

Empatica's Platform Receives New FDA Clearance for Cardiac Digital Biomarkers

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Powerful and comprehensive health monitoring platform now offers FDA-cleared biomarkers for pulse and respiratory rate

BOSTON, Nov. 2, 2023 /PRNewswire/ -- Empatica, a digital health and AI company developing medical-grade wearables and digital biomarkers for health monitoring and diagnostics, today announced US Food and Drug Administration (FDA) 510(k) clearance for two new digital biomarkers for its Empatica Health Monitoring Platform: pulse and respiratory rate.

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With the addition of pulse and respiratory rate, the Empatica Health Monitoring Platform now includes six FDA-cleared digital biomarkers, among the most offered for use in clinical trials. These are among the 128 digital measures supported by the platform, the largest offering available in a single solution, delivering confidence to a broad spectrum of health care professionals and researchers as they seek to validate treatments, better understand diseases, and innovate to improve health outcomes.

"We are delighted to announce the expansion of our Empatica Health Monitoring Platform to encompass two additional FDA-cleared biomarkers, pulse rate and respiratory rate," said Marisa Cruz, Chief Medical Officer at Empatica. "This clearance reflects our continued commitment to rigorous analytical and clinical validation of digital biomarkers for use in clinical research and patient care. The Empatica Health Monitoring Platform is a leading example of how reliable, accurate, and intuitive technology can support development of novel therapeutics and improve patient outcomes."

The Empatica Health Monitoring Platform is a full-stack remote health monitoring and data collection solution for research and healthcare professionals, built on data collected by the company's medical-grade, EmbracePlus wearable. In addition to the EmbracePlus wearable, the Empatica Health Monitoring Platform also includes Empatica's proprietary Care software suite, secure cloud infrastructure, and clinically validated digital biomarkers.

The Empatica Health Monitoring Platform received its initial FDA clearance in November 2022. Included within that clearance were clinically validated digital biomarkers used to monitor Electrodermal Activity, SpO2, skin temperature and movement during sleep. Beyond the FDA-cleared measures provided, the Empatica Health Monitoring Platform also offers access to raw data from the EmbracePlus sensors, and over 100 research-grade biomarkers, making it a highly capable and versatile measurement tool for today's clinicians and researchers.

To learn more about utilizing the Empatica Health Monitoring Platform, please visit us at <https://www.empatica.com/talk-to-our-team/>.

About Empatica

Empatica Inc is a pioneer in continuous, unobtrusive remote health monitoring driven by AI. Empatica's platform and technology are used by thousands of institutional partners for research purposes, in studies examining stress, sleep, epilepsy, migraine, depression, addiction, and other conditions. Its flagship medical wearable, EmbracePlus, has been developed with key partners including HHS, USAMRDC, and the NASA-funded TRISH.

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