MAQUET
GETINGE GROUP

March 24, 2014

PRODUCT RECALL
URGENT – MEDICAL DEVICE FIELD CORRECTION

PRODUCT: Datascope System 98/98XT, CS100®/CS100i and CS300™ Intra-Aortic Balloon Pumps (IABP)

IABP	Model Numbers	
System 98	0998-00-0446-xx	0998-UC-0446-xx
System 98XT	0998-00-0479-xx	0998-UC-0479-xx
CS100i	0998-UC-0446Hxx	0998-UC-0479Hxx
CS100	0998-00-3013-xx	0998-UC-3013-xx
CS300	0998-00-3023-xx	0998-UC-3023-xx

Product Distribution Dates: January 17, 2003 – June 30, 2011

PLEASE FORWARD THIS INFORMATION TO ALL POTENTIAL INTRA-AORTIC BALLOON PUMP (IABP) USERS WITHIN YOUR INSTITUTION

Dear Risk Manager,

As a result of customer complaints related to a malfunction of the System 98/98XT, CS100, CS100i and CS300 Intra-Aortic Balloon Pumps (IABP), Datascope Corp. conducted an investigation and identified a potential mechanical failure of the fan assembly associated with the power supply. A fan assembly failure could result in the power supply overheating and cause the IABP to shut down without warning.

Product Affected
The products affected by the Field Correction are specific System 98/98XT, CS100/CS100i and CS300 IABPs containing an affected fan assembly. Between January 1, 2003 and June 30, 2011, specific System 98/98XT, CS100/CS100i and CS300 IABPs were manufactured with an affected fan assembly, or may have received an affected fan assembly during an upgrade/service of the IABP in the field.

A review of our records indicates that you may have an IABP unit in your facility that may be affected by this recall.

Identification of Problem
The fan assembly for specific System 98/98XT, CS100/CS100i and CS300 IABPs could potentially contain a misshapen retaining ring. This retaining ring could disengage within the fan assembly, causing the fan to stop rotating, which causes the power supply to overheat and the IABP to shut down without any visual or audible warning.

Adverse Effect on Patients
As part of the internal investigation, Datascope Corp. conducted a Health Hazard Evaluation and the Hazard/Risk Index associated with this issue was determined to be "moderate". Patients receiving IABP therapy are in critical condition and a sudden interruption of therapy could result in unsafe hemodynamic instability. Additionally, pursuant to the WARNINGS section of our IABP Operating/User Instructions, clinicians are instructed to not leave the patient unattended during IABP therapy.

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 IABP Operating Instructions:

WARNING: The patient balloon should not remain inactive in the patient (i.e., no inflating or deflating) for more than 30 minutes, due to the potential for thrombus formation.

In the unlikely event that this situation was to occur, transfer the patient to an alternative Datascope IABP. If an alternative Datascope IABP is unavailable; manually inflate the IAB with air or helium and immediately aspirate. Please refer to the IAB Instructions for Use, *Manually Inflating and Deflating a Catheter*. The IAB Instructions for Use reiterates that a catheter should not remain inactive for more than 30 minutes, due to the potential for thrombus formation. Alternatively, the IABP could be removed.

Corrective Action
At your convenience, your Service Representative will contact you to schedule the replacement of the fan assembly. This work will be done at no cost to you at your facility. Upon completion of the replacement, you will be requested to sign a service repair order to verify satisfactory completion of the work. Your cooperation is greatly appreciated.

We apologize for any inconvenience this may cause. For customers with technical questions, please contact our Technical Support Department.

Sincerely,
Karen LeFevere

Karen LeFevere
Director of Regulatory Affairs and Field Action Compliance
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