
Urgent!
Field Safety Notice (FSN)

22nd of November 2016

FSN Number:	2016-11-15
FSN Title:	Revised disinfection procedure for Heater Unit HU 35
Type of Action:	Customer Notification
Affected Product:	Heater Unit HU 35
Unique Device Identification (UDI Code):	Not Assigned
Affected product details:	The FSCA affects all models and all serial numbers of the above mentioned device.
Description of the problem:	<p>Heater Unit HU 35 is used during extracorporeal life support (ECLS) in intensive care units to maintain the patient's blood temperature via an oxygenator heat exchanger. There is no contact between the blood stream of the patient and the system water circulating through the heat exchanger.</p> <p>Maquet Cardiopulmonary as well as different National Competent Authorities have received isolated reports confirming the presence of bacterial contamination in the system water of HU 35 including mycobacterial counts.</p> <p>It has to be pointed out: Maquet Cardiopulmonary has not received any reports that a mycobacterial infection or any other bacterial infection would have been caused by a Heater Unit HU 35.</p> <p>Our internal investigations have confirmed that the current published disinfection procedure of the HU 35 system's water paths (in the Instructions for Use) does not adequately meet contemporary hygienic requirements and effectiveness against atypical mycobacteria.</p> <p>Although the water in the HU 35 circuit does not come into direct contact with the patient, there is the unlikely, but potential risk that bacterial contaminated water could cause adverse health consequences to the patient, e.g. by transmission (insufficient hygiene) via clinical staff members while managing the extra corporeal life support.</p> <p>In this respect, the following has to be considered: The heat exchange with the blood is facilitated either by membrane</p>

fibers (polyurethane, polyethylene) built into the oxygenator or by dedicated metal based heat exchangers. As the water circuit is never sterile, every oxygenator heat exchanger has to be completely sealed without leakage between water and blood circuits (per standard ISO/CD 7199). This is tested by the perfusionist during priming for patient use. In conclusion excessive germ numbers in the water do not induce a significant hazard for these routes of transmission as long as the integrity of the oxygenator is maintained. The potential risk that a bloodstream contact with water could result from a damaged oxygenator heat exchanger has to be regarded as remote.

The HU 35's water circuit is a completely closed system. The device does not create an air flow. So due to the constructional design of HU 35 an airborne transmission of bacteria via contaminated aerosol can be excluded for the device. Investigations by an independent institute have confirmed that HU 35 does not emit any aerosol.

Corrective Action:

The current published Instructions for Use chapter 6 "Cleaning and Disinfection" for HU 35 Heater Units will be replaced by the attached Revised Instructions for Use – Cleaning, Descaling and Disinfecting Heater Unit HU 35. The latter outlines especially a new weekly routine disinfection as well as a high level disinfection and biofilm reduction – also effective against atypical mycobacteria in the water system.

All staff involved in the operation and or maintenance of HU 35 systems should be informed to incorporate these revised instructions into their internal operating and or hygiene control procedures.

Advice on action to be taken by the user:

Complete and return the enclosed Acknowledgement Form as soon as possible to your local Maquet representative.

Incorporate this revised procedure into your operating processes.

Conduct any training necessary for the revisions.

Continue to monitor the hygiene (contamination levels) in accordance with your internal practices.

Immediately report any contamination findings to your local Maquet representative by a complaint.

Referenced documents/attachments:

Acknowledgement Form

Revised Instructions for Use – Cleaning, Descaling and Disinfecting Heater Unit HU 35 | 1.0 | MCV-GK-10000708-XX-01| 01

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 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 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
Managing Director



Bernd Rakow
Safety Officer

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
Germany