June 5, 2023 via FedEx

URGENT MEDICAL DEVICE CORRECTION
FSCA 2249723-05/05/2023-008-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**

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 two issues that could affect IABP performance:

Getinge
45 Barbour Pond Drive
Wayne, NJ 07470 USA
www.getinge.com

Issue 1:
There have been reports of IABP units losing the ability to charge batteries in one or both bay slots due to a failure in the Power Management Board Charging Path Circuitry due to damage to the component from a previous electrical surge.

Therapy may be interrupted if batteries fail to charge and the device is disconnected from AC power. Low battery alarms may alert the User to the issue prior to interruption of therapy.

Issue 2:
An unexpected shutdown of the IABP may occur due to failures of tantalum capacitors in the Power Management Board and/or Solenoid Board.

This issue may lead to an unexpected interruption of therapy.

Issue 1: IABP will not charge battery due to failure of the Power Management Board Charge Path Circuitry

Identification of the issue:
Datascope/Getinge has received 252 complaints since beginning distribution in 2012 through April 2023 reporting events where Cardiosave IABPs are unable to charge the lithium-ion battery [P/N 0146-00-0097] in one or both battery bays. The complaint rate for this failure is 2.66%. Further investigation determined that the cause of these events was failure of the Cardiosave's charging circuitry (Power Management Printed Circuit Board Assembly [PCBA]) due to electrical surge(s). An electrical surge can result if an actively charging battery with a level of 80% or higher is removed from a Cardiosave unit.

Although there have been adverse events reported for battery failures and unexpected shutdowns, there have been no adverse events reported that we have been able to specifically identify as a result of these failures.

Risk to Health:
Should a Power Management Board Charging Path Circuit be damaged, the pump will be unable to charge inserted batteries despite being connected to AC power. Subsequently, when using battery power to provide therapy and the battery charge is depleted, therapy may be interrupted. Restoring AC power 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:
To prevent electrical surges that may impair the Cardiosave's ability to charge batteries, **do not remove the battery** from a Cardiosave **when the battery level is at 80% or higher and actively charging** (i.e. successfully connected to AC power). Keep the battery in the charging bay until fully charged.

Each Battery has five (5) LEDs indicating the battery's approximate state of charge. **A battery with 80% charge is represented by four (4) solid illuminated LEDs and when charging, the topmost LED on the battery will be flashing**. **Removing the battery when the top LED is flashing during the charging operation may result in damage to the Cardiosave's battery charging circuitry.**

Getinge
45 Barbour Pond Drive
Wayne, NJ 07470 USA
www.getinge.com

Battery can be safely removed when under 80% charge or when fully charged. To view the battery status, press the button located on the front of the battery. The LEDs will illuminate informing the user of the battery's approximate state of charge.

