



Medis Suite 2.1

Quick Start Manual

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Regulatory Information

Intended Use

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

Medis Suite is intended to support the following visualization functionalities:

- cine loop and 2D review
- performing caliper measurements

These measurements 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 are intended for use by cardiologists and radiologists to support clinical decisions concerning the heart and vessels.

Indications for Use

Medis Suite 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, CT and XA images of the heart and blood vessels for use on individual patients with cardiovascular disease.

When the quantified results provided by Medis Suite are used in a clinical setting on MR, CT and XA 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.

WARNINGS

Medis Suite 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 should not be used for purposes other than those indicated in the section Intended Use.

Users must make sure to read this manual to become familiar with the software and be able to obtain reliable analysis results.

Note on Monitor Aspect Ratio and Resolution

The shapes of objects and calipers displayed may get slightly distorted when the resolution is set to an aspect ratio different than the monitor's physical aspect ratio. This distortion does **NOT** affect the accuracy of measurements or analyses. To avoid distortion, set the resolution of the monitor to an aspect ratio equal to the physical aspect ratio. LCD monitors typically operate best at their native resolution. Microsoft Windows recommends a resolution when it has sufficient information to do so.

European Regulations



Medis Suite 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.

North American Regulations

Medis Suite 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.

Caution

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

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

Other Regulations

Medis Suite complies with the requirements of the Japanese Pharmaceutical and Medical Device Law and has been licensed as a Class II medical device.

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.

Click and drag Press and hold the primary mouse button. Drag the mouse to

perform a function. 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.

Wheel Rotate the mouse scroll wheel.

Keyboard

SHIFT+click Press and hold down the SHIFT key on your keyboard while you

click a button or object.

CTRL+K Press and hold down the CTRL key on your keyboard while you

press K, then release both keys.

Typographical Conventions

On the **Annotations** node of the

Procedures pane...

Names of buttons, fields, menus, menu options, and tab

names are capitalized and in bold.

Procedures > Text Annotation A sequence of menu options that you select to perform a

specific task is indicated by angular brackets.

Label: Aortic root Text that you type or that appears on the screen, such as

annotation labels, is displayed in Courier New.

Symbols Used



Tip: Provides helpful information or an alternative working method.

1

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.

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Introduction

1 About Medis Suite

Medis Suite is the Medis software solution for the visualization of magnetic resonance (MR), computed tomography (CT), and X-ray angiographic (XA) images. It provides intuitive tools for displaying MR, CT and XA images in 2D, and provides tools for easy and quick measurements.

Medis Suite integrates applications that can provide advanced manual and automated image analysis. Results from the integrated applications will be gathered in Medis Suite and can be used to generate a combined report.

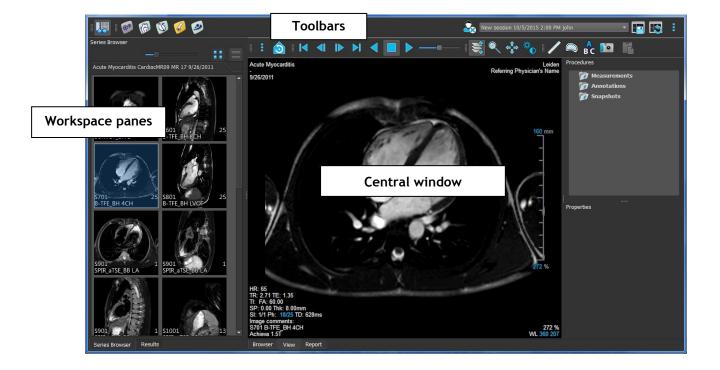
The Medis Suite software solution offers quantification results that enable cardiologists and radiologists to review MR, CT and XA images, and it provides a solid basis for the assessment of new therapies.

Getting Started

2 Medis Suite Workspace

2.1 Overview

The main workspace of Medis Suite consists of toolbars, several workspace panes, and the central window area.



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

The central window area holds the **Browser**, **View** and **Report** tabs that are provided by Medis Suite. Next to that, the central window is the area where integrated Medis Suite applications will be displayed after launching them.

