**Disabled**	When enabled, export measurements to a CSV file.

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Option	Values (Default value bolded)	Description
Path for Excel program	C:\Program Files\Microsoft Office\Office10\EXCEL.EXE	Launch Excel to export measurements to CSV file
Export measurements to XML file	Enabled/**Disabled**	When enabled, export measurements to an XML file.
Path for XML	C:\Program Files\Internet Explorer\iexplore.exe	Launch Internet Explorer to export measurements to an XML file
Export measurements to AIM XML file	Enabled/**Disabled**	Export measurements to a file in the Annotation Imaging Markup format.
Path for AIM XML	C:\Program Files\Internet Explorer\iexplore.exe	Launch Internet Explorer to export measurements to an AIM file
Play movie	Enabled/**Disabled**	When enabled, play AVI movie
Path for media player	C:\Program Files\Windows Media Player\wmplayer.exe	Launch Windows Media Player to play movie.

Mouse Operation

Option	Values (Default value bolded)	Description
Valid pixels per slice	2-50 (**Default: 5**)	The number of pixels of vertical mouse movement required to advance the 2D image one slice. A higher number means slower slice paging.
Non skipping slice mouse mode	Enabled/**Disabled**	When enabled, slice mode will display every slice without skipping any.
Enable default left mouse button setting. Select mouse button setting from pull-down menu.	Enabled/**Disabled** • Window Level • Pan • Zoom • Slice • **Rotate**	Allows you to define mouse button settings that map to image manipulation functions. Each mouse button or mouse button combination can be mapped to one of these functions. Note: the mapping for each button must be unique. **(Requires restart.)**

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Option	Values (Default value bolded)	Description
Enable user defined mouse button mappings. Select user-defined mouse button setting from pull-down menu.	Enabled/**Disabled** • **None** • Right • Left+Right • Middle • Middle+Right • Left+Middle (Note: **None** is the default for all functions.)	When enabled, you can select mappings from the mouse buttons to image manipulation functions, using the following preference setting. For any of the following functions, select a mouse button combination from the pulldown menu that will initiate that function: • W/L • Pan • Zoom • Slice • Rotate
Show the mouse modes at the top of the right click menu	Enabled/**Disabled**	List the mouse modes (Rotate, Pan, Zoom, etc) at the top of the right-click menu on the image. When this is disabled, the mouse modes are listed in a sub menu.
Simply click on 2D will focus there	Enabled/**Disabled**	A single click on a 2D image will move the cross cursor to the clicked location.

TDA

Option	Values (Default value bolded)	Description
Show original image under the map	Enabled/**Disabled**	In a viewing window showing a map, the original image is displayed underneath the map.
Reverse color lookup table for MTT map	Enabled/**Disabled**	Display MTT maps in reverse color scheme.
Automatically apply motion correction after loading volume (CT only)	**Enabled**/Disabled	Realign images that might not might up if the patient moved during the scan.
Automatically calculate TDA maps after loading volume	**Enabled**/Disabled	Calculate and display maps automatically when volume is loaded.
Change between 2x2 and 4x4 layout when changing stages	Enabled/**Disabled**	When clicking Next to go to the next stage, layout changes from 4x4 to 2x2.
Copy measurements to all levels	Enabled/**Disabled**	When a measurement is done on one level, propagate that measurement to all levels.
Send images to Output Panel / Patient List when capture in TDA	**Enabled**/Disabled	Captured images go to the TDA report. To send them to the Output Panel and/or Patient List in addition, check this item.
Show the same map type for all levels	**Enabled**/Disabled	When loading the data, the map type selected for each window should be the same in all levels.
Adjust ROI template to the current data	**Enabled**/Disabled	The ROI template will be adjusted so that it fits within the skull structure.

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Show measurement results as annotation	Enabled/**Disabled**	Show TDA measurements in the view window annotation.
Override Time interval (sec)	Enabled/**Disabled** (1.00)	When enabled, use the value entered in the input box. When disabled, use the value from the DICOM header.
Brain density (g/cc)	1.04	
Plasma ratio	0.85	The values of the map must be divided by the hematocrit to obtain the real CBV. This value can fall between 0.85 and 0.9.
Reset to last saved	N/A (button)	Reset all fields in this screen to the values that were most recently saved.
Set to Default	N/A (button)	Reset all fields to the initial default values.

TDA Functional Map

Option	Values (Default value bolded)	Description
BV(ml/100g) : Analysis	Min : 0.00 Max : 8.00	For each map, analyze results that fall within the specified range. When a value is discovered that is outside the range, it is clamped off (values below the range are clamped to the Min value, values above are clamped to the Max).
BF(ml/100g/min) : Analysis	Min : 0.00 Max : 120.00	
MTT(sec) : Analysis	Min : 1.00 Max : 300.00	
BV(ml/100g) : Display	Min : 0.00 Max : 6.00	Set the range that determines which colors are displayed for each value.
BF(ml/100g/min) : Display	Min : 0.00 Max : 100.00	
MTT(sec) : Display	Min : 0.00 Max : 15.00	
TOT(sec) : Display	Min : 5.00 Max : 20.00	
RT(sec) : Display	Min : 5.00 Max : 30.00	
TTP(sec) : Display	Min : 0.00 Max : 25.00	
Default overlay map type in viewers	Available map types are: BV, BF, MTT, TOT, RT, TTP, Map, Graph, MPR and MIP.	Select the map type for each viewing window to be the default type for that window when a study is loaded.
Analysis Resolution	• 512x512 • 256x256 • **128x128**	Resolution of data to be analyzed. Higher resultions result in a finer and more detailed map, but the calculations will take longer.
Default WW/WL	WW : 600 WL : 200	Set default values for window width and window level for TDA.
Reset to last saved	N/A (button)	Reset all fields in this screen to the values that were most recently saved.
Set to Default	N/A (button)	Reset all fields to the initial default values.

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

TDA Classification Map

The classifications are defined as Normal, Class 1 and Class 2. Class 1 and Class 2 can refer to either recoverable or unrecoverable, according to your preference. In this screen you can set the thresholds for each class. The values shown below are defaults and can be changed.

Option		Values and Defaults	Used
Normal Class	BV (ml/100g)	Min: 2.00 Max: 8.00	Disabled
	BF (ml/100g/min)	Min: 25.00 Max: 120.00	**Enabled**
	MTT (sec)	Min: 1.00 Max: 8.00	**Enabled**
Class 1	BV (ml/100g)	Min: 0.00 Max: 2.00	Disabled
	BF (ml/100g/min)	Min: 0.00 Max: 10.00	**Enabled**
	MTT (sec)	Min: 1.00 Max: 300.00	Disabled
Class 2	BV (ml/100g)	Min: 2.00 Max: 8.00	Disabled
	BF (ml/100g/min)	Min: 10.00 Max: 25.00	**Enabled**
	MTT (sec)	Min: 8.00 Max: 300.00	**Enabled**
Use post filtering	Default**:** **Enabled**/Disabled	Description: Make map images appear smoother.	
Reset to last saved		N/A (button)	Reset all fields in this screen to the values that were most recently saved.
Set to Default		N/A (button)	Reset all fields to the initial default values.

TDA Capture

Option	Values (Default value bolded)	Description
Preset maps to be captured for a TDA report - **CT modality**	**BF, BV, MTT, Map, TOT, RT, TTP, Graph, MPR, MIP**	Items checked in this list are captured when **Capture Preset Maps for All Levels** is selected in the TDA **Report** tab. The graphs can be reordered using the up and down arrow buttons.
Preset maps to be captured for a TDA report - MR modality	NEI,MTE, NEI, MTE, Map, MSI, MSD, TM, Graph, MPR, MIP	

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

TVA

Option	Values (Default value bolded)	Description
Patient Demographic Unit	• **International** • lb, ft, in	Metric or imperial units
Number of minimum series to proceed EF	8	If the number of loaded series is lower than the minimum specified here, ask whether user wants to use different data for EF.

TVA(LV)

Option	Values (Default value bolded)	Description
Analysis Method	• **Automatic** • Automatic (all phases) • Manual	Automatic: Calculate left-ventricle ejection fraction automatically. Automatic (all phases): Perform automatic TVA(LV) on all phases. Manual: The user performs each step of the analysis manually.
Perform Wall Analysis	**Enabled**/Disabled	If enabled, wall analysis is performed automatically
Myocardial Density	Numerical (g/ml) **(Default is 1.05 g/ml)**	Set the value of myocardial density.
Show grids on myocardium	Enabled/**Disabled**	Display grids on the myocardium during the Wall step of manual TVA(LV).

TVA(RV)

Option	Values (Default value bolded)	Description
Analysis Method	• **Automatic** • Manual	Automatic: Calculate right-ventricle ejection fraction automatically. Manual: The user performs each step of the analysis manually.

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Flythrough

Option	Values (Default value bolded)	Description
Default WW	1500	Default window width value
Default WL	-400	Default window level value
MPR cutplane VR mode	• Gray scale • **Color template**	
Create a new finding when:	An arrow is added.ì (**Enabled**/Disabled)	When any of these actions are taken, automatically create a new finding and add to the findings list.
	A distance is measured (**Enabled**/Disabled)	
	A polyp is picked (**Enabled**/Disabled)	
	CAD markers are turned on (Enabled/**Disabled**)	
Default perspective view angle	120 degrees	Default “lens” angle for viewing the flight path
Layout for Primary2D when double-click	• **1x2 Side by Side**	When one of the windows in the Primary2D layout is double-clicked, that window and the corresponding window from the other scan are displayed side-by-side. If you double-click again, it will go back to Primary2D.
	• 1x1	When one of the windows in the Primary2D layout is double-clicked, that window is displayed in the entire main window. If you double-click again, it will go back to Primary2D.
Findings to Report/Output/Text	• **Confirmed findings only** • Confirmed and pending findings • Display findings in the finding list	Select which findings to send to a report, to the Output Panel, or to a text file.
Capture to both Finding list and Output Panel	**Enabled**/Disabled	When selecting Capture for a finding, send the finding to both the Findsings List and to the Output Panel.
Show Reading style preference wizard every time	**Enabled**/Disabled	Display the Reading Style wizard each time the layout is changed. (When disabled, the wizard is displayed only when data is first loaded.)
Re-synchronize on path when switching layout/data	**Enabled**/Disabled	When switching from primary flythrough path to other data or layout, synchonize the new path to the primary path. When returning to the primary path, do not re-synchronize, but go back to where it was.

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Option	Values (Default value bolded)	Description
Show colon coverage in tool panel	Enabled/**Disabled**	Display percentage of colon viewed and button to show the unviewed list.
Skip colon segmentation and path creation when there is APS result	Enabled/**Disabled**	Use the APS result instead of doing these steps manually.
Show stool with color	**Enabled**/Disabled	Display stool in a different color to be easily identified.
Cache Flat view	**Enabled**/Disabled	Caching the flat view gives it better image quality and speed. However, the original load will take longer.
Show camera postion on 2D	**Enabled**/Disabled	Display arrow pointing to current camera position on the 2D views during flythrough.
Enable dual monitor	Enabled/Disabled	When enabled, Flythrough displays a dual-monitor layout on both monitors.

Output Panel

Option	Values (Default value bolded)	Description
Features available for 1x1 output layout	• Film • **Save** • Report • Print • **Email**	Images in the output medium are saved and/or displayed in 1x1 layout, regardless of the currently selected layout in the Output Panel.
Select where you want to dock the control panel	• **Top** • Bottom	Choose where the control panel will appear in the Output Panel (above or below the captured images). **(Requires restart.)**
Automatically open on sending images to output panel	Enabled/**Disabled**	When enabled, the Output Panel is automatically displayed whenever an image is captured and sent to the Output Panel.
Automatically close if output panel is empty	**Enabled**/Disabled	The Output Panel closes automatically when all captured images are deleted.
Delete images after DICOM transfer is completed	Enabled/**Disabled**	Delete images from Output Panel after **Send to DICOM** transfer is complete.
Save copy of images on AqNET server	Enabled/**Disabled**	If **Delete images after DICOM transfer** is checked, also checking this setting will save a copy of the images on the AqNET server, in case of lost data or network failure.
Save selected DICOM server as default	Enabled/**Disabled**	Each time you select a DICOM server, that server becomes the default server.

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Option	Values (Default value bolded)	Description
Bit depth (MIN, MPR, etc)	• **Colored** • Grayscale (12- or 8-bit) • Show more options	Set the bit depth for all captures to either grayscale or color. If Grayscale is selected, select whether 8-bit or 12-bit using the pull-down menu at right. If **Show more options** is selected, set bit depth separately according to the rendering mode or view (see next row).
Bit depth options (visible only when **Show more options** is checked, above)	Set bit depth for Preview, Sagittal, Coronal, Axial, Main, CPR, sMPR, cross-section MPR, and MAR.	Allows you to set the bit depth individually for different rendering modes or views.
Capture VR always as colored	**Enabled**/Disabled	When this is enabled, the Capture option does not ask whether you want a VR image to be captured in color or monochrome. It always captures in color.
Capture Image including Color Overlay	• BFA (Body fat analysis) (**On**) • Mask (**On**) • Plaque analysis (**On**) • Volume (Histogram) (**On**) • Colored Motion (**On**)	For any of the types of overlay that are checked, include that overlay in the capture.
Generated series starting number	User defined	You can specify a starting number for generated series.

Page Format

Option	Values (Default value bolded)	Description
Display setting	1x1: Enabled 1x2: Enabled 2x1: Enabled 2x2: Enabled 2x3: Enabled 2x4: Enabled 3x3: Enabled 3x4: Enabled 3x5: Enabled 4x4: Enabled 4x5: Enabled 4x6: Enabled 5x5: Enabled 5x7: Enabled 5x8: Enabled 5x9: Enabled 6x8: Enabled 7x8: Enabled 8x9: Enabled	These describe the number and layout of the images per page in the Output Panel.
New page format	All formats that are offered in the Display settings (no default)	Create a new page format to add to above list.

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Option	Values (Default value bolded)	Description
Page size setting	8x10 in.: Disabled 8.5x11 in.: Disabled 10x12 in.: Disabled 10x14 in.: Disabled 11x14 in.: Disabled 14x14 in.: Disabled 14x17 in.: Disabled 24x30 cm: Disabled 24x24 cm: Disabled A3 (Portrait): Disabled A4 (Portrait): Disabled 10x8 in.: Disabled 11x8.5 in.: Disabled 12x10 in.: Disabled 14x10 in.: Disabled 14x11 in.: Disabled 17x14 in.: Disabled 30x24cm: Disabled A3 (Landscape): Disabled A4 (Landscape): Disabled	Select all page dimensions to be available in the Page size pull-down menu. These dimensions refer to the size paper the images will be printed on.

Measurement Settings

Option	Values (Default value bolded)
Use Measurement Protocols from	• **Private** • Group
Specify the name after a measurement	Enabled/**Disabled**
Export measurement results when opening report for workflow	Enabled/**Disabled**
Export measurement results when output workflow images	Enabled/**Disabled**
Export folder - choose the location for exporting the images	**C:\Documents and Settings\Administrator\Desktop**
Capture to Output Panel when measurement is added or edited	Enabled/**Disabled**
Delete measurement in the viewer when it is erased in the measurement protocol panel	Enabled/**Disabled**
Erase measurement value from measurement protocol when it is deleted in the viewer.	Enabled/**Disabled**
Save images when exporting measurements as XML	**Enabled**/Disabled
Popup the measurement protocol selection dialog automatically	**Enabled**/Disabled
Save the measurement protocol automatically (when measurements are added/deleted/edited).	**Enabled**/Disabled

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Movie

Option	Values (Default value bolded)	Description
Resolution	256	Pixels per square inch (256x256, 512x512).
Square view	Enabled/**Disabled**	
Frame rate	8 frame/sec	The number of frames shown per second as the film is playing.
Codec (video compression)	Full Frames (uncompressed)	Select compression software from pull-down menu.

Patient Annotation

Option	Values (Default value bolded)	Description
Age/Birth patient annotation	• **Age** • Birth	Show either the patient's age or birthdate in patient annotation
Date/Time type	• **Acquisition date/time** • Study date/time	Show date as time of scan or time the data was received on AqNET.
Date format	• **Month/Day/Year (US)** • Year/Month/Day (JP) • Date-Short Name of Month-Year	Choose date format appropriate for country.
24-hour time format	Enabled/**Disabled**	Either 12-hour (with AM and PM to indicate which part of the day) or 24-hour clock, from 00:00 (midnight) to 23:59 (11:59 PM).

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Appendix B: Keyboard Shortcuts

Group	Function	Keyboard Shortcut
3D Mouse Operation	Rotate	Left button click and drag
	Re-center	Click Middle button
2D Mouse Operation	Paging	Scroll wheel
		Left button click and drag
		Middle and Right buttons click and drag
	Paging with Slow Speed	Left button click and drag, then Shift
		Middle and Right buttons click and drag, then Shift
	Link to 3D ON/OFF	Middle button double click
3D / 2D Mouse Operation	Window Level	Left and Right buttons click and drag
		Move mouse cursor over W/L and Left button click
		Key: 1-9. 0 is for reset.
	Pan	Right button click and drag
	Zoom	Middle button click and drag
	Re-center	Alt + Left button click
	Move Scale Bar	Left button double click on the scale bar. Left button click on it and drag.
Capture	Capture	c
	Capture All	Ctrl + Shift + c
	Capture All in One	Ctrl + Alt + c
	Capture Image and Annotation	Alt + c
	Capture to Folder	Ctrl + s

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Measurement	Distance	d
	Ellipse	e
	Profile	i
	Angle	Shift + comma (,) / Less than (<)
	Distance Pair	Ctrl+d
	Polygon	Ctrl+p
	Fat Analysis	Ctrl+o
	Volume Histogram	Ctrl+Alt+v
	Select Previous Result	Ctrl+Open Brackets ([)
	Select Next Result	Ctrl+Close Brackets (])
	Mouse Escape	Esc
	Delete Measurement	Delete
Measurement Protocol	Export AIM xml file	Shift + e
	Move to Next Step	b
Finding	New Finding	n
	Show Measurement Result	Semicolon (;)
Arrow / Text	Arrow/Text	m
	Landmark Arrow	Ctrl + m
	Text	t
Orientation	Anterior	a
	Posterior	p
	Head	h
	Feet	f
	Right	r
	Left	l
	Rotate to Up	Up (↑)
	Rotate to Down	Down (↓)
	Rotate to Left	Left (←)
	Rotate to Right	Right (→)
	Angle Setting (LAO, RAO)	o
Batch 2D	Wizard	F8
G-Bar	Show G-Bar	g
CPR	Enter CPR Mode	v, F7
	Show / Hide Centerline	Ctrl+t
CPR - Mouse movements are interpreted according to the mode invoked by each of the shortcut keys.	Redraw mode	Shift
	Draw circle around outer wall	Ctrl
	Nudge outer wall	Alt or Alt + Ctrl

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CPR - Edit Centerline	Quick Edit Mode	Shift + Move mouse over CPR window
	Add / Delete Point	Shift + Left button click
	Smooth Centerline	Ctrl + Left button click and drag
CPR - Edit Contour	Redraw	Shift + Left button and draw
	Nudge	Alt + Left button and draw
Region Growing	Region Growing	F5
	Select Visible Region	Shift + Left button hold
	Select Visible and Invisible Region	Shift + Ctrl + Left button hold
	Add RG area to existing volume	Shift + Ctrl + Left-click
Free ROI	Free Curve	F6
Free ROI - 3D	Exclude	Shift + Left button drug
	Edit	Shift + Left button click to draw region, then click button from Free ROI tool
	Add Back Previously removed Region	Shift + Right button click and drug
Free ROI - 2D	Edit	Shift + Left button click to draw region, then click button from Free ROI tool
Mask	Smooth Mask	Ctrl + e
Cross Hairs	Re-center MPR Cross Hairs	Alt + x
	Show / Hide Cross Hairs	x
Cutplane	Slab	w
	MPR Map ON/OFF	Alt + w
	Modify Thickness	Ctrl + Middle button click and drag
Cube view	Cube View	q
		Space + Left button click
	Change Cube Size	Middle button click and drag
	Zoom	Ctrl + Middle button click and drag
Render Mode	3D VR	F2
	3D Perspective	Alt + F2
	MPR	F3
	MIP	F4
	Draft/Fine ON/OFF	Ctrl + f
Workflow	Next	Tab
	Previous	Shift + Tab
	Validate	Ctrl + w

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4D Cine	Backward	Page Down
	Forward	Page Up
	Play Forward	Period (.)
	Speed Control	Comma (,)
Layout	1x1	Ctrl + F2
	2x2	Ctrl + F3
	2x2 Vessel Track	Ctrl + F4
	2x2 CPR Vertical	Ctrl + F5
	2x2 CPR Horizontal	Ctrl + F6
	Back to Previous Layout	Double click
Other	Undo	Ctrl + z, z
	Redo	Ctrl + y
	Control Panel ON/OFF	Ctrl + r
	Multidata Sync	Space bar
	Full Screen Mode	F11
	AQi Online Help	F1
Mouse Operation	Open Quick View Panel	Left button double click
	Paging with Slow Speed	Shift + Left buttons click and drag
Paging	Move Forward	Up (↑)
	Move Backward	Down (↓)
	Go First Slice	Home
	Go Last Slice	End
	4D Phase Forward	Right (→), Page Up
	4D phase Backward	Left (←), Page Down
	Drag and Drop an Image in Format	Left button click + drag and drop
		Ctrl + Left button click and drag
	Open Edit Window	Left button double click
	Backward	Left (←)
	Forward	Right (→)
	Level Down	Down (↓)
	Level Up	Up (↑)

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Rendering Mode	MPR	F3
	MIP	F4
	BF	F5
	BV	F6
	MTT	F7
	Penumbra	F8
	Permeability	F9
Colored Motion	Colored Motion	k
User Annotation	Landmark Arrow	m
Candidate Marker	Candidate Marker On/Off	Pipe (|)
	Previous Maker	Open Bracket ([)
	Next Marker	Close Bracket (])
Flythrough	Forward in Flat View Path	Left button click
	Backward in Flat View Path	Alt + Left button click
	Tilt Flat View Camera Angle between Left and Right	Left button click and drag horizontally
	Change Cube Size in Cube View	Shift + Middle button click and drag
	Orbit in Perspective View	Ctrl + Left button click and drag
	Show SpotMPR	s

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Index

Numerics

1x1 layout 2-137
1x2 axial 3D layout 2-137
1x2 bone edit layout 2-137
2+1 scan layout 2-141
2x2 CPR horizontal large 2-139
2x2 CPR horizontal layout 2-138
2x2 CPR vertical large layout 2-138
2x2 CPR vertical layout 2-138
2x2 EVAR layout 2-139
2x2 layout 2-137
2x2 scan layout 2-140
2x2 vessel track layout 2-139
360-Degree Fisheye view 9-26
3D settings 2-159
3D Viewer 2-1
    3D settings 2-159
    Advanced Processing 2-141
    Clinical tools 2-7
    Preferences A-6
    Screen 2-1
    Series list 2-163
    Tool panel 2-6
    Workflows 3-1
3x1 layout 2-138

A

Add new workflow 3-6
Add workflow element 3-7
Advanced Processing 1-19, 2-141, 6-3, 6-4, 11-3
Airway CPR 2-33
Anatomy List 2-59
Angio view 2-63
Angle measurement 2-122
Annotations 2-148, 2-150
Anterior cerebral artery (ACA) 7-12
Application error
    Preferences A-3
Application Launcher 13-1
APS 1-19
    Anatomy list 2-141
    Bone removal 2-146
    Candidate marker 2-142
    Centerline 2-142
    Functions 2-141
    Label 2-141
    Masks 2-143
    Medicsight 6-4
    With EVAR 11-3
    With SAT 6-3
AQMobile 12-5
Aquarius iNtuition i-2
Aquarius iNtution Mobile 12-5
AquariusWEB 12-1
    Image viewing tools 12-3
    Series list 12-2
    Using passwords 12-1
    Viewer 12-2
Automate i-1
Automate, Validate, Read i-1
AVR i-1
Axial layout 2-139

B

Batch 2-45
    Output as derived series 2-49
    Parellel mode 2-45
    Perpendicular 2-50
    Preferences A-15
    Radial mode 2-50
Batch3D 2-54
    Output images 2-56
Blood Flow 7-1
Blood Volume 7-1
Bone removal 2-42, 3-20

C

Calcium scoring 2-45, 3-23
Cancel send 1-12
Capture preferences A-10
Capturing images 2-55
Cardiac reports 3-28
Categories 2-155

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Centerlines
Automatic 2-14
Manual 2-15
Smooth 2-21
Clinical tools 2-7
Color maps
Fat analysis 2-130
Plaque analysis 2-23
TDA 7-4
Color Templates 2-154
Common mask controls 2-57
Coronal layout 2-140
CPR batch 2-50
CPR tool
CPR window toolbar 2-18
Right-click menu 2-20
Tools 2-13
Windows 2-16
Cube view 2-8
3D Viewer 2-8
Flythrough 9-25
Customizing the tool panel 2-92

D

Delete
Series 1-8
Studies 1-3
Derived series 2-49
DICOM header 1-22
Distance measurement 2-120, 2-128
Dynamic region growing 2-40

E

Edge detection 2-37
Editing workflows 3-13
Ejection fraction 3-24, 5-2
Email series URL 1-9, 12-20
Using passwords 1-10, 12-1
End-Diastole
TVA(RV) 5-19
Endovascular Aortic Repair 11-1
End-Systole
TVA(RV) 5-19
Erosion/dilation 2-58
Error maps 7-1
EVAR 11-1
Measurement Protocols 11-5
Obtaining measurements 11-7
Reports 11-19
With APS 11-3
Workflow 11-2
EVAR Common measurements 11-11
Marking locations 11-12
Min/max curved length 11-18
Outer walls 11-11
Path lengths 11-13
Exporting Template Categories 2-157
Extracting centerlines 2-15

F

Fat analysismeasurement 2-129
Filtering patient list 1-15
Fisheye view 9-26
Flythrough 9-1
360-Degree Fisheye view 9-26
Background color 9-4
Confirmation 9-34
Cube view 9-25
Editing connection 9-5
Editing flight path 9-7, 9-18
Findings 9-33
Flat view 9-29
Flight path creation 9-3
Keyboard shortcuts 9-2
Pick polyp 9-22
Preferences A-21
Reading styles 9-8
Rear perspective view 9-30
Recording 9-18, 9-19
Reports 9-35
Segmentation 9-3
Start 9-17
Stop 9-17
Synchronization 9-14
Tool panel 9-18
Workflow 9-17
Fragment cleanup 2-58
FreeROI 2-36
Edge detection 2-37
Fusion 14-1

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

G
General preferences A-2

H
Half Space 2-8
Help, online 1-13

I
Importing Template Categories 2-159
Input-Output log 1-12
Inverting W/L 2-59, 2-154

K
Keyboard shortcuts B-1
    Flythrough 9-2

L
Labels 2-59, 2-135
LD 2-67
LD2 2-73
Left-Ventricle TVA 5-2
Load
    Series 1-8
    Studies 1-3
Load button 2-1
Lobular Composition 2-67
Lobular Composition 2 2-73
Logging in i-3
Low Attenuation 2-86
LV EF 5-2

M
Macro 4-10
Manage series data 1-8
Manage study data 1-3
Manual TVA
    LV 5-3
    RV 5-18
Mask
    Controls 2-57
    Preferences A-8
    Threshold 2-62
Measurement preferences A-24
Measurement Protocols 2-66, 11-5
    Creating 10-5
    Exporting data 10-5, 11-19
    Reports 10-4
Measurement tools 2-119
    Angle 2-122
    Change color 2-131
    Change font 2-131
    Distance 2-120, 2-128
    Fat analysis 2-129
    Line segment 2-122
    Polygon 2-128
    Profile 2-121
    Volume 2-123
Movie preferences A-25
Multidata 14-1
Myocardial Volume 5-15

O
Online help 1-13
Opacity Control 2-161
Open Fusion 1-8
Open ThinClient
    Series 1-8
    Study 1-3
Orientation 2-12, 2-153
Output Batch3D images 2-56
Output panel 3-26, 3-27, 4-1
    Control panel 4-8
    Emailing images 4-7
    Page settings 4-1
    Printing images 4-7
    Saving images 4-8
    Sending images to DICOM 4-7

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

P

Parallel batch mode 2-45
Patient List 2-148
    DICOM Header 1-22
    Filtering 1-15
    Load button 1-15
    Preferences A-4
    Preview panel 1-21
    Quickview Panel 1-21
    Series information 1-18
    Series List 1-8
    Study List 1-3
    Sub-Series 1-18
Perpendicular batch mode 2-50
Plaque Analysis 2-20
Polygon measurement 2-128
Preferences A-1
    3D Viewer A-6
    Application error A-3
    Batch A-15
    Capture A-10
    CPR A-12
    Flythrough A-21
    General A-2
    Mask A-8
    Measurement A-24
    Movie A-25
    Patient List A-4
    TDA capture A-19
    Toolbar A-7
    TVA A-20
    Workflow A-7
Preferences button A-1
Preview panel 1-21
Prone position 9-1
Push series
    Cancel 1-12
Push study
    Cancel 1-12

Q

Quickview Panel 1-21

R

Radial batch mode 2-50
Registration 2-63
Rendering modes 2-153
Reports
    Calcium Scoring 8-11
    Cardiac 3-28
    EVAR 11-19
    Flythrough 9-35
    Measurement Protocols 10-4
    SAT 6-11
    Simple 3-5
    TDA 7-14
Right Panel 2-165
Right-Ventricle TVA 5-17
RV EF 5-17

S

Sagittal layout 2-140
SAT 6-1
    Advanced Processing 6-3
    Doubling time 6-12
    Findings window 6-11
    Main viewer 6-1
    Manual SAT 6-7
    Non-lung studies 6-14
    Reports 6-11
    Right-click menu 6-3
    Tool panel 2-63, 6-2
Saving scenes 2-147
Scene validation 3-2
Scout image 2-47
Security 4-9
Segmental Ejection Fraction 5-12
Segmentation, Analysis, and Tracking 6-1
Send series
    To DICOM 1-8
    To Output Panel 1-8
Send study
    To DICOM 1-3
    To Output Panel 1-3
Send to DICOM
    Cancel 1-12
Series tab 2-163
Simple reports 3-5
Slab view 2-3, 2-8
Smooth centerline 2-21
Smooth surface 2-3

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Start/Stop Flythrough 9-17
Sub-series 1-19
Subtraction 2-64
Superior sagittal venus sinus (SSVS) 7-13
Supine position 9-1

T

TDA 7-1
- Automatic 7-2
- Capture images 7-14
- Color map 7-4
- Draw region of interest 7-10
- Manual TVA 7-12
- Maps and graphs 7-2
- Reports 7-14
- Results 7-11

Template Categories 2-155
Templates 3-2
Templates,3D Templates 2-154
Temporal Maximum Intensity Projection 7-1
Time Dependent Analysis 7-1
Time-To-Peak 7-1
Time-Volume Analysis 5-1
Tool panel
- Anatomy list 2-59
- Angio view 2-63
- Batch 2-45
- Batch3D 2-54
- Bone removal 2-42
- Calcium scoring 2-45
- CPR tool 2-13
- Cube view 2-8
- Customizing 2-92
- Dynamic region growing 2-40
- FreeROI 2-36
- Mask threshold 2-62
- Measurement Protocols 2-66
- Orientation 2-12
- SAT 2-63
- Slab view 2-8
- Window level 2-58

Toolbar preferences A-7
TVA 5-1
- Preferences A-20
- Reports 5-25

TVA(LV) 5-2
- Algorithms 5-14
- Automatic TVA 5-3
- Calculation 5-10
- Chamber segmentation 5-7
- Display formats 5-11
- Manual TVA 5-3
- Myocardial Volume 5-15
- Positioning 5-4
- Results 5-10
- Segmental Ejection Fraction 5-12
- Threshold 5-4
- Wall correction 5-9

TVA(RV) 5-17
- Calculation 5-24
- Display formats 5-25
- Editing Labels 5-21
- Manual TVA 5-18
- Results 5-24
- Wall Correction 5-22

U

User annotation 2-148, 2-150

V

Validation 3-2
Vessel track 3-22
Volume measurement 2-123
Volume operation
- Clamp values 2-65
- Registration 2-63
- Remap values 2-65
- Subtraction 2-64

VR Curve Shapes 2-160

W

W/L 2-58, 2-154
- Control Box 2-160
- Inverting 2-59, 2-154
- Slider 2-160

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Window layouts 2-136
- 1x1 2-137
- 1x2 axial 3D 2-137
- 1x2 bone edit 2-137
- 2+1 scan 2-141
- 2x2 2-137
- 2x2 CPR horizontal 2-138
- 2x2 CPR horizontal large 2-139
- 2x2 CPR vertical 2-138
- 2x2 CPR vertical large 2-138
- 2x2 EVAR 2-139
- 2x2 scan 2-140
- 2x2 vessel track 2-139
- 3x1 2-138
- Axial 2-139
- Coronal 2-140
- Sagittal 2-140

Window/Level 2-58, 2-154
- Control Box 2-160
- Inverting 2-59, 2-154
- Slider 2-160

Workflows i-2, 1-4, 2-4, 3-1
- Editing 3-13
- Elements 3-1, 3-7
- Preferences A-7
- Scenes i-2

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AquariusNET Thin Client

Version 4.4

User Manual

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Chapter 10: Multiphase Studies

Multiphase study

In a multiphase study, you can view multiphase data, plot contrast “wash in – wash out” curves, and perform cine of the entire data.

Opening a Multiphase Study

To open a multiphase study, perform the following:

1. Click on the appropriate patient name from the Patient List.

2. Click on the first multiphase series, then hold the **SHIFT** key and click on the last multiphase series.

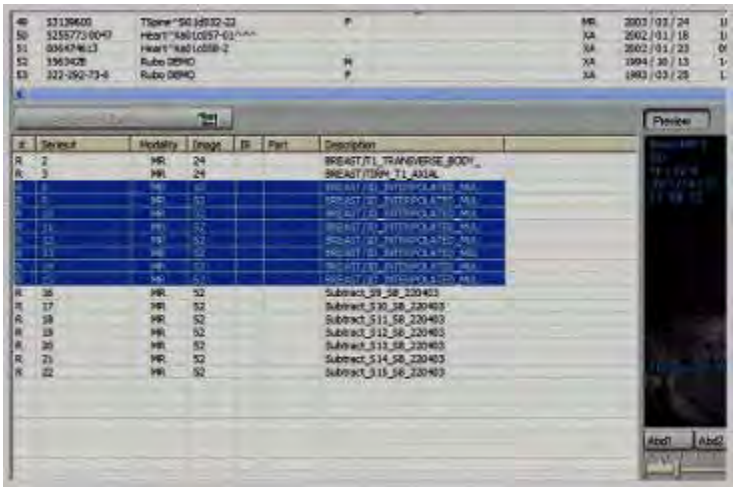

Figure 10-1: Selecting Multi-phase series from the Patient List

3. Right-click on the highlighted series and select **Open Multiphase View** from the pop-up menu.

Viewing Multiphase Data

All multiphase series open in the main view screen. You can scroll, pan, and adjust the window level of each series.

1. To rapidly scroll through a series, click the right mouse button and roll the mouse wheel. Move the mouse forward and back. When scrolling through a series, all the other series will automatically update to the same location.

2. Zoom an image by rolling the mouse wheel, and pan it using the right mouse button.

3. The top right corner of each image shows the label ‘n of N’, for example, 1/3, referring to image ‘1’ out of 3 images, as circled in Figure 10-2 on page 10-2.

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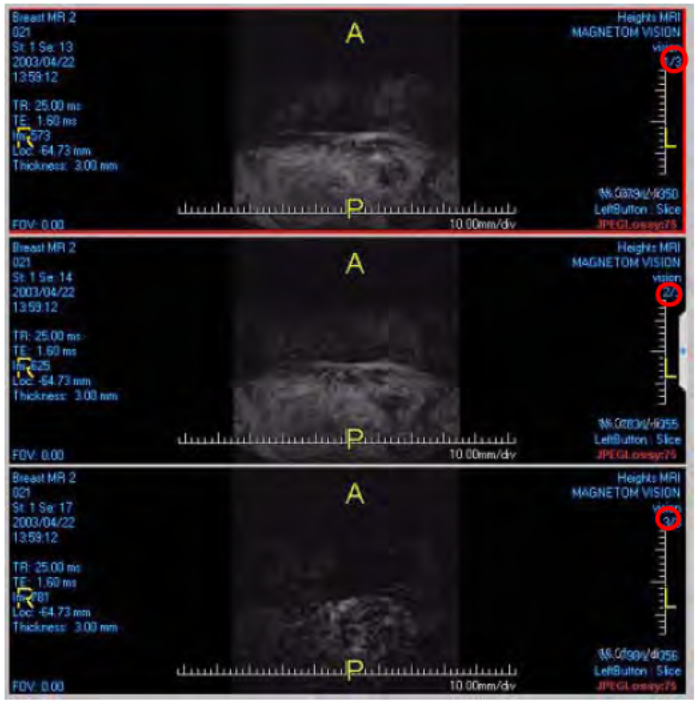

Figure 10-2: Images labeled 'n of N', circled in red

Creating a 'Wash In-Wash Out' Curve

You can plot and graph the movement of contrast in and out of an area of interest. First you must subtract the non-contrast studies from the contrast studies. To create a 'Wash In- Wash Out' curve, perform the following:

1. Currently **T zero** is selected as default to set this first image as "Time Zero". If this is not selected, right-click on the image in the upper left corner of the screen and select **T zero** from the pop-up menu.

2. Click the **Subtract** button from the right- panel. Notice that the remaining images reflect the process of subtraction.

3. Select a subtracted series and scroll to find the area of interest.

4. Once a desired area is located, click to open the measurement tools located at the upper toolbar.

Figure 10-3: Measurement tools

5. To draw a ROI, use one of the three tools labeled with a "**t**" on the far right of the toolbar. Click on one of the three ROI buttons, and move the mouse cursor to the area of interest on the selected image.

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Figure 10-4: The tools labeled 't' circled

6. Draw around the area of interest. The "Wash in – Wash out curve" graph will appear. The curve displays the intensity value for each phase, as indicated by the values on each vertical line.

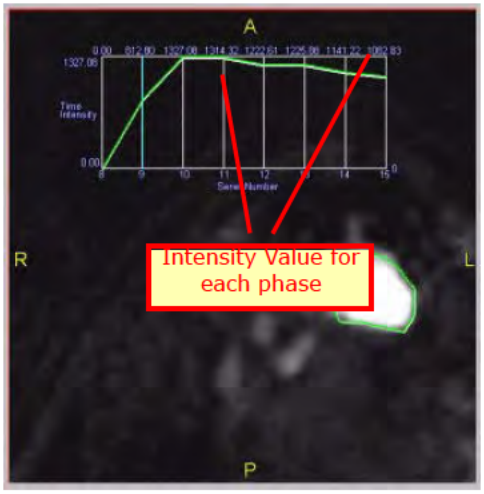

Figure 10-5: Wash in – wash out curve

NOTE: You can use the zoom and pan functions to position and size the image before drawing the ROI. All of the remaining images will automatically update.

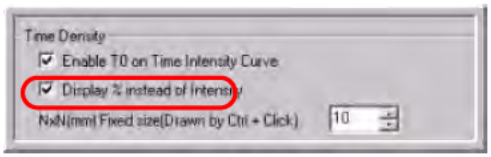

Figure 10-6: The time Density section of the Control Panel

7. To display the percentage of enhancement instead of the intensity, select the checkbox **Display % instead of intensity**.

8. You can move the graph around within the image by left clicking and dragging it.

9. You can resize and reshape a ROI. Left-click on the color line of the ROI and four small gray boxes will appear. Using the left mouse button, grab and drag to the desired size and shape.

10. To reposition a ROI, left-click on the colored line and drag it.

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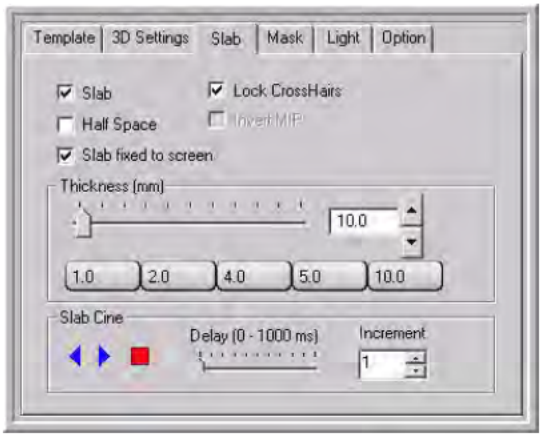
Viewing a phase in multiplanar views

You can view a phase in MPR, MIP, 3D, and Cine (or all phases) quickly to facilitate a complete examination of the data. Once you have examined and created curves in the multiphase images, perform the following steps to complete your examination:

To view the cine in 3D:



1. Click on the **3D** button located at the top left of the screen.
2. Open the **Slab** tab. The cine is active.
3. To view Cine of all the phases, use the positioning buttons located at the top right of the screen ("F" for Foot axial, "R & L" for right and left sagittal).
4. Use the movie control buttons to play the cine and use the slider bar to adjust the speed.

2D Cine:

Click the **2D** button from the main viewer. Use the movie control buttons to play the cine.

Figure 10-7: 2D Cine

Multi-phase MR Views

Note: Breast MR is optional in the Aquarius ThinClient Viewer.

You can view multi-phase MR studies in two different ways:

- **By time**. In this view, you can see all the positions in one scan (phase) at one time.
- **By position**. In this view, you can see all phases at the same position, one for each scan.

The series is loaded in time (phase) view by default. To see multiple phases in a single position, click the **t** button at the top of the screen (see Figure 10-8 on page 10-4):

Figure 10-8: MR Time and Position Views

In the circled buttons in Figure 10-8, the left button (**t**) displays the series by phase, and the right button (**p**) displays the series by position within each scan.

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Below, Figure 10-9 shows an MR multi-phase study viewed by time:

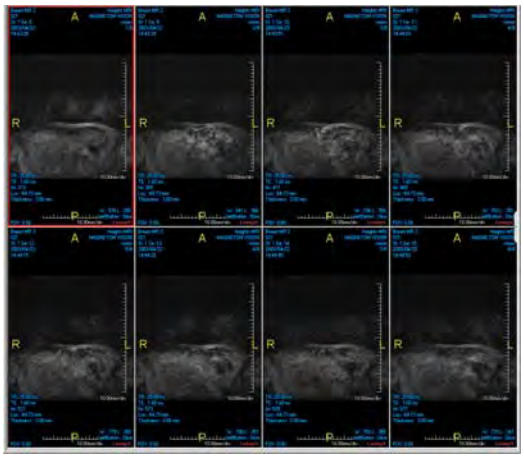

Figure 10-9: All Phases at a Single Position

Figure 10-10 shows the same study viewed by position:

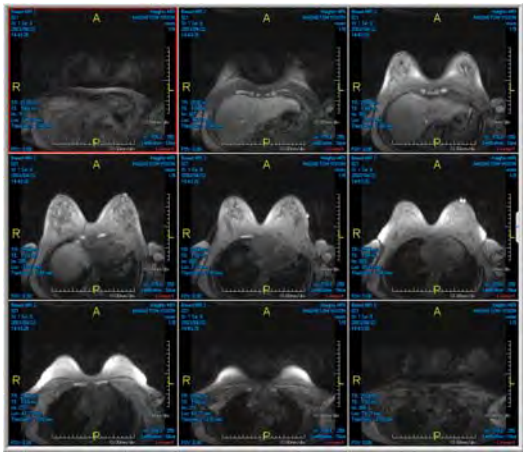

Figure 10-10: All Positions During a Single Phase

Color Coding in Parametric Map

When viewing a series with Parametric Map output, it is possible to configure the color-coding used to viewing the different phases of the time-density curve to a preferred color choice. The default is the standard red, blue and green, but a full color palette is available for an alternative.

When you change the color-coding, that information is stored in your login's profile on the AqNET server. If you log into the server from a different client, using the same login, your color settings will be the same ones you configured earlier.

To change the color coding, do the following:

1. Click the **Parametric Map** button under the **Review** tab, as shown in Figure 10-11. The Parametric Map color bar will be displayed.

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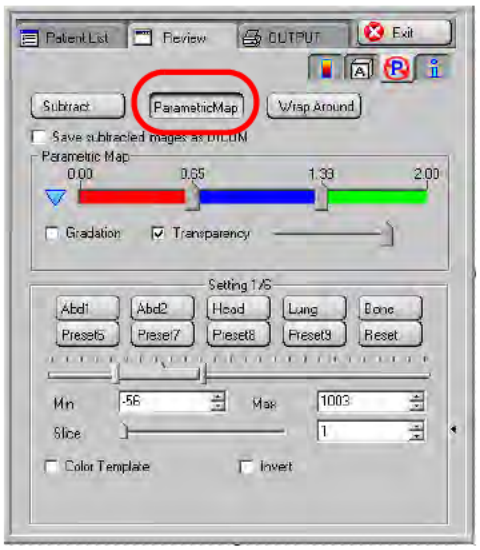


Figure 10-11: Parametric Map color bar

2. Place the cursor over the color to be changed and right-click. A color palette dialog will be displayed, as shown in the figure at right.

3. Select a new color and click **OK**. The color will change in the color bar to reflect the change.

4. Change the other two colors in the same way, if desired.

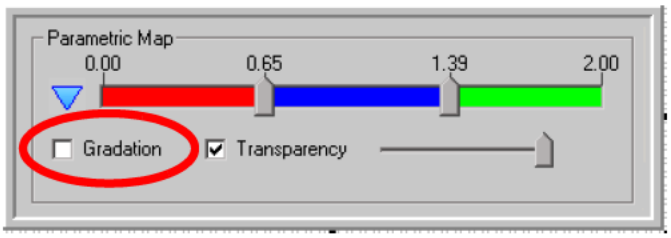
There is no need to save these changes, as your login profile on the server will be updated automatically.

Color Bar Options

You can change the color bar in a few different ways.

Gradation

The color bar can be displayed as three discrete color sections, as seen in Figure 10-11. It can also be displayed as a gradation of colors between each section. Enable gradation by clicking the **Gradation** checkbox.



The color bar is displayed as follows when gradation is enabled:

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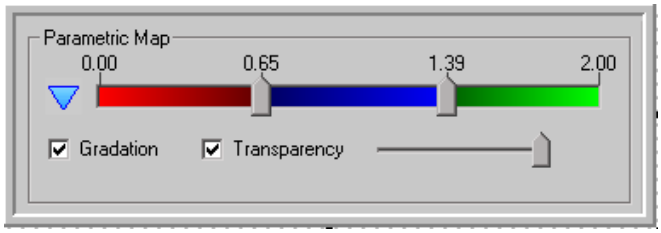


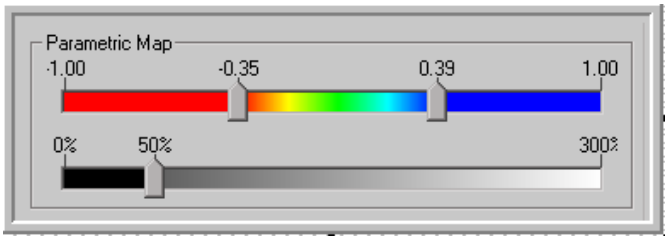
Other Color Bars

In addition to the solid color bar already discussed, there is another color bar you can use instead. To access it, you need to set a user preference.

Open the Preferences window and click the tabs until you reach the **Preference -> 2D** screen. At the bottom of that screen is the **Parametric Map Type** setting. Click the down-arrow to show the pulldown menu, and select **Rainbow Color Bar with uptake gradation**:

Note: for more information on this preference, see "2D" on page A-5.

