



Athena Pelvic Muscle Trainer™

INSTRUCTIONS



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

This manual explains how the Athena PMT treats incontinence, shows the parts of the PMT, and reviews the use and care of your new Athena PMT.

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

Athena Pelvic Muscle Trainer™

The Athena Pelvic Muscle Trainer™ (PMT) is an intravaginal pelvic floor exerciser that strengthens the pelvic floor muscles to aid in the control of urinary incontinence (UI) in women. *The Athena PMT is a single-user device and should be used by the prescribed patient only.*

Description of the Pelvic Muscle Trainer™

- The Athena Pelvic Muscle Trainer™ is an intravaginal exerciser constructed of medical-grade plastic and 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 myostimulation to the pelvic floor muscles to induce Kegel-like contractions.
- The exerciser is ergonomically designed for use by a single person.

WARNINGS

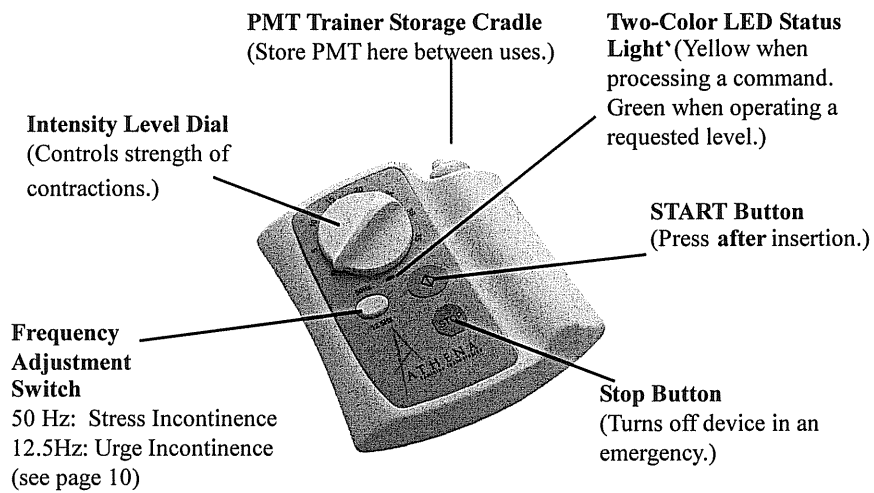
- Do not use in water or while bathing or swimming.
- Keep out of the reach of children.
- Do not use simultaneously with high frequency hospital equipment (e.g. diathermy equipment). It may result in burns at the site of the electrodes and possible damage to the trainer.
- Do not use if you have a pacemaker.

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

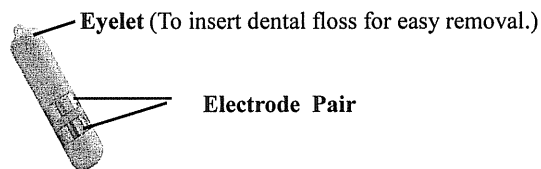
PRODUCT DESCRIPTION

The Athena Pelvic Muscle Trainer™ has two parts:

1. Wireless Controller with PMT Trainer storage cradle



2. PMT Trainer



3.

USING YOUR ATHENA PELVIC MUSCLE TRAINER™

Initial Treatment

The initial treatment with the Athena PMT should 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.

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.

Precautions


1. The PMT trainer should not remain inserted in the vagina when the unit is not in use.
2. The PMT should not be used while:
 - sleeping,
 - anything else is in your vagina such as a tampon or diaphragm; or are engaging in sexual intercourse.
 - engaging in any activity that could immerse the PMT in water while operating, e.g. swimming, bathing.
 - driving a motor vehicle.
 - menstruating.
3. Discontinue treatments and contact your physician if you:
 - feel any pain.
 - notice abnormal vaginal discharge, irritation to the tissue, 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).

Getting started

Before the PMT can be used, batteries must be installed:

1. Loosen the screw on the back of the wireless controller using a screw driver or coin and remove battery cover.
2. Install the three supplied AAA batteries as indicated by the marking inside the battery compartment. The negative part of the battery goes toward the spring.
3. Replace the battery cover and tighten the screw.

TEST MODE PROCEDURE

4. To make sure the batteries are in correctly and the trainer is communicating with the cradle, remove the trainer from the cradle (the LED light will be flashing yellow)
5. Press the STOP button (the yellow LED will remain steady and then turn off)

6. Replace the trainer in the cradle. (The LED light will turn green and then turn off).
7. The PMT trainer is now ready for use.

Note: Always return the trainer to the cradle when it is not in use.





Cleaning the PMT Trainer

- Wash the PMT trainer prior to initial use and after every use.
- Before cleaning the PMT trainer, remove any floss used during the session.
- Use a mild soap and water. Soap that is free of deodorants, fragrance and dyes is recommended.
You may put the trainer under running water but do not immerse completely in water.
- The PMT trainer can be air-dried or wiped off with a lint-free cloth.
- Be sure that the PMT trainer is clean and dry before replacing in the cradle.



To use for the first time

To prepare the trainer for use, wash and dry it. Add floss for easy removal if desired. Then return it to the cradle.

1. Set the frequency switch to 12.5 Hz for urge incontinence or 50 Hz for stress incontinence. (See page 10) For mixed incontinence set one session at 12.5 Hz and the other session at 50 Hz. 
2. Set the intensity dial to 5.
3. Remove the PMT trainer from the cradle. The LED status light will blink yellow. 
4. Recline comfortably and insert the trainer as you would a tampon.
- Use a water-based lubricant jelly if needed (not petroleum jelly)
5. Push the green START Button to start the PMT. The LED Status Light will turn solid yellow until it has reached the strength of 5 and will then turn solid green.
6. If you do not feel anything, increase the dial by 2 clicks (from 5 to 7) and wait for the light to turn green again. Keep doing this until a comfortable pulse can be felt. It should never be uncomfortable!
7. Lie back and relax for 15 minutes while the PMT does pelvic floor exercises for you.
8. The PMT will turn off after 15 minutes and the green light will go out. Remove the PMT trainer, wash and dry it (see page 5 for cleaning instructions) and replace it in the cradle for the next use. The light will flash twice every minute to remind you to replace the trainer in the cradle.
9. Leave the intensity dial on the setting you were using. It will automatically adjust to this level the next time you use the PMT.

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 those which are comfortable.

Regular use

1. Insert the PMT Trainer into your vagina.
2. Press the **green** START Button. The light will be constant yellow. Your 15 minute session will start.
3. The PMT trainer will automatically slowly adjust to the setting you previously used and the LED will turn solid green once it has been reached.
4. The green light will turn off at the end of the session.
5. After use, remove the floss if used, wash, dry, and replace in the cradle.

IMPORTANT Read Before Using

- The PMT trainer is best used when lying down or in a reclining chair.
- The PMT trainer slowly increases in intensity and is indicated by the yellow LED. Be patient when starting to use it.
- The PMT trainer starts to work only after you press the green START button.
- The PMT will automatically adjust to the level set on the dial.
- If you want to weaken or strengthen the contractions, use the intensity dial on the PMT wireless controller to adjust the strength as appropriate. Adjust slowly (1 to 2 clicks) to find the appropriate strength.
- The PMT trainer will automatically turn off after each 15-minute session.
- The STATUS LED LIGHT:
The blinking light on the PMT wireless controller tells you that the PMT trainer is waiting for a command. It will remain solid YELLOW after you push the START Button until it reaches the strength set on the dial. Then the LED will be solid GREEN when it is operating at the strength requested. The Green light will go out at the end of the session. It will then blink twice every minute until the trainer is returned to the cradle.
- If you need to remove the PMT trainer before the end of the session, push the button marked STOP. Wait for the LED to turn off and remove the PMT trainer.
- The PMT trainer *must* be returned to the cradle for storage to function properly.
- To increase the effectiveness of the contractions, you can physically contract your pelvic muscles when you feel the PMT trainer contraction, although this is not necessary for success.
- If you have difficulty removing the PMT trainer from the cradle insert a piece of dental floss through the eyelet and tie it to form a loop. Then pull it out.

QUESTIONS AND ANSWERS

1. **When I try the test mode the yellow light doesn't blink when the trainer is removed from the cradle.**
Check to make sure that you have fresh batteries and that the batteries are inserted correctly.
2. **I suddenly can't feel the PMT trainer when I'm using it. What should I do?**
You may not feel the PMT for a number of reasons:
Your session may be over. Check to see if the LED light has turned off.
The PMT may have turned off (see question 5).
The PMT trainer may have moved out of contact with the correct nerves. To remedy this, simply take the tip of your finger and move the PMT until you can feel the contractions again.
3. **Can I let others try my Athena PMT?**
No, the PMT is by prescription for single patient use only.
4. **How do I turn it on once I insert it?**
Press the green START button
5. **How do I stop it if I need to before the 15 minutes are up?**
Press the red STOP Button
6. **The PMT doesn't turn on when I press the START button.**
What should I do?
To enhance battery life, the PMT is designed to turn off after 2 minutes if the START button is not pushed. To reset, place the PMT trainer back into the cradle, remove, insert into the vagina and press the START button within 2 minutes.
7. **What can I do if I am too dry to insert the PMT trainer?**
You may use a vaginal lubricant when inserting the PMT. Use a water-based lubricant, not petroleum jelly.
8. **What will the stimulation feel like?**
The stimulation will feel like a flutter or gentle pulsating contraction of the muscles.

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. However, moving to higher levels of intensity should not be a goal. Most women achieve results staying at about the same setting during the entire time they use the PMT. NEVER use it at an intensity that is uncomfortable or painful.

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 of success.

When used as recommended, most patients suffering from urge incontinence will see improvement in 3 to 4 weeks. Patients with stress incontinence, or incontinence associated with sphincter weakness, usually see significant improvement in 8 to 12 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 your Athena PMT on a periodic basis even after your goal is reached. This will ensure that the pelvic muscle stays strong and will help to prevent future problems. Check with your doctor.

CUSTOMER CARE

Working with our customers to help them achieve the maximum results from their Athena Pelvic Muscle Trainer™ is our main priority. Feel free to call us.

Before you call:

- * Check to make sure the batteries in the controller are installed correctly.
- * Confirm that the PMT Trainer is working correctly by repeating the initial set up test mode procedure. (page 5, Getting Started, steps 4-6)

For more information on the Athena PMT, it's use, answers to questions and resources for incontinence information visit our website at www.athenaft.com

If you still have questions please call our customer careline:

866-308-4436 (M-F, 9:00.a.m. to 4:00 p.m. PST)

Urge and Stress Incontinence

Check with your physician for the correct settings for you.

Stress incontinence is defined as the leaking of urine when a pressure is exerted on the bladder, such as when laughing, sneezing or coughing. If you have this kind of incontinence you should probably use the PMT Trainer set on 50 Hz.

Urge Incontinence is present when you know you have to go to the bathroom but are unable to make it on time. It is sometimes referred to as "garage door incontinence" since some women involuntarily empty their bladder when they arrive home instead of being able to hold it until they reach the bathroom. If you have this kind of incontinence you should probably use the PMT Trainer set on 12.5 Hz.

Mixed Incontinence

If you have both kinds of incontinence, known as *mixed incontinence*, you might use one setting in the morning and another in the evening.

PATIENT LOG

Remember, consistency counts!

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

	Sun	Mon	Tues	Wed	Thurs	Fri	Sat
<i>Example</i>	✓	✓	✓	✓	✓	✓	✓
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

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 in 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 to not use the device)

This therapy may not be 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 you.

PRODUCT SPECIFICATIONS

Specifications



WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, IEC60601-1, CAN/C22.2 No. 601.1
Mode of Operations: Continuous

Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or oxygen or nitrous oxide.
IPX0 rating (no protection from dust and liquid ingress)



NON-IONIZED RADIATION



TYPE BF EQUIPMENT

Electrical Properties

Output Current: 0-70mA

Pulse Width: 200uS 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.

Patent Pending

Assembled in China

Federal Communications Commission (FCC) compliance Notice:

Pelvic Muscle Trainer (Wireless Control Unit)

Warning: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

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Athena Feminine Technologies, Inc.

Responsible Party:
Athena Feminine Technologies, Inc.
21 Orinda Way, C246
Orinda, CA 94563
(925) 254-2121

WARRANTY AND DISCLAIMER

Athena Feminine Technologies, Inc. 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, Inc. 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.

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.

Warning: This is a medical device that may break if it is dropped or misused. Athena Feminine Technologies takes no responsibility for devices that are returned in broken condition.

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 call 1-866-308-4436 for further instructions.

The Athena PMT Wireless Controller runs on three 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 Care at 866-308-4436 or visit us at our website: www.athenafit.com

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