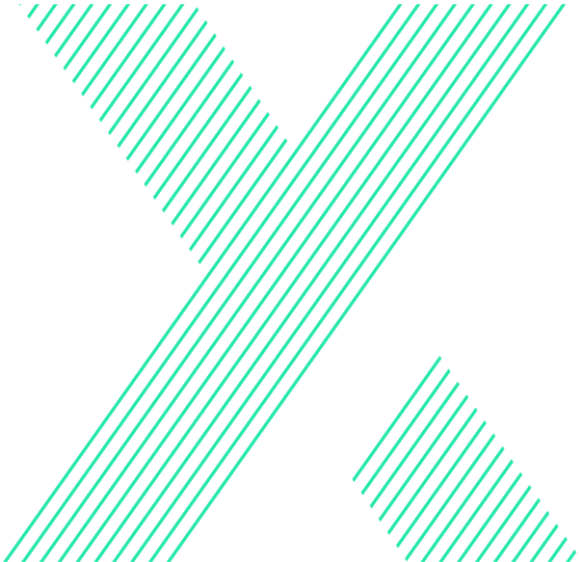


Instructions for Use

Axon 2



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Contents










1	Symbol Definitions and Terminology.....	5
2	Introduction	7
	2.1 Product description.....	7
	2.2 Indications for Use	7
3	Contraindications, Warnings, and Precautions.....	8
	3.1 Medical Contraindications	8
	3.2 General Warnings.....	9
	3.3 General Precautions	10
4	Getting Started	11
	4.1 Axon System Contents	11
	4.2 Before each use	11
	4.2.1 Headset preparation	11
	4.2.2 Install the Axon App.....	12
	4.3 Starting the Axon App for the first time.....	13
	4.3.1 Adding an Account	13
	4.4 Starting your first session.....	15
	4.4.1 Logging in to the App.....	15
	4.5 Wearing the headset.....	16
	4.5.1 Turning on the headset.....	16
	4.5.2 Preparing the Sensors	17
	4.5.3 Putting on the headset.....	17
	4.6 Progress tracking questionnaires and diaries.....	18
	4.7 Welcome Page	20
	4.8 Starting a Session.....	21
	4.8.1 Headset Connectivity Check.....	21
	4.8.2 Complete Pre-session baselines.....	21
	4.8.3 Choose your Game	23
	4.8.4 Rest Periods.....	25
	4.8.5 Complete final Baseline	25
	4.8.6 Session Complete	25
	4.8.7 After the Session is completed	26
5	Tracking Your Progress.....	27
6	Help & Support.....	28

7	Brain Visualisation	29
8	Maintenance & Cleaning	29
8.1	Cleaning the headset	29
8.2	Battery Life	30
8.3	Battery Replacement	30
9	Transporting, Storing and Disposing of your Headset	31
9.1	Shipping	31
9.2	Storage	31
9.3	Disposal	31
10	Technical specifications	32
10.1	Device specifications	32
10.2	EMC guidance & Declaration	32
11	Contact information	32

1 Symbol Definitions and Terminology

The table below explains the symbols used in these Instructions for Use, and on Axon labels and packaging.

Symbol	Definition	Reference
	Manufacturer details Name and address of the manufacturer	ISO 15223 5.1.1
	Country and Date of Manufacture NZ (New Zealand) Date format: YYYY-MM (Year-Month)	ISO 15223 5.1.11
	Type BF Applied Part Classification of protection against electrical shock, complying with IEC 60601-1.	IEC 60601-1 Table D1 No. 20
	Medical Device Indicates this device is a Medical Device	ISO 15223 5.7.7
	Serial Number Manufacturer's serial number to identify the specific device	ISO 15223 5.1.7
	Catalog Number Manufacturer's catalog number to identify the medical device	ISO 15223 5.1.6
	Unique Device Identifier Unique code identifying the specific device for traceability.	ISO 15223 5.7.10
	Bluetooth identifier Used by the Axon App to pair with the Axon headset	No regulatory requirement
	Consult Instructions for Use Read Instructions for Use prior to using the system	ISO 15223 5.4.3

Symbol	Definition	Reference
	Warnings Actions or situations that could lead to personal injury. Take note of all warnings before using the device.	No regulatory requirement
	Cautions Actions or situations that could damage the equipment or other property, or interfere with operating the device.	No regulatory requirement
	Notes Contains advisory information about some aspects of operation.	No regulatory requirement
	EU Only: Do not dispose of Axon as unsorted municipal waste. To arrange for return or collection contact your Axon supplier for disposal information.	EU directive 2012/19/EU
	US Only: Prescription Only CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed physician.	21 CFR 801.109
	Keep dry keep away from rain and in dry condition	ISO 15223 5.3.4
	Temperature Limitation Acceptable upper and lower limits of temperature for transport and storage	ISO 15223 5.3.7
	Humidity Limitation Acceptable upper and lower limits of relative humidity for transport and storage	ISO 15223 5.3.8
	UK Conformity Assessed UK product marking indicating compliance with relevant UK regulations.	UK Medical Devices Regulations 2002

2 Introduction

2.1 Product description

Axon uses Exsurgo's custom-designed EEG headset to read and record the unique EEG signature and brain activity patterns associated with each user, which are then transmitted to the app, enabling them to interact with these signals in real time.

