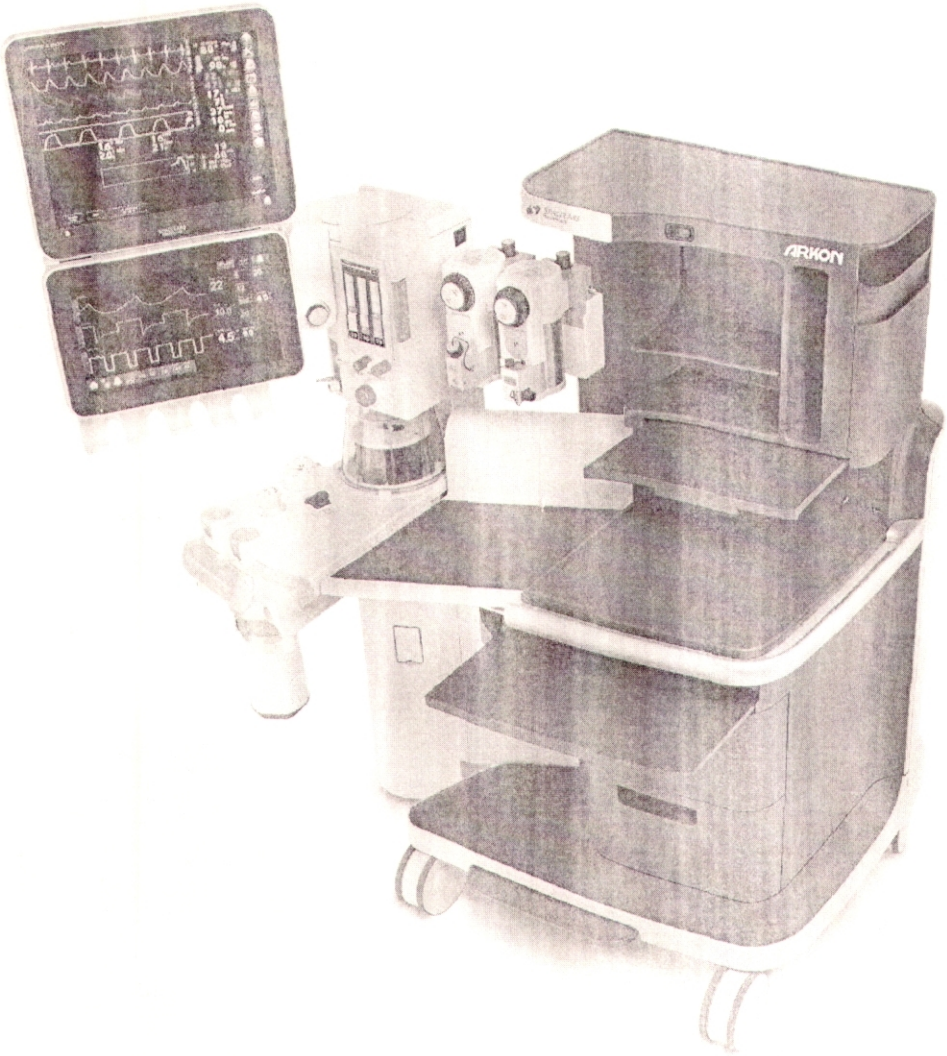
Arkon Anesthesia Delivery System recalled due to unexpected failed state while in use or idle

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death

Recalled Product:

- Name: Arkon Anesthesia Delivery System
- Product code: CBK
- Model Number: 99999
- Manufacturing Dates: September 21, 2012 to September 28, 2017
- Distribution Dates: October 1, 2012 to October 6, 2017
- Devices Recalled in the U.S.: 253 units/li>

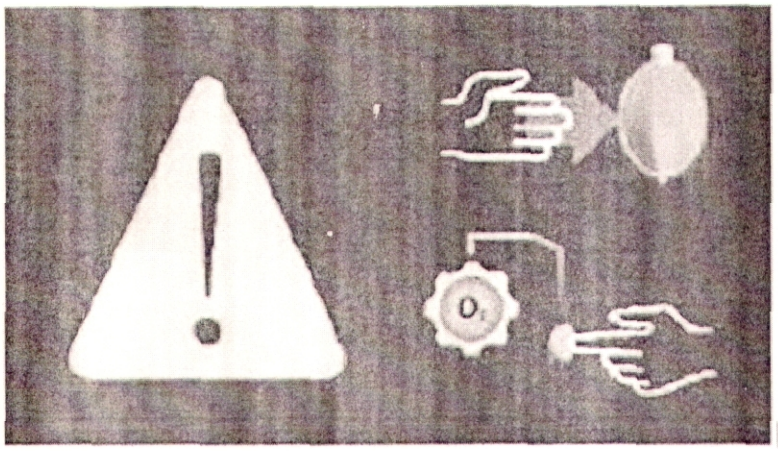
Device Use



The Arkon Anesthesia Delivery System is intended for use in hospitals and operating rooms. It may be used to deliver oxygen, air, and nitrous oxide in a controlled manner to various patient breathing circuits (accessory sets that include tubing and breathing bags) with or without the use of a mechanical ventilator, and may be used for the delivery of anesthetic vapor (anesthesia that can be inhaled) with a dismountable vaporizer.

Reason for Recall

Spacelabs Healthcare recalled the Arkon Anesthesia Delivery System due to the system going into a "failed state," during which the mechanical ventilation function stops working, while the machine is in use, or while idle. The firm has not identified the reason for the failed state. When the machine goes into a failed state, a buzzer sounds, and the following image is shown on the large display monitor:



Caption: *Failed state warning image, which alerts users of the error, and indicates that manual ventilation and emergency oxygen are available alternatives.*

During the failed state, the anesthesiologist cannot access mechanical ventilation or monitor ventilation, which could increase the risk of patient injury. Emergency oxygen, vaporized agent delivery, and manual ventilation are still available. The firm has not received any reports of malfunctions, injuries, or deaths.

Continued use of this product may cause serious adverse health consequences, including death.

Who May be Affected

Infant through adult patients receiving anesthesia and being monitored under anesthesia with the Arkon Anesthesia Delivery System.

What to Do

Spacelabs Healthcare sent an Urgent Medical Device Correction to hospitals and facilities with Arkon Anesthesia Delivery Systems with the following instructions:

- Weigh the benefits versus the risks when deciding whether to continue to use the Arkon Anesthesia Delivery System until it can be updated.
- If you continue to use the Arkon Delivery System, note that:
  - The failed state can be cleared by powering down and restarting the system (which takes less than 2 minutes)
  - Arkon is designed to allow for the continued delivery of manual ventilation, control of oxygen, and delivery of anesthetic agents in a power failure scenario. Clinicians can use emergency oxygen and manually ventilate the patient, providing gas and agent.
  - Fresh gas flow automatically continues at the last set emergency oxygen value.
- A Spacelabs representative will contact facilities to schedule a convenient time to update your Arkon Anesthesia Delivery System(s) at no cost.

Contact Information

Spacelabs Healthcare, Ltd
Technical Support
35301 SE Center St.
Snoqualmie, WA 98065
Phone: 425-363-5212

Date Recall Initiated:

July 11, 2018

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)** either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2018 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm590900.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)