



Athena Pelvic Muscle Trainer™

PHYSICIAN INSTRUCTIONS FOR USE



CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician

Athena Pelvic Muscle Trainer™

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INTRODUCTION

The Athena Pelvic Muscle Trainer™ (PMT) is a vaginal myostimulator that induces the pelvic muscles to contract and relax, similar to Kegel exercises. The system consists of a vaginal trainer (PMT trainer) with a sealed battery and a wireless controller to adjust the strength of the contractions while the PMT trainer is in use. The PMT trainer is housed in a cradle in the wireless controller. It is necessary for the patient to return the PMT trainer to the cradle in the wireless controller after each use in order for the system to function correctly.

Studies of other devices over the past 20 years have shown that pelvic floor myostimulation and neuromuscular reeducation can be up to 60% to 90 % effective in reducing or eliminating urinary incontinence. This manual provides an overview of pelvic floor stimulation and complete use instructions for the Athena Pelvic Muscle Trainer (PMT).

Pelvic Floor Stimulation is a treatment for incontinence.

Pelvic floor stimulation is a simple, low-risk treatment for incontinence resulting from lax pelvic floor muscles or a hyperactive bladder. An electrical current activates sensory nerve fibers that can facilitate or inhibit a sensory-motor response.

When used consistently, pelvic floor myostimulation has been clinically documented to have the following prolonged therapeutic effects:

1. Strengthening of the pelvic floor muscles.
2. Inhibiting the detrusor muscle through reflexive mechanisms.

For best results, the Athena Pelvic Muscle Trainer™ should be used twice a day. Other regimes may be appropriate for some patients.

PRODUCT DESCRIPTION

The Athena Pelvic Muscle Trainer™ (PMT) is an intravaginal pelvic floor exerciser that provides myostimulation and neuromuscular reeducation for the purpose of rehabilitation of weak pelvic floor muscles to aid in the control of urinary incontinence (UI) in women. This is a single-user device and should be used by one patient only.

Description of the Pelvic Muscle Trainer

- The Athena Pelvic Muscle Trainer™ is an intravaginal exerciser constructed of medical-grade plastic, and has one electrode pair.
- The trainer is not tethered and is controlled through a radio frequency (RF) signal from the wireless controller.
- The electrodes are designed to deliver current to stimulate the pelvic floor muscles to perform Kegel-like contractions.
- The exerciser is reusable and ergonomically designed.

The Athena Pelvic Muscle Trainer has two parts:

1. **Wireless Remote Control with PMT trainer storage cradle**
2. **PMT Trainer**



4.

Federal Communications Commission (FCC) Compliance Notices:

Pelvic Muscle Trainer (Wireless Control Unit)

FCC ID: RML E03946001

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Warning - Any changes or modifications not expressly approved by the party responsible for compliance (i.e. Athena Feminine Technologies) could void the user's authority to operate this equipment.

This unit was authorized under the FCC Certification Procedure

Pelvic Muscle Trainer (Trainer Unit)



Athena Feminine Technologies
ATHENA-PMT-II

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Warning - Any changes or modifications not expressly approved by the party responsible for compliance (i.e. Athena Feminine Technologies) could void the user's authority to operate this equipment.

This unit was authorized under the FCC Declaration of Conformity Procedure.

Responsible Party:

Athena Feminine Technologies
179 Moraga Way
Orinda, CA 94563
(925) 254-2121

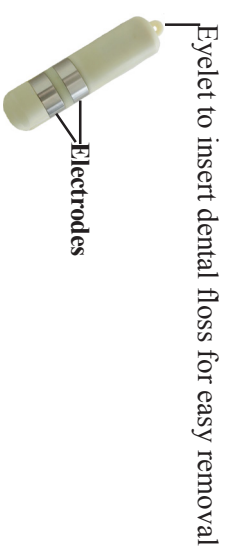


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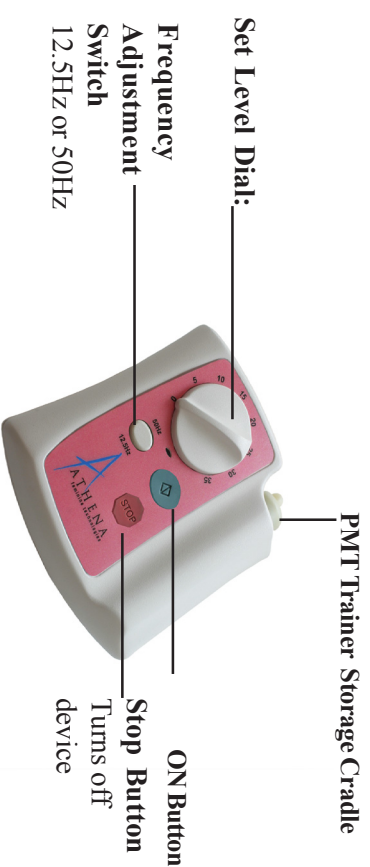
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PMT Trainer



Wireless Controller



CLINICAL INFORMATION

Indications for Use

The Athena Pelvic Muscle Trainer is intended to provide electrical stimulation and neuromuscular reeducation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in women.

Contraindications

- This therapy is not appropriate if a patient:
- has a neurological deficiency that does not permit proper sensory perception or stimulation.
 - is currently pregnant or attempting to get pregnant.
 - has a cardiac pacemaker or a history of heart rate or conductive disturbance.
 - has an anatomical vaginal structure that does not permit proper and complete placement of the trainer.
 - has irregular menstrual cycles.
 - has urinary or vaginal infections, localized lesions, or other undiagnosed symptoms.
 - has a history or symptoms of urinary retention.

Warnings

Review the following warnings with your patient:

- Do not use in water or while bathing.
- Keep out of the reach of children.
- Do not use simultaneously with high-frequency hospital equipment (e.g. diathermy equipment). It may result in burns at the site of the electrodes and possible damage to the trainer.

6.

WARRANTY AND DISCLAIMER

Athena Feminine Technologies warrants the Athena Pelvic Muscle Trainer for a period of one year from the date of purchase to be free from defects in workmanship and material and in material compliance with all published product specifications in effect on the date of shipment. During the warranty period, Athena Feminine Technologies shall, at its option, replace any products shown to Athena Feminine Technologies to be defective at no expense to the purchaser. The foregoing remedies shall be the purchaser's sole and exclusive remedies under this warranty.

Batteries

The Athena PMT Trainer contains a sealed battery compartment for your safety. The battery has a life of about two years. When it needs a replacement mail the PMTTrainer to:

BATTERY REPLACEMENT
Athena Feminine Technologies
179 Moraga Way
Orinda, CA 94563

The Athena PMT Wireless Controller runs on four AAA batteries. To replace the batteries loosen the small screw on the back of remote, remove the cover and replace the batteries.

Contact Athena Customer Support at 1-866-308-4436 or visit us online at www.athenaft.com

In the event the purchaser makes any modifications or alterations to the product, the foregoing warranties shall be void and of no future force or effect.

15.

PRODUCT SPECIFICATIONS

Specifications

Complies with IEC-601-1

Mode of Operations: Intermittent

Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or oxygen or nitrous oxide.

IPX7 rating (protected from dust and liquid ingress)



ATTENTION



TYPE BF EQUIPMENT



NON-IONIZED RADIATION

Electrical Properties

Output Current: 0-70mA

Pulse Width: 200µs at 1%

Frequency: 12.5Hz and 50 Hz

Power Source: PMT trainer: One- 3.6 volt lithium battery

Wireless controller: Four- AAA batteries

Output Type: Constant voltage over range of 100 to 1000 Ohms

Output Isolation:>100 meg Ohms

Transportation and Storage

Ambient temperature range: -40 degrees C to 70 degrees C.

(-40 degrees F to 158 degrees F)

Relative Humidity range: 10% to 100% including condensation

Atmospheric pressure range: 500hPa to 1060hPa. (7.25 PSI to

15.36 PSI)

Environmental

Please dispose of according to local regulatory standards in your area.

