

KIS1115

# VITAL

A Toshiba Medical Systems Group Company

**MR Core Software  
Special 510(k) Pre-market Notification**

FDA CDRH DMC

APR 27 2015

Received

Date: April 24, 2015

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

Attention: Office of In Vitro Diagnostics and Radiological Health (OIR), CDRH

**Re: Special 510(k) Notification- Device Modification for Vital Images, Inc.'s Softread Software (K040305)**

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), Vital Images, Inc. is submitting the attached Special 510(k) premarket notification for the following device:

<b>510(k) Clearance Name:</b>	Softread
<b>Proposed Commercial Name:</b>	MR Core
<b>Type of 510(k):</b>	Special 510(k): Device Modification
<b>Previous 510(k) No.:</b>	K040305
<b>510(k) Holder Name:</b>	Vital Images, Inc.
<b>510(k) Holder Address:</b>	5850 Opus Parkway, Suite 300 Minnetonka, MN-55343-4414 USA
<b>Establishment Registration Number:</b>	2134213
<b>Intended Use:</b>	MR Core is an option within Vitrea® that allows the examination and manipulation of a series of medical images obtained from MRI scanners. The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.
<b>Common Name:</b>	Radiological Image Processing Software
<b>Classification Name:</b>	System, Image Processing, Radiological
<b>Regulation Number:</b>	21 CFR 892.2050



A Toshiba Medical Systems Group Company

**MR Core Software  
Special 510(k) Pre-market Notification**

<b>Product Code:</b>	LLZ
<b>Regulatory Classification:</b>	Class II
<b>Device Panel:</b>	Radiology
<b>Prior Submission(s):</b>	There were no prior submissions for the device

The subject software is an enhanced module of the Softread software (only for MR Datasets) that has already been cleared by the Food and Drug Administration for the below mentioned intended use (K040305).

<b>Softread Intended Use Statement (K040305)</b>	<b>Updated Softread (MR Core) Intended Use Statement (Subset of our cleared Intended Use)</b>
<p>Softread, is an option within the Vitrea 2 system and is intended to allow the examination and manipulation of a series of 2D images in a variety of modalities, including CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc.</p> <p>The option also enables clinicians to compare multiple series' for the same patient, side-by-side, and to switch to Vitrea to further examine the data in a 3D volume.</p>	<p>MR Core is an option within Vitrea® that allows the examination and manipulation of a series of medical images obtained from MRI scanners.</p> <p>The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.</p>

Note: **MR Core is just a MR Datasets viewer that provides an ability to the user to launch available MR advance processing applications available on Vitrea platform.**

**Changes from the last 510(k) clearance (K040305):**

<b>No.</b>	<b>Change(s)</b>
1	<b><u>Change-1:</u></b> Completely re-designed User Interface (UI) screen to utilize enhancements in the software technology for better look and user experience.
2	<b><u>Change-2:</u></b> Added a new feature of "stitching" that combines MR images covering distinct contiguous, or slightly overlapping, regions of the human body anatomy into one or multiple images.



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No.	Change(s)
3	<b><u>Change-3: (Restricted Modality Support)</u></b> MR Core only allows the examination and manipulation of a series of medical images obtained from MRI scanners.
4	<b><u>Change-4: (Restricted Features)</u></b> MR Core does not support "Image Filtering" and "Image Set Splitting" (divide a single study into multiple stacks) features.

Since MR Core viewer has restricted modality support compared to our already cleared "Softread" software, Vital Images is planning to keep Softread" and the updated Softread, under the new marketing name "MR Core" software, in the US market for users.

**Basis for Submission:**

These modifications are eligible for the Special 510(k) process because they do not change intended use or fundamental scientific technology of the legally marketed Softread software (K040305).

**Special 510(k) Criteria Summary:**

Criteria	Predicate Device	Subject Device	Comparison
	<b>Softread Software (K040305)</b>	<b>MR Core Software (Modified Softread Software)</b>	
Intended Use	Softread, is an option within the Vitrea 2 system and is intended to allow the examination and manipulation of a series of 2D images in a variety of modalities, including CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc.  The option also enables clinicians to compare multiple series' for the same patient, side-by-side, and to switch to Vitrea to further examine the data in a 3D volume.	MR Core is an option within Vitrea® that allows the examination and manipulation of a series of medical images obtained from MRI scanners.  The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.	<b>Same</b>  <b>Note:</b> The Intended Use statement of the modified software is a subset of already cleared Intended Use of the legally marketed device.

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**MR Core Software  
Special 510(k) Pre-market Notification**

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
Fundamental Scientific Technology: <b>Control mechanism</b>	Not applicable, software device.	Not applicable, software device.	<b>Same</b>
Fundamental Scientific Technology: <b>Operating principle(s)</b>	Display MR datasets on computer screen by using standard software coding methods using C, C++, and Java languages.	Display MR datasets on computer screen by using standard software coding methods using C, C++, and Java languages.	<b>Same</b>
Fundamental Scientific Technology: <b>Energy Type</b>	Not applicable, software device.	Not applicable, software device.	<b>Same</b>
Fundamental Scientific Technology: <b>Environmental specifications</b>	Not applicable, software device.	Not applicable, software device.	<b>Same</b>
Fundamental Scientific Technology: <b>Performance specifications</b>	Improved in the MR Core software		The changes include a completely re-designed User Interface (UI) screen and improved performance of the software.  The software changes do not affect the indications for use/intended use.  No clinical data was necessary to establish safety and effectiveness for the purpose of substantial
Fundamental Scientific Technology: <b>Ergonomics of the patient-user interface change</b>	Improved in the MR Core software		
Fundamental Scientific Technology:	Software changed in the MR Core software		



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**MR Core Software  
Special 510(k) Pre-market Notification**

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
Software or firmware change			<p>equivalence.</p> <p>The modifications were found appropriate for reliance on results from the design control process to assure conformance safety and effectiveness for purpose of substantial equivalence.</p> <p>Therefore, a special 510(k) notification for device modification is appropriate.</p> <p><b>Ref.:</b> FDA guidance document: The New 510(k) Paradigm.  <a href="http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf">http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf</a></p> <p>Based on the FDA guidance document, <b>the changes to software are considered appropriate for review as Special 510(k).</b></p>
<p>Fundamental Scientific Technology:</p> <p><b>Dimensional specifications</b></p>	Not applicable, software device.	Not applicable, software device.	<b>Same</b>



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**MR Core Software  
Special 510(k) Pre-market Notification**

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
Fundamental Scientific Technology: <b>Packaging or expiration dating</b>	Same	Same	<b>Same</b>
Fundamental Scientific Technology: <b>Sterilization</b>	Not applicable, software device.	Not applicable, software device.	<b>Same</b>

**Special 510(k) Eligibility:**

These modifications are eligible for the Special 510(k) process because these modifications do not change the Intended Use or fundamental scientific technology of the legally marketed Softread software.

The enhanced Softread Software (MR Core) has the same intended use, indications, fundamental scientific technological characteristics, and principle of operation as the cleared Softread Software ("Predicate device") by K040305. The added "Stitching" feature is similar to the feature on the already cleared Intrasure, MYRIAN ("Reference device")'s "Image Alignment" feature by K091001. Therefore, these modifications do not raise new questions of safety and effectiveness.

As explained in the attached Special 510(k) notice Attachment-009\_Comparison to the Cleared Device, the minor differences between the MR Core software and the 510(k) cleared devices do not raise any new questions of safety or effectiveness.

The implemented design controls, risk management activities and successful verification and validation tests demonstrate that the device is as safe and effective as the predicate device. Thus, Vital Images, Inc. believes that the MR Core software is substantially equivalent. The concise summary of the related design control activities can be found in the Attachments-026 to 054.

In accordance with the Medical Device User Fee and Modernization Act Amendments of 2012 (MDUFMA III), Vital Images, Inc. has submitted the appropriate application fee. A copy of the User Fee Cover Sheet is provided with the attached Special 510(k) notice.

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**MR Core Software  
Special 510(k) Pre-market Notification****Design and Use of the Device:**

The following table provides the additional high level information regarding the design and use of the MR Core software:

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

According to the instructions on the FDA website, an electronic copy ("eCopy") is provided with this submission and the eCopy is an exact duplicate of the paper copy.

Vital Images, Inc. regards both the content and the existence of this submission as confidential commercial information and requests that it be treated as such by the FDA.

We look forward to the interactive and collaborative review process. Please contact me with any questions regarding this submission at (952)-487-9574 or via email at [pshah@vitalimages.com](mailto:pshah@vitalimages.com)

Best Regards,



Parthiv Shah  
Sr. Regulatory Affairs Specialist

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Center for Devices and Radiological Health  
Document Mail Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

RE: Special 510(k) Notification (21 CFR 807.90(e)) for the MR Core Software

Dear Sir/Madam,

Vital Images, Inc. submits this Special 510(k) Notification for MRCore software. Please find the attached paper submission for the same.

Vital Images, Inc. has also included an eCopy of this paper submission. **The eCopy is an exact duplicate of the paper copy.**

Vital Images, Inc. regards both the content and the existence of this response as confidential commercial information and requests that it be treated as such by the FDA.

We look forward the interactive and collaborative review process. Please contact me with any questions regarding this submission at (952) 487-9574 or via email at [pshah@vitalimages.com](mailto:pshah@vitalimages.com).

Best regards,



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**MR Core Software  
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<b>510(k) Clearance Name:</b>	Softread
<b>Proposed Commercial Name:</b>	MR Core
<b>Type of 510(k):</b>	Special 510(k): Device Modification
<b>Previous 510(k) No.:</b>	K040305
<b>510(k) Holder Name:</b>	Vital Images, Inc.
<b>510(k) Holder Address:</b>	5850 Opus Parkway, Suite 300 Minnetonka, MN-55343-4414 USA
<b>Establishment Registration Number:</b>	2134213
<b>Intended Use:</b>	MR Core is an option within Vitrea® that allows the examination and manipulation of a series of medical images obtained from MRI scanners. The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.
<b>Common Name:</b>	Radiological Image Processing Software
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<b>Regulatory Classification:</b>	Class II
<b>Device Panel:</b>	Radiology
<b>Prior Submission(s):</b>	There were no prior submissions for the device

The subject software is an enhanced module of the Softread software (only for MR Datasets) that has already been cleared by the Food and Drug Administration for the below mentioned intended use (K040305).

<b>Softread Intended Use Statement (K040305)</b>	<b>Updated Softread (MR Core) Intended Use Statement (Subset of our cleared Intended Use)</b>
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**Note: MR Core is just a MR Datasets viewer that provides an ability to the user to launch available MR advance processing applications available on Vitrea platform.**

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Since MR Core viewer has restricted modality support compared to our already cleared “Softread” software, Vital Images is planning to keep Softread” and the updated Softread, under the new marketing name “MR Core” software, in the US market for users.

**Basis for Submission:**

These modifications are eligible for the Special 510(k) process because they do not change intended use or fundamental scientific technology of the legally marketed Softread software (K040305).

**Special 510(k) Criteria Summary:**

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
Intended Use	<p>Softread, is an option within the Vitrea 2 system and is intended to allow the examination and manipulation of a series of 2D images in a variety of modalities, including CT, <b>MR</b>, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc.</p> <p>The option also enables clinicians to compare multiple series' for the same patient, side-by-side, and to switch to Vitrea to further examine the data in a 3D volume.</p>	<p>MR Core is an option within Vitrea® that allows the examination and manipulation of a series of medical images obtained from <b>MRI</b> scanners.</p> <p>The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.</p>	<p><b>Same</b></p> <p><b>Note:</b> The Intended Use statement of the modified software is a subset of already cleared Intended Use of the legally marketed device.</p>



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Special 510(k) Pre-market Notification**

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
Fundamental Scientific Technology: <b>Control mechanism</b>	Not applicable, software device.	Not applicable, software device.	<b>Same</b>
Fundamental Scientific Technology: <b>Operating principle(s)</b>	Display MR datasets on computer screen by using standard software coding methods using C, C++, and Java languages.	Display MR datasets on computer screen by using standard software coding methods using C, C++, and Java languages.	<b>Same</b>
Fundamental Scientific Technology: <b>Energy Type</b>	Not applicable, software device.	Not applicable, software device.	<b>Same</b>
Fundamental Scientific Technology: <b>Environmental specifications</b>	Not applicable, software device.	Not applicable, software device.	<b>Same</b>
Fundamental Scientific Technology: <b>Performance specifications</b>	Improved in the MR Core software		The changes include a completely re-designed User Interface (UI) screen and improved performance of the software.  The software changes do not affect the indications for use/intended use.  No clinical data was necessary to establish safety and effectiveness for the purpose of substantial
Fundamental Scientific Technology: <b>Ergonomics of the patient-user interface change</b>	Improved in the MR Core software		
Fundamental Scientific Technology:	Software changed in the MR Core software		



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<b>Software or firmware change</b>			<p>equivalence.</p> <p>The modifications were found appropriate for reliance on results from the design control process to assure conformance safety and effectiveness for purpose of substantial equivalence.</p> <p>Therefore, a special 510(k) notification for device modification is appropriate.</p> <p><b>Ref.:</b> FDA guidance document: The New 510(k) Paradigm.  <a href="http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf">http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf</a></p> <p>Based on the FDA guidance document, <b>the changes to software are considered appropriate for review as Special 510(k).</b></p>
<p>Fundamental Scientific Technology:</p> <p><b>Dimensional specifications</b></p>	Not applicable, software device.	Not applicable, software device.	<b>Same</b>



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Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
Fundamental Scientific Technology: <b>Packaging or expiration dating</b>	Same	Same	<b>Same</b>
Fundamental Scientific Technology: <b>Sterilization</b>	Not applicable, software device.	Not applicable, software device.	<b>Same</b>

**Special 510(k) Eligibility:**

These modifications are eligible for the Special 510(k) process because these modifications do not change the Intended Use or fundamental scientific technology of the legally marketed Softread software.

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The implemented design controls, risk management activities and successful verification and validation tests demonstrate that the device is as safe and effective as the predicate device. Thus, Vital Images, Inc. believes that the MR Core software is substantially equivalent. The concise summary of the related design control activities can be found in the Attachments-026 to 054.

In accordance with the Medical Device User Fee and Modernization Act Amendments of 2012 (MDUFMA III), Vital Images, Inc. has submitted the appropriate application fee. A copy of the User Fee Cover Sheet is provided with the attached Special 510(k) notice.

**Design and Use of the Device:**

The following table provides the additional high level information regarding the design and use of the MR Core software:

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

According to the instructions on the FDA website, an electronic copy ("eCopy") is provided with this submission and the eCopy is an exact duplicate of the paper copy.

Vital Images, Inc. regards both the content and the existence of this submission as confidential commercial information and requests that it be treated as such by the FDA.

We look forward to the interactive and collaborative review process. Please contact me with any questions regarding this submission at (952)-487-9574 or via email at [pshah@vitalimages.com](mailto:pshah@vitalimages.com)

Best Regards,



Parthiv Shah  
 Sr. Regulatory Affairs Specialist



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**MR Core Software  
Special 510(k) Pre-market Notification**
**Attachments:**

<b>Attachment</b>	<b>Section</b>
002	Medical Device User Fee Cover Sheet (FDA Form 3601)
003	CDRH Premarket Review Submission Cover Sheet (FDA Form 3514)
004	Table of Contents
005	Special 510(k) Acceptance Checklist
006	Statement of Indications for Use (FDA Form 3881)
007	510(k) Summary (21 CFR 807.92)
008	Description of the Modified Device
009	Comparison to the Cleared Devices
010	Software Information
011	Proposed Label: Education and Reference Guide (VPMC-13746)
012	Proposed Label: Release Notes (VPMC-13735)
013	Proposed Marketing Document (M-06107)
014	Premarket Notification Truthful and Accurate Statement
015	Standards Data Report Form - for DICOM (FDA Form 3654)
016	Standards Data Report Form - for ISO 14971:2007 (FDA Form 3654)
017	Standards Data Report Form - for IEC 62304:2006 (FDA Form 3654)
018	Certification of Compliance with ClinicalTrials.gov Data Bank (FDA Form 3674)
019	Design Control Declaration of Conformity – Verification and Validation
020	Design Control Declaration of Conformity – Design Control Procedures
021	Declaration of Conformity – Intended Use
022	K040305 510(k) Summary for Softread software (Predicate device)
023	Softread software User Guide provided in K040305 (Predicate device)
024	K091001 510(k) Summary for Myrian software (Reference device)



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**MR Core Software  
Special 510(k) Pre-market Notification**

Attachment	Section
025	Myrian Marketing Collateral (Reference device)

**Required Software Documents:** (As requested in the FDA guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued May 11, 2005)

Attachment	Document
<b>Software Requirements Specification</b>	
026	Software Requirements Specification – MR Core (TMVSE000587)
027	Software Requirements Specification – MR Stitching (TMVSE000592)
<b>Software Design Specification</b>	
028	Software Design Specification – MR Core (TMVSE000608)
029	Software Design Specification – MR Stitching (TMVSE000609)
<b>Software Architecture</b>	
030	Architecture Design Chart – MR Core (TMVSE000591)
031	Architecture Design Chart – MR Stitching (TMVSE000601)
<b>Risk Analysis</b>	
032	Risk Analysis with Applied Mitigations – MR Core (TMVSE00588)
033	Risk Analysis with Applied Mitigations – MR Stitching (TMVSE000593)
034	Summary of Risk Benefit Analysis – MR Core (TMVSE000614)
035	Summary of Risk Benefit Analysis – MR Stitching (TMVSE000615)
<b>Test Plan</b>	
036	Quality Strategy – MR Core (TMVSE000589)
037	Performance Test Specification – MR Core (TMVSE000617)
038	Test Case Inventory – MR Core (TMVSE000598)
039	Quality Strategy – MR Stitching (TMVSE000594)



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**MR Core Software  
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<b>Attachment</b>	<b>Document</b>
040	Performance Evaluation Plan – MR Stitching (TMVSE000616)
041	Test Case Inventory – MR Stitching (TMVSE000604)
<b>Test Results</b>	
042	Test Execution Summary – MR Core (TMVSE000600)
043	Validation Report – MR Core & MR Stitching (TMVSE000613)
044	Performance Evaluation Report – MR Core (TMVSE000610)
045	Test Execution Summary – MR Stitching (TMVSE000607)
046	Performance Evaluation Report – MR Stitching (TMVSE000611)
<b>Requirements Traceability Matrix (RTM)</b>	
047	Requirements Traceability Matrix – MR Core (TMVSE000595)
048	Requirements Traceability Matrix – MR Stitching (TMVSE000602)
<b>Unresolved Anomalies Report (UAR)</b>	
049	Unresolved Anomalies Report – MR Core (TMVSE000599)
050	Unresolved Anomalies Report – MR Stitching (TMVSE000605)
<b>Off-The-Shelf (OTS) Report</b>	
051	Supplied Component Report – MR Core (TMVSE000597)
052	Supplied Component Report – MR Stitching (TMVSE000606)
<b>Software Release Log</b>	
053	Software Release Log – MR Core (TMVSE000596)
054	Software Release Log – MR Stitching (TMVSE000603)
<b>Development Processes</b>	
055	Hazard Analysis Process
056	Test Process



A Toshiba Medical Systems Group Company

**MR Core Software  
Special 510(k) Pre-market Notification**

<b>Attachment</b>	<b>Document</b>
057	Defect Management Process
058	Configuration Management and Software Component Build Policy
059	Release Approval Process
060	Document and Record Control Policy

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>	PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.		
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">http://www.fda.gov/oc/mdufma/cover sheet.html</a>			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  VITAL IMAGES INC Vital Images Inc. 5850 Opus Parkway Suite 300 Minnetonka USA MN 55343 US  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****1776	2. CONTACT NAME Parthiv Shah 2.1 E-MAIL ADDRESS pshah@vitalimages.com 2.2 TELEPHONE NUMBER (include Area code) 952-4879574 2.3 FACSIMILE (FAX) NUMBER (Include Area code)		
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm</a> ) Select an application type: <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party  <input type="checkbox"/> 513(g) Request for Information  <input type="checkbox"/> Biologics License Application (BLA)  <input type="checkbox"/> Premarket Approval Application (PMA)  <input type="checkbox"/> Modular PMA  <input type="checkbox"/> Product Development Protocol (PDP)  <input type="checkbox"/> Premarket Report (PMR)  <input type="checkbox"/> 30-Day Notice                             </td> <td style="width: 50%; vertical-align: top;">                             3.1 Select a center  <input checked="" type="checkbox"/> CDRH  <input type="checkbox"/> CBER                              3.2 Select one of the types below  <input checked="" type="checkbox"/> Original Application  <u>Supplement Types:</u>  <input type="checkbox"/> Efficacy (BLA)  <input type="checkbox"/> Panel Track (PMA, PMR, PDP)  <input type="checkbox"/> Real-Time (PMA, PMR, PDP)  <input type="checkbox"/> 180-day (PMA, PMR, PDP)                             </td> </tr> </table>		<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
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4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <a href="http://www.fda.gov/cdrh/mdufma">http://www.fda.gov/cdrh/mdufma</a> for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates			

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

<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
<p>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).)</p> <p><input type="checkbox"/> YES                    <input checked="" type="checkbox"/> NO</p>	
<p>PAPERWORK REDUCTION ACT STATEMENT</p> <p>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.</p> <p>Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002          [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]</p>	
<p>MENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION</p> <p>(b) (4) <span style="background-color: black; color: black;">[REDACTED]</span> <span style="float: right;">20-Apr-2015</span></p>	

["Close Window"](#) [Print Cover sheet](#)

**Parthiv Shah**

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**From:** paygovadmin@mail.doc.twai.gov  
**Sent:** Monday, April 20, 2015 2:39 PM  
**To:** Parthiv Shah  
**Subject:** Pay.gov Payment Confirmation: FDA User Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or wish to cancel this payment, you will need to contact FDA User Fees at (301) 796-7200.

Application Name: FDA User Fees  
Pay.gov Tracking ID: 25KTEQ2J  
Agency Tracking ID: 6081302

Account Holder Name: VITAL IMAGES INC  
Transaction Type: ACH Debit  
Transaction Amount: \$5,018.00  
Payment Date: Apr 21, 2015  
Account Type: Business Checking

(b) (4)  
[Redacted]

Transaction Date: Apr 20, 2015 3:39:01 PM Total Payments Scheduled: 1  
Frequency: OneTime

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

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This email has been scanned for all viruses and found to be virus free.

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<b>Attachment</b>	<b>Content</b>	<b>Page(s)</b>
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023	Softread software User Guide provided in K040305 (Predicate device)	023-1 to 34
024	K091001 510(k) Summary for Myrian software (Reference device)	024-1 to 6
025	Myrian Marketing Collateral (Reference device)	025-1 to 4

**Required Software Documents:** (As requested in the FDA guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued May 11, 2005)

<b>Attachment</b>	<b>Documents</b>	
<b>Software Requirements Specification</b>		
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<b>Risk Analysis</b>		
032	Risk Analysis with Applied Mitigations – MR Core (TMVSE000588)	032-1 to 14



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<b>Attachment</b>	<b>Documents</b>	
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037	Performance Test Specification – MR Core (TMVSE000617)	037-1 to 13
038	Test Case Inventory – MR Core (TMVSE000598)	038-1 to 109
039	Quality Strategy – MR Stitching (TMVSE000594)	039-1 to 13
040	Performance Evaluation Plan – MR Stitching (TMVSE000616)	040-1 to 5
041	Test Case Inventory – MR Stitching (TMVSE000604)	041-1 to 117
<b>Test Results</b>		
042	Test Execution Summary – MR Core (TMVSE000600)	042-1 to 5
043	Validation Report – MR Core & MR Stitching (TMVSE000613)	043-1 to 17
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045	Test Execution Summary – MR Stitching (TMVSE000607)	045-1 to 4
046	Performance Evaluation Report – MR Stitching (TMVSE000611)	046-1 to 16
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048	Requirements Traceability Matrix – MR Stitching (TMVSE000602)	048-1 to 10
<b>Unresolved Anomalies Report (UAR)</b>		
049	Unresolved Anomalies Report – MR Core (TMVSE000599)	049-1 to 19



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<b>Attachment</b>	<b>Documents</b>	
050	Unresolved Anomalies Report – MR Stitching (TMVSE000605)	050-1 to 3
<b>Off-The-Shelf (OTS) Report</b>		
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052	Supplied Component Report – MR Stitching (TMVSE000606)	052-1 to 10
<b>Software Release Log</b>		
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054	Software Release Log – MR Stitching (TMVSE000603)	054-1 to 1
<b>Development Processes</b>		
055	Hazard Analysis Process	055-1 to 4
056	Test Process	056-1 to 3
057	Defect Management Process	057-1 to 2
058	Configuration Management and Software Component Build Policy	058-1 to 1
059	Release Approval Process	059-1 to 5
060	Document and Record Control Policy	060-1 to 2

*Contains Nonbinding Recommendations*  
**Acceptance Checklist**  
**for Special 510(k)s**

**(Should be completed within 15 days of DCC receipt)**

*The following information is not intended to serve as a comprehensive review.*

**510(k) Number:** \_\_\_\_\_ **Date Received by DCC:** \_\_\_\_\_

**Lead Reviewer Name:** \_\_\_\_\_ **Branch:** \_\_\_\_\_ **Division:** \_\_\_\_\_ **Office:** \_\_\_\_\_

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA and that element will be assessed during substantive review.

Special 510(k) Criteria		
The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.		
	<b>Yes</b>	<b>No</b>
<b>1. 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.</b>	Yes	
<p><b><u>Comments:</u></b></p> <p>Yes.</p> <p>This special 510(k) notification is submitted to modify a legally marketed device (predicate) AND submitted by the holder of the 510(k) for the predicate device.</p> <p>The subject software is an enhanced version of the Softread software that is already cleared by the Food and Drug Administration by 510(k) notification # K040305.</p>		
<b>2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).</b>	Yes	
<p><b><u>Comments:</u></b></p> <p>Yes.</p> <p>The Indications for Use of the proposed device are unchanged from the legally marketed device (Predicate device) K040305.</p>		

Special 510(k) Criteria																	
<b>The submission should not be reviewed as a Special 510(k) if “No” is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.</b>																	
<p><u>K040305:</u></p> <p>Softread, is an option within the Vitrea 2 system and is intended to allow the examination and manipulation of a series of 2D images in a variety of modalities, including CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc.</p> <p>The option also enables clinicians to compare multiple series' for the same patient, side-by-side, and to switch to Vitrea to further examine the data in a 3D volume.</p> <p>Note: MR Core has the same intended use as Softread (K040305) with a limited scope of modalities (only MR capable).</p>																	
<b>3. Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).</b>	Yes																
<p><b><u>Comments:</u></b></p> <p>The fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate). The rationale is as below:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr style="background-color: #cccccc;"> <th style="width: 50%; padding: 5px;">Technology</th> <th style="width: 50%; padding: 5px;">Not Applicable / No change / Yes <b>Note:</b> If Yes, please provide rationale for review as Special 510(k)</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">Control mechanism change?</td> <td style="padding: 5px;">Not applicable, software device</td> </tr> <tr> <td style="padding: 5px;">Operating principle(s) change?</td> <td style="padding: 5px;">No change</td> </tr> <tr> <td style="padding: 5px;">Energy Type change?</td> <td style="padding: 5px;">Not applicable, software device</td> </tr> <tr> <td style="padding: 5px;">Environmental specifications change?</td> <td style="padding: 5px;">Not applicable, software device</td> </tr> <tr> <td style="padding: 5px;">Dimensional specifications change?</td> <td style="padding: 5px;">Not applicable, software device</td> </tr> <tr> <td style="padding: 5px;">Changes in packaging or expiration dating?</td> <td style="padding: 5px;">No change</td> </tr> <tr> <td style="padding: 5px;">Change in sterilization?</td> <td style="padding: 5px;">Not applicable, software device</td> </tr> </tbody> </table>		Technology	Not Applicable / No change / Yes <b>Note:</b> If Yes, please provide rationale for review as Special 510(k)	Control mechanism change?	Not applicable, software device	Operating principle(s) change?	No change	Energy Type change?	Not applicable, software device	Environmental specifications change?	Not applicable, software device	Dimensional specifications change?	Not applicable, software device	Changes in packaging or expiration dating?	No change	Change in sterilization?	Not applicable, software device
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Dimensional specifications change?	Not applicable, software device																
Changes in packaging or expiration dating?	No change																
Change in sterilization?	Not applicable, software device																

**Special 510(k) Criteria**

**The submission should not be reviewed as a Special 510(k) if “No” is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.**

Changes to Fundamental Scientific Technology	Changes
Performance specifications change?	<p>Yes. The changes include completely re-designed User Interface (UI) screen and improved performance of the software.</p> <p>The software changes do not affect the indications for use. No clinical data was necessary to establish safety and effectiveness for the purpose of substantial equivalence.</p> <p>The modifications were found appropriate for reliance on results from design control process to assure conformance safety and effectiveness for purpose of substantial equivalence. Therefore, a special 510(k) notification for device modification is appropriate.</p> <p>Ref.: FDA guidance document: The New 510(k) Paradigm (<a href="http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf">http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf</a>)</p> <p><u>Note:</u> Based on the FDA guidance document, the changes to software are considered appropriate for review as Special 510(k).</p>
Ergonomics of the patient-user interface change?	
Software or firmware change?	

Special 510(k) Criteria		
<p><b>The submission should not be reviewed as a Special 510(k) if “No” is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.</b></p>		
<p><b>4. The submission includes only summary-level information (i.e., NO test reports with performance data).</b></p> <p>Note that if performance data are provided and are conducted <i>under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.</i></p>	Yes	
<p><b><u>Comments:</u></b></p> <p>The submission includes only summary-level information. Please refer Attachment 10 to 12 for summary level information of test reports conducted under design validation (21 CFR 820.30 (g)).</p>		

**Does the submission meet all 4 criteria above?**

- Yes, submission meets criteria for a Special 510(k). Continue with the remainder of this checklist below.
- No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional and apply the Traditional checklist.

<b><u>Organizational Elements</u></b>			
<i>Failure to include these items alone generally should not result in an RTA designation</i>			
	Yes	No	Comments/ Page
a. Submission contains Table of Contents	<input checked="" type="checkbox"/>		Attachment-004
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	<input checked="" type="checkbox"/>		
c. All pages of the submission are numbered <i>All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).</i>	<input checked="" type="checkbox"/>		
d. Type of 510(k) is identified– traditional, abbreviated, or special If type of 510(k) is not designated, review as a traditional	<input checked="" type="checkbox"/>		Attachment-001
<p><b><u>Comments:</u></b></p> <p>None.</p>			

<b><u>Elements of a Complete Submission (RTA Items)</u></b> <b><u>(21 CFR 807.87 unless otherwise indicated)</u></b> Submission should be designated RTA if not addressed					
<b>Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.</b>					
		Yes	N/A	No	Comments/ Page
	<ul style="list-style-type: none"> <li>Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
<b>A.</b>	<b>Administrative</b>				
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	<input checked="" type="checkbox"/>		<input type="checkbox"/>	
	<b><u>Comments:</u></b> None.				
2.	510(k) Cover letter that identifies: at a minimum:	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-001
a.	Device trade name or proprietary name	<input checked="" type="checkbox"/>		<input type="checkbox"/>	
b.	Device common name	<input checked="" type="checkbox"/>		<input type="checkbox"/>	
c.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	<input checked="" type="checkbox"/>		<input type="checkbox"/>	
	<b><u>Comments:</u></b> None.				

<b>Elements of a Complete Submission (RTA Items)</b> <b>(21 CFR 807.87 unless otherwise indicated)</b> Submission should be designated RTA if not addressed					
<b>Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.</b>					
		Yes	N/A	No	Comments/ Page
	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
	3. Submission contains Indications for Use Statement with Rx and/or OTC designated (see also and 801.109)  <i>Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.</i>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-006
	<b>Comments:</b> None.				
	4. Submission contains 510(k) Summary or 510(k) Statement  <i>Either a) or b) must be answered "Yes" to be considered complete.</i>  <i>Identify any missing element(s) as Comments.</i>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-007
	a. Summary contains all elements per 21 CFR 807.92  <i>See also 510(k) Summary Checklist</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	b. Statement contains all elements per 21 CFR 807.93	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Rationale provided.

<b><u>Elements of a Complete Submission (RTA Items)</u></b> <b><u>(21 CFR 807.87 unless otherwise indicated)</u></b> Submission should be designated RTA if not addressed					
<b>Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.</b>					
		Yes	N/A	No	Comments/ Page
	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
	<b><u>Comments:</u></b> 510(k) summary is attached per 21 CFR 807.92. Therefore, submission of 510(k) statement is not applicable for this submission.				
5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) <i>See recommended format</i>	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-014
	<b><u>Comments:</u></b> None.				
6.	Submission contains Class III Summary and Certification <i>See recommended content</i> <i>Form should be signed by a responsible person of the firm, not a consultant. CDRH is not currently able to accept a digital signature.</i> <i>"N/A" only if submission is not a Class III 510(k).</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Rationale provided.
	<b><u>Comments:</u></b> The submission is not a Class III 510(k); therefore Class III Summary and Certification are not required.				
7.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Attachment-015 Attachment-016 Attachment-017

<p align="center"><b><u>Elements of a Complete Submission (RTA Items)</u></b>  <b><u>(21 CFR 807.87 unless otherwise indicated)</u></b>            Submission should be designated RTA if not addressed</p>					
<p><b>Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.</b></p>					
		Yes	N/A	No	Comments/ Page
	<ul style="list-style-type: none"> <li>Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
	<p><i>There should be a completed form for each referenced national or international standard.</i></p> <p><i>“N/A” only if submission does not reference any standards.</i></p>				
	<p><b><u>Comments:</u></b> None.</p>				
	<p>8. The submission identifies prior submissions for the same device which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre- Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.</p> <p>This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.</p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Rationale provided.
	<p>a. If there are related submissions, within current submission, the sponsor has identified where in the current submission any issues related to substantial equivalence outlined in prior communications are addressed.</p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Rationale provided.

<b><u>Elements of a Complete Submission (RTA Items)</u></b> <b><u>(21 CFR 807.87 unless otherwise indicated)</u></b> Submission should be designated RTA if not addressed						
<b>Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.</b>						
			Yes	N/A	No	Comments/ Page
		<ul style="list-style-type: none"> <li>Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
		<b><u>Comments:</u></b> There were no prior submissions, i.e. Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn, associated with the changes covered by this special 510(k).				
<b>B. Device Description</b>						
9.	a	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.  <i>Select “N/A” if there are no applicable requirements in a device-specific regulation. Select “No” if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Attachment-008
	b	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.  <i>Select “N/A” if there is no applicable device-specific guidance. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Attachment-008

<b>Elements of a Complete Submission (RTA Items)</b> <b>(21 CFR 807.87 unless otherwise indicated)</b> Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
			Yes	N/A	No	Comments/ Page
		<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
		<i>specific guidance, etc., have been addressed should be assessed during the substantive review.</i>				
		<b>Comments:</b> The Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on May 11, 2005 has been used.				
	10.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labelling), including:				
	a.	A description of the principle of operation and mechanism of action for achieving the intended therapeutic/diagnostic effect.	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-030,031
	b.	A description of all conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-008
	c.	A list and description of each model for which clearance is requested.  <i>Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, or various sizes, etc.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Rationale provided.
		<b>Comments:</b> No different models are associated with this special 510(k) due to software device.				

<p align="center"><b>Elements of a Complete Submission (RTA Items)</b>  <b>(21 CFR 807.87 unless otherwise indicated)</b>                      Submission should be designated RTA if not addressed</p>					
<p><b>Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.</b></p>					
		Yes	N/A	No	Comments/ Page
	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
11.	A description of all device modification(s) including rationale for each modification.	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-008
	<p><b><u>Comments:</u></b> None.</p>				
12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.  <i>In lieu of drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.</i>  <i>Select "N/A" if the sponsor provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Attachment-008
	<p><b><u>Comments:</u></b> None.</p>				
13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system,  <i>Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.</i>	<input checked="" type="checkbox"/>			

<b>Elements of a Complete Submission (RTA Items)</b> <b>(21 CFR 807.87 unless otherwise indicated)</b> Submission should be designated RTA if not addressed						
<b>Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.</b>						
			Yes	N/A	No	Comments/ Page
		<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
	a.	Submission includes a list of all components and accessories to be marketed with the subject device.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Rationale provided.
	b.	Submission includes a description (as detailed in item #12.a. and b. and 14 above) of each component or accessory.  <i>Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	c.	510(k) number is provided for each component or accessory that received a prior 510(k) clearance.  <i>Select "N/A" if the submission states that the component(s)/accessory(ies) does not have a prior 510(k) clearance or the components/accessory(ies) is 510(k) exempt.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
		<b>Comments:</b> The device is not intended to be marketed with any components and accessories. The MR Core software is available on 510(k) cleared Vitrea platform (K150258).				
<b>C.</b>	<b>Substantial Equivalence Discussion</b>					
	14.	Submitter has identified a predicate(s) device	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-009
	a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided.	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-009

<b>Elements of a Complete Submission (RTA Items)</b> <b>(21 CFR 807.87 unless otherwise indicated)</b> Submission should be designated RTA if not addressed						
<b>Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.</b>						
			Yes	N/A	No	Comments/ Page
		<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
		For predicates that are preamendments devices, information is provided to document preamendments status.  <i>Information regarding documenting preamendment status is available online (<a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm</a>).</i>				
	b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing)	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-009 Attachment-007
		<b>Comments:</b> None.				
	15.	Submission includes a comparison of the following for the predicate(s) and subject device				
	a.	Indications for use	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-009
	b.	Technology, including features, materials, and principles of operation	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-009
		<b>Comments:</b> None.				
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-009

<p align="center"><b><u>Elements of a Complete Submission (RTA Items)</u></b>  <b><u>(21 CFR 807.87 unless otherwise indicated)</u></b>            Submission should be designated RTA if not addressed</p>					
<p><b>Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.</b></p>					
		Yes	N/A	No	Comments/ Page
	<ul style="list-style-type: none"> <li>Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
	<p>the device NSE (e.g., do not constitute a new intended use, affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(l)(A) of the FD&amp;C Act)</p> <p><i>If there is no difference between the subject and predicate(s with respect to the indications or technology), this should be explicitly stated, in which case “N/A” should be selected. Select “No” only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance.</i></p>				
	<p><b><u>Comments:</u></b> None.</p>				
<b>D.</b>	<b>Design Control Activities</b>				
17.	Design Control Activities Summary includes all of the following:				
a.	Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis	<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-055 Attachment-032 Attachment-033 Attachment-034 Attachment-035

<b><u>Elements of a Complete Submission (RTA Items)</u></b> <b><u>(21 CFR 807.87 unless otherwise indicated)</u></b> Submission should be designated RTA if not addressed						
<b>Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.</b>						
			Any “No” answer will result in a “Refuse to Accept” decision.  Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes N/A No	Comments/ Page	
	b.	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.		<input checked="" type="checkbox"/>	<input type="checkbox"/>	Attachment-036 Attachment-037 Attachment-038 Attachment-039 Attachment-040 Attachment-041
	c.	Declaration of conformity with design controls, including:  <i>All 3 must be present to answer “Yes”</i>		<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	i.	Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.				Attachment-019
	ii.	Statement that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30				Attachment-020
	iii.	Statement is signed by the individual responsible for these activities				Attachment-019 Attachment-020
	<b><u>Comments:</u></b> None.					
<b>E.</b>	<b>Proposed Labelling (see also 21 CFR part 801)</b>					

<p align="center"><b><u>Elements of a Complete Submission (RTA Items)</u></b>  <b><u>(21 CFR 807.87 unless otherwise indicated)</u></b>            Submission should be designated RTA if not addressed</p>						
<p><b>Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.</b></p>						
			Yes	N/A	No	Comments/ Page
	<ul style="list-style-type: none"> <li>Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>					
18.	Submission includes proposed labels, labelling (e.g., instructions for use, package insert, operator’s manual) and advertisements that describe the device, its intended use, and the directions for use		<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-011 Attachment-012
	a. All changes in proposed labelling resulting from device modification(s) are highlighted or prominently identified.		<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-011 Attachment-012 Attachment-013
	<p><b><u>Comments:</u></b> None.</p>					
19.	Statement that the intended use of the modified device, as described in the labelling, has not changed as a result of the modification(s).		<input checked="" type="checkbox"/>		<input type="checkbox"/>	Attachment-021
	<p><b><u>Comments:</u></b> None.</p>					
	<p><b><u>Comments:</u></b> None.</p>					

**Decision:** Accept \_\_\_\_\_ Refuse to Accept \_\_\_\_\_

**If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.**

**Reviewer Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Supervisory Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_





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## 510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part 807.92(c)

**Purpose of Submission:** Vital Images, Inc. hereby submits this special 510(k) to provide a notification submission for proposed software changes in the already 510(k) cleared Softread software (K040305).

**Submitter:** Vital Images, Inc.  
5850 Opus Parkway  
Suite 300  
Minnetonka, MN, 55343-4414

**Establishment Registration:** 2134213

**Contact Person:** Parthiv Shah  
Sr. Regulatory Affairs Specialist  
Phone : 952-487-9574  
Fax: 952-487-9510  
E-mail: [pshah@vitalimages.com](mailto:pshah@vitalimages.com)

**510(k) Type:** Special

**Summary Date:** April 24, 2015

**Device Trade Name:** MR Core Software

**Device Common Name:** Radiological Image Processing Software

**Device Classification Name:** System, Image Processing, Radiological

**Regulatory Description:** Picture Archiving and Communications System

**Regulation Number:** 21 CFR 892.2050

**Product Code:** LLZ

**Regulatory Classification:** Class II

**Device Panel:** Radiology

**Predicate Device:**

Predicate Device	Manufacturer	FDA 510(k) number
Softread Software (Legally Marketed Device)	Vital Images, Inc.	K040305

**Reference Device:**

Reference Device	Manufacturer	FDA 510(k) number
Myrian (Legally Marketed Device)	Intrasense	K091001

**Device Description:**

MR Core allows intuitive navigation, quantification, and manipulation of medical images obtained from MRI scanners. This application enables clinicians to compare multiple series of the same patient, side-by-side, and switch to other integrated applications to further examine the data. It provides rich clinical tools to review images for efficient and effective patient care.

**Key features:****General Viewing:**

- Linked 2D, MPR and 4D viewers for single and multi-study comparison
- Creation of retrievable evidence and snapshots
- User defined flexible display protocols

**Access to Advanced Applications and Workflows:**

- In-application access to advanced analysis applications
- Evidence creation and sharing across workflows

**General Image Display, Manipulation, and Analysis Tools:**

- Maximum and Minimum Intensity Projection (MIP/MinIP)
- Identification and Display of Regions of Interest (ROIs)
- CINE image display
- Multi-frame display
- Color image display
- Simultaneous multiple studies review
- Cross-reference lines support
- Display of selected images, series, or entire study
- Comparison of multiple series or studies
- Scroll
- Pan
- Zoom
- Focus
- Flip (Vertically, horizontally)

- Invert
- Rotate (Clockwise, counter-clockwise)
- Arrow
- Adjust Registration
- Window level/width selection and user configurable preset
- Auto window level/width setting
- Text/Arrow annotation (Label)
- Measurement of distance (Ruler), Angle, Cobb Angle, Ellipse ROI, and Freehand ROI

**Specialized MR Tools:**

- Image subtraction of two MR series/datasets
- Semi-automated image stitching
- Study and series linking
  - Automatic registration
  - Register two different series or groups that do not share a frame of reference to link them spatially

**Intended Use / Indications for Use:**

MR Core is an option within Vitrea® that allows the examination and manipulation of a series of medical images obtained from MRI scanners. The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.

**Changes from the last 510(k) clearance K040305:**

No.	Change(s)	Rationale for Changes
1	<b><u>Change-1: User Interface</u></b> Completely re-designed User Interface (UI) screen	To utilize enhancements in the software technology for better look and user experience.
2	<b><u>Change-2: Stitching of MR data</u></b> Added a new feature of "stitching" that combines MR images covering distinct contiguous, or slightly overlapping, regions of the human body anatomy into one or multiple images.	To combine separately acquired images into a single view for easier interpretation.
3	<b><u>Change-3: Restricted Modality Support</u></b> MR Core only allows the examination and manipulation of a series of medical images obtained from MRI scanners.	The current version of MR Core only supports MR modality.

No.	Change(s)	Rationale for Changes
4	<b>Change-4: Restricted Features</b> MR Core does not support “ <i>Image Filtering</i> ” and “ <i>Image Set Splitting</i> ” (divide a single study into multiple stacks) features.	The current version of MR Core does not support “ <i>Image Filtering</i> ” and “ <i>Image Set Splitting</i> ” features.

**Intended for Disease / Condition / Patient Population:**

MR Core is a medical image viewer software device. Therefore, particular information regarding the disease, condition, and patient population are not applicable.

**Substantial Equivalence Comparison:**

- **Regulatory Comparison with the Predicate Device**

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software	
Device Type / Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
Common Name	Radiological Image Processing Software	Radiological Image Processing Software	Same
Regulation / Classification Number	21 CFR 892.2050	21 CFR 892.2050	Same
Product Code	LLZ	LLZ	Same
Classification	Class II	Class II	Same
Review Panel	Radiology	Radiology	Same

- **Intended Use Comparison with the Predicate Device**

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software	
Indications for Use	<p>Softread, is an option within the Vitrea 2 system and is intended to allow the examination and manipulation of a series of 2D images in a variety of modalities, including CT, <b>MR</b>, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc.</p> <p>The option also enables clinicians to compare multiple series' for the same patient, side-by-side, and to switch to Vitrea to further examine the data in a 3D volume.</p>	<p>MR Core is an option within Vitrea® that allows the examination and manipulation of a series of medical images obtained from <b>MRI</b> scanners.</p> <p>The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.</p>	<p>Same</p> <p><b>Note:</b> The Intended Use statement of the modified software is a subset (i.e. only for MR datasets) of already cleared Intended Use of the legally marketed device.</p>

- **Technology Comparison with the Predicate Device**

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software	
Image Communication Standard: DICOM	Yes	Yes	Same
2D Image Review	Yes	Yes	Same
2D Comparative Review	Yes	Yes	Same
Multi-Planner Reformatting	Yes	Yes	Same
Maximum and Minimum Intensity Projection (MIP/MinIP)	Yes	Yes	Same



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Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software	
Image Editing, Setting, Saving	Yes	Yes	Same
Annotation & Tagging Tools (Label)	Yes	Yes	Same
Display Options (e.g. thickness)	Yes	Yes	Same
Quantitative Measurements	Yes	Yes	Same
Snapshot	Yes	Yes	Same
Report Generation	Yes	Yes	Same
Cine Image Display	Yes	Yes	Same
Multi-frame Display	Yes	Yes	Same
Color Image Display	Yes	Yes	Same
Simultaneous Multiple Studies Review	Yes	Yes	Same
Cross-reference Lines Support	Yes	Yes	Same
Display of Selected Images, Series, or Entire Study	Yes	Yes	Same
Comparison of Multiple Series or Studies	Yes	Yes	Same
Scroll Image	Yes	Yes	Same
Zoom Image	Yes	Yes	Same
Pan Image	Yes	Yes	Same
Focus Image	Yes	Yes	Same
Rotate Image	Yes	Yes	Same



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Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software	
Flip Image - Vertical	Yes	Yes	Same
Flip Image - Horizontal	Yes	Yes	Same
Rotate Image - Clockwise	Yes	Yes	Same
Rotate Image - Counter-clockwise	Yes	Yes	Same
Invert Image	Yes	Yes	Same
Arrow	Yes	Yes	Same
Window Level/Width Selection and User Configurable Preset	Yes	Yes	Same
Auto Window Level/Width Setting	Yes	Yes	Same
Measurement of Distance	Yes	Yes	Same
Measurement of Angle	Yes	Yes	Same
Measurement of Cobb Angle	Yes	Yes	Same
Identification and Display of Ellipse Regions of Interest (ROIs)	Yes	Yes	Same
Identification and Display of Freehand Regions of Interest (ROIs)	Yes	Yes	Same
Automatic Registration	Yes	Yes	Same
Adjust Registration	Yes	Yes	Same

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software	
Image subtraction of two MR series/datasets	Yes	Yes	Same
Study and Series Linking	Yes	Yes	Same
Ability to launching into Vitrea platform for any advanced applications	Yes	Yes	Same

- **Technology Comparison with the Reference Device**

Criteria	Reference Device	Subject Device	Comparison
	Myrian (K091001)	MR Core Software	
<b>Feature: Stitching</b> Stitching feature combines MR images covering distinct contiguous, or slightly overlapping, regions of the human body anatomy into one or multiple images.	Yes	Yes	Same  <b>Note:</b> The added "Stitching" feature is similar to the feature on the already cleared Intracore, MYRIAN ("Reference device")'s "Image Alignment" feature by K091001.  Therefore, the added feature does not raise new questions of safety and effectiveness.

- **Differences in Technology with the Predicate Device**

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software	
<p><b>Feature: Stitching</b></p> <p>Stitching feature combines MR images covering distinct contiguous, or slightly overlapping, regions of the human body anatomy into one or multiple images.</p>	No	Yes	<p>The added feature does not affect the intended use or fundamental scientific technology of already cleared Softread software (K040305).</p> <p><b>Note:</b> The added “Stitching” feature is similar to the feature on the already cleared Intrasure, MYRIAN (“Reference device”)’s “Image Alignment” feature by K091001. Therefore, the added feature does not raise new questions of safety and effectiveness.</p>
<p><b>Restricted Modality Support</b></p> <p>The current version of MR Core only supports MR modality.</p>	Multi-modality	MR	<p>The support for additional modalities is available in the predicate device but not in the subject device.</p> <p>Therefore, they do not raise any new questions of safety and effectiveness of the subject device.</p>
<p><b>Restricted Features</b></p> <p>The current version of MR Core does not support “Image Filtering” and “Image Set Splitting” features.</p>	<ul style="list-style-type: none"> <li>• Image Filtering</li> <li>• Image Set Splitting</li> </ul>	None	<p>These additional features are available in the predicate device but not in the subject device.</p> <p>Therefore, they do not raise any new questions of safety and effectiveness of the subject device.</p>

- **Substantial Equivalence Analysis**

The enhancements in the software do not affect the intended use or alter the fundamental scientific technology of legally marketed Softread software (K040305). The modified Softread software (known as MR Core) has the same indications for use, principle of operation, and performs similar technological functions as the already cleared Softread software (K040305) (Predicate Device). The added "Stitching" feature is similar to the already cleared Intrasure, Myrian software (K091001) (Reference Device). The modifications are not consequential from the standpoint of device operation, safety, effectiveness or intended use.

Any minor differences noted have been explained and do not raise any new questions of safety or effectiveness when used as labeled. The implemented design controls, risk management activities, labeling, and the performed verification and validation tests demonstrate the safety and efficacy of the device is equivalent to the predicate device. Based on the comparison data and test data, Vital Images believes the subject device should be found substantially equivalent to the predicate device.

**Summary of Non-Clinical Tests:**

The changes to the Softread software were designed, developed and tested according to written procedures that included applying risk management. Software testing was completed to ensure the new features operate according to their requirements.

Testing included verification, validation, and evaluation on previously acquired medical images. The following quality assurance measures were applied to the development:

- Risk Management
- Requirements reviews
- Code designs
- Code reviews
- Design reviews
- Verification of the software – that included performance and safety testing
- Validation of the software – that included simulated usability testing by independent experienced medical professionals.

**Risk Management:**

Each risk pertaining to this feature has been individually assessed to determine if the benefits outweigh the risk. Every risk has been reduced as low as possible and has been evaluated to have a probability of occurrence of harm of at least "Remote". All risks for this feature were collectively reviewed to determine if the benefits outweigh the risk. Based on the post market information contained in our Clinical Evaluation Report, injury or death is very rare for our product and products similar to ours. Because of this history and because of the risk control measures included in this feature, it is believed that the risk for the feature as a whole is extremely low. Taking into account all risks against the benefits of this feature, it has been assessed that the benefits do outweigh the risks for this feature.

During the design review, the following conclusions were reached:

- All risks were reduced as low as possible
- The medical benefits of the device outweigh the residual risk for each individual risk and all risks together
- The overall residual risk for the project is deemed acceptable

## **Verification:**

The software verification team's primary goal was to assure that the software fully satisfies all expected system requirements and features. Test cases were executed against the system features and requirements. As a part of creating the test cases, the verification team reviewed and monitored the Requirements Traceability Matrix ("RTM") to ensure coverage of the items within the RTM.

## **Validation:**

The software validation team's primary goal was assuring the software conforms to user needs and intended use. The validation team conducted workflow testing that provided evidence that the system requirements and features were implemented, reviewed and met.

## **External Validation:**

During external validation of MR Core software, experienced medical professionals evaluated the application. All validators confirmed that the MR Core software fulfills its intended uses.

## **Summary of Clinical Tests:**

The subject of special 510(k) notification, MR Core software, did not require clinical studies to support safety and effectiveness of the software.

## **Cyber and Information Security:**

- **Confidentiality**

The Vitrea platform (K150258) relies on built in Windows Login security to limit access to the system. The Vitrea platform can only be installed and configured by an administrator of the Windows machine.

- **Integrity**

The Vitrea platform complies with the DICOM standard for transfer and storage of this data and does not modify the contents of DICOM instances.

- **Availability**

The Vitrea platform is always available to the logged on user as long as the Windows machine itself is properly maintained.

- **Accountability**

The Vitrea platform includes an audit capability that tracks authenticated and authorized user operations along with information on what data was accessed. Vitrea audit logs are time stamped, enabling correlation with Windows system logging to track information accessed by a user.

**Performance Standards:**

The FDA has not established mandatory performance standards and no special controls exist for this device. General software verification and validation tests were conducted to confirm proper function of the device's features.

The MR Core software complies with the following voluntary recognized consensus standards:

Standard No.	Standards Organization	Standard Title	Version	Date
PS 3.1- 3.20 (2011) (Recognition Number 12-238)	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set (Radiology)	3	03/16/2012
ISO 14971:2007 (Recognition Number 5-70)	AAMI / ANSI / ISO	Medical Devices - Applications of Risk Management to Medical Devices	2007	03/16/2012
IEC 62304:2006 (Recognition Number 13-32)	AAMI / ANSI / IEC	Medical Device Software - Software Life Cycle Processes (Software / Informatics)	2006	08/20/2012

**Conclusion:**

Vital Images believes that the MR Core software application has the same intended use and indications and similar principle of operation, and technological characteristics as the predicate and reference devices. Any minor differences noted have been explained and do not raise any new questions of safety or effectiveness when used as labeled. The implemented design controls, risk management activities, labeling, and performed tests demonstrate the safety and efficacy of the device in comparison to the predicate device. Based on the comparison data and test data, Vital Images believes the subject device should be found substantially equivalent to the predicate device. The MR Core software device is as safe and effective as the predicate device.

## Description of the Modified Device

### 8.1 Device History

An image viewer component of the Vitrea software was cleared on 24<sup>th</sup> December, 2004 by a 510(k) notification (K040305) under name of "Softread" with the following Intended Use statement:

*"Softread, is an option within the Vitrea 2 system and is intended to allow the examination and manipulation of a series of 2D images in a variety of modalities, including CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc.*

*The option also enables clinicians to compare multiple series' for the same patient, side-by-side, and to switch to Vitrea to further examine the data in a 3D volume."*

Vital Images is now enhancing the Softread software to improve performance and User Interface screen for better user experience by utilizing advancement in the software technology.

#### The key enhancements are:

- Completely re-designed User Interface (UI) screen to utilize enhancements in the software technology for better look and user experience.
- Added a new feature of "stitching" that combines MR images covering distinct contiguous, or slightly overlapping, regions of the human body anatomy into one or multiple images.
- Provide ability to launch any advanced MR applications available on Vitrea platform.

**Note:** Since MR Core viewer has restricted modality support compared to our already cleared "Softread" software, Vital Images is planning to keep Softread" and the updated Softread, under the new marketing name "MR Core" software, in the US market for users.

### 8.2 MR Core Software

MR Core allows intuitive navigation, quantification, and manipulation of medical images obtained from MRI scanners. This application enables clinicians to compare multiple series of the same patient, side-by-side, and switch to other integrated applications to further examine the data. It provides rich clinical tools to review images for efficient and effective patient care.

#### **Key features: (Enhancements are highlighted in yellow color)**

##### **General Viewing:**

- Linked 2D, MPR and 4D viewers for single and multi-study comparison
- Creation of retrievable evidence and snapshots
- User defined flexible display protocols

##### **Access to Advanced Applications and Workflows:**

- In-application access to advanced analysis applications
- Evidence creation and sharing across workflows

## **General Image Display, Manipulation, and Analysis Tools:**

- Maximum and Minimum Intensity Projection (MIP/MinIP)
- Identification and Display of Regions of Interest (ROIs)
- CINE image display
- Multi-frame display
- Color image display
- Simultaneous multiple studies review
- Cross-reference lines support
- Display of selected images, series, or entire study
- Comparison of multiple series or studies
- Scroll
- Pan
- Zoom
- Focus
- Flip (Vertically, horizontally)
- Invert
- Rotate (Clockwise, counter-clockwise)
- Arrow
- Adjust Registration
- Window level/width selection and user configurable preset
- Auto window level/width setting
- Text/Arrow annotation (Label)
- Measurement of distance (Ruler), Angle, Cobb Angle, Ellipse ROI, and Freehand ROI

## **Specialized MR Tools:**

- Image subtraction of two MR series/datasets
- **Semi-automated image stitching**
- Study and series linking
  - Automatic registration
  - Register two different series or groups that do not share a frame of reference to link them spatially

### 8.3 Tools Available on MR Core Software

Tool	Name	Description
	Display Menu	Click the dropdown in the upper-left corner to launch the Display menu.  <div style="border: 1px solid black; padding: 5px; width: fit-content;"> <ul style="list-style-type: none"> <li>• 2D</li> <li>MPR Ax</li> <li>MPR Sg</li> <li>MPR Cr</li> </ul> </div> <p><b>NOTE:</b> MPR options available for 2D or Derived images.</p>
	Subtraction	Select this icon to launch the subtraction mode and display the subtraction tools.  Drag the series to be subtracted over the view. The series must have the same: <ul style="list-style-type: none"> <li>• Number of images</li> <li>• Image thickness</li> <li>• Field of view</li> </ul> <p><b>NOTE:</b> The initial series is labeled "A," the series you dragged over is labeled "B."</p>
	Subtraction — A - B / B - A	Select either of these icons to specify the subtraction order.
	Subtraction — A	Select this icon to return to initial series and turn off subtraction mode.
	Cine tools	Select this icon to open the cine tools and start the cine. Select it again to close the cine tools.
	Cine — Pause	With the cine tools open, select the Pause icon to pause.

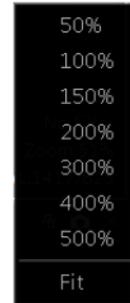
Tool	Name	Description
	Cine — Rock / Loop	With the cine tools open, select the Rock icon to cine through the series from first to last frame, then from last to first frame. Select the Loop icon to cine through the series from first to last frame, and then repeating. <p><b>NOTE:</b> The blue-highlighted icon is the one currently selected.</p>
	Cine - Frames per second	With the cine tools open, select this icon to open a menu of frames per second options. <div data-bbox="1166 774 1344 1108" style="border: 1px solid black; background-color: black; padding: 5px; margin: 10px 0;">                         2 fps                          5 fps                          7.5 fps                          10 fps                          12.5 fps                          • 15 fps                          20 fps                          25 fps                          30 fps                     </div> <p><b>NOTE:</b> The orange dot indicates the currently selected option.</p>
	Link / Unlink	Select this icon to link or unlink the series with the other displayed series with regard to pan, zoom, and scroll operations. <p><b>NOTE:</b> The icon displays the linking state currently selected.</p>
	Snapshot	Select this icon to take a snapshot of the view.
	Close	Select this icon to close the view.

Link	Name	Description
------	------	-------------

**Zoom:51%**

Zoom

Displays the currently selected zoom factor. Click this link to open the Zoom menu.



**WL:1338/603**

Window/Level

Displays the current window/level value. Click this link to enter specific window/level values.



Tool	Name	Description
------	------	-------------



Scroll

Click this icon and drag in the view to scroll through the stack of images.



Window/Level

Click this icon and drag in any view to adjust the window/level.

The window/level value is displayed in the lower-right corner of the view.



Pan

Click this icon and drag in any view to pan the image.



Zoom

Click this icon and drag in any view to zoom the image.



Focus

Click this icon and click in a view to triangulate to a point of interest in all available views.



Ruler

Click this icon and click and drag in the view to draw a simple line measurement.

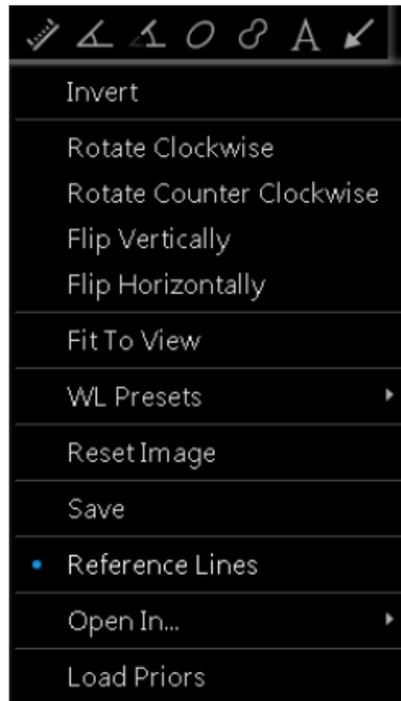
**NOTE:** Also available on the right-click menu.

Tool	Name	Description
	Angle	<p>Click this icon and click in the view to place the first endpoint, click again to place the vertex, then click a third time to place the second endpoint.</p> <p>The the angle in degrees displays.</p> <p><b>NOTE:</b> Also available on the right-click menu.</p>
	Cobb Angle	<p>Click this icon and click in the view to place the first endpoint of the initial line, then click again to place the second endpoint of the initial line.</p> <p>The second line displays as a mirror to the initial line and the angle between the two lines in degrees displays.</p> <p><b>NOTE:</b> Also available on the right-click menu.</p>
	Ellipse ROI	<p>Click this icon and click and drag in the view to create an elliptical contour.</p> <p>The perimeter, area, and other measurements display.</p> <p><b>NOTE:</b> Also available on the right-click menu.</p>
	Freehand ROI	<p>Click this icon and click multiple times in the view to place points that define the contour. Click near the first point to complete the contour.</p> <p>The perimeter, area, and other measurement display.</p> <p><b>NOTE:</b> Also available on the right-click menu.</p>
	Label	<p>Click this icon and click in the view to place the text cursor, then type the label. Press ENTER to complete the label.</p> <p><b>NOTE:</b> Also available on the right-click menu.</p>

Tool	Name	Description
	Arrow	Click this icon and click in the view to place the arrow head, drag, and click again to place the arrow tail.  <b>NOTE:</b> Also available on the right-click menu.
	Adjust Registration	Click this icon then click on the same anatomical feature in two views across studies with different time points to link them.   See Adjust Registration below for instructions.

**Right-click Menu:**

Right-click in any view to access commonly used tools and options.

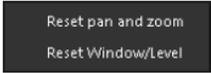


<b>Tool/ Option</b>	<b>Description</b>
Common Tools	Same as Common Tool header. <ul style="list-style-type: none"> <li>• Ruler</li> <li>• Angle</li> <li>• Cobb Angle</li> <li>• Ellipse ROI</li> <li>• Freehand ROI</li> <li>• Label</li> <li>• Arrow</li> </ul>
Invert	Select this option to invert the image to photo-negative dark anatomy on light background.
Rotate Clockwise, Rotate Counter-clockwise, Flip Vertically, and Flip Horizontally	Select one of these options to rotate or flip the view.
Fit To View	Select this option to fit the data to the size of the view.
WL Presets	Select this option to display a menu of window/level presets. <div data-bbox="932 1400 1133 1535" style="text-align: center; border: 1px solid black; padding: 5px; margin: 10px 0;"> Default  Estimated  Full-Range </div>
Reset Image	Select this option to reset the image to its state when initially loaded.
Save	Select this option to save a subtracted series and export this series as a derived series.
Reference Lines	Select this option to show or hide reference lines in all views.

Tool/ Option	Description
Open In	Select this option to open the study in another application.  <b>NOTE:</b> The entire study opens in the other application, regardless of the series selected.
Load Priors	Select this option to load all other studies with the same Patient ID as the current study.

**Stitching Tools:**

Tool	Name	Description
	Scroll	Select this icon and drag in the view to scroll through the stack of images,  <b>OR</b> Roll the mouse wheel to scroll.
	Window/Level	Select this icon and drag in any view to adjust the window/level of the entire view.  The window/level value is displayed in the lower-right corner of the view.
	Pan	Select this icon and drag in any view to pan the image.
	Zoom	Select this icon and drag in any view to zoom the image.  The current zoom factor is displayed in the lower-right corner of the view.
	Pixel Shift	Select this icon and pan portions of the Adjustment view to re-align the Stitched view.

Tool	Name	Description
	Segment W/L	Select this icon and click and drag in portions of the Adjustment view to adjust the window/level of the individual portions of the Stitched view.
	Reset	Select this option to reset the zoom and pan or the window/level to the initial values.
		
	Unstitch	Select this option to discard stitching and all actions.
	Save	Select this option to save the stitched image.

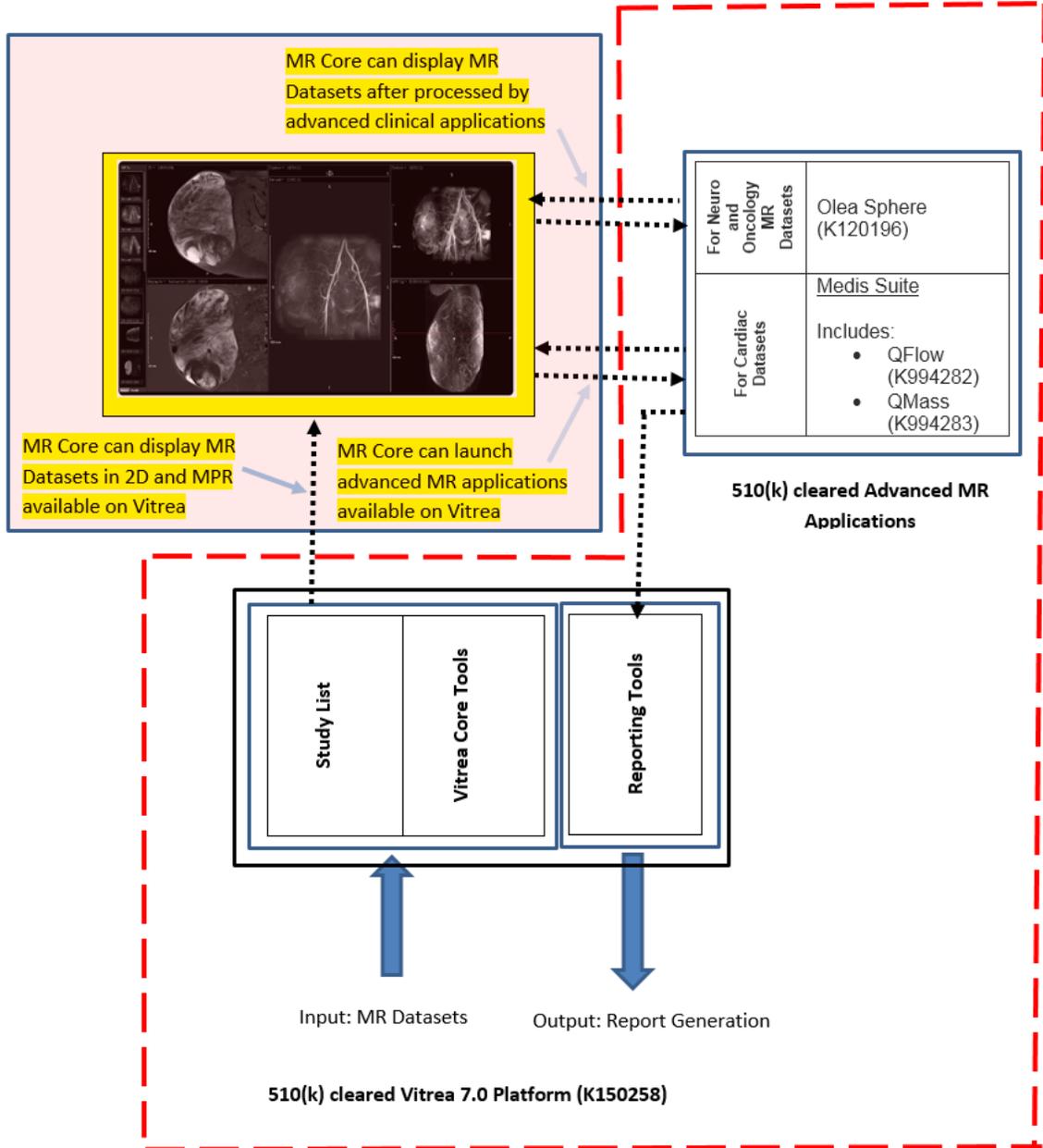
**8.4 Intended Use (Subset of already cleared Intended Use K040305 of Softread software)**

MR Core is an option within Vitrea that allows the examination and manipulation of a series of medical images obtained from MRI scanners.

The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.

## 8.5 Scope of this 510(k) Notification

Scope of this 510(k) notice is highlighted in yellow color below



## 8.6 Scope of Changes

No.	Change(s)	Rationale for Changes
1	<b><u>Change-1: User Interface</u></b> Completely re-designed User Interface (UI) screen	To utilize enhancements in the software technology for better look and user experience.
2	<b><u>Change-2: Stitching of MR data</u></b> Added a new feature of “stitching” that combines MR images covering distinct contiguous, or slightly overlapping, regions of the human body anatomy into one or multiple images.	To combine separately acquired images into a single view for easier interpretation.
3	<b><u>Change-3: (Restricted Modality Support)</u></b> MR Core only allows the examination and manipulation of a series of medical images obtained from MRI scanners.	<u>Product limitation:</u> The current version of MR Core only supports MR modality.
4	<b><u>Change-4: (Restricted Features)</u></b> MR Core does not support “ <i>Image Filtering</i> ” and “ <i>Image Set Splitting</i> ” (divide a single study into multiple stacks) features.	<u>Product limitation:</u> The current version of MR Core does not support “ <i>Image Filtering</i> ” and “ <i>Image Set Splitting</i> ” features.

### 8.6.1 Change-1: User Interface

Vital Images has completely re-designed User Interface (UI) screen to utilize enhancements in the software technology for better look and user experience.

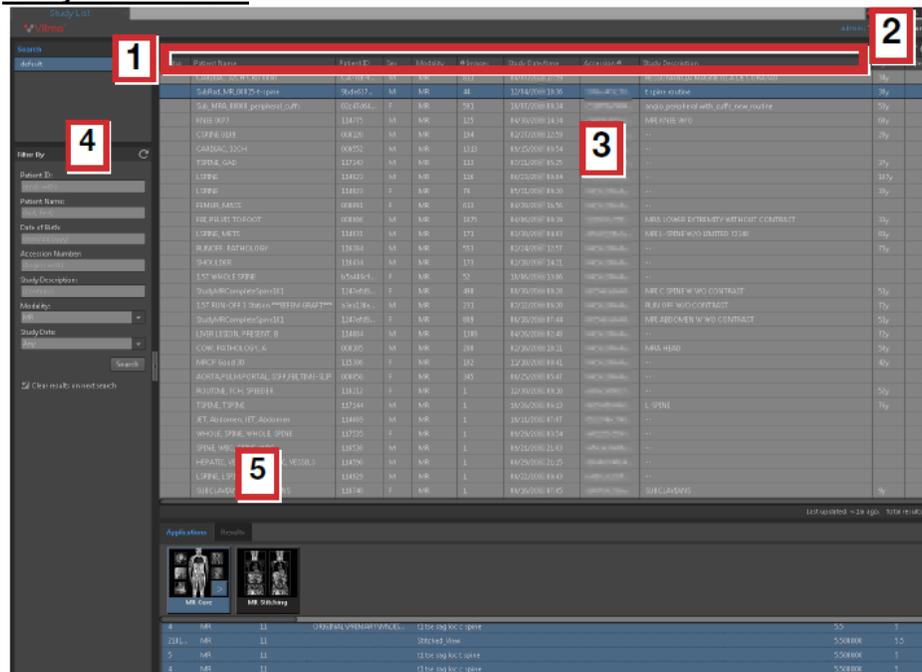
**Computer Screen:**



Callout Number	Description
1	Global patient information including the Global Options Menu button  .
<b>NOTE:</b> Always review patient information to ensure the correct patient study is loaded.	
2	Images  See Use the Images Panel below.

Callout Number	Description
3	Workspace of views displayed in a specified layout  See Work with the Workspace Layout below.
4	Layout button  – click to display a grid to select the Workspace layout  See Work with the Workspace Layout below.
5	Common tools  See the Common Tools section below.
6	View header
7	In-view tools - hover over the View header to display the in-view tools.
8	Editable demographics
9	Right-click menu

**Study List Window:**



The screenshot shows the 'Study List' window with a search bar at the top (callout 1) and a refresh button on the right (callout 2). A table of study entries is displayed in the center, with one row highlighted (callout 3). On the left, there is a filter sidebar (callout 4). At the bottom, there are application icons and a small table of application details (callout 5).

Study ID	Patient Name	Exam ID	Sex	Modality	# Images	Study Date/Time	Accession #	Study Description
114470	SARAI, MR. 0175 + spine	964617	M	MR	48	12/14/2014 13:36	114470101	MR LUMBAR W/O CONTRAST
114470	SARAI, MR. 0175 + spine	964617	M	MR	48	12/14/2014 13:36	114470102	MR LUMBAR W/O CONTRAST
114470	SARAI, MR. 0175 + spine	964617	M	MR	48	12/14/2014 13:36	114470103	MR LUMBAR W/O CONTRAST
114470	SARAI, MR. 0175 + spine	964617	M	MR	48	12/14/2014 13:36	114470104	MR LUMBAR W/O CONTRAST
114470	SARAI, MR. 0175 + spine	964617	M	MR	48	12/14/2014 13:36	114470105	MR LUMBAR W/O CONTRAST

Callout Number	Description
1	Column Headers <ul style="list-style-type: none"> <li>Click to sort.</li> <li>Click then type the first few letters to search.</li> </ul>
2	Study List tools
3	Patient (studies) List
4	Patient Information
5	Applications and Results tabs

**Applications Tab:**



#	Description
1	A list of Series that comprise the study.
2	Thumbnails representing the applications available for the study type.
3	Click <b>More</b> to display hidden application thumbnails
4	Click <b>Tools</b> to open a menu of Application tab options. <div style="border: 1px solid black; padding: 5px; margin: 5px 0;">                         Open Report Page editor                          Medium thumbnails                          Small thumbnails                     </div>
5	Click <b>List</b> to display the series in a list format.
6	Click <b>Images</b> to display the series in image thumbnails.
7	Right-click a series to display additional options or actions. <div style="border: 1px solid black; padding: 5px; margin: 5px 0;">                         Open                          Export Series                          Save Study to Media                     </div>

Please refer the attachment A-011\_ Proposed Label: Education and Reference Guide (VPMC-13746) for detailed information.

## 8.6.2 Change-2: Stitching of MR data

Vital Images has added a new feature of “stitching” that combines MR images covering distinct contiguous, or slightly overlapping, regions of the human body anatomy into one or multiple images.

The stitched image can be used for DICOM export and subsequent diagnostic reading, clinical review and/or post-processing in Vitrea-integrated MR applications.

### Workflow:

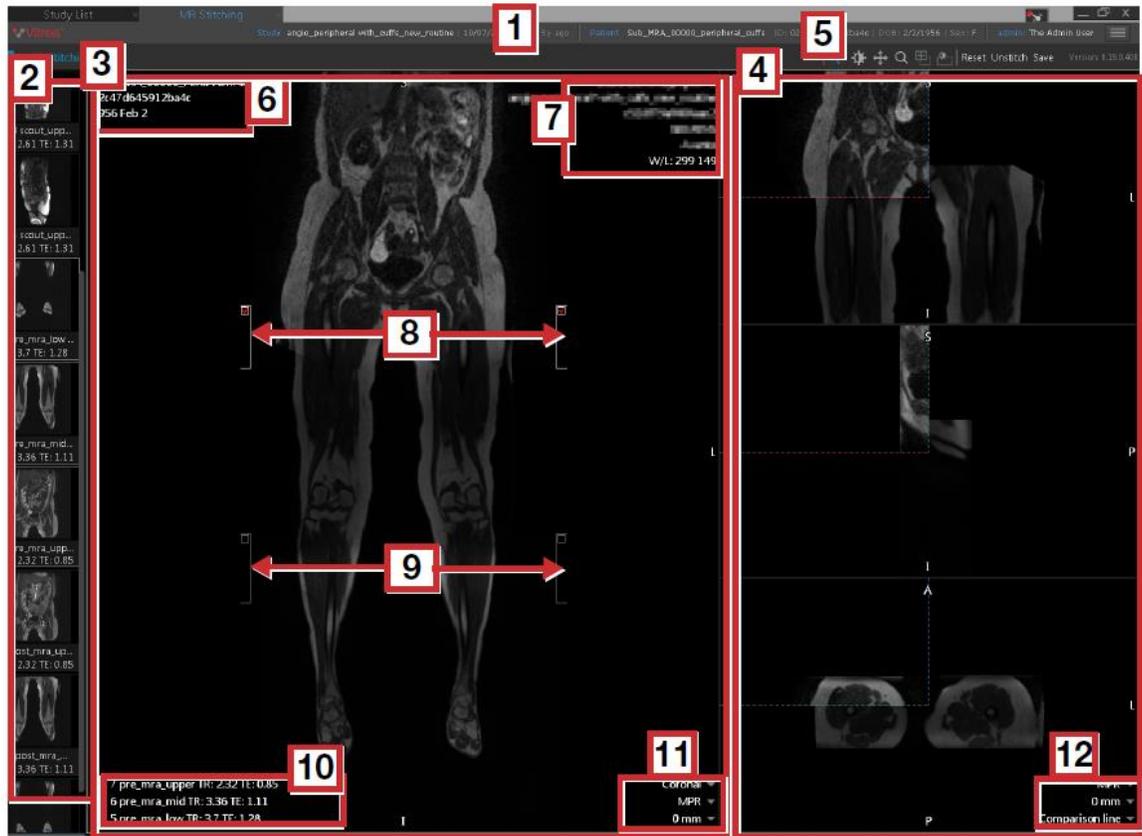
- Step-1: From the Patient List, select a patient name.
- Step-2: From the Applications tab, double-click the MR Stitching application thumbnail.



OR

- Step-1: From within the MR Core application, right-click in the view.
- Step-2: Select Open In.
- Step-3: Select MR Stitching.

**Computer Screen for MR Stitching:**



Callout Number	Description
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1	Global patient information including the Global Options Menu button  .
---	---

**NOTE:** Always review patient information to ensure the correct patient study is loaded.

2	Carousel  See Using the Carousel below.
---	---

Callout Number	Description
3	Stitched view  <b>NOTE:</b> The initial view is the first image in the Carousel.   See Stitching Images below.
4	Adjustment views   See Using the Adjustment Views below.
5	Common tools   See the Common Tools section below.
6	Patient information
7	Study information
8	Stitched overlap indicators - selected  <b>NOTE:</b> Select an overlap indicator to determine the images in the Adjustment views
9	Stitched overlap indicators - not selected
10	Series information of stitched stacks
11	Stitched image display settings
12	Adjustment view display settings

Please refer the attachment A-011\_ Proposed Label: Education and Reference Guide (VPMC-13746) for detailed information.

### **8.6.3 Change-3: (Restricted Modality Support)**

The current version of MR Core only supports MR modality.

### **8.6.4 Change-4: (Restricted Features)**

The current version of MR Core does not support “Image Filtering” and “Image Set Splitting” features.

## **8.7 Impact of Changes: Non-significant**

The MR Core software (modified Softread software) has the same intended use, indications, fundamental scientific technological characteristics, and principle of operation as the cleared Softread software (K040305).

## 8.8 Device Specific Guidance Document

The following information is recommended to be provided in the “The Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on May 11, 2005” document.

### 8.8.1 Programming Language

C, C++, Java

### 8.8.2 Recommended Hardware Platforms with Operating Systems

Hardware	Windows Client Operating System
HP Z600	Windows 7 Pro. 64-Bit SP1
HP Z420	Windows 7 Pro. 64-Bit SP1
HP Z800	Windows 7 Pro. 64-Bit SP1
HP Z620	Windows 7 Pro. 64-Bit SP1
HP Z600	Microsoft® Windows® 8.1 64-bit
HP Z420	Microsoft® Windows® 8.1 64-bit
HP Z620	Microsoft® Windows® 8.1 64-bit
HP Z800	Microsoft® Windows® 8.1 64-bit
HP Z820	Windows Server 2008 R2 Standard x64 Edition SP1

### 8.8.3 Off-the-Shelf Software

#### 8.8.3.1 ExtJS

ExtJS is a JavaScript framework used to build interactive web applications.

#### 8.8.3.2 iScroll

iScroll has been used to implement rich and smooth scroll behavior on complex widgets like the carousel used by MR Core.

#### 8.8.3.3 Jsoncpp

JSON is a lightweight data-interchange format. It can represent numbers, strings, ordered sequences of values, and collections of name/value pairs.

JsonCpp is a C++ library that allows manipulating JSON values, including serialization and deserialization to and from strings. It can also preserve existing comment in un-serialization/serialization steps, making it a convenient format to store user input files.

#### 8.8.3.4 Other software components

Boost, zlib, Microsoft C++ Runtime Libraries, Microsoft STL Libraries, WiX Toolset and Libraries, Intel C++ Runtime Libraries, AutoWL, VCF, VoxarLib/Origami, TMSHared, VitalLoaders, VitreaLicenseClient,



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Translation tool and translation helper libraries, Japanese translation lookup files, Help system, and MR Stitching Engine.

Please refer Attachment-051 and 052 for detailed information.

**8.8.4 Deployment**

The MR Core software is available on 510(k) cleared Vitrea platform (K150258). The Vitrea software can be deployed on a variety of hardware platforms with some base requirements:

- 64-bit operating system
- Intel-compatible

The Vitrea software can be deployed into the following deployments:

- Vitrea Enterprise Suite
- VitreaCore
- VitreaAdvanced
- VitreaAdvanced fX
- VitreaWorkstation
- VitreaWorkstation fX
- VitreaExtend

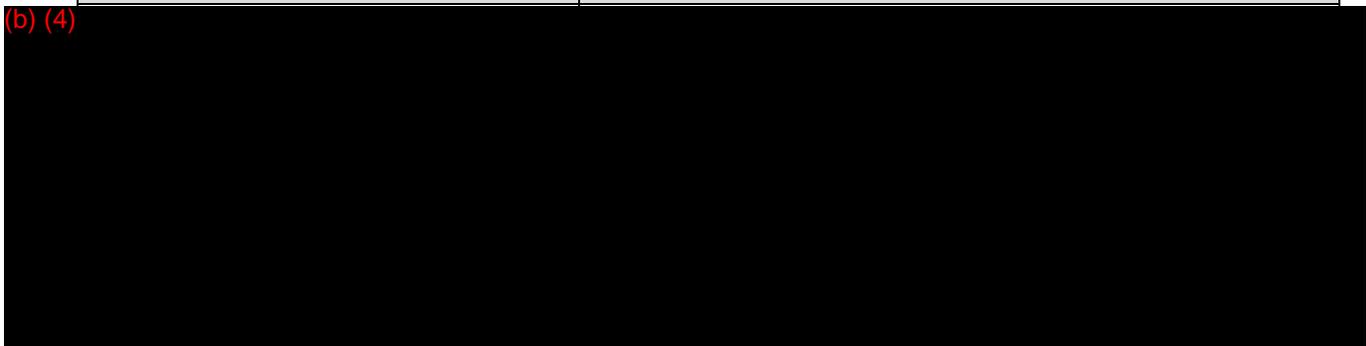
**8.9 Revision History**

**US Regulatory History:**

Vitrea Version	Changes
3.5	Initial 510(k) clearance (K040305) Softread was part of Vitrea 3.5 development.
7.0	Subject of this 510(k) notification. MR Core 1.0 is developed under part of Vitrea 7.0

**MR Core Development History:**

Internal Versioning	Description
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(b) (4)



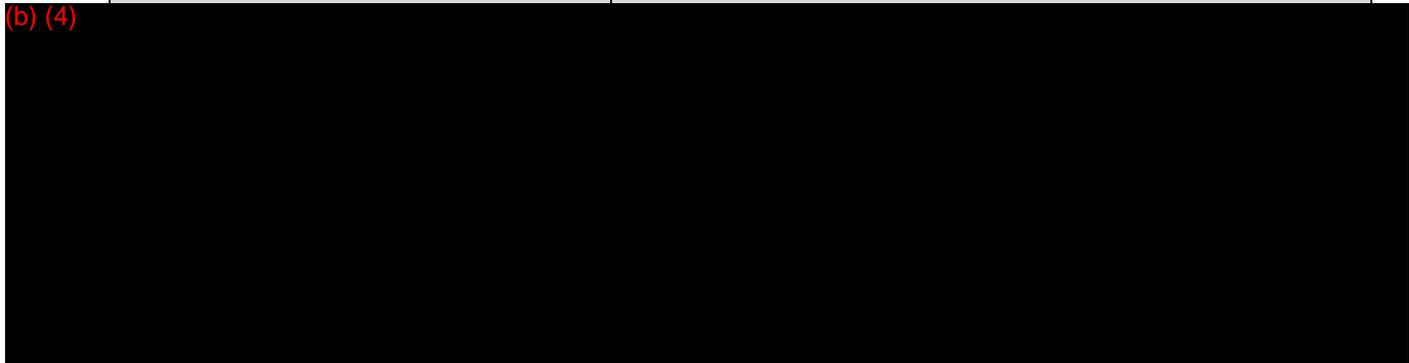
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Internal Versioning	Description
<p>(b) (4)</p> A large black rectangular redaction box covers the entire body of the table, obscuring all content under both the 'Internal Versioning' and 'Description' headers. The text '(b) (4)' is visible in the top-left corner of this redacted area.	



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Internal Versioning	Description
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**8.10 Software Level of Concern**

The company has determined that the Level of Concern for the software is **Moderate** by applying the method defined in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005.

**8.11 FDA Recognized Consensus Standards**

Standard No.	Standards Organization	Standard Title	Version	Date
PS 3.1- 3.20 (2011) (Recognition Number 12-238)	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set (Radiology)	3	03/16/2012
ISO 14971:2007 (Recognition Number 5-70)	AAMI / ANSI / ISO	Medical Devices - Applications of Risk Management to Medical Devices	2007	03/16/2012
IEC 62304:2006 (Recognition Number 13-32)	AAMI / ANSI / IEC	Medical Device Software - Software Life Cycle Processes (Software / Informatics)	2006	08/20/2012

**8.12 Patient Contacting Surfaces**

MR Core is a software application and has no patient contacting surfaces.

**8.13 Intended for Disease / Condition / Patient Population**

MR Core is a medical image viewer software device. Therefore, particular information regarding the disease, condition, and patient population are not applicable.

**V i T A L**

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**MR Core Software  
Special 510(k) Pre-market Notification**

## **8.14 Components**

MR Core has no additional components or accessories.

## Comparison to the Cleared Devices

### 9.1 Predicate Device

Vital Images believes that the modified Softread software (known as MR Core software) is subject to premarket notification requirements under Section 510(k) of the Federal Food, Drug and Cosmetic Act ("FFDCA" or "the Act") on the basis of its substantial equivalence to the already 510(k) cleared and marketed Softread software :

Predicate Device	Manufacturer	FDA 510(k) number
Softread Software (Legally Marketed Device)	Vital Images, Inc.	K040305

The following attachments describe the predicate device:

- Attachment-022\_K040305 510(k) Summary for Softread Software
- Attachment-023\_Softread Software User Guide provided in K040305

### 9.2 Reference Device

The added "Stitching" tool is similar to the feature on the already cleared Intrasure, MYRIAN by K091001 510(k) notification.

Reference Device	Manufacturer	FDA 510(k) number
Myrian (Legally Marketed Device)	Intrasense	K091001

The following attachments describe the reference device:

- Attachment-024\_K091001 510(k) Summary for Myrian software
- Attachment-025\_Myrian Marketing Collateral

### 9.3 Regulatory Comparison with the Predicate Device – Softread Software (K040305)

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
Device Type / Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
Common Name	Radiological Image Processing Software	Radiological Image Processing Software	Same
Regulation / Classification Number	21 CFR 892.2050	21 CFR 892.2050	Same

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
Product Code	LLZ	LLZ	Same
Classification	Class II	Class II	Same
Review Panel	Radiology	Radiology	Same

#### 9.4 Indications for Use Comparison with the Predicate Device – Softread Software (K040305)

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
Indications for Use	<p>Softread, is an option within the Vitrea 2 system and is intended to allow the examination and manipulation of a series of 2D images in a variety of modalities, including CT, <b>MR</b>, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc.</p> <p>The option also enables clinicians to compare multiple series' for the same patient, side-by-side, and to switch to Vitrea to further examine the data in a 3D volume.</p>	<p>MR Core is an option within Vitrea® that allows the examination and manipulation of a series of medical images obtained from <b>MRI</b> scanners.</p> <p>The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.</p>	<p>Same</p> <p><b>Note:</b> The Intended Use statement of the modified software is a subset (i.e. only for MR datasets) of already cleared Intended Use of the legally marketed device.</p>

**9.5 Indications for Use Comparison with the Reference Device – Intrasense, Myrian Software (K091001)**

Criteria	Reference Device	Subject Device	Comparison
	Myrian (K091001)	MR Core Software (Modified Softread Software)	
Indications for Use	Myrian is a <b>multi-modality</b> medical diagnostic device. It is aimed at <b>reviewing and analyzing anatomy</b> and pathology. It also includes DICOM communication capabilities and media interchange features (printing, CD burning, storing). It runs on any standard PC including laptops that might be purchased independently by the end user, It provides user a set of tools meant to create and modify objects of interest: points of interest, annotations of interest and volumes of interest.	MR Core is an option within Vitrea® that allows the <b>examination and manipulation of a series of medical images obtained from MRI scanners.</b>  The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.	Similar

**9.6 Device Description Comparison with the Predicate Device – Softread Software (K040305)**

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
Device Description	<p>Softread allows the examination and manipulation of a series of 2D images in a variety of modalities, including CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc.</p> <p>The option also enables clinicians to compare multiple series' for the same patient, side-by-side, and to switch to Vitrea to further examine the data in a 3D volume.</p>	<p>MR Core is an option within Vitrea® that allows the examination and manipulation of a series of medical images obtained from <b>MRI</b> scanners.</p> <p>The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.</p>	<p>Same</p> <p><b>Note:</b> The device description of the modified software is subset (i.e. only for MR datasets) of already cleared Intended Use of the legally marketed device.</p>

**9.7 Similarities in Technology with the Predicate Device – Softread Software (K040305)**

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
Image Communication Standard: DICOM	Yes	Yes	Same
2D Image Review	Yes	Yes	Same



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Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
2D Comparative Review	Yes	Yes	Same
Multi-Planner Reformatting	Yes	Yes	Same
Maximum and Minimum Intensity Projection (MIP/MinIP)	Yes	Yes	Same
Image Editing, Setting, Saving	Yes	Yes	Same
Annotation & Tagging Tools (Label)	Yes	Yes	Same
Display Options (e.g. thickness)	Yes	Yes	Same
Quantitative Measurements	Yes	Yes	Same
Snapshot	Yes	Yes	Same
Report Generation	Yes	Yes	Same
Cine Image Display	Yes	Yes	Same
Multi-frame Display	Yes	Yes	Same
Color Image Display	Yes	Yes	Same
Simultaneous Multiple Studies Review	Yes	Yes	Same
Cross-reference Lines Support	Yes	Yes	Same
Display of Selected Images, Series, or Entire Study	Yes	Yes	Same

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
Comparison of Multiple Series or Studies	Yes	Yes	Same
Scroll Image	Yes	Yes	Same
Zoom Image	Yes	Yes	Same
Pan Image	Yes	Yes	Same
Focus Image	Yes	Yes	Same
Rotate Image	Yes	Yes	Same
Flip Image - Vertical	Yes	Yes	Same
Flip Image - Horizontal	Yes	Yes	Same
Rotate Image - Clockwise	Yes	Yes	Same
Rotate Image - Counter-clockwise	Yes	Yes	Same
Invert Image	Yes	Yes	Same
Arrow	Yes	Yes	Same
Window Level/Width Selection and User Configurable Preset	Yes	Yes	Same
Auto Window Level/Width Setting	Yes	Yes	Same
Measurement of Distance	Yes	Yes	Same



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Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
Measurement of Angle	Yes	Yes	Same
Measurement of Cobb Angle	Yes	Yes	Same
Identification and Display of Ellipse Regions of Interest (ROIs)	Yes	Yes	Same
Identification and Display of Freehand Regions of Interest (ROIs)	Yes	Yes	Same
Automatic Registration	Yes	Yes	Same
Adjust Registration	Yes	Yes	Same
Image subtraction of two MR series/datasets	Yes	Yes	Same
Study and Series Linking	Yes	Yes	Same
Ability to launching into Vitrea platform for any advanced applications	Yes	Yes	Same



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**9.8 Differences in Technology from the Predicate Device – Softread Software (K040305)**

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
<p><b>Feature: Stitching</b></p> <p>Stitching feature combines MR images covering distinct contiguous, or slightly overlapping, regions of the human body anatomy into one or multiple images.</p>	No	Yes	<p>The added feature does not affect the intended use or fundamental scientific technology of already cleared Softread software (K040305).</p> <p><b>Note:</b> The added “Stitching” feature is similar to the feature on the already cleared Intrasure, MYRIAN (“Reference device”)’s “Image Alignment” feature by K091001. Therefore, the added feature does not raise new questions of safety and effectiveness.</p>
<p><b>Product Limitation: Restricted Modality Support</b></p> <p>The current version of MR Core only supports MR modality.</p>	Multi-modality	MR	<p>The support for additional modalities is available in the predicate device but not in the subject device.</p> <p>Therefore, they do not raise any new questions of safety and effectiveness of the subject device.</p>



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Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software (Modified Softread Software)	
<p><b>Product Limitation: Restricted Features</b></p> <p>The current version of MR Core does not support “Image Filtering” and “Image Set Splitting” features.</p>	<ul style="list-style-type: none"> <li>Image Filtering</li> <li>Image Set Splitting</li> </ul>	None	<p>These additional features are available in the predicate device but not in the subject device.</p> <p>Therefore, they do not raise any new questions of safety and effectiveness of the subject device.</p>

**9.9 Similarities in Technology with the Reference Device – Intrasense, Myrian Software (K091001)**

Criteria	Reference Device	Subject Device	Comparison
	Myrian (K091001)	MR Core Software (Modified Softread Software)	
<p><b>Feature: Stitching</b></p> <p>Stitching feature combines MR images covering distinct contiguous, or slightly overlapping, regions of the human body anatomy into one or multiple images.</p>	Yes	Yes	<p>Same</p> <p><b>Note:</b> The added “Stitching” feature is similar to the feature on the already cleared Intrasense, MYRIAN (“Reference device”)’s “Image Alignment” feature by K091001.</p> <p>Therefore, the added feature does not raise new questions of safety and effectiveness.</p>

## 9.10 510(k) Decision Making Flow Chart

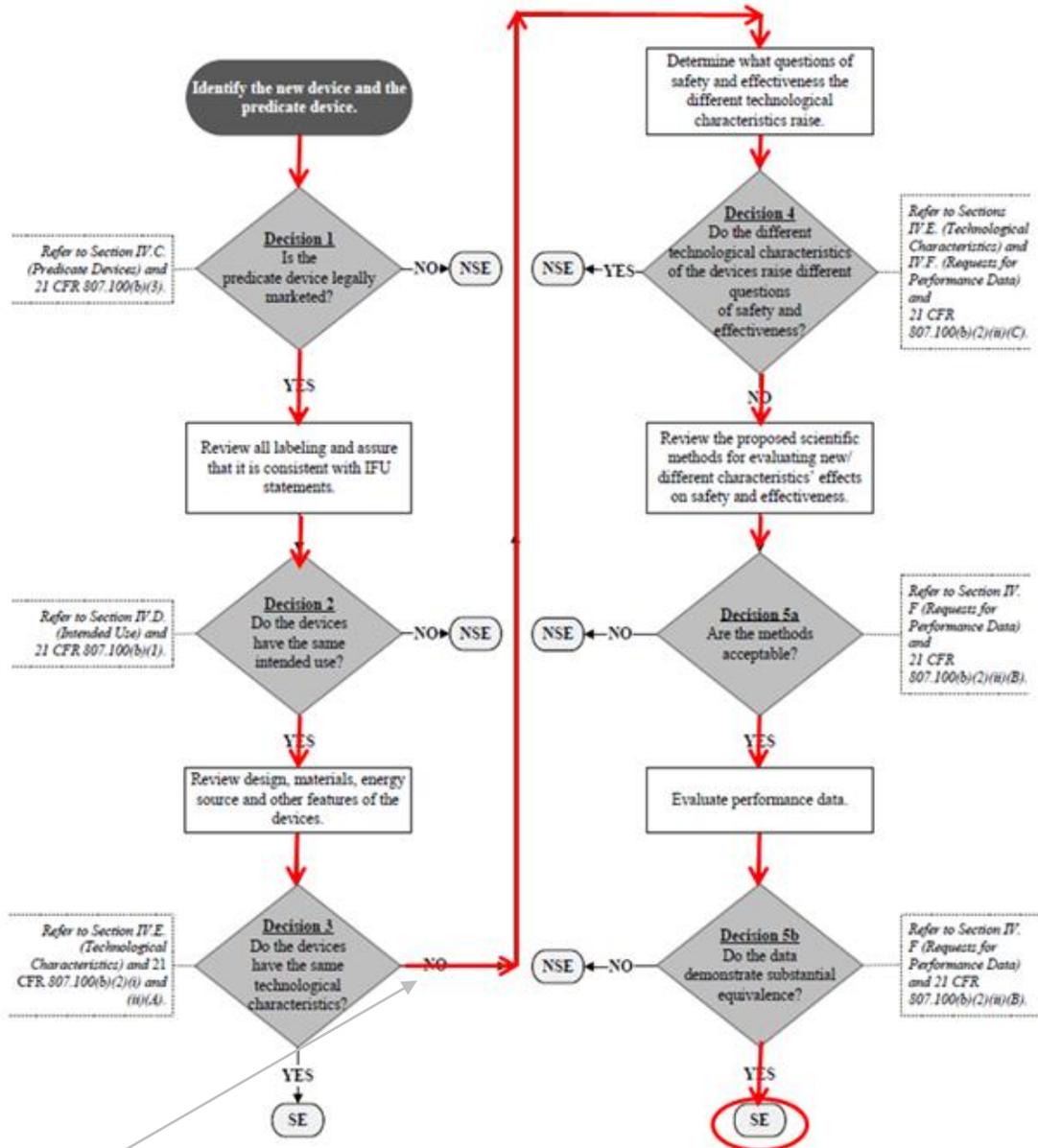
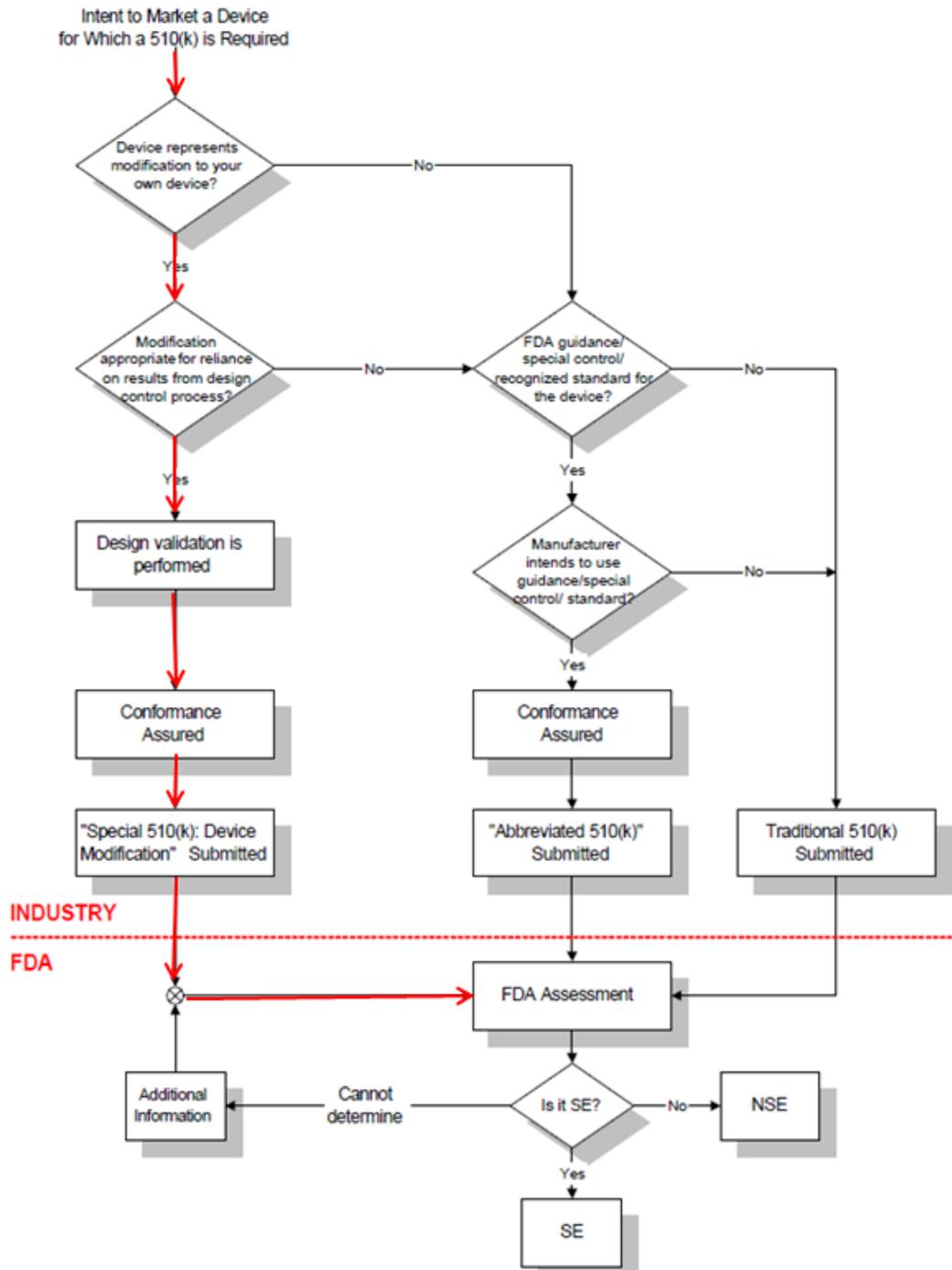


Fig-9.1: 510(k) Decision Making Flowchart

Changes: Re-designing of User Interface (UI) and addition of "Stitching" tool

**9.11 The New 510(k) Paradigm Approach**



**Fig-9.2: The New 510(k) Paradigm Approach**



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**MR Core Software  
Special 510(k) Pre-market Notification**

## **9.12 Substantial Equivalence Conclusion**

The enhancements in the software do not affect the intended use or alter the fundamental scientific technology of legally marketed Softread software (K040305). The modified Softread software (known as MR Core) has the same indications for use, principle of operation, and performs the similar technological functions as already cleared Softread software (K040305) (Predicate Device). The added "Stitching" feature is similar to the already cleared Intrasense, Myrian software (K091001) (Reference Device). The modifications are not consequential from the standpoint of device operation, safety, effectiveness or intended use.

Any minor differences noted have been explained and do not raise any new questions of safety or effectiveness when used as labeled. The implemented design controls, risk management activities, labeling, and the performed verification and validation tests demonstrate the safety and efficacy of the device is equivalent to the predicate device. Based on the comparison data and test data, Vital Images believes the subject device should be found substantially equivalent to the predicate device.

## Software Information

This section has been prepared in accordance with *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* issued May 11, 2005.

MRCore software is developed by Toshiba Medical Visualization Systems Europe, Ltd. (TMVS) for Vital Images. Therefore TMVS's internal Product Development Process (PDP) was followed for this product development activity. The PDP is developed and maintained in accordance with FDA Quality System Regulation for design controls in 21 CFR 820.30. The PDP contains all requirements elements from design planning through design transfer, design change, and design history file maintenance.

Please refer the following attached process documents used for this development:

Attachment	Document
055	Hazard Analysis Process
056	Test Process
057	Defect Management Process
058	Configuration Management and Software Component Build Policy
059	Release Approval Process
060	Document and Record Control Policy

### 10.1 Level of Concern: Moderate

The Level of Concern is Moderate by applying the method defined in the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005*.

First, the Major Level of Concern was evaluated and determined to not apply. If the answer to any one of the following questions is "Yes," the level of concern for the software device is likely to be Major:

- Does the software device qualify as blood establishment computer software?  
*Answer: No, the software device has no blood establishment functionality.*
- Is the software device intended to be used in combination with a drug or biologic?  
*Answer: No, the software device has no biologic or drug component.*
- Is the software device an accessory to a medical device that has a major level of concern?  
*Answer: No, the software device is not an accessory to another medical device with a major level of concern.*
- 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?  
*Answer: No. The device does not control a life supporting or sustaining function. The device delivers no harmful energy that could result in death or serious injury such as*

*radiation, defibrillators, and ablation generators. The device does not control the delivery of treatment or therapy such that an error or malfunction would result in death or serious injury. The device does not provide diagnostic information that directly drives a decision regarding treatment or therapy that if misapplied it could result in serious injury or death. The device provides no monitoring of vital signs.*

Therefore, the software device is NOT considered a “Major” Level of Concern.

Second, the Moderate Level of Concern was evaluated and determined to apply. If the answer to any one of the following questions is “Yes,” the level of concern for the software shall be considered Moderate:

- Is the software device an accessory to a medical device that has a moderate level of concern?  
*Answer: No, the software device is not an accessory to another medical device with a moderate level of concern.*
- 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?  
*Answer: No, the software device is used for post-processing and does not control energy or motion and therefore failure does result in injury.*
- 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?  
*Answer: Yes, the software device provides imaging information to assist physicians. The software device does not provide a diagnosis or determine recommended medical care.*

Therefore, the Level of Concern is considered Moderate, based on a potential that a malfunction of, or latent design flaw in, the software device could potentially lead to a delay in delivery of appropriate medical care.

## 10.2 Software Change Description

Please refer Attachment- “008\_Description of Modified Device” for details.

## 10.3 Software Development Environment Description

The MR Core software was designed, developed, and tested according to IEC 62304:2006 standard for Medical Device Software - Software Life Cycle Processes (Software / Informatics).

The following quality assurance measures were applied to the MR Core development:

- Risk Management
- Requirements reviews
- Code designs
- Code reviews
- Design reviews
- Verification of the software – that included performance and safety testing
- Validation of the software – that included simulated usability testing by independent experienced medical professionals

Software configuration management enables effective management and control of software development. This includes version control, automated workspace and parallel development

support, maintenance, and guidelines for review and approval of software development results, including the responsible organizational elements for such reviews and approvals.

#### 10.4 Software Requirements Specifications of Changes

Please refer the following attachments for information related to the software requirements specifications for the MR Core software:

Attachment	Document
026	Software Requirements Specification – MR Core (TMVSE000587)
027	Software Requirements Specification – MR Stitching (TMVSE000592)

#### 10.5 Software Design Specification of Changes

Please refer the following attachments for information related to the software design specification for the MR Core software:

Attachment	Document
028	Software Design Specification – MR Core (TMVSE000608)
029	Software Design Specification – MR Stitching (TMVSE000609)

#### 10.6 Software Architecture

Please refer the following attachments for information related to the software architecture for the MR Core software:

Attachment	Document
030	Architecture Design Chart – MR Core (TMVSE000591)
031	Architecture Design Chart – MR Stitching (TMVSE000601)

#### 10.7 Risk Analysis of Software Changes

Please refer the following attachments for information related to the performed risk analysis for the MR Core software:

Attachment	Document
032	Risk Analysis with Applied Mitigations – MR Core (TMVSE000588)
033	Risk Analysis with Applied Mitigations – MR Stitching (TMVSE000593)
034	Summary of Risk Benefit Analysis – MR Core (TMVSE000614)
035	Summary of Risk Benefit Analysis – MR Stitching (TMVSE000615)

### 10.8 Test Plan of Software Changes

Please refer the following attachments for information related to the test plans for the MR Core software:

Attachment	Document
036	Quality Strategy – MR Core (TMVSE000589)
037	Performance Test Specification – MR Core (TMVSE000617)
038	Test Case Inventory – MR Core (TMVSE000598)
039	Quality Strategy – MR Stitching (TMVSE000594)
040	Performance Evaluation Plan – MR Stitching (TMVSE000616)
041	Test Case Inventory – MR Stitching (TMVSE000604)

### 10.9 Test Results of Software Changes

Please refer the following attachments for information related to the test results for the MR Core software:

Attachment	Document
042	Test Execution Summary – MR Core (TMVSE000600)
043	Validation Report – MR Core & MR Stitching (TMVSE000613)
044	Performance Evaluation Report – MR Core (TMVSE000610)
045	Test Execution Summary – MR Stitching (TMVSE000607)
046	Performance Evaluation Report – MR Stitching (TMVSE000611)

### 10.10 Summary of Sterilization, Stability, and Shelf Life Tests

MR Core is a software application and is not sold as sterile. Therefore, sterilization, stability, and shelf life tests were not required or performed.

### 10.11 Summary of Biocompatibility Tests

MR Core is a software application and is intended for use only in an office setting and does not come into contact with patients. The only material exposure to medical professionals and administrators is through installation of the software from a DVD, which is standard computer physical media. Therefore, biocompatibility tests were not required or performed.

### **10.12 Summary of Electromagnetic Compatibility (EMC) and Electrical Safety Tests**

MR Core is a software application and resides on standard off-the-shelf computer hardware and peripherals. Therefore, Electromagnetic compatibility (EMC) and electrical safety tests were not required or performed.

### **10.13 Summary of Animal Testing**

MR Core is a software application. Therefore, animal testing was not required or performed to support substantial equivalence or evaluate performance characteristics.

### **10.14 Summary of Clinical Testing**

MR Core is a software application. Therefore, no clinical testing was conducted. During external validation, tests were conducted on non-patient-care data sets without any clinical data collected.

Vital Images, Inc. is not submitting clinical data in support of this Special 510(k) notice. For this reason, FDA's regulation regarding clinical investigators' financial interests and arrangements, i.e., 21 C.F.R. § 54.4, do not apply. Thus, Vital Images, Inc. is not providing a disclosure or certification to the absence of any disclosable financial interests or arrangements.

