July 14, 2025

URGENT MEDICAL DEVICE CORRECTION UPDATE
FSCA 2249723-11/16/2022-001-C / OT 744060
CARDIOSAVE Hybrid and CARDIOSAVE Rescue Intra-Aortic Balloon Pumps (IABPs)
Blood Back Field Action

Product Description	Product Code / Part Number	UDI Code
Cardiosave Hybrid IABP	0998-00-0800-31 0998-UC-0800-31	10607567109053
	0998-00-0800-32 0998-UC-0800-32	10607567111117
	0998-00-0800-33 0998-UC-0800-33	10607567109008
	0998-00-0800-34 0998-UC-0800-34	10607567111940
	0998-00-0800-35 0998-UC-0800-35	10607567109107
	0998-00-0800-36 0998-UC-0800-36	10607567114187
	0998-00-0800-45 0998-UC-0800-45	10607567108421
	0998-00-0800-52 0998-UC-0800-52	10607567108438
	0998-00-0800-53 0998-UC-0800-53	10607567108391
	0998-00-0800-55 0998-UC-0800-55	10607567108414
	0998-00-0800-65 0998-UC-0800-65	10607567113432
Cardiosave Rescue IABP	0998-00-0800-75 0998-UC-0800-75	10607567112312
	0998-00-0800-83 0998-UC-0800-83	10607567108407
	0998-00-0800-85 0998-UC-0800-85	10607567113449

Distributed Affected Lot Number:	**All**
Manufacturing Dates:	**Since December 01, 2011**
Distribution Dates:	**Since March 06, 2012**

PLEASE FORWARD THIS INFORMATION TO ALL CURRENT AND POTENTIAL CARDIOSAVE Hybrid and CARDIOSAVE Rescue Intra-Aortic Balloon Pumps (IABPs) USERS WITHIN YOUR HOSPITAL / FACILITY.

IF YOU ARE A DISTRIBUTOR WHO HAS SHIPPED ANY AFFECTED PRODUCTS TO CUSTOMERS, PLEASE FORWARD THIS DOCUMENT TO THEIR ATTENTION FOR APPROPRIATE ACTION.

Dear Risk Manager,

In November 2022, Datascope Corp., a subsidiary of Getinge, initiated a voluntary Medical Device Correction for the Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) due to the increased number of unexpected shutdowns reported due to blood entering the console following an Intra-Aortic Balloons (IAB) catheter perforation.

Today's notice reproduces the information provided in the original notice with minor revisions for clarity and includes new information on how to receive relevant Cardiosave hardware and software (D.03 version) updates as well as revised operating instructions for both Hybrid and Rescue IABP configurations.

The Cardiosave IABP is an electromechanical system used to inflate and deflate IABs. It provides temporary support to the left ventricle via the principle of counterpulsation as stated in the Cardiosave Operating Instructions for Hybrid and Rescue IABPs.

Getinge has implemented a design change to the Cardiosave Pneumatic Interface Module (PIM) by modifying the PIM housing to add a Containment Filter which will capture blood or fluid that enters the pump in the event of a perforated balloon catheter. The Containment Filter prevents the blood/fluid from reaching printed circuit boards and electronics within the Cardiosave IABP and the subsequent compromise of these electronic components that has led to unexpected shutdown of the pump.

In conjunction with the filter, Getinge has introduced a "Pump Failure – Service Required" alarm and an associated power up test failure alarm. The "Pump Failure – Service Required" alarm will be generated if the Cardiosave IABP is unable to vent due to blood or fluid within the the Containment Filter or if the vent valve fails. Once the Cardiosave IABP is powered off, subsequent startups of the Cardiosave IABP will result in the posting of "Power-Up Test Fails Code #15" alarm until the IABP is serviced. With either alarm, the affected pump must be removed from use, and assessed by biomedical or technical service before subsequent use. The Cardiosave IABP cannot provide therapy until it is serviced.

The updated D.03 software also allows for earlier detection of a balloon perforation. The sensitivity and frequency of monitoring for blood or fluid in the IAB circuit has been improved. The pump checks for pressure changes within the IAB circuit that may be associated with a perforated balloon. If the system suspects a balloon perforation, it will alert the user with the high priority alarm "Blood

Suspected – Check Catheter and Tubing" which replaces the previous "Autofill Failure – Blood Suspected" alarm and help screen.

