

2023-05-15

**URGENT FIELD SAFETY NOTICE**

<b>Manufacturer SRN:</b>	<u>DE-MF-000020091</u>
<b>FSCA Reference:</b>	617044 - HCU 40 - additional preventive measures
<b>Affected Product:</b>	Heater_Cooler Unit HCU 40, High Voltage (article number 701044054) Heater_Cooler Unit HCU 40, Low Voltage (article number 701054917)
<b>Affected Serial No.:</b>	All
<b>Unique Device Identifier(s) (UDI-DI):</b>	04037691917566, 04058863222844
<b>For Attention of:</b>	Users of the Heater_Cooler Unit HCU 40

The changes from version 1 to version 2 are underlined

Dear valued customer,

Maquet Cardiopulmonary GmbH determined two trends for complaints regarding the Heater\_Cooler Unit HCU 40: Degraded internal drain hoses and leaking vacuum valves.

The HCU 40 is intended for cooling or warming a patient connected to the extracorporeal perfusion circuit and keeping the required patient temperature constant. The temperature transfer occurs via a heat exchanger in the patient perfusion circuit and/or cardioplegia water circuit and/or via a warming/cooling blanket.

To prevent vacuum valve leaks and device failures caused thereby, Maquet Cardiopulmonary GmbH performed three field actions: FSCA-2018-07-18, FSCA-2020-08-06 and FSCA-2021-02-03. Despite these efforts, the issue could not be solved completely. Therefore, Maquet Cardiopulmonary GmbH has developed and verified a re-circulation hose system, which, in the event of leakage from the vacuum valves, directs escaping liquid back into the tank. Please be informed that this re-circulation hose system is not considered a new design but rather a mitigation of the current design. Secondly, the replacement of the tank drain hose shall be performed. In addition, an Armaflex heat shield to the main circuit drain hose shall be applied to mitigate the heat effect of the compressor line. This complementary measure is included even though no trend was identified for this failure mode. These mitigates shall improve the safety and reliability of the HCU 40 system and are subject of the present field action.

As a general precautionary measure according to 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 a leakage of the internal drain hose or vacuum valve leading to a device shutdown.

Considering the precautionary measure and based on the associated risk to both malfunctions, general decommissioning of the affected HCU 40 systems is not required. Please always check, if before, 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.

**Problem description and potential consequences****Degradation of the HCU 40 system drain hose**

The failure mode degradation was reported for several HCU 40 system drain hoses made of Polyurethane (PUR) (see Figure 1 and Figure 2). However, on closer inspection, the tank drain hose was affected most. It is

located under the water tank and follows a S-shape between the compressor and the transformer to the bottom of the HCU 40. This hose is required for emptying the water tank when replacing the system water or when draining disinfecting or descaling solution. The tank drain hose as well as the other internal blue drain hoses are inside the device and not accessible for the user.



Figure 1: Degraded drain hose



Figure 2: Degraded vs. intact blue colored hose

An internal investigation concluded that the tank drain hoses inside the unit do not withstand the expected service lifetime of the device of 10 years due to limited resistance of the PUR hose material against residual disinfectant Chloramine-T. In case of incomplete disinfection procedures of the water circuits, i.e., insufficient rinsing, residuals of the chemical agent can remain within the tank drain hose forcing its degradation. This material stress factor may ultimately result into leakage of the hose. The statistical reliability analysis revealed that, with 95% confidence, the probability of HCU 40 malfunctions due to degraded drain hoses within the expected service life is between 2.1% and 4.3% per year.

Depending on the amount of leakage, different consequences can be expected:

- If the water loss is minimal, the insulation material (Armaflex) that surrounds the tank drain hose to minimize thermal loss will suck up the water and the water will eventually evaporate. After the water is evaporated, residues of Chloramine-T would remain on the insulation material. In this scenario, the user will not detect the malfunction because the water circuit is inside of the housing of the HCU 40. However, the service will likely detect the leak during the yearly preventive maintenance inspection of the HCU 40.
- If the water loss exceeds a certain value, the water flows on the floor. The user detects the leakage, stops the HCU 40, and calls the authorized service.
- If the water loss is significant and the insulation material that surrounds the tank drain tube cannot suck up the water, the water will flow outside of the tank drain tubes on the top of the box that contains the control unit PCB (printed circuit board). The water will eventually get in contact with either the control unit PCB or internal electrical connections causing a short circuit. In case of a short circuit the fuse of the HCU 40 will trip and the HCU 40 will shut down i.e., will stop pumping water. The service would open the HCU 40 detecting signs of water and the short circuit on the control unit PCB and would subsequently replace the affected tubes and the control unit PCB.

