



Edwards

## HemoSphere Advanced Monitor Release Notes

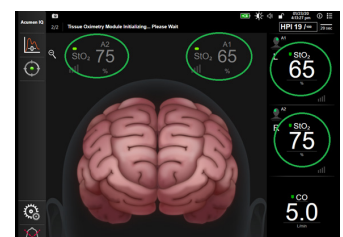
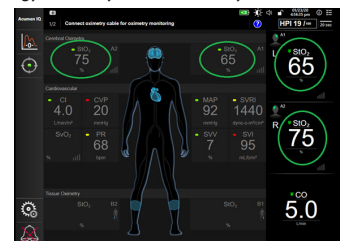
The following is a list of known device implementation anomalies and troubleshooting steps associated with the listed software release version. The software version is listed on the **Versions** screen (Settings → Help → Versions). These issues are continually updated and compiled as a result of ongoing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

### HemoSphere advanced monitor anomalies for software release version 2.00.000.025

Known anomaly	Cause	Suggested actions
The alarm flash rate for CVP parameter tile on graphical trend screen is 1Hz instead of 0.5Hz.	Some internal software timers handle use flash rates as their timer intervals.	No troubleshooting steps currently available. Incorrect timer intervals will be identified and set to half of flash rate for future software releases to resolve issue. User should address patient condition for any flashing parameter.
Empty parameter alarm target ranges causing the monitor to set an alarm.	The only parameters that had blank target settings were parameters with calculated "default" target settings. Software did not calculate target settings after the user entered patient demographics.	The parameters alarm regardless of what the values are. Alarm target ranges must be set manually.
'Audio Disabled' tone is still heard when there is no Alarm disabled on the screen.	Unable to reproduce anomaly.	No troubleshooting steps necessary. User will hear audio disabled tone.
Alarms of different priorities cycle when they shouldn't.	The logic which determines the next notice to display takes type of notice (notification, alarm, alert, fault) into account, but does not look at the priority.	Visual and audible indicators are still available to the user. User can manually cycle all alarms.
When the Alarm System Compliance is set to the 1st Edition and stays in the same screen, the Audio Alarm Minimum Volume dropdown option is not disabled and "Not available" is not displayed.	The screen was not updated immediately when changing alarm standard.	Re-navigating back to the screen to display the correct information for the selected Alarm System Compliance.
All indexed and non-indexed parameters are displayed despite selection of only one on indexed/non-indexed toggle button in Set custom Defaults settings screen.	Default target settings frames/screens use incorrect lists of indexed parameters and non-indexed parameters. This leads to observed issues with setting and restoring custom or Edwards parameter target defaults.	This shows for SVR and SVRI for custom default alarm settings. Confirm that custom defaults are configured as intended following any modification of the custom default settings.
While setting individual custom targets for a parameter on 'Set Custom Defaults Settings' screen and the screen times out, an empty area is shown instead of return to settings screen. <b>Note:</b> The 'Set Custom Defaults Settings' screen is an Advanced Feature and is password protected.	Popup screens are programmed to have a 2-minute time-out. When the time-out period is up the screen closes automatically. As the 'Set Custom Defaults Settings' frame stays hidden, time-out affects both screens.	Exit the Alarm/Targets screen and then navigate back.
SYS <sub>PAP</sub> and DIA <sub>PAP</sub> parameters do not display reference value on key parameter tile or on Intervals/ Averaging tab.	HemoSphere software does not set reference values for TruWave DPT monitored SYS <sub>ART</sub> , DIA <sub>ART</sub> , SYS <sub>PAP</sub> , and DIA <sub>PAP</sub> . It is a missing functionality.	Enter reference values for parameters as necessary.
While on Custom Defaults Settings screen, touching the cancel button will not remove any changes made to individual parameters made during current visit to settings screen. <b>Note:</b> The 'Set Custom Defaults Settings' screen is an Advanced Feature and is password protected.	Changes to parameter settings can be canceled or committed on one by one basis only.	Confirm that custom defaults are configured as intended following any modification of the custom default settings.
Parameter units on the Focused charting screen are truncated when parameters are not sent/timestamped.	Parameter units are rendered below the faulted timestamp which falls outside of the parameter tile on the Focused charting screen.	Values and parameter names are still visible on the screen. Refer to the Operator's manual for parameter units.
Time displayed on tabular trend parameters does not update to the current time.	If the user stops trending for an interval greater than the update interval, the End Time Timer needs to be adjusted to display the new tabular trend value when trending begins again. Otherwise, the Tabular Trend Parameter will not be updated until the user does one of the following: 1) Switch to another screen and return to tabular trend. This causes the End Time Timer to be adjusted. 2) Update End Time Timer with new start to trending.	Switch to other screen and return to tabular trend or Update End Time Timer.
Navigating to/from Focused screens changes the parameter tile setup on other screens.	The code keeps one set of key parameters amongst the different monitoring screens. The Focused screens has restrictions regarding key parameters, which may cause them to change on other monitoring screens.	Reselect the desired key parameters on other monitoring screens.

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Known anomaly	Cause	Suggested actions
'Connect pressure sensor for pulmonary artery monitoring' notification not displayed when PAP waveform is configured after creating new patient.	After creating a new patient, all notifications are cleared. The condition to display notice: 'Connect pressure sensor for pulmonary artery monitoring' is set when the user selects pressure source on the 'Select Pressure' tab. This condition is not re-evaluated when a new patient is created. This is why the notice is not displayed. Note: This issue only occurs when a sensor is re-used.	Toggle the pressure source on Zero & Waveform screen to force re-evaluation of the condition and current connections. The same logic applies to CVP and ART pressure sources. Per normal workflow, a new sensor must be used when a new patient profile is created.
The pressure-out channel gives an incorrect output when in between patient sessions.	Not all pressure-out ports were properly transitioned to zero state due to a signal mapping issue. This causes the last value to be continually sent on pressure-out channel.	Confirm zero levels when zeroing pressure on both HemoSphere advanced monitor and patient monitor.
SVR and SVRI parameter values become blank with no time stamp after touching the "Clear CVP Value" button in minimally-invasive monitoring mode.	Software notice evaluator did not run as there was no system status change to trigger a notice evaluation.	Re-enter a value on the CVP Entry screen to acquire SVR/SVRI parameter.
Slaved-In Analog Input MAP value does not populate physio-relationship MAP parameter box when arterial pressure sensor is disconnected. MAP value does not clear when arterial pressure sensor is connected and not zeroed.	Software does not reconcile MAP source on sensor connect event.	Re-zero to display the MAP value.
PAP beat-to-beat parameters are blinking when value is in red (alarm) targets region however the Alarm message is not displayed on status bar.	Waveform control not initialized on technology switch.	Observe visual indicators that indicate if the parameter is faulted.
On the Reference waveform screen for pulmonary artery catheter placement, the live waveform for MPAP is not updating relative to MPAP parameter tile value.	MPAP on 'PAC Insertion' screen was computed directly from live waveform in software.	Navigate back to the Zero & Waveform screen to observe current MPAP value.
Live waveform display resets when modules/cables/sensors unrelated to waveform display are connected/disconnected.	The live waveform re-initialization was performed in response to an unrelated system state changes. The live waveform should have only been re-initialized after re-evaluating the waveform of state/flag.	Wait for live waveform to reset and continue to display live waveform data.
'Alert: Transmit Pressure Not Active' tone is heard over pressure cable zeroing chime.	Two tones should not be played concurrently.	Confirm that zeroing has been completed by noting if relevant parameters are displayed. Ensure that HemoSphere pressure cable is properly connected.
Pressure-out reset to zero during cautery.	A hardware problem occurs where the system detects a connection on a disconnected channel when exposed to EMI during cauterization.	Re-zero the pressure-out channel. Connecting unused channels to invasive pressure channels on the patient monitor can help alleviate problem.
StO <sub>2</sub> values are not displayed when patient weight is entered as 882 lbs.	A rounding error occurs in converting the upper limit of 400 kg to lbs.	Patient weight of 882 lbs exceeds the maximum weight allowed. Re-enter weight at 881 lbs.
When selecting a flank/abdomen tissue oximetry sensor location (right or left), the central abdomen is also highlighted in Physiology screen for StO <sub>2</sub> .	The software code checks for either an abdomen or a flank tissue oximetry sensor location selection and highlights the liver/intestine/stomach.	Monitor StO <sub>2</sub> as intended. There is no impact to monitoring.
The absolute regional hemoglobin oxygen saturation of blood under the sensors (StO <sub>2</sub> ) parameter value, which is displayed on multiple screens of the HemoSphere advanced monitoring platform, may freeze on the main area of the physiology screen. This partial screen freezing (shown below), with the parameter values circled in red. The same information is also provided in the tiles on the right side of the screen, (circled in green), which perform and update as intended.	Incorrect implementation of event handler for StO <sub>2</sub> tile refresh on the cerebral oximetry/cardiovascular Physiology screen resulting in displayed StO <sub>2</sub> parameters on this screen not updating.	<p>Edwards Lifesciences advises utilizing alternate key parameter tiles and physiology screens (pictured below) when monitoring StO<sub>2</sub> until a subsequent software update is made available to resolve this anomaly. These tiles/screens perform and update as intended. The HemoSphere monitor offers several monitoring screens; two of these screens offer similar functionality to the cerebral oximetry/cardiovascular physiology screen and are recommended as alternatives:</p> <ol style="list-style-type: none"> <li>1) Physiology full body tissue oximetry screen</li> <li>2) Physiology cerebral tissue oximetry screen</li> </ol>



Known anomaly	Cause	Suggested actions
StO <sub>2</sub> key parameter is not removed from key parameter tile and monitors with value when tissue oximetry feature is deactivated.	Parameters are set to their defaults if a parameter is configured but is not available due to a feature limitation. However, this reset only occurs on either the side tiles or the small tiles, but not both if one of these did not have one of the deactivated parameters. This results in the possibility of duplicate parameters being configured.	Power cycle the system.
StO <sub>2</sub> parameter values on left and right channels do not match (difference in value of 5 or more).	Software did not compensate for Tissue Optical Properties (TOP) appropriately.	Disconnect/reconnect the ForeSight tissue oximeter module from the HemoSphere tissue oximetry module.
The percent change mode appears on the graphical trend graph after key parameters touched immediately after screen swipe.	The two finger touch event is not correctly released on the graphical trends screen resulting in the incorrect processing of next touch event.	Reactivate percent change vertical bar flags if desired.
Waveform is cleared and plot line is drawn with the current settings (scale of new data is not properly updated).	The waveform frame didn't respond properly and therefore the waveform and scale were not updated when the scales changed.	Change to Auto Scale or Sweep Speed to clear the waveform and properly update the scale (change the Y-axis).
Graphical trend plot values shift inconsistently.	The initial graph is plotted based on a default height of 100 regardless of range of data. This refreshes after 15 seconds.	The graphical trend plot refreshes to correct display after 15 seconds. Values on parameter tiles are correct.
When unmerging two merged trends, the top trend graph displays incorrectly until next trend refresh.	While unmerging the trends, the configuration/trend sizing is computed with one of the trends heights still set as merged causing the trend line to be drawn as if the control was double its height.	No troubleshooting steps currently available or needed. The trend graph refreshes after 15 seconds. In addition, values on parameter globes are correct.
Unmerging of Trends removes the trend line on one of the graphical trend lines.	While unmerging the trends, the configuration/trend sizing is computed with one of the trends heights still set as merged causing the trend line to be drawn as if the control was double its height.	No troubleshooting steps currently available or needed. The trend graph refreshes after 15 seconds. In addition, values on parameter globes are correct.
During CCO monitoring, when attempting to run "Patient CCO Cable Test", selecting NO on confirmation window still displays "Patient CCO Cable Test".	The Patient CCO Cable Test screen was ignoring a NO response to the Stop Monitoring popup.	Manually exit screen with the back button.
Countdown timer on CCO Start/Stop button indicates an initial countdown of 3 minutes and 20 seconds.	Initial countdown timer value is hard coded to the normal cold start time value even in 'Warm Start' conditions.	Wait for the first 3:20 timer to expire. After the initial 3 minute and 20 second timer expires, timer will return to 57 seconds per CO value.
The number of bolus injectates in Set do not match with number of bolus injectates accepted in Review Screen.	When the user accepts the bolus set, the new bolus set rather than the finished set (displayed on the review screen) gets accepted. So, depending on the timing when the user presses the Accept button, the number of boluses in the set could be different.	Refresh the desired bolus review screen and review bolus set if necessary.
Start Set button appears enabled when "Check Thermistor Connection fault" is active.	The iCO-related disconnect states are not faults unless you are on an iCO screen. Therefore, the fault is set while on the screen and subsequently cleared when you navigate away. At the time of initial entry into the screen, there is no fault and therefore the Start Set button is enabled. Immediately following initial entry to screen the fault is activated, however the screen is not refreshed to de-activate the button.	Resolve thermistor fault condition to continue iCO bolus measurement.
Graph not showing in iCO review screen.	Sequence number and iCO data packet is not in sync when sent to HemoSphere host module.	No troubleshooting steps available. Graphs in iCO review screen are missing.
The small cockpit target indicator ring does not go gray if targets are disabled.	Status of target range enable indicator not being checked properly by the system.	Alarms will still be active for out-of-range parameter conditions. Address out-of-range parameter conditions as necessary.
Small cockpits are not fully initialized when navigating from main monitoring screen (graphical trends/cockpit split view).	The target indicator is only initialized when users navigate from a non-graphical trends screen to graphical trends screen with small cockpits. Going to another screen that uses graphical trends first would not initialize this component.	Begin monitoring and the small cockpit display will return to normal state with values.
Small cockpit key parameters are not displaying red indicators on the gauge when target ranges are disabled.	Indicator position is being calculated based on a 270-degree arc rather than a 180-degree arc.	Enable target ranges for cockpit key parameters
Cockpit and small cockpit key parameter target range colors are not displayed when target ranges are enabled.	There are hidden CVP, MAP or ECG faults. A hidden fault state occurs when CVP/MAP analog-in data sources are not configured or data is not available. SVR/SVRI are derived from CVP and MAP, and therefore SVR/SVRI will be faulted (grayed out).	Start/resume monitoring of faulted parameters.
HPI parameter small cockpit gauge is yellow when adjusting scales. This anomaly is not present in standard cockpit screen.	The lower and upper limits for white display ( $HPI \leq 85$ ) are not calculated in refresh method.	Small cockpit key HPI parameter will show as yellow when adjusting scales. Alarms for HPI parameter will function as expected.
When replacing HPI parameter with another parameter on the Cockpit monitoring display, the target range appears all red.	Refresh issue with cockpit display of parameter targets.	Touch any button/icon to refresh the screen
Selecting dP/dt trend graph in HPI secondary screen mimics the previously chosen key parameter trend graph.	Software bug in internal Windows framework.	Only use HPI parameters when a valid Acumen IQ sensor is connected.

Known anomaly	Cause	Suggested actions
SVR parameter value is still shown in HPI secondary screen when CVP pressure sensor is disconnected.	HPI secondary screen does not handle the "Parameter Stale" state condition.	Configure SVR as key parameter and configure alarm ranges to ensure proper use of SVR.
User able to navigate away from a fluid responsiveness test (FRT) via Focused Charting Screen.	There is a missing check before displaying parameter settings frame on Focused Charting Screen.	Restart the fluid responsiveness test.
GDT Screen Redrawing on Update Cycle.	Start time of graph on GDT screen has potential to not be calculated according to the time scale when trend time scale is greater than the monitoring time of more than 24 hrs.	Set autoscale to "Disabled."
Small key parameters screen during GDT session allows the user to drag and replace the GDT key parameters with the small key parameters.	The small key parameters are incorrectly shown in GDT mode.	Exit the GDT session and update small key parameters if necessary. Use Graphical Trend screen (without small key parameters) when using GDT session.
GDT session cannot be paused if a parameter target has not been assigned.	A GDT session can be activated when a parameter is configured without a target. However, the system will wait for the user to set the target through the target control or by opening up the GDT session settings screen.	Set parameter target value prior to starting a GDT session.
Only backward scroll is available through GDT Historical Session.	Software compares the viewed GDT session start time to the current trend end time instead of the end time of the viewed GDT session.	Refresh viewing of GDT historical sessions and navigate backwards to desired session.
While on goal directed therapy (GDT) feature screen, units and alarm bell are cut off and not legible on parameter tiles when viewing live blood pressure waveform.	The vertical dimension of the waveform graph on GDT screen is too large for allotted space. Issue occurs only if the following conditions are met: 1. Active monitoring with 3 key parameters configured in Graphical Trend Screen ; 2. Alarm is triggered; 3. Silence Alarm; and 4. Start to GDT Session with one key parameter.	Close/hide the live blood pressure waveform and re-display it.
Alarm silence indicator overlaps (is obstructed) with target status indicator color (border) on key parameter tile.	The alarm icon location does not adjust itself accordingly based on tile control height and results in a partially obstructed alarm silence icon when the border is thick.	The red border indicates that the parameter value is out of range. The user will have a partial view of the bell icon indicating that the parameter has been silenced. The monitor provides visual alarm feedback with flashing LEDs to inform the user of any physiological alarms.
While in Demo Mode, the following anomalies have been observed:  1) Simulated patient data for HPI parameter is not read sequentially 2) Minimally-invasive mode incorrectly calls MAP or CVP parameter data from Analog Input 3) Minimally-Invasive mode can be initiated despite FloTrac feature being disabled. 4) TruWave/ART sensors are intermittently sending CO/SV parameters. 5) While in Demo Mode, DEMO banner is not displayed on 'New Patient Data' and 'Monitoring Mode Selection' screens.	These anomalies while in Demo Mode are caused by the following:  1) HPI data read from demo data file may skip entries. 2) The update mechanism for Analog-Input MAP or CVP parameter is always called, regardless of monitoring mode. 3) Disabling FloTrac algorithm during Demo Mode is not implemented in the system. 4) HemoSphere pressure cable is incorrectly sending data for CO/SV/SVV parameters when the connected sensor is a TruWave sensor. 5) Current specifications do not allow new patient creation in Demo Mode. Additionally, specifications of the New Patient Data screen do not allow for banner display.	No troubleshooting steps currently available or needed. These anomalies only occur in Demo Mode. As advised in section 7.4 of operator's manual, do not run demonstration mode in a clinical setting where simulated data can be mistaken for clinical data.
The Event Review logs channel B sensor locations when configuring channel, A as a key parameter on the monitor.	An unconnected ForeSight Elite module sensor location is indicated as "Unspecified", which does not match the selected location on-screen.	Ensure that displayed parameters match appropriate A/B channels for which the ForeSight module cable is connected to.
"CO Monitoring Stopped" event is logged in the Event Review Screen when TruWave PAP, AP, or CVP algorithms are stopped.	The log manager doesn't check algorithm type being started/stopped and logs inconsistently.	Note that inaccurate monitoring type information may be issued in event review when halting pressure monitoring. Review CO monitoring data, and if needed, enter in custom event to indicate the type (not CO) of monitoring that has started/stopped.
HR analog and MPAP values not auto populated on Derived Value Calculator screen.	The flag for MPAP was set to 'False' and therefore no signal is there to auto-populate that field.	Manually enter values on the Derived Value Calculator screen.
DO <sub>2</sub> calculation only used two parameters to display a value on the Historic Physio-Relationship screen.	When reversing the order of HGB and SaO <sub>2</sub> entry in historic set the CO value should and does not become faulted for purposes of calculating DO <sub>2</sub> .	Only use Physio-Relationship Screen DO <sub>2</sub> calculation during active monitoring of CO. Alternatively, Derived Value Calculator can be used.
Event Review screen does not display "Unspecified" when "Unspecified" is selected for following Intervention Events: Inotrope, Vasodilator, Vasopressor, Red Blood Cells, Colloid, Crystalloid, Passive Leg Raise, and Trendelenburg.	Current code does not include "Unspecified" in the Event text for following Intervention Events: Inotrope, Vasodilator, Vasopressor, Red Blood Cells, Colloid, Crystalloid, Passive Leg Raise, Trendelenburg.	No troubleshooting steps currently available or needed. When "Unspecified" is selected, event review text does not specify that intervention is "Unspecified".
Data Download .xls file does not open and Excel application returns a message of a problem occurring when loading the file.	Multiple "<" (less than) operators in GDT session causes the open and close node tags in Excel to form improperly.	No troubleshooting steps currently available. Occurs if using Goal Directed Therapy (GDT) feature. This is a post processing feature and does not affect Goal Directed Therapy (GDT) monitoring.
Software version not included in data download excel spreadsheet.	The update script was only run once before device info response was received by module manager.	Software Version is retrievable from the Versions screen in Advanced Settings.
Case report parameter selection screen shows tissue oximetry parameters when tissue oximetry feature is not activated.	Case report screen does not check if tissue oximetry feature is enabled and assumes it is activated.	No troubleshooting steps necessary. Tissue oximetry parameters will show on case report even when the feature is disabled.

Known anomaly	Cause	Suggested actions
HemoSphere Swan-Ganz module case report graph displays intermittent data trends.	20 second data point interval was selected for the report and the HemoSphere Swan-Ganz module update rate is 57 seconds.	No troubleshooting steps available or necessary. All available data is displayed. 20 second intervals are available from other technologies and therefore this is an option when exporting case reports. 20 second intervals are not available while monitoring with the HemoSphere Swan-Ganz module. The user will see extra empty data points if 20 second data point intervals are selected.
Zeroing ART blood pressure waveform after leaving the Historical Physio Relationship Screen causes a software crash that halts monitoring.	The anomaly is caused by a race condition. On occasions, the status of the pressure cable is referenced from another thread before it is fully initialized. Issue only occurs while monitoring in HemoSphere Swan-Ganz module mode/ technology with an active fault (FloTrac sensor connected) and then switching to minimally-invasive monitoring mode.	Power cycle the monitor.
Invalid HGB value when system attempts to recall an oximetry calibration causes system crash.	The code is calculating the HGB value by parsing the displayed value. If the displayed value is '---', an exception is thrown, resulting in error.	Monitor does not allow an invalid HGB value to be used for oximetry calibration. Power cycle the monitor if fatal system error (gold screen) appears.
A fatal system error occurs when the washout curve button is toggled on the iCO Bolus Review screen.	When the user accepts the bolus set, the new bolus set rather than the finished set (displayed on the review screen) gets accepted. So, depending on the timing when the user presses the Accept button, the number of boluses in the set could be different.	Reboot monitor if fatal system error (gold screen) appears. iCO bolus session works as intended.
Fatal system error when configuring Analog-Input ports.	A patient demographics value was being updated before actual patient demographics existed. Note: This anomaly only occurs when the monitor was turned off for at least two minutes while on the "Continue/Last Patient Data Screen and then an analog signal configuration is attempted through the Advanced Setup screen prior to resuming patient monitoring.	Power cycle the monitor.
The HemoSphere software can become non-responsive and generate a fatal system error when switching between parameters while Audible Alarms are disabled.	Software becomes locked up when quickly switching back-and-forth between parameters.	Power cycle the monitor.
Fatal system error occurred with "Fatal Exception Occurred" message for unknown reason.	The issue was caused by internal software race condition under rare occasions.	Power cycle the monitor if a fatal system error gold-screen is observed. If problem persists, contact Edwards technical support.
Fatal system error occurs when touching Reference Value button on Intervals/Averaging window for $E_{a_{dyn}}$ parameter.	$E_{a_{dyn}}$ does not have target assigned to it.	Power cycle the monitor if a fatal system error gold-screen is observed. If problem persists, contact Edwards technical support. Refrain from use of reference value for $E_{a_{dyn}}$ .
Frozen screen during shutdown.	A MicroSoft Windows issue. The internal Windows framework touch input processing engine stopped processing routed touch events.	Power cycle the monitor with a hard power off.
IFMout token y132250 (PPV), y132270 and y132271 (dP/dt alarm) is not included in packets sent out from the serial port.	PPV alarm y132251, y132270 and y132271 tokens are not included in the IFMout packet for EV1000 Compatibility mode.	No troubleshooting steps available. This anomaly is remote to IFMout.
IFMout blood temperature Token are not sent when the units are in Fahrenheit.	Missing code to handle the case to always send Blood Temperature in Celsius even when the selected Temperature unit is Fahrenheit.	Change units to Celsius.
Incorrect tokens for Tissue Oximetry sensor location.	The mapping values used to communicate with ForeSight Elite tissue oximeter module don't match with IFMout protocol specification ELS1291/AA.	No troubleshooting steps necessary as this anomaly is remote to IFMout. If needed, manually record any sensor location changes when using IFMout.
IFMout tokens are not transmitted.	Tokens were missing from EV1000 compatibility mode.	Primary parameters and parameter fault conditions are being transmitted as expected. If needed, manually record events where tokens are not being received.
IFMout token Y20xxx for Pulse Rate is being displayed twice.	Incorrect implementation of Y20xxx causing duplicate Y20xxx token	Note that an additional pulse rate entry will be received by connected device. Review HemoSphere advanced monitor screen for accurate information.
The Next button on New Patient Data screen is enabled despite blank patient demographics fields when changing language.	Navigate buttons are not refreshed in New Patient Data Screen when language changed.	Restart a new patient session.
After restoring factory defaults, changing settings disables the "New Patient" button and patient data is missing when continuing current patient.	When the Language entry is changed on General Monitor Settings screen, the signal to refresh the New/Continue Patient screen for that language is not recognized.	Power cycle the monitor.
After restoring to factory default, the language selection screen does not appear.	Restore defaults method may not be called on hard system reset.	Navigate to the General Settings screen to set the Language.
SvO <sub>2</sub> /ScvO <sub>2</sub> values are blank while oximetry faults are displayed.	The faults under consideration would be cleared when the user navigated to Focused Charting screen or to monitoring with no S02 parameter configured/visible.	Use graphical trend of parameter to see last known value.


Known anomaly	Cause	Suggested actions
"Fault: Oximetry Cable Memory" is not generated when 'Initialize Result' is set to 'Memory Fail'.	Fault had incorrect dependency on 'is calibrated' condition. System goes to safe state and monitoring will not be allowed until cable is calibrated.	Disconnect and reconnect cable.
Patient Query Screen skipped to display Technology Selection screen.	Cause unknown.	Power cycle the monitor and select new patient.
Fatal system error occurs when verifying values do not transmit to HL7.	Unable to reproduce anomaly.	No troubleshooting steps currently available.
EDV, RVEF, EDVI parameters not displaying.	Unable to reproduce anomaly.	No troubleshooting steps currently available.
System froze after downloading diagnostic logs.	Unable to reproduce anomaly.	Power cycle the monitor.
"Fault: Pressure Sensor Disconnected" is momentarily displayed (less than 0.5 seconds) as pressure source is switched and zeroed.	Unable to reproduce anomaly. This may occur when a second pressure cable is connected with no sensor attached.	No troubleshooting steps currently available or needed.
System freezes and then fatal system error occurs after quickly connecting/disconnecting HemoSphere pressure cable multiple times. "Application is unresponsive, please restart panel." is displayed on screen.	Unable to reproduce anomaly.	Power cycle the monitor.
System Settings file corrupted and fatal system error occurs on startup after a hard power cycle while monitoring or after a software upgrade performed.	When the system date changed 90 days ahead a new master key (used to encrypt system settings file and its backup) is generated and used to encrypt the system settings file. During a hard shutdown, the new master key is lost resulting in an un-decryptable system settings file. During subsequent power-on, or during a software upgrade, the system attempts to read/decrypt the system settings file but it fails and shows a fatal system error.	Power cycle the monitor. This anomaly only occurs if a hard shut down was performed.
Diagnostic Log screen displays successful export when USB is ejected early.	The necessary script is not called when the USB is unplugged during the export.	Redo diagnostic log export if USB is removed before notified that export is complete.
Fatal exception occurs on start up when certain USB drives are connected.	The USB drive involved has unusual registry behavior and doesn't appear when searching for it.	Power cycle the monitor if a fatal system error gold-screen is observed. If problem persists, contact Edwards technical support.
Wireless Connection - WiFi SSID name truncation and unable to connect to router.	The software uses the Linux command line to communicate with the wireless module which utilizes specific characters. User will be unable to connect to the router when using spaces and special character in SSID name.	Use an SSID that does not contain spaces or any of the special Linux command line characters.
'Fault: Wireless Module Fault' occurs unexpectedly.	Unable to reproduce anomaly. The HemoSphere software code lost communication with the wireless module and was unable to connect as the IP address 192.168.3.1 no longer exists.	Power cycle the monitor.
During software upgrade failure, WiFi password changed back to default.	HemoSphere monitor software cannot communicate with the wireless module after telling it to reboot. Only occurs during update.	Contact customer support if using WiFi with the monitor. Disable WiFi if not using the feature to use the monitor.
WiFi module becomes unusable after multiple reboots of the monitor.	The build where this original issue is found is repeatedly inserting a duplicate IPTABLES entry into the wifi-nat.conf firewall rules when it tries to apply cyber security.	Use an Ethernet connection.
Wireless connection issue after FIPS is Enabled then Disabled.	The control to enable/disable FIPS was enabled when wireless was disabled.	Allow WiFi to connect prior to changing FIPS enable/disable state.
Wireless connection does not automatically connect when disconnecting from another connection.	The Wireless module is configured to automatically connect to a known access point, but sometimes fails to do so.	Manually connect to wireless connection.
Monitoring pause confirmation popup displayed when Monitor is already in Monitoring Pause Mode.	HemoSphere allows request to enter the pause mode when it's already in the pause mode.	Confirm action on popup to remain in Monitoring Pause mode.
High CPU usage, monitor becomes unresponsive when graphical trends is displayed after performing fluid bolus tests. Note: The monitor becomes unresponsive to touch only.	The slow-down is caused by a large number of Intervention markers (approximately 10). When the user attempts to create more than 10 intervention markers, the graphical trends frame might become gradually less responsive.	Create a new patient to enable a fully responsive graphical trends frame screen.
Beat-to-beat heart rate (HR) is incorrectly displayed on the information bar where xxx.x is displayed instead of xxx (where xxx is the HR beat-to-beat value).	The beat-to-beat HR measurement type and units were not defined.	No troubleshooting steps currently available or needed. The displayed value is correct.
Screen stays locks up when monitor shutdown is not confirmed.	The system requires user input touch on New Patient or Continue Patient button if the New/Continue Patient screen is present. Issue occurs when the screen was previously locked, the system was powered down for more than 2 minutes, the power button was pushed but Shutdown was not confirmed. The screen will remain locked for the duration of the lock preventing a new patient from being created.	Wait for the timer to finish, or power cycle the monitor.
Screen remains locked after screen Lock timer has expired.	No code was found tracking lock time and reset accordingly when the monitor is powered down.	User must wait for the timer to finish.
Monitor does not complete decommissioning process.	This is a component issue. Newer models are not supporting the quick-erase feature.	Maintain control of Monitor following decommissioning and ship directly to an Edwards service center following decommission.

Known anomaly	Cause	Suggested actions
User is unable use the screen capture feature (snapshot) when Date or Time Adjust popup is shown despite the snapshot icon (camera) appearing enabled.	The popup frame was covering toolbar.	Screen snapshot will be re-enabled when exiting the Date or Time Adjust popups.
Patient Query results with HL7 active does not time out after 2 minutes.	The 2-minute timeout timer was not activated for that screen.	Manually select a patient to exit the Patient Query Results screen.
No prompt for "New Patient" screen.	The logic for checking whether to display technology selection screen did not also consider if current patient data was stale (older than 12 hours).	Navigate to Patient Data screen through clinical tools and create new patient.
Navigating to the analog input screen and back to physiology/physio relationship screens causes the CVP target indicator to disappear.	When the Home or Back button is touched, even if no changes were made on the analog input screen, the port settings are updated anyway, causing a reset in analog input values (MAP/CVP).	Values and Target indicator for parameters return after a 20-second update cycle.



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