July 31, 2023 via FedEx

URGENT MEDICAL DEVICE CORRECTION
FSCA 2249723-06/02/2023-009-C & FSCA 2249723-06/02/2023-012-C
Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP)

Product Description:	Product Code/Part Number:	UDI Code:
Cardiosave Hybrid	0998-00-0800-31 0998-UC-0800-31	10607567109053 N/A
Cardiosave Hybrid	0998-00-0800-32	10607567111117
Cardiosave Hybrid	0998-00-0800-33 0998-UC-0800-33	10607567109008 N/A
Cardiosave Hybrid	0998-00-0800-34	10607567111940
Cardiosave Hybrid	0998-00-0800-35	10607567109107
Cardiosave Hybrid	0998-00-0800-45	10607567108421
Cardiosave Hybrid	0998-00-0800-52 0998-UC-0800-52	10607567108438 N/A
Cardiosave Hybrid	0998-00-0800-53 0998-UC-0800-53	10607567108391 N/A
Cardiosave Hybrid	0998-00-0800-55 0998-UC-0800-55	10607567108414 N/A
Cardiosave Hybrid	0998-00-0800-65	10607567113432
Cardiosave Rescue	0998-00-0800-75	10607567112312
Cardiosave Rescue	0998-00-0800-83	10607567108407
Cardiosave Rescue	0998-00-0800-85	10607567113449

Distributed Affected Lot Number:	All
Manufacturing Dates:	Since December 2011
Distribution Dates:	Since March 06, 2012

Getinge
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Wayne, NJ 07470 USA
www.getinge.com

Dear Risk Manager,

Datascope Corp., a subsidiary of Getinge is initiating a voluntary Medical Device Correction for the Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) due to the following two (2) identified system conditions:

Issue 1: Docking/Power Battery Failure
Issue 2: Poor or No ECG Signal

The Cardiosave Intra-Aortic Balloon Pump (IABP) is an electromechanical system used to inflate and deflate intra-aortic balloons (IABs). It provides temporary support to the left ventricle via the principle of counterpulsation as stated in the Instructions for Use.

Please note that according to the FDA, a Recall is a method of removing OR correcting products. A Correction is defined as a means to repair, modify or adjust a product without its physical removal. This particular correction does not require physical removal of the device. For your convenience, we are providing the link to the FDA website, which includes these definitions as well as other related information: https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices.

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Issue 1: Docking/Power Battery Failure

Identification of the issue:
Datascope/Getinge has received 319 complaints over a two-year period (January 1, 2021 through December 31, 2022) where Cardiosave IABP users were reporting that the device was not charging as expected.

A detailed compliant investigation was performed where it was observed that there were 57 cases where users were unaware that the Cardiosave console was not completely inserted into the hospital cart. If the console is not fully inserted into the cart the IABP will not receive AC power and the battery(ies) will not charge. For the remaining complaint cases, Datascope/Getinge has open field actions where measures are being implemented to address the failure modes related to the remaining complaints.

One adverse event was reported which resulted in a patient death, however the customer does not attribute the patient's death to this device.

Risk to Health:
Should the Cardiosave not be seated in the cart properly, the device will not receive AC power and will run on the battery(ies). Therapy will be interrupted once the batteries are exhausted and if the user is unaware that the Cardiosave is not seated correctly. Interruption of therapy upon battery depletion will be unexpected, as the user will presume that the device is running on AC power. Additionally, if the Cardiosave is not seated in the cart properly, it will not receive AC power and the Cardiosave will not be able to charge the battery(ies) inserted.

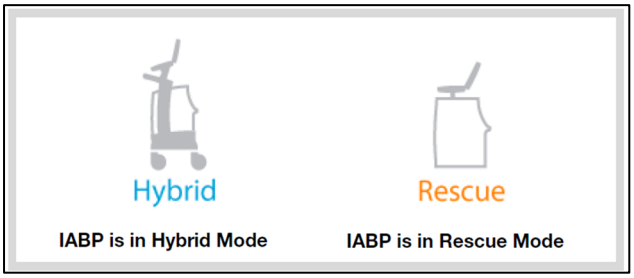
If circumstances develop where the user must rely upon battery power alone to provide support (such as a transport situation), counterpulsation therapy may be interrupted. Restoring AC power by reseating the Cardiosave device into the cart properly or inserting alternative (charged) batteries can prevent therapy interruption.

Should power not be re-established or another IABP console is not available for use, alternative means of providing hemodynamic support (vasopressors, inotropes or alternate therapies) may be initiated by a healthcare provider as a temporizing measure. If alternative supportive measures are unavailable or ineffective until therapy can be resumed, therapy interruption can lead to death.

