User Guide

Vivally™ System

A Wearable Bladder Control Therapy and Digital Health System for Overactive Bladder and Urge Urinary Incontinence

Models:

VCG-KTS01: Vivally Patient Kit - Small

VCG-KTM01: Vivally Patient Kit - Medium

Table of Contents

Symbols and Description

℞ Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.		Do not re-use
	Manufacturer – Avation Medical		Temperature
	Date of manufacture Date of Manufactur		Pressure Range (Opearting and Storage)
LOT	Batch code		Humidity Range (Operating and Storage)
REF	Catalog number		Caution
SN	Serial number		Type BF Applied Part – Garment (Electrode Pads)
	Waste electrical and electronic equipment (WEEE) should not be disposed as unsorted municipal waste; WEEE should be collected separately	**IP42**	Protected against solid foreign objects of 1 mm diameter and greater. Protected agains dripping water
	Us By date		Consult Instruction for use (User Guide)

The Vivally System is a wearable bladder control therapy and digital health system to help patients treat and manage the chronic conditions of overactive bladder (OAB) and urge urinary incontinence (UUI) and their associated symptoms including urinary urgency, urinary frequency, and urge urinary incontinence. The Vivally System is designed with the patient in mind - offering treatment that is easy, safe, personalized and able to be performed in the home without any need for surgery, needles or drugs. The System utilizes closed-loop control technology to personalize therapy by using the patient's own physiologic responses to objectively confirm activation of the target nerve and continuously monitor nerve recruitment throughout therapy, automatically adjusting to ensure both safety and therapeutic output. Finally, the System also connects with a digital health platform allowing the patient to track symptom and therapy data with history available in a HIPAA-compliant cloud server available to both patient and physician. The therapy does not cause pain or discomfort and can be performed during normal activities of daily life. The Vivally System is prescribed by a physician following a brief clinical screening and creation of treatment parameters to ensure that the therapy is personalized and provides each patient a comfortable therapy level, which can be modified by the patient, within certain parameters, if desired.

The Vivally System Patient Kit includes a Stimulator with rechargeable battery, a wearable Garment, Gel Cushions, and accessories. Its digital components include the Vivally Mobile Application that allows patients to control and monitor therapy, symptoms and other activities, and a cloud-based clinician web portal that collects patients' therapy history, bladder events and patient behavior, allowing the clinician to easily track the patient's progress in order to adjust therapy when appropriate.

Indication for Use

The Vivally™ System is a wearable bladder control therapy and digital health system to treat patients with the chronic conditions of overactive bladder (OAB) and urge urinary incontinence (UUI) and their associated symptoms including urinary urgency, urinary frequency, and urge urinary incontinence without the need for surgery, drugs, or needle-electrodes.

The Vivally System features closed-loop control technology that uses the patient's own physiologic response to objectively confirm activation of the target nerve and continuously monitor nerve recruitment, automatically adjusting the stimulation to ensure both safety, and optimal therapeutic output. The digital health and non-invasive therapy System is intended to provide personalized treatment with the ability to conduct therapy at home, during a time convenient for the patient.

Contraindications

- The Vivally System is contraindicated for use on patients who have the following history or conditions:
    a. Patients with pacemakers of implanted defibrillators
    b. 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.

Warnings

- This User Guide is not a comprehensive reference to therapeutic techniques for the treatment indications noted for the Vivally System.
- 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
- Metal or other implants in the ankle being treated can interfere with treatment
- The Vivally System has not been tested for patients who are pregnant or planning to become pregnant.
- 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 wear the Vivally System while bathing, showering or swimming. Do not immerse any components of the System in water.
- Do not apply the Vivally System Garment to other parts of the body except for the indicated 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 you feel pain or discomfort, stop the Therapy Session immediately.
- Concurrent use of medical monitoring equipment during therapy with the Vivally System is not recommended.
- System may be affected by Wi-Fi, Cellular networks or changes to network configuration.

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. Do not use the Vivally System with non-prescribed individuals.
- Always check the condition and position of the Gel Cushions before starting a Therapy Session to ensure they are properly adhered to the Garment and fully covering the electrode pad. Do not start a Therapy Session without Gel Cushions in place.
- 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
- Do not machine wash the Garment or place it in the dryer. Do not spot clean or wash Gel Cushions.
- 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.
- Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and placed into service according to EMC guidelines provided in the Electromagnetic Compatibility section.
- Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment. Portable and mobile RF Communications equipment other than the device used to control the system should not be used in close proximity to the Vivally System.
- Power frequency magnetic fields should not exceed levels characteristic of a typical home use device.
- Store all Vivally System components in a cool, dry location.

Vivally System Patient Kit Components

The Vivally System Patient Kit includes the following components:

1. Stimulator

2. Docking Station Set

3. Gel Cushions

4. Garment and Socket Plug

Socket plug

5. Carrying Case

6. Quick Start Guide

7. Postcard

In addition to the Patient Kit, Vivally System consists of the following digital health componnets that are provided separately to users.

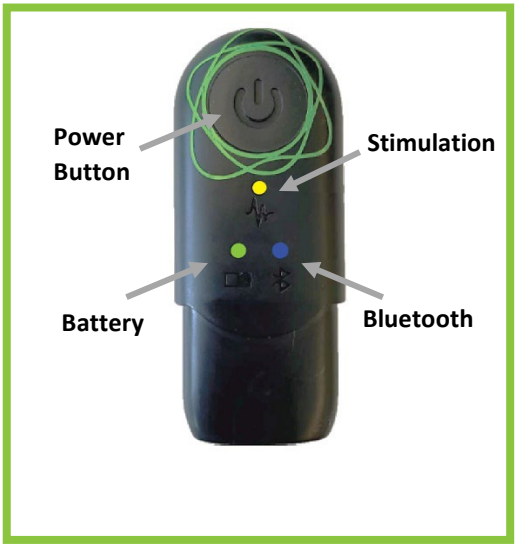
- **Vivally Mobile App**
- **Patient Web Portal**

Stimulator Indicator Light Status

The Stimulator has 3 indicator lights for Stimulation Therapy, Battery, and Bluetooth as shown.

Stimulation Therapy Light Indicator

- Solid Yellow – Therapy Session in progress
- Blinking Yellow – Therapy Session paused
- Off – Therapy Session not in progress



Battery Light Indicator

- Solid Green – Battery sufficiently charged, ready for therapy
- Blinking Green – Battery is still charging and
- sufficiently charged to complete a Therapy Session
- Blinking Red – Battery is charging and is not sufficiently charged to complete a Therapy Session
- Off – Stimulator is turned off

Bluetooth Indicator

- Solid Blue – Stimulator is connected to a mobile device
- Rapidly Blinking Blue – Stimulator is in pairing mode and is ready to connect to a mobile device
- Slowly Blinking Blue – Stimulator is not connected to a mobile device
- Off – Stimulator turned off

Stimulator Power Button

The Stimulator Power Button has multiple functions. Pressing the button once turns the Stimulator on. When the Stimulator is on, pressing and holding the Power Button for 4 seconds turns the Stimulator off. With a Therapy Session active, pressing the Power Button once will pause Therapy. When paused, pressing the Power Button again resumes therapy.

Download the Vivally Mobile Application and Sign In into your Account

Before you use the Vivally System for the first time you will need to download the Vivally App on your personal mobile device, either a smartphone or tablet - and then pair it with the Stimulator before you start a Therapy Session. Follow the steps below:

- Confirm that your personal mobile device is approved for use with the Vivally System.
  - Google Pixel 3 and newer, Samsung Galaxy 2017 and newer. The supported operating systems are Android 9 and newer.
  - iPhone 7 and newer. The supported operating systems are iOS13 and newer.

- Download the Vivally Mobile App available on the App Store or Google Play.

QR Code Link to app in App Store

QR Code Link to app in Google Play

- Open the Vivally Mobile App and press Sign Up.
- Enter the email address used during clinical screening.
- You will receive an email with an Access Code. Enter the Access Code and create a password.
- Sign In into the Vivally Mobile App using the email and password.

Pair your Mobile Device with the Stimulator

1. Remove the Stimulator from the Docking Station.
2. When the Stimulator is removed from the Docking Station it should automatically turn on. If needed, press the Power Button on the Stimulator to turn it on.
3. Ensure that your mobile device's Bluetooth is turned on
4. Ensure the Stimulator is powered on
5. Go to Pair mode (see screen below) and press Pair
6. Follow instructions; accept all applicable permissions
7. When prompted for a 6-digit Pairing Pin, read the number at the back of the Quick Start Guide and enter in the App

Prepare for a Therapy Session

Vivally Therapy can be performed at any time it is convenient for you. We recommend that you plan your Therapy Session for a time that you can sit or lay down for 30 minutes. Some movement, including casual walking, is acceptable, however performing strenuous exercise or significant movement of the lower extremities during a Therapy Session is not recommended.

1. Place the Gel Cushions inside the Garment

Gel Cushions ensure comfort and good signal conduction. The System should not be used without Gel Cushions in place.

Open the Garment with the tan pads facing you. Flip the garment in half to fully expose the tan ovals. Remove the blue coverings from two Gel Cushions and apply them, sticky side down to the tan ovals on either the left or right side of the garment (left or right denotes what foot the garment will be applied to for therapy) as shown in the illustrations. Gel Cushions tabs should be facing the edge of the Garment. Leave the clear coverings on the Gel Cushions in place until you are ready to begin therapy.

CAUTION: Always check the placement and condition of Gel Cushions prior to starting each Therapy Session. Using the System with incorrectly placed or worn Gel Cushions may cause discomfort.

IMPORTANT TIP: Gel Cushions should be replaced every 4 weeks. Replace sooner if they are excessively dry or dirty or if they no longer adhere to the Garment, or if therapy feels less comfortable than usual. Always check the condition of the Gel Cushions prior to starting a Therapy Session.

2. Place the Garment on your Foot

The Garment can be worn on either left or right foot. It is designed to ensure proper positioning of the therapy electrodes over the tibial nerve. Follow the steps below for the proper Garment donning procedure. The numbers printed inside the Garment correspond to the following steps.

2.1: Slide your heel to the back of the Garment as shown below. Ensure that you apply the Garment to the left or right foot corresponding to the placement of Gel Cushions. The Gel Cushions should be on the inside of the ankle.

1. Slide heel toward opening in Garment. 2. Align ankle bone with green hole. 3. Ensure Garment is snug.

2.2: Align the center of the inner ankle bone to the small green hole on the side of the Garment and secure the ankle strap as shown.

2.3: Secure the foot strap around the sole of the foot as shown. Make sure the Garment conforms to the ankle and sole of the foot. It should be a snug fit.

There may be gapping or wrinkling in the Garment after placement. Some gapping of the Garment is acceptable provided the Gel Cushions are in contact with the bottom of the foot and the side of the foot.

CAUTION: Do NOT place the Vivally System Garment on skin that is inflamed, infected, has open wounds or is otherwise compromised.

3. **Turn on the Stimulator**

When removing the Stimulator from the Docking Station it should automatically turn on. If you need to turn on the Stimulator, press the Power Button on the Stimulator to turn it on. If the Battery indicator light is solid green, the Stimulator is powered on, and ready. If the Battery indicator light is red, the Stimulator must be charged before use. The Stimulator should take about 2 hours to reach a full charge from empty.

NOTE: If you need to turn the Stimulator off, press and hold the Button on the Stimulator for 4 seconds. The LEDs will turn off to confirm that the Stimulator is powered off.

4. **Insert the Stimulator into the appropriate Socket on the Garment**

Attach the Stimulator to the inner ankle side of the Garment as shown below by pushing the Stimulator into the Socket until it is secure. A clicking sound will provide you with confirmation that the Stimulator is properly inserted.

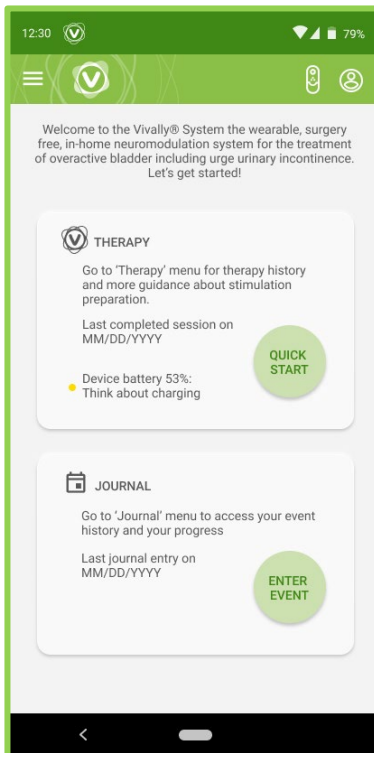
IMPORTANT TIP: Take care to ensure that the Stimulator is placed in the Socket on the inner ankle area (on the same side of your foot as your big toe). The Stimulator and Gel Cushions should both be on the same side of the Garment AND positioned on the inner ankle area (same side of the foot as the big toe). If this is not the case, reposition the Garment and/or the Stimulator.

5. **Open the Vivally Mobile App**

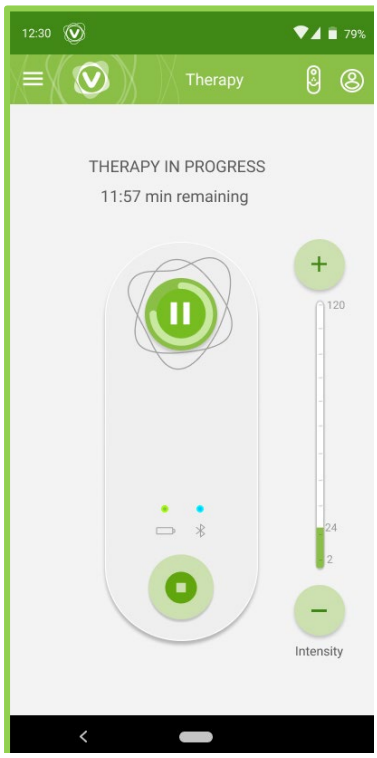
Turn your mobile device on and open the Vivally Mobile App by clicking the Vivally icon. When prompted, enter the PIN # that you set up when you first signed in to unlock the App. If you have forgotten your pin, simply log out of the App and log back in. The App will prompt you to create a new PIN #.

If the batter is low on your mobile device, you may still conduct a Therapy Session while your mobile device is charging. If your mobile device turns off, or Bluetooth connection is lost, Therapy will automatically continue and will turn off after 30 minutes have been completed.

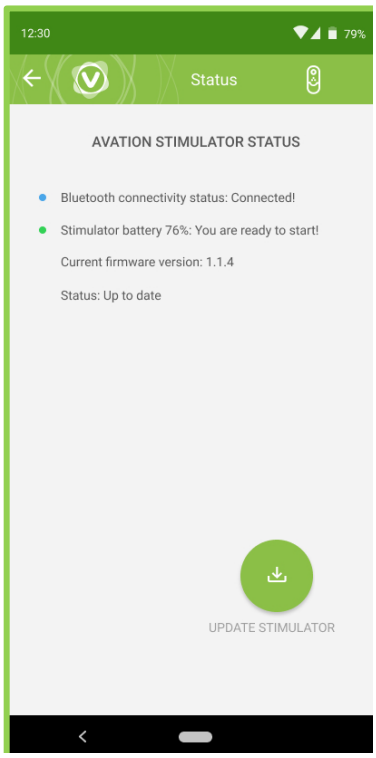
Vivally Mobile App Status Screens



Patient Home Page



Therapy in Progress



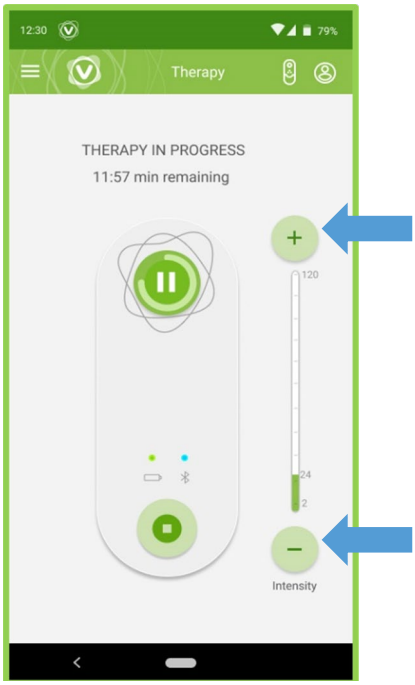
Stimulator Device Status

6. Start Vivally Therapy

Use the Vivally Mobile App to start a Therapy Session. From the Patient Home Page, select "Quick Start". Therapy will automatically begin.

Now sit back and relax while therapy takes place. You are free to stand, sit, lay down and move around and the Vivally System will automatically adjust to maintain your personalized therepeutic range.

After 30 minutes, Vivally Therapy will shut off automatically. A timer on the Therapy Page will alert you to the time remaining in your therapy session.



Adjust Therapy Intensity

The Vivally System provides you with a range of personalized therapy intensity as set by your physician. You may adjust intensity within this range at any time during your therapy session. Use the green arrow on the Therapy Level bar to increase or decrease the intensity of your therapy.

Pause Therapy

You may pause your therapy session at any time by pressing the Stop/Play button once on the Vivally Mobile App. To resume Therapy, simply press the Play/Stop button on the Vivally App again.

You may also press the power button on the Stimulator once to pause therapy. Press it again to resume therapy.

IMPORTANT TIP: You may only pause twice during a Therapy Session and for no longer than 5 minutes per pause. If you do not resume therapy within 5 minutes, the Therapy Session will end without being completed and you will need to restart a new therapy session.

CAUTION: If you feel discomfort during your Therapy Session, adjust the garment or decrease the intensity by using the [-] button on the Vivally Mobile App, or stop your Therapy Session by using one of the following methods.

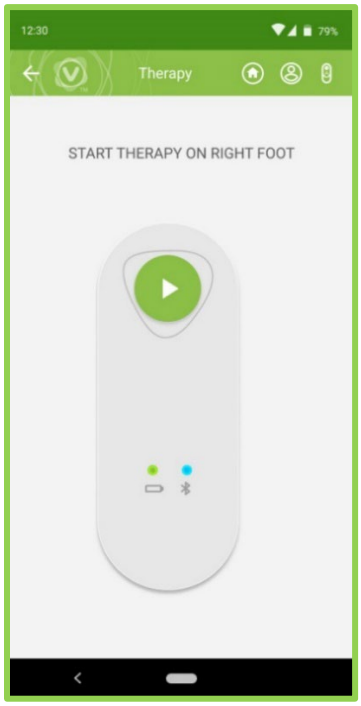
1. Use the App to pause or stop therapy:
   - Press the Pause button to Pause therapy
   - Press the Stop button to Stop therapy
2. Use the Stimulator to pause or stop therapy:
   - Press the power button on the Stimulator once to pause the Therapy
   - Press the power button on the Stimulator for 4 seconds to turn off the Stimulator

IMPORTANT TIP: If you use this option, your Therapy Session will be incomplete, and you will need to begin a new session at another time

3. Remove the Stimulator from the Garment to stop therapy:
   - Removing the Stimulator during a session will pause the Therapy Session. To resume the Therapy Session, re-insert the stimulator into the garment socket and press Play on the Vivally App.

IMPORTANT TIP: During a Vivally Session you may use other applications on your mobile device however, do not close the Vivally Mobile App during a therapy session.

Therapy Preparation



Start Therapy

Completing a Therapy Session

Your therapy session will automatically end after 30 minutes, and the journal will log your completed session.

Storage

When your therapy is complete, remove the Stimulator from the Garment and place it into the Docking Station so it is charged for your next Therapy Session. Remove the Garment by gently unfastening the two straps. Cover the two Gel Cushions inside the garment with the clear covers. This will keep them free of dust and prevent them from drying out prematurely.

IMPORANT TIP: As a safety feature, after a completed therapy session, the Vivally System will not allow another therapy session for 24 hours.

Vivally Therapy Schedule and Patient Journal

Follow the therapy schedule prescribed by your physician. All sessions are 30 minutes, typically one time to three times per week. Once you have achieved symptom improvement, your physician may allow you to reduce your therapy frequency, however, it is recommended that you continue to conduct therapy at least two times per month to maintain therapeutic effectiveness.

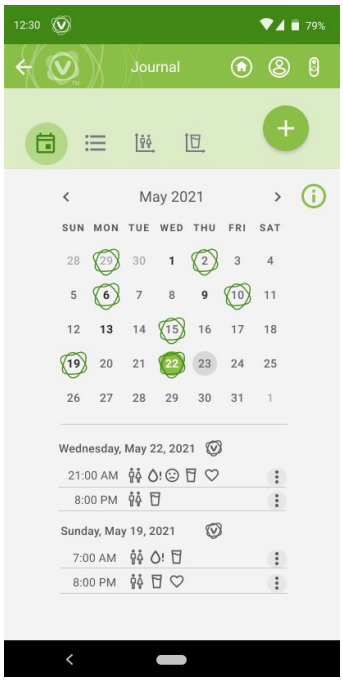
IMPORTANT TIP: Visit your physician every 6 to 12 months to review your progress and adjust your Personalize Therapeutic Range to ensure optimal therapy parameters.

Vivally System Patient Journal

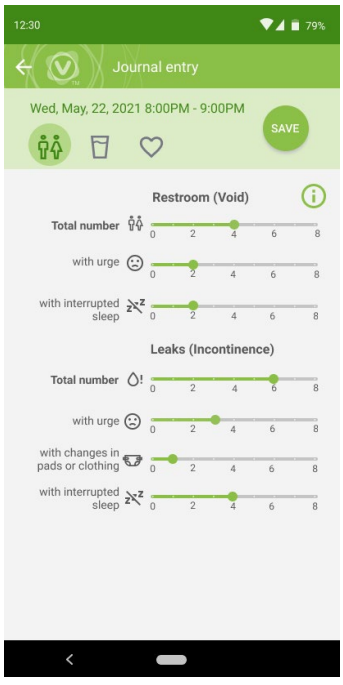
An important component of the Vivally System is the Patient App with Journal. This Journal allows the patient to track their Therapy history, their urinary symptoms and their fluid intake. The Journal displays the patient's progress and fluid intake allowing them to see the impact of their therapy over time. This information can also be shared with the patient's physician to help with adjustments to the prescribed therapy.

The Vivally System Journal should be used by the patient several times per week to actively monitor their therapy and symptoms.

Vivally System Progress Journal Screens



Journal History View



Entering Bladder Events

Vivally System Storage and Care

After you complete your Therapy Session, ensure that your Vivally System Components are ready for your next session. Confirm that the Gel Cushions are covered with the clear covers provided, and fold the Garment as shown, and place it in the Carrying Case. Place the Stimulator in the Docking Station and ensure that it is charging.

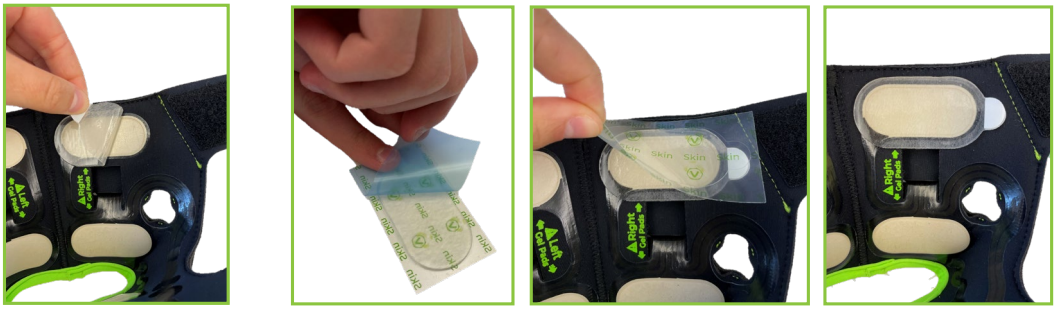
Charging the Stimulator Battery

When not in use, you may leave the Stimulator plugged into the Docking Station to charge the battery. A full battery will perform approximately 3 Therapy Sessions. A drained battery can be fully charged in approximately two hours. The battery can be sufficiently charged in approximately one hour to complete one Therapy Session.

Replacing Gel Cushions

Check the placement and condition of Gel Cushions prior to each Therapy Session. Gel Cushions should be replaced every 4 weeks, or sooner if they appear dry, cracked or dirty, if they no longer adhere to Garment or if your previous therapy session felt less comfortable than usual.

To replace the Gel Cushions, first remove the old Gel Cushions from the Garment by pulling the white tab. To attach new Gel Cushions, remove two Gel Cushions from the package and carefully remove the clear light blue plastic liners while holding down the white tab. Attach the Gel Cushion to the Garment by aligning it so it completely covers the electrode as shown,. Press it down firmly onto the Garment ensuring there are no wrinkles. Then, remove and save the upper clear plastic liner labeled Skin. Repeat the steps for the second Gel Cushion. See Step #1 of the procedure Section for information on left/right foot orientation. Please note the clear plastic liners are needed to cover the Gel Cushions during storage. Replacement Gel Cushions can be ordered through Avation customer support website.



Remove Gel Cushions **Remove Blue Liner** **Align Gel Cushion** **Finished**

NOTE: The Vivally System has been designed and tested only for use with the Vivally Gel Cushions. No other cushions or pads should be used.

Caution: Do not start a Therapy Session without Gel Cushions properly in place. Always check the condition and position of the Gel Cushions before starting a Therapy Session and replace them if they appear dirty,dry, cracked, or no longer adhere to the Garment.

Using the Socket Plug

The Socket Plug serve as a reminder to place the Stimulator on the appropriate side of the Garment each time. Plug the Socket Plug into the Socket on the unused side of the Garment as shown. This will serve as a reminder to place the Stimulator on the appropriate side of the Garment each time.

Cleaning the Garment

If necessary, spot clean the Garment with a cleaning wipe or a soft cloth with a mild detergent. Let the Garment air dry completely before you use it again.

IMPORTANT TIP: The Vivally Garment should not be placed in a clothes washer or dryer.

Prescription and System Settings by Physician

The Vivally System is available by a prescription from a physician. The physician will determine the correct size garment and will establish a Personalized Therapeutic Range by conducting a screening and objective confirmation of the therapy level at which the tibial nerve is activated. The steps below should be followed to prepare the patient to use the Vivally System:

1. Confirm diagnosis of overactive bladder and/or urge urinary incontinence
2. Confirmation of correct Vivally Garment size
3. Initiation of system setup to observe objective confirmation of tibial nerve activation and setting of patient's Personalized Therapeutic Range
    a. If desired, physician may repeat step 3 on both of the patient's feet
4. Physician may conduct a test therapy session
5. Physician/staff will instruct patient on Vivally System set up and proper use
6. Physician will provide a prescription for the Vivally System and collect necessary information from patient to order the Vivally System

Principles of Operation

The Vivally System utilizes neuromodulation to deliver electrical signals to the tibial nerve. The tibial nerve is a peripheral nerve that feeds into the sacral plexus which contains the nerves that innervate the detrusor muscle surrounding the urinary bladder. Neuromodulation is believed to work by regulating the signals sent by the nerves and reducing the rate of excessive contractions of the bladder muscle which cause frequency of urinary urge, frequency of urination, and sometimes urinary incontinence. The Vivally System features closed-loop control technology that uses the patient's own physiologic response to objectively confirm activation of the target nerve and continuously monitor nerve recruitment, automatically adjusting the stimulation to ensure both safety, and optimal therapeutic output. Its digital components include a mobile app that allows patients to control and monitor therapy, symptoms and

other activities, and a cloud-based clinician web portal that collects patients' therapy history, bladder events and patient behavior, allowing the clinician to easily track the patient's progress in order to adjust therapy when appropriate. The digital health and non-surgical therapy system is intended to provide personalized treatment with the ability to conduct therapy at home, during a time convenient for the patient.

To use the Vivally System, the patient dons the wearable Garment on either their left or right foot. The green hole on the side of the Garment serves as a guide for the patient to ensure the medial malleolus (the ankle bone on the inner side of the ankle) is centered and that the stimulating electrodes align with the tibial nerve. When inserted into the Socket on the Garment, the Stimulator, provides stimulation through the two electrodes built into on the garment using a bi-phasic rectangular electric waveform. The current amplitude is held constant at 20 mA through current-controlling circuitry. The intensity of stimulation is altered by changing the pulse width, or duty cycle, of the waveform between 10 to 600 microseconds. The stimulation parameters, such as the pulse width, are determined during a clinical screening session and is based on individual patient EMG response and comfort.

The Stimulator is powered using a rechargeable lithium-ion battery with necessary current limiters and safety elements. The Stimulator has a push button that is used to power up or down the Stimulator and to temporarily pause the therapy. The microprocessor on the device communicates to an app on a mobile device, such as a cellphone or a tablet, through Bluetooth®.

The circuit board also includes an analog input that measures the electromyogram signal from the patient's foot via three additional EMG electrodes embedded on the Garment. The system operates in a combination of closed-loop using EMG as the physiological feedback, as well as in open-loop when the feedback signal is unreliable or unreadable. In both closed and open-loop operating modes, the stimulation is limited to predefined limits to ensure safe and comfortable therapy session.

To begin a therapy session, the patient utilizes the Vivally Mobile Application on a personal smart-device which allows them to start, pause and cancel therapy. The Vivally App app also includes an electronic journal that allows the patient to track their symptoms, their therapy history, and their fluid intake.

Finally, the data from the System is periodically uploaded to a HIPAA-compliantcloud portal, and includes stimulation history, EMG, journal entries and some other general patient input. The data is encrypted and is handled per HIPAA and Cybersecurity guidelines and is available to the patient and prescribing physician to be used to optimze the patient's care.

Disposal

The Garment, Gel Cushions and Docking Station do not contain hazardous materials and may be disposed of in the trash.

The Stimulator contains a Lithium-Ion battery and must be disposed of according to national, state and local regulations.

You may also return all Vivally System components to Avation® Medical for proper disposal. A return label can be request from our website, www.Avation.com or by contacting our Customer Care department at CustomerCare@Avation.com. Simply attach this to a package with the System components enclosed and ship it back to us. Upon receipt, we will process your old device for

component recovery and recycling to help conserve the world's resources and minimize adverse effects on the environment.

Troubleshooting

1. **Stimulator insufficiently charged**

   If the Stimulator is not fully charged, the battery light will be red. In addition, the Vivally System App will notify you when the Stimulator is not sufficiently charged for a Therapy Session. To recharge the Stimulator, place it on the Docking Station and charge until the Battery strength indicator is blinking or solid green. It will take approximately 1 hour for the Stimulator to charge for a single session (blinking green) and 2 hours for a full charge (solid green).

   NOTE: You will NOT be able to conduct a Therapy Session while the Stimulator is charging.

2. **No network connection**

   If you have not connected your mobile device to a network (Wi-Fi or cellular data), the Vivally System App will notify you. Use the OS settings to connect to Data or WiFi.

   IMPORTANT TIP: Therapy Sessions can be completed without a network connection; however a network connection is needed to upload data to the Cloud and ensure the Patient Portal is updated.

3. **Loss of Bluetooth connection - Bluetooth light blinks**

   If there is no Bluetooth connection between the mobile device and the Stimulator, the Vivally System App will notify you. Loss of a Bluetooth connection may be temporary and may resolve by itself. To confirm this, place the Stimulator and mobile device in close proximity for 10 seconds. If Bluetooth connectivity is not restored, then re-pairing is needed.

   To establish/re-pair a Bluetooth connection, press the Menu Button in the Vivally System App and select Device Pairing. Select the Stimulator to be paired by pressing the correct Stimulator name. Then, press the Button on the Stimulator to make a Bluetooth connection. If the time runs out before the Stimulator is paired with the mobile device, repeat the process.

4. **Vivally Mobile Application does not respond**

   If the Vivally System App is not responding, close and reopen the app. If that does not work, turn off and restart your mobile device.

5. **Error message: Garment Check Failed**

   Check that the Gel Cushions are attached and aligned properly over the electrodes. Ensure the clear liners have been removed from the Gel Cushions and that they are tightly pressed against your skin. Also, check the fit of the Garment to ensure that it is snug around the ankle and toes.

6. **Error message: Stimulator Check Failed**

   Make sure that the Stimulator is fully plugged into the Garment Socket (on the inner ankle area) and that it is turned on.

7. **Therapy in progress but clock does not move**

If a Therapy Session is in progress but the countdown is frozen, move the Stimulator closer to the mobile device and the clock should start counting down again. If this does not work, the Bluetooth connection may have been lost. See Troubleshooting: Loss of Bluetooth connection - Bluetooth light blinks.

8. Therapy feels uncomfortable

During Therapy you may feel a slight tapping or tingling sensation near your inner ankle or on the bottom of your foot. This sensation should be mild and not uncomfortable. If you experience a stinging sensation, it is likely that your Gel Cushions are placed improperly or that your skin is excessively dry. Should this occur, stop Therapy and remove the Garment. Moisten your skin with either water or a light, non-petroleum based moisturizer. Check the condition and placement of the Gel Cushions and replace or reposition as necessary.

Servicing

The Vivally System contains no serviceable components. If the Vivally System is non-functional, contact Avation Medical Customer Care. Non-functional components of the Vivally System can also be individually replaced. Contact CustomerCare@Avation.com to order replacement components.

Limited Warranty

Avation Medical, Inc. manufactures its hardware products in accordance with industry standard practices. Avation Medical warrants the Vivally System to be free from defects in materials and workmanship at the time of shipment. The warranty term is one year beginning on the date of sale to the original purchaser, as further described in the following text. This warranty covers all contents of the Vivally System except the Gel Cushions.

This warranty does not cover damage due to external causes, including accident, abuse, misuse, problems with electrical power, usage not in accordance with product instructions, failure to perform required maintenance, and problems caused by use of parts or components not supplied by Avation Medical. This warranty does not apply to any product repaired or altered by anyone other than Avation Medical or an authorized Avation Medical representative. Vivally products purchased from unauthorized resellers are not covered by this warranty. Avation Medical will repair or replace, at our discretion, any product that is shown to be covered under the warranty above. To be considered for warranty repair or replacement, product(s) must be returned to Avation Medical with an Avation Medical issued Return Material Authorization (RMA) Number. To initiate a return, contact Avation Customer Care at (614) 591-4201. All products shipped to Avation Medical will become the property of Avation Medical. If Avation Medical repairs or replaces a product, the original warranty period remains in effect.

AVATION MEDICAL MAKES NO EXPRESS OR IMPLIED WARRANTIES OR REPRESENTATIONS BEYOND THOSE STATED IN THIS WARRANTY STATEMENT. AVATION MEDICAL DISCLAIMS ALL OTHER WARRANTIES AND REPRESENTATIONS, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. AVATION MEDICAL'S OBLIGATIONS FOR ANY FAILURE OF A PRODUCT TO BE AS WARRANTED ARE LIMITED TO, AT AVATION MEDICAL'S OPTION, REPAIR OR REPLACEMENT OF THE PRODUCTS SET FORTH IN THIS WARRANTY STATEMENT. UNDER NO CIRCUMSTANCES WILL AVATION MEDICAL BE LIABLE FOR ACTUAL

OR CLAIMED DEFECTS IN ANY PRODUCT BEYOND THE REMEDIES SET FORTH IN THIS WARRANTY STATEMENT. IN NO EVENT SHALL AVATION MEDICAL BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF, OR IN CONNECTION WITH, THIS AGREEMENT, REGARDLESS OF THE LEGAL THEORY UPON WHICH SUCH CLAIM IS BASED AND EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY THEREOF.

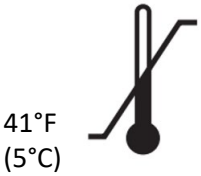
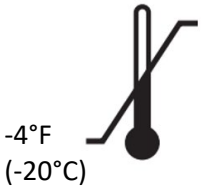
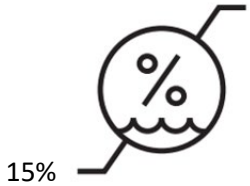
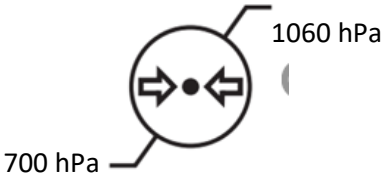
Components, Specifications and Expected Service Life

Article	Model Number	Material/Specifications	Expected Service Life
Garment	VCG-GAS01 (Small), VCG-GAM01 (Medium)	Accumed, Silver	1 Year
Stimulator	VCG-STN01	ABS-Polycarbonate, Rating: 3.7V, 240 mA	3 Year (includes battery)
Docking Station Set	VCG-DSN01 (Includes Wall Adapter)	Input Rating: 100-240V, 50/60 HZ, 0.3A Output Rating: 5V, 1000 mA ABS-Polycarbonate	3 Years
Wall Adapter	SAW06B-050-1000U		
Socket Plug	VCG-SPN01	ABS-Polycarbonate	3 Years
Gel Cushions	VCG-GC301 VCG-GC601,	Hydrogel	4 Weeks

Stimulation Specifications	
Parameters	**Technical Description**
Pulse type	Charged balanced biphasic
Stimulation Frequency	20 Hz
Stimulation Current	20 mA fixed
Stimulation Pulsewidth	10 – 600 µs
Stimulation interphase spacing	100 µs
Maximum Load Impedance	20 kΩ
Number of stimulation electrodes	2 (one cathode, one anode)
Number of recording electrodes	3 (two differential inputs, one reference input)
Power source	Lithium-ion battery
Connection to mains power	No connectionduring therapy

Environmental Specifications

Caution: Always ensure that the product is operated and stored within the environmental limits specified above. Exceeding those limits may cause an unforeseeable hazardous situation for the user or the operator.

Environmental Conditions	Operating	Storage and Transport
Temperature		
Relative Humidity		
Atmospheric Pressure		Not Applicable

Electromagnetic Compatibility

The Vivally System is intended for use in electromagnetic environment specified below. The user of the Vivally System should assure that it is used in such an environment.

- The use of accessories and options other than those specified by the manufacturer may result in increased emissions or decreased immunity of the Vivally System.
- In the event of intermittent function of the device due to exposure to electromagnetic interference, power cycle the device as per IFU instructions provided above.
- In the event of permanent damage of the device due to electromagnetic interference, stop use of the device. Contact Avation Customer Care.
- 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 Vivally System including power adapter. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions The Vivally System is intended for use in the electromagnetic environment specified below.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
RF Emissions CISPR 11	Group 1	The Vivally System 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.

RF Emissions CISPR 11	Class B	The Vivally System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Vivally System is intended for use in the electromagnetic environment specified below.			
Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ± 15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Interference may occur in the vicinity of equipment marked with the following symbol:  The Vivally System is suitable for use in all establishments with public low-voltage network that supplies buildings used for domestic purposes.
Electrical fast transient/burst (Power Lines) IEC 61000-4-4	±2 kV, 100 kHz repetition frequency	±2 kV, 100 kHz repetition frequency	
Surge immunity IEC 61000-4-5	±0.5 kV, ±1 kV line(s) to line(s)	±0.5 kV, ±1 kV line(s) to line(s)	
Voltage dips and Voltage interruptions on power supply input lines IEC 61000-4-11	Voltage dips: 0% UT for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles at single phase (0°) Voltage interruptions: 0% UT, 250/300 cycle	Voltage dips: >95% UT for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. >95% UT for 1 cycle and 70% UT for 25/30 cycles at single phase (0°) Voltage Interruptions: 100% UT for 250 cycles	
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m; 50 Hz or 60 Hz	30 A/m; 50 Hz and 60 Hz	
Radiated RF EM Fields IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz, 80% AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz, 80% AM at 1 kHz	
Conducted disturbances induced by RF fields IEC 61000-4-6	3* Vrms 0.15 MHz – 80 MHz 80% AM at 1 kHz	3* Vrms 0.15 MHz – 80 MHz 80% AM at 1 kHz	

Proximity Fields from RF Wireless communications equipment IEC 61000-4-3	Table 9 of IEC 60601-1-2 ed. 4.0	Table 9 of IEC 60601-1-2 ed. 4.0	
NOTE 1: *Tested 6 Vrms in the ISM bands The ISM band is 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Travel or International Use

If traveling outside of North America, refer to current TSA guidance for external medical devices. The Vivally System Stimulator can be charged with a standard 110 V U.S. power outlet or a 5 V USB power supply.

System Manufacturer

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