[Month DD, YYYY] [INSERT METHOD]

URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE CORRECTION

MAQUET CARDIOSAVE hybrid and MAQUET CARDIOSAVE rescue

Product Code/Part Number:	**0998-XX-0800-XX**
Distributed Affected Lot Number:	**All**
Distribution Dates:	**Since March 6, 2012**

Dear Hospital Contact,

Datascope/Getinge is initiating a voluntary Medical Device Correction for the Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) due to two issues that could affect IABP performance:
Issue 1:
Helium Indicator Inaccuracy in the Presence of Continuous EMC Disturbances
Issue 2:
Shutdown Upon Battery Removal

A review of our records indicates that you may have a Cardiosave IABP in your facility that may have one or more of the issues affected by this field correction. Please review Table 1 on the following page for a description of issues and actions to be taken.

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

Issue:	Identification of Issue	Action(s) to be taken	Corrective Action(s)
1. Helium Indicator Inaccuracy in the Presence of EMC	During Electromagnetic Compatibility (EMC) testing, Getinge determined that in the presence of radiated RF disturbances, the Helium Indicator on the Cardiosave IABP would intermittently over-report the remaining Helium Capacity, (Figure 1). It is important to note that upon removal of the source of EMC interference the Helium Indicator performs as intended.	Refer to Issue 1: "Immediate Actions to be taken now" for actions to be taken to limit possibility of loss of therapy due to an over-reporting of remaining helium on the Helium Indicator (Pages 4-5)	Datascope/Getinge is developing a hardware correction to address this issue. A Datascope/ Getinge service representative will contact you to schedule the installation of the correction when available. The correction approximately will begin late Q2 2022.
2. Unexpected Shutdown Upon Battery Removal	The Cardiosave IABP may unexpectedly shut down when the device is running on AC power, only one battery is inserted in the IABP, and the battery is physically removed while the battery is being charged. An audible sudden shutdown alarm will sound if this condition occurs. This issue can only happen in the presence of clinical personnel as the battery must be physically removed. Refer to Page 6 for specific conditions that must be met for the issue to occur.	Refer to Issue 2 "Immediate Actions to be taken now" for actions to be taken to prevent the loss of therapy due to system shutdown (page 7)	Datascope/Getinge is developing a software correction to address this issue. A Datascope/ Getinge service representative will contact you to schedule the installation of the updated software. The correction approximately will begin late Q2 2022.

Table 1: Description of Issues

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Issue 1: Helium Indicator Inaccuracy in the Presence of EMC

Identification of the issue:

During Electromagnetic Compatibility (EMC) testing at an external lab, Getinge personnel determined that in the presence of some radiated RF disturbances, the Helium Indicator on the Cardiosave IABP (refer to Figure 1) would intermittently over-report the remaining Helium Capacity. Once the disturbance was removed the Helium indicator always fully recovered within 10 seconds to display the proper level without any over-reporting.

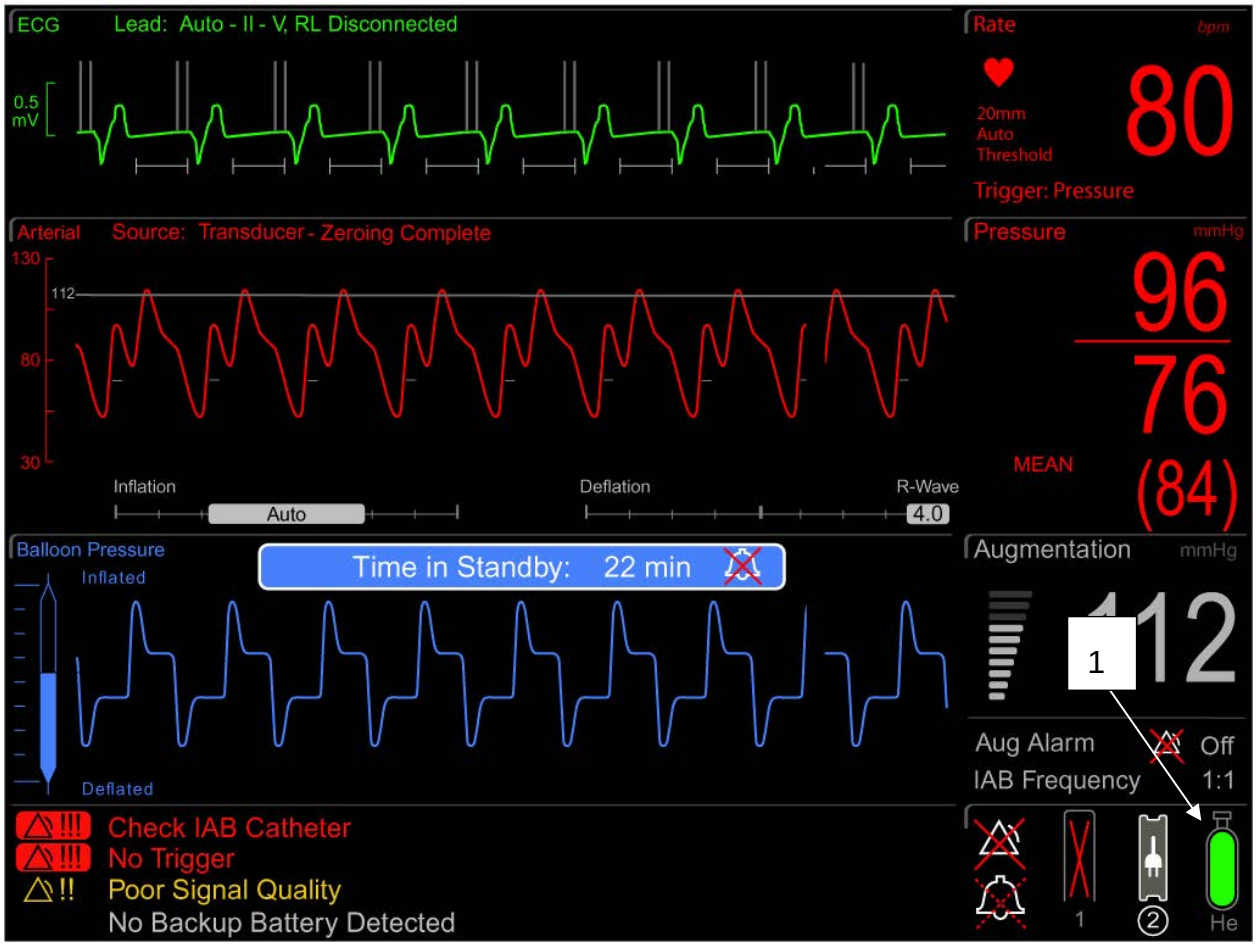

Figure 1 – Monitor Display (1 – Helium Indicator)

Note that the test levels specified in Medical Device EMC standards include safety factors with higher levels of radiated RF disturbance than would normally be seen in patient care environments.

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Getinge's investigation revealed that the over-reporting of Helium Capacity would intermittently occur at frequency ranges between 80 MHz – 1 GHz. Potential sources of interference include: radio communication, cell phone, Wi Fi, RFID equipment and equipment that does not meet current electromagnetic compatibility standards.

It is important to note that upon removal of the source of EMC interference the Helium Indicator performs as intended.

Issue 1: Immediate Actions to be taken now:

Users should perform the following actions to limit the possibility of loss of therapy due to an over-reporting of remaining helium on the Helium Indicator.

Cardiosave Hybrid

Since the mechanical gauge is not influenced by EMC, view the mechanical gauge on the Cardiosave Top Panel (See figure 2) to assess remaining helium capacity in case of suspected EMC disturbances.

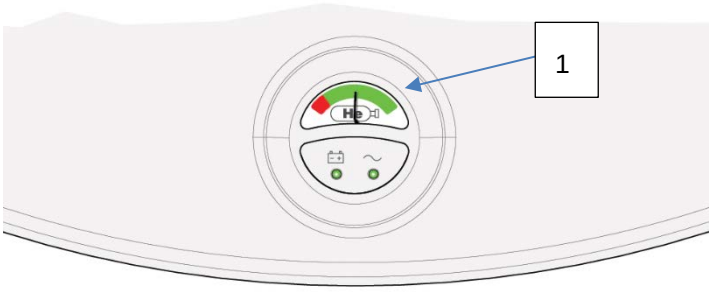

Figure 2 – Top Panel (1 – Mechanical Helium Gauge)

Where practical, maximize separation of Cardiosave system from other electronic equipment, communication devices and cables (e.g. power and communication cables). In particular, follow the recommended separation distances between communications equipment and the Cardiosave equipment as specified in the Cardiosave Operating instructions manual.

Cardiosave Rescue

Prior to any use of the Cardiosave Rescue, ensure the internal helium reservoir is full. If the on-screen helium indicator is not showing full, fill the internal helium reservoir via the hospital cart or Helium Refilling Station. Please review the Cardiosave IABP Operation – Transport Quick Reference Guide (0002-08-9772) for details on using the Cardiosave Rescue in transport.

Where practical maximize separation of Cardiosave system from other electronic equipment, communication devices and cables (e.g. power and communication cables). In particular, follow the recommended separation distances between communications equipment and the Cardiosave equipment as specified in the Cardiosave Operating instructions manual.

Datascope/Getinge is developing a hardware correction to address this issue. A Datascope/Getinge service representative will contact you to schedule the installation of the correction when available. This work will be done at no cost to your facility.

