Urgent Field Safety Notice

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

Date of Letter Deployment

GEHC Ref. # 34126

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

RE: **CARESCAPE R860 Ventilators, and Engström Carestation and Engström PRO Ventilators with affected Field Replacement Batteries – Insufficient battery backup power resulting in premature shutdown of the ventilator when not connected to AC mains power supply.**

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

Back up batteries in CARESCAPE R860 Ventilators manufactured on or after April 1, 2019 and GE Healthcare recommended replacement back up batteries distributed on or after April 1, 2019 for CARESCAPE R860, Engström Carestation and Engström PRO can fail earlier than their estimated life. For these batteries, the alarm that alerts the user on battery run time remaining could potentially be inaccurate. This issue could result in the ventilator shutting down sooner than indicated by the alarm when running on the backup battery, which could potentially lead to loss of ventilation. If the ventilator shuts down, a patient may not receive necessary oxygen. If this goes unnoticed and untreated, it may be life threatening.

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

Actions to be taken by Customer/User

1. You can continue to use the affected ventilators while the ventilator is connected to an **AC mains power source** that is supported by **backup emergency power.**
2. If it is absolutely necessary to use the ventilator by relying on the battery (such as during required transport where there are no other options), ensure you follow standard clinical practice of having a readily accessible means of appropriate alternative ventilation (for example a bag-valve system) and personnel with the capability to administer this alternative means at all times.
3. Immediately after receiving this communication, perform the Battery Performance Test as described in Appendix A. **Replace the batteries when necessary, before patient use.**
4. When not in patient use, it is recommended that the **device always remains connected to the AC mains power source** to prevent battery discharge and degradation, **even when in storage**.
5. It is recommended that the **Battery Performance Test be completed every three months** as described in Appendix A.
6. If the device has been in storage for over three months, perform the Battery Performance Test as described in Appendix A prior to use.
7. **The backup batteries must be replaced at a minimum every three years**.
8. Complete the attached Medical Device Notification Acknowledgement Response form and send to FMI34126RC.BATTERY@ge.com

Affected Product Details	CARESCAPE R860 Ventilators (GTIN) 00840682102346 manufactured on or after April 1, 2019 The following Field Replacement Unit Batteries distributed on or after April 1, 2019 for CARESCAPE R860, Engström Carestation and Engström PRO ventilators: FRU PN: 1009-5682-000-S (BTRY SEALED LEAD ACID RECHARGEABLE 12V) FRU PN: 5856787-S (BTRY SEALED LEAD ACID RECHARGEABLE 12V PAIR) Intended Use: The CARESCAPE R860, Engström Carestation, and Engström Pro ventilators are designed to provide mechanical ventilation or support to neonatal, pediatric, and adult patients weighing 0.25 kg and above.
Product Correction	GE Healthcare will correct all affected products when the correction is available, at no cost to you. If support is needed to perform the battery testing described in Appendix A, please contact a GE Healthcare representative.
Contact Information	If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

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 per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

Appendix A

Battery Performance Test Procedure

Only use batteries recommended by GE Healthcare. Dispose of used batteries in accordance with local regulatory requirements in effect at the place of disposal.

1. Connect the ventilator to the main power source for eight hours to make sure the batteries are fully charged.
    - To see battery status, select Menu >System
2. Connect a patient circuit and test lung to the ventilator
3. Set the following parameters:
    - Mode: A/C PC
    - Rate: 12 /min
    - I:E: 1:2
    - Pinsp: 20 cmH2O
    - PEEP: 5 cmH2O
    - Bias Flow: 4 l/min
4. Start ventilation
5. Disconnect the power cord from the main power source
    - If the batteries continue to power the ventilator for 60 minutes or longer, the batteries have sufficient charge
    - If the batteries do not continue to power the ventilator for 60 minutes, contact an authorized service representative and have the batteries replaced
    - Record the time to shut down on the provided form

Important
After this test is completed, connect the ventilator to the main power source for eight hours before it is used on a patient to make sure the batteries are fully charged.

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MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

Please complete this form and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Urgent Field Safety Notice.

*Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

Please complete the requested information and send back via one of the methods below.

☐ We acknowledge receipt and understanding of the Urgent Field Safety Notice and have executed the instructions as provided in this notification and below are the results of our testing based on the instructions provided.

Please see the next page to document additional Ventilator Serial Number information.

Ventilator Serial Number	Discharge Time	Date of battery performance test
ABCD123456	**Xx mins**	**DD-MMM-YYYY**

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

Signature: _____

*Printed Name: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Ventilator Serial Number	Discharge Time	Date of battery performance test
ABCD123456	Xx mins	DD-MMM-YYYY

Please return completed form by scanning or taking a photo of the completed form and email to: FMI34126RC.BATTERY@ge.com