The color bar is now displayed as follows:



Effect on Images

Each color bar produces different effects in the images:

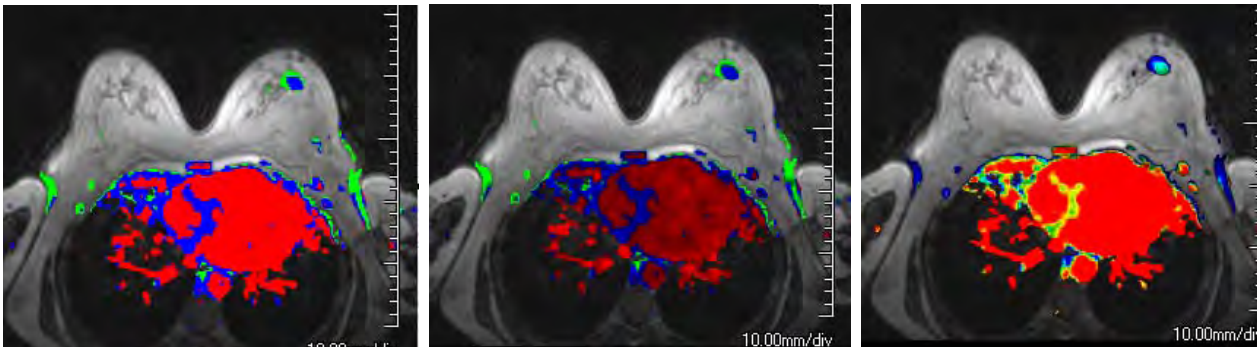


Figure 10-12: Left: Solid Color Bar; Middle: Solid Color Bar with Gradation; Right: Rainbow Color Bar

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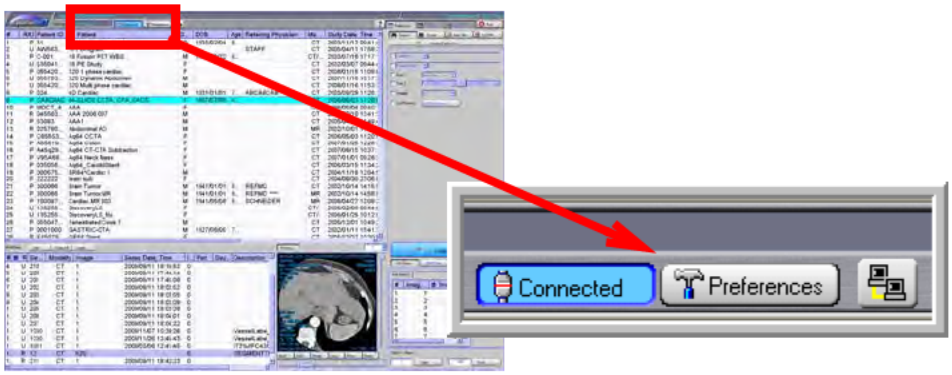
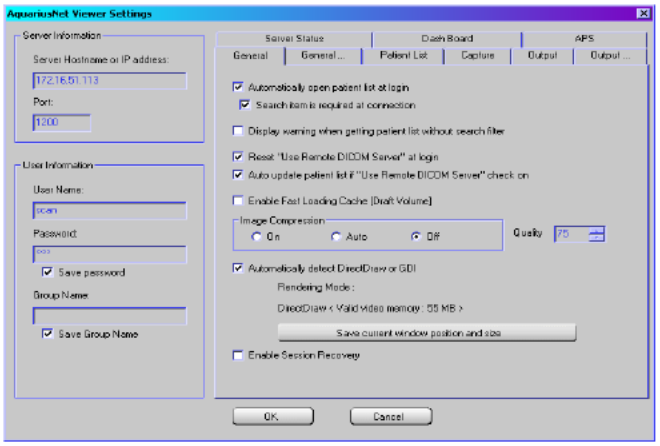
Appendix A: User Preferences

Click the **Preferences** button (located on top of the Patient List) from the top toolbar (see the following image).



The **Preferences** dialog is displayed:



Links

Use these links to navigate to the desired Preferences tab description.

General (left)
General (bottom right)
3D
CPR
Measurement
Capture
Output (right)
Dashboard
General (bottom left)
2D
4D
Fusion
Patient List
Output (left)
Server Status
APS

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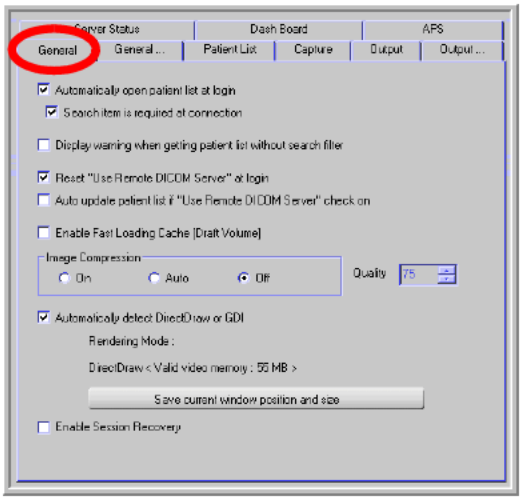
General (left)



Setting	Values	Description
Automatically open patient list at login	**Enabled**/Disabled	The Patient List automatically opens when you start the AqNET Thin Client.
Search item is required at connection	**Enabled**/Disabled (Only available when the previous setting is enabled.)	Only the items that you search for will be displayed in the Patient List. You can specify the search criteria from the **Search** panel to the right of Patient List
Display warning when getting patient list without search filter	**Enabled**/Disabled	Show dialog when the AqNET client is first started and the Patient List is displayed without any search filter.
Reset "Use Remote DICOM Server" at login	**Enabled**/Disabled	If the **Use Remote** box in the **Search** panel is checked, reset it to unchecked at login.
Auto update patient list if "Use Remote DICOM Server" check on	Enabled/**Disabled**	If **Use Remote** box in the **Search** panel is checked, update the Patient List automatically.
Enable Fast Loading Cache (Draft Volume)	Enabled/**Disabled**	Cache study data for faster loading.
Image Compression	• On • Auto • **Off**	When **On** is checked, compress the image (defined by the quality in the Quality box).
Quality	Can be set to any number between 25-100. (**Default: 75**)	100 equals no compression. 1 is the lowest quality image.
Automatically detect DirectDraw or GDI	**Enabled**/Disabled	Direct Draw is used for rendering graphics, and is part of Microsoft's DirectX API.
Save current window position and size	N/A (Click the button to save.)	Click this button to save current position and size of the AqNET Client window.

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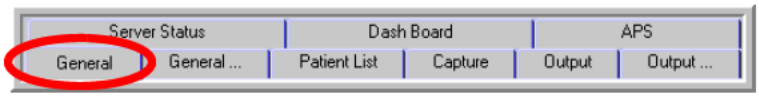
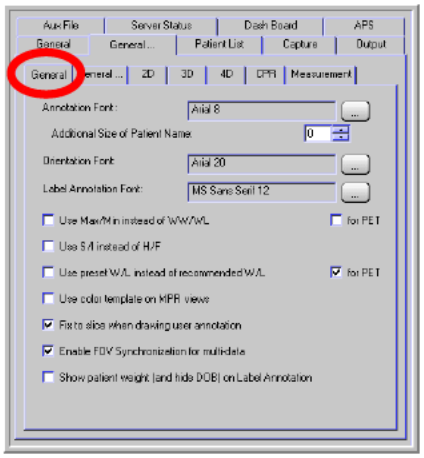
Setting	Values	Description
Enable Session Recovery	Enabled/**disabled**	If the Thin Client is disrupted during a session, it will reload the data after the system is restarted.

General (bottom left)

To access this tab, first click the right-hand **General** tab:



This tab contains seven sub-tabs, including two more General tabs. The left panel appears as follows:



The following table contains a description of each setting in this panel.

Setting	Legal Values/Defaults (bolded)	Description
Annotation Font	Any available font and size allowed. **Default: Arial, size 8**	Font, size and color of the patient annotation on images.
Additional Size of Patient Name	Between 0 and 25. **(Default: 0)**	Increases the font size of the patient's name on the annotations. Input value represents the amount over the size of all other annotation.
Orientation Font	Any available font and size allowed. **Default: Arial size 20**	Font, size and color of the orientation letters on the images.
Label Annotation Font	Any available font and size allowed. **Default: MS San Serif size 12**	Font, size and color of label annotation text.

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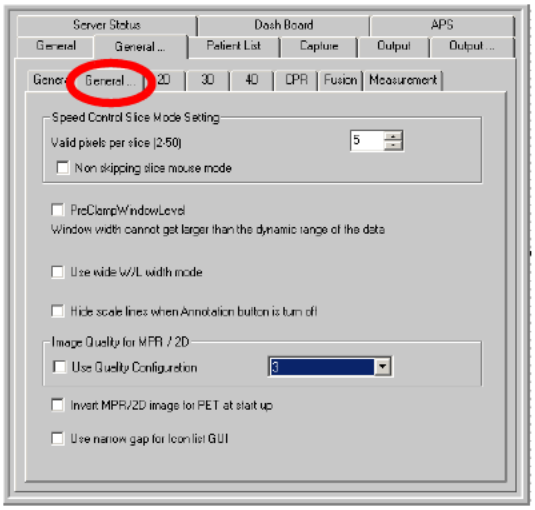
Setting	Legal Values/Defaults (bolded)	Description
Use Max/Min instead of WW/WL	Enabled/**Disabled**	In the W/L tab, show the text entry fields as Min and Max values rather than Window Width and Window Level.
For PET	Enabled/**Disabled**	Use preset Max/Min values for PET data also.
Use S/I instead of H/F	Enabled/**Disabled**	Use superior/inferior display rather than head/foot display.
Use preset W/L instead of recommended W/L	Enabled/**Disabled**	Viewer uses the selected preset Window/ Level values, rather than the values in the DICOM header of the data.
For PET	**Enabled**/Disabled	Use preset W/L values for PET data also.
Use color template on MPR views	Enabled/**Disabled**	When enabled, the **Color Template** box in the Main Viewer's tool panel will be automatically enabled each time new data is loaded.
Fix to slice when drawing user annotation	**Enabled**/Disabled	When **disabled**, user annotations remain on 2D image while paging through slices.
Enable FOV Synchronization for multi-data	**Enabled**/Disabled	When the field of view is changed in one data set, update any other loaded data to show the same field of view.
Show patient weight (and hide DOB) on Label Annotation	Enabled/**Disabled**	Multi-modality SUV only.

General (bottom right)

This table refers to the second **General** tab on the bottom row:



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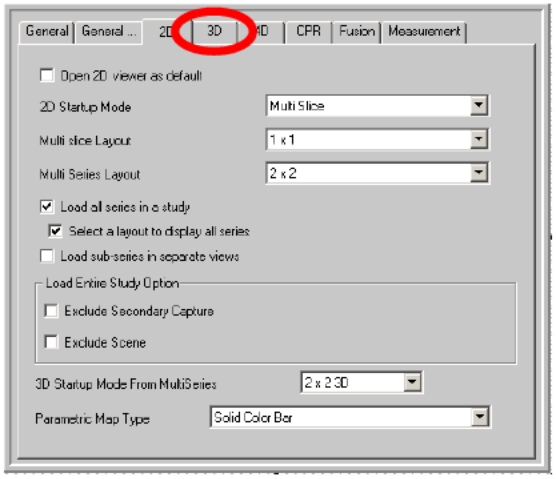
Setting	Legal Values/ Defaults (bolded)	Description
Speed control slice mode setting - valid pixels per slice (2-50)	2-50 **(Default: 5)**	The number of pixels of vertical mouse movement required to advance the 2D image one slice. A higher number means slower slice paging.
Non skipping slice mouse mode	Enabled/**Disabled**	When enabled, slice mode will display every slice without skipping any.
PreClampWindowLevel	Enabled/**Disabled**	Controls the W/L for MPR. When enabled, the LUT template is activated, and the Window/ Level of the MPR adapts to Axial, Coronal, and Sagittal views. This enables you to change the W/L for MR studies.
Use wide W/L width mode	Enabled/**Disabled**	Increase the width of the window width/level.
Hide scale lines when Annotation button is turn off	Enabled/**Disabled**	When patient annotation is turned off, the measurement scale will remain on unless this feature is enabled.
Use Quality Configuration	**Enabled**/Disabled	Use the quality level selected in the pull-down menu to the right of this checkbox.
(Quality level pull-down)	• 1 - Performance (faster) • 2,3,4 - In-between • **5 - Quality**	Quality of image from 1 (lowest quality/fastest-loading) to 5 (highest quality, slowest-loading)
Invert MPR/2D image for PET at startup	**Enabled**/Disabled	Always load PET data with the HU values of the MPR images inverted.
Use narrow gap for Icon list GUI	Enabled/**Disabled**	Display windows and panels with a smaller space between the icons in the window, so that more icons are visible.

2D



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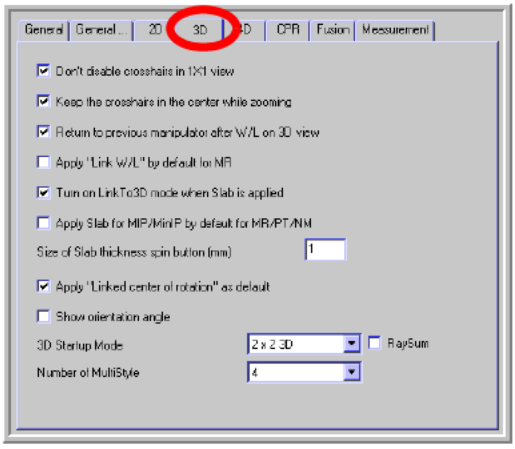
Setting	Legal Values/Defaults (bolded)	Description
Open 2D viewer as default	Enabled/**disabled**	If enabled, the 2Dviewer is opened when data is loaded.
2D Startup Mode	• Multi Slice • **Multi Setting**	Set the startup mode in 2D to multi-slice or multi-series. (Note: The change takes effect the next time data is loaded.)
Multi slice Layout	Select an item from the pulldown menu. **(Default: 1x1)**	Layout for multi-slice when study is loaded. (The change takes effect the next time data is loaded.)
Multi Series Layout	Select an item from the pulldown menu. **(Default: 2x2)**	Layout for multi-series when study is loaded. (The change takes effect the next time data is loaded.)
Load all series in a study	**Enabled**/disabled	When loading a study, load all series in the dataset.
Load sub-series in separate views	Enabled/**disabled**	This allows sub-series to be displayed in a different view from the series.
Exclude Secondary Capture	Enabled/**disabled**	Do not load secondary capture files from the Series List when loading a study.
Exclude Scene	Enabled/**disabled**	Do not load scene files from the Series List when loading a study.
3D Startup Mode From MultiSeries	Select an item from the pulldown menu. **(Default: 2x2 3D)**	Layout used when starting 3D viewer from 2D viewer.
Parametric Map Type	• **Solid Color Bar** • Rainbow Color Bar with uptake gradation	Color scheme to use for identifying the different stages of perfusion in a multi-phase study.

3D



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Setting	Values	Description
Don't disable crosshairs in 1X1 view	**Enabled**/disabled	Display the crosshairs on 2D image when in 1x1 view.
Keep the crosshairs in the center while zooming	**Enabled**/disabled	When enabled, the image center remains on the page after a Pan and Zoom.
Return to previous manipulator after W/L on 3D view	**Enabled**/disabled	This feature is useful for making sure that the left mouse operation goes back to what it was last set to before changing the W/L. When this is disabled, the left mouse operation always goes back to rotation.
Turn on LinkTo3D mode when Slab is applied	**Enabled**/disabled	When 3DVR image is in slab view, link rotation and pan of 3D image to the 2D images.
Apply Slab for MIP/MinIP by default for MR/PT/NM	Enabled/**disabled**	Set the default slab thickness.
Size of Slab thickness spin button (mm)	Range: 0.01-100 **(Default: 1)**	Default slab thickness when slab is first applied.
Apply "Linked center of rotation" as default	**Enabled**/disabled	When enabled, all currently loaded images have the same center of rotation.
Show orientation angle	Enabled/**disabled**	Show RAO and CRA in 3D image annotation.
3D Startup Mode	Select an item from the pulldown menu. **(Default: 2x2 3D)**	Layout default when study is loaded into 3D Viewer.
RaySum	Enabled/**disabled**	This algorithm is used to create a slab for the ThickMPR rendering mode.
Number of MultiStyle	2, 3, 4	A series can be displayed redundantly in the Main Window when you click on the Multi Style button in the top toolbar. This preference allows you to select the number of times the series will appear (side by side) in the Main Window.

4D

Setting	Values	Description
Initial Phase for 4D(%R-R)	0-100 **(Default: 5)**	Default phase to be considered the initial phase in a multiphase study.

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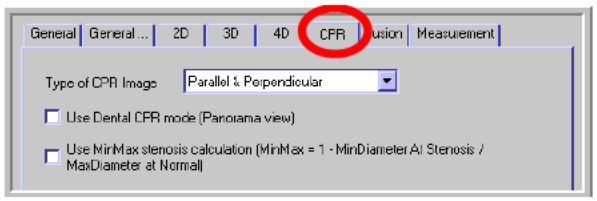
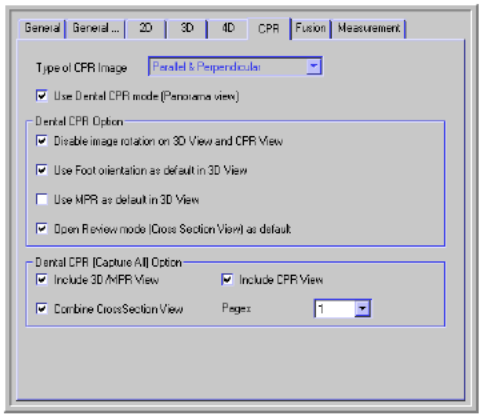
CPR



Setting	Values	Description
Type of CPR Image	• Parallel • Perpendicular • **Parallel & Perpendicular**	Type of CPR image to display when starting CPR mode. In a parallel image, the structure being examined has the same orientation as it has in the 3D image. The perpendicular image is a cross-section of the structure.
Use Dental CPR mode (Panorama view)	Enabled/**disabled**	When enabled, the Dental CPR settings show in this dialog. (See the next section for a description of Dental CPR settings.)
Use MinMax stenosis calculation (MinMax = 1 - MinDiameter At Stenosis / MaxDiameter at Normal)	Enabled/**disabled**	Calculate stenosis using tthe min and max diameters.

Dental CPR

Note: The items in this table are part of the CPR preference dialog, but they are only shown when Use Dental CPR mode is checked.



Setting	Values	Description
Type of CPR Image	N/A	Not used in dental mode

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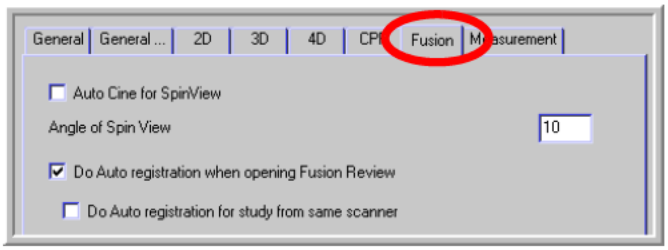
Setting	Values	Description
Use Dental CPR mode (Panorama view)	**Enabled**/disabled	This setting must be enabled for Dental CPR settings to show in this dialog.
Disable image rotation on 3D View and CPR View	**Enabled**/disabled	This prevents accidental rotation of the images.
Use Foot orientation as default in 3D View	**Enabled**/disabled	Foot orientation is the same as Axial view.
Use MPR as default in 3D View	**Enabled**/disabled	Rendering mode for image is MPR by default.
Open Review mode (Cross Section View) as default	**Enabled**/disabled	Displays the data in 3x3 layout, beside a 1x2 layout.
Include 3D/MPR View	**Enabled**/disabled	Include 3D and MPR views in capture.
Include CPR View	**Enabled**/disabled	Include CPR view in capture.
Combine CrossSection View	**Enabled**/disabled	Combine the thumbnail images for each data point.
Pages	**1** - 5	Total number of pages for each capture.

Fusion



Setting	Values	Description
Auto Cine for SpinView	Enabled/**disabled**	Whenever the Axial, Sagittal or Coronal buttons are clicked, spinning man automatically begins spinning.
Angle of Spin View	Range: 5-45 **Default: 10**	The angle for each step of the circling motion. Another way to think of it is the speed of rotation - a smaller number means a slower rotation.
Do Auto registration when opening Fusion Review	**Enabled**/disabled	The two studies are automatically registered when entering Fusion.
Do Auto registration for study from same scanner	Enabled/**disabled**	Only do auto registration if studies are from the same scanner.

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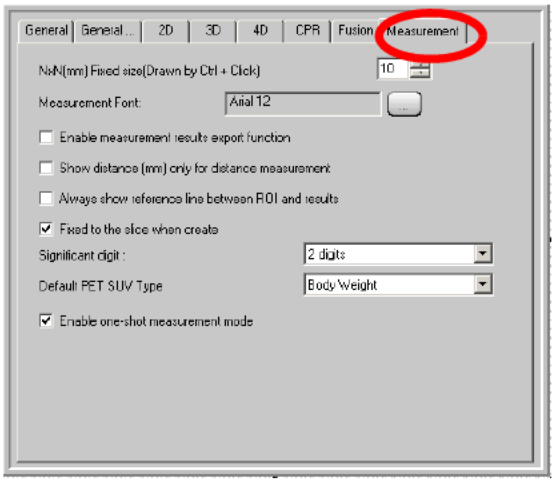
Measurement



Setting	Values	Description
NxN(mm) Fixed size (Drawn by Ctrl + Click)	User input (no limit)	
Measurement Font:	Any available font and size allowed. **Default: Arial size 12**	User-selected font and size for measurements shown on an image.
Enable measurement results export function	Enabled/**disabled**	Allow user to export mesaurement results.
Show distance (mm) only for distance measurement	Enabled/**disabled**	Do not show max, min/mean or Sdev for distance measurements.
Always show reference line between ROI and results	Enabled/**disabled**	Show a dotted line connecting the area being measured and the results annotation.
Fixed to the slice when create	**Enabled**/disabled	When enabled, measurement annotations are visible only on the slice where the measurement was taken. When disabled, measurement annotations remain on the 2D image while paging through slices.
Significant digit:	2-5 total digits (floating decimal)	Total number of significant digits in measurement result, including both left and right sides of the decimal point.
	No decimal	Integer value only.
	1-4 fixed decimal (Default: **2 digits**)	Number of digits to the right of the decimal point.
Default PET SUV Type	• **Body Weight** • Lean Body Mass • Body Surface Area	Use the selected data (body weight, lean body mass or body surface area) to calculate SUV values.

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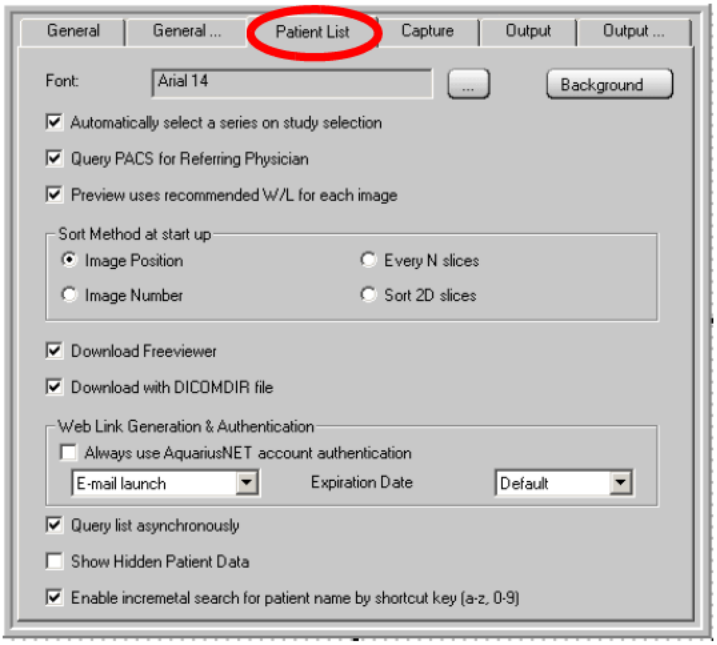
Setting	Values	Description
Enable one-shot measurement mode	Enabled/**disabled**	By default, the main viewer remains in measurement mode, using the same selected measurement tool after obtaining a measurement. When this setting is enabled, the viewer goes back to the currently selected mouse mode.

Patient List



Setting	Values	Description
Font	Any available font and size allowed. **Default: Arial size 14**	Font and size of items listed in the Patient List.
Background	N/A (Button opens dialog)	Click Background button to open dialog. Allows you to set font and background colors coded for read status, transfer status.
Automatically select a series on study selection	**Enabled**/disabled	Main series for study is automatically selected when the study is selected.
Query PACS for Referring Physician	**Enabled**/disabled	When enabled, PACS is queried for the referring physician's name to be displayed in the viewer.
Preview uses recommended W/L for each image	**Enabled**/disabled	Preview uses the suggested W/L in the DICOM header.

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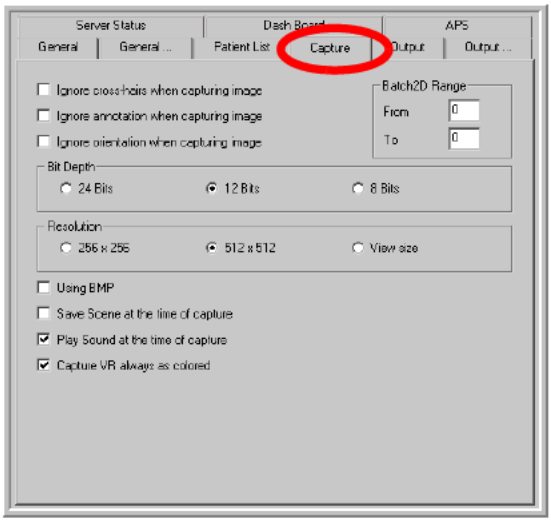
Setting	Values	Description
Sort Method at start up	• **Image Position** • Image Number • Every N slices • Sort 2D slices	Sub-series sort method default.
Download Freeviewer	**Enabled**/disabled	Download the AqNET Freeviewer to your PC.
Download with DICOMDIR file	**Enabled**/disabled	Download DICOM files from the specified directory.
Always use AquariusNET account authentication	Enabled/**disabled**	When enabled, a password is automatically generated during Email Series URL. The recipient will be required to enter a username and password. When disabled, the sender can either set a password or not, when sending a link.
Pull-down (where to send URL)	• **E-mail launch** • Clipboard copy	Select whether to copy the series URL to the Microsoft Office clipboard, or send it in an email.
Expiration Date	• **Default** • 1 Month • 2 Months • 6 Months • 12 Months • Forever	Determines how long a Web link is valid.
Query list asynchronously	Enabled/**disabled**	Asynchronous query is faster, while synchronous query is more reliable.
Show hidden patient data	Enabled/**Disabled**	Allows you to display all hidden studies.
Enable incremental search for patient name by shortcut key	Enabled/**disabled**	Allows user to find a patient name in the Patient List by typing the name on the keyboard.

Capture



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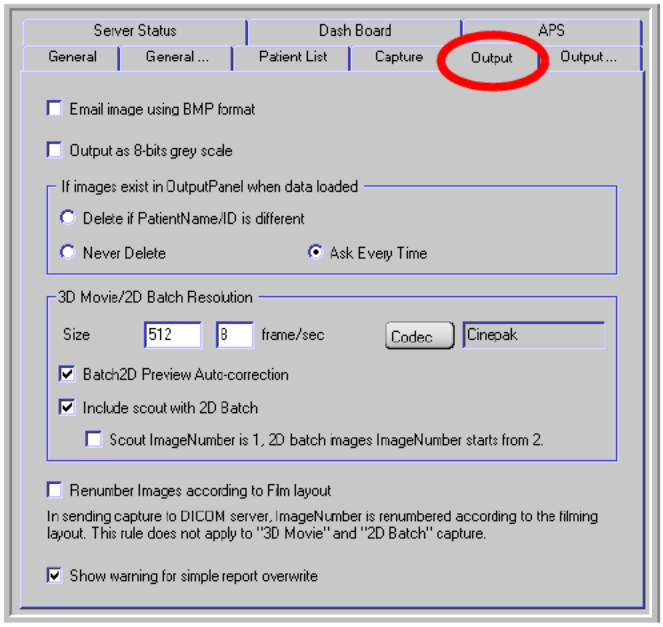
Setting	Values	Description
Ignore cross-hairs when capturing image	Enabled/**disabled**	Do not capture the crosshairs with the image.
Ignore annotation when capturing image	Enabled/**disabled**	Do not capture annotation with the image.
Ignore orientation when capturing image	Enabled/**disabled**	Do not capture orientation cube (lower-left corner of image) with the image.
Batch2D Slice Range	• From - user text input • To - user text input	The user can configure a range of slices (starting and ending slice numbers) for a batch set.
Bit Depth	• **24 Bits** • 12 Bits • 8 Bits	Capture in color (24-bit) or grayscale (8- or 12-bit).
Resolution	• 256 x 256 • **512 x 512** • View size	High speed or high quality
Using BMP	Enabled/**disabled**	Use Windows .bmp uncompressed image format.
Save Scene at the time of capture	Enabled/**disabled**	Save as secondary capture while capturing images to Output Panel.
Play Sound at the time of capture	**Enabled**/disabled	Play the sound of a camera click when an image is captured.
Capture VR always as colored	**Enabled**/disabled	Always capture 3D images as color images, regardless of the Bit Depth setting.

Output (left)



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Setting	Values	Description
Email image using BMP format	Enabled/**disabled**	Use Windows .bmp uncompressed image format.
Output as 8-bits grey scale	Enabled/**disabled**	Email, save, send, etc, images in low-resolution greyscale.
If images exist in Output Panel when data loaded	• Delete if PatientName/ ID is different • Never Delete • **Ask Every Time**	If there are images in the Output Panel from a previous study, when new data is being loaded, either: • Delete them automatically, unless they have the same patient name or ID • Never delete the images. • Ask user each time data is loaded.
3D Movie/2D Batch Resolution: Size	Range: 64-1024 **Default: 512**	Image quality of output (higher quality will be slower).
3D Movie/2D Batch Resolution: frame/sec	**Default: 8**	Speed of movie or batch determined by the number
Codec (button)	Button opens dialog where you can select a codec. **Default: Cinepak**	Select compression software.
Batch2D Preview Auto-correction	**Enabled**/disabled	This maximizes the resolution in the preview.
Include scout with 2D Batch	**Enabled**/disabled	Save the 3D image containing the batch grid along with the 2D batch images.
Scout ImageNumber is 1, 2D batch images ImageNumber starts from 2.	Enabled/**disabled**	This setting determines how the numbering is displayed on the PACS GUI. It is not visible in the Thin Client.
Renumber Images according to Film layout	Enabled/**disabled**	Captured images are reassigned an image number according to the film layout.
Show warning for simple report overwrite	**Enabled**/disabled	If you initiate a simple report when another simple report is in progress, a warning is displayed.

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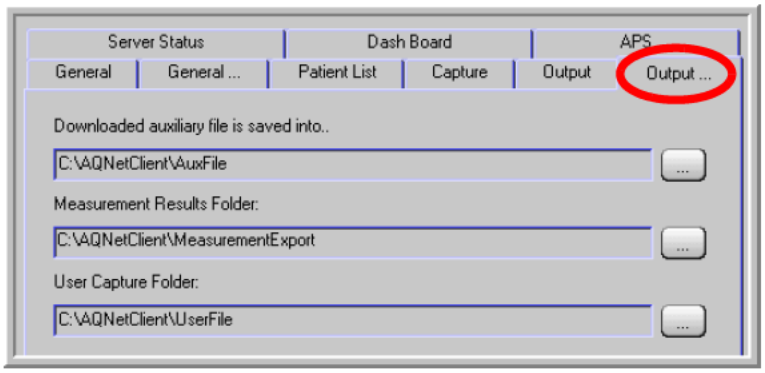
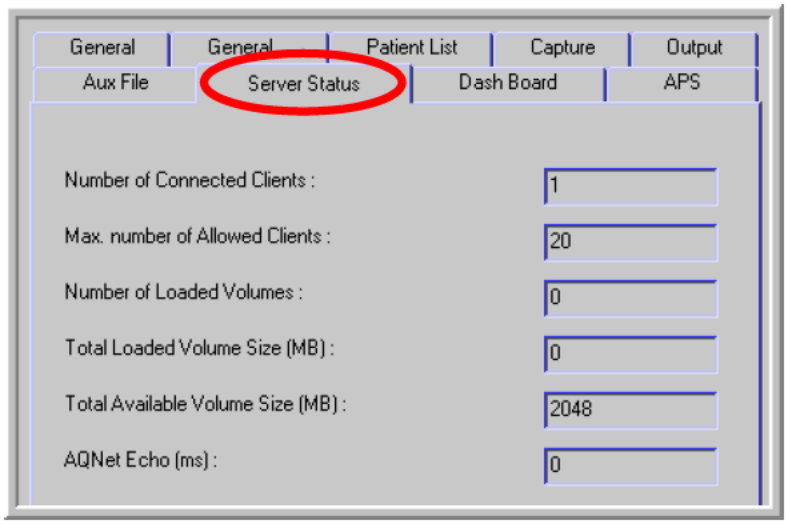
Output (right)



Setting	Values	Description
Downloaded auxiliary file is saved into..	**Default: C:\AQNetClient\AuxFile**	Click browse button to select a folder where the auxiliary file will be stored.
Measurement Results Folder	**C:\AQNetClient\Measurement\Export**	Default folder for saving exported measurements.
User Capture Folder	**C:\AQNetClient\UserFile**	Default folder for user captures.

Server Status



This is a read-only tab. The following table describes each item:

Setting	Description
Number of Connected Clients	Number of AqNET Thin Clients currently connected to the server

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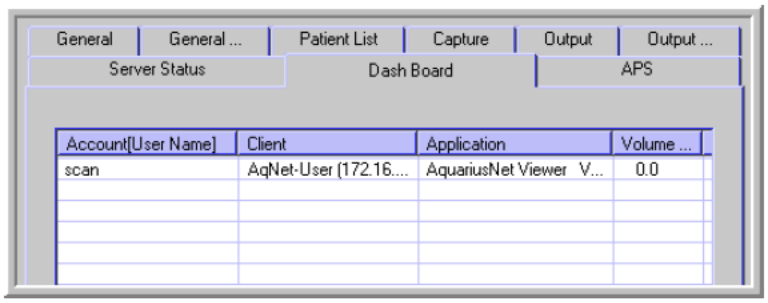
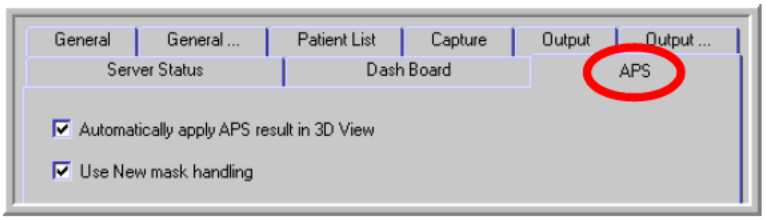
Setting	Description
Max. number of Allowed Clients	Maximum number of AqNET Thin Clients allowed to be connected to the server simultaneously
Number of Loaded Volumes	Number of data sets currently loaded
Total Loaded Volume Size (MB)	Total size of all images currently loaded
Total Available Volume Size (MB)	Maximum total size of data loaded at the same time
AQNet Echo (ms)	The time it takes the client to ping the server, or vice versa (in milliseconds)

Dashboard

Dashboard is a read-only screen that shows which AqNET Clients are currently logged in.



APS



Setting	Values	Description
Automatically apply APS result in 3D View	**Enabled**/disabled	When opening 3D viewer, apply any APS results to 3D image.
Use New mask handling	**Enabled**/disabled	When enabled, the 3D volume measurement tool becomes available. For PET scans, the SUV measurement tool also becomes available.

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Index

Numerics

2D Batch 9-9
2D Cine 10-4
2D Viewer 6-1
3D cine 10-4
3D Settings 7-10
3D Viewer 7-1

A

AQMobile 13-5
Aquarius iNtution Mobile 13-5
AquariusNET 1-1
AquariusNetViewer.exe 2-2
AquariusWEB 13-1
    Image viewing tools 13-3
    Series list 13-2
    Using passwords 13-1
    Viewer 13-2
Automatic Segmentation 7-19
Auto-super sampling mode 7-23

B

Bone Removal 7-20
Button
    2D 6-1
    2D Batch 9-9, 11-18
    Advanced 7-21
    Anonymize 4-6
    Auto 7-19
    Clear 7-16
    Clear All ROI 7-16
    Clear Curve 7-16
    Conference 4-32
    Connect 9-5
    Continue 7-4
    CPR 7-27
    Cut 7-16, 7-22
    DICOM Server 9-8
    Dilation 7-21
    Download Conference Viewer 4-35
    Download ThinClient Viewer 2-1
    Enable/Disable Outline 7-28, 7-29
    Erosion 7-21
    Every N 4-26
    Extract Centerline 7-28, 7-29
    FreeROI 7-15, 7-21
    Fusion 11-2
    HFlip 8-4
    Image Num 4-26
    Image Position 4-26
    Import Folder 4-21
    Keep 7-16
    Load 4-3, 4-27, 7-1
    Load 4D 7-23
    Load Fusion Template 11-11
    Load Multidata 4-28, 11-1
    Multi-Monitor 5-2
    Multi-setting 6-10
    Multi-slice 6-8
    Multi-study 4-29
    Open Scene 4-31
    Preferences A-1
    Preview 4-24
    Printer 9-7
    Reverse 7-16
    Rotate Left 8-4
    Rotate Right 8-4
    Save Fusion Template 11-11
    Scene 4-31
    Simple Report 9-6
    Single Study 4-29
    Smoothing 7-16
    Sort 2D 4-26
    Stenosis Review 7-28, 7-29
    Subtract 10-2
    Synchronization 4-29, 5-4
    To Filming 9-9, 11-18
    Undo 7-16
    Vessel Review 7-28, 7-29, 7-33
    VFlip 8-4

C

Calibrated Measurement 6-7
Capture 9-2
Capture All Views 9-2
Centerline Extraction 7-27
Channel 7-11
Channel Number 7-10

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015
DRAFT

Checkbox
    Save subtracted images as DICOM 11-15
Cine 6-10
Cine 4D 7-23, 7-24
Clamp 11-14
Color Bar Options 10-6
Color coding
    Parametric Map 10-5
Color Map 7-31
Color Template 11-13
Conference 4-32
Configuring Options 7-23
Continue mode 7-4
Contrast slider bar 11-12
CPR 7-27
    Toolbar 7-27
CR 8-1
CT
    Image 11-1
    Table Removal 7-18, 7-19

D

Data Stitching 4-17
Dental CPR 7-35
Desktop 2-1
DICOM 3-1
    Files 4-21
    Header 4-24
Dilation 7-21
Download
    Series 4-23
    Study 4-22
DR 8-1
DX 3-1

E

Email series URL 4-15, 13-20
    Using passwords 4-7, 13-1
Erosion 7-21
Exporting 4-21

F

Filtering 4-19
Fixed Axial Orientation mode 7-39
Free Line Annotation 7-42
Fusion 11-1

G

Get CPR 7-28
Get list of series with this Patient ID 11-1

H

Half Space 7-13
Histogram 7-32
HU Pixel Value 4-4, 11-7

I

Importing 4-21
Incremental Search 4-20
Invert PET Image 11-5

L

Light Shape switch 8-2
Line-Out tool 12-3
Linked center of rotation mode 7-23
Linked MPR Mode 7-23
Load New Series 4-30
Lock/Unlock Series 4-16
Login 2-2

M

Macro 4-2
Main Viewer 4-1
Marker
    End 4-29
    Start 4-29
Measurements
    On 2D Images 7-24
    On 3D images 7-24
Menu
    AquariusNET Interactive Report 9-6
Modality
    CR 3-1
    CT 3-1
    DR 3-1
    DX 3-1
    MG 3-1
    MRI 3-1
    SC 3-1

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

XA 3-1
Modality filter 11-1
Mode
Create 7-36
Keep Patient List 5-2
Multiple Review 5-3
Review 7-39, 7-40
MPR Views 7-5
MS Word Security 4-2
Multi-data 4-29
List 11-1
Multi-modality Exams 11-1
Multi-Monitor 5-1
Multiphase study 10-1
Color coding 10-6
Multiplanar views 10-4
Multiple studies 4-27
Multi-setting menu 6-10
Multi-Slice mode 6-8

N

NT 2-1

O

Oblique Graphic Curve switch 8-2
Oblique MPR 7-6
Oblique Plane 7-34
One-Shot Measurements 7-25
Opacity Control 7-10, 8-2
Open Multiphase View 10-1
Open MultiSeries View 4-30
Output Panel 9-1
Overlay 11-1
Overlay Study Toolbar 11-8
Overlay Tool 11-1

P

PACS systems 3-1
Parametric Map
Color coding 10-5
Patient Database 4-18
Patient List 1-2, 4-2
PET image 11-1
PET/CT
Spinning Man 11-4, 11-8
SUV 11-5
Window Layouts 11-2
Pixel Value
HU 4-4, 11-7
SUV 11-7
Position/Cine 7-5
Preview Window 4-23
Profile Measurement 6-7

R

Radial orientation 9-10, 11-19
RaySum 7-6
Registering Images 11-11
Remap 11-14
Review Modes 5-4
Rib Cage 7-18
Removal 7-18
Right Panel 4-18
ROI Segmentation 7-21
Rotate 7-16

S

Save Scene 4-31
Scenes 4-31
Screenshot 4-36
Search Shortcut Keys 4-20
Security, MS Word 4-2
Series View switch 4-29
Show Toolbar 7-28
Significant digits 7-25
Simple Reports 9-6
Skipping Frames 6-11
Slab 7-13
Rendering 7-12
Slab Fixed To Screen 7-14
Slice Data 6-8
Slice Information 5-4
Soft Plaque Review 7-31
Spinning Man 11-4, 11-8
Stand-alone Conference 4-34
Standard Uptake Value 11-5
Stenosis Review 7-28
Stitch Data 4-17

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015
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Study List 4-4
Sub-Series 4-23
Subtraction 11-14
SUV 11-5
SUV Pixel Value 11-7
Sync Pan/Zoom 11-9
Sync WW/WL 11-9

T

Tab
    Host 4-33
    Output 9-2
    Registration 11-11
    Remote 4-33
    Subtraction 11-14
ThinClient 1-1
Transparency slider bar 11-12
Trash Box icon 5-2

U

User Annotation 4-35
User Password 2-3

V

Vessel Review 7-33
Volume Calculations 7-32
VR Curve
    Shapes 7-10
VR Curve Graph
    Switch 7-10

W

W/L
    Direct Control Box 7-10, 8-2
    Presets 7-10
    Slider 7-10
Wash In-Wash Out curve 10-2
Window
    Adjust Light 7-9
    Color Setting 11-12
    Conference 4-33
    Multi-monitor Control 5-2
    Preview 4-23, 4-25
    Target Fusion 11-9
Windows 2000 2-1

X

XA 3-1, 8-1
XP 2-1

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AquariusAPS

Version 4.4

User Manual

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Chapter 1: Introduction to AquariusAPS

Purpose of this Manual

The purpose of this manual is to supply the user with the information necessary to properly configure and make the best use of the AquariusAPS system.

A Brief Overview of AquariusAPS

The purpose of the AquariusAPS system is to automatically perform various kinds of data processing on incoming DICOM data sets, according to pre-configured rules and schedules. The processed images are then routed to the appropriate destination ready for workflow. This eliminates the number of steps the medical professional needs to perform for each image, and could substantially increase the efficiency of medical professionals.

The following diagram shows the data flow among nodes in the AquariusAPS system. The data flow begins with the modality. Data sets are pushed to the AquariusAPS Server, where advanced processing is performed on the data. AquariusAPS then routes the original data, along with any derived series produced by advanced processing, to the AquariusNET Server or to a PACS system.

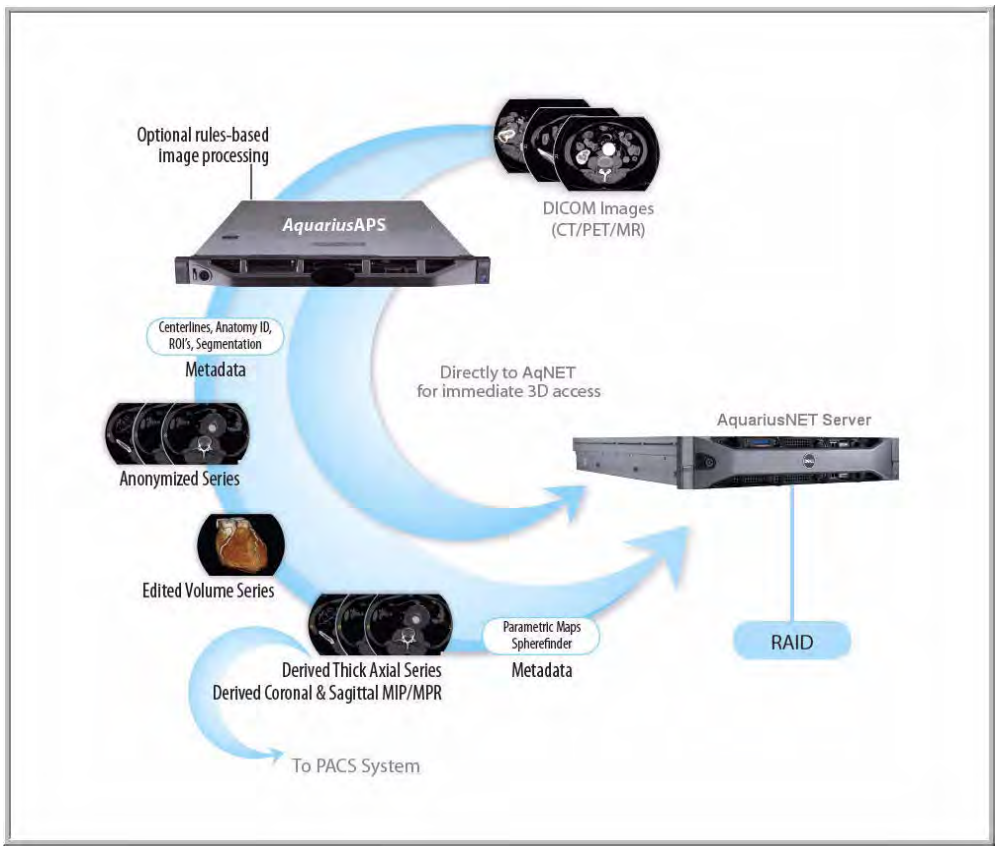

Figure 1.1 : Data flow diagram

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Web Interface Functions

The following functions are available from the AquariusAPS Web interface:

- Manage local and remote AEs
- Manage DICOM tags and tag filters
- Manage Clinical Protocols, associating tag filters, processing engines (PEs) and routing nodes
- Manage Auto Pre-Fetch, Basic and Advanced Auto Routing, Auto Batch and Auto Anonymizer
- Add, modify and delete SphereFinderL, Subtraction and Volume Filter engines
- Manage Studies and Series - Push, Delete, and Anonymize
- Trigger the AquariusAPS workflow on a study or series
- Manage Advanced Processing Jobs, Routing Jobs, and Pre-Fetch Jobs
- Manage the Log Display page
- Manage auto deletion
- Configure email
- Configure the APS, DICOM and Web servers
- Configure the high watermark for disk storage
- Start and stop the DICOM server and Job Manager
- Reboot the Server
- Change the password
- View information about the PE modules installed on APS
- Take a server snapshot
- Log out

Implementations of AquariusAPS

There are two configurations of AquariusAPS:

- The AquariusAPS stand-alone server

The stand-alone server (as shown in Figure 1.1) is a separate physical machine, with its own DICOM server, for receiving and pushing data from/to local and remote AEs. The stand-alone AquariusAPS requires its own Web interface for managing all server processes.

- AquariusAPS on the AquariusNET Server

AquariusAPS on the AquariusNET functions in a similar way, except that the post-processed data might be stored on the AquariusNET server rather than automatically routed to another DICOM server. In addition, the Web admininistration functions for AquariusAPS must be accessed through the AquariusNET Web Admin page.

