MODEL 31DT

User's Manual

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Pulse Oximeter User's Manual

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CHAPTER 1:
INTRODUCTION OF THE MODEL 31DT PULSE OXIMETER

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.

INTENDED USES

The Model 31DT is for prescription use only. The Mediaid Model 31DT pulse oximeters are intended to non-invasively measure arterial oxygen saturation and pulse rate in hospitals, physician's offices, emergency medical facilities, or at home.

IMPORTANT NOTE:
The Mediaid Model 31DT pulse oximeter does not have storing and retrieval of data facility such as IR, USB features.

GENERAL OPERATING PRINCIPLES AND CONDITIONS

The Mediaid Model 31DT pulse oximeter is designed to measure the percentage of functional oxygenated hemoglobin to total hemoglobin.

Noninvasive arterial oxygen saturation measurement is obtained by directing red and infrared light through a pulsating vascular bed. The pulsating arterioles in the path of the light beam cause a change in the amount of light detected by a photodiode. The pulse oximeter determines the oxygen saturation of arterial blood by measuring the ratio of transmitted red to infrared light within the pulse waveform. The non-pulsatile signal is removed electronically for the purpose of calculation. Therefore, skin, bone, and other non-pulsating substances do not interfere with the measurement of arterial oxygen saturation.

INTRINSIC CALIBRATION

The light absorption by hemoglobin is wavelength-dependent. Mediaid red and infrared LED (light emitting diode) wavelengths are tightly controlled by testing in production.

PRINCIPAL FEATURES

The Mediaid Model 31DT pulse oximeter is a lightweight Desk Top instrument designed to monitor both functional arterial oxygen saturation (SpO_2) and pulse rate non-invasively.

The principal features of the Model 31DT pulse oximeters are as follows:

- Displays SpO2 percentage (%SpO) and pulse rate (BPM: Beats per minute) on a 3-digit, 7-segment LED Display.
- Displays Perfusion Quality (PQ) & Pulse Amplitude (PA) in 10-bar bargraph displays.

- Works with any Mediaid sensors with the CompuShield® connector.
- Provides increased longevity and functionality to the pulse oximeter with the removable and replaceable sensor modules.
- The Model 31DT has visual and audible alarms for oxygen saturation and pulse rate.
- The Model 31DT can be powered by Standard electric power.

CAUTIONS

General Cautions

- The Model 31DT is restricted to sale by or on the order of a physician. It is a prescription device and is to be operated by qualified personnel only.
- Become thoroughly familiar with the information in this user's manual and all the other accompanying documents before using the pulse oximeter.
- Do not attempt to modify or repair the pulse oximeter – doing so voids the warranty.
- Dispose of this instrument and its accessories according to governmental regulations and WEEE norms.
- Adhere to all cautions, stipulations, and instructions included with the sensors used.
- **Explosion hazard.** Do not use Model 31DT in presence of flammable anesthetics or gases. Do not use Model 31DT in presence of any flammable agents.
- The use of equipment is restricted to one patient at a time.
- Use accessories specified by our company only, otherwise; the device may not function normally.
- The system may not meet its performance specifications if stored or used outside the specified temperature and humidity ranges.
- Do not drop the Model 31DT oximeter or its accessories which may result in certain damages.
- Do not use a Model 31DT oximeter, AC power cord, sensor, sensor cable or connector that appears to be damaged or broken. Failing to comply with this may result in damage or electric shock hazard to the user/operator as mechanical/electrical integrity of the monitor and/or its accessories could have been hampered.

- Use of damaged sensor or oximeter may result in erroneous or faulty readings or no alarm.
- Do not attempt to lift the oximeter by its mains power cord (or) sensor cable. Any attempt made to lift may result in the detachment of the cables and the fall of the oximeter resulting in damage.

Environmental Cautions

- Do not use the pulse oximeter in the presence of flammable agents or flammable anesthetics.
- Do not immerse in liquid and do not allow any liquid to penetrate the pulse oximeter`s interior.
- Operate the pulse oximeter in normal light conditions.
- Avoid bright light or glare on the sensing area to ensure correct reading of the displays and indicators.
- Keep away from MRI (Magnetic Resonance Imaging) equipment.
- Move the pulse oximeter away from other electromagnetic emitting equipment if you experience interference problems.
- Keep away from the equipment that emits x-ray, alpha particles, beta particles, neutrons particles, or microwave emissions.

