

Drägerwerk AG & Co. KGaA, 23542 Lübeck

To all customers and users of 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

November 2015

Important Safety Notice!!!
Optional PS500 power supply unit in conjunction with
Evita Infinity V500, Babylog VN500 or Evita V300
Limited runtime on battery power

Dear Madam/Sir,

Within the framework of our market and product surveillance activities, we have become aware of cases in which the battery runtimes of the optional PS500 power supply unit with the Infinity Workstation Critical Care (Evita Infinity V500) were cut unexpectedly short. The batteries were prematurely depleted despite the device displaying a sufficient charge status. The “battery depleted” alarm was not given in all cases five minutes before the battery was totally depleted, as is specified. Once the batteries were totally depleted, the devices each gave the correct alarm to indicate the power failure.

Dräger already informed you in the past about possible runtime reductions in the external PS500 batteries. You were made aware of the causes in our correspondence at that time. Independently of this, we have unfortunately discovered that the current design of the charging algorithm for the new PS500 batteries is not able to appropriately prevent premature battery ageing in all application scenarios. For this reason, Dräger has decided to test your batteries, replace them if necessary and update the battery charging software.

Current analysis of the battery data available indicates that an operating time of at least 20 minutes can normally be maintained after the device is disconnected from the power supply, which sufficiently bridges the gap in the event of a mains power failure until the emergency power supply can be activated.

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Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRB 7903 HL
Komplementär: Drägerwerk Verwaltungs AG
Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRB 7395 HL

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If you use the aforementioned devices for patient transport, we would kindly request you to contact your local DrägerService representative immediately. If this is the case, we would like to exchange your batteries and update your software as a matter of priority. In all other cases (e.g. when the device is used as a power supply unit for the event of a possible mains power failure) you will be contacted by our DrägerService representative who will plan with you when the check of the batteries and -if necessary- the exchange of the batteries, as well as the software update can be carried out. This approach was chosen because a premature loss of capacity was only noted in the batteries of those optional PS500 units that are regularly used for patient transport.

Until the batteries can be replaced, we urgently recommend the following:

- Do not rely on the battery charge status indicator!
- If your device issues a "battery depleted" alarm when you are using the PS500, connect it immediately to the mains power.
- If the device issues a mains power failure alarm, use the emergency ventilation bag, connect the ventilator immediately to mains power and resume ventilation of the patient!
- Use the device for patient transport only if absolutely necessary!

Please inform any staff who require knowledge of this issue.

Please note that only the aforementioned devices with the optional PS500 power supply unit are affected (see attachment).

We would like to apologize for any inconvenience this measure may cause, but believe it is an essential preventive measure to increase patient safety.

If you should have any questions, please do not hesitate to contact your local Dräger representative.

With kind regards,



Frank Ralfs
Head of Product Management
Respiratory Care



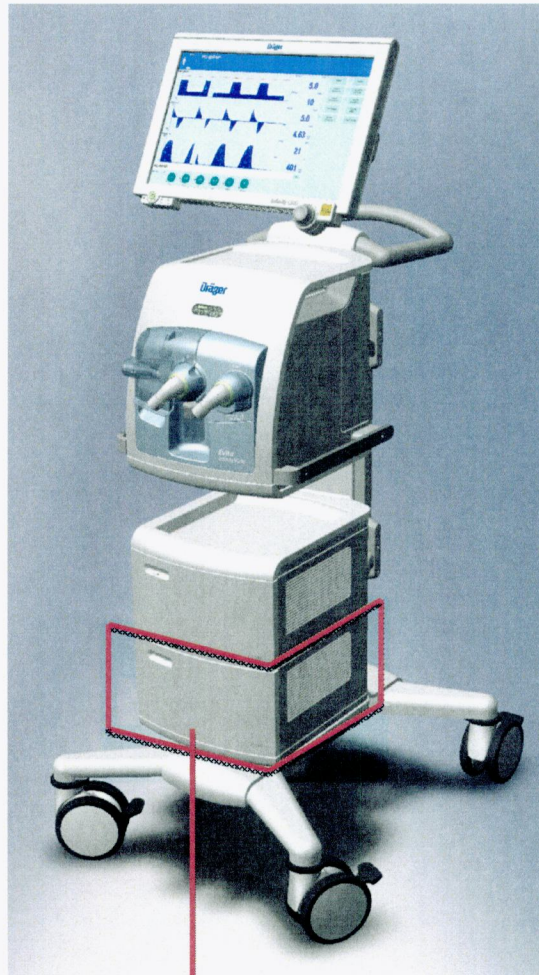
Frank Clanzett
Head of Post Market Surveillance
Quality and Regulatory Affairs

Attachment:

Illustration of optional PS500 power supply unit

Information about the battery usage and capacity indicator

Optional PS500 power supply unit



Optional PS500 power supply unit