
Masimo Announces FDA 510(k) Clearance for TFA-1™ Single-Patient-Use Forehead Senso



Masimo announced today FDA 510(k) clearance for the TFA-1™ Single-Patient-Use Adhesive Forehead Sensor. This single-patient-use sensor allows clinicians to monitor patients using Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry from an alternative monitoring site, the forehead, rather than a finger.

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Masimo TFA-1 Single-Patient-Use Adhesive Forehead Sensor

Forehead sensors may provide oxygen saturation measurements that are less susceptible to peripheral perfusion changes, and were shown in a 2004 study to have faster detection of desaturation and resaturation, as compared to digit sensors.¹ Forehead sensors can also be easily accessed during surgery and resuscitation and on patients with finger deformities or whose fingers are not accessible. As a single-patient-use sensor, TFA-1 avoids the management complexities (cleaning, storage, and inter-department transport) that accompany reusable sensors.

Masimo SET® includes measurement of oxygen saturation (SpO₂), pulse rate (PR), perfusion index (PI), and PVI®, a measure of the dynamic changes in PI that occur during the respiratory cycle. Masimo SET® addresses the challenges of low perfusion and motion artifact that limit conventional pulse oximetry by harnessing the power of adaptive filters to reduce measurement inaccuracy. Masimo SET® helps clinicians monitor more than 100 million patients a year² and is used by 8 of the top 10 hospitals listed in the 2016-17 U.S. News and World Report Best Hospitals Honor Roll.³

Source & Image Credit : [Masimo](#)

References

1. Redford DT et al. Intraoperative Perfusion Changes at Two Pulse Oximetry Monitoring Sites: The Digit vs. the Nare. *Anesth Analg.* 2004;98(2S)S-94.
2. Estimate: Masimo data on file.
3. <http://health.usnews.com/health-care/best-hospitals/articles/best-hospitals-honor-roll-and-overview>.

Published on : Mon, 19 Dec 2016