Medis Suite MRCT 2023

User Manual

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Regulatory Information

Intended Use

Medis Suite MRCT is a software intended to be used for the visualization and analysis of MR and CT images of the heart and blood vessels.

Medis Suite MRCT is intended to support the following visualization functionalities:

- cine loop and 2D review

- double oblique review

- 3D review by means of MIP and volume rendering

- 3D reformatting

- performing caliper measurements

Medis Suite MRCT is also intended to support the following analyses:

- cardiac function quantification

- MR velocity-encoded flow quantification

- anatomy and tissue segmentation

- signal intensity analysis for the myocardium and infarct sizing

- MR parametric maps (such as T1, T2, T2* relaxation)

Medis Suite MRCT is also intended to be used for:

- quantification of T2* results in MR images that can be used to characterize iron loading in the heart and the liver

- MR velocity-encoded flow quantification of cerebral spinal fluid

These analyses are based on contours that are either manually drawn by the clinician or trained medical technician who is operating the software, or automatically detected by the software and subsequently presented for review and manual editing. The results obtained are displayed on top of the images and provided in reports.

The analysis results obtained with Medis Suite MRCT are intended for use by cardiologists and radiologists to support clinical decisions concerning the heart and vessels.

Indications for Use

Medis Suite MRCT is indicated for use in clinical settings where more reproducible than manually derived quantified results are needed to support the visualization and analysis of MR and CT images of the heart and blood vessels for use on individual patients with cardiovascular disease. Further, Medis Suite MRCT allows the quantification of T2* in MR images of the heart and the liver. Finally, Medis Suite MRCT can be used for the quantification of cerebral spinal fluid in MR velocity-encoded flow images.

When the quantified results provided by Medis Suite MRCT are used in a clinical setting on MR and CT images of an individual patient, they can be used to support the clinical decision making for the diagnosis of the patient. In this case, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis, and they are only intended for use by the responsible clinicians.

Limitations

Currently no limitations have been specified for Medis Suite MRCT 2023.

WARNINGS

⛔ Medis Suite MRCT must be used by cardiologists, radiologists, or trained technicians who are qualified to perform cardiac analysis. If the analysis results are used to reach a diagnosis, the results must be interpreted by a qualified medical professional. In clinical practice Medis Suite MRCT should not be used for purposes other than those indicated in the section Intended Use.

⛔ Users must have sufficient proficiency in the English language, read this manual, become familiar with the software, and must be certified by Medis before using Medis Suite MRCT in a clinical environment in order to obtain reliable analysis results.

European Regulations

CE 1639	Medis Suite MRCT 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.

Medis Suite MRCT is registered as a medical device (class II) by the MoH in Turkey.

North American Regulations

Medis Suite MRCT has been cleared for market in the United States by the FDA (Food and Drug Administration) under the provisions of Section 510(k) of the Food, Drug, and Cosmetic Act. The QTavi module has not been cleared for clinical use in the USA.

Caution
Federal law restricts this device to sale by or on the order of a physician.

Medis Suite MRCT complies with the requirements of the Canadian Medical Devices Regulations and has been licensed as a Class II medical device.

South American Regulations

Medis Suite MRCT complies with the requirements of INVIMA and has been licensed in Colombia as a Class II medical device. The QFlow 4D, QStrain and QTavi modules have not been cleared for clinical use in Colombia.

Asia-Pacific Regulations

Medis Suite MRCT complies with the requirements of the Australian Therapeutic Goods Administration and has been licensed as a Class IIa medical device. The QTavi module has not been cleared for clinical use in Australia.

Medis Suite MRCT complies with the requirements of the Japanese Pharmaceutical and Medical Device Law and has been licensed as a Class II medical device. The QFlow 4D, QStrain and QTavi modules have not been cleared for clinical use in Japan.

Medis Suite MRCT complies with the requirements of the South Korean Medical Device Act and has been licensed as a Class II medical device. The QTavi module has not been cleared for clinical use in South Korea.

Conventions Used

The following conventions are used throughout this manual to indicate mouse and keyboard actions and to refer to elements in the user interface.

Mouse

Click	Press and release the primary mouse button. If you are left-handed, you may have set the right mouse button as your primary mouse button.
Right-click	Press and release the secondary mouse button. If you are left-handed, you may have set the left mouse button as your secondary mouse button.
Middle-click	Press and release the wheel button or the middle mouse button. If you have a two-button mouse, press and release the left and the right mouse button simultaneously.
Double-click	Press and release the primary mouse button twice.
LMB, MMB, RMB	Left Mouse Button (LMB), Middle Mouse Button (MMB), and Right Mouse Button (RMB).

Keyboard

SHIFT/CTRL+click	Press and hold down the SHIFT or CTRL key on your keyboard while you click a button or object.
CTRL+O	Press and hold down the CTRL key on your keyboard while you press O, then release both keys. This example opens the dialog window for opening a study.

