Edwards Lifesciences

EV1000 Clinical Platform NI

Operator's Manual

Edwards

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Because of continuing product improvement, prices and specifications are subject to change without notice. Changes to this manual, either in response to user input or to continuing product improvements, are accomplished through reissue. If, in the normal use of this manual, errors, omissions, or incorrect data are noted, please contact Edwards Technical Support or your local Edwards representative.

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Using This Manual

The Edwards Lifesciences EV1000 Clinical Platform NI Operator's Manual is comprised of 14 chapters, seven Appendices and an Index. Figures in this manual are intended for reference only and may not be an exact replication of the screens as a result of continuous software improvements.

Chapter	Description
1	***EV1000 Clinical Platform NI Overview***: Provides an overview of the EV1000 Clinical Platform NI.
2	***Safety and Symbols***: Includes WARNINGS, CAUTIONS, and NOTES that are found in the manual, as well as illustrations of labels found on the Monitor and Pump-Unit surfaces.
3	***Unpacking and Initial Setup***: Provides information about setting up the EV1000 Clinical Platform NI and cables as well as information for initial startup of the system.
4	***EV1000 Clinical Platform NI Quick Start***: Provides experienced clinicians and users of bedside patient monitors instructions for immediate monitor use.
5	***Navigating the EV1000 Clinical Platform NI***: Provides information on how to use the touch screen and monitoring cables.
6	***Monitor Display Options***: Provides information about the various monitor display settings including patient information, language and international units, alarm volume, system time, and system date. It also provides instructions for selecting the monitor screen appearance.
7	***Methodology and Monitoring***: Describes the methodology behind ClearSight technology and gives instructions for setup and application of patient monitoring equipment as well as how to measure cardiac output, stroke volume, stroke volume variation, and systemic vascular resistance.
8	***Physiology and Physio Relationship Monitoring Screens:*** The Physiology screen and Physio Relationship monitoring screens provide a graphic display of monitored parameters and their relationship to each other.
9	***Enhanced Parameter Tracking:*** The EV1000 Clinical Platform NI provides tools to aid in Goal Directed Therapy.
10	***Clinical Actions and Analysis***: Describes information about using the EV1000 Clinical Platform NI to compute derived parameters, perform event reviews and other advanced options.
11	***Demonstration Mode and Data Download:*** Describes how to use the EV1000 Clinical Platform NI for training and demonstration and how to download monitored data to a USB drive.
12	***Help and Troubleshooting***: Describes how to use the help menu and lists faults and alerts.
13	***EV1000 Clinical Platform NI Accessories:*** Describes accessories available for use with the EV1000 Clinical Platform.
14	***EV1000 Clinical Platform NI Advanced Features:*** Describes additional features available.

Appendix	Description
A	***Specifications***
B	***Equations for Calculated Patient Parameters***
C	***Monitor Settings and Defaults***
D	***EV1000 Unit Conversions***
E	***System Care, Service and Support***
F	***Guidance and Manufacturer's Declaration***
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Chapter 1: EV1000 Clinical Platform NI Overview

The EV1000 Clinical Platform NI monitors key hemodynamic parameters derived from continuous noninvasive measurement of the arterial pressure waveform. The EV1000 Clinical Platform NI assists the clinician in assessing the patient's physiologic status and supports clinical decisions related to hemodynamic optimization.

> **CAUTION**
> Federal (USA) law restricts this device to sale by or on the order of a physician.

ClearSight™ Technology Noninvasive Arterial Pressure and Cardiac Output Monitoring

The EV1000 Clinical Platform NI consists of the EV1000 Monitor in conjunction with the EV1000 Noninvasive System, which is comprised of the EV1000 Pump-Unit (PMP), Pressure Controller (PC2), Heart Reference Sensor (HRS) and ClearSight Finger Cuff. The ClearSight Finger Cuff has a built in plethysmograph sensor to noninvasively measure the continuous finger arterial blood pressure using Volume Clamp and Physiocal™ methods. The brachial arterial pressure waveform is then reconstructed from the measured finger blood pressure pulsations to monitor Systolic (SYS), Diastolic (DIA) and Mean Arterial (MAP) pressures. Hemodynamic parameters, Cardiac Output (CO), Cardiac Index (CI), Stroke Volume (SV), Stroke Volume Index (SVI), Stroke Volume Variation (SVV), and Pulse Rate (PR) are calculated using a novel pulse contour method (ClearSight Algorithm). Systemic Vascular Resistance (SVR) and Systemic Vascular Resistance Index (SVRI) can also be calculated after the user manually inputs a CVP value. In addition, the Heart Reference Sensor is used to compensate for hydrostatic pressure differences due to changes in height of the finger relative to the heart, with one end placed at the level of the patient's finger and the other at heart level.

Monitored Parameters

The following hemodynamic parameters can be measured noninvasively, using ClearSight technology, and displayed on the EV1000 Monitor.

Table 1-1 EV1000 Clinical Platform NI Parameters

Parameter	Description
Cardiac Output (CO)	Continuous measurement of the volume of blood pumped by the heart measured in liters per minute
Cardiac Index (CI)	Cardiac output relative to body surface area (BSA)
Diastolic Pressure (DIA)	Diastolic blood pressure
Mean Arterial Pressure (MAP)	Averaged systemic blood pressure over one cardiac cycle
Pulse Rate (PR)	Number of arterial blood pressure pulses per minute
Stroke Volume (SV)	Volume of blood pumped with each heart beat
Stroke Volume Index (SVI)	Stroke volume relative to body surface area (BSA)
Systemic Vascular Resistance (SVR)	The resistance that the left ventricle must overcome to eject stroke volume with each beat
Systemic Vascular Resistance Index (SVRI)	SVR relative to body surface area
Stroke Volume Variation (SVV)	The percent difference between SVmin, max and mean
Systolic Pressure (SYS)	Systolic blood pressure

Indications for Use

Intended Medical Indication. The EV1000 Clinical Platform NI and ClearSight™ Finger Cuffs are indicated for patients over 18 years of age in which the balance between cardiac function, fluid status and vascular resistance needs continuous assessment. In addition, the noninvasive system is indicated for use in patients with co-morbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The EV1000 Clinical Platform NI and ClearSight™ finger cuffs noninvasively measures blood pressure and associated hemodynamic parameters.

User Profile(s). The EV1000 Clinical Platform NI is intended for use by trained clinicians in a hospital setting.

Intended Conditions of Use. The system is intended for use in the hospital environment or other appropriate clinical setting.

Contraindications. In some patients with extreme contraction of the smooth muscle in the arteries and arterioles in the lower arm and hand, such as may be present in patients with Raynaud's disease, blood pressure measurement can become impossible.

WARNING
The EV1000 Clinical Platform NI is intended for use only as an adjunct in patient assessment. This instrument should be used in conjunction with a bedside physiologic monitor. If the accuracy of any reading is questionable, first check the patient's vital signs by alternate means.

WARNING
Read this Manual carefully before attempting to use the Edwards Lifesciences EV1000 Clinical Platform NI. Improper use of the EV1000 Clinical Platform NI could present a hazard to the patient. Carefully read the "Warnings" section of this manual before using the platform.

WARNING
Use of the EV1000 Clinical Platform NI is restricted to one patient at a time.

Edwards EV1000 Clinical Platform NI Operator's Manual

The EV1000 Clinical Platform NI Operator's Manual is intended for use with the Edwards Lifesciences EV1000 Clinical Platform NI by trained clinicians in a hospital setting. This manual provides the operator with setup and operating instructions. It also provides instructions for user configurations and describes the operational environment in which the EV1000 Clinical Platform NI can be installed. This includes connections and communications to devices and monitors within that environment.

Acronyms and Abbreviations

The following acronyms and abbreviations are used in this manual.

Table 1-2 Acronyms and Abbreviations

Abbreviation	Definition
A/D	Analog/Digital
AP	Arterial Pressure
ART	Brachial Arterial Waveform
BP	Blood Pressure
BSA	Body Surface Area
CI	Cardiac Index
CO	Cardiac Output
CPO	Cardiac Power Output
CPI	Cardiac Power Index
CVP	Central Venous Pressure
DO_2	Oxygen Delivery
DO_2I	Oxygen Delivery Index
DIA	Diastolic Pressure
EV1000 NI	EV1000 Clinical Platform NI
GDT	Goal Directed Therapy
HIS	Hospital Information Systems
HGB	Hemoglobin
HRS	Heart Reference Sensor
MAP	Mean Arterial Pressure
PaO_2	Partial pressure of arterial oxygen
PC2	Pressure Controller
PM	Bedside Patient Monitor
PMP	Pump-Unit
PR	Pulse Rate
$ScvO_2$	Central venous oxygen saturation
SpO_2	Peripheral arterial oxygen saturation
SV	Stroke Volume
SVI	Stroke Volume Index
SvO_2	Mixed Venous Oxygen Saturation
SVR	Systemic Vascular Resistance
SVRI	Systemic Vascular Resistance Index
SVV	Stroke Volume Variation
SYS	Systolic Pressure
Touch	Interact with the EV1000 system by touching the monitor screen.
USB	Universal Serial Bus
VO_2e	Estimated oxygen consumption

Chapter 2: Safety and Symbols

This chapter describes the symbols that appear in the manual or on product labels, including those used to identify warnings, cautions, and notes. A list of all warnings and cautions used in this manual is provided in this chapter.

This chapter also includes a list of relevant standards to which the EV1000 Clinical Platform NI complies.

Safety Identifying Symbols

The terms warnings, cautions, and notes are graphically identified and have specific meanings as used in this manual.

WARNING
Advises against certain actions or situations that could result in personal injury or death.

CAUTION
Advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

* *This is a note. It draws attention to useful information regarding a function or procedure.*

Warnings

The following warnings are presented in the EV1000 Clinical Platform NI Operator's Manual where relevant to the function or procedure being described.

WARNING
The EV1000 Clinical Platform NI is intended for use only as an adjunct in patient assessment. This instrument should be used in conjunction with a bedside physiologic monitor. If the accuracy of any reading is questionable, first check the patient's vital signs by alternate means.
(Chapter 1)

WARNING
Read this Manual carefully before attempting to use the Edwards Lifesciences EV1000 Clinical Platform NI. Improper use of the EV1000 Clinical Platform NI could present a hazard to the patient. Carefully read the "Warnings" section of this manual before using the platform.
(Chapter 1)

WARNING
Use of the EV1000 Clinical Platform NI is restricted to one patient at a time.
(Chapter 1)

WARNING
No modification of the EV1000 Clinical Platform NI is allowed.
(Chapter 3, Appendix F)

WARNING
Explosion Hazard! Do not use the EV1000 Clinical Platform NI in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
(Chapter 3)

WARNING
To avoid the risk of electric shock, the Pump-Unit must only be connected to a supply mains with protective earth.
(Chapter 3)

WARNING
Grounding reliability can only be achieved in Canada and in the USA when the instrument is connected to a receptacle marked "hospital only", "hospital grade", or its equivalent.
(Chapter 3)

WARNING
In the USA the instrument shall be connected only to a single phase 110-120V supply system.
(Chapter 3)

WARNING
Do not use extension cords or multiple socket devices to connect the Pump-Unit to AC mains. Do not use detachable power cords other than the power cord provided.
(Chapter 3)

WARNING
For noninvasive monitoring, the EV1000 Monitor must be powered by the Pump-unit using the EV1000 NI Power Cable.
(Chapter 3)

WARNING
Shock hazard: Do not attempt to connect/disconnect system cables while hands are wet. Ensure that hands are dry prior to disconnecting system cables.
(Chapter 3)

WARNING
Only use ClearSight Finger Cuffs, EV1000 Heart NI Reference Sensor and other EV1000 Noninvasive System accessories, cables and or components that have been supplied and labeled by Edwards. Using other unlabeled accessories, cables and or components may affect patient safety and measurement accuracy.
(Chapter 3,7,13, Appendix A)

WARNING
Use of accessories, sensors, and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity.
(Chapter 3, Appendix F)

WARNING
The EV1000 Clinical Platform NI meets the requirements of IEC 60601-1:2005 for the system configurations described in this manual. Connecting external equipment or configuring the system in a way not described in this manual may not meet this standard.
(Chapter 3, 14)

WARNING
Do not use the Ethernet cable to connect anything to the Pump-Unit other than the Monitor.
(Chapter 3)

WARNING
All non Edwards IEC/EN 60950 equipment, including printers, must be positioned no closer than 1.5 meters to the patient's bed, the operating table and persons touching the patient.
(Chapter 3)

WARNING
Do not obstruct the EV1000 Clinical Platform NI ventilation openings.
(Chapter 3)

WARNING
Make sure the EV1000 Clinical Platform NI is securely mounted, and that all cords and accessory cables are appropriately arranged to minimize the risk of injury to patients, users or the equipment. Refer to directions on proper setup.
(Chapter 3,13)

WARNING
The Monitor must be positioned in an upright position to ensure IPX1 fluid ingress protection.
(Chapter 3)

WARNING
The Pump-Unit must be positioned in an upright position to ensure IP4X ingress protection.
(Chapter 3,13)

WARNING
Do not position the Pump-Unit so that it is difficult to disconnect the mains power cord.
(Chapter 3)

WARNING
Components that are not indicated as APPLIED PARTS should not be placed in as location where the patient may come into contact with the component.
(Chapter 4,7)

WARNING
Do not apply ClearSight Finger Cuff(s) on a hand/finger when external constriction (that may prevent circulation to the hand/finger) is present.
(Chapter 4)

WARNING
Physiological visual and audible physiological alarms are activated only if the parameter is selected and displayed on the screens as a key parameter (1-4 parameters). If a parameter is not selected and displayed as a key parameter, the audible physiological alarms are silenced.
(Chapter 4,6,7,8)

WARNING
Make sure that **Demo Mode** is not activated in a clinical setting to ensure that simulated data is not mistaken for clinical data.
(Chapter 4, 11)

WARNING
Perform **New Patient** or clear the patient data profile whenever a new patient is connected to the EV1000 Clinical Platform NI. Failure to do so may result in previous patient data in the historical displays.
(Chapter 6)

WARNING
Do not turn off the audible physiological alarms in situations in which patient safety could be compromised.
(Chapter 6)

WARNING
Make sure that the alarm volume is set to a level that allows alarms to be adequately monitored. Failure to do so could result in a situation where patient safety is compromised.
(Chapter 6)

WARNING
Do not sterilize any components of the EV1000 Noninvasive System. The EV1000 Noninvasive System is provided non sterile.
(Chapter 7)

WARNING
Refer to cleaning instructions. Do not disinfect the instrument by autoclave or gas sterilization.
(Chapter 7, Appendix E)

WARNING
Refer to the directions provided with each accessory for specific instructions on placement and use, and for relevant WARNINGS, CAUTIONS, and specifications.
(Chapter 7)

WARNING
Do not use damaged components/sensors or components/sensors with exposed electrical contacts to prevent patient or user shocks.
(Chapter 7, Appendix E)

WARNING
The EV1000 Noninvasive System monitoring components are not defibrillation proof. Disconnect the system before defibrillating.
(Chapter 7)

WARNING
Do not touch system connectors of the EV1000 Clinical Platform NI and the patient at the same time.
(Chapter 7)

WARNING
Always remove EV1000 Noninvasive System sensors and components from the patient and completely disconnect the patient from the instrument before bathing the patient.
(Chapter 7)

WARNING
Do not overtighten the Pressure Controller Band or ClearSight Finger Cuff(s).
(Chapter 7)

WARNING
Do not apply the ClearSight Finger Cuff or Pressure Controller on injured skin as this can cause further injury.
(Chapter 7)

WARNING
Measurement on one finger in contradiction with the instructions for use may affect patient comfort and/or lead to minor injuries.
(Chapter 7)

WARNING
To reduce the risk of skin irritation and tissue damage, do not monitor longer than 8 hours continuously on a single finger. To continue to monitor, apply the ClearSight Finger Cuff to another finger or use two cuffs to measure more than 8 hours.
(Chapter 7)

WARNING
Do not use two ClearSight Finger Cuffs simultaneously on the same finger.
(Chapter 7)

WARNING
If using the instrument during full body irradiation, keep all EV1000 Noninvasive System monitoring components out of the irradiation field. If a monitoring component is exposed to the irradiation, the readings may be affected.
(Chapter 7)

WARNING
Strong magnetic fields may cause malfunction of the instrument and burn wounds to the patient. Do not use the instrument during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.The device may affect the MR image, and the MRI unit may affect the accuracy of the measurements.
(Chapter 7)

WARNING
Do not use the EV1000 Clinical Platform NI as a heart rate monitor.
(Chapter 7)

WARNING
The analog output signal from the EV1000 Clinical Platform NI will experience brief interruptions due to Physiocal which will be displayed on the bedside patient monitor.
(Chapter 7)

WARNING
Make sure that **Demo Mode** is not activated in a clinical setting to ensure that simulated data is not mistaken for clinical data.
(Chapter 11)

WARNING
EV1000 Databox and EV1000 Monitor power must be supplied through the same Pump-Unit when using integrated noninvasive and minimally invasive technologies for patient monitoring.
(Chapter 14)

WARNING
The EV1000 Clinical Platform NI, cables and sensors contain no user-serviceable parts. Removing the cover or any other disassembly will expose you to hazardous voltages.
(Appendix E)

WARNING
Shock or fire hazard! Do not immerse the EV1000 Monitor, Pump-Unit, Pressure Controller or Cables in any liquid solution. Do not allow any fluids to enter the instrument.
(Appendix E)

WARNING
DO NOT:

- Allow any liquid to come in contact with the power connector
- Allow any liquid to penetrate connectors or openings in the case

If any liquid does come in contact with any of the above mentioned items, DO NOT attempt to operate the platform. Disconnect power immediately and call your Biomedical Department or local Edwards Representative.
(Appendix E)

WARNING
The EV1000 Clinical Platform NI should not be used adjacent to, or stacked with other equipment. If adjacent or stacked use is necessary, the EV1000 Monitor, Databox and Pump-Unit should be observed to verify normal operation in the configuration in which it is used.
(Appendix F)

WARNING
Portable and mobile RF communication equipment can potentially affect all electronic medical equipment, including the EV1000.
Guidance on maintaining appropriate separation between communications equipment and the EV1000 is provided in Table F-3.
(Appendix F)

Cautions

The following cautions are presented in the Edwards EV1000 Clinical Platform NI Operator's Manual where relevant to the function or procedure being described.

CAUTION
Federal (USA) law restricts this device to sale by or on the order of a physician.
(Chapter 1)

CAUTION
Do not use any damaged system components. Use of a damaged system component may result in inaccurate measurements or may damage the EV1000 Clinical Platform NI.
(Chapter 3, Appendix E)

CAUTION
Do not expose the EV1000 Clinical Platform NI to extreme temperatures.
(Chapter 3)

CAUTION
Do not expose the EV1000 Clinical Platform NI to dirty or dusty environments.
(Chapter 3)

CAUTION
Do not apply strong shock to or drop the instrument.
(Chapter 3)

CAUTION
Clean and store the instrument and accessories after each use.
(Chapter 3, Appendix E)

CAUTION
When moving the instrument, be sure to turn off the power and remove the connected power cord.
(Chapter 3)

CAUTION
The EV1000 Monitor should only be connected to a single Pump-Unit and/or single Databox.
(Chapter 3)

CAUTION
When connecting the EV1000 Clinical Platform NI to any external device, refer to the device's instruction manual for complete instructions. Verify proper operation of the system before clinical use.
(Chapter 3)

CAUTION
Do not use the EV1000 Monitor in environments where strong lighting makes the LCD screen difficult to view.
(Chapter 3)

CAUTION
Do not use the Monitor as a handheld device.
(Chapter 3)

CAUTION
Improper ClearSight Finger Cuff placement or sizing can lead to inaccurate monitoring.
(Chapter 4,7)

CAUTION
Make sure that the HRS is correctly applied so that it can be leveled to the phlebostatic axis.
(Chapter 4,7)

CAUTION
Pump-Unit includes a Lithium-Ion battery backup.
(Chapter 5)

CAUTION
The system power status information, including battery information, is only displayed on EV1000 Monitor when the Pump-Unit is connected to the EV1000 Monitor with the supplied Ethernet cable.
(Chapter 5,14)

CAUTION
Restore Defaults replaces all settings with factory defaults. Any settings changes or customizations will be permanently lost. Do not restore defaults while monitoring a patient.
(Chapter 6)

CAUTION
The effectiveness of EV1000 Noninvasive System has not been evaluated in patients under 18 years of age.
(Chapter 7)

CAUTION
Always grasp the connector, not the cable, when connecting or disconnecting cables. Do not twist or bend the connectors. Confirm that all sensors and cables are connected correctly and completely before use.
(Chapter 7)

CAUTION
Never bend a finger cuff to a flat shape, it will damage the cuff and affect measurement accuracy
(Chapter 7)

CAUTION
Excessive ambient light may interfere with ClearSight Finger Cuff measurements.
(Chapter 7)

CAUTION
The effectiveness of the ClearSight finger cuff has not been established in pre-eclamptic patients.
(Chapter 7)

CAUTION
The EV1000 Noninvasive System is not intended for use as an apnea monitor.
(Chapter 7)

CAUTION
In patients with extreme contraction of the smooth muscle in the arteries and arterioles in the lower arm and hand, such as may be present in patients with Raynaud's disease, blood pressure measurement can become impossible.
(Chapter 7)

CAUTION

Inaccurate noninvasive measurements can be caused by factors such as:

- Improperly zeroed and/or leveled HRS
- Excessive variations in blood pressure. Some conditions that cause BP variations include, but are not limited to:
  * Intra-aortic balloon pumps
- Any clinical situation where the arterial pressure is deemed inaccurate or not representative of aortic pressure.
- Poor blood circulation to the fingers
- A bent or flattened ClearSight Finger Cuff
- Excessive patient movement of fingers or hands.
- Artifacts and poor signal quality
- Incorrect placement or position of the ClearSight Finger Cuff
- Electrocautery or electrosurgical unit interference

(Chapter 7)

CAUTION

Always disconnect the ClearSight Finger Cuff when it is not wrapped around a finger, to prevent damage by accidental over-inflation.

(Chapter 7)

CAUTION

The pulsations from intra-aortic balloon support can be additive to the pulse rate on the instrument pulse rate display. Verify patient's pulse rate against the ECG heart rate.

(Chapter 7)

CAUTION

The pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias.The pulse rate should not be used as a replacement or substitute for ECG based arrhythmia analysis.

(Chapter 7)

CAUTION

The **LIVE DEMO** mode can only be initiated by an Edwards sales representative and is different from **Demo Mode**. If a **LIVE DEMO** banner appears on the screen, as shown in Figure 11-3, discontinue use the EV1000 Clinical Platform NI and contact your local sales representative.

(Chapter 11)

CAUTION

Use Windows Embedded Standard 2009 compatible USB devices.

(Chapter 11)

CAUTION

Lightly wipe the top, bottom and front surfaces with a cloth, but the monitor screen and its accessories MUST NOT have liquid poured or sprayed directly on them. Do not expose the instrument to excessive moisture. Excessive moisture can cause the device to perform inaccurately or fail.

(Appendix E)

CAUTION

Conduct periodic inspections of all cables for defects. Do not coil cables tightly when storing.

(Appendix E)

CAUTION

If any electrolytic solution, for example NaCl or lactated Ringer's solution, is introduced into the cable connectors while they are connected to the platform, the excitation voltage can cause electrolytic corrosion and rapid degradation of the electrical contacts.

(Appendix E)

CAUTION

Do not immerse any cable connectors in fluid or use a hot air gun to dry cable connectors. Refer to cleaning instructions.

(Appendix E)

CAUTION

This product contains batteries. If you no longer need to use this product, protect the environment by bringing it to your local distributor or designated collection point for proper disposal.

(Appendix E)

CAUTION

The instrument has been tested and complies with the limits of IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Consult the manufacturer for help.

(Appendix F)

Monitor Display Symbols

Table 2-1 Monitor Display Symbols

Symbol	Description
	Audible alarm silence button
	Monitoring pause exit button
	Symbol used to indicate the audible alarm indicator for the parameter has been disabled.
	Symbol used to indicate the audible alarm indicator for the parameter has been enabled.
	Vertical scroll buttons
	Horizontal scroll buttons
	Enter button
	Keypad enter key
	Keypad backspace key
	Move cursor left by 1 character
	Move cursor right by 1 character
	Keypad cancel key
	Item enabled
	Item not enabled
	GDT Tracking button
	Monitor screen selection button
	Clinical Actions menu button

Table 2-1 Monitor Display Symbols (Continued)

Symbol	Description
	Zero and waveform icon on Clinical Actions menu
	CVP manual entry button on Clinical Actions menu
	Derived value calculator button on Clinical Actions menu
	Event review button on Clinical Actions menu
	Cuff Options button on Clinical Actions menu
	Advanced Options button on Clinical Actions menu
	Historical Data button on Clinical Actions menu
	Settings menu button
	Screen capture button
	Start Monitoring button
	Stop Monitoring button
	Resume Monitoring button
	Return to main monitoring screen
	Return to previous menu
	Cancel
	HIS enabled icon on information bar
	Battery life indicator icons on information bar

Table 2-1 Monitor Display Symbols (Continued)

Symbol	Description
	Battery information is unavailable.
	Physiocal Interval ≥ 30 beats
	Physiocal Interval < 30 beats
	Physiocal Interval status not available
	Time until Cuff Pressure Release Mode
	Time until conclusion of Cuff Pressure Release Mode
	SVV Filtering Exceeded Indicator: High degree of pulse rate variability may be impacting SVV values.
	Clock/Waveform icon that allows user to view historical data
	Arterial Waveform Display button on graphical trend screen
	Arterial Waveform Hide button on graphical trend screen
	Intervention analysis button
	Intervention analysis type indicator for custom event (grey)
	Intervention analysis type indicator for positional challenge (purple)
	Intervention analysis type indicator for a fluid challenge (blue)
	Intervention analysis type indicator for intervention (green)
	Edit button on intervention information balloon
	Add Target button on GDT Tracking Screen
	Target Value button on GDT Tracking Screen

Table 2-1 Monitor Display Symbols (Continued)

Symbol	Description
	Exit Target Selection button on GDT Tracking Screen
	Edit Target button on GDT Tracking Screen
	Time In Target symbol on GDT Tracking Screen
	Clinical/alarm indicators: Green: In target range Yellow: Out of target range Red: Red alarm and/or target zone Gray: No target set Blue: In GDT target range Black: Out of GDT target range
	Clinical indicator: SVV slope

Symbols on Product Labels

This section provides the symbol descriptions for symbols that are on the EV1000 Pump-Unit, EV1000 monitor, EV1000 accessories, and/or shipping container.

Table 2-2 Symbols on Product Labels

Symbol	Description
	Manufacturer
	Date of Manufacture
Rx only	Federal (USA) law restricts this device to sale by, or on the order of a physician.
IPX1	Extent of protection against vertically falling water
IP4X	Extent of protection against the ingress of objects and dripping water
	Separate collection for electrical and electronic equipment in accordance with EC directive 2002/96/EC.
	Connector: USB
	Direct current only
	Unit network indicator or connection

Table 2-2 Symbols on Product Labels (Continued)

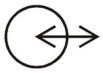
Symbol	Description
	Indicates “ON” condition for part of the equipment
	Identifies a control that returns the device to its initial state
	Consult instructions for use.
	Consult instructions for use.
	Caution
	Intertek ETL
	Class II
	Video equipment output control
	Connector: Serial COM output
	Keep contents dry
	Fragile. Handle with care
	This end up
	Keep away from direct sunlight.
	Catalogue number
	Quantity
	Serial Number

Table 2-2 Symbols on Product Labels (Continued)

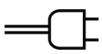
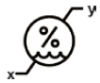
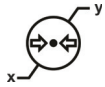
Symbol	Description
	Use by
	Lot Number
	Non-sterile
	Single Use
	Authorized representative in the European Community
	Magnetic resonance unsafe
	CE conformity marking per European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
	No serviceable parts inside
	Type BF applied part
	Alarm, general (Pump-Unit)
	Battery Status
	AC Mains Status
	Equipotentiality
	Continuous, noninvasive arterial blood pressure
	Indoor use only
	Analog output
	ClearSight Finger Cuff Size (S=Small, M=Medium, L=Large)
	Warehouse Storage Temperature Limitations (X = lower limit, Y = upper limit)

Table 2-2 Symbols on Product Labels (Continued)

Symbol	Description
	Warehouse Storage Humidity Limitations (X = lower limit, Y = upper limit)
	Transport and Storage Atmospheric Pressure Limitations (X = lower limit, Y = upper limit)

Applicable Standards

Table 2-3 Applicable Standards

Standard	Title
IEC 60601-1:2005 (3rd ed)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance + Correction AC:2010
IEC 60601-1-2: 2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8:2006	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance-Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-49:2011	Medical electrical equipment Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment.
IEC 60601-2-57:2011	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
ISO 13485:2003/ AC:2009	Medical devices - Quality management systems - Requirements for regulatory purposes
IEC 62366:2007	Medical devices - Application of usability engineering to medical devices
ISO-10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system
ISO 14971:2007	Medical devices - Application of risk management to medical devices

Table 2-3 Applicable Standards (Continued)

Standard	Title
ISO 15223-1:2012	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC 62471:2008	Photobiological safety of lamps and lamp systems
AAMI ES 60601-1: 2006	Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance; with AMD C1; 2009, AMD 2; 2010, AMD 1; 2012.
CSA C22.2#60601-1: 2008	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; COR 2: 2011/06/01.

EV1000 NI Essential Performance

The system shall provide noninvasive measurement of arterial blood pressure according to the specification*. The system shall provide alarm, alert, indicator, and/or system status when unable to provide accurate measurement of the above parameter.

* *The Essential Performance specification refers to the finger cuff blood pressure stated in Appendix A:Table A-3, "Base Parameters" on page A-2.*

Documentation and Training

Available documentation and training for the EV1000 Clinical Platform NI includes:

- EV1000 Clinical Platform NI Operator's Manual
- EV1000 Clinical Platform NI Instructions for Use

Instructions for Use are included with EV1000 Clinical Platform NI components. See Table A-4, "EV1000 Clinical Platform NI Components," on page A-2. For more information on how you can receive training or available documentation for the EV1000 Clinical Platform NI, contact your local Edwards Representative or Edwards Technical Support. See Appendix E: System Care, Service and Support.

Chapter 3: Unpacking and Initial Setup

This chapter covers unpacking and the initial setup of the EV1000 Clinical Platform NI. The ClearSight Finger Cuff is a required accessory.

Unpacking

Examine the shipping container for any signs of damage that may have occurred during transit. If you do detect any damage, we recommend you photograph the package and contact Edwards Technical Support for assistance.

Table 3-1 EV1000 NI Main Components

EV1000 Noninvasive System	EV1000 Clinical Platform NI	EV1000 Noninvasive Disposables
EV1000 Pump-Unit	EV1000 Noninvasive System	ClearSight Finger Cuff
Pressure Controller	EV1000 Monitor	EV1000 Heart Reference Sensor Body Pads
Pressure Controller Band		
Heart Reference Sensor		
Operator's Manual		

Contents List

The EV1000 Clinical Platform NI contents include the EV1000 Noninvasive System and EV1000 monitor. See Table 3-1. Disposable items, such as ClearSight Finger Cuffs and Heart Reference Sensor (HRS) body pads may be delivered separately. We recommend you confirm receipt of all ordered equipment.

Examine the contents of the shipping container. Perform a visual inspection of the Pump-Unit, Pressure Controller, HRS and all cables. Report any evidence of external damage, frayed cords, or broken or bent connector pins. Refer to Appendix A: Table A-4, for a full list of system parts and accessories.

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* *The Pressure Controller is shipped with plastic caps covering the ClearSight Finger Cuff and HRS connection ports. These should be removed when using the system for the first time. It is recommended that the cuff connector caps be kept and used to protect the Pressure Controller against the ingress of water and dirt when only a single cuff is used.*

Parameter Monitoring Accessories

The ClearSight Finger Cuff enables the EV1000 to noninvasively monitor Brachial Arterial Pressure and other key hemodynamic parameters. The ClearSight Finger Cuff is intended for single patient use. The system parameters available when using ClearSight technology are CO, CI, DIA, MAP, PR, SV, SVI, SVV and SYS. Although not required for noninvasive CO monitoring, a CVP value is required for continuous SVR/SVRI monitoring.

Monitor and Pump-Unit Installation

For environmental requirements, see Appendix A: Specifications.

⚠	**WARNING** No modification of the EV1000 Clinical Platform NI is allowed.
⚠	**WARNING** **Explosion Hazard!** Do not use the EV1000 Clinical Platform NI in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
⚠	**WARNING** To avoid the risk of electric shock, the Pump-Unit must only be connected to a supply mains with protective earth.
⚠	**WARNING** Grounding reliability can only be achieved in Canada and in the USA when the instrument is connected to a receptacle marked "hospital only", "hospital grade" or its equivalent.
⚠	**WARNING** In the USA the instrument shall be connected only to a single phase 110-120V supply system.
⚠	**WARNING** Do not use extension cords or multiple socket devices to connect the Pump-Unit to AC mains. Do not use detachable power cords other than the power cord provided.

WARNING
For noninvasive monitoring, the EV1000 Monitor must be powered by the Pump-unit using the EV1000 NI Power Cable.

WARNING
Shock hazard: Do not attempt to connect/disconnect system cables while hands are wet. Ensure that hands are dry prior to disconnecting system cables.

WARNING
Only use ClearSight Finger Cuffs, Heart Reference Sensor and other EV1000 Noninvasive System accessories, cables and or components that have been supplied and labeled by Edwards. Using other unlabeled accessories, cables and or components may affect patient safety and measurement accuracy.

WARNING
Use of accessories, sensors, and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity.

WARNING
Do not use the Ethernet cable to connect anything to the Pump-Unit other than the monitor.

WARNING
All non Edwards IEC/EN 60950 equipment, including printers, must be positioned no closer than 1.5 meters to the patient's bed, the operating table and persons touching the patient.

WARNING
Do not obstruct the EV1000 Clinical Platform NI ventilation openings.

CAUTION
Do not use any damaged system components. Use of a damaged system component may result in inaccurate measurements or may damage the EV1000 Clinical Platform NI.

CAUTION
Do not expose the EV1000 Clinical Platform NI to extreme temperatures.

CAUTION
Do not expose the EV1000 Clinical Platform NI to dirty or dusty environments.

CAUTION
Do not apply strong shock to or drop the instrument.

CAUTION
Clean and store the instrument and accessories after each use.

CAUTION
When moving the instrument, be sure to turn off the power and remove the connected power cord.

CAUTION
The EV1000 Monitor should only be connected to a single Pump-Unit and/or a single Databox.

CAUTION
When connecting the EV1000 Clinical Platform NI to any external device, refer to the device's instruction manual for complete instructions. Verify proper operation of the system before clinical use.

CAUTION
Do not use the EV1000 Monitor in environments where strong lighting makes the LCD screen difficult to view.

Mounting Recommendations

Securely mount the Monitor and Pump-Unit with the supplied brackets to an IV pole or equivalent, according to your institution's practices. Contact your local Edwards representative for recommendations on mounting carts, racks or other options.

WARNING
Make sure the EV1000 Clinical Platform NI is securely mounted, and that all cords and accessory cables are appropriately arranged to minimize the risk of injury to patients, users or the equipment. Refer to directions on proper setup.

WARNING
The Monitor must be positioned in an upright position to ensure IPX1 ingress protection.

WARNING
The Pump-Unit must be positioned in an upright position to ensure IP4X ingress protection.

WARNING
Do not position the Pump-Unit so that it is difficult to disconnect the mains power cord.

CAUTION
Do not use the Monitor as a handheld device.

Connecting the Monitor and Pump-Unit

1 After the Monitor and Pump-Unit are securely mounted, attach the main power cable supplied with the system to the back panel of the Pump-Unit. Use the DC output connector to connect the Pump-Unit to the bottom of the Monitor. See Figure 3-1 on page 3-3.

2 Attach the Ethernet cable between the Pump-Unit and Monitor.

* *Grounding normally occurs through the AC power cord. However for installation in rooms that fall in category 2 (IEC 60364-7-710), the back of the Pump-Unit is equipped with a standard grounding terminal (to achieve equipotentiality) which can be connected to a local earth point.*

3 Connect the main plug from the Pump-Unit to a hospital grade outlet.

The Pump-Unit is equipped with a battery to allow uninterrupted monitoring during power loss. There are four indicator lights on the Pump-Unit. See Chapter 12: *Pump-Unit Communication and Power* for a description of these indicators.

* *The EV1000 Clinical Platform NI is rated for power voltages from 100 to 240VAC.*

See Appendix A: *Specifications* for physical, electrical, thermal, and atmospheric requirements.

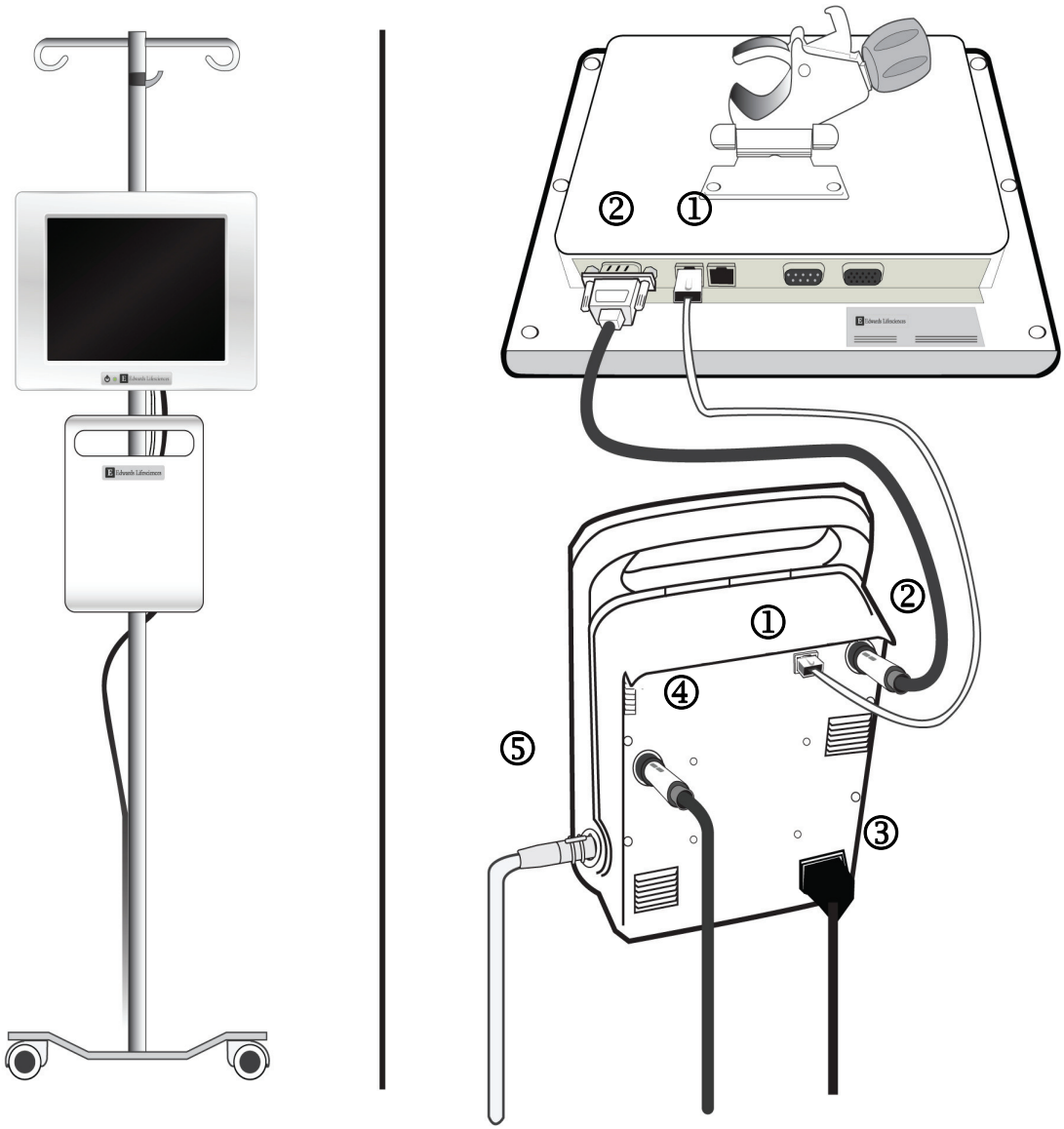


Figure 3-1 EV1000 Clinical Platform NI Cable Connections

① Ethernet Connection from Pump-Unit to EV1000 Monitor
② Power to EV1000 Monitor from Pump-Unit
③ Detachable Power Cord
④ Patient Monitor Adapter Cable
⑤ Pressure Controller Cable

WARNING
The EV1000 Clinical Platform NI meets the requirements of IEC 60601-1:2005 for the system configurations described in this manual. Connecting external equipment or configuring the system in a way not described in this manual may not meet this standard.

Connecting the Patient Cables

Refer to the directions for proper attachment of the Pressure Controller, Heart Reference Sensor and ClearSight Finger Cuffs provided in Chapter 7: Methodology and Monitoring. These directions contain specific guidelines for a successful measurement and for relevant WARNINGS, CAUTIONS and NOTES.

* *Location of cable connections and appearance of Monitor shown in Figure 3-1 are for example only. Actual cable connection locations and appearance may vary depending on Monitor model. See "EV1000 Monitor Types" on page 13-2.*

Initial Startup

Upon initial EV1000 startup, the system displays language options affecting the displayed language, time and date formats, and units of measurement. After turning on the system, the Edwards screen is displayed followed by the Power-On Self Test (POST). The POST verifies the monitor meets basic operating requirements by exercising critical hardware components and is performed each time the system is turned on. POST status message is displayed on the Startup Screen along with system information such as serial numbers and software version numbers.

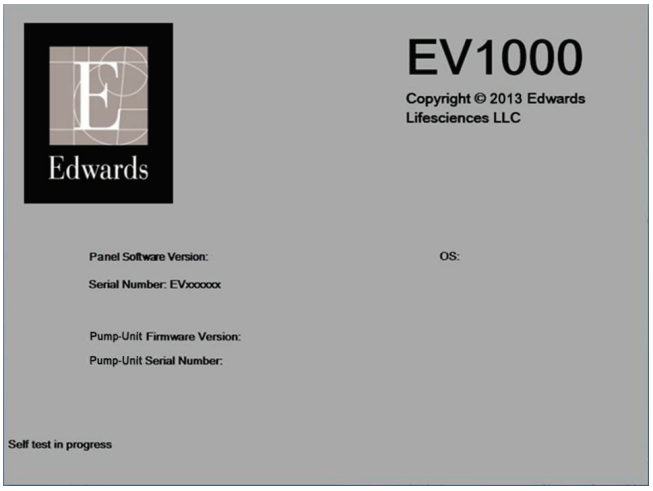


Figure 3-2 Startup Screen

To turn on the Monitor:

1. Ensure that the Pump-Unit is connected to AC mains and to the Monitor. See *Connecting the Monitor and Pump-Unit* on page 3-2.
2. Wait for the light on the Pump-Unit to indicate that the AC mains is plugged in.
3. Press the power button on the Monitor and wait for the Ethernet light to turn green on the Pump-Unit.

* *The power button can be located on the front or back of the Monitor. See "EV1000 Monitor Types" on page 13-2.*

To turn off the Monitor:

1. Press the power button and wait until the status light on the Monitor turns amber, indicating that the Monitor has entered standby mode.
2. Disconnect Pump-Unit from AC mains.

NOTE: If the diagnostic tests detect an error condition, a System Error Screen will replace the Startup screen. See Chapter 12: Help and Troubleshooting or Appendix E: System Care, Service and Support. Otherwise, call your Edwards Lifesciences representative for assistance.

Select Language

The language selection screen appears after the software has initialized and the self test is complete. Selecting the language also sets the display units and the time and date format to the default settings for that language (See Appendix C: *Monitor Settings and Defaults*).

Each of the language-related settings can be changed later in the Date / Time screen of the Monitor Settings Screen and in the Language option of the General Monitor Settings Screen.

When the Language Selection Screen appears, touch the desired language for use.

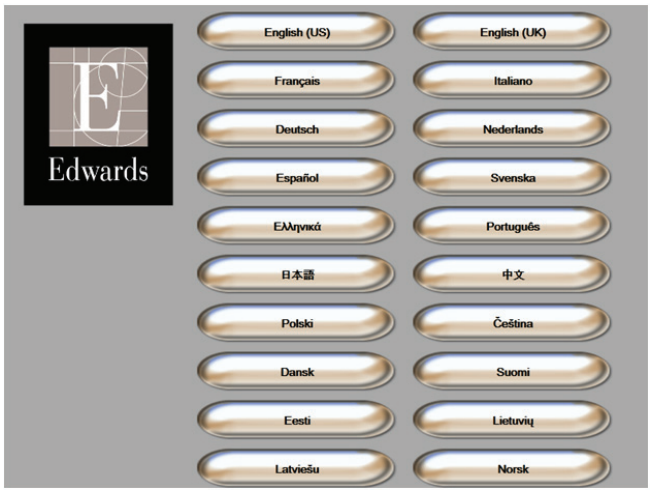


Figure 3-3 Language Selection Screen

After the language is selected, the New Patient Screen prompts you to enter a new patient.

Figures 3-2 and 3-3 are examples of Startup and Language Selection screens.

Chapter 4: EV1000 Clinical Platform NI Quick Start

This chapter is intended for experienced clinicians. It provides brief instructions when monitoring with the EV1000 Clinical Platform NI. Refer to Chapter 7: "Methodology and Monitoring" for more detailed information.

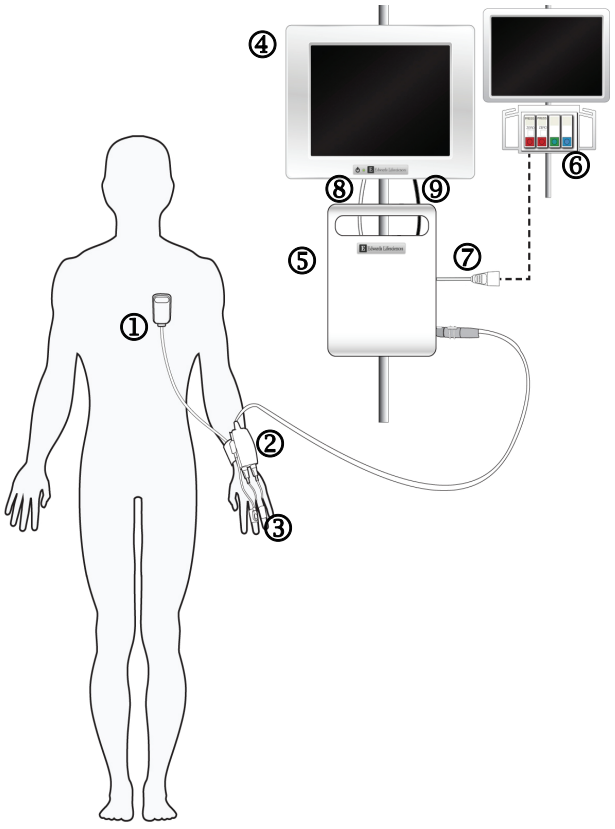


Figure 4-1 EV1000 Noninvasive System Cable Connection

① Heart Reference Sensor*
② Pressure Controller*
③ ClearSight Finger Cuff(s)*
④ EV1000 Monitor
⑤ EV1000 Pump-Unit
⑥ Bedside Patient Monitor
⑦ EV1000 Patient Monitor Adaptor Cable
⑧ Ethernet Connection from Pump-Unit to EV1000 Monitor
⑨ Power to EV1000 Monitor from Pump-Unit

** Component is an APPLIED PART (indicated by *) as defined in IEC 60601-1 3rd Ed. In normal use this component necessarily comes into physical contact with the patient for the EV1000 Clinical Platform NI to perform its function.*

WARNING
Components that are not indicated as APPLIED PARTS should not be placed in a location where the patient may come into contact with the component.

ClearSight Technology Blood Pressure and Hemodynamic Monitoring

The EV1000 Noninvasive System measures patient blood pressure and provide continuous calculation of CO, SV and SVV. SVR is calculated when a CVP value is available. The ClearSight Finger Cuff measures arterial blood pressure by sensing volumetric changes in the finger artery. Pressure changes due to patient hand movement are compensated using the Heart Reference Sensor (HRS)

1. Connect the system power cable and ethernet cable from the Pump-Unit to the EV1000 Monitor.
2. Connect the Pressure Controller to the Pump-Unit.
3. Connect the Pump-Unit to AC mains.
4. Turn on power to the EV1000 Clinical Platform NI by pressing the power button on the EV1000 Monitor.
5. All functions are accessed through the touch screen
6. Enter the patient information on **New Patient Data Screen**, by touching each field to enter or select the patient demographic data.

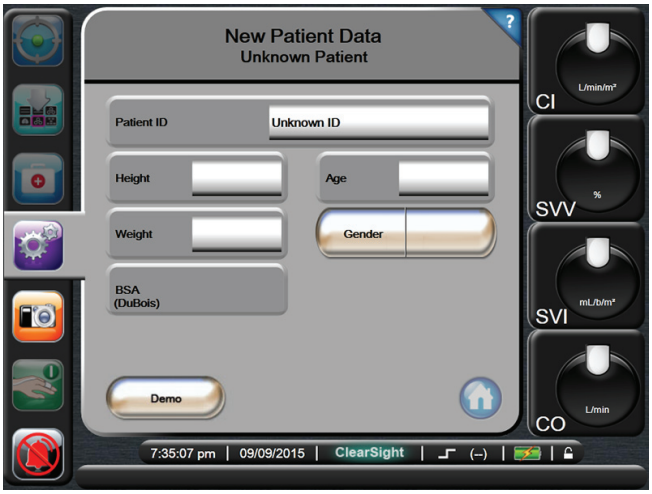


Figure 4-2 Patient Data Entry Screen

7 Wrap the Pressure Controller Band around the patient's wrist and attach the Pressure Controller to the band. Either wrist can be used however the non-dominant arm is preferred.

> **WARNING**
> Make sure that **Demo Mode** is not activated in a clinical setting to ensure that simulated data is not mistaken for clinical data.

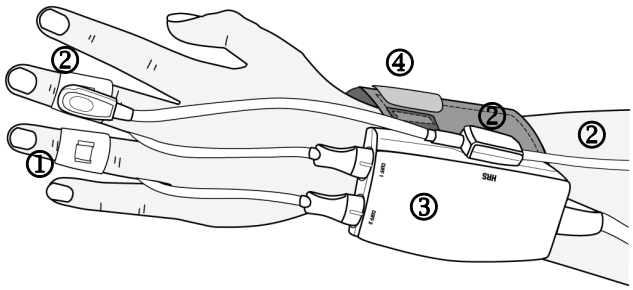


Figure 4-3 EV1000 Pressure Controller Attachments

① ClearSight Finger Cuff
② Heart Reference Sensor
③ Pressure Controller
④ Pressure Controller Band

8 Select the proper size ClearSight Finger Cuff by using the ClearSight Finger Cuff Sizing Aid.

9 Place the middle phalanx of the patient's finger onto the cuff and gently lead the cuff cable in between two fingers to the back side of the hand. The cuff must be lined up between the first and second knuckles.

10 Line the finger up between the two green lines on the cuff.

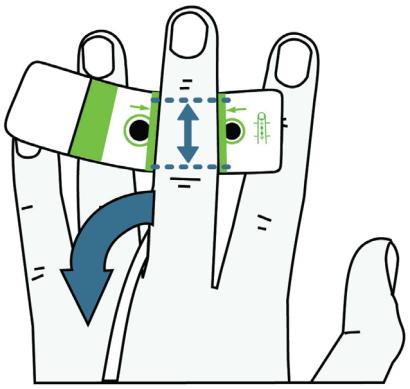


Figure 4-4 ClearSight Finger Cuff Placement

11 Wrap the ClearSight Finger Cuff tightly around the finger. Do not rotate the ClearSight Finger Cuff after application.

> **WARNING**
> Do not apply ClearSight Finger Cuff(s) on a hand/finger when external constriction (that may prevent circulation to the hand/finger) is present.

> **CAUTION**
> Improper ClearSight Finger Cuff placement or sizing can lead to inaccurate monitoring.

* *Proper cuff placement is essential for accurate monitoring. Always take enough time to select correct cuff size and properly apply the ClearSight Finger Cuff. See Chapter 7: Methodology and Monitoring and cuff directions for use for detailed instructions. For accumulated monitoring lasting longer than 8 hours, a second cuff must be used on an additional finger.*

12 Connect the ClearSight Finger Cuff to the Pressure Controller.

13 Connect the Heart Reference Sensor (HRS) to the Pressure Controller.

14 Zero the HRS before attaching it to the patient.

Zero and Apply Heart Reference Sensor (HRS)

1 Touch the **Clinical Actions** button.

2 Touch **Zero & Waveform**.

Figure 4-5 Zero HRS

3 Vertically align the two ends of the HRS and touch the **Zero** button.

4 Keep the HRS ends vertically aligned until the Zeroing procedure has ended.

5 Attach the heart end of the HRS to the patient at the phlebostatic axis by using an HRS body pad or clip.

> **CAUTION**
> Make sure that the HRS is correctly applied so that it can be leveled to the phlebostatic axis.

6 Attach the other end of the HRS to a single ClearSight Finger Cuff.

7 Touch the **Start Monitoring** button to initiate monitoring.

Steps 8-9 are Optional for waveform output to Patient Monitor. For more information on this connection See Chapter 7: Output Signal to Patient Monitor on page 7-8

8 Touch the **Zero** button of the Pressure Output Selection and then zero the patient monitor.

9 Touch the **Signal** button of the Pressure Output Selection to begin pressure signal output.

10 Touch the **Home** button to begin parameter monitoring.

Alarms and Targets

1 To change alarms and targets, touch inside the globe and use the arrows or buttons to adjust the upper and lower alarm limits.

2 Touch the **Enter** button.

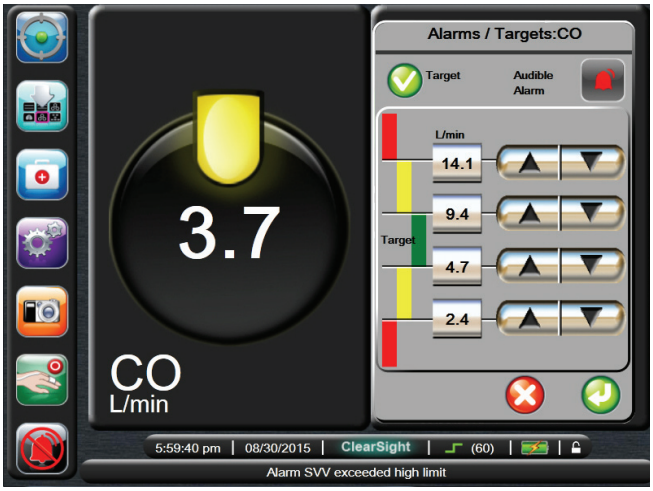


Figure 4-6 Set Alarms and Targets

> **WARNING**
> Physiological visual and audible physiological alarms are activated only if the parameter is selected and displayed on the screens as a key parameter (1-4 parameters). If a parameter is not selected and displayed as a key parameter, the audible physiological alarms are silenced.

Central Venous Pressure Manual Entry (For SVR and SVRI calculations)

Touch the **CVP entry** button on the **Clinical Actions** menu to enter a CVP value.

Chapter 5: Navigating the EV1000 Clinical Platform NI

All monitoring functions are initiated by touching the appropriate area on the touch screen. The navigation bar includes various controls for scrolling and selecting screens, performing clinical actions, adjusting system settings, capturing screen shots and silencing alarms.

Navigation Bar

The Navigation Bar is present on most screens. Exceptions are the startup screen and screens indicating the EV1000 has stopped monitoring, for example when Demo Mode ends.

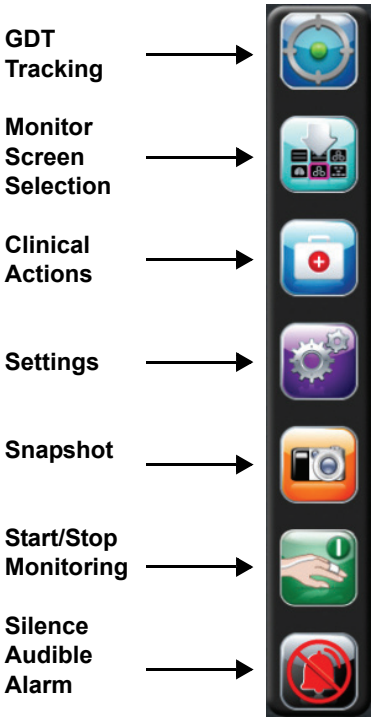


Figure 5-1 Navigation Bar

GDT Tracking. This button displays the GDT Tracking Menu. Enhanced parameter tracking allows a user to manage key parameters in the optimal range. See Chapter 9: GDT Tracking on page 9-1.

Monitor Screen Selection. The monitor screen selection button allows the user to select the desired number of monitored parameters displayed and the type of monitoring view used to display them, which is highlighted in color (see Figure 5-2, “Example of Monitoring Screen Selection Window,” on page 5-2). When a monitoring view screen is selected, that monitoring mode is immediately displayed.

To return to the most recent monitoring screen displayed, touch the **Cancel** button.

Clinical Actions. The Clinical Actions button provides access to the following clinical actions:

- Zero & Waveform
- CVP Entry
- Derived Value Calculator
- Event Review
- Advanced Options
- Cuff Options
- Historical Data

Settings. The Settings button provides access to configuration screens which include:

- Patient Data
- Monitor Settings
- Parameter Settings
- Data Download
- Demo Mode
- Engineering
- Help

Snapshot. The Snapshot button captures an image of the screen at the current time. A portable drive attached to the USB port on the Panel “monitor” is required to save the image.

Start Monitoring. The Start Monitoring button allows the user to initiate noninvasive hemodynamic monitoring directly from the Navigation bar.

Stop Monitoring. The Stop Monitoring button indicates that noninvasive hemodynamic monitoring is underway. The user can immediately stop monitoring by touching this button.

Resume Monitoring. This button appears on the Navigation bar during **Cuff Pressure Release Mode**. This mode is entered automatically at set intervals during single cuff monitoring and active monitoring is temporarily paused. See Chapter 7: Cuff Pressure Release Mode on page 7-9.

Silence Audible Alarms. This button silences all alarms for two minutes. New alarms are silenced during the two minute period. Alarms will resume sounding after the two minutes have elapsed. Faults are silenced until the fault is cleared and re-occurs. If another fault or error occurs, the alarms and audible faults resume sounding.

Audible Alarms Silenced. Indicates that alarms are temporarily silenced. A two minute countdown timer and "**Alarms Paused**" appear.

Alarms Disabled. Indicates the alarms are disabled.

Monitoring Pause Exit. When the silence audible alarms button is touched for 3 consecutive seconds, a monitoring pause confirmation popup will appear asking the user to confirm suspension of monitoring operations. This function is used when the user wishes to pause monitoring. After confirmation, the silence audible alarm button on the navigation bar will switch to the monitoring pause exit button and a "Monitoring Pause" banner will be displayed. To return to monitoring, touch the monitoring pause exit button.

Monitor Views

There are seven monitoring views: Graphical Trend, Tabular Trend, Big Numbers, Physiology, Cockpit, Goal Positioning and Physio Relationship. Up to four monitored parameters can be displayed on these screens at one time.

To select a monitoring view:

1 Touch the **Monitor Screen Selection** button.The Monitor Screen Navigation Bar contains buttons that are based upon the look of the monitoring screens.

Figure 5-2 Example of Monitoring Screen Selection Window

2 Touch the circled number, **1**, **2**, **3**, or **4**, that represents the number of key parameters to be displayed on the monitoring screens.

3 Select and touch a monitor view button to display the key parameters in that screen format.

Change Parameters

1 Touch outside the globe of a displayed parameter to change it to a different parameter.

2 A popup screen will show the selected parameter highlighted in color and other parameters currently being displayed outlined in color. Available parameters appear on the screen without highlights.

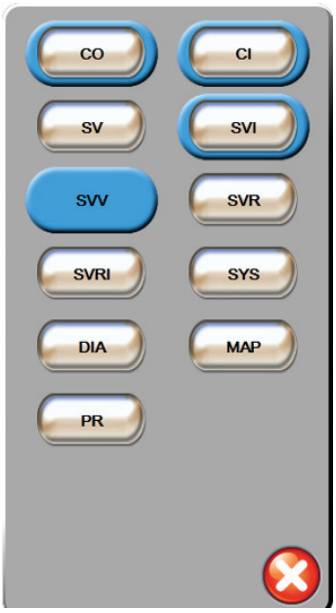


Figure 5-3 Change Monitored Parameter

3 Touch an available parameter to select the replacement parameter.

Change Alarm/Target

The Alarm Target screen lets the user view and set up alarm and target values for the selected parameter or enable/disable the audible alarm and target settings. Additionally, the target settings can be adjusted with a numbered key pad or with the scroll buttons when a minor adjustment is needed. This popup screen is accessed by touching anywhere inside a monitored parameter globe or through the parameter settings screen. For more information, see “Alarms / Targets” on page 6-5.

---

* *There is a two minute inactivity timer associated with the popup screen.*

Graphical Trend Monitoring View

The graphical trend screen displays the current status and history of monitored parameters and the continuous, real-time arterial (ART) waveform when selected. The amount of history shown for monitored parameters can be configured by adjusting the time scale.

When the target range for the parameter is enabled, the graph color codes the plot line, green indicating within the target range, yellow indicating the value is outside the target range but within the physiological alarm range, and red indicating the value is outside the alarm range. When the target range is disabled for the parameter the plot line is white. The colors match those of the clinical target indicator (lantern) on the key parameter globes in the graphical trend graph when targets are enabled for the parameter. The Alarm Limits for each parameter are displayed as colored arrows on the graph scales.

To change the time scale of a displayed parameter, touch outside of the plot area along the x or y-axis, and a scale popup menu will appear. Touch the value side of the **Graphical Trend Time** button to select a different time period.

Arterial Waveform (ART) Display

To display the real-time blood pressure waveform, touch the **Display Arterial Waveform** button. An arterial waveform graph panel will be displayed above the first monitored parameter graph.

A numeric reading of the beat to beat Systolic, Diastolic and Mean Arterial Pressure will be displayed above the first monitored parameter globe. Regular interruptions to the ART display occur for one or more heart beats to perform Physiocal, the automatic calibration of the arterial waveform. See “Physiocal Method” on page 7-1 and “Physiocal Control” on page 7-10.

To change the sweep speed (x-axis scale) of the graph, touch the scale area and a popup menu will appear to allow input of a new sweep speed.

To stop display of blood pressure waveform, touch the **Hide Arterial Waveform** button.

If there are 4 Key Parameters being displayed when the ART display button is touched, display of the 4th key parameter is temporarily removed and the ART graph is placed at the top of the remaining 3 Key Parameter trend graphs.

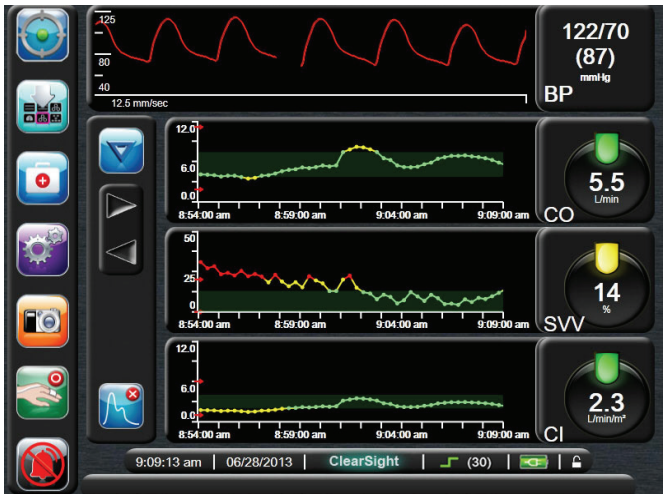


Figure 5-4 Graphical Trend Screen - Arterial Waveform Display

Intervention Events

While in the Graphical Trend screen, selecting the **Intervention** button provides a menu of Intervention types, details and a notes section.

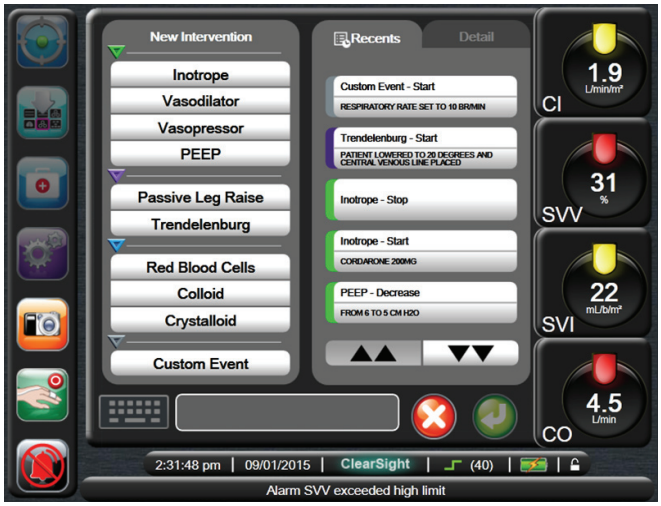


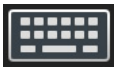
Figure 5-5 Graphical Trend- Intervention

To enter a new **Intervention**:

1 Select the **Intervention** Type from the **New Intervention** menu on left.

2 Select **Detail** from right menu tab. Unspecified is set as a default.

3 Select the Keyboard icon to enter notes (optional).

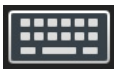


4 Touch the **Enter** button.

To enter a previously used **Intervention**:

1 Select the **Intervention** from the **Recents** list tab.

2 To add, edit or remove a note, touch the Keyboard icon.



3 Touch the **Enter** button.

Table 5-1 Intervention Events

Intervention	Indicator	Type
Intervention	(green)	Inotrope Vasodilator Vasopressor PEEP
Positional	(purple)	Passive Leg Raise Trendelenburg
Fluids	(blue)	Red Blood Cells Colloid Crystalloid
Custom	(grey)	Custom Event

After selection of the intervention type, markers indicating the intervention are visually displayed on all graphs except the real-time ART display. These markers can be selected for more information. Upon touching the marker, an information balloon will appear. See Figure 5-6: Graphical Trend Screen - Intervention information balloon. The information balloon displays the specific intervention, date, time and notes pertaining to the intervention. Touching the edit button allows the user to edit intervention time, date, and note. Touching the exit button closes the balloon.

The Information balloon has a 2 minute time out.

