

QStrain 3.2

Quick Start User Manual



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Regulatory Information

Intended Use

QStrain is software intended to be used for the visualization and analysis of MR 2D images of the heart and blood vessels. QStrain is intended to support the following visualization functionalities:

- cine loop and 2D review

QStrain is also intended to support the following analyses:

- cardiac function quantification
- anatomy and tissue segmentation

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

Indications for Use

QStrain is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the visualization and analysis of MR images of the heart and blood vessels for use on individual patients with cardiovascular disease.

When the quantified results provided by QStrain are used in a clinical setting on MR images of an individual patient, they can be used to support the clinical decisions making for the diagnosis of the patient or the evaluation of the treatment applied. 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 QStrain 3.2.

WARNINGS

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

 You are explicitly recommended to measure strain parameters only in sequences that are validated for strain measurements. Reliable measurement results can only be obtained with validated acquisitions.

 Users must have sufficient proficiency in the English language, read this manual and 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 be 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

 <p>1639</p>	<p>QStrain 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.</p>
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North American Regulations

QStrain has clearance 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.

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

Other Regulations

QStrain 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 and acronyms 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/CTRL+click	Press and hold down the SHIFT/CTRL 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 Results 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.
View > Movie	A sequence of menu options that you select to perform a specific task, is indicated by angular brackets.
Label: <code>QStrain Analysis</code>	Text that you type or that appears on the screen, such as annotation labels, is displayed in Segou UI.
In the Display tab, select the Hide all drawings option.	Names of buttons, fields, menus, menu options, and tab names are capitalized and in bold.

Symbols Used



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



Tip: Provides helpful information or an alternative working method.



Note: Promotes additional information.



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



Warning: Warns you of 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 QStrain

QStrain is the Medis software solution designed to support the 2D visualization and quantification analysis MR and CT studies. It enables cardiologists, radiologists, and technicians to quantify global function and regional strain.

Myocardial function assessment is essential for determining the health status of the myocardium. Global assessment of myocardial function is predominantly determined using the ejection fraction. Regional myocardial, which isolates deformed wall motion, can be quantified using myocardial strain analysis, which is measured as longitudinal radial and circumferential strain.

QStrain runs as an app in the Medis Suite product. The functionality of Medis Suite, including instructions on how to start QStrain and load image data, is described in the Medis Suite user manual. The Medis Suite documentation is available from the User documents tab, which can be opened as follows;

- Press F1.
- Select the  help button.
- Select the Medis Suite main menu button in the upper right corner  > **Help > User Documents**

1.1 QStrain Usage

Availability of the product QStrain is dependent on licenses. If you would like to purchase a license for one or more of the QStrain applications, please contact Medis.

2 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 in 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  > **Help** > **About...**

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Getting Started

3 The QStrain Workspace

QStrain is launched from the app toolbar, app context menu, or app pane of Medis Suite, by

selecting the QStrain is app icon . Detailed information on how to start an application and how to load series into the application, is described in the Medis Suite user manual. QStrain can also be started from QMass.

This chapter covers the following topics:

- Overview
- Toolbars
- Windows Layouts
- Mouse Controls
- Frame selection

3.1 Overview

QStrain application consists of four primary windows each representing a step in the analysis process. A vertical toolbar to the right-hand side of the application, shows the buttons required to complete that step in the analysis process.

The following list describes both the windows and the steps to complete a generic QStrain analysis.

- Series & Analysis selection window.
- Contour Editing window.
- Analysis window.
- ED-ES review window.

3.2 Toolbars

A vertical toolbar on the right-hand side of the application allows one to navigate through the different steps of an analysis. In each step of the analysis process, different icons are shown in the toolbar.

The list below describes the purpose of each icon.

Icon	Function
Series & Analysis Selection Toolbar	
	Forward button
	Back button
Contour Editing Toolbar	
Analysis Toolbar	
	About Box.
	
	
	Window Width, Window Level
	
	
	
	
	Modifying the contour for the ED or ES phase. Make a new tracing contours from scratch.
	Segmental and detailed strain results!
	HemoDynamic's.
Etc..	

Icon	Function
Review ED ES Toolbar	

❗ You cannot move toolbars to another part of the main application window.

❗ You cannot hide toolbars.

QStrain also contains many individual buttons, that are not located in the toolbar. The list below describes the purpose of each icon in the application, that is not located in the toolbar.

