

# TAC-STIM non-invasive Vagus Nerve Stimulator (nVNS) **Application & User Guide**

### About TAC-STIM

TAC-STIM™, non-invasive Vagus Nerve Stimulator (nVNS) is a Low-Risk General Wellness Product. The product is not regulated by the US FDA and is not intended to treat or diagnose any medical condition or disease.

TAC-STIM (nVNS) delivers proprietary electrical signals via two small electrodes placed on the skin at the cervical level. The electrical energy stimulates the vagus nerve, which triggers neurotransmitters in the brain.

**NOTE:** TAC-STIM will deliver 200+ stimulations in a 24-hour period, starting when the product is turned on for the first time and the intensity level is increased above 3.

### Get to know TAC-STIM



The icons below indicate what the number on the display represents.



**Months remaining** 



**Intensity** level



Sessions remaining in a 24-hour period

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## **Charging TAC-STIM**

- Plug the charging cord into the back of the charging case and connect it to an electrical outlet.
- Place TAC-STIM into the charging case.
- "Ch" will appear on the display, indicating it is placed correctly and charging.
- Charge TAC-STIM for at least one hour prior to first use.

## **Cleaning TAC-STIM**

- Clean TAC-STIM after each use by gently wiping the case and the stimulation surfaces with a soft, dry cloth to remove leftover gel.
- Put the cap back on the product after use to protect the stimulation surfaces from dirt, debris, and damage.

### Using TAC-STIM: Sample Dosing Schedule



2 two-minute sessions

2 two-minute sessions

### 1. Locate your vagus nerve.

- 1. Use 2 fingers to locate your pulse in the cervical region; the vagus nerve is in the same area.
- 2. Make sure the application site is clean and dry.
- 3. Remove anything blocking the application site.



- 4. Remove the cap.
- 5. Apply a pea-sized amount of the provided gel to the stimulation surfaces.
  - a. Not applying the gel as described may cause the session to be uncomfortable or less effective.
- 6. Turn TAC-STIM on by pressing the power button. When TAC-STIM is ready for use, it will beep once.





### 3. Administer the sessions.

- 7. Place TAC-STIM over the vagus nerve at the cervical region.
- 8. Increase the intensity level until you notice a slight muscle contraction at the corner of your mouth.
- 9. TAC-STIM will stop automatically after 2 minutes.

**NOTE:** You will likely feel muscle contractions at the application site and may experience a lip pull. These are normal and should stop after the session is complete. If muscle contractions are too strong or uncomfortable, try:

- Lowering the intensity level by pressing the bottom area of the control button.
- Repositioning the electrodes on the neck over the pulse and slowly increasing the intensity level again by pressing the top area of the control button.

If the intensity level is still too strong, stop the session and turn TAC-STIM off by pressing and holding the power button for 3 seconds.

NOTE: Additional gel may be needed between sessions.

### For more assistance, visit tac-stim.com or call 888-901-7846.

### Warnings and Precautions



#### Do not use TAC-STIM if:

- You have an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic product.
- You are in an explosive atmosphere or in the presence of flammable gas mixtures.
- You have an open wound at the application site.



### PRECAUTIONS

- TAC-STIM should only be used as described in the User Guide.
- Do not use TAC-STIM if there are signs of damage or defects.
- Do not use if an error code is displayed on the screen when the product is turned on.
- Do not submerge TAC-STIM in water; it is not water resistant.

NOTE: There is no data on the use of TAC-STIM if you are pregnant or breastfeeding.



## Troubleshooting

#### TAC-STIM does not turn on

- TAC-STIM is not charged. Charge TAC-STIM by placing it in the charging case.
- Restart TAC-STIM by pressing and holding the power button for 3 seconds.

#### TAC-STIM does not charge

• If "Un" is displayed, remove and place back in charging case. If "Un" continues to be displayed, move product around in the charging case.

• Ensure the AC power cord is plugged into a live power outlet and into the charging case. Only use the provided AC power cord with the charging case.

#### TAC-STIM displays an error code

• Contact the TAC-STIM Customer Experience Team.

### Handling TAC-STIM

#### **Operating Conditions (TAC-STIM Product)**

- Range: -40°F to 140°F (-20°C to 60°C).
- Maximum Output: 30V (peak), 60mA (peak).
- Load Impedance: 450 to 550 Ohms.
- TAC-STIM produces an electrical signal consisting of five 5,000-Hz pulses, repeating at a rate of 25 Hz. The waveform of the TAC-STIM pulse is approximately a sine wave.

