

Pronto-7™



Pronto-7 – with rainbow 4D™ Technology – for noninvasive and quick spot checking of total hemoglobin (SpHb®), SpO2, pulse rate, and perfusion index



A New Solution for Hemoglobin Spot-Check Testing

Traditional invasive lab testing provides delayed results and requires a painful needle stick and time-consuming blood draws.

The Pronto-7 offers noninvasive and quick spot-check testing of total hemoglobin (SpHb), SpO₂, pulse rate, and perfusion index, which may provide the following benefits:

CLINICIAN

- > Facilitates timely patient assessment
- > Reduces the need to wait for lab results

STAFF

- > Easy-to-use – Improves efficiency
- > Decreases risk of accidental needle sticks and exposure to blood-borne pathogens
- > Requires no lab consumables or waste disposal

PATIENT

- > Reduces painful needle sticks and time-consuming blood draws
- > Enables immediate face-to-face counseling with clinician



FOUR SIMPLE STEPS

1

SELECT SENSOR SIZE



2

PLACE SENSOR ON FINGER



3

PRESS TEST BUTTON



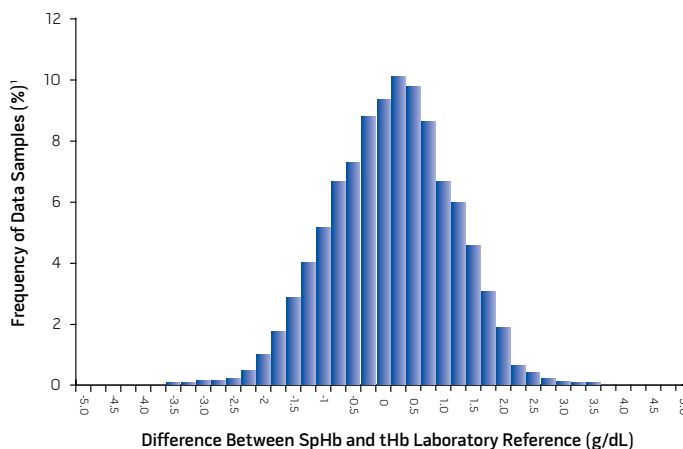
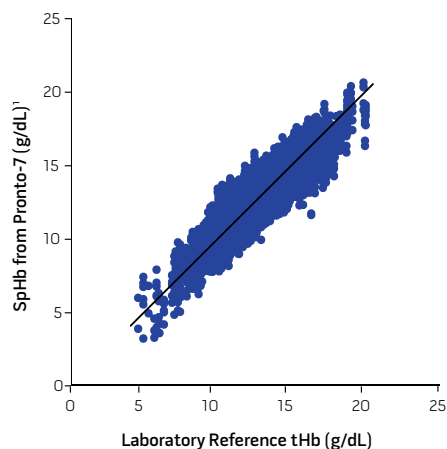
4

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:¹

- > -0.02 g/dL bias
- > 0.99 g/dL at one standard deviation
- > Between 6 - 12 g/dL, greater than 95% of SpHb readings were within 2 g/dL of the laboratory tHb value
- > Between 12 - 18 g/dL, greater than 95% of SpHb readings were within 2 g/dL of the laboratory value

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.

PERFORMANCE

Measurement	Range	Resolution	Accuracy ²
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%	

SPECIFICATIONS

Pronto-7 Device

General

Type	Pulse CO-Oximeter
Mode of operation	Spot check
Test storage capacity	8,000
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 (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

Date Display	SpO ₂ %, pulse rate (PR) beats per minute, SpHb g/dL, PI%, battery level indicator, time, and number of tests
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
Test replenishment	Pre-load or via online download

Physical Characteristics

Length	47" (119.4 cm)
Weight	3.7 oz (105 g)

¹ Masimo FDA 510(k) Submission Data using normal sensitivity mode.

² SpO₂ 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. SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentations in the range of 4.5 g/dL to 20 g/dL SpHb against a reference laboratory device. 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.