

Intended Use & Precautions

The BioSticker™ System is a 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, and skin temperature. Data are transmitted via wireless connection from the BioSticker™ 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™ System 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** incorrectly handle, exert excessive force, or drop the device. Doing so 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 left 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 hold the power button for 2 seconds. Release the power button and 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 inches 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.

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, 2 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



Symbol Library

	FCC icon		Apply by date		Temperature limitation
	Consult instructions for use		Date of manufacture		Humidity limitation
	Don't use if package is damaged		Model number		Keep dry
	Type BF applied part		Lot number		Latex-free

FCC Statement & Legal Notices

Model: B1OST03080
FCC ID: 2ASE7- B1OST0308

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.

BioIntellisense and BioSticker are trademarks or registered trademarks of BioIntellisense, Inc.

Responsible Party:
BioIntellisense, Inc.
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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: B1OST03080 Battery: 620mAh, Lithium Coin Cell	Operating Conditions: Temperature Range: 0 - 50°C Humidity Range: 10 - 95% RH Atmospheric Pressure: 70 - 102 kPa Water Resistance: IP47
Heart Rate Range: 40-125 beats per minute (< ± 5 beats per minute).	Storage Conditions: Temperature Range: -20 - 50°C Humidity Range: 10 - 95% RH
Respiratory Rate Range: 10-30 breaths per minute with a mean absolute error of < 3 breaths per minute.	
Skin Temperature Accuracy: 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)	

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 on its own?

Occasionally, the device will perform a system reboot. After the reboot is complete, the light will blink.

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

The device may have shut down, automatically. To activate the device, press and hold the button for 2 seconds. When you release the button, the light should blink.

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