



## Urgent Medical Device Recall

### **Perseus A500 Anesthesia Workstation Faulty Power Switch, for USA Perseus A500 versions, only**

November 2015

**Risk Manager  
Cc: Director of Clinical Engineering**

Dear Sir or Madam,

We would like to inform you about a potential problem with the device main power switch of the Perseus A500 Anesthesia Workstation. The device power switch may spontaneously fail during use, causing one the following to occur:

- 1) The workstation has a fresh gas delivery failure and a ventilator failure with respective alarms.**
- 2) The workstation shuts down completely with an audible alarm.**

In both cases, automatic ventilation will no longer be available, but it is still possible to provide manual ventilation with the Perseus® A500 breathing bag as described in the instruction for use, chapter "Operation in case of emergency".

The device power switch of the affected workstations must be replaced. Our records indicate that an affected Perseus A500 Workstation(s) was shipped to your facility (please refer to the attached list of affected serial numbers). As soon as new switches are available, you will be contacted by a DrägerService Representative to schedule the replacement of the power switch free of charge.

**Until the device power switch has been replaced, the workstation may only be operated under continuous supervision. Increased attention is necessary to notice the potential failure case early.**

We regret any inconvenience this information may cause but consider it necessary as a preventive measure to ensure patient and user safety.

Please inform all affected users in your hospital.

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

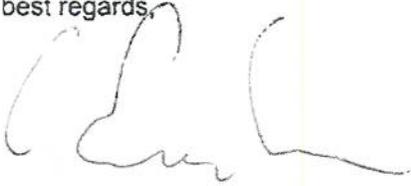
Dräger Medical, Inc.  
3135 Quarry Road  
Telford, PA 18969  
Tel: 215-721-5400  
Toll-free: 800-4DRAGER (437-2437)  
Fax: 215-721-0412  
E-mail: [wwwinfo@draegermed.com](mailto:wwwinfo@draegermed.com)

<http://www.draeger-medical.com>

If you have any questions regarding this letter please 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 Perseus A500 please contact DrägerService Technical Support at 1-800-543-5047 (press 4 at the prompt).

The US Food and Drug Administration has been advised of this action.

With best regards,



Dr Christian Engeln  
Head of Product Management Anesthesiology  
Drägerwerk AG &Co. KGaA

Appendix: Perseus A500 Serial Number List

Perseus A500 – Serial Number List

For Urgent Medical Device Recall Notification, November 2015, USA

ASHB-0140
ASHF-0039
ASHF-0055
ASHF-0056
ASHF-0057
ASHH-0008
ASHH-0009
ASHH-0010
ASHH-0011
ASHH-0012
ASHH-0013
ASHH-0014
ASHJ-0095
ASHJ-0096
ASHJ-0097
ASHJ-0098
ASHJ-0099
ASHK-0001
ASHK-0002
ASHK-0003
ASHK-0008
ASHK-0009
ASHK-0010
ASHK-0056
ASHK-0057
ASHK-0079
ASHK-0080
ASHK-0081
ASHK-0082
ASHK-0083
ASHK-0084
ASHK-0085
ASHK-0086
ASHK-0087