

About Vital®

Medical Imaging Software

V i T A L

A Toshiba Medical Systems Group Company

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7,590,272; 7,660,481; 7,929,748; 7,991,210; 8,214,756; 8,249,687; 9,037,988 Other Patents Pending in the U.S. and other countries.
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This publication is valid for Vitrea® 6.7, VitreaAdvanced® 6.7, VitreaWorkstation® 6.7, Vitrea® fx 6.7, Vitrea® Enterprise Suite (VES) 6.7, VitreaCore 6.7, and VitreaView 6.5.9 and later version and later software versions.

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Table of Contents

Interpreting Symbols on the Product	5
Contact Vital Information	7
Partner Integration Information	9
Cedars-Sinai Medical Center	9
Medis Cardiac MR	10
MeVis Visia Dynamic Review	11
Mirada Medical	11
Olea Sphere	12
TomTec Imaging Systems	12
Product Availability by Location	13
Vitrear[®] Safe and Effective Use of Vital Medical Imaging Software	15
Vitrear Product Overview	15
Safety and Regulatory Considerations	16
Intended Use Statements	16
Caution Statements	29
General Safety Considerations	37
VitrearCore[™] Safe and Effective Use of Vital Medical Imaging Software	39
VitrearCore Product Overview	39
Safety & Regulatory Considerations	39
Intended Use Statements	40
Caution Statements	41
General Safety Considerations	47
Display Settings	47
VitrearView[®] Safe and Effective Use of Vital Medical Imaging Software	49
VitrearView Product Overview	49
Safety and Regulatory Considerations	50

VitreView Indications for Use51
Caution Statements52
General Safety Considerations55
Display Settings55

Interpreting Symbols on the Product

Symbol	Location	Description
	Help tab, Software DVD	Consult instructions for use
	Legal Page of Education and Reference Guides, Legal Page of Release Notes, Legal Page of Administration/ Installation Guides, Software DVD	Manufacturer Name and Address
	Legal Page of Education and Reference Guides, Legal Page of Release Notes, Legal Page of Administration/ Installation Guides, Software DVD	<p>Conformity assessment procedure according to directive 93/42/EEC</p> <ul style="list-style-type: none"> Annex V section 3.2 for manufacture of software for medical imaging applications Annex VII for design
	Legal Page of Education and Reference Guides, Legal Page of Release Notes, Legal Page of Administration/ Installation Guides	Indicates the Authorized Representative in the European Community
	Legal Page of Education and Reference Guides, Legal Page of Release Notes, Legal Page of Administration/ Installation Guides, Software DVD	Reference Number and Order Code of the product or document
	Within Education and Reference Guides, Release Notes, and Administration/ Installation Guides	Indicates the need to pay special attention to the information

Contact Vital Information

- For general, non-technical support questions, contact us through our Web site: 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.
- To provide feedback about this or other Vital Images product documentation, send an email to feedback@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.

Partner Integration Information

Medical imaging software from Vital Images can integrate with a variety of applications from partner vendors. Certain features or functions may vary from what is described in the partners' user guides, depending on how the application was integrated. These variances are most likely to occur in input/output features of the software.

Cedars-Sinai Medical Center

Cedars-Sinai Cardiac Suite is CE Marked to the Medical Device Directive 93/42/EEC.



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QFlow

European Regulations

QFlow is qualified as a class IIa medical device. It complies with the requirements of the Dutch Medical Devices Decree (Besluit Medische Hulpmiddelen, Stb. 243/1995) and the European Medical Device Directive 93/42/EEC.



0120

U.S. Regulations

QFlow has been cleared for market in the United States under the provisions of Section 510(k) of the Food, Drug, and Cosmetic Act by the FDA (Food and Drug Administration).

QMass MR

QMass MR is qualified as a class IIa medical device. It complies with the requirements of the Dutch Medical Devices Decree (Besluit Medische Hulpmiddelen, Stb. 243/1995) and the European Medical Device Directive 93/42/EEC.



0120

U.S. Regulations

QMass MR has been cleared for market in the United States under the provisions of Section 510(k) of the Food, Drug, and Cosmetic Act by the FDA (Food and Drug Administration).

MeVis Visia Dynamic Review



Manufacturer:

MeVis Medical Solutions AG
Caroline-Herschel-Str. 1
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Mirada Medical



In compliance with Council Directive 93/42/EEC.

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Year of CE Marking: 2012



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Product Availability by Location

Availability of products and features varies by geographic location. Contact your Vital Sales Representative or Customer Support for more information.

Vitreia[®] Safe and Effective Use of Vital Medical Imaging Software

This section contains:

- Vitrea Product Overview
- Safety and Regulatory Considerations

Vitreia Product Overview

With Vitrea, you can:

- Communicate with configured DICOM (Digital Imaging and Communications in Medicine) devices to retrieve and export patient data
- Preview images as acquired by the scanner, using the 2D Study Viewer feature
- Load one or multiple volumes for a patient
- Select from a gallery of predefined clinical viewing protocols
- Adjust visualization parameters to enhance images
- Review multiple image files in 2D, side-by-side views
- Measure regions of interest
- Locate and observe points of interest, using a mix of MPR (Multi-Planar Reformatted) 2D and 3D images
- Trim with 3D and 2D segmentation to focus images on regions of interest
- Fly through or around anatomical images

- Save snapshots highlighting regions of interest to a printable, Intranet-ready report
- Capture image sequences in batches to create printed reports or make Intranet-ready digital movies

Safety and Regulatory Considerations

PLEASE READ THIS SECTION CAREFULLY BEFORE USING VITREA.

This section contains information essential for the safe and effective use of Vitrea. You must understand this information before using Vitrea.

Intended Use Statements

Vitrea should not be used for purposes other than those indicated in the following intended use statements:

General

Vitrea® 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. Vitrea provides the ability to review digital images from original DICOM data for multiple modalities.

Vitrea is not meant for primary image interpretation in mammography.

Automated Vessel Measurements

Vitrea® Automated Vessel Measurements (AVM) is intended for the study/analysis of selected vessels for stenosis analysis, pre/post stent planning and directional vessel tortuosity evaluation.

Cedars-Sinai Medical Center Cardiac SPECT Suite (Powered by Cedars-Sinai)

The Cedars-Sinai Medical Center Cardiac Suite is intended to enable an automated display, review, and quantification of Nuclear Medicine Cardiology medical images and datasets. CSMC Cardiac Suite may be used in multiple settings including the hospital, clinic, doctors office, or remotely. The results provided should be reviewed by qualified healthcare professionals (e.g., radiologists, cardiologists, or general nuclear medicine physicians) trained in the use of medical imaging devices.

CT Body Perfusion 4D

Vitrea[®] CT Body Perfusion 4D is a noninvasive post-processing application designed to evaluate perfusion of organs and tumors. The software can calculate perfusion characteristics from dynamic CT image data acquired after the injection of contrast media. The software also allows the separate calculation of the arterial and venous components of perfusion in organs. It supports evaluation of regions of interest and the visual inspection of time density curves. When used by a trained and qualified physician a potential application is to differentiate blood flow between normal and diseased tissue. Determination of the change of perfusion parameters during the course of treatment may be helpful in therapy monitoring.

