FIELD SAFETY NOTICE

MAQUET
GETINGE GROUP

MAQUET CARDIOVASCULAR INFORMATION

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

FIELD SAFETY CORRECTIVE ACTION

Subject:	**CARDIOHELP-i Software Update 3.3.2.0 ("Step 1")**
Products affected:	**All CARDIOHELP devices up to S/N: 90410628 - except S/N: 90410622 and 90410626**

Dear CARDIOHELP Users,

This letter is to inform you about a voluntary field correction of MAQUET's CARDIOHELP-i software.This field correction addresses two potential software problems which may occur during use of the CARDIOHELP equipment:

1) Human Machine Interface (HMI) restart:

It has come to the attention of MAQUET that there have been episodes of a brief unexpected shutdown, followed by an automatic device restart of the human machine interface (touchscreen) of the CARDIOHELP device. The human machine interface (HMI) is the central display of the CARDIOHELP device, where measured values, settings and alarms are displayed and adjusted/confirmed, with the exception of blood flow which is set by a separate rotary knob located at the front of the device.

When these episodes occur, the touchscreen goes black for up to 15 seconds, followed by an automatic restart/reboot of the device. As a result, manually selected settings and alarms revert back to hospital "clinic configuration" settings, which have been pre-set via password control. The malfunction appears as follows:

- The display screen goes black, and the unit then restarts, however all settings revert back to the hospital settings stored in the clinic configuration of the device, originally set by the key user under password control.
- Any manual settings prior to the HMI reset are lost, including: warning limits, alarm limits, and intervention messages.
- During the fifteen (15) second interval when this anomaly occurs, there are no alarms, and changes to the settings cannot be made.
- If the pump was operating before the HMI restart, the CARDIOHELP-i displays a pop-up

window informing the user that the unit was restarted and directs the user to check the settings.

- If the CARDIOHELP-i pump was not operating before the HMI restart, the pop-up message will not be displayed, however all manual settings will be lost as stated above.

Patient Risk:

No patient injuries have been reported. It is important to note that blood flow is not affected during the restart of the HMI, therefore there is no risk of circulatory impairment. However, the hospital's clinic configuration settings are then reverted to after the event.

Caution: It is unlikely that air should enter the circuit during the occurrence of this event, however if this were to occur, there is a risk of air embolism. For this reason per the IFU, the user should closely monitor the circuit during use.

2) "Frozen" pressure values through electromagnetic interference:

We have detected through internal testing that there is a possibility that electromagnetic interference, due to electric current fluctuations, may cause pressure values on the display to "freeze". The internal pressure values that could be affected are:

- Blood inflow pressure before the blood pump (P_{ven})
- Pressure after pump, but before oxygenator (P_{int})
- Outflow pressure after oxygenator (P_{art})

Should the described malfunction occur, the CARDIOHELP-i pump must be shut-down and the power cord disconnected, followed by re-inserting the power cord and a restart of the unit by the user. The duration of a pump-shut-down, power cord disconnection and device reboot can take up to 30 seconds at which time hand-cranking during device shut-down is necessary.

Patient Risk:

Although the risk of this malfunction occurring is extremely low, the duration of a pump shutdown may be sufficient to cause temporary hemodynamic and persistent cerebral dysfunction, particularly for those patients fully dependent on device support. To avoid these adverse health effects, hand-cranking during device shut-down is necessary to maintain sufficient circulatory support, as indicated in the instructions for use.

To date, no customer complaints or patient injuries have been reported.

MAQUET's Corrective Actions:

MAQUET has updated its current CARDIOHELP-i software to version 3.3.2.0. This new software version shall be installed by an authorized MAQUET service technician.

According to our shipping records your facility has received one or more CARDIOHELP-i systems with the affected software. Your facility will be contacted by a representative of the MAQUET Service team within two weeks of receiving this letter to schedule an on-site service of the affected equipment.

MAQUET Service will exchange all affected CARDIOHELP-i software with the 3.3.2.0 updated version.

The current User Manual is still valid.

We apologize for any inconvenience the update may cause. Your local MAQUET representative will contact you to arrange a field corrective action of your CARDIOHELP.
We appreciate your patience and thank you for your continued support. We apologize for any inconvenience this field action may cause you.

If you have any additional questions, please contact your local MAQUET representative, or alternatively MAQUET Customer Service at +49 7222 932-1106.

Yours sincerely,

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