MEDLEY™

MEDICATION SAFETY SYSTEM

SpO$_2$ MODULE
Model 8210

DIRECTIONS FOR USE

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GENERAL CONTACT INFORMATION

Customer Advocacy

For clinical and technical questions, feedback, and troubleshooting assistance.

Phone, toll-free, within the United States and Canada:

(800) 854-7128, Ext. 7812

Technical Support

For technical information related to maintenance procedures and service manual support.

Phone:

(858) 458-6003

Toll-free, within the United States: (800) 854-7128, Ext. 6003

Toll-free, within Canada:
Eastern: (800) 227-7215
Western: (800) 667-2335

For more detailed information, refer to the "Service Information" section of this document.

About the System

The MEDLEY™ Medication Safety System is a modular infusion and monitoring system designed to provide SpO$_2$ monitoring capabilities and accurate, automated infusion of a broad range of intravascular fluids, medications and blood products.

The MEDLEY™ Medication Safety System consists of the MEDLEY™ Programming Module (Model 8000) and detachable MEDLEY™ Modules (or "channels") which provide infusion or monitoring capabilities. The MEDLEY™ System is intended for use in hospitals and healthcare facilities on adult, pediatric and neonatal patients.

This document provides Directions for Use for the Model 8210 SpO$_2$ Module. Please read all instructions for both the SpO$_2$ Module and the Programming Module before using the device. Only one SpO$_2$ Module can be connected to a MEDLEY™ Programming Module

The 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.

The MEDLEY™ System 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 MEDLEY™ SpO$_2$ Module with Nellcor® DOC–10, OC-3 patient cables and Nellcor® OXIMAX™ series sensors are contraindicated for use as an apnea monitor.

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.

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).

Principle of Operation (Continued)

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

functional saturation=

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

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

Ease of Use Features

To enhance safety and ease of operation, the MEDLEY™ Medication Safety System provides a full range of audio and visual alarms, advisories and prompts.

Guardrail® Safety Software

The Guardrails® Safety Software is designed to help reduce programming errors by:

- Customizing device configurable settings to meet the need of the selected hospital area/patient type (Profile).
- Comparing user programming with hospital-defined best practice guidelines.
- Providing an advisory if an out-of-best clinical practice entry is made.

Nellcor® Sensors

Disposable and reusable sensors are available for neonatal, pediatric and adult patients.

Pre-Silence

Alarms can be pre-silenced for 120 seconds. The pre-silence alarm can be cancelled before the 120 seconds are complete.

Profiles Feature

A Profiles feature is a unique set of device options configured to optimize device function for a specific hospital area or patient type. A Profile is comprised of a Configuration, with device settings and defaults customized by the user to best meet the needs of the Profile area/patient type.

SatSeconds™ Alarm Management Technology

With the SatSeconds™ Alarm Management Technology, upper and lower alarm limits are set in the same way as with traditional alarm management. The clinician also sets a SatSeconds™ limit that allows the monitoring of %SpO$_2$ below the selected low alarm limit for a period of time before an audible alarm sounds.

% SpO$_2$ Alarm Limits	The upper and lower saturation alarm limits are displayed.
% SpO$_2$ Display	The functional arterial hemoglobin oxygen saturation is displayed in units of percentage SpO$_2$.
Limit Mode	The limit mode displays either the adult or neonatal monitoring mode.
Pleth Waveform	The plethysmographic (pleth) waveform is a graphic representation of changes in the extremity blood volume during the events of the cardiac cycle.
Pre-Silence	Alarms can be pre-silenced for 120 seconds. The pre-silence alarm can be cancelled before the 120 seconds are complete.
Pulse Beat Volume	Pulse beat volume can be configured to a volume level of 1, 2, 3 or off.
Pulse Rate Alarm Limits	The upper and lower pulse rate alarm limits are displayed.
Pulse Rate Display	The patient's pulse rate is displayed in beats per minute (bpm).
SatSeconds™	The SatSeconds™ limits controls the time that the %SpO$_2$ level may fall outside the alarm limits before an audible alarm sounds. The method of calculation is as follows:

The number of percentage points that the %SpO$_2$ falls outside of the alarm limit is multiplied by the number of seconds that the %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, the %SpO$_2$ levels may fluctuate above and below the alarm limit, reentering the nonalarm range several times. During such fluctuations, the SpO$_2$ Module integrates the number of %SpO$_2$ points, both positive and negative, until either the SatSeconds™ limit (SatSeconds™ time setting) is reached or the %SpO$_2$ level returns to within a normal range and remains there.

The SatSeconds™ "Safety Net" is for patients with saturation levels having frequent excursions below the limit but not staying below the limit long enough for the SatSeconds™ time setting to be reached. When three or more limit violations occur within 60 seconds, an alarm will sound, even if the SatSeconds™ time setting has not been reached.

System Configuration	The System Configuration mode provides the ability for qualified personnel to customize device settings. If the Profiles Feature is enabled, the system settings defined for the selected profile are automatically activated.
Trend Data	The trend data is a tabular display of the %SpO$_2$ and Pulse Rate. The display shows the alarm conditions for the time period displayed and the average, high and low values. The data is stored for 24 hours.

⚠ 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.

Consult operating instructions.

Type BF Applied part

IPX1 Protection against fluid ingress: Drip Proof

IUI Connector: Inter-Unit Interface connector used to establish power and communications between Programming Module and add-on channels.

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 the order of a physician.

Warnings/Cautions and Definitions

For WARNINGS and CAUTIONS for the Programming Module, refer to its Directions for Use.

℞ Only

> *NOTE: Although the MEDLEY™ System is built and tested to exacting specifications, it is not intended to replace the supervision of IV infusions and Patient Monitoring by medical personnel. The user should become thoroughly familiar with the features and operation of the MEDLEY™ System and exercise vigilance in its utilization.*

Definitions

WARNING

This heading alerts the user to potential serious outcomes (death, injury or serious adverse events) to the patient or user.

CAUTION

This heading alerts the user to take special care for the safe and effective use of the device.

Warnings and Cautions

To ensure proper performance of the MEDLEY™ System and to reduce potential injury, observe the following WARNINGS and CAUTIONS:

WARNING

The SpO_2 Module is NOT to be used as an apnea monitor.

WARNING

Pulse oximetry readings and pulse signal can be affected by certain ambient conditions, sensor application errors and certain patient conditions.

WARNING

The SpO_2 Module is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

WARNING

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.

WARNING

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.

WARNING

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.

WARNING

Do not use the SpO$_2$ Module or sensors during Magnetic Resonance Imaging (MRI).

WARNING

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.

WARNING

Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

WARNING

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.

WARNING

Check alarm limits each time the SpO$_2$ Module is used, to ensure they are appropriate for the patient being monitored.

WARNING

Use only Nellcor® approved Oximax™ sensors and DOC-10, OC-3 pulse oximetry cables with the SpO$_2$ Module Model 8210. Use of other 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$_2$.

WARNING

Before use, read sensor Directions for Use, including all warnings, cautions and instructions.

WARNING

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 as per manufactures instructions, refer to Oximax™ Sensors Instructions For Use. The sensor disconnect error message and associated alarm indicate that 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.

WARNING

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

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.

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)

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 compatibillity 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 (refer to Radio Frequency Interference Warning for additional information).

User Precautions

To ensure proper performance of the MEDLEY™ SpO$_2$ Module and to reduce potential injury to the operator, observe the following WARNINGS and CAUTIONS:

WARNING

Do not open the instrument case. There are no user serviceable parts inside. The instrument case should only be opened by qualified service personnel using proper grounding techniques. When the instrument case is opened, an electrical shock hazard exists which can result in serious injury to persons and instrument component damage.
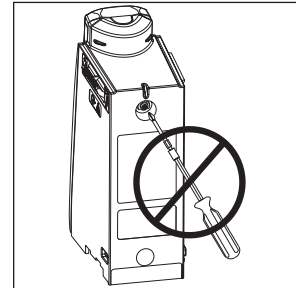
Dropping/Jarring

Should an instrument be dropped or severely jarred, it should be immediately taken out of use and inspected by qualified service personnel, to ensure its proper function prior to reuse.
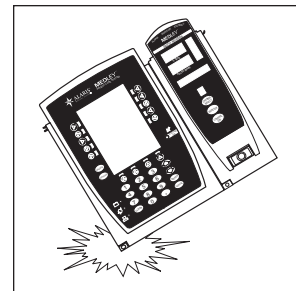
Maintenance

Disconnect from the Programming Module when performing maintenance.

Operating Environment

Not for use in the presence of flammable anesthetics.

◄ DANGER ►

Explosion risk if used in the presence of flammable anesthetics.

Radio Frequency Interference

Operating the system near equipment which radiates high energy radio frequencies (electrosurgical/cauterizing equipment, portable radios, cellular telephones, etc.) may cause false alarm conditions. If this happens, reposition the device away from the source of interference or turn off the device and manually monitor the vital parameters using an appropriate clinical alternative.

GETTING STARTED
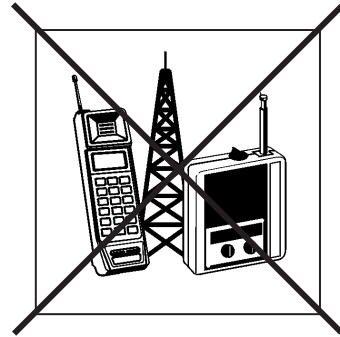
If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and then check the MEDLEY™ SpO$_2$ Module to ensure it is functioning properly.

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.
- Placement of a sensor 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 the nail polish and/or move the sensor to an unaffected site.
- Placement too close to electrosurgery equipment.
- Defibrillation

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

- The 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.
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, intravascular line or other causes of insufficient perfusion.
- The patient has hypotension, severe vasoconstriction, severe anemia or hypothermia.
- There is arterial occlusion proximal to the sensor.
- The patient is in cardiac arrest or is in shock.
- Placement too close to electrosurgery equipment.

Status Indicators

Alarm (red)　　　Monitor (green)　　　Standby (yellow)

IUI Connector, Left (not visible)

IUI Connector, Right

%SpO$_2$ Display

Pulse Rate Display

Channel Message Display

ALARM　MONITOR　STANDBY

MEDLEY™

SpO$_2$ Module

%SpO2

PULSE (BPM)

Pulse Bar Display

Channel Identification:. A, B, C or D

Channel Select Key: When pressed, selects the corresponding channel for patient monitoring and setup.

CHANNEL SELECT

MONITOR

CHANNEL OFF

Monitor Key: When pressed, begins patient monitoring.

Channel Off Key: When pressed and held for one second and then released, stops the operation of that channel, deselects that channel, and if only that channel had been operating, the system powers down. Repeat for other operating channels to power off each channel.

Channel Release Latch

Patient Cable Connector

GETTING STARTED

Installation Procedure

Instruments are tested before they are packaged for shipment. They met the specifications listed in the Directions for Use at that time. To ensure proper operation after shipment, it is recommended that an incoming inspection is performed by your facility before putting the instrument into use.

Unpacking the SpO$_2$ Module

1. Remove product from its carton.

2. Check for any loose parts.

If the product is damaged, contact ALARIS Medical Systems for authorization to return the equipment for repair, whether damage or malfunction is the responsibility of the carrier or of ALARIS Medical Systems.

Attaching and Detaching Channels

Refer to the MEDLEY™ Programming Module (Model 8000) Directions for Use for detailed instructions on attaching and detaching channels.

Start-Up Sequence

Powering On the System

1. Connect the MEDLEY™ Programming Module to an external AC power source.

2. Attach SpO$_2$ Module to Programming Module.

3. Press **SYSTEM ON** key on Programming Module.

4. System self test begins:

    *   Diagnostics test causes all LED display segments and Status Indicator lights of attached channel(s) to illuminate briefly.

    *   Power Indicator illuminates.

    *   Appropriate channel identification (A, B, C or D) is displayed on attached channel(s).

    *   An Audio tone sounds.

5. At completion of system-on test, "**NEW PATIENT?**" screen appears on Programming Module.

NOTE: *If any of the following conditions are observed,
Programming Module or the affected channel must be removed
from use and inspected by qualified personnel:*

- *LED segments are not illuminated on the channel displays during
  the system on test.*
- *Indicator lights do not illuminate.*
- *Appropriate channel identification (A, B, C or D) is not displayed.*
- *Audio tone does not sound.*
- *Main Display does not appear backlit, appears irregular, or has
  evidence of a row of pixels not functioning properly. If the
  affected channel operates normally when it is attached via the
  alternate IUI connector, it may be used until a replacement
  channel can be substituted.*

General Setup and Use

NOTE: *Use only Nellcor® approved Oximax™ sensors and
DOC-10, OC-3, pulseoximetry cables.*

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 is
    correct for patient by selecting **CHANNEL SELECT** key.

    *NOTE: SEARCHING may appear in Channel Message Display
    until SpO$_2$ and pulse readings have stabilized (approximately
    15 seconds).*

    *NOTE: 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 one second.

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

GETTING STARTED

Displays

Main Display

Refer to the MEDLEY™ Programming Module (Model 8000) Directions for Use for detailed information in the Main Display.

Title Bar ————————

Channel Status
- A solid Channel Letter display indicates channel is operating.
- An outlined Channel Letter display indicates channel is attached and ready for use.

Soft Keys ——————

A SPO2

Ⓑ

AUDIO
ADJUST
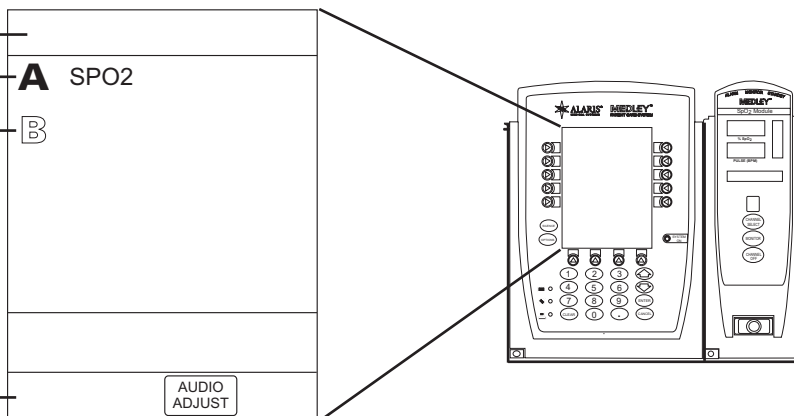
> *NOTE: Throughout the following sections of this chapter, display screens are aligned with the corresponding steps.*

Monitoring Mode

Navigating Main Display

1. Attach SpO$_2$ Module to Programming Module.

2. Power on system by pressing **SYSTEM ON** key on Programming Module. **NEW PATIENT?** screen will appear.

    - A **Yes** selection clears previous SpO$_2$ trend data.

    - A **No** selection retains previous SpO$_2$ trend data.

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

    - Once a selection is made, either Main Display will appear or, if the Guardrails® Safety Software is enabled, profiles screen (as shown on the right) will be displayed.

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

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

Navigating Main Display (Continued)

3. Attach patient cable and sensor as described in "General Setup and Use" section of this document.

```
Midtown Hospital
Adult ICU

A    SPO2




                    AUDIO
                    ADJUST
```
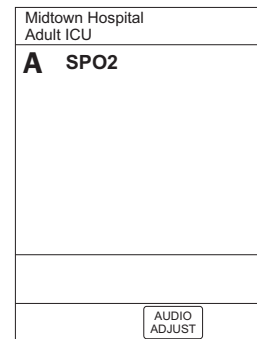
4. Press **CHANNEL SELECT** key on SpO$_2$ Module to view **SPO2 Main** display.

   The following information can be viewed in this display:
   - limit mode (**Adult** or **Neonatal**)
   - **%SPO2**, with high and low alarm limits
   - **PULSE RATE**, with high and low alarm limits
   - pleth waveform
   - SatSeconds

```
A SPO2 Main           Adult
                      Mode
% SPO2   97    Off
               90
PULSE    82    150
RATE           50

0                    100
 SatSeconds (% to Alarm)

TREND         LIMITS  MAIN
                      SCREEN
```

5. Press **MAIN SCREEN** soft key to return to Main Display.

```
Midtown Hospital
Adult ICU

A    SPO2




                    AUDIO
                    ADJUST
```
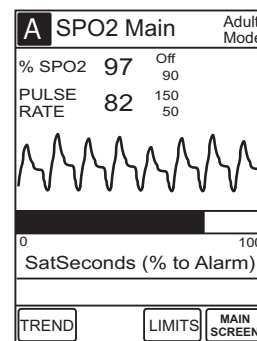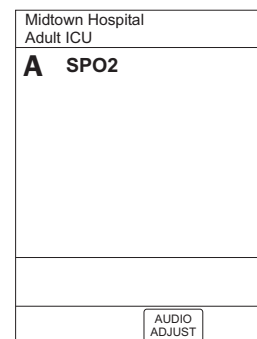
Setting Alarm Limits

1. Press **CHANNEL SELECT** key on SpO$_2$ Module.

```
A SPO2 Main           Adult
                      Mode
% SPO2   97    Off
               90
PULSE    82    150
RATE           50

0                    100
 SatSeconds (% to Alarm)

TREND         LIMITS  MAIN
                      SCREEN
```
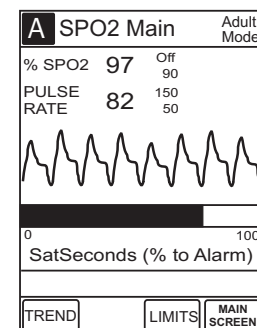
GETTING STARTED

Setting Alarm Limits (Continued)

2. Press **LIMITS** soft key. The following limits can be changed:

   - %SPO2 HIGH
   - %SPO2 LOW
   - PULSE HIGH
   - PULSE LOW

A

Adult Alarm Limits

%SPO2 HIGH	Off
%SPO2 LOW	90
PULSE HIGH	150
PULSE LOW	50

>*Select Parameter Limit*

Confirm

---

3. Press soft key for parameter limit being changed.

   - Selected parameter is highlighted.
   - Display prompts for a value to be entered.

A

Adult Alarm Limits

%SPO2 HIGH	Off
%SPO2 LOW	90
PULSE HIGH	150
PULSE LOW	50

>*Enter High %SPO2 Limit*

Confirm

---

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 three seconds, the display prompt changes to >Press ENTER to Confirm.*
   - *Pressing Confirm soft key will cause the screen to return to the SpO2 Main display.*

A

Adult Alarm Limits

%SPO2 HIGH	_98	Off
%SPO2 LOW	90
PULSE HIGH	150
PULSE LOW	50

>*Press ENTER to Confirm*

Confirm

---

5. Press **ENTER** key on Programming Module to confirm.

   NOTE: Once the ENTER key is pressed, the display highlights the next limit and prompts for an entry.

A

Adult Alarm Limits

%SPO2 HIGH	98
%SPO2 LOW	_90
PULSE HIGH	150
PULSE LOW	50

>*Enter Low %SPO2 Limit*

Confirm

Setting Alarm Limits (Continued)

6. Press **Confirm** soft key to return to **SPO2 Main** display.

```
┌──────────────────────────────┐
│ A SPO2 Main        Adult Mode │
│                               │
│ % SPO2    97    Off           │
│                 90            │
│ PULSE     82    150           │
│ RATE            50            │
│                               │
│  ∧∧∧∧∧∧∧∧∧∧∧∧∧                │
│                               │
│ 0                        100  │
│  SatSeconds (% to Alarm)      │
│                               │
│ TREND      LIMITS   MAIN      │
│                     SCREEN    │
└──────────────────────────────┘
```
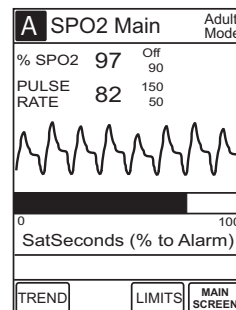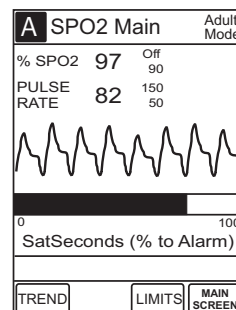
7. Press **MAIN SCREEN** soft key to return to Main Display.

```
┌──────────────────────────────┐
│ Midtown Hospital              │
│ Adult ICU                     │
│                               │
│ A   SPO2                      │
│                               │
│                               │
│                               │
│                               │
│                               │
│                               │
│                    AUDIO      │
│                    ADJUST     │
└──────────────────────────────┘
```

Navigating Trend Data View

1. Press **CHANNEL SELECT** key on SpO$_2$ Module to view **SPO2 Main** display.

```
┌──────────────────────────────┐
│ A SPO2 Main        Adult Mode │
│                               │
│ % SPO2    97    Off           │
│                 90            │
│ PULSE     82    150           │
│ RATE            50            │
│                               │
│  ∧∧∧∧∧∧∧∧∧∧∧∧∧                │
│                               │
│ 0                        100  │
│  SatSeconds (% to Alarm)      │
│                               │
│ TREND      LIMITS   MAIN      │
│                     SCREEN    │
└──────────────────────────────┘
```
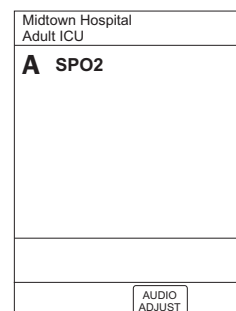
2. Press **TREND** soft key in **SPO2 Main** display to view **Trend Data** display.

> *NOTE: 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.*

<center>-- Continued Next Page --</center>

```
┌──────────────────────────────┐
│ A Trend Data       Adult Mode │
│ TIME      SPO2      PULSE     │
│ 2001-07-06 AVG MAX  AVG MAX   │
│               MIN       MIN   │
│ 07:39:17  97  100   82  155 🔒│
│               90        50    │
│ 07:39:00  97  100   82  150   │
│               90        50    │
│ 07:38:30  97  100   82  150   │
│               88        50    │
│ 07:38:00  97  100 🔒 82  150   │
│               86        50    │
│ 07:37:30  ---       ---       │
│ 07:37:00  97  100   82  150   │
│               90        50    │
│ ZOOM: 30min 15min 5min 1min 30sec│
│ >Press UP/DOWN Keys           │
│ to move cursor.               │
│ PAGE UP  ZOOM  SPO2   PAGE    │
│                MAIN   DOWN    │
└──────────────────────────────┘
```
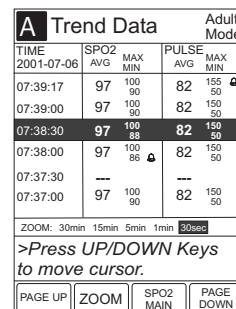
Navigating Trend Data View (Continued)

The following information is viewed in the **Trend Data** display:

- TIME period for data collection period
- average SPO2, with high and low values
- average PULSE rate, with high and low values
- alarm icon (🔔)

NOTES:

- *The 🔔 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.*

---

3. Press **PAGE UP** and **PAGE DOWN** soft keys to navigate from page to page.

    ---

    *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 always displays on the third row of data.*

    ---

4. To move cursor, press ⬠ or ⬡ key on Programming Module.

    NOTE: With further ⬡ key presses, the cursor stays in this position (as illustrated) and the data view scrolls up one row at a time.

    ---

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

    - New time period is highlighted in display.

    - Each press of **ZOOM** soft key changes one time period.

    - Available time periods are 30 minutes, 15 minutes, 5 minutes, 1 minute, and 30 seconds.

        ---

        *NOTE: Repeated pressing of the **ZOOM** soft key will cycle through the time period choices.*

Navigating Trend Data View (Continued)

6.   Press **SPO2 MAIN** soft key to return to **SPO2 Main** display.

```
┌─────────────────────────┐
│ A  SPO2 Main      Adult  │
│                    Mode  │
│ % SPO2   97    Off       │
│                 90       │
│ PULSE    82    150       │
│ RATE           50        │
│  ∿∿∿∿∿∿∿∿∿∿∿∿∿            │
│ 0                100     │
│  SatSeconds (% to Alarm) │
│ ┌─────┐  ┌──────┬──────┐ │
│ │TREND│  │LIMITS│ MAIN │ │
│ └─────┘  └──────│SCREEN│ │
└─────────────────────────┘
```

7.   Press **MAIN SCREEN** soft key to return to Main Display.

```
┌─────────────────────────┐
│ Midtown Hospital         │
│ Adult ICU                │
│ A   SPO2                 │
│                          │
│                          │
│                          │
│                          │
│                 ┌──────┐ │
│                 │AUDIO │ │
│                 │ADJUST│ │
└─────────────────────────┘
```
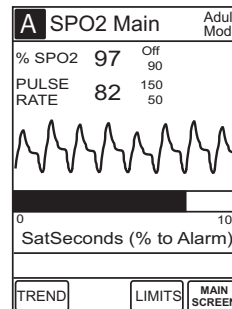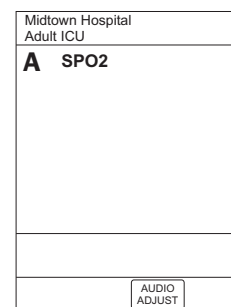
Pre-Silencing Alarm

1.   Press **SILENCE** key on Programming Module to pre-silence alarm.

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

```
┌─────────────────────────┐
│ Midtown Hospital         │
│ Adult ICU                │
│ A   SPO2            ⊠     │
│                          │
│                          │
│                          │
│                          │
│                 ┌──────┐ │
│                 │AUDIO │ │
│                 │ADJUST│ │
└─────────────────────────┘
```
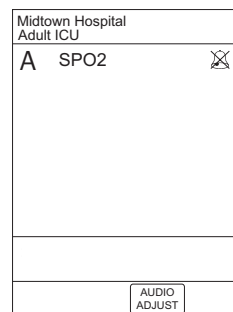
2.   To cancel pre-silence alarm

- Press **CHANNEL SELECT** key on SpO$_2$ Module.

- Press **CANCEL SILENCE** soft key to cancel pre-silence alarm and return to alarmable mode.

```
┌─────────────────────────┐
│ A  SPO2 Main      Adult  │
│                    Mode  │
│ % SPO2   97    Off       │
│                 90       │
│ PULSE    82    150       │
│ RATE           50        │
│  ∿∿∿∿∿∿∿∿∿∿∿∿∿            │
│ 0                100     │
│  SatSeconds (% to Alarm) │
│ ┌─────┬──────┬──────┬────┐
│ │TREND│CANCEL│LIMITS│MAIN│
│ │     │SILENCE      │SCREEN
│ └─────┴──────┴──────┴────┘
└─────────────────────────┘
```

GETTING STARTED
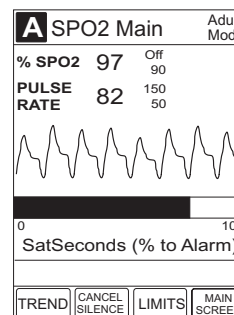
Setting Channel Options

To access and set channel options:

1. Press **CHANNEL SELECT** key on SpO$_2$ Module to view **SPO2 Main** display.

```
┌─────────────────────────────┐
│ A  SPO2 Main        Adult   │
│                     Mode    │
│ % SPO2   97    Off          │
│                90           │
│ PULSE    82    150          │
│ RATE           50           │
│  ∿∿∿∿∿∿∿∿∿∿∿∿∿               │
│ ████████████████░░░░░       │
│ 0                    100    │
│  SatSeconds (% to Alarm)    │
│                             │
│ TREND       LIMITS  MAIN    │
│                     SCREEN  │
└─────────────────────────────┘
```
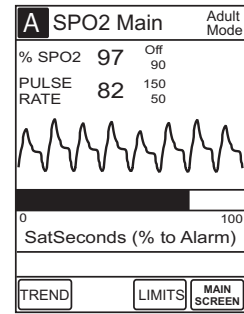
2. Press **OPTIONS** key on Programming Module. The following options are available:

   • Limit Mode
   • Pulse Beep Volume
   • SatSeconds Limits

```
┌─────────────────────────────┐
│ A  Channel Options 1 of 1   │
│                             │
│ Limit Mode:          Adult  │
│                             │
│ Pulse Beep Volume:  Off     │
│                             │
│ SatSeconds Limits:   10     │
│                             │
│                             │
│ >Select an Option or        │
│ EXIT                        │
│        EXIT                 │
└─────────────────────────────┘
```

Changing Limit Mode

1. Press **Limit Mode** soft key in **Channel Options** display.

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 can not be changed.*

```
┌─────────────────────────────┐
│ A                           │
│  Limit Mode Setup           │
│                   Adult     │
│                   Neonatal  │
│                             │
│                             │
│ >Select an Option or        │
│ EXIT                        │
│        EXIT                 │
└─────────────────────────────┘
```

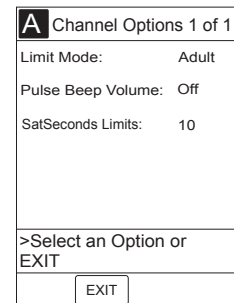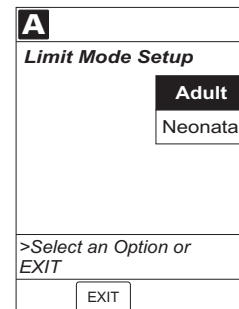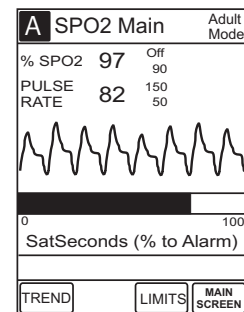3. If Limit Mode is not changed, press **EXIT** soft key to return to **SPO2 Main** display and press **OPTIONS** key on Programming Module to view other options.

```
┌─────────────────────────────┐
│ A  SPO2 Main        Adult   │
│                     Mode    │
│ % SPO2   97    Off          │
│                90           │
│ PULSE    82    150          │
│ RATE           50           │
│  ∿∿∿∿∿∿∿∿∿∿∿∿∿               │
│ ████████████████░░░░░       │
│ 0                    100    │
│  SatSeconds (% to Alarm)    │
│                             │
│ TREND       LIMITS  MAIN    │
│                     SCREEN  │
└─────────────────────────────┘
```

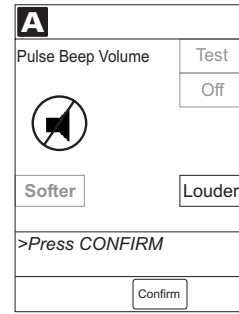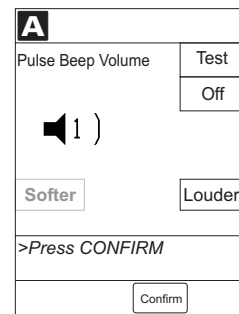### Viewing or Changing Pulse Beep Volume

1. Press **Pulse Beep Volume** soft key in **Channel Options** display.

   > *NOTE:* *The illustrated display reflects that 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**.*

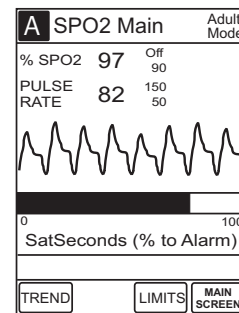 | A | |
   |---|---|
   | Pulse Beep Volume | Test |
   | | Off |
   | 🔇 | |
   | Softer | Louder |
   | >*Press CONFIRM* | |
   | | Confirm |

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 one cycle.*

A	
Pulse Beep Volume	Test
	Off
◀1)	
Softer	Louder
>*Press CONFIRM*	
	Confirm

3. Press **Confirm** soft key to return **SPO2 Main** display.

A SPO2 Main	Adult Mode
% SPO2 **97**	Off 90
PULSE RATE **82**	150 50
∿∿∿∿∿∿∿∿	
0 100	
SatSeconds (% to Alarm)	
TREND	LIMITS MAIN SCREEN

GETTING STARTED

Changing SatSeconds Limit

1. Press **SatSeconds Limits** soft key in **Channel Options** display.

```
┌─────────────────────────────┐
│ A  Channel Options 1 of 1   │
├─────────────────────────────┤
│ Limit Mode:         Adult   │
│                             │
│ Pulse Beep Volume:  Off     │
│                             │
│ SatSeconds Limits:  10      │
│                             │
│                             │
│                             │
├─────────────────────────────┤
│ >Select an Option or        │
│ EXIT                        │
│         ┌──────┐            │
│         │ EXIT │            │
│         └──────┘            │
└─────────────────────────────┘
```
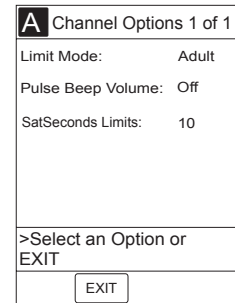
2. To change **SatSeconds**, press either **Increase** or **Decrease** soft key. Selectable options are **10**, **25**, **50 and 100** seconds, or **Off**.

```
┌─────────────────────────────┐
│ A                           │
├─────────────────────────────┤
│ SatSeconds Setup            │
│                 ┌──────────┐│
│                 │ Increase ││
│    10  SPO2     ├──────────┤│
│        Seconds  │ Decrease ││
│                 ├──────────┤│
│                 │   Off    ││
│                 └──────────┘│
│                             │
│ >Press CONFIRM              │
│            ┌─────────┐      │
│            │ Confirm │      │
│            └─────────┘      │
└─────────────────────────────┘
```

3. Press **Confirm** soft key to return **SPO2 Main** display.

```
┌─────────────────────────────┐
│ A  SPO2 Main        Adult   │
│                     Mode    │
├─────────────────────────────┤
│ % SPO2   97    Off          │
│                90           │
│ PULSE    82    150          │
│ RATE           50           │
│                             │
│  ∿∿∿∿∿∿∿∿∿∿∿∿∿∿              │
│                             │
│ ▓▓▓▓▓▓▓▓▓▓▓▓▓░░░░            │
│ 0                  100      │
│  SatSeconds (% to Alarm)    │
│                             │
│ ┌─────┐  ┌──────┐ ┌──────┐  │
│ │TREND│  │LIMITS│ │ MAIN │  │
│ └─────┘  └──────┘ │SCREEN│  │
│                   └──────┘  │
└─────────────────────────────┘
```
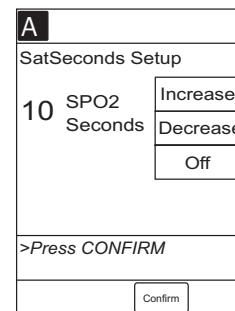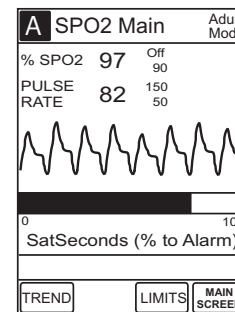
Powering Off

Powering Off System

1. Press **MAIN SCREEN** soft key to return to Main Display.

```
Midtown Hospital
Adult ICU

A    SPO2




                           AUDIO
                          ADJUST
```
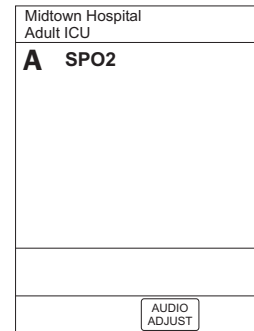
2. Press **OPTIONS** key on Programming Module.

3. Press **Power Down all Channels** soft key.

```
System Options 1 of 2

Display Contrast

Time of Day

Power Down All Channels

 Anesthesia Mode

Battery Runtime


>Select an Option or
EXIT
              EXIT         PAGE
                           DOWN
```
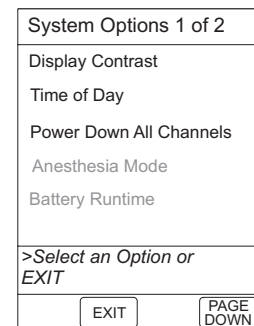
4. Press **Yes** soft key.

    During power off sequence, Main Display flashes **Powering Down**.

```
System Options


Power Down        Yes
All Channels?
                  No




>Press Yes or No
```
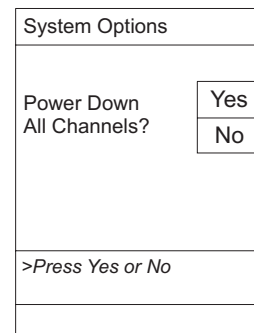
Powering Off One Channel at a Time

1. Press and hold **CHANNEL OFF** key on each operating channel for one second.

    > **NOTE:** *The channel will initiate the power down at the release of the* **CHANNEL OFF** *key.*

2. Once all attached channels are powered off, Programming Module automatically powers down.

    During power off sequence, Main Display flashes **Powering Down**.

```
        Powering Down
```

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Definitions

Advisory	A sequence of audio and/or visual signals indicating the operating status of the MEDLEY™ Medication Safety System. The audio may be silenced for approximately two minutes by pressing the **SILENCE** key on the Programming Module.
Alarm	An audio and visual signal that a potentially unsafe condition is present. Immediate action is required. The audio may be silenced for approximately two minutes by pressing the **SILENCE** key on the Programming Module.
Error	An audio and/or visual signal that a failure has been detected. The instrument should be taken out of service immediately and thoroughly tested and inspected by qualified service personnel, to ensure its proper function prior to reuse.
Prompt	An audio and/or visual signal, appearing on the bottom line of the Main Display or the Channel Message Display, to perform some action. The audio may be silenced for twelve seconds by pressing the **SILENCE** key on the Programming Module.
Pre Silence	The alarms for the SpO_2 Module can be silenced for up to 120 seconds by pressing the **SILENCE** key on the Programming Module. This will not silence the infusion alarms. To end the Pre-Silence period press the **CANCEL SILENCE** soft key on the SpO_2 Main display.

Audio Characteristics

The Programming Module and Main Display provide four types of alert information: advisories, prompts, alarms and malfunctions. For more information on the Programming Module, refer to Directions For Use. The characteristics of the accompanying audio sounds are as follows:

WARNING

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.

Type	Sound	Notes
Advisory	One short beep every two seconds	Variable volume; can be silenced for two minutes.
SpO_2 Alarm (HIGH PRIORITY)	A sequence of 5 beeps	Variable volume; can be silenced for two minutes.
SpO_2 Alarm (LOW PRIORITY)	One long beep approximately every 4 seconds	Variable volume; can be silenced for two minutes.
SpO_2 Error (Hardware Detected)	A single alarm tone volume	Fixed maximum decibel volume; cannot be silenced.
SpO_2 Error (Software Detected)	Pairs of long beeps	Fixed maximum decibel volume; can be silenced for two minutes.
Illegal Key Press	Two short beeps	Variable volume; cannot be silenced.
Key Click	One short beep	Fixed minimum volume; can be silenced and disabled in the System Configuration.
Prompt	One short beep every two seconds	Variable volume; can be silenced.

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. See Accessories 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.
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.

Alarms (Continued)

Alarm	Meaning	Response
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 the 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 one SpO_2 Module attached.	Remove additional SpO_2 Module.
Sensor Off	Sensor not properly attached to patient.	Reattach sensor to patient.

Advisories

Advisory	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.

The MEDLEY™ System Technical Service Manual is available from ALARIS Medical Systems. It includes 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.

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

Display Update Period: The display update period is 2.25 seconds.

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)

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

Electronic Memory: System configuration parameters stored in volatile memory will be retained for at least six months by the Programming Module internal backup lithium battery. Module specific SpO$_2$ parameters are stored for eight hours by the Programming Module when the system is turned off. After eight hours of continuous off time, or if the module is changed, the system will automatically purge module specific information.

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

Specifications (Continued)

Measurement Range:

Perfusion	0.03 to 20%
Pulse Rate	20 to 250 bpm
SpO$_2$	1 to 100%

Mode of Operation: Continuous

Weight: 2 lbs (0.91 kg)

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

Specifications/Sensor

Wave length and Power: Emitted light wavelength range is within 500nm to 1000nm. Output power does not exceed 15mw.

NOTE: Compliance to Standards

The MEDLEY™ Medication Safety System, with the Programming Module and SpO$_2$ Module, has been assessed and complies with the following standards: UL 2601–1, including A1 and A2; CSA C22.2 No. 601.1, including A1 and A2; IEC/EN 60601–2–24 (1998); IEC/EN 60601–1–2 (2001) AAMI ID26 (1998); EN865

NOTES:

1. *Specification applies to the 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 the SpO$_2$ Module. Neonate specifications are shown for OXIMAX™ MAX-N sensors with the SpO$_2$ Module. Saturation accuracy will vary by sensor type. Refer to the Sensor Accuracy Grid in the Appendix of this DFU.*

Configurable Settings

System Settings

Feature	Default Setting	Options
Alarm Audio	Profile 1	Profile 1, 2 or 3
Battery Meter	Disabled	Enabled - Disabled
Clock Setup (Date and Time)	N/A	Set date and time
Key Click Audio	Enabled	Enabled - Disabled
Tamper Resist	Disabled	Enabled - Disabled

SpO$_2$ Module Settings

Feature	Default Setting	Options
Limit Mode	Adult	Adult or Neonatal
Pulse Beep Volume	1	1, 2, 3 or 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 and 100 seconds, or Off
SpO$_2$ Alarm Limit, High	Adult: Off Neonatal: 95%	21 - 100%, Off
SpO$_2$ Alarm Limit, Low	Adult: 90% Neonatal: 80%	20 - 99%

DO NOT spray cleaning fluids directly onto instrument or immerse instrument in fluids.

DO NOT use solutions containing phosphoric acid (Foamy Q&A), aromatic solvents (naphtha, paint thinner, etc.), chlorinated solvents[1] (Trichloroethane, MEK, Toluene, etc.), ammonia, acetone, benzene, xylene or alcohol, other than as specified below.

DO NOT use hard or pointed objects to clean any part of instrument.

Acceptable cleaning solutions are:

> *NOTE: After application, rinse all surfaces with water.*

Warm water
Mild detergent (such as, Manu-Klenz)
10% bleach solution (1 part bleach to 9 parts water)
Compublend II
Envirocide
2% Glutaraldehyde in water
Hydrogen Peroxide 3%
70% Isopropyl Alcohol
2% Phenols in water (O-Syl 1:128, Pheno-Cen 1:256, Vesphene)
10% Providone Iodine (Betadine)
Quaternaries 1:512
WEX-CIDE

> *NOTE: All recommended solutions must be diluted per the Manufacturer's recommendation.*

1. Keep instrument upright and do not allow any part of instrument to become saturated with or submersed in fluid during cleaning operation.

2. Use a soft cloth dampened with warm water and a mild nonabrasive cleaning solution to clean all exposed surfaces. For sanitizing or antibacterial treatment, use 10% bleach solution and water.

> *NOTE: A soft-bristled brush may be used to clean hard to reach and narrow areas. For sensor/cable cleaning refer to Nellcor® sensor/cable cleaning instructions provided with sensor/cable packaging Directions for Use.*

WARNING

Turn the instrument off and disconnect the power cord from the AC power source before cleaning. Do not spray fluids directly onto the rear case of the instrument. Do not steam autoclave, EtO sterilize, immerse the instrument or allow fluids to enter the instrument case. Failure to follow these instructions may result in an electrical hazard.

CAUTION

The solutions/solvents identified as NOT to be used can damage the surfaces of the instrument.

[1] Excluding 10% bleach solution in water

To ensure the system remains in good operating condition, both regular and periodic inspections are required.

Regular inspections consist of a visual inspection for damage and cleanliness, and performing the procedure described in the Start–Up Sequence section of this Directions for Use before each usage of the instrument. Regular inspections are not covered under any contract or agreement offered by ALARIS Medical Systems and must be performed by the user.

Regular Inspections

PROCEDURE	FREQUENCY
Cleaning	As required
Inspect for Damage:	
Case	Each usage
IUI Connector	Each usage
Keypad	Each usage
Start-Up Sequence	Each usage

Periodic inspections of the hardware are required. For detailed instructions on performing periodic inspections and maintenance, refer to the SpO_2 Module Technical Service Manual and supplemental service bulletins. A service agreement may be obtained from ALARIS Medical Systems for the performance of all required periodic inspections.

NOTE: Periodic inspections should only be performed by qualified service personnel.

Preventive Maintenance Inspections

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

MAINTENANCE

Service Information

NOTE: If the instrument shows evidence of damage in transit, notify the carrier's agent immediately. Do not return damaged equipment to the factory before the carrier's agent has authorized repairs.

If the instrument fails to respond as described in this document and the cause cannot be determined, do not use the instrument. Contact qualified ALARIS Medical Systems® service personnel.

Customer Service

Within the United States and Canada, information or assistance may be obtained by calling one of the following Customer Service toll–free numbers:

United States:	(800) 482-4822
Canada:	
Eastern	(800) 908-9918
Western	(800) 908-9919

Technical Support

Technical Support can be contacted by calling one of the following toll–free numbers:

United States:	(800) 854-7128, extension 6003
Canada:	
Eastern	(800) 227-7215
Western	(800) 667-2335

Outside the United States and Canada, service information, applications, and manuals may be obtained by contacting your local ALARIS Medical Systems® Service Department or distribution center.

When submitting any request for service, include:

- a description of difficulty experienced
- Programming Module serial number, and description and serial number of all attached channels
- administration set/lot number
- solution(s) used
- message displayed at time of difficulty

Product Return

If it is necessary to return the instrument for service, obtain a return authorization number prior to shipment. Carefully package the instrument (preferably in the original packaging), reference the return authorization information, and return it to the appropriate service or distribution center. ALARIS Medical Systems does not assume any responsibility for loss of, or damage to, returned instruments while in transit.

WARNING

Instruments returned from the service depot to your facility may be set to factory defaults and not have a hospital-defined data set loaded. Biomedical personnel in the facility are responsible for checking-in the instrument and ensuring the current hospital-approved data set is loaded.

WARRANTY

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

A. Each new ALARIS Medical Systems MEDLEY™ Medication Safety System 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;

<div align="center">or</div>

(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

This section covers the use of the Nellcor® OXIMAX™ sensors, Nellcor® DOC-10 and OC-3 patient cables.

Nellcor® OXIMAX™ Sensors

NOTES:

- *Before use, carefully read the OXIMAX™ sensor directions for use.*
- *Use only Nellcor® oximetry sensors for SpO$_2$ Module measurements. Other oxygen transducers (sensors) may cause improper SpO$_2$ Module performance.*

Selecting a Nellcor® OXIMAX™ Sensor:

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, refer to the table at the end of this section or contact your 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.

NOTE: Failure to cover the sensor site with opaque material in high ambient light conditions may result in inaccurate measurements.

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.

WARNING

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.*)

CAUTIONS:

- Do not use damaged sensors. Do not use a sensor with exposed optical or electrical components.
- Always remove the sensor from the patient and completely disconnect the patient from the SpO$_2$ Module before bathing the patient.

Nellcor® OxiMax™ Sensors (Continued)

OxiMax™ Sensor	Model	Patient Size	
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	**Site Inspection Interval** 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.
Durasensor® 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) For use with Dura-Y® Sensor: Ear Clip (reusable, nonsterile)	D-YS D-YSE	>1 kg >30 kg	Check and move Sensor to a new site every 4 hours.
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.

Nellcor® Patient Cables

The Nellcor® DOC-10 and OC-3 patient cables interface the SpO$_2$ Module Model 8210 with the patient sensors.

Sensor Accuracy Grid

NELLCOR®

Sensor Accuracy Grid for MEDLEY™ System Model 8210 SpO$_2$ Module

Sensor Models	SPO$_2$ Range 70%-100%
Oximax™ Sensor Models Single Patient Use	
MAX-A,* MAX-AL*	± 2
MAX-N[T]* (Adult)	± 2
MAX-N[T]* (Neonate)	± 3
MAX-P *	± 2
MAX-I*	± 2
MAX-FAST	± 2
MAX-R[‡]	± 3.5
OxiCliq Sensor Models Single Patient Use	
OxiCliq A	± 2.5
OxiCliq P	± 2.5
OxiCliq N[†] (Adult)	± 2.5
OxiCliq N[†] (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
DS-100A	± 3
OXI-A/N (Adult)	± 3
OXI-A/N (Neonate)	± 4
OXI-P/I	± 3

Accuracy Specifications: Accuracy specifications are based on controlled hypoxia studies with healthy, non-smoking 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 ± one 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.

Oxygen saturation accuracy can be affected by certain environmental and patient physiological conditions, as discussed in the operator's manual for the monitor.

> **The ALARIS Medical Systems® MEDLEY™ Medication Safety System, SpO$_2$ Module Model 8210 is designed for use with Nellcor® cables and sensors.**

*   The accuracy specification under motion conditions is ± 3. For a definition of motion, contact Nellcor Technical Services or your local Nellcor representative.

†   The MAX-N and the OxiCliq N were tested on patients > 40 kg.

‡   The accuracy specification has been determined between saturations of 80%-100%.

![ALARIS Medical Systems logo]

ALARIS Medical Systems, Inc.
10221 Wateridge Circle
San Diego, California 92121 U.S.A.

Mail:
P.O. Box 85335
San Diego, California 92186-5335 U.S.A.