

Urgent!

Field Safety Corrective Action (FSCA)

MAQUET
GETINGE GROUP

13. October 2015

FSCA Number:	FSCA-2015-10-12
FSCA Title:	HCU 30 Type 2 – Replacement of Power Supply Board
Affected Product:	Heater-Cooler Unit 30 with Serial Number <93101480 HCU 30 Base Unit 100-120 V, article number 704629 / 70103.4371 HCU 30 base unit 200 - 240 V, article number 704631 / 70103.4642 HCU 30 base unit Canadian/US, article number 705501 / 70103.4653
Unique Device Identification (UDI Code):	N/A
Affected product details:	N/A
Description of the problem:	It is possible that a drop of more than 10% voltage leads to an overheating and subsequent failing of a component of the power supply board resulting in an inoperable compressor or in an inoperable HCU 30
Corrective Action:	Maquet technician replaces the power supply board. The new power supply board is robust against mains variations.
Advice on action to be taken by the user:	Always keep a replacement unit on standby in order to ensure continuous operation in the event of a failure of compressor or the entire HCU 30.
Referenced documents/attachments:	None

Dear valued Customer,

MAQUET Cardiopulmonary has received complaints associated with a failure of the power supply board of the HCU 30. An internal investigation showed that a drop of more than 10% voltage can cause an overheating and subsequent failing of the NTC (Negative Temperature Coefficient) R56 thermistor of the power supply board. This failure typically occurs when the compressor is switched on, i.e. before patient connection. A defective thermistor results in an inoperable compressor or in an inoperable HCU 30. There are no complaints reported associated with a patient injury or death.

Corrective actions:

- The power supply board is replaced by a Maquet technician. The new power supply board is equipped with a more robust NTC R56 thermistor.

- In the meantime, always keep a replacement unit on standby in order to ensure continuous operation in the event of a complete system failure.

Transmission of the Field Safety Notice:

- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which the action has an impact.

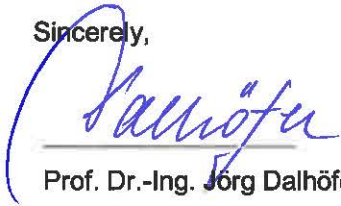
We apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

As required, we have provided this notification to the necessary Regulatory Agencies.

Please confirm the receipt of this Urgent Field Safety Notice by filling out the form on page 3 of this letter.

Should you have questions or require additional information, please contact your local MAQUET representative.

Sincerely,



Prof. Dr.-Ing. Jörg Dalhöfer
Chief Operations Officer (COO)



Michael Campbell
Safety Officer

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY

Subject: Mandatory Field Safety Corrective Action 2015-10-12 – Heater-Cooler Unit HCU 30

Action: Heater-Cooler Unit HCU 30 - Replacement of Power Supply Board

I confirm the receipt of this Urgent Field Safety Notice dated 2015-Oct-12. I also confirm that I have distributed this Field Safety Notice to the affected personal.

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Hospital

.....
Address

.....
Date

.....
Name (Function)

.....
Signature

Please return to MAQUET Cardiopulmonary's Quality Assurance department

- Email: quality.assurance@maquet.com
- Fax: +49 7222 932 1888
- Mail: Maquet Cardiopulmonary GmbH
Att. Quality Assurance
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