

0459

Viberect® Penile Vibratory Stimulation System

USER'S GUIDE

Made in USA

EC	REP	EMERGO EUROPE Molenstraat 15 2513 BH, The Hague The Netherlands Phone: +31.70.345.8570 Fax: +31.70.346.7299
----	-----	--

Indications for Use:

Viberect® Penile Vibratory Stimulation Device is a hand held medical device indicated to provoke erections for men who experience erectile dysfunction and to provoke ejaculation for spinal cord injured men.

CAUTION:

Federal law (US) restricts this device to sale by or on the order of physician.

TABLE OF CONTENTS

Introduction	3
Warranty.....	3
Battery.....	4
Precautions for safe use.....	5
Viberec [®] Operating Instructions	6-7
Directions for Use- Spinal Cord Injured.....	8-9
Directions for Use-Penile Erection and Rigidity	10-13
Cleaning Instructions	13
Pad Removal and replacement.....	14
Customer Service and Contact Information	14
Viberec [®] Product Specifications	15
Symbols Table	15

PLEASE READ THIS USER MANUAL IN ITS ENTIRETY FOR CORRECT USE AND OPTIMAL RESULTS.

INTRODUCTION

Viberect[®] penile vibratory stimulation device is a US manufactured hand-held therapeutic vibrator intended to provoke penile erection for erectile dysfunction, and to provoke ejaculation. The Viberect is CE certified and cleared by the US FDA as a class II medical device.

Penile vibratory stimulation is an easy and non-invasive nerve stimulation method, similar to sexual intercourse or manual stimulation that helps to activate nerve receptors (nerve antennas) that are located on the skin surface of the penis. These nerves communicate with sexual centers of the brain and spinal cord. Activation and initiation of sexual reflexes (pudendocavernosus & bulbocavernosus) by the Viberect device helps to initiate penile erection, rigidity, orgasm and ejaculation. This device is designed by urologists specializing in sexual dysfunction to help men benefit from this modality with ease in the comfort of their home.

This User's Guide provides information and instructions which must be followed to ensure safe performance of the **Viberect**[®] device. This User's Guide also contains warnings and precautions which must be observed at all times.

CAUTION: **ALL STATEMENTS IN THIS GUIDE SHOULD BE FOLLOWED AT ALL TIMES.**

Use of this device is subject to physician's orders only.
Read the instruction carefully before use.

WARRANTY

Manufacturer guarantees the **Viberect**[®] **Device** from mechanical and electrical failure resulting from defective parts and/or workmanship for 12 months from the date of purchase.

The warranty does not cover damage caused by accidents, tampering or alterations of product in any way or due to improper handling, cleaning or misuse of the product or failure to follow the instructions in the User's Guide. Manufacturer's liability is limited to the replacement of a defective product.

The Reflexonic company shall not be liable for any incidental or consequential damages whether direct or indirect.

BATTERY

The battery in your **Viberect®** has not been charged prior to delivery.

A completely discharged battery will take approximately 6-8 hours to fully charge. The Red charge indicator will extinguish once the charge cycle has completed.

To ensure that your Viberect® is always ready for use, it is recommended to recharge the battery after use.

A fully charged battery will allow about 30 minutes of vibration at medium frequency setting.

When completely discharged, allow 6-8 hours to recharge. Ensure that the vibrator is turned off before recharging.

Use only the charger supplied with the vibrator. Charge the Viberect while laying it on its side, as laying it standing can turn the device on.

DO NOT ATTEMPT to use the device while charging.

WARNING:

Avoid electromagnetic interference while using the device

Disposal of the battery

The rechargeable battery in the vibrator contains Nickel Metal Hydride (NiMH).

Like other batteries of this type, if burned or punctured, it could release toxic material which could cause injury.

Device has no replaceable internal power source. (Batteries are not replaceable. If you wish to dispose of the device, do not disassemble components. Discard in its entirety

Check with local solid waste officials for details concerning recycling options and proper disposal. In the United States, call toll free 1-800-8-BATTERY or visit the Battery Recycling Corporation website at <http://www.call2recycle.org/>

The life of NiMH batteries is strongly influenced by the care that they receive. If properly maintained, the battery is capable of more than 500 charge/discharge cycles before dropping to 80% of capacity. Do not exceed the allowable ambient temperatures during charging, operating, or storage.

WARNING

No modification of this equipment is allowed. Do not modify this equipment without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

PRECAUTIONS FOR SAFE USE



WARNING: Each Viberec device is intended for use by one person only. It should never be shared by another person, as this will increase risk of communicable or sexually transmitted diseases. Treat your device like a personal toothbrush or other personal hygienic products.

WARNING: This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in presence of unexplained calf pain. Consult your physician.

WARNING: This device should not be used for more than 10 minutes a day to avoid skin injury. Excessive vibratory stimulation can increase risk of skin irritation and temporary numbness.

Vibratory stimulation may cause superficial trauma to the skin resulting in bruising, bleeding or superficial ulceration. If any such condition occurs, refrain from vibrating and consult your physician. Do not immerse the vibrator in any type of fluid. Do not operate the vibrator in bathrooms or elsewhere under wet conditions. If the user is spinal cord injured an episode of autonomic dysreflexia may develop as a result of vibratory stimulation. If so, vibration should be stopped immediately. Consult your physician.

Autonomic dysreflexia may be caused by various factors such as for instance an over distended bowel or urinary bladder. Procedures which involve triggering of orgasm or including vibratory stimulation may precipitate an acute episode of autonomic dysreflexia.

If the user has spinal cord lesion and is above the T6 level the user should obtain careful instructions from your physician concerning autonomic dysreflexia, its potential consequences, and whether vibratory stimulation is acceptable form of treatment.

If the user is at risk of experiencing autonomic dysreflexia, it is recommended to use nifedipine (a calcium channel blocker), 10-20 mg, orally, 10-15 minutes before vibration is initiated and to stop vibration immediately at onset of ejaculation.

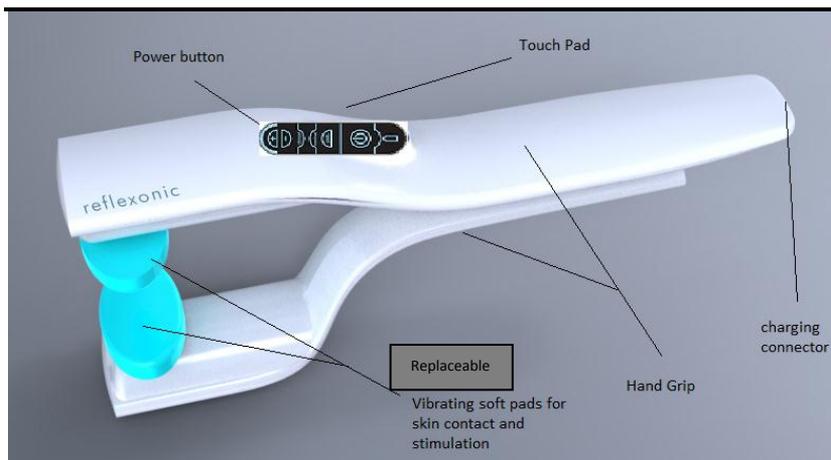
WARNING

If the user develops penile erection after use of the Viberec device that lasts for more than four hours, consult your physician or go the emergency room immediately, as the user may have developed **Priapism**, which is a medical emergency. Priapism is a medical condition in which poorly oxygenated red blood cells are entrapped in your penis. This requires urgent medical or surgical attention.

WARNING

Avoid Viberec use in temperatures exceeding 35 C° or 95° F.

VIBERECT® Penile Vibratory Stimulation Device Operating Instructions



Accessories and detachable parts

1. Soft Pads (A pair included) are detachable and replaceable. Soft Pads replacements order # 1680024W or #1680024BK, provided in pairs.
2. Battery Charger

(1) ON/OFF button on touch pad



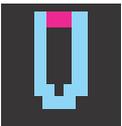
The device may be turned on and off by pressing the button on the touch pad. Hold the on/off button for 3 seconds to turn it off.

(2) FREQUENCY CONTROL



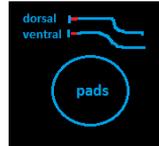
Pressing on the + or – buttons on the touch pad will increase the frequency from 70 Hz to maximum 110 Hz as desired. The LED lights will increase in increments of 5 Hz as visible with red LED lights which progressively turn on from right to left.

(3) CHARGING INDICATOR



Single red LED light indicates that the Viberect device requires charging. If no red LED light is visible, the device has adequate power for application. Charge the device. Keep the device laying on its side so the two arms are not brought together by gravity.

(4) Pad mode button and indicator



The device is capable of 3 modes of operation: 1. Vibrating only the top surface of the penis (Dorsal), 2. Vibrating only the bottom surface of the penis (Ventral), or 3. Both surfaces (recommended for maximal sexual response). The modes can be switched easily while the device is active by pressing on the pads button once, twice, or three times to the desired mode. The LED lights will indicate the modes.

(5) Charging Socket



The charging Socket is located in the back of the device

DIRECTIONS FOR USE

SPINAL CORD INJURED

CAUTION

If your lesion is above T6 spinal cord level, you must follow your physician's instructions carefully to prevent autonomic dysreflexia.

Autonomic dysreflexia is experienced as a sudden, pounding headache, and a rapid increase in the blood pressure due to excessive activation of the autonomic nervous system. If your spinal cord injury is above the T6 level; your body may have lost ability to automatically control the blood pressure.

It is recommended that at least two vibration procedures are performed in a clinical setting before using the Viberec at home.

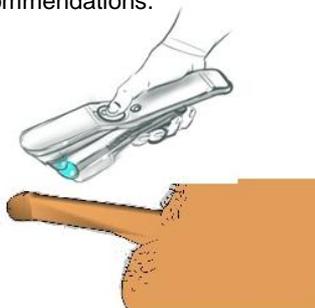
The following initial setting is recommended:

Frequency: 100 Hz
Amplitude: 2mm (constant)

Place yourself comfortably before turning on the **Viberec®** device

Follow the instructions as described in the next section, including pre-viberec stretch reflex exercises for 2-3 minutes before Viberec use.

Continue vibration until ejaculation occurs or for a maximum of 3 minutes followed by a pause of 1 minute. Speak to your physician for further setting recommendations.





Orientation of holding the device and the penis by the dominant hand

PRECAUTIONS

Do not perform penile vibratory stimulation more than once every 24 hours. In some cases, it is recommended to perform vibration once a week only in order to avoid “exhaustion” of the ejaculatory reflex.

Determine together with your physician how often vibration should be performed.

If the user has difficulties ejaculating at the recommended settings, the user may try another setting.

If the purpose of inducing ejaculation is to attempt to achieve pregnancy, the ejaculate should be collected in a non-spermicidal container, designed for sperm collection.

For the purpose of achieving penile erection, start with a low setting and advance to higher frequency for your comfort.

STEP BY STEP VIBERECT® OPERATING INSTRUCTION

For provoking penile erection

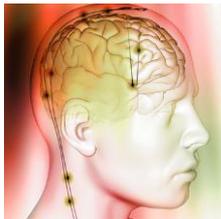
Approximate Stimulation time: 3-10 minutes

FOR OPTIMAL SEXUAL RESPONSE, IT IS IMPORTANT THAT YOU FOLLOW THESE IMPORTANT SUGGESTED OPERATING INSTRUCTIONS. IT MAY REQUIRE SEVERAL SESSIONS BEFORE YOU LEARN HOW TO PROPERLY USE YOUR VIBERECT DEVICE TO ACHIEVE OPTIMAL RESULTS.

Step 1: Choose a quiet, private, and dim room in your home. Your bedroom is an ideal location. Lie on your back with your knees flexed. Relax your pelvis.

Step 2: To get the best results, we recommend that you become as relaxed as possible, and think of sexual thoughts or memories, or perform Viberect as part of foreplay. **Remember, it is very difficult to obtain an erection if you are anxious, worried, and impatient. Do not focus on the use of the device. Focus on sexual thoughts.**

Remember:



Sexual Thoughts

+



Genital Nerve Stimulation

= Sexual Response

Step 3: Expose your penis, with your shorts down to prevent constriction of blood flow by your underwear. If you are uncircumcised, pull your foreskin to expose the head of your penis. The best position is lying down in the bed with your knees partially bent to relax your pelvic muscles.

Step 4: To prepare the penis for Vibratory stimulation, it is necessary to expose the nerve antennas that are located on the surface of your penis, especially on the head of your penis.



“Bulbocavernosus reflex”.

Now, perform the following exercise!

A. Using one or both of your hands, gently grab the head of your penis using your thumbs and index fingers. Only grab the head and not the ring (corona) of your penis.



A



B1



B2

B. Gently stretch your penis in the air until it reaches its normal limit as shown in image B1. Stretch and release without letting go of the head of the penis. After several repetitive stretch and releases every 2-3 seconds, you should feel your penis and pelvic muscles contracting very quickly and resisting your gentle pull for a tiny half a second after each pull. Never stretch your penis excessively, just enough to your normal length when you are erect.

STRETCH.....RELEASE.....STRETCH.....RELEASE....(B1-B2).

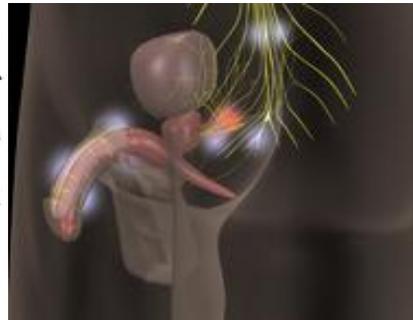
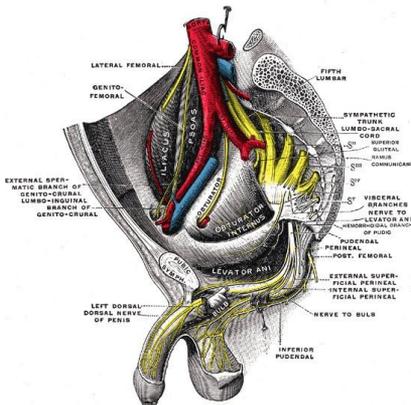
C. This “pull-back reaction” is a completely normal and painless body reflex. It is called the **Bulbocavernosus reflex**. As you gently stretch your penis to its limit, your penis quickly pulls back. This motion is caused by reflex contraction of many muscles in your pelvic area, including your rigidity muscles, anus, and urine control muscle (sphincter). You may need to repeat this exercise to fully learn this technique.

D. Once you learn this technique, you can gently pull the penis to its normal stretch and release to elicit this reflex repeatedly once every 2-3 seconds. This is not rubbing of the penis, but gentle pulling and releasing. Perform this technique for 2-3 minutes (2-3 seconds apart). Once you perform this exercise correctly, you can expect gradual engorgement of your penis, especially the head of your penis, and rigidity.

Step 5: Hold the device in your dominant hand, as demonstrated below: You may choose to use small amount of lotion or lubricant.



Step 6: Turn the device ON by pushing the touch pad power button. The device is ready, but no vibrations will occur until you bring the two bodies together with your hand grip.



Step 7: Keep your penis gently stretched by the device while stimulating. Apply pressure on both arms by closing your fingers. The device will activate.



Step 8: Bring the vibrating pads in contact with the surface of your **stretched** penis on both sides. Focus on the head of the penis. Keep your penis gently stretched. The Viberec device will now stimulate your penis. You can increase the pressure and sensation by putting your hand and grip closer to the vibrating end of the device, and even pushing more with your free hand pushing of the vibrating end. You should find a "sweet spot" on your penis, where sensations are the strongest. Apply the Viberec on the sweet spot. Note: The user should never force the device together excessively, as this can damage the device or your penis.

Step 9: As you stimulate the surface of the penis, you may choose to increase the intensity of stimulation by pushing the frequency adjustment buttons with your thumb that is holding the upper housing. Begin with the lowest frequency. You may also change the mode to A: Upper only B: Lower only and C: Both.