If the "Blood Suspected – Check Catheter and Tubing" alarm is generated and there **IS** blood visible in the tubing, the user is instructed to take the following actions:

- Disconnect the catheter extender tubing from the Cardiosave IABP console to allow the balloon to deflate.
- Clamp extracorporeal tubing between white y-fitting and male connector.
- Notify physician and prepare for IAB catheter removal.
- Consider IAB catheter replacement if the patient's condition warrants.

If blood is suspected of having entered the pump, take the pump out of service. It should be evaluated before use in another patient by Biomed/Technical Service to determine if replacement of contaminated components is necessary.

If the "Blood Suspected – Check Catheter and Tubing" alarm is generated and there **IS NOT** blood visible in the IAB catheter or tubing, the Cardiosave IABP can continue to be used. After confirming the IAB catheter is not perforated and it is appropriate to resume therapy, the user can power off the pump, power it back on and resume therapy.

The above described alarms and informational meassage have been added to the D.03 Cardiosave Operating Instructions for Hybrid and Rescue IABP. The screen shoot of these alarms and informational messages were added in Appendix. A.

Identification of the issue:

Datascope/Getinge received complaints reporting unexpected shutdown of the Cardiosave IABP while providing therapy in very rare instances. An unexpected shutdown occurs without forewarning; the screen abruptly turns off, no further instruction or status is available to the user and a high-pitched alarm is emitted. An internal investigation of the complaints determined an unexpected shutdown may be due to blood entering into the Cardiosave IABP when therapy is provided with a perforated IAB catheter.

Datascope/Getinge evaluated 375 reported incidents of blood entering the Cardiosave console over an eight-year period (October 2018 through March 31, 2025). 56 of those detailed an unexpected shutdown. From those 56 complaints, 6 adverse events were reported including three (3) serious injuries and three (3) deaths.

Risk to Health prior to Blood Back Updates:

The IAB membrane or inner lumen may be perforated from catheter malposition or from repeated contact with pre-existing calcium plaque(s). Should the inner lumen be damaged or small pinhole perforations develop in the balloon membrane, blood may accumulate within the balloon membrane, extracorporeal tubing, and/or the helium extender tubing. Once a perforated balloon is detected by the Cardiosave IABP, therapy is interrupted by the Cardiosave IABP, and an alarm is sounded. Should the user notice blood in the catheter tubing prior to the system alarming, the user is able to

stop therapy manually (as directed in operating instructions and educational materials). However, should the condition occur without the user or Cardiosave IABP recognizing it, blood can travel the length of the extender tubing into the Cardiosave console, and come in contact with the pump's electrical components.

A perforation of an IAB introduces risk to the patient, and blood may be permitted to enter the catheter and extender tubing. The amount of blood that may enter the IAB catheter and travel into the Cardiosave IABP is not restricted, and there is the possibility for different severities of blood loss based on patient status. Blood may be permitted to flow freely until the user takes further action.

If an IAB perforation occurs and blood is permitted to enter the Cardiosave IABP after it is already powered down, the Cardiosave IABP will not alarm and may not start on the next power up attempt if sufficient blood has entered the console.

An unexpected shutdown of the Cardiosave IABP due to a blood back event introduces the following additional harm(s) to the supported patient, user, and future patients supported by the impacted console.

- An unexpected shutdown may threaten the hemodynamic stability of the supported patient as the user is left unaware to the status of the Cardiosave IABP. Additionally, any subsequent attempts to use a Cardiosave console that experienced a blood back event without reconditioning may delay future therapy delivery.
- The user and subsequent maintenance or service personnel can be exposed to an unexpected biohazard should proper containment precautions not be taken.
- Subsequent patients may be exposed to an unexpected biohazard should an impacted console not be appropriately serviced prior to use.

Actions to be taken by Datascope/Getinge:

A Datascope/Getinge SSU representative will schedule a service visit to impacted customers to install the updated software (D.03), and hardware update to PIM and test the Cardiosave IABP to ensure it functions as intended prior to releasing it for clinical use. Also, the affected customers may contact Getinge to request a service visit to address the hardware and software updates.

The D.03 Operating Instructions for Hybrid and Rescue IABP configurations will be provided to the customer at the time of implementing the hardware and software (D.03) updates.

