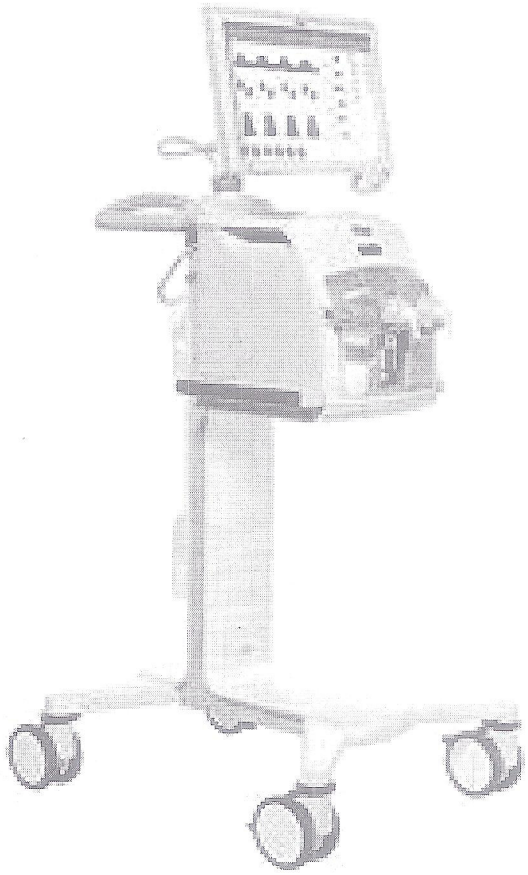
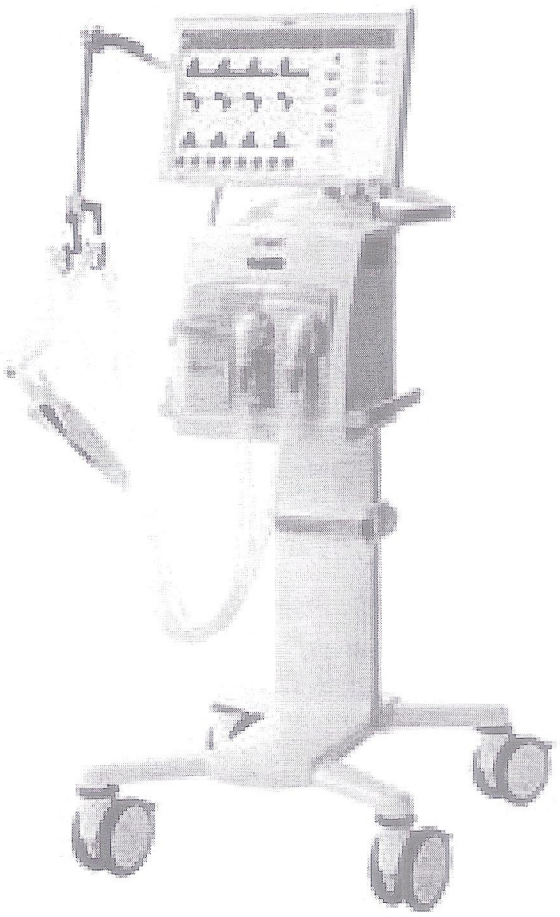
U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Dräger Evita V500 and Babylog VN500 Ventilators - Recall Expanded to Include Optional PS500 Batteries with New Power Supply Firmware

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.



Picture of Dräger Babylog® VN500



Picture of Dräger Evita® V500

Recalled Product:

- Device: Evita V500 and Babylog VN500 Ventilators
- Catalog Numbers: 8416400, 8417400
- Manufactured from: June 1, 2011 to December 1, 2015
- Distributed from: June 1, 2011 to January 31, 2016
- Devices Recalled in the U.S.: 2,501 units in Alaska, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Iowa, Illinois, Indiana, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia Washington, West Virginia, Wisconsin, Washington D.C. and Puerto Rico

Device Use

The PS500 is an optional battery power supply sold for use with the Dräger Evita and Babylog ventilators. 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.

Reason for Recall

Dräger Medical expanded its December 2015 recall to include the PS500 Optional Power Supply units that were updated with new software as part of the December recall. The new software installed failed to correct the issue depleting the battery and Dräger Medical will now replace all affected PS500 power supply units.

The ongoing PS500 power supply issue could cause the ventilator to shut down unexpectedly. If the ventilator shuts down, a patient may not receive necessary oxygen. This could cause patient injury or death.

Who May be Affected

- Health care providers using the PS500 battery power supply with Dräger Evita V500 and Babylog VN500 ventilators
- All patient groups who may be given breathing support with ventilators using this power supply

What to Do

On February 5, 2015, Dräger Medical sent their customers an urgent medical device recall extension letter. The letter instructed customers to:

- Notify all device users within your facility of the issue
- Not to use the device to transport patients unless necessary
- If the device is used during transportation, immediately contact Dräger Medical to downgrade the power supply software and to develop a short term solution
- Do not rely on the displayed charging status
- Connect the device to a power supply if it generates a "Battery low" alarm
- Contact Dräger Service to schedule a battery replacement

Contact Information:

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

Date Recall Initiated:

February 4, 2015

Additional Resources:

Original FDA Recall Notice (/MedicalDevices/Safety/ListofRecalls/ucm480135.htm) for December 2015 recall

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) online, by regular mail or by FAX.

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

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

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

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