Bitbrain

Ikon Sleep EEG

USER GUIDE

Modelo: HKB



V-HKB-IKONSLEEP-01-040326-EN

Index

05 Safety warnings

10 Conventions and symbols

11 Disclaimer of responsibility

12 Conditions for use

13 Ikon Sleep EEG

17 Technical specifications

18 What is included?

19 Preparing to record data

21 Equipment preparation

23 Fitting the Ikon Sleep Band

29 Signal acquisition
31 Removing the device
32 Cleaning and disinfection
33 Maintenance, adjustment and repairs
34 Troubleshooting
35 Compliance
37 EU Declaration of conformity
39 Note on product disposal
40 Warranty conditions

This is the user guide for the Ikon Sleep EEG device from Bitbrain.

This document will provide information for the proper setup and usage of the system.

The information and warnings provided must be strictly followed to ensure the safe operation of the product.

Safety warnings

To ensure the correct and safe operation of the product as well as to prevent serious personal injuries or property damage, please read the entire user guide carefully. Pay special attention to this section before using the product.

Follow these safety warnings while using the product to avoid potential hazards.

Careful usage and handling of the equipment

- Do not use the device on damaged, irritated, or injured skin. If this cannot be avoided, the band should NOT be used.
- To prepare the skin for equipment installation, it is recommended to use micellar water makeup remover wipes as suggested by the manufacturer. Using any other product may impair the performance of the device and affect the quality of the signal obtained.
- DO NOT use this device with other medical equipment such as pacemakers or electrical stimulators.
- Do not fold the band(s). This may damage the equipment.
- Keep the band(s) in the original packaging together with the equipment. Make sure you follow the storage temperatures indicated in these instructions.
- Do not use the device for any purpose other than that for which it was designed.
- This equipment is not intended for life support. Do not use it at any time for monitoring vital signs in operating rooms or intensive care units.
- Only use peripherals and accessories provided by the manufacturer. If you fail to comply with this requirement, it may reduce or affect negatively the performance of the product as well as impair its electromagnetic compatibility.
- Do not hit, throw, bite, open or burn the device.
- Avoid falls and knocks against other objects.
- Do not tamper with the battery under any circumstances. The battery shall only be replaced by the manufacturer or personnel authorised by the manufacturer. At the end of its expected lifetime, the equipment and its internal battery must be recycled or disposed of in accordance with local, state and European regulations. The product must not be disposed of together

Safety warnings

with other household waste.

- Do not tamper with the inside of the equipment.
- Do not expose the product to moisture or liquids.
- Do not use the product with wet or damp hands.
- Do not expose the product to direct sunlight for prolonged periods of time.
- Do not expose the product to extreme dust or external electrical loads.
- Keep the product away from any kind of heat sources at all times.
- Keep the product away from electrical sources and electromagnetic fields at all times.
- This equipment is not suitable for use in environments where children may be present and could potentially misuse or operate the device incorrectly.
- The equipment must be operated under the supervision of an adult/ by an adult when it is used to measure biometric data in children.

WARNING:

- If the equipment is going to be used by more than one user, disinfect the device according to the instructions given in this manual.
- Only use the disinfectants or washing soaps indicated in this user guide. Failure to do so may result in damage to the device.

Temperatures

- Do not expose the product to extreme temperatures.
- Optimal range of use 0ºC~+25ºC.

Storage Temperature:

- Less than 1 month: -20ºC~60ºC.
- Less than 6 months: -20ºC~30ºC.

Warnings on the Equipment to Prevent Misuse

- To charge the device, ONLY use the cable originally provided to you (1A limit). Using anything other than the provided cable may cause damage to the device.
- Do not use the device while charging.
- Do not open the device. If your

Safety warnings

device is not working properly, please contact support@bitbrain.com.

- Do not bring the electrodes or any metal part of the device or Band close to other conductive parts including earth.
- The device is not to be used in the presence of explosive gases as well as in the presence of flammable anaesthetic mixtures. Not following the warnings might result in burns and damage to the product.
- Do not bring this device near electronic devices or life-supporting electrical equipment.
- This equipment is not designed to withstand defibrillator discharge. Ignoring this warning may cause irreversible damage to the equipment.
- The device is not intended for direct contact with heart. Failure to comply may lead to permanent damage to the equipment.
- **WARNING**: this device does NOT incorporate means to protect the user from burns when used with surgical HF equipment.
- If you notice that the device emits strange smells, noises or is excessively hot, leave it out of the way and contact support@bitbrain.com.
- DO NOT shine any light emitted by the amplifier or point it directly into your eyes.
- DO NOT bring your eyes close to the PPG sensor if there is one on the equipment.
- **WARNING**: before each use, a visual inspection of the equipment shall be made to prevent wear and tear of materials or possible damage caused by unexpected use from endangering the user. In case of finding any, please contact support@bitbrain.com.
- Please read carefully the 'General Terms and Conditions of Sale and Use of Bitbrain Products'. You can find the document at https://downloads.bitbrain.com/documents/terms-and-conditions-eu