Battery Cautions

- Use only Li-ion batteries specified by Mediaid. Use of any other type of battery not specifically recommended. Use of such batteries could damage the pulse oximeter.
- Never dispose of batteries into fire, short-circuit the terminals, or attempt to disassemble or heat the battery. Doing so could damage the battery and cause a fire, injury, or environmental contamination. Dispose as per WEEE norms.
- Liquid leaking from battery can cause skin burns or damage the pulse oximeter. If a battery leaks inside the instrument, return the pulse oximeter for servicing.
- Remove the battery during shipment or if the pulse oximeter will be idle for several weeks.

Preventing Device Complications and Faulty Readings

- Trim the patient`s long fingernails and remove artificial nails or thick nail polish.
- Insert the patient`s finger completely into the sensor.
- Fit the sensor comfortably without constricting or compressing the application site when using a sensor that is attached to the cable adaptor.
- Do not apply the sensor to anything but a well-perfused extremity.

- Cold extremities can affect readings. Warm up the extremity, or move the sensor to a different site, if necessary.

- Check for intravascular dyes, which could affect pulse oximeter readings.

- Turn off very bright lights, such as surgical, bilirubin, fluorescent, or infrared heating lights if they interfere with sensor functioning. In cases where such lights are unavoidable, cover the sensor site with an opaque material.

- Route sensor cords carefully.

- Avoid applying excessive tension to the sensor or sensor cord.

- Consider conditions affecting the hemoglobin dissociation curve when interpreting pulse oximeter readings (such as intravascular dyes).

- Keep patient movement to a minimum.

- When not in use, do not wind the sensor cord around the pulse oximeter.

CHAPTER 2: KEYS, INDICATORS, SYMBOLS AND MARKINGS

PULSE OXIMITER FRONT VIEW, BACK VIEW & SIDE VIEW

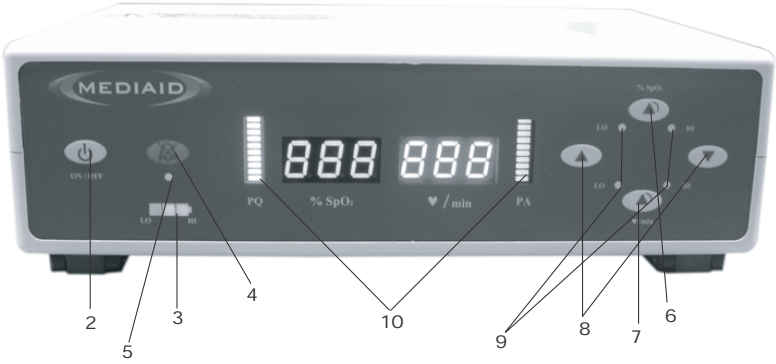

Fig 1

Fig 2

Fig 3

KEYS AND INDICATORS

1. POWER ON/OFF SWITCH

The POWER ON/OFF SWITCH is located at the left hand side of the oximeter. When this Switch is turned OFF the oximeter gets totally isolated from AC mains. 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 internal Li-ion battery.

2. ON / OFF KEY 

When the POWER ON/OFF SWITCH is turned ON, the unit is switched ON with a short depression of the ON/OFF KEY. A one-second display and indicator test is performed automatically, and all the segments of Light Emitting Diodes (LEDs) will be illuminated. The software version number will then be displayed as “Ver” in %SpO_2 display area and the version number in display area accompanied by a long beep.

Unit switches off automatically (auto-power off) when there is no sensor connected or no finger in sensor for more than 2 minutes.
The unit power OFF with a short-depression of the Power ON/OFF Key.

3. BATTERY LEVEL INDICATOR 

The Battery level indicator displays the battery level in a scale of 3. If the unit is connected to external power supply for charging (irrespective of whether the power ON / OFF key Switched ON or OFF), then the level indicator glows Green and displays the charging status. The LSB LED glows, if the charger is connected. The LSB & Middle LEDs glow, if the unit is partially charged. All 3 LEDs LSB, Middle and MSB glow if the unit is completely charged.

If the unit is operating in Battery mode, then the battery level indicator glows in Red. All three LEDs (MSB, Middle, LSB) glow if the battery voltage is between 95% to 100% voltage. 2 LEDs glow (middle & LSB) if the battery voltage is in the range of 90% to 95%. One LED (LSB) glows ON if the battery voltage is in the range of 80% to 90%.

CAUTION: Below 80% the LSB LED blinks indicating that the battery is near depletion and it is advisable to charge the battery.

4. ALARM OFF (MUTE) KEY

A short depression of this key silences the alarm for a period of 60 seconds. The ALARM OFF INDICATOR illuminates and remains on constantly, and the oximeter monitors normally. Silenced alarms can be reactivated by a short depression of the ALARM OFF KEY or automatically after a period of 60 seconds regardless of new alarms. Press and holding this key for more than 6 seconds activates permanent silence of Alarm.

CAUTION: Do not silence the audible alarm or decrease its volume else the patient safety could be compromised.

5. ALARM OFF INDICATOR

The ALARM OFF INDICATOR illuminates and remains on constantly when audible alarms are silenced.

6. OXYGEN SATURATION ALARM KEY

Short depression of the OXYGEN SATURATION ALARM KEY toggles the LED display between the high and low alarm settings, and respective HI/LO ALARM INDICATOR glows below the key. These alarm settings are adjusted using UP ARROW and DOWN ARROW KEYS. The alarm settings are retained in memory until reset by the user. (The default alarm settings are minimum of 85% for Low limit and 100% for high limit respectively. The display reverts back to normal monitoring after six seconds of key inactivity or Mute key press. The high/low reading of Oxygen Saturation keeps blinking when the reading is above the maximum preset value and when reading is below the minimum preset value.

NOTE:
The Mediaid Model 31DT pulse oximeter CAN INDICA INDICATE TE the SpO_2 values less than 85%, but the alarm would be continuously ON.

7. PULSE RATE ALARM KEY

Short depression of the PULSE RATE ALARM KEY toggles the LED display between the high and low alarm settings and respective HI/LO ALARM INDICATOR to glow above the key. These alarm settings can be adjusted using UP ARROW and DOWN ARROW KEYS. The alarm settings are retained in memory until reset by the user. The default pulse-rate alarm settings are as per the patient type selected: High 170 BPM and Low 40 BPM. The display reverts back to normal patient monitoring after a six-second period of key inactivity or Mute key press.

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

8. UP & DOWN ARROW KEYS

The pulse-tone volumes are adjusted using the UP & DOWN ARROW KEYS. There are 5 levels of audible (pulse) tone volume, and "off." The pulse tone volume is increased with the UP ARROW key, and decreased or silenced with the DOWN ARROW key. Default pulse-tone volume level is 3. Alarm levels are also adjusted with these keys during alarm condition but the alarm volume is never zero unless permanent silencing is selected.

9. VISUAL HI/LO ALARM INDICATORS

Located besides the OXYGEN SATURATION ALARM key and PULSE RATE ALARM key, these indicators illuminate when the patient's oxygen saturation or pulse rate reaches the preset high or low alarm settings. While setting alarm limits, the appropriate indicator is illuminated. During the high or low reading of SpO2 or pulse rate corresponding indicator would be ON.

10. BAR GRAPH DISPLAY

The 10-bar bargraph display perfusion quality and pulse amplitude of the signal.

SYMBOLOGY & MARKINGS

Symbol	Definition
%SpO_2	Oxygen Saturation Percentage
♥/min	Heart Beats per Minute (BPM)
PA	Pulse Amplitude Indicator
PQ	Perfusion Quality Indicator
	Power On/Off Key
	Alarm Off Key and Indicator
	Increment Key
	Decrement Key
LO ●	Low Alarm Indicator
● HI	High Alarm Indicator
	Oxygen Saturation Alarm Key
	Pulse Rate Alarm Key
	Low Battery Indicator (Blinking Red LED)
	Partially charged Battery Indicator (1 Red LED)
	Partially charged Battery Indicator (2 Red LED)
	Fully charged Battery Indicator (3 Red LED)
	AC Power Connection
	Attention: Consult Accompanying Documents
	Non-anesthetic Proof
	Type BF Applied Part
	SpO_2 Sensor port
	Waste Electrical and Electronic Equipment

CHAPTER 3: INITIAL SETUP

UNPACKING AND INSPECTION

Notify the carrier if the shipping carton is damaged. Unpack the model 31DT and components.
If anything is missing or damaged, contact Mediaid Technical Support.

LIST OF COMPONENTS

1. Model 31DT Monitor.

2. Mediaid Reusable Sensor.

3. AC Power Cord.

4. Model 31DT User's Manual.

5. Additional Accessories as ordered, if any.

MONITOR SETUP

General Warnings

WARNING: To ensure patient safety, do not place the monitor 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: Disconnect the Model 31DT and Mediaid sensor from the patient during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Model 31DT may affect the MRI image and the MRI unit may affect the accuracy of monitor measurements.

WARNING: To ensure accurate performance and prevent device failure, do not subject the Model 31DT to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.

WARNING: Follow local governing ordinances, WEEE norms and recycling instructions regarding disposal of device components, including batteries of the Model 31DT.

WARNING: Do not use a Model 31DT monitor, AC Power cord, sensor, Sensor cable or connector that appears to be damaged.