Intervention Editing. The time, date, and associated note for each intervention can be edited after initial entry:

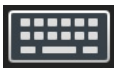
1 Touch the Intervention Event Indicator associated with the intervention to be edited.

2 Touch the Edit button on the information balloon.

3 To change the time of the selected intervention, touch on **Time Adjust,** and enter the updated time on keypad.

4 To change the date, touch on **Date Adjust**, and enter the updated date on keypad.

5 Touch the Keyboard icon to enter or edit notes.



6 Touch the **Enter** button.

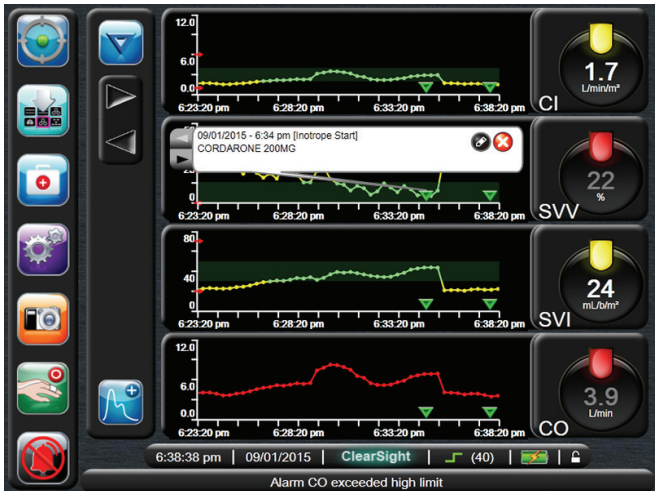


Figure 5-6 Graphical Trend Screen - Intervention information balloon

Graphical Trend Scroll Mode

Up to 72 hours of monitored parameter data can be viewed by scrolling back. The date appears above the parameter data during scrolling. Two dates will appear when appropriate. To start scrolling, touch the appropriate scroll mode button. Keep touching the scroll mode button to increase the scroll speed. The screen will return to live mode two minutes after the scroll button has been touched, or if the back button is touched.The scroll rate will appear below the scroll buttons.

Table 5-2 Graphical Trend Scroll Rates

Scroll Setting	Description
2x	Scrolls at 2 times the current time scale
1x	Scrolls at the current time scale (1 graph width)
½ x	Scrolls by ½ the current time scale

While in Scroll Mode the user can scroll to data older than the current time scale displays. Scroll Mode also allows display of the exact value of a point on the graph (indicated by the centered cursor).

✻ *It is not possible to touch past the most recent data or before the oldest data. The graph will scroll only as far as data is available.*

Historic Graphical Trend Screen

Historical parameter data is available when the user switches from a minimally invasive technology to the noninvasive ClearSight technology. The user has the option to view historic data in the graphical trend screen format from the clinical actions menu. See “Historical Data” on page 10-3.

Tabular Trends

The tabular trends screen displays selected physiological properties and their history in a tabular format.

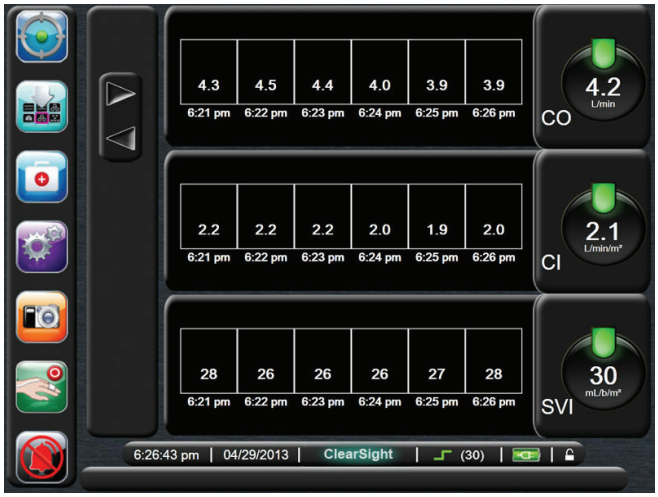


Figure 5-7 Tabular Trend Screen

✻ *The continuous % change indicator is not displayed on this monitoring screen.*

1 To change the interval between values, touch inside the table.

2 Select a value on the **Tabular Increment** popup.

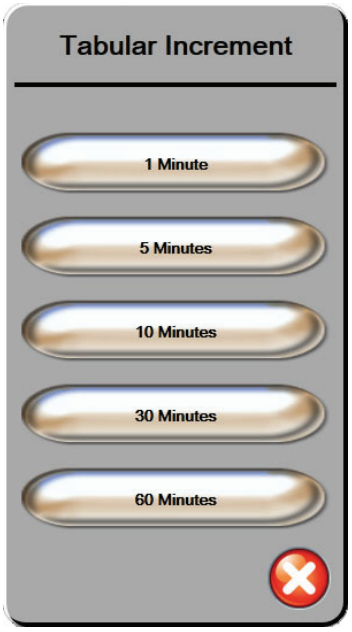


Figure 5-8 Tabular Increment Popup

Tabular Trend Scroll Mode

Up to 72 hours of data can be viewed by scrolling back. The scroll mode is based on the number of cells. Three scroll speeds are available: 1x, 6x, and 40x.

While the screen scrolls, the date appears above the table. If the time period overlaps two days, both dates will appear on the screen.

1 To start scrolling, touch and hold one of the gray arrows. The scroll rate will appear above the scroll buttons.

Table 5-3 Tabular Trend Scroll Rates

Setting	Time	Speed
1X	1 cells	Slow
6X	6 cells	Moderate
40X	40 cells	Fast

2 To exit scroll mode, stop touching the scrolling arrow or touch the **Return** button.

---

* *The screen will return to live mode two minutes after the last touch of the scroll button or if the Return button is touched.*

Big Numbers

The big numbers screen displays parameters in a larger size than the other screens. This makes it easier for clinicians and other personnel to see the values from a distance.

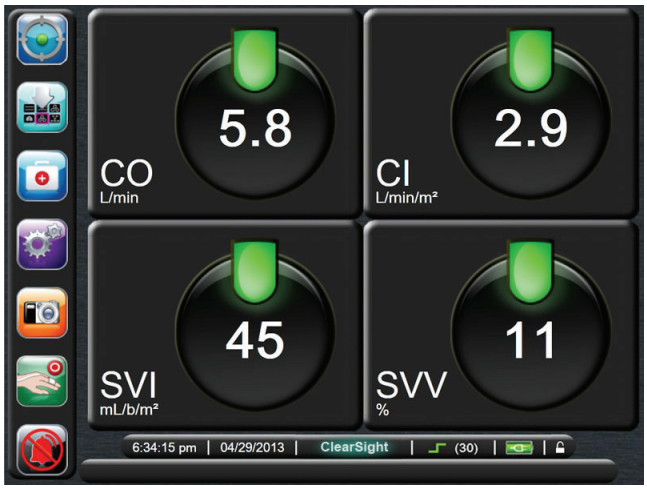


Figure 5-9 Big Numbers Monitoring Screen

Physiology Screen

The Physiology screen displays monitored parameters using a visual representation of the heart and circulatory system and their relevant measured volume.

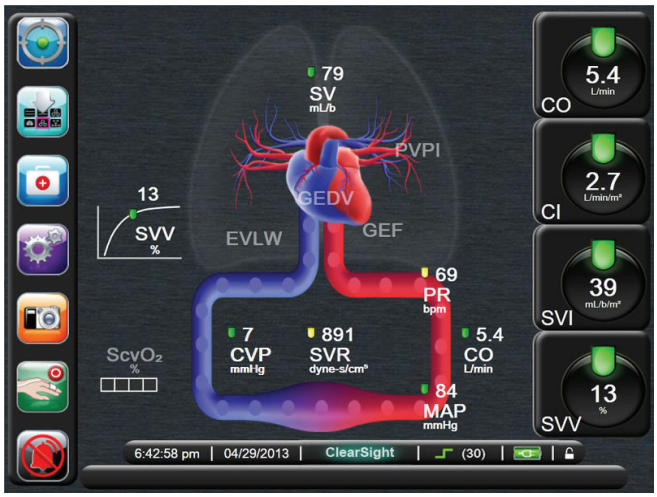


Figure 5-10 Physiology Screen

In the physiology screen the image of the beating heart is a visual representation of the pulse rate and is not an exact representation of beats per minute. Figure 5-10 shows the physiology screen during active monitoring after a CVP value has been entered.

See Chapter 8 “Physiology and Physio Relationship Monitoring Screens” for more information.

Cockpit Screen

This monitoring screen, shown in Figure 5-11, displays globes with the values of the parameter being monitored. They graphically indicate target, out of range and target values with needle indicators to show where the patient's parameter falls. In addition, the value within the globe will flash when the parameter is alarming.

The Key Parameters display a more complex target and alarm indicator. The full display range of the parameter is used to create a gauge from the graphical trends minimum to maximum settings. A needle is used to indicate the current value on the circular gauge scale. When target ranges are enabled, red, yellow and green are used to indicate the target and alarm regions within the circular gauge. When target ranges are not enabled, the circular gauge area is all gray in color and target or alarm indicators are removed. The value indicator arrow changes to indicate when the values are out of the gauge scale limits.

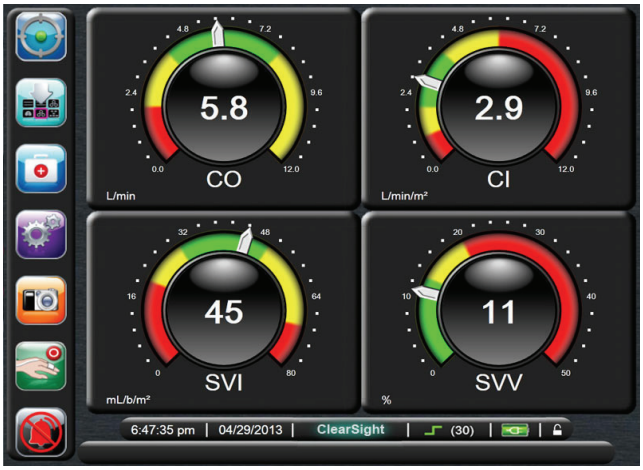


Figure 5-11 Cockpit Monitoring Screen

Goal Positioning Screen

The Goal Positioning Screen allows the user to monitor and track the relationship of two key parameters by plotting them against each other on an XY plane. See Chapter 14, "EV1000 Clinical Platform NI Advanced Features" , for more information.

Physio Relationship

The Physio Relationship screen, as shown in Figure 5-12, displays most of the parameters available on the system and their relationship to each other. The screen displays lines connecting the parameters highlighting the relationship of the parameters to each other.

Line colors correspond to the lanterns to draw your eye to problem areas. If a lantern turns yellow and the one above is green, the vertical line above and the horizontal line below turn yellow. See Chapter 8 "Physiology and Physio Relationship Monitoring Screens" for more information.

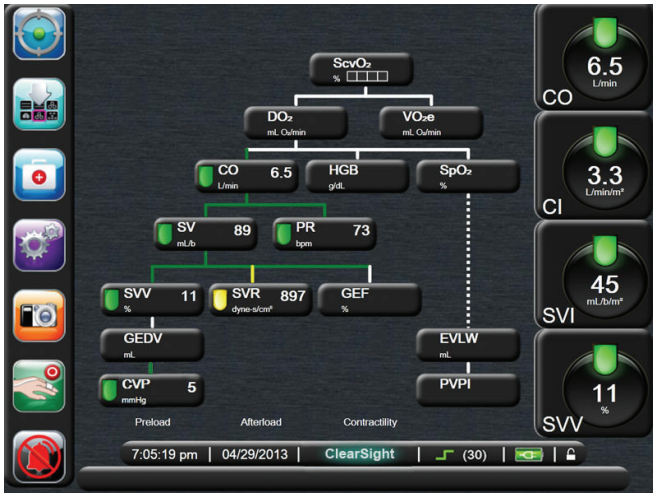


Figure 5-12 Physio Relationship Screen

Status Indicators

The lantern at the top of each parameter globe indicates the patient's current status. The color changes as the patient's status changes. The globes may display additional information:

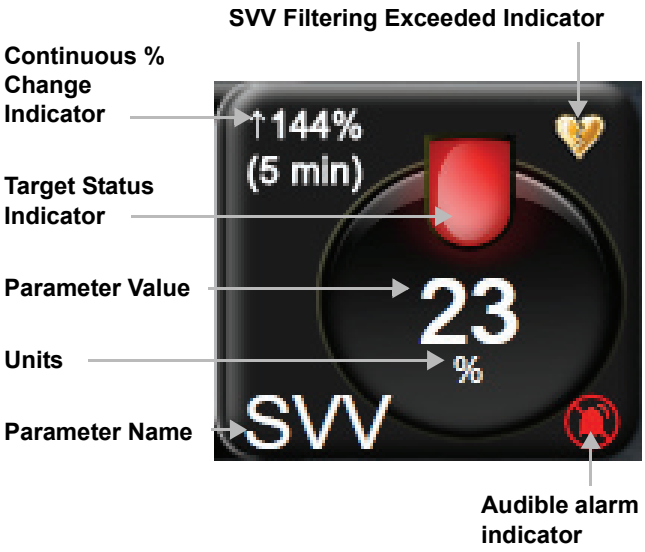


Figure 5-13 Parameter Globe

SVV Filtering Exceeded Indicator. The SVV Filtering Exceeded Indicator symbol appears if a high degree of pulse rate variability is detected that could affect the SVV value.

Fault. When a fault condition occurs, the fault message(s) will be displayed on the Status Bar until the fault condition is cleared. When there is more than one fault, alert or alarm, the message is cycled every two seconds.

When a fault condition occurs, parameter calculations are stopped, and each affected parameter globe displays the last value, time, and date at which the parameter was measured.

Continuous % Change Indicator. This indicator displays the percentage of change, followed by the time period over which it changed.

The continuous % change indicator appears on most of the monitoring screens, but does not appear on the Tabular Trends monitoring screen.

Target Status Indicators. The colored indicator at the top of each monitoring globe indicates the patient's clinical status. For indicator colors and their clinical indications, See Table 6-1: "Target Status Indicator Colors" on page 6-5.

Monitor Screen Navigation

There are several standard navigational procedures on the monitor screen.

Vertical Scrolling

Some screens will have more information than fits on the screen at one time. If vertical arrows appear on a review list, such as on the Event Review screen, touch the up or down arrow to see the next set of items.

Figure 5-14 Vertical Scrolling Review List

If selecting from a list, such as on the Faults category help screen, the vertical scroll arrows move up or down one item at a time.

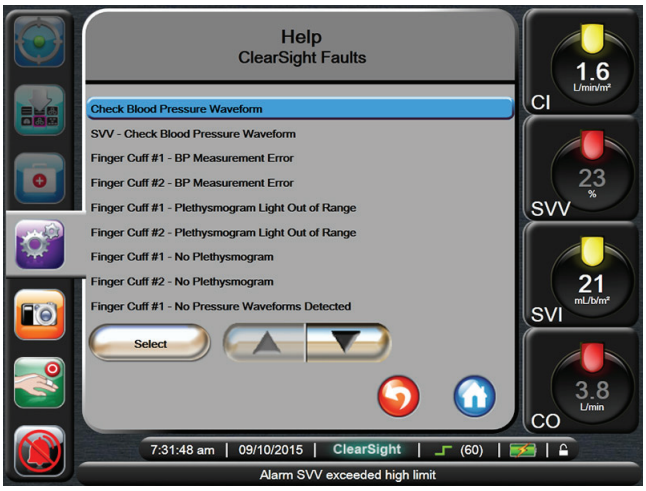


Figure 5-15 Vertical Scrolling Selection List

To perform any activity, touch the control button. There are some buttons that always perform the same function:

Home. The home button takes you to the most recently viewed monitoring screen and stores any modification made to data on the screen.

Return. The return button takes you to the previous menu screen and stores any modification made to data on the screen.

Cancel. The cancel button causes any entries to be discarded.

On some screens, for example Patient Data, there is no cancel button. As soon as you enter the patient's data, it is stored by the system.

List buttons. Some of the screens have buttons that appear to be split in two.

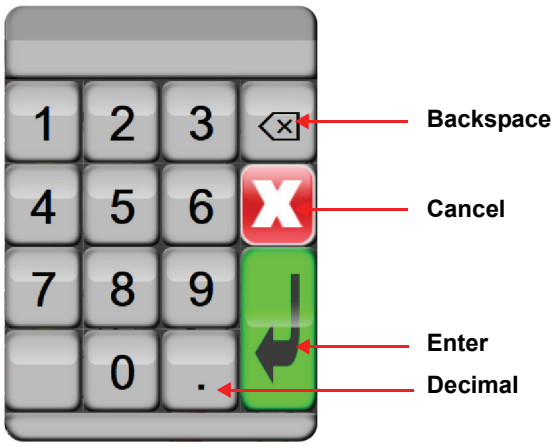
In these cases, touching anywhere on the button reveals a list of selectable items. The right side of the button displays the current selection.

Value button. Some screens have square buttons as shown below. Touch the button to display a keypad.

Toggle button. When an option exists between two choices, such as on/off, a toggle button appears.

Touch on the opposite side of the button to switch the choice.

Keypad. Touch the keys on the keypad to enter data.



Information Bar

The information bar appears on all active monitoring screens and most clinical action screens. It displays the current time, date, Physiocal interval status, battery status and the screen lock symbol. When the Pump-Unit is connected during non-invasive monitoring, the information bar will appear as shown in Figure 5-16.

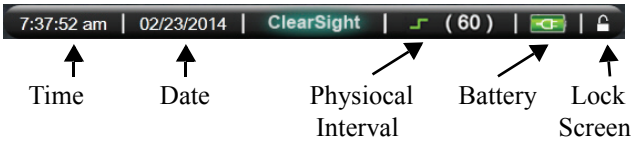


Figure 5-16 Information Bar

* *Figure 5-16 is an example of an information bar with U.S. standard defaults. To see the defaults for all languages, see Appendix C, Table C-5: Language Default Settings.*

Physiocal Interval

Physiocal is an automatic calibration of the arterial waveform which occurs at regular intervals during ClearSight monitoring. See "Physiocal Method" on page 7-1 and "Physiocal Control" on page 7-10. The interval between Physiocals is displayed on the information bar in parenthesis next to the Physiocal interval icon (see Table 5-4).

Table 5-4 Physiocal Interval Status

Icon Appearance	Icon Color	Physiocal Beats Interval
(60)	Green	≥30
(20)	Orange	<30
(--)	White	Physiocal status not available

Battery

The Pump-Unit is equipped with a battery to allow uninterrupted monitoring during power loss. Battery life is indicated on the information bar by the symbols shown in Table 5-5. For more information on the Pump-Unit battery, see"Pump-Unit Communication and Power" on page 12-3.

Table 5-5 Pump-Unit Battery Status

Battery Symbol	Indication
	The battery has greater than 50% charge remaining.
	The battery has less than 50% charge remaining.
	The battery has less than 20% charge remaining.
	The battery is charging and connected to mains power.
	The battery is fully charged and connected to mains power.
	Battery information is unavailable.

CAUTION
Pump-Unit includes a Lithium-Ion battery backup.

CAUTION
The system power status information, including battery information, is only displayed on EV1000 Monitor when the Pump-Unit is connected to the EV1000 Monitor with the supplied Ethernet cable.

Lock Screen

If the monitor is being cleaned or moved, lock the screen. For cleaning instructions refer to "Cleaning the EV1000 Clinical Platform NI" on page E-1. The screen will automatically unlock once the internal timer has counted down.

1 Touch the lock screen icon.

2 Touch the time that the screen will remain locked on the Screen Lock popup.

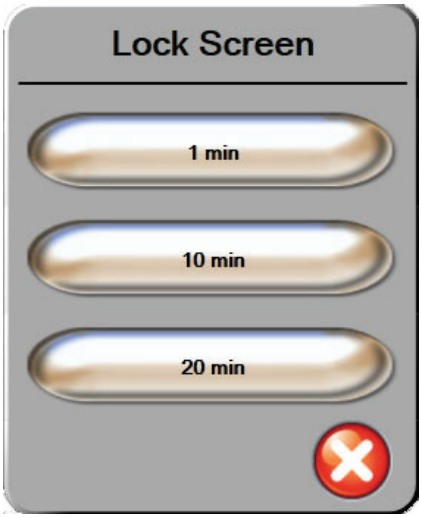


Figure 5-17 Lock Screen

3 The information and status bar appear similar to the following screen shot.

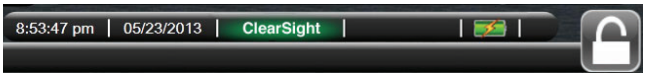


Figure 5-18 Screen Locked

4 To unlock the screen, touch and hold the lock icon.

Status Bar

The status bar appears at the bottom of all active monitoring screens. It displays faults, alarms, alerts, some warnings and notifications. When there is more than one fault, alert or alarm, the message is cycled every two seconds.

Figure 5-19 Status Bar

Chapter 6: Monitor Display Options

This chapter covers several options that allow the user to configure the monitor. These include display language, alarm volume, system date, time, and screen format.

Patient Data

After the system is turned on, the user has the option to either continue monitoring the last patient or to start monitoring a new patient.

* *If data for the last patient monitored is 12 hours or older, the only option is to start a new patient.*

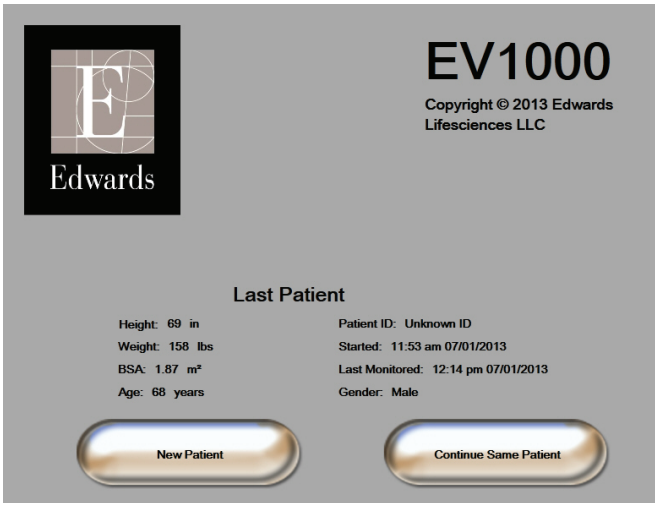


Figure 6-1 New or Continuing Patient Screen

New Patient

Starting a new patient clears all previous patient data. The alarm limits, and continuous parameters are set to their default values.

The user has the option of entering a new patient upon initial startup of the system or while the system is running.

> **WARNING**
> Perform **New Patient** or clear the patient data profile whenever a new patient is connected to the EV1000 Clinical Platform NI. Failure to do so may result in previous patient data in the historical displays.

1 After turning on the monitor, the New or Continuing Patient screen appears, Touch **New Patient** and continue to step 6.

OR

If the monitor is already on, touch the **Settings** button and continue to step 2.

2 Touch **Patient Data**.

3 Touch **New Patient**.

4 Touch **Yes** on the confirmation screen to start a new patient.

5 The **New Patient Data** screen appears.

6 Touch the **Enter** key on the keypad to save each patient demographic selection value and return to the Patient Data screen.

7 Touch **Patient ID** and use the keypad to enter the patient's hospital ID.

8 Touch **Height** and use the keypad to enter the patient's height. The unit default for your language is at the upper right of the keypad. Touch it to change the unit of measurement.

9 Touch **Age** and use the keypad to enter the patient's age.

10 Touch **Weight** and use the keypad to enter the patient's weight. The unit default for your language is at the upper right of the keypad. Touch it to change the unit of measurement.

11 Touch **Gender** and touch **Male** or **Female**.

12 The **BSA** is calculated from the height and weight using the DuBois formula.

13 Touch the **Home** button to navigate to the **Clinical Actions** menu and then the **Zero & Waveform** screen to zero the HRS.

* *The **Home** button is disabled until all patient data is entered.*

Continue Monitoring Patient

If the last patient's data is less than 12 hours old, the patient's demographics and patient ID will be displayed when the system is turned on. When monitoring of the last patient is continued, the patient's data is loaded and the trend data is retrieved. The most recently viewed monitoring screen is displayed. Touch **Continue Same Patient**.

View Patient Data

1 Touch the **Settings** button.

2 Touch **Patient Data** to see patient data. The screen will also include a **New Patient** button.

3 Touch the **Return** button to return to the Settings screen.

Monitoring Settings

The Monitor Settings screen allows the user to change several monitor related settings.

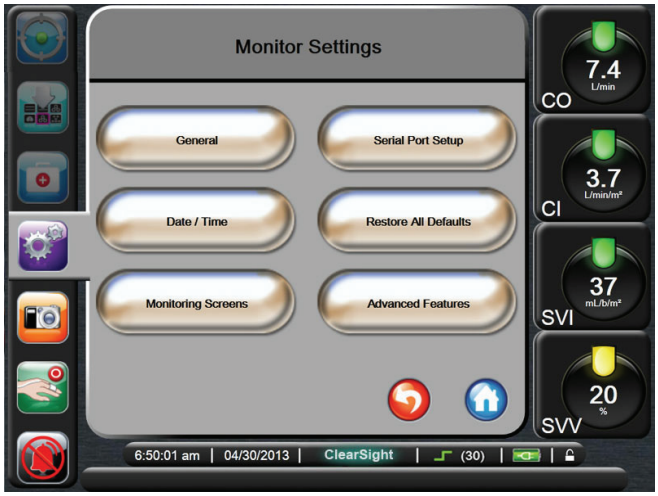


Figure 6-2 Monitor Settings

** The screen will return to the monitoring view after two minutes of inactivity.*

General Monitor Settings

The General Monitor Settings are those that affect every screen. These are the display language, units uses, alarm volume and snapshot sound. The snapshot sound button allows the user to turn the audible snapshot sound **On** or **Off.**

The EV1000 interface is available in several languages. A language selection screen appears the first time the EV1000 system is started. See Figure 3-3, “Language Selection Screen,” on page 3-5. The language screen will not appear again, but the display language can be changed at any time.

The selected language determines the default time and date format. These can also be changed independently of the language selected.

** If power is lost and restored to the EV1000, the system settings prior to the power loss, including alarm settings, alarm volume, target settings, monitoring screen, parameter configuration, language and unit selection, are automatically restored.*

Change Language

1 Touch the **Settings** button.

2 Touch **Monitor Settings**.

3 Touch **General**.

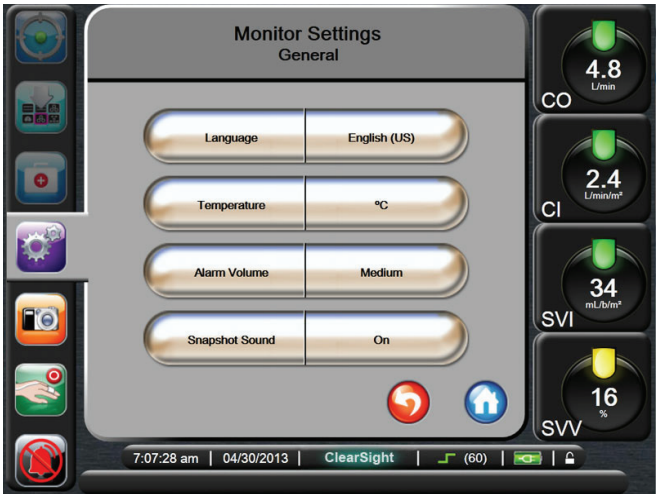


Figure 6-3 General Monitor Settings

4 Touch the value section of the **Language** button and select the language you want to use for the interface.

5 Touch the **Home** button to return to the monitoring screen.

** See Appendix C for all Language Default Settings.*

Change Date and Time Display

English (US) dates default to MM/DD/YYYY, and the time defaults to a 12 hour clock.

When an international language is selected, the date defaults to the format found in Appendix C “Monitor Settings and Defaults”, and the time defaults to a 24 hour clock.

1 Touch the **Settings** button.

2 Touch **Monitor Settings**.

3 Touch **Date / Time**.

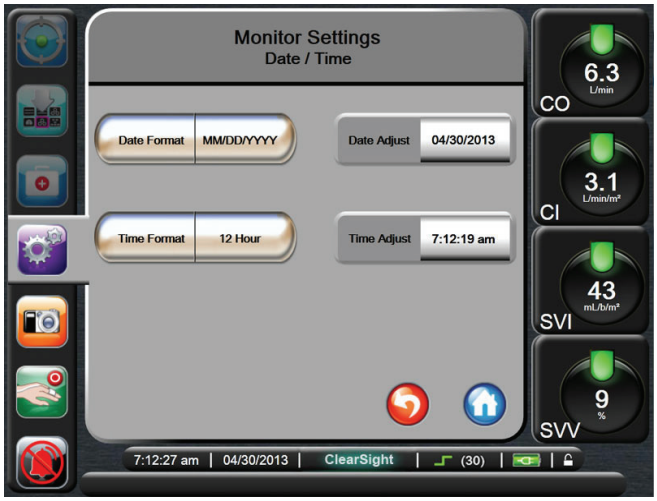


Figure 6-4 Date / Time Settings

4 Touch the value section of the **Date Format** button and touch the format you want to use.

5 Touch the value section of the **Time Format** button and touch the format you want to use.

6 Touch the **Home** button to return to the monitoring screen.

Adjust Date or Time

On occasion, the system time may need to be reset, for example to adjust for Daylight Saving Time. When the time or date is changed, trended data is updated to reflect the change.

Any retained data is updated to reflect the time change. The Pump-Unit is also updated with the new time when it is connected.

1 Touch the **Settings** button.

2 Touch **Monitor Settings**.

3 Touch **Date / Time**.

4 To change the date, touch the value section of the **Date Adjust** button and enter the date on the keypad.

5 To change the time, touch the value section of the **Time Adjust** button and enter the time.

6 Touch the **Home** button to return to the monitoring screen.

Monitoring Screens Settings

From the Monitor Settings screen, the user can set Physiology and Physio Relationship Options.

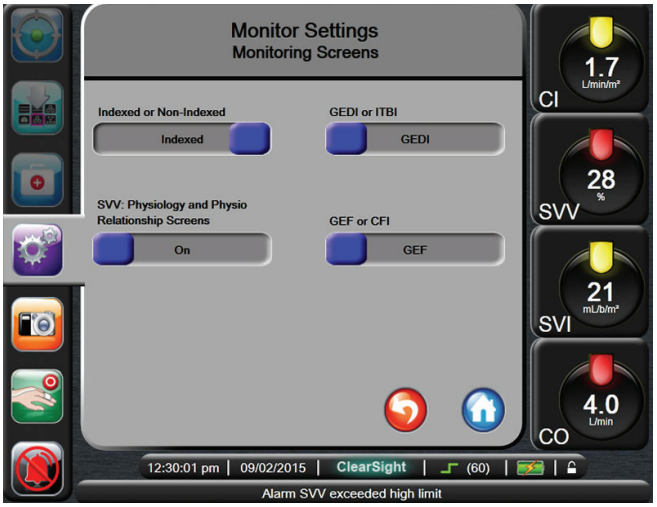


Figure 6-5 Monitor Screens

1 Touch the **Settings** button.

2 Touch **Monitor Settings**.

3 Touch **Monitoring Screens**.

4 Select the Indexed or Non-Indexed toggle for parameters in the Physiology, Physio Relationship, and Alarms & Targets screens.

5 To turn the SVV indicator **On** or **Off**, touch the **SVV: Physiology and Physio Relationship Screens** toggle.

Serial Port Setup

Use Serial Port Setup Menu to configure the serial port for digital data transfer.

The screen displays until you touch the Return button or until two minutes have passed with no activity.

1 Touch the **Settings** button.

2 Touch **Monitor Settings**.

3 Touch **Serial Port Setup**.

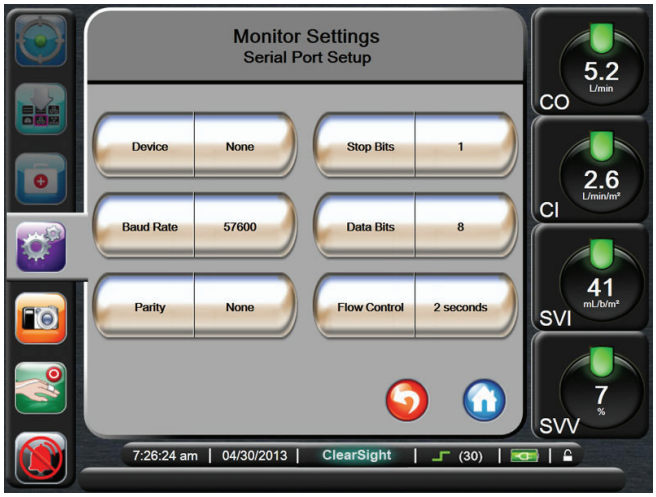


Figure 6-6 Serial Port Setup

4 Touch the button of any parameter to change it.

5 Touch the **Return** button when the configuration of serial port settings is complete.

---

* *A RS232 9 pin serial port is available for real time communication to support patient monitoring systems through the IFMout protocol.*

Restore Monitor Defaults

When the defaults are restored, the EV1000 platform stops all functions and restores the system to a factory default state.

> **CAUTION**
> Restore Defaults replaces all settings with factory defaults. Any settings changes or customizations will be permanently lost. Do not restore defaults while monitoring a patient.

