

01 July 2016

URGENT – MEDICAL DEVICE CORRECTION

Spacelabs Healthcare Inc.

91496 Ultraview SL Command Module Options A, B, C, I

Dear Sir or Madam,

Spacelabs Healthcare would like to inform you about a potential patient safety concern regarding one or more Command Module(s) installed at your facility. The information contained in this safety notice is intended to inform you about:

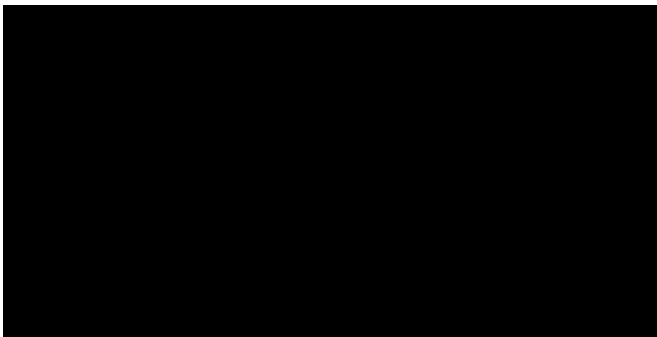
- The nature of the problem and the circumstances in which it can occur
- Actions the customer / user can take to minimize risk to patients or users
- Actions implemented by Spacelabs to correct the problem

Please circulate this notification to all staff members who may be affected by the issue described in this letter and add a copy to the appropriate user manual until such time as corrections have been implemented by Spacelabs. Spacelabs will contact you to schedule a convenient time for a Spacelabs service technician to update your affected Command Module(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.

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

Sincerely,



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91496 Ultraview SL Command Module, Options A, B, C, I

NIBP is non-functional

Affected Systems	91496 Ultraview SL Command Module, Options A, B, C, I Manifold Lot Codes: 128280, 129420, 129940, or 155640
Description of Problem	Spacelabs has received multiple reports of the Non-Invasive Blood Pressure (NIBP) parameter becoming non-functional with an associated message (No Reading). In addition, there is one of the following three error messages: Inflate Error, HW Error, or No Data. Spacelabs is not aware of any injuries related to this issue.
Identification of Risk	NIBP becomes non-functional causing a delay/loss of NIBP monitoring.
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 Command Module(s) until they can be updated. We recommend that you brief your staff regarding the failure modes listed above. If you continue to use the affected Command Module(s), please note:</p> <ul style="list-style-type: none"> • The other parameters will continue to work and alarm normally. • If the module fails, an alternate 91496 Command Module or a separate NIBP monitor can be utilized. • If this problem occurs, there will be a “No Reading” alarm and one of the following error messages: <ul style="list-style-type: none"> ○ Inflate Error ○ HW Error ○ No Data <p>These failures are not recoverable. Please contact Spacelabs Technical Support.</p>
Corrective Actions to be Conducted by Spacelabs	Spacelabs Healthcare will contact you to schedule a convenient time for a Spacelabs service technician to update your affected Command Module(s) 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>