
TRANSCUTANEOUS MECHANICAL NERVE STIMULATOR (TMNS)

User's Guide

TMNS is a therapeutic genital vibrator to treat sexual dysfunction or as adjunct to Kegel's exercise device. (Tightening of the muscles of the pelvic floor to increase muscle tone)

CAUTION: Federal law restricts this device to sale by or on the order of physician.

Distributed by:

Orion Medical Group, Inc.
29072 Silverado Canyon Rd.,
Silverado, CA 92676-0717
Phone: 714 649 9284
Fax: 714 649 9866
Email: info@medicalvibrator.com
www.medicalvibrator.com

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INTRODUCTION

Transcutaneous Mechanical Nerve Stimulation is a therapeutic genital vibrator to treat sexual dysfunction or as adjunct to Kegel's exercise (tightening of the muscle's of the pelvic floor to increase muscle tone) in women suffering with Urinary Stress Incontinence.

Clitoral or Perennial vibratory stimulation to induce pelvic floor contractions, non-invasive, drug free procedure which may take place both in the clinical and home setting.

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

CAUTION:

Statements marked in this way provide instructions which must 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 TMNS 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 repair or replacement, at its option, of a defective product. Manufacturer shall not be liable for any incidental or consequential damages whether direct or indirect.

MARKINGS



It is important that the user refers to the cautions and warnings on this guide.



Type B. Description: Body. Electrical safety classification.



Temperature limitations. Please refer to the specific section.



Relative Humidity.

OVERLOAD

Pressure indicator.

FREQUENCY Hz

Vibration Speed.

AMPLITUDE mm

Vibration Strength.

GENITILE VIBRATOR

Intended use.

ON OFF O

ON/OFF switch.

CHARGE

Recharge.

PINXXXX

Production indication.

Manufactured by:

Manufacturer.

BATTERY

The battery in your TMNS vibrator has not been charged prior to delivery. The battery must be charged with the enclosed charger for 14 hours before use. However, the battery may require 2-3 charging and discharging before it reaches its full capacity as specified. To ensure that your TMNS is always ready for use, it is recommended to recharge the battery after use.

A fully charged battery will allow 20 minutes of vibration capacity at an amplitude of 2.5 mm and a frequency of 100Hz. When completely discharged, allow 14 hours to recharge. Ensure that the vibrator is turned off before recharging. Use only the charger supplied with the vibrator. **DO NOT ATTEMPT** to use the device during the recharging.

To ensure the optimum lifetime of the battery, it is recommended to completely discharge and recharge the battery again once every second month.

Disposal of the battery

The rechargeable battery in the vibrator contains nickel and cadmium. Like other batteries of this type, if burned or punctured, it could release toxic material which could cause injury. The battery cannot be removed from the vibrator. Do not dispose the battery in household garbage. For information about recycling or proper disposal, consult your local solid waste (garbage) collection or disposal organization.

PRECAUTIONS FOR SAFE USE

WARNING

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

Vibratory stimulation may cause a 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 any type of fluid. Do not operate the vibrator in bathrooms or elsewhere under wet conditions.

