

URGENT FIELD SAFETY NOTICE

Manufacturer SRN: DE-MF-000020091

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 90035999

Dear valued customer,

This is an update of the status of field safety action 598097. All changes are made visible by underlining.

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

Based on the internal complaints investigation and extensive material compatibility testing under aggravated 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 Chloramine T used for disinfecting the water circuit of the unit.

Failure to correctly apply the disinfection procedures of the water circuit (e.g. wrong dosing and/or insufficient rinsings), or frequent, "preventive" use of the highly effective disinfection protocol with 5% chloramine T solution for 24 hours outside its application requirement (instead of the recommended weekly routine disinfection with 2% chloramine T for 90 min.), increases the material stress and potential degradation of HU 35 tank fittings.

Maquet Cardiopulmonary has identified and qualified a new resistant replacement material. However, the implementation of this material is unfortunately still pending due to missing regulatory approval by the Notified Body. When the approval is given, the material will be implemented as soon as possible. Until this time, the corrective measures of this field action remain active as described in the actions below.

Attention: a additional update of this field notification will follow when the new material is available.

Taking into consideration that a degraded tank fitting can cause water leakage of the HU 35, which may lead to contact of water 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

2023-08-16

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.

Preventive Action:

- Until the availability of successor components in a new, resistant material: For HU 35 units with Tank fittings older than 12 months, 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.
- This service will be performed repeatedly until the new material can be introduced.
- As soon as the HU 35 tank fittings and the screw cap of the tank outflow point are available in the new qualified resistant material: A final replacement of the components will be performed, using the new quality material during regular maintenance. This final replacement will close the preventive annual replacement activity of this field action.

Action to be taken by the user:

- **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.
- 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.
- 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.

2023-08-16

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
(on behalf of Managing Director)

Signature: *Johannes Schlenker* Electronically signed by: Johannes Schlenker
Reason: I approve this document.
Date: Aug 16, 2023 16:57 GMT+2
Email: johannes.schlenker@getinge.com

Person Responsible for Regulatory Compliance (PRRC)
(on behalf of PRRC)

Signature: *Alexander Bernhardt* Electronically signed by: Alexander Bernhardt
Reason: I approve this document.
Date: Aug 16, 2023 16:55 GMT+2
Email: alexander.bernhardt@getinge.com

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FIELD SAFETY NOTICE



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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, post or FAX.

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