



نتقدم بثقة
Moving Forward
with Confidence

رؤية عُمان
2040
Oman Vision

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 65 dated 14/5/2024 Regarding Field Safety Notice of System Monitor used with the HeartMate™ Left Ventricular Assist System (LVAS) from (mfr: Abbott).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



DSC
مركز سلامة الدواء
Drug Safety Center



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

✉ @DSCPHO Email: dscpho@moh.gov.om



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Circular No. 65 / 2024

06-11-1445 H

14 -05-2024

FSN of System Monitor used with the HeartMate™ Left Ventricular Assist System (LVAS) from Abbott.

Source	Abbott through their local agent Muscat Pharmacy & Stores LLC.
Product	System Monitor used with the HeartMate™ Left Ventricular Assist System (LVAS).
Description	Active Implantable Devices.
Manufacturer	Abbott.
Local agent	Muscat Pharmacy & Stores L.L.C.
The affected products	System Monitor used with the HeartMate™ Left Ventricular Assist System (LVAS). System Monitor Model Numbers: 1286, L1286, 1286A, L1286A, 1286INT and L1286INT.
Reason	Potential of atypical screen display behaviors.
Action	1. Please refer to the "Recommendations" and "Clinician Guidance" in the attachment. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General



DSC
مركز سلامة الدواء
Drug Safety Center



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

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Abbott

Urgent Field Safety Notice

FA-Q224-HF-1

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

System Monitor

Model Numbers: 1286, L1286, 1286A, L1286A, 1286INT and L1286INT

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 3 and HeartMate II (with System Controller):

When Abbott started offering the HeartMate Touch™ Communication System, Abbott notified customers that it was the next generation device for the System Monitor. Abbott stopped supporting and servicing the System Monitor for managing HeartMate 3 and HeartMate II patients with the System Controller. **System Monitor should not be used for managing HeartMate 3 and HeartMate II LVAS patients who are supported with the System Controller.** Customers that currently use HeartMate Touch™ should continue using the device. HeartMate Touch™ is not impacted by this notification.



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System Monitor

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Recommendation – Monitoring patients with HeartMate II (with External Peripheral Controller (EPC)):

The System Monitor provides the only clinician interface for managing HeartMate II LVAS patients who are supported by the External Peripheral Controller (EPC). Therefore, the System Monitor is recommended for continued care of HeartMate II LVAS EPC patients.

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.

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

Please report any adverse reactions or quality problems experienced with the use of these products 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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System Monitor
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Appendix A

