



BioIntelliSense BioSticker Medical Device for Single Use and Can Collect Data Instructions

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BioIntelliSense BioSticker Medical Device for Single Use and Can Collect Data



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INTRODUCTION

INTENDED USE

The BioSticker™ is a remote monitoring wearable device intended to collect physiological data in home and healthcare settings.

The data 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.

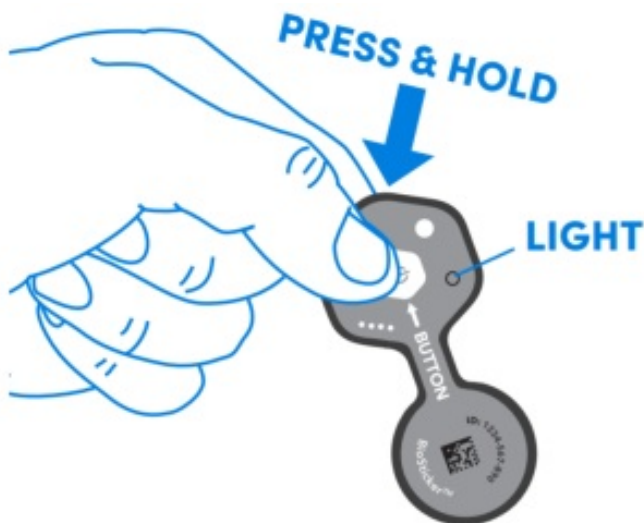
The device is not intended for use on critical care patients.

NOTICE: Use of the BioIntelliSense Product(s) is subject to our Website and Product User Terms of Use at (BioIntelliSense.com/website-and-productuser-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-privacypolicy). 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 button for **4 SECONDS**. The light will blink **GREEN**.

Press the button again, and the light will blink **YELLOW** (indicating that the device is ready to be activated).



2. **ACTIVATE** your BioSticker with the designated app or device indicated in your program's instructions.

Once activated, **PRESS THE BUTTON** on your BioSticker to verify activation. The light should blink **GREEN, 5 TIMES**.

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

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

NO RAZORS



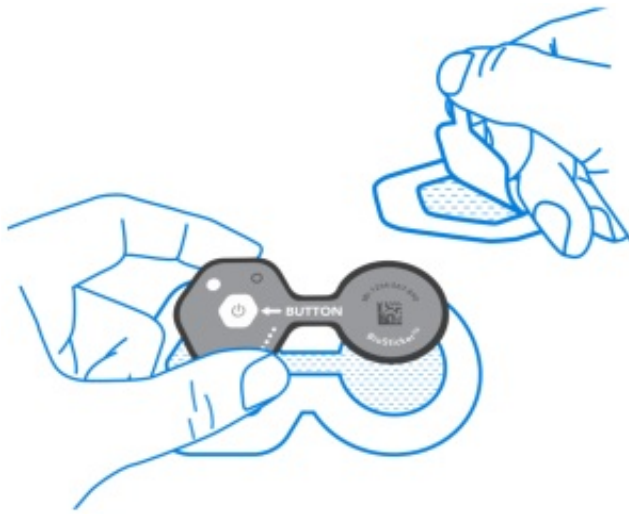
NO WAXING



NO ALCOHOL



5. Peel backing from **DEVICE SIDE** of adhesive. Place the BioSticker **ON** the exposed adhesive.



6. Turn over and **REMOVE** remaining adhesive backing. **ADHERE** BioSticker to chest horizontally or vertically.

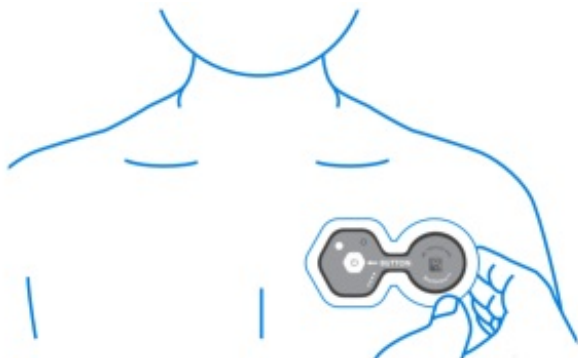


VERIFY THE DEVICE IS WORKING

At any time, press the BioSticker's button and confirm the light blinks GREEN, 5 TIMES. If the device does not blink green or does not blink at all, please contact support.

REPLACE YOUR ADHESIVE

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



REMOVE adhesive from bottom of device. Follow steps 4 and 5 to put on a new adhesive and reapply BioSticker.



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

TROUBLESHOOTING & FAQs

Can I shower or exercise with my device?

Yes, the device is water resistant and can be worn during showers and exercise. Do not apply any oil or lotion to the placement area as it will reduce adhesion of the device to the skin.

Can I swim or bathe with my device?

No, although the device is water resistant it should not be submerged underwater including while swimming or bathing. Prolonged submersion underwater may cause damage to the device and may cause the device to loosen from the skin.

If removed for swimming or bathing, replace the adhesive and reapply the device to the placement area.

How long can I wear my adhesive?

The adhesive is designed for continuous use and can be worn until the adhesive loosens from the skin. On average, it is recommended to replace the adhesive every 7 days. If the adhesive is removed while still firmly secured, use a skin adhesive remover or baby oil to help loosen the adhesive as you gently peel from your skin.

How long should I wear my device?

Please wear your device, as instructed, for up to 30 days and return in the prepaid postage envelope. Note: At 30 days, after pressing the button, the light will alternate between green and yellow.

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, discontinue wearing and immediately contact your physician.

Can I wear my device through a metal detector?

Yes, please tell TSA or any security representative that you are wearing a "medical device."

My device isn't blinking after I press the button, what do I do?

The device may no longer be active. To reactivate the device, press and hold the button for 4 seconds. When you release the button, the light should blink green. If the device does not blink, please immediately contact Customer Support.

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** attempt to remove the adhesive immediately after application. Early removal may be uncomfortable

and may cause irritation.

- **DO NOT** continue wearing if severe discomfort or irritation occurs.
- **DO NOT** submerge the device underwater. Submerging the device for an extended period of time may damage the device.
- **DO NOT** exert excessive force, drop, modify, or attempt to take apart the device, as it may cause malfunction or permanent damage. Doing so may cause malfunction or permanent damage.
- **DO NOT** wear or use the device during a magnetic resonance imaging (MRI) procedure or in a location where it will be exposed to strong electromagnetic forces.
- Remove the device prior to any defibrillation events. Clinical validation has not been performed for persons who have a defibrillator, pacemaker, or other implantable device.
- Keep the device away from children and pets. The device may be a choking hazard and may be harmful if swallowed.

ADHESIVE 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

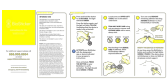
support@biointellisense.com

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.

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Documents / Resources

	BioIntelliSense BioSticker Medical Device for Single Use and Can Collect Data [pdf] Instructions BioSticker, Medical Device for Single Use and Can Collect Data
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