Operator's Manual

Pronto® Pulse CO-Oximeter®

Masimo

These operating instructions provide the necessary information for proper operation of all models of the Pronto. There may be information provided in this manual that is not relevant for your system. General knowledge of pulse oximetry and an understanding of the features and functions of Pronto are prerequisites for its proper use. Do not operate Pronto 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 (USA) law restricts this device to sale by or on the order of a physician.

Note: Cleared Use Only: The device and related accessories are cleared by the Food and Drug Administration (FDA) and are CE Marked 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 applicable regulatory authorities, or in any manner inconsistent with the directions for use or labeling.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

Masimo Corporation
40 Parker
Irvine, CA 92618, USA CE 0123
Tel.: 949-297-7000
Fax.: 949-297-7001
www.masimo.com

EU authorized representative for Masimo Corporation:

EC REP
MDSS GmbH
Schiffgraben 41
D-30175 Hannover, Germany

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

80fk

Patents: ***www.masimo.com/patents.htm***

Contents

About This Manual

This manual explains how to set up and use Pronto® Pulse CO-Oximeter®. Important safety information relating to general use of Pronto appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A *warning* is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient or user.

WARNING: This is an example 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.

CAUTION: This is an example of a caution statement.

A *note* is given when additional general information is applicable.

Note: This is an example of a note.

Product Description, Features, and Indications for Use

Product Description and Features

Pronto® Pulse CO-Oximeter® is a noninvasive device intended to monitor functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), perfusion index (PI), and total hemoglobin (SpHb®).

The following key features are available for Pronto:

- Masimo SET® and rainbow® SET technology performance.
- SpO2 and pulse rate monitoring in motion and low perfusion environments.
- Noninvasive spot-checking of total arterial hemoglobin concentration (SpHb).
- Download capabilities to transfer data from the device to a computer.

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 (SpO2), 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 in clinical and nonclinical settings (e.g., hospitals, hospital-type facilities, mobile environments, homes, clinics, physician offices, blood donation facilities, and ambulatory surgery centers).

Contraindications

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

Safety Information, Warnings, and Cautions

Caution: Pronto is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.

Safety Warnings and Cautions

WARNING: Do not use the Pronto if it appears or is suspected to be damaged.

WARNING: Do not start or operate Pronto unless the setup was verified to be correct.

WARNING: Do not use Pronto during magnetic resonance imaging (MRI) or in an MRI environment.

WARNING: 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.

WARNING: Do not place the Pronto or accessories in any position that might cause it to fall on the patient.

WARNING: To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.

WARNING: To protect against injury, follow the directions below:

- Avoid placing the device on surfaces with visible liquid spills.
- Do not soak or immerse the device in liquids.
- Do not attempt to sterilize the device.
- Use cleaning solutions only as instructed in this operator's manual.
- Do not attempt to clean Pronto while monitoring patient.

WARNING: To protect from electric shock, always remove the sensor and completely disconnect Pronto before bathing the patient.

WARNING: As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

CAUTION: Do not place the Pronto where the controls can be changed by the patient.

Performance Warnings and Cautions

WARNING: Pronto should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING: Variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.

WARNING: If any measurement seems questionable, first check the patient's vital signs by alternate means and then check Pronto for proper functioning.

WARNING: Do not use Pronto for continuous monitoring.

WARNING: Pronto is not an apnea monitor.

WARNING: Pronto should not be used for arrhythmia analysis.

WARNING: Do not use Pronto during defibrillation.

WARNING: Do not use Pronto during electrocautery.

WARNING: Do not place containers with liquids on or near Pronto. Liquids spilled on Pronto may cause it to perform inaccurately or fail.

WARNING: Interfering Substances: Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.

WARNING: SpO2 and SpHb are empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

WARNING: Inaccurate SpO2 readings may be caused by:

- Improper sensor application and placement
- Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Elevated levels of bilirubin
- Elevated levels of dyshemoglobin
- Vasospastic disease, such as Raynaud's, and peripheral vascular disease
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Hypocapnic or hypercapnic conditions
- Severe anemia
- Very low arterial perfusion
- Extreme motion artifact
- Abnormal venous pulsation or venous constriction
- Severe vasoconstriction or hypothermia
- Arterial catheters and intra-aortic balloon

- Intravascular dyes, such as indocyanine green or methylene blue
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.
- Skin color disorders

Warning: Inaccurate SpHb readings may be caused by:

- Improper sensor application and placement
- Low arterial oxygen saturation levels
- Elevated carboxyhemoglobin levels
- Elevated methemoglobin levels
- Elevated levels of bilirubin
- Elevated levels of dyshemoglobin
- Elevated PaO2 levels
- Vasospastic disease, such as Raynaud's, and peripheral vascular disease
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Hypocapnic or hypercapnic conditions
- Peripheral vascular disease
- Liver disease
- Severe anemia
- Low arterial perfusion
- Motion artifact
- Abnormal venous pulsation or venous constriction
- Severe vasoconstriction or hypothermia
- Arterial catheters and intra-aortic balloon
- Intravascular dyes, such as indocyanine green or methylene blue
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.
- Skin color disorders
- Elevated altitude
- EMI radiation interference

CAUTION: Do not place the Pronto on electrical equipment that may affect the device, preventing it from working properly.

