

BioHub™ Instructions for Use

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Indications for Use

The BioHub™ is a radio communications unit. The BioHub wirelessly, via Bluetooth, collects data from BioIntelliSense devices and authorized 3rd party medical devices. The BioHub seamlessly and securely transmits the data via cellular networks to the BioIntelliSense BioCloud. The BioHub is designed for ease of use within the home setting.



Package Contents

- BioHub Device
- USB Wall Adapter
- USB-C to USB-A Power Cable
- Instructions for Use

IN CASE OF EMERGENCY, CALL 911 IMMEDIATELY

Our support line is not for medical emergencies. If you believe you have an emergency, call 911.

Getting Started

IDENTIFY A LOCATION

Place the BioHub in an area with:

- A dedicated outlet** where others will not be tempted to unplug it.
- Good cellular signal.** Use your phone to check your signal strength.

We suggest placing it on your bedside table. If that's not possible, place the BioHub in a room that you visit often, like your living room.

WARNING: Keep BioHub away from water.

PLUG IN THE BIOHUB

- Plug the USB-C into the BioHub.** Insert the smaller end of the power cable into the BioHub.
- Plug the USB-A into the wall adapter.** Insert the larger end of the power cable into the wall adapter.
- Plug the wall adapter into an outlet.** Make sure the wall adapter fits snug in a standard electrical wall outlet.

CONFIRM NETWORK CONNECTION

- Screen will turn on.** After 10 seconds, the BioHub logo will appear on the screen.
- BioHub will search for a cellular network.** See our FAQs if BioHub is unable to find and make a connection.
- Network found. BioHub is ready for use.** When connected, the screen will show the current time.

Note: Keep your BioHub plugged in for the whole monitoring period. If BioHub becomes unplugged, plug it back in to re-establish radio communication.

Using the BioHub

NAVIGATION

Use the arrows to flip between the clock and the status screen.

STATUS ICONS



BioHub's bluetooth antenna is working as expected.



BioHub is currently connected to a device.
Note: This icon only displays occasionally.



Data is being uploaded to the BioCloud.
Note: This icon only flashes occasionally.



These bars show the cellular signal strength of the BioHub.

Troubleshooting and FAQs

Where should I set up my BioHub?

Place your BioHub in your bedroom on your bedside table. You should be able to view and interact with the BioHub screen. If you are unable to establish a connection, try plugging in your BioHub in a frequently visited room where you have good network reception. Note: The BioHub is not waterproof. Please keep away from water.

How do I know my BioHub is working?

If you are able to see the clock and navigate to the status screen, your device is working as expected.

How long do I keep my BioHub for?

Keep your BioHub for your entire prescribed monitoring duration.

The display reads “Not connected. Please unplug the BioHub and plug it back in.” What do I do?

Unplug the BioHub and plug it back into a standard wall outlet. Please watch the screen and verify that a network connection is reestablished. If this happens multiple times, you may be in an area with poor cellular network reception. Please try again in a different location.

WARNING: The BioHub is not waterproof. Please keep away from water.

Safety and Regulatory Information

REGULATORY STATEMENT

The BioHub is a Medical Device Data System (MDDS) as defined in FDA regulation 21 CFR Section 880.6310. The BioHub consists of software functions (Non-Device-MDDS) and hardware functions (Device-MDDS) that are intended to transfer, store, convert formats, and display medical device data and results.

The BioHub performs all intended functions without controlling or altering the function or parameters of any connected medical devices.

The BioHub is not intended to be used in connection with active patient monitoring (any device that is intended to be relied upon in deciding to take immediate clinical action).

FCC STATEMENT

Model: BIOHB01021

FCC ID: 2ASE7-BIOHB01021

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.

<!-- Radiofrequency radiation exposure information: the BioHub complies with the radiation exposure limits prescribed for an uncontrolled environment for fixed and mobile use conditions. The BioHub should be installed and operated with a minimum distance of 20cm between the radiator and the body of the user or nearby persons. This transmitter must not be co-located or operating in conjunction with any other antenna except as authorized in the certification of the product.

FCC STATEMENT (CONTINUED)

The BioHub 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. The BioHub 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 device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Increase the distance between the BioHub and television or radio receiver
- Consult the dealer, the manufacturer, or an experienced technician for help.

BioIntelliSense and BioHub are trademarks or registered trademarks of BioIntelliSense, Inc.

RESPONSIBLE PARTY:

BioIntelliSense, Inc.
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TERMS OF USE STATEMENT

NOTICE: Use of the BioIntelliSense Product(s) is subject to our

- Website and Product User Terms of Use at www.biointellisense.com/website-and-product-user-terms-of-use
- Website Privacy Policy at www.biointellisense.com/website-privacy-policy
- Product and Data-as-a-Service Privacy Policy at 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.

SYMBOL LIBRARY

| | | | |
|---|-----------------------------------|---|------------------------|
|  | Bluetooth |  | Temperature limitation |
|  | Consult with instructions for use |  | Humidity limitation |
|  | FCC icon |  | Warning |

Technical Specifications

| | |
|--------------------|--|
| Product Name | BioHub |
| Model Number | BIOHB01021 |
| Power | AC Power Adapter 120V
Direct Current (DC) Output 5V, 1A |
| Ports & Connectors | USB-C Connector, DC Power |
| Display | Single Color OLED |

STORAGE CONDITIONS

| | |
|-------------------|-------------------------------|
| Temperature Range | -4°F to 104°F (-20°C to 40°C) |
| Humidity Range | 0 - 95% RH |

OPERATING CONDITIONS

| | |
|----------------------|-----------------------------|
| Temperature Range | 32°F to 104°F (0°C to 40°C) |
| Humidity Range | 0 - 95% RH |
| Atmospheric Pressure | 70 - 102 kPa |

COMMUNICATIONS

| | |
|---------------------|--|
| Region Support | North America |
| Wireless Technology | Bluetooth (BT 4.2) |
| Cellular Technology | LTE Cat M1 (LTE-M)
LTE bands 2, 3, 4, 12, 13, 28
Channel bandwidth 1.4 MHz |
| Security | Secure boot
Secure updates
Encryption |

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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