




STANDARD WRITTEN PRESCRIPTION & ORDER FORM INSTRUCTIONS - VIVALLY THERAPY

Vivally Wearable At-Home OAB Treatment

The Vivally® System is a wearable at-home treatment for patients experiencing symptoms of overactive bladder (OAB), provided by Avation Medical. For assistance with prescriptions and ordering, please contact Avation Customer Care.

For Prescribers: Submit completed Prescription Form & Chart Notes, as described below.

For Patients: To receive the Vivally System, submit the signed Patient Agreement & Order Form, front & back of insurance card.

Prescriber to Submit		Patient to Submit		
1. Signed Prescription	2. Chart notes	3. Patient-signed Agreement	4. Patient-signed Order	5. Insurance Card
	<p>HCP Chart Notes</p> <ul style="list-style-type: none"> • Patient Face Sheet • Most recent visit chart notes • Medical necessity 			<p>Front of patient health insurance card</p> <p>Back of patient health insurance card</p>

For Patient & Prescriber - What Happens After the Rx, Order, & Agreement Are Submitted?

Avation Medical will ship the Vivally® System directly to the provided shipping address subject to Avation Medical's verification of the submitted documents and completion of any requirements based on the patient's insurance provider.

Indication for Use:

The Vivally System is a wearable neuromodulation system to treat patients with the bladder conditions of urge urinary incontinence and urinary urgency.

Description:

Vivally is an advanced solution providing a non-invasive, effective alternative to traditional OAB treatments utilizing FDA-cleared wTNM (wearable tibial neuromodulation) technology, offering patients a convenient and discreet way to manage their condition in sessions of 30 minutes, 3 times a week on their own schedule from the comfort of their own home.

Caution:

Federal law restricts this device to sale by or on the order of a physician. Before prescribing or use, please refer to product labeling and the Avation Medical User Guide (the "User Guide"), for complete product instructions for use, contraindications, warnings and precautions at avation.com/user-guide.

Submit documentation via:



Secure Patient
Fillable Form
Avation.com
Patient Kit



Fax
614.559.6771



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Call Avation Customer Care at 888.972.5694 for assistance

**VIVALLY THERAPY - STANDARD WRITTEN PRESCRIPTION FORM - PLEASE COMPLETE ALL FIELDS
PRESCRIBER TO COMPLETE AND SUBMIT FORM PER INSTRUCTIONS**

1 PATIENT INFORMATION

FIRST NAME	LAST NAME
GENDER	DOB (MM/DD/YYYY)

2 MEDICAL DIAGNOSIS

Diagnosis Code (ICD-10):	<input type="checkbox"/> R32- Unspecified Urinary Incontinence
<input type="checkbox"/> N32.81 Overactive Bladder	<input type="checkbox"/> R39.15 Urgency of Urination
<input type="checkbox"/> Other _____	<input type="checkbox"/> R39.41 Urge Incontinence

3 MEDICAL NECESSITY - TRIED / FAILED TREATMENTS FOR URINARY INCONTINENCE

<input type="checkbox"/> Behavioral Modification	<input type="checkbox"/> Other _____
<input type="checkbox"/> Pharmacologics	_____

Include previous tried & failed treatments and side effects in the most recent medical record notes

4 MEDICAL PRESCRIPTION

<input type="checkbox"/> Vivally System E0737

5 PRESCRIBER INFORMATION

This form serves as a Standard Written Order and Prescription for the Vivally System for this patient. As this patient's Prescriber, I attest that the clinical information in this document accurately reflects the patient's health status and condition. I further certify that the Vivally System is reasonable and medically necessary for the treatment of this patient's condition. I understand that my email address and a secure login to the Vivally System may be required for me to access Vivally System data for this patient.

REQUIRED FIELDS

PRESCRIBER'S SIGNATURE		DATE
FIRST NAME	LAST NAME	NPI #

RECOMMENDED FIELDS - (EMAIL MAY BE REQUIRED FOR ACCESS TO PATIENT VIVALLY THERAPY DATA)

PRESCRIBER'S DESIGNATED CONTACT PERSON	PRESCRIBER'S DESIGNATED CONTACT PHONE NUMBER
PRESCRIBER'S DESIGNATED CONTACT EMAIL	



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PATIENT AGREEMENT - VIVALLY THERAPY
PATIENT TO READ & SIGN ON PATIENT AGREEMENT FORM, PATIENT TO KEEP FOR RECORDS

PATIENT INFORMATION

NAME - FIRST & LAST	GENDER	DOB (MM/DD/YYYY)	
ADDRESS	CITY	STATE	ZIP
MOBILE PHONE	EMAIL		
PREFERRED WRITTEN LANGUAGE	PREFERRED SPOKEN LANGUAGE		
EMERGENCY CONTACT	EMERGENCY PHONE		

INSURANCE

PRIMARY PAYER	ID #	GROUP #	PHONE
PRIMARY POLICY HOLDER NAME	POLICY HOLDER DOB	RELATIONSHIP TO PATIENT	
SECONDARY PAYER	ID #	GROUP #	PHONE
SECONDARY POLICY HOLDER NAME	POLICY HOLDER DOB	RELATIONSHIP TO PATIENT	

READ PATIENT AGREEMENT

Section I. Patient Acknowledgement and Consent

1. I acknowledge and agree that my Prescriber has explained the nature of the Vivally System therapy, has evaluated me for the appropriateness of Vivally System therapy, and has determined that the benefits of my use of the Vivally System outweigh the possible harm, and that I have received sufficient information about the appropriate and safe use of Vivally System (including, without limitation, the User Guide accessible at [<https://avation.com/user-guide>]) to make an informed decision. I hereby authorize Avation Medical (including its personnel and agents) to provide me with the durable medical equipment as prescribed by my Prescriber.

2. Upon receipt of my device, I agree that I shall carefully read the instructions for use, indications for use, contraindications, product warnings and safety statements provided in the User Guide and device packaging/labelling before using the device (the "Product Labelling"). I agree that I take full responsibility for the safe use and care of the Vivally System and shall only use the Vivally system for its intended purpose and in accordance with my Prescriber's instructions and the Product Labelling. I will not modify, reverse engineer, or otherwise tamper with my Vivally system.

I understand the contraindications, warnings and precautions listed below are non-exhaustive, and I shall carefully review the contraindications, warnings and precautions listed in the User Guide at <https://avation.com/user-guide> before using the Vivally system.

Contraindications:

- The Vivally system is contraindicated for use on patients who have the following history or conditions:
 - Patients with pacemakers or implanted defibrillators
 - Patients with nerve damage that could impact either transcutaneous tibial nerve stimulation or pelvic floor function
- This product is not intended for intra-cardiac or trans-thoracic use

(Section I. continued on next page)

Section I continued:

Warnings:

- Patients with suspected or diagnosed heart problems, especially those relating to the pacing or electrical functioning of the heart should be evaluated by a clinician prior to use of the Vivally System.
- The Vivally System has not been tested for patients who are pregnant or planning to become pregnant.
- Metal or other implants in the ankle receiving therapy may interfere with treatment.
- Do not place the Vivally System Garment or conduct therapy on skin that is inflamed, infected, has open wounds or is otherwise compromised.
- Do not place the stimulation electrodes across or through the head, directly on the eyes, covering the mouth, on the front of the neck, on the chest or upper back, or crossing the heart.
- Do not wear the Vivally System while bathing, showering or swimming.
- Do not immerse any components of the Vivally System in water.
- Do not apply the Vivally System Garment to other parts of the body except for the foot and ankle area.
- The Vivally System has no serviceable parts. Unauthorized modification of this equipment may cause injury to either the patient or the device operator.
- The Vivally System is only intended to be used with the accessories and detachable components indicated in the User Guide. Use of the System with any other unauthorized accessories may cause a hazardous situation for the patient or the device operator.
- Do not exceed the recommended Therapy Session time of 30 minutes per session.
 - If patient feels pain or discomfort, stop the Therapy Session immediately.
- Concurrent use of medical monitoring equipment during therapy with the Vivally System is not recommended.
- Some symptoms may become worse depending upon presence of underlying medical conditions, such as Parkinson's Disease or similar neurological disorders.

