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Rx Only

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602-00826-001 Rev. A
06/2026



Portable Neuromodulation
Stimulator

Instructions for Use

ATTENTION:

Read instructions carefully and completely before first use.

Keep this booklet in an easily accessible location for future reference.

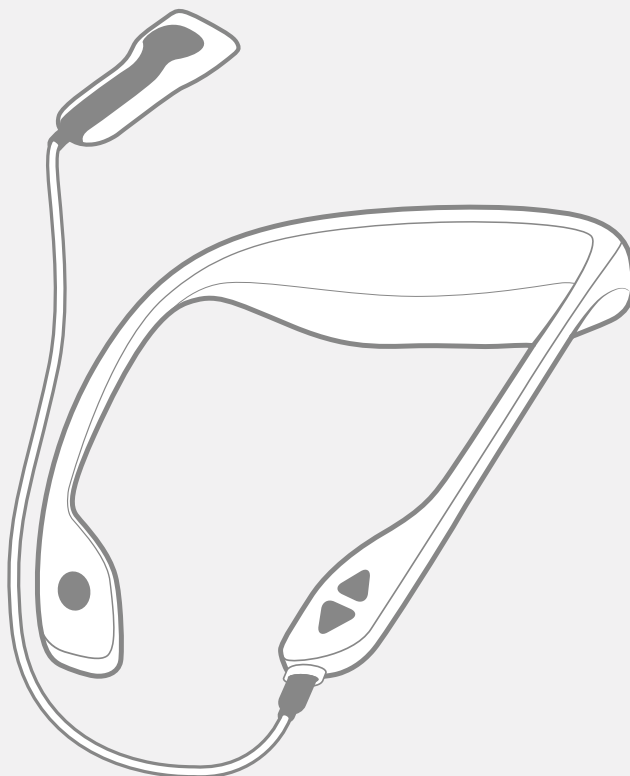


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GLOSSARY

PoNS – Portable Neuromodulation Stimulator.

Neuromodulation – change in nerve activity through delivery of stimulation to specific areas of the body.

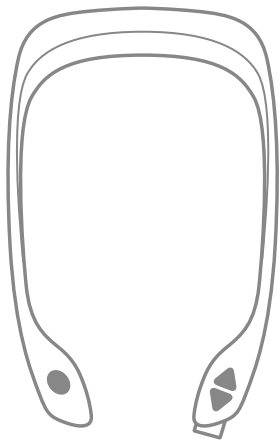
Neurostimulation – purposeful modulation of the nervous system through low level electrical impulses or drugs.

PoNS Trainer – a clinician who has been trained in how to administer PoNS Therapy and registered as a trainer in the Bioness database.

Session – a period of 20 minutes during which you use your PoNS while you perform a supervised therapeutic exercise routine.

Intensity – strength of the stimulation sent by the Controller to the Mouthpiece.

WHAT'S INCLUDED



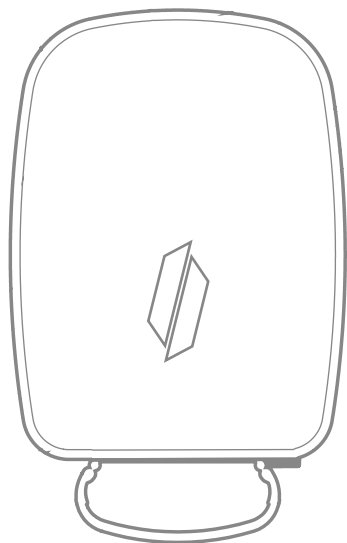
PoNS Controller



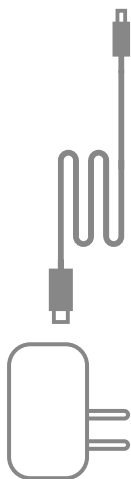
PoNS Mouthpiece



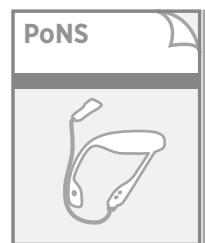
Mouthpiece Case



Carrying Case



**PoNS AC Power
Adapter and Cable**



Instructions For Use

ABOUT THE PoNS DEVICE

On behalf of Bioness Medical, Inc., congratulations on the purchase of your **Portable Neuromodulation Stimulator (PoNS)**. Years of scientific research have shown that the brain has powerful mechanisms and abilities to restructure, reorganize and relearn.

What is PoNS

The PoNS is a **portable, non-implantable** medical device that delivers a **unique** form of neurostimulation. It consists of a Controller and a Mouthpiece that are connected to each other by a cord. The Controller sends signals to the Mouthpiece which is placed on your tongue during use. Receptors on the surface of your tongue will pick up these signals over the duration of the treatment session and send millions of neural impulses to your brain through natural pathways. By combining targeted supervised therapeutic exercise with neurostimulation, PoNS provides an innovative and effective treatment.

The PoNS is suitable for use in domestic establishments including the home environment, doctor's office, or physiotherapy clinic.

Indications

The PoNS device is indicated for use as a treatment of dynamic gait deficits due to chronic symptoms from stroke and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only.

The PoNS device is indicated for use as a short term treatment of gait deficit due to mild to moderate symptoms from multiple sclerosis and is to be used as an adjunct to a supervised therapeutic exercise program for adults 22 years of age and over by prescription only.

Contraindications

The PoNS device delivers electrical stimulation directly to the surface of the tongue. Precautions for use are similar to those for transcutaneous electrical nerve stimulation (TENS).

