Site Instruction Manual for Dreem

Without Wi-Fi, the night's raw data will remain saved in the Dreem headband. Metrics will not be accessible to the researcher through the Dreem Viewer until the headband is connected to a Wi-Fi network then plugged in for charging. The headband can store up to 100 hours of sleep data in case Wi-Fi is unavailable.

Introduction

The purpose of this document is to provide appropriate and detailed instructions to researchers on how to use the Dreem headband during your trial.

The first section gives a general overview of the Dreem headband.

The following sections detail every action that needs to be performed during the study:

1. Before giving the headband to the participant for the first time.
2. When giving the headband to the participant.
3. During the participant home-period.

Your role in preparing the headband and showing the participant and how to use it is critical to ensure good data collection.

Along with this document, a training session by video will be proposed to you, including courses and modules to help you understand both the device, the application, and the 'Dreem Portal' web-platform.

Along with the training, the Dreem support team and Project Manager for Research will also be available during the entire study to answer all of your questions or issues.

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General Presentation

1. The Dreem Headband

1.1. General Information

The Dreem headband is a **dry-EEG system** that acquires brain, breathing, movements, and heart rate activities during sleep with a convenient set-up and a **25h battery life**.

The sleep data is directly transferred from the headband to the Dreem server through a Wi-Fi connection. This happens after the recording has been stopped and the headband is charging. The headband has **~100 hours of data storage** in case Wi-Fi is unavailable. Data is automatically processed when successfully uploaded to the server.

NOTE: DREEM HEADBANDS ARE FRAGILE AND SHOULD BE HANDLED WITH CARE

1.2. Box Content

1. Dreem band with the small adjuster set
2. Magnet charging cable (cable configuration may differ between regions; the use of an adaptor may be needed)
3. Adjustment strips in medium and large sizes

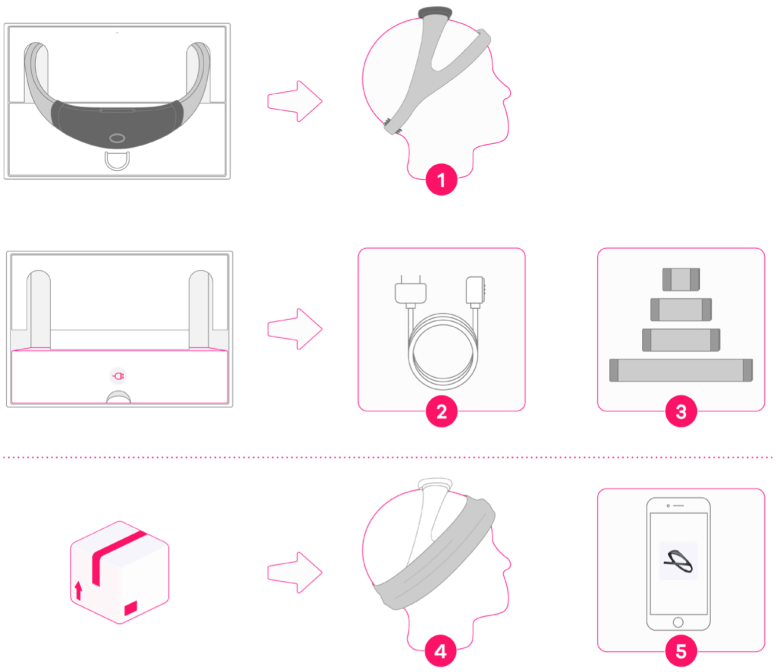

Fig.1: Content of the Dreem box

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1.3. Sensors Available

EEG sensors

5 EEG sensors to measure EEG:

A. 2 frontal sensors in F7 and F8 locations to measure frontal brain activity

B. 1 ground sensor on the frontal band (Fp2 location)

C. 2 occipital sensors in O1 and O2 locations to monitor occipital brain activity

D. R&D sensor

Audio

E. Bone conduction speaker for audio output.

Accelerometer

F. 3D accelerometer to measure movements, head position, and respiratory rate/trace during sleep.

Miscellaneous

G. Power button (Press 1 time to turn the headband on, press 3 times to start record when the headband is turned on, press for 3 seconds to turn the headband off)

H. Magnet port for charging.

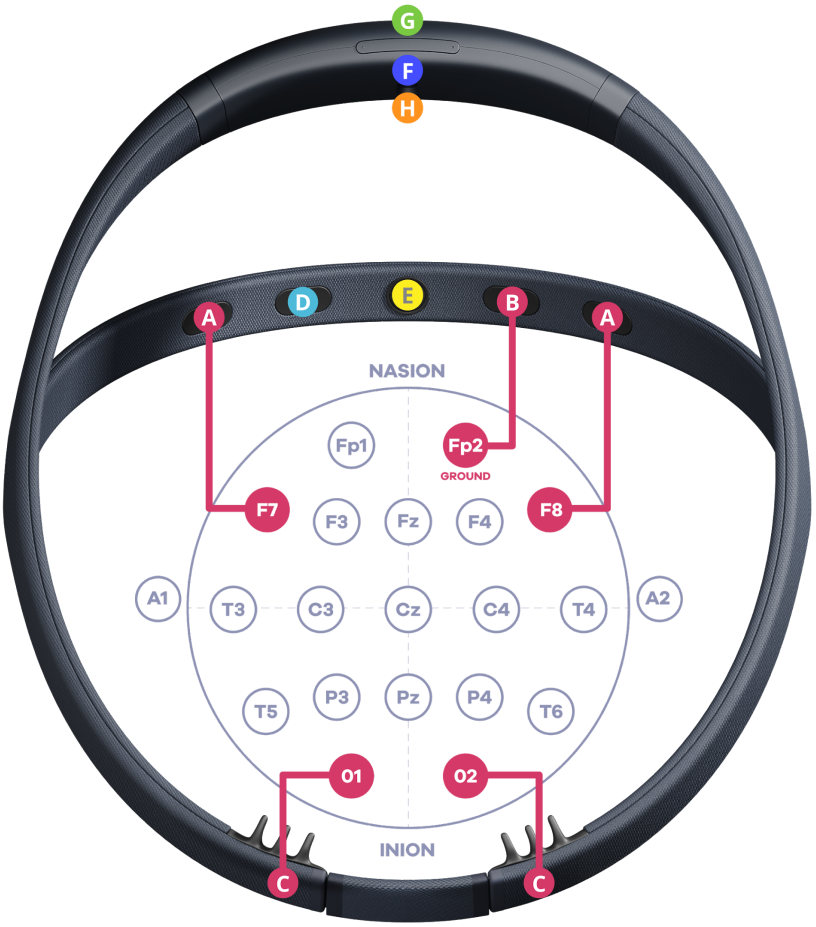

Fig.2: Dreem headband

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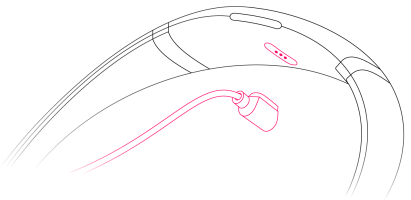
1.4. Charging

The headband can be charged using the charging cable and adaptors 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 in.**

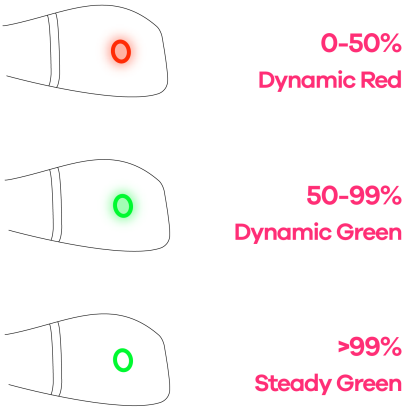


Make sure to follow this process:
1. The wall adaptor can remain plugged into the wall socket during the whole study.
2. **First, plug the magnetic cable into the headband**
3. **Then plug the cable attached to the headband on the USB output of the power supply unit**.

Fig.3: Cable plug

The LED located on the top arch indicates battery level through color variations (Fig.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 record.

Because the headband's battery life is 25 hours, it is important to remind participants to charge the headband after every use to ensure the device does not stop working during the night.

Fig.4: LED Charging stages

1.5. Care and Cleaning

The inside of the headband is lined with a soft fabric and the plastic parts are made of hypoallergenic 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 water , 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.

In between participants, you may clean the headband with a piece of cloth or a cotton swab dampened with isopropyl alcohol (IPA)

CAUTION: THE DREEM BAND ISN'T 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.

Make sure to clean the headband's sensors with a disinfectant wipe (e.g. IPA wipes), **between each patient**. This will ensure optimal signal quality.

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CAUTION: PLEASE REMEMBER THAT THE HEADBAND, IT'S FRONT BAND IN PARTICULAR, CONTAINS SENSORS AND NEEDS TO BE HANDLED WITH CARE.

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2. The Alfin App

2.1. What Is the App's Purpose?

The Dreem mobile app companion, Alfin, is the remote control to the Dreem headband. With this app, you will be able to:

- Configure a headband so it is linked with a participant using their designated Dreem credentials (Dreem User ID and password).
- Set-up the Wi-Fi network so the headband can upload sleep data directly to the server when charging.[1]

The Alfin app can be downloaded from either Apple's App Store, or Android's Play Store. Participants can also use it to configure their home Wi-Fi and review positioning instructions.

