Urgent field safety notice

GE Healthcare
3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 34079

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

RE: Avance CS^2, Avance, and Amingo System Malfunction when Lower Drawer Closed Forcefully

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue

GE Healthcare has become aware of a potential safety issue where certain Avance CS^2, Avance and Amingo anesthesia devices can transition to a System Malfunction state if the lower storage drawer containing the optional large tray insert accessory (see PIC01 below), is closed with an abnormally high amount of force.

Should the anesthesia device transition to a System Malfunction state the device will perform in the following manner:

- Automatically activate Alternate Oxygen flow within a few seconds,
- Provide high priority audible and visible alarms,
- Provide on display instructions to set the oxygen (O2) flow and manually ventilate the patient,
- Continue to deliver anesthetic agent at the existing vaporizer setting.

If the System Malfunction is left unresolved, it could result in loss of patient ventilation potentially resulting in hypoxia. There have been no injuries reported as a result of this issue.

PIC01 – 1009-3260-000 Large Tray Insert

Safety Instructions

You can continue to use your Avance CS2, Avance, and Amingo devices after removing the optional large tray insert accessory, if installed.

The optional large tray insert accessory can be removed from the device manually by any clinical user or site authorized personnel. No tools are required and no technical training is necessary to remove the large tray insert.

Avance CS2, Avance, and Amingo anesthesia devices with the optional large tray insert accessory installed (part number 1009-3260-000) are susceptible to the issue. The large tray insert accessory can also be used with the Aespire family of devices, however, the Aespire devices are not susceptible to this issue. The optional small tray insert does not produce this issue.

GE Healthcare requests that clinical users receiving this device correction notice destroy all large tray inserts in their possession.

After removal of the optional large tray insert, it is not required that you return the insert to GE Healthcare. However, if you would like to return the insert to GE Healthcare please send an e-mail request to "Avance_Drawer.Insert_RMA@ge.com."

Affected Product Details

Avance CS2, Avance, and Amingo anesthesia devices with the optional large tray insert accessory installed (part number 1009-3260-000).

Product Correction

After removal of the optional large tray insert, it is not required that you return the insert to GE Healthcare. However, if you would like to return the insert to GE Healthcare please send an e-mail request to "Avance_Drawer.Insert_RMA@ge.com."

Contact Information

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

Oxygen Care Ltd.
2 Holfeld Business Park,
Kilmacanogue,
Co. Wicklow,
Ireland .
Phone: ++353 1 276 9700
e-mail: k.long@oxygen-care.ie

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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 per the contact information above.

Sincerely,

James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

Jeff Hersh PhD, MD
Chief Medical Officer
GE Healthcare