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

CAUTION: If the Low SIQ Indicator illuminates frequently, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.

CAUTION: If using pulse oximetry 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.

CAUTION: When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.

CAUTION: If SpO2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.

Note: A functional tester cannot be used to assess the accuracy of the Pronto.

Note: It is recommended that Pronto battery is fully charged prior to use.

Note: All batteries lose capacity with age, thus the amount of run time at Low Battery will vary depending upon the age of the battery.

Note: Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.

Note: Additional information specific to the Masimo sensors compatible with Pronto, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).

Note: High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the Pronto to obtain vital sign readings.

Cleaning and Service Warnings and Cautions

WARNING: Do not adjust, repair, open, disassemble, or modify Pronto. Injury to personnel or equipment damage could occur. Return Pronto for servicing.

WARNING: Electrical Shock Hazard: The battery should be installed and/or removed from the Pronto by qualified personnel only.

WARNING: Do not incinerate battery.

WARNING: Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the Pronto. These substances affect the device's materials and device failure can result.

WARNING: Do not touch, press, or rub the display panels with abrasive cleaning compounds, instruments, brushes, rough-surface materials, or bring them into contact with anything that could scratch the display.

CAUTION: An operator may only perform maintenance procedures specifically described in the manual. Refer servicing to qualified service personnel trained in the repair of this equipment.

CAUTION: Do not submerge Pronto in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage Pronto.

CAUTION: Electric shock hazard: Do not open the Pronto cover except to replace the battery or batteries.

CAUTION: Electrical shock and flammability hazard: Before cleaning, always turn off the device and remove batteries.

CAUTION: Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.

Note: Excessive cleaning solution can flow into the monitor and cause damage to internal components.

Compliance Warnings and Cautions

WARNING: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

CAUTION: Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.

CAUTION: Dispose of used batteries according to country or regional regulations.

CAUTION: To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to Pronto.

Note: Use the Pronto in accordance with Environmental Specifications section in this manual.

Note: 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.

Note: 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.

Note: This equipment has been tested and found to comply with the Class B limits for medical devices according to the EN 60601-1-2: 2007, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Note: In order to maintain compliance with FCC regulations, shielded cables must be used with this equipment. Operation with non-approved equipment or unshielded cables is likely to result in interference to radio and TV reception. The user is cautioned that changes and modifications made to the equipment without the approval of manufacturer could void the user's authority to operate this equipment.

Note: To satisfy RF exposure requirements, this device and its antenna must operate with a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

Note: This Class B digital apparatus complies with Canadian ICES-003.

Chapter 1: Technology Overview

The following chapter contains general descriptions for the parameters, measurements, and technology used within Masimo products.

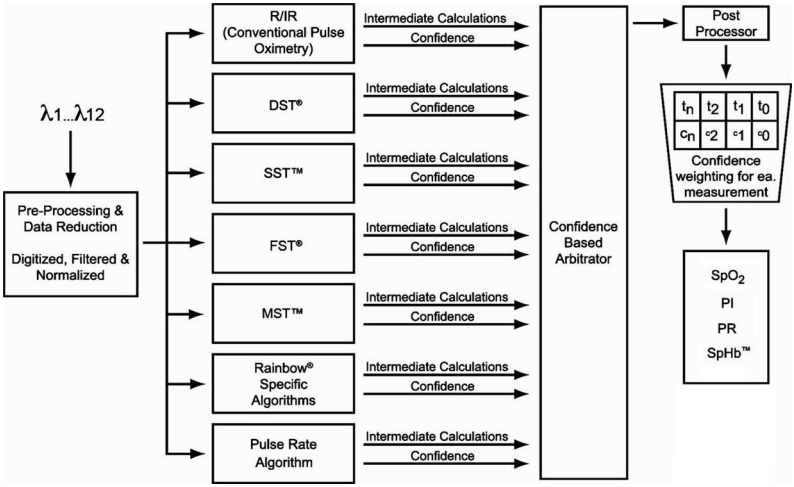
Masimo Signal Extraction Technology (Masimo SET®)

The signal processing in Masimo Signal Extraction Technology (Masimo SET®) differs from that of 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 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®), in parallel with Fast Saturation Transform (FST®), 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.

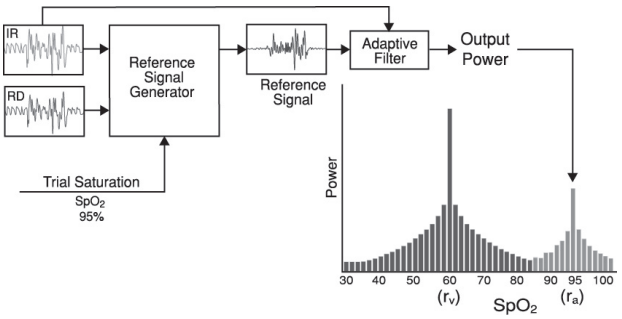
Masimo SET® Parallel Engines

This figure is for conceptual purposes only.



Masimo SET® DST

This figure is for conceptual purposes only.



General Description for Oxygen Saturation (SpO2)

Pulse oximetry is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).
2. The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

Functional Oxygen Saturation (SpO2)

The Pronto is calibrated to measure and display functional oxygen saturation (SpO2): the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen.

Note: Dyshemoglobins are not capable of transporting oxygen, but are recognized as oxygenated hemoglobins by conventional pulse oximetry.

General Description for Pulse Rate (PR)

Pulse rate (PR), measured in beats per minute (bpm), is based on the optical detection of peripheral flow pulse.

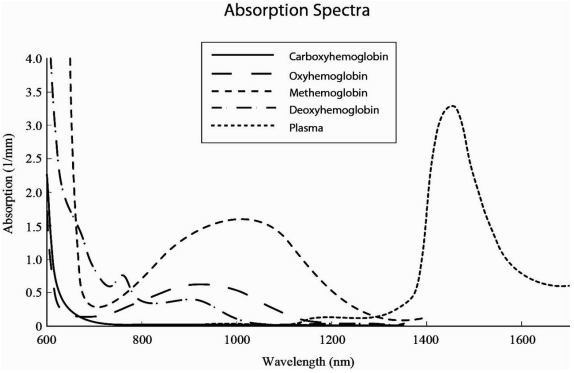
General Description for Perfusion Index (PI)

The Perfusion Index (PI) is the ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue. PI thus represents a noninvasive measure of peripheral perfusion that can be continuously and noninvasively obtained from a pulse oximeter.

rainbow Pulse CO-Oximetry Technology

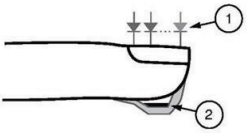
rainbow Pulse CO-Oximetry technology is governed by the following principles:

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



Pronto uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood, and blood plasma.

Pronto utilizes a sensor with various light-emitting diodes (LEDs) that pass light through the site to a diode (detector). Signal data is obtained by passing various visible and infrared lights (LEDs, 500 to 1400nm) through a capillary bed (for example, a fingertip, a hand, a foot) 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 ≤ 25 mW. The detector receives the light, converts it into an electronic signal, and sends it to Pronto for calculation.



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

Once the Pronto receives the signal from the sensor, it utilizes proprietary algorithms to calculate the patient's functional oxygen saturation (SpO2 [%]), total hemoglobin concentration (SpHb [g/dL]), and pulse rate (PR). The SpHb measurement relies on a multi-wavelength calibration equation to quantify the percentage of carbon monoxide and methemoglobin and the concentration of total hemoglobin in arterial blood. Maximum skin-sensor interface temperature was tested to be less than 41° C (106° F) in a minimum ambient temperature of 35° C (95° F). The tests were conducted with sensors operating at reasonable worst case power.

Pulse CO-Oximetry vs. Drawn Whole Blood Measurements

When SpO2 and SpHb measurements obtained from Pronto (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 SpO2 and SpHb measurements of Pronto. Any comparisons should be simultaneous, meaning the measurement on the device should be noted at the exact time that blood is drawn.

In the case of SpO2, 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 (pO2) and saturation, such as: pH,temperature, the partial pressure of carbon dioxide (pCO2), 2,3-DPG, and fetal hemoglobin.

In the case of SpHb, variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. As with most hemoglobin tests, a laboratory blood sample should be analyzed prior to clinical decision making.

High levels of bilirubin may cause erroneous SpO2 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 SpO2 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.

Measurements with Low Signal IQ should not be compared to laboratory measurements.

General Description for Total Hemoglobin (SpHb)

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of total hemoglobin (SpHb) in arterial blood. It relies on the same principles of pulse oximetry to make its SpHb measurement. The measurement is taken by a sensor capable of measuring SpHb, usually on the fingertip for adults and pediatric patients.

The sensor connects directly to the Pulse CO-Oximeter or with a patient cable. The sensor collects signal data from the patient and sends it to the device. The device displays the calculated data as measurement of total hemoglobin concentration.

Successful Monitoring for SpHb

A stable SpHb reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration, and perfusion. See ***Safety Information, Warnings, and Cautions*** on page 9.

SpO2 and SpHb Measurements During Patient Motion

Pronto displays measurements of SpO2 and may display SpHb during patient motion. However, because of the changes in the physiological parameters such as blood volume, arterial-venous coupling, etc. that occur during patient motion, the accuracy of such measurements may not be reliable during excessive motion. In this case, the Low SIQ indicator illuminates to alert the clinician that the device does not have confidence in the value displayed due to poor signal strength caused by excessive motion or other signal interference. For more information, see ***Low Signal I.Q. (Low SIQ)*** on page 40.

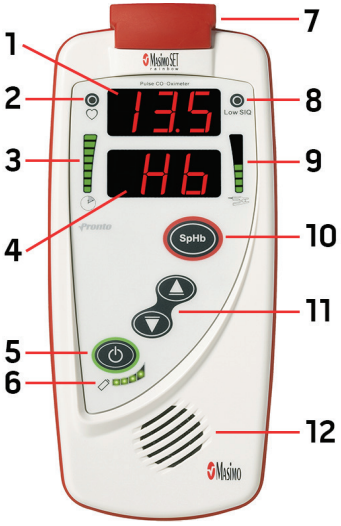
Chapter 2: System Description

Pronto is a Spot Check Pulse CO-Oximeter that includes noninvasive total hemoglobin (SpHb) measurement. 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.

Pronto is powered by four (4) AA alkaline batteries to provide up to eight (8) hours of continuous use when used with new, fresh batteries. Continuous 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 Pronto.

Front Panel



Ref.	Feature	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 Button	Powers the device on or off. Press the button once to power on. Press and hold the button for two (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. For more information, see ***Battery Level Indicator*** on page 30.
7	Patient Cable / Sensor Connector	The Patient Cable/Sensor connector is where a compatible sensor is connected to the device.
8	Low SIQ Indicator	This illuminates to indicate low confidence in the measurement displayed. For more information, see ***Low Signal I.Q. (Low SIQ)*** on page 40.
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. When navigating the device menu, pressing this button will move to the next menu option and will confirm a setting change. For more information, see ***Navigating the Menu*** on page 31.
11	Up/Down Arrow Buttons	Use the **Up** or **Down** arrow buttons to scroll between parameter or measurement spot check results. When in the device menu, use the **Up** or **Down** arrow buttons to scroll through menu setting options. For more information, see ***Navigating the Menu*** on page 31.
12	Speaker	Provides audible indication of alert conditions, pulse tone, and feedback for control button presses.

Rear Panel

Ref.	Feature
1	Serial Number Label
2	Certification Label
3	Battery Cover
4	Battery Cover Release

Chapter 3: Setup

This chapter contains information about setting up Pronto before use.

Unpacking and Inspection

To unpack and inspect the device

1. Remove the device from the shipping carton and examine it for signs of shipping damage.
2. 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.
3. If anything is missing or damaged, contact the Technical Service Department. See ***Return Procedure*** on page 59.

Power Requirements

Pronto uses four (4) AA alkaline batteries. Use of non-alkaline batteries may affect the accuracy of the battery level indicator on the device. Use of batteries with cell voltage of more than 1.5V could damage the device.

See ***Battery Level Indicator*** on page 30.

See ***Battery Replacement*** on page 57.

Initial Setup

1. Inspect Pronto case for damage.
2. If your device is equipped with a protective boot, remove it. To remove the boot, gently bend down on the boot at the bottom end of the device next to the speaker. Push up on the device and remove the boot.
3. Install four (4) new AA alkaline batteries. Fasten the boot onto the device, if required.
4. Turn on Pronto. All LEDs will briefly illuminate and an audible tone will sound.
5. If necessary, configure the device for your regional power line frequency (LF) (50 hz or 60 hz). See ***Default Settings*** on page 29.

Chapter 4: Operation

The information in this chapter assumes that Pronto is set up and ready for use. This chapter provides necessary information for proper operation of the device. Do not operate Pronto without completely reading and understanding these instructions.

Basic Operation

1. Select a compatible sensor. Remove any substances that may interfere with the transmission of light between the sensor's light source and detector.
2. Connect the sensor, or the patient cable and sensor, to the connector of Pronto. Make sure it is a secure connection and the cable is not twisted, sliced, or frayed. See ***Chapter 5: Messages*** on page 35 to view messages that may be displayed pertaining to sensors and cables.
3. Press the **Power** button to turn on Pronto.
   - All front-panel indicators will illuminate momentarily, and an audible tone will sound.
   - If applicable, the device will display the number of sensor uses remaining.
   - The device displays rdy, indicating that it is ready to use.
4. Attach the sensor to the patient. For more information, see the *Directions for Use* for the sensor.
5. Press the **SpHb** button to start a spot check. Values for PI, PR, and SpO2 will display while SpHb is being calculated. The **Spot Check Progress Indicator** begins to illuminate.
6. Verify that the **Pulse Indicator** light is illuminated. The light flashes when the pulse rate (PR) is acquired.

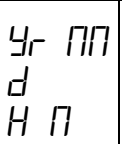
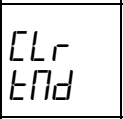
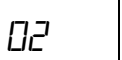
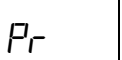
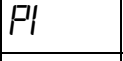
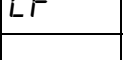
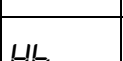
   Note: It will take about 30 seconds to three (3) minutes for Pronto to acquire an accurate spot check. During this period, the sensor is initializing and adjusting to the patient. PI, PR, and SpO2 parameters/measurements (depending on user configuration) will appear on the main display. No other quality control activities (such as calibration) are required.

