URGENT FIELD SAFETY NOTICE

Subject:	598097: Preventive replacement of HU 35 tank fittings
Affected Product:	Heater Unit HU 35, 230 V Heater Unit HU 35, 115 V
Affected Serial No.:	All HU 35, 230 V devices below serial number 90039999 and all HU 35, 115 V devices below serial number 90034999

Dear valued customer,

Maquet Cardiopulmonary GmbH has received complaints for the Heater Unit HU 35 about leakages in relation to the water tank fittings.

Statistical analysis indicates that with increasing operation time of the HU 35, the probability of leakage within its expected service life of 10 years increases due to material degradation of the tank fittings. In order to significantly reduce the probability of leakage, Maquet Cardiopulmonary GmbH is initiating a preventive field action for the replacement of the HU 35 tank fittings during the regular maintenance.

Problem description:

The Heater Unit HU 35 acts as a heat supply in order to maintain the patient's body temperature via a heat exchanger of a PLS Oxygenator or HLS Module or other oxygenator-heat exchangers as part of extracorporeal circuits. The HU 35 tank fittings inside the unit connect the water tank to the internal tubing system of the device.

Based on the internal complaints investigation and extensive material compatibility testing under aggrevated conditions simulating more robust real-time aging and material stress, it was exposed that the current HU 35 water tank fittings made of polyamide have a limited resistance to chlorine, which will be released to some extent by Chloramine T used for disinfecting the water circuit of the unit.

The statistical reliability analysis revealed that with 95 % confidence, the probability of leakages due to material degradation of the HU 35 tank fittings within the expected service life of 10 years of the device is between 1.6% and 5%.

Failure to correctly apply the disinfection procedures of the water circuit (e.g. wrong dosing and/or insufficient rinsings) or frequent, purely “preventive” use of the highly effective disinfection protocol with 5% chloramine-T solution for 24 hours without its application requirement (instead of the weekly routine disinfection with 2% chloramine T for 90 min.), increases the material stress and potential degradation of HU 35 tank fittings.

The HU 35 fulfils the requirements of a Class I ME Equipment according to 60601-1. This means that all metallic parts are connected to the protective earth as long as the power supply cable is connected to protective earth. Before switching on the HU 35, connect it according to the Instruction for Use to the equipotential bonding connection. The equipotential bonding conductor enables the electrical device to be directly connected to the

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equipotential bonding of the electrical installation, in addition to the protective ground conductor in the power cable.

Prior to clinical use of the Heater Unit HU 35, especially when staring the circulation of the device for de-airing, please check if any fluid leaks out of the HU 35 housing. If this is the case, or if water leaks out of the housing during or after using the device, please take the unit out of operation and contact an authorized Getinge service technician for repair.

Taking into consideration that a degraded tank fitting can cause water leakage of the HU 35 and water may come in contact with an electrical component, either before or during application of the device, some, none, or all of the following harms are potentially possible:

- Electric shock / burn / cardiac arrhythmia (user, patient, third party)
- Hypothermia
- Delay of therapy
- User inconvenience due to product/device replacement

Maquet Cardiopulmonary GmbH has not received any complaints of patient harm, serious injuries or deaths caused by a leaking HU 35 due to leaking tank fittings.

As a general precautionary measure in the instruction for use for HU 35, please always keep a replacement unit on standby in order to ensure continuous operation in the event of the described leakage.

Considering the precautionary measures and based on the associated risk assessment to a leaking HU 35, a general decommissioning of the device is not required.

Preventive Action:

- Pending the availability of successor components in a new, more robust material, in HU 35 units older than one year since installation, the HU 35 tank fittings made of polyamide will be exchanged by a kit of components of the same material, to prevent long-term degradation and leakage.
- As soon as the HU 35 tank fittings and the screw cap of the tank outflow point (currently also made of polyamide, but inconspicuous for degradation) are availabe in the new qualified resistant material (prospectively in October 2022), the replacement of the components will be continued in the new quality material during the regular annual maintenance.

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Action to be taken by the user:

- According to our post-market surveillance documentation, your current stock may include products affected by this action. Please examine your inventory immediately to determine, if you have any HU 35 units in your inventory.
- The Getinge authorized service personnel will contact you to arrange an appointment with you in order to perform the replacement of the tank fittings and screw cap as described above.
- Before switching on the HU 35, **connect it to the equipotential bonding connection**.
- **Please always keep a replacement unit on standby** in order to ensure continuous operation in the event of a leaking HU 35 housing.
- **Please always check, if prior, during or after usage of the HU 35 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.
- If you have an affected Heater Unit HU 35 unit, please duly complete and sign the enclosed customer response form and send it back to your local Getinge representative.
- Please report any adverse events in regard to the affected products to your Getinge Representative.

Enclosed documents:

- Customer response form

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.

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Sincerely,

Managing Director

Dieter Engel, 2022-05-09 08:52:01+0200
Approved: u2537767, Vice President Cardiopulmonary

Person Responsible for Regulatory Compliance (PRRC)

Timur Güvercinci, 2022-05-06 22:17:10+0200
Approved: u4023229, Sr. Director Quality Cardiopulmonary

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CUSTOMER RESPONSE FORM

Subject: FSCA-598097: Preventive replacement of HU 35 tank fittings

Affected Product: Heater Unit HU 35, 230 V
Heater Unit HU 35, 115 V

Affected Serial No.: All HU 35, 230 V devices below serial number 90039999 and all HU 35, 115 V devices below serial number 90034999

☐ I have read and understand this Field Safety Notice.

☐ I confirm that I have distributed this Field Safety Notice to the affected personal.

☐ Following affected products are in our inventory.

REF	Article Number	Description	Serial Number	Quantity

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Your Comments:

Country	Hospital / Clinic (full address)
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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