

To our customers and users of
Dräger Infinity ACS Workstation Critical Care (Evita Infinity V500)
Dräger Infinity ACS Workstation Neonatal Care (Babylog VN500)
with optional PS500 power supply unit

September 2014

Subject: Update regarding the Medical Device Recall for the optional PS500 Power Supply unit initiated in February 2014

Dear Sir / Madam,

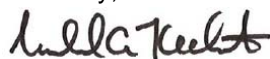
In February 2014 we informed you of a voluntary Medical Device Recall on the optional PS500 Power Supply used with the Evita V500 and Babylog VN500 ventilators. Over the past six months Dräger has precisely analyzed the battery charging management and the behavior of the battery types used and finalized a solution. As a result, effective immediately, we will be replacing all 15Ah type batteries used in the PS500 with a more robust 12Ah battery type. An additional service-charging algorithm has also been implemented which prevents the problem of sulfation of the batteries, which was identified as a main reason for the reduction of the PS500 battery capacity. All PS500 power supply units currently in use will be upgraded by Dräger free of charge.

A DraegerService representative will be contacting you to schedule the update to your Evita Infinity V500 and/or Babylog VN500 ventilators with the optional PS500. The technical details of the revised PS500 can be found in the additional insert for the Instructions for Use that will be provided during the update.

The revised external PS500 battery once again represents a reliable power supply solution for intra-hospital transport. The typical minimum life of the batteries in the PS500 now amounts to 240 minutes without the GS500 gas supply unit, or 120 minutes with the GS500 gas supply unit. The battery's charge display on the control unit informs you of the remaining battery capacity.

We regret any inconvenience caused as a result of this recall, but we consider it a necessary preventive measure to ensure patient safety. If you have any questions regarding this letter please feel free to 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).

Sincerely,



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

Appendix (1)

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optional PS500 – Power supply unit