7. The **Spot Check Progress Indicator** incrementally illuminates from bottom to top. When the **Spot Check Progress Indicator** is fully illuminated, the SpHb parameter/measurement value is displayed, and an audible tone sounds.
8. Use the **Up** or **Down** arrow buttons to navigate through the parameter and measurement values that have been spot checked. While the sensor remains on the finger of the patient, the parameter values will continue to update and be displayed for five (5) minutes from the time the SpHb parameter value was first displayed.
9. After removing the finger of the patient from the sensor, verify at each parameter/measurement display that the **Low SIQ Indicator** is not illuminated. If the **Low SIQ Indicator** is illuminated, the value may be checked again.
10. After the spot check is complete, remove the sensor from the patient and store or dispose of the sensor according to the governing rules. For more information, see the *Directions for Use* for the sensor.
11. 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** button for two (2) seconds to turn off Pronto.

Spot Check Results

1. SpHb data displays for five (5) minutes. After five (5) minutes, the data can only be obtained by downloading the data through the trend monitor or when another test is performed.
2. To view older readings after a reading has been performed, press the **Up** or **Down** arrow buttons to view different parameters. The parameter label blinks indicating the value obtained might be older or not correlate with the patient. Parameters display in this order: SpHb, PI, PR, and SpO2.

Default Settings

Option	Display	Factory Default Setting	Configurable Settings
Date and Time		N/A	Year/Month/Day (YY/MM/DD) Hour/Minute(hh:mm)
Clear Trend		No	No, Yes
Oxygen Saturation (SpO2)		On	On, Off
Pulse Rate (PR)		On	On, Off
Perfusion Index (PI)		On	On, Off
Line Frequency (LF)		60 Hz	50, 60 Hz
Software Version		HH	HH, MX (read only)
SpHb Calibration		Venous (SpHbv)	Venous, Arterial
Pulse Tone		Off	On, Off
SpHb Units of Measurement		Grams per Deciliter	Grams per Deciliter, Millimoles per Liter
Display Measurements During Low SIQ		On	On, Off

Audible Alerts

Pronto visually and audibly indicates the following conditions, using a three (3) beep audible tone with visual indicator:

- Low battery
- System failure

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:

LED Indicators	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 alert	9% to 0%

Navigating the Menu

Pronto settings are accessed through the menu system.

1. To access the menu, press and hold both **Up** and **Down** arrow buttons  for five (5) seconds
2. To scroll through the menu options (see table below), press the **SpHb** button  repeatedly.
3. To change a setting (see table below) for a menu option selected in the previous step, press **Up** and **Down** arrow buttons  .
4. Press the **SpHb** button  to confirm the change.

Menu Option	Settings
	Year (Current Year)
	Sets Year (00-99)
	Month (current month)
	Sets Month (01-12)
	Day (current day)
	Sets Day (00-31)
	Hour (current hour)
	Sets Hour (00-23)
	Minute (current minute)
	Set Minute (00-59)
	Clear Trend (Yes)
	Clear Trend (No) (Default)

Menu Option	Settings
02	SpO2 On (Default)
	SpO2 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*	SpHbv Calibration Venous(Default)
	SpHb Calibration Arterial
tON	Pulse Tone Off (Default)
	Pulse Tone On
HbU	Grams per Deciliter (g/dL) (Default)
	Milimoles per Liter (mmol/L)
dPL **	On (Default)
	Off

*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 SpHbv laboratory blood sample data. Changing the calibration setting from SpHbv to SpHb (and vice versa) will clear the trend memory.

**Allows user to choose whether to display values under Low SIQ conditions. For more information, see ***Low Signal I.Q. (Low SIQ)* on page 40.

Exit the Menu and Power Off the Device

To exit the menu, allow 10 minutes of inactivity, or press the **Up** and **Down** arrow buttons  simultaneously. Press the **Power** button for two (2) seconds to turn off the device.

Trend Setup and Use

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 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. For detailed download and operation instructions, see the TrendCom *Directions for Use (DFU)*.

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

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 Pronto off will not erase the trend data. For detailed instructions on erasing trend memory, see the TrendCom *Directions for Use (DFU)*.

Note: Do not turn off the device for at least one minute after clearing the trend.

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 ***Default Settings*** on page 29)
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 Masimo SET® mode. It requires a Masimo 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 SpO2, 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 SpO2, PR, PI, and SpHb. Pronto only stores data related to SpHb, SpO2, PR, and PI during spot check tests results.

Chapter 5: Messages

Messages

The following messages are specific to Pronto:

Message	Explanation	Next Steps
NO SEN	No Sensor Connected	1. Connect sensor to cable. 2. Check sensor connection to cable.
3.	The Masimo rainbow ReSposable® sensor system is not connected to the device	Assemble the ReSposable sensor system and then connect to the device.
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. See ***Low Signal I.Q. (Low SIQ)*** on page 40.
Single Battery Level Indicator flashes (with audible alert)	Battery level too low	Replace batteries immediately. See ***Battery Replacement*** on page 57.
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 ***Return Procedure*** on page 59.
rPL SEN	Defective sensor	Replace sensor.
	The Masimo ReSposable sensor system is non-functional.	Replace the Masimo ReSposable sensor system.

Message	Explanation	Next Steps
INC dEt (Blinking)	Interference detected	Ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required.
INC SEN	Incompatible sensor	Attach appropriate sensor.
INC CbL	Incompatible cable	Attach appropriate cable.
NO CbL	No cable	Attach appropriate cable.
rPL CbL	Cable life expired	Replace cable.
Temporarily blinking message: rPL CbL	Cable life expired	Replace cable as soon as possible.
Temporarily blinking message: rPL SEN	Sensor life expired	Replace sensor as soon as possible.
Temporarily blinking message: rPL AdH	Adhesive sensor life expired	Replace adhesive sensor as soon as possible.
CHC SEN	Check sensor connection	Reattach sensor.
SEN 000	Zero sensor uses remaining	Attach new sensor. Dispose of the old sensor per local governing ordinances. See ***Compliance Warnings and Cautions*** on page 14.
rE tSt	Spot check incomplete	Confirm sensor placement and press **SpHb** button again.

Message	Explanation	Next Steps
no AdH	The reusable part of the Masimo ReSposable sensor system is connected to the device, but 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 device.
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.

Chapter 6: Troubleshooting

Troubleshooting

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

Symptom	Possible Cause	Recommendation
Difficulty or no SpHb reading	Low battery Interference from line frequency induced noise Inappropriate sensor or sensor size Excessive motion	Minimize or eliminate interference from surgical or fluorescent lighting. Verify/set 50/60hz menu setting. See Initial Setup. Verify use of a SpHb capable sensor. Minimize or eliminate motion at the measurement site.
	Excessive ambient or strobing light	Shield the sensor from excessive light.
	See ***Safety Information, Warnings, and Cautions*** on page 9 and the sensor *Directions for Use (DFU)*.	
Unit does not power on	Low battery	Check/replace batteries. See ***Battery Replacement*** on page 57.
Continuous speaker tone	Internal failure	Unit requires service. If audible tone continues to sound, power down unit and/or remove batteries. See ***Return Procedure*** on page 59
Buttons don't work when pressed	Internal failure	Return for service. See ***Return Procedure*** on page 59.
Low battery alert sounds. Battery Level Indicator shows low battery capacity less than expected capacity.	Effective spot check uses will be reduced when operating the device below 5°F (-15°C) due to alkaline battery technology	Remove the batteries and allow them to warm up to room temperature, re-install them, and then check the battery indicator level. If the battery capacity remains low, replace batteries. See ***Battery Replacement*** on page 57.

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.)

Low Signal I.Q. (Low SIQ)

Note: The Display Measurements During Low SIQ option (dPL) must be turned on to display measurements (SpO2, PR, PI, and SpHb) under Low SIQ conditions. For more information about changing this setting, see ***Default Settings*** on page 29 and ***Navigating the Menu*** on page 31.

Pronto provides a visual indicator (LED), the **Low SIQ Indicator**, which provides an assessment of the confidence of the measurement displayed.

When the **Low SIQ Indicator** illuminates, confidence in the measurement displayed is low. 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 SIQ.
- 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.)
- Read ***Safety Information, Warnings, and Cautions*** on page 9 and the sensor *Directions for Use (DFU)*.

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

Low Battery Audible Alert

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

WARNING: Failure to replace batteries promptly after a low battery alert may result in the device 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 Indicator**.

WARNING: Use of batteries with a cell voltage of more than 1.5V could cause damage to the device.

WARNING: Effective battery life will be reduced when operating the device below 5°F (-15°C) due to alkaline battery technology.

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

Chapter 7: Specifications

Performance Specifications

Functional Oxygen Saturation (SpO2)		
Condition	**Range**	A_{rms}*
No Motion [1]	60% to 80%	3%
No Motion [2]	70% to 100%	2%
Motion [3]	70% to 100%	3%
Low Perfusion [4]	70% to 100%	2%

Pulse Rate (PR) [5]		
Condition	**Range**	A_{rms}*
No Motion	25 - 240 bpm	3 bpm
Motion [3]	25 - 240 bpm	5 bpm
Low Perfusion [4]	25 - 240 bpm	3 bpm

Total Hemoglobin (SpHb) [6]		
Condition	**Range**	A_{rms}*
No Motion	8 g/dL - 17 g/dL	1 g/dL

*The A_{rms} Accuracy is calculated based upon measurement values that are statistically distributed; approximately 68% of the measured values fell within +/- the A_{rms} value when compared to the reference device under a controlled study.

