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.

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>EV1000 Clinical Platform NI Overview: Provides an overview of the EV1000 Clinical Platform NI.</td>
</tr>
<tr>
<td>2</td>
<td>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.</td>
</tr>
<tr>
<td>3</td>
<td>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.</td>
</tr>
<tr>
<td>4</td>
<td>EV1000 Clinical Platform NI Quick Start: Provides experienced clinicians and users of bedside patient monitors instructions for immediate monitor use.</td>
</tr>
<tr>
<td>5</td>
<td>Navigating the EV1000 Clinical Platform NI: Provides information on how to use the touch screen and monitoring cables.</td>
</tr>
<tr>
<td>6</td>
<td>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.</td>
</tr>
<tr>
<td>7</td>
<td>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.</td>
</tr>
<tr>
<td>8</td>
<td>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.</td>
</tr>
<tr>
<td>9</td>
<td>Enhanced Parameter Tracking: The EV1000 Clinical Platform NI provides tools to aid in Goal Directed Therapy.</td>
</tr>
<tr>
<td>10</td>
<td>Clinical Actions and Analysis: Describes information about using the EV1000 Clinical Platform NI to compute derived parameters, perform event reviews and other advanced options.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Specifications</td>
</tr>
<tr>
<td>B</td>
<td>Equations for Calculated Patient Parameters</td>
</tr>
<tr>
<td>C</td>
<td>Monitor Settings and Defaults</td>
</tr>
<tr>
<td>D</td>
<td>EV1000 Unit Conversions</td>
</tr>
<tr>
<td>E</td>
<td>System Care, Service and Support</td>
</tr>
<tr>
<td>F</td>
<td>Guidance and Manufacturer’s Declaration</td>
</tr>
<tr>
<td>G</td>
<td>Glossary</td>
</tr>
</tbody>
</table>

Index
Contents

Chapter 1: EV1000 Clinical Platform NI Overview
  ClearSight™ Technology Noninvasive Arterial Pressure and Cardiac Output Monitoring ........................................... 1-1
  Monitored Parameters .......................................................... 1-1
  Indications for Use .................................................................. 1-1
  Cyber Security ........................................................................ 1-2
  HIPAA ............................................................................... 1-2
  Acronyms and Abbreviations .................................................... 1-3

Chapter 2: Safety and Symbols
  Safety Identifying Symbols ..................................................... 2-1
  Warnings ......................................................................... 2-1
  Cautions ........................................................................... 2-4
  Monitor Display Symbols ..................................................... 2-6
  Symbols on Product Labels ..................................................... 2-7
  Applicable Standards ............................................................. 2-9
    EV1000 NI Essential Performance ........................................ 2-9
  Documentation and Training .................................................. 2-9

Chapter 3: Unpacking and Initial Setup
  Unpacking ........................................................................ 3-1
    Contents List .................................................................... 3-1
    Parameter Monitoring Accessories ..................................... 3-1
  Monitor and Pump-Unit Installation ....................................... 3-1
    Mounting Recommendations ............................................. 3-2
    Connecting the Monitor and Pump-Unit .............................. 3-2
  Connecting the Patient Cables ............................................... 3-4
  Initial Startup .................................................................... 3-4
    Select Language ................................................................ 3-5

Chapter 4: EV1000 Clinical Platform NI Quick Start
  ClearSight Technology Blood Pressure and Hemodynamic Monitoring ................................................... 4-1
    Zero and Apply Heart Reference Sensor (HRS) .................. 4-2
    Alarms and Targets ........................................................... 4-3
    Central Venous Pressure Manual Entry (For SVR and SVRI calculations) .................................................. 4-3

Chapter 5: Navigating the EV1000 Clinical Platform NI
  Navigation Bar .................................................................... 5-1
  Monitor Views ................................................................... 5-2
    Change Parameters .......................................................... 5-3
    Change Alarm / Target ...................................................... 5-3
    Graphical Trend Monitoring View ....................................... 5-3
    Arterial Waveform (ART) Display ....................................... 5-3
    Intervention Events .......................................................... 5-4
    Graphical Trend Scroll Mode ............................................. 5-5
    Historic Graphical Trend Screen ........................................ 5-5
Tabular Trends
Tabular Trend Scroll Mode
Big Numbers
Physiology Screen
Cockpit Screen
Goal Positioning Screen
Physio Relationship
Status Indicators
Monitor Screen Navigation
Vertical Scrolling
Information Bar
Physiocal Interval
Battery
Lock Screen
Status Bar

Chapter 6: Monitor Display Options

Patient Data
New Patient
Continue Monitoring Patient
View Patient Data

Monitoring Settings
General Monitor Settings
Change Date and Time Display
Adjust Date or Time
Monitoring Screens Settings
Serial Port Setup
Restore Monitor Defaults

Parameter Settings
Alarms / Targets
Silence Alarms
Set Alarm Volume
Set Targets
Alarms / Targets Setup Screen
Configure All Targets
Set Custom Defaults
Configure Targets and Alarms for One Parameter
Time Intervals / Averaging
Adjust Scales
Engineering

Chapter 7: Methodology and Monitoring

EV1000 Noninvasive System Methodology
Volume Clamp Method
Physiocal Method
Waveform Reconstruction and Hemodynamic Analysis (ClearSight Algorithm)
Heart Reference Sensor
Discoloration, Numbness, or Tingling of the Fingertip
Single Cuff Monitoring
Double Cuff Monitoring

Connect the Patient Sensors
Apply the Pressure Controller
Select ClearSight Finger Cuff Size .............................................. 7-4
Apply the ClearSight Finger Cuff ............................................. 7-4

Enter Patient Data ................................................................. 7-5
Zero and Apply Heart Reference Sensor and Start Monitoring ........ 7-5
Set Targets and Alarm Limits .................................................. 7-7
Central Venous Pressure Manual Entry ...................................... 7-8
Continuous Waveform Display ................................................ 7-8
Output Signal to Patient Monitor ............................................. 7-8
Derived Value Calculator ....................................................... 7-8
Cuff Options ........................................................................... 7-9
  Cuff Pressure Release Mode .................................................. 7-9
Cardiac Output Calibration ..................................................... 7-9
Physiocal Control ................................................................. 7-10

Chapter 8: Physiology and Physio Relationship Monitoring Screens

Physiology Screen ................................................................. 8-1
  SVV Slope Indicator ............................................................. 8-2
Physio Relationship Screen ................................................... 8-2
  Continuous and Historical Modes .......................................... 8-2
  Parameter Boxes ............................................................... 8-3
  Physio Relationship Alarms/Targets and Historical Data Screens ...... 8-3

Chapter 9: Enhanced Parameter Tracking

GDT Tracking ......................................................................... 9-1
  Key Parameter and Target Selection ........................................ 9-1
  Active GDT Tracking ............................................................ 9-2
  Historical GDT ................................................................. 9-2
SV Optimization ...................................................................... 9-2
GDT Report Download ............................................................ 9-2

Chapter 10: Clinical Actions and Analysis

Zero & Waveform ................................................................... 10-1
  Zero Heart Reference Sensor (HRS) ....................................... 10-1
  Analog Pressure Out ........................................................... 10-1
Central Venous Pressure Manual Entry .................................... 10-1
Derived Value Calculator ....................................................... 10-1
Event Review .......................................................................... 10-1
Cuff Options ........................................................................... 10-2
Advanced Options ............................................................... 10-2
Historical Data ........................................................................ 10-3

Chapter 11: Demonstration Mode and Data Download

Data Download ........................................................................ 11-2

Chapter 12: Help and Troubleshooting

On Screen Help ....................................................................... 12-1
Cleaning the System Cables and Accessories ........................................... E-1
Cleaning the Patient Cables and Connectors ........................................... E-2

Service and Support .................................................................................. E-2
Edwards Lifesciences Regional Headquarters ........................................... E-3
System Disposal ....................................................................................... E-3
Preventive Maintenance .......................................................................... E-3
Warranty .................................................................................................... E-4

Appendix F: Guidance and Manufacturer’s Declaration
Electromagnetic Compatibility ................................................................. F-1
Instructions for Use ................................................................................ F-1

Appendix G: Glossary
List of Figures

Figure 3-1 EV1000 Clinical Platform NI Cable Connections .................................. 3-3
Figure 3-2 Startup Screen ................................................................. 3-4
Figure 3-3 Language Selection Screen .................................................. 3-5
Figure 4-1 EV1000 Noninvasive System Cable Connection ............................... 4-1
Figure 4-3 EV1000 Pressure Controller Attachments ....................................... 4-2
Figure 4-2 Patient Data Entry Screen ...................................................... 4-2
Figure 4-4 ClearSight Finger Cuff Placement ............................................ 4-2
Figure 4-5 Zero HRS ............................................................................ 4-3
Figure 4-6 Set Alarms and Targets ............................................................... 4-3
Figure 5-1 Navigation Bar ......................................................................... 5-1
Figure 5-2 Example of Monitoring Screen Selection Window ............................. 5-2
Figure 5-3 Change Monitored Parameter .................................................... 5-3
Figure 5-4 Graphical Trend Screen - Arterial Waveform Display ....................... 5-4
Figure 5-5 Graphical Trend - Intervention .................................................... 5-4
Figure 5-6 Graphical Trend Screen - Intervention information balloon ............... 5-5
Figure 5-7 Tabular Trend Screen .................................................................. 5-5
Figure 5-8 Tabular Increment Popup ............................................................ 5-6
Figure 5-9 Big Numbers Monitoring Screen ................................................ 5-6
Figure 5-10 Physiology Screen ..................................................................... 5-6
Figure 5-11 Cockpit Monitoring Screen ........................................................ 5-7
Figure 5-12 Physio Relationship Screen ....................................................... 5-7
Figure 5-13 Parameter Globe ....................................................................... 5-7
Figure 5-14 Vertical Scrolling Review List .................................................... 5-8
Figure 5-15 Vertical Scrolling Selection List .................................................. 5-8
Figure 5-16 Information Bar ......................................................................... 5-9
Figure 5-17 Lock Screen .............................................................................. 5-10
Figure 5-18 Screen Locked .......................................................................... 5-10
Figure 5-19 Status Bar ................................................................................ 5-10
Figure 6-1 New or Continuing Patient Screen .................................................. 6-1
Figure 6-2 Monitor Settings ......................................................................... 6-2
Figure 6-3 General Monitor Settings ............................................................... 6-2
Figure 6-4 Date / Time Settings ..................................................................... 6-3
Figure 6-5 Monitor Screens .......................................................................... 6-3
Figure 6-6 Serial Port Setup ......................................................................... 6-4
Figure 6-7 Parameter Settings ....................................................................... 6-4
Figure 6-8 Alarms / Targets Configuration ..................................................... 6-6
Figure 6-9 Set Custom Default Alarms / Targets ............................................ 6-7
Figure 6-10 Set Alarms and Targets ............................................................... 6-7
Figure 6-11 Time Intervals / Averaging .......................................................... 6-8
Figure 6-12 Graphical Trend Screen .............................................................. 6-8
Figure 6-13 Adjust Scales ............................................................................ 6-8
Figure 6-14 Tabular Increment Popup ............................................................ 6-9
Figure 7-1 Physiological During Blood Pressure Measurement ......................... 7-1
Figure 7-2 EV1000 Noninvasive System Connections ...................................... 7-3
Figure 7-3 Cuff size selection ..................................................................... 7-4
Figure 7-4 ClearSight Finger Cuff Placement ................................................ 7-4
Figure 7-5 Settings Screen .......................................................................... 7-5
Figure 7-6 Zero & Waveform Screen ............................................................. 7-6
Figure 7-7 Alignment of HRS .............................................................. 7-6
Figure 7-8 Parameter Settings ......................................................... 7-7
Figure 7-9 Alarms / Targets ............................................................ 7-8
Figure 7-10 Finger Cuff Pressure Release Icon and Timer .................... 7-9
Figure 7-11 Advanced Options Screen ............................................. 7-9
Figure 7-12 Advanced Options Screen - CO Calibration ....................... 7-10
Figure 8-1 Physiology Screen ......................................................... 8-1
Figure 8-2 Systemic Vascular Resistance ........................................... 8-1
Figure 8-3 SVV Slope Indicator ......................................................... 8-2
Figure 8-4 Physio Relationship Screen ............................................. 8-2
Figure 8-5 Physio Relationship Historical Data Screen ......................... 8-2
Figure 8-6 Physio Relationship Parameter Boxes ................................. 8-3
Figure 8-7 Physio Relationship Target Popup ...................................... 8-3
Figure 8-8 Parameter Settings .......................................................... 7-7
Figure 8-9 Alarms / Targets ............................................................. 7-8
Figure 8-10 Finger Cuff Pressure Release Icon and Timer ..................... 7-9
Figure 8-11 Advanced Options Screen .............................................. 7-10
Figure 8-12 Advanced Options Screen - CO Calibration ....................... 7-10
Figure 8-13 Physiology Screen ........................................................ 8-1
Figure 8-14 Systemic Vascular Resistance ......................................... 8-1
Figure 8-15 SVV Slope Indicator ....................................................... 8-2
Figure 8-16 Physio Relationship Screen ............................................ 8-2
Figure 8-17 Physio Relationship Historical Data Screen ....................... 8-2
Figure 8-18 Physio Relationship Parameter Boxes ............................... 8-3
Figure 8-19 Physio Relationship Target Popup ..................................... 8-3
Figure 9-1 GDT Menu Screen - Key Parameter Selection ....................... 9-1
Figure 9-2 GDT Menu Screen - Target Selection ................................ 9-1
Figure 9-3 GDT Active Tracking ..................................................... 9-1
Figure 10-1 Derived Value Calculator .............................................. 10-1
Figure 10-2 Event Review ............................................................... 10-1
Figure 11-1 Settings Screen ........................................................... 11-1
Figure 11-2 Demo Mode ................................................................. 11-1
Figure 11-3 Live Demo Banner ....................................................... 11-1
Figure 11-4 Data Download ............................................................ 11-2
Figure 12-1 Main Help Screen ........................................................ 12-1
Figure 12-2 Category Help Screen ................................................... 12-1
Figure 12-3 Secondary Help Screen ................................................ 12-1
Figure 12-4 Help Screen ............................................................... 12-2
Figure 12-5 Graphical Steps Help Screen ....................................... 12-2
Figure 12-6 Example of Detailed Graphical Steps Help Screen ............. 12-2
Figure 12-7 EV1000 Pump-Unit and Monitor LED Indicators ................ 12-3
Figure 12-8 Pressure Controller LED Indicators ................................ 12-4
Figure 13-1 EV1000 Table Stand ..................................................... 13-1
Figure 13-2 EV1000 Roll Stand ....................................................... 13-1
Figure 13-3 EV1000 Monitor Bracket .............................................. 13-2
Figure 13-4 EV1000 Monitor and Monitor Bracket ............................... 13-2
Figure 13-5 EV1000 Monitor Appearance and Location of Power Button ... 13-2
Figure 13-6 EV1000 Monitor Cable Connections ................................. 13-2
Figure 13-7 EV1000 Pump-Unit Bracket .......................................... 13-3
Figure 14-1 HIS - Patient Query ..................................................... 14-1
Figure 14-2 HIS - New Patient Data Screen .................................... 14-1
Figure 14-3 Goal Positioning Screen .............................................. 14-2
Figure 14-4 EV1000 NI Databox Adaptor Cable Power Connections ....... 14-3
Figure A-1 Spectral Irradiance ....................................................... A-1
Figure A-2 Location of Light Emission Aperture ................................ A-1
Figure E-1 Startup Screen ............................................................. E-2
List of Tables

