

To our customers of
Dräger Infinity ACS Workstation Critical Care (Evita Infinity V500)
Dräger Infinity ACS Workstation Neonatal Care (Babylog VN500) and
Dräger Evita V300
using optional Power Supply Unit PS500

February 2014

Important Safety Notice!!!

**Optional Power Supply Unit PS500 used in connection with
Evita Infinity V500, Babylog VN500 or Evita V300
Battery capacity will not last as long as expected,
failure of the “Battery low” and “Battery depleted” alarm**

Dear Sir or Madam,

Within the framework of our post market surveillance activities, we became aware about events in which the battery capacity of the optional PS500 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. Not in all cases neither the “Battery Low” nor the “Battery depleted” alarm was given, when the remaining battery capacity fell below 10%. However, when the battery depleted totally, the power fail alarm was generated.

Our investigation revealed that the battery capacity is reduced due to sulfation. Especially frequent short time use reduces the battery capacity. Even the connection to mains cannot guaranty full charged batteries. In these cases the charge indicator does not reflect the current available battery capacity. The current analysis of the battery data available indicates that the charged battery will at least last for 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 process to be designed.

In order to re-establish normal device operation at your facility, you will be contacted by your Dräger representative to organise a battery exchange as an interim solution. Please note, that only the optional PS500 is affected and therefore only Dräger ventilators using the PS500 are concerned (refer to appendix).

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Until this exchange of the battery, Dräger recommends:

- 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 to have a breathing bag available for manual ventilation as recommended in the instruction for use.**
- 4. If power fail alarm occurs during transport, provide manual ventilation and immediately connect the ventilator to wall power to resume ventilation.**

After the above mentioned battery exchange Dräger recommends to:

- 1. Minimise battery usage**
- 2. Avoid very short usage and charging of the PS500 (1 – 20 minutes)**
- 3. Avoid patient transport lasting longer than 1 hour**
- 4. Assure charging of the batteries for at least 24 hours**

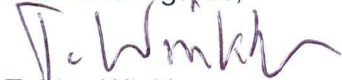
The exchange of the existing batteries under consideration of above recommendations is only a temporary solution to secure a minimum operating time of 1 hour independent from mains power supply.

We work with the highest priority together with our suppliers to provide a permanent solution as quickly as possible. As soon as this permanent solution is available, you will be contacted by a Dräger service representative again to arrange the implementation of the permanent solution.

Dräger sincerely appreciates your patience and support during this period. We apologise 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, please contact your local Dräger representative.

With kind regards,



Tobias Winkler
Head of Key Application Field
Respiratory Care

Appendix:
Picture illustrating optional PS500



optional PS500 - Power supply unit