



URGENT FIELD SAFETY NOTICE

Product name: Unique+

FSCA-identifier: 67/28062019

Type of action: Software update and Firmware update – see below advice on action to be taken.

Date: 01st of July 2019

Attention: Authorized Representative – Inspiration Healthcare Ltd., UK

Details on affected devices:

Unique+ devices with S/N UIHC1010-UIHC1069

Description of the problem:

A software 'bug' has been identified that when data is reviewed, the CFM trend display is correct, but the individual traces were intermittently not correct. This has been resolved and a new software update 7.0.3 has been issued. This is a field update that is required for all installations of Unique + (Serial numbers UIHC1010 to UIHC1069).

As this only affected individual traces and not the CFM trend display we consider that there was no risk to Patient Safety as the CFM trend display was correct at all times. Our evaluation of this bug following Guidelines on our Medical Devices Vigilance System (MEDDEV 2.12-1 rev 8) that concludes the only corrective action required is to bring systems using Serial Numbers UIHC1010 to UIHC1069 up to the new software level 7.0.3.

Our investigations have also found that the Bluetooth Module firmware, when Bluetooth is not 'paired' and Unique+ is connected with the PC via USB, regularly tries to pair and this may interfere with patient signals from electrodes to the Amplifier, and may corrupt the quality of the signal being processed by the Unique + software. This can affect the CFM trend display.

Required Corrective Action is to update the Unique+ Firmware to the version: WLAN_CFM_2_190701.bin on all systems using Amplifier Serial Numbers UIHC1010 to UIHC1069.

Advice on action to be taken by the user:

- Identify the device
- Update the Unique+ software to version 7.0.3
- Update the Unique+ Firmware to the version: WLAN_CFM_2_190701.bin
- Process corrective actions as soon as possible, but latest on 31st of July 2019
- Send back the confirmation form about the completed field safety actions to the manufacturer.

Transmission of this Field Safety Notice: [as appropriate]

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected product has been transferred. Please be aware of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.



Contact person for further information:

EMS Handels Gesellschaft m.b.H., Mr. Alfred Ortner, Jochingergasse 1, 2100 Korneuburg, Austria, tel.+43 2262 61655-0

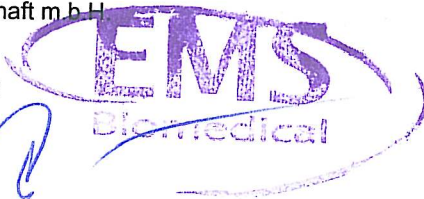
The undersigned confirms that this notice has been notified to the appropriate National Regulatory Authorities.

Signature:

EMS Handels Gesellschaft m.b.H.

Ppa. Ruzena Ortnerova

A handwritten signature in blue ink, appearing to read "Ppa. Ruzena Ortnerova", written over a faint purple circular stamp.



Annexes:

Instructions on firmware and software update, Document ref. no. 67/28062019/SW 7.0.3

Confirmation form about the completed field safety actions, Document ref. no. FSCA FORM 67/28062019