Electrical stimulation **SHOULD NOT** be used:

- if there is an active or suspected malignant tumor
- in areas of recent bleeding or open wounds
- in areas that lack normal sensation

The PoNS has not been tested on, and thus should not be used by individuals who are pregnant. Do not use the PoNS if you are sensitive to nickel, gold or copper.

Data Privacy

If your device is lost or stolen, there is no risk to personally identifiable information (PII) since the device does not record or store PII.

Use with caution

Electrical stimulation should only be used after seeking professional medical advice, and with caution in patients with any of the following:

- Implanted electronic devices, including:
 - Cardiac pacemakers
 - Cardioverter defibrillators
 - Deep Brain Stimulators
 - Vagal Nerve Stimulators
 - Sacral nerve stimulators
 - Cochlear Implants
- Metal in the mouth
 - e.g. piercings, braces, retainers, or other orthodontic appliance
- Seizure disorders
- Epilepsy
- Epistaxis (Nosebleed)

What to Expect

Your PoNS Trainer will be an important partner on your rehabilitative journey. A PoNS Trainer will evaluate your condition and prepare a challenging therapeutic exercise program (program) individualized for your needs. You will be trained on how to use your PoNS device when you start your program. You will then use your PoNS device during your program. Your PoNS Trainer will supervise your program to keep you on track and help you reach your rehabilitation goals.

Treatment with the PoNS device has been studied for 14-weeks in subjects with gait deficit, a symptom of mild-to-moderate MS. Note, in clinical testing patients taking medication for MS gait dysfunction achieved less improvement than those not taking gait dysfunction medication; you should talk to your doctor to determine if PoNS is suitable for you.

Treatment with the PoNS device has been studied for 12-weeks in subjects with gait deficit, a symptom of Stroke. Talk to your doctor to determine if PoNS is suitable for you.

Your Therapeutic Exercise Program

Your program will consist of multiple 20-minute sessions for balance, gait, motor pattern retraining, and mindfulness that are designed to challenge you. These exercises will need to be continually progressed by working with your PoNS Trainer. Your program will include exercising at home, with regular appointments with your PoNS Trainer to support your progress. The program requires multiple sessions a day; typically five to six sessions per day for five to six days a week for 14-weeks in people with MS. For Stroke, program typically require three sessions a day for four to six days a week for 12-weeks. Your PoNS Trainer will work with you to make sure your program is at the right level for you; for example, let them know if the exercise seems easy to perform or if you feel tired.

When using the device, you will feel a mild stimulation on your tongue. This is a normal sensation that is created by the electrical impulses generated by the PoNS. Included in the training is instruction on how to comfortably hold the mouthpiece in your mouth during training and how to swallow in order to control your saliva if necessary. Read this booklet carefully, follow the instructions and remember to communicate with your PoNS Trainer or Customer Support if you have any questions.

Customer Support information is located on page 24.

IMPORTANT INFORMATION

Read these instructions carefully before using your PoNS to ensure that you know how to operate it safely and correctly. Keep this booklet in a safe and easily accessible location for future reference.

WARNING

- **DO NOT** connect the Mouthpiece to the Controller before seeing your PoNS Trainer, to avoid premature expiration of the Mouthpiece.
- **DO NOT** place the Mouthpiece in your mouth while the Controller is charging or connected to your PoNS Trainer's computer.
- **DO NOT** use a power adapter or cable other than the one provided with your PoNS to charge the Controller. Always charge the Controller indoors.
- **DO NOT** wet the Controller or use your PoNS in the rain or snow.
- **DO NOT** wet the connector on the end of the Mouthpiece cord when cleaning the Mouthpiece. Always check and ensure the connector is dry before connecting and using the Controller.
- **DO NOT** use the PoNS if you are sensitive to nickel, gold or copper. The PoNS Mouthpiece contains nickel, gold and copper.
- **DO NOT** use your PoNS if you have open mouth sores, ulcers or tongue piercings.
- **DO NOT** eat, drink or smoke while using your PoNS.
- **DO NOT** talk while the PoNS Mouthpiece is in your mouth. Keep the Mouthpiece on your tongue and pressed against the roof of your mouth to secure it in the proper location, to avoid choking.
- If the materials on the Mouthpiece cause any allergic reactions or undesirable effects, discontinue using the PoNS immediately and contact your PoNS Trainer.
- **DO NOT** bite down on the Mouthpiece with excessive force.
- **DO NOT** use your PoNS while driving or operating machinery.
- **DO NOT** connect the Mouthpiece to any other device or modify any part of the equipment.
- **DO NOT** use your PoNS if it has been damaged.
- **DO NOT** use the Mouthpiece if it is cracked or broken.
- **DO NOT** dismantle, open, crush, or shred or incinerate the PoNS.
- **DO NOT** expose the PoNS to temperatures above 157°F (70°C).
- Keep your PoNS out of Magnetic Resonance Imaging (MRI) field.
- Keep your PoNS out of the sight and reach of children and pets.
- **BE AWARE:** the long-term effects of electrical stimulation are unknown.
- The PoNS Controller contains a rechargeable lithium battery.

