November 14, 2023

URGENT MEDICAL DEVICE – Correction

Reference Number: 8010762-11/10/2023-005-C

CARDIOHELP-i Heart Lung Support System

Product Name	CARDIOHELP-i Heart Lung Support System	
Product REF Number	701072780	701048012
UDI	04058863074863	04037691658384
Distributed Affected Serial Numbers:	All serial numbers up to and including 90415172	
Manufacturing Dates:	701072780 Feb 13, 2018 - Dec 16, 2022 701048012 April 2, 2014 - Sept 7, 2017	
Distribution Dates:	701072780 Feb 23, 2018 - Feb 10, 2023 701048012 April 24, 2014 – Sept 25, 2017	

Dear Risk Manager,

Maquet Cardiopulmonary GmbH (MCP)/Getinge is initiating a voluntary Medical Device Correction for the CARDIOHELP-i Heart Lung Support System, due to a non-conformance related to the assessment of leakage current during the manufacture of the CARDIOHELP-i System. Because the leakage current tests were not properly performed, MCP/Getinge will contact you to arrange for a MCP/Getinge service technician to perform a system check of any affected device to confirm leakage current is within specifications (IEC 62353). If a system fails the performed test, the MCP/Getinge service technician will replace the system's sensor panel for you. MCP/Getinge service may have already performed the required system check of your device during a past preventative maintenance. MCP/Getinge will check service records to confirm.

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:

A non-conformance in the production of the CARDIOHELP-i System was discovered. A production tool used to assess patient leakage current at the sensor panel connection/hub was not connected properly to the connection/hub due to an incorrect drawing of the tool, resulting in the tool being manufactured incorrectly. As a result, the CARDIOHELP-i System was not properly tested to measure leakage current.

There have been no complaints or reports of adverse events related to this issue.

Risk to Health:
The level of electrical shock that can result from the improper leakage current measurement is not expected to be perceptible or clinically relevant to a patient, user, or third party. Further, mitigating design factors (e.g., proper grounding, isolation of potent stray currents) and clinical factors (e.g.,

nitrile gloves, current isolating footwear) exist to minimize exposure. Therefore, such an exposure would carry with it no immediate or long-term consequences.

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 Correction.

- 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 - CORRECTION 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 Cardiopulmonary-cardiohelpleakage2023.cp@getinge.com or by faxing the form to 1-800-530-6084.
- If you report having any affected CARDIOHELP-i devices, a local Getinge representative will contact you to arrange a system check of the device to ensure that leakage current is within specifications.
- **Affected CARDIOHELP-i devices are not requested to be returned and can be used as usual.**
- **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.**

Type of Action by Getinge:

Getinge has identified the issue to be related to a supplier using an incorrect drawing to produce a tool used to measure leakage current of the CARDIOHELP-i. This issue has been corrected by the supplier.

MCP/Getinge will contact you to arrange for a MCP/Getinge service technician to perform a system check of any affected device you report to confirm leakage current is within specifications (IEC 62353). If a system fails the performed test, the MCP/Getinge service technician will replace the system's sensor panel for you. MCP/Getinge service may have already performed the required system check of your device during a past preventative maintenance. MCP/Getinge will check service records to confirm. MCP/Getinge will also be reaching out to those customers that are currently certified to perform maintenance on their own devices to provide the updated service manual containing the procedure to conduct the electrical safety test referenced in this Correction (See Chapter 3.4.5 "Applied Parts Leakage Current").

This voluntary correction only affects the products listed on Page 1; no other products are affected by this voluntary correction.

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 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

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

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

Sincerely,

Jessica Minaya

Regulatory Affairs and Field Action Compliance