CT Brain Perfusion 4D

The Vitrea 4D CT Brain Perfusion option is intended for post processing based on dynamic CT images continuously acquired during the injection of contrast, for the visualization of apparent blood flow in brain tissue and pictorial illustration of perfusion-related parameters to aid in the assessment of the type and extend of cerebral perfusion disturbances.

CT Brain Perfusion

Vitrea[®] CT Brain Perfusion is a noninvasive post-processing application designed to evaluate areas of brain perfusion. The software can calculate cerebral blood flow (CBF), cerebral blood volume (CBV), local bolus timing (i.e., delay of tissue response, time to peak), and mean transit time (MTT)

from dynamic CT image data acquired after the injection of contrast media. The package also allows the calculation of regions of interest and mirrored regions, as well as the visual inspection of time density curves. Vitrea® CT Brain Perfusion supports the physician in visualizing the apparent blood perfusion in brain tissue affected by acute stroke. Areas of decreased perfusion, as is observed in acute cerebral infarcts, appear as areas of changed signal intensity (lower for both CBF and CBV and higher for time to peak and MTT).

CT Cardiac Analysis

Vitrea® Coronary Artery Analysis (CT Cardiac Analysis), which is intended for determining the presence and extent of coronary obstructive disease by providing a non-invasive survey of a patient's coronary arteries. Clinicians can select any coronary artery to view the following anatomical references: the highlighted vessel in 3D, two rotatable curved MPR vessel views displayed at 90 degree angles to each other, and cross sections of the vessel. The clinician can semi automatically determines contrasted lumen boundaries, stenosis measurements, and maximum and minimum lumen diameters. In addition, clinicians can edit lumen boundaries and examine Hounsfield unit statistics.

CT EP Planning

Vitrea® Cardiac EP Planning is a post processing advanced visualization application that is intended to be used for the analysis and assessment of the heart including the atria, pulmonary veins, and coronary sinus. The application provides analysis tools which include a number of display, quantitative measurement, and 3D model export capabilities for use with the St. Jude Ensite® System. The application can be used to aid trained physicians in the visualization and assessment of cardiac anatomy.

CT Cardiac Functional Analysis (CFA)

Vitrea® CT CFA option is intended to be used with CT studies of the heart to assist cardiologists and radiologists in assessing function when producing a cardiac evaluation. The CFA option includes semi-automatic heart and left ventricle segmentation, including identification of long axis

and mitral valve boundaries across multiple phases; calculation of global metrics, including end diastolic volume, end systolic volume, stroke volume, ejection fraction, cardiac output, cardiac index, stroke index, and myocardial mass; and calculation of regional metrics; including wall motion, percentage of wall thickening, regional ejection fraction, and polar plots.

CT Multi-Chamber Cardiac Functional Analysis (CFA)

The Vitrea® CT Multi-Chamber CFA option is intended to be used with CT studies of the heart to assist cardiologists and radiologists in assessing function when producing a cardiac evaluation. The CT Multi-Chamber CFA option includes semi-automatic heart segmentation including three chambers (left ventricle, right ventricle, and left atrium) segmentation, including identification of long axis and mitral valve boundaries across multiple phases; calculation of global metrics, including end diastolic volume, end systolic volume, stroke volume, ejection fraction, cardiac output, cardiac index, stroke index, and myocardial mass; and calculation of regional metrics; including wall motion, percentage of wall thickening, regional ejection fraction, and polar plots.

CT Colon Analysis

Vitrea® CT Colonography (CT Colon Analysis) option is intended for closely examining the lumen of the colon using features such as auto-segmentation, axial imaging, multiplanar reformatting, fly-through, simultaneous display of prone and supine images, and transparent wall view.

CT Endovascular Stent Planning (EVSP)

The CT Endovascular Stent Planning software application is intended for use with CT (computed tomography) images to assist medical professionals in the analysis, treatment and follow-up of aortic vascular disorders that may require a stent procedure. The software performs 3D segmentation of the aorta and initializes stent measurements based on a template provided by the stent manufacturers. The user can review the

2D and 3D images, verify and correct the results of the segmentation and initialization, and generate a report with the stent measurements.

CT Liver Analysis

CT Liver Analysis is a noninvasive post-processing application designed to evaluate liver tumors and plan for liver surgery. It displays images for analysis and preoperative liver surgery planning, such as organ segmentation, tumor segmentation and intra hepatic vessels segmentation, as well as the approximation of vascular territories. It supports preoperative evaluation of specific surgery strategies by allowing the user to interactively define virtual resections splitting the liver. It also allows the user to evaluate safety-margins around lesions and to identify affected vascular branches and territories. Vitrea® CT Liver Analysis also provides automatic registration of multiple series and measurement tools for characterization and follow-up of the lesions. When used by a trained and qualified physician a potential application is to assist in the assessment of tumor response to therapy.

CT Lung Density Analysis (Not Available in the United States)

CT Lung Density Analysis is intended for the review and analysis of thoracic CT images for the purposes of characterizing lung tissue in a single study, or over the time course of several thoracic studies. Characterizations include density and volume. The system performs the measurements, allowing lung tissue and measurements to be displayed.

CT Lung Analysis

CT Lung Analysis is intended for the review and analysis of thoracic CT images for the purposes of characterizing nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.

CT Myocardial Perfusion

Vitreia CT Myocardial Perfusion is intended to assist a trained user for the visualization of hypo/hyper dense areas in patients with angina or with a previous myocardial infarction to assess the disease state and treatment. This software provides semi-automated heart and left ventricle segmentation and color polar maps of the myocardial tissue.

The information provided is intended to be qualitative in nature and, when used by a qualified physician, may aid in the identification of myocardial enhancement defects and the follow up of such findings.

CT Transcatheter Aortic Valve Replacement (TAVR)

Vitreia CT Transcatheter Aortic Valve Replacement (TAVR) Planning is a non-invasive post-processing application designed to assist medical professionals with the assessment of the aortic valve and in pre-operational planning and post-operative evaluation of transcatheter aortic valve replacement procedures.

Vitreia CT Transcatheter Aortic Valve Replacement (TAVR) Planning includes general functionality such as:

- The software processes CT (computed tomography) image data to provide 3D segmentation of heart structures and vessels relevant to approach planning.
- The user can review the 2D and 3D images to select and plan the delivery path.
- The user can determine C-arm angles for use during the procedure.
- The user can verify and adjust the results of segmentation and cross-section measurements.
- The software provides visualization techniques such as volume rendering, MIP, MPR and curved MPR.
- The user can identify and edit contours and the centerline automatically or manually.
- The user can generate a report with relevant approach planning data and measurements for device sizing.
- The software can provide visualization of calcium.

- The user can generate tortuosity calculations along a centerline.

CT VScore™

The Vitrea® VScore™ option is intended for cardiac scoring from whole body CT derived measurements, including non-invasive detection and quantification of atherosclerotic plaque. Two image processing options, EKG Gate and Auto Gate, allow the operator to select images with reduced motion artifacts when processing data for Coronary Artery Calcification Scoring.

General Vessel Probe

The separately-licensed general Vessel Probe option is intended for determining the presence and extent of peripheral vascular obstructive disease by providing a non-invasive survey of a patient's peripheral arteries. Clinicians can select any artery to view the following anatomical references: the highlighted vessel in 3D, two rotate-able curved MPR vessel views displayed at angles orthogonal to each other, and cross sections of the vessel. Cross-sectional measurements can be obtained using standard Vitrea software measuring tools. Clinicians can manually measure the lumen width to obtain percentage stenosis calculations, based on a ratio of the smallest to the largest diameter. In addition, clinicians can manually measure vessel length along the centerline in standard curved MPR views and examine Hounsfield unit or signal intensity statistics.

iCAD® VeraLook CT Colon CAD (Manufactured by iCAD, Inc.)

VeraLook CTC CAD Software is intended to automatically detect potential polyps in CT Colonography exams. The identified polyps can then be highlighted to the interpreting physician after initial review of the CTC exam with the intent of identifying additional potential polyps that may not have been identified on initial review.

Image Denoising

Vitreva[®] Image Denoising software is intended to assist radiologists and specialists in the enhancement of CT and 3D XA image presentation by enabling noise reduction and contrast enhancement technique.

Medicsight ColonCAD™ (Manufactured by Medicsight Ltd.) (No Longer Available for Sale)

The Medicsight ColonCAD™ API device is a computer-aided detection (CAD) tool designed to assist radiologists and other clinicians in searching for and segmenting polyps within the colon during review of multi-detector CT Colonography (CTC) examinations.

It is intended that ColonCAD™ be employed as an adjunct tool to alert the user to regions of interest (ROI) that may have been overlooked during review. ColonCAD™ can be used in either a “second read” paradigm – where the CAD is applied after the user has completed their initial read – or a “concurrent read” paradigm – where the user can view the CAD findings at the same time as they perform a review of the entire colon.

When used by a skilled physician, this software provides information that may be useful in interpreting studies for both symptomatic and asymptomatic patients. Patient management decisions should not be made solely on the results of ColonCAD™ analysis.

It is essential that the radiologist examines all images in the CT examination, not only the images with identified objects.

Medis[®] Cardiac MR - QMass[®] and QFlow[®] (Manufactured by Medis Medical Imaging Systems BV)

QMass[®]

MASS, including its option, has been developed for the objective and reproducible analysis of multi-slice, multi-phase left and right ventricular function from cardiac MR data sets. The software enables the display of images for use by trained medical personnel.

Intended purposes are:

- supporting clinical diagnoses about the status of the global and regional function and anatomy of the cardiac chambers;
- supporting the subsequent clinical decision making processes;
- supporting use in clinical research trials, directed at studying changes in function and anatomy of the heart chambers as a result of interventions.

QFlow®

FLOW has been developed for the objective and reproducible analysis of velocity-encoded cine MR imaging studies of arterial vessels and heart valves. Intended purposes are:

- supporting clinical diagnoses about the status of the function of the cardiac chambers;
- supporting clinical diagnoses about the flow velocity and volume flow through cardiac and peripheral vessels, both under basal and increased flow conditions;
- supporting subsequent clinical decision making purposes;
- supporting the use in clinical research trials, directed at studying changes in the function of the heart chambers and in the flow through cardiac and peripheral vessels a a result of interventions.

Medis Cardiac MR - Medis QPlaque® MR (Manufactured by Medis Medical Imaging Systems BV)

The QPlaque MR software performs quantitative analyses of the vessel wall and of plaque components in MR studies of atherosclerotic arteries. The quantitative analyses are based on semi-automatic segmentation of the MR studies. QPlaque quantifies vessel wall and plaque volumes, determines vessel wall thickness, thickness of the fibrous cap, and characterizes the plaque components.

Mirada® Medical RTx

RTx is intended to be used by trained medical professionals including, but not limited to, radiologists, nuclear medicine physicians, radiation oncologists, dosimetrists and physicists.

RTx is a software application to display and visualize 2D & 3D multi-modal medical image data. The user may process, render, review, store, print and distribute DICOM 3.0 compliant datasets within the system and/or across computer networks. Supported modalities include static and gated CT, PET, MR and SPECT. The user may also create, display, print, store and distribute reports resulting from interpretation of the datasets.

RTx allows the user to register combinations of anatomical and functional images and display them with fused and non-fused displays to facilitate the comparison of image data by the user. The result of the registration operation can assist the user in assessing changes in image data, either within or between examinations and aims to help the user obtain a better understanding of the combined information that would otherwise have to be visually compared disjointedly.

RTx provides a number of tools such as rulers and region of interests, which are intended to be used for the assessment of regions of an image to support a clinical workflow. Examples of such workflows include, but are not limited to, the evaluation of the presence or absence of lesions, determination of treatment response and follow-up.

RTx supports the loading and saving of DICOM RT objects and allows the user to define, import, display, transform, store and export such objects including regions of interest structures, isocenters and dose volumes to radiation therapy planning systems. RTx allows the user to transform regions of interest associated with a particular imaging dataset to another, supporting atlas-based contouring and rapid re-contouring of the same patient.

Mirada Medical XD3

XD3 is intended to be used by trained medical professionals including, but not limited to, radiologists, nuclear medicine physicians, and physicists.

XD3 is a software application intended to display and visualize 2D & 3D multi-modal medical image data. The user may process, render, review, store, print and distribute DICOM 3.0 compliant datasets within the system and/or across computer networks. Supported modalities include, static and gated CT and PET, and static MR, SPECT and planar NM. The

user may also create, display, print, store and distribute reports resulting from interpretation of the datasets.

XD3 allows the user to register combinations of anatomical and functional images and display them with fused and non-fused displays to facilitate the comparison of image data by the user. The result of the registration operation can assist the user in assessing changes in image data, either within or between examinations and aims to help the user obtain a better understanding of the combined information that would otherwise have to be visually compared disjointedly.

XD3 provides a number of tools such as rulers and region of interests, which are intended to be used for the assessment of regions of an image to support a clinical workflow. Examples of such workflows include, but are not limited to, the evaluation of the presence or absence of lesions, determination of treatment response and follow-up.

XD3 allows the user to define, import, transform and store and export regions of interest structures and dose volumes in DICOM RT format for use in radiation therapy planning systems.

Olea Sphere (Manufactured by Olea Medical)

Olea Sphere is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities.

Olea Sphere provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities; including a Diffusion Weighted MRI (DWI) / Fiber Tracking Module and a Dynamic Analysis Module (dynamic contrast enhanced imaging data for MRI and CT).

The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. The Fiber Tracking feature utilizes the directional dependency of the diffusion to display the white matter structure in the brain or more generally the central nervous system.

The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time where such techniques are useful or necessary. This functionality is referred to as:

Perfusion Module – the calculation of parameters related to tissue flow (perfusion) and tissue blood volume.

Permeability Module – the calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space.

Softread

Softread 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.

SUREPlaque™

The SUREPlaque™ software application is intended to assist trained physicians in the stratification of patients identified to have atherosclerosis. This software post processes images obtained using a multi-detector CT. The application provides tools for the measurement and visualization (color coded maps) of arterial vessels.

TomTec-Arena™ (Manufactured by TomTec Imaging Systems GmbH)

TomTec-Arena software is a clinical software package designed for review, quantification and reporting of structures and function based on multi-dimensional digital medical data acquired with different modalities.

