URGENT MEDICAL DEVICE CORRECTION

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

19th November 2018

GEHC Ref# 34095

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

RE: **CARESCAPE R860 ventilator Inspiratory Safety Guard (ISG) – Potential for loss of ventilation**

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

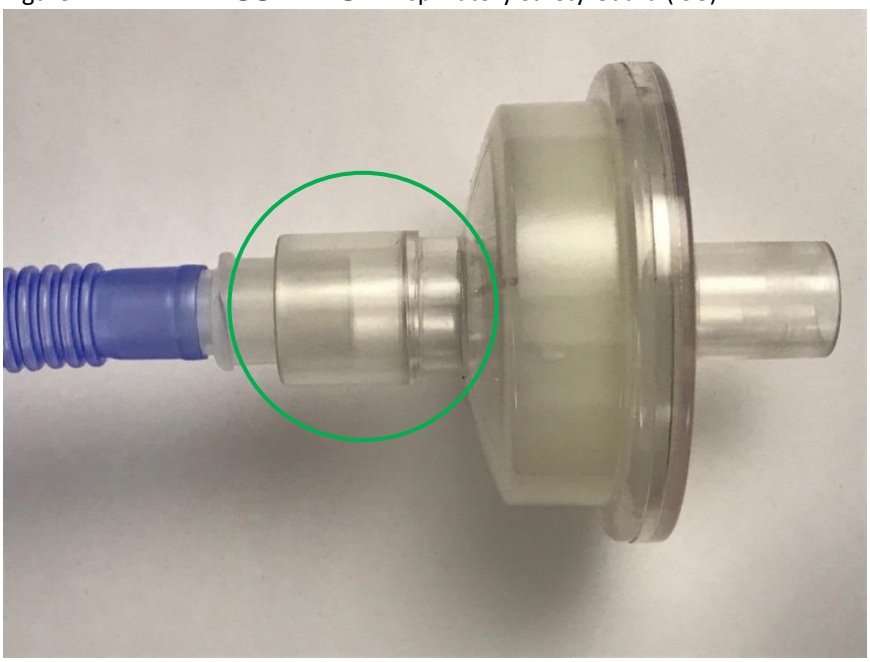
Safety Issue

The ventilator Inspiratory Safety Guard (ISG) may disconnect from the breathing circuit pathway. As a result, this could create a loss of ventilation which may lead to inadequate oxygenation for patients, increasing the possibility of hypoxia. There have been no reported injuries as a result of this issue.

Safety Instructions

1) You may continue to use your ventilator with the ISG outlet if the 15mm female conical connector is inspected for a secure fit in the location indicated below where engagement resistance would normally occur (see figure 1).

Figure 1: **CORRECT** Inspriratory Safety Guard (ISG)

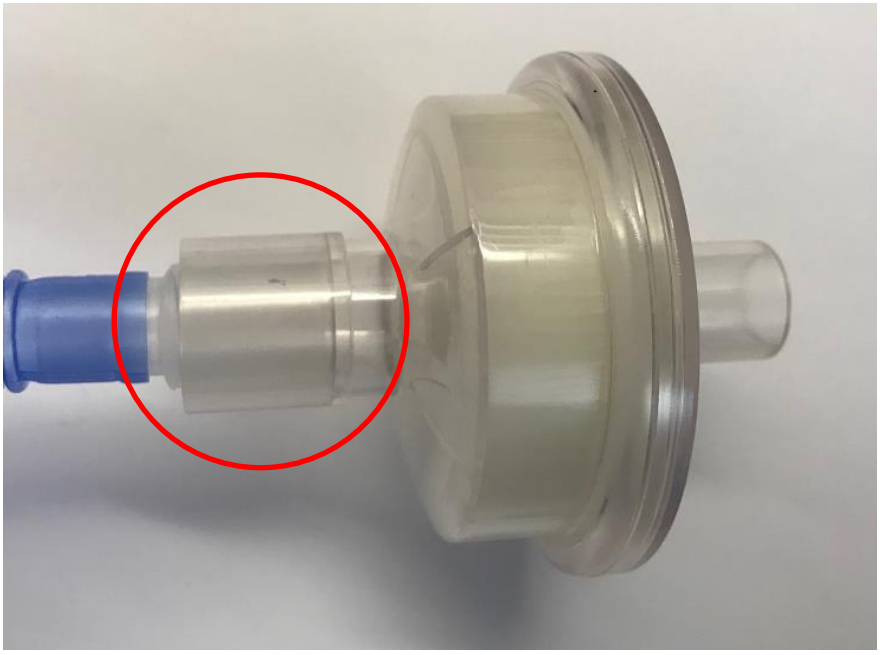


a. Ensure all breathing circuit conical connectors fit securely during initial breathing circuit assembly.
b. Follow the instruction for use outlined in the User Reference manual 2065490-001 section 4: Setup and Connections.
c. Run SYSTEM CHECK after patient circuit connection are made with all applied accessories outlined in Section 6 of the User Reference manual prior to connecting the patient.
d. Set all alarms appropriately to ensure accurate and timely detection of sudden patient disconnect.
e. 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 ISGs and e-mail to Recall34095.InspiratorySG@ge.com.

2) If the male connector looks like Figure 2, and freely slides up the entire length of the ISG female port, this indicates an incorrect ISG. In order to use the incorrect ISG you will need to use an adapter to ensure a pneumatic seal. If an adapter is not available, the ISG cannot be used for the 15mm connection.

If you have any incorrect ISGs, return to GE Healthcare or destroy on site, and **complete and return** the attached "Customer Response" form checking box #2 to indicate that you **do** have affected ISGs. E-mail the completed form to Recall34095.InspiratorySG@ge.com.

Figure 2: **INCORRECT** Inspiratory Safety Guard (ISG)



3) ISGs still remaining in original packaging with affected lot codes should be returned to GE Healthcare or destroyed on site. For ISGs not packaged and not currently in use, inspect for the 15mm conical taper per the instruction in Figure 1, 2. **Complete and return** the attached "Customer Response" form, checking the appropriate box to indicate whether you have affected ISGs. E-mail the completed form to Recall34095.InspiratorySG@ge.com.

Note: An ISG currently in use with Adult or Pediatric patients utilizing 22mm male circuit connection are not associated with this issue and are safe for continued use until replacement units arrive. When systems are no longer in use, inspect for 15mm incorrect connection per the instruction in Figure 1,2. **Complete and return** the attached "Customer Response" form and e-mail to Recall34095.InspiratorySG@ge.com.
It is important that after replacement ISG units arrive, that all incorrect material is returned to GE Healthcare or destroyed on site.

Affected Product Details

CARESCAPE R860 Inspiratory Safety Guard:
P/N: 2066713-001(single pack), P/N: 2083208-001 (10 pack)
Lot numbers: (17/00951, 17/01174, 17/01937, 17/01994, 17/02372, 17/02393, 18/00126, 18/00127, 18/00128, 18/00129, 18/00130)
GTIN # 00840682102346

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 Recall34095.InspiratorySG@ge.com and GE Healthcare will provide replacement ISG at no cost to you.

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,

[redacted]

James W. Dennison
Vice President - Quality Assurance
GE Healthcare

[redacted]

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

GE Healthcare

GEHC REF # FMI 34095

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 **do** have and 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:

Inspiratory Safety Guard P/N	**Lot Code (s)**	**Quantity scrapped**	**Quantity returned to GE**	**Quantity to be shipped**
2066713-001				
2083208-001 10 pack				

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: Recall34095.InspiratorySG@ge.com

QR (email)