

2023-08-31

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 since production start

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:

- 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
- Return Device
- Quarantine 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 **November 3, 2023**, the latest. Please give **FSCA-879551** as reference in the subject line of your email.

Action to be taken by the manufacturer:

- Product Removal
- Software upgrade
- Other
- On-site device modification/ inspection
- IFU or labelling change
- 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 List of affected products

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

**Person Responsible for Regulatory
Compliance (PRRC)**

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

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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.: Refer to Annex I

Please send this form at the latest by **November 3, 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 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.

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