

## Masimo Announces CE Marking for Pediatric O3™ Regional Oximetry



Masimo has announced the CE marking for the pediatric indication for O3™ regional oximetry with the O3 pediatric sensor. Regional oximetry, also referred to as tissue or cerebral oximetry, helps clinicians monitor cerebral oxygenation.

O3 regional oximetry uses near-infrared spectroscopy (NIRS) to continuously monitor absolute and trended regional tissue oxygen saturation (rSO<sub>2</sub>) in the cerebral region. Early detection and correction of imbalances in oxygen delivery to the brain and vital organs are important tools in helping patients avoid postoperative morbidity and adverse outcomes.<sup>1</sup> With the release of the O3 pediatric sensor, O3 regional oximetry monitoring of rSO<sub>2</sub> is now available to pediatric patients weighing less than 40 kg (88 lbs).

“O3 regional oximetry provides access to valuable data about cerebral oxygen saturation, and studies have shown that the risks of cerebral desaturations include neurological injury<sup>2,3</sup>, increased length of hospital stays<sup>3</sup>, increased time on mechanical ventilation<sup>4</sup>, and other adverse outcomes<sup>5</sup>,” said Joe Kiani, Founder and CEO of Masimo. “With adult trend accuracy of 3% and absolute accuracy of 4% without controlling CO<sub>2</sub>, and trend accuracy of 3% in pediatric patients<sup>6</sup>, Masimo O3 should help clinicians build a better picture of brain oxygenation – and hopefully better outcomes for all of their patients, including pediatric ones.”

Masimo O3 regional oximetry and SedLine® brain function monitoring are both available on a single platform, Masimo Root® – opening up a path to better understanding of the brain.

O3 regional oximetry for use with adults weighing 40 kg (88 lbs) or greater has received FDA 510(k) clearance. O3 regional oximetry for use with pediatric patients weighing less than 40 kg (88 lbs) has not received FDA 510(k) clearance; the O3 pediatric sensor is not currently for sale in the United States.

### References

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4. Goldman S, Sutter F, Ferdinand F, Trace C. Optimizing intraoperative cerebral oxygen delivery using noninvasive cerebral oximetry decreases the incidence of stroke for cardiac surgical patients. *The heart surgery forum.* 2004;7(5):E376-381.
5. Deschamps A, Lambert J, Couture P, et al. Reversal of decreases in cerebral saturation in high-risk cardiac surgery. *Journal of cardiothoracic and vascular anesthesia.* 2013;27(6):1260-1266.
6. Masimo data on file.

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