Phone: 888.972.5694 Fax: 614.559.6771

Email: CustomerCare@Avation.com

Web: Avation.com





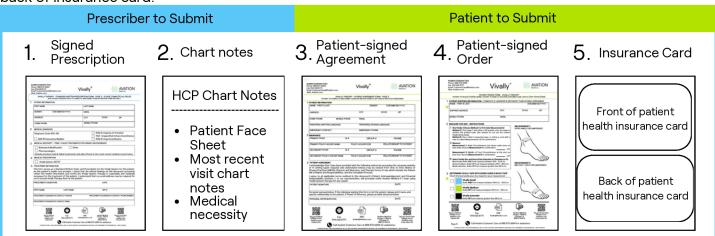
STANDARD WRITTEN PRESCRIPTION & ORDER FORM INSTRUCTIONS - VIVALLY THERAPY

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.



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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Avation Medical PO Box 736474 Chicago, IL 60673-6474



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

PATIENT INFORMATION	
FIRST NAME	LAST NAME
GENDER	DOB (MM/DD/YYYY)
MEDICAL DIAGNOSIS	
Diagnosis Code (ICD-10): N32.81 Overactive Bladder Other	R32- Unspecified Urinary Incontinence R39.15 Urgency of Urination R39.41 Urge Incontinence
MEDICAL NECESSITY - TRIED / FAILED TREATM	MENTS FOR URINARY INCONTINENCE
Pharmacologics Include previous tried & failed treatment	therts and side effects in the most recent medical record notes_
MEDICAL PRESCRIPTION Vivally System E0737	
PRESCRIBER INFORMATION This form serves as a Standard Written Ord	ler and Prescription for the Vivally System for this patient. As this al information in this document accurately reflects the patient's
	that the Vivally System is reasonable and medically necessary fo nderstand that my email address and a secure login to the Vivally Vally System data for this patient.
REQUIRED FIELDS	
PRESCRIBER'S SIGNATURE	DATE
FIRST NAME LAST NAME	NPI #
RECOMMENDED FIELDS - (EMAIL MAY BE REQ	UIRED FOR ACCESS TO PATIENT VIVALLY THERAPY DATA)
PRESCRIBER'S DESIGNATED CONTACT PERSON	PRESCRIBER'S DESIGNATED CONTACT PHONE NUMBER
PRESCRIBER'S DESIGNATED CONTACT EMAIL	
	PDF PDF





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

FATILIAT HAPONIVIATION					
NAME - FIRST & LAST		GEN	NDER	DOB (MM/D	DD/YYYY)
ADDRESS		CITY	Sī	TATE	ZIP
MOBILE PHONE		EMAIL			
PREFERRED WRITTEN LANGUAGE		PREFERRED SP	OKEN LAN	GUAGE	
EMERGENCY CONTACT		EMERGENCY PH	HONE		
INSURANCE					-
PRIMARY PAYER	ID#	GROU	P#	PHONE	
PRIMARY POLICY HOLDER NAME		POLICY HOLDER DOB		RELATIONSH	HIP TO PATIENT
SECONDARY PAYER	ID#	GROU	P#	PHONE	
SECONDARY POLICY HOLDER NAME		POLICY HOLDER DOB		RELATIONS	IIP 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)

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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

insurance policy and reimbursement. I may also contact Avation Medical at 888.972.5694 or customercare@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)

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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 customercare@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)

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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 customercare@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)

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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 customercare@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
Personal representative: If the individual signing this form is not the patient relationship to the patient; if Power of Attorney, please provide documents	
PERSONAL REPRESENTATIVE:	DATE

Submit documentation via:



Secure Patient Fillable Form Avation.com Patient Kit



Fax 614.559.6771



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Secure Prescriber Fillable Form Avation.com Prescriber Kit





SEND COMPLETED FORM TO:

Fax: 614-559-6771 or Email: AvationAssist@avation.com

HIPAA COMPLIANT AUTHORIZATION FOR THE RELEASE OF PATIENT INFORMATION AND APPOINTMENT OF AUTHORIZED REPRESENTATIVE (Privacy Rule, 45 C.F.R. §164.508(c)(1)

Authorization for Release:

I,	(Patient Name & DOB) hereby authorize	(Practice
Name) to release	my Protected Health Information (PHI) as described below to	o PRIA HEALTHCARE
MANAGEMENT	("PRIA"), and Avation Medical, Inc., and their employees/busine	ess associates as requested
by them for the pu	urpose of and in connection with my precertification, appeal, grie	vance and/or independent
review request of	a denial of insurance benefits and/or coverage, including but not	limited to:

<u>MEDICAL RECORDS</u>: Hospital records, chart and notes; laboratory records and reports; physical therapy records; doctors and nurse's notes; all correspondence of any kind; mental health, psychiatric and psychological records; substance abuse information; reports, tests and test results, x-ray films and reports; and, any and all other records which pertain to my medical care, treatment, history and prognosis.

