URGENT MEDICAL DEVICE CORRECTION

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

<Date of Letter Deployment>

GEHC Ref# 39002

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

RE: AMSORB® PLUS PREFILLED G-CAN® 1.0L — CO_2 Absorbers with high flow resistance

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.

Dear Customer,

This letter is to notify you that Armstrong Medical (a 3rd party manufacturer) is conducting a product corrective action related to an accessory that could be included with or sold individually for use with GEHC anesthesia machines: all Aisys, Avance, Aespire and 9100c variants.

A copy of the Armstrong Medical Urgent Medical Device Correction Notice is included in this mailing which describes the Corrective Action in detail. Please review the Armstrong Medical notice for instructions.

For Aespire 7100 and 9100c variants, discontinue use of any AMSORB® PLUS PREFILLED G-CAN® 1.0L that fall into the affected LOT numbers listed below.

NOTE: The «CHECK-OUT» test described in Armstrong Medical notice does not apply to Aespire 7100 and 9100c variants.

Please ensure that all potential users and supervisors at your facility are made aware of this Corrective Action immediately.

We apologize for any inconvenience this action may have caused and thank you for your continued cooperation and support.

Affected Product Details

AMSORB® PLUS PREFILLED G-CAN® 1.0L (GE part# 2105489-003) manufactured between Sep 09, 2020 and Jun 30, 2021 with **Lot codes identified in Table 1 that do not have the OK/PASS label on them as shown below.**

Products with the OK/Pass label have been tested and meet the specifications

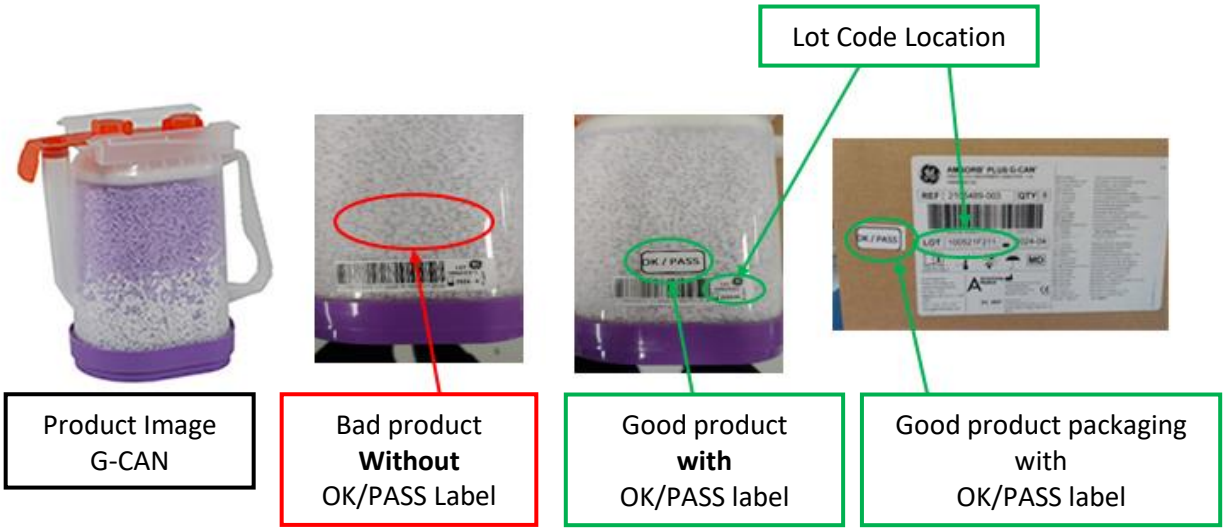


Table 1. Affected Products
[1]The first six digits of the LOT number is the date of manufacture and follows the format – DDMMYY (meaning 2 digits for Day Month Year). For example: LOT number **120820**F123 means that the devices were manufactured on 12 August 2020).

Product Code: AMAB3801GE (GE part number 2105489-003)					
LOT[1] Number					
090920F311	141220F112	180221F51	220321F41	060521F21	040621F411
090920F312	190121F512	180221F511	220321F411	060521F211	070621F31
090920F313	210121F21	250221F311	230321F51	070521F41	080621F11
160920F41	210121F211	250221F312	230321F511	070521F411	080621F111
160920F411	210121F212	250221F411	240321F11	100521F21	090621F21
160920F412	250121F31	010321F51	120421F211	100521F211	160621F11
160920F413	250121F311	090321F113	120421F212	100521F212	160621F111
210920F51	260121F41	100321F211	130421F31	110521F31	180621F21
210920F511	260121F411	100321F212	270421F312	110521F311	180621F211
210920F512	290121F21	110321F31	280421F51	180521F111	190621F31
210920F513	290121F211	110321F311	280421F511	250521F511	190621F311
240920F61	020221F21	120321F41	290421F41	260521F11	200621F41
240920F611	080221F11	120321F411	290421F411	260521F111	210621F11
290920F11	090220F21	150321F51	290421F11	270521F21	210621F51
290920F111	090221F211	150321F511	300421F11	270521F211	210621F111
290920F112	110221F11	160321F11	300421F111	280521F31	210621F511
011020F21	110221F111	160321F111	050521F41	280521F311	290621F211
011020F211	150221F21	170321F21	050521F411	310521F51	290621F31
091220F512	150221F211	170321F211	050521F51	310521F511	290621F311
141220F11	160221F31	180321F31	050521F511	010621F11	290621F212
141220F111	160221F311	180321F311	050521F512	010621F111	

Product Correction GE Healthcare will replace all affected products at no cost to you. Complete and return the attached "Customer Response" form via e-mail to FMI39002.CO2Absorber@ge.com and GE Healthcare will provide replacement.