WARNING

- **DO NOT** wrap the cord around your neck, to avoid strangulation.
- **DO NOT** use your PoNS in any situation or environment that is not directed by your PoNS Trainer.
- **The intensity should only be adjusted while the Mouthpiece is on the tongue. The patient should be the one who adjusts the intensity level.** In case the patient needs assistance in pressing the buttons on the Controller, the person assisting should use care to adjust the intensity by small increments. Check with the patient each time you press the INTENSITY UP/DOWN buttons, before pressing them again.
- **DO NOT** use your PoNS device within 4 feet (1.2 m) of equipment generating microwave or shortwave radiation.

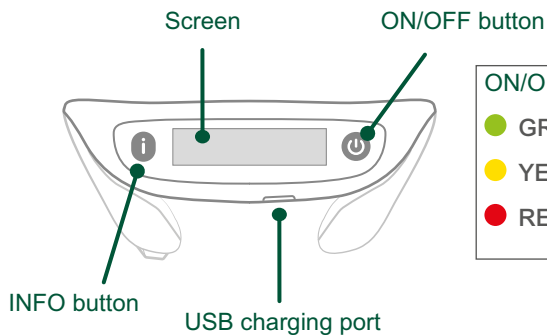
Precautions

- Only use or charge your PoNS between 41°F and 95°F (5°C and 35°C) temperature. If your PoNS has been stored outside of this temperature range leave for 1 hour to reach room temperature before using.
- Store your PoNS only between -20°F and 157°F (-29°C and 70°C) temperature. Avoid storage in direct sunlight.
- The Controller may arrive with some residual charge. Charge the PoNS controller for a minimum of 4 hours prior to first use. See instructions on 'Charging your PoNS Controller' on page 11.
- Mouthpieces expire after 14 weeks of use. A Mouthpiece expiration message will show daily when the Mouthpiece has 21 days or less remaining. Plan for appropriate steps with your PoNS Trainer before your Mouthpiece expires. See instruction on 'Summary of Button Functions' on page 10.
- Controllers function for a maximum of 14 weeks before requiring reset. Your PoNS Trainer will reset your Controller during therapy clinic visits. A Controller reset message will show daily when the Controller has 21 days or less remaining. See instruction on 'Summary of Button Functions' on page 10.
- **The PoNS is for use by a single individual and must not be shared.**
- The PoNS should not be used by individuals who are not trained in its use and/or without the supervision of a prescribing therapy specialist or PoNS therapist.
- Physical Therapists should adopt individualized rehabilitation regimens to mitigate the potential impact of physical exertion on the patient's compromised cardiovascular system viability. You must clean your Mouthpiece before first use. See instructions on 'Cleaning your PoNS' on page 13.
- During a treatment session, if stimulation is uncomfortable, decrease the intensity until a comfortable level is reached. See instruction on 'Using your PoNS' on page 17.

DESCRIPTION OF PARTS

PoNS Controller

(Back view)



ON/OFF button light:

- GREEN: Power for two or more sessions
- YELLOW: Power for one session
- RED: Insufficient power or error messages

PoNS Controller

(Top view)

SESSION button functions:

To **START**: Press

To **PAUSE**: Press during session

To **RESUME**: Press again

To **STOP**: Press and hold

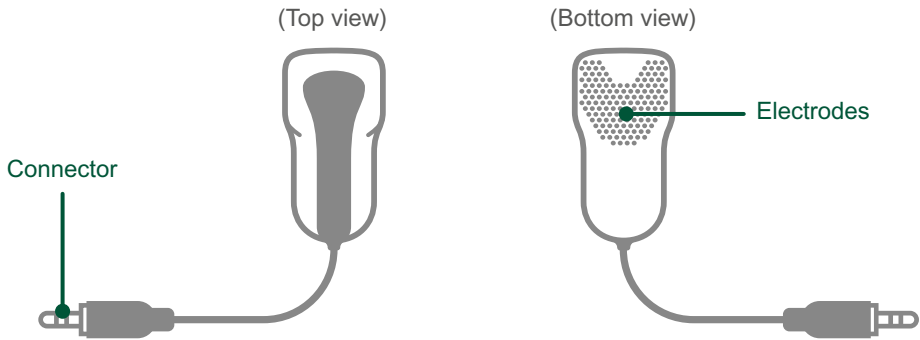
SESSION
button

INTENSITY UP button

INTENSITY DOWN
button

Mouthpiece
connection port

PoNS Mouthpiece



Summary of Button Functions

Function	When	Action
Power on	Before session	Press and hold the ON/OFF button
Power off	After session	Press and hold the ON/OFF button
Pause session	During session	Press the SESSION button
Resume session	When session is paused	Press the SESSION button again
Stop session	During session	Press and hold the SESSION button
Increase intensity	During session	Press the INTENSITY UP button
Decrease intensity	During session	Press the INTENSITY DOWN button
Cycle through device status and information on the Screen	While device is turned on but not providing stimulation or charging	Press the INFO button consecutively to cycle through information, including: READY status, daily minutes completed, days remaining until the Controller expires and days remaining until the Mouthpiece expires

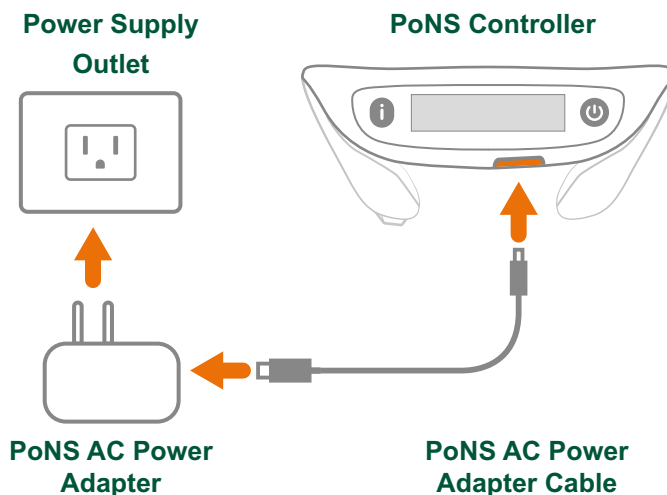
CHARGING YOUR PoNS CONTROLLER

Charge your Controller before first use and every night using the supplied PoNS AC Power Adapter for a minimum of 4 hours.

