Heart Failure Division
Abbott Medical
6035 Stoneridge Drive
Pleasanton, CA 94588

# Urgent Medical Device Correction

## System Monitor

## Model Numbers: 1286, L1286, 1286A, 1286A-CAN, L1286A,1286A-US, L1286A-US, 1286C, L1286C, 1286INT, L1286INT, and L1386

May 2024

Dear Valued Customer,

Abbott is notifying you about important information regarding the System Monitor which is used with the HeartMate™ Left Ventricular Assist System (LVAS). Abbott has received complaints of the System Monitor screen displaying atypical behavior and this letter provides recommendations and guidance to follow if you observe this issue. The System Monitor is not being removed from the field and does not need to be returned to Abbott.

System Monitor Atypical Screen Behavior

Abbott has received customer complaints for the System Monitor due to atypical screen display behaviors. All System Monitors can potentially show atypical screen display behaviors. Restarting the System Monitor should resolve these issues in most cases. There have not been any serious adverse health consequences associated with these complaints.

Some examples of atypical screen issues that may occur include:

- Overlapping screens/buttons
- Frozen screen
- Distorted text, blanks, or zeroes in place of values
- Unresponsive buttons where the user is unable to initiate a command.

See Appendix A for illustrations of an atypical screen behavior of the “Cancel Button” overlapping the “Pump Stop” button (Figure 1) and an example of the expected screen appearance (Figure 2).

Impact and Associated Risks

From January 2012 to April 2024, Abbott has received 299 reported complaints of atypical screen issues in the System Monitor (estimated rate of 0.049%). There have been no serious adverse health consequences reported. Of the reported complaints, twenty-two (22) resulted in extended surgical time during surgery (until the unit was restarted or replaced with the backup). In thirteen (13) instances (estimated rate of 0.0023%), the System Monitor had a display issue which resulted in the “Stop Pump” command to be accidentally selected and the LVAD (Left Ventricular Assist Device) stopped momentarily and automatically restarted. The patients did not present symptoms as a result of the pump stop, and the pump reset to the settings that were programmed before the unintended stop.

The rest of the complaints resulted in anxiety/user inconvenience. This issue has the potential for hemodynamic compromise if pump settings are accidentally altered, although Abbott has not received any related complaint to this risk.

Recommendation – Monitoring patients with HeartMate II or HeartMate 3:
The System Monitor provides the only clinician interface for managing HeartMate II and HeartMate 3 LVAS patients. Therefore, the System Monitor is recommended for continued care of HeartMate II LVAS and HeartMate 3 LVAS patients until another managing interface will become available.

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Clinician Guidance

Abbott is advising clinicians to restart the System Monitor unit before connecting to the Controller, if the unit has been running for a long period of time, or if screen issues are observed. To restart the unit, turn off and then turn on using the On/Off Switch located on the back of the System Monitor. It takes approximately 10 seconds to fully restart and display the information on the screen. See Appendix B, Figure 3 for a view of the back of the System Monitor illustrating where to locate the On/Off Switch (circled in red). If the unit is restarted while connected to the patient's Controller the LVAD settings will remain the same.

Upon System Monitor restart, if the screen display issues continue, check that all cables and connections are secure and undamaged. If the atypical screen issues persist, use a different System Monitor.

If the "Stop Pump" button is inadvertently pressed, the pump will stop momentarily and restart. If, however, the pump stop button is pressed longer than ten seconds, the pump will stop and the Controller will alarm "Pump Off Alarm". To resolve the "Pump Off Alarm" and restart the pump, clinicians can press any button on the Controller to attempt pump start as instructed in the Instructions for Use (IFU)[1].

Next Steps

Please distribute this notice to those who need to be aware within your institution and forward to any institution where potentially affected devices have been transferred. Complete the attached acknowledgment form included with this letter and return it to Abbott.

Abbott is in the process of notifying the applicable regulatory agencies about this issue.

Adverse reactions or quality problems experienced with the use of this product may be reported to your local Abbott representative.

We sincerely apologize for any difficulties or inconvenience this may cause you and your patients. Please know that Abbott is committed to providing the highest quality products and support, and we thank you for your partnership in assisting us with this process. Should you have any questions about this communication, please contact your local Abbott representative.

Sincerely,

Catalina Acon Ng
Director Quality Assurance
Abbott Heart Failure

[1] Refer to Instructions For Use, Chapter: Alarms and Troubleshooting, Pump Off Alarm