Typographical Conventions

On the **Display** tab, select the **Hide all drawings** option.	Names of buttons, fields, menus, menu options, and tab names are capitalized and in bold.
View > Movie	A sequence of menu options that you select to perform a specific task, is indicated by angular brackets.
mass.ini	Text that you type or that appears on the screen, such as file names and file locations, is displayed in Courier New.

Symbols Used

Reference. Points to related documentation or to related sections in the document that may be relevant in your situation.

Tip. Provides helpful information or an alternative working method.

Note. Brings additional information to your attention.

Caution. Tells you to be careful when performing a task.

Warning. Warns you for a potentially dangerous situation in the image representation or analysis, which may lead to incorrect results. You are advised to follow the instructions to avoid this.

Table of Contents

1 About Medis Suite MRCT

Medis Suite MRCT is Medis' software solution for the analysis of cardiac MRI and CT studies. It consists of a number of applications (apps) with specific functions: QMass, QFlow, QFlow 4D, 3DView, QTavi and QStrain.

⚠ **Please be aware that certain applications (or sub parts) might not be available in particular jurisdictions (see Section on Regulatory Information for information on this) or due to restrictions in the license configuration.**

Its automatic contour detection enables you to perform quantitative analyses quickly and accurately. Medis Suite MRCT features ventricular function analysis, infarct size analysis (referred to as Delayed Signal Intensity or DSI analysis), T2w analysis, Combined T2w-DSI, first-pass perfusion analysis (referred to as time-signal intensity or TSI analysis), stress level function analysis (referred to as comparison analysis), T1 analysis, T2/T2* analysis. Medis Suite MRCT can also read CT reformatted data and perform functional analysis on that data. Medis Suite MRCT can also be used for the quantitative analysis of velocity-encoded MR studies. Further, it enables the 3D visualization and 2D quantification analysis of 4D flow MR studies and supports visualization of Computed Tomography Angiography (CTA) and Magnetic Resonance Angiography (MRA) images. Finally, Medis Suite MRCT enables the calculation of global strain parameters and it can be used to support the planning or evaluation of TAVI or TAVR procedures.

🛑 Medis Suite MRCT must be used by qualified medical personnel or trained technicians. If the analysis results are used to reach a diagnosis, the results must be interpreted by a qualified medical professional. Medis Suite MRCT should not be used for purposes other than those indicated in the section Intended Use.

🛑 Medis Suite MRCT cannot perform the following analyses on CT reformatted data; infarct size tissue analysis, T2w analysis, perfusion analysis, T1 analysis, T2 analysis, and T2* analysis.

🛑 Automatically and manually created contours can lead to incorrect results. Make sure to review them and correct if necessary.

2 System Requirements

2.1 Hardware

Medis Suite MRCT:
- A 64 bit processor
- 8 GB RAM
- 10 GB free disk space after the software is installed
- A monitor with a screen resolution of 1.3 Megapixels (e.g. 1280 x 1024 pixel for a display ratio 4:3, 1600 x 900 pixels for display ratio 16:9)

Sentinel license server:
- A 32 or 64 bit processor
- 4 GB RAM
- 5 GB of available hard disk space

NOTES:
- All hardware must be compliant with the operating system.
- The requirement for the disk space does not take storage space for image data into account. If you want to store images on the local machine, make sure that sufficient disk space is available. Also note that client machines will cache image data from the server temporarily on the local machine.
- To view image data a dedicated graphics card supporting OpenGL and at least 512 MB memory is recommended.
- To connect your workstation with other machines in the network (e.g. a client-server configuration, or receive and send images to a remote DICOM node) a network connection will be required. A network interface card supporting at least 100 mbps is recommended.
- For the license server, a workstation with a fixed IP address or a reserved IP address in the DNS server is recommended.

2.2 Operating System

Medis Suite MRCT:
- Microsoft Windows 10, 64-bit
- Microsoft Windows 11, 64-bit
- Microsoft Windows Server 2012 R2, 64-bit
- Microsoft Windows Server 2016, 64-bit
- Microsoft Windows Server 2019, 64-bit
- Microsoft Windows Server 2022, 64-bit

Sentinel license server:
- Microsoft Windows 10, 32-bit and 64-bit
- Microsoft Windows 11, 64-bit
- Microsoft Windows Server 2012 R2, 64-bit
- Microsoft Windows Server 2016, 64-bit
- Microsoft Windows Server 2019, 64-bit
- Microsoft Windows Server 2022, 64-bit

3   Support

Medis is committed to offering high-quality products and services. If you have questions about the software or if you would like to make suggestions for improvements in the software or the documentation, please contact the Medis helpdesk.

If you contact the Medis helpdesk by e-mail, mention the name of the software and the version number in the subject field.

To look up the version number of your software, select the application menu by clicking in the upper right corner of the Medis Suite window, and then **Help > About….**

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4 Starting Medis Suite MRCT

Medis Suite MRCT is started by starting Medis Suite.

For a detailed description on starting applications and loading data in the applications, refer to the Medis Suite User Manual [1].

