



URGENT FIELD SAFETY NOTICE

GE Healthcare

3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 34093

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

RE: Potential Loss of Fresh Gas Flow - Carestation 620/650/650c A1, Carestation 620/650/650c A2, Carestation 30 and 9100c NXT Anesthesia Systems

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

**Safety
Issue**

On systems equipped with the Auxiliary Common Gas Outlet (ACGO), there is a potential for the auxiliary gas switch to unexpectedly switch from the ACGO position back to the circle position. On systems equipped with the Aux O2 + Air function the switch could unexpectedly switch from the Aux O2 + Air position back to the circle position. These situations could lead to hypoxia. It would still be possible to ventilate the patient using the circle breathing system in the manual bag or mechanical ventilation modes. There have been no injuries reported as a result of this issue.

**Safety
Instructions**

You can continue to use the anesthesia systems listed in the affected product details below. If you observe the switch change from the ACGO/Aux to circle positions while using ACGO or Aux O2+Air, use the circle breathing system to ventilate the patient. When the ACGO or Aux O2+Air is active there is an indication on the display. Should the switch change to circle position, it can be observed that the indication on the display disappears, the switch rotates to the circle position, and that the gas flow from the ACGO or Aux O2+Air port stops flowing. If you observe any of these signs, please use the circle breathing system to ventilate the patient. At any time, the clinician may use a self-inflating bag to ventilate the patient and/or switch to another anesthesia device.

**Affected
Product
Details**

Carestation 620/650/650c A1, Carestation 620/650/650c A2, Carestation 30 and 9100c NXT Anesthesia systems, see attached Appendix for list of affected serial numbers:

Carestation 620 A1 (GTIN: 00840682103985)
Carestation 650 A1 (GTIN: 00840682103947)
Carestation 650c A1 (GTIN: 00840682103954)

**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.

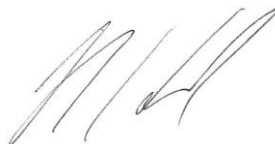
GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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, PhD MD
Chief Medical Officer – Medical Safety
GE Healthcare

Appendix

Affected Serial number list

Carestation 620/650/650c A1&A2 ACGO affected units

SM617220006WA	SM618040003WA	SM618040004WA	SM618050009WA	SM618050010WA	SM618060002WA
SM618060003WA	SM618060006WA	SM618060007WA	SM618060008WA	SM618060015MA	SM618060016MA
SM618060017MA	SM618060019MA	SM618060023MA	SM618060024MA	SM618060025MA	SM618060026MA
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SM618060033MA	SM618060034MA	SM618060035MA	SM618060036MA	SM618060037MA	SM618060038MA
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SM618060057MA	SM618060058MA	SM618060059MA	SM618060062MA	SM618060063MA	SM618060064MA
SM618060065MA	SM618060066MA	SM618060067MA	SM618060071WA	SM618060072WA	SM618060073WA
SM618060074WA	SM618060075WA	SM618060076WA	SM618060077WA	SM618060078WA	SM618060079WA
SM618060080WA	SM618070001WA	SM618070003WA	SM618070004WA	SM618070005WA	SM618070006WA
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SM618150036WA	SM618150037WA	SM618150038WA	SM618150039WA	SM618150040WA	SM618150041WA
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SM718220063MA	SM718220064WA	SM718220065WA	SM718220066WA	SM718220067WA	SM718220068WA
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SM818120001WA	SM818150001WA	SM818150002WA	SM818170001MA	SM818170002MA	SM818170005MA
SM818190001WA	SM818190002WA	SM818220001WA			

Carestation 620/650/650c A1 Aux O2+Air affected units

SM718060103WA	SM718220057MA	SM718250007WA	SM718250008WA	SM718250012MA	
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Carestation 30 ACGO affected units

MF18015046	MF18015047	MF18025059	MF18025060	MF18025061	MF18025062
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MF18025075	MF18025076	MF18025077	MF18025078	MF18025079	MF18025080
MF18025081	MF18025082	MF18025083	MF18025084	MF18025085	MF18025086
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MF18025093	MF18025094	MF18025095	MF18025096	MF18025097	MF18025098
MF18025099	MF18025100	MF18025101	MF18025102	MF18025103	MF18025104
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MF18045257	MF18045258	MF18045259	MF18045260	MF18045261	MF18045262
MF18045263	MF18045264	MF18045265	MF18045266	MF18055267	MF18055268
MF18055269	MF18055270	MF18055271	MF18055272	MF18055273	MF18055274
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MF18055282	MF18055283	MF18055284	MF18055285	MF18055288	MF18055291
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MF18055323	MF18055324	MF18055325	MF18055326	MF18055327	MF18055328
MF18065329	MF18065330	MF18065331	MF18065332	MF18065333	MF18065334
MF18065335	MF18065336	MF18065337	MF18065338	MF18065344	MF18065345

9100c NXT ACGO affected units

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