WARNING: When Model 31DT monitor is used along with other patient connected medical electronic equipment, care should be taken to ensure that the other medical electronic equipment and its sensor cables are safe to use. Please refer to the manufacturer's document for more information. Failing to comply with this may result in electrical hazard, burns to the patient.

CHARGING THE BATTERY

Connect Model 31DT to AC Mains (Refer to the section *"CONNECTING THE MODEL 31DT TO AC POWER SUPPLY"*) and turn ON the POWER ON/OFF switch on the left hand side of the monitor. The battery level indicator LED in the front panel glow in GREEN color. In this mode, the battery gets charged.

The Battery level indicator displays the battery level in a scale of 3LEDs. If the unit is connected to AC Mains for charging, then the LSB LED indicator should glow in Green and display the charging status. LSB & Middle LEDs glow, if the unit is partially charged (about 70%). All three LSB, Middle and MSB LEDs glow if the unit is fully charged.

CONNECTING THE MODEL 31DT TO AC POWER SUPPLY

The power inlet is located at the rear of the monitor. Insert one end of the power cord to the power inlet and the other end to the AC mains supply.

POWER ON

- Switch on the ON/OFF SWITCH located at the left hand side of the oximeter
- Verify that the BATTERY INDICATOR is glowing in GREEN color. If it is not, ensure that the POWER ON/OFF SWITCH is in the "ON" position. If the indicator still does not light or glows in RED color, 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

Connect the sensor to the sensor port (Refer to the section SENSOR CABLE CONNECTION) and switch on the ON/OFF KEY located at the front of the monitor. Internal self tests will run and the unit enters the monitoring mode.

SELF TEST STATE

Fig. 4

After the pulse oximeter is switched on, all the segments of 7 segment LED DISPLAY, BARGRAPHS are turned ON and all LEDs in the Keypad are also turned ON for about 2 seconds. This is as a part of self test to ensure that all display segments are functional. On completion of visual indicator test, the software version number is displayed with a long beep for a second to ensure that the audio circuitry is functional.

MODEL 31DT DISPLAYING SOFTWARE VERSION

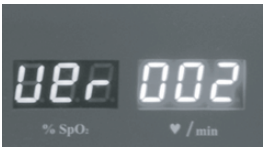

Fig. 5

CAUTION: A non-functioning LED segment will result in an incomplete numeral and possible erroneous reading.

CAUTION: A non-functioning beeper may result in compromising of patient safety. Do not use model 31DT when there is no beep sound during self-test

SENSOR CABLE CONNECTION

All Mediaid Pulse Oximeter sensors with Compushield® connectors are compatible with the Model 31DT. To connect a sensor to the monitor, align the sensor plug with the jack on the monitor's sensor port and insert gently until an audible "click" is heard. 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 monitor. Now insert the finger/ monitoring site in the sensor completely.

WARNING: Compushield® connector of the sensor should be snug fit into the female connector of the unit (with compulsorily two click sound). Failing which, the monitor may show erroneous readings.

WARNING: Sensor should not be connected or disconnected while the unit is ON. The unit should be powered off, before disconnecting and reconnecting the unit.

CHAPTER 4:
OPERATING THE MODEL 31DT PULSE OXIMETER

Monitoring Pulse Oximetry

The Mediaid model 31DT pulse oximeter does not have storing and retrieval of data facility such as IR, USB features.

The Monitoring mode is started by placing the finger in the sensor and powering on the monitor. In Monitoring mode, pulse oximetry data can be viewed on the LED DISPLAY, as follows:

- Left 3-digit GREEN LED display indicates %SpO_2.
- RIght 3-digit RED LED display indicates BPM (Beats per minute).
- Left 10-bar bargraph (Red Color) indicates PERFUSION QUALITY (PQ) and the right on (Green Color) indicates PULSE AMPLITUDE (PA).

After the power-on tests, the following information shows on the pulse oximeter:

- The PA Bar graph begins to blink, indicating the start of measurement. Then PQ Bar Graph starts to blink to the level of perfusion at the measuring site.
- Three dashes one each for SpO_2 and BPM indicators for 2-3 seconds while pulse oximeter gather the SpO_2 and BPM values.
- Once valid values are available, both SpO_2 and BPM values are displayed.
- Record the readings manually if required and switch off to save battery power.
- This completes one cycle of measurement using the Model 31DT.
- Please follow the cleaning instructions given in the manual before making next measurement on another patient.

NOTE: If the PQ and PA donít blink adjust the sensor position.

CAUTION: When Perfusion Quality (PQ) display is showing less than 3 LED Bars, it indicates that the PQ is too low. Either change the monitoring site to an alternative location or check if the sensor is applied correctly.

CAUTION: Reusing the device/sensor without prior cleaning may result in cross contamination.

PERFORMANCE CONSIDERATIONS

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

Inaccurate measurements can be caused by:

- Incorrect application of the sensor. Incorrect application may cause tissue damage. Inspect the sensor site periodically as directed in the sensor directions for use.
- Ambient light.
- Patient movement.

CAUTION: Calibration cannot be performed by the user/operator. Please contact Mediaid.

CAUTION: Reusing the device/sensor without prior cleaning may result in cross contamination.

ADJUSTING THE ALARM SETTINGS

The Model 31DT has an alarm for low or high readings of SpO_2 or BPM which can be set to the levels as required by the user. The following describes the alarm settings.

AUDIBLE ALARM INDICATORS

The alarm tone is a fixed pitch, and the volume is adjustable. Alarm tones are automatically silenced when the alarm condition goes away.

- HIGH PRIORITY alarm tones sound 0.75 seconds for every three seconds. HIGH PRIORITY alarms are caused by conditions such as: low/high oxygen saturation and pulse rate; no pulse.
- MEDIUM PRIORITY alarm tones sound for 0.75 seconds every five seconds. MEDIUM PRIORITY alarms are caused by measuring problems such as No finger in sensor, or a faulty sensor.
- LOW PRIORITY alarm tones sound for one second every 10 seconds. LOW PRIORITY alarms are caused by disconnected sensor.

ALARM OFF KEY

A short depression of this key silences the alarm for a period of 60 seconds. The ALARM OFF INDICATOR illuminates and remains on constantly, and the oximeter monitors normally. Silenced alarms shall be reactivated by a short depression of the ALARM OFF KEY. Press and holding this Key for more than 5 sec. silences the alarm permanently.

ALARM OFF INDICATOR

The ALARM OFF INDICATOR illuminates and remains on constantly when audible alarms are silenced. This indicator starts blinking when permanent silence of alarm is selected.

OXYGEN SATURATION ALARM KEY

Short depression of the OXYGEN SATURATION ALARM KEY toggles the LED display between the high and low alarm settings, and respective HI/LO ALARM INDICATOR glow below the key. These alarm settings can be adjusted using UP ARROW and DOWN ARROW KEYS. The alarm settings are retained in memory until reset by the user. Alarm setting can be minimum 85% for Low limit and accordingly 87% for High limit.

The default saturation alarm settings are

	Saturation
High	100%
Low	85%

The display reverts back to normal monitoring after six seconds of key inactivity or Mute key press.

PULSE RATE ALARM KEY

Short depression of the PULSE RATE ALARM KEY toggles the LED display between the high and low alarm settings and respective HI/LO ALARM INDICATOR glows below the key. These alarm settings are adjusted using UP ARROW and DOWN ARROW KEYS. The alarm settings are retained in memory until reset by the user.

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

CHAPTER 5: SPECIAL KEY FUNCTIONS

POWER ON FUNCTION OF A KEY

- To change patient mode (Adult / Neonatal)

  Press ON/OFF KEY + PULSE RATE ALARM KEY. The Oximeter has two modes for SpO_2 & Rate alarm for two types of patients Adult or Neonatal. The UP ARROW Key and the DOWN ARROW Key can be used to select the desired settings.

- To set alarm volume

  Press ON/OFF KEY + MUTE KEY. To set the alarm volume, the UP ARROW key and the DOWN ARROW key are be used to increase or decrease the alarm. There are 5 levels. The alarm volume can never be decreased to zero. Default Alarm volume is middle level (3 in a scale of 1 to 5).

DIAGNOSTIC TEST

Turning the unit ON by simultaneously pressing the Pulse Rate Alarm key + Oxygen Saturation alarm key will cause the unit to enter the self test mode. Upon entry the $\%SpO_2$ LED will show 'tst 'and the Pulse Rate LED will show the test number "0". The test number can be manually selected using UP/DOWN arrow keys. After 6 seconds of key inactivity or Mute key press, the corresponding testing sequences will start. The following tests will be carried out,

TEST 0 - Global test, initiates all user assurance tests that can be run.

TEST 1 - Display and indicator test, each icon and display segment will be activated. (Each segment will be set to ON one by one).

TEST 2 - Sensor and circuitry test, all sensors and circuits are tested to verify correct operation.

TEST 3 - Speaker test. This initiates alarm to sound from low volume to high volume.

TEST 4 - Internal circuitry test, and components are tested. Upon completion, if an internal problem was detected then the display shows "Err2".

