

Masimo Announces FDA Clearance of Radius PCG™ for Root® Patient Monitoring & Connectivity Platform



[Masimo](#) (NASDAQ: MASI) announced today that Radius PCG™, a portable real-time capnograph with wireless Bluetooth® connectivity, has received FDA 510(k) clearance. Radius PCG connects with the Root® Patient Monitoring and Connectivity Platform to provide seamless, tetherless mainstream capnography for patients of all ages. Radius PCG joins the growing family of tetherless Masimo technologies that includes Radius PPG™, which offers Masimo SET® Measure-through Motion and Low Perfusion pulse oximetry, and Radius T⁹™, which provides continuous temperature measurements. Radius PCG requires no routine calibration, with accurate end-tidal carbon dioxide (EtCO₂) and respiration rate measurements and continuous EtCO₂ waveforms displayed within 15 seconds—all in a small, portable package that can fit in the palm of a hand.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20210412005449/en/>

“Radius PCG has been a game changer for our clinical team,” commented Joseph DiMartino, MSN RN, NE-BC, CCRN-K, Associate Vice President of Nursing at Temple University Hospital in Philadelphia. “It provides us with a portable and rapid measure of capnography for confirming airway placement in accordance with AHA guidelines.”

Wirelessly connected to Root, Radius PCG presents a compelling mainstream capnography solution, offering:

- **Cable-free Capnography:** High-quality capnography without a tethered connection to Root reduces the possibility of an interruption in capnography monitoring by minimizing tugging on the breathing circuit. In busy operating rooms, where space is already at a premium, and where capnography cables can easily be pulled and dropped on the floor—potentially damaging the fragile and expensive capnography sensor head—the reduction in clutter may be especially welcome.
- **Automated Documentation:** Root, in conjunction with the Masimo Hospital Automation™ Platform, automates electronic charting of patient data, including the data collected by Radius PCG, in hospital electronic medical record (EMR) systems, to simplify and speed workflows, as well as reduce the likelihood of transcription errors.¹
- **Maximized Data Visibility and Manipulation:** Root’s large, multi-touch, high-resolution screen provides an easily interpretable secondary display of large, crisp EtCO₂ waveforms, improving visibility and assisting clinicians in identifying wave patterns suggestive of airway obstruction or tube dislodgement. Clearly displayed trend data for up to 96 hours helps clinicians review patient progress over time, helping guide ventilation efforts. And the intuitive touch-screen interface allows clinicians to quickly adjust the trend display range and configure alarm settings to meet the needs of each patient.
- **Hassle-free Connectivity:** Radius PCG quickly and effortlessly pairs with Root via Bluetooth, supporting seamless integration into clinical workflows while providing the benefits of reliable capnography.

Tom Friedland, MD, Emergency Medicine Physician, described Radius PCG as “the easiest and most affordable solution to switch your hospital from the unreliable color change CO₂ detector to waveform capnography. #NoTraceWrongPlace.”

“Radius PCG is indispensable for emergencies, as well as for monitoring the COVID patients in our house,” added Kai Schurig, Head of the

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Biomedical Department at Marien Hospital in Hamburg, Germany. "These handheld devices are very reliable and fail very rarely. The users are very satisfied and treat the device accordingly."

Root is a powerful, expandable hub that integrates an array of technologies, devices, and systems to provide multimodal monitoring and connectivity solutions. Root's plug-and-play expansion capabilities allow clinicians to simultaneously monitor with Radius PCG and many other measurements, such as Masimo SET®, advanced rainbow® Pulse CO-Oximetry measurements, O3® regional oximetry, and SedLine® brain function monitoring, for expanded visibility of patient status. Using Root in combination with the Hospital Automation Platform, monitoring data from all connected devices can be automatically charted in EMRs.

Joe Kiani, Founder and CEO of Masimo, said, "With its wireless connectivity, Radius PCG is a powerful and useful tool for assessing end-tidal CO2 in a multitude of clinical scenarios. Masimo continues to make clinically relevant, accurate patient data available, helping clinicians gain the insights they need to make the best decisions and improve patient outcomes."

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