2.2. Main Screens

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

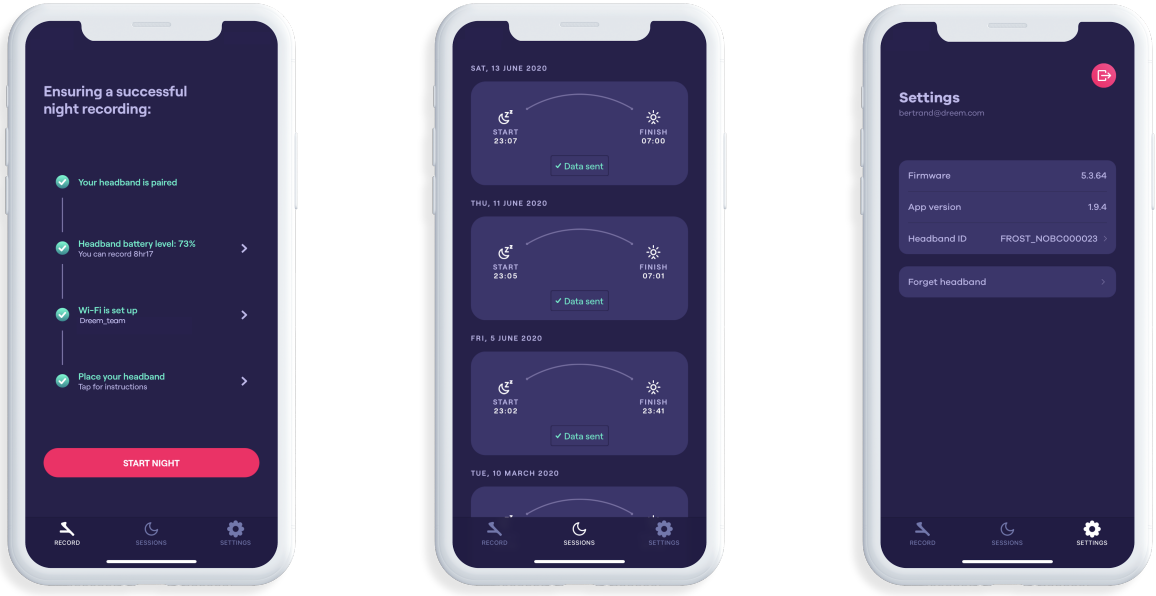

Fig. 5: Alfin app structure

1. **The Record section** acts as the headband's remote control for:
   - Pairing the headband
   - Checking battery life
   - Setting up Wi-Fi
   - Assessing signal quality
   - Launching recordings
2. **The Sessions section** where night recordings will be uploaded from the headband via Bluetooth and made available to the participant.
3. **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

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3. Dreem Portal

During the protocol, a short data quality verification should be performed daily for each uploaded recording. This quality check confirms that the raw data and notable metrics have successfully been uploaded, and will also allow you to assess the signal quality.

Using a Chrome browser, log in to DREEM's dedicated data quality check portal.

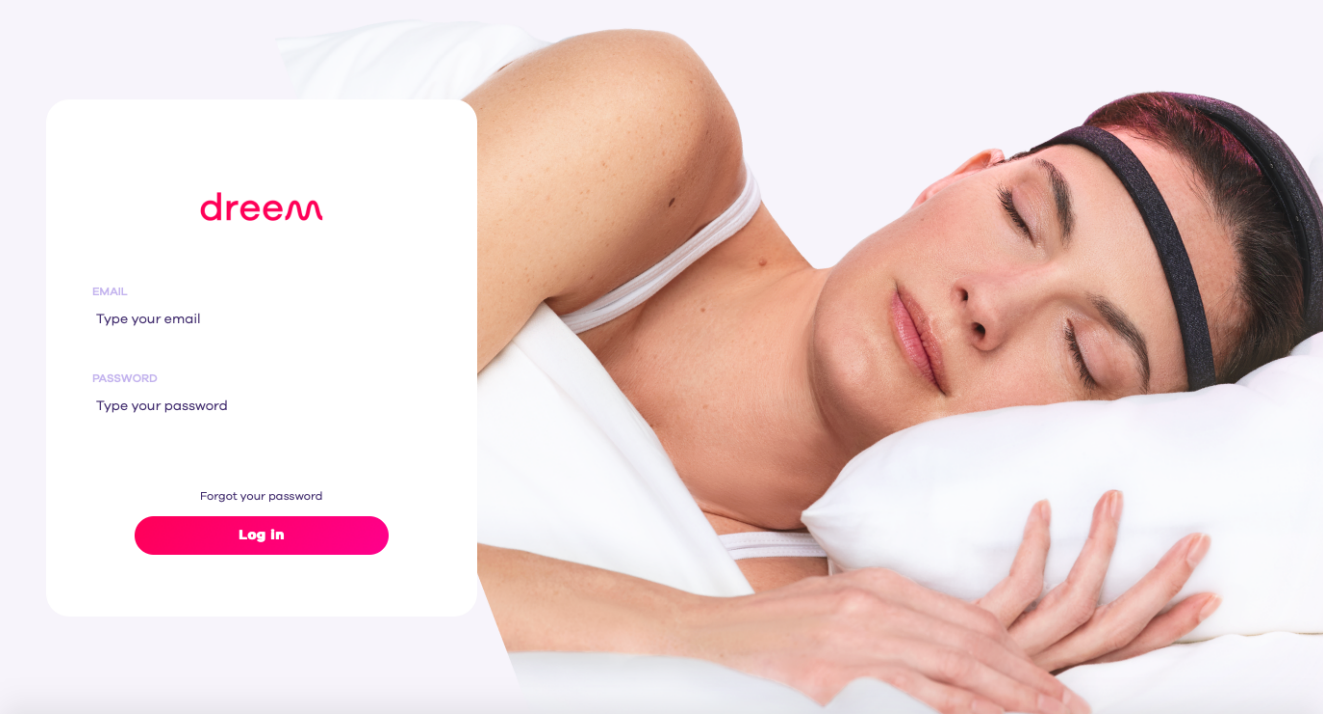

Fig.6: Dreem Portal login screen

You will have to create an administrator account to login to the Dreem Portal and access the data of your participants. Each of your participants will have a dedicated user account linked to your administrator account.

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3.1 Data Formats

From each recording, the three key outputs of the Dreem solution sleep assessment are:

Raw files	Raw data encoded in binary blobs (unfiltered)
.h5	Raw data in .h5 format (unfiltered
.EDF	EEG and 3D accelerometer data in the European Data Format. This is usually the preferred format for researchers wanting to import the file in their scoring software or for researchers using EEGlab on Matlab or a specific EEG toolbox on Python *Please note if you are aiming at benchmarking Dreem, we may have to reprocess our algorithm so that the scoring epochs are aligned with the reference PSG device.
JPG (hypnogram)	hypnogram image
.txt (hypnogram)	hypnogram in a time-series format. Sleep stages, which are determined by the sleep staging algorithm every 30 second epochs are listed chronologically in this file
.csv	General information about the record (record number, start time, duration, channel quality) and sleep metrics (WASO, TST, sleep stage duration, etc.). Time is expressed in epoch unix and can be retrieved using the ISO 8601 standard. Duration is expressed in seconds.

This is the exhaustive list of key physiological output derived from the Dreem headband sensors. Note that for each recording, the confidence level of each metric is calculated. It gives you an indication of the reliability of the output (the sleep metric) delivered by the algorithm. The reliability depends on three main factors: the quality of the recording, the distribution of sleep stages across the recording, and the ability of the algorithm to accurately score the reading.

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During the Participant Home Stay

1. Before the Participant Visit

Before the participant visits you, your task will be to prepare their headband for home-usage. **Before starting this process:**

- Make sure the headband is **fully charged** or has enough charge for a recording.
- Before starting the headband set-up, **make sure that the time of the phone/tablet is correct**.
- Make sure that the **Bluetooth** and **GPS location** of the smartphone/tablet is turned on.
- Make sure you have your **Lab Wi-Fi password** at hand to configure the headbands.
- Verify with your IT that you can **access Google Chrome** and that a **private Wi-Fi connection with no-portal access** is available for you to connect the headbands.
- Make sure that **only one headband is powered on at a time** to avoid mismatches. A headband that is plugged in to charge is considered to be **powered on**. Sites should **avoid** pairing the headband and app with multiple headbands charging within the same area.

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1.1. Assigning A Headband and User ID to A Participant

Under the top arch, each headband's serial number can be found **(e.g.1200XXXXXXXXX**). When preparing a device for a participant, we recommend that you create a dedicated spreadsheet where you can fill the serial number, the participant ID and the Alfin credentials (login and password).

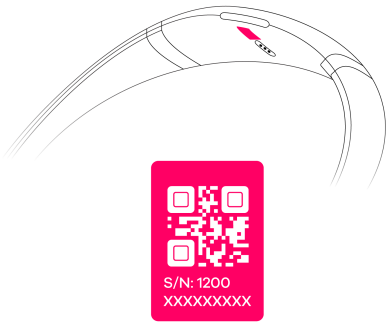

Fig.7: Headband reference under the top arch

1.2. Log in To the Alfin App, Pair Headband, and Set-up Wi-Fi

This step is crucial so that the headband can be linked to a user profile. This will allow for proper identification of each participant's record in the Dreem Quality Check Portal. You will have to configure each headband so they each are linked with a participant using their designated Dreem credentials (Dreem User ID and password).

It is also required that the Wi-Fi network is set-up at the laboratory. So firmware update can be performed if needed or to facilitate data transfer from the headband if the participant was unable to set up the connection with their home Wifi.

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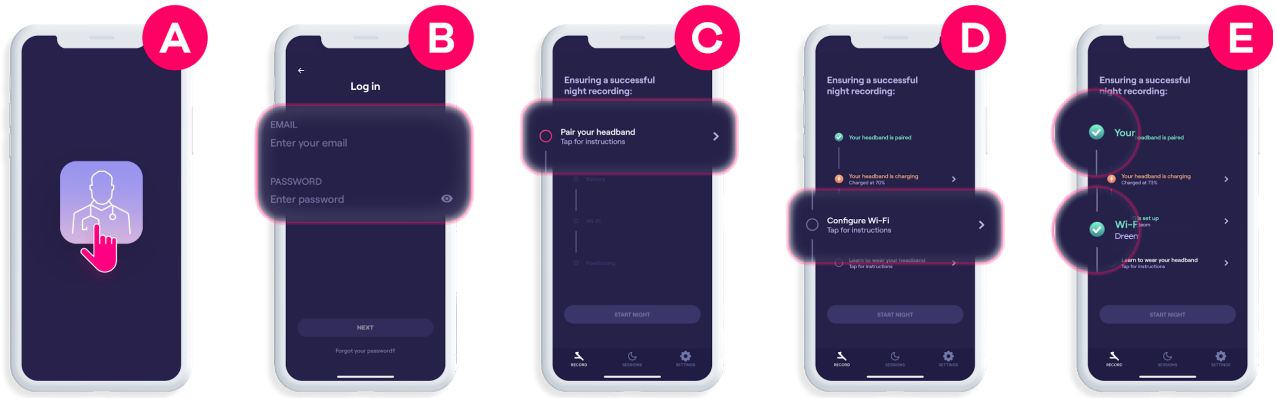


Fig.8: Log in, Pairing, and Wi-Fi Configuration

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

B. **Open the app.** Select Log In. You will need to enter the participant's login using the Dreem user ID and password that were provided to you.

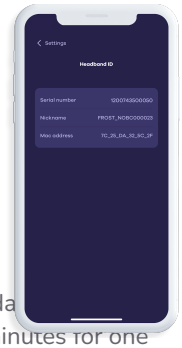
C. **Pair your headband.** On the app's homepage, select ***"Pair your headband"*** and follow the instructions for your headband to synchronize with the app. Select "Dreem 3" when asked for. Once your headband is paired, you will see a green checkmark on the left side of the home screen. The Battery status should display either a green checkmark or an orange bolt.

D. **Configure the Wi-Fi[2].** You can now connect to the Wi-Fi by selecting ***"Configure Wi-Fi"*** on the home screen. You will only have to set-up the Wi-Fi once using your laboratory website and password. The headband will automatically connect to the Wi-Fi when the headband is brought back to the laboratory..

E. **Checkmarks**. Green checkmarks 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.

F. During the first connection of the headband. Once the headbands are setup. It is time to plug all the headbands to their charger so that they can **update their internal firmware**. The LED will light up white, then green or red depending on the battery level. When the update is being performed, the LED will spin white. (it may take up to a minute to start downloading).

1.3. Headband and Dreem Credential Verification



Before moving to another headband, go to the app's Settings section, the Headband ID is displayed, along with the participant credentials, Firmware and App version. Press Headband ID to display the serial number of the headband that has been paired with the app.

[2] Every time the headband is charging, it automatically connects to the configured Wi-Fi network. The da automatically transfers from the headband to the Dreem 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.
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Make sure that you are paired to the corresponding headband in the app's Settings section. It should match with the headband assigned to the participant in your dedicated participant spreadsheet. If the displayed username is incorrect, please log-out and login again with the corresponding Dreem credentials. You will then need to pair the headband again to assign the correct credentials to the headband.

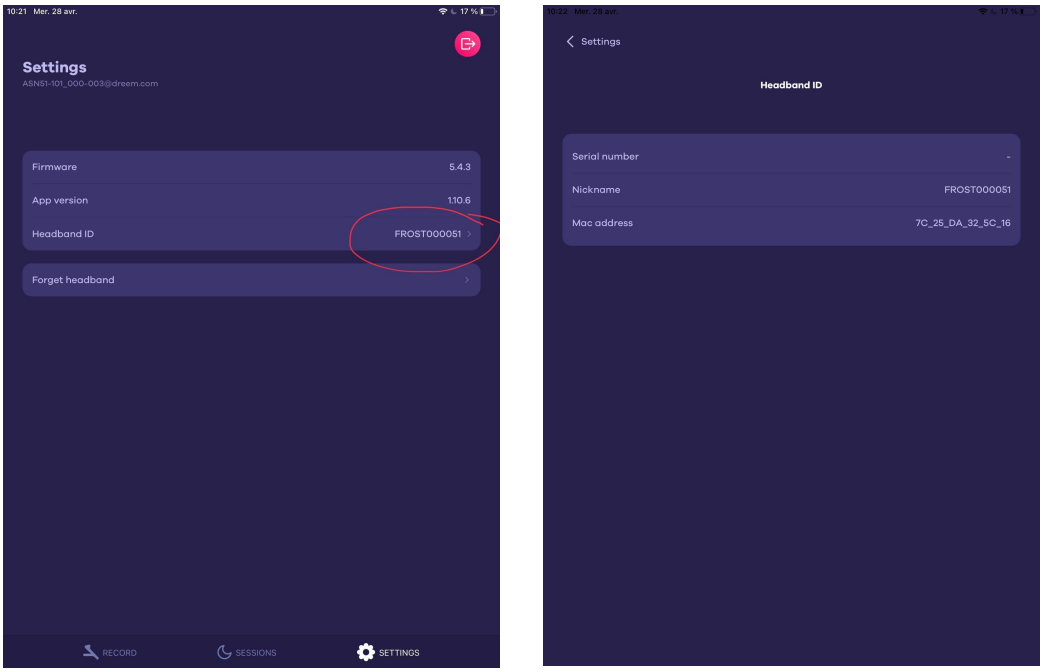

Fig.9: App settings

Once this step is complete, you can turn the headband off by pressing and holding the power button for 3 seconds until the LED turns off, and move on to the next headband. This headband will remain linked with the participant account displayed. There is no need to re-do the pairing with the participant account in the future.

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2. When the Participant is at the Lab

2.1. Sleep Hygiene Recommendations

Note: Interactions with participants are necessary to inform them of the required sleep hygiene during the protocol and to educate and advise of proper fit and use of the Dreem headband. This is a crucial step.

Throughout the study, and in particular, on the nights that sleep monitoring assessments will be performed, participants should ensure they have **adequate opportunity for sleep** (i.e., at no time during the study should the time allotted for sleep be shortened). The participants should be instructed to maintain a habit of going to bed at their regular bedtime and to wake up at regular hours as well. **The regular bedtime for participants should be between 8:00 PM (20:00) and 1:00 AM (01:00).**

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

- The at-home sleep monitoring device should be **applied to a clean surface (e.g., skin and hair) and in dry hair**
- **The participant 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**.

2.2. Verify the Headband's Fit on The Participant's Head

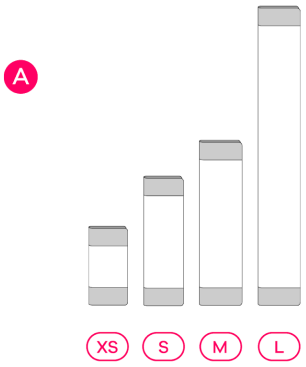
Special attention should be given to educating the participant about their specific headband fit needs, to guarantee acceptable signal quality at home.

The Dreem 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 Dreem support team if questions or issues arise.

2.2.1. Head Circumference with The Dreem Headband

The headband's fit can be adjusted with three sizes of adjustment strips **(Fig. 11, A)**, coming in:

- Extra-small (XS): 53 cm and less
- Small size (S): 54 to 56 cm.
- Medium size (M): 56 to 60 cm.
- Large size (L): +60 cm



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 Dreem headband.

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1. The two Velcro pads at the back of the headband need to be placed on top of each other by default to assess a participant's fit. This is the smallest fit possible. **(Fig. 11, B)**

2. Position the headband on the participant's head using this configuration. If the headband is snug on the head and the participant is comfortable, the desired fit for the participant's headband use is achieved. You can add the small Velcro adjuster **(Fig. 11, C)** 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. **(Fig. 11, D)**.

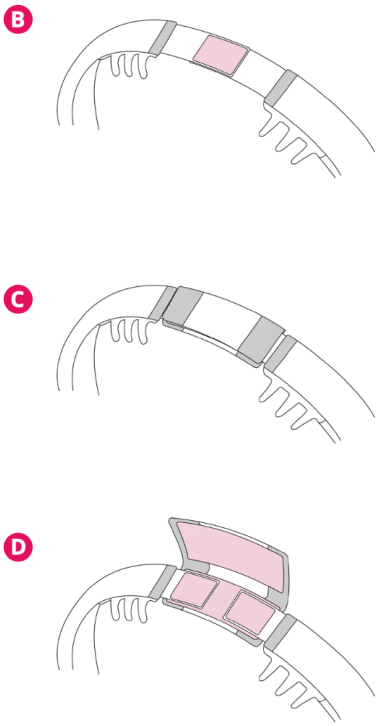

Fig. 10: Size adjuster

2.2.2. Headband Positioning

To make sure their headband is properly positioned on the participant's head, **it is essential that you go through each step below with them** so they can reproduce the instructions easily at home:

1. The power button and touchpad need to be on the top of the head. The participant needs to pull up their hair at the front and back of the head so that the sensors can touch their skin/scalp.

2. In case of long hair, tie hair up and pull hair over the back sensors to ensure good contact with the scalp.

3. The back sensors can be gently moved up and down to comb the sensor through the hair at the back of the head. If your participant has long hair at the back, we require that you lift the participant's hair over the rear elastic band of the headband before positioning the back (occipital) sensors (Example 3 below). Participants can then keep their 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.) ask the participant to remove the hairstyle.

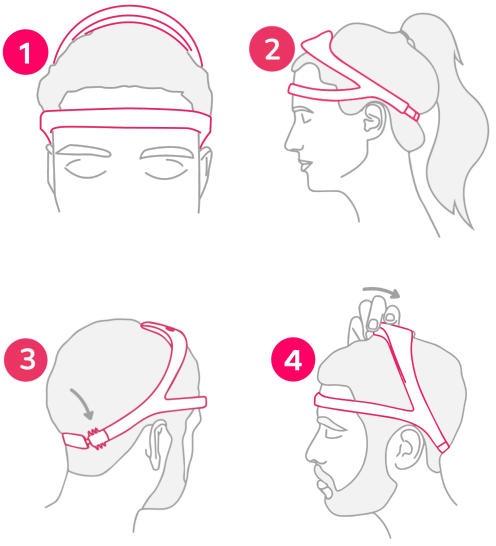

Fig.11:Headband positioning

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4. To ensure optimal support throughout the night, gently pull the upper arch backward.

2.2.3. Sweatband Use for Small Head Circumferences with The Dreem Headband

When a participant's head circumference is deemed too small for optimal Dreem headband fitting (**53cm or less**), a sweatband needs to be placed over the top of the Dreem Device. The goal is to create tension on the Dreem headband to contour to smaller head circumferences.

The sweatband should be placed over the frontal band and occipital sensors of the Dreem Device as shown below, which will create proper skin-to-sensor contact and reduce shifting and sliding of the Dreem Device at night, thus improving signal quality.

Long hair should be attached in a ponytail at the top of the head as seen in ***"2.2.2. Headband Positioning"*** to avoid any disruption of the sensors/headband. If the participant's hairstyle significantly impedes the sensor placement (toupee, tight braids, etc.), ask the participant to remove their hairstyle.

Participants with a 'normal' head circumference can also be given a sweatband for home use, in-case of sub-optimal fitting, poor signal quality, or headband shifting is noted during the in-lab assessment. However, comfort using the headband should be tested before sending the participant home. **Participants with 'normal' head circumferences with no observation of poor fitting should not use the sweatband**.

The sweatband is not provided in the Dreem3 box content, and is at your expense. You can ask your Project Manager for Research for product recommendations.

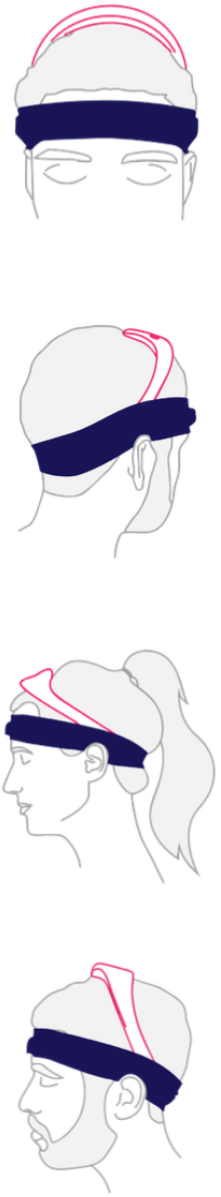

Fig.12: Headband worn with sweatband

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2.3. Instructions for the Participant

The most efficient way to train the participant to use the device is to go through the Participant Instruction Manual (PIM) with them. Any participant difficulties should lead to the adaptation of participant education. Below is the main information that should be explained.

2.3.1. Key Highlights

Start by giving the participant all the necessary items they will need. The participant should be given:

1. A Dreem box containing the Dreem headband and accessories.
2. And a sweatband if applicable.

Participants should be told where the headband sensors **(Fig. 13)** are located ***(General Presentation [1.3. Sensors Available])*** for them to understand their purpose and position them properly before going to bed. The back sensors are particularly important because they can be mistaken for hair combs, whereas they should be viewed as sensors and as such be in direct contact with the scalp.

Additionally, the participant must be instructed how to charge the headband, how to wear it and how to turn it on and off, as well as starting and stopping a recording.

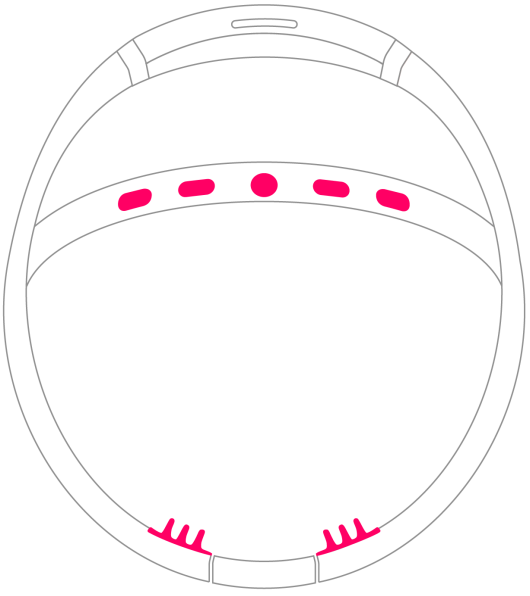

Fig. 13: Sensors location

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2.3.2. When Arriving Home

Make sure to remind your participant or caregiver to plug their headband to its magnetic charger before their first night at home. They should let the headband charge all day until they are ready to go to sleep. Make sure they follow this process:

1. First, plug the magnetic end of the cable into the headband.
2. Then plug the cable attached to the headband on a wall socket. Make sure the magnetic end of the cable doesn't detach itself during this step.

Then, the participant should proceed to connect the headband to their home Wi-Fi network with the help of the Alfin App and the Participant Instruction Manual. The participant should follow the instructions below:

A **Turn on the Headband** by pressing on the power button. The LED will turn green or red depending on charge level.

B **Open the Alfin app.** The smartphone's Bluetooth, Wi-Fi and Location settings must be turned on.

C The **headband should pair automatically** with the app. If not, follow the pairing tutorial by clicking on «Pair your Headband».

D **Enter the home Wi-Fi information** (if available) by clicking on «Configure Wi-Fi».

E Learn how to wear the headband by clicking on **«Place your headband».**

F You will be asked to check **the signal quality.** Lay down for 10 seconds. Three dots should appear.

G **Either the participant goes to sleep now and tap on start recording**. In which cas they will be instructed how to stop the recording the next morning.

H **Or they can turn off the Headband** by pressing the power button for 3 seconds. The button LED will turn white and blink several times, then turn off.

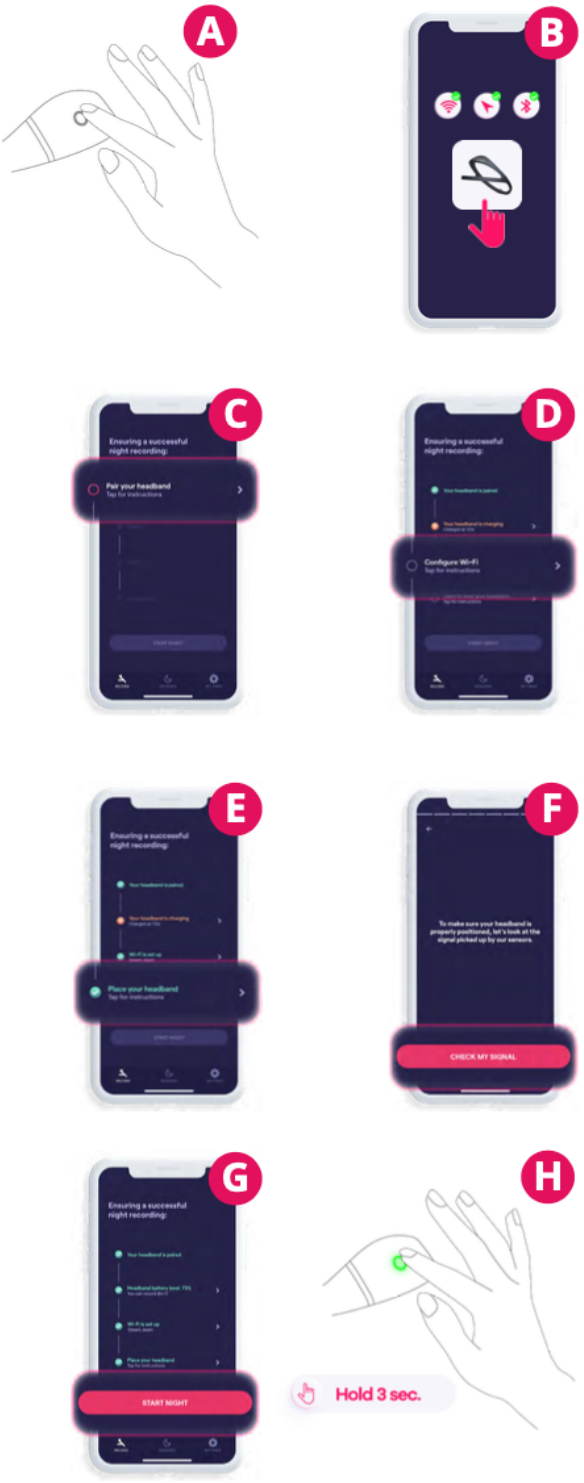

Fig.14: When arriving home steps

Without Wi-Fi, the night's raw data will remain saved in the Dreem headband. Metrics will not be accessible to the researcher through the Dreem Viewer until the headband is connected to a Wi-Fi network then plugged in for charging. The headband can store up to 100 hours of sleep data in case Wi-Fi is unavailable.

2.3.3. Start a recording

A. 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.

B. The participant can now position the headband on their head as previously instructed in ***"2.2.2. Headband Positioning"***. In case of long hair, pulling hair over the back sensors should be done to ensure good contact with the scalp. If your participant has long hair at the back, we require that you lift the participant's hair over the rear elastic band of the headband before positioning the back (occipital) sensors (Example 3 below). Participants can then keep their 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.) ask the participant to remove the hairstyle.

C. Once they have made sure their headband is properly positioned, show them how to initiate a record. The participant should be instructed to press the power button on top of the headband 3 times to initiate a record. The LED will turn blue and turn off a few moments after, and the participant will hear a voice confirmation that their record has started.

D. If the participant is unsure the record has started, simply instruct them to make a short press on the power button. The LED should briefly light up in blue, and they should hear an audio confirmation.

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

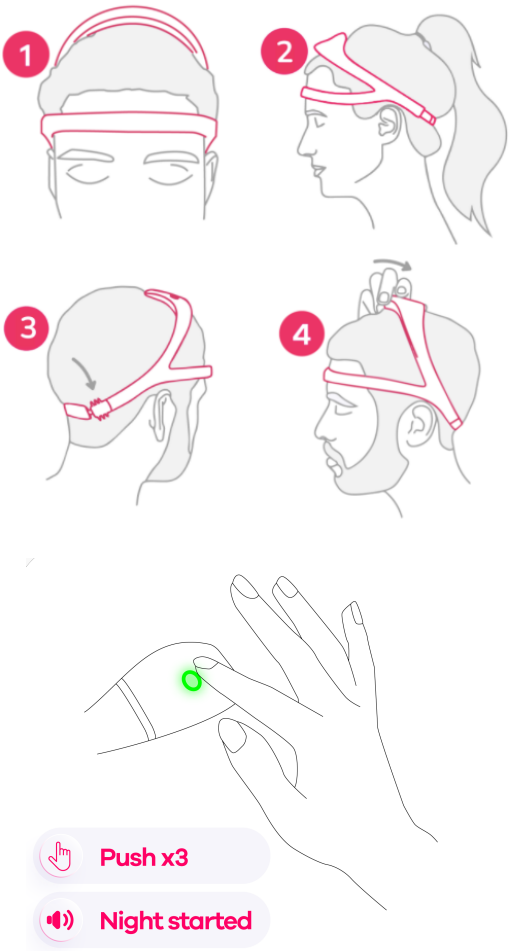

Fig. 16: Pressing the power button three times

2.3.4. 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. A vocal confirmation will indicate that the record has ended and the power button's LED should blink white, then turn off

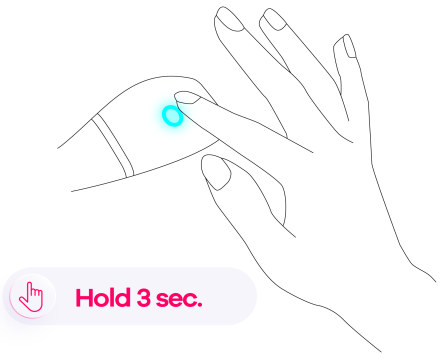

Fig.17: Holding the power button

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2.3.5. Charging the Headband

The participant can proceed to remove the headband from their head and plug the magnetic cable to the back of the headband to charge it during the day.

Participants should always plug the magnet cable to charge the Dreem 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 Dreem servers, as well as to ensure the device has enough battery charge for the next use.

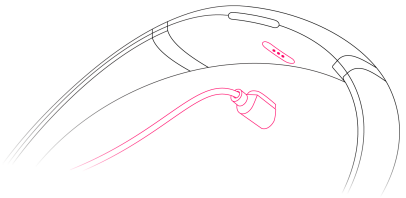

Fig.18: Cable plug

The participant 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 **(Fig.19)**. 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.

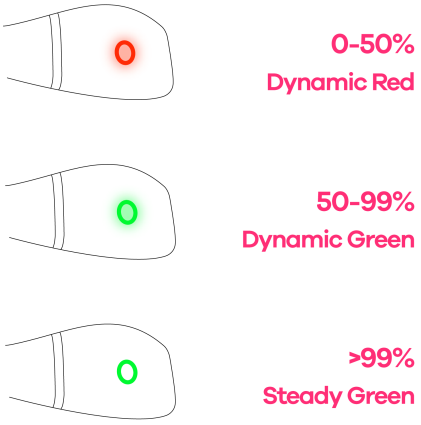

Fig.19: LED Charging stages

Optionally, a few minutes after the headband has been charging, the participant can open the Alfin app and go into the «Sessions» section.

They will be able to see the details of their nights.

Participants will be able to access basic information about their night such as how long they slept for and in which sleep stage, etc.

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2.3.6. Cleaning and Hygiene

Participants should be advised to wear their headband on clean skin, without applying any type of moisturizer on the sensors' contact points. This will ensure good signal quality.

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

CAUTION: PARTICIPANTS MUST AVOID SUBMERGING THEIR HEADBANDS IN WATER.

To clean the headband, participants should wipe the headband using a damp non-linting wipe with tap water. Thoroughly wipe all exterior surfaces of the device for a minimum of one (1) minute and until visibly clean. Use fine-tipped cotton swabs wetted with tap water to clean small seam spaces.

Replace soiled wipes/swabs as needed, changing wipes/swabs when necessary to ensure that all surfaces are uniformly cleaned. Pay attention to surfaces such as indentations and seams. Thoroughly dry the device using non-linting wipe(s) and/or fine-tipped cotton swabs.

The participant should visually inspect the surfaces of the device for the absence or presence of remaining soil in a well-lit area.

3. When the Participant is using Dreem

During part 1, 2 and 3 of the protocol, participants will be performing Dreem sleep recordings at home. You will need to verify that each headband of the cohort is working as it should by monitoring the participants' activity through the **Dreem Portal.** The main purpose of the portal is to verify record upload is completed after each recording, while noting if acceptable signal quality is being achieved.

3.1. Check Available Records

After logging in (refer to ***[General Information, "3. Dreem Portal"]*** to find the credentials), you will find a complete list of your participant's recordings that have been successfully uploaded. Records are organized by upload order (newest is first). This list includes produced metrics and raw data. **Please note that data may take 30 to 60 minutes to appear depending on the Wi-Fi connection.**

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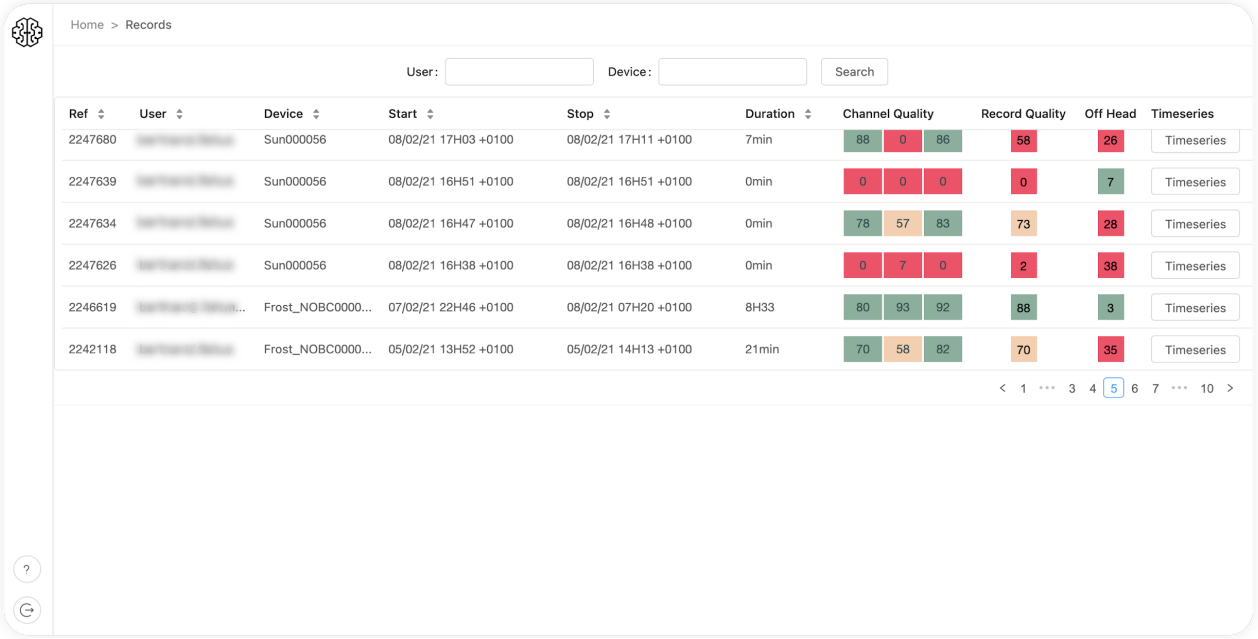

- **Grey records** are recordings that have been successfully uploaded to the servers.
- In some cases, recordings **can appear in red**. This is the case when the participant's smartphone has access to the internet but not the headband (either because Wi-Fi has not been successfully set-up on the headband or because the headband has not been plugged for charging yet).

For each recording, the Dreem User ID, the device's short name ID, the start and stop time of the recording, and the duration of the recording will appear. Channel quality, record quality, and device off-head metrics will also be produced and visualized.

If data is not displayed as anticipated, please contact Dreem support for further assessment and schedule assistance with the participant.

3.2. Checking the Record Quality Metric

On the home page, you will find - next to the recording Ref, User, Device and Start/Stop time columns - different information about the quality of the recording. These metrics will be used as a guide for assessing Dreem record quality and highlight possible needs to contact the patient in case of a bad signal. If any metric indicates a need for intervention, please review proper placement and use of the DREEM headband with the participant (see ***Section 2.2***).

The following is a step-wise way of analyzing the quality metrics. It should be used as a guideline for properly analyzing Dreem recordings **(Fig.21)**:

1. First look for the value under the 'Off Head' metric. This metric relays information about the duration of the recording in which the Dreem headband lost complete EEG signal, or was taken off the head. Values from 0 to 10 are acceptable, and the Record Quality metric should be inspected next. Any values above 10 should be considered substantial record loss, and intervention should be given with the participant to minimize durations of complete EEG signal loss.

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2. Look under the 'Record Quality' metric. This metric pertains to the percentage of the recording that is considered acceptable record quality. Values above 85 are considered acceptable, and no intervention is needed. Values below 85 are considered as poor quality recordings, and intervention should be given to the participant. Next, inspect the 'Channel Quality' metric to further understand the poor record quality's origins.

3. Last, seek the values of the 'Channel Quality' metric. The three values pertain to three sensors: the Left Occipital sensor, the Right Occipital sensor, and the frontal sensors respectively. When all values are below 85, the overall fit and position of the headband should be addressed with the participant. If one or both occipital values are the lowest, special attention should be given to assess the occipital sensor fit and use with the participant. If the frontal values are lowest, this may point to a use issue with the frontal sensors.

For additional participant sleep information, the record in question is clicked once and the summary report will be displayed (**Fig. 21**: Record highlighted in blue). Look for the sleep metrics and timeline section at the bottom of the page

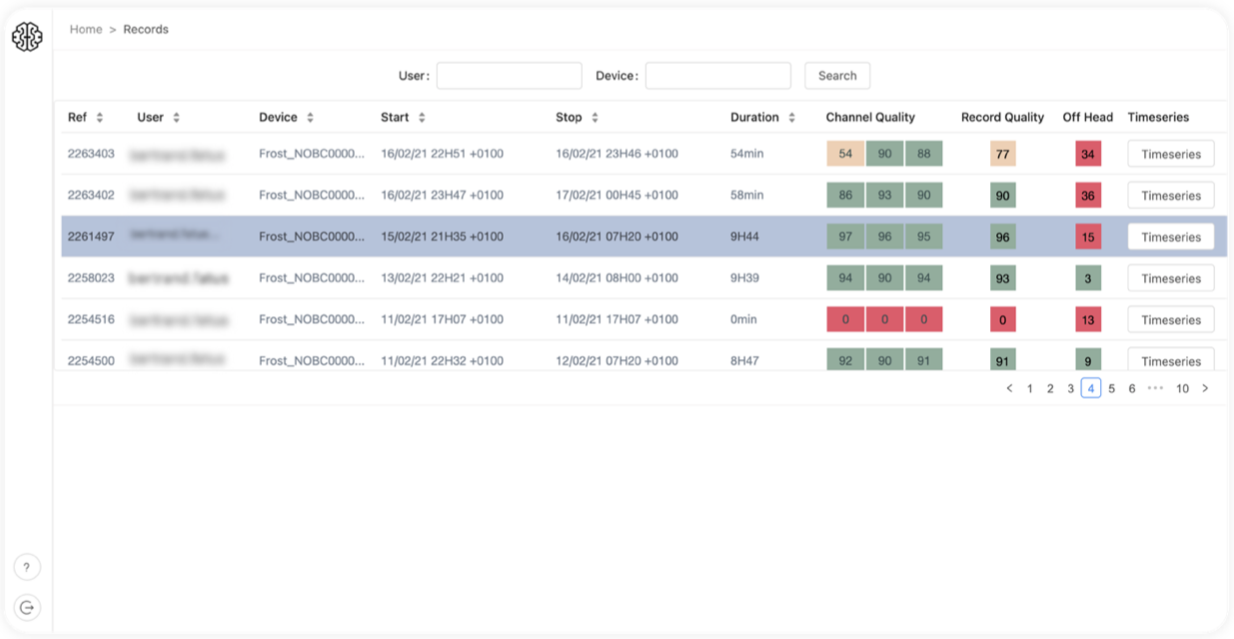

Fig.21: Record details: Quality

3.3. Conduct A Raw Data Quality "Quick-check"

The study investigator should check the raw data each time a record is uploaded. Dreem will also perform these checks as data is received. Reviewers of signals should contact the participant for intervention as needed. Dreem support is also available, should questions arise about proper Dreem use after participant intervention.

1. Click on the «Timeseries» button **(Fig. 21)** on the last column of the desired recording. A new page will be generated using DREEM's custom record viewer. This viewer will provide access to the entire raw EEG recording.

2. Set the workspace. By clicking the toolbox **(Fig. 22)** in the viewer, you will be able to set parameters for viewing the record (epoch duration, channels displayed, etc.). Configure the multi-channel EEG signal in the record by pressing the

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'Select Signal' button. This will display all available channels for analysis. Click and drag any channel from the 'Available' section to the 'Selected' section to view the channel in the viewer **(Fig. 23)**. Channels can also be moved up and down the page for viewing preference. Press multiplot to confirm your workspace.

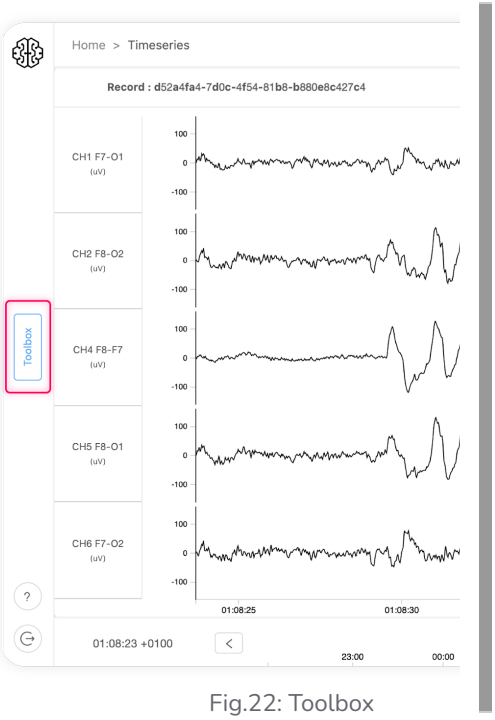

Fig.22: Toolbox

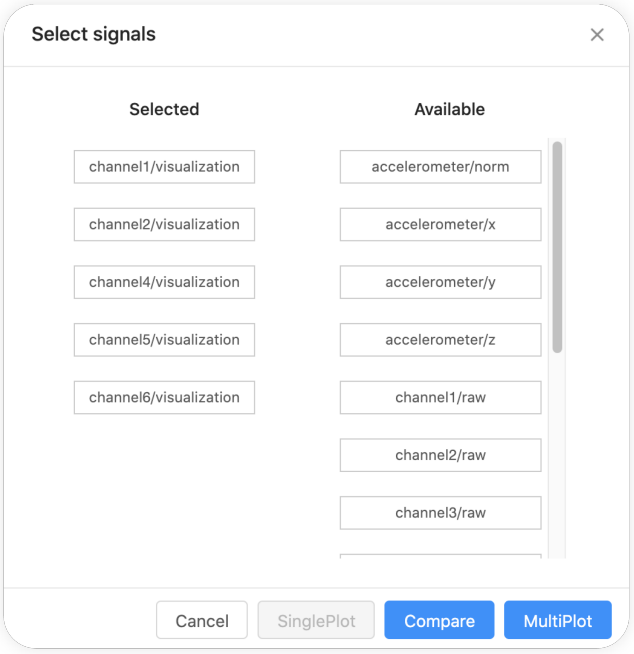

Fig.23: Signal selection

3. Inspect the recording: Scroll or click the timeline on the bottom of the page to move through the recording and consider the overall data quality of the EEG. You may notice typical sleep biomarkers (sleep spindles, K-complexes, delta waves, etc.) throughout the record. Examples of good data quality and bad data quality are shown below in Figs.24-27.

   a. When sleep biomarkers and sleep stages cannot be detected for long durations of the recording (>1 hour), these epochs should be considered poor quality signals (Fig.26). If you observe these during the outpatient period, please contact the participant and review the proper placement and use of the DREEM device.

   b. Records can simultaneously have good signal quality in some channels and poor signal quality in other channels (Fig.27). The signal quality is still considered acceptable when at least one occipital and one frontal EEG channel has sleep stage/sleep biomarker detectable signals.

4. Follow up with a participant: If a recording has failed due to a poor quality signal, contact the participant before the next night's recording to determine why the recording failed. Discuss with the participant ways to improve the recording quality during the next night's recording. Refer to ***Section 2.3*** for more information on headband fitting.

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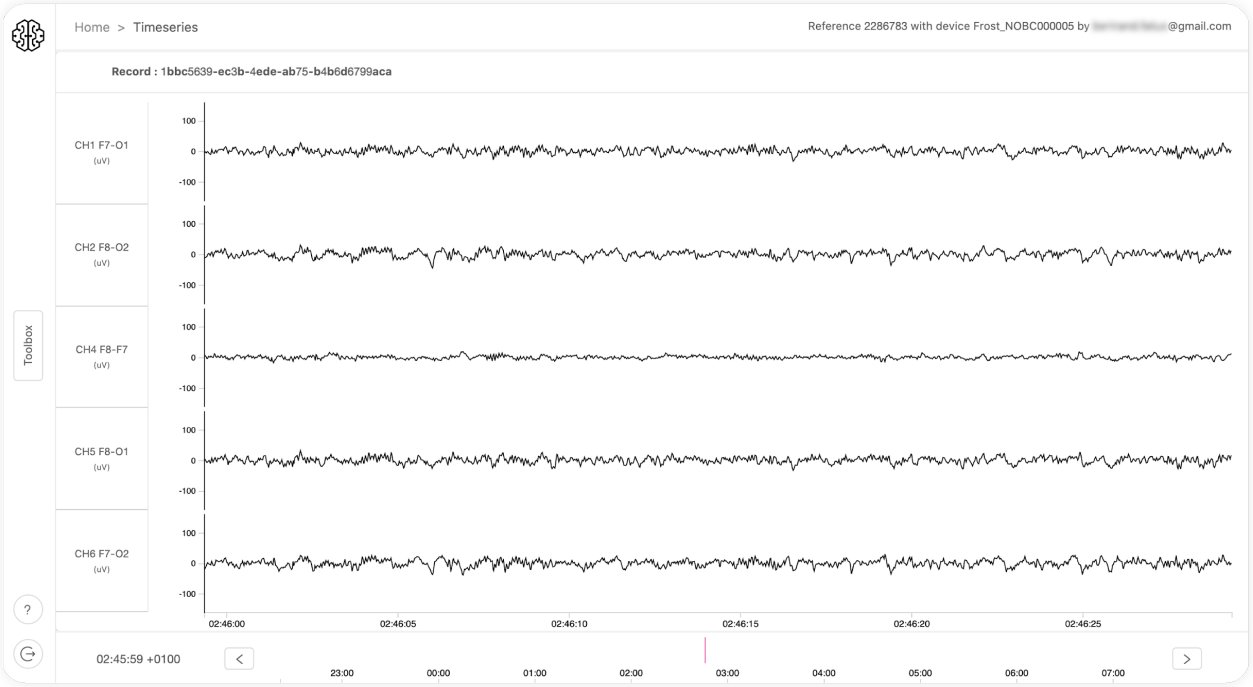

Fig.24: Good quality signal - Stage 2 sleep with sleep spindles is easily distinguished.

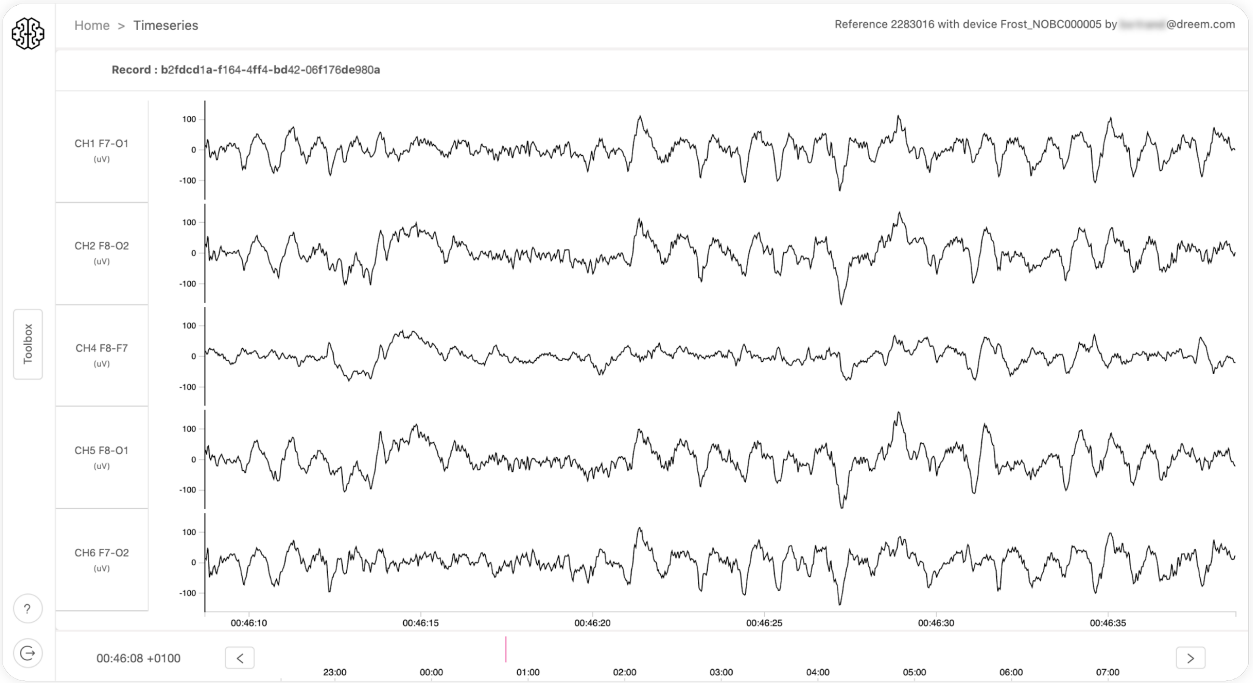

Fig.25: Good signal quality – Slow-wave brain activity during N3 epoch.

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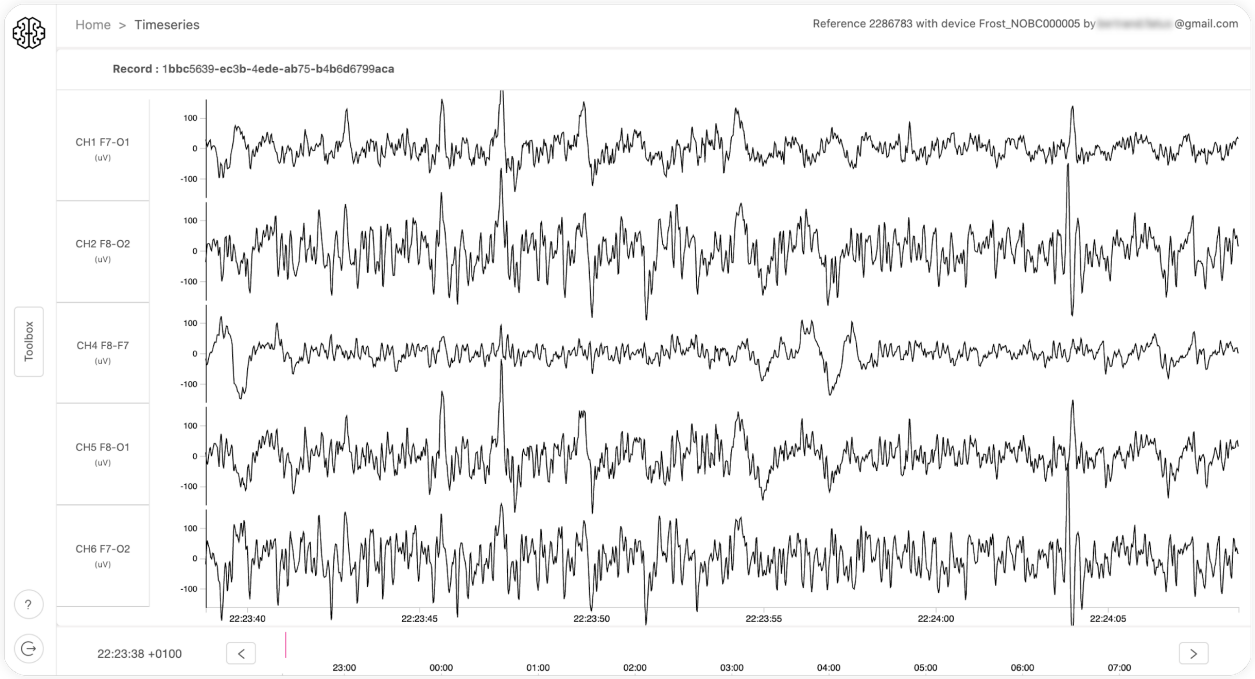

Fig.26: Poor signal quality- Sleep stage and biomarkers are not easily distinguished.

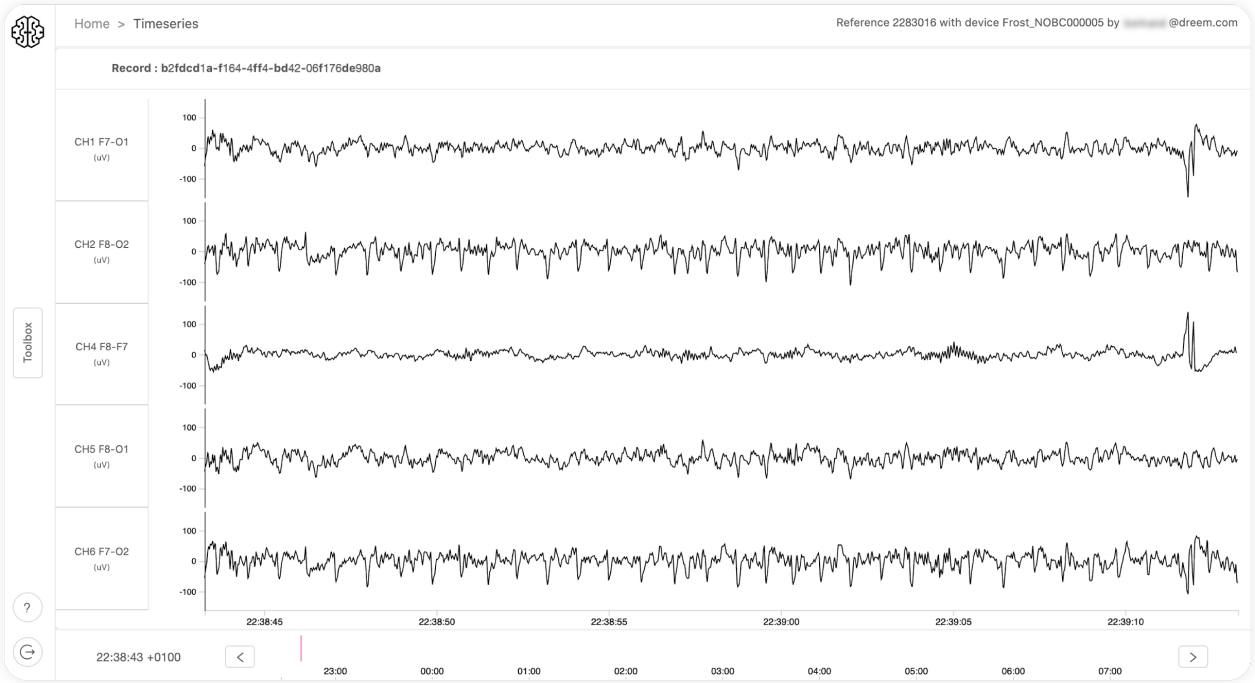

Fig.27: Mixed-signal quality- Poor signal originating from the O1 and O2 sensor. However, the frontal channel is of good quality. Intervention could be made to improve occipital sensor signal quality.

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Key Takeaways

1. Principal Actions to Carry Out at the lab

1. Before providing a headband to the participant and during the participant homestay

The headband needs to be plugged in for charging to ensure the device does not stop working during the night.

The **participant's anonymized dedicated credentials (Dreem Credentials) must be used to log into the app** on the provided device.

Finally, the participant's headband must be paired with the app & **Lab Wi-Fi set-up** is also required**.**

2. When a participant comes to the lab

The headband's fitting on the participant's head is a crucial step. If the headband is too tight, a larger adjuster can be added to the headband. If the participant's head circumference is below 54 cm, **a sweatband has to be given to the participant** to be placed over the headband. The headband should be **snug, and not shift** on the head when a **participant** moves during the night. A sweatband can also be used if the researcher feels the headband will not be snug or may shift during use at night.

Sleep hygiene and the importance of having a regular sleep schedule must be emphasized to the participant. *[During the Participant Home Stay, "2.1. Sleep Hygiene Recommendations"]*

By the end of the participant's visit, they must have understood:

- **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** to enable automatic data upload.

The participant should be given:

- A Dreem box containing the Dreem headband and accessories.
- And a sweatband if applicable.

Without Wi-Fi, the night's raw data will remain saved in the Dreem headband. Metrics will not be accessible to the researcher through the Dreem Viewer until the headband is connected to a Wi-Fi network then plugged in for charging. The headband can store up to 100 hours of sleep data in case Wi-Fi is unavailable.

3. During homestay

The **Dreem Portal** should be used daily by the study coordinator to make sure:

- The night recording has been successfully uploaded
- Verify the signal quality.

If data is not accessible in the Portal or if it is not of good quality, the study participant must be contacted for assistance.

Participants must connect the headband to home's wifi. If not, data won't be transferred during the home period and the battery will drain.

2. Troubleshooting

2.1. Headband

NOTE: DREEM HEADBANDS ARE FRAGILE AND SHOULD BE HANDLED WITH CARE

2.1.1. 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 Project Manager for Research.
4. If a headband does not turn off after a record, 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.

2.1.2. Recording

If you or the participant are unsure the record has started, simply make a short press on the power button. The LED should briefly light up in blue, and the participant 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. Make sure that the participant charges their headband after each use. If the participant has followed the guidelines and battery discharge is not the issue, please get in touch with the Dreem support team.

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

2.1.3. Cleaning and Hygiene

Participants should be advised to wear their headband on clean skin, without applying any type of moisturizer on the sensors' contact points. This will ensure good signal quality.

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

CAUTION: PARTICIPANTS MUST AVOID SUBMERGING THEIR HEADBANDS IN WATER.

To clean the headband, participants should wipe the headband using a damp non-linting wipe with tap water. Thoroughly wipe all exterior surfaces of the device for a minimum of one (1) minute and until visibly clean. Use fine-tipped cotton swabs wetted with tap water to clean small seam spaces.

Replace soiled wipes/swabs as needed, changing wipes/swabs when necessary to ensure that all surfaces are uniformly cleaned. Pay attention to surfaces such as indentations and seams. Thoroughly dry the device using non-linting wipe(s) and/or fine-tipped cotton swabs.

The participant should visually inspect the surfaces of the device for the absence or presence of remaining soil in a well-lit area..

NOTE: In between participants, you may clean the headband with a piece of cloth or a cotton swab dampened with isopropyl alcohol (IPA)

2.2. Dreem Portal

2.2.1. Records List

If data is not displayed as anticipated during the participant's homestay, please contact the Dreem support team for further assessment and schedule assistance.

2.2.2. Signal Quality

If a recording has failed due to a poor quality signal, contact the participant before the next night's recording to determine why the recording failed. Discuss with the participant ways to improve the recording quality during the next night recording:

1. The power button and touchpad need to be on the top of the head. The participant needs to pull up their hair at the front and back of the head so that the sensors can touch their skin/scalp.
2. In case of long hair, tie hair up and pull hair over the back sensors to ensure good contact with the scalp.
3. The back sensors can be gently moved up and down to comb the sensor through the hair at the back of the head. If your participant has long hair at the back, we require that you lift the participant's hair over the rear elastic band of the headband before positioning the back (occipital) sensors (Example 3 below). Participants can then keep their 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.) ask the participant to remove the hairstyle.

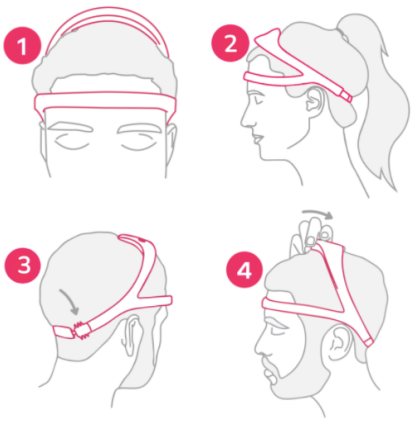

Fig.33: Headband positioning

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4. To ensure optimal support throughout the night, pull the upper arch backward.

2.2.3 Live EEG

If you are unsure the headband is picking up a good signal when fitting the headband on the participant's head, you can check the signal quality of the sensors while the participant is lying down in bed using the Live EEG feature available on the Alfin App after the positioning instructions.

After 5-10 seconds, the EEG signal should stabilize. Small peaks should appear in the EEG signal when blinking several times. The three green dots and the checkmark on the top of the screen **(Fig.34)** indicate that the headband positioning and fit are correct.

If the signal does not display 3 green dots, go through the headband positioning instructions once again and make sure all sensors are in good contact. If the headband signal is not synchronized with the app, retry pairing the Dreem device to the app.

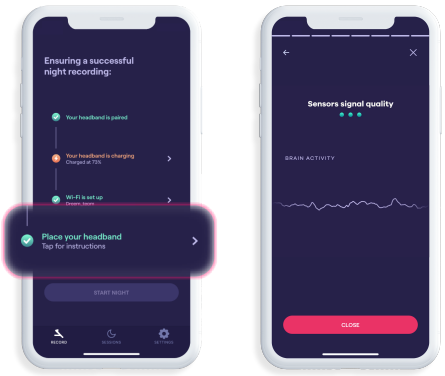

Fig.34: Live EGG

Without Wi-Fi, the night's raw data will remain saved in the Dreem headband. Metrics will not be accessible to the researcher through the Dreem Viewer until the headband is connected to a Wi-Fi network then plugged in for charging. The headband can store up to 100 hours of sleep data in case Wi-Fi is unavailable.