# truvagus nerve therapy



User Manual For your safety, always read the user manual carefully before using.

64000-00177 Rev 3

## Step 1: Find your vagus nerve

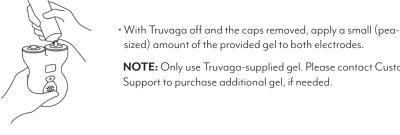


Application Site (Pulse) Muscle

- Find your vagus nerve by placing two fingers on either side of your neck to locate your pulse. Your vagus nerve passes through the neck in this area.
- Make sure your neck is clean, dry, and free of barriers such as jewelry.
- With Truvaga off, remove caps and practice placing it in this location.
- Make sure to place Truvaga vertically so the electrodes are one above the other, in the exact spot you found your pulse.
  - Truvaga's electrodes should line up with the following landmarks:
  - Over the pulse; this is the application site (orange)
  - In front of the large muscle at the side of the neck (yellow)
  - Just below the lower jaw (grey)

- Lined up next to the windpipe (green)

## Step 2: Prepare your Truvaga







NOTE: Only use Truvaga-supplied gel. Please contact Customer

sized) amount of the provided gel to both electrodes.

Support to purchase additional gel, if needed.

• Power on your Truvaga by pressing the (+) button. Your Truvaga will beep once and a green light will illuminate, indicating it's on.

**NOTE:** The display screen will indicate the number of sessions remaining (each Truvaga comes with 350 sessions).

- Position Truvaga on your neck as you practiced earlier. Both electrodes must be completely in contact with your skin for Truvaga to effectively activate your vagus nerve.

#### Get to know your Truvaga

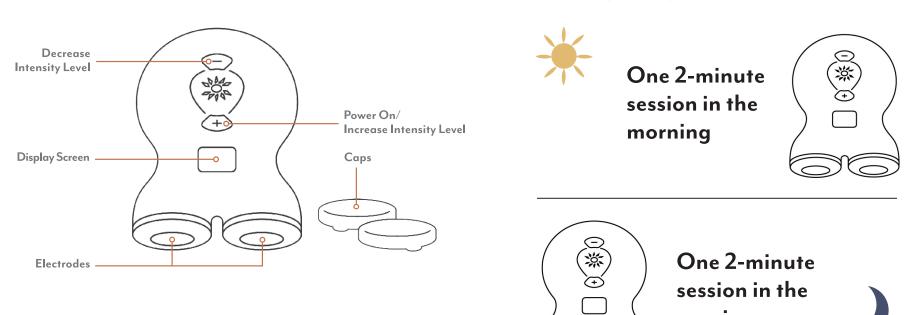
Truvaga<sup>™</sup> is a revolutionary handheld vagus nerve stimulator that reduces stress by using proven technology to guickly and gently activate your vagus nerve.

Designed to work with your body and rebalance the nervous system, Truvaga reduces stress so you can feel calmer, think clearer, and sleep better. Helping you get back to what matters most.

Truvaga works by delivering gentle electrical stimulation to the side of the neck, activating the vagus nerve which carries information to the central nervous system. Each session lasts 2 minutes; during these 2 minutes, the user has complete control over the intensity level.

**NOTE:** Truvaga comes preloaded with 350 sessions.

About Truvaga



## Step 3: Start your session

- Keeping the electrodes against your neck, increase the intensity (with the (+) button) until you notice a tingling sensation or a slight muscle contraction at the corner of your mouth.
- You should feel a tingling sensation that is strong but comfortable, this is typically felt between intensity levels 15-25.
- During your session, you can make small adjustments to the intensity level and placement, as needed.
- Intensity Level: You can increase or decrease the intensity level by pressing the (+) or (-) buttons.



session • When finished, remove Truvaga from your neck and wipe off any remaining gel on Truvaga and your neck using a soft cloth or tissue. Replace the caps, and you'll be ready for your next session

#### Using your Truvaga

Truvaga can be used almost any time, but we recommend at least twice a day, one session in the morning and one at night. If you are having an overly stressful day, can't sleep or focus, use as needed. It's safe to use up to 24x a day.

## evening



- Placement: If you don't feel a lip-pull or slight muscle contraction when using Truvaga, make small adjustments to the placement on your neck untill you do. It can make all the difference.

• Once you've found the right location and intensity level, hold Truvaga in place until it beeps twice. This indicates the end of your 2-minute session. Truvaga will automatically turn off after your

#### **Helpful Tips**

- 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 (-) button
- Repositioning the electrodes on the neck over the pulse and slowly increasing the intensity level again by pressing the (+) button

If the intensity level is still too strong, stop the session and turn Truvaga off by pressing and holding the (+) and (-) buttons.

- Truvaga has a limited number of sessions.
- The number of sessions remaining can be viewed by turning on Truvaga.
- Increasing the intensity level past 3 will start a session.
- There is a delay feature to prevent accidental starts.
- Attempting multiple sessions in a row will result in Truvaga not turning on immediately. To resolve, wait 10 seconds before turning it on again.
- You may need to apply additional gel between sessions.
- You should not use soap, hand sanitizer, detergents, or other cleansers when cleaning Truvaga.

