Urgent Field Safety Notice

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

GE Healthcare Ref: FMI 36099-2

May 5, 2015

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

RE: **Specific Neuromuscular Transmission Modules, E-NMT-00 and M-NMT-02, showing wrong values with the ElectroSensor.**
NOTE: The "specific" modules affected are those E-NMT-00 and M-NMT-02 modules where the M1238463 E-NMT-01 BOARD (spare part) has been installed.

GE Healthcare has recently become aware of a potential safety issue when using specific Neuromuscular Transmission Modules (E-NMT-00 and M-NMT-02) with the ElectroSensor. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

When specific E-NMT-00 and M-NMT-02 modules are used in conjunction with the ElectroSensor, the Neuromuscular Transmission (NMT) values could indicate a deeper level of muscle relaxation than the actual level of muscle relaxation. In the clinical situation visual movements of the hand are seen after TOF (Train of Four) stimulation, but the patient monitor shows no counts, or counts are not corresponding to the actual amount of movements.

This issue could lead to an inadequate dose of muscle relaxants.

This issue could occur when an affected E-NMT-00 or M-NMT-02 module is plugged into the CARESCAPE™ or the Datex-Ohmeda S/5 Modular monitor.

Safety Instructions

If you have an affected E-NMT-00 or M-NMT-02 module as defined in the Affected Product Details below, do not use the module with the ElectroSensor.

You can continue to use the E-NMT-00 or M-NMT-02 module with the MechanoSensor or Pediatric MechanoSensor.

Affected Product Details

The issue described above could occur when using specific Neuromuscular Transmission Modules (E-NMT-00 and M-NMT-02) in conjunction with the ElectroSensor. The "specific" modules affected are those E-NMT-00 and M-NMT-02 modules where the spare part has been installed. The spare parts were manufactured from January 2013 to January 2014.

The spare part includes affected software version M1236712-1.1. The software version in your E-NMT-00 or M-NMT-02 module can be checked from the host monitor's service menu by your internal biomed or GEHC service representative when the module is inserted.

CARESCAPE Bx50 monitors
→ select **Monitor setup** → select **Service** → select **Device Information** → see table **Acquisition Information – E-module** → check for affected NMT module software version M1236712-1.1.

Datex-Ohmeda S/5 Modular monitors
→ press **Monitor setup** hard key → select **Install/service** → select **Service** → check for affected NMT module software version M1236712-1.1.

Refer to the host monitors' technical manual for further details.

Product Correction GE Healthcare will provide a correction at no charge once it is available. We will contact you to arrange this correction.

Contact Information If you have any questions regarding this Field Safety Notice or the identification of affected items please contact your local Sales/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.

Sincerely,

[redacted]

Vice President Devices
GE Healthcare

Chief Medical Officer – Medical Solutions
GE Healthcare