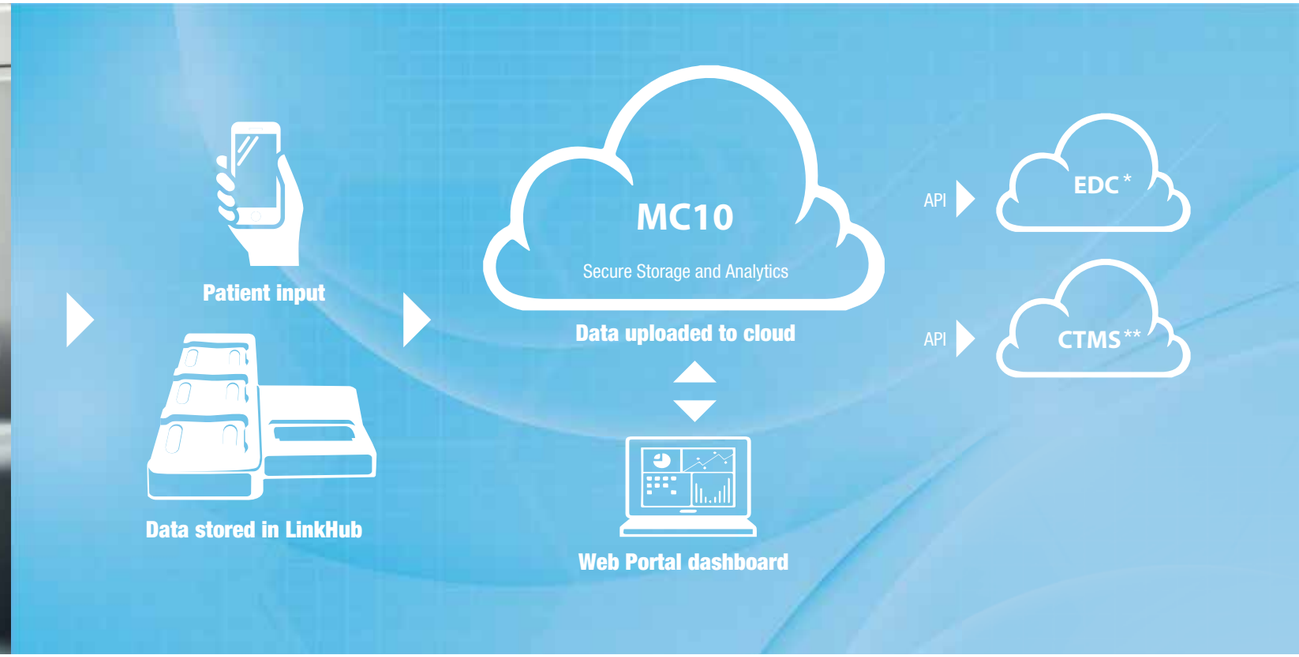
mc10®

BioStamp nPoint™

Bringing novel endpoints into focus



*Electronic Data Collection **Clinical Trial Management System

BioStamp nPoint
Making Virtual Clinical Trials a Reality

BioStamp nPoint is a FDA 510(k) cleared medical device designed to collect medical grade, clinical quality biometric, physiological and other eCOA data in a clinical trial setting. The system processes raw data into recognizable clinical metrics including vital signs, activity and posture classification, sEMG, and sleep metrics. The sensors are multi-modal, multi-location, rechargeable and reusable. Biostamp data are processed and stored in a secure cloud that can be synchronized with third party EDC and CTM systems.

BioStamp sensors can be worn on any of 25 locations, and thus discreetly collect targeted biometric data. The full system includes the sensors, 2-sided adhesives for adherence to the skin, a Link Hub for sensor recharging and data transfer, a dedicated smartphone for patient prompting and receipt of eCOA and other feedback, and secure cloud data storage. The system can be used in the clinic but is designed for use by study subjects in the home.

KEY FEATURES:

Enables Remote Trial Execution
- Optimized for unsupervised, in-home use
- Eliminates / reduces costly and inconvenient visits to clinic for data collection or clinical assessment

Single system replaces multiple disparate devices
- Supports delivery and collection of eCOAs, such as :
  - PRO
  - prescribed activities
  - diary functionality
- Broad functionality with single log-in

Single Point of Data Storage
- Cloud-based NOT device-based
- Automatic upload via WiFi or Cellular

Robust API Access
- Compliant with multiple Electronic Data Collection, Clinical Data Management and Clinical Trial Management Systems
- Streamlines the collection, processing and storage of subject data

Supports critical subject, site and cohort study insights
- Compliance
- Performance
- Risk Management

BioStamp® Sensors

Reusable, rechargeable, individually configurable, waterproof, wearable sensors adhered to the body via single-use adhesives. Data captured include 3-axis accelerometry, 3-axis gyroscopy and biopotential (HR, HRV, EMG). Sensors can be placed virtually anywhere on the body for targeted data collection.

Adhesive / Applicator

Sensors are attached to the skin by custom single-use double-sided adhesives that feature fully integrated hydrogel for enhanced skin/electrode conductivity. Adhesives are applied to the sensors using the applicator tool and then attached to the target body location.

Link Hub

Dedicated smartphone charging / sensor data synchronization platform for use in the home or clinic. Up to 3 Sensors can be wirelessly charged / synchronized simultaneously. Data are automatically uploaded to the secure MC10 Cloud via WiFi or cellular connection.

Investigator Portal

Web-client tool for trial study design and data collection configuration. Seamlessly synchronizes with sensors and smartphone and provides ongoing visibility into trial status, subject compliance, performance and reported assessments.

Mobile Devices

All systems are shipped with a dedicated smartphone that can be docked on the Link Hub when not in use. For in-home use, the Link App guides the subject through sensor application, trial activities, eCOAs, sensor removal, charging / synchronizing and data upload. For in-clinic use, the Sync App manages sensor removal, charging / synchronizing and data upload. An included tablet running the Investigator App allows clinicians / investigators to execute and manage studies in the clinic or lab.

Supported Metrics: (Lead II and thigh location)

Heart Rate
Heart Rate Variability
Respiration Rate
Sleep Onset, Duration, Wake
Activity Classification (standing, sitting, lying, step count, sleep, other)
Stationary Postural Classification (lying, standing, sitting)

Technical Specifications:

Size: 7.1 x 3.4 x 0.5cm (LxWxH) 8.7grams

Power: Lithium Polymer rechargeable battery (30mAh) Wireless Charging <2.5 hour charge time

Wireless Communication: Bluetooth® LE

Memory: 64MB

Sensor Water Resistance: IPX7

Synchronization: <1sec over 24hrs

Sensors:

- **Accelerometer:** +/-2-16G
- **Gyroscope:** +/-250-2000 degrees/sec
- **Electrodes**: +/-300mV - 125-1000Hz sampling rate

Certifications:

Sensor: IEC 60601-1, FCC Part 15, Link Hub: IEC 60601-1, FCC Part 15 &18

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