TEST 5 - Internal memory test, tests all internal memory. If this test is passed a display of "software version number" is shown.

CHAPTER 6: SPECIFICATIONS

PERFORMANCE

SpO_2 Performance Requirements

- Measurement Range — %SpO_2 : 0 – 100%
  Pulse : 25 – 255 beats per minute (BPM)
- Resolution — %SpO_2 : 1%
  Pulse : 1 BPM
- Accuracy — %SpO_2 : 70 – 100%, ± 2 digits
  ≤ 69%, Unspecified
  Pulse : 25 – 255BPM, ± 2 BPM

ELECTRICAL

AC POWER

Power Requirements	100 – 230 VAC, 50/60 HZ
Fuses	2 Qty,2.0A,250 volts,fast-blow, IEC (5 x 20 mm)

Note: Always use a 3 pin power cord with Proper Earthing Pin.

BATTERY

- Battery Type : Lithium-ion
- No. of Batteries : 1
- Nominal Battery Voltage : 7.4 Volts DC
- Battery Capacity : 1050 mAh.
- Minimum Battery Run Time : Approx. 10 hours using fully Charged battery
- Battery Recharge time : 4 hours maximum (internal protection available to avoid over-charging)
- Battery Cutoff Voltage : Approx. 6.0 Volts DC
- Low Battery Warning Level : Approx. 7.0 Volts DC
- Time to Shutdown from low battery : Approx. 1 hour

ENVIRONMENTAL CONDITIONS

Acceptable Conditions for Operating, Storage and Transport

- Operating Temperature — 0 – 40 ºC (32 – 104 ºF)
- Storage & Transport Temperature — -30 – 65 ºC (-22 – 149 ºF)
- Atmospheric pressure — 770 – 282.45 mmHg or 1026 – 377 hPa
- Relative Humidity — 5 – 95% (non condensing)

PHYSICAL CHARACTERISTICS

- Weight — 1.26 kgs. (without Accessories)
  1.63 kgs. (with Accessories)
- Dimensions — 11.8 (L) x 8 (W) x 3.3 (H) inch
  or
  30 (L) x 20.3 (W)x8.4 (H) cm

COMPLIANCE

- Type of Protection : Class 1 (on AC power)
  Internally powered (on battery power)
  Type BF – Applied Part - SpO_2 sensor
- Degree of Protection : IPX1
  Enclosure, Degree of Ingress
  Protection from Solids/Liquids
- Mode of operation : Continuous
- The equipment is designed to comply with : ISO 13485:2003, ISO 9001:2000

CHAPTER 7: ACCESSORIES

SENSORS

Use only Mediaid sensors with the device. Use of other sensors may result IN faulty data/injury to the user damage to the device

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	POX055-600S

CAUTION: Use of damaged/broken sensor may result in faulty or erroneous readings. Reuse of sensors beyond lifetime may deteriorate the performance and hence the sensors must be used within the lifetimementioned in the sensor instructions.

CAUTION: Reuse of single patient use disposable sensors may result in cross contamination.

BIOCOMPATIBILITY 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.

BATTERY

Single 7.4 Volt Li-ion battery with a connector.

CHAPTER 8: TROUBLESHOOTING

CLEANING

The pulse oximeter and the sensor can be wiped clean with a soft cloth lightly dampened with isopropyl alcohol, a glutaraldehyde solution, or soap and water. Do not immerse in liquid or allow any liquid to penetrate the interior of the pulse oximeter. Avoid caustic or abrasive cleaners that could damage the case, keypad, or sensors. Use extra care in cleaning the LED DISPLAY window to avoid scratching the finish.

CAUTION: Do not attempt to clean the unit while in use. May result in damage to unit/user. Before and after every use any excess moisture has to be wiped off.

WARNING: In case of accidental wetting of the equipment ensure that the equipment is switched off and excess liquid/moisture is wiped off/cleaned. Allow the unit to dry before using it again. In case of "Not Functioning" or unit not turn ON, contact local Mediaid technical support.

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

CAUTION: Reusing the device/sensor without prior cleaning may result in cross contamination.

TROUBLESHOOTING

Whenever an error occurs, the pulse oximeter displays the letters Err (error) in % SpO_2 LED and displays the error code by blinking in BPM LED.

CAUTION: There are no user-serviceable parts or adjustments inside the Model 31DT. Do not attempt to open the instrument voids the Mediaid warranty. Refer to the information in *"Mediaid Problem Correction Plan"*, in Chapter 10, for service information.

ERROR CODES

Whenever an error occurs the display shows the letters "Err" and the corresponding error number.

