Pulse Oximetry (SpO_2)

ZOLL M Series

9650-0202-01 Rev. K

The issue date or revision level for this operation guide is shown on the front cover.
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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 neonate s, 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 LNOP® oximetry sensor packages.

How to Use This Manual

This section explains how to set up and use the **M Series** Pulse Oximeter. Important safety information relating to general use of the **M Series** Pulse Oximeter appears in the "Safety Considerations" section of this manual. Other important safety information is located in the "Safety Considerations" section of the LNOP® 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 within.

Please thoroughly read both safety considerations and warnings sections before operating your M Series product.

SpO_2 Accessories

- LNOP® - Adt: Single use sensor for patients > 30 kg
- LNOP® - Pdt: Single use sensor for Pediatrics and Slender Adults > 10 kg and < 50 kg
- LNOP® - Neo: Single use sensor for Neonates < 10 kg
- LNOP® - Neo Pt: Single use sensor for Neonates < 1 kg (Pre-term)
- LNOP® - DC1: Reusable sensor for Adults and Pediatrics > 30 kg
- PC04: 4' Reusable Patient Cable
- PC08: 8' Reusable Patient Cable
- PC12: 12' Reusable Patient Cable

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SpO_2 Intended Use

The ZOLL **M Series** Pulse Oximeter with Masimo SET® technology and the LNOP® Series of Sensors are indicated for the continuous noninvasive monitoring of arterial oxygen saturation (SpO_2) and pulses rate 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 LNOP® 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 under any of the following situations:

- 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.
- 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.

sensor packages oximetry sensor packages products contain a DC defibrillator capable of delivering up to 360 joules of energy. It may be used in synchronized mode to perform synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference. The unit uses paddles or disposable, pre-gelled, MFE Pads for defibrillation.

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.

Safety Considerations

Warnings

General

- Before use, carefully read the *M Series Operator's Guide*, these operating instructions, and the ZOLL / Masimo LNOP® Sensor directions for use.
- The **M Series** Pulse Oximeter is to be operated by qualified personnel only.
- A pulse oximeter should NOT be used 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 LNOP® 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.
- As with all medical equipment, 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 LNOP® 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 LNOP® 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 LNOP® sensors or cables.
- Do not use an LNOP® 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 LNOP® 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.

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. (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:

1. **Grant of License:** In consideration of payment of the software license fee which is part of the price paid for this product ZOLL Medical Corporation grants the Purchaser a non-exclusive license, without right to sublicense, to use the system software in object-code form only.

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Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

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

SELECTING A LNOP® SENSOR

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
LNOP-Adt	Single Use	Adults > 30 kg
LNOP-Pdt	Single Use	Pediatrics and Slender Adults > 30 kg and < 50 kg
LNOP-Neo	Single Use	Neonates < 10 kg
LNOP-Neo Pt	Single Use	Neonates < 1 kg
LNOP-DC1	Reusable	Adults and Pediatrics > 30 kg

APPLICATION OF THE REUSABLE SENSOR

Site Selection

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.

Attaching Sensor to Patient

- Place the selected digit over the sensor window of the LNOP® • DC1. The fleshiest part of the digit should be covering the detector window in the lower half of the sensor. (Refer to **Figure A**).

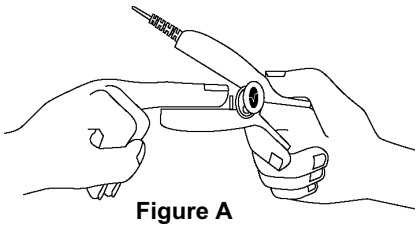


Figure A

- 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. (Refer to **Figure B**).

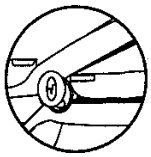


Figure B

- The hinged tabs of the sensor should open to evenly distribute the grip of the sensor along the length of the finger. Check position of sensor to verify correct positioning. Position is deemed correct when the top and bottom halves of the sensor are parallel. Complete coverage of the detector window is needed to ensure accurate data. (Refer to **Figure C**).

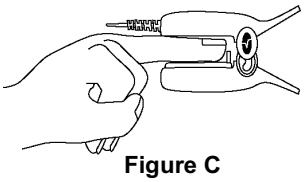


Figure C

- Orient the sensor so that the cable will be running towards the top of the patient's hand. Connect the LNOP® • DC1 connector to a patient cable (PC04/ PC08/PC12).

Note: With smaller digits, in order to completely cover the detector window, the digit might not need to be pushed all the way to the stop. The sensor is not intended for use on the thumb or across a child's hand or foot.

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.

Attaching Sensor to the Patient Cable

- Orient the connecting tab so that the “shiny” contacts are pointed up and mate the Masimo SET® logo to the logo on the patient cable. (Refer to **Figure D**).

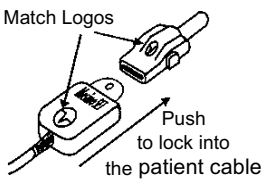


Figure D

- Insert the LNOP® • DC1 connector over the patient cable connector until there is a tactile or audible click connection. Gently tug on the connectors to ensure a positive contact. Tape may be used to secure the cable to the patient for ease of movement.

APPLICATION OF THE ADULT DISPOSABLE SENSOR (LNOP® • Adt)

Site Selection

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.

Attaching Sensor to Patient

- Open the pouch and remove the sensor. Holding the sensor with the tan printed side downward, bend the sensor backward and remove backing material from the sensor.
- Orient the sensor so that the digit can be attached to the detector side of the sensor first. (**Figure A**).

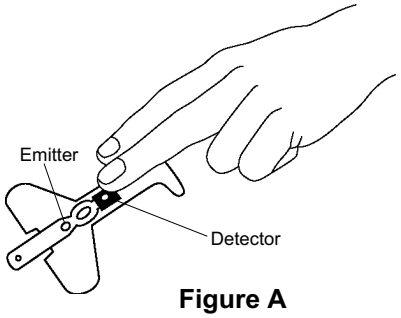


Figure A

- Press the detector onto the fleshy part of the finger near the tip of the finger.
- Press down the "T" shaped adhesive end of the sensor onto the finger and secure the wings in place.
- Next, wrap the sensor with the emitter positioned over the finger nail and secure the wings down one at a time around finger. When properly applied, the emitter and the detector should be vertically aligned. (**Figure B**).

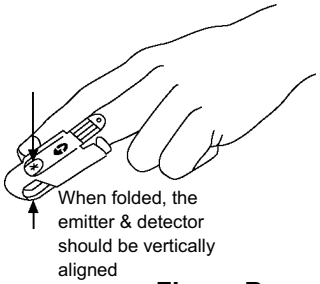


Figure B

- Check position of sensor to verify correct positioning and reposition, if necessary, so that the emitter and the detector are vertically aligned.
- Complete coverage of the detector window is needed to ensure accurate measurements.
- The connector tab is now oriented on the top side of the patient's finger so that the "shiny" contacts are pointed up. Mate the Masimo SET® logo on the sensor to the logo on the patient cable. Insert the patient cable to the sensor tab until there is a tactile or audible click of connection. Gently tug on the connectors to ensure a positive contact. If required, tape may be used to secure the cable to the patient. (**Figure C**).

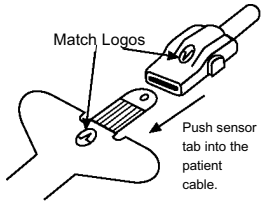


Figure C

- The 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: LNOP® • Adt sensors are not intended for use across a child's hand or foot.

For instructions on proper application of the neonatal sensors refer to the directions for use accompanying the LNOP® • Neo sensor.

ENSURING ACCURATE 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.

- The sensor must be removed and repositioned every eight (8) hours and, if indicated by circulatory condition or skin integrity, reapplied 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 an SpO_2 sensor on any extremity with an arterial catheter, blood pressure cuff, or intravascular line.

CLEANING AND REUSE OF SENSORS

Reusable sensors can be cleaned per the following procedure:

1. Remove 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.

Reattachment of Single Use Sensors

- LNOP® single use sensors 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.

PATIENT CABLES

ZOLL offers three reusable patient cables: PC04, a 4 foot cable, PC08, an 8 foot cable and PC12, a 12 foot cable. The cables are designed to work exclusively with LNOP® sensors and with the **M Series** pulse oximeter.