Precautions:

- Prior to using the Vivally System, read and understand all instructions in the Vivally System User Guide.
- The Vivally System is a prescription-only therapy using a personalized therapeutic range. The System should not be used by individuals for whom the product has not been prescribed.
- The following are potential health risks associated with this type of system and therapy:
 - Discomfort and pain (including throbbing pain) at or near, the site of therapy, including the patient's lower leg and foot.
 - Changes in skin color (reddening) under the stimulation electrodes.
 - Numbness of toes.
- Hypersensitivity to any materials of the System which may contact the body could cause skin irritation at the treatment site. Discontinue use if skin irritation or discomfort persists.
- When running a Therapy Session, ensure that there are no strong magnetic fields or power lines nearby.

Section II. Patient Financial Responsibility Terms

1. Personal Liability for Co-Payments, Deductibles and Insurance Shortfalls.

I certify that the information I have provided to Avation Medical about my active insurance coverage is correct to the best of my knowledge.

I understand that Avation Medical charges **\$6,900.00** (in-network rate) for the Vivally System (the "Purchase Price"). If Avation Medical is out-of-network with my insurance, I understand that my insurance may not cover any items or services furnished by Avation Medical. My actual out-of-pocket contribution depends on my insurance coverage, co-payments, deductibles, and other factors (e.g., Medicare coinsurance is 20%). I hereby authorize Avation Medical to bill my insurance carrier for the Purchase Price and I agree that I will be responsible for all deductibles, co-payments, co-insurance and/or any amounts not paid by my insurance.

I agree to contact my insurance company for eligibility of benefits and other questions related to my insurance policy and reimbursement. I may also contact Avation Medical at 888.972.5694 or customer@avation.com for help understanding my benefits. While Avation Medical will make reasonable efforts to inform me of Avation Medical's estimate of my out-of-pocket expenses, I understand that my insurance company has the ultimate right to determine my coverage, benefits, and reimbursement.

(Section II. continued on next page)

Section II. continued:

Patient Self-Pay Option: I understand that I have the option to choose to pay for the Vivally System out of my pocket and not involve my insurance company, and I should contact Avation Medical to understand the pricing, payment options, and financial assistance programs that may be available to me. If I elect this patient self-pay option, I agree that the payment terms of Avation Medical's Terms of Use (available at avation.com/terms-of-use) will apply and I authorize Avation Medical (through its payment processors) to charge the payment method that I provide for such purchase.

2. Assignment of Benefits and Rights of Appeal

I authorize Avation Medical to bill my insurance company for the products and services furnished to me by Avation Medical, and I hereby assign to Avation Medical all rights, benefits, and payments to which I am entitled under my benefit plan or insurance for such products and services.

I understand that Avation Medical may work with third party service providers for purposes of processing insurance reimbursement, and I hereby authorize Avation Medical (including its service providers) to act as my authorized representative to interact on my behalf with my insurance company, medical scheme or any other related party, to inquire about, submit claims for, appeal any full or partial denials of payment, and deal with, any issues concerning the payment for Avation Medical's products and services I purchased. I understand that if Avation Medical (including its third-party service providers) files an appeal that I cannot file an appeal on the same issue. I may be required to sign additional authorization forms for the aforementioned purposes.

I may revoke my authorization and appointment at any time by providing writing notice to Avation Medical. I will promptly notify Avation Medical of any changes to my insurance.

Section III. Limited Warranty; Limitations of Liabilities; Return; Disclaimers

1. Limited Warranty; Disclaimers; Limitations of Liabilities: I agree that the Limited Warranty Policy (available at <https://avation.com/limited-warranty>) is incorporated into this Patient Agreement by this reference, which applies to my Vivally System. I understand that individual patient results may vary, and no warranty or guarantee is made regarding my use of the Vivally Systems. Please refer to the Terms of Use (<https://avation.com/terms-of-use>) for the full warranty disclaimers and limitations of liabilities.

2. Return Policy. I will promptly report any malfunctions or defects in my Vivally System to Avation Medical. I understand that I cannot return any component of the Vivally Systems for a refund unless I comply with Avation Medical's return policy, available at <https://avation.com/returns-and-disposal>.

3. Customer Support. I may contact Avation Medical's customer support by calling 888.972.5694 or emailing customer care@avation.com during Monday-Friday 8am – 5pm Eastern time for any product or billing related complaints, concerns, or questions.

4. Adverse Reaction. I shall contact my Prescriber if any treatment reaction or adverse consequences occurs. I shall not hold Avation Medical responsible for any adverse consequences related to any misuse, failure to use, or discontinuation of the treatment. If a treatment reaction occurs when a Prescriber is absent, I will stop using the Vivally System immediately and contact my Prescriber before resuming use.

5. No Medical Advice; Not for Emergencies.

Avation does not offer medical advice or diagnoses, or engage in the practice of medicine. The products and services (offered by Avation Medical) are not intended to be a substitute for professional medical advice, diagnosis, or other treatments recommended by a Prescriber. THE PRODUCTS AND SERVICES SHOULD NEVER BE USED AS A SUBSTITUTE FOR EMERGENCY CARE. IF PATIENT HAS A MEDICAL EMERGENCY, PATIENT SHOULD SEEK EMERGENCY TREATMENT AT THE NEAREST EMERGENCY ROOM OR DIAL 911.

(Section IV. continued on next page)

Section IV. continued:

Section IV. Data Privacy and Protection

Authorization. I hereby authorize my Prescriber to disclose my Protected Health Information, as that term is defined under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as described below consistent with this authorization. I understand that this authorization is voluntary. No individual has coerced me into signing this authorization, and I am providing this authorization under my own free will.

Information to be disclosed. I understand and agree that this form authorizes my Prescriber to release my complete medical record, which may include treatment notes, images, test results, and other common medical record documentation made by the physician, nurse, or other ancillary personnel for the entire time I was treated by my Prescriber, as well records related to services rendered or treatments received from my physician(s) or hospital(s) as necessary for Avation Medical to obtain insurance approvals related to my use of the Vivally System. I understand that Protected Health Information may include information that is created both before and after the date of this authorization. I understand that my medical and financial records will be maintained by Avation Medical for a period of time prescribed by state and/or federal law, whichever is longer, and that they are available to me at no cost upon written request.

Non-Protected Health Information. As a condition of creating my Avation Medical mobile app account that is a component of the Vivally System, I shall read and hereby agree to Avation Medical's Privacy Policy (available at avation.com/privacy-policy). Avation Medical's Privacy Policy explains how Avation Medical processes and shares information received from me that is not covered by HIPAA ("Non-PHI").

Persons/organizations authorized to receive and/or use my Protected Health Information. I authorize Avation Medical, its authorized agents, business associates and subcontractors to receive Protected Health Information from my Prescriber and to use or disclose such information for the purposes consistent with this authorization.

Purpose of the use or disclosure. I authorize the parties authorized to receive my Protected Health Information consistent with this authorization to use and disclose all, or any part of, the Protected Health Information at my direction and as necessary: (i) for treatment purposes, (ii) for operation purposes, and (iii) to obtain insurance approvals related to my use of the Vivally Systems. These purposes may include enabling and customizing my use of the Products and Services; providing me with alerts regarding the Products and Services; providing me with updates and information about the Products and Services; and supporting, developing, and improving the Products and Services. I also understand that Avation Medical may de-identify, as that term is defined under HIPAA, information disclosed under this authorization, and that once de-identified the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

Revocation. I understand that I may revoke my authorization at any time by sending written notice to Avation Medical at customer care@avation.com. I understand that my revocation will be effective upon receipt and Avation Medical will cease the collection of my Protected Health Information, except to the extent that any party has acted in reliance on this authorization. I understand that I have the right to refuse to sign this authorization. My Revocation of this authorization does not affect Avation Medical's use of my Non-PHI.