Table 1-1 EV1000 Clinical Platform NI Parameters ........................................ 1-1
Table 1-2 Acronyms and Abbreviations ....................................................... 1-3
Table 2-1 Monitor Display
Symbols ........................................................................................................ 2-6
Table 2-2 Symbols on Product Labels ......................................................... 2-7
Table 2-3 Applicable Standards ..................................................................... 2-9
Table 3-1 EV1000 NI Main Components ...................................................... 3-1
Table 5-1 Intervention Events ....................................................................... 5-4
Table 5-2 Graphical Trend Scroll Rates ......................................................... 5-5
Table 5-3 Tabular Trend Scroll Rates ........................................................... 5-6
Table 5-4 Physiocal Interval Status .............................................................. 5-9
Table 5-5 Pump-Unit Battery Status ............................................................. 5-10
Table 6-1 Target Status Indicator Colors ...................................................... 6-5
Table 6-2 Target Defaults ............................................................................ 6-6
Table 9-1 GDT Target Status Indicator Colors ........................................... 9-2
Table 10-1 Reviewed Events ......................................................................... 10-2
Table 12-1 Pump-Unit Communication and Power Lights .......................... 12-3
Table 12-2 Pressure Controller Communication Lights ............................... 12-4
Table 12-3 System Errors ............................................................................ 12-5
Table 12-4 Numeric Keypad Errors ............................................................. 12-6
Table 12-5 ClearSight Faults and Alerts ....................................................... 12-7
Table 12-6 ClearSight Warnings .................................................................. 12-12
Table 12-7 ClearSight Troubleshooting ....................................................... 12-12
Table 12-8 CVP Troubleshooting ................................................................. 12-13
Table A-1 Physical and Mechanical Specifications ..................................... A-1
Table A-2 Environmental Specifications ....................................................... A-2
Table A-3 Base Parameters .......................................................................... A-2
Table A-4 EV1000 Clinical Platform NI Components .................................. A-2
Table A-5 EV1000 Monitor Technical Specifications ................................... A-3
Table A-6 EV1000 Pump-Unit Technical Specifications ............................... A-3
Table B-1 Cardiac Profile Equations ............................................................. B-1
Table C-1 Patient Information ...................................................................... C-1
Table C-2 Graphical Trend Parameter Scale Defaults .................................. C-1
Table C-3 Ranges for Key Parameters ......................................................... C-2
Table C-4 Parameter Alarm Red Zone and Target Defaults ......................... C-2
Table C-5 Language Default Settings ........................................................... C-3
Table F-1 List of Accessories, Cables and Sensors Necessary for Compliance F-1
Table F-2 Electromagnetic Emissions ............................................................ F-2
Table F-3 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the EV1000 Clinical Platform NI F-2
Table F-4 Electromagnetic Immunity (ESD, EFT, Surge, Dips and Magnetic Field) F-3
Table F-5 Electromagnetic Immunity (RF Radiated and Conducted) .......... F-4
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.

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

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

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. The EV1000 Clinical Platform may be used for the monitoring of hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol. 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.

Cyber Security

Patient data can be transferred to and from the EV1000 Clinical Platform, as described in the Data Download and HIS sections. It is important to note that any facility using the EV1000 clinical platform must take measures to protect the privacy of a patients personal information in accordance with country-specific regulations, and consistent with the facility’s policies for managing this information. Steps that can be taken to safeguard this information and the general security of the EV1000 clinical platform include:

- **Physical Access**: Limit use of the EV1000 clinical platform to authorized users.
- **Active use**: Users of the monitor should take measures to limit patient data storage. Patient data should be removed from the monitor after a patient is discharged and patient monitoring has ended.
- **Network Security**: The facility must take measures to ensure the security of any shared network to which the monitor may be connected to.
- **Device Security**: Users should only use Edwards approved accessories. In addition, ensure that any connected device is free of malware. The use of the EV1000 clinical platform outside of its intended purpose could pose cyber security risks. No EV1000 clinical platform connections are meant to control the operations of another device.

HIPAA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), introduced by the U.S. Department of Health and Human Services, outlines important standards to protect individually identifiable health information. If applicable, these standards should be followed during monitor use.

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

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/D</td>
<td>Analog/Digital</td>
</tr>
<tr>
<td>AP</td>
<td>Arterial Pressure</td>
</tr>
<tr>
<td>ART</td>
<td>Brachial Arterial Waveform</td>
</tr>
<tr>
<td>BP</td>
<td>Blood Pressure</td>
</tr>
<tr>
<td>BSA</td>
<td>Body Surface Area</td>
</tr>
<tr>
<td>CI</td>
<td>Cardiac Index</td>
</tr>
<tr>
<td>CO</td>
<td>Cardiac Output</td>
</tr>
<tr>
<td>CPO</td>
<td>Cardiac Power Output</td>
</tr>
<tr>
<td>CPI</td>
<td>Cardiac Power Index</td>
</tr>
<tr>
<td>CVP</td>
<td>Central Venous Pressure</td>
</tr>
<tr>
<td>DO₂</td>
<td>Oxygen Delivery</td>
</tr>
<tr>
<td>DO₂I</td>
<td>Oxygen Delivery Index</td>
</tr>
<tr>
<td>DIA</td>
<td>Diastolic Pressure</td>
</tr>
<tr>
<td>EV1000 NI</td>
<td>EV1000 Clinical Platform NI</td>
</tr>
<tr>
<td>GDT</td>
<td>Goal Directed Therapy</td>
</tr>
<tr>
<td>HIS</td>
<td>Hospital Information Systems</td>
</tr>
<tr>
<td>HGB</td>
<td>Hemoglobin</td>
</tr>
<tr>
<td>HRS</td>
<td>Heart Reference Sensor</td>
</tr>
<tr>
<td>MAP</td>
<td>Mean Arterial Pressure</td>
</tr>
<tr>
<td>PaO₂</td>
<td>Partial pressure of arterial oxygen</td>
</tr>
<tr>
<td>PC2</td>
<td>Pressure Controller</td>
</tr>
<tr>
<td>PM</td>
<td>Bedside Patient Monitor</td>
</tr>
<tr>
<td>PMP</td>
<td>Pump-Unit</td>
</tr>
<tr>
<td>PR</td>
<td>Pulse Rate</td>
</tr>
<tr>
<td>ScvO₂</td>
<td>Central venous oxygen saturation</td>
</tr>
<tr>
<td>SpO₂</td>
<td>Peripheral arterial oxygen saturation</td>
</tr>
<tr>
<td>SV</td>
<td>Stroke Volume</td>
</tr>
<tr>
<td>SVI</td>
<td>Stroke Volume Index</td>
</tr>
<tr>
<td>SvO₂</td>
<td>Mixed Venous Oxygen Saturation</td>
</tr>
<tr>
<td>SVR</td>
<td>Systemic Vascular Resistance</td>
</tr>
<tr>
<td>SVRI</td>
<td>Systemic Vascular Resistance Index</td>
</tr>
<tr>
<td>SVV</td>
<td>Stroke Volume Variation</td>
</tr>
<tr>
<td>SYS</td>
<td>Systolic Pressure</td>
</tr>
<tr>
<td>Touch</td>
<td>Interact with the EV1000 system by touching the monitor screen.</td>
</tr>
<tr>
<td>USB</td>
<td>Universal Serial Bus</td>
</tr>
<tr>
<td>VO₂e</td>
<td>Estimated oxygen consumption</td>
</tr>
</tbody>
</table>
# 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.

<table>
<thead>
<tr>
<th>WARNING</th>
<th>Use of the EV1000 Clinical Platform NI is restricted to one patient at a time.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 1)</td>
</tr>
<tr>
<td>WARNING</td>
<td>No modification of the EV1000 Clinical Platform NI is allowed.</td>
</tr>
<tr>
<td></td>
<td>(Chapter 3, Appendix F)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>(Chapter 3)</td>
</tr>
<tr>
<td>WARNING</td>
<td>To avoid the risk of electric shock, the Pump-Unit must only be connected to a supply mains with protective earth.</td>
</tr>
<tr>
<td></td>
<td>(Chapter 3)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>(Chapter 3)</td>
</tr>
<tr>
<td>WARNING</td>
<td>In the USA the instrument shall be connected only to a single phase 110-120V supply system.</td>
</tr>
<tr>
<td></td>
<td>(Chapter 3)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>(Chapter 3)</td>
</tr>
<tr>
<td>WARNING</td>
<td>For noninvasive monitoring, the EV1000 Monitor must be powered by the Pump-unit using the EV1000 NI Power Cable.</td>
</tr>
<tr>
<td></td>
<td>(Chapter 3)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Shock hazard: Do not attempt to connect/disconnect system cables while hands are wet. Ensure that hands are dry prior to disconnecting system cables.</td>
</tr>
<tr>
<td></td>
<td>(Chapter 3)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>(Chapter 3, 7, 13, Appendix A)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Use of accessories, sensors, and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity. (Chapter 3, Appendix F)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Do not use the Ethernet cable to connect anything to the Pump-Unit other than the Monitor. (Chapter 3)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Do not obstruct the EV1000 Clinical Platform NI ventilation openings. (Chapter 3)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>The Monitor must be positioned in an upright position to ensure IPX1 fluid ingress protection. (Chapter 3)</td>
</tr>
<tr>
<td>WARNING</td>
<td>The Pump-Unit must be positioned in an upright position to ensure IP4X ingress protection. (Chapter 3,13)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Do not position the Pump-Unit so that it is difficult to disconnect the mains power cord. (Chapter 3)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Do not turn off the audible physiological alarms in situations in which patient safety could be compromised. (Chapter 6)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Do not sterilize any components of the EV1000 Noninvasive System. The EV1000 Noninvasive System is provided non sterile. (Chapter 7)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Refer to cleaning instructions. Do not disinfect the instrument by autoclave or gas sterilization. (Chapter 7, Appendix E)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Refer to the directions provided with each accessory for specific instructions on placement and use, and for relevant WARNINGS, CAUTIONS, and specifications. (Chapter 7)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Do not use damaged components/sensors or components/sensors with exposed electrical contacts to prevent patient or user shocks. (Chapter 7, Appendix E)</td>
</tr>
<tr>
<td>WARNING</td>
<td>The EV1000 Noninvasive System monitoring components are not defibrillation proof. Disconnect the system before defibrillating. (Chapter 7)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Do not touch system connectors of the EV1000 Clinical Platform NI and the patient at the same time. (Chapter 7)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Do not overtighten the Pressure Controller Band or ClearSight Finger Cuff(s). (Chapter 7)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Do not apply the ClearSight Finger Cuff or Pressure Controller on injured skin as this can cause further injury. (Chapter 7)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Measurement on one finger in contradiction with the instructions for use may affect patient comfort and/or lead to minor injuries. (Chapter 7)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Do not use two ClearSight Finger Cuffs simultaneously on the same finger. (Chapter 7)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>Do not use the EV1000 Clinical Platform NI as a heart rate monitor. (Chapter 7)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
<tr>
<td>WARNING</td>
<td>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)</td>
</tr>
</tbody>
</table>
| 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.

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Federal (USA) law restricts this device to sale by or on the order of a physician.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 3, Appendix E)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Do not expose the EV1000 Clinical Platform NI to extreme temperatures.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Do not expose the EV1000 Clinical Platform NI to dirty or dusty environments.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Do not apply strong shock to or drop the instrument.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Clean and store the instrument and accessories after each use.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 3, Appendix E)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>When moving the instrument, be sure to turn off the power and remove the connected power cord.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>The EV1000 Monitor should only be connected to a single Pump-Unit and/or single Databox.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Do not use the EV1000 Monitor in environments where strong lighting makes the LCD screen difficult to view.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Do not use the Monitor as a handheld device.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Improper ClearSight Finger Cuff placement or sizing can lead to inaccurate monitoring.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 4,7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Make sure that the HRS is correctly applied so that it can be leveled to the phlebostatic axis.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 4,7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Pump-Unit includes a Lithium-Ion battery backup.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 5,14)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>The effectiveness of EV1000 Noninvasive System has not been evaluated in patients under 18 years of age.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Never bend a finger cuff to a flat shape, it will damage the cuff and affect measurement accuracy.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>Excessive ambient light may interfere with ClearSight Finger Cuff measurements.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>The effectiveness of the ClearSight finger cuff has not been established in pre-eclamptic patients.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>The EV1000 Noninvasive System is not intended for use as an apnea monitor.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(Chapter 7)</td>
</tr>
</tbody>
</table>
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>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Audible alarm silence button" /></td>
<td>Audible alarm silence button</td>
</tr>
<tr>
<td><img src="image" alt="Monitoring pause exit button" /></td>
<td>Monitoring pause exit button</td>
</tr>
<tr>
<td><img src="image" alt="Symbol used to indicate the audible alarm indicator for the parameter has been disabled." /></td>
<td>Symbol used to indicate the audible alarm indicator for the parameter has been disabled.</td>
</tr>
<tr>
<td><img src="image" alt="Symbol used to indicate the audible alarm indicator for the parameter has been enabled." /></td>
<td>Symbol used to indicate the audible alarm indicator for the parameter has been enabled.</td>
</tr>
<tr>
<td><img src="image" alt="Vertical scroll buttons" /></td>
<td>Vertical scroll buttons</td>
</tr>
<tr>
<td><img src="image" alt="Horizontal scroll buttons" /></td>
<td>Horizontal scroll buttons</td>
</tr>
<tr>
<td><img src="image" alt="Enter button" /></td>
<td>Enter button</td>
</tr>
<tr>
<td><img src="image" alt="Keypad enter key" /></td>
<td>Keypad enter key</td>
</tr>
<tr>
<td><img src="image" alt="Keypad backspace key" /></td>
<td>Keypad backspace key</td>
</tr>
<tr>
<td><img src="image" alt="Move cursor left by 1 character" /></td>
<td>Move cursor left by 1 character</td>
</tr>
<tr>
<td><img src="image" alt="Move cursor right by 1 character" /></td>
<td>Move cursor right by 1 character</td>
</tr>
<tr>
<td><img src="image" alt="Keypad cancel key" /></td>
<td>Keypad cancel key</td>
</tr>
<tr>
<td><img src="image" alt="Item enabled" /></td>
<td>Item enabled</td>
</tr>
<tr>
<td><img src="image" alt="Item not enabled" /></td>
<td>Item not enabled</td>
</tr>
<tr>
<td><img src="image" alt="GDT Tracking button" /></td>
<td>GDT Tracking button</td>
</tr>
<tr>
<td><img src="image" alt="Monitor screen selection button" /></td>
<td>Monitor screen selection button</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Clinical Actions menu button" /></td>
<td>Clinical Actions menu button</td>
</tr>
<tr>
<td><img src="image" alt="Zero and waveform icon on Clinical Actions menu" /></td>
<td>Zero and waveform icon on Clinical Actions menu</td>
</tr>
<tr>
<td><img src="image" alt="CVP manual entry button on Clinical Actions menu" /></td>
<td>CVP manual entry button on Clinical Actions menu</td>
</tr>
<tr>
<td><img src="image" alt="Derived value calculator button on Clinical Actions menu" /></td>
<td>Derived value calculator button on Clinical Actions menu</td>
</tr>
<tr>
<td><img src="image" alt="Event review button on Clinical Actions menu" /></td>
<td>Event review button on Clinical Actions menu</td>
</tr>
<tr>
<td><img src="image" alt="Cuff Options button on Clinical Actions menu" /></td>
<td>Cuff Options button on Clinical Actions menu</td>
</tr>
<tr>
<td><img src="image" alt="Advanced Options button on Clinical Actions menu" /></td>
<td>Advanced Options button on Clinical Actions menu</td>
</tr>
<tr>
<td><img src="image" alt="Historical Data button on Clinical Actions menu" /></td>
<td>Historical Data button on Clinical Actions menu</td>
</tr>
<tr>
<td><img src="image" alt="Settings menu button" /></td>
<td>Settings menu button</td>
</tr>
<tr>
<td><img src="image" alt="Screen capture button" /></td>
<td>Screen capture button</td>
</tr>
<tr>
<td><img src="image" alt="Start Monitoring button" /></td>
<td>Start Monitoring button</td>
</tr>
<tr>
<td><img src="image" alt="Stop Monitoring button" /></td>
<td>Stop Monitoring button</td>
</tr>
<tr>
<td><img src="image" alt="Resume Monitoring button" /></td>
<td>Resume Monitoring button</td>
</tr>
<tr>
<td><img src="image" alt="Return to main monitoring screen" /></td>
<td>Return to main monitoring screen</td>
</tr>
<tr>
<td><img src="image" alt="Return to previous menu" /></td>
<td>Return to previous menu</td>
</tr>
<tr>
<td><img src="image" alt="Cancel" /></td>
<td>Cancel</td>
</tr>
</tbody>
</table>
### 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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="manufacturer.png" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="date.png" alt="Date of Manufacture" /></td>
<td>Date of Manufacture</td>
</tr>
<tr>
<td><img src="rx.png" alt="Rx only" /></td>
<td>Federal (USA) law restricts this device to sale by, or on the order of a physician.</td>
</tr>
<tr>
<td><img src="ipx1.png" alt="IPX1" /></td>
<td>Extent of protection against vertically falling water</td>
</tr>
<tr>
<td><img src="ip4x.png" alt="IP4X" /></td>
<td>Extent of protection against the ingress of objects and dripping water</td>
</tr>
<tr>
<td><img src="separate.png" alt="Separate collection" /></td>
<td>Separate collection for electrical and electronic equipment in accordance with EC directive 2002/96/EC.</td>
</tr>
</tbody>
</table>
### Table 2-2 Symbols on Product Labels (Continued)

