

Pelvifine[®]
Pelvy Tone

Dispositivo per Allenamento Pelvico

Dispositivo de entrenamiento pelvic

Dispositif d'entraînement pelvien

Becken Trainingsgerät



Pelvic Floor Training Device

User Manual

Download the User Manual at the following link:

<https://www.meditaliaservice.com/prodotto/pelvifine-pelvy-tone/>

Warnings

- This unit must be used with the guidance of a Physiotherapist or Doctor.
- Type BF equipment, Continuous Operation.
- Do not insert lead wires into a mains power supply.
- Do not immerse unit into water or any other substance.
- The unit is not protect from the ingress of water droplets from a shower of rain if used outside the carrying case.
- Do not use the Pelvifine Pelvy Tone unit in the presence of a flammable anesthetic gas mixture and air or with Oxygen or Nitrous Oxide.
- Only use 9V alkaline batteries, do not use rechargeable batteries.
- Patient probes are for single patient use only.
- Keep out of reach of children.
- Do not use this stimulator on your facial area unless you are under strict guidance from a qualified Clinician.
- Application of probes near the thorax may increase the risk of cardiac fibrillation.
- Operation in dose proximity (e.g. m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.
- Simultaneous connection of a patient to a high frequency surgical equipment may result in burns at the site of the stimulator probes and possible damage to the stimulator.
- No modification of this equipment is allowed!

What is STIM?

Stimulation has been used for many years to stimulate muscle and nerve fibres to treat a number of muscle and nerve related conditions. Over the last 30 years numerous clinical trials and papers have been written.

Pelvifine Pelvy Tone is one of a new breed of modern Neuromuscular Stimulators (STIM) developed with the aim of achieving optimum pelvic health for women.

Our principle aim is to design a product to give women the opportunity to exercise their muscles, strengthen weak muscles and nerve fibres in a compact, easy to use device - we also wanted the device to be able to be versatile enough so that as a woman achieve greater muscle control, with high levels of functional use, are sensibly priced, compact and user friendly.

Pelvifine Pelvy Tone is a dual channel device combining several treatment programs into one unit. Neuromuscular Stimulation is increasingly understood by Therapists and Doctors. There is a better understanding of the mechanisms which exist between nerves and muscles that makes possible to stimulate the neuromuscular system with precise electrical signals. **Pelvifine Pelvy Tone** offers precision giving full control of Pulse Widths, Rates, Ramp up times, Work / Rest cycles as well as alternating or synchronous application if two channels are being applied.

Welcome to Pelvifine Pelvy Tone Pelvic muscle trainer

Thank you for choosing Pelvifine Pelvy Tone pelvic muscle trainer. You are now one step closer to having a stronger, healthier pelvic floor. Created especially for women, the Pelvifine Pelvy Tone pelvic muscle trainers an effective Pelvifine Pelvy Tone stimulator (STIM). That means Pelvifine Pelvy Tone pelvic muscle trainer works by producing electrical pulses to stimulate the muscles and nerve fibres in your pelvic area.

Using Pelvifine Pelvy Tone pelvic muscle trainer to exercise your pelvic area can:

- Relieve pain
- Improve the symptoms of urinary incontinence
- Promotes continence
- Increases muscle strength

If you have never used a Pelvifine Pelvy Tone stimulator before, you may be a little apprehensive. That's quite normal - lots of people are cautious at first, but soon realise that there is nothing to worry about. The probes are designed to comfort and while you will be able to feel the effects of electric pulses, they should not cause any discomfort.

If you follow the instructions in this User Guide, Pelvifine Pelvy Tone pelvic muscle trainers a safe and effective way of exercising your pelvic floor.

Customer Care

We welcome constructive comments on our equipment particularly those that might help us to improve existing features, add new ones or develop new products for the future.

Warnings

Please pay careful attention the following safety warnings :

- Do not insert lead wires in to a mains power supply.
- Do not immerse unit into water or any other substance.
- Patient Probes end Electrodes are for single patient use only.
- Keep out of reach of children.
- No modification of this equipment is permitted.

Contra indications & Precautions

Please read this Pelvifine Pelvy Tone pelvic muscle trainer User Guide before using this stimulator device.

Important Safety information

Who Can Use Pelvifine Pelvy Tone pelvic muscle trainer ?

Your Pelvifine Pelvy Tone pelvic muscle trainers is designed or women. Is a safe and effective way of strengthening pelvic floor muscles. However, as it works by using electrical pulses, there are some people that should seek medical advice before using Pelvifine Pelvy Tone pelvic muscle trainer.

DO NOT USE:

- If you have been fitted with a demand style cardiac pacemaker.
- During pregnancy.
- If you have undiagnosed pain, skin, vaginal or rectal conditions.
- On anaesthetized or desensitized skin.

Where Can You Use your Pelvifine Pelvy Tone pelvic muscle trainer?

Pelvifine Pelvy Tone pelvic muscle trainers not only designed for home use, but can be used in medical centers and hospitals too.

Using your Pelvifine Pelvy Tone pelvic muscle trainer Safely

- Only use the Pelvifine Pelvy Tone pelvic muscle trainer your vaginal and rectal regions as described in this user guide. Never use

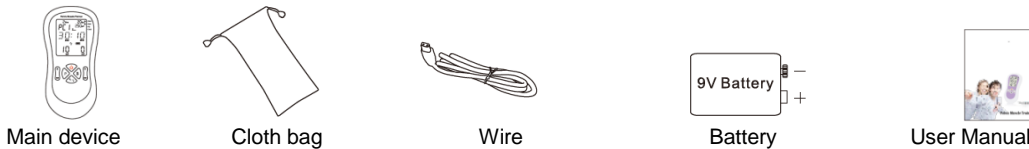
Pelvifine Pelvy Tone pelvic muscle trainer on other parts of your body as the electrical pulses could damage your health.

