# URGENT FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GE HealthCare Ref. # 34147

To: Chief of Anesthesia
Director of Clinical/Biomedical Engineering
Chief of Nursing
Risk Manager/Healthcare Administrator

RE: **Aisys CS², Aisys CS² with Et Control and S/5 Aisys Anesthesia Systems automatically transitioning to Alternate O2 control**

## Safety Issue

GE HealthCare has become aware that Aisys CS², Aisys CS² with Et Control and S/5 Aisys Anesthesia Delivery Systems (see Affected Products List in this letter), containing certain electronic gas mixer assemblies, can automatically transition to Alternate O2 control.

In Alternate O2 control, the system delivers 100% O2 to the breathing system enabling continued controlled or manual ventilation and initiates audible and visual alarms ("Set Alt O2 Flow! Agent delivery off!" or "Set Alt O2 flow! Check agent setting!").

When this issue occurs, anesthetic agent delivery will be interrupted and requires clinician intervention. If this is not provided, the patient may experience decreased anesthetic agent effect.

There have been no injuries reported to GE HealthCare as a result of this issue.

## Actions to be taken by Customer/User

Pending corrections from GE HealthCare, you can continue to use your Anesthesia system by following the instruction below:

1. Prior to each use, complete preoperative checkout and tests in accordance with the instructions in the User Reference Manual (URM).
2. When Alternate O2 control is enabled, the clinician should adjust the Alternate O2 flow as appropriate for the case. Use the Alternate O2 control knob to adjust the O2 flow.
3. When Alternate O2 control is enabled, flow from the electronic mixer is stopped and the agent concentration is set to off. Two situations are possible regarding the Agent quick key:
    a. The Agent quick key will be blank on the display if agent delivery is unavailable. Supplement with or transition to intravenous anesthetics as needed.
    b. The Agent quick key will be present on the display if agent delivery can be resumed. Press the Agent quick key to set the desired concentration and press the key again to confirm.
4. Please evaluate existing service stock for the Field Replaceable Unit (FRU) spare parts listed below and dispose of all affected FRU parts according to your facility procedures.

Please ensure all potential staff in your facility are made aware of this safety notification and the

recommended actions.

Please retain this document for your records.

Please complete and return the attached acknowledgement form electronically via FMI 34147 Digital Response Form or print, fill out manually, scan, and email to recall.34147@gehealthcare.com.

## Affected Product Details

The affected electronic mixers could have been shipped or used with the following products:

**Table 1: Products manufactured between November 13, 2025 and June 2, 2026 with potentially affected electronic mixers.**

| Product | REF# | GTIN Number |
|---|---|---|
| Aisys CS$^2$ | 1011-9050-000 | 00840682102292 |
| Aisys CS$^2$ With Et Control | 1011-9055-000 | 00195278588128 |

In addition to the products listed in Table 1 above, the affected electronic mixers could also be installed as spare part with the following product:

**Table 2: In addition to Table 1, Products for which affected electronic mixers can be used as a spare part**

| Product | REF# | GTIN Number |
|---|---|---|
| Aisys | 1011-9000-000 | Not Applicable |

In addition to the products listed in the above tables, the following Field Replaceable Unit (FRU) parts are affected:

**Table 3: Field Replaceable Units parts**

| ITEM NUMBER | NAME # | Lot/Serial Number Date Range |
|---|---|---|
| 1011-8000-000-S | Gas Mixer Electronic – Assembly | November 13, 2025, to June 2, 2026 |
| 5700665 | R-FMI34141 GAS MIXER ELECTRONIC | November 13, 2025, to June 2, 2026 |

**Intended Use**

The Anesthesia systems are intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonate, pediatric, and adult). The devices are intended for volume or pressure control ventilation.

## Product Correction

GE HealthCare will inspect and correct as necessary 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 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 GE HealthCare per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical & Safety Officer
GE HealthCare

GE HealthCare Ref. # 34147

**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.**

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Email Address: _____

Customer Phone Number: _____

By signing this form, we acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed all potential users and have taken and will take appropriate actions in accordance with that Notification.

We've evaluated existing service stock for the Field Replaceable Unit (FRU) parts and have disposed of all affected FRU parts.

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

Signature: _____

Printed Name: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

| **To complete this form electronically, please scan the QR Code below or click this link:** FMI 34147 Digital Response Form | **To complete this form via email, scan or take a photo of the completed form and email to:** recall.34147@gehealthcare.com |
|---|---|