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MEDISTIM

18 January 2018

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.

Please complete the Acknowledgement form in Attachment 2. Hospital and Health Care Organizations should return this to your local sales representative or distributor. Distributors and Medistim sales offices should return this to FSNMS18-001@medistim.com.

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,

[redacted]

Tone Veiteberg
Vice President Regulatory Affairs & Quality Assurance

Attachments:
1 Extracts from IFU for VeriQ and MiraQ systems
2 Acknowledgement Form

Attachment 1

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.

Attachment 2

Acknowledgement form

Return completed form to:
Distributors and Medistim sales offices: FSNMS18-001@medistim.com
End users: To your local distributor or sales office

Reference:
Field Safety Notice FSNMS18-001, Advice regarding use

In signing below, I confirm the following:

I acknowledge receipt of this Field Safety Notice and confirm that I completely understand the contents and the instructions. I acknowledge that all users and responsible personnel have been made aware on **Advice on action to be taken by the user**, following the information about the instructions for use update.

Identification

Institution Name (please check one and fill in):

- ☐ Hospital / Health Care Organization:.....
- ☐ Distributor :.....
- ☐ Medistim sales office: :.....

Address:.....

Zip code:..... City:..... State:..... Country.....

Person Responding (print name) :.....

E-mail address :.....

Position :.....

Signature:..... Date:.....

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2018 年 1 月 18 日

致：心胸/心血管/血管外科医生、风险管理人员、医院信托机构首席执行官和经销商。

现场安全通报
使用建议

涉及产品：	VeriQ 系统 VeriQ C 系统 MiraQ 系统
序列号：	所有序列号

尊敬的客户：

本通报旨在通知您有关上述产品使用说明书 (IFU) 更新的重要信息。

Medistim 适时对我们系统文件包中的 IFU 进行审查，以确保其能够适当指导用户安全使用我们的产品。

本通报仅出于提供补充信息之目的。

Medistim 已获悉 Medistim 系统血流测量通道存在明显零点偏移值运行的事件。 结果是这些通道所记录的血流测量值指示血流太高或太低。 对该问题的调查显示，该故障是由静电放电 (ESD) 损坏 Medistim 系统测量链中的一个组件所致，进而导致零点偏移。 在合规性测试中，Medistim 检测了 ESD 耐受性，以确保我们符合电子医疗器械安全标准所规定的要求。 但是，这些事件表明，严重 ESD 可导致超标。

建议用户采取的措施
为了防止问题发生，Medistim 已改进了受影响的硬件，提高了防护 ESD 的能力。 然而，这仍然无法保证系统永不发生故障。 因此，Medistim 进一步发布了更新版 IFU，其中澄清并强调了定期在使用前进行探头和系统功能测试的重要性，以确保系统和探头正常运行。

- *探头和系统功能测试*

根据 IFU 中有关探头和系统功能测试的章节（见附件）所述，将探头放在静水中来验证探头是否正确运行，并揭露任何潜在零点偏移问题。
即使一个通道或探头未能通过测试，其他血流测量通道和探头仍然可以使用。
时差法流量测量 (TTFM) 探头为可重复使用的医疗器械，在获担保使用次数内反复使用时可能意外受损。 上文所述观测到的零点偏移值也可能由损坏的探头导致。 因此，Medistim 强烈建议在使用 TTFM 探头之前始终执行此功能测试。

如果发现任何零点偏移相关问题，请联系 Medistim 予以解决。

- *使用说明书*

本函随附 IFU 中探头和系统功能测试相关章节的节选。
可通过
FSNMS18-001@medistim.com 联系 Medistim 获取完整 IFU。.
如需纸质 IFU，可向您当地 Medistim 代表索取。

本现场安全通报的传播

应向您组织内需要知悉的所有人或向其转让或经销所涉医疗器械的任何组织传播本通告。
请向临床医生、心胸/心血管/血管外科医生、风险管理人员、医院信托机构首席执行官以及经销商等传播本通告。

请填写完整附件 2 中的确认书。 医院和医疗组织应当将该确认书返回给当地销售代表或经销商。 经销商和 Medistim 销售办事处应当将该确认书回传至
FSNMS18-001@medistim.com。.

联系人：

如果您还有关于本通告的任何问题，请随时通过 FSNMS18-001@medistim.com 联系我们。.

或者，请随时联系您当地的 Medistim 代表。

此致　敬礼

Tone Veiteberg
法规事务与质保部副总裁

附件：
1　VeriQ 和 MiraQ 系统 IFU 节选
2　确认书

附件 1

IFU 节选

下述文本描述的 TTFM 探头和系统功能测试，可在现行系统和探头用户手册中的如下章节找到：

- *Medistim MiraQ 系统用户手册 (SMMQINen 1.0.0) 第 5.6 章。*
- *Medistim VeriQ 系统用户手册 (SMVQINen 1.0.0) 第 5.3.6 章。*

与前版手册的区别在于新增了故障排除章节。

TTFM 探头和系统功能测试

在每次使用前，都应当执行 TTFM 探头功能测试。 测试将揭露探头在处理和反复使用过程中可能遭受的任何功能减弱，并确保测量的准确性。 在每次使用之前应执行此检查，以确保探头和系统的最佳功能，并且还可改善探头置于血管上时的超声耦合。

使用探头的准备工作：

1. 从储存容器中取出无菌探头。
2. 将探头连接器插入 Medistim 系统。 对于每个连接的探头，可能会显示桥血管对话框，具体取决于系统的配置方式。 此时无需填写血管名称，按下"取消"关闭对话框。
3. 连接探头时，屏幕上将显示测量轨迹。 探头属性按钮将显示与探头连接器上的名称对应的通道名称。 如果系统设置为以探头测试模式启动，则将显示连接探头的探头测试视图，直至探头被激活。
4. 将探头置于装有无菌盐水溶液的容器中。 最好是塑料材质容器。

注意：
由于其声学特性，玻璃和金属容器可能会干扰测量，并在测试中引起错误。 因此，应谨慎使用玻璃或金属容器。

验证 ACI 是否良好：
将探头浸在盐水中，如显示绿色的超声耦合指数 (ACI)，则表示探头与血管之间的接触适当。 所有 TTFM 探头浸到盐水中都应读取到 > 90% 的 ACI 值，以确保在应用于桥血管上信号衰减更多时测得可接受值。 如果在测试过程中 ACI 值低于此，请确保探头周围没有气泡，因为这可能会严重影响 ACI 值。 在盐水溶液中轻轻晃动探头去除气泡。

检查零点偏移：
注意当探头静置于静止的盐水中时的零点偏移值。 观测到的偏移值将成为所有测量值的一部分并被纳入系统标称精度。 然而，对于血流量非常低的应用，零点偏移值影响较大，在评估血流测量值时需要予以考量。

对于在无菌盐水中无法测得 ACI 值 > 90% 的探头，或显示零点偏移过大的探头，将无法正常工作，应予以更换。 应当通知 Medistim，并对有缺陷的组件进行必要的维修或更换。

故障排除

如果探头和系统因 ACI 较低或零点偏移较大而未能通过功能测试，在大多数情况下，系统仍可投入使用。 请遵循下列步骤排除故障后，再继续使用系统。

- *更改通道*

将探头插入不同的血流测量通道（例如：使用 Q2 替代 Q1），然后重复测试。 如果这样做排除了故障，则可通过将流量探头插入正常运行的通道来照常使用系统。

- *更改探头*

更改为不同的 TTFM 探头，然后再执行探头和系统功能测试。 如果通过测试，则初始故障是由之前受测探头导致。 系统和正常运行的探头可照常使用。

附件 2

确认书

请将填写完整的确认书返回至：
经销商和 Medistim 销售办事处： FSNMS18-001@medistim.com
最终用户： 当地经销商或销售办事处

有关：
现场安全通报 FSNMS18-001，使用建议

通过在下方签字，本人确认：

本人确认收到该现场安全通报，并确认完全理解其中的内容和说明。 本人确认所有用户和负责人都已知悉**建议用户采取的措施**，将遵循使用说明书的更新信息。

确认

机构名称（请选择一项填写）：

□ 医院/医疗组织：……

□ 经销商 ：……

□ Medistim 销售办公室 ：……

地址：……

邮编：…… 城市：……州：…… 国家：……

收件人（印刷体姓名） ：……

电子邮箱 ：……

职务 ：……

签名：…… 日期：……