February 28, 2023 via FedEx

URGENT MEDICAL DEVICE CORRECTION

Datascope CARDIOSAVE Hybrid IABP, CARDIOSAVE Rescue IABP, Safety Disks, and Pneumatic Interface Module (PIM)

Product Description:	Product Code/Part Number: UDI Number:	Distributed Affected Serial Number:	Manufacturing Dates:	Distribution Dates
Cardiosave Hybrid	0998-00-0800-31 10607567109053	See *Note below	See *Note below	See *Note below
Cardiosave Hybrid	0998-00-0800-32 10607567111117			
Cardiosave Hybrid	0998-00-0800-33 10607567109008			
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			
Safety Disk	0202-00-0140	ALL	April 01, 2022 to July 31, 2022	April 07, 2022 to August 25, 2022
Pneumatic Interface Module (PIM)	0997-00-1178	ALL	May 05 , 2022 to July 21, 2022	June 23, 2022 to July 21, 2022

***Note:** This Field Safety Corrective Action applies to any Cardiosave IABPs containing a Safety Disk that was manufactured between the following dates April 01, 2022 – July 31, 2022. The Safety Disk may be installed at the time of manufacture in devices produced between April 08, 2022 and Sep 20, 2022, or may have been installed as the result of repair or preventive maintenance.

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

Dear Risk Manager,

This is a new recall, separate from the earlier reported recall involving four (4) issues regarding unexpected shutdown and helium leaks. Datascope Corp., a subsidiary of Getinge is initiating a voluntary Medical Device Correction for the Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP), Safety Disks, and PIMs, due to the Safety Disk not meeting a performance requirement that may result in the reduction of Intra-Aortic Balloon catheter (IAB) displacement volume by up to 3.6%.

Identification of the issue:

Datascope/Getinge has identified that, while conducting Safety Disk testing, expired tubing was used on the test fixture equipment between April 01, 2022 and July 31, 2022. This may have led to non-conforming Safety Disks inappropriately passing the test. The test referenced measures the displacement volume provided by the Safety Disk. Testing is conducted to ensure each Safety Disk manufactured by Datascope/Getinge meets the requirement. PIMs are included in the scope of this recall as PIMs contain Safety Disks.

There have been no complaints reported related to this issue.

Risk to Health:

This potential failure of an impacted Safety Disk may lead to slightly reduced IAB inflation during therapy or a reduction in the degree of augmentation provided to the patient during therapy. Decreased IAB inflation or augmentation may result in decreased levels of support with or without hemodynamic instability or decreased cardiac output. As there is no direct means of the clinician assessing the Safety Disk, the User remains unaware of any reduced performance. Further it is difficult to assess given the many patient conditions, such as elevated heart rate that may contribute to a decrease in augmentation.

Engineering Assessment

Despite the potential for volume displacement reduction, our assessment confirmed that an IABP with an affected Safety Disk continues to deliver counterpulsation safely, with no other mechanical system or safety feature impacted. Further, our assessment confirmed that an identified Safety Disk continues to meet the anticipated displacement volume for therapy delivery up to 100 beats per minute. However, for those instances when the rate of therapy is sustained between 100-130 beats per minute for three consecutive hours, there was a reduction of up to, but not greater than 3.6% volume displacement. Given the wide variety of clinical conditions in which counterpulsation therapy is utilized, a reduction in volume displacement of 3.6% will translate differently amongst patients and as such, direct clinical translation cannot be predicted.

User Actions to be taken:

A review of our records indicate that you may have a Cardiosave IABP at your facility with an affected Safety Disk or affected spare Safety Disks or PIM assembly installed recently into Cardiosave IABP.

1. Please examine your inventory immediately to determine if you have any Cardiosave IABPs with the affected Safety Disks and/or PIM, or any affected Safety Disk and/or PIM assembly spare parts, per attachment 1.

2. You may continue to use any affected IABPs until replacement parts are installed. Please keep in mind the potential health risks cited above, particularly with prolonged heart rates above 100 beats per minute for three consecutive hours. When transporting patients outside the hospital environment, consider using an unaffected console if available.

3. Should you have any unused affected spare parts of the Safety Disk or PIM Assembly in your inventory, please remove them from areas of use and contact your local Datascope/Getinge Customer Service department at 888-9GETUSA (888 943-8872) to request a return authorization (RMA) and shipping instruction to return the affected product for credit.

4. If you installed an affected spare part into one of your IABPs the Safety Disk will need to be replaced.

5. If you purchased spare parts and they are no longer in your inventory and you are unsure of their location, please contact Getinge Service. Getinge Service will schedule an on-site visit to inspect your IABP/(s) at no cost to your facility.

6. Should you have any affected Cardiosave IABPs you will be contacted by a Getinge Service Representative to schedule an on-site visit to replace the Safety Disk, free of charge. You can also arrange a visit by a Getinge trained or authorized service technician by contacting Getinge Technical Support at (888) 943-8872 (select option 4,2,1), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone).

7. Please note that given our current supply chain shortages we are unable to commit to a timely replacement of your affected safety disk.

8. 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 SafetyDisk2022.act@getinge.com or by faxing the form to 1-866-271-5024.

9. Please forward this information to all current and potential Cardiosave IABP users within your hospital/facility.

10. If you are a distributor who has shipped any affected products to customers, please forward this letter to their attention for appropriate action.

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

Actions to be taken by Datascope Corp./Getinge:

Getinge/Datascope is in the process of implementing the field action correction to replace the affected Safety Disk.

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