1 Touch the **Settings** button.

2 Touch **Monitor Settings**.

3 Touch **Restore All Defaults**. A confirmation screen appears.

4 Touch **Yes** to continue. You will see an instructional screen.

5 Turn the Monitor and Pump-Unit off and then follow the start-up process.

Parameter Settings

1 Touch the **Settings** button.

2 Touch **Parameter Settings**.

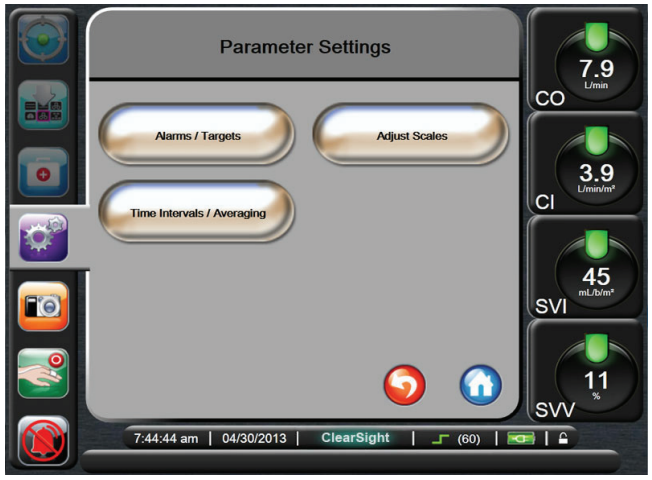


Figure 6-7 Parameter Settings

Alarms / Targets

From the Alarms / Targets screen, the user can adjust targets and enable/disable audible alarms. Alarms occur with either Medium or High priority. Only parameters that are displayed will have active visual and audible alarms.

For physiological parameters CO/CI and SV/SVI, the Above Limit Alarm Priority is Medium and the Below Limit Alarm Priority is High. For physiological parameters SVR/SVRI and SVV, the alarm priority is always Medium.

Silence Alarms

Alarms can be silenced directly from the monitoring screen. The audible alarm is silenced for two minutes.

EV1000 monitors that are configured to a non-English (US) language, except Japanese, will sound an audible tone for 3 seconds every 3 minutes when alarm is disabled for any of the key parameters.

1 Touch the **Silence Audible Alarms** button. 

* *Alarms can be silenced for two minutes, however alarms are not turned off unless targets are disabled. Information on disabling targets is included later in this chapter.*

WARNING
Do not turn off the audible physiological alarms in situations in which patient safety could be compromised.

Set Alarm Volume

The alarm volume ranges from low to high with a default of medium. It applies to alarms, faults, and alerts. Alarm volume can be changed at any time.

1 Touch the **Settings** button. 

2 Touch **Monitor Settings**.

3 Touch **General**.

4 Touch the right side of the **Alarm Volume** value button to select the desired volume.

5 Touch the **Home** button to return to the monitoring screen. 

WARNING
Make sure that the alarm volume is set to a level that allows alarms to be adequately monitored. Failure to do so could result in a situation where patient safety is compromised.

Set Targets

Targets are visual (lanterns) indicators set by the clinician to indicate if the patient is in the ideal target zone (green), warning zone (yellow), or caution zone (RED). The use of target zone ranges can be enabled or disabled by the clinician. Alarms (high /low) differ from target zones in that the alarm parameter flashes and has a audible alarm.

Parameters that can "Alarm" are indicated by a bell icon in the "Alarms / Target" settings screen. High / Low Alarms by default also become the ranges for the red caution zone for that parameter. Parameters which DO NOT have the ability to set a High / Low alarm will not have a Bell icon in the "Alarm/Target" settings screen for that parameter but can still have target ranges set.

Table 6-1 Target Status Indicator Colors

Color	Indication
Green 	Acceptable – Green target zone is considered an ideal range for parameter as set by the clinician.
Yellow 	Yellow target zone is considered a warning range and visually indicates that the patient has exited the ideal range but has not entered the alarm or caution range as set by the clinician.
Red 	Red alarm and/or target zones can be considered "Alarm" parameters indicated by a bell icon in the "Alarms /Target" settings screen. High / Low Alarms by default also become the range for the red caution zone for that parameter. Parameters which DO NOT have the ability to set a High / Low alarm will not have a Bell icon in the "Alarm/Target" settings screen for that parameter but can still have target ranges set. Ranges for the alarm and/or target zone are to be set by the clinician.
Grey 	If you don't set a target, the status indicator appears as grey.

Alarms / Targets Setup Screen

The Alarms / Targets Setup Screen allows you to view and set up alarms and targets for each key parameter. The settings for each key parameter are displayed in a parameter box. The currently configured key parameters are the first set of key parameters displayed. The remaining key parameters are displayed in a defined order. The parameters also indicate what the target ranges are based on: Custom Default, Edwards Default, and Modified.

Table 6-2 Target Defaults

Default Name	Description
Custom Default	A custom default was set for the parameter and the parameter has not been modified from that default.
Edwards Default	The parameter has not been changed from the original settings.
Modified	Parameter was changed for this patient.

* *Visual and audible alarm settings are only applicable to parameters being displayed.*

To modify Alarms / Targets:

1 Touch the **Settings** button.

2 Touch **Parameter Settings**.

3 Touch **Alarms / Targets**.

4 Touch anywhere in a parameter box to display the Alarm/ Target popup for the parameter.

Figure 6-8 Alarms / Targets Configuration

* *There is a 2 minute inactivity timer associated with this screen.*

The red, yellow and green rectangles are fixed shapes, and don't change size / shape.

Configure All Targets

Targets can easily be configured or changed all at the same time. From the Configure All screen, the user can:

- Set Custom Defaults for all parameter alarm and target settings.
- Restore all parameter alarm and target settings to Custom Defaults.
- Restore all parameter alarm and target settings to Edwards Defaults.
- Enable or disable audible alarms for all applicable parameters.
- Enable or disable target ranges for all parameters.

1 Touch the **Settings** button.

2 Touch **Parameter Settings**.

3 Touch **Alarms / Targets**.

4 Touch the **Configure All** button.

5 To turn audible alarms on or off for all parameters, touch the **Audible Alarm On/Off** buttons and enter the password.

6 To enable or disable all targets for parameters that support target ranges, touch the **Target On/Off** buttons.

7 To restore all settings to your custom defaults, touch **Restore All to Custom Defaults**. The message, "**This action will restore ALL Alarms and Targets to the Custom Defaults.**" appears.

8 Touch **Continue** on the confirmation popup to confirm the restore.

9 To restore all settings to the Edwards defaults, touch **Restore All to Edwards Defaults.** The message, "**This action will restore ALL Alarms and Targets to the Edwards' Defaults**." appears.

10 Touch **Continue** on the confirmation popup to confirm the restore.

Set Custom Defaults

When custom defaults are set up, they can be enabled or disabled at any time through the Configure All or individual Alarms/Targets Settings screen.

1 Touch the **Settings** button.

2 Touch **Parameter Settings**.

3 Touch **Alarms / Targets.**

4 Touch the **Configure All** button.

5 Touch the **Set Custom Defaults** button.

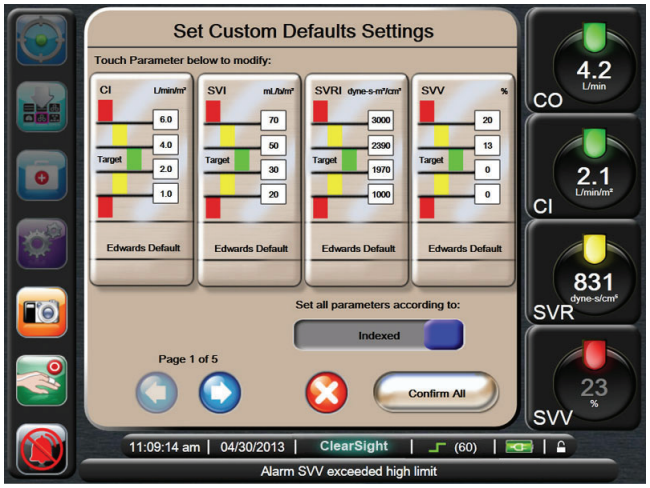


Figure 6-9 Set Custom Default Alarms / Targets

6 Touch the Parameter of interest.

7 Touch the value button for each target setting and enter the desired value.

8 Continue steps 6 and 7 for each parameter. Touch the right or left arrow at the bottom of the screen to display the next or previous set of parameters.

9 Touch the **Set all parameters according to: Indexed** or **Non-Indexed**.

10 When all desired parameters have been modified, touch **Confirm All**.

Configure Targets and Alarms for One Parameter

The Alarm Target Popup lets the user set up alarm and target values for the selected parameter. The user can also enable or disable the audible alarm and full alarm and target settings. Adjust the target settings by using the numbered keypad or by using the scroll buttons when a minor adjustment is needed.

1 Touch inside a globe to open the targets popup for that parameter.

2 To disable the audible alarm for the parameter, touch the **Audible Alarm** button at the top right of the popup.

3 To disable targets for the parameter, touch the **Target** button at the top left of the popup.

4 Use the arrows to adjust the zone settings or touch the value button to open a numeric keypad.

Figure 6-10 Set Alarms and Targets

5 When the values are correct, touch the **Enter** button.

6 To cancel, touch the **Cancel** button.

WARNING

Physiological visual and audible physiological alarms are activated only if the parameter is selected and displayed on the screens as a key parameter (1-4 parameters). If a parameter is not selected and displayed as a key parameter, the audible physiological alarms are silenced.

Time Intervals / Averaging

The Time Intervals / Averaging Screen lets the user select the continuous % change time interval.

** The screen will return to the monitoring view after two minutes of inactivity.*

1 Touch the **Settings** button.

2 Touch **Parameter Settings**.

3 Touch **Time Intervals / Averaging**.

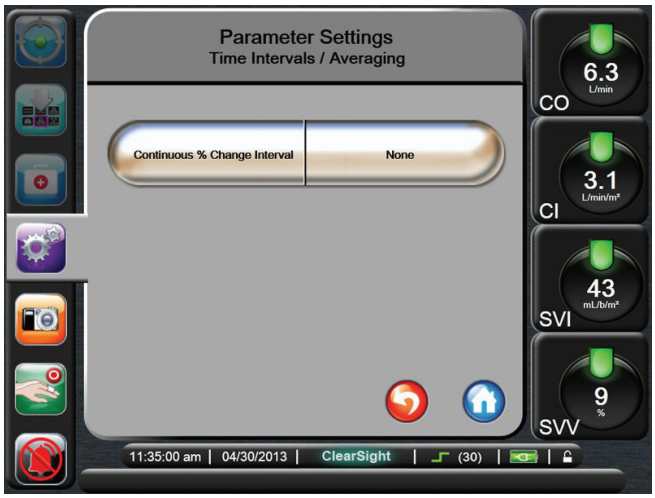


Figure 6-11 Time Intervals / Averaging

4 Touch the right side of the **Continuous % Change Interval** value button and touch one of the following time interval options:

- None
- 5 min
- 10 min
- 15 min
- 20 min
- 30 min

5 Touch the **Home** button to return to the monitoring screen.

Adjust Scales

The graphical trend data fills the graph from left to right with the most recent data at the right. The parameter scale is on the vertical axis with the time scale on the horizontal.

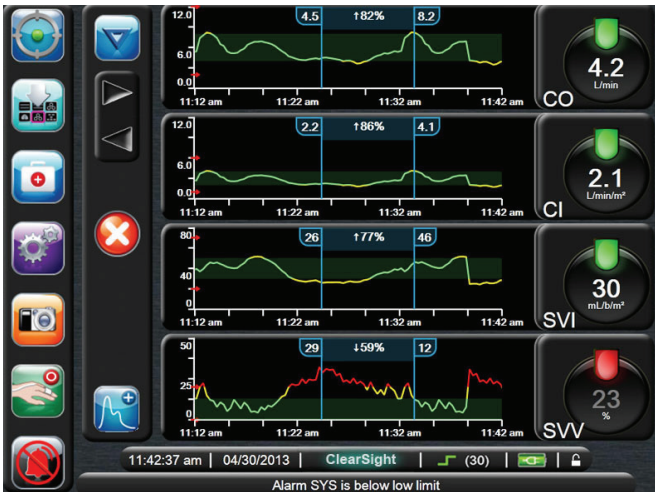


Figure 6-12 Graphical Trend Screen

The scales setup screen lets you set up both the parameter and time scales. The key parameters are at the top of the list. Use the horizontal scroll buttons to see additional parameters.

1 Touch the **Settings** button.

2 Touch **Parameter Settings**.

3 Touch **Adjust Scales**.

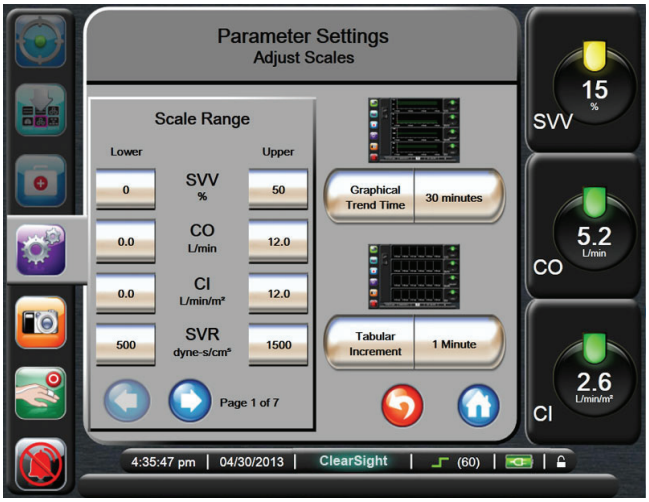


Figure 6-13 Adjust Scales

** The screen will return to the monitoring view after two minutes of inactivity.*

4 For each parameter, touch the **Lower** button to enter the minimum value to appear the vertical axis. Touch the **Upper** button to enter the maximum value.

5 Touch the right side of the **Graphical Trend Time** value button to set the total amount of time displayed on the graph. The options are:

- 3 minutes
- 5 minutes
- 10 minutes
- 15 minutes
- 30 minutes
- 1 hour
- 2 hours (default)
- 4 hours
- 6 hours
- 12 hours
- 18 hours
- 24 hours
- 48 hours

6 Touch the right side of the **Tabular Increment** value button to set the amount of time to each tabbed value. The options are:

- 1 minute (default)
- 5 minutes
- 10 minutes
- 30 minutes
- 60 minutes

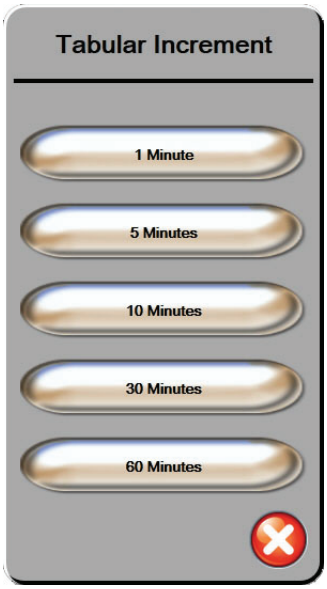


Figure 6-14 Tabular Increment Popup

7 To advance to the next set of parameters, touch the arrow at the bottom left.

8 Touch the **Home** button to return to the monitoring screen.

Engineering

The engineering function can only be operated by a system engineer and is password protected. If an error is encountered, start by referring to Chapter 12 “Help and Troubleshooting”.

Chapter 7: Methodology and Monitoring

The EV1000 Clinical Platform NI continuously measures the patient's arterial pressure waveform and calculates Cardiac Output along with other key hemodynamic parameters. This chapter gives a brief background on the methodology of the ClearSight technology, instructions on how to perform a measurement and advanced features of the system.

EV1000 Noninvasive System Methodology

Accurate measurement of the patient's blood pressure and key hemodynamic parameters is based on the Volume Clamp method, Physiocal method and ClearSight algorithm.

Volume Clamp Method

The ClearSight Finger Cuff uses the Volume Clamp method developed by Czech physiologist J.Peñáz. The cuff is equipped with a plethysmograph sensor, which is a combination of a light source and light receiver, to continuously monitor changes in finger arterial blood volume. An inflatable bladder within the cuff rapidly adjusts to this change in volume to equilibrate the pressure of the cuff with the pressure inside of the artery. The artery is therefore clamped at its "un-stretched" volume and the pressure of the cuff is equal to that of the finger arterial pressure at all times.

Physiocal Method

The Physiocal method, developed by K.H. Wesseling et al., is short for physiological calibration. Physiocal adjusts for changes in the "un-stretched" volume during a normal measurement period. Cuff pressure is kept constant for one or more heart beats and blood pressure measurement is momentarily interrupted to observe the physiological properties of the finger artery. Early in the measurement period, these interruptions occur regularly. If the properties of the artery are sufficiently constant over time, the interval between Physiocals will be increased up to 70 heart beats, with higher intervals representing increased measurement stability.

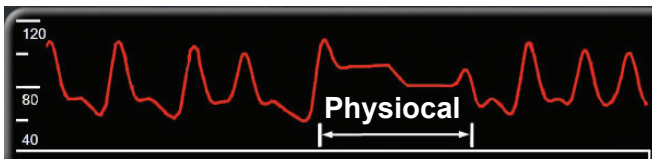


Figure 7-1 Physiocal During Blood Pressure Measurement

Waveform Reconstruction and Hemodynamic Analysis (ClearSight Algorithm)

The arterial blood pressure waveform is known to gradually change between the brachial and finger arteries due to physiological reasons. The ClearSight algorithm uses advanced processing methods to reconstruct the brachial arterial pressure waveform (P. Gizdulich et al. 1997). Waveform reconstruction yields beat-to-beat values of Systolic (SYS), Diastolic (DIA) and Mean Arterial (MAP) Pressures and is displayed.Waveform hemodynamic analysis yields values for Cardiac Output (CO), Cardiac Index (CI), Stroke Volume (SV), Stroke Volume Index (SVI), and Pulse Rate (PR) using a pulse contour method (ClearSight algorithm). Advanced algorithms are used to compute Stroke Volume Variation (SVV) to evaluate dynamic fluid responsiveness. Systemic Vascular Resistance (SVR), and Systemic Vascular Resistance Index (SVRI) are available when a Central Venous Pressure (CVP) value is entered.

Heart Reference Sensor

The Heart Reference Sensor (HRS) takes into account differences in pressure between the finger and heart. The hydrostatic pressure changes due to difference in height between the finger and heart are compensated by the HRS. One ending of the HRS is placed on the finger at the cuff level, and the other ending is placed at heart level.

Discoloration, Numbness, or Tingling of the Fingertip

The Volume Clamp methodology places a continual pressure on the finger which never fully occludes the arteries, but inhibits venous return and causes some venous congestion in the fingertip distal to the cuff. As a result, the patient's fingertip may often experience discoloration (blue or red coloring) after a few minutes of monitoring. After longer periods of monitoring (approximately 30 minutes - 2 hours), some patients may experience some tactile sensations (tingling or numbness) in the fingertip. Immediately after removing the cuff, the middle phalanx often shows a slightly decreased volume and may show some reactive hyperemia or swelling. All of these phenomena generally subside within a few minutes of relieving the cuff pressure. Keeping the fingers and hand warm during the measurement improves the arterialization of the fingertip, which can improve coloration and reduce the rate of occurrence of tactile numbing.

Single Cuff Monitoring

A single ClearSight Finger Cuff can be used for accumulated monitoring in the same patient for up to 8 hours. During single cuff monitoring, the EV1000 Noninvasive System will automatically release the pressure in the cuff at regular intervals. See “Cuff Pressure Release Mode” on page 7-9.

* *After 8 hours of accumulated monitoring on the same finger, the EV1000 Noninvasive System will stop monitoring and display a warning to place the cuff on another finger if continued monitoring is desired.*

Double Cuff Monitoring

For monitoring periods lasting longer than 8 hours, the EV1000 Clinical Platform NI enables two ClearSight Finger Cuffs to be connected simultaneously on separate fingers. In this configuration, the system switches active monitoring between the two cuffs at a user selected interval to allow for uninterrupted continuous monitoring. See “Cuff Options” on page 7-8.

* *When using the double cuff configuration, ensure that each finger is sized separately. It is not uncommon for patients to have two different sized fingers requiring two different sized ClearSight Finger Cuffs. Failure to select the correct finger cuff can result in measurement inaccuracy.*

* *Upon starting a measurement, the Finger Cuff will expire after 72 hours for a single patient.*

Peñáz J (1973), “Photoelectric measurement of blood pressure, volume and flow in the finger,” *Digest of the 10th Int Conf Med Biol Engng, Dresden*, p. 104.

Wesseling KH, et al. (1995), “Physiocal, calibration finger vascular physiology for Finapres,” *Homeostasis* **36** (2-3), pp. 67-82.

Gizdulich P, Prentza A, Wesseling KH (1997), “Models of brachial to finger pulse wave distortion and pressure decrement,” *Cardiovascular Research* **33** (3), pp. 698-705.

Connect the Patient Sensors

Proper application of the Pressure Controller, Heart Reference Sensor and ClearSight Finger Cuff(s) is necessary for accurate monitoring when using the EV1000 Clinical Platform NI. The Heart Reference Sensor must be zeroed before being attached to the patient.

WARNING
Do not sterilize any components of the EV1000 Noninvasive System. The EV1000 Noninvasive System is provided non sterile.

WARNING
Refer to cleaning instructions. Do not disinfect the instrument by autoclave or gas sterilization.

WARNING
Refer to the directions provided with each accessory for specific instructions on placement and use, and for relevant WARNINGS, CAUTIONS, and specifications.

WARNING
Do not use damaged components/sensors or components/sensors with exposed electrical contacts to prevent patient or user shocks.

WARNING
The EV1000 Noninvasive System monitoring components are not defibrillation proof. Disconnect the system before defibrillating.

WARNING
Do not touch the system connectors of the EV1000 Clinical Platform NI and the patient at the same time.

WARNING
Only use ClearSight Finger Cuffs, Heart Reference Sensor and other EV1000 Noninvasive System accessories, cables and or components that have been supplied and labeled by Edwards. Using other unlabeled accessories, cables and or components may affect patient safety and measurement accuracy.

WARNING
Always remove EV1000 Noninvasive System sensors and components from the patient and completely disconnect the patient from the instrument before bathing the patient.

CAUTION
The effectiveness of EV1000 Noninvasive System has not been evaluated in patients under 18 years of age.

CAUTION
Always grasp the connector, not the cable, when connecting or disconnecting cables. Do not twist or bend the connectors. Confirm that all sensors and cables are connected correctly and completely before use.

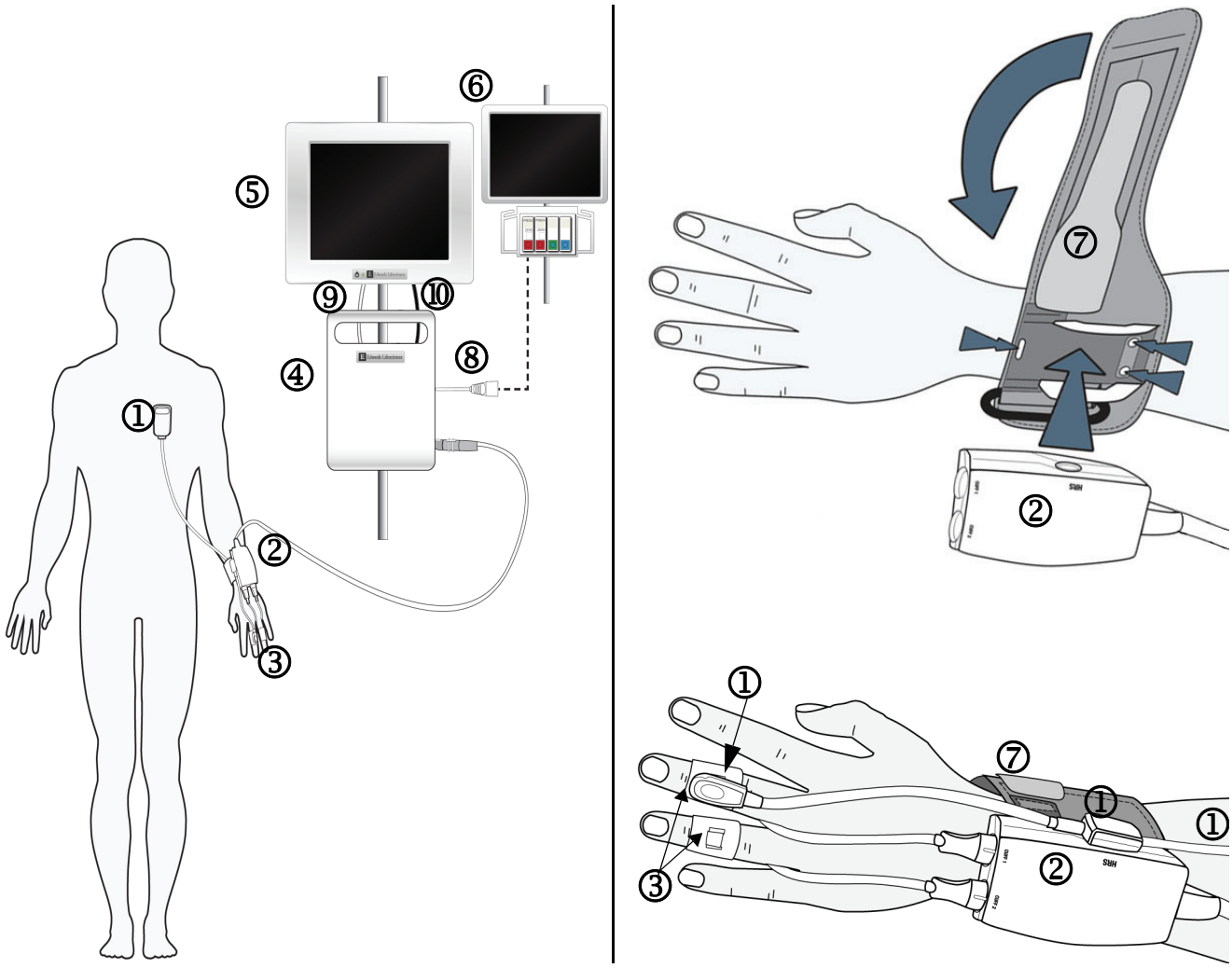


Figure 7-2 EV1000 Noninvasive System Connections

① Heart Reference Sensor*
② Pressure Controller*
③ ClearSight Finger Cuff(s)*
④ EV1000 Pump-Unit
⑤ EV1000 Monitor
⑥ Bedside Patient Monitor
⑦ Pressure Controller Band
⑧ EV1000 Patient Monitor Adaptor Cable
⑨ Ethernet Connection from Pump-Unit to EV1000 Monitor
⑩ Power to EV1000 Monitor from Pump-Unit

* *Component is an APPLIED PART (indicated by *) as defined in IEC 60601-1 3rd Ed that in normal use necessarily comes into physical contact with the patient for the EV1000 Clinical Platform NI to perform its function.*

WARNING
Components that are not indicated as APPLIED PARTS should not be placed in a location where the patient may come into contact with the component.

Apply the Pressure Controller

The Pressure Controller is worn on the patient's wrist and connects to the Pump-Unit, HRS and ClearSight Finger Cuff(s). See Figure 7-2, "EV1000 Noninvasive System Connections," on page 7-3.

1 Wrap the Pressure Controller band around the patient's wrist. The non dominant hand is preferred for monitoring in awake patients. (Figure 7-2 , top right)

2 Snap the Pressure Controller into the plastic sleeve of the band, making sure that the cuff connectors are facing towards the fingers.

3 Attach the Pressure Controller cable to the Pump-Unit.

WARNING
Do not overtighten the Pressure Controller Band or ClearSight Finger Cuff(s).

Select ClearSight Finger Cuff Size

CAUTION
Improper ClearSight Finger Cuff placement or sizing can lead to inaccurate monitoring.

1 Size the finger(s) that will be used for monitoring by using the ClearSight Finger Cuff sizing aid. Best results are obtained from the middle, ring or index finger. The cuff is not intended to be placed on the thumb or previously fractured fingers.

2 Wrap the sizing aid around the middle phalanx of the finger by pulling the color coded smaller end through the slot to create a snug fit.

3 The black arrow indicates suitable cuff size. Match the indicated color with the correct finger cuff size.

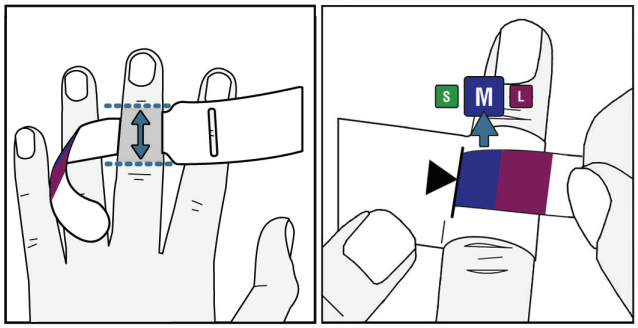


Figure 7-3 Cuff size selection

Apply the ClearSight Finger Cuff

For instructions 1-3 below, see corresponding numbers in Figure 7-4, "ClearSight Finger Cuff Placement," on page 7-4.

1 Place the middle phalanx of the finger onto the cuff with the cuff cable guided between the fingers to the back side of the hand. The cuff must be lined up between the two knuckles.

2 Line the finger up between the two green lines on the cuff.

3 Tightly wrap the cuff around the finger and ensure that the correct size cuff has been chosen by checking that the outer edge lines up within the green area of the cuff when wrapped tightly. See image in left inset of Figure 7-4 .

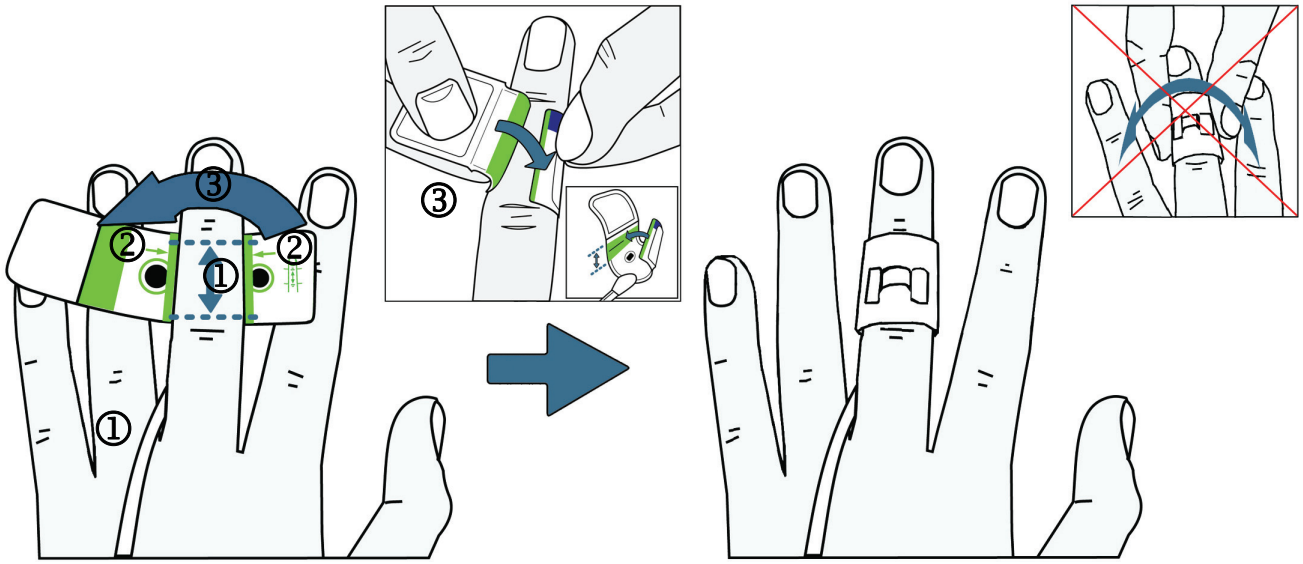


Figure 7-4 ClearSight Finger Cuff Placement

4 Connect the ClearSight Finger Cuff to the Pressure Controller.

** Do not rotate the cuff after application. The hook located on the outside of the finger cuff should be situated on the back of the finger at all times.*

5 If continuous monitoring is expected to last longer than 8 hours, or to increase patient comfort, repeat cuff sizing and steps 1-4 to apply an additional cuff to a second finger on the same hand.

Single Patient Use The ClearSight Finger Cuff is designed for single patient use. Upon starting a measurement, the Finger Cuff will expire after 72 hours for a single patient.

Double Cuff Application. The EV1000 NI allows two ClearSight Finger Cuffs to be connected simultaneously to alternate the measurement between two fingers. This feature allows for continuous monitoring for durations of up to 72 hours and is required for measurements that take longer than 8 hours. This feature can also be used to increase patient comfort. Accumulated monitoring on one finger is limited to 8 hours.

WARNING
Do not apply the ClearSight Finger Cuff or Pressure Controller on injured skin as this may cause further injury.

WARNING
Measurement on one finger in contradiction with the instructions for use may affect patient comfort and/or lead to minor injuries.

WARNING
To reduce the risk of skin irritation and tissue damage, do not monitor longer than 8 hours continuously on a single finger. To continue to monitor, apply the ClearSight Finger Cuff to another finger or use two cuffs to measure more than 8 hours.

WARNING
Do not use two ClearSight Finger Cuffs simultaneously on the same finger.

CAUTION
Never bend a finger cuff to a flat shape, it will damage the cuff and affect measurement accuracy

CAUTION
Excessive ambient light may interfere with ClearSight Finger Cuff measurements.

CAUTION
The effectiveness of the ClearSight finger cuff has not been established in pre-eclamptic patients.

