



INSTRUCTIONS FOR USE



Manufacturer:

**Headsafe MFG PTY LTD
Suite 204, 61 Marlborough Street
Surry Hills, NSW 2010 Australia**

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Chapter 1: Introduction and Product Safety Information

1.1 About Nurochek

The NUROCHEK-I System is a medical device that evokes and records steady-state visual-evoked potentials (SSVEP) via electroencephalography (EEG). It wirelessly communicates with an associated smartphone via Bluetooth and is controlled via a dedicated smartphone application (App).

The NUROCHEK-I System records EEGs through 3 channels of the 10-20 system (O1, O2 and Oz). Saline-soaked foam cylinders act as an electrical conduit to the scalp, allowing it to record brain activity non-invasively.



1.2 Intended Use

The NUROCHEK-I System is intended for prescription use in healthcare facilities or clinical research environments for subjects ages 14 years and older. The NUROCHEK-I System is indicated for the generation of visual evoked potentials (VEPs) and to acquire, transmit, display and store electroencephalograms (EEGs) during the generation of VEPs. The NUROCHEK-I System only acquires and displays physiological signals: no claims are being made for use as a diagnostic criterion or for the analysis of the acquired signals with respect to the accuracy, precision and reliability.

1.2.1 Environment for Use

Use in healthcare facilities or research environments, including:

- Doctor's room
- School "sick bay"/nurse's office

1.2.2 Contraindications

Contraindications include, but are not limited to:

- History of epilepsy and/or seizures
- History of "fits, faints or funny turns"
- Existing structural and/or functional brain diseases
- Blindness
- Open head wounds/breached skin

1.3 Symbol Glossary



Warnings or cautions. These indicate warnings that must be observed for safe operation of the device and/or system.



Consult the instructions for use. Refer to the instructions for use for more information.



Refer to instruction manual/instructions for use. Refer to the instructions for use for more information.



Type BF applied part. This is a conductive part which contacts the body.



Power switch.



Manufacturer lot number.



Manufacturer product code.



Date of manufacture.



Manufacturer details.



Indoor use only.



Single use only.



Medical device.



May be broken if not handled carefully.

Rx ONLY

Prescription only.



Waste Electrical and Electronic Equipment Directive (WEEE Directive). This product should not be disposed of in a landfill. See section 5.1, page 37, for more information.

1.4 Abbreviations

App	Application
CMRR	Common mode rejection ratio
EEG	Electroencephalography
IFU	Instructions for use
OEM	Original equipment manufacturer
OS	Operating system
SSVEP	Steady-state visual evoked potential
VEP	Visual evoked potential
FCC	Federal Communications Commission

1.5 Safety

This device should only be used by trained operators familiar with the device, its intended use and any additional instrumentation. Prior to use, read these instructions for use (IFU).



Warning

This device is to be used under direct medical supervision or by a medical professional.

Rx ONLY

Wear medical examination gloves when cleaning, fitting and manipulating the Headset.

Please read the contraindications (section 1.2.2, page 5) before use.

Charging

Use only the supplied charger to charge the Headset.

Charger must only be used with mains power: 100V-240V, 50/60Hz.

Avoid contacting applied parts (e.g. electrode openings) on the Headset while the Headset is connected to the charger.

Temperature of the Headset may increase while charging.

Disconnect the Headset from charger before use.

If the rear LED indicators flash amber, it is strongly recommended that the Headset is charged as soon as possible.

NOTE: The Headset when powered off enters a sleep mode, in which the device will draw less power but still drain the battery overtime if not placed on charge. It is recommended that if the device is to be used within 2 weeks of powering off, that it be placed on charge to have sufficient battery for use once powered back on.

Do not use excessive force when opening the charging port cover (Figure 2-1 C, page 9).

Discontinue use of the Headset if the charging port cover is dislodged or absent from the Headset.

Flashing Lights

The Headset produces bright flashing lights. These lights may trigger a seizure in people with photosensitive epilepsy.

Repair and Servicing

Do not repair, disassemble, service or perform maintenance on the Headset or its accessories.

No modification of the NUROCHEK-I System is allowed.

Cleaning

Follow the cleaning instructions prior to use and between each usage (see section 3.7, page 18).

Mechanical Failure

If the Headset has signs of mechanical failure, discontinue use and return to the manufacturer.

Foam Cylinders

Choking hazard. Do not consume the foam cylinders. Keep out of reach of children.



Foam cylinders are **single use only**. Dispose of foam cylinders after use.

Defibrillator Use

The Headset and all accessories are not defibrillator-proof. Personal harm and/or damage to the device may occur if used with a defibrillator.

Remove the Headset and all accessories from subject prior to defibrillation.

Potential Adverse Events

Discomfort from prolonged use of the Headset. Discontinue use on subject and seek medical advice.

Eyestrain from prolonged exposure to visual stimulus. Discontinue use on subject and seek medical advice.

Seizures in subjects with photosensitive epilepsy. Discontinue use on subject and then perform first aid. Contact an ambulance.

Flicker vertigo from prolonged exposure to visual stimulus. Discontinue use on subject and seek medical advice.

Electromagnetic Emissions and Immunity

The NUROCHEK-I System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

The use of accessories other than those specified for the device is not recommended as it may result in increased emissions or decreased immunity of the device.



Caution

Intended Use

The Nurochek device should not replace clinical evaluation. Intended use is as per section 1.2, page 5, and does not replace clinical judgement.

Batteries

The Headset contains an internal battery. Local ordinances should be followed to safely dispose of all electronics.

Do not use the NUROCHEK-I System in the presence of flammable gases.

Limitations of Use



The NUROCHEK-I System is intended for **indoor use only**.

The NUROCHEK-I System is designed to be used within 15-35°C (60 - 95°F) in 20-80% humidity.

The Headset is not waterproof: do not attempt to submerge Headset in liquid.

Wireless connectivity line-of-sight range is 1m (3ft). However, use in vicinity of other wireless devices and obstacles may lower this range.

App Use

The smartphone operating the App to be used with the Headset must be secured with PIN/Password or biometrics (e.g. fingerprint authentication).

Do not allow other persons access to the App or Headset.

1.6 Manufacturer



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Suite 204, 61 Marlborough Street,
Surry Hills, NSW 2010 Australia
Phone: +61 418 253 333
www.headsafe.com

