



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 34098

To: Chief of Anesthesia
Director of Biomedical / Clinical Engineering
Health Care Administrator / Risk Manager
Chairman Medical Board and relevant Head of Departments

RE: Aisys CS² anesthesia devices with software version 11 and Aisys anesthesia devices upgraded to software version 11 with End Tidal Control option (when Et Control auto-exits during Pause Gas procedure agent delivery is off and fresh gas total flow is 10 L/min, resulting in the agent concentration quickly decreasing).

This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

Safety Issue

Aisys CS² anesthesia devices with software version 11 and Aisys anesthesia devices upgraded to software version 11 can, on rare occasions involving a non-typical workflow, fail to deliver the set agent concentration in End Tidal Control (Et Control) if Et Control is automatically exited while a Pause Gas Flow procedure is in progress. Following the auto-exit in this situation, if the clinician re-enters Et Control, agent delivery will not function. Fresh Gas Control delivery mode is not affected.

If this situation occurs, the anesthesia device does not immediately notify the user of the error and the agent delivery remains off while in Et Control despite the agent setting showing a non-Off value. The fresh gas flow changes to 10 L/min during this condition, which purges agent out of the breathing system causing under delivery of agent. The anesthetic gas concentration might become insufficient potentially leading to awareness. There have been no injuries reported as a result of this issue.

Safety Instructions

You can continue to use your anesthesia device.
If the above issue occurs, use one of the methods below to resolve the issue:
Option 1: Exit Et Control to Fresh Gas Control mode which allows manual control of fresh gas flows and anesthetic agent concentration,
Option 2: Re-enter Et Control and start and stop a Pause Gas Flow procedure, or
Option 3: Turn the anesthesia device off and back on.

Affected Product Details

All upgraded Aisys anesthesia devices (i.e. Aisys devices upgraded to software version 11SP01 or 11SP02) and Aisys CS² anesthesia devices with software version 11SP01 or 11SP02 (GTIN: 840682102292) and Et Control option.

Note: Software versions other than 11SP01 and 11SP02 are not affected. Anesthesia devices without the Et Control option 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. If your site has not yet received the correction from Ref# 34094, those updates will be included in this correction.

After the GE representative has updated your system to Aisys CS2 11 SP03, any earlier versions of Aisys CS2 11 software media on site should be destroyed.

**Contact
Information**

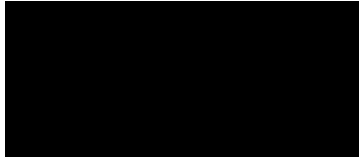
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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,



James W. Dennison
Vice President - Quality Assurance
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare



GE Healthcare

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**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED**

Please complete this form and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice Ref# 34098.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who has completed this form.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form scanning or taking a photo of the completed form e-mailing to:

Recall34098.SP03SW@ge.com

You may obtain this e-mail address through the QR code below:

