



QFlow[®] 5.6

Quick Start Manual



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Regulatory Information

Intended Use

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.




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

Indications for Use


QFlow 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 images of the heart and blood vessels for use on individual patients with cardiovascular disease. Finally, QFlow can be used for the quantification of cerebral spinal fluid in MR velocity-encoded flow images.

When the quantified results provided by QFlow are used in a clinical setting on MR 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.

GENERAL WARNINGS

-  You are explicitly recommended to measure flow parameters **only in sequences that are validated for flow measurements**. Reliable measurement results can only be obtained with validated acquisitions.
-  QFlow must be used by cardiologists, radiologists, or trained technicians who are qualified to perform cardiac analyses. If the analysis results are used to reach a diagnosis, the results must be interpreted by a qualified medical professional. In clinical practice QFlow should not be used for purposes other than those indicated in the section Intended Use.
-  Users must make sure to read this manual to familiarize themselves with the software and be able to obtain reliable analysis results.

European Regulations

 0120	QFlow is qualified as a class IIa medical device. It complies with the requirements of the Dutch Medical Devices Decree (Besluit Medische Hulpmiddelen, Stb. 243/1995) and the European Medical Device Directive 93/42/EEC.
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North American Regulations

QFlow® 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.

QFlow complies with the requirements of the Canadian Medical Devices Regulations 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.
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.

Keyboard

SHIFT+click	Press and hold down the SHIFT 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, clear the Show patient data check box.	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.
Contours can be saved in a <code>.CON</code> file.	Text that you type or that appears on the screen, such as file names and file locations, is displayed in <code>Courier New</code> .

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.


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Introduction

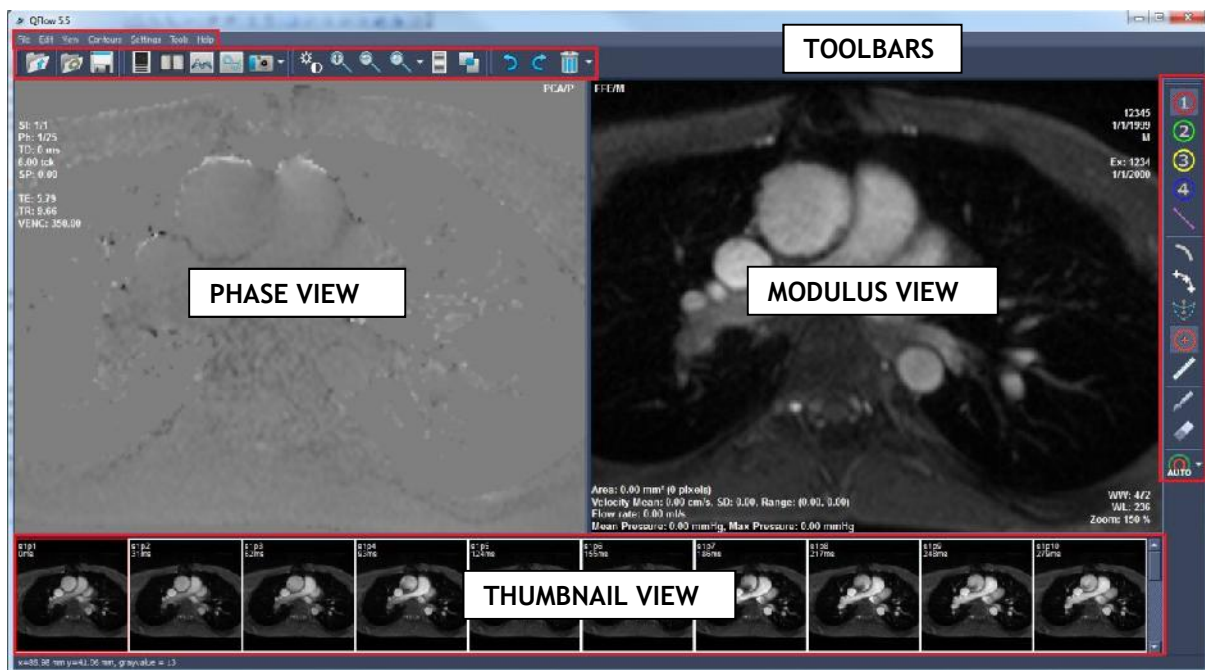
About QFlow

QFlow is the Medis software solution for the quantitative analysis of velocity-encoded MR studies. Its automatic contour detection enables you to quantify arterial and transvalvular blood flow quickly and accurately.

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

The QFlow Workspace

The QFlow workspace consists of a menu bar, a set of toolbars, and three views.




Quick Tour

In this quick tour, you will get to know QFlow's key features and basic workflow. You will open a study, review it, perform a vascular flow analysis, view analysis results, apply background correction, save the analysis, create a report, and save the report.

Starting QFlow and Reviewing Studies

QFlow is usually installed by Medis support personnel or by your system administrator. If you need installation instructions, refer to the QFlow Installation Manual on the installation CD-ROM.

