alevia PRO

Neurofeedback Headset

Instructions for Use

Alevia PRO is a wearable and non-invasive EEG neurofeedback system for managing chronic pain at home.



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alevia

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1 Getting Started

To install the Alevia app, you need access to a mobile device or laptop/desktop and internet connection. Alevia PRO is for one user only. Your headset and app are linked to your account and should not be used or shared by anyone else.

1.1 Install the Alevia App (first time only)

You can do this by either:

- Visiting our website at **vermillionhealth.com/product/alevia-neurofeedback-system/**
- Scanning the relevant QR Code below
- Searching for Vermillion Health Alevia on the Apple App Store or Google Play Store. Desktop version can be found on Microsoft Store.

Download on the App Store — SCAN ME

GET IN ON Google Play — SCAN ME

Get it from Microsoft — SCAN ME

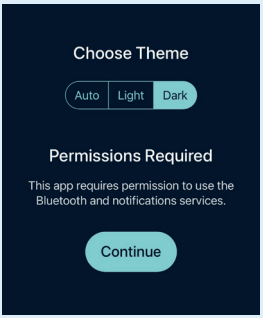
Software Requirements:
iOS: 16.4 or higher, Android: 11 or higher, with at least 4 GB RAM, Windows: 10 (version 1809) or higher.

1.2 Setting up the Alevia PRO account ready for your first session

A

Open the Alevia app on your mobile device.

B

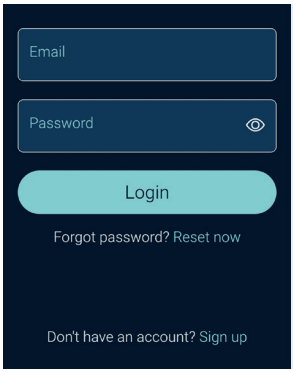


Grant permission for app and choose either light or dark theme for the app.

The theme can be changed later in the app Account section under Theme.

When prompted by your device, grant all requested permissions by selecting “Allow,” “While Using the App,” or the equivalent option. These permissions are required for Alevia PRO to connect to the headset via Bluetooth and deliver notifications.
If these permissions are not granted, the app may not function correctly and could prevent you from using the system as intended.

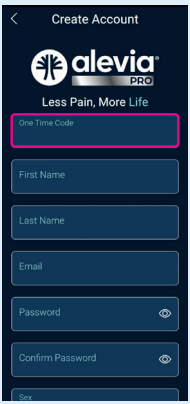
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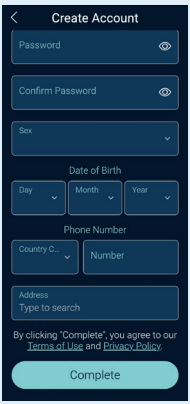


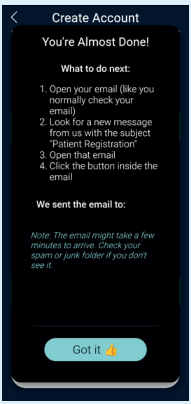
The login screen will ask for your Email and Password. If using the first time press the “sign up” to set up a new account.

D

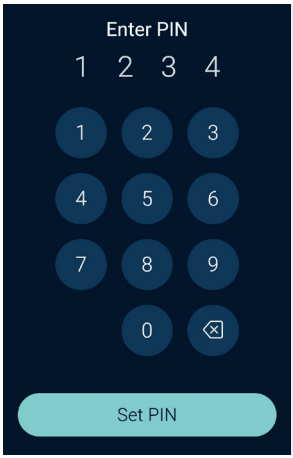
Enter the One-Time Code found inside the case. Complete the sign-up form to create your account. Then confirm your email using the link in the confirmation email. If you have not received a registration confirmation email, check your spam folder. Confirm your email by clicking the "Confirm my email" button.







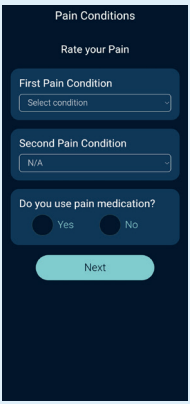
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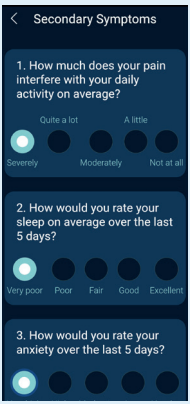


Go back to the Alevia app to sign in. The app will ask you to enter a PIN. Create a four-digit PIN to be used for future log-ins. You will be asked to confirm your PIN by pressing the “Set PIN” button. Next time you use the App, you can log with your PIN or username/ password.

F

The Alevia app will prompt you to complete Pain Conditions and Secondary Symptoms questions. the first time you use the app and then at specific intervals coinciding with badge awards.





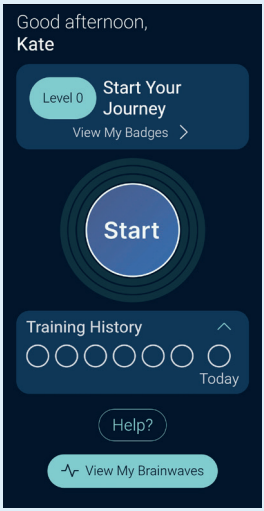
IMPORTANT:

It is essential to fill in these details to define your baseline for the coming treatment. The details you fill in using the app the first time cannot be changed later.

When completing the questionnaires, please base your responses on your best recollection of how you have felt over the previous 5 days, including whether you have taken any medication during that time. You can review this information any time on the Trends screen in the app.

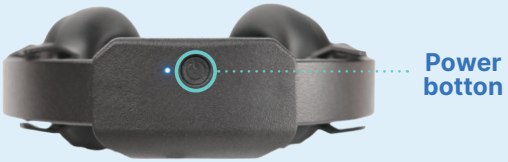
After the 60th badge questions will be only every 15th session. These questionnaires cover your selected pain conditions and any secondary symptoms and are designed to help monitor your overall progress throughout the training period.

After you finished the questionnaire, the home screen will open.

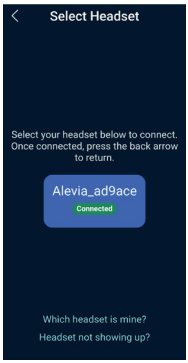


1.3 Connecting the Headset

Press the power button located on the top of your headset to turn it on. The status indicator will flash blue, indicating that the headset is powered on and waiting to establish a Bluetooth connection.



To help conserve battery life, the headset automatically enters sleep mode if it does not connect to the app within three (3) minutes of being powered on. To resume operation, press the power button to turn the headset on.



Go to Account and select your headset. When connected, the headset indicator changes from flashing to solid blue. If the headset does not connect automatically, press Connect Headset. Once connected (green), return to the Home screen.

First-time Use: When you press Start for the first time, the Alevia App detects your Alevia PRO headset and displays its unique Bluetooth ID (BTID). Verify that the BTID shown in the app matches the BTID printed on the headset label.

The signal quality can be improved by lightly moistening the electrode with water. Using the supplied water pen, gently apply water to the surface of each sensor.





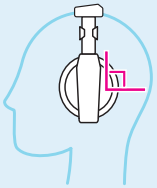
For a visual guide, watch the **“Before you start”** video available in the **Alevia App** (Explore tab) and on the **Alevia website.**

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1.4 Headset fitment guide

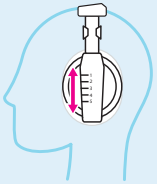
Position

Place the headset comfortably, evenly and firmly across the crown of the head. Use the L (left) and R (right) markings inside the ear cups to align with your left and right ears.



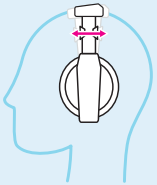
Adjust

The Headset should be vertical, and your ears must be inside the ear cups. Use the adjustment slider to position the ear cups to sit comfortably with the numbers matching on each side.



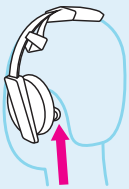
Sensor Electrodes (Top)

Using the sensor grips, massage the top sensors onto the scalp to dislodge any hair that may be trapped, ensuring good contact with the scalp.



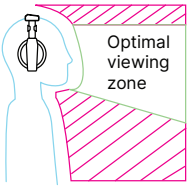
Sensor Electrodes (Bottom)

The bottom sensors should have direct contact with the skin, unobstructed by hair. Remove any long earrings and tie long hair back.



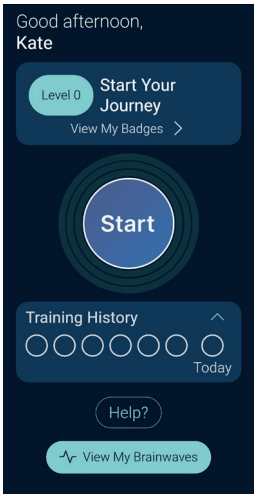
1.5 **Positioning your mobile device** (e.g. tablet)

Please make sure you set up an area where you can sit comfortably in a quiet place where you will not be disturbed, and position your device at eye level.



For a visual guide, watch the **“Fitting the Headset”** video available in the **Alevia App** (Explore tab) and on the **Alevia website.**

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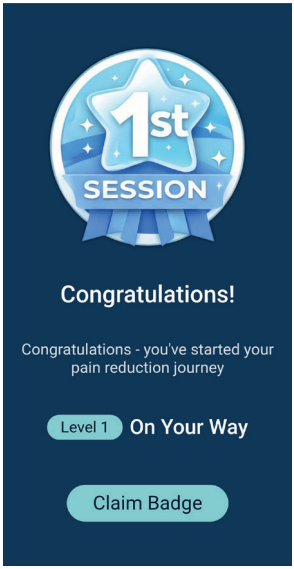


To start your first session—or any future sessions—press the “Start” button in the centre of the Home screen.

For additional guidance, please refer to the Help menu within the Alevia app.

1.6 Session Completion

Once the training session is complete, the app will return to the home screen. From the home screen, you may choose to exit the app or review the progress from the current session.



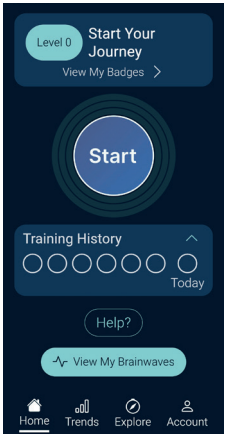


After each training session you should:

- Close the Alevia app.
- Turn off the headset.
- Place the headset in its protective case.

1.7 App Home page

This is the **main page** of the Alevia app, where you can start your neurofeedback training session. From here, you can also navigate to the following sections:



- **Home** – My Badges, Training History, Brainwaves, and access the Help menu.
- **Trends** – Review trend data related to your pain symptoms.
- **Explore** – Watch instructional videos.
- **Account** – View and update your account, connect the headset.

For a visual guide, watch the **"Getting started with the Alevia app"** video available in the **Alevia App** (Explore tab) or the **Alevia website.** More support videos can be found here.

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Data Sharing

You may receive a data-sharing request in the Alevia app. If you receive a request, please make sure you accept it to allow your healthcare provider to view your neurofeedback sessions, pain ratings, and symptom ratings.



2 In the Box

One Alevia PRO Headset with protective case



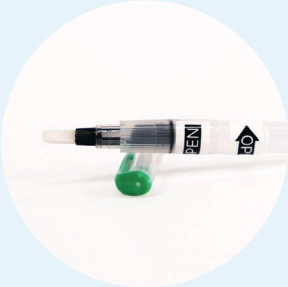
Spare electrodes (qty 2) and the electrode replacement tool

There are two types of electrodes included with your headset. The dome electrodes are designed to sit behind the ears, and the longer ‘spiked’ Flex electrodes are designed to pass through different hair types to connect with the scalp. The headset comes fitted with a set of electrodes, and a spare set of Flex electrodes.



Water Pen (qty 1)

Use the water pen to improve contact between the electrodes and your scalp. For additional guidance, please refer to the Help menu within the Alevia app.



One-Time-Code (qty 1)

Use this code to create your account and activate your subscription.

Note: Water pens are opened clockwise.

To use the Alevia PRO system, you need access to a mobile device, laptop, or desktop computer to install and use the Alevia app.

3 Intended Use and Indications for Use

Alevia PRO is an EEG biofeedback (neurofeedback) system, comprised of an EEG-based neurofeedback headset and a software application that provides visual and auditory signals corresponding to the status of brain activity. Alevia PRO is a battery-powered, non-invasive, non-sterile device that is indicated to support patients in managing chronic pain and anxiety and other associated secondary symptoms. Alevia PRO measures natural electrical activity from the scalp using silver-chloride electrodes.

Alevia PRO is indicated for use by adults (18 years and above) in both a professional (e.g. clinical) and/or home environment.

4 Contraindications, Warnings, and Precautions

Medical Contraindications:

DO NOT use Alevia PRO unless you have discussed its use with a healthcare professional if you have any of the following conditions:

- A head injury, concussion, or similar condition within the past six (6) months that may impair alertness or cognitive function.

- Epilepsy or history of seizures.
- Wounds, active dermatitis, eczema, or open sores on the scalp.
- If you currently have an implanted active electronic device (e.g. pacemaker, Implantable Cardioverter-Defibrillator, loop recorder).



General Warnings:

You need to read and understand all warnings before the use of the device. Failure to do so may result in ineffective treatment or personal injury.

- DO NOT consume beverages high in sugar (e.g. soda or other fizzy drinks) or beverages containing caffeine (including tea, coffee, or energy drinks) for at least one hour prior to a training session.
- DO NOT use the device under the influence of alcohol.
- DO NOT use the device under the influence of prescription medications that may impair alertness or cognitive function, unless approved by a healthcare professional.
- DO NOT use the device if you have a known allergy to silver or silver-chloride.
- DO NOT use the device in the presence of strong magnetic or electrical fields.

- DO NOT use the headset if damaged, or if battery leakage is observed.
- Use only high quality 1.5v AAA alkaline batteries (compliant with IEC LR03).
- NO modification of this equipment is allowed.
- The Alevia PRO headset includes small parts (electrodes) that may present a choking hazard to children. Store in protective case away from children when not in use.



General Precautions

Please observe the following precautions to ensure proper use of Alevia PRO device, and to avoid damage to the equipment or other property.

- Hairstyles or head coverings that cannot be removed (e.g. dreadlocks, beads, or similar) may interfere with proper contact between the headset electrodes, and the scalp.
- Store the headset in its protective case when not in use.
- DO NOT use the device outdoors or while in transit.
- DO NOT expose to direct sunlight for prolonged periods.
- DO NOT use harsh solvents or abrasive cleaners to clean the device. Refer to section 6 for cleaning instructions.
- DO NOT immerse the device in water or any other liquid.

Potential Side Effects

For some users, mild and temporary side effects may occur after performing a neurofeedback session, including:

- Mild headaches
- Fatigue
- Mild scalp irritation

These effects are self-limiting and will resolve on their own without the need for medical intervention. If any effect persists or worsens, discontinue use and consult your healthcare provider.

Precautions Regarding Changes in Device Performance

If the Alevia PRO system does not operate as expected, discontinue use and check the headset fit, electrode contact, battery status, and mobile application function. Poor signal quality, interrupted sessions, connection failures, unexpected application behaviour, or visible device damage may affect device performance.

Do not continue using the device if malfunction is suspected. Refer to the Help & Support on the Alevia App and contact Vermillion Health Technical Support if the issue cannot be resolved. See contact information in section 10.

5 Maintenance

Visually inspect the Alevia PRO headset for wear prior to use to ensure it is in good condition and free from damage. Check the following components:

- Plastic housing

> Do not use the headset if any part of the plastic housing is cracked, damaged or compromised. If damage is observed, discontinue use and contact Vermillion Health Support.

- Silver coating on the electrodes

Inspect the electrodes to ensure the silver coating is intact. Replace the electrodes if the silver coating is damaged or worn (see examples below).

Worn/damaged flex electrodes



Worn/damaged dome electrodes



Replacement electrodes can be ordered by contacting Vermillion Health support.

The Alevia PRO headset must be used only with electrodes supplied by Vermillion Health. Use of non-approved or third-party electrodes will invalidate the product warranty, and correct performance, safety, and measurement accuracy cannot be guaranteed.

6 Cleaning

You can clean the plastic surfaces with an alcohol-free and chlorine-free wipe, e.g. **Clinell® Universal Wipes** (GAMA Healthcare Ltd, UK) or **Tuffie 5® Sanitising Wipes** (Vernacare Ltd, UK).



Do not use any solvent- or alcohol-based cleaners to prevent damaging the headset.

7 Battery Replacement

7.1 Battery Life

A new AAA battery provides approximately **20 hours of normal use.** Actual battery life will vary based on the brand (quality) and chemistry of the battery.

To help conserve battery life, the headset automatically enters **sleep mode** if it does not connect to the app within **three (3) minutes** of being powered on. To resume operation, press the **power button** to turn the headset on.

7.2 Replacing the Battery



For a visual guide, watch the **“How to Replace the Batteries”** video available in the **Alevia PRO App** and on the **Alevia PRO website.**

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To replace the battery:

- Remove the battery compartment cover.
- Remove the battery by gently pulling the battery ribbon.
- Take note of battery orientation. Insert a new AAA battery, ensuring correct polarity as indicated in the battery compartment and ensuring the ribbon remains positioned under the battery.

Only use 1.5V AAA alkaline battery compliant with IEC-LR03 / ANSI-24A (e.g. Energizer Max® AAA).

- Replace the battery compartment cover securely.

DO NOT use the headset without the battery compartment cover in place.

- Switch on the headset and confirm the status indicator light is blue.
- Dispose of used batteries in accordance with local regulations.

8 Electrode Replacement

- Over time, electrodes will wear out. Inspect your electrodes for signs of damage. If you notice **scratches, defects, or wear on the silver coating**, the electrode must be replaced.
- Electrode wear occurs more frequently on the **flex electrodes** located on the top of your head, than on the **dome electrodes** positioned behind your ears.
- For a visual guide, watch the **"How to Replace Electrodes"** video available in the **Alevia PRO App (Trends tab)** and on the **Alevia PRO website.**

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8.1 Replacing Flex Electrodes

1 Remove the old electrode

Gently pull the electrode away from the snap button connector using light pressure.



Flex electrodes and electrode replacement tool

2 Prepare the new electrode

Place the new electrode into the groove of the electrode replacement tool supplied with your headset.

3 Attach the new electrode

Use the tool to press the Flex electrode firmly onto the snap button connector.

4 Attach the second electrode

Repeat the steps above for the second Flex electrode until both are securely attached.

8.2 Replacing Dome Electrodes

Dome electrodes rarely require replacement.

If replacement is necessary:



Dome electrodes

1. **Gently pull the old Dome electrode off the snap button connector.**
2. **Align the new Dome electrode with the connector.**
3. **Press it on firmly by hand.**

No tool is required for Dome electrode replacement.

9 Storage and Disposal

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

As the Alevia PRO headset includes small parts (electrodes) that may present a choking hazard to children, ensure the headset is stored out of reach of children.

Do not dispose of Alevia PRO in regular household waste. Return to your retailer or recycle through official collection points.

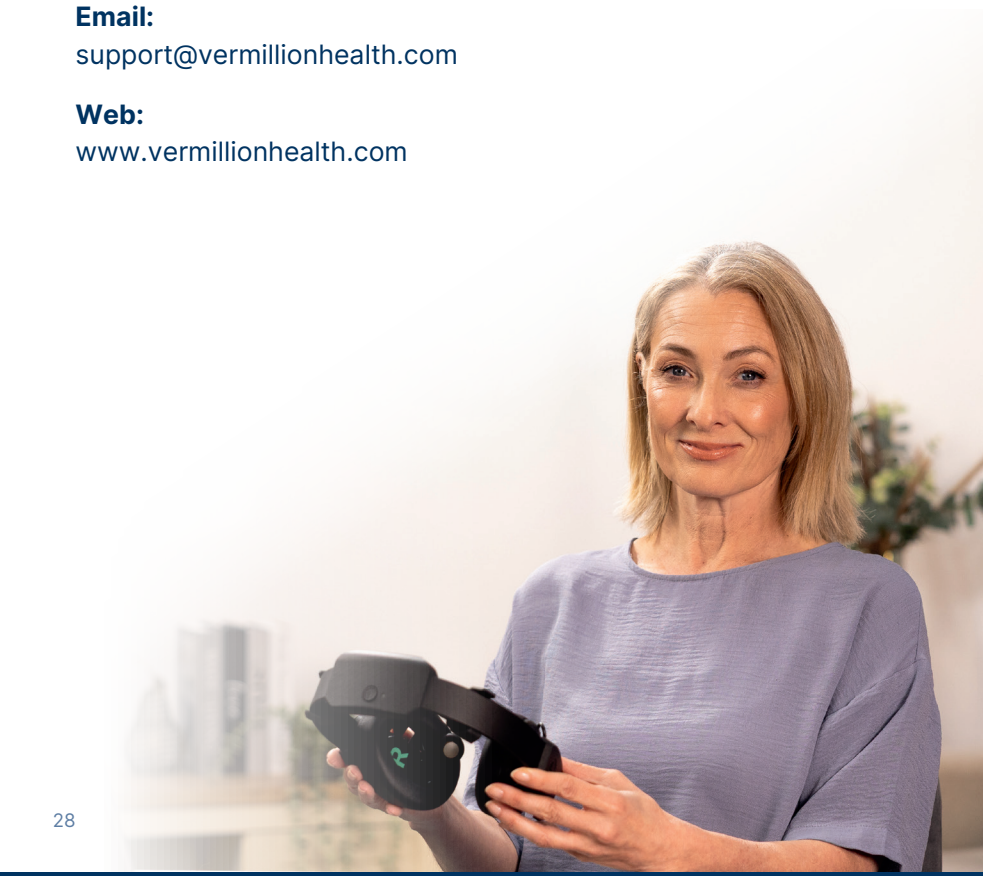
10 Contact Information

For further information about servicing of the device, or the company or product contact the manufacturer using the details provided below:

Alevia Helpdesk:
https://aleviahelpdesk.zohodesk.com.au/portal/en/home

Email:
support@vermillionhealth.com

Web:
www.vermillionhealth.com



Technical specifications

Device specifications

Dimensions	21cm (l) X 20cm (w) X 8cm (h)
Weight	0.3Kg
Battery Type and Size	1.5V AAA alkaline (IEC-LR03 / ANSI-24A compliant)
Operating Temperature and Humidity	5˚C to 40˚C 15% to 90% at 25˚C (non-condensing)
Storage Temperature and Humidity	0˚C to 55˚C 15% to 90% at 25˚C (non-condensing)

Alevia PRO does not require electrical calibration.

EMC guidance & Declaration

Guidance and Manufacturer's Declaration – Electromagnetic Emissions and Immunity

Alevia PRO is intended for use in a typical home, commercial or hospital environment, and meets all relevant requirements.

Alevia PRO uses Bluetooth Low Energy wireless technology operating in the 2.4 GHz ISM band.

If wireless communication is interrupted, neurofeedback may pause, or data may be temporarily unavailable. Move away from strong electrical or magnetic sources if communication instability occurs.

Symbol Definitions and Terminology

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

Symbol	Definition	Reference
	**Manufacturer details** Name and address of the manufacturer	ISO 15223 5.1.1
	**Country and Date of Manufacture** UK (United Kingdom) 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
	**Catalogue Number** Manufacturer's catalogue 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 Alevia PRO App to pair with the Alevia PRO headset	No regulatory requirement
	**Warning: Refer to Instructions for Use** Read Instructions for Use prior to using the system	IEC 60601-1 7.2.3 ISO 7010 M002
	**Warning** Actions or situations that could lead to personal injury. Take note of all warnings before using the device.	IEC 60601-1 Table D2 symbol 2

Symbol	Definition	Reference
	**Caution** Actions or situations that could damage the equipment or other property or interfere with operating the device.	No regulatory requirement
	**Do not dispose of Alevia PRO as unsorted municipal waste.** Do not place in regular waste. Return to your retailer or recycle through official collection points.	UK WEEE Regulations 2013 (S.I. 2013/3113)
	**Power ON/Stand-by button** The Power/Stand-by button toggles the device between the ON state and the low-power Stand-by state.	IEC 60601-1 Table D1, symbol 29
IP22	**Ingress Protection 22** Protected against solid foreign objects of 12.5 mm and greater, and against vertically falling water drops when ENCLOSURE tilted up to 15°	IEC 60601-1 Table D3, Symbol 2
	**Fragile, handle with care** Medical device can be broken or damaged if not handled carefully.	ISO 15223 5.3.1
	**Keep dry** keep away from rain and moisture.	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 CA	**UK Conformity Assessed** UK product marking indicating compliance with relevant UK regulations.	UK Medical Devices Regulations 2002



Alevia PRO is manufactured by:
Vermillion Health Technologies (UK) Ltd
Dukes House 4-6 High Street
Windsor, Berkshire, SL4 1LD
United Kingdom



5-40 C



15%-90%





IFU-0001 Rev 01 Alevia PRO Instructions for Use
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