Waveband Rev 1 Instructions for Use

Waveband Rev 1

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Rx only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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1. About Waveband Rev 1

1.1. Technical specifications

Product Name	Waveband Rev 1 Model: WB1CLMD	**External Materials**	ABS Soft polyester fabric
Size	One Size Fits All Adjustable with XS, S, M, L spacers	**Compatibility**	iOS 16.4 iPhone 8 and more recent Android 8.0 and more recent supporting Bluetooth Low Energy (BLE)
Weight	90 grams	**Connectivity**	BLE 5.4
Dimension	Head perimeter 540mm - 620mm	**Audio**	Internal buzzer
Battery	520mAh - Up to 24 hours	**Interface**	Sound feedback RGB LED indicator
Charging time	2 hours	**Languages**	English, Spanish
Sensors	EEG sensors Accelerometer	**Expected Service Life**	2 years
Headband Power Rating	Input: 5 Vdc, 0.5 A		

NOTE: **The Power Supply Unit is part of the Medical Electrical Equipment. All the sensors of the device (e.g., EEG sensors, Accelerometer) are considered applied parts according to IEC 60601-1.**

NOTE: **Beacon Biosignals shall make available on request detailed servicing information (e.g., circuit diagrams, component part lists, descriptions, calibration instructions, etc.) to assist service personnel in repairing the device.**

1.2. Conditions of use and storage

The device must be used in a dry, room temperature environment.

Do not expose the device to water or projections of water. Any storage or use outside these conditions may result in malfunction or premature wear of the device. Allow the device to acclimate to ambient temperatures for 1 hour prior to use if the device has been stored in extreme cold (4°F/-20°C) or extreme hot (140°F/60°C) conditions.

Storage and transport Conditions:

Temperature	4°F to 140°F -20°C to 60°C
Relative Humidity	95 % Maximum
Environmental Operating Condition:	
Temperature	59°F to 95°F 15°C to 35°C
Relative Humidity	15% to 90%
Pressure	From 1060 hPa to 700 hPa

FUNCTION	FREQUENCY	EQUIVALENT ISOTROPIC RADIATED POWER (EIRP)
Bluetooth	2402-2480 MHz	Class I

1.3. Description and purpose of the device

The Waveband Rev 1 system, hereafter referred to as Waveband, is a dry-electrode electroencephalograph (EEG) system consisting of a physical headband device and a connected mobile application acting as a companion software to configure the headband and transfer data to Beacon servers.

The Waveband records electrical activity of the brain during sleep or while awake as well as movement using dry sensors that are in contact with the subject's head. The headband has up to 24 hours of battery life and is rechargeable.

The recorded electrical activity and movement data are transferred from the headband to the mobile application through a Bluetooth connection. Data is automatically uploaded from the mobile application, if used, to the Beacon servers through an internet connection. The data is then processed and results in two types of outputs, only available to be viewed by the healthcare professional:

- A PDF report
- An EDF file with the raw data

The Waveband device may also be used without a connected mobile application by starting and stopping recordings directly from the headband. The data is then stored on the headband until it can be offloaded via a Bluetooth connection.

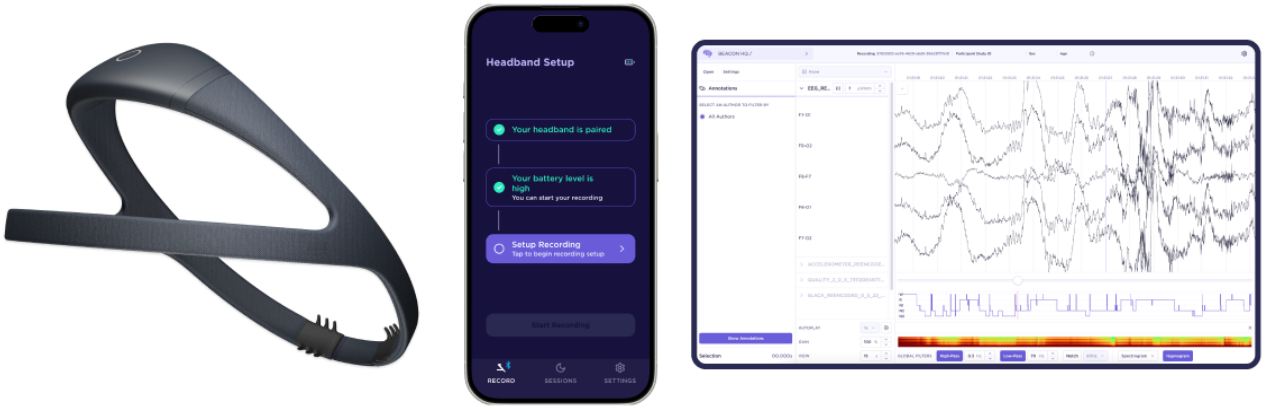


Figure 1: Waveband Device with Companion App and Raw Data

1.3.1. INTENDED USE

The Waveband Rev 1 is intended for prescription use to measure, record, display, transmit and analyze the electrical activity of the brain to assess sleep and awake in the home or healthcare environment.

The Waveband Rev 1 can also output a hypnogram of sleep scoring by 30-second epoch and summary of sleep metrics derived from this hypnogram.

The Waveband Rev 1 is used for the assessment of sleep on adult individuals (22 to 65 years old). The Waveband Rev 1 allows for the generation of user/predefined reports based on the subject's data.

1.3.2. ENVIRONMENT OF USE

Home (device configuration, data acquisition, and data retrieval), and/or healthcare environment (device configuration, data acquisition, and data retrieval).

The device is worn by the patient overnight, for multiple nights, or during the day as directed by their healthcare provider. The device is designed for home sleep monitoring taking place in the patient's typical sleep setup and autonomously operated by the patient or accompanying individual/caregiver. The study and the set-up of the system are easy to follow for patients or care givers familiar with the use of smartphones, tablets and mobile applications.

1.3.3. INTENDED USER

The device is intended for adult individuals (22 to 65 years old) and is to be prescribed by a clinician for assessing sleep. The intended active operator is the patient or an accompanying individual/caregiver.

The Waveband Rev 1 should be used only in accordance with the clinician's instructions. For contraindications, general warnings and precautions see Section 1.3.8. through Section 1.3.10.

Only qualified medical personnel may authorize the use of the Waveband Rev 1. Patients or accompanying individuals (if needed) must be instructed on how to set-up, position and use the device prior to use.

1.3.4. ESSENTIAL PERFORMANCE

The Waveband records the electrical activity of the brain through non-invasive electrodes to measure and assess sleep. Therefore, the essential performance of the Waveband is its ability to measure sleep through EEG. The Waveband has been tested and found to be compliant with the particular requirements of IEC 60601-2-26:2012 (with modified noise threshold) for the basic safety and essential performance of electroencephalographs.

Specifications are summarized in the following table:

SPECIFICATION	VALUE
Amplitude Measurement Error	<= 20%
Maximum Differential AC Input Before Clipping	+/-2400 mV
Maximum Differential DC Input Before Clipping	+/-2400 mV
Input Noise (peak to peak)	Max 18 µV @ 0.5Hz~50Hz bandwidth
Channel Bandwidth (-3 dB)	DC to 62.5 Hz
Common Mode Rejection Ratio	≥ 96 dB @ 50/60Hz

1.3.5. CLINICAL PERFORMANCE

Sleep Staging Algorithms in Production

How to find version information:
The specific service version used to generate hypnograms is recorded on the Beacon Platform and is displayed in the Sleep Reports generated by Waveband.

The Waveband performance has been assessed through the following investigations:

Performance compared to lab PSG

Performance compared to lab PSG. A clinical investigation was completed that compared Waveband Sleep Staging output with a 510(k)-cleared PSG system in a sleep lab setting on patients with disturbed sleep. This study included 50 subjects ranging from 22 to 66 years old (average: 43.9, std: 12.2). 28 subjects were female and 22 were male. The study included individuals self-identified as White or Caucasian, Black or African American, Hispanic, and some not identified. A total of 41,399 epochs, corresponding to about 345 hours of sleep, were included in the study.

Data from this study is summarized in a confusion matrix below in Table 1 comparing the performance of the Waveband device with expert-scored sleep stages from a cleared device. The overall agreement between Waveband and consensus from manual staging is 87.1%.

Table 1: Confusion matrix comparing Waveband (Sleep Staging Algorithm) and consensus of expert-scored PSG for all sleep epochs.

		Consensus from manual staging				
		W	**N1**	**N2**	**N3**	**R**

Waveband (Automated Analysis)	**W**	89.8%	13.6%	1.0%	0.2%	1.5%
	N1	4.2%	45.2%	1.6%	0.0%	0.5%
Waveband (Automated Analysis)	**N2**	4.9%	37.4%	91.3%	18.4%	3.7%
	N3	0.2%	0.1%	3.8%	81.4%	0.0%
	R	0.9%	3.8%	2.2%	0.0%	94.3%
	Epoch count	9,691	2,546	17,761	6,073	5,328

EEG Data Quality

A study was conducted to establish that EEG data quality from Waveband is sufficient for manual review and scoring of data. 96.6% epochs per night of recording were determined to be acceptable for manual scoring and sleep staging by at least two out of three reviewers qualified to read EEG and/or PSG data. All data recordings reviewed had ≥4 hours of data considered to be scoreable by at least two out three reviewers.

