



Dolphin Medical

An OSI SYSTEMS Company

USER MANUAL

2150 Dolphin ONE Handheld PULSE OXIMETER



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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 Dolphin Medical for return authorization and instructions. See *Maintenance and Service* section for more information.

If an examination by Dolphin Medical Inc discloses such products or component parts to be defective, Dolphin Medical's sole obligation is limited to repair or replacement (at Dolphin 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 Dolphin Medical Inc or an authorized Dolphin Medical Inc agent. This warranty does not extend to any accessories, or other external instruments or devices that are connected to the oximeter.

Dolphin ONE 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 DOLPHIN MEDICAL INC. IS THE SOLE AND EXCLUSIVE WARRANTY AS TO DOLPHIN MEDICAL INC'S PRODUCTS. THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY ORAL OR IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. DOLPHIN MEDICAL INC 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 Dolphin Medical Inc 2150 Pulse Oximeter is intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂), pulse rate (measured by an SpO₂ sensor), and temperature (measured by YSI 400 series probe)

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 (photo-plethysmography).
- 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.

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 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 Dolphin Medical Inc.'s Dolphin ONE Oximeter Sensors and Extension Cables for SpO₂ measurements by the oximeter. Other manufacturer's sensors and patient cables may cause improper performance.

Before use, carefully read the Oximeter Sensor Directions for Use.

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

Do not use damaged Dolphin ONE Oximeter Sensors or Patient Cables. Do not use a Dolphin ONE Oximeter 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 Dolphin ONE Oximeter Sensors or Extension Cables by irradiation, steam, or ethylene oxide. See the cleaning instructions in the Directions for Use for Dolphin ONE 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 Dolphin ONE Oximeter Sensors and Extension Cables for proper connection and disconnection instructions.

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 Dolphin ONE Oximeter 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 Oximeter measurements.

Interfering Substances: Carboxyhemoglobin may erroneously increase SpO₂ 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 Dolphin Medical Inc or an authorized Dolphin Medical Inc 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.

Grounding:

- Only use the power transformer that was provided by Dolphin Medical for use with the 2150 oximeter. Contact Dolphin Medical to obtain a replacement if the power transformer is damaged.
- Connect the oximeter power transformer 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 transformer.
- Do not use extension cords or adapters of any type. The power transformer 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.

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

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

Cautions

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

Do not place the oximeter on electrical equipment that may affect 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.

The internal battery is a NiMh battery, which requires proper disposal. 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 Dolphin Medical Inc or an authorized distributor.

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 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	
KEYS	INDICATORS
 On / Off Key	 AC Power LCD Indicator
 Alarm Silence Key	 Battery Status LCD Indicator
 Backlight Key	 Alarm Silence LCD Indicator
 Alarm Limits Key	 Adult Mode LCD Indicator
 Menu Key	 Neonatal Mode LCD Indicator
 Alarm Volume Key	 High Sensitivity LCD Indicator

REAR PANEL SYMBOLS	
 Rated supply voltage 100-240 VAC, 50-60 Hz	 Type BF applied part
Product Nbr Product Reference Number	 Attention: Consult accompanying documents before use
Serial Nbr Serial Number	 Indicates this device is in compliance with MDD 93/42/EEC. 0459 is the Notified Body Number.
  Indicates product is UL and CSA Classified.	

Section 4: Preparation for Use

Initial inspection

1. Unpack and inspect the oximeter for external damage.
2. Review the oximeter and identify the connectors, controls, and indicators.
3. Connect the oximeter to external power by plugging in the external power transformer into a medical grade power outlet. Verify the AC indicator is illuminated on LCD.
4. Unpack the Dolphin ONE Sensors and remove any substances that may interfere with the transmission of light between the sensor's light source and detector.
5. Press  and hold over 2 seconds, listen for the two-beep tone of the oximeter's self-test.
6. Select a Dolphin ONE Oximeter 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 patient.
7. After approximately 10 seconds, verify the readings for SpO₂ and pulse rate.
8. Verify the patient alarms are functioning by setting the high and low SpO₂ and pulse rate alarm limits so the patient readings violate the limits (refer to appropriate section in this manual for details on how to set alarm limits). Ensure the following occurs:
 - An alarm tone sounds.
 - The violated alarm limit arrow and the corresponding patient reading flashes on the display.
9. Verify temporary alarm silence operation. Press  momentarily. Ensure the following occurs:
 - The alarm tone ceases (will be for 120 seconds).
 - The  LCD indicator flashes to indicate monitor is in the temporary alarm silence mode
10. Verify the sensor alarms are functional by removing the sensor from the sensor site after a valid SpO₂ and heart rate reading has been displayed. Ensure the following occurs:
 -  (Probe off) appears in the message display area.
 - The alarm tone sounds.
11. Unplug the sensor from the oximeter. Ensure the following occurs:
 -  (no probe) appears in the message display area.