Using Drag 'n Drop (D'nD) one can load data into any of the Medis Suite MRCT applications. Depending on the modifier keys pressed during the D'nD Medis Suite MRCT will have a different load behavior:

|	
D'nD	Data will be added to the current session and the first series will be made active.
D'nD + Shift	Data will be added. Current active series will remain active.
D'nD + Ctrl	Current data will be closed. New data will be loaded. First series will be made active.

5 The Medis Suite MRCT Applications

This chapter provide an overview of main application windows of Medis Suite MRCT.

5.1 Overview QMass Application

QMass offers automatic contour detection that enables you to perform quantitative analyses quickly and accurately. QMass features ventricular function analysis, infarct size analysis (referred to as Delayed Signal Intensity or DSI analysis), T2w analysis, Combined T2w-DSI, first-pass perfusion analysis (referred to as time-signal intensity or TSI analysis), stress level function analysis (referred to as comparison analysis), T1 analysis, T2/T2* analysis. QMass can also read CT reformatted data and perform functional analysis on that data

The QMass main workspace consists of a set of toolbars, a study matrix and three views. Depending on the type of study, its orientation and the chosen analysis, icons are either enabled/visible or disabled/invisible in their respective toolbars.
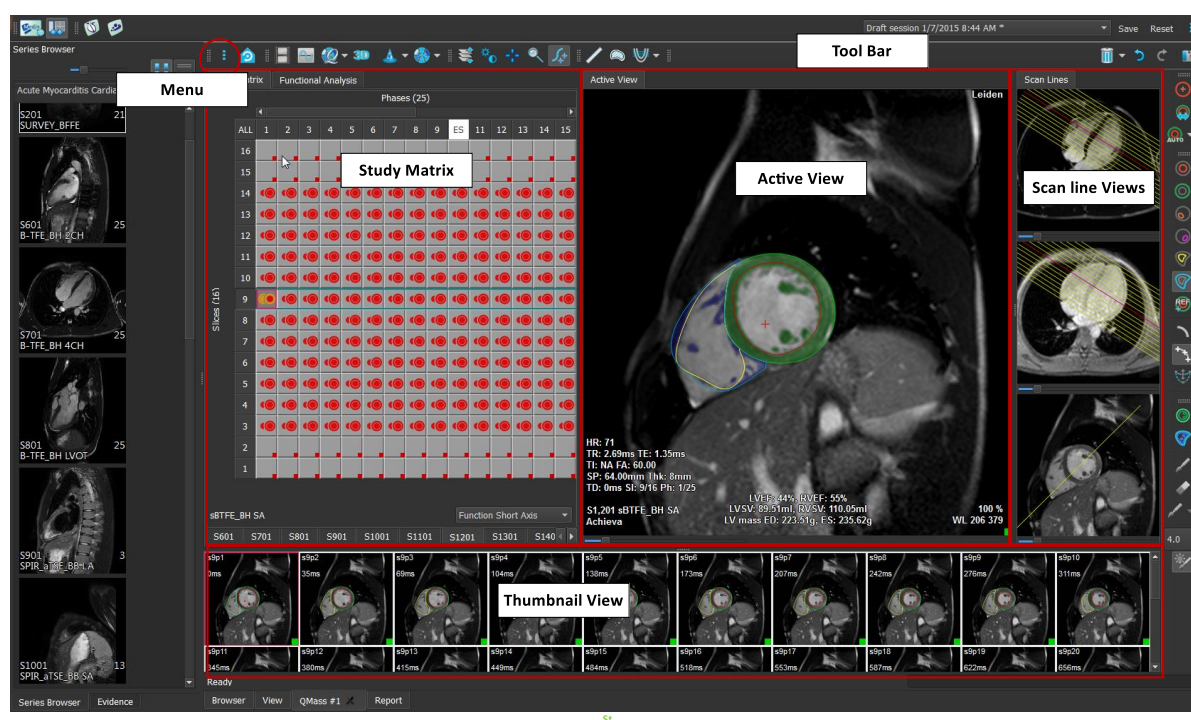
Menu

The application menu is accessible through the ⋮ button and can be used to, for example, reset the layout, to view graphs, to view reports, to view study parameters, to change settings, to detect and edit contours, to undo or redo actions and to cut, copy and paste elements.

Study Matrix
The study matrix shows an overview of the images of the selected series.

Active View
The viewport shows the image selected in the study matrix.

Scanline View
The scan line views present the slice position of the selected series. In the first two views, you can switch to another series by right-clicking and selecting the new series. You can also pan, and you can zoom in or zoom out by using the sliders.

Thumbnail View
The thumbnail view shows thumbnail images of the selected series. The thumbnail view shows either phase images or modulus images. This can be configured through the application menu. The thumbnail marked with the red border corresponds to the image displayed in either the phase view or the modulus view.

Toolbar
The toolbar area consists of a Medis Suite toolbar and several QMass toolbars. The QMass toolbars can be used for example to access the application menu, to start a movie, to show a graph, to access the main settings, and to perform some basic image manipulations like panning or zooming. The QMass toolbars can also be used to undo and redo some actions, to create a snapshot, to detect or draw contours and to edit or delete them.

For further explanation please refer to the [QMass User Manual](#).

5.2 Overview QFlow Application

QFlow can be used for the quantitative analysis of velocity-encoded MR studies.

The QFlow main workspace consists of a set of toolbars, a phase view, a modulus view and a thumbnail view. The application menu is accessible through a menu icon in the toolbar.
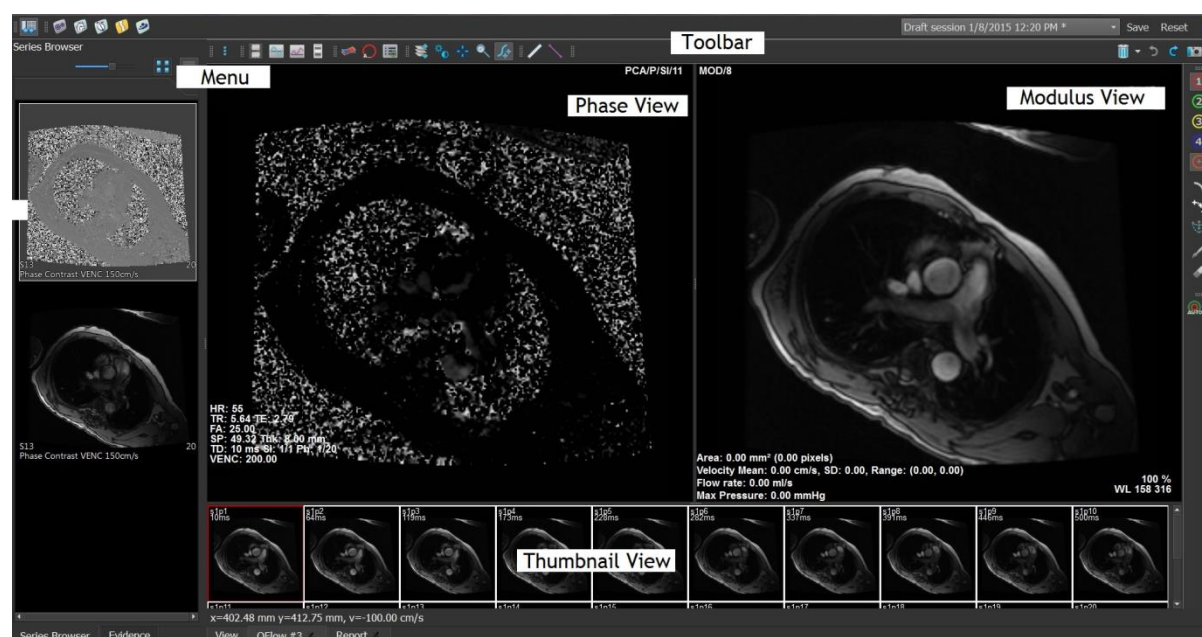
Menu

The application menu is accessible through the ⋮ button and can be used for example to reset the layout, to view graphs, to view reports, to view study parameters, to change settings, to detect and edit contours, to undo or redo actions and to cut, copy and paste elements.

Phase view
The Phase view shows a velocity image of the selected series.

Modulus View
The Modulus view shows a modules image of the selected series.

Thumbnail View
The Thumbnail view shows images in each timepoint of the selected series. It can either show the modulus or phase images. This can be configured through the application menu. The thumbnail marked with the red border corresponds to the image displayed in either the phase view or the modulus view.
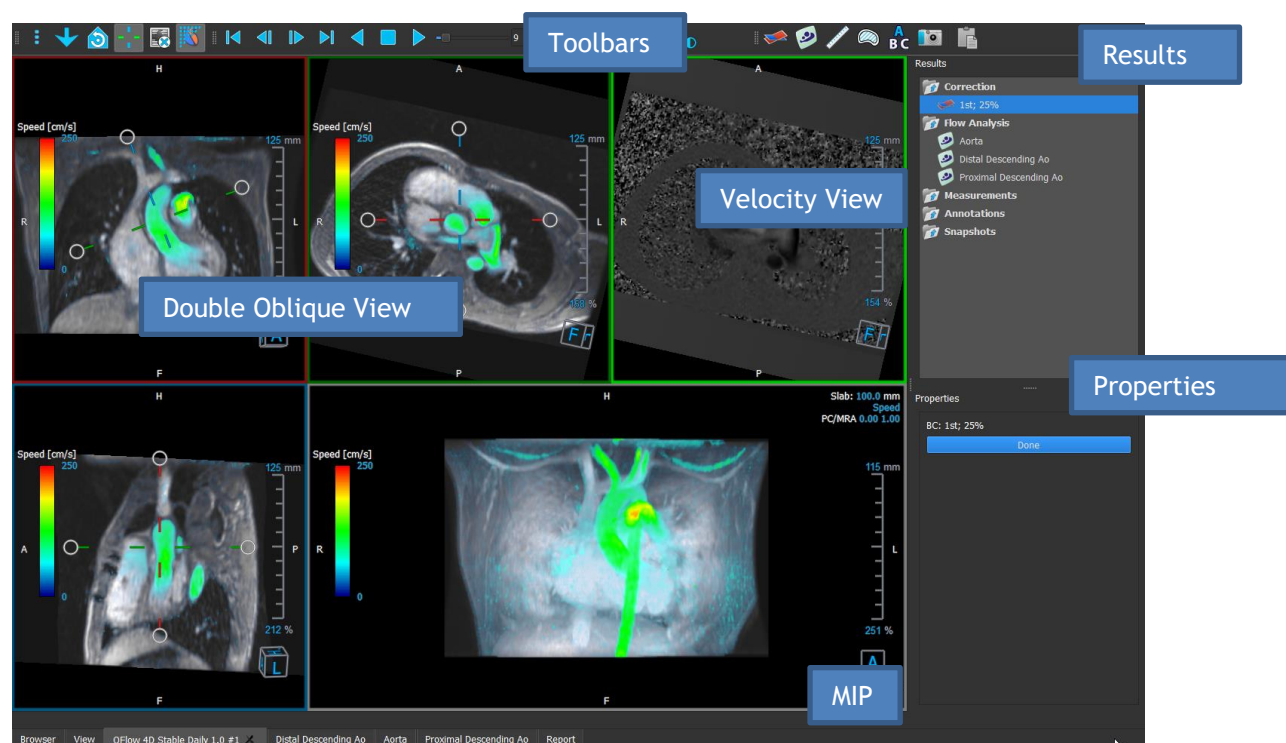
Toolbar
The toolbar area is divided into two groups; Medis Suite-specific group and QFlow-specific group. The QFlow toolbars can be used for example to access the application menu, to start a movie, to show a graph, to access the main settings, and to perform some basic image manipulations like panning or zooming. The QFlow toolbars can also be used to undo and redo some actions, to create a snapshot, to detect or draw contours and to edit or delete them (part of Medis Suite-specific group).