 QFlow requires both phase and modulus series.

To start QFlow

- Double-click the QFlow icon on the desktop.

Or,

- Select **Start > (All) Programs > Medis QFlow > QFlow 5.6.**

To open a study

1. Click  or select **File > Open Study...**

In the dialog window, browse the directory structure and select the directory in which the studies are located.

2. In the top right pane of the dialog window, select the study and click **OK.**

To browse the images



- Use the arrow keys on your keyboard to browse the images in the Modulus View and Phase View.

To select an image

- Click an image in the Thumbnail View to select it.

This displays the image in the Phase and Modulus Views.

To zoom in or out

- In the toolbar, click  or .

Or,

- Press + or -.

To pan

- Press the middle mouse button or mouse wheel, hold it down and drag.


This pans the image.

To return to editing mode, release the middle mouse button or mouse wheel.

To adjust window width and level

- In the Phase View or Modulus View, hold down the middle mouse button or mouse wheel and drag.

To view the series in the Movie window


- Click  in the toolbar or press F5.

To switch between phase and modulus images in the Thumbnail View

- Select **View > Modulus Images** or **View > Phase Images**.

Performing Vascular Flow Analyses

Now that we have reviewed the series, we are going to perform a vascular flow analysis using the automatic contour detection.

 If you want to perform a transvalvular flow analysis, you have to create contours manually. For detailed instructions, refer to the QFlow User Manual.

To perform a vascular flow analysis


1. Select the image that shows most contrast between the vessel and the background.

2. Click  in the toolbar.




3. Click .




4. In the Phase or Modulus View, click to select the center point of the vessel you want to analyze.


5. Verify that the contour is correct.


 The maximum velocity pixel within the contour in this phase is marked by an orange square, the minimum velocity pixel is marked by a blue square.

To create a new contour, you can place the center point again.

To draw or edit the contour, click  or  and trace the contour in the Modulus or Phase View, or click  and drag the contour.

6. If you want to analyze a second, third, or fourth vessel in the same series, click , , or  in the toolbar, and repeat steps 3 through 5 for each vessel.


7. Click  to automatically detect all contours.






 Some series require customized contour detection. For a detailed description of when best to use which type of contour detection, refer to the QFlow User Manual.

8. Check if all contours have been detected correctly. Make sure to edit contours if needed.


To apply background correction using the ROI4 area method

If needed, you can apply background correction. The ROI4 area method is one of three methods for background correction that are available.

 Refer to the QFlow User Manual for instructions on performing background correction using one of the other methods.


1. Select **Settings > Main...** or click .
2. On the **Background subtraction** tab, from the **Subtract background flow** drop-down list, select **ROI 4 area** and close the settings dialog.
3. In the toolbar, select , and then select  or .
4. In the Phase or Modulus View, trace a contour in an area where you expect no flow. Make sure that you do so as close to the vessel as possible.
5. Press CTRL+C and then CTRL+SHIFT+V. This copies the contour to the other images.
6. Check the area in all images to verify that it does **not** cover areas where flow is to be expected. Edit the contours if necessary.
 You can move a contour as follows. Select its ROI icon in the toolbar, then press CTRL and use the left mouse button to move the contour.
7. Any results that you now view are corrected for background flow.

To view analysis results

1. Click , press F7, or select **View > Graph**.
This displays the Mean Velocity diagram.
2. Select the diagram of your choice from the **Show** drop-down list.

If you want to check the background correction curve, click .

To save an analysis


1. Click  or select **File > Save**.
2. In the dialog window, select the directory in which you want to save the analysis contours, then select **.CON** or **.DCM** as the file type from the **Save as type** drop-down list.
3. Click **Save**.

Creating Reports

Reports contain a summary of patient and study information and a number of analysis results. You can create graphic reports (save as HTML, PDF or as DICOM SC), plain text reports (save as TXT or as DICOM SC), or XML reports. Graphic reports may contain images, movie frames, movies and result diagrams.

To create and save a report



1. Click  or press F9.
2. From the **Report Layout** drop-down list, you can select another type of report.

This immediately creates the new report.

3. To create a text or XML report, click **Plain text** or **XML**.

If you are creating a text report, you can select the results you are interested in by selecting the corresponding check boxes under **Contents**.

4. Click **Save...** at the bottom of the Report window.

More Information

This Quick Start Manual outlines the basics of working with QFlow. You can find more details and more instructions, for example on performing transvalvular analyses and on performing more types of background correction, in the QFlow User Manual.

On the QFlow installation CD-ROM you can also find the QFlow Installation Manual, Release Notes, Reference Manual, DICOM Conformance Statement and Declaration of Conformity.

To access the QFlow User Manual

- In QFlow, press F1.

To access all QFlow documentation

1. Look up the QFlow installation directory in your file system.
2. You can find the QFlow documentation set in the `Documents` directory.

Or,

1. Insert the QFlow CD-ROM.
2. In Windows Explorer, browse the directory structure of the CD-ROM.

The documentation is located in the `Documents` directory.