

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. The new material is now available and a final replacement will be performed in course of the next preventive maintenance.

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

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.

2025-06-25

Corrective Action:

- Replacement of the HU 35 tank fittings and the tank screw cap with the new qualified resistant material on the next preventive maintenance.

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 **until latest 2025-07-25**.
- 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.

Sincerely,

2025-06-25

Managing Director

Signature:

*Electronically signed by: Dieter Engel
Reason: I approve this document
Date: Jun 26, 2025 14:12 GMT+2*

Email: dieter.engel@getinge.com

Person Responsible for Regulatory Compliance (PRRC)

Signature:

*Electronically signed by: Alexander
Bernhardt
Reason: I approve this document
Date: Jun 26, 2025 17:11 GMT+2*

Email: alexander.bernhardt@getinge.com

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GERMANY
Phone: +49 7222 932 - 0
Email: FSCA.cp@getinge.com

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 90035999

- ☐ 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.

[illegible]

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.