Pronto-7™

Spot Check Pulse CO-Oximeter

Operator's Manual

Masimo

These operating instructions intend to provide the necessary information for proper operation of the Masimo Rainbow® SET® Pronto-7™ Pulse CO-Oximeter.

General knowledge of Pulse CO-Oximetry and an understanding of the features and functions of the Pronto-7 are prerequisites for proper use.

Do not operate the Pronto-7 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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EC	REP

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Covered by one or more of the following U.S. Patents: 5919134; 6002952; 6067462; 6229856; 6388240; 6463311; 6606511; 6643530; 6684090; 6699194; 6816741; 6961598; 6979812; 7003339; 7044918; 7186966; 7215984; 7215986; 7221971; 7254433; 7489958; 7496393; 7596398; international equivalents, or one or more of the patents referenced at www.masimo.com/patents.htm. Other patents pending.

Printed in USA

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 within 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-7 is contraindicated for use as an apnea monitor. The Pronto-7 is also contraindicated for use as a continuous monitor.

Safety Information, Warnings and Cautions

The Pronto-7 is designed to minimize the possibility of hazards from errors in the sofware program by following sound engineering design processes, Risk Analysis and Software Validation.

- The Pronto-7 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-7 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-7 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-7 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) directed on the sensor, may not allow the Pronto-7 to obtain readings.
- EMI radiation interference such as computer displays and/or LCD/plasma TVs can cause errors or incorrect measurements on the Pronto-7.
- The Pronto-7 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-7 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-7 or accessories in any position that might cause it to fall on the patient. Do not lift the Pronto-7 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-7 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-7 or sensor during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Pronto-7 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-7 during electrocautery.
- Do not use the Pronto-7 or sensors during defibrillation.
- If using the Pronto-7 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 instrument might read zero for the duration of the active irradiation period.
- Do not place the Pronto-7 where the controls can be changed by the patient.
- Do not place the Pronto-7 on electrical equipment that may affect the instrument, preventing it from working properly.
- Do not expose the Pronto-7 to excessive moisture such as direct exposure to rain. Excessive moisture can cause the instrument to perform inaccurately or fail.
- Do not place containers with liquids on or near the Pronto-7. Liquids spilled on the instrument 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
  - Hemoglobin synthesis disorders
  - Hemoglobinopathy
  - Peripheral vascular disease
  - EMI radiation interference
- Do not place the Pronto-7 against a surface. This can cause the a system or battery (non-clinical) alarm to be muffled.
- Additional information specific to the Masimo Rainbow PDC-SC reusable sensor including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's *Directions For Use* (DFU).
- Do not expose the PDC-SC reusable sensor to moisture, liquids or a humid environment, as this may make the sensor perform inaccurately or fail.
- If the Pronto-7 fails any part of the setup procedures or leakage spot check, remove the instrument from operation until qualified service personnel have corrected the situation.
- 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-7 or its PDC-SC reusable sensor.
- 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.

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Table of Contents

About this Manual

This manual explains how to set up and use the Pronto-7. Important safety information relating to general use of the instrument 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 instrument.

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** Specifications
- **Section 8** Sensor
- **Section 9** Service And Maintenance

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 box.

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 instrument or damage to other property.

CAUTION: THIS IS A SAMPLE OF A CAUTION STATEMENT.

A ***Note*** is provided when extra general information is applicable.

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

Product Description

The Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter (instrument) with Masimo Rainbow SET Technology is developed to simultaneously and non-invasively measure functional arterial oxygen saturation (SpO_2), pulse rate (PR), total hemoglobin (SpHb) and perfusion index (PI). The instrument has a single on/off button and an interactive touchscreen for administering tests along with user selectable options.

Features and Benefits

Accurate and Non-invasive Measurement and Display of Functional Arterial Oxygen Saturation (SpO_2) and Pulse Rate (PR)

The instrument uses multiple wavelengths of light and proprietary algorithms to obtain functional arterial oxygen saturation (SpO_2) and pulse rate (PR) readings.

Total Hemoglobin (SpHb)

The instrument measures total hemoglobin (SpHb) using similar principles as pulse oximetry with more wavelengths of light and proprietary algorithms to obtain the measurements.

Perfusion Index (PI)

The instrument measures the Perfusion Index (PI). This indicates arterial pulse signal strength.

