URGENT MEDICAL DEVICE CORRECTION

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

June 11, 2014

GEHC Ref# 36101

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

RE: **Failure of the CO2 Detector in Single-width Airway Module E-miniC and Extension Modules N-FC, N-FCREC**

GE Healthcare has recently become aware of a potential safety issue due to failure of the CO_2 detector associated with Single-width Airway and Extension Modules. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

Failure of the CO_2 detector in Single-width Airway and Extension modules may cause a slow continuous decrease of measured Et-/FiCO_2 values. Incorrect Et CO_2/Fi CO_2 value may impair clinical decision making for both mechanically and spontaneously ventilated patients because of incorrect low CO_2 values.

Safety Instructions

Single-width Airway and Extension modules in continuous use should have a calibration check every 2 months. The calibration procedure is described in the monitor user manual instructions delivered with your host monitor.

To determine if your Single-width Airway and Extension modules are affected by the issue above, conduct the following calibration procedure. During this calibration procedure use calibration gas bottle part number 755580 (5% CO_2 in air) with a regulator part number 755534. No other calibration gases should be used during this calibration procedure.

1. Before adjusting the calibration reading to match the gas bottle part #755580 calibration gas concentration, check the CO_2 reading shown in the calibration menu.
2. If the CO_2 reading shown in the calibration menu is:
    a. Above 4.4%, adjust the CO_2 reading value to match the bottle concentration.
    b. 4.4% or below, stop using the module and contact technical support or your local service representative.
3. Reset the module by unplugging and inserting the module back to the host device. Repeat the calibration check procedure when the host monitor allows it (typically after 5 minutes).
4. The CO_2 reading in the calibration menu before adjustment should have remained within ± 0.2 vol% of the calibration gas (part # 755580) concentration, meaning that with 5.00% gas concentration acceptable reading displayed on the calibration menu should be within the range of 4.80 – 5.20%. **If the CO_2 reading, after successful first calibration procedure, is outside of this specified range, stop using the module and contact technical support or your local service representative.**

Affected Product Details

Potentially affected modules were manufactured from February 10, 2012 through October 8, 2012. Single-width Airway Modules E-miniC manufactured in this timeframe are within the serial number range of 6818561 - 6898777 and Extension Modules N-FC and N-FCREC manufactured in this timeframe are within the serial number range of 6799191 - 6905206. The serial number can be found on the device plate attached to the module.

In addition, modules serviced with FRU (Field Replaceable Unit) catalog number M1013204 (miniC Unit, N-FC(REC)) between February 2012 and May 2014 could also be affected.

The affected modules may be in use with any of the following host devices: E-miniC module with CARESCAPE Monitors B850, B650 and B450, S/5 modular monitors, Engstrom Carestation and extension modules N-FC(REC) with Patient Monitor B30 and S/5 FM and FML monitors.

Product Correction GE Healthcare will provide a correction at no charge. We will contact you to arrange for this correction.

Contact Information If you have any questions regarding this notice, please contact Technical Support at 1-800-558-7044 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.

Sincerely,

James Dennison
Vice President QARA
GE Healthcare Systems

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