November 6, 2023

URGENT MEDICAL DEVICE – Correction

Reference Number: 8010762-11/06/2023-004-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 90415177	
Manufacturing Dates:	Manufactured on or before January 24, 2023	
Distribution Dates:	Distributed before May 15, 2023	

Dear Risk Manager,

Maquet Cardiopulmonary GmbH (MCP)/Getinge is initiating a voluntary Medical Device Correction for the CARDIOHELP-i Heart Lung Support System to provide a new version of the Instructions for Use (IFU) to customers who received previous versions of the IFU that incorrectly described certain factory settings for the device (see **Figure 1** through **Figure 6** below). The devices, however, are manufactured with the appropriate factory settings and functioning as intended.

Identification of the issue:

There is incorrect information in the CARDIOHELP-i IFU related to the warning limits for P_{Ven} and P_{Aux}, and the default settings for the venous bubble sensor (VBS) and the automatic lock in the Minimized Extracorporeal Circulation (MECC) ThApp. Details of the incorrect and correct information are below. Note that the incorrect information is contained in the IFU only, and that the devices are manufactured with the appropriate factory settings.

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

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_{Inf}[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 English (EN) IFU on P_{Ven} factory settings

The following correct information is now 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

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

The following correct information is now 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 2: Correct information in the EN IFU on P_{Aux} and Venous Bubble Intervention

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[a]	activated

Figure 3: Incorrect information in the EN IFU on factory settings regarding automatic locking

The following correct information is now 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[a]	deactivated

Figure 4: Correct information in the EN IFU on factory settings regarding automatic locking

Risk to Health:

Incorrect information in the IFU can lead to User inconvenience, although MCP has not received any complaints, including of patient harm, serious injuries, or deaths, related to this error.

Actions to be taken by the Customer:

Our records indicate that you have received a CARDIOHELP-i having 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.
- Please review, download, and print the updated IFU for these products at: https://us.getinge.com/l/950532/2023-10-13/ppb1d2
- Please remove and destroy any previous versions of the IFU at your facility.
- As noted in the “Key User Functions” section of the IFU:
    - Before beginning the application, ensure that the selected warning and alarm limits, as well as interventions, are suitable and safe for the patient and the current situation.
    - Before beginning the application, check every intervention selected by simulating an alarm condition.

- Should you have any questions or need additional copies of the IFU, 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).
- **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.**
- 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 5) to acknowledge that you have received this notification. Return the completed form to Getinge by e-mailing a scanned copy to CardiohelpIFU2023.qrc@getinge.com or by faxing the form to 1-800-861-0842.

Type of Action by Getinge:

The corrected IFU for the CARDIOHELP-i Heart Lung Support System is available at the web link included in this letter. Getinge will also send a hard copy of the IFU to those customers who request one.

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,

Marylou Insinga
Senior Specialist, Regulatory Affairs and Field Action Compliance
Getinge