Pronto®

OPERATOR'S MANUAL

Masimo Pronto

Pulse CO-Oximeter™

Masimo®

These operating Instructions intend to provide the necessary information for proper operation of the Masimo Pronto® Pulse CO-Oximeter.

General knowledge of Pulse CO-Oximetry and an understanding of the features and functions of the Masimo Pronto Pulse CO-Oximeter are prerequisites for proper use.

Do not operate the Masimo Pronto Pulse CO-Oximeter without completely reading and understanding these instructions.

NOTICE

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

CAUTION:

FEDERAL LAW (U.S.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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80fk

MEDICAL ELECTRICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1/CAN/CSA C22.2 No. 601.1

Non-Invasive Total Hemoglobin (SpHb) Accuracy Compared to Invasive Laboratory Methods*

In 3519 comparisons of non-invasive total hemoglobin (SpHb) and invasive hemoglobin (tHb) measurements from a laboratory CO-Oximeter, SpHb accuracy was as follows:

- 0.91 correlation
- 0.8 g/dL standard deviation
- Below 12 g/dL, 99% of SpHb readings were < 2 g/dL of the laboratory tHb value
- At or above 12 g/dL, 99% of SpHb readings were within 2 g/dL of the laboratory value

* Masimo FDA Submission Data

CONTRAINDICATIONS: The Pronto is contraindicated for use as an apnea monitor. The Pronto is also contraindicated for use as a continuous monitor.

Safety Information, Warnings and Cautions

The Pronto is designed to minimize the possibility of hazards from errors in the software program by following Sound Engineering Design Processes, Risk Analysis and Software Validation.

- The Pronto is to be operated by qualified personnel only. This manual, accessories, Directions for Use, all precautionary information, and specifications should be read before use.
- Variation in hemoglobin measurements may be profound and may be affected by sample type, body positioning, as well as other physiological conditions. As with most hemoglobin tests, Pronto test results should be scrutinized in light of a specific patient's condition. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data.
- Explosion hazard. Do not use the Pronto in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- Electric shock hazard. Do not open the Pronto instrument. Only a qualified operator may perform maintenance procedures specifically described in this manual. Refer servicing to Masimo for repair of this equipment.
- High intensity extreme lights (including pulsating strobe lights and direct sunlight) directed on the sensor, may not allow the Pronto to obtain readings.
- EMI radiation interference such as computer displays and/or LCD/plasma TVs can cause errors or incorrect measurements on the Pronto.
- The Pronto should be considered an early warning device. For measurements of high or low SpHb readings, blood samples should be analyzed by laboratory instruments to completely understand the patient's condition.
- If patient hypoxemia is indicated, blood samples should be analyzed by laboratory devices to completely understand the patient's condition.
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The Pronto should not be used as a replacement or substitute for ECG based arrhythmia analysis.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the Pronto or accessories in any position that might cause it to fall on the patient. Do not lift the Pronto by the cable or sensor.

- Patient Safety - If a sensor is damaged in any way, discontinue use immediately.
- Always remove the sensor from the patient and completely disconnect the patient from the Pronto before bathing the patient.
- Interfering Substances: Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- Do not use the Pronto or sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Pronto may affect the MRI image and the MRI device may affect the accuracy of the Pulse CO-Oximetry parameters and measurements.
- Do not use the Pronto during electrocautery.
- Do not use the Pronto or sensors during defibrillation.
- If using Pronto during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.
- Do not place the Pronto where the controls can be changed by the patient.
- Do not place the Pronto on electrical equipment that may affect the Pronto, preventing it from working properly.
- Do not expose the Pronto to excessive moisture such as direct exposure to rain. Excessive moisture can cause the device to perform inaccurately or fail.
- Do not place containers with liquids on or near the Pronto. Liquids spilled on the device may cause it to perform inaccurately or fail.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- SpO_2 is empirically calibrated to functional arterial oxygen saturation in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb). The Pulse CO-Oximeter cannot measure elevated levels of COHb or MetHb. Increases in either COHb or MetHb will affect the accuracy of the SpO_2 measurement.
- Inaccurate SpO_2 readings can be caused by:
  - Elevated levels of COHb and MetHb
    - For increased COHb: COHb levels above normal tend to increase the level of SpO_2. The level of increase is approximately equal to the amount of COHb that is present.
      - ***NOTE***: High levels of COHb may occur with a seemingly normal SpO_2. When elevated levels of COHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
    - For increased MetHb: the SpO_2 may be decreased by levels of MetHb of up to approximately 10% to 15%. At higher levels of MetHb, the SpO_2 may tend to read in the low to mid 80s. When elevated levels of MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
  - Intravascular dyes such as indocyanine green or methylene blue
  - Externally applied coloring (such as nail polish)

- Elevated levels of bilirubin
- Severe anemia
- Low arterial perfusion
- Motion artifact

- Inaccurate SpHb readings can be caused by:
  - Intravascular dyes such as indocyanine green or methylene blue.
  - Externally applied coloring (such as nail polish)
  - Elevated levels of bilirubin
  - Low arterial perfusion
  - Motion artifact
  - Low arterial oxygen saturation levels including altitude induced hypoxemia
  - Hemoglobin synthesis disorders
  - Hemoglobinopathy
  - Thalassemias
  - Peripheral vascular disease
  - EMI radiation interference
- Do not place the Pronto face against a surface. This can cause the a system or battery (non-clinical) alarm to be muffled.
- Additional information specific to Masimo sensors including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's *Directions For Use* (DFU)..
- Always use the Pronto precisely in accordance with the directions in this manual.
- If the Pronto fails any part of the setup procedures or leakage spot check, remove the instrument from operation until qualified service personnel have corrected the situation.
- Use the Pronto in accordance with *Section 7, Specifications: Environmental* in this manual.
- Do not incinerate battery.
- To protect against injury from electric shock, follow the directions below:
  - Avoid placing the device on surfaces with visible liquid spills.
  - Do not soak or immerse the device in liquids.
  - Use cleaning solutions sparingly.
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is

no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

- In accordance with international telecommunication requirements, the frequency band of 5,150 MHz to 5,250 MHz is only for indoor usage to reduce potential for harmful interference to co-channel mobile satellite systems
- This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2: 2002, Medical Device Directive 93/42/EEC and Class B. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.
- A functional tester cannot be utilized to assess the accuracy of the Pronto or any sensors.
- Cleared Use Only: The device and related accessories are cleared by the Food and Drug Administration (FDA) for noninvasive patient monitoring and may not be used for any processes, procedures, experiments or any other use for which the device is not intended or cleared by the FDA, or in any manner inconsistent with the instructions for use or labeling. The device and related accessories are not intended for use in combination with other medical devices or in high-risk applications.
- Disposal of product - Comply with local laws in the disposal of the instrument and/or its accessories.
- This Class B digital apparatus complies with Canadian ICES-003.

Table of Contents

About this Manual

This manual explains how to set up and use the Masimo Pronto Pulse CO-Oximeter. Important safety information relating to general use of the device appears before this introduction. Other important safety information is located throughout the manual where appropriate.

Read the entire safety information section before you operate the device.

In addition to the safety section, this manual includes the following sections:

- **Section 1 Overview**
- **Section 2 System Description**
- **Section 3 Setup**
- **Section 4 Operation**
- **Section 5 Messages**
- **Section 6 Troubleshooting**.
- **Section 7 Specification**s
- **Section 8 Sensors and Patient Cables**
- **Section 9 Service and Maintenance**
- **Section 10 Accessories**

Warnings, Cautions and Notes

Please read and follow any warnings, cautions and notes presented throughout this manual. An explanation of these labels are as follows:

A **WARNING** is provided when actions may result in a serious outcome (i.e., injury, serious adverse affect, death) to the patient or user. Look for text in a gray shaded box.

Sample of Warning:

WARNING: THIS IS A SAMPLE OF A WARNING STATEMENT.

A **CAUTION** is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device or damage to other property.

Sample of Caution:

CAUTION: This is a sample of a caution statement.

A ***NOTE*** is provided when additional general information is applicable.

Sample of Note:

NOTE: *This is a sample of a Note.*

Product Description

The Pronto Handheld Spot Check Pulse CO-Oximeter with Masimo Rainbow® SET® Technology is developed to simultaneously and non-invasively measure total hemoglobin (SpHb), functional arterial oxygen saturation (SpO_2), pulse rate (PR) and perfusion index (PI).

Features and Benefits

Single-Button Operation
Simply connect the sensor to the device, properly align the sensor on the finger and press the "SpHb" button.

Accurate and non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate (PR)
The Pronto uses multiple wavelengths of light and proprietary algorithms to obtain functional arterial oxygen saturation (SpO_2) and pulse rate (PR) readings.

Accurately and non-invasively measures and displays total hemoglobin (SpHb)
The Pronto measures total hemoglobin (SpHb) using similar principles as pulse oximetry with additional wavelengths of light to obtain the measurements.

Clinically proven Masimo SET (Signal Extraction Technology) performance
Clinically proven accurate in excessive motion and low perfusion environments.

Additional Features:

- Signal I.Q.® (SIQ™) for signal identification and quality indication
- Lightweight, ergonomic handheld design
- Bright, multicolored lights and display
- Sensor life indicator shows approximate sensor uses remaining
- Progress indicator shows progress to completion of spot check
- Parameter/Measurement Select: "Up/Down" allows user to determine values to display
- Automatic shutdown power conservation

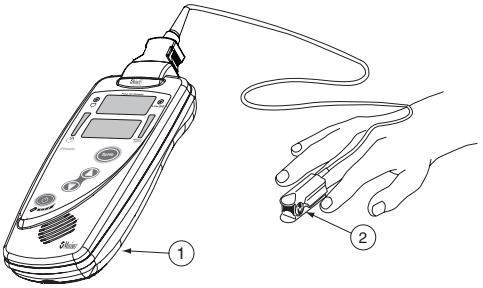
Indications for Use

The Masimo Rainbow SET Pronto Pulse CO-Oximeter and Accessories are indicated for noninvasive spot checking of functional saturation of arterial oxygen hemoglobin (SpO_2), pulse rate, and total hemoglobin concentration (SpHb). The Masimo Rainbow SET Pronto Pulse CO-Oximeter and Accessories are indicated for use by trained personnel, with adult and pediatric individuals during both no motion and motion conditions and for individuals who are well or poorly perfused and in clinical and non-clinical settings (e.g., hospitals, hospital-type facilities, home, clinics, physician offices, blood donation facilities and ambulatory surgery centers).

Pulse CO-Oximetry

SpO_2 General Description

Pulse oximetry is a noninvasive method of measuring the level of functional arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults and pediatric patients. The sensor connects to the pulse oximetry device directly or with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as a percent value for functional arterial oxygen saturation (SpO_2).



1. Instrument
2. Sensor

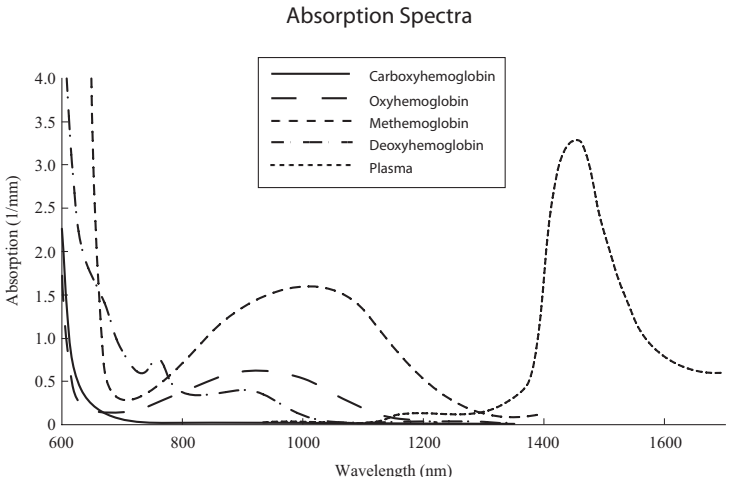
SpHb General Description

Pulse CO-Oximetry instruments offer a noninvasive method of measuring the levels of total hemoglobin (SpHb) in blood. It relies on the same principles as pulse oximetry to make the SpHb measurement. The measurements are taken by placing a sensor (2) on a patient, usually on the fingertip for adults as shown in the figure above. The sensor connects directly to the instrument (1). The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as measurement of total hemoglobin concentration.

Principles of Operation

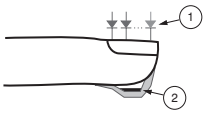
Pulse CO-Oximetry is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), methemoglobin (blood with oxidized hemoglobin) and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry, see figure below).



2. The amount of arterial blood in tissue changes with a person's pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of blood changes as well.

The Pronto uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood and blood plasma. The Pronto utilizes a sensor with various light-emitting diodes (LEDs) that pass light through the site to multiple photodiodes (detectors) (see figure below).



1. Light Emitting Diodes (LEDs) (7+ wavelengths)
2. Detectors

Signal data is obtained by passing various visible and infrared lights (500nm to 1300nm) through a capillary bed (for example, a fingertip) and measuring changes in light absorption during the blood pulsatile cycle. This information may be useful to clinicians. The maximum radiant power of the strongest light is rated at ≤ 25mW. The detectors receive the light, convert it into an electronic signal and sends it to the Pronto for calculation.

Once the Pronto receives the signal from the sensor, it utilizes Masimo Rainbow SET signal extraction technology to calculate the patient's functional oxygen saturation, (SpO_2%), total hemoglobin concentration (SpHb [g/dl]) and pulse rate (PR). The SpHb measurement relies on a multiwavelength calibration equation to quantify the percentage of total hemoglobin in blood. In an ambient temperature of 95ºF (35º C) the maximum skin surface temperature has been measured

at less than 106º F (41º C), verified by Masimo sensor skin temperature test procedure.

Functional Oxygen Saturation

The Pronto is calibrated to measure and display functional oxygen saturation (SpO_2): the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen. See the *Safety information, Warnings and Cautions* section in front of this manual for details.

Pronto vs. Drawn Whole Blood Measurements

When SpO_2 and SpHb measurements obtained from the instrument (noninvasive) are compared to drawn whole blood (invasive) measurements by blood gas and/or laboratory CO-Oximetry methods, caution should be taken when evaluating and interpreting the results. The blood gas and/or laboratory CO-Oximetry measurements may differ from the SpO_2 and SpHb measurements of the Pronto Pulse CO-Oximeter.

In the case of SpO_2, different results are usually obtained from the arterial blood gas sample if the calculated measurement is not appropriately corrected for the effects of variables that shift the relationship between the partial pressure of oxygen (PO_2) and saturation, such as: pH, temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin. High levels of bilirubin may cause erroneous SpO_2 and SpHb readings. As blood samples are usually taken over a period of 20 seconds (the time it takes to draw the blood) a meaningful comparison can only be achieved if the oxygen saturation, carboxyhemoglobin and methemoglobin concentration of the patient are stable and not changing over the period of time that the blood gas sample is taken. Subsequently, blood gas and laboratory CO-Oximetry measurements of SpO_2 and SpHb may vary with the rapid administration of fluids and in procedures such as dialysis. Additionally, drawn, whole-blood testing can be affected by sample handling methods and time elapsed between blood draw and sample testing.

