BioIntelliSense

# BioButton® Multi-Patient Instructions for Use

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## Indications for Use

The BioButton System ("the Device") is a remote monitoring wearable device intended for continuous collection of physiological data in home and healthcare settings while the patient is at rest. This could include heart rate, respiratory rate, skin temperature, and other data such as activity level, body position, sleep, and step and gait analysis.

Data are securely transmitted via wireless connection for storage, review, analysis, and display.

The Device can include the ability to display data and notify healthcare professionals when physiological data fall outside clinician specified parameters.

The data from the Device are intended as an aid to diagnosis, diseases management, and treatment.

The Device is intended for use on patients who are 18 years of age or older.

The Device is not intended to output physiological measurements while the patients undergoes significant motion or is active.

The Device is not intended for critical care.

**Important:** The Device is intended for prescription use only under the supervision or authorization of a licensed healthcare professional. It is not intended for over-the-counter sale or use. Consult your healthcare provider for guidance on proper usage and to obtain a prescription if required.

℞ ONLY

**IN CASE OF EMERGENCY, CALL 911 IMMEDIATELY**
Our support line is not for medical emergencies. If you believe you have an emergency, call 911.

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## Warnings and Precautions

**DO NOT** wear device over excessive body hair. Excessive body hair should be trimmed using only an electric trimmer, before application.

**DO NOT** place on broken skin including wounds, sores, or abrasions.

**DO NOT** continue wearing if severe discomfort or irritation occurs.

**DO NOT** charge the device while it is adhered to the body.

**DO NOT** submerge the BioButton device in more than 3 feet of water or submerge for longer than 30 minutes at a time. Prolonged exposure to water may cause the device to loosen from the skin.

**DO NOT** exert excessive force, drop, modify, or attempt to take apart the device. Doing so may cause malfunction or permanent damage.

**DO NOT** wear or use the BioButton device during a magnetic resonance imaging (MRI) procedure or in a location where it will be exposed to strong electromagnetic forces.

**DO NOT** position the equipment such that it is difficult to operate the disconnection device.

**DO NOT** use accessories, detachable parts, and / or materials not described in the Instructions for Use.

**WARNING:** Use of the Device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the Device and the other equipment should be observed to verify that they are operating normally.

**WARNING:** Use of accessories other than those specified or provided by the manufacturer of the Device could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Device and result in improper operation.

**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of the Device could occur.

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## Warnings and Precautions

- The patient is the intended operator of this Device.
- Keep the BioButton device away from children and pets. The device is a choking hazard and is harmful if swallowed.
- Remove the BioButton device prior to using a defibrillator.
- Clinical validation has not been performed for patients who have an implantable device such as a defibrillator or pacemaker.
- The BioButton has not been evaluated specifically in patients experiencing cardiac arrhythmias. Reported heart rate at rest values may be inconsistent relative to other heart rate monitoring modalities for patients experiencing an arrhythmia.
- The Device is not intended for use as an apnea monitor.
- Certain types of motions or vibrations may cause inaccurate heart rate or respiratory rate measurements.
- Heart rate and respiratory rate data are only reported when the wearer is at rest and not reported during periods of significant motion or activity.
- The Device is not intended to output physiological measurements while the user undergoes significant motion or is active.
- Press the device's button regularly to check the indicator light and to verify that the device is in active monitoring mode.
- Clinical validation has not been performed on pregnant or breastfeeding patients.
- The Device is intended to be used in homes and hospitals, except for near active high frequency surgical equipment, magnetic resonance imaging (MRI), or other environment where the intensity of electromagnetic disturbances is high.
- In the presence of extreme electromagnetic disturbances, performance of device measurements should not be affected. However, temporary loss of connection between the device and the gateway can be expected, but should be restored shortly without need for operator intervention, after the presence of electromagnetic disturbances stop.