The user learns to modulate their activity through neurological exercises in the form of simple animated games, using positive reinforcement to redirect brain activity towards frequencies associated with relaxation and calm focused attention.

Axon facilitates changes in brain activity by harnessing neuroplastic processes, thus reducing symptoms and introducing new patterns of brain activity, in a process known as operant conditioning. As the user progresses and completes the required sessions, the brain learns to regulate itself through neuroplastic (Hebbian) learning.

2.2 Indications for Use

Axon is an EEG-based Neurofeedback system that uses the principles of operant conditioning to enable users to self-regulate and optimize their own brain activity via a brain computer interface, allowing personalized treatments for a range of conditions.

Axon is indicated for use by adults in both a professional (e.g. clinical) and/or home environment, and can function as an adjunctive treatment to improve symptoms related to chronic pain and anxiety.

3 Contraindications, Warnings, and Precautions

We recommend you consult with your primary healthcare provider/clinician before using Axon.

3.1 Medical Contraindications



Please do not use Axon unless you have discussed with your clinician, if you have had any of the following:

- Head injury or concussion within the past 6 months
- History of seizures (e.g. epilepsy).
- Diagnosis of a neurological disorder.
- Hospitalization for psychiatric treatment.
- Undergone treatment for a serious disease (e.g. cancer), within the past 6 months
- Using an electronic implanted device (e.g. pacemaker, loop recorder)

3.2 General Warnings

Please take note of all warnings before operating. Failure to do so may result in ineffective treatment or personal injury.



- **DO NOT** drink any beverages high in sugar (e.g. soda / fizzy drinks), or any caffeine (including tea, coffee, and energy drinks) for at least **one hour** prior to a training session.
- **DO NOT** use under the influence of alcohol.
- **DO NOT** use under the influence of mind-altering prescription drugs not approved by your doctor, and/ or illicit drugs.
- **DO NOT** expose to any flames, sources of ignition or incandescent material.
- **DO NOT** use in presence of strong heat, magnetic or electrical field.

3.3 General Precautions

Please take note of the following precautions for optimal use of Axon, and to avoid possible damage to the equipment or other property.



- Dreadlocks, beads, or any other hairstyle or head covering that cannot be removed may interfere with the headset sensors.
- Store the headset in its case when not in use.
- **DO NOT** smoke while using Axon.
- **DO NOT** use outdoors.
- **DO NOT** leave exposed to sunlight for long periods of time
- **DO NOT** use harsh solvents to clean the device.
- **DO NOT** immerse in water or any other liquid.
- **DO NOT** dispose of improperly or expose to fire in any way for disposal.

4 Getting Started

4.1 Axon System Contents

- 1 x Axon 2 headset
- 1 x Axon 2 headset case
- 1 x Quick Start Guide
- 4 x spare sensors
- 1 x water pen



4.2 Before each use

4.2.1 Headset preparation

Check the general condition of the Axon headset visually to ensure there are no signs of damage to:

- Any of the plastic housing

Do not use the headset if the plastic housing is damaged, and contact Exsurgo Support.

- The silver coating on the sensors

Replace the sensors if the silver coating is damaged, exposing

the uncoated area underneath; see examples below.



4.2.2 Install the Axon App



A smartphone or tablet is required to run the Axon App, with compatibility for iOS 16 or later, or Android 9 or later.

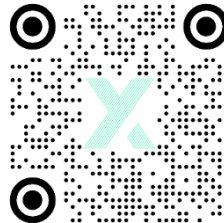
Install the Axon App by:



Axon

- visiting our website at <https://exsurgo.com/products/axon>
- scanning the QR Code below,
- or searching for **Exsurgo Axon** on the Apple App Store or Google Play Store.

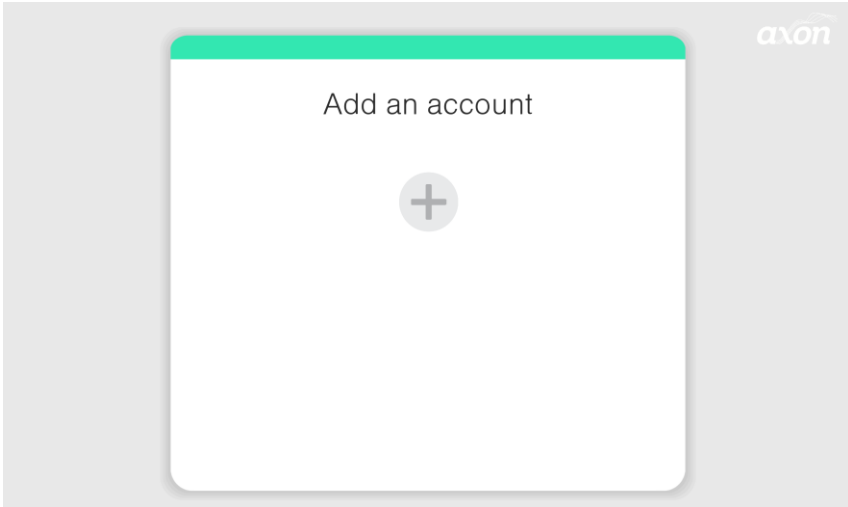
Follow the prompts in the App to log in, using the Email address and Password you entered when you registered.



