Medical Devices

Medical Device Safety
Medical Device Recalls
2014 Medical Device Recalls
2013 Medical Device Recalls
2012 Medical Device Recalls

Spacelabs Healthcare Ltd., ARKON Anesthesia Delivery System with Version 2.0 Software - Software Defect May Cause System to Stop Working

Recall Class: Class I

Date Recall Initiated: March 10, 2014

Product: ARKON Anesthesia Delivery System with Version 2.0 Software

Serial Numbers of Units Distributed in the U.S. ARKN-000011, ARKN-000016, ARKN-000017, ARKN-000019, ARKN-000020, ARKN-000021, ARKN-000022, ARKN-000023, ARKN-000024, ARKN-000025, ARKN-000026, ARKN-000027, ARKN-000028, ARKN-000029, ARKN-000030, and ARKN-000031

Affected products were manufactured and distributed from March 18, 2013 through June 17, 2013.

Sixteen units were distributed to hospitals in North Carolina and South Carolina.

Use: The Spacelabs ARKON Anesthesia Delivery System is used in hospital operating rooms. It may be used for the delivery of oxygen, air and nitrous oxide in a controlled manner to various patient breathing circuits with or without the use of a mechanical ventilator, and may be used for the delivery of anesthetic vapor by use of a dismountable vaporizer. The primary users of this device are qualified physicians.

Reason for Recall: Spacelabs Healthcare is recalling the ARKON Anesthesia System with Version 2.0 Software due to a software defect. This software issue may cause the System to stop working and require manual ventilation of patients. In addition, if a cell phone or other USB device is plugged into one of the four USB ports for charging, this may also cause the System to stop working.

This defect may cause serious adverse health consequences, including hypoxemia and death. Spacelabs Healthcare received one report related to the software defect. There has been no injuries or deaths associated with this malfunction.

Public Contact: The firm may be contacted at 1-800-522-7025, select 2 for Technical Support.

Recalling Firm:
Spacelabs Healthcare Ltd.
1 Harforde Court, John Tate Road
Hertford, SG137NW
Hertfordshire, United Kingdom

FDA District: Seattle District Office

More Information about this Recall:
On March 11, 2014, Spacelabs Healthcare of Snoqualmie, Washington sent customers an Urgent Medical Device Correction letter and followed up with a letter on March 26, 2014. The letters identified the product, the problem, the action to be taken by the customer.

Spacelabs Field Service personnel are contacting customers affected by this recall to schedule a free software update installation that may resolve this issue. Until the software updates are installed, Spacelabs Healthcare provided the following recommendations for health care facilities with ARKON Anesthesia Delivery Systems:

- If you continue to use your ARKON Anesthesia System, we recommend that you do NOT save spirometry loops until Spacelabs has remedied the software defect. The error is triggered by the combination of a spirometry loop save and a change in waveform configuration.
- Advise users NOT to use the USB ports until after your ARKON software is updated.
- If the error does occur, the user will hear a buzzer and a warning icon will appear on the main display screen. We recommend that the user switch to emergency O2 and manually ventilate the patient until such time as they can safely remove the system from patient use.
- If you cycle power, the system will reboot in roughly 3 minutes and recover from the above software anomaly and mechanical ventilation can continue.

For questions about this corrective action program, please contact Spacelabs Healthcare at 1-800-522-7025 and select 2 for Technical Support.

About Class I Recalls
Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program either online, by regular mail or by FAX.

Page Last Updated: 04/16/2014
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA