Pulse Oximetry (SpO$_2$)

ZOLL® M Series®

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PULSE OXIMETRY (Sp0$_2$)
General Information

Product Description

The M Series$^®$ Pulse Oximeter (SpO$_2$) continuously and non-invasively measures the oxygen saturation of arteriolar hemoglobin at a peripheral measurement site, (i.e. foot, toe or finger). It is used for monitoring patients who are at risk of developing hypoxemia. SpO$_2$ 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 non-invasive, continuous, easily applied and painless.

The oximetry sensor contains two light emitting diodes (LEDs) that transmit red and infrared light through the body's extremities. The transmitted light is then received by a photodetector.

Oxygen-saturated blood absorbs light differently than unsaturated blood. Thus the amount of red 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$_2$. Normal values typically range from 95% to 100% at sea level.

The quality of SpO$_2$ measurements depends on correct application and size of the sensor, adequate blood flow through the sensor site, and exposure to ambient light. For correct placement and location of the sensors refer to the *Directions for Use* contained on all LNCS$^®$ oximetry sensor packages.

How to Use This Manual

This insert provides information required for operation and maintenance of the Pulse Oximetry option on the M Series unit. Place this insert into the three-ring binder containing the *M Series Operator's Guide* and all other M Series option inserts.

Important safety information relating to general use of the M Series Pulse Oximeter appears in the "Safety Considerations" section of this document. Other important safety information is located in the "Safety Considerations" section of the LNCS oximetry sensor packages.

The *M Series Operator's Guide* provides information operators need for the safe and effective use and care of the M Series products. It is important that persons using this device read and understand all the information contained therein.

Please thoroughly read the Safety Considerations section before operating your M Series product.

Safety Considerations

Warnings

General

- Before use, carefully read the *M Series Operator's Guide*, these operating instructions, and the ZOLL/ Masimo LNCS Sensor directions for use.
- The M Series Pulse Oximeter is to be operated by qualified personnel only.
- Do NOT use the pulse oximeter as an apnea monitor.
- Do NOT immerse the M Series device, patient cables or sensors in water, solvents, or cleaning solutions.
- A pulse oximeter should be considered an early warning device. As a trend towards 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 alarms are suspended, the suspended alarm indications will only be visual displays and symbols.
- To ensure patient safety, the ECG-out jack and modem (if available) should only be connected to other equipment with galvanically isolated circuits.
- 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.
- Do not use the M Series pulse oximeter or LNCS sensors during magnetic resonance imaging (MRI). Induced current could potentially cause burns. The M Series Pulse Oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Use ONLY the line cord supplied by ZOLL Medical Corporation for continued safety and EMI performance.

Sensors

- Use only ZOLL/Masimo LNCS Oximetry Sensors for SpO_2 measurements. Other manufacturer's sensors may cause improper oximeter performance.
- Tissue damage can result from incorrect application or use of an LNCS sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensors' Directions for Use to ensure skin integrity, correct positioning and adhesion of the sensor.
- Do NOT use damaged LNCS sensors or cables.
- Do NOT use an LNCS sensor with exposed optical components.
- Do NOT sterilize the sensor by irradiation, steam, or ethylene oxide. See the cleaning instructions in the Directions for Use for reusable Masimo LNCS sensors.
- 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 should occur. Refer to the sensor's specific directions for use.
- Do NOT attach the SpO_2 sensor to a limb being monitored with a blood pressure cuff or limb with restricted blood flow.
- A poorly applied sensor may give incorrect saturation values. 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.
- 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.
- Before use, carefully read the SpO_2 Sensor directions for use.
- 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.

SpO$_2$ Intended Use

The ZOLL M Series Pulse Oximeter, with Masimo SET® technology and the LNCS series of sensors, is indicated for the continuous noninvasive monitoring of arterial oxygen saturation (SpO$_2$) and pulse rate. The Pulse Oximeter is indicated for use during both no-motion and patient motion conditions for adult patients, and no-motion conditions for pediatric and neonatal patients, in a hospital and pre-hospital environment.

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.

The M Series Pulse Oximetry option is intended for use only with ZOLL/Masimo LNCS sensors.

Measurement Complications

If the accuracy of any reading is suspect, first check the patient's vital signs by alternate means and then check the M Series Pulse 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

SpO$_2$ Connector and Sensors

The SpO$_2$ connector is located on the rear panel of the M Series unit. Only ZOLL or Masimo accessories and sensors can be used with the M Series Pulse Oximetry option.

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 it as described in the sensor's *Directions for Use*, keep the sensor at the level of the patient's heart, and always observe all warnings and cautions.

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). Refer to the *Directions for Use* provided with each sensor for specific instructions on application and use.

Warranty (U.S. Only)

(a) ZOLL Medical Corporation warrants to the original equipment purchaser that beginning on the date of installation, or thirty (30) days after the date of shipment from ZOLL Medical Corporation's facility, whichever first occurs, the equipment (other than accessories and electrodes) will be free from defects in material and workmanship under normal use and service for the period of one (1) year. During such period ZOLL Medical Corporation will, at no charge to the customer, either repair or replace (at ZOLL Medical Corporation's sole option) any part of the equipment found by ZOLL Medical Corporation to be defective in material or workmanship. If ZOLL Medical Corporation's inspection detects no defects in material or workmanship, ZOLL Medical Corporation's regular service charges shall apply. (b) ZOLL Medical Corporation shall not be responsible for any equipment defect, the failure of the equipment to perform any function, or any other nonconformance of the equipment, caused by or attributable to: (i) any modification of the equipment by the customer, unless such modification is made with the prior written approval of ZOLL Medical Corporation; (ii) the use of the equipment with any associated or complementary equipment, (iii) installation or wiring of the equipment other than in accordance with ZOLL Medical Corporation's instructions, (iv) abuse, misuse, neglect or accident. (c) This warranty does not cover items subject to normal wear and burnout during use, including but not limited to lamps, fuses, batteries, patient cables and accessories. (d) The foregoing warranty constitutes the exclusive remedy of the customer and the exclusive liability of ZOLL Medical Corporation for any breach of any warranty related to the equipment supplied hereunder. (e) Limitation of Liability: ZOLL shall not in any event be liable to Purchaser, nor shall Purchaser recover, for special, incidental or consequential damages resulting from any breach of warranty, failure of essential purpose, or under any other legal theory including but not limited to lost profits, lost savings, downtime, goodwill, damage to or replacement of equipment and property, even if ZOLL has been advised of the possibility of such damages.

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For additional information, please call ZOLL Medical Corporation at 1-800-348-9011. International customers should call the nearest authorized ZOLL Medical Corporation service center.

Software License

Read this Operator's Manual and License agreement carefully before operating any of the M Series products.

Software incorporated into the system is protected by copyright laws and international copyright treaties as well as other intellectual property laws and treaties. This software is licensed, not sold. By taking delivery of and using this system, the Purchaser signifies agreement to and acceptance of the following terms and conditions:

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Note: The M Series software has been validated for use with Masimo SET pulse oximetry technology.

How SpO$_2$ is Displayed

The M Series Pulse Oximetry option displays a plethysmograph waveform derived from the sensor. The numeric 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).

SpO2%

98

Signal Strength Indicator

Numeric Oxygen Saturation

Alarm Status Indicator
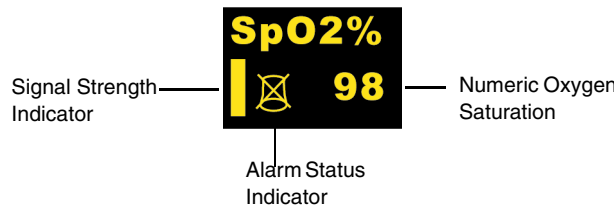
Note: The SpO$_2$ numeric will display dashes (-----) whenever pulse oximetry values are likely to be contaminated due to the presence of excessive ambient light, inadequate perfusion, high signal artifact, a defective or disconnected sensor, etc.

Displaying the Plethysmographic Waveform

The M 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 plethysmographic waveform below the ECG trace for a visual indicator of SpO$_2$ monitoring.

Pressing the **Wave2** softkey from the physiological monitoring menu cycles the display from the capnogram waveform, to the plethysmograph waveform, to no second waveform displayed.
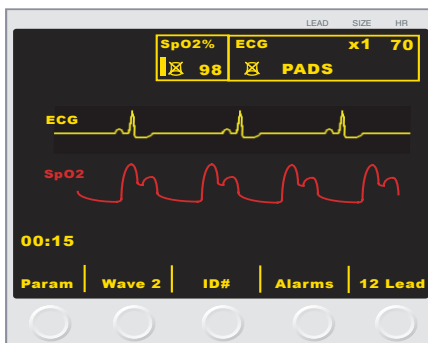
The unit temporarily removes the second waveform from the display when the user presses the **CHARGE**, **ANALYZE**, or **ENERGY SELECT** buttons, or the **Sync On/Off** softkey. The unit restores the second waveform to the display:

- 3 seconds after a shock is delivered
- 3 seconds after an analysis is completed, unless the defibrillator is charging

- 4 seconds after the last **Energy Select** button press
- 3 seconds after Sync mode is turned off

Physiological Monitoring

When the user turns the M Series unit to **MONITOR** mode, the physiological monitoring menu will be displayed with the following softkeys: **Param**, **Wave2**, **ID#**, **Alarms** and **12 Lead** (if installed).

Param	Wave 2	ID#	Alarms	12 Lead

Param Softkey

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

SpO2
EtCO2
NIBP

Select	Enter			Return

Pressing the **Select** softkey scrolls the highlight area among the different available physiological parameters. Pressing the **Enter** softkey selects the highlighted parameter. Pressing the **Return** softkey returns the user to the physiological monitoring menu.

When the user selects the SpO$_2$ parameter, the following softkeys appear: **Sens.**, **Average**, **Alarms** and **Return**.

Sens.	Average		Alarms	Return

Sens. (Sensitivity) Softkey

The **Sens.** softkey allows the user to select either "Normal" or "High" sensitivity for SpO$_2$ monitoring.

The "Normal" sensitivity setting is the recommended setting and should be selected for most patients.

The "High" sensitivity setting allows SpO$_2$ monitoring to be performed even under very low perfusion conditions. Such conditions may include severe hypotension or shock. When the "High" sensitivity setting is used however, SpO$_2$ results are more easily contaminated by artifact. In order to assure accuracy of SpO$_2$ readings when the "High" sensitivity setting is in use, it is recommended that the patient be carefully and continuously observed.

Normal and High sensitivity modes can be selected by pressing the **Sens.** softkey. The highlight toggles between the "Normal" and "High" options, allowing the user to select the appropriate sensitivity.

Normal
High

Sens.	Enter			Return

Pressing the **Enter** softkey selects the highlighted sensitivity. Pressing the **Return** softkey returns the user to the SpO$_2$ submenu.

Average Softkey

The M Series provides three (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, the 4 second setting is recommended. The 16 second setting should only be used when the 8 second setting (default) is inadequate due to extremely high artifact conditions.

The user can select the averaging period (4, 8, or 16 seconds) by pressing the **Average** softkey. When the user presses the **Average** softkey, the following softkeys appear: **Average**, **Enter** and **Return**.

```
    4 secs
    8 secs
    16 secs

Average   Enter                    Return
```

The highlight area scrolls among the different averaging periods of 4, 8, and 16 seconds every time the **Average** softkey is pressed.

Pressing the **Enter** softkey selects the highlighted averaging period. Pressing the **Return** softkey returns the user to the SpO$_2$ submenu.

