15 September 2016

URGENT – MEDICAL DEVICE CORRECTION

Spacelabs Healthcare Inc.

Xhibit Central Station, Model 96102
Xhibit Telemetry Receiver, Model 96280

Dear Hospital Administrator/Biomedical Manager/Office Manager:

This is an amendment to our notification dated 25/Aug/2016. We have identified an additional issue which we would like to bring to your attention.

Spacelabs Healthcare would like to inform you about a potential patient safety concern regarding the Xhibit Telemetry System(s) installed at your facility. The information contained in this safety notice is intended to inform you about:

- The nature of the problem and the circumstances in which it can occur
- Actions the customer / user can take to minimize risk to patients or users
- Actions implemented by Spacelabs to correct the problem

Please circulate this notification to all persons affected by the information it contains and add a copy to the appropriate monitor user manual until such time as corrections have been implemented by Spacelabs. Spacelabs will contact you to schedule a convenient time for Spacelabs to update your Xhibit Telemetry System(s) at no cost.

As always, patient safety is a top priority at Spacelabs as we partner with you to provide the best care experience to patients and their families.

If you have any questions about this corrective action, please contact Spacelabs at 1-800-522-7025 and select 2 for Technical Support.

We confirm that this notice has been sent to the appropriate regulatory agencies.

Sincerely,

Al Van Houdt
Sr. Mgr. Regulatory Affairs & Compliance
Spacelabs Healthcare, Inc.

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Affected Systems	Xhibit Central Station, Model 96102, that is used for telemetry monitoring with the Xhibit Telemetry Receiver, Model 96280, which is our Xhibit Telemetry System.
Description of Problem	Spacelabs has received reports of certain short-duration asystole alarms generated by the Xhibit Telemetry Receiver (XTR) where there may be no audible or visual alarm.
Identification of Risk	The Xhibit Telemetry System is accurately detecting and recording the event; however, the problem is that the cancelation of alarms may occur before the alarm has been recognized. When the asystole alarm is activated by a short-duration asystole event lasting approximately 5-6 seconds and is followed immediately by a heartbeat which clears the asystole alarm criteria, the alarm tone and visual flashing alarm may be cancelled.
Actions to be Implemented by Users	We at Spacelabs recognize and share your concern for patient safety. Please weigh the benefits versus the risks when deciding whether or not to continue to use your Xhibit Telemetry System until it can be updated. We recommend that you brief your staff regarding the failure mode listed above. If you continue to use your Xhibit Telemetry System(s), please note: • Patient waveforms and numerics are displayed on the Xhibit Central. • There is a latched alarm message. • The alarm event is shown in the alarm history bar. • Xhibit Central Stations used alone, without Xhibit Telemetry Receivers, are not affected.
Corrective Actions to be Conducted by Spacelabs	Spacelabs Healthcare will contact you to schedule a convenient time for Spacelabs to update your Xhibit Telemetry System at no cost. Customers with Xhibit Telemetry Receivers will get all Xhibit Central Stations updated regardless if connected to an Xhibit Telemetry Receiver.
Information and Technical Assistance	For additional information or technical assistance, please contact: Technical Support MEDI-LAN AG HAMMERSTRASSE 3 STEINHAUSEN, SWITZERLAND CH-6312 Phone: 41417485200

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