- To ensure your personal hygiene, do not allow other people to use your probes. Always clean your probes thoroughly after use.
- Only use Pelvifine Pelvy Tone approved vaginal or rectal probes with your Pelvifine Pelvy Tone pelvic muscle trainer. All official Pelvifine Pelvy Tone pelvic muscle trainer probes are Pelvifine Pelvy Tone approved .
- To power your Pelvifine Pelvy Tone pelvic muscle trainer device, use a 9v battery. Never connect your Pelvifine Pelvy Tone pelvic muscle trainer device or its probes to a mains power supply as this could result in electrocution .
- Do not Immerse your Pelvifine Pelvy Tone pelvic muscle trainer device or its probes in water, fluids or any other substance.

Pelvifine Pelvy Tone pelvic muscle trainer Check List

When you open the Pelvifine Pelvy Tone pelvic muscle trainer packaging, you should find: •1 x Trainer unit •2 x Wire•1 x 9V Battery •1 x User Guide

Getting to Know Your Pelvifine Pelvy Tone pelvic muscle trainer



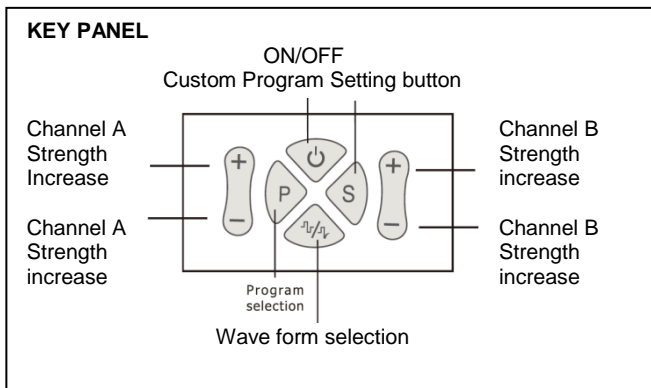
Main device

Channel A Channel B



LCD

Keys



P button -Selects the desired set program from P01 - P11 or customized program PC1 - PC3.

-Pauses (reducing the intensity (mA) to zero) and escapes from a running program .

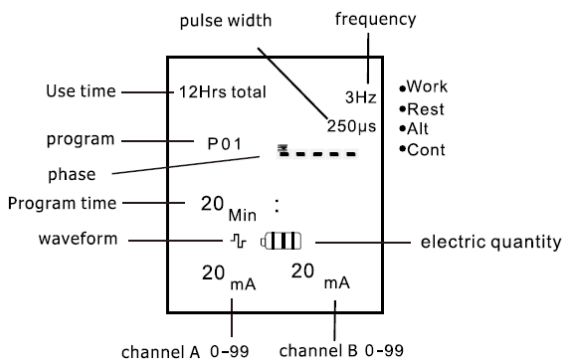
S button -Displays the menu for programs PC1 - PC3 and allows the parameters for Time, Work , Rest, Ramp up time, CH.A/ CH.B Synchronous or Alternating and delay to be set.

- ⌚ Asymmetrical , rectangular bi-phasic with zero DC current., It is soft Waveform for beginning.
- ⌚ Symmetrical, rectangular bi-phasic with zero DC current., It is stronger Waveform for general patients

You will use Channel A and Channel B to connect the probe with your Pelvifine Pelvy Tone pelvic muscle trainer device. We recommend that you connect a vaginal probe to Channel A.

The front of the Pelvifine Pelvy Tone pelvic muscle trainer also has two sets of (+)and(-) buttons. You can use these button to increase (+) or decrease (-) the strength of the electrical pulse being sent via Channel A and Channel B respectively. (The buttons labelled A are for Channel A, those labelled B are for Channel B).

When you first power up your Pelvifine Pelvy Tone pelvic muscle trainer, the LCD will display the following information:



LCD display

Hz Hz amount is the number of electrical pulses per second (Hertz). This value will vary, depending on the program you have selected .

µs The µs amount is the duration of a single electrical pulse. The higher the value, the more It penetrates your muscles. Again , this amount will vary depending on the program you have selected.

Program Number or Program Timer

The top right area of the LCD shows either the number of the program that is currently selected or the amount of time remaining on the program (currently running).

Total Time

The top area of the LCD shows the time your total trainer time.

How Your Pelvifine Pelvy Tone pelvic muscle trainer Works?

If you haven't used e Pelvifine Pelvy Tone stimulator before, the idea of applying electric pulses to your body can seem a little strange. But there's no need to worry because your body has already generated biological electrical signals. For example , let's say you want to tense the bicep muscle In your arm. To do this, your brain sends an electrical signal your muscle via nervous system. When the signal reaches your

bicep, it causes the muscle to contract, and when the signal is not exist, your muscle relaxation again.

Pelvifine Pelvy Tone pelvic muscle trainer works in a very similar way - it sends electric pulses to precise areas of the weakened muscles In your pelvic area, causing them to contract and relax. Over time, this strengthens the muscles and nerve fibres, giving you greater muscle control and improving tone and tightness.

Pelvifine Pelvy Tone pelvic muscle trainer features several pre-set programs for pelvic floor exercise. These programs have been carefully planned so that they:

- **Work** your muscles appropriately, helping them to strengthen gradually
- **Allow** your muscles to rest for the correct amount of time
- **Are** easy to use in 20-60 minute sessions.

Using Pelvifine Pelvy Tone pelvic muscle trainer for the First Time

What to expect from your Pelvifine Pelvy Tone pelvic muscle trainer.

When you first use Pelvifine Pelvy Tone pelvic muscle trainer, you most likely begin by choosing one of the pre-set programs. These programs are designed to treat a variety of female health problems, so you should choose the program that is best suited to your needs.

At the start of every program, Pelvifine Pelvy Tone pelvic muscle trainer begins at OmA, which means there is no electrical pulse. When you are ready to begin, you press the + button or the appropriate channel repeatedly to increase the electrical current.

When the electrical current reaches a certain level, you will begin to feel a knocking sensation in your pelvic muscles. This happens when the electrical current begins to stimulate your muscles at low levels. You may also feel a tingling sensation. When you get to this stage, slowly increase the electrical current to a level that is working your muscles but is comfortable too.

Many women find that they start to feel their muscles being stimulated when Pelvifine Pelvy Tone pelvic muscle trainers set to around 25mA, with settings over 30mA giving the muscles a full workout. But everybody is different, so you need to choose settings that you are comfortable with. The stronger the sensation you can feel, the more work your pelvic muscles are doing. But don't push yourself too hard. If you feel discomfort, press the - button for the channel to reduce the current.

As you exercise, you will feel your muscles pull up, tighten, and then relax again. During the relaxation part of the exercise, your Pelvifine Pelvy Tone pelvic muscle trainer will produce a lower amount of electrical current. If you use Pelvifine Pelvy Tone pelvic muscle trainer as described, 1 or 2 times per day, your pelvic muscles will get stronger. This will give you greater control and you will be able to gradually increase the amount of current.

Starting Your Pelvifine Pelvy Tone pelvic muscle trainer Exercises

Ready to start your pelvic floor exercises? Then let's get to it!

1. Before you start using your Pelvifine Pelvy Tone pelvic muscle trainer, please read the Important Safety Information.
2. On the back of your Pelvifine Pelvy Tone pelvic muscle trainer, slide off the battery cover and insert the battery.
3. Make sure the probe is clean by rinsing it in cold or warm water. Unclean probes could cause infection.
4. Connect the lead wire to the vaginal probe and Pelvifine Pelvy Tone pelvic muscle trainer unit. All of the wires are fitted with the appropriate connections.
5. Insert the probe
 - Get into a comfortable position. Many of women choose to use Pelvifine Pelvy Tone pelvic muscle trainer a sitting position or standing up. Inserting a probe is similar to inserting a tampon, so you may know what position suits you best
 - Hold the base of the probe. The base is the plastic part at the 'tail' end (the end with the wires).
 - Gently insert the 'head' end of the probe into your vagina/anus. Push the probe 2 inches (5.5cm) inside your vagina/anus. This is less than you would insert a tampon. The base part of the probe should always be outside of your body.

If you are very sensitive by electronic stimulator, please choose © waveform

To ease insertion, we recommend that you use a good quality water-based lubricant such as Gel. The lubricant will also help to improve the transfer of the electrical pulse from the probe to your muscles.

If the lubricant doesn't help, you may be suffering from vaginal atrophy, a condition that causes dryness and thinning of your vaginal walls. Your doctor can prescribe an oestrogen cream that can help. When you have completed the treatment, resume using the Pelvifine Pelvy Tone pelvic muscle trainer - you should find that you can insert the probe much more easily.

Please do not let vaginal atrophy stop you from experiencing the benefits of Pelvifine Pelvy Tone pelvic muscle trainer. There are effective solutions available to overcome this painful condition.

6. Press the power button on the Pelvifine Pelvy Tone pelvic muscle trainer control unit.
7. Press P button to choose one mode. to start the program, press the + button on Channel A on the left hand side, you will see the mA change to 1, this will start your exercise program. The mA's can reach a maximum of 99. The timer (min:sec) will count down through the routine and switch the unit off when your exercise is complete.

Once your program has started, press the relevant + button to increase the amount of power (milliamps) in the electrical pulses. The higher the amount of mAs, the more effective your program will be, but always choose a level that feels comfortable. If you are feeling discomfort or pain, reduce the amount of mAs by pressing the - button for the channel you are using.

8. When the program is complete, remove the probe by pulling gently at its base. Do not pull the wires as this could damage your probe.
9. Clean your probe under running warm water. Do not place your probe in boiling water as this will damage your probe.

You can wash your probes with sterilising fluid. We also recommend that you wipe your Pelvifine Pelvy Tone pelvic muscle trainer unit clean with a damp cloth or antiseptic wipe. Do not use alcohol-based products as this could damage the LCD.

Dry your probe and store it in a clean, dry place. We recommend that you keep your Pelvifine Pelvy Tone pelvic muscle trainer in its original packaging.

Exercise Tips

- Try to Start with a Power Output of 30 mAs or Above

The amount of power needed to stimulate pelvic floor muscles varies from person to person. By default, the Pelvifine Pelvy Tone pelvic muscle trainer unit has a 0 mAs output and you need to increase the power manually, by pressing the + button. You should increase the power to a level where you can feel the effects of the electric pulse, but it is not causing any discomfort. Many women find that a setting of around 30 mAs is a good starting point, but only you can tell what is comfortable for you.

As your pelvic floor muscles begin to strengthen, you should find that you can increase the power output.

