

**To customers of  
Dräger anesthesia machines  
Fabius GS Premium,  
Fabius OS,  
Fabius Plus,  
Fabius Tiro**

August 2013

### **Important safety notice!!!**

**Potential failure of automatic ventilation, accompanied by an alarm.  
Fabius deliveries from February up to and including July 2013 and also power  
supply units which were exchanged during this period.  
Other Fabius deliveries are NOT affected.**

Dear Customers,

Some units did not pass the high voltage final test during the final checking of the Fabius in our production facility. Investigations carried out revealed that on some power supply units from a particular batch, the required minimum clearance between an electrical component and the unit housing was not maintained. Under the influence of mechanical forces (e.g., movement of the device), this may result in small bypass currents flowing in the interior of the unit which in extreme cases cause failure of the automatic ventilation function of the device. When such faults occur, the standard required manual ventilation is possible, an acoustic alarm is generated and the indicators on the device flash.

Even though the occurrence of this fault during use has not yet been reported to Dräger, we consider it necessary to inform you of the increased risk of the potential device failure. Should you experience such a failure of the automatic ventilation function, please switch over to the manual ventilation mode by pressing the Man/Spont key then confirming with the rotary knob and commence manual ventilation. In this mode you can also meter the fresh gas with the total flow tube in the event of a fault. Fresh gas will also continue to flow through the vaporizer.

In this regard we would also point to the details in the Fabius instructions for use, where the switch-over to the manual ventilation mode is described in the "Fault-Cause-Remedy" and "Ventilator Fail State" sections.

Please inform all affected users in your organization accordingly.

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The DrägerService technician who is responsible for you will contact you to arrange a date for the soonest possible, and free of charge, replacement of the power supply unit.

We regret any inconvenience that this action may cause but consider the action necessary as a preventive measure to increase patient safety.

We thank you for your support.

Yours sincerely,

Dräger Medical GmbH  
Key Application Field  
Anaesthesiology



Attachment:

Overview of the affected device serial numbers

## **Attachment to the Safety Notice List of Serial Numbers affected**

**Serial numbers are printed on the type plate at the rear of the Fabius**

### **Serial Numbers of affected Devices in Countries other than China**

**ASEB-0219 to ASEB-nnnn** (nnnn means any number higher than 0219)  
**ASEC- nnnn** (nnnn means any number)  
**ASED- nnnn** (nnnn means any number)  
**ASEE- nnnn to ASEE- 0118** (nnnn means any number from 0000 to 0118)

### **Serial Numbers of Devices in China**

**USEA-0017 to USEA-nnnn** (nnnn means any number higher than 0017)  
**USEB - nnnn** (nnnn means any number)  
**USEC - nnnn** (nnnn means any number)  
**USED - nnnn** (nnnn means any number)  
**USEF - nnnn to USEF- 0038** (nnnn means any number from 0000 to 0038)

### **Serial Numbers of power supplies sent as replacement parts**

H3130F0030, H3130F0034, H3130F0035, H3130F0041, H3130F0042, H3130F0043,  
H3201F0017, H3201F0018, H3201F0019, H3201F0020, H3201F0021, H3201F0022,  
H3201F0023, H3201F0024, H3201F0025, H3201F0026, H3201F0027, H3201F0029,  
H3201F0030, H3201F0032, H3201F0049, H3201F0050, H3201F0051, H3201F0052,  
H3201F0053, H3201F0054, H3201F0055, H3201F0056, H3201F0057, H3201F0058  
H3201F0059, H3201F0060, H3201F0062, H3201F0063, H3201F0064