



AuraStim



User Manual

Please thoroughly read this manual before using the product and keep it readily available for future reference.

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Indications for Use

1. The acute treatment of migraines with or without aura in patients 18 years of age or older.
2. The preventative treatment of episodic migraine in patients 18 years of age or older.

General Description

■ AuraStim, an eye-goggle-shaped and highly functional device designed for migraine treatment, delivers electrical pulses, green LED light, and soothing music to the trigeminal nerve. This unique combination aims to alleviate migraine symptoms and reduce the frequency of migraine attacks.

■ Controlled wirelessly by a remote, the AuraStim device features corresponding voice prompts for various operations, ensuring user-friendly and intuitive control.

■ For optimal results, utilize the forehead electrode pads and electrode wires provided by HiDow. Thoroughly read this manual to familiarize yourself with the included components, accessories, and proper operation for achieving the best treatment effects.

Contraindications

Refrain from using AuraStim if you:

1. Have implanted metallic or electronic devices in the head.
2. Are experiencing pain of unknown origin.
3. Possess a cardiac pacemaker or have an implanted or wearable defibrillator.

General Warnings and Cautions

Usage Precautions:

- Do not use AuraStim while sleeping.
- Avoid using AuraStim in a wet environment, such as in the bath or shower.
- Refrain from using AuraStim while driving, operating machinery, or

engaging in any activity that requires alertness. Wait for 1 hour after each treatment session before resuming such activities.

- Avoid use in the presence of electronic monitoring equipment (e.g., cardiac monitors, electrocardiogram (ECG) alarms).

Application Guidelines:

- AuraStim and electrodes are specifically designed for use only in the forehead regions.
- Do not use AuraStim in the neck region.
- Avoid using AuraStim close to the thorax (chest region).

Skin Conditions:

- Use AuraStim only on normal, intact, and clean skin.
- Do not use over open wounds, skin eruptions, swollen, infected, or inflamed areas.
- Avoid use over or close to cancerous lesions or skin abnormalities that could be cancerous.
- Exercise caution or refrain from using AuraStim if there is any loss of feeling in the skin of your forehead or scalp until normal feeling is resumed.

Recommended Usage:

Use AuraStim only with the electrodes and accessories recommended by HiDow. For best results, lightly spritz HiDow conductor spray on the electrodes before connecting to the unit, then use the finger to rub the surface of the electrode to let it dry out a little bit. Then connect the electrode to the unit. The use of the spray will increase the conductivity and make the sensation more comfortable during application.

Safety Measures:

- Keep AuraStim out of the reach of children.
- Be cautious of strangulation risk due to the length of the charging system

cable.

- Be aware of suffocation risk in case of swallowing the electrode.

Ask a doctor before use if you:

- You are under 18 years of age.
- You are over 65 years of age.
- You are pregnant or may become pregnant.
- You suspect or know that you have heart problems.
- You have had a recent head injury.
- You have ever suffered a seizure.
- You have never been diagnosed with a migraine by a health professional.
- You have a headache that is different from your usual migraines.
- You have the worst headache of your life.
- You have a fever or a stiff neck.
- Your headache began after a head injury, exertion, coughing, or bending.
- You experienced your first headache after the age of 50 years.
- You have a migraine so severe that it requires bed rest. Consult your healthcare provider before using the AuraStim if you have Medication Overuse Headache, Chronic Tension-Type Headache, or Refractory Migraine, as the safety and effectiveness of the device have not been demonstrated for subjects with such conditions.
- If the frequency of your headache is not reduced after 2 or 3 months of daily use of Program 2 (prevention), consult your doctor.
- The long-term effects of chronic use of AuraStim unknown. Migraines may indicate a serious medical condition, and you should have them checked by a doctor.
- Check with your doctor if you do not understand or are unsure whether any of the above “Contraindications” or “Warnings” apply to you or your condition.
- Seeking professional guidance is crucial for ensuring the device's safe and appropriate use based on individual health circumstances.

Important Usage Information:

- Consult your doctor before using the AuraStim device if you have ever had a seizure or have been diagnosed with epilepsy.
- The AuraStim device is not a cure for migraines.
- The long-term effects of chronic use of the unit are unknown.
- Use this unit only with the electrodes and accessories recommended by the manufacturer.
- Avoid using AuraStim in close proximity (less than 3.5 feet) to shortwave or microwave therapy equipment, as it may produce instability in the AuraStim output.
- Use is incompatible with the simultaneous use of high-frequency surgical equipment.
- It may be dangerous to connect the AuraStim with devices not identified in this user manual.
- Do not modify this equipment without written authorization from the manufacturer.
- The AuraStim contains a rechargeable lithium battery. Do not attempt to tamper with or misuse the battery, as it could result in a fire, explosion, or dangerous gas leak.

Adhering to these guidelines ensures the safe and effective use of the AuraStim device. If you have specific health concerns or conditions, it is advisable to consult with your healthcare provider before use.

FCC Caution:

Part 15.21

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

Part 15.19

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.

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.
3. The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Part 15.105

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

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Conformity to safety standards

Statement of EMC

IEC 60601-1-2:2014+A1:2020

Conformity to MDD Requirements

IEC 60601-1:2005+AMD1:2012+AMD2:2020/AAMI ES60601-1:2005,

ES 60601-1:2005/AMD1:2012, ES60601-1:2005/AMD2:2021

IEC 60601-1-11:2015+A1:2020

IEC 60601-2-10:2012+A1:2016

Conformity to FCC Requirements

The devices are in compliance with 47 CFR FCC Part 15 Subpart B;

FCC CFR Title 47 Part 15 Subpart C Section 15.247

ANSI C63. 27:2017

AAMI TIR69:2017(R2020)

Warranty Information

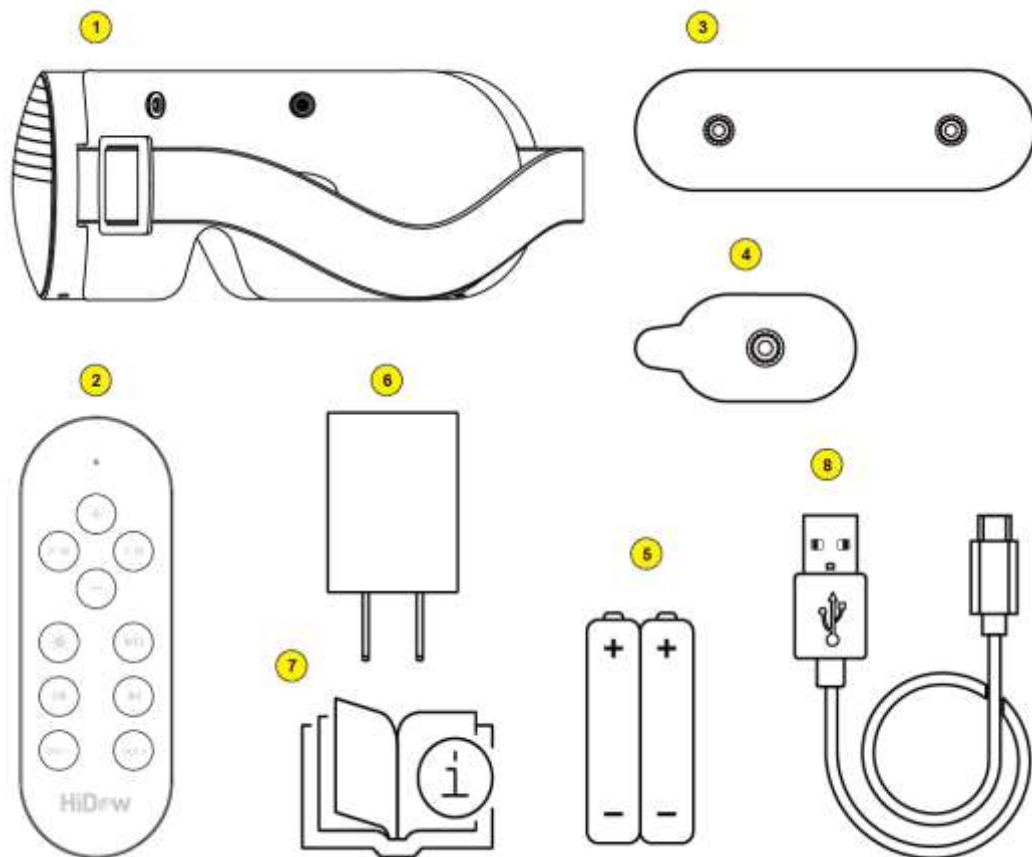
■ The HiDow AuraStim carries a warranty of 2 years from the date of purchase. The warranty applies to the AuraStim device and REMOTE, but the electrodes, wires, charging cables, and other accessories are excluded from this warranty.

