



URGENT FIELD SAFETY NOTICE

GE Healthcare
Healthcare System
9900 Innovation Drive
Wauwatosa, WI 53226
United States

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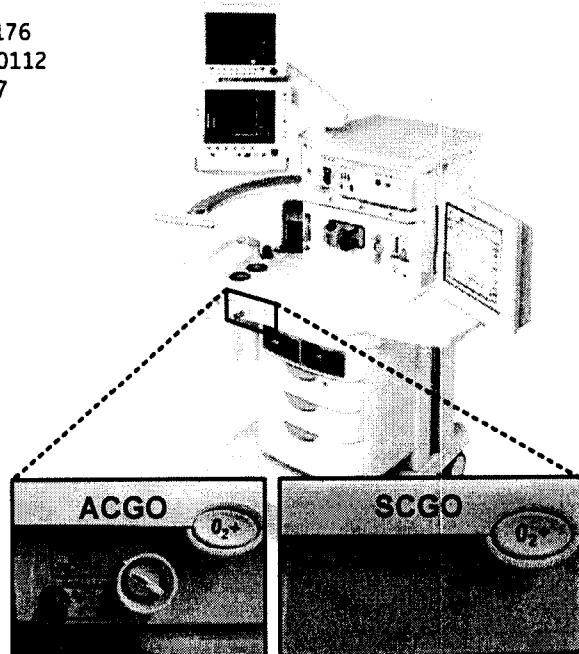
To: Chief of Anesthesia
Health Care Administrator/Risk Manager
Director of Biomedical/Clinical Engineering

RE: **Test Plug inadvertently left in inspiratory port after completing the Low P Leak Check on GE Datex-Ohmeda Avance, Amingo, and Aisys anesthesia machines**

GE Healthcare has become aware that some users have inadvertently left a test plug in the inspiratory flow sensor after completing Low P Leak Check on the SCGO (Switched Common Gas Outlet) configuration of Avance, Amingo, and Aisys anesthesia machines that may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the safety actions described below.**

Safety Issue If a user inadvertently leaves a test plug in the inspiratory flow sensor following the Low P Leak Check and therapy is initiated, the machine is not capable of providing gas to the patient. This may result in difficulty ventilating in mechanical or manual mode, potentially resulting in hypoventilation, leading to hypoxia.

Affected Product Details Avance, Amingo, and Aisys anesthesia machines configured with the SCGO option shipped between June 1, 2003 and July 1, 2010. Serial number ranges are indicated below:
Avance - ANBG00100 to ANBP01176
Amingo - AMNM00101 to AMNP00112
Aisys - ANAH00100 to ANAP00727



Note: Aisys shown; similar features on Avance and Amingo

This correction does not affect machines with the ACGO (Auxiliary Common Gas Outlet)

option, as the Low P Leak check is performed using a negative pressure leak test (Squeeze Bulb test).

**Safety
Instructions**

Safety instruction for the Low P Leak check:

1. Ensure the plug is removed at the completion of the Low P Leak check.
 - Remove the plug from the right-hand port (See picture below).
 - Reconnect the patient circuit.
 - Select the Back button.



2. Review the Preoperative Checkout procedure listed in section 4 of the User Reference Manual with appropriate personnel. Ensure that the Preoperative Checkout procedure is completed in its entirety prior to each case, or as required.

**Product
Correction**

Your local GE Field Technical Service /Distribution Partner will be contacting your facility to schedule installation of a software update and a revised test plug for your machines configured with SCGO.

**Contact
Information**

Please contact your local GE Healthcare Technical Support / Distribution Partner if you need additional information regarding this notification.

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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