Press release

Dräger issues voluntary nationwide recall of optional PS500 power supply for Evita V500 and Babylog VN500 ventilators

TELFORD, PA – Today Dräger initiated a nationwide recall of the optional PS500 Power Supply Unit used with the Evita V500 and Babylog VN500 ventilators. This voluntary action was a result of an internal investigation by Dräger into complaints that found that the batteries installed in the PS500 depleted much earlier than expected, although the battery indicator showed a significantly charged battery. As a result, the device may not indicate a low battery charge. The first indication of diminished battery capacity may occur when the battery is totally depleted.

This recall only affects Evita V500 and Babylog VN500 ventilators equipped with the optional PS500 power supply unit. Affected devices were distributed nationally between June 2011 and January 2014.

Initial investigation revealed that the battery capacity was reduced due to the occurrence of sulfation within the battery. Frequent short-time use of PS500 battery power can increase sulfation, further reducing the battery capacity. When sufficient sulfation occurs, the connection to main power cannot guarantee fully charged batteries and the charge indicator may not reflect the currently available battery capacity.

In some cases, neither the “Battery Low” nor the “Battery Depleted” alarm was triggered when the remaining battery capacity fell below 10%. However, when the battery depleted totally, the power fail alarm was generated.

To date, there have been no patient injuries reported due to this issue. Should the battery become totally depleted, mechanical ventilation will stop. Manual ventilation will be required until the device is connected to main power.

The current analysis of the battery data available indicates that a charged battery exhibiting internal sulfation will still last for at least 3 minutes. In case of a main power loss, this 3-minute battery back-up should typically be sufficient until the emergency main power supply is re-established. The

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investigation is ongoing and a permanent solution is being investigated, designed, and qualified.

As an interim solution, the batteries in the PS500 will be replaced free of charge. Until the batteries are exchanged, Dräger recommends that the user:

1. Use an affected device for patient transport only if absolutely necessary.
2. Not rely on the battery charge status indicator.
3. Always supervise the patient and the ventilator during transport. Ensure that a manual resuscitator is available for manual ventilation, as recommended in the instructions for use.
4. If the power failure alarm occurs during transport, immediately provide manual ventilation and connect the ventilator to a wall power source to resume ventilation.

After the above mentioned battery exchange, Dräger recommends the following:

1. Minimize battery usage.
2. Avoid brief usage and charging of the PS500 (1 – 20 minutes).
3. Avoid patient transport lasting longer than 1 hour.
4. Make sure to charge the batteries for at least 24 hours.

The exchange of the existing batteries and the above recommendations are only a temporary solution to ensure a minimum operating time of 1 hour independent from main AC power.

The permanent solution, once available, will also be provided free of charge.

A recall notification has been sent to all current users of the recalled Evita 500 and Babylog VN500 ventilators and is available on the Dräger website at www.draeger.com. Users are being contacted by a DrägerService representative to schedule the replacement of the PS500 batteries free of charge.

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For questions regarding the operation and/or servicing of affected Dräger ventilators in the United States, call DrägerService Technical Support at 1-800-543-5047 (press 4 at the prompt) between the hours of 8AM to 8PM EDT Monday through Friday, or contact Dräger by email at info.usa@draeger.com. The US Food and Drug Administration has been notified of this action.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm[1]
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm[2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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