PULSE CO-OXIMETER®

Pronto-7®

Pronto-7 – with rainbow 4D™ technology – for noninvasive and quick spot-checking of total hemoglobin (SpHb®), oxygen saturation (SpO_2), pulse rate (PR), and perfusion index (PI)

MEDICAL DESIGN EXCELLENCE AWARDS®

MASIMO®

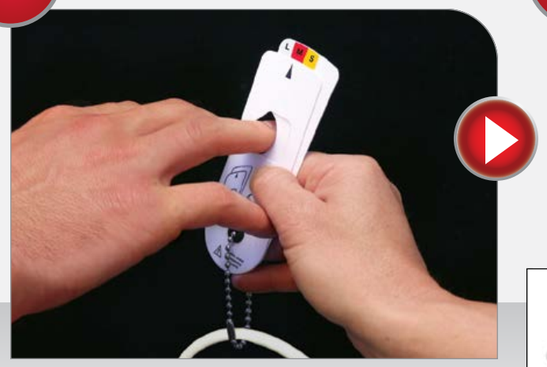
Your Solution for Hemoglobin Spot-checking

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



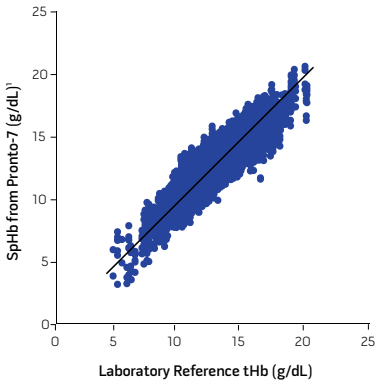
2 PLACE SENSOR ON FINGER

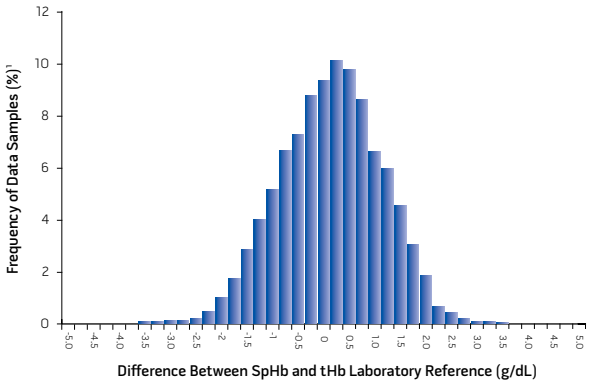
3 PRESS TEST BUTTON

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 A_{RMS} 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

Performance

Measurement	Range	Resolution	Accuracy[1]
Total Hemoglobin (SpHb) Normal sensitivity mode	0-25 g/dL	0.1 g/dL	6-18 g/dL ± 1.0 g/dL @ 1Std.
Total Hemoglobin (SpHb) Maximum sensitivity mode	0-25 g/dL	0.1 g/dL	4.5-20 g/dL ± 1.1 g/dL @ 1Std.
Arterial Oxygen Saturation (SpO_2)	0-100%	1%	70% to 100% ± 2%
Pulse Rate (PR)	30-250 bpm	1 bpm	± 3 bpm
Perfusion Index (PI)	0.02%-20%	0.01%	

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	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 -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	SpO_2%, 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

General

Type	Direct connect spot-check reusable sensor
Small (yellow)	8mm - 12mm (.31" - .47") diameter
Medium (red)	12mm - 16mm (.47" - .63") diameter
Large (gray)	16mm - 20mm (.63" - .79") diameter
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] SpO_2 accuracy has been validated on healthy adult male and female volunteers with light to dark skin pigmentations 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 8 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 SpHb accuracy with rainbow 4D DC sensors was validated in adults and pediatrics greater than 30kg. The SpHb 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 Biotek Index2 simulator. The variation in accuracy specifications equals plus or minus 1 standard deviation which encompasses 68% of the population. Contact Masimo for testing specifications.

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

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