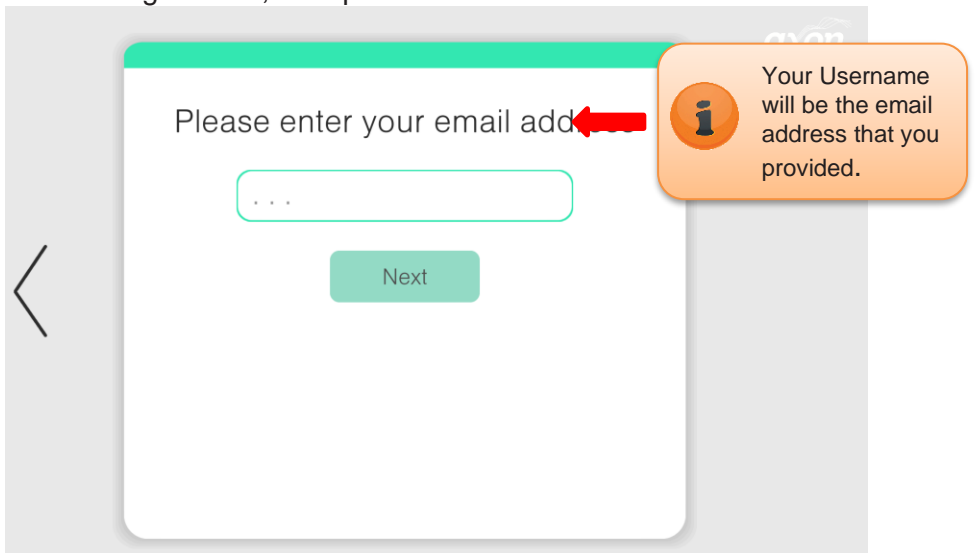
4.3 Starting the Axon App for the first time

4.3.1 Adding an Account

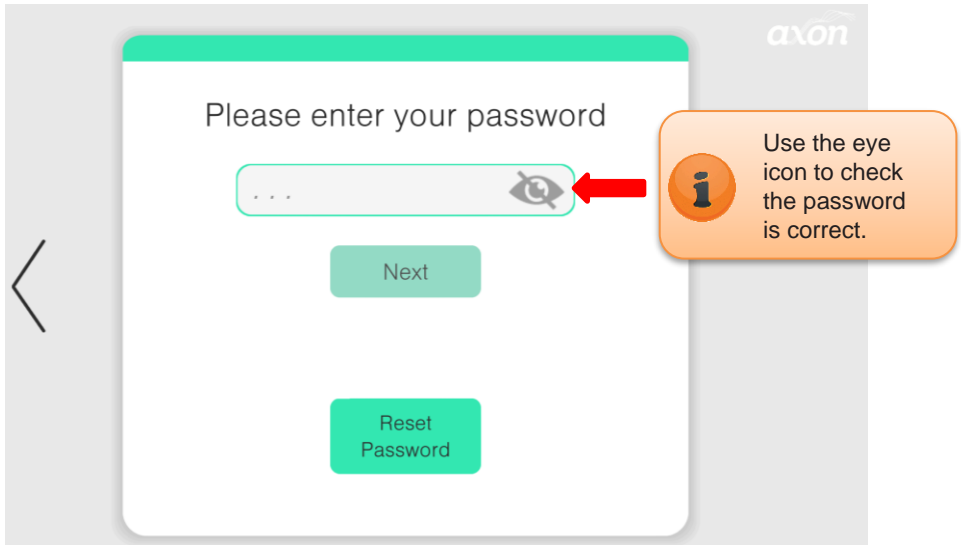
To add a user account for the first time select 'Add an account'



