URGENT FIELD SAFETY NOTICE

Date of Letter Deployment

GE HealthCare Ref. # 34136

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

RE: **Aisys CS², Avance CS², Avance CS² Pro, Aisys, Avance, Amingo, Aespire 100, Aespire View, Aespire 7900, and Aespire 7100 anesthesia devices equipped with the Auxiliary Common Gas Outlet (ACGO)**

Safety Issue

GE HealthCare has become aware of a potential issue that may arise if the limb of a patient breathing circuit is mistakenly connected to the Auxiliary Common Gas Outlet (ACGO) port.

The ACGO, when selected, provides fresh gas flow to auxiliary manual breathing systems (e.g., a Mapleson-D circuit) connected to the ACGO port.

If the expiratory limb of a patient breathing circuit is mistakenly connected to the ACGO port rather than to the Advanced Breathing System port, it can result in excessive pressure within the breathing system. The Anesthesia devices that are potentially impacted have several alarms that would alert the clinician of increased breathing system pressures. However, in the unlikely event that the misconnection to the ACGO port is not noticed, the increased pressure can lead to patient injury.

Actions to be taken by Customer/ User

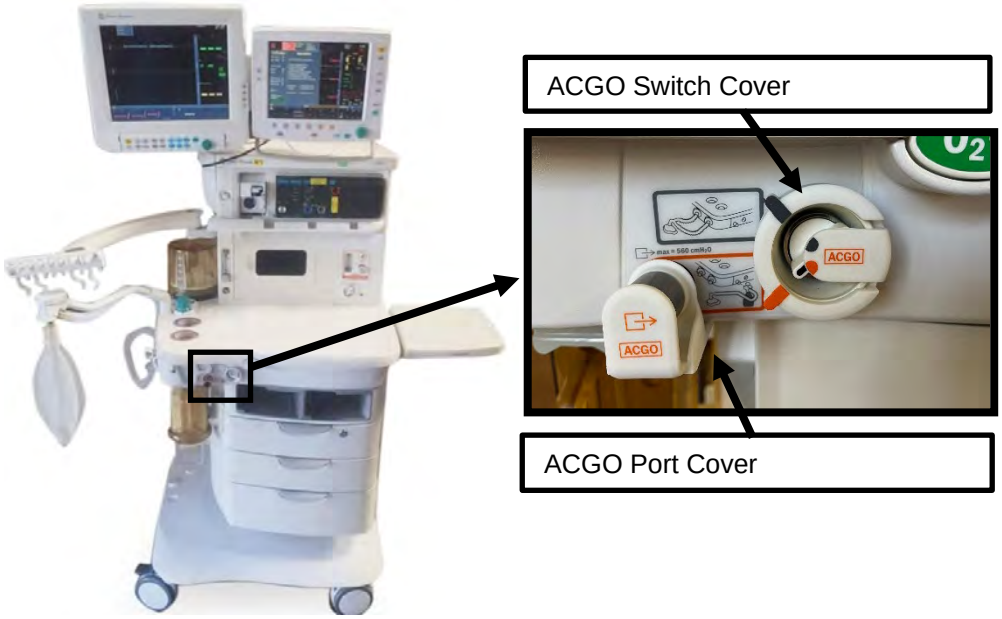
You can continue to use your anesthesia system in accordance with the instructions in the User Reference Manual (URM) and the actions described below:

1. Ensure all potential users complete the Preoperative Checkout procedure in its entirety, as detailed in the URM.
2. Specifically, make sure that the breathing circuit is correctly connected.
3. Only connect an auxiliary manual breathing circuit to the ACGO port.
4. Please place the attached addendum with the URM.

In addition to following the four (4) instructions above:

Inspect all potentially affected devices for the presence of covers applied to the ACGO Port and ACGO Switch as depicted in **Figure 1**. If the covers are available but not on the device, apply the covers as depicted in **Figure 1.**

Figure 1. Covers applied to ACGO Port and ACGO Switch



Please complete and return the attached acknowledgement form to FMI34136.ACGO@gehealthcare.com to indicate whether you have the covers and have applied them to the ACGO Port and ACGO Switch OR that you do not have the covers. If you do not have the covers, GE HealthCare will provide you with customer-installable kit containing covers for you to apply to your device ACGO Port and ACGO Switch, at no cost to you.

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

Affected Product Details

Aespire 7100, Aespire 100, S/5 Aespire 7900 (GTIN-00840682102261)
Aespire View (GTIN-00840682102285)
Avance, Amingo, Avance CS2 and Avance CS2 Pro (GTIN-00840682102322)
Aisys, Aisys CS2 (GTIN-00840682102292)
Aisys CS2 with Et Control (GTIN-00195278588128) machines configured with ACGO option.

NOTE: This correction does not affect Anesthesia devices with the Switched Common Gas Outlet (SCGO).

Intended Use: The GE Datex-Ohmeda Anesthesia Systems are intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation.

Product Correction

GE HealthCare will provide a customer-installable kit containing covers for the ACGO Port and ACGO Switch of impacted devices, at no cost to customers who indicate in the attached acknowledgement form that they do not have the covers.

If you need support to install the ACGO Port and ACGO Switch covers, please contact your GE HealthCare representative.

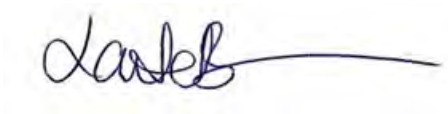
Contact Information

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

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 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. # 34136

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.

There are two options for your convenience:

1) Electronic response form (this page)

   OR

2) Manual filled and scanned response form (next page)

Electronic response form

Please scan the QR code or follow the link below to complete the form

https://app.sc.ge.com/esurveys/takesurvey/18446744073711477876

Manual response form GE HealthCare Ref. # 34136

If the electronic workflow on the previous page is not possible, 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.

*Customer/Consignee Name: _____

*Street Address: _____

*City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

It is important that we confirm our customers have received this correction notice. This step needs to be completed before the replacement and shipping process can commence.
Please check **one** of the following and complete the requested information and send back via one of the methods below:

☐ We acknowledge receipt and understanding of the Urgent Medical Device Correction Notice. We have placed the addendum with the URM. We have confirmed that we **do not** have ACGO Port and Switch Covers to install on our device(s). We require the number of field action kits detailed in the table below:

Number of Field Action Kits needed	Name of Field Action Kit recipient (if different than signature on the response form)

OR

☐ We acknowledge receipt and understanding of the Urgent Medical Device Correction Notice. We have placed the addendum with the URM. We have confirmed that we **do** have ACGO Port and Switch Covers and have installed them on all of our device(s) as pictured in Figure 1 of the Urgent Medical Device Correction Notice. Therefore, we do not require any field action kits.

OR

☐ We acknowledge receipt and understanding of the Urgent Medical Device Correction Notice. We have identified that we **do not** have any of the affected products that were identified in the Urgent Medical Device Correction Notice.

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

*Signature: _____

*Printed Name: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to FMI34136.ACGO@gehealthcare.com.
You can obtain this email address through the QR code below: