Model 100
Pulse Oximeter

User's Manual

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Principles of Operation

Intended Uses

The Mediaid Model 100 pulse oximeter is intended to non-invasively measure arterial oxygen saturation and pulse rate in hospitals, physicians' offices, emergency medical facilities, or at

> **WARNING**
>
> Before using the Model 100, become thoroughly familiar with the information in this manual.

home. The Model 100 is not intended for continuous patient monitoring.

Principles of Pulse Oximetry

The Mediaid Model 100 pulse oximeter is designed to measure the percentage of functional oxygenated hemoglobin to total hemoglobin. Non-invasive 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 wavelengths are tightly controlled by testing in production. 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.

Principle Features

The Mediaid Model 100 pulse oximeter is a portable, lightweight, pocket-sized instrument that monitors functional arterial oxygen saturation and pulse rate non-invasively.

> **WARNING**
> Do not use the Model 100 for continuous patient monitoring.

The principal features of the Model 100 are as follows:

- Gives an alternating readout of SpO_2 percentage ($\%SpO_2$) and pulse rate in beats per minute (BPM) on a 3-digit, 7-segment LED (light-emitting diode) display.
- Can be used with either the Integral Finger Sensor or any Mediaid pulse oximetry sensor that has a CompuShield® Connector that attaches to the Cable Adapter.
- Increases the longevity and functionality of the pulse oximeter with the removable and replaceable sensor modules.
- Performs approximately 1200 spot checks on a single 1.5 volt, AA-sized alkaline battery (when using a Duracell® Ultra battery, which is recommended).

Cautions

General Cautions

- US federal law restricts this device to sale by or on the order of a physician.
- Become thoroughly familiar with the information in this User's Manual and all accompanying documents before using the Model 100.
- Do not attempt to modify or repair the instrument—doing so voids the warranty.
- Dispose of this device according to governmental regulations.
- Adhere to all cautions, stipulations, and instructions included with the Integral Finger Sensor, the Cable Adapter., and all Mediaid sensors used with the Cable Adapter..

Environmental Cautions

- Do not use the instrument in the presence of flammable agents or flammable anesthetics.
- Do not immerse in liquid and do not allow any liquid to penetrate the instrument'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 the pulse oximeter away from MRI (Magnetic Resonance Imaging) equipment.
- Move the pulse oximeter away from other electromagnetic-emitting equipment if you experience interference problems. This device complies with electromagnetic compatibility standard EN 60601-1-2.
- Keep away from equipment that emits x-ray alpha particles, beta particles, neutron particles, or microwave emissions.

Battery Cautions

- Use only 1.5 volt, AA-sized alkaline batteries (Duracell Ultra batteries are recommended). Never use manganese batteries, lithium batteries, or any other type of battery not specifically recommended. Use of such batteries may damage the pulse oximeter.
- Never dispose of batteries into fire, short-circuit the terminals, or attempt to disassemble, heat, or recharge the batteries. Doing so may damage the batteries and cause a fire, injury, or environmental contamination.
- Liquid leaking from the 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 Model 100 is to be idle for several weeks.

Preventing Device Complications and Faulty Readings

To prevent device complications or faulty readings:
- Trim the patient's long fingernails and remove artificial nails and thick nail polish.
- Insert the patient's finger completely into the Integral Finger Sensor.
- When using the Integral Finger Sensor, both the pulse oximeter and the patient's hand should rest on the same flat surface.
- Fit the sensor comfortably without constricting or compressing the application site when using a sensor that is attached to the Cable Adapter.
- Do not apply the sensor to anything but a well-perfused extremity.
- Do not apply the sensor on extremities that have blood pressure cuffs or arterial or venous catheters.

- Avoid extremity positions that could compromise venous return.
- Keep sensors at heart level whenever possible.
- Check for intravascular dyes, which may affect pulse oximeter readings.
- Turn off very bright lights, such as surgical, bilirubin, fluorescent, or infrared heating 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 cable.
- 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 oximeter.

Chapter 2:

Features, Indicators, and Symbols

Model 100 Front View

A. Module Release

The Module Release mechanism allows for removal of the Integral Finger Sensor or the Cable Adapter module from the Model 100.

B. Module Connector

The Module Connector connects the Integral Finger Sensor or the Cable Adapter module to the Model 100.
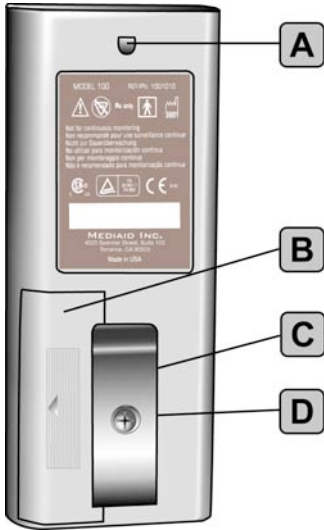
C. LED Display

The LED Display alternates between showing the pulse rate and the oxygen saturation values. The LED Display also shows error code numbers and functions.

D. Visual Pulse Indicator

The Visual Pulse Indicator is an orange LED that flashes with every pulse detected by the Model 100.
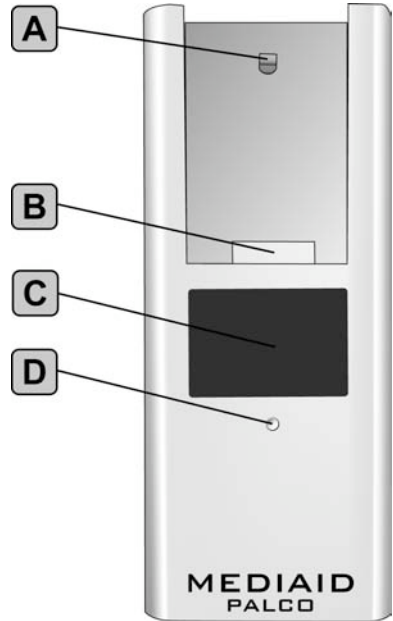
Model 100 Back View

A. Module Release

The Module Release mechanism allows for removal of either the Integral Finger Sensor or the Cable Adapter module from the Model 100.

B. Battery Compartment

The Battery Compartment holds a single 1.5 volt, AA-sized alkaline battery that provides operating power for the Model 100.

C. Belt Clip

The removable Belt Clip provides a convenient method of carrying the Model 100.

D. Belt Clip Retaining Screw

The Belt Clip Retaining Screw attaches the Belt Clip to the Model 100.

LED Display
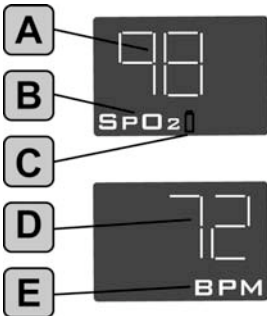
A. Oxygen Saturation Display

The Oxygen Saturation Display shows the oxygen saturation values.

B. Oxygen Saturation Indicator

The Oxygen Saturation Indicator lights whenever an oxygen saturation value is displayed.

C. Low Battery Indicator

The Low Battery Indicator lights up whenever the remaining operation time is less than 30 minutes.

D. Pulse Rate Display

The Pulse Rate Display shows the pulse rate values.

E. Pulse Rate Indicator

The Pulse Rate Indicator lights up when a pulse rate value is displayed.

Pulse Oximeter Top View

A. Module Connector

The Module Connector connects the Integral Finger Sensor or the Cable Adapter module to the pulse oximeter.

B. Insertion Guides

The Insertion Guides align with the Insertion Tabs on the Integral Finger Sensor or the Cable Adapter to ensure proper attachment.
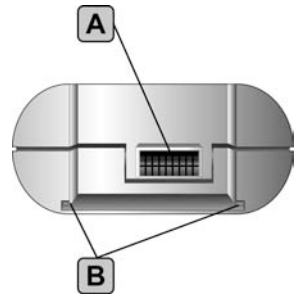
Integral Finger Sensor Front/Top View

A. Sensor Top Lever

The Sensor Top Lever is pressed to open the sensor so that a finger can be inserted. Pressing the Sensor Top Lever when the Integral Finger Sensor is attached powers on the Model 100.

B. Finger Insertion Area

The Finger Insertion Area is the location for insertion of a finger or a thumb into the sensor.

C. Insertion Tabs

The Insertion Tabs align with the Insertion Guides on the pulse oximeter to ensure proper attachment.

Cable Adapter Front/Top View
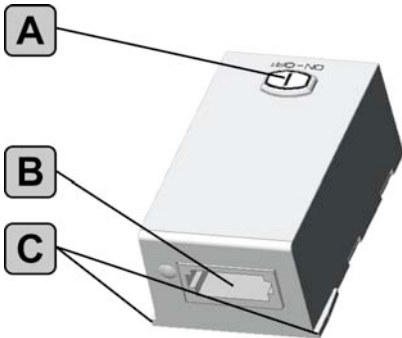
A. Cable Adapter On/Off Key

The Cable Adapter On/Off key powers on the pulse oximeter when the Cable Adapter is attached.

