

## MC10 Receives FDA 510(k) Clearance for the BioStamp nPoint™ System

Lexington, MA MC10 Inc., the company developing wearable systems for seamless healthcare data collection, announced today that their BioStamp nPoint™ system has received Food and Drug Administration (FDA) 510(k) clearance. BioStamp nPoint is a wireless, biometric data collection platform intended for use by healthcare professionals and researchers for the continuous collection of physiological data in the home or traditional healthcare settings. The system is designed for use in clinical trials and research studies where collection of relevant data is needed.

The BioStamp nPoint system includes numerous improvements and enhancements to BioStampRC®, its successful predecessor. The flexible, body-conforming rechargeable sensor patches are reusable and can record data for 24 hours. The system can be configured to measure, record and display general activity, postural classifications, vital signs and sleep metrics, all with clinically validated accuracy. “The nature, location, and endpoints of clinical trials for new drug development are all evolving rapidly. The BioStamp nPoint system was designed and clinically validated to meet this rapidly growing and expanding unmet need. BioStamp nPoint produces clinical quality, medical grade physiological data from research subjects in their own homes, available to investigators from virtually anywhere.” commented Dr. Arthur Combs MD, Chief Medical Officer of MC10.

The BioStamp nPoint in-home kit includes a smartphone running the MC10 Link App that guides patients through sensor application, protocol specific tasks, prescribed activities and ePRO assessments. The BioStamp nPoint in-clinic kit includes a tablet running the MC10 Investigator App that allows for patient management and sensor command and control. Sensors are removed after use and placed on the included Link Hub to automatically recharge while simultaneously synchronizing collected data with the HIPAA Compliant MC10 Cloud. Processed metrics and raw data can be viewed through the Investigator Portal web-client or accessed through an API.

BioStamp nPoint offers clinical investigators the option of collecting validated metrics such as heart rate, step count or sleep disturbances as well as the raw data associated with each measurement. “We need objective, sensitive measures of health that can be assessed by anyone, anytime, anywhere. MC10's new sensor brings us one step closer to a reality that can improve health and accelerate the development of new therapies.” noted Dr. Ray Dorsey, MD, MBA and the Director of the Center for Health & Technology (CHET) at the University of Rochester, Rochester, NY.

The BioStamp nPoint system is configured and packaged to meet both in-home and in-clinic needs and is available for sale or rental beginning June 2018.

Contact Don Fuchs [dfuchs@mc10inc.com](mailto:dfuchs@mc10inc.com) for sales information

**About MC10, Inc.**

MC10 is a private company, backed by a strong syndicate of financial and strategic investors, that is improving human health through digital healthcare solutions. The company combines its proprietary ultra-thin, flexible body-worn sensors with advanced analytics to unlock health insights from physiological data. MC10 has received widespread recognition for its revolutionary technology and was recently named in Fast Company's Most Innovative Companies in 2016 as a leader in healthcare. MC10 is headquartered in Lexington, MA. Visit MC10 online at [www.mc10inc.com](http://www.mc10inc.com).

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