- **Exercise 1-2 Times per Day for 12 Weeks**

We recommend that you use Pelvifine Pelvy Tone pelvic muscle trainer 1 or 2 times per day for 12 weeks. Alternate between your choice of program P01 and P11.

If you decide to exercise twice a day, it is important that you do not do back-to-back sessions. This is because your pelvic floor muscles need time to relax and recover between sessions. We suggest that you use Pelvifine Pelvy Tone pelvic muscle trainer once in the morning and once at night.

- **Be Patient.**

Everybody's different. Some people respond to Pelvifine Pelvy Tone pelvic muscle trainer exercises very quickly, whereas with others it takes a number of weeks to feel real improvements. But rest assured, if you use Pelvifine Pelvy Tone pelvic muscle trainer regularly and follow our instructions carefully, your pelvic floor muscles and nerve fibres will get stronger.

Pelvic Health Program Specifications

PROGRAM	P01		P02		P03		P04		P05		P06		P07	
	Pain Relief		Urge/Prolapse		Stress 1		Stress 2		Frequency/Urge1/ NewMothers		Frequency / Urge 2		Frequency / Urge 3	
Phase		1		1		1		1		1		1		1
Phase time	min	20	min	20	min	20	min	20	min	20	min	15	min	20
Mode		Cont		W/R		W/R		W/R		W/R		Cont		Cont
Frequency work	Hz	3	Hz	10	Hz	40	Hz	30	Hz	10	Hz	10	Hz	10
Pulse duration	µS	150	µS	250	µS	200	µS	200	µS	200	µS	200	µS	220
Ramp up time	secs	1.0	secs	1.0	secs	1.0	secs	0.8	secs	1.0	secs	1.0	This program works continuously with no rest period. It is used in some countries where they have found continuous stimulation can work effectively.	
Ramp down time	secs	0	secs	0	secs	0	secs	0	secs	0	secs	0		
Work time	secs	Coni	secs	5	secs	6	secs	5	secs	5	secs	Cont		
Rest time	secs	0	secs	5	secs	15	secs	8	secs	5	secs	0		
Alternating														
Synchronous		*		*										
Overall time		20 min		20 min		20 min		20 min		20 min		15 min		20 min

PROGRAM	P08					P09					P10		P11			
	Lack of Sensitivity					Pelvic Floor Work Out					Endurance		Relaxing the Pelvic muscle			
Phase		1	2	3	4	5		1	2	3	4	5		1		1
Phase time	min	3	10	5	4	3	min	4	15	8	8	10	min	20	min	20
Mode		W/R	W/R	W/R	W/R	W/R		W/R	W/R	W/R	W/R	W/R		W/R		W/R
Frequency work	Hz	3	10	20	30	40	Hz	20	10	20	30	10	Hz	20	Hz	2
Frequency rest	Hz															
Pulse duration	µS						µS	250	250	250	200	250	µS	250	µS	220
Modulation time	secs	250	250	250	200	200										
Ramp up time	secs	0.8	0.8	0.8	0.7	0.7	secs	0.8	0.8	0.8	0.6	0.8	secs	0.8	secs	1.2
Ramp down time	secs	0	0	0	0	0	secs	0	0	0	0	0	secs	0	secs	0
Work time	secs	4	4	4	4	4	secs	5	5	5	5	5	secs	5	secs	6
Rest time	secs	4	4	4	6	6	secs	5	5	5	6	7	secs	5	secs	10
Alternating																
Synchronous		*	*	*	*	*		*	*	*	*	*		*		*
Overall time		25 min					45 min					20 min		20 min		

W/R = INTERMITTENT WORK/REST
CONT = CONTINUOUS

Which Program to select?

P01 - Pain Relief Vulvodynia: is a chronic pain condition characterized by burning, stinging, irritation, and/or rawness in the female genital area this program is designed to help. It also helps in cases where unknown pelvic pain has been diagnosed by a health care professional.

P02 - Urge/Prolapse Urge: in this program refers to a woman who does not have leakage problems, just the urge to pass urine. This program is suitable for women suffering from bladder and vaginal prolapse.

P03 • Stress 1Stress: incontinence is due to leakage of the bladder in particular when people jump up and down end when exercising or during lovemaking. This program is set at a rate of 40Hz.

P04 • Stress 2Stress incontinence: is due to leakage of the bladder in particular when people jump up and down and when exercising or during lovemaking. This program is set at a rate of 30Hz.

P05 - Frequency/Urge / New Mothers When a woman has the urge end frequency to actually pass urine several times during the day and night.

This program is recommended or new mothers who want to get back in shape after childbirth, start after your 6 week check up when you health care professional says it is OK to do so. After 12 weeks you can progress onto P08 the thorough Pelvic Floor Workout, a couple of time a week

P06 and P07 -Frequency/Urge When a woman has the urge and frequency to actually pass urine several times during the day and night. This program is used primarily In Scandinavian countries. It offers continuous stimulation. They prefer continuous stimulation, whereas here In the UK we prefer a work/rest program allow the muscle to rest and recuperate.

P08 - Lack of Sensitivity In some women following childbirth, although they have good muscle control, they have a lack of sensitivity. This could mean nerve damage end this program helps to recondition the muscle and to facilitate nerve sprouting to regain sensitivity.

PO 9 - Pelvic Floor Workout An excellent overall pelvic floor workout. Good for women entering or out of the menopause .

P10 - Endurance This program is ideal if you feel your muscle tone is reasonable, and you can contract the muscle but you can't hold the contraction for long.

P11 - Relaxing the Pelvic Muscles This program is to help relax the pelvic muscle after the excercises, when the pelvic muscle has been working hard and some fatigue may have resulted. The very low 2 Hz frequency will help to relax the muscle.

Custom Program

Custom procedures setting need to be under the guidance of your physical therapist!

Setting up the Customized Programs PC1, PC2 PC3

First, if a program is running, press the P button twice to return to the home screen.

1. Press the P button until PC1, PC2 or PC3 is selected.
2. Press and hold the S button for three seconds, the phase indicator arrow and Hz symbol will flash on and off.
3. Press CH.B (+/-)lo set the frequency between 2 Hz and 100 Hz.
4. Press CH.A(+),the μS symbol will flash , press CH.B (+/-)to set the pulse duration between 50 μS and 450 μS.
5. Press CH.A(+),the MIN symbol will flash, press CH.B (+/-) to set the length of the phase time between 1and 99 minutes. Set the time to zero to end the program on this phase.
6. Press CH.A {+}, the WORK / REST or the CONT symbols will flash, press the CH.B (+/-)to select WORK / REST or CONT (continuous).

Note: If continuous is selected, he menu will loop back to step 2.

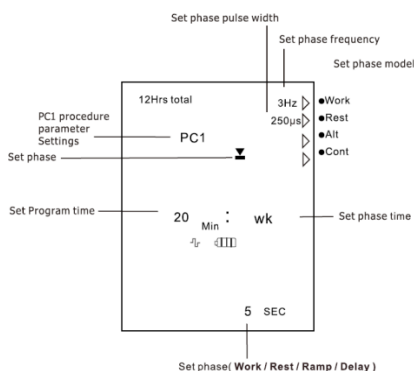
7. Press CH.A (+),WK will appear and flash, press CH.B (+/-)to set the work seconds between 2 and 99 seconds.
8. Press CH.A(+), RT will appear and flash, press CH.B (+/-)to set the rest seconds between 2 and 99 seconds.
9. Press CH.A(+), RP will appear and flash, press CH.B +/-to set the ramp seconds between 0.1 and 4.0 seconds.
10. Press CH.A(+),AL or SY will appear and flash, press CH.B (+/-)lo select alternating or synchronous current.

Note: If alternating is selected, the menu will loop back to step 2.

11. Press CH.A(+), DY will appear and flash, press CH.B (+/-)lo set the delay of channel B starting between 0 and 4 seconds after channel A.
12. The menu will now loop back to step 2 and the Hz symbol will flash.
13. To set the next phase, press the set button. The phase symbol will flash over the next phase, continue with step 2 to set this phase.
14. When finished setting the phases, press the P button to save he settings and return to the home screen. The program will be saved permanently. Setting the phase time of phase 2,3,4 or 5 o zero will cause the program to end at this phase.

Following procedures 1 to 12 can reprogram a customized program.

Custom program LCD diagram PC1-3



Applications

Why every woman should use

- *promotes continence.
- *increases and improves muscle strength.
- *maintains or improves range of movement.
- *increases and improves the blood supply to the muscle.
- *strengthens the pubococcygeus (PC) muscles In order to prevent or reduce pelvic floor problem and to increase sexual satisfaction .
- *can be used to treat Vagina! and Uterine prolapses, depending on the severity of symptoms .
- *can strengthen the levator muscles, weakened by damage or lost nerve input from childbirth , especially in the case of c-sections, operations for hernia and hysterectomy.

Program Settings - Explained

Each Pelvifine Pelvy Tone Pelvic muscle trainer program has several settings that you will need to understand if you are creating a custom program . Getting to know how these settings work will also help you lo understand the specifications for the pre-set programs.

- Hz - The number al electrical pulses per second (in Hertz). Generally, 1-15HZ is far treating slow responding muscle fibres, and 35Hz-45Hz or fast responding muscle fibres. Values of 45Hz and above are used or treating muscle fatigue and promoting muscle strength and flexibility.
- μS - The duration of a single pulse (the 'pulse width'). The wider a pulse is the more muscle penetration it has.
- RMP (Ramp Up) - How long it takes to achieve full muscle contraction (in seconds).
- WRK (Work) - How long the electrical current will keep the muscle tiight (working). Again, this is in seconds.
- RST (Rest) - The amount of time between each pulse (In seconds). The muscles will rest for this amount of time.
- ALT (Alternating) - The device will output an electric current through one channel at a time.
- SYN (Synchronous) - The device will output an electric current through both channels at the same time.

Taking Care of your Pelvifine Pelvy Tone pelvic muscle trainer

Accessories and Modifications

Only use Pelvifine Pelvy Tone approved accessories

Do not modify the device. Making unauthorised adjustments to the device will invalidate your warranty and could result in injury.

Screen (LCD) Care

LCD is covered with a thin protective layer. This layer help to protect your LCD from scratches.

robe Care

Each probe is designed for ease of use and should last 12-18 months with proper care.

- Never immerse your probe in boiling water or boiling liquids. This could damage your probe.
- When inserting a probe, hold its base. Do not hold it by the wires as this could damage the probe.
- Before use, always clean the probe in warm, but not boiling, soapy water.
- Alter use, rinse with clean water, dry and store in a cool place.
- Only use CE approved vaginal probe (Model:KM-503) from konmed

Lead Wires and Connections Care

The lead wires and connections are vital to the device, so please treat them with care:

- Always handle the wires carefully
- Do not stretch or twist the wires as this could damage them. If your wires are damaged , the device may be unable to send the electric pulses to your probe.
- Do not cui the wires or attempt to modify the connections .