### **10.15 Requirements Traceability Matrix (RTM)**

Please refer the following attachments for information related to the Requirements Traceability Matrix (RTM) for the MR Core software:

<b>Attachment</b>	<b>Document</b>
047	Requirements Traceability Matrix – MR Core (TMVSE000595)
048	Requirements Traceability Matrix – MR Stitching (TMVSE000602)

### **10.16 Unresolved Anomalies Report (UAR)**

Please refer the following attachments for information related to the Unresolved Anomalies Report (UAR) for the MR Core software:

<b>Attachment</b>	<b>Document</b>
049	Unresolved Anomalies Report – MR Core (TMVSE000599)
050	Unresolved Anomalies Report – MR Stitching (TMVSE000605)

**10.17 Off-The-Shelf Report (OTS)**

Please refer the following attachments for information related to the Off-The-Shelf (OTS) Report for the MR Core software:

Attachment	Document
051	Supplied Component Report – MR Core (TMVSE000597)
052	Supplied Component Report – MR Stitching (TMVSE000606)

**10.18 Software Release Log (Software Revision History)**

Please refer the following attachments for information related to the software revision history of MR Core software:

Attachment	Document
053	Software Release Log – MR Core (TMVSE000596)
054	Software Release Log – MR Stitching (TMVSE000603)

**10.19 Cyber and Information Security**

Vitreia follows security best practices, including those outlined by HIPAA, to limit the risk of unauthorized access to the system or data. A set of design guidelines and best practices inspired by HIPAA security standards have been documented in the product and detailed requirements, covering the following areas:

- HIPAA §164.312 User Identification
- HIPAA §164.312 Automatic logoff
- HIPAA §164.312 Audit
- HIPAA §164.312 Data integrity
- HIPAA §164.312 Authentication

**Confidentiality**

The Vitrea platform (K150258) relies on built in Windows Login security to limit access to the system. The Vitrea platform can only be installed and configured by an administrator of the Windows machine.

Once a user is authenticated by Windows, the system provides full access to the features of Vitrea. The only actions limited for this user is to uninstall the software or reconfigure it. For these actions, the administrator must log on to the system.

It is the user's responsibility to log out of the system when completing use. The Safe and Effective Use Guide recommends limiting access to patient data to authorized individuals by physical security measures (locking systems), software-based password security systems, or both.

**Integrity**

The source of information for the Vitrea platform is images that are produced by medical imaging devices such as CT scanners. These are received and stored unaltered from either the scanners themselves or from PACS. DICOM is a network standard protocol. The standard ensures that



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“electronically transmitted electronic protected health information is not improperly modified without detection until disposed of.” Vitrea platform complies with the DICOM standard for transfer and storage of this data and does not modify the contents of DICOM instances.

**Availability**

The Vitrea platform is always available to the logged on user as long as the Windows machine itself is properly maintained. The recommended hardware for this system is standard commercially available computer equipment which simplifies repair or replacement of failed parts. A mirrored RAID configuration is recommended in the technical specifications for Vitrea platform, so that data will not be lost and the system will remain running if the hard drive fails. Proper setup and maintenance are documented in the user and installation guides accompanying Vitrea platform.

**Accountability**

The Vitrea platform includes an audit capability that enables accountability by tracks authenticated and authorized user operations along with information on what data was accessed. Vitrea audit logs are time stamped, enabling correlation with Windows system logging to track information accessed by a user.

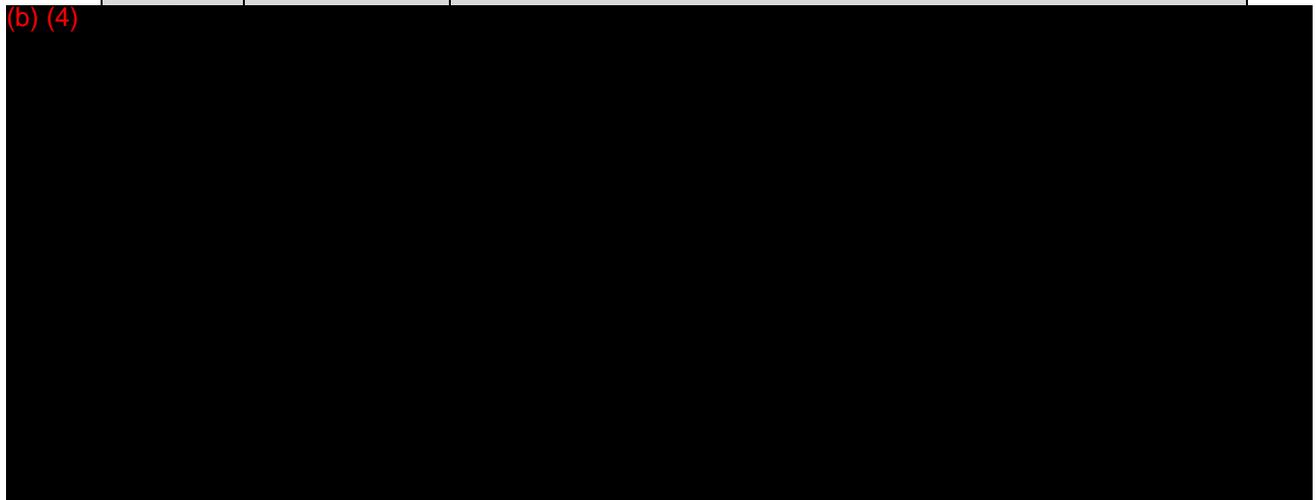
**10.20 Anti-Virus Software**

The Vitrea platform is compatible with most major Anti-virus software. The Vitrea install guide instructs the user to install Anti-virus software using the default settings. Anti-virus software is installed and used during product development.

**10.21 Known Limitations**

The following known limitation for the MR Core software is being communicated to users by release notes:

As of Version	Products	Description
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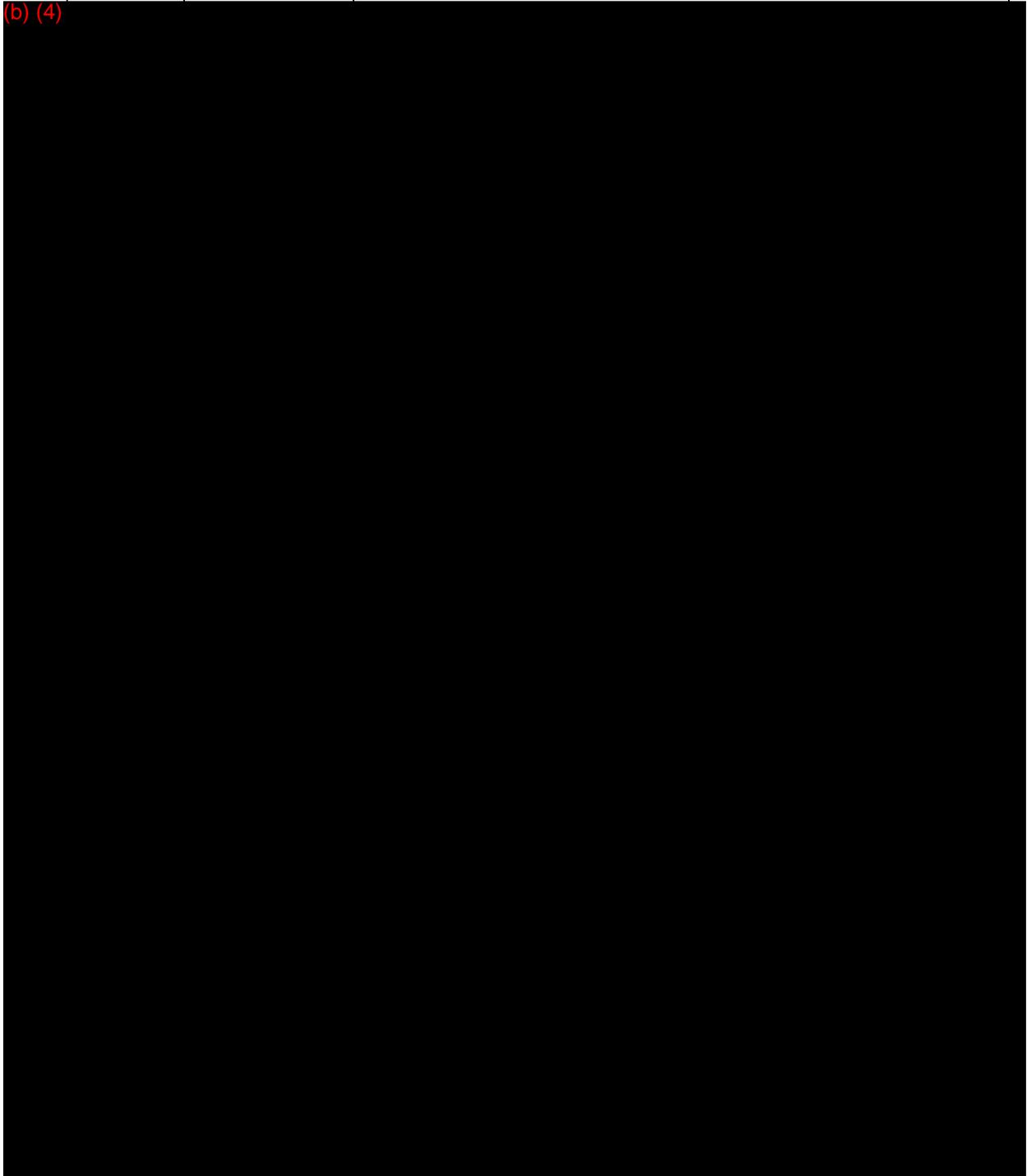


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### 10.22 Known Issues

The following known issues for the MR Core software is being communicated to users by release notes:

As of Version	Products	Description
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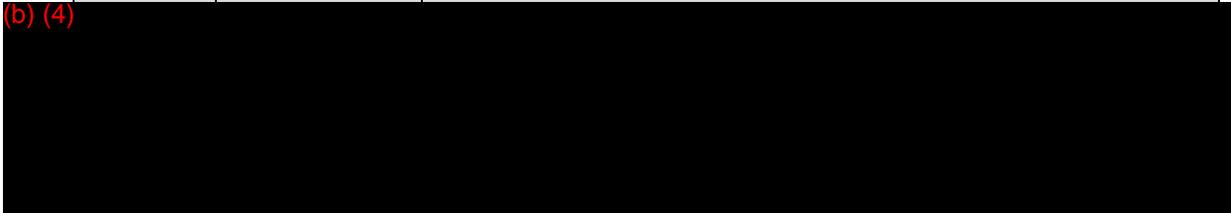




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As of Version	Products	Description
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(b) (4)

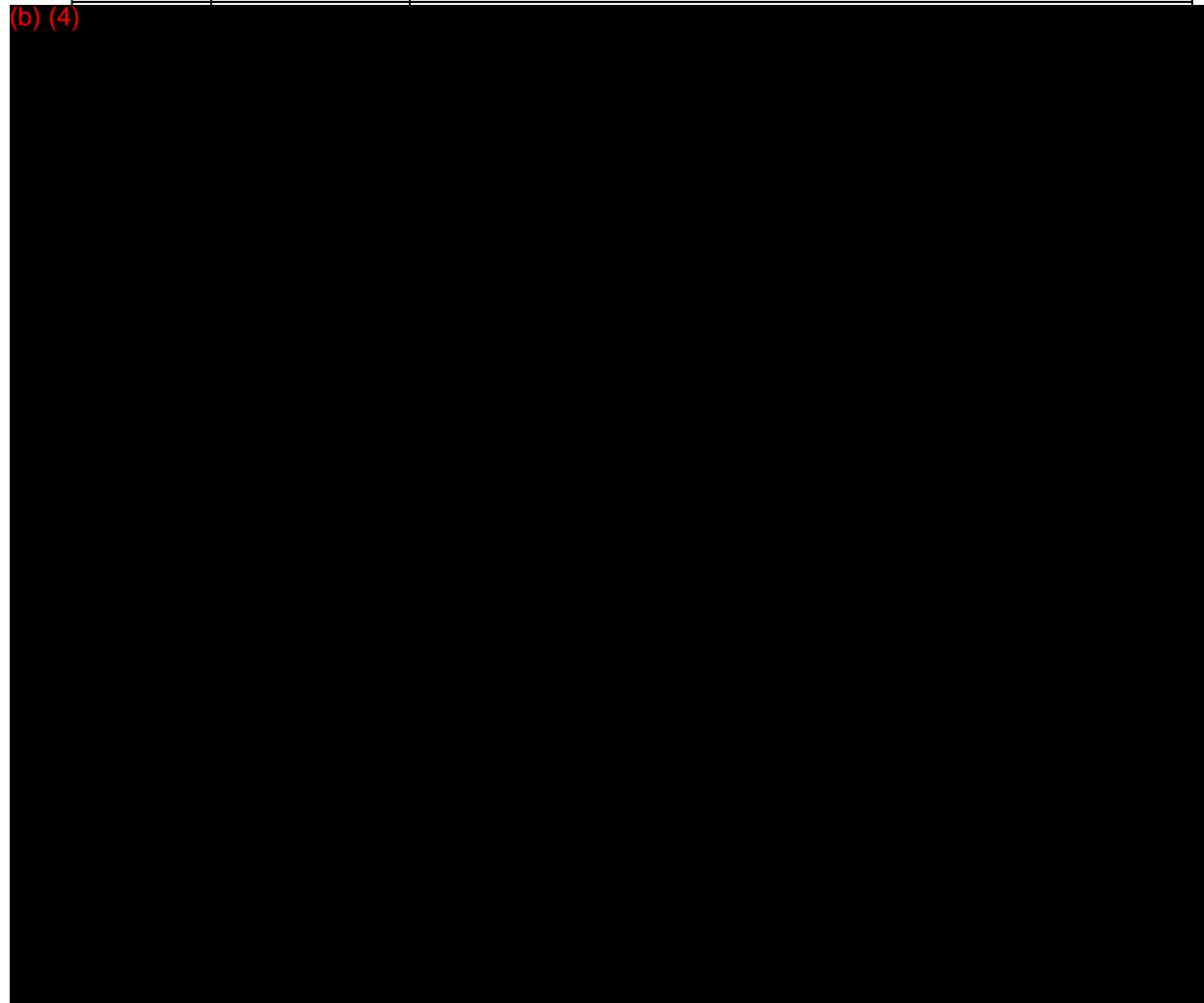


### 10.23 User Warnings

The following warning related to the MR Core software is being communicated to users by release notes:

As of Version	Products	Description
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(b) (4)





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As of Version	Products	Description
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### 10.24 General Notes

The following general notes related to the MR Core software are being communicated to users by release notes:

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As of Version	Products	Description
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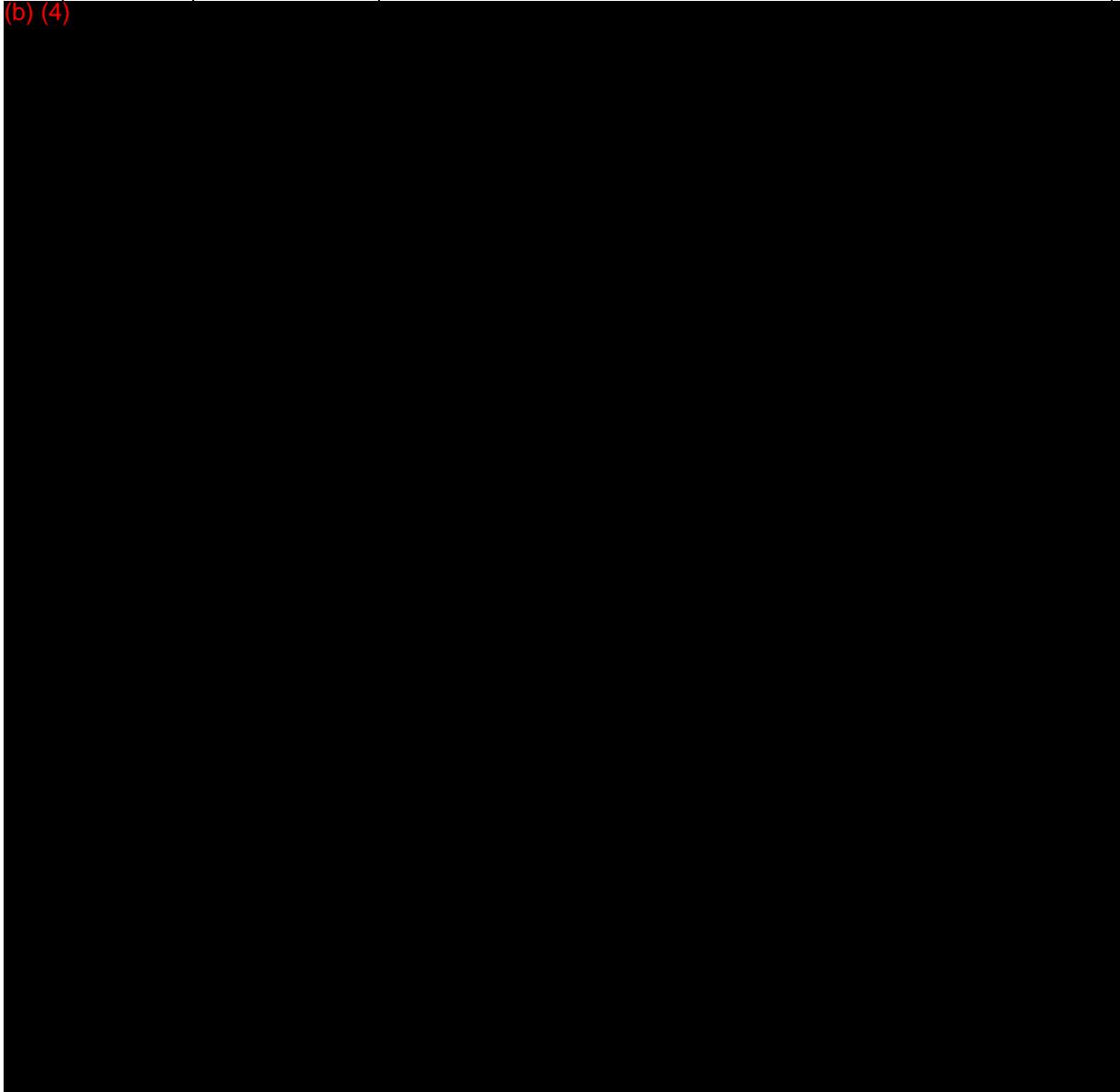
(b) (4)

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As of Version	Products	Description
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Please refer the following attachment for more information:

Attachment	Document
012	Proposed Label: Release Notes (VPMC-13735)

**10.25 DICOM Conformance**

The MR Core software accepts DICOM compliant images. It uses the DICOM infrastructure of the Vitrea software platform.

<b>Standard No.</b>	<b>Standards Organization</b>	<b>Standard Title</b>	<b>Version</b>	<b>Date</b>
PS 3.1- 3.20 (2011) (Recognition Number 12-238)	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set (Radiology)	3	03/16/2012

# **MR Core Education and Reference Guide**

- MR Core Viewer
- MR Stitching

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## **REF** VPMC-13746 A MR Core Education and Reference Guide

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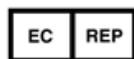
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## Safety and Regulatory Considerations

PLEASE REFER TO THE **ABOUT VITREA MEDICAL IMAGING SOFTWARE** DOCUMENT BEFORE USING THIS PRODUCT. This document includes important information regarding general Vitrea Safety and Regulatory considerations.



**CAUTION: Federal law restricts this device to sale by or on the order of a physician, as directed by 21 CFR 801.109(b)(1).**

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## Contact Us

- For general, non-technical support questions, contact us through our Web site: [www.vitalimages.com](http://www.vitalimages.com).
- For customer technical support, contact us:
  - In the U.S., call the Customer Support line at 1.800.208.3005.
  - Outside the U.S., contact your Vital distributor.
  - Send an email to [support@vitalimages.com](mailto:support@vitalimages.com).
- For a printed version of the Release Notes, Education and Reference Guide, or Installation Guides, contact Customer Support at 1.800.208.3005.

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## Release Notes

Vitrea Release Notes contain late-breaking information not available at the time the Education and Reference Guide was released. This document is available from your System Administrator or from Vital Images.

## Intended Use

MR Core is an option within Vitrea that allows the examination and manipulation of a series of medical images obtained from MRI scanners. The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further exam the data.

## Components

The MR Core application is comprised of the following features:

- MR Core Viewer
- MR Stitching

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# MR Core Viewer

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## MR Core Viewer Overview

MR Core is an option within Vitrea that allows the 2D and MPR examination and manipulation of a series of medical images obtained from MRI scanners. The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.

The MR Core Viewer supports image processing for subtraction of two MR series/datasets.

## Caution Statements and Notes

---



**CAUTION:** Users should treat outputs from the product as supplemental information to aid them in the diagnosis or treatment-planning process. In particular, users should always exercise clinical judgment when assessing outputs from MR Core and always consider other clinical information (for example, patient symptoms, demographics, history, and so on) in reaching treatment or diagnostic decisions.



**CAUTION:** The quality of information derived from MR Core depends on quality of the input data. Poor input data can result in erroneous, inaccurate or misleading output. In general, MR Core cannot detect when input data is:

- **Poor**
- **Of too low a resolution for the diagnostic task**
- **Incomplete (for example, not all series transferred)**
- **Inaccurate (for example, poorly calibrated)**
- **Degraded (for example, after lossy compression and decompression)**

In particular, some scanners may be configured to produce intermediate images that lack some final reconstruction steps e.g. distortion correction. MR Core will not detect that these images are not final and will treat them as valid planar images, including representing their intersections with other images as straight lines.

Users should therefore take steps to check the quality of input data themselves.



**CAUTION:** When MR Core is used on a remote client there is a possibility that image frames may be skipped due to a lack of sufficient network bandwidth resulting in one or more images not being displayed on the remote client.

The MR Core application can neither control this behavior nor can it detect when it has occurred. The only indication to the user that this is occurring will be slow response to user input and irregular display updates. Therefore when using a remote client, the user should exercise additional caution to ensure that all images have been reviewed.



**CAUTION:** When MR Core is used on a remote client there is a possibility that image frames be shown at lower quality due to a lack of sufficient network bandwidth, resulting in temporarily degraded image quality during (quick) navigation.

The MR Core application can neither control this behavior nor can it detect when it has occurred. The only indication to the user that this is occurring will be altered image quality during quick navigation. Therefore when using a remote client, the user should exercise additional caution with regards to image quality of the displayed data, and apply slower navigation at the level of clinically relevant anatomy or (suspect) lesions.



**CAUTION:** After applying subtraction between acquired images/volumes, the user must visually check the accuracy of subtraction. Although major attention was given to the correct functioning of subtraction algorithm, the user must apply clinical experience and judgment during diagnostic reading.



**CAUTION:** The user should take extreme care with subtraction of images that are result of a stitching operation, whether executed on a a modality or

**by means of dedicated software. Small differences in stitching registration of both datasets to be subtracted might lead to unexpected results.**

- Only suitably qualified and trained medical professionals should use the product or interpret its outputs, and all users should be aware of these warnings.
- MR Core performs sophisticated image processing which may result in unpredictable or surprising effects, including:
  - Introduction of image artifacts which may be misinterpreted as pathology
  - Blurring or hiding of pathology, especially small pathology
  - Rendering of low quality or low resolution data such that it appears of higher quality or resolution
  - Display of images at lower resolutions than the original data
  - Hiding, or rendering invisible, portions of data which contain important anatomy or pathology
  - Use of colors which suppress or emphasize features relative to grayscale images

Users should therefore exercise caution when interpreting output images, and especially when examining features that are small compared to the resolution or slice index of the acquired data. In addition, the issues surrounding the interpretation of processed images are well documented, and we encourage users to investigate them.

- Note that other medical imaging systems may present information differently. This means that MR Core may present the series in a study in a different order than a PACS system, or may present image demographics in a different way. Users should not assume consistency of presentation between MR Core and other systems.
- MR Core should be used on a system that meets the hardware and software specification provided by your supplier. Using MR Core on other systems may result in degraded performance, lower image quality, or system failure. Hardware and software should be maintained in accordance with manufacturer's and supplier's instructions, and with advice from relevant professional bodies.

- MR Core is intended to operate as part of a larger system. Availability of MR Core depends on the availability and correct functioning of other parts of the system (for example, network infrastructure, license servers, acquisition devices, and so on).
  - The MR Core Series Carousel only features thumbnails for image and other data which is supported by the MR Core application. Please consult the Study List to gain full understanding on the contents of the study.
  - Certain display parameters can be altered by interacting with text displaying those parameters in the lower right corner of the view. The set of such parameters may vary depending on the data and view type, but will generally include:
    - Zoom
    - Window width and level
- For MPR views:
- Slab thickness
  - Projection mode
  - Slice interval
- Measurement Accuracy: MR Core is designed to produce measurements that are accurate with respect to input data. However, accuracy with respect to real anatomy or pathology is affected by many factors beyond the control of the product, and it can only be assessed by users knowledgeable of the complete imaging process from acquisition to visualization. The imaging process and its accuracy issues are well documented, and we encourage users to investigate them.
- When image frames are displayed with a Zoom factor of less than 100%, they are displayed with reduced resolution compared to the acquired image data. This might impair the user's ability to make a diagnostic reading of the images.
- Image zoom is displayed as the ratio of screen pixels to source data pixels, expressed as a percentage. For data with square pixels, 100% zoom means that the displayed image is approximately the same size as the source image.

For information about the real-world size of displayed data, the user should refer to the scale ruler or use the ruler measurement.

- Applications launched from MR Core will not preserve MR Core's image display parameters such as window width and level, zoom, and pan. Users may need to use tools provided by the launched application to match the image presentation from MR Core.
- The ability to archive Findings in an external storage system (such as a PACS) will be affected by the configuration and policies for that system. For example, a PACS may reject Findings which have been created on studies which are already marked as reported. The MR Core workflow does not reflect such external storage configuration restrictions.
- Linked operations affect all views in the current layout, including views which are not currently visible due to maximization of one view. Changes in a maximized view will affect other views and be reflected when the maximized view is restored to its previous size. Specifically, scrolling in a maximized view will cause other linked views to scroll even if they are not visible. The presentation seen in other views when restoring the maximized view to its previous size will reflect any linking with the maximized view.
- The reset action in one view will cause changes in other linked views. The user can unlink a view before reset if this is not desired.
- Linking between views is based on the DICOM Frame of Reference tag associated with the image data. This does not guarantee precise registration between data sets. If two data sets are linked inappropriately, the user can unlink them to avoid misleading navigation through linking.
- Linked scrolling will match images in other views with those displayed in the view being scrolled. This means that if linked image stacks have different acquisition parameters (slice thickness, slice interval), images in the linked stack may be skipped and potential findings missed. Users can ensure all images are reviewed by scrolling through each image stack independently.

- Subtraction is only available when image sets match in their number of images, image and pixel dimensions, and image position and orientation. The user must determine if the images themselves are meaningful for subtraction.

Quality of the subtraction output will depend on many factors, including acquisition parameters and patient motion. There are no facilities in MR Core to correct for incorrect alignment between image sets used in subtraction.

# The Study List Window

When you start Vitrea, the Study List opens.

The screenshot shows the Vitrea Study List interface. Callout 1 points to the column headers, callout 2 to the top navigation bar, callout 3 to the main list of studies, callout 4 to the filter sidebar, and callout 5 to the Applications and Results tabs at the bottom.

1	2	3	4	5
Column Headers	Study List tools	Patient (studies) List	Patient Information	Applications and Results tabs

## Callout Number

## Description

- 1 Column Headers
  - Click to sort.
  - Click then type the first few letters to search.

---

- 2 Study List tools

---

- 3 Patient (studies) List

---

- 4 Patient Information

---

- 5 Applications and Results tabs

## Filter the Study List

When you set selection criteria to filter the list of studies, the Patient List displays studies matching the selection criteria and studies that are already open.

**TIP:** To further filter the Study List, set the selection criteria for multiple columns.

**EXAMPLE:**

**1.** In the Filter By area click in the field under the **Modality** header and select **MR** from the dropdown list.

The Patient List displays only MR studies.

**2.** Click in the field under the Date of Last Study header and select **1 week** from the dropdown list.

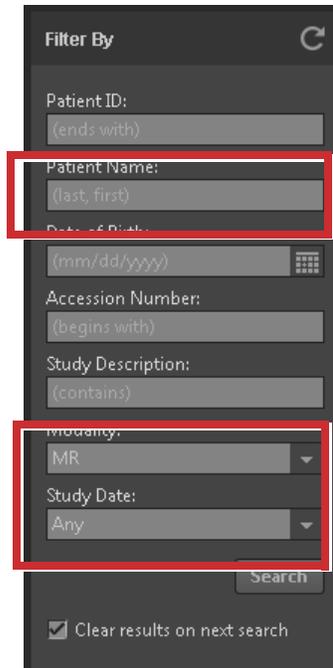
The Patient List displays only MR studies occurring in the last 2 days.

**3.** Click the **Patient Name** header and enter the information.

The Patient List displays MR studies occurring in the last 2 days, sorted by patient name in ascending order.

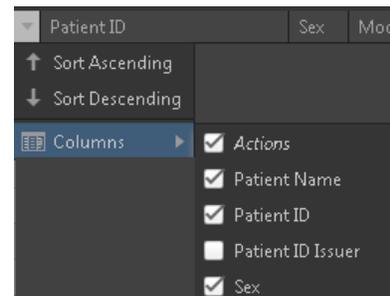
**4.** Click the **Patient Name** header again.

The Patient List displays MR studies occurring in the last 2 days, sorted by patient name in descending order.



**Sort Columns in Ascending or Descending Order**

- Click the column header, then click the dropdown arrow to display a menu to select **Sort Ascending** or **Sort Descending**.
- Select **Columns** to change the include or exclude criteria.

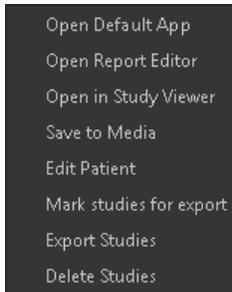


**Adjust the Column Width**

- Place the cursor on the line between columns, and drag the line.

## Patient List Right-click Menu

When you right-click on a study, a menu displays containing the following options:



Menu Item	Description
<b>Open Default App</b>	Open the default application used for the study.
<b>Open Report Editor</b>	Opens the editor to build a report. See Distribute Results section
<b>Save to Media</b>	Save data to media (CD/DVD/USB/Local Disk/Network Data). See Distribute Results section
<b>Edit Patient</b>	Opens the Edit dialog where you edit patient information.
<b>Mark Studies for Export</b>	Marks study for export. Studies marked for export display  in the Status column.
<b>Export Studies</b>	Opens the Export dialog where you select export options and location. See Distribute Results section
<b>Delete Studies</b>	Removes the studies from the server.

## Study List Tools



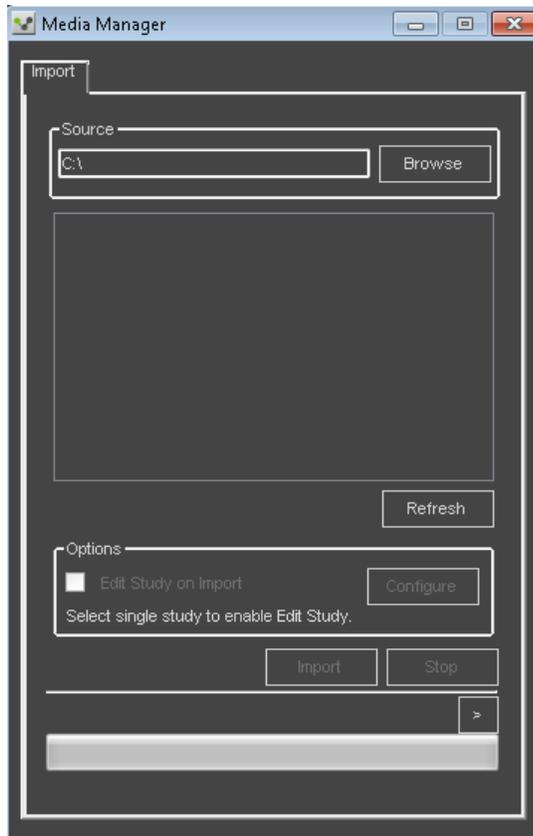
Use the tools located in the upper-right corner of the Patient List to perform the following actions:

Tool	Description
Delete Study	Click to delete the selected study from the server
Save to Media	Click to export selected study to media (CD/DVD/USB/Local Disk/Network Data)
Export Study	Click to export the selected study See the Distribute Results section

Tool	Description
------	-------------

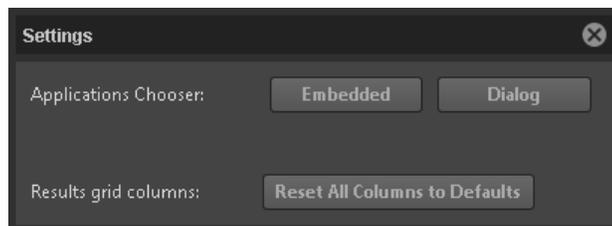
 **Import Media**

Click to launch the Media Manger where you select studies to import



 **Settings**

Click to open the Settings dialog



**Select a Study**

1. Click the study entry to select it and display the Applications tab.
2. To load a study directly into the default application, right-click a study entry and select **Open [Application name]**.

**OR**

Click  for the study listing.

Vitreia launches the application in a new tab at the top of the window.



**OR**

Continue with the Applications tab.

## The Applications Tab

When you click a study, the **Applications** tab displays.



### # Description

- 1 A list of Series that comprise the study.
- 2 Thumbnails representing the applications available for the study type.
- 3 Click **More** more to display hidden application thumbnails
- 4 Click **Tools** Tools to open a menu of Application tab options.
 

Open Report Page editor  
 Medium thumbnails  
 Small thumbnails
- 5 Click **List** List to display the series in a list format.
- 6 Click **Images** Images to display the series in image thumbnails.
- 7 Right-click a series to display additional options or actions.
 

Open  
 Export Series  
 Save Study to Media

## Load a Series or Stack in MR Core

1. From the Patient List, select a study.

**OR**

Press **CTRL** and select multiple studies.

2. From the Applications tab, double-click the **MR Core** application thumbnail.



3. Click  **List** or  **Images**.

4. Select the series or image.

**OR**

Press **CTRL** and select multiple series or images.

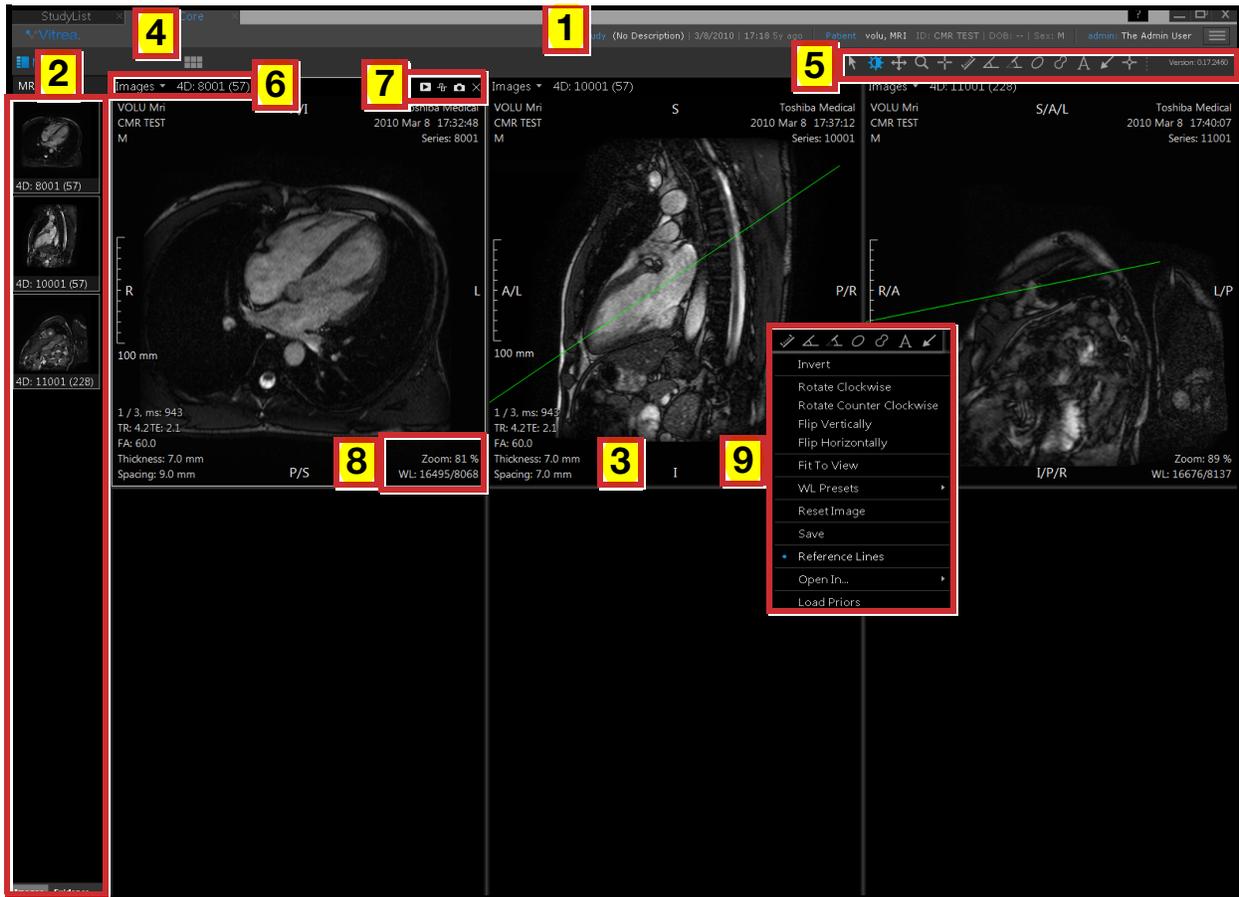
5. Click  on the MR Core thumbnail.

