



15/3/2019

URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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

GEHC Ref# 34095-A

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**

This is a supplement to a previous notification you may have received to add a second Safety Issue and Safety Instructions. Please follow the below instructions and complete the response form.

Please ensure that all potential users in your facility are made aware of this amended safety notification and the additional recommended actions provided below in Safety Issue #2 and Instructions #2.

**Safety
Issue #1**
(same as
original
notice)

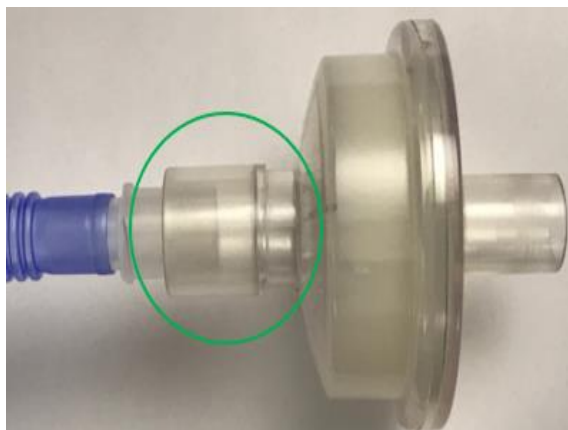
The ventilator Inspiratory Safety Guard (ISG) may disconnect from the breathing circuit pathway. As a result, the disconnection could create a loss of ventilation which may lead to inadequate oxygenation for patients, increasing the possibility of hypoxia. There have been no reported injuries as a result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

**Safety
Instructions
#1**
(same as
original
notice)

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).

15 MM - Breathing Circuit

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



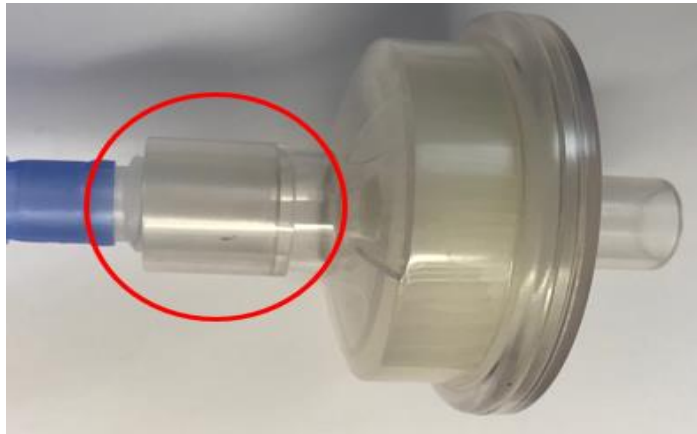
Note: An ISG currently in use with Adult or Pediatric patients utilizing 22mm male circuit connection are not associated with this issue and are safe for continued use after

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inspection of both inlet and outlet issues have been completed. When systems are no longer in use, inspect for 15mm incorrect connection per the instruction in Figure 1.

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.

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



**Safety
Issue #2
NEW**

**Safety
Instructions
#2 NEW**

NEW ISSUE: The ventilator Inspiratory Safety Guard (ISG) may disconnect from the ventilator outlet port. As a result, the disconnection 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.

You may continue to use your ventilator with the ISG inlet if the connector engages in the ventilator Outlet Port with a secure fit in the location indicated below. (see figure 3).

Figure 3: Ventilator Outlet Port with the ISG inlet connection



Note: The metal ventilator outlet port is correct.

- a. Ensure all breathing circuit conical connectors fit securely during initial breathing circuit assembly.
- b. Follow the instructions for use outlined in the User Reference manual 2065490-001 section 4: Setup and Connections.
- c. Run a 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.

If you have followed the safety instructions #1 & #2 and have identified you have the correct ISG's and secure connections, 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.

ISGs still remaining in original packaging with affected lot codes should be returned to GE Healthcare or destroyed on site. ISGs not packaged and not currently in use, check both connector fittings of the ISGs per the above Safety Instructions #1 & #2 and Complete the attached Customer Acknowledgement Form by checking the appropriate box to indicate if you have affected ISGs and return by e-mail to: Recall34095.InspiratorySG@ge.com.

**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**

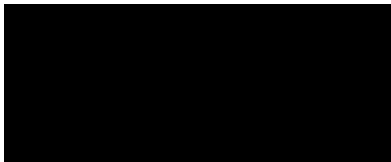
GE Healthcare will replace all affected products at no cost to you. Complete and return the attached "Customer Response" form via e-mail to Recall34095.InspiratorySG@ge.com and GE Healthcare will provide replacement ISG at no cost to you.

**Contact
Information**

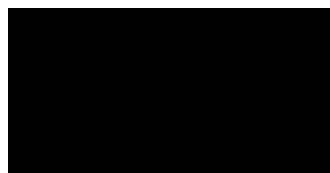
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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,



James W. Dennison
Vice President - Quality Assurance
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare



GE Healthcare

GEHC REF#

34095-A

**MEDICAL DEVICE CORRECTION CONFIRMATION
CUSTOMER RESPONSE REQUIRED**

Please complete this form and return it to GE Healthcare immediately upon receipt but no later than within 30 days. This will confirm receipt and understanding of the Medical Device Correction Notice Ref# 34095-A.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____ Phone Number: _____

Please provide the name of the individual with responsibility and has 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 listed product codes or lot numbers with incorrect inlet/outlet connections for this product. (See figure 1 and figure 3 with secure inlet connection)

OR

☐ 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 numbers for this product and have either scrapped or returned to GE. (See figure 2 and/or figure 3 with a loose ISG inlet connection that disconnects)

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				

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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)

