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To: Cardiothoracic/Cardiovascular/Vascular Surgeons, Risk Managers, Chief Executives of Hospital trust and distributors.

Field Safety Notice
Advice regarding use

Products:	VeriQ Systems VeriQ C Systems MiraQ Systems
Serial Numbers:	All Serial Numbers

Dear Customer,

This notice is to inform you about important information concerning updates to the Instructions for Use (IFU) for the above products.

Medistim has taken the opportunity to perform a review of the IFU for our system portfolio to ensure that the Instructions for Use provide adequate guidance for safe use of our products.

The purpose of this notice is to provide supplementary information only.

Medistim is aware of incidents where flow measurement channels on Medistim systems have been operating with a significant zero-point offset value. The result is that flow measurements recorded with these channels will indicate too high or too low flow. Exploration of the issue have shown that this malfunction was caused by electrostatic discharge (ESD) damaging a component in the measurement chain on the Medistim systems, causing an offset from zero. Medistim test the ESD resistance during compliance testing to ensure we meet the requirements in the electromedical safety standard. However, these events have shown that a severe ESD can surpass these requirements.

Advice on action to be taken by the user
To prevent the problem from happening, Medistim has improved the affected hardware with improved ESD protection. However, this still cannot guarantee that a system will never fail. Medistim has therefore further issued an updated IFU which clarifies and emphasizes the importance of routinely performing the Probe and System Functionality Test prior to use in order to ensure that the system and probes function appropriately.

- *Probe and System Functionality Test*

The IFU section describing the test (enclosed) instructs to put the probe in still water to verify correct function and uncover potential zero-point offset issues.
Other flow channels and probes may still be used even though one channel or probe fails the test.
Transit-time flow measurement probes (TTFM) are reusable devices that might accidentally be damaged during reprocessing within the guaranteed number of usages. An observed zero-point offset value as described above can also originate from a damaged probe. Medistim therefore strongly recommends that this functionality test is always performed before a TTFM probe is used.

Contact Medistim to resolve any issues with zero-point offset identified.

- *Instructions For Use*

Attached with this letter is an excerpt of the chapter in the IFU that covers the Probe and System Functionality Test.
The complete IFU can be obtained by contacting Medistim at FSNMS18-001@medistim.com.
A printed version of the IFU can be obtained by contacting your local Medistim representative.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organization or to any organization where the devices are transferred or distributed. Please consider Clinicians, Cardiothoracic/Cardiovascular/Vascular Surgeons, Risk Managers, Chief Executives of Hospital trust, distributors, etc. in the circulation of this notice.

Contact reference person:

Should you have further questions regarding this communication, please do not hesitate to contact us at FSNMS18-001@medistim.com.

Alternatively, please feel free to contact your local Medistim representative.

Best Regards,

Tone Veiteberg
Vice President Regulatory Affairs & Quality Assurance

1 attachment: Extracts from IFU for VeriQ and MiraQ systems

Extract from Instructions For Use

The following text, describing the TTFM Probe and System functionality test, can be found in the current user manuals for systems and probes at these locations:

- *Medistim MiraQ System User Manual (SMMQINen 1.0.0) Chapter 5.6.*
- *Medistim VeriQ System User Manual (SMVQINen 1.0.0) Chapter 5.3.6*

Changes from the previous manual version are the addition of the troubleshooting section.

TTFM Probe and System Functionality Test

Before every use, a TTFM probe functionality test should be performed. This test will reveal any reduction in functionality the probe may have suffered during handling and reprocessing, and ensures an accurate measurement. Performing this check before every use will ensure that the probe and system is functioning optimally and will also improve the acoustical coupling of the probe when placed on a vessel.

Preparing a probe for use:

1. Remove the sterile probe from the container it has been stored in.
2. Connect the connector plug to the Medistim system. For each connected probe, a graft dialog may appear depending on how the system has been configured. It is not necessary to fill in a vessel name at this point, press Cancel to close the dialog.
3. When the probe is connected a measurement trace will appear on screen. The probe properties button will show the channel name corresponding to the name on the probe connector. If the system is set up to start in probe test mode, the probe test view will be shown for the connected probe until the probe is activated.
4. Place the probe in a container with sterile saline solution. A plastic container is preferred.

Note:
Due to their acoustic properties, glass and metal containers can disturb the measurement and introduces an error in the test. Glass or metal containers should therefore be used with caution.

Verify good ACI:
With the probe immersed in saline, look for the green Acoustical Coupling Index (ACI), which indicates appropriate contact between the probe and the vessel. All TTFM probes should obtain an ACI value of > 90% in saline to ensure an acceptable value when used on a graft where the signal is attenuated more. If the ACI value is lower than this during testing, ensure that there are no air bubbles surrounding the probe, as this can significantly affect the ACI value. Simply shake the probe gently in the saline solution to remove.

Check zero-point offset:
Take note of the zero-point offset value when the probe is stationary in still saline. The observed offset value will be part of all measurements and is included in the systems stated accuracy. For applications with very low flow volumes, the zero-point offset value can however be significant and needs to be considered when evaluating the flow measurement.

Probes that fail to register an ACI value of > 90% in sterile saline or exhibit a large zero-point offset are not working properly and should be replaced. Medistim should be notified and necessary repair or replacement of the defective components should be performed.

Troubleshooting

Should the probe and system functionality test fail, either due to low ACI or large zero-point offset, the system can in most cases still be used. Follow these steps to troubleshoot the failure and continue using the system.

- *Change the channel*

Plug the probe into a different flow measurement channel (example: Q2 instead of Q1) and repeat the test. If this resolves the problem the system can be used as per usual with flow probes plugged in the functioning channel.

- *Change the Probe*

Change to a different TTFM probe and perform the probe and system functionality test. If this test passes the initial failure is due to the previously tested probe. The system and the functioning probe can be used as per usual.