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 (IABP) in your facility. Please examine your inventory immediately to determine if you have any Cardiosave Hybrid and/or Rescue IABPs.
- Please ensure that all Cardiosave IABP users and nurse Educators are able to access and receive the updated Cardiosave IABP education and training materials available at the following link: https://fs7.formsite.com/MedicalAffairs/s94juj9zlb/index.

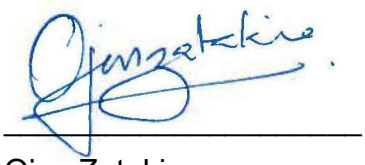
- Please complete and sign the attached attached **MEDICAL DEVICE CORRECTION UPDATE RESPONSE FORM** (page X) to acknowledge that you have received this notification. Return the completed form to Getinge by e-mailing a scanned copy to XXXXXXXX@getinge.com or by faxing the form to (XXX) XXX-XXXX.
- If you are a distributor who has shipped any affected products to customers, please forward this letter to their attention for appropriate action.

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

We apologize for any inconvenience this recall may cause. If you have any questions, please contact your Datascope/Getinge representative or call the Datascope/Getinge Customer Support at (XXX) XXX-XXXX (press option X, then option X), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Time Zone).

We regret any inconvenience this may cause. Datascope/Getinge is committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,



Ojas Zatakia,

Sr. Director Quality Assurance & Regulatory Compliance

July 14, 2025

OT 744060 MEDICAL DEVICE CORRECTION UPDATE RESPONSE FORM

Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP)

Blood Back Field Action

0998-00-0800-31 / 0998-UC-0800-31 - CARDIOSAVE HYBRID TYPE I (AU)

0998-00-0800-32 / 0998-UC-0800-32- CARDIOSAVE HYBRID TYPE J PLUG

0998-00-0800-33 / 0998-UC-0800-33- CARDIOSAVE HYBRID TYPE D PLUG

0998-00-0800-34 / 0998-UC-0800-34- CARDIOSAVE HYBRID TYPE K PLUG

0998-00-0800-35 / 0998-UC-0800-35- CARDIOSAVE HYBRID TYPE M PLUG

0998-00-0800-36 / 0998-UC-0800-36- CARDIOSAVE HYBRID - TYPE "N" PLUG

0998-00-0800-45/ 0998-UC-0800-45- CARDIOSAVE HYBRID, TYPE I PLUG

0998-00-0800-52 / 0998-UC-0800-52- CARDIOSAVE HYBRID, TYPE G PLUG

0998-00-0800-53 / 0998-UC-0800-53- CARDIOSAVE HYBRID, TYPE B PLUG

0998-00-0800-55 / 0998-UC-0800-55- CARDIOSAVE HYBRID W/ E/F PLUG

0998-00-0800-65 / 0998-UC-0800-65- CARDIOSAVE HYBRID, 3.1 EDITION

0998-00-0800-75 / 0998-UC-0800-75- CARDIOSAVE RESCUE, CHINESE

0998-00-0800-83 / 0998-UC-0800-83- CARDIOSAVE RESCUE

0998-00-0800-85 / 0998-UC-0800-85- CARDIOSAVE RESCUE, 3.1 EDITION

FAX BACK TO: (XXX) XXX-XXXX or EMAIL TO: XXXXXXXX@getinge.com

DISTRIBUTION DATES: Since March 06, 2012

ADD ACCOUNT#
[FACILITY NAME
STREET ADDRESS

CITY, STATE, ZIP CODE]

Please acknowledge that you have read and understand this Medical Device Recall 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:_____

Title:_____ Department:_____

Hospital Name:_____

Address, City and State:_____

Return the completed form by FAX to (XXX) XXX-XXXX or by EMAIL to XXXXXXXX@getinge.com

Appendix A

Updated High Priority Alarm

Blood Suspected – Check Catheter and Tubing

A perforation of the balloon membrane is suspected. Check for evidence of blood in the tubing. If any blood is visualized or perforation is suspected, perform the following procedure.

1. Disconnect the catheter extender tubing from the IABP console to allow the balloon to deflate.
2. Clamp extracorporeal tubing between white y-fitting and male connector.
3. Notify physician and prepare for IAB catheter removal.
4. Consider IAB catheter replacement if the patient's condition warrants.
5. If blood is suspected of having entered the pump, take pump out of service. It should be evaluated before use in another patient by Biomed/Technical Service to determine if replacement of contaminated components is necessary.