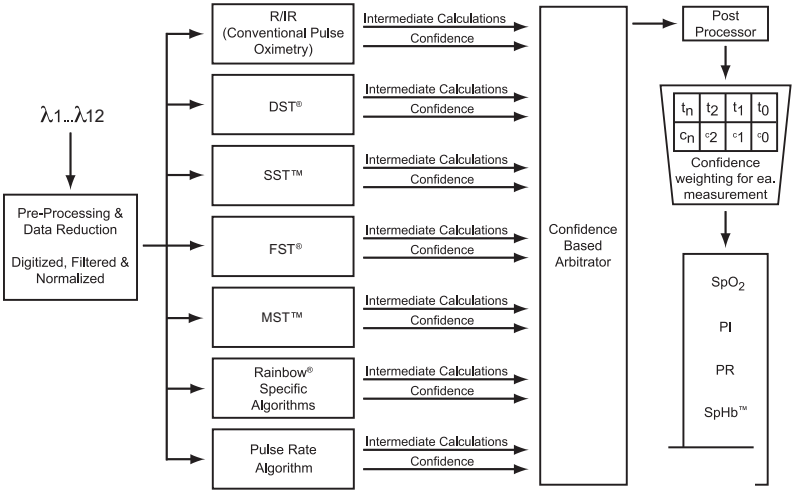
Signal Extraction Technology (SET)

Masimo Signal Extraction Technology's signal processing differs from conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the venous blood also moves, causing conventional pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise). Masimo SET pulse oximetry utilizes parallel engines and adaptive digital filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or noise and separate them by looking at the whole signal and breaking it down to its fundamental components. The Masimo SET signal processing algorithm, Discrete Saturation Transform® (DST®) reliably identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

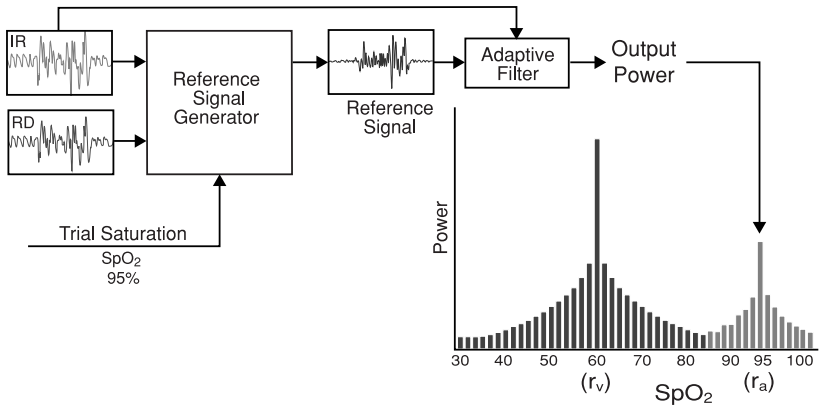
SpO_2 and SpHb Measurements During Patient Motion

SpO_2 and SpHb measurement accuracy may not be reliable during excessive motion because of the changes in the physiological parameters such as blood volume, arterial-venous coupling, etc. that occur during patient motion. When the Pronto does not have confidence in the value of a parameter due to poor signal quality caused by excessive motion or other signal interference, the Low SIQ LED will illuminate. See *Section 4, Low Signal IQ (Low SIQ*).

Masimo SET Parallel Engines



Masimo SET DST®



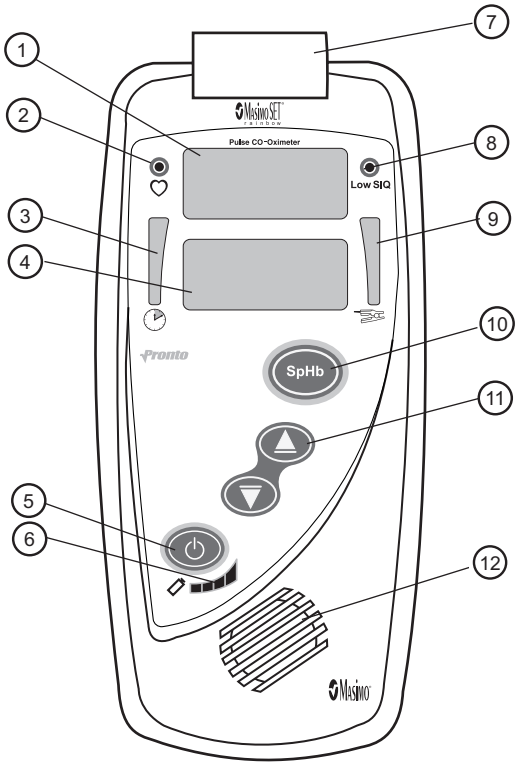
Introduction

The Pronto is a spot check Pulse CO-Oximeter which includes non-invasive total hemoglobin (SpHb) measurement. The device is designed for accuracy and ease of operation. All hemoglobin pulse oximetry measurement information, as well as device status data, is displayed on the front panel of the device. All user input is handled by control buttons on the front panel and the sensor cable connection is located at the top edge of the device.

The Pronto is powered by 4 AA alkaline batteries to provide the capacity of up to 8 hours of continuous use, when fully charged. Continous use is defined as consecutive spot check tests with each consecutive spot check test initiated immediately upon the conclusion of the previous spot check test.

A spot check sensor or patient cable attaches to the connector on the top of the Pronto.

Front Panel Controls

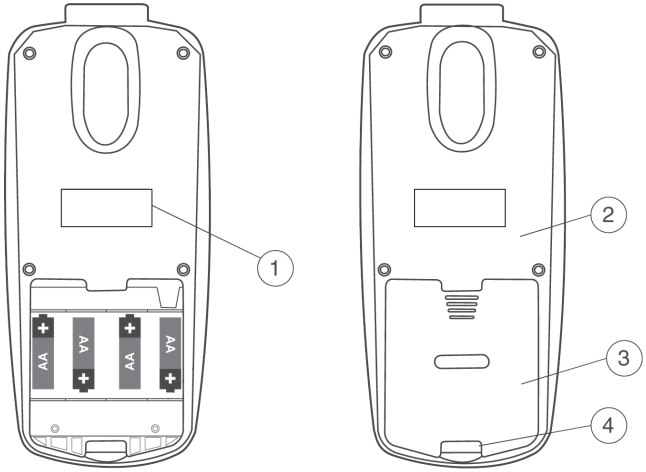


Pronto

Front Panel Controls, continued

	CONTROL / INDICATOR	DESCRIPTION
1	**Parameter/ Measurement Numeric Display**	Displays parameter/measurement numeric values once a spot check test is complete.
2	**Pulse Indicator**	Flashes with patient's pulse reading (PR) during spot check test period.
3	**Spot Check Progress Indicator**	Incrementally illuminates upward after a SpHb spot check has been initiated. This indicates progress towards completion of a SpHb spot check. A fully illuminated spot check progress indicator indicates a competed spot check.
4	**Parameter/ Measurement Label Display**	Displays parameter/measurement label once a spot check test is complete.
5	**Power On / Off**	Powers the instrument on or off. Press the button once to power on. Press and hold the button for 2 seconds to power off.
6	**Battery Level Indicator**	Battery charge level is indicated by four LED indicators. All four indicators will be lit when the batteries are full, with fewer indicators being lit as the batteries lose their charge.
7	**Patient Cable /Sensor Connector**	The Patient Cable/Sensor connector is where a compatible sensor is connected to the Pronto.
8	**Low SIQ Indicator**	SIQ is a signal identification and quality indicator. When this indicator illuminates, re-checking the measurement is necessary.
9	**Sensor Use Indicator**	This illuminates to display the approximate number of uses remaining for the attached sensor. The bottom LED will turn red when the remaining uses for the connected sensor are low. The approximate number of sensor uses remaining is displayed upon power up (if a sensor is attached) and when a sensor is connected.
10	**SpHb Button**	Press to initiate total hemoglobin (SpHb) spot check information on display or to display a Total Hemoglobin (SpHb) spot check test. Oxygen saturation (SpO_2), perfusion index (PI) and pulse rate (PR) are automatically displayed. When in the configuration menu, pressing this button will confirm a menu setting and navigate to the next menu option. (See *Section 4, Operation*).
11	**Up/Down Arrow Buttons**	Use the Up and Down arrow buttons to scroll between parameter or measurement spot check results. When in the configuration menu, use the Up and Down arrow buttons to scroll through menu setting options. (See *Section 4, Operation.*)
12	**Speaker**	Provides audible indication of alarm conditions, pulse tone, and feedback for control button presses.