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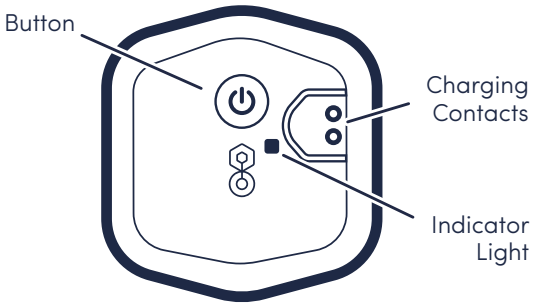
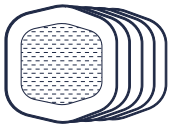
# Use Instructions

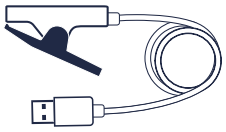
## DEVICE + COMPONENTS OVERVIEW



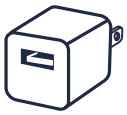

**BioButton Device**



**Adhesives**
(Provided Separately)



**Charging Cable**
(Optional, Provided Separately)

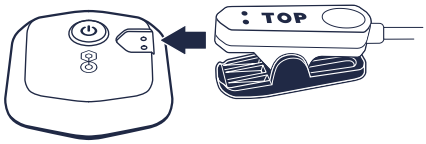


**5V 1A USB-A Power Adapter***
(Optional, Provided Separately)

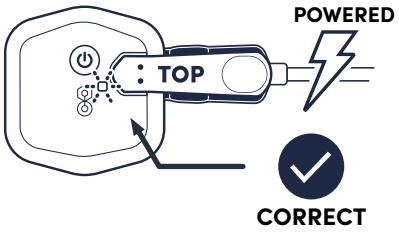
## GET STARTED

1. **PLUG** the USB-A end of the charging cable into a 5V 1A USB-A power adapter*.


2. **ATTACH** the charging cable to the BioButton device (see image to the right). The indicator light will **BLINK** when device is charging.




3. Proceed when the indicator light turns **SOLID GREEN**, indicating a full charge.




| INDICATOR LIGHT BLINK PATTERN | CHARGE LEVEL |
|---|---|
| Blink orange | 0% – 10% |
| Blink yellow | 11% – 70% |
| Blink green | 71% – 99% |
| Solid green | 100% |

*The power adapter must comply with IEC 60601-1.

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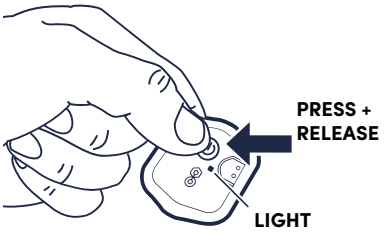
# Use Instructions

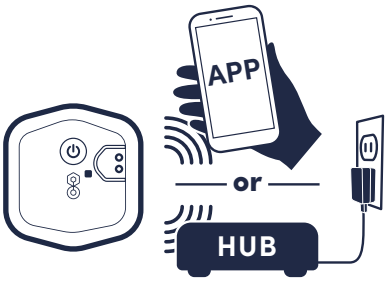
## GET STARTED (CONTINUED)

4. **DISCONNECT** charging cable and **PRESS** the button. The light will blink **BLUE 10 TIMES** after the device has powered on. (**Note:** the device may take up to 15 seconds to power on).




5. **ACTIVATE** your BioButton device, following the instructions for either your BioMobile® app or BioHub® device.

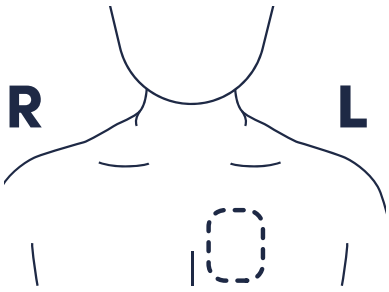
   **Note:** Device may perform a firmware update before activation. If so, the light will slowly blink **BLUE** for a few minutes.




6. **CONFIRM BIOBUTTON ACTIVATION** by pressing the button and verifying that the light blinks **GREEN 4 TIMES**.

   If the blink pattern is different or the light does not blink, refer to the **INDICATOR LIGHT PATTERN GUIDE** after **STEP 12** for guidance.

7. Locate placement area on **UPPER LEFT CHEST**, two inches below collar bone, and close to the sternum (breastbone).




8. **CLEANSE AREA** with a warm, damp cloth. Note: **TRIM ANY BODY HAIR** using only an electric trimmer.

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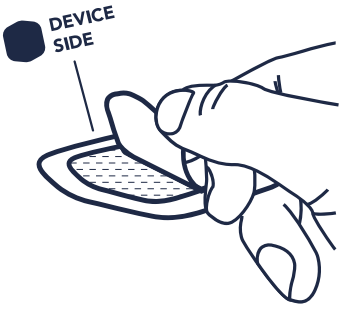
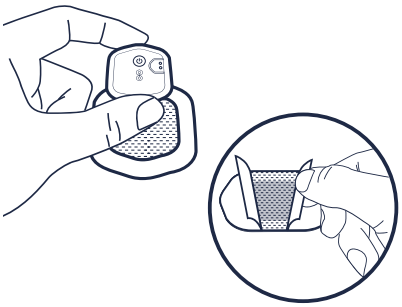
# Use Instructions

## GET STARTED (CONTINUED)

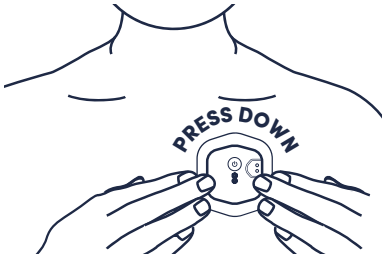
9. **TAKE** one adhesive. Peel the backing from **DEVICE SIDE** of adhesive.




10. Place the **BIOBUTTON** on the exposed adhesive. Turn the device over and remove remaining adhesive backing.



11. **ADHERE** the BioButton device to the upper left chest placement area near the sternum. Apply pressure for **15 SECONDS.**




12. Press the button to check the device status. See **INDICATOR LIGHT PATTERN GUIDE** below.

| PATTERN | MEANING |
|---|---|
| **3 Slow Yellow Blinks** | Not Ready for Use - Return Device to Charger |
| **10 Blue Blinks** | Ready for Activation |
| **Continuous Slow Blue Blinks** | Firmware Update in Progress |
| **4 Green Blinks** | Actively Monitoring |
| **5 Orange Blinks** | Low Battery |
| **No Light** | Dead Battery or Device Error |

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## During Monitoring Period

### REPLACE YOUR ADHESIVE

- When no longer sticky.
- If you experience redness or irritation in the placement area.

**REMOVE** adhesive from bottom of device. Follow **STEPS 7 THROUGH 11** to put on a new adhesive and reapply the device.

When replacing the adhesive, you should apply the device to a different location within the placement area.

### OFFLOAD YOUR DATA

Refer to your healthcare provider for more instructions on how to connect to the BioButton and view your data.

## End of Monitoring

After the monitoring period is complete, remove the BioButton and return it to the clinician or healthcare provider. They will follow necessary instructions for cleaning and disinfection to prepare for reuse.

Other than removing the BioButton, no other action is required.

For tips on long-term wear and additional adhesive support, visit: **biointellisense.com/support**

If additional support is required, please call **888.908.8804** (US) or email **support@biointellisense.com**

## Cleaning and Disinfection

The BioButton device must be properly cleaned and disinfected prior to re-use. For detailed instructions, reference the **Clinical Staff User Guide - BioButton Multi-Patient Cleaning and Disinfection (SM-BBM-10046).**

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# Troubleshooting and FAQs

**Can I shower or exercise with the device?**
Yes, the BioButton device is water resistant and can be worn during showers and exercise. Do not apply any deodorant or lotion to the placement areas as it will reduce adhesion of the device to the skin.

**Can I swim or bathe with the device?**
Yes, the BioButton device is water resistant and will continue working as long as it is not submerged more than 3 feet or kept underwater for longer than 30 minutes at a time. Prolonged exposure to water may cause the device to loosen from the skin.

**I'm experiencing some skin irritation, what should I do?**
Minor skin irritation and itching may occur while wearing the device. If a severe reaction develops (i.e. hives or blisters), discontinue wearing and contact your physician.

**How long should I wear my BioButton Rechargeable device?**
Please wear your BioButton device for the entire monitoring period. Each adhesive is designed for longer wear duration, typically up to 7 days, before replacing. For additional adhesive tips, visit biointellisense.com/support.

**How do I know my device is working?**
Press and release the device's button. The device light will blink GREEN 4 TIMES. If your device light is blinking a different color, please see the Button Press Light Patterns table on page 5 of this document.

**I've tried powering on the device several times, and the light still won't blink blue. What should I do?**
Contact Customer Support immediately. We may ask you to return the device. We would send you a replacement kit if more data is needed for the monitoring period.

## SYMBOL LIBRARY

MRI unsafe


Don't use if package is damaged

Latex-free


Must read instructions for use


Type BF applied part


FCC icon


Warning


Temperature limitation

Humidity limitation

Lot number

Model number


Apply by date
(for adhesive only)


Single-use only
(for adhesive only)

Prescription use only

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# Safety and Regulatory Information

## FCC STATEMENT

**Model:** BBRM
**FCC ID:** 2ASE7- BIOST06040

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.

This device complies with part 15 of the FCC Rules. Operation 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:** "Harmful interference" is defined in 47 CFR 52.1 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the International Telecommunication Union (ITU) Radio Regulations.

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



**RESPONSIBLE PARTY:**
BioIntelliSense, Inc.
570 El Camino Real #200
Redwood City, CA 94063

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## TERMS OF USE STATEMENT

Use of the BioIntelliSense Product(s) is subject to our:

- Privacy Policy
- Service Level and Support Terms
- Website, Application, and Product User Terms of Use.

You can find these policies at: **biointellisense.com/legal**

By using the Product(s), you indicate you have read these terms and policies and that you agree to them, including the limitations and disclaimers of liability. In particular, you understand and consent that use of the Product(s) measures and records personal information about you, including vital sign and other physiologic measurements. That information may include respiratory rate, heart rate, temperature, activity level, sleep duration, body position, step count, gait analysis, coughing, and other symptomatic or biometric data. You understand that the Product(s) do not render medical advice or diagnose or prevent any specific disease, including any communicable disease or virus. If you have any concerns about your health, including whether you have been exposed to or have contracted any disease or virus, immediately contact your healthcare provider.

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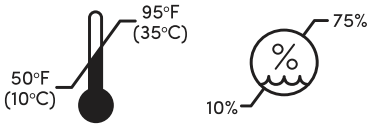
# Technical Specifications

| | |
|---|---|
| **Product Name** | BioButton Multi-Patient Device |
| **Model Number** | BBRM |
| **Battery** | Lithium ion |
| **Operation Time** | Typically 7-30 days depending on mode |
| **Battery Lifetime** | 300 charging cycles |
| **Shelf Life** | 2 years. After 2 years, battery must be charged prior to use. |
| **Service Life** | 2 years from initial device activation. |
| **Heart Rate* Range** | 40-150 beats per minute (<± 5 beats per minute) |
| **Respiratory Rate* Range** | 5-35 breaths per minute (<± 3 breaths per minute) |
| **Skin Temperature Range** | 86°F - 107.6°F (30°C - 42°C) |
| **Skin Temperature Accuracy** | < 96.4°F ± 0.5°F (< 35.8°C ± 0.3°C)<br>96.4°F to 98°F ± 0.3°F (35.8°C to 37°C ± 0.2°C)<br>98°F to 102°F ± 0.2°F (37°C to 39°C ± 0.1 °C)<br>102°F to 106°F ± 0.3°F (39°C to 41ºC ± 0.2°C)<br>> 106°F ± 0.5°F (> 41ºC ± 0.3°C) |
| **Skin Temperature Stability** | Skin temperature shall reach to a stable measurement within 20 minutes. |

