Pronto®

Pronto — with rainbow® 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 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 – reduces training time and 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 counselling with clinician

FOUR SIMPLE STEPS

1 SELECT SENSOR SIZE
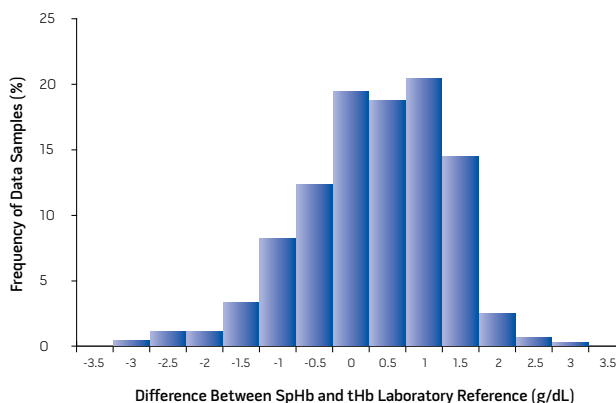
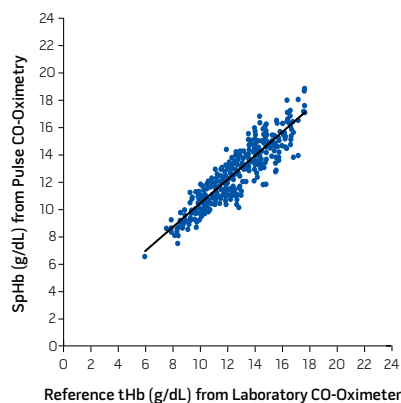**2** PLACE SENSOR ON FINGER

3 PRESS SpHb BUTTON

4 OBTAIN RESULTS

SpHb ANALYTICAL PERFORMANCE

In 492 comparisons of SpHb and invasive hemoglobin (tHb) measurements from a laboratory CO-Oximeter, SpHb accuracy was as follows[1]:

> 0.08 g/dL bias

> 0.96 g/dL at one standard deviation

> Below 12 g/dL, 99% of SpHb readings were <2 g/dL of the laboratory tHb value

> At or above 12 g/dL, 94% of SpHb readings were <2 g/dL of the laboratory tHb value

Please note: These results were obtained 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)	0-25 g/dL	0.1 g/dL	8-17 g/dL ± 1 g/dL
Arterial Oxygen Saturation (SpO2)	0-100%	1%	70% to 100% ± 2%
Pulse Rate (PR)	25-240 bpm	1 bpm	± 3 bpm
Perfusion Index (PI)	0.02%-20%	0.01%	

SPECIFICATIONS

Pronto Device

General

Type	Pulse CO-Oximeter
Mode of operation	Spot Check
Test storage capacity	10,000 Time Stamped Spot Check Results

Electrical

Battery power	4 AA Alkaline
Capacity	Operates Continuously for up to 8 Hours Without Changing Batteries
Number of spot checks on fully charged battery	140
Isolation	No external power or ground connection, internally powered only, DC current

Environmental

Operating temperature	0 °F to 129 °F (-18 °C to +54 °C)
Storage temperature	-40 °F to 158 °F (-40 °C to +70 °C)
Operating humidity	5% to 95% non-condensing
Operating altitude	500 mbar to 1060 mbar pressure -1,000 ft to 18,000 ft (-304 m to 5,486 m)

Physical Characteristics

Dimensions	6.2" x 3.0" x 1.4" (15.8 cm x 7.6 cm x 3.6 cm)
Weight	13 oz (367 g)
Visual alarms	Low Battery, System Failure

Display/Indicators

Data display	SpO2%, pulse rate (PR) beats per minute, SpHb g/dL, PI%, low signal IQ, battery level indicator and sensor use indicator
Type	LED

Compliance

EMC compliance	EN60601-1-2, Class B
Equipment classification	IEC 60601-1
Type of protection (battery power)	Internally Powered
Degree of protection-sensor	Type BF-applied part

SpHb rainbow Sensor

General

Type	Direct Connect Spot Check Reusable Sensor
Adult Reusable	> 30 kg
Pediatric Reusable	10 kg - 50 kg

Physical Characteristics

Length	36" (91.4 cm)
Weight	13 oz (367 g)

Protective boots are available in your choice of seven different colors.

[1] Masimo FDA Submission Data (Technical Bulletin, SpHb Accuracy)

[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 8 g/dL to 17 g/dL SpHb against a laboratory CO-Oximeter. 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.

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