U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

GE Healthcare, LLC, Single-Width Airway Modules (E-MiniC) and Accessories and Extension Modules (N-FC, N-FCREC) - CO2 Detector May Fail Leading to Injury

Recall Class: Class I

Date Recall Initiated: June 11, 2014

Products: Single-Width Airway Modules (E-MiniC) and Accessories and Extension Modules (N-FC, N-FCREC)

Manufacturing Dates: February 10, 2012 through October 2, 2012
Distribution Dates: February 2012 to April 2014

Affected Product Details:

- Single-Width Airway Modules (E-miniC) -Serial Numbers 6818561 through 6898777.
- The Extension Modules N-FC and N-FCREC - Serial Numbers 6799191 through 6905206.
- The serial number can be found on the device plate attached to the module.

Modules serviced with FRU (Field Replaceable Unit) catalog number M1013204 (miniC Unit, N-FCREC) between February 2012 and May 2014 may also be affected by this recall.

Complete listing of affected serial and model numbers (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=127384).

Use: These devices are used in hospitals and other health care facilities for monitoring CO2 and respiration rates in patients weighing over 11 pounds (5 kg).

Recalling Firm:
GE Healthcare, LLC
3000 North Grandview Boulevard
Waukesha, Wisconsin 53188-1615

Manufacturer:
GE Healthcare Finland Oy
Kuortaneenkatu 2
Helsinki, Finland 00510

Reason for Recall: The affected CO2 detectors may fail or provide incorrect CO2 values for mechanically and spontaneous ventilated patients. Physicians may make decisions based on incorrect values which could lead to permanent, irreversible impairment or life-threatening changes in patients.

Patients may experience an inadequate exchange of gases (hypoventilation), causing an increased concentration of CO2 (hypercapnia). Death may also occur as a result of low CO2 values.

There are no reports of injuries or deaths associated with the malfunctioned devices.

Public Contact: For questions about this recall, customers may contact GE Healthcare Technical Support at 1-800-558-7044, Monday - Friday, 8:00 a.m. - 5:00 p.m., Central Time or the local service representative.

FDA District: Minneapolis District Office

More Information about this Recall:
On June 11, 2014, the firm sent an **Urgent Medical Device Correction letter (http://www3.gehealthcare.com/~/media/documents/us-global/products/patient-monitoring/customer-letters/ge_fmi_36101_customer-letter_062014.pdf) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** to their customers. The letter identified the affected products and problem and provided safety instructions. Customers should read the letter and follow the instructions provided.

About Class I Recalls:
Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/)** either online, by regular mail or by FAX.

Additional Resources:

- Urgent Medical Device Correction Letter (http://www3.gehealthcare.com/~/media/documents/us-global/products/patient-monitoring/customer-letters/ge_fmi_36101_customer-letter_062014.pdf) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm) [pdf]