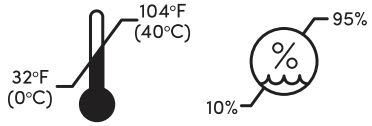
## LONG TERM STORAGE

| | |
|---|---|
| **Temperature Range** | 50°F to 95°F (10°C to 35°C) |
| **Humidity Range** | 10 to 75% RH |
| **Atmospheric Pressure** | 70 - 102 kPa |




## OPERATING CONDITIONS

| | |
|---|---|
| **Temperature Range** | 32ºF to 104ºF (0ºC to 40°C) |
| **Humidity Range** | 10 - 95% RH |
| **Atmospheric Pressure** | 70 - 102 kPa |
| **Dustproof and Waterproof Rating** | IP47 |




## COMMUNICATIONS

| | |
|---|---|
| **Communication Technology** | Bluetooth (BT4.2) |
| **Distance** | Max. 10 meters (30 feet) line of sight |
| **Radio Modulation** | GFSK (Gaussian Frequency Shift Keying) |
| **Radio Frequency** | 2.4 – 2.5 GHz |
| **Transmit Power** | 0dBm |
| **Security** | AES-CTR 128 bit encryption (Advanced encryption standard counter mode) |

* Measurements are taken at rest

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# Guidance and Declaration — Electromagnetic Compatibility

## ELECTROMAGNETIC EMISSION

The BioButton sensor is intended for use in the electromagnetic environment specified below. The user of the device shall ensure that the device is used in such an environment.

| EMISSION TEST METHOD | COMPLIANCE LEVEL | ELECTROMAGNETIC ENVIRONMENT & GUIDANCE |
|---|---|---|
| **RF emissions CISPR 11: 2015 + AI: 2016, A2:2019** | GROUP 1 | The BioButton sensor uses RF energy only for its internal function.<br>Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| **Emissions IEC 61000-3-2, IEC 61000-3-3** | CLASS B, CLASS A | The BioButton sensor 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. |

## ELECTROMAGNETIC IMMUNITY

The BioButton sensor is intended for use in the electromagnetic environment specified below. The end user of the device should ensure that it is used in such an environment.

| IMMUNITY TEST | IEC 60601 TEST LEVEL | COMPLIANCE LEVEL | ELECTROMAGNETIC ENVIRONMENT - GUIDANCE |
|---|---|---|---|
| **Electrostatic discharge (ESD) IEC 61000-4-2** | ± 8 kV contact<br>± 15 kV air | ± 8 kV contact<br>± 15 kV air | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| **Electrical fast transient/burst IEC 61000-4-4** | ±2 kV for power supply lines<br>±1 kV for input / output lines | ±2 kV for power supply lines<br>±1 kV for input / output lines | Mains power quality should be that of a typical residential environment. |
| **Surge IEC 61000-4-5** | ±1 kV differential mode | ±1 kV differential mode | Mains power quality should be that of a typical residential environment. |
| **Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11** | Voltage Dips 30% reduction, 25/30 periods At 0°<br>Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° | Voltage Dips 30% reduction, 25/30 periods At 0°<br>Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° | Mains power quality should be that of a typical residential environment. If the user of the BioButton requires continued operation during power mains interruption...s, it is recommended that the BioButton be powered from an uninterruptible power supply or a battery. |

## ELECTROMAGNETIC IMMUNITY (CONTINUED)

| IMMUNITY TEST | IEC 60601 TEST LEVEL | COMPLIANCE LEVEL | ELECTROMAGNETIC ENVIRONMENT - GUIDANCE |
|---|---|---|---|
| **Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11** | Voltage Dips > 95% reduction, 1 period At 0°<br>Voltage Interruptions > 95% reduction, 250/300 periods | Voltage Dips > 95% reduction, 1 period At 0°<br>Voltage Interruptions > 95% reduction, 250/300 periods | Mains power quality should be that of a typical residential environment. If the user of the BioButton requires continued operation during power mains interruptions, it is recommended that the BioButton be powered from an uninterruptible power supply or a battery. |
| **Power frequency (50/60 Hz) magnetic field IEC 61000-4-8** | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| **Proximity Magnetic Fields IEC 61000-4-39** | 65 A/m, PM at 2.1 kHz, 50% duty cycle, 134.2 kHz; 7.5 A/m, PM at 50kHz, 50% duty cycle, 13.56 MHz; 8 A/m, CW, 30 kHz | 65 A/m, PM at 2.1 kHz, 50% duty cycle, 134.2 kHz; 7.5 A/m, PM at 50kHz, 50% duty cycle, 13.56 MHz; 8 A/m, CW, 30 kHz | Proximity magnetic fields should be that of a typical residential environment. |
| **Conducted RF IEC 61000-4-6** | 3 Vrms, 150 kHz to 80 MHz (6 Vrms in ISM and amateur radio Bands within 150kHz – 80MHz) | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the BioButton, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>**Recommended separation distance**<br>• **Conducted RF IEC 61000-4-6:**<br>  • $d = 1.2\sqrt{P}$<br>• **Radiated RF IEC 61000-4-3:**<br>  • $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz<br>  • $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz<br><br>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] |
| **Radiated RF IEC 61000-4-3** | 10 V/m, 80 MHz to 2.7 GHz | 10 V/m | |

## ELECTROMAGNETIC IMMUNITY (CONTINUED)

**NOTE 1:** At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BioButton is used exceeds the applicable RF compliance level above, the BioButton should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BioButton.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

c. EMC performance of the device working with medical emitters such as electrocautery, electrosurgical units, and diathermy devices have not be assessed. Intenstive and direct exposure to these sources should be avoided while wearing the device.

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## IMMUNITY TO RF WIRELESS COMMUNICATIONS EQUIPMENT

| TEST FREQUENCY (MHZ) | BAND[A] (MHZ) | SERVICE[A] | MODULATION[B] | MAXIMUM POWER (W) | DISTANCE (M) | IMMUNITY TEST LEVEL (V/M) |
|---|---|---|---|---|---|---|
| **385** | 380-390 | TETRA 400 | Pulse modulation[b] 18 Hz | 1.8 | 0.3 | 27 |
| **450** | 430-470 | GMRS 460, FRS 460 | FM[c] ± 5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 |
| **710, 745, 780** | 704 – 787 | LTE Band 13, 7 | Pulse modulation[b] 217 Hz | 0.2 | 0.3 | 9 |
| **810, 870, 930** | 800 – 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation[b] 18 Hz | 2 | 0.3 | 28 |
| **1720, 1845, 1970** | 1700 – 1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation[b] 217 Hz | 2 | 0.3 | 28 |
| **2450** | 2400–2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7[a] | Pulse modulation[b] 217 Hz | 2 | 0.3 | 28 |
| **5240, 5500, 5785** | 5100 –5800 | WLAN 802.11 a/n | Pulse modulation[b] 217 Hz | 0.2 | 0.3 | 9 |

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

BioIntelliSense

### RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND BIOBUTTON

The BioButton is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The end user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BioButton sensor as recommended below, according to the maximum output power of the communications equipment.

| RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W) | SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (M) | | |
|---|---|---|---|
| | 150 KHZ TO 80 MHZ<br>D = 1.2√P | 80 MHZ TO 800 MHZ<br>D = 1.2 √P | 800 MHZ TO 2.7 GHZ<br>D = 2.3 √P |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

## Contact Us

For non-urgent support or questions about our product, please call **888.908.8804 (US)** or email **support@biointellisense.com**

### MANUFACTURED BY

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