1.7 Country of Origin

Australia

Chapter 2: Product Introduction

2.1 Product Details

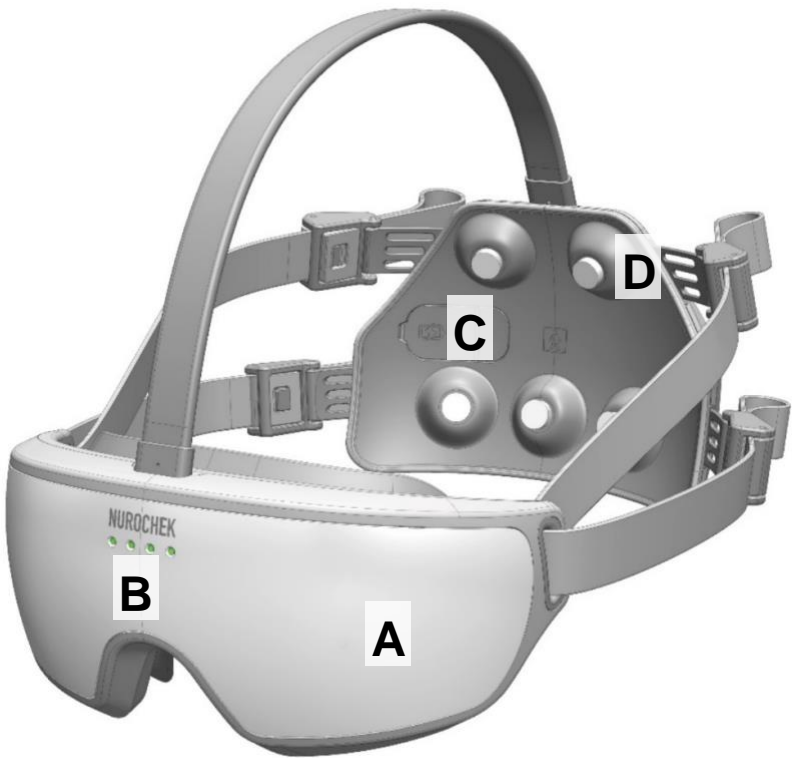
2.1.1 Product Components

Table 2-1: Nurochek components and part names.

Part	Product Code	Old Product Code
Nurochek Headset	HS01-001	CRY09-01
Nurochek Foam Cylinders (100-pack)	HS01-092	CRY09-213
Nurochek Strap	HS01-059	CRY09-161
Charger	HS01-014	CRY09-46
Charger Blades (USA, AU, EU, UK)	HS01-093	CRY09-214
Nurochek iOS Application	HS01-053	CRY09-154

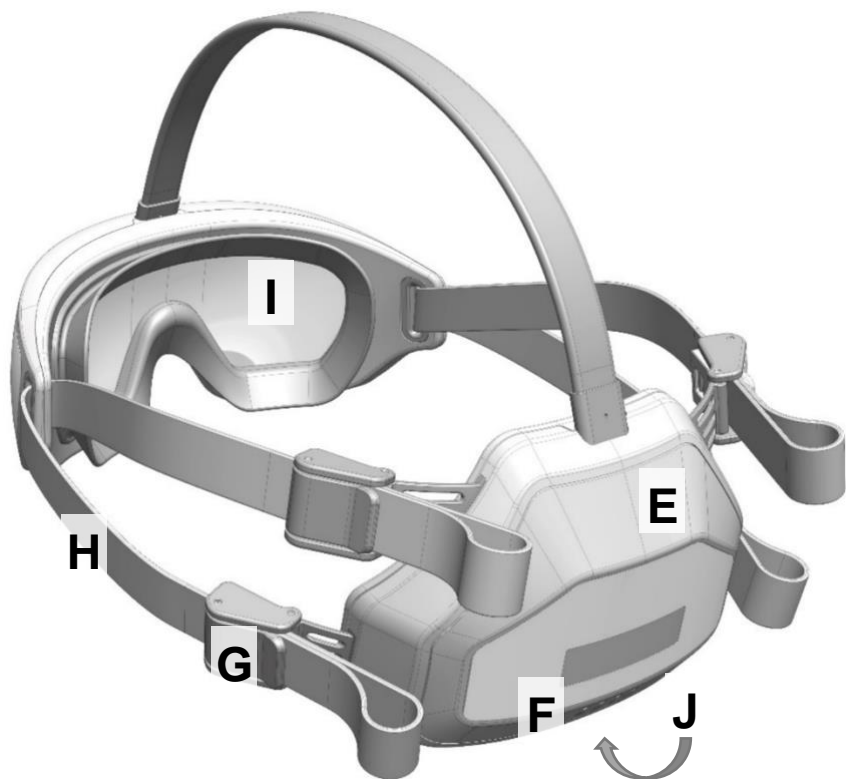
Disclaimer: Old product code apply to NUROCHEK-I system manufactured prior to 19-Oct-2020.

2.1.2 Device Features



- A: Front visor housing
- B: Front indicator LEDs
- C: Charging port cover
- D: Electrode openings (with foam cylinders inserted)

Figure 2-1: Front view of Nurochek Headset



- E: Rear sensor housing
- F: Rear indicator LEDs
- G: Buckles
- H: Straps
- I: Visual stimulus
- J: Power button (below rear indicator LEDs)

Figure 2-2: Rear view of Nurochek Headset

2.1.3 System Diagram



Figure 2-3: NUROCHEK-I System diagram

Disclaimer: Old product code apply to NUROCHEK-I system manufactured prior to 19-Oct-2020.

2.2 Packaging

Table 2-2: Packaging Contents

Part	Product Code	Old Product Code	QTY
Nurochek Headset	HS01-001	CRY09-01	1
Nurochek Foam Cylinders (100-pack)	HS01-092	CRY09-213	1
Nurochek Strap	HS01-059	CRY09-161	1
Charger	HS01-014	CRY09-46	1
Charger Blades Kit (includes USA, AU, EU, UK blades)	HS01-093	CRY09-214	1
Instructions for Use	HS01-019	CRY09-71	1
Nurochek EVA pouch	HS01-228	CRY09-383	1

Disclaimer: Old product code apply to NUROCHEK-I system manufactured prior to 19-Oct-2020.

Packaging should be intact upon receipt. All contents should be carefully checked for damage prior to use. Damaged packages or contents should not be used and should be returned to manufacturer. Manufacturer details are in section 1.6.

Saline solution is not supplied as part of the packaging.

2.2.1 Storage and Handling

All components should be stored, handled and transported in the EVA pouch under dry and ambient conditions.

See cleaning instructions in section 3.7, page 18.

The Headset is not waterproof. Avoid spraying, pouring or spilling any liquid on the Headset except when directed by the instructions.

All components and packaging should be treated with care. Improper use or handling may lead to damage or improper functioning of the device.

Store Headset securely to prevent non-authorized access.

Insert and then dampen foam cylinders carefully with normal saline (not supplied) to prevent excess liquid spillage onto rear of Headset, connectors and charging port.

Always ensure charging port cover is present, intact and pressed into place after disconnecting charger and before cleaning or use.

2.2.2 Use Lifetime

1,500 light stimulus cycles.

Chapter 3: Headset and Application Use

3.1 Minimum System Requirements

To operate the Nurochek App, the smartphone must meet the following requirements:

- Model: iPhone 6s
- iOS version: iOS 13.6.0 and subsequent. The latest iOS version must be installed
- Do not install the Nurochek App on a "jailbroken" smartphone (i.e. factory restrictions on the device have been removed)

3.2 Cybersecurity

Internet connectivity (Wi-Fi and/or cellular data) is required to use this App. **Ensure that only trusted networks are used.**

Only download and update the Nurochek App from the Apple's official App Store.

Never share your Nurochek account credentials with anyone.

Each account must be associated with at least 1 Headset prior to creating or viewing subjects. Please go to section 3.5, page 14, for instructions on associating your Headset to your account.

Log files are kept on a server to document any potential cybersecurity breaches. These logs record login attempts (successful and unsuccessful), tests performed and all other activities that communicate with the server.

Ports: only HTTPS outbound (port 443) is used for all communications.

When communicating, mutual authentication between the server and the App takes place. If either authentication is compromised, no communication will be possible and the app is effectively disabled, preventing any further cybersecurity breaches.

If a cybersecurity incident becomes known, immediately discontinue use of the app. Log out of the App on all devices, and contact the manufacturer.

When the app reaches end of life, Headsafe MFG may no longer be able to reasonably provide security patches or software updates. If the device remains in service following the end of support, the cybersecurity risks for end-users can be expected to increase over time.

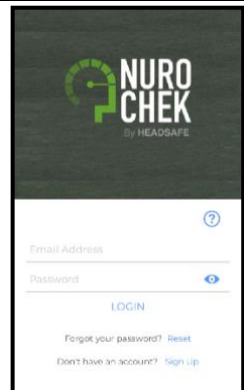
3.3 First Time Setup

Before the NUROCHEK-I System can be used for the first time, the Nurochek App must be downloaded from the App Store and a new account must be registered.

- | | |
|----|---|
| a) | Remove the protective film on the front of the Headset and over the label on the back of the Headset. |
| b) | Charge the Headset with the included charger until fully charged (Section 3.12, page 31). Disconnect Headset from charger when fully charged and close the charging port cover. |
| c) | Establish internet connection on the smartphone.

Download the App onto the smartphone via the App Store. |
| d) | Search for 'Nurochek' in the search tab on the App Store. Select 'Nurochek by Headsafe' App.
Select 'GET' to download and install the App.
After the download is completed, the App will be on the desktop screen on your iPhone. |

- e) Open the App and create a new account by selecting the **'Sign Up'** link on the bottom right. This will redirect to the Nurochek online server to register a new account.



Input your licensed healthcare professional information required on the 'Registration' screen.

Password: Your chosen password must have the following features:

- f)
- minimum of 8 characters
 - at least one capital letter, one number and one non-alphanumeric (special) character

Select **'Register'** on the bottom of the 'Registration' screen to finalize registration.



- g) After registration, an authentication email will be sent to the registered email address.

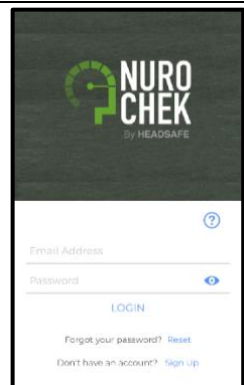
- h) Open the link provided in the email to authenticate your account.

In the App, enter your registered user credentials (email address and password) and select **'LOGIN'** to login.

- i) If you have forgotten your password, select **'Reset'** to initiate a password reset through the Nurochek online server.

The Nurochek App can only be accessed with your registered user credentials. Keep these details secure.

Warning: Do not share your user credentials with others.



3.4 App Navigation

The App has tabs at the bottom of the screen, which will be referenced throughout these instructions:



The tabs allow navigation within the App. Select the respective icon to switch to the tab. The current tab is highlighted in black; all other tabs are in white.

3.5 Device Association

Prior to use, the Headset must be associated with your account.

Headset:

Turn on Headset by holding the power button (see Figure 2-2 J, page 10) for at least 2 seconds. The Headset lights will flash when powered on.

If you cannot turn on the Headset, please charge the Headset for at least 1 hour (see Section 3.12, page 31).

Smartphone:

Ensure Bluetooth is enabled on your phone.

Go to the Headsets tab. The Headset will then attempt to pair to your phone.

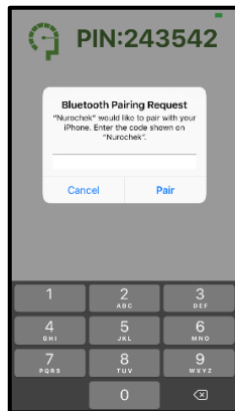
If a prompt appears on your smartphone asking for permission to pair, press 'Yes'.

When the Headset attempts to pair with your smartphone, a prompt may ask for the pairing code. The pairing code will be a 6 digit randomly generated code displayed in the background of the screen. Enter this code to pair the device.

Upon successful connection, your phone may vibrate (depending on your phone's settings).

After success pairing, the rear of the Headset will have a solid blue light.

After confirming this, please log out of the App and then log back into the App to activate all features.

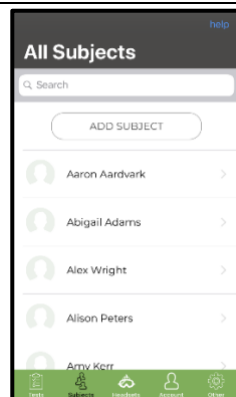


3.6 Subject Information Management

3.6.1 New Subject

Before the NUROCHEK-I System may be used on a subject, the subject must be added to the testing database. **Before you can add a subject, you must associate your Headset with your account (see Section 3.5, page 14).**

- a) Select the 'Subjects' tab on the bottom green bar. The 'All Subjects' list is displayed. (For new users, this list will be blank.)
- To add a new subject select the '**ADD SUBJECT**' button below the search bar.



- b) Consult the subject to answer the screening questions. If the subject answers '**Yes**' to any question, the subject is ineligible for testing.
- Once all questions have been answered, select '**CONTINUE**' at the bottom of the screen.
- If a subject is ineligible, a pop-up message will be displayed. Select '**Dismiss**' to be redirected to the 'Subjects' tab.



- If the subject is eligible, then the App will ask for the subject's Date of Birth (DOB).
- Scroll through the date-picker to enter the DOB. Then select '**CONFIRM**' to confirm age and proceed.
- c) If the subject is less than 14 years old, a page is displayed with the message "Subject is not eligible. Under 14 years of age". Select '**CANCEL**' to be redirected to the 'Subjects' tab.
- If the subject is between 14 and 18 years old, a page is displayed for the collection of parent/guardian email and name of the subject (see step d). Select '**CONTINUE**' to be directed to the 'Subjects' tab.
- If the subject is over 18 years old, select '**CONFIRM**' to be directed to the subject's details page.



d)

If the subject is between 14 and 18 years old, consent forms are emailed to the holder of parental responsibility (HPR) to give consent for the minor to use Nurochek. The minor is also required to give assent. This process is managed through the Nurochek online server.

e)

After screening and age collection, enter the subject details. The minimum details required are:

- Email address
- First name
- Last name
- DOB (this auto-populates)

Subject gender, contact and photograph are optional.

Note that all subjects require a photo ID for authentication prior to testing.

Select **'CONTINUE'** (blue icon) at the bottom of the screen to proceed.

f)

The subject's identity is confirmed using photo ID. Select **'CONFIRM'** to continue.

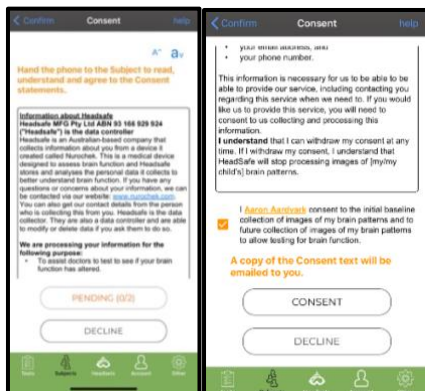
If the subject is over 18, the Nurochek Consent statements will be available for the subject to read and to give consent by ticking the two boxes as shown.

