2023-10-26

URGENT FIELD SAFETY NOTICE

Manufacturer SRN:	DE-MF-000020091
FSCA Reference:	879551 CARDIOHELP-i – IFU contains incorrect factory settings
FSN Type:	New
Affected Product:	CARDIOHELP-i (Mat. 701048012) CARDIOHELP-i (US Variant) (Mat. 701072780)
Unique Device Identifier(s) (UDI-DI):	04037691658384 04058863074863
Affected Serial No.:	All devices delivered between production start and 2023-03-09
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 CARDIOHELP-i due to incorrect information on factory settings in the Instruction for Use (IFU).

The intended use of the CARDIOHELP-i is to drive, control, monitor and protocol an extracorporeal circulation.

Problem description

The IFU of the CARDIOHELP system states incorrect factory settings. The device itself is working as intended and the error only refers to the IFU. The following factory settings are incorrect (for further information, please refer to Annex I):

- Mismatching information in IFU regarding P_{Ven}, P_{Aux}, Venous Bubble Intervention
- False statement in IFU regarding deactivated automatic locking in MECC Thapp

Hazardous situation

No hazardous situations were identified.

Potential harm

There are no foreseen immediate and/or long-range health consequences of the nonconformance due to the improper labelling/descriptions of CARDIOHELP in the attending IFU.

Maquet Cardiopulmonary GmbH has not identified any complaints of patient harm, serious injuries, or deaths due to failure mode 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 CARDIOHELP-i unit 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 **April 30, 2024,** the latest. Please give **FSCA-879551** 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 Incorrect factory settings

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:

Email:

Person Responsible for Regulatory Compliance (PRRC)

Signature:

Email:

CUSTOMER RESPONSE FORM

FSCA Reference:	879551 CARDIOHELP-i – IFU contains incorrect factory settings
Affected Product:	CARDIOHELP-i (Mat. 701048012) CARDIOHELP-i (US Variant) (Mat. 701072780)
Affected Serial No.:	All devices delivered between production start and 2023-03-09

Please send this form at the latest by **April 30, 2024,** 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 CARDIOHELP-i. 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 CADRIOHELP-i in my inventory.
☐ I have following CADRIOHELP-i 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 Incorrect factory settings

This Annex I Incorrect factory settings is considered a supplementary attachment to the 879551 Field Safety Notice.

1. **Parameter p_{Ven}**

The following incorrect information was listed in chapter Warning limits, alarm limits and interventions:

Parameter	Possible settings		Factory setting	
	Limits	Resolution	Lower / upper limit	Intervention
Flow	-9.99 ... 9.99 l/min	0.01	0.00 / 8.00	deactivated
Speed	0 ... 5000 rpm	1	0 / 4500	deactivated
Pressures:				
■ p_{Int}[a], p_{Art}	-500 ... +900 mm Hg[b]	1	Warning: – / 400 Alarm: – / 500	deactivated
■ p_{Ven}	-500 ... +900 mm Hg[b]	1	Warning: – / 100 Alarm: – / 150	deactivated

Figure 1: Incorrect information in the EN IFU on P_{Ven} factory settings

The following correct information is listed in chapter Warning limits, alarm limits and interventions:

Parameter	Possible settings		Factory setting	
	Limits	Resolution	Lower / upper limit	Intervention
Flow	-9.99 ... 9.99 l/min	0.01	0.00 / 8.00	deactivated
Speed	0 ... 5000 rpm	1	0 / 4500	deactivated
Pressures:				
■ p_{Int}[a], p_{Art}	-500 ... 900 mmHg[b]	1	Warning: – / 400 Alarm: – / 500	deactivated
■ p_{Ven}	-500 ... 900 mmHg[b]	1	Warning: -100 / – Alarm: -150 / –	deactivated

Figure 2: Correct information in the EN IFU on P_{Ven} factory settings

2. Parameter p_{Aux} and Venous Bubble intervention

The following incorrect information was listed in chapter Warning limits, alarm limits and interventions:

Parameter	Possible settings		Factory setting	
	Limits	Resolution	Lower / upper limit	Intervention
Flow	-9.99 ... 9.99 l/min	0.01	0.00 / 8.00	deactivated
Speed	0 ... 5000 rpm	1	0 / 4500	deactivated
Pressures:				
■ p_{Int}[a], p_{Art}	-500 ... 900 mmHg[b]	1	Warning: – / 400 Alarm: – / 500	deactivated
■ p_{Ven}	-500 ... 900 mmHg[b]	1	Warning: -100 / – Alarm: -150 / –	deactivated
■ p_{Aux}[a]	-500 ... 900 mmHg[b]	1	Warning: --- / --- Alarm: --- / ---	deactivated
■ Δp	-500 ... 900 mmHg[b]	1	deactivated / 60	–
Bubbles:				
■ venous	–	–	–	activated

Figure 3: Incorrect information in the EN IFU on P_{Aux} and Venous Bubble Intervention

The following correct information is listed in chapter Warning limits, alarm limits and interventions

Parameters	Possible settings		Factory setting	
	Limits	Resolution	Lower / upper limit	Intervention
Flow	0 ... 9.9 l/min	0.1	0.0 / 8.0	deactivated
Speed	0 ... 5000 rpm	1	0 / 4500	deactivated
Pressures:				
■ p_{Int}[a], p_{Art}	-500 ... +900 mmHg[b]	1	Warning: – / 400 Alarm: – / 500	deactivated
■ p_{Ven}	-500 ... +900 mmHg[b]	1	Warning: -100 / – Alarm: -150 / –	deactivated
■ p_{Aux}[a]	-500 ... +900 mmHg[b]	1	Warning: deactivated / 400 Alarm: deactivated / 500	deactivated
■ Δp	-500 ... +900 mmHg[b]	1	deactivated / 60	–
Bubbles:				
■ Venous	–	–	–	deactivated

Figure 4: Correct information in the EN IFU on P_{Aux} and Venous Bubble Intervention

3. Option Locking, automatic lock (During MECC Thapp only)

The following incorrect information was listed in chapter General settings

Option	Possible settings	Factory setting
thApp	v-a ECLS, VAD, MECC, v-v ECLS, PALP	MECC
Pump:		
■ Control mode	RPM, LPM	RPM
Data recording:		
■ Interval	3 s, 15 s, 30 s, 45 s, 1 min, 2 min, 5 min, 10 min	5 min
■ Offline recording	started, stopped	stopped
Locking:		
■ Automatic lock	activated, deactivated*	activated

Figure 5: Incorrect information in the EN IFU on factory settings regarding automatic locking

The following correct information was listed in chapter General settings

Option	Possible settings	Factory setting
thApp	v-a ECLS, VAD, MECC, v-v ECLS, PALP	MECC
Pump:		
■ Control mode	RPM, LPM	RPM
Data recording:		
■ Interval	3 s, 15 s, 30 s, 45 s, 1 min, 2 min, 5 min, 10 min	5 min
■ Offline recording	started, stopped	stopped
Locking:		
■ Automatic lock	activated, deactivated*	deactivated

Figure 6: Correct information in the EN IFU on factory settings regarding automatic locking