



Pronto® Spot-Check Pulse Co-Oximeter®

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



Reimbursement for Quantitative, Transcutaneous Total Hemoglobin

CODING¹

CPT Code: 88738 (Effective January 1, 2010)
Description: Total Hemoglobin (Hgb), quantitative and transcutaneous

NATIONAL LIMITATION AMOUNT²

\$6.83 per measurement (Effective January 1, 2015)
Medicaid and commercial payers may reimburse at a different rate than Medicare.

CLIA CERTIFICATION^{3,4}

CPT 88738 is CLIA excluded. CLIA certification or CLIA "waiver" is not required to perform and bill for a noninvasive hemoglobin measurement.

CLAIMS PROCEDURE⁵

The claims submission process under CPT Code 88738 is the same as the process for any other service or procedure. Medicare only covers services or procedures that are medically reasonable and necessary. All services and procedures must be ordered by a licensed healthcare provider and must be reasonable and necessary.

ICD-9 DIAGNOSIS CODES⁶

Providers are required to submit ICD-9 codes with every procedure to indicate why the service or procedure is necessary. Healthcare providers should utilize ICD-9 codes that reflect the patient's condition.

CODING EDITS^{7,8}

Medicare National Correct Coding Initiative (NCCI) Edits do not preclude payment for both a Complete Blood Count (CBC) under CPT Codes 85025 or 85027, and a quantitative, transcutaneous total hemoglobin measurement under CPT Code 88738, on the same patient on the same day by the same provider, so long as the treating provider orders both procedures and both are medically necessary.

QUESTIONS

For more information go to www.codemap.com/masimo

PLEASE NOTE

The coding, coverage, and payment information contained herein is gathered from various resources and is subject to change without notice. Masimo cannot guarantee success in obtaining third-party insurance payments. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine and submit appropriate codes, charges, and modifiers for services that are rendered. Providers should contact their third-party payers for specific information on their coding, coverage, and payment policies.

¹ CPT is a registered trademark of the American Medical Association.

² 2015 CMS Clinical Laboratory Fee Schedule. Available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/clinlab.html> Amount paid in the following states differs from the National Limitation Amount: LA = \$4.73; WA = \$6.28; OH & WV; \$5.49; and WY = \$6.45.

³ CMS transmittal #1912, entitled "Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits", change request #6812. Department of Health and Human Services, February 5, 2010.

⁴ CPT-4 Codes Excluded from CLIA Edits (Within 8000 Series); <https://www.cms.gov/CLIA/downloads/CpT4exc.pdf>

⁵ AMA CPT Manual, CMS Claims Processing Manual Publication 100-4.

⁶ International Classification of Diseases, 9th Revision.

⁷ National Coding Correct Initiative Policy Manual for CMS Services.

⁸ CMS NCCI Edits - Physician and Hospital Outpatient PPS, version 17.2 effective date October 1, 2011.

Masimo rainbow® Pulse CO-Oximetry Devices



PRONTO Starter Kit with SpHb (spot check hemoglobin),
Masimo SET® SpO2, & Pulse Rate

3584	Pronto Starter Kit 400 Combo	Includes: (9167) Pronto Handheld Pulse Co-Oximeter plus (2405) RC-1 Patient Cable (1981) Red Protective Boot/Stand		(3418) rainbow DCI SC-200 Adult Reusable Finger Sensor (3419) rainbow DCIP SC-200 Pediatric/Slender Digit Reusable Finger Sensor
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Rainbow® Reusable Spot Check SpHb Sensors (200 Spot Checks)



Part #	Sensor Size	SpHb Spot Checks
3418	Adult > 30 kg	200
3419	Peds/Slender Digit 10 - 50 kg	200
3420	Adult > 30 kg	400
3421	Peds/Slender Digit 10 - 50 kg	400
3647	Adult > 30 kg	1,000
3648	Peds/Slender Digit 10 - 50 kg	1,000



Upgradeable PRONTO SpO2 (Masimo SET® SpO2, & Pulse Rate)



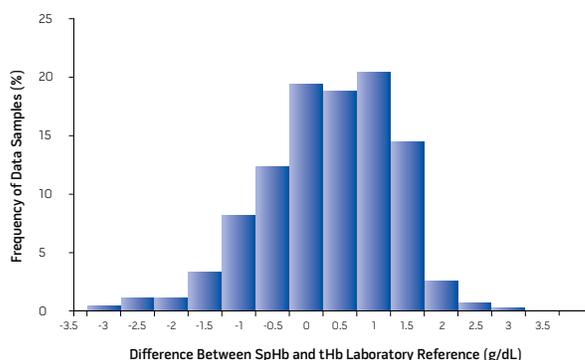
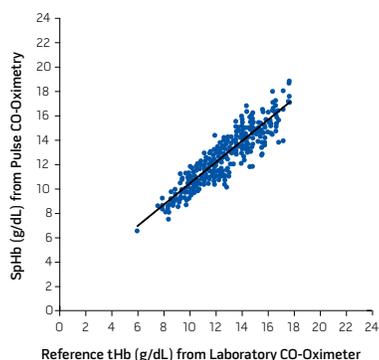
9167	Pronto Device Only	Includes: (9167) Pronto Handheld Pulse Co-Oximeter plus (2405) RC-1 Patient Cable (1981) Red Protective Boot/Stand <i>SpO2 Sensor(s) must be ordered separately. Select from sensors below.</i>
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Masimo Set® SpO2 Sensors



M-LNCS Reusable Sensors		M-LNCS Adhesive Sensors	
2501	2501 Finger Sensor Adult > 30 kg	2513	2513 Infant 3 - 20 kg
	2502 Finger Sensor Peds/Slender Digit 10 - 50 kg	2307	2307 Replacement Tapes for 2513 Sensors
	2503 Tip Clip Ear TC-1 Adult > 30 kg	2515	2515 Neonate/Adult > 3 & < 40 kg
	2505 Y1 Multisite Sensor Peds/Slender Digit > 1 kg	2308	2308 Replacement Tapes for 2515 Sensors
2502	1598 Petite Wraps for 2505 Y1 Sensor		
	1602 Foam Wraps for 2505 Y1 Sensor		

SpHb ANALYTICAL PERFORMANCE



In 492 comparisons of SpHb and invasive hemoglobin (tHb) measurements from a laboratory CO-Oximeter, SpHb accuracy was as follows¹:

- > 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.

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.

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	± 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	M-LNCS 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 (Accuracy of Noninvasive Total Hemoglobin (SpHb) Measurement with Pulse CO-Oximetry)

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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