B. CompuShield Connector

The CompuShield Connector connects an appropriate Mediaid sensor to the Cable Adapter.

C. Insertion Tabs

The Insertion Tabs align with the Insertion Guides on the pulse oximeter to ensure proper attachment.

Cable Adapter and Integral Finger Sensor Bottom View
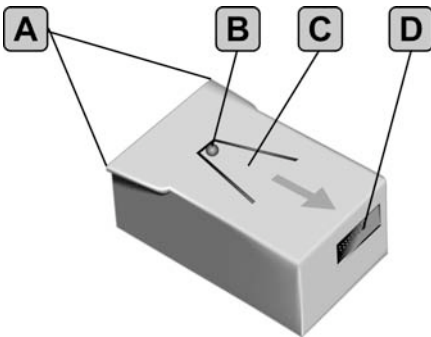
A. Spring Clip

The Spring Clip secures either the Integral Finger Sensor or the Cable Adapter to the pulse oximeter.

B. Module Release

The Module Release mechanism allows for removal of either the Integral Finger Sensor or the Cable Adapter from the pulse oximeter.

C. Insertion Tabs

The Insertion Tabs align with the Insertion Guides on the pulse oximeter to ensure proper attachment.

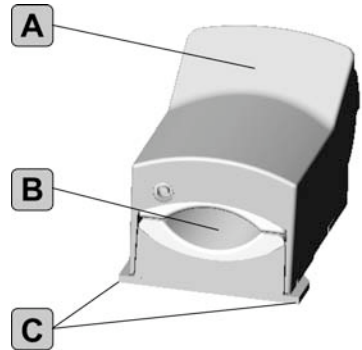### D. Rear Connector

The Rear Connector electrically connects Integral Finger Sensor or the Cable Adapter to the pulse oximeter.

Symbols

Symbols	Definition
	Cable Adapter On/Off
SpO2	Oxygen Saturation
BPM	Pulse Rate Indicator
	Low Battery Indicator
	Battery Polarity Symbol
	Attention: Consult accompanying documents
	Not anesthetic proof
	Type BF equipment
	Date of manufacture
RX Only	US federal law restricts this device to sale by or on the order of a physician

Chapter 3:

Operating the Model 100

Replacing the Battery

The Model 100 is powered by a single 1.5 volt, AA-sized alkaline battery that will operate the instrument for approximately 1200 spot checks (when using a Duracell Ultra battery).

> CAUTION
>
> Always adhere to all of the cautions listed in "*Battery Cautions*," in Chapter 1.

To replace the battery, complete the following steps.

1. Gently press down on the Battery Compartment door and push it out of the pulse oximeter.
2. Insert the battery.

   Follow the correct polarity indicated by the Battery Polarity symbol located on the inside of the compartment.
3. Insert the tabs on the Battery Compartment Door into the Battery Compartment and gently slide the door into place.

Battery Compartment

Attaching the Integral Finger Sensor or the Cable Adapter

To attach either the Integral Finger Sensor or the Cable Adapter to the Model 100, complete the following steps.
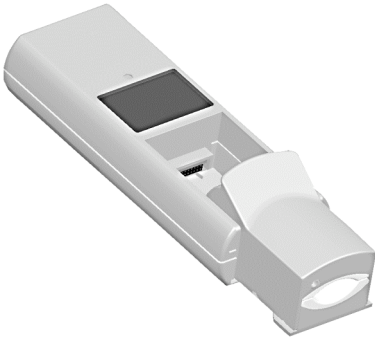
> CAUTION
> To obtain accurate oximetry readings, choose an appropriate Mediaid pulse oximeter and sensor according to the intended use. Follow all instructions stated within this manual as well as those included with each sensor.

FIGURE 1

> NOTE
> The Integral Finger Sensor or the Cable Adapter can be left connected to the pulse oximeter.

FIGURE 2

1. Set the Integral Finger Sensor or the Cable Adapter module into the pulse oximeter, pointing the Rear Connector of the module toward the Module Connector of the pulse oximeter (Figure 1).

   The arrow on the bottom of the module will point toward the LED Display of the pulse oximeter.

2. Slide the Integral Finger Sensor or the Cable Adapter module completely into the pulse oximeter (Figure 2).

   The Insertion Tabs at the end of the module will fit into the Insertion Guides on the pulse oximeter.

Removing the Integral Finger Sensor
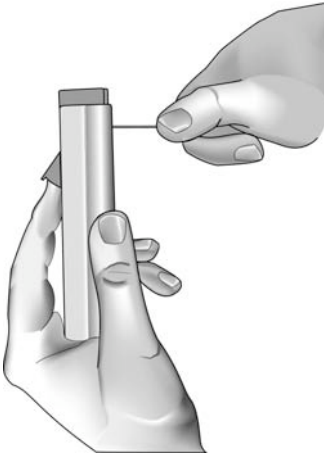
To remove the Integral Finger Sensor from the Model 100, complete the following steps.

1. Locate the Module Release mechanism at the back of the instrument (just above the label).

2. Push the pointed end of a paper clip into the Module Release mechanism, while simultaneously pushing gently upward on the Sensor Top Lever (Figure 3), until the Integral Finger Sensor is released.

Slide the Integral Finger Sensor out of the pulse oximeter.

FIGURE 3

Removing the Cable Adapter
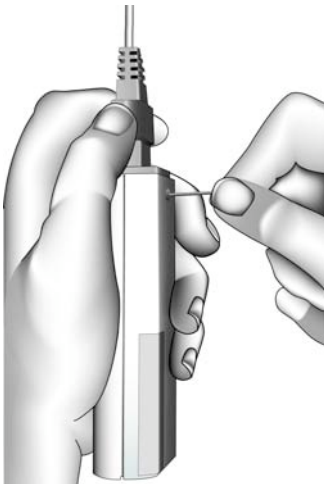
To remove the Cable Adapter from the pulse oximeter, complete the following steps.

1. Locate the Module Release mechanism at the back of the pulse oximeter (just above the label).

2. Push the pointed end of a paper clip into the Module Release mechanism, while simultaneously pushing upward on the Cable Adapter or pulling upward on the attached sensor connector (Figure 4).

Slide the Cable Adapter out of the pulse oximeter.

FIGURE 4

Removing the Belt Clip

To remove the Belt Clip from the Model 100, complete the following steps.

1. Use a #1 Jeweler's (small Phillips) screwdriver to remove the Belt Clip Retaining Screw.

2. Remove the Belt Clip from the pulse oximeter.

Attaching the Belt Clip

If the Belt Clip has been removed from the pulse oximeter, complete the following steps to replace it.

Belt Clip

Belt Clip
Retaining Screw

1. Place the flat part of the Belt Clip on the back of the pulse oximeter, lining up the screw holes on the Belt Clip and the pulse oximeter.

2. Place the Belt Clip Retaining Screw into the hole in the Belt Clip.

3. Use a #1 Jeweler's (small Phillips) screwdriver to tighten the Belt Clip Retaining Screw.
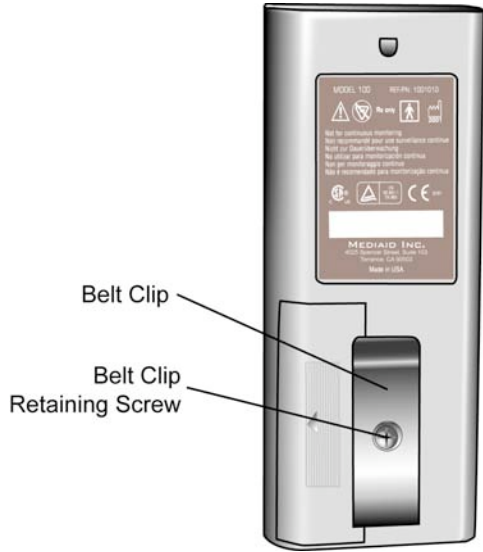
Powering On the Model 100

To power on the Model 100, complete one of the following two steps.

- If the Integral Finger Sensor is attached, press the Sensor Top Lever until the Model 100 powers on.

- If the Cable Adapter is attached, press the Cable Adapter On/Off key.

> WARNING
> To ensure personal safety and proper operation of the pulse oximeter, adhere to all directions, warnings, cautions, and policies stated within this manual as well as those included with each accessory.

After power-on, the pulse oximeter tests the sensor availability, internal functions, and the battery. The LED Display shows three dashes (- - -) during the power-on tests, which last 1-2 seconds.

When the pulse oximeter has successfully passed the power-on tests, it begins measuring oxygen saturation and pulse rate data. If the battery is low, the Low Battery Indicator will light. An error code will show if any other malfunction occurs. See "Troubleshooting," in Chapter 4, for error code interpretation.

Powering Off the Model 100

To power off the pulse oximeter, complete one of the following steps.

- If the Integral Finger Sensor is attached, remove the finger from the sensor.
- If the Cable Adapter is attached, either press the On/Off key or disconnect the sensor from the Cable Adapter.

> **WARNING**
>
> To ensure personal safety and proper operation of the pulse oximeter, adhere to all directions, warnings, cautions, and policies stated within this manual as well as those included with each accessory.

If the pulse oximeter cannot detect oxygen saturation or pulse rate, or if the finger is positioned incorrectly, it will power off automatically.

Measuring Oxygen Saturation and Pulse Rate

The Model 100 displays pulse oximetry data whenever a sensor is attached to a patient and the monitoring site has sufficient perfusion. Pulse oximetry data can be viewed on the LED Display, as follows:

- Oxygen saturation values display for 7.5 seconds.
- Pulse rate values display for 2.5 seconds.

To measure pulse oximetry data, complete the following steps.

1. Apply the sensor to the patient.

   Either insert the patient's finger into the Integral Finger Sensor, or apply the sensor that is attached to the Cable Adapter.

2. If the Cable Adapter is attached, press the Cable Adapter On/Off key to power on the Model 100.

   The LED Display shows three dashes (- - -) for 1-2 seconds while the Model 100 performs the power-on tests.

   The Pulse Indicator begins to blink, signalling that the Model 100 is measuring a site with sufficient perfusion.

3. If the Pulse Indicator does not blink, adjust the sensor position.

After the power-on tests, the following information shows on the Model 100:

- With each pulse detected by the pulse oximeter, the Vistual Pulse Indicator flashes.
- SpO2 values show on the LED Display when the Oxygen Saturation Indicator lights.
- Pulse rate values show on the LED Display when the Pulse Rate Indicator lights.

The following conditions apply when the Model 100 cannot detect pulse rate or oxygen saturation values:

- If the Model 100 cannot detect a pulse rate (but can detect oxygen saturation values), three dashes (- - -) will show on the LED Display each time the Pulse Rate Indicator lights.
- If the Model 100 cannot detect oxygen saturation values (but can detect a pulse rate), three dashes (- - -) will show on the LED Display each time the Oxygen Saturation Indicator lights.
- If the Model 100 can detect neither a pulse rate nor oxygen saturation values, it will power off automatically.

Chapter 4:

Maintaining the Model 100

Cleaning the Model 100

The Mediaid Model 100 Pulse Oximeter, the Integral Finger Sensor, and the Cable Adapter 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 will mar

> CAUTION
>
> There are no user-serviceable parts or adjustments inside the Model 100. Do not attempt to open the instrument case—any attempt to open the instrument voids the Mediaid warranty. Refer to the information in "Mediaid Problem Correction Plan," in Chapter 6, for service information.

the case or the sensors. Use extra care in cleaning the LED Display window to avoid scratching the finish.

Troubleshooting

Whenever an error occurs, the pulse oximeter displays the letters "Err" (error) for 2 seconds, and then displays the error code for 2 seconds. Error messages cycle three times, then the pulse oximeter powers off.

Table 1 explains the error code messages and gives possible solutions to the problems described in the messages.

Table 1

Error Code	Description	Solution
2	The pulse oximeter will not power off	Remove the battery and contact Mediaid Inc. Technical Support.
3	The battery needs to be replaced.	Replace the battery. If replacing it does not clear the code, contact Mediaid Inc. Technical Support.
7,8	The Cable Adapter, the sensor attached to the Cable Adapter, or the Integral Finger Sensor is malfunctioning.	Replace the Integral Finger Sensor or the sensor attached to The Cable Adapter with a functioning sensor. If replacing the sensor does not clear the code, try replacing the Cable Adapter. If the error code persists, contact Mediaid Inc. Technical Support.
11	The pulse oximeter cannot detect the sensor, either because of a sensor malfuntion or the sensor is not properly attached.	Remove, then reattach the Cable Adapter and the sensor connected to the Cable Adapter, or the Integral Finger Sensor. If reattaching does not clear the error code, contact Mediaid Inc. Technical Support.
4,6,9,10,12,13,14,15	An internal failure has occurred.	Contact Mediaid Inc. Technical Support.

If any other error codes appear, contact Mediaid Technical Support.

