



## IMPORTANT PRODUCT INFORMATION

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 34090

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 Systems have been modified from manufacturing specifications**

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

**Issue** GE Healthcare regional team in Singapore carried out an unauthorized modification to the CARESCAPE R860 systems sold to a specific Singapore customer to allow an external speaker to be plugged into the display to make the alarm audio louder at request from the Hospital.

**Instructions** You may continue to use the system under the conditions described in the User Reference Manual which indicates:

1. Warning: The ventilator must not be enclosed in a room where the auditory alarm signals cannot be heard by the clinician
2. Warning: If both the primary and backup audio tones do not sound or the alarm lights do not function correctly when the ventilator is powered on, take the ventilator out of service.

If the CARESCAPE R860 needs to be used in an enclosed room where the alarm audio cannot be heard, use one of these alternate solutions to accommodate the customer need for improved alarm alerts:

- Nurse Call output that can communicate to Central Station or other notification system that indicates when a medium or high priority alarm is active
- OhmedaCom output can communicate active alarms, as well as other ventilator data to a third party or hospital developed tool.

**Affected Product Details** CARESCAPE R860 Systems:  
CBRU02131, CBRU02132, CBRU02133, CBRU02160, CBRU02168, CBRU02170, CBRU02171, CBRU02172, CBRU02176, CBRU02180, CBRU02181, CBRU02182, CBRV00457 CBRV00459, CBRV00551, CBRV01770, CBRV02566, CBRV02599, CBRV02607, CBRV02608, CBRV02754, CBRW00612, CBRW00613, CBRW00614, CBRW00615, CBRW00616, CBRW00617, CBRW00618, CBRW00619, CBRW00620, CBRW00621, CBRW00626, CBRW00638, CBRW00640, CBRW00641, CBRW00642, CBRW00644, CBRW00645, CBRW00646, CBRW00647, CBRW00648, CBRW00649, CBRW00652, CBRW00653, CBRW00654, CBRW01540, CBRW01545, CBRW01642

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 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 & Regulatory  
GE Healthcare



Jeff Hersh, PhD MD  
Chief Medical Officer – Medical Safety  
GE Healthcare