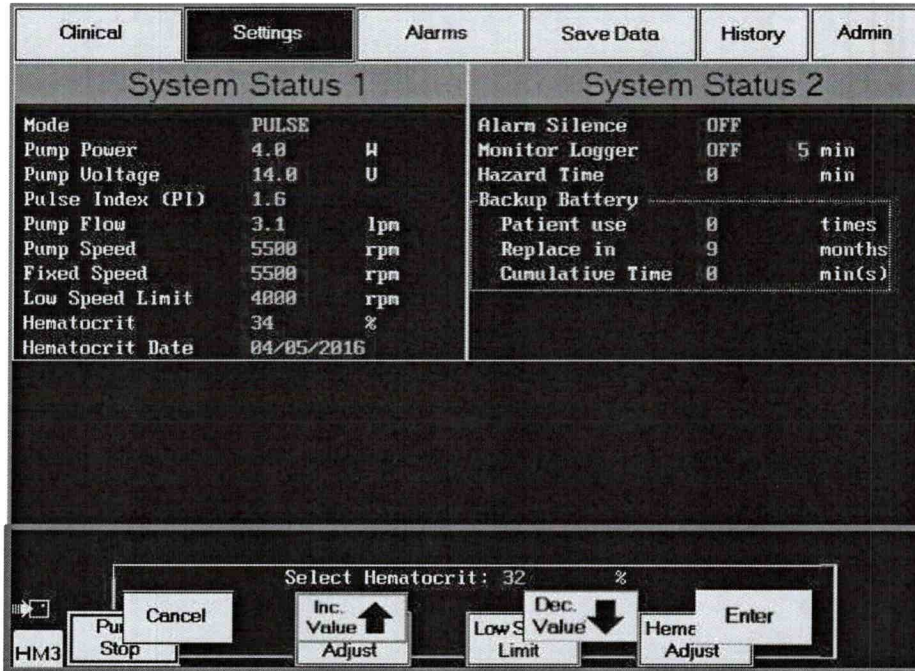


Figure 1 – Example of Atypical Screen Behavior, Overlapping Buttons

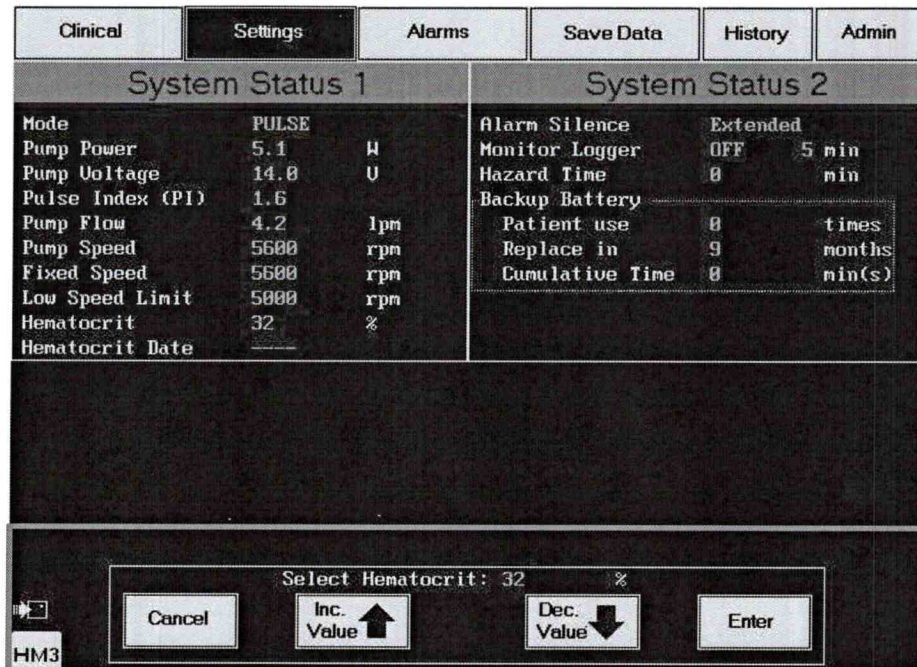


Figure 2 – Example of Expected Appearance of the Screen



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Appendix B

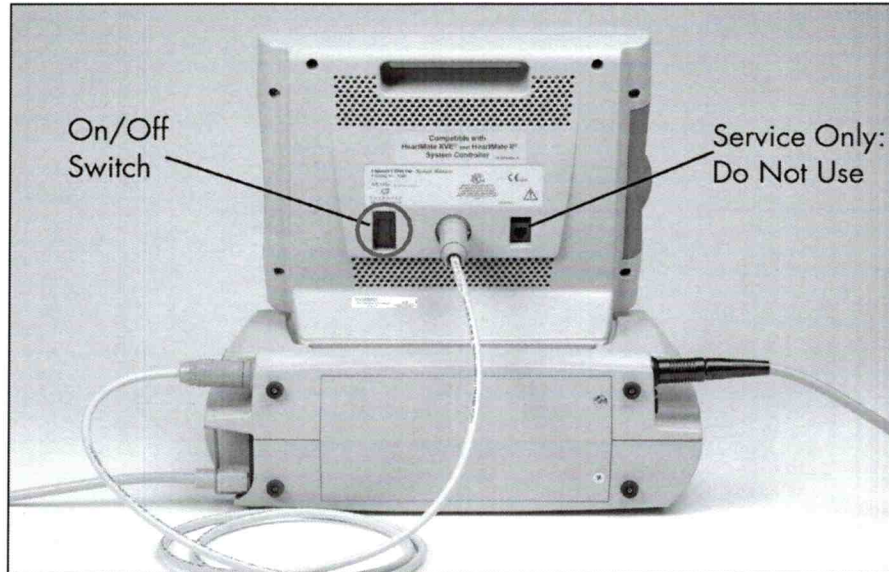


Figure 3 – Back of the System Monitor, On/Off Switch Circled in Red