ZOLL®

E SERIES®

# Pulse CO-Oximetry ($SpO_2$, SpCO, SpMet)

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# PULSE CO-OXIMETRY ($SpO_2$, SpCO, SpMet)

# General Information

## Product Description

The E Series® pulse CO-oximeter continuously and noninvasively measures the oxygen saturation of arterial hemoglobin ($SpO_2$), carboxyhemoglobin saturation (SpCO) and methemoglobin saturation (SpMet) at a peripheral measurement site, (i.e. foot, toe or finger). This monitoring gives information about both the cardiac and respiratory systems, and provides details of oxygen transportation in the body. It is widely used because it is noninvasive, continuous, easily applied and painless.

The E Series pulse CO-oximetry option is intended for use only with ZOLL / Masimo LNCS® or Rainbow™ sensors. The CO-oximetry sensor contains light-emitting diodes (LEDs) that transmit various visible and infrared light through the body's extremities. The transmitted light is then received by a photodetector, which converts it to an electronic signal. The signal is then sent to the E Series unit for processing.

Oxygen-saturated blood absorbs light differently than unsaturated blood. Thus the amount of visible and infrared light absorbed by blood flowing through a suitable peripheral area of the body, typically the finger in adults and the foot in neonates, can be used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood. The monitor displays this ratio as percent $SpO_2$, alternating with SpCO and SpMet values. The SpCO and SpMet measurements rely on multiwavelength calibration equations to estimate the percentages of carboxyhemoglobin and methemoglobin in arterial blood.

The quality of measurements depends on correct size and application of the sensor, adequate blood flow through the sensor site, and the sensor's exposure to ambient light. For correct placement and location of the sensors, refer to *Directions for Use* included with all LNCS or Rainbow oximetry sensor packages.

## How to Use This Manual

This insert describes how to set up, use and maintain the pulse CO-oximetry option on the E Series unit.

Important safety information relating to the general use of the E Series pulse CO-oximeter appears in "Safety Considerations" on page 2 of this document. Other important safety information is located in the "Safety Considerations" section of the LNCS or Rainbow oximetry sensor packages. The *E Series Operator's Guide* provides the information that you need to know for the safe and effective use and care of the E Series products. It is important that you read and understand all the information contained therein before operating your E Series product.

Please thoroughly read both the safety consideration sections before operating your E Series product.

## Safety Considerations

### Warnings

#### General

- Before use, carefully read the *E Series Operator's Guide*, these operating instructions, and the *Directions for Use* included with each LNCS or Rainbow sensor being used.
- Only qualified personnel should operate the E Series Pulse CO-oximeter.
- Do not use the pulse CO-oximeter as an apnea monitor.
- Do not immerse the E Series device, patient cables, or sensors in water, solvents, or cleaning solutions.
- Consider a pulse CO-oximeter an early warning device. As a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory CO-oximeter to completely understand the patient's condition.
- If an alarm occurs while the audio alarms are suspended, the suspended alarm indications will only be visual displays and symbols.
- Interfering Substances: Carboxyhemoglobin and methemoglobin may erroneously alter $SpO_2$ readings. The level of change is approximately equal to the amount of carboxyhemoglobin or methemoglobin present. Dyes, or any substance containing dyes, that alter arterial pigmentation may cause erroneous readings.
- Elevated levels of methemoglobin will lead to inaccurate $SpO_2$ and SpCO measurements.
- Severe anemia may cause erroneous $SpO_2$ readings.
- Do not use the E Series pulse CO-oximeter or LNCS sensors during magnetic resonance imaging (MRI). Induced current could potentially cause burns. The E Series pulse CO-oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- If using pulse CO-oximetry during full body irradiation, keep the sensor out of the irradiation field. If the sensor is exposed to the irradiation, the reading may be inaccurate or read zero for the duration of the active irradiation period.
- Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Functional testers cannot be used to assess the accuracy of the pulse CO-oximeter.

#### Sensors

- Use only ZOLL / Masimo approved oximetry sensors for $SpO_2$ measurements. Other manufacturers' sensors may cause improper oximeter performance.
- Tissue damage can result from incorrect application or use of a sensor (for example, by wrapping the sensor too tightly). Inspect the sensor site as directed in *Directions for Use* (included with each sensor) to ensure skin integrity, correct positioning and sensor adhesion.
- Do not use damaged sensors or cables.
- Do not modify or alter the sensor in any way. Alterations or modification of the sensor may affect performance and/or accuracy.
- Do not use a sensor with exposed optical components.
- Do not sterilize the sensor by irradiation, steam, or ethylene oxide. See the cleaning instructions included with each sensor.
- Do not allow the sensor to remain on one site for a prolonged period of time, especially when monitoring neonates. Check the application site at regular intervals - at least every two hours - and change the site if any compromise in skin quality occurs. Refer to the *Directions for Use* included with each sensor.
- Do not attach the $SpO_2$ sensor to a limb being monitored with a blood pressure cuff or with restricted blood flow.
- A poorly applied sensor may give incorrect measurements. The signal strength indicator can be used to identify a poorly applied sensor or poorly chosen site.
- Choose a site with sufficient perfusion to ensure accurate oximetry values.
- Venous congestion may cause under-reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from the monitored site. The sensor should not be below heart level, e.g. on the hand of a patient in a bed with the arm dangling to the floor.
- Certain nail aberrations, nail polish, fungus, etc. may cause inaccurate oximetry readings. Remove the nail polish and/or move the sensor to an unaffected digit.
- High ambient light sources such as surgical lights (especially those with xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can affect the accuracy of $SpO_2$ readings. To prevent interference from ambient light, ensure that the sensor is properly applied and cover the sensor with opaque material if required.

