



Urgent Medical Device Recall

**Optional Power Supply Unit PS500 Used With:
Dräger Infinity ACS Workstation Critical Care (Evita Infinity V500)
Dräger Infinity ACS Workstation Neonatal Care (Babylog VN500)**

**Battery Capacity May Not Last as Long as Expected,
Failure of the “Battery Low” and “Battery Depleted” Alarm**

February 2014

**Risk Manager
Cc: Director of Clinical Engineering**

Dear Madam/Sir:

Within the framework of our post market surveillance activities, we became aware of instances where the battery capacity of the optional PS500 Power Supply Unit of the Infinity ACS Workstation Critical Care (Evita Infinity V500) did not last as long as expected. The batteries installed in the PS500 depleted much earlier than expected although the battery indicator showed a sufficiently charged battery. In some cases neither the “Battery Low” or 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. There have been no patient injuries reported.

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

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 investigation is still ongoing and a permanent solution is in the process of being investigated, designed, and qualified.

Please note that only the optional PS500 is at issue. Therefore only Dräger ventilators incorporating the PS500 are affected (refer to appendix).

As an interim solution, the batteries in the PS500 will be replaced Free of Charge. **Until the batteries are exchanged, Dräger recommends that you:**

- 1. Use an affected device for patient transport only if absolutely necessary.**
- 2. Do not rely on the battery charge status indicator.**
- 3. Always supervise the patient and the ventilator during transport. Ensure that you have a manual breathing bag available for manual ventilation as recommended in the instructions for use.**
- 4. If the power fail alarm occurs during transport, immediately provide manual ventilation and connect the ventilator to a wall power source to resume ventilation.**

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Our records indicate that at least one Evita V500 or Babylog VN500 equipped with the optional PS500 was shipped to your facility. A Dräger Service Representative will contact you to schedule the replacement of the PS500 batteries.

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. Ensure charging of the batteries for at least 24 hours**

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

We are working with our suppliers to provide a permanent solution as quickly as possible. As soon as this solution is available, you will be contacted by a DrägerService representative again to schedule the implementation. The permanent solution will also be provided free of charge.

Please distribute this information to users of the Evita V500 and/or Babylog VN500 Ventilators to make them aware of this device behavior and risk mitigation measures.

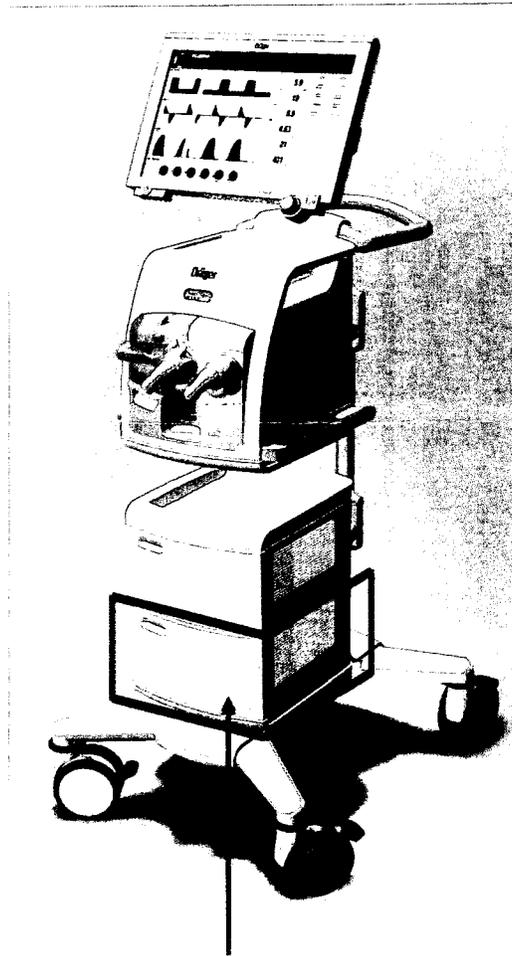
Dräger sincerely appreciates your patience, cooperation and support during this period. We apologize for any inconvenience this action may cause, but believe these measures to be essential in the interests of patient safety. If you have any questions regarding this letter please contact Michael Kelhart at 1-800-543-5047 (press 1 at the prompt, then 2, then 32349). For questions regarding the operation and/or servicing of your Dräger ventilator please contact DrägerService Technical Support at 1-800-543-5047 (press 4 at the prompt).

The US Food and Drug Administration has been advised of this action.

Sincerely,

Michael A. Kelhart
Director, Quality
Dräger Medical, Inc.

Appendix: Picture illustrating the optional PS500 Power Supply



Optional PS500 - Power supply unit