Vitrea launches the application in a new tab at the top of the window.



# Buttons, Tools, and Controls

The Viewer contains a Workspace and a Carousel of images associated with the patient study.



## Callout Number

## Description

**1** Global patient information including the Global Options Menu button .

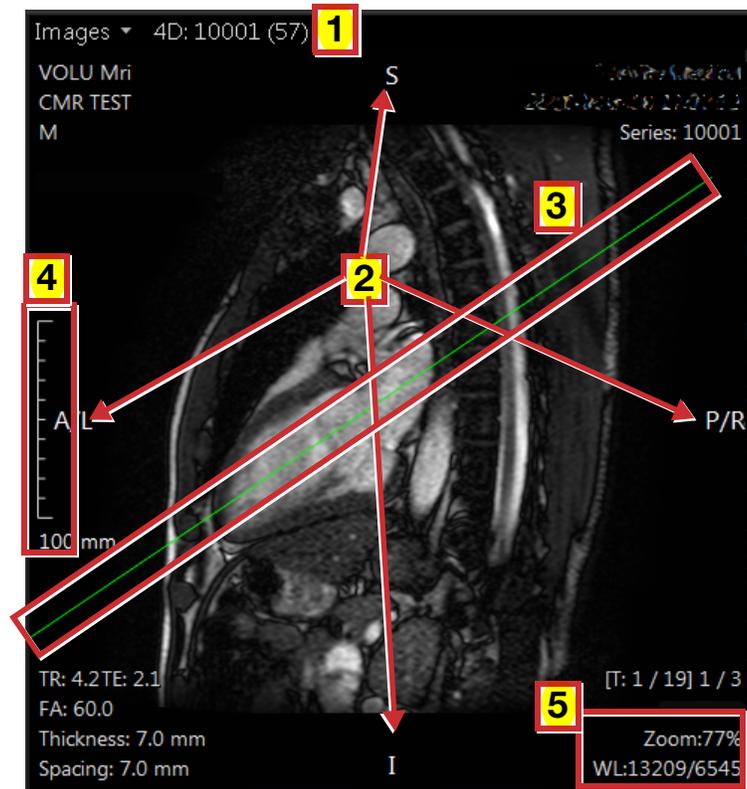
**NOTE:** Always review patient information to ensure the correct patient study is loaded.

**2** Images  See Use the Images Panel below.

Callout Number	Description
3	Workspace of views displayed in a specified layout  See Work with the Workspace Layout below.
4	Layout button  — click to display a grid to select the Workspace layout  See Work with the Workspace Layout below.
5	Common tools  See the Common Tools section below.
6	View header
7	In-view tools - hover over the View header to display the in-view tools.
8	Editable demographics
9	Right-click menu
10	Images and Results tabs

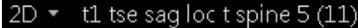
## Image Views

The Workspace is divided into individual image views. The number of views depends on the specified layout.



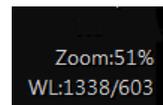
Callout Number	Description
1	Image Header — displays the image type, series/group name (as listed in the Images Panel), number of images in respective group, and in-view tools
2	Orientation markers
3	Reference line — shows the intersection of the active view with the other displayed views
4	Measurement bar — provides an indication of length within the view
5	Editable demographics

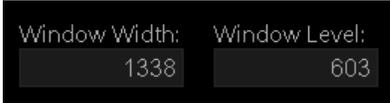
Use the in-view tools to manipulate the individual views. The tools display when you hover on the Image Header.

Tool	Name	Description
	Display Menu	Click the dropdown in the upper-left corner to launch the Display menu. <div data-bbox="1052 474 1240 646" style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <ul style="list-style-type: none"> <li>• 2D</li> <li>MPR Ax</li> <li>MPR Sg</li> <li>MPR Cr</li> </ul> </div> <p><b>NOTE:</b> MPR options available for 2D or Derived images.</p>
	Subtraction	Select this icon to launch the subtraction mode and display the subtraction tools. <p>Drag the series to be subtracted over the view. The series must have the same:</p> <ul style="list-style-type: none"> <li>• Number of images</li> <li>• Image thickness</li> <li>• Field of view</li> </ul> <p><b>NOTE:</b> The initial series is labeled "A," the series you dragged over is labeled "B."</p>
	Subtraction — A - B / B - A	Select either of these icons to specify the subtraction order.
	Subtraction — A	Select this icon to return to initial series and turn off subtraction mode.
	Cine tools	Select this icon to open the cine tools and start the cine. Select it again to close the cine tools.
	Cine — Pause	With the cine tools open, select the Pause icon to pause.

Tool	Name	Description
	Cine — Rock / Loop	With the cine tools open, select the Rock icon to cine through the series from first to last frame, then from last to first frame. Select the Loop icon to cine through the series from first to last frame, and then repeating.  <b>NOTE:</b> The blue-highlighted icon is the one currently selected.
	Cine - Frames per second	With the cine tools open, select this icon to open a menu of frames per second options.    <b>NOTE:</b> The orange dot indicates the currently selected option.
	Link / Unlink	Select this icon to link or unlink the series with the other displayed series with regard to pan, zoom, and scroll operations.  <b>NOTE:</b> The icon displays the linking state currently selected.
	Snapshot	Select this icon to take a snapshot of the view.
	Close	Select this icon to close the view.

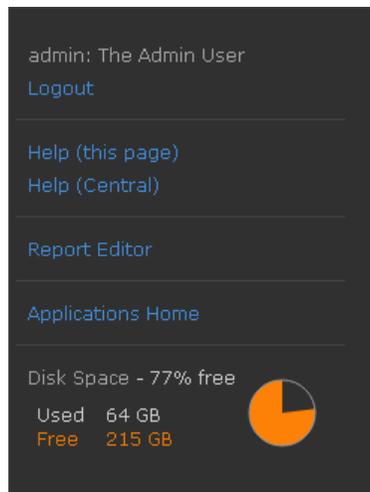
Change the appearance of the view by using the editable demographics links in the lower-right corner of the view.



Link	Name	Description
Zoom:51%	Zoom	Displays the currently selected zoom factor. Click this link to open the Zoom menu.
		
WL:1338/603	Window/Level	Displays the current window/level value. Click this link to enter specific window/level values.
		

## Global Options Menu

Click  in the upper-right corner of the view to display the Global Options menu.



From the Global Options menu, you can:

- Logout

- Access Help Central for links to user documentation and release notes
- Display application-specific user documentation
- Create a new report in the Report Page editor
- Go to Applications Home for access to clinical, administration, and other applications
- View the available disk space

## Common Tools

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These tools are common to all views. The active tool is highlighted in blue.

**TIP:** Hover on any tool to display a brief description.

 See the Keyboard Shortcuts section for information on activating tools using the keyboard.

Tool	Name	Description
	Scroll	Click this icon and drag in the view to scroll through the stack of images.
	Window/Level	Click this icon and drag in any view to adjust the window/level.  The window/level value is displayed in the lower-right corner of the view.
	Pan	Click this icon and drag in any view to pan the image.
	Zoom	Click this icon and drag in any view to zoom the image.
	Focus	Click this icon and click in a view to triangulate to a point of interest in all available views.
	Ruler	Click this icon and click and drag in the view to draw a simple line measurement.

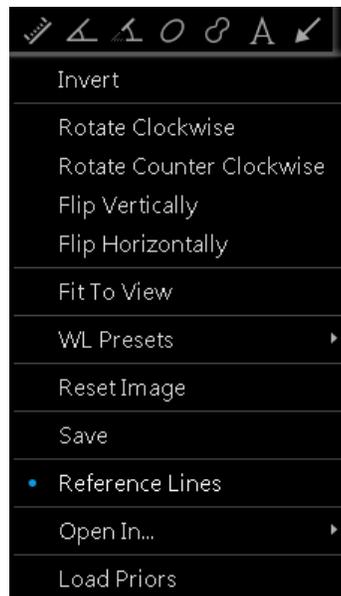
**NOTE:** Also available on the right-click menu.

Tool	Name	Description
	Angle	<p>Click this icon and click in the view to place the first endpoint, click again to place the vertex, then click a third time to place the second endpoint.</p> <p>The the angle in degrees displays.</p> <p><b>NOTE:</b> Also available on the right-click menu.</p>
	Cobb Angle	<p>Click this icon and click in the view to place the first endpoint of the initial line, then click again to place the second endpoint of the initial line.</p> <p>The second line displays as a mirror to the initial line and the angle between the two lines in degrees displays.</p> <p><b>NOTE:</b> Also available on the right-click menu.</p>
	Ellipse ROI	<p>Click this icon and click and drag in the view to create an elliptical contour.</p> <p>The perimeter, area, and other measurements display.</p> <p><b>NOTE:</b> Also available on the right-click menu.</p>
	Freehand ROI	<p>Click this icon and click multiple times in the view to place points that define the contour. Click near the first point to complete the contour.</p> <p>The perimeter, area, and other measurement display.</p> <p><b>NOTE:</b> Also available on the right-click menu.</p>
	Label	<p>Click this icon and click in the view to place the text cursor, then type the label. Press ENTER to complete the label.</p> <p><b>NOTE:</b> Also available on the right-click menu.</p>

Tool	Name	Description
	Arrow	Click this icon and click in the view to place the arrow head, drag, and click again to place the arrow tail.
<b>NOTE:</b> Also available on the right-click menu.		
	Adjust Registration	Click this icon then click on the same anatomical feature in two views across studies with different time points to link them.
 See Adjust Registration below for instructions.		

## Right-click Menu

Right-click in any view to access commonly used tools and options.

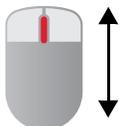
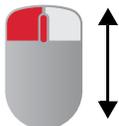
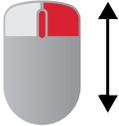


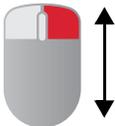
Tool/ Option	Description
Common Tools	Same as Common Tool header. <ul style="list-style-type: none"> <li>• Ruler</li> <li>• Angle</li> <li>• Cobb Angle</li> <li>• Ellipse ROI</li> <li>• Freehand ROI</li> <li>• Label</li> <li>• Arrow</li> </ul>
Invert	Select this option to invert the image to photo-negative dark anatomy on light background.
Rotate Clockwise, Rotate Counter- clockwise, Flip Vertically, and Flip Horizontally	Select one of these options to rotate or flip the view.
Fit To View	Select this option to fit the data to the size of the view.
WL Presets	Select this option to display a menu of window/level presets.
<div style="background-color: #333; color: #fff; padding: 5px; width: fit-content; margin: 0 auto;">                         Default                          Estimated                          Full-Range                     </div>	
Reset Image	Select this option to reset the image to its state when initially loaded.
Save	Select this option to save a subtracted series and export this series as a derived series.
Reference Lines	Select this option to show or hide reference lines in all views.

Tool/Option	Description
Open In	Select this option to open the study in another application.  <b>NOTE:</b> The entire study opens in the other application, regardless of the series selected.
Load Priors	Select this option to load all other studies with the same Patient ID as the current study.

## Keyboard and Mouse Shortcuts

### Mouse shortcuts:

Mouse Button	Press to:
 Click	Activate Tool
 Double-click	Maximize the view
 Right-click	Display Right-click Menu
 Middle-click and drag	Pan
 Left + Middle click and drag <b>OR</b>	Zoom
 Right + Middle click and drag	

Mouse Button	Press to:
	Right-click and drag
OR	
	Roll the mouse wheel

Keyboard shortcuts:

Key	Function
\	Activate Scroll tool
W	Activate Window/Level tool
P	Activate Pan tool
Z	Activate Zoom tool
H	Activate Focus tool
R	Activate Ruler tool
V	Activate Angle tool
C	Activate Cobb Angle tool
E	Activate Ellipse ROI tool
F	Activate Freehand ROI tool
L	Activate Label tool
A	Activate Arrow tool
CTRL A	Select all measurements and annotations
DEL	Delete selected measurements and annotations
CTRL I	Hide demographics
CTRL D	Hide Carousel
HOME	Skip to the first slice in the group
END	Skip to the last slice in the group
' (directly below the ESC key)	Cycle the MPR views (axial, coronal, sagittal)
[ and ]	Display the previous or next image or group from the Carousel.

## Work in MR Core Viewer

When you first launch MR Core, the first few series shown in the image panel display in Views in the Workspace. The number of initial images depends on the number of views in the layout.

## Switch Between Images Panel and Results Tabs

Select these tabs to display the Images Panel or your Results.



 See the Restore Workflow section for information on the Results tab.

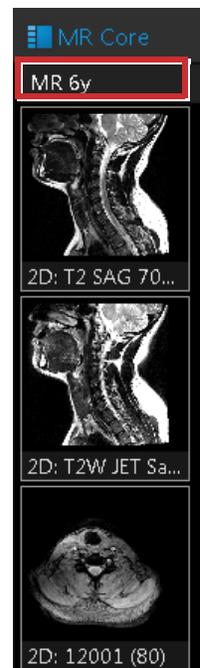
## Use the Images Panel

The images panel is displayed on the left side of the application when the Images tab is selected.

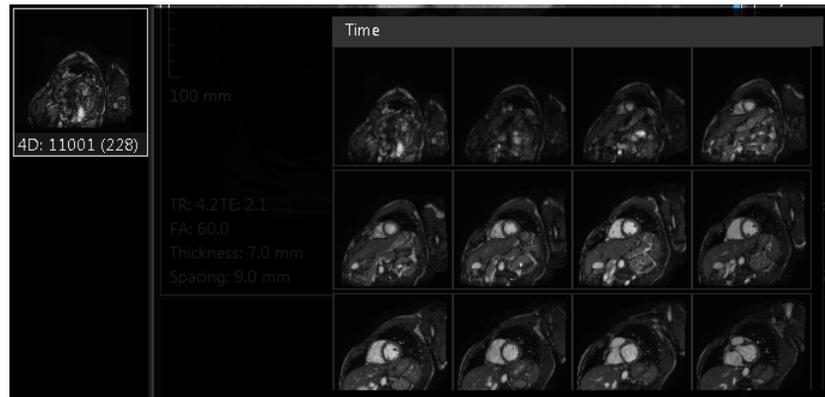
Thumbnails representing each loaded series or groups of dynamic series display. The modality type and age of the study display at the top of each group of series. Each thumbnail lists the type of series and number of slices. Hover on the thumbnail to display the entirety of truncated series names.

The series currently displayed in the Workspace have a border around the thumbnails.

If multiple studies are loaded, the images for each study are separated by a header. You can collapse or expand the images panel for each study by clicking on the study's header.



With 4D or dynamic series groups, click the thumbnail to display the sub-groups of series.



Use the thumbnails to replace or add images in the Workspace.

### Hide or Display Carousel

1. Click  to hide the Carousel.

The Hide/Display Carousel button is highlighted orange when the carousel is displayed.

2. Click  to display the Carousel.

### Work with the Workspace Layout

---

The Workspace shows images, or views, in a useful screen arrangement, or layout, which you can change during review.

Click in any view to make it active. The currently active view displays a white border.

### Replace Images in the Views

1. Click a thumbnail in the Carousel.

2. Drag the thumbnail to a view in the Workspace.

A blue check mark displays on the thumbnail to indicate a valid operation.

## Add Images to the Workspace

1. Click a thumbnail in the Carousel.
2. Drag the thumbnail to the margin of any view in the Workspace.

This will increase the number of view panes in the Workspace.

**NOTE:** The margin of the existing view is highlighted when the cursor is in the correct position to insert the image. A green check mark displays on the thumbnail to indicate a valid operation.

**NOTE:** If you insert an image from the Carousel that is already in the Workspace, a duplicate view will be created.

## Rearrange Images

1. Click an image header.  
A thumbnail of the image displays.
2. Drag the thumbnail to a different view.  
The two views swap positions.

## Clone Images

1. Click an image header.  
A thumbnail of the image displays.
2. Drag the thumbnail to the margin of any view in the Workspace.

This will increase the number of view panes in the Workspace.

**NOTE:** The margin of the existing view is highlighted when the cursor is in the correct position to insert the image. A green check mark displays on the thumbnail to indicate a valid operation.

## Maximize a View to Full Screen

- Double-click in a view.

**NOTE:** Double-click in the view again to return to the previous layout.

## Change the Layout using the Layout Button

Use the Layout button to display the layout grid to select the Workspace layout.

1. Click  to display the layout grid.



2. Hover on the grid to indicate the desired number of images vertically and horizontally from 1x1 to 4x4.

The selected layout is highlighted in orange.

3. To save the currently displayed layout:

- a. Select **Save Layout**.

- b. Enter a name for the layout in the field.

**NOTE:** Give each layout a unique name.

The name of the saved layout will display in the menu on future activations.

- c. To rename or delete the layout, click the dropdown arrow for the layout name and select the desired action.

4. To set the currently displayed layout as the default:

- a. Select **Set as default**.

- b. If you have not named the view, enter a name for the layout in the field.

**NOTE:** Give each layout a unique name.

The name of the saved layout will display in the menu on future activations.

- c. To rename or delete the layout, click the dropdown arrow for the layout name and select the desired action.

5. To expand an individual view to one-up, double-click in the view.

6. Double-click in the view again to return to the original layout.

## Resize Views

1. Hover on the border of a view until the cursor changes to a double arrow.
2. Drag the border to a new size.

**NOTE:** Dragging a vertical border will resize all the views in the column. Dragging a horizontal border will resize the individual view, unless the horizontal borders are linked.

## Resize Linked Views

1. Hover on the horizontal border of a view.
2. Drag the border to a new size.
3. Hover on the horizontal border of an adjacent view.
4. Drag the border to close the to first border.

The Link Toggle button displays at the cross-section of the borders.



5. Click the **Link Toggle** button.

The Link Toggle button displays as a solid gray box when it is active.

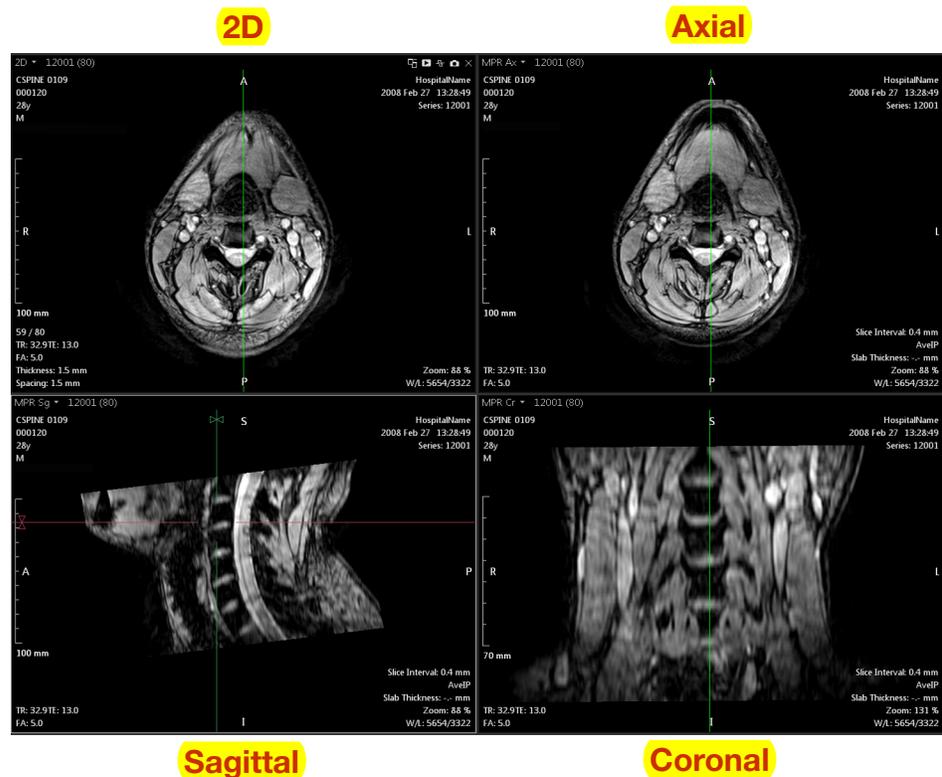


6. To link more views, repeat steps 4 and 5.
7. Drag any of the linked borders to a new location.  
All linked views resize.
8. To unlink the views, click the **Link Toggle** button again.

## Display MPR Orientations

MR Core supports MPR viewing for certain studies.

Click the dropdown in the upper-left corner to launch the Display menu.



With MPR images displayed, the editable demographics area in the lower-right corner of the MPR views allow you to edit the views.

## Change the Slice Interval of MPR Images

1. In the editable demographics area, select **Slice Interval**.

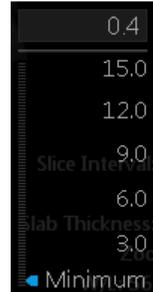
2. From the menu, select a value.

**OR**

At the top of the menu, enter a value.

**OR**

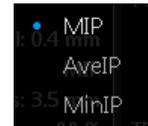
At the left side of the menu, drag the slider.



## Change the Rendering of MPR Images

1. In the editable demographics area, click **MIP**.

2. From the menu, select a rendering.



## Change the Slab Thickness of MPR Images

1. In the editable demographics area, select **Slab Thickness**.

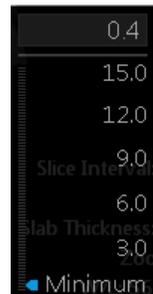
2. From the menu, select a value.

**OR**

At the top of the menu, enter a value.

**OR**

At the left side of the menu, drag the slider.



## Create Measurements and Annotations

Use the common tools to add measurements and annotations to the views. Images with measurements and annotations are included on the Findings tab.

The measurement and annotations display only on the slice they are created.

In general, once a measurement or annotation has been created, you can edit or delete it. You can add more than one measurement or annotation to a view. The currently selected measurement displays control points.

Adding a measurement or annotation to an image automatically creates a finding in the Results tab.

Click any measurement or annotation to select it.

### Draw a Simple Line Measurement

1. Click  or press R.
2. Click and drag in the view.  
The length in mm displays.

### Draw an Angle

1. Click  or press V.
2. Click in the view to place the first endpoint.
3. Click in the view again to place the vertex.
4. Click in the view a third time to place the last endpoint  
The angle in degrees displays.

### Draw a Cobb Angle

1. Click  or press C.
2. Click in the view to place the first endpoint of the initial line.
3. Click again to place the second endpoint of the initial line.  
The second line displays as a mirror to the initial line and the angle between the two lines in degrees displays.

### Draw an Ellipse ROI

1. Click  or press E.
2. Click and drag in the view to create an ellipse.

The perimeter in mm and the area in mm<sup>2</sup> display.

3. Click **More** near the ellipse to display more data.

Minimum, maximum, average, and standard intensity values display.

### Draw a Freehand ROI

1. Click  or press F.

2. Click in the view multiple times to place points that define the contour.

3. Click near the first point to complete the contour.

The perimeter in mm and the area in mm<sup>2</sup> display.

4. Click **More** near the contour to display more data.

Minimum, maximum, average, and standard intensity values display.

### Add a Label Annotation

1. Click  or press L.

2. Click in the view to place the location of the label annotation.

3. Type the text.

4. Press ENTER to complete the label.

### Draw an Arrow

1. Click  or press A.

2. Click in the view to place the arrow head.

3. Drag then click again to place the arrow tail.

### Edit a Measurement

1. If the control points do not display on the measurement, click it, or the text associated with it, to make it active.

2. Click on one of the control points and drag it to a new location.

### Move a Measurement or Label

1. If the control points do not display on the measurement or label box, click it, or the text associated with it, to make it active.
2. Click on an area NOT near one of the control points and drag it to a new location.

### Move Measurement Text

- Click the text associated with a measurement and drag it to a new location.  
A dotted line displays to show the association between the text and measurement.

### Delete a Measurement and Label

1. If the control points do not display on the measurement or label box, click it, or the text associated with it, to make it active.
2. Press DELETE.  
**OR**
  1. Right-click the measurement or label box.
  2. Select **Delete**.

## Apply and Save Subtraction

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Use subtraction to display an image where the data from one image is subtracted from another.

The subtraction tools display when there are two or more series or series groups in the Carousel that are equal in:

- number of images,
- image thickness, and
- field of view.

**NOTE:** If the properties above do not match, the subtraction tools will not display when you hover in the viewer.

## Apply Subtraction

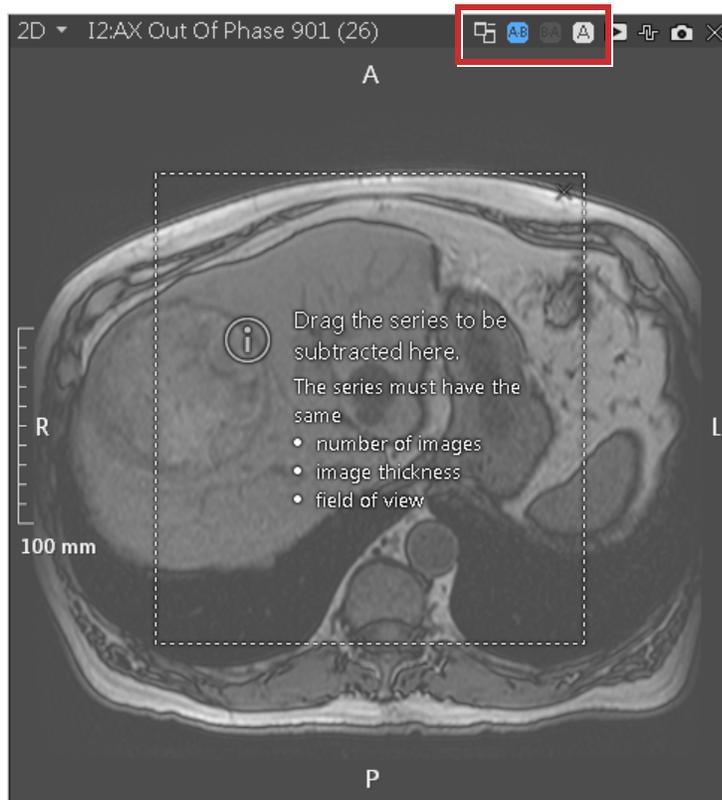
1. Decide which series or series group you want as the “base” series.

This series is named “Series A.”

2. Hover in the upper-right corner of the series to display the Image Header tools.

3. Click .

The subtraction tools display in the Image Header and the subtraction overlay displays over the image.



4. In the Carousel, select the series that you want to subtract.

This series is “Series B.”

5. Click and drag the series from the Carousel and drop on the subtraction overlay.

A blue check mark displays to indicate a valid operation.

In the image header, one of the **A - B** or **B - A** buttons is highlighted blue to specify the subtraction order.

6. To switch the series being subtracted, select  or .
7. To save the subtracted series, right-click and select **Save**.
8. To return to the original image, click .

## Adjust Registration

---

Use the Adjust Registration tool to register two different series or groups of series that do not share a frame of reference so they can be linked spatially. This is typically used for studies that have series separated by a period of time. In order to scroll, zoom, and pan as linked images, it is necessary to manually register to the same point, usually an anatomical feature, in both series.

### Adjust Registration

1. In the Common Tools area, click .
  2. Click a reference point in the first image, usually an anatomical feature.
  3. Click the same reference point in the second image.
- The images are linked with regard to scroll, zoom, and pan operations.

## Restore Workflow

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When you perform measurements or annotations on, or take snapshots of, an image, that image is added to the Results tab. From the Results tab, you can restore an image with findings. Results are automatically sent to the Results tab on the Study List when you close the MR Core application.

A single finding consists of all measurements and annotations created on a single slice.

**NOTE:** MR Core also supports loading a subset of findings from other applications. Typically, MR Core can load findings that include a secondary capture artifact. If such an image is placed in the workspace, it behaves in a manner similar to an image group containing a single image. If an MR Core finding is committed, it then behaves as above when restored rather than restoring the live annotations and measurements.

The following actions create a finding:

- Line measurement
- Angle measurement
- Cobb angle measurement
- Elliptical ROI
- Freehand ROI
- Label annotation
- Arrow
- Snapshot

**NOTE:** Edits made to unpublished findings are updated on existing ones. If findings are made after image presentation, a new finding is created.

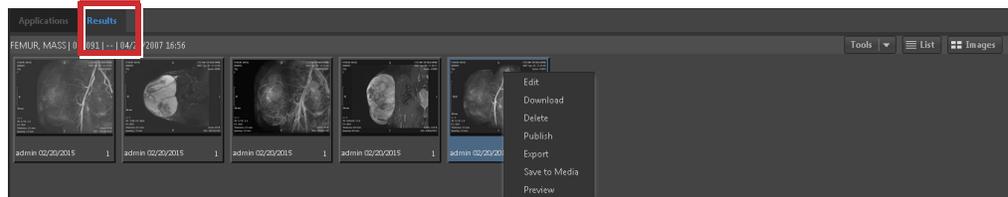
### Restore a Finding

1. At the bottom of the Image Pane, select the **Results** tab.  
All image slices with results display in the Image Pane.
2. Click a thumbnail in the Image Pane.
3. Drag the thumbnail to a view in the Workspace.  
A blue check mark displays on the thumbnail to indicate a valid operation.

## Distribute Results

Return to the Study List to distribute results by export or to create a report.

At the bottom of the Study List, select the Results tab.



From the Results tab, you can:

- Display results in list or images format
- Export results
- Download the study to a local or network location
- Launch the Report Page editor
- Edit the results description
- Delete the results

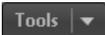
## Results Tab

Manage the display of results listings on the Results tab.

### Display Results in a List

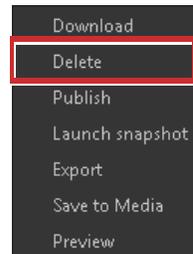
- Click  .

### Display Results in Image Thumbnails

1. Click  .
2. To change the size of the thumbnails, click  then select any thumbnail size option.

## Delete Results

1. Right-click the results listing (either list item or image thumbnail).
2. Select **Delete**.

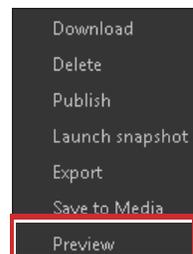


## Preview Results

Preview snapshots before export or save to verify patient information and results capture.

1. Right-click the results listing (either list item or image thumbnail).
2. Select **Preview**.

A large view of the snapshot displays.



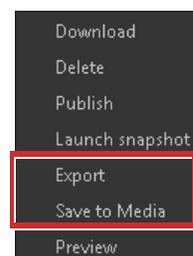
## Results and Study Export

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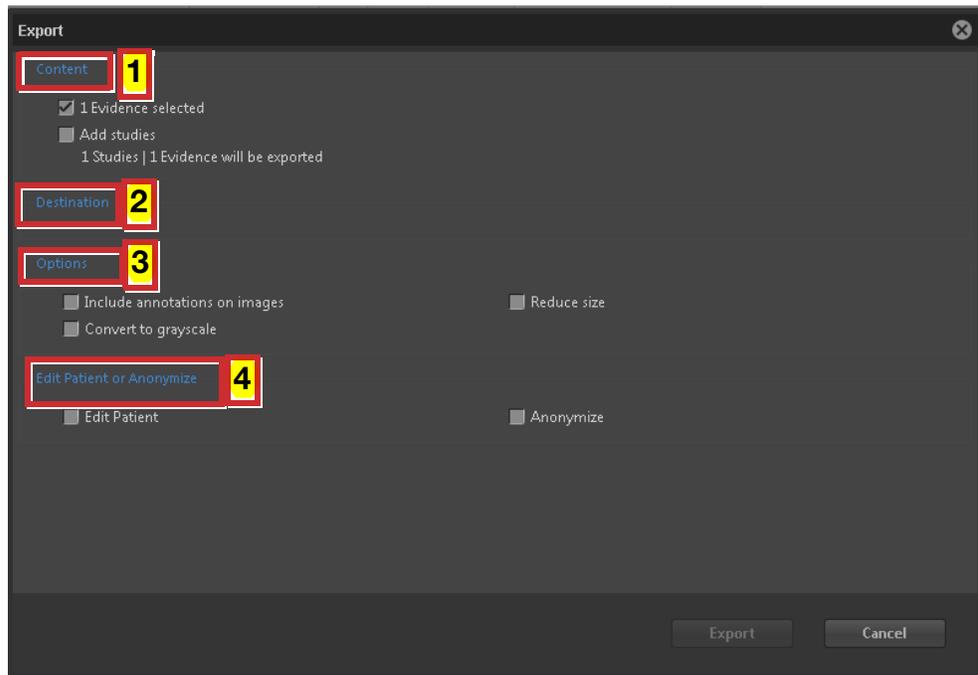
From the Results tab, you can export results and the associated study to a DICOM device, or download a study to a network location or local machine.

## Export Results or Save Results to Media

1. Right-click the results listing (either list item or image thumbnail).
2. Select **Export**.  
**OR**  
Select **Save to Media**.



3. From the Export dialog box, choose options for Content, Destination, Options, and Edit Patient or Anonymize.

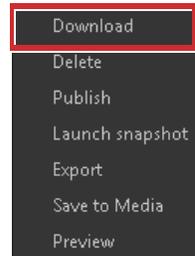


Callout #	Description
1	Content: Select the content to be included in the export. <ul style="list-style-type: none"> <li>The number of Results selected</li> <li>Select <b>Add studies</b> to include the studies in the export.</li> </ul>
2	Destination: Enter the destination for the export.
3	Options: Select options for the results. <ul style="list-style-type: none"> <li><b>Include annotations on images</b></li> <li><b>Convert to grayscale</b></li> <li><b>Reduce size</b></li> </ul>
4	Edit Patient or Anonymize <ul style="list-style-type: none"> <li><b>Edit Patient</b> info</li> <li><b>Anonymize</b></li> </ul>

4. Click **Export** or **Save**.

## Download Results or a Report to a Network Location or Local Drive

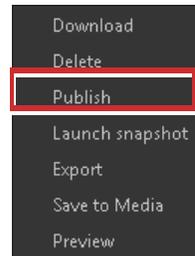
1. Right-click the results listing (either list item or image thumbnail).
2. Select **Download**.
3. Browse to the proper file location.
4. Click **Save**.



## Publish Results

Use the Publish Results feature to lock snapshots that have been included in a report or exported.

1. Create a report or export results.
2. Right-click the results listing (either list item or image thumbnail).
3. Right-click and select **Publish**.  
A green check mark displays on the image thumbnail to indicate its status as Published.



**NOTE:** Results that are marked Published are locked from deletion.



# MR Stitching

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## MR Stitching Overview

MR Stitching is an application in Vitrea which can be launched from the Study List or from other Vitrea-integrated applications, and is able to handle 2D medical images of modality type MR.

The application assists you in combining images covering distinct contiguous, or slightly overlapping, regions of the human body anatomy into one or multiple images for the purpose of DICOM export and subsequent diagnostic reading, clinical review and/or post-processing in Vitrea-integrated applications other than the MR Stitching application itself, or in any other external application which is able to receive and handle DICOM images of modality type MR.

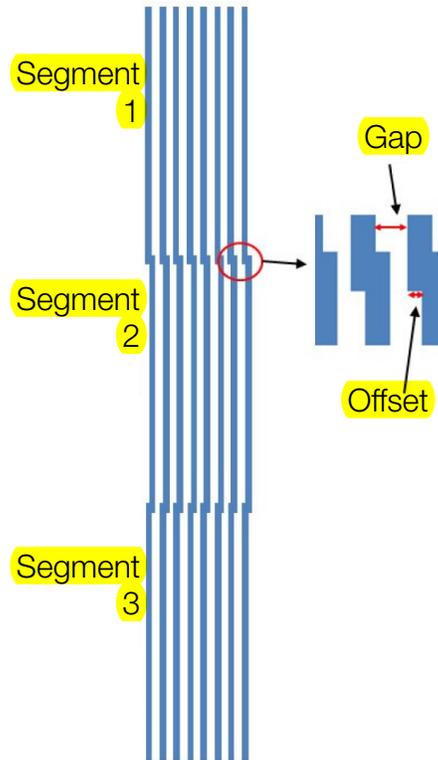
The application provides an algorithm to combine aforementioned images in an automated fashion while allowing the user at any time to verify and correct the algorithm output result.

The application is not to be considered as a diagnostic viewing application on its own, but allows you to create stitched image output of diagnostic quality when viewed in MR Core or any other diagnostic grade combination of DICOM viewer and appropriate graphics hardware and display.

The stitching application only accepts DICOM data with SOP Class "MR Image Storage" or "Enhanced MR Image Storage."

