Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: October 17, 2013

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: GE Healthcare Recall [Medical Device]

AFFECTED PRODUCT: **Engström ventilator and Aespire View, Aisys, and Avance anesthesia machines due to a potential safety issue**

SUMMARY: **Unclassified Recall; GE Healthcare has initiated a voluntary field corrective action for the Engström ventilator and Aespire View, Aisys, and Avance anesthesia machines due to a potential safety issue. The affected units were manufactured between the dates of April 23, 2013 and July 22, 2013.**

Clinicians may continue to use their Engström ventilator and Aespire View, Aisys, and Avance anesthesia machines, but should be aware of a potential safety issue involving unresponsive buttons on the display the Engström ventilator and Aespire View, Aisys, and Avance anesthesia machines. Due to a manufacturing issue the buttons on the left, right, and bottom keypads may not always detect a user's button presses. This may result in the inability to access certain menu functions which could possibly lead to delay in treatment.

SUGGESTED ACTION: **The affected units were manufactured between the dates of April 23, 2013 and July 22, 2013. GE Healthcare is following up with all customers and will correct all affected systems at no cost to customers. For additional information regarding this field action, please contact GE Healthcare's Customer Service line (24 hours a day, 7 days a week) at 1-800-345-2700. Furthermore, if any recalled products are found, please notify this office at 317-233-3213.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company

Voluntary Field Corrective Action Issued for GE Healthcare's Engström Ventilator and Aespire View, Aisys, and Avance Anesthesia Machines

Contact:
Consumer:
1-800-345-2700

Media:
Annette Busateri
1-262-442-0966
E-mail: annette.busateri@ge.com

FOR IMMEDIATE RELEASE - October 16, 2013 - GE Healthcare has initiated a voluntary field corrective action for the Engström ventilator and Aespire View, Aisys, and Avance anesthesia machines due to a potential safety issue. The affected units were manufactured between the dates of April 23, 2013 and July 22, 2013.

Clinicians may continue to use their Engström ventilator and Aespire View, Aisys, and Avance anesthesia machines, but should be aware of a potential safety issue involving unresponsive buttons on the display the Engström ventilator and Aespire View, Aisys, and Avance anesthesia machines. Due to a manufacturing issue the buttons on the left, right, and bottom keypads may not always detect a user's button presses. This may result in the inability to access certain menu functions which could possibly lead to delay in treatment.

GE Healthcare has begun notifying customers with affected units through an Urgent Medical Device Correction letter, which alerts users of the concern and provides instructions to mitigate the issue. The instructions explain that to mitigate this issue: (1) The user may notice that a button press may not actuate the desired function. Usually by pressing the key again, the device will respond as expected. (2) If a button has no response, the menu function may be accessible through the use of the control wheel. The instructions direct that if none of the above steps can be performed, discontinue use and contact a GE Healthcare Service Representative.

GE Healthcare is following up with all customers and will correct all affected systems at no cost to customers. To date, no patient injuries have been reported with regards to this issue.

For additional information regarding this field action, please contact GE Healthcare's Customer Service line (24 hours a day, 7 days a week) at 1-800-345-2700.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm[1] (form available to fax or email), or
- Call FDA 1-800-FDA-1088.

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