By default, the workspace displays two panes on the left of the application area; the **Series Browser** pane and the **Results** pane. A third pane is hidden by default, and when it is activated it will be displayed on the right of the application area; the **Applications** pane.

The **Series Browser** pane shows information about the loaded patients, studies and series in Medis Suite. The series of each patient / study combination are displayed on a tab in the **Series Browser**. The name of each tab shows the patient name, patient ID, modality, number of contained series, and content date. The **Series Browser** can present all series in image view and text view.

The **Results** pane shows all results that are available for the current session of the current study. The results are gathered from the Medis Suite viewer or any of the running Medis Suite apps.

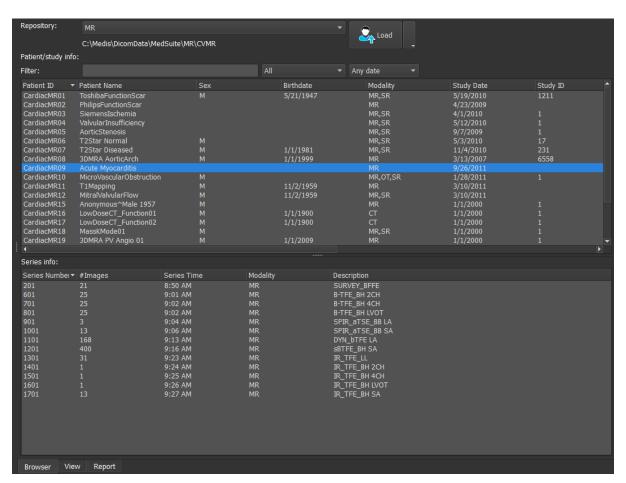
① When Medis Suite apps are closed, their accompanying results will be removed from the Medis Suite **Results** pane and the report.

The **Applications** pane shows icons of the applications (apps) that are integrated into Medis Suite. Apps can be used to perform detailed image analysis, and to create new results.

By default, the **Applications** pane is hidden. To show the **Applications** pane, click **Panes** > **Applications**.

2.2 Browser

The **Browser** tab in the central window of Medis Suite provides functionality to import, view, filter and load data.



Any data that you would like to process must be contained in a Medis Suite **Repository**, which points to a location on your local machine or network drive. You can have one or multiple repositories to work with.

To configure the Medis Suite repositories:

- Click on the dropdown icon next to the Load button

 Configure... This will open the Options dialog in the Browser section.
- Configure the existing repository, or
- Click to add a new repository, double click in the Name field to edit the repository name, and double click in the Root path field to edit the root folder of this repository, or click to browse to the root folder of the repository.

All configured repositories are listed in the repository drop down in the Browser.

To change the active Medis Suite repository:

- Open the repository dropdown box to see all configured repositories.
- Click on the name of the repository to activate it. The folder that is associated with the repository is displayed directly underneath the dropdown box.

① The Medis Suite repositories are shared with all users on the computer system. The active repository is saved for each Windows user.

Data can be imported into the Medis Suite repository directly from the Browser. This is especially useful to import data from CD, DVD, USB, or any folder on your computer or network. Note that it is also possible to copy files directly into the repository folder, for example using the Windows Explorer. The new files in the repository folder will automatically be detected by Medis Suite.

To import data into the Medis Suite repositories:

- Click on the dropdown icon next to the Load button in the Browser, and select Import....
- Browse to the folder you would like to import and click **Select Folder**.
- Medis Suite will copy all files from the import folder into your repository folder.

Medis Suite will automatically keep track of all files that are in your repository folders. For this, Medis Suite does not have to be active or running, the processing takes place in the background as a Windows service. New and deleted files will be automatically by shown or hidden from the Browser window. In rare cases, you may find that the content of the repository folder is not up to date. In those cases, a rescan of the repository folder is required to synchronize the Browser window with the repository folder content.

