September 24, 2018 via [INSERT METHOD]

URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE FIELD CORRECTION
Maquet/Getinge Cardiosave Intra-Aortic Balloon Pump (IABP)

AFFECTED PRODUCT	PART NUMBER	DISTRIBUTION DATE
Cardiosave Hybrid IABP **Cardiosave Rescue IABP**	**0998-00-0800-XX &** **0998-UC-0800-XX**	**March 06, 2012 to** **August 31, 2018**

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

Dear Risk Manager,

Maquet/Getinge is initiating a voluntary Medical Device Correction for the Cardiosave Intra-Aortic Balloon Pump (IABP) due to the issue presented below. This issue could result in an interruption and/or inability to start therapy to the patient prior to or during use of Cardiosave IABP for users who are at altitudes above 975 Meters. This condition could potentially lead to patient hemodynamic instability.

Our records indicate that your facility received one or more of the Cardiosave IABP units.

Identification of the Issue:

Maquet/Getinge has received complaints involving the Cardiosave IABPs regarding the use of certain Intra-Aortic Balloons (IABs) at altitudes above 975 Meters. The Cardiosave may not successfully complete the autofill process required to initiate pumping. This failure may result in either interruption of therapy upon the first maintenance autofill or the inability to start therapy.

It is important to note, there have been no adverse events or deaths attributed to this issue.

IABs used with the CS100 or CS300 IABPs are not affected by this issue.

Maquet/Getinge has evaluated the potential failure and is implementing the following corrections to address this situation.

Interim Immediate actions to be taken by User:

The only action to be taken by the user is to follow the operating altitudes as specified below for the Cardiosave IABP. (Instructions for Use Addendum attached).

Balloon Name and Size: • Sensation 34cc / 40cc, • Sensation Plus 40cc / 50cc	Operating Altitude: -381 meters to 975 meters (795 mmHg to 676 mmHg) (1060 hPa to 901 hPa)
Balloon Name and Size: • Mega 50cc	Operating Altitude: -381 meters to 1524 meters (795 mmHg to 632 mmHg) (1060 hPa to 843 hPa)
Balloon Name and Size: • Mega 30cc / 40cc • Linear 25cc / 34cc / 40cc	Operating Altitude: -381 meters to 3657 meters (795 mmHg to 483 mmHg) (1060 hPa to 644 hPa)

Alternatively, use a CS100 or CS300 IABP since they are not affected by this issue.

Please complete the Urgent Medical Device Correction Response Form on page 3 to acknowledge that you have received this Medical Device Correction letter. Please fax the completed form to your local Maquet/Getinge office.

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

Corrective Action:

Maquet/Getinge is currently developing a software correction to address this issue. Maquet/Getinge anticipates the installation of the updated software to begin February 2019. A Maquet/Getinge Service representative will contact you to schedule the installation of the updated software. This work will be done at no cost to you at your facility.

Maquet/Getinge apologizes for any inconvenience you may experience as a result of this Medical Device Correction. If you have any questions, please contact your local Maquet/Getinge representative.

Thank you for your cooperation and immediate assistance.

Sincerely,

[redacted]

September 24, 2018

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[ACCOUNT NO.]
[ENTER FACILITY NAME]
[ADDRESS]

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.

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

Facility Representative:

Signature:_____ Date:_____

Name:_____ Phone:_____

Title:_____ Department:_____

Facility Name:_____

Address, City and State: _____

Please return the completed form to your local Maquet/Getinge office.