Audio setup

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

To adjust the audible alarm volume:

- Press  until desired volume is produced. Volume will increase one step per second

To adjust the volume of the pulse beep:

1. Press  to raise or lower the pulse beep volume while in the patient monitoring mode.



Section 5: Monitor Identification

SIDE SENSOR CONNECTIONS AND FRONT LCD AND FRONT PANEL

Interface Cable Connector



Temperature 1/8" phone jack connector

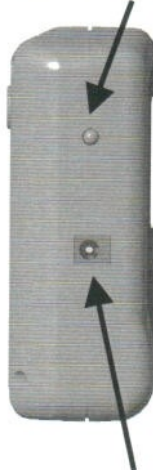
LCD



Front Panel Buttons

REAR PANEL & SIDE POWER CONNECTIONS

Infra Red (IR) output LED



Power entry module: Connects the oximeter to external power supply. **Use ONLY the power supply that was provided by Dolphin Medical for use with the 2150 oximeter.** Permanent damage to the monitor can occur if an incompatible power supply is plugged into the monitor.

Belt or Pole Mount Clip



Product identification label: Lists product reference number and serial number.



On / Off Key



Alarm Silence Key



Alarm Limits Key



Backlight Key



Menu Key










Alarm Volume Key

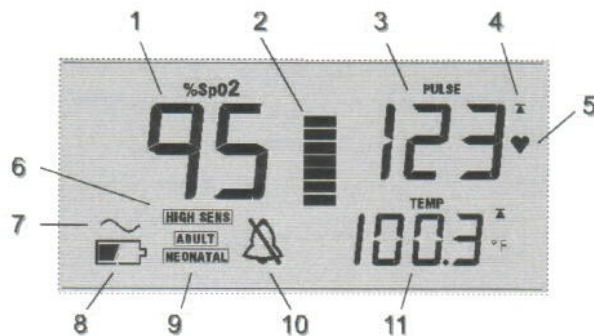


AC Power Indicator

Front Panel Buttons

-  **Press and hold over 2 seconds** - turns the oximeter on and off.
-  When pressed, alarms are temporarily silenced. If pressed and held over 2 seconds, all audible alarms are muted indefinitely until pressed again.
-  Turns on and off the LCD backlight.
-  Adjusts the pulse beep volume when in normal monitoring mode. When in the menu mode the up and down arrows changes the options within each menu.
-  When pressed, menu mode is entered. Each additional press changes to the next menu. Menu mode will exit if nothing is pressed for 10 seconds
-  When pressed, will adjust the alarm volume. Will cycle back to lowest volume after the highest volume
-  When pressed, alarm limit mode is entered. Each parameter's upper and lower alarm limit is toggled through with each consecutive press. Use up and down arrow to adjust limit when desired parameter alarm limit is displayed

LCD Control Indicators





1. % SpO2 – Flashes when upper or lower alarm limits are violated
2. Pulse Strength Bar
3. Pulse Rate - Flashes when upper or lower alarm limits are violated
4. Upper Alarm Arrow – upper or lower arrow will flash to the right of violated parameter
5. Pulse Indicator
6. High Sensitivity Mode indicator
7. AC Power Indicator
8. Battery Level Indicator
9. Adult or Neonatal Mode indicator
10. Alarm Silence Indicator
11. Temperature - Flashes when upper or lower alarm limits are violated






Section 6: Routine Use

AC and battery power usage


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

When approximately 15 minutes of battery power remain, the  indicator flashes and an audible tone is produced. If the all-mute function is active the unit will exit this mode and enunciate the audible tone. The all-mute mode can be reentered by pressing the alarm silence button over 2 seconds.


When battery power is depleted,  illuminates, an alarm sounds for 15 seconds. The alarm sounds even if the all-mute function is active. Connect the oximeter to AC power to recharge the battery.

