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 2 [Medical Device]

AFFECTED PRODUCT: **Avance, Aisys and Avance CS2 anesthesia delivery systems with 8.00 (Avance and Aisys) or 10.00 (Avance CS2) software due to a potential safety issue**

SUMMARY: **Unclassified Recall; GE Healthcare has initiated a voluntary field corrective action for the Avance, Aisys and Avance CS2 anesthesia delivery systems with 8.00 (Avance and Aisys) or 10.00 (Avance CS2) software due to a potential safety issue. The affected units were manufactured from February 2011 through July 2013.**

Clinicians may continue to use their Avance, Aisys and Avance CS2 anesthesia delivery system, but should be aware that a unique sequence of inputs and a collapsed bellow could result in delivery of higher-than-expected tidal volume when using the Pressure Control Ventilation – Volume Guarantee (PCV-VG) mode. All safety over-pressure controls and alarms will continue to function properly. However, over delivery of tidal volume this may result in alterations to blood flow within the thorax that, under extreme circumstances, may result in gradual reductions in blood pressure. The unique sequence of inputs includes transitioning from mechanical PCV-VG mode to manual ventilation, changing the set tidal volume (while in manual mode), and then returning to mechanical PCV-VG mode. To avoid this situation, when using PCV-VG mode, do not adjust the ventilator tidal volume while in a manual ventilation mode. At any time during the use of the device should an over delivery of tidal volume occur while in PCV-VG mode, transitioning to a different ventilation mode will resolve the issue.

SUGGESTED ACTION: **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. 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 Avance, Aisys, and Avance CS2 Anesthesia Delivery Systems

Contact:
Consumer:
(800) 345-2700

Media:
Annette Busateri
(262) 442-0966
info@virilispro.com

FOR IMMEDIATE RELEASE - October 15, 2013 - GE Healthcare has initiated a voluntary field corrective action for the Avance, Aisys and Avance CS2 anesthesia delivery systems with 8.00 (Avance and Aisys) or 10.00 (Avance CS2) software due to a potential safety issue. The affected units were manufactured from February 2011 through July 2013.

Clinicians may continue to use their Avance, Aisys and Avance CS2 anesthesia delivery system, but should be aware that a unique sequence of inputs and a collapsed bellow could result in delivery of higher-than-expected tidal volume when using the Pressure Control Ventilation – Volume Guarantee (PCV-VG) mode. All safety over-pressure controls and alarms will continue to function properly. However, over delivery of tidal volume this may result in alterations to blood flow within the thorax that, under extreme circumstances, may result in gradual reductions in blood pressure. The unique sequence of inputs includes transitioning from mechanical PCV-VG mode to manual ventilation, changing the set tidal volume (while in manual mode), and then returning to mechanical PCV-VG mode. To avoid this situation, when using PCV-VG mode, do not adjust the ventilator tidal volume while in a manual ventilation mode. At any time during the use of the device should an over delivery of tidal volume occur while in PCV-VG mode, transitioning to a different ventilation mode will resolve the issue.

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. 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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