



GE Healthcare

Urgent Field Safety Notice

February 2009

To: Health Administrator / Risk Manager
Head of Anaesthesia
Director of Clinical Engineering

RE: **On/Standby Switch Failures on certain GE Datex-Ohmeda Aisys and GE Datex-Ohmeda Avance Anaesthesia Machines**

Dear valued customer,

GE Healthcare is aware of issues associated with the On/Standby Switch used on certain GE Datex-Ohmeda Aisys and GE Datex-Ohmeda Avance anaesthesia machines that may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

There have been reported cases of a potential intermittent electrical connection with the On/Standby Switch that can cause the machine to shutdown without clinical intervention. When the machine is in therapy mode, the machine will always alert the clinician of the pending shutdown by a high priority alarm and a message on the screen that states "System shutdown in 8 sec". The AM Monitor, if present and interfaced to the system On/Standby function, can be turned on independently with its own On/Off switch on the monitor's display.

There have been no reported deaths or injuries associated with this issue.

Affected Product Details

Aisys Anaesthesia Systems manufactured from May 2005 to May 2008 and Avance Anaesthesia Systems manufactured from June 2003 to May 2008. The serial number ranges are listed below:

Aisys ANAH00100-ANAM00498
Avance ANBG00100-ANBM00530

Safety Instructions

If the "System shutdown in 8 sec" alarm occurs during therapy, the following actions can be taken to potentially correct the issue:

- Toggle the On/Standby Switch from the "On" position to the "Standby" position and back to the "On" position before the 8 seconds has elapsed.

In the rare situation in which the intervention stated above is not successful and the machine powers down, as long as the On/Standby Switch is in the "On" position, Alt O2 automatically engages and Oxygen begins flowing into the breathing system. Mechanical ventilation will cease. Manual ventilation is available. In most cases the machine will execute its power up sequence normally after the On/Standby Switch is moved from the "Standby" position back to the "On" position.

With the Avance anaesthesia machine, the agent continues to be delivered.

With the Aisys anaesthesia machine, agent delivery stops. Alternative anaesthesia, such as IV sedation may need to be considered.



Product Correction A GE Service Representative will replace the On/Standby Switch on all Aisys and Avance Machines affected.


A Service representative will be contacting you in the near future regarding this issue.

Contact Information If you have any questions regarding this letter, or the actions you should take please contact your local GE Healthcare Service.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Thank you,




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