Display Ranges

Measurement	Display Range
SpO2 (Functional Oxygen Saturation)	0% to 100%
SpHb (Hemoglobin)	0 g/dL to 25 g/dL
PR (Pulse Rate)	25 bpm to 240 bpm
PI (Perfusion Index)	0.02% to 20%

Resolution

Parameter	Resolution
SpO2	1%
SpHb	0.1 g/dL
Pulse Rate	1 bpm

Electrical

Battery	
Type	Four (4) AA alkaline
Capacity	Operates continuously for up to eight (8) hours without changing batteries [7]
Isolation	No external power or ground connection, internally powered only, DC current

Environmental

Operating Temperature	41°F to +104°F (5°C to +40°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)

Trend Memory

Trending Memory	Stores a minimum of 10,000 time-stamped spot check result data in trend memory

Alerts

Audible Alerts	Low Battery, System Failure
Audible Tone	500 Hz tone, three (3) pulse burst, repeat time: 5s

Display Indicators

Data Display	%SpO2, SpHb g/dl, Pulse Rate bpm, PI
Indicators	Low Signal IQ Indicator, Battery Level Indicator, Spot Check Progress Indicator, Pulse Indicator, and Sensor Use Indicator
Type	LED

Compliance

Safety Compliance
UL 60601-1
CSA C22.2 No. 601.1
IEC/EN 60601-1, 2nd Ed.
IEC/EN 60601-1, 3rd Ed.
IEC 60601-1-11
IEC 62366
ISO 80601-2-61

EMC Compliance
EN 60601-1-2, Class B

Equipment Classification per IEC 60601-1	
Type of Protection	Internally powered (battery powered)
Degree of Protection Against Electric Shock	Type BF-Applied Part
Environment	Not for use in the presence of flammable anesthetics
Mode of Operation	Continuous Operation

Citations

1. SpO2 accuracy was determined by testing on healthy adult volunteers in the range 60% - 100% SpO2, 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% SpO2 against a laboratory CO-Oximeter and ECG monitor.
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% SpO2 against a laboratory CO-Oximeter and ECG monitor.
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%.
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.
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 SpHb accuracy has not been validated with motion or low perfusion.
7. Continuous 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.

**Registered trademark of Fluke Biomedical Corporation, Everett, Washington.*

Symbols

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

Symbol	Definition
	Follow Instructions for Use
	Consult Instructions for Use
	Type BF Applied Part
	Not for Continuous Monitoring
	Separate Collection for Electronic Waste (WEEE)
	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
	Manufacturer
	Date of Manufacture
	Product contains no natural rubber latex
	Product contains no PVC (polyvinyl chloride) material

Symbol	Definition
	Non-Sterile
	Atmospheric Pressure Limitation
	Storage Temperature Range
	Storage/Transport Relative Humidity Range
	Keep Dry
	Fragile/Breakable, Handle with Care
	Authorized representative in the European community
	UL, LLC. Certification
	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note**: eIFU is not available for CE mark countries.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Guidance and Manufacturer's Declarations - Electromagnetic Emissions		
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	ME Equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	Suitable for use in all establishments, including domestic environments.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+6 kV contact +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME SYSTEM] be powered from an uninterruptible power supply or a battery.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-3	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ME Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 150 kHz to 80MHz	3 V/m	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
ISO 80601-2-61, Clause 202	20 V/m 80 MHz to 2.5 GHz	20 V/m	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ME Equipment is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME Equipment. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Recommended Separation Distances

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the ME Equipment			
The ME Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME Equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME Equipment as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output power of transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.018	0.035
0.1	0.37	0.057	0.11
1	1.17	0.18	0.35
10	3.7	0.57	1.1
100	11.7	1.8	3.5
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Chapter 8: Service and Maintenance

The following chapter contains information about cleaning, battery operation, performance verification, service, repair, and warranty.

Cleaning

Pronto is a non-sterile and reusable device. The surface of the Pronto should be cleaned when the device is visibly dirty, before and after each procedure, and/or according to hospital practice.

To surface clean, wipe down the outer surface of Pronto using any of the following:

- A soft cloth dampened with a mild detergent and warm water solution
- Cidex Plus (3.4% glutaraldehyde)
- 10% bleach solution
- 70% isopropyl alcohol solution

Note: Do not allow liquids to enter the interior of the device.

Note: The performance of a device with a touchscreen will not be affected when using the recommended cleaning solutions.

Battery Replacement

Pronto is powered by four (4) AA alkaline batteries. Do not use any other type of batteries or power source to run the device.

Replacing the batteries

1. Locate the battery compartment on the back of the device.
2. 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.
3. Remove the batteries and install new batteries in the directions indicated by the battery orientation icons (+ and -) inside the battery compartment.
4. Replace the battery cover by sliding it back up from the bottom of the device until the rectangular locking button snaps back into position.

For more information about battery disposal, see ***Compliance Warnings and Cautions*** on page 14.

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 device back to the user.

Before performing the following tests, verify or install new batteries into the Pronto. See ***Battery Replacement*** on page 57. Also disconnect any patient cables, serial cables, or sensors from the device.

Power-On Self-Test

1. Turn on the device by pressing the **Power** button. For about 5 seconds, all available LEDs are illuminated and a brief beep tone sounds.
2. Verify that the sensor uses remaining displays.
3. Pronto is ready for use (the rdy message displays).

Service and Repair

Repair Policy

Masimo or an authorized service department must perform warranty repair and service. Do not use malfunctioning equipment. Have the device repaired.

