URGENT FIELD SAFETY NOTICE

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 34071

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

RE: **Drive Gas Check Valve stuck open on certain Anesthesia products**

GE Healthcare has recently become aware of a potential safety issue with the Drive Gas Check Valve of certain Anesthesia products. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

The Drive Gas Check Valve could become stuck in a fixed open position which could cause pressure to build in the mechanical ventilation cycle. If this issue is left unresolved, it could result in excessive or prolonged pressure in the patient breathing circuit during ventilation potentially resulting in barotrauma. There have been no injuries reported as a result of this issue.

Safety Instructions

In the event the issue described above does occur, your anesthesia device provides alarms and automatic inherent safety mitigations to help ensure patient safety. You can continue to use your anesthesia device.

The relevant alarms include one or a combination of the following:

- Ppeak High
- PEEP High
- MVexp Low
- Inspiration Stopped (this alarm is triggered if pressure exceeds Pmax)

The relevant automatic inherent safety mitigations include one or a combination of the following:

- Airway Pressure which is limited by the higher of Pmax (40 cm H2O factory default - clinician settable) or the bleed resistor flow.
- Drive Pressure Limit (DPL) switch which is activated at 104 cm+5/-4 H2O and vent cycles to exhalation to relieve airway pressure.
- Mechanical Over Pressure Valve (MOPV) relief which is provided at 110 cm H2O.

Affected Product Details

Specific Aespire 7900, Aespire View, Aestiva 7900, Aestiva MRI, Aisys, Aisys CS2, Avance, and Avance CS2 Anesthesia devices shipped from the GE Healthcare manufacturing center and installed from April 20, 2015 through October 2015.

Service kits containing the ventilator Drive Gas Check Valve shipped from April 20, 2015 through October 2015 are also affected and could have been installed on Aespire 7900, Aespire View, Aestiva 7900, Aestiva MRI, Aisys, Aisys CS2, Avance, Avance CS2 Anesthesia, and Amingo devices. (Service kit part numbers: 1009-8216-000, 1503-3006-000, 1503-8102-000, 1009-8423-000, 1503-8101-000).

Product Correction

GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative at:

UKI Technical Support Representative.
01707 263570 or askuktechnicalsupport@ge.com

UKI Regulatory Affairs
Paul Mardle
01707 263570 or paul.mardle@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,

James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

Jeff Hersh, M.D.
Chief Medical Officer – Medical Solutions
GE Healthcare