Voluntary Field Correction Action Issued for GE Healthcare’s Resuscitation Systems with Blender, Installed in GE Giraffe and Panda Infant Warmers

The Associated Press

LAUREL, Md.--(BUSINESS WIRE)--Jan 31, 2013--On October 15, 2012, GE Healthcare initiated a voluntary field corrective action of the field upgrade kit for GE Healthcare’s resuscitation systems with blender, installed in GE Giraffe and Panda infant warmers.

The field upgrade kit for GE Healthcare’s resuscitation unit with blender, used with GE’s Giraffe and Panda infant warmers, may impact patient safety. The oxygen and air wall inlet fittings and/or labels on the back panel may have been reversed during assembly.As a result, this could potentially reverse the air/oxygen mixer concentrations; for example, a setting of 100% oxygen could have an output of 21% oxygen, and vice versa.The settings of the blender knob would no longer be accurate.

This voluntary field correction only impacts field upgrade kits for GE Healthcare’s resuscitation systems with blender, installed in GE’s Giraffe and Panda infant warmers. The affected resuscitation system upgrade kits were manufactured from April 2008 to September 2012.

GE Healthcare initiated the field correction on October 15, 2012, and began notifying customers with affected units through an Urgent Medical Device Correction letter, which provided instructions and illustrations to allow hospital personnel to conduct immediate inspection and mitigation, and follow up has been conducted to confirm their receipt of the letter.GE field service engineers have inspected units at approximately 89% of the identified customer sites.The remaining unconfirmed customers are being contacted and scheduled for inspection by GE field service technicians.To date, no patient injuries have been reported with this issue.

The U.S. Food and Drug Administration (FDA) has classified this recall as a Class I recall. FDA defines Class I recalls as “a situation in which there is a reasonable probability that the use of or exposure to the violative product will cause serious adverse health consequences or death.” For additional information regarding this field action, please contact GE Healthcare Customer Service at 1-800-345-2700.

About GE Healthcare GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services help our customers to deliver better care to more people around the world at a lower

cost. In addition, we partner with healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.

Our "healthymagination" vision for the future invites the world to join us on our journey as we continuously develop innovations focused on reducing costs, increasing access and improving quality and efficiency around the world. Headquartered in the United Kingdom, GE Healthcare is a $17 billion unit of General Electric Company (NYSE: GE). Worldwide, GE Healthcare employs more than 46,000 people committed to serving healthcare professionals and their patients in more than 100 countries. For more information about GE Healthcare, visit our web site atwww.gehealthcare.com.

CONTACT: GE Healthcare Annette Busateri +1-262-442-0966 annette.busateri@ge.com KEYWORD: UNITED STATES NORTH AMERICA MARYLAND INDUSTRY KEYWORD: HEALTH MEDICAL DEVICES MEDICAL SUPPLIES SOURCE: GE Healthcare Copyright Business Wire 2013 PUB: 01/31/2013 01:42 PM/DISC: 01/31/2013 01:42 PM http://www.businesswire.com/news/home/20130131006391/

Source URL (retrieved on *10/20/2014 - 1:22am*):
http://www.mdtmag.com/news/2013/01/voluntary-field-correction-action-issued-ge-healthcare%E2%80%99s-resuscitation-systems-blender-installed-ge-giraffe-and-panda-infant-warmers?qt-recent_content=0&qt-most_popular=0