

# Pronto-7®



Pronto-7 – with rainbow 4D™ technology – for noninvasive and quick spot-checking of total haemoglobin (SpHb®), oxygen saturation (SpO<sub>2</sub>), pulse rate (PR), and perfusion index (PI)



# Your Solution for Haemoglobin 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



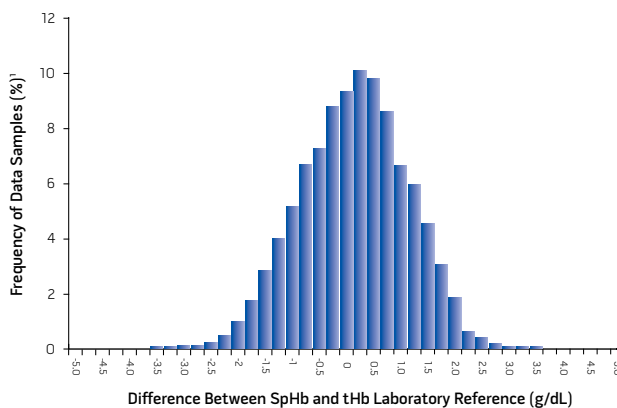
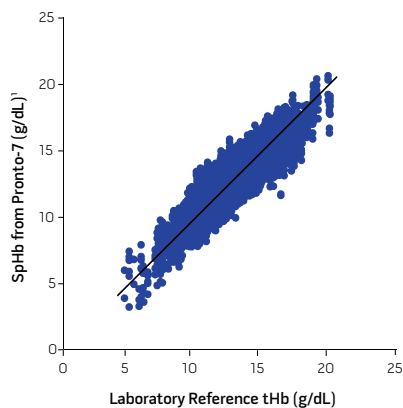
4

OBTAIN RESULTS

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



# SpHb ANALYTICAL PERFORMANCE



In 11,335 comparisons of SpHb and invasive haemoglobin (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

### Performance

Measurement	Range	Resolution	Accuracy <sup>1</sup>
Total Haemoglobin (SpHb) Normal sensitivity mode	0-25 g/dL	0.1 g/dL	6-18 g/dL $\pm$ 1.0 g/dL @ 1Std.
Total Haemoglobin (SpHb) Maximum sensitivity mode	0-25 g/dL	0.1 g/dL	4.5-20 g/dL $\pm$ 1.1 g/dL @ 1Std.
Arterial Oxygen Saturation (SpO <sub>2</sub> )	0-100%	1%	70% to 100% $\pm$ 2%
Pulse Rate (PR)	30-250 bpm	1 bpm	$\pm$ 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)

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 haemoglobin measurements may be affected by sample type, collection technique, physiological, and other factors.

<sup>1</sup> SpO<sub>2</sub> 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 Biote Index 2 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.

### 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<sub>2</sub>%, 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)

