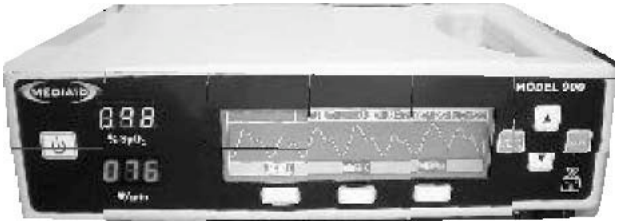
Model 900

Pulse Oximeter User's Manual



MEDIAID INC.
17517 Fabrica Way Suite H, Cerritos, CA 90703 USA
Phone: 714-367-2848; Fax: 714-367-2852
Website: www.mediaidinc.com

POX010-900

Table of Contents

Chapter 10: *Principles of Operation*

Chapter 11: *Data Port Protocol*

Chapter 12: *Warranty Information*

Chapter 1:
Safety Information

1.1 GENERAL SAFETY INFORMATION

This section contains important safety information related to general use of the Model 900 pulse oximeter. Other important safety information appears throughout the manual in sections that relate specifically to the precautionary information.

Important!! Before using the pulse oximeter, the user should become thoroughly familiar with the information in this manual and with all information included with the sensor.

WARNING
Explosion hazard. Do not use the Model 900 pulse oximeter in the presence of flammable anesthetics or gases.

WARNING
The Model 900 is a prescription device and is to be operated by qualified personnel only.

WARNING
Chemicals from broken LCD display panel are toxic when ingested. Use caution when handling an oximeter with a broken display panel.

WARNING
Pulse oximeter readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of the manual for specific safety information.

CAUTION

When connecting the Model 900 to any instrument, verify proper operation before clinical use. Both the Model 900 and the instrument connected to it must be grounded properly. Accessory equipment connected to the oximeter's data interface must be certified according to IEC Standard 950 for data-processing equipment or IEC Standard 60601-1 for electro medical equipment. All combinations of equipment must be in compliance with IEC Standard 60601-1 systems requirements. Anyone who connects additional equipment to the signal input port or signal output port (Model 900 data port connector) configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of system standard IEC Standard 60601-1 and the electromagnetic compatibility system standard IEC Standard 60601-1-2. The Model 900 accuracy may degrade if it is connected to secondary I/O devices when the instrument is not connected to earth reference.

To ensure accurate readings, consider the environment conditions that are present and the condition of the patient. See the appropriate sections of the manual for specific safety information related to these conditions.

Chapter 2:
Introduction

2.1 INTENDED USE

The Model 900 is a portable pulse oximeter intended for use as a continuous noninvasive oximeter of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The intended patient population comprises adult, pediatric, and neonatal patients. The intended environments of use are hospitals, hospital type facilities, intra-hospital transport environments and home care. The Model 900 is for prescription use only. Hospital use typically covers such areas as general care floors, operating rooms, special procedure areas, intensive and critical care areas within the hospital plus hospital-type facilities such as surgical centers, sub-acute centers, special nursing facilities and sleep labs, outside of the hospital. Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility.

WARNING
The Model 900 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

2.2 GENERAL OPERATING PRINCIPLES AND CONDITIONS

The Model 900 uses pulse oximeter to measure functional oxygen saturation in the blood. Pulse oximeter works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector.

Bone, tissue, pigmentation and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of

light absorbed is translated into a measurement of functional oxygen saturation (SpO_2).

Since the measurement of SpO_2 is dependent upon light from the sensor, excessive ambient light can interfere with this measurement. Specific information about ambient environment conditions, sensor application and patient conditions is contained throughout this manual.

Chapter 3:
Controls, Indicators and Symbols

3.1 DISPLAYS, CONTROLS, INDICATORS AND CONNECTORS

Figure 1,2 and 3 show the front, rear and side views of the Model 900 and identify displays, controls and connectors.

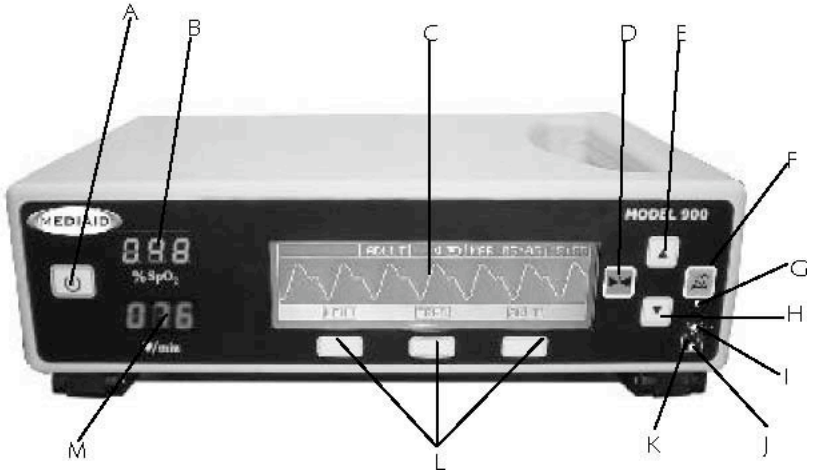


Figure 1: Model 900 Front Panel Display (Pleth View)

A	Power On/Off Key	**H**	DOWN Key
B	%SpO_2 Display (Green)	**I**	AC Power Indicator (Green)
C	Pleth Waveform Display	**J**	Battery Operation Indicator (Orange)
D	Freeze / Unfreeze Key	**K**	Battery Low Indicator (Red)
E	UP Key	**L**	Soft Function Keys
F	MUTE Key	**M**	Pulse Rate Display (Red)
G	Alarm MUTE Indicator (Red)		

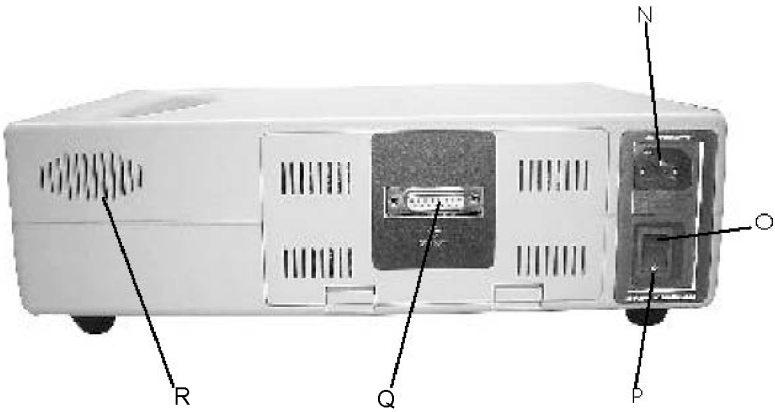


Figure 2: Model 900 Rear Panel
N AC Power Inlet **Q** Data Port Connector **O** Fuse Receptacle **R** Speaker
P AC / Battery Power ON Switch

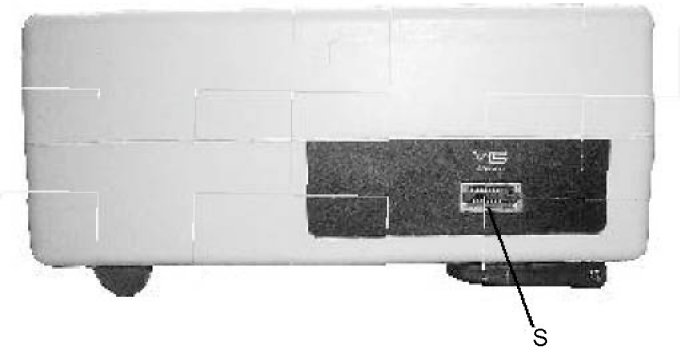


Figure 3: Model 900 Left Side Panel **S** SpO_2 Sensor Port

3.2 SYMBOLOGY & MARKINGS

Symbol	Definition
%SpO_2	Oxygen Saturation Percentage
♥/min	Heart Beats per Minute (BPM)
	Power On / Off
	MUTE Alarm Mute
	Waveform Freeze & Unfreeze
	Increment Key
	Decrement Key
	Battery / Low Battery Indicator
	Data Port
	Sensor Cable Connection
	AC Power Connection
	Attention: Consult Accompanying Documents
	Non-anesthetic Proof
	Type BF Applied Part

3.3 DESCRIPTION OF CONTROLS & CONNECTORS

A. Power ON/OFF Key

The unit is powered on with a short depression of the POWER ON/OFF KEY. A long beep sound followed by a three (3)-seconds display, indicator test and self test is performed automatically. All Light Emitting Diodes (LED's) and the LCD backlight, are illuminated. Carefully observe the Saturation and Pulse Rate LED displays for proper operation of all segments of the display; a non-functioning segment will result in an incomplete numeral and possible erroneous reading.

B. Power ON/OFF Switch

The POWER ON/OFF SWITCH is located at the back of the oximeter below the AC POWER INLET port. When this Switch is turned Off the oximeter gets totally isolated from the AC power and the battery power. When this Switch is turned On, the oximeter gets powered from AC Mains, when it is connected to AC Mains, else it gets powered by battery.

C. Sensor Cable Connection

All Mediaid pulse oximeter sensors with Compushield connectors are compatible with the Model 900. To connect a sensor to the oximeter, align the sensor plug with the jack on the oximeter sensor port and insert gently until an audible "click" is heard, indicating that the plug tab is latched in place. To remove, squeeze the locking tab on the plug and slide the plug out of the jack. Always route cords in such a way so as to prevent accidental tripping and subsequent damage to the oximeter.

D. Power Inlet

For electric power, plug the AC power cord into the AC POWER INLET on the rear panel of the oximeter and then plug the other end of cord into a standard electrical outlet.