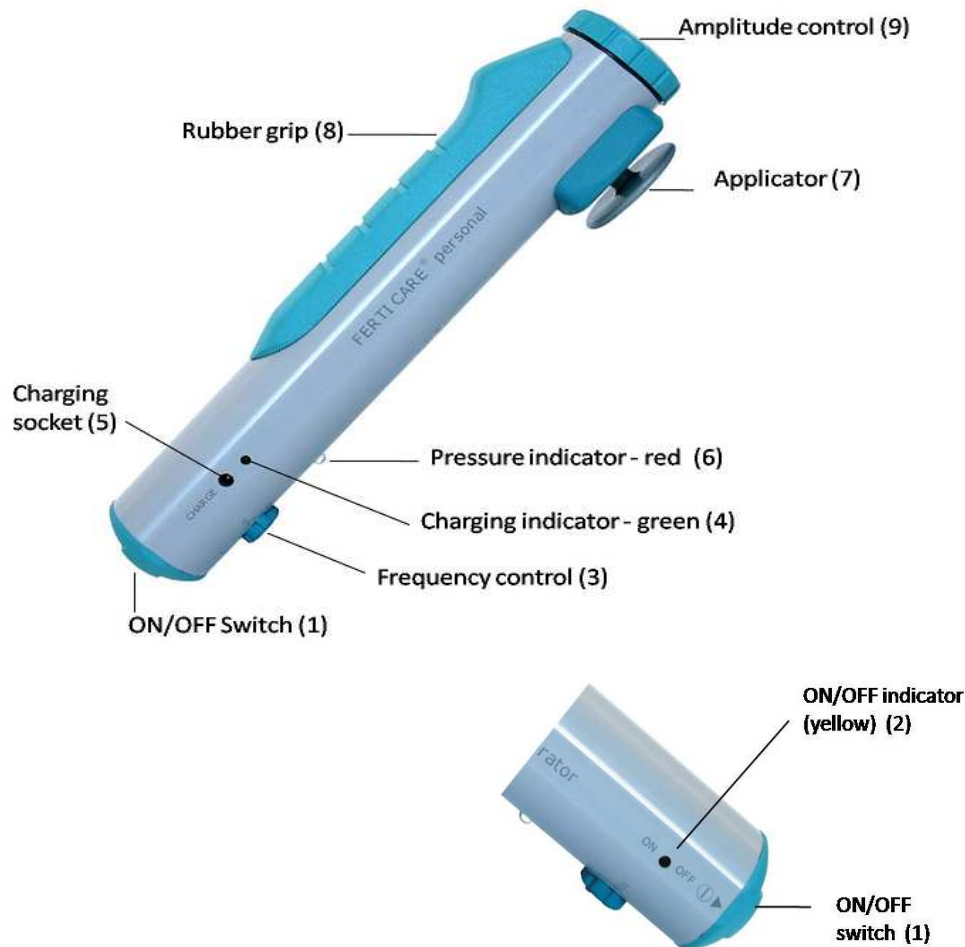
If the user is spinal cord injured an episode of autonomic dysreflexia may develop as a result of vibratory stimulation. If so, vibration should be stopped immediately. Consult your physician.

Spinal Cord Injured men/women may have lost the ability to control the blood pressure and you may be at risk of experiencing episodes of autonomic dysreflexia. The condition 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 you have spinal cord lesion and is above the T6 level you should obtain careful instructions from your physician concerning autonomic dysreflexia, its potential consequences, and treatment in response to symptoms as well as prophylactic ally prior to initiating vibratory stimulation.

If you are 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 climax.

Transcutaneous Mechanical Nerve Stimulation



OPERATING INSTRUCTIONS

- **ON/OFF switch.** The device may be turned on and off by pressing the switch
- **ON/OFF INDICATOR.** When the vibrator is on the ON position, the yellow light appears.
- **FREQUENCY CONTROL.** The frequency may be sent at any value between 70 and 100 Hz.
- **CHARGING SOCKET.** The battery charger is connected for recharging at this port.
- **CHARGE INDICATOR.** When recharging the battery, the green light is on- either constantly or it flashes.
- **PRESSURE INDICATOR.** The red light marked *overload* is present to appear when specific pressure is applied and indicates that excessive pressure is applied.
- **APPLICATOR.** To be applied to the frenulum of the penis to provide the vibration activity.
- **RUBBER GRIP.** Helps you get a firm grip on the vibrator.
- **AMPLITUDE CONTROL.** The amplitude may be set at any value between .5 and 3.5mm.

DIRECTIONS FOR USE TO TREAT URINARY STRESS INCONTINENCE FOR WOMEN

TMNS or Transcutaneous Mechanical Nerve Stimulator can be used in two different ways.

Method 1

The following initial setting is recommended for stress incontinence:

Frequency: 100 Hz
Amplitude: 2.0mm

Place yourself in a comfortable position before turning on TMNS.

Place the vibrating disc (35mm centimeters) at the perineum area (between the vagina and anus) for 10 seconds followed by a pause of 10 seconds with this pattern repeated for a total of 10 cycles per session. TMNS should be performed at least once a week along with the standard pelvic floor muscle contractions.