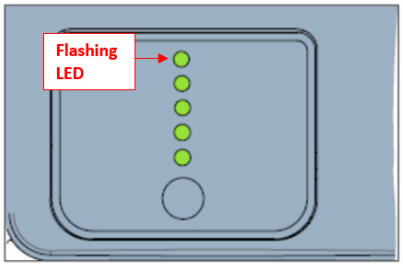


Figure 1: Battery is 80% - 100% Charging

Do NOT remove battery

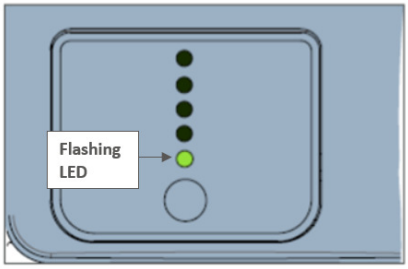


Figure 2: Battery 0%-20% Charging

Safe to remove battery

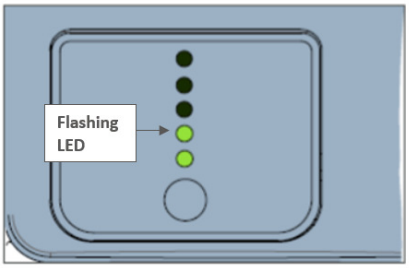


Figure 3: Battery 20%-40% Charging

Safe to remove battery

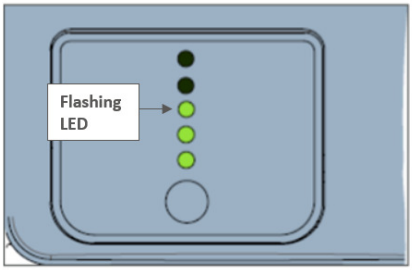


Figure 4: Battery 40%-60% Charging

Safe to remove battery

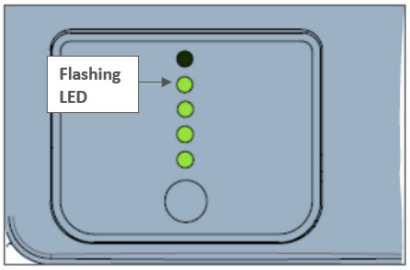


Figure 5: Battery 60%-80% Charged

Safe to remove battery

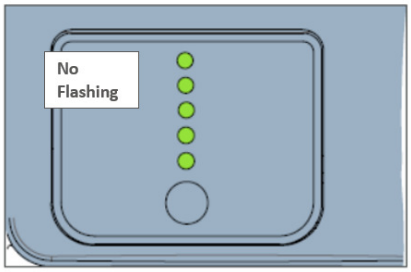


Figure 6: Fully Charged Battery

Safe to remove battery

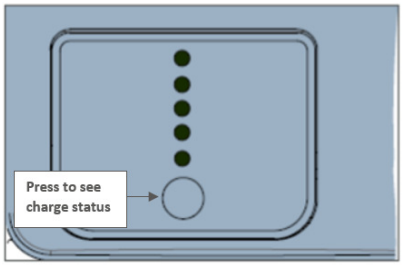


Figure 7: Not Actively Charging

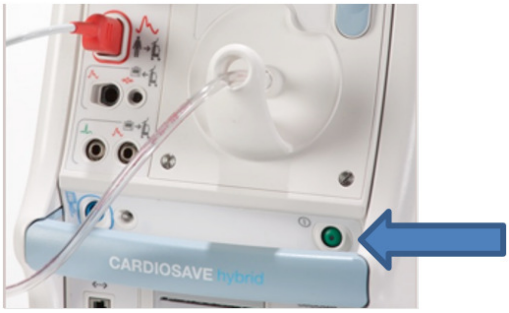
Press button to view charge status

- At the completion of the charging operation, all 5 LEDs will be lit briefly and then go dark.
- Always verify the state of charge by pressing the button below the LEDs on the front of the battery.
- If all 5 LEDs are not lit after pressing the button, the battery charging operation was not successful.

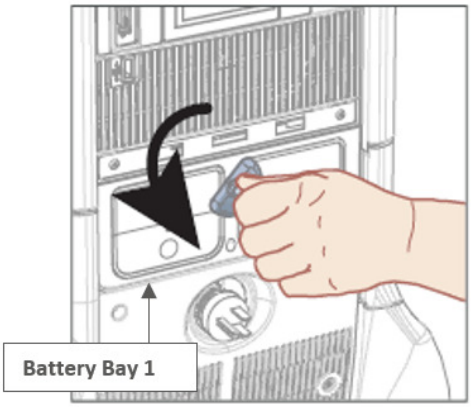
If it is deemed absolutely necessary to remove a battery before it is fully charged (top green indicator is flashing), follow the directions below to prevent damaging the battery charging path circuitry:

- If the battery being removed is in a Cardiosave actively delivering therapy, connect the IAB catheter to an alternative IABP to prevent any therapy interruption.