Clinically Useful Features Include:

- Lightweight, ergonomic handheld design
- Interactive color touchscreen interface
- Audible voice guided feedback (English)
- Spot check test results in approximately 45 seconds
- Test countdown timer
- Plethysmograph display
- Real time feedback of sensor motion
- Review and sort previous test results
- Optional input for patient identification number, name and other details
- Interference Scanner mode for detecting interference in testing environments
- Print and email options

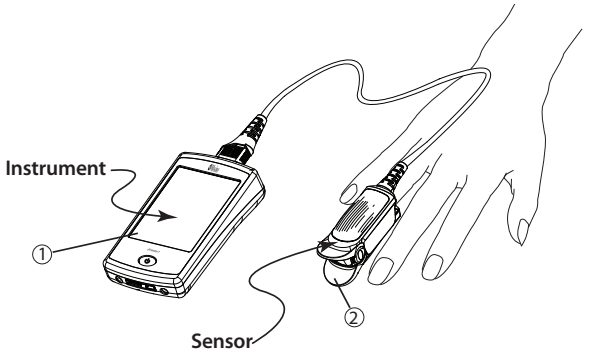
Indications for Use

The Masimo Rainbow SET Pronto-7 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 Pronto-7 Pulse CO-Oximeter and Accessories are indicated for use by trained personnel, with adult and pediatric individuals, 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-Oximeter

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 instrument 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).



SpHb General Description

Instruments containing Masimo Rainbow SET Technology offer a non-invasive method of measuring the levels of total hemoglobin in blood (SpHb). It relies on the same principles of pulse oximetry to make SpHb measurements. The measurements are taken by placing a sensor on a patient, usually on the fingertip for adults as shown in the figure above. The sensor connects directly to the instrument. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as grams/deciliter (g/dL) for SpHb (with different units of measure available in the display menu).

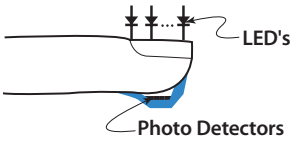
Principles of Operation

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):
2. The amount of 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-7 uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood and blood plasma. The Pronto-7 utilizes a sensor with various light-emitting diodes (LEDs) that pass light through the site to multiple photodiodes (detectors). See the figure below.

Signal data is obtained by passing various infrared lights (ranging from 500 up 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 send it to the instrument for calculation.



Once the Pronto-7 receives the signal from the sensor, it utilizes Masimo Rainbow SET technology to calculate the patient's functional oxygen saturation (SpO_2%), pulse rate and total hemoglobin (SpHb [g/dl]). The SpHb measurement relies on a multiwavelength calibration equation to quantify the percentage of total hemoglobin in blood. In an ambient temperature of 95º F (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 Saturation

The Pronto-7 is calibrated to measure and display functional 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.

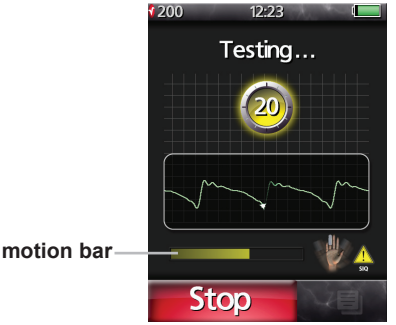
Pronto-7 vs. Drawn Whole Blood Measurements

When 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 SpHb measurements of the Pronto-7. High levels of bilirubin may cause erroneous 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 carboxyhemoglobin or mehemoglobin 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 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 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 motion or low signal quality are detected during a test, the screen will display a poor signal quality indication progress bar. If this bar fills completely the test will not be able to complete. (See example below)



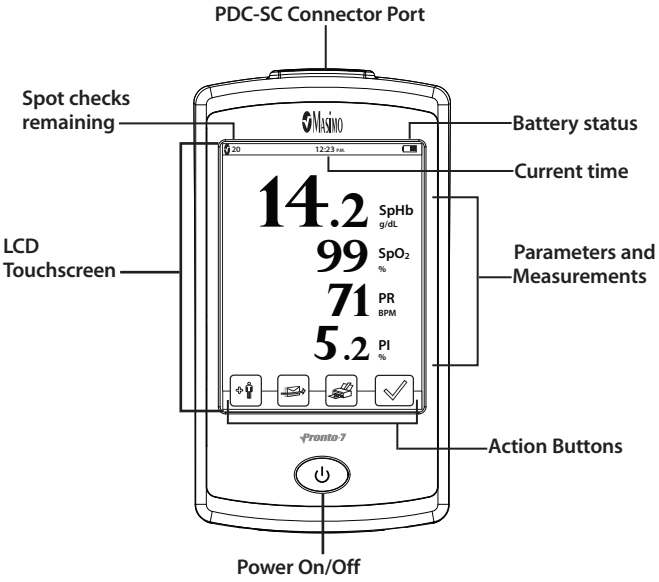
A Test Incomplete message will display with information describing the problem encountered and if any corrective course of action is needed.

Introduction

The Pronto-7 is a Spot Check Pulse CO-Oximeter which provides functional arterial oxygen saturation (SpO_2) and non-invasive total hemoglobin (SpHb) measurements. The instrument is designed for accuracy and ease of operation. All pulse CO-Oximetry measurement information, as well as instrument status data, is displayed on the front panel's touchscreen.

A Masimo Rainbow Pronto-7 Direct Connect-Spot Check (PDC-SC) reusable sensor attaches to the top of the Pronto-7. The Pronto-7 is powered by a rechargeable lithium polymer battery.

Front Panel and Touchscreen



Front Panel and Touchscreen Details

Power On/Off

Press Power to turn the instrument on or off.

LCD Touchscreen

The touchscreen is interactive. Move through screens, select options, enter information, view instrument specific messages.

Spot Checks Remaining

Displays the number of spot checks remaining. Press the number to see details and how to order more spot checks.

PDC-SC Connector Port

Connect a PDC-SC (Pronto-7 Direct Connect-Spot Check) reusable sensor to enable spot checks and instrument capability.

Battery Status

Displays the battery power remaining. Press the battery icon to see details about the current battery. Use only the included power cable to recharge.

Current Time

Displays the current time. Press the time to see detailed information.

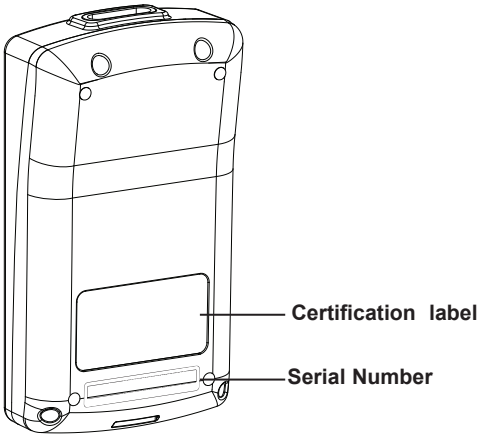
Parameters and Measurements Display

Default parameters and meaurements are displayed.

Action Buttons

Refer to Chapter 3, *Commonly Used Buttons* for details about the action buttons.

Back Panel



Back Panel Details

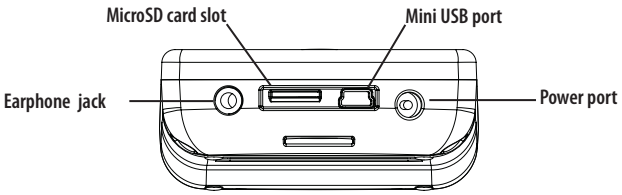
Certification Label

The instrument's certification marks are displayed.

Serial Number

This number can be used to uniquely identify the instrument and will be needed if Masimo Service is called.

Bottom Panel



Bottom Panel Details

Earphone Jack

To listen to the parameter or measurement results of a successful spot check, plug a standard earphone into the 3.5mm earphone jack.

MicroSD Card Slot

A MicroSD flash memory card is optional. To use, insert the card into the MicroSD card slot until you feel a click. This ensures the card is securely connected. The MicroSD card can currently be used to upload new software or additional spot check credits.

Mini USB Port

A mini USB to USB cable is included with the instrument. To connect the instrument to a computer, plug the mini USB cable into the port on the instrument and plug the USB cable to the USB port on a computer. Use the mini USB to USB cable to download data to the instrument or upload information to the computer. To protect the instrument, connect only to a medical grade computer to ensure grounding is sufficient. Use only the included mini USB to USB cable.

- Do not connect the mini USB to USB cable during a test.
- To prevent possible data loss or interruption, plug the instrument into an AC power supply while uploading or downloading files.
- Do not disconnect the USB cable from the instrument or the computer while a file transfer is in place.
- Eject the instrument as you would any other external drive, per the recommended requirements of your computer manufacturer.

Power Port

To charge the instrument, plug the included medical grade +5V/3A power cable into the power port of the instrument and plug the other end into an AC power outlet. Use only the included power cable. Spot check tests can be run while the power cable is plugged into an outlet.

Symbols

The following symbols may be found on the Pronto-7 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 restricts this device to sale by or on the order of a physician (USA audiences only)
	Year of manufacture
	Storage humidity range: 5% to 95%
	Storage temperature range: +70˚C to -40˚C Storage altitude range: +1600hPa to +500hPa
	Keep dry
	Fragile/breakable, handle with care
EC REP	EU authorized representative
	Manufacturer
	ETL
	Wireless features can be used in member states with the restriction of indoor use in France
	Federal Communications Commission (FCC) licensing.
	Non-ionizing electromagnetic radiation
IPX1	Protection against vertically falling water drops
	No parameter alarms

Introduction

Before the Pronto-7 can be used, it needs to be inspected, properly setup and have the battery fully charged.