Icon	Function
Describe every icon in the application, that has not been addressed in the toolbar overview.	

4 Analysis Selection

4.1 Series & Analysis Selection

The opening window presents both the series browser and an analysis selection component. This section of the document describes;

- Loading series
- Analysis selection

4.1.1 Loading Series

A serie, or multiple series can be loaded into QStrain from the **Series Browser** of Medis Suite. Refer to the Medis Suite user manual for detailed instructions.

QStrain supports short and long-axis MR and CT series.

To load series from the Series Browser of Medis Suite

1. Select the set of strain series in the image or text view of the Medis Suite **Series Browser**.
2. Click and drag the selected items onto the QStrain application icon.

Or,

1. Double click an item in the image view or text view of the Medis Suite **Series Browser**.

Or,

1. Select all series in the image or text view of the Medis Suite **Series Browser**.
2. Right-click above the selected series to open a context menu.

Choose QStrain.

This will load the series into the series analysis selection viewport.

To load series from QMass

- Select the icon  in the **General** toolbar in QMass.

ⓘ All the series data loaded in QMass and their related contours that have been created in QMass, will be loaded into QStrain.

ⓘ QStrain only loads MR and CT DICOM series.

4.1.2 Analysis Selection

After loading and selecting a series, each series can be coupled with a given QStrain analysis.

To couple a series with a SAX Analysis.

- Drag the series...

To couple a series with a LAX Analysis.

- Drag the series...

To couple a series with a yyyY Analysis.

- Drag the series...

To couple a series with a xxxX Analysis.

- Drag the series...

4.2 Contour Editing

When a series has been coupled with an analysis, contours can be added, deleted, or modified in a series. This section describes the contour management aspects of a QStrain analysis.

To continue from the Series Selection window to the Contour Editing.

- Select the  icon in the toolbar.

4.2.1 Adding contours

QStrain contours are added as follows.

To add contours to a LAX series Analysis.

- Select the  to enable point mode contour definition.
- Start editing by left-clicking the mouse along the endocardium wall.
- To finish editing, right-click the mouse button.

To add contours to a SAX series Analysis.

- Select the ...

4.2.2 Removing contours

QStrain contours are removed as follows.

To delete contours from a LAX series Analysis.

- Select the ...

To add contours to a SAX series Analysis.

- Select the ...

4.2.3 Modifying contours

QStrain contours are removed as follows.

4.3 Finish Contour Editing

After contours have been defined, the analysis maybe started.

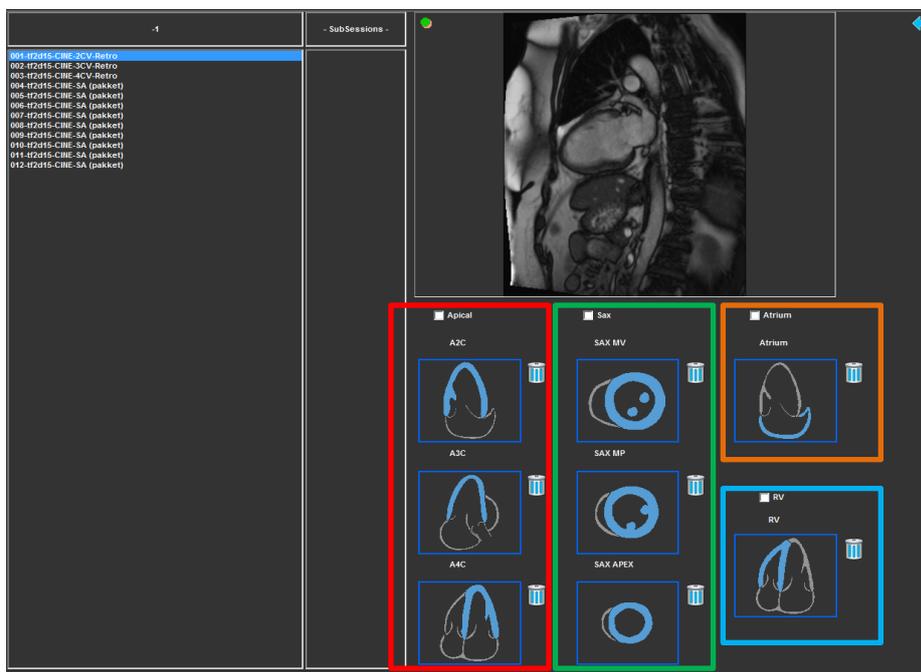
To continue from the Contour Editing window to the Analysis window.

- Select the  icon in the toolbar.

5 Performing a QStrain Analysis

QStrain application supports the following strain related analyses.

- LV long axis
- LV short axis
- Atrial images
- RV images



All analyses share a similar workflow.

- Loading a Series & Analysis selection.
- Contour Editing.
- Completing an Analysis.
- ED-ES review.

Additional analysis tools are available

- M-Mode

QStrain Results

6 QStrain Results

Each QStrain analysis has the following set of graphs and results that are applicable to that analysis.

- SAX
- LAX

Reporting

QStrain results are made available in the Medis Suite Results pane and in the Medis Suite report.

Report created by:
Report date/time:
Session name:

Medis

Patient Study Info

Name: 11/11/2010
ID: Description: MRI Heart Morph + Func w/ + w/o Con
Birthdate: Accession number:
Age/Gender: Referring physician's name:
Modality: Institution name:
Manufacturer: Performing physician's name:
Manufacturer model: Operator's name:
Acquisition number: 1

Reason for Referral [Edit]

QFlow 4D Stable Daily 1.0 #1

Background Correction

Fitting Order: 1
Std Threshold: 25%

Reconstruction 01 Results ROI 1:[ROI 1] slice 1

	per HB	per Minute
Net flow volume	34.17 ml/beat	3.04 l/min
Forward flow volume (S.I)	34.45 ml/beat	3.06 l/min
Backward flow volume (S.I)	0.27 ml/beat	0.02 l/min
Regurgitant fraction (S.I)	0.80 %	
Average flow velocity	14.97 cm/s	
Peak flow velocity	145.10 cm/s	
Peak pressure gradient	4.42 mmHg	
Min vessel area	257.63 mm ²	
Max vessel area	293.36 mm ²	

Reconstruction 01 Results ROI 2:[ROI 2] slice 1

	per HB	per Minute
Net flow volume	-14.14 ml/beat	-1.26 l/min
Forward flow volume (S.I)	18.95 ml/beat	1.68 l/min
Backward flow volume (S.I)	4.81 ml/beat	0.43 l/min
Regurgitant fraction (S.I)	25.39 %	
Average flow velocity	-16.07 cm/s	
Peak flow velocity	102.20 cm/s	
Peak pressure gradient	4.18 mmHg	
Min vessel area	107.46 mm ²	
Max vessel area	128.93 mm ²	

Conclusions [Edit]

Figure 1 Medis Suite Report with QStrain Results

The Reporting functionality of Medis Suite is described in the Medis Suite user manual. The Medis Suite documentation is available from the User documents tab, which can be opened as follows;

- Press F1.
- Pushing the  help button.
- Select the Medis Suite main menu button in the upper right corner  > **Help** > **User Documents**

7

Sessions

The QStrain state can be saved in a Medis Suite session. The session can be reloaded to continue or review the analyses.

The session functionality in Medis Suite is described in the Medis Suite user manual. The Medis Suite documentation is available from the User documents tab, which can be opened as follows;

- Press F1.
- Pushing the  help button.
- Select the Medis Suite main menu button in the upper right corner  > **Help** > **User Documents**

8 Shortcut Keys

When you are working with QStrain, you can use several combinations of keys on your keyboard and mouse actions to quickly perform the following tasks.

Press	To
Layout	
F11	Show or hide the workspace window panes
Image control	
Middle-click and hold	Hide all graphics
Middle-click and drag, or Ctrl and drag	Pan
Ctrl+Shift and drag	Zoom
Alt+Shift and drag	Stack
Procedures	
A	Create an area measurement
D	Create a distance measurement
S, or CTRL+SPACE	Create a snapshot
Esc	Stop editing the procedure
Delete	Delete the currently selected procedure

Press	To
SHIFT+Delete	Delete all procedures
Navigation Controls	
HOME	Display the first time point
END	Display the last time point
Arrow up	Display the previous slice
Arrow down	Display the next slice
Arrow left	Display the previous time point
Arrow right	Display the next time point
CTRL+arrow left	Play cine backward
CTRL+arrow right	Play cine forward
Esc	Stop playing cine
Page Up	Display the previous series
Page Down	Display the next series

9 General References

Anterior (or ventral) Describes the front or direction toward the front of the body. The toes are anterior to the foot.