URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref#32036

To: Manager Biomedical/Clinical Engineering
Nurse Manager, Labor & Delivery/ NICU
Manager, Respiratory Therapy/ Director of Risk Management

RE: Potential Safety Issue Involving GE Warmers with Nellcor SpO_2

GE Healthcare has recently become aware of a potential safety issue associated with the Nellcor SpO_2 alarm settings on the following GE Giraffe and Panda iRes Warmers:

- **Giraffe Warmers integrated with Nellcor SpO_2**
- **Panda iRes Warmers integrated with Nellcor SpO_2**
- **Panda Freestanding Warmers integrated with Nellcor SpO_2**
- **Panda Wall-Mount Warmers integrated with Nellcor SpO_2**
- **Nellcor SpO_2 Upgrade kit**

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

Safety Issue

There may be a loss of internal communication that manages the user-adjusted Nellcor SpO_2 alarm settings of the affected Giraffe and Panda iRes Warmer systems with Nellcor SpO_2 listed above. If the issue exists, the alarms may not activate as expected, which can result in false positive or false negative saturation and pulse rate alarm notifications to the caregiver.

The patient's oxygen saturation and pulse rate values are accurate, as displayed; however, the displayed user-set alarm limits may be different than the actual alarm limits used for alarm activation. All other clinical functionality of the warmer is unaffected.

This alarm failure is caused by a software issue that does not detect a loss of internal communication that manages the user-adjusted Nellcor SpO_2 alarm settings.

Safety Instructions

You may continue to use your system provided you follow the GE recommended actions:

1) If in use with a patient, turn off the Nellcor SpO_2 function in the control panel and switch to an approved alternate form of SpO_2 measurement.

2) Prior to using the affected GE warmer with the Nellcor SpO_2 function, or resuming the use of this function with any patient, contact your hospital Bio-Med or qualified technician to check the Nellcor SpO_2 alarm functionality using either an adult Nellcor SpO_2 sensor or a Nellcor SpO_2 simulator following the applicable instructions in the Appendix (see pages 3-4).

3) If the test activates a 'Low Pulse Rate' alarm, the user-adjusted Nellcor SpO_2 alarm limits are functioning properly and the warmer can be placed back in clinical service.

PLEASE NOTE: Alarm functionality must be re-checked following every service event requiring access to the internal electronics and during annual preventative maintenance, until revised software is installed.

4) If the test does NOT activate a 'Low Pulse Rate' alarm, remove the warmer from clinical service and contact your local GE Healthcare Service Representative.

Affected Product Details

All Giraffe Warmers integrated with Nellcor SpO_2
Panda iRes Warmers integrated with Nellcor SpO_2
Panda Freestanding Warmers integrated with Nellcor SpO_2
Panda Wall-Mount Warmers integrated with Nellcor SpO_2
Nellcor SpO_2 Upgrade kit

Product Correction

GE Healthcare will correct all affected systems with a software revision at no cost to you. A GE Healthcare service representative will contact you to arrange for this correction.

Contact Information

If you have any questions or concerns regarding this notification, please call the following phone numbers:
Saudi Arabia Toll Free number: 8004292222
Saudi Arabia Service Center: SaudiArabiaServiceCenter@ge.com

You can also contact your local GE Healthcare 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 Dennison
Vice President QARA
GE Healthcare Systems