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 the invoice, bill of lading and all packing materials. These may be required if it is necessary 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.*

Included in the package:

1 Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter (instrument)

1 Masimo Rainbow PDC-SC reusable sensor

1 AC power cable

1 mini USB to USB cable

1 LCD cleaning cloth

1 Pronto-7 *Operator's Manual*

1 PDC-SC Sensor *Directions for Use (DFU*)

Commonly Used Buttons

Button	Description
	Turn the instrument on or off.
	Start a test.
	Go to the Main menu screen.
	To submit inputs and exit the menu screen.
	To move back one screen, press and release. Press and hold to return to "Ready" screen.
	To exit a screen.
	Scroll down a list or page.
	Scroll up a list or page.
	Displays an interactive dialogue for user options: printing, e-mailing, or deleting test results.
	Add patient specific information such as name or ID number (#).

Preparation for Use

Introduction

To operate the Pronto-7 effectively, the operator must:

- Know how the Pronto-7 derives its readings (see Section 1, *Pulse CO-Oximeter*)
- Be familiar with its controls and operation.
- Understand its status and messages (see Section 5, *Messages* and Section 6, *Troubleshooting*)

Initial Setup

1. Inspect the Pronto-7 case for damage.
2. Power the instrument on. The touchscreen will illuminate and an audible tone will sound. The time and date need to be set. Enter your region's correct date and time and press  to confirm.
3. Fully charge the instrument using the included AC power cable.

Note: *The intial battery charge can take up to 6 hours. The battery should be recharged as needed. It will operate for approximately 2 hours at a time when fully charged. See Section 4,* ***Battery Level Indicator*** *section for more information about the battery.*

No other setup is required.

Spot Check System

To administer a non–invasive test using the Pronto-7, use a Masimo Rainbow PDC-SC reusable sensor with spot check credits.

To see if the PDC-SC reusable sensor contains spot check credits, connect it to a Pronto-7. A numeric value will appear in the top left corner of the screen, next to the Masimo icon, with the number of available spot check credits it contains (e.g. 200).

If there is 1 or more credits the instrument's main screen will display the title “Ready” across the screen.

If no spot checks are available, the instrument's main screen will show 0 credits in the upper left corner in red and the main screen message will show No Spot Check Credits.

Pronto-7 Operation

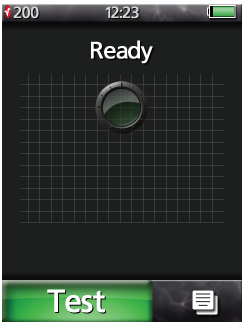
Connecting and Testing

1. Connect the included patient PDC-SC reusable sensor to the instrument's patient sensor connector port.
2. Press  to power on the instrument. There will be an audible tone and the following screen will display:

3. If a sensor is not attached or not connected completely, this screen displays:

Attach a sensor and continue with step 4.

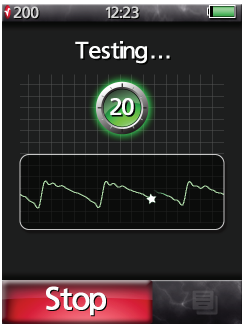
4. When a sensor is attached, the following screen displays and testing can begin:



Patient Testing

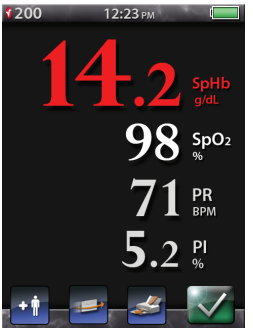
Note: *It is recommended to perform patient testing with the patient in a seated position.*

5. Press Test on the instrument's display screen.
6. When the test is running, a timer will count down the seconds until the test is complete:



If motion is detected, the motion bar at the bottom of the screen will begin to fill. (If the entire bar is full, the test will fail as a result of too much motion). If the test needs to be interrupted, press Stop.

7. After a successful test there will be an audible tone and the results screen will display:



Test Results

Completed Test

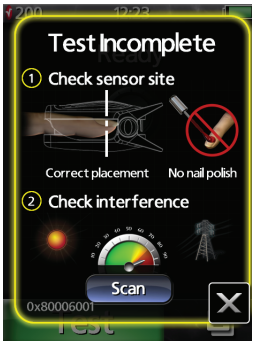
After a successful Spot Check test, detailed information about the patient can be entered by pressing the button. If the printer or email options were set up, a printer and/or email button will appear at the bottom of the screen. The results can be sent to a designated printer or email address by following the on-screen instructions.

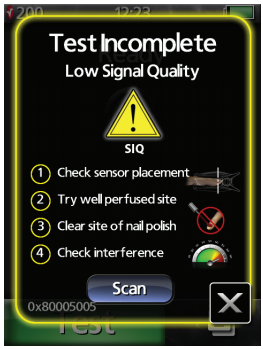
Press the parameter name or value for more information and references for understanding the measurement.

Press to exit and return to the "Ready" screen. The test results will dim and turn grey after 5 minutes of inactivity to indicate to the user that the numbers they are viewing are not current.

Incomplete Test

An incomplete test can occur due to excessive motion, interference to the instrument or if Stop was pressed. The examples below show incomplete test message screens.





Ensuring a Successful Spot Check

The following general points will aid in ensuring successful measurement.

- Place the sensor on a site that has sufficient perfusion (preferably the middle or ring finger of the non-dominant hand) and provides proper alignment of the LEDs and detector.
- 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.

Masimo Sensors

Before use, carefully read the Masimo Rainbow PDC-SC reusable sensor's *Directions for Use*.

Use only a PDC-SC reusable sensor 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 DIRECTIONS FOR USE. SEE THE CLEANING INSTRUCTIONS IN THE DIRECTIONS FOR USE FOR ALL MASIMO REUSABLE SENSORS.
- 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 - SpO_2

An 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 levels of Bilirubin
- Severe anemia
- Low arterial perfusion
- Motion artifact

Numeric Display - SpHb

An 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
- Hemoglobin synthesis disorder
- Hemoglobinopathy
- Peripheral vascular disease
- EMI radiation interference

Numeric Display - Pulse Rate

The Pulse Rate displayed on the Pronto-7 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-7 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 I.Q. (Low SIQ)

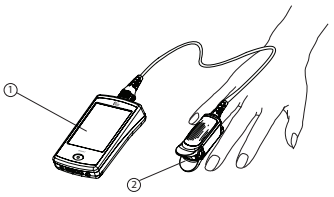
The Masimo Pronto-7 Pulse CO-Oximeter provides a visual indicator of low signal quality through the display when displayed waveforms are not based on adequate signal quality. The device will not debit a spot check for a Low SIQ value. When the signal quality is poor, the Low SIQ Indicator

is displayed as a warning and will abort the measurement if Low SIQ continues. When the measurement is aborted due to low SIQ 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



Example of Correct Sensor Placement

- Make sure the emitters and detectors are aligned directly opposite each other.
- Select a site where the distance between the emitters and detectors 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.
- Do not expose the sensor to moisture, humid environments or liquids.
- 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-7 with integrated Masimo Rainbow technology has significant immunity to ambient light, excessive ambient light may cause readings to be incorrect.
- Check for possible EMI radiation interference such as, computer displays and/or LCD/plasma TVs.

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.

Main Menu Screen

To access the Main menu, press from any screen where it is shown.

Menu Options Table

Menu	Factory Default	Options
Test Results		
Sortable by column. From the test results screen a user can press the options button to delete tests, edit patient information, print or e-mail the test results (if those options are setup).		
Time	Descending	Ascending or descending
ID # or Name	ID #, one Name, All Names	ID #, Name (either can be descending or ascending)
SpHb	Most recent tests	Most recent tests, Single test
Sound		
Volume	7	Off-10
Sound Effects	On	On, Off
Voice	On	On, Off

Menu	Factory Default	Options
Connections		
Connections should be created or modified by an Administrator familiar with wireless networking and it is recommended that the instrument be connected to a secure wireless network. Completed test result screens can be emailed or printed. Printing can be done over an internet connection or through a Bluetooth printer and Bluetooth barcodes can be included.		
Wireless Network		
Wireless Connection	Off	On, Off
LAN Configuration	DHCP	View, DHCP, Static
Networks Available	available networks list	user selectable from list
New Network	n/a	user selectable (SSID, Security On, Off, encryption key WEP64, WEP-128, WPA-TKIP, WPA2-AES, Network password key)
Outgoing Email		
Reply to address	n/a	user editable (About Owner screen)
User Name	n/a	enter Masimo server name
Password	n/a	enter Masimo server password
Attach Image (test screen shot)	Yes	Yes, No
Attach .CSV (.csv data file)	Yes	Yes, No
Bluetooth Pairing		
Bluetooth (2.0)	Off	On, Off
Available Devices	Scan	Scan (user editable On, Off for available devices)
Printer Configuration		
Printer Address	n/a	User editable
Port	n/a	User editable
Print Style	Color	Color, B & W (Black & White)
Paper Size	Letter	Letter
Include Picture	Yes	Yes, No
Include Barcodes Bluetooth Printouts	No	Yes, No
Interference		
Check Environment for Interference	n/a	Scan

Menu	Factory Default	Options
Display - The display and voice languages will be the same		
Brightness	10	1-10
SpHb Units of Measure	g/dL	g/dL, g/L, mmols
Display Parameters	All	All, PR Off, PI Off
Language	English	English
Settings		
Date & Time		
Clock Display	On	On, Off
Time Format	12 hour	12 hour, 24 hour
Time	hh/mm/pm	user editable
Date Format	yy/mm/dd	yy/mm/dd, mm/dd/yy, dd/mm/yy
Date	n/a	user editable
Pin # Protection	Off	On, Off
Restrict Access	Both	Testing, Menu, Both
Create/Change Pin#	n/a	Up to 15 digit numeric PIN, user editable
If the PIN # is forgotten, press the "Forgot Pin" button along the upper right edge of the Enter PIN keypad.		
About Pronto		
Masimo Contact Information	Tech Support Contact Info	n/a
About Owner		
Registered to information	n/a	user editable
Restore Default Settings	n/a	No, Yes
Help		
Quick Start	A short slide show of basic testing operation	
Common Questions	A list of questions and answers to features about the instrument	
Contact Tech Support	Masimo Tech Support contact information	
Equipment Report which includes:	Device Serial #, Software Version, Total Device Run Time, Last Service/ Location, Sensor Serial #, Total Sensor Run Time, Spot Checks Obtained	
Software Update	Select to upgrade or downgrade the software version from one of three locations: MicroSD, Internal Storage, or PDC-SC reusable sensor	
Load Credits	Load Credits - Select to view available credit files and/or load them in to the PDC-SC reusable sensor	

Battery Level Indicator

The Pronto-7 is powered by a rechargeable lithium polymer battery. It can also be powered by AC power, when used with the included AC power cable. Battery charge level is indicated by the battery icon in the upper right hand corner of the touchscreen. Battery conditions are:

- When the battery is fully charged, the icon will be solid green:

- When the battery is fully charged and plugged into AC power, an electrical plug symbol displays on the battery icon:

- As the battery discharges, the capacity will be equivalent to the fraction of green filling the icon:

- When the battery is charging, a charging symbol will display on the battery icon:

Low Battery Alarm

- It the battery power level is too low, the instrument will not allow a test to be taken. There will be a visual display, indicating the AC power cable must be used to continue.

WARNING: FAILURE TO PLUG IN THE AC POWER CABLE PROMPTLY AFTER A LOW BATTERY ALARM MAY RESULT IN THE INSTRUMENT SHUTTING DOWN.

WARNING: ONLY USE THE INCLUDED AC POWER CABLE. USING A DIFFERENT AC POWER CABLE COULD CAUSE DAMAGE TO THE PRONTO-7.

Checking Battery Status

Press the battery icon, at any time to see the current battery status.

Messages

The Pronto-7 will indicate other data or system errors. Message conditions follow:

Message	Type	Solution
Ready	Ready for spot check	Initiate spot check by pressing the green "Test" button
Connect Sensor	No sensor is connected	Connect a Masimo Rainbow PDC-SC sensor to the instrument
Test Incomplete	Excessive Motion Poor Signal Quality Other	Follow on-screen recommendations
Low Battery Warning	Battery level too low at start of measurement	Plug in AC power cord
Test Stopped	Occurs when the "Stop" button is pressed during a test	Initiate new spot check by pressing the green "Test" button

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Troubleshooting

The following chart describes what to do if the Pronto-7 system does not operate properly or fails.

Problem	Possible Cause(s)	Recommendation
Incomplete or no reading	Sensor Placement	Ensure sensor is placed on a well perfused site. Make sure the patient's finger is all the way in the sensor and touching the finger stop. Route sensor cable along the back of the patient's hand to ensure that the sensor is on in the correct orientation (see DFU figure).
	Excessive Motion	Minimize or eliminate patient movement at the sensor site
	Signal Quality	Make sure measurement site is well perfused, free of debris and there is no nail polish on the patient's nail. Check the testing environment for interference using the interference scanner in the Settings menu (see Section 4, *Menu Options Table*). If interference is high, shield the sensor from excessive light, modulated light sources (such as computer displays) or strobbing lights.
	Reflective and/or metallic nail polish	Remove all nail polish
	Also, see Section 4, *Successful Spot Check* for additional information.	
Device does not power on	Low battery	Plug in included AC power cable, then power on the instrument
PDC-SC sensor does not connect to instrument.	Sensor orientation is incorrect	The sensor can only connect one way. Make sure the sensor plug is oriented correctly, according to the DFU and on-screen directions and diagrams
A computer connected with the included USB cable does not recognize the Pronto-7	Connection issue	1. Make sure the instrument is powered on and plugged into AC power 2. Check the available drives on your computer. If the Pronto-7 still does not appear, search your computer's *User Manual* for proper external drive mapping and troubleshooting
Touchscreen buttons do not respond when pressed	System Failure	Turn off the instrument and then power it on. If the problem reoccurs or persists return for service (see Section 9, *Service and Repair*).

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Specifications

Performance	
Measurement Range	
SpO_2	0-100%
PR (pulse rate)	30 - 250 bpm
SpHb (total hemoglobin)	0 - 25 g/dL
PI (perfusion index)	0.02% - 20%
Accuracy	
Arterial Oxygen Saturation, 70% to 100%[1]	± 2%
Pulse Rate Accuracy [2]	± 3 bpm
Total Hemoglobin concentration accuracy (SpHb g/dl)[3]	6-18 g/dL ±1 g/dL
Resolution	
Arterial Oxygen Saturation (SpO_2)	1%
Pulse Rate	1 bpm
Total Hemoglobin	0.1 g/dL
Interfering Substances	
Refer to *Safety Information, Warnings and Cautions (see pages ii - iii)*	
Product	
Test time	45 seconds
Test storage capacity	8000
Wireless connectivity	802.11 b/g, Bluetooth
Reporting modes	Print, email, audible
Report formats	Single test, multiple test, device summary
Reporting devices	Optional Bluetooth thermal printer, USB 802.11 wireless (PCL5, 5e 6), or Bluetooth printing to validated printers
Electrical	
Battery Power	Rechargeable lithium polymer
Capacity	Approximately 2 hours after full charge
Number of spot checks on fully charged battery	140
Battery charging time	5 hours when powered off 6 hours when powered on
Isolation	Medical Grade AC/DC Adapter
AC Power	100-240V, 50-60 Hz, 15VA max.
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)
Operating humidity	5% to 95%, non-condensing
Operating altitude	500 mbar to 1060 mbar pressure -1000 ft to 18,000 ft (-304 m to 5,486 m)
Physical Characteristics	
Dimensions	5.1" x 2.8" x 1" (13cm x 7.2cm x 2.5 cm)
Weight	10.5 oz (296.4 g)
Visual alarm	low battery, system failure
Display/Indicators	
Data display: SpO_2%, pulse rate (PR) beats per minute, SpHb g/dL, PI%, battery level indicator, pulse plethysmograph waveform	
Type	3.7" Resistive Touchscreen
Compliance	
EMC Compliance	EN60601-1-2, Class B
Equipment Classification	IEC 60601-1
Type of Protection (battery power)	Internally powered
Type of Protection (AC Power)	Class 2
Degree of Protection-Sensor	Type BF-Applied Part
Mode of Operation	Spot Check

1.The SpO_2 accuracy has been validated 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. Plus or minus one standard deviation encompasses 68% of the population weight.

2. Masimo sensors have been validated for pulse rate accuracy for the range of 30-250 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.

3 The SpHb accuracy has been validated with (arterial/ venous) blood from healthy adult male and female volunteers and on patients with light to dark skin pigmentation in the range of 6 - 18 g/dl SpHb against a laboratory CO-oximeter. This 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

Introduction

This section describes the use and cleaning of the Masimo Rainbow PDC-SC reusable sensor. It should be used as a reference and not as a substitute for the sensor's *Directions for Use (DFU).*

Use only the PDC-SC reusable sensor with the Pronto-7.

CAUTIONS:

- Tissue damage can be caused by incorrect application or use of a sensor. Inspect the sensor site as directed in the sensor's *Directions for Use* to ensure skin integrity and correct positioning of the sensor.
- Carefully route sensor cable to reduce the possibility of patient entaglement or strangulation.
- 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 may fail or work inaccurately from exposure to moisture or humidity).
- Do not sterilize sensors.
- Do not attempt to reprocess, recondition or recycle any Masimo sensors as these processes may damage the electrical components, potentially leading to patient harm.
- The PDC-SC reusable sensor is designed for use with the Pronto-7. Verify the compatibility of the instrument and sensor before use, otherwise patient injury can result.
- High intensity extreme lights (such as pulsating strobe lights) directed on the PDC-SC reusable 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.

Masimo Rainbow PDC-SC (Pronto-7 Direct Connect-Spot Check) Reusable Sensor

Sensor Accuracy

Complete accuracy specifications are located in the PDC-SC reusable sensor's *DFU* and are specific for the type of Masimo sensor used.

Cleaning And Reuse Of the PDC-SC Reusable Sensor

The sensor can be cleaned per the following procedure:

1. Remove the sensor from the patient.
2. Disconnect the sensor from the instrument.
3. Clean the sensor by wiping it with a 70% isopropyl alcohol pad. To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not sterilize.
4. Allow to air dry thoroughly before returning it to operation.

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.*

Introduction

This chapter covers how to test the operation, properly clean and how to obtain service for the Pronto-7.

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.

The Pronto-7 is a reusable instrument. The instrument is supplied and used non-sterile.

Cleaning

The outer surface of the Pronto-7 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, and 70% Isopropyl Alcohol.

CAUTIONS:

- Do not sterilize the Pronto-7.
- Do not soak or immerse the Pronto-7 in any liquid.
- Use the cleaning solution sparingly. Excessive solution can flow into the Pronto-7 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.
- Use the included LCD cleaning cloth to remove fingerprints from the touchscreen.
- Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the Pronto-7. These substances erode the instrument's materials and instrument failure can result.

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

Ordering Spot Check Credits

New Masimo Rainbow PDC-SC reusable sensors typically come with a certain number of credits preinstalled. To verify the number of credits, follow the procedure described in Section 3, *Setup.*

Note: *Each PDC-SC reusable sensor has a serial number that can be found by connecting the sensor to the Pronto-7 and then selecting Menu > Help > Equipment Report. It is necessary to have this number when you call to purchase credits. Credits can only be installed on the sensor that has that specific serial number.*

Installing Credits

Once credits have been ordered, a digital file will be transmitted (downloaded to a computer, sent via email or physically mailed on a MicroSD card). To install credits onto the PDC-SC reusable sensor, credits must be loaded through the Pronto-7 instrument. There are currently two ways to load credits through the Pronto-7 onto the PDC-SC reusable sensor.

Using a MicroSD Card to Load Spot Check Credits

1. Connect the PDC-SC reusable sensor to the Pronto-7 instrument.
2. Insert the MicroSD card with spot check credits on it into the Pronto-7 MicroSD card slot.
3. Press on the Ready screen, select Help, then press the Load Credits button, and finally press the MicroSD Load button. After pressing the Load button a dialog will appear confirming the credits have been successfully loaded.

Using a USB Cable to Load Spot Check Credits

1. Connect the PDC-SC reusable sensor to the Pronto-7 instrument.
2. Connect the Masimo supplied USB cable to a computer*. The Pronto-7 should appear as a mass storage device (like a USB jump drive on a computer).
3. When the Pronto-7 instrument is visible as a drive, drag the purchased spot check credits file into the Pronto-7 drive.
4. Once the file has completed downloading to the Pronto-7 drive, follow the computer's standard procedure to eject an external mass storage device.
5. After the file has downloaded to the instrument successfully and the Pronto-7 has been correctly ejected as a mass storage device the USB cable can be disconnected from the instrument and the computer.
6. Press on the Ready screen, then select Help, next press the Load Credits button, and finally, press the MicroSD Load button. After pressing the Load button a dialog will appear confirming the credits have been successfully loaded.

* To protect the instrument, connect only to a medical grade computer to ensure grounding is sufficient. Use only the included mini USB to USB cable.

Note: *If multiple Spot Check credit files have been purchased, it is important to load the credit files in sequential order (i.e. credit file purchased April 3, 2010 prior to credit file purchased April*

15, 2010). Non-sequential loading of credit files will obsolete any skipped credit files. If credit files are available in different locations (one on the MicroSD and one on the Internal Device Storage) the Pronto-7 will only allow you to load the oldest file. After the oldest file is loaded, then the next most recent credit file can be loaded.

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.

WARNING: 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.

Please clean contaminated and/or 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-7 for service, please follow the Return Procedure.

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 to request 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-7. 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 instrument 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-7 has been decontaminated for bloodborne pathogens.

Return the Pronto-7 to the following shipping address:

USA, Canada & Asia Pacific (except Japan):	Japan:	Europe:	All other locations:
Masimo Corporation 40 Parker Irvine, California 92618 Tel: 949-297-7000 FAX: 949-297-7001	Masimo Japan Corporation Kojimachi Office World Time Bldg. 4F 10-7, Ichiban-cho, Chiyoda-ku, Tokyo 102-0082 JAPAN Tel: 03 3237 3057, FAX: 03 3238 1110	Masimo International Sàrl Puits-Godet 10 2000 Neuchatel - Switzerland Tel: +41 32 720 1111 Fax.: +41 32 724 1448	Contact your local Masimo Representative

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.

Warranty

Masimo warrants to the initial Purchaser for a period of one (1) year from the date of purchase that: (i) each new Product and the Software media as delivered are free from defects in workmanship or materials, and (ii) the Product and Software will perform substantially as labeled in the directions for use. Masimo's sole obligation under this warranty is to repair or replace any Product or Software that is covered under warranty.

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 and the cost of shipment covered. All other shipping costs shall be the responsibility of Purchaser.

Exclusions

The warranty does not extend to, and Masimo is not responsible for, repair, replacement, or maintenance needed because of: a) modification of the Product or Software without Masimo's written authorization; b) supplies, devices or electrical work external to the Product or not manufactured by Masimo; c) disassembly or reassembly of the Product by anyone but an authorized Masimo agent; d) use of the Product with sensors or other accessories other than those manufactured and distributed by Masimo; e) use of the Product and Software in ways or in environments for which they are not labeled; and f) neglect, misuse, improper operation, accident, fire, water, vandalism, weather, war, or any act of God. This warranty does not extend to any Product that has been reprocessed, reconditioned or recycled.

This warranty also does not apply to any Products provided to Purchaser for testing or demonstration purposes, any temporary Products modules or any Products for which Seller does not otherwise receive a usage or purchase fee; all such Products are provided AS-IS without warranty.

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