If the battery is too low to operate and  is pressed, the  indicator flashes. 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

Pressing and holding the  over 2 seconds will turn the oximeter on or off. The oximeter automatically executes a self-test when turned on. Two tones are produced to indicate self-test has passed.

Pulse tone adjustments


Press  during normal operation while SpO₂ and heart rate are being displayed to raise or lower the pulse tone volume. This setting is retained after the oximeter is turned off.

SpO₂, Pulse rate, and Temperature Alarms

The oximeter provides visual and audible indications when SpO₂, pulse rate, or temperature values violate alarm limits. The violating SpO₂, pulse rate, or temperature value flashes, and the violated upper or lower alarm limit arrow to the right of the value shows which limit was met or exceeded. A priority alarm sounds unless the  was pressed in the previous two minutes, or the all-mute function is active.

Alarm limit adjustment

To view or change the alarm limits, press  and to toggle through each parameter and its upper and lower limit.

Use  to change the highlighted parameter. The up and down arrow to the right of the selected parameter will indicate which limit is being displayed or changed. The settings are NOT retained after the oximeter is turned off.



Alarm Defaults



On power up the alarm default will be set to the following;

Adult Mode	
Limit	Value
High spo2%	- - - (OFF)
Low Spo2 %	85%
High Heart Rate	150 bpm
Low Heart Rate	40 bpm


Neonatal Mode	
Limit	Value
High spo2%	100%
Low Spo2 %	85%
High Heart Rate	200 bpm
Low Heart Rate	100 bpm






Sensor Alarms

The oximeter provides visual and audible indications when the Dolphin ONE 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 appropriate message, **P2B OFF** (Probe Off) or **no P2B** (No Probe), appears in the display, and an audible alarm sounds.

When  is pressed, the alarm tone is temporarily silenced for 120 seconds. Press  and hold over a 2-second period to put the monitor in all-mute mode and to indefinitely mute the alarms.

Audible alarms adjustment

Press  to change the alarm volume setting.

Press  to temporarily silence alarms. The Alarm Silence period is 120 seconds. The oximeter has the capability to indefinitely mute alarms. Press  and hold over a 2-second period. The  indicator appears and does not flash on the display when the all-mute function is active. All alarms are muted until this function is cleared by pressing  again. If a sensor off patient **P2B OFF** or a sensor disconnect **no P2B** occurs while in the all mute mode, the unit will exit the all mute mode and will require the user to reinitiate the all mute mode if desired by pressing and holding the  over 2 seconds. If a low battery shutdown or system failure occurs, an alarm sounds even if all mute is active or alarms are temporarily silenced.





Temperature Display

If the unit is powered up without a YSI 400 series thermistor the temperature feature is disabled along with any associated alarm temperature limits. To enable the temperature feature simply plug in a YSI 400 series thermistor. If a YSI 400 series thermistor is plugged into the monitor at any time then the temperature feature cannot (one word) be disabled, unless the unit is powered down and the thermistor is unplugged from the monitor before the unit is powered back on.

ONLY use a YSI 400 Series compatible thermistor with this monitor to ensure accuracy. Stated temperature accuracy of this monitor does not reflect added tolerances that are associated with the particular YSI 400 Series thermistor chosen. Refer to the manufactures literature for tolerances of the particular YSI 400 Series thermistor that is to be used with the 2150 monitor.


Patient Type Mode Selection

The patient mode type can be set to either  ADULT or  NEONATAL. The modes will change default alarm limits. The ADULT is the standard mode for patients greater than 30 Kgs. In patients less than 30 Kgs the NEONATAL mode should be selected.

Dolphin ONE disposable sensors and reusable sensors automatically set the mode depending on the sensor type plugged into the monitor. Use this "override" feature when sensors type and patient type do not match.




Example; Dolphin ONE Neonatal Disposable sensor used on a patient greater than 30 kgs.

Sensitivity Mode Selection

The sensitivity mode selects the sensitivity mode. The default is Normal sensitivity, which has no LCD indicator and High sensitivity, which is indicated by the LCD Icon . The High Sensitivity mode may be selected when the patient is very poorly perfused.

In High Sensitivity mode, the 2150 will detect and measure the smallest pulsatile signals; however, because of this, the High Sensitivity mode is more likely to be affected by external interference (motion artifact, light noise, etc.) Additionally, the ability to detect an asystole (no Pulse) event is greatly diminished. This High Sensitivity mode should only be used when the patient is being closely monitored by a clinician.