⚠ WARNING

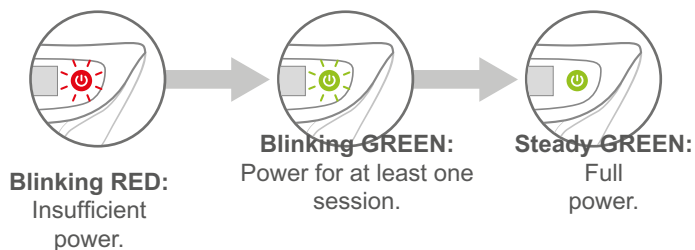
DO NOT charge your Controller with the Mouthpiece connected.

DO NOT use a power adapter or cable other than those provided with your PoNS.



Note: Ensure PoNS AC Power Adapter is easily accessible at all times so that it can be disconnected from the power supply outlet if required.

The **ON/OFF** button light will blink while charging. Your Controller is fully charged when the **ON/OFF** button is steady green.



Note: The AC Power Adapter supplied with your PoNS is specified for the North American market. A fully charged Controller has enough power for 2 or more sessions.

CLEANING YOUR PoNS

Follow these steps to clean your PoNS before the first use, after each use and before storing.

⚠ WARNING

DO NOT wet the Controller.

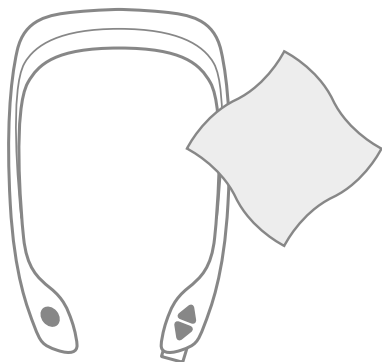
DO NOT wet the Mouthpiece connector.

Always check to ensure the connector is dry before reconnecting to the Controller.

The Mouthpiece is for use by a single individual and must not be shared.

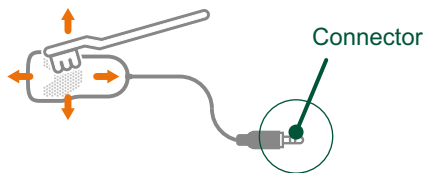
1. Wipe Controller

Only use a dry cloth for wiping the Controller.

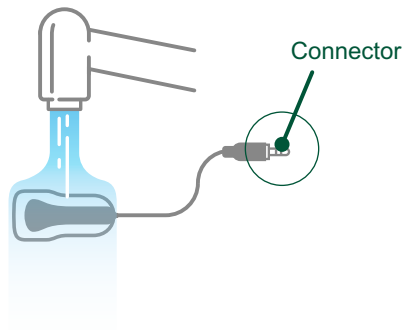


2. Brush and Rinse Mouthpiece

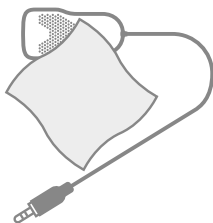
Gently brush the Mouthpiece with warm water and a soft toothbrush being sure to thoroughly clean the Mouthpiece. Keep the Mouthpiece connector dry. Do not use toothpaste



Rinse the Mouthpiece with water, be sure to keep the Mouthpiece connector dry.



3. Dry the Mouthpiece



Gently dab the Mouthpiece with a lint free towel to dry.



Once the Mouthpiece is dry, store it in the Mouthpiece case. See page 18 for more details.

Note: During each cleaning, ensure all debris is removed. Check for worn or loose electrodes. If found, do not use and contact Customer Support.

Note: Discoloration of the electrodes or Mouthpiece can occur. This does not impact the use or effectiveness of the PoNS device.

USING YOUR PoNS

⚠ WARNING

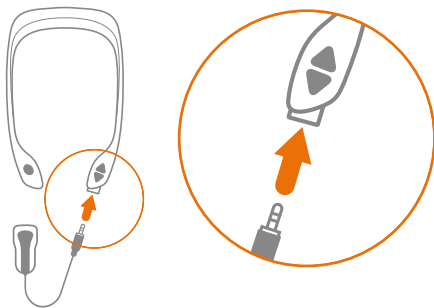
DO NOT place the Mouthpiece in your mouth while the Controller is charging or connected to your PoNS Trainer's computer.

DO NOT use your PoNS in extreme temperatures. If your PoNS has been stored in an extreme temperature range such as a hot car or at freezing temperatures leave for 1 hour to reach room temperature before using.

Before each use, check that the Controller is not damaged, the battery is charged and the Mouthpiece is clean.

1. Attach Mouthpiece

Plug the Mouthpiece connector fully into the connection port on the Controller.



⚠ Inspect Mouthpiece and verify it is not cracked or broken.

DO NOT use a damaged Mouthpiece, to avoid choking.

2. Turn On Controller

Press and hold ON/OFF button.

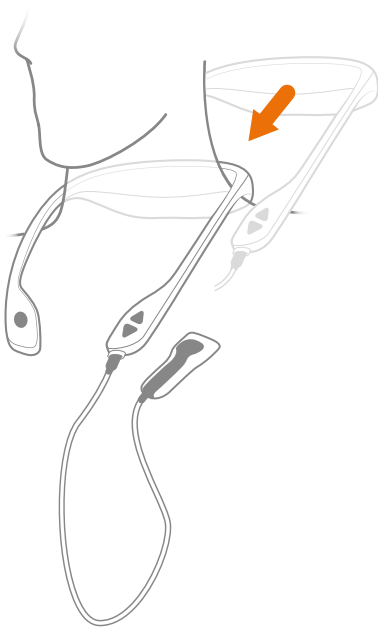


Your PoNS is ready for use when 'READY' appears on Screen. The battery icon  indicates the level of charge. For charging instructions see page 11.

Note: In some cases, another message may be displayed and there may be more than one message to read. Use the INFO button to cycle through the messages. Depending on the message, you may not be able to start a session. For more information, see 'Screen Messages' on page 21.

3. Place Controller

Place the Controller around the back of your neck.



⚠ Only use the device as shown, with the Mouthpiece cord plugged into the Controller and away from your neck.

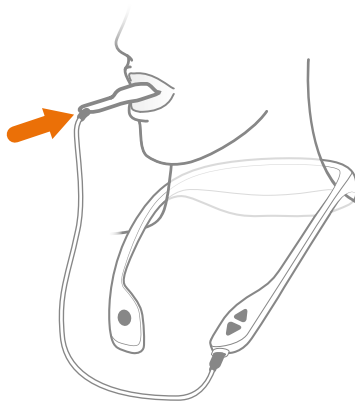
DO NOT wrap the cord around your neck, to avoid strangulation.

4. Insert Mouthpiece

Place the Mouthpiece in your mouth with the electrode side on your tongue.

Gently close your lips around the Mouthpiece and press your tongue towards the roof of your mouth.

⚠ **DO NOT** bite down on the Mouthpiece with excessive force.



Tongue Placement

The tip of your tongue should be just beyond the electrodes.



(Bottom view)

USING YOUR PoNS

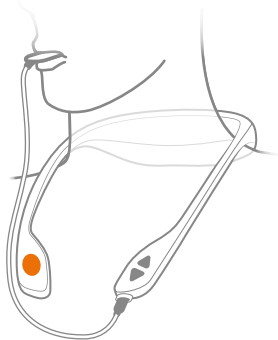
WARNING

The intensity should only be adjusted while the Mouthpiece is on the tongue. The patient should be the one who adjusts the intensity level.

In case the patient needs assistance in pressing the buttons on the Controller, the person assisting should use care to adjust the intensity by small increments. Check with the patient each time you press the INTENSITY UP/DOWN buttons, before pressing them again.

5. Initiate Session

Press **SESSION** button. A full session lasts 20 minutes.



Note: If the session does not initiate, remove the Mouthpiece and Controller and check the Screen on the Controller. See 'Troubleshooting' screen messages listed on page 23.

Information points

- Using PoNS produces a tingling and non-painful sensation on your tongue. **You must be able to feel the tingling sensation throughout the session for PoNS treatment to be effective.**

6. Setting Intensity

Note: Your PoNS re-starts each session at a lower intensity than the prior session. You should adjust the intensity to a comfortable level at the beginning of each session.

Setting the Mouthpiece intensity to a comfortable level involves determining your sensitivity by slowly increasing the intensity then lowering to that level. You should experience a tingling sensation on your tongue that is clearly felt, but not painful, throughout the session:

- First, slowly and repeatedly press the **INTENSITY UP** button to increase the intensity to just above your comfort level;



- then Press the **INTENSITY DOWN** button to reduce the intensity until you reach a comfortable and non-painful setting as a greater intensity does not equate to a better outcome.



7. Perform Prescribed Exercise

Perform exercises as prescribed by your PoNS Trainer.

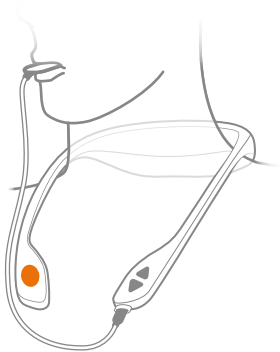
To Pause Session

- Press **SESSION** button to pause, and press again to resume.

Note: A session can be paused multiple times, but the total pause time is limited to 2 minutes. If the total pause time is reached the session incomplete message will be shown. See 'Troubleshooting' screen messages listed on page 23.

To Stop Session

- Press and hold **SESSION** button to stop a session before the timer ends.



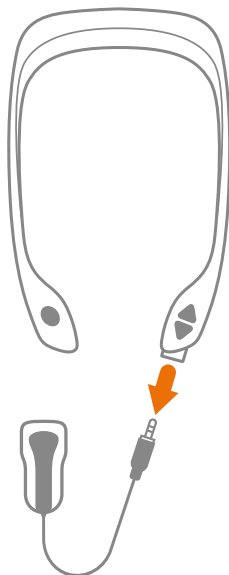
8. End of Session

Once the session has ended, remove the Mouthpiece and Controller.

Press and hold the **ON/OFF** button to turn your PoNS off.

Unplug the Mouthpiece from the Controller.

