2023-11-10

URGENT FIELD SAFETY NOTICE

FSCA Reference:	881842 - Replacement of the broken venous probe cable
FSN Type:	New
Affected Product:	701048012 CARDIOHELP-i and 701072780 CARDIOHELP-i (US-Version) with the parts venous probe 701048804 (accessory) + 701069333 (spare part)
Unique Device Identifier(s) (UDI-DI):	04037691658384 and 04058863074863
Affected Serial No.:	All CARDIOHELPs until 2021-03
For Attention of:	Customers and users of the medical device listed below

Dear valued customer,

The product focus of this Field Service Corrective Action (FSCA) is the CARDIOHELP System that is a miniaturized extracorporeal life support system. The general intended use of the device is to drive, to control, to monitor, and to protocol the extracorporeal circulation (ECC).1 The CARDIOHELP System is designed for intra-hospital and inter-hospital transportation. The CARDIOHELP System is designed for continuous operation.

The companion disposable products for users with the CARDIOHELP device are the HLS/HIT 7.0 Set Advanced, HLS/HIT 5.0 Set Advanced, and the Quadrox-iR.

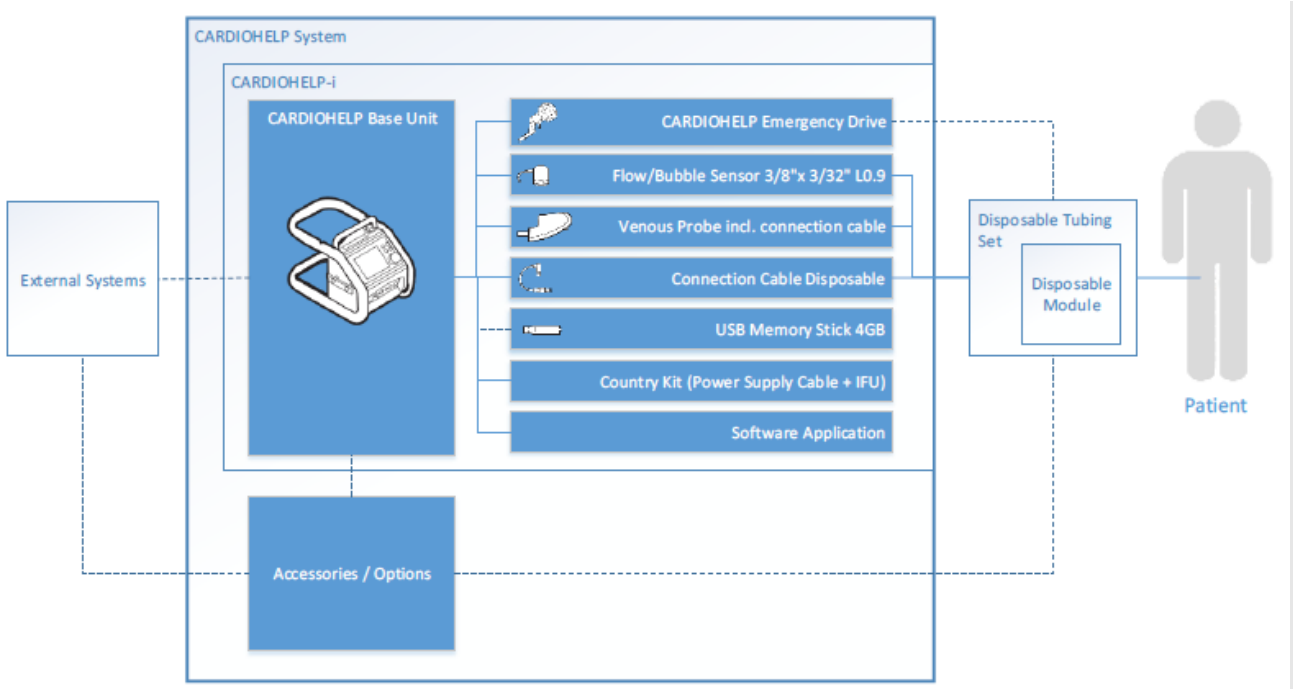

Figure 1: CARDIOHELP System Composition

Problem description

The quality issue under investigation is applicable to the "Connection cable venous probe, L0.23m", material# 701048804 (accessory) as well as 701069333 (spare part). The part causing the nonconformance under investigation is responsible for data transmission between the CARDIOHELP-i and the Venous Probe.
A noticeable high number of breaks in the insulation sheath and a shielding breach of the venous probe connection cable was observed.

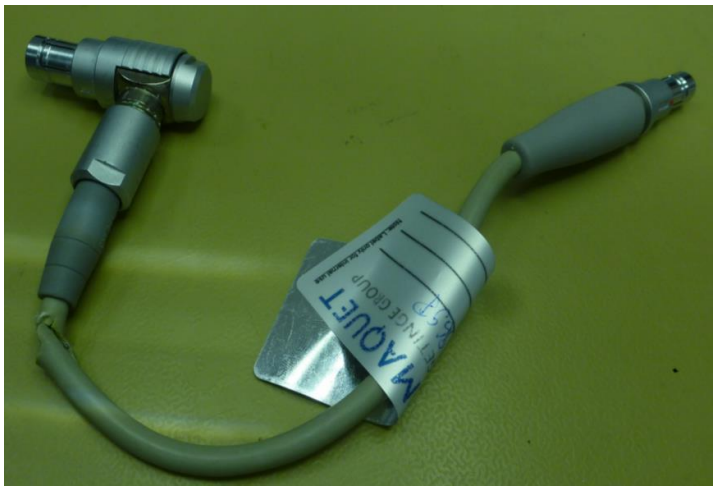

Figure 2: Example of torn cable insulation from the field

Hazardous situation

The Venous Probe of the CARDIOHELP-i transmits the results of SvO_2, hemoglobin, hematocrit, and venous temperature values to the user interface of CARDIOHELP-i. The venous probe cable, which connects the Venous Probe to CARDIOHELP-i, is the subject of this FSCA. Fracture of the venous probe cable may influence the management of extracorporeal support due to missing or incorrectly reported values reported to the CARDIOHELP user interface. However, numerous clinical redundancies exist (e.g., arterial temperature availability on CARDIOHELP-I, external blood gas measurement, esophageal temperature, etc.) that would likely serve to mitigate either the loss or incorrect reporting of these values due to a fracture of the venous probe cable.

Potential harms

The potential immediate and/or long-range health consequences (injuries or illnesses) that could result from use of, or exposure to, a defective venous probe cable may be any, some, or all of the following:

- Ischemia
- Hyperthermia
- Hemolysis
- Thromboembolism
- Anemia
- Brain damage
- Hypothermia
- Cardiac Arrhythmia
- Coagulation disorder(s)

Maquet Cardiopulmonary GmbH has not identified any complaints of patient harm, serious injuries, or deaths due to the failure modes described above.

Action to be taken by the user:

☒ Identify Device

- 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 any affected product in your inventory.
- **Affected CARDIOHELP-i are not requested to be returned and can be used as usual.**
- A local Getinge representative will contact you to arrange the replacement of venous probe cable of the CARDIOHELP-i.
- Please always report any adverse events, e.g., problems with the venous probe cable 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 29th, 2023**, at the latest. Please give **FSCA-881842** as reference in the subject line of your email

Action to be taken by the Manufacturer:

☒ On-site device inspection

- Inform all customers possessing the affected products promptly about this Field Action by sending the Field Safety Notice to Customers.
- The local Getinge representative will contact the customer to arrange the replacement of the Venous Probe cable.

Enclosed documents:

- Customer Response Form

Transmission of the Field Safety Notice

- Please ensure in your organization that all users of the above-mentioned products and other people 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 10, 2023 16:10 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 13, 2023 09:41 GMT+1*

Email: tom.peters@getinge.com

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CUSTOMER RESPONSE FORM

FSCA Reference:	881842 - Replacement of the broken venous probe cable
Affected Product:	701048012 CARDIOHELP-i and 701072780 CARDIOHELP-i US-Version) with the parts venous probe (701048804 (accessory) + 701069333 (spare part))
Affected Serial No.:	All CARDIOHELPs until 2021-03

Please send this form at the latest by **December 29th, 2023**.

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 products CARDIOHELP. 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.

Following affected products are in our inventory:

Article Number	Description	Serial Number	Quantity

Your Comments:

Country

Hospital / Clinic (full address)

Date

Name (Function)

Signature

Please return the completed form to your local Getinge representative by email FSCA.cp@getinge.com.