BioStamp nPoint™

Instructions for Use

℞ Only

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Introduction, Safety, and Component Overview

BioStamp nPoint™

System Description

BioStamp nPoint is a wireless remote monitoring platform intended for use by healthcare professionals and researchers for the continuous collection of physiological data in healthcare and home settings. BioStamp nPoint is designed to capture objective, real-world data from study subjects participating in clinical or academic studies, and may be used wherever collection of relevant data is needed.

BioStamp nPoint centers on body-worn BioStamp Sensors that can be worn for up to 24 hours at a time in both laboratory (clinic) and home settings. Investigators (either researchers or physicians) design studies and the data to be collected using a web-based study configuration tool, called the Investigator Portal. For laboratory or clinic ("Supervised") settings, BioStamp nPoint includes a Tablet Investigator Application ("Investigator App") to be used for the set-up and configuration of the sensors. When BioStamp nPoint is used in the home or outside of the clinic ("Remote") setting, study subjects interact with the system through a Mobile Phone Application called the "Link App." The recharging and data transmission hub ("Link Hub") is used to recharge the sensors and synchronize data from the Sensors. BioStamp nPoint includes an algorithm package that delivers a dashboard presentation of processed metrics on general activity (including step count and activity classification), heart rate, heart rate variability, posture (body position relative to gravity), sleep, and respiration during sleep. The system is also capable of surface electromyography and monitoring limb and body movements during daily living and sleep. Data are transmitted wirelessly from the Sensors through the Link Hub to the MC10 Cloud for storage, processing, and analysis.

Important Safety Information

Indications for Use
The BioStamp nPoint system is a wireless remote monitoring system intended for use by researchers and healthcare professionals for continuous collection of physiological data in home and healthcare settings. These physiological data include heart rate, heart rate variability, respiration rate, activity (including step count and activity classification), and posture (body position relative to gravity). The system is also intended for measurement of surface electromyography and to monitor limb or body movements during daily living and sleep. Data is transmitted wirelessly from the Sensors for storage and analysis.

The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor to provide physiological information. The data from the BioStamp nPoint system is intended for use by researchers and healthcare professionals for research applications or, at the discretion of a qualified healthcare professional, as an aid to diagnosis and treatment. The device is not intended for use on critical care patients.

Contraindications
The device is not intended for use on:
- patients who have implanted pacemakers or defibrillators
- patients with known allergies or hypersensitivities to adhesives or hydrogel

Warnings
- The wearable sensor may cause mild discomfort, skin irritation, redness, itching, rash or contact dermatitis in some individuals. The device should be removed if any pain or discomfort occurs.
- Histories of skin irritations should be considered prior to placing the wearable sensor on a patient
- The wearable sensor should not be applied to broken, damaged, or
- irritated skin.
- The wearable sensor should be removed prior to external defibrillation or an MRI scan and should not be used in the presence of strong
- electromagnetic fields.
- Keep Link Hub components, tablet, and mobile devices away from water and other liquids.
- No modification of this equipment is allowed.
- Clinical validation has not been performed on children or on patients who are pregnant or breastfeeding.

Precautions

- The wearable sensor should be removed prior to external defibrillation or an MRI scan.
- Sensors and Adhesive Stickers are non-sterile. Adhesives are single use only on a single patient.
- Do not apply the wearable sensor if it appears damaged
- Similar devices may cause signal interference during data transmission. If you experience this affect, avoid operating near interfering devices.
- Do not wear the device over regions of the body with excessive body hair. Excessive body hair should be removed prior to wear.
- No creams or lotions should be applied to the skin immediately prior to application of the wearable sensor
- Keep the device away from children and pets. The device may be a
- choking hazard, and may be harmful if swallowed.
- If any component of the BioStamp nPoint system fails to operate after attempting all suggested troubleshooting methods, contact your health care provider and/or study staff immediately.
- The battery used in this device may present a risk of fire, explosion or chemical burn if mistreated. Do not expose to excessive heat or fire. Do not crush, puncture, or incinerate as doing so can result in fire, explosion, or the release of toxic gases. Do not use or charge if unit appears to be leaking, discolored, deformed, or in any way abnormal.
- Return all components of the BioStamp nPoint system to your health care provider and/or study staff at the conclusion of your prescribed period of use.
- Dispose of the BioStamp nPoint system per local laws, care facility laws or hospital laws for routine/non-hazardous electronic waster.

Storage and Handling

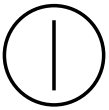
- Storage temperature range: 15 – 30°C
- Storage relative humidity range: 40 – 60% RH
- Ensure your hands are clean and dry before handling any system
- components. Gloves are recommended for healthcare professionals when handling the wearable sensor.

Changes or modifications made to this equipment not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note

Device and Packaging Symbols and Markings

Meaning	Symbol	Description
Instructions for Use		To identify the location where the operator's manual is stored or to identify information that relates to the operating instructions. To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.
Manufacturer		To identify the manufacturer of a product. This symbol shall be used filled in all applications to differentiate it from ISO 7000-2497.
Use by Date		To indicate that the device should not be used after the date accompanying the symbol, for example on a medical device or its packaging.
Ingress Protection Rating	IP24	This symbol indicates the ingress protection rating of the Link Hub
Catalogue Number	REF	To identify the manufacturer's catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.
Batch Code	LOT	To identify the manufacturer's batch or lot code, for example on a medical device or the corresponding packaging. The code shall be placed adjacent to the symbol.

Meaning	Symbol	Description
Serial Number		To identify the manufacturer's serial number, for example on a medical device or its packaging. The serial number shall be placed adjacent to the symbol.
Choking Warning Symbol		Keep out of reach of children; choking hazard for children ages 0-3 years.
Electrical Safety Classification		To identify a type BF applied part complying with IEC 60601-1. The BioStamp Sensor is a Type BF Applied Part.
ON/OFF Symbol		To indicate connection to or disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved. Each position, "ON" or "OFF", is a stable position.
For Indoor Use Only		To identify electrical equipment designed primarily for indoor use.
Follow Operating Instructions		To signify that the instruction manual/ booklet must be read.
Temperature Limitations		To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.
Upper Temperature Limitation		To identify the maximum temperature limit. The temperature value may be shown adjacent to the symbol.

Meaning	Symbol	Description
Lower Temperature Limitation		To identify the minimum temperature limit. The temperature value may be shown adjacent to the symbol.
Direct Current		To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.
Do Not Re-Use		To indicate that the item is for single use only and must not be used more than once, for example on packages of medical disposables.
Humidity Limitation		To indicate the acceptable upper and lower limits of relative humidity for transport and storage.
Atmospheric Pressure Limitation		To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.

Regulatory Information

Applicable Standards

Standard	Description
IEC 60601-1	Labeling Requirements; Safety Testing
IEC 62366	Usability Engineering for Medical Devices

FCC Compliance Notification

The BioStamp nPoint System was verified for RF exposure and found to comply with Council Recommendation 1999/519/EC and FCC OET-65 RF exposure requirements. This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

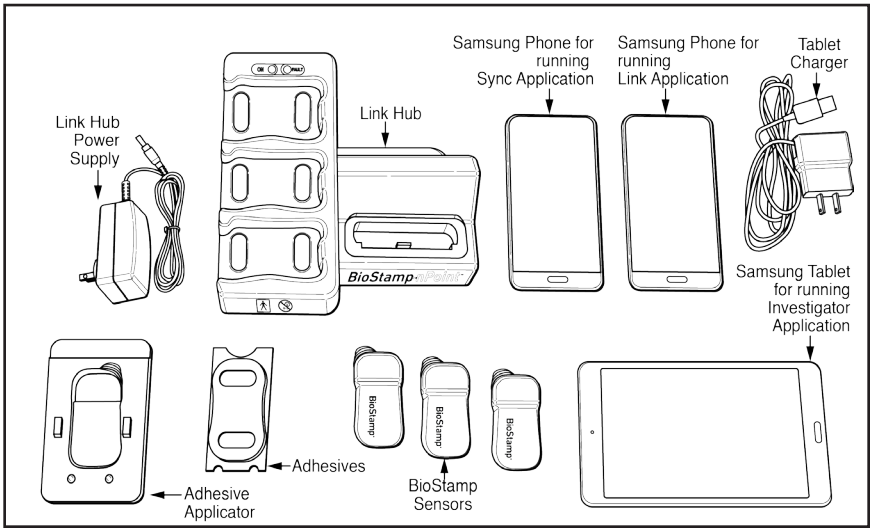
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna;
- Increase the separation between the equipment and receiver;
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected;
- Consult the dealer or an experienced radio/TV technician for help.

