2023-11-14

URGENT FIELD SAFETY NOTICE

Manufacturer SRN:	DE-MF-000020091
FSCA Reference:	925393 HCU 40 – IFU not in national language
FSN Type:	New
Affected Product:	Heater-Cooler Unit HCU 40 High Voltage (Mat. 701044054)
Unique Device Identifier(s) (UDI-DI):	04037691917566
Affected Serial No.:	90442337, 90442336, 90440259, 90442299, 90440220
For Attention of:	Users of the medical device listed above

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP) would like to inform you with this letter about a corrective action for the above-mentioned HCU 40 due to the Instruction for Use (IFU) not being in the local language.

The heater-cooler unit HCU 40 is intended for cooling or warming a patient connected to the extracorporeal perfusion circuit and keeping the required patient temperature constant. The temperature transfer occurs via a heat exchanger in the patient perfusion circuit and/or cardioplegia water circuit and/or via a warming/cooling blanket.

Problem description

The Field Action pertains to the absence of the IFUs in the official language necessary in adherence to national requirements. The countries concerned are Lithuania (LT), Croatia (HR), Bulgaria (BG), and Slovakia (SK).

Hazardous situation

The following hazardous situations were identified:

- Patient exposed to pathogenic agent
- Patient, user, or other person is exposed to toxic substances
- The patient is exposed to too low temperature
- The patient is exposed too high temperature
- Exposed to inappropriately low cardioplegia temperature
- Exposed to inappropriately high cardioplegia temperature
- Inability to use device

Potential harm

The potential immediate and/or long-range health consequences (injuries or illnesses) that could result from use of, or exposure to, the nonconforming components may be any, some, or all, of the following harms (for further information refer to Annex I):

- Inflammation
- Infection
- Reaction to a toxic substance
- Hyperthermia (patient)
  - Cardiac Arrhythmias
  - Coagulation disorders
- Hyperthermia (cardiac)
- Hypothermia (patient)
  - Hemolysis
  - Thromboembolism
  - Neurocognitive dysfunction (Brain damage)
- Hypothermia (cardiac)
  - Cardiac Dysrhythmias

Maquet Cardiopulmonary GmbH has not identified any complaints of patient harm, serious injuries, or deaths due to IFU not being in the national language described above.

Corrective Action:

- Replacement of the incorrect Instruction to Use

Action to be taken by the user:

☒ Identify Device ☐ Quarantine Device
☐ Return Device ☐ Destroy Device

Details of the further action(s):

- According to our post-market surveillance documentation, you may have products affected by this action. Please examine your inventory immediately to determine, if you have the affected HCU 40 in your inventory.
- Please **always** report any adverse events, e.g., infections potentially related to the affected products, to your Getinge representative.
- Duly fill out the enclosed Letter of Acknowledgement and return it to your local Getinge representative by **December 5, 2023,** the latest. Please give **FSCA-925393** as reference in the subject line of your email.

Action to be taken by the manufacturer:

☐ Product Removal ☐ On-site device modification/ inspection
☐ Software upgrade ☒ IFU or labelling change
☐ Other ☐ None

- Inform all customers possessing the affected products **promptly** about this Field Action by sending the Field Safety Notice for Customers.
- Provide the customers with the correct IFU version.

Enclosed documents:
- Customer response form
- Annex I Further information regarding Hazardous situation, Harms and Risk Levels

Transmission of the Field Safety Notice

- Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Field Safety Notice.
- Please transfer this notice to other organizations on which the action has an impact.
- If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.
- 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,

Managing Director

Signature: Dieter Engel

Electronically signed by: Dieter Engel
Reason: I approve this document.
Date: Nov 15, 2023 13:22 GMT+1

Email: dieter.engel@getinge.com

Person Responsible for Regulatory Compliance (PRRC)

Signature: Tom Peters

Electronically signed by: Tom Peters
Reason: I approve this document.
Date: Nov 15, 2023 17:32 GMT+1

Email: tom.peters@getinge.com

Contact details of manufacturer

Tom Peters
Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY
Phone: +49 7222 932 - 0
Email: FSCA.cp@getinge.com

CUSTOMER RESPONSE FORM

FSCA Reference:	925393 HCU 40 – IFU not in national language
Affected Product:	Heater-Cooler Unit HCU 40 High Voltage (Mat. 701044054)
Affected Serial No.:	90442337, 90442336, 90440259, 90442299, 90440220

Please send this form at the latest by **December 5, 2023,** to your local Getinge representative.

By completing this document and signing it, I acknowledge that I have read and understand the following associated points:

- I have read and understand this Field Safety Notice for affected product HCU 40. We will take action as soon as possible according to given instructions.
- I confirm that I have distributed this Field Safety Notice to the affected personal.

☐ I do not have any affected HCU 40 in my inventory.
☐ I have following affected HCU 40 in my inventory:

Article Number	Description	Serial Number

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.

Annex I Further information regarding Hazardous situation, Harms and Risk Levels

This Annex I Further information regarding Hazardous situation, Harms and Risk Levels is considered a supplementary attachment to the 925393 Field Safety Notice.

Hazardous situation	Harm	S from part III	P from above	Risk		
				Low	Med	High
Patient exposed to pathogenic agent	Inflammation	3	**3**	☐	☒	☐
	Infection	4	**3**	☐	☒	☐
Patient, user, or other person is exposed to toxic substances	Reaction to a toxic substance	4	**2**	☐	☒	☐
Exposed to inappropriately low blood temperature (patient)	Hypothermia (patient)	3	**3**	☐	☒	☐
	Cardiac Arrhythmias	3	**2**	☐	☒	☐
	Coagulation disorders	3	**2**	☐	☒	☐
Exposed to inappropriately high blood temperature (patient)	Hyperthermia (patient)[d]	3	**3**	☐	☒	☐
	Hemolysis	3	**2**	☐	☒	☐
	Thromboembolism	3	**2**	☐	☒	☐
	Neurocognitive dysfunction (Brain damage)	4	**2**	☐	☒	☐
Exposed to inappropriately low cardioplegia temperature (patient)	Hypothermia (cardiac)	3	**3**	☐	☒	☐
	Cardiac Dysrhythmias	3	**2**	☐	☒	☐
Exposed to inappropriately high cardioplegia temperature (patient)	Hyperthermia (cardiac)	3	**3**	☐	☒	☐
Inability to use or properly deploy device	User inconvenience	2	**2**	☐	☒	☐

Severity Definitions:
Negligible (1) Inconvenience or temporary discomfort of patient, user or third party. No medical intervention or follow-up treatment is required
Low (2) Temporary injury or disability of patients, users or third parties. No medical intervention or follow up treatment is required.
Critical (3) Temporary injury or disability of patients, users or third parties. Medical intervention or follow-up treatment is required.
Catastrophic (4) Permanent injury or disability (e.g., loss of a body part), a life-threatening situation or death of patients, users or third parties

Probability Definitions:
Improbable (1) Harm is not likely.
Remote (2) Harm occurs infrequently
Occasional (3) Harm may occur occasionally / intermittent
Probable (4) Harm may occur often
Frequent (5) Harm will occur repeatedly