For further explanation please refer to the [QFlow User Manual](#).

5.3 Overview QFlow 4D Application

QFlow 4D is the Medis software solution designed to support the 3D visualization and 2D quantification analysis of 4D flow MR studies. It allows cardiologists, radiologists, and technicians to quantify arterial and transvalvular blood flow. QFlow 4D supports a double-oblique view layout that includes a transverse view of the phase image and MIP of the data. Once the required view is selected, a quantitative flow analysis can be performed.

The main workspace of QFlow 4D consists of a menu bar, toolbars, workspace panes and the central window area which is comprised of Double Oblique, 3D-MIP and Velocity image viewports. There are also results and properties panes.

You can customize the workspace by hiding, resizing or moving the workspace panes and toolbars. Any changes that you make to the workspace are saved for each individual Windows user.

Double Oblique view
The main purpose of the Double Oblique views is used to determine the plane of interest to be used for Flow Analysis in Medis Suite MRCT. They show the orthogonal views of the 3D volume.

Velocity View
The Velocity View is a viewport that shows the velocities in the selected plane in the Double Oblique View.

MIP View
The MIP View is a viewport that shows the selected series rendered in 3D.

Results Pane
The Results pane shows the following:
• It shows standard procedures, i.e. measurements, annotations and snapshots performed on the series that is loaded in the viewport.
• It shows the Background Correction.
• It shows the list of Flow Analyses.

Properties Pane
The **Properties** pane shows the properties of the selected procedure. You can modify Medis Suite MRCT standard procedures, i.e., measurements, annotations, or snapshot procedures as well as the Flow Analysis reconstructions.

Toolbar
The QFlow 4D toolbar provides several functionalities, such as access the application menu, Cine actions (play, pause, stop, etc.), performing some basic image manipulations like panning or zooming and starting procedures.

For further explanation please refer to the QFlow4D User Manual.

5.4 Overview 3DView Application

3DView can be used for the visualization of Computed Tomography Angiography (CTA) and Magnetic Resonance Angiography (MRA) images. It provides intuitive tools for manipulating CTA/MRA images, displaying CTA/MRA images in 2D and 3D, and provides tools for easy and quick measurements.

