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 02.03.000.103

Known anomaly	Cause	Suggested actions
The Event Review screen logs an extra (duplicate) Monitoring Stopped message when switching between monitoring modes.	After a monitoring mode switch from Minimally- Invasive to Invasive or Non-Invasive, the pressure module manager is still processing events from HemoSphere pressure cables.	No troubleshooting steps currently available. Proceed as usual. The time-stamp on the duplicate messages are the same.
"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.
While in Non-Invasive monitoring mode, the ART source indicator is not dimmed on the Patient Monitor tab of Zero & Waveform screen despite no source signal (HemoSphere ClearSight module disconnected) or pressure-out channel disconnected.	The cause for this anomaly is still under investigation.	No troubleshooting steps currently available. A signal can-not be sent without an actively monitored waveform and connected pressure-out cable. Check connections.
Internal system failure occurs after 24 hours of monitoring.	The cause for this anomaly is still under investigation. The host module lost communication with the data bridge module and connection could not be re-established.	Power cycle the monitor.
Touch screen of monitor slows or freezes during normal user interaction.	The cause for this anomaly is still under investigation.	Power cycle the monitor.
When an Acumen IQ sensor is disconnected and "Fault: Cable Port {0} – Pressure Sensor Disconnected" is triggered, HPI key parameter is deconfigured to another and HPI value is cleared instead of time-stamped.	HPI parameters are de-configured when the Acumen IQ sensor is disconnected resulting in cleared values.	Go to trend screen to review previous HPI value.
If HPI is configured as the fourth key parameter and then de-configured by switching to three key parameter display, or by displaying waveform, a High Alert popup will still appear when HPI>85 despite the HPI parameter setting "Always Alert when HPI is High" being disabled.	System only checks configured key parameters, not whether they are actively displayed on-screen.	Dismiss the popup and de-configure HPI as a key parameter.
The HemoSphere advanced monitor overwrites HRS zero status data on a re-connected pressure controller.	The monitor is holding HRS zero time data from previous pressure controller connection.	When switching pressure controller and HRS between HemoSphere advanced monitors, ensure that HRS zeroed timestamp is correct. If not, re-zero the HRS.
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.

Known anomaly	Cause	Suggested actions
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.
ClearSight module and monitor communication recovery sometimes fails when disconnect is triggered in artificial conditions.	Ethernet Stack is causing a communication error between ClearSight module and data bridge module of monitor.	Power cycle the monitor.
During a communication recovery between the HemoSphere ClearSight module and monitor, the monitor issues a module reboot.	The monitor terminates recovery from communication failure prematurely.	Power cycle the monitor.
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.
"Fault: L-Tech Module Slot - Software Failure" is displayed during connection of a valid HemoSphere ClearSight module.	The monitor does not receive a timely response to the "set date and time" command.	Disconnect and re-connect the HemoSphere ClearSight module or power cycle the monitor.
Following a software upgrade, the HemoSphere advanced monitor beeps for up to two minutes.	There is a delay in connection to the data bridge module while the monitor is powering on.	No troubleshooting steps necessary. After a connection is established the beeping will stop.
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.
Internal system failure occurs.	This can be caused by a memory leak issue. In certain cases, the cause for this anomaly is still under investigation.	Power cycle the monitor.
The "Disconnect HRS to Continue" message is erroneously cleared from the screen with no user action.	The screen prior to the displayed message had a two minute timeout assocated with it (e.g. Settings screen). The screen refresh is erroneously triggered by the two minute timeout instead of waiting for user response on HRS connection message.	The message will be displayed again requiring user interaction.
While sending tissue oximetry monitoring data to an external patient monitoring system through IFMout protocol, a low StO_2 alert can be displayed on the external monitor for channels with no StO_2 connection.	A low StO_2 value was assigned to the channel out instead of an unassigned value.	View and verify StO_2 parameter values on HemoSphere 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.
"**Default CVP Entry**" text on **CVP Entry** screen appears in English for all languages.	Incorrect text translation.	No troubleshooting steps currently available. **CVP Entry** button to access screen is correctly translated. User can still change the default CVP entry, which is an advanced parameter setting.

Edwards

Telephone   949.250.2500   Web IFU
              800.424.3278
FAX   949.250.2525

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