



Athena Pelvic Muscle Trainer™

PATIENT 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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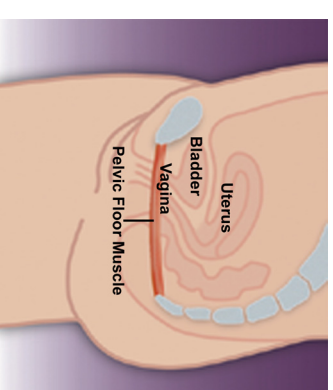
INTRODUCTION

The Athena Pelvic Muscle Trainer™ (PMT) is a mild electrical vaginal stimulator that treats urinary incontinence in females. It has been shown to be effective in strengthening the pelvic muscles that can control incontinence. This is a single-user device and should not be shared.

This manual discusses how the Athena PMT treats incontinence, shows you the parts of the PMT, and explains how to use and care for your new Athena PMT.

Why Incontinence Occurs

Incontinence can occur for many reasons. One of the most common causes is the weakening of the pelvic muscle. The pelvic muscle is like a hammock that holds up the bladder and other organs.



When this muscle is weak it may not hold up the bladder correctly and may allow urine to leak. Strengthening the pelvic muscle can often help control incontinence.

Pelvic Muscle Stimulation

Many studies have shown that one way to strengthen weakened muscles is to apply mild myostimulation to them. This causes the muscles to contract, making them stronger in the same way physical exercise does.

Contracting the muscles in the floor of the pelvis voluntarily is called the Kegel exercise. The Athena PMT causes the pelvic floor muscles to contract, similar to the way they are contracted when doing the Kegel exercise. The difference between the two is that the Athena PMT causes the muscles to contract for you, by applying gentle myostimulation to them. You can then lie back and exercise with little voluntary effort.

Studies of other devices during the last 20 years have shown that intra-vaginal myostimulation of weakened muscles in the pelvic floor can lead to control of the most common forms of incontinence in females up to 60% to 90% of the time. Because of its effectiveness and lack of side effects, intravaginal myostimulation is an ideal first choice of treatment for urinary incontinence in women.

What will the stimulation feel like?

The stimulation will feel like a gentle pulsating contraction of the muscles. It may feel like a flutter at lower settings. Each time you use the Athena PMT you should try to use it at a high enough intensity to feel contractions. As your muscles get stronger you may want to gradually increase the intensity so that you use the strongest stimulation that is comfortable for you. NEVER turn it up to an intensity that is uncomfortable or painful.

Federal Communications Commission (FCC) Compliance Notices:

Pelvic Muscle Trainer (Wireless Control Unit)

FCCID: 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)



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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Indications for Use

The Athena Pelvic Muscle Trainer is intended to provide myostimulation 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.

This therapy may be appropriate if you:

- experience incontinence due to weak pelvic floor muscles.
- are willing to comply with the therapy program on a consistent basis.
- understand how to use the Athena PMT as described in this instruction booklet.
- are generally in good health.

Contraindications (When you should not use the device)

This therapy is not appropriate if you:

- have a neurological deficiency that does not permit proper sensory perception or stimulation (have areas of numbness that might interfere with your feeling the stimulation).
- are currently pregnant or attempting to get pregnant.
- have a cardiac pacemaker or a history of heart rate or conductive disturbance.
- have irregular menstrual cycles.
- have urinary or vaginal infections.
- have a history of urinary retention, or current symptoms.

Your physician will determine if this device is appropriate for your use.

ATHENA Pelvic Muscle Trainer™ (PMT)

PRODUCT DESCRIPTION

The Athena Pelvic Muscle Trainer™ (PMT) is an intravaginal pelvic floor exerciser that strengthens the pelvic muscles to aid in the control of urinary incontinence (UI) in women. This is a single-user device and should be used by one person 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 probe is not tethered and is controlled through a radio frequency (RF) signal from the wireless controller.
- The electrodes are designed to deliver myostimulation to the pelvic floor muscles to induce Kegel-like contractions.
- The exerciser is only reusable by a single person and is ergonomically designed.

The Athena Pelvic Muscle Trainer has two parts:

1. **Wireless Controller with PMT trainer storage cradle**
2. **PMT Trainer**



6.

ATHENA Pelvic Muscle Trainer™ (PMT)

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 PMT Trainer 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 at our website www.athenaf.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.

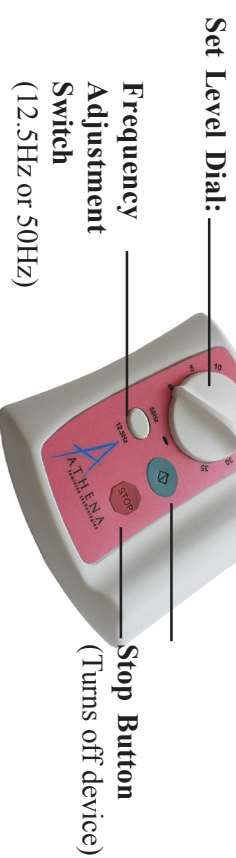
PMT Trainer

Eyelet to insert dental floss for easy removal



Wireless Controller

PMT Trainer Storage Cradle



Warnings

- 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.

INSTRUCTIONS FOR USE

Initial Treatment

The initial treatment with the Athena PMT will be done under medical supervision. You will then be sent home to use the Athena PMT on your own for a period of two to 14 weeks. It is very important that you follow the instructions as directed by your physician. Much like medication, if you don't do the treatments, you will not experience improvement.

If you miss one or two treatments don't be alarmed. But if you miss several in a row, call the physician or clinic for a possible revision in your treatment regimen. They will review how far you have progressed in your treatment regimen and whether there have been any changes in your bladder activity to determine what would be best for you.

Note: Using the Athena PMT every day, as directed, is like doing exercise on a regular basis. It will produce the best and most rapid results.

Note: The stimulation should always be at a comfortable level. If you feel any discomfort, turn the intensity down slightly until comfortable. It is not necessary or beneficial to stimulate at levels higher than are comfortable.

RECOMMENDED TREATMENT PROTOCOL

Achieving Success

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

When used for the recommended 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 you continue to show improvement, your physician may recommend that you continue the therapy until there is no further improvement.

Assessing Success

To assess treatment success, you might keep a one week voiding diary prior to treatment and immediately following treatment. You might also want to make milestones on your chart, i.e. fewer pads used, dry day, etc.

Continuing Success

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

PATIENT DIARY/LOG

To receive maximum benefits you should use the Athena PMT as prescribed by your physician. Regular use of the PMT is necessary for improvement to occur. Take an active part in the treatment and try to be as consistent as possible.

	Sun	Mon	Tues	Wed	Thurs	Fri	Sat
Example	✓	✓	✓	✓	✓	P	P
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 Menstral Cycle

Overview of PMT Use

- The Athena PMT is inserted into the vagina for 15-minute sessions. It is best used when lying down or in a reclining chair.
- The device starts to work when you press the ON button.
- It will automatically adjust to the level of your previous session.
- If you want to lessen or strengthen the contractions, use the dial on the PMT wireless controller to adjust the strength as appropriate.
- The PMT will automatically turn off after a 15-minute session.
- If you need to take the PMT trainer out before the end of the session, use the STOP button. Then remove the PMT trainer.
- Wash the PMT trainer with warm water and soap, then dry.
- Return the PMT trainer to its spot in the controller cradle.
- **THE PMT TRAINER MUST BE RETURNED TO THE CRADLE TO FUNCTION PROPERLY.**
- To increase the effectiveness of the contractions, physically contract your pelvic muscles when you feel the PMT trainer contraction.

Precautions

The PMT trainer should not remain inserted when the unit is not in use.

The PMT should not be used while you:

- are sleeping.
- have anything else in your vagina such as a tampon, diaphragm or are engaging in sexual intercourse.
- are engaging in any activity that could place the PMT in contact with water e.g. swimming, bathing
- are driving a motor vehicle.
- are having your menstrual period.

Discontinue treatments and contact your physician if you:

- feel any pain.
- notice abnormal vaginal discharge, irritation to the tissues, or vaginal bleeding not associated with your usual menstrual cycle
- experience burning when you urinate or other symptoms associated with a urinary infection.
- develop any lesions on your perineum (any bumps or sores appear around the area where you insert the Athena PMT).

CLEANING THE PMT

1. Wash the PMT trainer prior to initial use and after every use. Use a mild water and 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.
10.

DIRECTIONS FOR HOME USE

- ◆ Remove the PMT trainer from the cradle and thread a piece of dental floss through the eyelet. Tie floss together to form a loop. This loop allows for easy removal.
- ◆ Place the PMT trainer back into the cradle (this is important for proper PMT functioning).
- ◆ Empty your bladder before beginning a session.
- ◆ Find a comfortable place to lie or recline for the 15-minute session.
- ◆ Set the switch on the wireless controller to either 12.5Hz or 50Hz, as directed by your physician.
- ◆ Remove the PMT trainer from the cradle and insert it like you would a tampon.
- ◆ Lie back and relax. Push the ON button. The PMT will automatically slowly adjust to the level set by your physician.
- ◆ You will begin to feel a sensation and then small contractions.
- ◆ If you do not feel any contractions within 2 or 3 minutes, gently take the tip of your finger and reposition the PMT trainer slightly until you feel the muscle contracting.
- ◆ If you want to change the contraction level, use the dial on the wireless controller. Increase the level slowly to avoid over-stimulating the muscle.
- ◆ If at any time during the cycle you need to remove the PMT trainer, press the STOP button and then remove it.
- ◆ After 15 minutes the contractions will stop.
- ◆ Use the floss to remove the PMT trainer. You may also remove the trainer by standing up and gently squeezing your pelvic muscle.
- ◆ Wash the PMT trainer with warm water and soap. **DO NOT IMMERSE IN WATER**
- ◆ Return the PMT trainer to its proper place in the cradle. **IF THE PMT TRAINER IS NOT RETURNED TO THE CRADLE, IT WILL NOT WORK THE NEXT TIME.**
- ◆ Once replaced in the cradle, it is now ready for your next use.
11.