Douglas M. Hansell, M.D., MPH
Chief Medical Officer
GE Healthcare

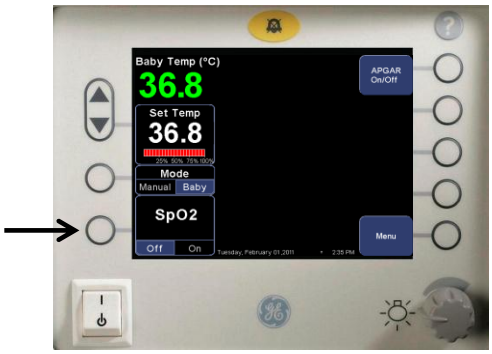
Appendix

A. Testing Nellcor SpO_2 Alarm Functionality Using SpO_2 Simulator

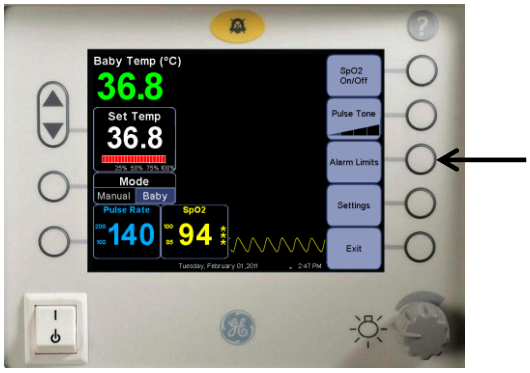
To confirm that the warmer with Nellcor SpO_2 is activating the alarms based on the user-set limits, ensure patient is removed, and then generate a 'Low Pulse Rate' alarm by completing the following steps:

1. Connect SpO_2 simulator to the Nellcor probe jack shown below.

2. Turn On the SpO_2 feature by pressing the key to the left of the SpO_2 box.



3. Access the SpO_2 Alarm Limit settings by first pressing "Menu" key on the right of the screen and then the "SpO_2" key. Next, press the "Alarm Limits" key (shown below) to change the alarm limit settings for pulse rate or SpO_2.



4. Set the 'Low Pulse Rate' limit to 110.
5. Using the SpO_2 Simulator, simulate a pulse rate greater than 40 and lower than 110.
6. Confirm a "Low Pulse Rate" alarm activates.

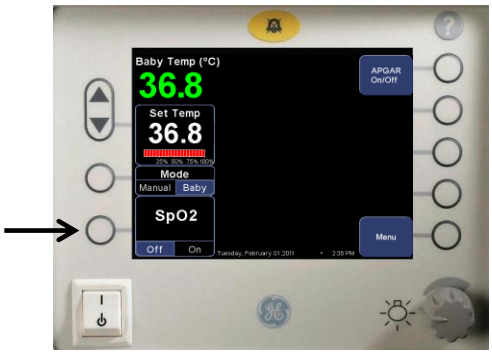
Appendix

B. Testing Nellcor SpO_2 Alarm Functionality Using an Adult Nellcor SpO_2 Sensor

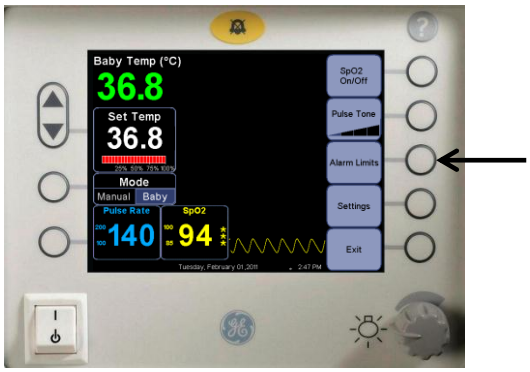
To confirm that the warmer with Nellcor SpO_2 is activating the alarms based on the user-set limits, ensure patient is removed, and then generate a 'Low Pulse Rate' alarm by completing the following steps:

1. Position the adult SpO_2 sensor on the adult finger.
2. Next, connect the sensor to the patient cable.
3. Plug the patient cable into the Nellcor probe jack shown below.

4. Turn On the SpO_2 feature by pressing the button to the left of the SpO_2 box.



5. Access the SpO_2 Alarm Limit settings by first pressing "Menu" key on the right of the screen and then the "SpO_2" key. Next, press the "Alarm Limits" key (shown below) to change the alarm limit settings for pulse rate or SpO_2.



6. Set the Low Pulse Rate limit to 110.
7. Measure the pulse rate. The measured pulse rate must be greater than 40 and less than 110, if it is not please use a SpO_2 simulator to test the system.
8. Confirm a Low Pulse Rate alarm activates.