ERROR CODE	ERROR CODE MESSAGE	SOLUTION
2	The instrument will not power off	Remove the battery and contact Mediaid Technical Support
3	The oximeter cannot detect the sensor because of sensor malfunction or sensor not properly attached	Replace/Reattach the sensor. If the error code persists, contact Mediaid Technical Support
4, 5, 6, 7, 8, 9, 10, 12, 13, 14, 15	An internal failure has occurred	Contact Mediad Technical Support

CHAPTER 9: PRINCIPLES OF OPERATION

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.

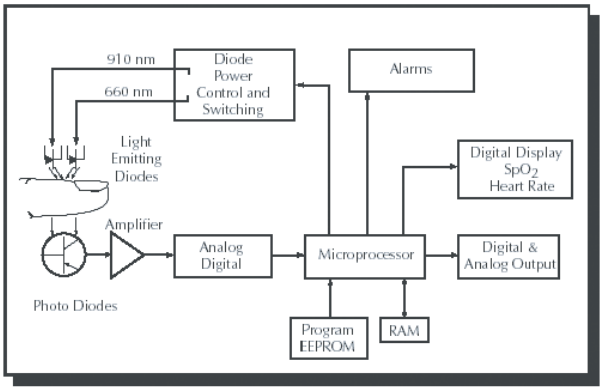

Fig. 6: Principles of Pulse Oximetry

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. 6). All constituents of the human body, venous and arterial blood and tissue absorb light (Fig. 7). The pulsating of arterial blood results in changes in the absorption due to added hemoglobin (Hb) and oxygenated hemoglobin (HbO2) in the path of the light. Since (HbO2) and (Hb) absorb light to varying degrees, this varying absorption is translated into plethysmographic waveforms at both red and infrared wavelengths (Fig. 8). 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 SpO2 is approximately 85% (Fig. 9).

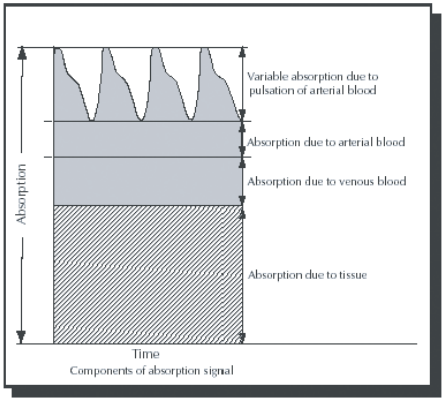

Fig. 7: Light Absorption

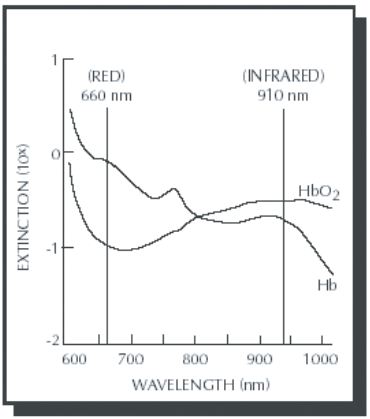

Fig. 8: Varying Absorption by (HbO_2) & (Hb)

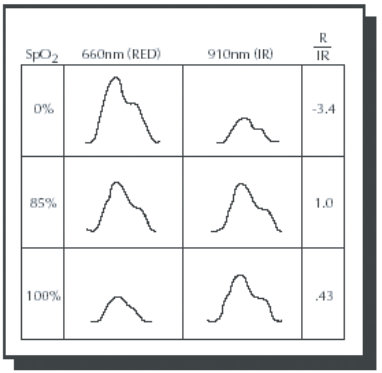

Fig. 9: Pleth Amplitude at 660nm & 910nm

CALIBRATION OF PULSE OXIMETERS

The light absorption by hemoglobin is wavelength dependent. Mediaid 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 pulse oximetry sensors to be used interchangeably without calibration.

VALIDATION OF ACCURACY

Mediaid 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 10 and Figure 11 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.