#### **Operating Conditions (Charging Case)**

- Range: -40°F to 140°F (-20°C to 60°C).
- Only use the charging case indoors.
- Do not place any object except TAC-STIM on the charging surface.
- Maximum Output: 5.5V DC, 5W.
- Input: 100 to 240 VAC, 50 to 60 Hz, 0.4A max.
- The expiration date of the conductive gel is 5 years after the date of manufacture.

#### **Storage/Transport Conditions**

- TAC-STIM should be stored at room temperature away from moisture.
- Range: 32°F to 100°F (0°C to 38°C).
- Replace cap after each use.
- Store TAC-STIM in such a way (e.g., drawer or shelf) that the cap remains in place and is not accidentally removed.

#### Service Life

- The service life of TAC-STIM is 3 years after the date the product has been activated.

### **TAC-STIM Disposal**



Regulations require that the disposal of electrical and electronic equipment is handled in a controlled manner. A product that may be contaminated after use or contain chemicals or elements that may present hazards to people, or the environment must be disposed of in accordance with the applicable government regulations. Contact the TAC-STIM Customer Experience Team if you have questions about the appropriate disposal of this product.

**NOTE:** TAC-STIM contains lithium batteries that the user cannot remove.

**NOTE:** Please dispose of TAC-STIM like a cell phone or other electronic product. Check with your local municipality to do this according to your local electronic waste regulations.

## Symbols and Nomenclature Description

2	Expiration date	Ĩ	Follow operating instructions
LOT	Lot number		Manufacturer
REF	Catalog number / Reference number	IP22	Protection from solid foreign objects ≥12.5 mm and ingress of water at 15°
A	Electric shock hazard	Ϋ́	Type BF applied part
SN	Serial number	-20°C	Storage temperature
NON	Non-sterile	xxxdyyzzzz (package label)	Date of Manufacture on package label, where "D" is the year of manufacture, e.g. 254DDK1001 indicates the year of manufacture is 2023
	WARNING Failure to follow instructions may result in serious injury or death to the user	((••))	Non-ionizing electromagnetic radiation
	<b>PRECAUTION</b> Failure to follow instructions may result in damage to the equipment or degradation in the quality of treatment	MR	Magnetic resonance unsafe
	Refer to instruction manual	ECREP	Authorized representative
	Information or additional information available	×	Keep away from sunlight
X	Separate collection for waste of electrical and electronic equipment		Do not use if package is damaged
$\sim$	Date of Manufacture	MD	Medical device

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## **Electrical Classification**

#### **Electrical Classification (TAC-STIM Product)**

- UL 60601-1 Class III; EN 60601-1 Internally Powered Equipment.
- Type BF Applied part.
- IP22 Protected against ingress of solid foreign objects ≥ 12.5 mm diameter and protected against vertically falling water drops when enclosure tilted up to 15°.
- Product contains Bluetooth RF transmitter: Frequency range of 2.379 to 2.496 GHz, GFSK Modulation, 1mW max power.

#### Electrical Classification (Charging Case)

- UL 60601-1 Class III.
- Accessible Part.
- IP22 protected against ingress of solid foreign objects ≥ 12.5 mm diameter and protected against vertically falling water drops when enclosure tilted up to 15°.

### **Electromagnetic Compatibility Guidance**

All engineering specifications have passed the required test levels. All specifications are available upon request.

## **Contact Information**

#### **Customer Experience Team:**

E-mail: support@tac-stim.com electroCore, Inc. 200 Forge Way, Suite 205 Rockaway, NJ 07866 United States Telephone: 888-901-7846

#### Manufacturer:

E-mail: support@tac-stim.com electroCore, Inc. 200 Forge Way, Suite 205 Rockaway, NJ 07866 United States Telephone: 888-901-7846

### Product Complaint Reports and/or related issues may be submitted directly to electroCore, Inc.:

Telephone: +1 (973) 355-6708 E-mail: complaints@electrocore.com

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Customer Service Limited Liability: electroCore guarantees against any out-of-box failures and warrants that the Products shall meet the Product Standard. The warranty does not apply to any Product that: (i) has been subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper installation, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions, or use contrary to any instructions issued by electroCore; or (ii) has been reconstructed, repaired, or altered by persons other than electroCore or its authorized Representative. Customers shall not service, repair, modify, alter, replace, reverse engineer, or otherwise change any Products.

electroCore, Inc. 200 Forge Way, Suite 205 Rockaway, NJ 07866 United States Telephone: 888-901-7846

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