

# SAFETY ALERT LETTER

MAQUET CARDIOVASCULAR INFORMATION

**MCV /2011-03-03**

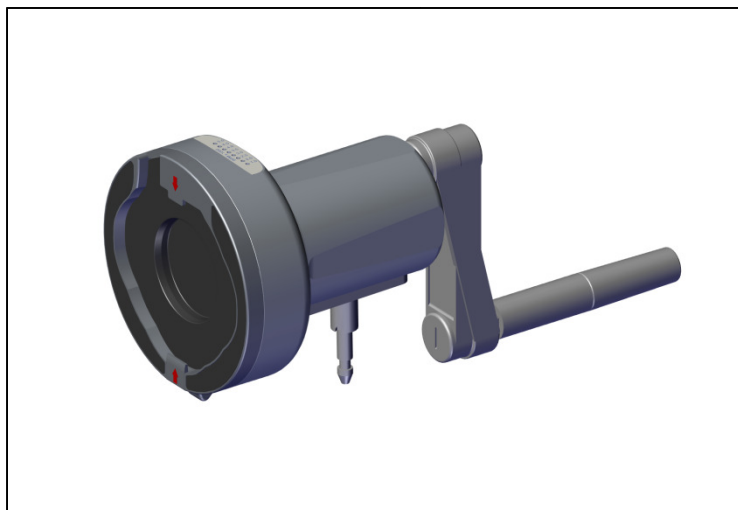
**PLEASE FORWARD THIS INFORMATION TO ALL USERS AND  
TO ALL BIOMEDICAL STAFF CONCERNED**

**Subject: CARDIOHELP Emergency Drive – may block during use**  
**Products affected: CARDIOHELP Emergency Drives, REF: 70104.8002,  
with serial numbers from S/N 90420011 to S/N 90420246.**

Dear CARDIOHELP Users,

It has come to our knowledge that in very rare cases the backup unit of the CARDIOHELP-i, the manually operated CARDIOHELP Emergency Drives (REF: 70104.8002, see picture 1) may block during use. In this case hand cranking an extracorporeal circuit will be almost impossible.

To date we have received two reports from the market which are not related to routine patient treatment.



*Picture 1: CARDIOHELP Emergency Drive*

The rootcause for this possible defect is a mechanical weakness of an internal fixation system of the CARDIOHELP Emergency Drive. In very rare cases it is possible, that this fixation system may fail due to the excessive strain and subsequently lead to a blocking of the CARDIOHELP Emergency Drive.

All affected CARDIOHELP Emergency Drives with serial numbers from S/N 90420011 to S/N 90420246 require a field update to ensure a reliable and durable function of the manually operated emergency device over the complete lifetime of the device.

**IMPORTANT NOTICE:**

Please note that the CARDIOHELP-i is not affected by this field action. The CARDIOHELP-i operates reliably and according to its specification.

This field action affects the manual operated backup unit, the CARDIOHELP Emergency Drive.

However, to minimize the patient risk the CARDIOHELP-i shall only be used on a patient if a second CARDIOHELP Emergency Drive or an additional CARDIOHELP-i is available in close proximity.

If no additional suitable backup system is available MAQUET will provide you with a Loaner Unit until the CARDIOHELP Emergency Drive has been updated.

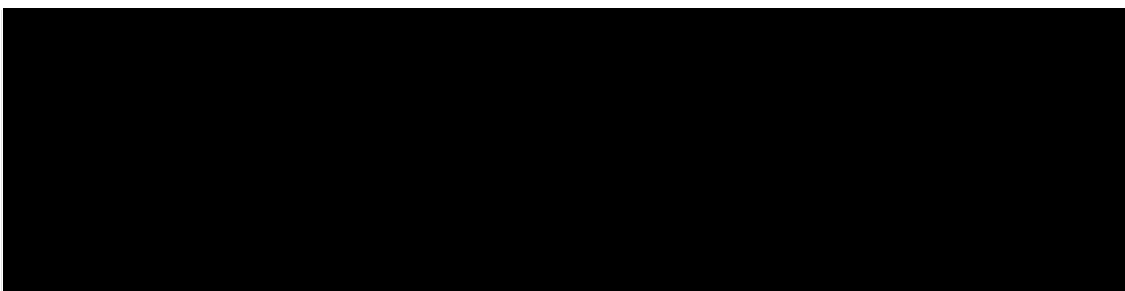
MAQUET has sufficient quantity of updated CARDIOHELP Emergency Drives and Update Kits on stock to provide you either a Loaner Unit or update your CARDIOHELP Emergency Drive as soon as possible.

Your local MAQUET representative will contact you regarding this matter.

We appreciate your understanding and thank you for your continued support as we provide you with up-to-date information on the quality of our products. We apologize for any inconvenience or concern this field action may have caused you.

If you have any additional questions, please contact your local MAQUET representative.

Yours sincerely,



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