**Avation Customer Care**
Phone: 888.972.5694
Fax: 614.559.6771
Email: CustomerCare@Avation.com
Web: Avation.com

Vivally®

AVATION MEDICAL

# PRESCRIPTION & ORDER FORM INSTRUCTIONS - VIVALLY THERAPY

## Vivally Wearable At-Home OAB Treatment

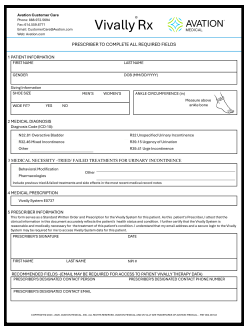
The Vivally® System, by Avation Medical, is a wearable at-home treatment for patients experiencing symptoms of overactive bladder (OAB). Vivally is an FDA-cleared wearable tibial neuromodulation (wTNM) technology, offering patients a convenient and discreet way to manage their condition in sessions of 30 minutes, on their own schedule.

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

**For Patients:** To receive the Vivally System, submit the signed Patient Agreement, PRIA Agreement, and front & back of insurance card. Avation Medical will ship the Vivally System directly to the patients.

### Prescriber to Submit

1. Signed Prescription




2. Chart notes

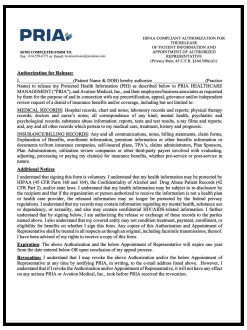
**HCP Chart Notes**

- Patient Face Sheet
- Most recent visit chart notes
- Medical Necessity

### Patient to Submit

3. Signed Patient Agreement


4. Signed PRIA Agreement




5. Insurance Card

- Front of patient health insurance card
- Back of patient health insurance card

### 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.

### 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, for complete product instructions for use, contraindications, warnings and precautions.

## Submit documentation via:

Secure Patient Fillable Form
Avation.com
Patient Kit

Fax
614.559.6771

PDF
Intake@Avation.com

Avation Medical
PO Box 736474
Chicago, IL
60673-6474

Secure Prescriber Fillable Form
Avation.com
Prescriber Kit

Call Avation Customer Care at 888.972.5694 for assistance

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# Vivally® Rx

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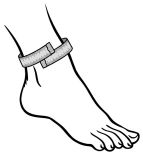
PRESCRIBER TO COMPLETE ALL REQUIRED FIELDS

## 1 PATIENT INFORMATION

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

Sizing Information

| SHOE SIZE ☐ MEN'S ☐ WOMEN'S | ANKLE CIRCUMFERENCE (in) |
|---|---|
| WIDE FIT? ☐ YES ☐ NO | Measure above ankle bone  |

## 2 MEDICAL DIAGNOSIS

Diagnosis Code (ICD-10):

- ☐ N32.81 Overactive Bladder
- ☐ R32.46 Mixed Incontinence
- ☐ Other _____
- ☐ R32 Unspecified Urinary Incontinence
- ☐ R39.15 Urgency of Urination
- ☐ R39.41 Urge Incontinence

## 3 MEDICAL NECESSITY -TRIED/ FAILED TREATMENTS FOR URINARY INCONTINENCE

- ☐ Behavioral Modification
- ☐ Pharmacologies
- ☐ Other _____

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

## 4 MEDICAL PRESCRIPTION

- ☐ 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.

| 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) |
| SHIPPING ADDRESS | CITY | STATE ZIP |
| MOBILE PHONE | EMAIL | |
| PREFERRED WRITTEN LANGUAGE | PREFERRED SPOKEN LANGUAGE | |
| EMERGENCY CONTACT | EMERGENCY PHONE | |

## 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 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.

## Submit documentation via:

Secure Patient Fillable Form
Avation.com
Patient Kit

Fax
614.559.6771

PDF
Intake@Avation.com

Avation Medical
PO Box 736474
Chicago, IL
60673-6474

Secure Prescriber Fillable Form
Avation.com
Prescriber Kit

Call Avation Customer Care at 888.972.5694 for assistance

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## 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 **$4,995.00** (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 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.

**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.

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**Section Ill. 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 DIAL911.**

**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.

**(Section IV. continued on next page)**

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## Section IV. Continued

**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.

**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, User Guide including and Data Privacy and Protection, and (ii) the Terms of Use, PrivacyPolicy, 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.

**AGREED**

| PATIENT SIGNATURE | DATE |
|---|---|
| | |

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 |
|---|---|
| | |

**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 PRIA HEALTHCARE MANAGEMENT ("PRIA"), and Avation Medical, Inc., and their employees/business associates as requested by them for the purpose of and in connection with my precertification, appeal, grievance and/or independent review request of a denial of insurance benefits and/or coverage, including but not limited to:

MEDICAL RECORDS: 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.

INSURANCE/BILLING RECORDS: 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:**

I hereby designate and appoint PRIA and their employees/business associates to act as my authorized representative(s) with my insurance plan _____ (Insurance Plan/Claims Admin), particularly with respect to my appeal of denied pre-service, concurrent or post-service claims, and to sign any future authorization or appeal forms on my behalf that are required by my insurance plan.

**Eligibility Understanding**

I understand that PRIA has not provided me with any guarantees or assurances that I am eligible for this appeal program or, in the event I am eligible, I acknowledge that I have NOT been promised any specific outcome to my appeal and that this appeal may ultimately denied or not processed by the payer. I further understand that this appeal program will not impact the personal financial responsibilities that I have with my health care provider, facility, and/or insurance plan.

I also understand that I may be asked to provide information, sign certain forms, obtain certain records or otherwise participate and assist PRIA during this appeal. I agree to respond to such requests in a timely fashion and understand that my failure to do so may negatively affect the outcome of my appeal. While I understand there are no costs for me to participate in this appeal program, some health care providers or other entities may require payment for copying medical records. Accordingly, I understand that if I want those records to be a part of my appeal package, I will be directly responsible for paying those providers.

**Patient or Legal Representative Signature for Appointment of Representative:** _____

**Legal Representative's Relationship to Patient** _____

**Printed Name:** _____ **Date:** _____