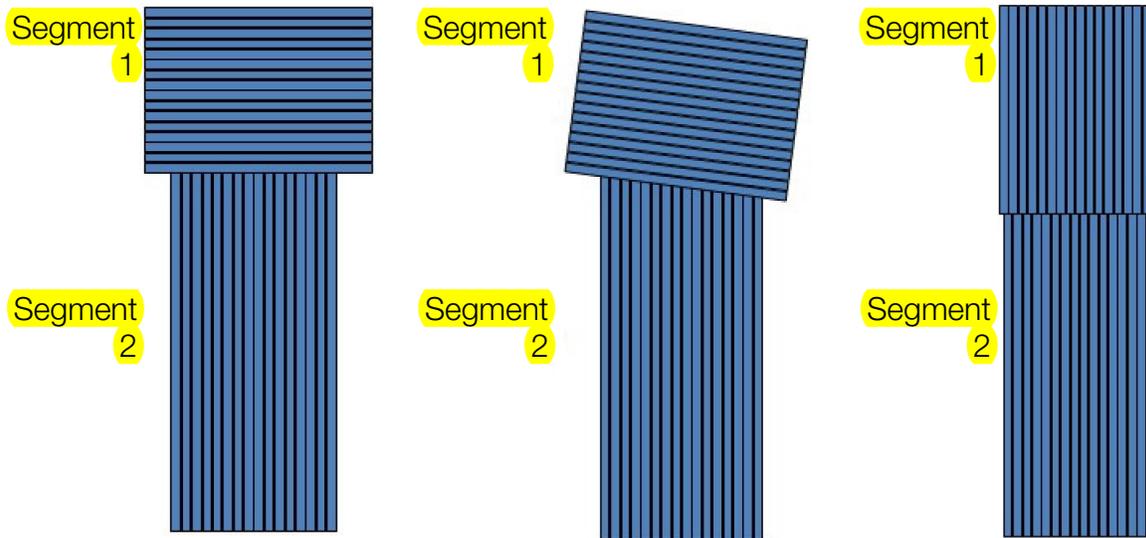
The application accepts **parallel** images (a stack of images which are limited in number, but nevertheless encompass a substantial anatomical area by leaving a gap in between the acquired images) or **volume** images (a stack of contiguous images without gap in between). Some functionality might not be available when loading parallel images.

The application accepts segments of parallel images, where the slices in the different segments run parallel to each other, but are not necessarily aligned: segments can show an offset in relation to one another along one or more modality or patient axes.



The software accepts multiple segments of scanned volumes (represented as adjacent slices with possibly, but not necessarily, isotropic voxels).

The slice orientation of these segments is either equal or different. This means the slices representing the scanned volume can have a different, not necessarily orthogonal, orientation.



The default orientation of the Stitched view equals the orientation of the first segment to be stitched, except when the first segment's orientation is axial. In that case, the default orientation is coronal.

If all composing series have axial orientation, the default orientation of the Stitched view is coronal.

The following rules are applied to define the initial Stitched view orientation:

Composing segment orientation	Stitched view orientation
Segment 1: coronal	Coronal
Segment 2: coronal	
Segment 3: coronal	
Segment 4: coronal	
Segment 1: sagittal	Sagittal
Segment 2: sagittal	
Segment 3: sagittal	
Segment 4: sagittal	
Segment 1: axial	Coronal
Segment 2: sagittal	
Segment 3: sagittal	

Composing segment orientation	Stitched view orientation
Segment 4: sagittal	
Segment 1: axial	Coronal
Segment 2: coronal	
Segment 3: coronal	
Segment 4: coronal	
Segment 1: axial	Coronal
Segment 2: axial	
Segment 3: axial	
Segment 4: axial	
Segment 1: coronal	Coronal
Segment 2: sagittal	
Segment 1: sagittal	Sagittal
Segment 2: coronal	

The terms “axial,” “coronal,” and “sagittal” can be interpreted as “mainly axial,” “mainly coronal,” and “mainly sagittal” for datasets where the scanning orientation is not along strict standard modality or patient axes.

## Caution Statements and Notes



**CAUTION:** Users should treat outputs from the product as supplemental information to aid them in the diagnosis or treatment-planning process. In particular, users should always exercise clinical judgment when assessing outputs from MR Stitching and always consider other clinical information (for example, patient symptoms, demographics, history, and so on) in reaching treatment or diagnostic decisions.



**CAUTION: The quality of information derived from MR Stitching depends on quality of the input data. Poor input data can result in erroneous, inaccurate or misleading output. In general, MR Stitching cannot detect when input data is:**

- **Poor**
- **Of too low a resolution for the diagnostic task**
- **Incomplete (for example, not all series transferred)**
- **Inaccurate (for example, poorly calibrated)**
- **Degraded (for example, after lossy compression and decompression)**

**Users should therefore take steps to check the quality of input data themselves.**

- Only suitably qualified and trained medical professionals should use the product or interpret its outputs, and all users should be aware of these warnings.
- MR Stitching performs sophisticated image processing which may result in unpredictable or surprising effects, including:
  - Introduction of image artifacts which may be misinterpreted as pathology
  - Blurring or hiding of pathology, especially small pathology
  - Rendering of low quality or low resolution data such that it appears of higher quality or resolution
  - Display of images at lower resolutions than the original data
  - Hiding, or rendering invisible, portions of data which contain important anatomy or pathology
  - Use of colors which suppress or emphasize features relative to grayscale images

Users should therefore exercise caution when interpreting output images, and especially when examining features that are small compared to the resolution or slice index of the acquired data. In addition, the issues surrounding the interpretation of processed images are well documented, and we encourage users to investigate them.

- Note that other medical imaging systems may present information differently. This means that MR Stitching may present the series in a study in a different order to your PACS system, or may present image demographics in a different way. Users should not assume consistency of presentation between MR Stitching and other systems.
- MR Stitching should be used on a system that meets the hardware and software specification provided by your supplier. Using MR Stitching on other systems may result in degraded performance, lower image quality, or system failure. Hardware and software should be maintained in accordance with manufacturer's and supplier's instructions, and with advice from relevant professional bodies.
- MR Stitching is intended to operate as part of a larger system. Availability of MR Stitching depends on the availability and correct functioning of other parts of the system (for example, network infrastructure, license servers, acquisition devices, and so on).
- When image frames are displayed with a Zoom factor of less than 100%, they are displayed with reduced resolution compared to the acquired image data. This might impair the user's ability to make a diagnostic reading of the images.
- After applying automatic registration between acquired volumes, the user must visually check the accuracy of the automatic registration. Although major attention was given to the correct functioning of the registration algorithm, the user must apply clinical experience and judgment during diagnostic reading.
- The MR Stitching application allows the images in the Stitched View and the Adjustment Views to have several different rendering methods applied to (e.g. MIP, MIP slab, AvelP slab, etc.). This is meant to make it easy for the user to assess whether the stitching action succeeded, and whether manual corrections are necessary. However the selected rendering method does NOT influence the output of the application which is generated when clicking the 'save' button. This output always consists of a stack of 2D images with image characteristics that are the same as or very close to the image characteristics of the input data.

## Loading Studies into MR Stitching

1. From the Patient List, select a patient name.
2. From the Applications tab, double-click the **MR Stitching** application thumbnail.

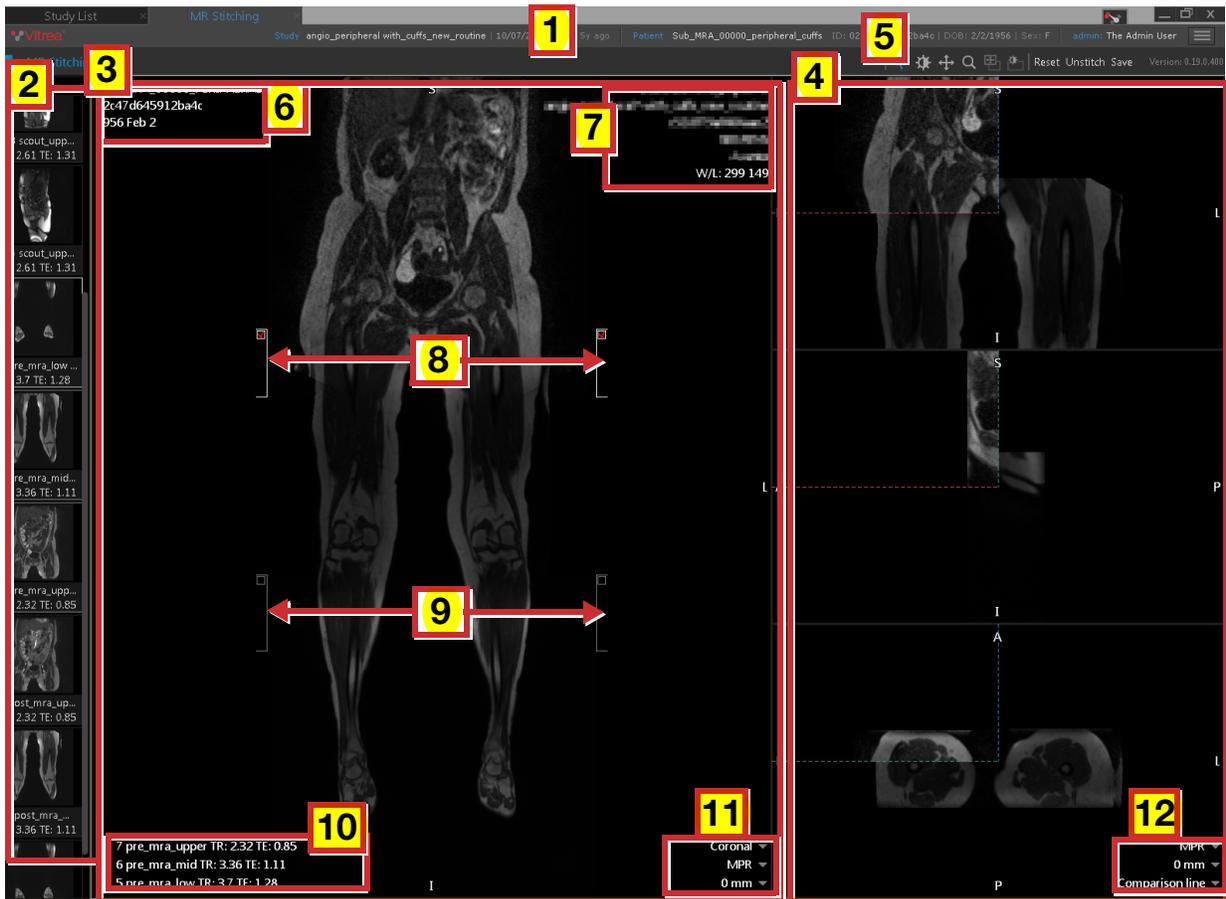


**OR**

1. From within the MR Core application, right-click in the view.
2. Select **Open In.**
3. Select **MR Stitching.**

# Buttons, Tools, and Controls

The Viewer contains a Workspace and a Carousel of images associated with the patient study.



Callout Number	Description
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1	Global patient information including the Global Options Menu button  .
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**NOTE:** Always review patient information to ensure the correct patient study is loaded.

2	Carousel
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 See Using the Carousel below.

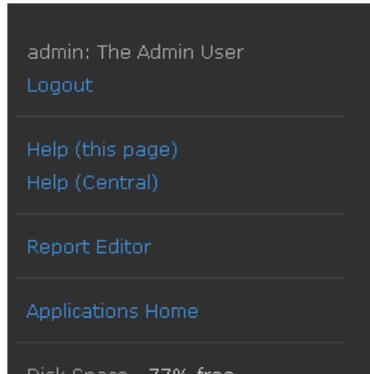
Callout Number	Description
3	Stitched view  <b>NOTE:</b> The initial view is the first image in the Carousel.   See Stitching Images below.
4	Adjustment views   See Using the Adjustment Views below.
5	Common tools   See the Common Tools section below.
6	Patient information
7	Study information
8	Stitched overlap indicators - selected  <b>NOTE:</b> Select an overlap indicator to determine the images in the Adjustment views
9	Stitched overlap indicators - not selected
10	Series information of stitched stacks
11	Stitched image display settings
12	Adjustment view display settings

## Global Options Menu

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Click the Global Options button  in the Global Header to display the Global Options menu. From there, you can create a new report, return to

the Applications Home, or navigate to the Education and Reference Guides.

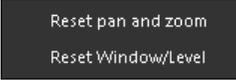


## Common Tools

These tools are common to all views. The active tool is highlighted in blue.

**TIP:** Hover on any tool to display a brief description.

Tool	Name	Description
	Scroll	Select this icon and drag in the view to scroll through the stack of images,  <b>OR</b> Roll the mouse wheel to scroll.
	Window/Level	Select this icon and drag in any view to adjust the window/level of the entire view.  The window/level value is displayed in the lower-right corner of the view.
	Pan	Select this icon and drag in any view to pan the image.
	Zoom	Select this icon and drag in any view to zoom the image.  The current zoom factor is displayed in the lower-right corner of the view.
	Pixel Shift	Select this icon and pan portions of the Adjustment view to re-align the Stitched view.

Tool	Name	Description
	Segment W/L	Select this icon and click and drag in portions of the Adjustment view to adjust the window/level of the individual portions of the Stitched view.
	Reset	Select this option to reset the zoom and pan or the window/level to the initial values.
		
	Unstitch	Select this option to discard stitching and all actions.
	Save	Select this option to save the stitched image.

## Keyboard and Mouse Shortcuts

### Mouse shortcuts:

Mouse Button		Press to:
	Click	Activate Tool
	Click and drag	Use the Active Tool
	Middle click and drag	Pan an Image
	Roll the mouse wheel	Scroll

**Keyboard shortcuts:**

<b>Key</b>	<b>Function</b>
\	Activate Scroll tool
W	Activate Window/Level tool
P	Activate Pan tool
Z	Activate Zoom tool
SHIFT P	Activate Pixel Shift tool
SHIFT W	Activate Segment W/L tool

---

## **Working in the MR Stitching Application**

When you first launch MR Stitching, and the software cannot automatically detect a number of image stacks that can be stitched, the first image in the Carousel displays in the Stitched View and nothing displays in the Adjustment Views. If the software can detect a number of image stacks that can be stitched, those will be stitched automatically after which a stitched result shows in the Stitched View. The Adjustment Views will show image content related to the stitching region of the most superior and second most superior stitching segments.

## Using the Carousel

---

The carousel is displayed on the left side of the application.

Thumbnails representing the loaded stacks display. The stacks are not necessarily grouped as they were acquired by the modality, but rather by TE (echo time) or region of anatomy. Each thumbnail lists the type of series and number of slices. Hover on the thumbnail to display the entirety of truncated series names.

The series currently displayed in the Stitched view have a border around the thumbnails.

**NOTE:** The MR Stitching Series Carousel only features thumbnails for image data which is supported by the MR Stitching application.

Use the thumbnails to select the images to be stitched.



### Hide or Display Carousel

1. Click  to hide the Carousel.
2. Click  to display the Carousel.

## Stitching Images

---

The Stitched view is the main viewing area for stitched images.

### Select Images to Stitch

1. Scroll through the initial view to determine if it is the appropriate stack to be stitched.

**TIP:** To replace the initial view, drag a thumbnail of a stack **of the same anatomy** to the Stitched view.

Dragging a stack of the same anatomy, or a stack that can not be stitched to the initial stack, will replace the stack in the view.

2. From the Carousel, drag a thumbnail of a subsequent (anatomically) stack to the Stitched view.

A progress bar displays indicating the stitching process.

3. Repeat step 2 as necessary to complete the stitched view.

**TIP:** When a thumbnail is dragged into the Stitched view, and other image stacks in the Carousel can potentially stitch with it automatically, then these image stacks will automatically be loaded and stitched.

**NOTE:** It is not necessary to wait until the progress bar completes before adding subsequent stacks to the view.



**NOTE:** If the stacks dragged to the Stitched view cover non-contiguous anatomical regions, gap indicators display in the view.



### Change the Display of the Stitched Image

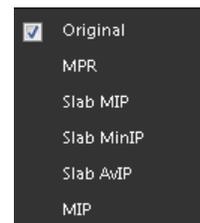
For volume image stacks loaded and stitched, you can change the orientation and rendering of the image.

4. To change the rendering of the image, click the rendering dropdown in the lower-right corner of the Stitched view.



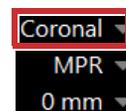
5. Select a rendering option:

- **Original** — the same rendering as the input images.



- **MPR** — the same rendering as the input images. Allows you to change the orientation of the stitched image.
- **Slab MIP** — MIP (maximum intensity projection) rendering and thickness applied (default of 20 mm). Allows you to change the orientation and thickness of the stitched image.
- **Slab MinIP** — MinIP (minimum intensity projection) rendering and thickness applied (default of 20 mm). Allows you to change the orientation and thickness of the stitched image.
- **Slab AvIP** — AvIP (averaged intensity projection) rendering and thickness applied (default of 5 mm). Allows you to change the orientation and thickness of the stitched image.
- **MIP** — MIP rendering and full thickness of the entire scan applied. Allows you to change the orientation of the stitched image.

6. To change the orientation of the stitched image, with any rendering option except Original selected, click the orientation dropdown in the lower-right corner of the Stitched view.

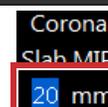


**NOTE:** The orientation dropdown does not display when the Original rendering option is used.

7. Select an orientation option.



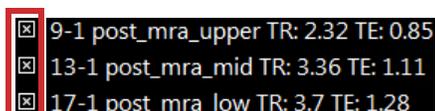
8. To change the thickness of the stitched image, with any Slab rendering option selected, click in the thickness text box and enter a value.



**NOTE:** Editing the thickness value with Original, MPR, and MIP rendering options will change the rendering option to a Slab rendering option.

### Remove a Stack from the Stitched Image

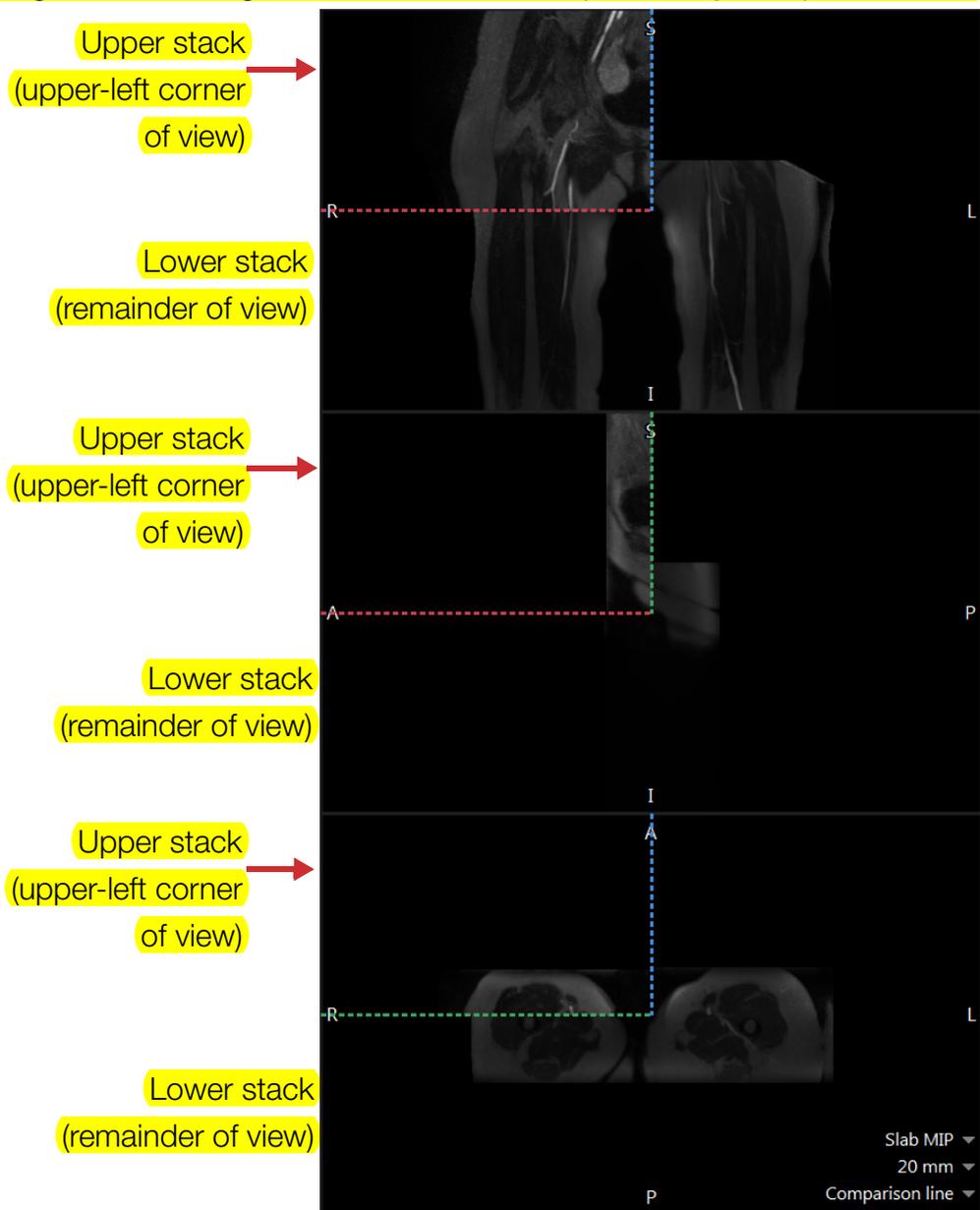
9. To remove a stack from the stitched image, clear the corresponding check box in the lower-left corner of the Stitched view.



**TIP:** To remove all stacks from the stitched image at once, click **Unstitch** in the toolbar.

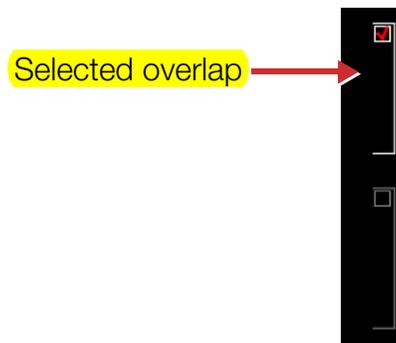
## Using the Adjustment Views

The Adjustment views display the selected stitching overlap in coronal, sagittal, and axial orientations, each divided into upper (representing the most cranial stack) and lower (representing the most caudal stack) segments. The segments of the view are separated by Comparison lines.



Use the Adjustment views to verify and correct the stitching segments related to the Overlap Indicator selected in the Stitched view.

The selected overlap is indicated by a red check mark in the Overlap indicator.



### Select an Overlap Indicator

10. Select a check box in one of the pairs of Overlap indicators.

The adjustment views display the data within the overlapped area.

### Use the Comparison Lines Method to Verify and Adjust Stitching

The Comparison lines define the upper segment of the Adjustment views. The red line indicates the axial orientation, the blue line indicates the sagittal orientation, and the green line indicates the coronal orientation. Move the lines to view more or less of the upper or lower overlapped segments.

**NOTE:** The Comparison line method is recommended with low-contrast images with dense or small vasculature.

11. To move a Comparison line, hover on it and drag it to a new location.

The other Adjustment views update automatically.

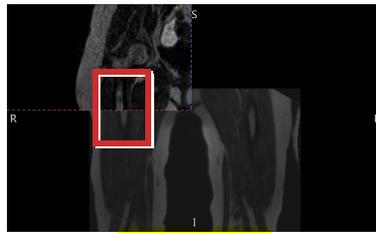
12. As you move the Comparison lines, inspect both segments of the Adjustment view to determine whether the stitching requires correction.

13. To correct the window/level of a segment of the Adjustment view,

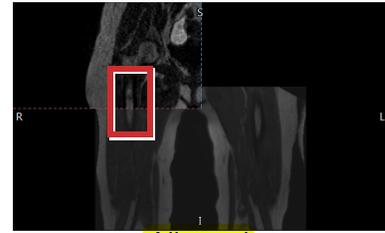
click  and drag in the segment.

The other Adjustment views and Stitched view update accordingly.

14. To correct the alignment of the segments, click  and pan one of the segments using anatomical features as a guide.



Misaligned



Aligned

The other Adjustment views and Stitched view update accordingly.

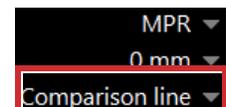
15. Move Comparison lines after making edits to verify the corrections.

### Use the Fusion Method to Verify and Correct Stitching

The Fusion method displays a superimposed and blended view of both segments, with the upper (cranial) segment colored green and the lower (caudal) segment colored red.

**NOTE:** The Fusion method is recommended with high-contrast images and larger vasculature.

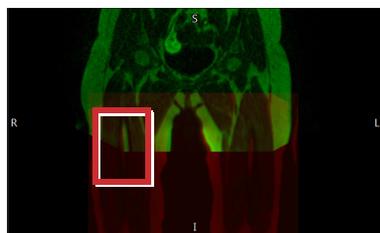
16. Click the method dropdown in the lower-right corner of the view, and select **Fusion**.



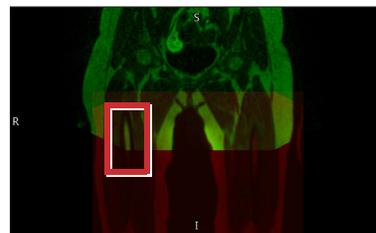
17. To correct the window/level of the lower segment of the Adjustment view, click  and drag in the segment.

**NOTE:** Only the lower segment is corrected in the Fusion method. The other Adjustment views and Stitched view update accordingly.

18. To correct the alignment of the segments, click  and pan one of the segments using anatomical features as a guide.



Misaligned



Aligned

The other Adjustment views and Stitched view update accordingly.

19. Scroll through the Fusion views to verify the corrections.

### Change the Display of the Adjustment Views

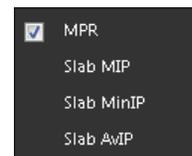
In some cases, you may want to display slab rendering of the Adjustment views to make verification and correction easier.

20. To change the rendering of the Adjustment views, click the rendering dropdown in the lower-right corner of the view.



21. Select a rendering option:

- **MPR** — default rendering.
- **Slab MIP** — MIP (maximum intensity projection) rendering and thickness applied (default of 20 mm). Allows you to change the orientation and thickness of the stitched image.
- **Slab MinIP** — MinIP (minimum intensity projection) rendering and thickness applied (default of 20 mm). Allows you to change the orientation and thickness of the stitched image.
- **Slab AvIP** — AvIP (averaged intensity projection) rendering and thickness applied (default of 5 mm). Allows you to change the orientation and thickness of the stitched image.



22. To change the thickness of the Adjustment views, with any Slab rendering option selected, click in the thickness text box and enter a value.



**NOTE:** Editing the thickness value with the MPR rendering option will change the rendering option to a Slab rendering option.

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## Exporting Stitched Images

Export the stitched images for further review and processing in the MR Core application or in any other application that can display MR images.

Exported stitched images are handled as newly acquired series (not as findings or evidence).

### Export Stitched Images

**23.** Click **Save** in the common tools area.

**24.** Return to the Study List to load the new series into the MR Core application or another application.

Exported images have the same characteristics as the initial input images, regardless of viewing orientation, rendering method, or slab thickness applied to the Stitched view or Adjustment views.

For parallel input images, the exported stitched images have the same orientation as the input images.

For volume input images, the orientation of the exported stitched images is defined by the image orientation of the first stack of images stitched.























# MR Core

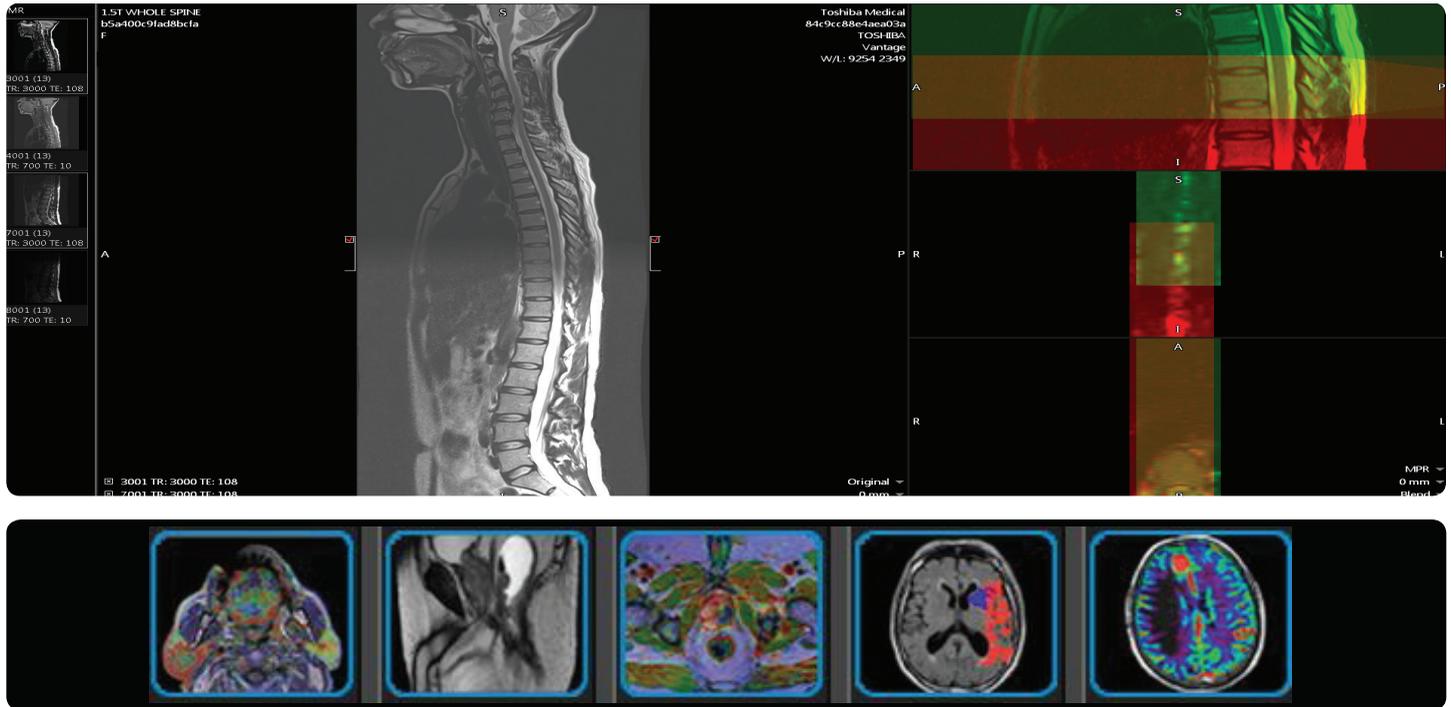


MR Core allows intuitive navigation, quantification and manipulation of MRI images. The application enables streamlined workflows to compare multiple series and the ability to switch to additional integrated applications to further assess the data.

## General Viewing

- Linked 2D, MPR and 4D viewers for single and multi-study comparison
- Context-based launch of advanced workflows and applications
- Creation of retrievable evidence and snapshots
- User defined flexible display protocols

# MR Core



## Access to Advanced Applications and Workflows

- In-application access to advanced analysis applications
- Evidence creation and sharing across workflows

## Specialized MR Tools

- Image subtraction
- Semi-automated image stitching
- Comprehensive set of measurement tools
- Study and series linking
  - Automatic registration, or
  - Register two different series or groups that do not share a frame of reference to link them spatially

MR Core is only available in select countries. Not available for sale in the United States

**VITAL**  
A Toshiba Medical Systems Group Company

Vital Images, Inc., a Toshiba Medical Systems Group Company, is a leading provider of health imaging informatics solutions, including: advanced visualization, enterprise image viewing solutions and business intelligence technology designed to help healthcare organizations deliver exceptional care while optimizing resources across multi-facility organizations.

Vital Images, Inc. | 5850 Opus Parkway, Suite 300 | Minnetonka, MN 55343 | USA | +1 866.433.4624 Vital Images Europe | Zilverstraat 1 | 2718 RP Zoetermeer | Netherlands | +31 79 206 5800

[www.vitalimages.com](http://www.vitalimages.com)

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Questions? Contact FDA/CDRH/OCE/DID at [CDRH-FOISTATUS@fda.hhs.gov](mailto:CDRH-FOISTATUS@fda.hhs.gov) or 301-796-8118

**Pre-Market Notification Truthful And Accurate Statement  
[As Required by 21 CFR 807.87(k)]**

I certify that, in my capacity as Sr. Regulatory Affairs Specialist of Vital Images, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



---

Parthiv Shah  
Sr. Regulatory Affairs Specialist

24<sup>th</sup> April 2015

---

Date







Error - Couldn't merge file with following reason - PdfReader not opened with owner password  
09002621823848f9.pdf

System attempted to attach the file. Please look at attachments to open this file manually.

## Declaration of Conformity – Verification and Validation

I certify that, in my capacity as Vice President, Research and Development of Vital Images, Inc., I believe to the best of my knowledge that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met



\_\_\_\_\_  
Scott Galbari  
VP, Research & Development

April 24, 2015  
\_\_\_\_\_  
Date

## Declaration of Conformity – Design Control Procedures

I certify that, in my capacity as Sr. Regulatory Affairs Specialist of Vital Images, Inc., I believe to the best of my knowledge that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21CFR 820.30 and records area available for review. During a recent Quality System inspection in January 2013, the FDA auditor did not find any violations.



---

Parthiv Shah  
Sr. Regulatory Affairs Specialist



---

Date

## Declaration of Conformity – Intended Use

I certify that, in my capacity as Sr. Regulatory Affairs Specialist of Vital Images, Inc., I confirm that the intended use of the modified device, as described in its labeling, has not changed as a result of the modification(s).



\_\_\_\_\_  
Parthiv Shah  
Sr. Regulatory Affairs Specialist



\_\_\_\_\_  
Date

6.0 510(k) Summary

FEB 24 2004

**Submitter's Name / Contact Person**

Timothy J. Kappers, RAC  
Manager, Regulatory Affairs  
Vital Images, Inc.  
3300 Fernbrook Lane N, Suite 200  
Plymouth, MN 55447

**General Information**

<b>Trade Name</b>	Vitrea 2, Version 3.5 Medical Image Processing Software
<b>Common / Usual Name</b>	System, Image Processing, Radiological
<b>Classification Name</b>	LLZ, Class II, CFR 21 892.2050
<b>Predicate Devices</b>	Vitrea 2, Version 3.4 (K032748) Vital Images, Inc. Fusion7D (K020546) Mirada Solutions, Ltd.

**Device Description**

The Vitrea 2 system is a medical diagnostic device that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. Vitrea 2, Version 3.5 is an upgrade to Vitrea 2, Version 3.4 (cleared under K032748).

The Vitrea 2 system provides multi-dimensional visualization of digital images to aid clinicians in their analysis of anatomy and pathology. The Vitrea 2 user interface follows typical clinical workflow patterns to process, review, and analyze digital images, including:

- Retrieve image data over the network via DICOM
- Display images that are automatically adapted to exam type via dedicated protocols
- Select images for closer examination from a gallery of up to six 2D or 3D views
- Interactively manipulate an image in real-time to visualize anatomy and pathology
- Annotate, tag, measure, and record selected views
- Output selected views to standard film or paper printers, or post a report to an Intranet Web server or export views to another DICOM device
- Retrieve reports that are archived on a Web server

## Intended Use

Vitreau™ 2 is a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. In addition, the Vitrea 2 system has the following specific indication:

Fusion7D™ is an option within the Vitrea 2 system and is intended to register pairs of anatomical and functional volumetric images (e.g., MRI-SPECT, MRI-PET, CT-SPECT, CT-PET), or pairs of anatomical volumetric images (e.g., MRI-MRI, CT-CT, and MRI-CT) as a means to ease the comparison of image data. The result of the registration operations aims to help the clinician obtain a better understanding of the joint information that would otherwise have to be compared separately. This is useful for a wide range of clinical and therapeutic applications. It is important to note that the clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard procedures, including visual comparison of the separate unregistered images. Fusion7D is a complement to these standard procedures.

Softread, is an option within the Vitrea 2 system and is intended to allow the examination and manipulation of a series of 2D images in a variety of modalities, including CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc. The option also enables clinicians to compare multiple series' for the same patient, side-by-side, and to switch to Vitrea to further examine the data in a 3D volume.

## Predicate Device Comparison

The Vitrea 2, Version 3.5 system and its predicate devices allow for the analysis, communication and media interchange of digital images acquired from a variety of acquisition devices. All devices support the DICOM protocol for communication of images with other medical imaging devices.

## Summary of Studies

The software utilized was designed, developed, tested, and validated according to written procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding, testing, validating and maintenance.

The Vitrea 2, Version 3.5 system will successfully complete integration testing/verification testing prior to Beta validation. Software Beta testing/validation will be successfully completed prior to release. In addition, potential hazards have been studied and controlled by a Risk Management Plan.

## Conclusion

The Vitrea 2, Version 3.5 system has the same intended use as the predicate device and has very similar technological characteristics. Minor technological differences do not raise any new questions regarding safety or effectiveness of the device. Thus, the Vitrea 2, Version 3.5 system is substantially equivalent to the predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 24 2004

Vital Images, Inc.  
% Mr. Mark Job  
Responsible Third Party  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

Re: K040305  
Trade/Device Name: Vitrea™ 2 Version 3.5 Medical  
Image Processing Software  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and  
communications system  
Regulatory Class: II  
Product Code: 90 LLZ  
Dated: February 4, 2004  
Received: February 9, 2004

Dear Mr. Job:

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.

