mente™ AUTISM

User Manual

A Neurotech company

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1. Intended Use

Mente Autism is an active medical device intended to read brain activity of patients diagnosed with Autism Spectrum Disorder (ASD) to provide a home-based therapeutic means to relax the mind. This is done through reading of the various waveforms of brain activity augmented in a real-time sonified neurofeedback therapy. The therapy is delivered through sonified neurofeedback transmitted via earphones that are connected directly to the headband. Mente Autism is targeted for children between the ages of 3 and 12. After initial setup, Mente Autism can be run together with a tablet running the Mente Autism software.

2. Safety Information

Mente Autism is a Class IIa device according to the classification in the Council Directive 93/42/EEC for medical devices. Mente Autism is intended for non-continuous use.

It conforms to the following Standards and Directives:

- Directive 93/42/EEC for medical devices, with amendments by 2007/47/EC
- Subsidiary Legislation 427.44, Malta – Medical Devices Regulations, Legal Notice 210 of 2008
- ISO 13485
- EN 60601-1
- EN 60601-1-2
- EN 60601-1-11
- IEC 60601-2-26
- R&TTE Council Directive 1999/5/EC

This product user guide and manual is available in a number of languages.
Contact your local distributor should you require a copy of this manual in another language.

3. Regulatory Information

Manufacturer:	Brand:	Model:
AAT Medical Ltd Block LS3, Malta Life Sciences Park, San Gwann Industrial Estate, San Gwann, SGN 3000 Malta Tel: +356 21330588 Email: info@mentetech.com	Mente Autism	MEN-03

4. Environment of use

The Mente Autism system has been designed for use in a home and/or clinical environment in accordance with specifications as explained in Section 6 – Conditions of Use.

5. Advice & Safety Warnings

⚠	Each Mente Autism system should ideally be used by one user to avoid the possibility of skin-related infection. Where this is not the case, be sure to follow the cleaning and disinfecting instructions in this manual.
⚠	Listening to Mente Autism therapy at high volumes above the safety limit of 105dbA can result in auditory damage. Be sure to use earphones at an appropriate volume so as not to harm the user's hearing. The ideal volume is 85dB.
⚠	The device should not be used by anyone who does not have a clear diagnosis of Autism Spectrum Disorder.
⚠	Use only under the supervision of an adult to avoid asphyxiation or detaching and swallowing of sensors, and to avoid the child switching off or removing the headband in the middle of a session.
⚠	Clean the headband and sensors regularly using a cloth dampened with alcohol to avoid build-up of bacteria as described in Section 13.
⚠	Clean user's forehead using alcohol wipes prior to starting a session to enhance conductivity and to avoid transfer of dirt, oils or bacteria to the headband.
⚠	Make sure that there is no hair between the skin and the drypad sensors on the forehead. This is important because hair could interfere with the signal being picked up by the electrodes.
⚠	Do not use or wear the Mente Autism device while charging. As a safety feature, this device does not work while charging as an internal system prevents this.
⚠	Mente Autism sessions should be carried out as early as possible in the morning. This will ensure that the user fully benefits from the effects of the therapy during the day.
⚠	Do not perform more than one 40-minute session a day. Multiple sessions may cause headaches and disrupt sleep patterns.
⚠	Sessions must be done every day for benefits to become apparent and consistent.
⚠	It is imperative that Mente Autism is used with the earphones provided.
⚠	It is recommended that metal-framed spectacles are not used while using Mente Autism. If the user opts to wear metal-framed spectacles, make sure that the metal does not touch the Mente Autism electrodes. Metal can act as a conductor of any electrical leakages.
⚠	When a pop-up appears requesting that you position a sensor properly, check that all the sensors are making good contact with the locations indicated in the diagrams provided.
⚠	Check that the provided earphones are functioning properly on a regular basis, at least once a week. The therapy consists of auditory stimulation and if sound cannot reach the user properly, the therapy is not effective.
⚠	When taking the headband off after a session, small pressure marks might be visible on the user's forehead. These are the result of the sensors putting pressure on the forehead as the headband is tightened. These pressure marks will disappear after a few minutes.
⚠	Ensure that your software is up to date. AAT Medical may issue software updates to improve the performance of the system and to introduce new features.
⚠	No modification of this equipment is allowed. Warranty is forfeited if the device is tampered with.
⚠	Do not point sprays or nebulisers at the device; keep the device clear of these substances.

⚠	Keep the device away from sources of heat or open flames.
⚠	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
⚠	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Mente Autism device and components (including earphones). Otherwise, degradation of the performance of this equipment could result.
⚠	Keep the device away from children and pets when not in use to minimize the risk of mechanical damage due to mishandling.
⚠	It is highly recommended that a short EEG test is carried out in an appropriate centre and the digital file (.edf or .bdf) is uploaded by a medical professional according to our QEEG protocol document available on the medical professional dashboard. This will indicate whether the patient would benefit from the use of Mente Autism.
⚠	Use only the USB adapter provided to charge the device. Other commercially available adapters may not meet the safety requirements for use with medical devices. Do not charge the device by connecting it to a laptop or computer.
⚠	Ensure that the Mente Autism device is only switched on when it is already placed on the user's head.

6. Conditions of use

Mente Autism must be used in normal temperature and pressure conditions (temperature range: 5-40°C, humidity 15-93%, atmospheric pressure 700-1060 hPa).

7. Contents of the Box

- A printed neoprene headband, to which the five detachable sensors provided are to be attached on the inner side. The sensors are internally connected to casing that holds the Mente Autism EEG chipset, Wi-Fi module and battery. The headband can be secured with Velcro® from both sides of the band, and should be centred on the head using the buckle at the back of the band, with the reference marker at the front of the band.
- A small box with five sensors: three padded sensors to be applied at the front of the head and two hard flexible sensors to be applied at the back of the head.
- A USB adapter, with multiple connections, and cable are provided to charge the device.
- A pair of in-ear earphones with a 3.5mm jack is also included. These are intended to be plugged in the casing prior to the daily 40-minute session for the child to engage more deeply in the therapy, as their auditory system is fully dedicated to the auditory stimulation generated by the Mente Autism device.

NOTE: The earphones provided have the following characteristics:

- Impedance: 16-32Ω
- Sensitivity: At least 96dB/mW
- Frequency response: 20-20000 Hz
- They do not make any contact with any sensor when worn
- They do not have a metal frame

- A quick start and daily usage guide, providing a quick explanation on getting started with Mente Autism as well as an explanation for daily use of Mente Autism.

- An activation card with a PIN code and serial number that matches the serial number on the headband and packaging. This card is to be retained in a secure location as the card contains all details pertaining to the individual device.
- A fabric pouch in which the contents of the Mente Autism package can be placed for easy transport and storage.

8. Technical Specifications & Requirements

Brain Activity Monitoring Functionality

Number of Input Channels: 4
Bandwidth: 0.1-40 Hz
Sampling Rate: 250 Hz
Resolution: 24-bit
Measurement Noise: for 65Hz Bandwidth (gain of 8V/V) - 24nV/√Hz
Amplifier Input Impedance: >500MΩ

Other Technical Specifications

Communication: Wi-Fi

- Operating frequency range: (2.412-2.462) GHz, Channel 1 to 11
- TX power:
  - 18.0 dBm @ 1 DSSS
  - 14.5 dBm @ 54 OFDM
- RX Sensitivity:
  - 95.7 dBm @ 1 DSSS
  - 74.0 dBm @ 54 OFDM
- Wi-Fi Standard: 802.11 b/g/n
- Wi-Fi Security: WPA

Output: Auditory neurofeedback representation, html online report
Operating Time: Daily 40-minute sessions
Dimensions: (enclosure) 56 x 42 x 23 mm
Weight: <100g

Other Requirements:

An Android tablet or smartphone with a stable connection to the Internet for downloading/installing the software, registering Mente Autism and uploading report data to a secure cloud server.