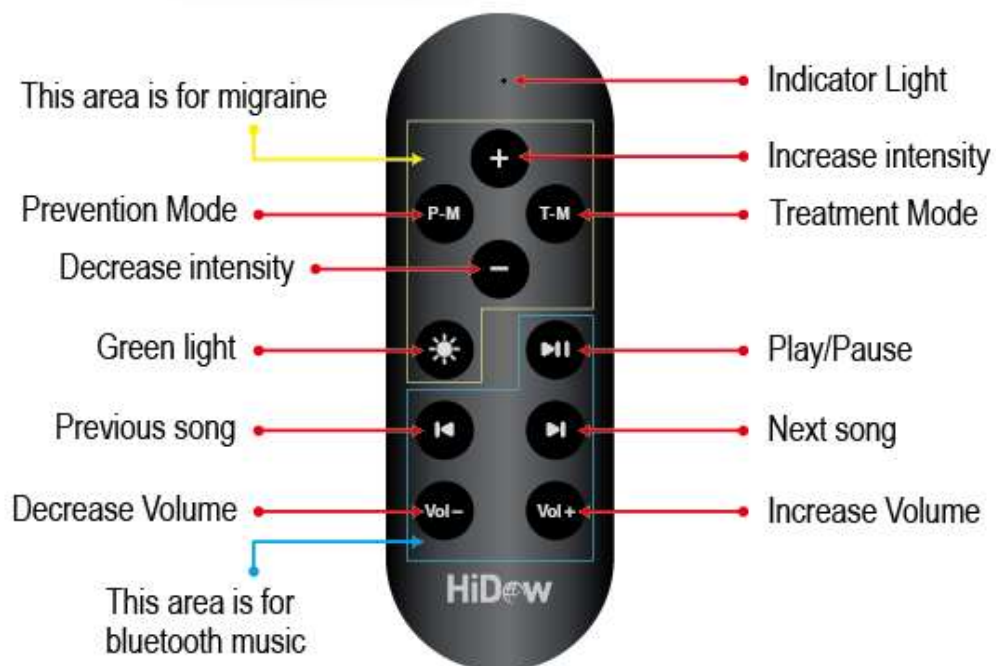
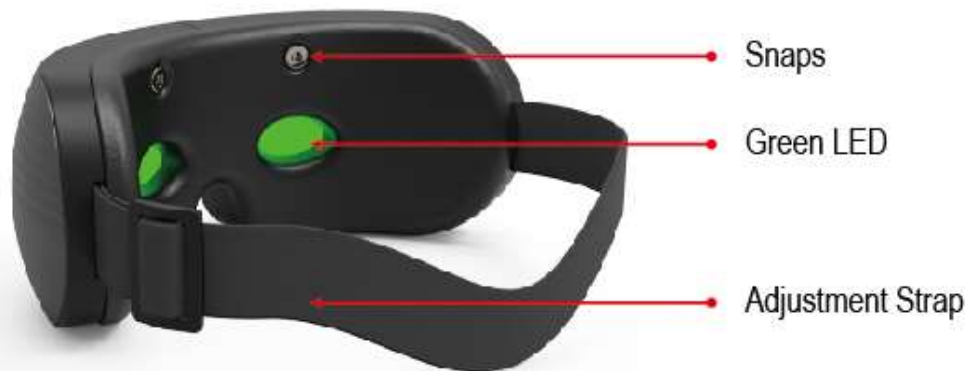
■ The warranty does not apply to damage resulting from failure to following the operating instructions, accidents, abuse, alteration or disassembly by unauthorized personnel.