The BioStamp Sensors comply with Part 15 of the FCC Rules. The included Link Hub complies with Part 15 and Part 18 of the FCC Rules. Operation of each device is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

BioStamp nPoint Platform Components

BioStamp nPoint includes the following components:



Documentation	Instructions for Use
	Subject Instructions for Use for Remote Studies
Core Components and Accessories	Link Hub and Power Supply
	BioStamp Sensors
	Adhesive Stickers
	Adhesive Applicator
	Investigator Web Portal (MDDS or MC10 Cloud)
Supervised Components	Tablet with Investigator Application and Tablet Charger
	Mobile Phone with Sync Application
Remote Components	Mobile Phone with Link Application

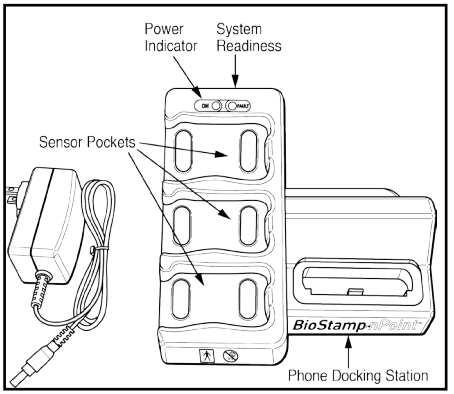
Note Remote components of BioStamp nPoint are intended for operational use by the patient. Supervised components of BioStamp nPoint are intended for operational use by investigators.

BioStamp nPoint Component Assembly and Function Overview

Ensure system components are fully charged before each use.

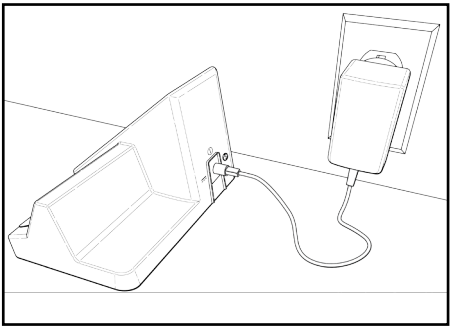
Note

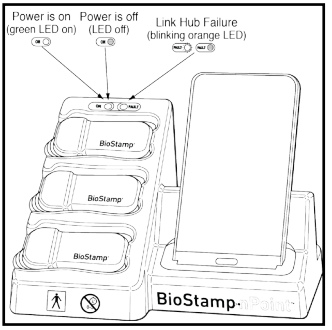
Link Hub



BioStamp nPoint includes a charging platform, called the Link Hub that holds and charges the Link Phone (for Remote Studies), Sync Phone (for Supervised Studies) and the BioStamp Sensors. The Link Hub also synchronizes data from three Sensors and the Phone simultaneously.

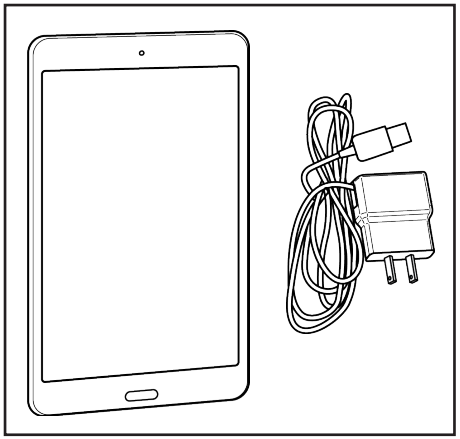
The Link Hub stores captured data from each Sensor on an internal SD memory card. When the Link or Sync Phone is connected to the Link Hub, data from the Sensors can be transferred via a cellular or Wi-Fi connection to the MC10 Cloud.





To assemble the Link Hub with power supply, set the Link Hub on a flat, stable surface. Do not position the Link Hub so that it is difficult to unplug the power supply cord. Plug the provided Link Hub power supply into the back of the Link Hub, and insert the wall adapter plug end into a nearby outlet. To power down, unplug the power supply cord from the Link Hub.

Tablet

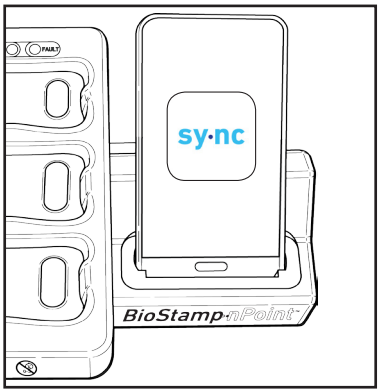


For Supervised Studies, BioStamp nPoint comes with a Samsung Galaxy Tab A tablet (and charger) for running the Investigator App, a tool used to communicate with Sensors and run studies in the clinic or lab.

The tablet is configured with the Android operating system (do not exchange or alter) and the Investigator Application. The Investigator App is synchronized to the study parameters set by the investigator in the Investigator Portal any time a study is accessed. For Supervised Studies, the investigator uses the Investigator App to assign Sensors to subjects and to initiate recordings. Subject information in the form of activity tags and survey entries can be entered using the Investigator App. For full functionality, the tablet must be connected to a Wi-Fi network and have Bluetooth turned on.

You can log in to the Investigator App using your BioStamp nPoint credentials and log out through the Investigator App settings. Turn off the tablet by holding down the power button and selecting the "power off" option.

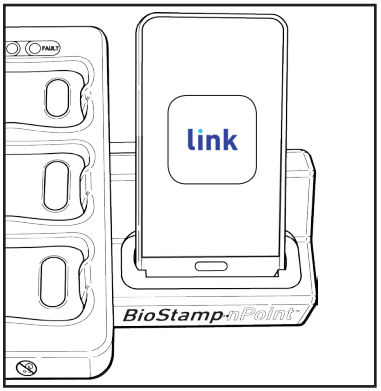
Sync Phone



For Supervised Studies, BioStamp nPoint comes with a Samsung Galaxy J3 smartphone for running the Sync App, used to upload study data collected in the clinic or lab.

The Sync Phone is configured with the Android operating system (do not exchange or alter) and the Sync Application. To charge the Sync Phone, place it in the phone dock on the Link Hub. Once an investigator is logged into the Sync App, the app is configured to upload Sensor data from the Link Hub to the MC10 Cloud. For full functionality, the Sync Phone must be connected to a data network (Wi-Fi, mobile, etc) and have Bluetooth turned on. You must be an investigator to log in to the Sync App using your BioStamp nPoint credentials. To sign out press the "sign out" button in the Sync App. Turn off the Sync Phone by holding down the power button and selecting the "power off" option.

Link Phone

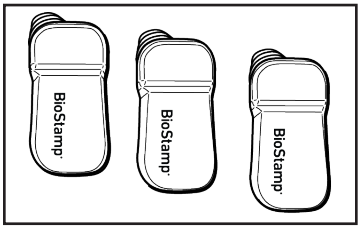


For Remote Studies, BioStamp nPoint comes with a Samsung Galaxy J3 smartphone for running the Link App, used to guide subjects through study activities and upload study data.

The Link Phone is configured with the Android operating system (do not exchange or alter) and the Link Application. To charge the Link Phone, place it in the phone dock on the Link Hub. Once a study subject is logged into the Link App, the application is configured to the study parameters set by the investigator in the Investigator Portal. The Link App displays a daily schedule for the subject to complete including Sensor placement, survey entries, prescribed activities, and Sensor removal. The Link App is also used to upload Sensor data from the Link Hub to the MC10 Cloud. For full functionality, the Link Phone must be connected to a data network (Wi-Fi, mobile, etc) and have Bluetooth turned on.

You can generate a unique subject passcode on the Investigator Portal to use to log in to the Link App. You can then provision a Remote Kit (Link Phone, Link Hub, and Sensors) to a specific subject and track hardware status. Once the subject has completed the prescribed program, you can reset the hardware by following the reset instructions in the Link App settings menu.

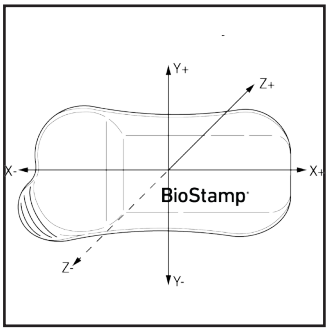
BioStamp Sensors



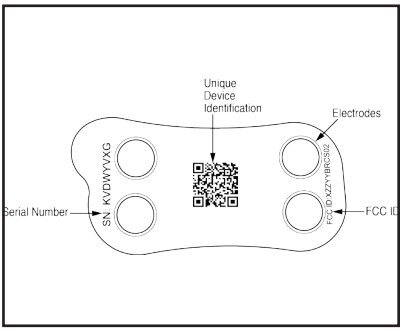
The BioStamp Sensor is an extremely thin, body-worn system designed to measure and record biometric signals.

The Sensor is optimized for small size and low power operation. BioStamp Sensors can collect biopotential (surface electromyography) and accelerometry (limb and body movement) data.

Sensor Coordinate System



Sensor Back View



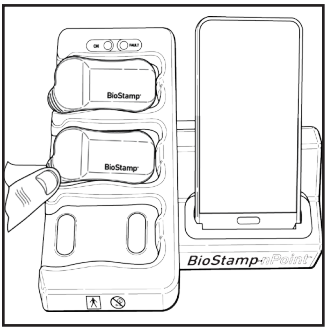
The Sensor can be placed in numerous orientations in various locations, and multiple Sensors can be placed on a single person. Once activated using the Investigator App or Link App, each Sensor operates independently, storing data in its local memory. The data can then be transferred wirelessly for display and subsequent analysis. The Sensor is designed for use cases involving up to 24 hours of continuous wear.

Inspect Sensors

Inspect all Sensors for damage prior to use.

Damage includes cracked, split, or broken encapsulation; exposed electronics other than the electrodes; tears or splits in the device; or any other deviation from the manufactured state that might impair functionality. Do not use Sensors that have visible damage.

Power Sensors On and Off



To power Sensors on, simply place the Sensors in the sensor pockets on the Link Hub.

BioStamp Sensors are shipped in a powered-off state. The LED light in the upper right corner of the Sensor will be solid blue when charging and solid green when ready.

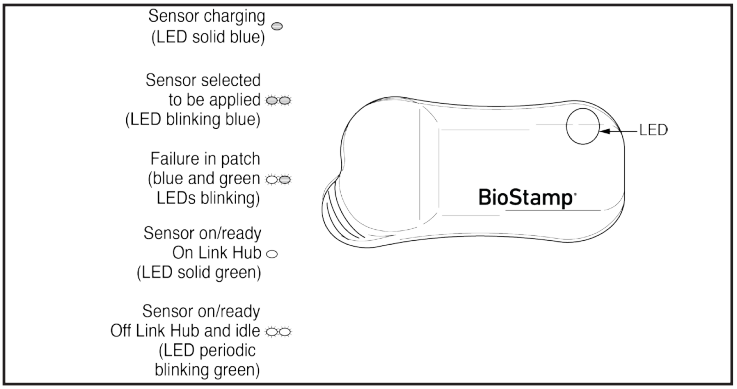
For long-term storage, Sensors should be powered off. Sensors can be powered off using the Investigator App on the tablet. Remove the Sensor from the Link Hub before powering off. Sensors will automatically turn off 3 hours after being removed from the Link Hub if they are idle/ready for use and not set to record or if they are not ready for use.

Charge Sensors

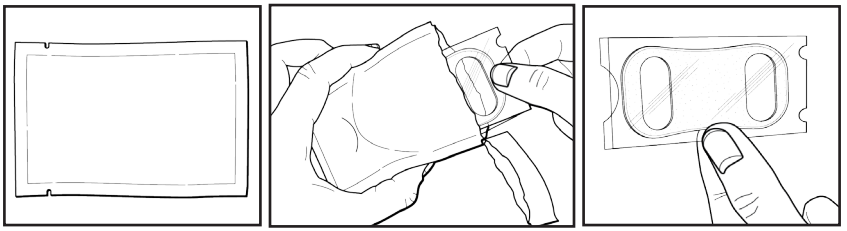
Charge Sensors by placing them in the sensor pockets on the Link Hub.

Sensors are equipped with a rechargeable battery. Before the Sensors can be used, the user must ensure they are fully charged.

Sensor Status Indications



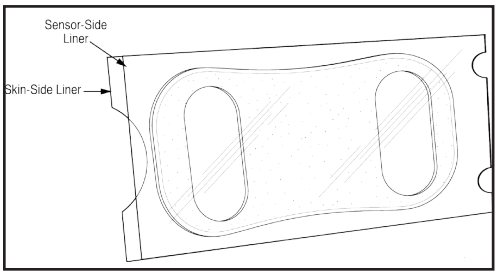
Adhesives



BioStamp Sensors are applied to the body using disposable adhesives for attachment that also contain hydrogel to optimize electrode contact to the skin. These double-sided adhesives have a sensor-side and a skin-side and should be applied to the Sensor using the provided applicator as a guide.

The adhesives are intended to adhere the Sensors to the body for up to 24 hours.

Under certain conditions the provided adhesive might not be sufficient (e.g. prolonged swimming, very intense exercise) to adhere the Sensors to the body for the full 24-hour wear duration. The Dorsal Foot and Dorsal Hand locations are particularly prone to adhesion issues due to the movement and body morphology of these specific areas. MC10 recommends providing an additional method of securing the Sensors to these body locations and for use during certain activities.

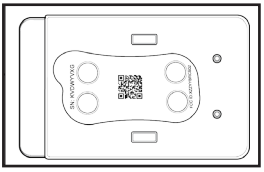


Apply the Adhesive Stickers to Sensors

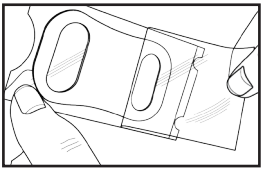
Each adhesive will be packaged individually in a sealed foil pouch. Do not open the adhesive pouch until you are ready to apply the adhesive to the Sensor.

Note

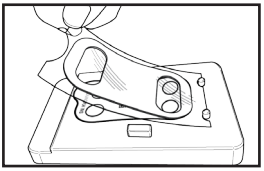
For locations outside of the required analytics sensor locations (see Investigator Portal Study Design), extra means to secure the sensors to the body are recommended (e.g. Tegaderm™, Coban™ wrap).



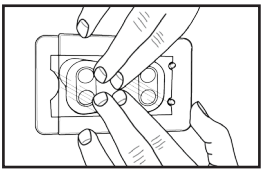
1. Place the adhesive applicator guide on a flat surface. Fit the Sensor, electrode side up, in the applicator sensor pocket.



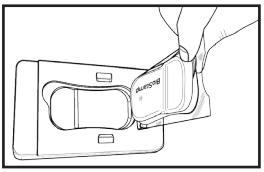
2. Remove the labeled sensor-side liner from the adhesive sticker.



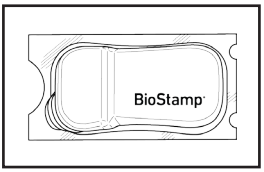
3. Align the two semi-circular cutouts on the bottom side of the remaining liner to the applicator peg guides, and lower the adhesive onto the Sensor.



4. Press down firmly for at least 10 seconds on the edges and middle of the sticker to apply the adhesive to the Sensor



5. Use the liner finger tabs to remove the Sensor with adhesive sticker from the applicator pocket.



6. Leave the remaining skin-side liner on the Sensor until you are ready to apply to the body location.

Applying Sensors to Body

During Remote Studies, the subject may refer to the Link App and the Subject Instructions for Use for Sensor application and removal instructions.

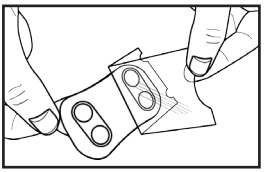
Skin Preparation

Proper skin preparation improves Sensor adhesion and signal quality. Before applying the Sensor, prepare the skin of the subject by trimming any excess hair at the application site and cleaning the site thoroughly with soap and water. Dry the area vigorously before applying the Sensor.

Note

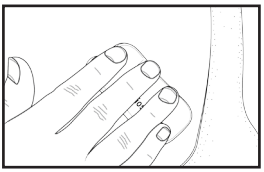
Alcohol wipes are not recommended as they dry the skin, which reduces adhesion and electrode signal quality. Additionally, using body lotion or other skin preparations may interfere with Sensor adhesion.

Apply Sensor



1

To apply, remove the remaining skin-side liner from the Sensor and adhesive. Be careful not to touch the adhesive or electrode area.



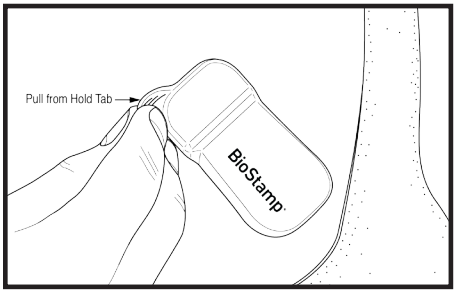
2

Place the Sensor on the target body location. Press firmly on the Sensor for at least 10 seconds.

Note

The Sensor should stay in place by itself. If necessary, it can be secured by a secondary method such as an adherent wrap or tape. Do not wear the Sensor and adhesive for more than 24 hours without changing the adhesive and cleaning and recharging the Sensor.

Remove Sensor



To remove a Sensor, simply grab the hold tab on the thicker end of the Sensor and peel the Sensor and adhesive off the skin.

The Sensor and adhesive should peel off cleanly. Any adhesive residue on the skin can be removed with baby oil or alcohol-based solvents. Remove the adhesive from the Sensor by peeling it away using the Sensor hold tab and edge of the sticker. Dispose of the adhesive sticker. Clean and disinfect Sensors between subjects.

Maintenance

Upgrading System Components
In the event that an upgrade is needed for any component of BioStamp nPoint (BioStamp Sensor, Link Hub, Link App, Sync App, Investigator App) contact MC10, Inc.

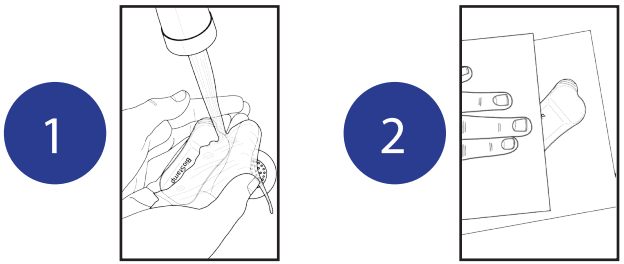
When new software versions are available the mobile applications will instruct you or the subject through the upgrade process. For Remote studies, the software is checked during the subject setup and system reset processes. Release notes of the changes are available in the app Update menu and detailed engineering changes can be sent upon request.

Cleaning and Disinfection
The system may be reused across multiple subjects, and reusable components must be cleaned and/or disinfected per instructions between subjects by the responsible organization or service personnel. The minimum service personnel requirements are an 8th grade education and the ability to read English. Clean and/or disinfect component before any service procedure.

Sensors must be cleaned and charged before initial use. If you remove a Sensor from a subject and plan to replace it later, clean the Sensor before reuse. We recommend cleaning the Sensor prior to recharging.

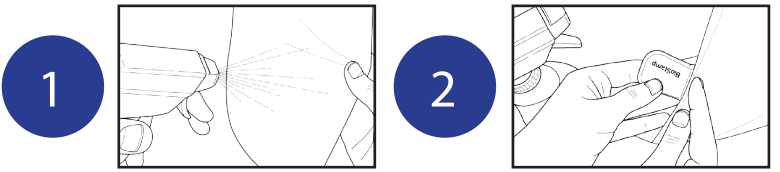
DO NOT expose any component or part of the system to heat above 40°C, dishwashers, clothes dryers, autoclaves, or other industrial cleaning processes.

Subject
The subject should **clean** BioStamp Sensors after each use. Simply remove and dispose of the one-time use adhesive sticker, wash the Sensor by hand with hand-soap and warm water to remove visible dirt and debris, and pat dry. Inspect sensors for any nicks, cuts, or tears, and if present, do not reuse.



Investigator
In addition to the subject cleaning the Sensors with soap and water, the Investigator should clean all Sensors and all Medical Electrical equipment and certain accessories between each subject. To **clean**, simply wipe down each component (BioStamp Sensor, Link Hub, Power Supply, Link Phone, Sync Phone, Tablet, Adhesive Applicator) with an alcohol wipe (70% Isopropyl Alcohol/30% De-ionized water) to remove visible dirt and debris or use a cleanroom wipe sprayed with a 70% isopropyl alcohol solution. Let all components dry, until no IPA is visible.

To further **disinfect** the BioStamp Sensor, use an additional alcohol wipe and allow Sensor to dry before reuse.



Note

BioStamp Sensors tolerate exposure to 70% isopropyl alcohol. The adhesives may interact with residual alcohol, however. Be sure to allow alcohol-exposed Sensors to dry thoroughly before applying adhesives.

Exposure to the following household chemicals will damage the Smart Charger and should be avoided:

- Nail Polish remover, both acetone and ethyl acetate based formulations
- Sunscreen
- Insect repellents containing DEET

All components can be used until their marked expiration date. All expired components except the adhesives should be returned to the manufacturer for proper decommissioning and disposal.

Executing a Study

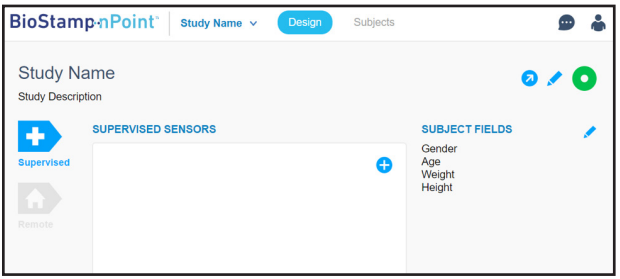
Investigator Portal Study Design

The Investigator Portal will be used by the investigator and sanctioned users to design a study, view, and export data collected from study subjects.

Computers used to access the Web Portal should be appropriately controlled against malware

Note

Log into the Investigator Portal at www.mc10cloud.com/biostampnpoint with your credentials (email to set password sent upon purchase) to access the BioStamp nPoint Software.

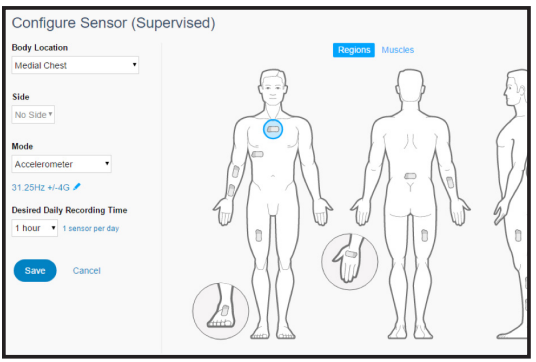


1

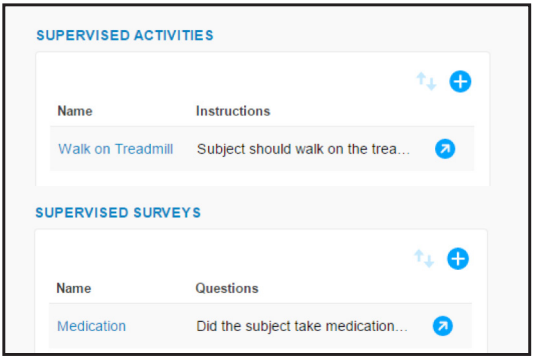
Create New Study

In the Design tab, click on New Study, provide a name and description, and select either the Supervised or Remote environments to begin designing your study.

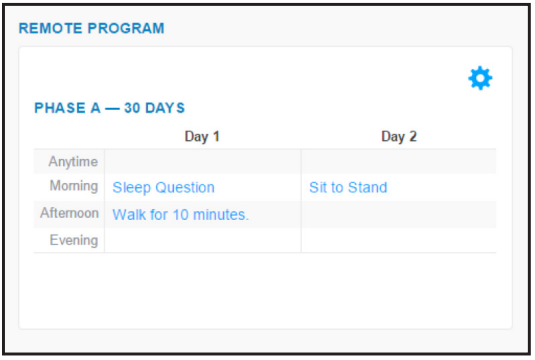
2 **Design Study in the Investigator Portal**



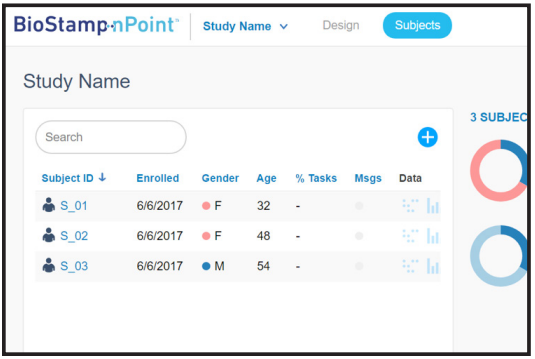
Configure Sensor Recording Modes and Locations



Add Prescribed Activites and Surveys

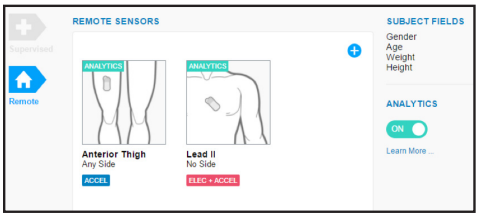


Design Remote Programs to Guide Subjects Through Study Tasks



Add Subjects and Subject Fields

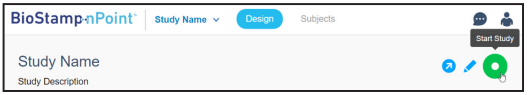
Remote Study Analytics



In the Remote environment, you can also add Analytics for daily reports of subject activity, posture, sleep and heart rate.

When analytics are activated, two pre-configured Sensors (anterior thigh with accel, Lead II with electrodes + accel) will be added to the Sensors field. These two Sensors cannot be edited and are necessary for analytics reporting, but additional Sensors can be added to the Remote Study configuration.

3 Start Study

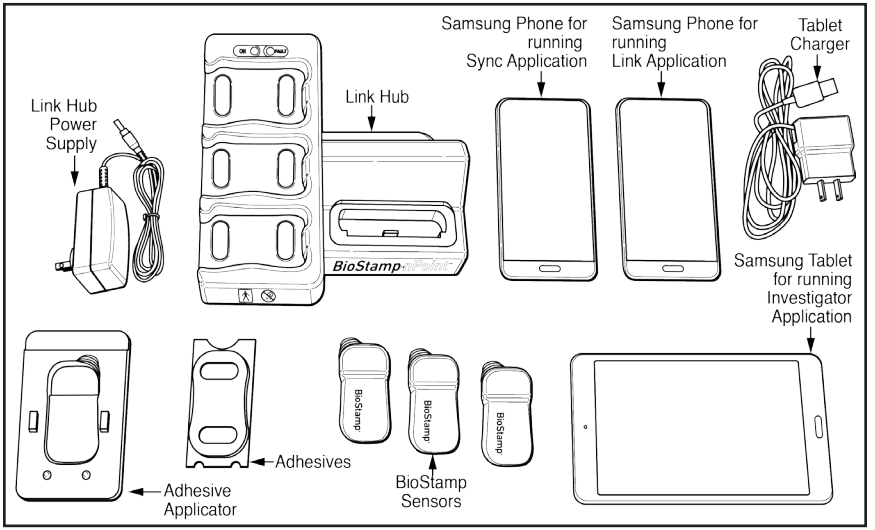


When your study is fully configured, select "start study" to lock parameters. Your study is now in progress.

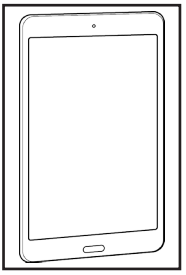
Run a Supervised Study

Investigators can design and run Supervised Studies to leverage BioStamp nPoint in more traditional clinical settings.

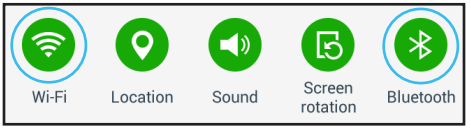
Supervised Studies utilize the following components:



1

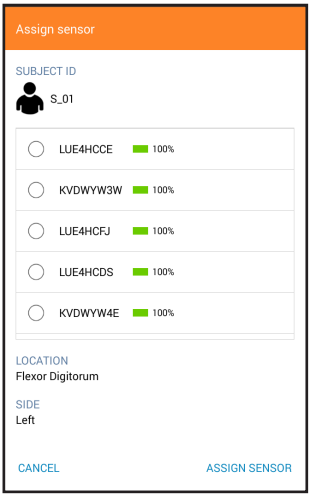


Add Additional Subjects and Assign Sensors with Investigator Application



Activate Bluetooth and connect to Wi-Fi on the provided tablet.

Open the Investigator App to run studies in the clinic or lab.



Using the app, you can add additional subjects to the study and assign BioStamp Sensors to subjects.

2

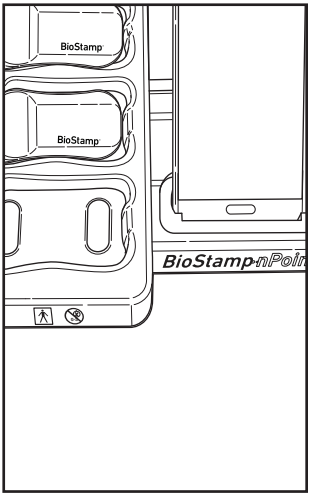
Apply Sensors to Subjects
Once Sensors have been assigned to study subjects, follow the BioStamp Sensor application instructions (page 20) to adhere adhesives and secure Sensor placement on the body.

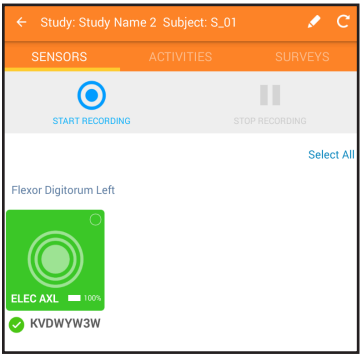
3

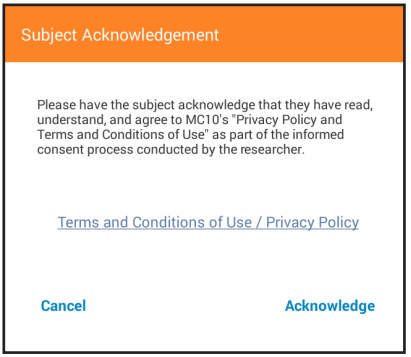
Run Study Using the Investigator Application
Use the Investigator App to activate Sensors, verify sensor signal, start recording, time-stamp activities, and collect survey responses.

Note

When checking Sensor biopotential signal quality at a muscle location, you can use the built-in Signal-to-Noise Ratio (SNR) feature. Press "Relaxed" when the subject is completely relaxing the muscle. When the "Contracted" button becomes available, have the subject contract the targeted muscle and hold the contraction. Press the "Contracted" button until the signal and noise voltage values appear. The subject does not need to continue contracting the targeted muscle.

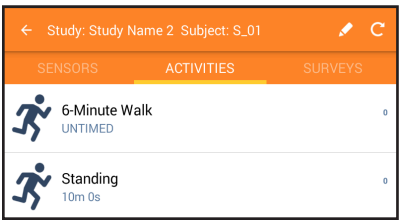


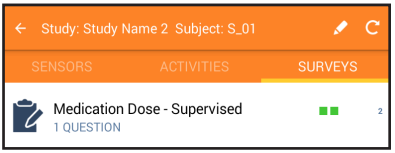




Note

Before beginning recording, you will need to review the BioStamp nPoint Terms and Conditions of Use and Privacy Policy with the patient and receive Subject Acknowledgement.

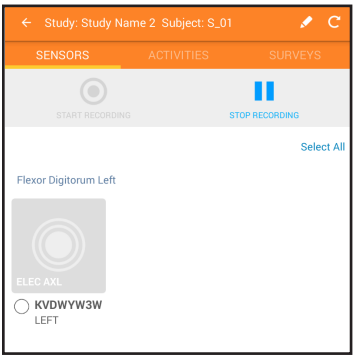




Note

Once an Activity or Survey has been completed, a green block will appear to the right indicating the number of times that Activity or Survey has been completed. Once an Activity or Survey has been completed more than ten times, visualized by ten green blocks, the number will increase for each further repetition but the ten blocks will remain.

4 Stop Sensor Recording



Navigate to the Sensors tab on the Investigator App, select the Sensors that no longer need to record, and press "stop recording."

Note

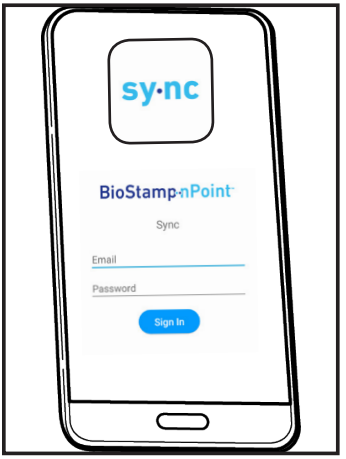
If a Sensor falls off while recording, press "stop recording," remove all Sensors, sync data, apply new adhesives and re-apply Sensors, press "start recording," and resume study activities.

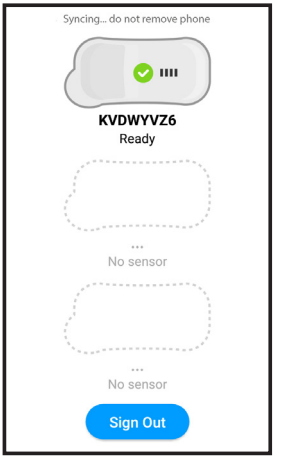
5 Remove and Clean Sensors

Remove Sensors from subject after a maximum 24 hours of wear. Dispose of adhesives, and clean Sensors for subsequent use (Maintenance page 24).

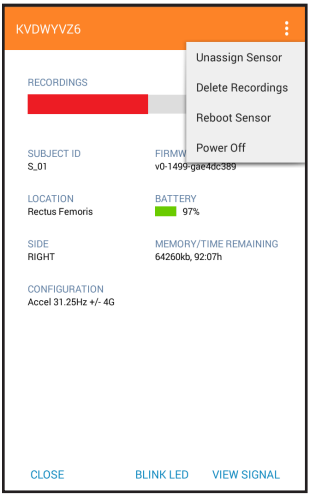
6 Synchronize Sensor Data

Synchronize data from the Sensors by first placing the Sensors on the Link Hub. Place the Sync Phone in the Link Hub dock. Then log in to the Sync App with your BioStamp nPoint credentials to begin syncing Sensor data to the Investigator Portal.





