

Pronto®



Pronto – with rainbow® technology – for noninvasive and quick spot-checking of total haemoglobin (SpHb®), oxygen saturation (SpO₂), pulse rate (PR), and perfusion index (PI)

Your Solution for Haemoglobin Spot-checking

The Pronto 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



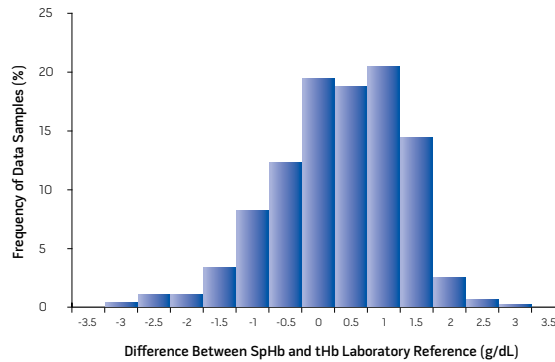
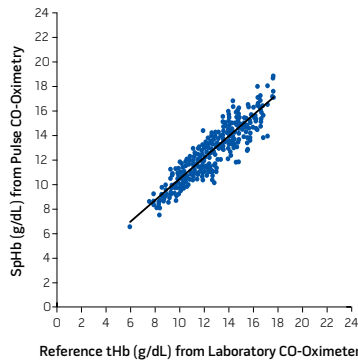
3 PRESS SpHb BUTTON



4 OBTAIN RESULTS



SpHb ANALYTICAL PERFORMANCE



In 492 comparisons of SpHb and invasive haemoglobin (tHb) measurements from a laboratory CO-Oximeter, SpHb accuracy was as follows.*

- > 0.08 g/dL bias
- > 0.96 g/dL ARMS accuracy
- > Below 12 g/dL, 99% of SpHb readings were <2 g/dL from the laboratory tHb value
- > At or above 12 g/dL, 94% of SpHb readings were <2 g/dL from the laboratory tHb value

*Masimo FDA Submission Data (Accuracy of Noninvasive Total Haemoglobin (SpHb) Measurement with Pulse CO-Oximetry). The study was performed in compliance with the requirements of ISO9919:(2005) Standard.

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.

SPECIFICATIONS

Performance

Measurement	Range	Resolution	Accuracy ¹
Total Haemoglobin (SpHb)	0-25 g/dL	0.1 g/dL	8-17 g/dL ± 1 g/dL
Arterial Oxygen Saturation (SpO ₂)	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%	

Product

Type	Pulse CO-Oximeter
Mode of operation	Spot check
Spot-check 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)
Alarms	Low battery, system failure

Display/Indicators

Data display	SpO ₂ %, pulse rate (PR) beats per minute, SpHb g/dL, PI%, Low Signal IQ, battery level indicator, spot check progress indicator, pulse 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	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.

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 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.

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

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