User Actions to be taken now:
Our records indicate that you may have a Cardiosave Hybrid and/or Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) in your facility. Please examine your inventory immediately to determine if you have any Cardiosave Hybrid and/or Rescue IABPs.

The Cardiosave device has two operating modes: Hybrid (docked within the hospital cart) and Rescue (transport). When in Hybrid mode the IABP may operate on both AC power and battery power; and when plugged in (AC power) can charge inserted batteries. When in Rescue (transport) mode, the IABP can operate on battery power, or AC Power with the use of the Transport Power Supply accessory (occupying a battery bay). However, unless the Cardiosave is powered off, the Transport Power Supply will not charge a battery inserted into the alternate battery bay unless the Transport Power Supply is connected directly to AC power.

The IABP Configuration Icon shows the current mode of configuration for the IABP, Hybrid (in the hospital cart) Mode or Rescue (transport) Mode. The icon is located at the top center of the IABP display screen.



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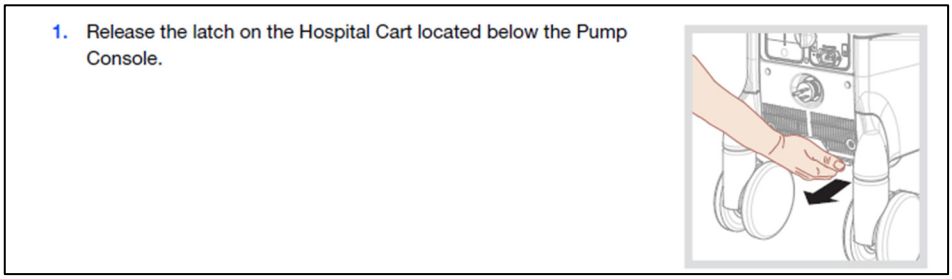
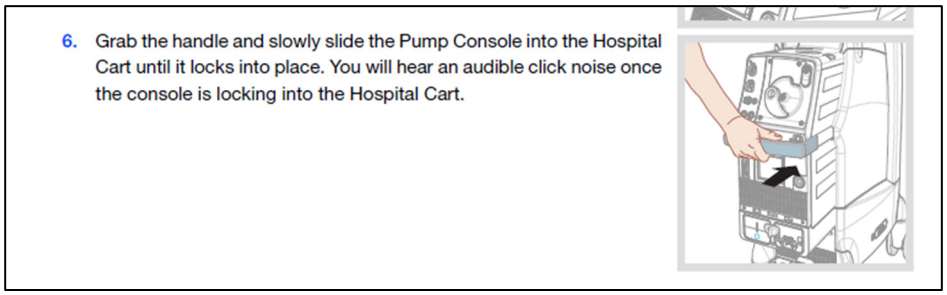
There are two methods where the IABP can be in transport/rescue mode without user intent:

1) The Cardiosave Hospital Cart's release latch has been released and the IABP console is not properly installed in the cart.



2) The IABP console is inserted into the hospital cart, but is not fully latched into the cart



In both cases, information is provided to the user that the system is not in Hybrid mode via the Rescue Mode Icon on the bottom Cardiosave screen (top center of the screen). In addition, the "battery in use" message will be displayed in the informational message area even if the AC power cord is plugged in.

Additionally, in both scenarios, the Cardiosave will not receive AC power and if the device is in operation, it will continue to operate on battery. When the Cardiosave is not receiving AC power, the batteries are unable to charge.

