

Indications for Use

The BioHub is a radio communications unit. The BioHub wirelessly, via Bluetooth, collects data from the BioSticker™ device 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.

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).

BioHub Safety & Regulatory Information



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.

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.

Storage and Operating Conditions

- **Operating Temperature:** 32°F to 122°F (-20°C to 50°C)
- **Storage Temperature:** -4°F to 122°F (0°C to 50°C)
- **Operating and Storage Humidity:** 10% to 95% RH
- **Operating and Storage Atmospheric Pressure:** 70 to 102 kPa

Any changes or modifications to this device not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.