Safety Notice 019/21

Flow Sensors used in selected GE Healthcare / Datex-Ohmeda Anaesthesia Machines

30 August 2021

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director, Regulation and Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Directors of Medical Services
- Directors of Nursing and Midwifery
- Directors of Surgery
- Managers of Operating Suites
- Anaesthetists
- Anaesthetic Nurses
- Biomedical Engineers

Expert Reference Group

Content reviewed by:

- Agency of Clinical Innovation
- HealthShare NSW
- Anaesthetic Staff
- Biomedical Staff

Clinical Excellence Commission

Tel: 02 9269 5500

Email: CEC-Recalls@health.nsw.gov.au

Internet Website: http://health.nsw.gov.au/sabs

Intranet Website: http://internal.health.nsw.gov.au/quality/sabs

Review date

August 2022

Situation

The Therapeutic Goods Administration (TGA) has issued a Product Defect Correction for Flow Sensors used in selected GE Healthcare's (GE) / Datex-Ohmeda anaesthesia machines, which are widely used across NSW. The manufacturer has identified the potential for a small number of flow sensors, manufactured before June 2021, to have damaged tubes with small punctures or cuts. These punctures or cuts may not always be evident to the naked eye.

The anaesthetic machine continuing to function in all modes (manual/bag, volume, pressure, and support modes), but the tidal volumes may be inaccurate, resulting in:

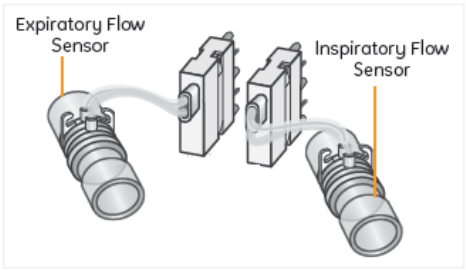
- under-delivery of tidal volume leading to insufficient ventilation
- over and excessive delivered tidal volume may lead to hyperventilation or barotrauma.

To date, no injuries have been reported as a result of this defect.

Background

The affected GE Flow sensor is a replaceable part which can be reprocessed and re-used. They cannot be inter-changed with another manufacturer's parts. Two flow sensors are used in each of the following GEHC anaesthetic machines:

1. Aisys CS^2
2. Avance CS^2
3. Aisys
4. Avance
5. Amingo
6. Aespire View
7. Aespire 7900
8. Aespire 7100/100
9. Protiva 7100
10. Aestiva MRI
11. Aestiva 7900
12. Aestiva 7100, 9100C NXT
13. Aelite NXT.



Ref: GE Healthcare Aespire View 6.X Participant Guide, Version A.

Other GE anaesthetic machines and flow sensors are not affected by this issue.

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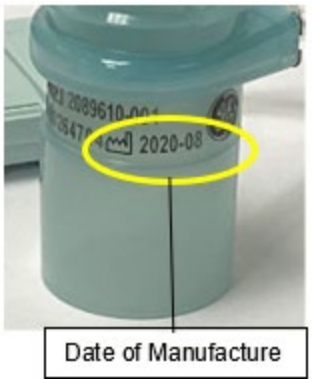
Assessment

- The risk to patient safety is LOW if the ANZCA PS31 Guideline on checking anaesthesia delivery systems on checking anaesthesia delivery systems is followed
- These checks should detect issues with the integrity of flow sensors prior to patient use
- Any significant leak during use will cause the machine to alarm
- In paediatric use a small circuit leak may have the potential to have a clinical effect. Anaesthetists should consider the mode of ventilation to minimise any risk where an affected flow sensor is in use
- HealthShare NSW is working with GE to obtain replacement of existing affected stock. However, GE has stated that they may not be able to replace all flow sensors in the market until May 2022.

Clinical Recommendations



Date of Manufacture

- Inspect all inventory of flow sensors, including those installed in anesthesia machines, in spare inventory, in reprocessing locations, and other locations not in use
    - Look for the date of manufacture on the flow sensor body
    - If the date of manufacture is “2021-06” or later, you can continue to use your flow sensor; it is not affected
    - If the date of manufacture is prior to “2021-06”, this flow sensor is affected
- Ideally, the affected product should not be used. However, if no unaffected sensors are available, affected sensors may be used once the flow sensor has passed the pre-operative checks
- Do not use any flow sensor that has failed the required pre-operative checks
- Where possible, Biomedical Engineers should be consulted in reference to performance of Level 1 checks of all affected GE anaesthetic machines
- Anaesthetic staff to continue to perform checks as per the ANZCA PS31 Guideline
- For paediatric patients: Anaesthetic staff consider the use of pressure limit ventilation instead of volume target ventilation
- During use, noting that affected flow sensors may pass the pre-use checkout yet still have issues during use, Anaesthetic staff should have a heightened awareness of the potential for flow sensor defect if a circuit leak is detected (refer to the Customer Letter for specific alarm instructions).
- Ensure spare flow sensors available in relevant clinical areas
- Affected flow sensors that fail checks should be returned to Biomedical Engineering for evaluation.

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant NSW Health stakeholders
2. Ensure all affected GE anaesthetic machines and flow sensors are inspected
3. Conduct a risk assessment of existing stock to determine if continued use of the affected flow sensors is required
4. Escalate any concerns to CEC-Recalls@health.nsw.gov.au
5. Report any incidents associated with the affected devices into ims+ and TGA
   For ims+ notifications, please ensure “GE Flow Sensor” is included in the Equipment tab “Item/Equipment Type” field, to assist in collation of incidents related to this issue.

Reference: ANZCA PS31 Guideline on checking anaesthesia delivery systems [Online]. Available: https://www.anzca.edu.au/getattachment/ae5886cc-d498-496c-a981-c2699c1b937a/PS31-Guideline-on-checking-anaesthesia-delivery-systems [Accessed 27 August 2021].

URGENT PRODUCT DEFECT CORRECTION

GE Healthcare
32 Philip Street
Parramatta, NSW 2150

27 August 2021

GEHC Ref# 34120
TGA # RC-2021-RN-01623-1

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

RE: **Flow Sensors with Potentially Damaged Tubes in GE Healthcare / Datex-Ohmeda Anesthesia Machines (ARTG 93955)**

This document contains important information for your product. Please ensure 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

GE Healthcare (GEHC) has internally identified that a small number of flow sensors built prior to June 2021 could have damaged tubes with small punctures or cuts.

The device will continue to function in all modes (manual/bag, volume, pressure, and support modes), but the tidal volumes may be inaccurate. This issue could cause leaks resulting in incorrect anesthesia machine tidal volumes, potentially leading to under-delivery or over-delivery of volume to the patient. There may be alarms in these scenarios to indicate a problem, as outlined below.
Please note, this issue is distinct from the GEHC Ref# 34109 / RC-2020-RN-00944-1. Ensure that you follow the Customer/User actions described below on all affected flow sensors, including those you may have received as part of GEHC Ref # 34109 / RC-2020-RN-00944-1.

To date, there have been no injuries reported as a result of this issue.

Health Risk

There is the potential that under-delivery of tidal volume may lead to insufficient ventilation, while over and excessive delivered tidal volume may lead to hyperventilation or barotrauma.

Actions to be taken by Customer / User

Always complete a pre-operative Checkout, including Circuit Leak test or Breathing system tests, on your anesthesia machine prior to use. Follow instructions in the anesthesia machine User's Reference Manual sections for "Preoperative Checkout" and "Preoperative Tests". Take care while handling Flow Sensors during removal, insertion, reprocessing, storing, or other types of handling, as damage could occur to the tubing and create cuts or punctures that affect flow sensor performance.

1. Inspect ALL inventory of flow sensors, including those installed in anesthesia machines, in spare inventory, in reprocessing locations, and other locations not in use.
   a. Look for the date of manufacture on the flow sensor body (see Figure 1 below). The date is listed as YYYY-MM (year then month), e.g., 2021-04 = April 2021.

   Important: Use the date etched on the flow sensor body (not on the outside packaging, as it could vary from the date etched on the flow sensor body). Flow sensors should be taken out of their packaging for inspection.

b. If the date of manufacture is “2021-06” or later, you can continue to use your flow sensor; it is not affected.

c. If the date of manufacture is prior to “2021-06”, this flow sensor is affected.

   i. GEHC will replace all affected flow sensors.

   ii. Ideally, the affected product should not be used. However, if it is necessary to use an anesthesia machine with an affected flow sensor (due to shortage of devices and clinical demand) then this should be done as safely as possible.

   iii. If you **only** have affected flow sensors in stock at this time, you can continue to use them by following all safety precautions, such as:, completing the pre-operative checkout, including a Circuit Leak test or Breathing System tests, on the anesthesia machine and ensuring heightened awareness of the potential for tidal volume inaccuracies. If the pre-operative Checkout fails, do not use your flow sensor.

   iv. It is possible that an affected flow sensor will pass a pre-operative checkout but still have issues during the case. If any of the following alarms appear, consider if an affected flow sensor may be the cause. These alarms can also occur for other reasons during a case:

   - “Volume sensors disagree”
   - “Reverse exp flow. Check valves OK?”
   - “Reverse insp flow. Check valves OK?”
   - “Check flow sensors”
   - “Calibrate, dry, or replace flow sensors” (after End Case is selected)
   - “TV not achieved”
   - “Circuit leak”
   - “System leak?”

   If you see any of these alarms, follow instructions in the anesthesia machine User’s Reference Manual and replace your flow sensor(s).

   v. Contact your local GEHC sales or service representative with any questions and/or to expedite replacement flow sensor(s).

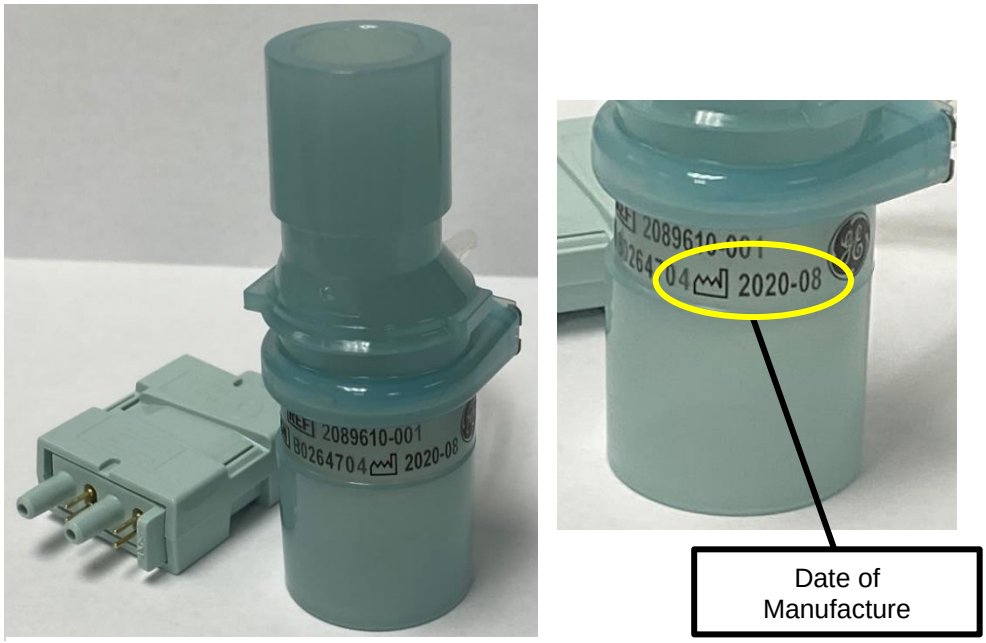


Figure 1: Flow Sensor Body Date of Manufacture

2. Complete and return the attached “Customer Response” form.
   a. If you DO NOT have any affected flow sensors, check box #1 to indicate that you do not have affected Flow Sensors. E-mail the completed form to FMI34120.FLOWSENSOR@GE.COM.

   b. If you DO have affected flow sensors, check box #2 to indicate that you do have affected Flow Sensors and provide the relevant information (e.g., quantities). E-mail the completed form to FMI34120.FLOWSENSOR@GE.COM.

Affected Product Details

Flow Sensors are used in the GEHC anesthesia machines listed below to measure flow to and from the patient. These anesthesia machines are intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). Flow Sensors are installed in your anesthesia machine or could be kept as standalone user replaceable spare parts.

- Affected Flow Sensor Part Numbers:

  2089610-001 FLOW SENSOR, LEGACY VAR ORF BCG (blue, cleanable)

  2089610-001-S FLOW SENSOR, LEGACY VAR ORF BCG, SERVICE (blue, cleanable)

  2087640-001 FLOW SENSOR, LEGACY VAR ORF AUTOCLAVABLE BCG (gray, autoclavable)

  2087640-001-S FLOW SENSOR, LEGACY VAR ORF AUTOCLAVABLE BCG, SERVICE (gray, autoclavable)

  2096513-001-S FLOW SENSOR ASSEMBLY

  5697309 R-FMI34109-FLOW SENSOR, LEGACY VAR ORF BCG

  5697310 R-FMI34109-FLOW SENSOR, LEGACY VAR ORF AUTOCLAVABLE BCG
- Affected Flow Sensors with Date of Manufacture: Prior to 2021-06
- Affected Flow Sensors are used in the following GEHC anesthesia machines: Aisys CS^2 (GTIN: 00840682102322), Avance CS^2 (GTIN: 00840682102292), Aisys, Avance, Amingo, Aespire View, Aespire 7900, Aespire 7100/100, Protiva 7100, Aestiva MRI (GTIN: 0080682102339), Aestiva 7900, Aestiva 7100, 9100C NXT, Aelite NXT

Note:
No other GEHC / Datex-Ohmeda anesthesia machines or flow sensors are affected.

Product Correction	GE Healthcare will replace all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the replacement.
Contact Information	If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-659-465 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

Eddy McFadden
QARA Leader ANZ
GE Healthcare

URGENT PRODUCT DEFECT CORRECTION CONFIRMATION -- CUSTOMER RESPONSE REQUIRED

Please complete this form and return it to GE Healthcare (GEHC) promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Product Defect Correction Notice.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

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

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

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 Product Defect Correction Notice and have identified that we **do not** have any of the affected flow sensors with date of manufacture prior to "2021-06".

OR

☐ We acknowledge receipt and understanding of the Product Defect Correction Notice, have identified that we **do** have affected flow sensors, have collected all the affected flow sensors with date of manufacture prior to "2021-06," and have either destroyed or returned to GEHC.

Flow Sensor P/N	Date of Manufacture	Quantity destroyed	Quantity returned to GEHC	Quantity to be shipped
2087640-001 or 2087640-001-S or 5697309	**Prior to 2021-06**			
2089610-001 or 2089610-001-S or 5697310	**Prior to 2021-06**			

Please return completed form by scanning or taking a photo of the completed form and email to:

~HEALTH ANZ FMI Customer ResponseRepository <ANZFMI.clientresponse@ge.com>