



BioButton™ Instructions for Use

AUGUST 2020

Table of Contents

1	Indications for Use	5	Replace Your Adhesive
2	BioButton Overview	5	Troubleshooting and FAQs
2	Package Contents	6	Safety and Regulatory Information
3	Warnings and Precautions	8	Technical Specifications
4	Use Instructions	9	Guidance and Declaration

Indications for Use

The BioButton™ 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.

Expanded Indications for Use Under the FDA Emergency Use Authorization (EUA)

The indications for use of this device that have expanded under the FDA Emergency Use Authorization (EUA) during the COVID-19 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.

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.

IN CASE OF EMERGENCY, CALL 911 IMMEDIATELY

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

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 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 during a magnetic resonance imaging (MRI) procedure or in a location where it will be exposed to strong electromagnetic forces.

- Remove the BioButton prior to any defibrillation events. Clinical validation has not been performed for persons who have a defibrillator or pacemaker device.
- Keep the device away from children and pets. The BioButton device may be a choking hazard and may be harmful if swallowed.
- Press the BioButton's button regularly to verify that it is working.

Use Instructions

GET STARTED

1. Press and hold the button for **2 SECONDS**. Proceed when the **LIGHT** blinks repeatedly.
2. Locate area on **UPPER LEFT CHEST**, two inches below collar bone.
3. **TRIM ANY BODY HAIR** using only an electric trimmer and **CLEANSE AREA** with a warm, damp cloth.
4. Find adhesive. Peel backing from **DEVICE SIDE** of adhesive.
5. Place the BioButton **ON** the exposed adhesive. Turn over and **REMOVE** remaining adhesive backing.
6. **ADHERE** BioButton to chest. Apply pressure for 15 seconds

You're done!

LIGHT PATTERN MEANINGS

Press the BioButton's button and confirm the light blinks 5 times.

LIGHTS	MEANING
4 regular blinks	Actively monitoring
5 rapid blinks	Worn for maximum wear time (up to 90 days)
10 rapid blinks (repeated 4 times)	Not monitoring, connect to BioMobile app, BioSync app, or BioHub to restart monitoring
Solid light or no light	Error detected, contact support immediately

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 4 through 6 to put on a new adhesive and reapply BioButton.

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

Troubleshooting and FAQs

Can I shower or exercise with my device?

Yes, the BioButton 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 BioButton?

Yes, the BioButton 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 BioButton. If a severe reaction develops (i.e. hives or blisters), discontinue wearing and immediately contact your physician.

How long should I wear my device?

Please wear your device for the entire monitoring period, but no longer than 90 days. Each adhesive may be worn for up to 7 continuous days. You may replace the adhesive more often, as needed, to ensure good contact is maintained with the skin.

How do I know my device is working?

Press and release BioButton's button. The device light will blink 4 times. If the device does not blink or blinks more than 4 times, please immediately contact Customer Support (see front cover).

I've tried activating the device several times, and the light still won't blink. What do I do?

Contact Customer Support immediately (see front cover). 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: BIOST03020
FCC ID: 2ASE7- BIOST03020

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.

This device complies with FCC Radiation Exposure limits set forth for an uncontrolled environment. This device should be installed and operated with a minimum distance of 20 cm between the radiator and your body.

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

RESPONSIBLE PARTY:

BioIntelliSense, Inc.
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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 Privacy Policy at www.biointellisense.com/website-privacy-policy
- Product and Data-as-a-Service Privacy Policy at www.biointellisense.com/product-and-service-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, sneezing and vomit frequency and other symptomatic or biometric data. The Product(s) may also be configured to track and record proximity and duration data in relation to other Product(s). 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
Model Number	BIOST03020F
Battery	140mAh, CR1632
Heart Rate* Range	40 to 125 beats per minute (<± 5 beats per minute)
Respiratory Rate* Range	10 to 30 breaths per minute
Skin Temperature Range	86°F to 107.6°F (30°C - 42°C)
Skin Temperature Accuracy	< 96.4°F ± 0.5°F (< 35.8°C ± 0.3°C) 96.4°F to 98°F ± 0.3°F (35.8°C to 37°C ± 0.2°C) 98°F to 102°F ± 0.2°F (37°C to 39°C ± 0.1 °C) 102°F to 106°F ± 0.3°F (39°C to 41°C ± 0.2°C) > 106°F ± 0.5°F (> 41°C ± 0.3°C)
Ambient Temperature	50°F to 110°F ± 1°F (10°C to 43°C)

STORAGE CONDITIONS

Temperature Range	-4°F to 122°F (-20°C to 50°C)
Humidity Range	0 - 95% RH

OPERATING CONDITIONS

Temperature Range	32°F to 122°F (0°C to 50°C)
Humidity Range	0 - 95% RH
Atmospheric Pressure	70 - 102 kPa
Water Resistance	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 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 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 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 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 sensor than recommended to the frequency of the transmitter.</p> <p>Recommended separation distance: $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz</p> <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).</p> <p>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 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.

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

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)	
	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** or email support@biointellisense.com

MANUFACTURED BY

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