MEDICAL

USER MANUAL

OSI MEDICAL 2100 PULSE OXIMETER

digital™

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Section 1: Warranty Information

This product is warranted against defects in material and workmanship, and to operate within published specifications under normal use for a period of one year from the date of original shipment. Batteries and fuses are not warranted.

To request a warranty claim, contact OSI Medical for return authorization and instructions. See *Section 9: Maintenance and Service* for more information.

If an examination by OSI Medical discloses such products or component parts to be defective, OSI Medical's sole obligation is limited to repair or replacement (at OSI Medical's option) of the defective product or component.

This warranty does not extend to any product that was subject to misuse, neglect or accident; that was damaged by causes external to the product; or that was used in violation of the operating instructions supplied with the product. This warranty does not extend to any product that was modified in any way, or disassembled or reassembled by anyone other than OSI Medical or an authorized OSI Medical agent. This warranty does not extend to any accessories, or other external instruments or devices that are connected to the oximeter.

Digital Dolphin Reusable Sensors and Extension Cables are not covered under this warranty. Refer to the information accompanying those products for warranty terms and conditions.

THIS WARRANTY, TOGETHER WITH ANY OTHER EXPRESS WRITTEN WARRANTY THAT MAY BE ISSUED BY OSI MEDICAL INC. IS THE SOLE AND EXCLUSIVE WARRANTY AS TO OSI MEDICAL'S PRODUCTS. THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY ORAL OR IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILTY OR FITNESS FOR A PARTICULAR PURPOSE. OSI MEDICAL SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE DIRECTLY OR INDIRECTLY ARISING FROM THE LOSS OR LOSS OF USE OF ANY PRODUCTS.

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

Section 2: Safety Information

READ THE ENTIRE SAFETY INFORMATION SECTION BEFORE OPERATING THE OXIMETER.

Intended use

The OSI Medical 2100 Pulse Oximeter is intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for adult, and pediatric patients greater than 30 kg in hospitals, hospital-type facilities, and home environments.

Indications for use

The OSI Medical 2100 Oximeter is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by a SpO_2 sensor). The oximeter is indicated for use with adult, and pediatric patients greater than 30 kg during both no motion and motion conditions, and for both well or poorly perfused patients in hospitals, hospital-type facilities, and home environments.

Principles of operation

The oximeter is based on three principles:

- 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 (photoplethysmography).
- Red and infrared light-emitting diodes (LEDs) in sensors serve as the light sources, and a photodiode serves as the photodetector.

Warnings and Cautions

A WARNING indicates possible injury to the patient or user.

A CAUTION indicates possible equipment damage or malfunction.

Warnings

The oximeter is to be operated by qualified personnel only. Read all instructions, precautionary information and specifications prior to use.

EXPLOSION HAZARD: Do not use the oximeter in the presence of flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments, or nitrous oxide.

Check alarm limit settings each time the oximeter is used.

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

An oximeter should NOT be used as an apnea monitor.

An oximeter should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.

If an alarm condition occurs while the audible alarm mute function is engaged, only the visual alarm indications are displayed.

Do not silence an audible alarm, engage the audible alarm mute function, or decrease the audible alarm volume if patient safety could be compromised.

The nurse call feature should not be used as the primary source for patient and system alarms. The oximeter's audible and visual alarms, used in conjunction with clinical signs and symptoms, are the primary sources for determining that an alarm condition exists.

Do not obstruct the speaker. Blocking the speaker may result in an inaudible alarm tone.

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

Do not place the oximeter where the controls can be changed by the patient.

Do not place the oximeter in any position that might cause it, or any device connected to it, to fall on the patient or operator. Do not lift or carry the oximeter by the power supply cable or patient cable.

Use only OSI Medical's Digital Dolphin Oximetry Sensors and Extension Cables for SpO_2 measurements by the oximeter. Other manufacturer's sensors and patient cables may cause improper performance.

Before use, carefully read the Digital Dolphin Oximetry Sensor Directions for Use and Extension Cable Directions for Use.

Tissue damage can be caused by incorrect application or use of an Digital Dolphin Oximetry Sensor. Inspect the sensor site as directed in the Digital Dolphin Oximetry Sensor Directions for Use to ensure skin integrity, and correct sensor positioning and adhesion.

Do not use damaged Digital Dolphin Oximetry Sensors or Patient Cables. Do not use a Digital Dolphin Oximetry Sensor with exposed optical or electrical components. Do not immerse the sensor or cable in water, solvents or cleaning solutions. The sensors, patient cables and connectors are not waterproof. Do not sterilize Digital Dolphin Oximetry Sensors or Extension Cables by irradiation, steam, or ethylene oxide. See the cleaning instructions in the Directions for Use for reusable Digital Dolphin Sensors and Extension Cables.

Do not pull on the sensor or extension cable, other than to disconnect the sensor from the extension cable, or to disconnect the extension cable from the oximeter. Refer to the Directions for Use for Digital Dolphin Oximetry Sensors and Extension Cables for proper connection and disconnection instructions.

If the oximeter is on a slippery surface, retain the oximeter while pressing the keys to prevent it from possibly slipping out of position.

Always remove the sensor from the patient and completely disconnect the patient from the oximeter before bathing the patient.

Do not use the oximeter or Digital Dolphin Oximetry Sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.

Interfering Substances: Carboxyhemoglobin may erroneously increase SpO_2 readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes or any substance containing dyes that change usual arterial pigmentation may cause erroneous readings.