To obtain the recommended pressure, when vibrating at 100Hz at 2.5mm of amp, apply pressure until the red overload light appears. Then release the pressure only until the red light turns off.

If you continue to apply more pressure than recommended, to obtain the desired result, the overload light will remain **on** and vibration output will decrease to less than the chosen setting. If increase pressure is applied ultimately, vibration will stop.

Method 2

The following initial setting is recommended for treatment of stress incontinence:

Frequency: 100 Hz
Amplitude: 2.0

Place yourself in a comfortable position before turning on TMNS.

Place the vibrating disc on the clitoris for 10 seconds, followed by a pause of 10 seconds with this pattern repeated for a total of 10 cycles per session. TMNS should be performed at least once a week along with standard pelvic floor muscle contractions daily.

Method 3

The following initial setting is recommended for treatment of stress incontinence:

Frequency: 100 Hz
Amplitude: Start at .5m and increase .5m after each 10 seconds repetition.

If you feel the first 2 recommended settings are too aggressive. Start with the amplitude control at .5-1.0 and follow instructions below:

Place yourself in a comfortable position before turning on TMNS. Place the center of the vibrating disc (35mm diameter) on the clitoris for 10 seconds, followed by a pause of 10 seconds, then place on the perineum for 10 seconds. This stimulation pattern should be repeated after 2 minute rest periods with progressively increasing vibratory amplitude (1.0-1.5-2.0-2.5-3.0). To obtain the recommended pleasure when vibrating at 100 Hz at 2.5mm amplitude, apply pressure until red overload light appears. Then release until the red light turns off. If you continue to apply more pressure than recommended, to obtain desired result, the overload light will remain **on** and vibration output will decrease to lessen the chosen setting. If increase pressure is applied, ultimately, vibration will stop.

DIRECTIONS FOR USE TO TREAT VAGINAL DRYNESS AND ORGASMIC DYSFUNCTION

The initial setting is recommended to treat vaginal dryness and orgasmic dysfunction:

Frequency: 100 Hz
Amplitude: .5- 2.5Hz

Place yourself in a comfortable position before turning on TMNS.
Place the vibrating disc on the clitoris or the perennial area for 1-5 minutes or until desired result is reached. TMNS can also be use before, during and after the intercourse.

In clinical studies, 7 out of 12 women were able to reach ejaculatory orgasm using TMNS. And over 95% of women with these conditions are completely cured of symptoms.

TMNS can be used prior to intercourse to treat vaginal dryness and during intercourse to increase your level of climax.

Full Clinical study and instructional video is available at www.medicalvibrator.com soon.

CLEANING

To ensure that you TMNS is always ready for use, it is recommended to clean the applicator and to recharge the battery after each use.

Personal Use

To clean device, unscrew the detachable applicator from the vibrator and wash it in warm, soapy water.

You may wipe the outside of the vibrator with a dry or alcohol-dampened cloth.

Do not immerse the vibrator in any type of fluid.

Clinical Use

Personnel cleaning the device must always wear latex gloves for personal protection.

The device must be cleaned immediately after each use.

Unscrew the applicator and wash it in warm, soapy water.

Immerse the applicator in 80% ethanol for 10 minutes. Clean the device thoroughly with a cloth dampened with soapy water followed by cleaning with a cloth damped with 80% ethanol.

PRODUCT SPECIFICATIONS

(with fully charged battery)

Frequency range.....	70 - 110 Hz
Amplitude range (peak to peak).....	0.5 - 3.5mm
Battery capacity (at 100 Hz and 2.5 mm).....	Min. 20 minutes
Battery.....	Ni-Cd, rechargeable, 6/1.2V/0.35Ah
Charger, mains voltage.....	110 - 220 volt

Use of this device should take place at:

temperatures between	+50°F +104°F (10°C + 40°C)
a relative humidity of	max 85 %

Transport and store this device at:

temperatures between	-13°F+158°F (-25°C--+70°C)
a relative humidity of	max 85 %