November 15, 2021 via FedEx

URGENT MEDICAL DEVICE CORRECTION

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

Product Description:	Product Code/Part Number:	UDI Code:
Cardiosave Hybrid	0998-00-0800-31	10607567109053
Cardiosave Hybrid	0998-00-0800-32	10607567111117
Cardiosave Hybrid	0998-00-0800-33	10607567109008
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	10607567108438
Cardiosave Hybrid	0998-00-0800-53	10607567108391
Cardiosave Hybrid	0998-00-0800-55	10607567108414
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 Serial Number(s):	All	
Manufacturing Dates:	Since December 2011	
Distribution Dates:	Since March 6, 2012	

Dear Risk Manager,

Datascope/Getinge is initiating a voluntary Medical Device Correction for the Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) due to the possibility of fluid ingress. Fluid entering the Cardiosave IABP may short various electronic components thus leading to system shutdown.

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

Identification of the issue:

Datascope/Getinge determined that the exterior of the Cardiosave Hybrid and Rescue IABP may be susceptible to fluid ingress at specific locations on the device. IABPs contain various electronic circuit boards. Liquid spills, such as saline, can create bridges of resistance between the circuit components; causing the circuit to not function as intended. This can impact initiation or continuation of counterpulsation therapy.

Datascope/Getinge had previously issued an Urgent Medical Device Correction letter on April 26, 2018 to install a Top Protective Cover for the Cardiosave Hybrid IABP to help reduce the potential for fluid ingress. However, in some instances and depending on the volume of spill, this Top Protective Cover can overflow and fluid can enter the device in other susceptible areas.

Risk to Health:

Failure to start or sudden interruption of therapy due to system shutdown could result in unsafe, hemodynamic instability. The potential for prolonged interruption to therapy and any resulting hemodynamic instability attributed to a spillage event is mediated by both the availability of temporizing measures to the clinician and the ability to exchange the impacted IABP console with another. The population(s) greatest at risk however, include those more clinically vulnerable to changes in support, or those within the transport environment. Transport personnel have limited access to temporizing measures, alternative therapies, or additional IABP console to address any therapy interruption.

As of October 27, 2021 there have been no adverse events reported to Datascope/ Getinge resulting in serious illness or injuries caused by fluid ingress since implementation of the Top Protective Cover.

Actions to be taken by the User:

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. A correction will be available in 2022. In the meantime, please continue to follow the IFU and adhere to the following instructions when using the Cardiosave Hybrid and/or Rescue IABP:

- Per the Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) Operating/User Instructions: “Caution: Never place fluids on top of this unit. Make sure that the saline container and tubing do not hang directly over the IABP. In case of accidental spillage, wipe clean immediately and have the unit serviced to ensure no hazard exists”.
- Per the Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) Operating/User Instructions: “The Plastic Weather Display and Rescue Cover is an accessory designed to protect the Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) in transport configuration from ingress of liquids during a transport situation. The cover is designed to fit over the Pump Console and Display while still allowing access to the pull handle, and maintaining visibility of the Monitor and Touchscreen. The Plastic Weather Display and Rescue Cover is to be used any

time the Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) is used outdoors, especially when there is the possibility of wet weather."

In the unlikely event that a sudden interruption of therapy occurs, transfer the patient to an alternative IABP. If an alternative IABP is unavailable; manually inflate the IAB with air or helium and immediately aspirate, repeat every 5 minutes until either an alternate IABP is available or alternatively, the intra-aortic balloon catheter should be removed from the patient. The Intra-Aortic Balloon (IAB) Catheter Instructions for Use reinforces that "The IAB catheter should not remain inactive (i.e. not inflating and deflating) for more than 30 minutes because of the potential for thrombus formation."

Please refer to the intra-aortic balloon catheter instructions for use and Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) Operating/User Instructions, for further information. The patient should be treated according to your facility's treatment protocols and caregivers' clinical judgment to ensure hemodynamic stability.

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.

Please complete and sign the attached MEDICAL DEVICE Correction - RESPONSE FORM (Page 5) to acknowledge that you have received this notification. Return the completed form to Datascope/Getinge by e-mailing a scanned copy to cardiosavefluid21.act@getinge.com or by faxing the form to 1-866-843-8614.

Type of Action by the Company:

Due to the limited protection of the Top Protective Cover, Datascope/Getinge is taking additional measures to enhance the Cardiosave Hybrid and Rescue IABP ingress protection while in the cart or in transport mode. These measures include various internal and external component upgrades that will be made available in an Ingress Prevention Upgrade Kit. Customers will also receive redesigned Display and Rescue Covers for the Cardiosave transport console.

When the Ingress Prevention Upgrade Kits are available, anticipated in 2022, a Datascope/Getinge service Representative will contact you about scheduling the installation of the Ingress Prevention Upgrade Kit, which includes a variety of upgraded components to protect the Cardiosave Hybrid and/or Rescue IABP(s). Additionally, you will be contacted by a trained Representative for training on the installation of the Display and Rescue Covers for your affected unit. This work will be done at no cost to your facility.

All existing Cardiosave Hybrid and Rescue IABPs will be eligible for this field upgrade. In addition, all newly purchased affected Cardiosave Hybrid and Rescue IABPs will also receive the Display and Rescue Covers with training by a trained representative and the pump will be upgraded during installation by a Datascope/Getinge Representative. Once the Ingress

Prevention Upgrade and Display and Rescue Covers are available (anticipated in 2022) all Cardiosave Hybrid and Rescue IABPs will be manufactured and shipped with the upgrade and covers.

This voluntary Medical Device Correction only affects the products listed on page 1; no other products are affected by this voluntary Medical Device 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,

Allison Jean Kaplan

Specialist II, Regulatory Affairs and Field Action Compliance