WAVEBAND

WAVEBAND INSTRUCTIONS FOR USE

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Beacon Biosignals, Inc.

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7th Floor, Unit 41

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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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GENERAL PRESENTATION

1 ABOUT THE WAVEBAND DEVICE

1.1 Technical Specifications

Product Name	Waveband Model: 3SCL1MD	**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 and Bluetooth
Weight	130g	**Connectivity**	Classic Bluetooth 4.0 Low Energy Bluetooth 4.0 Wi-Fi b/g/n 2.4Ghz
Dimension	Head perimeter 540mm - 620mm	**Audio**	Bone Conduction system
Battery	520mAh - Up to 24 hours	**Interface**	Sound feedback RGB LED indicator
Charging time	3h30	**Languages**	English
Sensors	EEG sensors x 6 Accelerometer Microphone (disabled)	**Expected Service Life**	2 years

NOTE

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

1.2 Conditions of use and storage

The device must be used and stored in dry, enclosed premises at room temperature.

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.

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)
Wi-Fi	2402-2480 MHz	15 dBm
Bluetooth	2402-2480 MHz	Class I

1.3 Description and purpose of the device

The Waveband system is a dry-electrode EEG system consisting of a physical device and a connected mobile application acting as a companion software to configure the headband.

The Waveband acquires brain, and movements activities during sleep with a convenient set-up and 24 hours **battery life**. The device is designed so that dry sensors are in contact with the subject's head, to measure brain activity during sleep.

The sleep data is directly transferred from the headband to the dedicated server through a Wi-Fi connection. This happens after the recording has been stopped and the headband is charging. Data is automatically processed when successfully uploaded to the server, in order to compute two types of outputs, only available to the healthcare professional:

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

FIGURE 1: WAVEBAND HEADBAND, THE BEACON PAL APP, AN EDF OUTPUT OF THE DEVICE (LEFT TO RIGHT)

1.3.1 INTENDED USE/INDICATIONS FOR USE

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

The Waveband is used for the assessment of sleep on adult individuals (22 to 65 years old). The Waveband 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 one or multiple nights. The device is then able to record EEG physiological signals during the night. The analysis of these parameters generate patients' sleep stages and derived sleep metrics.

Basic recording data are displayed to the patient (duration of the recording and data transmittal status), while sleep stages and sleep metrics are only provided to the healthcare professional.

The sleep data transfers directly from the headband to the dedicated server through a Wi-Fi connection. This happens when the recording has been stopped and the headband is charging. The headband has data storage capacity that allows it to record multiple nights in case Wi-Fi upload is temporarily unavailable. When data is on the server, the data is automatically processed.

The headband will automatically resume all wireless connections once charging and initiate data transfer via Wi-Fi to the dedicated servers. A few minutes later, the patient will see on the app that his night sleep was recorded.

1.3.3 INTENDED USER

The device is intended to be prescribed by a clinician for assessing sleep on adult individuals (22 to 65 years old) who present with disturbed sleep.

The Waveband should be used only in accordance with the clinician's instructions. For general warnings and precautions see Sections 1.3.9 and 1.3.10.

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

The Waveband is designed for home sleep monitoring taking place on the typical patient's sleep setup and independently operated by the patient. 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.

1.3.4 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 for the basic safety and essential performance of electroencephalographs.

Specifications are summarized in the following table:

SPECIFICATION	**VALUE**
Amplitude Measurement Error	1%
Maximum Differential AC Input Before Clipping	+/-650mV
Maximum Differential DC Input Before Clipping	+/-1600mV
Input Noise (peak to peak)	Max 5.06 µV @ 0.5Hz~50Hz bandwidth
Channel Bandwidth	0.1Hz to 50Hz
Common Mode Rejection Ratio	- ≥ 90 dB @ 50/60Hz

1.3.5 CLINICAL PERFORMANCE

1.3.5.1 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.

1.3.5.2 Clinical performances of Waveband Sleep Staging

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.

The performances of the active versions of the sleep staging deployed in production v0.2.13 and v2.0.0 or higher (unless specified otherwise) are described below. The overall agreement between Waveband and consensus from manual staging is respectively 85.1% for v0.2.13 and 87.1% for v2.0.0. Confusion matrices for both algorithms are provided in table 1 for v0.2.13 and Table 2 for v2.0.0+.

TABLE 1: CONFUSION MATRIX COMPARING WAVEBAND (SLEEP STAGING 0.2.13) AND CONSENSUS OF EXPERT-SCORED PSG FOR ALL SLEEP EPOCHS IS SUMMARIZED AS PERCENTAGES IN THE TABLE BELOW.

		Consensus from manual staging				
		W	**N1**	**N2**	**N3**	**R**
Waveband (Automated Analysis)	**W**	84.9%	8.0%	0.7%	0.1%	0.8%
	N1	8.1%	47.3%	2.1%	0.1%	1.2%
Waveband (Automated Analysis)	**N2**	4.4%	36.4%	89.3%	18.4%	4.1%
	N3	0.2%	0.2%	5.0%	81.2%	0.0%
	R	2.4%	8.1%	2.8%	0.2%	93.9%
	Epoch count	9,691	2,546	17,761	6,073	5,328

TABLE 2: CONFUSION MATRIX COMPARING WAVEBAND (SLEEP STAGING 2.0.0 +) 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

1.3.5.3 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.

1.3.6.1 Implemented PCCP modifications in Waveband Sleep Staging Algorithm

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.

1.3.6.1.1 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 performance results are presented in *Section 1.3.5*. 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 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 brings the accuracy of the sleep lab to a patient's home. Waveband' 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 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 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 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.

No attachments and/or accessories which are not approved by Beacon Biosignals should be used with the Waveband, to avoid 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 us at https://beacon.bio/contact/.

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 inform us at https://beacon.bio/contact/.

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.

A magnetic charging cable is used to charge the headband. Keep the magnetic charger more than 6 inches away from any magnetically susceptible medical devices.

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, the system can engage Wi-Fi communication, in this case its surface temperature may briefly reach a temperature of 43°C (109°F) and feel warm. When Wi-Fi communication or charging stops, or the device is unplugged, the temperature will 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, without limitation, sunlight, radiators, heater, stoves, open flames such as lighted candles, or heat producing devices, such as audio amplifiers, televisions, nebulizer).

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.

Gently remove any visible residues from the Waveband and from the electrodes on upper arch; presence of dust or lint on the electrodes might affect the quality of the data measured by the Waveband. Keep the medical system and its accessories far from children and pets, to avoid unintentional damage or swallowing.

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 your 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, or 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 Customer Support :

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

1.4 MANUFACTURER

Beacon Biosignals, Inc.

22 Boston Wharf Rd,

7th Floor, Unit 41

Boston, MA 02210

1.4.1 EXPLANATION OF THE SYMBOLS

Labels:

	Manufacturer
TW	Country of Manufacture
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
	Consult 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 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
95%	Humidity limitation
1060 hPa 700 hPa	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/ where we will be happy to address your questions 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 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.

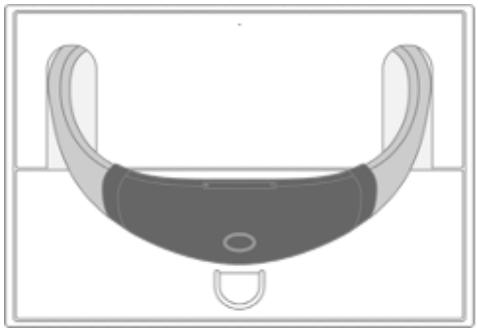
No Other Warranties: No Beacon Biosignals dealer, agent, or employee is authorized to make any modification, extension, or addition to this warranty.

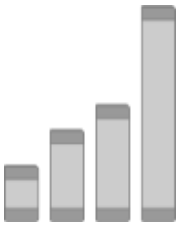
Warranty Periods: the product is guaranteed two (2) years after the purchase.

1.4.3 DISCLAIMER AND VENUE

Your use of the Waveband and accompanying Beacon Pal mobile application is governed by our Terms of Use. By using the Waveband, you consent to our Terms of Use. For more information, please visit https://beacon.bio/ . 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. For more information, please visit https://beacon.bio/.

1.5 Box Content

Waveband band with the small adjuster set	
List of detachable components to be used in combination with the Waveband System:	

Power Supply Unit *(Ref: UES06WU-050100SPA)*	
Adjustment strips available in multiple sizes *(Ref: LV37I00011U for L, LV37I00021U for M, LV37I00031U for S, LV37I00041U for XS)*	
Travel Bag *(Ref: ZLIP22TB)*	

2 PRODUCT OVERVIEW

2.1 Waveband Headband

FIGURE 2: WAVEBAND HEADBAND AND SENSORS

The Waveband electronic system is composed of high-density electronics containing the processing power, memory, battery drivers, communication features such as Wi-Fi and Bluetooth and acquisition capabilities for the EEG, and accelerometer subsystems; it also collects user inputs through a daughterboard driving the volume and power buttons.

Schematically, the EEG and accelerometer are converted for subsequent digital signals to be processed in the embedded system. The device works in a non-invasive way. The system contains embedded miniaturized electronics in order to run calculations onboard while maintaining low energy use and ultra-low latency. This also allows Wi-Fi and Bluetooth to be deactivated during the night.

The headband needs to be recharged by plugging into the mains charger supplied with the headband (charging time is 3h30 for 100%).

Up to 1.6MB per second of sensor data signal can be analyzed. A low-power-consumption of 65 mW (on average) allows the headband to have a battery life of 24 hours between charges. Real-time algorithms are coded via low-level embedded software requiring very low latency in execution time. Audio execution latency (25ms) is incorporated and compensated when running audio messages.

The raw data is transferred to the dedicated servers via Wi-Fi where they are analyzed to produce the hypnogram the sleep metrics outputs, and an optional EDF file that can be viewed in a 3rd party viewer.

2.1.1 CHARGING THE HEADBAND

Patients should charge the Waveband after each sleep session. This will ensure that the Waveband device is charged enough for the next sleep session.

FIGURE 3: CABLE PLUG

The headband can be charged using the charger (Ref: UES06WU-050100SPA): charging cable and adaptors are available in the box.

The cable attaches to the headband thanks to a **magnet** in both directions. To protect the headband from falling and potentially damaging its components, the cable has been designed to detach itself easily in case the cable is suddenly pulled, please make sure to keep this information in mind when charging the headband.

If the LED does not light up, make sure the charging cable is properly plugged.

2.1.2 LED BEHAVIOR

The LED located on the top arch has different behaviors:

- Headband On / Headband Off and Headband pairing status:
  - No light means the Waveband headband is off or in a sleep session.
  - A spinning light indicates it's attempting to pair with a device.
  - A fixed light shows that the Waveband headband has successfully paired and/or is paired.
- Charging status:
  - When the light indicator has a step increase pattern, your Waveband headband is currently charging.
  - When the light turns solid, your device is fully charged and ready to use.
- Boot and firmware update status: a white light that indicates your Waveband is booting or updating its firmware.

While using the device, the battery level can be identified through LED color variations (Figure 4):

- Flashing red LED indicates that the battery load is between 0% and 50%.
- Flashing green LED indicates that the battery load is between 50% and 99%.
- The headband is fully charged when the LED is steady green.

The LED should be green before starting a sleep recording.

Because the headband's battery life is 24 hours, it is important to charge the headband after every use to ensure the device does not stop working during the night.

FIGURE 4: LED CHARGING STATES

2.1.3 CARE AND MAINTENANCE

The inside of the headband is lined with a soft fabric, and the plastic parts are made of ABS. It is recommended to gently clean the headband every week, including the electrodes, with a piece of cloth or a cotton swab dampened with isopropyl alcohol (IPA), in case any deposit of external material is visible. Clean the power supply weekly with a dried piece of cloth to avoid the presence of dust or other residues over the equipment.

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. 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, AND ITS FRONT BAND, IN PARTICULAR, CONTAINS SENSORS, AND NEEDS TO BE HANDLED WITH CARE.

2.1.4 FIRMWARE UPDATE

The embedded software ("firmware") on the Waveband device 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 and the Wi-Fi is configured.
- When the clinician decides to update the firmware, he is expected to leave the device plugged to its charger. The update will happen while charging. The LED must show a white light.
- After the update is completed, the installed firmware version number is displayed on the mobile App.

2.2 The Beacon Pal App

Beacon Pal by Beacon Biosignals	Available on the App Store ANDROID APP ON Google play

The Beacon Biosignals mobile app companion, Beacon Pal, is the remote control to the Waveband headband. With this app, the patient will be able to:

- Configure a headband so it is linked with its specific credentials (provided by Beacon Biosignals).
- Set-up the Wi-Fi network so the headband can upload sleep data directly to the server when charging.[1]

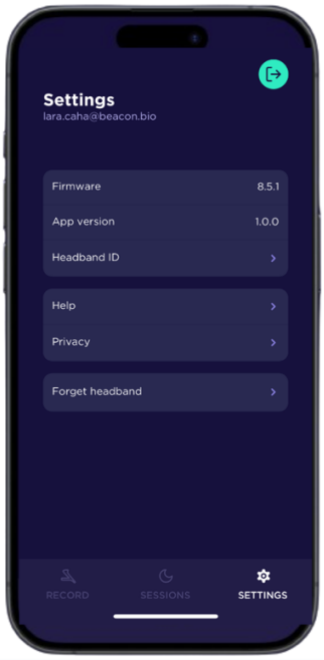
The Beacon Pal app can be preinstalled on a dedicated (compatible) smartphone. It should be used to configure the home Wi-Fi connection to allow data upload, and review headband's positioning instructions prior to a sleep study.

Note 1: Without Wi-Fi, the night's raw data will remain saved in the Waveband headband. Metrics will not be accessible to the physician until the headband is connected to a Wi-Fi network then plugged in for charging.

2.2.1 MAIN SCREENS

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

	The Record section acts as the headband's remote control for: a. pairing the headband b. checking battery life c. setting up Wi-Fi d. assessing signal quality e. launching recordings.

	The Sessions section where night recordings that have been **uploaded** from the headband to the server will be displayed.
	**The Settings section** displays relevant information about the **application**, the **user**, and the **headband**. This is also where to **log out** from a user account. The user is redirected to Beacon Biosignals privacy policies upon tapping on “Privacy”, and to additional help material upon clicking on “Help”.