Enter Patient Data

1 Patient data can be entered upon initial startup of the system or by touching the **Settings** button.

2 Touch **Patient Data** and enter the patient demographics (see “Patient Data” on page 6-1).

3 Touch the **Home** button.

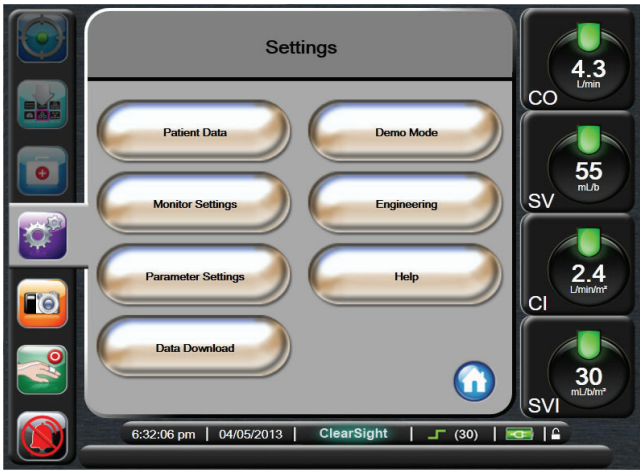


Figure 7-5 Settings Screen

Zero and Apply Heart Reference Sensor and Start Monitoring

CAUTION
Make sure that the HRS is correctly applied so that it can be leveled to the phlebostatic axis.

Before monitoring can be initiated, the Heart Reference Sensor (HRS) must be zeroed and applied to the patient.

1 Connect the HRS to the Pressure Controller.

2 Touch the **Clinical Actions** button.

3 Touch **Zero & Waveform**.

Figure 7-6 Zero & Waveform Screen

4 Vertically align both ends of the HRS (see top image in Figure 7-7) and touch the zero button.

5 Wait for indication that the HRS has been zeroed.

6 Apply the heart end of the HRS to the patient at phlebostatic axis level by using an HRS body pad or clip. See Figure 7-7 .

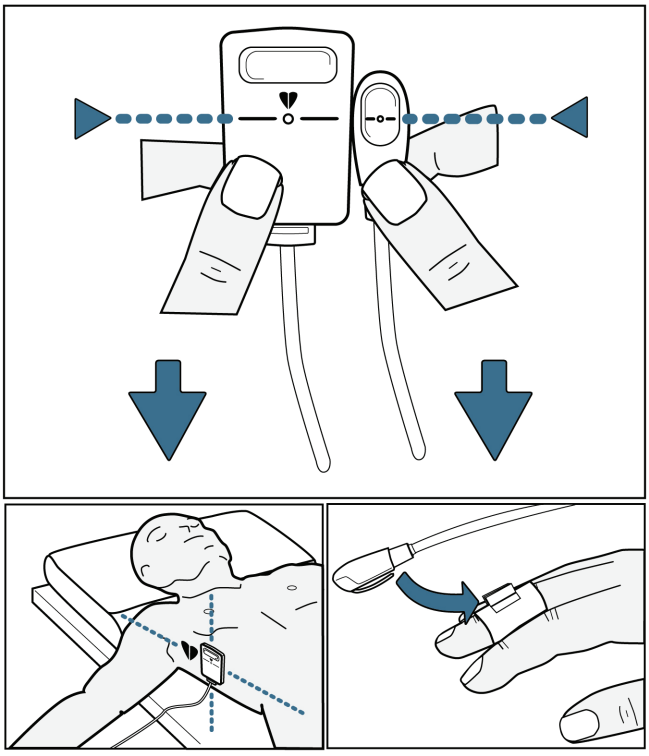


Figure 7-7 Alignment of HRS

** If the patient is rotated or moved, the phlebostatic axis will rotate or move with the patient. If necessary, be sure to reapply the heart end of the HRS to ensure that it is still at the same vertical level as the heart in the patient's new position.*

7 Attach the other end of the HRS to the ClearSight Finger Cuff.

8 Touch the **Start Monitoring** button to begin monitoring.

** During measurement, the tip of the finger being monitored by the cuff may show some coloring. This is normal and will disappear within a few minutes of cuff removal.*

During measurement, a conscious patient may notice slight pulsations in the finger to which the cuff is applied. These pulsations will stop momentarily during Physiocals. The patient should be made aware that these irregularities are normal and not caused by the patient's heart.

If the patient is responsive, instruct the patient to keep the hand relaxed and not tense the muscles or overstretch the hand.

Make sure that the blood flow to the hand is not (partially) obstructed, e.g. because the wrist is pressing on a hard surface.

Some situations, such as cold hands, may make it difficult to start monitoring. If the patient has cold hands, try to warm the hand.

9 Touch the **Home** button to navigate to the monitoring screens. See "Monitor Views" on page 5-2.

10 To change a parameter, touch outside the globe and select the replacement parameter. This affects every monitoring screen. See “Change Parameters” on page 5-3.

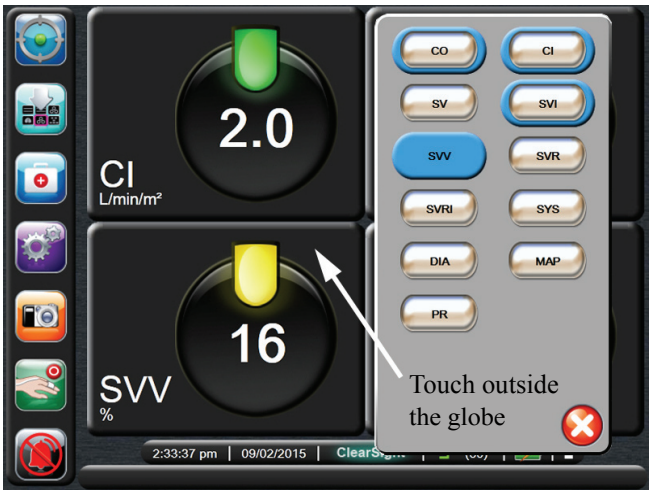


Figure 7-8 Parameter Settings

** The screen will return to the monitoring view after two minutes of inactivity.*

11 Touch the **Stop Monitoring** button on the Navigation bar to end monitoring at any time.

WARNING
If using the instrument during full body irradiation, keep all EV1000 Noninvasive System monitoring components out of the irradiation field. If a monitoring component is exposed to the irradiation, the readings may be affected.

WARNING
Strong magnetic fields may cause malfunction of the instrument and burn wounds to the patient. Do not use the instrument during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.The device may affect the MR image, and the MRI unit may affect the accuracy of the measurements.

CAUTION
The EV1000 Noninvasive System is not intended for use as an apnea monitor.

CAUTION
In patients with extreme contraction of the smooth muscle in the arteries and arterioles in the lower arm and hand, such as may be present in patients with Raynaud's disease, blood pressure measurement can become impossible.

CAUTION
Inaccurate noninvasive measurements can be caused by factors such as:

- Improperly zeroed and/or leveled HRS
- Excessive variations in blood pressure. Some conditions that cause BP variations include, but are not limited to:
  * Intra-aortic balloon pumps
- Any clinical situation where the arterial pressure is deemed inaccurate or not representative of aortic pressure.
- Poor blood circulation to the fingers.
- A bent or flattened ClearSight Finger Cuff.
- Excessive patient movement of fingers or hands.
- Artifacts and poor signal quality.
- Incorrect placement or position of the ClearSight Finger Cuff.
- Electrocautery or electrosurgical unit interference.

CAUTION
Always disconnect the ClearSight Finger Cuff when it is not wrapped around a finger, to prevent damage by accidental over-inflation.

Set Targets and Alarm Limits

Touch anywhere inside a globe, cockpit, or BP parameter window next to the arterial waveform display to access a popup target menu on top of the parameter globe. Use this menu to change the alarm and target values.Use the arrows to increase or decrease the upper and lower targets.

** The red, yellow and green bars don’t change size or shape when you change the limits (see “Set Targets” on page 6-5 for complete information).*

1 Touch the parameter globe to bring up the Alarms / Targets popup**.**

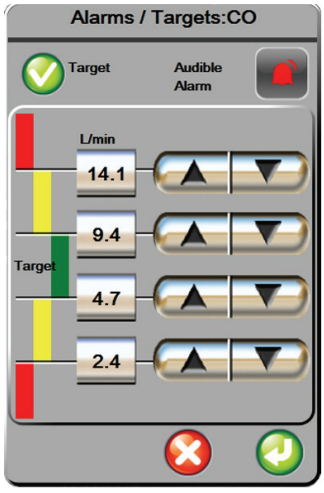


Figure 7-9 Alarms / Targets

2 Touch the scroll buttons to set the Alarm/Target values.

3 Touch the **Enter** button to save the values.

WARNING
Physiological visual and audible physiological alarms are activated only if the parameter is selected and displayed on the screens as a key parameter (1-4 parameters). If a parameter is not selected and displayed as a key parameter, the audible physiological alarms are silenced.

WARNING
Do not use the EV1000 Clinical Platform NI as a heart rate monitor.

CAUTION
The pulsations from intra-aortic balloon support can be additive to the pulse rate on the instrument pulse rate display. Verify patient's pulse rate against the ECG heart rate.

CAUTION
The pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias.The pulse rate should not be used as a replacement or substitute for ECG based arrhythmia analysis.

Central Venous Pressure Manual Entry

To calculate SVR/SVRI and assess patient hemodynamic afterload status, a CVP value must be entered.

1 Touch the **Clinical Actions** button.

2 Touch **CVP Entry**.

3 Enter a CVP value.

4 Touch the **Home** button.

Continuous Waveform Display

The blood pressure waveform can be checked through the **Zero & Waveform** screen or through the graphical trend screen. See “Arterial Waveform (ART) Display” on page 5-3.

Output Signal to Patient Monitor

The **Zero & Waveform** screen provides the user with the option to send the arterial waveform signal to a bedside patient monitor.

1 Connect the patient monitor adaptor cable from the back of the Pump-Unit to the patient monitor cable.

2 Touch the **Zero** patient monitor button and then zero the patient monitor.

3 Touch the **Signal** button of the Pressure Output Selection to begin pressure signal output.

WARNING
The analog output signal from the EV1000 Clinical Platform NI will experience brief interruptions due to Physiocal which will be displayed on the bedside patient monitor.

Derived Value Calculator

Select the **Derived Value Calculator** option to compute the patient’s DO_2, VO_2, SVR or CPO. The Derived Value Calculator provides a convenient way to display these parameters for a one-time calculation. For more information, see “Derived Value Calculator” on page 10-1.

Cuff Options

The **Cuff Options** screen allows the user to select the time interval between cuff pressure release and the switching time interval for double cuff monitoring. This screen also displays sensor status and information for connected Cuff(s) and HRS.

1 Touch the **Clinical Actions** button.

2 Touch **More**.

3 Touch **Cuff Options**.

4 For **Single Cuff** monitoring, select a cuff pressure release time interval from the available option list. At the end of the cuff pressure time release interval, the pressure will be released from the cuff for a duration indicated by the countdown timer on the information bar. See “Cuff Pressure Release Mode” on page 7-9.

5 For **Double Cuff** monitoring, select a switching time interval from the available option list.

Selection options on the Cuff Options screen are not available during active monitoring or during Cuff Pressure Release Mode.

Cuff Pressure Release Mode

During single cuff monitoring, the EV1000 Noninvasive System will automatically release pressure from the finger cuff at regular intervals.

Figure 7-10 Finger Cuff Pressure Release Icon and Timer

When ≤ 5 minutes remain until **Cuff Pressure Release Mode**, a white countdown timer icon will appear on the information bar along with the time remaining until pressure release. A notification pop up will indicate the that the countdown clock has been initiated. The user has the option to extend the countdown time until cuff pressure release by touching this portion of the information bar.

At the end of the cuff pressure time release interval, pressure will be released from the cuff and monitoring will be temporarily suspended. The cuff pressure release icon will appear yellow and the timer will indicate time until monitoring is automatically resumed.

During **Cuff Pressure Release Mode**, the Resume Monitoring button appears on the Navigation bar. By touching the Resume Monitoring button, the user can access available monitoring options.

Cardiac Output Calibration

The **Advanced Options** screen allows the user to calibrate CO.

1 Touch the **Clinical Actions** button.

2 Touch **More**.

3 Touch **Advanced Options**.

4 For **CO calibration**, choose a CO averaging time of:

- Historical 3 mins (only available after 3 minutes of continuous monitoring data is available)
- 1 min
- 3 min
- 5 min

The CO averaging time indicates how much monitored data is averaged to generate a calibration value.

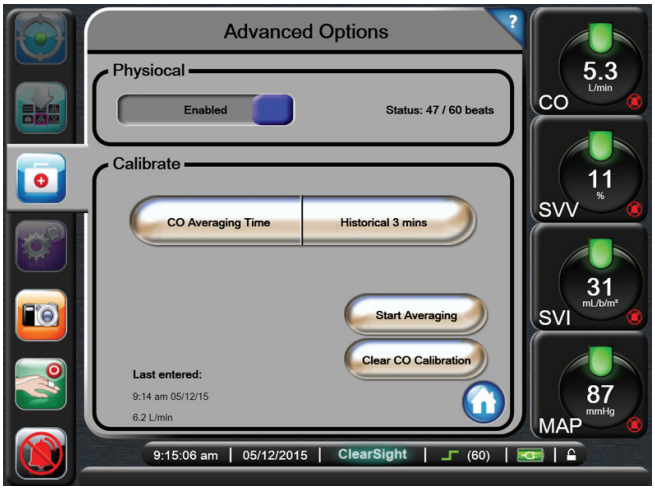


Figure 7-11 Advanced Options Screen

5 Touch **Start Averaging** to begin CO Averaging.

6 When averaging is complete, enter a **CO reference** value using the keypad.

7 Touch **Calibrate** to complete the calibration process.

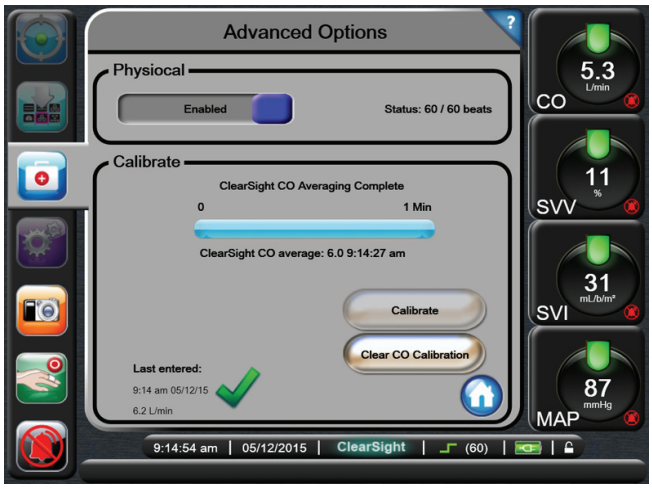


Figure 7-12 Advanced Options Screen - CO Calibration

8 To clear the last entered CO reference value, touch **Clear CO Calibration**.

Physiocal Control

Physiocal can be observed on the ART display as a stepwise increase in pressure upon startup and as brief interruptions throughout monitoring.To accurately account for changes in the finger artery characteristics throughout monitoring, Physiocal is performed at regular intervals resulting in momentary interruptions to the arterial waveform. Physiocal can be temporarily disabled. To disable Physiocal:

1 Touch the **Clinical Actions** button.

2 Touch **More**.

3 Touch **Advanced Options**.

4 To disable Physiocal, toggle the Physiocal button from enabled to disabled. Physiocal will automatically be enabled after 1 minute.

5 Toggle the Physiocal button to enabled to turn Physiocal back on.

6 Touch the **Home** button.

---

* *Physiocal should not be disabled until 5 minutes have passed from the start of monitoring. Measurements will be most stable once the Physiocal interval status is 30 beats or higher (‘Physiocal≥30’).*

Chapter 8: Physiology and Physio Relationship Monitoring Screens

The Physiology Screen and the Physio Relationship monitoring screens provide a graphic display of monitored parameters and their relationship to each other.

** The volumetric parameters and lungs appear grey as they are not available when using the noninvasive ClearSight technology. These parameters are available when using VolumeView technology.*

Physiology Screen

The Physiology screen is an animation depicting the interaction between the heart, lungs, blood, and vascular system. Continuous parameter values are displayed in association with the animation.When pulse rate and CO are available the heart beats and the blood flows in an animated representation.

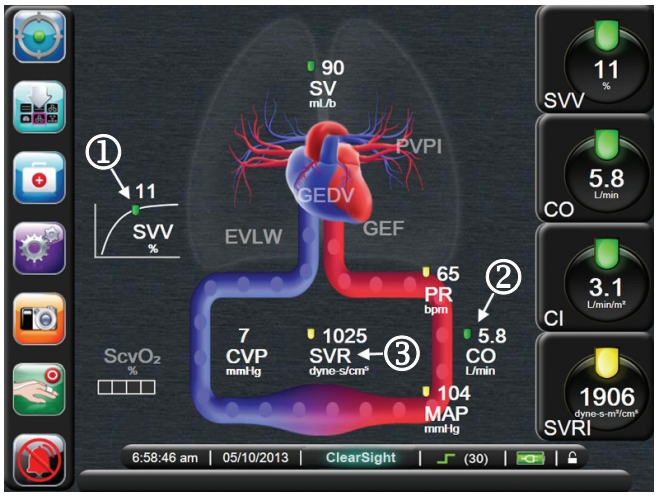


Figure 8-1 Physiology Screen

1 The curved line indicates the SVV slope. The lantern moves up and down the line according to the SVV value. The color of the lantern changes based upon set target ranges.

2 Cardiac Output is indicated on the arterial side of the vascular system animation.

3 Systemic Vascular Resistance, indicated in the center of the vascular system animation, is available with manual input of CVP with continuous calculation as SVR = [(MAP-CVP)/CO]*80.

In Figure 8-2 , the vessels are shown with differing levels of constriction. The first shows normal resistance, the second shows high SVR (resistance), and the third shows low SVR (resistance). When no CVP value has been entered and SVR is unavailable, the visual representation of the vessel will default to the visual representation of normal resistance.

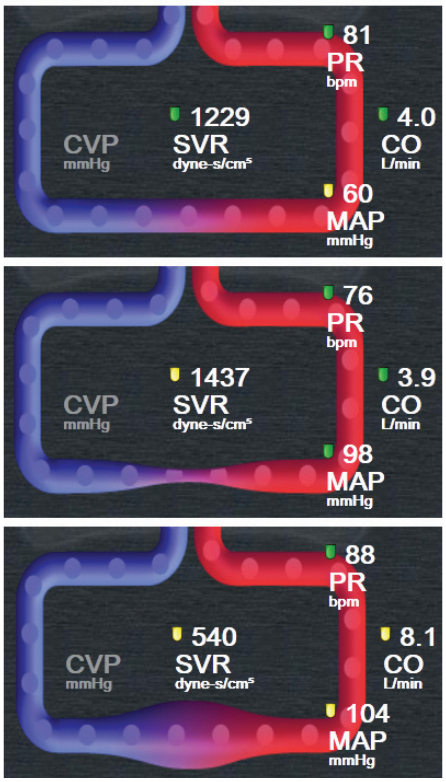


Figure 8-2 Systemic Vascular Resistance

The clinical target indicators are displayed with available parameters. SVV also displays the SVV Slope indicator.

The heart beats at a similar rate as the pulse rate. To depict Cardiac Output the blood flow is animated at three rates:

- Slow when CO is less than the low target setting.
- Medium when CO is within the target setting.
- High when CO is above the high target setting.

SVV Slope Indicator

The SVV Slope Indicator is a visual representation of the Frank-Starling curve used when assessing the Stroke Volume Variation value. The indicator displays the current SVV value and lantern which changes based upon set target ranges. An SVV value of 13% is displayed at approximately the inflection point of the curve, as shown in Figure 8-3 . The indicator is displayed on the Physiology and Historic Physiology screens.

Figure 8-3 SVV Slope Indicator

The user has the ability to enable or disable the display of the SVV Slope Indicator from the Monitor Screens Settings Menu. The default setting is enabled. When the SVV filtering exceeded indicator is on, the system will not show the SVV lantern on the SVV indicator curve.

Physio Relationship Screen

The Physio Relationship screen displays measured parameters with connecting lines highlighting the relationship of the parameters to each other. It automatically updates as parameter values change to display current values.

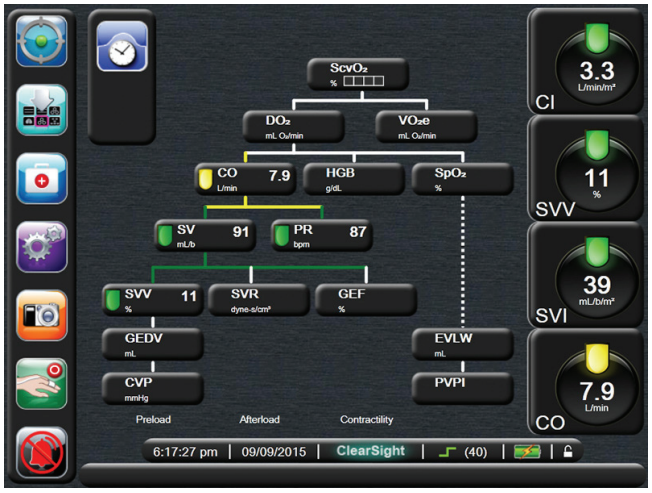


Figure 8-4 Physio Relationship Screen

Continuous and Historical Modes

The Physio Relationship screen has two modes: continuous and historical. When in continuous mode, derived values are always displayed as unavailable.

1 The vertical lines above the parameters appear in the same color as the parameter lantern.

2 The vertical lines below the parameter appear in the same color as the parameter lantern, except for the line below SVV, which is the same as the parameter above it.

3 The horizontal lines are the same color as the line above them.

4 The left bar appears after an historic physio record has been created. To create an historic physio record, touch the HGB, SpO_2 or SvO_2/$ScvO_2$ parameter button and enter a value using the number pad.

5 The new physio record is filled with current continuous parameter data, the entered value and any derived calculated values (See “Physio Relationship Alarms/ Targets and Historical Data Screens” on page 8-3).

---

* *Before any values are entered for HGB, SpO_2 or SvO_2/ $ScvO_2$ the clock/waveform icon does not appear. Only the available continuous parameters are displayed.*

Figure 8-5 Physio Relationship Historical Data Screen

---

* *The Historic Physio Relationship screen displays most of the parameters available on the system at a point in time. The screen displays lines connecting the parameters, highlighting the relationship of the parameters to each other. The Historic Physio Relationship screen displays the configured (1-4) Key Parameters on the right hand side of the screen. There is a horizontal tab composite at the top that allows the user to navigate through the database of historic records. The record times correspond to derived value calculations.*

The Historic Physio Relationship screen allows the user to enter parameters used to calculate derived parameters DO_2 and VO_2e, on only the most recent record. The values entered are for the time of the record and not the current time.

*The Historic Physio Relationship screen is accessed through the clock/waveform icon on the continuous Physio Relationship Screen. Touch the **Return** button to return to the continuous Physio Relationship Screen. There is no 2 minute time-out for this screen.*

Parameter Boxes

Each small parameter box displays:

- Parameter name
- Parameter units
- Parameter value (if available)
- Clinical target Indicator (if a value is available)
- For SVV, the two SVV indicators are displayed when applicable.

If the parameter is in a fault state, the value is blank, indicating it is or was unavailable at the time of the display.

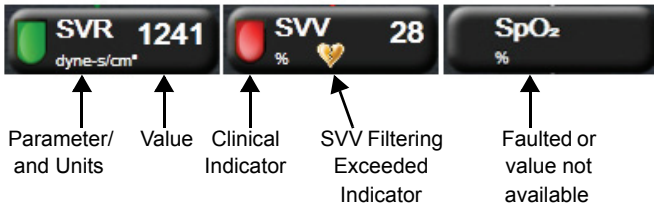


Figure 8-6 Physio Relationship Parameter Boxes

Physio Relationship Alarms/Targets and Historical Data Screens

Touch a parameter to bring up the Alarm/Target popup to change the target settings. See Chapter 6: *Alarms / Targets* on page 6-5.

Touching HGB, SpO_2 or $ScvO_2$ brings up a small popup allowing the user to change the target settings or enter a value.

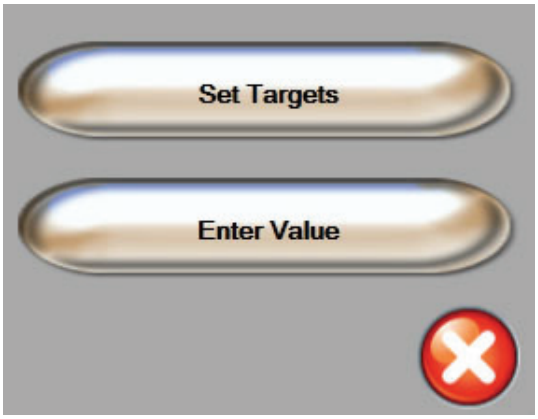


Figure 8-7 Physio Relationship Target Popup

When the value is accepted, a new record is created. It includes:

- Current continuous parameter data.
- The entered value and any derived calculated values.

The historic physio relationship screen is shown with the newly created record; the remaining manually entered values can then be entered to calculate the derived values.

WARNING
Physiological visual and audible physiological alarms are activated only if the parameter is selected and displayed on the screens as a key parameter (1-4 parameters). If a parameter is not selected and displayed as a key parameter, the audible physiological alarms are silenced.

Chapter 9: Enhanced Parameter Tracking

The EV1000 Clinical Platform provides tools for performing **Goal Directed Therapy** (**GDT**), enabling a user to track and manage key parameters in the optimal range. With enhanced parameter tracking, clinicians have the ability to create and monitor customized protocols.

GDT Tracking

Key Parameter and Target Selection

1 Touch the **GDT Tracking** button on the navigation bar to access the GDT Menu screen.

Figure 9-1 GDT Menu Screen - Key Parameter Selection

2 Touch the upper half of a parameter/target selection button and choose the desired parameter from the parameter panel. Up to four key parameters can be tracked.

3 Touch the lower half of the button to enter a range value on the keypad. The selected operator (<, ≤, > or ≥) and value represent the upper or lower boundary during parameter tracking. Touch the Enter key.

Figure 9-2 GDT Menu Screen - Target Selection

4 Touch any selected parameter to change it to a different available parameter or touch **None** on the parameter selection panel to remove it from tracking.

5 To view and select parameter/target settings from a previous GDT tracking session, touch the **Recents** tab.

6 Touch **OK** to begin GDT tracking.

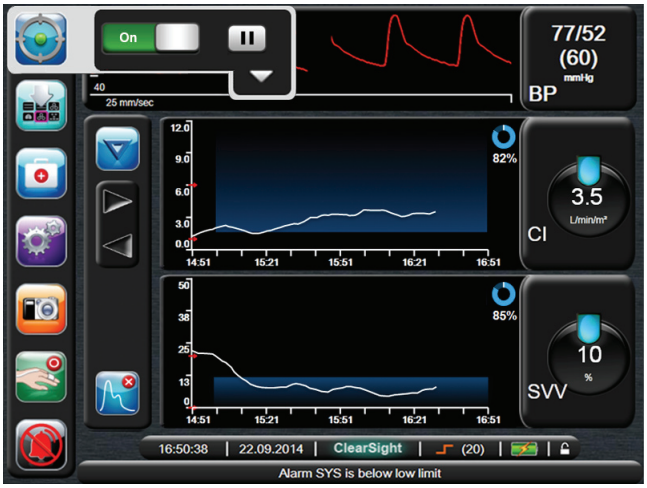


Figure 9-3 GDT Active Tracking

Active GDT Tracking

During active GDT tracking, the plot area of the parameter trend graph within targeted range appears shaded in blue. See Figure 9-3, “GDT Active Tracking,” on page 9-1.

GDT Tracking Control Panel. Touch the GDT Tracking button to pause or stop during active tracking. While tracking is paused, the plot area within target range on the parameter graph appears shaded in gray.

Time In Target Value. This is the primary output of enhanced parameter tracking. It is displayed below the **Time In Target** icon on the upper right corner of the parameter’s graphical trend plot. This value represents the accumulated percentage of time a parameter has been within target during an active tracking session.

Parameter Globe Target Indicator Colors. Table 9-1 defines clinical target indicator colors during GDT tracking.

Table 9-1 GDT Target Status Indicator Colors

Color	Indication
Blue 	Tracked parameter is currently within the configured target range.
Black 	Tracked parameter is currently outside of the configured target range.
Red 	Tracked parameter is currently below the low alarm limit or above the high alarm limit.
Gray 	Tracked parameter is unavailable, in a fault state, GDT tracking is paused, or a target has not been selected.

Auto Scale Trend Time. Upon initiating active GDT tracking, the graphical trend time is automatically scaled to fit all tracked data for the current session within the plot. The initial Graphical Trend time scale value is set to 15 minutes and increases as tracking time expands beyond 15 minutes. **Auto Scale Trend Time** can be disabled through the set scales popup menu while in GDT mode.

---

* *While viewing active GDT tracking on the Graphical Trend Screen, parameter selection popup menus are disabled.*

Historical GDT

Press the Historical Data button to display recent GDT tracking sessions. A blue “Viewing Historical GDT Session” banner will appear at the bottom of the screen. Current parameter values are displayed on key parameter globes while viewing a historical GDT session. Touch the scroll buttons to view different historical GDT sessions.

SV Optimization

During SV Optimization mode, the SV/SVI target range for GDT tracking is selected based on recent SV trends. This allows the user to identify the optimal SV value during active monitoring of fluid management.

1 Touch the **GDT Tracking** button on the navigation bar.

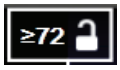
2 Select SV or SVI as a key parameter.

3 Do not specify a target value in the lower half of the parameter/target selection button. Touch **OK** to begin target selection.

4 Observe the SV trend while administering necessary fluid management to a achieve an optimal value.

5 Touch the Add Target button on the right side of the SV/SVI trend graph.The trend line will turn blue.

6 Touch within the plot area to view a trend line value. A target value button will appear along with an unlocked icon. A horizontal white dashed line will be displayed at 10% below the target cursor value. The area extending from this line to the top of the Y-axis will be shaded blue.



7 If desired, touch the Exit Target Selection button to return to monitoring of fluid management.

8 Touch the target value button to accept the displayed target range and initiate GDT tracking.

9 The edit target button can be touched at anytime after target selection to adjust the SV/SVI target value.

10 The GDT Tracking button can be touched at anytime when GDT mode is active to end the GDT tracking session.

GDT Report Download

The Data Download screen allows a user to export GDT reports to a USB drive. See Chapter 11: Data Download on page 11-2.

Chapter 10: Clinical Actions and Analysis

There are several tools that assist the user in evaluating patients. These include tools to compute derived parameters, perform event reviews and review patient data history from other EV1000 technologies.

Access all of these screens by touching the **Clinical Actions** button.

Zero & Waveform

Zero Heart Reference Sensor (HRS)

The **Zero & Waveform** screen allows the user to zero the HRS. The user is required to zero the HRS before initiating monitoring. See "Zero and Apply Heart Reference Sensor and Start Monitoring" on page 7-5 for more information.

Analog Pressure Out

The **Zero & Waveform** screen also allows the user to output the arterial waveform to a bedside patient monitor. See "Output Signal to Patient Monitor" on page 7-8 for more information.

Central Venous Pressure Manual Entry

The **CVP entry** screen allows the user to input a patient's CVP value to derive continuous SVR/SVRI calculation. See "Central Venous Pressure Manual Entry" on page 7-8.

Derived Value Calculator

The **Derived Value Calculator** lets the user compute a patient's DO_2, VO_2, SVR and CPO and provides a convenient way to display these parameters for a one-time calculation.

1 Touch the **Clinical Actions** button.

2 Touch **Derived Value Calculator**.

3 Enter the required values and the derived calculations will automatically display.

4 Touch the **Home** button to return to the monitoring screen.

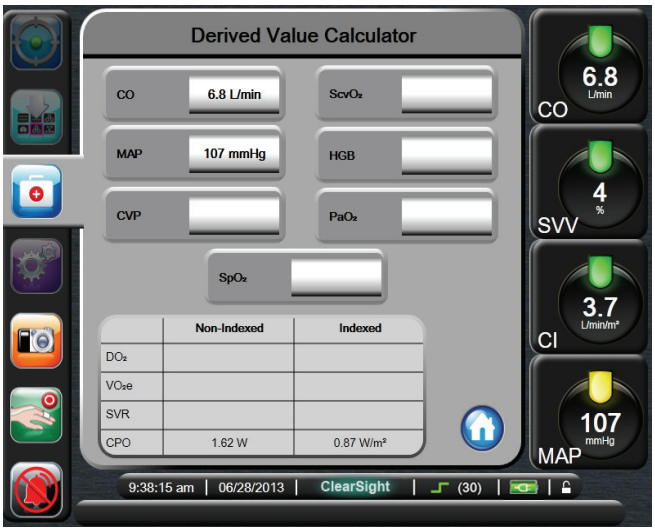


Figure 10-1 Derived Value Calculator

Event Review

Use **Event Review** to view parameter-related and system events that occurred during monitoring. Up to 72 hours of events are recorded in order with the most recent event at the top.

1 Touch the **Clinical Actions** button.

2 Touch **Event Review**.

Figure 10-2 Event Review

3 To scroll up or down, touch the arrow keys.

4 Touch the **Home** button to return to the monitoring screen.

The following events are included in the Event Review log.