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,

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

3rd August 2021 Coleraine, Northern Ireland
UMDC Ref: SI21-33
FSCA Ref: 2021/007/026/487/007

Urgent Medical Device Correction

Risk of device high gas flow resistance

Carbon dioxide absorbent canister AMSORB® PLUS PREFILLED G-CAN® 1.0L

Product codes AMAB3801 and AMAB3801GE

Please pass this Urgent Medical Device Correction (UMDC) to all persons in your organisation who need to be aware of it.

Type of Action:	To communicate an identified issue which may result in high and unexpected resistance to gas flow during clinical use
Device:	AMSORB® PLUS PREFILLED G-CAN® 1.0L
Manufacturer:	Armstrong Medical Limited (Coleraine, Northern Ireland)
Date of Issue:	3rd August 2021
For Attention of:	Nursing and medical staff (caregivers) working in anaesthesia and critical care areas of hospitals and all others to whom potentially affected devices have been transferred, including distributors.
Scope of Action:	**Manufacturing LOT specific recall**
Keywords:	Carbon Dioxide Absorbent, Anaesthesia, Breathing System, Resistance, Gas Flow

Summary
Armstrong Medical is aware of reports indicating that a small number of devices are associated with high and unexpected resistance to gas flow during clinical use. Such resistance could impact or prevent adequate ventilation of an anaesthetised patient, should a defective device go into clinical use. Assessment of available data and results from product testing suggest that these devices account for 0.25% of devices manufactured from June 2020 until 11th June 2021. The defect could present as failure to pass the pre-use test on the anaesthesia machine. This test is also known as **«CHECK-OUT»** test. The defect could also cause alarm **«Unable to drive bellows»** when used in mechanical ventilation modes. This will cause the anaesthesia machine to prematurely cycle to the expiratory phase, which could lead to hypoventilation of the patient. During spontaneous breathing while in *bag* mode, the patient's inspiratory work-of-breathing could be increased.

As the device is expected to be subjected to a pre-use test before clinical use, a canister exhibiting high flow resistance could be identified during set-up of the anaesthesia workstation. However, not all canisters, which could cause alarm **«Unable to drive bellows»** will be identified by the pre-use test. We recognise that this defect could give rise to a delay in treatment, whilst a defective G-CAN® is replaced. Further, we are aware that it is sometimes necessary to replace a CO_2 absorbent canister intraoperatively when the installed canister no longer adequately absorbs CO_2. If such a practice is employed, a pre-use test will not be performed. We suggest that, in the event of a device with high gas flow resistance being put into use in this manner, the consequent alarms from the anaesthesia machine must be investigated for a link to increased gas flow resistance in the canister.

Action to be taken by Users
Users are requested to review the list of potentially affected devices and return the completed UMDC response form to Armstrong Medical or to an appointed distributor to receive replacement units. Where users have opted to temporarily retain their stock of potentially affected devices, those users are asked to ensure that the revised pre-use test below is always completed.

To supplement the **«CHECK-OUT»** test before every patient as specified in the User Reference Manual, please also perform the following test:

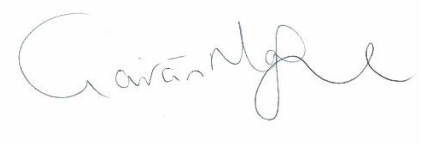
- **To check that the ventilator functions correctly:**
  - Connect a 3L reservoir bag as a test lung to the patient breathing circuit connection.
  - Set the ventilator to VCV mode and the settings to TV to 500mL; RR to 60; I:E to 1:2; Tpause to Off; and Pmax to the highest setting.
  - Set the MV High alarm to Off.
  - Set the Fresh Gas flow to the minimum setting, then:
    - Start a case.
    - Set the Bag/Vent switch to Vent.
    - Fill the bellows using O_2 flush.
    - Check that mechanical ventilation starts.
    - Check that the bellows inflate and deflate.
    - Check that the display shows the correct ventilator data.
    - Check that there are no inappropriate alarms.
      - If inappropriate alarms occur, which may stem from canisters with high flow resistance, replace the CO_2 absorbent canister and repeat this pre-use test.
    - Proceed to clinical use

Where unexpected, elevated gas flow resistance in clinical use is observed or suspected - with or without associated anaesthesia machine alarms - the canister should be replaced intraoperatively.

Where an installed canister no longer adequately absorbs CO_2 (due to absorbent exhaustion) during an anaesthesia procedure, we advise that fresh gas flow rate is increased above the required minute ventilation volume for the period until the end of the anaesthesia procedure – whereafter a new canister can be put through the revised pre-use tests specified above.

Field Safety Corrective Action
This Urgent Medical Device Correction is published to facilitate a manufacturing LOT specific device recall. See Table 1 for detail of all LOTs of finished medical devices that are subject to recall under this UMDC.

Description of Action
All devices identified in Table 1 can be used safely, provided that the devices are subjected to the revised machine pre-use tests above. Any device which fails the revised pre-use tests or generates system alarms should be disposed of or returned to Armstrong Medical or to an appointed distributor.



Dr Ciarán Magee
Technical Director
Armstrong Medical Limited

GE Healthcare

GEHC Ref# 39002

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.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

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 Medical Device Correction Notice and have identified that we **do not** have any of the affected Absorbers from the affect lots identified in the notification.

or

☐ We acknowledge receipt and understanding of the Medical Device Correction Notice, have identified that we **do** have affected absorbers, have collected all the absorbers, and have destroyed them.

- Number of Absorbers (P/N 2105489-003) destroyed after receiving this notification: _____ units.
- Number of Absorbers (P/N 2105489-003) that need to be replaced: _____ units.

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 by scanning or taking a photo of the completed form and e-mailing to: FMI39002.CO2Absorber@ge.com

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