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Masimo Announces FDA Clearance of Root Patient Monitoring Platform

Masimo has announced FDA 510(k) clearance of the Root™ patient monitoring and connectivity platform that is destined to transform patient care throughout the hospital. High-impact innovations in Root that are now available in the U.S. include:

- Iris™ - Built-in connectivity gateway through Iris™ for standalone devices such as IV pumps, ventilators, hospital beds, and other patient monitors
- MOC-9™ - Flexible measurement expansion through Masimo Open Connect™ (MOC-9™) with MOC-9 modules from Masimo or third-party measurement by other companies to expand the platform's measurements and capabilities. New MOC-9 modules will require new 510(k) clearances
- Capnography - ISA™ CO2 sidestream module featuring fast warm-up time and the innovative and cost-effective NomolineTM sampling line
- Wireless functionality – Capable of transmitting information through Bluetooth and Wi-Fi.

Masimo's breakthrough rainbow® and SET® measurements from the Radical-7® handheld monitor that docks into Root enable instant interpretation with a 10-inch high visibility, intuitive navigation touchscreen display. In addition, the previously released SedLine brain function monitoring MOC-9 module for Root advances brain function monitoring to improve the care of patients under anesthesia or sedation.

Built-in Connectivity Gateway through Iris™

Despite medical technology advances, the lack of device communication and integration creates risks to patient safety in hospitals around the world. Without device interoperability, critical patient information can go unnoticed – leaving busy clinicians in the dark and vulnerable patients in danger. Existing approaches for device interoperability require separate hardware, software, and/or network infrastructure, which can clutter the patient room, increase complexity, burden IT management, and increase costs.

To address these challenges, each Root can be used as a connectivity gateway to connect multiple standalone devices – such as IV pumps, ventilators, hospital beds, and other patient monitors – when used as part of the optional Iris connectivity package in Masimo Patient SafetyNet™. Iris allows standalone device information to be remotely viewed with Patient SafetyNet, transmitted through notification systems or sent to electronic health record (EHR) systems to facilitate better patient care. Iris connectivity enables standalone devices to leverage existing network infrastructure and reduce costs while enhancing clinical workflows and decision support to improve patient safety, whether the clinician is at the bedside, down the hall, or on the next floor.

ISA Capnography MOC-9 Module

The ISA CO2 module for Root provides ETCO2 and respiratory rate measurements with crisp waveforms and fast warm-up time. In addition, customers can use the Nomoline™ "No Moisture" fluid protection sample line, which is specially designed for low-flow applications and excellent response time – making gas measurement possible even at high respiratory rates. Nomoline supports extended monitoring in low- and high- humidity environments to reduce disposable costs, and can be used for all types of patients from infants to adults.

MOC-9: Designed for Third-Party Development of Expanded Measurements

Root is also designed to allow other companies to expand the platform's measurements with their own measurements through MOC-9 by following Masimo's established development and validation process.

Market barriers and development costs often keep small, innovative companies from delivering their products to clinicians and patients who need them most. With Root's accessible patient monitoring platform, Masimo is offering an open invitation to other companies to develop and commercialize their innovations through Masimo's ever-expanding customer base.

"With the new FDA clearance for Root, Masimo is eager to help U.S. clinicians usher in a new era of patient care and improved patient safety with a platform that should measurably improve the performance and cost curve," said Joe Kiani, founder and CEO of Masimo. "Root can be a hub at the bedside, enable Masimo's breakthrough noninvasive measurements to be used by experts and novices with the trend and analog views, take advantage of a rich set of additional measurements, and allow other companies a robust platform on which to develop other innovative measurements via MOC-9

Source: Masimo
Image caption: Root with Sedline brain functioning monitoring and ISA sidestream capnography

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