Table 10-1 Reviewed Events

Event	Log Time
BSA Change	The BSA value changes from the previous BSA value (including when BSA goes to/from blank).
CO Reference Cleared	An entered CO reference value is cleared.
CO Reference Entered: <value><units>	A CO reference value is entered.
CO Reference Value	The ClearSight algorithm is calibrated by the user.
Cuff 1 Monitoring	Cuff 1 monitoring begins.
Cuff 2 Monitoring	Cuff 2 monitoring begins.
Cuff monitoring stopped due to 8 continuous hours with a single cuff	Monitoring for 8 continuous hours on a single Cuff has occurred.
Cuff Pressure Release	A Cuff pressure release has occurred.
Custom Event	A customized user event
CVP Entered	A CVP value is entered and the value is noted.
CVP Cleared	An entered CVP value is cleared.
GDT Session Started: #nn	A GDT Tracking Session is started. 'nn' is the GDT tracking session number for the current patient.
GDT Session Stopped: #nn	A GDT Tracking Session is stopped. 'nn' is the tracking session number for the current patient.
GDT Session Paused: #nn	A GDT Tracking Session is paused. 'nn' is the tracking session number for the current patient.
GDT Session Resumed: #nn	A GDT Tracking Session is resumed. 'nn' is the tracking session number for the current patient.
GDT Session Targets Updated: #nn; <pppp>:<qqq><uuu>,<...>	GDT Tracking Session targets are updated. 'nn' is the tracking session number for the current patient, <pppp> is the parameter whose target range <qqq> with units <uuu> was updated. <...> additional targets were updated.
Fluid Challenge	A Fluid Challenge intervention analysis is performed.
HRS Zeroed	HRS is zeroed by the user.
Intervention	An Intervention analysis is performed.
Intervention Analysis (IA) Updated	When user edits a previously entered intervention time, date, or note
Monitoring Paused	Active monitoring paused to prevent audible alarms and parameter monitoring.
Monitoring Resumed	Normal monitoring resumed. Audible alarms and parameter monitoring are active.
ClearSight Monitoring Started	The user begins noninvasive system monitoring.
ClearSight Monitoring Stopped	The user or system stops noninvasive system monitoring.
ClearSight Monitoring Resumed	When monitoring resumes after a cuff pressure release.
Physiocal Disabled	Physiocal is temporarily disabled.
Physiocal Enabled	Physiocal is resumed by the system or user after having been stopped by the user.
Position Challenge	When a Position Challenge Intervention Analysis is performed.
System Restart Recovery	System has resumed monitoring without prompt following a power cycle.
Technology Switch Occurred	Monitoring is switched from one technology mode to another.
Time Change	The system clock is updated.

Cuff Options

The **Cuff Options** screen allows the user to select the time interval between Cuff Pressure Release and the switching time interval for double cuff monitoring. Cuff and HRS status are also displayed. See "Cuff Options" on page 7-8.

Advanced Options

The Advanced Options screen provides **CO Calibration**. During CO calibration, a fixed average of the CO value (up to 5 minutes) is calibrated against a reference CO value input by the user. See "Cardiac Output Calibration" on page 7-9. The Advanced Options screen also allows the user to disable Physiocal for up to 1 minute. See "Physiocal Control" on page 7-10.

Historical Data

This screen displays historical trend data for the same patient from previous EV1000 technology measurements when available.

1 Touch the **Clinical Actions** button.

2 Touch the **More** button.

3 Touch **Historical Data** button.

4 Historic graphical trend data will display from before the technology switch.

---

* *Actively monitored values will not be displayed when viewing Historical Data.*

Chapter 11: Demonstration Mode and Data Download

Demonstration Mode is used to display simulated patient data to assist in training and demonstration.

Demonstration mode displays data from a stored set and continually loops through a predefined data set. During Demo Mode the EV1000 user interface retains the same functionality as a fully operational EV1000 platform. Simulated patient demographics must be entered to demonstrate ClearSight technology functions. The user can touch the controls as if a patient was being monitored.

The Pump-Unit and Databox Ethernet cables must be disconnected from the EV1000 Monitor in order to enter demonstration mode. The system will not run Demo Mode when there is communication with the Pump-Unit and/or Databox.

When Demo Mode is entered, trended data and events are cleared from being displayed and saved for return to patient monitoring.

1 Disconnect Ethernet communication cable(s) from the Monitor.

2 Touch the **Settings** button. 

3 Touch **Demo Mode**.

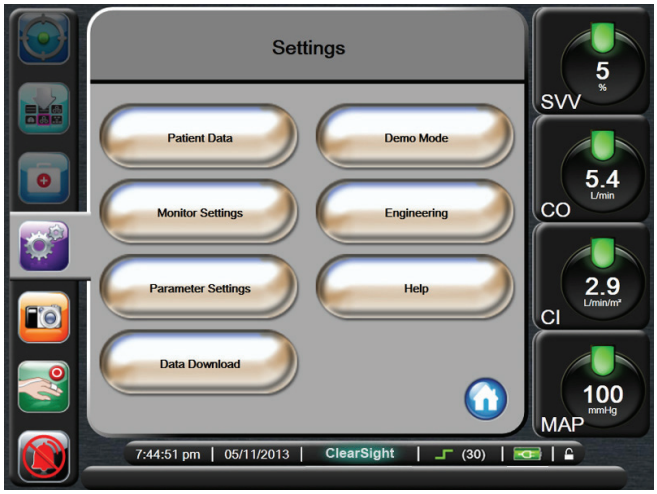


Figure 11-1 Settings Screen

* *When the EV1000 monitor runs in Demo Mode, all audible alarms are disabled.*

4 When the Demo Mode Confirmation Screen appears, the user has the option to demo the monitor in *FloTrac* mode, VolumeView mode or ClearSight mode. Select **ClearSight** and touch **Yes**.

Figure 11-2 Demo Mode

5 To initiate ClearSight continuous hemodynamic monitoring demonstration, simulate zeroing the HRS through the **Clinical Actions** screen. 

6 To start the display of continuous parameters touch the **Start Monitoring** button on the Navigation bar. 

7 The monitor must be restarted prior to monitoring a patient.

WARNING
Make sure that **Demo Mode** is not activated in a clinical setting to ensure that simulated data is not mistaken for clinical data.

Figure 11-3 Live Demo Banner

CAUTION
The **LIVE DEMO** mode can only be initiated by an Edwards sales representative and is different from **Demo Mode**. If a **LIVE DEMO** banner appears on the screen, as shown in Figure 11-3, discontinue use of the EV1000 Clinical Platform NI and contact your local sales representative.

Data Download

The Data Download screen allows the user to export monitored patient data to a USB device in Windows Excel XML 2003 format. This screen also exports Case Reports and GDT Reports in Adobe PDF format.

---

* *The screen will return to the monitoring view after two minutes of inactivity.*

---

1 Touch the **Settings** button.

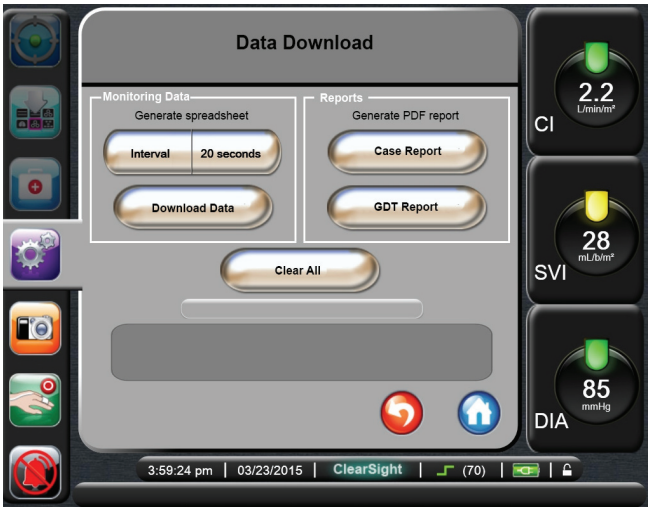


Figure 11-4 Data Download

2 Make sure an approved Edwards USB device has been inserted.

3 Touch **Data Download**.

Monitoring Data. To generate a spreadsheet of monitored patient data:

1 Touch the value side of the **Interval** button and select the frequency at which the data will be sampled for download. The shorter the frequency, the greater the amount of data. Options are:

- 20 seconds (default)
- 1 minute
- 5 minutes

2 Touch **Download Data**.

Case Report. To generate a report of key parameters:

1 Touch **Case Report**.

2 Select desired parameters from the Case Report popup menu.

3 Check **De-Identify** to exclude patient demographic data.

4 Touch Enter to export PDF

GDT Report. To generate a report of GDT tracking sessions:

1 Touch **GDT Report**.

2 Select desired GDT tracking session(s) from the GDT Report popup menu. Use the scroll buttons to select older tracking sessions.

3 Check **De-Identify** to exclude patient demographic data.

4 Touch Enter to export PDF

---

* *Do not disconnect the USB device until the message appears that the download is complete.*

If a message appears stating that the USB device is out of space, insert a different USB device and restart the download.

All monitored patient data may be cleared by the user if patient monitoring is stopped. Touch the **Clear All** button and confirm to clear.

CAUTION
Use Windows Embedded Standard 2009 compatible USB devices.

Chapter 12: Help and Troubleshooting

Use the information in this chapter to determine the cause and solution for error messages. This chapter also describes the Graphical Steps Help Screens which provide on screen instructions for device setup and monitoring.

On Screen Help

The main help screen allows the user navigate to specific help for ClearSight technology issues. Faults, alerts and warnings notify the user of error conditions affecting parameter measurements. Faults are technical alarm conditions that suspend parameter measurement. The category help screen provides specific assistance for faults, warnings, alerts, troubleshooting, device setup and monitoring.

1 Touch the **Settings** button.

2 Touch **Help** to access the main help screen.

Figure 12-1 Main Help Screen

3 Touch the **ClearSight** button.

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* *CO/SV, Oximetry, CVP and Thermodilution are not applicable Category Help Screens while using noninvasive ClearSight technology.*

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4 Touch the type of help needed: **Faults**, **Warnings**, **Alerts**, **Troubleshooting, Device Setup** or **Monitoring.** The problem type is listed at the top of the error message.

Figure 12-2 Category Help Screen

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* *To silence the audible fault alert, touch the* ***Silence Alarm*** *button. A new fault will generate a new tone.*

---

5 If **Faults** is selected, a new screen appears with a list of faults.

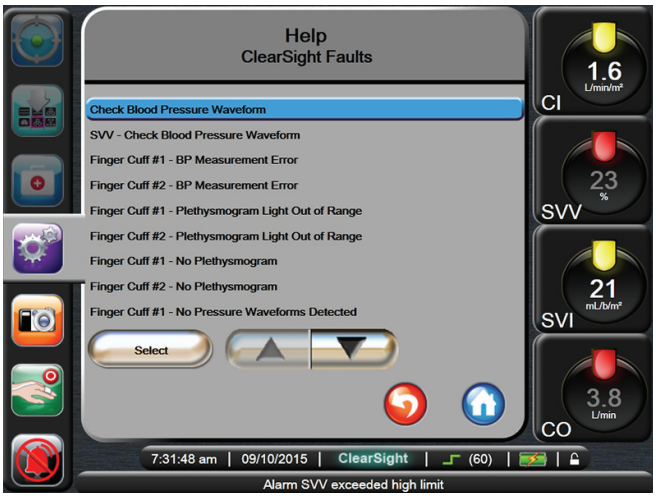


Figure 12-3 Secondary Help Screen

6 Touch a fault from the list and touch **Select** to access information for that fault. To view the full list of faults, use the arrow buttons to move the selection highlight up or down the list. The next screen displays the fault along with possible causes and suggested actions. See Figure 12-4, “Help Screen,” on page 12-2

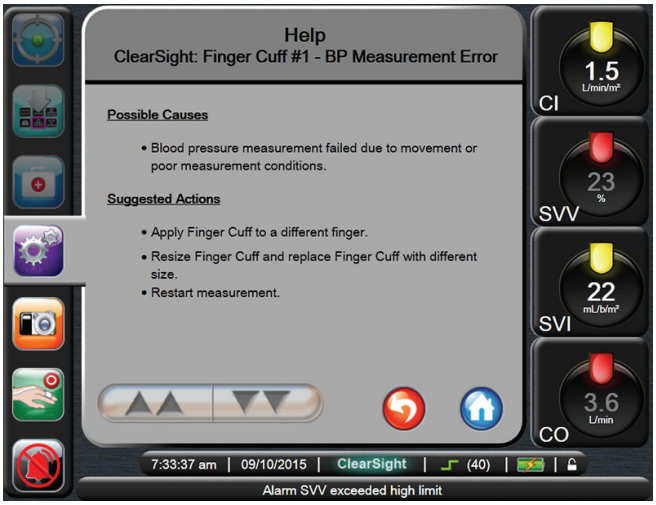


Figure 12-4 Help Screen

7 To capture a screen image, touch the **Snapshot** button.

** A USB drive must be attached for the snapshot feature to work.*

8 To return to the previous screen, touch the **Return** button.

9 Touch the **Home** button to return to the monitoring screen.

** The screen will return to the monitoring view after two minutes of inactivity.*

Graphical Steps Help Screen

Touch the **Device Setup** button or **Monitoring** button on the Category Help Screen for graphical assistance

Figure 12-5 Graphical Steps Help Screen

Touch the number that corresponds with the specific component of the system for which help is needed to view related detailed graphical step help screens.

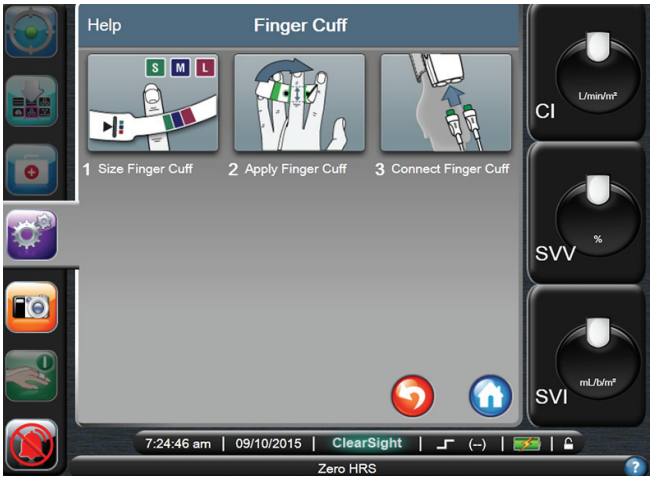


Figure 12-6 Example of Detailed Graphical Steps Help Screen

Pump-Unit Communication and Power

The Pump-Unit lights indicate the status of the system, communication with the Monitor, Pump-Unit battery and AC power. The Pump-Unit battery should not be removed or tampered with. The internal battery will charge automatically when the Pump-Unit is plugged into mains.

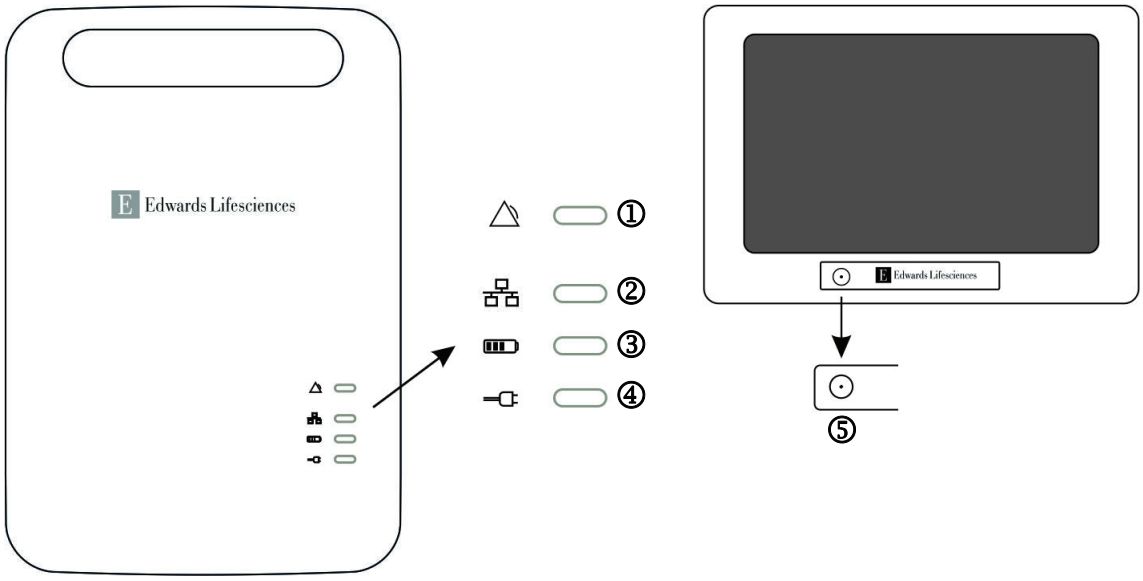


Figure 12-7 EV1000 Pump-Unit and Monitor LED Indicators

① Pump-Unit alert
② Ethernet communication status
③ Battery power status
④ AC power status
⑤ Monitor status

Table 12-1 Pump-Unit Communication and Power Lights

Condition	Color	Light Pattern	Suggested Action
① *PUMP-UNIT ALERT LIGHT*			
No Alarm	No light	Solid OFF	None
Alarm, severe error detected in the Pump-Unit.	Red	Flashing ON/OFF	Turn the power off by disconnecting the main power cord. The system will shut down in a few seconds. Disconnect and reconnect all cables and power on the system again using the monitor button. If the problem persists, contact Edwards Technical Support.
② *ETHERNET COMMUNICATION STATUS LIGHT*			
No Ethernet connection	No light	Solid OFF	Connect the Pump-Unit to the Monitor using the ethernet cable.
Ethernet communication active	Green	Solid ON	None
Ethernet communication error	Amber	Flashing ON/OFF	Check ethernet connections. If the problem persists, contact Edwards Technical Support.
③ *BATTERY POWER STATUS LIGHT*			
Battery charged	Green	Solid ON	None
Battery charging	Green	Fading ON/OFF	None
Battery power low	Amber	Solid ON	Connect the main power cable to charge battery.

Table 12-1 Pump-Unit Communication and Power Lights

Condition	Color	Light Pattern	Suggested Action
Battery power very low	Amber	Flashing ON/OFF	Connect the main power cable to charge battery. If the system is not connected to mains it will shut down in one minute. While connected to mains, the battery is not charged sufficiently to provide battery operation. Keep the system connected to mains to charge the battery.
④ *AC POWER STATUS LIGHT*			
AC Mains Plugged in	Green	Solid ON	None
AC Mains Disconnected	No light	Solid OFF	None
⑤ *MONITOR STATUS LIGHT*			
Monitor Power ON	Green	Solid ON	None
Monitor in STANDBY	Amber	Solid ON	Wait for the monitor to start up.
Monitor Power OFF	No light	Solid OFF	None

Pressure Controller Communication

The Pressure Controller lights indicate the status of the Clear-Sight Finger Cuff(s) and Heart Reference Sensor.

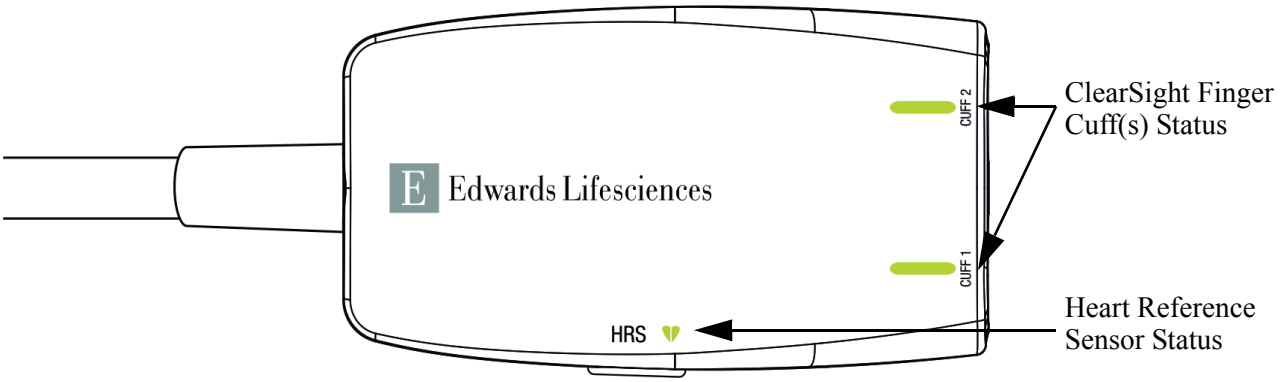


Figure 12-8 Pressure Controller LED Indicators

Table 12-2 Pressure Controller Communication Lights

Condition	Color	Light Pattern	Suggested Action
CUFF STATUS LIGHT			
No ClearSight Finger Cuff connected	No light	Solid OFF	None
ClearSight Finger Cuff connected	Green	Solid ON	None. The system is ready to start a measurement.
Active monitoring	Green	Flashing ON/OFF	None. The connected ClearSight Finger Cuff is actively monitoring.
Defective ClearSight Finger Cuff connected Expired ClearSight Finger Cuff connected Non Edwards Finger Cuff connected	Amber	Flashing ON/OFF	Verify that an Edwards Finger Cuff has been used. Disconnect and reconnect the ClearSight Finger Cuff. Replace the finger cuff with a genuine Edwards Cuff. Restart the measurement. If the problem persists, contact Edwards Technical Support.

Table 12-2 Pressure Controller Communication Lights

Condition	Color	Light Pattern	Suggested Action
Non Edwards Finger Cuff connected	No light	Solid OFF	Verify that an Edwards Finger Cuff has been used. Disconnect and reconnect the ClearSight Finger Cuff. Replace the finger cuff with a genuine Edwards Cuff. Restart the measurement. If the problem persists, contact Edwards Technical Support.
HEART REFERENCE SENSOR STATUS LIGHT			
No Heart Reference Sensor connected	No light	Solid OFF	None
Heart Reference Sensor connected	Green	Solid ON	None. The system is ready to start a measurement.
Defective Heart Reference Sensor connected Non Edwards Heart Reference Sensor detected	Amber	Flashing ON/OFF	Verify that an Edwards Heart Reference Sensor has been used. Disconnect and reconnect the Heart Reference Sensor. Replace the Heart Reference Sensor with a genuine Heart Reference Sensor. Restart the measurement. If the problem persists, contact Edwards Technical Support.

System Errors

Table 12-3 System Errors

Message	Possible Causes	Suggested Actions
Fault: Unsupported Power Configuration Detected	EV1000 Monitor connected to Pump-Unit is not powered by the same Pump-Unit. Databox connected to the EV1000 Monitor that is powered by a Pump-Unit, is not powered by the same Pump-Unit.	Ensure EV1000 monitor connected to Pump-Unit is powered by the same Pump-Unit. Ensure Databox connected to the EV1000 monitor that is powered by a Pump-Unit, is powered by the same Pump-Unit.
Fault: Databox Power Error[1]	A critical Databox power error was detected.	Disconnect Databox power cable and click continue to reset Databox power.[2] If the problem persists contact Edwards Technical Support.
Alert: Databox Power Error[1]	A critical Databox power error was detected.	Disconnect Databox power cable and click continue to reset Databox power. [2] If the problem persists contact Edwards Technical Support.
Fault: Incompatible Device Software Detected	EV1000 Databox or Pump-Unit connected to EV1000 Monitor has incompatible device software.	Contact Edwards Technical Support.
Fault: Second Pump-Unit detected	A second Pump-Unit is connected to the panel.	Disconnect the second Pump-Unit.
Fault: Patient Monitor Output Error	Internal system malfunction.	Power cycle the system.

*[1]Note: When a critical Databox power error is detected, the Databox Power Error is displayed as: An **Alert**, if Non-invasive CO technology is active. A **Fault,** if Minimally invasive CO technology is active.*

[2]Note: The power to Databox is turned off when a Databox Power Error is detected. Click Continue to turn on Databox Power Error popup and reconnect the Databox power cable to restart the Databox.

Numeric Keypad Errors

Table 12-4 Numeric Keypad Errors

Message	Possible Causes	Suggested Actions
Value out of range (xx-yy)	The entered value is either higher or lower than the allowed range.	Displayed when the user enters a value that is out of range. The range is displayed as part of the notification replacing the xx and yy.
Value must be ≤ xx	The entered value is in range, but is higher than the high value setting such as the high scale setting. xx is the associated value.	Enter a lower value.
Value must be ≥ xx	The entered value is in range, but is lower than the low value setting such as the low scale setting. xx is the associated value.	Enter a higher value.
Incorrect password entered	The password entered is incorrect.	Enter the correct password.
Please enter valid time	The time entered is invalid, i.e. 25:70.	Enter the correct time in 12- or 24-hour format.
Please enter valid date	The date entered is invalid, i.e. 33.13.009.	Enter the correct date.

ClearSight Faults and Alerts

Table 12-5 ClearSight Faults and Alerts

Message	Possible Causes	Suggested Actions
Fault: Invalid Finger Cuff #1 Connected	Non Edwards Finger Cuff #1 detected. Defective Finger Cuff #1 connected.	Verify that an Edwards Finger Cuff has been used. Disconnect and reconnect Edwards Finger Cuff #1. Replace Finger Cuff #1 with a genuine Edwards Cuff. Restart measurement. If problem persists, contact Edwards Technical Support.
Fault: Invalid Finger Cuff #2 Connected	Non Edwards Finger Cuff #2 detected. Defective Finger Cuff #2 connected.	Verify that an Edwards Finger Cuff has been used. Disconnect and reconnect Edwards Finger Cuff #2. Replace Finger Cuff #2 with a genuine Edwards Cuff. Restart measurement. If problem persists, contact Edwards Technical Support.
Fault: Finger Cuff Disconnected	Previously connected Finger Cuff(s) not detected.	Disconnect and reconnect Edwards Finger Cuff(s). Replace Finger Cuff (s). Restart measurement.
Fault: Finger Cuff #1 Error	Finger Cuff #1 defective. Poor connection between Finger Cuff #1 and Pressure Controller.	Disconnect and reconnect Edwards Finger Cuff #1. Replace Finger Cuff #1. Restart measurement. If problem persists, contact Edwards Technical Support.
Fault: Finger Cuff #2 Error	Finger Cuff #2 defective. Poor connection between Finger Cuff #2 and Pressure Controller.	Disconnect and reconnect Edwards Cuff #2. Replace Finger Cuff #2. Restart measurement. If problem persists, contact Edwards Technical Support.
Alert: Finger Cuff #1 Expiration in < 5 Minutes	Finger Cuff #1 approaching maximum use time.	Replace Finger Cuff #1 to ensure uninterrupted measurement.
Alert: Finger Cuff #1 Has Expired.	Finger Cuff #1 has exceeded maximum use time.	Replace Finger Cuff #1. Restart measurement.
Fault: Finger Cuff #1 Has Expired. Replace Cuff	Finger Cuff #1 has exceeded maximum use time.	Replace Finger Cuff #1. Restart measurement.
Alert: Finger Cuff #2 Expiration in < 5 Minutes	Finger Cuff #2 approaching maximum use time.	Replace Finger Cuff #2 to ensure uninterrupted measurement.
Alert: Finger Cuff #2 Has Expired	Finger Cuff #2 has exceeded maximum use time.	Replace Finger Cuff #2. Restart measurement.
Fault: Finger Cuff #2 Has Expired. Replace Cuff	Finger Cuff #2 has exceeded maximum use time.	Replace Finger Cuff #2. Restart measurement.
Fault: Accumulated Single Cuff Monitoring Has Reached The Duration Limit	Cumulative measurement on the same finger exceeded maximum duration of 8 hours.	Remove Cuff from finger. Place the Cuff on another finger and press 'Continue' on the Popup. Restart Measurement.
Fault: Check HRS Connection	HRS connection not detected.	Disconnect and reconnect Edwards HRS. Replace HRS.
Alert: HRS Out of Range	HRS incorrectly zeroed. HRS measurement exceeds allowed limit. HRS detached from Finger Cuff or phlebostatic axis. HRS is defective.	Rezero HRS. Verify HRS placement -The finger end should be attached to Finger Cuff and heart end should be placed at phlebostatic axis. Replace HRS. Restart Measurement.

Table 12-5 ClearSight Faults and Alerts (Continued)

Message	Possible Causes	Suggested Actions
Fault: HRS Out of Range	The HRS pressure offset exceeded limit during the zeroing process. Defective HRS.	Vertically align the two ends of HRS and re-zero. Replace HRS. If the problem persists, contact Edwards Technical Support.
Fault: HRS Has Expired. Replace HRS.	HRS has expired as it is past useful life.	Disconnect and reconnect Edwards HRS. Replace HRS. Restart Measurement. If problem persists, contact Edwards Technical Support.
Fault: Invalid HRS Connected	Non Edwards HRS detected. HRS is defective.	Verify that an Edwards HRS has been used. Disconnect and reconnect Edwards HRS. Replace HRS with a genuine Edwards HRS. Restart Measurement. If problem persists, contact Edwards Technical Support.
Fault: HRS Error	HRS is defective.	Disconnect and reconnect Edwards HRS. Replace HRS. Restart Measurement. If problem persists, contact Edwards Technical Support.
Fault: Pump-Unit Disconnected	Previously connected Pump-Unit not detected. Pump-Unit not powered on. Poor Ethernet connection. Damaged Ethernet cable. Defective Pump-Unit connected.	Confirm Pump-Unit connection. Confirm Pump-Unit powered on. Disconnect and reconnect Ethernet cable. Change Ethernet cable. If problem persists, contact Edwards Technical Support.
Fault: Invalid Pump-Unit Connected	Non Edwards Pump-Unit detected. Defective Pump-Unit connected.	Verify that an Edwards Pump-Unit has been used. Disconnect and re-connect Ethernet cable. Power cycle the system. Replace Pump-Unit. If problem persists, contact Edwards Technical Support.
Fault: Pump-Unit Error or Power Cable Error	Defective Pump-Unit. EV1000 Monitor not powered by Pump-Unit	Power cycle the system. Replace Pump-Unit. Power-off EV1000 Monitor. Connect EV1000 NI Power Cable to Pump-Unit and EV1000 Monitor. If problem persists, contact Edwards Technical Support.
Fault: Check Pressure Controller Connection	Pressure Controller connection not detected.	Disconnect and reconnect Edwards Pressure Controller. Replace Pressure Controller. If problem persists, contact Edwards Technical Support.
Fault: Invalid Pressure Controller Connected	Non Edwards Pressure Controller detected. Defective Pressure Controller connected.	Verify that an Edwards Pressure Controller has been used Disconnect and re-connect Edwards Pressure Controller Replace Pressure Controller with a genuine Edwards Pressure Controller If problem persists, contact Edwards Technical Support
Fault: Pressure Controller Error	Defective Pressure Controller. Poor connection between Pressure Controller and Pump-Unit.	Disconnect and re-connect Edwards Pressure Controller. Replace Pressure Controller. If problem persists, contact Edwards Technical Support.
Fault: Pressure Controller Communication Error	Unresponsive Pressure Controller. Poor connection between Pressure Controller and Pump-Unit. Defective Pressure Controller.	Disconnect and reconnect Edwards Pressure Controller Replace Pressure Controller If problem persists, contact Edwards Technical Support

Table 12-5 ClearSight Faults and Alerts (Continued)

Message	Possible Causes	Suggested Actions
Alert: Finger Cuff #1 - Plethysmogram Light Out of Range	Light signal too high.	Allow System to automatically resolve issue. Warm the hand. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size.
Alert: Finger Cuff #2 - Plethysmogram Light Out of Range	Light signal too high.	Allow System to automatically resolve issue. Warm the hand. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size.
Fault: Finger Cuff #1 - Plethysmogram Light Out of Range	Light signal too high.	Warm the hand. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size. Restart measurement.
Fault: Finger Cuff #2 - Plethysmogram Light Out of Range	Light signal too high.	Warm the hand. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size. Restart measurement.
Alert: Insufficient Pressure Build Up in Cuff #1 - Possible Air Leakage	Finger Cuff and/or Pressure Controller air tubes kinked. Finger Cuff bladder leaking. Poor connection between Pressure Controller and Pump-Unit.	Allow System to automatically resolve issue. Check Finger Cuff and Pressure Controller air tubes. Check Pressure Controller - Pump-Unit connection. Replace cuff.
Alert: Insufficient Pressure Build Up in Cuff #2 - Possible Air Leakage	Finger Cuff and/or Pressure Controller air tubes kinked. Finger Cuff bladder leaking. Poor connection between Pressure Controller and Pump-Unit.	Allow System to automatically resolve issue. Check Finger Cuff and Pressure Controller air tubes. Check Pressure Controller - Pump-Unit connection. Replace cuff.
Fault: Insufficient Pressure Build Up in Cuff #1 - Possible Air Leakage	Finger Cuff and/or Pressure Controller air tubes kinked. Finger Cuff bladder leaking. Poor connection between Pressure Controller and Pump-Unit.	Check Finger Cuff and Pressure Controller air tubes. Check Pressure Controller - Pump-Unit connection. Replace cuff. Restart measurement.
Fault: Insufficient Pressure Build Up in Cuff #2 - Possible Air Leakage	Finger Cuff and/or Pressure Controller air tubes kinked. Finger Cuff bladder leaking. Poor connection between Pressure Controller and Pump-Unit.	Check Finger Cuff and Pressure Controller air tubes. Check Pressure Controller - Pump-Unit connection. Replace cuff. Restart measurement.
Alert: Possibly Contracted Arteries	Very small arterial volume pulsations detected, possibly contracted arteries.	Allow System to automatically resolve issue. Warm the hand. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size.
Alert: Physiocal Currently Off	User Disabled Physiocal.	Wait 60 Seconds for reactivation of Physiocal. Re-enable Physiocal in Advanced Option Menu.
Alert: Finger Cuff #1 - No Pressure Waveforms Detected	The system failed to detect pressure waveforms. Pressure pulsations in finger diminished due to pressure applied to the upper arm, elbow or wrist.	Allow System to automatically resolve issue. Check if the blood flow in the arm of the patient is free of obstructions. Check the blood pressure waveforms. Reapply Finger Cuff(s).

