



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# FMI 34092

To: Director of Respiratory
Director of Biomedical / Clinical Engineering
Health Care Administrator / Risk Manager
Chairman Medical Board and relevant Head of Departments

RE: **Neonatal Flow Sensor Cable used on devices CARESCAPE R860, ENGSTROM CARESTATION, ENGSTROM PRO – Incomplete Cable Connectors Housing**

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

Safety Issue

The Neonatal Flow Sensor Cable may be missing the connector housing exposing the wires in the cable. If the exposed wires break, primary ventilation parameters could be lost (Flow and Tidal Volume). This issue may cause indirect but reversible changes in the patient's condition as these parameters, among other information, are used in choosing appropriate ventilator settings for the patient. There have been no injuries reported as a result of this issue.

Safety Instructions

1) You may continue to use the CARESCAPE R860, ENGSTROM Carestation, ENGSTROM Pro with the Neonatal Flow Sensor Cable if the cable has the appropriate connector housing (see picture #1 below). No further action is required except to **complete and return** the attached "Customer Response" form checking box#1 to indicate that you **do not** have affected cables and e-mail to Recall34092.NFSCable@ge.com

#1 Correct Cable Connector Housing



2) If the Neonatal Flow Sensor Cable is missing the connector housing exposing wires (see picture #2 below), discontinue use of the cable until a replacement cord is provided. **Complete and return** the attached "Customer Response" form checking box#2 to indicate that you **do** have affected cables and e-mail to: Recall34092.NFSCable@ge.com.

#2 Incorrect Cable Connector Incomplete Housing



**Affected
Product
Details**

Neonatal Flow Sensor Cable (1505-5604-000 Lot # 1804) used on CARESCAPE R860
1506-8600-000, ENGSTROM Carestation 1505-9000-000, Engstrom Pro 1505-9003-000.
Contained in Neonatal Software Upgrade Kit 2080496-010.

**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 Recall34092.NFSCable@ge.com
and GE Healthcare will provide replacement cables at no cost to you.

**Contact
Information**

If you have any questions or concerns regarding this notification, please contact 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,



James W. Dennison
Vice President - Quality Assurance
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare



**MEDICAL DEVICE CORRECTION CONFIRMATION
CUSTOMER RESPONSE REQUIRED**

PLEASE COMPLETE and return to GE Healthcare

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.

- ☐ #1 - We acknowledge receipt and understanding of the Medical Device Correction Notice and have identified that we **do not** have any of the listed product codes or lot numbers for this product.
(See Safety Instruction #1)
- ☐ #2 - We acknowledge receipt and understanding of the Medical Device Correction Notice and have identified that we have collected all of the affected lot number for this product and have either scrapped or returned to GE. (See Safety Instruction #2)

Please fill in the information below:

Neonatal Flow Sensor Cable P/N	Lot Code	Quantity scrapped	Quantity returned to GE	Quantity to be shipped
1505-5604-000	1804			

Please provide the name of the individual with responsibility for risk and compliance.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Customer Support will contact you with the return details and the replacement order information.
If you require a specific no charge PO, please provide: N/C PO # _____

Please return this form using the method below:
Scan or take photo of completed form and email to: Recall34092.NFSCable@ge.com
QR (email)



34092 – XXXX