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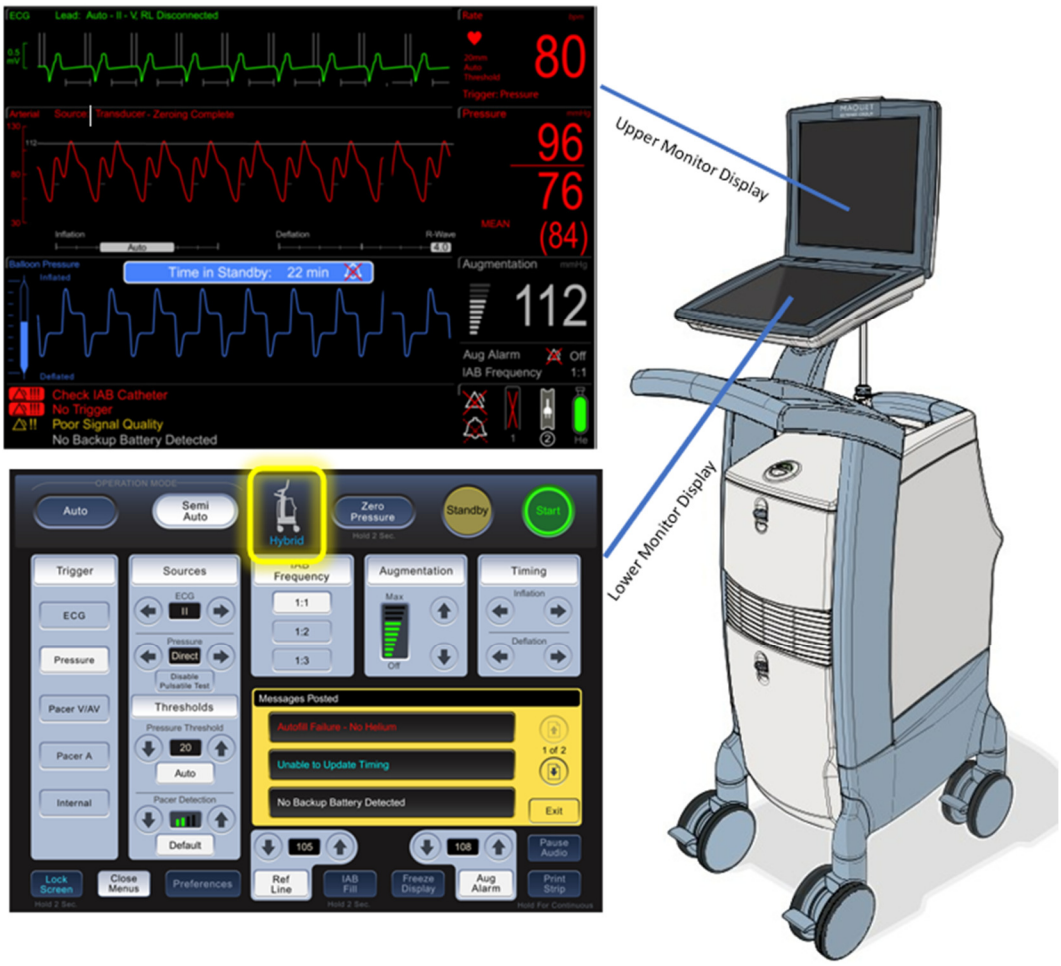
Cardiosave Upper and Lower Display



If the AC Plug Icon is not present and/or the Rescue Icon is present, release the latch on the Hospital Cart located below the Pump Console, then grab the handle and slowly slide out the console approximately one quarter of the way.

Grab the handle and slowly slide the Pump Console into the Hospital Cart until it locks into place. You will hear an audible click noise and three audio tones of increasing volume will sound once the console is locked into the Hospital Cart.

To ensure the Pump Console was successfully installed into the Hospital Cart, plug the Hospital Cart power cord into a compatible grounded AC receptacle, and confirm AC operation by checking the battery icon to confirm the pump is using AC power.

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Issue 2: Poor or No ECG Signal

Identification of the issue:
Datascope/Getinge has received 81 complaints over a two-year period (January 1, 2021 through December 31, 2022) where Cardiosave IABP users were unable to measure the ECG on a patient.

Poor or no ECG signal before or during therapy with the Cardiosave IABP can be caused by several factors such as poor quality skin-electrode, faulty ECG lead, or defective trunk cable.

There have been no adverse events reported that Datascope/Getinge has been able to specifically identify as a result of these failures.

Risk to Health:
Should poor or no ECG signal be experienced, therapy may be delayed or interrupted. As with any therapy interruption, the degree of subsequent hemodynamic stability is related to the patient's overall clinical condition, those critically ill are more vulnerable to clinical decline. When the Cardiosave is operating in AUTO mode, there is a reduced risk of therapy interruption if the ECG signal is poor or lost as the Cardiosave will automatically switch to arterial pressure for the trigger source to guide inflation and deflation of the IAB catheter.

However, if the Cardiosave is operating in SEMI AUTO mode with ECG selected as the trigger and the ECG signal is lost, the Cardiosave will alarm, alerting the user that therapy has been interrupted. User intervention is needed to select the appropriate ECG lead or identify an alternate trigger source in order to resume therapy.

In cases where the Cardiosave fails to recognize an ECG error, sustained dyssynchronous therapy has the potential to introduce additional stressors to an already compromised heart. It is anticipated that a prolonged period of dyssnychronous therapy results in decreased cardiac output, placing even a stable patient at a higher risk for clinical decline.