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The AquariusAPS Modules

The AquariusAPS modules will perform image preprocessing based on processing rules defined by the user. The effectiveness of this preprocessing will depend on the quality and nature of the incoming image acquisition. The modules are intended for use with images that were obtained without the use of CT or MR contrast agents, or obtained with the use of FDA cleared CT or MR contrast agents.

- **Bone Removal** (Standard)

  This processing module analyzes the incoming CT study for the presence of bone-like structures. If such structures are found, a *mask volume* is created in which the pixel locations corresponding to those occupied by these structures in the scan image are set to zero. All other locations in the mask are set to one. The mask volume is used by the processing module to hide the bones from view. It can also be used as a starting point for further post-processing by the user.

- **CT Table Removal** (Standard)

  This module analyzes a CT study for the presence of a CT table. If a structure is found that is highly likely to be the CT table, a mask volume is created. The pixel locations in the mask corresponding to those occupied by the table in the scan image are set to zero. All other locations in the mask are set to one. The mask volume is used by the processing module to hide the CT table from view.

- **Remove Duplicate Table Positions**

  This processing module analyzes incoming data and generates a derived volume in which subseries at duplicate table positions have been removed.

- **Rib Cage Removal** (Standard)

  This module analyzes a CT study for the presence of structures similar to the rib cage. If such structures are found, a mask volume is created. The pixel locations in the mask corresponding to those occupied by the heart and surrounding tissues in the scan image are set to one. All other locations in the mask are set to zero.

  The mask volume is used by the processing module to hide the overlying structures from view to reveal the heart and surrounding tissues. It can also be used as a starting point for further post-processing by the user.

- **Head Mount Removal**

  This module analyzes a CT study for the presence of a CT head mount. If a structure is found that is highly likely to be the CT head mount, a mask volume is created. The pixel locations in the mask corresponding to those occupied by the head mount in the scan image are set to zero. All other locations in the mask are set to one. The mask volume is used by the processing module to hide the CT head mount from view.

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- **Volume Filter / iGentle**

  This module generates a copy of the original images and applies a filter to them. This can be used to remove noise in the original images, such as with low dose acquisition data. Both the filtered and the original images are sent to the destination.

- **Parametric Map** (Optional)

  The Parametric Map module calculates a parametric color overlay map for a time-dependent MR scan. This module analyzes a set of images, each of which represents the same location over a certain period of time. A color is assigned to each location according to the shape of the time density curve at this location. Three colors (red, blue and green) are used to represent three types of time density curve, respectively: washout, plateau and **enhancing.**

  The Parametric Map module provides an option to perform rigid registration among all phases. However, this might not compensate for internal organ movements that may have occurred during the scan. Therefore, artifact may be present in the scan if there was any large organ movement among phases.

  This option also includes the **Deformable Registration** processing engine.

- **Subtraction** (Standard)

  This module requires two datasets: an initial scan (Volume A), and another scan of the same area, after the patient has been injected with contrast dye (Volume B). It removes everything in Volume B that is also contained in Volume A, so that the result consists completely of the area having contrast.

- **Spherefinder** (Optional)

  This identifies sphere-like structures in a CT scan and generates a list of the locations. The current engine is specifically designed for spherical objects with a certain degree of sphericity. Other structures, such as those attached to the organ wall, tubular structures, similar objects, or those that have inhomogeneous density distribution, may or may not be detected. It may also produce inaccurate results for objects whose diameters are smaller than twice the slice thickness, or objects whose HU values are lower than -600, due to the Partial Volume Effect (PVE).

  This feature includes these processing engines:

  - **SpherefinderL**
  - **SpherefinderC**

- **Vessel Label** (Optional)

  This feature includes the following processing engines:

  - **Abdominal Vessel**

    This module analyzes a CT study and automatically identifies vessel names and approximate locations in the abdominal area. Some of the supported vessels are: Abdominal Aorta, Celiac Artery, Superior Mesenteric Artery, and Left/Right Renal Artery.

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- **Upper Leg Vessel**

  This module analyzes a CT study and automatically identifies vessel names and approximate locations in the pelvis area. Some of the supported vessels are: Left/ Right Common Iliac Artery, Left/Right External Iliac Artery, Left/Right Femoral Artery, and Left/Right Deep Femoral Artery.

- **Heart Vessel**

  This processing module analyzes a CT study and automatically identifies vessel names and approximate locations in the heart. Some of the supported vessels are: Left Main (LM), Left Anterior Descending (LAD), Left Circumflex (LCX), and Right Coronary Artery (RCA).

  Note: When using this processor engine, the CT data needs to be ECG-gated and contrast-enhanced to get a meaningful result.

- **EP Lab**

  This processing module analyzes a CT study and automatically identifies vessel names and approximate locations in the heart. Some of the supported vessels are: Left/Right superior Pulmonary Vein, Left/Right inferior Pulmonary Vein. If a structure is found that is highly likely to be one of the Pulmonary Veins, a centerline is created for each vein. A mask volume is also created for the Left Atrium and all Pulmonary Veins.

- **Head / Neck**

  This module analyzes a CT study and automatically identifies vessel names and approximate locations in the head/neck area. Some of the supported vessels are: Left/Right Common Carotid Artery, Left/Right Internal Carotid Artery, Left/Right Middle Cerebral Artery, Left/Right Vertebral Artery, Basilar Artery.

- **Rib**

  This module analyzes a CT study and automatically identifies rib names and approximate locations in the chest area.

- **Vessel Centerline** (Optional)

  This feature includes the following three processing engines:

  - **Auto Coronary**

    This module analyzes a CT study for the presence of a structure similar to the heart. If a structure is found that is highly likely to be one of the major coronary arteries, a mask volume and a centerline are created for each artery.

    Note: When using this processor engine, the CT data needs to be ECG-gated and contrast-enhanced to get a meaningful result.

  - **Auto Body Centerlines**

    This module analyzes a CT study for the presence of a structure similar to the abdominal area or pelvis area. If a structure is found that is highly likely to be the Abdominal Aorta and Iliacs, a set of centerlines is created.

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- **Auto Head / Neck Centerline**

  This module analyzes a CT study for results of the Vessel Label Head Neck processor engine. If these results are found, a centerline and a mask are created.

- **Expose Coronary 4D**

  This module analyzes a CT study for the presence of structure similar to the heart. If such structures are found, multiple mask volumes are created, which hide the overlying structures from view and reveal the coronary arteries. These results can also be used as a starting point for further post-processing by the user.

- **Auto Coronary Consolidate 4D**

  This module analyzes the results of the **Extract Coronary** module on a 4D CT study, and makes a better judgement of the quality of the centerline extraction.

  Note: The result of some phases might be discarded.

- **Colon Segmentation** (Optional)

  This processing module analyzes the incoming CT study for the presence of colon-like structures. If such structures are found, a mask volume is created in which the pixel locations corresponding to those occupied by these structures in the scan image are set to one. All other locations in the mask are set to zero. The mask volume is used by the processing module to display the colon in Flythrough. It can also be used as a starting point for further post-processing by the user.

- **Colon Data Converter**

  These modules generate reformatted images for better image quality. The perspective view is greatly improved using the new generated images. This is important for use in the Flythrough module.

- **MedicSight LungCAD** (Optional)

  MedicSight LungCAD identifies nodule candidates for further examination. This software is designed to be applied only to CT studies of the thorax. If a region is identified, it is the radiologist's responsibility to classify the images using standard techniques. The radiologist may turn the filter off in order to evaluate fully any potential nodule candidate highlighted by the filter.

  Important Considerations

  It is essential that the radiologist examine *all* images in the CT examination, and not only the images that have been marked.

  The module will function on multi-detector CT thorax scans having a slice thickness less than or equal to 5mm. However, the software has been designed to produce *optimal* performance on scans having a slice thickness less than or equal to 3mm and a dose in the range of 60 – 300 mA.

  The software has been designed to highlight regions having a diameter less than or equal to 4mm, and has been optimised for regions having a diameter in the range of 5-20mm.

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The software has been designed to produce optimal performance in full-inspiration CT thorax cases that have been reconstructed using a Soft Tissue or standard Convolution Kernel. Performance of the module may be less than optimal in cases that have been reconstructed using a Lung or High Resolution Convolution Kernel, or where the lungs are suboptimally distended.

The software has been designed to function on DICOM standard 3.0 complete data sets. There should be no missing slices within the data set, and the software should not be used to process interpolated data. If slices from the image data set are missing then the results are not reliable.

- **MedicSight ColonCAD** (Optional)

MedicSight ColonCAD identifies polyp candidates in the colon for further examination. The software uses mathematical image-analysis techniques to highlight non-elongated, raised objects having spherical elements, and highlights the regions of interest (ROI). If a region is identified, it is the radiologist's responsibility to classify the images using standard techniques.

> **Note: The user must change the default sphericity filter setting to a value that is appropriate for the environment and appropriate for the user's clinical needs.**

- **Dual Energy Blender**

Dual Energy Blender generates a new derived series that is one of the following:

- A blending of the 2 original series (80 kV, 140 kV), using the percentage setting from the web configuration (Siemens).
- Monochromatic images using the keV setting input by administrator (Gemstone Spectral Imaging (GE)).

- **Dual Energy Extractor**

The Dual Energy Extractor extracts proprietary information from DICOM headers and stores them for later use in the dual energy workflow.

- **TDA Map**

The TDA Map processor calculates TDA color maps for the BF, BV, MTT, TOT, RT and TTP functions. Color captures of the maps are saved to DICOM. These results can be reviewed directly from the Patient List Preview, or from any DICOM viewer.

- **Auto-Anonymizer**

Automates anonymization of clinical studies based on rules, to comply with privacy regulations and clinical trial criteria. The auto-anonymizer is important for clinical research trials, medical journal publications and patient data used for teaching.

- **Autobatch**

AutoBatch generates reformatted images on scan data that has been pushed to APS server. Without Autobatch, the reformatted images need to be generated at the CT

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console, taking scanner time. The Autobatch PE provides the equivalent functionality previously performed by scanners. In addition, AutoBatch provides automatic batch functions similar to the Batch 2D functions performed manually on the Thin Client or AQi Client, using a user-specified range, angle, rendering mode and other parameters.

- **Auto Annotation**

  Auto Annotation marks the positions of candidates found by other PEs such as iCAD Colon, MedicSight Lung, MedicSight Colon, SphereFinderL or SphereFinderC. An additional series is created that contains circles embedded in the images, indicating the position of each candidate. Users will then be able to review the candidates on any DICOM viewer.

- **Merge Series**

  Merge Series stitches multiple series or sub-series together to create a single series. The component series can have different slice spacing, pixel spacing or image positions, but they must share the same frame reference UID and orientation.

- **CTA Generator**

  The CTA Generator detects the maximal arterial phase in 320 brain perfusion data and creates a new derived volume for the maximal phase.

- **Lung Segmentation**

  The Lung Segmentation module analyzes the incoming CT study for the presence of lung-like structures. If such structures are found, mask volumes are created for the left lung, right lung and trachea. The mask volume is used by the processing module to display the lung in SAT. It can also be used as a starting point for further post-processing by the user.

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Index

A

Abdominal Vessel Labeling 1-4
Advanced Auto Routing 4-17
Advanced Processing Jobs 6-4
Advanced Processing Manager 4-7
AE
    Hostname 3-1
    IP address 3-1
    Local 3-4
    Port Number 3-1
    Remote 3-1
    Title 3-1
Age of Dataset 8-1
Anonymization 4-34
Application Entity
    Local 3-4
    Remote 3-1
AquariusAPS modules
    Abdominal Vessel Labeling 1-4
    Auto Annotation 4-31
    Auto Anonymizer 4-34
    Auto Body Centerlines 1-5
    Bone Masking 4-40
    CT Table Removal 1-3
    Dual Energy Blender 4-41
    Expose Coronary 1-6
    Heart Vessel Labeling 1-5
    Parametric Map 1-4
    Rib Cage Removal 1-3
    TDA Map 4-46
    Upper Leg Vessel Labeling 1-5
Auto Annotation 4-31
Auto Anonymizer 4-34
    Creating 4-35
    File-Based Anonymizer 4-37
Auto Batch 4-27
Auto Body Centerlines 1-5
Auto Deletion 8-1, 8-2
    Scheduling 8-2
Auto Pre-fetch 4-11
Auto Routing
    Advanced 4-17
    Basic 4-14
AUTOVOX 3-4

B

Basic Auto Routing 4-14
Bone Masking 4-40

C

Cab File 11-3
Cancel Job 6-3, 6-6
Change Job Priority 6-3, 6-6
Change Password 11-1
Color Templates, TDA 4-46
Comparators,Tag Rules 4-3
Compression 4-14
    LosslessJ2K 4-14
    LossyJ2K 4-14
Configuration
    DICOM Server 8-2
    Email 8-5
    Web Server 8-8
CT Table Removal 1-3

D

Data Compression 4-14
Data, Raw 4-14
Dataset, Age of 8-1
De-Anonymization 4-37
Debug Verbose 8-4, 8-8
Deleting Studies 5-4
DICOM Listen Port 8-4
DICOM Merge Log
    Level 8-4
    Location 8-4
    Maximum Associations 8-4
    Maximum Size 8-4
DICOM Server
    Configuration 8-2
    Configuration Parameters 8-3
    Merger Log Level 8-4
    Start 9-1
    Stop 9-1
DICOM Server Service 9-1
Dual Energy Blender 4-41

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

E

Email Configuration 8-5
Email Management 8-5
Expose Coronary 1-6

F

File-Based Anonymizer 4-37
Force Transfer Syntax 8-5

H

Heart Vessel Labeling 1-5
High Watermark 8-1

J

Job
- Advanced Processing 6-4
- Based Upon Destination 6-6
- Cancel 6-3, 6-6
- Change Priority 6-3, 6-6
- Pre-fetch 6-7
- Resume 6-4, 6-6
- Routing 6-6
- Suspend 6-4, 6-6

Job Queue Management 6-1, 6-4

L

Log Display 7-1
Log Message Location 8-4
LosslessJ2K 4-14
LossyJ2K 4-14

M

Manage PreFetch Job Queue 6-6
Managing Local AE 3-4
Managing Remote AE 3-1
Managing Studies 5-1

N

Navigation Panel 2-2

P

Parametric Map 1-4
Password, Change 11-1

PE
- Abdominal Vessel Labeling 1-4
- Auto Annotation 4-31
- Auto Anonymizer 4-34
- Auto Body Centerlines 1-5
- Bone Masking 4-40
- CT Table Removal 1-3
- Dual Energy Blender 4-41
- Expose Coronary 1-6
- Heart Vessel Labeling 1-5
- Parametric Map 1-4
- Rib Cage Removal 1-3
- TDA Map 4-46
- Upper Leg Vessel Labeling 1-5

PE Log Level 8-8
Pre-fetch Jobs 6-7
Processing Jobs, Sequenced 4-10
Pushing Series 5-2
Pushing Studies 5-2

Q

QR Source AE 4-12
Queue Manager Service
- Start 9-2
- Stop 9-2

R

Raw Data 4-14
Resume Job 6-4, 6-6
Rib Cage Removal 1-3
Routing Jobs 6-6
Routing Schedule 4-14

S

Sensitivity Rules 4-32, 4-33
Sequenced Processing 4-10
Server Configuration 8-2
Server Options 8-7
Subtraction 4-43
- Negative Values 4-45

Suspend Job 6-4, 6-6

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

T

Tag Filters 4-3
    Rules 4-3
Tag Rule 4-3
Tag Rule Comparators 4-3
TDA 4-48
TDA Color Templates 4-46
TDA Map 4-46
Tmeout
    For Inactivity 8-4
    For Series Completion 8-4
    For Writing Message 8-4
Trigger Workflow 5-6

U

UID 8-5
Upper Leg Vessel Labeling 1-5

W

Watermark Configuration 8-7
Web Login Page 2-1
Web Server Configuration 8-8
Workflow Management 4-1

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iReview

Version 4.4

User Manual

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Chapter 3: The Viewer

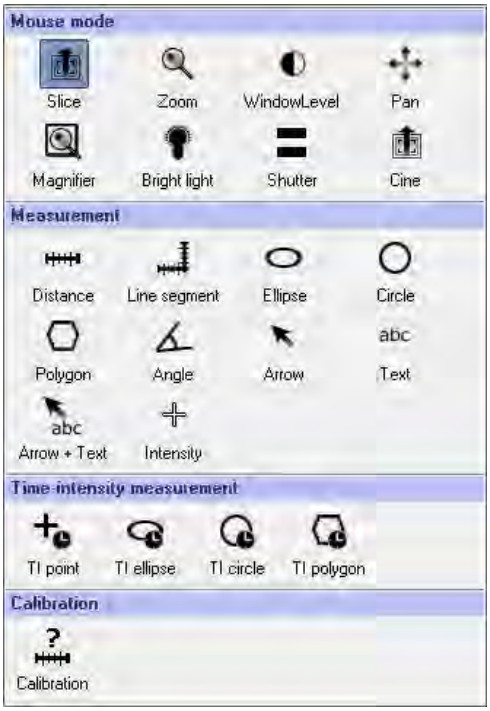
Top Tool Bar Functions

Each button pictured in the previous image is described in this section. Use these links to jump to the desired section:

Mouse Mode, Measurement, Time-intensity and Calibration
Display protocol
Navigation
Localizer
Scroll
Orientation
Cine
PMap
Layout
Workflow
Zoom
Sync
Annotations
Color
Register
CAD

Mouse Mode, Measurement, Time-intensity and Calibration

Click this button to show the complete menu:



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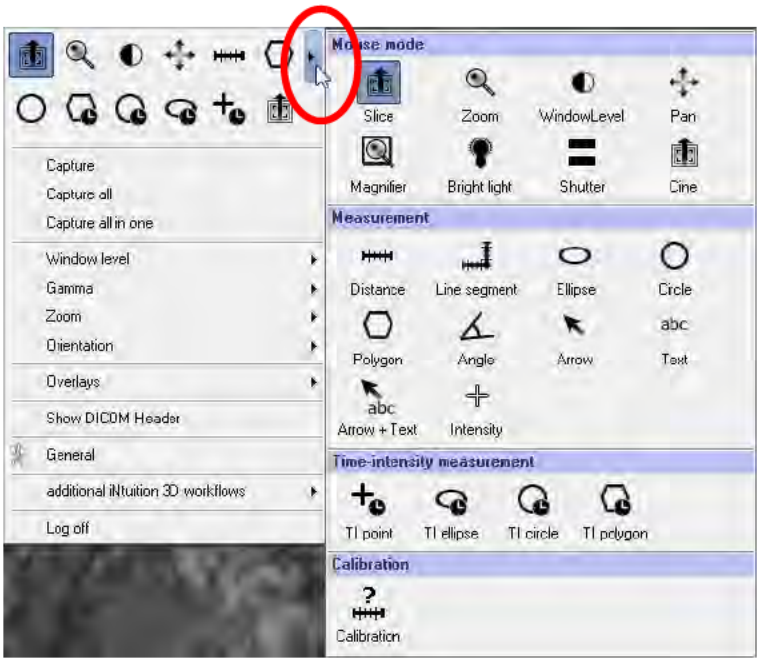
Note: You can also display this menu by right-clicking on the image. The top portion of the right-click menu contains some of the most commonly used measurements and mouse modes. To see the entire menu, hover over the right-arrow at the top of the right edge (see the following image).



Mouse Mode

The first group of items, **Mouse mode**, allow you to select the function of the *left* mouse button.

The top row sets the left mouse to:

- Slice (page through slices)
- Zoom (move up to make the image larger, down to make it smaller)
- WindowLevel (make the image brighter or darker)
- Pan (move image around in the window)

To use the items in the bottom row of the Mouse mode group (Magnifier, Bright light, Shutter and Cine), first select the item from the menu and then click and hold down the mouse on the image. The features are illustrated by the following images.

First, here is the original image as it appears prior to using any of the functions:

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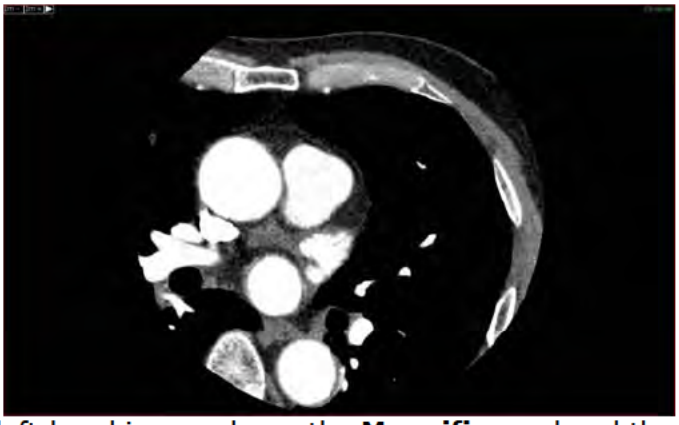
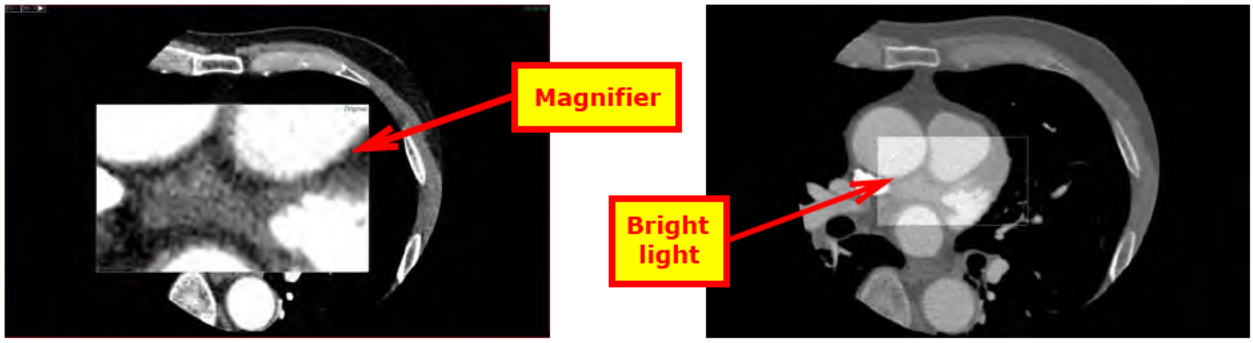
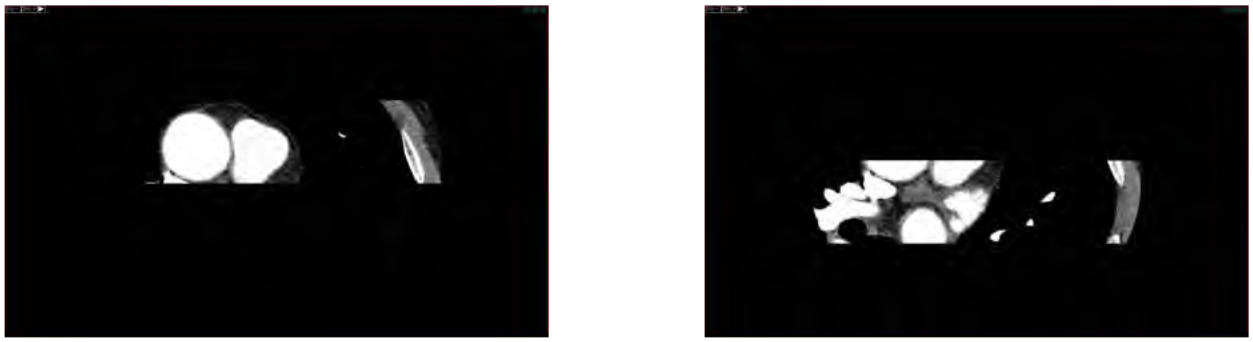


In the following, the left-hand image shows the **Magnifier** and and the right-hand image shows the **Bright light**.



The shutter shows a narrow vertical area of the image. You can move the shutter up and down to show different areas of the image. These two figures show the shutter in two different places on the same image.



Cine mode scrolls through slices as a movie. Select the **Cine** item from the menu and then click on the image. To begin the scrollling, move the mouse up or down.

Moving the mouse over the image while it is scrolling changes the speed. To increase the speed, move the mouse up. To decrease, move down. As you approach the middle of the image (vertically), the speed slows down to a stop, and if you continue moving the mouse in the same direction, the scrolling reverses direction. There is no need to hold down the mouse while changing the speed or direction. You can move the mouse just by hovering.

Click the image once to stop the cine.

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Measurement

- **Distance**

  This feature calculates the distance of a line drawn on the image.

  To draw a line, do the following:

  1. Click on one edge of the area to be measured.
  2. Drag the mouse across the area.
  3. Release the mouse to finish drawing.

- **Line Segment**

  This allows you to draw a series of connected line segments by clicking on the image, moving the mouse to another point on the image, and clicking again at a new point, repeating those actions as many times as required. The measurement given is the sum of the lengths of all line segments on the image.

  To place a **Line Segment** measuring tool onto an image, do the following:

  1. Click on one edge of the area to be measured.
  2. Move the mouse to the endpoint of that segment.
  3. Click on that point to complete the line segment.
  4. Repeat steps 1-3 to draw a new line segment, as many times as needed.
  5. Double-click to finish drawing.

- **Ellipse**

  This tool can be used only on MPR images in the active (upper right) window.

  This feature calculates the average HU value within an area, defined by the ellipse drawn on the image (see the figure at right).

  To draw an ellipse, do the following:

  1. Click on one edge of the area to be measured.
  2. Drag the mouse across the area to be measured.
  3. Release the mouse to finish drawing.

- **Circle**

  1. Click the center of the ROI and move the mouse in any direction.

  2. Click again when the region of interest is encircled.

- **Polygon**

  Polygon allows you to draw an outline around a region of interest by clicking on the image, moving the mouse to another point on the image, and clicking again at a new point, repeating those actions as many times as required.

  To measure the region of interest, do the following:

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1. Click on one edge of the area to be measured.
2. Move the mouse to the endpoint of the segment.
3. Click on that point to complete the line segment.
4. Repeat steps 1-3 to draw a new segment of the polygon, as many times as needed.
5. Double-click to finish drawing. The software connects the final point to the initial point to form a closed area.

- **Angle**

The angle measurement tool displays the degree of the angle between two lines drawn on an image.

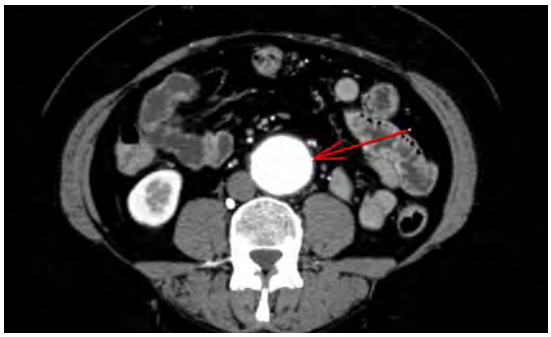
To measure an angle, do the following:

1. Click on the endpoint of the first line.
2. Move the mouse to the vertex point of the angle and click that point to complete the first line.
3. Move the mouse to the endpoint of the second line and click to complete the second line.

- **Arrows and Text**

To add an arrow to an image:

1. Select **Arrow** from the menu.
2. Click on the spot that you want the arrow to point to. The arrow is always drawn from the pointing end.
3. Drag the mouse away from the initial spot.
4. Release the mouse when the arrow has the desired length.



To add text:

1. Select **Text** from the menu.

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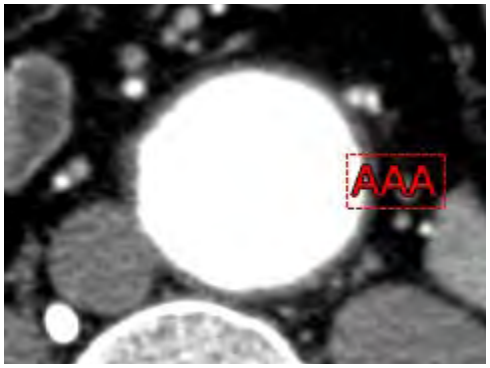
2. Click on the spot where you want to place the text. The following dialog is opened:

Figure 3-1: Add Text Dialog

3. Type in the desired text and click **OK**.

   The text is shown inside a box whose upper-left corner touches the spot you clicked on (see the following image).



To add an arrow and text in one step:

1. Select **Arrow + Text** from the menu.

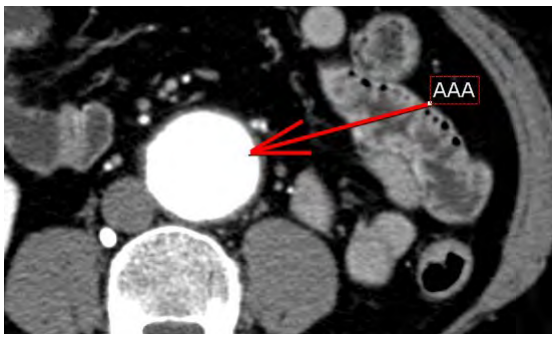
2. Click on the spot that you want the arrow to point to. The arrow is drawn from the pointing end.

3. Drag the mouse away from the initial spot.

4. Release the mouse when the arrow has the desired length. The Add Text Dialog (see Figure 3-1) is opened.

5. Type in the desired text and click **OK**.

   The text is shown inside a box whose lower-left corner touches the endpoint of the arrow.



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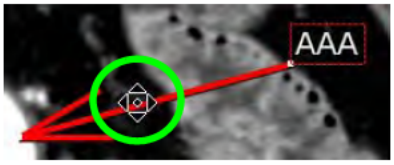
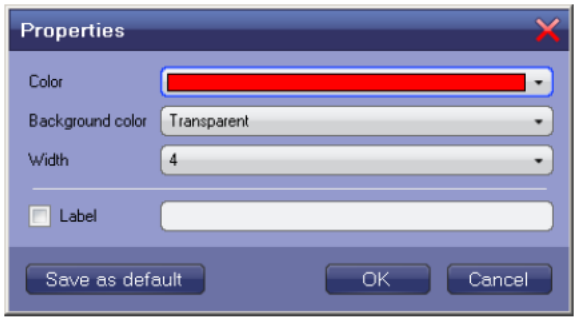
Properties





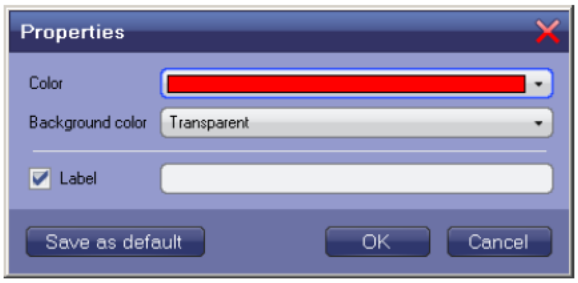
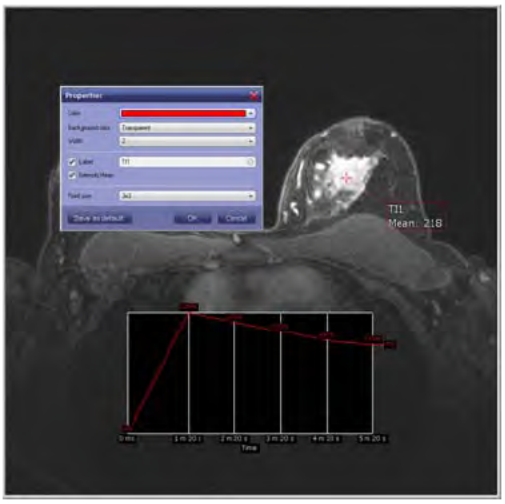


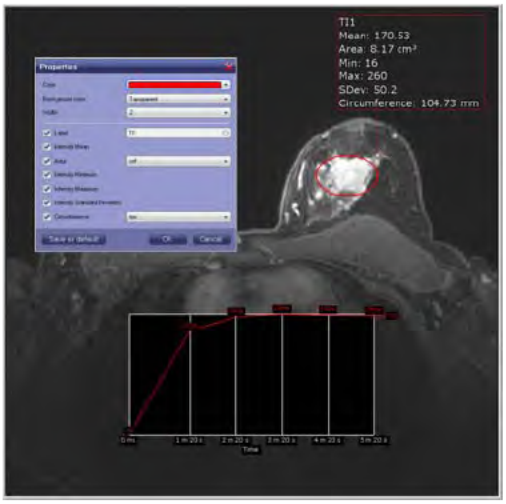
Figure 3-2: Left - Arrow Properties; Right - Text Properties

Time-Intensity Measurement

There are four kinds of time-intensity measurements: point, ellipse, circle and polygon. These objects are drawn in the same way as described above.

The following two images show the time-intensity point (left) and time-intensity ellipse (right).





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Calibration

To calibrate measurements, draw a distance measurement line on the image. The length of the line is displayed and the Properties dialog is opened. Enter the correct length in the Value field. By doing this, you are telling the Viewer that the length of the line has the value you have specified, and that all other measurements should be calculated relative to this value.

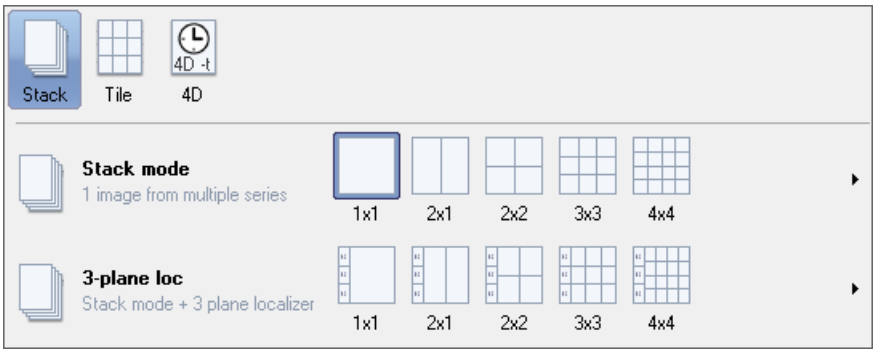
Layout

There are two kinds of layouts, **Compare** and **Layout**. **Layout** allows you to configure layouts for comparing different series within a single study. **Compare** is used to compare different *studies*.

Standard Layouts

Layout has three subgroups: **Stack**, **Tile** and **4D**.

- <u>Stack</u>



The **Stack** layout is used to compare multiple series. Standard layouts are pictured in the dialog shown in the following image. Each window of the layout is called a Viewport, which displays one image from each series.

Each layout also has a localizer version, **3-plane loc**, which has three extra images on the left side of the screen.

Select a layout that provides a viewport for each series in the study.

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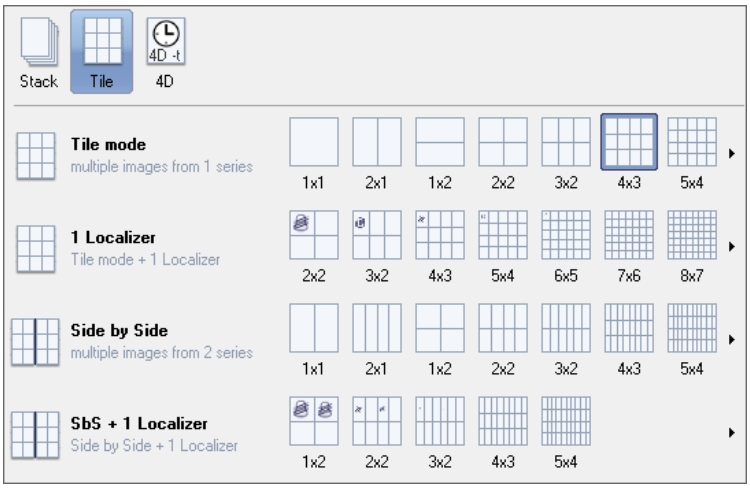
- Tile



Tile mode is used to view slices from a single series. This way you can view multiple slices at the same time. The **1 Localizer** layout provides a localizer image in the upper-left viewport.

The **Side by Side** layout is used to view multiple slices from two series, side-by-side. **SbS + 1 Localizer** provides a localizer image in each of the series' upper-left viewport.

- 4D

The **Time based** 4D layout is used for viewing the contrast change over time in a single position.

Position based 4D is used to view a set of slices (for example, from the apex to the base in a heart) within the same phase.

User-defined Layout

If none of the standard layouts is exactly right for your needs, you can create your own layout. At the end of each array of standard layouts for each category, there is a right-arrow. Hovering the mouse over the arrow opens a blank grid (the **Select layout** panel), where you can choose the dimensions of a desired layout of the same type. For example, in the following image, dimensions will be chosen for a layout in single-series **Tile mode**.

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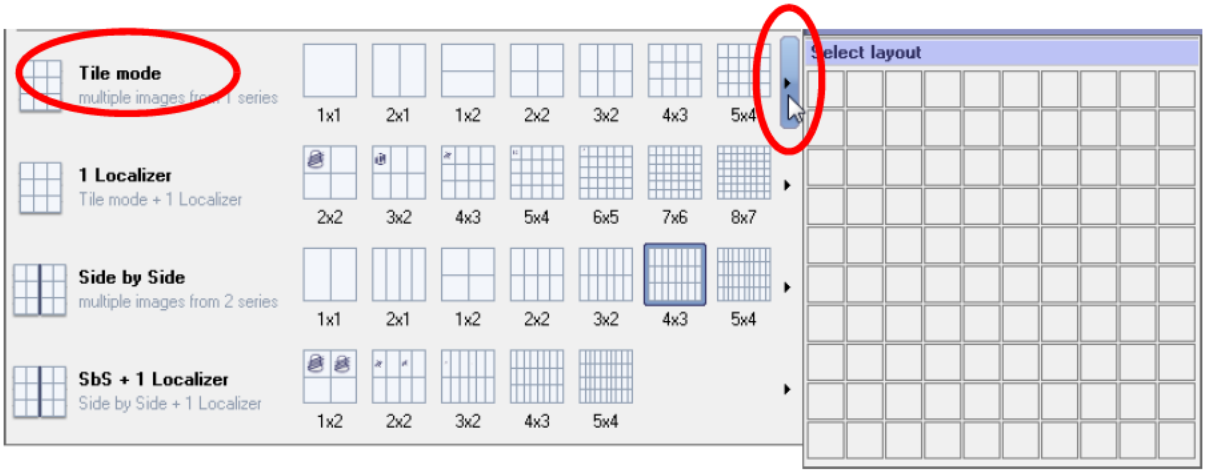

To define the dimensions of the new layout, hover the mouse over the top-left square and move the mouse across, down, or diagonally to the right and down through the squares, until the number of squares in the desired dimensions has been marked. In the following image, the user is creating a 7x6 layout in **Tile mode**:

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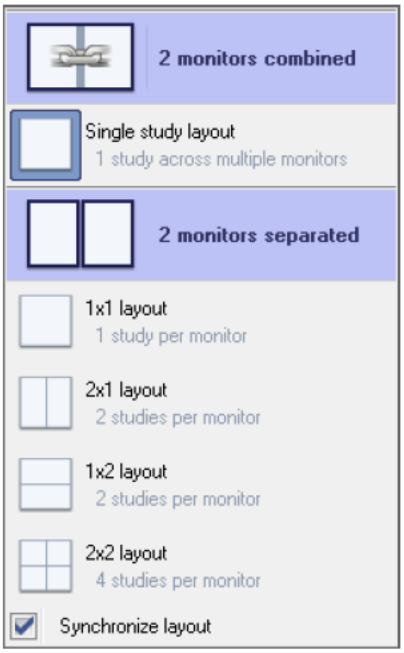
Compare Mode



As stated earlier, **Compare** mode is used to compare different studies at the same time. A dual monitor system (at the minimum) is required to use this layout mode.

There are two categories of layouts: **2 monitors combined** and **2 monitors separated**.

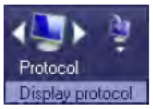
By default, the two screens are linked in the **2 monitors combined** layout category. There is only one layout choice in this category, **Single study layout**. If you choose a tile layout, you can see multiple images from a single series displayed across the two monitors.

In the **2 monitors separated** category, you can choose 1x1, 1x2, 2x1 or 2x2 layout, and display up to four studies on a single monitor. (Therefore, eight studies is the maximum number of studies, total, that can be displayed on two monitors.)

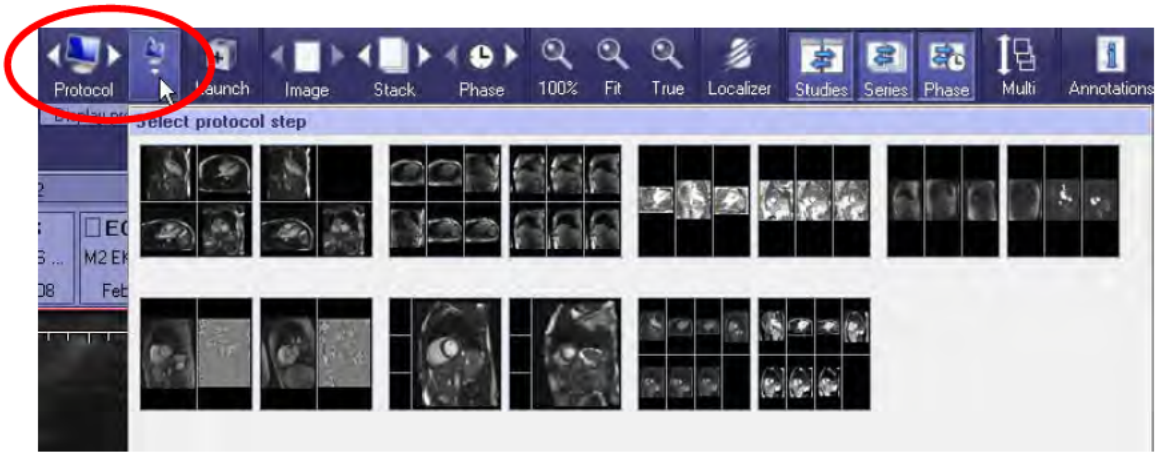
Compare mode is used primarily when you want to load two studies, each from a different patient. You cannot mix different patient studies in a single layout. Even when you are loading two studies from the same patient, you still must use Compare mode if each study used a different modality.

The **synchronize layout** button links both screens when changing to a **Compare** layout.

Display protocol



This tool allows you to step from one protocol step to the next (or the previous) step. Click the right-arrow to advance to the next step in the protocol (or the left-arrow to go back to the previous step).



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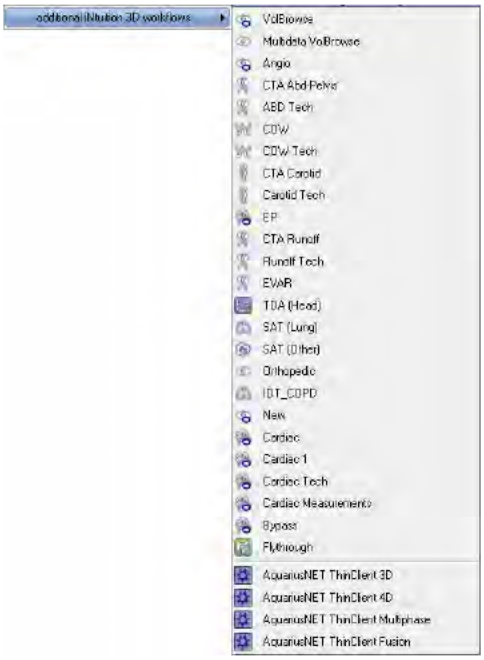
You can also use the **Select protocol step** panel to select a protocol step out of order. Click the down-arrow to open this panel. Then click the desired protocol.

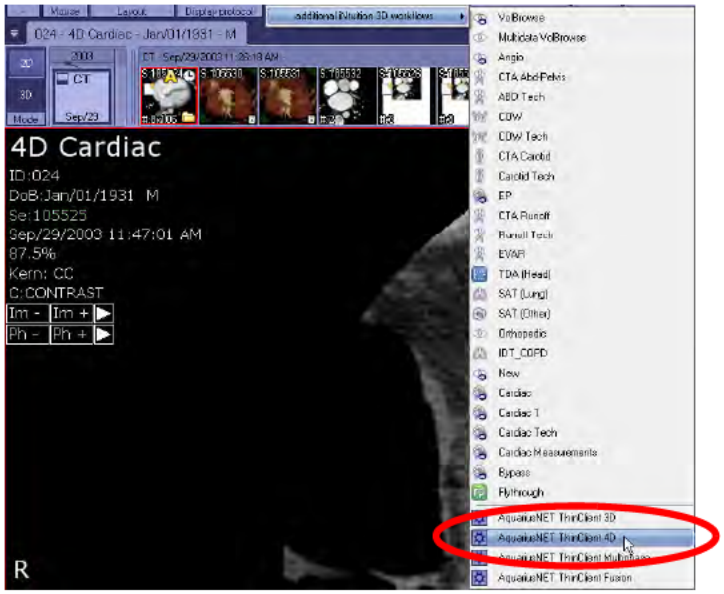
Workflow

With this tool, you can work with the 3D imaging tools available on the AQi Client or AqNET Thin Client. To use the AQi Client, select a Workflow from the drop-down menu (see image at right). This launches AQi and loads your study into the selected Workflow.

The AqNET Thin Client has some specialized functions such as Fusion, which also provides advanced 3D imaging tools. Do not select a Workflow to launch the Thin Client - Workflows are part of the AQi Client. The bottom of the drop-down menu has options for opening the Thin Client. The number of options listed in the menu depends on the study you currently have loaded.



Select the desired Thin Client module:



The Thin Client is launched with your study:

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Navigation

- Image - Navigate to the previous or next image in the same series.
- Stack - Navigate to the previous or next series in the same study.
- Phase (shown only when a multiphase study is loaded) - Navigate to the previous or next phase in the same multiphase series.

Zoom

iReview has three zoom options:

- 100% - The image is displayed in the original size of the DICOM data.
- Fit - The image is displayed to fit the screen
- True - The image is displayed in the real size of the patient.

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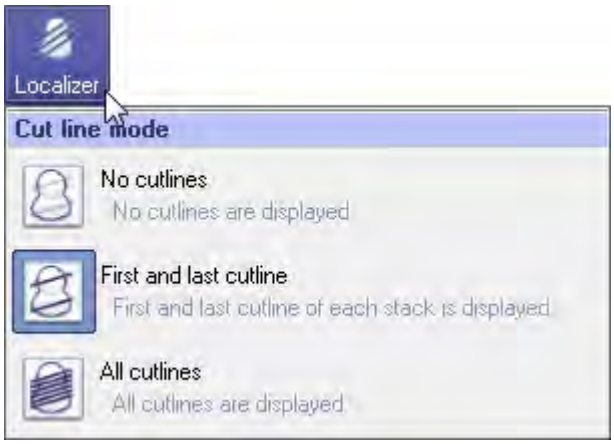
You can also access these options by clicking the **Zoom** annotation in the upper-right corner of the image.

If the monitor has not been calibrated, the True display size is not available. In that case, the following message is displayed:

For information on how to configure calibration, see "Pixel size calibration" on page 1-13.

Localizer

Display the localizer with different number of cutline options.



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Sync

The sync buttons enable or disable the currently configured synchronization settings in the Synchronization page of the Preferences. When a sync button is disabled, *all* synchronization is disabled for the corresponding data (study, series or phase).

The function of each button is as follows:

- **Studies** - Enable/disable synchronization for images from different studies, for example, when loading prior and current studies on the same patient.
- **Series** - Enable/disable synchronization for images from different series, for example, when loading multiple series of the same exam.
- **Phase** - Enable/disable synchronization for images between multiple phases of a 4D series.

You can change the setting temporarily by using these buttons. This change remains in effect while the study or series is loaded. Click the appropriate button to toggle the synchronization on or off, for the desired sets if data. For example, to disable synchronization of two series within a study, click the **Series** button.

When synchronization is enabled, the button has a light color and appears sunken. When it is disabled, the color is darker and the button appears flat. See Figure 3-3 below.

Figure 3-3: Series Synchronization Buttons; Left: Enabled; Right: Disabled

To have greater control over different kinds of synchronization, you must configure the settings in the Preferences. See "Synchronization" on page 1-39 for details.

Scroll

The scroll option has two settings, single and multi.

- Single scroll - Scroll through one series only.
- Multi scroll - Scroll through all loaded series.

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Annotations

Show or hide all annotations on images.

Orientation

There are four orientation functions:

- CW - Rotate 90 degrees Clockwise
- CCW - Rotate 90 degrees Counter-Clockwise
- Flip V - Vertical Flip
- Flip H - Horizontal Flip

Color

- Invert - Invert the color scale for the image. This applies to both grayscale and color images.

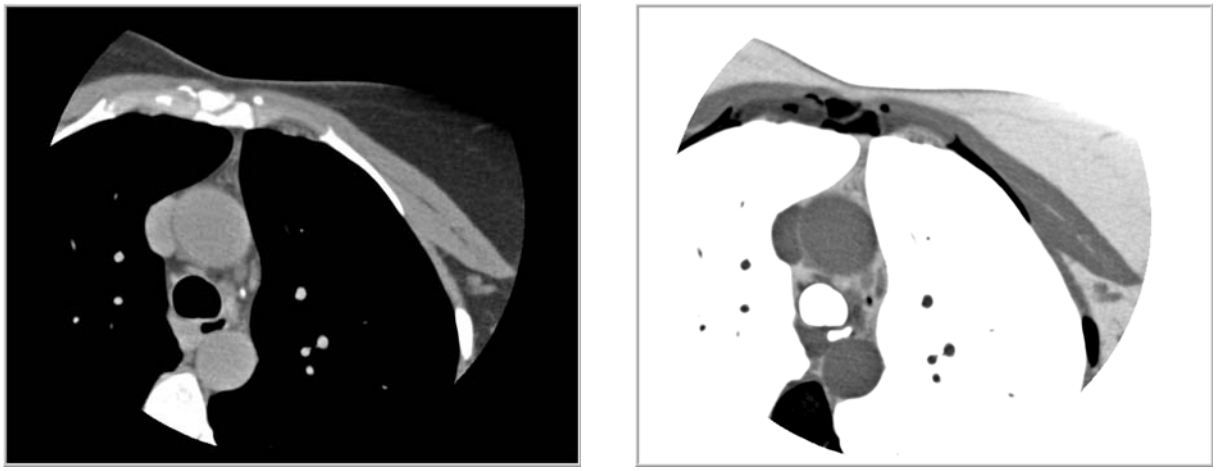

Figure 3-4: Left - Original Grayscale; Right - Color Inverted

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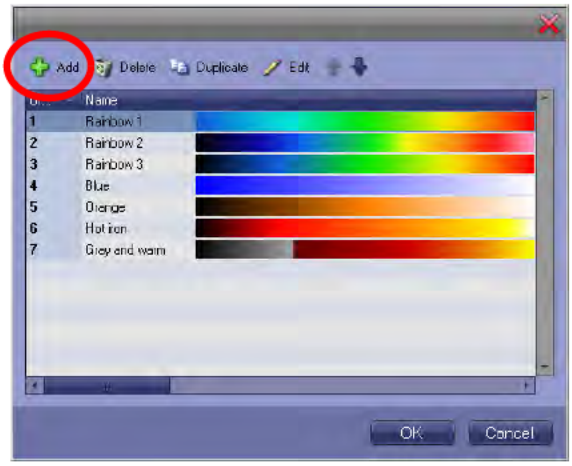
- Color - Apply the selected pseudo-color template to a grayscale image. (This also applies to color images.)

To add customized color templates, click on **Customize color templates**. The color template manager dialog is opened (see the image below):



Click the **Add** button (circled in the image above). The add template dialog is opened. Type in a name for the template in the **Name** field.

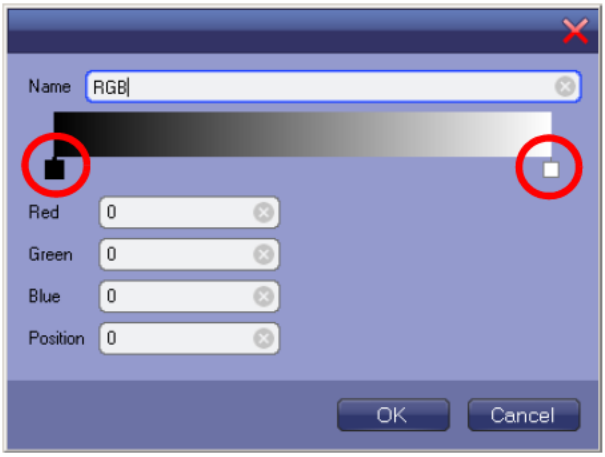


Figure 3-5: Add Template Dialog

You can now add colors to the template. Just under the color bar, there are two small square markers, one at each end (circled in the previous image). To add another marker, do the following:

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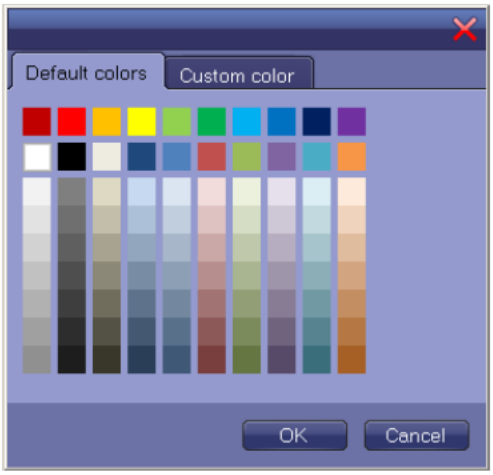
1. Click on or just under the colorbar. A third marker is added under the colorbar. You can move it to the position where you want the color to change.

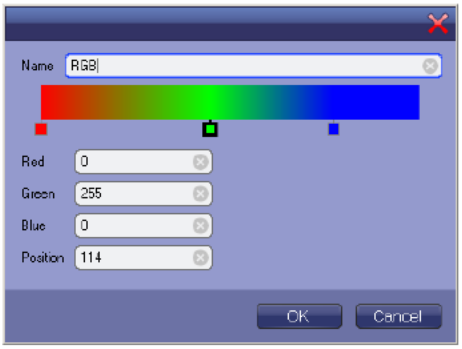
2. To add a color, you can either change the RGB values in the corresponding fields below the colorbar (see Figure 3-5 on page 3-17), or double-click the marker. Double-clicking opens the color palette:



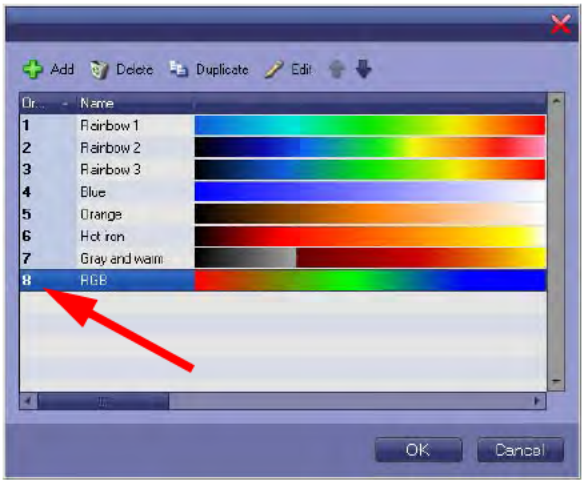
3. Select a color from the **Default colors** tab, or click the **Custom color tab** to create your own.

4. Click **OK**. That color is now added to the colorbar, starting at the marker:

5. You can continue adding markers and colors until the template is completed. When done, click **OK**.



6. The new template is added to the bottom of the existing template list.



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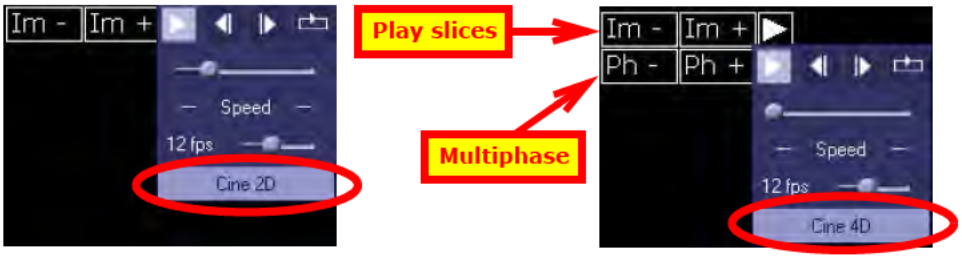
7. Click **OK** to exit the template editor.

Cine

There are two **Play** buttons in the **Cine** tool. The first (leftmost) plays through the slices of a single series. The second **Play** button plays a multiphase image as it changes over time, while remaining in the same image position.

The Cine tool is also available on the image as annotation. The top line plays a 2D cine just as the first **Play** button does. The bottom line plays a 4D cine just as the second **Play** button above does. The expanding arrows open a small dialog (see the following image) containing extra controls, including one for speed.



Register

The **Register** tool is used to register all currently displayed data.

PMap

PMap displays the parametric map for breast MR data. **Sub** subtracts T0 images from the current image.

Parametric Map

Parametric Map is a color-coded visualization of the change in intensity over time. To analyze the time-density curve, two thresholds are used in the Parametric Map module. One is the uptake value, which describes how fast the intensity changes between the pre-contrast and peak phases (also known as the initial, or wash-in phase). Each pixel in the image has an uptake threshold that indicates by what percentage that pixel's intensity increased between the two phases. In comparing the pixel intensities of the pre and the peak phases, it is usually the case (depending on the scanning protocol, scanner, and contrast media used),

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that areas with wash-in below 40-60% can be ignored. This threshold is set using the Uptake bar.

The second map shows the speed of the contrast washing out, also called the delayed phase. Each pixel is compared between the peak and post phases, to derive the difference in intensity for that pixel. There are three possible results:

- Type I: The pixel intensity has increased gradually.
- Type II: The pixel intensity has not changed.
- Type III: The pixel intensity has decreased gradually.

Each of these three types is represented by a different color. By default, Type I is respresented by blue, Type III by red, and Type II by the rainbow in the middle. There is no official standard that defines the percentage borders between each of the 3 types. By default, the border between Type I and Type II is set to 20% in iReview. This means that an increase in contrast of 20% or more is shown with the blue overlay, a decrease of 20% or more is shown with red, and values in between use the rainbow overlay. These borders can be changed, as can the colors themselves.

To see the parametric map, click the **Parametric Map** button. The uptake bar (on the left) and color bar (at right) are displayed on the image. These determine the colors used to show the changes in intensity during the delayed phase:

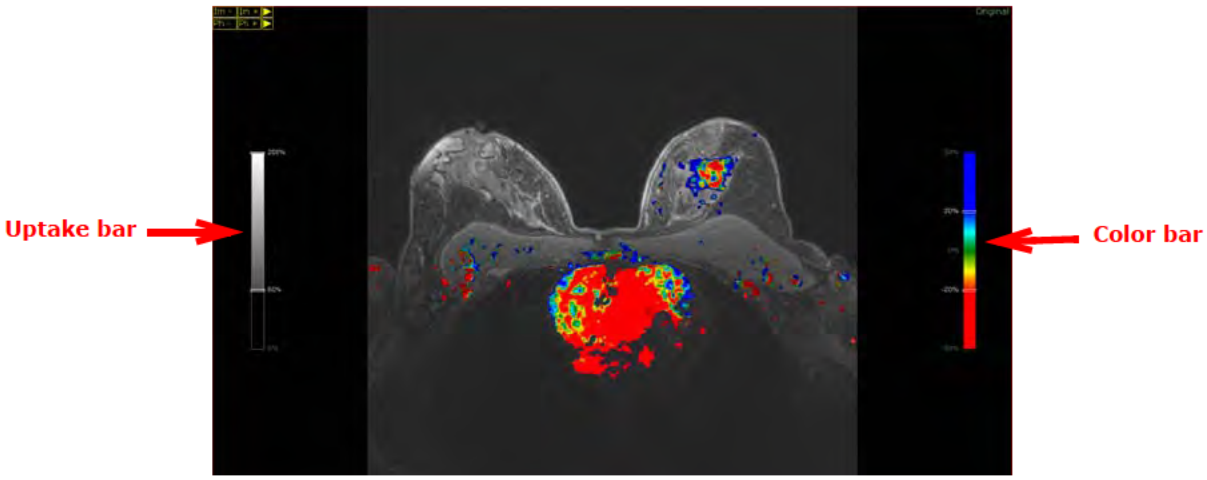

Figure 3-6: Parametric Map

The Color Bar

The color bar shown in Figure 3-6 controls the color map of the delayed phase. There are three color areas, one for each type of change. Between each pair of adjacent colors is a slider that allows you to change the percentage border for both colors.

To change the percentage border between two colors, click and drag the slider up or down (see Figure 3-7 on page 3-21). For example, to lower the threshold between the Type I and Type II colors, drag the upper slider downward. As this threshold is lowered, the amount of the Type I color will be increased on the image.

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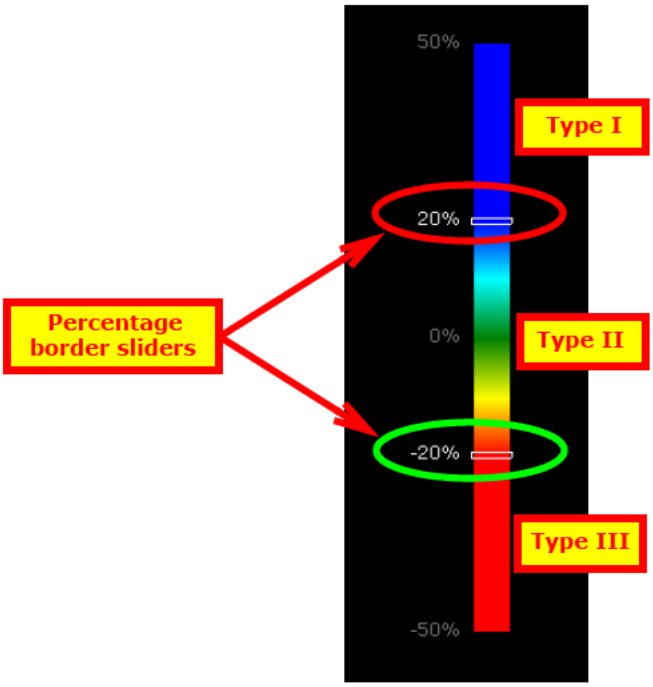
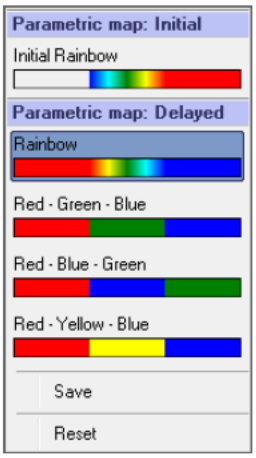


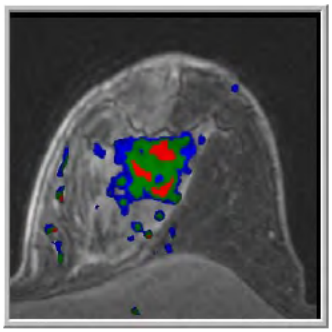
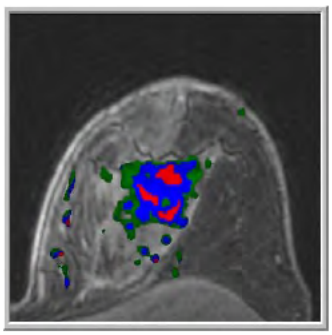
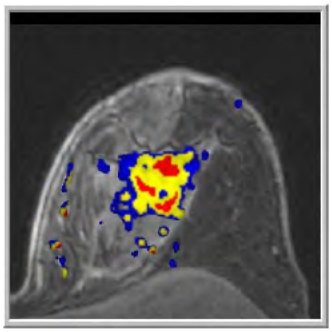
Figure 3-7: Color Bar

To change the colors used for the delayed phase, do the following:

1. Click the color bar. A menu is opened, as shown in the figure at right.
2. The alternate color maps are shown under the Rainbox color map. Click a different color map to select it.



The following images show (from left to right) how the Red/Green/Blue, Red/Blue/Green and Red/Yellow/Blue color maps highlight the pathology:

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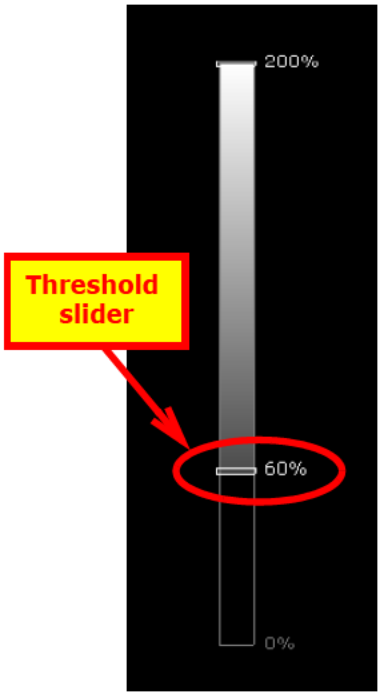
The Uptake Bar

The Uptake bar allows you to control how much color overlay to show on the image.

Drag the threshold slider up and down to increase or decrease the percentage threshold at which color is shown on the image. Any pixel whose percentage change is below the threshold will not show any color.

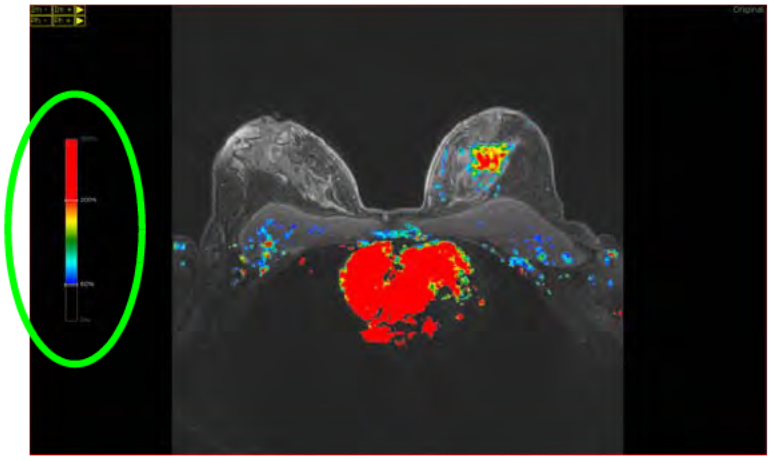
A lower threshold allows more color to be displayed. This makes it less likely that diseased tissue will be missed, but there will also be more noise on the image. The Uptake bar allows you to try different percentages until the amount of color suits your needs.



The Initial Phase Bar

To access the initial phase bar, click the color bar to display the menu. Then click **Initial Rainbow**, at the top of the menu (see image at right).

The Initial Phase bar is then displayed on the left side of the viewer. The color map for the initial phase is displayed on the image, as shown below:



You can use the sliders to change the borders between the colors, as described in "The Color Bar" on page 3-20. However, no other colors are available for the initial phase. Note that the percentage ranges on this bar are different from those on the delayed phase color bar.

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Save and Reset

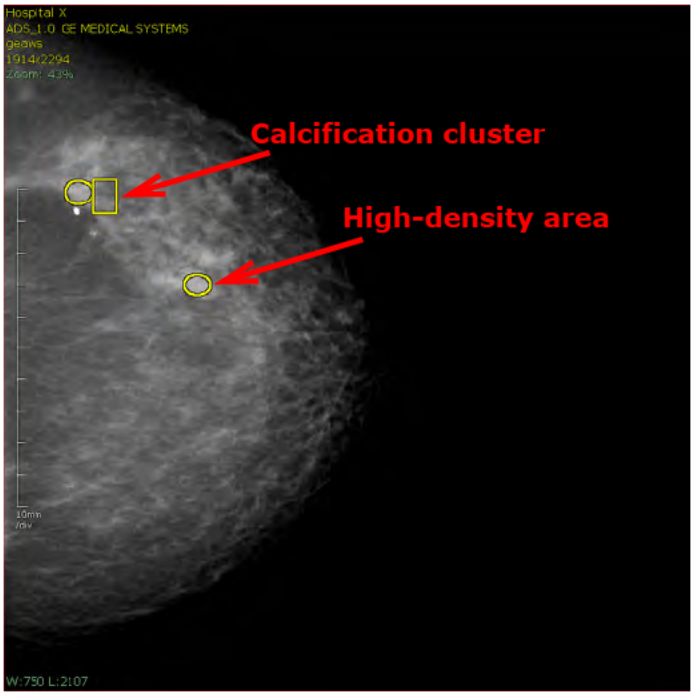
These items appear at the bottom of the menu.

Select **Save** to make the current color map the default map for future studies. If you change the colors or the borders between colors in the color map and then save it, the saved color scheme is used by default the next time a study containing Parametric Map APS data is loaded, .

Select **Reset** to restore the original default color map (Delayed Rainbow).

CAD

Show CAD markers. CAD markers identify potential lesions.



- Ellipse markers identify a high-density area.
- Rectangular markers identify a calcification cluster.

Viewing Studies

Just beneath the Top Tool Bar, the studies or series currently loaded are displayed as thumbnail images. The name of each study is shown on a tab that contains the Patient ID, Patient Name, Study Date and Description. To view a different study, click the corresponding tab.

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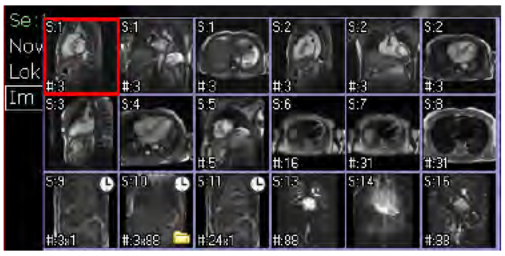
If there are too many series to be visible all at once, use the slider bar to scroll to a series not currently visible.

When you hover the mouse over the series icons, a panel containing detailed information about the series is displayed (see the following image).

Clickable Annotations

The annotations on the image are configurable based on the **annotation** setup in viewer configuration. The green annotations are clickable and selectable.

- Series number - Show thumbnails for all series. To view a different series, click on the thumbnail having the desired series number.



- Zoom Factor - Select the Zoom option.

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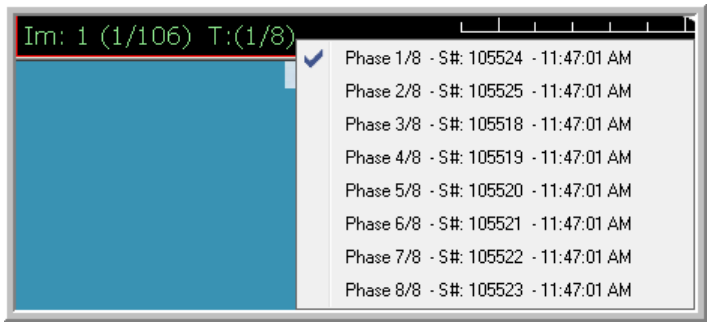
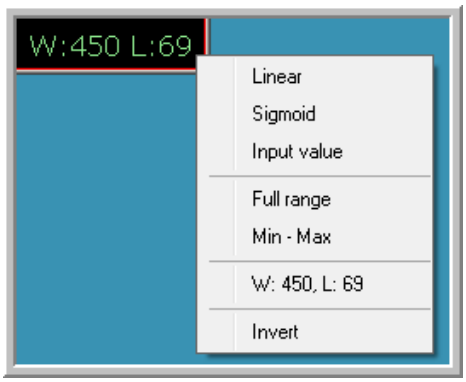
- Phases - Select another phase of the 4D image to display.



- W/L - Select different options to apply to the Window Width and Window Level.

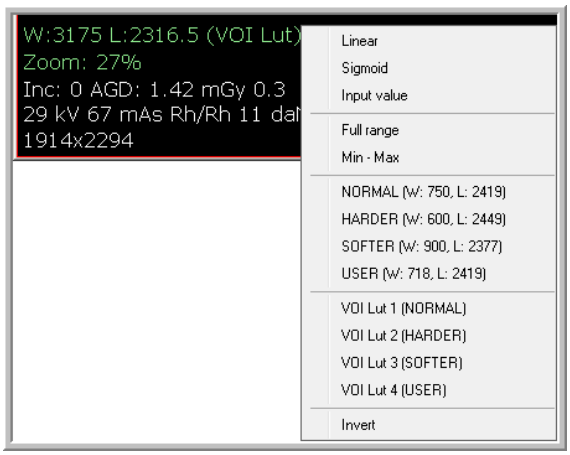


There are five options for Window/Level curves:

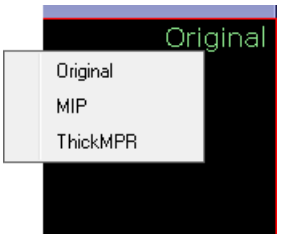
- Linear - The standard linear curve.
- Sigmoid - Sigmoid uses an S-shaped curve for the Window/Level. The contrast then appears more like an X-Ray film.
- Input_Value - Arbitrary LUT stored in the DICOM files (often used with CR, DX and MG).

  The curve is calculated and optimized on the scanner to provide the same perceived image on the console, monitor and in print. You can select **Input Value** only if the LUT is stored in the DICOM header.

- Full Range - Displays the full acquisition range of HU.
- Min-Max - Selects a Window/Level range that displays the image so that the full range of HU values in the data can be seen.



- 2D Image_Format - Display the image in one of three formats: the original format, MIP and ThickMPR



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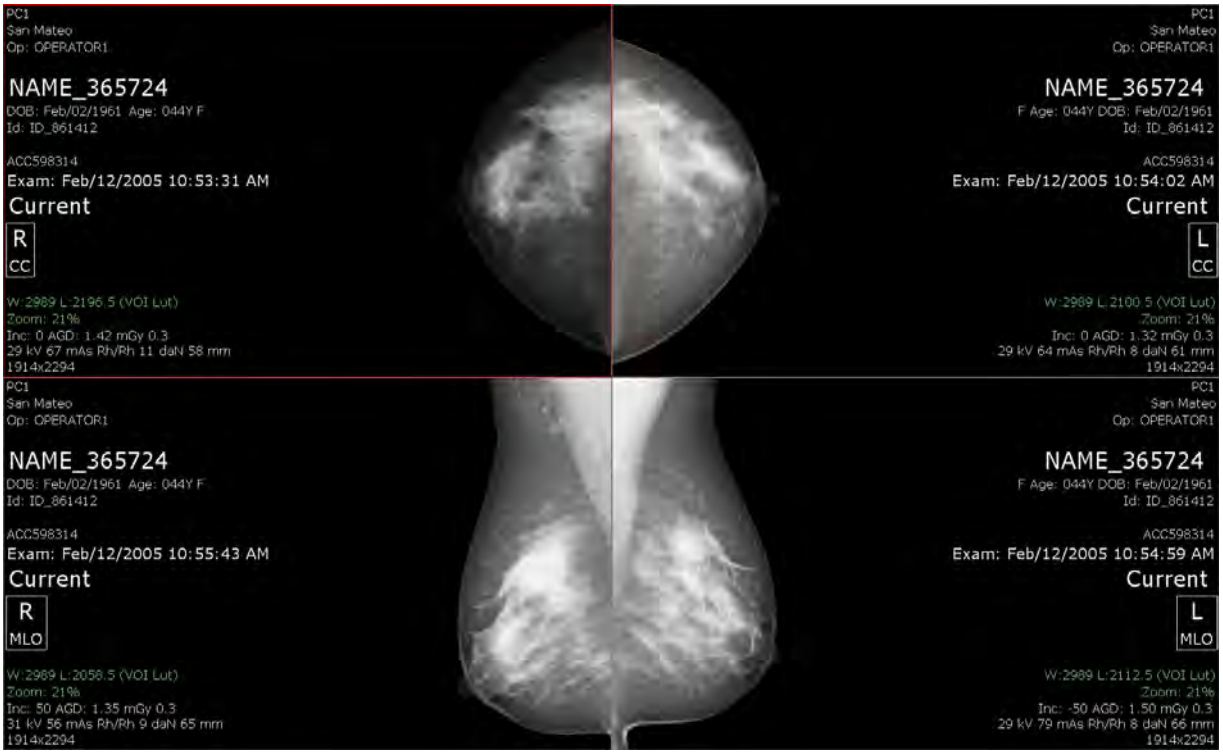
Viewing Mammographic Data

iReview supports all DICOM format images, including Mammographic data. However, MG images require high resolution monitors. You can configure a display protocol to display the MG data in the way it is normally viewed.



Right-Click Menus on Study Images

The contents of the right-click menu on images are different, depending on the modality of the study. Most of the items are the same for all modalities, but some modalities have extra functions or are layed out slightly differently.

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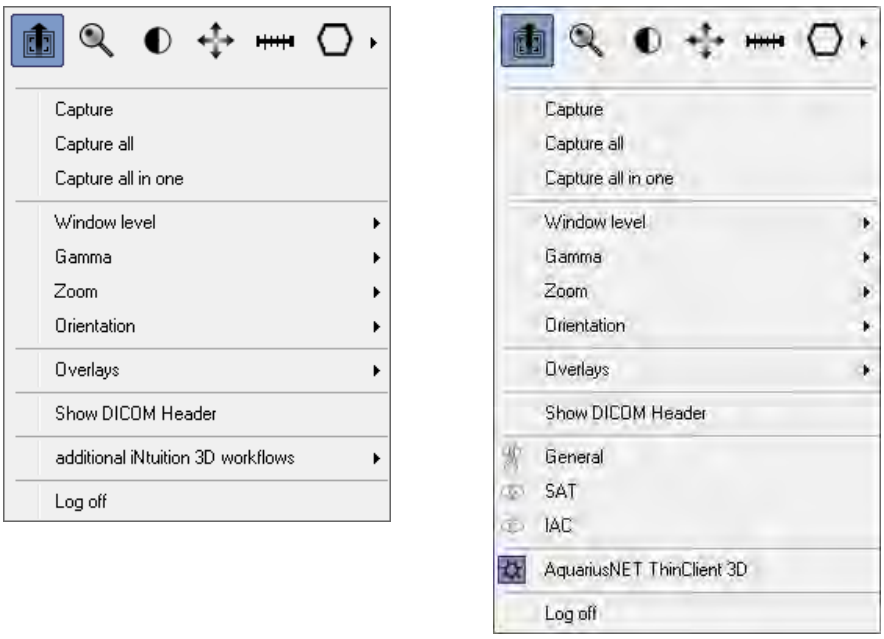

Figure 3-8: Left - Right-click menu on CT study; Right - Right-click menu on MR

Function	Description
Measurement Icons	These are the same as the measurement icons described in "Mouse Mode, Measurement, Time-intensity and Calibration" on page 3-1.
Capture	Capture the selected image.
Capture all	Capture all images currently displayed in the viewer, and place each image in a separate cell of the Output Panel.
Capture all in one	Capture all images currently displayed in the viewer, and place them all in a single cell of the Output Panel.
Window Level	
Gamma	Adjusts the brightness and contrast of the image.
Zoom	This option is the same as the top bar tool button. See "Zoom" on page 3-13.
Orientation	This option is the same as the top bar tool button. See "Orientation" on page 3-16.
Overlays	Show/hide overlays on the image. See "Show/Hide DICOM Overlays" on page 3-28.
Show DICOM Header	Opens a window containing the full DICOM header for the study.
additional iNtuition 3D Workflows	(Available only for CT and MR studies.) Opens AQi in the selected Workflow. Note that the specific Workflows available depends on the modality.

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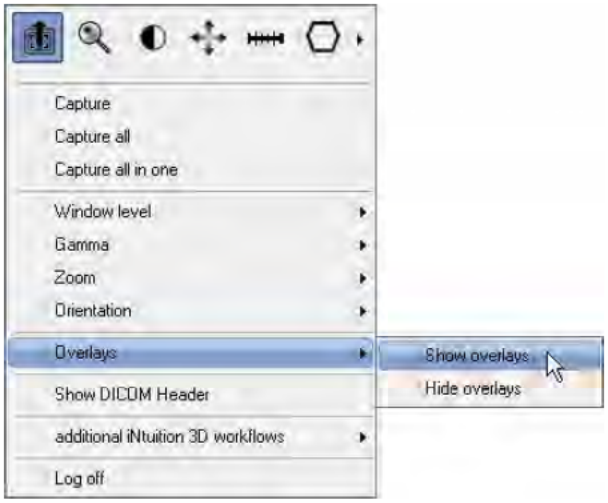
Function	Description
AquariusNET ThinClient 3D	Open the series in the AqNET Thin Client.

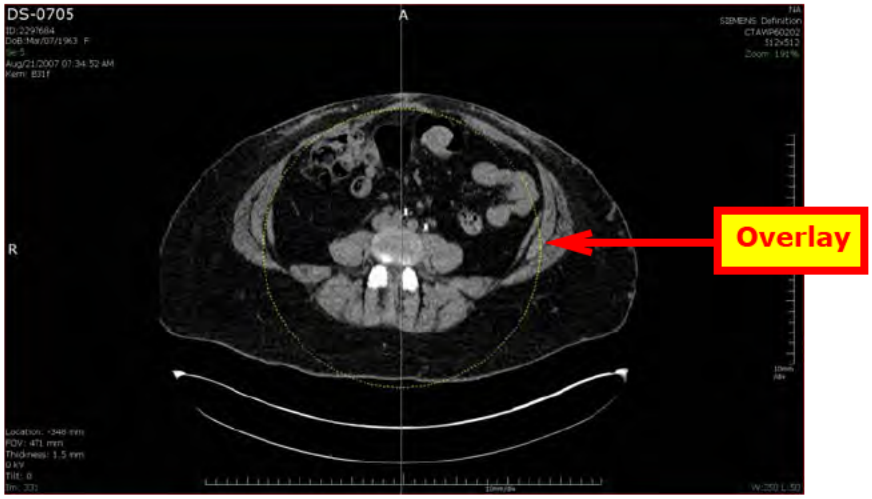
Show/Hide DICOM Overlays

The DICOM header of a study may contain overlay images that give additional information about the images.

To show an overlay on an image, right-click on the image and select **Overlays**, then select **Show overlays**.



The following example shows an overlay used for dual energy scans. It is a circular outline that shows the FOV of the energy source that is not shown in the image.



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iNtuition™

Sophistication and power in the datacenter.
Simplicity and elegance at your fingertips.

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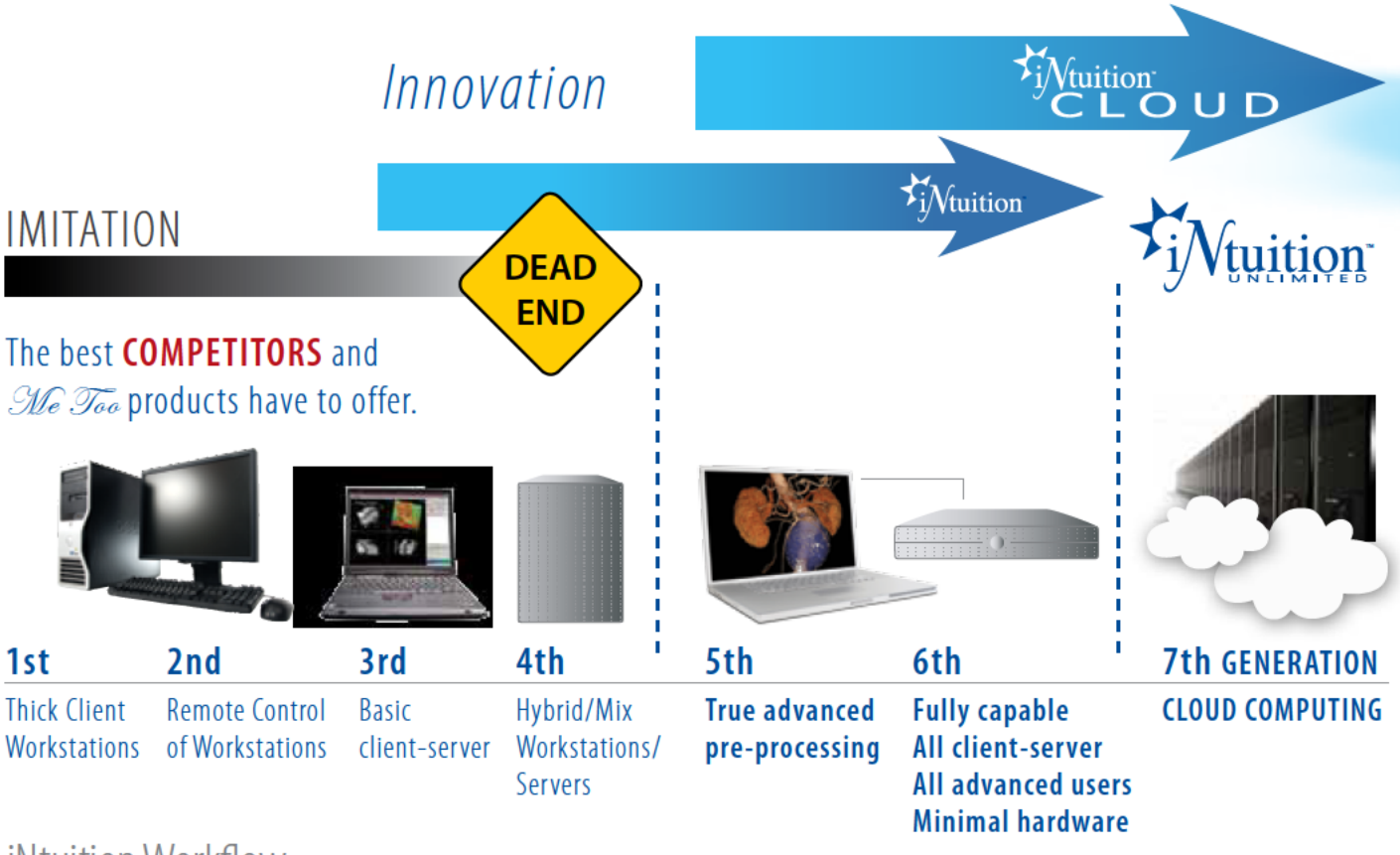
Innovation that defined a new genre...

Courage, creativity, the freedom to think clearly and envision new possibilities – these are the hallmarks that have distinguished TeraRecon throughout more than a decade of pioneering innovation in advanced visualization and decision support.

A decade ago, as we entered the new millennium, an era of advanced imaging was gaining pace driven by advances in multi-slice CT, MRI and PET. However the advanced visualization offerings of modality vendors were developed as cumbersome extensions of scanners, and the independent offerings on the market were deeply beholden to the modality vendors that would ultimately acquire them, limiting their ability to seek and embrace a wider vision.

Into this environment, in 2001, TeraRecon's *Aquarius*NET was born. The first true advanced visualization server, *Aquarius*NET achieved what had never been possible before – it placed advanced visualization into the hands of the physician as a true interpretation tool.

The original pioneer in client-server advanced visualization... *is still generations ahead*



iNtuition Workflow

iNtuition is a seamless solution designed to orchestrate clinical workflow with effortless grace. Working with iNtuition, it is easy to forget that multi-gigabyte datasets are being manipulated in effortless real-time, and shared with consulting colleagues across the healthcare enterprise, and even across the globe.

A single, unified server architecture supports a variety of workflow participants, from the zero-click *Aquarius*APS server, which automatically applies intelligent analysis and metadata extraction to volumetric studies immediately upon scan completion, to 3D technologists, interpreting physicians, surgeons, and every other stakeholder in the lifecycle of an advanced imaging study.

iNtuition offers an appropriate and empowering client to every imaging stakeholder, without ever compromising on functionality or performance.

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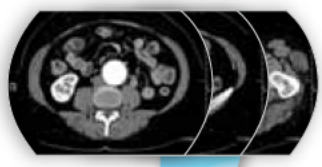
DICOM Images



AUTOMATE

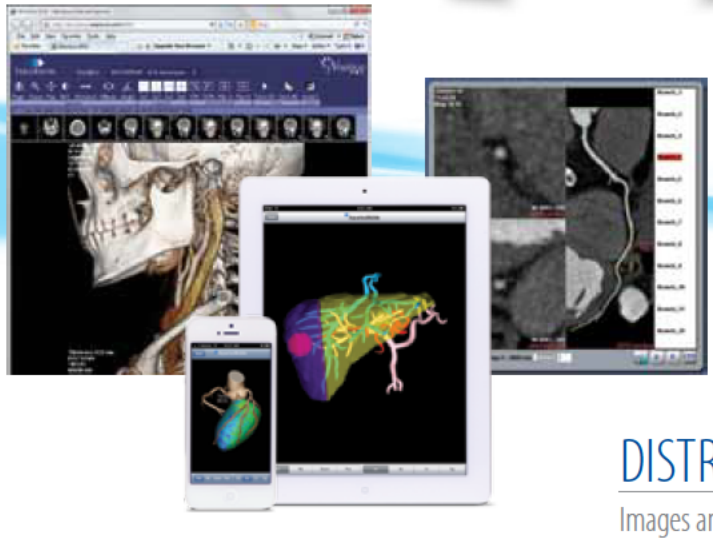
Images sent to the *Aquarius*GATE are routed to the *Aquarius*APS and/or the *Aquarius*NET Rendering Node. The *Aquarius*APS pre-processes images based upon user preferences and sends these results to the *Aquarius*NET Rendering Node to await clinical interaction.

*Aquarius*GATE/APS
(Routing/Metadata extraction)

*Aquarius*NET Server
(Render Node)

VALIDATE

The pre-processed images are reviewed, improved and validated by a technologist or physician, creating a Workflow Scene.



READ

Interpreting physicians read the validated Workflow Scene or validate the study themselves, if preferred.

DISTRIBUTE

Images and/or Workflow Scenes are available for review anywhere via either the iNtuition Client or iEMV (Enterprise Medical Viewer) web client.

Workflow Templates, Workflow Scenes

iNtuition provides, and allows you to customize, Workflow Templates, to deliver structured workflow with intelligent automation at each step. As you follow the Workflow Template, a Workflow Scene is created for the specific study, that you can then share and distribute to clinical colleagues.

iNtuition Client Standard Features

- Perspective (endoluminal view)
- Medial Axial Reformat (MAR)
- Curved Planar Reformat (CPR)
- Double-oblique MIP and MPR
- 3D triangulation
- Multi-monitor support
- Image enhancement filters
- Cube view
- Multi-mask display
- Synchronized center of rotation viewing
- Synchronized side-by-side review
- iNtuition Workflow Templates (3D Presentation States)
- Workflow Scenes: restore saved state
- CT, MR, Nuc, PET, Angio, US/Echo, CR/DR Review
- Volume rendering, MIP, MPR, MinIP, Raysum (ThickMPR)
- Distance, ROI and volume measurement
- Measurement calibration and ratio tools
- Output to DICOM, JPEG, BMP, AVI, Word
- Editing tools: crop, cut, free-hand
- Dynamic region grow segmentation
- Angulation tools including Cobb angle
- Distance pair
- User-defined measurement protocols
- Structured reporting with XML output
- 2D/3D Batch Movie Tool
- Conferencing and collaboration

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iNtuition CLOUD

TeraRecon has launched the 1st true CLOUD computing solution for advanced visualization, iNtuition CLOUD. This provides the company's award-winning, flagship iNtuition solution for advanced visualization, as an Internet-based service. Facilities can now securely upload their scans to the iNtuition CLOUD site, and then log in via a browser from any Mac or PC to access the full suite of truly thin-client iNtuition tools.

iNtuition™ CLOUD

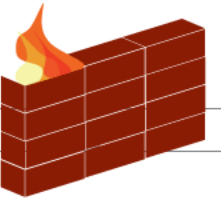
"The capabilities of TeraRecon continue to improve our ability to care for patients, and furthermore, the new iNtuition CLOUD capability has permitted me to enhance training both during in house and external conferences."

Dr. Gary Danton, M.D., Ph.D., - Chief of Imaging Informatics and Program Director for Radiology Residency, Director of the Division of Radiology at Jackson Memorial Hospital, and Assistant Professor of Radiology, Department of Radiology, University of Miami Miller School of Medicine

try it for free today, visit terarecon.com/cloud

Securely upload your data into our CLOUD...

iNtuition UPLOADER



Datacenter Firewall

Global Server Farm

Then log in via your browser to access the full clinical features...

Your web browser

You control a full virtual iNtuition client from your PC's browser.

Virtual Client

iNtuition CLOUD technology is proven and robust, and can be deployed in your own Private Cloud.

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

SAFETY FIRST! Read our position statement, inside page 5 flap.

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The iNtuition Private Cloud

Proven, Scalable, Affordable

Once you have evaluated our iNtuition CLOUD, deploy your own:

- 100% within your own enterprise
- 100% under your control

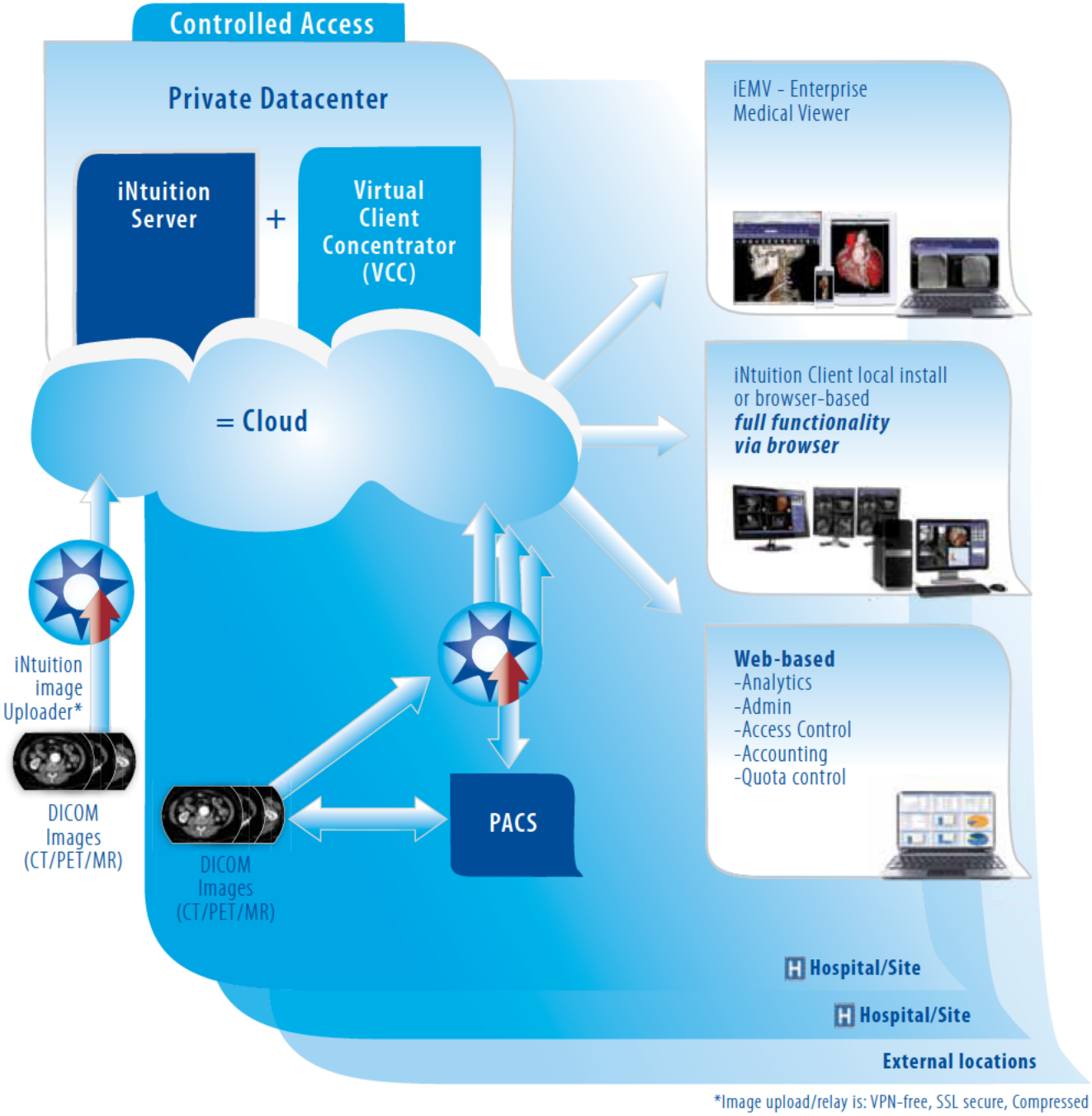

*Image upload/relay is: VPN-free, SSL secure, Compressed

The TeraRecon-hosted iNtuition CLOUD proves the viability and scalability of iNtuition's CLOUD technology, in a form which you can freely evaluate yourself – visit www.terarecon.com/cloud. Since iNtuition's CLOUD technology is 100% self-contained, with NO reliance on cloud services hosting providers such as Google or Amazon, you can then deploy your own private cloud affordably, securely, and 100% under your control, within the confines of your own enterprise.

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SAFETY FIRST! Read our position statement, inside page 3 flap.

Optional Clinical Modules

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VESSEL ANALYSIS A comprehensive package supporting the analysis of CT and MR data with centerline extraction, straightened view, diameter and length measurements, CPR and axial renderings, and V-Track mode for automated thin-slab MIP.

CALCIUM SCORING Identify coronary calcium and calculate parameters including Agatston Score and volume. An integrated reporting package with customization options is included.

TDA - TIME DEPENDENT ANALYSIS The time-dependent behavior of appropriate examinations can be studied, such as time-resolved planar or volumetric 4D examinations acquired with CT or MR. The TDA package supports color encoding of various parameters such as mean enhancement time and enhancement integral, with selection tools for input function and baseline, to speed analysis. TDA supports rapid processing of dynamic 4D area-detector CT examinations to aid interpretation within minutes of acquisition.

CT/CTA SUBTRACTION Helpful in the removal of bright non-enhancing structures from CT angiography examinations, the CT/CTA option includes tools to register pre- and post-contrast images, followed by a dense-voxel masking algorithm which removes high-intensity structures from the CTA scan without increasing noise, aiding the isolation of contrast-enhanced structures.

LD – LOBULAR DECOMPOSITION Identifies tree-like structures within a volume of interest, e.g. a scan region containing a vascular bed. The LD tool then identifies sub-volumes of interest based on proximity to a given branch of the tree or one of its sub-branches. Research applications include the analysis of the lobular structure of organs.

iGENTLE General Enhancement & Noise Treatment with Low Exposure. An advanced volumetric filter architecture applying noise management techniques to improve the effectiveness of 3D, centerline, contouring and segmentation algorithms even when source image quality is not optimum.

SAT - SEGMENTATION, ANALYSIS & TRACKING SAT supports analysis and characterization of masses and structures identified as potential lesions by the operator. Tools are provided to select and segment regions of interest, and to then apply measurement criteria, such as RECIST and WHO, leading to tabulated reporting of findings and follow-up comparison. Display and management of candidate markers from optional detection engines are supported, including iNtuitionís Spherefinder.

TVA - TIME VOLUME ANALYSIS TVA provides automated calculation of ejection fraction from a chamber in rhythmic motion. A fast and efficient workflow is offered to enable the user to identify the wall boundaries of interest, and, based on these user-confirmed regions of interest, to report ejection fraction, defined as (max volume - min volume)/(max volume), wall volume (propotional to mass assuming constant density) and wall thickening from multi-phasic CT data. Tabulated reporting output is included.

MAXILLO-FACIAL To support the analysis and visualization of DICOM input data with modality type "CT", with particular workflow suited to examinations of the Maxillo-facial region. This option applies the CPR tool to generate "panoramic" projections in various planes and of various thicknesses, and cross-sectional MPR views at set increments along the defined curve plane.

FLYTHROUGH Applicable to endoluminal CT or MR investigations, the Flythrough option supports side-by-side review, painting of previously-viewed areas, percent coverage tracking, and multiple screen layouts including forward, reverse, fisheye and flat volume rendered views. Tools are provided for contrast subtraction (setting high-intesity image areas to transparent), "Cube View", and integrated contextual reporting. Display and management of candidate markers from optional detection engines are supported, including iNtuition's Spherefinder.

VOLUMETRIC HISTOGRAM The Volumetric Histogram option allows a volume of interest to be segmented and analyzed for composition. Research applications include the analysis of low-attenuation regions of CT examination, threshold-based division of volumes of interest into voxel populations, investigation of scans of thrombosed vessels or aneurysms, or other pathology.

FINDINGS WORKFLOW This option provides a framework for tracking findings across serial examinations. A database holds measurements and key images, and provides support for structured comparisons and tabulated reporting of findings over time, such as the RECIST 1.1 approach for presenting serial comparisons. The Annotation and Image Markup (AIM) XML schema is supported, for automated integration with voice-recognition systems or clinical databases, and Word-based reports may be derived from the database.

FUSION FOR CT/MR/PET/SPECT With this module, any two CT, PET, MR or SPECT series, or any two-series combination thereof can be overlaid with one assigned a semi-transparent color coding and the other shown in grayscale and volume rendering for anatomical reference. Registration tools are provided and subtraction to a temporary series or to a saved, third series is possible. Support for PET/MR visualization is included.

MULTI-PHASE MR Configured for convenient workflow with MR examinations involving a series of image acquisitions taken over a period of time, where certain structures become progressively enhanced relative to other structures, this module features the ability to subtract a pre-enhancement image from all post-enhancement images to emphasize visualization of enhancing structures. Time-dependent region-of-interest tools are provided to plot time-intensity graphs of a given region.

PARAMETRIC MAPPING An optional enhancement to the Multi-Phase MR tool, the parametric mapping option calculates overlay maps where each pixel in an image is color-coded depending on the time-dependent behavior of the pixel intensity. As an example, this tool can be used in time-dependent MR to speed identification and investigation of enhancing regions.

SPHEREFINDER The Spherefinder option performs analysis of volumetric examinations to identify the location of structures with a high sphericity index. Spherefinder can be configured to focus within a defined region of interest, such as the segmentation mask for Lung or Colon.

MULTI-KV The MultiKv option provides support for Dual Energy and Spectral Imaging acquisitions from multiple vendors, providing standard image processing algorithms such as segmentation or contrast suppression, as well as generic toolkits for precise analysis and development of new techniques.

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

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SAFETY FIRST!

Position statement on **Computer-Assisted** and **Quantitative Imaging**

The rapid advance of volumetric imaging technologies such as CT, MR and PET, has opened up a wide range of new possibilities in medical imaging. Such new techniques have been the subject of extensive research and in many cases, adoption into routine clinical practice. The high speed and high resolution of modern imaging devices has driven a growing demand for tools to help make more efficient the review of such images.

TeraRecon is a committed pioneer, innovating in this field, to improve the quality and performance of advanced visualization tools, and their accessibility by physicians. Such advanced applications include fast 3D visualization, to assist with qualitative review of images, and also quantitative tools, tools for distribution to a range of computing platforms, and computer-assistance whereby image processing algorithms are applied to derive data of potential interest to the operator.

By their nature, advanced visualization systems process input data, typically DICOM image data from a variety of imaging modalities. In a typical imaging environment, the circumstances under which these images have been acquired are diverse, and hence the content of the images themselves are affected by a wide range of parameters that can interact with each other and affect the resulting images in complex and unpredictable ways.

When regulatory authorities review such systems, it is typical to focus on a specific set of reference data, and a narrow, often generic, indication for use. It would be impossible, in the context of such a regulatory process, to cover all possible combinations of the factors that influence the content of the images the system may process, or how future improvements to scanning technology may further impact the image content that the system may process in the future.

Variables that impact the performance of advanced visualization include (amongst other things) the body habitus of a specific patient, the specific type and concentration of contrast medium (if any), the administration parameters of any such contrast medium, the x-ray dose parameters selected for a given patient (if applicable), the possible use of novel reconstruction techniques on the acquisition device to improve image quality with lower-dose scans, and any complex co-morbidities the patient may have which could impact the imaging acquisition. These parameters can vary significantly from those that were available and used, when a technique was originally submitted for regulatory review.

This variability has consequences regarding measurement and other tools provided in advanced visualization systems. Such tools can be validated and relied upon for geometric quantities (for example, length, volume, change in pixel intensity over time, location of image areas with a certain shape profile), but should not be relied upon in terms of physiological quantities (for example, ejection fraction, cerebral blood volume, location of tumors), since these quantities are related to the geometric quantities in complex and unpredictable ways that the advanced visualization software cannot fully determine from the input data.

It should also be noted that even geometric measurements rely upon the calibration data provided in the DICOM header that is generated by the image acquisition device and hence such tools are more "calculating tools" than "measuring tools", since any quantitative data reported is only as accurate as the underlying calibration of the input data.

Noble efforts are underway to establish standards and to define validated algorithms for quantitative imaging, under well-defined and controlled circumstances, driven by the Radiological Society of North America (in the form of the Quantitative Imaging and Biomarkers Alliance, or QIBA) and by the American College of Radiology (in the form of ACR Image Metrix). TeraRecon enthusiastically supports such efforts and has actively participated. However, to date, such standards have not yet been fully defined by these standards organizations and consequently software companies have not adopted a unified standard.

Accordingly, until industry-wide reference standards are defined and adopted for such advanced visualization techniques, TeraRecon advises that advanced visualization techniques should be used with care, and that beyond the core indication for use of multi-dimensional geometric measurement, shape detection and advanced 3D visualization using an off-the-shelf computer, no assumption is made regarding the validation of the system or its suitability for use in any specific medical undertaking. Independent confirmation via an alternative validated technique is always advisable, and only the professional judgment of a qualified and authorized physician can determine patient care decisions. Using such tools in this way, and in this context, ensures the appropriate and safe use of the technology for the optimum benefit.

Note: iNtuition refers to the family of Aquarius products "Aquarius Workstation", AquariusNET Server, and Aquarius APS Server.

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

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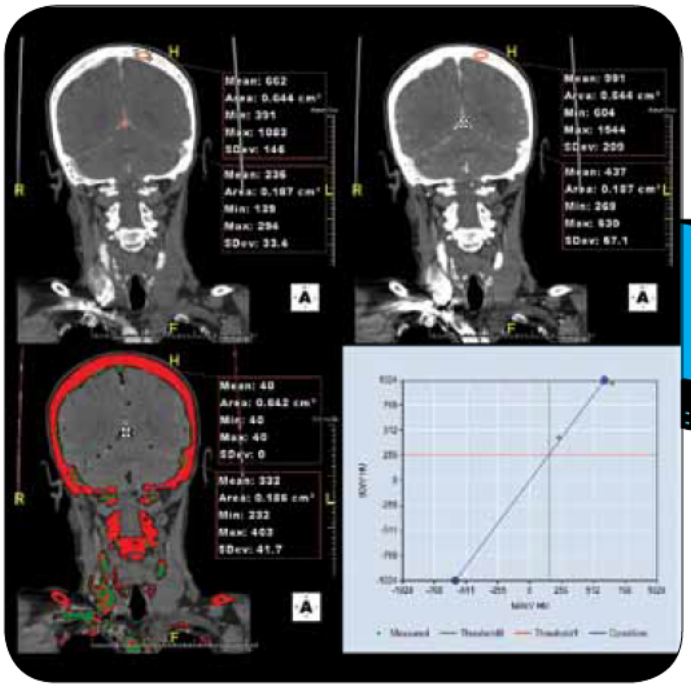
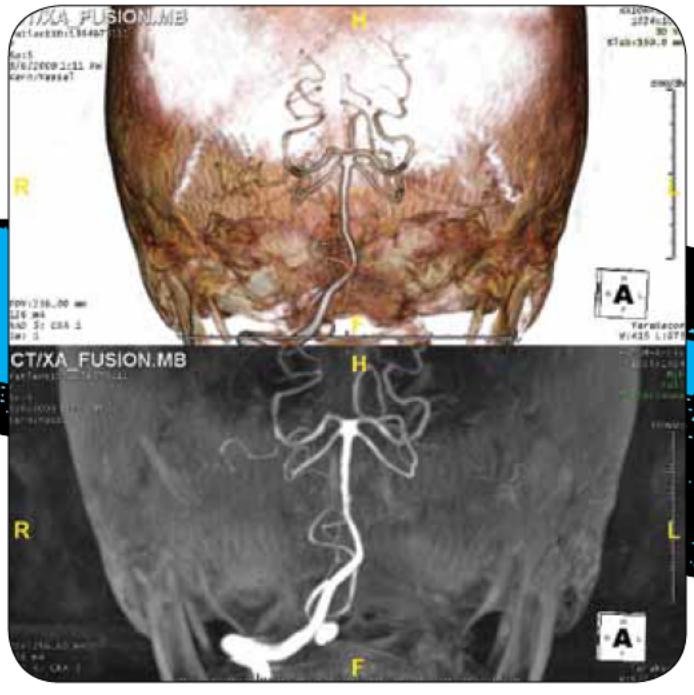
NEUROIMAGING

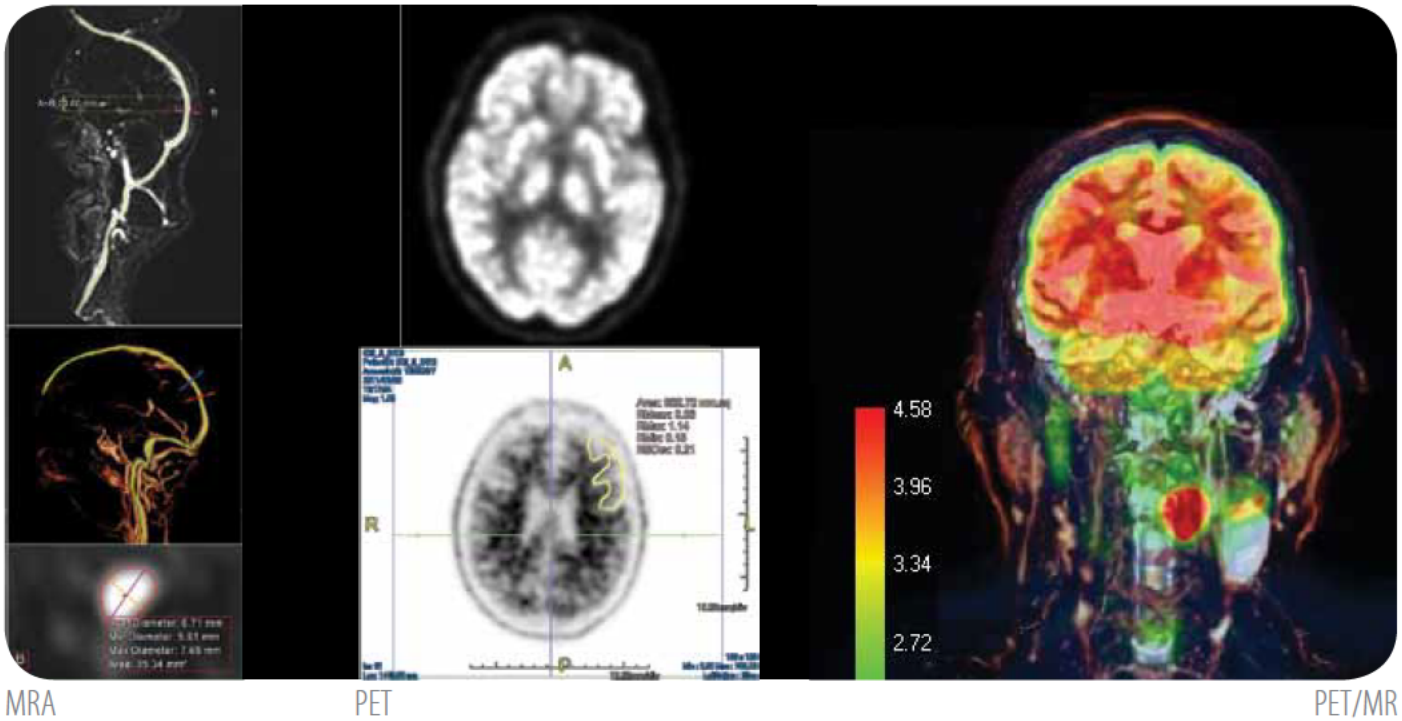
iNtuition supports the widest range of tools for neuroimaging analysis and research, from 3D visualization to parametric analysis to segmentation, tracking and analysis. iNtuition's unparalleled performance advantage enables fast processing and visualization of 4D volumetric acquisitions, and optimum workflow for the most time-sensitive examinations.



MultiKV Toolkit



CT/XA Fusion



MRA PET PET/MR

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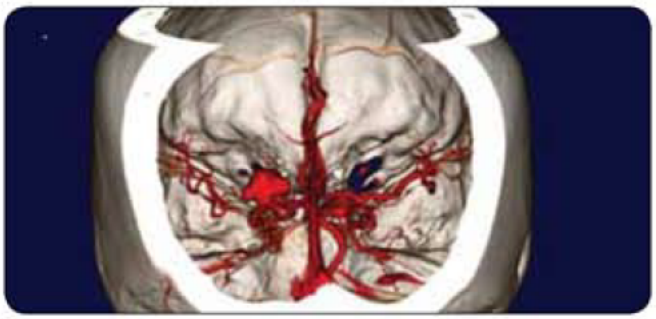
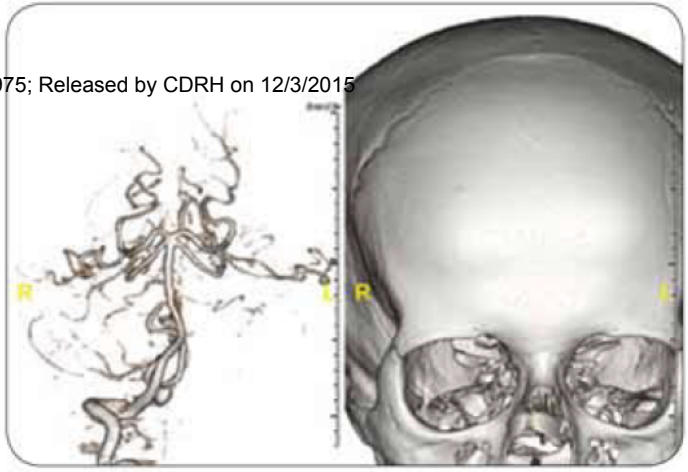
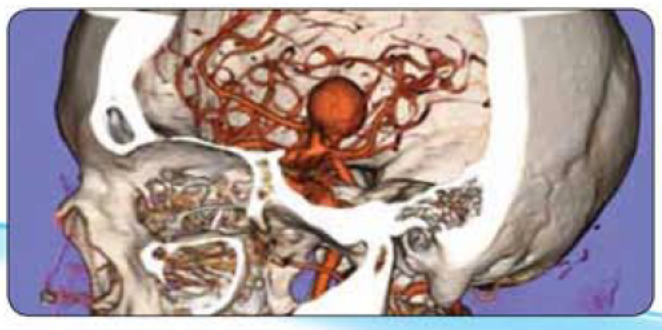
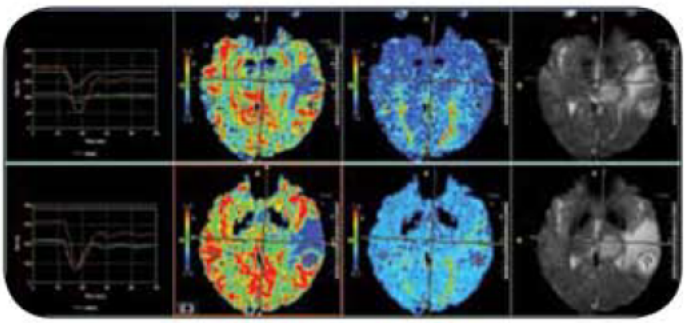


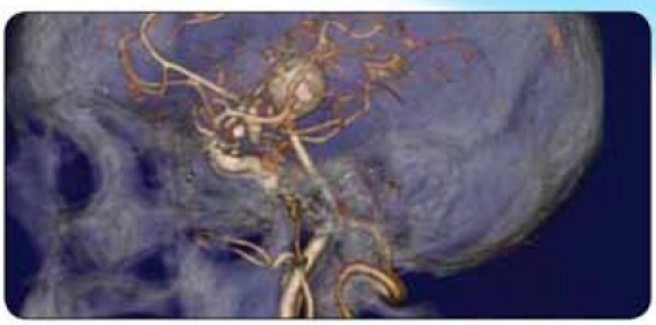


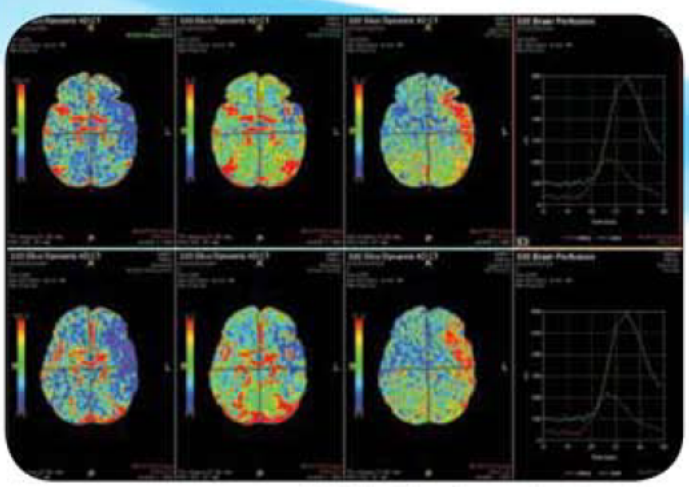
Segmentation & Visualization





MR TDA - Time Dependent Analysis





CT TDA - Time Dependent Analysis

Optional Modules for Neuroimaging

- [x] Vessel Analysis
- [ ] Calcium Scoring
- [x] TDA - Time Dependent Analysis
- [x] CT/CTA Subtraction
- [ ] LD - Lobular Decomposition
- [x] iGENTLE
- [x] SAT - Segmentation Analysis & Tracking
- [ ] TVA - Time Volume Analysis
- [ ] Maxillo-facial
- [ ] Flythrough
- [ ] Volumetric Histogram
- [ ] Findings Workflow*
- [x] Fusion for CT/MR/PET/SPECT
- [ ] Multi-Phase MR
- [ ] Parametric Mapping
- [ ] Spherefinder
- [x] MultiKV*

*Scheduled for early-2013

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SAFETY FIRST! Read our position statement, inside page 5 flap.

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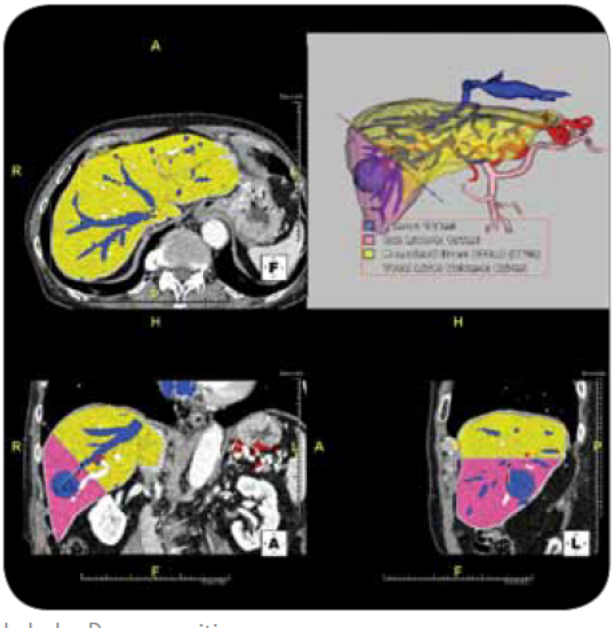
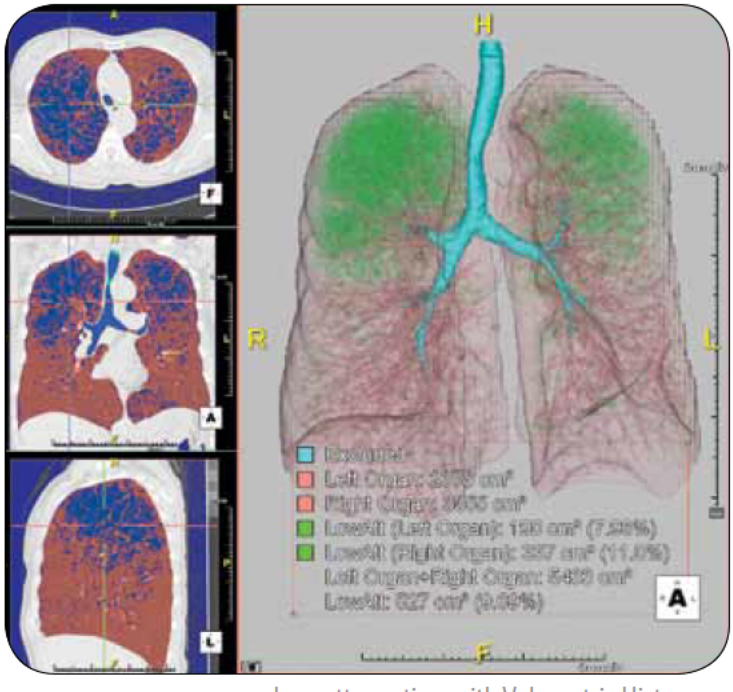
ONCOLOGY & CLINICAL RESEARCH

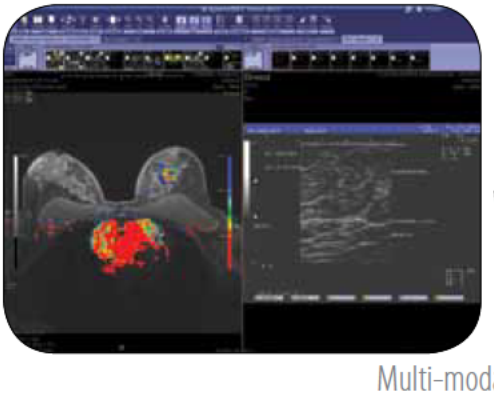
iNtuition offers an unparalleled suite of **Quantitative Imaging** capabilities to support in oncology and clinical research. However, even more than this, iNtuition offers a deeply sophisticated and powerful image management engine to support the most demanding distributed projects, to provide image routing, anonymization, upload and sharing, and to eliminate the need for CDs. Let iNtuition enhance your research program and reduce your research management costs.

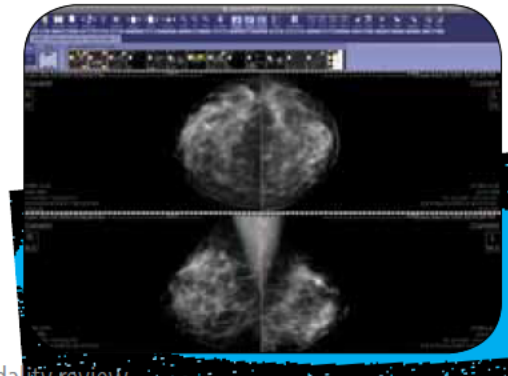


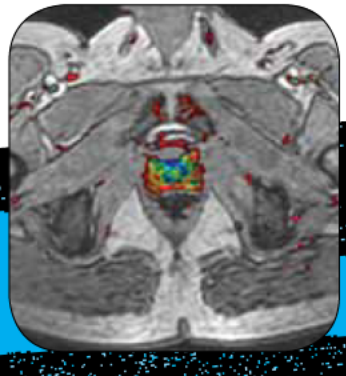
Lobular Decomposition



Low attenuation with Volumetric Histogram





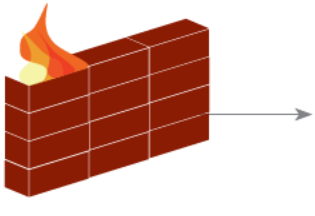


Multi-modality review

Secure upload and image sharing for clinical trial management...

iNtuition UPLOADER
(with SSL encryption)

Remote site firewall



Core lab firewall

Core lab iNtuition Servers

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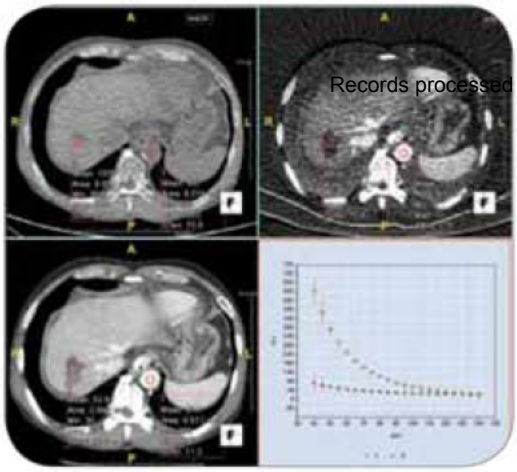
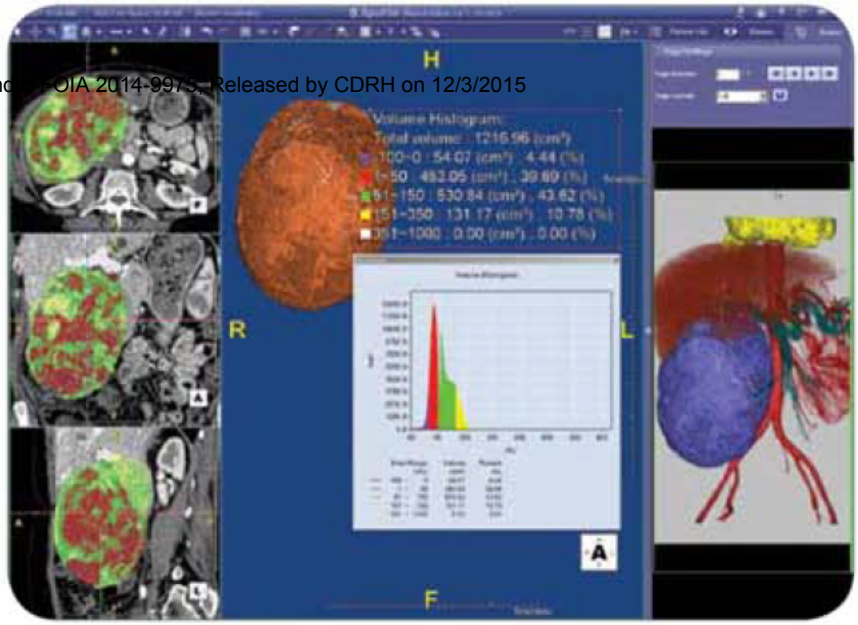
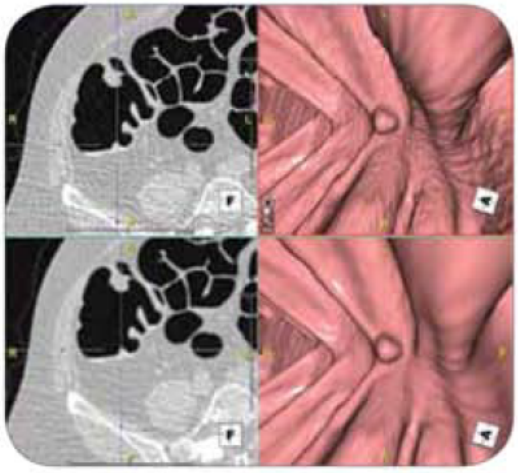


MultiKV – Dual Energy & Spectral Imaging

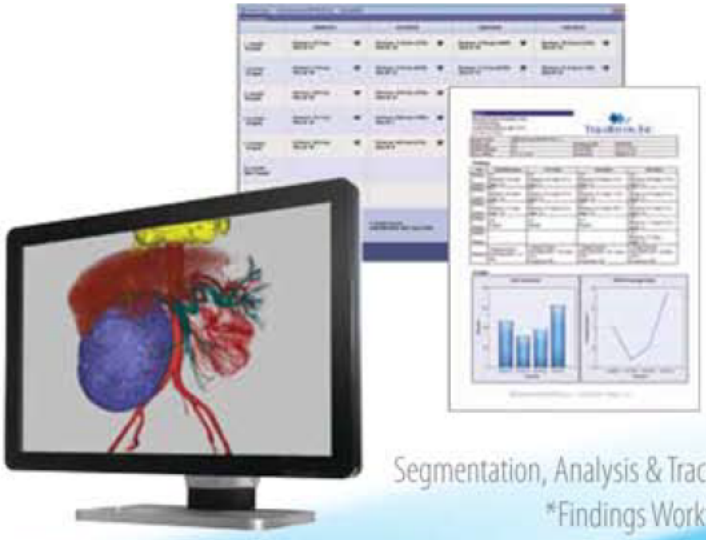


Analysis with Volumetric Histogram



iGENTLE

General Enhancement & Noise Treatment with Low Exposure
An advanced volumetric filter architecture applying noise management techniques to improve the effectiveness of 3D, centerline, contouring and segmentation algorithms even when source image quality is not optimum.



Segmentation, Analysis & Tracking
*Findings Workflow

Optional Modules for Oncology & Clinical Research

- ☐ Vessel Analysis
- ☐ Calcium Scoring
- ☐ TDA - Time Dependent Analysis
- ☐ CT/CTA Subtraction
- ☐ LD - Lobular Decomposition
- ☐ iGENTLE
- ☐ SAT - Segmentation Analysis & Tracking
- ☐ TVA - Time Volume Analysis
- ☐ Maxillo-facial
- ☐ Flythrough
- ☐ Volumetric Histogram
- ☐ Findings Workflow*
- ☐ Fusion for CT/MR/PET/SPECT
- ☐ Multi-Phase MR
- ☐ Parametric Mapping
- ☐ Spherefinder
- ☐ MultiKV*

*Scheduled for early-2013

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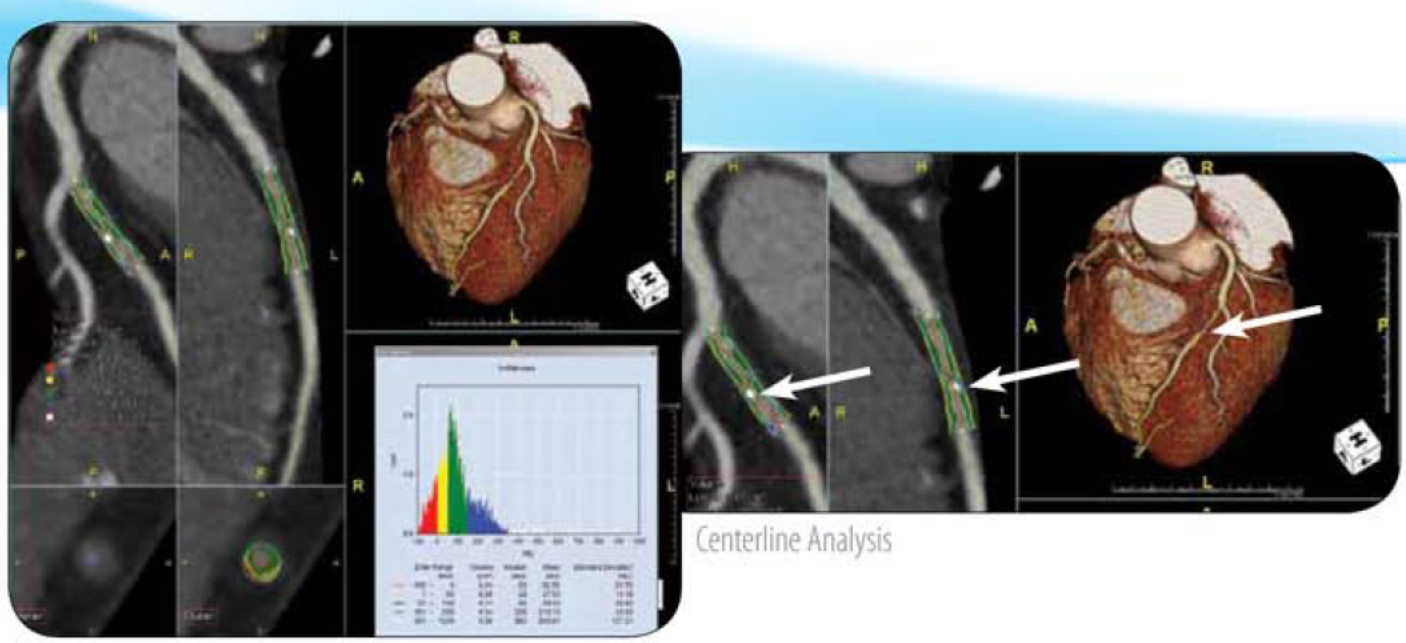
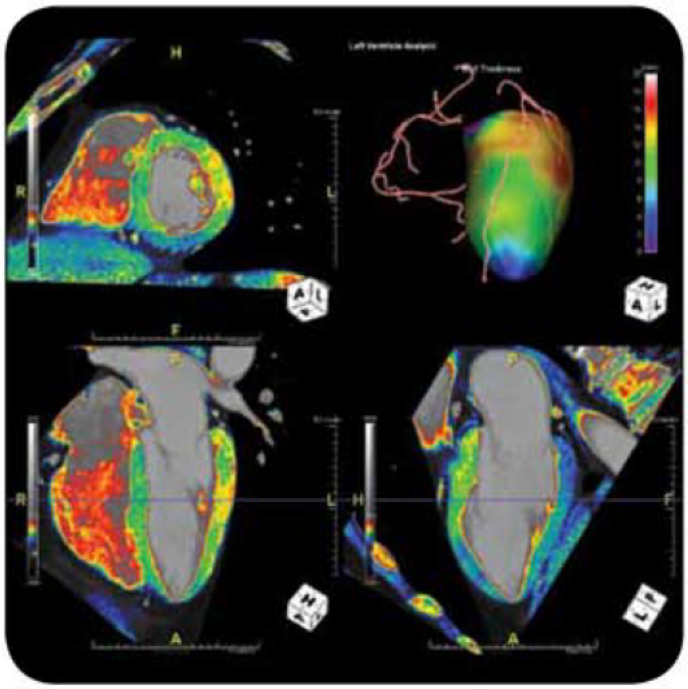
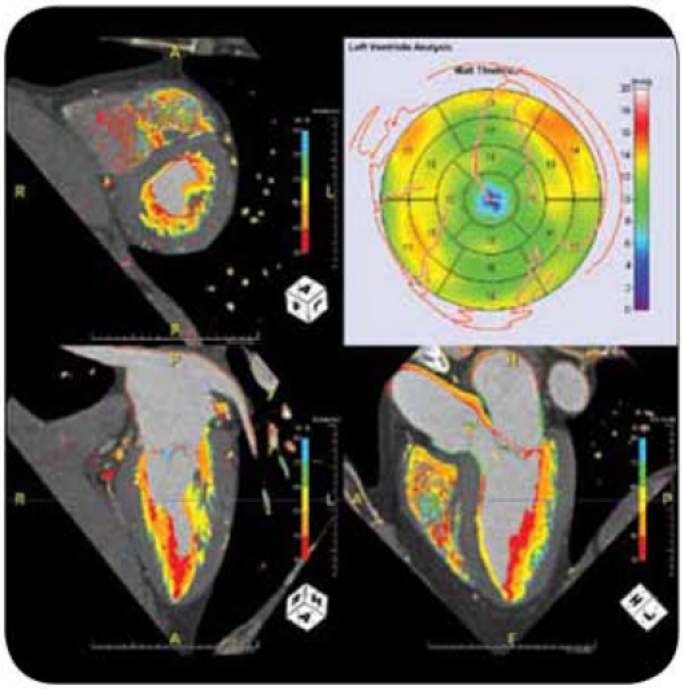
For over a decade, TeraRecon has been the leading pioneer and innovator in the field of visualization tools for volumetric cardiac and coronary imaging. This tradition of innovation continues as iNtuition expands support for additional modalities and analysis techniques supporting both diagnostic interpretation, and clinical research, leveraging the power of the iNtuition workflow.



Centerline Analysis



TVA – Time Volume Analysis & Enhancement Analysis



Territory & Motion Maps

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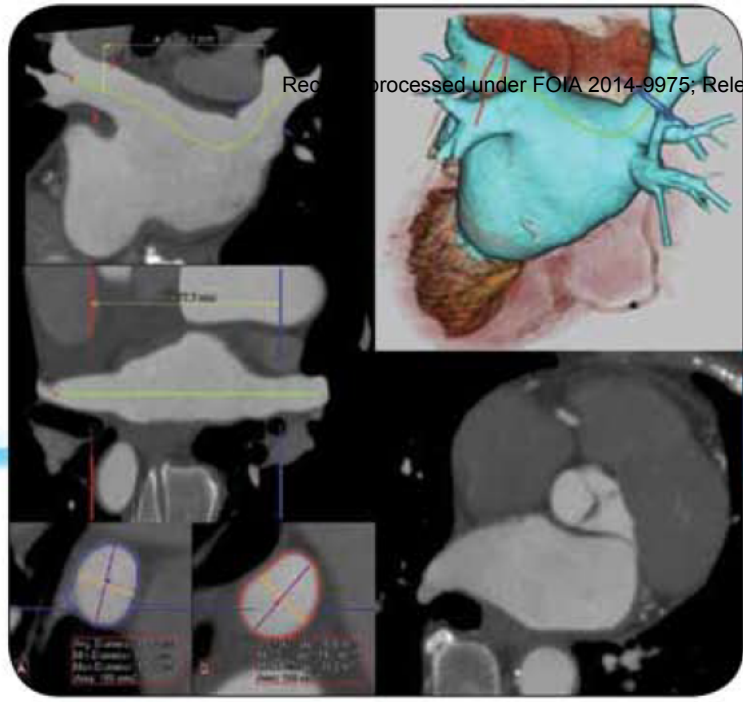
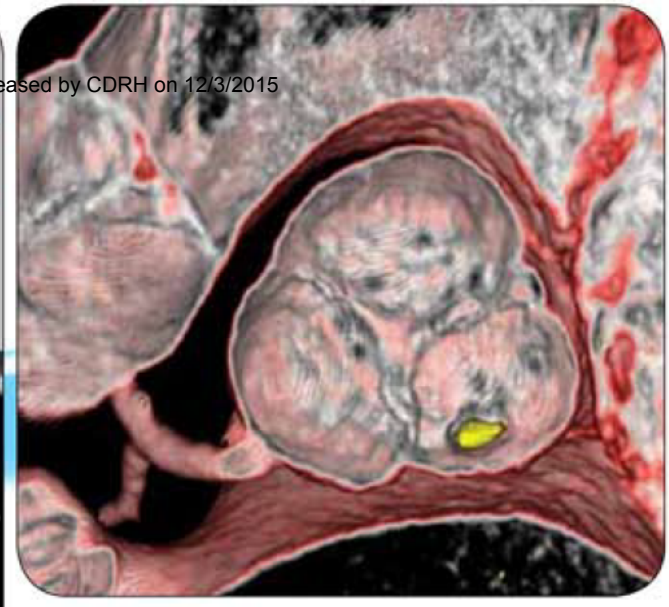
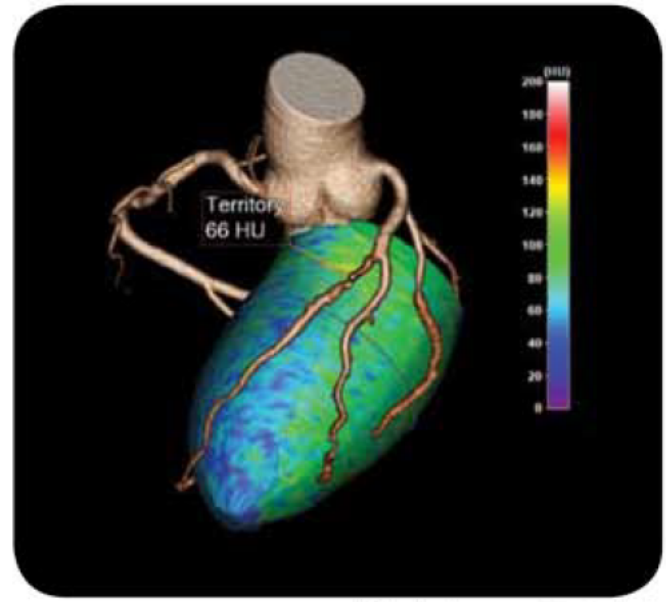




LA Visualization



LSA - Lesion-specific Analysis

Optional Modules for Cardiac & Coronary

- [x] Vessel Analysis
- [x] Calcium Scoring
- [ ] TDA - Time Dependent Analysis
- [ ] CT/CTA Subtraction
- [ ] LD - Lobular Decomposition
- [x] iGENTLE
- [ ] SAT - Segmentation Analysis & Tracking
- [x] TVA - Time Volume Analysis
- [ ] Maxillo-facial
- [ ] Flythrough
- [ ] Volumetric Histogram
- [x] Findings Workflow*
- [x] Fusion for CT/MR/PET/SPECT
- [x] Multi-Phase MR
- [ ] Parametric Mapping
- [ ] Spherefinder
- [x] MultiKV*

*Scheduled for early-2013

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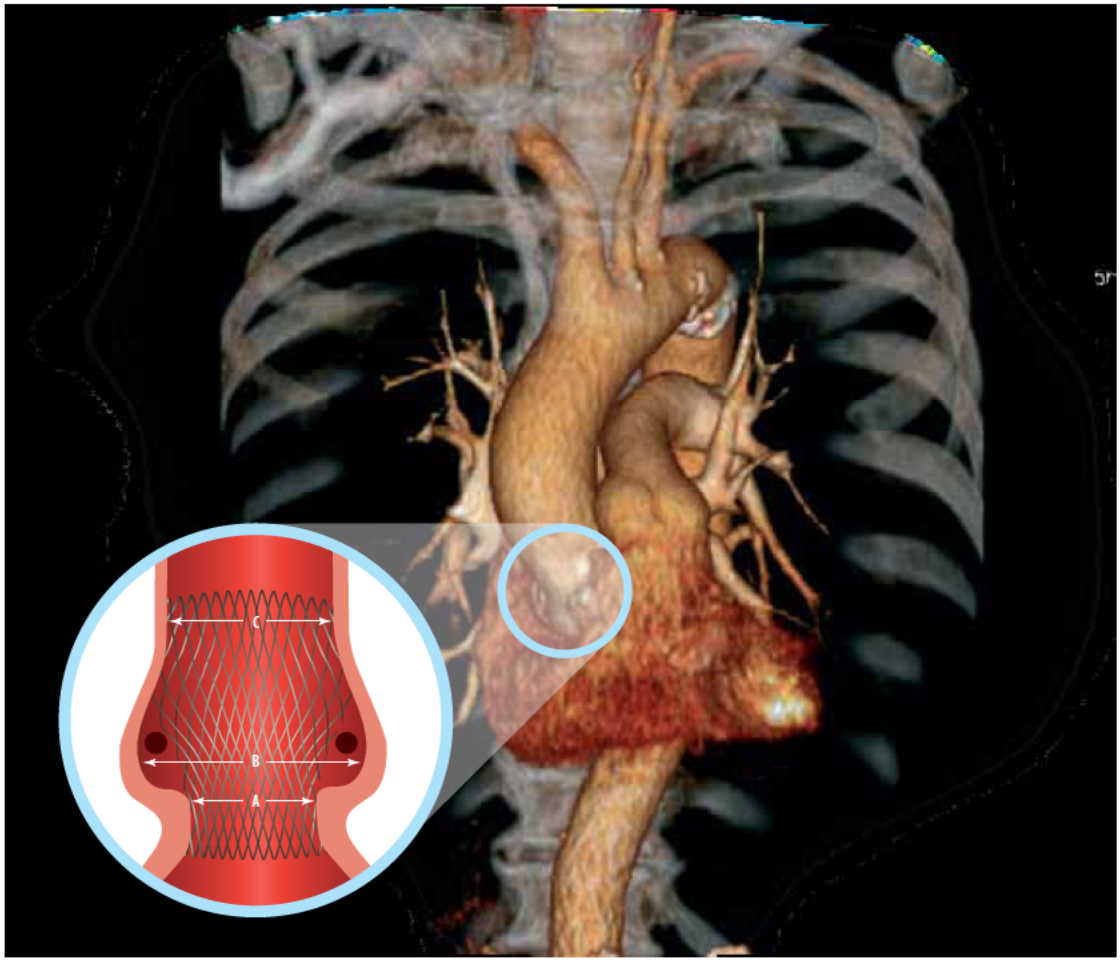
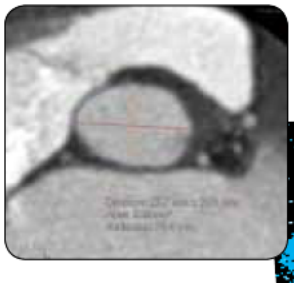
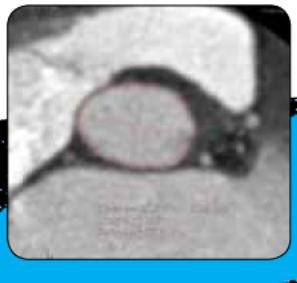
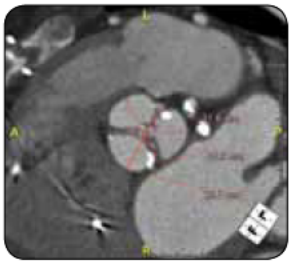
VASCULAR & INTERVENTIONAL

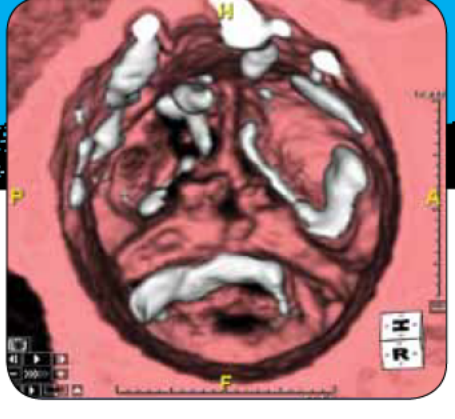
iNtuition defines the standard for advanced visualization support in interventional planning and follow-up, unmatched in the industry. Long accepted as the platform of choice for EVAR, iNtuition continues this tradition of unparalleled vascular workflow and efficiency, in support of new procedures like TAVI, and established protocols such as carotid and peripheral intervention.











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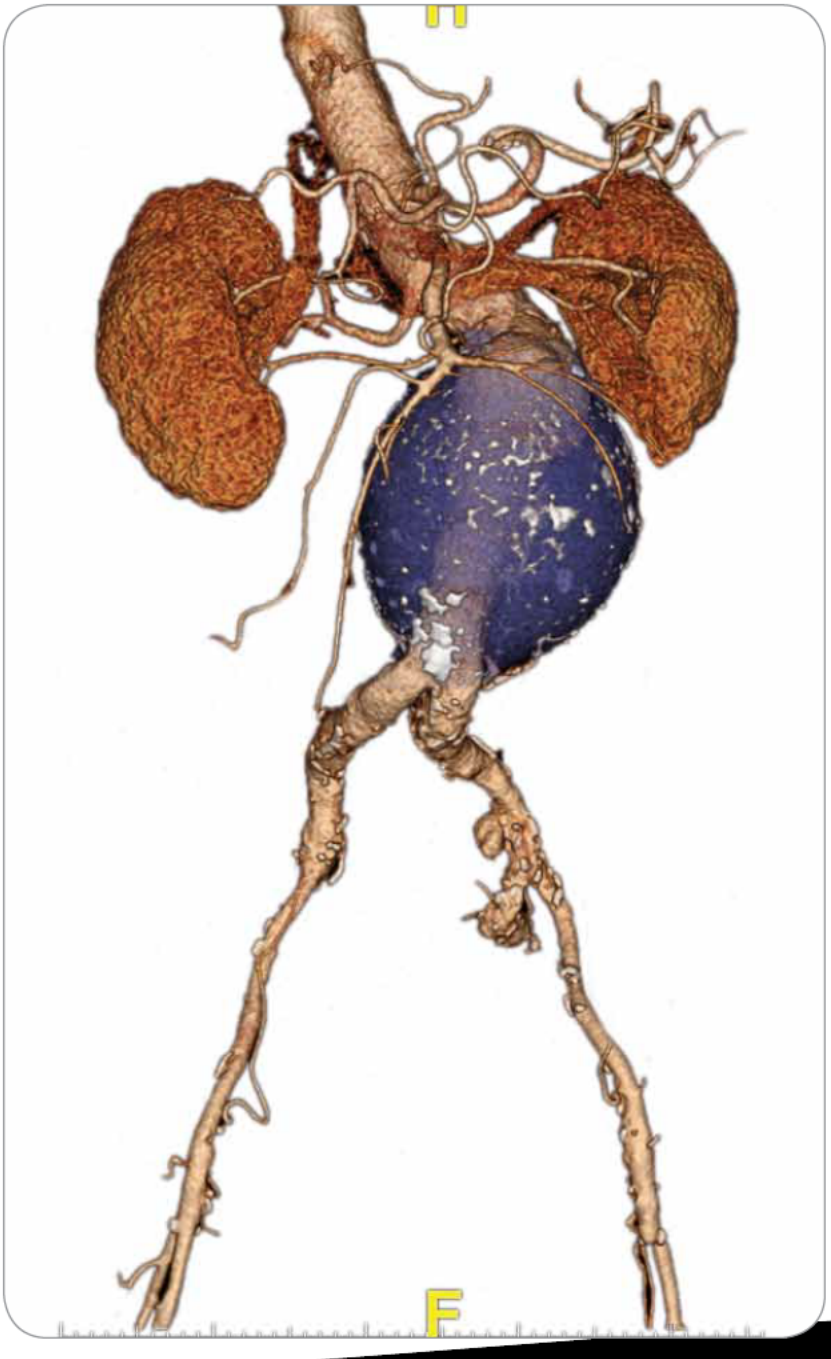

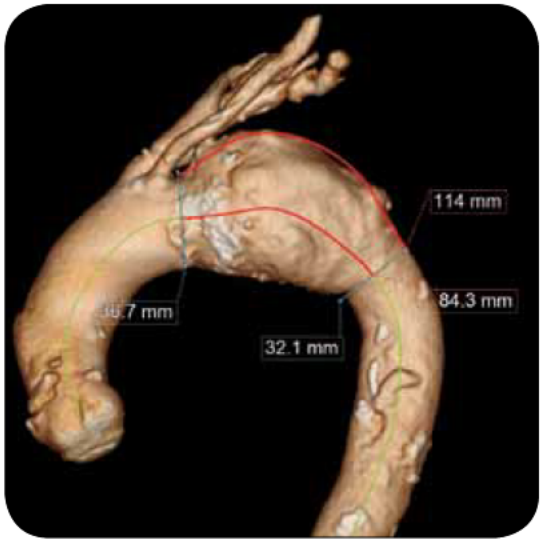

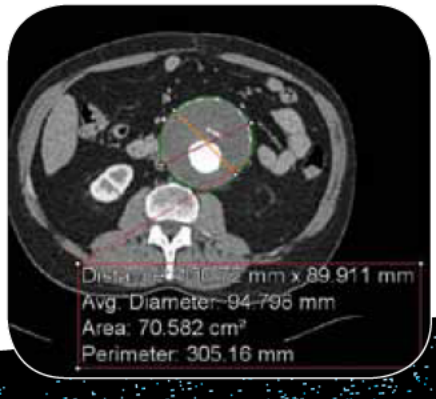

Optional Modules for Vascular & Interventional

- [x] [illegible]
- [ ] TDA - Time Dependent Analysis
- [x] CT/CTA Subtraction
- [ ] LD - Lobular Decomposition
- [x] iGENTLE
- [ ] Maxillo-facial
- [ ] Flythrough
- [x] Volumetric Histogram
- [x] Findings Workflow*
- [ ] Multi-Phase MR
- [ ] Parametric Mapping
- [ ] Spherefinder
- [x] MultiKV*

*Scheduled for early-2013

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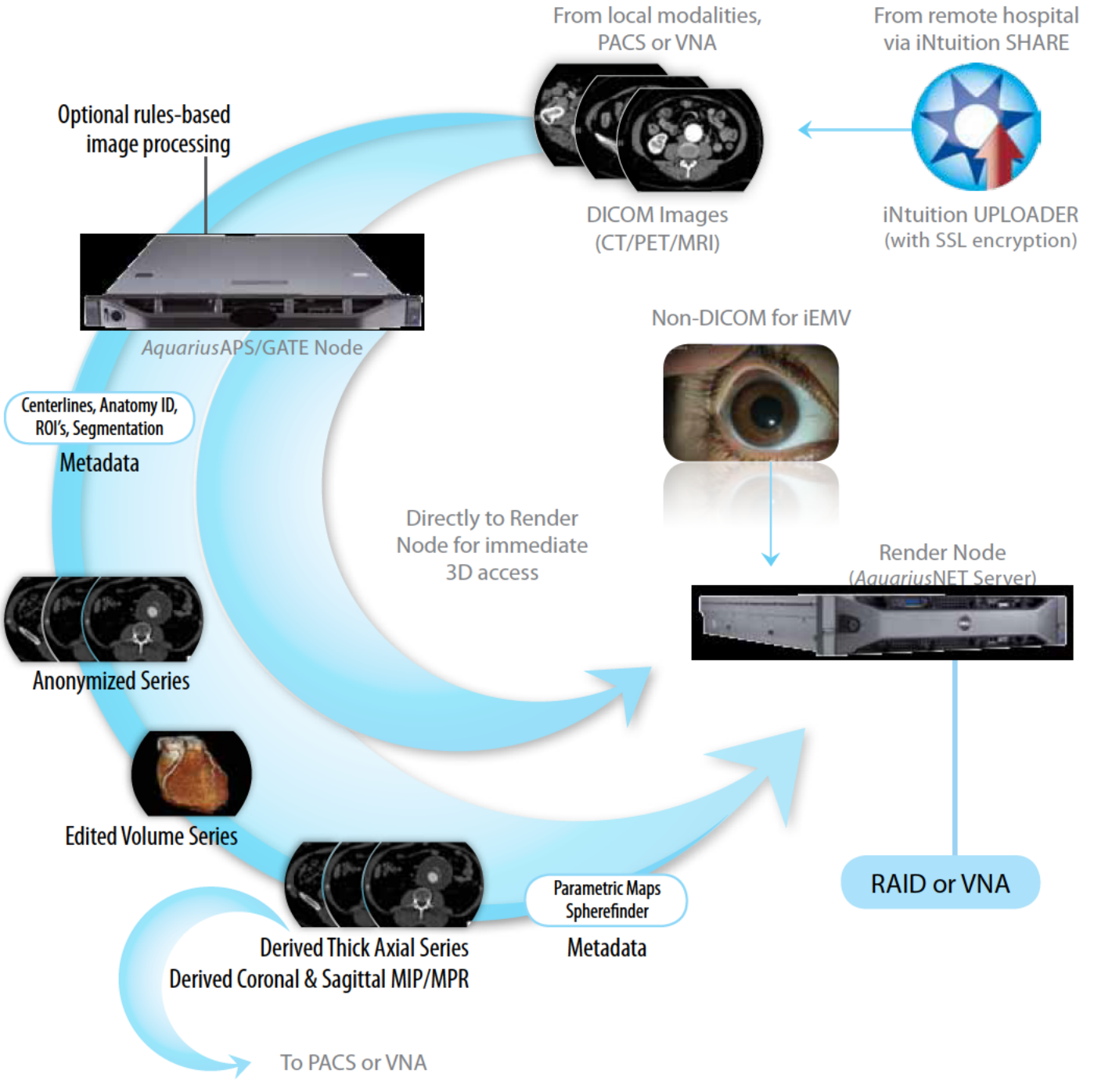
Architectural Excellence

There is no solution available on the market today that comes close to iNtuition, in terms of architecture and scalability. The smallest hardware footprint, the most powerful rendering with the lowest power consumption, and extensive support for high availability, load-balancing, distributed or centralized processing, and server and application virtualization. Look behind iNtuition's powerful clinical applications and you will find the result of a decade of innovation in advanced imaging informatics, which is unmatched by any competing solution.



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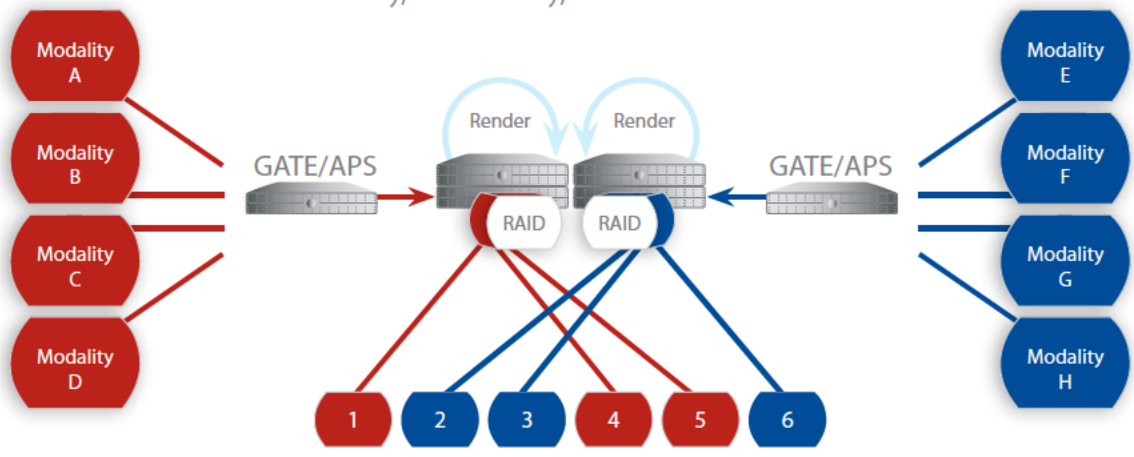
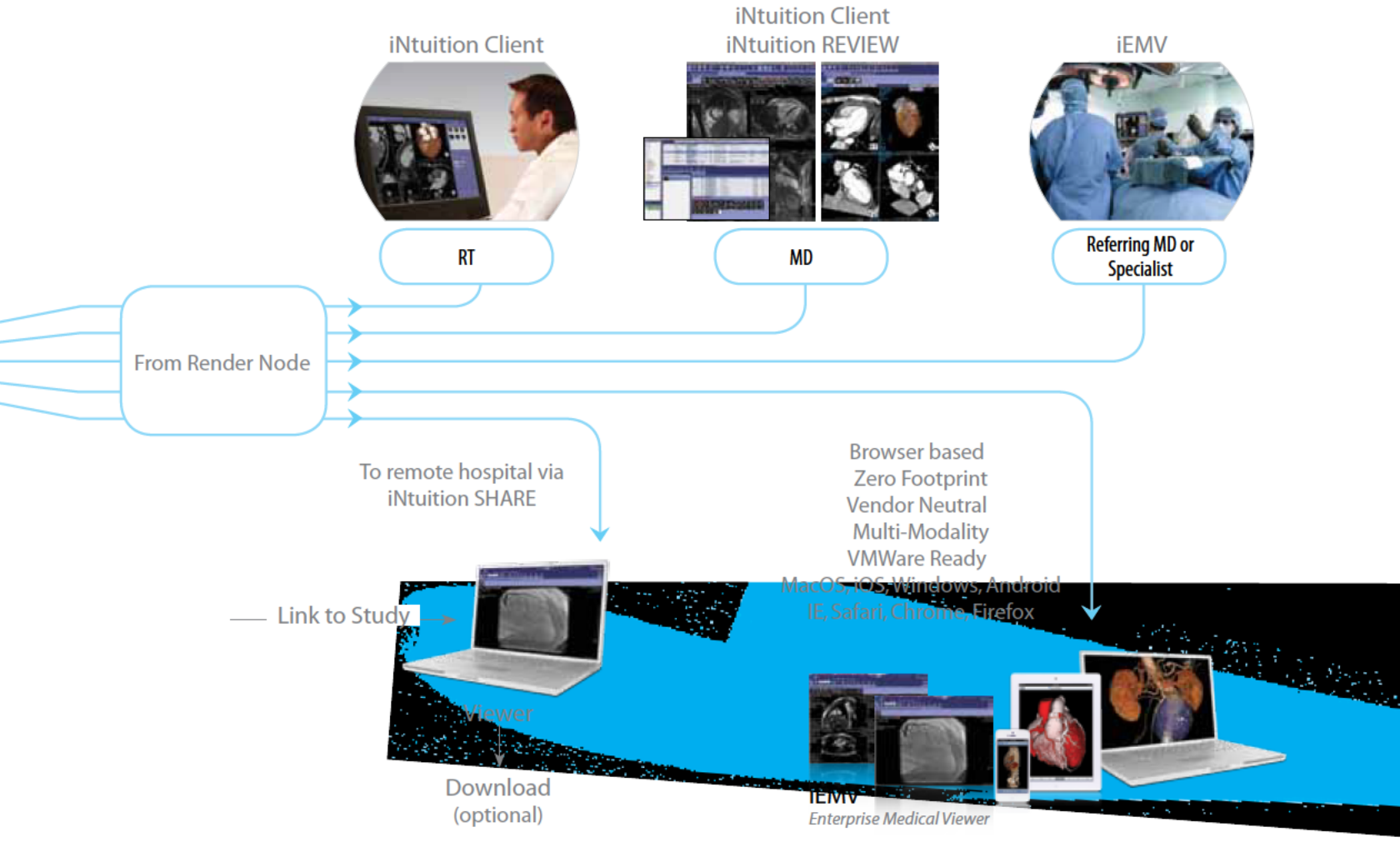
Mutual Awareness

Scalability, Redundancy, Distributed or Centralized



Clients evenly distributed among render nodes



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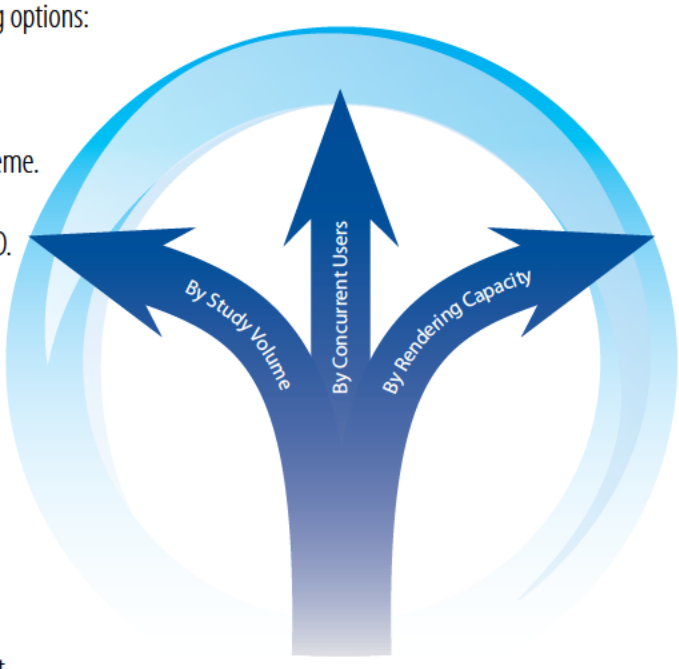
Licensing & Professional Services

iNtuition: Licensing Unlimited

iNtuition offers more power, more capacity and more true client-server features than any other solution on the market today. Combined with the best price: performance ratio amongst its peers, this ensures iNtuition is the best value proposition, by far. Furthermore, to help you optimize your iNtuition investment, TeraRecon offers the following flexible licensing options:

iNtuition UNLIMITED: Enterprise Software Licensing

iNtuition UNLIMITED is TeraRecon's unique and flexible licensing scheme. Select and fix one parameter – study volume, concurrent users, or concurrent slice rendering capacity, and the other two are UNLIMITED. Select the locations where servers will be deployed, and then over time, deploy hardware as needed to support your workflow, sharing the same iNtuition UNLIMITED license. iNtuition UNLIMITED scales with your enterprise, within a well-defined multi-year total cost of ownership.



iNtuition Appliance: Turnkey Server Licensing

When a fixed server deployment fits the need and budget, iNtuition Appliance licensing is the ideal choice. iNtuition Appliance licensing allows you to purchase node-locked rendering capacity or concurrent users. With the largest data capacity in the industry, the rendering power to actually use it all, and the smallest rack footprint, iNtuition clearly stands in a class of its own.

TeraRecon Professional Services

An iNtuition deployment typically has tremendous latent capability, which is often not fully appreciated or leveraged in an initial deployment, where time and resources are focused on achieving the core needs of an institution at the time, as defined in the purchasing process. However, as time moves on, staff change, and the goals and capabilities of your imaging enterprise evolve, it is very possible that you already have what you need to meet your changing requirements, already available in your iNtuition system. TeraRecon's global professional services organization is available and working daily to help our customers get more from their iNtuition solution, through training, expert IT consulting, and deployment customization services. If you are already one of TeraRecon's thousands of customers, contact your representative today for a free initial consultation about how to maximize your investment in iNtuition to meet the needs of your enterprise.

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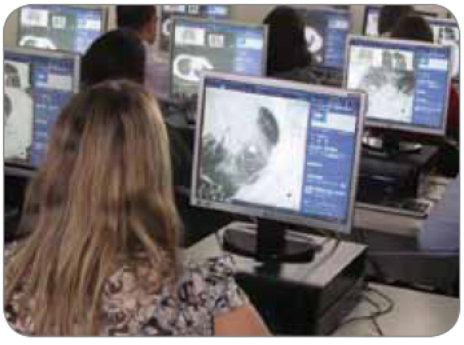

Training and Education

As part of a new iNtuition deployment, TeraRecon recognizes that training is the cornerstone of a successful implementation. For existing iNtuition installations, as staff and situations change over time, our professional educators are available to help with keeping skills current, and optimizing iNtuition for your evolving needs.

TeraRecon offers a variety of training options, from onsite applications training to interactive web-based training, or offsite training courses. Amongst other locations worldwide, regular training courses are held at our global HQ just 15 minutes from San Francisco airport.

To learn more about the available educational options, please contact your representative or visit the education section of our website:

www.terarecon.com/education ... or send us an email: education@terarecon.com

Award Winning Innovation

TeraRecon has been consistently recognized by independent research for innovation, technology and clinical excellence. "The leading independent vendor in the North American advanced visualization industry today", with the highest ratings for "remote access and integration", "most advanced technology", "Highest performance", "Highest ratings for customer satisfaction" and "Highest ratings for ease of use". "TeraRecon the market leader for delivering advanced visualization enterprise-wide".

7-time Frost & Sullivan Award Recipient, 2002-2012

Interoperability UNLIMITED

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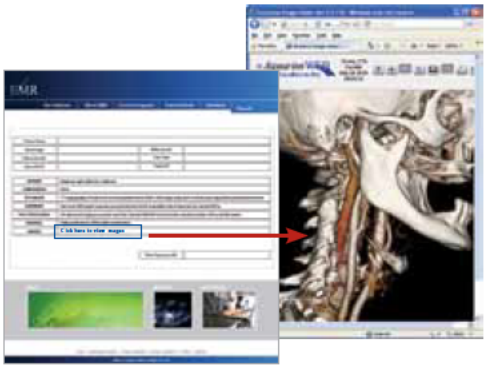

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120512-AQB-Company-A4

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16.1 Level of Concern

TeraRecon Inc. has determined the level of concern of this device to be (b)(4) [redacted]. This is consistent with FDA Guidance Document "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices (May 11, 2005)." Justification and rational for this determination is included in paragraphs below:

Major Level of Concern

If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.

1. Does the Software Device qualify as Blood Establishment Computer Software? (Blood Establishment Computer Software is defined as software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.)

Response) No. iNtuition-TDA, TVA, Parametric Mapping are standalone software/ applications, designed for use in medical device imaging management

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

Response) No. iNtuition-TDA, TVA, Parametric Mapping are standalone medical imaging software/ applications that do not require any drug or biologic for its performance.

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

Response) No. iNtuition-TDA, TVA, Parametric Mapping are standalone medical imaging software/ applications . They are not an accessory.

4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:

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

   Response) No. iNtuition-TDA, TVA, Parametric Mapping are not used in a life supporting or life sustaining application

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

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Response) No. Ntuition-TDA, TVA, Parametric Mapping do not contain or control any potential sources of harmful energy.

c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?
Response) No. iNtuition-TDA, TVA, Parametric Mapping do not control the delivery or treatment of any therapy.

d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?
Response) (b)(4) [redacted]

e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?
Response) No. iNtuition-TDA, TVA, Parametric Mapping are not monitoring devices.

Moderate Level of Concern

If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.

1. Is the Software Device an accessory to a medical device that has a Moderate Level of concern?

Response) No. iNtuition-TDA, TVA, Parametric Mapping are standalone medical imaging software/ applications . They are not an accessory.

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

(b)(4) [redacted]

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

Response) (b)(4) [redacted]

Conclusion: Level of Concern is Moderate.

Based on the above responses to questions under major and moderate level of concern, iNtuition-TDA, TVA, Parametric Mapping qualify as (b)(4) [redacted] application.

The risk management activity identifies potential hazards during software life cycle and addresses and mitigates of such occurrences.

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16.2 Software Description

iNtuition – TDA, TVA, Parametric Mapping are post-processing modules intended to provide solutions to various medical image analysis and viewing problems, which come about as modalities generate more and more images. It also supports image distribution over networks, and is DICOM compliant.

(b)(4)

[redacted]

TeraRecon seeks clearance for the following three optional features:

1: TDA – Time-Dependent Analysis (Optional Feature)

The TDA tool provides for the analysis of time-dependent data such as can be obtained with CT, MR and other volumetric imaging modalities. Such data presents either as a slice or stack of slices through a section of the subject of the scan, which is repeatedly scanned in time to provide an image data set with at least two spatial dimensions, and potentially three, plus one dimension of time (3D plus time is referred to as 4D). The TDA tool allows analysis of such dynamic data which is obtained to aid in the assessment of time-dependent behavior of the image intensity or density of regions of interest. Such 2D+time or 3D+time (4D) imaging acquisitions are typically performed by physicians to study perfusion of blood into or around tissue in the brain or other organs, pathology, or regions of the body.

After a registration step by the user to remove the effects of global motion between the acquisitions, the software provides the ability to study the time-dependent behavior of voxels within a given volume of interest, through the creation of parametric maps which encode the time-dependent behavior of each voxel in the form of color overlays. Such parameters include time to peak, mean time to enhance, take off time, recirculation time, mean transit time (MTM), blood volume (BV/CBV) and blood flow (BF/CBF). The reported quantities relating to the delivery of arterial blood, such as blood volume (BV/CBV) and blood flow (BF/CBF), are derived from stated assumptions regarding the relation between the other parametric quantities and these quantities and are intended to be considered only in the context of these assumptions. The calculations are based upon the user's selection of image regions corresponding to input to (e.g. artery and/or portal vein) and output from (e.g. vein) the closed fluid system.

(b)(4)

[redacted]

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(b)(4) CCI

[redacted]

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(b)(4) [redacted]

(b)(4) [redacted] which are prepared for confirmation and acceptance by the user, or correction, as appropriate, to achieve the user's desired analysis goal.

Multiple such parametric maps can then be displayed at the same time in a many-on-one screen display, potentially in combination with the original source data in 2D or 3D mode, with the ability to cine in time as necessary to see the dynamic evolution of the original acquisition. All these datasets may then be manipulated in synchrony, with the ability to apply cutplanes or oblique reformats, to review the parametric maps or original source data at any given location or set of locations.

Specific regions of interest can be delineated, and if a plane of symmetry has been defined and confirmed by the user, the corresponding matching region or regions of interest will be created on the opposite side of the plane of symmetry, to speed comparison analysis in approximately symmetric structures (such as the brain). Groups of such regions of interest can be defined and saved as a template for later application to different datasets, to allow organized comparison from scan to scan over time. For the regions of interest so defined, the software will report the various parameters from all the parametric volumes and potentially the original data, in terms of mean quantities calculated within the region of interest and possibly other derived values such as standard deviation. These will be reported in a table of results where further tools to compare, combine and report on these readouts will be provided. It will also be possible to view the volumetric data in simple Axial, Coronal and Sagittal planar slice or slab views, with similar measurement and reporting tools provided.

(b)(4) [redacted]. Each class is then assigned a color for overlay such that classification maps can be viewed overlaid on the original images or other parametric images.

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Note: (b)(4) [redacted].

A report can be generated from the captured images, maps and graphs with measurement results and saved or exported as text file, comma-separate-value file, XML file or DICOM secondary capture object.

2: TVA – Time Volume Analysis (Optional Feature)

The TVA module provides tools to support the efficient analysis of a volumetric, time-dependent scan (e.g. CT, MR) of a chamber in rhythmic motion, such as a cardiac atrium or ventricle, with the goal of providing a framework to investigate the extent to which the motion is even and consistent, and to enable quantification of various parameters derived from volumetric regions of interest defined by the user.

The system opens the image set in question and presents an overlay which the user should then adjust to delineate the wall boundaries that are of interest. (b)(4) [redacted]

Stroke volume, (b)(4) [redacted] is also reported. The wall volume (b)(4) [redacted] and wall thickening are reported. Tabulated reporting output is included. The selected volume between the user defined inner and outer boundaries is also presented in the form of graphs or polar plots showing the various parametric quantities with color encoding. If available, centerlines obtained from the vessel analysis feature can be overlaid on the volumetric visualization to illustrate the juxtaposition of the selected volume of interest and vascular structures. Report output is supported, with importation of calculated parameters into a predefined template, which can be adapted to the needs of the user. A color-coded MPR overlay within the volume of interest is supported, to better enhance small differences in image contrast, which may be employed to help illustrate areas of low enhancement by a user, for the purposes of communicating findings. The multi-phase data can also be represented in a single 2D image in which the location of the boundaries in question are represented by different color bands, corresponding to different positions in time, to illustrate the motion present in multiple time points, in a single 2D image.

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The features herewith are equivalent when compared to legally marketed device (Refer V&V documents in Section 16) and do not introduce any new risk for safety and effectiveness.

Note: The user is obliged to define the wall boundaries in question.

(b)(4)

[redacted]

3: Parametric Mapping (Optional Feature)

The Parametric Mapping module analyzes a set of CT or MR images which represent the same location in space over a certain period of time. The module may perform a registration step first to ensure good spatial correlation between the images in case the subject of the scan may have moved during the examination. Each pixel in the images is analyzed for its behavior over time. Typically in such scans, pixels within certain organs will become bright at the start of the time period and then fade out over time. Information relating to the delay with which pixels come bright, and how quickly they fade out over time (if at all), can on occasion be useful to a reviewer of these images and being able to present this information as a color overlay aids with rapid identification by the user of areas worthy of more detailed examination. The module creates "parametric maps" charting values for all these pixel-by-pixel behaviors for each pixel in the images. These maps may be displayed by another device (image review system) to help save the user time of calculating these values manually. The parametric mapping tool may be focused on a specific region of interest such as the area of a scan relating to heart, brain, lung, or liver, to prevent distracting color overlay being created in non-relevant areas. Secondary capture images can be created automatically containing the color overlay, for later review.

(b)(4)

[redacted]

There is no change to the core parametric algorithm listed above, the same as previously cleared product (K061214). There are changes made to improve the visual appearance:

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1. Reduce isolated noise
2. Provide rainbow color map option, in addition to the standard solid color map, for users.

Note: The user is obliged to define the parameter ranges in question. When first accessed, the user interface for setting these parameters holds generic default values with no significance and the user must acknowledge this by dismissing a warning message to this effect.

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Parametric map result validation

(b)(4)

[redacted]

(b)(4)

[redacted]

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(b)(4) [redacted]

Data 3 - (b)(4) [redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

(b) (6)

[redacted]

(b) (6) [redacted] Radiologist

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16.3 Device Hazard Analysis

(b)(4)

[redacted]

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(b)(4)

[redacted]

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16.4 Software Requirements Specifications (SRS)

Hardware requirements:
The hardware platform for iNtuition – TDA, TVA, Parametric Mapping is an "off-the-shelf" personal computer running Microsoft Windows Operating System, or equivalent. The server software supports single or multiple processors as supported by the operating system providing they are of (b)(4) [redacted]. A standard Ethernet interface is recommended for network connectivity. The "thin client" graphical user interface application is designed to operate on any compatible desktop or notebook computer. When the intended use is for diagnosis, an appropriate monitor is required, such that all the digital information can be faithfully displayed.

Programming Language:
iNtuition– TDA, TVA, Parametric Mapping utilizes a combination of (b)(4) [redacted]

User Interface:
The user interacts with the system through a standard keyboard, a wheelmouse and a touch panel. All buttons are marked with commonly understood symbols, or marked in the language associated with the territory in question.

Data Input:
(b)(4) [redacted]

Data Output:
(b)(4) [redacted]

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(b)(4)

[redacted]

Functional Requirements:
The detailed narration in Section 16.2 titled 'Software Description,' describe in detail the functionality of iNtuition– TDA, TVA, Parametric Mapping.

Performance standard:
There are no applicable FDA mandated performance standards for this device. However, voluntary standards such as DICOM, various in-house Standard Operating Procedures and vendor qualification procedures are in place and utilized in the production of the software.

(b)(4)

[redacted]

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16.5 Architecture Design Chart:

(b)(4)

[redacted]

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(b)(4)

[redacted]

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16.6 Software Design Specifications (SDS)

(b)(4)

[redacted]

Please refer to Appendix C for Software Design Specifications (SDS) documentation.

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LOCATION: X **San Mateo** _____ **Concord** _____ **Other** _____

DOCUMENT NUMBER F04201

DOCUMENT TITLE

Time Dependant Analysis Module for Aquarius Workstation

Author:	(b)(4) [redacted]	**Title:**		**Date:**	August 30, 2002
Approved By:	(b)(4) [redacted]	**Title:**		**Date:**	09/09/04
Approved By:		**Title:**		**Date:**	
Approved By:		**Title:**		**Date:**	

Revision History

Rev. Level	Description	Revised By	Approved By	Date
A	(b)(4) [redacted]	(b)(4) [redacted]		September 15, 2003
B			(b)(4) [redacted]	September 9, 2004
C				July 22, 2009
D				June 10, 2010
E			(b)(4) [redacted]	6/24/2010
F				7/29/2010
G				10/20/2010
H				2/15/2012

Reference Documents

Document Number	Rev. Level	Description

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

(b)(4) Software Design

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LOCATION: x **San Mateo** _____ **Concord** _____ **Other** _____

DOCUMENT NUMBER **S2720**

DOCUMENT TITLE

AQi Design – TDA Viewer

Author:	(b) (6) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	**5/20/2008**
Approved By:	(b) (6) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	
Approved By:	----------	**Title:**	----	**Date:**	----
Approved By:	----------	**Title:**	----	**Date:**	----

Revision History

Rev. Level	Description	Revised By	Approved By	Date
A	(b) (6), (b) (4) [redacted]			
B				10/26/2009
C				1/14/2013
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Reference Documents

Document Number	Rev. Level	Description

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F04201	C	Design_APS_PE_TDA.doc

1. Introduction 2
2. Scope 2
3. Definitions 2
4. Requirement 3
http://10.10.0.121/svn/Aquarius/trunk/ISODocs/MRS_CF0101/SRS/TDA_Requirements.doc 3
Level-1 3
Level-2 3
Level-3 4
Level-4 4
Level-5 4
5. Design 4
5.1 Layout 4
5.2 Tool Panel 5
5.3 Overlays: 8
5.4 Graph 10
5.5 MR support 11
5.6 User confirmation for automatic results 11
6. Implementation 11
6.1 Protocol menu 11
6.2 Calculate 11
6.3 Coordinates 12
6.4 Motion correction, artery/vein position and brain center 12
6.5 Measurements 12
6.5 Data Management 12
6.6 Preference 12
6.7 related files: 13

1. Introduction

The classic Aquarius workstation (version 3.7) has a fully functional TDA viewer, but is stand-alone machine. On Aquarius iNtuition viewer, we want to move all complex functions of classic TDA viewer to the server-client architecture.

2. Scope

This document designs the TDA viewer on the iNtuition system.

3. Definitions

TDA Time Dependent Analysis

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LOCATION: _____ **San Mateo** __x__ **Concord** _____ **Other** _____

DOCUMENT NUMBER **XXXXX**

DOCUMENT TITLE

Design_APS_PE_ParametricMap.doc

Author:	(b) (6) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	**09/21/2005**
Approved By:	(b)(4) [redacted]	**Title:**		**Date:**	
Approved By:	(b) (6) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	**May 17, 2007**
Approved By:		**Title:**		**Date:**	
Reviewed By:	(b) (6) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	**May 17, 2007**
Reviewed By:		**Title:**		**Date:**	
Reviewed By:		**Title:**		**Date:**	

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Revision History

Rev. Level	Description	Revised By	Approved By	Date
A	(b)(4) [redacted]			09/21/2005
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C				10/14/05
D				11/16/06
E				05/02/07
F			(b) (6) [redacted]	12/10/2012

Reference Documents

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1 Introduction and Overview 4
2 Definitions 5
3 Scope 5
4 Requirements 6
5 Design 7
5.1 Parametric Map 7

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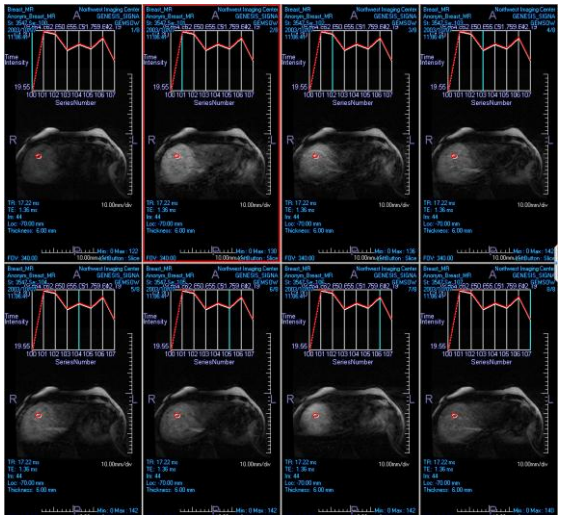
1 Introduction and Overview

Clinical researches show that tumor angiogenesis is related to the tumor types. Some researches also show that tumor angiogenesis could be an independent prognostic indicator for the survival outcome of cancer.

One way to analyze the characteristics of angiogenesis is to use region-of-interest (ROI) temporal-enhancement curves (time density curve currently available on thin client).



Clinical researches have demonstrated that certain types of curves are related to certain types of tumor. Three basic curve shapes have been described by Kuhl and co-investigators (Kuhl, 1999) for breast MRI: Type I is slowly enhancing in which gradual steady enhancement occurs over about 5 minutes. Type II is a plateau with early strong enhancement (1-2 min) and a subsequent plateau phase. This is suspicious and often indicates malignancy. Type III is washout with early strong enhancement (1-2 min) and a subsequent decline in enhancement. This enhancement curve is strongly associated with malignancy. Although those three curve types described above are defined for breast MRI, the similar type definitions could also apply to other organs.

Parametric map is a color map to represent various curve types. For example, red represents type III and blue represents type II and green represents type I.

The scan protocol set up for time density curve analysis usually acquires multiple phases for same body position, which captures pre-contrast phase and phases at various contrast stage including maximum contrast phase and several phases after that. According to Kuhl's group's investigation, the temporal resolution is critical to differentiate three basic curve shapes.

The time density measurement tool on thin client asks user to define a ROI, then software automatically calculates time density curve for this ROI region and display the curve on

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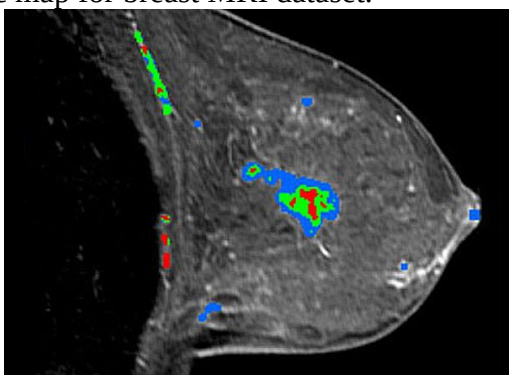
all phases. This measurement tool does not analyze the curve and classify it as a particular type.

Automatically generated parametric map, which

- automatically analyzes time density curve for each region (normally a rectangle region, for example, 3mm by 3mm by 3mm. The size of region will affect the resolution of the parametric map.)
- and assign a color to each region to help visualizing the curve type
- and present users the overlaid color map on top of one temporal image.

To suppress the signal from fat, parametric map could be applied only on regions whose time density variation is bigger than a predefined threshold. The following picture shows an example of parametric map for breast MRI dataset.



To improve the accuracy when analyzing time density curve, registration is needed to align corresponding regions among various phases to compensate body movement. A deformable registration PE will be optionally used by APS before generating parametric map due to most of organ movement in breast MRI study is non-rigid.

This document describes the method used in AqAPS 2.0 to automatically generate parametric map through preprocessing a series of temporal images when they push to AqAPS server. The presentation of parametric map on thin client will not be covered in this document.

2 Definitions

PE: process engine
AqAPS: Aquarius Application Processing Sever
Deformable registration: The registration process which can compensate the nonlinear motion

3 Scope

- This engine is to be run as an offline PE by APS server.
- This engine is limited to multi-phase MR studies.
- The result will be two volumes, which are uptake and enhancing ratio volume.

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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DOCUMENT NUMBER **S560**

DOCUMENT TITLE

CF0303RevD-AQi-Viewer-Measurement.doc

Author:	Title:	Date:
(b) (6) [redacted]	(b)(4) [redacted]	11/12/2012
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Revision History

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Reference Documents

Document Number	Rev. Level	Description
-	-	svn://aqbuildportal/Trunk/NGP/Document/Design/NGP_WS/Viewer/Design-AQWSi-Viewer-Measurement.doc
-	-	http://10.10.0.121/svn/Aquarius/trunk/ISODocs/AQWSi/DesignDocs/References/Shortcut_Reference.xls

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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(b)(4)

[redacted]

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[redacted]

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[redacted]

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LOCATION: _____ **San Mateo** _____ **Concord** _____ **Tokyo** X

DOCUMENT NUMBER **S5795**

DOCUMENT TITLE

Thinclient Parametric Map

Author:	(b) (6) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	(b)(4) [redacted]
Approved By:	(b) (6) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	
Approved By:	---	**Title:**	---	**Date:**	---
Approved By:	---	**Title:**	---	**Date:**	---

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Reference Documents

Document Number	Rev. Level	Description
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@FDA.HHS.gov or 301-796-8118

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TDA (Time Dependent Analysis) Requirements

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1 Introduction and Overview 4
2 Definitions 4
3 Scope 4
4 Requirements 5
5 Design 7
5.1 Chamber Analysis 7
5.1.1 Functional spec 7
5.1.2 Implementation 7
5.1.2.1 Inputs/Outputs 7
5.1.2.2 Workflow 7
5.1.2.3 Algorithm 9
5.1.2.4 Class Diagram 15
5.2 Wall Analysis 16
5.2.1 Functional spec 16
5.2.2 Implementation 16
5.2.2.1 Inputs/Outputs 16
5.2.2.2 Workflow 17
5.2.2.3 Algorithm 18
5.2.2.4 Class Diagram 23
6 Limitations 24
6.1 Chamber analysis 24
6.2 Wall analysis 25

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1 Introduction and Overview

This document describes a new Cardiac Analysis Package for the Aquarius Intuition. The goal of this package is to do volumetric analysis and wall based analysis for left ventricle of heart and to report cardiac function indexes. The cardiac function indexes are in two categories:

- Volumetric analysis:
  - Ventricular end diastolic volume
  - Ventricular end systolic volume
  - Ejection fraction
  - Time curve of ventricular volume
  - Ventricular stroke volume
  - Cardiac output
  - Stroke index
  - Cardiac index
- Wall-based analysis:
  - Left ventricular wall thickness
  - Left ventricular wall thickening
  - Segmental ejection fraction
  - Left ventricular wall intensity

The cardiac analysis is able to be performed in two different running modes: zero-click automatic mode for quick cardiac index review and step by step mode with minimal intervention from user. The automatic analysis will calculate all the cardiac indexes. In the manual analysis, user can adjust all parameters manually or accept some parameters from automatic mode which will save time on user's intervention.

2 Definitions

APS:	Advanced Processing Server
PE:	Processing Engine, intended to be run offline
Plugin:	Online version of processing engine, plugged in to the imaging server
LV:	Left Vetricle
EF:	Ejection Fraction
SV:	Stroke Volume

3 Scope

- This project is to be run as online plugin.
- This project is limited to multi-phase cardiac CT studies.
- Chamber analysis is for this version. The result will be LV mask, position and direction and cardiac indexes for each case.

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

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LOCATION: x **San Mateo** ____ **Concord** ____ **Other** ____

DOCUMENT NUMBER **S547**

DOCUMENT TITLE

Design – Time-Volume Analysis in Aquarius Workstation iNtuition

Author: (b) (6) **Title:** (b)(4) [redacted] **Date:** (b)(4)

Approved By: ____ **Title:** ____ **Date:** ____

Approved By: ____ **Title:** ____ **Date:** ____

Approved By: ____ **Title:** ____ **Date:** ____

Revision History

Rev. Level	Description	Revised By	Approved By	Date
A	(b)(4) [redacted]			
B	(b) (6) [redacted]	[redacted]		[redacted]

Reference Documents

Document Number	Rev. Level	Description
D0005	A	AQWS_TVA_Cardiac_Analysis

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

		http://10.10.0.121/svn/Aquarius/trunk/ISODocs/AQWSi\DesignDocs\ \References\Design-AQWSi-Viewer-TVA-GUI.ppt

1. Introduction 2
2. Scope 2
3. Definitions 2
4. Requirement 3
5. Level-2 Design 7
   Level-2 GUI 7
6. Level-3 Design 9
   Workflow 9
   Level-3 GUI 11
7. Level-4 Design 14
   Workflow 14
   GUI ..... **Error! Bookmark not defined.**

1. Introduction

Time-Volume Analysis (TVA) has been a module in Aquarius Workstation since version 3.0. It analyzes volume changes along time, and the goal was to calculate and report the cardiac function indexes of both left ventricle and right ventricle of heart. The most useful cardiac function index is ejection fraction.

From version 4.1, TVA functionality is going to be moved to iNtuition viewer, so it will be available on server-client architecture.

At this time, the iNtuition viewer already has the ability to load 4D data, play movie from the EKG annotation, align the 3 basic MPR views to double-oblique. The heart labeling engine can automatically find the center of LV and the apex reasonably well, and the very rough position of mitral valve.

2. Scope

This document designs the TVA on iNtuition, focusing on the user interface and client-server communication. The design of the engine (on the server side) is not within the scope of this document.

3. Definitions

TVA	Time-Volume Analysis
LV	Left Ventricle (of the heart)
EF	Ejection Fraction (see **D0005** for detailed definition of this and other cardiac indexes)
APS	Advanced Processing Server
Plug-in	Plug-in process of the imaging server, to be run on-line with the client

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

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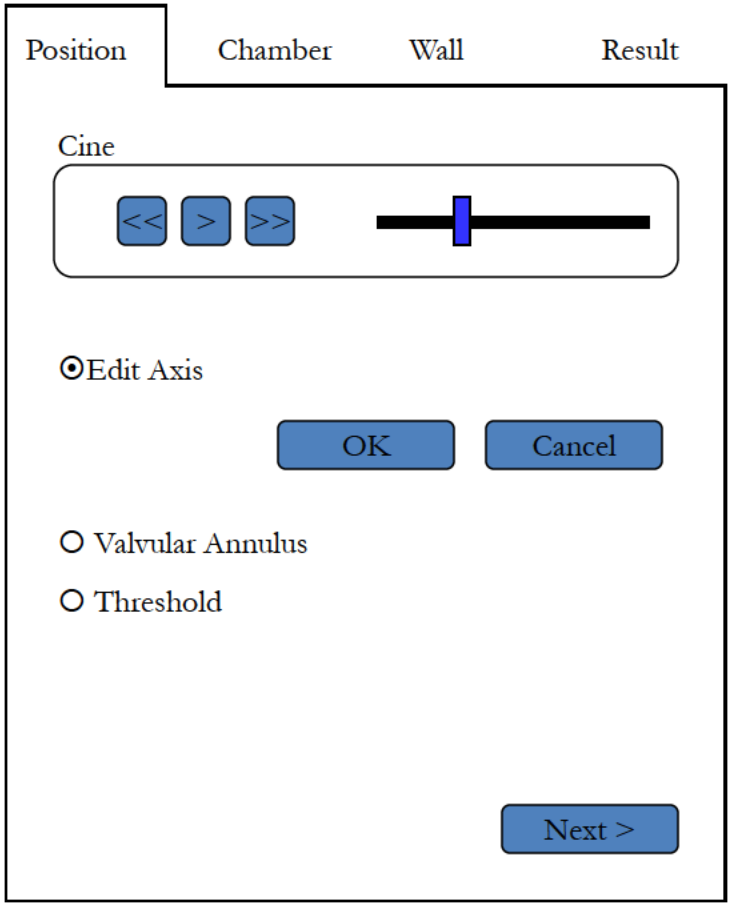
"Position" Step

- 3 MPR images are started in cardiac long/short axis.
- Rotation and position are restricted.
- User can enter the "Edit Axis" mode to adjust the position, orientation by using double oblique mode
- User can enter the "Valvular Annulus" mode to adjust level of valvular annulus.
- User can enter the "Threshold" mode to adjust the threshold with overlay and W/L control.



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

(b)(4) Software Design

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Records processed under FOIA 2014-9075; Released by CDRH on 12/2/2015

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DOCUMENT NUMBER **S7008**

DOCUMENT TITLE

CF0303RevD-AQi-CMR-TVA

Author:	Title:	Date:
Yoshinori Kimura	Sr. Software Engineer	Nov/28/2012
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Revision History

Rev. Level	Description	Revised By	Date
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Reference Documents

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DOCUMENT NUMBER **S7009**

DOCUMENT TITLE

CF0303RevD-AQi-CMR-Flow

Author:	Title:	Date:
(b) (6)	(b)(4)	(b)(4)
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Reference Documents

Document Number	Rev. Level	Description
S4090	-	svn://aqbuildportal/Trunk/NGP/Document/Design/NGP_WS/Viewer/Design-Design-AQWSi-Viewer-CardiacMR-Flow.doc

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

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

LOCATION: x **Foster City** _____ **Concord** _____ **Other** _____

DOCUMENT NUMBER **S7362**

DOCUMENT TITLE

Design_Plugin_MRTVA.doc

Author:	(b)(4) [redacted]	**Title:**	(b)(4) [redacted].	**Date:**	(b)(4) [redacted]
Approved By:	(b)(4) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	(b)(4) [redacted]
Approved By:		**Title:**		**Date:**	
Approved By:		**Title:**		**Date:**	
Reviewed By:		**Title:**		**Date:**	
Reviewed By:		**Title:**		**Date:**	
Reviewed By:		**Title:**		**Date:**	

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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

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1 Introduction and Overview 4
2 Scope 4
3 Requirements 4
4 Design 4
4.1 Inputs/Outputs 4
4.2 Workflow 4
4.3 Algorithms 5

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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LOCATION: _____ **San Mateo** _____ **Concord** x **Other** **Tokyo**

DOCUMENT NUMBER **S982**

DOCUMENT TITLE

Design-AQWSi- Viewer-TVA-RV

Author:	(b) (6) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	(b)(4) [redacted]
Approved By:		**Title:**		**Date:**	
Approved By:		**Title:**		**Date:**	
Approved By:		**Title:**		**Date:**	
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Reviewed By:		**Title:**		**Date:**	
Reviewed By:		**Title:**		**Date:**	

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Reference Documents

Document Number	Rev. Level	Description
D0005	A	AQWS_TVA_Cardiac_Analysis
S547	A	Design-AQWSi-Viewer-TVA.doc

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

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1. Introduction

We can use Time-Volume Analysis (TVA) for left ventricle of the heart since 4.2 of Aquarius iNtuition viewer. It analyzes volume changes along time, and the goal was to calculate and report the cardiac function indexes of left ventricle of heart.

Since other vendors viewer support TVA for not only left ventricle but also right ventricle, there are a lot of request to support TVA for right ventricle in Aquarius iNtuition viewer.

The workflow and some calculation is similar to TVA for left ventricle.
But because of the shape of right ventricle is more complex and contrast is low, there are slight difference.

2. Scope

This document designs the TVA of RV, focusing on the user interface and client-server communication. The design of the engine (on the server side) is in other document

3. Definitions

TVA	Time-Volume Analysis
LV	Left Ventricle (of the heart)
RV	Right Ventricle (of the heart)
ED	End diastole
ES	End systole
EF	Ejection Fraction (see D0005 for detailed definition of this and other cardiac indexes)
Plug-in	Plug-in process of the imaging server, to be run on-line with the client
RCX	Right circumflex

Note: Not implemented item is grayed out.

4. Requirement

The requirement is in levels, with level 1 being the basic and most important.

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

(b)(4) Design document

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(b)(4) Design document

[redacted]

End of Document

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

LOCATION: _____ **San Mateo** __x__ **Concord** _____ **Other** _____

DOCUMENT NUMBER **XXXXX**

DOCUMENT TITLE

Design_APS_PE_ParametricMap.doc

Author:	(b) (6)	**Title:**	(b)(4) Design	**Date:**	(b)(4)
Approved By:	(b) (6) [redacted]	**Title:**		**Date:**	
Approved By:		**Title:**	(b)(4) Design document	**Date:**	(b)(4) Design
Approved By:		**Title:**		**Date:**	
Reviewed By:		**Title:**	(b)(4) Design document	**Date:**	(b)(4) Design
Reviewed By:		**Title:**		**Date:**	
Reviewed By:		**Title:**		**Date:**	

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

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Revision History

Rev. Level	Description	Revised By	Approved By	Date
A	(b)(4) Design document [redacted]			
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Reference Documents

Document Number	Rev. Level	Description

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

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1 Introduction and Overview 4
2 Definitions 5
3 Scope 5
4 Requirements 6
5 Design 7
5.1 Parametric Map 7

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

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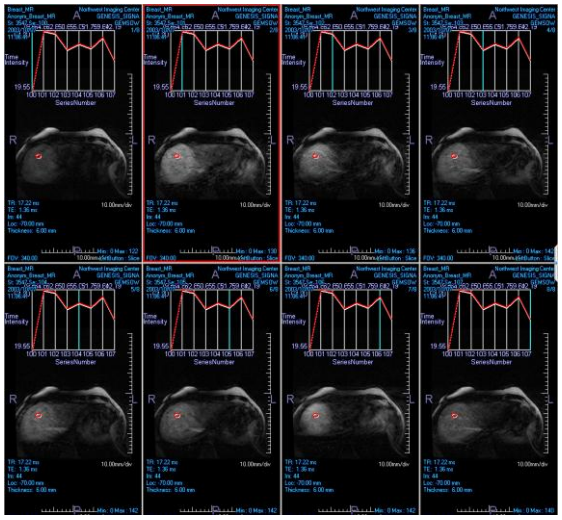
1 Introduction and Overview

Clinical researches show that tumor angiogenesis is related to the tumor types. Some researches also show that tumor angiogenesis could be an independent prognostic indicator for the survival outcome of cancer.

One way to analyze the characteristics of angiogenesis is to use region-of-interest (ROI) temporal-enhancement curves (time density curve currently available on thin client).



Clinical researches have demonstrated that certain types of curves are related to certain types of tumor. Three basic curve shapes have been described by Kuhl and co-investigators (Kuhl, 1999) for breast MRI: Type I is slowly enhancing in which gradual steady enhancement occurs over about 5 minutes. Type II is a plateau with early strong enhancement (1-2 min) and a subsequent plateau phase. This is suspicious and often indicates malignancy. Type III is washout with early strong enhancement (1-2 min) and a subsequent decline in enhancement. This enhancement curve is strongly associated with malignancy. Although those three curve types described above are defined for breast MRI, the similar type definitions could also apply to other organs.

Parametric map is a color map to represent various curve types. For example, (b)(4) [redacted]

The scan protocol set up for time density curve analysis usually acquires multiple phases for same body position, which captures pre-contrast phase and phases at various contrast stage including maximum contrast phase and several phases after that. According to Kuhl's group's investigation, the temporal resolution is critical to differentiate three basic curve shapes.

(b)(4) Design document [redacted]

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[redacted]

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

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(b)(4) Design document

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(b)(4) Design document

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

LOCATION: _____ **San Mateo** _____ **Concord** _____ **Tokyo** X

DOCUMENT NUMBER **S5795**

DOCUMENT TITLE

Thinclient Parametric Map

Author:	(b)(4)	**Title:**	(b)(4) [redacted]	**Date:**	(b)(4)
Approved By:	(b)(4)	**Title:**	(b)(4) [redacted]	**Date:**	
Approved By:	---	**Title:**	---	**Date:**	---
Approved By:	---	**Title:**	---	**Date:**	---

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[redacted]

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16.7 Traceability Analysis

COP03A - Design and Development – Software Validation

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

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(b)(4) Procedure

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(b)(4) Procedure

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16.8 Software Development Environment Description

COP03A - Design and Development – Software Validation

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

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(b)(4) Procedure

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(b)(4) Procedure

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16.9 Verification & Validation documentation

Please refer to Appendix D for detailed device level testing documentation.

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

DOCUMENT NUMBER DK-101204

DOCUMENT TITLE

CF0304A_RevB-RECORD-Regression_APS_TDA

Author:	(b) (6) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	(b)(4) [redacted]
			-		-
Approved By:	(b) (6) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	(b)(4) [redacted]
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Approved By:		**Title:**	-	**Date:**	-

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1.0 INTRODUCTION

This document describes regression test for Time Density Analysis-TDA for CT data. The module analyzes a 4D dynamic data or, so-called, perfusion data to provide a time-density curve (the density being the CT number or Hounsfield unit) of arbitrary region-of-interest (ROI) and create a several variety of functional maps (cerebral blood volume (CBV), cerebral blood flow (CBF), mean transit time (MTT), time-to-peak, temporal maximum intensity projection (MIP), error map etc).

2.0 SCOPE

TDA-Time Density Analysis

3.0 DEFINITIONS

User story: Feature, new feature, RFE.
RFE: Request For Enhancement
Defect: Bugs, bad design, issues.

4.0 EQUIPMENT (Test Machine specifications, supplies, etc.)

Manufacturer	Model	OS	Language
Dell	490	Windows XP X32	English

Note: The regression tests covered in this document are not equipment specific.

5.0 RESPONSIBILITIES

(b)(4) [redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Index of tests:

Contents

Test 1: [APS-Workflow] TDA workflow 4
Test 2: Create color map from TDA protocol 4
Test 3: Trigger TDA for correct study when multiple studies with same patient Id are present 5

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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DOCUMENT NUMBER JZ-20120227-TDAMR

DOCUMENT TITLE

CF0304A_RevB-RECORD-Regression_AQi_TDA(MR)

Author:	(b) (6) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	(b)(4) [redacted]
Approved By:	(b) (6) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	
Approved By:		**Title:**	-	**Date:**	-
Approved By:		**Title:**	-	**Date:**	-

Revision History

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A	(b)(4) [redacted]			
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Reference Documents

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

1.0 INTRODUCTION

This is a regression test document for MR TDA module.

TDA: Time-Density Analysis is used for studying time-dependence of contrast enhancement, such as enhancement of brain tissue due to perfusion with contrast-enhanced blood. The TDA modules studies blood flow through a structure after the patient is injected with a contrast dye. The study creates several kinds of functional maps: Relative Blood Volume (rBV) or Negative Enhancement Integral (NEI), Relative Blood Flow (rBF) or NEI/MTE, Mean Time to Enhancement (MTE), etc.

2.0 SCOPE

This test doc applies to MR TDA (Time Density Analysis) module. It includes GUI test, ROI geometry measurement correctness test, and general workflow test.

The correctness of the calculated maps (NEI, MTE, NEI/MTE, MSI, TM, MSD, etc) is not directly tested in this regression test document. In this test doc, the calculated maps are compared against the reference maps in TDA design document. The reference maps in the design document were calculated by AQi and are validated by the development team (David Guigonis) to constitute a reference (baseline) for SQA.

Summary of the scope:

1) Functional aspect (GUI testing)
   [1a. Workflow + GUI testing]
   [1b. Qualitative comparison of engineering results using Siemens and Philips datasets]

2) Safety aspect
   [2a. Correctness and accuracy of distance values displayed in the result tab]
   [2b. Correctness and accuracy of area values displayed in the result tab]
   [2c. Correctness and accuracy of intensity profile displayed in the graph]
   [2d. Correctness of NEI, MTE, NEI/MTE, MSI, TM, MSD values]
   [2e. Value-to-color correspondence correctness (color map/scale)]

3.0 DEFINITIONS

User story: Feature, new feature, RFE.
RFE: Request For Enhancement
Defect: Bugs, bad design, issues.

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

4.0 EQUIPMENT (Test Machine, specifications, supplies, etc.)

Manufacturer	Model	OS	Language
Dell	Precision T5400	Windows 7 x64	English
Dell	Precision 490	Windows XP x64	English
Dell	Latitude D830	Windows 7 x32	English

Note: The regression tests covered in this document are not equipment specific, unless specified in test case otherwise.

5.0 RESPONSIBILITIES

(b)(4) [redacted]

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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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

DOCUMENT NUMBER JZ-20101123-TDA

DOCUMENT TITLE

CF0304A_RevB-RECORD-Regression_AQi_TDA

Author:	(b) (6) [redacted]	(b)(4) [redacted]	Date: (b)(4) [redacted]
		-	-
Approved By:		(b)(4) [redacted]	Date: (b)(4) [redacted]
Approved By:		-	Date: -
Approved By:	-	Title: -	Date: -

Revision History

Rev. Level	Description	Revised By	Approved By	Date
A	(b)(4) [redacted]			
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C				
D				

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Document Number	Rev. Level	Description

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

1.0 INTRODUCTION

This is a regression test document for TDA module.

TDA: Time-Density Analysis is used for studying time-dependence of contrast enhancement, such as enhancement of brain tissue due to perfusion with contrast-enhanced blood. The TDA modules studies blood flow through a structure after the patient is injected with a contrast dye. The study creates several kinds of functional maps: Blood Volume (BV), Blood Flow (BF), Mean Transit Time (MTT), Time-to-Peak (TTP), etc.

2.0 SCOPE

TDA (Time Density Analysis) module

3.0 DEFINITIONS

User story: Feature, new feature, RFE.
RFE: Request For Enhancement
Defect: Bugs, bad design, issues.

4.0 EQUIPMENT (Test Machine, pecifications, supplies, etc.)

Manufacturer	Model	OS	Language
Dell	Precision T5400	Windows 7 x64	English
Dell	Precision 490	Windows XP x64	English
Dell	Latitude D830	Windows 7 x32	English

Note: The regression tests covered in this document are not equipment specific, unless specified in test case otherwise.

5.0 RESPONSIBILITIES

(b)(4) [redacted]

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

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Index of tests:

Contents

Test 1: TDA Workflow 4
Test 2: Output 13
Reference: Data List 17

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

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(b)(4) Testing

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

DOCUMENT NUMBER JZ-20110404-TDA

DOCUMENT TITLE

CF0304A_RevB-RECORD-Regression_Safety_AQi_TDA

Author:	(b) (6) [redacted]	Title:	(b)(4) [redacted]	Date:	(b)(4) [redacted]
Approved By:	(b) (6) [redacted]		-		-
		Title:	(b)(4) [redacted]	Date:	(b)(4) [redacted]
Approved By:	[redacted]	Title:	-	Date:	-
Approved By:	-	Title:	-	Date:	-

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1.0 INTRODUCTION

TDA (Time Density Analysis) is the module for quantitatively analyzing the blood circulation in brain or other organs. Parameters that describe the blood circulation condition, such as BV, BF, MTT, TOT, and etc, are calculated from the 4D perfusion data. Maps can be generated to visually indicate the tissue areas with poor blood circulation.

2.0 SCOPE

This regression test document covers the test for the correctness of the algorithm's output.

3.0 DEFINITIONS

User story: Feature, new feature, RFE.
RFE: Request For Enhancement
Defect: Bugs, bad design, issues.

4.0 EQUIPMENT (Test Machine, pecifications, supplies, etc.)

Manufacturer	Model	OS	Language
Dell	Precision T5400	Windows 7 x64	English
Dell	Precision 490	Windows XP x64	English
Dell	Latitude D830	Windows 7 x32	English

Note: The regression tests covered in this document are not equipment specific, unless specified in test case otherwise.

5.0 RESPONSIBILITIES

(b)(4) [redacted]

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

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(b)(4)

[redacted]

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

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TERARECON, INC.

TEST CASES

(b)(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 2014-9975; Released by CDRH on 12/3/2015

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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 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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

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

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MR TDA validation

(b)(4)

[redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b) (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 2014-9975; Released by CDRH on 12/3/2015

TERARECON		TEST CASES
Document №: CF 0304A	Revision Level: C	Revision Date: 01/31/2013
Process Owner: Director of Software Quality Assurance		Page 1 of 6

DOCUMENT NUMBER: DC-TVACT-021413

DOCUMENT TITLE: CF0304A_RevA-RECORD-Test_Cases_iNtuition_TVACT-Predicate_DC

Author/ Revised by: (b) (6) [redacted] **Title:** (b)(4) [redacted] **Date:** (b)(4) [redacted] **Signature:** (b)(4) [redacted]

Approved by: (b) (6) [redacted] **Title:** [redacted] **Date:** [redacted] **Signature:** [redacted]

Approved by: [redacted] **Title:** [redacted] **Date:** [redacted] **Signature:** [redacted]

Approved by: [redacted] **Title:** [redacted] **Date:** [redacted] **Signature:** [redacted]

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DOCUMENT NUMBER DN-2012.06TVA

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Author:	(b)(4) [redacted]	Title:	(b)(4) [redacted]	Date:	(b)(4) [redacted]
Approved By:	(b)(4) [redacted]			Date:	-
Approved By:	[redacted]			Date:	(b)(4) [redacted]
Approved By:	[redacted]			Date:	-
Approved By:	-	Title:	-	Date:	-

Revision History

Rev. Level	Description	Revised By	Approved By	Date
0	Original document	-	-	-

Reference Documents

Document Number	Rev. Level	Description

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

1.0 INTRODUCTION

This is a regression test document for TVA module.

The **Time-Volume Analysis** (TVA) optional module calculates time-dependent behavior of volumes in multi-phase studies from CT. An example of a time-dependent behavior is the change in the volume of the left ventricle of the heart.

2.0 SCOPE

CT dataset

3.0 DEFINITIONS

User story: Feature, new feature, RFE.
RFE: Request For Enhancement
Defect: Bugs, bad design, issues.

4.0 EQUIPMENT (Test Machine specifications, supplies, etc.)

Manufacturer	Model	OS	Language
Dell	T5400	Windows 7 x64	US
Dell	T5400	Windows 7 x32	US
Dell	T5500	Windows XP x64	US

Note: The regression tests covered in this document are not equipment specific, unless specified in test case otherwise.

5.0 RESPONSIBILITIES

(b)(4) [redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Note:

Index of tests:

Contents

Section I: Functional Test cases 4
- Test 1: [TVA] Colored Motion (Formal Release) 4
- Test 2: Add surface mode (3D polar map) 5
- Test 3: [TVA] Support Comprehensive computation 6
- Test 4: Ca and MR-TVA need to be disabled for Japan 6
- Test 5: TVA: Automatically validate EF when complete the EF steps 7
- Test 6: Ability to edit LVEF segmentation 7
- Test 7: [TVA] RV support (Level-1) 8
- Test 8: [TVA] RV support (Level-2) 11
- Test 9: Added "Interpolation mode" check box in wall stage of RV. 14
- Test 10: [MSP][TVA]: support output LV EF and RV EF to Measurement protocol 15

Section II: [TVA-LV Preference] Test cases 16
- Analysis Method: "Automatic" 16
- Analysis Method: "Automatic (All phases)" 16
- Analysis Method: "Manual" 17

Section III: [TVA-RV Preference] Test cases 17
- Analysis Method: "Automatic (All phases)" 17
- Analysis Method: "Manual" 17

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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DOCUMENT NUMBER DN-20120607

DOCUMENT TITLE

CF0304A_RevB-RECORD-Regression_AQi_TVA_ Measurement _Manual_RVEF

Author:	(b) (6) [redacted]	Title:	(b)(4) [redacted]	Date:	(b)(4) [redacted]
Approved By:		Title:		Date:	
Approved By:		Title:		Date:	
Approved By:	-	Title:	-	Date:	-

Revision History

Rev. Level	Description	Revised By	Approved By	Date
0	Original doc.	-	-	-

Reference Documents

Document Number	Rev. Level	Description

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

1.0 INTRODUCTION

The AQi TVA is the iNtuition TVA module which replaces the classic TVA. Classic TVA (CT) can only be run in Workstation mode with classic modules installation required. The "iNtuition" TVA can be run from either "pure" client mode or Workstation mode, without classic modules installation required.

TVA: Time-Volume Analysis is used for analyzing changes in volume over time. The TVA module calculates time-dependent behavior of volumes in multiple phased studies from CT and MR. An example of a time-dependent behavior is the change in the volume of the left ventricle of the heart. Using TVA one can calculate wall thickness, wall thickening, segmental ejection fraction, and wall intensity, along with time-volume graphs with velocity and acceleration curves.

2.0 SCOPE

TVA LV EF has been released for some time, but TVA RV EF is a new feature in the iNtuition TVA module. The scope of this test doc is focusing specifically to TVA RV EF measurement, to ensure measurement accuracy on TVA (RV) EF. The scope is limited to CT in this regression test document.

3.0 DEFINITIONS

TVA = Time Volume Analysis.
CT = Computed Tomography

4.0 EQUIPMENT (Test Machine specifications, supplies, etc.)

Manufacturer	Model	OS	Language
Dell	T5500	Win7x64	English

Note: The regression tests covered in this document are not equipment specific.

5.0

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

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RESPONSIBILITIES

(b)(4) [redacted]

Index of Tests

Table of Contents

Section A: Phantom Dataset info 4
Section B: TVA correctness - CT 5
Test 1: Volume correctness 6
Test 2: Volume-derived values correctness 7
Test 3: Manual Distance measurement correctness for the following items: 9
Phase 1: Measurement correctness 9
Phase 2: Measurement correctness 9
Phase 3: Measurement correctness 9
Phase 4: Measurement correctness 9
Phase 5: Measurement correctness 9
Phase 6: Measurement correctness 10
Phase 7: Measurement correctness 10
Phase 8: Measurement correctness 10

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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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 2014-9975; Released by CDRH on 12/3/2015

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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]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

DOCUMENT NUMBER DN-20110603535

DOCUMENT TITLE

CF0304A_Regression_Test_Cases_DN_AQi_TVA_ Measurement

Author:	David Nguyen	**Title:**	SQA engineer	**Date:**	June 3,2011
Approved By:	(b) (6) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	(b)(4) [redacted]
Approved By:		**Title:**		**Date:**	
Approved By:		**Title:**		**Date:**	

Revision History

Rev. Level	Description	Revised By	Approved By	Date

Reference Documents

Document Number	Rev. Level	Description

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

1.0 INTRODUCTION

The AQi TVA is the new TVA module which replacing the classic TVA. Classic TVA (CT) can only be run in Workstation mode with classic modules installation required. The "new" TVA can be run from either "pure" client mode or Workstation mode, without classic modules installation required.

TVA: Time-Volume Analysis is used for analyzing changes in volume over time. The TVA module calculates time-dependent behavior of volumes in multiple phased studies from CT and MR. An example of a time-dependent behavior is the change in the volume of the left ventricle of the heart. Using TVA one can calculate wall thickness, wall thickening, segmental ejection fraction, and wall intensity, along with time-volume graphs with velocity and acceleration curves.

The tests have been automated with QuickTest Professional. The test cases described in this test documents are guidance of what the automated scripts do, and also including instructions to run the test scripts in conformance.

2.0 SCOPE

To ensure measurement accuracy on TVA module. The scope is limited to CT in this regression test document. For reference, TVA-MR is beta.

3.0 DEFINITIONS

TVA = Time Volume Analysis.
CT = Computed Tomography

4.0 EQUIPMENT (Test Machine specifications, supplies, etc.)

Manufacturer	Model	OS	Language
Dell	T5500	Win7x64	English

Note: The regression tests covered in this document are not equipment specific.

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

5.0 RESPONSIBILITIES

TVA = Time Volume Analysis.
CT = Computed Tomography

Index of Tests

Table of Contents

Prerequisite: Run the calibration tests 4
Run the test scripts: 4
Section A: Phantom Dataset info 5
Section B: TVA correctness - CT 6
Test 1: LV Volume correctness 7
Test 2: Volume-derived values correctness 8
Test 3: Manual Distance measurement correctness for the following items: 10
Phase 1: Measurement correctness 10
Phase 2: Measurement correctness 10
Phase 3: Measurement correctness 10
Phase 4: Measurement correctness 10
Phase 5: Measurement correctness 10
Phase 6: Measurement correctness 11
Phase 7: Measurement correctness 11
Phase 8: Measurement correctness 11
Acceptance (“pass”) Criteria: 14

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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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 2014-9975; Released by CDRH on 12/3/2015

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[redacted]

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[redacted]

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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 2014-9975; Released by CDRH on 12/3/2015

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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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 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

DOCUMENT NUMBER DN-20120622

DOCUMENT TITLE

CF0304A_RevB-RECORD-Regression_QTP_AQi_TVAmeasurement_Auto_RVEF_LVEF

Author:	(b) (6) [redacted]	Title:	(b)(4) [redacted]	Date:	(b)(4) [redacted]
Approved By:	(b) (6) [redacted]	Title:		Date:	
Approved By:		Title:		Date:	
Approved By:		Title:	-	Date:	-

Revision History

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0	(b)(4) [redacted]	-	-	-

Reference Documents

Document Number	Rev. Level	Description

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

1.0 INTRODUCTION

This is a regression test document to ensure the automatic calculation of volume measurement is correct from the TVA module.

2.0 SCOPE

CT dataset

3.0 DEFINITIONS

User story: Feature, new feature, RFE.
RFE: Request For Enhancement
Defect: Bugs, bad design, issues.

4.0 EQUIPMENT (Test Machine specifications, supplies, etc.)

Manufacturer	Model	OS	Language
Dell	T5400	Windows 7 x64	US
Dell	T5400	Windows 7 x32	US

Note: The regression tests covered in this document are not equipment specific, unless specified in test case otherwise.

5.0 RESPONSIBILITIES

(b)(4) [redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Index of tests:

Contents

Prerequisite: Run the calibration tests 4
Run the test scripts: 4
Section A: Dataset info 5
Section B: [Test cases] 6
Test case 1: LV Automatic (All Phases) Volume calculation 6
Reference: LV Automatic (All Phases) Volume calculation 7
Test case 2: LV Automatic Volume calculation 8
Reference: LV Automatic Volume calculation 9
Test case 3: RV Automatic Volume calculation 10
Reference: RV Volume: Automatic calculation 11

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

(b)(4) Test cases

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

DOCUMENT NUMBER DN-02062013

DOCUMENT TITLE

CF0304A_RevB-RECORD-Regression_Safety_AQi_CMR_TVA_EF_measurement

Author:	(b) (6) [redacted]	**Title:**	[redacted]	**Date:**	[redacted]
			-		
Approved By:		**Title:**	[redacted]	**Date:**	
Approved By:		**Title:**	-	**Date:**	-
Approved By:	-	**Title:**	-	**Date:**	-

Revision History

Rev. Level	Description	Revised By	Approved By	Date
0	[redacted]	-	-	-

Reference Documents

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Document Number	Rev. Level	Description

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

1.0 INTRODUCTION

This is a safety regression test document for AQi CMR TVA. The objective is to ensure the measurement performed by CMR TVA are correct.

2.0 SCOPE

Correctness CMR TVA measurement

3.0 DEFINITIONS

User story: Feature, new feature, RFE.
RFE: Request For Enhancement
Defect: Bugs, bad design, issues.

4.0 EQUIPMENT (Test Machine specifications, supplies, etc.)

Manufacturer	Model	OS	Language
Dell	Precision T5400	Windows 7x64	English

Note: The regression tests covered in this document are not equipment specific.

5.0 RESPONSIBILITIES

[redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Table of Contents

Section A: Phantom Dataset info 5
Section B: CMR TVA correctness 7
[CMR TVA]: LV EF correctness 7
[CMR TVA]: RV EF correctness 8
Section C: Reference 10
1. Work sheet for CMR TVA: LV 10
2. Work sheet for CMR TVA: RV 11

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

(b)(4) Testing

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DOCUMENT NUMBER: FB-TVAMR-122612

DOCUMENT TITLE: CF0304A_RevB-RECORD-Test_Cases_iNtuition_TVA(MR)-Predicate_FB

Author/ Revised by:	(b) (6) [redacted]	Title:	(b)(4) [redacted]	Date	(b)(4) [redacted]	Signature	(b) (6) [redacted]
Approved by:	[redacted]	Title:	[redacted]	Date	[redacted]	Signature	[redacted]
Approved by:	[redacted]	Title:	[redacted]	Date	[redacted]	Signature	[redacted]
Approved by:	[redacted]	Title:	[redacted]	Date	[redacted]	Signature	[redacted]

REVISION HISTORY

Revision Level	Description	Author/Revised By	Approved By	Approved Date
0	(b)(4) [redacted]			
1				

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

REFERENCE DOCUMENTS

Document Number	Rev. Level	Description
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1.0 INTRODUCTION

TVA (Time Volume Analysis) for MR dataset provides calculation of ejection fraction from a chamber in rhythmic motion. A fast and efficient workflow is offered to enable the user to edit contours of the wall boundaries, and, based on these regions of interest, to report ejection fraction, defined as (max volume - min volume)/(max volume), wall volume (proportional to mass assuming constant density) and wall thickening from multi-phasic MR data.

This test documents record the testing performed on 20 cases to compare the results performed with Argus from the Siemens Leo (MMWP), our predicate device for TVA (MR).

(b) (6) [redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Description of acquisition and analysis technique:
Argus is a ventricular function and mass analysis available on the Siemens Leo (MMWP). The dataset came from Siemens Magnetom Avanto MR scanner.

2.0 SCOPE

"Magnetic Resonance (MR) data acquisition for cardiac function is analyzed (including manual delineation of ventricle boundaries) using both Siemens Argus and TeraRecon Time-Volume Analysis (TVA) software"

3.0 DEFINITIONS

LV = Left Ventricular
DSCT = Dual Source Computed Tomography
CAD = Coronary Artery Disease
CTCA = Computed Tomography Coronary Angiography
cMRI = Cardiac MRI
ROI = Region Of Interest
EDV = End-Diastolic Volume
ESV = End-Systolic Volume
EF = Ejection Fraction
WS = Workstation
SV = Stroke Volume

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

TERARECON

TEST CASES

(b)(4)

[redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

TERARECON

TEST CASES

(b)(4)

[redacted]

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TERARECON

TEST CASES

(b)(4)

[redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

TERARECON

TEST CASES

(b)(4)

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

TERARECON

TEST CASES

(b)(4)

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

DOCUMENT NUMBER CL-WR0034

DOCUMENT TITLE

CF0304A_Regression_Test_Cases_EA_AqNET_CL-WR0034_ParametricMap

Author:	(b) (6) [redacted]	Title:	(b)(4) [redacted]	Date:	(b)(4) [redacted]
Approved By:		Title:		Date:	
Approved By:		Title:		Date:	
Approved By:		Title:		Date:	

Revision History

Rev. Level	Description	Revised By	Approved By	Date
A	(b)(4) [redacted]			

Reference Documents

Document Number	Rev. Level	Description

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

1.0 INTRODUCTION

This is a regression test document to be used for Parametric map testing major functionalities

2.0 SCOPE

Transparency, Color selection, Gradation, Compression

3.0 DEFINITIONS

User story: Feature, new feature, RFE.
RFE: Request For Enhancement
Defect: Bugs, bad design, issues.
TDA: Time-Density Analysis module for studying time-dependence of contrast enhancement, such as enhancement of brain tissue due to perfusion with contrast-enhanced blood.
SAT: Segmentation Analysis Tracking module for analyzing and tracking volumes such as soft tissue masses or solitary pulmonary nodules.
EVAR: Endovascular Aneurysm Repair module for endograft planning.

4.0 EQUIPMENT (Test Machine specifications, supplies, etc.)

Manufacturer	Model	OS	Language
2900	Dell	Windows 2003 x64	English

Note: The regression tests covered in this document are not equipment specific.

5.0 RESPONSIBILITIES

(b)(4) [redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Index of tests:

Contents

Test 1: Transparency 4
Test 2: Colors selections in Parametric Map. 4
Test 3: Gradation colors 5
Test 4: Compression 5
Test 5: Parametric map display using uptake 5
Test 6: Interpolation for parametric map volume 6
Test 7: Parametric map series in 16 bit rendering 7

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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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 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

DOCUMENT NUMBER DK-101207

DOCUMENT TITLE

CF0304A_RevB-RECORD-Regression_APS_ParametricMap

Author:	(b) (6) [redacted]	Title:	(b)(4) [redacted]	Date:	(b)(4) [redacted]
Approved By:		Title:		Date:	
Approved By:		Title:	-	Date:	-
Approved By:	-	Title:	-	Date:	-

Revision History

Rev. Level	Description	Revised By	Approved By	Date
A	(b)(4) [redacted]			
B				

Reference Documents

Document Number	Rev. Level	Description

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

1.0 INTRODUCTION

This is a regression test document for Parametric Map test. Parametric Map is a PE performed mostly on Breast MR Subtracted data. It is an independent protocol or a part of MultiphaseMR protocol. This document covers the individual Parametric Map protocol.

2.0 SCOPE

Aqnet,Aps

3.0 DEFINITIONS

User story: Feature, new feature, RFE.
RFE: Request For Enhancement
Defect: Bugs, bad design, issues.

4.0 EQUIPMENT (Test Machine specifications, supplies, etc.)

Manufacturer	Model	OS	Language
Dell	Power Edge 2900	Windows XP X32 (64)	English
Dell	Power Edge 4600	Windows Server 2003	English
Dell	Power Edge 2950	Windows Server 2003	English
Dell	Power Edge 2950	Windows 2008	English

Note: The regression tests covered in this document are not equipment specific.

5.0 RESPONSIBILITIES

(b)(4) [redacted]

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

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Index of tests:

Contents

Test 1 : Parametric Map 4
Appendix: 11

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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16.10 Revision level history

(b)(4)

[redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4) Verification Validation report

[redacted]

(b)(4) Verification Validation report

(b)(4) Verification Validation report

(b)(4) Verification Validation report

(b)(4) Verification Validation report

(b)(4) Verification Validation report

(b)(4) Verification Validation report

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Risk Analysis

[redacted]

(b)(4) Risk Analysis

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Risk Analysis

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Risk Management

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Risk Management

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Risk Management

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Risk Management

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

From: Reviewer Name Sanaz Jansen

Subject: 510(k) Number K131447/S001

To: The Record

Please list CTS decision code: SE

☐ Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)

☐ Hold (Additional Information or Telephone Hold)

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page *(Attach IFU)*	X	
510(k) Summary or 510(k) Statement *(Attach Summary or Statement)*	X	
Truthful and Accurate Statement *(Must be present for a Final Decision)*	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach Form 3654.)		X
Is this a combination product?		X
Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices.)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		
Neonate/Newborn (Birth to 28 days)		
Infant (29 days to < 2 years)		
Child (2 years to <12 years)		
Adolescent (12 years to <18 years)		
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.)		
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		

5

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Nanotechnology		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Regulation Number:	892.2050
Class:	II
Product Code:	LLZ
Additional Product Codes:	

Digital Signature Concurrence Table
(Not all signatures may be required)

Branch Chief Sign-Off	Robert A Ochs	Robert A. Ochs 2013.12.24 12:57:04 -05'00'
Division Sign-Off	Janine M. Morris	Janine M. Morris -A 2013.12.24 14:13:20 -05'00'

6

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

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TERARECON

K131447 | S001

November 29, 2013

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

FDA CDRH DMC
DEC 02 2013
Received

RE: K131447, Amendment 1 (AI Response) [Confidential]
Trade Name: iNtuition-TDA, TVA, Parametric Mapping
Common Name: Medical Imaging System
Establishment Registration #: 2954793

Dear Dr. Jansen,

The purpose of this amendment to K131447 is to address the additional information request dated July 18, 2013. We are responding with two (2) copies of the additional information requested, addressing the deficiencies to assist in substantial equivalent determination. TeraRecon, Inc., submitted a 510(k) premarket notification of intent to market its iNtuition-TDA, TVA and Parametric Mapping software, referenced above, on May 17, 2013.

To comply with "eCopy Program for Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff," TeraRecon, Inc., submits one copy of the AI response in ecopy (CD) format. The eCopy is an exact duplicate of the paper copy.

May we please advise, this amendment contains trade secrets and confidential information that, in accordance with 21 CFR §20.61(c), is not available for public disclosure. TeraRecon, Inc., hereby requests that the information designated as confidential in this submission be exempt from disclosure under Exemption 4 of the Freedom of Information Act.

Should you have any questions concerning this submission, please do not hesitate to contact me.

Sincerely,

Emilly Tojima Nurthen, RAC
Regulatory Affairs Manager
TeraRecon, Inc.
4000 E 3rd Ave, Suite 200,
Foster City, CA 94404

Tel: (650) 653-4282
Fax: (650) 372-1101
Email: emilly@terarecon.com

Enclosed: One (1) hardcopy and one (1) ecopy

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

37

Records processed under FOIA 2014-9975, Released by CDRH on 12/3/2015

TERARECON

November 29, 2013

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

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K131447, Amendment 1

Additional Information Response

iNtuition-TDA, TVA, Parametric Mapping

TeraRecon, Inc.

4000 East 3rd Avenue

Foster City, CA 94404

November 29, 2013

CONFIDENTIAL

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

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1. Based on our review, the iNtuition—TDA, TVA and Parametric Mapping modules were initially included in a previous submission (K121916) for the iNtuition device. Based on our understanding, you elected to remove these modules from this previous submission and submit them separately herein. However, during review of K121916 you had received questions/feedback from the FDA regarding these modules. Please identify where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed, if at all. This information will assist in our determination of substantial equivalence.

TeraRecon Response:

(b)(4) [redacted]

2. The TDA and Parametric Mapping software modules analyze the time-dependent behavior of tissue after administration of a contrast agent (CT or MR). Please provide a list of the features that must be, or are intended to be, used with contrast agent. Please indicate if these features are available in a previously cleared or approved device, or if the features are unique to your device. This information will assist in our determination of substantial equivalence.

TeraRecon Response:

(b)(4) [redacted]

Table 1: TDA (CT) Predicate Device Comparison

Feature	iNtuition-TDA	CT Predicate Devices *Aquarius Workstation (K011142)* *Aquarius APS (K061214)* *CT Perfusion 4 (K052839)*
(b)(4) [redacted]		

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

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Table 2: TDA (MR) Predicate Device Comparison

Feature	iNtuition-TDA	Syngo.Mr Neurology (*K121459*)
(b)(4) [redacted]		

(b)(4) [redacted]

3. Your submission describes the TDA software module for analysis of perfusion images (CT/MRI) primarily for the brain.

   a. On page 12-4 of the *Substantial Equivalence Discussion* you provide a comparison table of the TDA module in the subject device compared to primary and secondary predicate devices. This table presents a general explanation that the devices are similar. However, the specifics of which features are new or not is not clear from your submission. Please specify which TDA features (e.g., CBF, CBV, MTT, TOT, methods for mathematical modeling and arterial input function selection) in the subject device are included in a primary predicate device, and which features are new. For features that are new compared to the primary predicate devices, please identify the reference device that includes an analogous feature. This information will assist in determining substantial equivalence.

TeraRecon Response:

(b)(4) [redacted]

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

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Feature	iNtuition – TDA	AQWS (K011142)	AQAPS (K061214)	CT Perfusion 4 (K052839)	Syngo.MR Neurology (K121459)
Modality Support	(b)(4) [redacted]	CT	CT	CT	MR
Basic Reading Functionality	[redacted]	Same	N/A	Same	Same
Region-of-Interest (ROI) markers	[redacted]	Same	N/A	Same	Same
Measurement capability	[redacted]	Same	N/A	Same	Same
Perfusion Color maps	[redacted]	Same	Same	Same	Same
Export Capability	[redacted]	Same	Export results are DICOM files (color maps)	Same	Same
Methods for Mathematical Modeling	[redacted]	SVD	SVD	SVD	Unknown
Arterial Input Function Selection	[redacted]	Same	Automatic	Same	Same

b. The *Software Description* describes the mathematical model used to calculate the TDA parameters. Please clarify whether there are recommended/required image acquisition characteristics (e.g., temporal resolution) for the effective use of your device and modeling, and update the User Manual accordingly. This information will promote the effective use of your device.

TeraRecon Response:

(b)(4) [redacted]

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

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(b)(4)

[redacted]

c. On page 7-2 of the *User Manual* you state that initially the software calculates the TDA and displays the results. Please clarify whether the software automatically selects the arterial input and venous output functions. If so, please provide a brief description of the methods used and include in the *User Manual.* Please provide instructions to the user on examining the adequacy of the automatically selected artery/vein profiles and proceeding to a manual selection (Manual TDA, page 7-12), if desired. This information is required to evaluate the technological characteristics of your device.

TeraRecon Response:

(b)(4)

[redacted]

d. For MR applications of the TDA, please clarify how signal intensity is converted to contrast concentration. Please clarify whether information is required from the user to facilitate this conversion (e.g., relaxivity, TE), or whether this happens automatically. Please also clarify what TDA parameters are calculated from the MR-based acquisitions. This information is required to evaluate the technological characteristics of your device.

TeraRecon Response:

(b)(4)

[redacted]

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

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(b)(4) [redacted]

- (b)(4) [redacted]

e. Your description of the TDA option in *Software Description* also includes a classification map feature (page 16.2-3). It is unclear how the parameter thresholds are set in this feature. Please clarify whether the parameter thresholds are pre-determined values set in the software or if they are set by the user. If the thresholds are pre-determined and set in the software, please provide justification for the values of the thresholds. Please also update the User Manual with information regarding this feature.

TeraRecon Response:

(b)(4) [redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) [redacted]

f. On pages 64-69 of *Verification and Validation Documentation-Time Dependent Analysis* you have provided screenshots qualitatively displaying TDA parameters in the subject and secondary predicate devices, and have provided a signed statement by a physician. However, the criteria used for clinical evaluation of the images was not provided. Additionally, based on our review we did not find performance testing quantitatively comparing the TDA parameters calculated by the subject and predicate devices. Please provide such testing. Please also provide additional details regarding the testing methods (e.g., cases included, how arterial and venous ROIs are selection). This information is needed to determine the substantial equivalence of your device.

TeraRecon Response:

Background

(b)(4) [redacted]

Clinician Evaluation Description (as conducted in K131447)

(b)(4) [redacted]

Quantitative/Qualitative Testing

(b)(4) [redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)
[redacted]

4. Your submission describes the TVA software module for analysis of volumetric changes in cardiac images (CT/MRI).

a. On page 12-5 of the *Substantial Equivalence Discussion* you provide a comparison table of the TVA module in the subject device compared to primary and secondary predicate devices. This table presents a general explanation that the devices are similar. However, the specifics of which features are new or not is not clear from your submission. Please specify which TDA features (e.g., EF, stroke volume, methods for calculation, CT/MR acquisition) in the subject device are included in a primary predicate device, and which features are new. For features that are new compared to the primary predicate devices, please identify the reference device that includes a similar feature. This information will assist in determining substantial equivalence.

TeraRecon Response:

(b)(4)
[redacted]

b. Chapter 5 of the User Manual describes the TVA module focuses on cardiac CT images and describes the TVA parameters to be calculated. Pages 2-102 to 2-111 describe the TVA module functionality for MRI. Please clarify what TVA parameters are to be calculated from cardiac MRI datasets. This information is required to evaluate the technological characteristics of your device.

TeraRecon Response:

(b)(4)
[redacted]

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

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

- (b)(4) [redacted]

(b)(4) [redacted]:

- (b)(4) [redacted]

(b)(4) [redacted]

- (b)(4) [redacted]

c. On pages 77-84 of *Verification and Validation Documentation-Time Volume Analysis* you have provided comparison testing of the TVA parameters calculated in the subject and secondary predicate device. This testing is based on cardiac MRI. Please also provide comparison testing for cardiac CT datasets. This information will assist in our determination of substantial equivalence.

TeraRecon Response:

(b)(4) [redacted]

5. The *Software Description* describes the Parametric Mapping software module for analysis and visualization of signal intensity changes over time.

a. On page 16.2-5 you state that the enhancing ratio is calculated using Intensity2, the pixel value measure in a late post-enhancement image. Please clarify what time-point is used for selection of Intensity2 and update the User Manual accordingly. This information will help users effectively interpret the functionality of your device.

TeraRecon Response:

(b)(4) [redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4)
[redacted]

b. On page 16.2-6 you state that one modification in the subject device compared to the predicate is reduced isolated noise. Please clarify further how this modification was implemented. This information is required to evaluate the technological characteristics of your device.

TeraRecon Response:
(b)(4)
[redacted]

6. On page 3-23 of the User Manual you describe the CAD feature and state that CAD markers identify potential lesions. Please clarify if this feature was included in a predicate device. This information is required to evaluate the technological characteristics of your device.

TeraRecon Response:

(b)(4)
[redacted]

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

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(b)(4)

[redacted]

7. In *Unresolved Anomalies-Bugs or Defects* you identify the unresolved anomalies in your device. Please provide additional clarification regarding DE14392 "TDA-ROI measurement does not match" and DE15963 "Sometimes TDA ellipse ROI measurement does not match the general ellipse measurement" and your future plan to resolve these anomalies. This information is required to evaluate the technological characteristics of your device.

TeraRecon Response:

8	DE14392	(b)(4) [redacted]	[redacted]
10	DE15963	[redacted]	(b)(4) [redacted]

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

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(b)(4)

[redacted]

8. You have provided a 510(k) Summary that includes many of the required elements regarding your device. However, it does not present an adequate technological comparison of the subject and predicate devices. Please provide this comparison.

TeraRecon Response:

(b)(4) [redacted]

9. You have provided an iNtuition-TDA, TVA PM-User Manual with detailed instructions for use.

a. Please clarify whether there are any additional software/hardware requirements specific to the TDA, TVA or Parametric Mapping modules, beyond what is already included for iNtuition (K121916), and update the User Manual accordingly.

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

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TeraRecon Response:

(b)(4) [redacted]

b. On page 7-1 you provide a note to users to define parameter ranges prior to using the TDA modules. Please also include information regarding where the user can learn more about what the default ranges are (based on my review, this information is on page A-18).

TeraRecon Response:

(b)(4) [redacted]

10. Please provide an updated Indications for Use form using the attached OIR-DRH template. Please also include your 510(k) number, K131447.

TeraRecon Response:

(b)(4) [redacted]

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

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List of Appendices

Appendix 1: Prior FDA Communication

Appendix 2: Revised user manual page 7-1

Appendix 3: Revised user manual page 7-12

Appendix 4: TDA User Evaluation Report

Appendix 5: TDA Predicate Device Comparison

Appendix 6: Revised TVA Substantial Equivalence Chart

Appendix 7: TVA Predicate Device Comparison

Appendix 8: User Manual Revised Pages for Parametric Mapping

Appendix 9: Second Look Viewer 510(k) summary

Appendix 10: iNtuition CAD Marker Display Test Report

Appendix 11: Revised User Manual Page 3-23

Appendix 12: Bug Fix Test Report

Appendix 13: Revised 510(k) Summary

Appendix 14: Indications for Use

Appendix 15: Revised User Manual Page 5-1

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

Appendix 1

(b)(4)

[redacted]

Time Density Analysis (TDA)

(b)(4)

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

TeraRecon Response:

(b)(4)

[redacted]

Time Volume Analysis (TVA):

(b)(4)

[redacted]

TeraRecon Response:

1) (b)(4)

[redacted]

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

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(b)(4) [redacted]

2) (b)(4) [redacted]

3) (b)(4) [redacted]

4) (b)(4) [redacted]

5)

Parametric Mapping:

(b)(4) [redacted]

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

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TeraRecon Response:

(b)(4) [redacted]

TDA

(b)(4) [redacted]

TeraRecon Response:

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

TVA

(b)(4) [redacted]

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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Chapter 7: Time Dependent Analysis

(b)(4) draft document

[redacted]

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(b)(4) draft document

[redacted]

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TERARECON		TEST CASES
Document №: CF 0304A	Revision Level: C	Revision Date: 01/31/2013
Process Owner: Director of Software Quality Assurance		Page 1 of 22

DOCUMENT NUMBER: TDA-EVALUATION-26NOV2013

DOCUMENT TITLE: iNtuition TDA User Validation (CT/MR)

Author/ Revised by: (b) (6) [redacted] **Title:** (b)(4) [redacted] **Date:** (b)(4) [redacted] **Signature:** (b) (6) [redacted]

Approved by: [redacted] **Title:** [redacted] **Date:** [redacted] **Signature:** [redacted]

Approved by: _____ **Title:** _____ **Date:** _____ **Signature:** [redacted]

Approved by: _____ **Title:** _____ **Date:** _____ **Signature:** [redacted]

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Revision Level	Description	Author/Revised By	Approved By	Approved Date
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REFERENCE DOCUMENTS

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1.0 INTRODUCTION

The objective of this test is to conduct an external user evaluation of iNtuition-TDA brain perfusion map output in comparison to GE CT 4 and Siemens Syngo MR.

2.0 SCOPE

TDA-Time Density Analysis

3.0 DEFINITIONS

CBV/BV-Cerebral Blood Volume/Blood Volume
CBF/BF-Cerebral Blood Flow/Blood Flow
MTT-Mean Transit Time

4.0 TEST CASES

4.1 Test Method:

TeraRecon provided a combination of two CT and one MR brain perfusion datasets to clinicians for qualitative analysis and comparison of specified parameters. The clinicians were provided with the cerebral blood flow (CBF), cerebral blood volume (CBV) and mean transit time (MTT) maps from TeraRecon with a comparison map from either GE or Siemens software, with masked vendor identification markers in a Microsoft word document. The clinicians were only provided images for analysis, and did not have access to patient history or other diagnostic information.

4.2 Clinicians:

Three qualified clinicians, familiar with reading brain perfusion datasets were selected to evaluate the test data. The three neuroradiologists who completed the evaluation:

- (b) (6) [redacted]

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(b)(4) Test Cases

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DOCUMENT NUMBER: JZ-20130930TDA2

DOCUMENT TITLE: CF0304A_RevB-RECORD- _AQi_TDA_Predicate_Comparison

Author/ Revised by: (b) (6) [redacted] **Title:** (b)(4) [redacted] **Date:** (b)(4) [redacted] **Signature:** (b) (6) [redacted]

Approved by: [redacted] **Title:** [redacted] **Date:** [redacted] **Signature:** [redacted]

Approved by: [redacted] **Title:** [redacted] **Date:** [redacted] **Signature:** [redacted]

Approved by: [redacted] **Title:** [redacted] **Date:** [redacted] **Signature:** [redacted]

REVISION HISTORY

Revision Level	Description	Author/Revised By	Approved By	Approved Date
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REFERENCE DOCUMENTS

Document Number	Rev. Level	Description
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@FDA.HHS.gov or 301-796-8118

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1.0 INTRODUCTION

TDA (Time Density Analysis) is used for studying time-dependence of contrast enhancement such as enhancement of brain tissue due to perfusion with contrast enhanced blood. The TDA module studies blood flow through a structure after the patient is injected with a contrast dye. The study creates several kinds of functional maps, including but not limited to Blood volume (BV), Blood Flow (BF), Meant Transit time (MTT).

2.0 SCOPE

This test will provide a quantitative comparison of the AQWS and iNtuition TDA-CT software module.

3.0 DEFINITIONS

TDA -- Time Density Analysis
MTT -- Mean Transit Time
BV/CBV -- Blood Volume/ Cerebral Blood Volume
BF/ CBF -- Blood Flow/ Cerebral Blood Flow
ACA -- Anterior Cerebral Artery
MCA -- Medial Cerebral Artery
ROI -- Region Of Interest
HU -- Hounsfield Unit

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

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Table of Contents

1.0 Test Cases 4
2.0 Methodology 5
3.0 Result 6
3.1 Test results for data "Patient10200" 6
3.2 Test results for data "WJ" 10
3.3 Test results for data "CCFTDA" 14
4.0 Conclusion 18

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

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1.0 Test Cases

Criteria for test case selection:

- Contrast enhanced multiphase CT dataset
- Datasets must come from different CT scanners

Three datasets that met the above criteria were selected for this test:

Number	Patient Name	Series Description	Scanner Manufacturer
1	Patient10200	PCT2 SHUTTLE OVERLAP	GE Medical Systems
2	WJ		Toshiba
3	CCFTDA	VPCT Volume Perf 5.0 H20f	Siemens

The test datasets can be found at:
\\dev-vm-fs\SQA_files\DATACENTER\TDA_4_FDA\Patient10200.zip
\\dev-vm-fs\SQA_files\DATACENTER\TDA_4_FDA\WJ.zip
\\dev-vm-fs\SQA_files\DATACENTER\TDA_4_FDA\CCFTDA.zip

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

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2.0 Methodology

(b) (4)

[redacted]

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

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TEST CASES

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(b)(4)

[redacted]

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

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TEST CASES

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TEST CASES

(b)(4)

[redacted]

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TEST CASES

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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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TEST CASES

(b)(4)

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(b)(4)

[redacted]

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TEST CASES

(b)(4)

[redacted]

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Appendix 6

Table 1: Revised TVA Substantial Equivalence Chart

Feature	Subject Device **iNtuition – TVA** (K131447)	Primary Predicate **Aquarius Workstation** (K011142)	Secondary Predicates **Siemens** (K042203, K040970, K110366)
Indications for Use	(a)	(b)	(c)
Image Modality	(b)(4) [redacted]	CT	CT, MR
Basic Reading Functionality	[redacted]	Same	Same
Multiple MPR review planes	[redacted]	Same	Same
Heart isolation	[redacted]	Same	Same
4D chamber Modeling and Contouring	[redacted]	Same	Same
4D movie	[redacted]	Same	Same
Left Ventricle Analysis	[redacted]	Same (excluding automatic axis/valve plane section)	Same
Right Ventricle Analysis	[redacted]	Not present	Same

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

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Polar Maps	(b)(4) [redacted]	Same (excluding expanded feature)	Similar
Color templates	[redacted]	Same (excluding expanded feature)	Similar
Graphs	[redacted]	Same	Same
DICOM compatible	[redacted]	Same	Same

Indications for Use

(a) iNtuition TDA, TVA, Parametric Mapping

iNtuition-TDA, TVA, and Parametric Mapping are software modules which supports assessment of time-dependent behavior of image intensity, density, dimensions or volume of regions of interest over time, for volumetric or planar dynamic image types such as CT or MR. Parametric mapping tools encode in color various parameters derived from the temporal or spatial characteristics of the planar or volumetric data.

Support is provided for digital image processing to derive metadata or new images from input image sets, for internal use or for forwarding to other devices using the DICOM protocol. Image processing tools are provided to extract metadata to derive parametric images from combinations of multiple input images.

iNtuition-TDA, TVA and Parametric Mapping are iNtution based software features with dedicated workflows and basic tools and thus support post-processing, displaying and manipulation of reports and medical images from acquisition devices and visualization in 2D, 3D and 4D for single or multiple datasets, or combinations thereof.

iNtuition-TDA, TVA, Parametric Mapping are designed for use by healthcare professionals and are intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions.

(b) Aquarius Workstation

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

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To acquire, store, transmit, and display medical images from medical scanning devices such as EBT, CT or MRI and patient reports of various types. Teleradiology, image acquisition, distribution, archiving, image manipulation, 3D and 4D visualization are supported. The software supports post-processing based on dynamic CT or MR images continuously acquired to aid in the assessment of time-dependent behavior of the image density or dimensions of certain regions of interest. Calcium Scoring from whole body computed tomography derived measurements, for non-invasive detection and quantification of atherosclerotic plaque. Tools for histogram analysis of the density distribution of certain regions of interest are provided. A database management and report generation tool is included.

(c) Siemens

LEONARDO *syngo* Cardiology Workstation-Argus(K042203)

The LEONARDO syngo Cardiology Workstation is a medical diagnostic workstation for viewing, manipulation, communication and storage of medical images and data on exchange media.

The LEONARDO syngo Cardiology Workstation can be configured as a stand-alone diagnostic review and post-processing workstation with a variety of syngo or Windows based software options, which are intended to assist the physician in diagnosis or treatment planning. These includes commercially available post-processing techniques.

LEONARDO (K040970)

The LEONARDO is a medical diagnostic workstation for viewing, manipulation, communication, and storage of medical images and data on exchange media.

The LEONARDO can be configured as a satellite console, sharing a database with the main console of a CT, MR, or radiographic/ fluoroscopic imaging system, as well as stand-alone diagnostic review and post-processing workstation.

The LEONARDO can be configured with a variety of syngo or Windows XP-based software options, which are intended to assist the physician in diagnosis or treatment planning. This includes commercially available post-processing techniques.

Syngo.CT Cardiac Function (K110366)

Syngo.CT Cardiac Function is an image analysis software package for evaluating cardiac CT angiography (CTA) volume data sets. Combining digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, minimum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT)), evaluation tools (left and right ventricular (LV/RV) volume calculation, left ventricular myocardial wall calculation and visualization of myocardial enhancement by color coding of hypo-/hyperdense areas) and reporting tools (finding location, finding characteristics and key images), the software package is designed to support the physician in determining the functional parameters of the left and right ventricles, confirming the presence or absence of physician-identified myocardial enhancement defects and evaluation, documentation and follow-up of any such finding.

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

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These visualization/evaluation tools allow for quantification of functional parameters and characterization of myocardial enhancements defects over time, helping the physician to assess any changes. It is also designed to help the physician classify conspicuous regions of tissue.

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

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APR 1 2 2011

510(k) - Summary

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

I. GENERAL INFORMATION

1. Device Name and Classification

Product Name:	*syngo.CT Cardiac Function*
Classification Name:	Accessory to Computed Tomography System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

2. Importer/Distributor Establishment:

Registration Number: 2240869

Siemens Medical Solutions, Inc.
51 Valley Stream Pkwy
Malvern, PA 19355

3. Manufacturing Facility:

Siemens AG
Medical Solutions
Henkestrasse 127

D-91052 Erlangen, Germany

4. Contact Person:

Mr. Ralf Hofmann
Regulatory Affairs Specialist
Siemensstr.1; D-91301 Forchheim
Phone: +49 9191 18-8170
Fax: +49 9191 18-9782

5. Date of Preparation of Summary: Mar. 23rd 2011

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

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II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

6. General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

7. Device Description and Intended Use:

Syngo.CT Cardiac Function is an image analysis software package for evaluating cardiac CT angiography (CTA) volume data sets. Combining digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, minimum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT)), evaluation tools (left and right ventricular (LV/RV) volume calculation, left ventricular myocardial wall calculation and visualization of myocardial enhancement by color coding of hypo-/hyperdense areas) and reporting tools (finding location, finding characteristics and key images), the software package is designed to support the physician in determining the functional parameters of the left and right ventricles, confirming the presence or absence of physician-identified myocardial enhancement defects and evaluation, documentation and follow-up of any such finding.
These visualization/evaluation tools allow for quantification of functional parameters and characterization of myocardial enhancements defects over time, helping the physician to assess any changes. It is also designed to help the physician classify conspicuous regions of tissue.

8. Substantial Equivalence:

syngo.CT Cardiac Function software package, designed for post processing images that have been continuously acquired with computed tomography (CT) imaging systems which meet certain minimal requirements, is substantially equivalent to the following devices:

Manufacturer	Product	510(k)	Clearance date
1. Siemens AG	syngo® Circulation	K063762	01/05/2007
2. Siemens AG	syngo®.x	K092519	08/27/2009
4. GE Medical Systems	CardIQ Function Xpress	K073153	02/26/2008
5. GE Medical Systems	CardIQ Xpress 2.0	K073138	02/26/2008

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

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9. Summary of Technological Characteristics of the Principle Device as Compared with the Predicate Devices

syngo.CT Cardiac Function is a post-processing software package which provides a combination of functionality similar to functionality provided by one or more of the predicate devices as listed below. It uses the same data for evaluation as the predicate devices and provides results in the same format as the predicate devices.

As basis for data viewing, *syngo.CT Cardiac Function* uses basic reader and image display functionality as provided by syngo®.x. In addition to basic viewing capabilities, *syngo.CT Cardiac Function* provides tools for visualization, analysis and reporting of cardiac function conditions. These tools are based on segmentation of cardiovascular structures such as coronary arteries and heart chambers. Accordingly, *syngo.CT Cardiac Function* has equivalent technological characteristics as the predicate devices. Moreover, *syngo.CT Cardiac Function* uses current image processing algorithms, in order to provide results that are substantially equivalent to those obtained with one or more of the predicate devices.

*syngo.*CT Cardiac Function	Description	Comparison to predicate devices
Basic Reading Functionality	Conventional navigation on 2D and 3D views, change of layouts, adapt window values	Same
Cardiac, Aortic Valve and Mitral Valve Planes	Rotate MPR planes to short/long axis, aortic or mitral plane views	Extended. Additional planes for aortic and mitral valve.
Review Marker	Functionality for setting location of a clinical finding on any view	Extended. Additional bookmarking functionality.
Integrated Reporting (Reporting Tools)	Functionality for editing values of clinical findings such as location, pathology, etc	Same
Heart Isolation	Masking of structures around the heart	Same
4D Movie and Movie Series	Start/stop movie and adjust all views. Select MPR views for movie series	Extended. Storage for movie series added.
4D Chamber Modeling and Contouring	Contouring of heart chambers contours, edit and correction of contouring	Extended. Added editing functions.
4D Left Ventricle Analysis	Volumetry of left ventricle over complete heart cycle. Selection of volumetry mode.	Extended. Added support for dual analysis mode.
Dynamic Volume Graph	Volume graph over heart cycle.	Same
Functional Parameters	Measurement of global and local cardiac function parameters.	Extended. Additional display options.
Polar Maps	Bulls-eye plots for display of local cardiac function parameters.	Same
4D Right Ventricular Analysis	Volumetry of right ventricle over complete heart cycle.	Same
Vizualization of relative Enhancement in Myocardium	Colouring of left ventricular myocardium based on relative HU enhancement.	Same
Delayed Relative Enhancement View	Colouring of left ventricular myocardium based on HU enhancement.	Same
Hybrid View	VRT visualization of coronary anatomy combined with local functional parameters in a single view.	Extended. Left ventricular epicardial model added to VRT.
DICOM compatible		Same

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

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Siemens is of the opinion that *syngo.CT Cardiac Function* software package is intended for the same indications for use as the predicate devices. It does not introduce any new potential safety risk and is substantial equivalent to and performs as well as the predicate devices.

10. Summary of non-clinical and/or clinical testing

syngo.CT Cardiac Function is designed to fullfill the requirements of following standards

- IEC 60601-1-6 : 2006; Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
- IEC 62304 Ed. 1.0, "Medical Device Software – Software Lifecycle Processes"
- ISO 14971:2007; Medical devices - Application of risk management to medical devices
- DICOM (Digital Imaging and Communications in Medicine) Standard: 2008
  DICOM conformity is fully covered by syngo®.x implementations.

Non clinical tests are conducted for *syngo.CT Cardiac Function* software package during product development. The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria.

Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

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

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Indication for use

510(k) Number (if known): K110366

Device Name: **syngo.CT Cardiac Function**

Syngo.CT Cardiac Function is an image analysis software package for evaluating cardiac CT angiography (CTA) volume data sets. Combining digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, minimum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT)), evaluation tools (left and right ventricular (LV/RV) volume calculation, left ventricular myocardial wall calculation and visualization of myocardial enhancement by color coding of hypo-/hyperdense areas) and reporting tools (finding location, finding characteristics and key images), the software package is designed to support the physician in determining the functional parameters of the left and right ventricles, confirming the presence or absence of physician-identified myocardial enhancement defects and evaluation, documentation and follow-up of any such finding.

These visualization/evaluation tools allow for quantification of functional parameters and characterization of myocardial enhancements defects over time, helping the physician to assess any changes. It is also designed to help the physician classify conspicuous regions of tissue.

Prescription Use X AND/OR Over-The-Counter Use _____

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

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

Concurrence of the CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pohl

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110366

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

DOCUMENT NUMBER: AQi-TVA-20130815-SH

DOCUMENT TITLE: **AQi TVA Predicate Device Comparison (CT)**

Author/ Revised by: (b) (6) [redacted] **Title:** (b)(4) [redacted] **Date** (b)(4) [redacted] **natu** (b) (6) [redacted]

Approved by: [redacted] **Title:** [redacted] **Date** [redacted] **natu** [redacted]

Approved by: [redacted] **Title:** [redacted] **Date** [redacted] **natu** [redacted]

Approved by: [redacted] **Title:** [redacted] **Date** [redacted] **natu** [redacted]

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1.0 INTRODUCTION

TVA: Time-Volume Analysis is used for analyzing changes in volume over time. The most frequent use is to segment and measure the volume of Left Ventricle (LV) of the heart and calculate the Ejection Fraction (EF). Another use is to segment and measure the volume of LV myocardial volume.

The iNtuition TVA module can be run from either client-server mode or Workstation mode (software on the same computer as the viewer). The Aquarius Classic TVA (CT) module can only be run in Workstation mode with module installation.

The accuracy test of these measurements is covered in test document (DN-20110603535), titled "CF0304A_Regression_Test_Cases_DN_AQi_TVA_Measurement". That test was using a digital phantom data in which the true value is known.

Another test document (DN-20120622), titled "CF0304A_RevB-RECORD-Regression_QTP_AQi_TVAmeasurement_Auto_RVEF_LVEF", is used to ensure that measurements are not changed between released versions.

This test compares the iNtuition (AQi Viewer) TVA module to the Aquarius Classic TVA module utilizing CT patient data.

2.0 SCOPE

The test case in this document is to ensure key measurements from the iNtuition AQi TVA have the accuracy equivalent to the established Aquarius Classic TVA module.

The test loads the same set of CT data onto two systems, performs the same set of measurements, and compares the result. The scope of function is limited to CT data, Left Ventricle, and global cardiac functions (regional cardiac function is not widely used in medical practice so it's not covered).

3.0 DEFINITIONS

TVA = Time Volume Analysis
CT = Computed Tomography
LV = Left Ventricle
EF = Ejection Fraction
EDV = End-Diastolic Volume
ESV = End-Systolic Volume

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4.0 TEST CASES

Contents

4.1 Patient Data vs. Phantom Data 4
4.2 Methodology in General 4
4.3 Test Cases 5
4.4 Calculation Method 6
4.5 Acceptance Criteria 6
4.6 Documenting Results 7
Conclusion 9

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Test Results

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Test Results

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Test Results

[redacted]

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TERARECON

TEST CASES

(b)(4) Test Results

[redacted]

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(b)(4) Test Results

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Test Results

[redacted]

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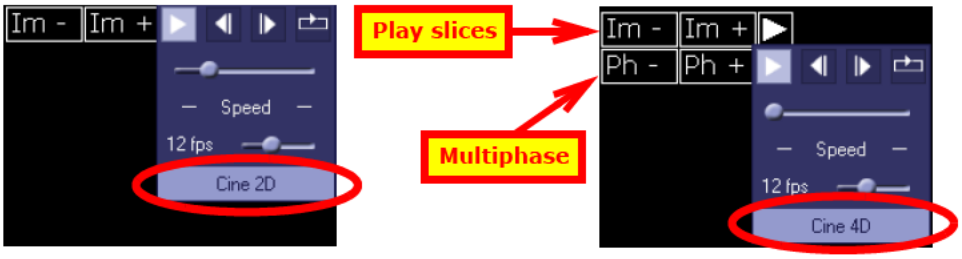
7. Click **OK** to exit the template editor.

Cine

There are two **Play** buttons in the **Cine** tool. The first (leftmost) plays through the slices of a single series. The second **Play** button plays a multiphase image as it changes over time, while remaining in the same image position.

The Cine tool is also available on the image as annotation. The top line plays a 2D cine just as the first **Play** button does. The bottom line plays a 4D cine just as the second **Play** button above does. The expanding arrows open a small dialog (see the following image) containing extra controls, including one for speed.



Register

The **Register** tool is used to register all currently displayed data.

PMap

PMap displays the parametric map for breast MR data. **Sub** subtracts T0 images from the current image.

Parametric Map

Parametric Map is a color-coded visualization of the change in intensity over time. To analyze the time-density curve, two thresholds are used in the Parametric Map module. One is the uptake value, which describes how fast the intensity changes between the pre-contrast and peak phases (also known as the initial, or wash-in phase). Each pixel in the image has an uptake threshold that indicates by what percentage that pixel's intensity increased between the two phases. In comparing the pixel intensities of the pre and the peak phases, it is usually the case (depending on the scanning protocol, scanner, and contrast media used),

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that areas with wash-in below 40-60% can be ignored. This threshold is set using the Uptake bar.

The second map shows the speed of the contrast washing out, also called the delayed phase. Each post phase pixel (post phases are identified by comparing the last post enhancement phase to the pre-contrast phase) is divided by the peak phase (first post-enhancement phase compared with the pre-contrast phase), to derive the difference in intensity for that pixel. There are three possible results:

- Type I: The pixel intensity has increased gradually.
- Type II: The pixel intensity has not changed.
- Type III: The pixel intensity has decreased gradually.

Each of these three types is represented by a different color. By default, Type I is respresented by blue, Type III by red, and Type II by the rainbow in the middle. There is no official standard that defines the percentage borders between each of the 3 types. By default, the border between Type I and Type II is set to 20%. This means that an increase in contrast of 20% or more is shown with the blue overlay, a decrease of 20% or more is shown with red, and values in between use the green overlay. These borders can be changed, as can the colors themselves.

To see the parametric map, click the **Parametric Map** button. The uptake bar (on the left) and color bar (at right) are displayed on the image. These determine the colors used to show the changes in intensity during the delayed phase:

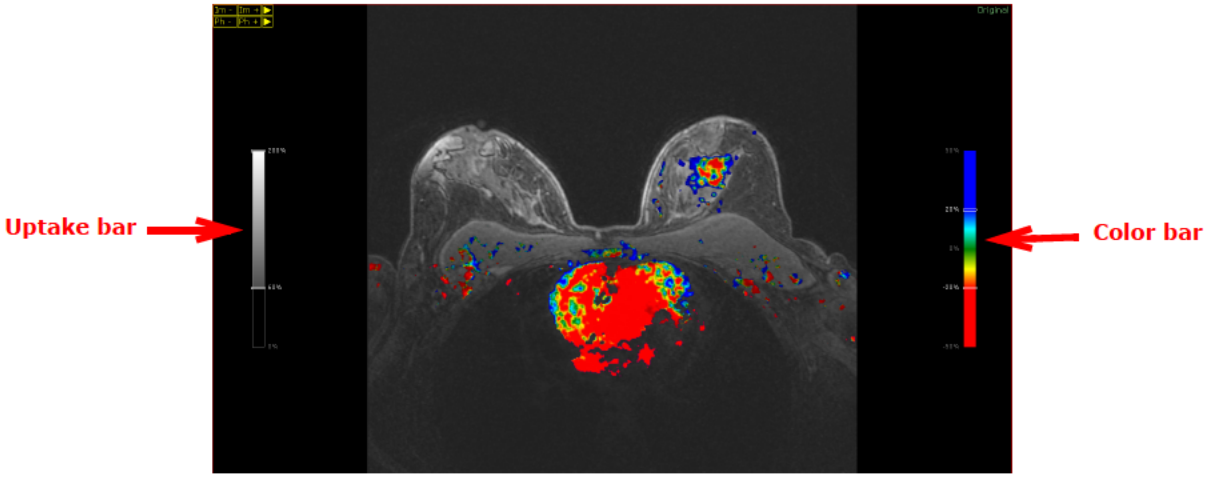

Figure 3-6: Parametric Map

The Color Bar

The color bar shown in Figure 3-6 controls the color map of the delayed phase. There are three color areas, one for each type of change. Between each pair of adjacent colors is a slider that allows you to change the percentage border for both colors.

To change the percentage border between two colors, click and drag the slider up or down (see Figure 3-7 on page 3-21). For example, to lower the threshold between the Type I and Type II colors, drag the upper slider downward. As this threshold is lowered, the amount of the Type I color will be increased on the image.

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Below, Figure 10-9 shows an MR multi-phase study viewed by time:

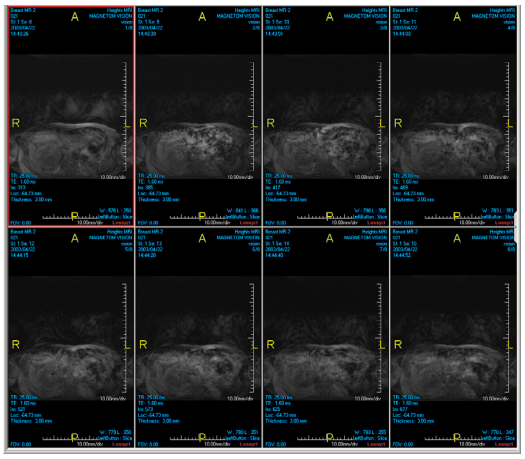

Figure 10-9: All Phases at a Single Position

Figure 10-10 shows the same study viewed by position:

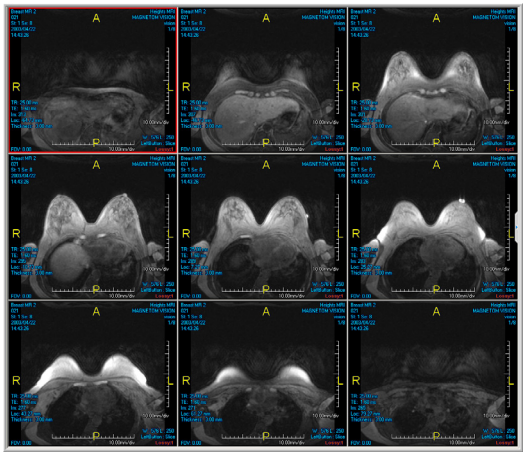

Figure 10-10: All Positions During a Single Phase

Color Coding in Parametric Map

Parametric Map is a color-coded visualization of the change in intensity over time. To analyze the time-density curve, two thresholds are used in the Parametric Map module. One is the uptake value, which describes how fast the intensity changes between the pre-contrast and peak phases (also known as the initial, or wash-in phase). Each pixel in the image has an uptake threshold that indicates by what percentage that pixel's intensity increased between the two phases. In comparing the pixel intensities of the pre and the peak phases, it is usually the case (depending on the scanning protocol, scanner, and contrast media used), that areas with wash-in below 40-60% can be ignored. This threshold is set using the Uptake bar.

The second map shows the speed of the contrast washing out, also called the delayed phase. Each post phase pixel (post phases are identified by comparing the last post enhancement phase to the pre-contrast phase) is divided by the peak phase (first post-enhancement phase

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compared with the pre-contrast phase), to derive the difference in intensity for that pixel. There are three possible results:

Type I: The pixel intensity has increased gradually.
Type II: The pixel intensity has not changed.
Type III: The pixel intensity has decreased gradually.

Each of these three types is represented by a different color. By default, Type I is respresented by blue, Type III by red, and Type II by the rainbow (AQNET text listed green, iReview lists rainbow. Is green still correct?)in the middle. There is no official standard that defines the percentage borders between each of the 3 types. By default, the border between Type I and Type II is set to 20%. This means that an increase in contrast of 20% or more is shown with the blue overlay, a decrease of 20% or more is shown with red, and values in between use the green overlay. These borders can be changed, as can the colors themselves.

When you change the color-coding, that information is stored in your login's profile on the AqNET server. If you log into the server from a different client, using the same login, your color settings will be the same ones you configured earlier.

To change the color coding, do the following:

1. Click the **Parametric Map** button under the **Review** tab, as shown in Figure 10-11. The Parametric Map color bar will be displayed.

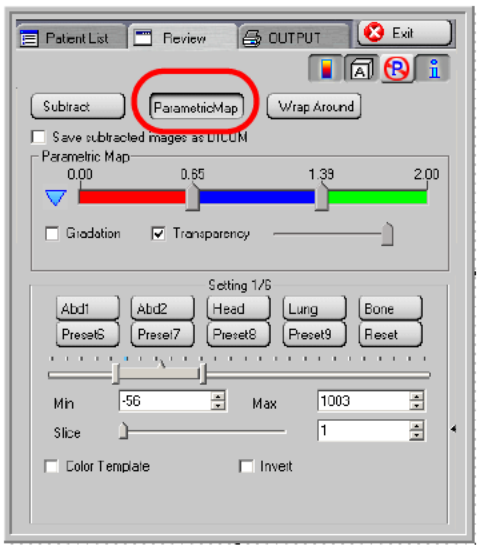

Figure 10-11: Parametric Map color bar

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510(k) Summary

NOV 19 2004

Submitter: iCAD, Inc.
2689 Commons Blvd., Suite 100
Beavercreek, OH 45431

Contact Person: John Rosenstengel

Date Prepared: November 18, 2004

Device Trade Name: Second Look® Viewer

Common Name: System, Image Processing, Radiological

Classification Name: Picture archiving and communications system (21 CFR 892.2050)

Predicate Device(s): Consultiva™ Report Station (RS) by MiraMedica, Inc.

Device Description: The Second Look® Viewer is composed of three primary components. The major component is the computer (1), which is supported by a touchscreen monitor (2) and a barcode reader (3). The computer is a conventional Intel based computer that is connected to the Second Look® CAD processing unit via a network. The Second Look Viewer serves no other purpose than viewer support. The physician interfaces to the software using the touch screen or barcode reader. The physician first barcodes a given patient whose mammography case has already been processed by the Second Look CAD processing unit. The viewer displays the Mammagraph™s with the pre-computed CAD marks overlayed. Second Look Viewer allows a radiologist to review Second Look® Analog CAD output, in softcopy format. The physician may touch any of the small images and see a higher resolution, magnified image along with characterization information for that image. After viewing the mammography case, the radiologist may use the Second Look® Viewer to review pre-computed ultrasound results, such as CADStream® output, if such results already exist for the case under review.

Indication for Use: The Second Look® Viewer is intended to be used to display low resolution, nondiagnostic medical images with annotations such as pre-computed regions-of-interest or pre-computed CAD marks.

Technological Characteristics and Testing:

Conclusion:
Results of performance and validation testing indicate that the Second Look® Viewer is substantially equivalent to the predicate device

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
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2004

Mr. John E. Rosenstengel
Director, Quality &
Regulatory Affairs
ICAD, Inc.
2689 Commons Blvd., Suite 100
BEAVERCREEK OH 45431

Re: K042697
Trade/Device Name: Second Look® Viewer
Regulatory Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 30, 2004
Received: September 30, 2004

Dear Mr. Rosenstengel:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

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

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological 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 2014-9975; Released by CDRH on 12/3/2015

510(k) Number (if known): K042697

Device Name: Second Look® Viewer

Indications for Use:

The Second Look® Viewer is intended to be used to display low resolution, nondiagnostic medical images with annotations such as pre-computed regions-of-interest or pre-computed CAD marks.

Prescription Use__X__ ~~AND~~/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Part C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042697

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

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DOCUMENT NUMBER SM-20121308

DOCUMENT TITLE

CF0304ARevB-RECORD_Test_Cases_AQNV_4.4.8_SM

Author:	(b) (6) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	(b)(4) [redacted]
	–		–		–
Approved By:	(b) (6) [redacted]	**Title:**	(b)(4) [redacted]	**Date:**	(b)(4) [redacted]
Approved By:	[redacted]	**Title:**	–	**Date:**	–
Approved By:	–	**Title:**	–	**Date:**	–

Revision History

Rev. Level	Description	Revised By	Approved By	Date

Reference Documents

Document Number	Rev. Level	Description

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

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1.0 INTRODUCTION

This document records the testing of user stories and/or defects for Aquarius NET Viewer of 4.4.8 release project.

2.0 SCOPE

Aquarius NET Viewer 4.4.8

3.0 DEFINITIONS

User story: Feature, new feature, RFE.
RFE: Request For Enhancement
Defect: Bugs, bad design, issues.

4.0 EQUIPMENT (Test Machine specifications, supplies, etc.)

Manufacturer	Model	OS	Language
DELL	T5500	Windows 7	US [EN]

5.0 RESPONSIBILITIES

(b)(4) [redacted]

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

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(b)(4) Test Report

[redacted]

Index of test cases with test results:

(b)(4) Test Report

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Test Report

[redacted]

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Test Report

[redacted]

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

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(b)(4) Test Report

[redacted]

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(b)(4) Test Report

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Test Report

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Test Report

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Test Report

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Test Report

[redacted]

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(b)(4) Test Report

[redacted]

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(b)(4) Test Report

[redacted]

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Test Report

[redacted]

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(b)(4) Test Report

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(b)(4) Test Report

[redacted]

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

(b)(4) Test Report

[redacted]

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Save and Reset

These items appear at the bottom of the menu.

Select **Save** to make the current color map the default map for future studies. If you change the colors or the borders between colors in the color map and then save it, the saved color scheme is used by default the next time a study containing Parametric Map APS data is loaded, .

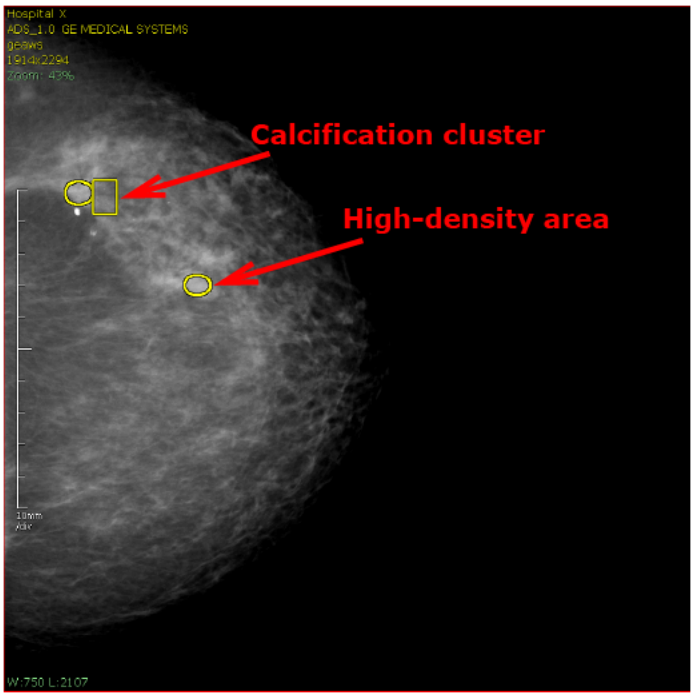
Select **Reset** to restore the original default color map (Delayed Rainbow).

CAD

This is an image display feature of pre-processed CAD markers from iCAD SecondLook® software. CAD marker displays from other manufacturers are not supported at this time; however, TeraRecon will support other CAD vendors in the future. The pre-processed CAD markers are overlayed on the image and imbedded within the DICOM dataset pushed to the iNtuition viewer. This is NOT a CAD processing feature.

For the CAD algorithm design, function, processing steps, classifiers, reference standard, scoring methodology and image review method refer to the iCAD SecondLook Instructions for Use.

WARNING: For safe and effective use of this CAD marker display feature, review the iCAD SecondLook Instructions for Use prior to use.



- Ellipse markers identify a high-density area.

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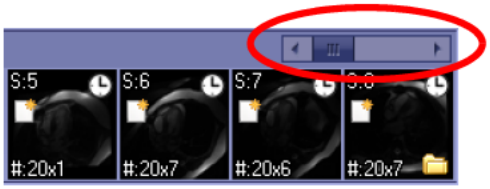
- Rectangular markers identify a calcification cluster.

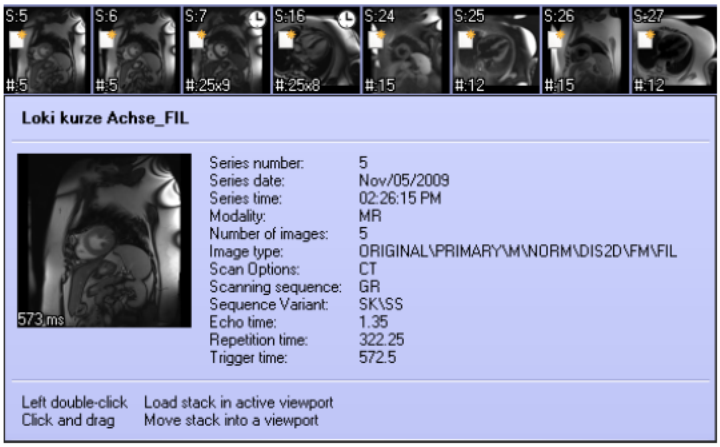
Viewing Studies

Just beneath the Top Tool Bar, the studies or series currently loaded are displayed as thumbnail images. The name of each study is shown on a tab that contains the Patient ID, Patient Name, Study Date and Description. To view a different study, click the corresponding tab.

If there are too many series to be visible all at once, use the slider bar to scroll to a series not currently visible.



When you hover the mouse over the series icons, a panel containing detailed information about the series is displayed (see the following image).



Clickable Annotations

The annotations on the image are configurable based on the **annotation** setup in viewer configuration. The green annotations are clickable and selectable.

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

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DOCUMENT NUMBER: RT-130801JZ

DOCUMENT TITLE: CF0333RevA-RECORD_Rally_Test_Cases_iNtuition_4.4.8_Patch2_DE15963

Approved By: (b) (6) [redacted] **Title:** (b)(4) [redacted] **Date:** (b)(4) [redacted] **Signature:** (b) (6) [redacted]

REVISION HISTORY:

Revision Level	Description	Created/Revised By	Approved By	Approved Date
0	(b)(4) [redacted]	(b) (6) [redacted]		

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

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http://10.10.0.121/svn/Aquarius/trunk/ISODocs/_iNtuition/v4.4.8_Patch2/TestResults/CF0333RevA-RECORD_Rally_Test_Cases_iNtuition_4.4.8_Patch2_DE15963.doc

1.0 INDEX OF TEST CASES

TEST CASE PROTOCOL APPROVAL							TEST CASE EXECUTION APPROVAL			
Product	Rally ID	Test Case Name	Author	Date & Sign-off	Approved By:	Date & Sign-off	Tester Name	PASS/FAIL & Date	Authentication	Notes or Defects ID
(b)(4) [redacted]										

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

2.0 TABLE OF CONTENTS

Rally ID: (b) (6) [redacted] 4

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

Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

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RALLY TEST CASES

(b)(4)

[redacted]

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RALLY TEST CASES

(b)(4)

[redacted]

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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RALLY TEST CASES

(b)(4)

[redacted]

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

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RALLY TEST CASES

(b)(4)

[redacted]

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

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RALLY TEST CASES

(b)(4)

[redacted]

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(b)(4)

[redacted]

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Records processed under FOIA 2014-9975; Released by CDRH on 12/3/2015

TERARECON

Date of Summary: November 14, 2013

510(k) Summary of Safety and Effectiveness (As required by 21 CFR 807.92(c))	**iNtuition**

Submitter/Applicant/Sponsor: TeraRecon Inc.
4000 E 3rd Ave, Suite 200
Foster City, CA 94404

Contact Person: Emilly Tojima Nurthen
Regulatory Affairs Manager
Ph: 650.653.4282
Fax: 650.372.1101
Email: emilly@terarecon.com

Establishment: Registration # 2954793

Device Information:

Name of Device:	iNtuition – TDA, TVA, Parametric Mapping
Common Name:	Medical Imaging System
Classification Name:	§ 892.2050, Picture Archiving and Communication System. ProCode: LLZ
Classification Panel:	Radiology
Device Classification:	Class II device

Substantial Equivalence:

iNtuition – TDA, TVA, Parametric Mapping, as addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

- Aquarius Workstation (K011142)
- AquariusAPS Server (K061214)
- LEONARDO syngo Cardiology Workstation (Argus) (K042203)
- LEONARDO (K040970)
- Syngo.CT Cardiac Function (K110366)
- CT Perfusion 4 (K052839)
- Syngo.MR Neurology (K121459)

iNtuition TDA has similar technological characteristics to the Aquarius Workstation, AquariusAPS Server and CT Perfusion 4, with added MR modality support as included in Syngo.MR Neurology.

iNtuition TVA has similar technological characteristics to the Aquarius Workstation, with improvements and additional features. These additional features include MR modality support

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and right ventricle analysis (CT, MR) which are included in the Leonardo, Leonardo Argus and Syngo.CT Cardiac Function (excludes MR).

In comparison to AquariusAPS, iNtuition Parametric Mapping has improved visual appearance and additional color display options.

Indications for Use:

iNtuition-TDA, TVA, and Parametric Mapping are software modules which supports assessment of time-dependent behavior of image intensity, density, dimensions or volume of regions of interest over time, for volumetric or planar dynamic image types such as CT or MR. Parametric mapping tools encode in color various parameters derived from the temporal or spatial characteristics of the planar or volumetric data.

Support is provided for digital image processing to derive metadata or new images from input image sets, for internal use or for forwarding to other devices using the DICOM protocol. Image processing tools are provided to extract metadata to derive parametric images from combinations of multiple input images.

iNtuition-TDA, TVA and Parametric Mapping are iNtution-based software features with dedicated workflows and basic tools and thus support post-processing, displaying and manipulation of reports and medical images from acquisition devices and visualization in 2D, 3D and 4D for single or multiple datasets, or combinations thereof.

iNtuition-TDA, TVA, Parametric Mapping are designed for use by healthcare professionals and are intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions.

Device Description:

iNtuition – TDA, TVA, Parametric Mapping are post-processing modules, part of iNtuition, which is a software device generally used with off-the-shelf hardware, offered in various configurations, with the simplest configuration being a stand-alone workstation capable of image review, communications, archiving, database maintenance, remote review, reporting and basic 3D capabilities. It can also be configured as a server with some, all, or none of its optional features disabled. A fully-configured iNtuition system is capable of various image processing and visualization functions to support the physician in medical image reviewing.

iNtuition – TDA, TVA, Parametric Mapping intended used is to provide solutions to various medical image analysis and viewing problems, which come about as modalities generate more and more images. They also support image distribution over networks, and are DICOM compliant.

iNtuition Time-Dependent Analysis (TDA) and Time-Volume Analysis (TVA) features can obtain quantitative information relating to the evolution of the intensity, density or

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dimensions of certain regions of CT, MR or other images over time. Statistical analysis such as a histogram representation of the image density values in an image is supported, and analysis of changes in volume over time from multi-phase volumetric images; for example, ejection fraction and stroke volume measurement calculation can be performed using the Time-Volume Analysis tools.

iNtuition Parametric Mapping tools encode in color various parameters derived from the temporal or spatial characteristics of the planar or volumetric data.

iNtuition – TDA, TVA and Parametric Mapping are iNtuition-based optional features, and employ all standard features offered by iNtuition, such as convenient tools to support creation of a report, transmitting and storing this report in digital form, and tracking historical information about the studies analyzed with the software.

These three modules can be sold separately or as a part of the bigger iNtuition package.

Technological Characteristics:
iNtuition-TDA, TVA, Parametric Mapping will be marketed as iNtuition-based software only solution for the end-user (with recommended hardware requirements).

Summary of Non-Clinical Performance Tests:
There are no applicable FDA mandated performance standards for this device. However, voluntary standards such as DICOM, various in-house standard operating procedures are in place and utilized in the production of the software.

In all material aspects, iNtuition-TDA, TVA, Parametric Mapping is substantially equivalent to the predicate devices. Performance testing was carried out according to internal company procedures. Software testing and validation were done according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to formalize after ensuring that the software fully satisfies all expected and previously defined system requirements and features. Test results support the conclusion that actual device performance satisfies the design intent and is equivalent to its predicate devices.

Summary of Clinical Performance Tests:
The subject of this traditional 510k notification, iNtuition-TDA, TVA, Parametric Mapping, did not require clinical studies to show safety and effectiveness of the software.

General Safety and Effectiveness Concerns:
The introduction of iNtuition-TDA, TVA, Parametric Mapping has no significant concerns of safety and efficacy. iNtuition-TDA, TVA, Parametric Mapping in comparison with their

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predicate devices are iNtuition-based software modules which have the same intended use and technological characteristics.

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Risk management is ensured via risk analysis, which is used to identify and mitigate potential hazards beginning early in the design cycle and continuing throughout the development of the product. These potential hazards are controlled via software development, verification and validation testing. Furthermore, the operators are healthcare professionals familiar with and responsible for making all final patient management decisions.

Conclusion:

iNtuition-TDA, TVA, Parametric Mapping as described in this premarket notification have the same intended use and similar technical characteristics to the predicate devices listed above. These devices are substantially equivalent in terms of basic design, features and intended use.

In summary, TeraRecon, Inc. is of the opinion that iNtuition-TDA, TVA, Parametric Mapping are iNtuition-based software modules which does not include any new potential safety or effectiveness risks and are substantially equivalent to and perform as well as the predicate devices.

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Indications for Use

510(k) Number: K131447

Device Name: iNtuition-TDA, TVA, Parametric Mapping

Indications for Use:

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iNtuition-TDA, TVA, Parametric Mapping are designed for use by healthcare professionals and are intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions.

Prescription Use ___**X**___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

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Chapter 5: TVA and Cardiac Function

Introduction

The **Time-Volume Analysis** (TVA) optional module calculates time-dependent behavior of volumes in multi-phase studies from CT. An example of a time-dependent behavior is the change in the volume of the left ventricle of the heart.

Note: The user is obligated to define the wall boundaries in question.

Note: When first accessed, the user interface for wall boundary outline holds generic default values with no significance. The user must acknowledge this by dismissing a warning message to this effect.

Starting TVA for CT Studies

To load a study for TVA, do the following:

1. From the Patient List, select an appropriate CT study comprised of multiple series or subseries.

2. Highlight multiple series/subseries in the Series (or Subseries) List by clicking the desired series or subseries with the left mouse button, while holding down the **Ctrl** key.

   NOTE: Each series that you select should have the same number of images.

3. Load the series/subseries into the Cardiac Workflow by doing one of the following:

   - Right-click and select **Cardiac** from the pulldown menu.

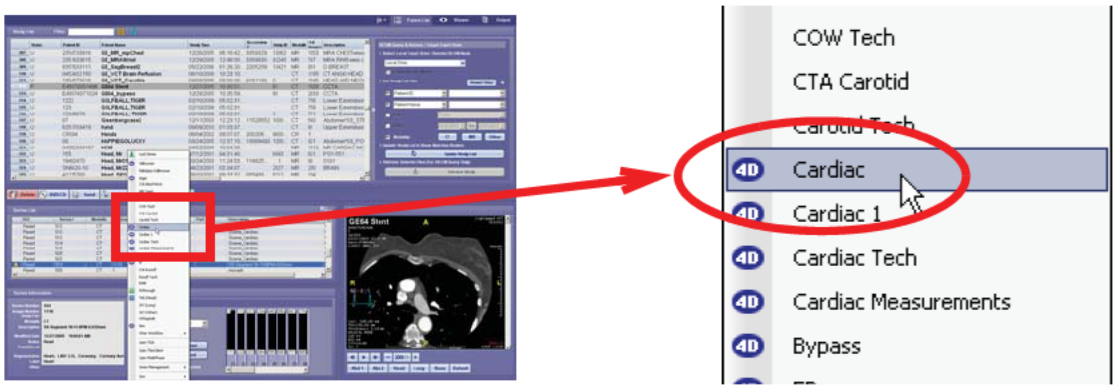

Figure 5-1: Right-Click on Series List and Select Cardiac Workflow

   - Click **Load** in the Data Management Tool Buttons (located in the middle-left of the screen), and then click **Cardiac** from the workflow buttons.

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