LivaNova
Health innovation that matters

FSCA Ref: FA-CP-MUN-2024-004

Urgent Field Safety Notice (FSN)

Essenz Heart-Lung Machine (HLM) with Software Version HLM.1.5
Potential for Cockpit Graphical User Interface (GUI) Reset and Restore

October 18th, 2024

To the attention of: Healthcare Professionals (HCP) who are users of the Essenz HLM.

Purpose of this Letter

The purpose of this letter is to advise you that LivaNova Deutschland GmbH ("LivaNova" or "the Company") is executing a voluntary medical device correction for specific serial numbers of Essenz HLM installed with SW HLM.1.5. You are receiving this notice because you/your organization has received one or more Essenz HLMs with an affected serial number, as identified in the attached Customer Response Form.
The Essenz Heart-Lung Machine is intended to perform, control, monitor and support extracorporeal blood circulation replacing the mechanical pumping function of the heart, monitoring and regulating physiologic parameters during procedures requiring extracorporeal circulation.

This notification outlines the issue, provides instructions on immediate actions, and details the corrective measures LivaNova is implementing to resolve the issue.

Reason for this Field Safety Corrective Action (FSCA)

LivaNova has received reports of the cockpit graphical user interface (GUI) of the Essenz HLM with SW HLM.1.5 (see Table 1) activating a self-resetting safety feature, with the operation of the GUI being restored during use. During the reported events, the touchscreen display has temporarily gone dark (black/grey) and reset back to the home screen after approximately 10-15 seconds. Importantly, the machine's safety and performance functions remained operational during this time, with continuous control maintained through the backup control panel.

In all cases, the GUI self-reset worked as designed. No patient injuries have been reported.

Table 1: List of Devices

Catalogue item	Catalogue description	Software revision
49-00-10	Essenz HLM	1.5

Potential Risk to Health

The potential harms associated with the GUI self-reset are Hypoxia and Hypoperfusion. No patient harm has been reported in combination with a GUI self-reset.

The Essenz HLM includes a safety feature that triggers the cockpit GUI to reset if an unexpected GUI malfunction occurs. During a reset, the HLM's essential functions, including the pumps, alarms, sensors, and safety features, continue to operate as intended.

The backup control panel ensures that the machine remains controllable during the reset process.

After a reset, users are prompted with the "LAST CASE" button on the GUI to retrieve the previous settings, allowing for a continuation of the procedure from the cockpit GUI.

The reset reloads the gas blender flow values from the user-selected profile of the last case. If the user has adjusted the gas blender settings from the profile's default values, the user will need to manually restore those values after the reset.

In some instances, after selecting the 'LAST CASE' button, a second reset may occur. After the second reset, the 'LAST CASE' button may not be available.
Throughout the resetting of the system, the HLM's essential functions, including the pumps, alarms, sensors, and safety features, continue to operate as intended.
However, after the second reset, the Gas Blender may go to Standby. If this occurs, the operator should reactivate the Gas Blender from the user interface on the Gas Blender unit to maintain operation of the Gas Blender for the procedure. After the second reset, a new case should be started from the home screen; while the machine distributes the profile again, the sensors are momentarily deactivated until the user selects the start case button. The user can skip the safety checks since they have already been performed before the reset and enter bypass mode. After starting the case, the user should update the case settings as needed.
The "LAST CASE" function and Starting a New Case are described in Essenz's Instruction For Use (IFU) section *"7.1.3 Returning to the last case" and "7.1.1 Starting a case"*

Actions to be taken by the User

1. Continue using the Essenz Heart-Lung Machine with SW HLM.1.5 as intended.
2. In the event of any cockpit reset during a procedure, use the backup control panel to make any setting adjustments as described in Essenz HLM IFU section 3.3.2 "Backup control panel."
    A. When prompted, press the "LAST CASE" button to retrieve the previous settings as described in Essenz HLM IFU chapter "7.1.3 Returning to the last case." If the gas blender settings were manually changed prior to the reset, adjust the settings as needed.
    B. If after selecting the 'LAST CASE' button a second reset occurs, the 'LAST CASE' button may not be available. Throughout the resetting of the system, the HLM's essential functions, including the pumps, alarms, sensors, and safety features, continue to operate as intended. After the second reset, the Gas Blender may go to Standby. If this occurs, the operator should reactivate the Gas Blender from the user interface on the Gas Blender unit to maintain operation of the Gas Blender for the procedure. After the second reset, a new case should be started from the home screen; while the machine distributes the profile again, the sensors are momentarily deactivated until the user selects the start case button. The user can skip the safety checks since they have already been performed before the reset and enter bypass mode. After starting the case, the user should update the case settings as needed. The

start Case function is described in Essenz HLM IFU chapter “7.1.1 Starting a case”

3. Acknowledge and confirm receipt of this letter by completing and returning the enclosed Customer Response Form (Attachment 1). Return it by email to LivaNova.FSCA@livanova.com or by hand to your LivaNova contact person to confirm that you have received this letter and that you have read and understood its content.

Next Steps

A LivaNova representative will contact you to schedule a software update to correct the behavior of the HLMs with Software Version HLM.1.5. The software update will be made available starting no later than October 31. We appreciate your cooperation during this time and will make every effort to minimize disruption to your operations.

Transmission of this Field Safety Notice

Please ensure that this notice is promptly communicated to all personnel within your organization who need to be aware of it. If you have transferred any of the affected devices to a third party, please communicate this information to them and inform LivaNova at LivaNova.FSCA@livanova.com.
Please transfer this notice to other organizations on which this action has an impact.
Please maintain awareness on this notice and resulting action until your Essenz HLMs have been updated with the SW correction.

A copy of this letter is being provided to Your Competent Authority. Adverse reactions or quality problems experienced with the use of this product should be reported to LivaNova through your usual representative or by email to customerquality@livanova.com.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Contact reference person

For questions regarding this Medical Device Correction, please contact your LivaNova contact person or send an e-mail LivaNova Quality Assurance Team at:
LivaNova.FSCA@livanova.com.

Thank you for your cooperation in this matter. LivaNova is committed to providing quality products and service to its customers and we apologize for any inconvenience this situation may have caused.

Sincerely,

LivaNova
Health innovation that matters

FSCA Ref: FA-CP-MUN-2024-004

[redacted]

Enrico Milani
Senior Director Customer Quality, Microbiology and Supplier Quality Engineering - Cardiopulmonary

Attachment 1: Customer Response Form

LivaNova
Health innovation that matters

FSCA Ref: FA-CP-MUN-2024-004

Attachment 1

Customer Response Form

Urgent Field Safety Notice (FSN)

Essenz Heart-Lung Machine (HLM) with Software Version HLM.1.5
Potential for Cockpit Graphical User Interface (GUI) Reset and Restore

Customer Information:

Customer Name	PREFILLED BY LIVANOVA
Facility Name	PREFILLED BY LIVANOVA
Street Address	PREFILLED BY LIVANOVA
City, State, Zip Code	PREFILLED BY LIVANOVA

Table 2: List of the serial number of the Essenz HLM impacted at your facility

Catalog item	Description	Serial number
		PREFILLED BY LIVANOVA
		PREFILLED BY LIVANOVA

Please, complete this response form and return it via e-mail to LivaNova.FSCA@livanova.com **no later than October 25th, 2024.**

☐ I confirm I have received the present Medical Device correction letter and that I have read and understood its content.

☐ I confirm the information have been brought to the attention of all relevant users.

☐ I confirm that I have not transferred any device listed in Table [2] above to any other person or location or, if I have done so, I have forwarded this Urgent Medical Device Correction notice to the transferee and notified LivaNova by email at LivaNova.FSCA@livanova.com.

If you need additional information on the content of the letter, please specify the additional information needed below or contact LivaNova.FSCA@livanova.com

_____

_____

Name/Title	
Signature	
Telephone or Email address	

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN. Your organisation's reply is the evidence we need to monitor the progress of the corrective actions. Your Response is required to ensure all corrective actions are executed: thanks a lot