



URGENT MEDICAL DEVICE CORRECTION

Date of Letter Deployment

GEHC Ref. # 34131

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

RE: **Potential resistor failure in the Control Sample Board (CSB) for 9100C NXT and Aelite NXT Devices**

This document contains important information for your product. Please ensure all potential Users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

Safety Issue

9100c NXT and Aelite NXT anesthesia devices with CSB boards manufactured prior to June 2020 have resistors that could potentially fail due to electrolytic corrosion.

If the resistor fails during system checkout, "System malfunction – C8 error" will appear on the display and the system will not move to mechanical ventilation and in this case the system cannot be used.

If the resistor fails during use, "System malfunction – C8 error" will appear on the display and mechanical ventilation will stop. In the unlikely situation that this issue is not identified and addressed by the attending clinician, the loss of ventilation can be life threatening.

There have been no injuries reported as a result of this issue.

Actions to be taken by Customer /User

You can continue to use the 9100c NXT and Aelite NXT devices by:

1. Following the instructions in the anesthesia machine User's Reference Manual sections for "Turning on the system", "Preoperative Checkout" and "Preoperative Tests".
2. Performing all tests from the Checkout menu.
3. Following the instructions in the anesthesia machine User's Reference Manual sections for "Full Test".

If the display shows 'System malfunction C8 error' during checkout, remove device from service and utilize an alternative device and contact a GE Healthcare representative.

If the error occurs during use, mechanical ventilation will stop. The user should switch to manual ventilation to continue delivery of anesthesia gas at its previously set levels. Refer to User Reference Manual section "Start manual ventilation". The patient will need to be switched to a backup anesthesia device for mechanical ventilation. Contact a GE Healthcare representative.

Complete the attached Medical Device Notification Acknowledgement Response form and send to: FMI.34131@ge.com

Affected Product Details

9100c NXT and Aelite NXT Manufactured from Sept 2017 to May 2020.
GEHC spare parts (FRU) 2095011-001-S distributed from Sept 2017 to Dec 2020.

See attached Appendix for a list of affected device serial numbers and FRU serial numbers.

Intended Use: The 9100c NXT and Aelite NXT are designed to provide general inhalation anesthesia and ventilator support.

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 at 1-800-437-1171 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,



Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare



**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED**

Please complete this form and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.

*Customer/Consignee
Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who completed this form.

Signature: _____

*Printed Name: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to: FMI.34131@ge.com

You may obtain this e-mail address through the QR code below:



Appendix

Affected Device Serial Numbers:

9100c NXT:

SPC17360024WA THROUGH SPC17360035WA, SPC17370036WA THROUGH SPC17370041WA
SPC17380042WA THROUGH SPC17380053WA, SPC17390054WA THROUGH SPC17390067WA
SPC17410068WA THROUGH SPC17410109WA, SPC17430110WA THROUGH SPC17430119WA
SPC17440120WA THROUGH SPC17440123WA, SPC17450124WA THROUGH SPC17450151WA
SPC17460152WA THROUGH SPC17460153WA, SPC17470155WA THROUGH SPC17470184WA
SPC17480185WA THROUGH SPC17480187WA, SPC17490188WA THROUGH SPC17490209WA
SPC17510210WA, SPC18010001WA THROUGH SPC18010045WA
SPC18020046WA THROUGH SPC18020101WA, SPC18030102WA THROUGH SPC18030206WA
SPC18040207WA THROUGH SPC18040289WA, SPC18050290WA THROUGH SPC18050413WA
SPC18060414WA THROUGH SPC18060494WA, SPC18070496WA THROUGH SPC18070592WA
SPC18080593WA THROUGH SPC18080692WA, SPC18300578WA
SPC18320636WA THROUGH SPC18320639WA, SPC18330672WA THROUGH SPC18330695WA
SPC18340696WA THROUGH SPC18340732WA, SPC18350733WA THROUGH SPC18350749WA
SPC18360750WA THROUGH SPC18360785WA, SPC18370786WA THROUGH SPC18370787WA
SPC18380788WA THROUGH SPC18380794WA, SPC18390795WA THROUGH SPC18390818WA
SPC18400819WA THROUGH SPC18400840WA, SPC18410841WA THROUGH SPC18410867WA
SPC18420868WA THROUGH SPC18420922WA, SPC18430923WA THROUGH SPC18430957WA
SPC18440958WA THROUGH SPC18441022WA, SPC18451023WA THROUGH SPC18451070WA
SPC18461071WA THROUGH SPC18461131WA, SPC18471132WA THROUGH SPC18471147WA
SPC18481148WA THROUGH SPC18481160WA, SPC18501161WA THROUGH SPC18501186WA
SPC18521187WA THROUGH SPC18521188WA, SPC19010001WA THROUGH SPC19010030WA
SPC19020031WA THROUGH SPC19020058WA, SPC19030059WA THROUGH SPC19030101WA
SPC19040102WA THROUGH SPC19040149WA, SPC19050150WA THROUGH SPC19050290WA
SPC19060291WA THROUGH SPC19060300WA, SPC19070301WA THROUGH SPC19070336WA
SPC19080337WA THROUGH SPC19080373WA, SPC19090375WA THROUGH SPC19090398WA
SPC19120399WA THROUGH SPC19120409WA, SPC19130412WA THROUGH SPC19130419WA
SPC19140420WA THROUGH SPC19140435WA, SPC19150436WA THROUGH SPC19150469WA
SPC19160470WA THROUGH SPC19160515WA, SPC19170516WA THROUGH SPC19170555WA
SPC19190556WA THROUGH SPC19190586WA, SPC19200587WA THROUGH SPC19200616WA
SPC19210617WA THROUGH SPC19210642WA, SPC19220643WA THROUGH SPC19220655WA
SPC19230656WA THROUGH SPC19230675WA, SPC19240676WA THROUGH SPC19240677WA
SPC19250678WA THROUGH SPC19250685WA, SPC19260686WA THROUGH SPC19260688WA
SPC19270689WA THROUGH SPC19270749WA, SPC19280750WA THROUGH SPC19280784WA
SPC19290785WA THROUGH SPC19290815WA, SPC19300816WA THROUGH SPC19300856WA
SPC19320857WA THROUGH SPC19320881WA, SPC19330882WA THROUGH SPC19330925WA
SPC19340926WA THROUGH SPC19340963WA, SPC19350964WA THROUGH SPC19350976WA
SPC19360977WA THROUGH SPC19361000WA, SPC19371001WA THROUGH SPC19371026WA
SPC19381027WA THROUGH SPC19381031WA, SPC19391032WA THROUGH SPC19391033WA
SPC20140314WA, SPC20150328WA THROUGH SPC20150338WA
SPC20160339WA THROUGH SPC20160356WA, SPC20170378WA THROUGH SPC20170399WA
SPC20190485WA, SPC20200529WA THROUGH SPC20200577WA
SPC20210592WA THROUGH SPC20210604WA, SPC20220639WA THROUGH SPC20220706WA