The main workspace consists of toolbars, multiple workspace panes, and the image view.
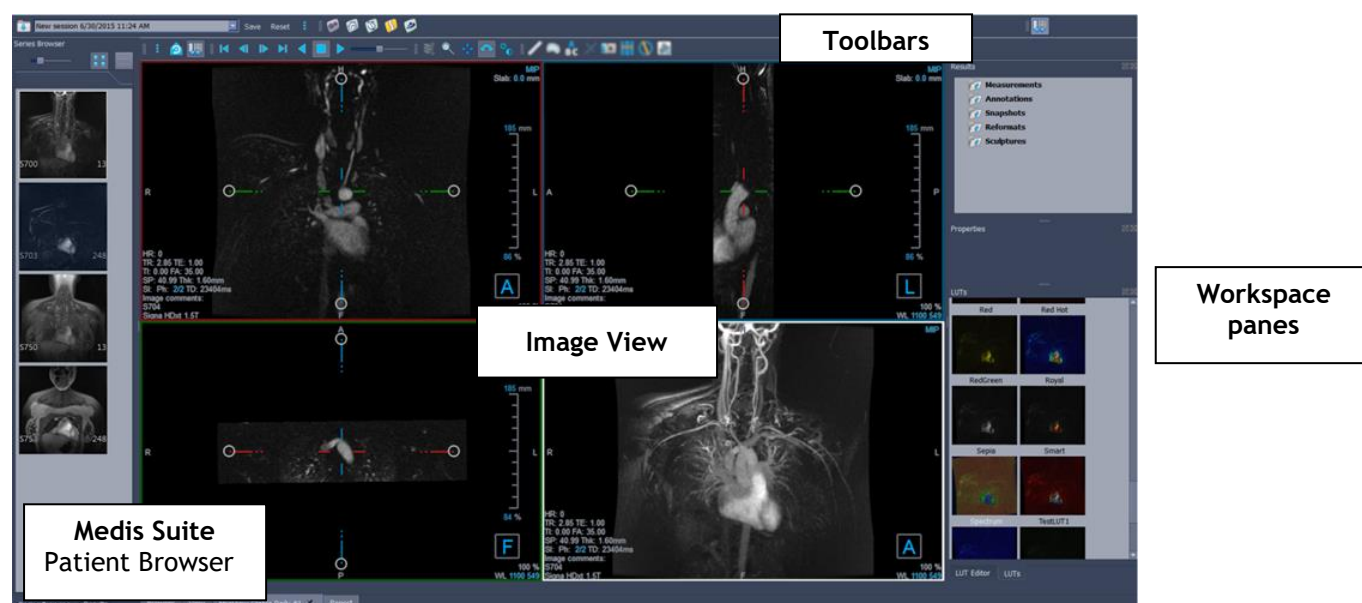
Image View
The Image view displays the currently loaded volume 2x2 in several different representations. By default, the images in the Image View display a number of patient details and volume information. You can show or hide these overlays from the image.

Workspace Panes
The Workspace panes consist of the following:
- The Results pane lists the results of actions performed on the volume: annotations, measurements, snapshots, reformats and sculptures.
- The Properties pane shows the properties of the selected result. You can always modify the Label, but you must activate a reformat or sculpture to view or modify their other properties.
- The LUTs Pane is used to enhance visualization in the 3DVR view.

Toolbar
The 3DView toolbar offers to access the application menu, basic Cine functionality, some image manipulations techniques such as like panning or zooming, and a set of procedures applicable to the application.

For further explanation please refer to the 3DView User Manual.

5.5 Overview QTavi Application

QTavi is designed to support the planning or evaluation of TAVI or TAVR procedures.

The main workspace of QTavi consists of a menu bar, toolbars, several workspace panes, and the central window area with Double Oblique/3D/MIP/VR image viewports.
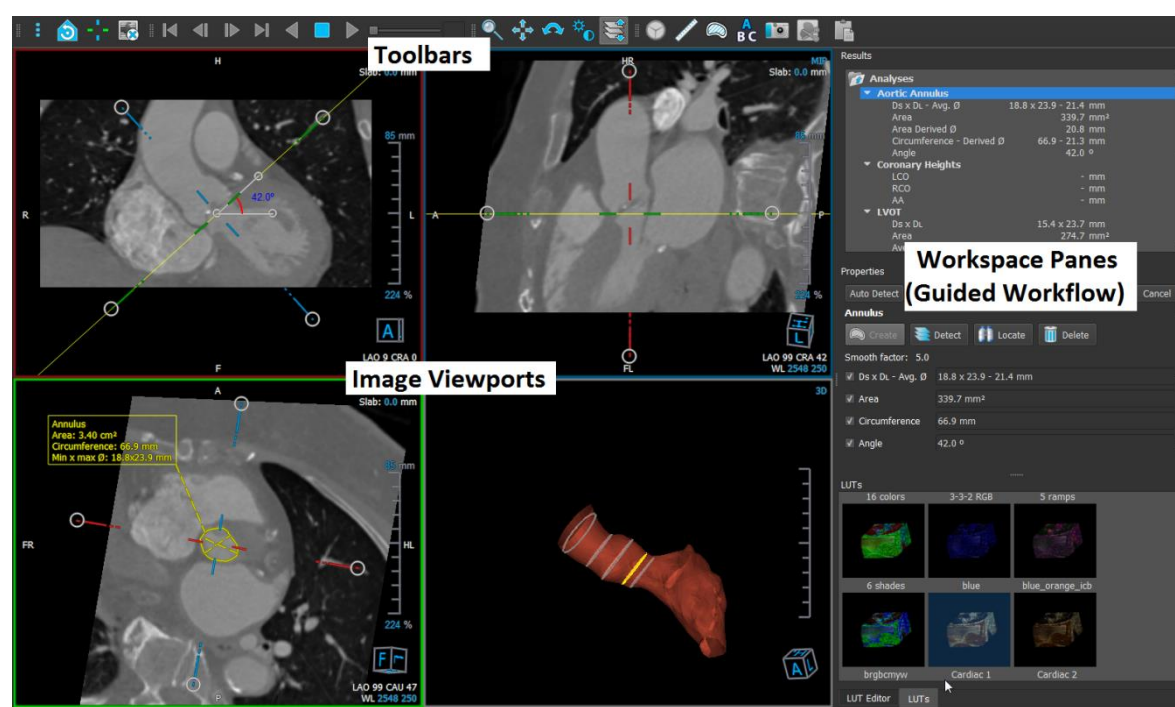

Image Viewports
The Image View displays the currently loaded volume in double-oblique view. Once the detection of the aorta is complete and the mesh is made available, the 3D viewport shows a rendering of the mesh. The 3DVR and MIP viewports are also provided to assist in better visualization.