Safety warnings

Warnings on assembly, installation and maintenance

- Disconnect the charging cable when the battery of the device is fully charged, otherwise the life cycle of the battery may be reduced.
- If you are going to store the device for long periods (more than a week), it is recommended not to have the battery charged 100%. This may degrade the battery, leading to a decrease in device's autonomy.
- Store the device in a dry environment between 5ºC and 40ºC: prolonged exposure to high temperatures may affect the stability of the battery.
- We highly recommend using only the pre-impregnated wipes for surface cleaning and disinfection as advised by the manufacturer. Using any other product could deteriorate the functioning of the equipment and affect the signal obtained.
- DO NOT USE UNDER ANY CIRCUMSTANCES! Only approved cleaning products or disinfectants with the specified composition shall be used. The use of any non-validated cleaning product can potentially damage the equipment and compromise the accuracy of the signal. Modification is strictly prohibited.

No modification warning

- Any unauthorised modification of the product may invalidate its conformity and warranty. The manufacturer is not responsible for any hazardous or incompatible situation that may cause damage or malfunction to the product or other equipment if the product has been modified without the authorisation.
- ATTENTION: Do not modify this unit! Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- Note: under no circumstances may the end-user modify aspects of the product that may change the specifications declared in the conformity assessment, as this could invalidate the conformity of the product. Example: Radiated power, frequency bands, channel hopping.

Safety warnings

Important

- Ikon is a system designed by Bitbrain to measure biometric data for research purposes.

Conventions and symbols

The Following Conventions and Symbols are Used in this Manual:

Conventions:

- **Note:** used to highlight relevant information.
- **Caution:** used to point out aspects that if not observed, may cause damage to the equipment, injury to persons or deviations in the operation of the equipment with respect to its specifications.
- **Warning:** used to inform of a specific action which, if not observed, may cause damage to the equipment, injury to persons or deviations in the operation of the equipment from its specifications

Symbols:

The following symbols are to be found both in this manual and on the labelling of the equipment or its packaging:



This product contains electrical and electronic components and must not be disposed of using the standard waste collection system. Please refer to your local regulations for the disposal of electrical and electronic equipment.



This product contains batteries that must not be disposed of with household waste. At the end of its useful life, it must be taken to an appropriate collection point for the proper recycling of the batteries it contains.



Caution.



Product complies with CE Marking regulations. See instructions for use.



Check the instructions for use.



Manufacturer.



Date and country of manufacture.



Serial number.



Reference number.



Model number.

Direct current.



Power button.



Product complies with FCC Marking regulations.

Disclaimer of responsibility

Hardware equipment included in the Products (EEG, biosensors, indoor localisation, eye tracking) are not medical devices. They are not designed or manufactured to provide healthcare services, nor are they intended to be marketed for the purpose of diagnosis, cure, palliation, medical advice, or prevention of a disease, but are marketed for research purposes.

Please read the 'General Terms and Conditions of Sale and Use of Bitbrain Products' before purchasing the equipment for full understanding. You can find the document at https://downloads.bitbrain.com/documents/terms-and-conditions-eu

Bitbrain reserves the right to review this user guide and make changes to its content as it deems appropriate at any time without obligation to notify any person or entity of such changes made. Despite every effort to ensure the accuracy of the information contained herein, it should not be construed as a commitment on the part of Bitbrain. To ensure that you have the latest version, please visit the download section of the product page at www.bitbrain.com.

Conditions of use

- Carefully read the safety information on the device and keep the manual for future reference.
- Carefully read the ‘General Terms and Conditions of Sale and Use of Bitbrain Products’, you can find the document at https://downloads.bitbrain.com/documents/terms-and-conditions-eu

Ikon Sleep EEG

Ikon Sleep is an electroencephalography (EEG) recording system with up to 2 channels. It is designed for applications requiring fast and easy set-up and signal quality equivalent to systems used in the clinical environment.

Indications for Use:

- The devices that make up the system are meant both for use by professionals as well as independent users or those assisting them.
- For individuals with special needs, disabilities, the elderly, or others requiring assistance, it is recommended to use the device with the support of family members or caregivers.
- The device can be used anywhere if suitable including user's own home. There are no known contraindications.

Sensor band associated with the uses of the device:

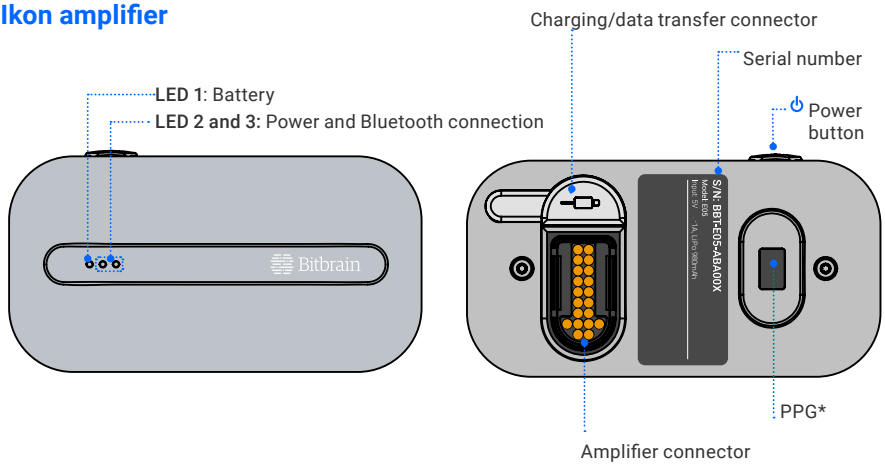
- Ikon Sleep Band with clip-on interface connectors for the use of gel-type sensors (Ikon Sleep Band, model SB2).

Manufacturer's Information

BIT&BRAIN TECHNOLOGIES, S.L.

C/Sta Teresa de Jesús 32, 50006 Zaragoza, España.

Ikon amplifier



*Deactivation for the Ikon Band model with a neck-mounted amplifier.

Integrated Sensors:

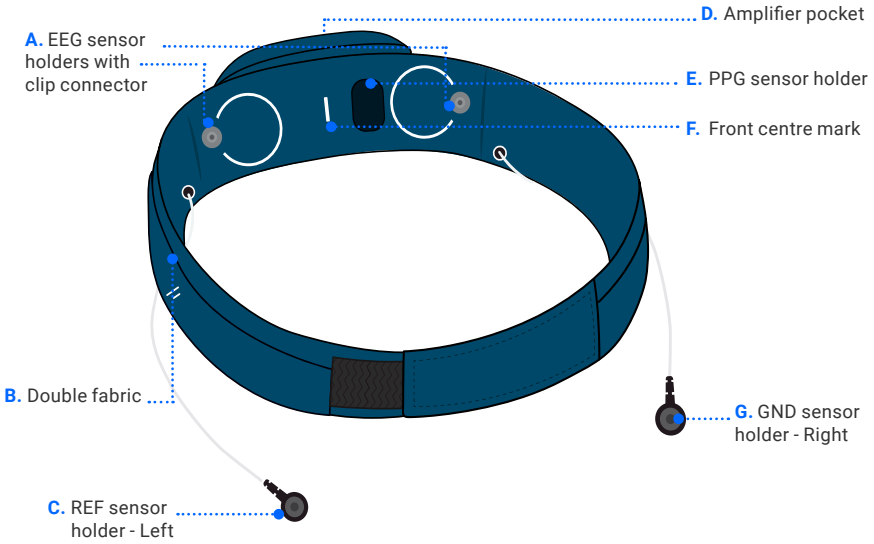
- **Accelerometer, gyroscope and magnetometer:** allows measurement of head movement and positioning.
- **PPG* sensor:** allows measurement of pulse-related metrics.

Interface LEDs:

Status LED 1	Status LED 2
Low battery	Bluetooth connected
Charging the battery	Connecting the Bluetooth
Battery charged	

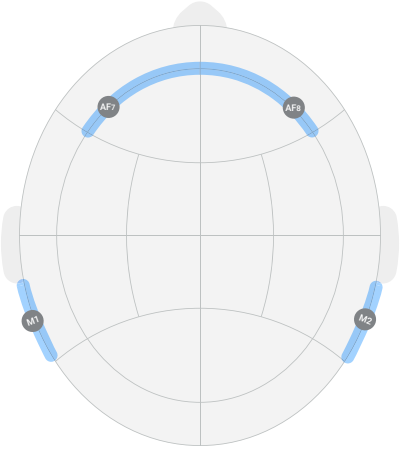
Ikon Sleep Band

The gel-type sensor headband covers head circumferences from 52cm to 60cm. With the size extender piece, it covers up to 70cm.



Sensor Layout

The Ikon Sleep Band with 2 EEG sensors, ground (GND) and reference (REF), arranged according to the international EEG 10/10 standard.



Electrode Positions:

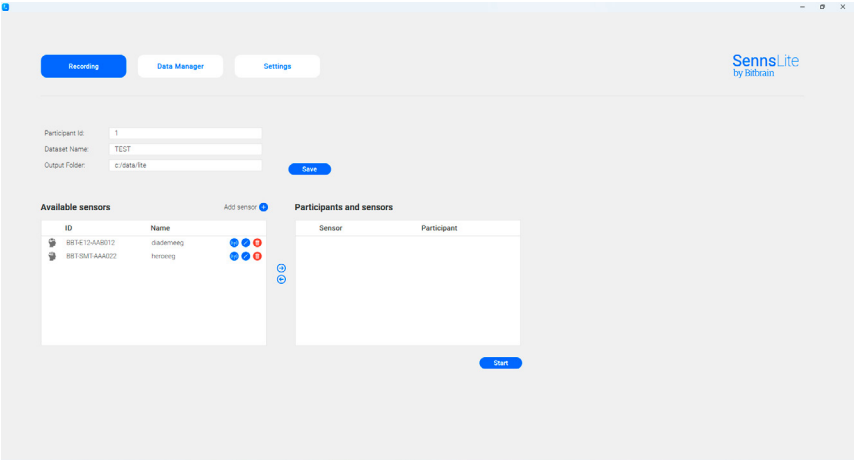
- Sensors: AF7 - AF8
- Ground (GND): cable for placement
- at M2
- Reference (REF): cable to be placed
- on M1

Acquisition software

All subsystems are delivered with the SennsLite software that allows to display and record EEG signals and the signals of the integrated sensors. The amplifier is connected to the software via Low Energy (BLE) and the data can be displayed in real time and filtered.

Minimum Hardware Requirements:

- Operating system: Windows 10 or higher
- Processor: i5
- RAM: 8GB
- Other: Bluetooth v5 or higher. USB port
- Resolution: not applicable



Technical specifications

HW version of the V12 amplifier	V13
Firmware	Upgradeable via web
Rated voltage	3.7V
Rated power	360mW
Battery	Battery type: Li-Po 980mAh Battery life: >9h. 500 cycles ≥ 80%. Charging time: ≤3h
Working temperature	0°C~+25°C
Sampling frequency	256Hz
Wireless technology	BLE 5.0 2,4GHz + EDR
Maximum radiated power per band	4dbm
Dimensions and weight	Amplifier: 79x42x35mm, 65g
Head circumference	520 - 700mm
Charging/data transfer connection	USB type C
Other connections	EEG connector between amplifier and band
Data backup	Internal 16Gb
Conformity	CE (Directive 2014/53), FCC

What is included?

Object	Name/description	Quantity
	**Amplifier** • Powered by internal battery • Made of ABS	1
	**Ikon Sleep Band** • 2 sensors + GND + REF. • Housing for connection of gel sensors with clip-on interface	1
	**Gel Sensors** • Enables to acquire EEG signal with Ikon Sleep	Samples of one sensor type.
	**Extension Strap** • Extends the initial size of the band by 10cm.	1
	**USB Type A - USB C Cable** • Allows the device to be connected to the charger for charging.	1

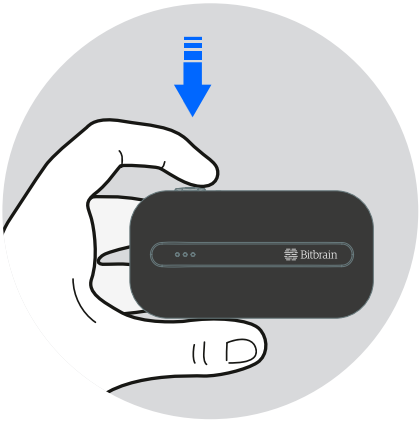
Preparing to record data

1

Turn on the amplifier by pressing the **power button** (⏻). The white LED for wireless connection will blink until a connection with the software is established, after which it will remain steady.

When the device has low battery, the amber battery LED will turn on.

ATTENTION: It is not recommended to start a recording with low battery, as this may affect the quality of the recorded signal. Do not use the equipment while it is charging



Preparing to record data

2

The amplifier wirelessly transmits data using BLE technology.

The data can be stored in:

- **The connected computer.** If the equipment loses Bluetooth connectivity with the computer, these disconnections will result in data loss.
- **Internal MicroSD card.** In this mode, the signal will continue to be transmitted wirelessly, allowing real-time visualization and recording on the computer while the data is simultaneously saved on the internal memory card

Connection

Ensure that the computer has a Bluetooth adapter of version 5 or higher.
The device's name corresponds to its serial number (S/N), indicated on the device label

Data Backup with MicroSD

1. Activate the "SD card" data backup option in SennsLite
2. To access the internal storage data, it can be downloaded by connecting the amplifier to a computer using the USB cable provided with the equipment
3. The saved files are recorded in .sdf format. To convert the files to .csv format, use the "Import record" function in the software.

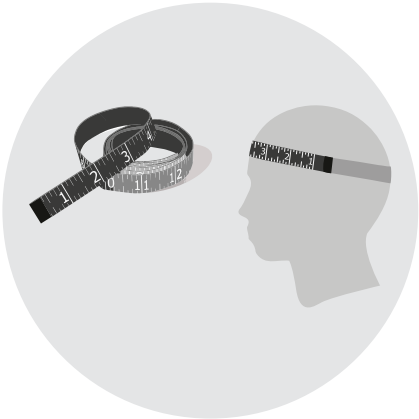
Equipment preparation

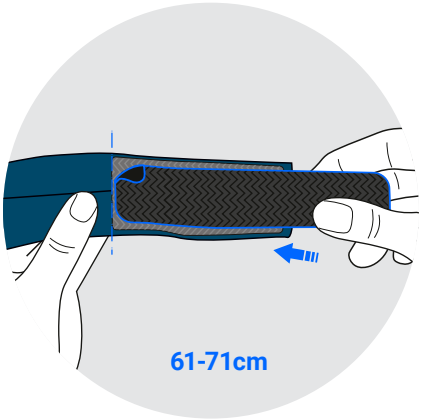
1

Measure the circumference of the user's head. The band's usage range is **52 - 60cm. If it falls between 60 and 70cm, the size extension tape should be applied.**

To attach the size extension tape, affix the rough side of the tape to the soft side of the band's Velcro. They should overlap by about 3cm, providing an additional 10cm of band size.

Note: It is recommended to use the device in environments with temperatures between 21-25 ºC and a 40-60% relative humidity to ensure participant comfort.





Fitting the Ikon Sleep Band

Follow the steps described below for placing Ikon Sleep.

1

If your **hair is long**, put it up in a ponytail.
It is important to remove any hair that may be on your forehead and behind your ears.



2

Use the recommended make-up **wipes** to clean your forehead and the area **behind your ears between head and ear** as shown in the picture following the manufacturer's instructions

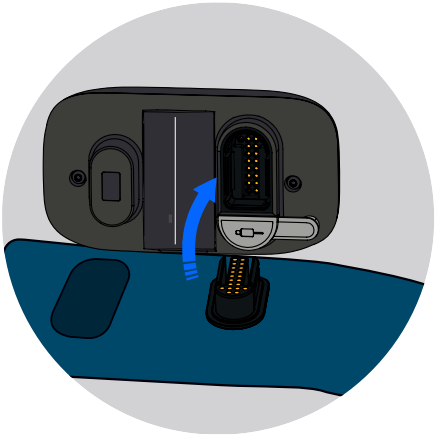
CAUTION:
The use of micellar water make-up wipes recommended by the manufacturer is advised. Using any other product could deteriorate the performance of the equipment and affect the signal obtained.



Placing the equipment

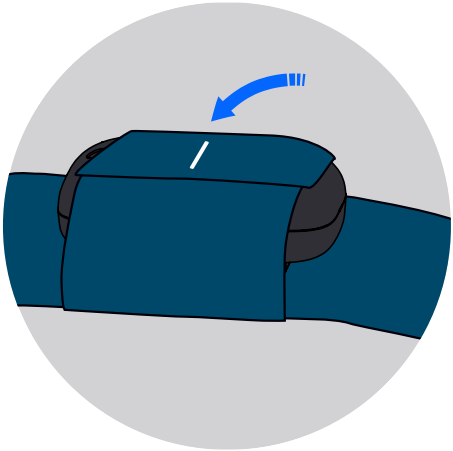
3

Take the strap and carefully **connect** the **amplifier to the EEG connector**. The PPG sensor should fit into the hole designed for it and you should hear a '**click**'.



4

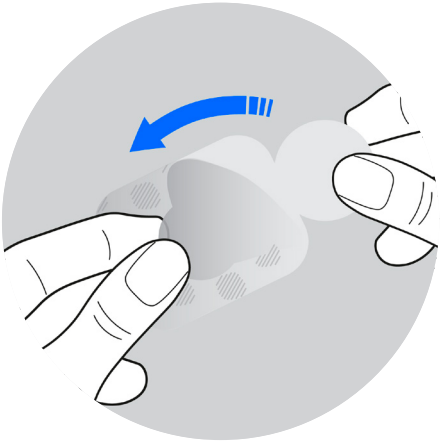
Close the pocket around the amplifier. Remember that the amplifier must already be turned on and paired with the computer using the serial number located on the amplifier label.



Placing the equipment

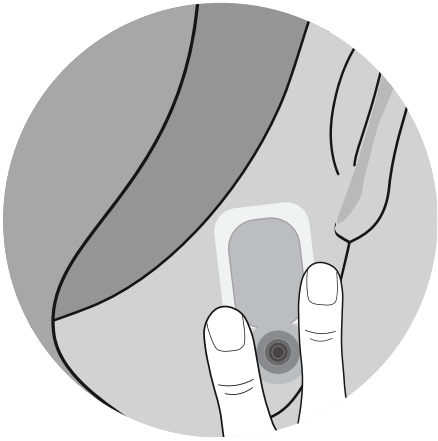
5

Take a sensor and, without pressing the centre, use the tab to remove the clear plastic.



6

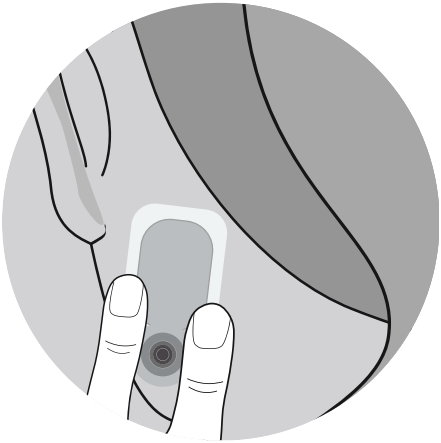
With the skin clear of hair and without pressing the centre of the sensor, carefully stick it behind the earlobe.



Placing the equipment

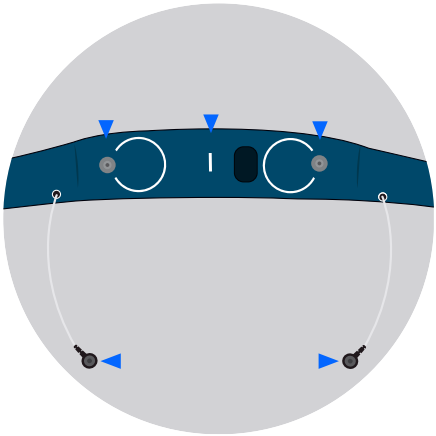
7

Repeat the same steps on the other ear. Remember to stick the sensor with the skin clear of hair and without pressing the centre.



8

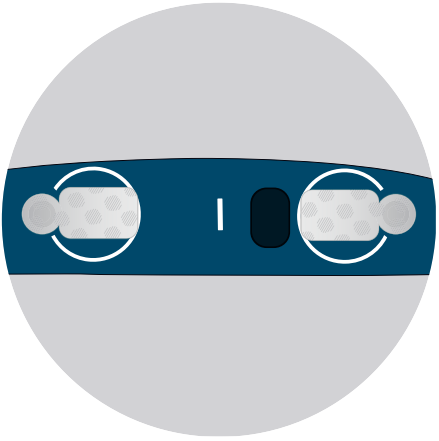
Identify the centre mark on the band, the two clips on the fabric and the two clips on the wires.



Placing the equipment

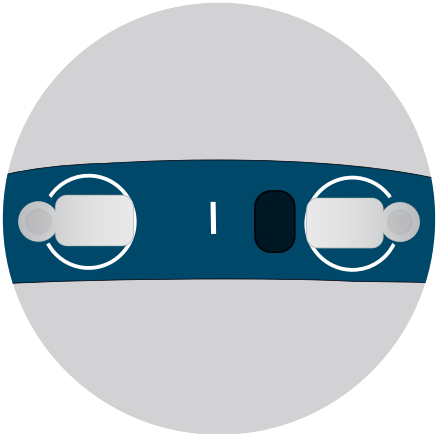
9

Attach two sensors to the fabric clips. You should hear a ‘click’. The sensors must be inside the circles marked on the strap.



10

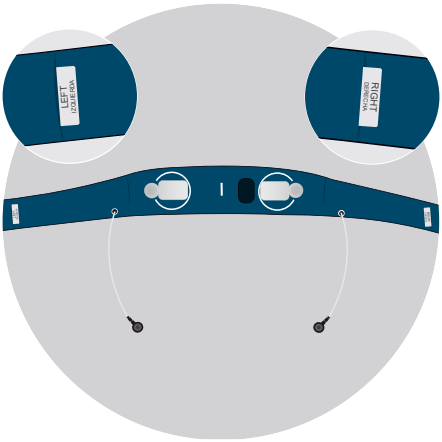
Remove the plastic covering the two sensors in the same way as previously for the ear sensors, without pressing the centre.



Placing the equipment

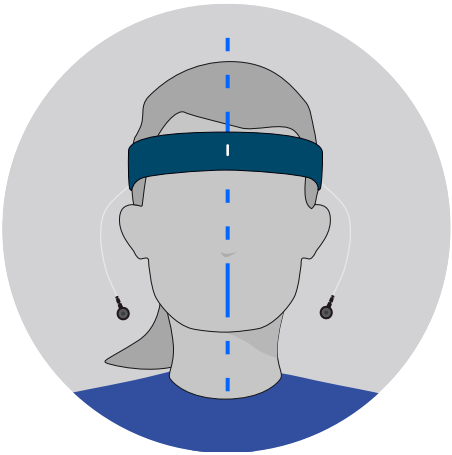
11

The wires must be pointing downwards and the ‘left’ and ‘right’ texts must be positioned correctly.



12

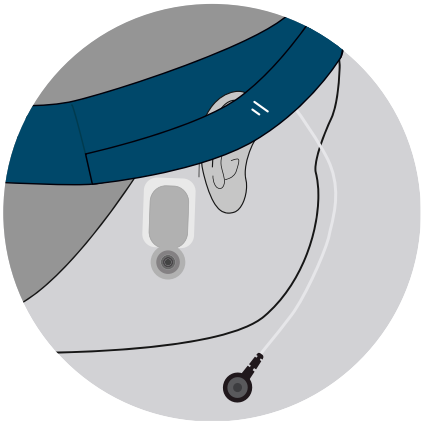
Look in the mirror and **place the band around your head with the front mark centred on your forehead.** Be careful not to cover the eyebrows.



Placing the equipment

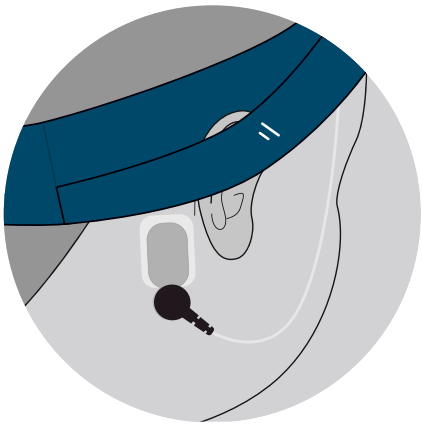
13

Place the **outer layer of fabric** covering the ears.



14

Finally, **attach the cable clips to each ear sensor.** You should hear a ‘click’.

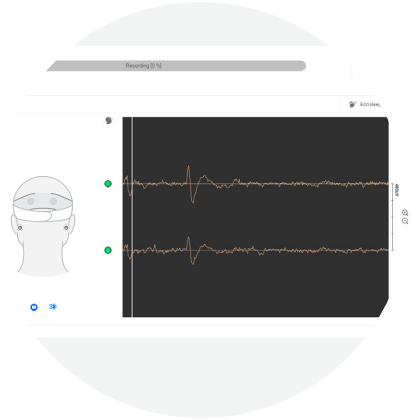


Signal acquisition

1

On the software screen you can view the EEG signal collected by the device in real time.

The colour of the impedances will indicate the quality each contact. The quality will depend on the placement.



Signal acquisition

2

In case any of the sensors indicate low impedance quality.

Make sure that the strap is centred on the forehead and aligned with the nose.

The sensors should be in contact with the skin on the inside.

3

If you wear glasses, the temples should always be outside the fabric.

4

The front sensors should not be placed over the eyebrows and you should make sure that all sensors are in contact with the skin and in a clear area.

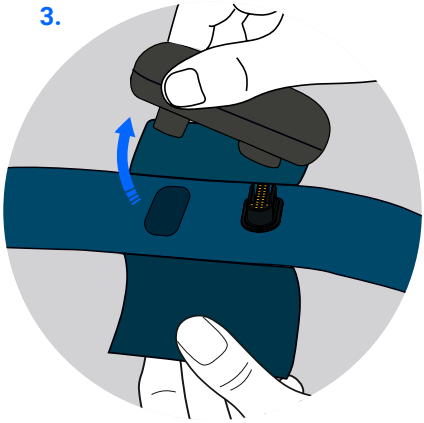
5

Ears should be covered by double fabric to ensure that the band does not move during use.

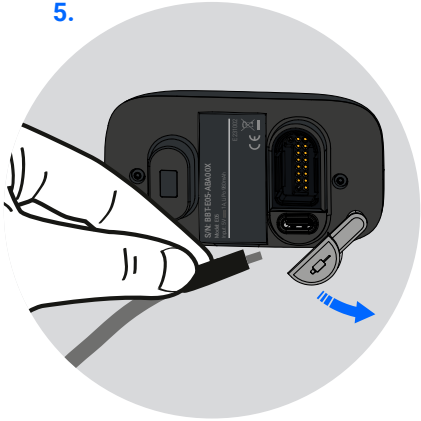
Removing the device

1. Remove the band by opening the Velcro.
2. Open the band pocket and turn off the amplifier.
3. Detach the amplifier from the band stretching from the tip of the velcro and the amplifier to the same time for the band don't get damaged.
4. Connect the charging cable to the head and plug it into the power source.
5. Now, take the amplifier and connect it to the cable by opening the plastic tab.
6. Once the amplifier is fully charged, store all the materials inside the equipment case.
7. The gel sensors are for single use only. After use, they must be disposed of according to the manufacturer's instructions.

3.



5.



Cleaning and disinfection

Disinfecting the amplifier

- To disinfect the device please use surface disinfectant wipes which are optionally available from Bitbrain.

  1.Put on protective gloves and remove a wipe from its container.

  2. Wipe the surface in an 'S' pattern, moving from clean to dirty areas, ensuring each section is only wiped once.

  3.Replace the wipe when dry or soiled and discard it. Wipe gently without applying excessive pressure, as this could damage the sensors or cause liquid to seep into the amplifier, potentially harming the device internally. Allow the surface to air dry.

Clening the textile band

• To clean the textile band, please see the Handwashing Protocol Annex for further instructions.

• DO NOT UNDER ANY CIRCUMSTANCES USE ANY OTHER CLEANING PRODUCTS! No other cleaning or disinfecting products or disinfectants with any other composition shall be used. Using any other non-validated cleaning product could deteriorate the equipment and affect the signal obtained.

Storage

- Store the product in its original packaging when not in use.
- If the device is to be stored for long periods (more than a week), it is recommended not to have the battery charged 100% as this may degrade it, leading to a decrease in the device's autonomy.

Maintenance, adjustment and repairs

No technical adjustments are required for the product to operate correctly. Repairs should only be performed by the manufacturer's personnel or authorized representatives. The maintenance tasks outlined in this document for the user do not involve accessing the internal components of the product. Only the instructions provided in the **Cleaning and Disinfection** section as well as the **Handwashing Protocol Annex** should be followed.

Do not attempt any action that requires removal of the product covers. Any damage resulting from improper maintenance or repairs carried out by anyone other than the manufacturer or authorized personnel will be the sole responsibility of the user.

If you experience any issues during normal use, refer to the Troubleshooting section of this manual before contacting technical support.

CAUTION: This product contains no user adjustable or serviceable parts. Opening, repairing, or modifying the product by unauthorised personnel may cause severe damage to the product and will void the warranty.

Troubleshooting

This section offers recommendations for solving common issues that may occur during the operation of the product (excluding computer-related problems, which should be addressed in your manufacturer's documentation).

The following suggestions focus on potential hardware-related issues that may come up during registration. If you encounter such problems, try these steps before contacting technical support.

Note: If the issue is not covered here or the suggested solution doesn't resolve the problem, contact your supplier for technical assistance without hesitation.

Issue	Possible cause	Recommended solution
LED lights on the amplifier are not turning on.	The amplifier is out of battery.	Charge the amplifier with the charging cable supplied for this purpose.
Software does not identify the band in use.	The amplifier is not connected correctly.	Remove the amplifier from the band and replace it. You should hear a 'click'.
Signal quality check is not satisfactory.	The equipment is placed incorrectly.	See page 36.

Compliance

This device is classified as both radio equipment and information technology equipment.

The CE marking indicates compliance with the essential requirements of the RED Directive (2014/53/EU).

The Bluetooth module it incorporates is pre-compliant with that Directive, and is used in accordance with the manufacturer's instructions taking into account the requirements specified by the manufacturer.

CE

This product contains an FCC certified module with FCC ID SQGBL653

- MANUFACTURER: Laird Conectivity (Now Ezurio)
- MODEL REFERENCE: BL653
- Radio Module Hardware & Software version 453-00039R

Note: 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.”

ATTENTION: Do not modify this unit! Changes or modifications not expressly approved by the party responsible

for compliance could void the user’s authority to operate the equipment.

Made in Spain.

EU Declaration of conformity

BIT & BRAIN TECHNOLOGIES, S.L.
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As a manufacturer of:

- Brand: BITBRAIN
- Product: IKON
- Model: HKB

Product composition		
Ikon Amplifier, model BBT-E05	Ikon Band, model BB5	Ikon Sleep Band, model SB2

DECLARES under its sole responsibility that the mentioned equipment complies with the essential requirements and other relevant requirements of:

- Radio Equipment Directive 2014/53/EU (RED).
- Directive 2011/65/EU and its amendment, Directive (EU) 2015/863 on the restriction of certain Hazardous Substances in electrical and electronic equipment (RoHS).

And that the following standards and regulations have been applied in full in accordance with both directives:

Article 3.1 (a) Health and safety of the user (RED):

- UNE EN IEC 62368-1:2020 + /AC:2020 + A11:2020
- EN 62479:2010

Article 3.1 (b) Electromagnetic Compatibility (EMC-RED):

- ETSI EN 301 489-1 V2.2.3 (2019-11)
- ETSI EN 301 489-17 V3.2.4 (2020-09)
- EN 55032:2015 + /A1:2020 + A11:2020
- EN 61000-4-2:2009
- EN 61000-4-3:2020

Article 3.2 Effective use of the allocated spectrum (RED):

- EN 300 328 V2.2.2

Article 4: Restriction of Hazardous Substances (RoHS)

- EN IEC 63000:2018

In Saragossa on 02/08/2024



Signed María López Valdés, CEO Bitbrain

Note on product disposal

If this product is irreparably damaged or its useful life has ended, please follow local, state, and European regulations for the proper disposal and recycling of lead-containing components, batteries, plastics, and other materials. Check for designated collection and disposal points for these items.

Do not discard electrical and electronic devices in the trash! In accordance with European Directive 2012/19/EU on waste electrical and electronic equipment, these items must be disposed of at appropriate collection facilities for environmentally friendly recycling.



This symbol indicates that this product be disposed of with household waste and should be taken to an appropriate collection point for the recycling of electrical equipment. Proper recycling helps prevent environmental and health risks.



This symbol indicates that the product contains batteries which must not be disposed of with household waste. This product, at the end of its useful life, should be taken to a designated collection point for proper battery recycling.



This product is recyclable and should be recycled accordingly.

Warranty conditions

The warranty conditions of the product, the time limits, the warranty claim procedure, as well as possible exclusions and limits are set out in the ‘General Terms and Conditions of Sale and Use of Bitbrain Products’ accessible from https://downloads.bitbrain.com/documents/terms-and-conditions-eu

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