

### FIELD SAFETY NOTICES

### MAQUET CARDOIVASCULAR INFORMATION

27/6/11

MCV/2011-06-10/01

MCV/2011-06-10/02

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

**Subject:** HL20 Twin Pump Module – Transient increase in pump speed  
HL20 – PSB Cover – Protection against entry of liquids

**Products Affected:** All HL20 4 Pump and 5 Pump Consoles and Twin Pump Modules (release version 11 ref: 703323 (Anti-clockwise) and ref: 706159 (Clockwise)) manufactured before 2011.

Dear HL20 Users,

Your local Maquet engineer will contact you to arrange a software update of your HL 20 Twin Pump Modules and sealing of the console/mast interfaces as the Field Safety Notices referenced above. All HL 20 4 & 5 pump consoles and TPM modules manufactured before the year 2011 are affected. To minimize disruption both improvements will be carried out together.

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 these field actions may cause you.

Please complete and return the enclosed acknowledgement form to confirm that the information has been received and circulated or email [cmoralee@maquet.co.uk](mailto:cmoralee@maquet.co.uk).

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

Yours Sincerely



Colin Moralee  
Regulatory Affairs Officer



## 1.0 MCV/2011-06-10/01 Twin Pump Module – Transient increase in pump speed

Based on observations in the field and during laboratory testing it has been determined that in very rare cases, it is possible for a HL 20 Twin Pump Module (TPM) (see Picture 1) to unintentionally increase its speed for a 1½ - 2 second period before returning to its originally set speed.

This malfunction can only occur when the TPM is used for cardioplegia and set up in a master/slave configuration. During the malfunction, an incorrect mixing of the cardioplegia solution can occur before the pump speed returns to its original setting.

This behaviour can only occur when one of the TPM pumps is set as cardioplegia slave and the other as the cardioplegia master. When the TPM is used in any other configuration, this malfunction does not occur.

There have been no reported patient injuries or death.



Picture 1: HL20 Twin Pump Module

The root cause of this potential problem is a software bug in version 2.4 or lower which is running on the EPROMS located on the TPM control boards.

New software will be installed by exchanging the old EPROMS on the TPM control boards with new EPROMS containing software Version 2.5. (Figure 2)

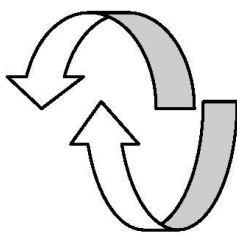


Figure 2: EPROMS on the Control Boards

Until the software update is performed we advise that you to keep the patient side of the cardioplegia delivery line clamped at all times between cardioplegia deliveries and that you switch off, i.e. power off, the slave pump between between cardioplegia deliveries if you are using the HL20 TPM in cardioplegia master/slave mode.



## 2.0 MCV/2011-06-10/02 HL20 PSB Cover – Protection against entry of liquids

In very rare cases, during cleaning or disinfecting, it is possible for liquids to enter into the HL 20 – 4 pump console or HL 20 – 5 pump console. If an excessive amount of liquid is used, the liquid can accumulate inside the HL 20 console and drip onto the HL 20 power supply board where it might cause the power supply board to malfunction.

We have received a small number of reports from the market. All reported malfunctions occurred before or after an operation. There have been no reports of patient or user injuries or deaths.

The root cause for this potential problem is, that the tolerances of the HL 20 mast diameter, the holes where the masts enter the HL 20 console (Figure 3: arrows show where the liquids can enter the HL20 Console), and the sealing rings may combine in such a way that the overall sealing effect is no longer effective in preventing liquids from entering the machine. This effect may be further compounded by additionally flushing the HL 20 System with excessive water.

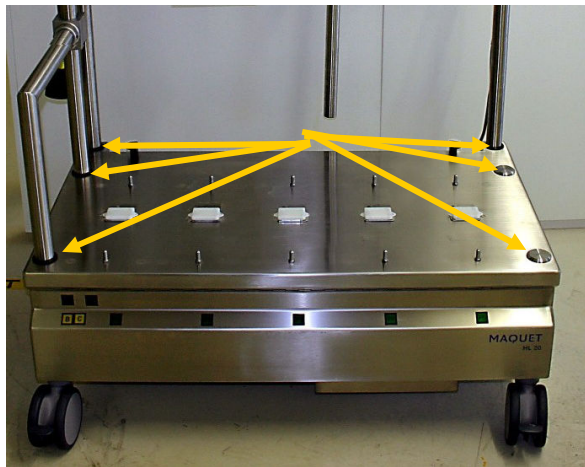


Figure 3: HL20 – 4 Pump Console (Example – identical for HL20 – 5 Pump console)  
The arrows show where the liquid can enter the HL20 Console

All console/mast interfaces will be sealed (Figure 4: Cover Plug Sealing) and a cover (Figure 5: PSB Cover) will be mounted over the power supply board inside the HL20 console. In the very unlikely event that liquid finds its way into the console, the installation of this cover will prevent these fluids coming into contact with the power circuit board.



Figure 4: Cover Plug Sealing



Figure 5: PSB Cover

Please ensure that until the update is performed, no excessive amount of liquid is applied to your HL 20 during normal use and in particular during cleaning and disinfection. Please also refer to the HL 20 User's Manual, Section "Cleaning and Disinfection". This section instructs users not to flush the HL 20 system with excessive water, as this could damage the electronics. The User's Manual also provides information on the chemical solvents (such as alcohol, ether and acetone) which should not be used and that anesthetics (such as Foram (Isofluoran)) should not be spilled over the HL 20 system as these can damage the machine.

