



27 April 2015

URGENT – MEDICAL DEVICE CORRECTION

Spacelabs Healthcare Inc.

Ultraview SL Command Module, Model 91496 with the Masimo SpO₂ PCBA, PN: 010-1636-02

Dear Sir or Madam,

Spacelabs Healthcare would like to inform you about a patient safety concern regarding certain Ultraview SL Command Modules installed at your facility. The information contained in this safety notice is intended to inform you about:

- 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

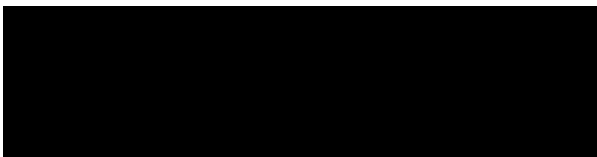
Please circulate this notification to all persons concerned by the information it contains and add a copy to the appropriate system user manuals until such time as corrections have been implemented by Spacelabs.

As always, patient safety is a top priority at Spacelabs Healthcare 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 Healthcare 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.



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Affected Systems	Ultraview SL Command Modules with the Masimo SpO ₂ PCBA, PN: 010-1636-02. Only modules shipped or repaired after March 8, 2014 are affected by this recall.
Description of Problem	<p>This letter is to inform you of a potential hazard associated with the use of the Spacelabs Medical Ultraview SL Command Module with the Masimo SpO₂ PCBA, PN: 010-1636-02. We have received two complaints of Ultraview SL Command modules resetting.</p> <p>The reset sequence takes approximately 10 seconds and during this period monitoring of all parameters will be suspended. Upon completion of the reset sequence, all alarm limits will be reset to their site-defined default values. Critical alarms for ventricular fibrillation and asystole are always enabled after the reset. If invasive pressure is being monitored, labels will be reset to default values and the zero calibration will be lost. If non-invasive pressure is being monitored, the automatic measurement mode will be disabled.</p> <p>A separate failure mode can also occur where the SpO₂ menu keys become unresponsive and prevent user changes to SpO₂ operation and alarm settings. In this state, all alarm limits, alarm functions and parameter monitoring continue unaffected and all alarm limits other than SpO₂ can still be adjusted.</p>
Actions to be Implemented by Users	<p>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 modules until they can be upgraded.</p> <p>If you continue to use affected SL Command Modules, please enable the “CHECK SETUP” feature on the module. With this feature enabled, a “CHECK SETUP” message will be displayed and a low priority alarm tone may sound to alert the user that alarm limits and operations settings have changed as the result of a reset condition. (Note: No action is required for modules with software version 2.04.00 and later as this feature is automatically enabled.)</p>
Corrective Actions Conducted by Spacelabs	Spacelabs Healthcare will contact you to schedule a convenient time for Spacelabs to correct all of your facility's affected Command Modules at no cost.
Information and Technical Assistance	<p>For additional information or technical assistance, please contact:</p> <p>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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