

HemoSphere Alta Advanced Monitoring Platform Release Notes

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

HemoSphere Alta advanced monitoring platform anomalies for software release version 1.0.14

Known anomaly	Cause	Suggested actions
After beginning a new monitoring session and switching to a different patient population (adult to pediatric or pediatric to adult), the incorrect full body graphic appears on the Physiology Split monitoring screen.	Conflicting patient data viewing files are created: one for the new patient and a second for the current patient. Depending on timing, the incorrect file is selected for the Physiology graphic.	Toggle between the adult and pediatric monitoring mode on the Sensor Location tab on the StO_2 parameter configuration window.
After starting a new monitoring session, the monitor will enter an alarm state and display a technical fault indicating that a system recovery is in process.	This is caused by an internal communication error.	Wait for the system to recover and resume monitoring.
While transmitting monitored data through the RS-232 serial port and monitoring with a Swan-Ganz catheter, TruWave pressure transducer and ClearSight cuff, all Swan-Ganz catheter technology and associated monitored data should be prioritized in IFMout protocol. However, ClearSight cuff arterial waveform data is transmitted instead of TruWave pressure transducer arterial waveform data.	The software does not recognize TruWave pressure transducer data as pressure cable sourced.	View TruWave pressure transducer arterial waveform on the HemoSphere Alta monitor or use a FloTrac or Acumen IQ sensor to monitor arterial blood pressure.
Touch screen of monitor freezes while custom defaults are applied and "Fault: Tissue Oximetry - Sensor Off" is triggered.	A four second timed popup is displayed after custom defaults are applied to the Patient Alarm/Target threshold settings. During that initial four second time period, the tissue sensor off Fault triggers a second popup. When the four second timer elapses, the second popup (tissue oximetry sensor off) is closed instead of the initial custom defaults popup which causes the monitor screen to freeze.	Power cycle the monitor. Adjust the patient's alarm/target settings prior to monitoring.
While actively monitoring arterial blood pressure with a TruWave transducer, a VAMP system blood draw results in the need to re-zero the arterial pressure waveform.	A TruWave pressure transducer fault condition stops the pressure cable algorithm. A re-zero is needed to restart the algorithm.	Re-zero the TruWave pressure transducer.
"Fault: ClearSight System - Subsystem Malfunction - Servicing Required" displayed while attempting to transmit a pressure-out signal to an external patient monitor during non-invasive ClearSight technology monitoring.	The monitor requests service data while the internal ClearSight module is transmitting a pressure-out signal. This causes an internal data issue.	Power cycle the monitor.
Unplugging the HemoSphere Alta patient cable while Swan-Ganz catheter monitoring is recovering after an EMC (electromagnetic compatibility) event results in an unrecoverable error.	The system does not terminate EMC recovery when the HemoSphere Alta Swan-Ganz patient cable is disconnected.	Allow the system to recover from the EMC event before unplugging the patient cable.
"Fault: Swan-Ganz System - Catheter Error" is not cleared after Start Swan-Ganz system button is touched.	The fault is not disabled if it's still active (persistant filament verifiation sub-fault) after Start Swan-Ganz system button touched.	Touch the alarm Reset button.

Known anomaly	Cause	Suggested actions
After ClearSight technology monitoring is stopped or disrupted - for example by a fault condition - previously displayed arterial waveform data still appears on the blood pressure waveform display.	Although other pressure waveforms are cleared on faulted or timestamped conditions, ClearSight technology waveforms are not.	A faulted condition will be displayed and the ClearSight technology parameter tiles will be timestamped. Refer to an external patient monitor or the timestamped key parameter tiles to confirm that no values are displayed and monitoring is halted.
Unexpected display of "Fault: Swan-Ganz System - Blood Temp Out of Range (< 31 °C or > 41 °C)" during Non-Pulsatile mode. Swan-Ganz technology monitoring should be suspended during non-pulsatile mode.	The Swan-Ganz sub-system logged numerous faults resulting in erroneous reporting logic between disconnected and faulted notifications.	No troubleshooting steps currently available.
${\rm SvO_2}$ calibration data is unavailable for recall from the oximetry cable after the cable is disconnected and reconnected to the HemoSphere Alta monitor.	Storage of calibration data was incomplete or interrupted.	Re-calibrate the oximetry cable (in vivo or in vitro).



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