U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Dräger Medical, Evita V500 and Babylog VN500 Ventilators - Faulty Batteries

Recall Class: Class I

Date Recall Initiated: July 13, 2015

Device: Evita V500 Ventilator and Babylog VN500 Ventilator

- Lot numbers: All lots are affected (Catalog Numbers: 8416400, 8417400)
- Manufactured from: June 1, 2011 to June 30, 2015
- Distributed from: June 1, 2011 to June 30, 2015
- Devices Recalled in the U.S.: 2,081

Use: The Evita V500 Ventilator provides constant breathing support for adults and children, including premature babies weighing at least 14 ounces. The Babylog VN500 provides constant breathing support for premature babies weighing at least 14 ounces. Both ventilators are used in hospitals or during patient transport.

Recalling Firm:
Dräger Medical, Inc.
3135 Quarry Road
Telford, Pennsylvania 18969

Reason for Recall: The battery (part of the PS500 Power Supply Unit) that powers the Evita V500 and Babylog VN500 Ventilators does not last as long as expected. The battery indicator light shows a sufficiently charged battery even when the battery is depleted.

When the "battery low" and "battery depleted" alarms sound, the devices do not indicate how much time is left before the ventilator will shut down due to lack of power. Analysis by Dräger indicates that the battery should last approximately 30 minutes. If the power is lost, the 30-minute battery back-up should last until the ventilator is connected to a main power supply.

If the ventilator shuts down, a patient may not receive necessary oxygen. This could cause patient injury or death.

Public Contact: Customers with questions can contact Dräger Medical Customer Support at 800-543-5047. At the prompt, press 1, then 2, then 32349.

FDA District: Philadelphia District Office

More Information about this Recall:

In July 2015, Dräger Medical sent an Urgent Medical Device Recall letter to its customers informing them that Dräger Medical plans to replace all faulty batteries. The letter instructed customers to follow these recommendations until the new batteries are installed:

- Notify all device users within your facility of this issue.
- Do not rely on the battery status indicator
- Provide manual ventilation and immediately connect the ventilator to a main power supply, if the power fail alarm sounds.
- Do not use the device to transport patients unless necessary
- If you need to use the device for patient transport, first determine the battery capacity:
  - Charge the battery of your device for at least 24 hours as described in the Instructions for Use
  - Let the device run without a patient on battery.
  - Determine how much time is remaining on the battery:
    - More than 2 hours: Device may be used for 6 months for patient transports lasting a maximum of 1 hour. Contact Dräeger Service to schedule battery replacement.
    - Less than 2 hours: Do not use the device for patient transport. Contact Dräeger Service for immediate exchange of the battery.

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 (https://www.accessdata.fda.gov/scripts/medwatch/)** online, by regular mail or by FAX.

Additional Resources

- Related Recall: Dräger Medical Inc., Evita V500 and Babylog VN500 Ventilators with Optional PS500 Power Supply Units - Battery Depletion (/MedicalDevices/Safety/ListofRecalls/ucm391562.htm)

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

2015 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)

2014 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)