

FDA-CLEARED

# Empatica Health Monitoring Platform

## FOR CLINICAL TRIALS

### About Empatica

Empatica is a digital healthcare company pioneering digital biomarker development and continuous patient monitoring driven by AI. The FDA-cleared Empatica Health Monitoring Platform consists of the medical-grade EmbracePlus wearable, software, and digital biomarkers, that can accurately and continuously monitor patient health remotely and unobtrusively, across a range of health conditions. Empatica's solutions are currently being used by thousands of research partners, institutions, and patients, to run decentralized clinical trials, develop novel digital biomarkers, conduct academic research with real-world data, and monitor neurological conditions.

### A committed team that knows your needs

- All our clients benefit from dedicated onboarding, an account manager, and site support to walk you through every step of the process
- We provide accelerated timelines, with immediate deployment and onboarding that can be delivered within weeks
- Start collecting data in less than 5 minutes with auto-generated, secure QR codes for patient enrollment
- We handle the logistics and provide IRB materials so you can focus on your research
- Dedicated customer and technical support across continents, providing prompt assistance when needed

### Clinical-quality data from everyday life



#### EmbracePlus

The world's most advanced wearable to collect clinical-grade data from everyday life



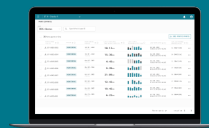
#### Care App

An intuitive app for patients that ensures engagement and timely troubleshooting



#### Empatica Cloud

Secure data storage and access directly from the Cloud



#### Care Portal

Remote enrollment, data collection, and adherence monitoring for sites

### Regulatory and Compliance

Empatica's constant and decisive efforts aim at ensuring the safety, effectiveness, and quality of its medical devices as well as providing products that meet customer, applicable statutory, and regulatory requirements.

FDA CLEARED  
K221282



FDA cleared as part of the Empatica Health Monitoring Platform  
Cleared measurements: SpO2, Skin Temperature, EDA, Sleep Detection, Pulse Rate, Respiratory Rate

# embrace<sup>PLUS</sup>

EmbracePlus has been designed to be a pleasure for patients to wear, making it the missing link between medical devices and consumer wearables. It continuously measures and records physiological parameters through its sensors, and streams the data via Bluetooth® to the companion Care App.

## Sensors

- ACCELEROMETER
- PERIPHERAL TEMPERATURE SENSOR
- GYROSCOPE
- ADVANCED OPTICAL PPG
- VENTRAL EDA SENSOR

## Also benefits from

- On-board memory
- Always-on E Ink display
- Waterproofing
- Button for event tagging
- Fast charging
- Customized data collection capabilities via sensor modes



## Care App

The Care app is the companion app for EmbracePlus, which enables the secure recording and transmission of raw data and digital biomarkers to the Empatica Cloud.

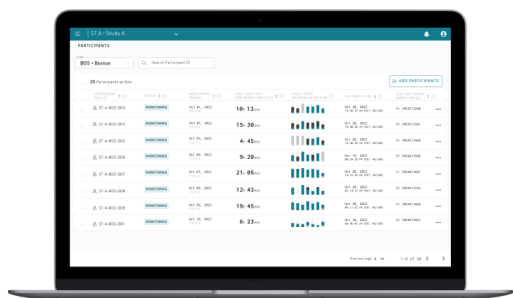
## Features

- Live system check for patients
- Notifications to maximize compliance
- Wearing time to provide daily feedback
- Intuitive color-coding to invite patient intervention where needed
- Available on iOS and Android, across most popular smartphone models
- Compatible smartphones may be provided upon request



## Care Portal

Opt for a fully-managed solution with the Care Portal. Manage patients across sites, while simultaneously visualizing and monitoring the digital biomarkers measured by EmbracePlus.



## Features

- Review patient data at a glance
- Easy online access from Empatica's secure cloud service
- Detailed view of individual patient digital biomarkers
- Visualize compliance directly in the Portal and receive regular adherence reports via email
- Explore different resolutions and timeframes
- View new data against patients' historical averages

## Empatica Cloud and Data

Combine EmbracePlus and the Care App for data collection and access, directly from the Empatica Cloud. 24/7 secure access to the data is available, and comes in the form of digital biomarkers, reports, and raw sensor data. All patient data is de-identified.

## Digital Biomarkers

- Pulse Rate
- Pulse Rate Variability
- Activity Counts
- Step counts
- EDA: Skin conductance level (SCL)
- Accelerometer Magnitude Standard Deviation
- SpO2
- Wearing Detection
- Respiratory Rate
- Skin Temperature
- Sleep Detection
- Activity Classification
- Activity Intensity
- Body Position
- MET
- Gait Speed

## Reports

- Wearing Detection
- Sleep
- Convulsive seizures
- Autonomic Arousal
- Actigraphy

If you are interested in finding out more about how the **Empatica Health Monitoring Platform** can enhance your trials, you can write to us at [research@empatica.com](mailto:research@empatica.com), or fill out [this quick form](#) and our team will be happy to provide more information and arrange a demo.