BioIntelliSense

BioSticker™ Instructions for Use

AUGUST 2020

Table of Contents

Indications for Use

The BioSticker™ is a remote monitoring wearable device intended to collect physiological data in the home and healthcare setting, while the user is at rest. The data can include heart rate, respiratory rate, and skin temperature. Data are securely transmitted via wireless connection from the BioSticker for storage and analysis.

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

BioSticker

The device is not intended to output physiological measurements while the user undergoes significant motion or is active.

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

The device is authorized to have expanded indications for use under the FDA Emergency Use Authorization (EUA) during the COVID-19 health emergency.

IN CASE OF EMERGENCY, CALL 911 IMMEDIATELY
Our support line is not for medical emergencies. If you believe you have an emergency, call 911.

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BioSticker Overview

The BioSticker wearable device is made of medical grade silicone and is adhered with a double-sided medical grade silicone adhesive.

Package Contents

- BioSticker Device
- Fabric Skirt Adhesives
- Instructions for Use
- Return Instructions
- Postage-paid Return Envelope

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Warnings and 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.
- The BioSticker is to be worn on the upper left chest.
- This device is non-sterile.
- This device contains parts and assemblies susceptible to damage by electrostatic discharge.
- The device is not intended to detect abnormal cardiac rhythm episodes (such as atrial fibrillation).
- Electronic equipment, including portable and mobile Radio Frequency (RF) communications equipment, and RF emitters such as diathermy, electrocautery, RFID, and security systems (e.g., electromagnetic anti-theft systems, and metal detectors), can be sources of electromagnetic disturbances which will affect the operation of the BioSticker device. Operating non-essential equipment in the vicinity of the BioSticker device should be avoided. If interference is suspected, the responsible equipment and associated cables should be moved away from the BioSticker device.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to the BioSticker device.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Depending on strength of electromagnetic or radio frequency disturbances, a temporary interruption of data collection is possible, which may impact continuous monitoring. If encountering such event, consult the troubleshooting section of this document.

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Use Instructions

BEFORE YOU START

a. Download and install the **BioMobile**™ app for iOS or Android phones.
We support iOS 13+ and Android 9+

b. Set up BioHub™ unit by **following the instructions in the BioHub box.**

DO NOT proceed until BioMobile app or BioHub is set up.

GET STARTED

1. Press and hold the button for **4 SECONDS.** The light will blink **GREEN.**
2. Locate placement 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. Peel backing from **DEVICE SIDE** of adhesive. Place the BioSticker **ON** the exposed adhesive.
5. Turn over and **REMOVE** remaining adhesive backing. **ADHERE** BioSticker to chest horizontally or vertically.
6. **PRESS DOWN** for 15 seconds.

You're done!

LIGHT PATTERN MEANINGS

Press the BioSticker's button and confirm the light blinks 5 times.

LIGHTS	MEANING
5 green blinks	Actively monitoring
3 green blinks, 3 yellow blinks	Worn for maximum wear time (up to 30 days)
Red light or no light	Error detected, contact support immediately

The device may turn off in the presence of strong Electro-Magnetic Interference (EMI). If this happens, reactivate the device by pressing and holding the button for 5 seconds. When you release the button, the light should blink. If the device does not blink, please try activating the device in another room, away from heavy machinery, motors, or generators.

The device is expected to operate for 30 days once activated. If you suspect your device is no longer working, press the button. The light will either not blink, or blink red if not operable.

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Replace Your Adhesive

- **When no longer sticky.**
- **If you experience redness or irritation in the 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.

For tips on long-term wear and additional adhesive support, visit: **BioIntelliSense.com/support**

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

Troubleshooting and 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 deodorant 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.

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.

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Safety and Regulatory Information

FCC STATEMENT

Model: BIOST01021F
FCC ID: 2ASE7- BIOST01021

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.

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RESPONSIBLE PARTY:
BioIntelliSense, Inc.
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PRIVACY POLICY

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).

When you use this product, BioIntelliSense, Inc. ("BioIntelliSense") collects several types of information about you, including:

- By which you may be personally identified, such as name, mailing address, email address, telephone number, audio recordings, date of birth, gender, medical history, health information, or other information defined as "Protected Health Information" under HIPAA/HITECH laws and regulations ("personal information").
- About your use of our products and services, time and date of visits to our Product, and information about your wearable BioIntelliSense device.
- About your internet connection, the equipment you use to access our Product or Portal and usage details.

To the extent the information above constitutes protected health information ("PHI") under the U.S. Health Insurance Portability and Accountability Act ("HIPAA"), BioIntelliSense will only use PHI to perform our services, to respond to you or your health care provider ("Provider"), or as otherwise permitted by your Provider or applicable law. We may use your PHI to contact you, to provide requested services, to provide information to your Providers and insurers, to obtain payment for our services, to respond to your inquiries and requests, to improve our products or services, and to respond to inquiries and requests from your Providers and benefits program. We may combine your information with other information about you that is available to us, including information from other sources, such as from your Providers, insurers or benefits program, in order to maintain an accurate record of our participants. PHI will not be used for any other purpose, including marketing, without your consent.

For more information about how we collect, use, and share your information please review our Privacy Policy at biointellisense.com/legal

BY USING THE BIOINTELLISENSE PRODUCTS AND SERVICES YOU ACKNOWLEDGE AND AGREE TO THE BIOINTELLISENSE PRIVACY POLICY AND TERMS OF USE, WHICH IS AVAILABLE AT biointellisense.com/legal. IF YOU DO NOT AGREE WITH OUR PRIVACY POLICY AND TERMS OF USE, DO NOT USE THE BIOINTELLISENSE PRODUCTS AND SERVICES.

THE BIOINTELLISENSE PRODUCT MAY CREATE, TRANSMIT, DISCLOSE, AND USE AUDIO RECORDINGS OF YOU WHILE YOU USE AND INTERACT WITH OUR PRODUCTS AND SERVICES. BY USING THE BIOINTELLISENSE PRODUCTS AND SERVICES YOU AGREE TO SUCH RECORDINGS. IF YOU DO NOT AGREE TO SUCH RECORDINGS, DO NOT USE OUR PRODUCTS AND SERVICES.

SYMBOL LIBRARY

MRI unsafe


Don't use if package is damaged

Latex-free


Consult with instructions for use


Type BF applied part


FCC icon


Single-use only


Temperature limitation


Humidity limitation


Apply by date

Lot number

Model number


Warning

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Technical Specifications

Product Name	BioSticker
Model Number	BIOST01021F
Battery	620mAh, Lithium coin cell (3V)
Heart Rate* Range	40-125 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
Skin Temperature Range	86°F - 107.6°F (30°C - 42°C)
Skin Temperature Accuracy	< 96.4°F ± 0.5°F (< 35.8°C ± 0.3°C) 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 41ºC ± 0.2°C) > 106°F ± 0.5°F (> 41ºC ± 0.3°C)

STORAGE CONDITIONS

Temperature Range	-4ºF to 104ºF (-20ºC to 40°C)
Humidity Range	10 - 95% RH

OPERATING CONDITIONS

Temperature Range	32ºF to 104ºF (0ºC to 40°C)
Humidity Range	10 - 95% RH
Atmospheric Pressure	70 - 102 kPa
Water Resistance	IP47

COMMUNICATIONS

Communication Technology	Bluetooth (BT4.2)
Distance	Max. 10 meters (30 feet) line of sight
Radio Modulation GFSK	Guassian frequency shift keying
Radio Frequency	2.4 – 2.5 GHz
Transmit Power	0dBm
Security	AES-CTR 128 bit encryption (Advanced encryption standard counter mode)

* Measurements are taken at rest

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Guidance and Declaration — Electromagnetic Compatibility

ELECTROMAGNETIC EMISSION

The BioSticker sensor is intended for use in the electromagnetic environment specified below. The user of the device shall ensure that the device is used in such an environment.

EMISSION TEST METHOD	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT & GUIDANCE
RF emissions CISPR 11: 2009 + AI:2010	GROUP 1	The BioSticker sensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11: 2009 + AI:2010	CLASS B	The BioSticker sensor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

ELECTROMAGNETIC IMMUNITY

The BioSticker sensor is intended for use in the electromagnetic environment specified below. The end user of the device should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the BioSticker sensor than recommended to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey(a) should be less than the compliance level in each frequency range(b). Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BioSticker is used exceeds the applicable RF compliance level above, the BioSticker should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BioSticker.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

IMMUNITY TO RF WIRELESS COMMUNICATIONS EQUIPMENT

TEST FREQUENCY (MHZ)	BAND[A] (MHZ)	SERVICE[A]	MODULATION[B]	MAXIMUM POWER (W)	DISTANCE (M)	IMMUNITY TEST LEVEL (V/M)
385	380-390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM[c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710, 745, 780	704 – 787	LTE Band 13, 7	Pulse modulation[b] 217 Hz	0.2	0.3	9
810, 870, 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
1720, 1845, 1970	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7[a]	Pulse modulation[b] 217 Hz	2	0.3	28
5240, 5500, 5785	5100 –5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND BIOSTICKER

The BioSticker is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The end user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BioSticker sensor as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (M)	
	80 MHZ TO 800 MHZ $D = 1.2\sqrt{P}$	800 MHZ TO 2.7 GHZ $D = 2.3\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23

Contact Us

For non-urgent support or questions about our product, please call **888.908.8804** or email **support@biointellisense.com**

MANUFACTURED BY

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