E. Data Port

The DATA PORT is used for serial, analog output and for Nurse Call feature. To eliminate risk of shock, take care not to touch the DATA PORT 15-pin Connector and the patient simultaneously. The DATA PORT should be used only for connection to equipment that complies with CSA/IEC/UL601-1.

F. Alarm Mute Key

The ALARM MUTE KEY will be operational only when any oximeter alarm is activated. A short depression of this key silences the alarm for a period of 60 seconds. The ALARM MUTE indicator in the LCD screen (a crossed speaker symbol) will be displayed and the ALARM MUTE indicator LED will glow. Silenced alarms can be reactivated by a short depression of the ALARM MUTE KEY. A long, three-second depression of the key will completely disable the audible alarm till the next Power up. The ALARM MUTE in the LCD screen (a crossed speaker symbol) will begin to flash and the ALARM MUTE indicator LED will glow. Disabled alarms are reactivated by a long depression of the ALARM MUTE KEY. Also the Silenced & Disabled alarms will be reactivated as soon as a fresh alarm condition is generated.

G. Freeze/Unfreeze Key

The FREEZE/UNFREEZE KEY is used to freeze and unfreeze the plethysmographic waveform on the graphic LCD display.

H. Up Key & Down Key

The pulse tone volumes can be adjusted using the UP and DOWN keys. There are five
(5) levels of audible (pulse) tone volume, and “Off”. The pulse tone volume can be increased with the UP key, and decreased or silenced with the DOWN key. These keys are also used to adjust the Alarm limits, alarm volume, contrast, patient type, date & time values, and to move the cursor in the menu / trend view.

I. Soft Function Keys

The three SOFT FUNCTION KEYS have multiple uses depending on the legend displayed in the LCD screen above the key.

3.4 DESCRIPTION OF DISPLAYS & INDICATORS

A. Oxygen Saturation Display

Whenever the pulse oximeter receives at least three (3) valid pulses during a 15-second period, the top green LEDs display the patient's $\%SpO_2$ levels. The display is updated with every normal pulse. A blinking display signals that $\%SpO_2$ monitoring may be adversely affected and indicates that the $\%SpO_2$ levels are out of alarm limits. Dashes "- - - " are displayed under conditions of No Sensor, No Finger, No Pulse and Searching (signal). Blinking Dashes "- - - " are displayed under Low Perfusion condition. "Err" is displayed when there is a hardware error in the oximeter, to indicate an Error.

B. Pulse Rate Display

Whenever the pulse oximeter receives at least three (3) valid pulses during a 15-second period, the bottom red LEDs display the patient's Pulse Rate levels in beats-per-minute. The display is updated with every normal pulse. A blinking display signals that Pulse Rate monitoring may be adversely affected and indicates that the Pulse Rate levels are out of alarm limits. Dashes "- - - " are displayed under conditions of No Sensor, No Finger, No Pulse and Searching (signal). Blinking Dashes "- - - " are displayed under Low Perfusion condition. The Error Code is displayed when there is a hardware error in the oximeter, to indicate an Error.

C. Graphic LCD Display

The GRAPHIC LCD DISPLAY has multiple uses depending on the current mode. In the normal operation whenever the pulse oximeter receives at least three (3) valid pulses during a 15-second period, the plethysmographic waveform is displayed. It also displays Visual Alarms; Searching (for signal); Patient type ; Beep volume level; Alarm Mute status; Battery-charge status; Date & Time details; Function Key labels including Menu Settings, Trend Data and Back light.

D. Battery Operation Indicator

The orange LED for Battery Operation Indication will illuminate when the oximeter is being operated on battery.

E. Battery Low Indicator

The red LED for Battery Low Indication will illuminate when the battery is near depletion, prompting the user to suspend operation of the unit and recharge/change the battery. The oximeter will power off shortly after Battery Low Indication.

F. AC Power Indicator

The green LED for AC Power Indication, located above the BATTERY INDICATORS will illuminate when the oximeter is being powered by AC power. It also indicates that the battery is charging. It is off when the oximeter is being powered by its internal battery.

G. Alarm Mute Indicator

The ALARM MUTE INDICATOR will illuminate and remain on constantly when audible alarms are silenced or disabled.

3.5 DESCRIPTION OF AUDIBLE ALARMS & INDICATORS

A high-pitched, beep-beep tone alarm is activated under the following Alarm conditions:

High or Low Oxygen Saturation Levels

When the high or low Oxygen Saturation levels are breached, a beep alarm along with a blinking SpO_2 display and “SAT-HIGH” or “SAT-LOW” visual indicator is displayed in the graphical LCD display.

High or Low Pulse Rate Levels

When the high or low Pulse Rate levels are breached, a beep alarm along with a blinking SpO_2 display and “BPM-HIGH” or “BPM-LOW” visual indicator is displayed in the graphical LCD display.

Low Perfusion

Under the low perfusion condition, a beep alarm along with blinking Dashes “- - - “ in the %SpO_2 & Pulse Rate displays and a “LOW PERF” visual indicator is displayed in the graphical LCD display.

No Pulse

When the oximeter does not detect a valid pluse after searching for approximately 45 seconds and no valid pulse signal is detected, Dashes "- - - " in the $\%SpO_2$ & Pulse Rate displays are indicated and "NO PULSE" visual indicator is displayed in the graphical LCD display.

No Finger in Sensor

When there is no finger in the sensor, beep alarm along with Dashes "- - - " in the $\%SpO_2$ & Pulse Rate displays and a blinking "NO FINGER" visual indicator is displayed in the graphical LCD display.

No Sensor / Disconnected Sensor

When the sensor is removed, disconnected or not inserted in the oximeter, beep alarm is sounded along with Dashes "- - - " in the $\%SpO_2$ & Pulse Rate displays and a blinking "NO SENSOR" visual indicator is displayed in the graphical LCD display.

Power-On Audio Indicator

When the oximeter is powered on with the press of the POWER ON/OFF Key, a long beep indicating that the oximeter is powered on.

Pulse Beep Audio Indicator

A single beep sounds for each detected valid pulse that varies in pitch with changing oxygen saturation, falling in pitch with reduced saturation and rising as saturation increases.

Chapter 4:
Setup

4.1 UNPACKING AND INSPECTION

Notify the carrier if the shipping carton is damaged. Unpack the Model 900 and components. If anything is missing as per the List of Components or damaged, contact Mediaid Inc. or the Mediaid local authorized distributor.

4.2 LIST OF COMPONENTS

1. Model 900 Pulse Oximeter
2. Mediaid Reusable sensor
3. Model 900 User's Manual
4. AC Power Cord
5. Additional Accessories as ordered, if any

4.3 OXIMETER SETUP

General Warnings

WARNING

To ensure patient safety, do not place the oximeter in any position that might cause it to fall on the patient.

WARNING

As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

WARNING

To ensure accurate performance and prevent device failure, do not subject the Model 900 to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.

WARNING

Disconnect the Model 900 and Mediaid sensor from the patient during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Model 900 may affect the MRI image and the MRI unit may affect the accuracy of oximeter measurements.

WARNING

Do not use a Model 900 oximeter, AC Power cord, sensor, sensor cable or connector that appear to be damaged.

WARNING

The Model 900 is not defibrillator-proof. However, it may remain attached to the patient during defibrillation or while an electrosurgical unit is in use, but the readings may be inaccurate during use and shortly thereafter.

Connecting the Model 900 to AC Power

The POWER ON/OFF SWITCH is located at the back of the oximeter below the AC POWER INLET port. When this Switch is turned Off the oximeter gets totally isolated from the AC power and the battery power. When this Switch is turned On, the oximeter gets powered from AC Mains, when it is connected to AC Mains, else it gets powered by battery.
The Model 900 operates on AC power when the oximeter is connected to the AC power source (wall outlet) with a power cord.

Operating on a Discharged Battery

The battery may discharge during prolonged storage or shipment. If the oximeter has been in storage for more than 2 months, it is advisable to plug the oximeter into an AC outlet and allow the battery to charge for approximately 45 minutes before attempting to operate the instrument on AC power.

To charge a low battery, connect the oximeter to AC power. A full charge of a completely discharged battery takes approximately 16 hours while the oximeter is turned off and it takes approximately 20 hours while the oximeter is turned on.

Setting Up

- Place the Model 900 on a flat surface near the patient.
- Plug the female connector end of the power cord into the rear of the oximeter. Use only the AC power cord provided by Mediaid.
- Plug the male connector end of the power cord into a properly grounded AC outlet.
- Switch on the POWER ON/OFF SWITCH located at the rear side of the oximeter.
- Verify that the AC POWER INDICATOR is lit. If it is not, ensure that the POWER ON/OFF SWITCH is in the “ON” position. If the indicator still does not light, check the local AC power at the wall outlet. If the problem still persists, contact Mediaid Inc. or the Mediaid local authorized distributor/service center.
- Select a Mediaid sensor appropriate for the patient to be monitored (see the *Sensors* section of this manual for sensor selection information).

Chapter 5:
Sensors

5.1 SELECTING A SENSOR

WARNING
Before use, carefully read the sensor directions for use, including all warnings, cautions and instructions.

WARNING
Use only Mediaid sensors and sensor cables with this oximeter. Other sensors or sensor cables may cause improper Model 900 performance

WARNING
Do not use a damaged sensor or sensor cable. Do not use a sensor with exposed optical components.

WARNING
Do not attach any cable intended for other use, to the Model 900 sensor port.

WARNING
Tissue damage can be caused by incorrect applications or duration of use of a SpO_2 sensor. Inspect the sensor site periodically as directed in the sensor directions for use.

When selecting a sensor, consider the patient's weight and activity level, the adequacy or perfusion, the available sensor sites, the need for sterility, and the anticipated duration of monitoring. For more information, refer to Table 1 or contact Mediaid Inc. or the Mediaid local authorized distributor.