Do not use malfunctioning equipment. Have the unit repaired by OSI Medical or an authorized OSI Medical service representative.

ELECTRIC SHOCK HAZARD: Do not remove the oximeter cover. There are no user-serviceable items inside the oximeter. An operator may only perform maintenance procedures specifically described in this manual. Measure the leakage current whenever an external device is connected to the serial or analog output ports. Leakage current must not exceed 100 μA.

Grounding:

- Connect the oximeter only to a three-wire, grounded, hospital grade receptacle. The three-conductor plug must be inserted into a properly installed three-wire receptacle. If a three-wire receptacle is not available, a qualified electrician must install one in accordance with the governing electrical code.
- Do not under any circumstances remove the grounding conductor from the power plug.
- Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.
- If there is any doubt about the integrity of the protective earth conductor arrangement, operate the oximeter on internal battery power until the AC power supply protective conductor is fully functional.

If there is exposed metal on the keypad, do not touch the patient and the oximeter keypad simultaneously due to risk of shock.

Do NOT connect the oximeter to an electrical outlet controlled by a wall switch or dimmer.

To ensure patient electrical isolation, connect the oximeter only to other equipment with electronically isolated circuits.

Substances from a broken liquid crystal display (LCD) Module are toxic when ingested. Use caution with handlinga oximeter with a broken display module.

In all circumstances the oximeter must be connected to a grounded power supply if AC power is used.

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC-601-1-1. Any person who connects additional equipment to the signal input part of signal output part configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC-601-1-1. If in doubt, consult the technical service department or your local representative.

Cautions

U.S. Federal and Canadian laws restrict this device to sale by or on the order of a licensed medical practitioner.

Confirm the accuracy of the real-time clock settings each time the oximeter is used to collect patient trend data.

Do not place the oximeter on electrical equipment that may effect the oximeter from working properly.

Do not expose the oximeter to extreme moisture, such as direct exposure to rain. Extreme moisture can cause the oximeter to fail or perform inaccurately.

Do not place containers holding liquids on or near the oximeter. Liquids spilled on the oximeter may cause it to perform inaccurately.

In the event the oximeter is damaged and cannot be repaired, dispose of the oximeter through an approved hazardous materials disposal facility in accordance with local regulations, or return it to OSI Medical or an authorized distributor. The internal battery contains lead and acid, which are hazardous wastes.

Cleaning:

- Do not autoclave, pressure sterilize, or gas sterilize the oximeter.
- Do not soak or immerse the oximeter in any liquid.
- Use cleaning solution sparingly. Excessive solution can flow into the oximeter and cause damage to internal components.
- Do not touch, press, or rub the oximeter display panels or front keypad panel with abrasive cleaning compounds, instruments, brushes or rough surface materials.
- Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the oximeter. These substances attack the device's materials, and failure can result.

Measurement accuracy

If the accuracy of any measurement by the oximeter does not seem reasonable, first check the patient's vital signs by alternate means, and then check the oximeter for proper functioning.

Inaccurate measurements may be caused by:

- Incorrect sensor application or use.
- Significant levels of dysfunctional hemoglobins (e.g., carboxyhemoglobin or methemoglobin);
- Intravascular dyes such as indocyanine green or methylene blue.
- Exposure to excessive illumination, such as surgical lamps (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight. Exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material.
- Excessive patient movement.
- Venous pulsation.
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.

Loss of pulse signal can occur in any of the following situations:

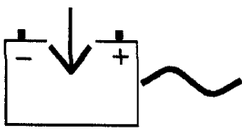
- The sensor is too tight.
- There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or direct sunlight.
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- There is arterial occlusion proximal to the sensor.
- The patient is in cardiac arrest or shock.

Section 3: Symbol Definitions

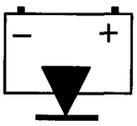
FRONT PANEL SYMBOLS

On

Off



AC power



Low battery

Alarm condition

Alarm silence key

Display contrast adjustment

REAR PANEL SYMBOLS

Type and rating of fuses
2.0A / 250Vac, slow acting

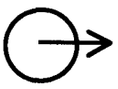
Rated supply voltage
100-240 VAC, 50-60 Hz

REF Reference number

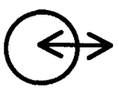
SN Serial number

Type BF applied part

Attention: consult accompanying documents



Analog signal output connector
6-pin DIN, female



RS-232

RS-232 serial data connector

If present, indicates product is UL and CSA Classified.

Indicates this device is in compliance with MDD 93/42/EEC.

0301 is the Notified Body Number.

Section 4: Preparation for Use

Initial inspection

1. Unpack and inspect the oximeter for external damage.
2. Review the front and rear panels of the oximeter and identify the connectors, controls, and indicators.
3. Connect the oximeter to external power. Verify the green indicator is illuminated.
4. If using a reusable sensor, make sure it opens and closes smoothly. Remove any substances that may interfere with the transmission of light between the sensor's light source and detector.
5. Press [%] and listen for the two beep tone of the oximeter's self-test. Verify that the yellow and red indicators flash briefly.
6. Select a Digital Dolphin Oximetry Sensor and Extension Cable for use. Connect the extension cable and sensor. Verify the red sensor LED illuminates and changes in brightness periodically. Attach the sensor to a finger.
7. After approximately 10 seconds, verify the readings for SpO_2 and pulse rate.
8. Verify the patient alarms are functioning by setting the high and low SpO_2 and pulse rate alarm limits so the patient readings violate the limits. Ensure the following occurs:
   - An alarm tone sounds.
   - The violated alarm limit is highlighted, and the corresponding patient reading flashes on the display.
9. Verify the sensor alarms are functional by removing the sensor from the sensor site. Ensure the following occurs:
   - SENSOR OFF PATIENT appears in the message display area.
   - The alarm tone sounds.
   - The red indicator flashes.
10. Unplug the sensor from the oximeter.
    - Make sure NO SENSOR CONNECTED appears in the message display area.
11. Verify alarm silence operation. Press [ ]. Ensure the following occurs:
    - The alarm tone ceases.
    - The red indicator stops flashing.

System time and date

Refer to *Section 6: Softkeys and Setup Menu* to set the system clock.

Audio setup

The volume level for the pulse beep and the audible alarm tones are user adjustable. The pulse beep volume has six levels, and OFF. The audible alarm volume has six levels.

To adjust the audible alarm volume:

- Press [SETUP] to display the Setup Menu.
- The current alarm volume setting is displayed and highlighted.
- Press [▲] and [▼] to change the setting. Press [NEXT], [PREVIOUS] or [MORE] to adjust another item, or press [EXIT] to return to patient monitoring display mode.

To adjust the volume of the pulse beep:

1. Press [▲] and [▼] to raise or lower the pulse beep volume while in the patient monitoring display modes; or

2. Use the Setup Menu:

   - Press [SETUP] to display the Setup Menu. When monitoring, the current patient data is displayed, but the pulse beep is temporarily silenced.
   - Press [NEXT] to highlight the Pulse Volume setting.
   - Use [▲] and [▼] to change the setting. Press [NEXT], [PREVIOUS] or [MORE] to adjust another item, or press [EXIT] to return to patient monitoring display modes.

Alarm limits

Default alarm limits are user-selectable. The settings are retained after the oximeter is turned off. To use this feature, refer to *Section 6: Softkeys and Setup Menu* for instructions. To set specific alarm limits for a particular patient, refer to *Section 5: Routine Use.*

The oximeter displays alarm limits continuously. It can also display limits when they are reviewed and adjusted, or when an alarm limit is violated. To use this feature, refer to *Section 6: Softkeys and Setup Menu.*

Sensitivity settings

The OSI Medical 2100 Pulse Oximeter can be adjusted to suit various clinical situations. Refer to *Section 6: Softkeys and Setup Menu* for more information.

Front panel controls, indicators and symbols

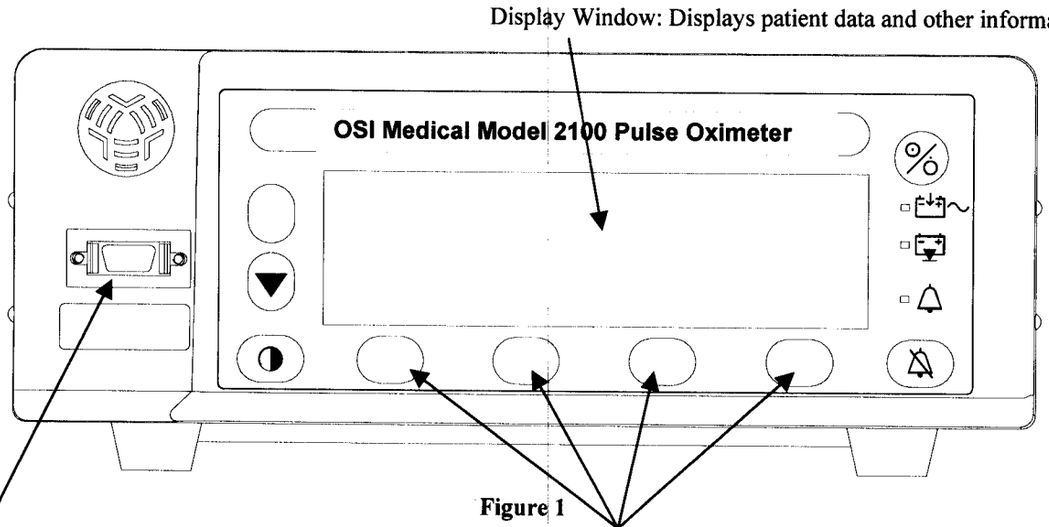


Figure 1

Patient cable connector: Connects to a Digital Dolphin Extension Cable. Refer to *Section 7: Sensors And Accessories.*

[%]: Turns the oximeter on and off.

indicator: Illuminates green when the oximeter is connected to AC power.

indicator: Flashes amber when approximately 5 to 10 minutes of battery operation remains.

indicator: Flashes red to indicate an alarm condition.

Note: Items in [ ] are keys.

Main softkeys: Used to control various functions. Refer to *Section 6: Softkeys and Setup Menu.*

[🔕]: When pressed, alarms are temporarily silenced. If pressed three times in less than three seconds, all audible alarms are muted until pressed again.

[◑]: Adjusts the contrast of the display window.

[▲]/[▼]: Adjusts the pulse beep volume of the. When using the menu to access different functions, they have different functions. Refer to *Section 6: Softkeys and Setup Menu.*

REAR PANEL CONNECTIONS

Power entry module: Connects the oximeter to AC power using a powercord.

