



URGENT FIELD SAFETY NOTICE

GE Healthcare

9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 34094

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

RE: Upgraded Aisys anesthesia devices (i.e. Aisys devices upgraded to software version 11) and Aisys CS2 anesthesia devices with End Tidal Control option (inability to set fresh gas settings) and/or PSVPro option (non-functional back-up ventilation after Cycling Procedure).

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

**Safety
Issue #1**

Upgraded Aisys anesthesia devices and Aisys CS² anesthesia devices utilizing End-Tidal Control (EtC mode) on rare occasions may lose ability to change Fresh Gas and Agent settings when stopping the EtC mode. Should this occur the gas concentrations are reasonably expected to meet the needs of the patient when the EtC mode is stopped. However, during the remaining part of the case it is possible that there is a need to change the concentrations. The anesthetic gas concentration might become insufficient potentially leading to awareness, the anesthetic gas concentration might become excessive potentially leading to hypotension or the oxygen concentration might become too low potentially leading to hypoxia. There have been no injuries reported as a result of this issue.

**Safety
Instructions
#1**

You can continue to use your anesthesia device. Re-entering Et Control and exiting Et Control resolves the issue. In the event the Fresh Gas and Agent quick keys are ineffective after exiting Et Control, re-enter Et Control and exit again. This will return the ability to change Fresh Gas and Agent settings.

**Safety
Issue #2**

Upgraded Aisys anesthesia devices and Aisys CS2 anesthesia devices with PSVPro Spontaneous Breathing Modes do not provide the PSVPro ventilation mode feature of transitioning to SIMV PCV backup ventilation mode. PSVPro Spontaneous Breathing Modes do not provide the feature of transitioning to SIMV PCV backup ventilation mode for a patient who stops spontaneous breathing if the PSVPro ventilation mode is in use prior to the clinician starting the Cycling Procedure. If a patient stops spontaneous breathing after the Cycling Procedure has delivered the sequence of lung recruitment breaths, the ventilator will not automatically provide backup ventilation. There have been no complaints or injuries reported as a result of this issue.

**Safety
Instructions
#2**

You can continue to use your anesthesia device. The issue can only occur if the patient stops spontaneous breathing in PSVPro ventilation mode after completion of lung recruitment breaths. Stopping the Cycling Procedure resolves the issue. Continue to monitor patient as is normal for Apnea.

Affected Product Details All upgraded Aisys anesthesia devices (i.e. Aisys devices upgraded to software version 11) and Aisys CS² anesthesia devices (GTIN: 840682102292) with PSVPro option and/or End Tidal Control option. Software versions other than 11.00 and 11 SP01 are not affected.

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.

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 Assurance
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare