

User Manual

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

Contact Information

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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 "Using Truvaga" Instructions
In Use	Green Light On	Intensity Level (min 1 – max 40)		Short beep each time intensity level is increased/decreased	Follow "Using Truvaga" Instructions
Session Complete	None	1. Unlimited Number 2. Number of Days Remain		2 short beeps	NONE: Truvaga turns off automatically

Symbols and Nomenclature Description

	Expiration date	i	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, 252CS1001 indicates the year of manufacture is 2022		
	WARNING Failure to follow instructions may result in serious injury or death to the patient or user	MR	Magnetic resonance unsafe		
<u>^</u>	PRECAUTION Failure to follow instructions may result in damage to the equipment or degradation in the quality of treatment	<u>سا</u>	Date of Manufacture		
	Refer to User Manual		Do not use if package is damaged		
	Information or additional information available	类	Keep away from sunlight		
Z	Separate collection for waste of electrical and electronic equipment				

Warnings and Precautions

WARNINGS 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
- 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.



PRECAUTIONS

- 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
- · Do not submerge Truvaga in water; it is not water resistant
- · Store in a safe location out of reach of children.

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.

Potential Adverse Reactions

Users with sensitive skin may experience application site discomfort, irritation and/or redness. If you experience light-headedness, dizziness, or chest pain, excessive skin irritation, local pain, face/head/neck area (including toothache), 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.

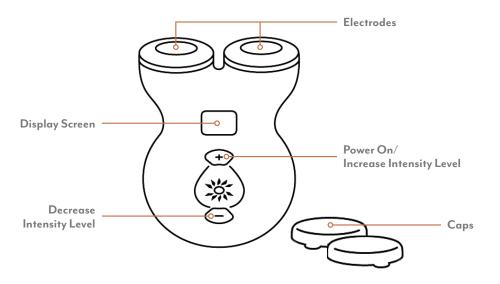
About Truvaga

Truvaga is a hand-held vagus nerve stimulator that brings balance to your day-to-day, by providing science-backed vagus nerve therapy for reliable stress relief, so that you can feel calmer, think clearer, and sleep better.

Truvaga works by using gentle electrical stimulation to the side of the neck, activating the vagus nerve and carrying 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.

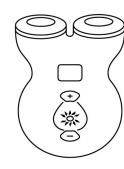
Get to know your Truvaga





Using your Truvaga

One 2-minute session in the morning





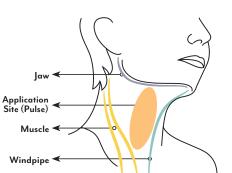
One 2-minute session in the evening



Step 1: Find your vagus nerve



- 1. Remove anything blocking the application site.
- 2. Find a comfortable position. (A place where you can see your neck in a mirror is preferred.)
- 3. Find the application site by finding your pulse on the side of the neck. The vagus nerve is in the same area. Make sure the application site is clean and dry.



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)
- \cdot Lined up next to the windpipe (green)

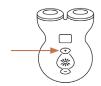
Step 2: Prepare your Truvaga



. Remove the caps.



- Apply a small (pea-sized) amount of gel to both electrodes.
 Not applying the gel as described may cause the session to be uncomfortable or less effective.
- **NOTE:** Only use a Truvaga supplied gel. Please contact Truvaga Customer Support to purchase additional gel, if needed.



6. Turn Truvaga on by pressing the (+) button. When Truvaga is ready for use, it will beep once. The number of sessions remaining will be displayed on the display screen.

Step 3: Start your session



- 7. Position Truvaga on the side of the neck over the application site. Use mild to moderate pressure so the electrodes make good contact with the skin; however, do not apply too much pressure to the neck.
- 8. Increase the intensity level by repeatedly pressing or holding the (+) button. Once you have found a strong but comfortable intensity level (between 1-40), hold Truvaga in place for the remainder of the 2-minute session.

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 (-) 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.

NOTE: Truvaga has 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.

NOTE: Additional gel may be needed between sessions.

Display and Troubleshooting

Icon Description	Icon	Example Display	Description	
Sessions Remaining		8	9 sessions remaining	
Intensity Level		28 €	Intensity level is at 20	
Unlimited Days	[31]	355 8	Unlimited days. Display will always show "365"until it stops delivering sessions	
Intensity Level at Last Use			Last delivered intensity level was 20	

- 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 questions or need support, please contact us.

Step 4: Complete your session



 After completing a session, the display screen will show the number of sessions remaining and the last intensity level used before automatically turning off.

NOTE: The number of sessions remaining can be viewed by turning Truvaga on.

NOTE: Increasing the intensity level past 3 will start a session.

NOTE: Truvaga has a limited number of sessions.

- 10. Clean Truvaga by wiping the leftover gel off the electrodes with a soft, dry cloth.
- 11. Clean the remaining gel off your neck with a cloth or tissue.
- 12. Put the caps back on the electrodes after use.

NOTE: Do not use soap, hand sanitizer, detergents, or other cleansers when cleaning the product.

For more assistance, visit truvaga.com/support