

15 February 2017

MEDICAL DEVICE CORRECTION

Spacelabs Healthcare Limited

Arkon Anesthesia Delivery System

Dear Hospital Administrator/Biomedical Manager/Office Manager:

Spacelabs Healthcare would like to inform you about an issue with the Arkon Anesthesia Delivery System(s) installed at your facility. The information contained in this notice is intended to inform you about:

- The nature of the issue and the circumstances in which it can occur
- Actions the facility / user can take to mitigate the issue
- Actions implemented by Spacelabs to resolve the issue

Please circulate this notification to all persons affected by the information it contains 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 Spacelabs to update your Arkon Anesthesia Delivery System(s) at no cost.

As always, your customer experience 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 1-425- 363-5212 for Technical Support.

Sincerely,

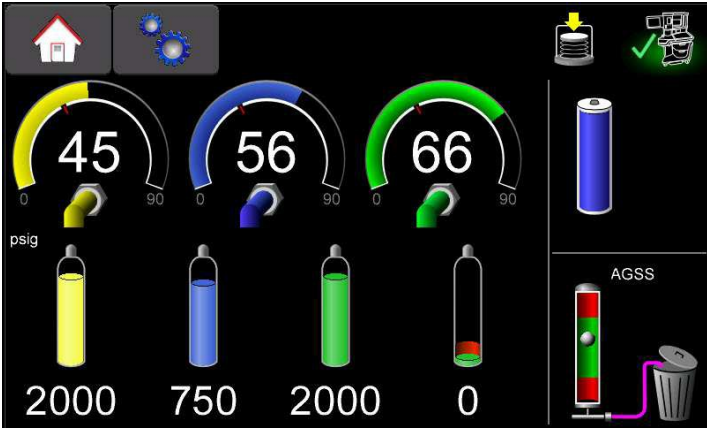
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Spacelabs Healthcare, Inc.

URGENT – MEDICAL DEVICE CORRECTION

Arkon Anesthesia Delivery System, Model 99999

Affected Systems	Arkon Anesthesia Delivery System, Model 99999
Description of Issue	Spacelabs has received reports of the failure of the power supply that provides electricity to the Arkon subsystems. This failure causes the system to run on its internal battery(s) without charging them or providing the user the “On Battery” display messages. Once the batteries reach their minimal charge level, the Arkon powers down and the backup audible buzzer alarm activates.
Identification of Risk	Emergency oxygen, vaporized agent delivery and manual ventilation remain available. The anesthesiologist will not have access to mechanical ventilation or the monitoring of ventilation. No one has been injured due to this issue.
Actions to be Implemented by Users	<p>Please weigh the benefits versus the risks when deciding whether or not to continue to use your Arkon Anesthesia Delivery System until it can be updated. We recommend that you brief your staff regarding the issue listed above. If you continue to use your Arkon Anesthesia Delivery System(s), please note:</p> <ul style="list-style-type: none"> The battery symbol will always show the correct battery status, providing you with a visual indication if the battery is depleting:  <ul style="list-style-type: none"> All auxiliary outlets remain powered, so any devices connected to the auxiliary power outlets, including a patient monitor, will continue to operate. Arkon is designed to allow for the continued delivery of manual ventilation, control of O₂, and delivery of anesthetic agents in a power failure scenario. Clinicians are able to use Emergency O₂ and manually ventilate the patient, providing gas and agent. Fresh gas flow automatically continues at the last set emergency O₂ value.

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Page 3 of 3

Arkon Anesthesia Delivery System, Model 99999

<p>Corrective Actions to be Conducted by Spacelabs</p>	<p>Spacelabs Healthcare is developing a software upgrade that corrects the “On Battery” alarm issue. A Spacelabs representative will contact you once the upgrade is available to schedule a convenient time to update your Arkon Anesthesia Delivery System(s) 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;">Steve Elms Spacelabs Healthcare Ltd. 44 (0) 1992 507725</p>