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="USB" /></td>
<td>Connector: USB</td>
</tr>
<tr>
<td><img src="image" alt="Direct Current" /></td>
<td>Direct current only</td>
</tr>
<tr>
<td><img src="image" alt="Network Indicator" /></td>
<td>Unit network indicator or connection</td>
</tr>
<tr>
<td><img src="image" alt="ON Condition" /></td>
<td>Indicates “ON” condition for part of the equipment</td>
</tr>
<tr>
<td><img src="image" alt="Control" /></td>
<td>Identifies a control that returns the device to its initial state</td>
</tr>
<tr>
<td><img src="image" alt="Instruction" /></td>
<td>Consult instructions for use.</td>
</tr>
<tr>
<td><img src="image" alt="Instruction" /></td>
<td>Consult instructions for use.</td>
</tr>
<tr>
<td><img src="image" alt="Caution" /></td>
<td>Caution</td>
</tr>
<tr>
<td><img src="image" alt="Intertek ETL" /></td>
<td>Intertek ETL</td>
</tr>
<tr>
<td><img src="image" alt="Class II" /></td>
<td>Class II</td>
</tr>
<tr>
<td><img src="image" alt="Video Equipment Output Control" /></td>
<td>Video equipment output control</td>
</tr>
<tr>
<td><img src="image" alt="Serial COM Output" /></td>
<td>Connector: Serial COM output</td>
</tr>
<tr>
<td><img src="image" alt="Keep Dry" /></td>
<td>Keep contents dry</td>
</tr>
<tr>
<td><img src="image" alt="Fragile" /></td>
<td>Fragile. Handle with care</td>
</tr>
<tr>
<td><img src="image" alt="This End Up" /></td>
<td>This end up</td>
</tr>
</tbody>
</table>

### Table 2-2 Symbols on Product Labels (Continued)

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Keep Away" /></td>
<td>Keep away from direct sunlight.</td>
</tr>
<tr>
<td><img src="image" alt="Catalogue Number" /></td>
<td>Catalogue number</td>
</tr>
<tr>
<td><img src="image" alt="Quantity" /></td>
<td>Quantity</td>
</tr>
<tr>
<td><img src="image" alt="Serial Number" /></td>
<td>Serial Number</td>
</tr>
<tr>
<td><img src="image" alt="Use By" /></td>
<td>Use by</td>
</tr>
<tr>
<td><img src="image" alt="Lot Number" /></td>
<td>Lot Number</td>
</tr>
<tr>
<td><img src="image" alt="Non-Sterile" /></td>
<td>Non-sterile</td>
</tr>
<tr>
<td><img src="image" alt="Single Use" /></td>
<td>Single Use</td>
</tr>
<tr>
<td><img src="image" alt="Authorized Representative" /></td>
<td>Authorized representative in the European Community</td>
</tr>
<tr>
<td><img src="image" alt="Magnetic Resonance Unsafe" /></td>
<td>Magnetic resonance unsafe</td>
</tr>
<tr>
<td><img src="image" alt="No Serviceable Parts" /></td>
<td>No serviceable parts inside</td>
</tr>
<tr>
<td><img src="image" alt="Type BF Applied Part" /></td>
<td>Type BF applied part</td>
</tr>
<tr>
<td><img src="image" alt="Alarm" /></td>
<td>Alarm, general (Pump-Unit)</td>
</tr>
<tr>
<td><img src="image" alt="Battery Status" /></td>
<td>Battery Status</td>
</tr>
<tr>
<td><img src="image" alt="AC Mains Status" /></td>
<td>AC Mains Status</td>
</tr>
<tr>
<td><img src="image" alt="Equipotentiality" /></td>
<td>Equipotentiality</td>
</tr>
</tbody>
</table>
Table 2-2 Symbols on Product Labels (Continued)

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Symbol]</td>
<td>Continuous, noninvasive arterial blood pressure</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Indoor use only</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Analog output</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>ClearSight Finger Cuff Size (S=Small, M=Medium, L=Large)</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Warehouse Storage Temperature Limitations (X = lower limit, Y = upper limit)</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Warehouse Storage Humidity Limitations (X = lower limit, Y = upper limit)</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Transport and Storage Atmospheric Pressure Limitations (X = lower limit, Y = upper limit)</td>
</tr>
</tbody>
</table>

Table 2-3 Applicable Standards (Continued)

<table>
<thead>
<tr>
<th>Standard</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 13485:2003/AC:2009</td>
<td>Medical devices - Quality management systems - Requirements for regulatory purposes</td>
</tr>
<tr>
<td>IEC 62366:2007</td>
<td>Medical devices - Application of usability engineering to medical devices</td>
</tr>
<tr>
<td>ISO-10993-1:2009</td>
<td>Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system</td>
</tr>
<tr>
<td>ISO 14971:2007</td>
<td>Medical devices - Application of risk management to medical devices</td>
</tr>
<tr>
<td>ISO 15223-1:2012</td>
<td>Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements</td>
</tr>
<tr>
<td>IEC 62471:2008</td>
<td>Photobiological safety of lamps and lamp systems</td>
</tr>
<tr>
<td>CSA C22.2#60601-1:2008</td>
<td>Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; COR 2: 2011/06/01.</td>
</tr>
</tbody>
</table>

Applicable Standards

Table 2-3 Applicable Standards

<table>
<thead>
<tr>
<th>Standard</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 60601-1-2: 2007</td>
<td>Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests</td>
</tr>
<tr>
<td>IEC 60601-1-6:2010</td>
<td>Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability</td>
</tr>
<tr>
<td>IEC 60601-1-8:2006</td>
<td>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</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>EV1000 Noninvasive System</th>
<th>EV1000 Clinical Platform NI</th>
<th>EV1000 Noninvasive Disposables</th>
</tr>
</thead>
<tbody>
<tr>
<td>EV1000 Pump-Unit</td>
<td>EV1000 Noninvasive System</td>
<td>ClearSight Finger Cuff</td>
</tr>
<tr>
<td>Pressure Controller</td>
<td>EV1000 Monitor</td>
<td></td>
</tr>
<tr>
<td>Pressure Controller Band</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart Reference Sensor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operator’s Manual</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 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.

*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.

<table>
<thead>
<tr>
<th>WARNING</th>
<th>No modification of the EV1000 Clinical Platform NI is allowed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>WARNING</td>
<td>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.</td>
</tr>
<tr>
<td>WARNING</td>
<td>To avoid the risk of electric shock, the Pump-Unit must only be connected to a supply mains with protective earth.</td>
</tr>
<tr>
<td>WARNING</td>
<td>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.</td>
</tr>
<tr>
<td>WARNING</td>
<td>In the USA the instrument shall be connected only to a single phase 110-120V supply system.</td>
</tr>
<tr>
<td>WARNING</td>
<td>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.</td>
</tr>
</tbody>
</table>
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.

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.

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.

*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
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.

![Figure 3-2 Startup Screen](image)

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.

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](image)

**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.

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**.

![Image](image1)

**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.

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.

![Image](image2)

**Figure 4-6 Set Alarms and Targets**

*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.*

---

**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.

---

*If monitoring or screen updates on the system stop without operator action, including any system error screens, touch the Power button on the EV1000 monitor and power cycle the system.*

---

**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 “Audible Alarms Silenced” 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](image)

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.

3 Touch an available parameter to select the replacement parameter.

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 Physiccal, the automatic calibration of the arterial waveform. See “Physiccal Method” on page 7-1 and “Physiccal 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.
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.

Intervention Events

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

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

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Indicator</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>(green)</td>
<td>Inotrope Vasodilator Vasopressor PEEP</td>
</tr>
<tr>
<td>Positional</td>
<td>(purple)</td>
<td>Passive Leg Raise Trendelenburg</td>
</tr>
<tr>
<td>Fluids</td>
<td>(blue)</td>
<td>Red Blood Cells Colloid Crystalloid</td>
</tr>
<tr>
<td>Custom</td>
<td>(grey)</td>
<td>Custom Event</td>
</tr>
</tbody>
</table>

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.

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

<table>
<thead>
<tr>
<th>Scroll Setting</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2x</td>
<td>Scrolls at 2 times the current time scale</td>
</tr>
<tr>
<td>1x</td>
<td>Scrolls at the current time scale (1 graph width)</td>
</tr>
<tr>
<td>½ x</td>
<td>Scrolls by ½ the current time scale</td>
</tr>
</tbody>
</table>

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.

* 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.

![Tabular Increment Popup](image)

### 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.

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

<table>
<thead>
<tr>
<th>Setting</th>
<th>Time</th>
<th>Speed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1X</td>
<td>1 cells</td>
<td>Slow</td>
</tr>
<tr>
<td>6X</td>
<td>6 cells</td>
<td>Moderate</td>
</tr>
<tr>
<td>40X</td>
<td>40 cells</td>
<td>Fast</td>
</tr>
</tbody>
</table>

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.

![Big Numbers Monitoring Screen](image)

### Physiology Screen

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

![Physiology Screen](image)

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 alarm 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.

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.

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:

- Continuous % Change Indicator
- Target Status Indicator
- Parameter Value
- Units
- Parameter Name

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.
**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.

![Continuous % Change Indicator](image)

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.

![Vertical Scrolling Review List](image)

**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.

![Vertical Scrolling Selection List](image)

**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.

![Home Button](image)

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

![Return Button](image)

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

![Cancel Button](image)
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.

![Information Bar](image)

**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**

<table>
<thead>
<tr>
<th>Icon Appearance</th>
<th>Icon Color</th>
<th>Physiocal Beats Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>![beats-60]</td>
<td>Green</td>
<td>≥30</td>
</tr>
<tr>
<td>![beats-20]</td>
<td>Orange</td>
<td>&lt;30</td>
</tr>
<tr>
<td>![beats-0]</td>
<td>White</td>
<td>Physiocal status not available</td>
</tr>
</tbody>
</table>
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>
<thead>
<tr>
<th>Battery Symbol</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The battery has greater than 50% charge remaining.</td>
</tr>
<tr>
<td></td>
<td>The battery has less than 50% charge remaining.</td>
</tr>
<tr>
<td></td>
<td>The battery has less than 20% charge remaining.</td>
</tr>
<tr>
<td></td>
<td>The battery is charging and connected to mains power.</td>
</tr>
<tr>
<td></td>
<td>The battery is fully charged and connected to mains power.</td>
</tr>
<tr>
<td></td>
<td>Battery information is unavailable.</td>
</tr>
</tbody>
</table>

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.

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

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.
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.

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, excluding “/” character.

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.

* Changing patient data during a monitoring session may result in a stop in measurement. Touch Start Monitoring to resume ClearSight monitoring.

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.
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.
Monitor Display Options

1 Touch the **Settings** button.

2 Touch **Monitor Settings**.

3 Touch **Date / Time**.

4 Touch **Date / Time**.

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

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 **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.

**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.

**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.
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.

* Restoring monitor defaults does not restore Serial Port
Setup settings.

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.

* Allow system to restart. If restart process does not
proceed to New Patient Screen, turn off monitor and repeat
power cycle.

Parameter Settings
1 Touch the Settings button.
2 Touch Parameter Settings.

* Figure 6-6 Serial Port Setup
* 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.

**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*

Do not turn off the audible physiological alarms in situations in which patient safety could be 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. Parameter target limits should not be set to exceed the high or low alarm limits.

---

**Table 6-1 Target Status Indicator Colors**

<table>
<thead>
<tr>
<th>Color</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green</td>
<td>Acceptable – Green target zone is considered an ideal range for parameter as set by the clinician.</td>
</tr>
<tr>
<td>Yellow</td>
<td>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.</td>
</tr>
<tr>
<td>Red</td>
<td>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.</td>
</tr>
<tr>
<td>Grey</td>
<td>If you don’t set a target, the status indicator appears as grey.</td>
</tr>
</tbody>
</table>

---

*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.
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

<table>
<thead>
<tr>
<th>Default Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Custom Default</td>
<td>A custom default was set for the parameter and the parameter has not been modified from that default.</td>
</tr>
<tr>
<td>Edwards Default</td>
<td>The parameter has not been changed from the original settings.</td>
</tr>
<tr>
<td>Modified</td>
<td>Parameter was changed for this patient.</td>
</tr>
</tbody>
</table>

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.

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.

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

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.

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**.
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.

1. Touch the **Settings** button.
2. Touch **Parameter Settings**.
3. Touch **Adjust Scales**.

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

**Figure 6-11 Time Intervals / Averaging**

**Figure 6-12 Graphical Trend Screen**

**Figure 6-13 Adjust Scales**
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.

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

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

**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”.

**Figure 6-14 Tabular Increment Popup**

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

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

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.

