Urgent Field Safety Notice

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

GE Healthcare Ref: 34120

October 27, 2021

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.**

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) internally identified that a small number of flow sensors built prior to June 2021 could have damaged tubes with small punctures or cuts. This issue could cause leaks resulting in incorrect anesthesia machine tidal volumes, potentially leading to over-delivery of volume to the patient.
Please note, this issue is distinct from the GEHC Ref# 34109. Ensure that you follow Customer/User actions described below on all affected flow sensors including those you may have received as part of GEHC Ref # 34109.

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

Safety Instructions

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. You can destroy them or return them to GEHC.

        ii. If you only have affected flow sensors in stock at this time, you can continue to use them after successfully completing the pre-operative Checkout, including a Circuit Leak test or Breathing system tests, on the anesthesia machine. If the pre-operative Checkout fails, do not use your flow sensor.

iii. If the pre-operative Checkout passes but your flow sensor is affected by this issue, it is still possible that some of the alarms listed below could occur during a case. These alarms can also occur for other reasons during a case:

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

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

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

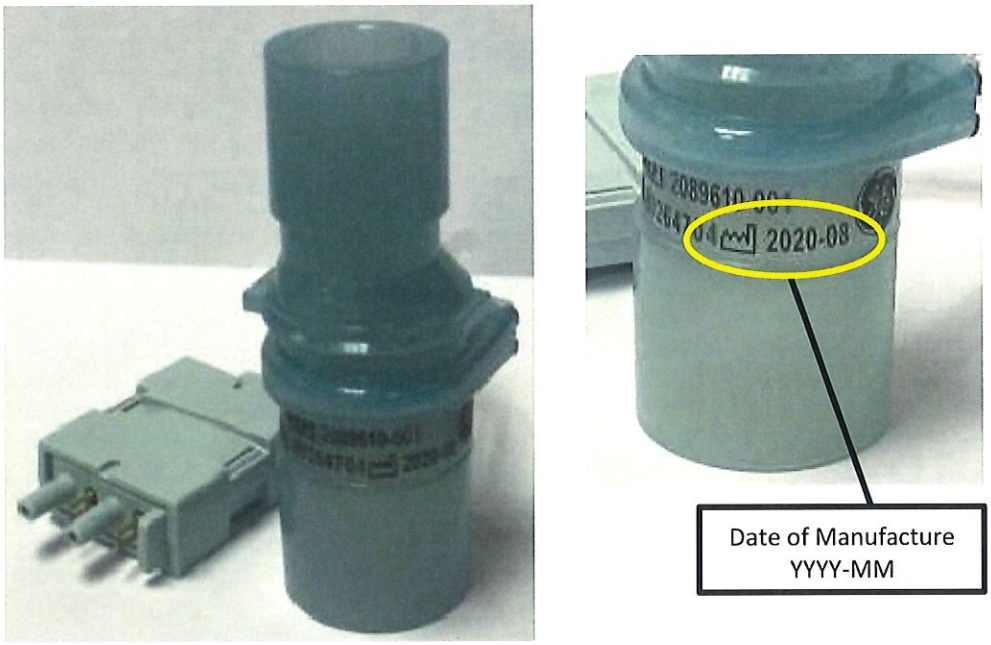

Figure 1: Flow Sensor Body Date of Manufacture

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 correct 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 regarding this Field Safety Notice or the identification of affected items please contact your local Sales/Service representative.

UKI Technical Support Representative.
01707 263570 or askuktechnicalsupport@ge.com

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 immediately.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

GE Healthcare

GEHC Ref# 34120

MEDICAL DEVICE 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 Medical Device 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 Medical Device 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 Medical Device 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:
FMI34120.FLOWSENSOR@GE.COM

44130127 - NHS SUPPLY CHAIN (SCCL)