Rear Panel



Pronto	
CONTROL / INDICATOR	
1	Serial Number Label
2	Certification Label
3	Battery Cover
4	Battery Cover Release

Symbols

The following symbols may be found on the Pronto or packaging and are defined below:

SYMBOL	DESCRIPTION
	Caution, consult accompanying documents
	Type BF applied part complying with IEC 60601-1
	WEEE Compliant
CE 0123	Mark of Conformity to European Medical Device Directive 93/42/EEC
R_x Only	Federal law (USA) restricts this device to sale by or on the order of a physician
	Year of manufacture
	Storage humidity range: 5% to 95%
	Storage temperature range: +70˚C to -40˚C Storage altitude range: 500 mbar to 1060 mbar
	Keep dry
	Fragile/breakable, handle with care
EC REP	EU authorized representative
	Underwriter's Laboratories Inc. certification

Introduction

Before the Masimo Pronto Pulse CO-Oximeter can be used, it needs to be inspected and properly setup, including inserting the batteries.

Unpacking and Inspection

Remove the instrument from the shipping carton and examine for signs of shipping damage. Check all materials against the packing list. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier.

If anything is missing or damaged, contact the Technical Service Department. The contact address and phone numbers are listed in Section 9, *Service and Repair*.

Preparation for Spot Checking

The following sections of the manual describe the preparation, set-up and initial installation of the Masimo Pronto Pulse CO-Oximeter.

Power Requirements

The Pronto is powered by 4 AA alkaline batteries. Do not use any other type of batteries or power source to run the instrument. The battery compartment is accessed from the back of the device. To install the batteries first remove the battery cover by depressing the small rectangular button at the bottom of the cover, and sliding the cover down off the bottom of the device. Install the batteries in the directions indicated by the battery icons inside the battery compartment. Replace the battery cover by sliding it back up from the bottom of the device until the rectangular locking button snaps back into position.

WARNING: USE ONLY ALKALINE BATTERIES. USE OF NON ALKALINE BATTERIES MAY AFFECT THE ACCURACY OF THE BATTERY LEVEL METER.

WARNING: USE OF BATTERIES WITH A CELL VOLTAGE OF MORE THAN 1.5V COULD CAUSE DAMAGE TO THE PRONTO.

Battery charge level is indicated by four LED indicators at the bottom of the front panel. All four indicators will be lit when the batteries are fully charged, with fewer indicators being lit as the batteries lose their charge. When battery life is approaching depletion, the final battery indicator will begin to flash and an audible alarm will sound.

Instrument Setup

Initial Setup

1. Inspect the Pronto case for damage.
2. If your instrument is equipped with a protective boot, remove it. To remove the boot, gently bend down on the boot at the bottom end of the instrument next to the speaker. Push up on the instrument and remove the boot.
3. Install 4 (four) new AA alkaline batteries. Fasten the boot onto the instrument, if required.
4. Turn the instrument on. All LEDs will briefly illuminate and an audible tone will sound.
5. Configure the device for your regional power line frequency (LF) (50 or 60 hz) if needed. Default is 60 hz (standard for the United States). See *Section 4, Operation*.

CAUTION: The instrument must be configured to match your local power line frequency to allow for the cancellation of noise introduced by fluorescent lights and other sources.

No other setup is required. Refer to *Section 4, Operation, General Setup and Use* for additional steps to verify proper functioning of the device.

Introduction

To operate the Masimo Pronto Pulse CO-Oximeter effectively, the operator must:

- Know how the Pulse CO-Oximeter derives its readings (see *Section 1, Pulse CO-Oximetry*)
- Be familiar with its controls and operation.
- Understand its status and messages (see Section 5, *Messages* and Section 6, *Troubleshooting*).

NOTE: *For your convenience, a quick reference guide is inserted into the protective boot underneath the strap. Unfasten the strap to view the guide. This guide provides initial setup and operating instructions, parameter information, and SpHb display options. If your device does not have a protective boot, the quick reference guide is included in the packaging.*

Basic Operation

General Setup and Use

1. Inspect the Pronto case for damage.
2. Ensure that the batteries are correctly installed.
3. Select a compatible sensor. See *Section 8, Sensors and Patient Cables*. Remove any substances that may interfere with the transmission of light between the sensor's light source and detector.
4. Connect the sensor, or the patient cable and sensor, to the connector of the Pronto. Make sure it is a secure connection and the cable is not twisted, sliced or frayed. See *Section 5, Messages*, to view messages that may be displayed pertaining to sensors and cables.
5. Press the Power Button to turn the Pronto on.
6. Verify all front-panel indicators momentarily illuminate and a tone is heard.
7. If applicable, the instrument will display numeric sensor uses remaining.
8. Attach the sensor to the patient. Refer to the *Directions for Use* of the sensor.
9. PI, SpO_2, and PR will automatically display. The Spot Check progress indicator begins to illuminate.
10. Verify that the pulse indicator light is illuminated. The light flashes when the pulse rate (PR) is acquired.

NOTE: *It will take about 1-3 minutes for the Pronto to acquire an accurate spot check. During this period, the sensor is initializing and the sensor is adjusting to the patient and PI, SpO_2, and/or PR parameters/measurements (depending upon user configuration) appear on the main display. No other quality control activities (such as calibration) are required.*

11. The Spot Check Progress Indicator incrementally illuminates from bottom to top, and the device generates a tone when the test is ready to display. When the Progress bar is fully illuminated, the SpHb parameter/measurement value is ready to display, and an audible sound is generated. If the SpHb button was pressed, the SpHb parameter/measurement is immediately displayed.
12. Use the Up or Down Arrow buttons to navigate through the parameter and measurement values that have been spot checked.

General Setup and Use, continued

13. Verify at each parameter/measurement display that the Low SIQ light is off. If the Low SIQ light is on, the value may be checked again. (For a period of time after the initial spot check, additional spot checks may be initiated without decreasing the uses available on the sensor.)
14. After the spot check is complete, remove the sensor from the patient and store or dispose of the sensor according to the governing rules. See the sensor's *Directions for Use* for details.
15. SpHb data display for five (5) minutes. After five minutes, the data can only be obtained by downloading the data through the trend monitor or when another test is performed.
16. The Pronto will power off automatically after five (5) minutes of inactivity to save battery life, except when downloading trend data. (The user can also press and hold the Power On/Off button for 2 seconds to power off the Pronto). If the patient's finger is in the sensor, the device reverts back to a continuous display of SpO_2, PR and PI.
17. To view older readings after a reading has been performed, press the up/down arrows to view different parameters. The parameter label blinks indicating the value obtained might be older or not correlate with the patient. Parameters display in his order: SpHb, SpO_2, PR, and PI.

Default Settings

OPTION	DISPLAY	FACTORY DEFAULT SETTING	CONFIGURABLE SETTINGS
Date and Time	Yr mnd hn	N/A	Year/Month/Day (YY/MM/DD) Hour/Minute(hh:mm)
Clear Trend	CLr tNd	No	No, Yes
Oxygen Saturation (SpO_2)	O2	On	On, Off
Pulse rate (PR)	Pr	On	On, Off
Perfusion Index (PI)	PI	On	On, Off
Line Frequency (LF)	LF	60 Hz	50, 60 Hz
Software Version	UEr	HH	HH, MX (read only)
SpHb Calibration	Hb	Venous ($SpHb_V$)	Venous, Arterial
Pulse Tone	ton	Off	On, Off
SpHb Units of Measurement	HbU	Grams per Deciliter	Grams per Deciliter Millimoles per Liter
Display Low SIQ Values	dPL	Off	On, Off

Successful SpHb Spot Check

The following general points will aid in ensuring successful measurement.

- Place the sensor on a site that has sufficient perfusion and provides proper alignment of the LEDs and detector.
- Use Perfusion Index (PI) as an indication of adequate perfusion.
- Place the sensor on a site that has unrestricted blood flow.
- Do not secure the sensor with tape.
- Do not select a site near potential electrical interference (electrosurgical device, for example).
- Read the sensor's *Directions for Use* for proper sensor application.

Note: The device tries to obtain a reading for approximately three minutes. The device displays a retest message indicating a spot check test could not be performed. (See: Troubleshooting)

Masimo Sensors

Before use, carefully read the Masimo sensor's *Directions for Use*.

Use only Masimo Rainbow (SpHb) sensors for spot checking measurements.

CAUTIONS

- Do not use damaged sensors.
- Do not use a sensor with exposed optical or electrical components.
- Do not immerse the sensor in water, solvents, or cleaning solutions (the sensors and connectors are not waterproof).
- Do not sterilize by irradiation, steam, autoclave or ethylene oxide unless otherwise indicated in the sensor's directions for use. Sensor cleaning instructions are in the *Directions for Use*.
- Do not attempt to reprocess, recondition or recycle Masimo sensors as these processes may damage the electrical components, potentially leading to patient harm.

Numeric Display - SpHb

A SpHb reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Hemoglobin synthesis disorders may cause erroneous SpHb readings. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion. Inaccurate measurements may be caused by:

- Intravascular dyes such as indocyanine green or methylene blue
- Externally applied coloring (such as nail polish)
- Elevated levels of bilirubin
- Low arterial perfusion
- Motion artifact
- Low arterial oxygen saturation levels, including altitude induced low SpO_2
- EMI radiation interference

- Hemoglobin synthesis disorder
- Hemoglobinopathy
- Thalassemias
- Peripheral vascular disease

Numeric Display - SpO_2

A SpO_2 reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Inaccurate measurements may be caused by:

- Elevated levels of carboxyhemoglobin
- Elevated levels of methemoglobin
- Intravascular dyes such as indocyanine green or methylene blue
- Externally applied coloring (such as nail polish)
- Elevated total bilirubin levels
- Severe anemia
- Low arterial perfusion
- Motion artifact

Numeric Display - Pulse Rate

The Pulse Rate displayed on the Pronto may differ slightly from the heart rate displayed on ECG monitors due to differences in averaging times. There may also be a discrepancy between cardiac electrical activity and peripheral arterial pulsation. Significant differences may indicate a problem with the signal quality due to physiological changes in the patient or one of the devices or application of the sensor or patient cable. The pulsations from intra-aortic balloon support can cause the pulse rate displayed on the Pronto to be significantly different than the ECG heart rate.

Numeric Display - PI

The Perfusion Index (PI) display provides a numeric indication of the pulse strength at the measurement site. It is a calculated percentage between the pulsatile signal and non-pulsatile signal of arterial blood moving through the site. It displays an operating range of < .02 percent to 20 percent. A percentage greater than 1.00 percent is desired.

Low Perfusion

It has been suggested that at extremely low perfusion levels, Pulse CO-Oximeters can measure peripheral saturation, which may differ from central arterial saturation*. This "localized hypoxemia" may result from the metabolic demands of other tissues extracting oxygen proximal to the measurement site under conditions of sustained peripheral hypoperfusion. (This may occur even with a pulse rate that correlates with the ECG heart rate.)

* Severinghaus JW, Spellman MJ. Pulse Oximeter Failure Thresholds in Hypotension and Vasoconstriction Anesthesiology 1990; 73:532-537

Low Signal IQ (Low SIQ)

The Masimo Pronto Pulse CO-Oximeter provides a visual indicator of low signal quality through the LED when displayed SpO_2, SpHb, PI and/or PR values are not based on adequate signal quality.

NOTE: *When the Display Low SIQ option is enabled, the LOW SIQ parameters/measurements will be displayed.*

When the signal quality is poor the Low SIQ Indicator LED illuminates. When the Low Signal IQ LED illuminates proceed with caution and do the following:

- Assess the patient.
- Check the sensor and ensure proper sensor application. The sensor must be well secured to the site to obtain accurate readings. Also, misalignment of the sensor's emitter and detector can result in low quality signals.
- Determine if an extreme change in the patient's physiology and blood flow at the measurement site occurred, (e.g. an inflated blood pressure cuff, a squeezing motion, sampling of an arterial blood specimen from the hand containing the pulse oximetry sensor, severe hypotension, peripheral vasoconstriction in response to hypothermia, medications, or an episode of Raynaud's syndrome.)

After performing the above, retest. An arterial blood specimen for laboratory CO-Oximetry analysis may be considered to verify the oxygen saturation and hemoglobin values.

Troubleshooting Sensor Placement

NOTE: *This information is not a substitute for the sensor's Directions for Use (DFU). Refer to the DFU for complete information regarding the sensor's application and use*

- Make sure the emitter and detector are aligned directly opposite each other.
- Select a site where the distance between the emitter and detector is minimized.
- Wipe the sensor site with a 70% isopropyl alcohol pad or rubefacient cream (10-30% methyl salicylate and 2-10% menthol) for 20-30 seconds to increase perfusion. However, strong vasodilator creams, such as nitroglycerin paste, are not recommended.
- If possible, remove electrical noise sources such as electrosurgical devices or other electrical/ electronic equipment.
- If artificial nails or excessive fingernail polish are present, select another site or remove the polish/artificial nails.
- If possible, ensure that the sensor is placed in a location with low ambient light. Although the Pronto with integrated Masimo Rainbow SET technology has significant immunity to ambient light, excessive ambient light may cause readings to be incorrect.

CAUTION: If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the Pulse CO-Oximeter for proper functioning.

Low Battery Audible Alarm

If a low battery condition occurs while a measurement is being taken, an audible alarm will sound. If a low battery condition occurs, immediately replace the batteries.

NOTE: Remove batteries when storing device for prolonged periods to maintain battery life.

WARNING: FAILURE TO REPLACE BATTERIES PROMPTLY AFTER A LOW BATTERY ALARM MAY RESULT IN THE PULSE CO-OXIMETER SHUTTING DOWN AND LEAVING THE PATIENT IN AN UNMONITORED CONDITION.

WARNING: USE ONLY ALKALINE BATTERIES. USE OF NON ALKALINE BATTERIES MAY AFFECT THE ACCURACY OF THE BATTERY LEVEL METER.

WARNING: USE OF BATTERIES WITH A CELL VOLTAGE OF MORE THAN 1.5V COULD CAUSE DAMAGE TO THE PRONTO.

WARNING: EFFECTIVE BATTERY LIFE USES WILL BE REDUCED WHEN OPERATING THE DEVICE BELOW 5ºF (-15º C) DUE TO ALKALINE BATTERY TECHNOLOGY.

Alarm Identification

The Pronto visually and audibly indicates alarm conditions that the system detects. A three beep medium priority audible alarm with visual indicator occurs for both the system and low battery audible alarm.

Battery Level Indicator

Four LED indicators provide information on the remaining battery capacity. The operator should monitor these indicators periodically to determine remaining spot check uses and if the batteries should be replaced. Battery capacity is indicated in the following chart.

INDICATION	BATTERY CAPACITY
4 LEDs	100% to 75%
3 LEDs	74% to 50%
2 LEDs	49% to 25%
1 LED	24% to 10%
1 Flashing LED with Audible Alarm	9% to 0%

Setup Menu

To navigate through the menus, use the **Up** and **Down** keys located on the front panel of the Pulse CO-Oximeter below the LED display. The Pulse CO-Oximeter has options that allow user configuration to suit specific needs.

Menu Navigation

Set-up and configuration options are accessed through the menu system.