Alarms

The M Series SpO2 option provides user programmable "out of range" alarms for both SpO$_2$ and heart rate. See "Default Settings" on page 10 for low and high alarm limit default values and ranges.

When a patient's heart rate is being monitored using ECG, the High Heart Rate alarm limit range is 60 to 280 bpm, with a default setting of 150 bpm. When the heart rate is being monitored using pulse oximetry, however, the maximum High Heart Rate alarm limit is lowered to 235 bpm automatically 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 lower alarm limit to 95% and 105% of the patient's currently measured saturation percentage (the maximum setting being 100%) SpO$_2$ value respectively. The auto alarm limits are set only if valid measurements are present for the vital sign.

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

Automated External Defibrillator (AED) Operation

M Series AED units equipped with Pulse Oximetry operate in a slightly different way than Manual and Advisory models equipped with SpO$_2$, as outlined below.

Semi-Automatic Operation

The SpO$_2$ monitoring parameters can be changed by pressing the **Param** softkey as outlined in "Physiological Monitoring" on page 5. The plethysmographic waveform cannot be displayed in semi-automatic mode.

Although SpO$_2$ alarm functions are operational in semi-automatic mode, heart rate alarm functions are disabled. Background ECG analysis functions continue to operate as described in the "AED" section of the *M Series Operator's Guide*.

The **ALARM SUSPEND** button can be used to activate, deactivate, or audibly disable the SpO$_2$ alarms as described in the *M Series Operator's Guide*. The alarm limit settings cannot, however, be changed in semi-automatic mode; only the default alarm limits are available. See the *M Series Configuration Guide* for information on setting alarm limit defaults.

Manual Mode Operation

When the AED unit is in manual mode, the unit can display the plethysmographic waveform as described in "Displaying the Plethysmographic Waveform" on page 5.

Both heart rate and SpO$_2$ alarms are operational. The alarm limits can be changed by pressing the **Alarms** softkey. The SpO$_2$ monitoring parameters can be changed by pressing the **Param** softkey as described in "Physiological Monitoring" on page 5.

SpO$_2$ Setup

1. Inspect the M Series case and cables for damage.

2. Ensure that the sensor and cable are compatible models before connecting it to the M Series unit (see "Safety Considerations" on page 2).

3. Attach the sensor to the patient and connect the sensor to the SpO$_2$ patient cable (see "Applying a Reusable Sensor" on page 7 or "Applying a Disposable Sensor" on page 8).

   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 SpO$_2$ connector at the back of the M Series unit (see Figure 1).

SpO$_2$ Connector
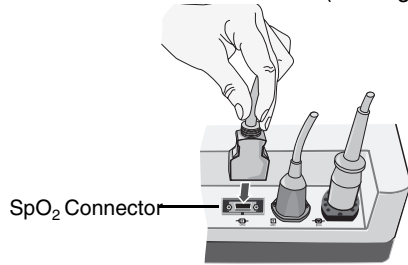
Figure 1

5. Turn the selector switch to MONITOR mode (ON for AED units). Verify that the sensor's red LED is on. The oximeter is now fully operational.

   A dashed line is displayed in the SpO2 field until a pulse is detected. Once the measurement has been established, the saturation values will be displayed in the numeric field (e.g., 98).

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

7. Adjust the alarm limits and enable SpO2 alarms if desired.

Note: If ECG Leads are not attached, the patient's pulse rate as measured by the SpO$_2$ sensor will be displayed as the Heart Rate (HR) in the ECG field and the heart symbol will not flash.

If the unit displays a "SpO2 FAULT XX" message shortly after power-up, the SpO$_2$ 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, and the anticipated duration of monitoring. For more information refer to the following table or contact ZOLL Medical Corporation.

Use only ZOLL/Masimo sensors and patient cables. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the *Directions for Use* accompanying the sensor.