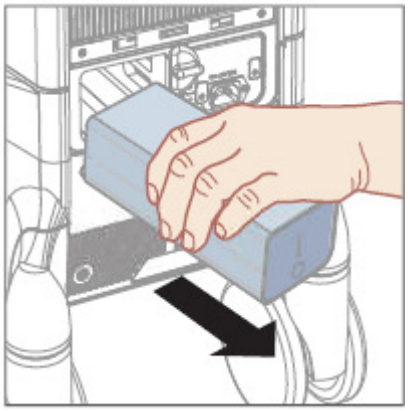
- Turn off the Cardiosave by pressing and holding the IABP Power Button, located on the back of the console, for 2 seconds.



- Unplug the IABP from the wall receptacle.
- Once disconnected from AC power, remove the battery using the following instructions:
  1. Turn the knob to unlock, and remove the battery from the Battery Bay (counter-clockwise for Battery Bay 1, or clockwise for Battery Bay 2)



  2. Slide the battery out of the Battery Bay



Unless a fully charged battery is inserted into the bay, the charge indicator LED on the cart should flash on and off. There should also be activity on the charge status LEDs on the battery packs. The upper most LED should flash while charging while those below it should be solidly lit. If the IABP charging function is not functioning as intended then please contact your Datascope/Getinge service representative.

Type of Action by the Company:

Datascope/Getinge is developing a hardware correction to address this issue. A Datascope/Getinge service representative will contact you to schedule the installation of the correction if your unit is affected as the correction kit becomes available. This work will be done at no cost to your facility.

Issue 2: Unexpected Shutdown due to failure of Tantalum Capacitors

Identification of the issue:
Datascope/Getinge has received 26 complaints since beginning distribution in 2012 through April 2023 reporting Cardiosave IABPs unexpectedly shutting down due to Power Management PCBA and/or Solenoid Control PCBA failures. The complaint rate for this failure is 0.27%. Further investigation of the complaints determined that the unexpected shutdown was due to tantalum capacitor failures within the Power Management Board and/or Solenoid Control Boards.

Although there have been adverse events associated with unexpected device shutdowns, there have been no adverse events reported that we have been able to specifically attribute to this failure(s).

Risk to Health:
Failure of tantalum capacitors in either of the boards (Power Management or Solenoid) may result in an unexpected shutdown condition without means to restore therapy. Tantalum capacitor failure cannot be predicted and may occur while actively providing therapy. The Cardiosave does not have means of conveying to the user if the pump is at risk of tantalum capacitor failure, nor that a shutdown is imminent due to tantalum capacitor failure. Should capacitor failure result in a loss of power to the IABP, the loss of power alarm will be emitted. An unexpected shutdown and resulting interruption to therapy may threaten the hemodynamic stability of the supported patient as the user is left unaware to the status of the Cardiosave IABP. Should another IABP console not be 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 another console is identified to resume therapy, therapy interruption can lead to death.

User Actions to be taken now:

1. Should an unexpected shutdown occur due to a loss of power of the Cardiosave IABP during therapy, therapy will be interrupted. Utilize another IABP (if available) to continue therapy. If the IABP remains non-operational, immediately remove from the patient care environment for further product evaluation.
2. If your device remains inoperable, please contact your service representative to identify the cause and take the necessary actions required.
3. It is recommended for users to have an alternate IABP on hand in the event that this issue may occur.

Type of Action by the Company:
Datascope/Getinge is developing a hardware correction to address this issue. A Datascope/Getinge service representative will contact you to schedule the installation of the correction if your unit is affected as the correction kit becomes available. This work will be done at no cost to your facility.

Actions to be taken by the User related to all issues 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 URGENT MEDICAL DEVICE CORRECTION - RESPONSE FORM (Page 9) checking off each issue checkbox (1 and 2) to acknowledge that you have received and understand this notification. Return the completed form to Datascope/Getinge by e-mailing a scanned copy to CardiosavePMB2023.act@getinge.com or by faxing the form to 1-877-564-7124.

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.

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

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

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

Sincerely,

Marylou Insinga
Senior Specialist, Regulatory Affairs and Field Action Compliance
Getinge

Getinge
45 Barbour Pond Drive
Wayne, NJ 07470 USA
www.getinge.com