October 2025

URGENT MEDICAL DEVICE CORRECTION
CARDIOSAVE IABP HYBRID AND RESCUE CONFIGURATIONS
NVRAM AND HELIUM O-RING PREVENTIVE MAINTENANCE
BATTERY RUNTIME AND VIBRATION AND SHOCK TABLE IFU INFORMATION

FSCA Title:	Reference Number:
NVRAM Preventive Maintenance	1289091
Vibration and Shock Table Specifications	1289090
Helium O-Ring Preventive Maintenance	2249723-01/24/2023-004-C
Battery Runtime Specifications	2249723-09/10/2021-001-R

Product Description:	Product Code/Part Number:	UDI Code:
Cardiosave Hybrid	0998-00-0800-XX 0998-UC-0800-XX	SSU to update to Correspond with Part Number distributed in country
Cardiosave Rescue	0998-00-0800-XX 0998-UC-0800-XX	SSU to update to Correspond with Part Number distributed in country

Distributed Affected Serial Number:	All
Manufacturing Dates:	December 2011 - Current
Distribution Dates:	Since March 06, 2012

Dear Risk Manager,

Datascope Corp., a subsidiary of Getinge, is initiating a voluntary Medical Device Correction for the Cardiosave Intra-Aortic Balloon Pumps (IABP) to provide information to address the following risks. This information will be published in a separate addendum for the IFU, accessible at the link provided below.

IFU Addendum Update	Prior Communication
1. NVRAM Preventive Maintenance	New FSCA – previously communicated in a Service Manual update
2. Vibration and Shock Table Specifications	New FSCA
3. Helium O-Ring Preventive Maintenance	FSCA 2249723-01/24/2023-004-C; and previously communicated in a Service Manual update
4. Battery Runtime Specifications	FSCA 2249723-09/10/2021-001-R

Identification of the issues:

Issue 1: NVRAM Preventive Maintenance

Description of Issue:

The IFU addendum revises the Preventative Maintenance schedule to align with the update introduced in the Service Manual as of June 2023.

The NVRAM (Non-Volatile Random Access Memory) Real Time Clock (RTC) Integrated Circuit (IC) is located on the Executive Processor Board of the Cardiosave. The NVRAM retains information, including real-time clock and IABP calibration data, on the IC during power-off cycles. An internal lithium battery powers the NVRAM when the Cardiosave is off. When the Cardiosave is on, it uses AC power or its inserted batteries.

It was previously identified that the expected battery life of the NVRAM internal lithium battery is shorter than the expected service life of the Cardiosave. There is no guidance in the preventative maintenance schedule in the IFU to change the NVRAM internal battery. As a result, if the NVRAM internal lithium battery loses charge when the device is powered off, the Cardiosave will be unable to access the information stored on the IC during the power-up sequence. Without this data, the system will not turn on and there may be a delay in delivering therapy.

Risk Associated if Preventative Maintenance is not Followed:

An NVRAM battery over 8 years old may lose its charge. Therapy will not be interrupted due to this issue as the NVRAM does not provide power to provide therapy. Rather, should the unit be powered off, the device will not be able to power back on if the NVRAM battery has lost charge. Additionally, should a patient receiving therapy require a unit replacement and one identified has a NVRAM battery that has lost its charge, transitioning to an alternate console may result in a prolonged therapy interruption, creating an opportunity for patient harm. The resulting harm will vary based on the clinical status of the patient being supported. The more critically ill the patient, the more significant the risk of any delay or interruption to therapy. The respective severity and probability of harm may be impacted by the alternate therapies available to the clinician.

From March 1, 2017 to September 30, 2025 a total of 85 complaints were reported globally to Datascope where the NVRAM or Executive Processor Board required replacement. There were no deaths, serious injuries, or other adverse events associated with these complaints.

IFU Addendum Update:

The IFU Addendum contains an updated Schedule B Preventive Maintenance, which requires the NVRAM to be replaced every 8 years (before its internal lithium battery loses charge). This NVRAM Preventative Maintenance change was implemented into the Service Manual June 2023.

Action to be taken by Customer for Issue 1:

- Review the IFU Addendum (see below for instructions on accessing the document) and local Preventive Maintenance Schedule and update facility Preventive Maintenance schedule accordingly.
- **Ensure that all NVRAM batteries are within their life expectancy.**
- **If a NVRAM is greater than 8 years old, until it can be replaced, it is advised a back-up Cardiosave IABP be available to provide therapy.**

Issue 2: Vibration and Shock Table Specifications

Description of Issue:

It was discovered during an engineering development test that the medical device transportation standards referenced in the IFU were not the ones cited in verification study reports. The IFU addendum updates the Vibration and Shock Table to reference the correct standards. No Cardiosave performance deficiencies were identified.

Risk Associated:

Inclusion of the applicable vibration and shock testing standards in the Cardiosave IFU had no impact on actual device performance and did not cause or contribute to any product malfunctions or failures.

There were no complaints identified for this issue between January 1, 2014 and September 30, 2025.

