February 7, 2023 via FedEx

URGENT MEDICAL DEVICE CORRECTION

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

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 four issues that could affect IABP performance:

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

Issue 1:
An unexpected shutdown of the IABP may occur due to a failure of the connection between the Coiled Cord cable (part number 0012-00-1801) and the Cable Assembly backplane (part number 0012-00-1796) to the Coiled Cord cable which provides the communication between the display head and base unit. Please refer to images below under Issue 1 for reference.
NOTE: This issue is limited to units distributed March 6, 2012 through July 24, 2017

Issue 2:
An unexpected shutdown of the IABP may occur due to the loss of communication between the Executive Processor PCBA and the Video Generator PCBA.

Issue 3:
There have been reported failures of the high pressure helium regulator which may cause a helium leak in the Cardiosave Hospital Cart. The high pressure helium regulator is located in the Cardiosave Hospital Cart and regulates the helium pressure of the external helium supply. In instance of helium regulator failure, a Pump Console's internal reservoir of helium will not be replenished when docked into an impacted Hospital Cart. This may result in an insufficient amount of helium within the internal reservoir. Please refer to images under Issue 3 for reference.

Issue 4:
There have been reports of damaged, worn, or torn O-rings on the Cardiosave Pump Console quick disconnect fitting resulting in helium tank leaks. The quick disconnect fitting is the point of connection that permits the refilling of the Pump Console's internal helium reservoir when the Pump Console is docked in the Hospital Cart. Please refer to images below under Issue 4 for reference.

Issue 1: Unexpected shutdown due to failure of the Coiled Cord cable and Cable Assembly backplane to Coiled Cord cable

Identification of the issue:
Datascope/Getinge has received complaints reporting Cardiosave IABPs unexpectedly shutting down.

An internal investigation of the complaints determined an unexpected shutdown may be due to damaged Coiled Cable Cords [part numbers 0012-00-1801 and 0012-00-1796] that provide bidirectional communication between the display head and base unit. Please refer to images below for reference.

Datascope/Getinge has received 25 reported complaints of damaged Coil cords resulting in unexpected shutdown over a 2 year period.

There have been 0 adverse events reported.

Risk to Health:
An unexpected shutdown and resulting interruption to therapy may threaten the hemodynamic stability of the supported patient.

User Actions to be taken now:

1. Prior to use of the Cardiosave IABP, inspect the coiled cable cord to ensure that there is no visible damage.

Old Pump Console Coiled Cord Connection:

New Pump Console Coiled Cord Connection:

Figure 1: Representative picture of both the old and new Coiled Cable cord design.

2. Should you experience an unexpected shutdown of the Cardiosave IABP during therapy, utilize another IABP to continue therapy. Until an alternative IABP is located you may attempt to restart the IABP. If the IABP remains non-operational, immediately remove from the patient care environment for further product evaluation.
3. If your device remains inoperable, please contact your service representative to identify the cause and take the necessary actions required.

Type of Action by the Company:

Datascope/Getinge has developed a hardware correction to address this issue. It is important to note that this issue is limited to units distributed prior to July 24, 2017. A Datascope/Getinge service representative will contact you to schedule the installation of the correction if your unit is affected as the correction kit becomes available. This work will be done at no cost to your facility.

Issue 2: Unexpected Shutdown due to loss of communication between the Executive Processor PCBA and the Video Generator PCBA.

Identification of the issue:
As part of an ongoing investigation into unexpected shutdown of the Cardiosave IABP, the Datascope/Getinge Investigation team determined there is a correlation between unexpected shutdown complaints and the loss of communication between the Executive Processor PCBA and the Video Generator PCBA. The loss of communication results in the IABP displaying error code 111 and error code 112.

Code 111: A local Virtual Address Space (VAS) Watch Dog Timer (WDT) Failure
Code 112: A main application Watch Dog Timer (WDT) Failure

Datascope/Getinge has received 28 reported complaints of Code 111 and/or Code 112 occurrences resulting in unexpected shutdown over a 2 year period.

There have been 0 adverse events reported.

Risk to Health:
An unexpected shutdown and resulting interruption to therapy may threaten the hemodynamic stability of the supported patient as the user is left unaware to the status of the Cardiosave IABP.