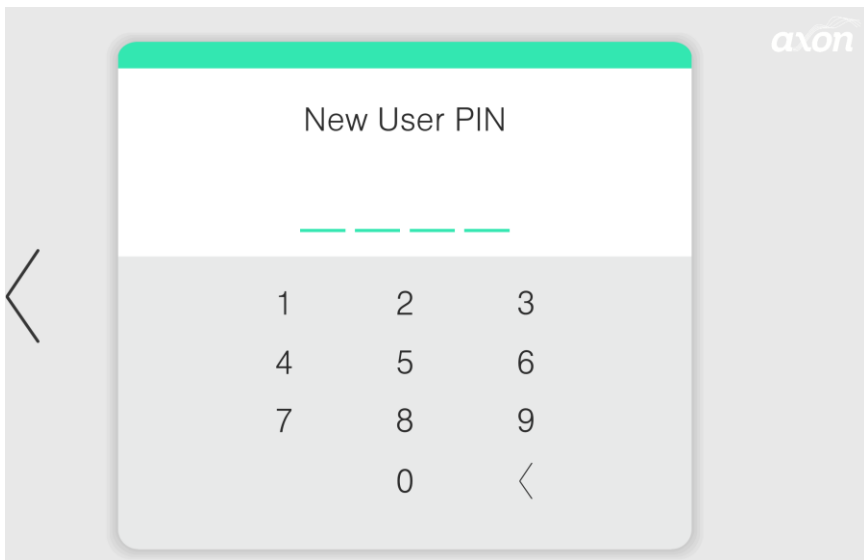
Enter your email address you provided when you completed the account registration, then press 'Next'



Enter your Password (case sensitive), then press 'Next'.



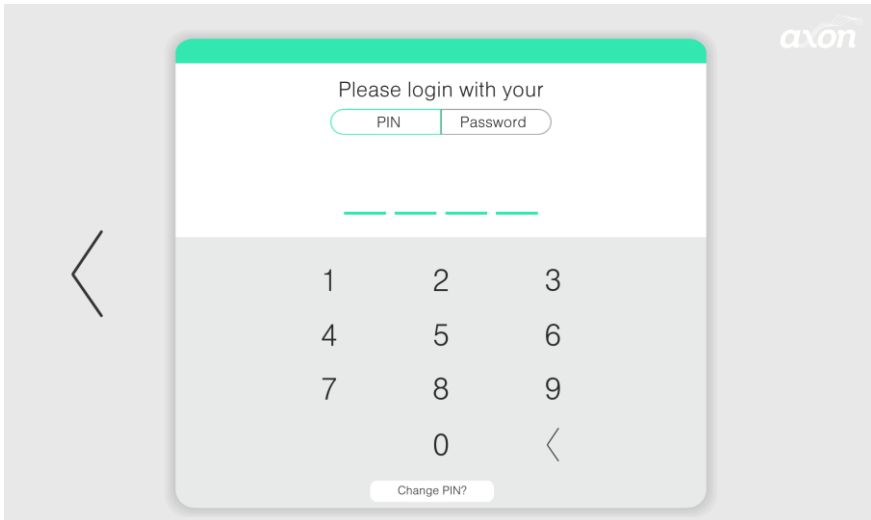
Create a four-digit PIN to be used for future log-ins. You will be asked to confirm your PIN by re-entering it.



4.4 Starting your first session

4.4.1 Logging in to the App

Select your user account from the user list and enter your four-digit pin or password.



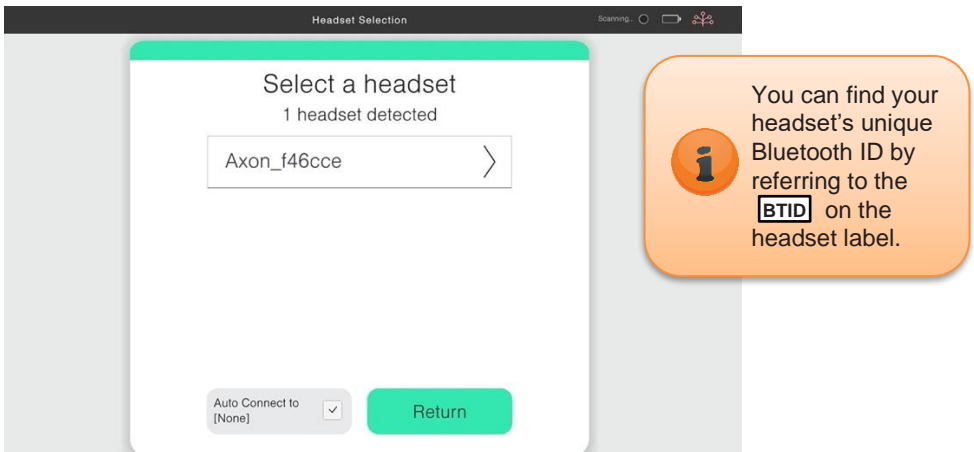
4.5 Wearing the headset

4.5.1 Turning on the headset

Press the power button on the top of the headset to turn the headset on. The Status Indicator on the headset will flash blue, indicating the headset is powered on and waiting for a Bluetooth connection.



Once switched on, the Axon app will detect the Axon headset and display the headset's Bluetooth ID.



Confirm your headset's Bluetooth ID by selecting it, to connect to your headset.

Once successfully connected, the Status Indicator on the headset will stop flashing and light up a steady blue.

4.5.2 Preparing the Sensors

The signal quality can also be improved by wetting the sensors with water. Using the included water pen, lightly brush water over the sensor surface.