IFU Addendum Update:

An IFU Addendum was created to reference the appropriate Transportation Standards that were tested in product specifications.

Issue 3: Helium O-Ring Preventive Maintenance

Description of Issue:

This issue was previously communicated to customers in a letter dated February 7, 2023. This notification is for awareness to the update of Datascope's preventative maintenance in the IFU addendum. Please reference the link below for previous communications of the issue.

https://www.getinge.com/int/products-and-solutions/cardiovascular-procedures/iabp-counterpulsation/iabp-product-information/

Risk Associated:

There is no increased risk associated with this update.

IFU Addendum Update:

The IFU Addendum contains an updated Schedule B Preventive Maintenance Schedule which calls for the Quick Disconnect Fitting O-Ring to be replaced and to lubricate the console release latch every 12 months or 2500 hours. The Service Manual has contained this update to Preventive Maintenance for the Helium O-Ring since June 2023.

Actions to be taken by Customer for Issue 3:

Review the IFU Addendum (see below for instructions on accessing the document) and local Preventive Maintenance Schedule and update your Preventive Maintenance schedule accordingly.

Issue 4: Battery Runtime Specifications

Description of Issue:

The previously communicated product recall regarding impacted batteries has been completed, however this notice conveys the changes that are being made to the IFU regarding battery run time specification. The IFU addendum updates the Battery Runtime Specification to match those published in the Service Manual in June 2023. Please reference the link below for previous communications associated with the completed recall.

https://www.getinge.com/int/products-and-solutions/cardiovascular-procedures/iabp-counterpulsation/iabp-product-information/

Risk Associated:

There is no increased risk associated with this update.

IFU Addendum Update:

The IFU addendum updates details the Battery Run Time is to be 80 Minutes Typical-new battery, 120 BPM, 22 +/- 5 degrees C min at 120 BPM.

NOTE: For a new battery, 80 Minutes at 120 bpm is equivalent to 90 Minutes at 90 bpm per previous battery runtime claims.

Actions to be taken by Customer for Issues 1-4:

Our records indicate that you may have one or more Cardiosave IABPs in your facility. Please forward this information to all current and potential Cardiosave IABP users within your facility. Complete and sign the attached Response Form to acknowledge that you have received and understand this notification. Return the completed form to [add SSU contact information].

If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.

Summary of Customer Actions

Issue	Action
1. NVRAM Preventive Maintenance	Review IFU Addendum and ensure local PM procedures are updated as required. Ensure that all NVRAM batteries are within their life expectancy. If a NVRAM is greater than 8 years old, until it can be replaced, it is advised a back-up Cardiosave IABP be available to provide therapy.
2. Vibration and Shock Table Specifications	Review IFU Addendum
3. Helium O-Ring Preventive Maintenance	Review IFU Addendum and ensure local PM procedures are updated as required.
4. Battery Runtime Specifications	Review IFU Addendum

Actions to be taken by Datascope:

Datascope created an IFU Addendum with clarification to the Battery Runtime and Vibration and Shock Table IFU information as well as updates to the Preventive Maintenance Schedule B for both NVRAM and the Helium O-Ring on the Quick-Disconnect Fitting. It can be accessed by the link or the QR code below:

https://www.getinge.com/int/products-and-solutions/cardiovascular-procedures/iabp-counterpulsation/iabp-product-information/

If you require a physical copy, please contact your local Datascope/Getinge representative, and one will be provided to you at no cost.

Adverse events or quality problems experienced with the use of any of the products mentioned in this document may be reported to local Competent Authorities. Please follow the current regulations on adverse event reporting in your country.

We apologize for any inconvenience this correction may cause. If you have any questions, please call Datascope/Getinge Customer Support [add SSU contact information].

Sincerely,

Ojas Zatakia

Senior Director Quality Assurance & Regulatory Compliance

October 2025

URGENT MEDICAL DEVICE CORRECTION

Reference Numbers: 1289091, 1289090, 2249723-01/24/2023-004-C, 2249723-09/10/2021-001-R

Datascope Cardiosave Intra-Aortic Balloon Pumps (IABP)

0998-00-0800-XX / 0998-UC-0800-XX - CARDIOSAVE HYBRID

0998-00-0800-XX / 0998-UC-0800-XX - CARDIOSAVE RESCUE

Distributed since 12-Dec-2012

ADD ACCOUNT#
[FACILITY NAME
STREET ADDRESS

CITY, STATE, ZIP CODE]

Please acknowledge that you have read and understand this Medical Device Correction Notice for the Cardiosave Hybrid and Rescue IABPs. Please ensure that all users of the Cardiosave Hybrid and Rescue IABPs at this facility have been notified accordingly.

Please provide the required information and signature below.

Facility Representative Information:

Signature:_____ Date:_____

Name:_____ Phone:_____

E-Mail Address:_____

Title:_____ Department:_____

Hospital Name:_____

Address, City and State:_____

Return the completed form to [add SSU contact information].