LCD Backlight On/Off






Press  to turn on LCD backlight. On AC power the backlight will remain on until the  is pressed again. On battery power the backlight will remain on for 15 seconds and then turn off. Pressing the  during that 15 seconds will immediately turn off the backlight.



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 SpO₂ data may be inaccurate.













Section 7: Status Messages and Status Indicators






























STATUS MESSAGES	
LCD Message	Description
	Dashes moving left to right <i>Pulse Search Mode – Monitor may take a few moments to obtain valid reading</i>
	No Probe <i>No sensor is connected to the oximeter. Plug Dolphin ONE sensor into interface cable.</i>
	Probe Off <i>The sensor is not properly attached to the patient. Apply sensor to the patient or relocate the sensor to a better site.</i>
	Probe Error <i>An incompatible or damaged sensor is connected. Discard sensor and replace with new functional Dolphin ONE sensor.</i>
	System Error <i>Contact Dolphin Medical</i>

STATUS INDICATORS	
	<u>Pulse Strength bar flashes</u> Only a very weak signal is detected <i>Move the sensor to a site with better perfusion. Refer to the <u>Directions for Use</u> accompanying the sensor.</i> <i>Switch to High Sensitivity Mode</i>
	<u>Only single bar in pulse section is illuminated and moves up and down to pulse</u> Low light levels or tissue too thick <i>Move sensor to a different location, Select another sensor site with less tissue thickness, or that allows better light transmission.</i> <i>Switch to High Sensitivity Mode</i> High levels of external light (from daylight, examination lights, infrared heat lamps, etc.) are detected. <i>Select another sensor site more protected from ambient light or cover the sensor site with dark or opaque material.</i>

Section 8: Menu Mode

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

Main Menu and Alarm Adjustment Modes:		
Main key -Press:	To Go To:	Description
		Sensitivity Mode <i>High or Normal (No Icon Indicator for Normal Sensitivity Mode)</i>
		Set Adult / Neonatal Mode <i>Sets Adult or Neonatal mode and will change default alarm limits</i>
		Data Index <i>Enters a number from 1 to 255 into stored trend data</i>
		Data Out <i>Turns on or off real time IR output. Data rate is once every 30 seconds</i>
		Trend Options Mode <i>Send (snd) stored trend data via IR output, Clear (clr) stored trend data, or do nothing (---)</i>
		Temperature Set Mode <i>Set to C or F. This setting is retained even after unit is turned off.</i>
		Battery Condition Mode <i>Turn on Battery Conditioning. Unit must remain on AC power during the 10-hour conditioning cycle.</i>
		Software Version <i>Displays software versions from 1-8 (Each number indicates a different portion of the software. The number displayed in the "temperature" area is the revision of that software portion)</i>
	Low SpO2	20-99% or off, "---"
	High SpO2	21-100% or off, "---"
	Low Pulse Rate	35-234 BPM or off, "---"
	High Pulse Rate	36-235 BPM or off, "---"
	Low Temperature	80-109 F (26.7 – 42.8 C) or off, "---"
	High Temperature	91-120 F (32.8 – 48.9 C) or off, "---"

Menu Modes:			
Main Menu Modes:	Press:	To Go To:	Description
			The default for sensitivity mode is "normal", which has no icon indicator.
			The High sensitivity mode allows very small pulse signals to still be obtained.
			Sets Adult mode and will change default alarm limits.
			Sets Neonatal mode and will change default alarm limits and help in motion rejection that is associated with neonatal patients.
			If no arrow is pressed the "----" display remains. If the user exits in this mode then no marker will be stored, this is the only way a marker will not be placed in trend memory.
			This number indicates the number that will be stored in the trend memory as a marker once the user exits this menu. When the up arrow is pressed the number is indexed from 1 to 255.
			Data out is set to OFF. Continuous data is not sent to the IR port. The state the data out is exited in is the mode the monitor will remain in until changed by the user.
			Data out is set to ON. Continuous data is sent to the IR port.
			Trend Options mode, If the user exits in this mode then no action will be taken.
			When user exits the menu in the send mode the trend data in memory will be sent to the IR port.
			When user exits the menu in the clear memory mode the data that is stored in memory will be cleared. This includes any markers in the memory.
			The small C or the F to the right of the temperature display will also indicate which mode you are in.. When the user exits the menu the displayed mode is then set.
			The up or down arrow will toggle between the C or F mode.
			Battery conditioning is defaulted to the "----" or off mode and can only be turned on while external power is applied to the unit.
			If battery conditioning is set to on the battery discharge cycle will begin once user exits this menu.

