

Masimo Announces FDA 510(k) Clearance for Root® with Noninvasive Blood Pressure and Temperature



Masimo announced today FDA 510(k) clearance for noninvasive blood pressure and temperature measurements for the Root® patient monitoring and connectivity platform.

Root with noninvasive blood pressure from SunTech Medical enables clinicians to measure arterial blood pressure for adult, pediatric, and neonatal patients, with three distinct measurement modes: spot-check, automatic interval, and stat interval. The temperature module from Welch Allyn is indicated to measure the temperature of adult and pediatric patients.

With the addition of noninvasive blood pressure and temperature to the Root platform, clinicians can easily and automatically chart vital signs data directly from Root. Enhancing the solution with Masimo Patient SafetyNet™ allows data to be sent directly to the patient's electronic medical record (EMR) while alarms and alerts are seamlessly forwarded to the patient's clinician.

Root with noninvasive blood pressure and temperature provides a monitoring solution for step-down, medical, and surgical environments. Clinicians on a unit equipped with this technology are expected to be able to continuously monitor their patients and automatically document vital signs while improving workflow, allowing them to spend more time with their patients.

Masimo Root® with noninvasive blood pressure and temperature

Root offers a high visibility display with intuitive, touchscreen navigation for easy and adaptable use in any hospital environment:

- > Integrates measurements from Masimo Radical-7® handheld for SET® Measure-through Motion and Low Perfusion™ pulse oximetry, continuous hemoglobin (SpHb®), PVI®, and other noninvasive rainbow® parameters, or the Radius-7™ patient-worn monitor for continuous pulse oximetry and respiration rate monitoring of mobile patients.
- > Flexible measurement expansion through Masimo Open Connect™ (MOC-9™), including:
- > ISA™ CO2 capnography for sidestream monitoring featuring Nomoline™ technology, allowing for the cost-effective use of consumables.
- > Additional MOC-9 modules available include measurements such as SedLine® brain function monitoring.
- > Automatic display of parameters, waveforms, and viewing configuration based on the clinician's presence through MyView™ technology enabled with Patient SafetyNet™ version 5000 or higher.
- > Optional USB barcode scanner for easy patient association.
- > Available roll stand for ease of transport throughout the hospital.
- > Built-in wireless radio allows data to be transmitted continuously during rounds.

"We are excited to bring this addition to the U.S. market," said Joe Kiani, Founder and CEO of Masimo. "We designed Root to do for patient monitoring what PCs did for computing. By creating a platform which allows third-party measurement expansion, with an intuitive user interface and network connectivity, we hope to speed up innovation while reducing the cost of monitoring, as well as potentially improving patient care and patient safety."

Source & Image Credit: Masimo
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