User Actions to be taken now:
1. Should you experience an unexpected shutdown of Cardiosave IABP during therapy, or a present frozen or black screen, utilize another IABP to continue therapy. Until an alternative IABP is located you may attempt to restart the IABP. If the IABP remains non-operational, immediately remove from the patient care environment for further product evaluation.
2. If your device remains inoperable, please contact your service representative to identify the cause and take the necessary actions required.

Type of Action by the Company:
Datascope/Getinge is developing a software correction to address this issue. Once available, a Datascope/Getinge service representative will contact you to schedule the installation of the updated software. This work will be done at no cost to your facility.

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

Issue 3: Leak in the High Pressure Helium Regulator

Identification of the issue:
There have been reported failures of the high pressure helium regulator which may cause a helium leak in the Cardiosave Hospital Cart. The high pressure helium regulator is located in the Cardiosave Hospital Cart and regulates the helium pressure of the external helium supply. In instance of helium regulator failure, a Pump Console's internal reservoir of helium will not be replenished when docked into an impacted Hospital Cart. This may result in an insufficient amount of helium within the internal reservoir. Please refer to images below for reference.

Datascope/Getinge has received 51 reported complaints of helium leak as a result of high pressure helium regulator failure over a 2 year period.

There have been 0 adverse events reported.

Risk to Health:
Should a Cardiosave's helium supply be depleted due to an impaired helium pressure regulator, therapy may be interrupted. 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. The risk of therapy interruption from a depleted helium supply is mitigated by the advanced notice provided to the User (a minimum of approximately 24 hours). The Pump Console's internal helium reservoir may be restored by utilizing another hospital cart or a helium refilling station. Should helium replacement not be feasible or another IABP console not be 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.

User Actions to be taken now:
1. During Installation and Replacement of the Helium Tank per the Cardiosave Operating Instructions, please ensure care is taken not to damage the helium tank or the helium tank yoke while inserting and/or removing the helium tank.
2. Please follow the instructions for use when changing the helium tank.

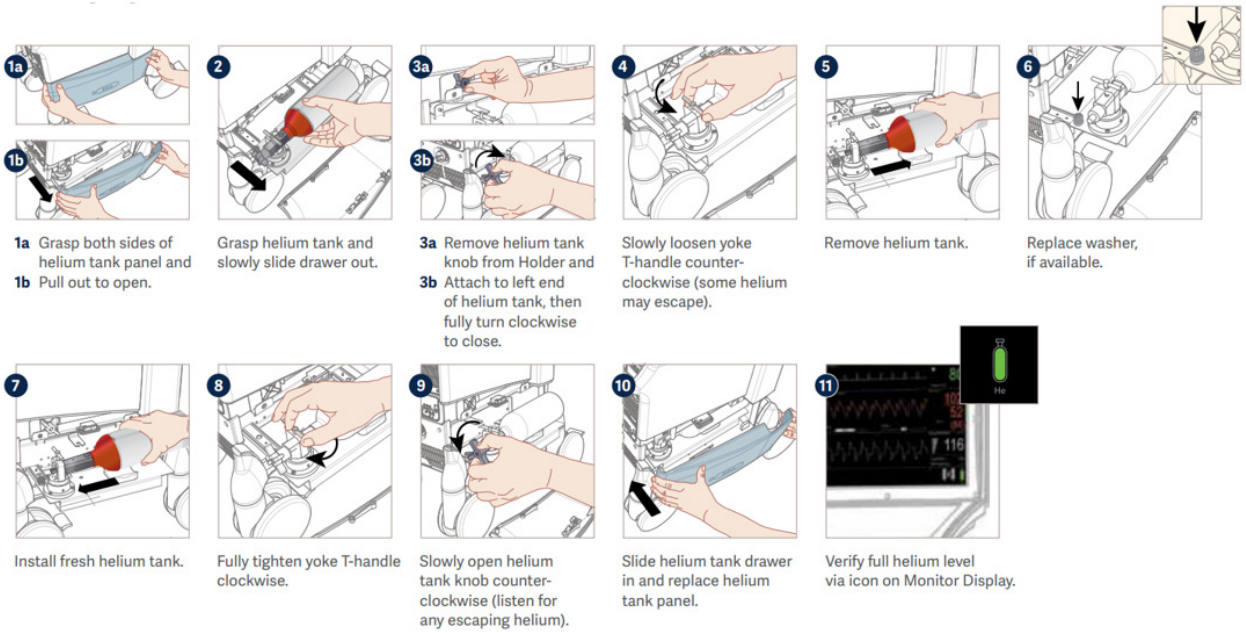

Figure 2: As pictured in **Cardiosave Hybrid and/or Rescue Operating Instructions**

3. If user observes any visual damage on High Pressure Regulator, please contact your Datascope/Getinge service representative.