DIRECTIONS FOR USE

Precautions

Review the following precautions with your patient:

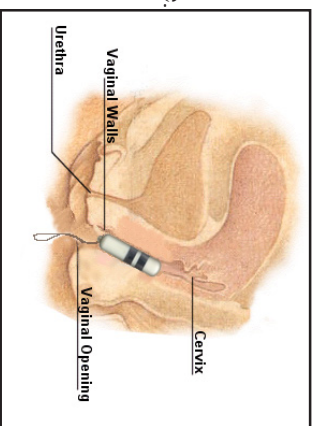
1. The PMT trainer should not remain inserted when the unit is not in use.
2. The PMT should not be used while patient:
 - is sleeping.
 - has anything else in her vagina such as a tampon, diaphragm or is engaging in sexual intercourse.
 - is engaging in any activity that could place the PMT in contact with water (e.g. swimming, bathing).
 - is driving a motor vehicle.
 - is having her menstrual period.
3. The patient should discontinue treatments and contact physician if patient:
 - feels any pain .
 - notices abnormal vaginal discharge, irritation to the tissues, or vaginal bleeding not associated with the usual menstrual cycle.
 - experiences burning when she urinate or other symptoms associated with a urinary infection.
 - develops any lesions on her perineum .

For Best Results

For best results, the patient should use the PMT twice a day during the treatment period. If this is not possible, the stimulation can still be effective, but improvement may take longer.

Initial Fitting and Treatment

1. Instruct the patient to clean the exerciser per “Cleaning the PMT” instructions (page 13) prior to initial placement.
2. The patient should be placed in standard lithotomy position.
3. If the patient does not have sufficient lubrication of her own, apply water or a water-based lubricant such as K-Y Jelly to the PMT trainer. Do not use a petroleum-based product as it will have a deleterious effect on the exerciser and will limit the flow of stimulating current.
4. Remove the PMT trainer from the cradle and show the patient how to thread a piece of dental floss through the eyelet in the PMT trainer. The patient should tie the floss to create a loop. This will allow for easy removal.
5. Instruct the patient to set switch to either 12.5Hz (urge) or 50 Hz (stress) incontinence. (For mixed incontinence, vary the level by session)
6. SHOW THE PATIENT HOW TO PLACE THE UNIT BACK INTO THE CRADLE. The PMT trainer is controlled through a magnet in the cradle. Putting it back into the cradle will set the unit to the start position.



CLEANING THE PMT

Review the cleaning instructions with the patient:

1. Wash the PMT trainer prior to initial use and after every use. Use water and a mild soap. Soap that is free of deodorants, fragrance and dyes is recommended. *Do not immerse in water.*
2. The PMT trainer can be air-dried or wiped off with a lint-free cloth.
3. Be sure that the PMT trainer is clean and dry before replacing in the cradle.
4. Should the PMT trainer develop an odor, wear out, or become discolored, it should be replaced.

Notes on Use

- The Athena PMT is most effective when used twice every day.
- If the contractions seem to stop during a session, the patient should gently use her fingertip to reposition the PMT trainer.

Assessing Success

To assess treatment success, we recommend that the patient keep a one week voiding diary prior to treatment and immediately following treatment. We also recommend a follow-up visit at week two of treatment to verify compliance and to address any concerns. You may wish to have the patient complete a voiding diary midway through treatment and evaluate progress with a patient visit between weeks six and eight of treatment.

Achieving Success

It is important to establish goals and guidelines for determining success with the patient. Frequently a patient's perception of success does not correlate with objective findings. By setting reasonable and mutually agreeable goals for "significant improvement," you will establish an acceptable measure for success.

When used for the recommended twice-daily, 15-minute sessions, typically most patients suffering from urge incontinence will see improvement in three to four weeks. Patients with stress incontinence, or incontinence associated with sphincter weakness, usually see significant improvement in six to eight weeks. A standard treatment program for pelvic floor stimulation is 12 to 14 weeks.

If the problem is not resolved in the treatment period and the patient continues to show improvement, continue the therapy twice a day until there is no further improvement.

It is recommended that patients continue to use the Athena PMT on a periodic basis even after the goal is reached. This will ensure that the pelvic muscles stay strong and will help to eliminate any further problems.

7. Remove the PMT trainer from the cradle. Insert the PMT trainer into the patient's vagina until it meets resistance from the cervix or cul-de-sac. Make sure the dial is initially set to 0.
8. When the correct position is reached, press the ON button to start the session. Slowly rotate the dial to increase the strength of the stimulation until it is comfortable for the patient. Future sessions will automatically go to the setting last used by the patient.

9. The patient should be asked to contract her pelvic muscles tightly in order to prevent the PMT trainer from being easily removed from the vagina. Concurrently, you should request the patient to place her finger(s) on the end tip of the PMT trainer and gently move or rotate until she feels a muscle contraction. In most cases, she will feel a slight pushing forward on the PMT trainer. If no contraction is felt and the exerciser is easily dislocated, perform a pelvic exam in order to locate the appropriate muscles; once identified, position the exerciser.
10. If the patient has difficulty holding the exerciser within the vagina, treatment should be prescribed for a supine position.
11. Have the patient practice inserting the PMT trainer on her own to make sure she does it correctly.

Note: The stimulation should always be at a comfortable level. If the patient expresses discomfort, turn the intensity down slightly until comfortable. It is not necessary or beneficial to stimulate at levels higher than those determined above.

INITIAL TREATMENT CHECKLIST

1. Show patient how to clean PMT trainer.
2. Show patient how to insert floss for PMT trainer removal string.
3. Set the controller to either 12.5Hz or 50Hz and the dial to 0. Return the PMT trainer to cradle.
4. Have the patient lie down.
5. If needed, use vaginal lubricant to allow for easier insertion.
6. Remove the PMTTrainer from the cradle and insert it into the vagina.
7. When the PMT trainer is in the right position, push the ON button and the session will begin.
8. Slowly increase the intensity dial until the patient feels a comfortable sensation. Once the level is set it will automatically increase to that level in future sessions. Therefore, the patient will not have to set the level each time it is used.
9. The PMT will begin to stimulate with an on/off cycle of 2.5 seconds on and 2.5 seconds off, thus inducing pelvic muscle contractions.
10. If necessary, further adjust the level to meet the patient's needs. More sensitive patients may need a lower setting. Older patients may require a much higher setting.
11. The Athena PMTTrainer will automatically shut off after 15 minutes of use. If a shorter treatment is desired, the PMT may be turned off at any time by pressing the STOP button on the wireless controller.
12. Remove the PMT trainer. Clean as per the "Cleaning the Athena PMT™" instructions (page 13).
13. After the PMT trainer is dry, store the probe in the storage cradle on the wireless controller.

10.

RECOMMENDED TREATMENT PROTOCOL

You may prefer to prescribe the use of 12.5 Hz for patients with urge incontinence, as some studies support the use of lower frequency for optimal inhibition of bladder contractions. Similarly, you may prefer to prescribe 50 Hz for patients with pure stress incontinence. Patients with mixed incontinence can alternate between the two channels from session to session. (For example, 12.5 Hz in the morning and 50 Hz in the evening.)

To receive maximum benefits, most patients should use the Athena PMT for 15 minutes, twice a day. Regular use of the PMT is necessary for improvement to occur. Encourage the patient to take an active part in the treatment and to try to be as consistent as possible in use.

When used consistently, patients with urge incontinence should show improvement in three to four weeks. Those with stress incontinence should show improvement in 12 to 14 weeks.

The following chart is also provided in the patient instructions. It may help the patient towards the consistency needed for improvement. There are spaces on the patient's page to write the goal of treatment, as well as any special instructions that you might have.

	Sun	Mon	Tues	Wed	Thurs	Fri	Sat
Example	✓	✓	✓	✓	✓	✓	✓
Week 1			✓				
Week 2							
Week 3							
Week 4							
Week 5							
Week 6							
Week 7							
Week 8							
Week 9							
Week 10							
Week 11							
Week 12							
Week 13							
Week 14							

✓ Done
 / Missed

P Menstrual Cycle

11.