# Urgent Field Safety Notice

GE Healthcare
GE Medical Systems
Information Technologies, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223, USA

GE Ref: FMI 36054

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To: Healthcare Administrator / Risk Manager
Chief of Nursing
Director of Biomedical Engineering

RE: **CARESCAPETM Monitor B850 Loss of User Inputs, Loss of Alarm Light, Incorrect SvO2 data, and, when used with Tram, Heart Rate Alarm Limits reverting back to default settings.**

GE Healthcare has become aware of four potential safety issues associated with the CARESCAPE™ Monitor B850:

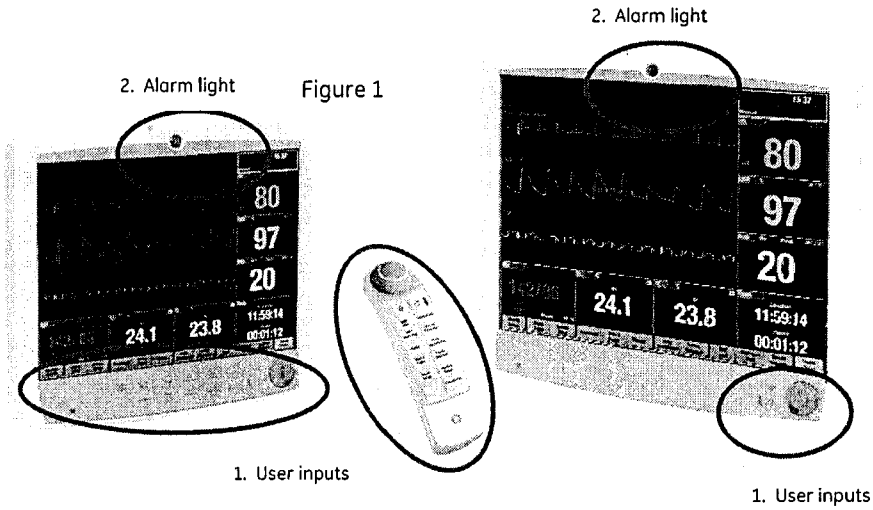
1. Loss of user input when using certain displays or the USB remote control.
2. Potential for a delay in treatment or missed alarm when the alarm light is used as a primary alarm source and audible alarms are turned down or off.
3. The CARESCAPE Monitor B850 will not use user entered hemoglobin values when calculating SvO2 values, which could result in incorrect treatment of a patient.
4. When CARESCAPE B850 is used in conjunction with Tram, the HR Alarm Limits may revert back to default settings, which could result in a missed alarm.

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

**Safety Issue**

**1. & 2. CARESCAPE Monitor B850 may experience a loss of user interface control and alarm light functionality.** Visual alarms on the monitor screen and audible alarms are not affected. The alarm light is located at the top of the monitor, as illustrated below. Additionally, the CARESCAPE Monitor B850 control panel on the display and USB remote may not register user inputs. Figure 1 illustrates the referenced control panel and USB remote.

Figure 1




**3. When using CARESCAPE Monitor B850 with the E-SvO2 measurement module, SvO2 calculation values may be incorrect since user entered hemoglobin values are not used**

**in the SvO2 calculation.** The monitor is not using the values entered by the user when calculating SvO2. If the hemoglobin values are between 70 g/l to 170 g/l the error is up to 7% and if the hemoglobin values are between 50 g/l to 200 g/l the error is up to 10%.

**4. When using CARESCAPE Monitor B850 with Tram, heart rate alarm limits may revert back to default settings.** The following conditions are required for this event to occur:

- CARESCAPE B850 Monitor is being used with Tram, and
- Invasive Pressure cable is inserted into the Tram, and
- CARESCAPE B850 Monitor HR Alarm setting is set to *Single*.

**Affected Product Details**

The CARESCAPE™ Monitor B850 CPU, TRAM modules with Invasive Pressure measurement, 15" non-touch and 19" touch displays and USB remote control.

**Safety Instructions**

**1. User Interface:** Please use the following steps to restore functionality of the display panel and USB remote.

1. Turn off the display using the mains power switch behind the display (not the on/off button on the front of the display). Wait a few seconds, and then turn the power back on.

2. If the problem is not corrected by cycling display power, then turn off the power to the B850 CPU using the mains power switch at the rear of the unit. Wait a few seconds, then turn the power back on.

**2. Alarm Light**: The CARESCAPE Monitor B850 is safe for use when caregivers rely on audible and visual display alarms. GE Healthcare does not recommend a workflow where the alarm light is the primary alarm source, or where the audible alarm volume is turned down.

**3. SvO2 Data:** Do not rely on the $SvO_2$ value calculated by the monitor. In critically ill patients, check the correct SvO2 value using a blood gas sample.

**4. HR Alarm Limits:** The CARESCAPE Monitor B850 is safe for use with Tram only when the HR Alarm setting is set to *Multiple*. GE Healthcare recommends setting the HR Alarms to *Multiple, and* that clinicians verify the HR Alarm Limits after inserting an invasive pressure cable into the Tram.
Please see the accompanying instructions on how to set the HR Alarm setting to Multiple.

**Product Correction**

GE Healthcare is working on a software update that will be provided to you at no charge once it is available. We will contact you to schedule the update.

**Contact Information**

If you have any questions regarding this medical device correction or the identification of affected items please contact Technical Support , 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.

Thank you,

Senior Executive QARA
GE Healthcare Systems
9900 Innovation Drive
Mail Stop: RP2130
Wauwatosa, WI 53226
USA