To rescan the files in a Medis Suite repository:

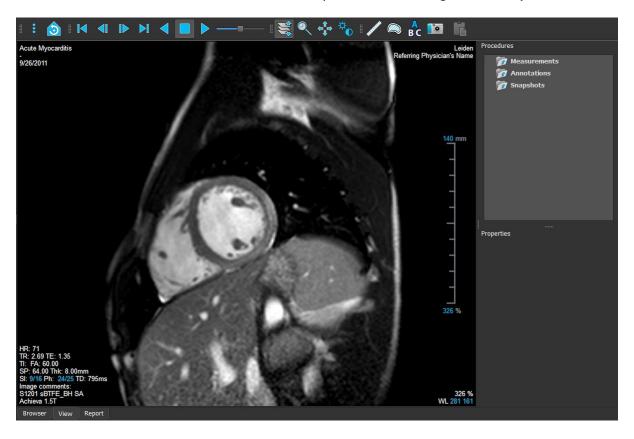
• Click on the dropdown icon next to the Load button Rescan.

Or,

• Press F5 with the Browser window active.

2.3 View

The View tab in the central window of Medis Suite provides the viewing functionality.

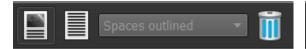


You can customize the viewer workspace by hiding or moving the workspace panes and toolbars. Any changes that you make to the viewer workspace are saved for each Windows user.

2.4 Report

The **Report** tab in the central window of Medis Suite provides the reporting functionality.

The positions and visibility of the toolbars in the **Report** tab are fixed.





Working with Medis Suite

3 Viewing

3.1 Loading Series

Series can be loaded in the viewport from the Series Browser.

To load series in the viewport

- 1. Click an item in the image view or text view of the Series Browser to select it.
- 2. Click and drag the selected series from the Series Browser to the viewport.

This will load the series into the viewport. When multiple slices are contained in the series, the middle slice is displayed by default. When multiple time points are contained in the series, the first time point is displayed by default. The **Series Browser** highlights the displayed series with a white border around the icon in the image view, or bold text in the text view.

To review all series in the active study

- 1. Press Page Down on your keyboard to load the next series into the viewport
- 2. Press Page Up on your keyboard to load the previous series into the viewport

3.2 Navigation

You can move forward or backward through the slices and time points in the series in several ways.

To move forward or backward through slices

Moving through slices can be done by using keys:

Press arrow up or down to move to the previous or next slice.

Or,

Press HOME or END to move to the first or last slice.

Moving through time points can be done by using interactive graphics:

• Click or right-click the interactive graphics for slice ('Sl') on the viewport to move to the first or last slice.

To move forward or backward through time points

Moving through time points can be done by using buttons:

on the Viewing toolbar to move to the previous or next time point.

Or,

on the Viewing toolbar to play a cine through the time points in backward or forward direction. Click to stop the cine.

Or,

on the Viewing toolbar to move to the first or last time point.

Moving through time points can be done by using keys:

Press the left or right arrow key to move to the previous or next time point.

Or,

Press CTRL + left arrow, CTRL + right arrow to play a cine through the time points in backward or forward direction. Press Esc to stop the cine.

Or,

Press HOME or END to move to the first or last slice time point.

Moving through time points can be done by using interactive graphics:

Click the interactive graphics for phase ('Ph') on the viewports to move to the next time point.

Or,

Right-click the interactive graphics for phase ('Ph') and enter the desired number of the time point.

Mouse Controls 3.3

You can move through the slices and time points using **Stacking** when you see the stack cursor $^{\bigcirc}$.

To activate the stacking mouse control

in the mouse controls toolbar.

Or,

Select Stacking from the viewport context menu.

You can zoom in and out of the viewport using **Zooming** when you see the magnify cursor $^{\circ}$.



To activate the zooming mouse control

Click in the mouse controls toolbar.

Or,

Select **Zooming** from the viewport context menu.

You can move the image within the viewport left, right, up and down using Panning when you see the hand cursor \\bigcap_.

To activate the panning mouse control

Click in the mouse controls toolbar.

Or,

Select **Panning** from the viewport context menu.

You can adjust the window width and level (WWL) when you see the WWL cursor .

To activate the window/level mouse control

Click in the mouse controls toolbar.

Or,

Select Window/Level from the viewport context menu.