AAT Medical recommends a tablet or smartphone with the following minimum specifications:

- CPU: MT8321, Quad-core @ 1.3 GHz - Cortex A7
- RAM: 1 GB
- Internal Storage: 8 GB
- Resolution: 1024 x 600 pixels
- Operating System: Android™ 5.1, Lollipop or higher
- Application Store: Google Play
- Internet browser: Chrome
- SIM Location and Type: 1 x standard SIM (3G) / 1 x standard SIM (2G)
- 3G/UMTS/WCDMA frequencies: 900 / 2100 MHz
- GSM / GPRS / EDGE frequencies: 850 / 900 / 1800 / 1900 MHz
- SMS / MMS: Yes
- Wi-Fi: Yes, 802.11 b/g/n
- GPS: Yes
- Battery Life - Video Playback: 345 min

NOTE: An Internet connection is used to register the device, log in to your account, upload session data to the cloud system, view daily reports, submit a technical support request, update your profile details and view the Resources section. An Internet connection is not required to perform the Mente Autism therapy sessions themselves.

9. Device Description

Headband

1) Neoprene band with Velcro® straps and buckle
2) 3 padded sensors to be applied at the front of the head
3) 2 hard flexible sensors to be applied at the back of the head
4) Reference marker in the middle of the band for correct sensor placement
5) Fabric Label with Device Serial Number

NOTE: The Serial Number includes the device code, batch code and product number.

Sensors

1) Detachable from the neoprene headband
2) All sensors are connected on the inside of the band
3) 2 types included:
    a. Padded sensor – for use on the forehead
    b. Hard flexible sensor – for use at the back of the head
4) Type BF applied part
5) Deliver physiological readings from the user to the device

Battery

1) Enclosed in case
2) Internally powered source
3) Changing of battery by authorised personnel only
4) Charging of battery only by provided charger

Headband Case

1) On/Off push button
2) LED indicators

LED	Colour	Description
	Red	Charging, no therapy
	Orange	Treatment paused
	Orange (Flashing)	Hardware fault: 1 Flash: Error related to RTC problem 2 Flash: Error related to SD Card unit problem 3 Flash: Error related to Wi-Fi Station mode 4 Flash: Error related to Wi-Fi AP mode 5 Flash: Error related to EEG front end initialisation 6 Flash: Error related to battery check initialisation
	Green	Device on and connected to tablet/phone, not charging
	Green (Flashing)	Device in hotspot mode and searching for network

Figure 1 – Device LED legend

NOTE: Do not connect USB wire to the connector when the device is on or when wearing the device. The device will not operate while charging.

3) CE mark with Notified Body number: Shown on the bottom of the casing.

4) Enclosures in Mente Autism are protected against the ingress of solid foreign objects of 12.5mm diameter and greater, and is protected against vertical drops when the enclosure is tilted at an angle up to 15° from its normal position. Classification is IP22.

WARNING: Do not open or tamper with case. Attempting to open the case will void the device warranty. Opening of case can lead to permanent damage to the device and can only be done by authorised personnel.

Packaging Label

Product Label

Figure 2 – Packaging and Product Labels

NOTE: Item Serial Number and Identification Code number shown here are fictitious and for information purposes only. Refer to Section 17 entitled "Symbols Used" for symbol description.

10. Install Mente Autism app

1. From the Android smartphone or tablet, go to Play Store and search for **Mente Autism** app

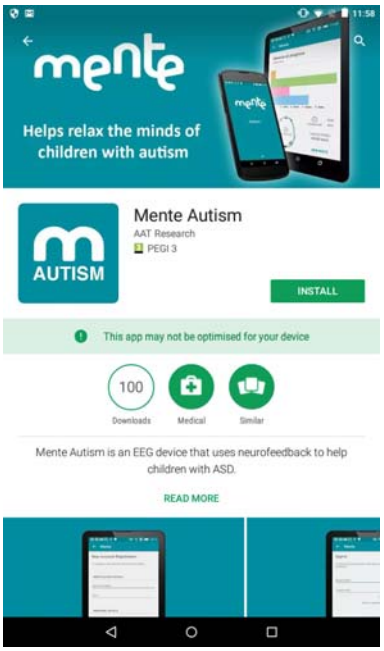


Figure 3:Mente Autism on Play Store

2. Click **Install** and a pop up will be displayed, click **Accept** and wait until the app downloads and installs on the Android smartphone or tablet.

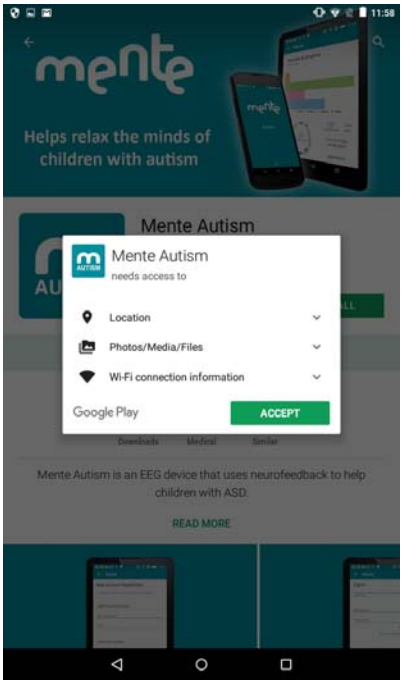


Figure 4: App installation Acceptance Screen

3. Once the Mente Autism app is installed, click on **Open** to open the Mente Autism app and an icon will be created on the Android smartphone or tablet. You can also click on the icon to open the Mente Autism App.

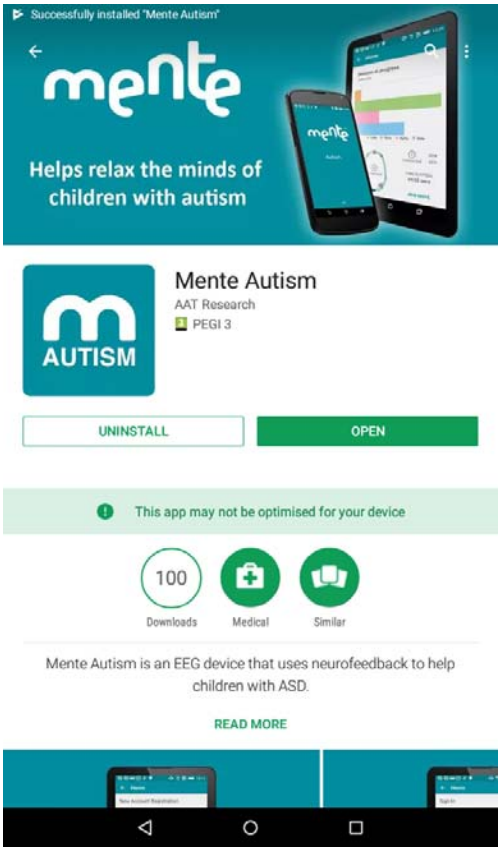


Figure 5: Mente App Completed Installation Screen

Figure 6: Mente App Icon

11. Registration

1. Open the Mente Autism app, tap on the ***'Register now'*** link. Register by entering the details found on the activation card and your personal details in the form provided.

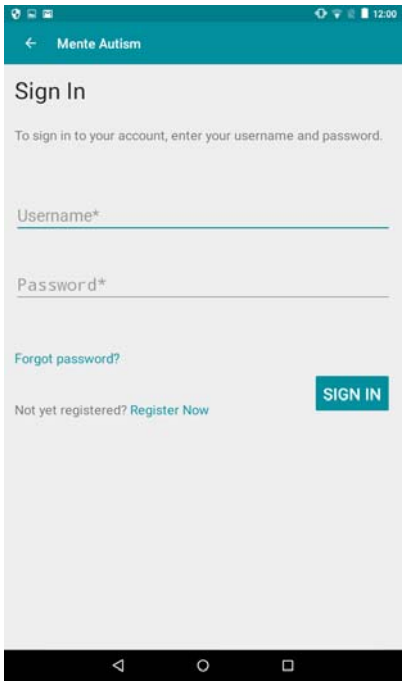


Figure 7: Mente App Sign In

Figure 8: Mente Autism Registration

2. After registering, an activation email will be sent to the email address you provided. Click on the link to activate your account. Registration is now complete.