TomTec-Arena is not intended to be used for reading of mammography images.

Indications for use of TomTec-Arena software are diagnostic review, quantification and reporting of cardiovascular, fetal and abdominal structures and function of patients with suspected disease.

Visia™ CT Lung CAD (Manufactured by MeVis® Medical Solutions, Inc)

Visia™ CT Lung CAD automatically detects actionable lung nodules, not just round objects or regions of interest. The system highlights nodules 4 mm to 30 mm in size, to focus attention on nodules that are most significant. Sophisticated volumetric segmentation excludes normal anatomy and detects nodules based on size, shape, density, and anatomical context. All nodule measurements are available to help support clinical decisions.

The AutoPoint™ temporal comparison tool consists of software that enables physicians to view, analyze, register and compare new and previous series of thoracic CT images. The software assists the physicians by calculating volume change and doubling time of selected segmented candidate thoracic abnormalities (such as pulmonary and pleural nodules and lesions) found on these images.

The software is designed to assist the radiologist in characterization and classification of these suspicious candidate thoracic abnormalities in terms of size, dimension, shape and position and thus aid in the patient management care decision process.

Visia™ Dynamic Review (Manufactured by MeVis Medical Solutions, Inc.)

Visia™ Dynamic Review is a software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies. Visia™ Dynamic Review supports evaluation of dynamic MR data.

Visia™ Dynamic Review automatically registers serial patient motion to minimize the impact of patient motion and visualizes different enhancement characteristics (parametric image maps). Furthermore, it performs other user-defined post-processing functions such as image subtractions; multi-planar reformats and maximum intensity projections. The resulting information can be displayed in a variety of formats, including a parametric image overlaid onto the source image. Visia™ Dynamic Review can also be used to provide measurements for diameters, areas and volumes. Furthermore, Visia™ Dynamic Review can evaluate the uptake characteristics of segmented tissues.

Visia™ Dynamic Review also displays images from a number of other imaging modalities; however, these images must not be used for primary diagnostic interpretation.

When interpreted by a skilled physician, Visia™ Dynamic Review provides information that may be useful in diagnosis. Patient management decisions should not be made based solely on the results of Visia™ Dynamic Review analysis.

Vitrear® CT Fat Measurement (Not Available in the United States)

Vitrear® CT Fat Measurement Application is a noninvasive post-processing application designed to isolate and quantify subcutaneous and visceral fat.

Caution Statements



General

- Federal law (USA) restricts this device to sale by, or on the order of, a physician.
- This product is intended for use only by appropriately qualified and trained personnel.
- This product is intended for use only as a supplement to standard methods of interpreting radiological images. It should not be exclusively relied upon for arriving at a diagnosis, treatment plan, or other decision that may affect patient care.
- Vital Images assumes no liability for problems attributable to unauthorized modifications, additions, or deletions to this product, or unauthorized installation of third-party software.
- Select slice thickness and slice spacing in image acquisition so that details of diagnostic interest are not lost due to too large interslice spacing. Keep in mind that the inherent limitations of scan slice thickness set the ultimate available resolution limit.

- As with any medical imaging process, you must be fully conversant with the limitations of the basic imaging modality and of ensuing image processing. This includes understanding the limitations of the initial series acquisition, image processing technology used, and image display methods. Also, be aware that medical imaging is valid only when appropriate measures have been taken to obtain optimal images with correct orientation and correct patient identifiers.
- For accurate and reliable 3D reconstructions, the following criteria must be met:
 - Interslice distance cannot exceed 10 mm.
 - Identical field of view and display center must be used for all images in the scanned series.
- The radiologic technologist must enter accurate orientation information at the scanner console for each series. If not, Vitrea will display incorrect orientation labels for the volume.
- In some protocols, Vitrea uses DICOM information for calculations. To ensure the most accurate calculations, be sure to enter DICOM information completely and correctly.
- It is essential that you read, understand, and follow the directions for loading a study or volume. Incorrect loading procedures could cause errors in image orientation, scaling, or measurements.
- Always verify patient information and DICOM headers to ensure the correct patient study is loaded.
- Before saving, editing, or reviewing the patient data, ensure that the contents correspond to the patient name. This provides additional assurance that the stored data correspond to the correct patient.
- When launching from Vitrea to a partner-integrated software, review patient information to verify correct patient study is loaded.
- Always use best professional judgment when viewing Vitrea images. Do not use for diagnosis or planning if you notice improper or unexpected images.
- The limitations of three-dimensional (3D) image processing are similar to the limitations of 2D imaging. For example, small pathologies may go undetected because the interslice distance is too great relative to

the size of the pathology. You must keep this limitation in mind when viewing 3D images. The creation of a 3D image using interpolation of data points between image slices based on the original image can create a smooth-looking 3D image. Just as with 2D images, the user must interpret the apparent lack of pathology in the context of the inherent limitation in the resolution of the original slice images as scanned.

- It is always possible, however unlikely, for incorrect images to be rendered or for images to be misinterpreted leading to a possible error in diagnosis or treatment plan. For this reason, it is essential that the user always verifies the correct protocol and views are loaded for each series. Possible causes of incorrect image rendering are algorithm failure, incorrect render settings, or incorrect information displaying in an image series header.
- For a series to be rendered properly, and for effective diagnostic viewing, it is essential that correct information displays in the image series header. For these reasons, it is essential the user always verifies the correct protocol and views have been loaded for each series. Incorrect information in the image series header may cause the following hazards:
 - Incorrect protocol and/or view selection, leading to error or delay in diagnosis or treatment plan.
 - Image reversal, causing misinterpretation of anatomical locations.
 - Dimensional error, leading to incorrect dimension measurement, possibly causing you to misjudge the size of anatomical structures.
 - Threshold error, causing processed images to contain less detail than the original images.
 - Transparency error, rendering key image areas transparent.



Vitreia Features

- Always verify the accuracy of any software-generated segmentation. Perform manual segmentation if automatic segmentation is incorrect.

- Always verify the accuracy of software-generated contours and centerlines. Edit contours and centerlines as necessary.
- After editing segmentation, contours, or centerlines, review the results to verify the Vitrea applied the edits correctly.
- It is possible, when adjusting the view, to reorient the volume so that its position no longer corresponds to the original orientation. You should interpret the relative positions of objects within the volume accordingly.
- It is possible, when adjusting the image, to partially or completely remove features from the screen image (but not from the original volume stored on disk).
- It is possible, when taking a snapshot of an image, to save an image in which features have been partially or completely removed. For example: When you rotate a 3D volume using the mouse, a reduced resolution image momentarily replaces the fully rendered volume. This image, in the same shape as your volume, allows you to retain your frame of reference as you position the volume. When you release the mouse, the fully rendered volume redisplay in the new orientation. If you want to take a snapshot, make sure the image has finished rendering before you take the snapshot.
- When restoring a snapshot, the software will, the majority of the time, restore the study to the workflow state at the time it was taken. However, there are some conditions in which the workflow cannot be restored exactly. Therefore, it is important to always review the images after a restored snapshot to verify the workflow has restored properly. It is also important to confirm clinically-relevant information that was restored with the snapshot.