Menu Mode

			<p>Displays software versions from 1-8 (Each number indicates a different portion of the software. The number displayed in the "temperature" area is the revision of that software portion)</p>
---	---	---	---

Note: The pulse beep is temporarily silenced whenever the Setup Menu is on the display.

Section 9: Sensors and Accessories





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

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

Compatible Dolphin ONE Sensors and patient cables		
Sensor	REF	Patient type
DOLPHIN ONE Adult Reusable	Model 210	Adult /Pediatric - Patients Over 30 kgs
DOLPHIN ONE Adult / Pediatric Disposable	Model 520	Patients over 30 kgs
DOLPHIN ONE Infant / Neonatal Disposable	Model 560	Patients under 30 kgs
DOLPHIN ONE Adult Y probe and / or Ear-Clip	Model 320	Adult / Pediatric Patients Over 30 kgs
DOLPHIN ONE Neonatal Y probe	Model 360	Neonatal / Infant Patients Under 30 kgs
3 ft Extension Cable	Model 120	All
5 ft Extension Cable	Model 110	All

OTHER ACCESSORIES	
Accessory	REF
Operator's Manual – English	10-00268
Quick Reference Guide – English	10-00269
Belt Clip	55-01014
Pole Mount	Cat 2190
Additional or replacement Power Transformer	21-00677

Section 10: Troubleshooting

Troubleshooting		
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 10 hours before using the oximeter on battery.
	Battery needs replacement.	Contact Dolphin Medical Inc for 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 8 hours before using the oximeter on battery.
		If condition persists, contact Dolphin Medical Inc 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 Dolphin Medical Inc for service.
Battery does not hold charge or battery life is short	Battery Conditioning is needed	Connect oximeter to AC power and activate battery conditioning, refer to appropriate section.
No response from oximeter when keys are pressed.	System failure.	Contact Dolphin Medical Inc for service.
No speaker sound.	Pulse beep volume is set to OFF, and no alarm conditions are active.	Press  to increase pulse beep volume.
	Obstruction over speaker holes	Remove Obstruction
	System failure.	Contact Dolphin Medical Inc for service.
Continuous speaker sound.	If sound is on for 15 seconds, batteries are low.	Plug unit into AC power or recharge batteries
	System failure.	Contact Dolphin Medical Inc for service.
Oximeter displays readings while sensor is not applied to patient.	Sensor is open to ambient lighting.	Disconnect sensor from oximeter, or turn sensor detector away from ambient light source.

Section 11: Maintenance and Service

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

Note: The oximeter does not require calibration. Calibration and test methods for SpO₂ and pulse rate are available upon request.

Battery Maintenance

The battery may discharge during prolonged shipment or storage times. If the oximeter was disconnected from AC power for more than one month, 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. It is recommended that if you use the monitor on battery power often that you perform a battery conditioning every 2 to 3 months. If you use the monitor on AC power most often a conditioning every 3 months is sufficient. Refer to battery conditioning instructions additional information and instruction. Store at the lowest feasible temperatures (0 to 30 °C being the generally recommended storage temperatures). Storage in a clean, dry, protected environment to minimize physical damage to batteries. Use good inventory practices (first in, first out) to reduce time batteries spend in storage.

Cleaning Unit and/or Reusable Sensor

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 Dolphin ONE Oximeter Sensor and Extension Cables.

Repair policy and procedure

All repair and service must be performed by Dolphin Medical Inc, or a service representative authorized by Dolphin Medical Inc. 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 your local distributor / service center or manufacturer directly:

Manufacturer & U.S. Office

Dolphin Medical Inc.
12525 Chadron Ave
Hawthorne CA 90250
Toll Free: 866.588.9530
Fax: 310.978.1816

www.dolphinmedical.com
support@dolphinmedical.com

International Distributor

Dolphin Medical PTE. Ltd.
996 Bendemeer Road, # 04-02
Singapore, 339944
Tel: +65.6.296.8452
Fax: +65.6.296.5595

Please clean contaminated equipment before returning it to Dolphin Medical Inc or distributor. 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 in the return packaging:

1. A letter describing in detail any difficulties experienced with the oximeter.
2. Please reference the Return Authorization Number obtained from Dolphin Medical Inc.
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 12: Specifications

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

Measurement Range:	
SpO ₂ (functional)	0 % – 100 %
Pulse Rate (bpm)	35 – 235 bpm (Beats Per Minute)
Temperature	32.0° – 138.9° F (0.0° – 60.0° C)
Perfusion	0.02 % - 20 %

Resolution:	
SpO ₂ (functional)	1 %
Pulse Rate (bpm)	1
Temperature	0.1 °F (0.1°C)

Accuracy:			
SpO ₂ (functional)	No Motion and Normal Perfusion	70 – 100	± 2 % Arms
		0 – 69	Unspecified
Pulse Rate (bpm)	No Motion and Normal Perfusion	30 – 240	± 3 bpm
SpO ₂ (functional)	Neonatal * No Motion and Normal Perfusion	70 – 100	± 3.5 % Arms
		0 – 69	Unspecified
SpO ₂ (functional)	Low Perfusion < 0.2 %	70 – 100	± 3 % Arms
		0 – 69	Unspecified
Pulse Rate (bpm)	Low Perfusion < 0.2 %	30 – 240	± 5 %
Temperature	Not including sensor accuracy	32.0° – 138.9° F	± 0.2° F

** Neonatal testing was completed on healthy adult subjects and 1% was added to the % Arms to account for Fetal Hemoglobin effects.*

Sensor LEDs	
Nominal wavelength and nominal power output values	660nm - 1.8mw and 905nm - 2.0mw

Display	
Type	Liquid Crystal Display (LCD) with Backlight
Data Displayed	SpO ₂ , Pulse Rate, Temperature, Alarms, and Status messages
<i>Note: There is no display delay from the calculated value</i>	

Alarm Limits

Low SpO2	20-99% or off, "---"
High SpO2	21-100% or off, "---"
Low Pulse Rate	35-234 BPM or off, "---"
High Pulse Rate	36-235 BPM or off, "---"
Low Temperature	80-109 °F (26.7 – 42.8 °C) or off, "---"
High Temperature	91-120 °F (32.8 – 48.9 °C) or off, "---"

Unit Dimensions & Weight

Dimensions	17.8 cm x 19.1 cm x 5.1 cm (7 in. x 7.5 in. x 2 in.)
Weight	1.1 kg (2.5 lb.)

Electrical

Voltage Input to Power Transformer	<ul style="list-style-type: none"> • 100 – 240 Vac
Frequency	<ul style="list-style-type: none"> • 50 – 60 Hz
Maximum Current Draw	<ul style="list-style-type: none"> • 2.5 Amps
Leakage Current	<ul style="list-style-type: none"> • Less than 100 µA, with power on, forward or reverse polarity • Ground resistance less than 0.1Ω
Battery	<ul style="list-style-type: none"> • Nickel Metal Hydride, 9Vdc, 1.5 A-hr • Minimum 4 hour battery operation • Recharge to 95% of capacity in 8 hours

The battery may discharge during prolonged shipment or storage times. If the oximeter was disconnected from AC power for more than one month. 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. Refer to battery conditioning instructions for further battery performance.

Store at the lowest feasible temperatures (0 to 30 °C being the generally recommended storage temperatures). Store in a clean, dry, protected environment to minimize physical damage to batteries. Use good inventory practices (first in, first out) to reduce time cells spend in storage.

Electromagnetic effects

The oximeter complies with the requirements of EN60601-1-2 2002 Electromagnetic Compatibility. The following basic EMC standards were applied to verify conformance.

Environment	EN60601-1-2 2002 Electromagnetic Compatibility
Emissions	EN60601-1-2 2002 Electromagnetic Compatibility CISPR 11 Group 1, class B
Immunity	EN60601-1-2 2002 Electromagnetic Compatibility

Data output	
Infrared (IR) Data output	IrDA protocol (Physical Layer Only) set to 19.2 Kbps output
Trend data storage	<ul style="list-style-type: none"> 3 hours of 30 second interval data of Duration marker, SpO₂, Pulse Rate, Temperature, Index Marker & Alarm Codes Battery protected EE Prom memory