Usability Study

An investigation was completed to assess usability in the home setting and showed that the device could be successfully used and was tolerated by study subjects.

1.3.6. PREDETERMINED CHANGE CONTROL PLAN

Waveband has been cleared with an authorized Predetermined Change Control Plan (PCCP) that allows planned changes to the machine learning and other algorithmic components of the software to be made without additional premarket clearance by the US Food and Drug Administration (FDA). This plan allows for the modification of the software for the purpose of improving the sleep staging performance within the existing indication for use.

This PCCP allows for the modification of the algorithmic components of Waveband including:

- Modification 1: Updating the EEG and accelerometer signal preprocessing steps
- Modification 2: Retraining/optimization/modification of the sleep staging machine learning model
- Modification 3: Updating methods for postprocessing of sleep stage probabilities

The testing of any modification to Waveband within the scope of the PCCP will include comprehensive software verification and validation testing related to the software components affected by the change. In addition, clinical performance validation will also be performed and will require that the performance of any modification to Waveband to be non-inferior to the original Waveband device. In addition, the performance of any modification to Waveband must also be non-inferior to the best performance among released versions of Waveband with respect to the multi-stage agreement.

Information regarding the availability of new versions of the Waveband Sleep Staging Algorithm software, details about software updates and any changes to software performance, will be made available. As a user, you can contact Beacon Biosignals at https://beacon.bio/contact/ for any inquiries.

The following PCCP modifications are implemented in v2.0.0:

- PCCP Modification 1 – Signal Preprocessing: The machine learning model ensemble was updated with a revised set of model architectures. Correspondingly, the signal preprocessing was updated to be specific per model type, including revised passband frequencies and adjusted scaling and clipping of the accelerometer and EEG signals.

- PCCP Modification 2 – Machine Learning Inference and Architecture: The inference ensemble has been updated from the previous model configuration to a new combination of model architectures. Models were re-trained on an expandeddataset composed of PSG and wearable sensor data with sleep staging annotations. The new dataset is significantly larger compared to the previous version of the algorithm. The algorithm continues to operate on 30-second sleep epochs and outputs identical probability distributions per epoch.

There were no updates made under PCCP Modification 3. The models pre- and post-PCCP modifications both use an ensemble of neural network models to classify 30-second sleep epochs based on EEG and accelerometer signals. The probabilities from all models are averaged, and the sleep stage with the highest probability is selected as the device's predicted sleep stage.

These modifications apply to v2.0.0 or higher unless specified otherwise.

Verification and Validation of Waveband Sleep Staging Algorithm

Unit, integration and system-level tests were executed to verify the updates to the algorithm.

The performance of the Waveband Sleep Staging algorithm was evaluated using an independent, sequestered simultaneous polysomnography (PSG) and Waveband dataset consistent with the FDA-authorized Predetermined Change Control Plan (PCCP). The updated algorithm increases the multi-stage accuracy of the previous algorithm from 85.1% to 87.1%, WAKE classification accuracy from 84.9% to 89.8%, N1 accuracy was slightly degraded from 47.3% to 45.2% and N2 accuracy was increased from 89.3% to 91.3%. N3 and REM classification performances are similar to the baseline version of the algorithm. These results confirm that updated sleep staging algorithm meets all PCCP acceptance criteria for safety and effectiveness and maintains substantial equivalence to the previously 510(k) cleared algorithm.

Please note that the minor performance degradation in N1 accuracy does not impact the safety or effectiveness of the algorithm, as it remains within the established non-inferiority margin relative to the reference standard.

1.3.7. BENEFITS, EXPECTATIONS AND RISKS OF THE DEVICE

<u>Benefits and expectations:</u>

The Waveband 1 is a wearable self-applied prescription use EEG sleep assessment device, intended to be used at home without any supervision, or in a healthcare environment, under the supervision of a clinician.
The Waveband 1 brings the accuracy of the sleep lab to a patient's home. Waveband 1's automatic sleep scoring algorithm has been shown to perform equivalently to lab-based polysomnography scored by experts, when assessing patients with disturbed sleep.

The Waveband 1 records the electrical activity of a subject's brain, and head movement during the night to measure sleep. Based on these measurements, the device automatically provides the prescribing clinician with a hypnogram of sleep stage by 30-seconds epoch and summary sleep metrics derived from this hypnogram. The

Waveband 1 makes it possible for clinicians to measure and monitor their patients' sleep in the comfort of their own home, for one or multiple nights, in a non-invasive way, with comparable accuracy to lab-based polysomnography.

Waveband 1 performance and usability have been validated in two clinical investigations in the intended population. A first performance study against lab-based PSG, to evaluate the device's automatic outputs compared to the reference standard for sleep studies, and an actual use study assessing the robustness and stability of the device's measures, and its usability over multiple nights, in patients' home setting. The studies confirmed the high sleep staging performance of the device, the consistency of its measures and outputs, and the overall good usability of the system, on patients with disturbed sleep.

1.3.8 CONTRAINDICATIONS

The Waveband is not intended to be used in patients undergoing a diagnosis of sleep breathing disorders.

The product shall not be placed on an individual's body locations different from the one mentioned in the instruction for use.

The Waveband shall not be placed on open wounds, sores or rashes, or over swollen, red, infected or inflamed areas of the skin. If any skin irritation occurs while wearing the device, the user must stop using the device immediately.

Attachments and/or accessories that are not approved by Beacon Biosignals shall not be used with the Waveband in order to avoid negative interactions or negative influence on electromagnetic compatibility.

1.3.9. GENERAL WARNINGS

- ⚠ The device must be kept dry. Do not use the device near water, including in or near the bath, shower, sauna, or swimming pool.

- ⚠ Carefully read and follow all instructions prior to starting to use the device. Do not, during use of the device or under any other circumstances, modify or attempt to modify or alter the Waveband and any other accessories provided along with the device (the power supply unit). Any modification of the Waveband by the user is forbidden and might be dangerous.

- ⚠ No user serviceable components are present in the Waveband. Do not use the device if any parts are damaged or if the device is not working properly. Do not use Waveband with any different accessories than those ones provided by Beacon Biosignals in the device package. The use of the device with accessories not provided by Beacon Biosignals might be dangerous.

- ⚠ The charging of the device shall be exclusively performed through the power supply provided within the packaging of the device. Do not charge the device with any other tool than the provided power supply unit.

- ⚠ Do not connect the device with any other equipment. If you notice any unexpected change in the performance of the device, suspend the use of the device and contact Beacon Biosignals.

⚠ The device or its materials may potentially cause minor allergic reactions in individuals with skin sensitivities. If you experience any type of adverse symptoms or reactions as a result of the use of the product, stop using the device, consult with your physician and contact Beacon Biosignals.

⚠ Do not use the device in the presence of a flammable anesthetic mixture in combination with oxygen or air, in the presence of nitrous oxide, or in an oxygen-enriched environment. Do not charge the device during lightning storms or when it is not being used for long periods of time.

⚠ The device is equipped with a non-serviceable rechargeable battery. Do not attempt to change the battery yourself.

⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Waveband, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ Do not use the Waveband with any type of electrosurgery equipment. This device should not be used adjacent to or stacked with other equipment.

⚠ The device shall be stored into the travel bag when not in use. Be sure to correctly close the travel bag to protect the device from dust and accidental contact with liquids.

⚠ When the device is plugged and its battery is charging, its surface temperature may briefly reach a temperature of 43°C (109°F) and feel warm. When charging stops or the device is unplugged, the temperature should rapidly drop.

1.3.10. GENERAL PRECAUTIONS

⚠ Do not use the device outside the environmental conditions specified in this user manual.

⚠ Do not use your product near heat sources, including but not limited to direct sunlight, radiators, heaters/stoves, open flames, or near heat producing devices, such as audio amplifiers, televisions, nebulizers, etc.

⚠ The exposure of temperature outside the operation limit mentioned in this manual might affect the quality of the data measured by the Waveband. If the device has been exposed to hot or cold temperature, allow the Waveband to adjust to room temperature before using it.

⚠ Keep the medical system and its accessories far from children and pets to avoid unintentional damage or swallowing.

⚠ Presence of dust or lint on the electrodes might affect the quality of the data measured by the Waveband. Gently remove any visible residues from the Waveband and from the electrodes on upper arch with a dry cloth.

⚠ Do not use detergents or cleaning gels to avoid any damage to the surface of the device.

⚠ Do not clean the device during use or during charging activities.

⚠ Do not immerse the product in liquid of any kind. Do not place the Waveband in the dishwasher, microwave, washing machine or dryer.

1.3.11. CONTACT ASSISTANCE

If you are unable to resolve any device-related issue with this Instructions For Use, require any assistance in setting up, using or maintaining your device, or you want to report any unexpected operation or events related to the device, contact Beacon Biosignals Customer Support:

web: https://beacon.bio/contact/

email: support@beacon.bio

1.4. Manufacturer

Beacon Biosignals, Inc.
22 Boston Wharf Rd,
7th Floor, Unit 41
Boston, MA 02210 USA

1.4.1. EXPLANATION OF THE SYMBOLS

	Manufacturer
TW	Country of Manufacture (Taiwan)
Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
SN	Serial Number
REF	Catalog Number
UDI	Unique Device Identifier
	Follow Instructions for Use

	Caution, Consult Accompanying Documents
	Fragile, handle with care
	Do not throw in trash. Requires a distinct disposal process
	Protect from heat and radioactive sources
	Type BF Applied Part
IPN1N2	Degree of protection against ingress of water and particulate matter
IP22	Ingress protection for POD only The POD of the device is protected against insertion of fingers and vertically dripping water shall have no harmful effect when the device is tilted at an angle up to 15° from its normal position
	Temperature limitation
	Humidity limitation
	Pressure limitation
	FCC symbol

1.4.2. LIMITED WARRANTY AND PRODUCT LIABILITY

Beacon Biosignals warrants to the original purchaser that the device shall be free from defects in material and workmanship for two (2) years. Except where prohibited by applicable law, this warranty is non-transferable and is limited to the original purchaser and the country in which the product was purchased. This warranty gives

you specific legal rights, and you may also have other rights, including a longer warranty duration that may vary under local laws.

How to start: The first thing to do if you think you have a warranty claim is to carefully read the Instructions for Use.

If you do not find a solution in the Instruction for Use or on our website, please go to https://beacon.bio/contact/ or email support@beacon.bio to contact Beacon Biosignals directly.

Remedies: Beacon Biosignals' entire liability and your exclusive remedy for any breach of this limited warranty shall be, at Beacon Biosignals' option 1: to repair or replace the product, or option 2: to refund the price paid, provided that the product is returned with a copy of the sales receipt or dated itemized receipt. Shipping and handling charges may apply except where prohibited by applicable law.

Beacon Biosignals may therefore, at its option, replace your product, offer to provide a functionally equivalent product, or repair any product with new, refurbished or used parts as long as such parts are in compliance with the product's technical specifications. Any replacement product will be warranted for the remainder of the original limited warranty period or thirty (30) days whichever is longer, or for any additional period of time that may be applicable in your jurisdiction.

This limited warranty does not cover problems or damage resulting from 1) accident, abuse, misapplication, or any unauthorized repair, modification or disassembly; 2) improper operation or maintenance, usage not in accordance with product instructions or connection to improper voltage supply; 3) use of consumables not supplied by Beacon Biosignals except where such restriction is prohibited by applicable law; 4) lost parts that were originally supplied with the Beacon Biosignals product; 5) normal wear and tear.

This limited warranty does not, under any circumstances, cover the replacement of or reimbursement for any electronic device or personal property that is not a Beacon Biosignals product.

Limitation of Liability:

BEACON BIOSIGNALS SHALL NOT BE LIABLE FOR ANY SPECIAL, INDIRECT OR INCIDENTAL OR CONSEQUENTIAL DAMAGES WHATSOEVER, INCLUDING BUT NOT LIMITED TO LOSS OF PROFITS, REVENUE OR DATA (WHETHER DIRECT OR INDIRECT) OR COMMERCIAL LOSS FOR BREACH OF ANY EXPRESS OR IMPLIED WARRANTY OR YOUR PRODUCT EVEN IF BEACON BIOSIGNALS HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

Some jurisdictions do not allow the exclusion or limitation of special indirect, incidental or consequential damages, so the above limitation or exclusion may not apply to you. National Statutory Rights: Consumers have legal rights under applicable national legislation governing the sale of consumer goods. Such rights are not affected by the Warranties in this Limited Warranty.

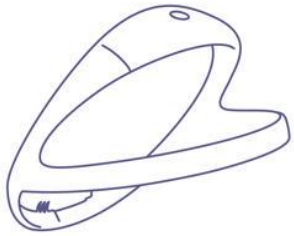
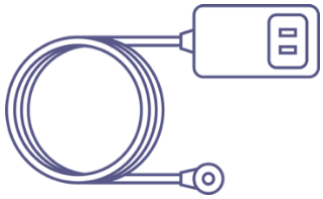
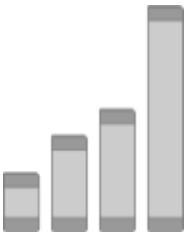
No Other Warranties: No Beacon Biosignals dealer, agent, or employee is authorized to make any modification, extension, or addition to this warranty.

Warranty Periods: the product is guaranteed two (2) years after the purchase.

1.4.3. DISCLAIMER AND VENUE

Your use of the Waveband Rev 1 and accompanying Beacon Pal mobile application is governed by our Terms of Use. By using the Waveband Rev 1, you consent to our Terms of Use. For more information, please visit https://app.beacon.bio/terms. We also collect and use certain information about you in accordance with the terms of our Privacy Policy, which you consent to by using the Waveband Rev 1. For more information, please visit https://app.beacon.bio/privacy.

1.5. Box content

Waveband headband with the small adjuster set	
List of detachable components to be used in combination with the Waveband System:	
Power Supply Unit *(Ref: PN 00019)*	
Adjustment Strips (Sizers) available in multiple sizes *(Ref: PN 00093 for L, PN 00092 for M, PN 00091 for S, PN 00090 for XS)*	
Travel Bag *(Ref: PN 00096)*	

2. Product Overview

Figure 2: Waveband headband sensors

2.1. Waveband Headband

The Waveband electronic system is composed of high-density electronics containing the processing power, memory, battery drivers, Bluetooth communication and acquisition capabilities for the EEG and accelerometer subsystems.

Schematically, the EEG and accelerometer are converted for subsequent digital signals to be processed. The device works in a non-invasive way.

The headband needs to be recharged by plugging into the charger supplied with the headband (charging time is approximately 2 hours for 100%). A low-power-consumption of approximately 40 mW (on average) allows the headband to have a battery life of up to 24 hours between charges.

The raw data is transferred to the dedicated servers via the mobile application. The data is analyzed to produce the hypnogram the sleep metrics outputs, and an optional EDF file that can be viewed by clinicians in a 3rd party viewer.

2.1.1. POWERING ON & OFF

- Power On - The headband can be powered on by briefly pressing the power button at the center of the headband.
- Power Off - The headband can be powered off by holding down the power button for 3 approximately seconds until a tone is heard.
    - Note: Powering off the device during an ongoing session will result in the session ending.

2.1.2. STARTING & STOPPING A RECORDING FROM THE HEADBAND

- Starting a recording - To start a recording from the headband press the power button 3 times in rapid succession.
- Stopping a recording - To stop a recording from the headband press and hold the power button for approximately 3 seconds until a tone is heard.

2.1.3. CHARGING THE HEADBAND

Patients are encouraged charge the Waveband after each sleep session to ensure that the Waveband device is sufficiently charged for the next session.

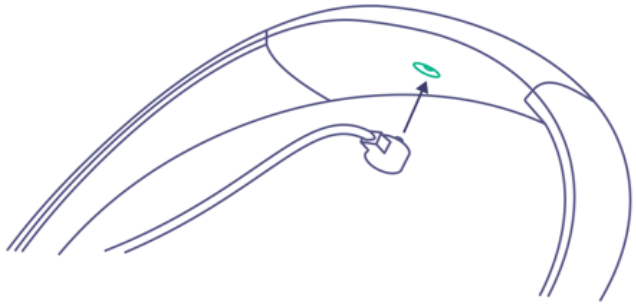


Figure 3: Charging the Headband

The charging cable attaches to the headband using a magnet. Since the cable is magnetic, the charger may become disconnected if the cable is suddenly pulled.

If the headband is on and the LED does not light up once on the charger, make sure the charging cable is properly attached to the headband and the power supply unit is plugged in to the outlet.

2.1.4. LED & AUDIBLE BEHAVIOR

LED Colors:

The LED located on the top arch has different behaviors:

- Green: Good status and idle
- White: Session or booting/loading related
- Blue: Bluetooth pairing
- Ruby: Attention or warning
- Magenta: Firmware update ongoing
- Orange: Memory status

LED Patterns:

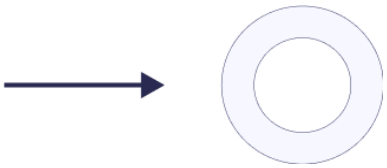
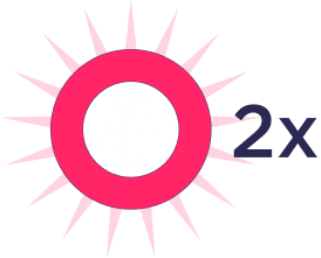
- Fixed (solid): normal operation
- Breathing: action is ongoing
- Blinking: error or attention needed
- Fade: transition from one state to another (one color to another, or to off)

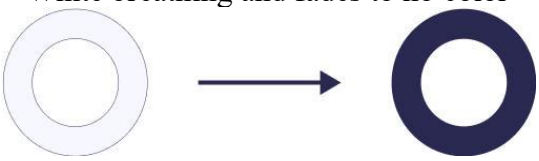
Audible Sounds:

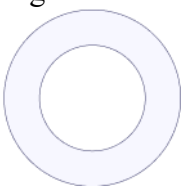
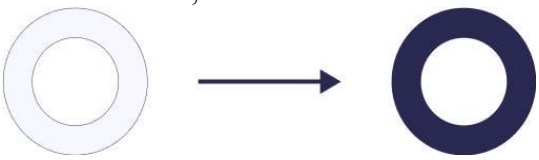
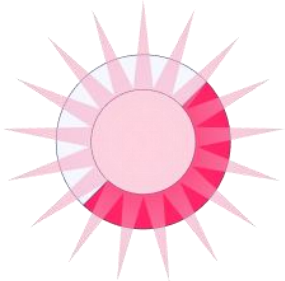
The headband has a buzzer that makes a simple sound when specific actions are initiated:

- Power On: Four (4) beeps increasing in pitch
- Power Off: Four (4) beeps decreasing in pitch
- Session has begun: Three (3) beeps increasing in pitch
- Session has ended: Three (3) beeps decreasing in pitch
- Memory is full: Three (3) beeps single pitch

Note: The headband does not have a speaker or microphone.

General Idle Status				
Description	Initiated By	LED State	Buzzer Sound	Action to Resolve
System is turning on and loading	Single press of power button	Fade to white 	4 beeps, increasing in pitch	N/A
Charged and ready	N/A	Solid green	None	N/A
Low battery (5% to 50%)	N/A	Blinking ruby 2 times per second 	None	Place on charger until LED is solid green
Critical low battery (<5%)	N/A	Solid ruby	None	Place on charger until LED is solid green
System is turning off	Hold power button for approximately 3 seconds until 4 beeps are heard	Fade to black	4 beeps, decreasing in pitch	N/A

Device is off or in an ongoing session	N/A	No light	None	N/A
Pairing				
Device is pairing Bluetooth with mobile device	Pairing initiated in Beacon Pal app	Solid blue	None	N/A
Charging				
Charging and has low battery (<50%)	Device placed on charger	Breathing ruby	None	Ready for use once LED is solid green
Charging and has high battery (50% to 95%)	Device placed on charger	Breathing green	None	Ready for use once LED is solid green
Charging and has full battery (>95%)	Device placed on charger	Solid green	None	N/A
Session				
Session has begun	Triple button press	White breathing and fades to no color 	3 beeps, increasing in pitch	N/A

Session has ended	Hold power button for approximately 3 seconds until 3 beeps are heard	White breathing and fades to idle status 	3 beeps, decreasing in pitch	N/A
Recording session in progress	Single button press	White, fades to no color 	None	N/A
Battery too low to begin recording	N/A	Solid ruby	If button is triple pressed - 3 beeps, single tone	Place on charger until LED is solid green
Memory is too low to begin recording	N/A	Solid orange	If button is triple pressed - 3 beeps, single tone	Return device for offloading of data
Update				
Updating firmware	Beacon Pal notified user of firmware update required and user plugs device into charger	Breathing magenta	None	Ready for use once LED is no longer magenta
Error				
Experiencing a general error	N/A	Blinking ruby and white 	None	Return device for servicing
Memory Storage				

Device memory almost full	N/A	Pulsing orange until recording starts	None	N/A
Device memory full	Triple button press	Solid orange	3 beeps, single tone	Return device for offloading of data

The LED should be green before starting a session. If the LED is blinking ruby or solid ruby, the device needs to be placed on the charger. Once the LED is solid green, the device is ready for use.

The headband's battery can last up to 24 hours on a single charge; however, it is encouraged to charge the headband after every use to ensure the device does not stop working during a session.

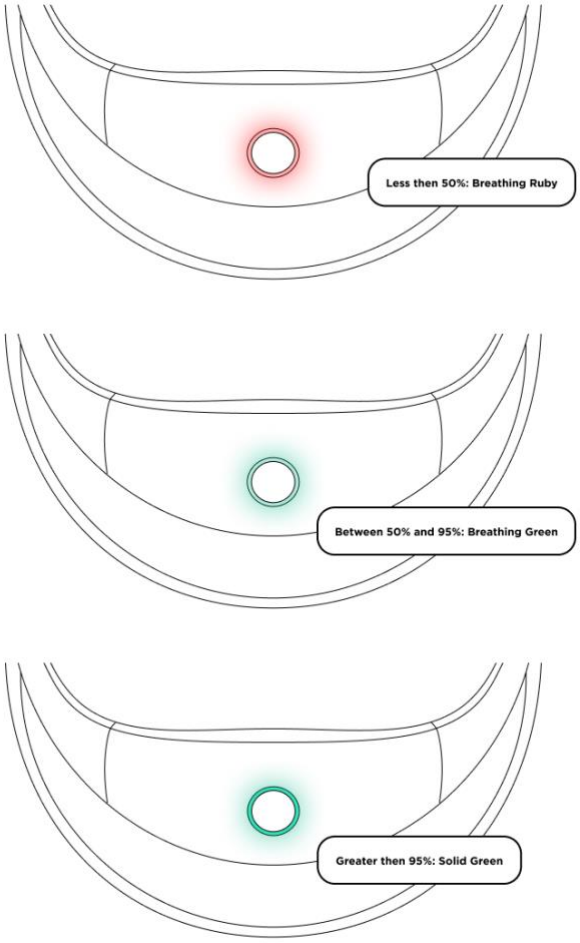


Figure 4: Charging states

2.1.5. CARE AND MAINTENANCE

The inside of the headband is lined with a soft fabric, and the plastic parts are made of ABS. For cleaning, it is recommended to gently wipe the headband and electrodes weekly with a dry cloth. A cotton swab dampened with isopropyl alcohol (IPA) should be used if any debris is visible. Wipe the power supply weekly with a dry cloth.

CAUTION: THE WAVEBAND HEADBAND IS NOT WATERPROOF. AVOID SUBMERGING IN WATER AND DON'T WEAR IT OUTSIDE WHEN RAINING.

To optimize signal reception through the headband, hair and face should be clean and dry. Face creams, moisturizers, and other oily products should be avoided before using the headband. If the participant is using a prescription cream, application on the headband's primary zones of contact (the forehead and temples) must be avoided.

CAUTION: PLEASE REMEMBER THAT THE HEADBAND CONTAINS SENSORS AND NEEDS TO BE HANDLED WITH CARE.

2.1.6. FIRMWARE UPDATE

The embedded software ("firmware") on the Waveband device can be updated.

- Periodic and automatic checks will be performed via the Beacon Pal mobile app to verify whether firmware updates are available. This happens when the Waveband is paired with the Beacon Pal mobile app and Bluetooth is connected.
- In case a firmware update is required, the Beacon Pal mobile app will notify the user to plug in the headband if needed. During a firmware update, the LED will show a magenta light.
- After the update is completed, the installed firmware version number is displayed on the mobile app.

2.1.7. DEVICE MEMORY

The Waveband device has sufficient on-device storage for approximately 50 hours of total recording time. The device can be used to record as long as the device storage is not full.

- **When the available Waveband storage may not be sufficient for a full-night's recording:** The Waveband power button will display a blinking orange light. In the event that a recording is started, the Waveband will continue to record until the storage is full.
- **When the Waveband storage is full:** It is not possible to begin a recording until recording data is retrieved from the Waveband via a Bluetooth connection to the mobile application. When the Waveband storage is full, the Waveband power button will display a solid orange light and the buzzer will triple beep at a single pitch. Please contact the Beacon Biosignals support team or your designated point of contact for the sleep study to return the device.

2.2. Beacon Pal App

Beacon Pal by Beacon Biosignals	Download on the App Store GET IT ON Google Play

The Beacon Pal App is a mobile companion application that may optionally be used with the Waveband headband. When used, the Beacon Pal App serves as a remote-control interface and enables the following:

- Activation of the patient's account
- Pairing of the headband via Bluetooth
- Viewing of headband status
- Performing a signal quality check
- Starting and stopping sessions
- Automatic data upload at the end of a session
- Viewing of session upload status

The Beacon Pal App can be preinstalled on a dedicated (compatible) smartphone or downloaded to a smartphone.

Without a Bluetooth connection to the Beacon Pal App, the session's raw data will remain saved in the Waveband headband. Metrics will not be accessible to the physician until the headband's Bluetooth connection is re-established with a BLE connected application or the Beacon Pal App on a device connected to the internet.

2.2.1. MAIN SCREENS

The app is composed of three sections identified by their name and logo at the bottom of the screen:

1.	The **Record** section acts as the headband's remote control for: a. pairing the headband b. checking battery status c. assessing signal quality d. launching recordings
2.	The **Sessions** section allows the user to check the **upload status** of a session from the headband.

3.	The **Settings** section displays relevant information about the application, the user, and the headband. This includes the application version, installed firmware version, participant ID, and headband ID. This is also where the user can change the **language** in the app. The user is redirected to Beacon Biosignals privacy policies upon tapping on "**View Privacy Policy**", and to view additional information upon tapping on "**Further Information**".

2.3. Data Flow

Throughout the session, the Waveband communicates recording data with the Beacon Pal App through **Bluetooth**. The storage pipeline is as follows:

1. During the recording, the data is continuously streamed from the headband to the Beacon Pal App via a secure Bluetooth connection. In case the Bluetooth is disconnected, the Beacon Pal App attempts to automatically reconnect to the device. Any portion of the recording that was not streamed to the Beacon Pal App is encrypted and stored on the internal storage of the headband until a connection can be re-established. Once the connection is re-established, the Beacon Pal App picks up the recording where it was last left off.

2. Upon completion of the recording and when the Beacon Pal App is the connected to the internet, the data is automatically uploaded to the dedicated servers. The raw recordings are then further processed by Beacon Biosignals internal services. The prescribing clinician will be informed of the availability of the analysis outputs for download via email.

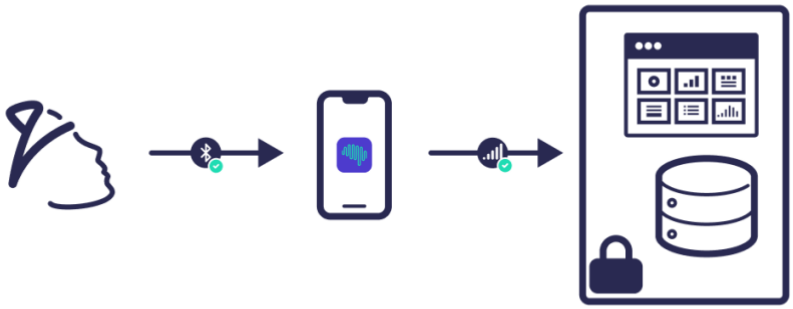


Figure 5: Flow of data between headband, mobile app, and Beacon Biosignals servers

2.4. Data Access and Data Analysis

2.4.1. DATA ACCESS

To access the data, the prescriber will be provided a dedicated administrator account, which will enable them to host and manage supervised patients accounts and access their session data.

The number of supervised accounts is unlimited so the clinician can register as many patients as they need.

Clinician's Admin account		Patients' accounts
Access patients' sleep study reports (pdf)	⇨	Only used to access the Beacon Pal App
Access patients' raw data (edf)		Patients cannot access their sleep study data

For each recording, the admin clinician will receive an email notifying them that a recording has been uploaded and analyzed. The email includes the following links:

- A link for the clinician to be able to download the **sleep study report on a pdf format**
- A link to be able to download the **raw data in an EDF format**, for further analysis on a third-party software.

2.4.2. WAVEBAND OUTPUTS

PDF REPORT

The sleep metrics for each recording are aggregated into a sleep report and form part of the core technology at Beacon Biosignals. It allows the clinician to obtain high level, reliable and validated processed sleep data.

DEVICE OUTPUT	HOW DERIVED	SUMMARY OF METHOD
Hypnogram	EEG, Accelerometer	A sleep stage hypnogram derived from the headband data using feature extraction and classification of EEG and accelerometer using a neural network. Displayed as: - Stage **N1** - Stage **N2** - Stage **N3** - **REM** Sleep - **Wake**

Sleep metrics	EEG, Accelerometer, Hypnogram	**- Total Sleep Time (TST)**: Total time (in minutes) the subject spends asleep **- Wake After Sleep Onset (WASO)**: Total time (in minutes) the subject spends awake from sleep onset to last epoch of sleep **- Time in N1**: Total time (in minutes) the subject spends in AASM N1 sleep stage **- % N1**: Percentage of TST spent in N1 sleep **- Time in N2**: Total time (in minutes) the subject spends in AASM N2 sleep stage **- % N2**: Percentage of TST spent in N2 sleep **- Time in N3**: Total time (in minutes) the subject spends in AASM N3 sleep stage **- % N3**: Percentage of TST spent in N3 sleep **- Time in REM**: Total time (in minutes) the subject spends in AASM REM sleep stage **- % REM**: Percentage of TST spent in REM sleep **- Sleep Efficiency (SE)**: expressed in %, according to AASM: portion of the total recording time spent asleep **- Sleep Onset Latency (SOL)**: according to AASM - Time from 'Lights out' to sleep onset **- Latency to Persistent Sleep (LPS)**: time between light off and the beginning of the first continuous 20 epochs (i.e., 10 minutes) of sleep.

EDF FILE

It is also possible to review individual recordings and select parameters such as epoch duration, channels, for further analysis.

Waveband does not provide an analysis software, but the EDF files can be opened and analyzed in separate third-party software.

Recording Report

Participant Information

PARTICIPANT/PATIENT ID
01928740572595

Recording Information

SITE ID
412

STUDY ID
01931

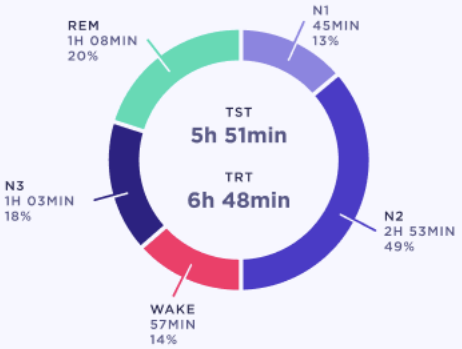
SPONSOR/PHYSICIAN ID
9871028

STUDY DATE
November 8, 2020

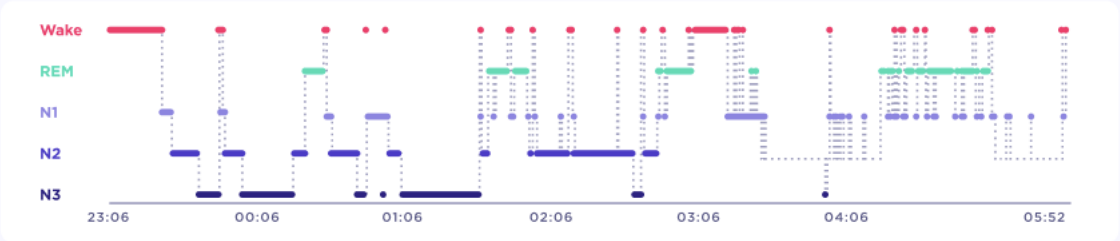
HEADBAND ID
69fe3ddb-43c6-4a47-8717-b93bc0c77e88

RECORDING START TIME
23:06 - 08 November 2020

RECORDING STOP TIME
05:53 - 09 November 2020



Sleep Stages



Metrics

6h 48min	**TRT (Total Recording Time):** Duration from "Lights off" to "Lights on"	**22min**	**SOL (Sleep Onset Latency):** Duration from "Lights off" to the first of any epoch in sleep
5h 51min	**TST (Total Sleep Time):** Duration of sleep from "Lights off" to "Lights on"	**22min**	**LPS (Latency to Persistent Sleep):** Duration between "Lights off" and the beginning of the first continuous 20 epochs of any sleep stage
86%	**SE (Sleep Efficiency):** Ratio of TST to TRT	**61min**	**REM Latency:** Time between lights off and the beginning of the first epoch of REM
32min	**WASO (Wake After Sleep Onset):** Wake duration from the first epoch of sleep to the last epoch of sleep	**28**	**Awakenings:** Number of awakenings
45min	**N1:** Duration of N1 sleep	**23:06:13**	**Lights Off:** Time when recording starts
2h 53min	**N2:** Duration of N2 sleep	**05:53:30**	**Lights On:** Time when recording stops
1h 03min	**N3:** Duration of N3 sleep	**23:28:43**	**Sleep Onset Time:** Time of the first epoch of any sleep stage
1h 08min	**REM:** Duration of REM sleep	**05:51:13**	**FRT (Final Rise Time):** Time of the last epoch of any sleep stage
57min	**W:** Duration of wake		

Reference: b41f57da-a1f7-415d-a225-e1daddc2cf9b 1 **Created:** 11 October 2022 17:06

Figure 6A: Waveband output - automatic sleep study report

Raw data	EEG	**EEG derivations**: F7-O1, F8-O2, F8-F7, F8-O1, F7-O2 *(Bandpass Butterworth order 2 between 0.4Hz and 25Hz.* *3 additional notch filters are added to remove 50Hz and 60Hz electrical noises, and 62,5Hz.)*

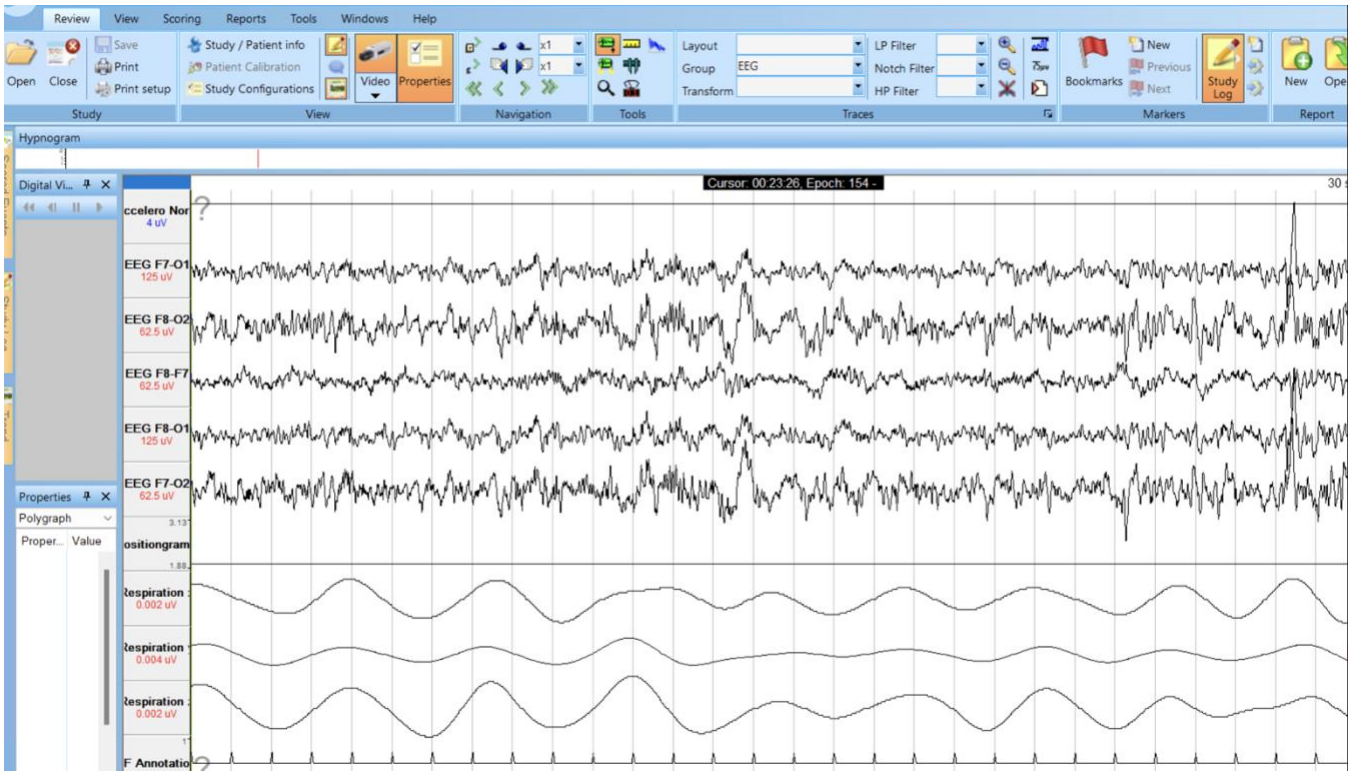


Figure 6B: Waveband output - EDF file

3. Operation Instructions

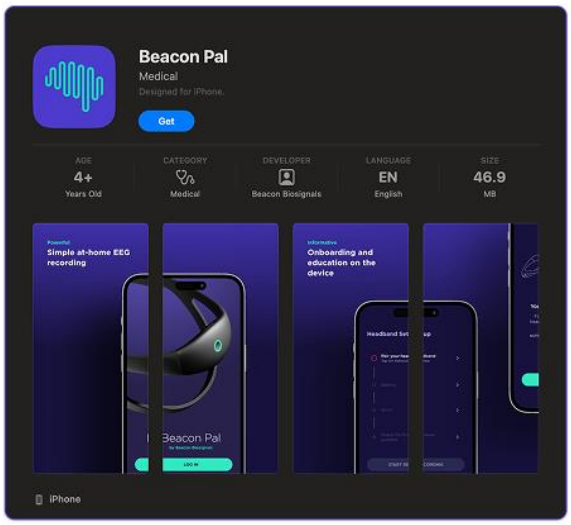
Prior to a sleep study with the Waveband, the patient should read this chapter after being trained by the clinical staff.

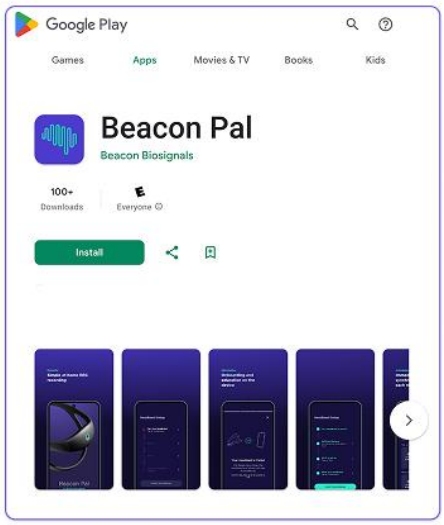
The Waveband can be use with or without a companion mobile application. Patients should adhere to a specific operation mode if instructed by clinical staff. To conduct a session with the mobile application follow instructions outlined in Section 3.1. If the patient is not using the mobile application to conduct their recording, proceed to Section 3.2.

3.1. Initial Set Up

A. Upon opening the box, make sure you have **all components identified in Section 1.5 Box content** and that the **device is fully charged.**	
B. Make sure that the **Bluetooth** of the smartphone/tablet is turned **on**.	
C. Before starting the set-up on the Beacon Pal App, make sure that the **time zone** of the phone/tablet is **correct** and reflects your current location.	
D. Before starting the set-up on the Beacon Pal App, make sure that you have your **login information** to the App.	

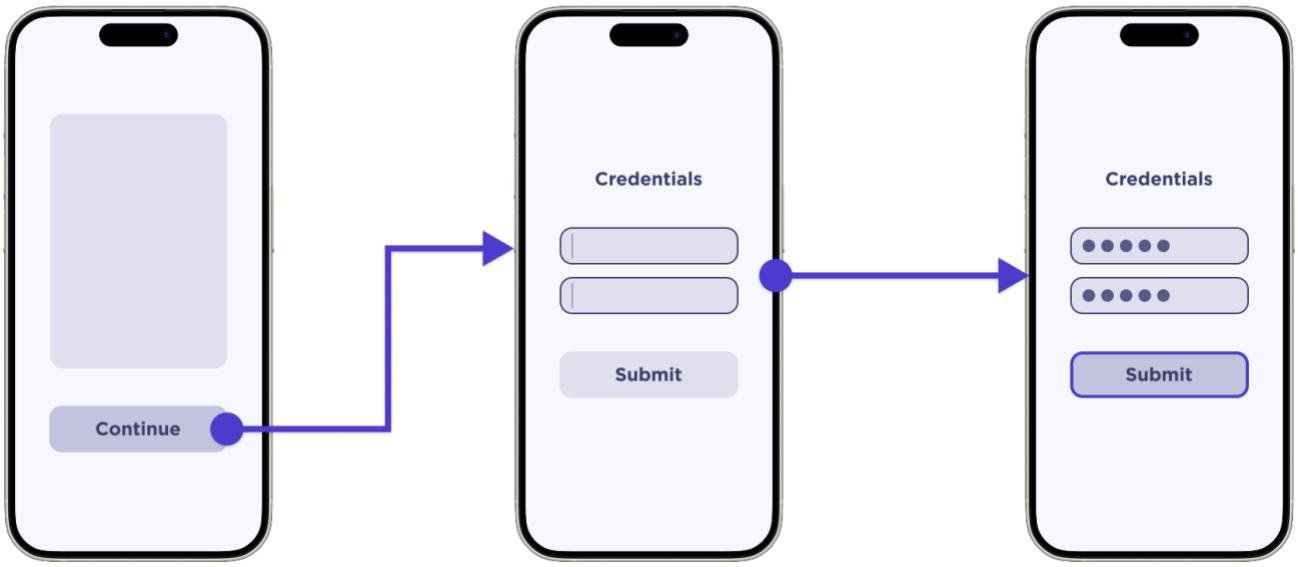
3.1.1. CONDUCTING A SESSION WITH THE MOBILE APP





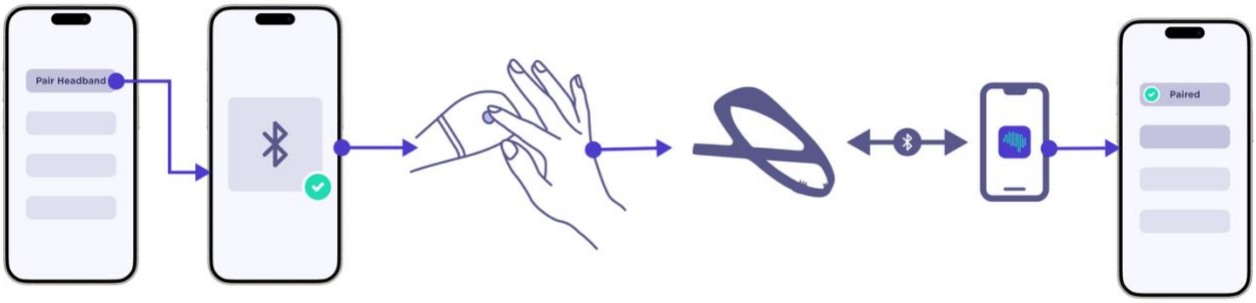
The Beacon Pal App can be downloaded on the iOS App Store or the Google Play Store.

3.1.2. INPUT CREDENTIALS



Open the Beacon Pal App. Select ***Continue.*** You will need to enter the credentials provided to you. This step is essential so that the headband can be linked to the user profile to allow for proper identification of each recording.

3.1.3. PAIR YOUR HEADBAND



Make sure the phone's/tablet's **Bluetooth** is turned on and that the **time zone** of the phone/tablet is **correct** and reflects your current location.

On the app's homepage, select ***Pair your headband*** and follow the instructions for your headband to pair with the app. Once your headband is paired, you will see a green checkmark on the left side of the home screen.

The **Battery status** should display either a **green checkmark**, meaning the headband is charged enough, or a **green charging bolt**, meaning that the headband is charging and has enough to record a night recording. If the **battery is low**, the charging bolt indicator will appear **ruby** and the device should be charged prior to use.

3.1.4. COMPLETE SET UP

Green check marks will appear next to the **Pairing** setting once it is configured. If not, the app will display an empty circle instead of a checkmark.

Please repeat until all check marks are green.

3.2. Preparing for a Night with the Device

3.2.1. SLEEP HYGIENE RECOMMENDATIONS

Throughout the medical process, and in particular, on the nights that sleep monitoring assessments will be performed, you should ensure you have **adequate opportunity for sleep** (i.e., at no time during the study should the time allotted for sleep be shortened). You should maintain a habit of going to bed at your regular bedtime and to wake up at regular hours as well.

"Bedtime" is defined as the time when you intend/attempt to fall asleep for the night (e.g., lying down or reclining with eyes closed to get a full night of sleep).

3.2.2. HEADBAND'S FIT

You should be particularly cautious about the headband fit to guarantee acceptable signal quality. The Waveband headband is embedded with sensors located on the front and back. **To ensure optimal signal quality, all the sensors must be in direct contact with the skin on the forehead and scalp at the back of the head.**

Please contact the Beacon Biosignals support team if questions or issues arise.

- The Waveband headband should be **applied to a clean surface (e.g., skin and hair) and on dry hair.**
- You should **sleep in a conducive environment** (i.e., a darkened room, a relatively quiet room [no computer, mobile device, television, radio], a room free from distractions).
- There is no need to remove the device **during bathroom visits** that occur while a session is ongoing.

3.2.3. HEAD CIRCUMFERENCE

The headband's fit can be adjusted with various sizes of adjustment strips/sizers **(Figure 7A)**, coming in:

- Extra-small (XS): 54 cm and less.
- Small size (S): 54 to 56 cm.
- Medium size (M): 56 to 60 cm.
- Large size (L): +60 cm.

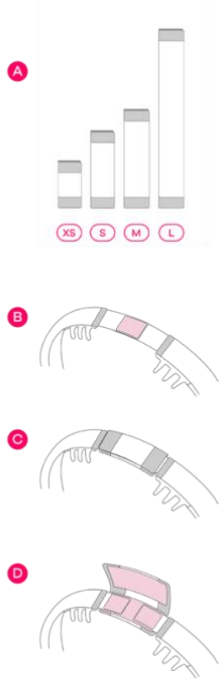


Figure 7A, 7B, 7C, & 7D: Size adjusters

A tight but comfortable fit of the headband will lead to better contact with the skin/scalp, and better signal quality will be acquired as a result. This is the desired fit of the Waveband headband.

1. The two Velcro pads at the back of the headband need to be placed on top of each other by default to assess your fit. This is the smallest fit possible. **(Figure 7B).**
2. Position the headband on your head using this configuration. If the headband is snug on the head and you are comfortable, the desired fit for the headband use is achieved. You can add the small Velcro adjuster **(Figure 7C)** on top of the Velcro pads to secure the configuration in place.
3. If the headband seems too tight with the smallest configuration, change the adjuster to a longer one until finding the appropriate length. The Velcro pads should be placed at both tips of the size adjuster. **(Figure 7D)**.

3.2.4. HEADBAND POSITIONING

To make sure the headband is properly positioned on your head, **it is essential that you go through each step below** so you can reproduce the instructions easily at each use:

1. The power button needs to be on the top of the head. The sensors in the front band should all be in contact with your forehead. Make sure no hair is caught between the headband and your forehead.
2. In case of long hair, pulling hair over the back sensors should be done to ensure good contact with the scalp. If you have long hair at the back, we require that you lift the hair over the rear elastic band of the headband before positioning the back (occipital) sensors **(Figure 8 Image 2)**. You can then keep your hair up in a ponytail or lay it back down over the top of the headband when sleeping. Gently move the sensors down to the scalp when complete. If the hairstyle significantly impedes the sensor placement (toupee, tight braids, dreadlocks, etc.) we ask you to remove the hairstyle to ensure a good fit.
3. The back sensors can be gently moved up and down to comb the sensor through the hair at the back of the head **(Figure 8 Image 3)**.

4. To ensure optimal support throughout the night, gently pull the upper arch backward **(Figure 8 Image 4)**.

Figure 8: Headband Positioning

3.3. Start a Session

- Unplug the headband from its charger. The power button LED should be green. If the LED doesn't light up, proceed to press the power button on the top of the headband to turn it on.
  You only need one brief push to power on the headband. Wait a few seconds until the LED is fixed green. If the patient is conducting a session with the mobile application, **make sure all checkmarks (Pairing, Battery) are green before proceeding with the tutorial.**
- Position the headband on your head as instructed. In case of long hair, pulling hair over the back sensors should be done to ensure good contact with the scalp. If you have long hair at the back, we require that you lift your hair over the rear elastic band of the headband before positioning the back (occipital) sensors. You can then keep your hair up in a ponytail or lay it back down over the top of the headband when sleeping. Gently move the sensors down to the scalp when complete. If the hairstyle significantly impedes the sensor placement (toupee, tight braids, dreadlocks, etc.), contact your clinician or your designated point of contact for the sleep study.
  If the patient is conducting a session with the mobile application, ensure they follow the headband positioning tutorial shown in the mobile application.
- Once you have made sure your headband is properly positioned, you can proceed with the next steps!

If the patient is conducting a session <u>with</u> the mobile application:

Start the recording directly from the app by clicking on the appropriate button at the end of the tutorial and after undergoing the signal quality check. A buzzer and LED on the Waveband will indicate that the recording has started.

Read the instructions for stopping the recording and ending the night tomorrow morning.

If the patient is conducting a session without the mobile application:

Start recording by pressing the power button on the headband 3 times in rapid succession. A buzzer and LED on the Waveband will indicate that the recording has started. Do not stop the recording to readjust the headband. The LED will turn off shortly after the recording is started. Read the instructions for stopping the recording and ending the night tomorrow morning.

- If you are unsure the recording has started, briefly press the power button. The LED should briefly breath white then fade back to black.

  Do not take your headband off if you need to go to the bathroom or if the session is during sleep and you are unable to sleep. The headband should remain on the head throughout the session.

3.4. End a Session

If the patient is conducting a session with the mobile application:

The session is ended by opening the mobile app and pressing "Complete Recording". Please make sure to **stop the recording as soon as you wake up.** Follow the instructions in the mobile app to ensure recording data is retrieved from the headband.

Note: If for some reason the mobile device is inaccessible or the app is not responding, holding down the power button for 3 seconds will turn off the headband and stop the recording.

If the patient is conducting a session without the mobile application:

If you are not using the mobile application to record, stop the recording by holding down the power button for approximately 3 seconds until a tone is heard. The buzzer and LED on the headband will indicate that the recording has stopped.

3.5. Remove Headband and Upload a Session

The headband can be removed from the head once the session has ended. You can proceed to plug the magnetic cable to the back of the headband to charge the device to ensure it is charged for the next session.

If using a BLE connected mobile device, the device should remain nearby the headband to ensure the full recording is uploaded from the app to the server if applicable. The data will be streamed automatically using the Bluetooth connection while the recording is produced if the Bluetooth connection is maintained throughout the recording. If the Bluetooth connection is interrupted, the recording will not complete streaming to the mobile

app until the connection is reestablished. The completion status of the session to the Beacon Pal App can be viewed in the Sessions section of the app.

If the session is still pending upload after 2 hours despite having correctly configured the Bluetooth and having the headband close to the mobile device, please contact the Beacon Biosignals support team or your designated point of contact for the sleep study.

The outputs of the Waveband sleep studies are only made available to the healthcare professional who prescribed the device.

3.5.1 Headband Memory Limitations

When the Waveband has not connected via BLE to a companion application (for example, the Beacon Pal App), the device can store up to 50 hours of data. Once the memory is full, another recording cannot be initiated from the headband until data on the headband has been retrieved. If the device indicates that memory is full, please contact the Beacon Biosignals support team or your designated point of contact for the sleep study to return the device.

Refer to section 2.1.4 for information on memory indications and section 2.1.8 for details on device memory management.

3.6. Device Disposal

Do not dispose of your product with other household waste. The device contains rechargeable batteries which may not be disposed of in municipal waste streams and require separate collection.

Your clinician should provide you with the appropriate instructions for returning the device.

3.7. Important Note

If you experience any issue with the device, or any adverse event, pain or discomfort, please end your study, review these instructions and contact the Beacon Biosignals support team: https://beacon.bio/contact/ or via email at support@beacon.bio.

4. Key Takeaways

4.1. Before the Recording

	a. The headband should be **fully charged** to ensure the device does not stop working during the session.
	b. You should have received **dedicated credentials to log into the Beacon Pal App** of the device.
	c. Your headband must be connected to your Beacon Pal App via **Bluetooth.**
	d. The **time zone** of the phone/tablet is correct and reflects your current location.

4.2. When Preparing for the Recording

	a. The **headband's fitting is essential**. If the headband is too tight, a larger adjuster can be added to the headband. The headband should be **snug and not shift** on the head when a participant moves during the night.
	b. The **mobile device** is nearby and **connected** to the headband. Alternatively, the mobile device can be retrieved in the morning at the end of the recording and placed next to the headband to allow for data to upload.
	c. Sleep hygiene and having a regular sleep schedule are crucial.
	d. Before starting the night recording, make sure you understand: • how to **wear the headband properly** to ensure good signal quality • how to **launch a recording** • how to **stop a recording** • how to **charge the headband** • how to **view data upload status**

4.3. After the Recording

	a. If applicable, must **have your mobile device within Bluetooth range and paired** with your headband to ensure the data is automatically sent to the mobile application. If the mobile device's Bluetooth is connected to the headband and the mobile device is connected to the internet, the recording should already be uploaded once the recording is ended. If neither are true, data won't be transferred for the home sleep study period.
	b. Place the headband on the charger to ensure it is charged for the next session.
	c. Review the session upload status in the "Sessions" tab. If the session is still pending upload after 2 hours despite having correctly configured the Bluetooth and having the headband close to the mobile device, please contact the Beacon Biosignals support team or your designated point of contact for the sleep study.

5. Troubleshooting

5.1. Headband Power

In case the headband's LED does not light up upon turning the device on:

1. Plug the headband into the charger. Make sure the headband's charging cable is properly plugged into the socket and that the magnetic end sticks to the headband's charging slot. The headband's LED should light-up automatically.
2. If not, proceed to press on the power one time. The LED should light up.
3. If you are still unable to power up the headband, please contact the Beacon Biosignals support team.
4. If the headband LED remains white after a session has ended, it is most likely frozen. To solve this issue, simply let the headband's battery drain out and proceed to plug the headband once the headband is turned off.

5.2. General Error

The Waveband device will blink ruby and white if it is experiencing a general error. If this occurs, the device needs to be returned to resolve the issue. Contact the Beacon Biosignals support team or your designated point of contact for the sleep study to return the device.

5.3. Beacon Pal App

In the case that the mobile application is not responding:

1. Verify Bluetooth is on, and the phone has internet access.
2. Verify that the mobile application is updated to the latest version of the app.
3. If problems still arise, select "Forget headband" and re-pair manually in case of critical connection issues. Alternatively, when pairing another headband, make sure to forget the original headband before pairing to another headband.
4. Force the Beacon Pal App to quit and reopen the application. Follow the normal steps for operation.

5.4. Recording

If you are unsure the recording has started, simply make a short press on the power button. The LED should briefly breath in white then fade to black.

If when attempting to start a recording, the LED is Orange and the headband beeps three time in a single tone, the memory is full. Another recording cannot be initiated from the headband until data on the headband has been retrieved. If the device indicates that memory is full, please contact the Beacon Biosignals support team or your designated point of contact for the sleep study to return the device.

If the headband has turned off during the recording and part of the night data is missing, this is most likely due to battery discharge. Please charge your headband after each use. If you have followed the guidelines and battery discharge is not the issue, please get in touch with the Beacon Biosignals support team.

6. EMC Information

<table>
<tr><th colspan="3">Manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The WB1CLMD is intended for use in the electromagnetic compatibility environment (for home and professional healthcare) specified below.

The customer or the user of the WB1CLMD should assure that it is used in such an environment.</td></tr>
<tr><th>EMISSIONS TEST</th><th>COMPLIANCE</th><th>ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
(FOR HOME AND PROFESSIONAL HEALTHCARE ENVIRONMENT)</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The WB1CLMD 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.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class B</td><td rowspan="3">The WB1CLMD is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic Emissions
IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage Fluctuations/
Flicker Emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Manufacturer's declaration - electromagnetic immunity			
This WB1CLMD is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the WB1CLMD should assure that the device is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT – GUIDANCE (FOR HOME AND PROFESSIONAL HEALTHCARE ENVIRONMENT)**
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV contact Air: ±2 kV, ±4 kV, ±8 kV ±15 kV	Contact: ±8 kV contact Air: ±2 kV, ±4 kV, ±8 kV ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for Power supply lines ±1 kV for input/output lines	±2 kV for Power supply lines Not applicable	Main power quality should be that of a typical home and professional healthcare environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	±0.5 kV, ±1 kV line(s) to line(s) Not applicable	Main power quality should be that of a typical home and professional healthcare environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % U_T; 0.5 cycle 0 % U_T; 1 cycle 70 % U_T; 25/30 cycles Voltage interruptions: 0 % U_T; 250/300 cycle	Voltage dips: 0 % U_T; 0.5 cycle 0 % U_T; 1 cycle 70 % U_T; 25 cycles Voltage interruptions: 0 % U_T; 250 cycles	Main power quality should be that of a typical home and professional healthcare environment. If the user of the WB1CLMD requires continued operation during power mains interruptions, it is recommended that the WB1CLMD be powered from an uninterruptible power source or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	The WB1CLMD power frequency magnetic fields should be at levels characteristic of a typical location in a typical home and professional healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration - electromagnetic immunity			
This WB1CLMD is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the WB1CLMD should assure that the device is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT – GUIDANCE (FOR HOME AND PROFESSIONAL EALTHCARE ENVIRONMENT)**
Conducted RF IEC 61000-4-6	3 Vrms: 0.15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0.15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	**Portable and mobile RF communications equipment should be used no closer to any part of the** WB1CLMD including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz 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 metres (m). Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distance between portable and mobile RF communications equipment and the WB1CLMD			
The WB1CLMD is intended for use in an electromagnetic environment (for home and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the WB1CLMD can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WB1CLMD 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		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**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	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Manufacturer's declaration - electromagnetic immunity							
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment The WB1CLMD is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the WB1CLMD should assure that it is used in such an environment.							
Test frequency (MHz)	**Band** [a)] (MHz)	**Service** [a)]	**Modulation** [b)]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)	**Compliance LEVEL** (V/m) (for home and professional healthcare)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0.2	0.3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28	28
870							
930							
1 720	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0.3	28	28
1 845							
1 970							
2 450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28	28
5 240	5,100 –	WLAN	Pulse	0.2	0.3	9	9

5 500 5 785	5,800	802.11 a/n	modulation b) 217 Hz				
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is							

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.

Manufacturer's declaration - electromagnetic immunity					
Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields The WB1CLMD is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the WB1CLMD should assure that it is used in such an environment.					
Frequencies	**Test Level [A/m]**	**Point / Window**	**Modulation**	**Dwell time [s]**	**Compliance LEVEL [A/m] (for home and professional healthcare)**
30 kHz (a)	8	All points on photo below	CW	3	8
134.2 kHz	65	All points on photo below	Pulse modulation (b) 2.1 kHz	3	65 (c)
13.56 MHz	7.5	All points on photo below	Pulse modulation (b) 50 kHz	3	7.5 (c)
Note: (a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME AND PROFESSIONAL HEALTHCARE ENVIRONMENT. (b) The carrier shall be modulated using a 50 % duty cycle square wave signal. (c) r.m.s., before modulation is applied.					

7. FCC Information

7.1. FCC Statement

1. This device complies with Part 15 of the Federal Communications Commission (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.

2. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

7.2. FCC Radiation Exposure Statement

This equipment complies with FCC radiation exposure requirement. The device can be used in portable exposure conditions without RF restriction.

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.

8. RF Information

This section covers the following topics:

- A summary of wireless functions and specific wireless technology incorporated into the device including equipment or system specifications.
- A summary of the operating characteristics of the wireless technology, effective radiofrequency (RF) radiated power output and operating range, modulation, specification of each RF frequency or frequency band of transmission, and bandwidth of the receiving section.
- A brief description of the wireless QoS needed for safe and effective operation.
- Functions and performance of the wireless data transmissions including data rate, and data integrity.
- A brief description of the recommended wireless security measures such as the WPA2 wireless encryption for IEEE 802.11 technology.

Bluetooth LE Specification	
Bluetooth Standards	**Bluetooth 5.4 Core Specification**
Compliance	FCC Part 15 Class B (47 CFR 15.247) Directive 2014/53/EU (RED) EN 301 489-1/-17
Operation Frequency Range	2.402 GHz - 2.480 GHz
Modulation	GFSK
Channel width	2 MHz
Output power	0.8 mW
Antenna	Chip antenna (W3008) with 1.1 dBi gain
Data Transmission Range	< 10 meters
Data Rate	2 Mbit/s
RF Physical Channels	79 channels with 2 MHz channel spacing
Data Integrity Check	Ensured by the BLE protocol itself. Additional checks are performed at the mobile App level.

Main Security Algorithms	AES-CCM
QoS	Best Effort

9. Cybersecurity

This section summarizes the cybersecurity considerations that have been taken into account during the Waveband design process:

> Device access:

- Only authorized patients can connect to the Beacon Pal App and pair their Beacon Pal App with their headband.
- Only authorized clinicians have access to their patients' recordings.
- Credentials are created by the Beacon Biosignals account manager and provided to the clinician who will distribute IDs and passwords to his patients.
- Credentials will all be at least 10 characters in length, with specific characters: mixture of lowercase and uppercase letters, numbers and symbol.

> Software and Firmware updates:

- The embedded software (“firmware”) on the Waveband can be updated.
- Periodic and automatic checks will be performed to verify whether updates are available. This happens when the Waveband is paired with the Beacon Pal mobile app.
- In case a firmware update is required, the Beacon Pal mobile app will notify the user to plug in the headband if needed. During a firmware update, the LED will show a magenta light.
- After the update is completed, the installed firmware version number is displayed on the mobile App.

> Enforced cybersecurity controls (not exhaustive):

- Signed firmware updates

> Device decommissioning:

- No patient recording data is stored on the headband after their night has been uploaded to the dedicated server.