

## **Class I / Perseus A500 Anesthesia Workstation / Draeger Medical, Inc. RECALL/ (12/15)**

### **Reason/Information:**

FDA issued a Class I on the following materiel (See Image on Message under Additional Documentation/Attachment). Reason: The device power switch may spontaneously fail during use, causing one of the following to occur:

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

### **Disposition/Instructions:**

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. As soon as new switches are available, a Draeger Service Representative will 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.

For questions regarding this recall, contact Michael Kelhart at 800-543-5047 (press 1 at the prompt, then 2, then 32349). For questions regarding the operation and/or servicing of the Draeger Perseus A500, call Draeger Service Technical Support at 800-543-5047 (press 4 at the prompt) or 215-721-5400.

### **Item Information:**

NSN (FSC-NIIN): 6515-NS1  
Part Number: MK06000  
Nomenclature: PERSEUS A500 ANESTHESIA WORKSTATION  
UI: EA  
Manufacturer: DRAEGER MEDICAL, INC.

### **LOT / SN:**

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

Additional information can be found by clicking [here](#).