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رؤية عمان 2040
Oman Vision

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoulia Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 182 dated 24/8/23 Regarding NCMDR Field Safety Corrective Action of Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP) from (mfr: Getinge).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



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نقدم بثقة
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Circular No. 182/2023

08 -02-1445 H

24 -08-2023

FSCA of Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP) from Getinge.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19658
Product	Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP).
Description	Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP).
Manufacturer	Getinge.
Local agent	Tiba Medserv.
The affected products	Refer to the attachment.
Reason	Issue 1: Docking/Power Battery Failure Issue 2: Poor or No ECG Signal Issue 3: Autofill Alarms Issue 4: Gas Loss & Gas Gain Alarms Issue 5: System Over-Temperature Issue 6: Fiber Optic Damage
Action	1. Please follow actions in the attachment that to be taken by the user related to these issues. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General



03rd August 2023

**URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE CORRECTION**

**FSCA 2249723-06/02/2023-009-C & FSCA 2249723-06/02/2023-012-C
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 Customer

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 the following two (2) identified system conditions:

Issue 1: Docking/Power Battery Failure

Issue 2: Poor or No ECG Signal

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.

Please note that according to the FDA, a Recall is a method of removing OR correcting products. A Correction is defined as a means to repair, modify or adjust a product without its physical removal. This particular correction does not require physical removal of the device. For your convenience, we are providing the link to the FDA website, which includes these definitions as well as other related information: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices>.

Issue 1: Docking/Power Battery Failure

Identification of the issue:

Datascope/Getinge has received 319 complaints over a two-year period (January 1, 2021 through December 31, 2022) where Cardiosave IABP users were reporting that the device was not charging as expected.

A detailed compliant investigation was performed where it was observed that there were 57 cases where users were unaware that the Cardiosave console was not completely inserted into the hospital cart. If the console is not fully inserted into the cart the IABP will not receive AC power and the battery(ies) will not charge. For the remaining complaint cases, Datascope/Getinge has open field actions where measures are being implemented to address the failure modes related to the remaining complaints.

One adverse event was reported which resulted in a patient death, however the customer does not attribute the patient's death to this device.

Risk to Health:

Should the Cardiosave not be seated in the cart properly, the device will not receive AC power and will run on the battery(ies). Therapy will be interrupted once the batteries are exhausted and if the user is unaware that the Cardiosave is not seated correctly. Interruption of therapy upon battery depletion will be unexpected, as the user will presume that the device is running on AC power. Additionally, if the Cardiosave is not seated in the cart properly, it will not receive AC power and the Cardiosave will not be able to charge the battery(ies) inserted.

If circumstances develop where the user must rely upon battery power alone to provide support (such as a transport situation), counterpulsation therapy may be interrupted. Restoring AC power by reseating the Cardiosave device into the cart properly or inserting alternative (charged) batteries can prevent therapy interruption.

