



URGENT FIELD SAFETY NOTICE

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 34063

To: Chief of Anesthesia
Health Care Administrator / Risk Manager
Director of Biomedical / Clinical Engineering

RE: **Engstrom Ventilator Potential Caster & Base Defect Causing Fall/Tip**

GE Healthcare has recently become aware of a potential safety issue due to potential hardware failures associated with accessory carts for the Engstrom Carestation and Engstrom Pro ventilators. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue Specific combinations of Engstrom ventilator casters and bases have been identified that pose an increased likelihood of failures of the caster mounting hardware. A failure of the caster mounting hardware may result in the ventilator falling/tipping (overbalancing). A fall/tip of the Engstrom ventilator can result in serious injury to patients or clinical staff.

Safety Instructions You can continue to use your Engstrom ventilator. If your ventilator is mounted on a cart, please ensure the caster hardware is fully tightened and does not show signs of damage. If there are signs of damage, contact GE Healthcare Service or your local Service Representative.

Affected Product Details Engstrom Carestation and Engstrom Pro ventilators that were provided with an accessory cart as part of the original order, with Engstrom serial numbers CBCN01062 through CBCQ01396.

Also affected are accessory carts shipped independently of an Engstrom ventilator from October 2009 through September 2011.

Product Correction GE Healthcare will correct all affected systems at no cost to you. A GE Healthcare Service Representative will contact you to arrange for this correction.

Contact Information If you have any questions or concerns regarding this notification, please call the following phone numbers:
Saudi Arabia Toll Free number: 8004292222.
Saudi Arabia Service Center: SaudiArabiaServiceCenter@ge.com.

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 per the contact information above.

Sincerely,

A handwritten signature in black ink, appearing to read "JDennison".

James W. Dennison
Vice President Devices
GE Healthcare

A handwritten signature in blue ink, appearing to read "Werner Van den Eynde".

Werner Van den Eynde, M.D.
Acting Chief Medical Officer
GE Healthcare