General Information

Included in this package:

1. AuraStim
2. Remote Control
3. 2 Pieces of Electrode Pads (Forehead)
4. 2 Pieces of Electrode Pads (Forehead)
5. 2 Pieces of Batteries
6. AC Adapter
7. User Manual
8. USB Cable





General Instructions for Use

Set Up

Step 1: Snap the pads to the AuraStim device.



Step 2: Remove the protective film from the pads and then wear the AuraStim device on your face.



Step 3: Adjust the tightness of the straps to ensure a comfortable fit.

Step 4: Powering On the AuraStim device:

- Press and hold the power button on the AuraStim device.
- Look for the green light, which indicates that the device is now turned on.
- A voice prompt will accompany the activation.

Operation

Mode Selection:

- Press “P-M” to choose the prevention mode.
- Press “T-M” to select the Treatment mode.

Intensity Adjustment:

- Press “+” to gradually increase intensity until you are satisfied with the intensity, then press “+” to stay at the current level.
- Press “-” to gradually decrease intensity until you are satisfied with the intensity, then press “-” to stay at the current level.

Light Controls:

- Press “  ” to toggle the green light on/off and adjust between two levels.

Pairing Steps of Bluetooth:

- Press and hold the power button on the AuraStim device and make sure the device is turned on.
- Turn on Bluetooth on your phone.
- Find your device "AuraStim" in the list of Bluetooth devices, and choose this device, then click “Pair”.
- The device will prompt “Connected” when paired successfully; and the device will prompt “Disconnected” when the Bluetooth is disconnected.
- After successful pairing, open the music player of your phone and enjoy the wonderful music.

Volume Adjustment:

- Press “ **Vol+** ” “ **Vol-** ” to adjust the volume, and there are 16 levels.
- Press “  ” “  ” to choose the previous and next music.
- Press “  ” to play or pause the music.

Notes:

When there is an external call coming, the user can answer the call by the mobile phone, and at the same time the AuraStim device will automatically stops playing music. After the call is finished, the device will go on playing music.

Turning Off the Migraine Plus Device:

Press and hold press the power button to initiate the shutdown process for the AuraStim device. By default, the device is set to turn off automatically after 1 hour.

Important Notes**Mode Descriptions:**

- “Treatment” Mode: This mode generates the treatment signal to stimulate and desensitize the trigeminal nerve, which can treat migraine attacks when

they begin so as to stop or relieve the migraine pain.

- “Prevention” Mode: This mode is designed for the preventative treatment of migraines and can help reduce the number of monthly migraine days.
- Everyone responds to the treatment differently. It may take a few weeks of consistent use before you feel an improvement. You can also use the goggle with green light for a quiet rest without turning on the stimulation function.

Session Time:

- For best results, the “Treatment” mode should be used for a full 60-minute session.
- For daily prevention, the “Prevention” mode should be used for 20-minute sessions.

Remote Indicator Lights:

- When any button on the remote is pressed, the green indicator light flashes under normal battery conditions.
- A flashing red indicator light means a low battery; prompt replacement is necessary.

Device Battery Status:

- Turn on the AuraStim device; the indicator light is green under normal battery conditions.
- A red indicator light indicates low battery; recharge promptly to prevent automatic shutdown.

Charging Instructions:

- The charging USB port is discreetly located in the middle of the AuraStim device. You can see it when you fold the goggle.
- Charge the device with AC adapters; the recommended output voltage is 5V, with an output current not less than 1A.

CAUTION:

When installing the battery in the remote, please ensure proper attention to the positive (+) and negative (-) directions. Failure to do so may result in damage to the remote.

Please refer to these instructions for optimal use and maintenance of the AuraStim device.

Technical Information

REMOTE: 2×AAA/1.5V

AURASTIM DEVICE: DC3.7V/1000mAh (Rechargeable lithium-ion battery)

LOAD RESISTANCE: 1000 Ω

PARAMETERS	Treatment	Prevention
PULSE FREQUENCY:	100Hz	60Hz
PULSE WIDTH:	250 μ s	250 μ s
PULSE DURATION:	500 μ s	500 μ s
MAXIMUM INTENSITY:	16mA	16mA

DEFAULT TIMER: 60 Minutes

COLOR: Black

DIMENSION: AuraStim: 8.94 x 4.4 x 3.6 in

Remote: 4.48 x 1.55 x 0.6 in

NET WEIGHT: AuraStim: 12.4 oz

Remote Control: 1.16 oz

OPERATING CONDITIONS:

Temperature: 5°C to 40°C (41°F to 104°F)

Humidity (non-condensing): 30% to 75%

Atmospheric pressure: 700 to 1,060 HPa

STORAGE AND TRANSPORTATION CONDITIONS:

Temperature: -10°C to 55°C (14°F to 131°F);

Humidity (non-condensing): 10% to 90%

Atmospheric pressure: 700 to 1,060 HPa

REMARK: Shall not deviate by more than $\pm 20\%$

Troubleshooting

Problem:The AuraStim device is not turning on.

Cause:The battery is depleted.

Solution:Make sure the device has been fully charged.

Problem:The indicator light of AuraStim device becomes red.

Cause:The battery is low.

Solution:Charge the device soon or it will turn off automatically.

Problem:The red indicator light of REMOTE flashes.

Cause:The battery is low.

Solution:Replace the battery.

Problem:Adhesive electrode pads do not stick to skin even after cleaning and moistening their surface.

Cause:Adhesive gel pads lose adhesiveness and need to be replaced.

Solution:Replace the adhesive gel pads. Pads can be purchased from your local distributor.

Problem:The AuraStim device doesn't seem to be charging.

Cause:Charging cable is not plugged in fully.

Solution:Ensure the USB cable is firmly in the device on one side and plugged into the AC adapter into the electrical socket on the other side.

Problem:During use the skin feels a painful burning sensation or the stimulation becomes weakened.

Cause:Adhesive gel pads are not adhering firmly to the skin or the gel pads are too dry.

Solution:Make sure the pads are pressed firmly to the skin during application. And put a few drops of water on your fingers and rub them on both

pads, which will help the electrode pads increase their adhesiveness.

Problem:During use, there is no sensation felt or the intensity is too low.

Cause:

- ①The electrode gel pads are not adhering firmly to the skin.
- ②Increasing the intensity of electrical pulses is a continuous and slow process.

Solution:

- ①Make sure the pads are pressed firmly to the skin during application. And put a few drops of water on your fingers and rub them on both pads, which will help the electrode pads increase their adhesiveness.
- ②Please wait until the intensity is increased to a comfortable level and then maintain it.

Problem:The REMOTE can not control the AuraStim device.

Cause:

- ①The distance of wireless communication is too long.
- ②The battery of the REMOTE is depleted.
- ③The device is not synced with the REMOTE.

Solution:

- ①Make sure the distance between the REMOTE and device is less than 8 meters.
- ②Replace the battery of the REMOTE.
- ③Remove the battery from the REMOTE, and reinstall the battery after 1 minute. Within 10 seconds, press and hold the button “T-M” till the indicator light of the REMOTE flash continuously. Press and hold the power button to turn on the device, then double click the power button, the indicator lights of the REMOTE and device will stop flashing if the sync is finished. If the indicator lights still flash, pls repeat the above steps to sync the REMOTE and device again.

User Manual Version:1.0

Software Version:1.0

Model : HD-18A



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