Edwards

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 → Help → 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.
The expiration of a connected heart reference sensor (HRS), which is a low-priority alert, halts ClearSight module monitoring.	When Heart Reference Sensor (HRS) expires during a measurement, the pressure controller reports that the HRS is not zeroed, despite the HRS still being zeroed. The ClearSight module does not allow monitoring with a non-zeroed HRS, and therefore stops the measurement.	No troubleshooting steps currently available. To continue monitoring, swap out the expired HRS with an unexpired HRS or use the optional HRS mode.

Known anomaly	Cause	Suggested actions
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.
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, CI20s, 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.

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Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA
Made in USA

Telephone 949.250.2500
800.424.3278
FAX 949.250.2525

Web IFU