BioStampRC™ User Manual

Revision B DRAFT

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1. Welcome

The BioStamp Research Connect™ system (also known as the BioStampRC™ system) is an incredibly wearable, easy to use biometric sensing platform. With the tools provided, you can go from a study concept to collecting data in just a few minutes. This powerful system also helps you organize and analyze your data, freeing you to spend more time doing research.

Thin, body-conforming BioStampRC™ *Sensors* can be placed nearly anywhere on the body to capture accelerometer, gyroscope, and surface biopotential signals which can be used to measure body motion, muscle, and heart activity. The *Sensors* adhere directly to the skin, capturing biometrics of targeted body locations. Because the *Sensors* store data locally, your subjects are free to move normally in natural environments.

This manual provides an introduction to help you understand the capabilities of your BioStampRC system, and provides necessary information for configuring and operating your BioStampRC system. The latest version of this manual is available at the MC10 web site.

For support, service, maintenance or further information on this product contact the manufacturer:

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FCC Compliance Notification

The BioStampRC *Sensors* and the included wireless charger have been found to satisfy the FCC radiation exposure limits set forth in Part 2 of the FCC's Rules for portable devices operating in an uncontrolled environment. To ensure exposure to RF radiation falls below those limits during operation, users must follow the specific operating instructions for these devices and must not co-locate or operate these devices with any other antenna or transmitter.

The BioStampRC *Sensors* comply with Part 15 of the FCC Rules. The included wireless Charger complies with 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.

NOTE: The BioStampRC *Sensors* have 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 included wireless battery charger has been tested and found to comply with the applicable limits under Part 18 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference to licensed radio services. However, the charger 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. 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, or to another authorized radio service, which can be determined by turning the charger off and on, the user is encouraged to try to correct the interference by one or more of the measures described immediately above.

CAUTION: Changes or modifications to either the *Sensors* or the included charger not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Responsible Party: MC10, Inc.
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NOTE: This device complies with Industry Canada's licence-exempt RSSs. Operation is subject to the following two conditions: (1) This device may not cause interference; and (2) This device must accept any interference, including interference that may cause undesired operation of the device.

AVIS : Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage; (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

1.1. Intended Use

The BioStampRC system is designed to collect certain physiological data in research studies. The system is intended to capture raw data about movements and biopotentials. The data collected by the BioStampRC system can provide quantifiable analysis of physical motion and electrophysiology. BioStampRC *Sensors* are research tools and are not intended for use in the diagnosis, cure, mitigation, treatment, or prevention of any disease or condition in humans or animals.

1.2. Safety Notices

- Carefully read this manual before using the BioStampRC system.
- BioStampRC *Sensors* and adhesive stickers are non-sterile. Adhesive stickers are for a single use on a single subject.
- BioStampRC *Sensors* are only for use on intact, unbroken and non-diseased skin.
- Upon BioStampRC *Sensor* removal, slight redness of skin may be observed and is typically resolved within 2 days. If serious skin reactions occur, discontinue use of BioStampRC *Sensors* on that person.
- BioStampRC *Sensors* may be susceptible to RF interference from other equipment used in their vicinity.
- BioStampRC *Sensors* are water resistant up to 1 m depth. Long term immersion in fluids may permanently damage the BioStampRC *Sensors*. Dry *Sensors* immediately after exposure to fluids.
- BioStampRC *Sensors* have not been tested on individuals who have a pacemaker or other sensitive medical device. To the extent that you opt to include individuals with pacemakers or other sensitive medical devices in any Study, you agree to instruct the individual to speak with his/her doctor before wearing the BioStampRC Sensors and obtain confirmation of the same. In addition, you must obtain informed consent from the individual indicating that the individual has been advised that the product has not been tested on individuals with pacemakers or other sensitive medical devices and agrees to participate anyway.
- BioStampRC *Sensors* have not been tested on pregnant women. To the extent that you opt to include pregnant women in any Study, you agree to instruct the individual to speak with her doctor before wearing the BioStampRC Sensors and obtain confirmation of the same. In addition, you must obtain informed consent from the individual indicating that the individual has been advised that the product has not been tested on pregnant women and agrees to participate anyway.
- You agree to assume all liability relating to any claims brought by individuals who have pacemakers or other sensitive medical devices or women who wore the device while pregnant.

- Individuals having an allergy to adhesives or silicone should not wear the BioStampRC Sensors. You agree to assume all liability relating to any claims brought by individuals who have an allergy to adhesives or silicone who wore the BioStampRC Sensors.
- Data privacy: data captured and provided by BioStampRC *Sensors* is not automatically anonymized, encrypted, or otherwise privacy-protected. It is your responsibility to assume any data security and privacy risks and to convey these risks to your subjects.

⚠	Modification or disassembly of BioStampRC *Sensors* or chargers poses a risk of electric shock. Do not use BioStampRC *Sensors* or chargers if internal circuitry is exposed or encapsulation is compromised in any way.

BioStampRC systems that have reached end-of-life should be disposed of properly. BioStampRC *Sensors* are rechargeable electronic units that contain lithium-polymer batteries. Such batteries are classified as hazardous substances in certain jurisdictions, and should be disposed of according to local laws and regulations.

2. Getting Started

The best way to get started with the BioStampRC system is to follow the Quick Start Guide available at http://www.mc10inc.com/ and included in your kit. The Quick Start Guide walks you through the process of applying the *Sensors*, capturing and downloading data, and completing *Activities* and *Diaries* using an example *Study*. This process will show you how the different system components work together. Later, you can use the *Investigator Portal* to design your own *Studies*.

3. BioStampRC Hardware

Figure 1 shows a representative BioStampRC system. The pictured configuration has 3 *Sensors*, 21 adhesives, conductive gel, a single charger, and a single tablet. This configuration is sufficient for a 7-day study with three *Subjects* wearing one *Sensor* each, or one *Subject* wearing three *Sensors*. The number of *Sensors*, adhesives, chargers, and tablets in the system can vary based on the size of your study.

Figure 1. Example contents of a BioStampRC System.

In general, each BioStampRC kit contains one or more:

- BioStampRC *Sensors* (Model BRCS01)
- Single-unit *Chargers* (Model BRCC01)
- Adhesive packs
- Tubes of conductive gel
- Tablet with Android™ and the BioStampRC Investigator App
- Quick Start Guide
- This User Manual

Other system components, such as the *Investigator Portal*, are available at the MC10 web site.

3.1. Sensors

The BioStampRC *Sensor* is an extremely thin, skin-wearable system designed to measure and record biometric signals. The *Sensor* is optimized for small size and low power operation. The *Sensor* contains the following sensing modules:

- Low-power 3-axis accelerometer (±2, 4, or 8 G range; 50, 100, or 200 Hz sample rate; 12 bit operation)
- High-range 6-axis gyroscope + accelerometer (±250, 500, 1000, 2000°/sec gyroscope range; ±2, 4, 8, or 16 G accel range; 25, 50, 100, 250 Hz sample rate; 16 bit operation)
- Analog front end (AFE) for sEMG and electro-cardiac activity measurement (±0.2V range at the electrodes; 125 and 250 Hz sample rate; 16 bit operation)

In addition, the *Sensor* has a microprocessor, Bluetooth® Smart connectivity, 32 MB of low-power, non-volatile memory, and a 15 mAh rechargeable battery with wireless inductive charging capability. The BioStampRC *Sensor* is shown in Figure 2, with the sensing axes for reference.

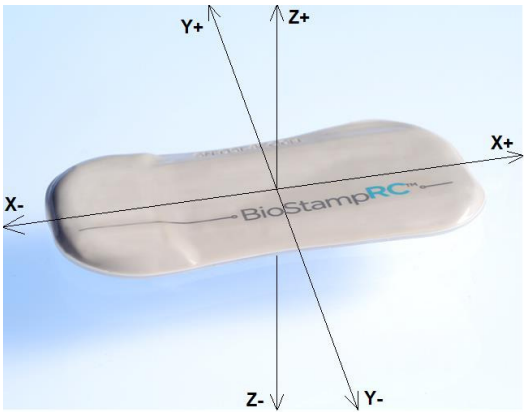


Figure 2. BioStampRC *Sensor* coordinate system. The *Sensor* axes are as shown in the diagram.

The BioStampRC *Sensor* can be placed in various body locations, and multiple *Sensors* can be placed on a single person. Once configured using the *Investigator App*, the *Sensor* operates independently, storing data in

its local memory. The data can then be transferred wirelessly for display and subsequent analysis. The BioStampRC *Sensor* is designed for use cases involving up to 24 hours of continuous wear.

3.1.1. Inspect and Clean *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.

BioStampRC *Sensors* are shipped clean, and do not require cleaning before use. If you remove a *Sensor* from a subject and plan to replace it later, clean the *Sensor* before re-use. We recommend cleaning the *Sensor* prior to recharging. To clean, simply remove and dispose of the adhesive sticker, wash the *Sensor* by hand with soap and water, and pat dry. BioStampRC *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.

DO NOT expose *Sensors* to heat above 60°C, dishwashers, clothes dryers, autoclaves, or other industrial cleaning processes.

3.1.2. Power On and Power Off

BioStampRC *Sensors* are shipped in a powered-off state. To power them on, simply place the *Sensor* on the charger as shown in Figure 3. Be sure to align the logo on the *Sensor* with that on the charger, and place the *Sensor* within the outline on the charger.

When the *Sensor* is powered on, a green light in the lower right corner of the *Sensor* blinks intermittently. Every ten seconds, the light will rapidly blink twice. Watch for this light to verify that the *Sensor* is powered on.

For long-term storage, *Sensors* should be powered off. *Sensors* can be powered off using the *Investigator App*. Consult the BioStampRC Software Manual for details. If the *Sensor* is on a charger, powering it off will have no effect.

3.2. Charging

BioStampRC *Sensors* are equipped with a rechargeable battery. The *Charger* included with your kit is designed to recharge the *Sensors* wirelessly. The *Charger* is designed to be plugged into the included voltage adapter. A suitable power outlet must be available near the location of installation and be easily accessible.

Figure 3. (Left) Single-unit *Charger*. (Center) The charging light at the bottom comes on when a *Sensor* is placed on the *Charger*. Note the alignment of the *Sensor* logo with the logo printed on the *Charger*. (Right) Charging light blinking patterns.

When the *Charger* is plugged into a wall outlet, the power light in the upper left corner comes on (Figure 3, Left). The charging light near the bottom of the charger should be off. If this light is blinking rapidly (Figure 3, Right), the charger experienced an error and must be restarted.

Place a *Sensor* on the *Charger* to charge it, being sure to align the logos as shown (Figure 3, Center). The charging lights at the bottom of the *Sensor* should pulse slowly while the *Sensor* is charging. When the *Sensor* is fully charged, the charging lights will stay on. To check the current charging state of the *Sensors*, use the *Investigator App*.

The BioStampRC charger is designed for indoor use only. Connect the charger to the included adapter and plug it into a wall outlet. The charger is designed for use at 20-40 °C. Clean the charger as needed with 70% isopropyl alcohol or soap and water. No other maintenance is required.

3.3. Sensor Application

Sensors are applied to the body using disposable adhesives for attachment and conductive gel for the electrodes. Adhesives come in packs of 7 or 21. These double-sided adhesives have an opaque liner on one side and a clear liner on the other. The side with the shiny liner adheres to the *Sensor*, while the side with the clear liner adheres to the skin. The adhesives and liners have holes to allow electrodes on the *Sensor* to contact the skin.

To use the adhesives, first place the *Sensor* electrode-side up on a flat surface. Remove the opaque liner and lower the newly-exposed adhesive surface onto the *Sensor*, pressing firmly for ten seconds. Make sure the electrodes are exposed through the holes in the adhesive (Figure 4). The bond between the *Sensor* and adhesive will grow stronger over the next few minutes. Meanwhile, apply conductive gel to the electrodes as described in the next paragraph.

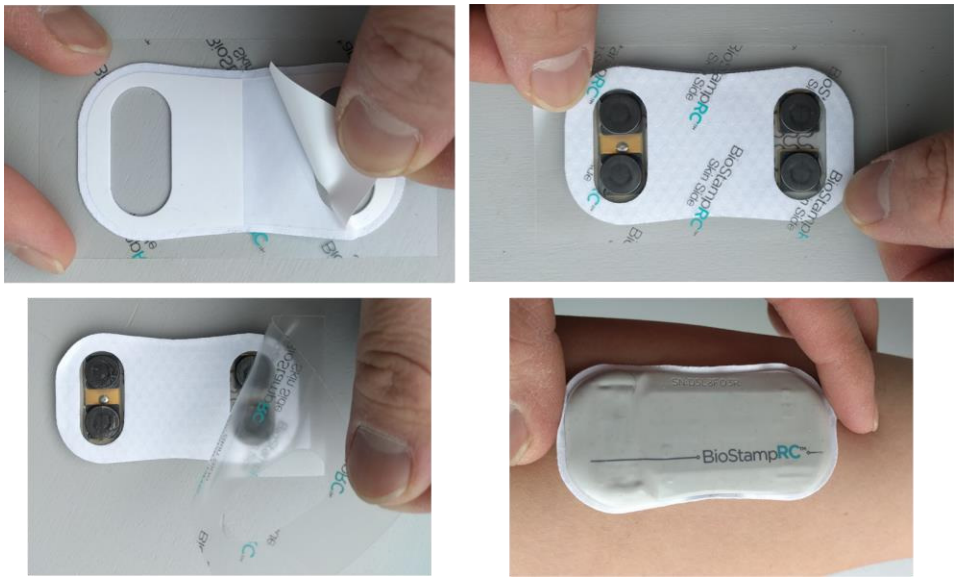


Figure 4. *Sensor* application. Top Left: remove opaque liner from *Sensor* side of adhesive. Top right: place adhesive on electrode side of *Sensor*. Bottom left: after applying gel (see Figure 5), remove clear liner. Bottom right: Place *Sensor* on skin and apply firm pressure.

The BioStampRC system comes with a tube of conductive gel for use in facilitating electrode measurements. The use of this gel is essential for obtaining the highest quality electrical signals from the BioStampRC system. Apply a small amount to each electrode as shown in Figure 5. Only a thin coating is needed; wipe off any excess gel. Excessive use of gel may adversely affect *Sensor* adhesion.

Figure 5. Electrodes after applying conductive gel. The gel gives the electrodes a shiny appearance.

3.3.1. Applying *Sensors* to Subjects

This process should be done in conjunction with performing a *Study* using the *Investigator App*. It is essential to note the ID of the *Sensor* applied to each body location. The *Sensor* ID is visible on the front of each *Sensor*.

3.3.1.1. Prepare Skin

Proper skin preparation improves *Sensor* adhesion and signal quality. Before applying the *Sensor*, prepare the skin of the subject:

1. Choose the location to apply the *Sensor*.
2. Trim any excess hair at the *Sensor* application site. Shaving is not required and may at times impair comfort.
3. Clean the site thoroughly with soap and water, a non-alcohol wipe, or a 4 x 4 gauze pad. Alcohol wipes are not recommended as they dry the skin, which reduces adhesion and electrode signal quality.
4. Dry the skin vigorously.

3.3.1.2. Apply *Sensor*

1. Remove the *Sensor* and adhesive from the clear liner. Be careful not to touch the adhesive or electrodes.
2. Place the *Sensor* in the chosen location, being careful to use the same location and *Sensor* orientation for each subject.
3. Apply firm pressure to the *Sensor* for at least 10 seconds.

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.

3.3.2. Removing *Sensors* from Subjects

To remove *Sensors*, simply grab them from the thicker end and peel the *Sensor* and adhesive off of the subject. The *Sensor* and adhesive should peel off cleanly. Adhesive residue on the subject can be removed with baby oil or alcohol-based solvents. Remove the adhesive from the *Sensor* by peeling it away, starting from the thicker part of the *Sensor*. Dispose of the adhesive after use.

3.4. Tablet

The BioStampRC system comes with a tablet running the Android operating system. This tablet comes with the *Investigator App* pre-installed. For full functionality, the tablet must be connected to a WiFi network and have Bluetooth turned on. The *BioStampRC User* account on the tablet allows you to control these settings in addition to running the *Investigator App*. If the tablet asks for a PIN, tap on the *BioStampRC User* icon in the upper right to switch to the correct account.

3.5. Wear Locations

Figure 6 shows some examples of recommended body locations for BioStampRC *Sensors*. This list is updated as new locations are validated. For most locations, *Sensors* can be placed on either side of the body. We recommend placing *Sensors* horizontally on trunk locations, and vertically on limbs. Consult Figure 2 for *Sensor* reference orientations, and choose a consistent placement location and orientation for all subjects.

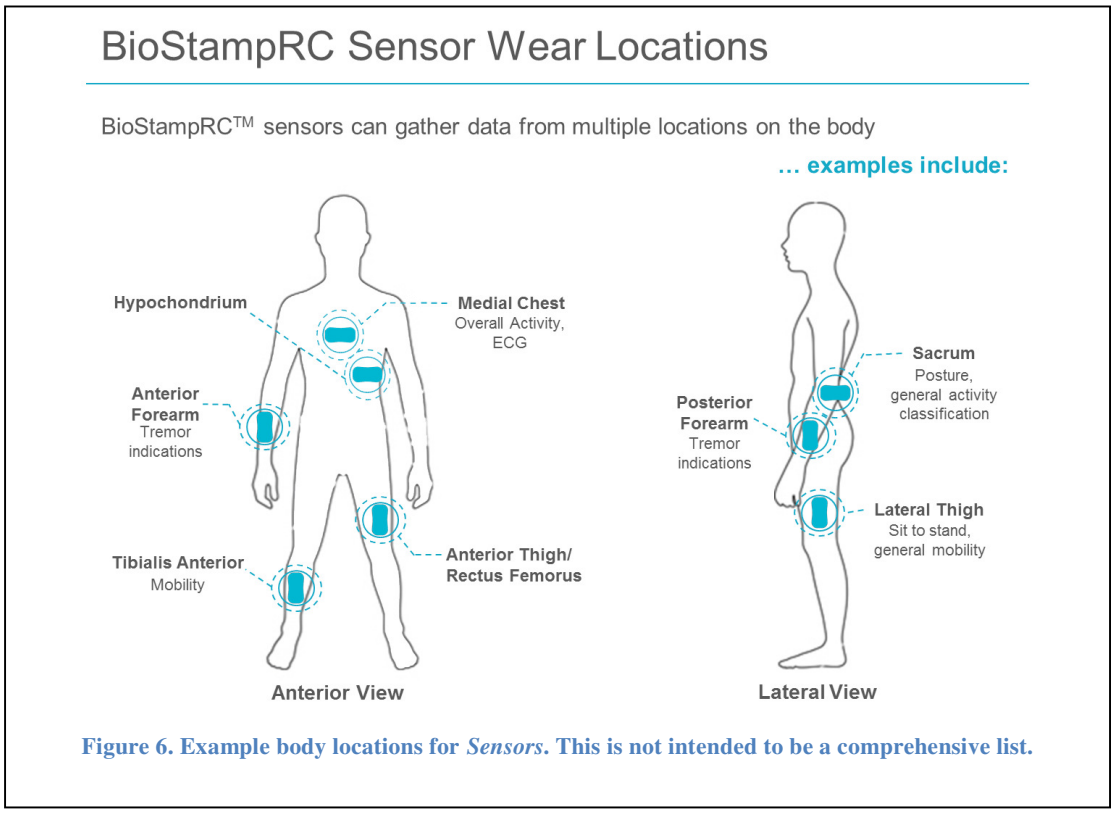


Figure 6. Example body locations for *Sensors*. This is not intended to be a comprehensive list.

Locations that are not on the list are not recommended. In particular, *Sensors* will not adhere properly to bony joints such as knees and elbows.

3.5.1. Recording Modes

The BioStampRC *Sensor* has multiple sensing modes with differing functionality. Different modes use different combinations of a three-axis accelerometer, a six-axis accelerometer+gyroscope, and a single-lead (two-electrode) analog voltage sensor. Table 1 lists the supported recording modes. The recording lifetime depends on both the recording mode and sampling rate chosen.

Table 1. Recording modes supported by BioStampRC

Mode	Sampling Rate	Dynamic Range	Recording Time (Approximate)
Accelerometer	50, 100, 200 Hz	±2, ±4, or ±8 G	8-35 hours
ECG	125, 250 Hz	±0.2 V	17-35 hours
EMG	250 Hz	±0.2 V	17 hours
Accel+ECG	50 Hz (accel) 125, 250 Hz (ECG)	±2, ±4, or ±8 G (accel) ±0.2 V (ECG)	11-22 hours
Accel+EMG	50 Hz (accel) 250 Hz (EMG)	±2, ±4, or ±8 G (accel) ±0.2 V (ECG)	11 hours

Gyro+Accel	25, 50, 100, 250 Hz	±2, ±4, ±8, ±16 G (accel) Off, ±250, ±500, ±1000, ±2000 °/sec (gyro)	2-4 hours

4. Technical Specifications

Figure 7 shows the technical specifications of the BioStampRC *Sensors* (FCC ID 2AGYUBRCS01).

BioStampRC™ System Specifications

SIZE

Dimensions	6.6 x 3.4 x 0.45cm (LxWxH max)
Weight	7g
Material	Low durometer silicone

SENSORS

Accelerometer

Range	± 8G
Resolution	10 mG
Sample Rate	50-200 Hz ± 10%

Gyroscope

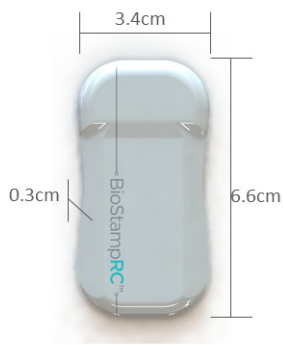
Range	± 2000 °/s
Resolution	0.2 °/s
Sample Rate	25-250 Hz ± 10%

Electrodes (1-Channel)

Range	± 200 mV
Resolution	0.006 mV
Sampling Rate	125-250 Hz ± 10%

MEMORY

256Mbit (32MB) Memory Capacity



WIRELESS COMMUNICATION

Bluetooth® Smart (BLE) enabled communication

SYNCHRONIZATION

Time-synchronized to within 1 second over 24 hours

POWER

Lithium polymer, rechargeable battery (15mAh)
Wireless recharging using 13.56 MHz power transfer
<90 Minute recharge time

SENSOR WATER RESISTANCE

IPX7 Compliant

OPERATING TEMPERATURE

Sensor: 0-40°C, Charger: 20-40°C

VERIFICATION

Sensor: FCC Part 15 Subpart B

CERTIFICATION

Sensor: FCC Part 15 Subpart C and UL/CSA 60950-1

Figure 7. Technical specifications for the BioStampRC *Sensors*.

The technical specifications for the charger are listed below.

Table 2. Charger specifications.

Dimensions	8.6 x 5.5 x 1.1 cm (LxWxH)
Weight	48.5 g
Material	Polycarbonate with Clear Coat
Cable Length	150 ± 1.2 cm
Certifications	FCC Part 18 Declaration of Conformity and UL/CSA 60950-1
Power	5V DC, 1A
Charging Frequency	13.56 MHz
IEC Protection Class	II

5. Troubleshooting

1. *My* Sensors *are not charging.*
   • Make sure the Charger is plugged into a wall socket using the provided adapter. One power light comes on when the Charger is correctly powered.
   • Align the *Sensor* with the outline on the charger. Make sure the orientation matches. When the *Sensor* is correctly aligned, the charging lights on the Charger should pulse slowly.

2. *My Charger has quickly blinking lights.*
   • The Charger is designed for use with the provided adapter. Do not use it with any other adapter, or with any other electronic system having USB ports.

3. *Some of my* Sensors *don't show up on the list.*
   • Power on the *Sensors* before use by placing them on the charger.

4. *The electrical signal looks noisy.*
   • The provided gel is required to ensure good electrical contact for bioelectric signal recording.

5. *My* Sensors *keep falling off.*
   • The adhesives provided with the BioStampRC system are intended for single-day use while performing typical life activities. Vigorous activities may require additional methods of securing the *Sensors* (tapes, wraps, etc.).

6. *My* Sensors *cause mild redness after multiple days of wear.*
   • Skin sensitivity varies widely among wearers. Mild redness may occur for some Subjects, but is typically not harmful. If Subjects experience significant irritation, discontinue use of BioStampRC *Sensors* on those Subjects.

7. *Other questions?*
   • Please contact MC10, Inc. for support at BioStampRCsupport@mc10inc.com or 857-214-5630.

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