Dear Mente Autism user,

Thank you for registering your Mente Autism device.

You have entered john.smith@mail.com as the contact email address for your Mente Autism account.
To complete the process, we just need to verify that this email address belongs to you.

Simply click on the link below (or copy and paste the URL into your browser) to verify your email address and to be able to access / log in to your Mente Autism account.

Link: http://www.mentetech.com/verify-email?id=MjM0Mg==&var=Z3JhemllbGxhLnNhbW11dEBhYXRybC5jb20=

For detailed information about Mente Autism, the device and operation, click here to download the user manual.

Regards,
Mente Autism team

12. How to Use

a. Charging the Device

Prior to initial use of the Mente Autism device, plug in the USB cable provided with the Mente Autism headband to the USB power adapter provided and charge it completely (approximately a 3-hour charge time).

NOTE: When the USB charging cable is plugged into the Mente Autism device the indication light on the Mente Autism device should turn red. Once fully charged, the red light will automatically switch off. The device will not operate while charging to ensure user safety.

b. Sensor Preparation

i. Drypad Sensors

The drypad sensors may need hydration before they are used for the first time and at regular intervals. Follow the Sensor Servicing steps in Section 13, Cleaning & Maintenance Instructions.

ii. Flex Sensors

Place the sensors between your thumb and your index finger as per the photos below. Press gently with your thumb to open and flex the sensor. Do not flex the sensor excessively to prevent any damage to the sensor. The legs of the sensors will easily break if they are bent towards their centre rather than their natural outward direction. Use the photos shown as a guide. Repeat this process for at least 10 times increasing the pressure slightly. Make sure the sensor is visibly more open at the end. The coatings at the end of the sensor legs are designed to be rubbed on skin and will wear down on more abrasive surfaces reducing sensor lifetime.

Figure 9 – Mente Autism Flex Sensor initial use Preparation

c. Sensor Attachment

Attach all sensors to the headband by connecting the snap of the sensor to the designated connectors in the band.

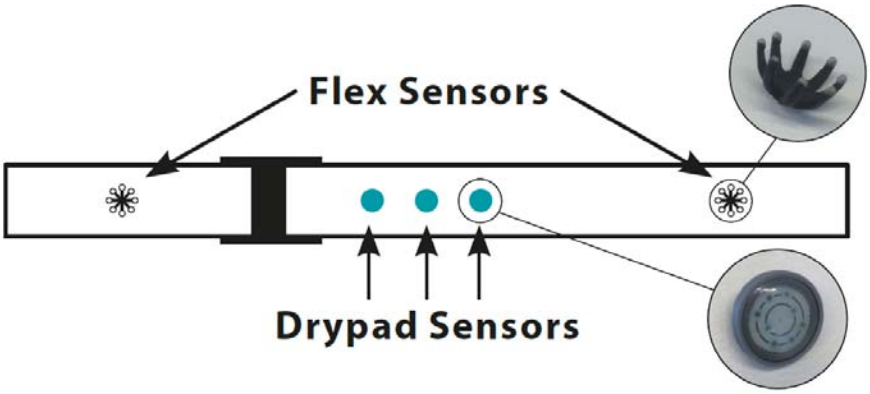


Figure 10 – Mente Autism Sensor Configuration

d. Headband Placing

The headband may now be placed on the child's head:

i. The band should be placed on the head with the white reference line, located on the opposite side of the middle front sensor, **placed in the middle of the forehead, in line with the user's nose**.
ii. Ensure the lower edge of the headband is just above the eyebrows as in Figure 11~~Figure 15~~ below.
iii. Tightly secure the headband using the Velcro straps. **Ensure that the buckle is placed in the centre of the back of the head**.
iv. Make sure that the headband fits securely and that all sensors are making good contact with the skin at the positions indicated in Figure 18~~Figure 23~~.
v. Plug in the earphones provided to the casing on the Mente Autism device.

NOTE: The device should always be placed on the head before being switched on. Once it is switched on, the device can be moved to achieve the correct positioning.

Figure 11 – Correct headband placement

e. Pairing the device

The device may be paired with the app as follows:

i. Switch on the smartphone or tablet and open the app. If signing in is required, insert your username and password and tap the 'Sign In' button.

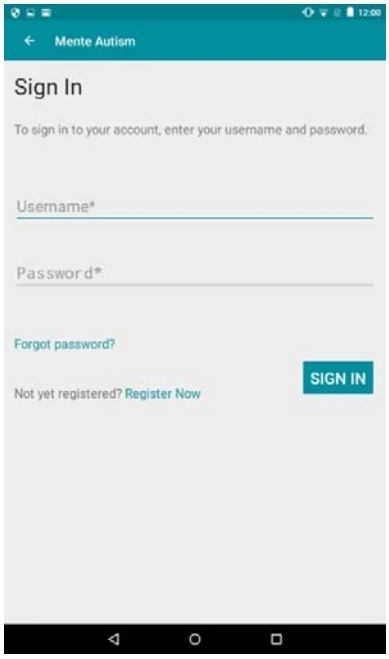


Figure 12: Mente Autism Sign in

ii. Once signed in, you will be redirected to the app's home screen. Switch on the Mente Autism headband (when it is placed on the head) by pressing the power button and from the app, click on **Connect** button.

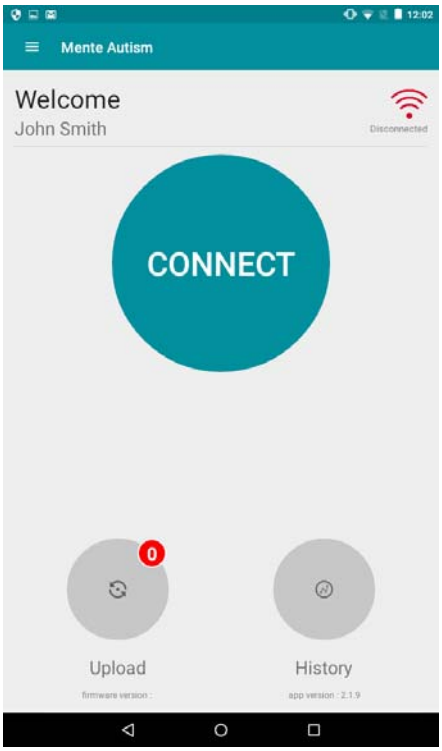


Figure 13: App Home Screen

iii. A pop up will be displayed and wait until the Mente Autism app connects to the Mente Autism Wi-Fi hotspot. The LED indicator will start blinking green.

Figure 14: Connecting Pop Up

NOTE: Ensure that the Android tablet or smartphone is connected to the Mente Autism device hotspot as per your device serial number. If the app takes long to connect to the Mente Autism device hotspot, connect to it manually.

iv. When both the Mente Autism device and tablet/smartphone are successfully connected, the LED indicator on the device will change from a blinking green to a solid green. Also, the wireless symbol on the top right-hand corner of the app changes from red to green and the battery life of the headband will be displayed. This means that the device and the app are paired.

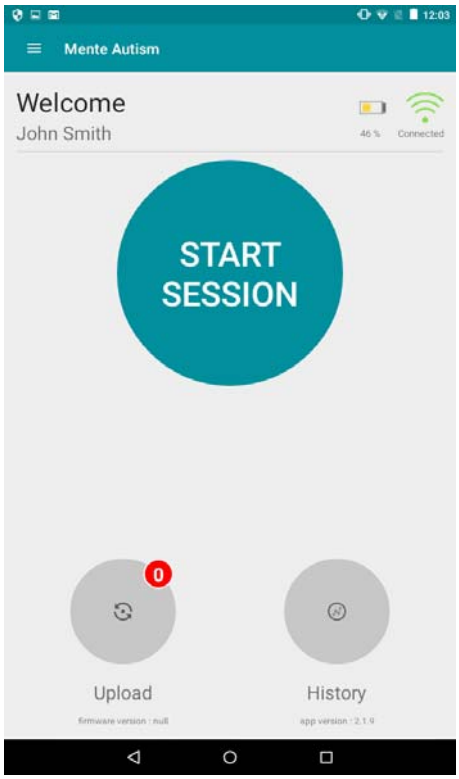


Figure 15: Successful Connection Home Screen

f. Pre-Therapy Checks

Tap on 'Start Session'. This will take you to a screen showing the functional checks that are performed by the device before initialising a session. Pre-therapy checks include:

- Bias test – Ensures that the bias sensor (middle sensor) is connected properly.
- Signal test – Ensures the signal can be read properly.
- Noise test – Ensures all equipment is connected and working properly.
- Battery check – Ensures there is enough charge for a full session.
- Audio check – Ensures the earphones are connected to the Mente Autism headband
- Sensor Impedance check- Ensure that EEG sensors are connected properly to users' head

NOTE: The device has the capability of performing self-testing for verification of functionality. Prior to the start of each session, the inputs are shorted together and data is sampled from the sensors. The information gathered is used to determine the level of noise appearing at the inputs and hence is termed the "Noise Test". To pass the test, the recorded signal must have a peak-to-peak voltage less than 2µV. Similarly, the device is capable of outputting to each of the inputs a precise 1.95mV square wave signal. Information gathered from the inputs whilst undergoing this test is used to confirm both the amplitude and offset of the signals being measured, hence verifying the calibration of the device. This test is termed the "Signal Test". To pass the test, the recorded signal must not vary more than 5% from the applied signal.

g. Setting the Volume Limit

Set the desired volume for the therapy session by varying the volume limit on the app while the user listens to the sound being generated by the device.

NOTE: The volume cannot be varied once the therapy has been started and therefore care must be taken to ensure that the user can hear the sounds properly and at the right volume before proceeding.

h. Start Session

With all checks completed, the Start button will become available and the user may start the therapy.

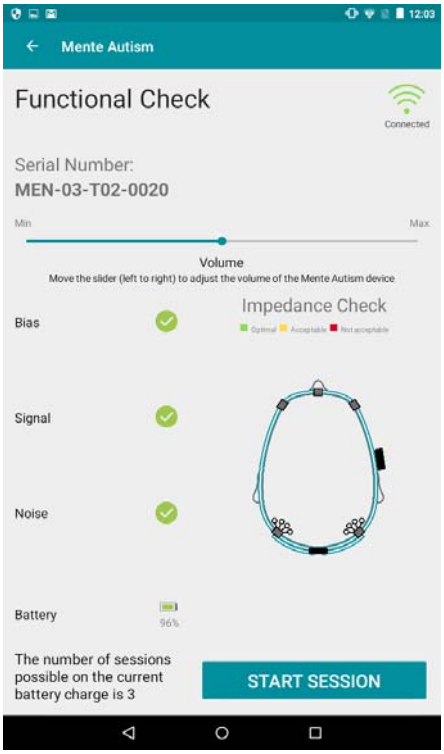


Figure 16: Functional Check Screen

NOTE: If the noise and signal check remain red after restarting the device, please contact authorised personnel.

i. During therapy usage

Once the therapy begins, the user can move around and the app does not need to relate to the Mente Autism Wi-Fi hotspot. It is only required to monitor the progress of the therapy through the app thus the user must stay close to the tablet/smartphone device. Throughout the session, Mente Autism performs impedance checks to ensure good sensor contact. If a problem is encountered, a pop-up will appear on the app asking you to adjust the sensor's contact with the head. The misplaced sensor will be marked in red in the image provided, and will turn back to green once a suitable impedance value is obtained. The earphone connection is also monitored. A similar pop-up will appear if the earphones are not connected to Mente Autism. When such problems are encountered, the LED on the device will turn to orange. Any issues during therapy will be prompted on the app, with the system being paused until the issue is acknowledged and resolved. If a sensor is not connected properly

or if there is a problem with the therapy, the light on the device will turn orange. At that point, a parent or carer should reconnect to the app to see what is wrong.

NOTE: If any of the sensor positions checks are indicated as red, please adjust sensor position until all sensors are marked green.

NOTE: If the audio check is red, please make sure that the in-ear headphones are plugged into the Mente Autism device.

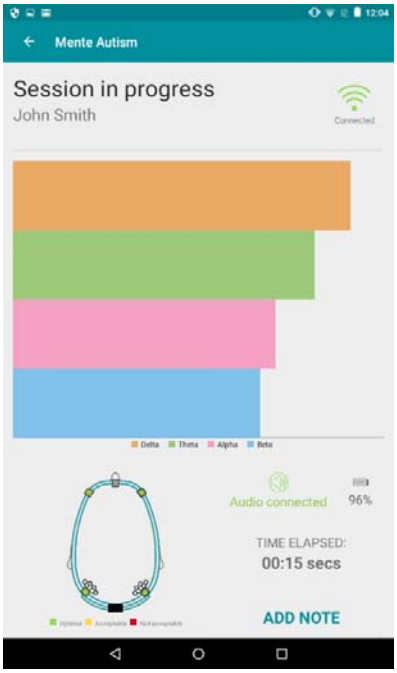
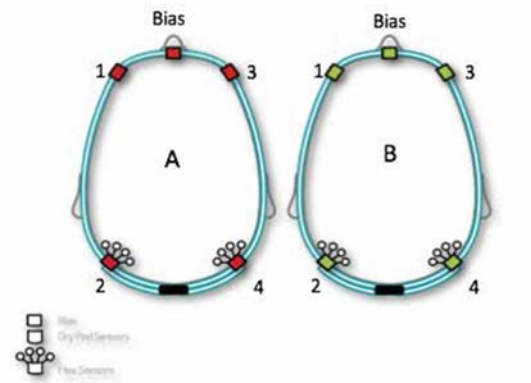


Figure 17: Session in Progress Screen



Sensor location on headband	Sensor location relative to typical 10-20 EEG setup
1	Fp1
2	O1
3	Fp2
4	O2

Figure 18 –Top view of Mente Autism device with (A) All sensors disconnected and (B) All sensors connected

j. Session Ending

After a complete session, the app will show a pop up that the session has been successfully completed. Tap 'OK' and the app will redirect you to the home screen. Then the device will automatically start transferring the data from Mente Autism to the tablet/smartphone and a pop up will be displayed. Wait until the transferring of data is ready.

Figure 19: Transferring Data Pop Up

NOTE: Do not turn off the Mente Autism headband while data is being transferred from Mente Autism to tablet/mobile and keep the Mente Autism headband and app close to each other.

Once the data has been transferred successfully to the tablet/smartphone, a number will be shown on the Upload button.

Switch off the Mente Autism headband and connect the tablet or smartphone to an internet connection.

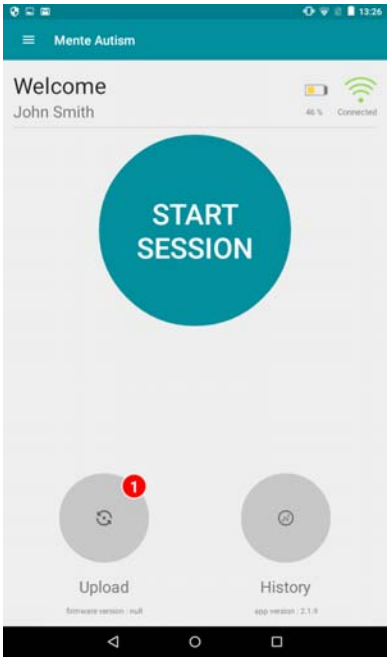


Figure 20: Upload Availability Screen

Press on the Upload button to upload the data to the Cloud server and a pop up will be displayed. Wait until the data has been successfully uploaded. Now the session report can be found in the History tab.

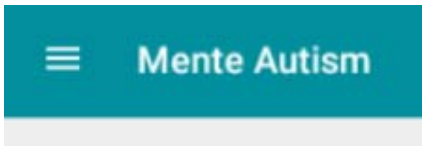
NOTE: If no Internet connection is available, the data can be uploaded later to the Cloud server however the report will not be available. The app can store a maximum of 3 sessions internally.

k. Power Down

The device will automatically power down if idle for 5 minutes. Should you wish to power off the device manually, simply hold down the on/off switch for a few seconds until the green LED turns off.

l. Logging Off

If you would like to Log Out from your profile, tap on the top left-hand icon to open the Mente Autism App Navigation Menu and then tap on 'Sign Out'.



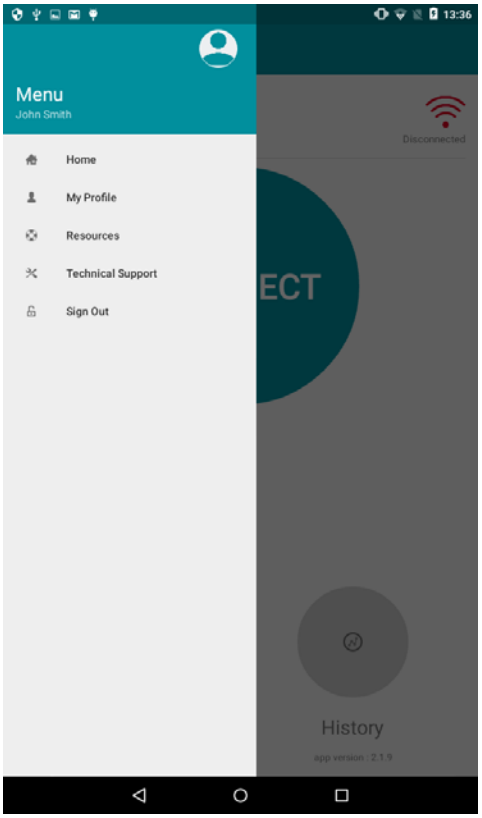


Figure 21: Mente Autism App Navigation Menu

13. The Report

A valid session produces a daily report that can be viewed on the app under the History tab or on the user dashboard via www.mentetech.com website.

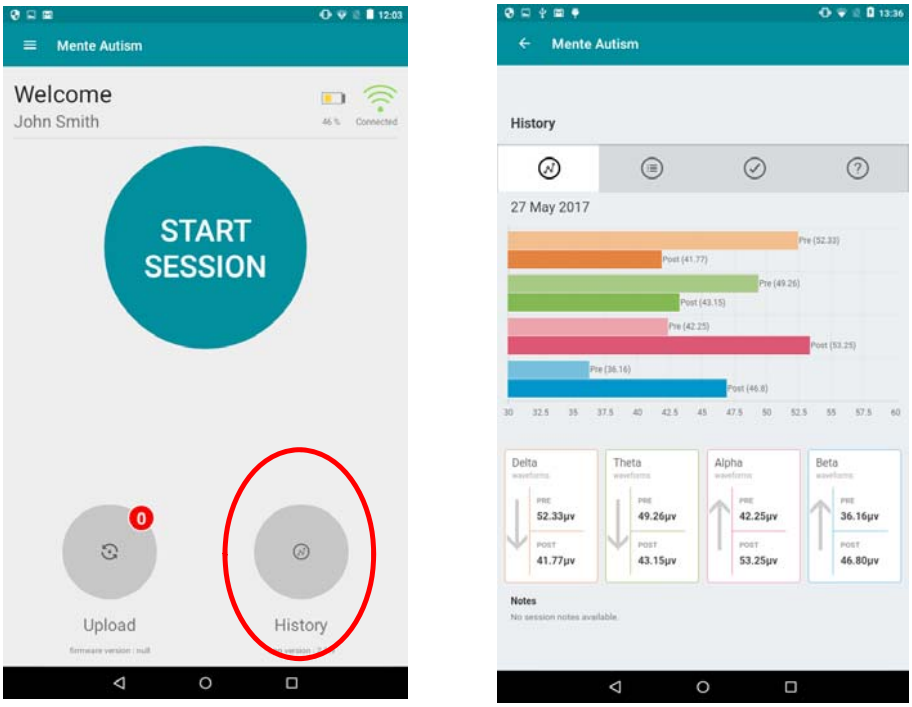
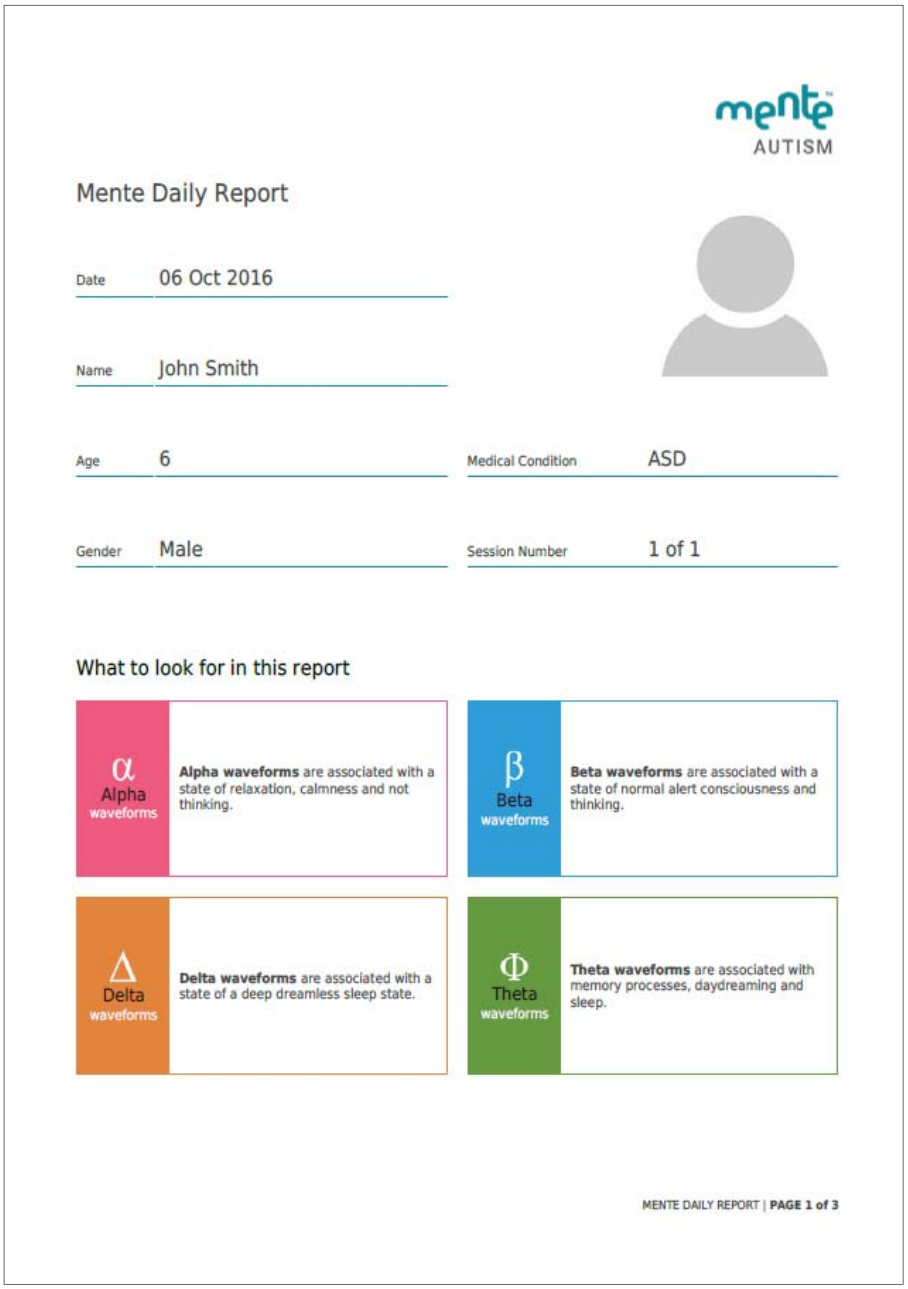


Figure 22: History Navigation Screen

NOTE: By default, the History tab will display the latest daily report.
NOTE: The daily report can be exported in PDF format via the user dashboard.

The following is an explanation of what the report contains.



mente AUTISM

Mente Daily Report

Date 06 Oct 2016

Name John Smith

Age 6

Medical Condition ASD

Gender Male

Session Number 1 of 1

What to look for in this report

α Alpha waveforms — **Alpha waveforms** are associated with a state of relaxation, calmness and not thinking.

β Beta waveforms — **Beta waveforms** are associated with a state of normal alert consciousness and thinking.

Δ Delta waveforms — **Delta waveforms** are associated with a state of a deep dreamless sleep state.

Φ Theta waveforms — **Theta waveforms** are associated with memory processes, daydreaming and sleep.

MENTE DAILY REPORT | **PAGE 1 of 3**

Figure 23: Mente Daily Report

- Details of the user appear at the top of each report. These include name, age, gender and medical condition, as well as session number and date. This section is only included on the pdf format online.
- Four types of waveforms and their roles in determining a state of mind are described. They are associated with a unique colour that is used to distinguish them throughout the report.

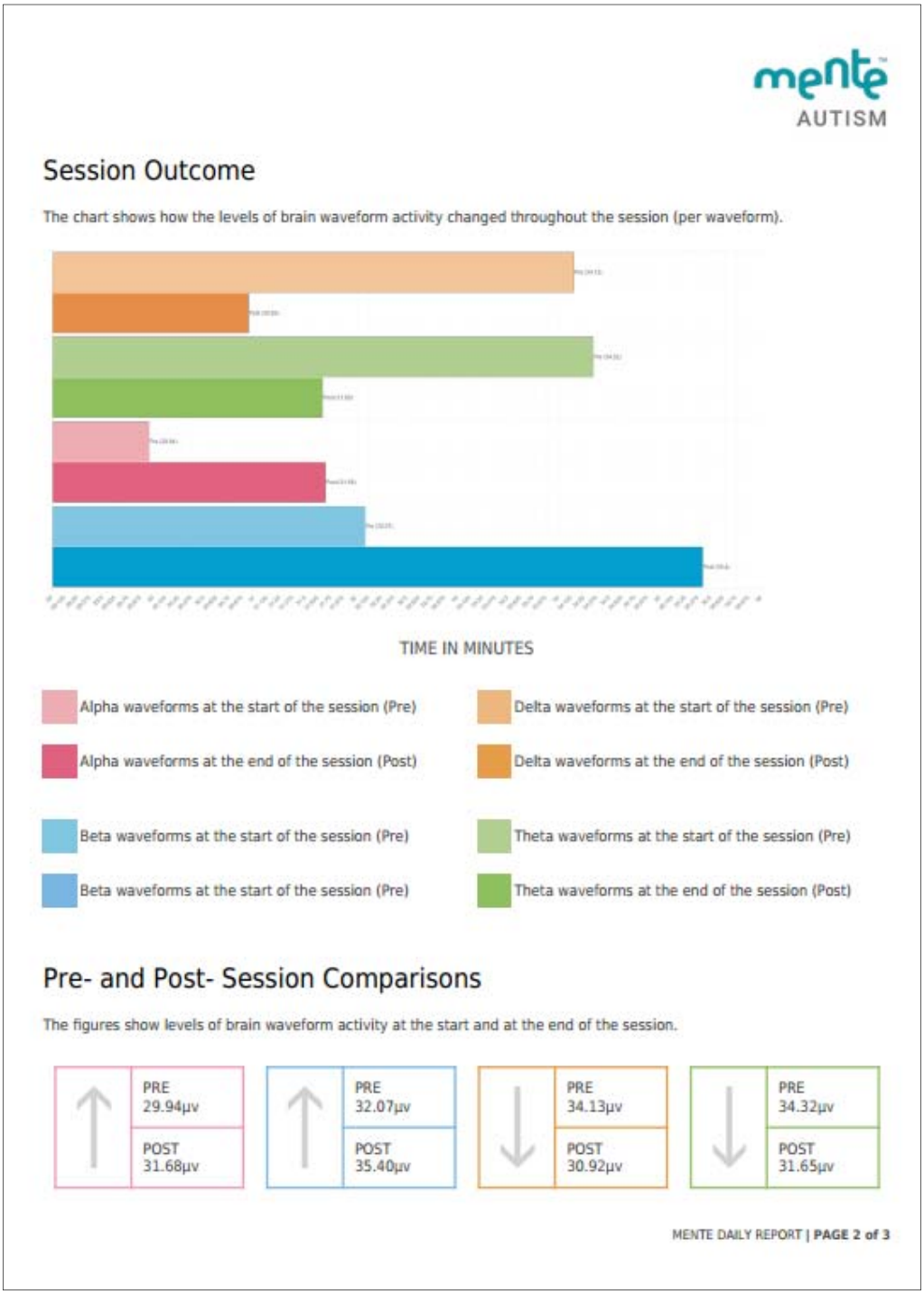


Figure 24: Session Outcome

- These charts indicate the pre- and post-levels of brainwave activity for alpha, beta, delta and theta as calculated from the trend line. Pre-values represent the brain wave levels at the start of the session and post-values represent those at the end of the session.

NOTE: Do not be alarmed if the results do not show a decrease in delta and theta immediately, especially in the first few weeks. The brain is a dynamic system which needs time to adapt to the therapy.

Remarks

If results are not in line with successful therapy outcomes, please ensure that the headband is being worn correctly.

It is imperative that the headband is not moved during calibration or impedance check. Throughout the session, the sensors must be properly placed on the user's head as described in the Quick Guide and User Manual. Failure to do so – especially on more than one occasion – will hinder progress as the therapy will not be delivered as intended.

Sessions should not be missed and synchronization should take place after each session.

Please keep an eye out for and record any changes in behaviour as the therapy sessions progress. If therapy has been carried out for less than 60 days, results presented are only indicative as time is needed for the user to become accustomed to the therapy.

It is highly recommended that, before starting Mente therapy, a qEEG is carried out by a medical professional to check whether the therapy is likely to be effective on the user. If this has not been carried out, please do so at your earliest convenience.

MENTE DAILY REPORT | **PAGE 3 of 3**

- This section contains advice about device use to ensure optimum results from the therapy. This section is only included on the pdf format online.
- The last report page also includes an 'Added Notes Section' to allow the parent or carer to input session details.

NOTE: A valid session is a session which is greater than 10 minutes and that has at least 10 minutes continuous without interruption at any point in time. The daily report is generated on longest valid session of that day.

NOTE: An invalid session is a session which is less than 10 minutes and that there was not a 10-minute continuous without an interruption.

14. Cleaning & Maintenance Instructions

General Cleaning

- The sensors must be removed from their snaps after use and stored in the box provided.
- The sensors should only be connected to the device for use and should be stored in a cool place, away from direct sunlight.
- The sensors can be cleaned with alcohol wipes of 70% concentration or less by rubbing gently in circular motions. Do not soak the sensors in alcohol or water.
- The earphones must be removed from the device after use and stored in the box provided. The earphones should only be connected to the device for use.
- The earphones must be regularly cleaned and maintained to last longer and perform better.
- Cleaning of the earphones can be done with alcohol wipes with 70% or less concentration, and this should be done before storing.
- The headband fabric should also be cleaned daily using the same alcohol concentration (70% or less), especially the inside of the headband where contact is made with the skin.

NOTE: Ensure that the device is turned off, with the sensors removed from the headband, before cleaning is performed.

Disinfection

Disinfection of the fabric headband is also recommended. When the device is used by one person only, it is recommended to disinfect it once a week. When the product is used daily by multiple users, such as in a clinic setting, the headband, sensors and earphones should be disinfected each time the device is used. It is recommended that disinfection is done using a base of sodium hypochlorite (for example, a 10% bleach solution with active sodium hypochlorite at about 0.6 % concentration) solution, in the form of wipes or spray. This has proven to be safe for both electrodes and headband.

NOTE: Avoid cleaning the white reference mark and the Mente Autism logo on the headband with the cleaning solution as these may be erased over time.

It is also possible to use disinfection products which are not specifically listed in this section but which have similar active ingredients to those mentioned above and are marketed for medical use.

To disinfect, mix the sodium hypochlorite disinfectant with clean water as indicated by the manufacturer; dampen a cloth with the cleaning solution obtained and wipe the headband and electrodes gently. When wiping the headband, do this slowly in circular movements. Wipe especially the internal part of the headband that encounters the skin. Do not spray the cleaning solution directly onto the headband because if liquid enters the device enclosure, it might cause a malfunction. It is important to let the device dry completely before use.

NOTE: Disinfectants containing mercury, phenols, bromine, iodine, zinc, tin and organo- metallic compounds should be avoided.

NOTE: Do not use steam sterilization as the electrodes and cable insulation might not withstand the heat.

NOTE: It is important that no water/cleaning agent/alcohol enters the electrodes and/or device case. Ensure that the cloth being used is only slightly wet to minimise the risk of the cleaning agent flowing into the device.

NOTE: The use of incorrect solution concentrations or the immersion of a transducer to a greater depth or for a longer period than indicated in the instructions could damage the device.

NOTE: Always use protective goggles and gloves when cleaning and disinfecting of any device or equipment.

NOTE: If using a premixed solution, always respect the disinfectant's "USE BY" date.

Storage

After each Mente Autism session, store the device in a cool dry place. It is recommended that Mente Autism is stored in the pouch provided with its original packaging. Sensors and earphones should be stored in their respective cases.

Maintenance and Servicing

General maintenance: For Mente Autism to remain in good operable condition, it is necessary to take the following precautionary measures:

a. Clean Mente Autism daily and disinfect as instructed depending on the number of people using it.
b. Avoid stretching the headband. The band should fit around the forehead and be secured with the Velcro® straps without stretching them (similarly, it should not be too tight).
c. Avoid mishandling of the band and enclosure. For this reason, it should be kept away from children and pets when not in use and stored securely.
d. Avoid charging the device excessively - device is to be charged only when required, as indicated on software. Once it is charged it should be disconnected and stored. It should be only charged using the USB adapter provided.
e. Upload the data regularly, ideally after each session. Upload of data is important so that all user reports and data are saved on the cloud system.

Sensor Servicing: For the sensors to remain in good operable condition, it is necessary to take the following precautionary measures:

a. All sensors should be removed at the end of every session and stored in the designated Sensor Case provided with the device.
b. The sensors should only be attached prior to a therapy session.
c. General inspection of the sensors should be done prior to every session, to ensure that the sensors are in good condition for use.
d. In general, the drypad sensors should be rehydrated with tap water by place them on a damp sponge once every two weeks. If the contact surface is deformed (see images below), rehydration is required.
e. For the best results, it is recommended that the set of sensors is changed every eight months.

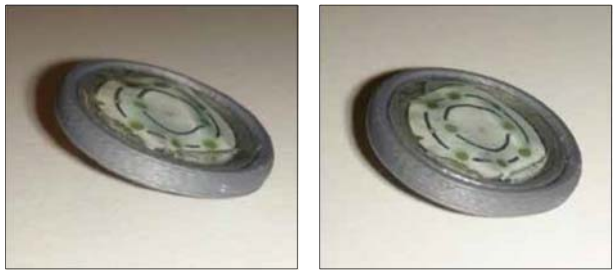


Figure 25 – Deformed Sensors

NOTE: Rehydration Process – Drypad sensors are best rehydrated by placing them face down on a damp sponge for 10-15 minutes. Drypad sensors are rehydrated when the contact surface is plump (see images below):

Figure 26 – Rehydration Method

Figure 27 – Rehydrated Sensor

Troubleshooting:

Please refer to the troubleshooting section on the User Dashboard under 'Technical Support' section or for any other problems, fill in the technical support form, available both online and through the Mente Autism App, and submit it to the technical team.

Servicing:

When you encounter the following problems, contact your local distributor for servicing. If needed, you will be provided with a temporary replacement device until yours is repaired. If the damage is not repairable, review the product warranty with your local distributor to define next steps. Some servicing examples include:

a. If the on/Off switch becomes jammed, or the LED light does not light up when the device is switched on, service repair personnel will replace the enclosure with a new one and attach it to existing headband.
b. If one or more sensors are broken, new sensors can be purchased from authorised distributors, and may be attached as per normal sensor connection instructions.
c. If the headband is torn, service repair personnel will replace the headband (with wires and electrodes) with a new one and attach it to existing device enclosure.
d. If the device enclosure breaks, service repair personnel will replace the enclosure with a new one and attach to existing headband.
e. If both the enclosure and headband are damaged, e.g., if the device has been submerged in water, the distributor will replace with a new device depending on the warranty.

Mente Autism should only be serviced by trained personnel appointed by the manufacturer. Contact your local distributor for more information. Service personnel are provided with all technical data needed for proper servicing and maintenance, upon request. **Terms of payment for repair and replacement depend on the warranty.**

Life Expectancy

The device's life expectancy depends mostly on its rechargeable battery. It has a life expectancy of at least 500 full cycles (charging and discharging). Thus, it is recommended to charge the device only when required to do so to maximise lifespan.

Disposal

If you need to dispose of Mente Autism for any reason or if it has reached its end of service life, please return the device with all original contents to the respective distributor or contact AAT Medical Ltd for proper disposal of the device. Before returning the device, it should be cleaned and disinfected and placed in its original packaging or in a similar cardboard box that is properly sealed and labelled. The courier used to transport the devices should be licensed to carry such devices, i.e., waste electrical and electronic equipment including Lithium Ion Batteries. The distributor will return the received device to AAT Medical Ltd which in turn will deliver it to the appropriate disposal site which processes electrical and electronic waste as per the DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE).

15. Continuous Support

Data access option

The Mente Autism system ensures that users and their carers receive continuous regular support from our Support team. Our Software department issues regular updates which will either automatically update your software version or notify and instruct you how to do so. These software updates are issued in response to the regular feedback and suggestions provided by users, as well as new features and performance optimisation of Mente Autism.

During **Registration**, the user is required to enter the requested personal details. Following this, the user is asked to read and accept the terms and conditions of use. This will allow AAT Medical Ltd to monitor the user's progress; upon request, a detailed report that summarises this progress can be provided to the user.

In-app support

The application itself also gives the option to review daily progress. This is available from the **History** screen, where you can access summary reports of all the sessions done.

Website Support Features

By logging into the website at www.mentetech.com and using your Username and Password, you can access several useful features.
You can view and access session reports after uploading the data from the respective device.
Manuals, guides and other material can also be downloaded from the **Resources** section of the dashboard.
The www.mentetech.com website can also be accessed by qualified clinical professionals who can access the user's data for analysis (subject to user's/carer's permission) as well as raw EEG and the daily reports.

NOTE: It is advised that data represented by the Raw EEG is always interpreted by a qualified medical professional.

NOTE: It is highly recommended that before purchasing Mente Autism, a short EEG test is carried out in an appropriate centre and the digital file (.edf or .bdf) is uploaded by a medical professional according to the QEEG protocol document available on the medical dashboard. This will indicate whether the patient would benefit or not from the use of Mente Autism.

To include a clinician in the portal, the user must send a request to the Clinician via the dashboard. Upon request approval, the User's data will be made available to the Medical Professional.

NOTE: Users can send requests to registered clinicians. However, they can also recommend unregistered clinicians to be added to the Mente database.

Feedback

The AAT Medical team is trained to help you maximise usage of the Mente Autism system and obtain the best possible results. We design any product iterations with our users in mind. Therefore, we greatly appreciate your comments and feedback. By completing the simple questionnaire sent from time to time through the Mente Autism app or by email, you can help guide us on what could be done to improve our products. Your feedback will help us design and develop future versions of the product.

Additionally, the Mente Autism software has a feature whereby the data upload of the device with its cloud system enables the AAT Medical team to easily monitor session reports and ensure that the desired outcome is obtained.

Frequently Asked Questions

A comprehensive list of FAQs is available on the website, www.mentetech.com. This list is regularly updated.

Contacting Support at AAT Medical Ltd

Customers with support requests should fill in the support form on the user dashboard or on the Mente Autism App. Alternatively they can contact the distributor or reseller from whom they purchased Mente Autism with their query, or can contact AAT Medical Ltd directly on support@mentetech.com.

16. What to Expect

Mente Autism affects each child differently. Generally, it might take a few weeks for any positive effects to be observed in the child's behaviour, although some parents have reported improvements after a few days.
After repeated use of Mente Autism, the child is expected to feel more relaxed. As a consequence of this, our experience and reports from parents and carers reveal that users are more relaxed and show improvement in one or more of the below:

a. Greater focus and concentration
b. Better understanding
c. Better speech abilities
d. More communicative
e. Improved social skills
f. Increased show of affection
g. Improved academic skills

Reports may not always show decreasing levels of Delta activity, especially in the first 4 to 8 weeks of using Mente Autism; this happens until the body adapts to the device. This is perfectly fine as the human brain is a dynamic system.

17. Battery Operating/Safety Instructions

Charging the Battery:

Battery charging will disable the use of the device, i.e., when the device is ON and plugged in for charging, the device will automatically switch OFF until recharged and USB connector unplugged. This is to ensure patient safety. Nonetheless, do not use or wear the Mente Autism device while charging.

The battery charger must be connected to the micro USB connector located at the side of the Mente Autism casing.

- The battery state of charge is measured by the software while the device is powered ON.
- The charging LED located near the connector is red when charging and off (no light) when it's fully charged.
- It should be noted that the battery will be over-discharged if the device is not used for a long time. To prevent over-discharging, the battery should be charged periodically.
- Over-discharging may cause loss of cell performance, or damage battery function. Expected life cycle> 500 cycles > 70 % of initial capacity.
- Charging with a higher voltage than specified may cause damage to cell.
- The usual time to charge a battery from the cut-off voltage to the maximum capacity is around 3 hours, but it depends on every specific battery (battery life and memory is a function of time).
- The system can be connected to any Class 2 electrical installation.

Operating Temperature	Storage Temperature	Mente Autism Electrical Specifications
Charging: 5°C – 40°C Discharging (During Use): 5°C – 40°C	1 year at -25°C – 70°C	Charging Voltage Input nominal: 5V DC Voltage input min/max: 4.25V – 7V Power input: 2.5W

18. Symbols Used

	SO 7010-W001 'Warning signal' according to UNE-EN 60601-1=2008 Parts marked with this symbol are not protected against defibrillator.
	'Device manufacturer' symbol according to UNE-EN 980
	ISO 7000-1641 'read instructions before use' symbol according to UNE-EN 980
	ISO 7010-M002 'Follow instructions for use' symbol
	Date of Manufacturing symbol according to UNE-EN 980
	'Do not throw away in generic waste' symbol. WARNING! When you want to dispose of the device, NEVER throw it in the trash, but go to the RECYCLABLE POINT or the nearest waste collection for further treatment, thus contributing to environmental care. Ideally, return device to distributor who will dispose of it appropriately.
CE 0426	CE marked device certified by the Notified Body n. 0426 of the European Community.
SN	SO 7000-2498 Serial Number according to UNE-EN 980
	Type BF Applied part
	ISO 7000-2606 'do not use device if product or packaging have been damaged' symbol according to UNE-EN 980
IP22	Device is protected against the ingress of solid foreign objects of 12,5mm diameter and greater, and it is protected against vertically falling water drops when enclosure is tilted at 15º.
	Do not wash
	Do not iron
	Keep away from sunlight

	Keep away from rain
	Class II equipment
	Not made with natural rubber latex
	The device should only be stored and used within the Temperature limits of -25°C and 70°C
	The device should only be stored and used within the Humidity limits of 15% and 93%
	The device should only be stored and used within the Atmospheric Pressure Limits of 70kPa and 106kPa
	The device is rated for an input direct current voltage of 4.25V-7V and 2.5W maximum power rating
	Batch code/ Lot number
	On/Off Push Button
	Auxiliary jack input for earphones
	USB Jack Input

19. EMC

Mente Autism is suitable for use in a specified electromagnetic environment. Mente Autism users should ensure that it is used in an electromagnetic environment as described below:

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	Mente Autism only uses RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	Mente Autism is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Mente Autism is suitable for use in a specified electromagnetic environment. Mente Autism users should ensure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	6 kV contact 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/ output lines	2 kV for power supply lines N/A	Main power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	1 kV differential mode N/A	Main power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % µ (>95% dip in µ) for 0,5 cycles 40% µ (60% dip in µ) for 5 cycles 70% µ (30% dip in U) for 25 cycles < 5 % µ (>95% dip in µ) for 5 secs	< 5 % µ (>95% dip in µ) for 0,5 cycles 40% µ (60% dip in µ) for 5 cycles 70% µ (30% dip in µ) for 25 cycles < 5 % µ (>95% dip in µ) for 5 secs	Main power quality should be that of a typical commercial and/or hospital environment. If the user of Mente Autism requires continued operation during power main interruptions, it is recommended that the Mente Autism image intensifier is powered from an uninterruptible power supply or a battery.

NOTE: U is the A/C main's voltage prior to application of the test level.

Mente Autism is suitable for use in a specified electromagnetic environment. Mente Autism users should ensure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	Vrms 50 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment can interfere with Mente Autism communication. This type of equipment, including cables, should be kept distant from Mente Autism with at least the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended Separation Distance d=1,2√P d=1,2√P 80 MHz to 800 MHz d=2,3√P 800MHz to 2,5 GHz 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interference may occur near equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 MHz to 1 GHz	

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which Mente Autism is used exceeds the applicable RF compliance level above, Mente Autism should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Mente Autism.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Mente Autism is intended to be used in a controlled radiated RF environment. Mente Autism users can help prevent electromagnetic interference by keeping a minimum distance between the portable RF device (transmitter) and Mente Autism as recommended below, according to the maximum output power of the communications device.

Rated Maximum Output Power of Transmitter - Watts	Separation Distance - Metres		
	150 kHz to 80 MHz d=1,2√P	150 kHz to 800 MHz d=1,2√P	800 MHz to 2,5 GHz d=2,3√P
0.01	0,12	0,12	0,23
0.1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

20. FCC Statement

FCC ID: 2AN82-MENTE003

This device complies with Part 15 of the 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.

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 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.

To assure continued compliance, any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

Radio Exposure Statement:
This equipment has been tested and shown to comply with FCC radiation exposure limits set forth for an uncontrolled environment (*). Users must follow the specific operating instructions in this manual for satisfying RF exposure compliance, especially with regard to positioning the equipment. No other than accessories described in this manual shall be used with the device.
(* further information about related test of the equipment to applicable FCC limits and results can be obtained from the public FCC Equipment Authorization system home page by filtering for the FCC-ID of the device.)

MODIFICATION:
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

21. Change Record

Issue	Date	Changes Made
1.0	06/09/2016	First version
2.0	23/03/2017	Wi-Fi option update

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AAT Medical Ltd is a wholly owned subsidiary of Neurotech International Ltd.