

Intended Use & Precautions

The BioSticker Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings while the patient is at rest. This can include heart rate, respiratory rate, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data can be transmitted either wirelessly or via a wired connection for storage and analysis.

The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the BioSticker Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment.

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

- ⚠ **DO NOT** wear device over excessive body hair in the torso area. Excessive body hair should be removed before application.

⚠ **DO NOT** place on broken skin including wounds, sores, or abrasions.

⚠ **DO NOT** continue wearing if severe discomfort or irritation occurs.

⚠ **DO NOT** wear more than one device at a time. Incorrect handling, excessive force, or dropping the device may cause malfunction or permanent damage.

⚠ **DO NOT** excessively bend or twist the BioSticker™.

⚠ **DO NOT** wear or use the BioSticker™ during a magnetic resonance imaging (MRI) procedure or in a location where it will be exposed to strong electromagnetic forces.

⚠ **DO NOT** modify or attempt to take the device apart.
- ⚠ **DO NOT** submerge the device in water. The device may be removed for a bath or shower and then re-applied afterwards.

⚠ Keep the device away from children and pets. The BioSticker™ may be a choking hazard and may be harmful if swallowed.

⚠ Clinical validation has not been performed on patients who are pregnant, breastfeeding, and those wearing a defibrillator or pacemaker.

⚠ This device is non-sterile.

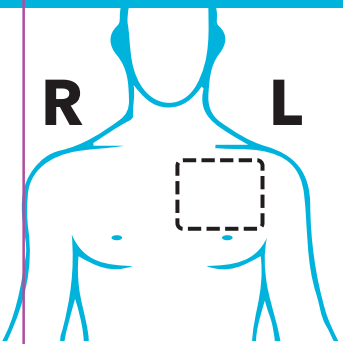
⚠ The BioSticker™ is to be worn on the chest.

⚠ Excessive sweat will reduce wear time. The device may be removed before exercise and then re-applied afterwards.

⚠ This device contains parts and assemblies susceptible to damage by electrostatic discharge.

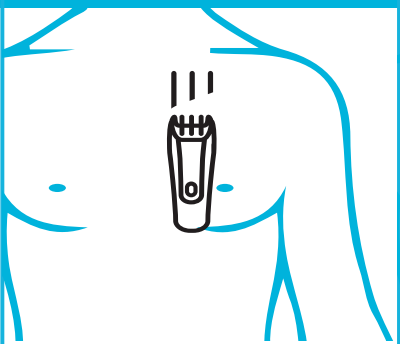
Wear Instructions

Step 1: Prepare the skin

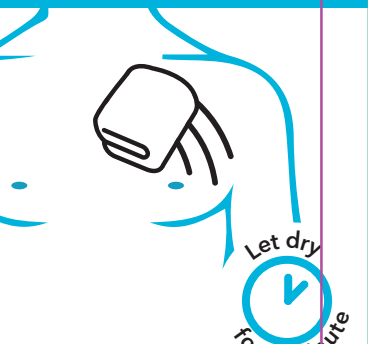


Identify the placement area

- Upper left chest
- A couple inches below **LEFT** collar bone

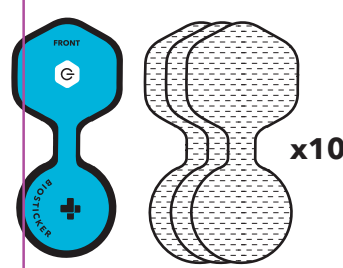


Trim body hair
If necessary, remove body hair from the upper left chest with an electric trimmer.

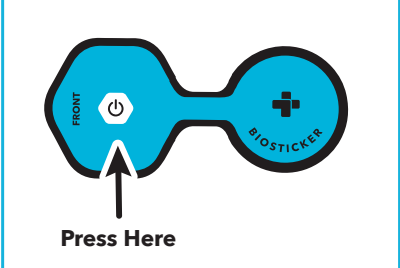


Clean the area with warm water
Once the skin is free of excess hair, wipe with a warm, damp cloth.

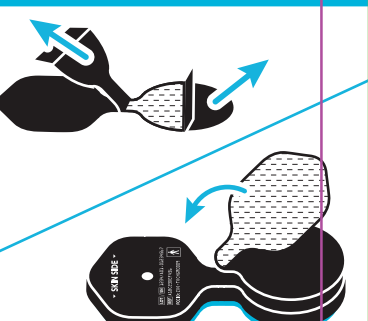
Step 2: Prepare the BioSticker™



Locate the BioSticker™ and adhesives
Locate and remove the BioSticker™ and adhesives from packaging.



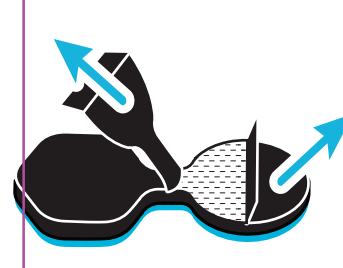
Activate the BioSticker™
Press and release the power button. The light should blink.



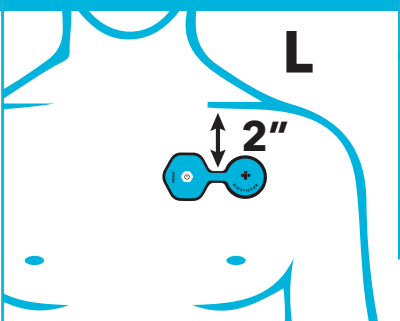
Apply adhesive to the BioSticker™

- Remove the adhesive backings from one side of the adhesive
- Attach it to black side of the BioSticker™

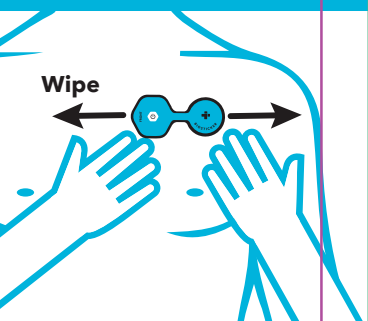
Step 3: Apply BioSticker™ to Left Chest



Remove adhesive backings
Remove remaining adhesive backings.



Apply BioSticker™ to placement area
Apply the BioSticker™ to the **flattest part** of your chest, 2" below your collar bone.



Apply pressure to the device
Press down and apply pressure to ensure good contact with the skin.

Wear the device for the prescribed duration.

Refer to your physician's instructions for wear time and return instructions.

For Best Results:

- Press the button on the device to verify that the device is working. The device light should blink. If your device is not blinking, please see Troubleshooting & FAQs.
- Place the device on the flattest part of your left chest, two inches below the collar bone.
- If the device falls off due to sweat or moisture, dry off the adhesive and reapply. If the device continues to fall off due to low adhesion, remove and replace the adhesive. Then, reapply the device to the placement area.
- If mild irritation occurs, replace the adhesive to maintain comfort.
- To allow skin to breathe, place the device in a new location when replacing the adhesive.
- Wear a shirt while sleeping to keep the device secure.

For help, email support@biointellisense.com

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

Wear Instructions & User Guide

BIO STICKER

Symbol Library

FCC icon

Consult instructions for use

Don't use if package is damaged

Type BF applied part

Apply by date

Date of manufacture

Model number

Lot number

Temperature limitation

Humidity limitation

Keep dry

Latex-free

FCC Statement & Legal Notices

Model: BIST0208
FCC ID: 2ASE7- BIST0208

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.

CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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Responsible Party:
BioIntellisense, Inc.
570 El Camino Real #200
Redwood City, CA 94063

Our full Notice of Privacy Practices and Terms of Service, found at www.biointellisense.com/legal, describes our privacy practices, our legal duties, and your rights concerning your Protected Health Information (PHI).

Technical Specifications

Product Name: BioSticker
Model Number: BIST0208
Battery: 620mAh, Lithium Coin Cell

Operating Conditions:
Temperature Range: 10-40°C
Humidity Range: 10-95% RH
Atmospheric Pressure: 70-102 kPa
Water Resistance: IPX8

Heart Rate Range: 30-130 beats per minute (< ± 5 beats per minute).

Respiratory Rate Range: 10-30 breaths per minute with a mean absolute error of < 3 breaths per minute. 4-42 breaths per minute with a mean absolute error of < 1.5 breaths per minute.

Skin Temperature: Complies with ASTM E1112.

Troubleshooting & FAQs

Can I shower with my device?
Yes, but showers should be short. We recommend showering with your back against the water and keeping soaps and lotions away. While drying off, hold the BioSticker™ down with one hand. **Please do not apply any deodorant or lotion to the application area.**

Can I swim or bathe with my device?
You should not submerge the device underwater. Baths should be fine as long as the device is kept above water.

What activities should I avoid?
Avoid activities that cause excessive sweating. They can cause the BioSticker™ to become loose and shorten wear time.

How long should I wear my device for?
Wear your device for the prescribed number of days. If you see moisture in the adhesive or are experiencing mild irritation, replace the adhesives to maintain comfort.

I'm experiencing some skin irritation, what should I do?
If you are experiencing severe skin irritation, contact support immediately.

How do I know my device is working?
Press and release the button on the hexagon side of the device. The device light should blink. If the device is not blinking, wait 2 minutes and try again.

Why is my device blinking blue?
Occasionally, the device will perform a system reboot. After the reboot is complete, the light will blink blue.

My device isn't blinking at all, what do I do?
The device may have shut down, automatically. To activate the device, press and hold the button for 5 seconds. When you release the button, the light should blink blue.

For additional support, please email support@biointellisense.com