Clean contaminated and/or dirty equipment before returning, following the cleaning procedure described in ***Cleaning*** on page 57. Make sure the equipment is fully dry before packing.

To return the device for service, refer to ***Return Procedure*** on page 59.

Return Procedure

Clean contaminated/dirty equipment before returning, following instructions in ***Cleaning*** on page 57. Make sure the equipment is fully dry before packing. 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. 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 Pronto 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 shipping address listed in ***Contacting Masimo*** on page 59 below.

Contacting Masimo

Masimo Corporation
40 Parker
Irvine, California 92618

Tel:+1 949 297 7000
Fax:+1 949 297 7001

Limited Warranty

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product (Pronto® Pulse CO-Oximeter®) and any software media contained in the original packaging against defects in material and workmanship when used in accordance with Masimo's user manuals, technical specifications, and other Masimo published guidelines for a period of 12 months from the original date the Product was obtained by the end-user purchaser.

Masimo's sole obligation under this warranty is the repair or replacement, at its option, of any defective Product or software media that is covered under the warranty.

To request a replacement under warranty, Purchaser must contact Masimo and obtain a returned goods authorization number so that Masimo can track the Product. If Masimo determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs must be paid by purchaser.

Exclusions

The warranty does not apply to any non-Masimo branded product or any software, even if packaged with the Product, or any Product that was: (a) not new or in its original packaging when supplied to purchaser; (b) modified without Masimo's written permission; (c) supplies, devices, or systems external to the Product; (d) disassembled, reassembled, or repaired by anyone other than a person authorized by Masimo; (e) used with other products, like new sensors, reprocessed sensors, or other accessories, not intended by Masimo to be used with the Product; (f) not used or maintained as provided in the operator's manual or as otherwise provided in its labeling; (g) reprocessed, reconditioned, or recycled; and (h) damaged by accident, abuse, misuse, liquid contact, fire, earthquake or other external cause.

No warranty applies to any Product provided to Purchaser for which Masimo, or its authorized distributor, is not paid; and these Products are provided AS-IS without warranty.

Limitation of Warranty

Except as otherwise required by law or altered by the purchase agreement, the above warranty is the exclusive warranty that applies to the Product and software media, and Masimo does not make any other promises, conditions, or warranties regarding the Product. No other warranty applies, express or implied, including without limitation, any implied warranty of merchantability, fitness for a particular purpose, satisfactory quality, or as to the use of reasonable skill and care. See the licensing terms for the terms and conditions that apply to and Software accompanying the Product. Additionally, Masimo will not be liable for any incidental, indirect, special, or consequential loss, damage, or expense arising from the use or loss of use of any Products or Software. In no event shall Masimo's liability arising from any Product or Software (under contract, warranty, tort, strict liability, or otherwise) exceed the amount paid by purchaser for the Product or Software. The above limitations do not preclude any liability that cannot legally be disclaimed by contract.

Sales & End-User License Agreement

This document is a legal agreement between you ("purchaser") and Masimo Corporation ("Masimo") for the purchase of this Product ("Product") and a license in the included or embedded Software ("Software") except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire agreement between the parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to Masimo for a full refund.

Restrictions

1. Copyright Restrictions: The Software and the accompanying written materials are copyrighted. Unauthorized copying of the Software, including Software that has been modified, merged, or included with other software, or the written materials is expressly forbidden. Purchaser may be held legally responsible for any copyright infringement that is caused or incurred by Purchaser's failure to abide by the terms of this Agreement. Nothing in this License provides any rights beyond those provided by 17 U.S.C. §117.
2. Use Restrictions: Purchaser may physically transfer the Product from one location to another provided that the Software is not copied. Purchaser may not electronically transfer the Software from the Product to any other device. Purchaser may not disclose, publish, translate, release, distribute copies of, modify, adapt, translate, reverse engineer, decompile, disassemble, or create derivative works based on the Software or the written materials.
3. Transfer Restrictions: In no event may Purchaser transfer, assign, rent, lease, sell, or otherwise dispose of the Product or the Software on a temporary basis. Purchaser shall not assign or transfer this License, in whole or in part, by operation of law or otherwise without Masimo's prior written consent; except that the Software and all of Purchaser's rights hereunder shall transfer automatically to any party that legally acquires title to the Product with which this Software is included. Any attempt to assign any rights, duties or obligations arising hereunder other than as set forth in this paragraph shall be void.
4. U.S. Government Rights: If Purchaser is acquiring Software (including the related documentation) on behalf of any part of the United State Government, the following provisions apply: the Software and documentation are deemed to be "commercial software" and "commercial computer software documentation," respectively pursuant to DFAR Section 227.7202 FAR 12.212, as applicable. Any use, modification, reproduction, release, performance, display or disclosure of the Software (including the related documentation) by the U.S. Government or any of its agencies shall be governed solely by the terms of this Agreement and shall be prohibited except to the extent expressly permitted by the terms of this Agreement.

Index

M

N

P

R

S

T

U

www.masimo.com

32900/5052J-0616