TABLE 1 : Mediaid Sensors

S.No.	Sensor	Part Number
1	Universal Hinged Sensor, Compushield connector, 30" cable	POX050-100S
2	Universal Hinged Sensor, Compushield connector, 96" cable	POX050-105S
3	Spot Check Soft Sensor, Compushield connector, 30" cable	POX050-150S
4	Great Toe Sensor, Compushield connector, 96" cable	POX050-220S
5	Small Soft Sensor, Compushield connector, 96" cable	POX050-300S
6	Large Soft Sensor, Compushield connector, 96" cable	POX050-400S
7	Pediatric Soft Sensor, Compushield connector, 96" cable	POX050-310S
8	Earlobe Clip Sensor, Compushield connector, 96" cable	POX050-710S
9	Pediatric Adjustable Sensor, Compushield connector, 96" cable	POS050-530S
10	Tape-on Sensor, Compushield connector, 96" cable	POX050-850S
11	Adult R-Adhesive Sensor, Compushield connector, 96" cable	POX050-905S
12	Pediatric R-Adhesive Sensor, Compushield connector, 96" cable	POX050-820S
13	6 Feet Extension Cable, Compushield to Compushield connector	POX055-600
14	6 Feet Adapter Cable, Compushield to RJ12 connector	POXxxx-xxx
15	Adult Adhesive Disposable Sensor, RJ12 connector	POX020-950
16	Pediatric Adhesive Disposable Sensor, RJ12 connector	POX020-960

5.2 BIOCOMPATIBILTY TESTING

Biocompatibility testing has been conducted on Mediaid sensors in compliance with ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1.

5.3 PERFORMANCE CONSIDERATIONS

Inaccurate Measurements can be caused by:

- Incorrect application of the sensor
- Placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Ambient light
- Prolonged patient movement

Loss of Pulse Signal can occur for the following reasons:

- The sensor is too tight
- A blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- There is an arterial occlusion proximal to the sensor

Use Only Mediaid Sensors and Sensor Cables

Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the directions of 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.

WARNING

Tissue damage can be caused by incorrect application or duration of use of a SpO2 sensor. Inspect the sensor site as directed in the sensor directions for use.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps and direct sunlight can interfere with the performance of the SpO_2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with an opaque material.

NOTE

Failure to take this precaution 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 that the sensor is properly and securely applied
- Move the sensor to a less active site
- Use an adhesive sensor that tolerates some patient movement.
- Use a new sensor with fresh adhesive backing

NOTE

The preceding section pertains to the patient and environmental conditions that can be addressed by sensor selection and application. For information regarding the impact of other patient environmental conditions on oximeter performance, see "Performance Considerations" in the *Start Up and Use* section of this manual.

Chapter 6:
Start Up and Use

6.1 BASIC OPERATION

WARNING
The Model 900 is a prescription device and is to be operated by qualified personnel only.

WARNING
Do not lift the oximeter by the sensor cable or power cord because the cable could disconnect from the oximeter, causing the oximeter to drop on the patient.

WARNING
The Model 900 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

WARNING
Pulse oximeter readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of the manual for specific safety information.

WARNING
Do not silence the audible alarm or decrease its volume if the patient could be compromised.

WARNING
Each time the oximeter is used, check alarm limits to ensure that they are appropriate for the patient being monitored.

Important! Prior to using the Model 900, carefully read this manual, accessory directions for use, all precautionary information in bold-face type, and all specifications.

Before using the Model 900 in a clinical setting, verify that the oximeter is working properly and is safe to use. Proper working condition can be verified by successful completion of the power-on self-test, and by following instructions contained in the "Monitoring Mode" paragraph of this section.

Power-On

WARNING
Ensure that the speaker is clear of any obstruction. Failure to do so could result in an inaudible alarm tone.

1. Align the plug with the jack on the left side panel of the oximeter and insert the Mediaid sensor with Compushield connector gently until an audible "click" is heard, indicating that the plug tab is latched in place. Always route cords in such a way so as to prevent accidental tripping and subsequent damage to the oximeter.
2. Apply the sensor to the patient as described in the sensor directions for use.
3. For electric power, plug the AC power cord into the pulse oximeter's AC POWER INLET and then plug the other end of cord into a standard electrical outlet.

4. Switch on the oximeter by pressing the POWER ON/OFF SWITCH located at the rear side of the oximeter to the down position.
5. Turn on the Model 900 by pressing the POWER ON/OFF Key in the front side of the oximeter. All the oximeter LEDs and graphic LCD display light up. The LCD displays the Mediaid logo, the software version, the model number and the unit undergoes a Self-test.
6. After the Mediaid logo disappears from the graphic LCD display, the option to “Clear previous Trend?” appears with a choice for “Yes” or “No” in the Soft keys, which lasts for approximately 3 seconds on the LCD screen. Depending on the choice made, the previous trend data is either erased or retained. If no choice is made then the trend data is retained and the oximeter automatically proceeds to the monitoring mode.
7. If a sensor is connected to the oximeter and the patient, the Model 900 displays dashes “- - -” in the %SpO_2 and the Pulse Rate Displays and a “Searching” message is displayed on the graphic LCD display, while it searches for a valid pulse. If a sensor is not attached to the oximeter, the Model 900 displays dashes “- - -” in the %SpO_2 and the Pulse Rate Displays and the blinking message of “No Sensor” appears in the graphic LCD display and an Audio alarm is activated. If the patient is not connected to the sensor but the sensor is connected to the oximeter, the Model 900 displays dashes “- - -” in the %SpO_2 and the Pulse Rate Displays and a blinking “No Finger” message appears in the graphic LCD display and an Audio alarm is activated.

When a valid pulse is detected, the Model 900 enters the Monitoring Mode and a display similar to the one in Figure 4 is displayed.

Figure 4: Monitoring Mode Display – Pleth View

Adult, Pediatric and Neonatal Settings

> WARNING
> Each time the oximeter is used, check alarm limits to ensure that they are appropriate for the patient being monitored.

Before monitoring, ensure that the Model 900 is in the patient setting (adult, pediatric or neonatal) appropriate for the patient being monitored. The default power-on setting from the factory is for adult patients. Patient type is displayed on the LCD display If the oximeter is in adult setting, the adult limits screen appears in the display on selection of the MENU and the ALRM soft keys.
To change the Model 900, from the adult to pediatric or to the neonatal setting, press the MENU and then the SYST soft keys. Then you may select the Patient option with the press of SELT soft key and then using the UP and DOWN keys change the patient setting to Pediatric or to Neonate. The same pattern of Soft key presses can be used to change back to the adult setting.
When the patient setting (adult, pediatric or neonatal) is changed, alarm limits return to power-on defaults for the respective settings and previous patient data is cleared from the display. Refer to the Default Setting under *Start Up and Use*.

Contrast

To adjust the screen contrast, press the MENU and then the SYST soft keys. Select the CONTRAST using the UP & DOWN keys, then press the “SELT” soft key. Now adjust the UP & DOWN keys to increase or decrease the contrast.

Monitoring Mode

In the Monitoring mode display-PLETH VIEW (Figure 4), the Model 900 displays the $\%SpO_2$ & the Pulse Rate readings on the LED displays and a plethysmographic waveform on the LCD display.
The $\%SpO_2$ is displayed for values between 0 to 100%. Pulse rates are displayed for values from 20 to 253 beats per minute.
A single beep sounds for each detected valid pulse that varies in pitch with changing oxygen saturation, falling in pitch with reduced saturation and rising as saturation increases.

NOTE

Verify that indicators, display information, and audible sounds including alarms are operational, indicating that the oximeter is functioning. Observe movement of the plethysmographic waveform, and listen for pulse beeps to verify that measurements are being made.

If any action does not seem appropriate, do not use the oximeter. Instead, contact Mediaid Inc. or the Mediaid local authorized distributor/service center.

Pulse Search

In the Monitoring Mode, if the acquired pulse is lost, the oximeter enters Pulse Search Mode during which, the oximeter attempts to detect a pulse from which to take a measurement and a “SEARCHING” indicator is displayed on the graphical LCD display. If the pulse is lost for more than 45 seconds then the oximeter enters the No Pulse Mode and a “NO PULSE” indicator is displayed on the graphical LCD display.

At Initial Power-Up (Sensor Attached to Oximeter)

The Model 900 displays the Mediaid logo, the software version number and the model number. The oximeter enters the Pulse Search Mode if the sensor is connected to a patient and the “SEARCHING” status is displayed on the graphic LCD display. If an attached sensor is not connected to a patient, the oximeter displays Dashes “- - -” in the $\%SpO_2$ & the Pulse Rate displays and the blinking “NO FINGER” indicator displays on the graphic LCD screen display. If the sensor is connected to the patient, the Model 900 enters the Monitoring Mode when a pulse is detected.

At Initial Power-Up (No Sensor Attached to Oximeter)

The Model 900 displays the Mediaid logo, the software version number and the model number. The oximeter displays Dashes “- - -” in the $\%SpO_2$ & the Pulse Rate displays and the blinking “NO SENSOR” indicator displays on the graphic LCD screen display.

After Taking Measurements

If a pulse was previously acquired and then lost, the Model 900 enters Pulse Search, and the "SEARCHING" status is displayed on the graphic LCD display. The last detected readings are displayed while the oximeter searches for a valid pulse. When the oximeter does not detect any valid pulse for more than 45 seconds, it considers it as No pulse, displays blinking Dashes "- - -" in the %SpO_2 & the Pulse Rate displays, "NO PULSE" indicator in the graphical LCD display and an Alarm beeps.
When a valid pulse is detected, the Model 900 exits the Pulse Search Mode and displays the current reading. The "SEARCHING" status displayed on the graphic LCD screen goes off.

