

QStrain 3.2

Quick Start User Manual

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On the Medis website, select "Products" and then the applicable product group. The user documentation can be found on that page.

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Regulatory Information

Intended Use

QStrain is software intended to be used for the visualization and analysis of MR and CT 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 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 and CT 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 and CT 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.

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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 selected operating language, have read this manual and became familiar with the software to 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



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.

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.

Asia-Pacific Regulations

QStrain complies with the requirements of the Australian Therapeutic Goods Administration and has been licensed as a Class IIa medical device.

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

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

Results pane... 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: QStrain Analysis Text that you type or that appears on the screen, such as

annotation labels, is displayed in Segou UI.

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Symbols Used

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

9

Tip: Provides helpful information or an alternative working method.

1

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

QStrain can be started as an independent application or an integrated component of QMass.

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 and the comprehensive QStrain 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

QStrain® is the Medis software solution for measuring cardiac strain for MR and CT.

The QStrain feature is only active if you have the appropriate license(s).

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 (sales@medisimaging.com).

2 System Requirements

The system requirements can be found in the Medis Suite user manual. There are no additional QStrain system requirements.

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 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. In MedSuite, you can look up the version number of your software. In

the top right-hand corner select > Help > About....

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Getting Started

4 Workflow Overview

A QStrain analysis can be started either from QMass, or as a standalone application.

The following table describes the steps in the workflow of a QStrain analysis started directly from QMass, or QStrain as a standalone application.

For further details refer to the section, Workflow: Performing a QStrain Analysis.

Table 1 : QMass + QStrain workflow / QStrain standalone workflow

QMass + QStrain	QStrain standalone
Load Series	
Automatic Contour Detection	
Review Contours	
Start QStrain Analysis:	Start QStrain Analysis
Automatic load series data & contours	
QStrain	QStrain
Select Series	Select Series
Select Analysis Type	Select Analysis Type
	Manually draw contours
	Review Contours
	Verify ED & ES phase
Complete strain analysis	Complete strain analysis

① The preferred workflow is to start QStrain from QMass, utilizing the automatically detected contours.

Workflow

5 Workflow: Performing a QStrain Analysis

QStrain application supports the following strain related analyses.

- LV long axis (Apical)
- LV short axis (SAX)
- Atrial images (Atrium)
- RV images (Right Ventricle)

To navigate through the analysis steps.

- Click in the vertical toolbar to continue to the next stage of an analysis.
- Click in the vertical toolbar to go to the previous stage of an analysis.
- Click in the vertical toolbar to go to the Loading a Series & Analysis stage.
- In the ED/ES Review viewport, click to accept and click to reject contour changes.
- In the Sequence M-Mode Selection window click to return to the analysis.
- In the Time to Peak Segmental Analysis window click to return to the analysis.

5.1 QStrain Analysis General Steps

QStrain analyses share the same steps.

- Loading Series
- Analysis Selection
- Creating Contours
- Completing Global Strain Analysis.
 - o Optional: SAX Analysis: Add a reference point, for each slice.
 - o ED ES Phase Review: Sequence M-Mode
 - o Complete detailed Regional analysis, in the Time to Peak Analysis.

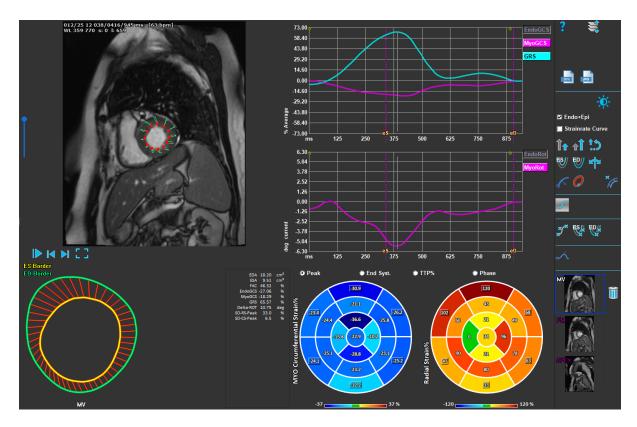


Figure 1 : SAX Analysis



Figure 2: LAX Analysis

5.2 Loading Series

The first step of a strain analysis is loading the series. A series, 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 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. 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.

① All the series data loaded in QMass and their related contours that have been created in QMass, will be loaded into QStrain.

① QStrain only loads MR and CT DICOM series.

5.3 Analysis Selection

QStrain application supports the following strain related analyses.

LV long axis (Apical)
LV short axis (SAX)
Atrial (Atrium)

• RV (Right Ventricle)



Figure 3 : Series & Analysis Selection

Series selection.

• Select a series from the left viewport.

Couple a series with an image orientation.

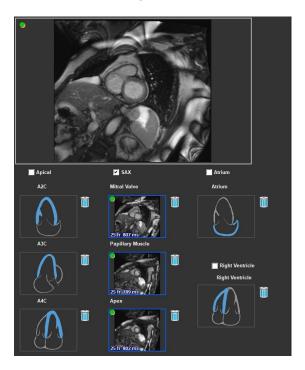


Figure 4: Couple a series with an orientation

Choose the analysis type.

• Check the checkbox of the analysis to perform.

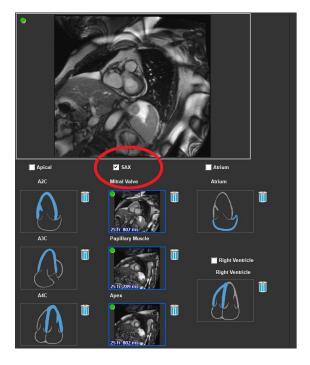


Figure 5 : Select QStrain Analysis Type

igodots Only one analysis type can be selected.

① A green or red circle in the upper left corner of the viewport indicates epi or endo contours are imported with the selected series.

The selected series are coupled with a given QStrain analysis. LAX and SAX analyses facilitate up to three series, each representing one slice. Atrium and RV analyses are limited to one series.

To couple a series with a SAX Analysis.

Select a series in from the series list.



Click and drag viewport image onto the corresponding level, Mitral Valve



To couple a series with a LAX Analysis.

Select a series in from the series list.



Click and drag viewport image onto the corresponding A2C



chamber view icons.

To couple a series with an Atrium Analysis.

Select a series in from the series list.



Click and drag viewport image onto the Atrium

To couple a series with a RV Analysis.

Select a series in from the series list.



Click and drag viewport image onto the RV

To remove a series from an Analysis

icon next to the series you want to remove

5.4 Contours Management

Contours are a prerequisite of a strain analysis. The following section explains the contour management related aspects of QStrain.

① When contours are imported from QMass, the Contour Editing workflow of the analysis is automatically surpassed.

5.4.1 Creating Contours

The first step of the QStrain analysis is to define the Endocardium and optionally the Epicardium contours. QStrain contours may be added via the ES or ED contour editing and review windows or the contours may be imported with the selected series.

5.4.1.1 Enable the Contour Creation window.



 After completing the series selection and analysis in the Series selection window, click in the vertical toolbar.

Or,

• In the analysis viewport, click or , or in the vertical toolbar.

Or,

• In the analysis viewport, select the checkbox Endo+Epi in the vertical toolbar.

5.4.1.2 To create a contour.

When the contour editing window is open, edit the contours as follows:

- 1. Click to set the first edit point on the image, in the recommended position displayed by the contour point indicator.
- 2. Click to set the second edit point on the image, in the recommended position displayed by the contour point indicator.
- 3. Right-click to set the last edit point on the image, in the recommended position displayed by the contour point indicator. A contour will be generated.

igoplus Select the check box Endo + Epi to generate both Endo and Epi contours.

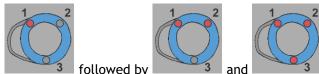
① Clear the check box Endo + Epi to generate the Endo contour only.

5.4.2 Creating Contours by Indicators

In the bottom right corner of the Contour Editing viewport, a contour position indicator recommends the ideal position placement of the progressive contour points.