Chapter 5:

Equipment Specifications

General Specifications

Dimensions	Size:	4.73 x 1.82 x 0.96 in
		12 x 4.67 x 2.46 cm
	Weight:	4.1 oz/113 g w/Cable Adapter
		3.9 oz/111 g w/Integral Finger Sensor
		(weight includes battery)

Display	Type:	3-digit, 7-segment LED display

Display Rate	SpO2:	Every 7.5 seconds
	BPM:	Every 2.5 seconds

Resolution	SpO2:	1%
	Pulse:	1 BPM

Range	SpO2:	20 to 100%
	Pulse:	25 to 250 BPM

Accuracy	SpO2:	100 to 70%	± 2%
		69 to 60%	± 3%
		< 60%	unspecified
	Pulse:	25 to 200 BPM	± 2 BPM, or 2%
		> 200 BPM	± 3%

Response Time	SpO2:	8 seconds for 80% of patients
	Pulse:	8 seconds for 80% of patients

Sensors

The Integral Finger Sensor, or any Mediaid pulse oximeter sensor with the CompuShield Connector for use with the Cable Adapter, is compatible with the Model 100.

Red LED	Wavelength:	660 ± 2 nm
	Energy:	60 uW
IR LED	Wavelength:	910 ± 10 nm
	Energy:	150 uW

Power Source

Battery Type:	One 1.5 volt, AA-sized alkaline battery (Duracell Ultra recommended)
Battery Life:	Approximately 1200 Spot Checks (using Duracell Ultra)

NOTE: Battery life varies with usage conditions and battery brand.

Environmental Conditions

Operating Temperature

0° to 40° C

32° to 104° F

Storage/Transport Temperature

-40° to 70° C

-40° to 158° F

Operational Relative Humidity

30 to 75%

Storage/Transport Relative Humidity

10 to 100% (including condensation)

Operational Atmospheric Pressure
    700 to 1060 hPa

Storage/Transport Atmospheric Pressure
    500 to 1060 hPa

Equipment Classification

The Mediaid Model 100 Pulse Oximeter is classified according to CAN/CSA C22.2, No. 601-1, IEC 601-1, Part 1, Section 1, Subclause 5, as follows:

• Type of protection against electric shock:
    Internally powered, Type BF applied parts.
• Degree of protection against harmful ingress of water:
    Ordinary equipment.
• Degree of safety of application in the presence of a flammable anesthetic mixture with air, or with oxygen or nitrous oxide:
    This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, or with oxygen or nitrous oxide.

Chapter 6:

Mediaid Inc. Limited Warranty

Applicability of Warranty

This warranty covers only the Mediaid Model 100 pulse oximeter and accessories as indicated. It is not extended to other products or components that the customer uses in conjunction with Mediaid

NOTE
This product is sold by Mediaid Inc. (referred to as Mediaid) under the warranties set forth herein.

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 service technician. Opening of the sealed enclosure or altering of the serial number voids the Mediaid Warranty. Use of equipment contrary to or inconsistent with the User's Manual will also void the warranty.

Warranty Coverage

Mediaid warrants that the Model 100 enclosed with this warranty will conform to the manufacturer's specifications and shall be free from defects in workmanship and materials for a period of two years from the date of purchase. Batteries and accessories are excluded from this warranty. The Integral Finger Sensor and the Cable Adapter 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 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 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 Problem Correction Plan

Should the Mediaid product prove to be defective, contact Mediaid by telephone at:

1.714.367.2848

info@mediaidinc.com

Have the product and serial numbers available when calling. Mediaid will then issue a Return Authorization Number (RAN). Return the instrument securely packaged in its original shipping carton (or equivalent packaging), and include the RAN.

Mediaid 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. 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 in better serving the user, please complete the included Warranty Registration Card and return it to:

Mediaid Inc

17517 Fabrica Way, Suite H

Cerritos, CA 90703 USA

Chapter 7:
User Information

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
17517 Fabrica Way, Suite H
Cerritos, CA 90703 USA

Returns Department
17517 Fabrica Way, Suite H
Cerritos, CA 90703 USA

Phone
714.367.2848

Fax
714.367.2852

Email
info@mediaidinc.com

Product Information

To better assist customers, Mediaid recommends that all users write down all pertinent product and warranty information in the spaces provided below:

Model 100

Product Number: POX010-100

Serial Number:

Warranty Expiration Date:

Integral Finger Sensor

Product Number: POX050-750-1S

Serial Number:

Warranty Expiration Date:

Cable Adapter

Product Number: POX055-200-1S

Serial Number:

Warranty Expiration Date: