URGENT MEDICAL DEVICE CORRECTION

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

Date of Letter Deployment

GEHC Ref. # 34127

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

RE: **Avance CS², Avance CS² Pro anesthesia devices and field replacement batteries for Avance CS², Avance CS² Pro, Avance, Amingo, Aespire View anesthesia devices – A potential battery issue can result in premature shutdown of the anesthesia device in situations where AC mains power is lost and back up emergency power is not available**

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

Backup batteries in Avance CS² and Avance CS² Pro anesthesia devices manufactured on or after April 1, 2019, and GE Healthcare recommended field replacement batteries distributed on or after April 1, 2019, for Avance CS², Avance CS² Pro, Avance, Amingo, and Aespire View can potentially fail earlier than their estimated life. For these batteries, the alarm that alerts the user on battery run time remaining could potentially be inaccurate. This issue could result in the anesthesia device shutting down sooner than indicated by the alarm, when running on the backup battery.

Anesthesia systems only operate on battery power in a rare event that AC mains power shuts off and there is no backup emergency power. If this situation is not identified and addressed by the attending clinician, the loss of ventilation may be life threatening.

There have been no reports of battery depletion occurring during patient use and no injuries have been reported as a result of this issue.

Actions to be taken by Customer /User

1. You can continue to use the affected anesthesia device while the device is connected to an **AC mains power source** that is supported by **backup emergency power.**
2. If this issue occurs, use the integrated manual ventilation and oxygen delivery features of the device.
3. Upon receiving this communication, perform the Battery Performance Test as described in Appendix A. **Replace the batteries, when necessary, before patient use.**
4. When not in patient use, it is recommended that the **device always remains connected to the AC mains power source** to prevent battery discharge and degradation. See your User's Reference Manual for storage recommendations.
5. It is recommended that the **Battery Performance Test be completed every three months** as described in Appendix A.
6. If the device has been in storage for over three months, perform the Battery Performance Test as described in Appendix A prior to use.

7. **The backup batteries must be replaced at a minimum every three years**. Aespire View batteries should be replaced every two years as stated in your User's Reference Manual.
8. Complete the attached Medical Device Notification Acknowledgement Response form and send to FMI34127ADS.BATTERY@GE.COM

Affected Product Details

Avance CS^2/ Avance CS^2 Pro (GTIN: 00840682102322) manufactured on or after April 1, 2019.

Avance CS^2, Avance CS^2 Pro, Avance, Amingo, and Aespire View with affected population of the following Field Replacement Unit (FRU) Batteries distributed on or after April 1, 2019, for:

FRU PN: 1009-5682-000-S (BTRY SEALED LEAD ACID RECHARGEABLE 12V)
FRU PN: 5856787-S (BTRY SEALED LEAD ACID RECHARGEABLE 12V PAIR)

Intended Use:
The GE Datex-Ohmeda Anesthesia Systems are intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation.

Product Correction

GE Healthcare will correct all affected products when the correction is available, at no cost to you. If support is needed to perform the battery testing described in Appendix A, please contact a GE Healthcare representative.

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

Appendix A

Battery Performance Test Procedure

Only use batteries recommended by GE Healthcare. Dispose of used batteries in accordance with local regulatory requirements in effect at the place of disposal.

1. Connect the anesthesia device to the main power source for eight hours to make sure the batteries are fully charged.
    - To see battery status, select System Setup>System Status. *
2. Connect a patient circuit and test lung to the anesthesia device.
3. On systems with an Airway Gas Module bay, connect an Airway Gas Module.
4. Turn on task light to maximum brightness.
5. Set the following parameters:
    - Mode: VCV
    - TV: 500ml
    - Rate: 12 /min
    - I:E: 1:2
    - PEEP: 5 cmH2O
6. Start mechanical ventilation.
7. Disconnect the power cord from the main power source.
    - If the batteries continue to power the anesthesia device for 60 minutes or longer, the batteries have sufficient charge.
    - If the batteries do not continue to power the anesthesia device for 60 minutes, contact an authorized service representative and have the batteries replaced.
    - Record the time to full battery discharge on the provided form.

Important
After this test is completed, connect the anesthesia device to the main power source for eight hours before it is used on a patient to make sure the batteries are fully charged.

*This feature not available on Aespire View.

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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: _____

Please complete the requested information and send back via one of the methods below.

☐ We acknowledge receipt and understanding of the Medical Device Correction Notice and have executed the instructions as provided in this notification and below are the results of our testing based on the instructions provided.

Please see the next page to document additional Anesthesia Device Serial Number information.

Anesthesia Device Serial Number	Discharge Time	Date of battery performance test
ABCD123456	**Xx mins**	**DD-MMM-YYYY**

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

Signature: _____

*Printed Name: _____

*Title: _____

*Date (DD/MM/YYYY): _____
*Indicates Mandatory Fields

Anesthesia Device Serial Number	Discharge Time	Date of battery performance test
ABCD123456	Xx mins	DD-MMM-YYYY

Please return completed form by scanning or taking a photo of the completed form and email to: FMI 34127ADS.BATTERY@GE.COM