URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment> GEHC Ref# 34075

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

RE: **Momentary, Self-Correcting Anesthetic Agent Bolus when Using 21% Oxygen on Aisys CS^2 and Upgraded Aisys Devices**

GE Healthcare has recently become aware of a potential safety issue involving a momentary, self-correcting anesthetic agent bolus when using 21% oxygen on all Aisys CS^2 and upgraded Aisys anesthesia devices. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

Aisys CS^2 anesthesia devices and upgraded Aisys anesthesia devices deliver a momentary, self-correcting increase of the anesthetic agent, affecting the inhaled and exhaled concentrations for a short time, upon either of the following setting changes:

- A fresh gas setting change from 95%-25% oxygen to only air (21% oxygen).
- Any total flow setting change while using 21% oxygen (air only).

The momentary bolus of anesthetic agent will not occur with nitrous oxide as the carrier (balance) gas or if the oxygen concentration is set above 21% (air only).

Delivery of this momentary bolus of anesthetic agent is potentially hazardous because it could lead to hypotension in certain vulnerable pediatric patients when 21% oxygen (air only) is used. There have been no injuries reported as a result of this issue.

Safety Instructions

You can continue to use your anesthesia device. If your practice involves use of 21% O2 in the fresh gas, any adjustment to the fresh gas flow rate will deliver a bolus of inhaled anesthetic agent. The effect of the bolus to the inhaled and exhaled agent concentrations is short in duration. Observe the potential effects of the short time higher concentrations of anesthetic agent.

In the event the issue described above does occur, your anesthesia device will automatically recover and return to the commanded steady-state anesthetic agent concentration without any required user action.

Depending on your system configuration, one or both of these alarms could trigger if this issue occurs:

- Clinician adjustable “Fi XXX High” alarm (XXX denotes the specific agent)
- Alarm if respiratory gas monitoring is not present

Affected Product Details

All Aisys CS^2 anesthesia devices (GTIN: 840682102292) and upgraded Aisys anesthesia devices (i.e. Aisys devices with a touch screen display and software version 10.X). Software versions other than 10.X are not affected.

Product Correction GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

Contact Information If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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,

[redacted]

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

[redacted]

Jeff Hersh, M.D.
Chief Medical Officer
GE Healthcare