FDA 510(k) Clearance for SimpleSense-BP

2024-01-06
Patented fabric-based nanosensor technology captures over 120+ million patient data points per day.

New York-headquartered Nanowear has received FDA 510(k) clearance for SimpleSense-BP, an advanced new cuffless continuous blood pressure monitor.

The company's SimpleSense remote diagnostic platform is a non-invasive undergarment which captures and analyzes 85+ unique biomarker data points across the heart, lungs, hemodynamic and central vascular system to monitor multiple patient vital signs such as heart rate and sounds, respiration rate, lung volume and physical activity.

The patented fabric-based nanosensor technology registers over 120+ million patient data points per day and the information collected generates AI-enabled real-time analytics in the form of easy-to-read reports for physicians, providing a smarter way to care for patients remotely.

The SimpleSense-BP clearance is in addition to the platform's previously cleared cardiopulmonary diagnostics, alongside 13 awarded and 12 pending patents covering its nanotechnology, scaled nanosensor manufacturing, multi-parametric wearable, software platform, ingestion pipeline and AI algorithms.

"Accelerated by the pandemic, the market has been eagerly searching for reliable, clinical-grade wearable and data service solutions," says Venk Varadan, CEO and co-founder of Nanowear. "Our nanotechnology and AI is capable understanding the individualised risk signatures and cardiopulmonary care pathways of each patient to enable precision medicine."

SimpleSense-BP has been extensively tested and is validated to track changes of above +/- 15mmHg systolic and +/- 10mmHg diastolic blood pressures over a continuous recording period across all classes of hypertension via the wearable undergarment.

NAMSA, the leading cardiovascular clinical research organisation, sees SimpleSense-BP as a breakthrough in customising clinical research.

“We often talk about whitecoat syndrome limiting our ability to understand the effect of therapeutics in blood pressure or other cardiopulmonary assessments,” says NAMSA chief medical officer, Ken Ouriel MD. “Just as a patient’s blood pressure may be high in a 30 second reading due to whitecoat syndrome, the same patient may reduce their blood pressure by breathing calmly for five minutes before the 30 second reading. So what are we actually learning about that individual patient or the therapeutic applied?

“To date, existing healthcare wearables and software platforms are either restricted in scope and time or are unreliable and unvalidated for what they can diagnose during ‘real-world’ conditions. Nanowear’s continuous device, software platform and AI algorithms can transform the way clinical research platforms operate. Efficiency, access, diversity and standardisation across geographies can be enhanced while significantly lowering costs.”

Read the original article on Innovation in Textiles.