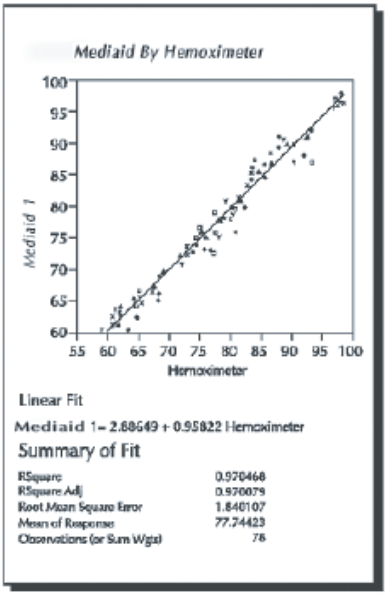

Fig. 10: Mediaid by Hemoximeter

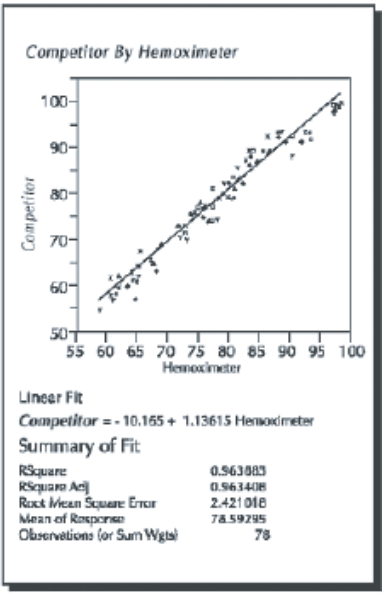

Fig. 11: Competitor by Hemoximeter

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 10:

Mediaid Inc. Limited Warranty

APPLICABILITY OF WARRANTY

This warranty covers only the Mediaid Model 31DT pulse oximeter and accessories as indicated. It is not extended to other products or components that the customer uses in conjunction with Mediaid products. 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 anyone other than an authorized Mediaid Inc. service technician. Opening of the sealed enclosure or altering of the serial number voids the Mediaid Inc. Warranty. Use of equipment contrary to or inconsistent with the User's Manual will also void the warranty.

WARRANTY COVERAGE

Mediaid Inc. warrants that the Model 31DT enclosed with this warranty will conform to the manufacturer's specifications and will be free from defects in workmanship and materials for a period of 1 year from the date of purchase. Batteries and accessories are excluded from this warranty. The Sensors are warranted according to information on their respective instruction sheets.

This warranty does not cover any damage done to the equipment during shipping, which shall be the sole responsibility of the transportation company.

There are no warranties, expressed or implied, which extend beyond the warranties set forth herein. 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 (or country to country). 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.

MEDIAID INC. PROBLEM CORRECTION PLAN

Should the Mediaid product prove to be defective, contact Mediaid Inc. at:

Mediaid Inc.
17517 Fabrica Way Suite H
Cerritos, CA 90703 USA
(Tel) 714-367-2848
(Fax) 714-367-2852
www.mediaidinc.com
E-mail: info@mediaidinc.com

Have the product and serial numbers available when calling. Mediaid Inc. will then issue a Return Authorization Number (RAN). Return the pulse oximeter securely packaged in its original shipping carton (or equivalent packaging), and include the RAN.
Mediaid Inc. will repair any faulty workmanship and will either repair or replace (at our 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 Inc. All transportation charges shall be the customer's responsibility.

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 to or inconsistent with the User's Manual voids the warranty.

OWNER'S REGISTRATION

To assist Mediaid Inc. in better serving the user, please complete the included Warrant Registration Card and return it to:

Mediaid Inc.
17517 Fabrica Way Suite H
Cerritos, CA 90703 USA
(Tel) 714-367-2848
(Fax) 714-367-2852
www.mediaidinc.com
E-mail: info@mediaidinc.com

CHAPTER 11:

USER REFERENCES

CONTACT/CUSTOMER SERVICE INFORMATION

For information on other Mediaid Inc. products, visit the Mediaid Inc. home page on the web at www.mediaidinc.com, or contact us at:

Customer Service & Returns Department

Mediaid Inc.
17517 Fabrica Way Suite H
Cerritos, CA 90703 USA

Telephone

714-367-2848

Fax

714-367-2852

Email

info@mediaidinc.com

PRODUCT INFORMATION

To better assist customers, Mediaid Inc. recommends writing down all pertinent product and warranty information in the spaces provided below:

Model 31DT

Product Number: POX010-31DT
Serial Number: _____
Warranty Expiration Date: _____

Universal Hinged Sensor

Product Number: POX050-105S
Serial Number: _____
Warranty Expiration Date: _____

WARRANTY REGISTRATION FORM

Please return to Mediaid Inc. / local distributor for validation

MEDIAID INC.

17517 Fabrica Way Suite H; Cerritos, CA 90703 USA

(Tel) 714-367-2848 (Fax) 714-367-2852

Email: info@mediaidinc.com Website: www.mediaidinc.com

Model _____ Serial Number _____

Date of Purchase _____

Institution/Physician _____

Address _____

_____

_____

Contact Department _____

Telephone _____

Distributor _____ Phone _____

Comments _____

_____

_____

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