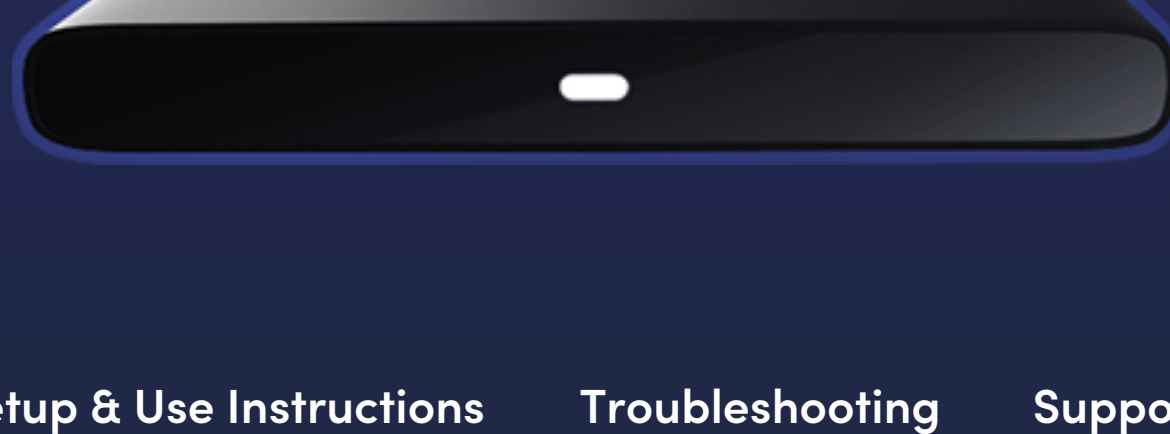


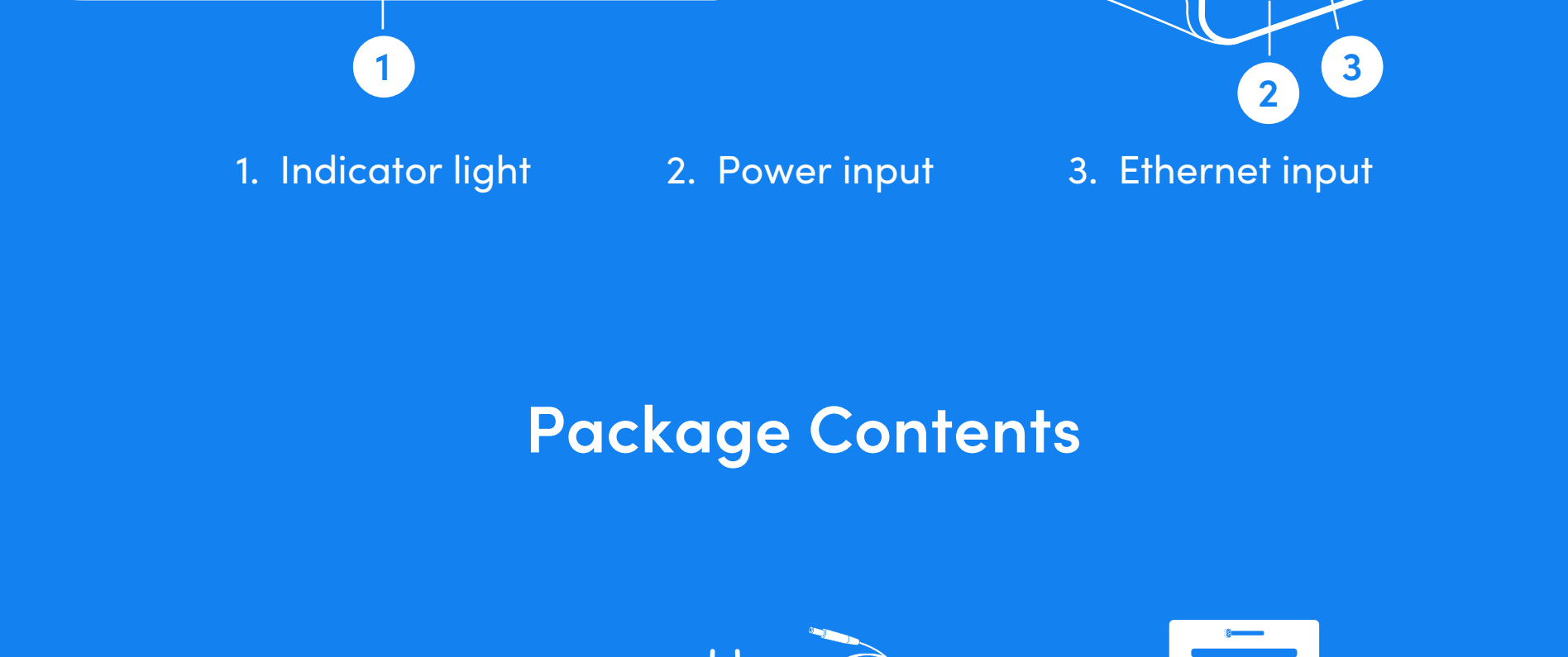
BioHub Wi-Fi

Setup and Instructions



- Device Overview
- Setup & Use Instructions
- Troubleshooting
- Support
- Regulatory & Legal

Device Overview

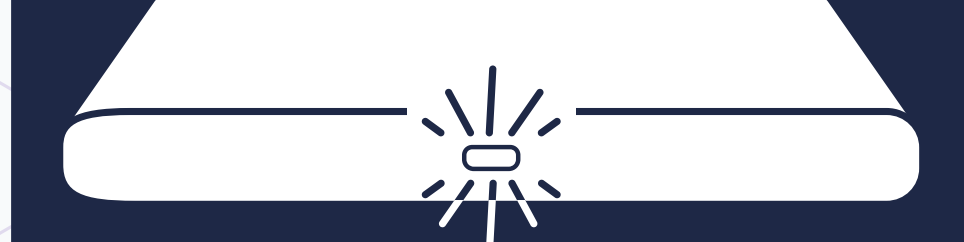


Package Contents



Setup & Use Instructions

Powered 24 / 7



1. Plug in the BioHub Wi-Fi to a wall outlet or power source that allows the device to remain powered 24/7.

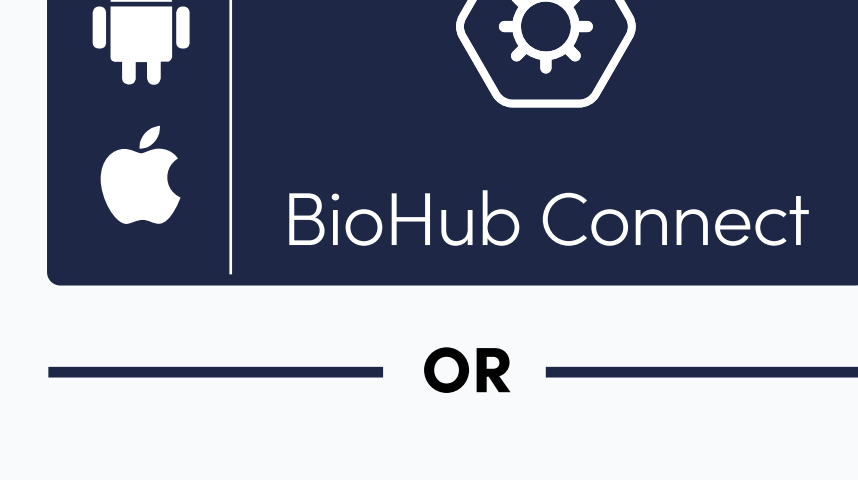


2. Confirm the BioHub Wi-Fi indicator light turns on.

CONNECT TO INTERNET

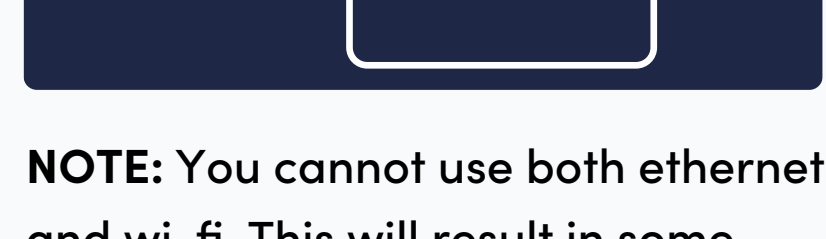


3. Connect the device to internet by plugging in an ethernet cable or connecting the BioHub Wi-Fi to Wi-Fi using the BioHub Connect App



OR

Ethernet Cable: Connect your BioHub Wi-Fi to your router via an ethernet cable (not included.)



