

2020-08-05

URGENT - FIELD SAFETY NOTICE

Subject: FSCA-2020-08-06 HCU 40 Replacement of vacuum valves

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 below S/N 90442012

Dear valued customers,

The HCU 40 Heater-Cooler Unit is intended for cooling or warming a patient connected to the extracorporeal perfusion circuit and keeping the required patient temperature constant. The system comprises two separate water circuits with temperature regulation. The first circuit is for connecting the oxygenator heat exchanger and/or the warming/cooling blanket. The second circuit is intended for connecting the cardioplegia heat exchanger.

Both water circuits of the HCU 40 feature multiple valves that control the water flow. One of these valves is the vacuum valve. There is a vacuum valve located in each circuit, the patient water circuit and the cardioplegia water circuit.

Maquet Cardiopulmonary GmbH has received complaints in relation to leaking vacuum valves of the HCU 40.

The vacuum valve in each water circuit is closed during the HCU 40 operations modes de-airing, warming and cooling as well as cleaning. During the emptying mode, which is regularly performed after surgery, an under pressure is applied to the respective water circuit that opens the vacuum valve. Air is sucked into the circuit in order to prevent the hoses from collapsing to allow the water to be pumped back into the tank

Based on engineering testing, it is possible that after performing the emptying mode, the vacuum valve does not fully close. When the HCU 40 is then operated again, water can leak while de-airing, cleaning, but also during regular cooling and warming through the incompletely closed vacuum valve into the inner compartment of the HCU 40. Depending on the amount of leakage different consequences can be expected:

- At a minimal water loss, the insulation material will absorb the escaping water and the water will eventually evaporate. In case of a leaking vacuum valve during the cleaning mode, crystalline residues of chloramine T (used for disinfection) and/or citric acid (used for descaling) could remain on the insulation material after evaporating.
- If the water or cleaning/disinfection solution loss is excessive, the insulation material cannot absorb it anymore, and fluid flows onto the floor. If the leakage remains undetected and the HCU 40 is not stopped, the flow sensor of the unit triggers a "water flow too low error" alarm, caused by air sucked into the water circuit due to the vacuum valve being incompletely closed.
- If the leakage is significant and the insulation material of the water circuit cannot absorb the outgoing water or cleaning/disinfection solution from the vacuum valve, the fluid can reach the box of the Printed Circuit Board. This may cause an electrical short circuit and could lead to a shut down of the HCU 40.

A significant leakage of an improperly closed vacuum valve is typically detected already during de-airing (in preparation of the device before surgery) or during the cleaning mode. Therefore, please check, if during or

after performing these operation modes any fluid leaks out of the HCU 40 housing. If this is the case, please take the unit out of operation and contact an authorized Getinge service technician for repair

If the malfunction is not detected prior to use on a patient, critical or catastrophic consequences for a patient are possible, but according to the risk assessment of Maquet Cardiopulmonary GmbH estimated as unlikely

Maquet Cardiopulmonary GmbH has not received any complaints of patient harm, serious injuries or deaths caused by a HCU 40 leaking vacuum valve.

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 the described vacuum valve leakage.

Considering the precautionary measure and based on the associated risk to the leaking vacuum valve, a general decommissioning of the affected HCU 40 systems is therefore not required.

Corrective Action:

- Maquet Cardiopulmonary GmbH qualified and verified a new vacuum valve type for HCU 40. Existing vacuum valves in the affected HCU 40 systems will be replaced by the successor with proven long-term material compatibility and functional reliability.
- Please note that this replacement also concerns HCU 40 customers, who were formerly affected by FSCA-2018-07-18 HCU 40 Leaking Vacuum Valve.

Advice on action to be taken by the user:

- According to our post-market surveillance documentation, 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 the described vacuum valve leakage.
- The vacuum valves in the affected HCU 40s shall be replaced by the new successor as soon as possible, at the latest during the next annual preventive maintenance.
- Your local Getinge representative will contact you to arrange the replacement of the vacuum valves of your HCU 40 system(s).
- If you have an affected HCU 40 unit, duly complete the enclosed Letter of Acknowledgement Customers and return it as soon as possible to FSCA.cp@getinge.com by mentioning FSCA-2020-08-06 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.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

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

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY

FA Number: FSCA-2020-08-06
FA Title: HCU 40 Replacement of vacuum valves
Affected Product: 70104.4054 Heater-Cooler Unit HCU 40 High Voltage
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The undersigned hereby acknowledges receipt and understanding of actions required to comply with the Field Action on hand. I also confirm that I have distributed this Field Safety Notice to the affected personnel.

- We do not have an affected HCU 40 unit in our **stock**.
- We have (an) affected HCU 40 unit(s) in our stock.

If yes:

Article Number (SAP No.)	Description	Serial Number
XXXXXX.XXXX		

Country Hospital / Clinic (full address)

Date Name (Function)

Signature

Please return to your local Getinge representative:

E-Mail: <enter local Getinge mail address> Comments:
 Address: <enter local Getinge address>
 <XXXXXXXXXXXXXXXX>
 <XXXXXXXXXXXXXXXX>