5.4.2.1 Contour Point Indicators (SAX)

SAX



SAX placement indicators as follows,



Atrium



LAX placement indicators are as follows,









Atrium placement indicators are as follows,

RV



RV placement indicators are as follows,

5.4.3 Editing Contours

5.4.3.1 To modify contours

To modify an existing contour.

1. Hover the mouse cursor over the contour edit point to be modified.

- 2. Click and drag the mouse to move the contour edit point.
- 3. Release the mouse to set the edit point.

5.4.3.2 To remove all contour points.

1. Click on the edit point in the vertical toolbar.

5.4.3.3 To remove a contour point.

1. Hoover the mouse cursor over the contour edit point to be removed.

Right-click to the contour edit point.

5.4.4 Finish Contour Editing

After contours have been defined, the analysis can be continued.

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

• Select the in the vertical toolbar.

Or,

• Right-click in the Viewport

5.5 Analysis Accessories

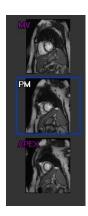
The vertical toolbar in the analysis window, contains utilities that assist in the strain analysis workflow.

5.5.1 Creating a Reference Point for SAX Analysis

Reference points enhance the accuracy of the results.

To set a reference point in a SAX analysis.

• Choose the SAX a slice from the vertical toolbar.



- Select the in the vertical toolbar.
- Click on the Anterior Septum.
- Click Confirm.
- igspace SAX strain analysis requires a reference point placement on the anterior septum of each slice.

5.5.2 ED ES Management

5.5.2.1 ED ES Contour Review & Modification

The ES contour review window facilitates updating the ED and ES contours.

To enable the ES Contour Review & Modification Window.

• In the analysis window click



in the vertical toolbar.

To enable the ED Contour Review & Modification Window.

• In the analysis window click in the vertical toolbar.



5.5.2.2 ED ES Phase Review: Sequence M-Mode

The Sequence M-Mode is a utility that assists in managing the position of the ED and ES phase. A Sequence M-Mode line is used to create an M-Mode image. Typically, the M-Mode line is drawn from the outer ventricular walls across the diameter of the ventricle. The ED and ES phase positions can then be adjusted on the M-Mode image.

Sequence M-Mode editing consists of three steps.

- Define a line across a ventricle.
- Evaluate the M-Mode image.
- Review/Modify the ED and ES position.

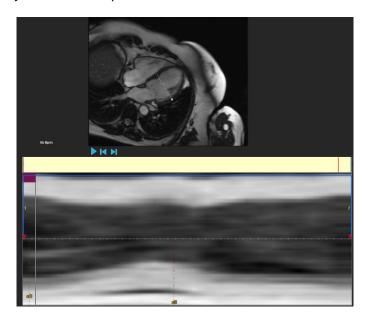


Figure 6: Sequence M-Mode ED ES Phase Review

The ED and ES phases can be verified and modified if necessary, using the M-Mode image. The resulting M-Mode overlay image will automatically be displayed in the volume graph of in the analysis window. The overlay can be toggled off and on.

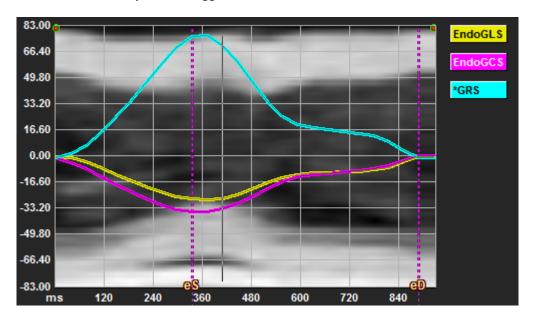


Figure 7: M-Mode Overlay in Analysis Window Volume Graph

To draw the M-Mode line.

- In the analysis viewport, click in the vertical toolbar.
- In the image, click to begin the M-Mode line.
- Right-click to end the M-Mode line.

To update the ED or ES phase.

- Click and drag the ED or ES vertical gridlines in the M-Mode image.
- Click in the vertical toolbar to return to the analysis window.

To enable / disable M-Mode overlay in volume graphs.

In the analysis window.

• Click to enable or disable the M-Mode in the strain graph.

