Pronto-7 – with rainbow 4D™ technology – for noninvasive and quick spot-checking of total hemoglobin (SpHb®), oxygen saturation (SpO₂), pulse rate (PR), and perfusion index (PI)
Your Solution for Hemoglobin Spot-checking

The Pronto-7 may provide the following benefits:

- Facilitates timely patient assessment
- Easy-to-use – Improves efficiency
- Expands information available to your clinician at time of assessment

FOUR SIMPLE STEPS

1. SELECT SENSOR SIZE
2. PLACE SENSOR ON FINGER
3. PRESS TEST BUTTON
4. OBTAIN RESULTS

Automatically saved – option to print, e-mail, or manually record
SpHb ANALYTICAL PERFORMANCE

In 11,335 comparisons of SpHb and invasive hemoglobin (tHb) measurements from a laboratory reference device, SpHb accuracy was as follows:*

-0.02 g/dL bias
> 0.99 g/dL Arms accuracy
- Between 6 - 12 g/dL, greater than 95% of SpHb readings were within 2 g/dL from the laboratory tHb value
- Between 12 - 18 g/dL, greater than 95% of SpHb readings were within 2 g/dL from the laboratory tHb value

*Masimo FDA 510(k) Submission Data using normal sensitivity mode.

Please note: These results were obtained in normal sensitivity mode following a specific protocol, in which all Directions for Use were followed and SpHb measurements were compared to validated laboratory reference measurements. Differences in results may be caused by many factors, such as those explained in Masimo’s Directions for Use. Some independent researchers have conducted their own testing and obtained similar results, while other researchers have reported larger differences when comparing SpHb measurements to laboratory measurements.

SPECIFICATIONS

<table>
<thead>
<tr>
<th>Performance Measurement</th>
<th>Range</th>
<th>Resolution</th>
<th>Accuracya</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Hemoglobin (SpHb) Normal sensitivity mode</td>
<td>0-25 g/dL</td>
<td>0.1 g/dL</td>
<td>6-18 g/dL ± 1.0 g/dL @ 1Std.</td>
</tr>
<tr>
<td>Total Hemoglobin (SpHb) Maximum sensitivity mode</td>
<td>0-25 g/dL</td>
<td>0.1 g/dL</td>
<td>4.5-20 g/dL ± 1.1 g/dL @ 1Std.</td>
</tr>
<tr>
<td>Arterial Oxygen Saturation (SpO2)</td>
<td>D-100%</td>
<td>1%</td>
<td>70% to 100% ± 2%</td>
</tr>
<tr>
<td>Pulse Rate (PR)</td>
<td>30-250 bpm</td>
<td>1 bpm</td>
<td>± 3 bpm</td>
</tr>
<tr>
<td>Perfusion Index (PI)</td>
<td>0.02%-20%</td>
<td></td>
<td>0.01%</td>
</tr>
</tbody>
</table>

Product

Type: Pulse CO-Oximeter
Mode of operation: Spot check
Spot-check storage capacity: 8,000 time-stamped spot-check results
Wireless connectivity: 802.11 b/g, Bluetooth
Reporting modes: Print, email, audible
Report formats: Single or multiple spot-checks, device summary
Reporting devices: Optional Bluetooth thermal printer, USB, 802.11 wireless (PCL 5, 5e, 6), or Bluetooth printing to validated printers
Included accessories: AC power cord, USB cable and Pronto-7 pouch

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: 6 hours when powered off
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: -1000 ft to 18,000 ft (304 m to 5,486 m)

Physical Characteristics

Dimensions: 5.1” x 2.8” x 1” (13 cm x 7.2 cm x 2.5 cm)
Weight: 10.5 oz (296.4 g)
Visual alarms: Low battery, system failure

Display/Indicators

Data Display: SpO2%, pulse rate (PR) beats per minute, SpHb g/dL, PI%, battery level indicator, time, and number of spot-check
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

rainbow 4D™ Sensor

Type: Direct connect spot-check reusable sensor
Small (yellow): 8mm – 12mm (0.31” – 0.47”)
Medium (red): 12mm – 16mm (0.47” – 0.63”)
Large (gray): 16mm – 20mm (0.63” – 0.79”)
Spot-check replenishment: Pre-load or via online download

Physical Characteristics

Length: 47” (119.4 cm)
Weight: 3.7 oz (105 g)

Prior to using this device, the user should read and understand the Operator’s Manual and Directions for Use. Laboratory diagnostic tests using blood samples should be conducted prior to clinical decision making to completely understand the patient’s condition. Comparisons between SpHb measurements and laboratory diagnostic hemoglobin measurements may be affected by sample type, collection technique, physiological, and other factors.

1 SpO2 accuracy has been validated on healthy adult male and female volunteers with light to dark skin pigmentation in the range of 60% - 100% against a laboratory CO-Oximeter. The Pronto-7 and rainbow 4D DC sensors are indicated for adults and pediatrics with the finger sizes of 6 mm – 20 mm in diameter (small sensor: 8 mm – 12 mm; medium sensor: 12 mm – 16 mm; and large sensor: 16 mm – 20 mm). The Pronto-7 SpO2 accuracy with rainbow 4D DC sensors was validated in adults and pediatrics greater than 30kg. The SpO2 has not been validated with motion or low perfusion. Pulse Rate accuracy has been validated in the range of 25-240 bpm in bench top testing against a Biocardi (IBS) simulator. The variation in accuracy specifications equals plus or minus 1 standard deviation which encompasses 68% of the population. Contact Masimo for testing specifications.

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Caution: Federal law restricts this device to sale by or on the order of a physician.