

23 January 2015

URGENT – MEDICAL DEVICE CORRECTION

Spacelabs Healthcare Inc.

XPREZZON™ Bedside Monitor, Model 91393 qube™ Compact Monitor, Model 91390

Dear Sir or Madam,

Spacelabs Healthcare would like to inform you about a potential patient safety concern regarding certain XPREZZON and qube monitors 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 to schedule a convenient time for Spacelabs to replace the PCBAs in all of your facility's affected XPREZZON and qube monitors at no cost. Also, if you have provided the devices to others, please provide that information to Spacelabs so that we may contact them and execute this recall.

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
Regulatory Affairs & Compliance
Spacelabs Healthcare, Inc.

URGENT – MEDICAL DEVICE CORRECTION

XPREZZON™ Bedside Monitor, Model 91393
qube™ Compact Monitor, Model 91390

Potential failure to boot up or loss of configuration settings following power on or reset

<p>Affected Systems</p>	<p>XPREZZON™ Bedside Monitor (Model 91393) shipped between June 18, 2014 and January 13, 2015, and qube™ Compact Monitor (Model 91390) shipped between December 16, 2013 and December 15, 2014. A total of 1,578 XPREZZON devices are affected by this action; 2,955 qube devices are affected by this action. The serial numbers of these affected products are listed in the addendum to this letter.</p> <p>In addition, a small number of printed circuit boards with the affected socket were distributed to customers to facilitate repair of customer monitors. Spacelabs will contact customers with these printed circuit boards to assist in identifying affected monitors.</p>
<p>Description of Problem</p>	<p>Spacelabs has received multiple reports of XPREZZON and qube monitors failing to boot up or returning to factory default configuration settings following power on or reset.</p> <p>Reported issues include:</p> <ul style="list-style-type: none"> • A failure to boot following power on or reset, resulting in a failure in monitor operation. • Loss of network connectivity, which may result in i) an inability to display alarms and data from the affected monitor on central stations and other bedside monitors, or ii) a failure to transmit parameter and alarms from the affected monitor to system printers and Spacelabs' Intesys Clinical Suite retrospective database (including the Clinical Events Interface remote notification feature). • Display of English language when previously configured for another language (the alarm messages displayed in the parameter waveform zone are not affected, as these are stored on a command module and not on the monitor). • Touchscreen failure where touching the screen does not produce the expected response. <p>The parameter alarms and information are still present and correct once the monitor has completely started up. No one has been injured as a result of these issues.</p> <p>Spacelabs believes this issue is caused by inadequate electrical contact on one of its printed circuit board assemblies.</p>
<p>Identification of Risk</p>	<p>There is a remote possibility that a failure may result in a delay in therapy while a device that is experiencing the fault is addressed or an alternative device is deployed. In addition, there is a remote possibility of death or serious injury if this condition occurs and is undetected and the patient experiences an event requiring care.</p>

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<p>Actions to be Implemented by Users</p>	<p>We at Spacelabs recognize and share your concern for patient safety. Please weigh the benefits versus the risks as well as your ability to deploy alternative devices when deciding whether or not to continue to use your XPREZZON or qube monitors until they can be updated. We recommend that you brief your staff regarding the failure modes listed above. If you continue to use affected monitors, please note:</p> <ul style="list-style-type: none"> • The reported issues occur mostly at initial power on of a monitor. Always check for proper operation (such as functionality of touchscreen, proper language, and network connectivity) when the monitor is first turned on. • If the product is monitored via a central station, ensure the notification feature for monitoring communication loss is on. This capability is on by default. • If a bedside monitor is not monitored via central station, check the bedside monitor frequently to ensure the display is functional. <p>If you experience any of the reported issues, remove the device from service and contact Spacelabs technical support immediately.</p> <p>If your facility operates any XPREZZON or qube monitors on a standalone basis, rather than via central monitoring, please contact Spacelabs technical support as these monitors will be the first repaired.</p>
<p>Corrective Actions to be Conducted by Spacelabs</p>	<p>Spacelabs Healthcare will contact you to schedule a convenient time for Spacelabs to replace the PCBAs in all of your facility's affected XPREZZON and qube monitors at no cost.</p>
<p>Information and Technical Assistance</p>	<p>For additional information or technical assistance, please contact:</p> <p style="padding-left: 40px;">Technical Support Spacelabs Healthcare, Inc 35301 SE Center St. Snoqualmie, WA 98065 1-800-522-7025 and select 2 for Technical Support</p>

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Affected qube (Model 91390) serial numbers

1390-000123
1390-000197
1390-000420
1390-000491
1390-000528
1390-000531
1390-000532
1390-000567
1390-000613
1390-000767
1390-000938
1390-001022 to 1390-001029
1390-001081
1390-001102
1390-001346
1390-001351
1390-001356
1390-100050
1390-100202
1390-100235
1390-100262
1390-100374
1390-100394
1390-100395
1390-100396
1390-100447
1390-100556
1390-100623
1390-100627 to 1390-100630
1390-100632 to 1390-100635
1390-100734
1390-100987
1390-100991
1390-101014
1390-101020
1390-101071
1390-101301
1390-101337
1390-101365

1390-101403
1390-101423
1390-101494
1390-101568
1390-101577
1390-101715
1390-101750
1390-101768
1390-101837
1390-101876
1390-101887
1390-101890
1390-101937
1390-101945
1390-101947
1390-101948
1390-101958
1390-101979
1390-101999
1390-102003 to 1390-102009
1390-102011 to 1390-102020
1390-102042
1390-102141
1390-102210
1390-102216
1390-102320
1390-102432
1390-102445 to 1390-102458
1390-102460 to 1390-102476
1390-102523 to 1390-102529
1390-102559 to 1390-102669
1390-102671 to 1390-102726
1390-102728 to 1390-102764
1390-102766
1390-102767
1390-102769 to 1390-102908
1390-102910 to 1390-102938
1390-102940 to 1390-102996
1390-102998 to 1390-103206