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## Appendix A

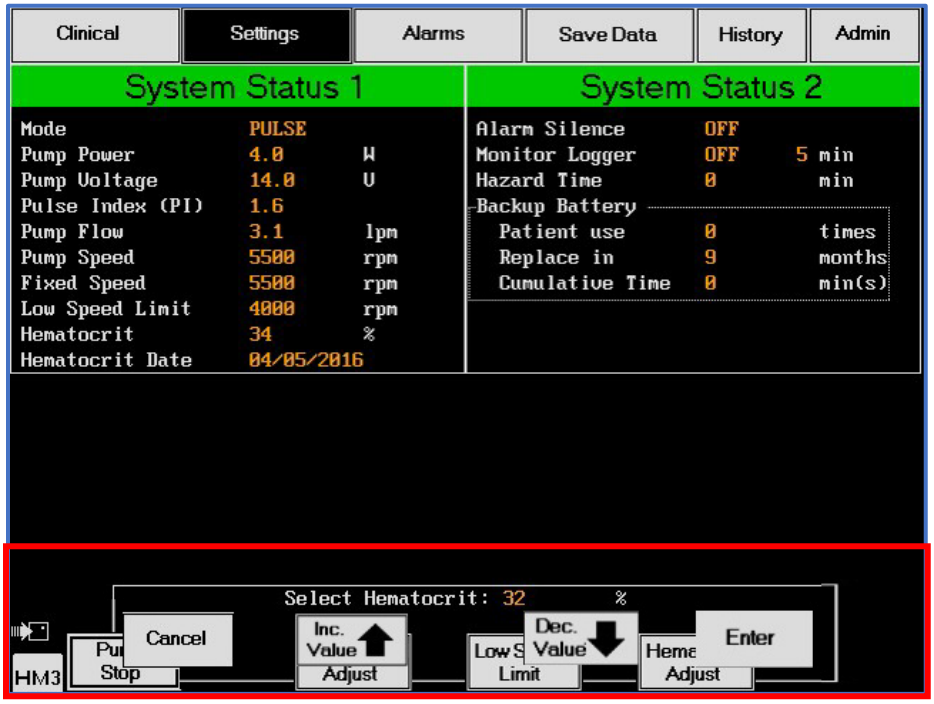


***Figure 1*** *– Example of Atypical Screen Behavior, Overlapping Buttons*

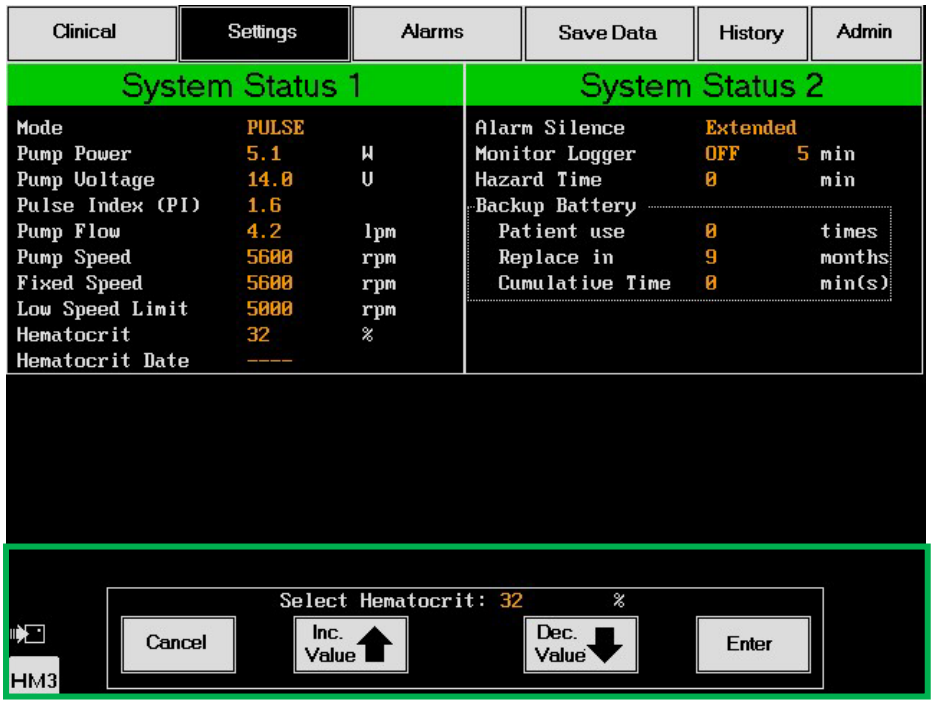


***Figure 2*** *– Example of Expected Appearance of the Screen*

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## Appendix B

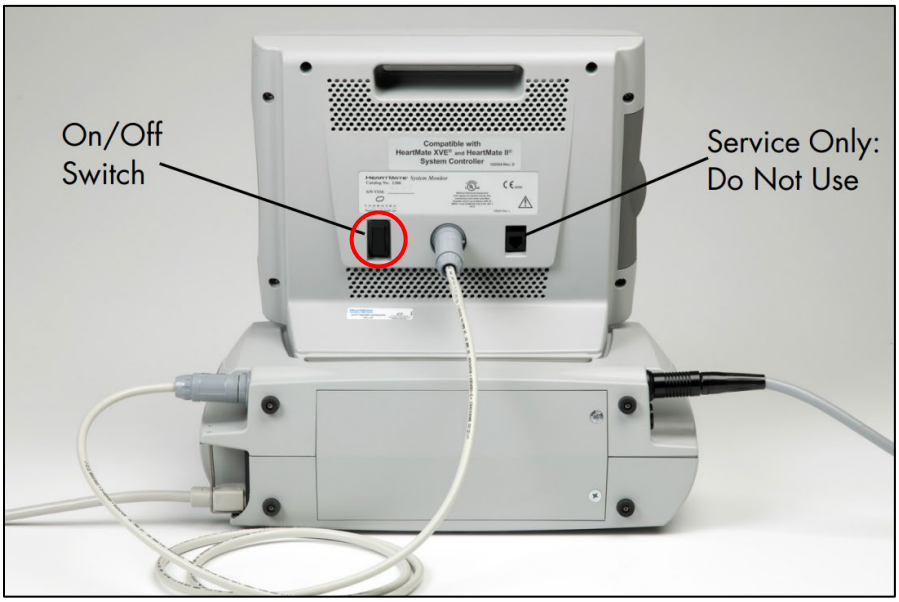


***Figure 3*** *– Back of the System Monitor, On/Off Switch Circled in Red*