



URGENT Field Safety Notice

GE Healthcare

Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

March 2013

GEHC Ref#34050

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

RE: **Avance CS² may experience an intermittent display unit failure.**

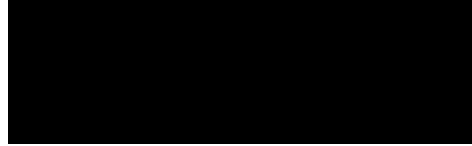
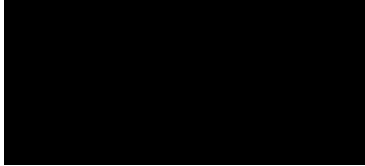
GE Healthcare has recently become aware of a potential safety issue involving the Avance CS². **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**


- Safety Issue** The Avance CS² may experience an intermittent display unit failure while in use, which could result in unexpected system performance and may include the loss of mechanical ventilation and balance gas delivery (Medical AIR or N₂O).
- Safety Instructions** You may continue to use your Avance CS², however in the event the display goes blank, please stop use of the device and contact your local GE Healthcare Representative. If the display goes blank, an audible alarm will notify the user of the loss of mechanical ventilation.
Below are the Avance CS² safety precautions in place if this should occur:
1. Alt O₂ automatically activates, continuing to flow O₂ and agent concentration (prevailing setting) at the previous setting to the patient breathing circuit
 2. Manual Ventilation is available
- Affected Product Details** All Avance CS² devices
- 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 contact your local GEHC Service representative.


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,




Vice President QARA
GE Healthcare Systems


Chief Medical Officer
GE Healthcare