

M  DIUS

USER MANUAL

Welcome to the Modius Family

Our technology was created to improve your health through a non-invasive and drug-free approach.

We hope that using Modius leads to a happier, healthier you.

A handwritten signature in blue ink that reads "Jason McKeown". The signature is fluid and cursive, with the first name "Jason" and the last name "McKeown" clearly legible.

Dr Jason McKeown

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Introduction

Modius Sleep is a non-invasive device created to help you reach improve your sleep management goals by delivering a small electrical current to the head.

We recommend that you use Modius Sleep for 30-60 minutes per day.

As a safety feature, your Modius Sleep will automatically stop stimulation after 60 minutes of use.

Whats Included:

Product Description	Product/Catalogue Code	Service Life
001 x Modius Sleep	MS600H	Lifetime of the device is 2 years
090 x Stimulation Pads	T832C	Do not use past expiry date specified on packaging. Pads are single use and are not to be reused.
100 x Skin Cleansing Wipes	326895	Do not use past shelf life/expiry date specified on packaging. Wipes are single use and are not to be reused.
001 x Charging Accessories (1 x USB Cable, 1 x Plug)	EDV1898349	Lifetime of the device is 2 years

Recommended Usage

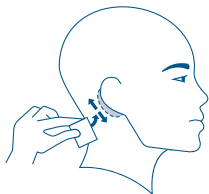
Modius Sleep may not work for everyone. If you feel that Modius Sleep is not working well for you, then please contact your health care practitioner.

Insomnia is usually improved after a few sessions but it may take up to 4 weeks before a significant improvement is noticed. Most people use Modius Sleep just before bedtime. The use of Modius Sleep 5-7 times per week is usually sufficient to maintain good results.

After using Modius Sleep there are usually no physical limitations imposed so most users can resume normal activities immediately. Some users may have a response that may affect their ability to perform potentially hazardous tasks, such as operating a motor vehicle or heavy machinery for up to several hours after treatment. However, no significant lasting side effects have been reported.

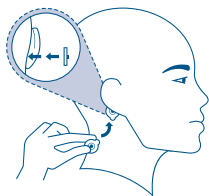
Possible hazards or adverse effects include; skin irritation; discomfort from the stimulation; sensation of feeling off-balance; headache; occasional nausea; and rarely vomiting. If a problem persists after 1-2 days, please consult your doctor.

How to Wear Modius Sleep



01.

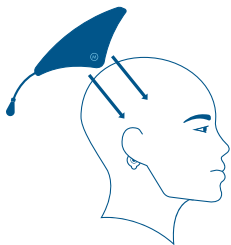
Use a skin cleansing wipe (provided) to clean the skin behind each ear (known as the mastoid area).



02.

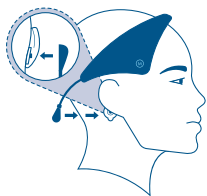
Once the area is dry, take a stimulation pad and peel off the plastic covering. Stick a stimulation pad firmly on the mastoid area behind each ear, ensuring you have removed any hair from the area.

How to Wear Modius Sleep



03.

Place Modius Sleep on top of your head, with the bottom aligning over your right ear.



04.

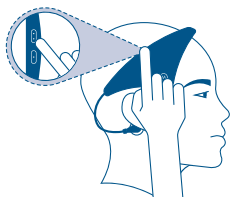
Move the cable end towards the stimulation pad and click into place.

Controlling Modius Sleep





01.

To turn on Modius Sleep, press the power button on the headset and hold for 2-3 seconds. The device will beep and the LED indicator will flash when successfully switched on.



02.

Use the buttons on top of Modius Sleep to increase and decrease the level of stimulation. Press the  button to increase the stimulation until you feel a gentle rocking sensation. We recommend you start at a low level of stimulation and increase as you use Modius Sleep over time. If you need to decrease the level of stimulation press the  button on the headset.



03.

When you have completed your 30-60 minute session, switch off Modius Sleep by pressing and holding the power button for 2-3 seconds. You will hear a low-pitched beep as Modius Sleep powers down.

How to Remove Modius Sleep

01.

To turn off Modius Sleep, press and hold the power button on the headset for 2-3 seconds. One low pitched beep will indicate that the device has been successfully switched off.



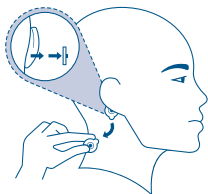
02.

Unclick the cable from the stimulation pad and remove Modius Sleep from the top of your head.



03.

Carefully remove the stimulation pad on the mastoid area behind the ear and dispose of.



Charging Your Modius Sleep

1. Connect the Micro USB charging cable (supplied) with your Modius Sleep to the USB plug (supplied) and connect the cable to the Modius Sleep.
2. When the headset is successfully charging, the LED indicator will illuminate a solid amber colour.
3. When the headset is fully charged the amber LED indicator will turn off and stop flashing.

Note: Please ensure you disconnect the Micro USB charging cable before attempting to use your headset.

To indicate a low battery level, the amber LED will flash and beep three times. These indicators mean there is less than 60 minutes of stimulation left on the device. Once the battery is completely depleted the device will turn itself off.

Resetting Modius Sleep

If you are experiencing issues with your Modius Sleep, it may be necessary to reset the device.

To reset your device follow steps below:

1. Connect Modius Sleep to the supplied Micro USB charging accessories.
2. Ensure the amber LED is illuminated (indicating the headset is charging).
3. Hold the power button on the side of the Modius Sleep for more than 10 seconds until you hear a series of 3 long beeps.
4. The Modius Sleep is now reset. Unplug from power source.
5. Now you can use your Modius Sleep as normal.

Safety & Product Information

Warnings & Precautions:

1. Please read the user manual and make sure that you understand the instructions before you use the product.
2. Only place stimulation 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.
3. If an unexpected reaction occurs, discontinue use of Modius Sleep immediately.
4. Keep this product away from children as small items such as stimulation pads are choking hazards.
5. It is recommended that you use this device only while seated or lying down.
6. Modius Sleep must not be used while driving or operating machinery of any kind.
7. Modius Sleep is for adults only (aged of 18+).

DO'S:

1. Only apply the stimulation pads to the mastoids, the hard bony area behind your ear, as directed in the instructions. Do not place on your chest or elsewhere on the head or neck.
2. Use only while seated or lying down.
3. Dispose of stimulation pads in a suitable bin after use.
4. Keep this product away from children. No-one under the age of 18 should use this product.

Safety & Product Information

DO NOT'S:

1. Do not use if you are pregnant or have an implanted pacemaker, cardiac defibrillator or neurostimulation device. Individuals with epilepsy should consult their primary care physician or other healthcare provider before using Modius Sleep as certain types of epilepsy, in particular reflex vestibular, can be triggered by vestibular stimulation.
2. Do not use while moving as it can affect your sense of balance.
3. Do not use while consuming alcohol, driving or operating machinery of any kind.
4. Do not use in wet environments or immerse the headset in water.
5. Do not share your stimulation pads with anyone else. They are for single person use only.
6. Do not use the stimulation pads for longer than the recommended 60 minutes per day session.
7. Do not use a stimulation pad for more than one 60 minute session, as it may reduce it's effectiveness or lead to irritation of the skin.
8. Do not apply the stimulation pads to broken or irritated skin.
9. Do not try to remove the batteries as they are non-user replaceable.

Note:

1. If you feel any discomfort during a session, pause the session and reduce the stimulation level on Modius Sleep via the buttons until it is at a comfortable level before resuming your session.
2. Possible hazards or adverse effects include; skin irritation; discomfort from the stimulation; sensation of feeling off-balance; occasional nausea; and rare vomiting. If a problem persists after 1-2 days, please consult your doctor.
3. It is recommended that you use Modius Sleep for 30- 60 minutes per day. As a safety feature, Modius Sleep will automatically stop stimulation after 60 minutes of use per day. You can start a new session after a 16 hour period has lapsed. This is to allow flexibility in your usage routine.

Troubleshooting

Problem	Possible Cause	Solution
My Modius Sleep turns on but won't let me start a session	The Modius Sleep is connected to the charging cable	Disconnect the cable before attempting to start a session
My Modius Sleep won't turn on	The Modius Sleep isn't charged	Connect the Modius Sleep to a power source using the Micro USB charging cable and plug
My Modius Sleep works for a while then turns off by itself	The resistance between the stimulation pads is too high	Ensure that you have used the alcohol wipes prior to applying the stimulation pads to your skin. Please allow time to dry. Then position the stimulation pads correctly behind your ears, and ensure there is no hair between the electrode pads and your skin
My Modius Sleep works for a while, then turns off by itself	The Modius Sleep has entered a deep standby mode	Connect the Modius Sleep to a power source via the micro USB charging cable and try to power it on
My Modius Sleep works for a while then turns off by itself	The stimulation pads attached to the electrodes are worn out	Replace the electrodes on the headset

Troubleshooting

Problem	Possible Cause	Solution
I'm experiencing discomfort when using Modius Sleep	The power level of the device may be too high	Reduce the power level of the Modius Sleep using the buttons until you feel a gentle rocking sensation or until the discomfort subsides
The LED indicator on my Modius Sleep is flashing amber and I hear 3 short, low-pitched beeps	The battery level of my Modius Sleep is low	Charge Modius Sleep (See "Charging your Modius Headset (page 19)")
My Modius Sleep has frozen	The Modius Sleep has entered a deep standby mode	Reset your Modius Sleep (See "Resetting your Modius Headset (page 20)")

Technical Spec

Power Characteristics	
Battery life	Approximately 10 hours at level 10 stimulation or 4-5 days of nominal use
Input plug	Fully insulated touch proof Micro USB port
Weight	85g
Size	180x140x70mm

Power Supply Inlet Information	
<p>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.</p> <p>Voltage: 4.75 – 5.25V Maximum current: 155mA DC</p>	
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	


Technical Spec

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°C to 40°C
Relative humidity	<95%
Storage life	The headset unit has no fixed shelf life
	Refer to manufacturers' information for shelf life of the accessories (electrode pads, leads and wipes)

Technical Spec

	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)
	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

	Storage conditions: 0°C to 40°C
	Relative humidity: <95%
	Protective earth (Ground)
	Do not use if pacemaker fitted
	No protection against contact, ingress of objects and no protection from liquid ingress
	Please refer to the instructions for use before using 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

Declaration of Conformity

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.

The Modius Sleep equipment is classified for non-continuous operation. Modius Sleep along with the Mirco USB charging cable 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.
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.

Certified via Silicon Labs: FCC-15C

FCC ID: QOQBGM113

IC ID: 5123A-BGM113

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

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