Sensor Disconnected at Oximeter End

If the sensor cable becomes disconnected from the oximeter during monitoring, an alarm sounds, values for SpO_2 and pulse rate are replaced with dashes "- - -", and a blinking "NO SENSOR" indicator is displayed on the graphic LCD display.

Sensor Disconnected at Patient End

If the sensor becomes disconnected from the patient during monitoring, an alarm sounds, values for SpO_2 and pulse rate are replaced with dashes "- - -" and a blinking "NO FINGER" message is displayed on the graphic LCD display.

6.2 DIAGNOSTIC-TEST

1. To get into the Diagnostic-test mode, the first left hand side Soft Key and the MUTE Key should be held pressed simultaneously for 3 seconds as soon as the Mediaid logo appears on the LCD display.
2. The oximeter starts a Diagnostic-test procedure in which it tests its circuitry in the following sequence:
   - the 7-segment LED displays for %SpO_2 & Pulse Rate test displays all "000", "111",….. up to "999" for 1 second duration each.
   - the graphic LCD display test lights up all the pixels starting from left to right and then top to bottom.
   - the speaker test for the 5 levels by sounding the beep tone in decreasing and then increasing speaker volumes

- Nurse Call feature test by activating the Nurse call relay for 5 on/off cycles
- RS 232 port test involves plugging the serial cable at the oximeter's data port and with the press of the MUTE key, the test result will be displayed as "PASS" or "FAIL"
- Analog channel test involves checking voltage levels at the SpO_2 & Pulse Rate pins with respect to the grounding pin of the analog port
- Key function test involves display of the respective key names against the press of the particular key.

To resume normal operation of the oximeter, the oximeter needs to be switched off and then turned on.

> CAUTION
> If any failure noticed in the above Diagnostic-test procedure, do not use the oximeter. Instead contact Mediaid Inc. or the local authorized distributor service center.

6.3 ALARMS

A high-pitched, beep-beep tone alarm is activated under the following conditions:

High or Low Oxygen Saturation Levels

When the high or low Oxygen Saturation levels are breached, a beep alarm along with a blinking SpO_2 display and "SAT-HIGH" or "SAT-LOW" visual indicator is displayed in the graphical LCD display.

High or Low Pulse Rate Levels

When the high or low Pulse Rate levels are breached, a beep alarm along with a blinking SpO_2 display and "BPM-HIGH" or "BPM-LOW" visual indicator is displayed in the graphical LCD display.

Low Perfusion

Under the low perfusion condition, a beep alarm along with blinking Dashes "- - - " in the %SpO_2 & Pulse Rate displays and a "LOW PERF" visual indicator is displayed in the graphical LCD display.

No Pulse

When the oximeter is searching for approximately 45 seconds and no valid pulse signal is detected, Dashes "- - - " in the %SpO_2 & Pulse Rate displays are indicated and "NO PULSE" visual indicator is displayed in the graphical LCD display.

No Finger in Sensor

When there is no finger in the sensor, beep alarm along with Dashes "- - - " in the %SpO_2 & Pulse Rate displays and a blinking "NO FINGER" visual indicator is displayed in the graphical LCD display.

No Sensor / Disconnected Sensor

When the sensor is removed, disconnected or not inserted in the oximeter, beep alarm is sounded along with Dashes "- - - " in the %SpO_2 & Pulse Rate displays and a blinking "NO SENSOR" visual indicator is displayed in the graphical LCD display.

6.4 ADJUSTABLE SETTINGS

The following adjustments can be made using the UP/DOWN and the MUTE keys.

- Pulse beep volume
- Alarm volume
- Alarm silence
- Disabling audible alarms

Pulse Beep Volume

To adjust the pulse beep volume during normal monitoring, press the UP or DOWN Key to change the beep volume setting. There are five (5) levels of audible (pulse) tone volume, and "Off".

Alarm Volume

To change the Alarm volume, press the MENU and then the ALRM soft keys.
Select the ALARM VOL using the UP & DOWN keys, then press the "SELT" soft key. Now adjust the UP & DOWN keys to increase or decrease the Alarm volume. There are five (5) levels of audible Alarm volume, and "Off".

Alarm Mute

The ALARM MUTE KEY will be operational only when any oximeter alarm is activated.

A short depression of this key silences the alarm for a period of approximately 60 seconds. The ALARM MUTE indicator in the LCD screen (a crossed speaker symbol) will be displayed and the ALARM MUTE indicator LED will glow. Silenced alarms can be reactivated by a short depression of the ALARM MUTE KEY.

The Silenced alarms will be reactivated as soon as a fresh alarm condition is generated.

Visual indications of an alarm conditions cannot be turned off. For example, if the $\%SpO_2$ upper alarm limit is breached, the audio alarm can be silenced for the alarm silence duration, but the $\%SpO_2$ value in the LED display and the "HIGH-SAT" indicator in the graphical LCD display will continue to blink indicating the Alarm condition.

If the alarm condition is still present when the alarm silence duration has elapsed, the alarm will sound again.

WARNING

Do not silence an audible alarm or decrease its volume if patient safety could be compromised.

Disabling Audible Alarms

A long, three (3)-seconds depression of the key will completely disable the audible alarm till the next Power up. The ALARM MUTE in the LCD screen (a crossed speaker symbol) will begin to flash and the ALARM MUTE indicator LED will glow. Disabled alarms are reactivated by a long, three (3)-seconds depression of the ALARM MUTE KEY.

The Disabled alarms will be reactivated as soon as a fresh alarm condition is generated.

Visual indications of an alarm conditions cannot be turned off. For example, if the $\%SpO_2$ upper alarm limit is breached, the audio alarm can be disabled, but the $\%SpO_2$ value in the LED display and the "HIGH-SAT" indicator in the graphical LCD display will continue to blink indicating the Alarm condition.

6.5 MENU

Menu Structure

The three Soft keys on the front panel are used to view or adjust the following Model 900 settings or functions:

- $\%SpO_2$ and Pulse Rate alarm limits
- Alarm volume
- Patient type
- Time and date settings
- Contrast
- Power Save mode select
- Tabular Trend data view ($\%SpO_2$ and Pulse Rate)
- Graphical Trend data view ($\%SpO_2$ and Pulse Rate)
- Display backlight On /Off

To select a menu field, press and release the corresponding soft keys directly below the field.

A description of each menu item is included in the following paragraphs.

NOTE

If, after accessing a submenu, no keys are pressed for approximately 15 seconds, the display will time out and return to the main menu.

6.6 LIMITS

WARNING

Each time the oximeter is used, check alarm limits to ensure that they are appropriate for the patient being monitored.

Overview

When the Model 900 is first turned on, alarm limits are set to their power-on factory default values.

Alarm limits may be changed from their power-on factory default values if necessary, as described below. Limit changes made will remain in effect until changed again.

Viewing Current Alarm Limits

To view the current alarm limit values from the main menu, press the MENU and then the ALRM soft keys. The current upper and lower alarm limits for %SpO_2 and Pulse rate displayed.

Changing Alarm Limits

Use the UP / DOWN keys to select the parameter. Press the SELT soft key to activate the parameter whose setting is to be changed. Use the UP/DOWN Keys to increase/ decrease the alarm limit. The settings take effect immediately and remain in effect when that alarm setting menu is exited.

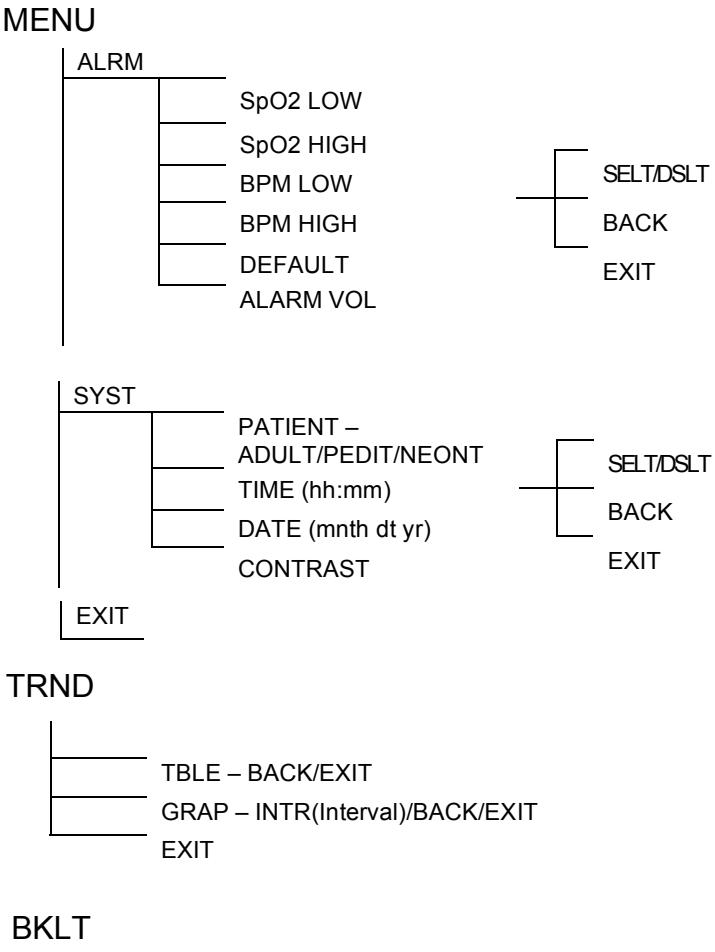
Power-On Factory Default Alarm Limits

If alarm limits are to be reversed back to the Model 900's power-on factory default values, then one has to select the MENU, ALRM soft keys and then using the UP/ DOWN key select DEFAULT. Press the SELT soft key. The oximeter reverts to the power-on factory default values of the %SpO_2 and Pulse Rate Alarm limits for that particular patient type.

Figure 5: Alarm Limits Selection

Table 2: Main Menu

Main Menu



6.7 TREND

The Model 900 can display tabular and graphical trends for SpO_2 and Pulse rate. The trend data is stored at 1minute interval. The oximeter stores up to 24 hours of trend data.

The trend data for SpO_2 and Pulse rate is displayed in tabular form with the use of the TRND and TBLE soft keys. The tabular trend displays the S.No., Date, Time, SpO_2 and Pulse rate values. The cursor is moved up or down to scroll across the range of stored readings by using the UP/DOWN Keys. When the trends are displayed in tabular form, the most recent readings are at the top of the table and subsequent readings follow this (Fig. 6).

> **NOTE**
> The screen will return to the monitoring mode if no keys are pressed for approximately 15 seconds.

The trend data for SpO_2 and Pulse rate is displayed in graphical form using the TRND, GRAP and INTR soft keys. Time intervals for display of the data are 30 minutes, 1, 2, 6, 12 and 24 hours. All data are displayed in a line graph format. When the trends are displayed, the most recent readings are on the left side of the graph. Using the UP/ DOWN keys, the cursor can be moved across the graphical trend. The values of the parameter at the cursor are indicated on the left side of the LCD display (Fig. 7). These values are not the current patient readings but represent the values at the cursor.

Periods of time when no measurements were acquired are indicated by blank spaces in the graph as shown in Fig. 7.

Figure 6: Tabular SpO_2 & Pulse Rate Trend

Figure 7: Graphical SpO_2 & Pulse Rate Trend

Scale

For the %SpO_2, the SCALE in the graphical trend is from 70% to 100% SpO_2. For the Pulse Rate the SCALE in the graphical trend is from 20 to 255. This will be a fixed vertical scaling.

Delete

When one turns on the Model 900 by pressing the POWER ON/OFF Key in the front side of the oximeter. All the oximeter LEDs and graphic LCD display light up. After this the Mediaid logo disappears from the graphic LCD display, the option to “Clear previous Trend?” appears with a choice of “Yes” or “No” in the Soft keys, which lasts for approximately 3 seconds on the LCD screen. Depending on the choice made, the previous trend data is either erased or retained. If no choice is made then the trend data is retained and the oximeter automatically proceeds to the monitoring mode.

6.8 SETUP

Time

By pressing the MENU and the SYST soft keys the users is provided with the option to change the Time settings of the oximeter.
Using the UP/DOWN keys the TIME option can be selected. Using the SELT soft key and then the UP/DOWN keys the hour settings can be selected. After the required change the press of DSLT soft key automatically moves the cursor to the minutes location. Using the UP/DOWN keys, the minutes settings can be selected. The press of DSLT soft key automatically moves the cursor back to the hour location. Then using the UP/DOWN keys other setting option can be selected. The press of the BACK or EXIT soft key options help you exit the Time change option.

Date

By pressing the MENU and the SYST soft keys the user is provided with the option to change the Date settings of the oximeter
Using the UP/DOWN keys the DATE option can be selected. Using the SELT soft key
and then the UP/DOWN keys the Month settings can be selected. After the required change the press of DSLT soft key automatically moves the cursor to the Date location. Using the UP/DOWN keys, the date settings can be selected. The press of DSLT soft
key automatically moves the cursor to the Year location. Then using the UP/DOWN keys, the Year settings can be selected. The press of the DSLT soft key automatically moves the cursor back to Month location. Then using the UP/DOWN keys other setting option can be selected.

The press of the BACK or EXIT soft key options help you exit the Date change option.

> NOTE
> The Model 900 will time out in approximately 15 seconds if none of the soft keys are pressed in the SYST or Time & Date change option.

Nurse Call

The NURSE CALL option provides the capability of communicating to a Nurse Alert system in any Alarm conditions, through the Serial Port provided at the rear side of the oximeter.

> WARNING
> The nurse call feature should not be used as the primary source of alarm notification. The audible and visual alarms of the oximeter, used in conjunction with the clinical signs and symptoms, are the primary sources for notifying medical personnel that an alarm condition exists.

The nurse call feature of the Model 900 works in conjunction with the nurse call system of the institution when the oximeter sounds an audible alarm. It is accessed through the data port (pins 7, 8 and 15, as indicated in Table 7-Data Port pinouts).

> WARNING
> The nurse call feature is not functional whenever the oximeter alarms are silenced.

The nurse call feature is available when the Model 900 is operated on AC power or its internal battery, and the oximeter has been electrically connected to the hospital's nurse call system. Qualified service personnel may refer to the Model 900 service manual for complete connection instructions.
Prior to using the oximeter in a clinical setting, test the nurse call feature by creating an alarm condition, then verifying that the hospital's nurse call system is activated.

Analog

The ANALOG option provides the capability to produce variable calibrating voltages to calibrate instruments such as a chart recorder. Refer to the “Analog Outputs” heading of Data Port Protocol for a more thorough explanation of these settings.

Back Light

The BKLT soft key turns the backlight on or off. The backlight can be turned off only when the patient is connected to the sensor and the sensor to the oximeter and there is no Alarm condition. When the backlight is off, pressing any soft key turns the backlight on. Any alarm will turn the backlight on. Turning the backlight off conserves the battery power.

> **NOTE**
> The Back Light cannot be turned off under any Alarm condition.

Default Settings

The Model 900 is shipped with factory default settings (Table 3 and Table 4). Users can change the factory default settings with the use of the menu options with the soft keys and the UP/DOWN keys. These user-defined settings will remain for that patient type even when the unit is powered on the next time.

> **NOTE**
> Factory default settings are constants that cannot be changed without re-compiling software.

Table 3: Factory Default Settings (Adult & Pediatric)

Monitoring Mode	Adult & Pediatric
%SpO2 Lower Alarm Limit:	85%
%SpO2 Upper Alarm Limit:	100%
Alarm Silence Duration:	60 Seconds
Alarm Volume:	75 dB (A) peak at 1 meter (volume setting of 5)
Data Port Baud Rate	9600
Data Port Protocol:	ASCII

Monitoring Mode	Adult & Pediatric
Display Contrast:	Midrange
Display Format:	Pleth on LCD & numeric value of SpO2 & Pulse Rate on 7-segment LED
Nurse Call Polarity:	Normally Low
Pulse Beep Volume:	72 dB(A) at 1 meter (volume setting of 4)
Pulse Rate Lower Alarm Limit:	40 beats per minute
Pulse Rate Upper Alarm Limit:	170 beats per minute
Trend Display:	%SpO2 & Pulse rate

Table 4: Factory Default Settings (Neonate)

Monitoring Mode	Neonate
%SpO2 Lower Alarm Limit:	80%
%SpO2 Upper Alarm Limit:	95%
Alarm Silence Duration:	60 Seconds
Alarm Volume:	75 dB (A) peak at 1 meter (Volume setting of 5)
Data Port Baud Rate	9600
Data Port Protocol:	ASCII
Display Contrast:	Midrange
Displace Format:	Pleth on LCD & numeric value of SpO2 & Pulse Rate on 7-segment LED
Nurse Call Polarity:	Normally Low
Pulse Beep Volume:	72 dB (A) at 1 meter (volume setting of 4)
Pulse Rate Lower Alarm Limit:	90 beats per minute
Pulse Rate Upper Alarm Limit:	190 beats per minute
Trend Display:	%SpO2 & Pulse rate

6.9 BATTERY OPERATION

The Model 900 has an internal battery that may be used to power the oximeter during mobile application or when AC power is not available. A new, fully charged battery will provide at least 3 hours of monitoring time under the following conditions: no audible alarms sound, and no analog or serial output devices attached.
Before attempting to turn on the Model 900 whose battery charge has been depleted, first plug the oximeter into an AC outlet to allow the battery to charge for a few minutes. The oximeter may then be powered on.
To charge a dead battery, connect the oximeter to AC power. To fully charge the battery it takes 16 hours while the oximeter is turned off.

NOTE
Whenever the oximeter is connected to AC power, the battery is being charged. Therefore, it is recommended that the oximeter remains connected to AC power when not in use. This will make available a fully charged battery for use at any time.

Low Battery Indicator

The red LED for Battery Low Indication will illuminate when the battery is near depletion, prompting the user to suspend operation of the unit and recharge/change the battery. Also the Battery symbol in the LCD display will blink. The oximeter will power off shortly after Battery Low Indication.
If the oximeter is not connected to AC power within approximately 15 minutes, it will shut down.
It is recommended that qualified service personnel replace the internal battery every 18 months.

NOTE
As the battery is used and recharged over a period of time, the amount of time between the onset of the low battery indicator and the instrument shut-off may become shorter.

CAUTION
If the Model 900 is to be stored for a period of 3 months or longer, notify service personnel to remove the battery from the oximeter prior to storage. Recharge the battery when it has not been charged for 2 or more months.

6.10 DISPOSAL OF DEVICE COMPONENTS

> CAUTION
> Follow local governing ordinances and recycling instructions regarding disposal or recycling of device components, including batteries.

6.11 PERFORMANCE CONSIDERATIONS

Impact of Patient Conditions on Oximeter Readings

Certain patient conditions can affect the measurements of the Model 900 and cause the loss of the pulse signal.

> WARNING
> Pulse oximetry readings and pulse signals can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

Inaccurate Measurements can be caused by:

- Prolonged patient movement
- Venous pulsations
- Intravascular dyes, such as indocyanine green or methylene blue
- Significant levels of dysfunctional hemoglobins
- Defibrillation

Ambient environmental conditions and sensor application errors, which can affect pulse oximetry readings, are discussed in the *Sensors* section of this manual and in the sensor directions for use.
The effects of electromagnetic interference on oximetry readings are discussed in the *Troubleshooting and Maintenance* section of this manual.

