

URGENT MEDICAL DEVICE RECALL
MAQUET/Datascope's Intra-aortic Balloon Pumps for Display Failure

CS300 Intra-Aortic Balloon Pump (0998-00-3023-XX)

CS100 Intra-Aortic Balloon Pump (0998-00-3013-XX)

Date:

Facility: **>Please add customer address<**

Attention: Hospital Administrator

Please route this letter to all potential Intra-Aortic Balloon Pump users within your facility.

MAQUET/Datascope has discovered that certain of the above identified MAQUET/Datascope Intra-Aortic Balloon Pumps (IABP) have the potential to experience display related issues. Although the IABP continues to deliver therapy to the patient, display related issues may cause the user to be unable to view the IABP information on the screen.

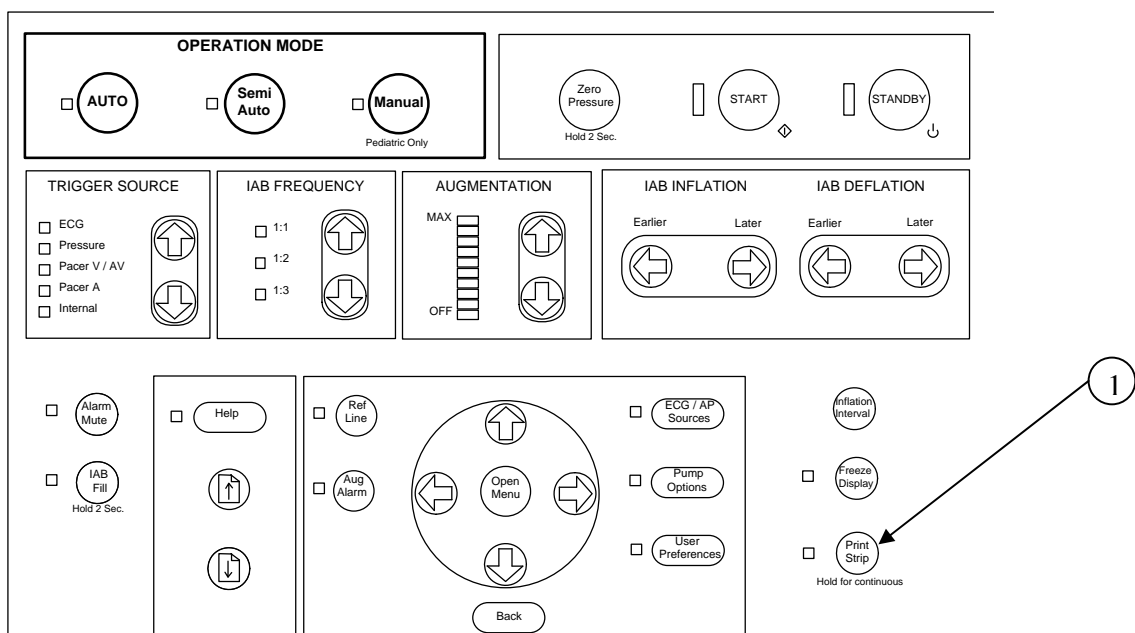
Affected Serial Numbers: **>Please add serial numbers<**

In the event that this scenario should take place, the pump will continue to deliver therapy to the patient appropriately and all audible alarms will be active.

1. All critical display information can be viewed from the dual trace chart recorder printout. The dual trace chart recorder provides an annotated hard copy record of patient waveforms, patient parameters and alarms. It is recommended that the IABP's are set to initiate a print strip automatically in the event of an alarm. This is accomplished by opening the **User Preferences menu** and selecting **Printer Preferences/auto print on**. This setting will be maintained with each patient use. (Instructions for the printer operation are included in the operating instructions).

2. If the **auto print on** has not been selected, a strip can be printed in the following way if desired or an alarm sounds (this allows the clinician to obtain a printed record of the alarm and respond in the same manner as if the alarm message was viewed on the display):

- Press the **Print Strip** key on the lower right hand corner of the keypad.
- To print a continuous strip hold the **Print Strip** key for two (2) seconds. The associated LED lamp will blink as printing continues. To stop continuous printing press the **Print Strip** key again.



3. If you wish to view the pressure waveform, an external monitor can be used (Please contact your Maquet/Datascope representative for details).
4. The clinician may also elect to remove the affected IABP from service and replace with a backup IABP.
5. Contact MAQUET/Datascope for prompt field service support.

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MAQUET/Datascope is initiating a field correction to repair the affected IABP's to ensure that the display screen functions correctly. A MAQUET/Datascope Service Representative will contact you shortly to arrange for repair of the affected IABP's. This work will be done at no cost to your facility.

MAQUET/Datascope is committed to providing product of the highest quality and we apologize for any inconvenience that this may cause. Please do not hesitate to contact your local Sales/Service Representative or myself at 973-244-6314 if you have any additional questions. Thank you for your cooperation.

Sincerely,

>Please sign<

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