5.5.3 Time to Peak Analysis

The Time to Peak analysis provides detailed 17 segment AHA model regional strain results. The regional results are distinguishable by color. The segment model and the corresponding graphs are interactive and facilitate enabling and disabling of the regional results.

The following color scheme is used to distinguish the different segment model regions and their corresponding results.

Basal		Mid		Apical	
Basal	Anterior	Mid	Anterior	Apical	Anterior
Basal	Anterorlateral	Mid	Anterorlateral	Apical	Inferior
Basal	Inferiorlateral	Mid	Inferiorlateral	Apical	Septal
Basal	Inferior	Mid	Inferior		Lateral
Basal	Inferorseptal	Mid	Inferorseptal		
Basal	Anterorseptal	Mid	Anterorseptal		

To start a Time to Peak analysis.

• Click in the vertical toolbar to return to the analysis window.

To select a region.

In the Time to Peak analysis window:

• Hover over the Segment model.

Or,

• Hover over the graphs.

To enable / disable a region.

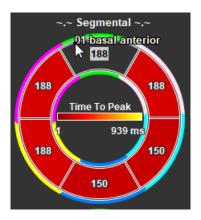


Figure 8 : Enable/Disable SAX TTP Region

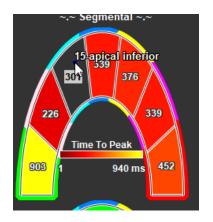


Figure 9: Enable / Disable LAX TTP Region

In the Time to Peak analysis window.

• Click the segment to enable or disable.

To enable / disable all regions.

In the Time to Peak analysis window.

• Click the center of the segment model to enable or disable all segments.

To switch regional analysis type.

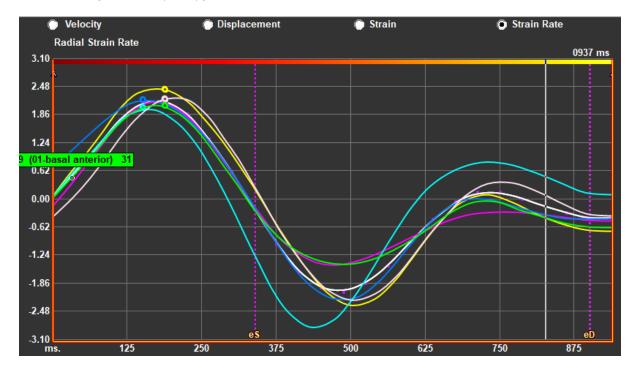


Figure 10 : Select Strain Results Type

In the Time to Peak analysis window.

• Select either 'Velocity', 'Displacement', 'Strain' or 'Strain Rate'.

To switch between Endocardium, Epicardium or Myocardium regional results.

In the Time to Peak analysis window.

Click in the vertical toolbar for the Endocardial regional results.

Click in the vertical toolbar for the Epicardial regional results.

Click in the vertical toolbar for the Myocardial regional results.



5.5.4 3D Movie

QStrain has a 2D/3D view to assist in the visualization of strain whilst performing a strain analysis.

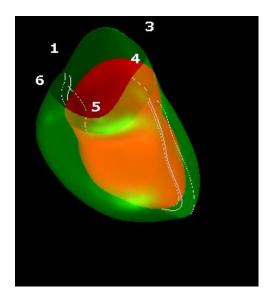


Figure 11: 3D View of Strain

To enable 3D view

- Load and complete an analysis of at least 2 LAX series.
- In the analysis viewport, click in the vertical toolbar.

Results

6 QStrain Results

The QStrain results are visible in QStrain, in the Medis Suite Findings and the Medis Suite Report. SnapShots and movies may also be added to the results. QStrain analysis provides the following sets of strain results.

- Global
- Standard Regional
- Detailed Regional (Time to Peak Analysis)

The primary strain results are as follows.

