

HemoSphere Advanced Monitor Release Notes

The following is a list of known device implementation anomalies and troubleshooting steps associated with the listed software release version. The software version is listed on the Versions screen (Settings \rightarrow Help \rightarrow Versions). These issues are continually updated and compiled as a result of ongoing product improvements.

HemoSphere advanced monitor anomalies for software release version 03.01.000.001

Known anomaly	Cause	Suggested actions
"Fault: Oximetry Cable Disconnected" is not cleared after touching the Silence Audible Alarm button while on New Patient Data screen.	Touching the Silence Audible Alarm button on the New Patient screen does not cancel any disconnect faults.	Re-connect the oximetry cable.
After performing a BP calibration while in Non-Invasive monitoring mode, and then switching to Invasive and back to Non-Invasive monitoring modes, the BP calibration status is cleared on BP Calibration screen. The BP calibration is not cleared after monitoring is stopped for 10 minutes.	Calibration data is stored on host module and HemoSphere ClearSight module resulting in a discrepancy in BP Calibration status when switching between monitoring technologies.	Re-calibrate BP.
While monitoring in non-invasive mode and connecting new finger cuffs, the incorrect cuff expiry dates are displayed on finger cuff settings screen.	During a measurement, the pressure controller only updates the expiration once per minute. Therefore, there is a delay on-screen of updated expiration time.	Close and re-open the finger cuff settings screen to see correct expiry date. Notifications for cuff expiration will still properly function.
The display of "Fault: Cuff Disconnected During Double Cuff Monitoring" is delayed after disconnecting cuff.	During the first five seconds of a measurement, the pressure controller performs several checks to ensure proper operation. If disconnect happens during this time a finger cuff error will be displayed instead.	Re-connect cuff and resume monitoring.
Immediately after the start of non-invasive monitoring, if the single cuff connection is switched to the other port on pressure controller, the incorrect cuff fault is displayed ("Fault: Cuff Disconnected During Double Cuff Monitoring" or "Fault: Second Cuff Connected During Single Cuff Monitoring").	The pressure controller is triggering the incorrect error due to timing discrepancies.	Start a new measurement to clear the fault.
The monitor freezes after entering the secure password to export data. This occurs following 72 hours of monitoring with a HemoSphere Swan-Ganz module and then a power cycle.	A Windows system function call for the input/ output operations of the inserted USB drive is erroneously blocked.	Power cycle the monitor.
The monitor freezes after 24 hours of monitoring with a HemoSphere Swan-Ganz module and no user interaction.	The monitor software is overwhelmed by a flood of notifications of Ethernet interface status changes (on-line/off-line).	Power cycle the monitor.
While powering on the HemoSphere advanced monitor after a software upgrade, the screen turns off (goes black).	The cause for this anomaly is still under investigation.	Wait for issue to resolve on its own or power cycle the monitor.
Key parameters configured on the Cockpit monitoring screen are not saved after monitor is powered off and on again.	The monitor is shut down before key parameter display settings are saved.	Reconfigure desired parameters on Cockpit screen upon monitor reboot.
If patient demographics are not provided, Assisted Fluid Management algorithm (AFM algorithm) initialization fails and "Fault: Assisted Fluid Management" is displayed.	The monitor does not check for skipped demographics when starting Assisted Fluid Management algorithm (AFM algorithm) and then opens the AFM algorithm dashboard. The AFM algorithm should not be available when patient demographics entry is skipped.	Enter patient demographics and restart AFM algorithm session.

Known anomaly	Cause	Suggested actions
When monitoring using minimally invasive technology, a fatal exception occurs and the monitor displays the following message: "Fatal Exception Occurred - Element Not Found."	The monitor cannot process an exception caused by the Wi-Fi Module.	Disable the Wi-Fi and restart the monitor.
When patient demographics are skipped and sCO and sCI are set as key parameters, the patient demographic icon does not glow yellow on the navigation bar and the "Enter Patient Demographics" banner is not displayed.	The banner, patient demographics icon, and notification are not linked to the display of sCO, sCI, EDV, sEDV, RVEF, sRVEF, CO20s, Cl20s, SV20s, and SVI20s.	Enter patient demographics and then begin monitoring parameters.
When using Assisted Fluid Management algorithm (AFM algorithm), if SVV is not selected as a key parameter, the value for (time) SVV ≤ 12% is displayed as 0%.	The value for (time) SVV ≤ 12% is calculated by a background goal directed therapy (GDT) session which uses graphical trends to update its calculations. When SVV is not configured as a key parameter, there is no data to perform the calculations.	Select SVV as a key parameter and restart the Assisted Fluid Management algorithm (AFM algorithm) session. Ensure SVV is selected as a key parameter for the entirety of the AFM algorithm session.
When monitoring is not active, the message "Monitor must be stopped prior to calibrating HRS" is still displayed instead of the HRS calibration instructions.	The cause for this anomaly is still under investigation.	Reconnect the heart reference sensor (HRS) to the pressure controller and return back to HRS calibration screen.
When monitoring with the Swan-Ganz module and Acumen IQ sensor (multiple technologies), HPI, PPV, SVV, dP/dt, and Ea _{dyn} parameters are not sent through IFMout.	IFMout in invasive mode does not support/ transmit HPI, PPV, SVV, dP/dt, and Ea _{dyn} parameters. They are not on the IFMout list of parameters for invasive mode.	If IFMout is used for the medical record keeping, manually record the affected parameters into the EMR instead of using the serial output.
When the HemoSphere advanced monitor is paired to the Viewfinder hub and moved away from Wi-Fi source, a Viewfinder hub connection error occurs and the monitor displays the following message: "Viewfinder Hub Connectivity Error - Viewfinder Hub Not Reachable".	The cause for this anomaly is still under investigation.	Power cycle the monitor.
After a system reboot, the HemoSphere advanced monitor does not display previously configured parameters on the selected monitoring screen.	The monitor shut down sequence starts before parameter configuration settings have been fully saved.	Reconfigure the monitoring screen with the preferred parameters.
After pairing the HemoSphere advanced monitor to the Viewfinder hub, an internal system failure occurs.	A update issue occurs while synchronizing the on-screen physician department list with the Viewfinder hub.	Power cycle the monitor.
After pairing the HemoSphere advanced monitor to the Viewfinder hub and power cycling the monitor, the red Edwards screen appears and the monitor alarms.	During monitor startup, there is a delay in showing the monitoring screen which causes the monitor to timeout and trigger the alarm and LED indicator.	No troubleshooting steps currently available. Monitor alarm is temporary and normal startup will continue as expected.
A new patient profile displays StO ₂ values from the previous monitoring session.	The monitor sometimes considers the StO ₂ parameter state as available when sensors are disconnected when a patient monitoring session is not active.	Wait for the values to disappear and then connect new sensors, or reinsert the technology module.
After entering patient demographics while using the ClearSight module, the pressure-out toggle on the Zero & Waveform screen is non-responsive and cannot be set to transmit.	The monitor will stop the waveform transmit before the waveform transmit event is complete. The monitor then enters a recursive state and stops transmit until the timing window closes.	Start ClearSight technology monitoring, or reopen the Zero & Waveform screen and retoggle to transmit.
When the HemoSphere advanced monitor is paired to the Viewfinder hub and actively monitoring, the "Wireless Module Fault" occurs and is displayed on the screen. The fault then disappears and clears throughout monitoring.	The monitor sends access point scan requests to the Wi-Fi module at least two times per minute. This causes additional resource load for the Wi-Fi module while servicing these requests, making the response times longer than normal. When there isn't a response to a request within the timeout period, the "Wireless Module Fault" is generated.	Disable the Wi-Fi functionality on the monitor and then continue monitoring.
When monitoring for 72 hours, a fatal error occurs and the monitor displays the following message: "System.OutofMemoryException".	System exceeds the expected memory allocation.	Power cycle the monitor.

Known anomaly	Cause	Suggested actions
When the HemoSphere advanced monitor is paired to the Viewfinder hub and actively monitoring, "L-Tech Communication Failure/ Hardware Failure Fault" is displayed on the screen, and monitoring stops.	During monitoring while connected to Viewfinder hub, periodic requests to retrieve service information from all modules are sent. ClearSight module does not have sufficient bandwidth to handle these requests, causing the system to time out.	Power cycle the monitor, then disable Viewfinder hub connection and functionality.
An error occurs and the message "Application is Not Responding" is displayed after attempting a download of more than 48 hours of data while the HemoSphere monitor is actively monitoring with all available technologies in the noninvasive (ClearSight technology) monitoring mode.	CPU usage is high when attempting to download a large amount of data while the system is fully loaded, causing the application to become non-responsive.	Download data from the system after monitoring is complete.
The translation of "Open" on the surgery mode setting selection of the AFM algorithm dashboard is incorrect for multiple languages.	A translation error occurred where "Open" surgery mode was translated as a verb instead of as adjective.	No troubleshooting steps currently available. Refer here for an updated translation: "Open" (not applicable for English).
If the pressure cable is re-zeroed and subsequent arterial pressure readings are below 10 mmHg but still registered as pulsatile, key parameters will display invalid (pre-zeroed) values.	Faults, alerts, and alarms are disabled immediately after zeroing if MAP is less than 10 mmHg. Therefore, the invalid values are not time stamped to indicate that they are no longer current.	Reconnect the pressure cable and re-zero the arterial pressure line.



07/24 10057635004 A / DOC-0248454 A © Copyright 2024, Edwards Lifesciences LLC All rights reserved