4 April 2016

URGENT PRODUCT RECALL
MEDICAL DEVICE FIELD CORRECTION

Maquet CARDIOSAVE® Hybrid Intra-Aortic Balloon Pump (IABP)
Maquet CARDIOSAVE® Rescue Intra-Aortic Balloon Pump (IABP)

AFFECTED PRODUCT	PART NUMBER	DISTRIBUTION DATE
CARDIOSAVE Hybrid IABP and CARDIOSAVE Rescue IABP	**0998-XX-0800-XX**	**March 6, 2012 to December 31, 2015**

PLEASE FORWARD THIS INFORMATION TO ALL CURRENT AND POTENTIAL CARDIOSAVE HYBRID and RESCUE INTRA-AORTIC BALLOON PUMP (IABP) USERS WITHIN YOUR INSTITUTION.

Dear Risk Manager,

You may have previously received the Maquet Urgent Product Recall notification, dated December 2015, regarding a potential issue relating to the scroll compressor of your CARDIOSAVE Hybrid and/or CARDIOSAVE Rescue Intra-Aortic Balloon Pumps (IABPs), which will be collectively referred to in this letter as CARDIOSAVE IABPs. Maquet continually monitors the performance of the CARDIOSAVE IABPs and has discovered four additional issues that could affect the CARDIOSAVE IABP performance. These issues may cause the CARDIOSAVE IABP to not meet performance specifications.

It is important to note that to date, there have been no reported patient harm or adverse events attributable to these issues.

Products Affected:
The products affected by the field correction are the CARDIOSAVE IABPs distributed from March 6, 2012 to December 31, 2015.

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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Table 1. CARDIOSAVE IABP Issues

Issue	Description	Risk to Patient	Action To Be Taken
Scroll Compressor*	The scroll compressor may not meet the performance specifications for output pressure or vacuum at specific flow rates. When the scroll compressor fails, one of two high priority alarms will appear on the IABP display. [Alarms: "Autofill Failure"; "IAB Catheter Restriction"]. Distribution Dates: March 6, 2012 – October 20, 2015	Interruption and/or Delay of Therapy	By Device User: Refer to Appendix A and CARDIOSAVE IABP Operating Instructions Manual to review IFU instructions on clearing the alarm. If not operational obtain an alternative Maquet IABP to continue therapy. By Maquet: Maquet Service to perform a software update to mitigate the issue.
Hospital Information System/Clinical Information System (HIS/CIS) communication	Due to an unintended increased size in the HIS/CIS connectivity packet, the interface may reject the packet due to increased packet size. The HIS/CIS may not be able to provide external data communications of electronic medical records as intended Distribution Dates: August 11, 2015 – December 31, 2015	None	By Device User: Obtain data via other means if HIS/CIS communication is interrupted. By Maquet: Maquet Service to perform an update to a new version of software to address the potential communication issue.
Video Display cables	The CARDIOSAVE IABP may have intermittent connectivity issues causing display blanking followed by a "System Failure" audible alarm and shut down. Distribution Dates: March 6, 2012 – October 20, 2015	Interruption and/or Delay of Therapy	By Device User: Turn IABP on again. If IABP is not operational, obtain an alternative IABP to continue therapy. By Maquet: Maquet Service to perform correction to address the issue.
Video Display Assembly (Internal PC Board)	During operation, the CARDIOSAVE IABP may shutdown due to a short on the video generator board. Distribution Dates: March 6, 2012 – October 20, 2015	Interruption and/or Delay of Therapy	By Device User: Turn IABP on again. If IABP is not operational obtain an alternative IABP to continue therapy. By Maquet: Maquet Service to perform correction to address the issue.
Pneumatic Assembly	Intermittent connection with the CARDIOSAVE Pneumatic Module Connector resulting in IABP startup failure and/or IABP shutdown Distribution Dates: March 6, 2012 – October 20, 2015	Interruption and/or Delay of Therapy	By Device User: Obtain an alternative IABP to continue therapy. By Maquet: Maquet Service to perform correction to address the issue.

*Note: Previously identified in the Maquet Urgent Product Recall notification, dated December 2015.

General Information and Overall Action for User:
Patients receiving IABP therapy are in critical condition and sudden interruption of therapy could result in unsafe, hemodynamic instability. Please adhere to the following instructions when using an affected CARDIOSAVE IABP:

1) Pursuant to the WARNINGS section of our CARDIOSAVE IABP Operating/User Instructions, clinicians are instructed not to leave the patient unattended during IABP therapy.

2) An additional hazard associated with a sudden shutdown is related to the static condition (no inflating or deflating) of the balloon during the interruption of therapy. It is important to note the following WARNING in the CARDIOSAVE IABP Operating Instructions Manual:

> ***WARNING: The patient balloon should not remain inactive in the patient (i.e., not inflating or deflating) for more than 30 minutes, due to the potential for thrombus formation.***

In the unlikely event that a sudden interruption of therapy was to occur, transfer the patient to an alternative IABP. If an alternative IABP is unavailable, the intra-aortic balloon catheter should be removed from the patient. The patient should be treated according to your facility's treatment protocols and caregivers' clinical judgment to ensure hemodynamic stability.

Your affected CARDIOSAVE IABP should not be used during either ground or air transport until it is serviced by a Maquet Service representative.

Corrective Action:
Your facility will be contacted by a representative of the Maquet Service team to schedule an on-site service of your CARDIOSAVE IABP.

Please complete the attached Medical Device Field Correction Response Form on page 5 to acknowledge that you have received this Medical Device Field Correction letter. Please return the completed form to your local Maquet office.

Maquet, Getinge Group apologizes for any inconvenience you may experience as a result of this field correction.

Sincerely,

Karen LeFevere

Karen LeFevere
Director of Regulatory Affairs and Field Action Compliance
Maquet, Getinge Group

Appendix A

Scroll Compressor

Maquet has received information that, in some CARDIOSAVE IABPs, the scroll compressor did not meet the specifications for output pressure or vacuum at specific flow rates. When the scroll compressor fails, one of two high priority alarms listed below will appear on the IABP display and patient therapy could be interrupted.

High Priority Alarms:

- "Autofill Failure"
- "IAB Catheter Restriction"

When either of the two high priority alarms mentioned above appears on the IABP display, first determine if the high priority alarm message can be resolved according to the instructions provided in the CARDIOSAVE IABP Operating Instructions Manual.

For example, the tables below are from the CARDIOSAVE IABP Operating Instructions Manual for the high priority alarms:

Autofill Failure	
The IABP cannot fill the IAB catheter system.	
1	Ensure that one correctly sized IAB extender tubing is tightly connected to the IAB and the IABP, and there are no restrictions in the tubing.
2	Check for evidence of blood in the IAB tubing. If found, stop pumping and notify physician. Refer to IAB manufacturer's instructions for IAB removal.
3	If blood is not present, press the START key to refill the IAB and resume pumping.
4	If the alarm message persists, switch to another MAQUET IABP if available.
5	Contact MAQUET Service.

IAB Catheter Restriction	
There is a restriction in the IAB catheter or tubing.	
1	Check the catheter tubing, extracorporeal tubing, and extender tubing for restriction, and relieve restriction if possible.
2	Press the START key to resume pumping.
The IAB membrane is not completely unfolded.	
1	Aspirate to assure blood is not returned through the extracorporeal tubing.
2	Using a syringe, manually inflate and deflate the IAB with 30 cc of air through the male Luer of the IAB.
3	Press the START key to Autofill and resume pumping.
The IAB remains in the sheath immediately after insertion.	
1	Check the markings on the IAB catheter to confirm that the balloon has fully exited the sheath. If the balloon has not fully exited the sheath, refer to the IAB catheter manufacturer's instructions for use to reposition the sheath relative to the IAB catheter.
2	Press the START key to resume pumping.

NOTE: Please refer to the CARDIOSAVE IABP Operating Instructions Manual for complete details regarding these high priority alarms.

If either of the high priority alarms cannot be resolved, the event may be attributable to the scroll compressor failure and therapy to the patient cannot be manually restarted.

4 April 2016

MEDICAL DEVICE FIELD CORRECTION RESPONSE FORM

Return the completed form to your local Maquet office

Maquet CARDIOSAVE® Hybrid Intra-Aortic Balloon Pump (IABP)
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I acknowledge that I have reviewed and understand the 4 April 2016 Medical Device Field Correction Letter for the affected Maquet CARDIOSAVE Intra-Aortic Balloon Pump(s) at this facility.

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

Institution Representative:

Signature:_____ Date:_____

Name:_____ Phone:_____

Title:_____ Department:_____

Hospital Name:_____

Address:_____

Country:_____