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Pronto-7™
Spot Check Pulse CO-Oximeter

# Pronto-7

## Operator's Manual

MASIMO®

Masimo rainbow SET Pronto-7 Spot Check CO-Oximeter, also referred to as Pronto-7, operating instructions provide the necessary information for proper operation of Pronto-7. There may be information provided in this manual that is not relevant for your system. Do not operate Pronto-7 without completely reading and understanding the instructions in this manual.

**Notice:**
Purchase or possession of this instrument does not carry any express or implied license to use this instrument with replacement parts which would, alone or in combination with this instrument, 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.**

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

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

CE
0123

EU Authorized Representative for Masimo Corporation:

EC REP

MDSS GmbH
Schiffgraben 41
D-30175 Hannover, Germany

3148433

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



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# Contents

# About this Manual

This manual explains how to set up and use Pronto-7. Important safety information relating to general use of the product 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 and, death) to the patient or user. The following is an example of a warning:

**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 Pronto-7 or damage to other property. The following is an example of a caution:

**CAUTION:** This is an example of caution statement.

A *note* is given when additional general information is applicable. The following is an example of a note:

**Note:** This is an example of a note.

**Read the entire safety information section before you operate the instrument.**

# Product Description

## Indications for Use

The Masimo rainbow SET Pronto-7 Spot Check CO-Oximeter and Accessories are indicated for noninvasive spot check testing of functional saturation of arterial oxygen hemoglobin ($SpO_2$), pulse rate (PR), and total hemoglobin concentration (SpHb). The Masimo rainbow SET Pronto-7 Spot Check 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, and ambulatory surgery centers).

The Masimo rainbow SET Pronto-7 Spot Check CO-Oximeter is designed to simultaneously and noninvasively measure functional arterial oxygen saturation ($SpO_2$), pulse rate (PR), total hemoglobin (SpHb), perfusion index (PI), and hematocrit (SpHct).

Advanced features available on the Pronto-7 include SpHct access, multi test mode, low signal I.Q., measurement through motion of SpHb and $SpO_2$, wireless download of spot check tests, $SpO_2$ only mode and EMR connectivity for parameter and measurement download.

The instrument is voice automated, provides step by step instructions when administering tests and is equipped with an interactive touchscreen for user selectable options.

## 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 following section lists warnings, cautions, notes, and safety information for Pronto-7.

Pronto-7 is to be operated by qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.

## Safety Information, Warnings, and Cautions

**Always use the Pronto-7 precisely in accordance with the directions in this manual, including finger selection, finger alignment in the sensor, and subject behavior during testing. Failure to follow all of the directions in this manual could lead to inaccurate measurements.**

**The Pronto-7 should be considered an early warning device. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.**

**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.**

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.

If $SpO_2$ values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.

$SpO_2$ is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

Inaccurate $SpO_2$ readings may be caused by:

- Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal $SpO_2$. When elevated levels of COHb or 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 and texture such as nail polish, acrylic nails, glitter, etc.
- Elevated levels of bilirubin
- Severe anemia
- Low arterial perfusion
- Motion artifact

Inaccurate SpHb readings may be caused by:

- Improper sensor application
- Intravascular dyes such as indocyanine green or methylene blue

- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Elevated $PaO_2$ levels
- Elevated levels of bilirubin
- Low arterial perfusion
- Motion artifact
- Low arterial oxygen saturation levels
- Elevated carboxyhemoglobin levels
- Elevated methemoglobin levels
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Vasospastic disease such as Raynaud's
- Peripheral vascular disease
- Liver disease
- EMI radiation interference

SpHct is NOT reliable in cases of abnormal blood composition and is not indicative of disease states. Abnormal values of SpHct that are displayed should warrant repeat testing by conventional laboratory methods.

High intensity extreme lights (including pulsating strobe lights and direct sunlight) directed on the sensor, may not allow the Pronto-7 to obtain readings.

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.

Ensure the sensor is physically intact, with no broken or frayed wires or damaged parts. Visually inspect the sensor and discard if cracks or discoloration are found.

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 sensor during defibrillation.

Do not place the Pronto-7 where the controls can be changed by the patient.

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.

Explosion hazard. Do not use the Pronto-7 in the presence of flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments, or nitrous oxide.

EMI radiation interference such as computer displays and / or LCD / plasma TVs can cause errors or incorrect measurements on the Pronto-7.

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.

Always remove the sensor from the patient and completely disconnect the patient from the Pronto-7 before bathing the patient.

A functional tester cannot be utilized to assess the accuracy of the Pronto-7 or its rainbow 4D DC reusable sensors.

Do not place the Pronto-7 on electrical equipment; it may prevent it from working properly. If Pronto-7 is used adjacent to other electrical equipment, the device should be observed to verify normal operation.

## Compliance Information, Warnings and Cautions

Use the Pronto-7 in accordance with the Environmental Specifications in this manual.

Do not incinerate device and/or battery.

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.

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 equipment has been tested and found to comply with Class B limits for medical devices according to the EN 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in all establishments, including domestic establishments.

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

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.

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.

Pronto-7 is provided with RF wireless capabilities. When used outside the US, consideration should be taken to account for local/ national regulations or restrictions for RF wireless technologies prior to using the wireless feature.

RF Exposure: The Pronto-7 was tested for SAR compliance with a 0mm separation distance. In order to maintain FR exposure compliance, the device should not be used for any other body worn accessories.

## Sensor Information, Warnings and Cautions

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.

Failure to apply the sensor properly may lead to incorrect measurements.

Do not loop the sensor cable into a tight coil or wrap around the device, as this can damage the sensor cable.

Additional information specific to Masimo's rainbow 4D DC 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 rainbow 4D DC reusable sensor to moisture, liquids or a humid environment, as this may make the sensor perform inaccurately or fail.

Do not use damaged sensors. Do not use a sensor with exposed optical or electrical components. Do not immerse the sensor in water, solvents, or cleaning solutions (the sensors and connectors are not waterproof). Do not sterilize by irradiation, steam, autoclave or ethylene oxide unless otherwise indicated in the sensor's directions for use. See the cleaning instructions in the sensors' directions for use.

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

# Chapter 1: Technology Overview

## Signal Extraction Technology (SET)

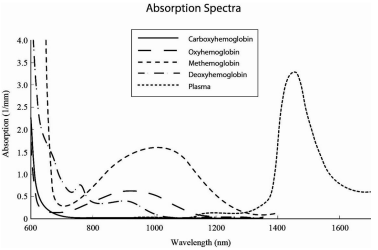
Masimo Signal Extraction Technology's signal processing differs from that of conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the venous blood also moves, causing conventional 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 digital filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or noise and separate them by looking at the whole signal and breaking it down to its fundamental components. The Masimo SET signal processing algorithm, Discrete Saturation Transform® (DST®), 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.

## rainbow Pulse CO-Oximetry Technology

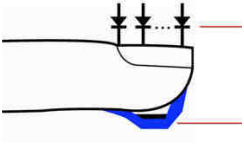
Pulse CO-Oximetry is governed by the following principles:

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



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

The Pronto-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 visible and infrared lights (ranging from 500nm 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 Pronto-7 for calculation.

Once the Pronto-7 receives the signal from the sensor, it utilizes proprietary algorithms to calculate the patient's functional oxygen saturation (%$SpO_2$), total hemoglobin concentration (SpHb [g/dL]) and pulse rate (BPM). The SpHb measurement relies on a multiwavelength calibration equation to estimate 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 Oxygen Saturation

The Pronto-7 is calibrated to measure and display functional oxygen saturation ($SpO_2$): the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen. Refer to the Safety information, Warnings and Cautions section in front of this manual for details.

## Pronto-7 vs. Drawn Whole Blood Measurements

When $SpO_2$ and SpHb measurements obtained from the instrument (noninvasive) are compared to drawn whole blood measurements (invasive)

by blood gas and/or laboratory hematology, caution should be taken when evaluating and interpreting the results. The blood gas and/or laboratory hematology measurements may differ from the $SpO_2$ and SpHb measurements of the Pronto-7.

In the case of $SpO_2$, different results are usually obtained from the arterial blood gas sample if the calculated measurement is not appropriately corrected for the effects of variables that shift the relationship between the partial pressure of oxygen ($PO_2$) and saturation, such as: pH, temperature, the partial pressure of carbon dioxide ($PCO_2$), 2,3-DPG, and fetal hemoglobin.

High levels of bilirubin may cause erroneous $SpO_2$ and SpHb readings. As blood samples are usually taken over a period of 20 seconds (the time it takes to draw the blood) a meaningful comparison can only be achieved if the oxygen saturation, carboxyhemoglobin and 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 hematology measurements of $SpO_2$ and SpHb may vary with the rapid administration of fluids and in procedures such as dialysis. Additionally, drawn whole blood testing can be affected by sample handling methods and time elapsed between blood draw and sample testing.

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

The following is data of the sensor compatible with the Pronto-7: Rainbow 4D DC Reusable Sensor.

### rainbow 4D DC Reusable Sensor

For Normal Sensitivity Mode in 10,253 comparisons of SpHb® and invasive hemoglobin (tHb) measurements from a laboratory reference device in the range of 8-17 g/dL, SpHb accuracy was as follows:

- 0.90 correlation
- 1.05 g/dL $A_{RMS}$ accuracy

For Maximum (MAX) Sensitivity Mode in 13,205 comparisons of SpHb and invasive hemoglobin (tHb) measurements from a laboratory reference device, SpHb accuracy was as follows:

- 0.86 correlation
- 1.00 g/dL $A_{RMS}$ accuracy

# Chapter 2: Product Description

## Pronto-7 Description

The Pronto-7 is designed to simultaneously and noninvasively measure functional arterial oxygen saturation ($SpO_2$), pulse rate (PR), total hemoglobin (SpHb), perfusion index (PI) and hematocrit (SpHct ). The instrument is voice automated, provides step by step instructions when administering tests, and is equipped with an interactive touchscreen for user selectable options.

The *Test Ready* screen, as seen in the following image, indicates a compatible sensor has been properly inserted into the Pronto-7 and the instrument is ready for testing.

The Main Menu icon, also available on the *Test Ready* screen, provides access to additional icons and user configurable options.

Parameters and measurements are displayed on the *Test Results* screen and may include functional arterial oxygen saturation ($SpO_2$), pulse rate (PR), total hemoglobin (SpHb), perfusion index (PI), and hematocrit (SpHct). Measurements are collected through the rainbow 4D DC sensor, connected via the connector port.

## Pronto-7 Front Panel and Touchscreen

| Ref. | Feature | Description |
|---|---|---|
| 1 | Power On/Off | Places instrument in Power On and Power Off modes. |
| 2 | LCD Touchscreen | Provides an interface for user interactions. |
| 3 | Test Ready Screen | Indicates Pronto-7 is ready for testing. |
| 4 | Connector Port | Provides connectivity for rainbow 4D DC sensors. |
| 5 | Time | Displays instrument's time. |
| 6 | Battery Status | Indicates the estimated percentage of battery power remaining. |
| 7 | Action Icons | Provides user selectable icons for navigation. |
| 8 | Test Icon | Allows for commencement of spot check test. |
| 9 | Main Menu Icon | Provides access to additional icons and user configurable options. |
| 10 | Radical Sign | Indicates the number of spot check test credits remaining on the attached sensor. |
| 11 | Sensor Size | Specifies the size of the attached sensor (small, medium or large). |
| 12 | Connectivity | Indicates Wi-Fi and Bluetooth status. |

## Pronto-7 Back Panel


| Ref. | Feature | Description |
|---|---|---|
| 1 | Certification Label | Documents the instrument's certification marks. |
| 2 | Serial Number | Lists unique serial number associated with the instrument. |

## Pronto-7 Bottom Panel


| Ref. | Feature | Description |
|---|---|---|
| 1 | Earphone Jack | 3.5mm earphone jack. |
| 2 | Micro SD Card Slot | Micro SD flash memory card slot. |
| 3 | Mini USB Port | Input port for mini USB cable to computer connection. |
| 4 | Power Port | Power supply connector for the Pronto-7 specific power cable. |

## Parameter and Measurement Descriptions

### 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 adult 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 instrument. The instrument displays the calculated data as measurement of total hemoglobin concentration.

## Arterial Oxygen Saturation (SpO2)

Pulse oximetry is a noninvasive method of measuring the level of functional arterial oxygen saturation in blood. The instrument displays the calculated data as a percent value for functional arterial oxygen saturation ($SpO_2$).

A $SpO_2$ reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site.

## Pulse Rate (PR)

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

## 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.

## Hematocrit (SpHct)

Hematocrit (SpHct) is the fraction of whole blood volume that consists of red blood cells. In normal conditions, there is a linear relationship between hematocrit and the concentration of hemoglobin. An estimated hematocrit as a percentage may be derived by multiplying the hemoglobin concentration in g/ dL times three and dropping the units 1,2. The hematocrit measurement is determined mathematically in the instrument as*:

$$\%SpHct = 3.0422 \times SpHb - 0.8059$$

The measurement is taken by a sensor capable of measuring SpHct, usually on the fingertip for adults or pediatric patients. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as measurement of SpHct. The hematocrit estimation is NOT reliable in cases of abnormal blood composition and is not indicative of disease states. Abnormal values of hematocrit that are displayed should warrant repeat testing by conventional laboratory methods.

***Note**: This is the relationship found between tHb and SpHb for 3,226 blood samples measured on a Coulter LH 500 Hematology Analyzer.

# Chapter 3: Setup

## Unpacking and Inspection the System

**To unpack and inspect the system**

1. Remove Pronto-7 and the components from the shipping carton.
2. Examine them for signs of shipping damage.
3. Check all materials against the packing list.
4. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier.

If anything is missing or damaged, contact the Masimo Technical Service Department, see ***Return Procedure*** on page 7369.

## Preparation for Use

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

**Note:** The initial battery charge can take up to 6 hours.

1. Power the instrument on. The touchscreen will illuminate and a series of audible tones will sound. To change the audible tone settings, see ***Sound Icon*** on page 5249.
2. The time and date need to be set. Enter your region's correct date and time.
3. Tap the *green check mark* icon to accept changes.
4. Fully charge the instrument using the included AC power cable.
5. Insert the rainbow 4D DC sensor to the connector port.

# Chapter 4: Operation

The information in this chapter assumes that Pronto-7 is set up and ready for use. Do not operate the Pronto-7 without completely reading and understanding these instructions.

The following sections describe how the Pronto-7 information is displayed, including available parameters, icons, features and accessing user configurable settings.


Pronto-7 may provide the following parameters and features:

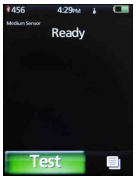
**Key Parameters:**

- Total Hemoglobin (SpHb)
- Arterial Oxygen Saturation ($SpO_2$)
- Pulse Rate (PR)
- Perfusion Index (PI)
- Hematocrit (SpHct)

**Key Features:**

- Viewing Select Parameters
- Viewing SpHct
- Low Signal I.Q. (Low SIQ)
- Sensitivity and Test MOdes
- Emailing Spot Check Test Results
- Download of Spot Check Tests
- EMR Connectivity

## Common Screens

| Item | Description |
|---|---|
|  | *Connect Sensor* screen indicates a compatible sensor should be properly connected to the Pronto-7 in order to begin testing. |
|  | *Test Ready* screen indicates the Pronto-7 is ready for testing. |
|  | *Test Results* screen provides parameter and measurement test results. |

## Commonly Used Icons

| Icons | Description |
|---|---|
|  | Turns the instrument on/off. |

| Icons | Description |
|---|---|
|  | Starts a test. |
|  | Provides access to additional icons and user configurable settings. |
|  | Submits inputs and exits the Main Menu. |
|  | Moves back one screen. Pressing and holding returns to *Test Ready* screen. |
|  | Exits pop-up windows. |
|  | Scrolls down the list or page. |
|  | Scrolls up the list or page. |
|  | Displays an interactive dialogue for user options: printing, e-mailing, or deleting test results. |

| Icons | Description |
|---|---|
|  | Adds patient specific information. |
|   | Discontinues test. |

## Recommended Initial Testing Procedure

### SpHb Spot Check Measurement

**Note**: Potentially inaccurate results can occur if the user does not properly follow the testing procedure. As with any diagnostic test, clinicians should always evaluate hemoglobin measurements in the perspective of the clinical context of the patient.

### Sensor Site Selection

1. Assess the patient's arm of the selected site for any restrictions from shoulder to fingertip.
2. Restrictive garments or accessories should be removed as it can impede blood flow to the sensor site. (Example: purse, backpacks, watches, jewelry and blood pressure cuff).

   Do not use sites with any of the following conditions:

   - An anatomically abnormal finger (e.g. damaged, clubbed, deviated, etc.)
   - A finger or arm that has experienced previous surgical procedures
   - A finger or arm that is currently receiving an IV infusion
3. Site should be cleaned of debris and dry prior to testing.
4. Select the patient's testing finger in the following priority:
   - Non-dominant ring or middle finger
   - Dominant ring or middle finger

## Sensor Selection

Pronto-7 is compatible with rainbow 4D DC sensors, which has three sizes: large, medium and small. Use the Finger Size Guide attached to the sensor to ensure the correct sensor is being used.

1. Measure the patient's finger size (diameter) at the cuticle to determine the correct sensor size using the Finger Size Guide.
2. Gently close sides of Finger Size Guide until the edges touch the outside of the finger. The arrow indicates which size of sensor should be used on the patients.
3. If Finger Size Guide falls on the line select the smaller sensor for testing.

## Sensor Placement

1. Rest patient's hand and arm with sensor on a horizontal surface. The hand and arm should be securely resting on a flat surface to limit the movement of the patient. The patient's hand should be placed on the table palm side down.
2. Ensure the test finger just touches the finger stopper at the end of the sensor without going over it, and sits in line with the finger. This allows the emitter and detector to be placed on the optimum location for monitoring.
3. Examine the finger while placed in the sensors to ensure the emitter and detector are directly aligned on top of each other.
4. Ensure the cable runs flat over the top of the hand directly in the middle of the finger with no kinks or twists so the cable does not pull on the sensor.

## Performing a Test

1. Ensure the patient has been in the sitting or supine position for 2-3 minutes.
2. With the sensor properly applied, ensure the patient's hand and arm are securely resting on a flat surface to limit movement of the patient during the reading.
3. Tap the *Test* icon on the *Test Ready* screen to commence the test.

In instances of test incomplete messages, try the following to increase the probability of a successful test:

- Remove Nail Polish/Acrylics as certain types of nail polish and acrylics may affect the reading.
- Warm Finger to increase perfusion.
- Use a light shield to cover the sensor from ambient light interference.

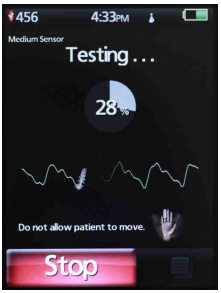
Do not perform measurements in environments with high ambient light or in front of monitors as incomplete tests may occur. In these environments, a Masimo ambient light shield should be used to limit the effect on the measurement

## Patient Testing

**Note**: The patient should be in a seated position for 2-3 minutes prior to, and during testing. Do not allow the patient to talk, laugh, cough or move during testing. If this occurs, stop and re-test.

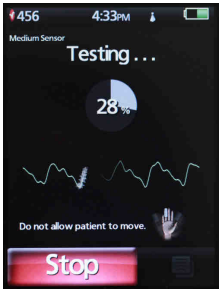
Tap the *Test* 

icon on the instrument's *Test Ready* screen. When the test is running, there will be an indicator of progress as it relates to the completion of a test, as seen in the following image.

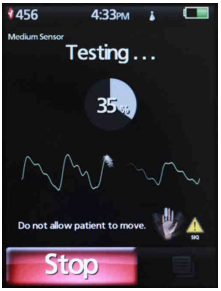



**Successful Testing Ongoing**

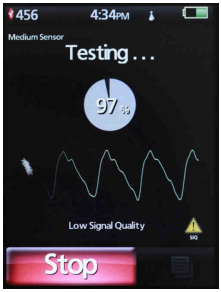
If motion is detected, a hand icon will appear at the bottom right side of the screen. (If the motion is not stopped and *Measure Through Low SIQ* is not on, the test may be incomplete, in some cases, a measurement can be displayed despite low signal quality conditions). See ***Low Signal I.Q. (Low SIQ)*** on page 3836.




**Patient Motion Detected**




**Patient Motion and Low SIQ Detected**




**Low SIQ Detected**

After a complete test there will be a series of audible tones and the *Test Results* screen will display.

## Completed Test

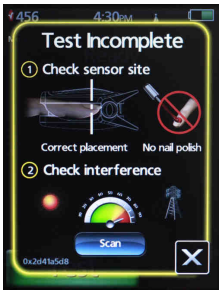
After a successful spot check test, parameters may be seen on the *Test Results* screen. Additional parameters may be seen by tapping the  icon when available. Detailed information about the patient can be entered by pressing the  icon. If the printer or email options are configured, they can be accessed through the print/email icon  at the bottom of the screen. See ***Emailing Spot Check Test Results*** on page 4442 for further details.

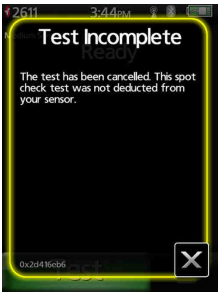
Completed test results can be sent to a designated printer, email address or exported as a .csv file, by following the on-screen instructions.

The test results will dim and turn gray after 5 minutes of inactivity to indicate to the user that the numbers they are viewing are from the previous test. Tap the green check mark icon to exit the *Test Results* screen and return to the *Test Ready* screen.

## Incomplete Test

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




When a test is incomplete, error code text may display at the bottom left corner of the screen.

See the recommended initial testing procedure ***SpHb Spot Check Measurement*** on page 3030 on for proper sensor and site selection. For troubleshooting, see ***Chapter 6: Troubleshooting*** on page 6359.

## Key Features

The following section details some of the features available on the Pronto-7. See ***Main Menu Options*** on page 5147 for additional features.

## Viewing Select Parameters

Upon successful completion of a spot check test, the default parameters shown on the firs page of the *Test Results* screen are SpHb, $SpO_2$, PR, and PI.

If the user would like the *Test Results* screen to display specific parameters, on page 2, perform the following:

1. Tap the *Main Menu* icon.
2. Tap the *Display* icon.
3. Toggle parameters accordingly to display the parameters preferred on page 1. Parameters listed under *Display Parameters* in green are those that may be displayed on the *Test Results* screen page 1, those in gray will be displayed on page 2.
4. Tap the *green check mark* icon to accept changes.

Information about each parameter is available. Tap directly on the parameter for access. A pop-up window appears for the selected parameter.

## Viewing SpHct

There are two ways to access SpHct.

**To access prior to conducting a test, perform the following:**

1. Tap the *Main Menu* icon.
2. Tap the *Display* icon.
3. Toggle to SpHct under *Units of Measure*.
4. Tap the *green check mark* icon to accept changes.

**To access upon completion of a test, perform the following:**

1. Tap the *SpHb* text next to the *SpHb* numeric result.
2. The text will spin to show the resulting SpHct measurement. Tap on the *SpHct* text next to the SpHct numeric result to return to SpHb.

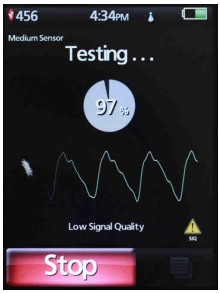
## Low Signal I.Q. (Low SIQ)

The Pronto-7 provides a visual indication of low signal quality by displaying, as seen in the following image, a Low SIQ icon at the bottom of the screen during a measurement when the displayed waveforms are based on inadequate signal quality. Additionally, a hand icon may be displayed as a warning when there is motion during the measurement.

In both cases, the test may be canceled if low signal quality continues. In some cases, a measurement can be displayed despite low signal quality conditions.

If the Low SIQ icon is displayed, it indicates that the accuracy specifications claimed have not been met. When the test is canceled due to low SIQ conditions, proceed with caution and do the following:

1. Assess the patient.
2. Check the sensor and ensure proper sensor application. The sensor should not be placed upside down or sideways on the finger and the sensor must be well secured to the site to obtain accurate readings.
3. 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.
4. 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.



## Modes

Pronto-7 is equipped with five modes; three sensitivity modes and two test modes. The sensitivity modes include normal, max and multi. The test modes include $SpO_2$ only and Measure through Motion, identified on the Pronto-7 screen as measure under Low SIQ.

If any of the three sensitivity modes are toggled to On, the Pronto-7 will remain in the test mode until the user manually configures the mode to Off, or if $SpO_2$ only test mode is turned On, as this test mode overrides all sensitivity modes.

Measure through Motion test mode can be turned on and used simultaneously with any of the four other modes. If either of the two test modes is toggled to On, the Pronto-7 will remain in this test mode until the user manually configures the mode to off.

All modes can be accessed from the Main Menu icon. Some modes can be accessed in additional ways.

**Sensitivity Modes Details**

- Normal is the default sensitivity mode for the Pronto-7.
- Max sensitivity mode should provide fewer “Test Incomplete” messages compared to normal sensitivity mode.
- Multi test mode provides an averaged result based upon three tests. Pronto-7 will perform multiple individual tests until three quality samples are obtained which will be averaged for the single test result.

**Test Modes Details**

- $SpO_2$ only test mode displays $SpO_2$, PI and PR only. Using this mode does not consume a spot check test. If SpHb is needed after the $SpO_2$ only mode test is complete the user can access SpHb, which will deduct a spot check test. See ***Accessing SpHb in SpO2 Only Test Mode*** on page 4341 for details.
- If $SpO_2$ only test mode is on, the Pronto-7 will remain in this test mode until the user manually configures the mode to off. See ***Accessing Sensitivity and Test Modes*** on page 4139 for details.
- Measure through Motion mode allows for fewer incomplete tests and can be enabled from the Test Mode icon.
- If Measure through Motion test mode is on, the Pronto-7 will remain in this test mode until the user manually configures the mode to off. See ***Accessing Sensitivity and Test Modes*** on page 4139 for details.

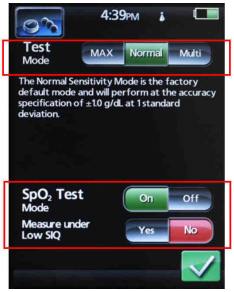
| Mode | Accuracy under no motion conditions | Accuracy under *Measure Through Motion Test Mode* | Notes |
|---|---|---|---|
| Normal | $A_{RMS}$ accuracy over 6-18 g/dL: ± 1.1 g/dL<br>$A_{RMS}$ accuracy over 8-17 g/dL: ± 1.0 g/dL | $A_{RMS}$ accuracy over any range is ± 1.5 g/dl | Default mode for Pronto-7 |
| MAX | $A_{RMS}$ accuracy over 4.5-20 g/dL: ± 1.1 g/dL | $A_{RMS}$ accuracy over any range is ± 1.5 g/dl | MAX sensitivity mode should provide less “Test Incomplete” messages compared to the Normal Sensitivity Mode |
| Multi | $A_{RMS}$ accuracy over 6-18 g/dL: ± 1.1 g/dL<br>$A_{RMS}$ accuracy over 8-17 g/dL: ± 1.0 g/dL | $A_{RMS}$ accuracy over any range is ± 1.5 g/dl | - In multi test mode, Pronto-7 will perform multiple individual tests until three quality samples are obtained which will be averaged for a single test result. |

| Mode | Accuracy under no motion conditions | Accuracy under *Measure Through Motion Test Mode* | Notes |
|---|---|---|---|
| $SpO_2$ Only | $A_{RMS}$ accuracy over 6-18 g/dL: ± 1.1 g/dL<br>$A_{RMS}$ accuracy over 8-17 g/dL: ± 1.0 g/dL | $A_{RMS}$ accuracy over any range is ± 1.5 g/dl | When $SpO_2$ Only mode is On, Normal, Max and Multi sensitivity modes will be overridden. SpHb measurements are only accessible by pressing SpHb measurement following $SpO_2$ Only measurement. |

## Accessing Sensitivity and Test Modes

All modes can be accessed from the main menu. To access modes;

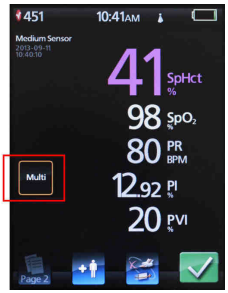
1. Tap the *Main Menu* icon.
2. Tap the *Settings* icon.
3. Tap the Test Mode icon.
4. Toggle the mode to the desired test mode
5. *Tap* the *green check mark* icon to accept changes



## Accessing Multi Sensitivity Mode

In addition to accessing multi sensitivity mode from the main menu, it can also be accessed directly from a Test Results screen upon completion of a spot check test. To test in multi sensitivity mode upon successful completion of a spot check test:

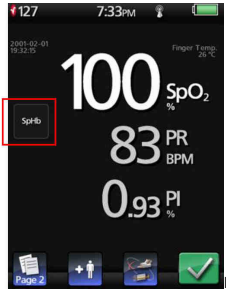
1. Tap the Multi icon to transition into multi test mode.
2. The Pronto-7 will direct you to complete the following steps:
   - Remove the sensor completely.
   - Reattach the sensor to the same finger and verify correct positioning.
   - Tap *Continue* to conduct the second of three tests.
   - Repeat steps 2-3 for the final third test.



## Accessing SpHb in SpO2 Only Test Mode

SpHb is needed after the $SpO_2$ only mode test is complete the user can access SpHb, which will deduct a test credit.

To access SpHb in this mode, the user can tap the *SpHb* icon on the left side of the screen. This will provide the SpHb reading, and a spot check credit will be deducted.



If

## Emailing Spot Check Test Results

In order to email spot check test results, the user must first have an online account for the Pronto-7.

**Setting up a Pronto-7.com account**

1. On a computer, go to the following website: www.pronto7.com.
2. Click the New User link and enter required information.
3. In the *Sponsor Key* field, enter the word *email*.
4. If registration is successful, your user name and password information is saved. Retain this information for your records.

**Configuring Outgoing Email Settings**

1. From the Main Menu on the Pronto-7, navigate to the Connections icon.
2. From the Connections icon, navigate to the *Outgoing Email* screen.
3. Enter the user name and password for the Pronto7.com account.
4. In the *Reply-To Address* field, enter an appropriate email address for receiving responses.
5. In the *Attach Image* field, choose *Yes* if the test results screen image should be attached to an outgoing email.
6. In the *Attach .CSV* field, choose *Yes* if the test results spreadsheet should be attached to an outgoing email.

**Emailing Results**

Test results can be emailed from the *Test Results* screen or Test Results icon, which is accessible from the Main Menu. You can email all test results or individual test results.

**To send all test results to a single email address**

1. Tap the  icon.
2. Tap the *Email* All Tests icon.
3. Enter email address to which the test results will be sent.
4. Tap the *Accept* icon.

**To send individual test results**

Tap the  icon.

1. Tap the *Email Single Test* icon.
2. Enter email address to which the test results will be sent.

3. Tap the *Accept* icon.

## Download of Spot Check Tests

Purchased spot check tests can be wirelessly or non-wirelessly downloaded to the Pronto-7 sensor. The number next to the radical sign indicates the quantity of remaining tests left on the sensor.

To download spot check tests directly using the Pronto-7, the instrument must be connected to a wireless network.

There are two ways to access wireless download of spot check tests, either from the Main Menu icon or the radical sign.

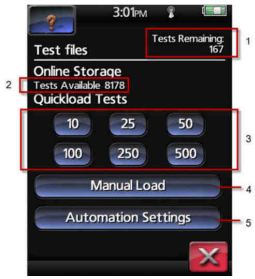
Main Menu:

1. Connect Pronto-7 to a wireless network by accessing the Connections icon from the Main Menu icon, see ***Main Menu Access*** on page 5148.
2. Connect the sensor to the Pronto-7.
3. Tap the *Main Menu* icon.
4. Tap the Help icon.
5. Tap the Load Tests icon.
6. Tap the Download icon.

Radical Sign:

1. Connect Pronto-7 to a wireless network by accessing the *Connections* icon from the Main Menu icon, see ***Main Menu Access*** on page 5148.
2. Connect the sensor to the Pronto-7.
3. Tap the radical sign at the top left corner of the *Test Ready* screen.
4. Tap the Download icon.

The following image and table explains the various features and displays of wireless spot check test download once the Download icon is accessed.




| Step | Features / Display | Description |
|---|---|---|
| 1 | Tests Remaining | Number of tests remaining on the connected sensor. |
| 2 | Tests Available | Number of tests purchased and available for download. |
| 3 | Quickload Tests | Selectable shortcuts to download preset quantities of tests (10, 25, 50, 100, 250 or 500 tests). |
| 4 | Manual Load | Download user-specified quantities of tests. |
| 5 | Automation Settings | Auto downloads a minimum quantity of tests based on a user-specified threshold. |

To begin the download, using either Quickload or Manual Load:

1. Select one of the following:
   - Quickload: Tap on one of the quantity icons to indicate the quantity of tests to download.
   - Manual Load: Tap the Manual Load icon, enter a specific quantity of tests to download in the new screen and tap *Accept*.
2. When prompted to verify the number of tests to be downloaded, if the number is correct, tap *Yes*.
3. When the tests are being downloaded, the message *Please Wait* displays in the bottom-left corner of the screen. When the tests are

downloaded, the message *Download Complete* appears. To close this message, tap  .

## Using a Micro_SD Card:

1. Connect a compatible sensor to the Pronto-7.
2. Insert the micro SD card with spot check tests on it into the Pronto-7 micro SD card slot.
3. Tap the *Main Menu* icon on the *Test Ready* screen.
4. Tap the *Help* icon.
5. Tap the *Load Tests* icon, and finally tap the *micro SD Load* icon. After pressing the Load icon a dialog will appear confirming the tests have been successfully loaded.

## Using a USB Cable:

1. Connect a compatible sensor to the Pronto-7.
2. Connect the Masimo supplied USB cable to a computer*. The Pronto-7 should appear as a mass storage device (such as a USB drive on a computer).
3. When the Pronto-7 is visible as a drive, drag the purchased spot check tests 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. Tap the *Main Menu* icon on the *Test Ready* screen.
7. Tap the *Help* icon.
8. Tap the *Load Tests* icon, and then tap the *Internal Mass Storage Load* icon. After pressing the *Load* icon a dialog will appear confirming the tests 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 test files have been purchased, it is important to load the test files in sequential order (i.e. test files purchased April 3, 2010 prior to test files purchased April 15, 2010). Non-sequential loading of test files

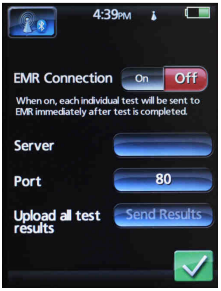
will obsolete any skipped test files. If test files are available in different locations (one on the micro SD and one on the Internal Device Storage) the Pronto-7 will only allow you to load the oldest files. After the oldest file is loaded, then the next most recent spot check test file can be loaded.

To confirm that new tests have been downloaded to the sensor, the test count in the upper-left corner of the screen should be automatically increased by the number of tests downloaded.

## EMR Connectivity

The Pronto-7 can wirelessly connect to compatible EMR systems, allowing test results to be sent to onsite EMR systems automatically. EMR connectivity is supported by Telcor and Apex. Contact your local Masimo sales representative for available EMR system compatibility.

To enable this feature, Pronto-7 must be connected to a wireless network and EMR Connectivity settings must be configured in the EMR Connectivity icon as seen in the following image.



Uploading of files to the EMR can be performed manually or automatically.

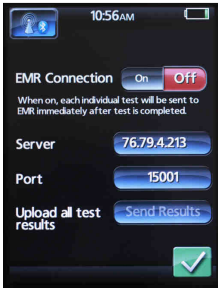
Manual Upload:

1. Tap the Main Menu icon.
2. Tap the Connections icon.
3. Tap the EMR Connectivity icon.
4. Populate the Server and Port settings depending on the specific EMR setup on-site.
5. Tap *Send Results*.
6. Tap the green check mark icon to accept changes.

Automatic Upload:

1. Tap the Main Menu icon.
2. Tap the Connections icon.
3. Tap the EMR Connectivity icon.
4. Toggle the EMR Connection to On.
5. Populate the Server and Port settings depending on the specific EMR setup on-site.
6. Tap the green check mark icon to accept changes.

After each complete spot check test the file will be uploaded to the EMR.




Consult Masimo Technical Services for EMR connectivity support and maintenance.

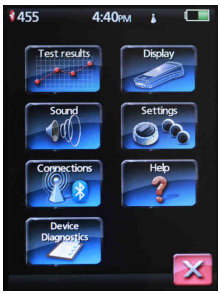
## Main Menu Options

The following section outlines all Main Menu features available on the Pronto-7 and user configurable options.

### Main Menu Access

**To access the Main Menu:**

1. Tap  from any screen where it is shown.
2. The Main Menu icon allows access to the following icons.
   - Test Results
   - Sounds
   - Connections
   - Device Diagnostics
   - Display
   - Settings
   - Help
3. To access these icons, tap the needed icon.



## Test Results Icon

The test results icon provides the date of patient testing, the patient ID and the results produced. Sortable by column, data can be rearranged by pressing the column header to sort. The data cannot be sorted by *Results*.

| Option | Factory Default | Configurable Settings |
|---|---|---|
| Date | Descending | Ascending or descending |
| Patient ID | Patient ID | Ascending or descending |
| Results | Most recent tests | N/A |

**To access the patient and test details:**

1. Tap the row of the patient in which data is needed. The details will be visible in a pop-up window.
2. Tap the *Page 2* icon where available for remaining measurements or tap the  icon to return to the Test Results icon details.

From the test results icon a user can tap the  icon to search all tests (displays a keyboard), delete all tests, print or e-mail the test results, and export results to the Micro SD card (if Micro SD card is inserted).

From an individual test result screen a user can tap the  icon to print or e-mail the test result (if those options are setup), export the test to the Micro SD card, edit patient information, delete a single test and e-mail results.

## Sound Icon

The sound icon provides volume, sound effect and voice controls.

| Option | Factory Default | Configurable Settings |
|---|---|---|
| Volume | 10 | 1 - 10 |
| Sound Effects | On | On, Off |

| Option | Factory Default | Configurable Settings |
|---|---|---|
| Voice | On | On, Off |

## Connections Icon

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.

With an appropriately setup network, completed test result screens can be emailed or printed and spot check tests can be downloaded.

Printing can be done over an internet connection or through a Bluetooth printer (Bluetooth barcodes can be included).

| Option | Factory Default | Configurable Settings |
|---|---|---|
| **Wireless Network** | | |
| Wireless Connection | Off | On, Off |
| LAN Configuration | DHCP | DHCP, Static |
| Available Networks | 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** | | |
| User Name | N/A | Enter Masimo server name |
| Password | N/A | Enter Masimo server password |
| Reply to Address | N/A | User editable (About Owner screen) |

| Option | Factory Default | Configurable Settings |
|---|---|---|
| Attach Image (test screen shot) | No | Yes, No |
| Attach .CSV (.csv data file) | Yes | Yes, No |
| **Bluetooth Pairing** | | |
| Bluetooth (2.0) | Off | On, Off |
| Security (if Bluetooth is On) | Off | On, Off |
| **Printer Configuration** | | |
| Printer Address | N/A | User editable |
| Port Number | N/A | User editable |
| Print Style | Color | Color, B/W (Black and White) |
| Include Picture | Yes | Yes, No |
| Include Barcodes | No | Yes, No |
| **EMR Connectivity** | | |
| EMR Connection | Off | On, Off |
| Server | N/A | User editable |
| Port | N/A | User editable |
| Upload all test results | N/A | Tap to send all pending results to EMR. |

## Device Diagnostics Icon

| Option | Factory Default | Configurable Setting |
|---|---|---|
| Interference Scan | N/A | Check Environment for Interference |

## Display Icon

| Option | Factory Default | Configurable Settings |
|---|---|---|
| Brightness | 10 | 1 - 10 |
| SpHb Units of Measure | g/dL | g/dL, g/L, mmol/Ls, SpHct (%) |
| Display Parameters | SpHb, SpO2, PR, PI | SpHb, SpO2, PR, PI, SpHct |
| *Finger Temp. | Off | ℃, ℉, Off |

***Note**: The temperature displayed is the temperature of the finger where the sensor is placed. This is not the patient's core body temperature and should not be used to make clinical decisions.

## Settings Icon

| Option | Factory Default | Configurable Settings |
|---|---|---|
| **Test Mode** | | |
| Measure under Low SIQ | No | Yes, No |
| Sensitivity | Normal | MAX, Normal, Multi |
| $SpO_2$ Test Mode | Off | On, Off |
| **User ID/Patient ID/PIN** | | |

| Option | Factory Default | Configurable Settings |
|---|---|---|
| User ID | Off | On, Off |
| Patient ID | Off | On, Off |
| Pin# Protection | Off | On, Off |
| Test | Off | On, Off |
| Menu | Off | On, Off |
| Create/Change Pin# | N/A | Up to 15 digit numeric PIN, user editable |
| If the PIN # is forgotten, tap the *Forgot Pin* icon along the upper right edge of the Enter PIN keypad. | | |
| **Language** | | |
| Language | English | List available, user selectable |
| **Date and Time** | | |
| Clock Display | On | On, Off |
| Time Format | 12 hour | 12 hour, 24 hour |
| Time | hh/mm/pm | User editable |
| Date Format | mm/dd/yy | yy/mm/dd, mm/dd/yy, dd/mm/yy |
| Date | N/A | User editable |
| **Power Save Mode** | | |
| Power Save Mode | On | On, Off |
| **About Pronto-7 /Owner** | | |
| About Pronto-7 | Masimo Contact | N/A |

| Option | Factory Default | Configurable Settings |
|---|---|---|
| | Information | |
| About Owner | Registered to information | Name, street address, cite, state, country, phone number, email, website |
| **Restore Settings** | | |
| Restore Default Settings | N/A | No, Yes |

## Help Icon

| Option | Description |
|---|---|
| Quick Start | Presents short slide show of basic testing operation |
| Common Questions | List of questions and answers about the instrument features |
| Contact Tech Support | Specifies Masimo Tech Support contact information |
| Equipment Report | Documents device serial number, software version, total device run time, last service/location, sensor serial #, total sensor run time, spot checks administered and remaining |
| Software Update | Provides access to upgrade or downgrade the software version from one of four locations: micro SD, internal mass storage, compatible sensor or wireless network |
| Load Tests | Provides access Load Tests - Select to view available spot check test files and/or load them in to the a compatible sensor |
| Clear Database | Supplies access to erase all measurements and patient/user database |
| Device | Allows download of latest configurations of Pronto-7 that is available, displays a list of features enabled based on |

| Option | Description |
|---|---|
| Configurations | existing configuration of the instrument |

## Battery

### 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 LCD 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

- If 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

Tap the *battery* icon at any time to see the current battery status.

# Chapter 5: Alarms and Messages

## Messages

The Pronto-7 will indicate other data or system errors. Messages are:

| Message | Possible Indication | Recommendation |
|---|---|---|
| *Ready* | Ready for spot check test | Initiate spot check test by pressing the green *Test* icon. |
| *Connect Sensor* | No compatible sensor is connected | Connect a compatible sensor to the instrument. |
| *Test Incomplete* | Sensor disconnect or interference | Check sensor connection or perform interference scan. |
| *Low Battery Warning* | Pronto-7 battery is too low at start of measurement | Plug in Pronto-7 AC power cord. |
| *Test Stopped* | *Stop* icon is pressed during test | Initiate new spot check test by pressing the green *Test* icon. |

# Chapter 6: Troubleshooting

## Troubleshooting

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

| Problem | Possible Sources | Recommendation(s) |
|---|---|---|
| Incomplete test or no reading | Sensor placement | Ensure sensor is placed on a well perfused site.<br>Make sure the patient's finger is all the way in the sensor and touching the finger stop.<br>Route sensor cable along the back of the patient's hand to ensure that the sensor is on in the correct orientation (see sensor 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.<br>Check the testing environment for interference using the interference scanner in the Main Menu (see ***Device Diagnostics Icon*** on page 55~~51~~).<br>If interference is high, shield the sensor from excessive light, modulated light sources (such as computer displays) or strobe lights. |
| | Reflective and / or metallic nail polish or acrylic nails | Remove all nail polish.<br>Remove acrylic nails. |

| Problem | Possible Sources | Recommendation(s) |
|---|---|---|
| Device does not power on | Low battery | Plug in included AC power cable, then power on the instrument. |
| Compatible 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 sensor DFU and on-screen directions and diagrams. |
| A computer connected with the included USB cable does not recognize the Pronto-7 | Connection issue | Make sure the instrument is powered on and plugged into AC power.<br>Check the available drives on your computer.<br>If the Pronto-7 still does not appear, search your computer's User Manual for proper external drive mapping and troubleshooting. |
| Touchscreen icons 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 ***Service and Repair*** on page 7167. |

# Chapter 7: Specifications

## Specifications

| **Measurement Range** | |
|---|---|
| SpHb (total hemoglobin) | 2 - 25 g/dL |
| PR (pulse rate) | 30 - 240 bpm |
| $SpO_2$ (arterial oxygen saturation) | 0 - 100% |
| PI (perfusion index) | 0.02 - 20% |
| SpHct (hematocrit) | 5 - 75% |
| **Accuracy** | |
| Arterial Oxygen Saturation, 70% to 100% [1] | ± 2% (± 3% under motion) |
| Pulse Rate [2] | ± 3 bpm (± 5 bpm under motion) |
| Total Hemoglobin Concentration (SpHb g/dL) for 4D DC Sensor [3] | **Normal and Multi Sensitivity Modes**<br>$A_{RMS}$ accuracy over 6-18 g/dL: ± 1.1 g/dL<br>$A_{RMS}$ accuracy over 8-17 g/dL: ± 1.0 g/dL<br>**MAX Sensitivity Modes**<br>$A_{RMS}$ accuracy over 4.5 - 20 g/dL: ± 1.1 g/dL<br>**Note**: For all sensitivity modes under motion, $A_{RMS}$ accuracy over any range is ± 1.5 g/dL. |
| **Resolution** | |
| SpHb (total hemoglobin) | 0.1 g/dL |
| PR (pulse rate) | 1 bpm |
| $SpO_2$ (Arterial Oxygen Saturation) | 1 % |

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| | |
|---|---|
| PI (perfusion index) | 0.01% |
| SpHct | 1 % |
| **Interfering Substances** | |
| Refer to ***Safety Information, Warnings, and Cautions*** on page 99. | |
| **Product** | |
| Test storage capacity | 8000 |
| Wireless connectivity | 802.11 b/g, Bluetooth |
| Reporting modes | Print, email, audible, micro SD |
| 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<br>6 hours when powered on |
| Isolation | Medical Grade AC/DC Adapter |
| AC Power | 100-240V, 50-60 Hz, 15VA max. |
| **Environmental** | |
| System Operating Temperature | 41℉ to 104℉ (5℃ to 40℃) |

| | |
|---|---|
| Storage Temperature | -40℉ to 158℉ (-40℃ to 70℃) |
| Operating Humidity | 5% to 95%, non-condensing |
| Operating Altitude | 500 mbar to 1060 mbar<br>-1000 ft to 18,000 ft (-304 m to 5,486 m) |
| **Physical Characteristics** | |
| Dimensions | 5.1" x 2.8" x 1"<br>(13 cm x 7.2cm x 2.5 cm) |
| Weight | 10.5 oz (296.4 g) |
| Visual Alarm | Low Battery, System Failure |
| **Display / Indicators** | |
| Data display: $SpO_2$%, PR beats per minute, SpHb g/dL, PI%, SpHct %, wifi status, Bluetooth status, time, date, spot check tests remaining, sensor size, battery level indicator, pulse plethysmograph waveform, action icons. | |
| 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, which encompasses 68% of the population.*

*[2] Masimo sensors have been validated for pulse rate accuracy for the range of 30-240 bpm in bench top testing against a Fluke Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.*

*[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 4.5 – 20 g/dL ~ 6-18 g/dL and 8-17 g/dLSpHb against a laboratory CO-oximeter. This variation equals plus or minus one standard deviation which encompasses 68% of the population.*

## Calibration Verification

Pronto-7 does not require calibration during clinical use. The calibration coefficients are embedded in the software and validated during manufacturing testing in compliance with Masimo's ISO-certified quality system procedures. Once the systems have been placed into clinical use, both monitors automatically perform a system verification (self-check) every time the monitors are powered up and at the beginning of every measurement cycle. No other calibration or quality control verification is required.

If any component of the system is not operating within specification, the monitor will not allow a test to be performed and will alarm and display an error code message. In this case, contact your Masimo representative and return the device for service.

## Symbols

The following symbols may be found on the Pronto-7 or packaging and are defined below:

| Symbol | Description |
|---|---|
|  | Caution, consult accompanying documents |

| Symbol | Description |
|---|---|
|  | Follow Instructions for Use |
|  | Type BF applied part complying with IEC 60601-1 |
|  | Separate collection for electrical and electronic equipment (WEEE) |
|  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) |
|  | Date of manufacture |
|  | Storage humidity range: 5% to 95% |
|  | Storage temperature range: +70˚C to -40˚C<br>Storage altitude range: 500 mbar to 1060 mbar |
|  | Keep dry |
|  | Fragile/breakable, handle with care |

| Symbol | Description |
|---|---|
|  | MDSS GmbH, Schiffgraben 41, D-30175 Hannover, Germany |
|  | 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 |
|  | Protection against vertically falling water drops |
|  | No parameter alarms |

# Chapter 8: Service and Repair

## Service and Repair

### Introduction

This chapter covers how to properly clean and 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.

The Pronto-7 is a reusable instrument. The instrument is supplied 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, 70% Isopropyl Alcohol.

**WARNING**: Before cleaning the instrument, always turn it off.

**CAUTIONS:**

1. Do not sterilize the Pronto-7.
2. Do not soak or immerse the Pronto-7 in any liquid.
3. Use the cleaning solution sparingly. Excessive solution can flow into the Pronto-7 and cause damage to internal components.
4. 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.
5. Use the included LCD cleaning cloth to remove fingerprints from the touchscreen.
6. Do not use petroleum-based, acetone solutions, or other harsh solvents, to clean the Pronto-7.
7. These substances erode the instrument's materials and instrument failure can result.

For cleaning instructions of the sensor, refer to the appropriate sensor Directions for Use.

## Repair Policy

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

**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.

To return the Pronto-7 for service, please follow the Return Procedure.

## Return Procedure

Remove all saved patient identifying data by deleting all tests (For configuration details, see ***Main Menu Options*** on page 5147 ). Please clean contaminated/dirty equipment (See ***Cleaning*** on page 7167) before returning and make sure it is fully dry before packing the equipment. Call Masimo Technical Services to request return authorization (RMA), at the phone number below.

Package the equipment securely – in the original shipping container if possible – and enclose or include the following information and items:

1. A letter describing in detail any difficulties experienced with the Pronto-7. Please include the RMA number in the letter.
2. Warranty information – a copy of the invoice or other applicable documentation must be included.
3. Purchase order number to cover repair if the instrument is not under warranty, or for tracking purposes if it is.
4. Ship-to and bill-to information.
5. Person (name, telephone / telex / fax number, and country) to contact for any questions about the repairs.
6. 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<br>40 Parker<br>Irvine, California 92618<br>Tel: 949-297-7498, or 800-326-4890 (option 2)<br>Fax: 949-297-7499 | Masimo Japan Corporation<br>Kojimachi Office<br>World Time Bldg. 4F<br>10-7,<br>Ichiban-cho,<br>Chiyoda-ku<br>Tokyo 102-0082<br>Japan<br>Tel: 03 3237 3057<br>Fax: 03 3238 1110 | Masimo International Sàrl<br>Puits-Godet 10<br>2000 Neuchatel<br>Switzerland<br>Tel: +41 32 720 1111<br>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: each new Product and the Software media as delivered are free from defects in workmanship or materials.

Batteries are warranted for six (6) months.

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.

Masimo's sole obligation under this warranty is to repair or replace any Product or Software that is covered under warranty.

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Additional typefaces for this product can be obtained at www.fonts.com

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