

# FDA Clears Caretaker Medical's Wireless Monitor for Continuous, NonInvasive Cardiac Output, Stroke Volume & Hemodynamics

*VitalStream™ is the World's Only Wireless Wearable with FDA Clearance for Continuous Blood Pressure, Cardiac Output & Hemodynamics: with a simple Finger Sensor*

CHARLOTTESVILLE, VA, USA, April 25, 2022 /EINPresswire.com/ -- [Caretaker Medical](https://www.caretakermedical.com), a digital health leader in continuous “beat by beat” wireless patient monitoring technologies, today announced that it has received FDA 510(k) Clearance for four new continuous hemodynamic parameters, adding cardiac output, stroke volume, heart rate variability, and left ventricular ejection time to its [VitalStream™](https://www.vitalstream.com) non-invasive patient monitoring platform. This is the company's 5th FDA Clearance expanding the capabilities of its industry leading VitalStream™ wireless wearable, which is built for high-acuity, ICU-grade hemodynamic monitoring without limiting patient mobility or requiring invasive catheters and wires that tether patients to bedside equipment.

The new advanced hemodynamic measurements are built on Caretaker's proprietary Pulse Decomposition Analysis ([PDA™](https://www.pda.com)) waveform analysis technology which uses a simple and comfortable Finger Sensor to measure continuous cuffless blood pressure and hemodynamics to eliminate “blind-spots” between manual spot-check measurements and enable high-acuity, uninterrupted monitoring across the continuum of care, including critical-care, sub-acute, emergency, medical-surgical floors, hospital-at-home and other environments. VitalStream™ provides actionable, beat-by-beat data to help clinicians identify patient deterioration earlier, intervene earlier, and optimize treatment decisions such as whether and when to administer fluids, drugs, or therapies.



Caretaker Medical's FDA-Cleared VitalStream Wearable Monitor for Continuous Non-Invasive Blood Pressure, Cardiac Output, Advanced Hemodynamics, and Vitals untethers patients from Invasive Catheters & Wires for uninterrupted physiological insights with full mobility

Continuous hemodynamic monitoring is performed to assess the impact that surgery, anesthesia or critical illness may have on a patient and to guard against adverse outcomes from hypotension or hypoperfusion. Post-operative hypotension is common and strongly associated with major vascular events. Complications of untreated hypotension with poor cardiac output can be severe and may lead to multi-organ failure and ultimately death . Compared to existing invasive monitoring and expensive non-invasive alternatives, Caretaker Medical's wireless and non-invasive advanced hemodynamic parameters are expected to reduce risk and cost, increase patient mobility, and enable clinicians & patients to benefit from comfortable, continuous, high-acuity monitoring.



Caretaker Medical's FDA-Cleared VitalStream Wireless Wearable for Continuous Non-Invasive Blood Pressure, Cardiac Output, and Advanced Hemodynamics

“Post-operative hypotension is a frequent occurrence that is unrecognized with intermittent spot checks-based monitoring in most hospital ward patients. Myocardial injury is strongly

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*Dr. Ashish Khanna, M.D. Wake Forest University School of Medicine*

associated with hypotension in this period of recovery from surgery,” said Ashish Khanna, M.D., associate professor, vice chair for Research, Department of Anesthesiology, Section on Critical Care Medicine at Wake Forest University School of Medicine. “With FDA Cleared wireless wearable technology we can now continuously monitor a patient’s changing hemodynamic status through surgery and their entire hospital stay. The ability to noninvasively see beat-by-beat blood pressure and hemodynamic deterioration in real time allows us to make early interventions and potentially improve outcomes.”

VitalStream™ is a non-invasive alternative to invasive A-Lines, Arterial Catheters, and intrusive hemodynamic

methods, enabling ICU-grade patient monitoring across all points of care to provide clinicians with streaming patient data for early indications of patient deterioration, faster life-saving interventions, and better treatment decisions. VitalStream’s continuous beat-by-beat hemodynamics, waveforms, and vital sign data can be streamed remotely to the company’s

mobile app or secure cloud portal or integrated into other monitoring systems and EMR's with their FDA-cleared software interface SDK's.

"This FDA Clearance adding advanced hemodynamics to our wireless VitalStream platform reaffirms our strategy and leadership in developing new ICU-grade parameters never before available in one mobile device," said Jeff Pompeo, Caretaker Medical's CEO. "We are proud to offer the world's only wireless wearable to be clinically validated and FDA cleared to measure continuous Blood Pressure, Cardiac Output, and other Hemodynamic parameters continuously, non-invasively, and wire-free. With VitalStream's disposable Finger Sensor, 30-second setup time and intuitive workflow to boost nurse productivity, there is simply no reason for clinicians to rely on intermittent, spot-check measurements with 'blind spots' that miss critical clinical insights or endure wires and hoses that tether patients to bedside equipment."

Perioperative studies show continuous hemodynamic monitoring could save an estimated \$970 per patient and up to \$1.2 – \$4.6 million for a hospital with 10,000 non-cardiac surgical patients per year. Caretaker's VitalStream™ provides key benefits to hospitals, clinicians and patients by providing thousands of "beat-by-beat" insights per minute that can lead to early interventions and reduced complications; automating data collection and reporting for improved nurse productivity and staff optimization; and enabling faster patient transition to lower cost beds without compromising monitoring safety.

The VitalStream™ wireless hemodynamic monitor is available immediately in the USA directly from the company and its distribution partners. Caretaker Medical expects to make VitalStream™ available in Europe and Asia later this year.

#### About Caretaker Medical

Caretaker Medical, founded in 2014, is a Charlottesville, Virginia based digital health company focused on developing wireless, high-acuity, continuous patient monitoring platforms that improve outcomes, increase clinician productivity, and maximize patient compliance & comfort.

More information is available at <http://www.CaretakerMedical.net>.

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