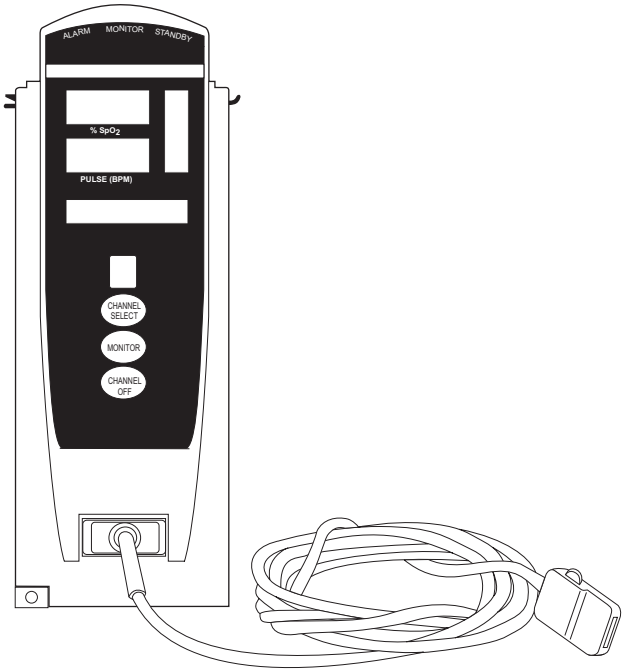
Directions for Use

SpO_2 Module, 8210 Series



SpO_2 MODULE
MODEL 8210

ALARIS Medical Systems, Inc.

Medley™ Medication Safety System

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About the SpO_2 Module

The Medley™ SpO_2 Module is indicated for continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate measured by an SpO_2 sensor. The SpO_2 Module and accessories are indicated for use with adult, pediatric and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

Only 1 SpO_2 Module can be connected to a Medley™ Point-of-Care Unit.

NOTE: The Medley™ Point-of-Care Unit was formerly known as the Medley™ Programming Module.

The SpO_2 Module uses a Nellcor® DOC-10 patient cable and a wide variety of Nellcor® OxiMax® series sensors. The Nellcor® cable and sensors are designed for use with the Model 8210 SpO_2 Module. For specific directions for use, refer to the cable and sensor packaging.

Contraindications: The SpO_2 Module with Nellcor® DOC–10, OC-3 patient cables and Nellcor® OxiMax® series sensors are contraindicated for use as an apnea monitor.

This document provides directions for use for the Medley™ SpO_2 Module, Model 8210.

WARNING

Read all instructions, for both the SpO_2 Module and Point-of-Care Unit, before using the Medley™ System.

Principle of Operation

The operation of the Medley™ SpO_2 Module is based on the principles of pulse oximetry. Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry). The volume of arterial blood in tissue and the light absorbed by the blood changes during the pulse (plethysmography). A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry sensor serve as light sources; a photo diode serves as the photo detector.

Principle of Operation (Continued)

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation to identify the oxygen saturation of arterial hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The SpO_2 Module bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers; such as, venous blood, tissue and bone.

Because light absorption by hemoglobin is wavelength dependent and the mean wavelength of LEDs varies, an oximeter must know the mean wavelength of the sensor's red LED to accurately measure SpO_2. During monitoring, the instrument's software selects coefficients that are appropriate for the wavelength of that individual sensor's red LED. Those coefficients are then used to determine SpO_2.

To compensate for differences in tissue thickness, the light intensity of the sensor's LEDs is adjusted automatically.

The SpO_2 Module measures functional saturation (oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen). It does not detect significant amounts of dysfunctional hemoglobin; such as, carboxyhemoglobin or methemoglobin. In contrast, hemoximeters (such as, IL482) report fractional saturation (oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobin).

To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted as follows:

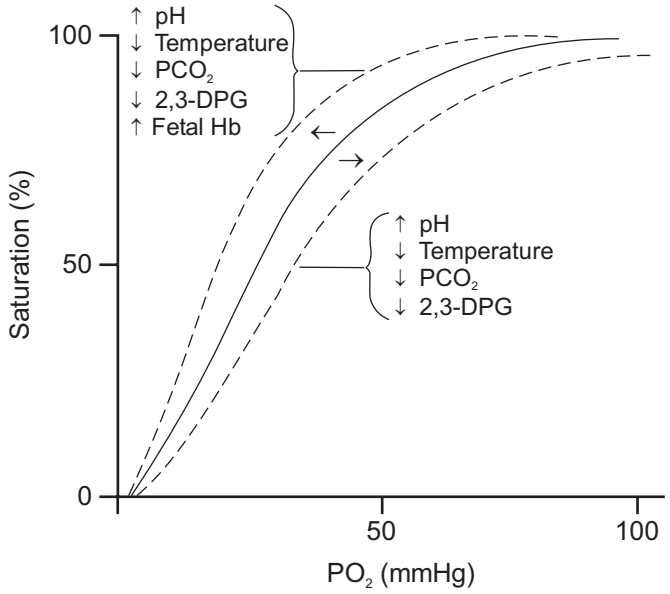
$$\text{functional saturation} = \frac{\text{fractional saturation}}{100 - (\%\text{carboxyhemoglobin} + \%\text{methemoglobin})} \times 100$$

About the SpO_2 Module (Continued)

Principle of Operation (Continued)

When saturation is calculated from a blood gas partial pressure of oxygen (PO_2), the calculated value may differ from the SpO_2 measurement of the SpO_2 Module, this usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO_2 and pH, temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin. To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted as follows:

Oxyhemoglobin Dissociation Curve



Features and Definitions

Reference the “Alarms, Errors, Messages” chapter of the Medley™ Point-of-Care Unit Directions for Use (DFU) for the definitions of various alerts. Reference the Point-of-Care Unit DFU for system features and definitions.

% SpO_2 Alarm Limits — Upper and lower saturation alarm limits are displayed.

% SpO_2 Display — Functional arterial hemoglobin oxygen saturation is displayed in units of percentage SpO_2.

Limit Mode — Displays either adult or neonatal monitoring mode.

Pleth Waveform — Plethysmographic (pleth) waveform is a graphic representation of changes in extremity blood volume during events of cardiac cycle.

Presilence — Alarms can be presilenced for 120 seconds. Presilence alarm can be cancelled before 120 seconds are complete.

Pulse Beat Volume — Can be configured to be off or to a volume level of 1, 2 or 3.

Pulse Rate — Displayed in beats per minute (bpm).

Pulse Rate Alarm Limits — Upper and lower limits are displayed.

SatSeconds — SatSeconds limits controls time %SpO_2 level may fall outside alarm limits before an audible alarm sounds. Method of calculation is as follows:

Number of percentage points %SpO_2 falls outside of alarm limit is multiplied by number of seconds %SpO_2 level remains outside that limit.

