

Urgent!
Field Safety Notice (FSN)

5th of December 2016

FSN Number: 2016-11-30

FSN Title: Revised disinfection procedure for Heater-Cooler Unit HCU 40

Type of Action: Customer Notification

Affected Product: Heater-Cooler Unit HCU 40

Unique Device Identification (UDI Code): Not Assigned

Affected product details: The FSCA affects all models and all serial numbers of the above-mentioned device below 90441000.

Description of the problem: The Heater-Cooler Unit HCU 40 is used for cooling or warming a patient connected to an extracorporeal perfusion circuit and keeping the required patient temperature constant. The thermal transfer occurs via a heat exchanger in the patient perfusion circuit and/or cardioplegia water circuit and/or via a warming/ cooling blanket. There is no contact between the patient's blood stream and the system water circulating through the heat exchanger.

Note: Heater-cooler devices have never been and are not considered sterile products and have to be handled carefully in regard to hygiene conditions in an operation theater.

Maquet Cardiopulmonary as well as different National Competent Authorities have received isolated reports indicating bacterial contamination in the system water of HCU 40 including mycobacterial counts.

For clarification: Maquet Cardiopulmonary has not received any reports that a mycobacterial infection or any other bacterial infection has been caused by a Heater-Cooler Unit HCU 40.

Our internal investigations showed that the currently published disinfection procedure of the HCU 40 system's water paths (in the Instructions for Use) has to be improved for effectiveness against atypical mycobacteria.

In this context it is worth knowing that a hazard to the patient due to escaping microorganisms during operation of the Heater-Cooler Unit HCU 40 can be excluded with almost complete certainty. An independent testing institute has also concluded this. Its conclusion is based on recent test results for a simulated operating room scenario providing evidence that an excessively microbial inoculated HCU 40 does not emit

any germs to the sterile OR field in any operation mode of the device.

The HCU 40 is designed in a way that the tank water is separated from the air flow of the active cooling system. The air flow from or to the fan does not pass the area above from the water tank and therefore cannot carry aerosols from the water tank into the operating area. The HCU 40 expels the 'technical' exhaust air over a large area through lattice grids directly above the floor. Investigations by an independent testing institute have confirmed that no particles larger than 5 µm, which potentially could be a vehicle of germs, exited the HCU 40 during heating and cooling. All measured particles were within the specified particle counts requirements for clean rooms class B.

Corrective Action:

Maquet Cardiopulmonary developed and validated new and revised cleaning and disinfection procedures for HCU 40 including a routine disinfection protocol and a protocol for highly effective disinfection also effective against atypical mycobacteria in the water system to be implemented on all HCU 40 systems in the field.

The implementation of the new procedures for installed HCU 40 units (all serial numbers below 90441000) requires an update by authorized Maquet service personnel according to the Update Instruction – FSCA-2016-11-30 – Heater-Cooler Unit HCU 40 (MCV-UI-10000833-EN-01).

This update includes the following actions:

(1) Replacement of Valves:

Existing valves will be replaced by successors with proven material compatibility with the new cleaning and disinfection procedure.

(2) Replacement of Flow Sensors:

In HCU 40 devices with serial number below 90440266 the mechanical flow sensor will also be replaced by its successor to ensure material compatibility with the new cleaning and disinfection procedure.

(3) Software Update Release 1.2.3.0:

HCU 40 devices will be updated with the new software (release 1.2.3.0) including a new cleaning wizard guiding the user through the new cleaning and disinfection process step by step.

(4) Final testing, descaling and disinfection of the updated HCU 40

After the hardware and software update and final testing of the HCU 40, authorized Maquet service personnel will perform a subsequent descaling and routine disinfection of the system.

Depending on the microbiological status of a HCU 40 system, a highly effective disinfection with 24 hours contact time overnight may be indicated and performed on request.

(5) Replacement of the Instructions for Use and Training of the HCU 40 user

The Instructions for Use for Heater-Cooler Unit HCU 40 will be replaced by the new version (MCV-GA-10000733). The user will be instructed on the software updates and on the new cleaning and disinfection procedures.

If you have questions or require additional information regarding the content of the new cleaning and disinfection procedures or new software, please contact your local Maquet representative.

Your local Maquet representative will contact you to arrange the update of your HCU 40 system.

Advice on action to be taken by the user:

- The update on your HCU 40 systems has to be performed by authorized Maquet service personnel according to the Update Instruction – FSCA-2016-11-30 – Heater-Cooler Unit HCU 40 (MCV-UI-10000833-EN-01) as soon as possible.
- Fill out the enclosed Acknowledgement Form and return it as soon as possible to your local Maquet representative.
- Incorporate the new cleaning and disinfection procedures into your operating processes, and conduct any training necessary.
- Continue to monitor the hygiene (contamination levels) in accordance with your internal practices.
- Immediately report any contamination findings to your local Maquet representative by filing a complaint.

Referenced documents/attachments:

- Letter of Acknowledgement
- Instructions for Use – Heater-Cooler Unit HCU 40 (MCV-GA-10000733)
- Instruction for Use for Clorina by Lysoform
- Safety Data Sheet for Clorina by Lysoform

Transmission of the Field Safety Notice:

- This notice needs to be forwarded to all those who need to be aware of it within your organization or to any organization to where the potentially affected devices have been transferred.
- Please forward this notice to other organizations on which the action has an impact.
- Please maintain awareness of the notice and resulting actions for an appropriate period of time to ensure effectiveness of the corrective action.

We apologize for any inconvenience this may cause you and we will do our utmost to finish 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 Maquet representative.

Sincerely,

Mikael K. Johansson
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Safety Officer

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