Analog connector: 6-pin female connector for analog communications. Refer to the *Section 11: Serial and Analog Communications.*

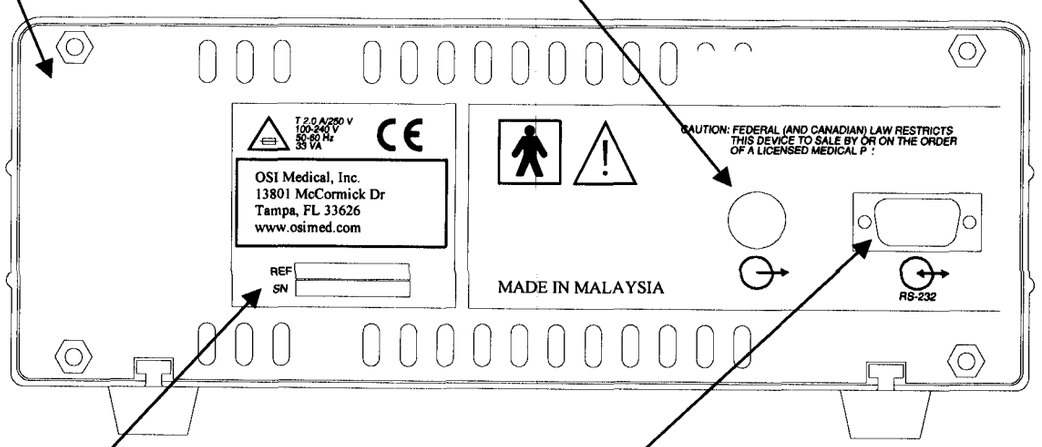


Figure 2

Product identification label: Lists product reference and serial number.

Digital RS-232 connector: 9-pin female connector for serial data communications. DO NOT attempt to connect the optical sensor probe to this part. Refer to *Section 11: Serial and Analog Communications.*

Section 5: Routine Use

AC and battery power usage

The oximeter operates on AC or battery power or on its internal battery. When AC power is connected, the green indicator is illuminated.

When approximately 5 to10 minutes of battery power remain, the amber indicator flashes and a message is displayed. When battery power is depleted, the amber indicator illuminates, an alarm sounds for a minimum of 10 seconds, and a status message is displayed before the oximeter turns off. The alarm sounds even if theall mute function is active. Connect the oximeter to AC power to recharge the battery.

If the battery is too low to operate the oximeter and [%] is pressed, the amber indicator flashes 10 times. Connect the oximeter to AC power to operate the oximeter. Allow the oximeter to recharge at least 8 hours before using it again on battery power.

On and off

The [%] turns the oximeter on and off. The oximeter automatically executes a self-test when turned on.

If the oximeter is set to have an initial SpO2 alarm limit below 80%, the message SPO2 LIMIT < 80% will be displayed, and a high priority alarm tone sounds after a short delay. The user must press a menu key to begin patient monitoring. [CONFIRM] uses the existing alarm limits, [ADULT] sets the alarm limits to the Adult Default Alarm Limits and allows the user to set the alarm limits to patient-specific settings.

SpO_2 and pulse rate alarms

The oximeter provides visual and audible indications when SpO_2 or pulse rate values violate alarm limits. The [🔔] indicator and violating SpO_2 or pulse rate value flashes, and the violated alarm limit is highlighted. If the display limits feature is OFF, the oximeter automatically displays and highlights the violated alarm limit. A high priority alarm sounds unless the [🔕] was pressed in the previous two minutes, or the all mute function is active.

Alarm limit adjustment

Each time the oximeter is turned on, the alarm limits are reset to default values. To change the highlighted alarm limits, press [LIMITS] and use [▲] and [▼]. Press [PREVIOUS] and [NEXT] to select the alarm limit to change. *Refer to Section 6: Softkeys and Setup Menu.*

Sensor alarms

The oximeter provides visual and audible indications when the Digital Dolphin Sensor is removed from the patient but is still connected to the oximeter or the sensor or patient cable is disconnected from each other or oximeter. The [🔔] indicator flashes, the appropriate message, SENSOR OFF PATIENT or NO SENSOR CONNECTED, appears in the display, and a high priority alarm sounds. Refer to *Section 8: Messages and Troubleshooting.*

When [🔕] is pressed, the alarm tone is silenced and the [🔔] indicator turns off.

Alarm limit default values

	High SpO_2	Low SpO_2	High pulse rate	Low pulse rate
Adult	---(Off)	85%	150 BPM	40 BPM

Other factory default values

Feature	Value	Feature	Value
Alarm volume	4 / 6	Alarm silence	120 Seconds
Pulse volume	4 / 6	Alarm mode	Standard
Display limits	ON	Baud Rate	19200
LCD mode	Normal	Analog SpO2	0 – 100%
Default limits	Adult	Analog 2 Mode	Pulse Rate (BPM)
Display Format	Waveform	Language	English
Trend Storage	24 Hours	Date Format	MM/DD/YYYY
Patient Type	Adult / Pediatric		
Sensitivity	Normal NOTE: High sensitivity should be used only when the clinician wants to have the absolute low perfusion performance of the oximeter, and is willing to sacrifice some sensor-off and asystole detection capability. Each time the oximeter is turned on, the sensitivity mode is set to normal.		
Nurse call	Low WARNING: The nurse call feature should not be used as the primary source for patient and system alarms. The audible and visual alarms of the oximeter, used in conjunction with clinical signs and symptoms, are the primary sources for determining that an alarm condition exists.		

Audible alarms adjustment

Use [▲] and [▼] to change the alarm volume setting in the Setup Menu.

Press [🔔] to temporarily silence alarms. The Alarm Silence period can be adjusted to 60 or 120 seconds. When [🔔] is pressed after a SENSOR OFF PATIENT or NO SENSOR CONNECTED condition, audible and visual alarms are cleared.

The oximeter has the capability to indefinitely mute alarms. Press [🔔] three times within a 3-second period. The 🔔 indicator appears on the display when this function is active. All alarms are muteduntil this function is cleared by pressing [🔔] again. If a low battery shutdown or system failure occurs, an alarm sounds even if all mute is active or alarms are temporarily silenced. For more information, refer to *Section 6: Softkeys and Setup Menu.*

LCD display adjustment

Press [◑] to adjust the display contrast. When held, [◑] scrolls through its range. Press the [LIGHT] menu key to turn the backlight off, and back on.

Displayed data validity

Compare the displayed pulse rate to the patient's palpated pulse rate. If the oximeter's pulse rate varies significantly from the palpated rate, the SpO_2 data may be inaccurate.

Patient monitoring display modes

The oximeter has several patient monitoring display modes:

Waveform

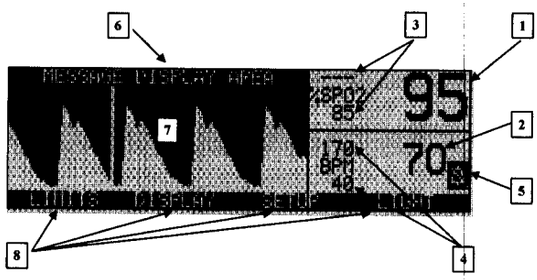


Figure 3

1. SpO_2 value
2. Pulse rate value
3. SpO_2 alarm limits
4. Pulse rate alarm limits
5. All mute indicator
6. Message display area
7. Waveform display
8. Main softkeys

Large number

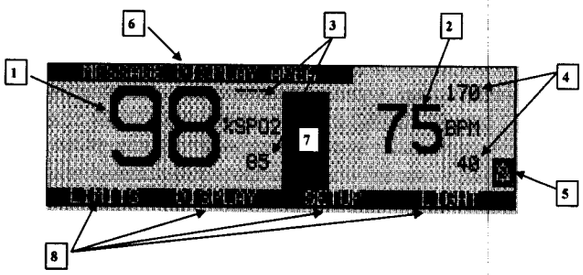


Figure 4

1. SpO_2 value
2. Pulse rate value
3. SpO_2 alarm limits
4. Pulse rate alarm limits
5. All mute indicator
6. Message display area
7. Pulse amplitude bar
8. Main softkeys

SpO_2 trend

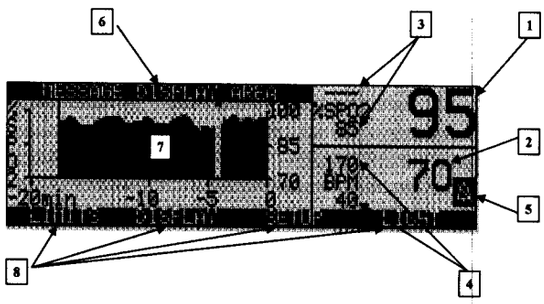


Figure 5

1. SpO_2 value
2. Pulse rate value
3. SpO_2 alarm limits
4. Pulse rate alarm limits
5. All mute indicator
6. Message display area
7. SpO_2 trend display
8. Main softkeys

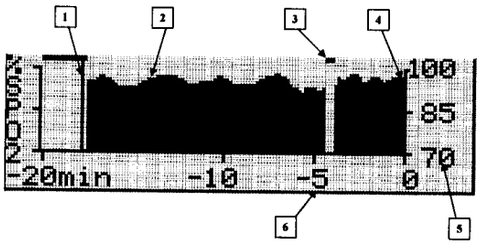


Figure 6

1. Solid vertical line indicates the oximeter was turned on.
2. Shows the minimum SpO_2 value for the time interval (10 seconds for 20 minutes and 30 seconds for 60 minutes).
3. A mark at the top of the graph indicates no SpO_2 data due to conditions such as PULSE SEARCH, SENSOR OFF PATIENT or NO SENSOR CONNECTED.
4. The most recent SpO_2 data appears at the right edge.
5. %SpO_2 scale reference.
6. Time scale reference (20 or 60 minutes).

Section 6: Softkeys and Setup Menu

The oximeter has options that allow the user to configure the oximeter to suit specific needs.

Main Softkey:	Press:	To Go To:	Press:	To Select or View:
[LIMITS]	[PREVIOUS], [NEXT]	High SpO_2 alarm limit	▲▼	70 – 100, – – – (Off)
		Low SpO_2 alarm limit		– – – (Off), 20 – 100
		High pulse rate alarm limit		30 – 240, – – – (Off)
		Low pulse rate alarm limit		– – – (Off), 30 – 240
	[EXIT]	Main softkey		
[DISPLAY]	WAVEFORM	Patient monitoring display with plethysmographic waveform		
	LARGE #	Patient monitoring display with large numbers and pulse bar		
	TREND20	Patient monitoring display with 20 minute trend SpO_2 graph		
	TREND60	Patient monitoring display with 60 minute trend SpO_2 graph		
[SETUP]	[PREVIOUS], [NEXT], [MORE]	ALARM VOLUME	▲▼	1 – 6
		PULSE VOLUME		0 – 6
		MONITOR LOCK		Lock menu keys (CONFIRM, CANCEL)
				Return to normal operation
		ANALOG SIGNAL		Data, High, Low
		TREND DATA	START	Start trend data output
			STOP	Stop trend data output
			ERASE	Clear trend data. (CONFIRM, CANCEL)
			EXIT	Return to [SETUP]
		LCD MODE	▲▼	Normal, Inverse
		ALARM SILENCE		60, 120 seconds
		ALARM MODE		Standard, Alternate
		DISPLAY LIMITS		On, Off
		DEFAULT LIMITS		Adult, User
		USER LIMITS		Save current limits as User (CONFIRM, CANCEL)
		NURSE CALL		Low, High
		TIME		Adjust time
		DATE		Adjust date
		LIGHT		On, Off
		SENSITIVITY		Normal, High
		ANALOG SPO2		0-100%, 0-50%
		ANALOG 2 MODE		BPM, Pleth
		LANGUAGE		English, French, German, Italian, Spanish
		DATE MODE		mm/dd/yyyy, dd/mm/yyyy
		BAUD RATE		19,200 baud
		TREND STORAGE		24, 48, 72, 96 hours
		DIAGNOSTICS		OSI Medical software versions
				Service Mode 1
				Service Mode 2
				Test RAM memory (CONFIRM, CANCEL) (Erases stored trend data)
		RESET DEFAULTS		Yes, No
	[EXIT]	Main softkey		
[ADULT / PEDIATRIC]	-	-	-	Set Patient Type

The Setup Menu shows the current configuration. The pulse beep is temporarily silenced whenever the Setup Menu is on the display.

Section 7: Sensors and Accessories

Note: Refer to the Directions for Use accompanying Digital Dolphin Oximetry Sensors and Extension Cables for complete instructions about sensor selection and use, and use and maintenance of patient cables.

Compatible Digital Dolphin sensors and patient cables

When selecting a sensor, consider the patient's weight, adequacy of perfusion, available sensor sites, and expected duration of monitoring.

Sensor	REF	Use	Patient type
DIGITAL DOLPHIN Adult Sensor	210	Single patient	Adults and pediatrics > 30 kg
8 ft Extension Cable	110	Reusable	All

OTHER ACCESSORIES

Accessory	REF
Operator's Manual, English	LT-022100
Operator's Manual, French	LT-052100
Operator's Manual, German	LT-062100
Operator's Manual, Italian	LT-072100
Operator's Manual, Spanish	LT-082100
Service and Maintenance Manual	LT-032100

Section 8: Messages and Troubleshooting

STATUS MESSAGES

Message	Potential cause	Suggested action(s)
DEFECTIVE SENSOR	An incompatible or damaged sensor is connected.	Use a compatible and functional Digital Dolphin sensor.
INSUFFICIENT LIGHT	The sensor does not a sufficient signal to accurately monitor.	Select another sensor site with less tissue thickness, or that allows better light transmission. Remove nail polish or artificial nail if in use.
INTERFERENCE DETECTED	Outside signal is disrupting oximeter.	Remove outside signal source or move sensor, patient cable and oximeter away from signal source.
LOW BATTERY	Battery requires recharging.	Connect the oximeter to AC power.
LOW BATTERY SHUTDOWN	The battery power is extremely low and insufficient to operate the oximeter .	Connect the oximeter to AC power.
LOW PERFUSION	Only a very weak signal is detected.	Move the sensor to a site with better perfusion. Refer to the Directions for Use accompanying the sensor.
NO SENSOR CONNECTED	No sensor is connected to the oximeter.	Connect patient cable and sensor to the oximeter.
PULSE SEARCH	Oximeter is searching for patient pulse.	If SpO_2 and pulse rate values are not displayed within 30 seconds, move the sensor to a site with better perfusion and/or light transmission.
SENSOR OFF PATIENT	The sensor is not properly attached to the patient.	Attach the sensor to the patient. Refer to the Directions for Use accompanying the sensor.
SPO2 LIMIT < 80%	The monitor has been turned on with an SpO2 alarm limit set below 80%.	Confirm or adjust the alarm limit setting.
TOO MUCH AMBIENT LIGHT	High levels of external light (from daylight, examination lights, infrared heat lamps, etc.) are detected.	Cover the sensor site with dark or opaque material. Select another sensor site more protected from ambient light.
UNRECOGNIZED SENSOR	The sensor is damaged, defective or incompatible.	Use a compatible and functional Digital Dolphin sensor.
SYSTEM FAILURE	System failure.	Contact OSI Medical for service.

Troubleshooting

Other abnormal conditions may occur that are not associated with one or the system status messages above.

Problem	Potential cause	Suggested action(s)
Oximeter does not power on.	Battery is too low to operate oximeter.	Connect oximeter to AC power to operate. Leave connected for at least 12 hours before using the oximeter on battery.
	Battery needs replacement.	Contact OSI Medical for service.
	Fuses need replacement.	Replace fuses. See the *Section 9: Maintenance and Service.*
The indicator flashes several times when [%] is pressed. No other response from oximeter.	Battery power is too low to operate the oximeter.	Connect oximeter to AC power to operate. Leave connected for at least 12 hours before using the oximeter on battery.
		If condition persists, contact OSI Medical for service.
Oximeter powers on, but display is blank.	[◑] is not set correctly.	Press [◑] until the display is visible.
		If condition persists, contact OSI Medical for service.
Power cord is connected but the indicator is not illuminated.	AC power source is not active.	Check AC power source and circuit breakers.
	System failure.	Contact OSI Medical for service.
No response from oximeter when keys are pressed.	System failure.	Contact OSI Medical for service.
No speaker sound.	Pulse beep volume is set to OFF, and no alarm conditions are active.	Press [▲] to increase pulse beep volume.
	System failure.	Contact OSI Medical for service.
Continuous speaker sound.	System failure.	Contact OSI Medical for service.
Oximeter displays readings while sensor is not applied to patient.	Sensitivity is set to high.	Set sensitivity to normal.
	Sensor is open to ambient lighting.	Disconnect sensor from oximeter, or turn sensor detector away from ambient light source.

