

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

June 2015

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

Dear Sir or Madam,

Within the framework of our post market surveillance activities, we became aware about an event in which the battery capacity of the optional PS500 of an IACS 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. The sequential alarms „Battery low“ followed by “Battery depleted” were given, however, the remaining time until the ventilator shut down was not foreseeable. When the battery depleted totally, the power fail alarm was generated.

You may remember that Dräger issued a measure in February 2014 and July 2014 regarding battery capacity failures. The root cause for the reduced battery capacity at that time was due to an incorrect charging algorithm that subsequently caused sulfation within the battery. The new battery that we exchanged with this corrective action was tested and qualified. However, we learned from the supplier that batteries of this lot may be affected by a manufacturing defect that may lead to shorter battery life times. As a consequence, Dräger has decided to replace all batteries for the PS500 again.

The current analysis of the battery data available indicates that the charged battery will at least last for 30 minutes. In case of a main power loss, this 30 minutes battery back-up should typically be sufficient until the emergency main power supply is re-established.

If you use the device for patient transport, please contact your DrägerService representative. You will be put on priority for the exchange. Otherwise (using the optional PS500 primarily as a backup for the loss of mains power supply), a DrägerService representative will contact you to schedule the battery exchange at your facility. This proceeding was chosen because batteries which are not used for patient transport purposes will not experience the behaviour of early battery depletion, as reported.

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Until the new batteries are installed we strictly recommend:

- Do not rely on the battery status indicator!
- If power fail alarm occurs, provide manual ventilation and immediately connect the ventilator to mains power to resume ventilation.
- Do not use the device for patient transports, unless absolutely necessary!
- If you must use the device for transport, we recommend determining the battery capacity:
 - Charge the battery of your device for at least 24 hours like described in the Instructions for use.
 - Let the device run without a patient on battery thereafter (without external Gas Supply Unit GS500).
 - For further proceeding please refer to the table below:

Determined time till alarm „Battery low“	Proceeding
>2 h	Device maybe used for further 6 months for patient transports lasting max. 1 hour. Contact Dräger Service to schedule battery replacement.
<2 h	Do not use the device for patient transport. Contact Dräger Service for immediate exchange of batteries.

Please inform all users of your facility about the above mentioned recommendation.
Please note, that only Dräger ventilators using the optional PS500 are affected (refer to appendix).

We apologize for any inconvenience this corrective measure may cause, but believe these measures are essential for patient safety.

If you have any questions, please contact your local Dräger representative.

Sincerely,



Frank Ralfs
Head of Product Management
Respiratory Care & Thermoregulation



Frank Clanzett
Head of Post Market Surveillance
Quality and Regulatory Affairs

Appendix:
Picture illustrating optional PS500



optional PS500 - Power supply unit