Spectrum--vtedical

Spectrum Medica! Limited
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URGEN T FIELD SAFETY CORRECTION
Product Name: Quantum Perfusion Systems®
Model Number: All Systems

29 May 2019

Spectrum reference: SCC085/SCC086

Dear Distributors and Customers,

The purpose of this letter is to inform you that Spectrum Medical is in the process of installing the most recent software update v6.2.3.16 to the Quantum Perfusion Systems®. This software update corrects an error that could potentially lead to power loss. All Quantum Perfusion Systems are in scope of this issue.

Issue Description:
Spectrum Medical received an incident report on 26th April 2019 that the Quantum Pump Console, of the Quantum Perfusion Systems, unexpectedly shut down while in use. An analysis of the software concluded that incorrect data was being queried from the battery firmware leading to power loss to the accessory ports on the HLM.

Software update v6.2.3.16 is required to ensure adequate power remains to the device. Without the software update the Quantum Pump Console will remain vulnerable to this power supply malfunction. Through 29 May 2019, Spectrum Medical has received two complaints regarding this issue. There have been no (0) reports of patient harms or complications.

Potential Hazard:
Loss of power to the pump console leads to pump stop. This requires user intervention to use hand crank to continue treatment.

Harm:
This will cause a delay in giving treatment that can lead to potential temporary harm to patient.

Actions:
Our records show you have one or more of these in your inventory. Please take the following steps:

1. Be aware that user intervention may be necessary with continued use before the software update.
2. Assure that all users receive notice of this issue.
3. Confirm receipt of this Urgent Medical Device Correction by returning this form.
4. Spectrum Medical service team will contact you and arrange a time and date to update your systems with the most recent software update.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the listed devices have been transferred. Spectrum Medical confirms that all appropriate Regulatory Agencies will be notified.

We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Spectrum Medical representative.

Sincerely,

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URGENT FIELD SAFETY CORRECTION NOTICE

Product: Quantum Perfusion System® Software

Type of Action: Field Safetv Corrective Action

Please complete this form and return a copy either by email or post.

Email: Regulatory@spectrummedical.com

Attention: Regulatory Affairs Department
Spectrum Medica! Ltd.
Harrier4, Meteor Business Park, Cheltenham Road East
Glouster, GL2 9QL, United Kingdom
+44 0 1242 387082

Customer Name and Address:	
Reply confirmation completed by:	
Telephone Number:	
Email:	

D We have read and understand the Field Safety Correction.