2.3 Data Flow

Before a recording, the Beacon Pal App communicates with the headband through **Bluetooth**. When a recording is over, the Waveband headband communicates with the app through **Bluetooth** to transmit the night summary. It also communicates with the server to transfer raw data, through **Wi-Fi**.

Currently, recordings must go through our servers for them to be accessible. The storage pipeline is as follows:

1. First, the recording is created and stored, encrypted, in the headband on its internal storage.

2. Once the recording is over and the headband is plugged in and connected to Wi-Fi, the recording is uploaded to dedicated servers through an encrypted HTTPS connection and deleted from the headband.

3. The raw recordings are then accessed and processed by Beacon Biosignals internal services, making them available for download afterward.

The prescribing clinician will be informed of the availability of the analysis outputs through a specific email.

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 sleep data.

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

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

At the end of the sleep study, the Waveband device will automatically upload the recorded session on the dedicated servers. This can only happen if the patient has correctly configured his Wi-Fi connection on the Beacon Pal App and has plugged his headband for charging. Charging the headband will restore the internet connection and allow data to be uploaded.

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

subject of mail : [New_Recording] Record 77f0fe84-0ec3-4318-9f33-fe3c552c085c

A new recording has been successfully made !

Information about the recording:

Patient ID: JDXXXX
Patient email: johndoe_123@dreem.com
Date of recording (start time): 02 April 2022
Duration: 8:01:23
Record ID: 77f0fe84-0ec3-4318-9f33-fe3c552c085c

Please find below the links to download the night report and the raw data in EDF format:
report_pdf
raw_data_edf

- By clicking on the first link the clinician will be able to download the **sleep study report on a pdf format**
- By clicking on the second link, he will 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.

Recording Report

Participant Information

PARTICIPANT/PATIENT ID
01928740572595

Recording Information

SITE ID
412

STUDY ID
01931

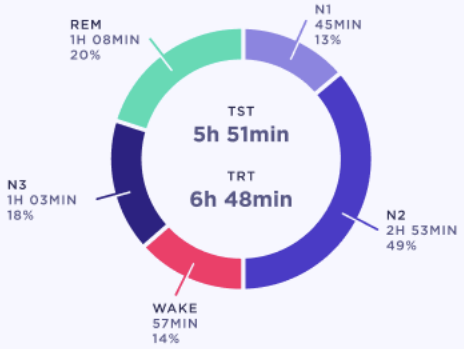
SPONSOR/PHYSICIAN ID
9871028

STUDY DATE
November 8, 2020

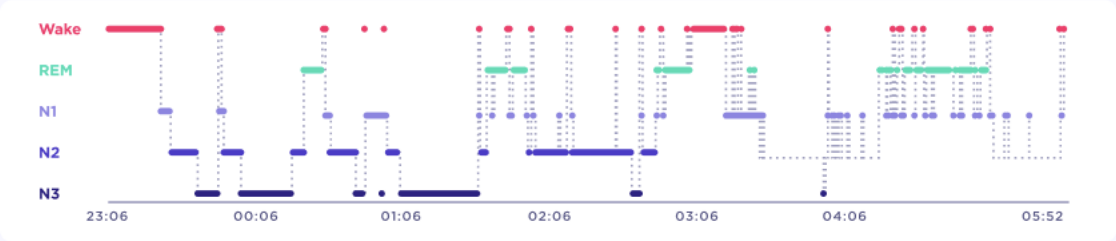
HEADBAND ID
69fe3ddb-43c6-4a47-8717-b93bc0c77e88

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 5: WAVEBAND OUTPUT – AUTOMATIC SLEEP STUDY REPORT

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.

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.)*

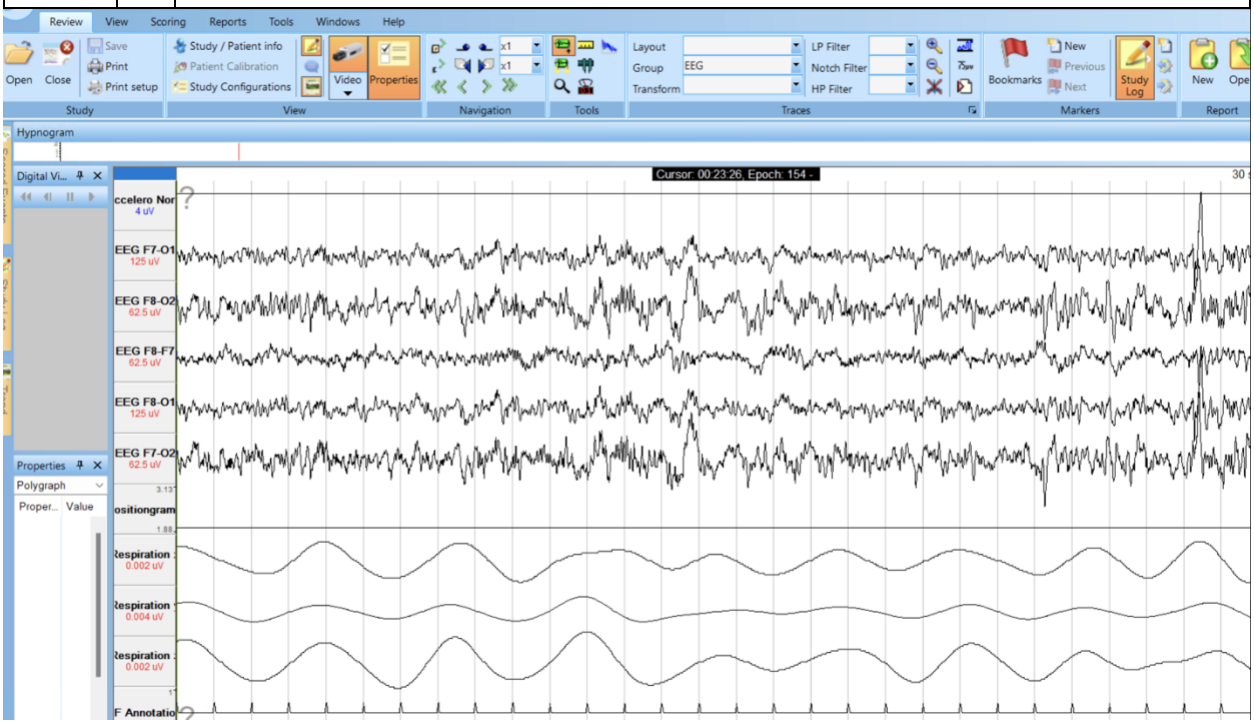


FIGURE 6: WAVEBAND OUTPUT – EDF FILE

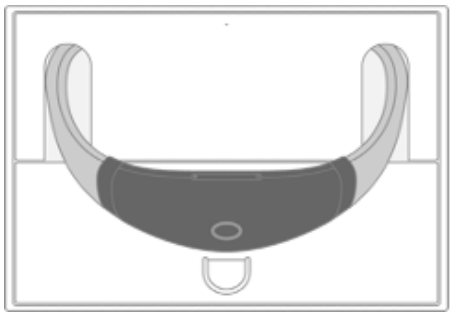
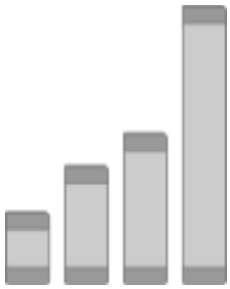
OPERATIVE INSTRUCTIONS