MENU ACCESS	MENU DISPLAY	AVAILABLE OPTIONS
For **Menu Access**: Press and hold both the up and down arrows  for 5 seconds. **Press SpHb**  repeatedly, to scroll through the **Screens** until the **Menu Display** appears. Press the up or down arrow  to select an **Available Option.** Press SpHb  to confirm your choice.	Yr	Year (Current Year)
		Sets Year (00-99)
	nn	Month (current month)
		Sets Month (01-12)
	d	Day (current day)
		Sets Day (00-31)
	h	Hour (current hour)
		Sets Hour (00-23)
	nn	Minute (current minute)
		Set Minute (00-59)
	CLr	Clear Trend (Yes)
	End	Clear Trend (No) (Default)
	02	SpO_2 On (Default)
		SpO_2 Off
	Pr	PR On (Default)
		PR Off
	PI	PI On (Default)
		PI Off
	LF	LF 60(Default)
		LF 50
	UEr	Software Version HH Software (Default)
		Software Version MX Software
	Hb*	$SpHb_V$ Calibration Venous(Default)
		SpHb Calibration Arterial

MENU ACCESS	MENU DISPLAY	AVAILABLE OPTIONS
	tOn	Pulse Tone Off (Default)
		Pulse Tone On
	HbU	Grams per Deciliter (g/dL) (Default)
		Milimoles per Liter (mmol/L)
	dPL †	On
		Off (Default)

*The hemorheologic profile of arterial and venous blood samples can vary. To accommodate this difference, Pronto provides the option of displaying a SpHb parameter that is based on either Arterial SpHb or Venous $SpHb_V$ laboratory blood sample data. Changing the calibration setting from $SpHb_V$ to SpHb (and vice versa) will clear the trend memory.

†Allows user to choose whether to display values under LOW SIQ conditions.

Exit the Menu and Power Off the Device

To exit the menu, allow 10 minutes of inactivity, or press the Up and Down arrows simultaneously. Press the Power On/Off button for 2 seconds to turn off the instrument.

Trend Setup and Use

Introduction

The Pronto can store at least 10,000 spot checks. The trend data can then be transferred to a PC for evaluation. The data is not intended to be used for trending purposes.

A Data Transfer Cable is required to connect the Pronto to a PC. Patient measurement is not possible while trend memory is being transferred to a PC.

Trend data is stored in non-volatile memory, so it is not erased when the device is shut off. A trend data download is initiated using the TrendCom utility (not included) which downloads the spot check trend data and saves it to an ASCII text (.out) file with an output delimiter option.

NOTE: *Before collecting trend data, it is recommended to set (or reset) the date and time on the device.*

TrendCom Utility Installation and Operation

Copy the TrendCom utility from the TrendCom CD onto a PC running MS-Windows. Refer to the TrendCom *Directions for Use (DFU*) for detailed instructions on Download and Operation.

NOTE*: During download of spot check trend information, all normal Pronto functions are unavailable and the keypad is locked, except for the power button.*

Erasing Trend Memory

Refer to the *TrendCom Directions for Use (DFU*) for detailed instructions on Erasing Trend Memory. The Pronto automatically captures all parameters/measurements. When performing a new study and gathering data on a new patient, it is highly recommended the "Clear Trend Function" be utilized prior to data collection in order for the results to be separate. Turning the Pronto off will not erase the trend data.

Trend Data Format

After a successful download of the trend data, a .out file will be created containing the trend-dump information in ASCII delimited format. The format is defined in the following table.

PARAMETER	SPECIFICATION
Date	MM\DD\YY
Time	HH:MM:SS
Installed Parameter/ Measurement	Numeric value (see the display ranges in the Factory and User Configurable Default Settings table located at the beginning of this section)
Exception Messages	The exceptions are displayed as a 3 digit, ASCII encoded, hexadecimal value. The binary bits of the hexadecimal value are encoded as follows: 000 = Normal operation; no exceptions 004 = Low Perfusion 400 = Low Signal IQ 800 = Masimo SET. This flag means the algorithm is running in full SET mode. It requires a SET sensor and needs to acquire some clean data for this flag to be set

Sample Trend Output

```
11/30/11 00:09:36 SpO2=100 PR=070 PI=01.32 SpCO=00.00 Met=00.00 SpHb=15.1 PVI=000 EXC=00000000
12/01/11 00:12:45 SpO2=096 PR=068 PI=03.52 SpCO=00.00 Met=00.00 SpHb=13.8 PVI=000 EXC=00000000
12/01/11 00:13:14 SpO2=100 PR=069 PI=02.20 SpCO=00.00 Met=00.00 SpHb=14.3 PVI=000 EXC=00000000
12/02/11 00:09:27 SpO2=100 PR=068 PI=01.52 SpCO=00.00 Met=00.00 SpHb=14.2 PVI=000 EXC=00000000
12/02/11 00:10:58 SpO2=099 PR=071 PI=03.64 SpCO=00.00 Met=00.00 SpHb=15.8 PVI=000 EXC=00000000
12/02/11 00:15:04 SpO2=097 PR=068 PI=01.52 SpCO=00.00 Met=00.00 SpHb=10.8 PVI=000 EXC=00000000
12/03/11 00:11:31 SpO2=100 PR=072 PI=04.69 SpCO=00.00 Met=00.00 SpHb=12.5 PVI=000 EXC=00000000
```

NOTE: *Trend output data appears for the parameters/measurements noted above. Pronto only stores output data for SpO_2, PR, PI, and SpHb parameters/measurements. SpCO, SpMet, and PVI measurements are not available with Pronto.*

NOTE: *Pronto does not store continuous output data for SpO_2, PR, PI, and SpHb. Pronto only stores data related to SpHb, SpO_2, PR and PI during spot check tests results.*

Messages

The Pronto will indicate other data or system errors. Messages are:

DISPLAY	TYPE	SOLUTION
NO SEN	No Sensor Connected	1. Connect sensor to cable. 2. Check sensor connection to cable
	The Masimo ReSposable Sensor System is not connected to the instrument	Assemble the ReSposable Sensor System and then connect to the instrument.
SEN OFF	Sensor off patient	1. Reattach sensor to patient. 2. Verify proper sensor placement.
Circulating LEDs	Sensor is initializing/ determining measurement	Wait for pulse detection. (This search should occur whenever a spot check is performed). If necessary, shield the sensor from excessive ambient or strobing light.
Low SIQ indicator Illuminates	Low Signal IQ	1. Rule out occlusion of blood flow. 2. Verify placement of sensor. 3. Move sensor to a better perfused site. 4. Refer to Section 4, *Low Signal IQ*
Single battery Level Indicator flashes (with audible alarm)	Battery level too low	Replace batteries immediately.
Err ##	System Fault	Return for service. There are several error codes. All error codes require return of the device to an authorized service center for repair. See Section 9, *Service and Repair* for return procedure.
rPL SEN	Defective sensor	Replace sensor.
	The Masimo ReSposable Sensor System is non-functional.	Replace the Masimo ReSposable Sensor System
INC dEt (Blinking)	Interference detected	Ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required.

Messages, continued

DISPLAY	TYPE	SOLUTION
INC SEN	Incompatible sensor	Attach appropriate sensor.
INC CbL	Incompatible cable	Attach appropriate cable.
NO CbL	No cable	Attach appropriate cable.
SEN 000	Zero sensor uses remaining	Attach new sensor. Dispose of the old sensor per local governing ordinances.
rE tSt	Spot check incomplete	Confirm sensor placement and press Start Test button again.
NO AdH	The reusable part of the Masimo ReSposable sensor system is connected to the instrument, the adhesive part is not connected.	Disconnect the reusable part of the ReSposable Sensor System. Assemble the ReSposable Sensor System and then connect to the instrument.
InC AdH	The adhesive part of the Masimo ReSposable Sensor System is incompatible or unrecognized.	Replace the adhesive part of the ReSposable Sensor System.
rPL AdH	The adhesive part of the Masimo ReSposable Sensor System is non-functional.	Replace the adhesive part of the ReSposable Sensor System.

Troubleshooting

The following chart describes what to do if the Pronto system does not operate properly or fails.

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
Difficulty or no SpHb reading	Interference from line-frequency induced noise	Minimize or eliminate interference from surgical or fluorescent lighting. Verify/set 50/60hz menu setting. Refer to Section 3, *Initial Setup* for details.
	Inappropriate sensor	Verify use of a SpHb capable sensor.
	Excessive motion	Minimize or eliminate motion at the measurement site. See Section 4, *Successful SpHb Spot Check* for additional information.
	Excessive ambient or strobing light	Shield the sensor from excessive light.
	Also, see Section 4, *Successful SpHb Spot Check* for additional information.	
Unit does not power on	Low battery	Check/replace batteries.
Continuous speaker tone	Internal Failure	Unit requires service. If alarm continues to sound, power down unit and/or remove batteries.
Buttons don't work when pressed	Internal Failure	Return for service.
Low battery alarm sounds. Battery indicator shows low battery capacity less than expected capacity	Effective spot check uses will be reduced when operating the device below 5 degrees Fahrenheit due to alkaline battery technology	Remove the batteries and allow them to warm up to room temperature, re-install them and check the battery indicator level. If the battery capacity remains low, replace batteries.

