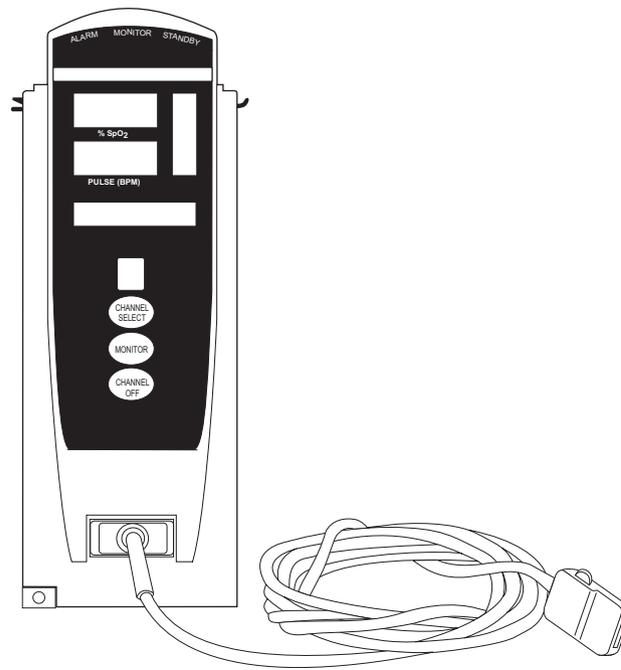


Directions for Use

SpO₂ Module, 8220 Series



SpO₂ MODULE
MODEL 8220

ALARIS Medical Systems, Inc.
Medley™ Medication Safety System

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About the SpO₂ Module

The Medley™ SpO₂ Module is indicated for continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate measured by an SpO₂ sensor. The SpO₂ 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 SpO₂ 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 SpO₂ Module uses a wide variety of Masimo® PC patient cables and Masimo® LNOP® series sensors. The Masimo® cables and sensors are designed for use with the Model 8220 SpO₂ Module. For specific directions for use, refer to the cable and sensor packaging.

Contraindications: The SpO₂ Module with Masimo® PC patient cables and Masimo® LNOP® series sensors are contraindicated for use as an apnea monitor.

This document provides directions for use for the Medley™ SpO₂ Module, Model 8220.

WARNING

Read all instructions, for both the SpO₂ Module and Point-of-Care Unit, before using the Medley™ System.

Principle of Operation

The operation of the Medley™ SpO₂ 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).

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation.

About the SpO₂ Module (Continued)

Principle of Operation (Continued)

The SpO₂ Module uses the Masimo® Signal Extraction Technology® (SET®) to decompose the red and infrared pulsatile absorbance signal into an arterial signal plus a noise component. Its value is used to find the SpO₂ saturation in an empirically derived equation in the Masimo® SET® software. The values in the look-up table are based on human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia states during motion and nonmotion conditions.

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.

% SpO₂ Alarm Limits	Upper and lower saturation alarm limits are displayed.
% SpO₂ Display	Functional arterial hemoglobin oxygen saturation is displayed in units of percentage SpO ₂ .
Fast SAT	When Fast SAT is enabled and there is 1 data point that is significantly different from a previous data point, averaging is disregarded and most recent data point is displayed. For example, if readings were 97%, 96%, 95% and 85%, displayed saturation level would be 85%.
Limit Mode	Displays either adult or neonatal monitoring mode.
PI	Perfusion Index (PI) is a scaled numeric value derived from magnitude of pulsations displayed on plethysmographic (pleth) waveform. It is calculated as a percentage of pulsatile signal to nonpulsatile signal. PI is used to find best perfused site for sensor placement (larger the PI, stronger the perfusion). Operating range is 0.02 to 20.0. Desired number is >1.00 or as large as possible.
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.

Features and Definitions (Continued)

Pulse Rate	Displayed in beats per minute (bpm).
Pulse Rate Alarm Limits	Upper and lower limits are displayed.
Saturation Averaging Time	Averaging time can be set to 2, 4, 8, 10, 12, 14 or 16 seconds.
Sensitivity Mode	Sensitivity mode, normal or maximum, of current monitoring configuration is displayed in options mode. Normal setting is used for normal patient monitoring purposes. Maximum setting is used for improved low perfusion performance.
SET® Technology	Signal Extraction Technology® (SET®) uses adaptive filters to separate arterial signal from nonarterial noise. SET® provides for accurate readings under extreme conditions; such as, low perfusion and motion.
Signal I.Q.™ Feature	A visual indication of pulsation at sensor site. Vertical bar height indicates quality of measured signal. Signal I.Q.™ feature is related to proper sensor application, adequate arterial signal and intensity of motion. Use Signal I.Q.™ feature to verify optimal sensor placement.
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.

Rx 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.

Warnings and Cautions

Warnings and Cautions provided throughout this Directions for Use (DFU) provide information needed to safely and effectively use the Medley™ SpO₂ Module and accessories. Medley™ System Warnings and Cautions, and definitions, are covered in the Point-of-Care Unit DFU.

Rx Only

General

WARNINGS

- The SpO₂ 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 SpO₂ Module is **intended only as an adjunct in patient assessment**. It must be used in conjunction with clinical signs and symptoms.
- The SpO₂ 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 SpO₂ Module or sensors during Magnetic Resonance Imaging (**MRI**).
- The SpO₂ 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 SpO₂ 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 SpO₂ Module is used, to ensure they are appropriate for the patient being monitored.
- Do not lift the SpO₂ 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 SpO₂ 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 SpO₂ 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.

Warnings and Cautions (Continued)

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 Masimo® LNOP® sensors and PC Series patient cables.** Use of sensors, transducers, cables and accessories other than those specified may cause improper SpO₂ Module performance resulting in inaccurate readings, increased emission and/or decreased immunity, and degraded electromagnetic compatibility performance of the SpO₂ Module.
- Do not use a sensor, cable, connector or SpO₂ 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 LNOP® 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 SpO₂ 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.

Measurements (Continued)

- 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.

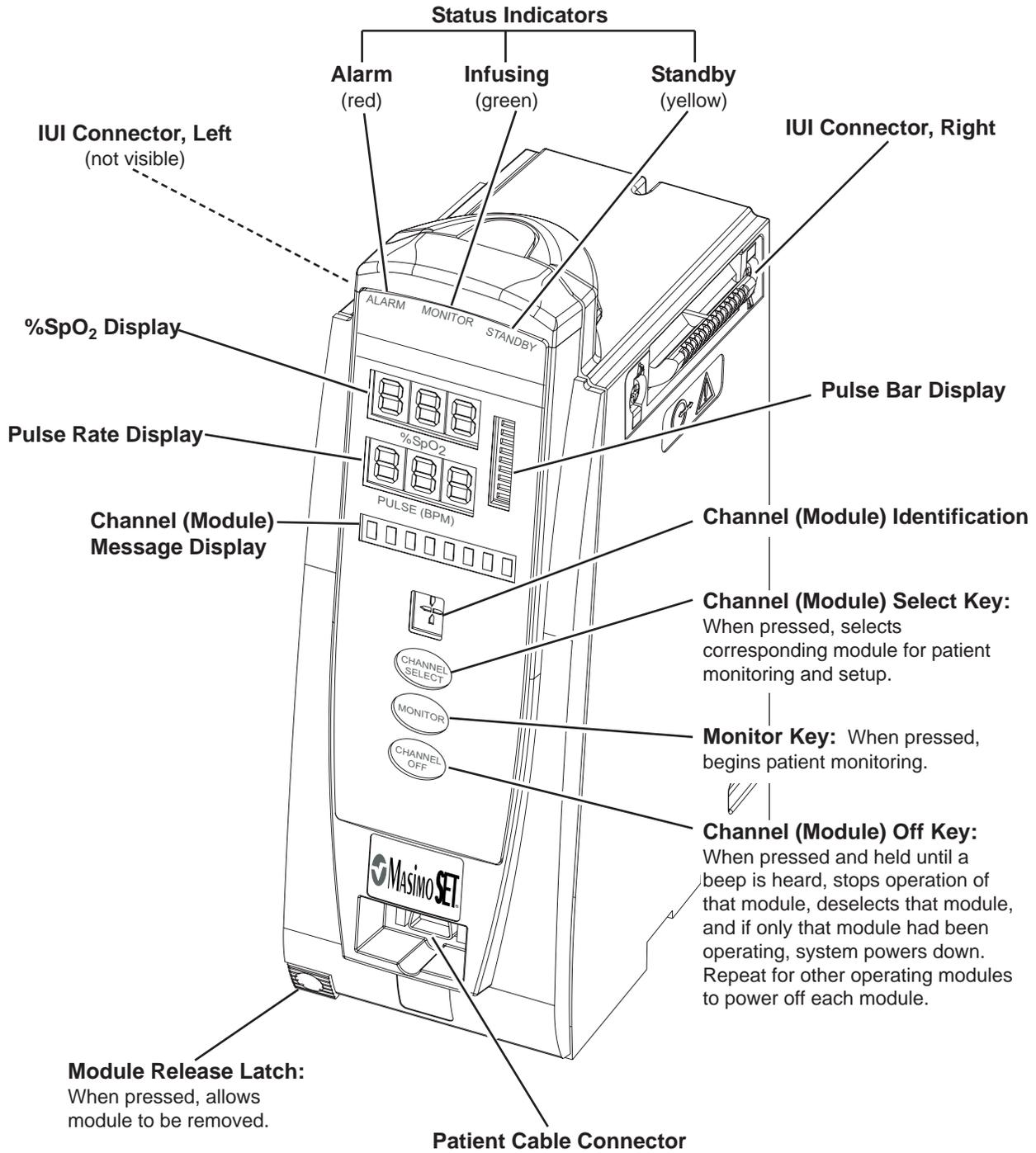
NOTE: Exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material.

- 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 Masimo® patient cable to SpO₂ Module. Ensure secure connection and patient cable is not twisted, sliced or frayed.
2. Attach Masimo® LNOP® sensors to Masimo® 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 SpO₂ and pulse rate are correct for patient by selecting **CHANNEL SELECT** key.

NOTES:

- **SEARCHING** may appear in Channel Message Display until SpO₂ 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 SpO₂ 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 Masimo® LNOP® sensors and PC Series patient cables. Use of sensors, transducers, cables and accessories other than those specified may cause improper SpO₂ Module performance resulting in inaccurate readings, increased emission and/or decreased immunity, and degraded electromagnetic compatibility performance of the SpO₂ Module.

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Monitoring Mode

Navigating Main Display

1. Attach SpO₂ Module to Point-of-Care Unit.
2. Power on system by pressing **SYSTEM ON** key on Point-of-Care Unit.
 - **NEW PATIENT?** screen appears.

Midtown Hospital	
NEW PATIENT ?	Yes
"Yes" Clears Previous Patient Data	No
>Select Yes or No	
[DISPLAY CONTRST]	

3. To clear previous SpO₂ trend data, press **Yes** soft key.
OR

To retain previous SpO₂ trend data, press **No** soft key.

- Main Display appears.

OR

Midtown Hospital Adult ICU
A SPO2
[AUDIO ADJUST]

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.

Midtown Hospital Profiles	1 of 2
Adult ICU	View
Adult General Care	View
Neonatal	View
Peds ICU	View
Neonatal ICU	View
>Select a Profile Confirm	
[CONFIRM]	[PAGE DOWN]

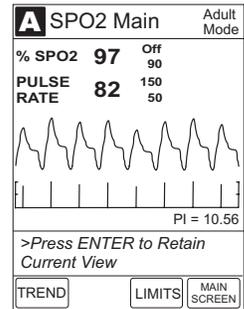
4. Attach patient cable and sensor as described in “Getting Started” chapter, “General Setup and Use” section.

Monitoring Mode (Continued)

Navigating Main Display (Continued)

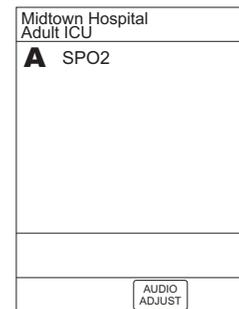
- To view **SPO2 Main** display, press **CHANNEL SELECT** key.

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.



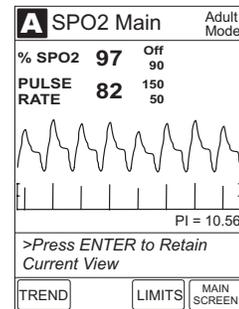
- pleth waveform
- Signal I.Q.™
- PI

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

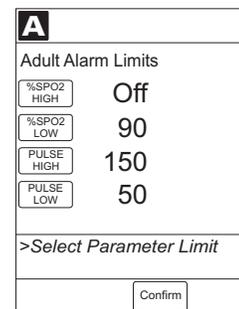


Setting Alarm Limits

- Press **CHANNEL SELECT** key.



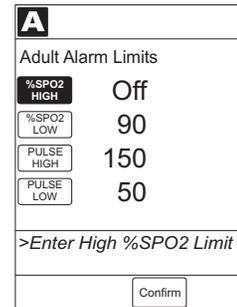
- Press **LIMITS** soft key.



Monitoring Mode (Continued)

Setting Alarm Limits (Continued)

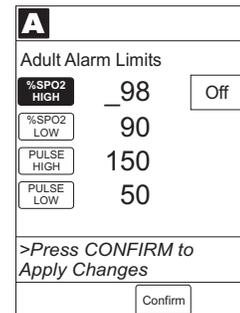
3. To change a limit setting, press soft key next to applicable parameter.
 - Selected parameter is highlighted.
 - Display prompts for a value to be entered.



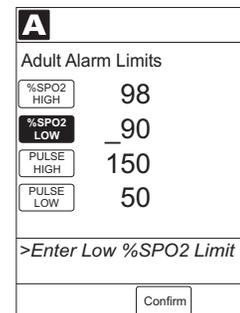
4. Enter a numeric value for selected alarm limit.

NOTES:

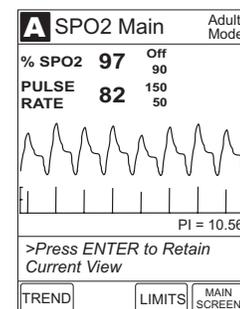
- The **%SPO2 HIGH** limit can be **Off** or a numeric value. Numeric values can be entered using the keypad or the \leftarrow and \rightarrow keys. After the field containing a valid value has been highlighted for 3 seconds, the display prompt changes to **>Press CONFIRM to Apply Changes**.
- Pressing **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.



Monitoring Mode (Continued)

Navigating Trend Data (Continued)

- 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.

- To scroll data 1 row at a time, press \uparrow or \downarrow key on Point-of-Care Unit.

Trend Data Adult Mode				09:00	
2001-07-06 TIME	SPO2 AVG	MAX MIN	PULSE AVG	MAX MIN	
07:01	97	100 90	82	150 50	
05:01	97	100 83	82	150 50	
03:01	97	100 88	82	150 50	
01:01	---		---		
23:01	97	100 90	82	150 50	
21:01	97	100 90	82	150 50	

ZOOM: 120 60 30 5 1 minutes

>Press UP/DOWN Keys to Move Cursor.

ZOOM SPO2 MAIN PAGE DOWN

- 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.

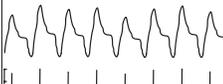
Trend Data Adult Mode				09:00	
2001-07-06 TIME	SPO2 AVG	MAX MIN	PULSE AVG	MAX MIN	
07:01	97	100 90	82	150 50	
06:01	97	100 90	82	150 50	
05:01	97	100 90	82	150 50	
04:01	97	100 88	82	150 50	
03:01	97	100 88	82	150 50	
02:01	---		---		

ZOOM: 120 60 30 5 1 minutes

>Press UP/DOWN Keys to Move Cursor.

ZOOM SPO2 MAIN PAGE DOWN

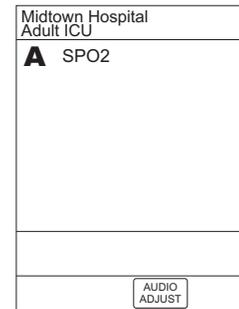
- To return to **SPO2 Main** display, press **SPO2 MAIN** soft key.

SPO2 Main		Adult Mode
% SPO2	97	Off 90
PULSE RATE	82	150 50
		
PI = 10.56		
>Press ENTER to Retain Current View		
TREND	LIMITS	MAIN SCREEN

Monitoring Mode (Continued)

Navigating Trend Data (Continued)

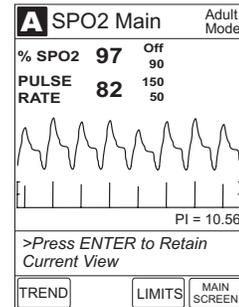
7. To return to Main Display, press **MAIN SCREEN** soft key.



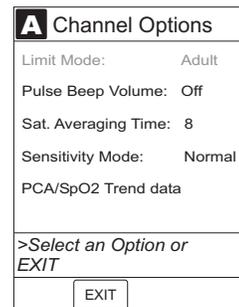
Navigating PCA / SpO₂ Trend Data

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 SpO₂ Module.



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



Monitoring Mode (Continued)

Navigating PCA / SpO₂ 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 SpO₂ 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.

A Morphine 1mg/mL 09:00			
2003-06-06 TIME	TOTAL DOSE (mg)	SPO2 AVG	PULSE AVG
08:00	---	97	82 
08:01	2.55	97	82
08:02	1.2	97	82
08:03	5.01	97 	82
08:04	---	---	---
08:05	2	97	82

ZOOM: 120 60 30 5 **1** minutes
 >Press UP/DOWN Keys to Move Cursor.

ZOOM SPO2 MAIN PAGE DOWN

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.

A Morphine 1mg/mL 09:00			
2003-06-06 TIME	TOTAL DOSE (mg)	SPO2 AVG	PULSE AVG
08:01	2.55	97	82
08:02	1.2	97	82
08:03	5.01	97 	82
08:04	---	---	---
08:05	2	97	82
08:06	---	---	---

ZOOM: 120 60 30 5 **1** minutes
 >Press UP/DOWN Keys to Move Cursor.

ZOOM SPO2 MAIN PAGE DOWN

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.

A Morphine 1mg/mL 09:00			
2003-06-06 TIME	TOTAL DOSE (mg)	SPO2 AVG	PULSE AVG
08:01	2.55	97	82
08:06	1.2	97	82
08:11	5.01	97 	82
08:16	---	---	---
08:21	2	97	82
08:26	---	---	---

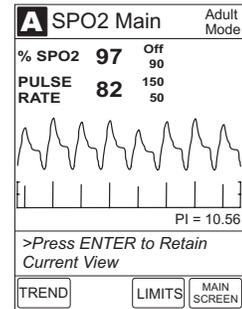
ZOOM: 120 60 30 **5** 1 minutes
 >Press UP/DOWN Keys to Move Cursor.

ZOOM SPO2 MAIN PAGE DOWN

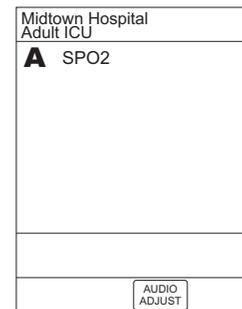
Monitoring Mode (Continued)

Navigating PCA / SpO₂ Trend Data (Continued)

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



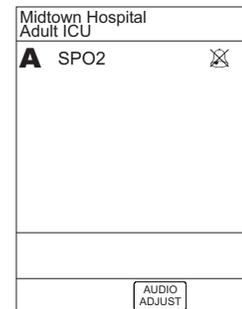
- To return to Main Display, press **MAIN SCREEN** soft key.



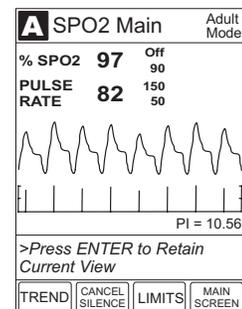
Presilencing Alarm

- 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.



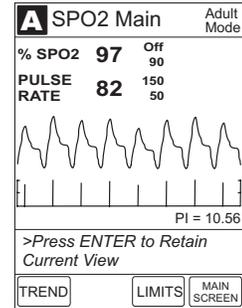
- To cancel presilence alarm and return to alarmable mode:
 - Press **CHANNEL SELECT** key on SpO₂ Module.
 - Press **CANCEL SILENCE** soft key.



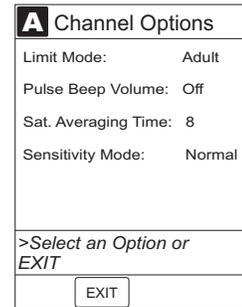
Channel Options

To access **Channel Options**:

- a. Press **CHANNEL SELECT** key on SpO₂ Module.



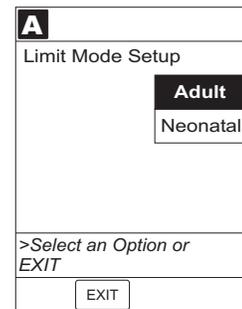
- b. Press **OPTIONS** key on Point-of-Care Unit.



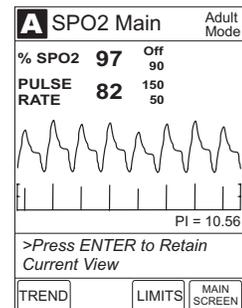
Changing Limit Mode

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.

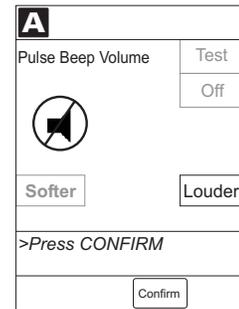


Channel Options (Continued)

Changing Pulse Beep Volume

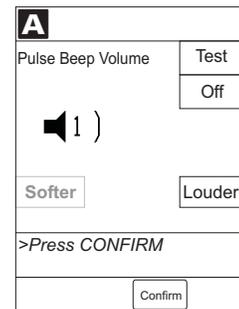
1. Access Channel Options display and press **Pulse Beep Volume** soft key.

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.

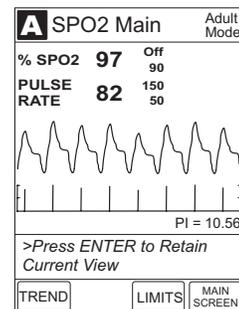


2. To increase volume, press **Louder** soft key until desired volume level is attained. To test volume level (when not attached to patient), press **Test** soft key. To turn off pulse beep entirely, press **Off** soft key.

NOTE: Audio sounds for 1 cycle.



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

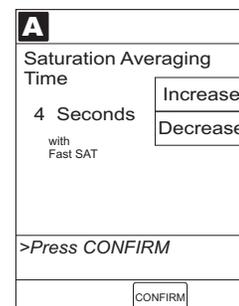


Changing Saturation Averaging Time

1. Access Channel Options display and press **Saturation Averaging Time** soft key.

NOTE: **Fast SAT** is enabled when **2** or **4** seconds is selected.

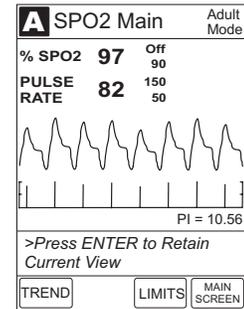
2. To change **Saturation Averaging Time**, press either **Increase** or **Decrease** soft key. Selectable options are **2**, **4**, **8**, **10**, **12**, **14** and **16** seconds.



Channel Options (Continued)

Changing Saturation Averaging Time (Continued)

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



Changing Sensitivity Mode

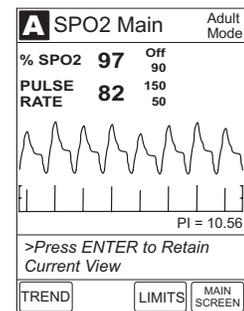
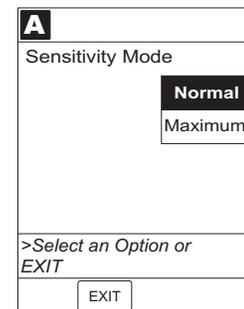
- Access Channel Options display and press **Sensitivity Mode** soft key.
- To change **Sensitivity Mode**, press either **Normal** or **Maximum** soft key.

NOTES:

- The **Normal** setting is for normal patient monitoring.
- The **Maximum** setting is for improved low perfusion performance.
- The sensitivity mode is displayed on the **SPO2 Main** display only when **Maximum** is selected.

- SPO2 Main** display appears.

- To view other options, press **OPTIONS** key on Point-of-Care Unit.



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.

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 SpO₂ 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 - Light	Light interference on sensor.	Check sensor. Remove or reduce lighting. Cover or reposition sensor.
Check Sensor - Low Perfusion	Patient’s low perfusion has inhibited monitoring.	Check sensor. Move sensor to a better perfused site.
Check Sensor - Low Signal I.Q.	Low signal quality being measured.	Check sensor. Confirm correct sensor placement. Move sensor to a better perfused site.

Alarms (Continued)

Alarm	Meaning	Response
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 - Low Perfusion	Patient's low perfusion has inhibited monitoring.	Check sensor. Move sensor to a better perfused site.
Check Sensor - Low Signal I.Q.	Low signal quality being measured.	Check sensor. Confirm correct sensor placement. Move sensor to a better perfused site.

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	
Adults, Pediatrics, Neonates	25 - 240 bpm, ±3 digits
Motion ^{2, 3}	
Adults, Pediatrics, Neonates	25 - 240 bpm, ±5 digits
No Motion ⁴	
Adults, Pediatrics, Neonates	25 - 240 bpm, ±3 digits
Resolution	1 bpm

Saturation:

Low Perfusion ¹	
Adults, Pediatrics	70 - 100%, ±2 digits
Neonate	70 - 100%, ±3 digits
Motion ^{2, 3}	
Adults, Pediatrics, Neonate	70 - 100%, ±3 digits
No Motion ⁴	
Adults, Pediatrics	70 - 100%, ±2 digits
Neonates	70 - 100%, ±3 digits
Resolution	1% SpO ₂

- 1 Masimo® Board performance has been validated for low perfusion accuracy in bench-top testing against a BIO-TEK simulator and a Masimo® simulator. Refer to service manual for more information.
- 2 Masimo® Board performance has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies, while performing rubbing and tapping motions at 2 to 4 Hz at an amplitude of 1 to 2 cm and a nonrepetitive range of 70-100% SpO₂ against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
- 3 Masimo® Board performance with Masimo® LNOP® Neo and Neo Pt sensors has been validated for neonatal motion accuracy in human blood studies on neonates, while moving the neonate's foot at 2 to 4 Hz at an amplitude of 1 to 2 cm against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
- 4 Masimo® Board performance has been validated for no-motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies, in the range of 70-100% SpO₂ against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Specifications (Continued)

Alarms:	Audible and visual alarms for high and low saturation and pulse rate, sensor condition, system failure and low battery conditions.	
Alarm Limits:	<u>Low</u>	<u>High</u>
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:	Approximately 1 second.	
Electrical Classification:	Class 1, Internally Powered Equipment, Type BF	
Environmental Conditions:	<u>Operating</u>	<u>Storage/Transport</u>
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	0.02 to 20%	
Pulse Rate	25 to 240 bpm	
SpO ₂	1 to 100%	
Mode of Operation:	Continuous	
Pulse Amplitude Display:	Proportional to height of I.Q. signal.	
Sensor:	Emitted light wavelength range is within 500 nm to 1000 nm. Output power does not exceed 1 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).

SpO₂ 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
SpO ₂ Alarm Limit, High	Adult: Off Neonatal: 95%	21 - 100%, Off
SpO ₂ Alarm Limit, Low	Adult: 90% Neonatal: 80%	20 - 99%
Saturation Averaging Time (display update period)	8 seconds	2, 4, 8, 10, 12, 14, 16 seconds
Sensitivity Mode	Normal	Normal, Maximum

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.

REGULAR INSPECTIONS

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

PREVENTIVE MAINTENANCE INSPECTIONS

<u>PROCEDURE</u>	<u>FREQUENCY</u>
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

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.

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™ SpO₂ 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

Masimo® LNOP® 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 Masimo sales representative. Use only Masimo® SET® 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 SpO₂ sensor. To prevent interference from ambient light, ensure that the sensor is properly applied and cover the sensor site with opaque material.

Reattaching a Sensor:

- Masimo® LNOP® single-use sensors may be reattached to the same patient if emitter and detector windows are clear and adhesive still adheres to skin.
- Adhesive can be partially rejuvenated by wiping it with an alcohol wipe and allowing it to thoroughly air dry prior to reattaching it to the patient.

NOTE: If the sensor fails to track the pulse consistently, it may be incorrectly positioned. Reposition the sensor or choose a different monitoring site.

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 SpO₂ Module and sensor.

WARNINGS

- Before use, **read sensor directions** for use, including all warnings, cautions and instructions.
- **Use only approved Masimo® LNOP® sensors and PC Series patient cables.** Use of sensors, transducers, cables and accessories other than those specified may cause improper SpO₂ Module performance resulting in inaccurate readings, increased emission and/or decreased immunity, and degraded electromagnetic compatibility performance of the SpO₂ Module.
- **Inspect the SpO₂ 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.

Accessories (Continued)

Masimo® LNOP® Sensors (Continued)

Masimo® Single-Patient SpO ₂ Adhesive Sensor	Model	Patient Size	Site Inspection Interval
LNOP®-Adt	1001	>30 kg	Check and move sensor to a new site every 8 hours, as necessary.
LNOP®-Neo	1002	<10 kg	Not Applicable
LNOP®-NeoPt	1003	<1 kg	Not Applicable
LNOP®-Pdt	1025	>10 or <40 kg	Not Applicable

Masimo® Reusable SpO ₂ Sensor	Part Number	Patient Size	Site Inspection Interval
LNOP®-DCI	1269	30 kg	Check and move sensor to a new site every 4 hours.
LNOP®-DCIP	1276	10 or <50 kg	Not Applicable
LNOP®-EAR, Ear Reusable Sensor w/Ear Hanger	1399	>30 kg	Not Applicable
LNOP®-Y1, Multisite Reusable Sensor	1544	1 kg	Not Applicable

Masimo® SET® Patient Cables

Reusable patient cables of various lengths are available. All cables that display the Masimo® SET® logo are designed to work with any Masimo® LNOP® sensor and with any SpO₂ Module displaying the Masimo® SET® logo.

WARNINGS

- **Carefully route patient cabling** to reduce the possibility of patient entanglement or strangulation.
- Do not use a cable that **appears damaged**.
- Do not lift the SpO₂ Module by the cable because the **cable could disconnect from the instrument**, causing it to drop on the patient.

ALARIS[®]

MEDICAL SYSTEMS

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Patents, Patente, 專利:

AT – 693,662; 703,178; 728,366; 730,203. **TW** – NI-107,963. **US** – 5,601,445; 5,713,856; 5,836,910; 5,941,846.

Masimo[®] – 5,482,036; 5,490,505; 5,632,272; 5,685,299; 5,758,644; 5,769,785; 6,002,952; 6,036,642; 6,067,462; 6,157,850; 6,206,830; and international equivalents.

Other Patents Pending