To reset the zooming, panning and window width and level settings to the initial view state

Click to reset the zooming, panning and window width and level.

4 Procedures

4.1 Annotations

To create an annotation

- 1. Click in the toolbar, or select Procedures > Text Annotation.
- 2. Click and drag in the image to draw the annotation arrow.
- 3. Select a predefined label, or type a custom label and press Enter.
- 4. Click and drag the arrowhead or the text to adjust the exact location of the image that you want to mark.
- 5. Click outside the annotation. The graphic changes to white indicating it has left edit mode.

This adds the annotation to the Annotations list in the **Procedures** pane. At any time while the annotation is still active you can press Esc to remove the annotation.

4.2 Distance Measurements

To measure a distance

- 1. Click in the toolbar, or press the D key, or select Procedures > Distance
- 2. Click and drag in the image from the start point of the measurement to the end point.
- 3. Select a predefined label, or type a custom label and press Enter.
- 4. Click and drag either arrowhead or the text to adjust the points of the image between which you want to measure.
- 5. Click outside the measurement. The graphic changes to white indicating it has left edit mode.

This adds the measurement to the Measurement list in the **Procedures** pane. At any time while the measurement is still active you can press Esc to remove the measurement.

4.3 Area Measurements

To measure an area

- 1. Click in the toolbar, or press the A key, or select Procedures > Area Measurement in the menu
- 2. Click and drag to draw the area. The contour is automatically closed when you release the mouse button.
- 3. Modify the contour as necessary (see Error! Reference source not found. below).
- 4. In the **Properties** pane, check **Area** or **Circumference** to display either or both measurements.
- 5. Click outside the contour. The graphic changes to white indicating it has left edit mode.

This adds the measurement to the Measurement list in the **Procedures** pane. At any time while the measurement is still active you can press Esc to remove the measurement.

4.4 Snapshots

You can create a snapshot of the current state of the viewport.

To save a snapshot

- 1. Click in the toolbar, or press the S key, or select > Procedures > Snapshot.
- 2. On the **Properties** pane, click the ellipsis on the right of the **Label** field and select a predefined label, or type a custom label and press Enter.

5 Medis Suite Apps

The Medis Suite procedures provide basic image analysis and results. For advanced image analysis and additional results, Medis Suite integrates dedicated applications, or 'apps'.

The clinical apps that are available in Medis Suite include:



QMass is software intended to be used for the visualization and analysis of MR and CT images of the heart and blood vessels.

QMass is intended to support the following visualization functionalities:

- cine loop and 2D review
- performing caliper measurements

QMass is also intended to support the following analyses:

- cardiac function quantification
- anatomy and tissue segmentation
- signal intensity analysis for the myocardium and infarct sizing
- MR parametric maps (such as T1, T2, T2* relaxation)

QMass 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

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.



QFlow is software intended to be used for the visualization and analysis of MR images of the heart and blood vessels.

QFlow is intended to support the following visualization functionalities:

- cine loop and 2D review
- performing caliper measurements

QFlow is also intended to support the following analyses:

- MR velocity-encoded flow quantification

QFlow is also intended to be used for:

- 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.



MRAView is software intended to be used for the visualization and analysis of MR images of the heart and blood vessels. This includes:

- double oblique review of MR Angiographic images,
- 3D review by means of MIP and volume rendering,

- 3D reformatting of MR Angiographic images, and
- performing caliper measurements.

The measurements are based on contours that are manually drawn by the clinician or trained medical technician who is operating the software.



QVentricle XA is the Medis software solution for the quantification of ventricles of the heart in biplane X-ray angiograms.

Medis Suite also supports apps for research use and/or investigation use only. For more information on these apps, please contact Medis.

Additional Medis Suite apps will become available in future releases of Medis Suite.

5.1 Starting a Medis Suite App

To start a Medis Suite app

• Click on the app icon in the **Applications** toolbar.

This will start the app without loading any series.

Or,

- 1. Right-click in the image viewport.
- 2. From the context menu, select the app name.

This will start the app, and load the series visible in the viewport into the app.

Or,

1. Select the series you want to load into the app in the Series Browser.

Multiple series can be selected by holding the SHIFT or CTRL key.

- 2. Right-click on one of the selected series in the Series Browser.
- 3. From the context menu, select the app name.

This will start the app, and load all selected series into the app.

Or,

1. Select the series you want to load into the app in the Series Browser.

Multiple series can be selected by holding the SHIFT or CTRL key.

2. Click and drag the selected series onto the app icon in the Applications toolbar.

This will start the app, and load all selected series into the app.

Or,

1. Select the series you want to load into the app in the **Series Browser**.

Multiple series can be selected by holding the SHIFT or CTRL key.

2. Click and drag the selected series onto the app icon in the **Applications** pane.

This will start the app, and load all selected series into the app.

Or,

Double-click on the app icon in the Applications pane.

This will start the app without loading any series.

When the Medis Suite app is started, it will be displayed on a tab in the central window area of Medis Suite. The launched apps will be displayed after the **View** tab and before the **Reporting** tab in the order they were started.

Multiple instances of Medis Suite apps can be started. They will be running next to each other and can be identified by a sequence number.

Multiple versions of an app can be installed, for example QMass version 8.0 and version 8.1. You can configure how Medis Suite handles multiple app versions when reloading data from a session in

the options. Click • Options... in the Main Medis Suite toolbar, and select the Version Management tab.

Results from the Medis Suite apps will be visible in the **Results** pane of Medis Suite automatically or by actively pushing results from the apps to Medis Suite. Refer to the user manuals of the Medis Suite apps for more detailed information.

5.2 Loading Series into Medis Suite Apps

You can load series into Medis Suite apps that were already running, appending or replacing data that was already loaded.

To load series into Running Medis Suite apps

- 1. Click on the tab that holds the running Medis Suite app in the central window of Medis Suite
- 2. Select the series you want to load into the Medis Suite app in the Series Browser.
 - Multiple series can be selected by holding the SHIFT or CTRL key.
- 3. Double-click one of the selected series, or click one of the selected series and drag the selection onto the running Medis Suite app.

The series will be loaded by the Medis Suite app and the first series will be activated.

Press SHIFT during dragging to add the data to the running Medis Suite app without modifying the app's series selection.

Press CTRL during dragging to unload previously loaded series from the Medis Suite App, and load the new series.

5.3 Closing a Medis Suite App

To close a Medis Suite app

• Click the 'X' on the tab that holds the running instance of the app.



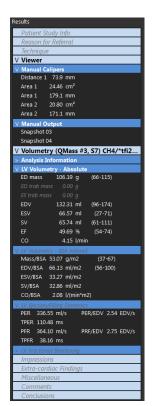
When Medis Suite apps are closed, their accompanying results will be removed from the Medis Suite **Results** pane and the report.

When you switch to another patient or study in the **Series Browser**, all running Medis Suite apps will be closed.

6 Reporting

6.1 Create a Report

You can create a Medis Suite report from the **Results** pane, by showing or hiding results, paragraphs or sections from the report.





To show or hide a result from the report

• Click on the result name or any of the result values to toggle the visibility.

To show or hide a paragraph with all contained results from the report

• Click on the paragraph name to toggle the visibility.

To show or hide a section with all contained paragraphs and results from the report

Click on the section name to toggle the visibility.

To hide all results from the report

• Click in the toolbar.

Sections, paragraphs and results that are hidden in the report, are displayed in the **Results** pane with a grayed out and italic font.

igcpress The **Results** pane is automatically activated when you activate the report.

Your organization name and logo can be configured in the Medis Suite options. To open the options dialog, click > Options... in the Main Medis Suite toolbar.

6.2 Textual Report

By default Medis Suite will show the report in a graphical layout. In addition, you can generate a textual report to allow copy-and-paste of results from Medis Suite to another application.

To open the textual report

• Select from the report toolbar

The textual report only includes the results that are visible in the graphical report. To change the report content, modify the selections in the **Results** pane.

To copy results from the textual report

- 1. Press CTRL+A or select Select All from the context menu.
- 2. Press CTRL+C or select Copy from the context menu.