Section 9: Maintenance and Service

WARNING: ELECTRIC SHOCK HAZARD: Do not disassemble the oximeter. There are no user-serviceable items inside the oximeter. Contact OSI Medical for service.

Note: The oximeter does not require calibration. Calibration and test methods for SpO_2 and pulse rate are available upon request.

Cleaning

To clean the front panel, use a cotton swab moistened with 70% isopropyl alcohol, or a 70% isopropyl alcohol wipe.

To clean the case, use a soft cloth dampened with a mild soap and water solution, or diluted bleach. Do not allow liquids to enter the inside of the oximeter.

To clean reusable sensors and patient cables, refer to the Directions for Use accompanying Digital Dolphin Oximetry Sensor and Extension Cables.

Fuse replacement

Materials Required: Small flat-blade screwdriver.
Two (2) 5mm x 20mm, 250V, 2A fast-acting fuses

1. Turn off the oximeter, and disconnect from AC power.
2. Use the small flat-blade screwdriver to gently pry the fuse holder from the power inlet module.
3. Remove the old fuses, and replace with new fuses.
4. Firmly snap the fuse holder back into the power inlet module.
5. Perform initial inspection. Refer to *Section 4: Preparation for Use.*

Repair policy and procedure

All repair and service must be performed by OSI Medical, or a service representative authorized by OSI Medical. Circuit diagrams, parts lists, and descriptions are available to qualified service personnel upon request.

Packaging and return procedure

Obtain a Return Authorization number and detailed shipping instructions before returning an oximeter for service by contacting the manufacturer / service center:

OSI Medical Support
12525 Chadron Ave.
Hawthorne, CA 90250 USA
Toll Free: (866) 588-9539
Fax: (310) 644-1727
www.osimed.com
support@osimed.com
sales@osimed.com

OSM Malaysia
No. 6 Jalan Angkasa Mas 1,
Kawasan PerindustrianTebrau 2
81100 Johor Bahru,
Johor, Malaysia
Telephone: +65 296-7600
Fax: +65 296-5595

Please clean contaminated equipment before returning it to OSI Medical. Ensure it is completely dry before packing the equipment. Package the equipment securely in the original shipping container and packaging materials.

Enclose the following items:

1. A letter describing in detail any difficulties experienced with the oximeter.
2. Please reference the Return Authorization Number obtained from OSI Medical.
3. Shipping and billing information of the sender for returning the serviced oximeter and invoicing for any repair charges.
4. A contact for any questions about the repairs including name, telephone/Telex/fax number, country, and email.

Section 10: Specifications

Note: Unless otherwise indicated, all specifications are nominal and are subject to change without notice.

Performance

Measurement Range:

SpO_2 (functional)	0 % – 100 %
Pulse Rate (bpm)	30 - 240 bpm
Perfusion	0.02 % - 20 %
Low Perfusion	0.02 % - 0.2 %
Normal Sensitivity	0.06% - 20%
High Sensitivity	0.02% - 0.06%

Where perfusion % = $(AC/DC)_{905}$ X 100

Resolution:

SpO_2 (functional)	1 %
Pulse Rate (bpm)	1

Accuracy:

SpO_2 (functional)	Adult Pediatric > 30 kg	No Motion and Normal Perfusion	70 – 100 0 – 69	± 2 % Unspecified
Pulse Rate (bpm)	Adult Pediatric > 30 kg	No Motion and Normal Perfusion	30 – 240	± 3 bpm
SpO_2 (functional)	Adult Pediatric > 30 kg	Motion or Low Perfusion < 0.2 %	70 – 100 0 – 69	± 3 % Unspecified
Pulse Rate (bpm)	Adult Pediatric > 30 kg	Motion or Low Perfusion < 0.2 %	30 – 240	± 5 bpm

Sensor LED nominal wavelength values 660nm and 905nm

Display

Type	Backlit LCD
Pixels	240 x 64
Dot Pitch	0.53 mm
Data Displayed	Pulse Rate, SpO2, Pleth wave, Alarms, Trends, Status messages.

SpO_2 and pulse rate alarms

High SpO_2	70% – 100%, – – – (Off)
Low SpO_2	70% – 100%, – – – (Off)
High pulse rate	30 BPM – 240 BPM, – – – (Off)
Low pulse rate	30 BPM – 240 BPM, – – – (Off)

Dimensions

- 10.2 cm x 27.9 cm x 25.4 cm (4 in. x 11 in. x 10 in.)
- 4.0 kg (8.8 lb.)

Electrical

Voltage Input	• 100 – 240 Vac
Frequency	• 50 – 60 Hz
Maximum Power Consumption	• 33VA
Leakage Current	• Less than 100 A, with power on, forward or reverse polarity • Ground resistance less than 0.1
Battery	• Sealed lead acid, 12Vdc, 2.2 A–hr • Minimum 4 hour battery operation • Recharge to 80% of capacity in 4.5 hours

The battery may discharge during prolonged shipment or storage times. If the oximeter was disconnected from AC power for more than two months. Connect the oximeter to AC power overnight before using on battery power. Where possible, connect the oximeter to AC power when not in use for extended periods of time.

Electromagnetic effects

The oximeter complies with the requirements of IEC 601-1-2. The following basic EMC standards were applied to verify conformance.

Environment	IEC 601-1-2.
Emissions	CISPR 11 Group 1, class B
Immunity	IEC 1000-4-2, 8kV, 3kV contact IEC 1000-4-3, 3V/m IEC 1000-4-4, 2kV power, 500V sensor cable IEC 1000-4-5, 2 kV line to earth, 1kV line to line

The oximeter was tested with RS-232 and analog cables attached (not connected to printers, recorders or other devices) while operating on AC power. Symptoms of possible electromagnetic interference include appearance of the INTERFERENCE DETECTED message, sudden variations in the plethysmographic waveform or pulse amplitude bar that do not correspond to physiological changes in the patient.

Data output

Analog output	6-pin female DIN connector for %SpO_2, pulse rate or plethysmographic waveform, and nurse call signals
Serial output	DB-9 female connector for real time and trend RS-232 data output
Real time clock	Y2K compliant, leap year compliant through 2100
Trend data storage	• User selection of 24 hours (2-second sample resolution) • 48 hours (4 second sample resolution) • 72 hours (6 second sample resolution) • or 96 hours (8 second sample resolution) • Battery protected RAM memory (date, time, %SpO_2, pulse rate)

Note: The precise data storage capacity of the oximeter may vary slightly from maximum capacity depending on oximeter usage patterns. This variation does not exceed 10 minutes of stored data at 24 hour capacity.

Environmental

Operating

Temperature	-5 – 45°C (23 – 113°F)
Relative Humidity	5 – 95%RH, non-condensing
Pressure	503 hPa – 1059 mbar
	Approximate elevation of –378 – 5946m (-1240 – 19508ft)

Storage

Temperature	-20 – 60°C (-4 – 140°F)
Relative Humidity	5 – 95%RH, non-condensing
Pressure	503 hPa – 1059 hPa
	Approximate elevation of -378 – 5946m (-1240 – 19508ft)

IEC (International Electrotechnical Commission) classifications

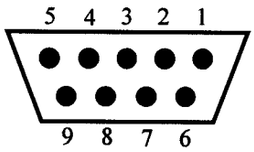
Type of protection against electric shock	Class I / Internal electric power source
Degree of protection against electric shock	Type BF
Mode of operation	Continuous
Degree of protection against ingress of liquids	Ordinary
Recommended methods of sterilization or disinfection	Refer to *Section 7: Sensors and Accessories* and *Section 9: Maintenance and Service*, and the Directions for Use for the SpO_2 sensor and Extension Cable being used for cleaning instructions.
Degree of safety of application in the presence of a flammable anesthetic	Not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

Section 11: Serial and Analog Communication

Serial data communication

DB-9 Connector Pin Assignments:

1. Data Receive – Not Used
2. Data Send
3. No Connection
4. No Connection
5. Ground
6. No Connection
7. No Connection
8. No Connection
9. No Connection



Serial connector

The serial data transmitted by the oximeter is 8-bit data, no parity, 1 start bit, 1 stop bit, full duplex. Use the BAUD RATE item of the Setup Menu to select 4800, 9600, or 19200 Baud. During normal operation the oximeter outputs real time data every two seconds. The ASCII real time data format is:

Date <SPACE> HH:MM:SS <SPACE> SpO_2% <SPACE> Pulse Rate BPM <CR><LF>

The trend data output provides SpO_2 and pulse rate values stored at the sample resolution selected by the TREND STORAGE item of the Setup Menu, accompanied by periodic time markers. The time markers are recorded every time the oximeter is turned on, and after approximately every 60 minutes of continuous operation thereafter.

The ASCII trend data time marker consists of: Date <SPACE> HH:MM:SS <CR> <LF>

The ASCII SpO2 and pulse rate trend data consists of: SpO_2% <SPACE> Pulse Rate BPM <CR> <LF>

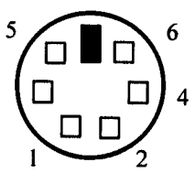
In both real time and trend data output, the ASCII Date is transmitted as MM/DD/YYYY (U.S. Format) or DD/MM/YYYY (International Format), as selected in the DATE MODE item of the Setup Menu. The ASCII SpO_2 and pulse rate data values are transmitted as three digits, with leading zeros where necessary.

When trend data is transmitted, real time patient monitoring functions are not operating. Refer to *Section 6: Softkeys and Menu Setup.*

Analog data communication

6-pin DIN connector pin assignments:

1. Analog data channel 1 – %SpO_2
2. Ground 1
3. Ground 3
4. Analog data channel 2 – pulse rate BPM or waveform
5. Nurse call signal
6. Ground



Analog connector

The two analog data channels provide linear 0-1VDC signals corresponding to real-time patient readings:

Analog Signal	0-100% SpO_2	50-100% SpO_2	Pulse Rate
0 VDC (Low)	0%	50%	0 BPM
1 VDC (High)	100%	100%	250 BPM

When analog data channel 2 is set to PLETH, the 0 – 1 VDC signal corresponds to the autoscaled waveform signal shown on the display.

The nurse call signal is a high or low signal indicating when the oximeter has an active alarm. It is normally HIGH (5Vdc), and an active alarm is indicated by a LOW (0Vdc) signal. This allows the oximeter to signal an abnormal situation in the event of a complete device failure. The user can set the nurse call signal to indicate an active alarm condition with a high signal.

The oximeter allows the user to send analog test signals to calibrate external devices. Refer to *Section 6: Softkeys and Setup Menu.*

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