

MODIUS®

User Guide

v1.0

Modius® is a revolutionary new careable technology® which helps give you a leaner body.

Warnings and precautions:

- Do not use this product if you have epilepsy or wear a pacemaker.
- Keep this product away from children. Small items such as electrode pads are choking hazards.
- Warning: No modification of this equipment is allowed.
- Please adhere to all warnings and precautions detailed in the Safety Warnings and Precautions section of this User Guide before use of the Modius® Headset

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1. Introduction to Modius®

Thank you for purchasing Modius®, congratulations on your first step towards a leaner you!

Modius® is a transdermal neurostimulation headset. It is a battery-powered headset designed to deliver low-level energy in the form of a neurostimulation waveform that stimulates the activity of the vestibular cranial nerve. The delivery of this waveform (current) is applied through two self-adhesive electrode pads. These pads are placed on the skin overlaying each mastoid process (behind the ears). When turned on, the product delivers a small electrical impulse which can be adjusted up or down by the user.

Once adjusted to a level where the user is aware of a tolerable, comfortable gentle swaying sensation, the stimulation delivered by the Modius® headset should ideally remain at this level for the duration of the session (1-hour). Further adjustments may be made using the Modius® App. The device can also be paused using the app by pressing the pause icon, or alternatively paused by pressing the power button on the headset twice in quick succession. When finished the user removes the headset and disposes of the electrode pads after each use. When the product is not being used it can be charged through a micro-USB cable. For safety reasons, there are software controls in place to prevent the device delivering electrical stimulation when it is plugged into the micro-USB cable to charge the battery.

The recommended use is 1 hour per day, the Modius® headset will automatically stop stimulation if the usage reaches one hour per day. The user cannot use the device again within a 16-hour period, this is to allow some flexibility of stimulation routines if required. The Modius® Headset is intended to be used by anyone over the age of 18 in the home environment.

2. Modius® pack – contents

1. Modius® Headset
2. Modius® User Manual
3. USB charging cable and charger
4. 150 electrode gel pads, 100 alcohol wipes.

Note: Items also required for Modius® Headset operation but not supplied:

Mobile Device i.e. Smart Phone or Tablet Computer, with operating system; Android 5.0 or higher; or iOS 9 or higher.

3. Getting started...

Charging your Modius® headset

- Connect the USB power cable supplied with your Modius® headset to the USB plug adaptor (supplied) and connect the cable to the headset.
- If the headset is charging successfully the LED indicator will illuminate solid amber.
- When the headset is charged, the amber LED indicator will turn off.
- If you connect the power cable to the headset and the LED indicator blinks amber, the headset is experiencing a charging error (see “Troubleshooting”).
- When the battery level is low you will see the amber light flashing in sequences of 3 flashes. There is also an audio indication of 3 beeps. Once you see these low battery indicators it means there is up to 60 minutes of stimulation (max) before the headset will turn itself off.

NOTE: Please ensure you disconnect the charging cable before attempting to use your headset. Make sure to allow the USB Charger enough room so that it can be safely removed from the headset and power source.

Pairing your headset to your Bluetooth Device

- Before you start, ensure that:
 - Your headset is charged (see “Charging your Modius® headset”), and the charging cable has been disconnected.
 - Bluetooth wireless technology is enabled on your mobile device.

Download the Modius® app from the Apple App Store or Google Play and complete the registration process.

- With the headset powered off:
 - o Press the power button on the side of the headset and hold for 2 seconds
 - o You will hear a high-pitched beep, the power button will flash white. A blue LED indicator will periodically flash to indicate the headset is ready to pair.
- Launch the Modius® app on your mobile device, the app will begin to scan for your headset.
- Once the headset connects to the app you will hear a beep and the LED indicator will flash blue. This is the headset letting you know that your mobile device has requested to pair with it.
- Click the power button on the headset once to accept the pairing.
- On your mobile device, you will be presented with a notification telling you that the headset wishes to pair with your device. Accept the pairing, the headset will beep twice confirming the pairing.
- It may take around 10 seconds for pairing to complete.
- When the pairing is complete, the App screen will change showing you the dashboard and the user controls to operate your headset.

4. Using your Modius® Headset

Recommended use

Recommended use is 1-hour maximum per day. As a safety feature, Modius® will automatically stop stimulation if you exceed 1-hour of use per day. You can start a new session after a 16-hour period has lapsed, this is to allow flexibility for your usage routine.

Note: See Warnings and Precautions for further information on product safety.

How to wear your headset

- Use an alcohol wipe to clean the skin on the hard-bony area behind your ears (mastoids).
- Remove the protective plastic cover from the gel pads.
Brush away any hair strands before attaching the gel pads to the clean skin on your mastoids.
- Place the headset on your head as in *Figure 1*, aligning the power button above your right ear.
- Attach the cable buttons of Modius® onto the gel pads behind each ear.

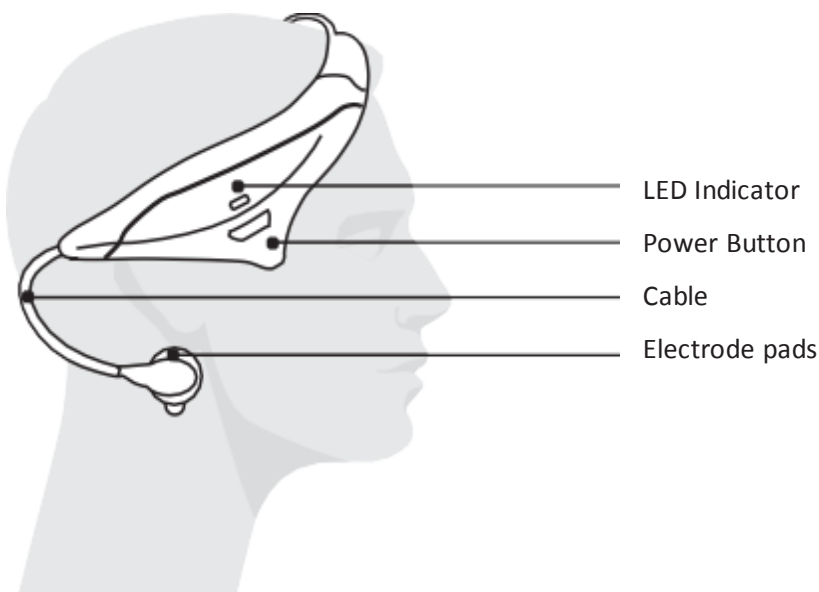


Figure 1

Turning your headset on and starting a new session

- Ensure that
 - The headset is charged and paired with your mobile device.
 - The headset is positioned comfortably on your head and the electrodes are attached as per the instructions.
- Turn headset on by pressing the power button for 2 seconds. You will hear a high-pitched beep and the white LED will begin to flash periodically.
- Launch the Modius® app and navigate to the “Dashboard” tab.
- Click the “Start” on screen button – This will begin your stimulation and session
- After 60 minutes use you will hear 3 short, high-pitched beeps and the LED indicator will flash white in sequence of 3 repeatedly, you have now finished your session.

Adjusting the Stimulation Level

- On the Modius® app, navigate to the “Dashboard” tab.
- The stimulation level can be adjusted using the on-screen controls, it can be adjusted up ‘^’ or down ‘v’
- Each time you adjust the stimulation level the headset will beep to notify you that the stimulation level has changed.
- The maximum power level of the headset is 10, if you try to increase the power level further you will hear 2 short high-pitched beeps to indicate you are at the maximum power level.
- The minimum power level of the headset is 1, if you decrease the power level further you will hear 2 short low-pitched beeps to indicate the headset is no longer stimulating and is at level ‘0’, essentially in standby mode.

* If you feel any discomfort during a session, pause the session and reduce the intensity before resuming. See additional warnings and precautions for more information.

Resetting your Modius® headset

Sometimes it may be necessary to reset your headset if you are experiencing issues. If you need to reset your headset follow the instructions below.

NOTE: Resetting your headset may cause data that hasn’t been synchronized with the app to be lost.

- Connect the Modius® Headset to the supplied power cable and USB charger
- Ensure orange LED is illuminated (indicating headset is charging)
- Hold the power button on the side of the headset for more than 10 seconds until you hear a series of 3 long beeps.
- The headset is now reset, unplug from power source. Now you should be able to continue use as normal.

Turning your headset off

- During use, or when the headset is in stand-by and ready to be used, press the power button on the side of the headset for at least 2 seconds.
- You will hear a low-pitched beep to indicate that the headset has powered off and after 10 seconds the app will revert to searching for your headset.
- Charge your headset after each use, ready for your next session.

5. Troubleshooting

Problem	Possible Cause	Solution
My headset turns on but won't let me start a session	The headset is connected to the charging cable	Disconnect the cable before attempting to start a session
My headset won't turn on	The headset isn't charged	Connect the headset to the charging cable
	The headset has entered a deep standby mode	Connect the headset to the charging cable and try to power it on
My headset works for a while then turns off by itself	The resistance between the pads is too high	Ensure that you have used the alcohol wipes prior to applying the gel pads to your skin, that the pads are positioned correctly behind your ears and that there is no hair between the pads and your skin
	The pads attached to the electrodes are worn out	Replace the gel pads on the headset
My headset won't connect to my mobile device	Bluetooth isn't enabled on your mobile device	Make sure that Bluetooth® has been enabled on your device
	Your mobile device is experiencing some issue when searching for the headset	Restart the app on your mobile device
During pairing I hear 3 short, low-pitched beeps and the LED indicator flashes blue 3 times	The headset has timed out when waiting for you to accept the pairing request from the mobile device	Turn off the headset and attempt the pairing again following the instructions in "Pairing your headset to your mobile device"
I'm experiencing discomfort when using the headset	The power level of the device may be too high	Reduce the power level of the headset using the app until you feel a gently rocking sensation or until the discomfort subsides

When I connect the headset to the charger the LED indicator is flashing amber	The headset is experiencing a charging error	Try connecting the charging cable to a different USB plug, if this does not resolve your issue please contact support
The LED indicator on my headset is flashing amber and I hear 3 short low beeps	The battery of the headset is low	Charge the headset (See “Charging your Modius® Headset”)
When I try to turn on the headset I hear 3 low beeps	The battery of the headset is critical	Charge the headset (See “Charging your Modius® Headset”)

6. Looking after your Modius®

Headset

- Only apply the pads to the mastoids, the hard-bony area behind your ear, as directed in the instructions above. Do not place on your chest or elsewhere on the head or neck. See “How to wear your Headset”.
- Use only while seated or lying down.
- Keep this product away from children. No-one under the age of 18 should use this product.
- Wipe clean with a soft cloth.
- Turn the headset off after use.
- Fully charge the headset before placing back into its case after each use.
- Do not use harsh abrasives or strong detergents.
- Avoid getting the headset wet
- Do not immerse in liquid.
- Do not leave in excessive sunlight.
- Do not leave Modius® in a situation where the headband is squashed or stretched. This will affect the comfort and security of fit to your head.

Gel pads

- Brush away any hair strands before attaching the gel pads to clean skin otherwise they may stick to the pads.
- Make sure your skin is clean and free of make-up, creams and other lotions before using pads.
- Clean hands before handling the pads and avoid touching them with your fingers as much as possible.

Dispose of pads in a suitable container or bin after use.

- Do not share the gel pads with anyone else. Pads are for single person use only.
- Do not use a pad for longer than the recommended 60 minutes per session.

7. General product information and technical specifications

Technical Specification: Modius® Headset








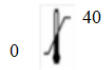





Power Characteristics	
Battery Life	Approx. 10hrs at level 10 Stim – Approx. 4 or 5 Days of Nominal use
Input Plug	Fully insulated touch proof micro USB
Weight	85g
Size	180x140x70mm
Power Supply Inlet Information	
Micro USB Port (Any USB port or USB charger must be certified to EN/IEC 60601-1, to ensure continued safety, only the charger supplied with the product should be used to charge Modius®) Voltage: 4.75 – 5.25V Max current 155mA DC	
Maximum output voltage Maximum output current	20V 600uA.
Bluetooth BLE - BGM113	
Operating frequency band	2.4GHz for the Bluetooth low energy functionality
Maximum RF power transmitted	+3 dBm
Battery (Battery is non-user replaceable) Lithium Polymer 4.2V 155mAh	
Operating Environmental Conditions	
Environment	Home Personal Use
Temperature Range	0°C to 40°C
Water Resistance	0m
Noise level	0dB
Storage Environmental Conditions	
Temperature Range	0 to 40°C
Relative Humidity	<95%
Expected Service life	The machine is guaranteed for 1 year but will often last longer. Accessories (leads, pads and wipes) are not covered by the guarantee <ul style="list-style-type: none"> • Lead life depends greatly on use. Always handle leads with care • Electrode pads only last for 1 application and please refer to manufacturers information for expiry. • Wipe please refer to manufacturers packaging for expiry.
Storage Life	<ul style="list-style-type: none"> • The headset unit has no fixed shelf life • Refer to manufacturers information for shelf life of the accessories (pads, leads and wipes)
Notice: This manufacturer warranty does not limit your statutory warranty rights.	

Symbol



Information

Please refer to additional symbols and the user guide for more information

	Serial number on product label to identify product
	Follow Instructions for Use (used in accordance with EN/IEC 60601-1)
5.0v 	Direct Current Direct electrical current at voltage shown.
	Type BF Applied Part
	Do not use if package is damaged
	The unit is not water resistant. Protect from moisture
	Number of items per pack
	Storage conditions: 0 – 40Degrees Celsius
	Relative Humidity: <95%
	Protective Earth (Ground)
	Do not use if Pacemaker fitted
	No protection against contact and ingress of objects and no protection from liquid ingress
	Please refer to the instructions for use before use of this device, failure to follow the instructions in the IFU (e.g. placement of electrodes in the right place) could cause harm to the user

Consumables (electrode pads, wipes)

Only use the consumables provided in the pack or recommended by Neurovalens. Consult manufacturer instructions detailed on the product packaging.

Return and Warranty policy

For further information go to www.modiushealth.com/returnsandwarranty

8. Regulatory and Safety notices

Declaration of Conformity - Model name: ML600

Hereby, Neurovalens declares that this product is in compliance with the essential requirements and other relevant provisions of Directives, General Product Safety Directive - 2001/95/EC and Radio Equipment Directive 2014/53 EU. To view the full Declaration of Conformity, go to www.modiushealth.com/compliance.

The Modius® headset equipment is classified for non-continuous operation. Modius® along with the USB charger supplied in accordance with electrical safety standards EN/IEC 60601-1 is considered as a Medical Equipment System (ME SYSTEM) to perform its function.

All applied parts are considered class BF. The IP rating of the headset is zero. This means there is no protection against contact and ingress of objects and no protection from liquid ingress.



Contains FCC ID: QOQBGM113

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 undesirable operation.



Modius® conforms to the applicable essential requirements of the Radio Equipment Directive 2014/53 EU.



Modius® complies with EMC standards in the Australian and New Zealand market.

Medical Device Regulators where Modius® is currently sold consider Modius® to be a General Wellness device and, therefore, are not enforcing medical device regulatory requirements.


Certified via Silicon Labs	FCC-15C
FCC ID:	QOQBGM113
IC ID:	5123A-BGM113

Safety statement

This equipment has been tested to comply with electromagnetic compatibility and safety certification in accordance with the specifications of EN Standards: EN301489-3, EN301489-17 and EN 60950-1, IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-11.

Modius® has been tested and complies with recognized standards for immunity to radio-frequency interference over operating frequency range 2.4 GHz.

Note: Modius® is indicated solely to assist adults, over the age of 18 years, with their weight loss and weight management goals.

 **Warnings and Precautions:**

Refer to the information and instructions provided before using the Modius® headset.

Only place electrode gel pads on the mastoids, behind the ears, as directed in the instructions provided. Do not place on your chest or elsewhere on the head or neck.

Do not use if you are pregnant, have reflex epilepsy triggered by vestibular stimulation or wear a pacemaker.

Use of Modius® should be discontinued immediately if unexpected reactions occur.

- Only apply the pads to the mastoids, the hard-bony area behind your ear, as directed in the instructions above. Do not place on your chest or elsewhere on the head or neck. See “How to wear your Headset”.
- Use only while seated or lying down.
- Keep this product away from children. No-one under the age of 18 should use this product. Small items such as electrode pads are choking hazards.
- Charge the headset in a well-ventilated area, gases may be produced when battery is charging hence charge in a well-ventilated area.

- Do not use if you are pregnant, have reflex epilepsy triggered by vestibular stimulation, or have an implanted pacemaker, cardiac defibrillator, or neurostimulation device. Note: Modius® stimulates the brain’s vestibular (balance) system. So, while this should not affect most people with epilepsy, it could trigger a seizure in someone with reflex vestibular epilepsy. If in doubt, potential users with epilepsy should first chat things over with their family doctor.
- Do not use while mobile (moving) as it can affect your sense of balance.
- Do not use while consuming alcohol, driving, or operating machinery of any kind.
- Do not use in wet environments or immerse the headset in water.
- Do not share your gel pads with anyone else. They are for single person use only.
- Do not use a pad for longer than the recommended 60 minutes per session.
- It is recommended to dispose of the pad after each use. Prolonged or repeated use of any one pad may reduce its effectiveness or lead to irritation of the skin.
- Do not apply the pads to broken or irritated skin.
- Remove pads carefully from the skin after use. Dispose of pads in a suitable container or bin.
- Do not try to remove the batteries. They are non-user replaceable.

Note:

The headset is not a medical device nor is it a substitute for a healthy lifestyle or for professional medical care.

Use of Modius® should be discontinued immediately if unexpected reactions occur. If you feel any discomfort during a session, pause the session and reduce the intensity before resuming.

Possible hazards or adverse effects include: skin irritation; discomfort from the stimulation; sensation of feeling off-balance; occasional nausea; and rarely vomiting. If a problem persists after 1-2 days, please consult your doctor.

Recommended use is maximum 1-hour per day. Modius® will automatically stop stimulation if you exceed 1-hour of use per day or a 16-hour period to avoid you from being 'locked out' if you want to use Modius® a few hours earlier one day.

Reset instructions should not be abused to increase personal daily usage.

Read and heed these warnings and instructions. Keep this guide with your headset

Built-in battery precautions

Your Modius® headset product has a built-in battery, which is not user replaceable. Users of Modius® should not attempt to replace the battery in the headset.

Do not tamper with your product or attempt to open it as this will void the warranty and can result in a safety hazard.

Charge the headset in accordance with the instructions supplied with this guide, using a power supply that is certified by a recognized testing laboratory.

Do not attempt to carry out any servicing or maintenance (included cleaning or charging) of the device whilst the device is in use

Disposal and recycling information



One of the provisions of the European directive 2002/96/CE is anything electronic should not be treated as electronic waste or thrown away. To remind you of this directive all affected products are now being marked with the crossed out wheellie bin symbol, as depicted above.

At the end of the product lifecycle, do not throw this product or batteries into the normal household bin but bring it to a collection point for the recycling of electronic equipment. Incorrect disposal can cause harmful toxins to build up in the air, water and soil and can be harmful to human health.

Note: Dispose of pads and wipes in a suitable container or bin.

License information



Modius® uses Bluetooth

Terms and Conditions

For further information go to www.modiushealth.com/termsandconditions

9. Contact

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support.modiushealth.com



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