Page 2

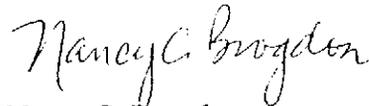
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

K040305

INDICATIONS FOR USE STATEMENT

510(k) Number (If known): \_\_\_\_\_

Device Name: **Vitrea™2, Version 3.5 Medical Image Processing Software**

**Indications for Use:**

Vitrea™ 2 is a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. In addition, the Vitrea 2 system has the following specific indication:

Fusion7D™ is an option within the Vitrea 2 system and is intended to register pairs of anatomical and functional volumetric images (e.g., MRI-SPECT, MRI-PET, CT-SPECT, CT-PET), or pairs of anatomical volumetric images (e.g., MRI-MRI, CT-CT, and MRI-CT) as a means to ease the comparison of image data. The result of the registration operations aims to help the clinician obtain a better understanding of the joint information that would otherwise have to be compared separately. This is useful for a wide range of clinical and therapeutic applications. It is important to note that the clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard procedures, including visual comparison of the separate unregistered images. Fusion7D is a complement to these standard procedures.

Softread, is an option within the Vitrea 2 system and is intended to allow the examination and manipulation of a series of 2D images in a variety of modalities, including CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc. The option also enables clinicians to compare multiple series for the same patient, side-by-side, and to switch to Vitrea to further examine the data in a 3D volume.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_

✓

*David A. Segerson*

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

K040305

# *Vitre*<sup>®</sup> 2 Softread

## *User Guide*



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**VITAL**

*The image of understanding*

VPMC-7565C



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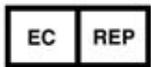
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## *Safety and Regulatory Considerations*

PLEASE READ THIS SECTION CAREFULLY BEFORE USING SOFTREAD.

This section contains information that is essential for the safe and effective use of the Vitrea 2 Softread option. You must understand this information before using this application.

For general Vitrea Safety and Regulatory Considerations, refer to the *Safety and Regulatory Considerations* section of the *Basic Vitrea 2* manual.

### **Intended Use**

The separately-licensed Vitrea Softread option is intended to allow the examination and manipulation of a series of 2D images in a variety of modalities, including CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc. The option also enables clinicians to compare multiple series for the same patient, side-by-side, and to switch to Vitrea to further examine the data in a 3D volume.

**CAUTION** *To use Softread, your monitor should have a luminance of at least 50 foot-Lamberts. The monitors provided with the Vitrea Windows XP workstations meet this requirement. Vital Images does not assume any responsibility for customer-supplied hardware or monitor calibration.*

This manual is intended to be used by customers who have purchased the separately-licensed Vitrea 2 Softread option. It assumes a working knowledge of Vitrea and familiarity with the concepts covered in the *Basic Vitrea 2* manual.



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## Overview

The Softread software is designed for viewing original 2D images in a variety of modalities, including CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF. In general, Softread can display any valid DICOM image.

Using Softread, you can perform the following tasks:

- View a series in 2D
- Compare multiple series for multiple patients, side-by-side
- Cine, window/level, pan, zoom
- Rotate right or left 90 degrees, invert grayscale
- Make linear and polygonal rulers, measure angles, and outline ROIs
- Switch to Vitrea to examine a 3D volume (if one exists for the series)
- View grayscale images as color images
- View grayscale images with pseudo-color maps
- Mark key images for use in dictation, or take snapshots for saving to the Vitrea Report page

---

## Monitor Configuration Choices

When Vital Images configures your system for Softread, you have four monitor configuration choices, depending on how many and what kind of monitors you will use for Softread (and Vitrea). You can choose from the following options:

- One color
- Two color
- Three color
- One color and two Barco Coronis (portrait/landscape)

**NOTE** *If you use more than two monitors, one is left blank, assuming you will use it to display images in Vitrea.*

---

## Loading Studies

On the Study Directory, a **Load in 2D** button displays under the **Load Volume(s)** button. The right mouse button menu also contains an option for loading images in Softread.

**NOTE** *If you have not purchased the Softread option, the button will not be visible, and the right mouse button menu option will be grayed out.*

Once you have loaded a study into Softread, the green status icon in the Patient List will turn to gray, just like when you load it into Vitrea.

You can only run one instance of Softread at a time. If you already have an instance of Softread running when you try to load a new study, you will receive a warning dialog box, asking if you are sure you want to close the first instance.

#### To load single studies:

- 1 On the Study Directory, in the patient list, click on the study you want to load.
- 2 Click on the **Load in 2D** button.

FIGURE 1. Study Directory - Load in 2D button

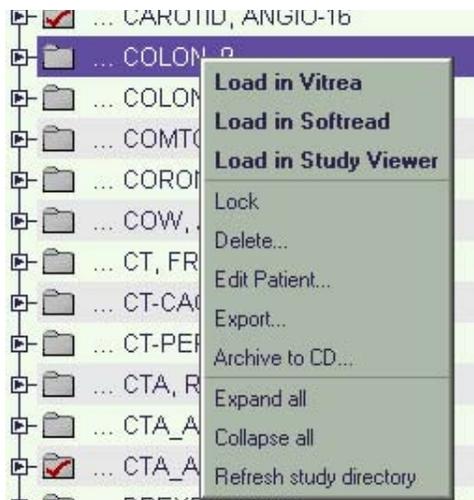


The Softread window opens.

OR

- 1 Right-click on the study you want to load.

FIGURE 2. Study Directory - Load in Softread



- 2 Select **Load in Softread**.

The Softread window opens.

#### To load multiple studies for the same patient:

- 1 On the Study Directory, in the patient list, press CTRL and SHIFT, then click on the studies you want to load to select them.
- 2 Click on the **Load in 2D** button.  
The Softread window opens.



**To load multiple studies for different patients:**

- 1 On the Study Directory, in the patient list, press CTRL and SHIFT, then click on the studies you want to load to select them.
- 2 Click on the **Load in 2D** button.  
The system displays the *Possible patient mismatch* warning message.
  - To launch Softread anyway, click on **Yes**.  
The Softread window opens.
  - To close the dialog box without launching Softread, click on **No**.  
You return to the Study Directory.

---

## Buttons, Tools, and Controls

FIGURE 3. Softread viewer window



FIGURE 4. Toolbar at the bottom of the viewer



FIGURE 5. Toolbar at the bottom of the viewer in 6- (or more) up format



**NOTE** Some of these tools are buttons and others are controls. As explained in the **Use** column in the following table, controls behave differently than buttons. The controls have a little blue cross symbol in the lower right corner. The buttons do not. You can float the cursor over any of the buttons and controls in the toolbar at the bottom of the viewer for tips on how to use them.

TABLE 1. Buttons and controls in the toolbar at the bottom of the viewer

Button/Control	Name	Use
	View Volume button	Click to load the study’s corresponding volume in Vitrea.  <b>NOTE</b> If no volume exists, Vitrea will display an error message.
	Cine control	Click and drag on <i>the control</i> to cine quickly through the images.
	Window/Level control	Without moving the cursor off the control, click and drag on <i>the control</i> to adjust the window/level settings in the viewer.
	Pan control	Without moving the cursor off the control, click and drag on <i>the control</i> to move the image around in the viewer.
	Zoom control	Without moving the cursor off the control, click and drag on <i>the control</i> to magnify or minify the image in the viewer.
	Key Image flag (button)	Click on the flag to mark an image as interesting. Key images are saved to the Findings window.
	Previous/Next (key image) arrows	Click on the <b>Previous</b> or <b>Next</b> arrows to jump between key images.
	Add image to locked set button	Click on the button to lock the image with other images on the screen.  You can cine through images in locked sets simultaneously.
	Tools menu button	Click on the button to display the Tools menu, which contains the following options: Rotate right, Rotate left, Flip, Invert, Pseudo-color, Slice Stacking, Montage, Image filter, Reset, Copy to clipboard.



Button/ Control	Name	Use
	Snapshot button	Click on the button to take a snapshot of the image in the viewer. The snapshot will be saved to the slide tray on the Vitrea Reports page, and to the Windows clipboard for pasting into other applications.
	Swap contents control	Click on the control and drag <i>it</i> into one of the other viewers to switch the images displayed in the two viewers.
	Add images control	<b>NOTE</b> <i>To use this control, both source series must contain the same number of images.</i> Click on the control and drag <i>it</i> into one of the other viewers to create a new dataset, which is the result of adding the images in the current viewer to the corresponding images in the other viewer, slice by slice.
	Subtract images control	<b>NOTE</b> <i>To use this control, both source series must contain the same number of images.</i> Click on the control and drag <i>it</i> onto one of the other viewers to create a new dataset, which is the result of subtracting the images in the current viewer from the corresponding images in the other viewer, slice by slice.
	Concatenate series control	Click on the control and drag <i>it</i> onto one of the other viewers to create a new dataset, which is the result of linking the series in the current viewer to the series in the other viewer.
	One-way scroll arrow	Click on the arrow to scroll the toolbar to the left. This button appears on the toolbar when the viewers are too small to display the entire width of the toolbar. This happens in 6- (or more) up format.
	Two-way scroll arrow	Click on the right arrow to scroll the toolbar to the right. Click on the left arrow to scroll the toolbar to the left. This button appears on the toolbar when the viewers are too small to display the entire width of the toolbar. This happens in 6- (or more) up format.

---

## Keyboard Shortcuts

A list of keyboard shortcuts (accelerators) is accessible from the Help menu.

- To display a dialog box containing all Softread keyboard shortcuts, click on the **Help** menu, and select **Keyboard help**.

A dialog box displays, containing all of the Softread keyboard shortcuts.

FIGURE 6. Keyboard Accelerators

Key	Function
=	Next series
-	16 up
/	Previous series
0	12 up
1	1 up
2	2 up
4	4 up
6	6 up
9	9 up
Ctrl-c	Copy to clipboard
d	Set mouse to Default mode
i	Estimated window/level
m	Set mouse to Measure mode
p	Previous format
q	Exit
u	Full range window/level
y	Image Default window/level
z	Set mouse to Zoom/Pan mode
End	Stack bottom
F1	Help
Home	Stack top
Left arrow	Cine up
Page Down	Page screen forward
Page Up	Page screen backward
Right arrow	Cine down
Tab	Maximize and Back

## *Working in Softread*

If a study contains multiple series, you can use Softread to initially examine the entire study. For detailed investigation of a specific area of interest, you can then load the corresponding volume into Vitrea. Unlike Vitrea, Softread is series-based, so you can cross-reference, lock, and cine through multiple series side-by-side.

Once you load volumes in Softread, you can work with the images using several available hanging protocols.

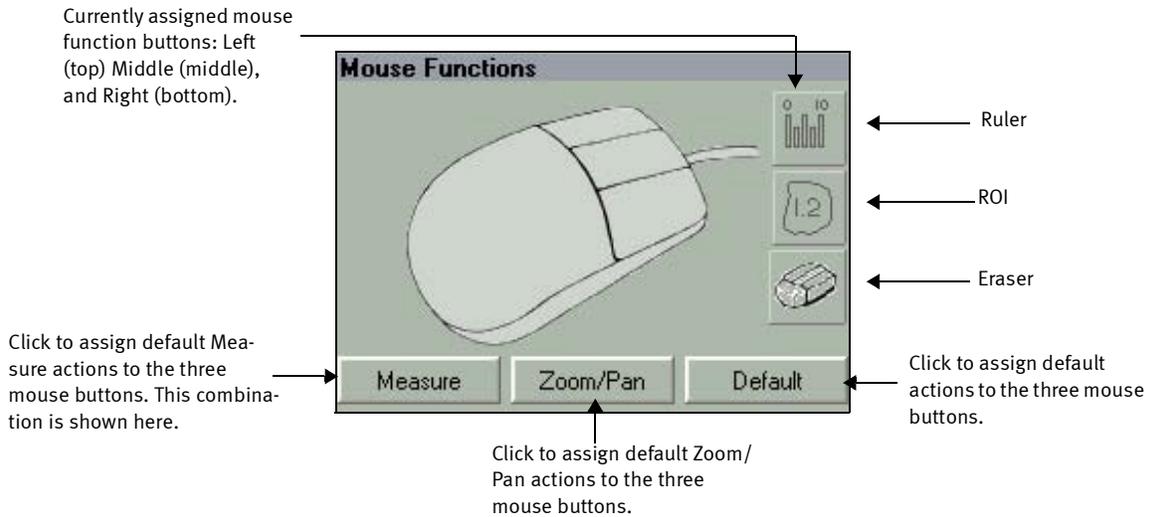
Within the Softread application, you can compare studies, link images, cine, pan, zoom, adjust window/level, scroll, rotate, invert, draw rulers, outline regions of interest (ROIs), and take snapshots of your work for use on the Vitrea Reports page.



## Assigning Mouse Functions

In Softread, you can assign separate functions to each of the three mouse buttons (left, middle, and right). When you click on the mouse button, the function you assign is activated. You can then drag the mouse in the viewer to perform the assigned action. You assign mouse button functions in one of two ways: using mouse function groups, or the mouse functions palette.

FIGURE 7. Mouse Functions



## Mouse Function Groups

Softread provides three pre-assigned mouse function groups. The groups provide a shortcut for assigning all three mouse button functions at once. You select a mouse function group by clicking on the corresponding button below the mouse picture in the Mouse Functions area. The following pre-assigned groups of mouse functions are provided:

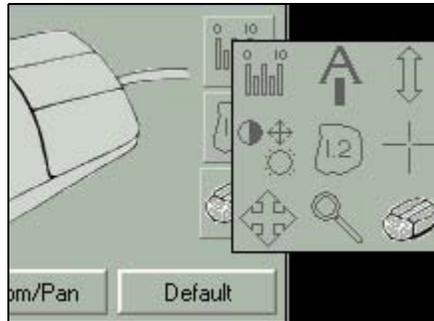
TABLE 2. Mouse Function Groups

Function	Measure	Zoom/Pan	Default
Left	Ruler 	Zoom 	Window/Level 
Middle	ROI 	Pan 	Crosshair 
Right	Eraser 	Cine 	Cine 

## Mouse Functions Palette

You can access additional mouse functions, and assign one mouse button function at a time using the mouse functions palette.

FIGURE 8. Mouse button function palette



In the Mouse Functions area, you display the mouse button function palette by clicking anywhere on the mouse picture, or on any of the three currently-assigned mouse function buttons, to the right of the mouse picture.

The right mouse button has two additional options: the outlined hammer and yellow hammer, as shown below.

FIGURE 9. Right-mouse button function palette

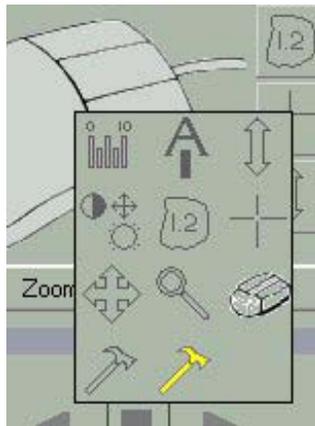


TABLE 3. Mouse button functions

Button	Name	Use
	<b>Ruler</b>	Draw single or multiple straight or polygonal rulers, create angles, or draw geometric ROI outlines on an image.
	<b>Arrow-tation</b>	Pinpoint and label anatomical features. Enter text in the dialog box, adjust font and color, then click and drag to draw an arrow from any corner of the text box. You can only draw one arrow for each text box.



Button	Name	Use
	<b>Cine</b>	Scroll through the images in the viewer (and any same-plane locked images).
	<b>Window/Level</b>	Adjust window and level settings for the image in the viewer.
	<b>ROI</b>	Draw freehand borders around ROIs. Softread displays the area in sq. cm.
	<b>Crosshair</b>	Navigate to a point of interest in the images in the opposite plane. If you use the crosshair tool in the axial plane, the images in the sagittal plane will automatically update to display the slice you are clicking on and vice versa.
	<b>Pan</b>	Move the image around in the viewer.
	<b>Zoom</b>	Magnify/minify the image in the viewer.
	<b>Eraser</b>	Erase ROI borders, annotations, arrowtations, or rulers you have drawn.
	<b>Hammer</b>	(Available for the right mouse button only.) Display the Viewer tools right mouse button menu.
	<b>Yellow Hammer</b>	(Available for the right mouse button only.) Display the mouse button function palette. Use the palette to change the function assigned to the <i>left</i> mouse button only.

## Using the Ruler Tool

Before you can create rulers and measurements in Softread, you must first assign the Ruler tool to a mouse button.

### To assign the Ruler tool to a mouse button:

**NOTE** For the purposes of the following procedures, you will assign the Ruler function to the left mouse button. However, you could assign it to the middle or right mouse button, instead.

- 1 In the Mouse Functions area, select **Measure**.

OR

Click on the mouse picture, then left-click on the **Ruler** button.

OR

Click on the top mouse function button, then click on the **Ruler** button.

## Rulers, Angles, and Geometric ROIs

In Softread, you use rulers to draw single or multiple straight or polygonal rulers, to create angles, or to draw geometric ROI outlines.

**NOTE** *You draw rulers in Softread differently than in Vitrea. Softread rulers were designed to follow standard Microsoft Windows conventions.*

If the image is calibrated, Softread displays the following measurements (see Figure 10):

- lengths of all rulers in millimeters
- angles (degrees) between two adjoining rulers
- average tissue density (pixel units)
- range of tissue densities (pixel units)
- area (square centimeters (cm))
- total length of the perimeter (millimeters (mm)) of geometric ROI outlines

**NOTE** *If the image is not calibrated, Softread displays all length and area measurements in pixels only.*

Marking an image with any kind of ruler automatically flags that image as a key image and places it on the Findings tab. Deleting the ruler from the image does not remove the image from the Findings tab. If you try to remove the key image flag from an image with rulers, you will be prompted to delete all other rulers from the image.

### To draw a ruler:

- 1 Click and drag in the viewer.
- 2 To end the ruler, release the mouse button.

Softread assigns an incremental ruler number (1) and displays the length measurement in millimeters (mm) in the lower left corner of the viewer (see Figure 10).

The image is flagged as a key image and saved to the Findings tab.

### To add another ruler:

- 1 Click and drag in the viewer.
- 2 To end the ruler, release the mouse button.

Softread assigns an incremental ruler number (2) and displays the length measurements for both rulers (1 and 2) in millimeters (mm) in the lower left corner of the viewer (see Figure 10).

The image on the Findings tab is updated with the new ruler and measurements.

### To shorten a ruler:

- 1 Click on one of the ends of the ruler, and drag toward the other end.
- 2 When you reach the desired length, release the mouse button.

The ruler shortens.



**To create an angle measurement:**

- 1 Press and hold the CTRL key on the keyboard, then click and drag from the end point of the first ruler.
- 2 To end the ruler, release the mouse button.  
Softread displays the angle created by the intersection of the two points, and the measurements for each line in millimeters (mm) in the lower left corner of the viewer (see Figure 10).

It labels the lines Xa and Xb, where X is the incremental number assigned to the first ruler.

The image is flagged as a key image and saved to the Findings tab.

**To create a multiple-segment line measurement:**

- 1 Press and hold the CTRL key on the keyboard, then click and drag in the viewer.
- 2 To end the line segment, release the mouse button, while continuing to press the CTRL key.
- 3 Click on the end of the line segment where you want to attach the next line segment, and drag.
- 4 To end the line segment, release the mouse button, while continuing to press the CTRL key.
- 5 Repeat steps 2-4 for all additional line segments.
- 6 When you are finished creating line segments, release the CTRL key.  
Softread displays the length of the entire line in millimeters (mm) in the lower left corner of the viewer (see Figure 10).

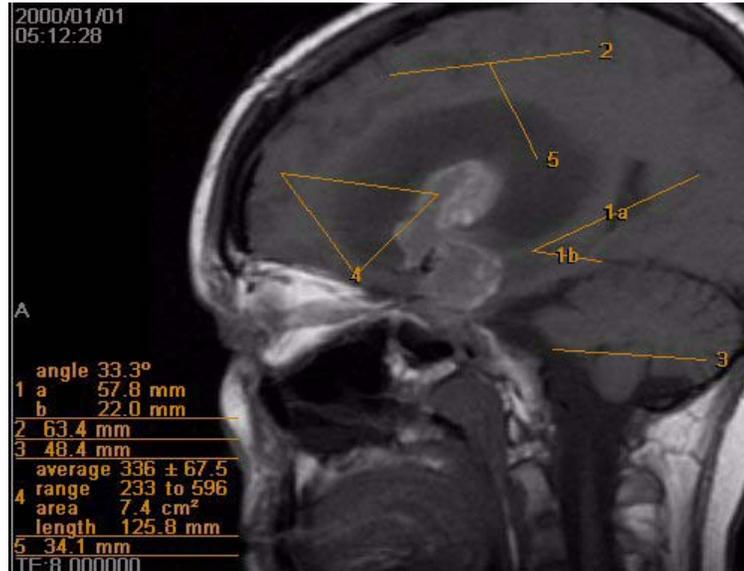
The image is flagged as a key image and saved to the Findings tab.

**To create a ruler connected along the length of another ruler:**

- 1 Press and hold the SHIFT and CTRL keys on the keyboard, then click on a point along the length of one ruler, then drag to create the second ruler.
- 2 To end the second ruler, release the mouse button.  
Softread gives the ruler a new number, and displays its length measurement in millimeters (mm) in the lower left corner of the viewer (see Figure 10).

The image on the Findings tab is updated with the new ruler and measurements.

FIGURE 10. Rulers and measurements

**To connect rulers to form a geometric ROI outline:**

- 1 Press and hold the CTRL key on the keyboard, then click and drag from the end point of the first ruler to the end point of the second ruler.
- 2 To end the ruler, release the mouse button.

This creates the third ruler, and the final border of a triangular ROI outline.

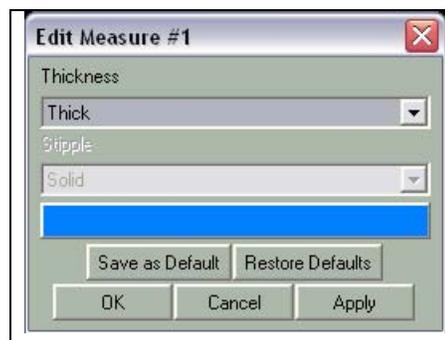
Softread assigns an incremental number to the entire outline, and displays the average tissue density inside the outline (pixel units), range of tissue densities inside the outline (pixel units), area of the ROI (in square centimeters (cm)), and total length of the perimeter in millimeters (mm) in the lower left corner of the viewer (see Figure 10).

The image on the Findings tab is updated with the new ROI outline and measurements.

**To edit ruler properties:**

- 1 Right-click on the ruler, then select **Properties**.
- 2 The Edit Measure #X dialog box displays.

FIGURE 11. Edit Measure dialog box





- 3 To adjust line thickness, click on the dropdown arrow at the end of the Thickness field, and choose from **Thick**, **Medium**, or **Thin**.
- 4 To change the color, click on the orange (or other colored) field. The Set Color dialog box displays.
- 5 Pick a color, or define one of your own.
- 6 Click on the **OK** button. The Set Color dialog box closes.
- 7 To save your ruler properties as the default for all other rulers you draw, click on the **Save as Default** button.
- 8 To restore the previously saved ruler properties (in this case, orange, thin lines), click on the **Restore Defaults** button.
- 9 To see your changes without exiting the dialog box, click on the **Apply** button.
- 10 To close the dialog box, click on the **OK** button.
- 11 To disregard your changes, click on the **Cancel** button. The dialog box closes.

#### To delete a ruler:

- Right-click on the ruler you want to delete, then select **Delete**.

OR

If you have assigned the **Eraser** function to one of the mouse buttons, click that button and drag over the ruler.

---

## *Basic Workflow*

In developing Softread, Vital Images assumed the clinician would use it to perform the following basic workflow:

- 1 A scan is performed at any of the accepted modalities.
- 2 The data is pushed or query/retrieved to a Vitrea workstation.
- 3 The reading radiologist uses the Vitrea Study Directory to select one or multiple studies to review.
- 4 The radiologist launches Softread and a default workflow (reading protocol) is automatically chosen, based on the studies selected.

The radiologist can change the workflow once the cases are loaded in Softread.

The following three workflows are available:

- **Generic Read** - initiated when you load one study for one patient, or when you load studies for different patients
- **Comparative Read** - initiated when you load more than one study for one patient
- **Lumbar Read** - initiated when you load a spine study

FIGURE 12. Workflow menu

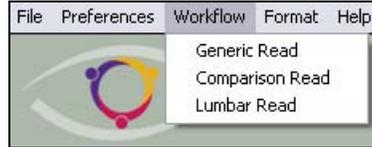


FIGURE 13. Workflow indicators



- 5 The radiologist uses the Softread tools to review images, mark findings, take measurements, mark key images for use on the Findings tab, and take snapshots for use on the Vitrea Report page.
- 6 The radiologist creates the official report using the Softread Findings page and key images while dictating, or outside Softread, on the Vitrea Report page.

## Scenarios

You can use Softread to review an entire study in 2D. This section will give you some examples of how to apply the features of Softread when reading various types of cases.

**NOTE** *The tools and techniques discussed within these scenarios can be applied to other types of studies as well.*

The following case studies provide good examples for illustrating the features of Softread:

- Basic MR studies, such as orthopedic and head MR
- Advanced MR cases, such as cardiac perfusion (4D) and dual echo
- Lumbar MR studies
- CT cases, such as localizers or multi-phase studies
- Other modality studies, such as nuclear medicine or ultrasound.

### Basic MR

#### To view a Basic MR case:

- 1 On the Study Directory in Vitrea, click on the MR study you want to load in Softread.
- 2 Click on the **Load in 2D** button.

The Softread application launches, displaying the images in the 4 up Series hanging protocol.

The 4 up Series hanging protocol sorts the study by series number and each individual series by image number. When hanging the series, Softread ignores the localizers. Each viewer displays either the first or middle image in the series, depending on the **Preferences, Start Middle Image** setting. All



available series in the study display as thumbnails in the thumbnail viewer in the lower left corner of the window.

### Thumbnail Borders

Borders and underlines around the thumbnails indicate viewing status, as shown below. The presence of a border, along with the type of border, indicates how many images within the series have been previously viewed. The presence of an underline indicates that the series is currently displayed in at least one of the viewers. The brightness of the underline indicates if it is displayed in the active viewer.

FIGURE 14. Thumbnail Borders



FIGURE 15. Patient and Exam Information



- 3 Click and drag different series into the viewers from the thumbnail viewer on the right, or press PAGE UP or PAGE DOWN keys on the keyboard.
- 4 For a list of keyboard shortcuts, in the menu bar, select **Help**, then select **Keyboard help**.
- 5 Ensure the mouse buttons are set to the **Default** function group: Window/Level (left), Crosshairs (middle), Cine (right), or that the left mouse button is assigned the **Window/Level** function.
- 6 **Adjust the window and level settings**
  - In any of the viewers, click and drag.

OR

  - Select from the pre-defined Window/Level settings by doing the following:
    - a In the menu bar, select **Format**. The Format menu displays.
    - b Select from the following window/level settings:
      - W/L - Image Default
      - W/L - Full Range
      - W/L - Estimated

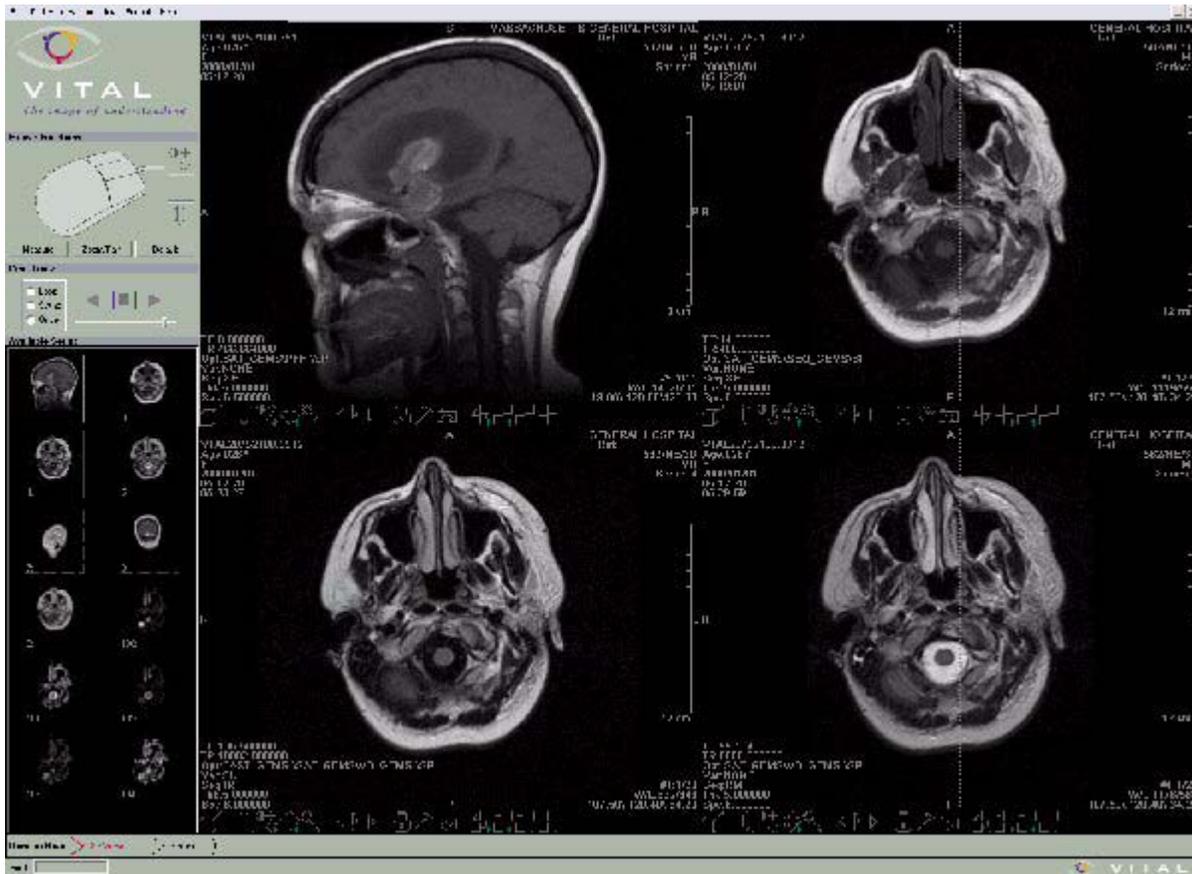


FIGURE 16. Format menu

Format	Help
Load hanging protocol	▶
Sort stack	▶
Split stack	▶
W/L - Image Default	[
W/L - Full Range	]
W/L - Estimated	\
1 up	1
2 up	2
4 up	4
6 up	6
9 up	9
12 up	0
16 up	-
Previous	p
Previous stacks	Page Up
Next stacks	Page Down

- 7 Scroll (cine) using any of the following methods:
- Roll the mouse wheel.
  - Use the assigned mouse button.
  - Use the **Cine** control in the toolbar at the bottom of the viewer.
  - Use the **Cine Tools** to auto-cine.

FIGURE 17. Head MR



- 8 To take snapshots, click on the **Snapshot** button in the toolbar at the bottom of the viewer.
- 9 To mark key images, click on the **Key Image Flag** button in the toolbar at the bottom of the viewer.
- 10 **Cine in Multiple Viewers Simultaneously**
  - a Click on the **Lock** button in the toolbar at the bottom of the viewer.  
The Lock button is outlined by a solid square line.
  - b Repeat step a for every viewer you want to lock.
  - c Use the **Cine** mouse function button or the **Cine** control in the toolbar at the bottom of one of the viewers to cine through images.  
The locked viewers cine simultaneously.
    - To unlock a viewer, click on the **Lock** button again.  
The solid square outline around the Lock button disappears.
- 11 **Rotate or Invert an Image**
  - a Click on the **Tools menu** button in the toolbar at the bottom of the viewer.
  - b In the tools menu, select one of the following options:



- To rotate the image in the viewer left, click on **Rotate left**.
- To rotate the image in the viewer right, click on **Rotate right**.
- To flip the image in the viewer upside down, select **Invert**.

## 12 Swap Images between Viewers

- In the toolbar at the bottom of one of the viewers, click on the **Swap Contents** control and drag *the control* into the viewer with which you want to switch images.

The two viewers swap series.

## 13 Use Cross-reference Lines to Locate an ROI in the Opposite Plane

- As you scroll through images in one viewer, watch the blue dotted line move in the other(s).

**NOTE** *If the two viewers contain images in (relatively) the same plane, the cross-reference lines do not display.*

OR

- a Ensure one of the mouse buttons is assigned the Crosshair function.
- b With that mouse button, click on the POI.

In the opposite plane viewers, a blue plus (+) sign appears at the POI.

In viewers displaying images in the same plane, a short blue line intersects with the blue cross-reference line at the POI. The size of the plus (+) sign is relative to the thickness of the image at the POI.

## 14 Switch to Vitrea to Examine a Volume

- In the toolbar at the bottom of the viewer, click on the **Volume** button.

**NOTE** *If the series containing the image does not contain any volumes, you will receive an error message.*

## Advanced MR

By default, all MR and CT studies display in the 4 up Series hanging protocol. For 4D cardiac studies, it is often preferable to view the series organized by time rather than position. To do this, you can switch the 2D viewer window to one of the hanging protocols named with the word *Time*. These hanging protocols create an image set for each position at various time increments within the series.

### To view a 4D cardiac case:

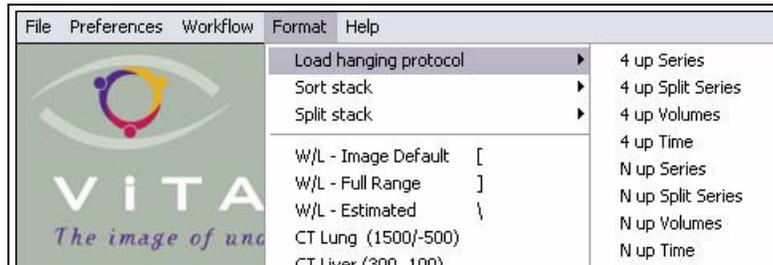
- 1 On the Study Directory in Vitrea, click on the cardiac perfusion study you want to load in Softread.
- 2 Click on the **Load in 2D** button.  
The Softread application launches.
- 3 To change the hanging protocol so you can see as many image sets as will fit on the screen separated by time:
  - a On the menu bar, select **Format**.

The Format menu displays.

- b** Select **Load Hanging Protocol**.

The list of hanging protocols displays.

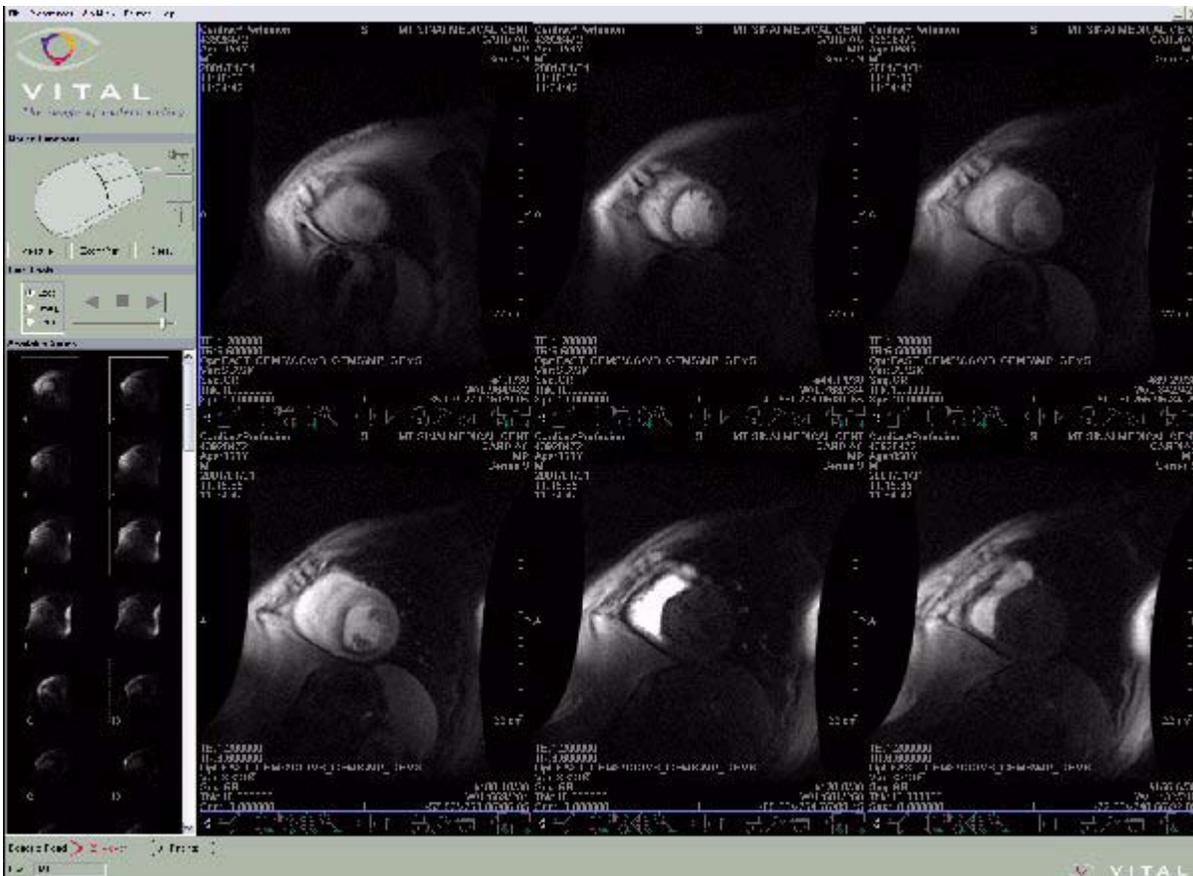
FIGURE 18. Format menu - Load hanging protocol



- c** Select the **N up Time** protocol.