Environmental	
Operating	
Temperature	-5 – 45°C (23 – 113°F)
Relative Humidity	5 – 95%RH, non-condensing
Pressure	503 mbar – 1059 mbar Approximate elevation of -378 – 5946m (-1240 – 19508ft)
Storage	
Temperature	-29 – 60°C (-20 – 140°F)
Relative Humidity	5 – 95%RH, non-condensing
Pressure	503 mbar – 1059 mbar 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 (IPX1)
Recommended methods of sterilization or disinfection	Refer to <i>Section: Sensors and Accessories</i> and <i>Section: Maintenance and Service</i> , and the <u>Directions for Use</u> for the SpO ₂ sensor and Extension Cable being used for appropriate 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 13: IrDA Communication

Inferred (IR) communication

- Serial data is transmitted by the IR port of the oximeter. The format of the IR communication is IrDA, physical layer only. The IR data out baud rate is set to 19.2 Kbps.
- If the monitor is set to "Data Out" (refer to menu modes) the IR port will output the Duration marker, SpO2, Heart Rate, Temperature, & Alarm Codes every 30 seconds.

Example:

TIMER	SpO2	HR	TEMP	ALC
000:00:30	95	98	98.6	
000:01:00	94	110	98.5	HU
000:01:30	92	123	98.6	SL HU

The alarm codes are as follows;

HR Upper rate violation = HU

HR Lower rate violation = HL

SpO2 Upper rate violation = SU

SpO2 Lower rate violation = SL

- If the user selects "Trend Send" (refer to menu modes) the entire trend data stored in memory will be sent to the IR port (up to 4 hours of trend data). This includes the Duration marker, SpO2, Heart Rate, Temperature, Index Marker (if entered) & Alarm Codes. Once all data is sent, normal IR operation will resume.

Example:

Begin

TIMER	SpO2	HR	TEMP	ALC
000:00:30	99	98	98.6	
000:01:00	98	110	98.5	HU

Index 23

000:01:30	98	112	98.6	HU
-----------	----	-----	------	----

000:00:30	95	82	99.2
-----------	----	----	------

000:01:00	96	83	99.2
-----------	----	----	------

End







*The "*****" indicates the unit was powered down and back on which should indicate a different patient. (The timer is set to zero after a power cycle)*

A recommended interface for the IR port monitor is the Actisys, ACT-IR220LN at 19.2kbps (www.actisys.com). This interface will allow a PC running HyperTerminal set to 19.2Kbps to capture the IR output of the 2150.

Make sure nothing is obstructing the view of the IR interface to the IR output LED of the monitor. The IR interface must be in direct line of site for the receiver of the interface to be able to "see" the IR output signal from the monitor.

Section 14: Battery Status Indicators and Conditioning features

The Battery indicator on the LCD has 4 different states to indicate the current stage of the battery.

					
Battery Full	Reduced Battery Life	Battery at low capacity	Outer flashing and alarm tone: Less than 15 minutes of battery left - Plug monitor into AC power.	Outer flashing, continuous alarm tone, and monitor turns off: Insufficient battery power to run monitor - Plug monitor into AC power.	At power up, outer flash and tone: insufficient battery power to turn on monitor - Plug monitor into AC power.

When batteries are charging, the outline icon will illuminate and the left inside icon will continually flash slow for a trickle charge and flash fast for a rapid charge. Once battery is fully charged all 3 battery icons will be continually illuminated.

Battery Conditioning

The internal battery is a NiMH (nickel metal hydride battery) to provide maintenance-free operation. However proper usage and periodic battery conditioning will extend the life of the battery. It is recommended that if you use the monitor on battery power often that you perform a battery conditioning every 2 to 3 months. If you use the monitor on AC power most often a conditioning every 3 months is sufficient.

- Battery conditioning will be activated by the user making the appropriate menu selection (see menu mode).
- This activation is only a one-time activation and will reset to normal function if the unit is turned off and back on.
- External power must be attached before the battery conditioning will start. Conditioning will stop if the unit is disconnected from external power.
- During battery conditioning the monitor can be on and operational. If during battery conditioning the monitor is turned off, the unit will continue to complete the battery conditioning and the appropriate icon display will indicate.
- When battery conditioning is activated the battery segments icons on the LCD will cycle between the left and right internal icons. The outer battery icon will remain on solid.



- Battery conditioning will discharge the batteries completely and then recharge the batteries. Once batteries are discharged and charging begins, the icons will return to normal operation.

Note: Please refer to the Battery Maintenance notes in the *Maintenance and Service* section of this manual for important additional battery information

Appendix A: End User License Agreement

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