User Actions to be taken now:
Our records indicate that you may have a Cardiosave Hybrid and/or Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) in your facility. Please examine your inventory immediately to determine if you have any Cardiosave Hybrid and/or Rescue IABPs.

Factors Contributing to ECG failure:

- Poor Quality Skin-Electrode Interface
- Front End PCBA Failure including Wetting (causes system to be unable to detect ECG lead faults)
- Faulty ECG Lead
- Failure of Executive Processor Board (the system cannot obtain or interpret the ECG)
- Defective ECG Lead Wire
- Defective Trunk Cable
- Defective connector between ECG cable and IABP unit

The type of skin electrode and application technique are major factors in determining the quality of the signal obtained. Use of MAQUET/Datascope electrodes is recommended. These are designed to acquire an ECG signal with excellent baseline stability, recovery from defibrillation and minimum artifact from patient movement. The use of Wet-Gel electrodes is recommended because, in general, they provide a better quality electrical contact immediately after being placed on the skin.

To ensure the safe and effective use of the Cardiosave IABP, follow the recommendation in the IFU, including the warning and Figures 2-1 and 2-2 regarding ECG lead placement locations and the use of third-party lead wires.

⚠ WARNING:

Use only MAQUET/Datascope Corp. ECG lead wires with the ECG Patient Cable. The use of any other lead wires may cause the system to function improperly.

1. When acquiring an ECG signal directly from skin electrodes:

   a. Ensure that the patient lead wires are securely inserted into the yoke of the MAQUET/ Datascope Corp. supplied ECG trunk cable. Connect each patient lead wire to a skin electrode. The following table shows the number of ECG Electrodes vs. Leads available. The recommended minimum number of electrodes is four (4) to provide optimal lead selection triggering options.

(#) ELECTRODES USED (AHA)	(#) ELECTRODES USED (IEC)	(#) ECG LEADS AVAILABLE
RA, LA, LL	R, L, F	I, II, III
RA, LA, LL, RL	R, L, F, N	I, II, III, aVR, aVL, aVF
RA, LA, LL, RL, V	R, L, F, N, C	I, II, III, aVR, aVL, aVF, V

   b. Attach electrodes to the patient at the appropriate locations, as shown.

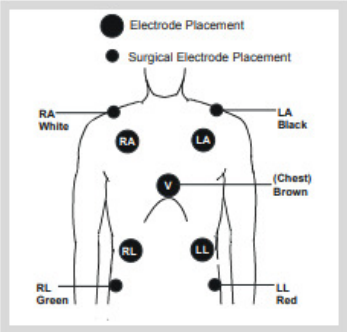

Figure 2-1: Electrode Placement AHA

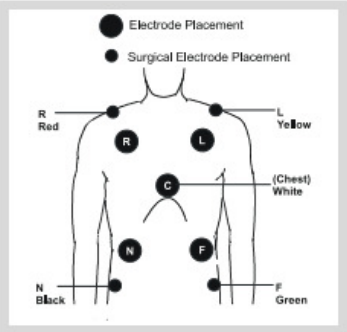

Figure 2-2: Electrode Placement IEC

Type of Action by the Company:

This Urgent Medical Device correction is being issued to inform Users of the issue(s) observed and actions to be taken should Users experience this issue. Datascope/Getinge is currently investigating this issue further to determine root cause and will notify customers in the event additional action needs to be taken to correct the issue.

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Actions to be taken by the User related to the issue provided in this notification:
A review of our records indicates that you may have a Cardiosave Hybrid and/or Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) in your facility. Please examine your inventory immediately to determine if you have any Cardiosave Hybrid and/or Rescue IABPs.

Please complete and sign the attached MEDICAL DEVICE CORRECTION – RESPONSE FORM (page 11) to acknowledge that you have received and understand this notification. Return the completed form to Datascope/Getinge by e-mailing a scanned copy to cardiosave-bdecg23.act@getinge.com or by faxing the form to (877) 622-5664.

Please forward this information to all current and potential Cardiosave Hybrid and/or Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) users within your hospital/facility.

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

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax using the following:

- **Online**: www.accessdata.fda.gov/scripts/medwatch/
- **Regular Mail**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form
- **Fax**: 1-800-FDA-0178

This voluntary recall only affects the products listed on page 1; no other products are affected by this voluntary correction.

We apologize for any inconvenience this Medical Device Correction may cause. If you have any questions, please contact your Datascope/Getinge representative or call Datascope/Getinge Technical Support at 1-888-943-8872, options 4, 2, 1, Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone).

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

Allison Jean Kaplan
Specialist, Regulatory Affairs and Field Action Compliance

Getinge

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