## Pulse CO-Oximetry Indications for Use

The ZOLL E Series pulse CO-oximeter, with Masimo Rainbow SET technology and the Rainbow series of sensors, is indicated for the continuous noninvasive monitoring of arterial oxygen saturation ($SpO_2$), pulse rate, carboxyhemoglobin saturation (SpCO), and/or methemoglobin saturation (SpMet). The pulse CO-oximeter is indicated for use on adult, pediatric, and neonatal patients who are stationary or in motion in a hospital or prehospital environment.

If the unit is configured for SpCO and/or SpMet monitoring and a Rainbow sensor is attached to the patient's finger, then SpCO and/or SpMet values are also continuously displayed. If a Red sensor is attached to the patient (or an LNCS sensor with a Red patient cable), then only the $SpO_2$ and pulse rate values are displayed.

Oxygen saturation measurements using pulse oximetry are highly dependent on proper placement of the sensor and patient conditions. Patient conditions such as smoke inhalation may result in erroneous oxygen saturation readings. If pulse oximetry measurements are suspect, verify the reading using another clinically accepted measurement method, such as arterial blood gas measurements.

## Measurement Complications

If the accuracy of any reading is suspect, first check the patient's vital signs by alternate means and then check the E Series pulse CO-oximeter for proper functioning.

Inaccurate measurements may be caused by:

- Incorrect sensor application or use.
- Significant levels of dysfunctional hemoglobins (e.g., carboxyhemoglobin or methemoglobin).
- Intravascular dyes such as indocyanine green or methylene blue.
- Exposure to excessive illumination, such as surgical lamps (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight; exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material.
- Excessive patient movement.
- Venous pulsations.
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.

Loss of pulse signal can occur when:

- The sensor is applied too tightly.
- There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight.
- A blood pressure cuff is inflated on the same extremity as the one with a $SpO_2$ sensor attached.
- There is excessive patient movement.
- The patient has hypotension, severe vasoconstriction, or hypothermia.
- There is arterial occlusion proximal to the sensor.
- The patient is in cardiac arrest or shock.

## CO-oximetry Connector and Sensors

The CO-oximetry connector is located on the rear panel of the E Series unit (see Figure 1). You can use only ZOLL or Masimo accessories and sensors with the E Series Pulse CO-Oximetry option.

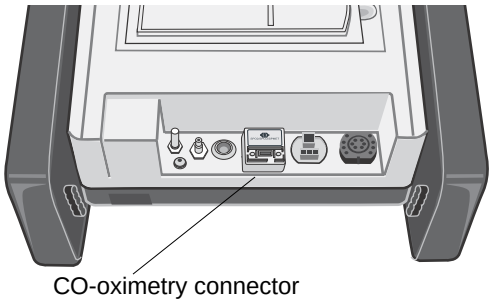



**Figure 1**

Each sensor is designed for application to a specific anatomical site on patients within a certain weight range.

To ensure optimal performance:

- Use an appropriate sensor.
- Apply the sensor as described in *Directions for Use* included with each sensor.

Tissue damage can result from incorrect application or use of a sensor (e.g., wrapping the sensor too tightly, applying supplemental tape, failing to periodically inspect the sensor site).

## Setup

Set up the $SpO_2$/SpCO/SpMet option as follows:

1. Inspect the E Series case and CO-oximetry cables for damage.
2. Ensure that the sensor and cable are compatible models before connecting them to the E Series unit (see “CO-Oximeter Accessories” on page 10).
3. Attach the sensor to the patient and connect the sensor to the CO-oximetry patient cable, if applicable (see “Applying a 2-piece Reusable Sensor/Cable” on page 4 or “Applying a Disposable Sensor” on page 5).

   If using a reusable sensor, make sure it opens and closes smoothly and check for foreign material such as tape or cotton on the emitter and detector windows. Remove any substances that may interfere with the transmission of light between the sensor's light source and detector.

4. Connect the patient cable to the CO-oximetry connector at the back of the E Series unit (see Figure 2).

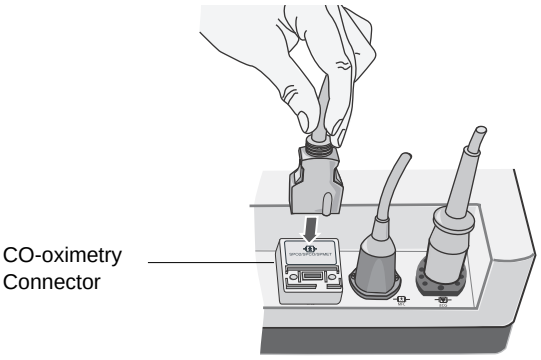



**Figure 2**

5. Turn the selector switch to MONITOR (ON for AED units).

   The CO-oximetry parameter box will appear momentarily on the screen.

6. Verify that the sensor's red LED is on. The oximeter is now fully operational.

   A dashed line is displayed in the CO-oximetry data field until a pulse is detected. Once the measurement has been established, the $SpO_2$ values are displayed (e.g., 98).

7. Ensure that appropriate oxygen saturation values are displayed and that the signal strength bar indicates the presence of a strong signal associated with each heartbeat.

8. Adjust the alarm limits and enable $SpO_2$ alarms if desired.

**Note:** If ECG leads are not attached, the patient's pulse rate as measured by the CO-oximetry sensor is displayed as the Heart Rate (HR) in the ECG field and the heart symbol does not flash.

If the unit displays a *SPO2 FAULT XX* message shortly after power-up, the CO-oximetry monitoring subsystem of the unit has failed. Contact the ZOLL Technical Service Department.

### Selecting a Sensor and Patient Cable

When selecting a sensor, consider the patient's weight, the adequacy of perfusion, the available sensor sites, the anticipated duration of monitoring, and the parameters to be monitored. For more information, refer to "CO-Oximeter Accessories" on page 10 or contact ZOLL Medical Corporation.

### Selecting a Sensor Application Site

Choose a site that is well perfused and restricts a conscious patient's movements the least. The ring finger or middle finger of the nondominant hand is preferred.

Alternatively, you can use the other digits on the nondominant hand. Be sure the sensor's detector is fully covered by flesh. You can use the great toe or long toe (next to the great toe) on restrained patients or patients whose hands are unavailable.

To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

### Applying a 2-piece Reusable Sensor/Cable

**Note:** These instructions describe how to apply a reusable LNCS sensor and mating Red patient cable. For all other reusable sensors, refer to the sensor packaging for application instructions.

**Note:** The reusable sensor is not intended for use on the thumb or across a child's hand or foot.

1. Place the selected digit over the sensor window of the reusable sensor, making sure that the sensor cable runs over the top of the patient's hand.

   The fleshiest part of the digit should cover the detector window in the lower half of the sensor (see Figure 3).

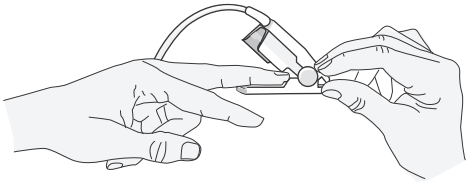


**Figure 3**

2. On finger sites, make sure the tip of the finger touches or extends beyond the raised digit stop inside the sensor (see Figure 4).

**Figure 4**

**Note:** With smaller digits, the digit may not need to be pushed all the way to the stop to completely cover the detector window.

3. Check the sensor position to ensure that the top and bottom halves of the sensor are parallel. To ensure accurate data, you must have complete coverage of the detector window (see Figure 4).

4. Lift the clear plastic protective cover from the female end of the mating patient cable, then plug the sensor

cable's male connector all the way into the patient cable connector (see Figure 5).

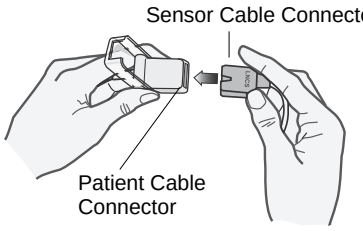



**Figure 5**

5. Lower the clear plastic protective cover over the connection to secure it (see Figure 6).

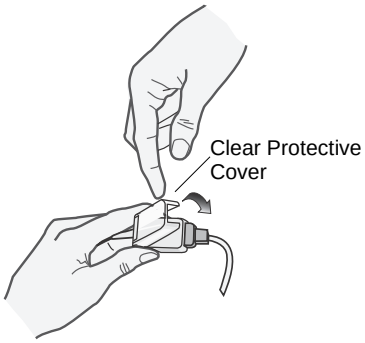



**Figure 6**

6. Connect the patient cable to the CO-Oximetry connector on the back of the E Series unit as shown in Figure 2 on page 4.

### Applying a Disposable Sensor

You can use a disposable LNCS sensor for $SpO_2$ monitoring or a disposable Rainbow sensor to monitor $SpO_2$, SpCO, and SpMet. Do not wrap the adhesive too tightly as this can cause venous pulsations that could lead to inaccurate saturation measurements.

You can reapply a disposable sensor to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.

You can partially rejuvenate the adhesive by wiping it with an alcohol wipe and allowing the sensor to thoroughly air dry prior to replacement on the patient.

**Note:** LNCS Adult disposable sensors are not intended for use across a child's hand or foot. For instructions on proper application of neonatal sensors, refer to the *Directions for Use* included with each LNCS sensor.

1. Open the pouch, and remove the sensor.
2. Holding the sensor with the printed side downward, bend the sensor backward and remove backing material from the sensor.
3. Orient the sensor so that the digit can be attached to the detector side of the sensor first (see Figure 7).

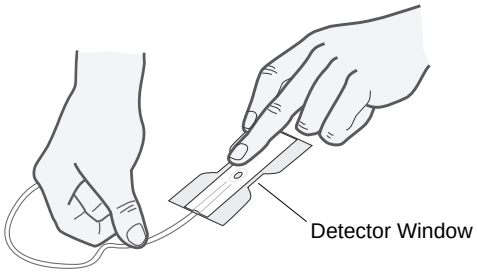



**Figure 7**

4. Press the detector onto the fleshy part of the finger near the tip of the finger. To ensure accurate data, you must have complete coverage of the detector window.
5. With the emitter positioned over the fingernail, secure the wings around the finger (see Figure 8).

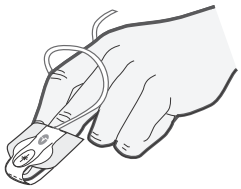


**Figure 8**

When positioned properly, the:

- emitter and detector are vertically aligned
- digit completely covers the detector window
- connector tab is located on the top side of the finger

6. Lift the clear plastic protective cover from the female end of the patient cable, then plug the sensor cable's male connector all the way into the patient cable connector (see Figure 5).
7. Lower the clear plastic protective cover over the connection to secure it (see Figure 6).
8. Connect the patient cable to the CO-Oximetry connector on the back of the E Series unit as shown in Figure 2 on page 4.

**Note:** For the Rainbow patient cable and Rainbow disposable sensor, plug the sensor cable's male connector all the way into the patient cable connector until it clicks.

## Ensuring Accurate Monitoring

The following points aid in ensuring oximetry monitoring success:

- Choose a site that is well perfused and allows for proper alignment of the light emitter and detector.
- Select a site that has unrestricted blood flow.

- Ensure that blood flow is not restricted when securing a sensor with tape.
- Select a site which is not near potential sources of electrical interference (electrical cords, for example).
- Use only sensors which show no obvious damage or exposed electrical circuits.
- Ensure that the sensor site is not subject to excessive motion. Excessive motion may adversely affect the performance of the sensor.
- Inspect the sensor site at least once every 2 hours to ensure adhesion, skin integrity, and correct alignment of the light emitter and detector. Should alterations of skin integrity occur, remove the sensor and reapply at another recommended site. Avoid application of the sensor to edematous or fragile tissue.
- Remove and reposition the sensor every 8 hours and, if indicated by circulatory condition or skin integrity, reapply to a different monitoring site.
- Avoid creating venous pulsations caused by overly tight adhesive or by using additional tape to secure the sensor. Venous pulsations could potentially lead to inaccurate saturation measurements.
- Reposition the sensor or choose a different monitoring site if the sensor fails to track the pulse consistently, as the sensors may be incorrectly positioned.
- Ensure that the signal strength bar graph indicates the presence of a strong signal associated with each heart beat.
- Avoid placing the sensor on any extremity with an arterial catheter, blood pressure cuff, or intravascular line.

## Cleaning and Reuse of Sensors

Reusable sensors can be cleaned as follows:

1. Disconnect the sensor from the patient cable, if appropriate.
2. Wipe the entire sensor clean with a 70% isopropyl alcohol moistened pad.
3. Allow the sensor to air dry before returning it to use.

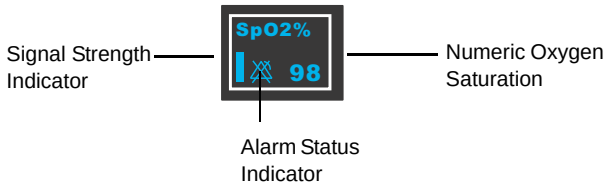
## Cleaning and Reuse of Patient Cables

Patient cables can be cleaned as follows:

1. Disconnect the sensor from the patient cable (if attached).
2. Disconnect the cable from the rear of the E Series unit.
3. Wipe the cable clean with a 70% isopropyl alcohol moistened pad.
4. Allow the cable to dry before using it.

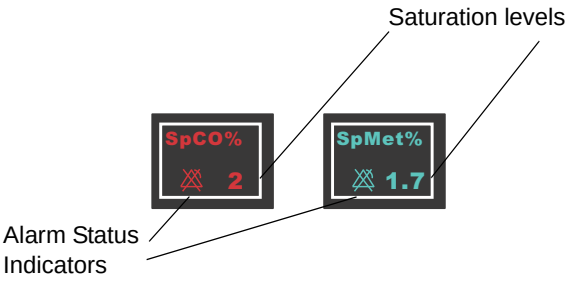
## How $SpO_2$ , SpCO and SpMet measurements are Displayed

The pulse CO-oximetry option displays a plethysmograph waveform derived from data supplied by the sensor. The oxygen saturation value is displayed as “SpO2%”. A signal strength indicator, left of the $SpO_2$ field, shows the relative change in the pulsatile signal (see below).




**Note:** The $SpO_2$ numeric displays dashes (-----) in the oxygen saturation field whenever pulse oximetry values are likely to be contaminated due to the presence of excessive ambient light, inadequate perfusion, high signal artifact, a defective or disconnected sensor, etc.

If SpCO or SpCO/SpMet is installed and Auto Display is enabled, the CO-oximetry data field will alternate between the $SpO_2$, SpCO and SpMet measurements. $SpO_2$ will display for 20 seconds, followed by SpCO for 10 seconds. $SpO_2$ will then display again for 20 seconds, followed by SpMet for 10 seconds (if installed). This alternating pattern will repeat until Auto Display is disabled.



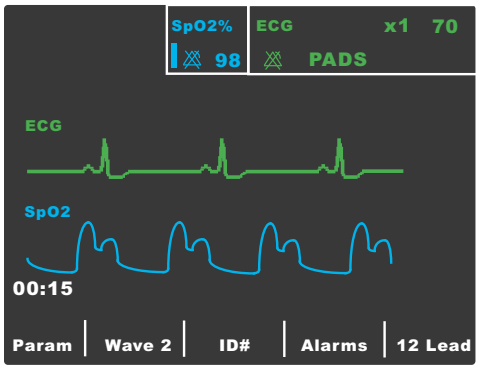

**Note:** The presence of factors such as excessive ambient light, inadequate perfusion, high signal artifact, or a defective or disconnected sensor can cause contamination to the SpCO and SpMet values. In this case, the numeric value will appear as dashes.

### Displaying the Plethysmographic Waveform

The E Series unit can display one or two waveforms in MONITOR, DEFIB, or MANUAL (AED) mode, as long as the defibrillator is not charging or ECG analysis is not in progress. The unit displays only one waveform in PACER mode.

With $SpO_2$ monitoring, the unit can display a normalized plethysmographic waveform below the ECG trace for a visual indicator of $SpO_2$ monitoring.

From the physiological monitoring menu, press the **Wave 2** softkey to cycle the display from the capnogram waveform, to the plethysmograph waveform, to no second waveform displayed.




The unit temporarily removes the second waveform from the display when you press the **CHARGE**, **ANALYZE**, or **ENERGY SELECT** buttons, or the **Sync On/Off** softkey. The unit restores the second waveform to the display 4 seconds after:

- A shock is delivered.
- A shockable rhythm analysis is completed, unless the defibrillator is charging.
- **ENERGY SELECT** button is pressed.
- Sync mode is turned off.

## Physiological Monitoring

When you turn the E Series unit to MONITOR (ON for AED units), the physiological monitoring menu is displayed with the following softkeys: **Param**, **Wave 2**, **ID#**, **Alarms** and **12 Lead** (if installed).


### Param Softkey

When the **Param** softkey is pressed, the following softkeys appear: **Select**, **Enter**, and **Return**.

Press the **Select** softkey to scroll the highlight area among the different available physiological parameters.

Press the **Enter** softkey to select the highlighted parameter.

Press the **Return** softkey to return to the physiological monitoring menu.

### The SpO2 Menu (SpCO/SpMet not installed)


When the SpO2 parameter is selected, the following softkeys appear: **Sens.**, **Average** and **Return** (See "$SpO_2$ Settings softkey", below).

Press the **Return** softkey to return to the main menu.

## The CO-Oximetry menu (SpCO/SpMet installed)


When the CO-Oxim. parameter is selected, the following softkeys appear: **SpO2 Settings**, **Enable Auto disp**, **SpCO**, **SpMet**, and **Return**.


Press the **Return** softkey to return to the main menu.

#### SpO2 Settings softkey

When you select the **SpO2 Settings** softkey, the following softkeys appear: **Sens.**, **Average**, and **Return**.


**Sens. Softkey:** The **Sens.** softkey allows you to select either Normal or High sensitivity for $SpO_2$ monitoring.

- The Normal sensitivity setting is the recommended setting; select it for most patients.
- The High sensitivity setting allows you to monitor $SpO_2$ even under very low perfusion conditions. Such conditions may include severe hypotension or shock. With the High sensitivity setting, however, $SpO_2$ results are more easily contaminated by artifact. To ensure accuracy of $SpO_2$ readings when using the High sensitivity setting, observe the patient carefully and continuously.

To select the sensitivity mode, press the **Sens.** softkey to toggle between the modes, then press the **Enter** softkey to select the highlighted mode.


Pressing the **Return** softkey returns to the $SpO_2$ Sensitivity/Average submenu without changing sensitivity.

**Average Softkey:** The E Series provides 3 different time periods over which $SpO_2$ values are averaged: 4 seconds, 8 seconds (default), and 16 seconds.

The averaging period is rarely changed from the 8 second default setting. For high risk patients with rapidly changing $SpO_2$ conditions, use the 4 second setting. Use the 16 second setting only when the 8 second setting (default) is inadequate due to extremely high artifact conditions.

To select the averaging period (4, 8, or 16 seconds), first press the **Average** softkey on the $SpO_2$ submenu. The following softkeys appear: **Average**, **Enter** and **Return**.


Press the **Average** softkey again to scroll through the different averaging periods, then press the **Enter** softkey to select the highlighted averaging period.

Pressing the **Return** softkey to returns to the SpO2 Sensitivity/Average submenu without changing the average.

#### Enable Auto disp softkey

This feature allows you to set the CO-oximetry data field to alternate between $SpO_2$, SpCO and SpMet readings, if installed. $SpO_2$ will display for 20 seconds, followed by SpCO for 10 seconds. $SpO_2$ will then display again for 20 seconds, followed by SpMet for 10 seconds (if installed). This alternating pattern will repeat until Auto Display is disabled. Press **Enable Auto disp** to enable the feature; press **Disable Auto disp** to disable it.

If Auto Display is enabled, then the **SpCO** and **SpMet** softkeys will not appear.

#### SpCO softkey

Pressing this softkey will instantly display the SpCO reading in the CO-oximetry data field. It will display for 10 seconds, then revert to the $SpO_2$ reading. This softkey will not appear if Auto Display is enabled.

