

2020-10-02

**URGENT - FIELD SAFETY NOTICE**

**Subject:** FSCA-2020-08-14 HCU 40 Replacement of internal wiring

**Affected Product:** 70104.4054 Heater-Cooler Unit HCU 40 High Voltage  
70105.4917 Heater-Cooler Unit HCU 40 Low Voltage

**Affected Serial No.:** All HCU 40 units with a serial number below 90441922

Dear valued customers,

Maquet Cardiopulmonary GmbH has received isolated complaints in relation to heat damage of the cable insulation at the crimp connections of the power cable and the internal electrical connection (L and N) cables between the main circuit breaker and line filter of the HCU 40 Heater-Cooler Unit.

Our investigation has shown that the crimp connections of those cables did not always meet the requirements and acceptance criteria of the IPC/WHMA-A-620 standard. Inadequate crimp connections can result in higher temperatures leading to heat damage of the cable insulation and in the worst case to a tripped main circuit breaker resulting in a non-operational HCU 40.

This effect can be accelerated if splashing tank water after disinfection of the water circuits containing residuals of the active ingredient Chloramine T reaches the circuit breaker and connected cables, if the user inadvertently does not close the stopcocks of the patient and cardioplegia water circuits prior to removal of the hoses (as prescribed in the Instruction for Use, section 7.2.1). Tank water containing Chloramine T can promote cable corrosion, which in turn can result in combination with inadequate crimping to the device failure described above.

A non-operational HCU 40 during extracorporeal circulation while cardio-thoracic surgery can have critical or catastrophic consequences for a patient, but according to the risk assessment of Maquet Cardiopulmonary GmbH this is estimated as unlikely.

Maquet Cardiopulmonary GmbH has not received any complaints of patient harm, serious injuries or deaths caused by such damage.

Based on our risk assessment a general decommissioning of the affected HCU 40 systems is not required.

- Corrective Action:**
- The power cable and internal wiring of the affected HCU 40 will be replaced at the latest during the next preventive maintenance.
  - The HCU 40 Service Manual now includes an instruction to inspect the crimp connections of the internal power/ electrical cables during annual maintenance and to replace them if heat damage is detected.

- Advice on action to be taken by the user:**
- Your current stock may include products affected by this action.
  - As a general precautionary measure in the instruction for use for HCU 40, please always keep a replacement unit on standby in order to ensure continuous full operation in the event of total device failure.
  - Please ensure that the stopcocks of the patient and cardioplegia water circuits are always closed after cleaning prior to removal of the hoses as described in the Instructions for Use in section 7.2.1. This ensures that no tank water containing Chloramine T can enter the inside of the HCU 40.
  - Your local Getinge representative will contact you to arrange the replacement of the power cable and internal wiring of your HCU 40 system(s).
  - Please duly complete the enclosed Letter of Acknowledgement Customer and return it as soon as possible to your local Getinge representative by mentioning FSCA-2020-08-14 as reference.

- Referenced documents/ attachments:**
- Letter of Acknowledgement Customer

**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.

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

Sincerely,

**Managing Director**

**Safety Officer**

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