Below are some examples where the workflow may not restore exactly as expected:

- It is possible to restore a snapshot associated with multiple volumes with too many, too few, or incorrect volumes loaded. Doing so may yield different results than the original calculations. The 'results' to which this warning refers are Vitrea-generated measurements or calculations, such as cardiac functional

measurements. If the workflow you are restoring does not include these types of measurements, the caution about differing results does not apply. However, it is generally not advisable to restore a multi-volume workflow if you cannot load ALL associated volumes.

- After upgrading to a new version of software, restoring snapshots may result in slightly different calculations than in the original snapshot, as the underlying infrastructure or algorithms may have been changed. The snapshots usually only store the inputs to complex calculations, and those calculations are re-run during snapshot restore.
- When restoring a snapshot on a system with a different screen resolution than when the snapshot was taken, some annotations or measurements may not be visible because they are dependent on the original screen resolution. Any annotations or measurements that do not restore will need to be recreated.
- If you create a snapshot, and then make edits that affect the findings included on the snapshot, be sure to create a new snapshot with the new findings.
- It is possible to render key image areas too transparent using the Transparency settings on the Viewer window. This could make key image areas, such as pathology, invisible, leading to misdiagnosis.
- It is possible to incorrectly or unknowingly modify rendering parameters. This could create threshold errors, which cause processed images to contain less detail than the original images, leading to possible misdiagnosis.
- Accuracy in measurements of lengths and angles, and of 2D and 3D regions of interest, depends on a number of factors. The accuracy of these measurements depends on the accuracy of the scale factors that describe the image resolution and the spacing between source images. The recommended method for performing linear measurements is through the placement of the ruler(s) in 2D images. If 3D is the method of choice for linear measurements, all ruler endpoints and angles need to be double-checked in multiple views to ensure proper placement on ruler endpoints. 3D measurements are reserved for surface and volumetric measurements.

- It is your responsibility to determine if the results of measurements are satisfactory. To reduce the margin of error introduced when you create measurements:
 - Pay attention to the zoom factor you apply to the image. The more you zoom in on the image before creating the measurement, the more accurate the measurement will be.
 - Adjust window/level and other visualization settings to achieve the best possible view of the ROI before you create the measurement.
 - Draw contour lines around the ROI as accurately as possible.
 - Place ruler endpoints as precisely as possible, exactly where you want them to display on the image.
 - Whenever possible, create measurements on the acquisition orientation of the image. The acquisition axis typically has the highest resolution and therefore contributes the smallest percentage of error.
 - Perform linear measurements on 2D or MPR views only. Measurements in 3D views are reserved for surface area and volume.
- Also, 3D volumetric measurements for MR studies are not as accurate as those calculated for CT studies, for the following reason:
 - When measuring 3D volumes, once Vitrea calculates the volumetric measurement, the measurement is no longer related to the defined contour lines.
 - For CT studies, you can achieve a more accurate volumetric measurement because you can adjust the window/level settings for the 3D volume so the structures you want to measure are visible. Because MR acquisition resolution varies, it is difficult to adjust the window/level of the MR volume so that all of a particular anatomy type is visible.
- When the Viewer window is in Crosshair mode, it displays the voxel density value in Hounsfield units (HU) at the intersection of the crosshairs. It is possible that the value displayed could be incorrect, due to a software error in the scanner or in Vitrea. Do not base any

decisions that affect patient welfare solely on the data HU values displayed.

- When using the Undo/Redo function, verify that Vitrea undid or redid the action appropriately. Not all features support the Undo/Redo function.
- When printing a posted report from the Review window browser, images may not have the same detail or exact colors as the images would if you printed them from the Report window.
- When creating a report or dictation table, verify all tables, graphs, measurements and other findings from the Viewer window are appropriately displayed.
- Reports can be sent to PACS (Picture Archiving and Communications Systems), other Vitrea workstations, or other storage devices by using the DICOM Export feature on the Vitrea Report window. Images in a Vitrea report are sent as a primary DICOM or secondary DICOM capture, depending on how they were created in Vitrea. Taking measurements (HU readings or dimensional rulers) and performing other similar operations on PACS or other devices on secondary capture images will not yield accurate results.
 - If you include images from more than one volume for the same patient in a report, the report headings, if any, will identify the images you loaded most recently. It may be important to identify which images are associated with which volume.

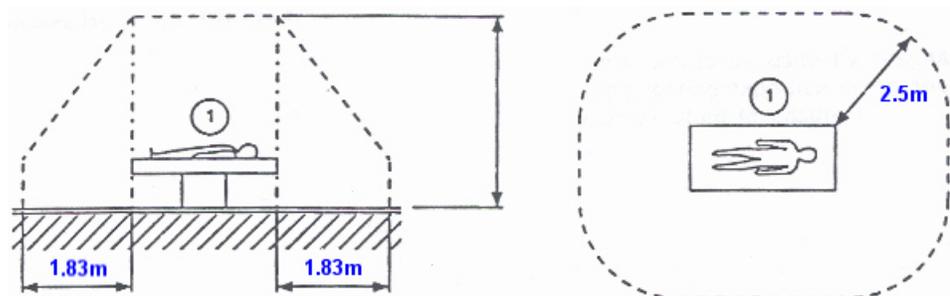


Hardware and Safety

- Some computer monitors (computer screen, CRT) are unshielded. Do not place the monitor, whether in its shipping carton or unpacked, inside the 1.3 Gauss line of any Magnetic Resonance Imaging (MRI) magnet. Exposure to this strength of magnetic field will permanently damage the monitor and may void the manufacturer's warranty. Assume all monitors, regardless of the manufacturer or source, are unshielded unless the manufacturer specifically states otherwise.

- The Vitrea workstation uses 24-bit color resolution or 8-bit grayscale resolution, which is lower than that of radiologic film. The user must use professional judgment at all times when interpreting images that may be influenced by resolution level.
- You must have enough random access memory (RAM) on your workstation. If you do not have sufficient memory, you may experience a significant decrease in system performance or even a system crash. It is important to provide enough memory to work with--more than the anticipated maximum size for a volume. If you think you are experiencing low memory issues, contact your System Administrator or Vital Images.
- Do not use the Vitrea workstation if any unsafe condition exists. If the hardware fails, resulting in a hazardous condition such as smoke or fire, turn off the power to the hardware and unplug the monitor and CPU. Do not use the equipment if a malfunction takes place. Contact your System Administrator or Vital Images to correct any malfunctions before proceeding.
- If the Vitrea screen goes blank or the system locks up at any time while you are using it, it could disrupt the interpretation of an image. Should this occur, be sure to restart Vitrea.
- Do not install the Vitrea workstation within six feet of a patient area. Patient vicinity is defined in Medical Electrical Equipment - Safety Requirements for Medical Electrical Systems (IEC 601-1-1), as 'any volume in which intentional or unintentional contact between the PATIENT and any parts of the SYSTEM or some other persons touching parts of the SYSTEM can occur'. See the following diagram for clarification:

FIGURE 1. **Patient Vicinity Diagram**



General Safety Considerations

The Vitrea software and its computer platform constitute the Vitrea workstation. The Vitrea workstation is a sophisticated combination of software and hardware.

The Vitrea workstation is intended to be used by the following individuals:

- Physicians
- Radiologic technologists
- Other medical personnel under a physician's supervision

Keep the electronic copy of this manual on your workstation. Review the Vitrea operating instructions on a regular basis, paying special attention to Caution statements and Notes.

