December 19, 2022

via FedEx

URGENT MEDICAL DEVICE CORRECTION

MAQUET CARDIOSAVE Hybrid and MAQUET CARDIOSAVE Rescue

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 increased risks to patients should blood within a perforated IAB catheter enter the IABP console. In addition to the risk of gas emboli from a perforated balloon catheter, an unexpected shutdown may occur. We are aware of other events of blood entering the device not leading to an unexpected shutdown, and we are continuing to investigate these events.

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The Cardiosave Intra-Aortic Balloon Pump is an electromechanical system used to inflate and deflate intra-aortic balloons. It provides temporary support to the left ventricle via the principle of counter pulsation as stated in the Instructions For Use.

Identification of the issue:

Datascope/Getinge has received complaints reporting unexpected shutdown of the Cardiosave IABP while providing therapy in very rare instances. 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 intra-aortic balloon catheter.

Datascope/Getinge has received 134 reported incidents of blood entering the Cardiosave console over a four year period (October 2018 through November 23, 2022). 12 of those detailed an unexpected shutdown. From those 12 complaints, five adverse events were reported including four serious injuries and one death.

Risk to Health:

A perforation of an IAB introduces risk to the patient, and blood may be permitted to enter the catheter and extender tubing. A perforated balloon may permit the release of helium into patient's blood stream, and should therapy continue using a perforated balloon, the patient may experience a gas emboli. The amount of blood that may enter the IAB catheter and travel into the Cardiosave 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.

As documented in the Intra-aortic Balloon (IAB) Instructions For Use (IFU), the balloon 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, therapy is interrupted by the 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 IFU and educational materials). However, should the condition occur without the User or Cardiosave recognizing it, blood can travel the length of the extender tubing into the Cardiosave console, coming in contact with the pump's electrical components.

The Cardiosave is able to accommodate a small volume of blood without shutting down. However, should that volume be exceeded and large quantities of blood from the IAB catheter enter the IABP console and contact the internal electrical components, pump function will be impacted, and an unexpected shutdown may occur. Despite the console's ability to accommodate some blood all attempts must be made to limit blood from entering the pump console.

In instances of unexpected shutdown, the user is not forewarned, the screen abruptly turns off, no further instruction or status is available to the User, and a high pitched alarm is emitted. If the unit is already powered down before blood enters the console, the Cardiosave will not alarm and may not start on the next power up attempt.

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

- An unexpected shutdown due to a blood back event may threaten the hemodynamic stability of the supported patient as the User is left unaware to the status of the Cardiosave. 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.

Datascope/Getinge anticipates updating guidance within the Cardiosave Intra-Aortic Balloon Pump Operating Instructions and IAB Instructions for Use. Until the respective Instructions For Use are updated, the above alarm information and guidance below should be adhered to:

**** IMMEDIATE CLINICAL GUIDANCE ****

Cardiosave identifies perforated balloons based on the shuttle gas (helium) pressure within the IAB catheter and catheter tubing. Monitoring of gas pressure occurs during both routine operation and every two hours during a helium replacement cycle (or "autofill"). Should blood be suspected during an autofill, the "Autofill failure – Blood Suspected" alarm is posted. **Outside of an autofill period, however, there are other IAB alarms that may also indicate balloon perforation. Do not bypass these alarms, and please pay close attention to the alarm notifications listed below, as these alarms may help identify a perforated balloon earlier, preventing any blood from traveling into the IABP:**

- Autofill Failure – Blood Suspected
- Autofill Failure
- Gas Gain in IAB Circuit
- Gas Loss in IAB Circuit
- IAB Catheter Restriction

Periodically check the IAB catheter tubing for blood both throughout therapy and when the above alarms occur. If any blood is noted or perforation is suspected, the following procedure must be performed immediately:

1. Stop pumping by placing IABP console in Standby.
2. Disconnect the catheter extender tubing from the IABP console to allow the balloon to deflate.
3. Clamp extracorporeal tubing between white y-fitting and male connector.
4. Place the patient in Trendelenburg as tolerated to guide any residual helium to travel away from the head vessels.
5. Notify physician, and prepare for IAB catheter removal.
6. Consider IAB catheter replacement, if the patient's condition warrants.
7. 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 are necessary.

This guidance is meant to augment current clinical recommendations of patient management strategies should an IAB perforation occur. Maintain established patient and device management strategies regarding timing to IAB catheter removal.

User Actions to be taken:

- 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.
- If a blood back event is suspected, clinicians are to remove the Cardiosave from patient use, and report the event to appropriate biomedical engineering staff for inspection of the safety disk prior to next patient use.
- Please ensure that all Cardiosave Intra-Aortic Balloon Pump users at your facility are aware of this notice and actions to perform.
    - Distribute the above clinical guidance to users per your institution policy.
- 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 cardiosavebloodback2022.act@getinge.com or by faxing the form to 1-877-690-5160.
- If you are a distributor who has shipped any affected products to customers, please forward this letter to their attention for appropriate action.

Actions to be taken by Datascope/Getinge

Datascope/Getinge is in the process of developing an addendum to the Cardiosave IABP and IAB Instructions For Use to document new warning(s) / action(s) to be taken by the User to minimize the risk of harm caused by blood entering the system. Upon completion, it is anticipated the addendum will be released with all new products, and distributed via Datascope/Getinge's website.

Furthermore, as complaints are continuously monitored and evaluated, Datascope/Getinge may develop longer term design solutions to address unexpected shutdowns caused by blood entering the system.

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 the 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