

2021-08-23

URGENT - FIELD SAFETY NOTICE

Subject: FSCA-2021-08-19 Preventive annually replacement of HC40 3-way-valve

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

Dear valued customers,

Maquet Cardiopulmonary GmbH has received complaints for the HCU 40 Heater-Cooler Unit about ice melting in relation to 3-way-valve malfunctions.

Statistical analysis indicates that with increasing operation time of the HCU 40 device the probability of the 3-way-valve to malfunction increases. In order to significantly reduce the probability of 3-way valve malfunction, Maquet Cardiopulmonary is initiating a preventive field action for the annual exchange of the HCU 40 3-way-valves during the regular maintenance.

Problem description:

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. The 3-way valves regulate the balance of warm and cold water circulated in both, the patient and cardioplegia water circuits.

A statistical reliability analysis revealed that with 95 % confidence the probability of the 3-way valve to malfunction within its expected service life of 10 years is between 14.1% and 22.8%.

Failure to correctly apply the disinfection and/or descaling procedures of the water circuits (e.g. insufficient dissolving of the agents when preparing the solution, too low temperatures, wrong dosing and/or insufficient rinsings) can lead to crystalline deposits in the 3-way-valve promoting corrosion and malfunctions.

If the 3-way-valve does not close completely, warm water is sent back to the cold-water tank, leading to an increase in water temperature of the tank. This, in turn, accelerates melting of the ice block present in the cold-water tank. Consequently, the decrease in ice block mass, with increasing tank temperature, reduces the capability of the device to cool a patient.

The fault pattern ranges from a slight functional impairment of the 3-way-valve associated with discreet premature melting of the ice block of the affected water circuit to a complete failure of the 3-way-valve with significantly premature, fast melting of the ice block and impaired temperature regulation due to insufficient cooling capacity.

Due to the nature of the issue, most users will not detect a malfunction, if the amount of water guided to the water tank is relatively low. The typical error "ice block melting fast" occurs, if the amount of warm water guided to the water tank reaches a limit that the customer will notice a significant loss of cooling performance after a relatively short cooling time.

According to our complaint review, 3-way-valve failures were predominately detected during service.

Taking into consideration the possibility of a 3-way-valve malfunction, either before or during clinical application, the following potential immediate and long-term health consequences (harms) are conceivable:

- Organ damage and/or ischemia if systemic and/or localized cooling is either delayed or not available.
- The delay or even the cancellation, of a procedure(s) due to the unavailability (short or long term) of a heater-cooler unit.

Maquet Cardiopulmonary GmbH has not received any complaints of patient harm, serious injuries or deaths caused by a HCU 40 3-way-valve malfunction.

Due to the direction of water flow through the 3-way-valve, the heating performance of the HCU 40 is not impacted and patient warming is therefore not affected by a 3-way-valve malfunction.

Preventive Action:

- The 3-way-valve will be exchanged on a 12-month basis during the regular annual maintenance, pending a long-term solution, to prevent long-term degradation and a failure of this component over the estimated service-life-time of the HCU 40.
- The updated HCU 40 Service Manual with the instruction to exchange the 3-way-valve during annual maintenance will be provided to Getinge authorized service technicians.

Actions to be taken by the user:

- According to our post-market surveillance documentation, your current stock may include products affected by this action.
- **Please follow the HCU 40 Instructions for Use** to prevent incidences related to HCU 40 3-way-valve malfunctions, especially
 - Chapter 2.2.1 Precautionary Measures
 - Chapter 2.2.5 Monitoring and Sensors
 - Chapter 4.6.2 Check before every application
 - Chapter 7.2 Descaling and disinfection of the water circuits
- Before every application:
 - Perform the self-test of the HCU 40: If the device is switched on already, switch it off and then on again, so that the functional check will be performed automatically.
 - Check that the size of the ice blocks in the HCU 40 tank are sufficient.
 - Ensure that crushed ice is available.
 - Keep always a replacement unit on standby in order to ensure continuous operation in the event of a significant malfunction of the 3-way-valve or complete system failure.
- During the application:
 - Continually monitor especially the temperature of the patient and the blood temperature of the perfusion system by an independent monitoring system.
 - If the temperature adjustment in case of cooling, visually inspect the actual size of the ice blocks in the HCU 40 tank.
 - If not enough ice is available, follow the procedures to add crushed ice to the tank according to the instruction for use or use a replacement device.
- Descaling and disinfection of the water circuits:
 - Follow the instructions for use for determining the correct dosing quantity for preparing the chloramine-T solution for disinfection and citric acid concentration for descaling.
 - Completely dissolve the chloramine-T and citric acid powder at approx. 35°C when preparing the solution for use to avoid any deposits of the substances in the circuits.
 - Carefully follow the rinsing procedures after applying the chloramine-T or citric acid solution.
- If you have an affected HCU 40 system, duly complete the enclosed Letter of Acknowledgement Customer 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,

Managing Director

Safety Officer

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