(Section IV. continued on next page)

Section IV continued:

Acknowledgments. I acknowledge that I have read and understand this authorization and that I have had an opportunity to discuss it with my Prescriber. I understand that I have a right to receive a copy of this authorization and may send a request for a copy to Avation Medical at customer care@avation.com. I understand that my treatment, payment, enrollment, or eligibility for benefits will not be conditioned on whether I sign this form. I acknowledge that my authorization will remain valid as long as I obtain services from Avation Medical unless earlier revoked by me or as otherwise limited by applicable law. I understand that once information is used or disclosed under this authorization, there is a potential for it to be redisclosed and may no longer be protected under federal or state privacy law. However, I further understand that state law may prohibit the person receiving my information from making future disclosures of my information unless another authorization for disclosure is obtained from me, or unless such disclosure is specifically required or permitted by law.

I acknowledge that I have been provided with, and have read and understood, the following agreements and notices (collectively, the **"Patient Agreement"**): (i) Patient Agreement attached hereto, which includes Patient Financial Responsibility Terms, contraindications, warnings and precautions, and Data Privacy and Protection, and (ii) the Terms of Use, Privacy Policy, Indications For Use, Limited Warranty, and Return Policy posted on Avation Medical's website at avation.com, which may be amended from time to time and include warranty disclaimers and limitations of liabilities.

I represent and warrant that I am an individual of legal age to form a binding contract.

AGREED

PATIENT SIGNATURE	DATE
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Personal representative: If the individual signing this form is not the patient, please print name and specify relationship to the patient; if Power of Attorney, please provide documentation.

PERSONAL REPRESENTATIVE:	DATE
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Submit documentation via:



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PATIENT ORDER FORM - VIVALLY THERAPY
PATIENT TO READ & CHOOSE SIZING, PATIENT TO SEND TO AVATION CUSTOMER CARE, KEEP A COPY FOR RECORDS

PATIENT SHIPPING INFORMATION - COMPLETE IF ADDRESS IS DIFFERENT THAN PATIENT AGREEMENT

NAME - FIRST & LAST		DOB (MM/DD/YYYY)	
SHIPPING ADDRESS	CITY	STATE	ZIP
MOBILE PHONE		EMAIL	

MEASURE FOR SIZE - INSTRUCTIONS

i. Size Vivally: (Choose Method A or B to take Measurements)

Method A: Print Patient Sizing Guide page and place a US quarter onto the page to confirm the printed scale. Use scissors to cut out the custom Vivally Sizing Guide.

Method B: Use a tailor's measuring tape, or string or cord with a ruler to collect Measurements 1 & 2 in centimeters.

ii. Measure:

Measurement 1: Ankle Circumference just above ankle bone on bare ankle. Record **Measurement 1** in centimeters. _____ cm

Measurement 2: Middle of Foot Circumference at the arch on bare foot. Record **Measurement 2** in centimeters. _____ cm

iii. Select Vivally Size and Record Size Selection in Checkbox in #3:

Blue/small, Ankle AND Foot measure between 19.0 - 23.9 cm.

Green/medium, Ankle OR Foot measure between 24.0 - 28.5 cm.

Black/extender, Ankle OR Foot measure greater than 28.5 cm.

MEASUREMENT 1:

UPPER ANKLE CIRCUMFERENCE






MEASUREMENT 2:

MID FOOT / ARCH CIRCUMFERENCE



DETERMINE VIVALLY SIZE WITH SIZING GUIDE & SELECT SIZE

Check the box beside your size, based on your measurement

<input type="checkbox"/>	 Vivally Small Ankle AND Foot measure between 19.0 cm - 23.9 cm
<input type="checkbox"/>	 Vivally Medium Ankle OR Foot measure between 24.0 cm - 28.5 cm
<input type="checkbox"/>	 Vivally Extender Ankle OR Foot measure greater than 28.5 cm

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Email: CustomerCare@Avation.com
Web: Avation.com

Vivally®



PATIENT SIZING GUIDE - VIVALLY THERAPY PATIENT SIZING, PRINT, CUT & MEASURE



Vivally®



Vivally® Sizing Guide
Customer Care: 888.972.5694

Place quarter here to
confirm printed scale



Quarter should
fit within lines

Centimeters

18

19

20

21

22

23

24

25

26

27

28

29

30



Small

Medium

Extender

Submit documentation via:



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