<u>INSURANCE/BILLING RECORDS</u>: Any and all communications, notes, billing statements, claim forms, Explanation of Benefits, enrollment information, premium information or other benefits information or documents to/from insurance companies, self-insured plans, TPA's, claims administrators, Plan Sponsors, Plan Administrators, utilization review companies or other third-party payers involved with evaluating, adjusting, processing or paying my claim(s) for insurance benefits, whether pre-service or post-service in nature.

Additional Notices

I understand that signing this form is voluntary. I understand that my health information may be protected by HIPAA (45 CFR Parts 160 and 164), the Confidentiality of Alcohol and Drug Abuse Patient Records (42 CFR Part 2), and/or state laws. I understand that my health information may be subject to re-disclosure by the recipient and that if the organization or person authorized to receive the information is not a health plan or health care provider, the released information may no longer be protected by the federal privacy regulations. I understand that my records may contain information regarding my mental health, substance use or dependency, or sexuality, and also may contain confidential HIV/AIDS-related information. I further understand that by signing below, I am authorizing the release or exchange of these records to the parties named above. I also understand that my covered entity may not condition treatment, payment, enrollment, or eligibility for benefits on whether I sign this form. Any copies of this Authorization and Appointment of Representative shall be treated in all respects as though an original, including facsimile transmissions, thereof. I have been advised of my rights to receive a copy of this form.

Expiration: The above Authorization and the below Appointment of Representative will expire one year from the date entered below OR upon conclusion of my appeal process.

Revocation: I understand that I may revoke the above Authorization and/or the below Appointment of Representative at any time by notifying PRIA, in writing, to the e-mail address listed above. However, I understand that if I revoke the Authorization and/or Appointment of Representative, it will not have any effect on any actions PRIA or Avation Medical, Inc., took before PRIA received the revocation.

Patient or Legal Representative Signature Authorizing Release:		
Printed Name:	Date:	
Appointment of Authorized Representative:		
representative(s) with my insurance plan	mployees/business associates to act as my authorized (Insurance Plan/Claims Admin), particularly oncurrent or post-service claims, and to sign any future required by my insurance plan.	
Eligibility Understanding		
appeal program or, in the event I am eligible, I ack outcome to my appeal and that this appeal may ult	any guarantees or assurances that I am eligible for this mowledge that I have NOT been promised any specific imately denied or not processed by the payer. I further the personal financial responsibilities that I have with my	
otherwise participate and assist PRIA during this a fashion and understand that my failure to do so ma understand there are no costs for me to participate in	formation, sign certain forms, obtain certain records or appeal. I agree to respond to such requests in a timely y negatively affect the outcome of my appeal. While I this appeal program, some health care providers or other records. Accordingly, I understand that if I want those directly responsible for paying those providers.	
Patient or Legal Representative Signature for Ap	pointment of Representative:	
Legal Representative's Relationship to Patient		
Printed Name:	Date:	

Phone: 888.972.5694 Fax: 614.559.6771

Email: CustomerCare@Avation.com

Web: Avation.com





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 DOB (MM/DD/YYYY) NAME - FIRST & LAST SHIPPING ADDRESS CITY STATE ZIP **EMAIL** MOBILE PHONE **MEASURE FOR SIZE - INSTRUCTIONS MEASUREMENT 1**: i. Size Vivally: (Choose Method A or B to take Measurements) UPPER ANKLE CIRCUMFERENCE 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. 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. **MEASUREMENT 2:** Green/medium, Ankle OR Foot measure between 24.0 - 28.5 cm. MID FOOT / ARCH CIRCUMFERENCE Black/extender, Ankle OR Foot measure greater than 28.5 cm. DETERMINE VIVALLY SIZE WITH SIZING GUIDE & SELECT SIZE Check the box beside your size, based on your measurement Vivally Small Ankle AND Foot measure between 19.0 cm - 23.9 cm Vivally Medium Ankle **OR** Foot measure between 24.0 cm - 28.5 cm **Vivally Extender**

Submit documentation via:



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Ankle OR Foot measure greater than 28.5 cm

Fax 614.559.6771



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