Use deionised or distilled water to avoid mineral residue building up on the sensors.



While some users may be able to get good signal quality without needing to wet the sensors, we recommend you start by using the water pen to obtain a good connection quickly and easily.

4.5.3 Putting on the headset

Position the headset in the correct orientation - facing down on a flat surface, with the earpiece sensors at the top (the left earcup on your left).

Pick up by holding the earpieces, and place over your ears. Adjust

the earpieces by sliding them up or down, to ensure a firm, comfortable fit.



Ensure the sensors remain symmetrical across the middle of your head by adjusting the earpieces on both sides to the same setting, indicated by the arrow and numbers on the side of the earcup sliders.

Try to move as much hair as possible away from underneath the sensors to ensure good skin contact.

Massage the sensors into the scalp to dislodge any hair that may be trapped, and to ensure good contact with the scalp.



The Axon headset should now sit comfortably, evenly, and firmly over the middle of the head.







All four sensors should have direct connection to the skin, unobstructed by hair.

4.6 Progress tracking questionnaires and diaries

The Axon app will prompt you to complete Progress Tracking Questionnaires and a Medication Diary. This will help you monitor your overall progress throughout your training period.

Give your best recollection of how you felt over the last 24 hours, and your daily medication.


Over the last 24 hours, please rate your...

<i>i</i> Pain	<i>i</i> Anxiety	<i>i</i> Depression	<i>i</i> Stress	<i>i</i> Activity	<i>i</i> Sleep
					
					
					
					
					
					

More

Less

Medication

Medication	Daily Dosage	Reason
 Add New Medication		

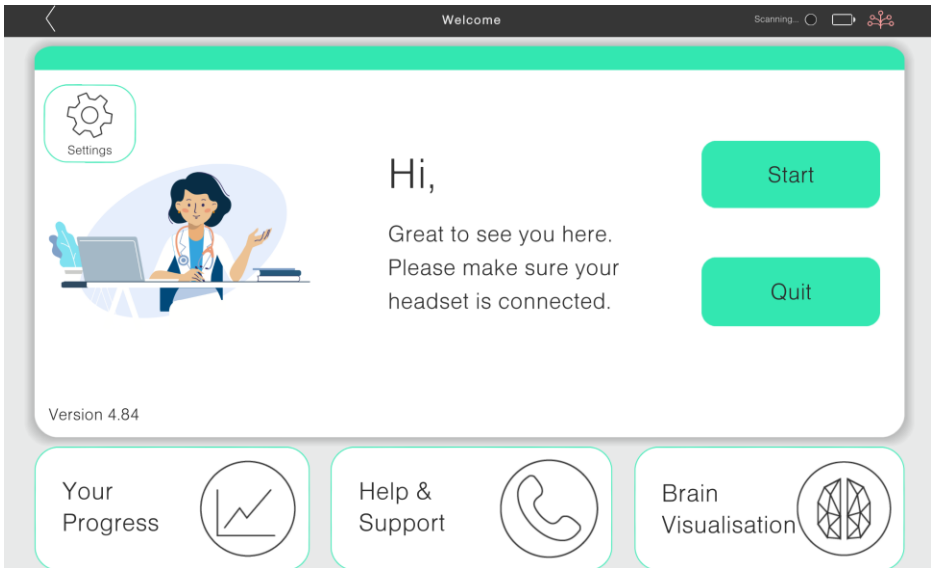
Press the forward arrow to proceed to the next page, or the back arrow if you want to change your previous answers.

4.7 Welcome Page

This is the main page where you can **Start** your Neurofeedback training session.

You can also navigate to the following sections of the Axon app:

- Your Progress** Track your training progress.
(Refer to Section 5)
- Help & Support** View instructional videos and support documentation.
(Refer to Section 6)
- Brain Visualisation** View a representation of your neuronal activity.
(Refer to Section 7)

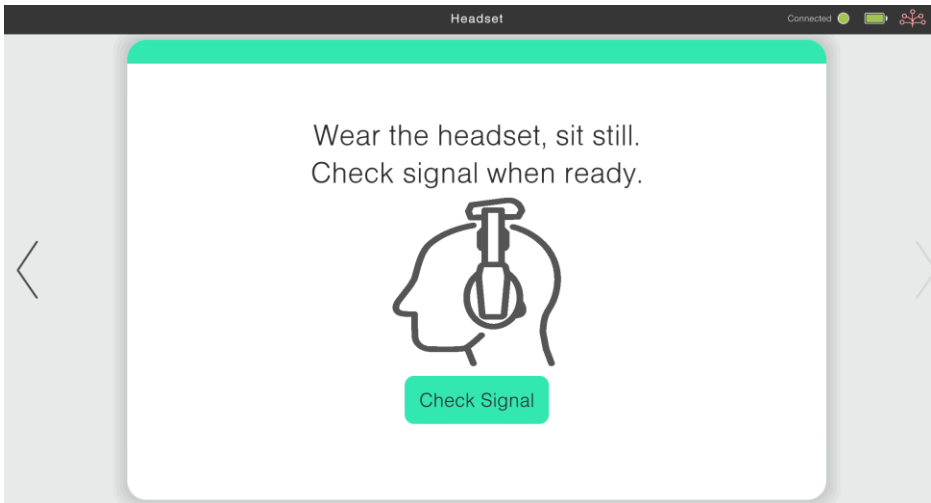


4.8 Starting a Session

When you are ready to commence your session, turn your headset on, wear your headset and press the 'Start' button.

4.8.1 Headset Connectivity Check

The Headset Check will help you to get the best possible connection for your session.



When you are ready, press the 'Check Signal' button to proceed.

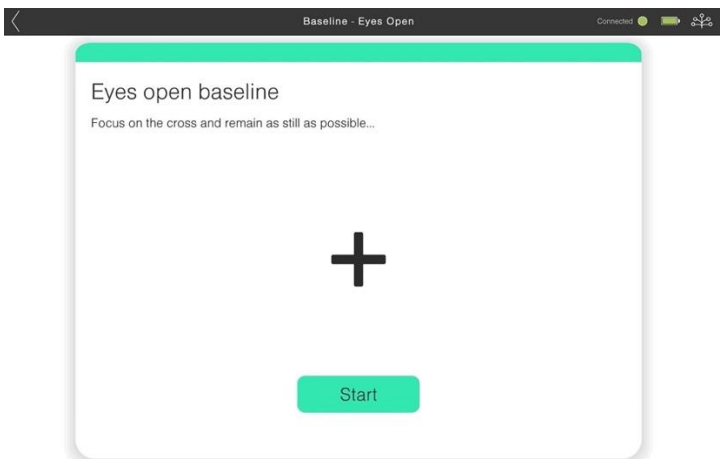
4.8.2 Complete Pre-session baselines

Before and after each training session you will be asked to complete baseline readings of your brain activity. There are two pre-session baselines – one with eyes open, followed by another with eyes closed.

Eyes Open Baseline

The eyes open baseline is important because it sets the game

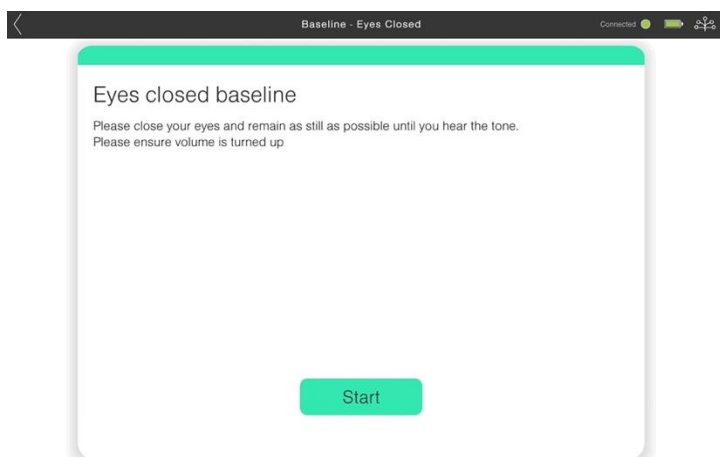
threshold for your session. Press 'Start', focus on the cross, remain as still as possible, and try to keep your mind clear of distracting thoughts in order to get an accurate reading.



Eyes Closed Baseline

Press 'Start' and close your eyes to begin the baseline.

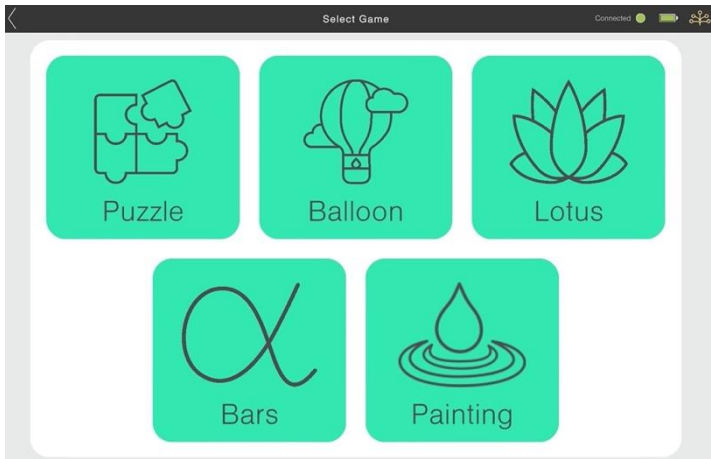
You should remain as still as possible with your eyes closed. The app will tell you when to open your eyes by sounding a tone and announcing the completion of the baseline.



Once the baseline measurements have been completed, proceed when you are ready to the game selection.

4.8.3 Choose your Game

Choose the game you would like to play for your session. You will stay with this game for the duration of the session.



When you are ready, press 'Start' to begin your training block. Relax, keep your eyes open, and try not to move too much.