Sensor	Single Use/ Reusable	Patient Weight
LNCS Adtx	Single Use	Adults > 30 kg
LNCS Pdtx	Single Use	Pediatrics and Slender Adults 10 - 50 kg
LNCS Neo-L	Single Use	Neonates < 3 kg
LNCS NeoPt-L	Single Use	Neonates < 1 kg
LNCS Inf-L	Single Use	Infant 3 - 20 kg

Sensor	Single Use/ Reusable	Patient Weight
LNCS DCI	Reusable	Adults and Pediatrics > 30 kg
LNCS DCIP	Reusable	Pediatrics 10 - 50 kg

ZOLL offers two reusable patient cables designed to work exclusively with LNCS sensors and with the M Series pulse oximeter:

- LNC-04 (4' cable),
- LNC-10 (10' foot cable)

Selecting a Sensor Application Site

Choose a site that is well perfused and will restrict a conscious patient's movements the least. The ring finger or middle finger of the non-dominate hand is preferred.

Alternatively, the other digits on the non-dominate hand may be used. Be sure the sensor's detector is fully covered by flesh. The great toe or long toe (next to the great toe) may be used on restrained patients or patients whose hands are unavailable.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of an SpO$_2$ sensor. 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 Reusable Sensor

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. The fleshiest part of the digit should cover the detector window in the lower half of the sensor (see Figure 2).
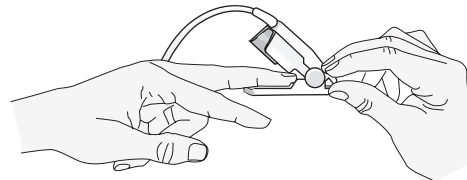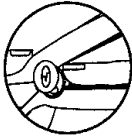

Figure 2

The hinged tabs of the sensor should open to evenly distribute the grip of the sensor along the length of the finger.

2. On finger sites, the tip of the finger should touch the raised digit stop inside the sensor. If the fingernail is

long, it may extend over and past the finger stop (see Figure 3).

Figure 3

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. Complete coverage of the detector window is needed to ensure accurate data (see Figure 4).
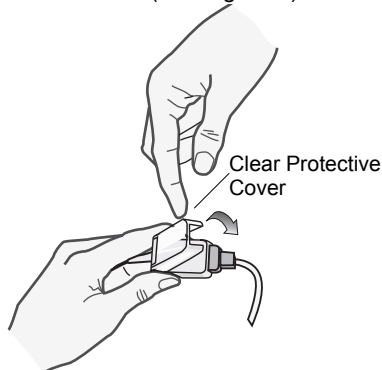

Figure 4

Orient the sensor so that the cable runs towards the top of the patient's hand.

4. 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 Figure5).

Sensor Cable Connector

Patient Cable Connector
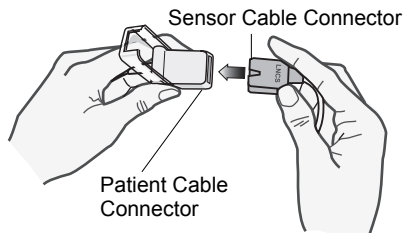
Figure 5

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

Clear Protective Cover

Figure 6

6. Connect the SpO$_2$ patient cable to the SpO$_2$ connector on the back of the M Series unit as shown in Step 4 of "SpO2 Setup" on page 6.

Applying a Disposable Sensor

A disposable sensor may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.

The adhesive can be partially rejuvenated by wiping with an alcohol wipe and allowing the sensor to thoroughly air dry prior to replacement on the patient.

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

1. Open the pouch and remove the sensor.

2. Holding the sensor with the tan 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).
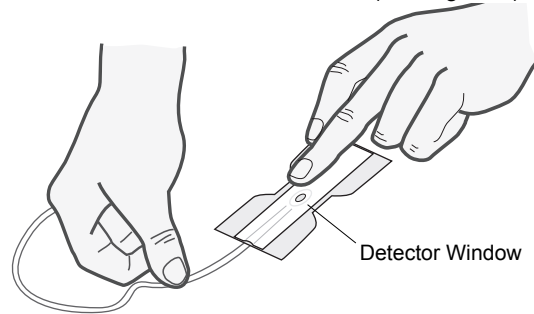
Detector Window

Figure 7

4. Press the detector onto the fleshy part of the finger near the tip of the finger. Complete coverage of the detector window is needed to ensure accurate measurements.