**SpMet softkey**

Pressing this softkey will instantly display the SpMet reading in the CO-oximetry data field. It will display for 10 seconds, then revert to the $SpO_2$ reading. This softkey will not appear if Auto Display is enabled.

## Alarms

The E Series CO-oximetry option provides user programmable "out of range" alarms for $SpO_2$, SpCO and SpMet. See "Default Settings" on page 10 for low and high alarm limit default values and ranges.

Once the $SpO_2$, SpCO or SpMet value reaches the high or low limit, there is a 4 second delay before the alarm occurs.

When an alarm occurs, the alarming parameter's value will be highlighted and the alarm symbol will flash in the CO-oximetry data field. If more than one alarm occurs at the same time, the multiple alarms will alternate on the display.

When monitoring a patient's heart rate using ECG, the high heart rate alarm limit range is 60 to 280 bpm, with a default setting of 150 bpm. When monitoring the heart rate using pulse oximetry, however, the maximum high heart rate alarm limit is automatically lowered to 235 bpm if it was previously set higher for ECG monitoring. The unit restores the original high heart rate alarm limit setting when ECG monitoring resumes.

When the $SpO_2$ alarm state is set to AUTO, the unit automatically sets the $SpO_2$ alarm limits to 95% and 105% of the patient's currently measured saturation (the maximum setting being 100%). The auto alarm limits are set only if valid measurements are present for the vital sign.

Auto alarm limits are not applicable to SpCO and SpMet.

See the *E Series Operator's Guide* for details on enabling, disabling, and suspending alarm functions on the E Series unit.

## Automated External Defibrillator (AED) Operation

E Series AED units equipped with pulse CO-oximetry operate in a slightly different way when in Semi-Automatic Mode:

- The plethysmographic waveform cannot be displayed.
- Heart rate alarm functions are disabled (although $SpO_2$, SpCO and SpMet alarm functions are operational). Background ECG analysis functions continue to operate as described in the AED section of the *E Series Operator's Guide*.
- You cannot change alarm limit settings; only the default alarm limits are available.

## Checkout Procedure

Perform the following checkout procedure daily to ensure that the pulse CO-oximetry option is functioning properly. Use a reusable sensor when performing this procedure.

1. Attach the sensor to your finger and connect the patient cable to the pulse CO-oximetry connector at the back of the E Series unit (as described in "Applying a 2-piece Reusable Sensor/Cable" on page 4).
2. Turn the selector switch to MONITOR (ON for AED units, then select Manual mode).
3. With alarms enabled, verify that the patient alarms are functional by adjusting the high and low $SpO_2$ limits until the unit:
   - Emits a continuous audio tone.
   - Highlights the alarming parameter's value and flashes the alarm symbol on the display.
4. Disconnect the ECG cable and verify that your pulse rate is equal to the rate that appears on the E Series heart rate display.
5. Verify the sensor alarms are functional by unplugging the sensor from the E Series unit. Make sure the unit:
   - Displays the *CHECK SPO2 SENSOR* message.
   - Emits a two-beep audio tone.
6. Verify the plethysmographic waveform display by pressing the **Wave 2** softkey and ensuring that the waveform repeats at your pulse rate. (not applicable to AED units).
7. If your E Series unit is configured for SpCO, attach a Rainbow sensor to your finger and connect to the pulse CO-oximetry connector at the back of the unit.
8. Press the **Param** softkey. Verify that the CO-Oxim. parameter is highlighted. Press the **Enter** softkey.
9. Press the SpCO softkey and verify that the SpCO value is correctly displayed.

## Default Settings

When the pulse CO-oximeter is turned on, the following default settings are automatically selected and remain in operation until changed.

| Parameter | Default Setting | Range |
|---|---|---|
| Averaging Mode | 8 seconds (medium) | 4 seconds (short)<br>8 seconds (medium)<br>16 seconds (long) |
| Sensitivity | Normal | Normal or High |
| High $SpO_2$ Alarm Limit | 100% | 72% to 100% |
| Low $SpO_2$ Alarm Limit | 85% | 70% to 98% |
| High SpCO Alarm Limit | 10% | 2% to 100% |
| Low SpCO Alarm Limit | 0% | 0% to 99% |
| High SpMet Alarm Limit | 3.0% | 1% to 100% |
| Low SpMet Alarm Limit | 0.0% | 0% to 99% |
| High Heart Rate Alarm Limit | 150 bpm (beats/minute) | 60 to 280 bpm (beats/minute) - monitoring via ECG<br>60 to 235 bpm (beats/minute) - monitoring via Pulse Oximetry |
| Low Heart Rate Alarm Limit | 30 bpm (beats/minute) | 20 to 100 bpm (beats/minute) |

**Note:** Only the default settings are available in AED Semi-Automatic operation. Default alarm limit setting may be adjusted in System Configuration mode. See the *E Series Configuration Guide* for more information.

## CO-Oximeter Accessories

The following table describes each of the $SpO_2$, SpCO, and SpMet accessories.