The entire textual report content is copied to the clipboard.

Or,

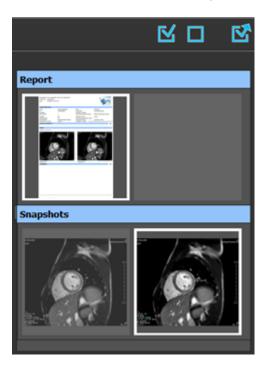
- 1. Select a part of the textual report content.
- 2. Press CTRL+C or select Copy from the context menu.

The selection is copied to the clipboard.

7 Exporting

7.1 Select Results for Export

You can select items from the export list to mark them for export.



To include or exclude results for export

• Click on a thumbnail image to include or exclude the result for export

Or,

• Click to include all results for export.

Or,

• Click to exclude all results for export.

Results that are included for export have a thumbnail that is visible in normal colors and is highlighted with a white border. Results that are excluded for export have a thumbnail that is grayed out and has no border.

7.2 Export Results

You can export all selected results in DICOM format to your repository or PACS for future review or reference.



 \cite{thm} The export format of the report can be set in the Medis Suite options.

To export results

- to export the selected results.
- In the Export dialog, select the export options to export to your PACS, and to include the Medis Suite session, and click OK.

7.3 **Export to Common Image Format**

Results can also be exported in common image formats.

To export a single result into a common image format:

- Right click on the result to export, and select Export...
- In the Export dialog, select the output format, specify a filename, and click OK.

To export a group of results into a common image format:

- Select or deselect the results in the group you would like to export.
- Right click on the header of the result group, and select Export selected...
- In the Export dialog, select the output format, specify a filename, and click OK.

8 Sessions

Status information of Medis Suite can be saved. The session can be reloaded to continue or review the image analyses performed by Medis Suite.

To save a Medis Suite session

Select from the Main toolbar and click Save session

The name of the session is updated to indicated that it is saved.

Or,

Select from the Main toolbar and click Save session as...

Specify the name of the session and click OK.

The name of the session is updated to indicated that it is saved.

Once a session is saved, it contents cannot be overwritten, modified of removed from Medis Suite.

To reset a Medis Suite session

Select from the Main toolbar.

A new session is created.

To select a Medis Suite session

 Open the session combobox in the Main toolbar Medis Suite session.



When you switch or reset a session, all open Medis Suite apps will be closed and their results will be removed from Medis Suite. The Medis Suite apps that were contained in the newly activated session will be started and their results will be loaded in Medis Suite.

Before Medis Suite closes a modified session, you will be asked if you want to save the session.

Medis Suite Services

9 DICOM Connectivity

Medis Suite supports the following DICOM services:

- Echo SCU to test the DICOM connection with a remote DICOM node, such as a PACS.
- Store SCP to receive data from a remote DICOM node, such as a PACS;
- Store SCU to send data to a remote DICOM node, such as a PACS;
- Only in PACS client integrated setup: Move SCU to retrieve data from a remote DICOM node, such as a PACS.

In order to create an efficient setup with DICOM connectivity, you can share the DICOM connectivity service on the Medis Suite server machine with one or more Medis Suite client machines.

The Medis Suite server does not necessarily have to be installed on a Windows Server machine, any supported Windows operating will be sufficient.

To configure the DICOM connectivity of the Medis Suite server

- Go to the machine that acts as a Medis Suite server and start Medis Suite.
- Click > Options... in the Main Medis Suite toolbar to open the Options toolbar and open the DICOM connectivity section.

10 Audit Trail

Medis Suite supports audit trailing functionality to maintain a log of relevant actions performed by Medis Suite or any of the integrated apps.

In order to create an efficient setup with audit trailing, you can share the audit trailing service on the Medis Suite server machine with several Medis Suite client machines.

The Medis Suite server does not necessarily have to be installed on a Windows Server machine, any supported Windows operating will be sufficient.

To configure the audit trailing of the Medis Suite server

- Go to the machine that acts as a Medis Suite server and start Medis Suite.
- Click > Options... in the Main Medis Suite toolbar to open the Options toolbar and open the Audit Trail section.