Clean the Mouthpiece and Charge the Controller following the instructions on pages 11 to 14.



STORAGE AND TRAVEL

WARNING

DO NOT store your PoNS in an extreme temperature range such as a hot car or at freezing temperatures. Avoid storage in direct sunlight.

Store PoNS device and accessories away from children.

1. Store Mouthpiece

Place the clean and dry Mouthpiece in the Mouthpiece Case.

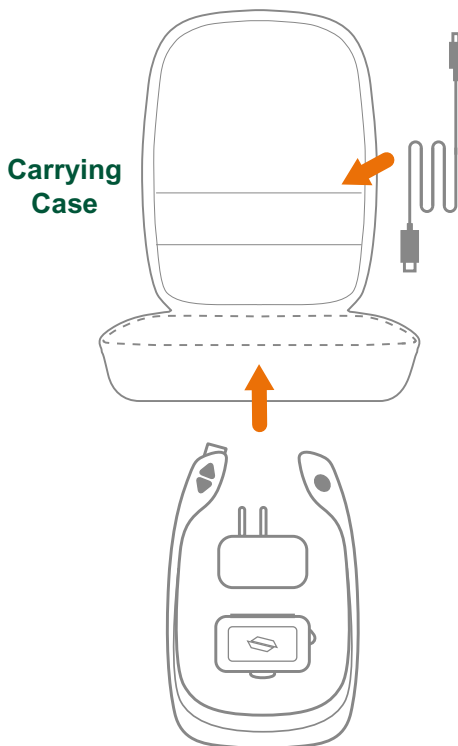


Mouthpiece Case

Note: For more information, see 'Cleaning your PoNS' on page 13.

2. Store PoNS

After powering it off, place the clean Controller and the Mouthpiece Case in the Carry Case. To protect the PoNS from environmental contamination, store the cleaned Controller and Mouthpiece in their cases when not in use.



Note: The PoNS controller contains a rechargeable lithium battery and may be subject to travel restrictions.

END OF USE LIFE

Expected Use Life

Mouthpieces expire after 14 weeks of use. A Mouthpiece expiration message will show daily when the Mouthpiece has 21 days or less remaining. Plan for appropriate steps with your PoNS Trainer before your Mouthpiece expires.

Your PoNS Trainer will reset your Controller during clinic visits. A Controller reset message will show daily when the Controller has 21 days or less remaining.

If you notice any malfunction, stop using your PoNS immediately and contact your PoNS Trainer. If additional help is needed, contact Customer Support.

PoNS part	Useful life
AC Power Adapter and Cable	Three years
Controller	Three years
Mouthpiece	14 weeks

Disposal and Recycling Information

This product must be disposed of separately from ordinary household waste at its end of life because the equipment is electronic and the Controller contains a lithium battery. Ensure that you dispose of your PoNS Controller and Mouthpiece at an appropriate recycling center. Do not incinerate.

For information about where to recycle electronic equipment, contact your local waste management authority.

SCREEN MESSAGES

	What you see on the Controller screen	Other signifiers
BEFORE SESSION	  Press INFO button	_____
	Charging...	Battery icon gradually changes from  to  . Blinking ON/OFF button light. See page 12.
	Fully charged	Battery icon is full. ON/OFF button light is steady green.
	READY	ON/OFF button light is steady green if the battery has power for two or more sessions; or yellow if remaining power is only enough for one session.
	Controller reset needed in   days.	_____
DURING SESSION	Mouthpiece expires in   days.	_____
	  (Session timer countdown)	Beeping and/or vibration at session initiation (optional features). Countdown starts from 20:00
AFTER SESSION	PAUSED   (Paused session timer countdown)	Beeping and/or vibration every 15 seconds (optional features). Time countdown starts from 02:00.
	Session COMPLETE	Beeping and/or vibration at session completion (optional features).
	   minutes completed today.	_____
	Goodbye	ON/OFF button light turns off.

What it means

Users have one or more messages to read.

Battery is currently charging.

Stimulation is disabled.

The Controller has enough power for 2 or more 20-minute sessions.

Confirmation that system is operating correctly and a Mouthpiece is connected. You can only start a new session when the READY message is displayed.

Controller overall countdown since Controller was reset by PoNS Trainer.

Mouthpiece overall countdown from first use.

What to do

Press the INFO button to cycle through the messages.

Allow battery to charge sufficiently before use.

Proceed with normal use.

Proceed with normal use.

Proceed with normal use.

Proceed with normal use.

Confirmation that session has started. Timer will countdown from time displayed.

Session is paused.

Faster rate of beeping and vibration indicates session timeout is within 15 secs.

Continue with normal use. For optional features, contact your PoNS Trainer.

Press SESSION button to resume current session; **or** Press and hold SESSION button to end current session. For optional features, contact your PoNS Trainer.

Confirmation that session is completed and stopped.

The total number of minutes of use completed in a day.

Confirmation of device powering off.

Proceed with normal use. For optional features, contact your PoNS Trainer.

Proceed with normal use.

Clean and store device.

