

# Accuracy of Noninvasive Spot-Check Testing of Total Haemoglobin by the Masimo Pronto-7™ with rainbow 4D™ Technology: Data Submitted by Masimo as Part of FDA 510(k) Clearance

## INTRODUCTION

The recent availability of noninvasive spot-check testing of total haemoglobin (SpHb®) may provide value to healthcare providers in hospitals, physician offices, ambulatory care centres, emergency medical services, and other outpatient settings.

The purpose of this study was to validate the accuracy of SpHb measurements from the Masimo Pronto-7, a noninvasive spot-check testing device, compared to invasive measurements of haemoglobin (tHb). These results were submitted as part of the FDA 510(k) clearance process.

## METHODS

All data was collected under institutional review board approval and all patients provided written, informed consent. A self-calibrating rainbow 4D™ device (Masimo Pronto-7, Masimo, Irvine, CA) with a spectrophotometric sensor (rainbow 4D Rev F) with multiple wavelengths of light were used to measure SpHb, along with oxygen saturation (SpO<sub>2</sub>) and pulse rate. Study subjects consisted of healthy adult volunteers undergoing a hemodilution procedure, desaturation procedure, or presenting as an adult or paediatric outpatient. Multiple measurements were taken on each subject by applying a sensor to the ring and middle finger of both hands. The hemodilution protocol consisted of replacing one unit of blood with 40 ml/kg of saline. Each SpHb measurement was matched with a corresponding invasive Hb measurement from an automated haematology analyser (Beckman Coulter LH 500). The Massey scale was used to categorise skin pigmentation. Bias, standard deviation, and the accuracy root mean square ( $A_{RMS}$ ) were calculated. The Pronto-7 has two user selectable sensitivity settings – Normal and Maximum Sensitivity. The Normal Sensitivity mode allows a smaller range of acceptable test results and more "Test Incomplete" messages may occur. The Maximum Sensitivity mode provides a wider range of acceptable test results and may reduce "Test Incomplete" messages. Results are reported for both modes.

## RESULTS

Data was collected at fourteen sites: three hospitals, two outpatient clinical research facilities, six outpatient physician offices, Cercacor (Irvine, CA), and two health screening events.

A total of 12,622 data pairs were included in Maximum Sensitivity mode from 1,473 total subjects and 11,335 data pairs were included in Normal Sensitivity mode from 1,445 total subjects. A total of 49 (3.3%) volunteer subjects underwent a hemodilution procedure, 18 (1.2%) underwent a desaturation procedure, and the remaining 1,406 (95%) subjects were measured in 13 settings including hospital emergency room, outpatient clinical settings including internal medicine, family practice, haematology & oncology, paediatrician, obstetrics-gynaecology, and community health screening events. Subjects in outpatient clinical settings presented with various diagnosis – chronic kidney disease, various carcinomas, hypertension, cardiovascular disease, high cholesterol, peripheral vascular disease, and diabetes. A total of 585 subjects (40%) were male. A total of 1,120 subjects had light pigmentation (76%), 331 subjects (22%) had medium pigmentation, and 22 (1.5%) had dark pigmentation.

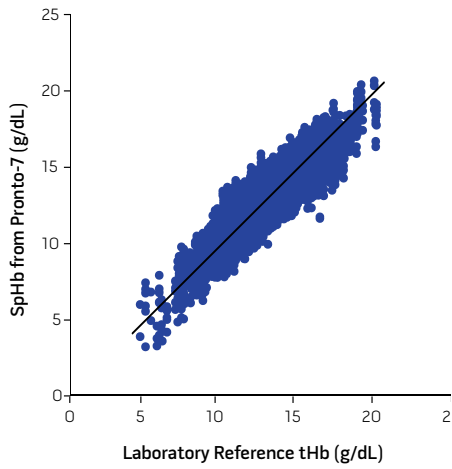
Performance results for both test modes are shown in the following tables and figures: Table 1 – Pronto-7 Performance Summary, Tables 2 and 3 – Range accuracy for Normal and Maximum Sensitivity modes respectively, Figures 1 and 2 – Scatter plot of tHb and SpHb measurements in Normal and Maximum Sensitivity modes, respectively, and Figures 3 and 4 – Histograms of difference between SpHb and tHb for Normal and Maximum Sensitivity modes, respectively.

| Table 1 – Pronto-7 Performance Summary |                    |                       |             |             |           |                  |
|--|--------------------|-----------------------|-------------|-------------|-----------|------------------|
| MODE                                   | Number of Subjects | Number of Data Points | Range       | Correlation | Bias      | A <sub>RMS</sub> |
| Normal Sensitivity                     | 1,445              | 11,335                | 6-18 g/dL   | 0.89        | 0.02 g/dL | 0.99 g/dL        |
| Maximum Sensitivity                    | 1,473              | 12,622                | 4.5-20 g/dL | 0.88        | 0.01 g/dL | 1.1 g/dL         |

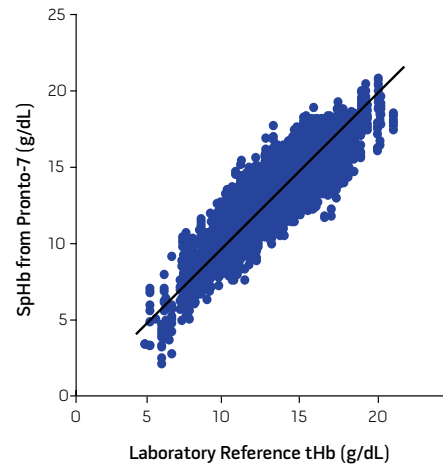
| Table 2 – Normal Sensitivity Mode<br>SpHb Performance by tHb Range |               |             |                           |                                 |            |            |
|--|---------------|-------------|---------------------------|---------------------------------|------------|------------|
| tHb Range  | N             | Bias (g/dL) | Standard Deviation (g/dL) | Difference Between SpHb and tHb |            |            |
|  |               |             |                           | ≤1.0 g/L                        | ≤1.5 g/dL  | ≤2.0 g/dL  |
| <8 g/dL  | 112           | 0.13        | 1.18                      | 71%                             | 86%        | 96%        |
| 8 to 9.9 g/dL  | 653           | 0.31        | 0.88                      | 78%                             | 91%        | 99%        |
| 10 to 11.9 g/dL  | 2,758         | 0.52        | 0.94                      | 67%                             | 86%        | 96%        |
| 12 to 13.9 g/dL  | 3,214         | 0.14        | 0.88                      | 83%                             | 94%        | 99%        |
| 14 to 15.9 g/dL  | 3,242         | -0.26       | 0.89                      | 92%                             | 98%        | 100%       |
| >16 g/dL   | 1,356         | -0.74       | 0.95                      | 97%                             | 99%        | 100%       |
| <12 g/dL   | 3,523         | 0.47        | 0.94                      | 69%                             | 87%        | 96%        |
| ≥12 g/dL   | 7,812         | -0.18       | 0.95                      | 89%                             | 97%        | 99%        |
| <b>Total</b>   | <b>11,335</b> | <b>0.02</b> | <b>0.99</b>               | <b>84%</b>                      | <b>94%</b> | <b>99%</b> |

| Table 3 – Maximum Sensitivity Mode<br>SpHb Performance by tHb Range |               |             |                           |                                 |            |            |
|---|---------------|-------------|---------------------------|---------------------------------|------------|------------|
| tHb Range   | N             | Bias (g/dL) | Standard Deviation (g/dL) | Difference Between SpHb and tHb |            |            |
|   |               |             |                           | ≤1.0 g/L                        | ≤1.5 g/dL  | ≤2.0 g/dL  |
| <8 g/dL   | 162           | 0.08        | 1.54                      | 70%                             | 80%        | 87%        |
| 8 to 9.9 g/dL   | 742           | 0.50        | 1.02                      | 71%                             | 84%        | 92%        |
| 10 to 11.9 g/dL   | 3,021         | 0.58        | 1.02                      | 65%                             | 83%        | 93%        |
| 12 to 13.9 g/dL   | 3,543         | 0.15        | 0.97                      | 82%                             | 92%        | 97%        |
| 14 to 15.9 g/dL   | 3,476         | -0.29       | 0.99                      | 91%                             | 97%        | 99%        |
| >16 g/dL  | 1,678         | -0.87       | 1.07                      | 96%                             | 99%        | 100%       |
| <12 g/dL  | 3,925         | 0.54        | 1.06                      | 66%                             | 83%        | 93%        |
| ≥12 g/dL  | 8,697         | -0.22       | 1.06                      | 88%                             | 95%        | 98%        |
| <b>Total</b>  | <b>12,622</b> | <b>0.01</b> | <b>1.1</b>                | <b>81%</b>                      | <b>91%</b> | <b>96%</b> |

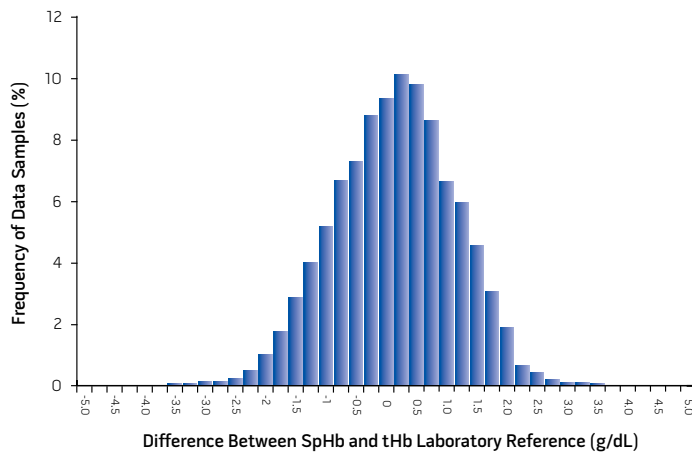
**Figure 1 – Normal Sensitivity Scatter Plot of SpHb vs. tHb Measurements (N=11,335)**



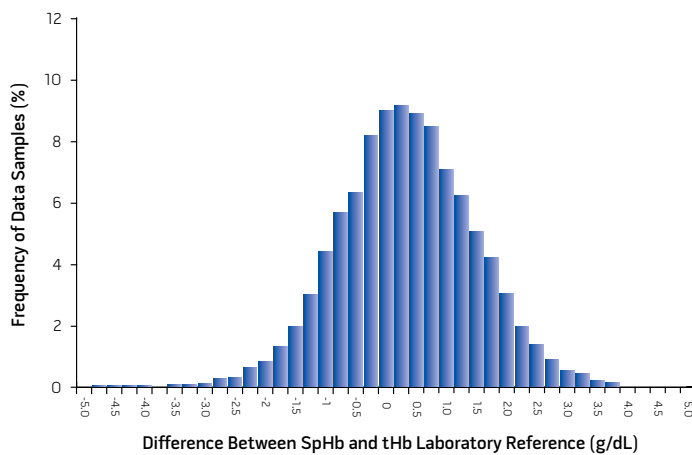
**Figure 2 – Maximum Sensitivity Scatter Plot of SpHb vs. tHb Measurements (N=12,622)**



**Figure 3 – Normal Sensitivity Mode: Histogram of Differences Between SpHb and tHb (N = 11,335)**



**Figure 4 – Maximum Sensitivity Mode: Histogram of Differences Between SpHb and tHb (N = 12,622)**



**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.

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