7 Unassign and Power Off Sensors

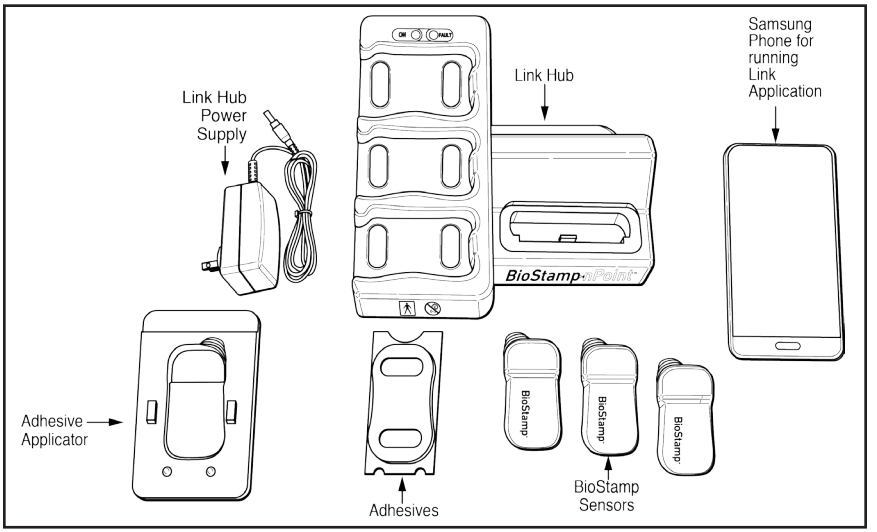


Once data has been synced, you may unassign and power off Sensors (for battery life preservation) in the Sensors tab on the Investigator App.

Run a Remote Study

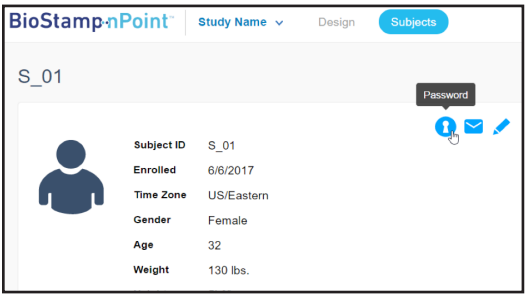
Investigators can design and run Remote Studies to collect data outside of the clinic or lab. The BioStamp nPoint Remote Kit contains all the tools necessary to gather insights from a subject's daily life or home environment.

Supervised Studies utilize the following components:

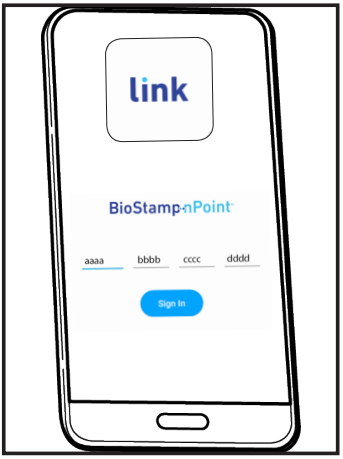


1

Assign BioStamp nPoint Remote Kits to Subjects
To active a subject's account and assign BioStamp nPoint take home components for a Remote Study, you will need to input a key code in the Link App on their assigned Link Phone.

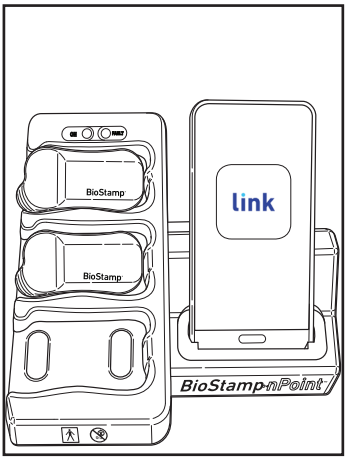


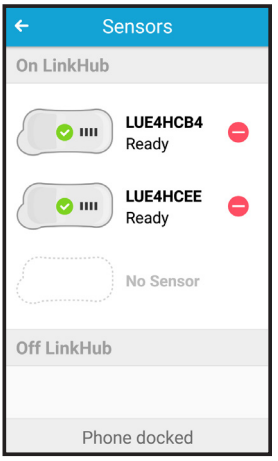
To generate this key code, open the subject's profile in the Investigator Portal, and press the Remote Password lock icon. This will generate a 16-letter code.



Input this code into the subject's Link App to associate the app with the subject's study program and assign the Link Phone to the subject.

This code will also be provided to the subject for logging in and out of the Link App.





Place the Link Phone into the Link Hub dock (that you plan to send home with the subject) and follow the prompt to assign BioStamp Sensors. Choose the Sensors and place them in the Sensor pockets on the Link Hub. If assigning more than 3 Sensors, wait until the first set of 3 Sensors have been recognized by the Link App and then replace with any additional Sensors you wish to assign. This can be repeated to assign as many Sensors to the system as needed.

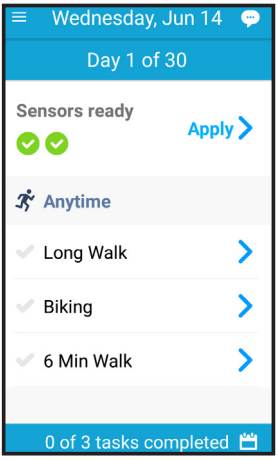
Note Once all Sensors have been recognized by the Link App, all system components have been assigned to the subject.

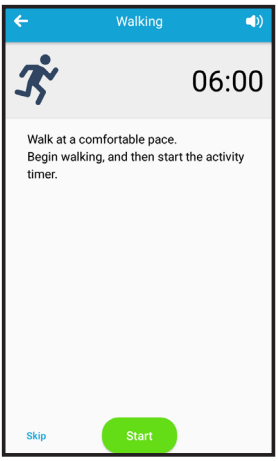
2

Train the Subject and Send Them Home with BioStamp nPoint Remote Kit

Remote Kit components are designed for Remote operational use by the subject. Train the subject on system use prior to sending the subject home with their Remote Kit and Subject IFU to initiate the study program.

Subject Study Procedure





At home, subjects will set the Link Hub on a flat, stable surface, plug the provided power supply into the back of the Link Hub, and insert the wall adapter plug end into a nearby outlet.

Subjects will then charge BioStamp Sensors by placing them in the sensor pockets on the Link Hub and will charge and connect the Link Phone by plugging into the phone stand in the Link Hub.

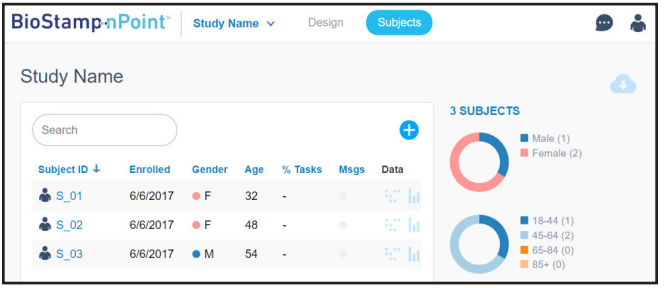
When the phone and Sensors are charged, they will open the Link App and follow instructions to apply Sensors (including Sensor position check), complete prescribed activities, and answer survey questions.

At the time of Sensor removal, subjects will follow instructions to remove, clean, and recharge Sensors. When Sensors are placed back on the Link Hub for recharging, the collected data will be sent to the Investigator Portal for i nvestigator review.

Subjects will follow Link Hub instructions until the end of the Remote Program, and then return the Remote Kit to the investigator.

Subject Assessment and Data Analysis

1 Assess Subject Progress

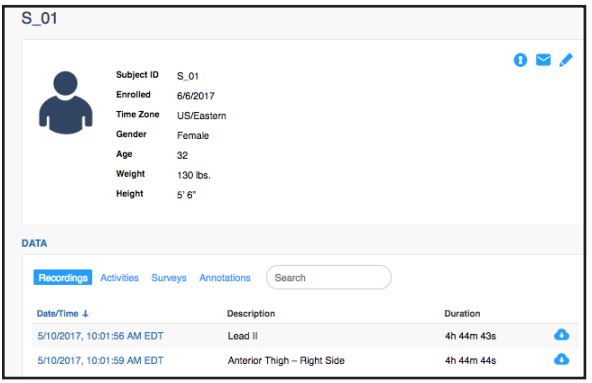


Open the Investigator Portal and click on the Subjects page to find the list of subjects that have been enrolled and their Gender (if entered), Age (if entered), Tasks Completed (%), and Data (linked to Raw Data and Analytics, if applicable).

Investigators can send messages to subjects, as well as view messages from subjects participating in Remote programs. Once a message from a subject is viewed, it can be marked as "Read" to reset the Msgs flag on the Subjects page.

2 View and Download Raw Data

Click on a subject's ID in the Investigator Portal Subjects page to access their data.



Under the Data section of the subject's profile, each recording is listed by Sensor. Click on the date and time of the recording for a raw signal visualization.

Plots of raw data versus time can be visualized on the dashboard for each sensor signal and can be navigated to a specific timestamp, activity, survey, or annotation. Navigation tools on the dashboard facilitate jumping to the beginning or end of a recordings, as well as specific points of interest. The calendar option allows investigators to visualize the dates when subjects have recordings. The timescales are dynamic (toggle between 1 hour and 12 hour view) and resolution options includes 5, 15, 30, and 60 second windowing intervals - as well as auto-scaling.

Activities and surveys are displayed on the timescale alongside the raw data and metrics (when enabled) so investigators can easily analyze time bounds of interest. In addition, the annotation feature in the raw data view allows investigators to contextualize the raw signal with custom notes, just by clicking on the plot. These manual annotations can be a single point or cover a time range and are exported with the other events in the subject's csv file.

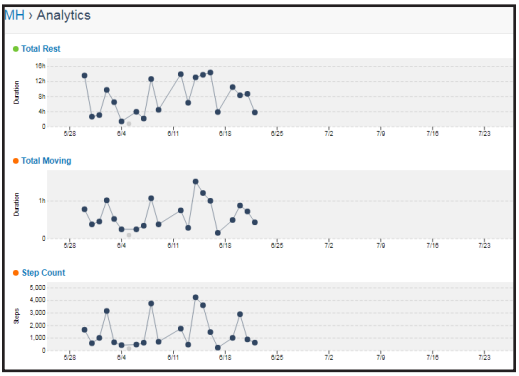
Click on the download icon to download the CSV file of Sensor data from each recording.

All Activities, Surveys, and Annotations data can be downloaded as a CSV file by clicking on the single download icon in the corner of either of the Activities, Surveys, or Annotations windows.

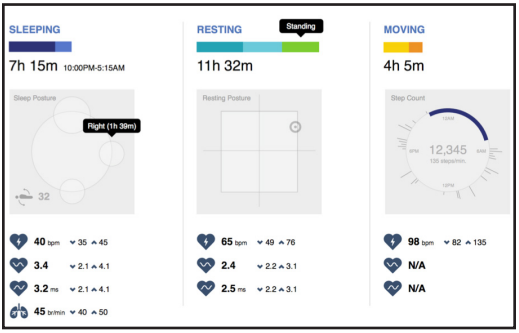
Raw data can also be accessed by clicking on the Raw Data icon located in the top right corner of the Subjects page of the Investigator Portal.

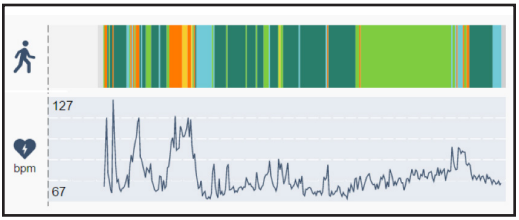
3

Access the Analytics Dashboard (Remote Studies Only)
For a Remote study, you can click on the Analytics Icon in the subject profile to view the analytics reports for that subject.



The Analytics icon brings you to a cumulative view of the 43 computed metrics over time, with a daily resolution. This view is customizable by selecting the settings icon in top right corner. Investigators can select which metrics to display and can also arrange the order.





Investigators can navigate to the daily subject metric dashboard by selecting one of the metrics on the timeline. Daily metrics are reported for 3 states: Sleeping, Resting, and Moving. Average, minimum, and maximum heart rate and heart rate variability values are reported for each of the 3 states.

The sleeping report shows sleep duration and sleep posture visualization. The resting report shows total resting duration (sitting, standing, lying) and posture visualization. The moving report shows total moving time (walking, other), cumulative number of steps when activity is classified as walking, step cadence (steps/min), and a visual-

ization of activity across 4 time periods.

Beneath the reports you will find the detailed outputs displayed across the time scale, which includes the activity class, respiration rate when activity is classified as sleeping, heart rate, and heart rate variability. This plot is dynamic and can be zoomed to a 1 hour view. Investigators can easily navigate to annotations and raw data from the daily metrics view.

Return to the Subjects page and click the Export Analytics icon to download all analytics from the study. The analytics export file contains all the subject metadata and metric outputs for the entire study. It can be requested while a study is in progress, and will be automatically generated upon completion of a study. Each subject will have a single csv file for the cumulative metrics (daily aggregates), as well as a file for each day that metrics were computed.

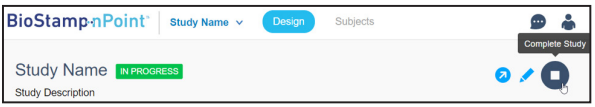
4

Access the API for Specific Downloads

Investigators can access the MC10 API through the API Docs link on the footer of the Investigator Portal or https://mc10cloud.com/apidoc/. This is an interactive API tool that enables efficient data queries through the REST API. The available study endpoints include studies, subjects, recordings, programs, activities, annotations, messages, equipment, and metrics.

5

Complete Study



Once all subject data for a study has been collected, click on the Complete Study icon in the Design Study page of the Investigator Portal. After the Complete Study icon is clicked, new subjects cannot be added or edited and new data can no longer be collected. A label will appear next to the study name to indicate the study has been completed.

Troubleshooting and Manufacturer

Troubleshooting

Software
If the Investigator App, Sync App, or Link App display any errors or become unresponsive, first check to ensure that Bluetooth and Wi-Fi are connected. If both are connected, turn each of them off and on again.

If the errors persist, force quit the MC10 application and restart the device.

Contact the responsible organization if issues continue to occur.

Hardware
If the BioStamp Sensor or Link Hub indicates a failure, stop using the product and contact the responsible organization or manufacturer.

FAQs
To review frequently asked questions, visit https://www.mc10inc.com/faq

Manufacturer

For support, service in setting up or using, maintenance, return of expired system components for proper decommissioning, or further information on this Medical Electrical (ME) System Equipment contact the manufacturer:

MC10, Inc.

10 Maguire Rd., Building 3, Floor 1, Lexington, MA 02421, USA

Phone: +1 (857) 214-5600

Fax: +1 (781) 538-6641

Web: www.mc10inc.com

Email: BioStampnPoint@mc10inc.com

Appendix A

BioStamp nPoint Platform Components

BioStamp nPoint includes the following components:

Documentation	Instructions for Use	
	Subject Instructions for Use for Remote Studies	
Core Components and Accessories	Link Hub and Power Supply	BRSD01; BSPS01 (SL Power Electronics Model ME-20A0900B02)
	BioStamp Sensors	BRCS02
	Adhesive Stickers	BRCA02
	Adhesive Applicator	BRCA05
	Investigator Web Portal (MDDS or MC10 Cloud)	
Supervised Components	Tablet with Investigator Application and Tablet Charger	BRCT02
	Mobile Phone with Sync Application	BRCP02
Remote Components	Mobile Phone with Link Application	BRCP01

BioStamp nPoint Component Service Life

Link Hub	24 months from date of original manufacture Expiration date is indicated on the device label
Tablet	24 months from date of original manufacture Expiration date is indicated on the device label
Sync Phone	24 months from date of original manufacture Expiration date is indicated on the device label
Link Phone	24 months from date of original manufacture Expiration date is indicated on the device label
BioStamp Sensor	19 months from date of original manufacture
Unopened Adhesive	13 months from date of original manufacture Expiration date is indicated on the adhesive packaging

Technical Specifications

BioStamp Technical Specifications

Size	
Dimensions	7.1 x 3.4 x 0.5 cm (LxWxH max)
Weight	8.7 grams
Material	Low durometer silicone
Sensors	
Accelerometer	
Range	±2-16g0 ± 10%
Bit Depth	16
Precision	0.6 mg
Sample Rate	15.625-250 Hz ± 15%
Zero-g Output	±60 mg
Gyroscope	
Range	±250-2000 °/s ± 10%
Bit Depth	16
Resolution	0.07 °/s
Sample Rate	15.625-250 Hz ± 2%
Zero Rate Output	±5 °/s
1-lead Analog Front End	
Range	±300 mV
Resolution	10 mV
Bit Depth	16
Sampling Rate	125-1000 Hz ± 2%

BioStamp Recording Modes

Sensor	Sample Rates Available	Dynamic Ranges Available
Accelerometer	15,625, 31.25, 62.5 125, 250 Hz	+/- 2G, +/- 4G, +/- 8G, +/- 16G
Gyroscope + Accelerometer	15,625, 31.25, 62.5 125, 250 Hz	Gyroscope Range +/- 250°/s, +/- 500°/s, +/- 1000°/s, +/- 2000°/s
		Accelerometer Range +/- 2G, +/- 4G, +/- 8G, +/- 16G
AFE	125, 250, 500, 1000 Hz	+/- 300 mVDC
Accelerometer + AFE	31.25 Hz (accelerometer) and 250, 500, 1000 Hz (AFE)	+/- 2G, +/- 4G, +/- 8G, +/- 16G (accelerometer) and +/- 300 mVDC (AFE)

Adhesive Technical Specifications

Size	
Dimensions	70 x 38 x 1.4 mm (L x W x H)
Weight	2.2 grams
Material	Biocompatible medical foam, adhesives, and hydrogel

Link Hub and BioStamp Sensor Frequency and Transmission Specifications

Frequency band of reception	2400-2500 MHz
Bandwidth of reception	1 MHz
Frequency band of transmission	2400-2500 MHz
Transmission type	IEEE 802.15.1 direct sequence spread spectrum (BLE), 0.015 mW EIRP

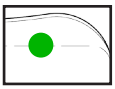
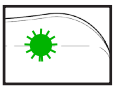
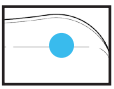
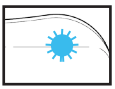
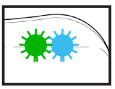
Note

No recurring testing is needed during the expected service life. Link Hub IEC 60127-1 internal fuse rated as F 2A, 63VDC.

Hardware LED Status Indicator Table

For any system or component failures including power failures (indicated by lack of any lights), please contact the provider for a replacement patient kit. There is no alarm system.

LED Indicator Messages

	Power On / Ready For Use	Charging	Ready to Apply	Warning/ Failure	Power Off
Link Hub		-----	-----		No LEDs
BioStamp Sensor	 (on Link Hub)  (off Link Hub)				No LEDs

EMC Declaration and Guidance

Guidance and Manufacturer's Declaration – Electromagnetic Emissions
The BioStamp nPoint system is intended for use in the electromagnetic environment specified below. The customer or the user of the BioStamp nPoint system should assure that it is used in such an environment.

Emissions Tests	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The BioStamp nPoint use RF energy only for system communication functions. Therefore it's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The BioStamp nPoint system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions EN61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions EN61000-3-3	Per Section 5 of the Standard	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
The BioStamp nPoint system is intended for use in the electromagnetic environment specified below. The customer or the user of the BioStamp nPoint system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) EN61000-4-2	+/-15 kV Air Discharge +/-8 kV Contact Discharge, VCP, HCP	+/-15 kV +/-8 kV	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated Electromagnetic Fields EN61000-4-3	10 V/m, 80-2700 MHz at 80%, 1 kHz AM Modulation	10 V/m	Portable RF communications equipment (including peripherals such as antenna cables and external antennas), microwave ovens, cordless phones, Wi-Fi devices should be used no closer than 30 cm (12 inches) to any part of BioStamp nPoint system, including cables specified by the manufacturer, otherwise, degradation of the performance of this equipment could result.
Radiated Electromagnetic and Proximity Fields EN610004-3	9-28 V/m, RF Wireless Communication Fields on Spot Frequencies from Table 9 at 50%, Square Wave Modulation	9-28 V/m	
Conducted EN61000-4-6	6 Vrms on ISM and Amateur Bands 3 Vrms, 0.15-80 MHz, AC Mains 3 Vrms, 0.15-80 MHz, SIP/SOP Ports	6 Vrms 3 Vrms 3 Vrms	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Power Frequency Magnetic Field EN61000-4-8	30 A/m at 50 or 60 Hz	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic environment. Electrical machinery should be used no closer than 30 cm (12 inches) to any part of BioStamp nPoint system, including cables specified by the manufacturer, otherwise, degradation of the performance of this equipment could result.
Electrical Fast Transient/ Burst EN610004-4	+/-2 kV on AC Mains N/A on SIP/SOP Ports	+/-2 kV N/A	Mains power should be that of a typical domestic environment
Surge EN61000-4-5	+/-2 kV Common Mode +/-1 kV Differential Mode N/A on SIP/SOP Ports	+/-2 kV +/-1 kV N/A	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply EN61000-4-11	0%, 0.5 Cycles 0%, 1 Cycle 70%, 25/30 Cycles 0%, 250/300 Cycles	0% 0% <70% 0%	Mains power should be that of a typical domestic environment

Appendix B

Programmable Electrical Medical System (PEMS) connection to an IT-Network

Data is transferred continuously among components during normal system operation. Raw (unprocessed) sensor data is transferred wirelessly from the patch to the mobile through Bluetooth LE. When network connectivity is available, sensor data is transferred from the mobile to the cloud. Once the cloud confirms receipt of the sensor data, the patch's on-board flash memory may be cleared for subsequent recording.

Implemented Protocols

BLE, USB, and HTTP standard protocols are implemented between the PEMS and the IT-network. These protocols encompass and incorporate the required characteristics of the IT-network incorporating the Portable Emissions Measurement System (PEMS), the required configuration of the IT-network incorporating the PEMS, and the technical specifications of the network connection of the PEMS including security specifications.

Information Flow

The intended information flow between the PEMS, the IT-network and other devices on the IT-Network, and the intended routing through the IT-network:

BioStamp Sensor to Link Hub	BLE/ESB
BioStamp Sensor to Tablet	BLE
BioStamp Sensor to Phone	BLE
Link Hub to Link App	USB, Android Open Accessory
Portal to Cloud	public internet, HTTPS
Investigator App/Tablet to Cloud	WiFi, public internet, HTTPS
Link App/Phone to cloud	WiFi or cellular, public internet, HTTPS

Note

This can include aspects of effectiveness and data and system security as related to basic safety and essential performance (see also Clause H.6 and IEC 80001-1:2010).

Sensor to Mobile Communication
Data stored on the patch's on-board memory is secured through a proprietary bit packing and memory block allocation scheme. Communication to the patch is only enabled through custom-built mobile applications. All MC10 applications require an authorized user login using valid credentials. During operation, each patch is uniquely assigned to a subject, in a specified configuration mode which includes the sensor modality and body location. Patch to mobile and mobile to patch communication is secured through a custom cmd-ctrl-data protocol and compression algorithm that runs across the Bluetooth LE protocol packets.

Mobile to MC10 Cloud Communication
Application data is encrypted (256-bit AES) and stored on the local SQLite database on the mobile.

Upon network connectivity, data is transmitted between the mobile and cloud using HTTPS protocols, which requires authentication with valid credentials. This encrypted connection protects the privacy and integrity of the exchanged data.

All cloud API interactions are logged with the following attributes:
- Authenticated user taking the action
- Source IP address of user
- Time of interaction
- Resources viewed or action taken

MC10's cloud network and systems are protected with standard security practices (firewalls, VPC, access restrictions, and automated configuration management). Access to the data is restricted at multiple levels and is protected by MC10's Access Control Lists (ACLs) framework. ACLs restrict resource availability to approved users and groups. Each user belongs to at least one group and is assigned one or more roles within their respective group. Roles define which resources and what actions are available to a user in a given group.

Hazardous Situations
Potential hazardous situations resulting from a failure of the IT-NETWORK to provide the characteristics required to meet the purpose of the PEMS connection to the IT-NETWORK:

- Investigator Portal, Investigator App, and/or Link App cannot connect to public internet;

- Investigator Portal, Investigator App, and/or Link App can't connect to MC10 MDDS;
- Erroneous data transfer between Investigator Portal, Investigator App, and/or Link App and MC10 Cloud;
- Data corruption on MC10 Cloud due to foreseeable misuse (i.e. hacking);
- Investigator App or Link App can't configure/control BioStamp Sensor;
- Link Hub cannot control/download BioStamp Sensor;
- Erroneous data transfer between BioStamp Sensor and Link Hub;
- Link App cannot control/download smart charger;
- Erroneous data transfer between Link App and Link Hub;
- Data corruption on smart charger due to foreseeable misuse (i.e. hacking).

Connection of the system to an IT-network that includes other equipment could result in previously unidentified risks to patients, operators, or third parties. The responsible organization should identify, analyze, evaluate and control these risks. Subsequent changes to the IT-network could introduce new risks and require additional analysis. Changes to the IT-network include:

- changes in the IT-network configuration;
- connection of additional items to the IT-network;
- disconnecting items from the IT-network;
- update of equipment connected to the IT-network;
- upgrade of equipment connected to the IT-network.