Figure 7-1 Physiocal During Blood Pressure Measurement
**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 7-9.

* 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.


**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.
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.
Methodology and Monitoring

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.

WARNING

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

CAUTION

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

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.

WARNING

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

CAUTION

Improper ClearSight Finger Cuff placement or sizing can lead to inaccurate monitoring.
4 Connect the ClearSight Finger Cuff to the Pressure Controller.

* Do not rotate the cuff after application. The HRS clip mount 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.

---

**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.
**Methodology and Monitoring**

3 Touch **Zero & Waveform**.

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.

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

8 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.

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

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

*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.
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.

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

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

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.

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.

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

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.

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.

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

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).

Touch the parameter globe to bring up the Alarms / Targets popup.
Methodology and Monitoring

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.

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.

Derived Value Calculator

Select the **Derived Value Calculator** option to compute the patient’s DO2, VO2, 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.

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 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.

Cuff pressure release intervals can only be changed when monitoring is stopped. Avoid frequent changes to cuff release intervals during a continuous monitoring session.

Cardiac Output Calibration

The Advanced Options screen allows the user to calibrate CO.

Avoid starting a CO Calibration within 5 minutes of Cuff Pressure Release, as indicated in countdown timer in Information Bar.

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.

5. Touch Start Averaging to begin CO Averaging.
6. When averaging is complete, enter a CO reference value using the keypad.

Figure 7-10 Finger Cuff Pressure Release Icon and Timer

Figure 7-11 Advanced Options Screen
7 Touch **Calibrate** to complete the calibration process.

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

*Rapidly starting and stopping CO Averaging may result in a CO Calibration Error. Avoid repeated starts/stops when calibration is in progress.*

---

**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.

*R 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.

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 8-1 Physiology Screen

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](image)

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](image)

**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, SpO2 or SvO2/ScvO2 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, SpO2 or SvO2/ScvO2 the clock/waveform icon does not appear. Only the available continuous parameters are displayed.*

![Figure 8-5 Physio Relationship Historical Data Screen](image)

*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\textsubscript{2} and VO\textsubscript{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.

### Physio Relationship Alarms/Targets and Historical Data Screens

Touching HGB, SpO\textsubscript{2} or ScvO\textsubscript{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](image)

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.

![Figure 8-6 Physio Relationship Parameter Boxes](image)

**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.

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.

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.
**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>
<thead>
<tr>
<th>Color</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue</td>
<td>Tracked parameter is currently within the configured target range.</td>
</tr>
<tr>
<td>Black</td>
<td>Tracked parameter is currently outside of the configured target range.</td>
</tr>
<tr>
<td>Red</td>
<td>Tracked parameter is currently below the low alarm limit or above the high alarm limit.</td>
</tr>
<tr>
<td>Gray</td>
<td>Tracked parameter is unavailable, in a fault state, GDT tracking is paused, or a target has not been selected.</td>
</tr>
</tbody>
</table>

**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. Percent change measurements displayed on the trend screen represent percent changes between two historical values.

**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 achieve 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 DO₂, VO₂, 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.

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.
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

<table>
<thead>
<tr>
<th>Event</th>
<th>Log Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSA Change</td>
<td>The BSA value changes from the previous BSA value (including when BSA goes to/from blank).</td>
</tr>
<tr>
<td>CO Reference Cleared</td>
<td>An entered CO reference value is cleared.</td>
</tr>
<tr>
<td>CO Reference Entered: &lt;value&gt;&lt;units&gt;</td>
<td>A CO reference value is entered.</td>
</tr>
<tr>
<td>CO Reference Value</td>
<td>The ClearSight algorithm is calibrated by the user.</td>
</tr>
<tr>
<td>Cuff 1 Monitoring</td>
<td>Cuff 1 monitoring begins.</td>
</tr>
<tr>
<td>Cuff 2 Monitoring</td>
<td>Cuff 2 monitoring begins.</td>
</tr>
<tr>
<td>Cuff monitoring stopped due to 8 continuous hours with a single cuff</td>
<td>Monitoring for 8 continuous hours on a single Cuff has occurred.</td>
</tr>
<tr>
<td>Cuff Pressure Release</td>
<td>A Cuff pressure release has occurred.</td>
</tr>
<tr>
<td>Custom Event</td>
<td>A customized user event</td>
</tr>
<tr>
<td>CVP Entered</td>
<td>A CVP value is entered and the value is noted.</td>
</tr>
<tr>
<td>CVP Cleared</td>
<td>An entered CVP value is cleared.</td>
</tr>
<tr>
<td>GDT Session Started: #nn</td>
<td>A GDT Tracking Session is started. ‘nn’ is the GDT tracking session number for the current patient.</td>
</tr>
<tr>
<td>GDT Session Stopped: #nn</td>
<td>A GDT Tracking Session is stopped. ‘nn’ is the tracking session number for the current patient.</td>
</tr>
<tr>
<td>GDT SessionPaused: #nn</td>
<td>A GDT Tracking Session is paused. ‘nn’ is the tracking session number for the current patient.</td>
</tr>
<tr>
<td>GDT Session Resumed: #nn</td>
<td>A GDT Tracking Session is resumed. ‘nn’ is the tracking session number for the current patient.</td>
</tr>
<tr>
<td>GDT Session Targets Updated: #nn; &lt;pppp&gt;:&lt;qqq&gt;:&lt;uuu&gt;,&lt;...&gt;</td>
<td>GDT Tracking Session targets are updated. ‘nn’ is the tracking session number for the current patient, &lt;pppp&gt; is the parameter whose target range &lt;qqq&gt; with units &lt;uuu&gt; was updated. &lt;...&gt; additional targets were updated.</td>
</tr>
<tr>
<td>Fluid Challenge</td>
<td>A Fluid Challenge intervention analysis is performed.</td>
</tr>
<tr>
<td>HRS Zeroed</td>
<td>HRS is zeroed by the user.</td>
</tr>
<tr>
<td>Intervention</td>
<td>An Intervention analysis is performed.</td>
</tr>
</tbody>
</table>

Table 10-1 Reviewed Events (Continued)

<table>
<thead>
<tr>
<th>Event</th>
<th>Log Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention Analysis (IA) Updated</td>
<td>When user edits a previously entered intervention time, date, or note</td>
</tr>
<tr>
<td>Monitoring Paused</td>
<td>Active monitoring paused to prevent audible alarms and parameter monitoring.</td>
</tr>
<tr>
<td>Monitoring Resumed</td>
<td>Normal monitoring resumed. Audible alarms and parameter monitoring are active.</td>
</tr>
<tr>
<td>ClearSight Monitoring Started</td>
<td>The user begins noninvasive system monitoring.</td>
</tr>
<tr>
<td>ClearSight Monitoring Stopped</td>
<td>The user or system stops noninvasive system monitoring.</td>
</tr>
<tr>
<td>ClearSight Monitoring Resumed</td>
<td>When monitoring resumes after a cuff pressure release.</td>
</tr>
<tr>
<td>Physiocal Disabled</td>
<td>Physiocal is temporarily disabled.</td>
</tr>
<tr>
<td>Physiocal Enabled</td>
<td>Physiocal is resumed by the system or user after having been stopped by the user.</td>
</tr>
<tr>
<td>Position Challenge</td>
<td>When a Position Challenge Intervention Analysis is performed.</td>
</tr>
<tr>
<td>System Restart Recovery</td>
<td>System has resumed monitoring without prompt following a power cycle.</td>
</tr>
<tr>
<td>Technology Switch Occurred</td>
<td>Monitoring is switched from one technology mode to another.</td>
</tr>
<tr>
<td>Time Change</td>
<td>The system clock is updated.</td>
</tr>
</tbody>
</table>

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 7-9.

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.
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](image)

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.

---

*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.

---

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

* Case and GDT Report files downloaded during Demo Mode include only data from the simulated patient to illustrate the look and feel of the reports. Do not use reports from Demo Mode for any clinical purposes.

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

1. Touch the Settings button.

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.
3 Touch the ClearSight button.

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

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.

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

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
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 12-4 Help Screen**

**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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Color</th>
<th>Light Pattern</th>
<th>Suggested Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 PUMP-UNIT ALERT LIGHT</td>
<td>No light</td>
<td>Solid OFF</td>
<td>None</td>
</tr>
<tr>
<td>No Alarm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alarm, severe error detected in the Pump-Unit.</td>
<td>Red</td>
<td>Flashing ON/OFF</td>
<td>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.</td>
</tr>
<tr>
<td>2 ETHERNET COMMUNICATION STATUS LIGHT</td>
<td>No light</td>
<td>Solid OFF</td>
<td>Connect the Pump-Unit to the Monitor using the ethernet cable.</td>
</tr>
<tr>
<td>No Ethernet connection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethernet communication active</td>
<td>Green</td>
<td>Solid ON</td>
<td>None</td>
</tr>
<tr>
<td>Ethernet communication error</td>
<td>Amber</td>
<td>Flashing ON/OFF</td>
<td>Check ethernet connections. If the problem persists, contact Edwards Technical Support.</td>
</tr>
<tr>
<td>3 BATTERY POWER STATUS LIGHT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Battery charged</td>
<td>Green</td>
<td>Solid ON</td>
<td>None</td>
</tr>
<tr>
<td>Battery charging</td>
<td>Green</td>
<td>Fading ON/OFF</td>
<td>None</td>
</tr>
<tr>
<td>Battery power low</td>
<td>Amber</td>
<td>Solid ON</td>
<td>Connect the main power cable to charge battery.</td>
</tr>
</tbody>
</table>
### Pressure Controller Communication

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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Color</th>
<th>Light Pattern</th>
<th>Suggested Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery power very low</td>
<td>Amber</td>
<td>Flashing ON/OFF</td>
<td>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.</td>
</tr>
<tr>
<td><strong>AC POWER STATUS LIGHT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AC Mains Plugged in</td>
<td>Green</td>
<td>Solid ON</td>
<td>None</td>
</tr>
<tr>
<td>AC Mains Disconnected</td>
<td>No light</td>
<td>Solid OFF</td>
<td>None</td>
</tr>
<tr>
<td><strong>MONITOR STATUS LIGHT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitor Power ON</td>
<td>Green</td>
<td>Solid ON</td>
<td>None</td>
</tr>
<tr>
<td>Monitor in STANDBY</td>
<td>Amber</td>
<td>Solid ON</td>
<td>Wait for the monitor to start up.</td>
</tr>
<tr>
<td>Monitor Power OFF</td>
<td>No light</td>
<td>Solid OFF</td>
<td>None</td>
</tr>
</tbody>
</table>

**Figure 12-8 Pressure Controller LED Indicators**

### Table 12-2 Pressure Controller Communication Lights

<table>
<thead>
<tr>
<th>Condition</th>
<th>Color</th>
<th>Light Pattern</th>
<th>Suggested Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CUFF STATUS LIGHT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No ClearSight Finger Cuff connected</td>
<td>No light</td>
<td>Solid OFF</td>
<td>None</td>
</tr>
<tr>
<td>ClearSight Finger Cuff connected</td>
<td>Green</td>
<td>Solid ON</td>
<td>None. The system is ready to start a measurement.</td>
</tr>
<tr>
<td>Active monitoring</td>
<td>Green</td>
<td>Flashing ON/OFF</td>
<td>None. The connected ClearSight Finger Cuff is actively monitoring.</td>
</tr>
<tr>
<td>Defective ClearSight Finger Cuff connected</td>
<td>Amber</td>
<td>Flashing ON/OFF</td>
<td>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.</td>
</tr>
<tr>
<td>Expired ClearSight Finger Cuff connected</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non Edwards Finger Cuff connected</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Help and Troubleshooting

System Errors

Table 12-3 System Errors

<table>
<thead>
<tr>
<th>Message</th>
<th>Possible Causes</th>
<th>Suggested Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fault: Unsupported Power Configuration Detected</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Fault: Databox Power Error¹</td>
<td>A critical Databox power error was detected.</td>
<td>Disconnect Databox power cable and click continue to reset Databox power.² If the problem persists contact Edwards Technical Support.</td>
</tr>
<tr>
<td>Alert: Databox Power Error¹</td>
<td>A critical Databox power error was detected.</td>
<td>Disconnect Databox power cable and click continue to reset Databox power.² If the problem persists contact Edwards Technical Support.</td>
</tr>
<tr>
<td>Fault: Incompatible Device Software Detected</td>
<td>EV1000 Databox or Pump-Unit connected to EV1000 Monitor has incompatible device software.</td>
<td>Contact Edwards Technical Support.</td>
</tr>
<tr>
<td>Fault: Second Pump-Unit detected</td>
<td>A second Pump-Unit is connected to the panel.</td>
<td>Disconnect the second Pump-Unit.</td>
</tr>
<tr>
<td>Fault: Patient Monitor Output Error</td>
<td>Internal system malfunction.</td>
<td>Power cycle the system.</td>
</tr>
</tbody>
</table>

¹Note: 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.

²Note: 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>
<thead>
<tr>
<th>Message</th>
<th>Possible Causes</th>
<th>Suggested Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value out of range (xx-yy)</td>
<td>The entered value is either higher or lower than the allowed range.</td>
<td>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.</td>
</tr>
<tr>
<td>Value must be ( \leq ) xx</td>
<td>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.</td>
<td>Enter a lower value.</td>
</tr>
<tr>
<td>Value must be ( \geq ) xx</td>
<td>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.</td>
<td>Enter a higher value.</td>
</tr>
<tr>
<td>Incorrect password entered</td>
<td>The password entered is incorrect.</td>
<td>Enter the correct password.</td>
</tr>
<tr>
<td>Please enter valid time</td>
<td>The time entered is invalid, i.e. 25:70.</td>
<td>Enter the correct time in 12- or 24-hour format.</td>
</tr>
<tr>
<td>Please enter valid date</td>
<td>The date entered is invalid, i.e. 33.13.009.</td>
<td>Enter the correct date.</td>
</tr>
</tbody>
</table>
### ClearSight Faults and Alerts