CLEANING AND REUSE OF PATIENT CABLES

Patient cables can be cleaned per the following procedure:

1. Remove the cable from the sensor.
2. Disconnect the cable from the rear of the **M Series**.
3. Wipe clean with a 70% isopropyl alcohol pad.
4. Allow the cable to dry before returning it to use.

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).

SpO_2 SETUP

Attach the sensor to the patient (Refer to the "Attaching the Sensor to Patient" Section).

Plug the sensor into the SpO_2 patient cable.

Attach the patient cable to the rear of the **M Series** product.

Turn the selector switch to MONITOR mode.

A dashed line will be displayed in the SpO_2 field until a pulse is detected. Once the measurement has been established, the saturation values will be displayed in the numeric window (e.g., 98).

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.

The SpO_2 display field consists of the label "SpO2%", an alarm indicator, a numerical value representing the saturation level, and a bar graph used as a signal strength indicator.

PHYSIOLOGICAL MONITORING

When the user turns the **M Series** device to MONITOR mode, the physiological monitoring menu will be displayed with the following softkeys: "**Param**", "**Wave2**", "**ID#**", "**Alarms**" and "1**2 Lead**."

"Param" Softkey

When the "**Param**" softkey is pressed, the following softkeys will be displayed: "**Select**", "**Enter**", and "**Return**".

Pressing the "**Select**" softkey will scroll the highlighted area among the different available physiological parameters. Pressing the "**Enter**" softkey allows the user to select the parameter that is highlighted. Pressing the "**Return**" softkey allows the user to return to the physiological monitoring menu.

Selecting the SpO_2 parameter causes the following softkeys to appear; "**Sens.**", "**Average**", "**Alarms**" and "**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 "Normal" and "High" allowing the user to select the appropriate sensitivity.

Pressing "**Enter**" allows the user to enter the highlighted sensitivity. Pressing "**Return**" will return 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 "**Average**" softkey is pressed the following softkeys will be displayed: "**Average**", "**Enter**" and "**Return**".

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

Pressing the "**Enter**" softkey allows the user to select the highlighted averaging period. Pressing the "**Return**" softkey will return the user to the SpO_2 submenu. Pressing the "**Return**" softkey again will return the user to the physiological monitoring menu.

Displaying the Plethysmographic "Waveform"

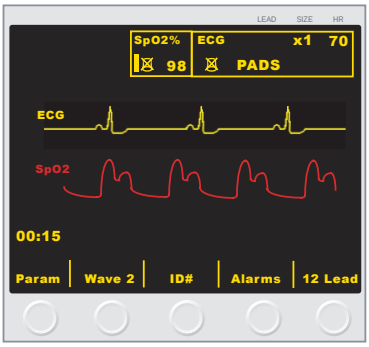
M Series systems allow the user to display one or two waveforms when in Monitor or Defib mode. Only one waveform will be displayed in pace mode.

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.

A second waveform can be displayed provided that the defibrillator is not charging or an ECG analysis is not in progress. The waveform will be temporarily removed from the display, if currently visible, when any of the following buttons are pressed: **CHARGE**, **ANALYZE**, **ENERGY SELECT**, **SYNC ON/OFF**.

The second waveform will be restored to the display under the following conditions:

- 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



Alarms

Press the "**Alarms**" softkey to display the Set Alarm screen and softkeys.

Press the **Inc** or **Dec** softkeys to select "ENABLE", "DISABLE", or "AUTO" in the State field. Pressing the **Next Field** softkey when either "ENABLE or "DISABLE" has been chosen will set the selected State and move the highlight to the next field (Low limit field).

When "AUTO" has been selected and the **Next Field** softkey is pressed, the unit will set the lower and upper limits to 95% and 105% of the patient's currently measured saturation percentage (maximum setting being 100%) if valid measurements are present for the vital sign. The highlight then shifts to the next Parameter field. Refer to the “Alarms” section of the *M Series Operator’s Guide* for further details.

The **M Series** device has three levels of alarms.

1. **High Priority**: If enabled, these alarms reflect physiological parameters that are out of bounds. They will cause a continuous audio tone, highlight the alarming parameter and flash the associated alarm bell.
2. **Medium Priority**: These alerts reflect equipment related user correctable faults such as LEAD OFF and CHECK SPO2 SENSOR. They will cause a two beep audio tone and display a message for a timed period.
3. **Low Priority**: These are informational messages to the user only and have the same audio indication as the Medium priority alarms.

Alarm Limits

The Low Heart Rate Alarm Limit range is 20 to 100 bpm with a default setting of 30 bpm.

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 original High Alarm Limit setting will be restored when ECG monitoring resumes.

The Low SpO2 Alarm Limit range is 70% to 98% saturation with a default setting of 85%. The High SpO2 Alarm Limit range is 72% to 100% saturation with a default setting of 100%. (See the *M Series Configuration Guide* for information on setting alarm limit defaults).

Suspending Alarms

When a high priority alarm occurs, a continuous audible tone will sound, the value of the alarming parameter will be highlighted and the bell associated with that parameter will flash.

Press the **ALARM SUSPEND** button to silence the alarm. An “X” will be placed through the flashing bell ( ) to indicate that alarms associated with the affected parameter have been audibly disabled. The value of the alarming parameter remains highlighted. Pressing the **ALARM SUSPEND** button again or correcting the alarm violation will reactivate the alarm processing.

If a second alarm occurs while the first alarm is suspended, press the **ALARM SUSPEND** button to suspend the second alarm tone.

Activating / Deactivating Alarms

Pressing and holding the **ALARM SUSPEND** button for approximately 3 seconds will deactivate alarm functions. All bells will have an "X" through them) to indicate that alarms are deactivated.

If all alarms are deactivated and the **ALARM SUSPEND** button is briefly pressed, all of the enabled alarm functions will be activated. (Refer to the “Setting Alarms” section of the *M Series Operator’s Guide*).

Automated External Defibrillator (AED) Operation

M Series AED's equipped with Pulse Oximetry operate in a slightly different way than Manual and Advisory models equipped with SpO_2. These differences are explained below.

Semi-Automatic Operation

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, however, 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 previously. 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.

The SpO_2 monitoring parameters can be changed by pressing the "**Param**" softkey.

Manual Mode Operation

The plethysmographic waveform can be displayed by pressing the "**Wave2**" softkey provided that the defibrillator is not charging or an ECG analysis is not in progress. The waveform will be temporarily removed from the display, if currently visible, when any of the following buttons are pressed: **CHARGE**, **ANALYZE**, **ENERGY SELECT**, **SYNC ON/OFF**. The second waveform will be restored to the display under the following conditions:

- 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

The waveform cannot be displayed in pace mode.

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.

Using SpO_2

- Inspect the **M Series** case and cables for damage.
- Check that the sensor is a compatible model before connecting it to the M Series Pulse Oximeter. (See the "Accessories" section).
- 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.
- Attach the sensor to the patient (see the "Attaching Sensors to Patient" sections of this manual).
- Attach sensor to the patient cable; make sure it is a firm connection.
- Connect the patient cable to the SpO_2 connector located on the rear of the **M Series** product.
- Turn the unit to Monitor mode. Check that the sensor's red LED is on. The oximeter is now fully operational.
- If a "SpO2 FAULT XX" message is displayed shortly after powering the M Series on, the SpO_2 monitoring subsystem of the unit has failed. Contact the ZOLL Technical Service Department.
- Ensure that appropriate numeric oxygen saturation values are being displayed.
- Ensure that the signal strength bar indicates the presence of a strong signal associated with each heartbeat.
- Adjust the alarm limits and enable SpO_2 alarms if desired.
- 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.

Checkout Procedure

1. 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.
2. Disconnect the ECG cable and verify that your pulse rate is equal to the rate that appears on the **M Series** heart rate display.
3. Verify the sensor alarms are functional by removing the sensor from the sensor site.
   - "CHECK SpO2 SENSOR" appears in the message rea of the graphic display.
   - a two-beep audio tone sounds.
4. Unplug the sensor from the oximeter. Make sure:
   - "CHECK SpO2 SENSOR" message appears.
   - a two-beep audio tone sounds.
5. Verify second waveform display:
   - Plug the sensor into the oximeter.
   - Attach the sensor to test subject (yourself)
   - 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.

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
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
Averaging Mode	8 seconds (medium)	4 seconds (short) 8 seconds (medium) 16 seconds (long)
Sensitivity	Normal	Normal or High

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.

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	
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: 0º to 40º C Storage and Shipping Temperature:-20º to 60º 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.