Workspace Panes
The Workspace panes consist of the following:
- The Results pane lists the results of actions performed on the volume: annotations, measurements, snapshots, reformats, and sculptures.
- The Properties pane shows the properties of the selected result. You can always modify the Label, but you must activate a reformat or sculpture to view or modify their other properties.
- The LUTs Pane is used to enhance visualization in the 3DVR view.

Toolbar
The QTavi toolbar offers access the application menu, basic Cine operations (start, stop, skip, etc.), performing basic image manipulations like panning or zooming and a list of available procedures. By default, the Aortic root procedure is always started and only a single instance of that procedure is allowed.

For further explanation please refer to the QTavi User Manual.

5.6 Overview QStrain Application

QStrain is meant to be used for myocardial assessment to determine the health status of the myocardium. A global assessment can indicate several abnormalities in flow and tissue, thereby quantifying the extent of these abnormalities.
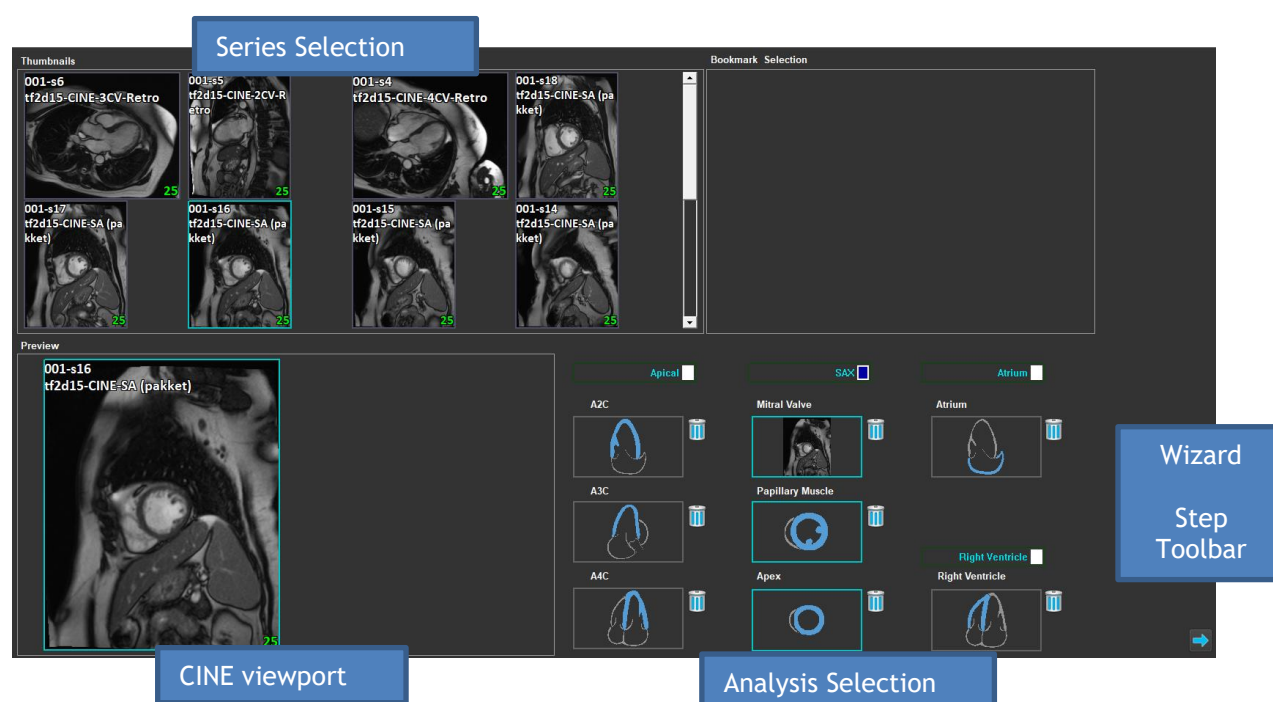
QStrain reads both MR and CT data. It allows 4 different types of analysis: Apical (LAX), SAX, Atrium and Right Ventricle. Each slice can be assigned to its appropriate block depending on the orientation and the analysis to be performed.

Series Selection
The loaded images are grouped based on slices. Each slice contains a number of timepoints. The slice can be assigned to a specific analysis by clicking on it.

