
Masimo Announces FDA 510(k) Clearance of Radius T⁹™ for Prescription and Over-the-Counter (OTC) Use



The Radius T⁹ Wearable Continuous Body Temperature Thermometer Is Now Available for Use in Hospital and at Home

[Masimo](#) announced today that Radius T⁹™, a wearable, wireless thermometer that measures body temperature continuously and noninvasively, has received FDA 510(k) clearance for both prescription and over-the-counter (OTC) use on patients and consumers five years and older. Featuring continuously trending temperature measurements and Bluetooth® connectivity, Radius T⁹ automates remote, continuous body temperature status for clinicians through its paired connection to a Masimo patient monitoring or telehealth solution, and for consumers through the Masimo Radius T⁹ smartphone application. Radius T⁹ is part of 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 PCG™, which provides mainstream capnography.

This press release features multimedia. View the full release [here](#)

For prescription use, Radius T⁹ is compatible with both the Root® Patient Monitoring and Connectivity Hub and the Rad-97® patient monitor for use in the hospital, as part of the Masimo Hospital Automation™ platform. Radius T⁹ can also be paired to a patient's smartphone using the Masimo SafetyNet™ app, for remote patient management from the home or other care location. The wireless thermometer is designed to help streamline workflows, with its convenient wearability, continuous measurements, and wireless connectivity, reducing the need for intermittent manual temperature checks with traditional probes that require a clinician's presence at the bedside. Each Radius T⁹ wireless thermometer is single-patient use, to reduce the risk of cross-contamination between patients, with an 8-day battery life and shower-proof adhesive, reducing the need to remove or replace the sensor—thus supporting a hospital's or caregiver's temperature monitoring and infection control workflow.

Using a proprietary algorithm, Radius T⁹ provides continuous body temperature measurements that are approximations of sublingual temperatures captured from an oral probe. Radius T⁹ supports continuous body temperature performance that goes beyond simple skin surface temperature measurements, and remains reliable even when environmental temperatures are fluctuating. Radius T⁹ provides trended data to help clinicians manage and review a patient's high fever risks and fever progress over time.

Radius T⁹ is easily integrated into the Masimo Hospital Automation platform, through Root or Rad-97, allowing automatic transfer of continuous body temperature data to a hospital's electronic medical records (EMRs) or surveillance monitoring solution, thus streamlining clinicians' ability to gain a more insightful picture of each patient's physiological status, regardless of the clinician's physical location.

For consumers, Radius T⁹ represents a paradigm shift in thermometry by making it continuous, wearable, and hassle-free. Traditional periodic and invasive methods depend on the user repeatedly conducting a series of steps that can interrupt daily activities, including sleep, and can miss body temperature trends and patterns. With a traditional thermometer, a person may only notice a spike in temperature hours after a spike has occurred, or may not even become aware of it if it is during sleep. By contrast, Radius T⁹ continuously measures temperatures and seamlessly transmits data and customizable temperature notifications to the Masimo Radius T⁹ app on the user's smartphone – helping caregivers, such as parents, monitor loved ones' temperatures even while they sleep and providing continuous insight into changes and trends in their temperature. In addition, Radius T⁹ is applied comfortably on the upper chest, avoiding the potential discomfort of other wearable devices that rely on placement in the armpit.

Joe Kiani, Founder and CEO of Masimo, said, "Radius T⁹ was first made available in the U.S. under an FDA COVID-19 enforcement policy for thermometers as part of Masimo SafetyNet – where it quickly demonstrated its value in improving clinician workflows through its continuous, remotely accessible body temperature measurements for patients recovering or quarantined at home. Now, with the FDA 510(k) clearance, the

availability of the Radius T⁹ is being expanded for use by both clinicians and consumers to help monitor and track body temperatures in all thermometer applications.”

Published on : Mon, 21 Jun 2021