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Issue 2: Unexpected Shutdown Upon Battery Removal

Identification of the issue:

The Cardiosave IABP may unexpectedly shut down when the device is running on AC power, only one battery is installed in the IABP, and the battery is physically removed while the battery is being charged. An audible sudden shutdown alarm will sound if this condition occurs. This issue can only happen in the presence of clinical personnel as the battery must be physically removed.

Cardiosave Hybrid

This occurs during a very specific set of **conditions** as noted below:

Unexpected shutdown can only happen while in Hybrid Configuration (Figure 3) when all four of the below conditions are met:

1. IABP is running on AC power and charging a single battery in voltage charging mode. Voltage charging mode occurs during the last 15-20 minutes of the full charging cycle, when the 5th and final LED charge indicator on the battery pack is flashing.
2. The other battery bay is empty, i.e. no battery is inserted into the second battery bay.
3. The battery is ejected while a system signal erroneously reports the AC power supply is low, this will only happen intermittently when the first two conditions are met.
4. Battery is ejected when all above conditions are met.

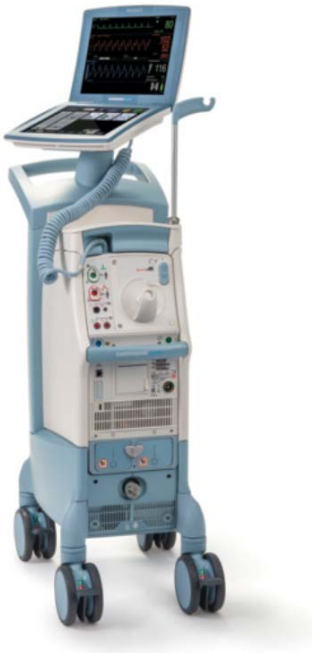

Figure 3: Cardiosave in Hybrid Configuration

Cardiosave Rescue (Figure 4)

An unexpected shutdown upon battery removal cannot occur for Cardiosave Rescue.

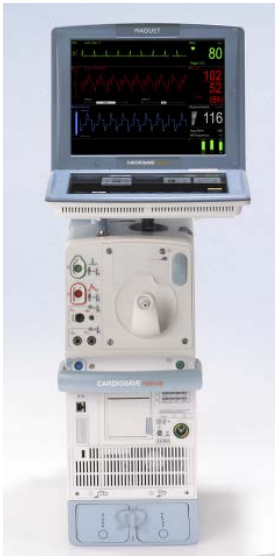

Figure 4: Cardiosave in Transport Configuration

Issue 2: Immediate Actions to be taken now:

To ensure that the Cardiosave Hybrid is not susceptible to the shutdown during the removal of a battery, users should not eject a battery when:

- There is a singular battery in either battery charging bay and unused battery bay is empty.
- The battery is charging on AC power (indicated by a flashing LED on the battery pack).

Additionally, the user can prevent the issue by ensuring that a battery is inserted into each of the two battery bays. Should a charging battery be ejected inadvertently, the unit will automatically switch over to the second battery, thus preventing system shutdown.

Furthermore, Datascope/Getinge is developing a software correction to address this issue. 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.

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Actions to be taken:

Please examine your inventory immediately to determine if you have a Cardiosave Hybrid or Rescue IABP.

Please complete and sign the attached URGENT FIELD SAFETY NOTICE MEDICAL DEVICE CORRECTION - RESPONSE FORM (Page 9) to acknowledge that you have received this notification.
Return the completed form to Datascope/Getinge by e-mailing a scanned copy INSERT LOCAL SSU EMAIL ADDRESS or by faxing the form to INSERT LOCAL SSU FAX NUMBER.

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

Please forward this information to all current and potential Cardiosave Hybrid and Cardiosave Rescue 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.

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

Sincerely,

_____

[NAME]
[TITLE]
Getinge

[Month DD, YYYY]

URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE CORRECTION
RESPONSE FORM

MAQUET CARDIOSAVE hybrid and MAQUET CARDIOSAVE rescue

FAX BACK TO: INSERT LOCAL SSU FAX NUMBER or EMAIL TO: INSERT LOCAL SSU EMAIL ADDRESS

ADD ACCOUNT#
[FACILITY NAME
STREET ADDRESS
CITY, STATE, ZIP CODE]

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

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

Please provide the required information and signature below.

Facility Representative:

Signature:_____ Date:_____

Name:_____ Phone:_____

Title:_____ Department:_____

Hospital Name:_____

Address, City and State:_____

Return the completed form by FAX to INSERT LOCAL SSU FAX NUMBER **or by EMAIL to** INSERT LOCAL SSU EMAIL ADDRESS

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