CINE viewport
The CINE viewport allows visualization of the chosen series. On hovering, the movie starts playing.
If contours are available for that slice, an icon is shown on the top-left corner.

Analysis Selection
An analysis can be selected simply by clicking on a slice from the Series Selection pane and
subsequently clicking on one of the orientation blocks (A2C, A3C, A4C, Mitral Valve, etc.).
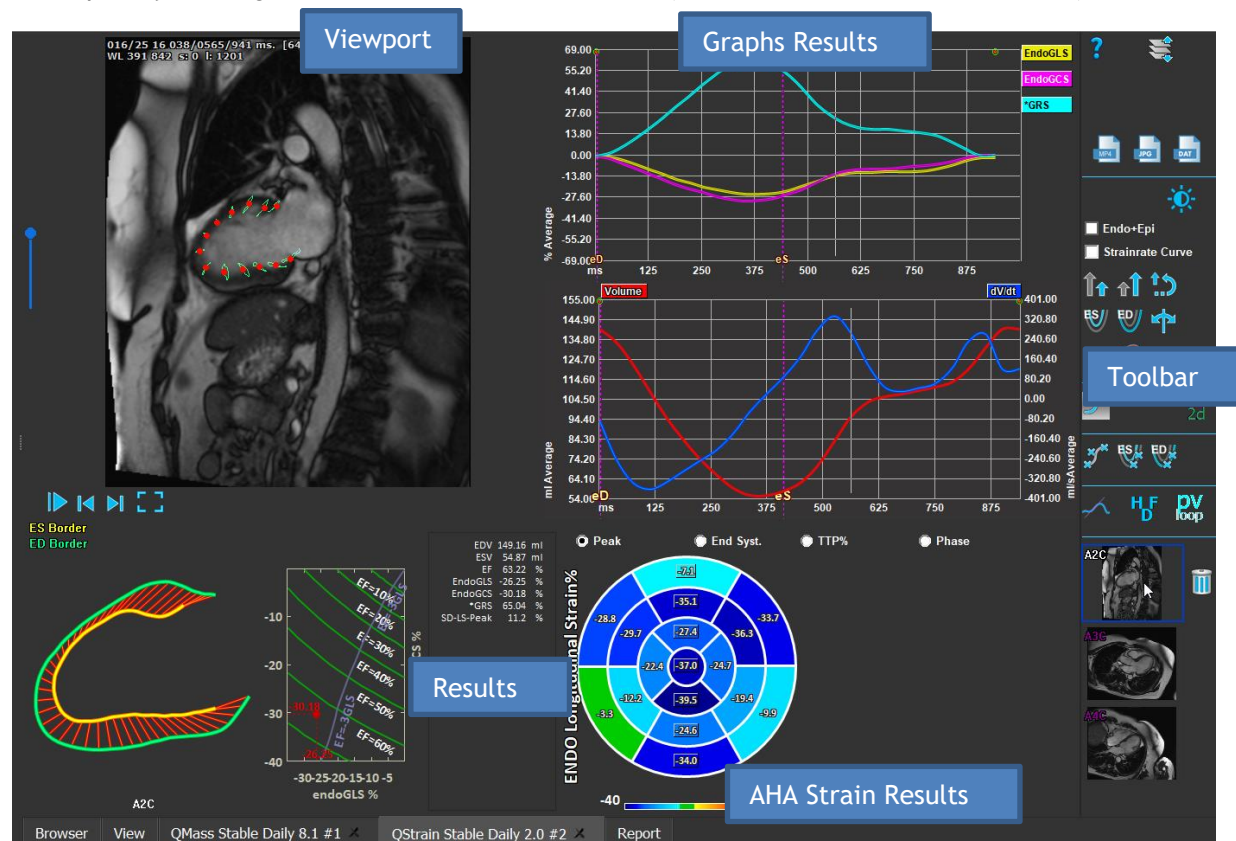
Viewport
The Viewport provides visualization of the contour tracking based on the drawn contours for the ES
and ED phases.

Results/Graph Results/AHA Strain Results
These sections give an objective view of the myocardium. They show the results and graphs to
indicate the myocardium movement. The Results are simply medical values derived based on input
data and drawn contours.

Toolbar
The Toolbar exposes several utilities, such as, access to data-selection viewport, export of images,
movies and data, contour-related landmarks, other available analysis, and the current analysis
being shown.

For further explanation, please refer to the QStrain User Manual.

6   References

1.   *Medis Suite 4.0 User Manual, Medis Medical Imaging Systems, 2023.*

2.   *QMass 8.1 User Manual, Medis Medical Imaging Systems, 2023.*

3.   *QFlow 8.1 User Manual, Medis Medical Imaging Systems, 2023.*

4.   *QFlow 4D 1.1 User Manual, Medis Medical Imaging Systems, 2023.*

5.   *3DView 3.2 User Manual, Medis Medical Imaging Systems, 2023.*

6.   *QTavi 1.0 User Manual, Medis Medical Imaging Systems, 2023.*

7.   *QStrain 4.3 User Manual, Medis Medical Imaging Systems, 2023.*