- Global Radial Strain (GRS)Global Circumference Strain (GCS)
- Global longitudinal Strain (GLS)
- Refer to

Results Overview for further details on the Results

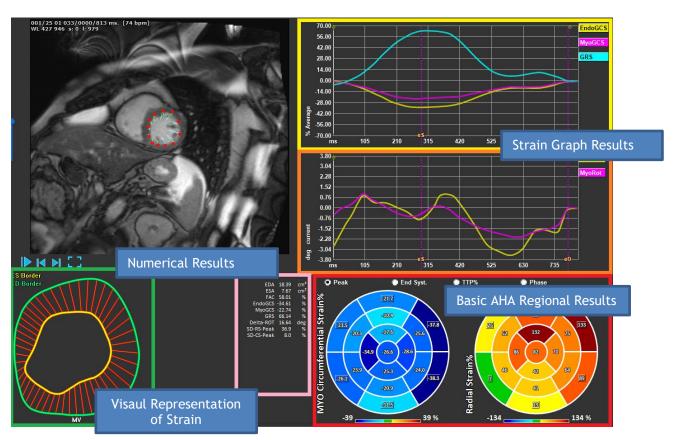


Figure 12: Results Sections Overview

6.1 Global Strain Results Graphs

The global results are accessible from the analysis window. There are two graphical results graphs. The upper graph shows Global Strain curves, while the lowers shows Rotational Strain curves in SAX analysis and Area Curves in the LAX, Atrium and RV analysis.

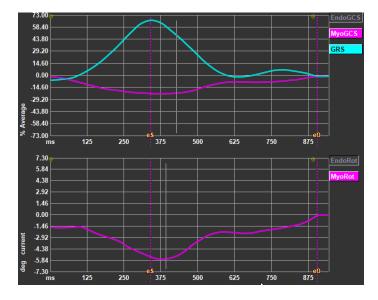


Figure 13: Analysis Strain Graphs

To enable Strain Rate curve

In the analysis viewport, select the checkbox Strainrate Curve in the vertical toolbar.

- Myocardial Strain results are available when both Endo and Epi contours are available.
- The rotation strain is slice dependent and therefore reflects the strain of the selected slice.ndo

6.2 Global Strain Numerical Results

The numerical global results are accessible from the analysis window.

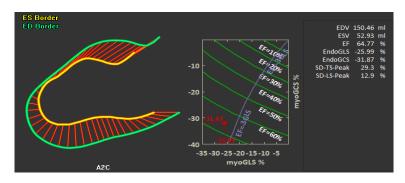


Figure 14: LAX Numerical Results

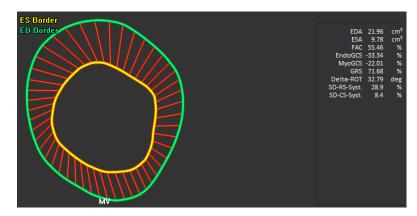


Figure 15: SAX Numerical Results

6.3 Standard Regional Strain Results

The standard regional results are accessible from the analysis window.

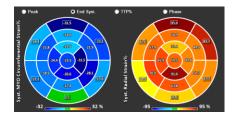


Figure 16: Standard Regional Results

6.4 Detailed Regional Results (Time To Peak)

Detailed regional results are accessible from the analysis window.

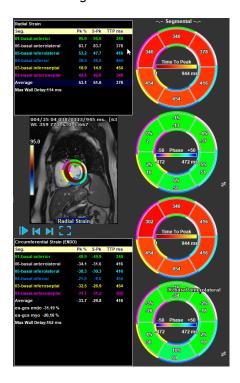


Figure 17: Detailed Regional Results. TTP

7 Results Overview

The following lists define the results that are available from each QStrain analysis.