#### For more assistance, visit truvaga.com/support

#### Display

Icon Description	lcon	Example Display	Description
Sessions Remaining	$\bigcirc$	<b>9</b>	9 sessions remaining
Intensity Level	$\heartsuit$		Intensity level is at 20
Unlimited Days	31	3551 B	Unlimited days. Display will always show "365"until it stops delivering sessions
Intensity Level at Last Use	<b>V I</b>		Last delivered intensity level was 20

#### **Troubleshooting**

- Truvaga does not turn on Restart your Truvaga by pressing and holding the (+) and (-) buttons at the same time for 10 seconds and then release. Wait 5 seconds and turn on again. If Truvaga still does not turn on, contact us.
- Flashing green light with "Err" code Restart your Truvaga by pressing and holding the (+) and (-) buttons at the same time for 10 seconds and then release. Wait 5 seconds and turn on again. If Truvaga still displays "Err", contact us.
- Flashing green light with "Lo" code Your battery may be low which likely means you have used up most of your 350 sessions. You can continue to use your Truvaga until all sessions are done.
- Flashing green light with "O" code Congratulations, you've successfully used all 350 sessions! It's time to order your next Truvaga on truvaga.com. If you have any guestions or need support, please contact us.

#### Warnings and Precautions

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#### Do not use Truvaga if:

- You have an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic product.
- You are using another product at the same time (e.g., TENS Unit, muscle stimulator).
- You are driving, operating machinery, or during any activity that may put patient at risk of injury.
- You are in the presence of strong electromagnetic fields, such as MRI scanners.
- · You are in an explosive atmosphere or in the presence of flammable gas mixtures. • You have an open wound, rash, infection, swelling, cut, sore, drug patch, or surgical scar(s) on the neck at the application site.
- You have wet skin, are in the water, or just stepped out of the water (e.g., shower, bath, pool).

#### It is not recommended to use Truvaga:

- If you have had surgery to cut the vagus nerve at the neck as it may not be effective.
- If you are younger than 12.
- If you are pregnant or breastfeeding.
- More than 24 times a day.

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- Truvaga should be used only as described in the User Manual.
- · Only use a Truvaga-supplied conductive gel.
- Do not apply Truvaga across or through the head, directly on the eyes, covering the mouth, on the chest, on the upper back, or over the heart.
- · Do not use Truvaga if there are signs of damage or defects.
- Do not use if the light is flashing green and "Err" is displayed on the screen when the product is turned on.
- Do not submerge Truvaga in water; it is not water resistant
- Store in a safe location out of reach of children.

#### **Status Indicators**

Status	Light	Display	Sound	Action
Start Up / Ready for Use	Green Light On	1. Unlimited Number of Days 2. Sessions Remaining	l short beep after power ON	Follow User Manual
In Use	Green Light On	Intensity Level (min 1 – max 40)	Short beep each time intensity level is increased/decreased	Follow User Manual
Session Complete	None	1. Unlimited Number 2. Number of Sessions 3. Last Intensity Level of Days Remaining Used	2 short beeps	Follow User Manual

#### **Potential Adverse Reactions**

Users with sensitive skin may experience application site discomfort, irritation and/or redness. If you experience light-headedness, dizziness, chest pain, excessive skin irritation, local pain, face/ head/neck area (including toothache), excessive muscle twitching, tingling, contractions, or other adverse reactions, DISCONTINUE USE. These reactions typically resolve after the session is complete; however, if it persists after the session, consult your physician.

#### Handling Conditions

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

• Store at room temperature away from moisture • Range: 32°F to 100°F (0°C to 38°C) • Do not expose gel to direct sunlight

#### Service Life

• The service life of Truvaga is 1.5 years after the date of manufacture. • The expiration date of the conductive gel is 5 years after the date of manufacture.

#### **Ordering Instructions**

Please visit Truvaga.com to purchase a new Truvaga, learn more about Truvaga, and to contact customer support.

#### **Electrical Classification**

- UL 60601-1 Class III; EN 60601-1 Internally Powered Equipment
- Type BF Applied part
- Only the manufacturer should change the battery
- Protection from solid foreign objects ≥12.5 mm and ingress of water at 15°

#### **Electromagnetic Compatibility Guidance**

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

#### 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 Truvaga Customer Support if you have questions about the appropriate disposal of this product.

NOTE: Truvaga contains lithium batteries that the user cannot remove.

**NOTE:** Please dispose Truvaga 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

25	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°		
4	Electric shock hazard	×	Type BF applied part		
SN	Serial number	0°C	Storage temperature		
NON STERILE	Non-sterile	xxxcyzzzz (package label)	Date of Manufacture on package label, where: "C" is the year of manufacture, eg, 252CSI001 indicates the year of manufacture is 2023		
	WARNING Failure to follow instructions may result in serious injury or death to the patient or user	MR	Magnetic resonance unsafe		
	<b>PRECAUTION</b> Failure to follow instructions may result in damage to the equipment or degradation in the quality of treatment	~~~	Date of Manufacture		
<b>(</b>	Refer to User Manual	$\bigotimes$	Do not use if package is damaged		
	Information or additional information available	紊	Keep away from sunlight		
X	Separate collection for waste of electrical and electronic equipment				

#### **Contact Information**

Truvaga Customer Support: e-mail: support@truvaga.com

electroCore, Inc. 200 Forge Way, Suite 205 Rockaway, NJ 07866 United States

Telephone: 1 (800) 643-2036

Manufacturer

e-mail: support@truvaga.com

electroCore. Inc. 200 Forge Way, Suite 205 Rockaway, NJ 07866 United States

#### 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:

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