Table 12-5 ClearSight Faults and Alerts (Continued)

Message	Possible Causes	Suggested Actions
Alert: Finger Cuff #2 - No Pressure Waveforms Detected	The system failed to detect pressure waveforms. Pressure pulsations in finger diminished due to pressure applied to the upper arm, elbow or wrist.	Allow System to automatically resolve issue. Check if the blood flow in the arm of the patient is free of obstructions. Check the blood pressure waveforms. Reapply Finger Cuff(s).
Fault: Finger Cuff #1 - No Pressure Waveforms Detected	The system failed to detect pressure waveforms. Pressure pulsations in finger diminished due to pressure applied to the upper arm, elbow or wrist.	Check if the blood flow in the arm of the patient is free of obstructions. Check the blood pressure waveforms. Reapply Finger Cuff(s). Restart measurement.
Fault: Finger Cuff #2 - No Pressure Waveforms Detected	The system failed to detect pressure waveforms. Pressure pulsations in finger diminished due to pressure applied to the upper arm, elbow or wrist.	Check if the blood flow in the arm of the patient is free of obstructions. Check the blood pressure waveforms. Reapply Finger Cuff(s). Restart measurement.
Alert: Finger Cuff #1 - Pressure Waveform Oscillations Detected	Possibly contracted arteries. Finger Cuff too loose.	Allow System to automatically resolve issue. Warm the hand. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size.
Alert: Finger Cuff #2 - Pressure Waveform Oscillations Detected	Possibly contracted arteries. Finger Cuff too loose.	Allow System to automatically resolve issue. Warm the hand. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size.
Alert: Finger Cuff #1 - No Plethysmogram	No measurable Plethysmogram detected on startup. Possibly contracted arteries.	Allow system to automatically resolve issue. Warm the hand. Apply Finger Cuff to a different finger.
Alert: Finger Cuff #2 - No Plethysmogram	No measurable Plethysmogram detected on startup. Possibly contracted arteries.	Allow system to automatically resolve issue. Warm the hand. Apply Finger Cuff to a different finger.
Fault: Finger Cuff #1 - No Plethysmogram	No measurable Plethysmogram detected on startup. Possibly contracted arteries.	Warm the hand. Apply Finger Cuff to a different finger. Restart measurement.
Fault: Finger Cuff #2 - No Plethysmogram	No measurable Plethysmogram detected on startup. Possibly contracted arteries.	Warm the hand. Apply Finger Cuff to a different finger. Restart measurement.
Alert: Finger Cuff #1 - BP Measurement Error	Blood pressure measurement failed due to movement or poor measurement conditions.	Allow system to automatically resolve issue. Apply Finger Cuff to a different finger Resize Finger Cuff and replace Finger Cuff with different size
Alert: Finger Cuff #2 - BP Measurement Error	Blood pressure measurement failed due to movement or poor measurement conditions.	Allow system to automatically resolve issue. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size.
Alert: Unable to Switch to Finger Cuff #1	Error detected in Finger Cuff #1. Error detected in Pressure Controller.	Allow System to automatically resolve issue. Check Finger Cuff and Pressure Controller air tubes. Check Pressure Controller - Pump-Unit connection. Replace Cuff. Replace Pressure Controller.

Table 12-5 ClearSight Faults and Alerts (Continued)

Message	Possible Causes	Suggested Actions
Alert: Unable to Switch to Finger Cuff #2	Error detected in Finger Cuff #2. Error detected in Pressure Controller.	Allow System to automatically resolve issue. Check Finger Cuff and Pressure Controller air tubes. Check Pressure Controller - Pump-Unit connection. Replace Cuff. Replace Pressure Controller.
Fault: Finger Cuff #1 - BP Measurement Error	Blood pressure measurement failed due to movement or poor measurement conditions.	Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size. Restart measurement.
Fault: Finger Cuff #2 - BP Measurement Error	Blood pressure measurement failed due to movement or poor measurement conditions.	Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size. Restart measurement.
Fault: Check Blood Pressure Waveform	Arterial waveform is inadequate to measure CO accurately. Poor pressure waveform over extended period of time. Systolic pressure too high or diastolic pressure too low.	Assess EV1000 system starting from patient leading to Finger Cuff and Pump-Unit. Check the arterial waveform for severe hypotension, severe hypertension, and motion artifact. Make sure the heart end of Edwards HRS is aligned with the patient's phlebostatic axis. Confirm electrical connections of cables. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size.
Alert: Unstable Blood Pressure Signal	Arterial waveform is inadequate to measure CO accurately. Systolic pressure too high or diastolic pressure too low.	Assess EV1000 system starting from patient leading to Finger Cuff and Pump-Unit. Check the arterial waveform for severe hypotension, severe hypertension, and motion artifact. Make sure the heart end of Edwards HRS is aligned with the patient's phlebostatic axis. Confirm electrical connections of cables. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size.
Fault: SVV - Check Blood Pressure Waveform	Arterial waveform is inadequate to measure SVV accurately. Poor pressure waveform over extended period of time. Frequent Physiocals within waveform. Systolic pressure too high or diastolic pressure too low.	Assess EV1000 system starting from patient leading to Finger Cuff and Pump-Unit. Check the arterial waveform for severe hypotension, severe hypertension, and motion artifact. Make sure the heart end of Edwards HRS is aligned with the patient's phlebostatic axis. Confirm electrical connections of cables. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size.
Fault: Battery Depleted	The battery is depleted and the system will shut down in 1 minute if not plugged in.	Connect EV1000 NI to an alternate source of power to avoid loss of power and resume monitoring.
Alert: Low Battery	The battery has less than 20% charge remaining or will be depleted within 8 minutes.	Connect EV1000 NI to an alternate source of power to avoid loss of power and continue monitoring.
Alert: Battery Information Unavailable	Previously connected Pump-Unit not detected. Poor Pump-Unit Ethernet connection.	Confirm Pump-Unit Ethernet connection. Disconnect and reconnect Pump-Unit Ethernet cable. Change Pump-Unit Ethernet cable. If problem persists, contact Edwards Technical Support.

ClearSight Warnings and Troubleshooting

Table 12-6 ClearSight Warnings

Message	Possible Causes	Suggested Actions
HRS Out of Range	The HRS pressure offset exceeded limit during the zeroing process. Defective HRS.	Vertically align the two ends of HRS and re-zero. Replace HRS. If the problem persists, contact Edwards Technical Support
HRS Zero Unsuccessful	Prior to zero, no HRS movement detected. During zero, HRS movement detected.	Disconnect and reconnect HRS. Vertically align the two ends of HRS Re-zero HRS. Minimize movement of HRS ends during zeroing process. Replace HRS and re-zero HRS. If problem persists, contact Edwards Technical Support.
Unstable Arterial Pressure	System detecting large variability in the arterial pressure due to physiological or artificial noise.	Ensure no external or artificial noise is interfering with arterial pressure measurements. Stabilize arterial pressure.
Large CO difference from Reference	A large difference is detected between the CO value and input Reference value.	Recalibrate the CO value. Perform another Reference measurement. Press Continue to proceed with user input Reference value.
Calibration time has been exceeded	The time between the completion of CO averaging and user input Reference value for calibration has exceeded system limits.	Perform a new CO calibration, ensuring a timely duration between the completion of CO averaging, and the acceptance of the Reference CO value.
Continuous Monitoring Has Reached The 72 Hour Limit	Continuous monitoring has reached the 72 hour limit.	Perform monitoring on opposite hand.

Table 12-7 ClearSight Troubleshooting

Message / Question	Possible Causes	Suggested Actions
Connect Finger Cuff	No Finger Cuff(s) detected. Defective Finger Cuff(s) connected.	Connect Finger Cuff(s). Replace Finger Cuff(s).
Finger Cuff #1 Approaching Maximum Use Time	Finger Cuff #1 approaching maximum use time.	Replace Finger Cuff #1 to ensure uninterrupted measurement.
Finger Cuff #2 Approaching Maximum Use Time	Finger Cuff #2 approaching maximum use time.	Replace Finger Cuff #2 to ensure uninterrupted measurement.
Connect HRS	HRS connection not detected.	Connect HRS. Replace HRS.
Zero HRS	HRS not zeroed.	Ensure HRS is connected and Zero HRS to Start Measurement.
Connect Pressure Controller	Pressure Controller not connected. Defective Pressure Controller connected.	Connect Pressure Controller. Replace Pressure Controller. If problem persists, contact Edwards Technical Support.
EV1000NI Use Not Recommended For Patient Age < 18 yrs	Non invasive BP measurement technology not validated for patients under 18 years of age.	Measurement with an alternate BP / Cardiac Output technology recommended.
Pump-Unit Service Required	Pump-Unit service time is approaching.	Replace Pump-Unit.

Table 12-7 ClearSight Troubleshooting

Message / Question	Possible Causes	Suggested Actions
Pressure Difference: ClearSight BP vs. Other BP	HRS detached from Finger Cuff or phlebostatic axis. HRS not properly zeroed. Possibly contracted arteries (due to cold fingers). Finger Cuff too loose. Other BP measurement device not zeroed. Other BP measurement sensor incorrectly applied.	Verify HRS placement -The finger end should be attached to Finger Cuff and heart end should be placed at phlebostatic axis. In case of invasive BP reference, HRS heart end and the transducer should be at the same level. Rezero HRS. Warm the hand. Reapply Finger Cuff (to a different finger) or replace Finger Cuff with proper size. Re-zero other BP measurement device. Remove and reapply other BP measurement sensor.
Service Battery	Battery full charge capacity has dropped below recommended level. Battery malfunction.	To ensure uninterrupted measurement, make certain EV1000 NI is connected to electrical outlet. Condition the battery (ensure a measurement is not active): • Connect Pump-Unit to an electrical outlet to fully charge battery. • Allow the battery to rest in fully charged state for at least two hours. • Disconnect the Pump-Unit from electrical outlet and continue to run the system on battery power. • EV1000 NI System will power down automatically when the battery is fully depleted. • Allow the battery to rest in fully depleted state for five hours or more. • Connect Pump-Unit to an electrical outlet to fully charge battery. • If the Service Battery message persists, replace Pump-Unit. Contact Edwards Technical Support to service Pump-Unit battery.
HRS Expires in <4 Weeks	HRS will expire in less than 4 weeks.	Replace HRS to prevent delay in start of monitoring.
HRS Expires in <2 Weeks	HRS will expire in less than 2 weeks.	Replace HRS to prevent delay in start of monitoring.

CVP Troubleshooting

Table 12-8 CVP Troubleshooting

Message	Possible Causes	Suggested Actions
SVR > SVRI	Incorrect patient BSA BSA < 1	Verify units of measure and values for patient's height and weight.
Enter CVP Value for SVR/SVRI Measurements	No CVP Value Entered.	Enter CVP value.

Chapter 13: EV1000 Clinical Platform NI Accessories

The EV1000 Clinical Platform NI offers various accessories. This chapter identifies and describes the use of some of the accessories available. Refer to Appendix A, Table A-4 for associated model numbers on all EV1000 Clinical Platform NI accessories.

Stands

All stands are compatible with the clamp supplied with your EV1000 system which is suitable for 19-38 mm poles only. Contact your Edwards representative on mounting carts, racks or other options.

EV1000 Table Stand

The EV1000 Table stand is intended for use with the EV1000 monitor and EV1000 Pump-Unit. The EV1000 Table stand comes pre-assembled (see Figure 13-1). Ensure rigidity of the stand by verifying that the post is securely mounted to the base. Place the table stand on a flat surface and securely mount the monitor and Pump-Unit to the pole.

Figure 13-1 EV1000 Table Stand

EV1000 Roll Stand

The EV1000 Roll Stand is intended for use with the EV1000 monitor and EV1000 Pump-Unit. Follow included directions for EV1000 Roll Stand assembly and warnings. Place the assembled roll stand on the floor, ensuring that all wheels are in contact with the floor, and securely mount the Monitor and Pump-Unit to the pole using the supplied clamps.

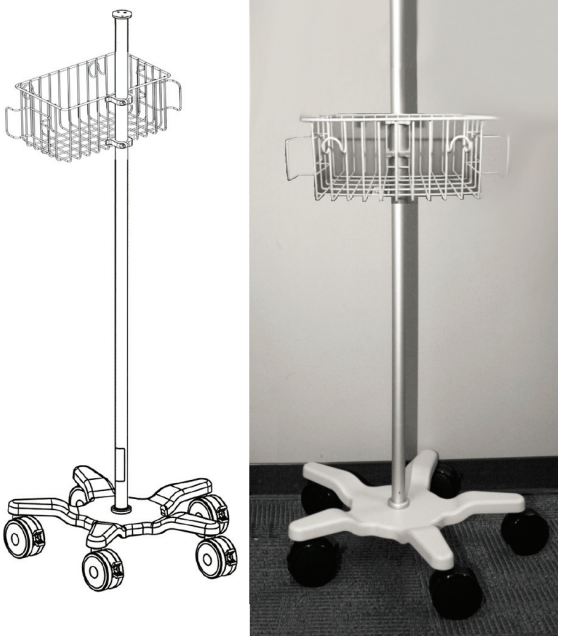


Figure 13-2 EV1000 Roll Stand

EV1000 Monitor Bracket

The EV1000 monitor bracket is intended for use with the EV1000 monitor. To install the monitor bracket to the rear panel of the monitor, align the 4-hole mounting pattern in the mounting bracket with the corresponding mounting pattern on the back of the EV1000 monitor. Securely fasten the bracket to the EV1000 monitor with the 4 screws provided (see Figure 13-4) using a torque of 10 lb·in. Once the monitor bracket is securely fastened to the EV1000 monitor, examine the monitor's exterior for general physical condition. Make sure the housing is not cracked, broken or dented.

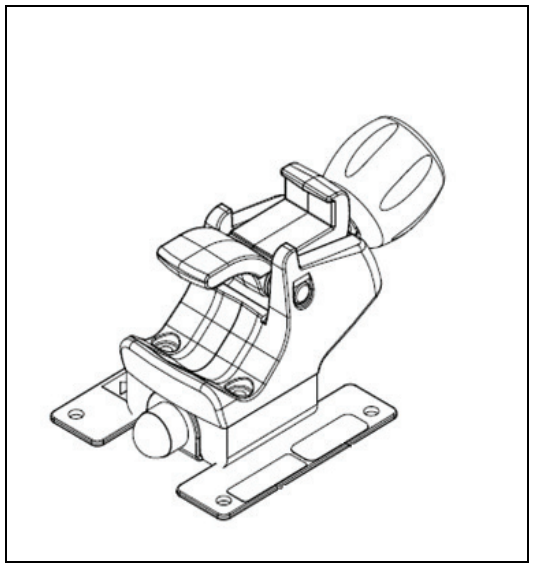


Figure 13-3 EV1000 Monitor Bracket

Figure 13-4 EV1000 Monitor and Monitor Bracket

EV1000 Monitor Types

EV1000 Monitor appearance and location of EV1000 Monitor cable connections shown throughout this operator's manual are for example only. Monitor appearance may vary as seen in Figure 13-5. New Monitors (Advantech Model, Figure 13-5, bottom row) have an additional cable cover and the location of the power button is located on the rear of the Monitor. Locations of cable connections may also vary between Monitor types as shown in Figure 13-6.

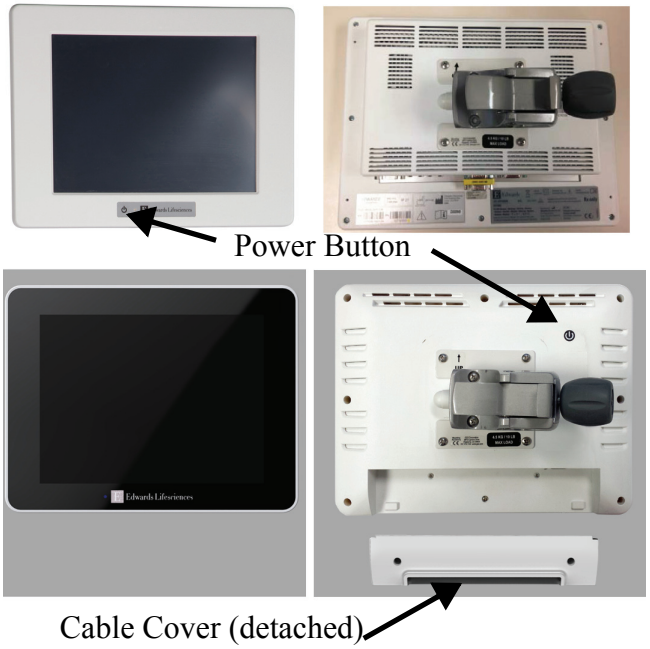


Figure 13-5 EV1000 Monitor Appearance and Location of Power Button

Figure 13-6 EV1000 Monitor Cable Connections

EV1000 Pump-Unit Bracket

The EV1000 Pump-Unit bracket is intended for use with the EV1000 Pump-Unit. The EV1000 Pump-Unit is supplied with the Pump-Unit Bracket attached. If installation is necessary, use all 4 screws provided to securely fasten the bracket on to the back panel of the Pump-Unit, similar to the EV1000 Monitor Bracket installation**.** Ensure that the Pump-Unit and bracket are stable and secure prior to mounting the post clamp to an IV Pole, post or approved roll stand.

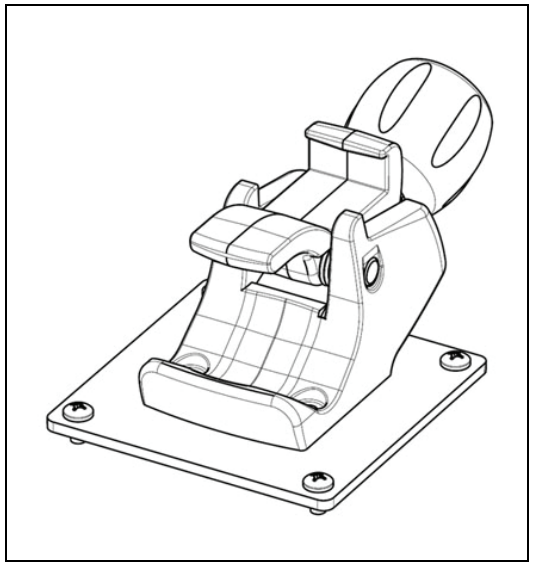


Figure 13-7 EV1000 Pump-Unit Bracket

WARNING
Make sure the EV1000 Clinical Platform NI is securely mounted, and that all cords and accessory cables are appropriately arranged to minimize the risk of injury to patients, users or the equipment. Refer to directions on proper setup.

WARNING
Only use ClearSight Finger Cuffs, Heart Reference Sensor and other EV1000 Noninvasive System accessories, cables and or components that have been supplied and labeled by Edwards. Using other unlabeled accessories, cables and or components may affect patient safety and measurement accuracy.

WARNING
The Pump-Unit must be positioned in an upright position to ensure IP4X ingress protection.

Chapter 14 : EV1000 Clinical Platform NI Advanced Features

The EV1000 Clinical Platform NI provides users with the opportunity to upgrade the EV1000 system with advanced features and usability. For more information regarding these features, contact your local sales representative or Edwards Technical Services. See Appendix E, for contact information.

HIS Connectivity

The EV1000 system has the ability to interface with the Hospital Information Systems (HIS) to send and receive patient demographics and physiological data. The EV1000 system supports Health Level 7 (HL7) messaging standard and implements Integrating Healthcare Enterprise (IHE) profiles. HL7's version 2.x messaging standard is the most commonly used means for electronic data exchange in the clinical domain. The EV1000 HL7 communication protocol, also referred to as HIS Connectivity, facilitates the following types of data exchanges between the EV1000 monitor and external applications and devices:

- Sending of physiological data from the EV1000 system to the HIS and/or medical devices
- Sending of physiological alarms and device faults from the EV1000 system to the HIS
- EV1000 system retrieval of patient data from the HIS.

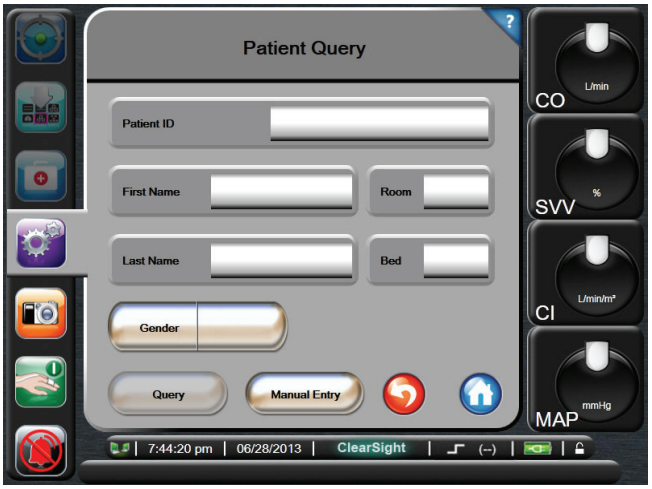


Figure 14-1 HIS- Patient Query

Patient Demographic Data

The EV1000 system, with HIS Connectivity enabled can retrieve patient demographics data from enterprise application. Once the HIS Connectivity feature is enabled, the Patient Query screen allows the user to search for a patient based on name, patient ID or room and bed information. The Patient Query screen can be used to retrieve patient demographics data when starting a new patient or to associate the patient physiological data being monitored on the EV1000 system with a patient record retrieved from HIS.

Once a patient is selected form the query results, patient demographics data is displayed in the New Patient Data screen.

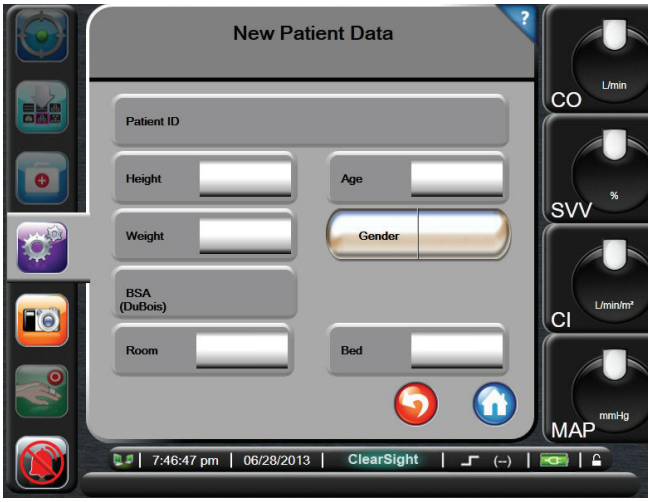


Figure 14-2 HIS- New Patient Data Screen

The user can enter or edit patient height, weight, age, gender, room and bed information on this screen. The selected or updated patient data can be saved by touching the Home button. Once patient data is saved, the EV1000 system generates unique identifiers for the selected patient and sends out this information in outbound messages with physiological data to the enterprise applications.

Patient Physiological Data

The EV1000 system can send monitored and calculated physiological parameters in outbound messages. Outbound messages can be sent to one or more configured enterprise

applications. Continuously monitored and calculated parameters with the EV1000 Clinical Platform NI can be sent to the enterprise application:

Physiological Alarms and Device Faults

The EV1000 system can send physiological alarms and device faults to configure HIS. Alarms and faults can be sent to one or more configured HIS. Statuses of individual alarms including change in states are sent out to the enterprise application.

For more information on how to receive access to HIS Connectivity, contact your local Edwards Representative or Edwards Technical Services.

Goal Positioning Screen

The Goal Positioning Screen allows the user to monitor and track the relationship of two key parameters by plotting them against each other on an XY plane.

A single, pulsating blue dot represents the intersection of the two parameters and moves in real time as parameter values change. The additional circles represent the historical parameter trend with the smaller circles indicating older data.

The green target box represents the intersection of the green parameter target zone. The red arrows on the X and Y axis represent the parameter alarm limits.

If not activated, the user must first enable the screen via the Monitoring Screen Navigation Bar Menu.

1 Touch the **Settings** button.

2 Touch **Monitor Settings**.

3 Touch **Advanced Features.**

The platform requires the user to enter a password to enable the Advanced Features. Please contact your local Edwards Representative for more information on enabling these Advanced Features.

Once the screen is enabled, the user can access the screen via the Monitor Screen Selection button.

1 Touch the **Monitor Screen** selection button.

2 Touch the circled number **2, 3**, or **4** representing the number of key parameters to be displayed on the monitoring screen.

3 Touch the **Goal Positioning Screen** button.

Parameter Selection

The user can select the parameters for the X and Y axis.

1 Touch outside the globe on the top parameter. The currently selected Y axis parameter appears highlighted in color and other displayed parameters are outlined in color.

2 If the currently selected Y-axis parameter is not desired, touch which parameter should appear on the Y axis.

The user can change the X axis by applying the same steps to the 2nd parameter globe.

Trend, Target and Alarm Customization.

To adjust the time interval between the historical trend circles, touch the trend interval icon displayed on the screen.

To turn the trend interval icon **On/Off**, touch within the X/Y plane.

To adjust the green box and red arrows, access the target menu by touching inside the corresponding parameter globes.

To adjust the scale of the X or Y axis, touch along the corresponding axis.

If the current intersection of parameters moves outside the scale of the X/Y plane, a message will appear indicating this to the user.

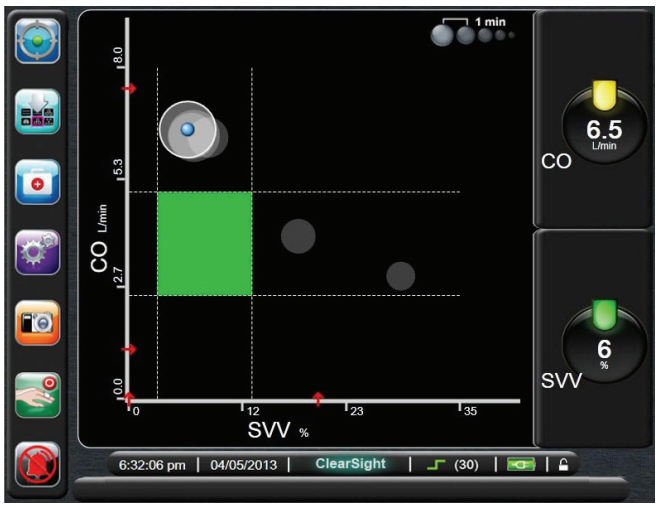


Figure 14-3 Goal Positioning Screen

Technology Selection

The EV1000 NI Databox Adaptor Cable enables clinicians to monitor a patient's hemodynamic parameters via a streamlined power supply configuration. The EV1000 Pump-Unit is equipped with a battery backed power supply to allow uninterrupted monitoring using both Platforms during power loss. See Chapter 5: Battery on page 5-10 for information on Pump-Unit battery status.

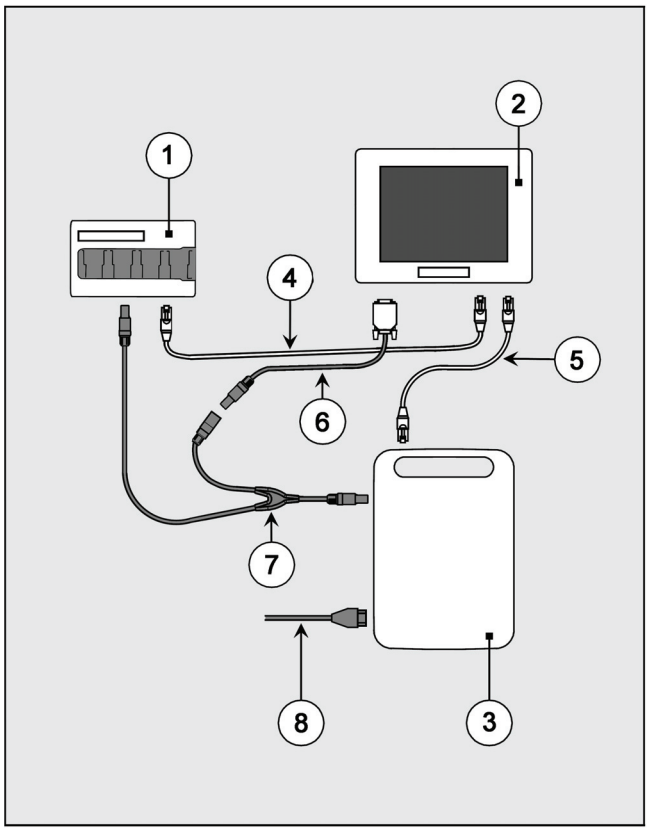


Figure 14-4 EV1000 NI Databox Adaptor Cable Power Connections

① EV1000 Databox
② EV1000 Monitor
③ EV1000 Pump-Unit
④ Ethernet Cable from Databox to Monitor
⑤ Ethernet Cable from Pump-Unit to Monitor
⑥ EV1000 NI Power Cable
⑦ EV1000 NI Databox Adaptor Cable
⑧ Mains Power Cable (Detachable Power Cord)

WARNING
The EV1000 Clinical Platform NI meets the requirements of IEC 60601-1:2005 for the system configurations described in this manual. Connecting external equipment or configuring the system in a way not described in this manual may not meet this standard.

CAUTION
The system power status information, including battery information, is only displayed on EV1000 Monitor when the Pump-Unit is connected to the EV1000 Monitor with the supplied Ethernet cable.

EV1000 NI Databox Adaptor Cable Connection

Refer to the schematic overview shown in Figure 14-4 for cable connections. After the Monitor, Pump-Unit and Databox are securely mounted, attach the Mains Power Cable to the back panel of the Pump-Unit. Use the EV1000 NI Power Cable and Databox Adaptor Cable to connect the Pump-Unit to the Monitor and Databox. Use two Ethernet Cables to connect the Pump-Unit with the Monitor and the Databox with the Monitor.

If the EV1000 Databox fails turn on, when the EV1000 NI is powered on, check the Databox Adapter cable connections. If the problem persists, call Edwards Technical Support.

Do not use the EV1000 Power Adapter to power the Databox in this configuration. Ensure the Databox is powered by the same Pump-Unit powering the EV1000 Monitor.

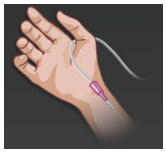
Technology Selection Screen

The Technology Selection screen can be accessed by touching the technology logo located at the center of the information bar.

From this screen, the user can select from connected monitoring technologies.

Non-Invasive Technology Button. The user can select this button for **non-invasive** hemodynamic monitoring using ClearSight technology.

Minimally-Invasive Technology Button. The user can select this button for **minimally-invasive** hemodynamic monitoring using *FloTrac*, VolumeView, or Oximetry technologies.



* *Please refer to the EV1000 Clinical Platform Operator's Manual for instructions on minimally-invasive monitoring using the EV1000 Databox including cleaning, connection of patient cables, patient monitoring, and warranty information.*

To continue, touch the Enter button. The **Zero & Waveform** screen of the selected technology will then appear.

WARNING

EV1000 Databox and EV1000 Monitor power must be supplied through the same Pump-Unit when using integrated noninvasive and minimally-invasive technologies for patient monitoring.

Appendix A: Specifications

The EV1000 Clinical Platform NI measures blood pressure and Cardiac Output (CO) when used with the Heart Reference Sensor, Pressure Controller and Clear-Sight Finger Cuff(s).

Appendix A includes summaries of the following:

- Physical and Mechanical Specifications
- Environmental Specifications
- Base Parameter Specifications
- Accessories for use with the EV1000 Clinical Platform NI
- Technical Specifications

Table A-1 Physical and Mechanical Specifications

Monitor		
Weight	2.1 kg (4.6 lbs)	
Dimensions	Height	226 mm
	Width	296 mm
	Depth	58.6 mm
Display	Active Area	257 mm (10.4”)
	Resolution	800 x 600 LCD
Operating System	Windows XPe	
Speaker count	2	
Monitor (Advantech Model)		
Weight	2 kg (4.4 lbs)	
Dimensions	Height	217 mm
	Width	280 mm
	Depth	46 mm
Display	Active Area	266 mm (10.4”)
	Resolution	1024 x 768 LCD
Operating System	Windows XPe	
Speaker count	2	
Pump-Unit		
Weight (with Bracket)	3.1 kg (6.8 lbs)	
Dimensions (with Bracket)	Height	280 mm
	Width	195 mm
	Depth	165 mm
Pressure Controller		
Weight	0.35 kg (0.77 lbs)	
Dimensions	Height	97 mm
	Width	54 mm
	Depth	35 mm
	Cable Length	3.5 m

Table A-1 Physical and Mechanical Specifications

Heart Reference Sensor		
Weight	36 g (0.08 lbs)	
Dimensions	Length	1.2 m
ClearSight Finger Cuff		
Maximum Weight	11g (0.02 lbs)	
LED Spectral Irradiance	See Figure A-1	
Max Optical Output over treatment area	0.013 mWatts	
Max variation of output over treatment area	50%	

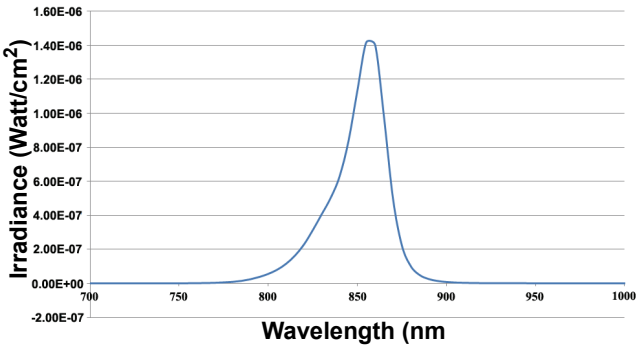


Figure A-1 Spectral Irradiance

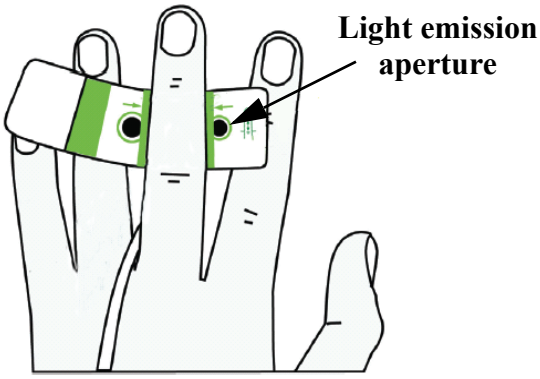


Figure A-2 Location of Light Emission Aperture

Table A-2 Environmental Specifications

EV1000 Clinical Platform NI		Value
Temperature	Operation	10 to 37° C
	Storage and Transportation	0 to 45° C
Relative Humidity	Operation	15% to 85% non-condensing
	Storage and Transportation	10% to 95% non-condensing
Altitude	Operation	0 meter to 3,000 meter (9,843 ft)
	Storage and Transportation	-396 meter (-1,300ft) to 6,000 meter (19,685 ft)

Table A-3 Base Parameters

Parameter	Specification	
Finger Cuff Pressure	Display Range	0 to 300 mmHg
	Accuracy[1]	1% of full scale (max 3 mmHg)
CO	Display Range	1.0 to 20.0 L/min
	Accuracy	Bias ≤ ± 0.6 L/min or ≤ 10% (whichever is greater). Precision (1σ) ≤ ± 20% over the range of Cardiac Output from 2 to 20 L/min
	Reproducibility[2]	±6%
	Update Rate	20 seconds

[1]Accuracy tested under laboratory conditions compared to a calibrated pressure gauge.
[2]Coefficient of variation - measured using electronically generated data

Accessories

WARNING
Only use ClearSight Finger Cuffs, Heart Reference Sensor and other EV1000 Noninvasive System accessories, cables and or components that have been supplied and labeled by Edwards. Using other unlabeled accessories, cables and or components may affect patient safety and measurement accuracy.

Table A-4 EV1000 Clinical Platform NI Components

Description	Model Number
EV1000 System	
EV1000 Clinical Platform	EV1000A
EV1000 Clinical Platform NI	EV1000NI
EV1000 NI Upgrade	EVNIUPG

Table A-4 EV1000 Clinical Platform NI Components

Description	Model Number
EV1000 Monitor	
Monitor	EV1000M
Monitor Bracket	EVMB1
EV1000 Panel Cover	EV1000CVR
EV1000 Pump-Unit	
Pump-Unit	EVPMP
Pump-Unit Bracket	EVPMPBRKT
EV1000 Noninvasive Peripheral Hardware	
Pressure Controller Kit	PC2K
Pressure Controller	PC2
Pressure Controller Band Multi Pack	PC2B
Pressure Controller Cuff Connector Cap	PC2CCC
Heart Reference Sensor	EVHRS
EV1000 NI System Cables	
Mains Power Cable	*
EV1000 NI Power Cable, 3 Feet	EVNIPCL3
EV1000 NI Power Cable, 12 Feet	EVNIPCL12
EV1000 NI Patient Monitor Adaptor Cable	EVPMAC
EV1000 Ethernet Cable, 3 Feet	EVEC3FT
EV1000 Ethernet Cable, 12 Feet	EVEC12FT
EV1000 NI Databox Adaptor Cable	EVNIDBAC
EV1000 Stands	
EV1000 Table Stand	EVS1
EV1000 Roll Stand	EVRS
Additional EV1000 NI Accessories	
ClearSight Finger Cuff Small Multi Pack	CSCS
ClearSight Finger Cuff Medium Multi Pack	CSCM
ClearSight Finger Cuff Large Multi Pack	CSCL
Heart Reference Sensor Body Pads	EVHRSBP
EV1000 NI Panel SW Upgrade	EVNISWUPG
EV1000 Clinical Platform NI Operator's Manual	**
EV1000 Clinical Platform NI Service Manual	**

* Please contact your Edwards representative for model and ordering information.
**Please contact your Edwards representative for the most current version.
Note: Accessories provided with an "R" suffix, indicate refurbished products.

Table A-5 EV1000 Monitor Technical Specifications

Input/Output	
Touch Screen	Resistive type
RS232 Serial Port	Edwards proprietary protocol; Maximum data rate = 57.6 kilo baud
USB Port	Three USB V1.1 compatible type A connectors on the monitor.
RJ-45 Ethernet Port	Two
VGA Port	One
Electrical	
Voltage	24V, 1.8A max

Table A-6 EV1000 Pump-Unit Technical Specifications

Electrical	
Voltage	100 to 240 Volts AC 50/60 Hz
Power Consumption	100 VA, maximum
Protection against electric shock	Class I equipment

Appendix B: Equations for Calculated Patient Parameters

This section describes the equations used to calculate continuous patient parameters displayed on the EV1000 monitor.

* *Patient parameters are calculated to more decimal places than are displayed on the screen. For example, a screen CO value of 2.4 may actually be a CO of 2.4492. Consequently, attempts to verify the accuracy of the monitor's display using the following equations may produce results that are slightly different from the data computed by the monitor.*

* *SI = Standard International Units*

Table B-1 Cardiac Profile Equations

Parameter	Description and Formula	Units
BSA	Body Surface Area (DuBois formula) $BSA = 71.84 \times (WT^{0.425}) \times (HT^{0.725}) / 10{,}000$ where: WT - Patient Weight, kg HT - Patient Height, cm	m^2
CaO_2	Arterial Oxygen Content $CaO_2 = (0.0138 \times HGB \times SpO_2) + (0.0031 \times PaO2)$ (mL/dL) $CaO_2 = [0.0138 \times (HGBSI \times 1.611) \times SpO_2] + [0.0031 \times (PaO_2SI \times 7.5)]$ (mL/dL) where: HGB – Total Hemoglobin, g/dL HGBSI – Total Hemoglobin, mmol/L SpO_2 – Arterial O2 Saturation, % PaO_2 – Partial Pressure of Arterial Oxygen, mmHg PaO_2SI – Partial Pressure of Arterial Oxygen, kPa	mL/dL
CvO_2	Venous Oxygen Content $CvO_2 = (0.0138 \times HGB \times SvO_2) + (0.0031 \times PvO_2)$ (mL/dL) $CvO_2 = [0.0138 \times (HGBSI \times 1.611) \times SvO_2] + [0.0031 \times (PvO_2SI \times 7.5)]$ (mL/dL) where: HGB – Total Hemoglobin, g/dL HGBSI – Total Hemoglobin, mmol/L SvO_2 – Venous O_2 Saturation, % PvO_2 – Partial Pressure of Venous Oxygen, mmHg PvO_2SI – Partial Pressure of Venous Oxygen, kPa and PvO_2 is assumed to be 0	mL/dL
$Ca\text{-}vO_2$	Arteriovenous Oxygen Content Difference $Ca\text{-}vO_2 = CaO_2 - CvO_2$ (mL/dL) where: CaO_2 – Arterial Oxygen Content (mL/dL) CvO_2 – Venous Oxygen Content (mL/dL)	mL/dL

Table B-1 Cardiac Profile Equations (Continued)

Parameter	Description and Formula	Units
CI	Cardiac Index CI = CO/BSA where: CI - Cardiac Index, CO - Cardiac Output, L/min BSA - Body Surface Area, m^2	$L/min/m^2$
CPI	Cardiac Power Index CPI = MAP x CI x 0.0022	W/m^2
CPO	Cardiac Power Output CPO = CO x MAP x *K* where: Cardiac power output (CPO) (W) was calculated as MAP x cardiac output/451 *K* is the conversion factor (2.22×10^{-3}) into watts MAP in mmHg CO L/min	W
DO_2	Oxygen Delivery $DO_2 = \{(1.38 \times HGB \times SpO_2) + (0.31 \times PaO_2)\} \times CO$ $\frac{\qquad\qquad\qquad\qquad\qquad\qquad\qquad\qquad}{10}$ where: CO - Cardiac Output, L/min HGB - Total Hemoglobin, g/dL PaO_2 - Partial Pressure of Arterial Oxygen, mmHg SpO_2 - Pulse Oximetry Saturation %	mL O_2/min
DO_2I	Oxygen Delivery Index $DO_2I = \frac{\{(1.38 \times HGB \times SpO_2) + (0.31 \times PaO_2)\} \times CO}{10 \times BSA}$ where: BSA - Body Surface Area, m^2 CO - Cardiac Output, L/min HGB - Total Hemoglobin, g/dL PaO_2 - Partial Pressure of Arterial Oxygen, mmHg SpO_2 - Pulse Oximetry Saturation	mL $O_2/min/m^2$
SV	Stroke Volume SV = (CO/PR) x 1000 where: CO - Cardiac Output, L/min PR - Pulse rate, beats/min	mL/beat
SVI	Stroke Volume Index SVI = (CI/PR) x 1000 where: CI - Cardiac Index, $L/min/m^2$ PR - Pulse rate, beats/min	$mL/beat/m^2$
SVR	Systemic Vascular Resistance SVR = {(MAP - CVP) x 80} /CO ($dyne\text{-}s/cm^5$) where: MAP - Mean Arterial Pressure, mmHg CVP - Central Venous Pressure, mmHg CO - Cardiac Output, L/min	$dyne\text{-}s/cm^5$

Table B-1 Cardiac Profile Equations (Continued)

Parameter	Description and Formula	Units
SVRI	Systemic Vascular Resistance Index SVRI = {(MAP - CVP) x 80} /CI where: MAP - Mean Arterial Pressure, mmHg CVP - Central Venous Pressure, mmHg CI - Cardiac Index, L/min/m^2	dyne-s-m^2/cm^5
SVV	Stroke Volume Variation SVV = 100 x (SVmax - SVmin) / mean(SV)	%
VO_2	Oxygen Consumption VO_2 = Ca-vO_2 x CO x 10 (mL O_2/min) where: Ca-vO_2 – Arteriovenous Oxygen Content Difference, mL/dL CO – Cardiac Output, L/min	mL O_2/min
VO_2e	Estimated Oxygen Consumption when $ScvO_2$ is being monitored and used to calculate Ca-vO_2 instead SvO_2 VO_2e = Ca-vO_2 x CO x 10 (mL O_2/min) where: Ca-vO_2 – Arteriovenous Oxygen Content Difference, mL/dL CO – Cardiac Output, L/min	mL O_2/min
VO_2I	Oxygen Consumption Index VO_2 / BSA	mL O_2/min/m^2
VO_2Ie	Estimated Oxygen Consumption Index VO_2 e/ BSA	mL O_2/min/m^2

Appendix C: Monitor Settings and Defaults

Patient Data Input Range

Table C-1 Patient Information

Parameter	Minimum	Maximum	Available Units
Gender	**M** (Male) / **F** (Female)	N/A	N/A
Age	2	120	years
Height	12 in / 30 cm	98 in / 250 cm	inches (in) or cm
Weight	2 lbs / 1.0 kg	880 lbs / 400.0 kg	lbs or kg
BSA	0.08	5.02	m^2
ID	0 digits	12 digits	None

Trend Scale Default Limits

Table C-2 Graphical Trend Parameter Scale Defaults

Parameter	Units	Minimum Default Value	Maximum Default Value	Setting Increment
CO	L/min	0.0	12.0	1.0
CI	$L/min/m^2$	0.0	12.0	1.0
SV	mL/b	0	160	20
SVI	$mL/b/m^2$	0	80	20
SVV	%	0	50	10
SVR	$dyne\text{-}s/cm^5$	500	1500	100
SVRI	$dyne\text{-}s\text{-}m^2/cm^5$	500	3000	200
SYS	mmHg	80	160	5
DIA	mmHg	50	110	5
MAP	mmHg	50	130	5
PR	bpm	40	130	5

Parameter Display and Configurable Alarm/Target Ranges

Table C-3 Ranges for Key Parameters

Parameter	Units	Range
CO	L/min	1.0 to 20.0
CI	$L/min/m^2$	0.0 to 20.0
SV	mL/b	0 to 300
SVI	$mL/b/m^2$	0 to 200
SVR	$dyne\text{-}s/cm^5$	0 to 5000
SVRI	$dyne\text{-}s\text{-}m^2/cm^5$	0 to 9950
SVV	%	0 to 99
MAP*	mmHg	10 to 300
SYS*	mmHg	10 to 300
DIA*	mmHg	10 to 300
PR	Bpm	0 to 220

** Display range for MAP, SYS and DIA is 0 to 300 mmHg*

Alarm and Target Defaults

Table C-4 Parameter Alarm Red Zone and Target Defaults

Parameter	Units	EW Default Lower Alarm (Red Zone) Setting	EW Default Lower Target Setting	EW Default Upper Target Setting	EW Default Upper Alarm (Red Zone) Setting
CI	$L/min/m^2$	1.0	2.0	4.0	6.0
SVI	$mL/b/m^2$	20	30	50	70
SVRI	$dyne\text{-}s\text{-}m^2/cm^5$	1000	1970	2390	3000
SVV	%	0	0	13	20
SYS	mmHg	90	100	130	150
DIA	mmHg	60	70	90	100
MAP	mmHg	60	70	100	120
PR	bpm	60	70	100	120

Language Default Settings*

Table C-5 Language Default Settings

Language	Default Display Units				Time Format	Date Format
	PaO_2	HGB	Height	Weight		
English (US)	mmHg	g/dL	in	lbs	12 hour	MM/DD/YYYY
English (UK)	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY
Français	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY
Deutsch	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY
Italiano	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY
Español	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY
Svenska	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY
Nederlands	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY
Ελληνικά	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY
Português	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY
日本語	mmHg	g/dL	cm	Kg	24 hour	MM/DD/YYYY
中文	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY
Čeština	kPa	mmol/l	cm	kg	24 hour	DD.MM.YYYY
Polski	kPa	mmol/l	cm	kg	24 hour	DD.MM.YYYY
Suomi	kPa	mmol/l	cm	kg	24 hour	DD.MM.YYYY
Norsk	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY
Dansk	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY
Eesti	mmHg	mmol/L	cm	kg	24 hour	DD.MM.YYYY
Lietuvių	mmHg	g/dl	cm	kg	24 hour	DD.MM.YYYY
Latviešu	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY
Note: Temperature defaults to Celsius for all languages.						

* *Languages listed above are for reference only and may not be available for selection.*

Appendix D: EV1000 Unit Conversions

lbs vs. kg

Conversion factors: lb → kg ⇨ lb ÷ 2.2
kg → lb ⇨ kg x 2.2

inches vs. cm

Conversion factors: inches → cm ⇨ inches x 2.54
cm → inches ⇨ cm ÷ 2.54

mmHg vs. kPa

1 mmHg = (1mmHg) x $\left(\frac{(Newton)/m^2}{0.0075 mmHg}\right) \times \left(\frac{Pa}{(Newton)/m^2}\right) \times \left(\frac{1kPa}{1000Pa}\right) = \left(\frac{1kPa}{7.5mmHg}\right)$

or 7.5 mmHg = 1 kPa

Conversion factors: mmHg → kPa ⇨ mmHg ÷ 7.5
kPa → mmHg ⇨ 1 kPa x 7.5

g/dL vs. mmol/L (hemoglobin)

1 g/dL = $\left(\frac{1g}{dL}\right)$ x $\left(\frac{1mol}{64,458g}\right)$ x $\left(\frac{1000mmol}{mol}\right)$ x $\left(\frac{10dL}{1L}\right)$ x 4 = $\left(\frac{0.6206mmol}{1}\right)$

1 dyne–s/cm^5=
or
1 mmol/L = $\left(\frac{g/(dL)}{0.6206}\right)$

Conversion factors: g/dL → mmol/L ⇨ g/dL x 0.6206
mmol/L → g/dL ⇨ mmol/L ÷ 0.6206

°F vs. °C

°F = °C x 1.8 + 32

°C = $\frac{°F-32}{1.8}$

Appendix E: System Care, Service and Support

The EV1000 Clinical Platform NI contains no user-serviceable parts, and should be repaired only by qualified service representatives. It is recommended to perform a yearly pressure calibration check and send the EV1000 Clinical Platform NI to a qualified Edwards Service Center for routine service and preventive maintenance checks every two years. Contact your local Edwards Lifesciences representative for more information.

This appendix provides instructions for cleaning the monitor and system accessories and contains information on how to contact your local Edwards representative for support and information on maintenance, repair and/or replacement.

WARNING
The EV1000 Clinical Platform NI, cables and sensors contain no user-serviceable parts. Removing the cover or any other disassembly will expose you to hazardous voltages.

Cleaning the EV1000 Clinical Platform NI

Clean any exposed surfaces of the EV1000 Clinical Platform NI with a cloth dampened with any of the following cleansers and disinfectants.

- 70% isopropyl alcohol solution
- 10% Sodium Hypochlorite water solution

WARNING
Shock or fire hazard! Do not immerse the EV1000 monitor, Pump-Unit, Pressure Controller or Cables in any liquid solution. Do not allow any fluids to enter the instrument.

WARNING
DO NOT:

- Allow any liquid to come in contact with the power connector
- Allow any liquid to penetrate connectors or openings in the case

If any liquid does come in contact with any of the above mentioned items, DO NOT attempt to operate the platform. Disconnect power immediately and call your Biomedical Department or local Edwards Representative.

Cleaning the Monitor and Pump-Unit

Use a lightly dampened cloth to clean the surface of the monitor and Pump-Unit. If necessary, use the previously specified disinfectants.

CAUTION
Clean and store the instrument and accessories after each use.

CAUTION
Lightly wipe the top, bottom and front surfaces with a cloth, but the monitor screen and its accessories MUST NOT have liquid poured or sprayed directly on them. Do not expose the instrument to excessive moisture. Excessive moisture can cause the device to perform inaccurately or fail.

Cleaning the System Cables and Accessories

The system cables, pressure controller and Heart Reference Sensor can be cleaned using the specified disinfectants previously mentioned. Sterile alcohol preps containing 70% alcohol solution can also be used to clean the EV1000 Clinical Platform NI and other accessory cables.

* *The Heart Reference Sensor is designed for limited re-use with an expected useful life of 3 months given proper care and handling.*

WARNING
Refer to cleaning instructions. Do not disinfect the instrument by autoclave or gas sterilization.

CAUTION
Conduct periodic inspections of all cables for defects. Do not coil cables tightly when storing.

1. Moisten a clean cloth with disinfectant and wipe the surfaces.
2. Dry the surface with a clean dry cloth.

The Pressure Controller Band is intended for limited reuse. The operator shall assess whether reuse is appropriate. When reused, the cleaning and disinfectant agents can be use as specified in *Cleaning the EV1000 Clinical Platform NI*.

** The ClearSight Finger Cuff is designed for single patient use only. Do not attempt to clean and reuse the ClearSight Finger Cuff on more than a single patient.*

Cleaning the Patient Cables and Connectors

The patient cables contains electrical and mechanical components and is therefore subject to normal use wear and tear. Visually inspect the cable insulation jacket, strain relief and connectors before each use. If any of the following conditions are present, discontinue use of the cable.

- Broken insulation
- Frays
- Connector pins are recessed or bent.
- Connector is chipped and/or cracked.

The patient cables are not protected against fluid ingress. To clean, wipe the cable with a damp, soft cloth using 10% bleach and 90%water solution as needed and then air dry the connector. Please contact Technical Support or your local Edwards Representative for further assistance.

WARNING
Do not use damaged components/sensors or components/sensors with exposed electrical contacts to prevent patient or user shocks.

CAUTION
Do not use any damaged system components. Use of a damaged system component may result in inaccurate measurements or may damage the EV1000 Clinical Platform NI.

CAUTION
If any electrolytic solution, for example NaCl or lactated Ringer's solution, is introduced into the cable connectors while they are connected to the platform, the excitation voltage can cause electrolytic corrosion and rapid degradation of the electrical contacts.

CAUTION
Do not immerse any cable connectors in fluid or use a hot air gun to dry cable connectors. Refer to cleaning instructions.

Service and Support

See the *Troubleshooting* chapter for diagnosis and remedies. If this information does not solve the problem, contact Edwards Lifesciences.

Edwards provides monitor operations support:

- Within the United States and Canada, call 1.800.822.9837.
- Outside the United States and Canada, contact your local Edwards Lifesciences representative.
- E-mail operational support questions to tech_support@edwards.com.

Have the following information before you call:

- The serial number of the Monitor, Pump-Unit and Pressure Controller, located on the rear panel of these units.
- Software version which is displayed at the bottom of the screen during monitor initialization;

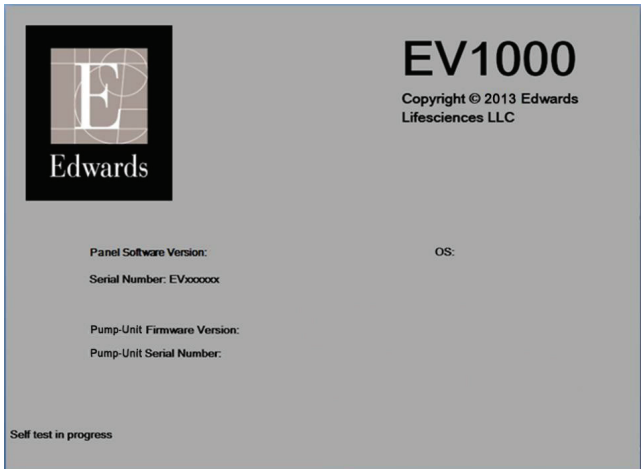


Figure E-1 Startup Screen

- The text of any error message and detailed information as to the nature of the problem.

** Figure E-1 is an example of the Startup screen.*

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System Disposal

To avoid contaminating or infecting personnel, the environment or other equipment, make sure the Monitor, Pump-Unit and/or cables are disinfected and decontaminated appropriately in accordance with your country's laws for equipment containing electrical and electronic parts prior to disposal.

For single use parts and accessories, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

CAUTION
This product contains batteries. If you no longer need to use this product, protect the environment by bringing it to your local distributor or designated collection point for proper disposal.

Preventive Maintenance

Before every use, it is recommended that all exterior housing be checked for cracks, dents and other signs of damage. In addition, check the condition of all cables, especially for exposed wire, splits, cracks, or signs of stress. If damage is evident contact your local Edwards' representative. Check all mountings to ensure that they are secure.

It is recommended to send the EV1000 Clinical Platform NI to a qualified Edwards Service Center for routine service and preventive maintenance checks every two years. It is recommended to perform a yearly pressure calibration check. Additional testing includes a visual inspection, a software inspection, safety testing and functional testing. For more information on the testing contact your local Edwards Lifesciences representative.

The Pump-Unit has an internal battery that should not be removed or tampered with. The internal battery will charge automatically when the Pump-Unit is plugged into mains. The Pump-Unit should be plugged in at least every 3 months to recharge the internal battery.

Warranty

Edwards Lifesciences (Edwards) warrants that the EV1000 Monitor, Pump-Unit and Pressure Controller are fit for the purposes and indications described in the labeling for a period of one (1) year from the date of purchase when used in accordance with the directions for use. Unless equipment is used in accordance with such instructions, this warranty is void and of no effect. No other express or implied warranty exists, including any warranty of merchantability or fitness for a particular purpose. This warranty does not include the Heart Reference Sensor, Pressure Controller Band, ClearSight Finger Cuffs, or any cables used with the EV1000 NI system. Edwards' sole obligation and purchaser's exclusive remedy for breach of any warranty shall be limited to repair or replacement of the EV1000 system at Edwards' option.

Edwards shall not be liable for proximate, incidental, or consequential damages. Edwards shall not be obligated under this warranty to repair or replace a damaged or malfunctioning EV1000 system if such damage or malfunction is caused by the customer's use of patient sensors other than those manufactured by Edwards.

Appendix F: Guidance and Manufacturer's Declaration

Electromagnetic Compatibility

Reference: IEC/EN 60601-1-2:2007

The EV1000 Clinical Platform NI is intended for use in the electromagnetic environment specified below. The customer or the user of the EV1000 Clinical Platform NI should assure that it is used in such an environment.

Table F-1 List of Accessories, Cables and Sensors Necessary for Compliance

Description	Length
EV1000 Pressure Controller cable	11.5 ft 3.5 m
HRS cable	4.0 ft 1.2 m
ClearSight Finger Cuff, Small	7.1 in 18 cm
ClearSight Finger Cuff, Medium	7.9 in 20 cm
ClearSight Finger Cuff, Large	8.7 in 22 cm
EV1000 NI Power cable	3.3 ft or 11.5 ft 1.0 m 3.5 m
EV1000 Ethernet cable	3.3 ft or 11.5 ft 1.0 m 3.5 m
Mains Power cable	USA EU 10 ft 8.2 ft 3.1 m 2.5 m
EV1000 Patient Monitor Adaptor cable	6.0 in 15 cm
EV1000 NI Databox Adaptor cable	3.9 ft 1.2 m
When connected to the Databox, the following apply:	
FloTrac Cable	12.2 in or 17 ft 31.0 cm or 5.2 m
FloTrac Sensor	12.2 in 31 cm
EV1000 VolumeView Thermodilution Cable	7.75 ft 236 cm

Instructions for Use

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following information and tables.

WARNING
Use of accessories, sensors, and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity.

WARNING
No modification of the EV1000 Clinical Platform NI is allowed.

WARNING
The EV1000 Clinical Platform NI should not be used adjacent to, or stacked with other equipment. If adjacent or stacked use is necessary, the EV1000 Monitor, Databox and Pump-Unit should be observed to verify normal operation in the configuration in which it is used.

WARNING
Portable and mobile RF communication equipment can potentially affect all electronic medical equipment, including the EV1000.
Guidance on maintaining appropriate separation between communications equipment and the EV1000 is provided in Table F-3.

CAUTION
The instrument has been tested and complies with the limits of IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Consult the manufacturer for help.

Table F-2 Electromagnetic Emissions

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The EV1000 Clinical Platform NI is intended for use in the electromagnetic environment specified below. The customer or user of the EV1000 Clinical Platform NI should assure that it is used in such an environment.		
Emissions	**Compliance**	**Description**
RF emissions CISPR 11	Group 1	The EV1000 Clinical Platform NI uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class A	The EV1000 Clinical Platform NI is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuation/ Flicker emissions IEC 61000-3-3	Complies	

Table F-3 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the EV1000 Clinical Platform NI

The EV1000 Clinical Platform NI is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. To help prevent electromagnetic interference, maintain a minimum distance between portable and mobile RF communications equipment (transmitters) and the EV1000 Clinical Platform NI as recommended below, according to the maximum output power of the communications equipment.

Transmitter Frequency	**150 kHz to 80 MHz**	**80 to 800 MHz**	**800 to 2500 MHz**
Equation	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
Rated Maximum Output Transmitter Power (watts)	**Separation Distance (meters)**	**Separation Distance (meters)**	**Separation Distance (meters)**
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.8	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table F-4 Electromagnetic Immunity (ESD, EFT, Surge, Dips and Magnetic Field)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment -Guidance
The EV1000 Clinical Platform NI is intended for use in the electromagnetic environment specified below. The customer or user of the EV1000 Clinical Platform NI should assure that it is used in such an environment.			
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact	±6 kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±8 kV air	±8 kV	
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for 1 kV for input/output lines > 3 meters	±2 kV for power supply lines ±1 kV for 1 kV for input/output lines > 3 meters	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	
	±2 kV line(s) to earth	±2 kV line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply AC input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	<5% U_T	Mains power quality should be that of a typical commercial or hospital environment. If the EV1000 Clinical Platform NI user requires continued operation during power mains interruptions, it is recommended that the EV1000 Clinical Platform NI be powered by an uninterruptible power supply or battery.
	40%U_T (60% dip in U_T) for 5 cycles	40% U_T	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T	
	<5% U_T (>95% dip in U_T)for 5 sec	<5% U_T	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Table F-5 Electromagnetic Immunity (RF Radiated and Conducted)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
The EV1000 Clinical Platform NI is intended for use in the electromagnetic environment specified below. The customer or user of the EV1000 Clinical Platform NI should assure that it is used in such an environment.			
Conducted RF IEC 61000-4-6	3 Vms150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communication equipment should be used no closer to any part of the EV1000 platform, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance *d* = [1.2] x $\sqrt{P}$; 150 kHz to 80 MHz *d* = [1.2] x $\sqrt{P}$; 80 MHz to 800 MHz *d* = [2.3] x $\sqrt{P}$; 800 MHz to 2500 MHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m80 to 2500 MHz	3 V/m	

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EV1000 Clinical Platform NI is used exceeds the applicable RF compliance level above, the EV1000 Clinical Platform NI should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EV1000 Clinical Platform NI.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix G: Glossary

Alarms
Audible and visual indicators that notify operator that a measured patient parameter is outside the alarm limits.

Alarm Limits
Maximum and minimum values for monitored patient parameters.

Blood Pressure (BP)
Blood pressure measured from the ClearSight Finger Cuff.

Body Surface Area (BSA)
The calculated surface area of a human body.

Button
A screen image that, when touched, initiates an action or provides access to a menu.

Cardiac Index (CI)
Cardiac output adjusted for body size.

Cardiac Output (CO)
Volume of blood ejected per minute from the heart into the systemic circulation measured in liters per minute.

Central Venous Oxygen Saturation ($ScvO_2$)
Percentage of hemoglobin saturated with oxygen in the venous blood as measured in the superior vena cava (SVC). Displayed as $ScvO_2$.

Central Venous Pressure (CVP)
The average pressure in the superior vena cava measured from the TruWave sensor.

Databox
A central input of multiple physiologic minimally invasive signal sources which communicates with the EV1000 Monitor. The Databox can only be operated separately from the Pump-Unit.

Default Settings
Initial operating conditions assumed by the system.

Estimated Oxygen Consumption (VO_2e)
An expression of the estimated rate at which oxygen is used by tissues, usually given in mL/min of oxygen consumed in 1 hour by 1 milligram dry weight of tissue. Calculated with $ScvO_2$.

Diastolic Pressure (DIA)
Diastolic pressure measured from the reconstructed brachial arterial waveform.

Hemoglobin (HGB)
Oxygen carrying component of red blood cells. Volume of red blood cells measured in grams per deciliter.

Heart Reference Sensor (HRS)
A system used for compensation of hydrostatic pressure due to differences in height between the finger and heart.

Icon
An image that represents a specific screen, window, file, or program.

Intervention
Steps taken to change a patient's condition.

Mean Arterial Pressure (MAP)
Average systemic arterial blood pressure.

Mixed Venous Oxygen Saturation (SvO_2)
Percentage of hemoglobin saturated with oxygen in the venous blood as measured in the pulmonary artery. Displayed as SvO_2.

Oxygen Consumption (VO_2)
An expression of the rate at which oxygen is used by tissues, usually given in mL/min of oxygen consumed in 1 hour by 1 milligram dry weight of tissue. Calculated with SvO_2.

Oxygen Delivery (DO_2)
Amount of oxygen in milliliters per minute (mL/min) delivered to the tissues.

Oxygen Delivery Index (DO_2I)
Amount of oxygen in milliliters per minute ($mL/min/m^2$) delivered to the tissues, adjusted for body size.

Oximetry (Oxygen Saturation, $ScvO_2/SvO_2$)
Percentage of hemoglobin saturated with oxygen in the blood.

Phlebostatic Axis
Reference axis in the patient that passes through the patient's right atrium in any anatomical plane.

Physiocal
A physiological calibration procedure used to obtain accurate blood pressure readings from the artery of the finger.

Plethysmograph Sensor

A device built into the ClearSight Finger Cuff that measures fluctuations of volume within the finger artery

Pressure Controller (PC2)

The unit worn on the patient's wrist that connects the Heart Reference Sensor and ClearSight Finger Cuffs to the Pressure Unit.

Pump-Unit (PMP)

The central input and output for pressure signals from noninvasive hemodynamic measurement which communicates with the EV1000 Monitor.

Pulse Rate (PR)

Number of arterial blood pressure pulses per minute.

Stroke Volume (SV)

Amount of blood ejected from the ventricles with each contraction.

Stroke Volume Index (SVI)

Stroke volume adjusted for body size.

Stroke Volume Variation (SVV)

Stroke volume variation is the percent difference between minimum and maximum stroke volume.

Systemic Vascular Resistance (SVR)

A derived measure of impedance to blood flow from left ventricle (afterload).

Systemic Vascular Resistance Index (SVRI)

Systemic vascular resistance adjusted for body size.

Systolic Pressure (SYS)

Systolic pressure measured from the reconstructed brachial arterial waveform.

USB

Universal Serial Bus.

Volume Clamp Method

Arterial blood volume is kept constant using the signal from the photo-plethysmograph and a rapidly changing pressure in the air bladder.

Index

W

Y

Z

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information.

Edwards Lifesciences devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

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