Refer to the instruction manuals for your specific computer hardware and for any other system software for additional safety information.

It is your responsibility to limit access to patient data to authorized individuals. Access control can be achieved by physical security measures (locking systems), by software-based password security systems, or both. If you have questions, contact your System Administrator or Vital.

VitreCore™ Safe and Effective Use of Vital Medical Imaging Software

- VitreaCore Product Overview
- Safety & Regulatory Considerations

VitreCore Product Overview

VitreCore™ is a Web-based medical diagnostic aid that allows physicians to gain remote access to 2D and 3D advanced visualization. The software enables users to measure, rotate, and analyze images. VitreaCore includes a collaboration mode that enables multiple physicians in different locations to confer while interacting with the same images in real time.

Safety & Regulatory Considerations

READ THE TOPICS IN THIS SECTION CAREFULLY BEFORE USING THE SOFTWARE.

This section contains information essential for the safe and effective use of the VitreaCore system. You must understand this information before using the product.

Intended Use Statements

The VitreaCore system is a medical diagnostic software system intended to process, analyze, review, and distribute multi-dimensional digital images acquired from a variety of imaging devices including: CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc.

VitreaCore is not meant for primary image interpretation in mammography.

In addition, the VitreaCore system has the following specific intended uses:

CT Cardiac Analysis

Vitrea® Coronary Artery Analysis (CT Cardiac Analysis), which is intended for determining the presence and extent of coronary obstructive disease by providing a non-invasive survey of a patient's coronary arteries.

Clinicians can select any coronary artery to view the following anatomical references: the highlighted vessel in 3D, two rotatable curved MPR vessel views displayed at 90 degree angles to each other, and cross sections of the vessel. The clinician can semi automatically determines contrasted lumen boundaries, stenosis measurements, and maximum and minimum lumen diameters. In addition, clinicians can edit lumen boundaries and examine Hounsfield unit statistics.

General Vessel Probe

The separately-licensed general Vessel Probe option is intended for determining the presence and extent of peripheral vascular obstructive disease by providing a non-invasive survey of a patient's peripheral arteries. Clinicians can select any artery to view the following anatomical references: the highlighted vessel in 3D, two rotate-able curved MPR vessel views displayed at angles orthogonal to each other, and cross sections of the vessel. Cross-sectional measurements can be obtained using standard Vitrea software measuring tools. Clinicians can manually measure the lumen width to obtain percentage stenosis calculations, based on a ratio of the smallest to the largest diameter. In addition, clinicians can manually measure vessel length along the centerline in

standard curved MPR views and examine Houndsfield unit or signal intensity statistics.

Caution Statements

General

- Federal law (USA) restricts this device to sale by, or on the order of, a physician.
- This product is intended for use only by appropriately qualified and trained personnel.
- This product is intended for use only as a supplement to standard methods of interpreting radiological images. It should not be exclusively relied upon for arriving at a diagnosis, treatment plan, or other decision that may affect patient care.
- Vital Images assumes no liability for problems attributable to unauthorized modifications, additions, or deletions to this product, or unauthorized installation of third-party software.
- Always use best professional judgment when viewing VitreaCore images. Do not use for diagnosis or planning if you notice improper or unexpected images.
- Always verify patient information and DICOM headers to ensure the correct patient study is loaded.
- Select slice thickness and slice spacing in image acquisition so that details of diagnostic interest are not lost due to the interslice spacing being too large. Keep in mind that the inherent limitations of scan slice thickness set the ultimate available resolution limit.
- As with any medical imaging process, you must be fully conversant with the limitations of the basic imaging modality and of ensuing image processing. This includes understanding the limitations of the initial series acquisition, image processing technology used, and image display methods. Also, be aware that medical imaging is valid only when appropriate measures have been taken to obtain optimal images with correct orientation and correct patient identifiers.

- For accurate and reliable 3D reconstructions, the following criteria must be met:
 - Interslice distance cannot exceed 10 MM.
 - Identical field of view and display center must be used for all images in the scanned series.
- The radiologic technologist must enter accurate orientation information at the scanner console for each series. If not, the system will display incorrect orientation labels for the volume.
- It is essential that you read, understand, and follow the directions for Loading Studies. Incorrect loading procedures could cause errors in image orientation, scaling, or measurements.
- The limitations of three-dimensional (3D) image processing are similar to the limitations of 2D imaging. For example, small pathologies may go undetected because the interslice distance is too great relative to the size of the pathology. You must keep this limitation in mind when viewing 3D images. The creation of a 3D image using interpolation of data points between image slices based on the original image can create a smooth-looking 3D image. Just as with 2D images, the user must interpret the apparent lack of pathology in the context of the inherent limitation in the resolution of the original slice images as scanned.
- It is always possible, however unlikely, for incorrect images to be rendered or for images to be misinterpreted leading to a possible error in diagnosis or treatment plan. For this reason, it is essential that the user always verifies that the correct protocol and views are loaded for each series. Possible causes of incorrect image rendering are algorithm failure or incorrect information appearing in an image series header.
- For a series to be rendered properly, and for effective diagnostic viewing, it is essential that correct information appear in the image series header. For these reasons it is essential that the user always verifies the correct protocol and views have been loaded for each series. Incorrect information in the image series header may cause the following hazards:

- Incorrect protocol and/or view selection, leading to error or delay in diagnosis or treatment plan.
- Image reversal, causing misinterpretation of anatomical locations.
- Dimensional error, leading to incorrect dimension measurement, possibly causing you to misjudge the size of anatomical structures.
- Threshold error, causing processed images to contain less detail than the original images.
- Transparency error, rendering important image areas transparent.



VitreCore Features

- While using the VitreaCore system, you are responsible for associating an electronic report with a specific patient/study. To make sure that the correct patient/study is associated with the report, you must compare the patient on the Patient List tab to the patient/study named in the report.
- It is possible to begin image processing while slices are still downloading from the server. To ensure that the volume is rendered from the full number of slices, check the number of images on the Patient List tab before you start processing.
- While the image is loading, the image quality is lower than the system default. The Updating image... message displays while the image is loading. To ensure you are viewing an image at the specified image quality, wait for this message to disappear.
- It is possible, when adjusting the view, to reorient the volume so that its position no longer corresponds to the original orientation. You should interpret the relative positions of objects within the volume accordingly.
- It is possible, when adjusting the image, to partially or completely remove features from the screen image (but not from the original volume stored on disk).
- It is possible, when taking a snapshot of an image, to save an image in which features have been partially or completely removed. For

example: When you rotate a 3D volume using the mouse, a reduced resolution image momentarily replaces the fully rendered volume. This image, in the same shape as your volume, allows you to retain your frame of reference as you position the volume. When you release the mouse button, the fully rendered volume displays in the new orientation. If you want to save an image, make sure the image has finished rendering before you save it.

- It is possible to render important image areas too transparent using the Opacity/Threshold slider on the Viewer window. This could make areas of an image containing pathology invisible, leading to misdiagnosis.
- It is possible to incorrectly or unknowingly modify rendering parameters. This could create threshold errors, which cause processed images to contain less detail than the original images, leading to possible misdiagnosis.
- Accuracy in measurements of lengths and angles, and of 2D and 3D regions of interest, depends on a number of factors. The accuracy of these measurements depends on the accuracy of the scale factors that describe the image resolution and the spacing between source images. The recommended method for performing linear measurement is through the placement of the ruler(s) in 2D images. If 3D is the method of choice for linear measurements, all ruler endpoints and angles need to be double-checked in multiple views to ensure proper placement on ruler endpoints.
- It is your responsibility to determine if the results of measurements are satisfactory. To reduce the margin of error introduced when you create measurements:
 - Pay attention to the zoom factor you apply to the image. The more you zoom in on the image before creating the measurement, the more accurate the measurement will be.
 - Adjust window/level and other visualization settings to achieve the best possible view of the ROI before you create the measurement.
 - Draw contour lines around the ROI as accurately as possible.
 - Place ruler endpoints as precisely as possible, exactly where you want them to display on the image.

- Whenever possible, create measurements on the acquisition orientation of the image. The acquisition axis typically has the highest resolution and therefore contributes the smallest percentage of error.
- Perform linear measurements on 2D or MPR views only.
- When using the Undo/Redo function, verify that VitreaCore undid or redid the action appropriately. Not all features support the Undo/Redo function.
- If you export images to a DICOM image server, the exported images may not have the same detail as the original scanned images, and it is possible (though extremely unlikely) that the exported series will not have the same detail as the original series.
- Images can be sent to PACS (Picture Archiving and Communications Systems), other workstations, or other storage devices. Images are sent as a primary DICOM or secondary DICOM capture, depending on how they were created. Taking measurements (HU readings or dimensional rulers) and performing other similar operations on secondary capture images on PACS or other devices will not yield accurate results.

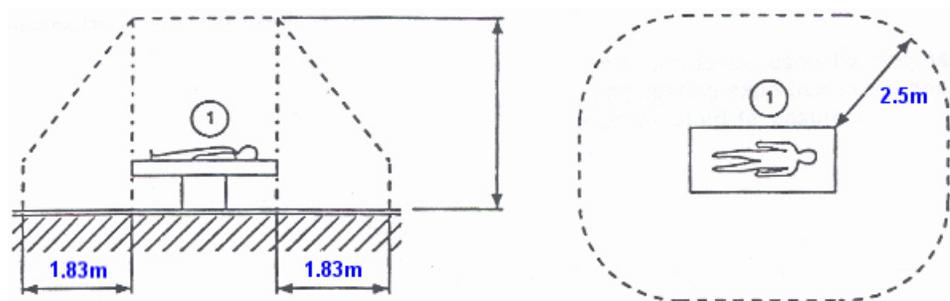


Hardware and Safety

- Some computer monitors are unshielded. Do not place the monitor, whether in its shipping carton or unpacked, inside the 1.3 Gauss line of any Magnetic Resonance Imaging (MRI) magnet. Exposure to this strength of magnetic field will permanently damage the monitor and may void the manufacturer's warranty. Assume all monitors, regardless of the manufacturer or source, are unshielded unless the manufacturer specifically states otherwise.
- Most monitors and PCs use 24-bit color resolution or 8-bit greyscale resolution, both of which are lower than that of radiologic film. You must use professional judgment at all times in interpreting images that may be influenced by resolution level.

- The client PC must have a minimum amount of random access memory (RAM) to run the software. If the PC does not have sufficient RAM, you may experience a significant decrease in performance. It is important to provide enough memory to work with -- more than the anticipated maximum size for a volume. If you think you are experiencing low memory issues, contact your System Administrator.
- Vital Images is not responsible for any DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES to the client PC resulting from the downloading and installation of the software from the server.
- Do not use the client PC or server if any unsafe condition exists. If your client PC or server hardware fails, resulting in a hazardous condition such as smoke or fire, turn off the power and unplug the device. Do not use the equipment if a malfunction takes place. Contact your System Administrator to correct any malfunctions before proceeding.
- If the screen goes blank or the system locks up at any time while you are using it, it could disrupt the interpretation of an image. Should this occur, be sure to restart the system.
- Do not install the Vitrea workstation within six feet of a patient area. Patient vicinity is defined in Medical Electrical Equipment - Safety Requirements for Medical Electrical Systems (IEC 601-1-1), as 'any volume in which intentional or unintentional contact between the PATIENT and any parts of the SYSTEM or some other persons touching parts of the SYSTEM can occur'. See the following diagram for clarification:

FIGURE 2. **Patient Vicinity Diagram**



General Safety Considerations

The software is intended to be used by the following individuals:

- Physicians
- Radiologic technologists
- Other medical personnel under a physician's supervision

Review the operating instructions on a regular basis, paying special attention to **Caution** statements and **Notes**.

Contact Vital Images for your specific computer hardware configuration requirements and for any other system software for additional safety information.

It is your responsibility to limit access to patient data to authorized individuals. Access control can be achieved by physical security measures (locking systems), by software-based password security systems, or both. If you have questions, contact your System Administrator or Vital Images.

Display Settings

Make sure that your PC Windows display settings are set to “Scale at 100% of normal size,” or “9 point Segoe UI at 96 pixels per inch.” If other settings are used, VitreaCore interface items such as buttons, dialog boxes, and image viewers will not be positioned correctly on the display.

NOTE: If the VitreaCore window does not display properly (buttons, menus, and other items are in the wrong locations), check that the Windows display driver is set as described above.

VitreaView® Safe and Effective Use of Vital Medical Imaging Software

This section contains:

- VitreaView Product Overview
- Safety and Regulatory Considerations

VitreaView Product Overview

VitreaView is a cross-browser, cross-platform, zero-footprint universal image viewer solution capable of displaying both DICOM and non-DICOM medical images. VitreaView enables clinicians and other medical professionals to access patients' medical images with integrations into a variety of medical record systems, such as Electronic Health Record (EHR), Electronic Medical Record (EMR), Health Information Exchange (HIE), Personal Health Record (PHR), and image exchange systems. VitreaView is a communication tool which supports the physician in the treatment and planning process by delivering access to images at the point of care. VitreaView is not intended for primary diagnosis.

VitreaView offers medical professionals a universal viewer for accessing imaging data in context with reports from enterprise patient health information databases, fosters collaboration, and provides workflows and interfaces appropriate for referring physicians and clinicians. IT departments will not have to incur time to install client systems, due to the zero footprint, zero- download nature of VitreaView. VitreaView offers scalability to add new users as demand grows, may be deployed in a

virtualized environment, and is designed to be integrated with enterprise patient health information databases.

Some of the general features include:

- Performance speed
- Zero-footprint architecture
- DICOM and non-DICOM display
- Vendor neutrality
- Function within a virtual environment
- 2D multi-modality review of data
- Basic 2D review tools (zoom, pan, measure)
- Easy study navigation and search capability
- Radiology key images
- Comparative review
- Cross-platform viewing capabilities (Windows, Linux, Mac OS)
- Leveraging of next-generation protocols for image viewing (i.e. MINT)
- Single sign-on
- MPR and 3D viewing
- Access on various iOS and Android tablet devices through the default Internet browser

Safety and Regulatory Considerations



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



CAUTION: Read the topics in this section carefully before using the software.

This section contains information essential for the safe and effective use of the VitreaView system. You must understand this information before using the product.

Medical professionals typically access VitreaView from their health information systems, which have a web-based link to patient images. Users can access the patient images and can conduct the functionalities listed in the Overview section of the VitreaView User Guide.

VitreaView displays patient imaging studies and other patient data but does not interpret or provide a diagnosis. Medical diagnosis is the responsibility of users. VitreaView is not intended for primary diagnosis.

VitreaView Indications for Use

VitreaView is a medical image viewing and information distribution application that provides access, through the Internet and within the enterprise, to multi-modality softcopy medical images, reports, and other patient-related information that may be hosted within disparate archives and repositories for review, communication, and reporting of DICOM and non-DICOM data. VitreaView is not intended for primary diagnosis. When accessed from a mobile tablet, VitreaView is for informational purposes only and not intended for diagnostic use.

Display monitors used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance.

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

Caution Statements



CAUTION: The medical professional retains the ultimate responsibility for making a pertinent diagnosis based on his or her standard procedures, including visual comparison of separate images.



General

- Federal law (USA) restricts this device to sale by, or on the order of, a physician.
- This product is intended for use only by appropriately qualified and trained personnel.
- VitreaView displays patient studies and other patient data but does not interpret or provide a diagnosis. Medical diagnosis is the responsibility of users.
- As with any medical imaging process, you must be fully conversant with the limitations of the basic imaging modality and of ensuing image processing. This includes understanding the limitations of the initial series acquisition, image processing technology used, and image display methods. Also, be aware that medical imaging is valid only when appropriate measures have been taken to obtain optimal images with correct orientation and correct patient identifiers.
- Vital Images assumes no liability for problems attributable to unauthorized modifications, additions, or deletions to this product, or unauthorized installation of third-party software.
- Always use best professional judgment when viewing VitreaView images. Do not use for diagnosis or planning if you notice improper or unexpected images.
- Always verify patient information to ensure the correct patient study is loaded.



VitreView Features

- The minimum recommended computer screen resolution for VitreaView is 1024 X 768. A warning message displays for lower screen resolutions. The minimum recommended screen resolutions are 1280 X 800 for Thrive and Excite multi-touch devices and 1024 X 768 for iPad multi-touch devices.
- VitreaView automatically logs users out after 10 minutes of inactivity, but this time can be configured. Contact your System Administrator for information on configuring the time out value.
- It is possible to render important image areas too transparent using the Window/Level tool. This could make areas of an image invisible.
- Accuracy in measurements of lengths and angles depends on a number of factors. The accuracy of these measurements depends on the accuracy of the scale factors that describe the image resolution.
- On secondary capture images, intensity values are displayed as RGB (red, green, blue) color model values and linear measurements are indicated in number of pixels.
- The VitreaView MINT API allows non-DICOM objects to be attached to a patient study. In some cases, these objects can be viewed by the user. These attachments do not have the DICOM headers needed to ensure consistency of patient information. The user must ensure any non-DICOM objects viewed in VitreaView are appropriate for the current patient and study.



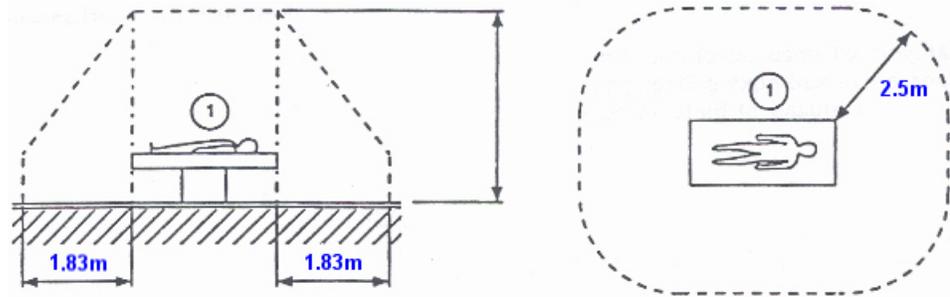
Hardware and Safety

- Be aware that environments with high levels of ambient lighting are not ideal for viewing medical images. This risk may especially be present when viewing medical images on tablet devices. Please use the ambient lighting check to verify whether use is appropriate.

- Log out promptly after completing use of VitreaView. Do not leave a logged-in device unattended, which could result in unauthorized access by another individual.
- Some computer monitors are unshielded. Do not place the monitor, whether in its shipping carton or unpacked, inside the 1.3 Gauss line of any Magnetic Resonance Imaging (MRI) magnet. Exposure to this strength of magnetic field will permanently damage the monitor and may void the manufacturer's warranty. Assume all monitors, regardless of the manufacturer or source, are unshielded unless the manufacturer specifically states otherwise.
- Most monitors and PCs use 24-bit color resolution or 8-bit grayscale resolution, both of which are lower than that of radiologic film. You must use professional judgment at all times in interpreting images that may be influenced by resolution level. Ideally, images are viewed on calibrated monitors in low-background light. Please be aware that if viewing images with no-diagnostic monitors in normally-lit environments, small differences in areas of the image may go unseen.
- If the PC does not have sufficient RAM, you may experience a significant decrease in performance. If you think you are experiencing low memory issues, contact your System Administrator.
- Vital Images, Inc. is not responsible for any DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES to the client PC resulting from the downloading and installation of the software from the server.
- Do not use the client PC or server if any unsafe condition exists. If your client PC or server hardware fails, resulting in a hazardous condition such as smoke or fire, turn off the power and unplug the device. Do not use the equipment if a malfunction takes place. Contact your System Administrator to correct any malfunctions before proceeding.
- If the screen goes blank or the system locks up at any time while you are using it, it could disrupt the interpretation of an image. Should this occur, be sure to restart the system.
- Do not install or operate the server or the client PC within six feet of a patient area. Patient vicinity is defined in Medical Electrical Equipment - Safety Requirements for Medical Electrical Systems (IEC 601-1-1), as “any volume in which intentional or unintentional contact between

the PATIENT and any parts of the SYSTEM or some other persons touching parts of the SYSTEM can occur.” See the following diagram for clarification:

FIGURE 1. **Patient Vicinity Diagram**



General Safety Considerations

The software is intended to be used by the following individuals:

- Physicians
- Referring Physicians
- Other medical personnel under a physician’s supervision

Review the operating instructions on a regular basis, paying special attention to Caution statements and Notes. Contact Vital for your specific computer hardware configuration requirements and for any other system software for additional safety information.

It is your responsibility to limit access to patient data to authorized individuals. Access control can be achieved by physical security measures (locking systems), by software-based password security systems, or both. If you have questions, contact your System Administrator or Vital.

Display Settings

Ensure your Windows display settings are set at “Normal size (96 DPI).” If settings other than 96 DPI are used, VitreaView interface items such as

buttons, dialog boxes, and image viewers will not be positioned correctly on the display.

NOTE: If the VitreaView window does not display properly (buttons, menus, and other items are in the wrong locations), check the Windows display driver is set at Normal size (96 DPI).

The minimum recommended screen resolution for VitreaView is 1024 X 768. A warning message displays for lower screen resolutions. The minimum screen resolutions are 1280 X 800 for Android multi-touch devices and 1024 X 768 for iOS multi-touch devices.