If blood is not visualized, perform the following procedure.

1. Turn the IABP OFF by pressing and holding the green IABP Power Button for 2 seconds.
2. Wait 10 seconds, then turn the IABP ON by pressing and releasing the green IABP Power Button.
3. Press the START key to fill the IAB catheter and resume pumping.
4. If another "Blood Suspected - Check Catheter and Tubing" alarm is activated, there is a likelihood the IAB is perforated even if blood is not seen in the catheter tubing. Therapy should be stopped or the IAB catheter replaced as deemed appropriate by the clinician.

When the IAB catheter is replaced, and blood is not suspected of entering the IABP console, perform the following procedure.

1. Turn IABP OFF by pressing and holding green IABP Power Button for 2 seconds.
2. Wait 10 seconds, then turn the IABP ON by pressing and releasing the green IABP Power Button.
3. Press the START key to fill the IAB catheter and resume pumping.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: While the system was evaluating for an IAB perforation, a pressure change in the balloon membrane was detected.
System Response: Vent / IAB deflated.
Reset: Attempt to clear by cycling power OFF and ON.

NOTE

The length of time a balloon membrane can survive such contact with plaque or unusual folding is unpredictable. A leak in an IAB catheter within the bloodstream may allow gas to enter the patient's bloodstream which may result in patient injury. Large perforations are rare, therefore the small quantity of gas released is usually asymptomatic. The rate of incidence at each individual hospital may be influenced by the degree of vascular disease in that patient population, by the location of the IAB catheter in the aorta, or by using a balloon membrane size inappropriate for the specific patient.

New Technical Alarm:

Pump Failure - Service Required

IABP inoperable. This may be caused by blood entering the IABP console.
If blood is seen in extracorporeal tubing and/or catheter extender tubing:

1. Disconnect the catheter extender tubing from the IABP console to allow the balloon to deflate.
2. Clamp extracorporeal tubing between white y-fitting and male connector.
3. Notify physician and prepare for IAB catheter removal.
4. Consider IAB catheter replacement if the patient's condition warrants.
5. Remove pump from service and have it evaluated by Biomed/Technical Service before using it on another patient.
6. The IABP cannot be used on another patient until serviced.

IABP inoperable. If blood is NOT seen in extracorporeal tubing and/or catheter extender tubing:

1. Therapy may continue with a replacement IABP.
2. Remove affected pump from service and have it evaluated by Biomed/Technical Service before using it on another patient.
3. The IABP cannot be used on another patient until serviced.

Alarm Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: An error has been identified in the balloon vent system, possibly due to contamination by blood or fluids.
System Response: Pneumatic Module is vented to atmosphere / IAB deflated. Service is required. Once IABP has powered down, IABP will display "Power-Up Test Fails Code #___" and will be unavailable for clinical use.
Reset: Message is cleared once corrective service is performed.

NOTE

The length of time a balloon membrane can survive such contact with plaque or unusual folding is unpredictable. A leak in an IAB catheter within the bloodstream may allow gas to enter the patient's bloodstream which may result in patient injury. Large perforations are rare, therefore the small quantity of gas released is usually asymptomatic. The rate of incidence at each individual hospital may be influenced by the degree of vascular disease in that patient population, by the location of the IAB catheter in the aorta, or by using a balloon membrane size inappropriate for the specific patient.

New Inforrmational Messages

Checking for Balloon Perforation

1 IABP is evaluating the IAB catheter and tubing for loss of helium.

2 If a loss of helium is suspected, a check for balloon perforation will be completed.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The System is performing a check for IAB leaks upon entry into the Standby state, or catheter alarms have detected a condition that may indicate that a potential leak in the system occurred.
System Response: IAB deflated.
Reset: When the leak check is completed or the IAB FILL or START key is pressed.

No Balloon Perforation Detected

1 The balloon is without evidence of perforation.

2 If "Gas Loss in IAB Circuit" occurred, Press and Hold the IAB FILL key for 2 seconds.

3 Then press START to resume pumping.

or

4 For all other alarms - Press START to resume pumping.

Message Attributes:
Operation Mode: All
Trigger Source: All
Detailed Cause: The IAB leak check has determined there is no leak in the IAB.
System Response: IAB deflated.
Reset: Entry into Assist mode