

MiraQ Cardiac

Intraoperative Surgical Guidance
and Quality Assessment



For best surgical outcomes

Improve surgical outcomes, demonstrate quality, and increase cost efficiency.

The Medistim **MiraQ™ Cardiac** System combines ultrasound imaging and transit time flow measurement (TTFM) in a single system that is specifically designed for cardiac surgery.

There is growing support of the idea that checking grafts and anastomoses during cardiac surgery should be standard of care. Reliability and ease of use is a major determinant for this to become reality.

The **MiraQ™ Cardiac** has built-in support for Guided Workflows. These are software protocols that assist the user to a standardized approach to quality assessment. Intraoperative quality assessment has become easier to adopt, is customizable to the surgeon's needs and enhances work efficiency.

Guidelines-endorsed technology

TTFM and Epiortic ultrasound imaging are included in various guidelines and endorsed by EACTS/ESC, NICE, ASE/EACVI and ACCF/AHA.^{1,2,3,4}

Medistim's TTFM probes utilize transit time technology to accurately measure blood volume flow intraoperatively. The Medistim **L15 High-frequency Ultrasound Imaging Probe** provides high-resolution images that allow the surgeon to assess morphology.

The **MiraQ™ Cardiac** System combines the spatial information from epicardial ultrasound imaging and quantitative data from TTFM which enables the surgeon to perform a prompt and accurate assessment and revise the graft when necessary.

Epicardial imaging

Epicardial ultrasound imaging gives a simple, fast and safe view of coronary stenoses and graft anastomoses, providing immediate feedback on the quality of the CABG surgery.

Transit Time Flow Measurement

Performing flow measurements with the **MiraQ™ Cardiac** is the quickest and most accurate way to verify graft patency while the patient is still in the operating room.

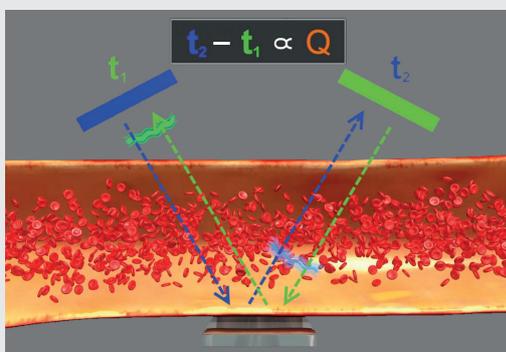
Epiortic imaging

Epiortic imaging provides a sensitive and direct diagnosis of aortic disease. This may lead to modifications of the surgical strategy and thus contribute towards reduced rates of major adverse cardiac and cerebrovascular events (MACCE).

TTFM - a proven technology

TTFM technology provides:

- Objective and reliable data
- Robust and user independent
- Easy to use

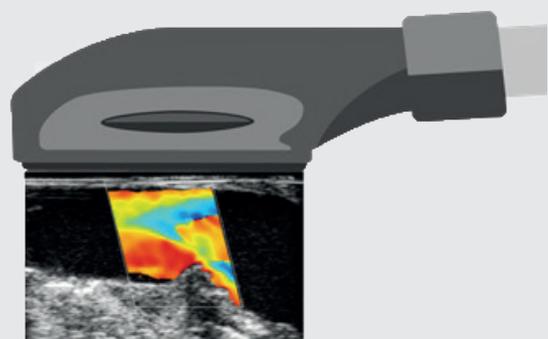


The TTFM principle is based on measuring the difference between upstream and downstream transit time of a wide ultrasound beam. The transit time difference is directly proportional to the blood volume flow. This measurement principle gives an accurate quantification of the real time volume flow that complements the ultrasound imaging.

High-frequency ultrasound imaging

Medistim HFUS provides:

- High-resolution, near-field images during surgery
- Probe head designed for small incisions
- Reusable and sterilizable probe



Ultrasound imaging generates images by transmitting ultrasound pulses and receiving echoes from the pulses as they travel through the body. The received echoes are used to create an image of the target area. The color flow mode uses the Doppler principle to detect and visualize blood flow. Pulsed Wave (PW) Doppler uses the same principle to estimate blood flow velocity.

MiraQ Cardiac

Specialized design for cardiac applications

A flexible monitor display arm provides optimized visibility. The screen can be rotated to suit both the surgeon's and operator's needs.

Connect to external screens and the hospital information systems

Spatially efficient design allows for flexible system placement and movement in the operating room



Easy access to imaging and flow data through optimized screen view and interactive user interface

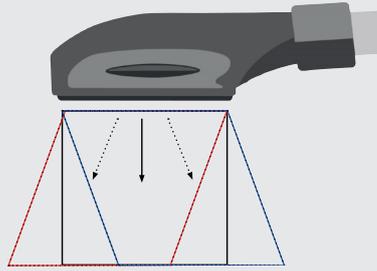
Use a *Guided Workflow* for a simplified approach

Practical storage for user manual and interface cables

The MiraQ™ Cardiac may be delivered as a "Flow only" system, but can easily be upgraded onsite to include an imaging module at a later stage

Spatial compound imaging

High quality images



Enhanced image quality

Spatial compound imaging reduces speckle, improves definition and decreases image noise.

Reduce imaging artifacts

Make wall shadowing and enhancements less prominent.

Easier data interpretation

By smoothing the speckle in an image, compounding makes it is easier to interpret what you see.

Operating room integration

Expanded options



Connect to an external overhead screen using the easily accessible DVI port located on the media panel. The **MiraQ™ Cardiac** software has native support for configuring screen size and resolution.

Export and import data to the hospital's information system using the DICOM option. All **MiraQ™ Cardiac** Systems come equipped with an isolated network connection, allowing for safe and secure access to the hospital network.

Side by side comparison

Before and after



Use the side by side feature to compare any measurement against a reference measurement. Evaluate improvement and perform functional tests on the grafts.

Store and report the compared results with all values and indexes easily accessible.

Upgrade to imaging

Modular design

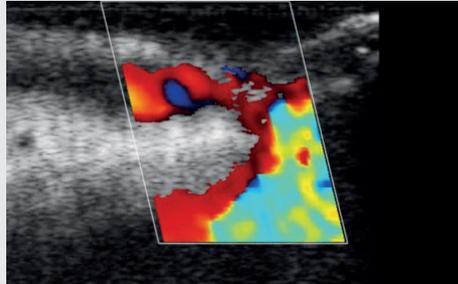


The **MiraQ™ Cardiac** may be delivered as a 'Flow only' system, but can easily be upgraded on-site to include an imaging module at a later stage.

MiraQ™ Cardiac gives surgeons ultimate control, enabling planning, navigation, and verification during cardiac surgery.

Instant feedback

See and measure

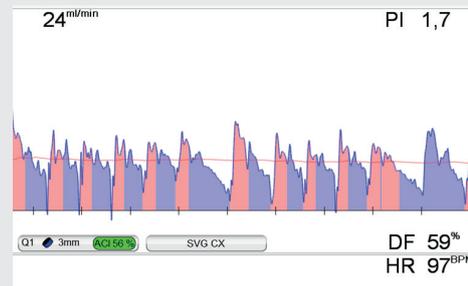
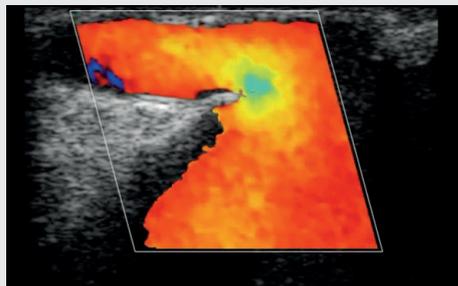


The **MiraQ™ Cardiac** provides instant feedback on the performance of a graft. Eliminate guesswork with ultrasound imaging visualization and quantifiable TTFM data.

In the SVG-CX tracings presented here, ultrasound imaging was used to scan both the distal and proximal anastomosis for defects. An occluded proximal anastomosis was discovered and verified by a TTFM measurement (PI 15.1, DF 40% and Flow 3 ml/min).

Revise on the spot

Before closing



When occluded or underperforming grafts are detected, they can be revised on the spot. Take every measure to avoid reinterventions.

The occluded SVG-CX was immediately revised, and the improved result was documented with ultrasound imaging and TTFM. As shown above, the graft flow was significantly improved (PI 1.7, DF 59% and Flow 24 ml/min).

TTFM

Reliable flow volume measurement



The established numeric indices Pulsatility Index (PI), Diastolic Filling (DF%) and Mean Flow, the basis of our 3-parameter assessment method, provide an accurate insight into the dynamics of graft function.

Medistim MiraQ™ Cardiac System

MQC1 - Standard configuration

Profile	Channel configuration	System features
Cardiac adapted interface with imaging and flow	Imaging 2 Flow 1 AUX	Ultrasound imaging <ul style="list-style-type: none"> • B-Mode imaging • Color Doppler imaging • Pulsed Wave (PW) Doppler Transit Time Flow Measurement AUX/ECG display Guided Workflow

MQC0 - Standard configuration

Profile	Channel configuration	System features
Cardiac adapted interface with flow only	2 Flow 1 AUX	Transit Time Flow Measurement AUX/ECG display Guided Workflow

Customizable Options	MQC1 Factory configuration	MQC0 Factory configuration
2 extra flow channels	✓	✓
1 Doppler channel		✓
1 Pressure channel*	✓	✓
1 extra AUX channel**	✓	✓
Printer support	✓	✓
Printer support and color printer	✓	✓
DICOM interface	✓	✓



* Pressure channels are intended to be connected to a transducer to measure pressure directly.
** AUX channels are designed to receive signals from other monitoring systems, such as ECG and pressure.

Field Upgrade Module

Name	System features
Ultrasound Imaging Upgrade Kit*	Add ultrasound imaging module to a flow-only system

* When a flow system with Doppler is upgraded, an ultrasound imaging module will be substituted in its place.

References

- 2018 ESC/EACTS Guidelines on myocardial revascularization. *European Heart Journal* (2018) 00, 1-96.
- MiraQ for assessing graft flow during coronary artery bypass graft surgery. Last updated: February 2018. www.nice.org.uk/guidance/mtg8b.
- Multimodality Imaging of Diseases of the Thoracic Aorta in Adults: From the American Society of Echocardiography and the European Association of Cardiovascular Imaging. *Journal of the American Society of Echocardiography* 2015;28:119-82.
- 2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery. A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2011;124:e652-e735.
- Intraoperative TTFM and HFUS Assessment in CABG - REQUEST. Taggart DP, Thuijs DJFM, Di Giammarco G, Puskas JD, Wendt D, Trachiotis GD, Kieser TM, Kappetein AP, & Head SJ. *J Thorac Cardiovasc Surg* 2019;:-1-10.
- Transit-time flow predicts outcomes in coronary artery bypass graft patient: a series of 1000 consecutive arterial grafts. *European Journal of Cardio-thoracic Surgery* 38 (2010) 155-162.

All products mentioned in this brochure are in compliance with the European Medical Device Directive 93/42/EEC. Please refer to the User Manual for indications, contraindications, warnings, precautions, and further specifications and descriptions. Specifications may be changed without notice. For a list of flow probes for other applications, contact your Medistim representative.

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