SCREEN MESSAGES

TROUBLESHOOTING	What you see on the Controller screen	Other signifiers
	Charge now. Insufficient battery.	Low battery visual  . ON/OFF button light is steady red.
	Check Mouthpiece connection.	ON/OFF button light is steady red.
	Mouthpiece expired. Please replace.	ON/OFF button light is steady red.
	Call customer support. Mouthpiece error.	ON/OFF button light is steady red.
	Call customer support. Controller error.	ON/OFF button light is steady red.
	Session INCOMPLETE	ON/OFF button light is steady green.
	Session INCOMPLETE	ON/OFF button light is steady red.
	Call PoNS Therapist. Controller reset in 00 days.	_____
	See PoNS Therapist to reset Controller.	_____
	Daily session time limit reached.	_____
	Re-order Mouthpiece. Expires in 00 days.	_____

What it means

Not enough battery power remaining for a 20-minute session. **Stimulation is disabled.**

Device is turned on but a Mouthpiece is not connected (or a full connection is not made). **Stimulation is disabled.**

Connected Mouthpiece is expired; a new Mouthpiece is required.

Stimulation is disabled.

Controller or Mouthpiece may be defective, please call Customer Support for further assistance

Stimulation is disabled.

Controller is malfunctioning, please call Customer Support for further assistance.

Stimulation is disabled.

Session paused for more than 2 minutes. The full 20-minute session was not completed.

Mouthpiece disconnection has stopped session.

Stimulation is disabled.

Controller has 21 days or less remaining and requires reset by your PoNS Trainer.

Controller has reached its 14 week calendar limit. **Stimulation is disabled.**

The daily limit of 200 minutes of session time has been reached.

Stimulation is disabled.

Mouthpiece is approaching its expiration. (This prompt appears before the READY screen and counts down from 21 days prior to Mouthpiece expiration).

What to do

Charge controller, 4 hours minimum.

Connect a Mouthpiece, or ensure connector on Mouthpiece is fully plugged into port on Controller.

Acquire and insert a new Mouthpiece.

Refer to page 25 for Customer Support.

Refer to page 25 for Customer Support.

Press INFO button to cycle to the READY screen to start another session or press and hold ON/OFF button to power off.

Fully insert mouthpiece connector. ON/OFF button turns green. Press INFO button until READY message is seen. Press SESSION button to re-start session.

Plan appropriate steps when the calendar limit is reached. Contact your PoNS Trainer to continue sessions.

Contact your PoNS Trainer.

Wait until midnight for next cycle of available session time.

Plan for appropriate steps for when Mouthpiece expires and further sessions are desired.

CUSTOMER SUPPORT

Helpline

Contact your PoNS Trainer if you require assistance or have any questions. For additional technical support, complaints, or returns, call 800-211-9136. Customer Support will be ready to assist you. See Warranty Information below.

12-Month Product Warranty

Bioness Medical, Inc guarantees the Controller for the duration of the warranty period of 12 months from the date of purchase. Bioness Medical, Inc guarantees the Mouthpiece for the duration of the warranty period of 12 months from the date of purchase or for 14 weeks if the controller has been activated and mouthpiece has been utilized, whichever comes first. Once used, the Mouthpiece must be replaced after 14 weeks. In the unlikely event that your product displays a defect of a functional nature covered under warranty, Bioness Medical, Inc is ready to replace your product at any time. Furthermore, we understand that product wear and tear over time or due to frequent use is inevitable and can be expected. Our warranties do not cover natural wear and tear. We highly recommend reading the 'Cleaning your PoNS' and 'Charging your PoNS Controller' sections of this booklet to best take care of your PoNS.

TECHNICAL SPECIFICATION

Operational Conditions

- Temperature range between 41°F and 95°F (5°C and 35°C)
- Humidity range between 15% and 90% RH non-condensing
- Atmospheric pressure range between 10.2 PSI and 15.4 PSI

Transportation and Storage Conditions

- Temperature range between -20°F and 157°F (-29°C and 70°C)
- Humidity range between 15% and 90% RH non-condensing
- Atmospheric pressure range between 10.2 PSI and 15.4 PSI

Shelf Life

- Mouthpiece may be stored for 4 years from date of manufacture prior to first use.

TECHNICAL INFORMATION

Mode or Program Name	Portable Neuromodulation Stimulator (PoNS)
Waveform (e.g., pulsed monophasic, biphasic)	Pulsed biphasic (unbalanced)
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular
Maximum Output Voltage (volts) (+/- 5%)	17.5V @ 500 Ω 20V @ 5 k Ω
Maximum Output Current (specify units) (+/- 5%)	3.5 mA @ 500 Ω (channel: 26 mA) 440 μ A @ 5 k Ω (channel: 3.85 mA)
Duration of primary (depolarizing) phase (μ sec)	0-60 μ sec
Pulse Duration (μ sec)	312.5 μ sec
Frequency (Hz or pps), single electrode	Triplets at 200 Hz intervals, repeating every 50 Hz
Frequency (Hz or pps), channel	Channel pulses stimulating different tongue locations at 3.2 kHz; groups of 16 channel pulses delivered in triplets at 200 Hz; repeats every 50 Hz
Net Charge (microcoulombs (μ C) per pulse), single electrode, (If zero, state method of achieving zero net charge.)	-0.002 @ 500 Ω (channel: -0.016) -0.0041 @ 5 k Ω (channel: -0.036)
Maximum Phase Charge, single electrode (μ C)	0.21 @ 500 Ω (channel: 1.56)
Maximum Current Density, single electrode (mA/cm ² , rms)	18.79 @ 500 Ω 2.36 @ 5 k Ω
Maximum Average Current, single electrode (average absolute value), (mA)	0.082 @ 500 Ω 0.009 @ 5 k Ω
Maximum Average Power Density, single electrode (W/cm ²)	0.025 @ 500 Ω 0.0041 @ 5 k Ω
Power supply	100-240V AC 50/60Hz, 0.18A max. Use only with the supplied AC power adapter. The AC power adapter is the (mains) power supply disconnect device.

