



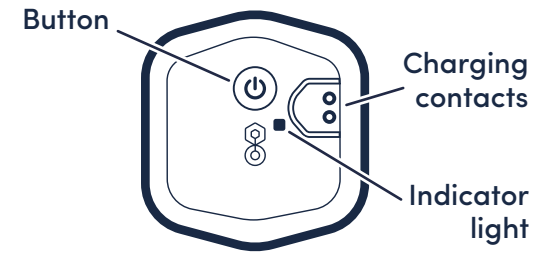
BioButton

RECHARGEABLE

IN-FACILITY INSTRUCTIONS FOR USE

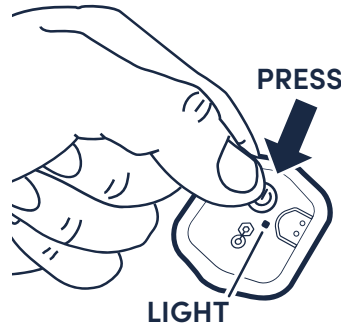
For complete instructions, visit: BioIntelliSense.com/support

DEVICE OVERVIEW



GET STARTED

1 POWER ON THE DEVICE, by pressing the center 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)

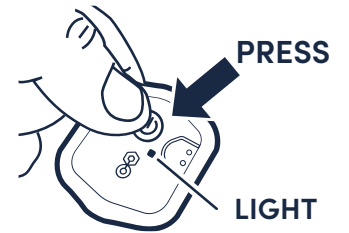


If the device is within range of a nearby hub, then the device will activate.

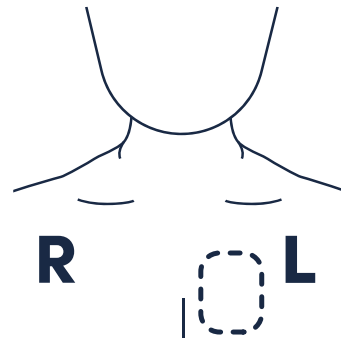
Note: Activation may take around 60 seconds. Device may perform a firmware update before activation. If so, the light will **SLOWLY BLINK BLUE** for a few minutes.



2 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** on step 8 for guidance.



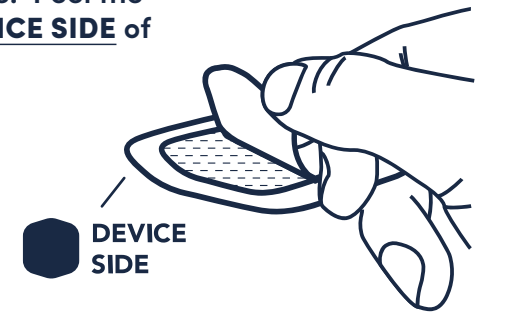
3 Locate placement area on **UPPER LEFT CHEST**, two inches below collar bone, and close to the sternum.



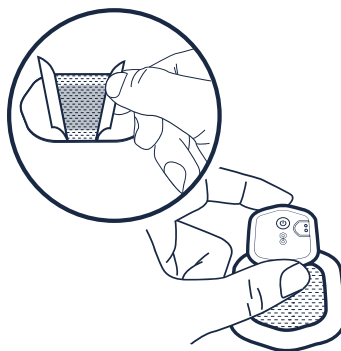
4 CLEANSE AREA with a warm, damp cloth. **Note: TRIM ANY BODY HAIR** using only an electric trimmer. **ENSURE** the area is fully dry before applying the adhesive. **NOTE:** No razors, no waxing, no alcohol.



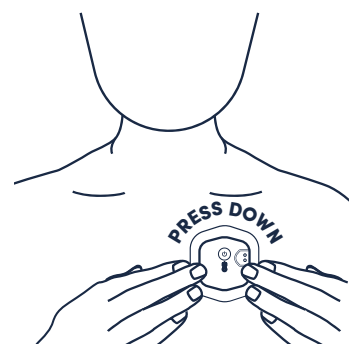
5 TAKE one adhesive. Peel the backing from **DEVICE SIDE** of adhesive.



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



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



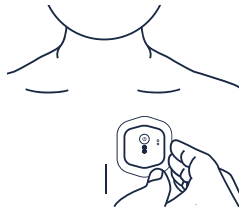
8 Press the button to check the device status. See **Indicator Light Pattern guide** below.

PATTERN	MEANING
10 blue blinks	Not Activated
Continuous slow blue blinking	Updating Firmware
4 green blinks	Actively Monitoring
5 orange blinks	Low Battery
Solid red light or no light	Error detected, contact support

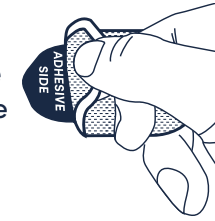
REPLACE THE ADHESIVE

- When no longer sticky.
- If patient experiences minor irritation or redness in placement area.

REMOVE adhesive from bottom of device. Follow steps 3 - 7 to put on a new adhesive and reapply the device.



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



IN THE EVENT OF A MEDICAL EMERGENCY, CONTACT YOUR MEDICAL EMERGENCY SERVICE.

For additional support including tips on long-term wear and adhesive information. Email support@biointellisense.com, call 888.908.8804 (US ONLY), or visit [BiointelliSense.com/support](https://www.biointellisense.com/support)

TROUBLESHOOTING & FAQs

Can patient 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 patient 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.

Patient is experiencing some skin irritation, what should they do? Minor skin irritation and itching may occur while wearing the de-

vice. If a severe reaction develops (i.e. hives or blisters), patient should discontinue wearing and check with their clinician.

How long should patient wear the BioButton device? Patient should wear their 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](https://www.biointellisense.com/support).

How to know the device is working: Press and release the device's button. The device light will blink **GREEN 4 TIMES**. If device light is blinking a different color, please reference the Button Press Light Patterns table on the front page.

After trying to power on the device several times, the light still won't blink blue. What to do next: Contact Customer Support immediately. Clinician 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 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.
- **REMOVE** the BioButton Rechargeable device prior to any defibrillation events. Clinical validation has not been

performed for persons who have a defibrillator, pacemaker device, and other implantable devices.

- **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.
- Keep the BioButton Rechargeable device away from children and pets. The device is a choking hazard and is harmful if swallowed.

- Press the device's button regularly to check the indicator light and to verify that the device is in active 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.

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. **NOTICE:** Use of the Biointelli-

Sense Product(s) is subject to our Website and Product User Terms of Use at ([BiointelliSense.com/website-and-product-user-terms-of-use](https://www.biointellisense.com/website-and-product-user-terms-of-use)), Website Privacy Policy at ([BiointelliSense.com/website-privacy-policy](https://www.biointellisense.com/website-privacy-policy)), and Product and Data-as-a-Service Privacy Policy at ([BiointelliSense.com/product-and-service-privacy-policy](https://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. 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. provider

Manufactured by BiointelliSense, Inc.
570 El Camino Real #200, Redwood City, CA 94063
IFU-BBR-3675 Ver.0