Urgent!

Field Safety Corrective Action (FSCA)

MAQUET
GETINGE GROUP

26th of October 2017

FSN Number:	2017-10-16
FSN Title:	New Water Quality Management for Heater-Cooler Units HCU 20 and HCU 30
Type of Action:	Customer Notification
Affected Product:	Heater-Cooler Units HCU 20 and HCU 30
Unique Device Identification (UDI Code):	Not Assigned
Affected product details:	The FSCA affects all models and all serial numbers of the above-mentioned devices.
Description of the problem:	The Maquet Heater-Cooler Units HCU 20 and HCU 30 are 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 20 and HCU 30 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 20 or HCU 30. Our internal investigations showed that the currently in the User's Manuals published preparation and maintenance procedures for HCU 20 and the cleaning procedure of the HCU 30 system's water paths have to be improved. In this context it is worth knowing that a hazard to the patient due to escaping microorganisms during operation of the Heater-Cooler Units HCU 20 and HCU 30 can be excluded with almost complete certainty. An independent testing institute

has also concluded this. Its conclusion is based on test results for a simulated operating room scenario providing evidence that excessively microbial inoculated HCU 20 and HCU 30 do not emit any germs to the sterile OR field in any operation mode of the devices.

The HCU 20 and HCU 30 are 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. 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 20 or HCU 30 tank during heating and cooling. All measured particles were within the specified particle counts requirements for clean rooms class B.

Corrective Action:

Even though HCU 20 and HCU 30 do not emit contaminated aerosols, Getinge developed and validated new safe and user-friendly water quality management procedures to be implemented on all HCU 20 and HCU 30 systems in the field.

These new procedures will maintain the water circuits of HCU 20 and HCU 30 clean and plumbing and provide reproducible and constant system water conditions, which create a “microbial unfriendly” environment – also against atypical mycobacteria.

Disinfection is only periodic and does not mitigate microbial growth between the disinfection intervals. The new water HCU 20/ HCU 30 quality management approach continuously maintains the water quality constant for the applied interval.

The current published User’s Manual for HCU 20 Heater-Cooler Units chapter 2 “preparation for operation – filling an empty unit” and chapter 5 “maintenance” will be replaced by the Revised Instructions for Use – Water Quality Management Heater-Cooler Unit HCU 20 (MCV-GK-10000705) in the required language.

Correspondingly the current published User’s Manual for HCU 30 Heater-Cooler Units chapter 4.1 information to the water hardness, 4.1.2 “weekly”, 4.1.3 “monthly (or after every 100 hours of operation”) and 4.3 “cleaning” will be replaced by the Revised Instructions for Use – Water Quality Management Heater-Cooler Unit HCU 30 (MCV-GK-10000706) in the required language.

In order to prevent recontamination as far as possible, it is highly recommended to replace the external water hoses for HCU 20 and/or HCU 30 by new hoses, when introducing the water quality management procedures, and to follow the defined replacement interval on a yearly basis. Otherwise the HCU 20/ HCU 30 water quality management efficiency will may

be compromised.

In very rare cases, HCU 20 devices of model HCU 20-602 (and retrofitted HCU 20-601) may still be equipped with an active UV lamp in the tank. Before applying the new water quality management for HCU 20, this UV lamp has to be deactivated by a Getinge authorized service technician in order to prevent any side effects with the use of Trisodium phosphate.

Advice on action to be taken by the user:

Fill out the enclosed Acknowledgement Form and return it as soon as possible to your local Maquet representative.

- Contact your local Maquet representative for an exchange of the external connectable HCU 20 and/or HCU 30 water hoses and for the deactivation of the HCU 20 UV lamp (if applicable).
- Incorporate the new water quality management 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 Customer
- Annex I: List of Affected Products
- Revised Instructions for Use – Water Quality Management Heater-Cooler Unit HCU 20 (MCV-GK-10000705-EN)
- Revised Instructions for Use – Water Quality Management Heater-Cooler Unit HCU 30 (MCV-GK-10000706-EN)

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 and inform your personnel.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of this action.

Your understanding is much appreciated. Thank you for your continued support as we provide you with up-to-date information on the quality of our products. 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 shall be providing this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Maquet representative.

Sincerely,

Markus Medart
Managing Director

Bernd Rakow

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