

BioButton® Rechargeable Instructions for Use

AUGUST 2022

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Indications for Use

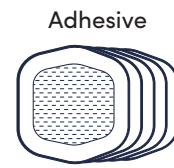
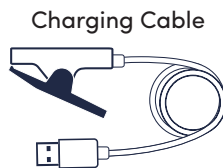
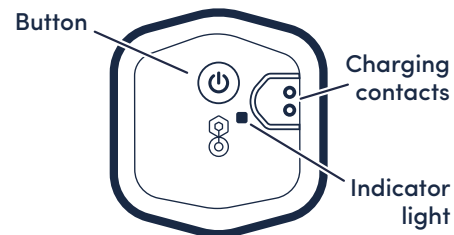
The BioButton® Rechargeable is a remote monitoring wearable device intended to collect physiological data which can include heart rate, respiratory rate, skin temperature, and other symptomatic or biometric data.

The device is intended for use on users who are 18 years of age or older.

The device does not output heart rate or respiratory rate measurements during periods of motion or activity.

The device is not intended for use on critical care patients.

Device + Components Overview



NOTE: 5V 1A USB-A Wall Adapter is not included in packaging.

The power adapter must comply with IEC 60601-1.

IN CASE OF EMERGENCY, CALL 911 IMMEDIATELY

Our support line is not for medical emergencies. If you believe you have an emergency, call 911.

Expanded Indications for Use Under FDA Enforcement Policies during the COVID-19 Public Health Emergency

The indications for use of this device have expanded under the FDA Enforcement Policies during the COVID-19 Public Health Emergency are:

- Indications for use have been expanded to persons who are 18 years of age or older (from 21 years of age or older)
- The device does not require physician prescription due to the Over-the-Counter (OTC) designation

Further, modifications were made to the FDA-cleared device design that resulted in a smaller device footprint.

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 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 continue wearing if severe discomfort or irritation occurs.

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.

The expanded indications for use are not reviewed by the FDA and/or may not have full clinical validation.

Recommendations provided by the device are adjunctive (supporting) and should not be solely or primarily relied upon to prevent, diagnose, or treat COVID-19 or co-existing conditions.

- The patient is the intended operator of this device.
- Keep the BioButton Rechargeable device away from children and pets. The device is a choking hazard and is harmful if swallowed.
- Remove the BioButton Rechargeable device prior to any defibrillation events.
- Clinical validation has not been performed for persons who have an implantable device such as a defibrillator or pacemaker.
- The BioButton Rechargeable 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 motion or vibration may cause inaccurate heart rate or respiratory rate measurements.
- Press the device's button regularly to check the indicator light and to verify that the device is in active

Warnings and Precautions (Continued)

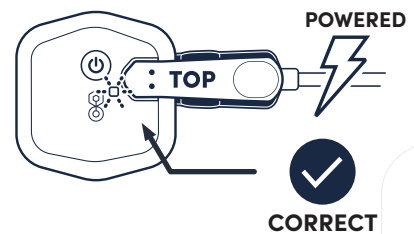
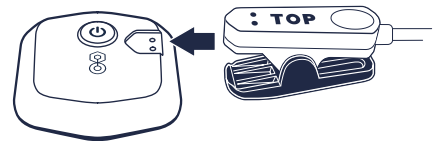
monitoring mode.





- Heart Rate and Respiratory Rate data is only reported when the wearer is at rest and not reported during periods of significant motion or activity.
- Certain motion or vibration may cause inaccurate heart rate or respiratory rate measurements.
- The use of accessories, detachable parts, and materials not described in the instructions for use shall not be used.
- Clinical validation has not been performed on child-bearing or breast-feeding patients.
- **DO NOT** charge the device while it is adhered to the body.

Use Instructions

GET STARTED

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



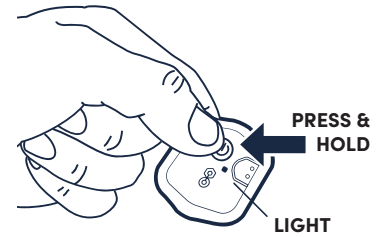
INDICATOR LIGHT BLINK PATTERN	CHARGE LEVEL
 Blink orange	0% - 10%
 Blink yellow	11% - 70%
 Blink green	71% - 99%
 Solid green	100%

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

Use Instructions

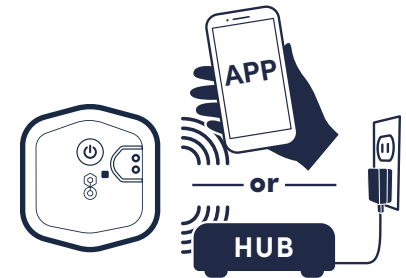
GET STARTED (CONTINUED)

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 Rechargeable device with the designated **APP** or **HUB DEVICE** indicated in your program's instructions.

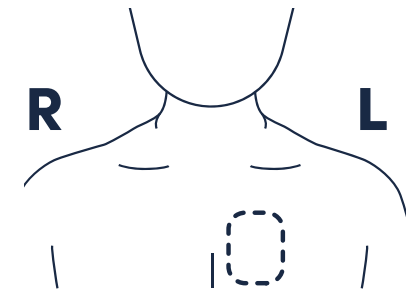
Note: Device may perform a firmware update before activation. If so, the light will slowly blink blue for a few minutes.



6. **CONFIRM BIOBUTTON RECHARGEABLE 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 **Button 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.



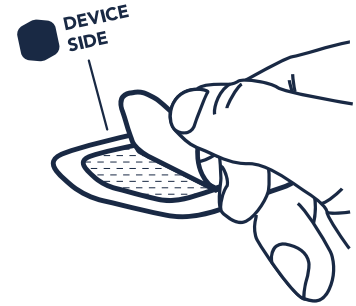
8. **CLEANSE AREA** with a warm, damp cloth. Note: **TRIM ANY BODY HAIR** using only an electric trimmer.



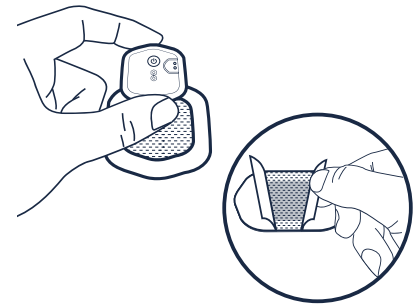
Use Instructions

GET STARTED (CONTINUED)

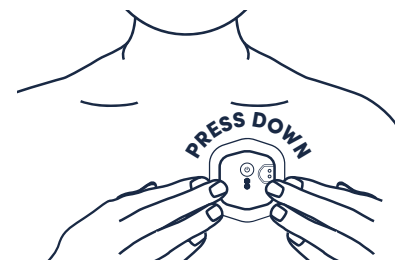
9. **TAKE** one adhesive. Peel the backing from **DEVICE SIDE** of adhesive.








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



11. **ADHERE** the BioButton Rechargeable 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 Button Light Pattern guide below.

BUTTON LIGHT PATTERN	MEANING
 10 blue blinks	Device not activated. Please follow activation instructions or call customer support for help setting up your device.
 Continuous slow blue blinking	Updating firmware
 4 green blinks	Device activated and actively monitoring
 5 orange blinks	Low battery
 Solid red light or no light	Device error -- contact support immediately

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, it is advised to apply the device to a different location within the placement area.

OFFLOADING YOUR DATA

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

End of Monitoring

After your monitoring period is complete, please remove the BioButton Rechargeable and dispose as electronic waste containing lithium ion batteries per local laws and regulations.

Other than removing the BioButton Rechargeable, no other user interaction 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

Troubleshooting and FAQs

Can I shower or exercise with the device?

Yes, the BioButton Rechargeable 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 Rechargeable 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 Rechargeable 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 reference 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 do I do?

Contact Customer Support immediately. You may be instructed to return the device and may receive a replacement kit if more data is needed for the monitoring period.

Safety and Regulatory Information

FCC STATEMENT

Model: BIOST06040F

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.

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

BioIntelliSense and BioButton are trademarks or registered trademarks of BioIntelliSense, Inc.

RESPONSIBLE PARTY:

BioIntelliSense, Inc.

570 El Camino Real #200

Redwood City, CA 94063

TERMS OF USE STATEMENT

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

- Website and Product User Terms of Use at www.biointellisense.com/website-and-product-user-terms-of-use
- Website and Product Privacy Policy at www.biointellisense.com/legal/privacy-policy

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.

SYMBOL LIBRARY



MRI unsafe



Don't use if package is damaged



Latex-free



Consult with instructions for use



Type BF applied part



FCC icon



Single-use only



Temperature limitation



Humidity limitation



Apply by date



Lot number



Model number



Warning

Technical Specifications

Product Name	BioButton Rechargeable
Model Number	BIOST06040F
Battery	Lithium ion
Service Life	18 months from manufacturing date
Heart Rate* Range	40-125 beats per minute (± 5 beats per minute)
Respiratory Rate* Range	10-30 breaths per minute with a mean absolute error of <math>< 3</math> breaths per minute
Skin Temperature Range	86°F - 107.6°F (30°C - 42°C)
Skin Temperature Accuracy	<math>< 96.4^{\circ}\text{F} \pm 0.5^{\circ}\text{F}</math> (<math>< 35.8^{\circ}\text{C} \pm 0.3^{\circ}\text{C}</math>) 96.4°F to $98^{\circ}\text{F} \pm 0.3^{\circ}\text{F}$ (35.8°C to $37^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$) 98°F to $102^{\circ}\text{F} \pm 0.2^{\circ}\text{F}$ (37°C to $39^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$) 102°F to $106^{\circ}\text{F} \pm 0.3^{\circ}\text{F}$ (39°C to $41^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$) $> 106^{\circ}\text{F} \pm 0.5^{\circ}\text{F}$ ($> 41^{\circ}\text{C} \pm 0.3^{\circ}\text{C}$)

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

SAFE EXPOSURE / SHORT TERM STORAGE

Temperature Range	-4°F to 104°F (-20°C to 40°C)
Humidity Range	10 to 95% RH

OPERATING CONDITIONS

Temperature Range	32°F to 104°F (0°C 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

Guidance and Declaration – Electromagnetic Compatibility


ELECTROMAGNETIC EMISSION

The BioButton Rechargeable 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: 2009 + AI:2010	GROUP 1	The BioButton Rechargeable sensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11: 2009 + AI:2010	CLASS B	The BioButton Rechargeable 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 Rechargeable sensor is intended for use in the electromagnetic environment specified below. The end user of the device should assure 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 ± 15 kV air	± 8 kV contact ± 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 %.
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.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the BioButton Rechargeable sensor than recommended to the frequency of the transmitter. Recommended separation distance:</p> $d = 1.2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3 \sqrt{P} \text{ 800 MHz to 2.7 GHz}$ <p>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 meters (m).</p> <p>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). Interference may occur in the vicinity of equipment marked with the following symbol: </p>

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 Rechargeable is used exceeds the applicable RF compliance level above, the BioButton Rechargeable should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BioButton Rechargeable.

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

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.

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

The BioButton Rechargeable 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 Rechargeable 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)	
	80 MHZ TO 800 MHZ $D = 1.2 \sqrt{P}$	800 MHZ TO 2.7 GHZ $D = 2.3 \sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	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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