Type of Action by the Company:

Datascope/Getinge is currently investigating this issue to determine root cause and will notify customers if additional action is to be taken to correct the issue.

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

Issue 4: Helium Leak at the Pump Console Quick Disconnect Fitting

Identification of the issue:
There have been reports of damaged, worn, or torn O-rings on the Cardiosave Pump Console quick disconnect fitting resulting in helium tank leaks. The quick disconnect fitting is the point of connection that permits the refilling of the Pump Console's internal helium reservoir when the Pump Console is docked in the Hospital Cart. Please refer to images below for reference.

Datascope/Getinge has received 51 reported complaints of helium leak as a result of damaged, worn, or torn O-rings over a 2 year period.

There have been 0 adverse events reported.

Risk to Health:
Should a Cardiosave's helium supply be depleted due to an impaired quick disconnect, therapy may be interrupted. 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. The risk of therapy interruption from a depleted helium supply is mitigated by the advanced notice provided to the User (a minimum of approximately 24 hours). The Pump Console's internal helium reservoir may be restored by utilizing another hospital cart or a helium refilling station. Should helium replacement not be feasible or another IABP console not be 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.

User Actions to be taken now:

1. If user observes any visual damage to the O-ring installed as part of the quick disconnect fitting, please contact your Datascope/Getinge service representative. If possible, remove the IABP from patient use until appropriate repairs can be made.

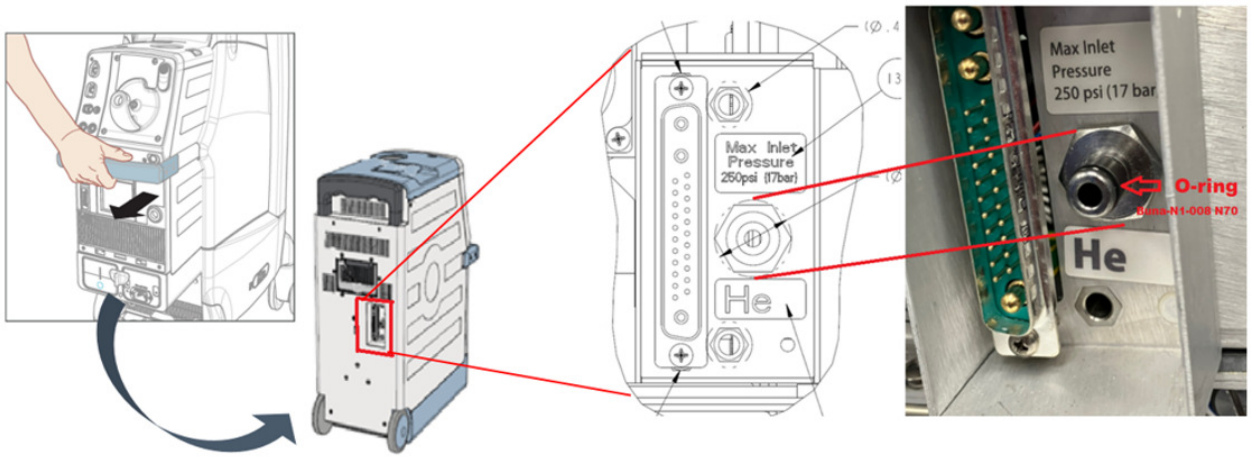

Figure 3: Drawings as pictured in **Cardiosave Hybrid and/or Rescue Operating Instructions**, along with a final picture of the O-ring as it appears on the unit.

Type of Action by the Company:

Datascope/Getinge is currently updating the annual Preventive Maintenance instruction to include replacement of the quick disconnect fitting O-ring.

Actions to be taken by the User related to all issues 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 MEDICAL DEVICE CORRECTION - RESPONSE FORM (Page 11) checking off each issue checkbox (1-4) to acknowledge that you have received and understand this notification. Return the completed form to Datascope/Getinge by e-mailing a scanned copy to cardiosave-sdhl23.act@getinge.com or by faxing the form to 1-877-660-5841.

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

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 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, Regulatory Affairs and Field Action Compliance
Getinge