Points x Seconds = SatSeconds

Points = %SpO_2 percentage points outside of limit

Seconds = number of seconds %SpO_2 remains at that point outside of limit

Saturation levels may fluctuate rather than remain steady for a period of several seconds. Often, %SpO_2 levels may fluctuate above and below alarm limit, reentering nonalarm range several times. During such fluctuations, SpO_2 Module integrates number of %SpO_2 points, both positive and negative, until either SatSeconds limit (SatSeconds time setting) is reached or %SpO_2 level returns to within a normal range and remains there.

SatSeconds “Safety Net” is for patients with saturation levels having frequent excursions below limit but not staying below limit long enough for SatSeconds time setting to be reached. When 3 or more limit violations occur within 60 seconds, an alarm sounds, even if SatSeconds time setting has not been reached.

Features and Definitions (Continued)

SatSeconds Alarm Management Technology

With SatSeconds Alarm Management Technology, upper and lower alarm limits are set in the same way as with traditional alarm management. A SatSeconds limit can be set to allow monitoring of $\%SpO_2$ below selected low alarm limit for a period of time before an audible alarm sounds.

Trend Data

A tabular display of $\%SpO_2$ and Pulse Rate. Display shows alarm conditions for time period displayed and average, high and low values. Data is stored for 24 hours.

Symbols

Attention: Refer to accompanying documentation.

Canadian and U.S. Certification Mark: Products bearing this mark have been tested and certified in accordance with applicable U.S. and Canadian electrical safety and performance standards (CSA C22.2 No. 601.1, UL 60601–1).

Consult operating instructions.

Electrical Shock Protection Rating: Type BF applied part.

IPX1

Protection against fluid ingress: Drip Proof

IUI Connector: Inter-Unit Interface connector used to establish power and communications between Point-of-Care Unit and attached modules.

Manufacturing Date: Number adjacent to symbol indicates month and year of manufacture.

℞ Only

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on order of a physician.

Do not use if package is damaged.

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Warnings and Cautions

℞ Only

Warnings and Cautions provided throughout this Directions for Use (DFU) provide information needed to safely and effectively use the Medley™ SpO_2 Module and accessories. Medley™ System Warnings and Cautions, and definitions, are covered in the Point-of-Care Unit DFU.

General

WARNINGS

- The SpO_2 Module is **NOT to be used as an apnea monitor**.
- **Pulse oximetry readings and pulse signal** can be affected by certain ambient conditions, sensor application errors and certain patient conditions.
- The SpO_2 Module is **intended only as an adjunct in patient assessment**. It must be used in conjunction with clinical signs and symptoms.
- The SpO_2 Module 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.
- **Interfering Substances:** Carboxyhemoglobin and methemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.
- Do not use the SpO_2 Module or sensors during Magnetic Resonance Imaging (**MRI**).
- The SpO_2 Module is **not rated for defibrillation use**. Disconnect the sensor from the patient or patient cable from the module prior to defibrillation.
- If an alarm condition on the SpO_2 Module occurs **while the audio alarm is silenced**, the only alarm indications will be visual displays and symbols related to the alarm condition.

Warnings and Cautions (Continued)

General (Continued)

WARNINGS

- **Check alarm limits** each time the SpO_2 Module is used, to ensure they are appropriate for the patient being monitored.
- Do not lift the SpO_2 Module by the cable or power cord because the **cable or cord could disconnect from the instrument**, causing it to drop on the patient. Do not place the SpO_2 Module in any position that might cause it to fall on the patient.

CAUTION

To ensure **Electromagnetic Compliance** Integrity, accessories including external communication systems (hospital data communication equipment and/or Nurse call systems) must be certified to applicable standards:

- IEC 60601-1 (Electromedical Equipment) or
- IEC 950 (Data Processing Equipment)

> **NOTE:** Nurse Call systems must be certified to UL 1069 (Hospital Signaling and Nurse Call Equipment) or comply with requirements specified in IEC 60601-1.

Compliance with the electromagnetic compatibility standard (IEC 60601-1-2) is a function of all interconnected equipment including cabling; as such, it is the responsibility of the user to ensure external equipment complies with the applicable EMC standards. Failure to verify such external equipment meets applicable EMC standards may result in degraded electromagnetic compatibility.

Sensors and Cables

WARNINGS

- **Inspect the SpO_2 sensor site regularly** to ensure correct sensor positioning, application and site integrity. Tissue damage could occur over prolonged time periods, depending on the patient profile (such as, neonates) and method of application. Refer to the sensor instructions for additional information.

Sensors and Cables (Continued)

WARNINGS

- **Carefully route patient cabling** to reduce the possibility of patient entanglement or strangulation.
- Before use, **read sensor directions** for use, including all warnings, cautions and instructions.
- **Use only approved Nellcor® OxiMax® sensors and DOC–10, OC–3 pulse oximetry cables**. Use of sensors, transducers, cables and accessories other than those specified may cause improper SpO_2 Module performance resulting in inaccurate readings, increased emission and/or decreased immunity, and degraded electromagnetic compatibility performance of the SpO_2 Module.
- Do not use a sensor, cable, connector or SpO_2 Module that **appears damaged**. Do not use a sensor with **exposed optical components**. **Do not immerse or wet** the sensor or cable. Clean per manufacturer's instructions (refer to Nellcor® OxiMax® sensors instructions for use).
- The **sensor disconnect error message** and associated alarm indicate the sensor is either disconnected or the wiring is faulty. Check the sensor connection and, if necessary, replace the sensor and/or pulse oximetry cable.

Measurements

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and then check the SpO_2 Module to ensure it is functioning properly.

An inaccurate measurement may be caused by:

- Incorrect sensor application or use.
- Significant levels of dysfunctional hemoglobins; such as, carboxyhemoglobin or methemoglobin.
- Intravascular dyes such as, indocyanine green or methylene blue.

- Exposure to excessive illumination; such as, a surgical lamp (especially one with a xenon light source), bilirubin lamp, fluorescent light, infrared heating lamp or direct sunlight.

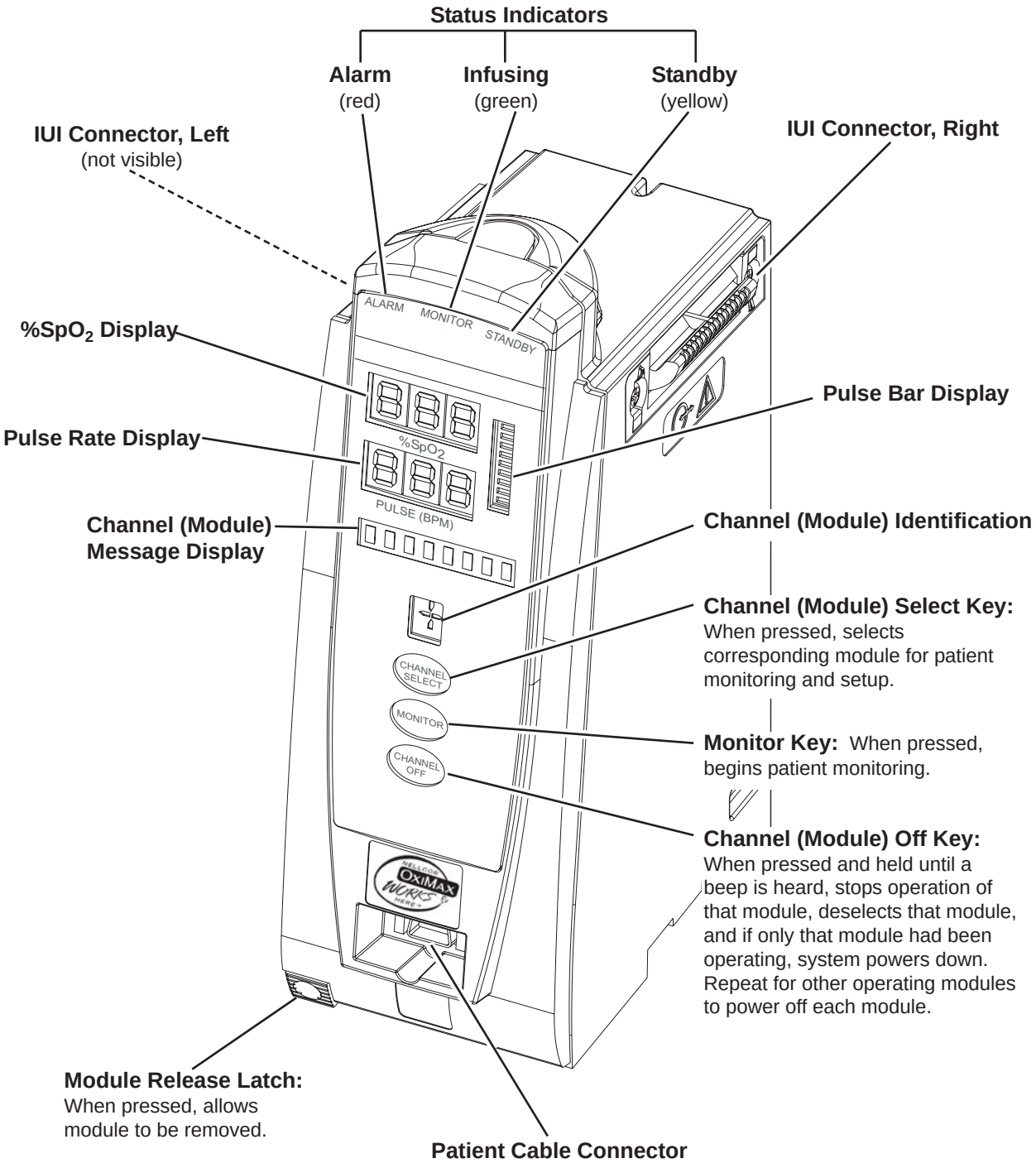
> **NOTE:** Exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material.

- Prolonged and/or excessive patient movement.
- Venous pulsations.
- Sensor placed on an extremity with a blood pressure cuff, arterial catheter, intravascular line or other causes of insufficient perfusion.
- Nail aberrations, nail polish, fungus, etc. Remove nail polish and/or move sensor to an unaffected site.
- Placement is too close to electrosurgery equipment.
- Defibrillation.

The loss of a pulse signal can occur in any of the following situations:

- Sensor is too tight.
- Exposure to excessive illumination; such as, a surgical lamp (especially one with a xenon light source), bilirubin lamp, fluorescent light, infrared heating lamp or direct sunlight.
- Sensor placed on an extremity with a blood pressure cuff, arterial catheter, intravascular line or other causes of insufficient perfusion.
- Patient has hypotension, severe vasoconstriction, severe anemia or hypothermia, is in cardiac arrest or is in shock.
- There is arterial occlusion proximal to sensor.
- Placement is too close to electrosurgery equipment.

Operating Features, Controls and Indicators



Installation

Instruments are tested and calibrated before they are packaged for shipment. To ensure proper operation after shipment, it is recommended that an incoming inspection be performed before placing the instrument in use.

Prior to placing the Medley™ System in use: Perform check-in procedure per Medley™ Maintenance Software/User Manual (Model 8970C, or later).

Attaching and Detaching Modules

Reference the Medley™ Point-of-Care Unit DFU.

Displays

The displays illustrated throughout this document are for illustration purposes only. The display content will vary, depending on configuration settings and other variables.

Main Display

Reference the Medley™ Point-of-Care Unit DFU.

Start-Up

Reference the Medley™ Point-of-Care Unit DFU for the following procedures:

Powering On System
Responding to Maintenance Reminder
Selecting New Patient and Profile Options
Entering Patient ID
Modifying Patient ID

General Setup and Use

1. Attach Nellcor® patient cable to SpO_2 Module. Ensure secure connection and patient cable is not twisted, sliced or frayed.
2. Attach Nellcor® OxiMax® sensors to Nellcor® patient cable. Refer to sensor's directions for use for detailed instructions.
3. Ensure sensor's red LED is on.
4. Attach sensor to patient. Refer to sensor's directions for use for detailed instructions.
5. Verify high and low alarm rates for SpO_2 and pulse rate are correct for patient by selecting **CHANNEL SELECT** key.

> **NOTES:**
>
> - **SEARCHING** may appear in Channel Message Display until SpO_2 and pulse readings have stabilized (approximately 15 seconds).
> - If sensor is not attached to a site after powering up, module will display **SENSOR OFF**. If sensor is not attached during message display, module will go into sleep mode. To begin monitoring once module is in this mode, press **MONITOR** key.

6. Monitor patient.
7. After patient monitoring is complete, remove sensor from patient according to hospital protocol.
8. Turn off SpO_2 Module by pressing and holding **CHANNEL OFF** key for 1 second.

> **NOTE:** Module will initiate power down when **CHANNEL OFF** key is released.

WARNING

Use only approved Nellcor® OxiMax® sensors and DOC–10, OC–3 pulse oximetry cables. Use of sensors, transducers, cables and accessories other than those specified may cause improper SpO_2 Module performance resulting in inaccurate readings, increased emission and/or decreased immunity, and degraded electromagnetic compatibility performance of the SpO_2 Module.

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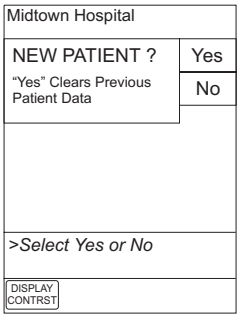
Monitoring Mode

Navigating Main Display

1. Attach SpO_2 Module to Point-of-Care Unit.
2. Power on system by pressing **SYSTEM ON** key on Point-of-Care Unit.
   - **NEW PATIENT?** screen appears.



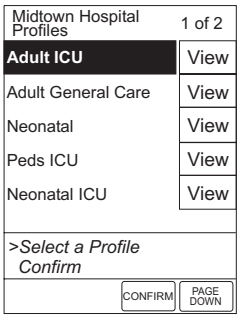
3. To clear previous SpO_2 trend data, press **Yes** soft key.

   OR

   To retain previous SpO_2 trend data, press **No** soft key.
   - Main Display appears.

   OR

   If Guardrails® Safety Software is enabled, profiles screen appears.



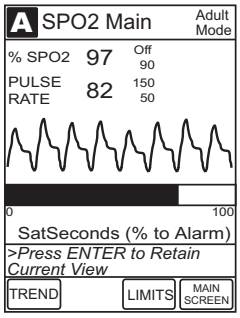
> **NOTE:** When Guardrails® Safety Software is enabled:
> - If **Yes** is selected, a prompt to confirm last profile selected appears.
> - If **No** is selected, a prompt to choose a profile appears.

4. Attach patient cable and sensor as described in "Getting Started" chapter, "General Setup and Use" section.

Navigating Main Display (Continued)

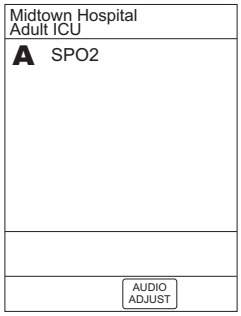
5. To view **SPO2 Main** display, press **CHANNEL SELECT** key.

> **NOTE:** To prevent the screen from reverting to the Main Display, press the **ENTER** key within 30 seconds after the **SPO2 Main** screen is initially displayed.



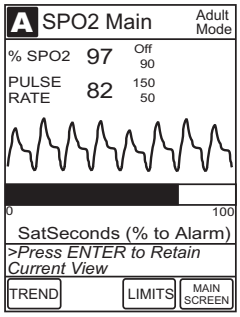
- pleth waveform

6. To return to Main Display, press **MAIN SCREEN** soft key.

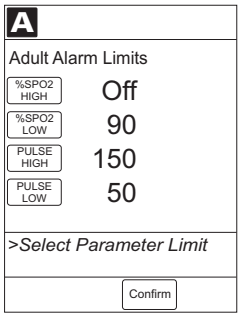


Setting Alarm Limits

1. Press **CHANNEL SELECT** key.

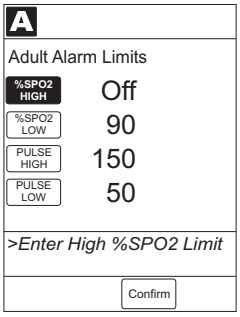


2. Press **LIMITS** soft key.



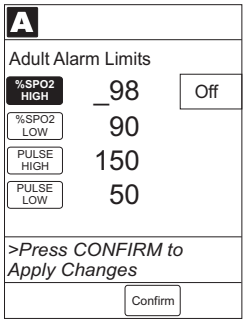
Setting Alarm Limits (Continued)

3. To change a limit setting, press soft key next to applicable parameter.
   - Selected parameter is highlighted.
   - Display prompts for a value to be entered.

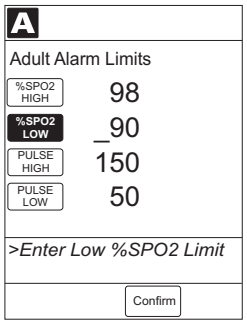


4. Enter a numeric value for selected alarm limit.

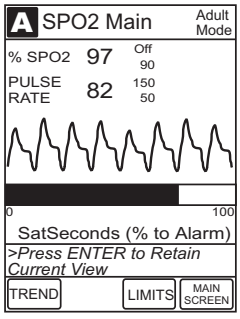
   NOTES:
   - The **%SPO2 HIGH** limit can be **Off** or a numeric value. Numeric values can be entered using the keypad or the ⇧ and ⇩ keys. After the field containing a valid value has been highlighted for 3 seconds, the display prompt changes to **>Press CONFIRM to Apply Changes**.
   - Pressing **Confirm** soft key will confirm the alarm limits and return to the **SPO2 Main** display.



5. To move to next limit, press **ENTER** key on Point-of-Care Unit.

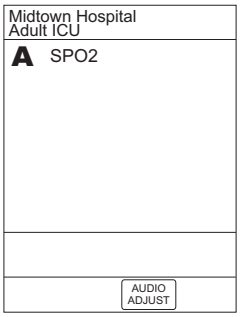


6. To confirm alarm settings and return to **SPO2 Main** display, press **Confirm** soft key.



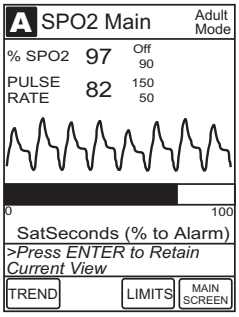
Setting Alarm Limits (Continued)

7. To return to Main Display, press **MAIN SCREEN** soft key.

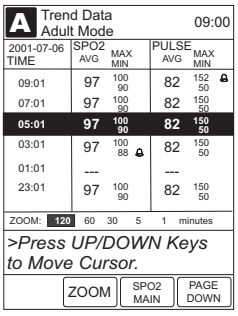


Navigating Trend Data

1. To view **SPO2 Main** display, press **CHANNEL SELECT** key.



2. To view **Trend Data**, press **TREND** soft key.



NOTES:

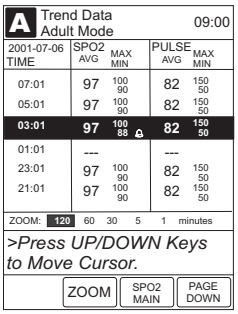
- Tabular information will not be updated while the **Trend Data** view is displayed. The tabular data will be updated, using the new trend data stored in the SpO_2 Module, after leaving the **Trend Data** view. To view the latest data, return to the Trend Data view.
- 🔔 will only be displayed if a limit violation occurred for the indicated limit in the time window.
- If there are no **SPO2** or **PULSE** rate values for the time period displayed, dashes (**---**) will be displayed.
- Six data collection periods are displayed on a screen page.

Navigating Trend Data (Continued)

3. To navigate from page to page, press **PAGE UP** and **PAGE DOWN** soft keys.

> **NOTE:** The last page does not have a **PAGE DOWN** soft key and the first page does not have a **PAGE UP** soft key. When moving from page to page, the cursor (highlight) always displays on the third row of data.

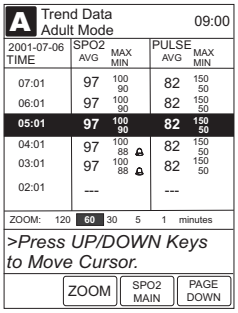
4. To scroll data 1 row at a time, press ⇧ or ⇩ key on Point-of-Care Unit.



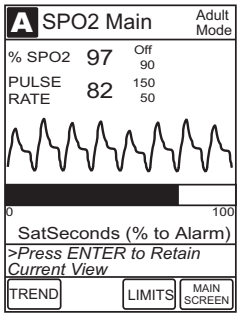
5. To change **TIME** period for data collection period, move cursor to desired time period and press **ZOOM** soft key.

> **NOTE:** Repeated pressing of the **ZOOM** soft key cycles through the time period choices.

- New time period is highlighted.

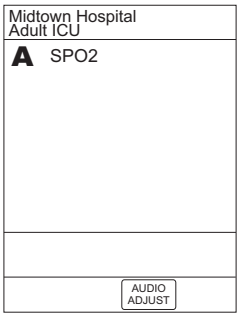


6. To return to **SPO2 Main** display, press **SPO2 MAIN** soft key.



Navigating Trend Data (Continued)

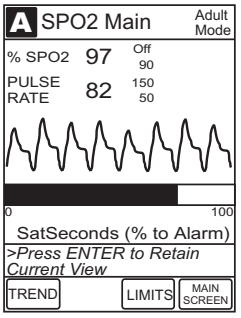
7. To return to Main Display, press **MAIN SCREEN** soft key.



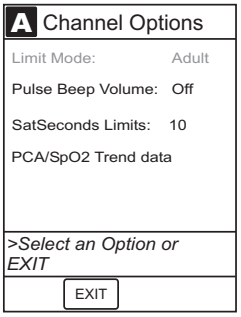
Navigating PCA / SpO_2 Trend Data

To navigate the trend data when a Medley™ PCA Module is present, perform the following steps.

1. To view **SPO2 Main** display, press **CHANNEL SELECT** key on SpO_2 Module.

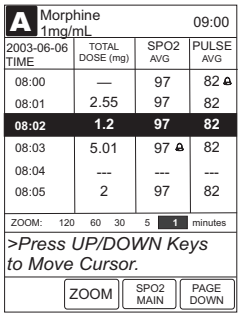


2. To access option to view trend data, press **OPTIONS** key on Point-of-Care Unit.



Navigating PCA / SpO_2 Trend Data (Continued)

3. To view **Trend Data**, press **PCA/SpO2 Trend data** soft key.

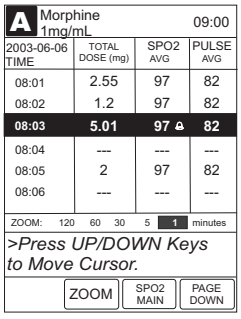


> **NOTES:**
>
> - Tabular information will not be updated while the **Trend Data** view is displayed. The tabular data will be updated, using the new trend data stored in the SpO_2 Module, after leaving the **Trend Data** view. To view the latest data, return to the Trend Data view.
> - 🔔 will only be displayed if a limit violation occurred for the indicated limit in the time window.
> - If there are no **SPO2** or **PULSE** rate values for the time period displayed, dashes (**---**) will be displayed.
> - Six data collection periods are displayed on a screen page.

4. To navigate from page to page, press **PAGE UP** and **PAGE DOWN** soft keys.

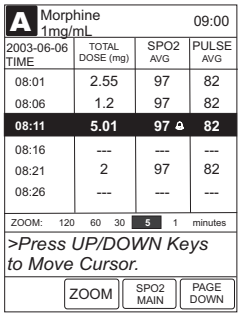
> **NOTE:** The last page does not have a **PAGE DOWN** soft key and the first page does not have a **PAGE UP** soft key. When moving from page to page, the cursor (highlight) always displays on the third row of data.

5. To scroll data 1 row at a time, press ⇧ or ⇩ key on Point-of-Care Unit.



> **NOTE:** The cursor (highlight) remains on the third row of data.

6. To change **TIME** period for data collection period, move cursor to desired time period and press **ZOOM** soft key.

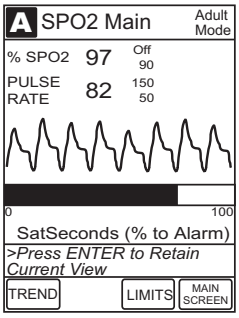


> **NOTE:** Repeated pressing of the **ZOOM** soft key cycles through the time period choices.

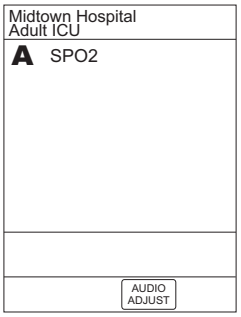
- New time period is highlighted.

Navigating PCA / SpO_2 Trend Data (Continued)

7. To return to **SPO2 Main** display, press **SPO2 MAIN** soft key.



8. To return to Main Display, press **MAIN SCREEN** soft key.

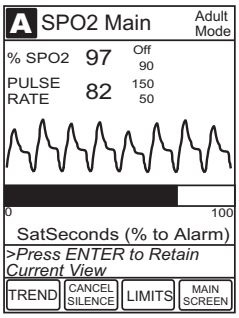


Presilencing Alarm

1. To presilence alarm, press **SILENCE** key on Point-of-Care Unit.

> **NOTE:** All monitoring alarms will be silenced for 120 seconds. Infusion alarms will not be silenced.

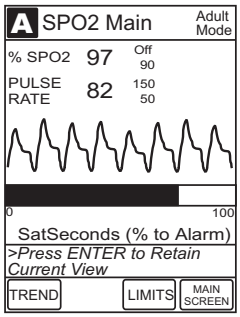
2. To cancel presilence alarm and return to alarmable mode:
   - Press **CHANNEL SELECT** key on SpO_2 Module.
   - Press **CANCEL SILENCE** soft key.



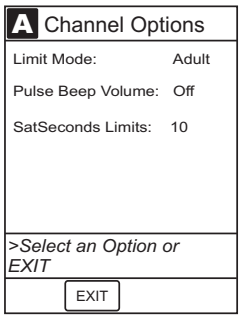
Channel Options

To access **Channel Options**:

a. Press **CHANNEL SELECT** key on SpO_2 Module.



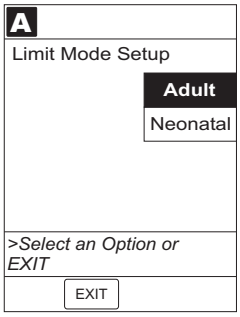
b. Press **OPTIONS** key on Point-of-Care Unit.



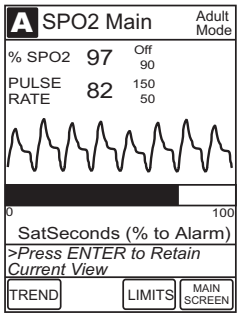
Changing Limit Mode

1. Access Channel Options display and press **Limit Mode** soft key.
2. To change **Limit Mode Setup**, press either **Adult** or **Neonatal** soft key.

> **NOTE:** If a profiles option is being used for programming, the Limit Mode cannot be changed.



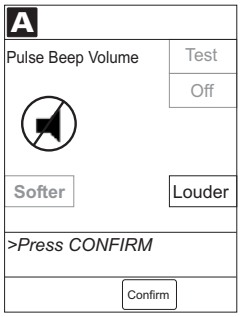
3. If Limit Mode is not changed, press **EXIT** soft key to return to **SPO2 Main** display and press **OPTIONS** key on Point-of-Care Unit to view other options.



Channel Options (Continued)

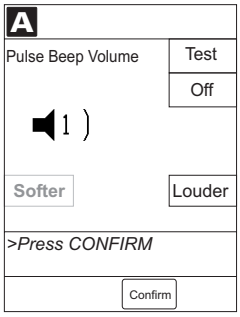
Changing Pulse Beep Volume

1. Access Channel Options display and press **Pulse Beep Volume** soft key.



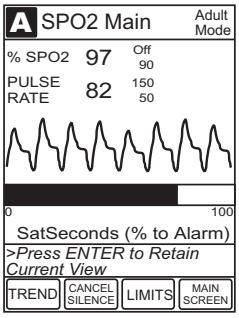
> **NOTE:** In the illustrated display, the Pulse Beep Volume is **Off**. To display the volume options, press the **Louder** soft key. The selectable options are **Off**, Level **1**, Level **2** and Level **3**.

2. To increase volume, press **Louder** soft key until desired volume level is attained. To test volume level (when not attached to patient), press **Test** soft key. To turn off pulse beep entirely, press **Off** soft key.



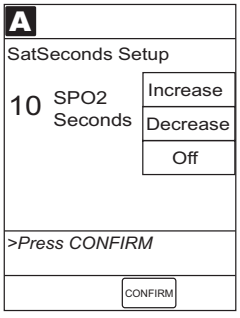
> **NOTE:** Audio sounds for 1 cycle.

3. To return **SPO2 Main** display, press **Confirm** soft key.



Changing SatSeconds Limit

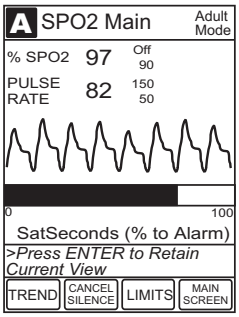
1. Access Channel Options display and press **SatSeconds Limits** soft key.
2. To change **SatSeconds**, press either **Increase** or **Decrease** soft key. Selectable options are **10**, **25**, **50** and **100** seconds, or **Off**.



Channel Options (Continued)

Changing SatSeconds Limit (Continued)

3. To return **SPO2 Main** display, press **Confirm** soft key.



Powering Off

Reference the Medley™ Point-of-Care Unit DFU for the following procedures:

Powering Off System

Powering Off Module

Reviewing Serial Number

Reference the Medley™ Point-of-Care Unit DFU.

Reviewing Software Version

Reference the Medley™ Point-of-Care Unit DFU.

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ALARMS AND MESSAGES

To enhance safety and ease of operation, the Medley™ System provides a full range of audio and visual alarms, errors, and messages.

Definitions

Reference the Medley™ Point-of-Care Unit Directions for Use (DFU).

Audio Characteristics

Reference the Medley™ Point-of-Care Unit DFU.

WARNING

If an alarm condition on the SpO_2 Module occurs while the audio alarm is silenced, the only alarm indication will be a visual display and symbol related to the alarm condition.

Alarms

Alarm	Meaning	Response
Bad Sensor	Broken, unknown or nonsystem sensor or patient cable attached.	Check sensor and patient cable. Confirm correct sensor and patient cable are chosen. Reference “Appendix” chapter, “Accessories” section for a list of sensors designed for use with this module.
Check Sensor - Electrical or Optical Interference	External interference on sensor.	Check sensor. Identify source of external interference if other than sensor.
Check Sensor - High Pulse Amplitude	Artifact interfering with pulse reading.	Check sensor - relocate sensor to a site with less artifact interference.
Check Sensor - Excessive Ambient Light	Light interference on sensor.	Check sensor. Remove or reduce lighting. Cover or reposition sensor.
Check Sensor - Motion Interference	Patient’s motion has inhibited monitoring.	Check sensor. Move sensor to a site with less motion.

Alarms (Continued)

Alarm	Meaning	Response
Check Sensor - No signal	Sensor not properly attached to patient cable or patient cable not properly attached to SpO_2 Module.	Attach sensor to patient cable or attach patient cable to SpO_2 Module.
Check Sensor - Weak Pulse	Patient's low perfusion has inhibited monitoring.	Check sensor. Move sensor to a better perfused site.
Check Sensor - Weak Signal	Low quality of signal being measured.	Check sensor. Confirm correct sensor placement. Move sensor to a better perfused site.
High Pulse Rate Alarm	High pulse rate alarm limit has been exceeded.	Access patient's condition. Confirm correct alarm limit values are selected.
High SpO_2 Alarm	High SpO_2 alarm limit has been exceeded.	Access patient's condition. Confirm correct alarm limit values are selected.
Low Pulse Rate Alarm	Low pulse rate alarm limit has been exceeded.	Access patient's condition. Confirm correct alarm limit values are selected.
Low SpO_2 Alarm	Low SpO_2 alarm limit has been exceeded.	Access patient's condition. Confirm correct alarm limit values are selected.
No Sensor	Sensor not properly attached to patient cable or patient cable not properly attached to SpO_2 Module.	Attach sensor to patient cable or attach patient cable to SpO_2 Module.
No Signal	Failure to find a patient signal after 30 seconds of searching.	Check sensor. Confirm correct sensor placement.
Remove Module (Max=1)	More than 1 SpO_2 Module attached.	Remove additional SpO_2 Module.
Sensor Off	Sensor not properly attached to patient.	Reattach sensor to patient.

Messages

Message	Meaning	Response
Check Sensor - Electrical or Optical Interference	External interference on sensor.	Check sensor. Identify source of external interference if other than sensor.
Check Sensor - High Pulse Amplitude	Artifact interfering with pulse reading.	Check sensor. Relocate sensor to a site with less artifact interference.
Check Sensor - Excessive Ambient Light	Light interference on sensor.	Check sensor. Remove or reduce lighting. Cover or reposition sensor.
Check Sensor - Motion Interference	Patient's motion has inhibited monitoring.	Check sensor. Move sensor to a site with less motion.
Check Sensor - Weak Pulse	Patient's low perfusion has inhibited monitoring.	Check sensor. Move sensor to a better perfused site.
Check Sensor - Weak Signal	Low quality of signal being measured.	Check sensor. Confirm correct sensor placement. Move sensor to a better perfused site.

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MAINTENANCE

The Medley™ System Technical Service Manual is available from ALARIS Medical Systems. It includes routine service schedules, interconnect diagrams, component parts lists and descriptions, test procedures, and other technical information, to assist qualified service personnel in repair and maintenance of the instrument's repairable components. Maintenance procedures are intended to be performed only by qualified personnel, using the service manual and Medley™ Maintenance Software.

Specifications

Accuracy and Motion Tolerance:

Pulse Rate:	
Low Perfusion[1]	20 - 250 bpm, ±3 digits
Motion	normal physiologic range (55 -125 bpm) ±5 digits
No Motion[1]	20 - 250 bpm, ±3 digits
Functional Saturation:	
Low Perfusion[1]	70 - 100%, ±2 digits
Motion[2]	
Adults and Neonates	70 - 100%, ±3 digits
No Motion[3]	
Adults	70 - 100%, ±2 digits
Neonates	70 - 100%, ±3 digits

1 Specification applies to Nellcor® Board performance and was validated with BIO-TEK and Nellcor® Simulators.

2 Applicability: OxiMax® MAX-A, MAX-AL, MAX-P, MAX-I and MAX-N sensors.

3 Adult specifications are shown for OxiMax® MAX-A and MAX-N sensors with SpO_2 Module. Neonate specifications are shown for OxiMax® MAX-N sensors with SpO_2 Module. Saturation accuracy will vary by sensor type. Reference "Appendix" chapter, "Nellcor® Sensor Accuracy Grid" section.

Alarms: Audible and visual alarms for high and low saturation and pulse rate, sensor condition, system failure and low battery conditions.

Alarm Limits:	**Low**	**High**
Pulse Rate:	30-239 bpm	31-240 bpm
SpO_2	20-99%	21-100%

Dimensions: 3.3"W x 8.9"H x 5.5"D
(8.4cm W x 22.6cm H x 14cm D)

Display Update Period: 2.25 seconds

Electrical Classification: Class 1, Internally Powered Equipment, Type BF

Specifications (Continued)

Environmental Conditions:	Operating	Storage/Transport
Temperature Range:	41 to 104°F (5 to 40°C)	-4 to 140°F (-20 to 60°C)
Relative Humidity:	20 to 90% Noncondensing	5 to 85% Noncondensing
Atmospheric Pressure:	525 to 4560 mmHg (700 to 6080 hPa)	375 to 760 mmHg (500 to 1013 hPa)

Fluid Ingress Protection: IPX1, Drip Proof

Measurement Range:

Perfusion	0.03 to 20%
Pulse Rate	20 to 250 bpm
SpO_2	1 to 100%

Mode of Operation: Continuous

Pulse Amplitude Display: Visual indicators for pulse signals represent proportional pulse amplitude strength.

Sensor: Emitted light wavelength range is within 500 nm to 1000 nm. Output power does not exceed 15 mw.

Weight: 2 lbs (0.91 kg)

NOTE: Compliance to Standards

The Medley™ Medication Safety System has been assessed and complies with the following standards: UL 60601–1; CSA C22.2 No. 601.1, including A1 and A2; IEC 60601–1–2.

Configurable Settings

If the configuration settings need to be changed from the "Factory Default" settings, reference the applicable Technical Service Manual or contact ALARIS Medical Systems, Technical Support, for technical, troubleshooting, and preventive maintenance information.

NOTE: With the Profiles feature enabled, the settings are configured independently for each profile. A hospital-defined, best-practice data set must be uploaded to enable the Profiles feature. Date and Time is a system setting and is the same in all profiles.

System Settings

Reference the Medley™ Point-of-Care Unit Directions for Use (DFU).

SpO_2 Module Settings

Feature	Default Setting	Options
Limit Mode	Adult	Adult, Neonatal
Pulse Beep Volume	1	1, 2, 3, Off
Pulse Rate Alarm Limit, High	Adult Mode: 120 bpm Neonatal Mode: 200 bpm	31 - 240 bpm
Pulse Rate Alarm Limit, Low	Adult Mode: 50 bpm Neonatal Mode: 100 bpm	30 - 239 bpm
SatSeconds	Off	10, 25, 50, 100 seconds; Off
SpO_2 Alarm Limit, High	Adult: Off Neonatal: 95%	21 - 100%, Off
SpO_2 Alarm Limit, Low	Adult: 90% Neonatal: 80%	20 - 99%

Cleaning

Reference the Medley™ Point-of-Care Unit DFU for module cleaning instructions. For sensor/cable cleaning, reference the instructions provided with the sensor/cable.

Inspection Requirements

To ensure the system remains in good operating condition, both regular and preventive maintenance inspections are required. Reference the Medley™ Maintenance Software/User Manual (Model 8970C, or later) for detailed instructions.

WARNING

Failure to perform these inspections may result in improper instrument operation.

CAUTION

Regular and preventive maintenance inspections should only be performed by qualified service personnel.

REGULAR INSPECTIONS

PROCEDURE	FREQUENCY
CLEANING	As required
INSPECT FOR DAMAGE:	
Case	Each usage
IUI connector	Each usage
Keypad	Each usage
START-UP	Each usage

PREVENTIVE MAINTENANCE INSPECTIONS

PROCEDURE	FREQUENCY
Alarm Test	12 months
Channel Identification Test	12 months
Channel Operation Test	12 months
Functional test	12 months
Keypad Test	12 months
Patient Lead Electrical Leakage Test	12 months

Service Information

Reference the Medley™ Point-of-Care Unit DFU.

WARRANTY

ALARIS Medical Systems, Inc., (hereinafter referred to as "ALARIS Medical Systems") warrants that:

A. Each new ALARIS Medical Systems® Medley™ SpO_2 Module is free from defects in material and workmanship under normal use and service for a period of one (1) year from the date of delivery by ALARIS Medical Systems to the original purchaser.

B. Each new accessory is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by ALARIS Medical Systems to the original purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the relevant account representative to determine the appropriate repair facility. Except as provided otherwise in this warranty, repair or replacement will be carried out at ALARIS Medical Systems' expense. The product requiring service should be returned promptly, properly packaged and postage prepaid by purchaser. Loss or damage in return shipment to the repair facility shall be at purchaser's risk.

In no event shall ALARIS Medical Systems be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any ALARIS Medical Systems® Product. This warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and ALARIS Medical Systems shall not be responsible for, any loss or damage arising in connection with the purchase or use of any ALARIS Medical Systems® Product which has been:

(a) repaired by anyone other than an authorized ALARIS Medical Systems Service Representative;

(b) altered in any way so as to affect, in ALARIS Medical Systems' judgment, the product's stability or reliability;

(c) subjected to misuse or negligence or accident, or which has had the product's serial or lot number altered, effaced or removed;

or

(d) improperly maintained or used in any manner other than in accordance with the written instructions furnished by ALARIS Medical Systems.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of ALARIS Medical Systems, and ALARIS Medical Systems does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of ALARIS Medical Systems any other liability in connection with the sale or use of ALARIS Medical Systems® Products.

ALARIS MEDICAL SYSTEMS DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

See packing inserts for international warranty, if applicable.

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Accessories

Nellcor® OxiMax® Sensors

When selecting a sensor, consider the patient's weight, the adequacy of perfusion, the available sensor sites and the duration of monitoring. For more sensor information, reference the table at the end of this section or contact a Nellcor sales representative. Use only Nellcor® OxiMax® sensors. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the directions for use accompanying the sensor.

Clean and remove any substances (such as, nail polish) from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

High ambient light sources (such as, surgical lights, especially those with a xenon light source, bilirubin lamps, fluorescent light, 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 patient movement presents a problem, try one or more of the following remedies to correct the problem:

- Verify sensor is properly and securely applied.
- Move sensor to a less active site.
- Use an adhesive sensor that tolerates some patient motion.
- Use a new sensor with fresh adhesive backing.

If poor perfusion affects performance, consider using the Nellcor® MAX-R™ sensor; it obtains measurements from the nasal septal anterior ethmoid artery (an artery supplied by the internal carotid). This sensor may obtain measurements when peripheral perfusion is relatively poor.

WARNINGS

- Before use, **read sensor directions** for use, including all warnings, cautions and instructions.
- **Use only approved Nellcor® OxiMax® sensors and DOC-10, OC-3 pulse oximetry cables**. Use of sensors, transducers, cables and accessories other than those specified may cause improper SpO_2 Module performance resulting in inaccurate readings, increased emission and/or decreased immunity, and degraded electromagnetic compatibility performance of the SpO_2 Module.
- **Inspect the SpO_2 sensor site regularly** to ensure correct sensor positioning, application and site integrity. Tissue damage could occur over prolonged time periods, depending on the patient profile (such as, neonates) and method of application. Refer to the sensor instructions for additional information.
- **Do not use** a sensor that appears damaged. **Do not use** a sensor with exposed optical components.

CAUTIONS

- Failure to **cover the sensor site with opaque material** in high ambient light conditions may result in inaccurate measurements.
- **Before bathing** the patient, completely disconnect the patient from the SpO_2 Module and sensor.

Accessories (Continued)

Nellcor® OxiMax® Sensors (Continued)

OxiMax® Sensor	Model	Patient Size	Site Inspection Interval
Oxygen Transducer (sterile, single-use only)	MAX-N MAX-I MAX-P MAX-A MAX-AL MAX-R	<3 or >40 kg 3 - 20 kg 10 - 50 kg >30 kg >30 kg >50 kg	Check and move sensor to a new site every 8 hours, as necessary.
Oxiband® Oxygen Transducer (reusable with disposable nonsterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3 - 40 kg	Check and move sensor to a new site every 4 hours.
Oxiband® Oxygen Transducer (reusable, nonsterile)	DS-100A	>40 kg	Check and move sensor to a new site every 4 hours.
OxiCliq® Oxygen Transducer (sterile, single use only)	P N I A	10 - 50 kg <3 or >40 kg 3 - 20 kg >30 kg	Check and move sensor to a new site every 8 hours, as necessary.
OxiCliq® Extension Cable	OC-3		
Dura-Y® Multisite Oxygen Transducer (reusable, nonsterile)	D-YS	>1 kg	Check and move sensor to a new site every 4 hours.
For use with Dura-Y® Sensor: Ear Clip (reusable, nonsterile)	D-YSE	>30 kg	
PediCheck™ Pediatric Spot-Check Clip (reusable, nonsterile)	D-YSPD	3 - 40 kg	For attended spot check only (not to exceed 20 minutes)
MAX-FAST™ Adhesive Reflectance oxygen transducer	MAX-FAST™	>40 kg	Check and move sensor to a new site every 12 hours, as necessary.

NOTE: Refer to Nellcor® Oximax® sensor selection guide and sensor accompanying instructions for additional and/or updated information.

Accessories (Continued)

Nellcor® Patient Cables

The Nellcor® DOC-10 and OC-3 patient cables interface the SpO_2 Module with the patient sensors.

Nellcor® Sensor Accuracy Grid

Accuracy Specifications: Accuracy specifications are based on controlled hypoxia studies with healthy, nonsmoking adult volunteers over the specified saturation SpO_2 range. Pulse oximeter SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by hemoximetry. All accuracies are expressed as ± "X" digits. This variation equals ±1 standard deviation (±1 SD), which encompasses 68% of the population.

Neonatal Accuracy: When sensors are used on neonatal subjects as recommended, the specified accuracy range is increased by ±1 digit as compared to adult usage, to account for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood. For example, MAX-N accuracy on neonates is ±3 digits, rather than ±2.

OxiMax® Sensor Models Single Patient Use	
MAX-A[1], MAX-AL[1]	±2
MAX-N[1, 2] (Adult)	±2
MAX-N[1, 2] (Neonate)	±3
MAX-P[1]	±2
MAX-I[1]	±2
MAX-FAST	±2
MAX-R[3]	±3.5

OxiCliq® Sensor Models Single Patient Use	
OxiCliq A	±2.5
OxiCliq P	±2.5
OxiCliq N[2] (Adult)	±2.5
OxiCliq N[2] (Neonate)	±3.5
OxiCliq I	±2.5

Reusable Sensor Models	
D-YS (Infant to Adult)	±3
D-YS (Neonate)	±4
D-YS & D-YSE	±3.5
D-YS & D-YSPD	±3.5
D-100A	±3
OXI-A/N (Adult)	±3
OXI-A/N (Neonate)	±4
OXI-P/I	±3

[1] Accuracy specification under motion conditions is ±3. For a definition of motion, contact Nellcor Technical Services or local Nellcor representative.

[2] MAX-N and OxiCliq N were tested on patients >40 kg.

[3] Accuracy specification has been determined between saturations of 80 - 100%.

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Brevets, Patente, Patenter, Patentes, Patents, 專利, 特許:
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Other Patents Pending

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