Noninvasive Next Generation SpHb® Technology

Quick, Noninvasive Total Hemoglobin (SpHb) Spot-check Monitoring with the Handheld Rad-67™ Pulse CO-Oximeter® and rainbow® DCI®-mini Sensor

How Does SpHb Measure Up?

- No calibration required by the end user
- SpHb spot-check monitoring in just a few simple steps
- SpHb spot-check monitoring results display in as few as 30 seconds
- Multiple physiologic parameters, including SpO_2, available simultaneously
- Noninvasive technology does not introduce risk of exposure to bloodborne pathogens
- Noninvasive hemoglobin spot-check monitoring can be both efficient and cost-effective

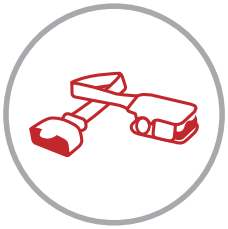
The following table represents the accuracy of SpHb measurements obtained using Rad-67 spot-check monitoring and tHb measurements using an invasive point-of-care device, each compared to a laboratory reference device.

Device	Subjects	Samples	Limits of Agreement[2]
SpHb vs Laboratory Hematology Analyzer	319	660	-1.82 to 2.07
Invasive Point-of-care Device (Capillary Blood Draw) vs Laboratory Hematology Analyzer	283	283	-2.5 to 1.98

Masimo study. Data collected at five different centers on healthy and sick subjects.

Masimo

Spot-check Monitoring Simplified



Measure SpHb, SpO_2, pulse rate (PR), and perfusion index (Pi) using the rainbow® DCI-mini sensor*

Label spot-check monitoring results with unique patient identifiers for simplified data management

SpHb spot-check monitoring results display in as few as 30 seconds

Flexible Options for Reviewing Patient Data

Review historical spot-check monitoring results directly on the device, sorted by unique patient identifier and date of measurement

Print measurement results at the point of care using a compatible wireless printer

Rad-67 with rainbow® DCI-mini Performance Specifications

ACCURACY	
Oxygen Saturation (SpO_2) Accuracy Range	70–100%
No Motion Adults/Pediatrics/Infants (A_{RMS})[1]	2%
Motion Adults/Pediatrics/Infants (A_{RMS})[1]	3%
Low Perfusion Adults/Pediatrics/Infants (A_{RMS})[1]	2%
Pulse Rate (PR) Accuracy Range	25–240 bpm
No Motion Adults/Pediatrics/Infants (A_{RMS})[1]	3 bpm
Motion Adults/Pediatrics/Infants (A_{RMS})[1]	5 bpm
Low Perfusion Adults/Pediatrics/Infants (A_{RMS})[1]	3 bpm
SpHb Limits of Agreement (LoA)	
Total Hemoglobin (SpHb) Accuracy Range	8–17 g/dL
Upper 95% LoA[2]	2.07
Lower 95% LoA[2]	-1.82

[1] A_{RMS} accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within ± A_{RMS} of the reference measurements in a controlled study. [2] The differences between measurements by the two methods are used to calculate the mean and standard deviation. The lower 95% limit of agreement is the mean minus 1.96 standard deviation and the upper 95% limit of agreement is the mean plus 1.96 standard deviation. These limits are expected to contain 95% of the differences between measurements between the two methods in controlled environments. Accuracy testing for SpHb was performed on healthy and sick subjects.

* SpHb indicated for adult patients only.

SpHb monitoring with Rad-67 is not intended to replace laboratory blood testing.
Blood samples should be analyzed by laboratory instruments prior to clinical decision making.
SpHb is not intended for use on pediatric patients, pregnant patients, and patients with renal disease.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

Rad-67 is not licensed for sale in Canada.

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