

Urgent!
Field Safety Notice (FSN)

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Version
(Version)
V01

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2019-08-01

FSCA Number: FSCA-2019-07-15

FSCA Title: Heater Unit HU 35 - Potentially incorrect software version

Affected product: Heater Unit HU 35

Affected product details: Serial number range and material number of potentially affected products produced within the timeframe September, 2017 until October, 2018:

1.) 70107.2162 Heater Unit HU 35, 230 V
S/N: 90031802 - 90032235

2.) 70107.2163 Heater Unit HU 35, 110-115V
S/N: 90034502- 90034539

Please refer to the Annex I for details. Not all serial numbers within the range above are affected. If your serial number is within this range, but is not on the list in Annex 1, then your device is not affected by this FSCA.

Description of the problem:

Dear valued colleagues and business partners,

Maquet Cardiopulmonary GmbH has determined that the above listed HU 35 Heater Units produced within the timeframe September, 2017 until October, 2018 might have been delivered with an incorrect software version - not in correspondence with the set point temperature range described in the Instructions for Use for these devices. The affected units potentially have received the software version 1.01 instead of the correct software version 1.02.

In version 1.01 of the HU 35 software, the set point water temperature can be set between 33°C and 39°C, while in the correct software version 1.02 for the above listed units the set point temperature range is limited between 35°C and 39°C.

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Furthermore in software version 1.01 a high priority alarm (visual and acoustic alarm) is triggered if the water temperature falls to 32°C or below while in the new correct software version 1.02 a high priority alarm is already triggered if the water temperature drops to 34°C or below in order to avoid unintended hypothermia of a patient connected.

According to the intended use for the affected Heater-Units HU 35, the device 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 an extracorporeal circuits. The HU 35 is not indicated for cooling a patient.

To check whether the unit you have in place is affected by the incorrect software version, please compare first if the serial number of your unit is listed in Annex 1.

- If the serial number is not listed in Annex 1, the device is not affected by this field action. No further action is required.
- If the serial number is listed in Annex 1, set the lowest possible set point temperature, when the device is not clinically in use.
- If the set point temperature cannot be set below 35°C, you do not have an affected device. Please complete the Letter of Acknowledgement for Customers and return it as soon as possible to your local Getinge representative by mentioning FSCA-2019-07-15 as reference. No further action is required.
- If the set point temperature can be set below 35°C, you have an affected device with the incorrect software version 1.01. Please follow the further instructions below.

The customer can further use affected HU 35 units with the incorrect software version 1.01 before the corrective action has been implemented by not setting the set point temperature **below 35°C** as a precaution to prevent unintended hypothermia of the patient.

As described in the Instructions for Use for HU 35, monitor the patient's body temperature and electrocardiography using an external independent monitoring system during the application, and monitor the blood temperature at the oxygenator.

Maquet Cardiopulmonary GmbH has not received any complaints associated with hypothermia or following serious injuries or deaths due to the potentially incorrect software version 1.01 installed on affected HU 35.

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Corrective Action:

- Replacement of the HU 35 control board for all HU 35 units with the S/N listed in Annex 1, which have been delivered with the incorrect software version 1.01

**Advice on action
to be taken by the
User:**

- According to our post-market surveillance documentation, your current stock may include products affected by this action.
- The replacement of the HU 35 control board of the affected HU 35 systems must be performed by authorized Getinge service personnel.
- If you have an affected product in place listed on Annex 1, please identify the software version on the device by:
 - Setting the lowest possible set point temperature, when the device is not clinically in use.
 - If the set point temperature can be set below 35°C, you have an affected device with the incorrect software version 1.01.
- Duly fill out the enclosed Letter of Acknowledgement for Customers and return it as soon as possible to your local Getinge representative by mentioning FSCA-2019-07-15 as reference.

**Referenced
documents/attach
ments:**

- Letter of Acknowledgement Customer
- Annex 1: List of affected products

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Transmlssion 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.

After the feedback to your local Getinge representative, whether you have a HU 35 unit(s) with incorrect software in place you will be contacted for planning and performing the replacement of the HU 35 control board for your HU 35 unit(s).

We apologize for any inconvenience this may causa 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,

.....

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
Germany