Aelite NXT:

SPD18390002WA THROUGH SPD18390005WA, SPD18420006WA THROUGH SPD18420008WA
SPD18470009WA THROUGH SPD18470024WA, SPD18480025WA THROUGH SPD18480028WA
SPD18490029WA THROUGH SPD18490040WA, SPD18500041WA THROUGH SPD18500047WA
SPD18510048WA THROUGH SPD18510051WA, SPD18520052WA THROUGH SPD18520056WA

SPD19020001WA THROUGH SPD19020011WA, SPD19030012WA THROUGH SPD19030013WA
SPD19040014WA, SPD19060015WA THROUGH SPD19060021WA
SPD19080022WA THROUGH SPD19080024WA, SPD19090025WA THROUGH SPD19090032WA
SPD19100033WA THROUGH SPD19100062WA, SPD19120063WA THROUGH SPD19120105WA
SPD19130106WA THROUGH SPD19130167WA, SPD19150168WA
SPD19160169WA THROUGH SPD19160178WA, SPD19170179WA THROUGH SPD19170183WA
SPD19190184WA, SPD19220185WA THROUGH SPD19220202WA
SPD19230203WA THROUGH SPD19230218WA, SPD19240219WA THROUGH SPD19240241WA
SPD19250242WA THROUGH SPD19250294WA, SPD19260295WA THROUGH SPD19260305WA
SPD19330306WA THROUGH SPD19330307WA, SPD19340308WA THROUGH SPD19340321WA
SPD19360321WA THROUGH SPD19360326WA, SPD19370327WA THROUGH SPD19370348WA
SPD19380349WA THROUGH SPD19380420WA, SPD19390421WA THROUGH SPD19390466WA
SPD20150072WA, SPD20160073WA THROUGH SPD20160077WA
SPD20210096WA, SPD20220099WA THROUGH SPD20220101WA

SSH19320867WA

Affected GEHC spare parts (FRU) 2095011-001-S Serial Numbers

V00002095011-001 E71577HE20170807 ---- G222000263 THROUGH G222000320
V00002095011-001 E71577HE20171011 G222000356
V00002095011-001 E71577HE20171209 ---- G222000506 THROUGH G222000520
V00002095011-001 E71577HE20180208 G222000592
V00002095011-001 E71577HE20180310 G222000669
V00002095011-001 E71577HE20180403 G222000785
V00002095011-001 E71577HE20180420 G222000851
V00002095011-001 E71577HE20180522 G222001054
V00002095011-001 E71577HE20180605 ---- G222001142 THROUGH G222001195
V00002095011-001 E71577HE20180706 G222001271
V00002095011-001 E71577HE20181004 ---- H222001930 THROUGH H222001995
V00002095011-001 E71577HE20181122 H222002219
V00002095011-001 E71577HE20190125 ---- H222002369 THROUGH H222002377
V00002095011-001 E71577HE20190308 ---- H222002565 THROUGH H222002595
V00002095011-001 E71577HE20190323 ---- H222002871 THROUGH H222002970
V00002095011-001 E71577HE20190509 ---- J222003023 THROUGH J222003160
V00002095011-001 E71577HE20190628 ---- J222003382 THROUGH J222003477
V00002095011-001 E71577HE20190713 J222003542
V00002095011-001 E71577HE20190730 ---- J222003545 THROUGH J222003679
V00002095011-001 E71577HE20200304 ---- J222004710 THROUGH J222004778