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

**CODING**

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

**NATIONAL LIMITATION AMOUNT**

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

**CLIA CERTIFICATION**

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

**CLAIMS PROCEDURE**

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 CODES**

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**

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.

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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/CptT4exc.pdf
6 International Classification of Diseases, 9th Revision.
7 NationalCoding 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

<table>
<thead>
<tr>
<th>Part #</th>
<th>Sensor Size</th>
<th>SpHb Spot Checks</th>
</tr>
</thead>
<tbody>
<tr>
<td>3418</td>
<td>Adult &gt; 30 kg</td>
<td>200</td>
</tr>
<tr>
<td>3419</td>
<td>Peds/Slender Digit 10 - 50 kg</td>
<td>200</td>
</tr>
<tr>
<td>3420</td>
<td>Adult &gt; 30 kg</td>
<td>400</td>
</tr>
<tr>
<td>3421</td>
<td>Peds/Slender Digit 10 - 50 kg</td>
<td>400</td>
</tr>
<tr>
<td>3647</td>
<td>Adult &gt; 30 kg</td>
<td>1,000</td>
</tr>
<tr>
<td>3648</td>
<td>Peds/Slender Digit 10 - 50 kg</td>
<td>1,000</td>
</tr>
</tbody>
</table>

Rainbow® Reusable Spot Check SpHb Sensors (200 Spot Checks)

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

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

SpO2 Sensor(s) must be ordered separately. Select from sensors below.
In 492 comparisons of SpHb and invasive hemoglobin (tHb) measurements from a laboratory CO-Oximeter, SpHb accuracy was as follows:

- > 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

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Range</th>
<th>Resolution</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Hemoglobin (SpHb)</td>
<td>0-25 g/dL</td>
<td>0.1 g/dL</td>
<td>8-17 g/dL ± 1 g/dL</td>
</tr>
<tr>
<td>Arterial Oxygen Saturation (SpO2)</td>
<td>0-100%</td>
<td>±1%</td>
<td>70% to 100% ± 2%</td>
</tr>
<tr>
<td>Pulse Rate (PR)</td>
<td>25-240 bpm</td>
<td>0.02%-20%</td>
<td>±3 bpm</td>
</tr>
<tr>
<td>Perfusion Index (PI)</td>
<td></td>
<td></td>
<td>±0.01%</td>
</tr>
</tbody>
</table>

### 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
- 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: -18 °C to +54 °C
- Storage temperature: -40 °C to 50 °C
- Operating humidity: 5% to 95% non-condensing
- Operating altitude: 0 m to 3,000 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 perfusion,
- Signal IQ, battery level indicator and sensor use indicator
- Type: LED

**Compliance**
- EME 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.