Step 10: If sensations are too intense or you wish to stop the device immediately, you can easily relax your grip and the device will immediately stop. You can decrease the intensity of stimulation by lowering the frequency as well.

Step 11: Continue stimulating your shaft and head of the penis. **Focus mostly on the head of the penis.** If you feel an area that is especially sensitive, then hold the device there for about 3-10 minutes depending on your body and the situation. **It is important for you to relax completely and focus on thoughts of sexual nature. Sexual reflexes and pathways won't work in a non-relaxed setting.** The process takes several minutes and is NOT immediate! You may feel your penis slowly filling with blood and becoming more firm. The device will open easily and gradually to accommodate the enlarging penis.

Step 12: You can easily deactivate the device by either turning the device off, or just letting go of your hand and releasing the pressure. Push the power button for 3 seconds, and the device will turn off.

Once you reach optimal rigidity, release your grip, and set the device away. You may begin sexual intercourse if your rigidity is satisfactory.

Note: Not all men may respond to the Viberec stimulation in the beginning. It may take several sessions until you become comfortable with the operation of the device.

For men using the device for purpose of rehabilitation, we recommend daily use of the device for 7-10 minutes in a sexual setting to enhance recovery of sexual response.

CLEANING

To ensure that your **Vibrect®** device is always ready for use, it is recommended to clean both vibrating pads and the entire surface, and to recharge the battery after each use.

Personal Use

Wipe the outside of the vibrator with a dry or alcohol-dampened cloth. Do not immerse the vibrator in any type of fluid.

It is important to wipe off any lotion or moisture off the pads and body of the device after each use with a clean dry cloth and to wipe them with alcohol pads.

Clinical Use

Personnel cleaning the device must always wear non-latex gloves for personal protection. The device must be cleaned immediately after each use.

Pull both touch pads and discard them. Place new pads after each use by a different person.

Clean the device thoroughly with a cloth dampened with soapy water followed by cleaning with rubbing alcohol pads.

Removal and Replacement of Vibrect® Pads

If the pads start showing any signs of wear and/or degradation, replace them immediately. Specifically, ① check the surface of the pad over-mold for any signs of wear/degradation and replace if needed; and ② check the integrity of the pad-pad over-mold assembly. Simply pull each pad, in the direction directly away from the body of the device (see image). Place new pads by easily snapping them into the pad attachment. Make sure device is in the OFF position when replacing the pads. Dispose old pads in a closed trash container.



Direction of pull to
remove touch pads

Touch Pads or Pad
Over-Molds



Additional pads can be purchased from www.reflexonic.com

Contact Information:

Customer Service:

Customerservice@reflexonic.com (recommended & most efficient method)
Tel: 001.717.267.1155 9:00 am – 4:30 pm, M-F US-Eastern time
Toll-Free Fax: 800.886.1470 and 717.267.0364

Reflexonic LLC

Innovative Urological Solutions
5504 Skye Avenue
Chambersburg, PA 17202

VIBERECT® PENILE VIBRATORY STIMULATION SYSTEM PRODUCT SPECIFICATIONS

Power Supply: (For E.U. Region).....SL Power (AULT) MENB1010A0903F01
with country specific wall plugs

Frequency range (with fully charged battery)..... 70 - 110 Hz

Amplitude (peak to peak)..... 2.0 mm

BatteryNi-MH, rechargeable 4 AA

Temperature.....Avoid Viberec use in temperatures exceeding 35° C or 95°F

Storage.....ambient temperature 68-77°F (20-25° C)

Transport temperature between 0°F to 100°F (-17° C to 37° C) and a relative
humidity of max 85 %)

Symbols Table

Symbol	Meaning
	Batch Code
	Catalogue Number
	Consult Instructions for Use
	Type B applied part. " Device provides protection against electrical shock"
	Do not discard device improperly (see page 4)

Symbol	Meaning
	Caution
	Do Not Use if Package is damaged
	Manufacturer and Date of Manufacture
	Fragile