



Instructions for Use

For complete instructions, visit:
BioIntelliSense.com/support

For additional support, please call

888.908.8804

or email

support@biointellisense.com

In the event of a medical
emergency, dial 911 immediately.

INTRODUCTION

INTENDED 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.

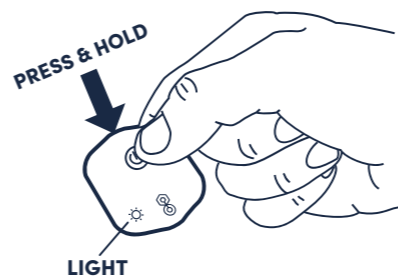
The device does not output heart rate or respiratory rate measurements during periods of motion or activity.

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

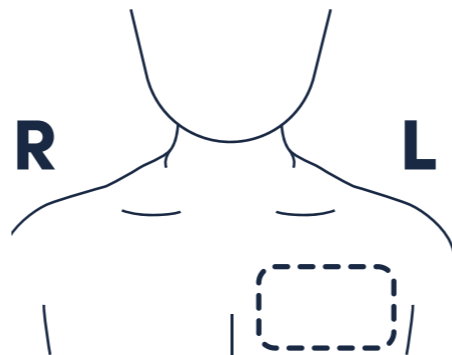
NOTICE: Use of the BioIntelliSense Product(s) is subject to our Website and Product User Terms of Use at (BioIntelliSense.com/website-and-product-user-terms-of-use), Website Privacy Policy at (BioIntelliSense.com/website-privacy-policy), and Product and Data-as-a-Service Privacy Policy at (BioIntelliSense.com/product-and-service-privacy-policy). 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.

GET STARTED

- 1 Press and hold the BioButton™ button for **2 SECONDS**. Proceed when the **LIGHT** blinks repeatedly.



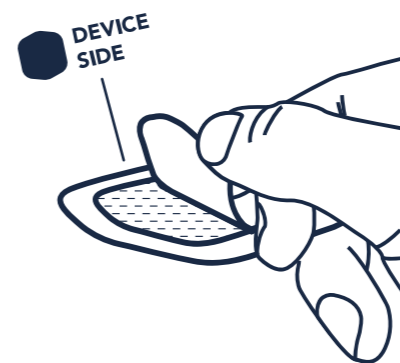
- 2 Locate area on **UPPER LEFT CHEST**, two inches below collar bone.



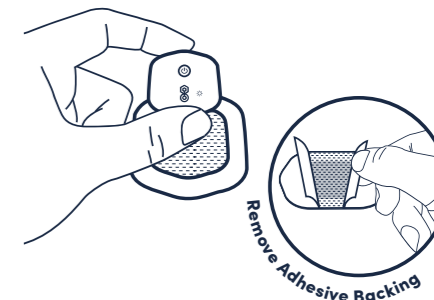
- 3 **TRIM ANY BODY HAIR** using only an electric trimmer and **CLEANSE AREA** with a warm, damp cloth.



- 4 Find adhesive. Peel the backing from **DEVICE SIDE** of adhesive.



- 5 Place the BioButton **ON** the exposed adhesive. Turn over and remove remaining adhesive backing.

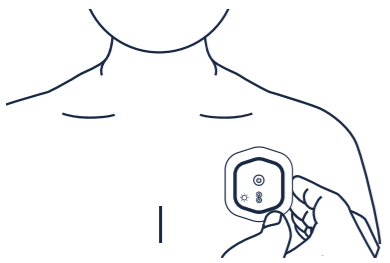


- 6 Adhere BioButton to chest. Apply pressure for **15 SECONDS**.

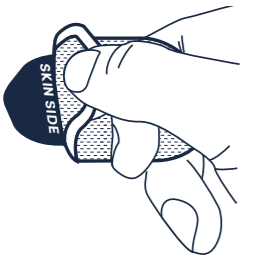


REPLACE YOUR ADHESIVE

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



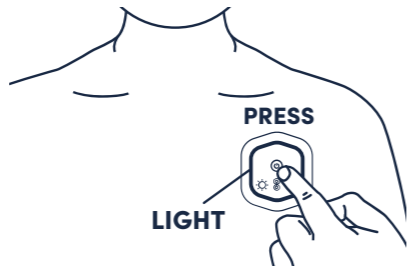
REMOVE adhesive from bottom of device. Follow steps 4 thru 6 to put on a new adhesive and reapply BioButton.



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

VERIFY DEVICE IS WORKING

Press the BioButton's button and confirm the light blinks **4 TIMES**. If the device blinks more than 4 times or does not blink at all, please contact support.



SUPPORT

For tips on long-term wear and additional adhesive support, visit:
[BioIntelliSense.com/support](https://biointellisense.com/support)

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

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.

Manufactured by BioIntelliSense, Inc.
570 El Camino Real #200, Redwood City, CA 94063

TROUBLESHOOTING & FAQs

Can I shower or exercise with the BioButton? 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.

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.

WARNINGS & 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.

BBN Instructions for Use (Printed) (DOC-888) Ver. 1

Approved By:

[\(CO-84\) BBN-LCO-002 Change Order to Release BBN FDA MP Labeling](#)

Description

Officially release the labeling we plan to use for the FDA version of the BioButton Labeling

Justification

Design Transfer

Assigned To:

Ray Hsieh

Initiated By:

Eleanor Drake

Priority:

High

Impact:

Major

Version History:

Author	Effective Date	CO#	Ver.	Status
Ray Hsieh	December 8, 2020 11:49 PM GMT	CO-84	1	Published
Eleanor Drake	October 15, 2020 1:00 AM GMT	CO-79	0	Superseded

FCC Part 15.19 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 FCC Part 15.21 information for user You are cautioned that changes or modifications not expressly approved by the party responsible for compliance could void your authority to operate the equipment. FCC Section 15.105 Information to the user. NOTE: 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. IMPORTANT NOTE :FCC Radiation Exposure Statement :This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.