

## FDA Clearance for Masimo O3® Regional Oximetry for Extended Use in Cerebral & Somatic Applications



Masimo today announced that O3® Regional Oximetry has received FDA clearance for expanded use in monitoring somatic tissue oxygenation saturation in all patient populations and monitoring relative changes in hemoglobin, oxyhemoglobin, and deoxyhemoglobin in adult brains. With this FDA clearance, O3 is now indicated for use in both cerebral and somatic applications, both in the U.S. and in CE mark countries, for all patient populations.

This press release features multimedia. View the full release [here](#).



Masimo Root® with O3® Regional Oximetry (Photo: Business Wire)

O3 Regional Oximetry provides regional or tissue hemoglobin oxygen saturation with a trending specification of 3% ARMS\* (cerebral and somatic, all ages) and absolute accuracy specifications of 4% ARMS (cerebral, adults) and 5% ARMS (cerebral, pediatric patients) through the use of O3 multi-wavelength sensors and O3 Regional Oximetry near-infrared spectroscopy (NIRS) technology. Unlike peripheral pulse oximetry, which reflects the body's general arterial blood oxygenation, O3 provides information about the local tissue's hemoglobin oxygen saturation, both in cerebral and somatic applications. This information provides additional insight that may help inform clinicians of changes in cerebral or somatic tissue oxygen levels. Monitoring renal tissue oxygenation in neonates has been found to help provide early warning of renal dysfunction.<sup>1</sup> Monitoring both brain and somatic tissue oxygenation simultaneously may further improve clinicians' ability to provide rapid and accurate care.<sup>2</sup>

André Denault, MD, PhD, Department of Anesthesiology, Critical Care Program at the Montreal Heart Institute and Central Hospital of the University of Montreal, said, "There is a growing interest in the use of somatic NIRS owing to the association of cerebral and somatic desaturation with unfavorable outcomes in shock states. As an addition to O3 cerebral oximetry, the somatic component could serve as an earlier warning of impaired tissue perfusion. Somatic NIRS has been validated as a monitor of peripheral perfusion and shows an excellent correlation with peripheral perfusion compared with radionuclide plethysmography. As previously reported,<sup>3</sup> cerebral and somatic NIRS combined with bedside whole-body ultrasound can help in early detection of different types of shock to formulate proper therapeutic strategies."

Along with FDA clearance for somatic monitoring, the O3 measurements  $\Delta\text{cHb}$ ,  $\Delta\text{O2Hb}$ , and  $\Delta\text{HHb}$  are cleared for the monitoring of relative changes in oxygenated hemoglobin ( $\Delta\text{O2Hb}$ ), deoxygenated hemoglobin ( $\Delta\text{HHb}$ ), and total hemoglobin ( $\Delta\text{cHb}$ ) in adult brains. With the expanded indications for  $\Delta\text{cHb}$ ,  $\Delta\text{O2Hb}$ , and  $\Delta\text{HHb}$ , clinicians gain information that may provide insight into the dynamic relationship between oxygen and hemoglobin in the brain that brain oxygenation saturation (rSO<sub>2</sub>) alone may not provide.

Dr. Aamer Ahmed, FRA FESC FACC, Consultant Cardiovascular Anesthesiologist at University Hospitals of Leicester, UK, said, “When using regional oximetry to monitor the brain, rSO<sub>2</sub> helps track the oxygenation state of the brain, but understanding the dynamic variations in rSO<sub>2</sub> is even more valuable. Changes in rSO<sub>2</sub> may be a function of a change in hemoglobin or perfusion, or may result from an oxygen desaturation event. In my practice, I use Masimo O3  $\Delta\text{cHb}$ ,  $\Delta\text{O2Hb}$ , and  $\Delta\text{HHb}$  to gain insight into the relative changes in hemoglobin and perfusion in the brain to help enable earlier detection and intervention during adverse changes to cerebral blood flow.”

O3 seamlessly integrates with Masimo SedLine® brain function monitoring on the Root® Patient Monitoring and Connectivity Platform, a powerful, expandable hub that integrates an array of technologies, devices, and systems to provide multimodal monitoring and connectivity solutions. Root’s plug-and-play expansion capabilities allow clinicians to simultaneously monitor with O3, SedLine, and other measurements, such as SET®Measure-through Motion and Low Perfusion™ pulse oximetry, providing clinicians with expanded visibility of oxygenation status. Additional modalities available on Root include advanced rainbow® noninvasive measurements such as total hemoglobin (SpHb®) and PVi® (an indicator of fluid responsiveness), NomoLine® capnography, and more – all via an easy-to-interpret, customizable display. Using Root in combination with Masimo Iris Gateway®, monitoring data from O3 can be automatically charted in electronic medical records (EMRs).

Joe Kiani, Founder and CEO of Masimo, said, “O3’s expanded indication as a monitor of the oxygenation and deoxygenation components of cerebral tissue, along with the oxygen saturation of somatic tissue, represents an important milestone in helping clinicians and researchers shed additional light on how the body utilizes oxygen and in uncovering organ hypoxemia.”

Published on : Mon, 31 Aug 2020