When you first begin your neurofeedback training, you should try a different game each day and choose the one that makes you feel most relaxed and happy.



Once you have chosen your favourite, stick with that game for the first two weeks of your training period, while your brain gets used to neurofeedback.

Try different games if you wish, as your preference may change during your training period.

The most important point to remember is that the aim of the games is to make you feel relaxed and comfortable.

Game overview

Around the edges of the game screen are elements that will help you visualise your progress.



The Alpha bar (on the left)

This bar indicates your Alpha frequency level, and the session reward threshold. When you exceed your reward threshold the bar will turn green, the game will progress and you will hear an audible tone when you stay above your threshold for a time.

The Movement bar (on the right)

This bar will indicate excessive movement or interference with the sensors. Excessive movement or interference will pause the game. This includes clenching

The Block Progress bar (on the bottom)

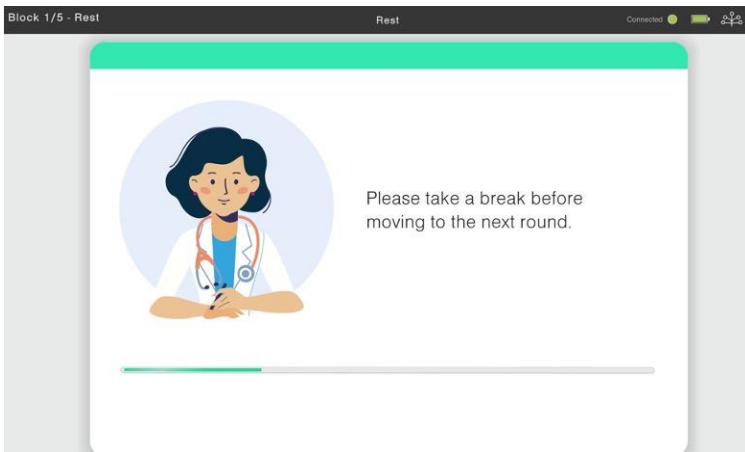
indicates your progress through the current training block.

4.8.4 Rest Periods

After each training block you will be asked to rest before starting the next training block.



This is a good time to adjust your training position, have some water, or close your eyes briefly if you feel sleepy.



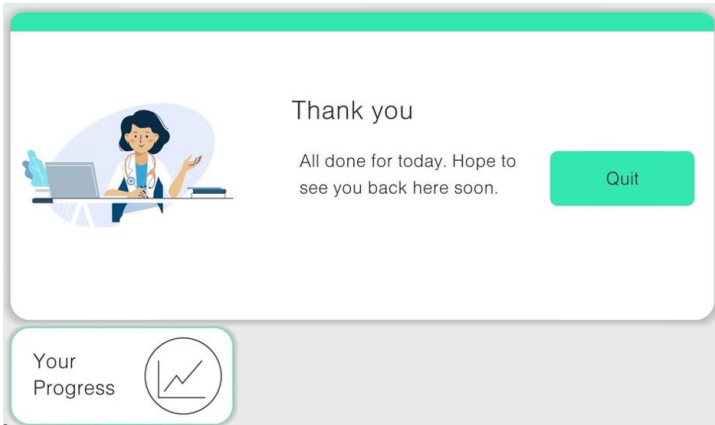
Proceed to the next training block when you are ready.

4.8.5 Complete final Baseline

Once you have completed the five training blocks, you will be asked to complete another eyes-open baseline. This will be identical to the pre-session eyes-open baseline described in Section 4.8.2.

4.8.6 Session Complete

Your training session is now complete! You will return to the home screen, where you can choose to quit and close the App, or review your current session progress.



4.8.7 After the Session is completed

After each training session you should:

Turn off the headset.

Place the headset in its case.

Close the app.

5 Tracking Your Progress

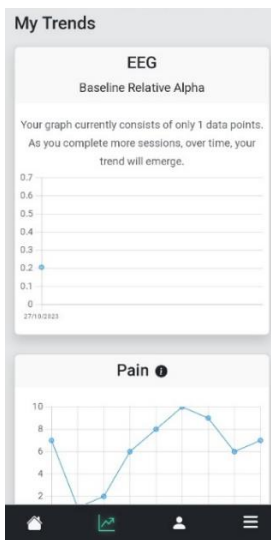
You can review your training progress by selecting 'Your Progress' on the Welcome page, or after you have completed your session.

The app will open a web browser where you can view your overall progress summary, your EEG and Questionnaire trends, as well as your profile and subscription status, by selecting the tabs on the bottom of the screen.

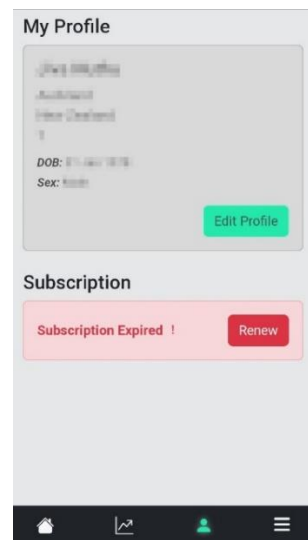
This feature will help you review your training frequency to ensure you are completing enough sessions to achieve your goals.



Overall Summary



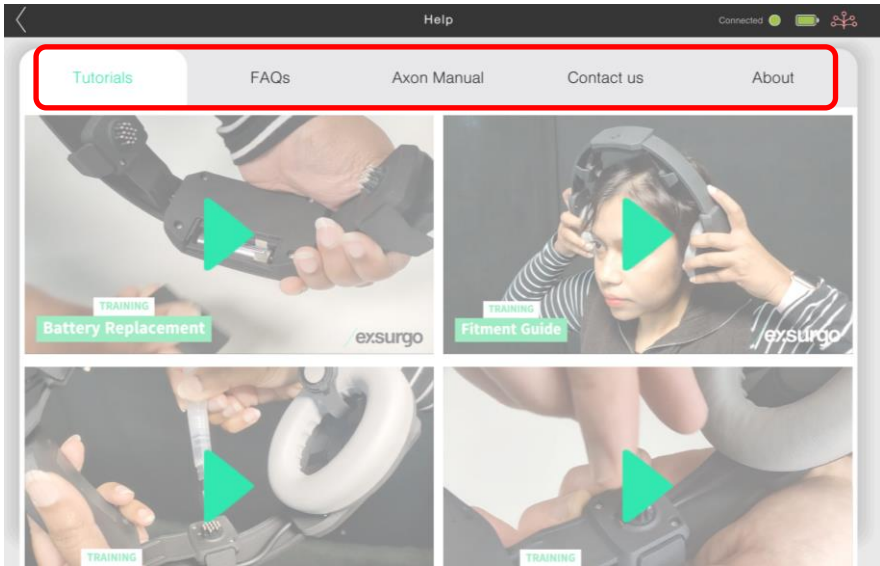
My Trends



My Profile

6 Help & Support

The Help & Support panel has additional resources, viewed by selecting the tabs at the top of the panel.



Tutorials

Short instructional videos to help with fitment and maintenance.

FAQs

Frequently asked questions. Please take the time to read the FAQs as they will help you to have successful training sessions.

Axon Manual

Instructions for use; a copy of this manual.

Contact Us

Contact details for technical support.

About

Information about the software App.

7 Brain Visualisation

The Brain Visualisation page allows you to view your brain activity in real time.



Try clenching your jaw to see the headset respond to your movements.

This shows you how important it is to keep nice and still during your training blocks.

8 Maintenance & Cleaning

8.1 Cleaning the headset

Use a microfibre cloth to wipe down the outer surfaces of the headset after every use. Do not use any solvent- or alcohol-based cleaners to prevent damaging the headset.

Check the sensors for damage or wear, and replace them if necessary. Replacement sensors can be ordered by contacting Exsurgo support.

8.2 Battery Life

A new AAA battery can provide approximately 20 hours of usage. The battery life will be influenced by various factors, including:

- Ambient temperature
- The age and usage history of the battery

To conserve battery life, the headset will enter sleep mode if it has not connected to the App after 3 minutes. To restart, press the power button to turn the headset on.

8.3 Battery Replacement



- Remove the battery cover.
- Remove the battery by pulling on the battery ribbon.
- Install a new battery, taking note of battery orientation and ensuring the ribbon remains under the battery.
- Replace the battery cover.
- Switch on the headset and confirm the blue light appears.
- Dispose of the empty battery according to local regulations.

9 Transporting, Storing and Disposing of your Headset

9.1 Shipping

Ensure the headset and its accessories are safely packaged, prior to shipment.



Insert the battery into the headset prior to shipment.

CAUTION

DO NOT leave any batteries loose in the shipping box.

9.2 Storage

When not in use, the Axon headset and its accessories should be stored in the provided case, in a safe dry location out of direct sunlight.

9.3 Disposal



DO NOT dispose of as unsorted municipal waste. Must be recycled in accordance with WEEE Directive 2012/19/EU.

WARNING

To arrange for return or collection contact your Axon supplier for disposal information.

10 Technical specifications

10.1 Device specifications

Dimensions	21cm (l) X 20cm (w) X 8cm (h)
Weight	0.3Kg
Battery Size	AAA
Battery Voltage	1.5V
Operating Temperature	5°C to 45°C
Operating Relative Humidity	45% to 85% at 25°C (non-condensing)

10.2 EMC guidance & Declaration

Guidance and Manufacturer's Declaration – Electromagnetic Emissions and Immunity

Intended for use in a typical electromagnetic environment such as may be found in a typical home, commercial or hospital environment.

11 Contact information

For further information about this user manual, service of the device, the company or product please contact us at:

Email: support@exsurgo.com

Phone: New Zealand Customers - 0800 AXONXA or
0800 296 692

International Customers - +64 (9) 218 3583

Web: www.exsurgo.com