ELECTROMAGNETIC COMPATIBILITY (EMC)

The PoNS is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes such as a typical doctor's office or physiotherapy clinic. The customer or user of the PoNS should assure that it is used in such an environment.

The PoNS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Note: "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: *Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.*

WARNING

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- **DO NOT** use a power adaptor or cable other than the ones provided with your PoNS. Use of a power adaptor or cable may affect compliance of the PoNS with the EMC requirements of IEC 60601-1-2.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PoNS, including cables supplied with the PoNS. Otherwise, degradation of the performance of the PoNS device could result.
- To ensure stability of the PoNS output, do not use the device within 4 feet (1.2m) of equipment generating microwave or shortwave radiation.

The PoNS does not include any serviceable parts.

Compliance

The PoNS has been tested and shown to comply with the EMC requirements of IEC 60601-1-2 and TS60601-4-2 for both emissions and immunity. No deviations from this standard have been used in testing the PoNS. Note that during AC power interruptions the PoNS device may momentarily stop charging the internal battery, and will resume charging the battery automatically within 3 seconds after power is restored.

Electromagnetic emissions

Emissions test	Compliance
Radiated emission (CISPR 11)	Group 1, Class B
Conducted power line emissions (CISPR 11)	Group 1, Class B
Harmonic emissions (IEC 61000-3-2)	Not applicable
Voltage fluctuations/flicker emissions (IEC 61000-3-3)	230V/ 50Hz

Electromagnetic immunity

Immunity test	Compliance level
Electrostatic discharge (ESD) (IEC 61000-4-2)	±8 kV contact discharge ±15 kV air discharge
Radiated RF (IEC 61000-4-3)	10 V/m except 95-120.625 MHz @ 3 V/m
Electrical fast transient/burst (IEC 61000-4-4)	±2 kV for power supply lines
Surge (IEC 61000-4-5)	±1 kV line to line ±2 kV line to earth
Conducted RF (IEC 61000-4-6)	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands
Voltage dips, short interruptions and voltage variations on power supply input lines (IEC 61000-4-11)	>95% reduction for 0.5 cycles >95% reduction for 1 cycle 30% reduction for 25 cycles >95% reduction for 250 cycles
Power Frequency Magnetic Field (IEC 61000-4-8)	30 A/m
Proximity Magnetic Field (IEC 61000-4-39)	IEC 60601-1-2 Table 11
Proximity Fields from Wireless Comm (IEC 61000-4-3)	IEC 60601-1-2 Table 9

ADDITIONAL INFORMATION

Symbol	Meaning	Reference
	Refer to Instructions for Use	IEC 60601-1:2005/A1:2012 Reference: ISO 7010-M002
	Caution	IEC 60601-1:2005/A1:2012 Reference: ISO 7010-W001
	This product is classified as a Type BF applied part (electrically connected to the patient but not directly to the heart)	IEC 60601-1:2005/A1:2012 Reference: IEC 60417-5333
	Please dispose product per WEEE (Waste from Electrical and Electronic Equipment) requirements	WEEE Directive 2012/19/EU
5V==1A	Charger direct current power rating	IEC 60601-1:2005/A1:2012 Reference: IEC 60417-5031
	Manufacturer	ISO 15223-1:2016 Symbol reference: 5.1.1
	Catalogue number	ISO 15223-1:2016 Symbol reference: 5.1.6
	Manufacturing date	ISO 15223-1:2016 Symbol reference: 5.1.3
	Keep away from sunlight	ISO 15223-1:2016 Symbol reference: 5.3.2
	Serial number	ISO 15223-1:2016 Symbol reference: 5.1.7
	Temperature limit: minimum and maximum storage temperatures	ISO 15223-1:2016 Symbol reference: 5.3.7
	Do not wet the Controller or the Mouthpiece connector	ISO 15223-1:2016 Symbol reference: 5.3.4
	Use by date: indicates the date after which the medical device is not to be used	ISO 15223-1:2016 Symbol reference: 5.1.4
	Mouthpiece Case recycling code - PP Polypropylene	European Parliament and Council Directive 94/62/EC Article 8, B (revision referenced: 1994)

Symbol	Meaning	Reference
	UL product safety certification mark	ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 CAN/CSA-C22.2 NO. 60601-1:14 (R2018)
Rx Only	Prescription only - device restricted to use by or on the order of a physician.	21CFR801.109 (revision referenced: 2018)
IP22	Protection against ingress of solid foreign objects ≥ 12.5 mm diameter and vertically falling water drops when the product is tilted up to 15° .	IEC 60601-1:2005/A1:2012 Reference: IEC 60601-1-11

GENERAL STANDARDS

The PoNS device has been evaluated to comply with standards including:

Standard	Reference
AAMI ES60601-1 AMD 2 (2021) Medical Electrical Equipment	Part 1: General Requirements for Basic Safety and Essential Performance, Amendment 1
IEC 60601-2-10 (2023) Medical Electrical Equipment	Part 2-10: Particular Requirements for the Safety of Nerve and Muscle Stimulators
AAMI HA60601-1-11 (2021) Medical Electrical Equipment	Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
IEC 60601-1-6 (2020) Medical Electrical Equipment	Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability