

Masimo Announces 510(k) Clearance for O3™ Regional Oximetry



[Masimo](#) has announced FDA 510(k) clearance for O3™ regional oximetry. Regional oximetry, also referred to as tissue or cerebral oximetry, may help clinicians monitor cerebral oxygenation in situations in which pulse oximetry alone may not be fully indicative of the oxygen in the brain due to various factors, such as the type of clinical procedure being performed.

O3 regional oximetry uses near-infrared spectroscopy (NIRS) to continuously monitor absolute and trended regional tissue oxygen saturation (rSO₂) in the cerebral region. In a study on 27 subjects published in *Anesthesia and Analgesia* in 2014, Dr. Daniel Redford of the University of Arizona compared cerebral oxygen saturation measurements obtained from O3 with saturations obtained from blood samples (SavO₂) through induced hypoxia.¹ O3 regional oximetry provided absolute root-mean-squared error of 4% and relative root-mean-squared error of 2.1%.¹ This study did not require that end tidal carbon dioxide (EtCO₂) levels be fixed in the study protocol, allowing the rSO₂ measurement to be responsive to changes in tissue oxygen saturation due to changes in CO₂ in the blood. Follow up studies with O3 extended the subject pool to 74 subjects and demonstrated that O3 maintained its absolute and relative accuracy.²

“O3 regional oximetry delivers again on Masimo’s technical prowess and gives clinicians access to valuable, accurate data about cerebral oxygen saturation,” stated Joe Kiani, Founder and CEO of Masimo. “With the addition of O3 regional oximetry to the Root platform, clinicians can simultaneously access rSO₂ and other measurements including SedLine brain function monitoring, Masimo SET SpO₂, PVI, and SpHb monitoring – all in one monitoring platform.”

O3 regional oximetry is currently intended for use with adults weighing 40 kg (88 lbs) or greater.

References

1. Redford D, Paidy S, Kashif F. Absolute and Trend Accuracy of a New Regional Oximeter in Healthy Volunteers During Controlled Hypoxia. *Anesth Analg*. 2014 Dec;119(6):1315-1319.
2. Masimo FDA submission data on file.

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