NOTE: You cannot use both ethernet and wi-fi. This will result in some issues.



4. If you have a wearable monitoring device, refer to the device instructions to power on, activate, and wear the device.

You're all set!

Troubleshooting

My BioHub Wi-Fi unit won't turn on.

If your BioHub Wi-Fi is not turning on, please contact support to replace your device.

How do I know if my BioHub Wi-Fi is working?

If the indicator light is illuminated on the BioHub Wi-Fi, the unit is working. You may confirm data is being offloaded by viewing your data via a BioReport or by confirming data flow with your physician.

Where should I set up my BioHub Wi-Fi?

Set up your BioHub Wi-Fi in a central location of the home or in a frequently visited room, ideally near your Wi-Fi router.

Support

IN CASE OF EMERGENCY, CALL YOUR LOCAL EMERGENCY MEDICAL SERVICES IMMEDIATELY.

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

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

Regulatory & Legal

CAUTION!

NOTICE: To prevent fire and electric shock, do not expose this receiver to rain or moisture. In order to avoid any possible risk of electric shock, never attempt to open the unit. In case of the unit breaking down, repair of the unit should be carried out by qualified technicians. No part of this unit should be repaired by users.

WARNING!

- Place the receiver in a well-ventilated location to prevent accumulation of internal heat.
- Protect the receiver from high temperatures, humidity, water and dust.
- Do not place any objects that might damage your unit near it (e.g. liquid filled objects or candles).

Indications For Use

The BioHub™ Wi-Fi is a radio communications unit. The BioHub™ Wi-Fi wirelessly, via Bluetooth, collects data from authorized devices. The BioHub™ Wi-Fi seamlessly and securely transmits the data via wifi or ethernet connection to the Cloud Data Platform.

Safety & Regulatory Information

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: BIOHBX1020800 (US); BIOHBX1020801 (UAE)
FCC ID: 2ASE7-BIOHBX10208

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 device complies with the radiation exposure limits prescribed for an uncontrolled environment for a fixed and mobile use conditions. The device 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.

The device 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 device 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 device and television or radio receiver
- Consult the dealer, the manufacturer, or an experienced technician for help.

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Responsible Party

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

Terms of Use

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

- Website and Product User Terms of Use at <https://biointellisense.com/legal/website-and-product-user-terms-of-use>
- Website and Product Privacy Policy at <https://biointellisense.com/legal/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, and other medical or diagnostic biometric data. You understand that the Product(s) do not render medical advice or diagnose 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 icon	FCC icon
HDMI icon	European conformance icon

Technical Specifications

Physical Features

Operating Temperature
• 0°C - 50°C, 32°F - 122°F

Storage Temperature
• -20°C - 70°C, -4°F - 158°F

Network

Wi-Fi
• 802.11 b/g/n/a/ac 2.4G/5G 2T2R Wi-Fi 5

Ethernet
• 10/100Mbps

Bluetooth
• Bluetooth 4.2

Regional Support

Region Support
• North America, Middle East

Hardware Platform

Chipset
• Amlogic S905X3

GPU
• ARM Mali -G31 MP2

RAM
• 2GB LPDDR4

Flash
• eMMC 8GB

Power

DC Input Range
• 1x 12V 1.0 A DC Adapter

Power Consumption
• Maximum 12 W

BioHub Wi-Fi Instructions For Use, September 2021

MANUFACTURED BY
BioIntelliSense, Inc.
570 El Camino Real #200
Redwood City, CA 94063

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