



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# FMI 34087

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

RE: **CARESCAPE R860 ventilator – Potential for the display processor to experience an unexpected failure.**

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

Safety Issue

There is a potential for the display processor to experience an unexpected failure. If this failure occurs, the device screen will temporarily go blank and will then display an Error Code "EC01 XX". The blank display results in loss of monitored data being displayed to the user. There have been no injuries reported as a result of this issue.

Safety Instructions

You may continue to use the system. Device performance is not affected on devices where no such display failure occurs.

In the event this issue occurs, an audible alarm will sound. Mechanical ventilation will continue at previous settings. A device restart is required to clear the alarm condition. Consider using appropriate alternative means of ventilation such as a self-inflating bag or another ventilator to prevent patient injury while restarting the device.

Affected Product Details

CARESCAPE R860 ventilators with software version 10SP05
GTIN # 00840682102346

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 or concerns regarding this notification, please contact GE Healthcare Service at Toll Free number (Inside Saudi Arabia Only): LCS: 8004292222 or SaudiArabiaServiceCenter@ge.com 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.