**Note:** LNCS single use and reusable sensors are capable of measuring $SpO_2$ only. Rainbow single use sensors are capable of measuring $SpO_2$, SpCO, and SpMet.

| Item | Description | REF |
|---|---|---|
| LNCS Adtx | Single use sensor for patients > 30 kg | 8000-0320 |
| LNCS Pdtx | Single use sensor for Pediatrics and Slender Adults 10 - 50 kg | 8000-0321 |
| LNCS Inf-3 | Single use sensor for Infants 3 - 20 kg | 8000-0322 |
| LNCS Neo-3 | Single use sensor for Neonates < 3 kg | 8000-0323 |
| LNCS NeoPt-3 | Single use sensor for Neonates < 1 kg (Pre-term) | 8000-0324 |
| LNCS DCI | Reusable sensor for Adults and Pediatrics > 30 kg | 8000-0294 |
| LNCS DCIP | Reusable sensor for Pediatrics 10 - 50 kg | 8000-0295 |
| Red LNC-04 | 4' Reusable Patient Cable - connects to LNCS single use and reusable sensors listed above for monitoring $SpO_2$. | 8000-0330 |
| Red LNC-10 | 10' Reusable Patient Cable - connects to LNCS single use and reusable sensors listed above for monitoring SpO2. | 8000-0331 |

| Item | Description | REF |
|---|---|---|
| Red DCI-dc3 | 3' Adult Reusable Patient Cable / Sensor for monitoring $SpO_2$. | 8000-0332 |
| Red DCIP-dc3 | 3' Pediatric Reusable Patient Cable / Sensor for monitoring $SpO_2$. | 8000-0333 |
| Red DCI-dc12 | 12' Adult Reusable Patient Cable / Sensor for monitoring $SpO_2$. | 8000-0334 |
| Red DCIP-dc12 | 12' Pediatric Reusable Patient Cable / Sensor for monitoring $SpO_2$. | 8000-0335 |
| Rainbow R25 | Single use sensor for patients > 30 kg | 8000-0336 |
| Rainbow R25-3 | Single use sensor for patients < 3kg, > 30 kg | 8000-0337 |
| Rainbow R20 | Single use sensor for Pediatrics 10 - 50 kg | 8000-0339 |
| Rainbow R20-3 | Single use sensor for Infants 3 - 10 kg | 8000-0340 |
| Rainbow Patient Cable RC-4 | 4' Reusable Patient Cable - connects to Rainbow single use sensors listed above for monitoring $SpO_2$, SpCO, and SpMet. | 8000-0341 |
| Rainbow Patient Cable RC-12 | 12' Reusable Patient Cable - connects to Rainbow single use sensors listed above for monitoring $SpO_2$, SpCO, and SpMet. | 8000-0342 |
| Rainbow DCI-dc8 | 8' Adult Reusable Patient Cable / Sensor for monitoring $SpO_2$, SpCO, and SpMet. | 8000-0343 |
| Rainbow DCI-dc12 | 12' Adult Reusable Patient Cable / Sensor for monitoring $SpO_2$, SpCO, and SpMet. | 8000-0344 |
| Rainbow DCIP-dc8 | 8' Pediatric Reusable Patient Cable / Sensor for monitoring $SpO_2$, SpCO, and SpMet. | 8000-0345 |
| Rainbow DCIP-dc12 | 12' Pediatric Reusable Patient Cable / Sensor for monitoring $SpO_2$, SpCO, and SpMet. | 8000-0346 |

## Messages and Troubleshooting

The following table lists the error messages associated with the $SpO_2$ option, and the corresponding corrective action(s). Read this section carefully before using the oximeter for patient monitoring.

| Message | Possible Cause(s) | Recommended Action(s) |
|---|---|---|
| CHECK SPO2 SENSOR | The $SpO_2$ readings may be invalid due to excessive motion, inappropriate sensor site, poor placement, low perfusion, no patient cable or sensor attached, an unrecognized patient cable or sensor is attached, or an incompatible patient cable is attached. | Reposition or relocate the sensor and/or increase perfusion.<br>Verify that the patient cable and/or sensor are properly attached.<br>Select a patient cable and/or sensor that is compatible with the device. |
| CHECK SPO2 SITE | Low perfusion or low signal strength. | Reposition or relocate the sensor. |
| DEFECTIVE SPO2 CABLE | Patient cable cannot be identified or is defective. | Replace patient cable. |
| DEFECTIVE SPO2 SENSOR | Sensor cannot be identified or is defective. | Replace sensor. |
| SPO2 FAULT XX | The $SpO_2$ subsystem of the unit has failed.<br>The unit is configured for SpCO and/or SpMet, but the option is not installed. | Call ZOLL Technical Service Department. |
| SPO2 PULSE SEARCH | The oximeter is searching for the patient's pulse. | If values are not displayed within 30 seconds, disconnect and reposition sensor and/or increase perfusion. |
| SPO2 SENSOR CALIBRATING | The oximeter is checking the sensor for proper functionality and performance. | If values are not displayed within 30 seconds, disconnect and reposition sensor. If values are still not displayed, replace with a new sensor. |
| WRONG SPO2 SENSOR | The user is trying to display SpCO and/or SpMet with a sensor other than the Rainbow sensor attached. | Connect a Rainbow sensor to the unit. |
| Dashes (-----) appear in place of SPO2 numeric and do not change to a real number. | Excessive ambient light, inadequate perfusion, high signal artifact, a defective or disconnected sensor, etc. | Reposition or relocate the sensor and/or increase perfusion. |

## Specifications

| General | | |
|---|---|---|
| Range | Oxygen Saturation (% $SpO_2$) | 1% - 100% |
| | Carboxyhemoglobin Saturation (% SpCO) | 0% - 99% |
| | Methemoglobin Saturation (% SpMet) | 0% - 99% |
| | Pulse Rate (bpm) | 25 - 240 beats per minute |
| Accuracy | Oxygen Saturation (% $SpO_2$) - During No Motion Conditions | |
| | Adults, Pediatrics[1] | 70% - 100%, ±2 digits<br>0% - 69%, unspecified |
| | Neonates[2] | 70% - 100%, ±3 digits<br>0% - 69%, unspecified |
| | Oxygen Saturation (% $SpO_2$) - During Motion Conditions[3] | |
| | Adults, Pediatrics | 70% - 100%, ±3 digits<br>0% - 69%, unspecified |
| | Neonates | 70% - 100%, ±3 digits<br>0% - 69%, unspecified |
| | Oxygen Saturation (% $SpO_2$) - During Low Perfusion Conditions[4] | |
| | Adults, Pediatrics | 70% - 100%, ±2 digits |
| | Neonates | 70% - 100%, ±3 digits |
| | Carboxyhemoglobin Saturation (% SpCO)[5] | 1% - 40% ±3 digits |
| | Methemoglobin Saturation (% SpMet)[5] | 1% - 15% ±1 digit |
| | Pulse Rate (bpm) - During No Motion Conditions[1] | |
| | Adults, Pediatrics, Neonates | 25 - 240 ±3 digits |
| | Pulse Rate (bpm) - During Motion Conditions[3] | |
| | Adults, Pediatrics, Neonates | 25 - 240 ±5 digits |
| Resolution | $SpO_2$: 1%<br>SpCO: 1%<br>SpMet: 0.1% for range up to 9.9%<br>1% for range 10 - 99%<br>Pulse rate: 1 bpm (beats per minute) | |

**1** The Masimo SET Technology with LNOP sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70 - 100% $SpO_2$ against a laboratory CO-oximeter and ECG monitor.
**2** The Masimo SET Technology with LNOP sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70 - 100% $SpO_2$ against a laboratory CO-oximeter and ECG monitor. 1% has been added to the saturation accuracy to account for the effects of fetal hemoglobin. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
**3** The Masimo SET Technology with LNOP sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70 - 100% $SpO_2$ against a laboratory CO-oximeter and ECG monitor. 1% has been added to the saturation accuracy to account for the effects of fetal hemoglobin. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
**4** The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and a Masimo simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
**5** The Masimo SET Rainbow Technology with Rainbow DC-dc sensors have been validated in human blood on healthy adult volunteers against a laboratory CO-oximeter from 1 - 40% for carboxyhemoglobin and 1 - 15% for methemoglobin. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.

| | | |
|---|---|---|
| Alarm Limits | On/Off displayed on monitor. User selectable.<br>$SpO_2$: High 72 - 100% saturation, Low 70 - 98% saturation<br>SpCO: High 2 - 100% saturation, Low 0 - 99% saturation<br>SpMet: High 1 - 100% saturation, Low 0 - 99% saturation<br>Pulse Rate: High 60 - 235 beats per minute, Low 20 - 100 beats per minute | |
| $SpO_2$ Wavelength for LNCS Sensors | Nominal Red LED Wavelength: 660 nanometers<br>Nominal Infrared LED Wavelength: 905 nanometers | |
| Energies (Radiant Power) of light for LNCS Sensors at 50 mA pulsed | ≤ 15 mW | |
| $SpO_2$ Wavelength for Rainbow Sensors | The Rainbow sensors use 8 different LEDs with wavelengths of 610 - 905 nanometers | |
| Energies (Radiant Power) of light for Rainbow Sensors at 100 mA pulsed | ≤ 25 mW | |
| Bio-Compatibility | Patient contacting material meets requirements of ISO 10993-1, Biological Evaluation of Medical Device - Part I, for external devices, intact surfaces and short-term exposure | |
| Environmental | Operating Temperature: 0º to 40º C (32º to 104º F)<br>Storage Temperature: -40º to 70º C (-40º to 158º F)<br>**Note:** The E Series device may not perform to specifications when stored at the upper or lower extreme limits of storage temperature and immediately put into use | |
| Electromagnetic Immunity ($SpO_2$ Option Only) | AAMI DF-80; EN61000-4-3:2002 to 10 V/m | |
| Operating Time | For a new, fully charged PD4410 battery pack at 20°C (68°F):<br>• 35 defibrillator discharges at maximum energy (200 J), or<br>• 2.0 hours minimum of continuous ECG monitoring, or<br>• 1.75 hours of continuous ECG monitoring/pacing at 60 mA, 70 beats per minute. | For a new, fully charged lithium ion battery pack at 20°C (68°F):<br>• 95 defibrillator discharges at maximum energy (200 J), or<br>• 3.75 hours minimum of continuous ECG monitoring, or<br>• 3.25 hours of continuous ECG monitoring/pacing at 60 mA, 70 beats per minute. |

**Note:** The E Series Pulse Oximetry Option is calibrated for functional saturation.