HOW TO SET-UP THE WAVEBAND AND UNDERGO A SLEEP STUDY

3 INSTRUCTIONS

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

Here's the Waveband box content:

Waveband band with the small adjuster set	
List of detachable components to be used in combination with the Waveband System:	
Power Supply Unit *(Ref: UES06WU-050100SPA)*	
Adjustment strips available in multiple sizes *(Ref: LV37I00011U for L, LV37I00021U for M, LV37I00031U for S, LV37I00041U for XS)*	
Travel Bag *(Ref: ZLIP22TB)*	

PREPARING THE DEVICE: STEP BY STEP

3.1 Checkout procedures

A. Open the box, make sure you have all the detachable components, and make sure the headband has no default and is fully charged.	
B. Make sure that the Bluetooth and GPS location of the smartphone/tablet is turned **on**.	
C. Download the Beacon Pal App on the iOS or Play Store.	Available on the App Store ANDROID APP ON Google play
D. Before starting the set-up on the Beacon Pal App, make sure that the **time** of the phone/tablet is **correct**.	
E. Before starting the set-up on the Beacon Pal App, make sure that you have your home **Wi-Fi credentials and your login information to the App**.	

3.1.1 Log in To the Beacon Pal App, Pair Headband, and Set-up Wi-Fi

This step is crucial so that the headband can be linked to the user profile. This will allow for proper identification of each recording.

It is also required that the Wi-Fi network is set-up so the headband can upload sleep data directly to the Beacon server when charging, at the end of the night. **The Wi-Fi network should be considered as the default Wi-Fi hotspot the headband will be connecting to.**

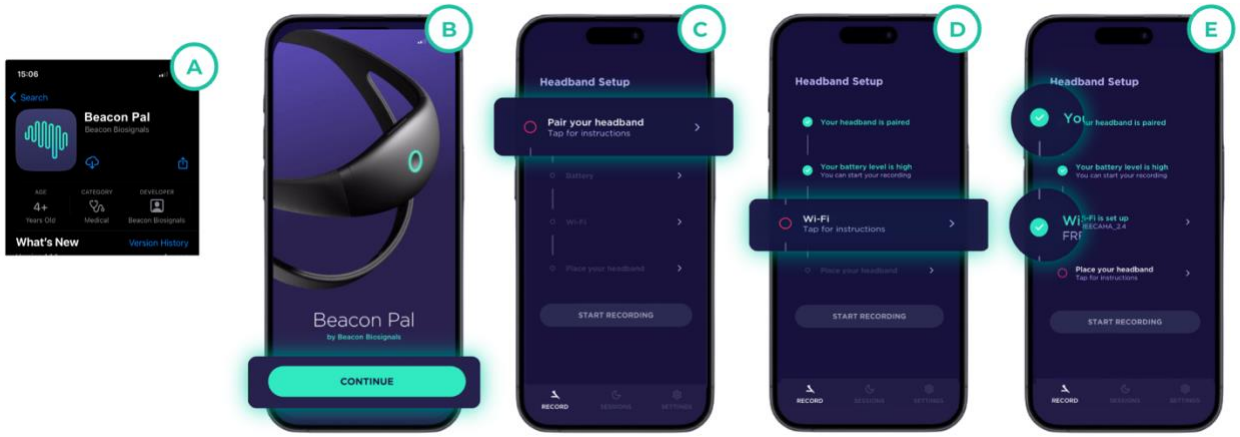
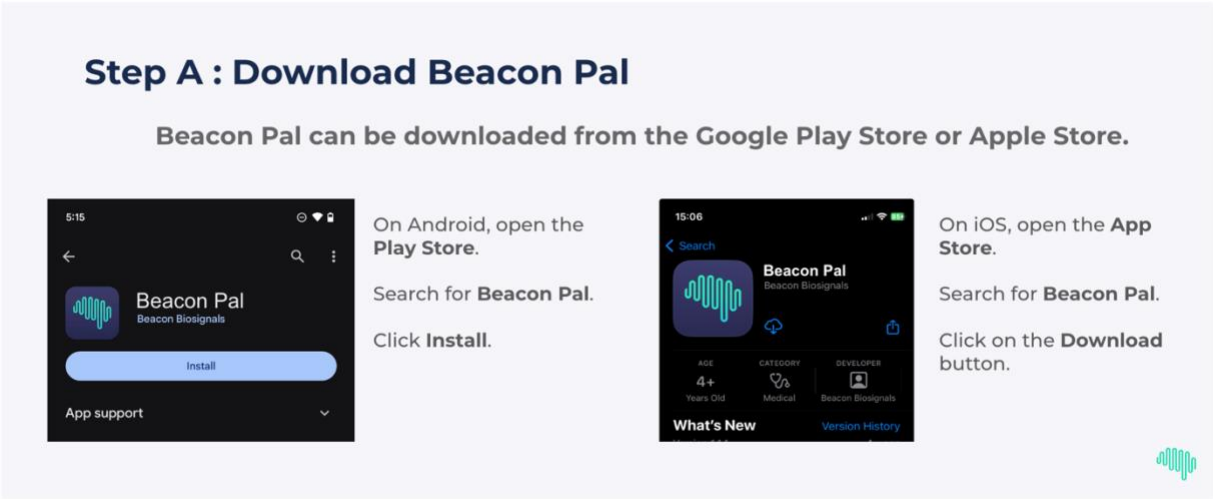


FIGURE 7: AUTHENTICATION, PAIRING AND WI-FI SETUP

A. Download the Beacon Pal App (on the App Store or the Google Play Store). Make sure the phone's/tablet's **Bluetooth, Wi-Fi, and Location settings** are turned on. **B. Open the app.** Select Continue. You will need to enter the credentials provided to you to authenticate. **C. Pair your headband.** On the app's homepage, select ***"Pair your headband"*** and follow the instructions for your headband to synchronize 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.	**D. Configure the Wi-Fi[2].** You **<u>must</u>** now connect to the Wi-Fi by selecting ***"Wi-Fi"*** on the home screen. You will only have to set-up the Wi-Fi once. The headband will now automatically connect to the Wi-Fi. **E. Checkmarks**. Green check marks will appear next to both the Pairing and Wi-Fi settings once they are configured. If not, the app will display an empty circle instead of a checkmark. **Please repeat until all checkmarks are green.**

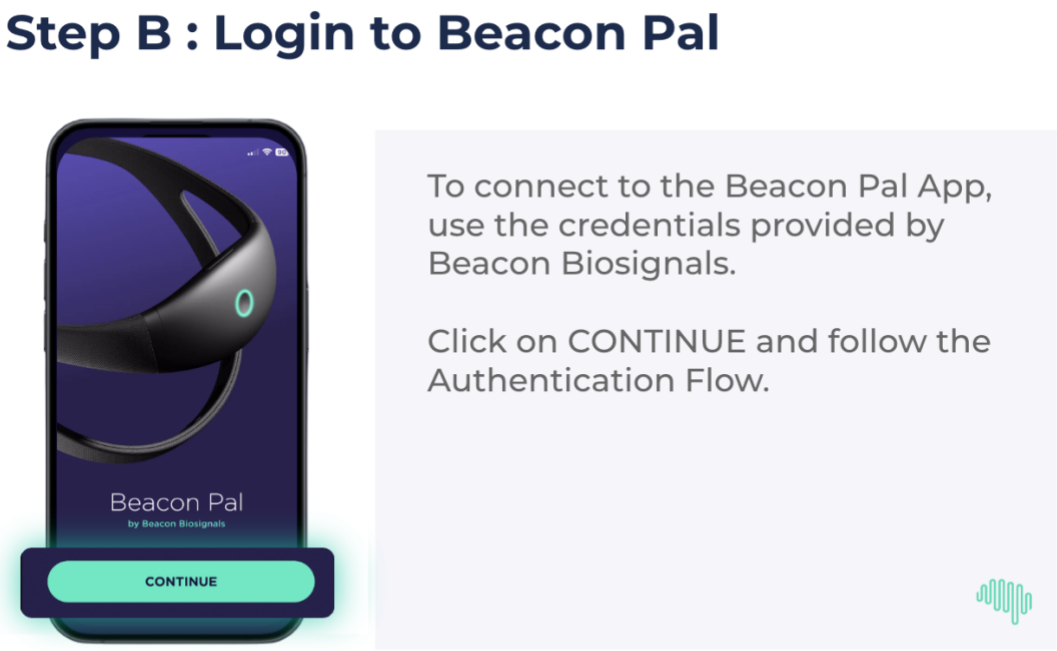
Note 2: Every time the headband is charging, it automatically connects to the configured Wi-Fi network. The data automatically transfers from the headband to the dedicated server. Note that it takes on average 3 to 10 minutes for one recording to upload. Upload time can vary depending on the network connection speed. When the raw data transfer is completed, it takes our servers up to 30 minutes to process sleep and quality metrics.

3.1.1.1 Get Beacon Pal and verify phone's configuration



Make sure the phone's/tablet's **Bluetooth, Wi-Fi, and Location settings** are turned on.

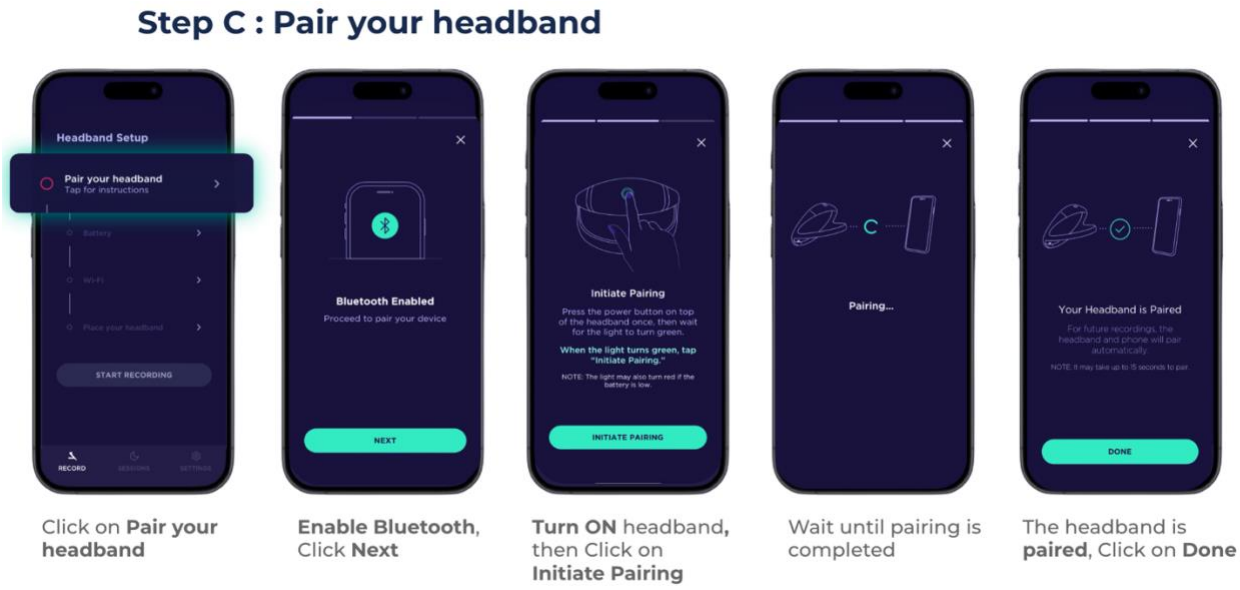
3.1.1.2 Open the app on your smartphone



Select **Continue.**

You will need to enter the credentials provided to you.

3.1.1.3 Pair your headband with your Beacon Pal app

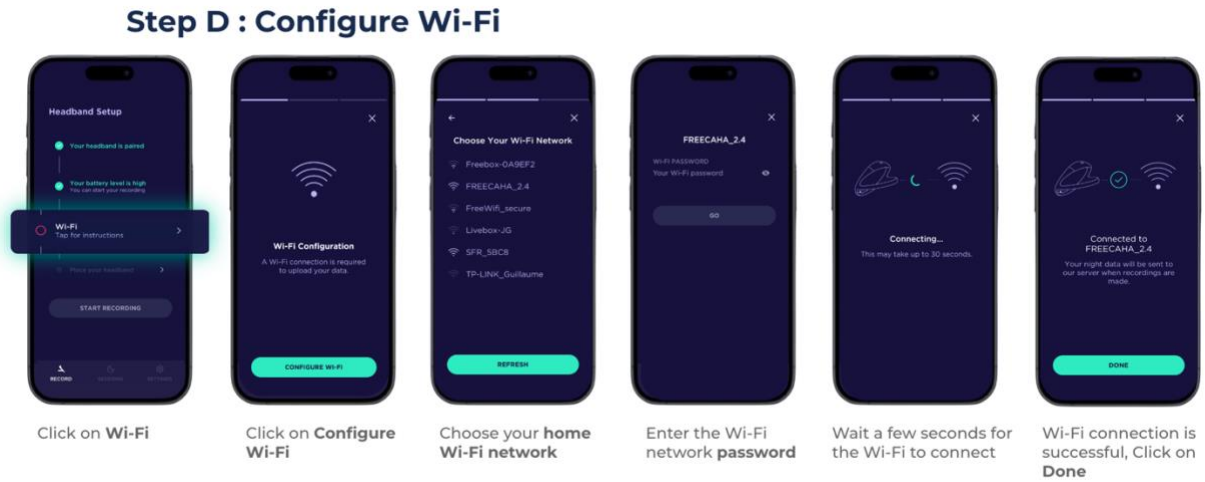


On the app's homepage, select ***"Pair your headband"*** and follow the instructions for your headband to synchronize with the app.

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 or a green charging bolt.

3.1.1.4 Configure the Wi-Fi[3] on the App to allow data upload



You **must** now connect to the Wi-Fi by selecting ***"Wi-Fi"*** on the home screen.

The initial Wi-Fi setup only has to be performed once.

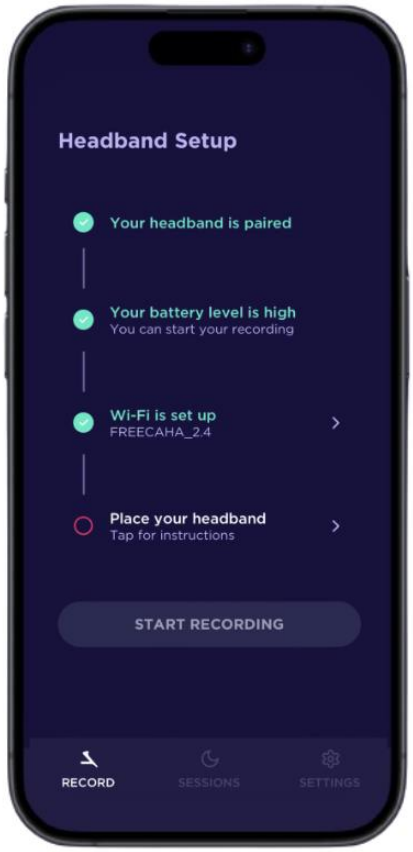
The headband will now automatically connect to the Wi-Fi.

This step is crucial to allow data being uploaded and analyzed on dedicated servers at the end of the recording.

Note 3: Every time the headband is charging, it automatically connects to the configured Wi-Fi network. The data automatically transfers from the headband to the server. Note that it takes on average 3 to 10 minutes for one recording to upload. Upload

time can vary depending on the network connection speed. When the raw data transfer is completed, it takes our servers up to 30 minutes to process sleep and quality metrics.

3.1.1.5 Make sure you are all set-up.



Green check marks will appear next to both the Pairing and Wi-Fi settings once they are configured.

If not, the app will display an empty circle instead of a checkmark.

Please repeat until all check marks are green.

NIGHT RECORDING: STEP BY STEP

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 their 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 in 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**.

3.2.3 HEAD CIRCUMFERENCE

The headband's fit can be adjusted with three sizes of adjustment strips **(Figure 8)**, 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.

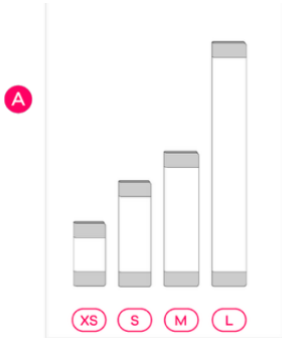


FIGURE 8: SIZE ADJUSTERS

A tighter 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 9B).**
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 9C)** 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 9D)**.

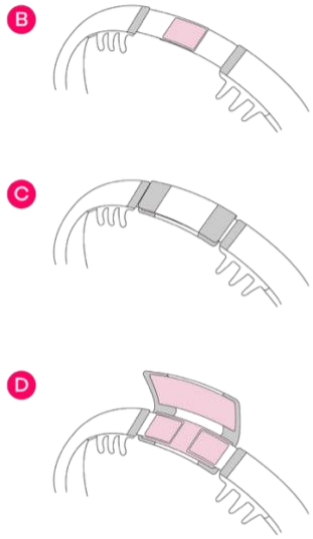


FIGURE 9: SIZE ADJUSTERS

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. **(Figure 10.1)**.
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 10.2)**. 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 10.3)**.
4. To ensure optimal support throughout the night, gently pull the upper arch backward **(Figure 10.4)**.

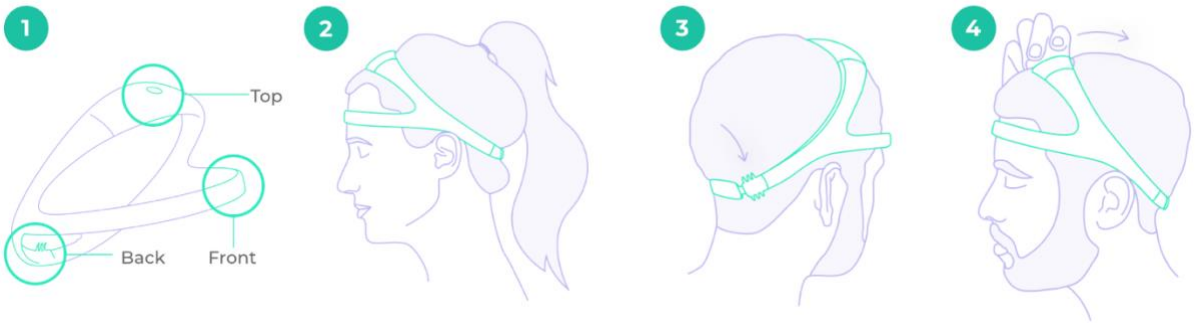
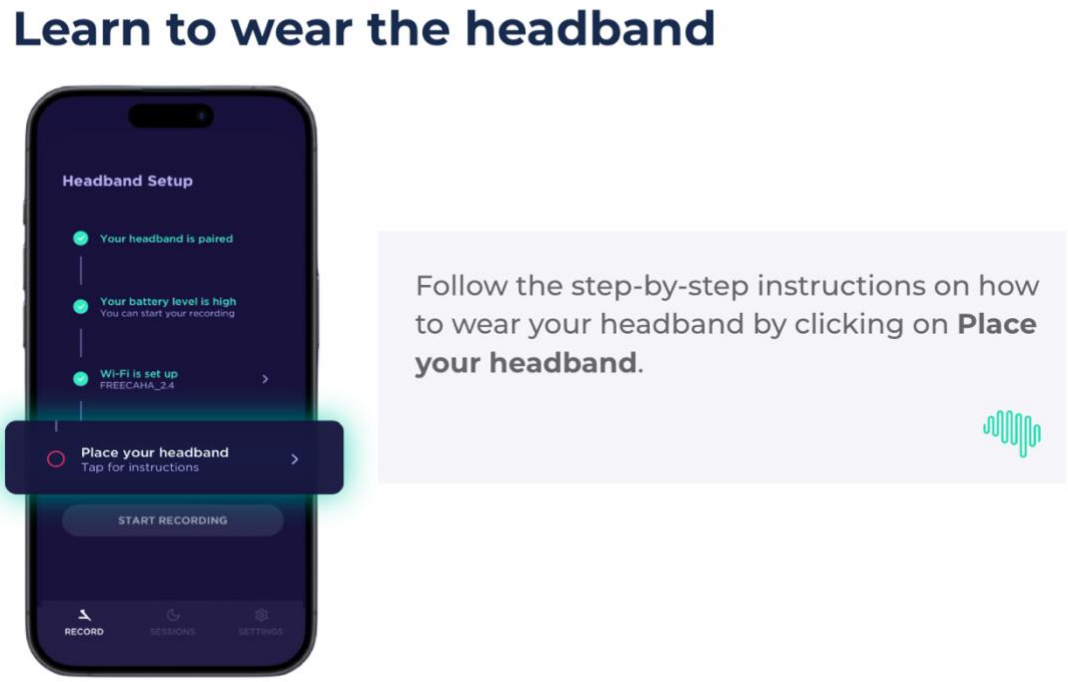


FIGURE 10: HEADBAND POSITIONING

3.3 Start a Recording

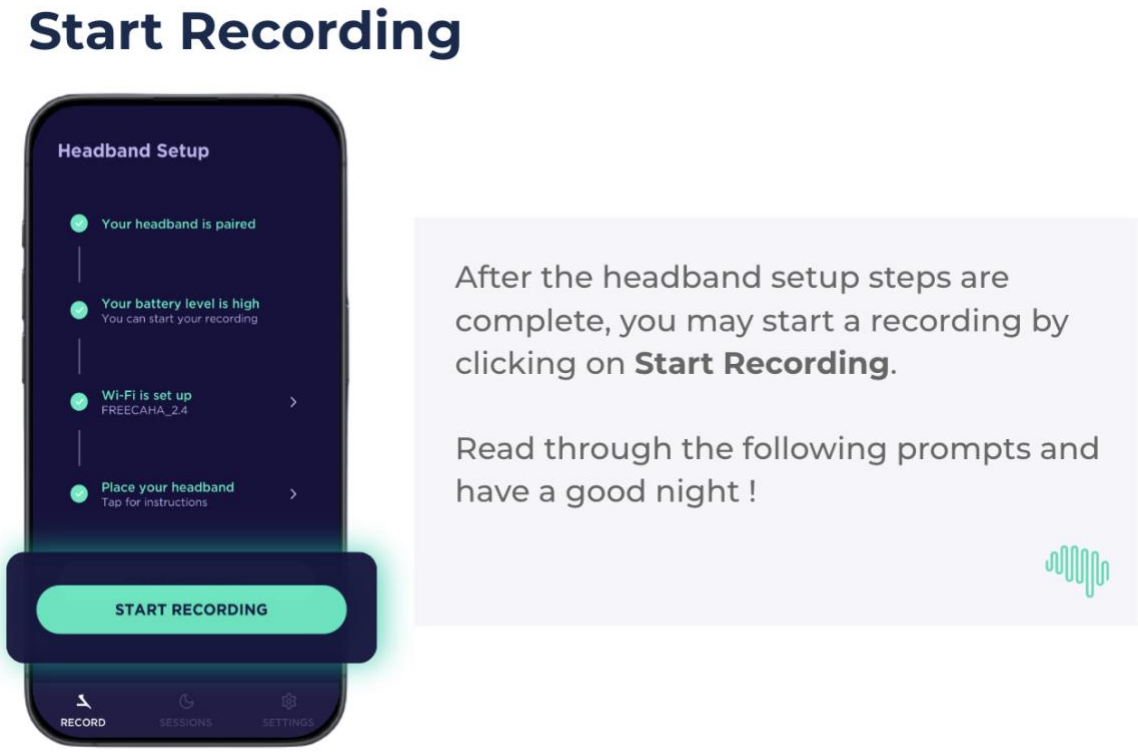
- Unplug the headband from its charger. The power button LED should be green. If the LED doesn't light up, proceed to press the power button on the top of the headband to turn it on.
  You only need one fast push (< 2 seconds) to power on the headband. Then wait a few seconds until the LED is fixed green.
  Make sure all checkmarks (Pairing, Battery, Wi-Fi) are green before proceeding with the tutorial.



- Position the headband on your head as previously instructed in *Section 3.2.4*. 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.), we ask you to remove the hairstyle.
Undergo the tutorial.

- Once you have made sure your headband is properly positioned, you can proceed with the next steps!



Start the recording <u>directly from the app</u> by clicking on the appropriate button at the end of the tutorial and after undergoing the signal quality check.

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

- If you are unsure the recording has started, simply make a short press on the power button. The LED should briefly light up in blue, and you should hear an audio confirmation.

NOTE: WHEN A RECORDING BEGINS, THE HEADBAND WILL AUTOMATICALLY STOP EMITTING BLUETOOTH OR WI-FI.

Do not take your headband off if you need to go to the bathroom at night. The same applies if you cannot sleep.

<u>AFTER RECORDING: MANDATORY STEPS</u>

3.4 Stop Recording

A short press on the power button will wake the headband.

The power button LED should light up in blue.

Holding down the power button for **3 seconds** will turn off the headband. The power button's LED should blink blue and turn off.

Please make sure to stop the recording as soon as you wake up.

FIGURE 11: HOLDING THE POWER BUTTON

3.5 Charge the headband to allow data upload

You can proceed to remove the headband from your head and plug the magnetic cable to the back of the headband to charge it during the day.

Caution, as it is a magnetic plug, make sure that the wire doesn't move to allow stable connection.

You should **always plug the magnet cable to charge the device after each recording**. This action will automatically resume all wireless connections and is needed to initiate the night data transfer over Wi-Fi to the dedicated servers, as well as to ensure the device has enough battery charge for the next use.

Please **plug your device near your Wi-Fi router** to allow good internet connection and fast data upload.

FIGURE 12: PLUGGING THE MAGNETIC CABLE

You can easily check the battery level while charging the headband by looking at the LED indicator located on the top arch, which indicates battery level through color variations **(Figure 4)**. If the LED does not light up, make sure the charging cable is properly plugged:

- Flashing red LED indicates that the battery load is between 0% and 50%.
- Flashing green LED indicates that the battery load is between 50 %and 99%.
- The headband is fully charged when the LED is steady green.

3.6 Recording upload notification

Charging your device is essential so that the data can be uploaded and sent to your physician.

The data will be uploaded automatically using the Wi-Fi connection in which the device has been initially configured, each time a recording is produced. A notification of data upload is available on the Beacon Pal app.

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

You are asked to check on the app if the recording has been uploaded. If no upload is notified in the Beacon Pal App, despite having correctly configured the Wi-Fi and having plugged the device for charging, please contact the Beacon Biosignals support team.

Caution, the temperature of the device may increase when charging, due to the Wi-Fi connection.

3.7 Care, maintenance and cleaning instructions

You must wear your headband on clean skin, without applying any type of moisturizer on the sensors' contact points. This will ensure good signal quality. If you are forced to apply a cream for medical reasons, you should avoid the areas of contact with the sensors as much as possible.

The inside of the headband is lined with a soft fabric, and the plastic parts are made of ABS. It is recommended to gently clean the headband every week, including the electrodes, with a piece of cloth, or a cotton swab dampened, with isopropyl alcohol (IPA), in case any deposit of external material is visible. Clean the power supply weekly with a dried piece of cloth to avoid the presence of dust or other residues over the equipment.

The Waveband headband isn't waterproof, avoid submerging in water and don't wear it outside when raining.

Please remember that the headband, and its front band contains sensors, and needs to be handled with care.

3.8 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 must have provided you with the appropriate instructions for returning the device.

3.9 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/.

- **Key Takeaways**

4 PRINCIPAL ACTIONS TO CARRY OUT

4.1 Before the Night Recording

	a. The headband needs to be plugged in for charging to ensure the device does not stop working during the night.
	b. You should have received **dedicated credentials to log into the Beacon Pal app** of the device.
	c. Finally, your headband must be connected to your Wi-Fi**.**

4.2 When Preparing for the Night Recording

	a. The headband's fitting is a crucial step. 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. Sleep hygiene and having a regular sleep schedule are crucial.
	c. 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 **allow data upload,** • how to **receive upload notification.**

4.3 After the Night Recording

	a. You must **charge** your headband at the end of the night to ensure the data is automatically sent to dedicated servers. If not, data won't be transferred during the home sleep study period, and the battery will drain.
	b. If data transfer is not notified in the night cards "Records" session of the Beacon Pal App, you should ensure the Wi-Fi is correctly configured and then contact the **support** team for assistance.

5 TROUBLESHOOTING

5.1 Headband

5.1.1 POWER

In case the headband's LED doesn't light up upon turning it on:

1. 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 a headband does not turn off after a recording, 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.

5.1.2 RECORDING

If you are unsure the recording has started, simply make a short press on the power button. The LED should briefly light up in blue, and you should hear an audio confirmation.

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.

If you need to go to the bathroom during the night, you must keep your headband on. The same applies if you cannot sleep.

5.1.3 CLEANING AND HYGIENE

You must wear your headband on clean skin, without applying any type of moisturizer on the sensors' contact points. This will ensure good signal quality.

If you are forced to apply a cream for medical reasons, you should avoid the areas of contact with the sensors as much as possible.

Caution: do not wash your headband with water.

Waveband results are intended to be used for sleep structure characterization and as an aid for diagnosis in patients with disturbed sleep.

Results are to be used by sleep study professionals.

The two key outputs of the Waveband sleep assessment are:

- a hypnogram, with associated sleep metrics, in a pdf report.
- the raw data file, that includes EEG channels, in an edf format that may be read in a commercially available edf viewer and will include all the information needed for full analysis of the raw data (i.e., to generate the hypnogram).

ADDITIONAL TECHNICAL INFORMATION

6 EMC INFORMATION

Guidance and manufacturer's declaration - electromagnetic emissions of the Waveband System

This device is intended for use in the electromagnetic environment specified below.

The customer or the user of the device should ensure that the device is used in such an environment.

EMISSIONS TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function, for Wi-Fi and Bluetooth. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 Harmonic Emissions IEC 61000-3-2 Voltage Fluctuations Flicker Emissions IEC 61000-3-3	Class B Class A Complies	The device 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.

Guidance and manufacturer's declaration – electromagnetic immunity of the Waveband System

This device is intended for use in the electromagnetic environment specified below.

The customer or the user of the device should assure that the device is used in such an environment.

IMMUNITY TEST	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for Power supply lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT 0.5 cycle, 45 deg inc 0% UT 1 cycle 70% UT 25 cycles (30 cycles if US) 0% UT 5 sec	Main power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power source.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environments.

Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz 6Vrms in ISM & amateur radio bands between 150 kHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3.5}{V1}\right]\sqrt{p}$ $d = \left[\frac{3.5}{E1}\right]\sqrt{p}$ 80MHz to 800 MHz $d = \left[\frac{7}{E1}\right]\sqrt{p}$ 800MHz to 2500 MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz Up to 28 V/m in telecommunication bands as specified in clause 8.10 of IEC 60601-1-2:2014	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, * should be less than the compliance level in each frequency range. ** Interference may occur in the vicinity of equipment marked with the following symbol:

*Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered.

If the measured field strength in the location in the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

**Over the frequency range 150kHz to 80MHz, field strengths should be less than 6 V/m.

7 FCC INFORMATION

7.1 FCC statement

1. 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.

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 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 4.2 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	3.77 mW
Antenna	Chip antenna with -3.55 dBi gain
Data Transmission Range	< 10 meters
Data Rate	1 Mbit/s
RF Physical Channels	79 channels with 1 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
Bluetooth BR/EDR Specification	
Bluetooth Standards	**Bluetooth 4.2 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	8 DPSK, PI/4 DQPSK, GFSK
Channel width	1 MHz
Output power	5.26 mW
Antenna	Chip antenna with -3.55 dBi gain
Data Transmission Range	~ 10 meters
Data Rate	3 Mbit/s
RF Physical Channels	40 channels with 2 MHz channel spacing
Data Integrity Check	Ensured by the Bluetooth protocol itself. Additional checks are performed at the mobile App level.
Main Security Algorithms	HMAC-SHA-256, AES-CCM
QoS	Best Effort

Wi-Fi Specification	
Bluetooth Standards	802.11b/g/n
Compliance	FCC Part 15 Class B (47 CFR 15.247) Directive 2014/53/EU (RED) EN 301 489-1/-17
Operation Frequency Range	2.412 GHz - 2.462 GHz
Modulation	CCK, DQPSK, DBPSK for DSSS 64QAM, 16QAM, QPSK, BPSK for OFDM

Modulation Technology	DSSS, OFDM
Channel width	22 Mhz
Output power	211.35 mW
Antenna	Chip antenna with -3.55 dBi gain
Data Transmission Range	~ 50 meters
Data Rate	802.11b: 11.0 / 5.5 / 2.0 / 1.0 Mbit/s 802.11g: 54.0 / 48.0 / 36.0 / 24.0 / 18.0 / 12.0 / 9.0 / 6.0 Mbit/s 802.11n: up to 150 Mbit/s
RF Physical Channels	11 channels with 5 MHz channel spacing
Data Integrity Check	Ensured by the 802.11 protocol itself. Additional checks are performed at the network level.
Main Security Algorithms	RC4 (for WEP, deprecated, see note below) TKIP (for WPA, also deprecated, see note below) CCMP (for WPA2, recommended)
QoS	Best Effort

The security of the Wi-Fi connection depends on the configuration of the used Access Point.

Hence, it is strongly advised to avoid:

- Open Wi-Fi network. They offer no encryption.
- Wi-Fi network using the insecure and deprecated WEP and WPA encryption methods.

Beacon Biosignals recommends using WPA2 connections. In case an unsecure Wi-Fi access point needs to be used, the headband does provide additional HTTPS encryption layers to ensure data authenticity and privacy.

9 CYBERSECURITY TRANSPARENCY

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

9.1 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.

9.2 Network ports expected to receive and/or send data from the Waveband:

- Both the Beacon Pal mobile app and headband are expected to output data on secured TCP port 443 (HTTPs) and UDP port 53 (DNS).
- The headband may also use UDP port 123 from time to time (NTP, network time protocol).

9.3 Network requirements:

- Within the Beacon Pal App, the user will be asked to set up Wi-Fi credentials to allow access to an internet connection and permit data upload at the end of the recording.
- Wi-Fi options are: open, WEP or WPA/WPA2 Personal.
    - **Beacon Biosignals recommends using WPA2.**
- A DHCP server is expected.
- Unfiltered outgoing traffic is needed for TCP 443 and UDP 53 and 123.

9.4 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 and the Wi-Fi is configured.
- When the clinician decides to update the firmware, he is expected to leave the device plugged to its charger. The update will happen while charging. The LED must show a white light.
- After the update is completed, the installed firmware version number is displayed on the mobile App.

9.5 Enforced cybersecurity controls (not exhaustive):

- Factory reset feature, triggered in case of a buggy firmware or over BLE
- Signed firmware updates
- Disabled USB port only accessible while dismantling the device

9.6 Device decommissioning:

- No patient recording data is stored on the headband after his night has been uploaded to the dedicated server.
- However, a factory reset, triggered over BLE, can be used before sending a same device to a new patient.