#### Table 12-5 ClearSight Faults and Alerts

<table>
<thead>
<tr>
<th>Message</th>
<th>Possible Causes</th>
<th>Suggested Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fault: Finger Cuff Disconnected</td>
<td>Previously connected Finger Cuff(s) not detected.</td>
<td>Disconnect and reconnect Edwards Finger Cuff(s). Replace Finger Cuff(s). Restart measurement.</td>
</tr>
<tr>
<td>Alert: Finger Cuff #1 Expiration in &lt; 5 Minutes</td>
<td>Finger Cuff #1 approaching maximum use time.</td>
<td>Replace Finger Cuff #1 to ensure uninterrupted measurement.</td>
</tr>
<tr>
<td>Alert: Finger Cuff #1 Has Expired. Replace Cuff</td>
<td>Finger Cuff #1 has exceeded maximum use time.</td>
<td>Replace Finger Cuff #1. Restart measurement.</td>
</tr>
<tr>
<td>Fault: Finger Cuff #1 Has Expired. Replace Cuff</td>
<td>Finger Cuff #1 has exceeded maximum use time.</td>
<td>Replace Finger Cuff #1. Restart measurement.</td>
</tr>
<tr>
<td>Alert: Finger Cuff #2 Expiration in &lt; 5 Minutes</td>
<td>Finger Cuff #2 approaching maximum use time.</td>
<td>Replace Finger Cuff #2 to ensure uninterrupted measurement.</td>
</tr>
<tr>
<td>Alert: Finger Cuff #2 Has Expired. Replace Cuff</td>
<td>Finger Cuff #2 has exceeded maximum use time.</td>
<td>Replace Finger Cuff #2. Restart measurement.</td>
</tr>
<tr>
<td>Fault: Finger Cuff #2 Has Expired. Replace Cuff</td>
<td>Finger Cuff #2 has exceeded maximum use time.</td>
<td>Replace Finger Cuff #2. Restart measurement.</td>
</tr>
<tr>
<td>Fault: Accumulated Single Cuff Monitoring Has Reached The Duration Limit</td>
<td>Cumulative measurement on the same finger exceeded maximum duration of 8 hours.</td>
<td>Remove Cuff from finger. Place the Cuff on another finger and press ‘Continue’ on the Popup. Restart Measurement.</td>
</tr>
<tr>
<td>Fault: Check HRS Connection</td>
<td>HRS connection not detected.</td>
<td>Disconnect and reconnect Edwards HRS. Replace HRS.</td>
</tr>
<tr>
<td>Alert: HRS Out of Range</td>
<td>HRS incorrectly zeroed. HRS measurement exceeds allowed limit. HRS detached from Finger Cuff or phlebostatic axis. HRS is defective.</td>
<td>Razero 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.</td>
</tr>
</tbody>
</table>
### Table 12-5 ClearSight Faults and Alerts (Continued)

<table>
<thead>
<tr>
<th>Message</th>
<th>Possible Causes</th>
<th>Suggested Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fault: HRS Out of Range</td>
<td>The HRS pressure offset exceeded limit during the zeroing process. Defective HRS.</td>
<td>Vertically align the two ends of HRS and re-zero. Replace HRS. If the problem persists, contact Edwards Technical Support.</td>
</tr>
<tr>
<td>Fault: HRS Has Expired. Replace HRS.</td>
<td>HRS has expired as it is past useful life.</td>
<td>Disconnect and reconnect Edwards HRS. Replace HRS. Restart Measurement. If problem persists, contact Edwards Technical Support.</td>
</tr>
<tr>
<td>Fault: Invalid HRS Connected</td>
<td>Non Edwards HRS detected. HRS is defective.</td>
<td>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.</td>
</tr>
<tr>
<td>Fault: Invalid Pump-Unit Connected</td>
<td>Non Edwards Pump-Unit detected. Defective Pump-Unit connected.</td>
<td>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.</td>
</tr>
</tbody>
</table>
### Table 12-5 ClearSight Faults and Alerts (Continued)

<table>
<thead>
<tr>
<th>Message</th>
<th>Possible Causes</th>
<th>Suggested Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alert: Finger Cuff #1 - Plethysmogram Light Out of Range</td>
<td>Light signal too high.</td>
<td>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.</td>
</tr>
<tr>
<td>Alert: Finger Cuff #2 - Plethysmogram Light Out of Range</td>
<td>Light signal too high.</td>
<td>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.</td>
</tr>
<tr>
<td>Fault: Finger Cuff #1 - Plethysmogram Light Out of Range</td>
<td>Light signal too high.</td>
<td>Warm the hand. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size. Restart measurement.</td>
</tr>
<tr>
<td>Fault: Finger Cuff #2 - Plethysmogram Light Out of Range</td>
<td>Light signal too high.</td>
<td>Warm the hand. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size. Restart measurement.</td>
</tr>
<tr>
<td>Alert: Insufficient Pressure Build Up in Cuff #1 - Possible Air Leakage</td>
<td>Finger Cuff and/or Pressure Controller air tubes kinked. Finger Cuff bladder leaking. Poor connection between Pressure Controller and Pump-Unit.</td>
<td>Allow System to automatically resolve issue. Check Finger Cuff and Pressure Controller air tubes. Check Pressure Controller - Pump-Unit connection. Replace cuff.</td>
</tr>
<tr>
<td>Alert: Insufficient Pressure Build Up in Cuff #2 - Possible Air Leakage</td>
<td>Finger Cuff and/or Pressure Controller air tubes kinked. Finger Cuff bladder leaking. Poor connection between Pressure Controller and Pump-Unit.</td>
<td>Allow System to automatically resolve issue. Check Finger Cuff and Pressure Controller air tubes. Check Pressure Controller - Pump-Unit connection. Replace cuff.</td>
</tr>
<tr>
<td>Fault: Insufficient Pressure Build Up in Cuff #1 - Possible Air Leakage</td>
<td>Finger Cuff and/or Pressure Controller air tubes kinked. Finger Cuff bladder leaking. Poor connection between Pressure Controller and Pump-Unit.</td>
<td>Check Finger Cuff and Pressure Controller air tubes. Check Pressure Controller - Pump-Unit connection. Replace cuff. Restart measurement.</td>
</tr>
<tr>
<td>Fault: Insufficient Pressure Build Up in Cuff #2 - Possible Air Leakage</td>
<td>Finger Cuff and/or Pressure Controller air tubes kinked. Finger Cuff bladder leaking. Poor connection between Pressure Controller and Pump-Unit.</td>
<td>Check Finger Cuff and Pressure Controller air tubes. Check Pressure Controller - Pump-Unit connection. Replace cuff. Restart measurement.</td>
</tr>
<tr>
<td>Alert: Possibly Contracted Arteries</td>
<td>Very small arterial volume pulsations detected, possibly contracted arteries.</td>
<td>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.</td>
</tr>
<tr>
<td>Alert: Finger Cuff #1 - No Pressure Waveforms Detected</td>
<td>The system failed to detect pressure waveforms. Pressure pulsations in finger diminished due to pressure applied to the upper arm, elbow or wrist.</td>
<td>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).</td>
</tr>
</tbody>
</table>
Table 12-5 ClearSight Faults and Alerts (Continued)

<table>
<thead>
<tr>
<th>Message</th>
<th>Possible Causes</th>
<th>Suggested Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alert: Finger Cuff #2 - No Pressure Waveforms Detected</td>
<td>The system failed to detect pressure waveforms. Pressure pulsations in finger diminished due to pressure applied to the upper arm, elbow or wrist.</td>
<td>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).</td>
</tr>
<tr>
<td>Fault: Finger Cuff #1 - No Pressure Waveforms Detected</td>
<td>The system failed to detect pressure waveforms. Pressure pulsations in finger diminished due to pressure applied to the upper arm, elbow or wrist.</td>
<td>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.</td>
</tr>
<tr>
<td>Fault: Finger Cuff #2 - No Pressure Waveforms Detected</td>
<td>The system failed to detect pressure waveforms. Pressure pulsations in finger diminished due to pressure applied to the upper arm, elbow or wrist.</td>
<td>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.</td>
</tr>
<tr>
<td>Alert: Finger Cuff #1 - Pressure波形Oscillations Detected</td>
<td>Possibly contracted arteries. Finger Cuff too loose.</td>
<td>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.</td>
</tr>
<tr>
<td>Alert: Finger Cuff #2 - Pressure波形Oscillations Detected</td>
<td>Possibly contracted arteries. Finger Cuff too loose.</td>
<td>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.</td>
</tr>
<tr>
<td>Alert: Finger Cuff #1 - No Plethysmogram</td>
<td>No measurable Plethysmogram detected on startup. Possibly contracted arteries.</td>
<td>Allow system to automatically resolve issue. Warm the hand. Apply Finger Cuff to a different finger.</td>
</tr>
<tr>
<td>Alert: Finger Cuff #2 - No Plethysmogram</td>
<td>No measurable Plethysmogram detected on startup. Possibly contracted arteries.</td>
<td>Allow system to automatically resolve issue. Warm the hand. Apply Finger Cuff to a different finger.</td>
</tr>
<tr>
<td>Fault: Finger Cuff #1 - No Plethysmogram</td>
<td>No measurable Plethysmogram detected on startup. Possibly contracted arteries.</td>
<td>Warm the hand. Apply Finger Cuff to a different finger. Restart measurement.</td>
</tr>
<tr>
<td>Fault: Finger Cuff #2 - No Plethysmogram</td>
<td>No measurable Plethysmogram detected on startup. Possibly contracted arteries.</td>
<td>Warm the hand. Apply Finger Cuff to a different finger. Restart measurement.</td>
</tr>
<tr>
<td>Alert: Finger Cuff #1 - BP Measurement Error</td>
<td>Blood pressure measurement failed due to movement or poor measurement conditions.</td>
<td>Allow system to automatically resolve issue. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size.</td>
</tr>
<tr>
<td>Alert: Finger Cuff #2 - BP Measurement Error</td>
<td>Blood pressure measurement failed due to movement or poor measurement conditions.</td>
<td>Allow system to automatically resolve issue. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size.</td>
</tr>
<tr>
<td>Alert: Unable to Switch to Finger Cuff #1</td>
<td>Error detected in Finger Cuff #1. Error detected in Pressure Controller.</td>
<td>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.</td>
</tr>
</tbody>
</table>
### Table 12-5 ClearSight Faults and Alerts (Continued)

<table>
<thead>
<tr>
<th>Message</th>
<th>Possible Causes</th>
<th>Suggested Actions</th>
</tr>
</thead>
</table>
| 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

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

### Table 12-7 ClearSight Troubleshooting

<table>
<thead>
<tr>
<th>Message / Question</th>
<th>Possible Causes</th>
<th>Suggested Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connect Finger Cuff</td>
<td>No Finger Cuff(s) detected.</td>
<td>Connect Finger Cuff(s).</td>
</tr>
<tr>
<td></td>
<td>Defective Finger Cuff(s) connected.</td>
<td>Replace Finger Cuff(s).</td>
</tr>
<tr>
<td>Finger Cuff #1 Approaching Maximum Use Time</td>
<td>Finger Cuff #1 approaching maximum use time.</td>
<td>Replace Finger Cuff #1 to ensure uninterrupted measurement.</td>
</tr>
<tr>
<td>Finger Cuff #2 Approaching Maximum Use Time</td>
<td>Finger Cuff #2 approaching maximum use time.</td>
<td>Replace Finger Cuff #2 to ensure uninterrupted measurement.</td>
</tr>
<tr>
<td>Connect HRS</td>
<td>HRS connection not detected.</td>
<td>Connect HRS.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Replace HRS.</td>
</tr>
<tr>
<td>Zero HRS</td>
<td>HRS not zeroed.</td>
<td>Ensure HRS is connected and Zero HRS to Start Measurement.</td>
</tr>
<tr>
<td>Connect Pressure Controller</td>
<td>Pressure Controller not connected.</td>
<td>Connect Pressure Controller.</td>
</tr>
<tr>
<td></td>
<td>Defective Pressure Controller connected.</td>
<td>Replace Pressure Controller.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If problem persists, contact Edwards Technical Support.</td>
</tr>
<tr>
<td>EV1000NI Use Not Recommended For Patient Age &lt; 18 yrs</td>
<td>Non invasive BP measurement technology not validated for patients under 18 years of age.</td>
<td>Measurement with an alternate BP / Cardiac Output technology recommended.</td>
</tr>
<tr>
<td>Pump-Unit Service Required</td>
<td>Pump-Unit service time is approaching.</td>
<td>Replace Pump-Unit.</td>
</tr>
</tbody>
</table>
Table 12-7 ClearSight Troubleshooting (Continued)

<table>
<thead>
<tr>
<th>Message / Question</th>
<th>Possible Causes</th>
<th>Suggested Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure Difference: ClearSight BP vs. Other BP</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Service Battery</td>
<td>Battery full charge capacity has dropped below recommended level. Battery malfunction.</td>
<td>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.</td>
</tr>
<tr>
<td>HRS Expires in &lt;4 Weeks</td>
<td>HRS will expire in less than 4 weeks.</td>
<td>Replace HRS to prevent delay in start of monitoring.</td>
</tr>
<tr>
<td>HRS Expires in &lt;2 Weeks</td>
<td>HRS will expire in less than 2 weeks.</td>
<td>Replace HRS to prevent delay in start of monitoring.</td>
</tr>
</tbody>
</table>

CVP Troubleshooting

Table 12-8 CVP Troubleshooting

<table>
<thead>
<tr>
<th>Message</th>
<th>Possible Causes</th>
<th>Suggested Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>SVR &gt; SVRI</td>
<td>Incorrect patient BSA BSA &lt; 1</td>
<td>Verify units of measure and values for patient’s height and weight.</td>
</tr>
<tr>
<td>Enter CVP Value for SVR/SVRI Measurements</td>
<td>No CVP Value Entered.</td>
<td>Enter CVP value.</td>
</tr>
</tbody>
</table>
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.

**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 13-1 EV1000 Table Stand**

**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.

HIS Connection Status should only be queried through the Monitor Settings menu after the HL7 connectivity feature has been configured and tested by the facility network administrator. If HIS Connection Status is queried while the feature setup is incomplete, the Connection Status Screen will remain open for 2 minutes before timing out.

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.

*Stopping an incomplete patient query may result in a connection error. If encountered, close error window and restart the query.*

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

To complete the query, the configured HIS must have patient gender values of either “M”, “F”, or blank. If the query exceeds the maximum duration defined in HIS configuration file, an error message will be displayed to prompt manual entry of patient data.

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.

Figure 14-1 HIS - Patient Query

Figure 14-2 HIS - New Patient Data Screen
14-2 EV1000 Clinical Platform NI Advanced Features

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 configured 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.

For additional technical or service questions about the HIS Connectivity feature, contact Edwards Technical Support. See Appendix E: “System Care, Service and Support” on page E-1, for contact information.

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.

 EV1000 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.

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.

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)
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 ClearSight 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

<table>
<thead>
<tr>
<th>Monitor</th>
<th>Weight</th>
<th>2.1 kg (4.6 lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>Height</td>
<td>226 mm</td>
</tr>
<tr>
<td></td>
<td>Width</td>
<td>296 mm</td>
</tr>
<tr>
<td></td>
<td>Depth</td>
<td>58.6 mm</td>
</tr>
<tr>
<td>Display</td>
<td>Active Area</td>
<td>257 mm (10.4&quot;)</td>
</tr>
<tr>
<td></td>
<td>Resolution</td>
<td>800 x 600 LCD</td>
</tr>
<tr>
<td>Operating System</td>
<td>Windows</td>
<td></td>
</tr>
<tr>
<td>Speaker count</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitor (Advantech Model)</th>
<th>Weight</th>
<th>2 kg (4.4 lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions (with Bracket)</td>
<td>Height</td>
<td>217 mm</td>
</tr>
<tr>
<td></td>
<td>Width</td>
<td>280 mm</td>
</tr>
<tr>
<td></td>
<td>Depth</td>
<td>46 mm</td>
</tr>
<tr>
<td>Display (with Bracket)</td>
<td>Active Area</td>
<td>266 mm (10.4&quot;)</td>
</tr>
<tr>
<td></td>
<td>Resolution</td>
<td>1024 x 768 LCD</td>
</tr>
<tr>
<td>Operating System</td>
<td>Windows</td>
<td></td>
</tr>
<tr>
<td>Speaker count</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pump-Unit</th>
<th>Weight (with Bracket)</th>
<th>3.1 kg (6.8 lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions (with Bracket)</td>
<td>Height</td>
<td>280 mm</td>
</tr>
<tr>
<td></td>
<td>Width</td>
<td>195 mm</td>
</tr>
<tr>
<td></td>
<td>Depth</td>
<td>165 mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pressure Controller</th>
<th>Weight</th>
<th>0.35 kg (0.77 lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>Height</td>
<td>97 mm</td>
</tr>
<tr>
<td></td>
<td>Width</td>
<td>54 mm</td>
</tr>
<tr>
<td></td>
<td>Depth</td>
<td>35 mm</td>
</tr>
<tr>
<td></td>
<td>Cable Length</td>
<td>3.5 m</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Heart Reference Sensor</th>
<th>Weight</th>
<th>36 g (0.08 lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>Length</td>
<td>1.2 m</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ClearSight Finger Cuff</th>
<th>Maximum Weight</th>
<th>11g (0.02 lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LED Spectral Irradiance</td>
<td>See Figure A-1</td>
<td></td>
</tr>
<tr>
<td>Max Optical Output over treatment area</td>
<td>0.013 mWatts</td>
<td></td>
</tr>
<tr>
<td>Max variation of output over treatment area</td>
<td>50%</td>
<td></td>
</tr>
</tbody>
</table>

**Figure A-1 Spectral Irradiance**

**Figure A-2 Location of Light Emission Aperture**
Table A-2 Environmental Specifications

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

Table A-3 Base Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finger Cuff Pressure</td>
<td></td>
</tr>
<tr>
<td>Display Range</td>
<td>0 to 300 mmHg</td>
</tr>
<tr>
<td>Accuracy¹</td>
<td>1% of full scale (max 3 mmHg)</td>
</tr>
<tr>
<td>CO</td>
<td></td>
</tr>
<tr>
<td>Display Range</td>
<td>1.0 to 20.0 L/min</td>
</tr>
<tr>
<td>Accuracy</td>
<td>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</td>
</tr>
<tr>
<td>Reproducibility²</td>
<td>±6%</td>
</tr>
<tr>
<td>Update Rate</td>
<td>20 seconds</td>
</tr>
</tbody>
</table>

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

Table A-4 EV1000 Clinical Platform NI Components

<table>
<thead>
<tr>
<th>Description</th>
<th>Model Number</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EV1000 System</strong></td>
<td></td>
</tr>
<tr>
<td>EV1000 Clinical Platform</td>
<td>EV1000A</td>
</tr>
<tr>
<td>EV1000 Clinical Platform NI</td>
<td>EV1000NI</td>
</tr>
<tr>
<td>EV1000 NI Upgrade</td>
<td>EVNIUPG</td>
</tr>
<tr>
<td><strong>EV1000 Monitor</strong></td>
<td></td>
</tr>
<tr>
<td>Monitor</td>
<td>EV1000M</td>
</tr>
<tr>
<td>Monitor Bracket</td>
<td>EVMB1</td>
</tr>
<tr>
<td>EV1000 Panel Cover</td>
<td>EV1000CVR</td>
</tr>
<tr>
<td><strong>EV1000 Pump-Unit</strong></td>
<td></td>
</tr>
<tr>
<td>Pump-Unit</td>
<td>EVPMP</td>
</tr>
<tr>
<td>Pump-Unit Bracket</td>
<td>EVPMPBRKT</td>
</tr>
<tr>
<td><strong>EV1000 Noninvasive Peripheral Hardware</strong></td>
<td></td>
</tr>
<tr>
<td>Pressure Controller Kit</td>
<td>PC2K</td>
</tr>
<tr>
<td>Pressure Controller</td>
<td>PC2</td>
</tr>
<tr>
<td>Pressure Controller Band Multi Pack</td>
<td>PC2B</td>
</tr>
<tr>
<td>Pressure Controller Cuff Connector Cap</td>
<td>PC2CCC</td>
</tr>
<tr>
<td>Pressure Controller Cover</td>
<td>PCCVR</td>
</tr>
<tr>
<td>Heart Reference Sensor</td>
<td>EVHRS</td>
</tr>
<tr>
<td><strong>EV1000 NI System Cables</strong></td>
<td></td>
</tr>
<tr>
<td>Mains Power Cable</td>
<td>*</td>
</tr>
<tr>
<td>EV1000 NI Power Cable, 3 Feet</td>
<td>EVNIPCL3</td>
</tr>
<tr>
<td>EV1000 NI Power Cable, 12 Feet</td>
<td>EVNIPCL12</td>
</tr>
<tr>
<td>EV1000 NI Patient Monitor Adaptor Cable</td>
<td>EVPMAC</td>
</tr>
<tr>
<td>EV1000 Ethernet Cable, 3 Feet</td>
<td>EVEC3FT</td>
</tr>
<tr>
<td>EV1000 Ethernet Cable, 12 Feet</td>
<td>EVEC12FT</td>
</tr>
<tr>
<td>EV1000 NI Databox Adaptor Cable</td>
<td>EVNIDBAC</td>
</tr>
<tr>
<td><strong>EV1000 Stands</strong></td>
<td></td>
</tr>
<tr>
<td>EV1000 Table Stand</td>
<td>EVS1</td>
</tr>
<tr>
<td>EV1000 Roll Stand</td>
<td>EVRS</td>
</tr>
<tr>
<td><strong>Additional EV1000 NI Accessories</strong></td>
<td></td>
</tr>
<tr>
<td>ClearSight Finger Cuff Small Multi Pack</td>
<td>CSCS</td>
</tr>
<tr>
<td>ClearSight Finger Cuff Medium Multi Pack</td>
<td>CSM</td>
</tr>
<tr>
<td>ClearSight Finger Cuff Large Multi Pack</td>
<td>CSL</td>
</tr>
<tr>
<td>Heart Reference Sensor Body Pads</td>
<td>EVHRSBP</td>
</tr>
<tr>
<td>EV1000 NI Panel SW Upgrade</td>
<td>EVNISWUPG</td>
</tr>
<tr>
<td><strong>EV1000 Clinical Platform NI Operator’s Manual</strong></td>
<td></td>
</tr>
<tr>
<td><strong>EV1000 Clinical Platform NI Service Manual</strong></td>
<td></td>
</tr>
</tbody>
</table>

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.

Note: Accessories provided with an “R” suffix, indicate refurbished products.
### Table A-5 EV1000 Monitor Technical Specifications

<table>
<thead>
<tr>
<th>Input/Output</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Touch Screen</td>
<td>Resistive type</td>
</tr>
<tr>
<td>RS232 Serial Port</td>
<td>Edwards proprietary protocol; Maximum data rate = 57.6 kilo baud</td>
</tr>
<tr>
<td>USB Port</td>
<td>Three USB V1.1 compatible type A connectors on the monitor.</td>
</tr>
<tr>
<td>RJ-45 Ethernet Port</td>
<td>Two</td>
</tr>
<tr>
<td>VGA Port</td>
<td>One</td>
</tr>
</tbody>
</table>

**Electrical**

| Voltage            | 24V, 1.8A max |

### Table A-6 EV1000 Pump-Unit Technical Specifications

<table>
<thead>
<tr>
<th>Electrical</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage</td>
<td>100 to 240 Volts AC</td>
</tr>
<tr>
<td></td>
<td>50/60 Hz</td>
</tr>
<tr>
<td>Power Consumption</td>
<td>100 VA, maximum</td>
</tr>
<tr>
<td>Protection against electric shock</td>
<td>Class I equipment</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description and Formula</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSA</td>
<td>Body Surface Area (DuBois formula)</td>
<td>m²</td>
</tr>
<tr>
<td></td>
<td>BSA = 71.84 x (WT(^{0.425})) x (HT(^{0.725})) / 10,000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>where:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>WT - Patient Weight, kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HT - Patient Height, cm</td>
<td></td>
</tr>
<tr>
<td>CaO₂</td>
<td>Arterial Oxygen Content</td>
<td>mL/dL</td>
</tr>
<tr>
<td></td>
<td>CaO₂ = (0.0138 x HGB x SpO₂) + (0.0031 x PaO₂) (mL/dL)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CaO₂ = [0.0138 x (HGBSI x 1.611) x SpO₂] + [0.0031 x (PaO₂SI x 7.5)] (mL/dL)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>where:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HGB – Total Hemoglobin, g/dL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HGBSI – Total Hemoglobin, mmol/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SpO₂ – Arterial O₂ Saturation, %</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PaO₂ – Partial Pressure of Arterial Oxygen, mmHg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PaO₂SI – Partial Pressure of Arterial Oxygen, kPa</td>
<td></td>
</tr>
<tr>
<td>CvO₂</td>
<td>Venous Oxygen Content</td>
<td>mL/dL</td>
</tr>
<tr>
<td></td>
<td>CvO₂ = (0.0138 x HGB x SvO₂) + (0.0031 x PvO₂) (mL/dL)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CvO₂ = [0.0138 x (HGBSI x 1.611) x SvO₂] + [0.0031 x (PvO₂SI x 7.5)] (mL/dL)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>where:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HGB – Total Hemoglobin, g/dL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HGBSI – Total Hemoglobin, mmol/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SvO₂ – Venous O₂ Saturation, %</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PvO₂ – Partial Pressure of Venous Oxygen, mmHg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PvO₂SI – Partial Pressure of Venous Oxygen, kPa</td>
<td></td>
</tr>
<tr>
<td></td>
<td>and PvO₂ is assumed to be 0</td>
<td></td>
</tr>
<tr>
<td>Ca-vO₂</td>
<td>Arteriovenous Oxygen Content Difference</td>
<td>mL/dL</td>
</tr>
<tr>
<td></td>
<td>Ca-vO₂ = CaO₂ - CvO₂ (mL/dL)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>where:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CaO₂ – Arterial Oxygen Content (mL/dL)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CvO₂ – Venous Oxygen Content (mL/dL)</td>
<td></td>
</tr>
</tbody>
</table>
### Table B-1 Cardiac Profile Equations (Continued)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description and Formula</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>CI</td>
<td>Cardiac Index&lt;br&gt;CI = CO/BSA&lt;br&gt;where:&lt;br&gt;CI - Cardiac Index, CO - Cardiac Output, L/min&lt;br&gt;BSA - Body Surface Area, m²</td>
<td>L/min/m²</td>
</tr>
<tr>
<td>CPI</td>
<td>Cardiac Power Index&lt;br&gt;CPI = MAP x CI x 0.0022</td>
<td>W/m²</td>
</tr>
<tr>
<td>CPO</td>
<td>Cardiac Power Output&lt;br&gt;CPO = CO x MAP x K&lt;br&gt;where:&lt;br&gt;Cardiac power output (CPO) (W) was calculated as MAP x cardiac output/451&lt;br&gt;K is the conversion factor (2.22 x 10⁻³) into watts&lt;br&gt;MAP in mmHg&lt;br&gt;CO L/min</td>
<td>W</td>
</tr>
<tr>
<td>DO₂</td>
<td>Oxygen Delivery&lt;br&gt;DO₂ = {(1.38 x HGB x SpO₂) + (0.31 x PaO₂)} x CO&lt;br&gt;where:&lt;br&gt;CO - Cardiac Output, L/min&lt;br&gt;HGB - Total Hemoglobin, g/dL&lt;br&gt;PaO₂ - Partial Pressure of Arterial Oxygen, mmHg&lt;br&gt;SpO₂ - Pulse Oximetry Saturation %</td>
<td>mL O₂/min</td>
</tr>
<tr>
<td>DO₂I</td>
<td>Oxygen Delivery Index&lt;br&gt;DO₂I = {(1.38 x HGB x SpO₂) + (0.31 x PaO₂)} x CO&lt;br&gt;where:&lt;br&gt;BSA - Body Surface Area, m²&lt;br&gt;CO - Cardiac Output, L/min&lt;br&gt;HGB - Total Hemoglobin, g/dL&lt;br&gt;PaO₂ - Partial Pressure of Arterial Oxygen, mmHg&lt;br&gt;SpO₂ - Pulse Oximetry Saturation</td>
<td>mL O₂/min/m²</td>
</tr>
<tr>
<td>SV</td>
<td>Stroke Volume&lt;br&gt;SV = (CO/PR) x 1000&lt;br&gt;where:&lt;br&gt;CO - Cardiac Output, L/min&lt;br&gt;PR - Pulse rate, beats/min</td>
<td>mL/beat</td>
</tr>
<tr>
<td>SVI</td>
<td>Stroke Volume Index&lt;br&gt;SVI = (CI/PR) x 1000&lt;br&gt;where:&lt;br&gt;CI - Cardiac Index, L/min/m²&lt;br&gt;PR - Pulse rate, beats/min</td>
<td>mL/beat/m²</td>
</tr>
<tr>
<td>SVR</td>
<td>Systemic Vascular Resistance&lt;br&gt;SVR = ((MAP - CVP) x 80)/CO (dyne-s/cm⁵)&lt;br&gt;where:&lt;br&gt;MAP - Mean Arterial Pressure, mmHg&lt;br&gt;CVP - Central Venous Pressure, mmHg&lt;br&gt;CO - Cardiac Output, L/min</td>
<td>dyne-s/cm⁵</td>
</tr>
</tbody>
</table>
## Table B-1 Cardiac Profile Equations (Continued)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description and Formula</th>
<th>Units</th>
</tr>
</thead>
</table>
| **SVRI**  | Systemic Vascular Resistance Index  
SVRI = \((\text{MAP} - \text{CVP}) \times 80\) /CI  
where:  
MAP - Mean Arterial Pressure, mmHg  
CVP - Central Venous Pressure, mmHg  
CI - Cardiac Index, L/min/m² | dyne-s/m²/cm⁵ |
| **SVV**   | Stroke Volume Variation  
SVV = 100 x (SVmax - SVmin) / mean(SV) | % |
| **VO₂**   | Oxygen Consumption  
VO₂ = \(\text{Ca-vO₂} \times \text{CO} \times 10\) (mL O₂/min)  
where:  
\(\text{Ca-vO₂}\) – Arteriovenous Oxygen Content Difference, mL/dL  
\(\text{CO}\) – Cardiac Output, L/min | mL O₂/min |
| **VO₂ₑ**  | Estimated Oxygen Consumption when ScvO₂ is being monitored and used to calculate  
\(\text{Ca-vO₂}\) instead SvO₂  
VO₂ₑ = \(\text{Ca-vO₂} \times \text{CO} \times 10\) (mL O₂/min)  
where:  
\(\text{Ca-vO₂}\) – Arteriovenous Oxygen Content Difference, mL/dL  
\(\text{CO}\) – Cardiac Output, L/min | mL O₂/min |
| **VO₂₁**  | Oxygen Consumption Index  
VO₂ / BSA | mL O₂/min/m² |
| **VO₂ₑ₁** | Estimated Oxygen Consumption Index  
VO₂ₑ / BSA | mL O₂/min/m² |
Appendix C: Monitor Settings and Defaults

Patient Data Input Range

Table C-1 Patient Information

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Available Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>M (Male) / F (Female)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Age</td>
<td>2</td>
<td>120</td>
<td>years</td>
</tr>
<tr>
<td>Height</td>
<td>12 in / 30 cm</td>
<td>98 in / 250 cm</td>
<td>inches (in) or cm</td>
</tr>
<tr>
<td>Weight</td>
<td>2 lbs / 1.0 kg</td>
<td>880 lbs / 400.0 kg</td>
<td>lbs or kg</td>
</tr>
<tr>
<td>BSA</td>
<td>0.08</td>
<td>5.02</td>
<td>m²</td>
</tr>
<tr>
<td>ID</td>
<td>0 digits</td>
<td>12 digits</td>
<td>None</td>
</tr>
</tbody>
</table>

Trend Scale Default Limits

Table C-2 Graphical Trend Parameter Scale Defaults

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Units</th>
<th>Minimum Default Value</th>
<th>Maximum Default Value</th>
<th>Setting Increment</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO</td>
<td>L/min</td>
<td>0.0</td>
<td>12.0</td>
<td>1.0</td>
</tr>
<tr>
<td>CI</td>
<td>L/min/m²</td>
<td>0.0</td>
<td>12.0</td>
<td>1.0</td>
</tr>
<tr>
<td>SV</td>
<td>mL/b</td>
<td>0</td>
<td>160</td>
<td>20</td>
</tr>
<tr>
<td>SVI</td>
<td>mL/b/m²</td>
<td>0</td>
<td>80</td>
<td>20</td>
</tr>
<tr>
<td>SVV</td>
<td>%</td>
<td>0</td>
<td>50</td>
<td>10</td>
</tr>
<tr>
<td>SVR</td>
<td>dyne-s/cm⁵</td>
<td>500</td>
<td>1500</td>
<td>100</td>
</tr>
<tr>
<td>SVRI</td>
<td>dyne-s-m²/cm⁵</td>
<td>500</td>
<td>3000</td>
<td>200</td>
</tr>
<tr>
<td>SYS</td>
<td>mmHg</td>
<td>80</td>
<td>160</td>
<td>5</td>
</tr>
<tr>
<td>DIA</td>
<td>mmHg</td>
<td>50</td>
<td>110</td>
<td>5</td>
</tr>
<tr>
<td>MAP</td>
<td>mmHg</td>
<td>50</td>
<td>130</td>
<td>5</td>
</tr>
<tr>
<td>PR</td>
<td>bpm</td>
<td>40</td>
<td>130</td>
<td>5</td>
</tr>
</tbody>
</table>
Parameter Display and Configurable Alarm/Target Ranges

Table C-3 Ranges for Key Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Units</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO</td>
<td>L/min</td>
<td>1.0 to 20.0</td>
</tr>
<tr>
<td>CI</td>
<td>L/min/m²</td>
<td>0.0 to 20.0</td>
</tr>
<tr>
<td>SV</td>
<td>mL/b</td>
<td>0 to 300</td>
</tr>
<tr>
<td>SVI</td>
<td>mL/b/m²</td>
<td>0 to 200</td>
</tr>
<tr>
<td>SVR</td>
<td>dyne-s/cm⁵</td>
<td>0 to 5000</td>
</tr>
<tr>
<td>SVRI</td>
<td>dyne-s-m²/cm⁵</td>
<td>0 to 9950</td>
</tr>
<tr>
<td>SVV</td>
<td>%</td>
<td>0 to 99</td>
</tr>
<tr>
<td>MAP*</td>
<td>mmHg</td>
<td>10 to 300</td>
</tr>
<tr>
<td>SYS*</td>
<td>mmHg</td>
<td>10 to 300</td>
</tr>
<tr>
<td>DIA*</td>
<td>mmHg</td>
<td>10 to 300</td>
</tr>
<tr>
<td>PR</td>
<td>Bpm</td>
<td>0 to 220</td>
</tr>
</tbody>
</table>

* 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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Units</th>
<th>EW Default Lower Alarm (Red Zone) Setting</th>
<th>EW Default Lower Target Setting</th>
<th>EW Default Upper Target Setting</th>
<th>EW Default Upper Alarm (Red Zone) Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>CI</td>
<td>L/min/m²</td>
<td>1.0</td>
<td>2.0</td>
<td>4.0</td>
<td>6.0</td>
</tr>
<tr>
<td>SVI</td>
<td>mL/b/m²</td>
<td>20</td>
<td>30</td>
<td>50</td>
<td>70</td>
</tr>
<tr>
<td>SVRI</td>
<td>dyne-s-m²/cm⁵</td>
<td>1000</td>
<td>1970</td>
<td>2390</td>
<td>3000</td>
</tr>
<tr>
<td>SVV</td>
<td>%</td>
<td>0</td>
<td>0</td>
<td>13</td>
<td>20</td>
</tr>
<tr>
<td>SYS</td>
<td>mmHg</td>
<td>90</td>
<td>100</td>
<td>130</td>
<td>150</td>
</tr>
<tr>
<td>DIA</td>
<td>mmHg</td>
<td>60</td>
<td>70</td>
<td>90</td>
<td>100</td>
</tr>
<tr>
<td>MAP</td>
<td>mmHg</td>
<td>60</td>
<td>70</td>
<td>100</td>
<td>120</td>
</tr>
<tr>
<td>PR</td>
<td>bpm</td>
<td>60</td>
<td>70</td>
<td>100</td>
<td>120</td>
</tr>
</tbody>
</table>
# Language Default Settings*

<table>
<thead>
<tr>
<th>Language</th>
<th>Default Display Units</th>
<th>Time Format</th>
<th>Date Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>English (US)</td>
<td>mmHg</td>
<td>g/dL</td>
<td>in</td>
</tr>
<tr>
<td>English (UK)</td>
<td>kPa</td>
<td>mmol/L</td>
<td>cm</td>
</tr>
<tr>
<td>Français</td>
<td>kPa</td>
<td>mmol/L</td>
<td>cm</td>
</tr>
<tr>
<td>Deutsch</td>
<td>kPa</td>
<td>mmol/L</td>
<td>cm</td>
</tr>
<tr>
<td>Italiano</td>
<td>kPa</td>
<td>mmol/L</td>
<td>cm</td>
</tr>
<tr>
<td>Español</td>
<td>kPa</td>
<td>mmol/L</td>
<td>cm</td>
</tr>
<tr>
<td>Svenska</td>
<td>kPa</td>
<td>mmol/L</td>
<td>cm</td>
</tr>
<tr>
<td>Nederlands</td>
<td>kPa</td>
<td>mmol/L</td>
<td>cm</td>
</tr>
<tr>
<td>Ελληνικά</td>
<td>kPa</td>
<td>mmol/L</td>
<td>cm</td>
</tr>
<tr>
<td>Português</td>
<td>kPa</td>
<td>mmol/L</td>
<td>cm</td>
</tr>
<tr>
<td>日本語</td>
<td>mmHg</td>
<td>g/dL</td>
<td>cm</td>
</tr>
<tr>
<td>中文</td>
<td>kPa</td>
<td>mmol/L</td>
<td>cm</td>
</tr>
<tr>
<td>Čeština</td>
<td>kPa</td>
<td>mmol/l</td>
<td>cm</td>
</tr>
<tr>
<td>Polski</td>
<td>kPa</td>
<td>mmol/l</td>
<td>cm</td>
</tr>
<tr>
<td>Suomi</td>
<td>kPa</td>
<td>mmol/L</td>
<td>cm</td>
</tr>
<tr>
<td>Norsk</td>
<td>kPa</td>
<td>mmol/L</td>
<td>cm</td>
</tr>
<tr>
<td>Dansk</td>
<td>kPa</td>
<td>mmol/L</td>
<td>cm</td>
</tr>
<tr>
<td>Eesti</td>
<td>mmHg</td>
<td>mmol/L</td>
<td>cm</td>
</tr>
<tr>
<td>Lietuvių</td>
<td>mmHg</td>
<td>g/dl</td>
<td>cm</td>
</tr>
<tr>
<td>Latviešu</td>
<td>kPa</td>
<td>mmol/L</td>
<td>cm</td>
</tr>
</tbody>
</table>

*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**

\[
1 \text{ mmHg} = (1\text{ mmHg}) \times \left(\frac{\text{Newton}}{m^2}\right) \times \left(\frac{Pa}{\text{Newton/m}^2}\right) \times \left(\frac{1\text{kPa}}{1000\text{Pa}}\right) = \left(\frac{1\text{kPa}}{7.5\text{mmHg}}\right)
\]

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)**

\[
1 \text{ g/dL} = \left(\frac{1\text{g}}{dL}\right) \times \left(\frac{1\text{mol}}{64.458}\right) \times \left(\frac{1000\text{mmol}}{1\text{mol}}\right) \times \left(\frac{10\text{dL}}{1\text{L}}\right) \times 4 = \left(\frac{0.6206\text{mmol}}{1}\right)
\]

1 dyne–s/cm² =

or

\[
1 \text{ mmol/L} = \left(\frac{\text{g/dL}}{0.6206}\right)
\]

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

**°F vs. °C**

\[
°F = °C \times 1.8 + 32
\]

\[
°C = \frac{°F - 32}{1.8}
\]
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.

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

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.

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.

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 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.

WARNING
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.

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.

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](image)

- 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.*
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.

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


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

<table>
<thead>
<tr>
<th>Description</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>EV1000 Pressure Controller cable</td>
<td>11.5 ft</td>
</tr>
<tr>
<td>HRS cable</td>
<td>4.0 ft</td>
</tr>
<tr>
<td>ClearSight Finger Cuff, Small</td>
<td>7.1 in</td>
</tr>
<tr>
<td>ClearSight Finger Cuff, Medium</td>
<td>7.9 in</td>
</tr>
<tr>
<td>ClearSight Finger Cuff, Large</td>
<td>8.7 in</td>
</tr>
<tr>
<td>EV1000 NI Power cable</td>
<td>3.3 ft</td>
</tr>
<tr>
<td></td>
<td>or</td>
</tr>
<tr>
<td>EV1000 Ethernet cable</td>
<td>11.5 ft</td>
</tr>
<tr>
<td></td>
<td>or</td>
</tr>
<tr>
<td>Mains Power cable</td>
<td>USA</td>
</tr>
<tr>
<td></td>
<td>10 ft</td>
</tr>
<tr>
<td></td>
<td>or</td>
</tr>
<tr>
<td></td>
<td>3.1 m</td>
</tr>
<tr>
<td>EV1000 Patient Monitor Adaptor cable</td>
<td>6.0 in</td>
</tr>
<tr>
<td>EV1000 NI Databox Adaptor cable</td>
<td>3.9 ft</td>
</tr>
</tbody>
</table>

When connected to the Databox, the following apply:

<table>
<thead>
<tr>
<th>Description</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>FloTrac Cable</td>
<td>12.2 in</td>
</tr>
<tr>
<td></td>
<td>or</td>
</tr>
<tr>
<td>FloTrac Sensor</td>
<td>12.2 in</td>
</tr>
<tr>
<td>EV1000 VolumeView Thermodilution Cable</td>
<td>7.75 ft</td>
</tr>
</tbody>
</table>

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.
  - No modification of the EV1000 Clinical Platform NI is allowed.
  - 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.
  - 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

<table>
<thead>
<tr>
<th>Emissions</th>
<th>Compliance</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>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.</td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class A</td>
<td>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.</td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuation/ Flicker emissions</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Transmitter Frequency</th>
<th>150 kHz to 80 MHz</th>
<th>80 to 800 MHz</th>
<th>800 to 2500 MHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equation</td>
<td>(d = 1.2 \sqrt{P})</td>
<td>(d = 1.2 \sqrt{P})</td>
<td>(d = 2.3 \sqrt{P})</td>
</tr>
<tr>
<td>Rated Maximum Output</td>
<td>Separation Distance</td>
<td>Separation Distance</td>
<td>Separation Distance</td>
</tr>
<tr>
<td>Transmitter Power (watts)</td>
<td>(meters)</td>
<td>(meters)</td>
<td>(meters)</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
<td>0.12</td>
<td>0.24</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
<td>0.37</td>
<td>0.74</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
<td>1.2</td>
<td>2.3</td>
</tr>
<tr>
<td>10</td>
<td>3.7</td>
<td>3.8</td>
<td>7.4</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
<td>12</td>
<td>23</td>
</tr>
</tbody>
</table>

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>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601-1-2 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6 kV contact</td>
<td>±6 kV</td>
<td>Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td></td>
<td>±8 kV air</td>
<td>±8 kV</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>±2 kV for power supply lines</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial and/or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±1 kV for 1 kV for input/output lines &gt; 3 meters</td>
<td>±1 kV for 1 kV for input/output lines &gt; 3 meters</td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV line(s) to line(s)</td>
<td>±1 kV line(s) to line(s)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>±2 kV line(s) to earth</td>
<td>±2 kV line(s) to earth</td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply AC input lines</td>
<td>&lt;5% $U_T$ (&gt;95% dip in $U_T$) for 0.5 cycle</td>
<td>&lt;5% $U_T$</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>40% $U_T$ (60% dip in $U_T$) for 5 cycles</td>
<td>40% $U_T$</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% $U_T$ (30% dip in $U_T$) for 25 cycles</td>
<td>70% $U_T$</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;5% $U_T$ (&gt;95% dip in $U_T$) for 5 sec</td>
<td>&lt;5% $U_T$</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

NOTE: $U_T$ is the AC mains voltage prior to application of the test level.
<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601-1-2 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
</table>
| Conducted RF        | IEC 61000-4-6            | 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:

\[
d = [1.2] \times \sqrt{P}; \ 150 \text{ kHz to } 80 \text{ MHz}
\]

\[
d = [1.2] \times \sqrt{P}; \ 80 \text{ MHz to } 800 \text{ MHz}
\]

\[
d = [2.3] \times \sqrt{P}; \ 800 \text{ MHz to } 2500 \text{ MHz}
\]

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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment with the following symbol:

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.

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 (ScvO₂)
Percentage of hemoglobin saturated with oxygen in the venous blood as measured in the superior vena cava (SVC). Displayed as ScvO₂.

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 (VO₂e)
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 ScvO₂.

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 (SvO₂)
Percentage of hemoglobin saturated with oxygen in the venous blood as measured in the pulmonary artery. Displayed as SvO₂.

Oxygen Consumption (VO₂)
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 SvO₂.

Oxygen Delivery (DO₂)
Amount of oxygen in milliliters per minute (mL/min) delivered to the tissues.

Oxygen Delivery Index (DO₂I)
Amount of oxygen in milliliters per minute (mL/min/m²) delivered to the tissues, adjusted for body size.

Oximetry (Oxygen Saturation, ScvO₂/SvO₂)
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

Symbols
°F vs. °C D-1

Numerics
61000-4-3 F-4

A
A/D
  def. 1-3
AAMI ES 60601-1
    2006 2-9
Abbreviations 1-3
Accessories A-2
  ClearSight Cuff 3-1
Acronyms 1-3
Adjust scales 6-8
Advanced Features 14-1
Alarm
  silence 5-2
Alarm / Target
    change 4-3, 5-3
  Defaults C-2
Alarm button 5-2
Alarm Limits
  glossary G-1
Alarm volume 6-5
Alarms
  configure for one parameter 6-7
  Disabled indicator 5-2
  glossary G-1
  set limits 7-7
Alerts 12-1
Altitude
  Environmental Specifications A-2
AP
  def. 1-3
Applicable Standards 2-9
ART
  def. 1-3
  display 5-3
Arterial Waveform
  display 5-3

B
Base parameters A-2
Big numbers monitoring screen 5-6
Blood Pressure
  glossary G-1
Body Surface Area (BSA)
  glossary G-1
BP
  def. 1-3, G-1
BSA 6-1
  def. 1-3
  equation B-1
  glossary G-1
BSA Change 10-2
Button
  glossary G-1
  list 5-9
  Buttons 5-1
ClearSight Cuff
  size selection 7-4
  Weight A-1
C
Cable
  cleaning E-1, E-2
  length F-1
Cancel button 5-8
CaO2
  equation B-1
Cardiac index
  def. 1-1
Cardiac Index (CI)
  glossary G-1
Cardiac output
  def. 1-1
Cardiac Output (CO)
  glossary G-1
Cardiac Output Calibration 7-9
Cardiac profile equations B-1
Case symbols 2-7
CAUTION
  def. 2-1
Cautions 2-4
Ca-vO2
  equation B-1
Central Venous Oxygen Saturation
  glossary G-1
Central Venous Pressure
  glossary G-1
Change Alarm / Target 5-3
Change parameters 5-3
CI
  def. 1-1, 1-3
  equation B-2
CISPR 11 F-2
Class A Harmonic Emissions F-2
Class B RF Emissions F-2
Cleaning
  cable and connectors E-2
  cables E-1
  monitor E-1
ClearSight
  algorithm 1-1, 7-1
  Cuff 1-1
  Faults and Alerts 12-7
  Warnings and Troubleshooting 12-12
ClearSight Finger C 7-4
ClearSight Finger Cuff
  equation B-1
C
CVP
  def. 1-3
  Troubleshooting 12-13

ClearSight Monitoring
  Resumed 10-2
  Started 10-2
  Stopped 10-2
ClearSight Technology 4-1
  available parameters 3-1
  overview 1-1

Clinical actions button 5-1
CO 1-3
  def. 1-1
  Parameter Specifications A-2
CO Calibration 7-9
CO Reference Cleared 10-2
CO Reference Entered 10-2
CO Reference Value 10-2
CO reference value 7-10
Cockpit monitoring screen 5-7
Conducted RF IEC 61000-4-6 F-4
Configure All Targets 6-6
Connect patient cables 3-4
Connection
  monitor 3-2
  Patient cable diagram 3-3
  Pump-Unit 3-2
Connectors
  cleaning E-2
  Container symbols 2-7
  Contents, package 3-1
  Continue monitoring patient 6-1
  Continue Same Patient 6-1
  Continuous % Change
    Indicator 5-8
    Interval 6-8
  Continuous mode, Physio
    Relationship 8-2
CPI
  def. 1-3
  equation B-2
CPO
  def. 1-3
  equation B-2
CSA C22.2#60601-1
  2008 2-9
Cuff 1 Monitoring, Event Review 10-2
Cuff 2 Monitoring, Event Review 10-2
Cuff monitoring stopped 10-2
Cuff Pressure Release Mode 7-9
Cuff Pressure Release, Event
  Review 10-2
Custom defaults, set 6-7
Custom Event 10-2
CvO2
  equation B-1
  CPO
CVP Cleared 10-2
CVP Entered 10-2

**D**
- Date change 6-2
- Date Format 6-3
- Daylight savings time 6-3 def. 1-3
- Default Settings
glossary G-1
- Defaults, restore 6-4
- Defaults, set custom 6-7
- Demonstration mode 9-1, 11-1
- Depth, monitor A-1
def. 1-1
- Derived Value Calculator 7-8, 10-1
- Device Setup 12-1
- DI A
def. 1-1
- Diastolic Pressure
def. 1-1
- Dimensions, Monitor A-1
- Display
  - Monitor A-1
- Display options 6-1
- Display size A-1
- Display symbols 2-6
- Disposal, monitor, Pump-Unit E-3
- Distances F-2

**E**
- Edwards Lifesciences locations E-3
- Electrical fast transient/ burst F-3
- Electromagnetic compatibility F-1
emissions F-2
- Electrostatic discharge F-3
- Engineering 6-9
- Enter value 5-9
- Environmental Specifications A-2
- Environmental specifications A-2
- Equations B-1
cardiac profile B-1
- Error
  - keypad 12-6
  - system 12-5

EV1000 Clinical Platform NI
- Overview 1-1
EV1000 Clinical Platform NI
- Parameters 1-1
EV1000 Power Supply A-2
EV1000 Pump Unit Bracket 13-3
EV1000 Stands A-2
Event Review 10-1

**F**
- Fault
  - Duplicate Technology
    - Connected 12-5
- Faults 12-1
- Faults and Alerts
  - ClearSight 12-7
- Fluid Challenge 5-4, 10-2

**G**
- g D-1
g/dL vs. mmol/L D-1
- GDT
def. 1-3
gDT Session
- Active Tracking 9-2
- Parameter/Target Selection 9-1
- Paused 10-2
- Resumed 10-2
- Started 10-2
- Stopped 10-2
- Targets Updated 10-2
- Gender 6-1
- General 6-5
- General monitor settings 6-2
- Getting started 4-1
- Goal Positioning Screen 14-2
- Graph, waveform confirmation 10-1
- Graphical trend monitoring screen 5-3
- Graphical Trend scroll rates 5-5
- Graphical Trend Time 6-9
- Green
  - indicator 6-5, 9-2
  - Pressure Controller 12-5
  - Pressure Controller Cuff status light 12-4
- Grey
  - indicator 6-5, 9-2
- Group 1 RF Emissions F-2

**H**
- Harmonic emissions IEC 61000-3-2 F-2
- Heart icon 5-8
- Heart Reference Sensor
  - alignment 7-6
  - application 4-3, 7-6
  - introduction 1-1
- Weight A-1
  - zero 7-5
  - zeroing 4-2
- Height, monitor A-1
- Height, patient data 6-1
- Help, on screen 12-1
- Hemodynamic parameters 1-1
- Hemoglobin
glossary G-1
- HGB
def. 1-3
- HIS
def. 1-3
- historic mode 8-2
- Historical mode, Physio Relationship 8-2
- Home button 5-8, 14-3, 14-4
- IEC 60601-1
  - 2005 2-9
  - 2007 2-9
- IEC 60601-1-2
  - 2007 2-9
- IEC 60601-1-6
  - 2010 2-9
  - 2006 2-9
  - 2011 2-9
  - 2012 2-9
- IEC 60601-1-8
  - 2009 2-9
  - 2011 2-9
  - 2012 2-9
- IEC 61000-3-2 F-2
- IEC 61000-3-3 F-2
- IEC 61000-4-11 F-3
- IEC 61000-4-2 F-3
- IEC 61000-4-4 F-3
- IEC 61000-4-5 F-3
- IEC 61000-4-6 F-4
- IEC 61000-4-8 F-3
- IEC 62366
  - 2007 2-9
  - 2008 2-9
  - 2009 2-9
  - 2010 2-9
- IEC/EN 60601-1-2
  - 2007 2-9
- IEC/EN 60601-1-2
  - 2007 F-1
- inches vs. cm D-1
- Incorrect password entered 12-6
- Indications for use 1-1
- Information bar 5-9
- Initial setup 3-1
- Initial Startup 3-4
- Install monitor 3-1
- Intervention 10-2
glossary G-1
Intervention Analysis (IA) [Updated 10-2]

ISO 13485
2003/AC
2009 2-9

ISO 14971
2007 2-9
ISO 15223-1
2012 2-9
ISO-10993-1
2009 2-9

K

Keypad errors 12-6
Keypad, using 5-9

L

Language
change 6-2
default settings C-3
select 3-5
lbs vs. kg D-1
LED, Pump-Unit 3-3
Length of cables F-1
Lights
Pressure Controller 12-4
Pump-Unit 12-3
List button 5-9
Lock screen 5-10

M

Maintenance E-3
Manual 1-2
MAP
def. 1-1, 1-3
Mean Arterial Pressure
def. 1-1
glossary G-1
Mechanical specifications A-1
Message area 5-10
Mixed Venous Oxygen Saturation
glossary G-1
mmHg vs. kPa D-1
Monitor A-2
case symbols 2-7
cleaning E-1
connect 3-2
defaults 6-4
dimensions A-1
display A-1
display options 6-1
disposal E-3
installation 3-1
screen descriptions 5-2
screen selection icon 5-1
symbols 2-6
using 5-1
views 5-2
Weight A-1
weight A-1

Monitor Bracket A-2
Monitor screen navigation 5-8
Monitor settings
General 6-2
Monitoring 12-1
Monitoring Pause 10-2
Monitoring Pause Exit 5-2
Monitoring Resumed 10-2
Monitoring settings 6-2
Mounting recommendations 3-2

N

Navigation 5-1, 5-8
Navigation bar 5-1
New patient 6-1
Noninvasive Cardiac Output
overview 1-1
Note
def. 2-1

O

On screen help 12-1
Operating System A-1
Operator’s Manual 1-2
Overview 1-1
Oximetry Oxygen Saturation

glossary G-1
Oxygen Consumption
glossary G-1
Oxygen delivery
glossary G-1
Oxygen Delivery Index
glossary G-1
Oxygen Saturation, ScvO2/SvO2)
def. G-1

P

Packaging contents 3-1
Panel Cable Cover A-2
Parameter settings 6-4
Parameters
base A-2
change 5-3
Display and Alarm Ranges C-2
hemodynamic 1-1
Part numbers A-2
Patient
continue monitoring 6-1
data 6-1, 6-2
data parameters C-1
ID 6-1
new 6-1
Patient cables, connect 3-4
Patient data
Age 6-1
enter 6-1
Patient data, view 6-2
Patient Sensors
collection 7-2

PC
def. 1-3
PC2
glossary G-2
Physical specifications A-1
Physio Relationship 8-2, 8-3
continuous mode 8-2
Physio Relationship monitoring
screen 5-7
Physio Relationship screen 8-2
Physio
control 7-10
methodology 7-1
waveform artifacts 7-10
Physio Disabled 10-2
Physio Enabled 10-2
Physio method 1-1
Physiology monitoring screen 5-6, 8-1
Platform
accessories A-2
Please enter valid date 12-6
Please enter valid time 12-6
Plethysmograph Sensor
glossary G-2
PM
def. 1-3
PMP
def. 1-3
glossary G-2
Positional Challenge 10-2
Power
consumption A-3
frequency F-3
Power-On Logo screen 3-4, E-2
PR
def. 1-1, 1-3
Pressure
Parameter Specifications A-2
Pressure Controller
application directions 7-4
attachments 4-2
band 4-2
communication lights 12-4
depth A-1
glossary G-2
height A-1
weight A-1
width A-1
Preventive maintenance E-3
Pulse Rate
def. 1-1
glossary G-2
Pump-Unit
case symbols 2-7
connect 3-2
depth A-1
disposal E-3
glossary G-2
height A-1
LED 3-3
Power and communication lights 12-3
Weight A-1
Width A-1

Quick start 4-1

Radiated RF IEC 61000-4-3 F-4
Red indicator 6-5, 9-2
Relative Humidity
   Environmental Specifications A-2
Restore defaults 6-4
Reviewed events 10-2
RF emissions F-2
RJ-45 Ethernet connector
   (Monitor) A-3
RS232 Serial Port A-3

Safety 2-1
Safety Identifying Symbols 2-1
Scales, adjust 6-8
Screen
descriptions 5-2
layouts 5-2
lock 5-10
Power-On Logo 3-4, E-2
symbols 2-6
unlock 5-10
Screen navigation 5-8
Screen size A-1
Scroll 5-8
Scroll rates, graphical trend 5-5
Scroll rates, tabular trend 5-6
ScvO2
def. 1-3
Select language 3-5
Separation distances F-2
Serial port setup 6-4
Service E-2
set alarms and targets 8-3
Set Targets 6-5
Settings button 5-1
Settings Screen 9-1, 11-1
Setup 3-1
Shipping container symbols 2-7
Silence alarms 6-5
Silence audible alarms 5-2
Snapshot button 5-1
Speakers A-1
Specifications A-1
   environmental A-2
   mechanical A-1
   physical A-1
SpO2
def. 1-3
Start Monitoring Button 5-2
Startup 3-4
Status bar 5-10
Status indicators 5-7
Stop Monitoring Button 5-2, 7-9
Stroke Volume
def. 1-1
glossary G-2
Stroke Volume Index
def. 1-1
glossary G-2
Stroke Volume Variation
def. 1-1
glossary G-2
Support E-2
Surge IEC 61000-4-5 F-3
SV
def. 1-1, 1-3
equation B-2
SV equation B-2
SVI
def. 1-1, 1-3
equation B-2
SVI equation B-2
SvO2
def. 1-3
SVR
def. 1-1, 1-3
equation B-2
SVR > SVRI 12-13
SVR equation B-2
SVRI
def. 1-1, 1-3
equation B-3
SVRI equation B-3
SVV
def. 1-1, 1-3
equation B-3
SVV filtering exceeded indicator
description 5-8
SVV slope indicator 8-2
Symbols 2-1
   Case 2-7
   shipping 2-7
SYS
def. 1-1, 1-3
System
   errors 12-5
Systemic Vascular Resistance
def. 1-1
glossary G-2
Systemic Vascular Resistance Index
def. 1-1
glossary G-2
Systolic Pressure
def. 1-1
Tabular Increment 6-9
Tabular trend monitoring screen 5-5
Tabular Trend scroll rates 5-6
Target
   change 5-3
   Target status indicators 5-8
Targets
   configure for one parameter 6-7
   Targets, set 6-5, 7-7
   Technical support E-2
Technology Selection Screen 14-3
Technology Switch Occurred 10-2
Technology switching 14-3
Temperature
   Environmental Specifications A-2
Time
   change 6-2
   Time / Date 6-3
   Time Change 10-2
   Time Format 6-3
   Time Intervals 6-8
time scale 5-3
Tool bar 5-1
Touch
def. 1-3
Touch Screen A-3
Trend
   scale limits C-1
Troubleshooting 12-1
Troubleshooting help, on screen 12-1
Unit
   conversions D-1
Unlock screen 5-10
Unpacking 3-1
USB
def. 1-3
glossary G-2
USB Port A-3
Use indications 1-1
Using monitor 5-1
Value
   must be greater than 12-6
   must be less than 12-6
   out of range 12-6
   enter 5-9
   Vertical scrolling 5-8
   VGA Port A-3
   View patient data 6-2
Views, monitor 5-2
VO2
def. G-1
equation B-3
VO2e
def. 1-3
equation B-3
VO₂I
  equation B-3
VO₂Iₑ
  equation B-3
Voltage
  Monitor A-3
  Pump-Unit A-3
Voltage fluctuation/ Flicker emissions F-2
Volume Clamp Method 1-1, 7-1

W
  Warnings 2-1, 12-1
  Warranty E-4
  Waveform confirmation 10-1
  Weight, ClearSight Finger Cuff A-1
  Weight, Heart Reference Sensor A-1
  Weight, Monitor A-1
  Weight, patient data 6-1
  Weight, Pressure Controller A-1
  Weight, Pump-Unit A-1
  Width, monitor A-1
  Windows A-1

Y
  Yellow indicator 6-5, 9-2

Z
  Zero
    Heart Reference Sensor 7-5
  Zero & Waveform 10-1
  ART display 7-8
  output to PM 7-8