Battery Care

To take care of the battery:

- Replace the battery when it is low on power (a battery indicator is shown on the LCD when the power is low).
- If you are not going to use the device for a week or longer, please remove the battery.
- We recommend you use a GP 9V Alkaline battery.

Frequently Asked Questions

Q: I can't get the mA's past 6, 7 or 8

If you do not get an effective contact with the probe you will find that you cannot increase the mA's past level 6, 7 or 8. Initially we recommend you use the Pelvifine Pelvy Tone pelvic muscle trainer either lying down or sitting with your legs elevated. This will help you to get used to the Pelvifine Pelvy Tone pelvic muscle trainer sensation but also to stop the probe being displaced. It is important that the probe maintains contact with the muscle to contract and exercise it properly. Conductivity is also improved by using the lubricant provided, it is water based, and body friendly and you'll get better results.

Q: I have an IUD or Mirena Coil • can I use the Pelvifine Pelvy Tone Pelvic muscle trainer?

Yes . The Mirena is plastic so not problems there .An IUD contains copper which is unaffected by the Pelvifine Pelvy Tone pelvic muscle trainer and STIM so no problems there either.

Q: Can I use my Pelvifine Pelvy Tone pelvic muscle trainer when I have my period? There are no problems with this, however if you are at the peak of your period and flow is heavy you may prefer not to. Many users have reported it helps with menstrual cramps too .Here in the office we tend to use iton lighter flow days.

Rinse the probe in warm water and towel dry, the probe can be sterilized

using a mild sterilizing solution if necessary, do not immerse the connectors at the ends of the leads in water, do not boil (it will cause the plastic to crack).

Q: Can I use it whilst pregnant?

Clinical guidelines advise against using any STIM machines vaginally during pregnancy.

Q: How far do I put the probe in?

The vaginal probe needs to be inserted just 2 inches (5.5 cm) this is the optimum level to stimulate the pelvic floor muscle.

Q: I aim to have my mA's at 40, but on some programs it drops to 30 - why is that?

While the program goes through its preset routine the pulse width and pulse length varies, when the pulse rate and length increase the mA's drop so that the intensity does not take you by surprise, the mA's can again be increased . So if you feel a decrease in intensity increase the mA's back up to a comfortable level.

Q: How soon after the birth of my baby can I start with my Pelvifine Pelvy Tone Pelvic muscle trainer ULTRA?

Consult with your Midwife or Doctor. Generally women feel happy to start after a successful six week check-up .

Q: I have had Pelvic surgery - how soon can I start using my Pelvifine Pelvy Tone Pelvic muscle trainer ULTRA?

Consulting your Doctor or Consultant, every case is different, but the Pelvifine Pelvy Tone pelvic muscle trainer could help to speed recovery. Stress incontinence, and prolapse is usually a sign of a weak pelvic floor, so if you have had an operation to help with either of these conditions you will still need to strengthen it. The Pelvifine Pelvy Tone pelvic muscle trainer is ideal, but check with your Doctor or physiotherapist.

Q: I find it painful inserting the probe.

Use the lubricant, this isn't supplied just too help make insertion easier, it also helps with the conductivity.

The better conductivity, the more the muscle will be exercised and the more mA's you'll be able too achieve.

If you are menopausal you could be suffering from vaginal atrophy, his causes vaginal dryness, thinning of the vaginal membrane and great discomfort .

If the lubricant does not help, your Doctor can prescribe a course of oestrogen cream, use this for the recommended time, and then re commence using the Pelvifine Pelvy Tone pelvic muscle trainer. Remember the pelvic floor needs to be exercised, do not be put off by vaginal atrophy, there are easy solutions for all women to overcome this painful condition.

Q: Why are there two channels?

Channel A (left hand side)is generally used for a vaginal probe, Channel B on the right hand side is generally used for an anal probe or electrode pads.

Q: How do I clean my probe?

Simply rinse the insertable part under the tap, keeping the wires dry al all times. Do not boil the probe. It can be sterilized using a mild sterilizing solution.

If you want to use the same probe vaginally and anally this is fine, but always clean the probe thoroughly.

Q: How long will the battery last?

If you use the Pelvifine Pelvy Tone pelvic muscle trainer daily, it should last about 1 months. You can get replacements from us or at your local supermarket - please choose a quality battery that will not leak. You will know when your battery is low because the battery icon will flash on your Pelvifine Pelvy Tone pelvic muscle trainer screen.

Q: How long will my probe last?

With normal using, your probe should last between 12 - 18 months. We recommend you replace it after this time to keep getting the maximum results from your Pelvifine Pelvy Tone Pelvic muscle trainer. We recommend you take care with the leads and wires of the probe don't bend them in two, or lie them up, this could cause wire damage and stop the probe working effectively. When inserting and removing the probe always hold the base of the probe, not the wires, especially when removing the probe. If you pull the wires instead of the probe base, you can damage the wires. We always offer a range of different probes for all uses.

Technical Specifications

1. Dual channel: individually isolated circuits.
2. Amplitude : 0 - 99 mA
3. Waveform:
Asymmetrical, rectangular bi-phasic with zero DC
Symmetrical, rectangular bi-phasic with zero DC
4. Selectable pulse width: 50 µS - 450 µS
5. Pulse Rate selection: In the continuous mode 2 Hz - 100 Hz.
6. Time duration of the treatment selectable: 1 minute or 90 minutes.
7. Open Electrode Detect: If an open circuit is detected at the output of channel A or B the output current will be reset at zero.
8. Ramp up time 0.1- 4 .0 seconds.
9. If the battery voltage is below 5.6 (±0.3) volts the unit will not turn on.

Environmental Conditions for use: +10 to +30 degrees Centigrade. 0-90% Humidity.

Environmental conditions for storage & transport: - 10 to +50 degrees Centigrade. 0-90% Humidity. **Information regarding Electromagnetic compatibility and interference (EMC)**

Pelvifine Pelvy Tone products are designed to produce very low levels of radio frequency (RF) emissions (interference), to be immune from effects of interference produced by other equipment operating in their vicinity and damage due to electrostatic discharge all when operating in a typical domestic and or clinical environment.

They are certified to meet the international EMC standard EN60601-1-2. For more information please refer to the tables 201, 202, 204 and 206.

Tabella 201: Linee guida e dichiarazione del produttore emissioni elettromagnetiche

Il prodotto Pelvifine Pelvy Tone è destinato all'uso nell'ambiente elettromagnetico specificato di seguito. Il cliente o l'utente del prodotto deve assicurarsi che venga utilizzato in tale ambiente.

Emissioni	Compliance	Ambiente elettromagnetico: guida
Emissioni RF CISPR 11	Gruppo 1	Il prodotto Pelvic Muscle Trainer utilizza l'energia RF solo per la sua funzione interna. Pertanto, le sue emissioni RF sono molto basse e non possono causare alcuna interferenza nelle apparecchiature elettroniche vicine. Il prodotto Pelvic Muscle Trainer è adatto per l'uso in tutti gli stabilimenti, compresi quelli domestici e quelli direttamente collegati alla rete di alimentazione pubblica a bassa tensione che alimenta gli edifici utilizzati per scopi domestici.
Emissioni RF CISPR 11	Classe B	
Emissioni armoniche IEC 61000-3-2 IEC 61000-3-2	Non applicabile	
Fluttuazioni di tensione/emissioni di sfarfallio IEC 61000-3-3	Non applicabile	


Tabella 202: Linee guida e dichiarazione del produttore Immunità elettromagnetica

Il prodotto Pelvifine Pelvy Tone è destinato all'uso nell'ambiente elettromagnetico specificato di seguito. Il cliente o l'utente del prodotto deve assicurarsi che venga utilizzato in tale ambiente e che vengano osservate le precauzioni relative a tale ambiente.

Test immunità	Livello test IEC 60601	Livello Compliance	Ambiente elettromagnetico guida
Campo magnetico a frequenza di rete (50/60 Hz). IEC 61000-4-8	± 6 kV contatto ± 8 kV aria	± kV contatto ± kV aria	I pavimenti dovrebbero essere in legno, cemento o piastrelle di ceramica. Se i pavimenti sono ricoperti di materiale sintetico, l'umidità relativa deve essere almeno del 30%.
Campo magnetico a frequenza di rete (50/60 Hz). IEC 61000-4-8	3 A/m	3 A/m	I campi magnetici a frequenza di rete devono essere a livelli caratteristici di una posizione tipica in un tipico ambiente commerciale o ospedaliero.

Tabella 204: Guida e dichiarazione del produttore sull'immunità elettromagnetica

Il prodotto Pelvifine Pelvy Tone è destinato all'uso nell'ambiente elettromagnetico specificato di seguito. Il cliente o l'utente del prodotto Pelvifine Pelvy Tone deve assicurarsi che venga utilizzato in tale ambiente.

Test immunità	Livello test IEC 60601	Livello Compliance	Ambiente elettromagnetico guida
RF Condotta	3 Vrms	3 Vrms	Le apparecchiature di comunicazione RF portatili e mobili non devono essere utilizzate a una distanza inferiore a qualsiasi parte del prodotto, compresi i cavi, della distanza di separazione consigliata calcolata dall'equazione applicabile alla frequenza del trasmettitore. Distanza di separazione consigliata D=1.2 P (150kHz a 80 MHz) D=1.2 P (150kHz a 800 MHz) D=2.3 P (800kHz a 2.5 GHz) Dove P è la potenza nominale di uscita massima del trasmettitore in watt (W) secondo il produttore del trasmettitore e d è la distanza di separazione consigliata in metri (m). Le intensità di campo da trasmettitori RF fissi, come determinato da un'indagine elettromagnetica del sito, dovrebbe essere inferiore al livello di conformità in ciascuna gamma di frequenza. b Possono verificarsi interferenze in prossimità di apparecchiature contrassegnate dal seguente simbolo: 
IEC 61000-4-6	150 kHz a 80MHz 3 V/m	150 kHz a 80MHz 3 V/m	
Radiato RF IEC 61000-4-3	80 MHz a 2.5GHz	3 V/m 80 MHz a 2.5GHz	

NOTA 1 A 80 MHz e 800 MHz, si applica la gamma di frequenza più alta.

NOTA 2 Queste linee guida potrebbero non essere applicabili in tutte le situazioni. La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone.

a. Le intensità di campo da trasmettitori fissi, come stazioni base per telefoni radio (cellulari/cordless) e radiomobili terrestri, radioamatori, trasmissioni radio AM e FM e trasmissioni TV non possono essere previste in teoria con precisione. Per valutare l'ambiente elettromagnetico dovuto ai trasmettitori RF fissi, dovrebbe essere presa in considerazione un'indagine elettromagnetica del sito. Se l'intensità del campo misurata nel luogo in cui viene utilizzato il letto profilato modello AST-300C Elite supera il livello di conformità RF applicabile sopra indicato, è necessario osservare il letto profilato modello AST-300C Elite per verificarne il normale funzionamento. Se si osservano prestazioni anomale, potrebbero essere necessarie misure aggiuntive, come il riorientamento o il trasferimento del letto profilato modello AST-300C Elite.

b. Nell'intervallo di frequenza da 150 kHz a 80 MHz, le intensità di campo devono essere inferiori a 3 V/m.

Tabella 206: Distanze di separazione consigliate tra portatili e mobile Apparecchiature e prodotti per comunicazioni RF

Il prodotto Pelvic Muscle Trainer è destinato all'uso in un ambiente elettromagnetico in cui i disturbi RF irradiati sono controllati. Il cliente o l'utente del prodotto può aiutare a prevenire le interferenze elettromagnetiche mantenendo una distanza minima tra le apparecchiature di comunicazione RF portatili e mobili (trasmettitori) e il prodotto come raccomandato di seguito, in base alla potenza di uscita massima delle apparecchiature di comunicazione.

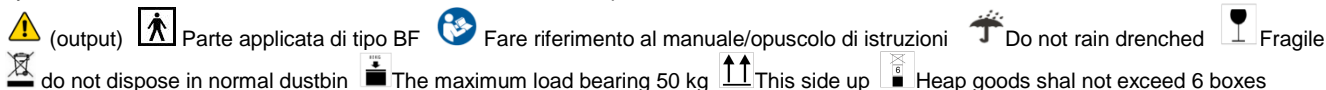
Potenza di uscita max nominale del trasmettitore (W)	Distanza di separazione in base alla frequenza del trasmettitore (m)		
	150 kHz a 80 MHz $d=1.2 \sqrt{P}$	80 MHz a 800 MHz $d=1.2 \sqrt{P}$	800 MHz a 2.5 GHz $d=2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Per i trasmettitori con potenza di uscita massima non elencata sopra, la distanza di separazione raccomandata d in metri (m) può essere stimata utilizzando l'equazione applicabile alla frequenza del trasmettitore, dove P è la potenza di uscita massima del trasmettitore in watt (W) secondo il produttore del trasmettitore.

NOTA 1: A 80 MHz e 800 MHz, si applica la distanza di separazione per la gamma di frequenza più alta.

NOTA 2: queste linee guida potrebbero non essere applicabili in tutte le situazioni. La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone.

Symbols on the rear cabinet of Pelvifinr Pelvic Muscle Trainer explained:



Shenzhen Konmed Technology Co., Ltd ADD: 601, Building B4, Scenchengtou Creative Factory Life Science Park, Julongshan A Road, Xiuxin Block Kengzi Street, Pingshan District, Shenzhen, Guandong, CN 518118

Shanghai International Holding Corp. GmbH (Europe) ADD. Eifferstrasse 80, 20537 Hamburg, Germany

Caution: Static electricity may damage this product.

NOTE: Only our appointed distributors/importers are approved to take servicing.

Responsible Recycling Initiative

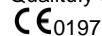
In compliance with Waste Electronic Equipment (WEE) Regulation 2006, we aim to reduce the amount of electrical waste being sent to landfill sites.

Electronic devices contain toxic materials which seep into the ground when dumped irresponsibly causing serious health and environmental problems. To recycle responsibly, all you need to do is return your device to us. We will:

- Carefully and correctly dispose of your Pelvifine Pelvy Tone Pelvic Muscle Trainer product
- Ensure as much of it is recycled as possible

This product is manufactured in compliance with the European Union Medical Device Directive MDD93/42/EEC under the supervision of TUV, Notified Body number 0197.

Quality Standards: ES ISO 13486: 2016



Customer Service

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Factory Life Science Park, Julongshan A Road,
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Clinical References**Neuromuscular Stimulation:**

Knight S, Laycock J, Naylor D. [1998] Evaluation of neuromuscular electrical stimulation in the treatment of genuine stress incontinence; *Physiotherapy* 84, No. 2, 61 - 71.

Gibson J.N, Smith K, Rennie M.J. [1988] Prevention of disuse muscle atrophy by means of electrical stimulation. Maintenance of protein synthesis; *The Lancet*; 2(8614: 767-70).

Lindstrom S, Fall M, Carlson C A, Erlandson BE. [1983] The neurophysiological basis of bladder inhibition in response to intravaginal electrical stimulation.

Fall M, Ahlstrom K., Carlsson C, Ek A, Erlandson BE, Frankenberg AS, Mattiasson A. [1986] Contelle: Pelvic floor stimulator for female stress-urge incontinence. A multicentre study; *Urology* 27, 282-287.

Berghmans L C, Hendriks H J, Bo K, Hay Smith E J, deBie R A, van Waalwijk Van Doorn E S. [1998] Conservative treatment of stress urinary incontinence in women: a systematic review of randomised clinical trials. *Br. J.Urol.* 82(2), 181 - 191.

Eriksen B C, Bergman S, Eik-Nes S H. [1989] Maximal Electrostimulation of the pelvic floor in female idiopathic detrusor instability and urge incontinence. *Neurourol. Urodynam*, 8, 219 - 230.

Miller K, Richardson D A, Siegel S W, Karram M M, Blackwood N B, Sand P K. [1998] Pelvic Floor electrical stimulation for genuine stress incontinence, who will benefit and when? *Int. Urogynecol. J. Pelvic Floor Dysfunction*, 9(5), 265 - 270.

Osterberg, Graf W, Eeg-Olofsson K, Hallden M, Pahlman L. [1999] Is electrostimulation of the pelvic floor an effective treatment for neurogenic faecal incontinence. *Scan J Gastroenterology* 34(3):319-24.

Filename: KM518-A-C

Date: 2020-04-20

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