

Drägerwerk AG & Co. KGaA, 23542 Lübeck

To our customers and users of the
Dräger Infinity ACS Workstation Critical Care (Evita Infinity V500)
Dräger Infinity ACS Workstation Neonatal Care (Babylog VN500) and
Dräger Evita V300
with optional PS500 power supply unit

January 2016

Important safety notice!!!
Optional PS500 power supply unit in combination with
Evita Infinity V500, Babylog VN500 or Evita V300
Limited duration of battery supply

Dear Madam/Sir,

As part of our continued market and product monitoring we have become aware of cases in which the battery capacity of the optional PS500 power supply unit for the IACS Workstations Critical Care (Evita Infinity V500) and Neonatal Care (Babylog VN500) was rapidly and unexpectedly reduced despite using the most recent power supply software (FW1.50), which was released in November 2015. The batteries prematurely discharged, even though an adequate battery charge status was displayed on the device. The "Battery discharged" alarm was not in all cases triggered five minutes prior to battery discharge, as specified. When the batteries were completely discharged, the devices triggered the existing power failure alarm correctly.

Nine customers worldwide ever reported the aforementioned behavior. The recently reported cases that involved the new power supply firmware (FW 1.50) concerned four of these customers. The commonality of these customers is that transports are frequently carried out using these devices. We have taken different measures with these customers on-site to detect the causes and to prevent the potential for ventilator failure during the typical clinical workflow caused by insufficient battery capacity during patient transport.

All quality data and results from long-term tests show that batteries, which are only used as backup batteries in case of a power failure, continue to supply power for such an event. Power supply via the battery ensures continued ventilation.

Given these new findings, the decision was made to cancel the distribution of the updated power supply software (FW1.50) and to downgrade devices on which this software version is already installed. This measure is being taken because with the older software (FW1.49) we have more

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detailed knowledge of the behavior of the software during the entire battery life in those cases where the battery is used for backup, rather than transport.

Additionally, based on our current analysis, the new software does not represent an improvement in terms of battery charge in transportation devices. As a precaution, we will replace the batteries in your PS500 again as a part of this downgrade.

If you typically use the devices on battery power to transport patients, please contact your responsible Dräger representative if you have not already done so. The representative, together with the technical experts in Lübeck, will work with you to develop a short-term solution until a permanent solution is achieved.

If you only use your PS500 batteries as a backup (rather than transport), this backup function is still fully functional, as described above.

Nevertheless, we strongly recommend to only use these devices during transportation in cases of emergency or if the patient is closely monitored, until a permanent technical solution is available.

In addition, please do not rely on the displayed charging status and connect the device to a power supply if your device generates a "Battery low" alarm.

Please inform all members of staff who require information about this.

Please note that only the above-mentioned devices with the optional PS500 power supply unit (see Annex) are affected.

Dräger continues to work diligently towards providing a permanent solution and we will inform you about further measures as soon as possible.

We apologize for the inconvenience to you during this action but consider the action necessary as a preventative measure for increasing patient safety.

Please feel free to contact your local Dräger representative if you have any questions.

With best regards,



Frank Ralfs
Head of Product Management
Respiratory Care



Frank Clanzett
Head of Post Market Surveillance
Quality and Regulatory Affairs

Annex:

Illustration of the optional PS500 power supply unit

Optional PS500 power supply unit



Optional PS500 power supply unit