7.1 LV long axis (Apical) results

QStrain provides the following list of results:

- EDV
- ESV
- EF
- Endo GLS
- Endo GCS
- Myo GLS (Only if EPI contour is segmented)
- Myo GCS (Only if EPI contour is segmented)
- GRS (Only if EPI contour is segmented)
- SD-LS-Peak (Only when Peak AHA view is selected)
- SD-TS-Peak (Only when Peak AHA view is selected, and EPI contour is segmented)
- SD-LS-Syst. (Only when End Syst. AHA view is selected)
- SD-TS-Syst. (Only when End Sys. AHA view is selected, and EPI contour is segmented)
- SD-Ttp%-LS (Only when TTP% AHA view is selected)
- SD-Ttp%-TS (Only when TTP% AHA view is selected, and EPI contour is segmented)
- SD-Ph%-LS (Only when Phase AHA view is selected)
- SD-Ph%-TS (Only when Phase AHA view is selected, and EPI contour is segmented)

7.2 Short axis (SAX) results

QStrain provides the following list of results:

- EDA
- ESA
- FAC
- Endo Rot
- Endo GCS
- Myo Rot (Only if EPI contour is segmented)
- Myo GCS (Only if EPI contour is segmented)
- GRS (Only if EPI contour is segmented)
- Delta Rot (Only when all slices in SAX-LV are present)
- SD-CS-Peak (Only when Peak AHA view is selected)
- SD-RS-Peak (Only when Peak AHA view is selected, and EPI contour is segmented)
- SD-CS-Syst. (Only when End Syst. AHA view is selected)
- SD-RS-Syst. (Only when End Syst. AHA view is selected, and EPI contour is segmented)
- SD-Ttp%-CS (Only when TTP% AHA view is selected)
- SD-Ttp%-RS (Only when TTP% AHA view is selected, and EPI contour is segmented)
- SD-Ph%-CS (Only when Phase AHA view is selected)
- SD-Ph%-RS (Only when Phase AHA view is selected, and EPI contour is segmented)

7.3 Atrium results

QStrain provides the following list of results:

- EDV
- ESV
- EF
- Endo GLS
- Endo GCS
- FAC

7.4 RV long axis (Right Ventricle)

QStrain provides the following list of results:

- EDA
- ESA
- FAC
- Endo GLS
- Myo GLS (Only when EPI contour is segmented)
- GRS (Only when EPI contour is segmented)

8 Reporting

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

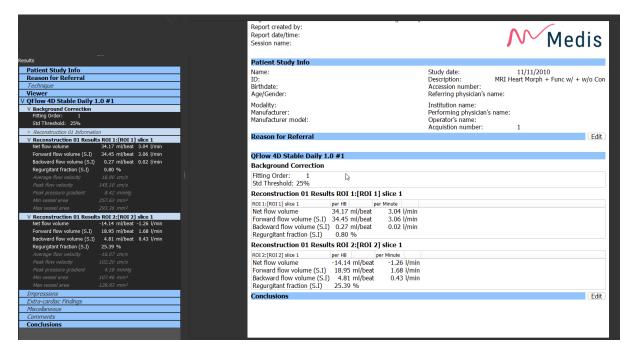


Figure 18 Medis Suite Report with QStrain Results

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

9 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

Reference

10 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	То				
Layout					
F11	Show or hide the workspace windowpanes				
Image control					
Scroll wheel	Zoom				
Procedures					
Navigation Controls					
Arrow left	Display the previous time point				
Arrow right	Display the next time point				

11 Parameters / Measurements

11.1Strain Parameters

GLS Global Longitudinal Strain

GRS Global Radial Strain

GCS Global Circumferential Strain

MyoRot Myocardial Rotation

Delta-ROT Delta Rotation, difference between basal and apical rotation

Pk% Peak strain value as a percentage

S-Pk Strain value at ES as a percentage

TTP ms Time to peak in milliseconds

11.2Velocity Parameters

Pk Peak velocity

S-Pk Velocity at ES

TTP ms Time to the peak velocity in milliseconds

11.3Displacement Parameters

Pk Maximum displacement

S-Pk Displacement at ES

TTP ms Time to the maximum displacement in milliseconds

11.4Strain Rate Parameters

Pk 1/s Strain rate peak in 1/s

S-Pk Strain rate at ES in 1/s

TTP ms Time to the strain rate peak in milliseconds

11.5 General Parameters

ED End diastolic phase

ES End systolic phase

EDA ED Area

ESA ES Area

FAC Fraction Area Change

EDV ED Volume

ESV ES Volume

EF Ejection Fraction

TTP Time to Peak

Max Wall Delay Difference between lowest and highest TTP