The text size of the Consent statements can be altered by selecting either 'A' to enlarge, or 'a' to minimize, in the top right-hand corner of the screen.

g) **Hand the phone to the Subject to read, understand and agree to the Consent statements.**

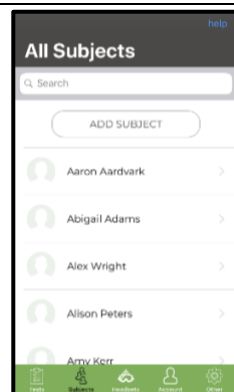
Once the Subject has consented to all Consent statements, the 'PENDING' icon will change to 'CONSENT'. Select this icon to confirm consent and finalize subject addition.

Note: there may be a slight delay between selecting 'CONSENT' and being redirected to the 'All Subjects' list.



h) **After the new subject is created and has given consent, their name will appear on the 'All Subjects' list.**

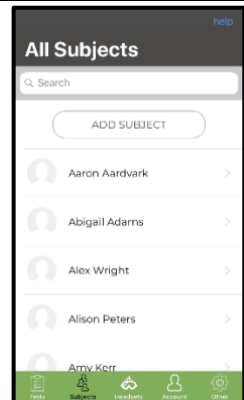
Scroll down the list to their name, or search their name in the 'Search' bar at the top of the list.



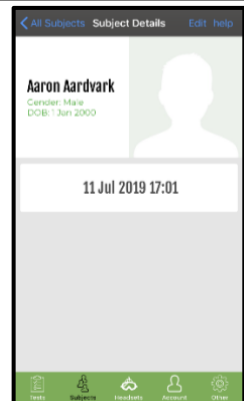
3.6.2 Editing Subject Details

To edit a subject's details, perform the following steps.

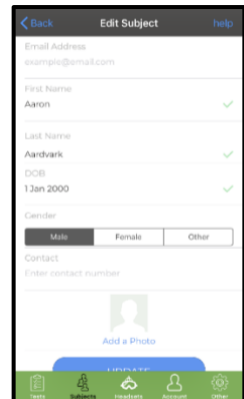
- a) Select the 'Subjects' tab on the bottom green bar and then select the subject to edit from the 'All Subjects' list.



- b) Select 'Edit' near the top right.



- c) The 'Edit Subject' screen will appear. Edit the desired details. When all details are updated, select '**UPDATE**'.



3.7 Cleaning

The Headset must be cleaned according to the following instructions before every use.

The cleaning method is comprised of 4 main steps:

1. **DISINFECT**
2. **DRY**
3. **RINSE & WIPE**
4. **DRY**

3.7.1 *Disinfect*

- a) **Ensure gloves are worn.**
- b) Remove used foam cylinders from the Headset.
- c) Ensure charging port cover is closed (see Figure 2-1 C, page 9).

With a disinfectant wipe (for example, Caviwipes), wipe **all** surfaces of the Headset to **remove visible soil** for a minimum of 1 minute. Pay extra attention to the seams, crevices and gaps of the Headset, by cleaning these with the following method:

- Place a cotton swab on a disinfectant wipe and fold the wipe down around the swab, as displayed in below.



- Using the cotton swab wrapped in the disinfectant wipe, wipe the seams, crevices and gaps of the Headset and the following **CRITICAL AREAS**:
 - Underside of the USB Port Cover and pay particular attention to the inner edges as seen below.

d)



- Inside of each Electrode Frustum – create full circular motions with the cotton swab inside each frustum.



- Inside crevice of the Visor Cushion, identified in red in the figure below.



-
- e) Using additional disinfectant wipes as needed, ensure the Headset remains visibly wet for an additional 2 minutes after initial wiping. If needed, use additional cotton swabs wrapped in disinfectant wipes to ensure the seams, crevices, gaps and CRITICAL AREAS remain visibly wet for 2 minutes.
-

3.7.2 Dry

- f) Dry the Headset with a clean lint-free cloth. To dry seams, crevices, gaps and critical areas, wrap a clean lint-free cloth around a cotton swab and use the techniques shown in step d).
-

3.7.3 Rinse & Wipe

- g) **Ensure the USB Port Cover is closed.**
-

Rinse **all** surfaces by spraying with water (as shown below), paying close attention to the seams, crevices, gaps, and subject contacting surfaces including the straps, electrode frustum/posterior surface and visor cushion. Ensure all surfaces are wet.

- h)



- i) Use a clean lint-free cloth dampened with water to thoroughly wipe, in an overlapping circular motion, all surfaces of the device giving extra attention to the subject contacting surfaces (visor cushion, electrode frustum/posterior surface and straps). For seams, crevices, gaps and critical areas, wrap a clean dampened lint-free cloth around a cotton swab to clean using the techniques described in step d).

- Wipe for a minimum of 1 minute.
 - Use additional dampened lint-free cloths as needed.
-

- j) **REPEAT step g), h) and i) TWICE more (for a total of 3 rinse-wipe cycles).**
-

3.7.4 Dry

- k) Dry the device by thoroughly wiping all surfaces with a dry, clean, lint-free cloth. To dry seams, crevices, gaps and critical areas, wrap a dry, clean lint-free cloth around a cotton swab and use the technique shown in step d).
-

- l) Visually inspect the device; if needed, continue wiping using additional clean lint-free cloths until all surfaces are dry. Use the technique shown in step d) to dry seams, crevices, gaps and critical areas.
-

3.8 Test

To perform a test, all of the following steps must be completed in order.

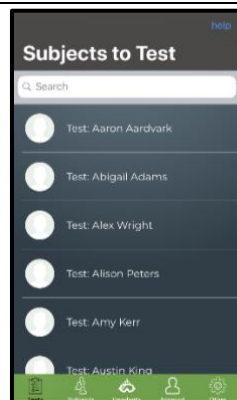
Select the 'Tests' tab on the bottom green bar. The 'Subjects to Test' list will be displayed.

Select the subject from the list on the 'Subjects to Test' screen by scrolling down the list to their name or by using the 'Search' function at the top of the list.

a)

Select the subject desired subject and the 'Confirm Identity' screen will be displayed.

Note: subjects must be added prior to the test. To add a new subject, see 'New Subject' steps (Section 3.6.1, page 14).



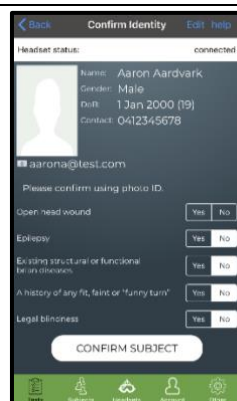
Confirm the subject's identity via photo ID provided by the subject.

Examine the subject for open head wounds to answer whether the subject has an open head wound. Confirm the subject's answers to the screening questions.

c)

If the subject has an open head wound, they may not be tested until the head wound is healed. If the subject answers 'Yes' to any of the other questions they are ineligible for assessment with the NUROCHEK-I System.

After confirming the subject's identity and answering the screening questions, select '**CONFIRM SUBJECT**'.



Pairing (Connecting) Headset to Smartphone

Headset:

Turn on Headset by holding the power button (see Figure 2-2 J, page 10) for at least 2 seconds. The Headset lights will flash when powered on.

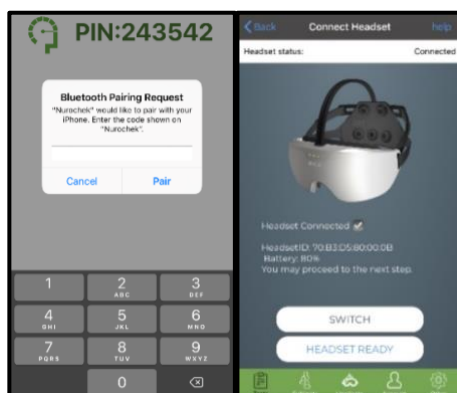
Smartphone:

d)

When the Headset attempts to pair with your smartphone, a prompt may ask for the pairing code. The pairing code will be a 6 digit randomly generated code displayed in the background of the screen. Enter this code to pair the device.

Upon successful connection, your phone may vibrate (depending on your phone's settings).

When the desired Headset connects or if it is already connected, select '**HEADSET READY**' to continue.



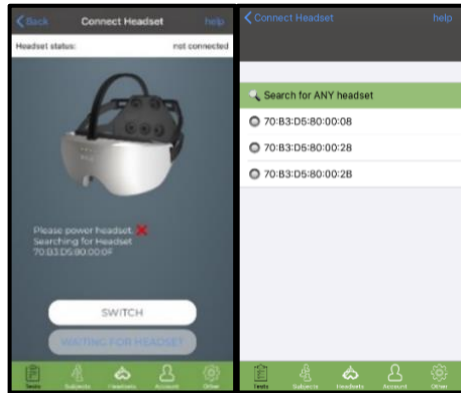
Switching Headsets

To connect to a different Headset, select '**SWITCH**'. A list of Headsets you have previously used will be displayed.

To connect to a previously paired Headset, select the desired Headset by selecting the Headset's serial number.

To connect to a new Headset, select '**Search for ANY headset**'.

When the desired Headset is connected, select '**HEADSET READY**' to continue.



Test Preparation

Seat the subject in a quiet environment.

Ensure the charger is not connected to Headset and the charging port cover is closed.

Clean Headset prior to use. Cleaning instructions can be accessed through the App by selecting 'click here'. Also, see section 3.7, page 18, for cleaning instructions.

Insert unused foam cylinders into the electrode openings on the rear of the Headset.

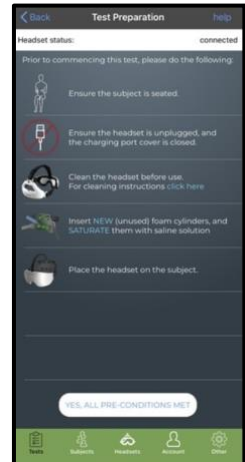
- e) **Dampen foam cylinders** with saline solution until the cylinder is visibly dampened. **Minimize spillage on the Headset; wipe all spillages.**



WARNING

Disconnect charger from the Headset and close charging port before fitting the Headset on the subject's head.

Clean Headset prior to use.



Fitting Headset on Subject

Open the buckles and pre-tighten the straps symmetrically so there is a slight amount of slack in the straps. Close the buckles.

Ask the subject to brush their hair on the back of the head in an upwards motion to expose the scalp.

- f) If subject has long hair, ask them to spread their hair up and out to the sides, in order to best expose the scalp.

Place the Headset on to the subject's head such that:

- The bottom of the rear sensor housing is in line with the small bony bump at the back of the skull (**inion**) – about the same level as the top of the ears in most individuals. Place a finger on the inion to guide you to the correct positioning. The bottom of the rear housing sensor

will then sit flush above your finger. The power button should also be directly above your finger.

- The visor is over the subject's eyes, with the **nasion** (top of nasal bridge, in-between the eyes) completely covered.
- The straps are secured above the subject's ears, with the bottom strap being roughly parallel to the ground when the subject is seated upright.
- The Headset is symmetrical.

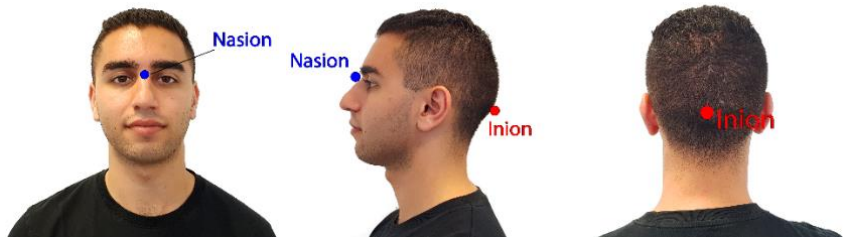
It is recommended to **position the rear portion first**, and then pull the visor down over the subject's eyes or ask them to fit the visor themselves (as they would a diving mask or ski goggles). While the subject is adjusting the front visor, ensure you hold the rear portion in its correct position to limit migration.

To adjust the tightness of the Headset, open the buckles and pull the strap through the buckle towards the sensor housing to tighten or towards the visor to loosen. Ensure the straps remain symmetrical. Close the buckles when the fit is right. The Headset should sit **snugly on the subject's head**.

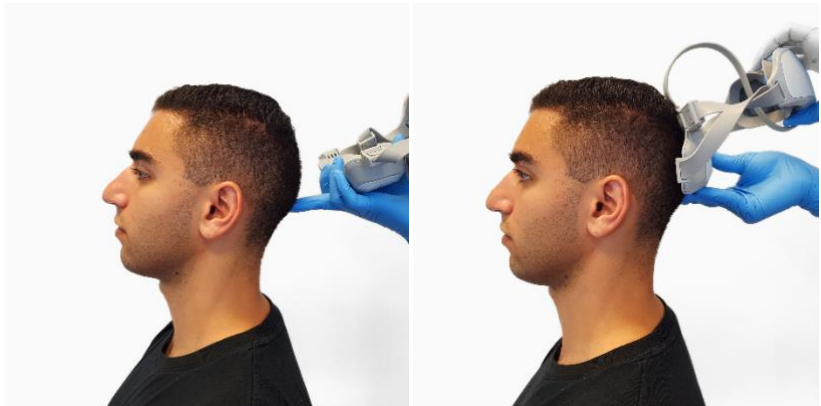
Smartphone:

Select '**YES, ALL PRE-CONDITIONS MET**' after Step e) is completed and the headset is fitted.

Anatomical Locations



Headset Fitting





Correctly Fitted Headset



Impedance Test

Headset:

Good skin contact is indicated by green circles. Poor skin contact is indicated by amber squares. Adjust Headset by gently shifting the rear portion of the Headset until any amber squares are replaced by green circles.

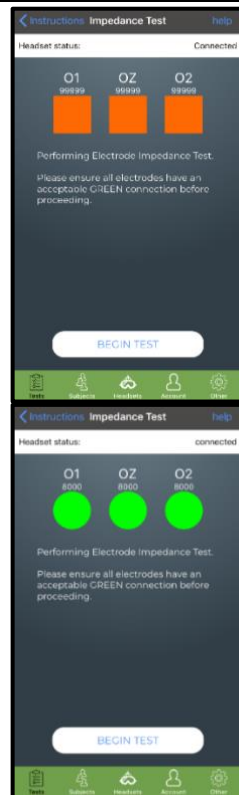
If any of the indicators remain amber squares, remove Headset from subject, **re-dampen foam cylinders** and re-fit the Headset on subject's head as per Step f).

- g) When all of the indicators are green circles, inform the subject of the following:

- The test is about to begin,
- There will be two rounds of flashing lights for 30 seconds each, with a rest in between
- Eyes are to remain open at all times (blinking is OK)
- Avoid movement (e.g. looking around or away) of eyes
- The test may be stopped at any time.

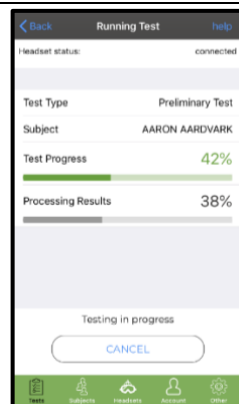
Smartphone:

When all three indicators are represented by green circles and the subject is ready, select '**BEGIN TEST**' to start the first test.



- h) After the first test begins, a progress graph will be displayed during testing.

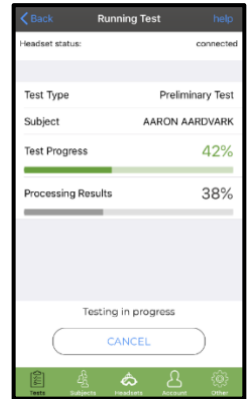
To cancel the test at any time, select '**CANCEL**'.



- i) At 100% (both 'Test Progress' and 'Processing' Results bar graph) the first test will stop.

If the test is successful, a dialog box will appear notifying the user the test is complete. To continue to the 'Second Test' select 'Continue'. To cancel the second test, select '**CANCEL**' and no results will be recorded.

- j) On commencement of the second test, the progress bars will reset to 0% and progress as before.



App:

When both bars reach 100%, testing is complete.

- k) **Headset:**

Remove the Headset from the subject by holding the rear section and asking the subject to lift up the front section (the reverse of putting Headset on). If tight, it may be necessary to unlock the buckles and loosen the straps.

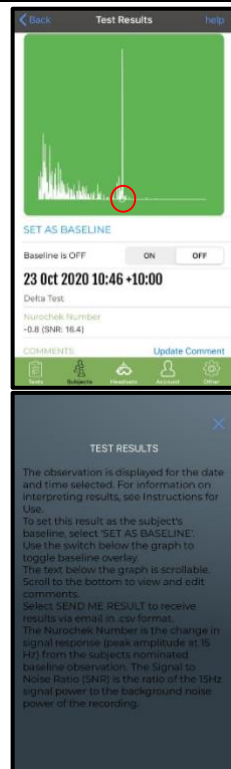
Remove the foam cylinders and discard appropriately.

The Test Results screen will appear when test is complete. The results will be automatically uploaded to the secure database.

The results screen is scrollable and contains several features:

- Results can be viewed and overlaid with baseline results via the 'Baseline is ON/OFF' toggle
- The current reading can be set as the subject's baseline by selecting '**SET AS BASELINE**'.
- The circle below the graph (highlighted by the red circle on the right) corresponds to the stimulus frequency.
- The Nurochek Number is the change in signal response (peak amplitude at 15Hz) from the subjects nominated baseline observation.
- The Signal-to-Noise Ratio (SNR) is the ratio between the amplitude of the stimulated frequency (15Hz) and the background noise.
- Notes can be added by writing in the 'Comments' field.
- To receive an email of the results data, select '**SEND ME RESULT**'.

I)



After viewing the results, you can either:

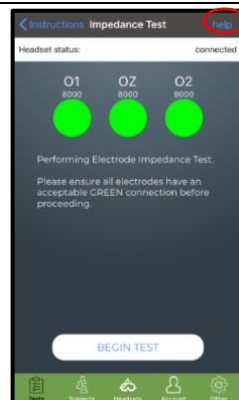
- m)
- Return to the Tests tab by selecting '**Back**'
 - Quit the App

The Nurochek App should not be left open when not in use.

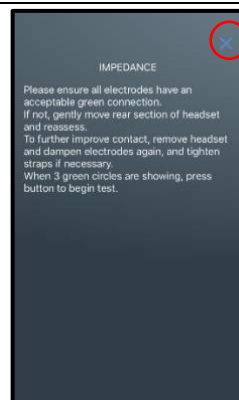
3.9 Help Screens

The App has various in-built help screens which provide extra information and troubleshooting for most of the App's functions.

- a) To access help screen for the displayed screen, select the 'help' icon in the top right-hand corner.



- b) The help screen for the corresponding function is displayed.
To go back, select on 'X' at top right of the open help screen.

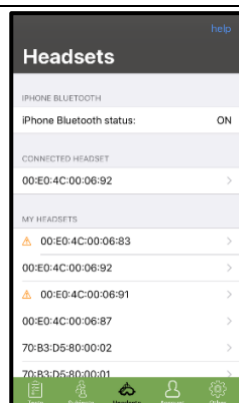


3.10 Headset Management

Headset details and pairing information can be accessed through the App.

Headset management and details can be accessed under the 'Headsets' tab on the green bottom bar.

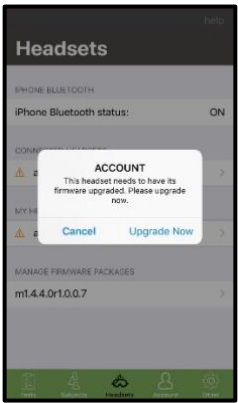
This tab can be used to connect to the Headset.



3.11 Firmware Upgrade

When a firmware upgrade is available, a notification will be displayed prompting an upgrade to occur. Prior to a firmware upgrade, the Headset should be **fully charged**.

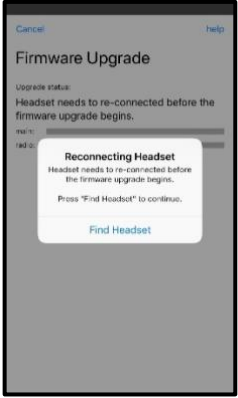
- a) To begin the upgrade process, select 'Upgrade Now'.



- b) To continue with the upgrade, select 'upgrade now'.



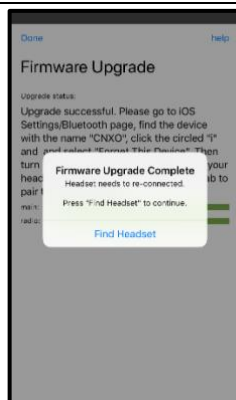
- c) The Headset will then be disconnected from the smartphone. To reconnect the Headset and continue the upgrade process, select 'Find Headset'.



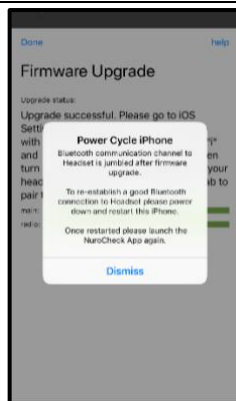
- d) To start the upgrade, select '**start upgrade now**'.



- e) When firmware upgrade is complete, reconnection to the Headset is required. Select '**Find Headset**' to continue.



- f) Select '**Dismiss**', then power the smartphone off, then back on again. After powering back on, launch the Nurochek App.



3.12 Charging

The charger included in the packaging is the only charger approved for use with the Headset. See Section 5.2, page 37, for charger specifications.

3.12.1 Attaching Charger Blades



WARNING: Do not place blades into mains electrical socket before it is attached to charger

- a) Select the appropriate region-specific blade. See Figure 3-1, page 31, for the correct blade to use for the regions: Australia, US, EU and UK.

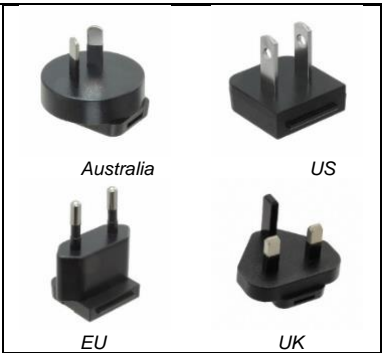


Figure 3-1: Charger blades and regions

- b) Position the protruding lip of the blade (visible in Figure 3-1, page 31) as shown in Figure 3-2A, page 31, so the lip is facing in the direction of the arrow (identified in Figure 3-2A, page 31). Once positioned, push down on the charger blade until it is locked into position (Figure 3-2B, page 31).

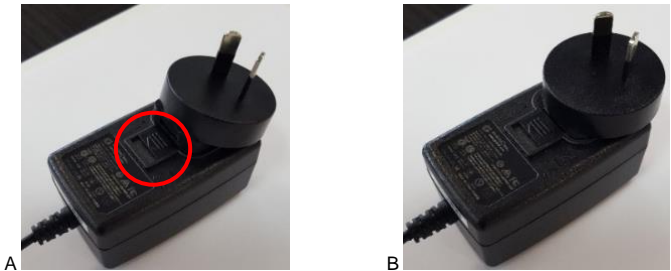


Figure 3-2: Charger blade insertion procedure

3.12.2 Charging Process



WARNING: Use only the supplied charger to charge the Headset

- a) Ensure Headset is dry. Remove foam cylinders if any are still in the Headset.

Turn off Headset by holding the power button (see Figure 2-2 J, page 10) on the Headset for 3 seconds. All indicator lights are off when the Headset is off.

- b) NOTE: The Headset when powered off enters a sleep mode, in which the device will draw less power but still drain the battery overtime if not placed on charge. It is recommended that if the device is to be used within 2 weeks of powering off, that it be placed on charge to have sufficient battery for use once powered back on.

- c) Plug charger into mains socket.



WARNING: Connect charger only to mains voltage rated for 100-240V, 50-60Hz

- d) Open charging port cover located on the rear of the Headset (see Figure 2-1 C, page 9).
- e) Carefully insert the charger into Headset charging port.
- f) When charging, the rear LED is orange. When the Headset is fully charged, a green LED will appear. See section 3.13.1, page 32, for more information.

3.12.3 Removing Charger Blades



WARNING: Remove charger from mains before removing blades

To remove the blade, press down on the slider below the charger port (highlighted in Figure 3-3, page 32). The blade will then unlock.



Figure 3-3: Charger blade removal procedure

3.13 LED Indicators

















There are two sets of indicator LEDs on the Headset: on the rear and on the front. These LEDs provide feedback regarding the status of the Headset.

Table 3-1 LED indicator legend





























Status	Definition
	Light off
	Solid amber light
	Solid green light
	Solid blue light
	Flashing amber light
	Flashing green light
	Flashing blue light

3.13.1 Rear LEDs – feedback on the battery and pairing status

LED Status	Headset Status
	Not charging. The device is off.
	Headset is charging.
	Headset is fully charged.
	Insufficient charging current. Contact manufacturer.
	Battery error. Contact manufacturer.

   	Headset on, pairing mode.
   	Headset low battery, pairing mode. Charge the Headset as soon as possible.
   	Headset on, paired to phone.
   	Headset low battery, paired to phone. Charge the Headset as soon as possible.

3.13.2 Front LEDs – feedback on the test progress

LED Status	Headset Status
   	Standby (not in test) (intermittent flashing)
   	Current test progress: 0-24%
   	Current test progress: 25-49%
   	Current test progress: 50-74%
   	Current test progress: 75-99%
   	Current test progress: 100%. Lights will remain in this state, then go to standby.
   	Test error. Refer to App for details.

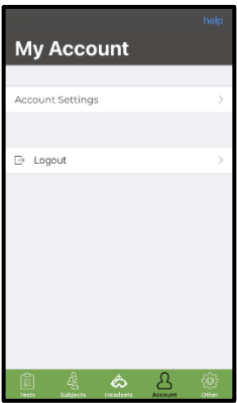
3.14 Account Settings and Logout

To view account settings or logout, select the 'Account' tab.

3.14.1 Logout

To logout, select **Logout** under 'My Account'.

To access your records, you will need to login again.

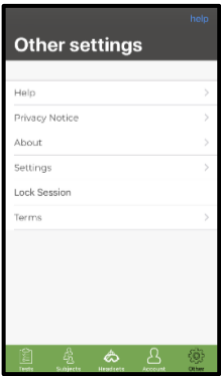


3.15 Other Settings

To view 'Other settings' select the 'Other' tab.

Select **Help**, **Privacy Notice**, **About**, **Settings**, or **Terms** to access the respective page.

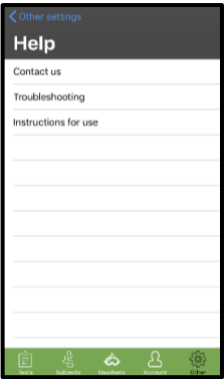
Selecting **Lock Session** will take you back to the login screen where your password will need to be re-entered to gain access the App.



3.15.1 Help

Additional help pages can be accessed through the App.

Select **Help** in 'Other Settings' to access additional help information. Select **Contact Us**, **Troubleshooting** or **Instructions for Use** to access the respective page.



3.15.2 Privacy Notice

The privacy notice can be accessed through the App.

Select 'Privacy Notice' in 'Other Settings' to access the Privacy Notice.



3.15.3 About

Information about Nurochek can be accessed through the App.

Select 'About' in 'Other Settings' to view regulatory information about Nurochek.



3.15.4 Settings

Additional settings can be changed to alter App behaviour.

Select 'Settings' in 'Other Settings' to change additional App settings.

'Show result after test' can be toggled **'YES/NO'** to display or hide the result immediately after a test is run.

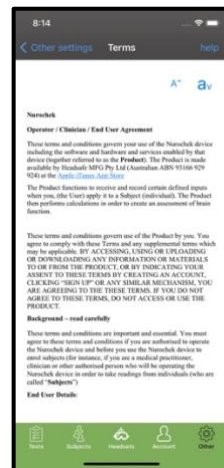
'Show historic results' can be toggled **'YES/NO'** to display or hide the historic results under each subject.

Both settings are defaulted to 'Yes'.



3.15.5 Terms

The terms can be accessed through the App.



Select 'Terms' in 'Other Settings' to access the terms.

Chapter 4: Troubleshooting

4.1 Cannot Turn On Headset

If your Headset cannot be turned on after holding the power button, attempt the following steps in order:

- Disconnect charger from Headset.
- Attempt to charge Headset, and verify that an amber LED is displayed on the back of the Headset.
 - If not, return unit to manufacturer.

4.2 Cannot Connect Smartphone to Headset

If your smartphone cannot connect to the Headset, attempt the following steps in order:

- Turn on Bluetooth on the smartphone.
 - Open the 'Settings' application, then select 'Bluetooth'. Ensure the toggle slide for Bluetooth is highlighted and on.
- Disconnect Headset from charger. While charging, all functionality of the Headset is disabled.
- Turn on Headset, if it is not on already.
- 'Forget' the Headset from the Bluetooth device history in the smartphone.
 - Open the 'Settings' application, then select 'Bluetooth'. Select the ⓘ icon and select 'Forget this Device'.
- Observe rear blue indicator light. If it is solid blue, that means the Headset has been connected to another smartphone.

4.3 High Impedance

If the impedance on the Impedance screen remains high (amber square), attempt the following steps in order:

- Gently move the rear of the Headset in a circular motion (approximately 1-inch diameter) to shift hair out of the way.
- Remove Headset from the subject.
- If the subject has thick or long hair, gently spread their hair apart to expose the scalp, then reposition Headset on subject.
- Re-apply saline solution and ensure the foam cylinders are as deep as possible to maximize contact with the gold plate.
- Pre-tighten Headset straps symmetrically and re-fit the Headset on to the subject.

4.4 Headset Suddenly Off

The Headset is designed to turn off after 5 minutes if no test has been performed. Please power on the device to continue use.

4.5 Flashing Amber LEDs Upon Powering the Headset

If the Headset flashes amber while it is turned on, this means the battery is insufficient for a test. Please power off the device and charge it with the provided charger for at least 30 minutes.

Chapter 5: NOTE: The Headset when powered off enters a sleep mode, in which the device will draw less power but still drain the battery overtime if not placed on charge. It is recommended that if the device is to be used within 2 weeks of powering off, that it be placed on charge to have sufficient battery for use once powered back on. Legal

5.1 EU Waste Electrical and Electronic Equipment (WEEE) Directive



The symbol on the left means used electrical and electronic equipment (WEEE) should not be mixed with general household waste. For proper treatment, recovery and recycling, please take this product(s) to designated collection points where it will be accepted free of charge. Alternatively, in some countries, you may be able to return your product(s) to your local retailer upon purchase of an equivalent new product.

Disposing of this product correctly will help save valuable resources and prevent any potential negative effects on human health and the environment, which could otherwise arise from inappropriate waste handling.


Please contact your local authority for further details of your nearest designated collection point.

Penalties may be applicable for incorrect disposal of this waste, in accordance with your national legislation.

5.2 Electromagnetic Compatibility

This device is intended to be used in the electromagnetic environment specified below:

Emissions Level	Compliance	Guidance
RF emissions (CISPR 11)	Group 1	Group 1 equipment is equipment which does not use high powered radiofrequency energy. Therefore, it is unlikely to cause any interference with nearby electronics equipment.
	Class B	Class B equipment is equipment suitable for use in establishments directly connected to a low voltage power supply network. For example, in general practice clinics.
Electrostatic discharge immunity 61000-4-2	±15 kV	This equipment is resistant to electrostatic discharge. However, use in low humidity environments (<30% RH) should be avoided if possible.
Radiated RF IEC 61000-4-3	80 MHz to 2.7 GHz 3 V/m	The NUROCHEK-I System complies with all applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2:2014, for residential, commercial and light industry environments. Portable and mobile RF communications equipment should be used no closer to any part of the machine, including cables, than the recommended separation distance. Should you suspect that the device performance (e.g. connection quality) is affected by other equipment: <ul style="list-style-type: none">• Reorient or relocate the device receiving the interference.• Increase the separation between the equipment.

		<ul style="list-style-type: none"> Consult the manufacturer for help.
Proximity Fields from RF equipment 62000-4-3	385 MHz 27 V/m 450 MHz 28 V/m 710, 745, 780 MHz 9V/m 810, 870, 930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450MHz 28 V/m 5240, 5500, 5785 MHz 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. The recommended separation distance is: $d = 0.67 \sqrt{P}$ $d = 0.26 \sqrt{P}$ (385 – 2450 MHz) Where (P) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey: <ul style="list-style-type: none"> Should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:  Interference may occur when in the vicinity of equipment operating at 2450MHz. This is the frequency which the Nurochek uses to communicate with the smartphone.

The NUROCHEK-I System contains a radiofrequency emitter which emits the following frequencies:

Frequency	Modulation	Radiated Power
2.402 GHz to 2.480 GHz	Gaussian frequency shift keying	1 mW (0 dBm)

The NUROCHEK-I System contains a radiofrequency receiver which receives the following frequencies:

Frequency	Frequency Bands	Bandwidth
2.402 GHz to 2.480 GHz	BLE bands 1-40	Maximum 1Mbit/s

5.2.1 Federal Communications Commission (FCC) Compliance

This device (NUROCHEK-I) complies with part 15 of the Federal Communication Commission (FCC) Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/TV technician for help.

5.3 Technical Specifications

5.3.1 Headset

Table 5-1: Headset specifications

Identification	
Model number	HS01-001
Power	
Energy source	Lithium-ion battery
Expected use time	At least 30 tests
Charging time	3 hours (0-100%)
Input connector port	USB type-C
Visual Stimulus	
Source	5x LEDs per side
Colour	White
Frequency	15Hz
Duty cycle	50%
Electroencephalography	
Electrodes	3 (O1, O2, Oz) + 2 (bias, reference)
Sampling rate	250 samples/second
Dynamic range	113.5 dB
Noise	1.97 μ V
CMRR	110 dB
Input impedance	> 1 G Ω
Communications	
Communication	Bluetooth Low Energy 4.2 (wireless)
Connectivity range	1m line-of-sight
Antenna power	1mW (0 dBm)
Bluetooth class	Class III
Mechanical	
Headset material	Polymer
Weight	500g
Use Life	
Light Stimulus Cycles	1500

5.3.2 Strap

Table 5-2: Straps specifications

Identification	
Product code	HS01-081 (strap only) HS01-059 (assembly)
Mechanical	
Colour	Grey

5.3.3 Foam Cylinders

Table 5-3: Foam cylinders specification

Identification	
Product code	HS01-058 (foam only) HS01-092 (assembly)
Mechanical Properties	
Colour	Grey

5.3.4 App

Table 5-4: App specifications

Identification	
Product code	HS01-053

Requirements	
<i>Supported OS</i>	Apple iOS 13.6.0 and above
<i>Devices supported</i>	iPhone 6s

5.3.5

Charger Specifications

Table 5-5: Charger specifications

Identification	
<i>Product code</i>	HS01-014
<i>OEM</i>	GlobTec, Inc
<i>OEM model no</i>	GTM96180-1507-2.0
Input	
<i>Input voltage</i>	100-240V AC
<i>Input frequency</i>	50-60Hz
<i>Input connector</i>	Adjustable
Output	
<i>Output voltage</i>	5V
<i>Output current</i>	Up to 3A
<i>Output connector</i>	USB type-C, 1.2m cable
Safety	
<i>Class</i>	II
<i>Insulation</i>	Double insulated

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