

Masimo Announces Full Market Release of Next Generation SpHb® Spot Check Pronto®



Masimo has announced the full market release outside the U.S. of the Pronto® Pulse CO-Oximeter® with Next Generation SpHb® Spot Check technology. Next Generation Pronto features rainbow SET™ technology, for noninvasive spot checking of total hemoglobin (SpHb), oxygen saturation (SpO2), pulse rate (PR), and perfusion index (PI).

In addition to the Next Generation SpHb technology, Masimo has also released the rainbow® DCI®-mini reusable sensor to accompany the Pronto. The DCI-mini is a universal sensor usable on patients greater than 3 kg, making Pronto an even more versatile solution.

The Next Generation SpHb technology in Pronto offers motion tolerance and a 40% reduction in time to display SpHb results. Field accuracy has been improved in the range of 6 to 11 g/dL, and is comparable to certain portable invasive point of care devices.

"This is a significant enhancement to the noninvasive measurement we introduced 7 years ago," stated Joe Kiani, Founder and CEO of Masimo. "Since then, all of the clinical outcome studies we're aware of on our continuous SpHb technology have been positive,¹⁻³ which is something that couldn't be said for standard pulse oximetry before the introduction of Masimo SET SpO2. We will continue to improve SpHb until it has the same measure-through motion and low perfusion performance as our SET SpO2 technology."

An upgrade program will be available for qualified existing Pronto customers. Pronto with Next Generation SpHb and the DCI-mini reusable sensor have not received FDA510(k) clearance and are not currently available for sale in the United States.

References

1. Ehrenfeld JM, Henneman JP, Bulka CM, Sandberg WS. Continuous Non-invasive Hemoglobin Monitoring during Orthopedic Surgery: A Randomized Trial .2014. *J Blood Disorders Transf.* 5:237.
2. Awada WN, Mohmoued MF, Radwan TM, Hussien GZ, Elkady HW. Continuous and noninvasive hemoglobin monitoring reduces red blood cell transfusion during neurosurgery: a prospective cohort study. *J Clin Monit Comput.* 2015 Dec;29(6):733-40.
3. Ponsonnard S, Yonnet S, Marin B, Cros J, Ben Miled S, Nathan N. "Continuous Hb and plethysmography variability index (PVI) monitoring is associated to a decreased mortality at the scale of a whole hospital." Proceedings of the European Society of Anaesthesiology's Euroanaesthesia 2015 Annual Congress, May 30-June 2, Berlin, Germany, 16AP3-2, Room A1 – Poster Abstract Presentation Session, e-Board 8.

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