April 15, 2024

URGENT MEDICAL DEVICE - Removal
FSCA 8010762-04/09/2024-001-R
CARDIOHELP-i System

Product Name:	CARDIOHELP-i System
Product REF Number:	70104.8012 and 70104.8012R
UDI Device Identifier:	04037691658384
Distributed Affected Serial Numbers:	90410021, 90410029, 90410165, 90410254, 90410255
Manufacturing Dates:	May 10, 2010 through February 28, 2012
Distribution Dates:	June 4, 2015 through May 21, 2020

Dear Risk Manager,

Maquet Cardiopulmonary GmbH (MCP)/Getinge is initiating a voluntary Medical Device Removal for certain units of the CARDIOHELP-i System, due to a non-conformance related to the assessment of leakage current during the manufacture of the CARDIOHELP-i System and a non-conforming sensor panel that can result in leakage current that exceeds the allowable limit. MCP/Getinge will contact you to arrange for the return of any affected device to upgrade the system's sensor panel and to confirm leakage current is within specifications (IEC 62353). MCP/Getinge will provide you with a loaner device until your repaired unit can be returned. If you have already returned the device to MCP/Getinge for repair/maintenance, this upgrade will be included.

The CARDIOHELP System is a blood oxygenation and carbon dioxide removal system used to pump blood through the extracorporeal bypass circuit for circulatory and/or pulmonary support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also intended to provide circulatory and/or pulmonary support during procedures not requiring cardiopulmonary bypass (for periods up to six hours).

Identification of the issue:

Getinge previously initiated a Medical Device Correction on November 14, 2023 (reference FDA recall number Z-0595-2024) to address a non-conformance that occurred during the production of the CARDIOHELP-i System that prevented it from properly measuring leakage current. The prior Medical Device Correction stated that this non-conformance was not expected to result in perceptible levels of electrical shock. As part of the corrective action for this issue, MCP/Getinge added measurement of leakage current to the preventive maintenance for all CARDIOHELP-i devices. During the execution of this preventive maintenance, the company identified that the measured patient leakage current in some devices significantly exceeded the expected levels.

Further investigation showed that these devices with unexpectedly higher leakage current were limited to only those CARDIOHELP-i devices that were installed with sensor panels that predate January 18, 2011, but these devices were distributed in the US after 2011. Devices containing the

newer sensor panels do not present this issue. Five devices are affected in the United States. This error cannot be detected by the user, or via device performance or patient behaviour.

There has been one complaint related to this issue in CARDIOHELP-i devices containing the older sensor panel, but there have been no reports of adverse events related to this issue.

Risk to Health:

The potential immediate and/or long-range health consequences for a patient exposed to leakage current due to the above-described non-conformance include the following:

- Electrical shock
- Cardiac arrhythmia

Additionally, the user of the device may encounter some degree of user inconvenience due to equipment exchange or replacement while the device is being serviced to address this issue.

Actions to be taken by the Customer:

Our records indicate that you have received a CARDIOHELP-i with a serial number that is affected by this voluntary Medical Device Removal (see top of page 1).

- Please examine your inventory immediately to determine if you have any affected CARDIOHELP-i in your inventory.
- **Whether or not your facility has affected product(s) listed in this notice, please complete and sign the attached MEDICAL DEVICE-REMOVAL RESPONSE FORM (Page 4) to acknowledge that you have received this notification**. Return the completed form to Getinge by e-mailing a scanned copy to **CHLeakage2024.cp@getinge.com**
- If you report having any affected CARDIOHELP-i devices, Getinge will contact you to arrange for the return of the affected device to upgrade the system's sensor panel and perform testing to ensure that leakage current is within specifications. You can also contact Getinge Technical Support at (888) 943-8872 (select option 4, then option 2, then option 1), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone) to make these arrangements. A loaner device will be provided to you until the repaired unit is returned to you. If you have already returned the device to MCP/Getinge for repair/maintenance, this upgrade will be included.
- **Do not use the affected device for any additional patients until it has been cleared by the MCP/Getinge system check, repaired, or replaced.** If the affected CARDIOHELP-i device is already in use, it can continue to be used until the end of the patient treatment.
- **Please forward this information to all current and potential CARDIOHELP-i users within your hospital / facility.**
- **If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.**

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax using the following:

- **Online**: www.accessdata.fda.gov/scripts/medwatch/
- **Regular Mail**: Download form at www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form
- **Fax**: 1-800-FDA-0178 (1-800-332-0178)

Actions to be taken by Getinge:

MCP/Getinge will contact you to arrange the return of the affected device to upgrade the system's sensor panel and perform testing to ensure that leakage current is within specifications.

This voluntary Medical Device Removal only affects the products listed on Page 1; no other products are affected by this voluntary removal.

We apologize for any inconvenience this Medical Device Removal may cause. If you have any questions, please contact Getinge Technical Support at (888) 943-8872 (select option 4, then option 2, then option 1), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone).

This Medical Device Removal notice is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

Regulatory Affairs Field Action Compliance