Specifications

PERFORMANCE	
Measurement Range	
SpO_2:	0 -100%
SpHb	0 - 25 g/dl
Pulse Rate:	25 - 240 (bpm
Perfusion Index:	0.02% - 20%
ACCURACY	
Saturation	60% to 80%
No Motion[1]	
Adults, Pediatrics	± 3%
Saturation	70% to 100%
No Motion[2]	
Adults, Pediatrics	± 2%
Motion[3]	
Adults, Pediatrics	± 3%
Low Perfusion[4]	
Adults, Pediatrics	± 2%
Pulse Rate[5]	
Pulse Rate	25 - 240 bpm
No Motion	
Adults, Pediatrics	± 3 bpm
Motion[3]	
Adults, Pediatrics	± 5 bpm
Low Perfusion[4]	
Adults, Pediatrics	± 3 bpm
Total Hemoglobin concentration accuracy (SpHb g/dl)[6]	
Adults, Pediatrics	8 - 17 g/dl ±1 g/dl
Resolution	
Oxygen Saturation (%SpO_2)	1%
Total Hemoglobin concentration (SpHb g/dl), digital display	0.1 g/dl
Pulse Rate (PR)	1 bpm
Interfering Substances	
Refer to Safety Information, Warnings and Cautions	
ELECTRICAL	
Batteries	
Type	4 AA alkaline
Capacity	Operates continuously for up to 8 hours without changing batteries[7]
Isolation	No external power or ground connection, internally powered only, DC current

Specifications, continued

ENVIRONMENTAL	
Operating Temperature	0°F to 129°F (-18°C to 54°C)
Storage Temperature	-40°F to 158°F (-40°C to +70°C)
Storage Humidity	5% to 95%, non-condensing
Operating Altitude	500 mbar to 1060 mbar -1000 ft to 18,000 ft (-304 m to 5,486 m),
PHYSICAL CHARACTERISTICS	
Dimensions:	6.2" x 3.0" x 1.4" (15.8 cm x 7.6cm x 3.6 cm)
Weight:	13oz. (0.37 kg)
Trending Memory:	
Stores a minimum of 10,000 time-stamped spot check result data in trend memory	
Alarms:	Low Battery, System Failure
Medium Priority Audible Alarm	500 Hz tone, 3 pulse burst, repeat time: 5s
Display/Indicators:	
Data display: %SpO2, SpHb g/dl, Pulse Rate, PI, Low Signal IQ, Battery Level Indicator, Spot Check Progress Indicator, Pulse Indicator, and Sensor Use Indicator.	
Type	LED
COMPLIANCE	
EMC Compliance	EN60601-1-2, Class B
Equipment Classification	IEC 60601-1
Type of Protection	Internally powered (on battery power)
Degree of Protection-Patient Cable	Type BF-Applied Part

1. SpO_2 accuracy was determined by testing on healthy adult volunteers in the range 60% - 100% SpO_2, against a laboratory CO-Oximeter. Contact Masimo for testing specifications.
2. The Masimo sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
3. The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
4. The Pronto has been validated for low perfusion accuracy in bench-top testing against a Fluke Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70-100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
5. Masimo sensors have been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Fluke Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
6. SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8 g/dL to 17 g/dL SpHb against a laboratory CO-Oximeter. The variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.
7. Continous use is defined as consecutive spot check tests with each consecutive spot check test initiated immediately upon the conclusion of the previous spot check test.

Introduction

This section covers the use and cleaning of Masimo sensors and patient cables. It should be used as a reference and not as a substitute for the sensor's *Directions for Use (DFU).*

Use only Masimo sensors and cables with the Pronto. Other transducers, sensors and cables may affect the device's performance.

CAUTIONS:

- Tissue damage can be caused by incorrect application or use of a sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor's *Directions for Use* to ensure skin integrity, correct positioning and adhesion of the sensor.
- Do not use damaged sensors or patient cables. Do not use a sensor or patient cable with exposed optical or electrical components.
- Do not immerse the sensor or patient cable in water, solvents, or cleaning solutions (the sensors and connectors are not waterproof).
- Unless otherwise specified, do not sterilize sensors or patient cables by irradiation, steam, autoclave or ethylene oxide. See the cleaning instructions in the sensor's *Directions for Use*.
- Do not attempt to reprocess, recondition or recycle any Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.
- All sensors and cables are designed for use with specific monitors. Verify the compatibility of the monitor, cable and sensor before use, otherwise patient injury can result.
- High intensity extreme lights (such as pulsating strobe lights) directed on the Rainbow sensor, may not allow the sensor to obtain vital sign readings. High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

Selecting a Rainbow SpHb Sensor Only

When selecting a sensor, consider the patient's weight, the adequacy of perfusion, the available sensor sites, and the duration of measuring. For more information refer to the following tables or contact your Sales Representative. Use only Masimo SpHb Rainbow sensors and patient cables. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the *Directions for Use* accompanying the sensor. Monitor, cables and sensors must be compatible to ensure optimal performance. Incompatible components affect operation or data recovery.

Masimo Rainbow® Sensors

Masimo SpHb Rainbow sensors must be used for the Masimo Pronto Pulse CO-Oximeter parameters to enable measurement of Oxyhemoglobin (SpO2) and Total Hemoglobin (SpHb). Rainbow sensors will only function with devices containing Masimo Rainbow SET Technology or licensed to use Rainbow compatible sensors.

SpHb Rainbow sensors connect to the device directly or with a Rainbow patient cable.

SpHb Rainbow Reusable and Adhesive Sensors

SpO_2, SpHb and pulse rate accuracy for the SpHb Rainbow reusable sensors is specified in the following tables.

Rainbow Direct Connect sensors connect to the device directly.

Sensor	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy		SpHbAccuracy
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate	
DC-3 DC-12 DC SC-3	> 30 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1 g/dl
DCP-3 DCP-12 DCP SC-3	10 - 50 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1 g/dl

Sensor	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy		SpHb Accuracy
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate	
DCI	> 30 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1 g/dl
DCIP	10 - 50 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1 g/dl

SpO2, SpHb and pulse rate accuracy for the SpHb Rainbow adhesive sensors is specified in the following table.

Sensor	Weight Range	Saturation Accuracy		Pulse Rate Accuracy		Low Perfusion Accuracy		SpHb Accuracy
		No Motion	Motion	No Motion	Motion	Saturation	Pulse Rate	
R1 25	> 30 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1 g/dl
R1 25L	> 30 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1 g/dl
R1 20	10 - 50 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1 g/dl
R1 20L	10 - 30 kg	60 - 80 ± 3% 70 -100 ± 2%	± 3%	± 3 bpm	± 5 bpm	± 2%	± 3 bpm	± 1 g/dl

SpHb Rainbow Resposable Pulse Oximeter Sensor System

SpO_2, SpMet, SpHb and pulse rate accuracy for the Rainbow ReSposable Pulse CO-Oximeter Sensor System is specified in the following table.
The reusable sensor is attached to the adhesive senor to make the two-piece sensor system.

SENSOR	Weight Range	Saturation Accuracy	Pulse Rate Accuracy	Low Perfusion Accuracy		SpMet Accuracy*	SpHb Accuracy
				Saturation	Pulse Rate		
R2-25a R2-25r	> 30 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3 bpm	± 2%	± 3 bpm	± 1%	± 1 g/dl
R2-20a R2-20r	10 - 50 kg	60 - 80% ± 3% 70 - 100% ± 2%	± 3 bpm	± 2%	± 3 bpm	± 1%	± 1 g/dl

NOTE: *The R2-25a must be used with a R2-25r and the R2-20a must be used with a R2-20r.*

*SpMet is not currently available with the Pronto Pulse Oximeter.