Chapter 7:
Troubleshooting and Maintenance

7.1 TROUBLE SHOOTING

WARNING
If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the oximeter is functioning correctly.

WARNING
The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.

Error Codes

When the Model 900 detects an error condition, it will display the letters "ERR" in the display for %SpO2 followed by an error code in the display for Pulse Rate.
When an error code (other than the ones listed in Table 5) is displayed, turn the instrument off and back on again. If the error code reappears, record it and notify service personnel.
Error messages will be displayed along with the error codes listed in Table 5. If the error codes are encountered, perform the prescribed action as indicated in the table.

Table 5: Error Codes and Messages.

Error Code	Error Message
001	Module Communication Error
002	RTC No Updation Error
003	EEPROM Read/Write Error
004	ADC Error

Other Messages

In addition to the messages listed in Table 5, the following messages may be encountered.

NO SENSOR – The sensor has disconnected or removed from the oximeter, or the sensor /cable wiring is defective. Press the ALARM SILENCE Key to silence the alarm. Check the connections. If this does not correct the problem, replace the sensor and / or cable.

NO FINGER – The sensor has become disconnected from the patient. Press the ALARM SILENCE key to silence the alarm. Check the sensor to patient connection. If this does not correct the problem, replace the sensor.

Suggested Corrective Actions

If you experience a problem while using the model 900 and are unable to correct it, contact Mediaid Inc. or the Mediaid local authorized distributor/service center. The Mediaid service manual, which is for use by qualified service personnel, provides additional troubleshooting information.

Following is a list of possible errors and suggestions for correcting them.

1. There is no response to the POWER ON/OFF Key.
    - The ON/OFF SWITCH may not have been switched On.
    - If operating on AC power, the fuse at AC mains may have blown. Notify service personnel to check and, if necessary replace the fuse.

- If operating on battery power, the battery may be missing or discharged.
- If the battery is discharged, notify service personnel to charge or replace the battery.

2. One or more display elements or indicators do not light during the power-on self-test.
   - Do not use the model 900; contact Mediaid Inc. or the Mediaid local authorized distributor/service center.
3. The oximeter is operating on battery power, even though it is connected to AC.
   - Make sure that the power cord is properly connected to the Model 900
   - Check to see if power is available to other equipment on the same AC circuit.
   - The fuse at AC mains may have blown. Notify service personnel to check and, if necessary replace the fuse.
4. The SEARCHING Indicator is lit for more than 45 seconds (before any measurements are taken).
   - Check the sensor directions for use to determine if an appropriate sensor is being used and it is applied properly. Check sensor and sensor cable connections. Test the sensor on someone else. Try another sensor or sensor cable.
   - Perfusion may be too low for the model 900 to track the pulse. Check the patient. Test the instrument on someone else. Change the sensor site. Try another type of sensor.
   - Excessive patient movement may be preventing the model 900 from tracking the pulse. Keep the patient still, if possible. Verify that the sensor is securely applied, and replace it if necessary. Change the sensor site. Use a type of sensor that tolerates more patient movement; for example, an adhesive sensor OR Tape-On Finger Sensor.
   - The sensor may be too tight, there may be excessive ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition sensor, as necessary.
   - Excessive environmental motion or electromagnetic interference may be preventing the model 900 from tracking the pulse.

Remove the source of interference or try to stabilize the environment, or do both.

5. The SEARCHING Indicator lights after successful measurements have been made.
   - Check the patient.
   - Perfusion may be too low for the model 900 to track the pulse. Test the instrument on someone else. Change the sensor site. Try another type of sensor.
   - Prolonged patient movement may be preventing the Model 900 from tracking the pulse. Verify that the sensor is securely applied and replace it if necessary. Change the sensor site. Use a type of sensor that tolerates more patient movement; for example, an adhesive sensor or Tape-On Finger Sensor.
   - The sensor may be too tight, there may be excessive ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition sensor, as necessary.
   - Excessive environmental motion or electromagnetic interference may be preventing the Model 900 from tracking the pulse. Remove the source of interference to try to stabilize the environment, or do both.

Other physiological conditions or medical procedures that may interfere with the oximeter's measurements include dysfunctional hemoglobin, arterial dyes, and dark pigment.

7.2 EMI (ELECTROMAGNETIC INTEFERENCE)

CAUTION

This device has been tested and found to comply with the limits for medical devices to the IEC 601-1-2:1993, EN 60601-1-2:1994, Medical Device Directive 93/ 42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare environments (for example, electrosurgical units, cellular phones, mobile tow-way radios, electrical appliances, and high-definition television), it is possible that high level of such interference due to close proximity or strength of a source may result in disruption or performance of this device.

The model 900 is not designed for use in environments in which the pulse can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or oximeter may not seem to operate correctly.

Erratic readings, cessation of operation, or other incorrect functioning may evidence disruption. If this occurs, the site of use should be surveyed to determine the source of this disruption, and the following actions taken to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the offending device.
- Reorient or relocate the interfering equipment.
- Increase the separation between the interfering equipment and this equipment.

The Model 900 generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity.

If assistance is required, contact Mediaid Inc. or the Mediaid local authorized distributor / service center.

7.3 OBTAINING TECHNICAL ASSISTANCE

For technical information and assistance, or to order parts or a service manual, contact Mediaid Inc. or the Mediaid local authorized distributor/service center. The service manual includes block diagrams and a parts list required by qualified personnel when servicing the Model 900.

When calling Mediaid Technical Services Department or your local Mediaid representative, you may be asked to tell the representative, you may be asked to tell the representative the software version number of model 900.

The software version appears in the oximeter display each time the oximeter is switched on. Write the number down and have it available whenever requesting technical assistance.

Returning the Model 900

Contact Mediaid Inc. or the Mediaid local authorized distributor/service center, for shipping instructions including a "Return Authorization Number (RAN)". Pack the model in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect it during shipping.

Return the model by any shipping method that provides proof of delivery.

7.4 MAINTENANCE

Service

The Model 900 requires no calibration

The battery should be replaced at least every 12 months. Refer to the Model 900 service manual for the battery changing procedure.

WARNING
The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.

If service is necessary, contact Mediaid Inc. or the Mediaid local authorized distributor/ service center.

Periodic Safety Checks

It is recommended that the following checks be performed every 12 months.

- Inspect the equipment for mechanical and functional damage.
- Inspect the safety relevant labels for legibility.

Performance Verification

If the oximeter has been visibly damaged or subjected to mechanical shock (for example, if dropped), qualified service personnel should perform the procedure in the Performance Verification section of the service manual.

Cleaning

> **WARNING**
> Do not spray, pour or spill any liquid on the Model 900, its accessories, connectors, switches, or openings in the chassis.

For *surface-cleaning* and *disinfecting* follow your institution's procedures or:

- The model may be surface-cleaned by the using a soft cloth dampened with either a commercial, nonabrasive cleaner or a solution of 70% alcohol in water, and lightly wiping the surfaces of the oximeter.
- The Model 900 may be disinfected using a soft cloth saturated with 10% chlorine bleach in tap water solution.

Before attempting to clean a SpO_2 sensor, read the directions for use enclosed with the sensor. Each sensor model has cleaning instructions specific to the sensor.

Chapter 8:
Specifications

8.1 SPECIFICATONS

Performance

Measurement Range

$\%SpO_2$	0-100%
Pulse	20 – 253 beats per minute (bpm)

Resolution

$\%SpO_2$	1%
Pulse	1 beat per minute (bpm)

Accuracy

$\%SpO_2$	100 – 70%, + 2% 69 – 60%, + 3% < 59%, Unspecified
Pulse	20 – 255BPM, + 2 BPM

Alarms

High SpO_2	2 – 100%
Low SpO_2	0 – 98%
High Pulse	22 – 253 BPM
Low Pulse	20 – 251 BPM

Electrical

Instrument

Power Requirements	85 – 260 VAC, 50/60 Hz
Fuses	1 Qty, 0.5 A, 250 volts, slow-blow, IEC (5 x 20 mm)

Battery

Type	Rechargeable Lead-Acid internal battery
Battery Life	3 hours of continuous operation with a new, fully charged battery under the following conditions: no alarms, and no analog or serial output devices.

In excess of 6 hours in power save mode; using new, fully-charged battery. A completely discharged battery can be fully recharged in approximately 16 hours while unit is turned off or 20 hours while turned on.

Charge/discharge cycles	Minimum of 200

Sensor

Entire range of Mediaid Opto-Plethysmographic Pulse Oximeter sensors with Compushield connector.

Environmental Conditions

Acceptable Conditions for Operating, Storage and Transport

Operating Temperature	00 to 400 C (320 to 1040 F)
Storage & Transport	
Temperature	-300 to 650 C (-220 to 1490 F)
Atmospheric	770 to 282 mm Hg
Pressure	1026 to 377 hPa
Relative Humidity	5 – 95% (non condensing)

Physical Characteristics

Weight	2.54 kgs. (5.6 lbs.)
Dimensions	11.8 (L) x 8 (W) x 3.3 (H) inch 30 (L) x 20.3 (W) x 8.4 (H) cm

Compliance

Emissions Compliance	EN55011, CISPR 11, GROUP 1, Class B
Equipment Classification	IEC 60601-1 / CSA 601.1 I UL 2601 – 1
Type of Protection	Class 1 (on AC power) Internally powered (on battery power)
Degree of Protection	Type BF – Applied Part
Enclosure Degree of Ingress Protection from Solids/ Liquids	IPXI
Mode of operation	Continuous
EMI Compatibility	IEC 60601-1-1

Chapter 9:
Quick Guide to Operations

9.1 QUICK GUIDE TO OPERATIONS

Introduction

This Quick Guide to Operation is intended for use by experienced Model 900 users. First time users of the oximeter should read the entire Operator's Manual before use. To turn off the oximeter on or off press

Settings Adjustments

Table 6 contains the procedures necessary to adjust or view the Model 900 settings. In general, press EXIT to return to main menu.

TABLE 6: Settings Adjustments

To Adjust	Action	Key
Alarm Limits	Press	MENU Soft key
	Press	ALRM Soft key
	Press	UP or DOWN key
	Press (to select parameter)	SELT Soft key
	Press	UP or DOWN key
	Press	DSLT Soft key
	Press	EXIT Soft key
Alarm Duration	Press (for less than 3 secs.)	MUTE key – 1 min Alarm silence
	Press (for more than 3 secs.)	MUTE key – permanent Alarm disable

To Adjust	Action	Key
Alarm Volume	Press Press Press (to select ALARM VOL in Soft key) Press Press (to change the volume) Press Press	MENU Soft key ALRM Soft key UP or DOWN key SELT Soft key UP or DOWN key DSLT Soft key EXIT Soft key
Contrast	Press Press Press (to select CONTRAST in Soft key) Press Press (to change the contrast) Press Press	MENU Soft key SYST Soft key UP or DOWN key SELT Soft key UP or DOWN key DSLT Soft key EXIT Soft key
Time and Date Settings	Press Press Press (to select Date or Time) Press Press (to change Settings) Press Press	MENU Soft key SYST Soft key UP or DOWN key SELT Soft key UP or DOWN key DSLT Soft key EXIT Soft key
Trends (Tabular)	Press Press Press (to view the desired trend data) Press	TRND Soft key TBLE Soft key UP or DOWN key EXIT Soft key
Trends (Graphical)	Press Press Press (to view the desired trend data) Press	TRND Soft key GRAP Soft key UP or DOWN key EXIT Soft key
Backlight OFF/ON (only when SpO_2, BPM readings are displayed)	Press (to switch off) Press (to switch on)	BKLT Soft key BKLT Soft key

Chapter 10:
Principles of Operation

10.1 OXIMETRY OVERVIEW

Pulse oximeters provide a spectrophotometric assessment of functional arterial Hemoglobin oxygenation (SpO_2). Pulse oximetry is based on the following two principles. First, hemoglobin (Hb) and oxygenated hemoglobin (HbO_2) differ in their absorption of red and infrared light. Second, the volume of arterial blood in tissue (and therefore, light absorption by the hemoglobin) changes during the pulse. Therefore, a pulse oximeter passes red and infrared light into an arteriolar bed, measures changes in light absorption, and determines SpO_2.

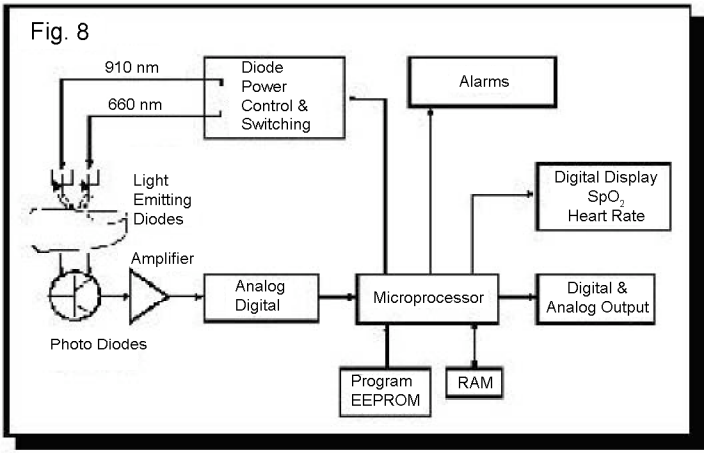


Figure 8: Principles of Pulse Oximetry

How Pulse Oximeters Work

Pulse oximeter sensors have red and infrared low voltage light-emitting diodes (LEDs) which serve as light sources. The emitted light is transmitted through the tissue, and then detected by the photodetector where it is then sent to the microprocessor of the pulse oximeter (Fig. 8). All constituents of the human body, venous and arterial blood and tissue

absorb light (Fig. 9). The pulsating of arterial blood results in changes in the absorption due to added hemoglobin (Hb) and oxygenated hemoglobin (HbO_2) in the path of the light. Since (HbO_2) and (Hb) absorb light to varying degrees, this varying absorption is translated into plethysmographic waveforms at both red and infrared wavelengths (Fig. 10). The relationship of red and infrared plethysmographic signal amplitude can be directly related to arterial oxygen saturation. For example, when the plethysmographic amplitude at 660nm and 910nm are equal and the ratio R/IR=1, the SpO_2 is approximately 85% (Fig. 11).

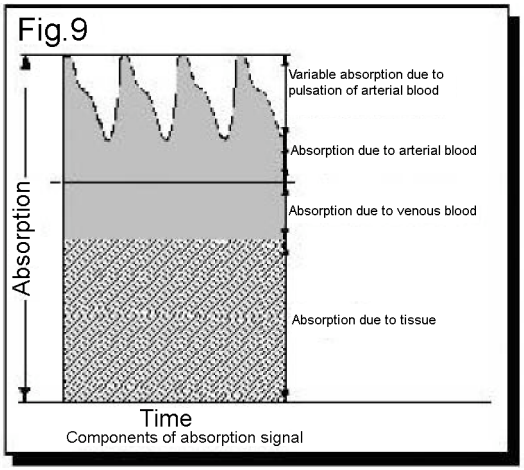
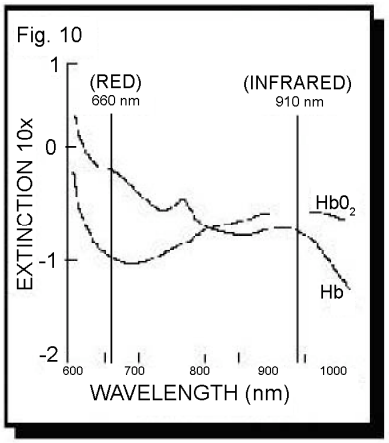


Figure 9: Light Absorption



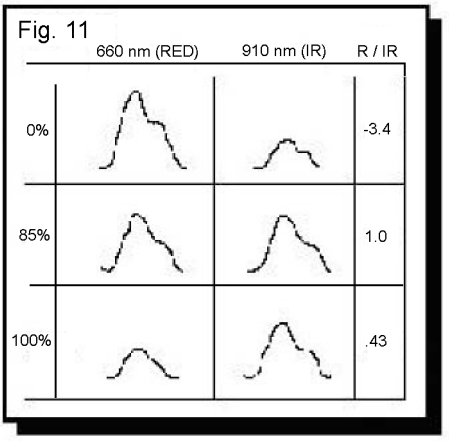


Figure 10: Varying absorption by (HbO_2) & (Hb)

Figure 11: Pleth amplitude at 660nm & 910nm

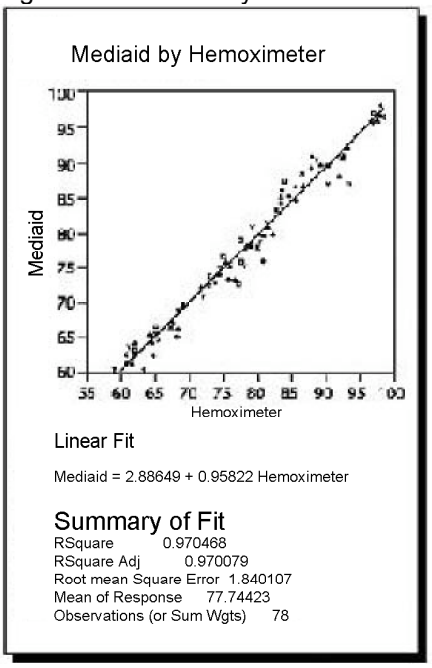
Calibration of Pulse Oximeters

The light absorption by hemoglobin is wavelength dependent. Mediaid's red and infrared LED wavelengths are tightly controlled by testing each individual sensor. In addition, the LED intensity recorded at the detector is automatically adjusted for amplitude. This allows Mediaid Palco pulse oximetry sensors to be used interchangeably without calibration.

Validation of Accuracy

Mediaid Palco pulse oximeters and sensors are tested for accuracy at the Anesthesia Research Laboratory of the University of California Medical Center in San Francisco. Validation consists of inducing hypoxemia in healthy subjects and comparing pulse oximeter readings (SpO_2) to co-oximeter readings (SpO_2) using arterial samples. Figure 12 and Figure 13 compare results from a typical Mediaid pulse oximeter and a Competitor's pulse oximeter. Both instruments show a small bias and similar distribution of sampling points.

Figure 12: Mediaid by Hemoximeter



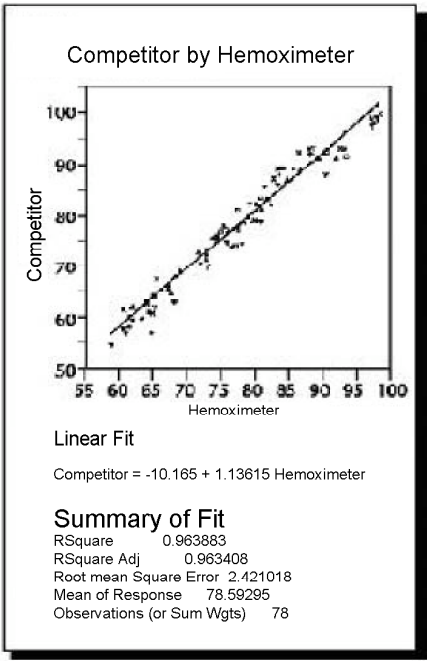


Figure 13: Competitor by Hemoximeter

Clinical Use of Pulse Oximetry

Pulse oximeters may be used in a variety of situations that call for monitoring oxygenation and pulse rates. Pulse oximeters increase patient safety by alerting the hospital staff to the onset of hypoxia during or following surgery. Oximeters confirm adequate oxygenation during mechanical ventilation. Physician and dental offices utilize pulse oximetry for spot checking respiratory status, as well as for monitoring during procedures that call for sedation. Truly, pulse oximetry is the fifth vital sign, essential to complete patient monitoring.

Chapter 11:
Data Port Protocol

11.1 DATA PORT PROTOCOL

Overview

Serial and analog data can be communicated through the data port to a peripheral device. Analog output of oxygen saturation (0-100 %SpO_2) and pulse rate (0-255 bpm) are each transmitted on a scale of 0.0 to 1.0 V. Serial output of oxygen saturation (0-100 %SpO_2) and pulse rate (0-255 bpm) are transmitted once per second in a data packet. For tests regarding data transmission and the data port, please refer to the Test section.

Table 7: DATA PORT PINOUTS

Pin No.	Description
1	TREND-RX RS 232
2	POM-RX RS 232
3	POM-TX RS 232
4	TREND-RX RS 232
5	Ground
6	Analog – SpO2
7	Nurse Call- NO
8	Nurse Call- NC
9	Nurse Call ACK RS232
10	Ground
11	Not Used
12	Nurse Call LVL RS 232
13	Analog- Pulse Rate
14	Analog- Pleth
15	Nurse Call Common

Serial Data Transmission

- Serial data can be transmitted with a Mediaid Palco Serial Cable
- Transmission speed is 9600 baud
- The data field is 8 bits, one stop bit, no parity

- The data packet output by the Model 900 is comprised of four (4) data bytes sent in the following order: the Status byte, the % SpO_2 byte, the Pulse Rate byte, and the Checksum byte.

Table 8: SERIAL DATA COMMUNICATION FORMAT

Byte	Specification
1	START BYTE (Always 0XA5)
2	No of Bytes (Always 0X08)
3	SpO2
4	BPM
5	Perfusion LSB
6	Perfusion MSB
7	STATUS
8	CHECKSUM(1 Byte) = Start Byte + No of Bytes+ SPO_2 + BPM + Perfusion LSB + Perfusion MSB + STATUS

Table 9: BIT SPECIFICATION OF THE STATUS BYTE

Bit	Specification
BIT 0	D0 - (Don't Care)
BIT 1	D1- (Don't Care)
BIT 2	D2- (Don't Care)
BIT 3	D3- (Don't Care)
BIT 4	D4 – (Low Perfusion Status Bit)
BIT 5	D5 – (No Finger)
BIT 6	D6 – (No Sensor)
BIT 7	D7 – (Pulse Detected)

Trend Request – 0XD5
Wait for Acknowledgment "ACK" (3 Bytes).

After receiving the acknowledgment commend the following information can be extracted.

Table 10: OFF LINE TREND DATA COMMAND FORMAT

Byte	Specification
Byte 0	Month
Byte 1	Date
Byte 2	Year
Byte 3	Hour
Byte 4	Min.
Byte 5	SPO_2
Byte 6	BPM continue….

End of communication – 0XA5

11.2 NURSE CALL

WARNING

The nurse call feature should not be used as the primary source of alarm notification. The audible and visual alarms of the oximeter, used in conjunction with clinical signs and symptoms, are the primary source for notifying medical personnel that an alarm condition exists.

The Model 900 provides two different types of nurse call interfaces: an RS-232 level and solid relay closure. The solid state relay based nurse call function is available when the oximeter is operating either on AC power or when powered by battery.
The remote location will be signaled anytime there is an audible alarm.
Pin 11 on the data port is the RS-232 level nurse call signal and pin 10 is ground(see Table11). The nurse call polarity(normally high or normally low) and whether the oximeter is in alarm determine the voltage between

these pins. The nurse call polarity is set by using the procedures in the StratUp and Use section. To access the nurse call menu from the main menu, press softkeys SETUP, NEXT, NEXT, and NCALL.
When the nurse call polarity setting is normally high(NORM+) and there is no alarm condition, the voltage between pins 11 and 10 will be +5 to +12 volts DC. Whenever the oximeter is in an alarm condition, the output is between pins 11 and 10 will ne 5 to -12 volts DC. When the setting is normally low (NORM-), the readings are opposite.
These voltages are present only when the oximeter is operating on AC power.
If the audible alarm has been turned off, or silenced, the nurse call alarm is also indicated.

Table 11: Voltage Between Pins 10 and 11

Alarm State	Nurse Call Polarity Setting	Voltage from pins 10 to 11
No current alarms	Normally high	+5 to +12 VDC
Alarm conditions	Normally high	-5 to -12 VDC
No current conditions	Normally low	-5 to -12 VDC
Alarm conditions	Normally low	+5 to +12 VDC

Pins 7 and 15 provide a solid state relay that closes when an alarm is sounding on the oximeter. Pins 8 and 15 provide a solid state relay that opens when an alarm is sounding. Pin 15 is a common lead for both relays. The solid state operates whether the oximeter is operating on AC power or battery.

11.3 ANALOG OUTPUTS

The Model 900 data port also provides analog voltage outputs between pins 6, 13, 14 and ground (pins 5 or 10), which can be used to calibrate instruments such as a chart recorder.

Analog data can be transmitted with a Mediaid Analog cable in Model 900.

Analog outputs are as follows:

0% Scale – 0.000 V
50% Scale – 0.500 V
100% Scale -1.000 V

The voltage represents a specific measured parameter's current value. The voltage differential varies over its full range of values, as indicated in Table 14.

Table 12: Analog Pinouts

Pin	Parameter	Parameter Range
6	%SpO2	0-100 %
13	Pulse rate	0-250 bpm
14	Pleth wave	0-225

For example, as the current value of %SpO2 varies from 0 to 100 %, the voltage from pin 6 to ground (pin 10) would vary from 0 to 1 volt. A voltage of .94 volts indicates a current %SpO2 value of 94.

The analog output calibertaion function can be accessed from the main menu by pressing SET UP, NEXT, NEXT, ANALOG. Selecting "0 VOLT" or "1VOLT" causes the voltage to increase from 0 to 1 volt at 1/10th – volt increments, with each step lasting at least 1 second.

Qualified service personnel using the procedure described in the Model 900 service manual can perform caliberation of the analog output and the attached device.

Chapter 12:
Mediaid Inc. Warranty Information

12.1 MEDIAID INC. WARRANTY INFORMATION

PLEASE NOTE
THIS PRODUCT IS MANUFACTURED AND SOLD BY MEDIAID INC. (HEREAFTER REFERRED TO AS MEDIAID) UNDER THE WARRANTIES SET FORTH BELOW.

Application of Warranty

This warranty covers only the Mediaid Oximeter Model 900 and accessories as indicated. It is not extended to the other products or components that the customer uses in conjunction with the Mediaid product. This warranty shall not apply if the manufacturer determines that the product has been damaged due to abuse, misuse, misapplication, accident, negligence, tampering or as a result of service or modification by any other person other that an authorized Mediaid service technician. Opening of the sealed enclosure or altering the serial number will void warranty. Use of equipment contrary to or inconsistent with the User manual will also void the Warranty.

What is covered by this Warranty?

Mediaid warrants that the Mediaid product enclosed with this warranty will conform to the manufacturer's specifications, and shall be free from defects in workmanship and materials for a period of two (2) years from the date of original purchase. Items excluded from this two year term are the batteries, sensor extension cables, sensors and other accessories.

What Mediaid will do to correct the problems?

Should your Mediaid product prove to be defective, contact Mediaid Inc. or the Mediaid local authorized distributor/service center for repairs.
Please have your model and serial number available when calling. Mediaid will then issue a "Return Authorization Number (RAN)".

Return your instrument securely packaged in its original shipping carton (or equivalent packaging), include your Return Authorization Number. Mediaid Inc. will repair any faulty workmanship and either repair or replace (at its option) any defective part with new or refurbished parts. For non-warranty repairs, the customer will be charged the current repair rate at the time of receipt by Mediaid and all transportation charges shall be customer's responsibility. Mediaid shall not be liable for any damages including, but not limited to, incidental damages, consequential damages or special damages. This Warranty does not cover any damage to the equipment during shipping, which shall be the sole responsibility of the transportation company.
Always read the User's Manual carefully: The information included in the User's Manual will assist the user in preventing equipment misuse and ensuring patient safety. Operation of the equipment in a manner contrary or inconsistent with the User's Manual will void the Warranty.

12.2 OWNER'S REGISTRATION

To assist Mediaid Inc. in serving you, please complete the warranty Registration Card that is included and return it to MEDIAID INC., 17517 Fabrica Way Suite H, Cerritos, CA 90703 USA.

NOTE

THERE ARE NO WARRANTIES, EXPRESS OR IMPLIED, WHICH EXTEND BEYOND THE WARRANTIES SET FORTH ABOVE. MEDIAID INC., MAKES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE PRODUCT OR PARTS THEREOF. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS. YOU MAY HAVE OTHER LEGAL RIGHTS WHICH VARY FROM STATE TO STATE. MEDIAID INC. WILL NOT BE LIABLE TO THE USER FOR INCIDENTAL OR CONSEQUENTIAL DAMAGE OR LOSS ARISING OUT OF THE USER'S INABILITY TO USE THIS PRODUCT.

Product Information

To better assist customers, Mediaid Inc. recommends all users write down all pertinent product and warranty information.

Product # _____

Serial # _____

Software Version # _____

Warranty Expiration Date _____