5. With the emitter positioned over the finger nail, secure the wings around the finger (see Figure 8).
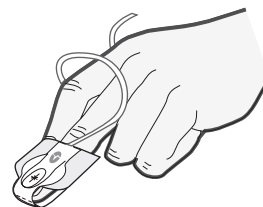
Figure 8

When positioned properly, the:

- emitter and the detector are vertically aligned
- digit completely covers detector window
- shiny contacts on the sensor are facing up

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 SpO$_2$ patient cable to the SpO$_2$ connector on the back of the M Series unit as shown in Step 4 of "SpO2 Setup" on page 6.

Ensuring Accurate SpO$_2$ Monitoring

The following general points will 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.
- Do not restrict blood flow when securing a sensor with tape.
- Do not select a site near potential sources of electrical interference (electrical cords, for example).
- Do not use a damaged sensor or one with 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 SpO$_2$ sensor site at least once every two (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 eight (8) hours and, if indicated by circulatory condition or skin integrity, reapply to a different monitoring site.
- Do not wrap the adhesive too tightly and do not use additional tape to secure the sensor, as this can cause venous pulsations that could potentially lead to inaccurate saturation measurements.
- If the sensor fails to track the pulse consistently, the sensors may be incorrectly positioned. Reposition the sensor or choose a different monitoring site.
- Ensure that the signal strength bar graph indicates the presence of a strong signal associated with each heart beat.
- Avoid placing the SpO$_2$ sensor on any extremity with an arterial catheter, blood pressure cuff, or intravascular line.

Checkout Procedure

1. Connect the sensor to the SpO$_2$ patient cable and attach the sensor to test subject (yourself).

2. Connect the SpO$_2$ patient cable to the SpO$_2$ connector at the back of the M Series unit.

3. Turn the selector switch to **MONITOR** mode (**ON** for AED units, then select "Manual Mode").

4. With alarms enabled, verify that the patient alarms are functional by placing the sensor on your finger and adjusting the high and low limits until:
   - a continuous audio tone sounds
   - the alarming parameter's value is highlighted and the alarm bell flashes on the display

5. Disconnect the ECG cable and verify that your pulse rate is equal to the rate that appears on the M Series heart rate display.

6. Verify the sensor alarms are functional by removing the sensor from the sensor site.
   - "CHECK SpO2 SENSOR" appears in the message area of the graphic display.
   - a two-beep audio tone sounds.

7. Unplug the sensor from the M Series unit. Make sure:
   - "CHECK SpO2 SENSOR" message appears
   - a two-beep audio tone sounds.

8. Verify second waveform display:
   - Press the **Wave2** softkey
   - Verify that the plethysmographic waveform appears and repeats at test subject's (your own) pulse rate or disappears if originally present.

Cleaning and Reuse of Sensors

Reusable sensors can be cleaned as follows:

1. Disconnect the sensor from the patient cable.

2. Wipe the entire sensor clean with a 70% isopropyl alcohol 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 M Series unit.

3. Wipe the cable clean with a 70% isopropyl alcohol pad.

4. Allow the cable to dry before returning it to use.

Default Settings

When the pulse 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) 8 seconds (medium) 16 seconds (long)
Sensitivity	Normal	Normal or High
High SpO$_2$ Alarm Limit	OFF (appears as: ---)	50% to 100% or OFF
Low SpO$_2$ Alarm Limit	85%	50% to 100% or OFF
High Heart Rate Alarm Limit	150 bpm (beats/minute)	60 to 280 bpm (monitoring via ECG) 60 to 235 bpm (monitoring via Pulse Oximetry)
Low Heart Rate Alarm Limit	30 bpm	20 to 100 bpm

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 *M Series Configuration Guide* for more information.

SpO$_2$ Accessories

The following table describes each of the SpO$_2$ accessories.

Item	Description	Part #
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-L	Single use sensor for Infants 3 - 20 kg	8000-0322
LNCS Neo-L	Single use sensor for Neonates < 3 kg	8000-0323
LNCS NeoPt-L	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
LNC-4	4' Reusable Patient Cable	8000-0298
LNC-10	10' Reusable Patient Cable	8000-0293
LNC Ext	LNC Extension Cable, DB-9 Termination, 4ft	8000-0325
LNCS-to-LNOP	Adapter Cable, LNCS Sensor to LNOP Patient Cable	8000-0327
LNCS DC-12	LNCS Adult Reusable Direct Connect 12' Cable	8000-0296

Note: LNOP single use and reusable sensors are no longer available, but remain compatible with the M Series.

Messages and Troubleshooting

The following chart lists the messages that may appear on the M Series unit relating to SpO$_2$, why the message appeared, and the action(s) to take if the message indicates a problem.

The operator should become thoroughly familiar with this information before using the oximeter for patient monitoring.

Message	Possible Cause(s)	Recommended Action(s)
SpO2 AMBIENT LIGHT/ CHECK SpO2 SENSOR	Excessive ambient light.	Relocate the sensor to a site more shielded from light or reduce the amount of light shining on the sensor.
SpO2 PULSE SEARCH	Appears when the oximeter cannot detect a patient's pulse.	Reposition or relocate the sensor, and/ or increase perfusion.
CHECK SpO2 SITE	Insufficient perfusion at sensor site.	Reposition or relocate the sensor, and/ or increase perfusion.
CHECK SpO2 SENSOR	Appears when SpO$_2$ readings may be invalid due to motion, to an unacceptable sensor site, to poor placement, low perfusion, or sensor is OFF.	For all causes, reposition or relocate the sensor, and/or increase perfusion.
SpO2 FAULT XX	Appears when SpO$_2$ subsystem of the unit has failed.	Call ZOLL Technical Service Department.
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	
Saturation (% SpO$_2$) Range	1% - 100%
Pulse Rate (bpm) Range	25 - 240 bpm
Saturation (% SpO$_2$) Accuracy During No Motion Conditions	Adults 70% - 100%, ±2 digits 0% - 69%, unspecified Neonates 70% - 100%, ±2 digits 0% - 69%, unspecified
Saturation (% SpO$_2$) Accuracy During Motion Conditions	Adults 70% - 100%, ±3 digits 0% - 69%, unspecified
Pulse (bpm) Accuracy During No Motion Conditions	25 - 240, ±3 digits
Pulse (bpm) Accuracy During Motion Conditions	25 - 240, ±5 digits
SpO$_2$ Alarm Limits	On/Off displayed on monitor. User selectable. High 72 - 100% saturation, Low 70 - 98% saturation
Pulse Rate Alarm Limits	On/Off displayed on monitor. User selectable. High 60 - 235 bpm, Low 20 - 100 bpm
Saturation (% SpO$_2$) Resolution	1%
Pulse Rate Resolution	1 bpm
Text Display Update Rate	100 milliseconds
Trace Update Rate	52 milliseconds
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: 0° to 40° C Storage and Shipping Temperature: -20° to 60° C **Note:** The M 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-2: IEC 1000-4-3 to 18 v/m
Operating Time	For a new, fully charged battery pack at 20°C: • 35 defibrillator discharges at maximum energy (360J), or • 2.0 hours minimum of continuous ECG monitoring, or • 1.75 hours of continuous ECG monitoring/pacing at 60 mA, 70 beats/min.

Note: The M Series Pulse Oximetry Option is calibrated for Functional saturation.