Sensor Accuracy

Refer to Section 7, *Specifications* for SpO2, SpHb and pulse rate accuracy. (Unless otherwise specified in the previous tables)

Complete accuracy specifications are located in the sensor DFUs and are specific for the type of Masimo sensor used.

Cleaning and Reuse of Masimo Reusable Sensors and Cables

Reusable Rainbow sensors and patient cables can be cleaned per the following procedure:

1. Remove the sensor from the patient.
2. Disconnect the sensor from the patient cable.
3. Disconnect the patient cable from the device.
4. Wipe the entire sensor and/or patient cable clean with a 70% isopropyl alcohol pad.
5. Allow to air dry thoroughly before returning it to operation.

CAUTION: Carefully route patient cables to reduce the possibility of patient entanglement or strangulation.

NOTE: *If the sensor fails to track the pulse consistently, the sensor may be incorrectly positioned. Reposition the sensor or choose a different measurement site.*

CAUTION: Do not attempt to reprocess, recondition or recycle any masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.

CAUTION: To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilize by irradiation, steam, autoclave or ethylene oxide.

Introduction

This chapter covers how to test the operation, properly clean and obtain service for the Pronto.

Under normal operation, no internal adjustment or recalibration is required. Safety tests and internal adjustments should be done by qualified personnel only. Safety checks should be performed at regular intervals or in accordance with local and governmental regulations.

WARNING: BEFORE CLEANING THE INSTRUMENT, ALWAYS TURN IT OFF AND REMOVE THE BATTERIES.

The Pronto is a reusable device. The device is supplied and used non-sterile.

Cleaning

The outer surface of the Pronto can be cleaned with a soft cloth dampened with a mild detergent and warm water solution. Do not allow liquids to enter the interior of the instrument. The outer surface of the instrument can also be wiped down using the following solvents: Cidex Plus (3.4% Glutaraldehyde), 0.25% Ammonium Chloride, 10% Bleach, 70% Isopropyl Alcohol.

CAUTIONS:

- Do not autoclave, pressure sterilize, or gas sterilize the Pronto.
- Do not soak or immerse the Pronto in any liquid.
- Use the cleaning solution sparingly. Excessive solution can flow into the Pronto and cause damage to internal components.
- Do not touch, press, or rub the display panels with abrasive cleaning compounds, devices, brushes, rough-surface materials, or bring them into contact with anything that could scratch the panel.
- Do not use petroleum-based, acetone solutions, or other harsh solvents, to clean the Pronto. These substances erode the instrument's materials and instrument failure can result.

Refer to *Section 8, Cleaning and Reuse of Masimo Reusable Sensors and Cables* for cleaning instructions of the sensor.

Battery Replacement

The Pronto is powered by 4 AA alkaline batteries. Do not use any other type of batteries or power source to run the instrument. The battery compartment is accessed from the back of the instrument. To replace the batteries first remove the battery cover by depressing the small rectangular button at the bottom of the cover, and sliding the cover down off the bottom of the instrument. Remove the batteries and install new batteries in the directions indicated by the battery icons inside the battery compartment. Replace the battery cover by sliding it back up from the bottom of the device until the rectangular locking button snaps back into position.

WARNING: FAILURE TO REPLACE BATTERIES PROMPTLY AFTER A LOW BATTERY ALARM MAY RESULT IN THE PRONTO SHUTTING DOWN.

WARNING: USE ONLY ALKALINE BATTERIES. USE OF NON ALKALINE BATTERIES MAY AFFECT THE ACCURACY OF THE BATTERY LEVEL METER.

WARNING: USE OF BATTERIES WITH A CELL VOLTAGE OF MORE THAN 1.5V COULD CAUSE DAMAGE TO THE PRONTO.

WARNING: EFFECTIVE BATTERY LIFE WILL BE REDUCED WHEN OPERATING THE PRONTO BELOW 5ºF (-15º C) DUE TO ALKALINE BATTERY TECHNOLOGY.

Battery charge level is indicated by four LED indicators at the bottom of the front panel. All four indicators will be lit when the batteries are full, with fewer indicators being lit as the batteries lose their charge. When the battery charge level is approaching depletion, the final battery indicator will begin to flash and an audible alarm will sound.

Be sure to follow local regulations in regards to battery disposal.

Performance Verification

To test the performance of the Pronto following repairs or during routine maintenance, follow the procedure outlined in this section. If the Pronto fails any of the described tests, discontinue its use and correct the problem before returning the instrument back to the user.

Before performing the following tests, verify or install new batteries into the Pronto. Also disconnect any patient cables, serial cables or sensors from the instrument.

Power-On Self-Test

1. Turn the instrument on by pressing the Power Button. For about 5 seconds all available LEDs are illuminated and a brief beep tone sounds.
2. The sensor uses remaining will display.
3. The Pronto is ready for use (the "rdy" message appears).

Service and Repair

Repair Policy

Masimo or an authorized Service Department must perform warranty repair and service. Do not use malfunctioning equipment. Have the instrument repaired prior to use.

Please clean contaminated dirty equipment before returning, following the cleaning procedure described in Section 9, *Cleaning*. Make sure it is fully dry before packing the equipment.

To return the Pronto for service, please follow the Return Procedure.

WARNING: DO NOT REMOVE THE COVER OF THE INSTRUMENT EXCEPT FOR BATTERY REPLACEMENT. AN OPERATOR MAY ONLY PERFORM MAINTENANCE PROCEDURES SPECIFICALLY DESCRIBED IN THIS MANUAL. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL TRAINED IN THE REPAIR OF THIS EQUIPMENT.

Return Procedure

Please clean contaminated/dirty equipment before returning and make sure it is fully dry before packing the equipment. Call Masimo at 800-326-4890 and ask for Technical Support. Ask for an RMA number. Package the equipment securely – in the original shipping container if possible – and enclose or include the following information and items:

- A letter describing in detail any difficulties experienced with the Pronto. Please include the RMA number in the letter.
- Warranty information – a copy of the invoice or other applicable documentation must be included.
- Purchase order number to cover repair if the device is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information.
- Person (name, telephone/Telex/fax number, and country) to contact for any questions about the repairs.
- A certificate stating the Pronto has been decontaminated for bloodborne pathogens.

Return the Pronto to the following shipping address:

For USA, Canada & Asia Pacific:

Masimo Corporation
40 Parker
Irvine, California 92618
Tel: 949-297-7000
FAX: 949-297-7001

For Europe:

Masimo International Sàrl
Puits-Godet 10
2000 Neuchatel
Switzerland
Tel: +41 32 720 1111
Fax.: +41 32 724 1448

All other locations:

Contact your
local Masimo
Representative

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Batteries are not warrantied.

To request a replacement under warranty, Purchaser must contact Masimo for a returned goods authorization. If Masimo determines that a Product must be replaced under warranty, it will be replaced or repaired and the cost of shipment covered. All other shipping costs shall be the responsibility of Purchaser.

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Accessories

PART NUMBER	DESCRIPTION
1842	Rubber protective boot, Grey
1908	TrendCom software
2063	20-pin Data Transfer Cable
1980	Rubber protective boot, Yellow
1981	Rubber protective boot, Red
1982	Rubber protective boot, Orange
2097	Rubber protective boot, Royal Blue
2098	Rubber protective boot, Light Blue
2099	Rubber protective boot, Pink
2208	Protective carrying case, black
2209	Protective carrying case, red
13158	Nylon protective carrying case
32901	Pronto Operator's Manual, French
32902	Pronto Operator's Manual, German
32903	Pronto Operator's Manual, Italian
32904	Pronto Operator's Manual, Spanish
32905	Pronto Operator's Manual, Swedish
32906	Pronto Operator's Manual, Dutch
32907	Pronto Operator's Manual, Danish
32908	Pronto Operator's Manual, Portuguese
32909	Pronto Operator's Manual, Chinese
32910	Pronto Operator's Manual, Japanese

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