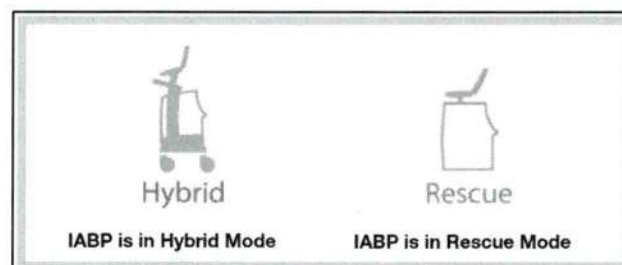
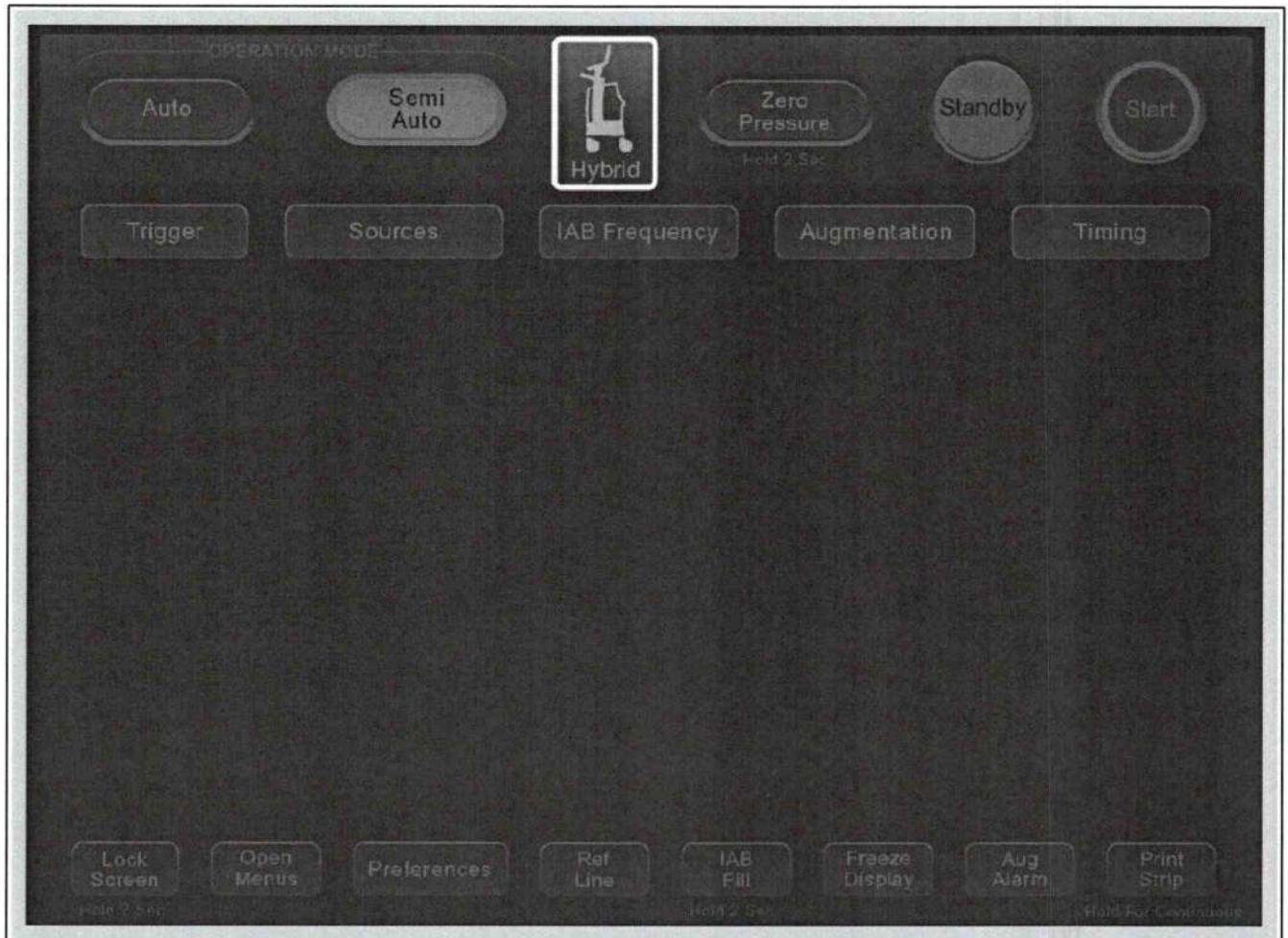
Should power not be re-established or another IABP console is not available for use, alternative means of providing hemodynamic support (vasopressors, inotropes or alternate therapies) may be initiated by a healthcare provider as a temporizing measure. If alternative supportive measures are unavailable or ineffective until therapy can be resumed, therapy interruption can lead to death.

User Actions to be taken now:

Our records indicate 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.

The Cardiosave device has two operating modes: Hybrid (docked within the hospital cart) and Rescue (transport). When in Hybrid mode the IABP may operate on both AC power and battery power; and when plugged in (AC power) can charge inserted batteries. When in Rescue (transport) mode, the IABP can operate on battery power, or AC Power with the use of the Transport Power Supply accessory (occupying a battery bay). However, unless the Cardiosave is powered off, the Transport Power Supply will not charge a battery inserted into the alternate battery bay unless the Transport Power Supply is connected directly to AC power.

The IABP Configuration Icon shows the current mode of configuration for the IABP, Hybrid (in the hospital cart) Mode or Rescue (transport) Mode. The icon is located at the top center of the IABP display screen.



There are two methods where the IABP can be in transport/rescue mode without user intent:

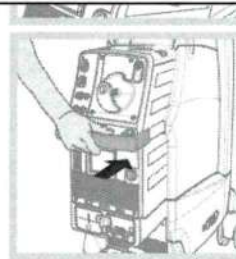
- 1) The Cardiosave Hospital Cart's release latch has been released and the IABP console is not properly installed in the cart.

1. Release the latch on the Hospital Cart located below the Pump Console.



- 2) The IABP console is inserted into the hospital cart, but is not fully latched into the cart

6. Grab the handle and slowly slide the Pump Console into the Hospital Cart until it locks into place. You will hear an audible click noise once the console is locking into the Hospital Cart.

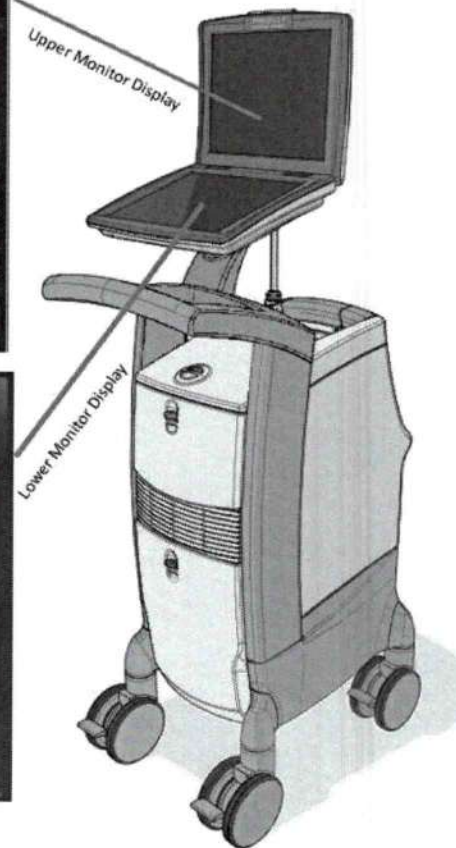
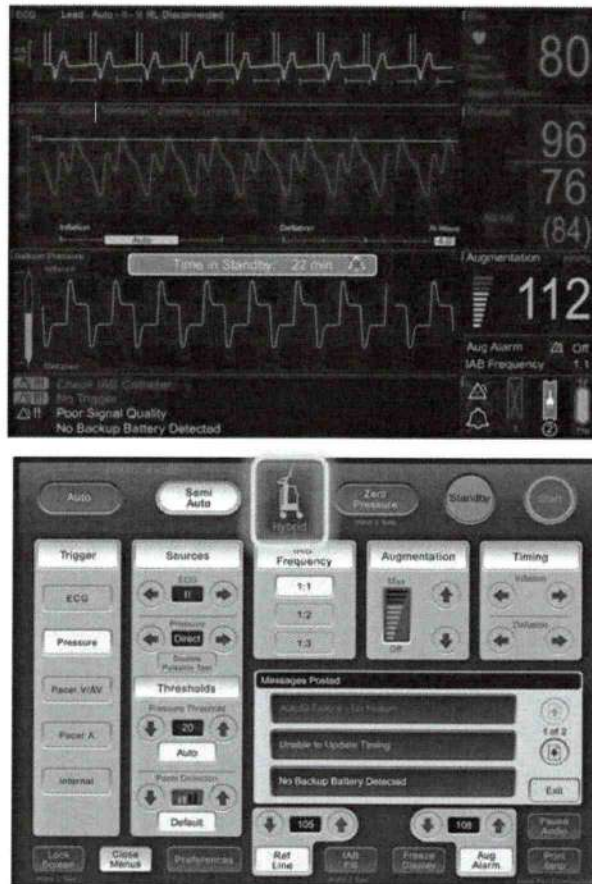


In both cases, information is provided to the user that the system is not in Hybrid mode via the Rescue Mode Icon on the bottom Cardiosave screen (top center of the screen). In addition, the "battery in use" message will be displayed in the informational message area even if the AC power cord is plugged in.

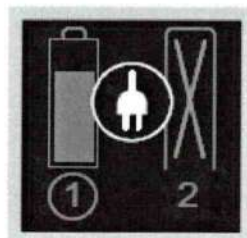


Additionally, in both scenarios, the Cardiosave will not receive AC power and if the device is in operation, it will continue to operate on battery. When the Cardiosave is not receiving AC power, the batteries are unable to charge.

Cardiosave Upper and Lower Display



If the AC Plug Icon is not present and/or the Rescue Icon is present, release the latch on the Hospital Cart located below the Pump Console, then grab the handle and slowly slide out the console approximately one quarter of the way.



Grab the handle and slowly slide the Pump Console into the Hospital Cart until it locks into place. You will hear an audible click noise and three audio tones of increasing volume will sound once the console is locked into the Hospital Cart.

To ensure the Pump Console was successfully installed into the Hospital Cart, plug the Hospital Cart power cord into a compatible grounded AC receptacle, and confirm AC operation by checking the battery icon to confirm the pump is using AC power.



Issue 2: Poor or No ECG Signal

Identification of the issue:

Datascope/Getinge has received 81 complaints over a two-year period (January 1, 2021 through December 31, 2022) where Cardiosave IABP users were unable to measure the ECG on a patient.

Poor or no ECG signal before or during therapy with the Cardiosave IABP can be caused by several factors such as poor quality skin-electrode, faulty ECG lead, or defective trunk cable.

There have been no adverse events reported that Datascope/Getinge has been able to specifically identify as a result of these failures.

Risk to Health:

Should poor or no ECG signal be experienced, therapy may be delayed or 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. When the Cardiosave is operating in AUTO mode, there is a reduced risk of therapy interruption if the ECG signal is poor or lost as the Cardiosave will automatically switch to arterial pressure for the trigger source to guide inflation and deflation of the IAB catheter.

However, if the Cardiosave is operating in SEMI AUTO mode with ECG selected as the trigger and the ECG signal is lost, the Cardiosave will alarm, alerting the user that therapy has been interrupted. User intervention is needed to select the appropriate ECG lead or identify an alternate trigger source in order to resume therapy.

In cases where the Cardiosave fails to recognize an ECG error, sustained dyssynchronous therapy has the potential to introduce additional stressors to an already compromised heart. It is anticipated that a prolonged period of dyssynchronous therapy results in decreased cardiac output, placing even a stable patient at a higher risk for clinical decline.

User Actions to be taken now:

Our records indicate 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.

Factors Contributing to ECG failure:

- Poor Quality Skin-Electrode Interface
- Front End PCBA Failure including Wetting (causes system to be unable to detect ECG lead faults)
- Faulty ECG Lead
- Failure of Executive Processor Board (the system cannot obtain or interpret the ECG)
- Defective ECG Lead Wire
- Defective Trunk Cable
- Defective connector between ECG cable and IABP unit

The type of skin electrode and application technique are major factors in determining the quality of the signal obtained. Use of MAQUET/Datascope electrodes is recommended. These are designed to acquire an ECG signal with excellent baseline stability, recovery from defibrillation and minimum artifact from patient movement. The use of Wet-Gel electrodes is recommended because, in general, they provide a better quality electrical contact immediately after being placed on the skin.

To ensure the safe and effective use of the Cardiosave IABP, follow the recommendation in the IFU, including the warning and Figures 2-1 and 2-2 regarding ECG lead placement locations and the use of third-party lead wires.

⚠ WARNING:

Use only MAQUET/Datascope Corp. ECG lead wires with the ECG Patient Cable. The use of any other lead wires may cause the system to function improperly.

1. When acquiring an ECG signal directly from skin electrodes:

- a. Ensure that the patient lead wires are securely inserted into the yoke of the MAQUET/Datascope Corp. supplied ECG trunk cable. Connect each patient lead wire to a skin electrode. The following table shows the number of ECG Electrodes vs. Leads available. The recommended minimum number of electrodes is four (4) to provide optimal lead selection triggering options.

(#) ELECTRODES USED (AHA)	(#) ELECTRODES USED (IEC)	(#) ECG LEADS AVAILABLE
RA, LA, LL	R, L, F	I, II, III
RA, LA, LL, RL	R, L, F, N	I, II, III, aVR, aVL, aVF
RA, LA, LL, RL, V	R, L, F, N, C	I, II, III, aVR, aVL, aVF, V

- b. Attach electrodes to the patient at the appropriate locations, as shown.

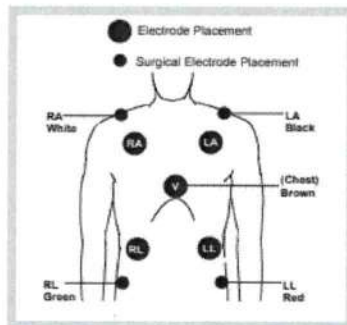


Figure 2-1: Electrode Placement AHA

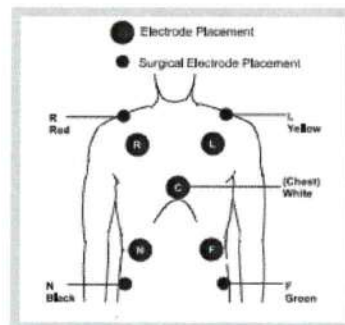


Figure 2-2: Electrode Placement IEC

Actions to be taken by Datascope/Getinge

This Urgent Medical Device correction is being issued to inform Users of the issue(s) observed and actions to be taken should Users experience this issue. Datascope/Getinge is currently investigating this issue further to determine root cause and will notify customers in the event additional action needs to be taken to correct the issue.

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 MEDICAL DEVICE CORRECTION – RESPONSE FORM (page 11) to acknowledge that you have received and understand this notification. Return the completed form to Datascope/Getinge by e-mailing a scanned copy or by faxing the form to your local Datascope/Getinge Representative or office.

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

We apologize for any inconvenience this Medical Device Correction may cause. If you have any questions, please contact your local Datascope/Getinge representative or office.

Sincerely,

03rd August, 2023

URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE CORRECTION – RESPONSE FORM
FSCA 2249723-06/02/2023-009-C & FSCA 2249723-06/02/2023-012-C
Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP)

I acknowledge that I have reviewed and understand this Urgent Medical Device Correction Letter for the affected Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s) (IABP(s)) at this facility.

I confirm that all users of the Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s) (IABP(s)) at this facility have been notified accordingly.

Please check the box next to each Issue 1-2 in order to acknowledge that you have reviewed, understand and have distributed this Letter to your facility accordingly.

- ☐ Issue 1: Docking/Power Battery Failure
☐ Issue 2: Poor or No ECG Signal

Please provide the required information and signature below.

Facility Representative Information:

Signature: _____ Date: _____
Name: _____ Phone: _____
E-Mail Address: _____
Title: _____ Department: _____
Hospital Name: _____
Address, City and State: _____

We have scrapped our Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s):

Circle one **YES NO** If yes, list Serial Numbers: _____
If yes, are all units scrapped? Circle one **YES NO**

We have sold/moved our Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s) to another facility:

Circle one **YES NO** If yes, list Serial Numbers: _____
If yes, are all units sold/moved? Circle one **YES NO**

Please provide new facility information below for the units sold/moved from your facility.

New Facility Name: _____
New Facility Address: _____
New Facility Contact Name: _____
New Facility Phone #: _____ New Facility E-Mail Address: _____

03rd August, 2023

**URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE CORRECTION**

**FSCAs 2249723-06/02/2023-010-C, 2249723-06/02/2023-011-C,
2249723-06/02/2023-013-C & 2249723-06/02/2023-014-C**

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 Customer,

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 the following four (4) identified system conditions:

- Issue 1: Autofill Alarms
- Issue 2: Gas Loss & Gas Gain Alarms
- Issue 3: System Over-Temperature
- Issue 4: Fiber Optic Damage

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.

Please note that according to the FDA, a Recall is a method of removing OR correcting products. A Correction is defined as a means to repair, modify or adjust a product without its physical removal. This particular correction does not require physical removal of the device. For your convenience, we are providing the link to the FDA website, which includes these definitions as well as other related information: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices>.

Issue 1: Autofill Alarms

Identification of the issue:

Datascope/Getinge has received 238 complaints over a two-year period (January 1, 2021 through January 31, 2023) where Cardiosave IABP users were identifying autofill failure conditions on the devices. Datascope/Getinge identified that 182 of these complaints were directly related to the IABP and described failure mode. Getinge is initiating a voluntary Medical Device Correction for the Cardiosave Intra-Aortic Balloon Pump (IABP) in order to mitigate the risk associated with these events.

Two adverse events were received where 1 death and 1 serious injury were reported. These complaints are currently under investigation.

Risk to Health:

Autofill failures are a means of communicating to the User that a feature of the IAB or IABP is unable to deliver therapy. The alarm state is an intentional means to prompt the user for patient or device assessment and/or intervention. Autofill failure is not always indicative that there has been a product compromise or failure.

However, for those Autofill failures that result from an equipment failure that the User cannot address directly, a prolonged interruption may be experienced until an alternative console can be identified. Further, if one is not available, or the patient is in transport, therapy cannot be continued.

In all instances of autofill failure, whether the source is generated by IAB or IABP status, therapy is proactively placed on standby (i.e., pumping stops) to prevent patient injury. 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, and those patients within the transport environment, there is greatest risk of harm as resources available are limited and therapy interruption may be prolonged.

Should autofill failure result in prolonged interruption to therapy, the hospital may obtain a different console. 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. If alternative supportive measures are unavailable or ineffective until therapy can be resumed, therapy interruption can lead to death.

User Actions to be taken now:

Our records indicate 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.

As a result of the investigation into the complaints, Getinge would like to reinforce information that is detailed in the Cardiosave Instructions for Use to help minimize the frequency and impact of these alarms:

As per the Cardiosave Operating Instructions in sections 2.1.8, "Initiation of Assist" and 2.1.9, "IAB Fill"; the system performs an autofill under the following three conditions:

- Initiation of Therapy
- Every two (2) hours while therapy is ongoing
- If during transport, the atmospheric pressure changes by a 25 mmHg (~1,000 ft.) rise or 50 mmHg (~2,000 ft.) drop during therapy to keep the balloon pressure acclimated to local conditions

If the autofill procedure fails to purge and fill the Pneumatic Module properly, the message Autofill Failure will be displayed, an audible alarm will be activated, and pumping will be suspended until the alarm is cleared. Corrective action can be obtained by pressing the Help Available key. The three high priority alarms are:

- Autofill Failure – No Helium
- Autofill Failure – Blood Suspected
- Autofill Failure

Note: *Autofill Failure – Blood Suspected* is caused by a leak in the IAB which results in blood migration back into the IABP system. The failure of the IAB is outside of the scope of this Field Safety Notification.

Autofill Failure – No Helium

- Verify that the Cardiosave device has sufficient Helium in the system.
- If the Cardiosave is in Hybrid mode (console within a hospital cart), verify the external Helium Tank is connected to the cart, is opened, and there is sufficient Helium in the tank to support the IABP therapy.
- If the Cardiosave is in Rescue (transport) mode, replenish the IABP's Helium gas supply by placing the IABP console into the hospital cart, or connect the IABP console to a helium refilling station (if available at your facility).

Once these steps are completed, initiate an autofill by pressing the START key, or by pressing the IAB FILL key for 2 seconds.

Autofill Failure

The Cardiosave monitors the volume of helium within the catheter by monitoring the pressure within the IAB catheter and tubing. To ensure reliable operation of the autofill system and proper IAB inflation pressures, it is important that the volume of helium within the IAB catheter and extender tubing is not altered. Using different length or sized tubing than that supplied with Getinge IAB products will change IAB inflation pressure levels and may result in Autofill failures. Consequently, such practices must be avoided.

If an Autofill Failure alarm is present:

- Ensure that only one correctly sized IAB extender tubing is tightly connected to the IAB and the IABP, and there are no restrictions in the tubing.
- Check for evidence of blood in the IAB tubing. If any blood is noted or perforation is suspected, the following procedure must be performed immediately:
 - Disconnect the catheter extender tubing from the IABP console to allow the balloon to deflate.
 - Clamp extracorporeal tubing between white y-fitting and male connector.
 - Place the patient in Trendelenburg as tolerated to guide any residual helium to travel away from the head vessels.
 - Notify physician, and prepare for IAB catheter removal.
 - Consider IAB catheter replacement, if the patient's condition warrants.
 - If blood is suspected of having entered the pump, take pump out of service. It should be evaluated before use in another patient by a Getinge or Biomed/Technical Service to determine if replacement of contaminated components is necessary.
- If blood is not present, press the START key to refill the IAB and resume pumping.

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

Issue 2: Gas Loss & Gas Gain Alarms

Identification of the issue:

Datascope/Getinge has received 140 complaints (including 1 death) over a two-year period (January 1, 2021 through December 31, 2022) where Cardiosave IABP users were reporting instances of "Gas Loss in IAB Circuit" and "Gas Gain in IAB Circuit" alarms while providing therapy.

An internal investigation of the complaints determined that there is a potential trigger for these alarms that was not listed in the IFU: Patient Movement (coughing, general movement, and swallowing) which leads to restrictions in the catheter/tubing. Patient movement during therapy can cause a temporary scenario where the IABP will sense a change in pressure (due to catheter/tubing kinking) that can trigger the Gas Loss or Gas Gain alarms. This situation is transient from the specific patient movement. As a precautionary measure, please ensure that patient movement is limited during IABP therapy to keep the catheter/tubing free of potential restrictions.

Further, as a result of the investigation into the complaints, Getinge would like to reinforce some information in the Instructions for Use with the Cardiosave users to help minimize the frequency and impact of these alarms:

The Gas Loss & Gas Gain alarms trigger when there is a change in the volume of gas in the IAB catheter and tubing through to the female luer port of the Cardiosave IABP. This situation can be caused by loose connections and/or abrasions to the tubing/catheter. In addition, patients that are febrile or tachycardic may experience a higher rate of gas loss due to diffusion through the balloon membrane.

If the Cardiosave IABP system detects a volume change of $\pm 5\text{cc}$ within 1 hour, a "Gas Gain in IAB Circuit" or "Gas Loss in IAB Circuit" high priority alarm message will be displayed, an audible alarm will be activated, and pumping will be suspended until the alarm is cleared. Corrective action can be obtained by pressing the Help Available key.

Risk to Health:

A delay in therapy or an interruption in therapy may be experienced while troubleshooting the patient alarm. 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.

Should the Gas Loss/Gas Gain failure result in prolonged interruption to therapy due to the inability to successfully troubleshoot the alarm (e.g., a component failure), the hospital will need to obtain a different console. 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. If alternative supportive measures are unavailable or ineffective until therapy can be resumed, therapy interruption can lead to death.

User Actions to be taken now:

Our records indicate that you may have a Cardiosave Hybrid and/or Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) affected by this correction in your facility. Please examine your inventory immediately to determine if you have any Cardiosave Hybrid and/or Rescue IABPs.

The following actions should be taken should you experience an alarm for "Gas Loss in IAB" & "Gas Gain in IAB":

Gas Gain in IAB Circuit

- Verify all of the tubing connections are leak free.
- Press the START key to initiate an Autofill and resume pumping.

Gas Loss in IAB Circuit

- Inspect the tubing from the patient through to the connection of the helium extender tubing to the female luer port of the Cardiosave IABP.
- If any blood is noted or perforation is suspected, the following procedure must be performed immediately:
 1. Disconnect the catheter extender tubing from the IABP console to allow the balloon to deflate.
 2. Clamp extracorporeal tubing between white y-fitting and male connector.
 3. Place patient in Trendelenburg as tolerated to guide any residual helium to travel away from the head vessels.
 4. Notify physician, and prepare for IAB catheter removal.
 5. Consider IAB catheter replacement, if the patient's condition warrants.
 6. If blood is suspected of having entered the pump, take pump out of service. It should be evaluated before use in another patient by a Getinge or Biomed/Technical Service representative who has been trained on Cardiosave service requirements, to determine if replacement of contaminated components is necessary.
- If blood is not detected, ensure that the IAB extender tubing is tightly connected to the IAB and the IABP. If appropriate, perform an Autofill by pressing and holding the IAB FILL key for 2 seconds, then press the START key to resume pumping.
- If the patient is febrile or tachycardic, consider increasing the frequency of Autofills by initiating an Autofill prior to the regularly scheduled 2-hour Autofill.

As described above, based upon field observations seen through complaints evaluations, there is a possibility that patient coughing, swallowing, and movement may induce gas gain and/or gas loss alarms. As a precautionary measure, please ensure patient movement is limited to avoid possible IAB tubing kinks and loose connections during usage. Datascope/Getinge is currently performing additional testing to verify these hazardous situations and will make appropriate changes to the Cardiosave Operating Instructions, recommended procedures, and/or device design to mitigate these situations, once the investigation is complete.

Should the Gas Loss/Gas Gain failure result in prolonged interruption to therapy, the hospital may obtain a different console. 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.

If another IABP console is installed and the new console also has Gas Loss/Gas Gain failures, the intra-aortic balloon (IAB) needs to be assessed for replacement.

Issue 3: System Over-Temperature

Identification of the issue:

Datascope/Getinge has received 148 complaints over a two-year period (January 1, 2021 through December 31, 2022) where Cardiosave IABP users reported "System Over Temperature" alarms associated with a loss of pumping and/or the Cardiosave system entering Standby mode.

One adverse event was received where death was reported.

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 to either provide alternative or supportive therapy to the patient.

Therapy will resume on restart once the Cardiosave has had time to cool sufficiently. However, due to the various conditions that can potentially cause an over-heat situation, there is no anticipated length of time required for a console to cool sufficiently to restart therapy. Furthermore, the affected IABP remains vulnerable to a failure of restarting or another overheat event resulting in subsequent therapy interruption unless the condition(s) causing the overheating are resolved. As such, if the IABP is unable to restart or another overheat event occurs, the User must obtain another IABP console for use.

Should an alternate IABP console not be available for use, a clinician within the hospital environment may have the opportunity to provide alternative means of clinical stabilization by administering pharmaceutical support to stabilize a compromised patient. Should a prolonged period of interruption result, an alternative treatment course may be pursued including the application of additional MCS therapies. For those patients receiving counterpulsation within the transport environment, should a console overheat, and a "System over temperature" alarm results in a pump remaining in standby mode, it may not be easily remedied (i.e. console cooled sufficiently to resume therapy). In the transport environment a clinician's resources are limited to those available en route; even if the standby period is brief following a "system over temperature" alarm, there is the potential for injury if not well tolerated by 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 supportive measures are unavailable or ineffective until therapy can be resumed, therapy interruption can lead to death.

User Actions to be taken now:

Our records indicate 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.

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, Operational Instruction for US and OUS:

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.

Consideration should be given to having a backup IABP available in the event the IABP doesn't cool sufficiently to restart or the alarm reoccurs. To help prevent such 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.

Issue 4: Fiber Optic Damage

Identification of the issue:

Datascope/Getinge has received 187 complaints over a two-year period (January 1, 2021 through December 31, 2022) where Cardiosave IABP users were experiencing a failure in the IAB Fiber Optic Sensor input on the IABP when inserting the Intra-Aortic Balloon Fiber Optic connector.

The Fiber Optic connector is designed to fit smoothly into the IAB Sensor Input. The red triangle on the top of the connector should align with the red triangle on the Cardiosave console. Inserting the Fiber Optic connector into the port without verifying the correct alignment can lead to internal damage. If difficulty is encountered when inserting the connector, verify that the connector is in the correct position and attempt to reinsert into the IAB Sensor Input.

Excessive force can cause damage to the connector and the internal fiber optic assembly of the IABP console. This may cause a disruption in the fiber optic signal acquisition resulting in an inability to acquire a fiber optic signal on the Cardiosave IABP. Following proper insertion procedures will minimize the potential for damage to the connector and a loss of signal. This conclusion is based on field observations seen through the complaints evaluation. As part of Datascope's investigation testing will be performed to confirm this observation.

Damaged Fiber Optic ports may not present as an immediate failure. There is a potential for the damage to cause an intermittent or delayed failure in the Fiber Optic connection.

There have been 2 deaths and 2 serious injuries reported, however these events have not been able to be definitively associated with the failure.

Risk to Health:

Should the event occur where fiber optic signal is not available and there is no ECG signal available, 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. It is important to note that use of fiber optics aides in the delivery of therapy, it is not required to deliver therapy.

The risk of therapy interruption from loss of the fiber optic signal can be mitigated by utilizing AUTO mode which automatically uses the ECG as a primary source to trigger the therapy or by connecting to an alternative pressure monitoring source (the catheter's inner lumen or another external source) to assist in guiding the therapy. If alternative supportive measures are unavailable or ineffective until therapy can be resumed, therapy interruption can lead to death.

User Actions to be taken now:

Our records indicate 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.

Fiber optics assists in the rapid acquisition and accuracy of the arterial pressure waveform although it is not required to provide therapy with a fiber optic catheter. As detailed within the IFU and educational guides, the patient's arterial pressure can also be obtained via the catheter's inner lumen by connecting a standard fluid-filled pressure bag system or by connecting an external arterial pressure source (typically a radial or femoral arterial line) to the IABP console.

Despite the ability of using fiber optics for pressure monitoring, the IFU continues to advise maintenance of the catheter's inner lumen. This guidance is provided within the IFU and Operating guides to both prevent thrombus formation at the end of the catheter, as well as to maintain the integrity of the inner lumen despite the use of the fiber optic signal for monitoring. This provides an alternative source for guiding the therapy if the fiber optic signal is lost.

Using AUTO Mode and the ECG as Trigger

If in Semi-AUTO MODE and using the fiber optic signal as the trigger source and the signal is not available, utilizing AUTO mode will automatically select the ECG or other available trigger source to guide therapy. When in AUTO mode should the fiber optic signal be lost, therapy can still be safely delivered using only the ECG. However, should the ECG not be a reliable or accurate signal, and the system seeks the arterial signal to guide therapy, the IABP will not have the information needed to guide therapy, and therapy is stopped.

Should no alternative arterial pressure source be available, the hospital can obtain a different console. 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.

Using an Alternative Pressure Source as the Trigger

If the fiber optic signal is not available, the inner lumen of the IAB catheter may instead be used to obtain the arterial pressure signal. When monitoring arterial pressure through the inner lumen, use a standard arterial pressure monitoring apparatus connected to a three-way stopcock. Connect the three-way stopcock to the female luer hub of the inner lumen. A 3cc/hour continuous flow through the inner lumen is recommended. Per hospital policy, a fast forward flush may be performed hourly to help maintain patency of the inner lumen. See the IAB instructions for use.

If alternative supportive measures are unavailable or ineffective, the hospital may obtain a different console. 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.

Instructions for Installation of Fiber-Optic Connection

The instructions for connecting the Fiber-Optic Sensor Connector are described in the Operator's manual in Section 2.1.4.1.1:

⚠ CAUTION:

Do not touch the exposed end of the Fiber-Optic IAB cable, or permit it to contact other surfaces. This could damage or contaminate the sensor connection.

1. With one hand, grasp the Fiber-Optic Sensor Connector as shown in Grasping the Fiber-Optic sensor connector, with the red triangle visible on top.

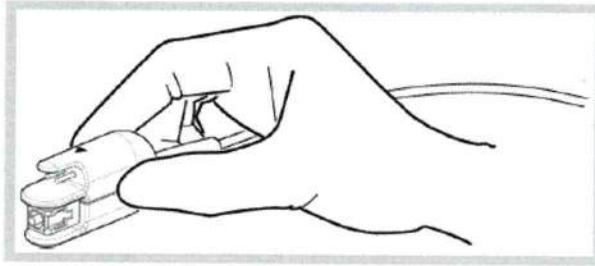


Figure 2-5: Grasping the Fiber-Optic sensor connector

2. Remove and discard the protective cover from the Fiber-Optic IAB connector. Do not touch the exposed end of the Fiber-Optic cable.
3. With the other hand, open the protective shutter that covers the opening for the IAB Sensor Input (item 11, section 1.5.1) by rotating it to the left.
4. Insert the Fiber-Optic IAB connector into the IAB Sensor Input until it "clicks".

Note:

Ensure that the red triangles on the Fiber-Optic IAB Sensor Connector and on the back panel are in alignment.

5. Connect the Fiber-Optic IAB catheter's male luer fitting to the female luer fitting on the MAQUET/Datascope Corp. catheter extender. Connect the male luer fitting of the MAQUET/Datascope Corp. catheter extender to the IAB Catheter Extender Input luer fitting (item 12, section 1.5.1).

⚠ CAUTION:

To ensure reliable operation of the Autofill system and proper IAB inflation pressures, it is important that the combined total volume of the IAB's membrane and extracorporeal tubing, plus the catheter extender tubing, is not altered. Using tubing of a different length or internal diameter from that supplied with MAQUET/Datascope Corp. IAB products will change IAB inflation pressure levels and may result in Autofill failures. Consequently, such practices must be avoided.

Note:

The Pneumatic Module will support all of MAQUET/Datascope Corp. adult intra-aortic balloons.

In step 4, when the Fiber-Optic connector is inserted into the IAB Sensor input until an audible "click" is confirmed, ensure that you are not using excessive force as that can lead to damage to the Cardiosave.

Actions to be taken by Datascope/Getinge

This Urgent Medical Device correction is being issued to inform Users of the issue observed and actions to be taken should Users experience this issue. Datascope/Getinge is currently investigating this issue further to determine root cause and will notify customers in the event additional action needs to be taken to correct the issue.

Datascope/Getinge is in the process of developing an addendum to the Cardiosave IABP Instructions For Use to document new warning(s), caution(s), and/or action(s) to be taken by the User to minimize the risk of harm caused by the aforementioned system conditions. 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.

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 MEDICAL DEVICE CORRECTION – RESPONSE FORM (page 16) to acknowledge that you have received and understand this notification. Return the completed form to Datascope/Getinge by e-mailing a scanned copy or by faxing the form to your local Datascope/Getinge Representative or office.

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

We apologize for any inconvenience this Medical Device Correction may cause. If you have any questions, please contact your local Datascope/Getinge representative or office.

Sincerely,

03rd August, 2023

URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE CORRECTION – RESPONSE FORM
FSCAs 2249723-06/02/2023-010-C, 2249723-06/02/2023-011-C, 2249723-
06/02/2023-013-C & 2249723-06/02/2023-014-C
Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP)

I acknowledge that I have reviewed and understand this Urgent Medical Device Correction Letter for the affected Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s) (IABP(s)) at this facility.

I confirm that all users of the Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s) (IABP(s)) at this facility have been notified accordingly.

Please check the box next to each Issue 1-4 in order to acknowledge that you have reviewed, understand and have distributed this Letter to your facility accordingly.

- ☐ Issue 1: Autofill Alarms
☐ Issue 2: Gas Loss & Gas Gain Alarms
☐ Issue 3: System Over-Temperature
☐ Issue 4: Fiber Optic Damage

Please provide the required information and signature below.

Facility Representative Information:

Signature: _____ Date: _____
Name: _____ Phone: _____
E-Mail Address: _____
Title: _____ Department: _____
Hospital Name: _____
Address, City and State: _____

We have scrapped our Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s):

Circle one **YES NO** If yes, list Serial Numbers: _____

If **yes**, are all units scrapped? Circle one **YES NO**

We have sold/moved our Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pump(s) to another facility:

Circle one **YES NO** If yes, list Serial Numbers: _____

If **yes**, are all units sold/moved? Circle one **YES NO**

Please provide new facility information below for the units sold/moved from your facility.

New Facility Name: _____
New Facility Address: _____
New Facility Contact Name: _____
New Facility Phone #: _____ New Facility E-Mail Address: _____