For the malfunction, all potential hazardous situations were evaluated with the following results:

- For device becoming inoperable with patient connected the potential harms 'organ damage/ ischemia', 'bleeding', 'prolongation of cardiopulmonary support and/ or total procedure time' as well as 'user inconvenience' were identified and the risk for each harm was evaluated as medium.

- For device becoming inoperable without patient connected the potential harms 'delay of procedure for greater than one (1) day' and 'user inconvenience' were identified and the risk for first harm was evaluated as medium and low for the second.

#### Leakage of the HCU 40 vacuum valve

The HCU 40 system consists of two separate water circuits with temperature regulation circuit, one for the oxygenator heat exchanger and/or the warming/cooling blanket (patient circuit), the second for the cardioplegia heat exchanger (cardioplegia circuit). There is a vacuum valve located in each circuit. The vacuum valve in each water circuit is closed during the HCU 40 operation modes de-airing, warming and cooling as well as cleaning. During the emptying mode, which is regularly performed after surgery, an underpressure 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.

The reported complaints for the HCU 40 vacuum valve include leakage in all cases and additionally short circuit in some cases. An internal investigation concluded that after performing the HCU 40 emptying mode, the vacuum valve might not close completely. When the HCU 40 is then operated again, water can leak into the inner compartment of the HCU 40 during de-airing, cleaning and also during regular cooling and warming. The statistical reliability analysis calculated that, with 95% confidence, the probability of HCU 40 vacuum valve failures is between 2.0% and 3.5% per year.

Depending on the amount of leakage, different consequences can be expected:

- At a minimal water loss, the insulation material (Armaflex) will absorb the escaping water and the water will eventually evaporate. 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.
- If the leakage is significant and the insulation material of the water circuit cannot absorb the outgoing water or cleaning/disinfection solution, 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.

For the malfunction, all potential hazardous situations were evaluated with the following results:

- For device becoming inoperable with patient connected the potential harms "organ damage/ Ischemia", "bleeding", "prolongation of cardiopulmonary support and/ or total procedure time" as well as "user inconvenience" were identified and the risk for each harm was evaluated as medium.
- For device becoming inoperable without patient connected the potential harms "delay of procedure for greater than one (1) day" and "user inconvenience" were identified and the risk for each harm was evaluated as medium.

While the HCU 40 is not a life-sustaining device per se, it is part of the family of life support equipment used to sustain and preserve normal physiologic function of those patients who require life-saving extracorporeal support. In some procedures, the absence, or delay, of the application of hypothermia, and/or the maintenance of normothermia, may have only little affect (if any) on physiological function. However, in complex, emergent procedures, a profound, adverse effect on physiological function is likely when either hypothermia cannot be applied or normothermia cannot be either achieved or maintained.

The absence of therapeutic hypothermia has the potential to be life threatening in certain, infrequent procedures, while the complete loss of an HCU40 may signal the postponement or the indefinite delay of necessary surgery until a suitable heater-cooler replacement is located.

Maquet Cardiopulmonary GmbH has not received any complaints of patient harm, serious injuries or deaths, neither due to HCU 40 tank drain hose degradation nor due to HCU 40 leaking vacuum valves.

#### **Corrective Actions**

- Replacement of the tank drain hose **during every annual preventive maintenance** until the new material is approved.

- Application of a heat shield made of Armaflex isolation to the main circuit drain hose during next preventive maintenance in order to protect the hose from heat stress of the compressor line.
- Inspection of all other blue colored hoses made of PUR **during every annual preventive maintenance** according to service manual and replacement if there are signs of degradation (e.g., signs of leakage).
- Installation of Vacuum Valve Recirculation system **during next preventive maintenance** in order to redirect leaking water from the vacuum valves back into the tank.

#### Actions to be taken by the customer

- HCU40 units are not requested to be returned and can be used following the regular cleaning and disinfection procedures as before.
- As a general precautionary measure according to the HCU 40 Instruction for Use, please **always** keep a replacement unit on standby in order to ensure continuous operation in the case of a total device failure.
- Please **always** check, if before, 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.
- Please identify all HCU 40 in your stock and arrange your next annual preventive maintenance with your local Getinge representative **as usual**.
- For customers without maintenance contract: A local Getinge representative will contact the customer to arrange the installation of the HCU 40 Vacuum Valve Upgrade Kit CE and the HCU 40 Vacuum Valve Kit.
- Please **always** report any adverse events in regard to the affected products to your Getinge Representative.
- Duly fill out the enclosed Letter of Acknowledgement Customer and return it as soon as possible, at the latest by **August 11, 2023**, to your local Getinge representative by mentioning FSCA-617044 as reference.

#### Actions to be taken by the manufacturer

- Inform all customers possessing the affected products **promptly** about this Field Action by sending the Field Safety Notice for Customers.
- Create a Replacement Instruction for Vacuum Valve Re-Circulation and System Drain Hoses.
- All spare parts required for performing the FSCA are included in HCU 40 Vacuum Valve Upgrade Kit CE (701079073) and HCU 40 Vacuum Valve Kit (701077143).
- Replace the tank drain hose **during every annual preventive maintenance** until the new material is approved.
- Apply heat shield made of Armaflex isolation to the main circuit drain hose during next preventive maintenance.
- Check all other hoses made of PUR **during every annual preventive maintenance** according to service manual and replace if there are signs of degradation. The respective optional spare parts (not free of charge)

are HCU 40 Internal Hose Kit CE (701079072) and HCU 40 Isolation Material Kit (701064710).

- Install Vacuum Valve Recirculation system **during next annual preventive maintenance.**
- For customers without maintenance contract: The local Getinge representative will contact the customer to arrange the installation of the HCU 40 Vacuum Valve Upgrade Kit CE and the HCU 40 Vacuum Valve Kit.

**Enclosed documents**

- Letter of Acknowledgement Customer

**Transmission of the Field Safety Notice**

- Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this urgent Field Safety Notice.
- Please transfer this notice to other organizations on which the action has an impact.
- If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.
- 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](mailto:FSCA.cp@getinge.com).

Sincerely,

**Managing Director**

**Signature:** *Dieter Engel*

Electronically signed by: Dieter Engel  
Reason: I approve this document.  
Date: May 15, 2023 17:10 GMT+2

**Email:** dieter.engel@getinge.com

**Person Responsible for Regulatory Compliance (PRRC)**

**Signature:** *Tom Peters*

Electronically signed by: Tom Peters  
Reason: I approve this document.  
Date: May 15, 2023 19:18 GMT+2

**Email:** tom.peters@getinge.com

**Contact details of manufacturer**

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Phone: +49 7222 932 - 0  
Email: [FSCA.cp@getinge.com](mailto:FSCA.cp@getinge.com)

CUSTOMER RESPONSE FORM

**FSCA Reference:** 617044 - HCU 40 - additional preventive measures

**Affected Product:** HCU 40 Heater\_Cooler Unit High Voltage (article number 701044054)  
HCU 40 Heater\_Cooler Unit Low Voltage (article number 701054917)

**Affected Serial No.:** N/A

Please send this form to your local Getinge representative at the latest by **August 11, 2023**.

By completing this document and signing it, I acknowledge that I have read and understand the following associated points:

- I have read and understand this Field Safety Notice for products HCU 40 Heater\_Cooler Unit High/ Low Voltage. We will take action as soon as possible according to given instructions.
- I confirm that I have distributed this Field Safety Notice to the affected personal.

- I do not have HCU 40 Heater\_Cooler Unit High/ Low Voltage in my inventory.
- I have the following HCU 40 Heater\_Cooler Unit High/ Low Voltage in my inventory and
  - I have a Preventive Maintenance Contract with Getinge or authorized representative.
  - I do not have a Preventive Maintenance Contract with Getinge or authorized representative.

Following affected HCU 40 Heater\_Cooler Unit High/ Low Voltage are in our inventory:

Article Number	Description	Serial Number

Your Comments:

Country

Hospital / Clinic (full address)

**FIELD SAFETY NOTICE**



**DMS No.:** 3243545 V 02

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\_\_\_\_\_  
Date

\_\_\_\_\_  
Name (Function)

\_\_\_\_\_  
Signature

Please return the completed form to your local Getinge representative by email [enter local Getinge mail address](#) or via post [enter local Getinge address](#) or FAX.

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