[Month DD, YYYY]

MEDICAL DEVICE CORRECTION UPDATE
FSCA 2249723-06/02/2023-013-C / OT 848212
Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP) System Over Temperature Field Action

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

Distributed Affected Serial Number:	**All**

Manufacturing Dates:	**Since December 2011**
Distribution Dates:	**Since March 06, 2012**

Dear Risk Manager,

In July 2023 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 an increase in "System Over Temperature" alarms. Today's letter reproduces the information provided in the July 2023 notice related to this issue, with minor revisions for clarity and provides new information on how to receive a recently released Cardiosave hardware update designed to reduce the occurrence of this issue.

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.

Identification of the issue:

Datascope received complaints where users reported Cardiosave IABP "System Over Temperature" alarms were associated with a loss of pumping and/or the Cardiosave system entered Standby mode. Since January 2021 there were reports of 4 deaths and 4 serious injuries associated with this issue. During our investigation, Datascope determined the deaths associated with the reported events were not attributed to the Cardiosave IABP. The reported Serious Incidents associated with the complaints did result in hemodynamic instability in some instances due to the therapy interruption.

Risk to Health:

Should the IABP internal temperature exceed a threshold of 80° C, the Cardiosave interrupts therapy by placing the pump in Standby and notifies the User of the event. Although the User is notified of the event by both audible and visual notification, the resulting standby mode is sudden and requires immediate User intervention address the clinical needs of the patient. It may be determined that therapy can be discontinued or an alternative IABP or supportive therapy are necessary to support the patient.

Following a System Over Temperature alarm, once the Cardiosave has had time to cool sufficiently therapy can be re-initiated after restarting the system. However, due to various conditions that can potentially cause a system over temperature event, there is no anticipated length of time required for a console to cool sufficiently to permit a console restart. Unless the condition(s) which caused the overheating are resolved, the affected IABP remains vulnerable to a failed restart or subsequent system over temperature events. As such, if the IABP is unable to restart or another system over temperature event occurs with the same IABP, the User must obtain another IABP console to provide therapy.

Should an alternate IABP console not be available for use, pharmaceutical support may be provided to stabilize the hemodynamic status of the patient. Should a prolonged period of therapy interruption result, an alternative treatment course may be pursued including the application of

alternate Mechanical Circulatory Support (MCS) therapies. For those patients receiving counterpulsation therapy within the transport environment, should a "System over temperature" alarm not be resolved (i.e. console cooled sufficiently to resume therapy) the clinician's resources are limited to those available in route. There is potential for injury if therapy may not resume and the resources available not sufficient to meet the hemodynamic needs of the patient.

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. If alternative support measures are unavailable or ineffective until therapy can be resumed, therapy interruption can lead to death.

User Actions to be taken:

When a System Over Temperature alarm is triggered, the device must be powered down and allowed to cool to a safe operating internal temperature before therapy can be re-initiated using the same IABP.

Should you experience a System Over Temperature of Cardiosave IABP during therapy, perform the following instructions documented in CARDIOSAVE Hybrid and Rescue Instructions for Use:

1. Turn the IABP OFF by pressing and holding the green IABP Power Button, located on the back panel, for 2 seconds
2. Wait 10 seconds
3. Turn the IABP ON by pressing and releasing the green IABP Power Button

If the alarm message persists, switch to another IABP if available and contact your Service representative. If 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.

During hospital use, it is advised that a back-up Cardiosave IABP be available to provide therapy should a Cardiosave IABP become unavailable unable to deliver therapy for any reason. It is advised not to transport a patient receiving counterpulsation therapy via Cardiosave unless the clinician deems the benefit of transport outweighs the risk of an unexpected shutdown.

To help prevent system over-temperature alarms from occurring, ensure that there are no restrictions to the airflow around the Cardiosave device. Restrictions to the vents on the device can significantly increase the internal temperature of the device, leading to such temperature excursions. Additionally, as per CARDIOSAVE Hybrid and Rescue Operational Instruction, it is essential not to operate the Cardiosave device outside of the posted operating ambient ranges. This is to prevent such temperature excursions and ensure the safe and effective use of the

device. Therefore, it is important to follow the manufacturer's instructions carefully and take appropriate precautions to ensure the proper ventilation and temperature control around the Cardiosave device.

7.12 ENVIRONMENTAL REQUIREMENTS

⚠ WARNING:

The CARDIOSAVE has not been tested for safe, effective, and/or intended performance at altitudes below sea level.

⚠ CAUTION:

After being stored at low temperature, allow CARDIOSAVE to be exposed to room temperature for at least 30 minutes before operating on battery power.

7.12.1 CONTINUOUS OR TRANSPORT OPERATING AMBIENT

Operating Temperature:	10 °C to 40 °C (50 °F to 104 °F)
Operating Humidity:	15% to 85% Relative Humidity (non-condensing)
Operating Altitude:	0 feet to 12,000 feet (760 mmHg to 483 mmHg) (1,013 hPa to 644 hPa)

Note:
In nature, the range of humidity specified is not found for all specified temperatures. Performance shall be verified at discrete temperature and humidity combinations per "ECRI -PB- 296 892" guidelines.

7.12.2 TRANSIENT OPERATING AMBIENT

Operating Temperature:	10 °C to 40 °C (50 °F to 104 °F)
Operating Humidity:	15% to 85% Relative Humidity (non-condensing)
Operating Altitude:	0 feet to 12,000 feet (760 mmHg to 483 mmHg) (1,013 hPa to 644 hPa)

Note:
In nature, the range of humidity specified is not found for all specified temperatures. Performance shall be verified at discrete temperature and humidity combinations per "ECRI -PB- 296 892" guidelines.

Further, please ensure that there are no restrictions to the airflow around the Cardiosave device. Restrictions to the vents on the Cardiosave can significantly increase the internal temperature of the device.

CAUTION:

Do not operate the unit with the ventilation or speaker vents obstructed.

CAUTION:

This product requires scheduled preventative maintenance in order to maintain its specified performance. Note that maintenance includes periodic cleaning to assure that proper cooling airflow of the system's electronics is maintained.

Actions to be taken by Datascope/Getinge:

Update Information: Datascope/Getinge has designed and released a hardware kit to update the Cardiosave Hybrid and Rescue IABPs to dissipate heat generated from internal components. A local Datascope/Getinge representative will contact your facility to arrange an on-site visit to perform the hardware update for your Cardiosave IABP at no cost to you.

For more information, or if you have any questions, please contact Getinge Technical Support at the following:

Insert SSU Contact Information

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 **OT848212 MEDICAL DEVICE CORRECTION UPDATE RESPONSE FORM** (page X) to acknowledge that you have received this notification. Return the completed form to Datascope/Getinge by e-mailing a scanned copy to XXXXXXXX@getinge.com or by faxing the form to (XXX) XXX-XXXX.

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

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 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. (XX 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

[Month DD, YYYY]

OT848212 MEDICAL DEVICE CORRECTION UPDATE RESPONSE FORM

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

System Over-Temperature Field Action

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

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

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

0998-UC-0800-32- CARDIOSAVE HYBRID TYPE J PLUG- Refurbished

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

0998-UC-0800-33- CARDIOSAVE HYBRID TYPE D PLUG- Refurbished

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

0998-UC-0800-34- CARDIOSAVE HYBRID TYPE K PLUG- Refurbished

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

0998-UC-0800-35- CARDIOSAVE HYBRID TYPE M PLUG- Refurbished

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

0998-UC-0800-36- CARDIOSAVE HYBRID - TYPE "N" PLUG- Refurbished

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

0998-UC-0800-45- CARDIOSAVE HYBRID, TYPE I PLUG- Refurbished

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

0998-UC-0800-52- CARDIOSAVE HYBRID, TYPE G PLUG- Refurbished

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

0998-UC-0800-53- CARDIOSAVE HYBRID, TYPE B PLUG- Refurbished

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

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

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

0998-UC-0800-65- CARDIOSAVE HYBRID, 3.1 EDITION- Refurbished

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

0998-UC-0800-75- CARDIOSAVE RESCUE, CHINESE- Refurbished

0998-00-0800-83- CARDIOSAVE RESCUE

0998-UC-0800-83- CARDIOSAVE RESCUE- Refurbished

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

0998-UC-0800-85- CARDIOSAVE RESCUE, 3.1 EDITION- Refurbished

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

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 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