The Softread 2D Viewer window rearranges to display as many viewers as will fit. Each viewer displays a stack of images for a given time increment.

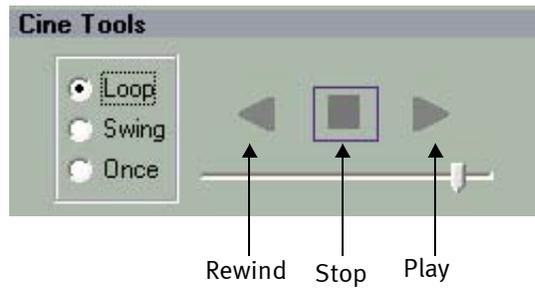
FIGURE 19. Cardiac perfusion



- 4** To cine through the images, in the Cine Tools area, click on the **Play** button.



FIGURE 20. Cine Tools



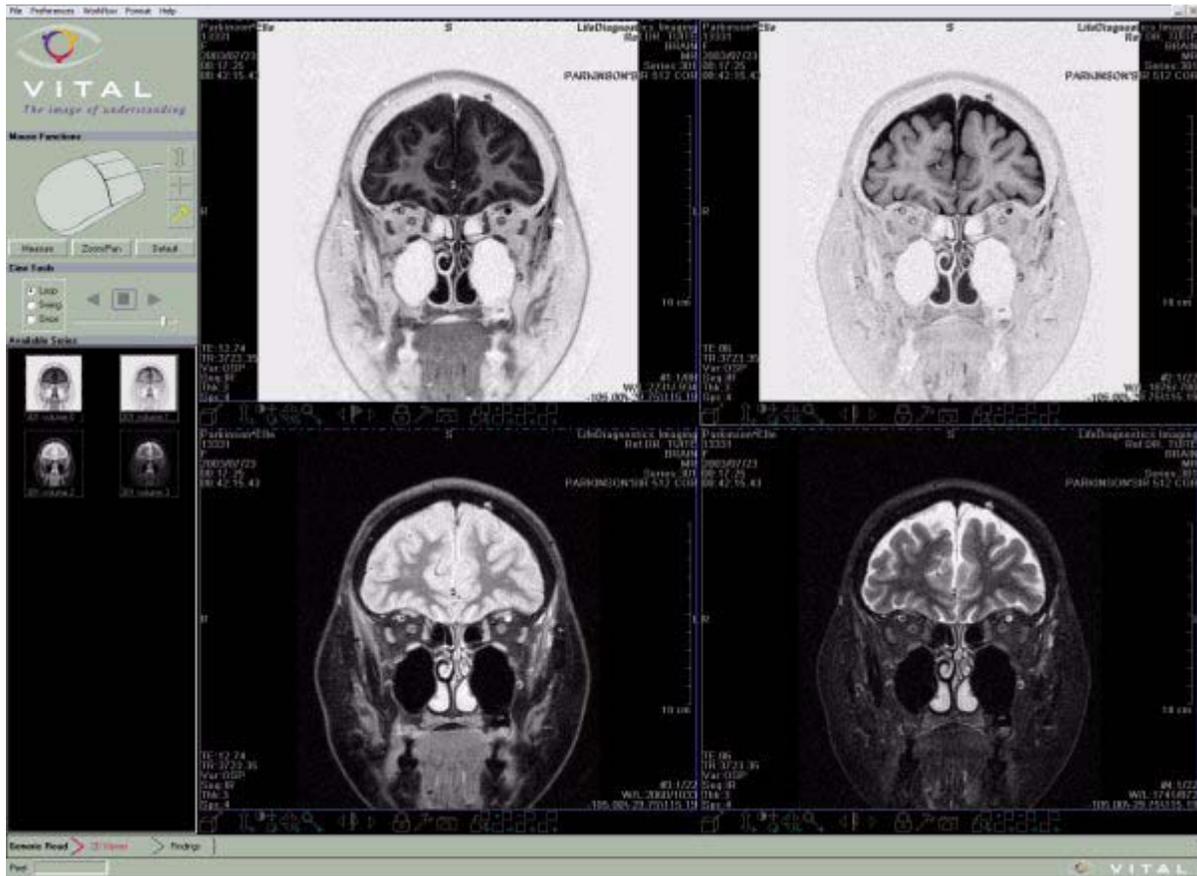
- 5 To cine through the images in the next time series, use the mouse button to scroll in the next viewer.

**NOTE** You do not have to click on the **Stop** button, then click on the **Play** (right arrow) button to do this.

#### To view a Dual Echo study:

- 1 On the Study Directory in Vitrea, click on the dual echo study you want to load in Softread.
- 2 Click on the **Load in 2D** button.  
The Softread application launches, displaying the images in 4 up Series hanging protocol.
- 3 Select **Format, Load Hanging Protocol, 4 up Split Series** or **4 up Volumes**.  
In the Available Series area, thumbnails display for all of the sequences in the dual echo series.
- 4 To display the T1 and T2 images in side-by-side viewers, click and drag the thumbnails into the viewers.

FIGURE 21. Dual Echo MR



- 5 Adjust the Window/Level.
- 6 Lock the same plane viewers together by clicking on the **Lock** button in each viewer.
- 7 Cine (scroll) through the locked images.
- 8 **Mark an ROI**
  - a Assign one of the mouse buttons the ROI function.
  - b In the viewer where you want to mark the ROI, click and drag with that mouse button around the border of the ROI.

Softread automatically connects the two ends of the line you draw, and displays the average (pixel units), range (pixel units), area (sq. cm) and length (perimeter) of the ROI outline (mm).

## Lumbar MR

Softread contains a hanging protocol specifically designed for lumbar MR studies. The hanging protocol displays two sagittal image sets in the upper viewers and two axial image sets in the lower viewers.

**NOTE** *The advantage to viewing lumbar cases in Softread is that Vitrea breaks the series into volumes (one for each angle or orientation), whereas Softread displays the entire series, so you can see it in its entirety.*

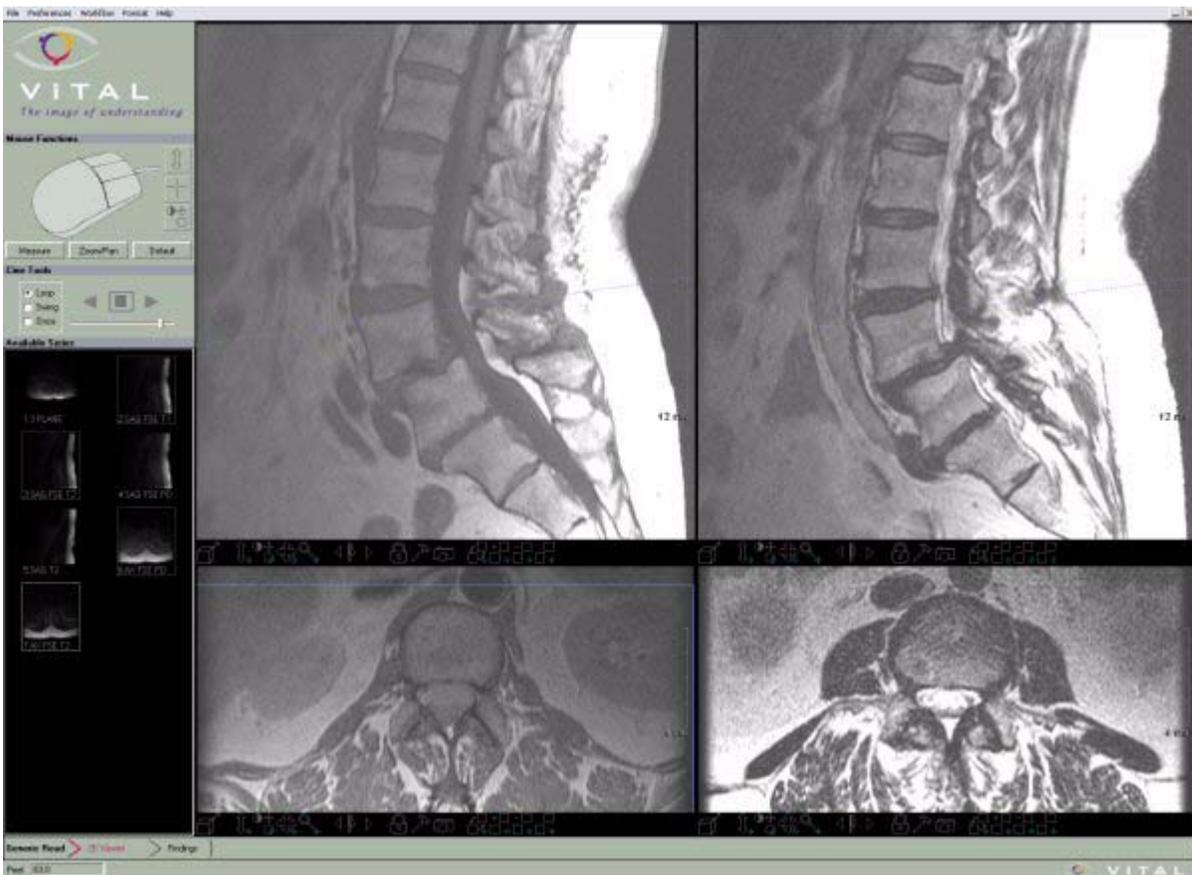


**To view a lumbar MR case:**

- 1 On the Study Directory in Vitrea, click on the lumbar MR study you want to load in Softread.
- 2 Click on the **Load in 2D** button.  
The Softread application launches.

**NOTE** If the study description does not contain the word lumbar, the images display in the 4 up Series hanging protocol. To reformat the viewer into the lumbar hanging protocol, select **Workflow, Lumbar Read**.

FIGURE 22. Lumbar MR



- 3 Click on a sagittal image, then press the PAGE UP or PAGE DOWN keys on the keyboard to display the next or previous sagittal image set.
- 4 Click on an axial image, then press the PAGE UP or PAGE DOWN keys on the keyboard to display the next or previous axial image set.
- 5 Scroll in a sagittal viewer and watch the cross reference lines move in the axial views.
- 6 Ensure the crosshair function is assigned to your middle mouse button.
- 7 Click and hold the middle mouse button on a point of interest in one of the views.

In the perpendicular views, a small blue plus (+) sign displays at the POI.

In the matching plane view(s), a small minus sign crosses the cross-reference line at the POI.

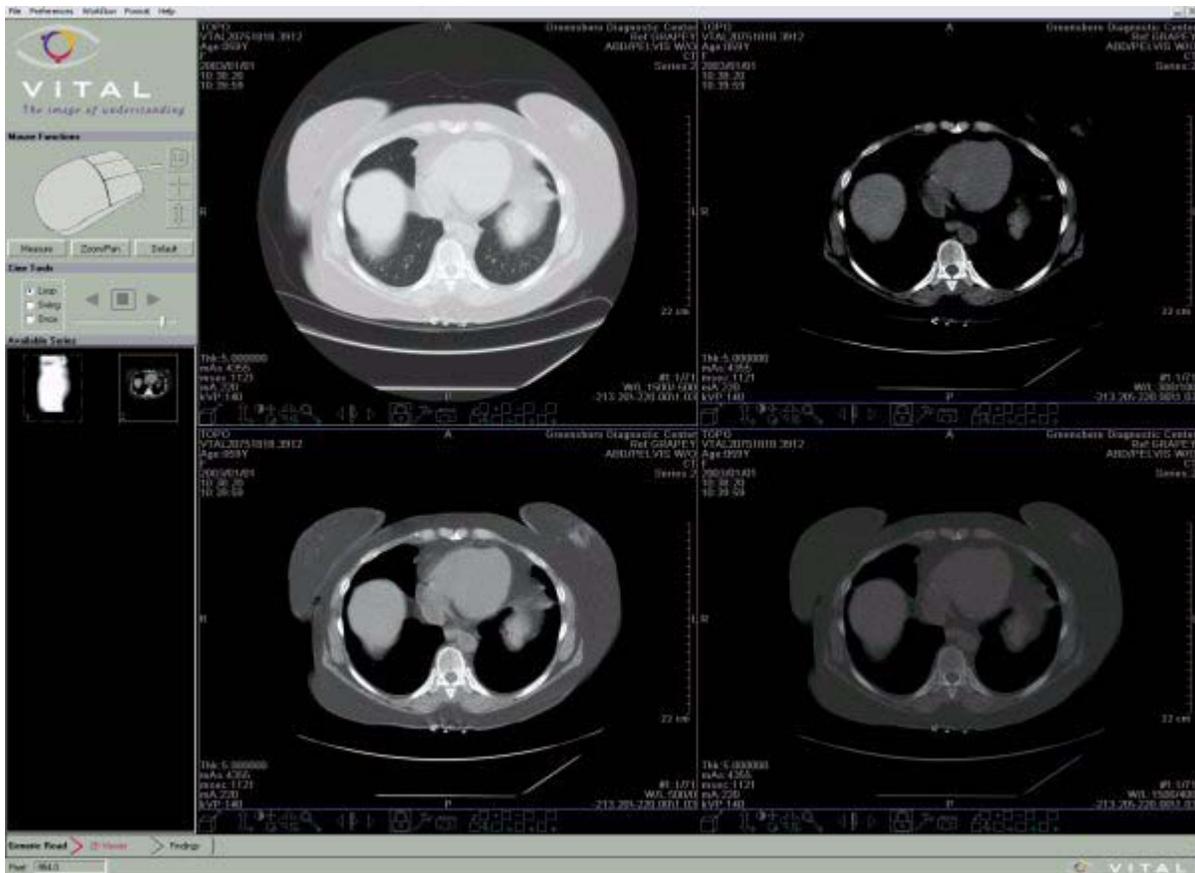
## CT

Many times with CT studies, you will want to examine the same image for various tissue types.

### To view a CT case:

- 1 On the Study Directory in Vitrea, click on the CT study you want to load in Softread.
- 2 Click on the **Load in 2D** button.  
The Softread application launches the 4 up Series hanging protocol.

FIGURE 23. CT study



- 3 Drag the thumbnail for the series you want to examine into all four of the viewers.
- 4 Adjust the Window/Level settings to **Liver**, **Lung**, **Soft**, and **Bone**.
- 5 Lock all four viewers together by clicking on the **Lock** button in each viewer.
- 6 Cine.



## 7 Add the Images in One Viewer to the Images in Another Viewer

- In the toolbar at the bottom of one of the viewers, click on the **Add Images** control and drag *the control* into the viewer displaying the series into which you want to add the images.

The images from the first viewer are added into the images in the second viewer. A thumbnail is added, labeled series number X + Y.

## 8 Subtract the Images in One Viewer from the Images in Another Viewer

- In the toolbar at the bottom of one of the viewers, click on the **Subtract Images** control and drag *the control* into the viewer displaying the series from which you want to subtract the images.

The images from the first viewer are subtracted from the images in the second viewer. A thumbnail is added, labeled series number X - Y.

## 9 Connect the Series in One Viewer to the Series in Another Viewer

- In the toolbar at the bottom of one of the viewers, click on the **Concatenate Series** control and drag *the control* into the viewer displaying the series to which you want to connect the series in the first viewer.

The series from the first viewer is linked to the end of the series in the second viewer. A thumbnail is added, labeled series number X ++Y.

10 Double-click on any of the viewers to examine the image in a 1 up format.

11 Double-click again to go back to the previous viewer format.

## Nuclear Medicine

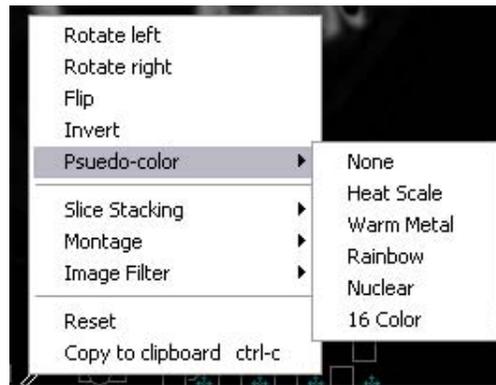
You can apply color scales to nuclear medicine images in Softread. Softread includes the following pre-defined color scales:

- Heat scale
- Warm metal
- Rainbow
- Nuclear
- 16 color

### To apply a color scale to a nuclear medicine study:

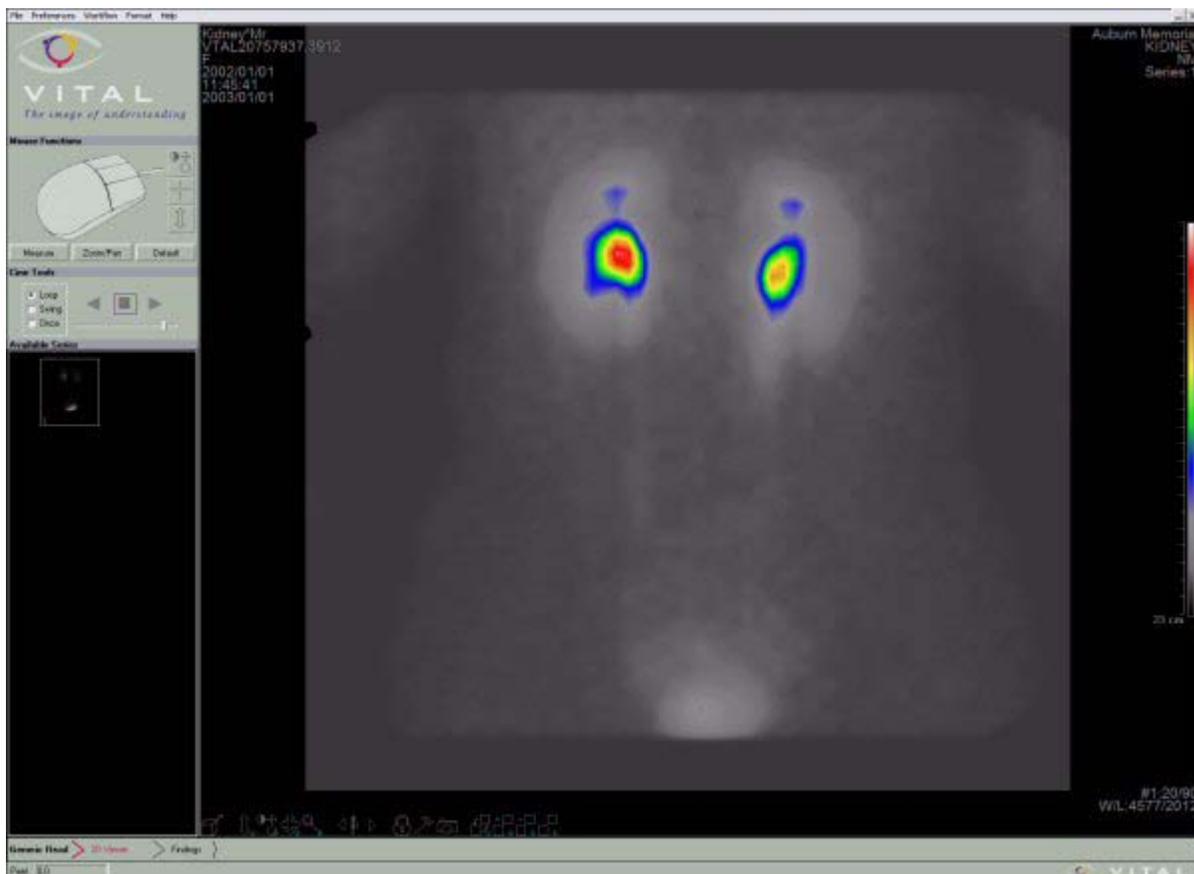
- 1 On the Study Directory in Vitrea, click on the nuclear medicine study you want to load in Softread.
- 2 Click on the **Load in 2D** button.  
The Softread application launches.
- 3 In the toolbar at the bottom of the viewer, click on the **Tools** button.  
The tools menu displays.
- 4 Select **Pseudo-color**.  
The list of pseudo-color scales displays.

FIGURE 24. Pseudo-color menu



- 5 Select the color scale you want to use.  
Softread applies the colors to image(s) in the viewer.

FIGURE 25. Kidneys shown in pseudo-color (Nuclear)



## Comparative Review

For two or more studies for the same patient, you can do a comparative review in Softread. The Comparative workflow parameters take effect when you load two or more studies for the same patient.



The PAGE UP or PAGE DOWN keys behave a bit differently for comparative review. They replace the contents in the active viewer(s) - upper or lower, with images from the corresponding study.

In addition, the thumbnail viewer splits in half. Instead of showing thumbnails for all Available Series, the upper half contains thumbnails for the primary study. The bottom half contains thumbnails for the secondary study or studies.

#### To load multiple studies for comparative review:

- 1 On the Study Directory in Vitrea, select the studies you want to compare.
- 2 Click on the **Load in 2D** button.

The Softread application launches.

The 2D Viewer window displays the 4 up Series hanging protocol in Comparison workflow mode. This hanging protocol displays four viewers, two image sets for the first study in the left viewers, and two image sets for the second study in the right viewers.

They are labeled **Primary** and **Secondary** studies. The primary study has the most recent acquisition time. The patient name for the secondary study is displayed as 'reverse video' (highlighted).

FIGURE 26. Comparative Review



## Taking Snapshots

Once you have 2D representations you want to use in the patient report, you can take a snapshot for use on the Vitrea Reports page.

### To take a snapshot:

- In the toolbar at the bottom of the viewer, click on the **Snapshot** button. You will hear the camera shutter sound as Softread saves the snapshot.

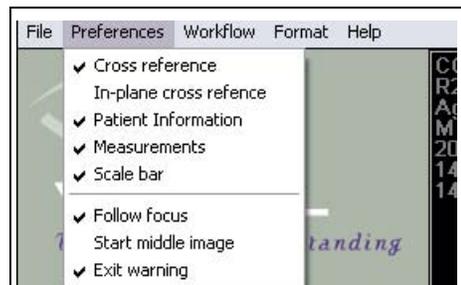
**NOTE** *If the snapshot you take in Softread belongs to a series containing the currently loaded volume in Vitrea, it is automatically displayed in the slide tray on the Reports page in Vitrea. If the snapshot belongs to a different series other than the one containing the currently loaded volume, you will need to either load that volume in Vitrea or click on the Load All Volumes button on the Reports page to get that snapshot to appear in the slide tray.*

## Setting Preferences

Using the Preferences menu, you can select the items that display on the Softread window and specify the window behaviors.

**NOTE** *Individual preferences are saved by user, according to your Windows login ID.*

FIGURE 27. Preferences menu



### To control the information displayed in the viewers:

- Select or deselect **Cross-reference** to display or hide the blue cross-reference lines in the viewers perpendicular to the plane in which you are scrolling.
- Select or deselect **In-plane cross-reference** to display or hide the cross-reference box in the viewers of the same plane as the one in which you are scrolling.
- Select or deselect **Patient Information** to display or hide all patient information.
- Select or deselect **Measurements** to display or hide measurements for any rulers you draw or ROIs you mark.
- Select or deselect **Scale bar** to display or hide the perspective scale bar that displays alongside the image.



### To control additional Softread window behaviors:

- Deselect **Follow focus** if you do not want the thumbnail viewer to reflect the current (active) viewer.
- By default, the viewer displays the first image in the image set. Select **Start middle image** if you want the viewers to first display the middle image in every new or just-opened image set.
- Deselect **Exit warning** if you do not want to see the warning dialog box when you close Softread.

The warning dialog box displays, *There are X number of unvisited images remaining in the study. Do you still want to exit?*

---

## Viewing Findings (Key Images)

When you mark an image as a key image, Softread saves it to the Findings tab for use during report dictation.

### To display the Findings tab:

- 1 At the bottom of the Softread window, click on the **Findings** workflow indicator.

The Findings window displays, including the total number of pages of key images.

FIGURE 28. Workflow indicators



- 2 To manipulate the images, use the mouse functions you assigned on the 2D Viewer window, or the buttons and controls in the toolbar at the bottom of one of the viewers.
- 3 To page through all of the pages of key images, click on the **Prev** and **Next** arrow buttons.
- 4 To change the viewing format to see more or fewer images on the page, click on the dropdown arrow in the **Page Format** field and select a different format.

---

## Closing Softread

- Click on the **X** (Close) button in the upper right corner of the Softread window.  
OR  
Click on **File** on the menu bar, then select **Exit**.  
OR  
Press **q** on the keyboard.  
Softread closes.



---

## Contact Us

- For general, non-technical support questions, contact us through our Web site: [www.vitalimages.com](http://www.vitalimages.com).
- For customer technical support, contact us using one of the following methods:
  - In the U.S., call the Customer Support line at 1.800.208.3005.
  - Outside the U.S., contact your Vital Images distributor.
  - Go to <http://support.vitalimages.com/requestinfo.aspx> and perform the following steps:
    - a In the **Destination** field, select **Technical Questions and Support Issues**.
    - b Fill out the rest of the form.
    - c Click **Send**.
  - Send an eMail to [support@vitalimages.com](mailto:support@vitalimages.com).
- To provide feedback about this document or other Vital Images product documentation, send an eMail to [feedback@vitalimages.com](mailto:feedback@vitalimages.com).

**Intrasense****PREMARKET NOTIFICATION 510(K)  
SUBMISSION**

MYRIAN 1.4

K091001

**5. 510(K) SUMMARY**[As Required by 21 CFR 807.92]  
Summary of Safety and Effectiveness

**Preparation date** April 2<sup>nd</sup>, 2009 JUN 29 2009

**Submitter**

**Name** INTRASENSE

**Registration number** 3006546169

**Address** CAP OMEGA, Rond Point Benjamin Franklin CS 39521 34960 Montpellier FR

**Tel Fax** (+33) 467 130 130 / (+33) 467 130 132

**Contact Persons**

Mr Frédéric BANEGAS  
Phone number : (+33) 467 130 131  
Fax number : (+33) 467 130 132

Mme Colette MAURIN  
Phone number : (+33) 467 130 137  
Fax number : (+33) 467 130 132

**Device name**

**Common Name** System, Image Processing

**Trade Name** MYRIAN

**Model number** N/A

**Device classification**

**Classification name** System, Image Processing, Radiological

**Code product** LLZ

**Panel** 892

**Regulation number** 892.=2050

**Regulatory class** II

**Predicate devices**

[K052995] Cleared [November 8, 2005] [General Electric Medical Systems] [Advantage Workstation Version 4.3], manufactured by [General Electric Medical Systems]

[K061624] Cleared [June 27, 2006] [Vital Images, Inc.] [Vitrea2 Version 3.9], manufactured by [Vital Images, Inc.]

[K082228] Cleared [July 31, 2008] [Pathfinder Therapeutics, Inc] [Planisight Linasys™], manufactured by [Pathfinder Therapeutics, Inc]

[K071000] Cleared [May 14, 2007] [intrasense], manufactured by [intrasense SAS]

**Description**

The Myrian® System is a software suite providing the following services:

- Import of DICOM files from any DICOM-compliant modality, workstation or PACS.
- Visualization of DICOM images in various standard visualization modes (e.g. MPR, 3D...etc.) with optional image-alignment feature. Creation of OOI (Objects Of Interest) for measurement purpose
- Follow-up of patient examination
- Generation of medical reports
- Export of DICOM images to any format, towards any DICOM entity or recognized media.
- Virtual Cutting surface tool for preoperative evaluation of surgery strategies.

# Intrasense

## PREMARKET NOTIFICATION 510(K) SUBMISSION

MYRIAN 1.4

**Explanation of how the device operates**

Myrian® with its modules is designed to run on standard PC hardware, through the installed operating system. The hardware is all "off-the-shelf" standard computer components and may be purchased independently by the end user.

**Intended use**

Myrian is a multi modality medical diagnostic device for the review and analysis of anatomy and pathology in multi-dimensional digital images acquired from a variety of imaging devices. It also includes DICOM communication capabilities and media interchange features (printing, CD burning, storing). It runs on any standard PC including laptops that might be purchased independently by the end user. Typical end users are trained medical professionals..

Myrian includes tools which enable the reviewing physician to provide any selected relevant information for diagnosis, surgery and treatment planning to the referring physician.

These toolsets are categorised as follow:

- Enhanced imaging tools such as:
  - Multi-Planar Reformation (MPR) views in any plane (orthogonal, oblique or curved), 3D views in any rendering mode (MIP, MiniP, Average, Volume Rendering)
  - Cross-sectional or Endoscope Exploration Modes along a centerline (e.g. of a vessel, a colon...etc.)
  - Filet Visualization Mode, to visualize as a flat surface any tubular hollow organ (such as a colon)
- Manual or interactive Objects Of Interest such as :
  - Annotations of Interest, for information or measurement purposes
  - Paths (considered as Annotations of Interest);
  - Regions of Interest, for anatomical and pathological structure isolation (such as liver, spleen, lungs, colon ...etc.) through which any measurement can be performed
  - Points of Interest, for marking areas such as lesions, tumors...etc.
- Reporting tools :

Objects of Interest generates reports which may be viewed and sent to standard film or paper printers or sent electronically to an intranet web server or any other DICOM device.

- Manual or assisted image alignment tools :
  - for multiphasic or time-based image comparisons
  - Cutting Surface Tool – based on ROI - for preoperative evaluation of surgery strategies (such as for the liver).

This device is not indicated for mammography use. Lossy compressed mammography-images and digitized film screen images must not be used for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 mega pixel resolution and meets other technical specifications approved by the FDA.

All Myrian functionalities can be packaged, licensed and marketed as individual modules. The Myrian System allows the OEM customization of both the graphical user interface and the available functionalities, while implying no impact on the system performance or system intended use.

**Performance data**

Performance data were verified versus the requirements of the FDA "Guidance of the Content of Pre Market Submissions for Software Contained in Medical Devices"

User Site Testing and Benchmarking demonstrate that MYRIAN meet the required specifications. No adverse affects have been detected.

# **Intrasense**

## **PREMARKET NOTIFICATION 510(K) SUBMISSION**

MYRIAN 1.4

### **Substantial equivalence summary**

The technological characteristics, features, specifications, materials, mode of operation, and intended use of MYRIAN device are equivalent to those of the predicate devices quoted above.

MYRIAN is the same as the predicate devices in K061624, K052995, K071000 and K082228

The differences that exist between the devices do not raise new issues of safety or effectiveness regarding MYRIAN Device.

It is substantially equivalent in terms of safety and effectiveness to the predicate devices.

The "Substantial Equivalence Decision Making Process" provided by the FDA has been followed, see dedicated section in this document.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 29 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Frederic Banegas  
Chief Technical Officer  
Intrasense  
CAP OMEGA, Rond Point Benjamin Franklin CS 39521  
Montpellier, 34960  
FRANCE

Re: K091001

Trade/Device Name: Myrian  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: June 10, 2009  
Received: June 16, 2009

Dear Mr. Banegas:

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

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

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

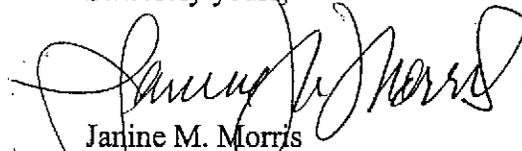
Page 2

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Intrasense**

**PREMARKET NOTIFICATION 510(K)  
SUBMISSION**

MYRIAN 1.4

**4. INDICATIONS FOR USE**

510(k) Number (if known):

*K091001*

Device Name: Myrian

Indications for Use (no change):

Myrian is a multi modality medical diagnostic device. It is aimed at reviewing and analyzing anatomy and pathology. It also includes DICOM communication capabilities and media interchange features (printing, CD burning, storing). It runs on any standard PC including laptops that might be purchased independently by the end user. It provides user a set of tools meant to create and modify objects of interest : points of interest, annotations of interest and volumes of interest.

This device is not indicated for mammography use. Lossy compressed mammography images and digitized film screen images must not be used for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 mega pixel resolution and meets other technical specifications approved by the FDA.

Prescription Use   
(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)

(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

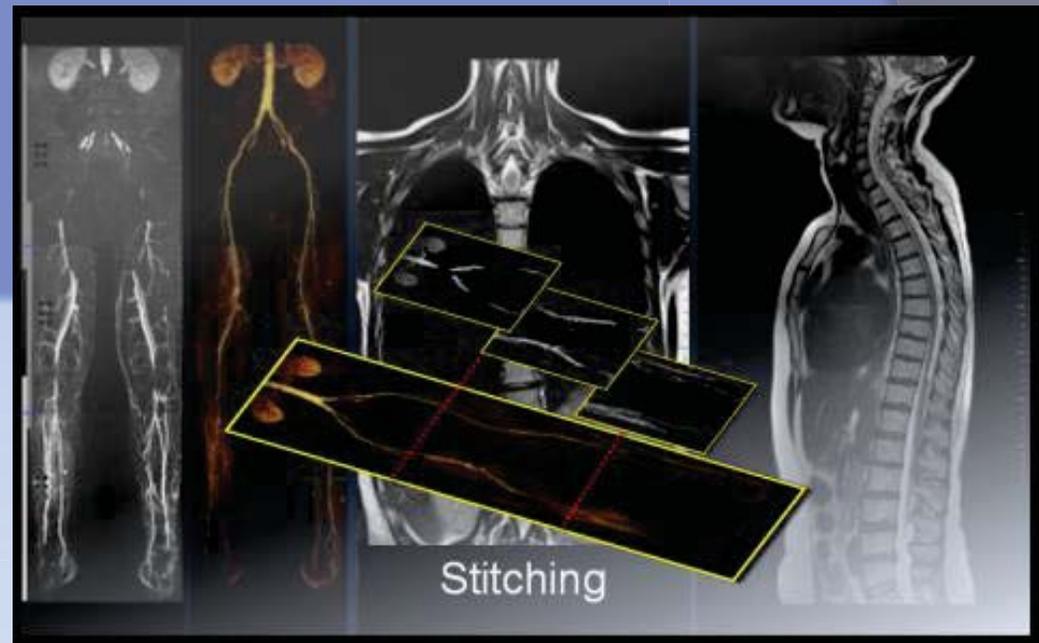
510(k) Number *K091001*

Myrian

***CT / MRI Clinicals Expert Module***

# *Stitching for Whole Body Imaging*

- **One-click application**
- **Automatic post-processing**
  - Automatic Centering
  - Automatic Slice localization
  - Interactive Preview of results in MPR, MIP or 3D



# *Stitching for Whole Body Imaging*

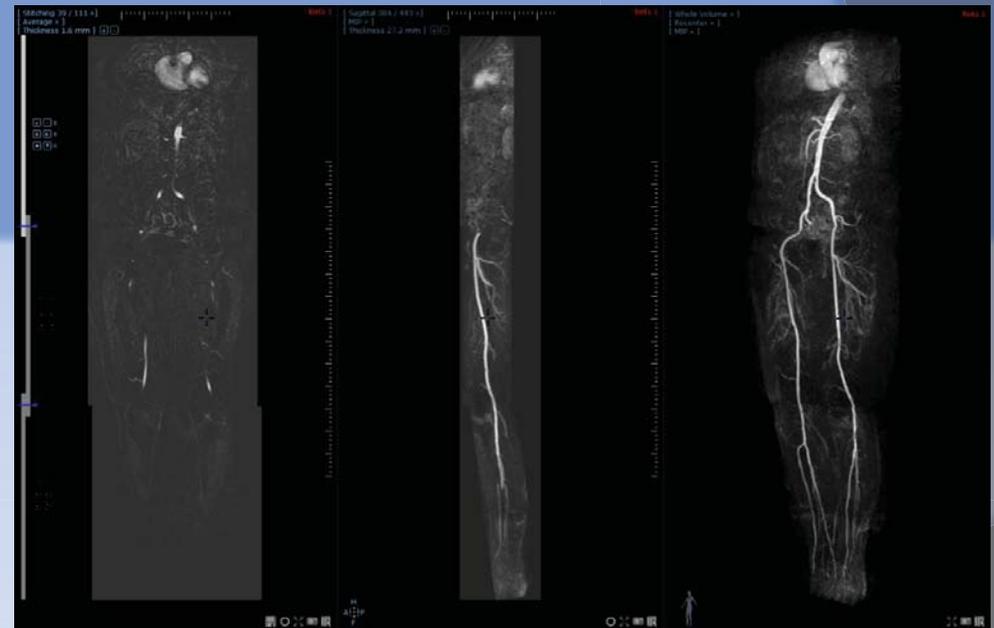
## Automatic post-processing

- Automatic Centering
- Automatic Slice localization

## Interactive Preview of Results

- in MPR, MIP or 3D

**Up to 6 series / Steps  
reconstruction ideal for whole  
body examinations**



Stitching

Coronal Plane

3D MIP

# *Stitching for Whole Body Imaging*

**Fully compatible with all types sequences, acquired in all orientations**

**One click for stitched series creation**

## **Re-Slicing :**

- is a unique reconstruction technique allowing to stitch multiples series with different tilting orientation
- Allows to reconstruct new images from series of different sizes (different number of slices) for acquisition time optimization

