2021-02-05

URGENT - FIELD SAFETY NOTICE

Subject:	**FSCA-2021-02-03** Cancelation of “FSCA-2020-08-06 HCU 40 Replacement of vacuum valves”, Reverse the conversion of updated HCU 40 systems by valve type “Römer”, Introduction of preventive annual replacement of HCU 40 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 systems below Serial Number 90442078

Dear valued customers,

On 2020-08-12, Maquet Cardiopulmonary GmbH issued FSCA-2020-08-06 to replace existing vacuum valves of the HCU 40 Heater-Cooler Unit by a new successor component in all HCU 40 systems below serial number 90442012. Despite intensive verification testing before releasing this new vacuum valve type “Römer” for production and spare part supply, complaints were received for this component in HCU 40 systems in the field, indicating a significantly higher probability of failure than for the predecessor vacuum valve type.

Maquet Cardiopulmonary GmbH, therefore,

- cancels FSCA-2020-08-06, i.e., stops this replacement by the “Römer” valve type,
- will reverse the conversion of already updated HCU 40 systems by this component and
- introduce an exchange of the predecessor vacuum valve type “LK” within the annual service maintenance.

A general temporary decommissioning of the affected HCU 40 systems with the vacuum valve type ”Römer“ is not required, if handled in accordance with the actions listed below (see “Actions to be taken by the user”).

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.

Problem description and expected consequences

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.

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 HCU 40 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 shutdown of the HCU 40.

If the malfunction of a leaking vacuum valve is not detected prior to use on a patient, critical or catastrophic consequences for a patient are possible.

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

Corrective Action:

- Maquet Cardiopulmonary GmbH cancels FSCA-2020-08-06, i.e., stops the replacement of the former vacuum valve type “LK” by the new valve type “Römer”.
- The valve type “Römer” will be replaced in all affected HCU 40 systems by the vacuum valve type “LK” within six months, with utmost urgency.
- The vacuum valve type “LK” will be exchanged on a 12-month basis during the annual service maintenance, pending a long-term solution.
- Inform users of HCU 40 systems equipped with the new vacuum valve type “Römer” not to use the emptying mode until replacement of this type of valve.

Actions to be taken by the user:

- According to our post-market surveillance documentation, your current stock may include products affected by this action. Your local Getinge representative will contact you to inform you which HCU 40 systems are equipped with the vacuum valve type “Römer” and arrange the replacement of the vacuum valves of your HCU 40 system(s). Maquet Cardiopulmonary GmbH recommends to mark these affected HCU 40 systems accordingly.
- **Please always keep a replacement unit on standby** in order to ensure continuous full operation in the event of the described vacuum valve leakage.
- **Please always check, if during or after performing any operation modes of the HCU 40 fluid leaks out of the housing**. If this is the case, please take the unit out of operation and contact an authorized Getinge service technician for repair.

  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.
- **Do not use the emptying mode on HCU 40 systems equipped with the vacuum valve type “Römer”** in order to prevent a malfunction of the device during surgery (until replacement of this type of valve). This prevents opening of the vacuum valves and thus reduces the risk for leakage.
- Not using the emptying mode after surgery implies the following manual procedure for the user:
  - Stop the HCU 40 water pumps, close the stopcocks for the cardioplegia and patient water circuits and clamp the end of the hoses over a bucket, and hold up the end of the hoses above the water level before disconnecting the heat exchanger in order to avoid water spillage.
  - Disconnect the heat exchangers from the Hansen-coupling of the hoses, connect the Double Hansen connector (cleaning connector) to close the water lines again and open the clamps.
  - For the connection of a new heat exchanger, follow this procedure correspondingly.

  - Check the water level in the tank before each procedure. If necessary, (to compensate the loss of water in the HCU 40 water tank due to the disconnection of filled heat exchangers) fill up the tank to the white level marking, using sterile water or water that has been filtered through a terminal sterile filter (with a pore size of 0.2 µm).

- The vacuum valves type “Römer” in affected HCU 40s shall be replaced by the vacuum type “LK” as soon as possible, at the latest within the period of six months after receiving this Field Safety Notice.
- If you have an affected HCU 40 unit, duly complete the enclosed Letter of Acknowledgement Customers and return it as soon as possible to your local Getinge representative.

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 sincerely apologize for any inconvenience this may cause you and 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, or send an e-mail to FSCA.cp@getinge.com.

Sincerely,

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Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY