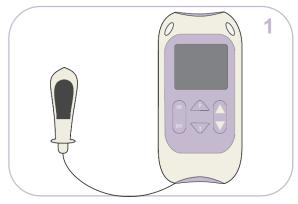
# **Kegel Toner**

## **Pelvic Floor Trainer**

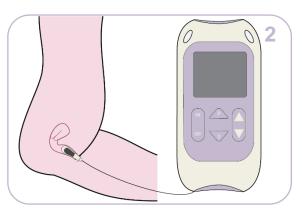




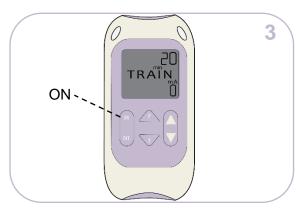
## **QUICKSTART GUIDE**



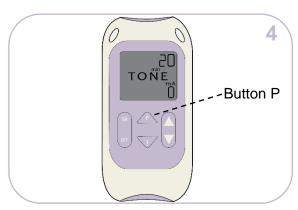
Connect the unit with the **Kegel Trainer** 



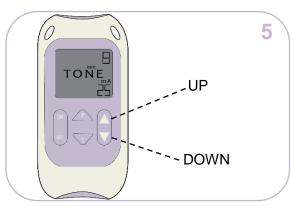
Insert the **Kegel Trainer** 



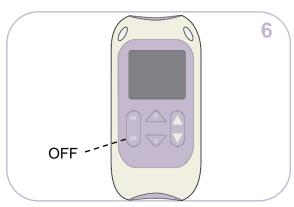
Press and hold the ON button to switch the device on



Select the program by pressing the button P



Regulate the output intensity with the buttons ▲ and ▼



Press and hold the OFF button to switch the device off

Dear Customer,

Thank you for choosing **Kegel Toner**. TensCare stands for high-quality, thoroughly tested products for the applications in the areas of gentle electrotherapy, muscle toning, continence management and pain relief during labour.

Please read these instructions for use carefully and keep them for later use and observe the information they contain.

Best regards,

Your TensCare Team

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#### SYMBOLS USED

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/	! \

Attention! Please follow the instructions in the user's instructions for use.



TYPE BF EQUIPMENT: Equipment providing a degree of protection against electric shock, with isolated applied part. Indicates that this device has conductive contact with the end user.



This symbol on the unit means "Refer to instructions for use".



Temperature Limitation: indicates the temperature limits to which the medical device can be safely exposed.



Lot Number: indicates the manufacturer's batch code so that the batch or lot can be identified.



Humidity Limitation: indicates the humidity limits to which the medical device can be safely exposed.



Serial Number: indicates the manufacturer's serial number so that a specific medical device can be identified.



Do not dispose in household waste.



Catalogue Number: indicates the manufacturer's catalogue number so that the device can be identified.



Atmospheric Pressure: indicates the atmospheric limits to which the medical device can be safely exposed.



Date of Manufacture: indicates the date which the medical device was manufactured. This is included within the serial number found on the device (usually in the battery compartment), either as "E/Year/Number" (YY/123456) or "E/Month/Year/Number" (MM/YY/123456).



This medical device is indicated for home use.



This medical device is not water resistant and should be protected from liquids.

**The first number 2:** Protected against access to hazardous parts with a finger, and the jointed test finger of 12 mm ø, 80 mm length, shall have adequate clearance from hazardous parts, and protected against solid foreign objects of 12.5 mm ø and greater.

**The second number 2:** Protected against vertically falling water drops when enclosure is tilted up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle up to 15° on either side of the vertical.

#### 1. INTRODUCTION

# **Device Description & Principles of Design**

Bladder leakage and incontinence are common problems for both women and men, affecting their long-term health. Exercising the pelvic floor muscles is recognized as the way of preventing and treating symptoms of incontinence and pelvic floor weakness.

The **Kegel Toner** is a powered muscle stimulator used for strengthening the pelvic floor muscles.

It sends a gentle stimulation (similar to your natural nerve impulses) direct to your pelvic floor muscles through a vaginal Trainer with stainless steel electrodes. These signals make your pelvic floor muscle contract. If you have forgotten how to contract your pelvic floor, are having trouble getting muscle response, or simply want to bring back the condition of your pelvic muscles, the Kegel Toner can work them for you to build up their strength and help you to develop your own muscle control. lt perfectly complements pelvic floor exercises.

The **Kegel Toner** is very easy to use, with two preset training programs, two choices of exercise time and simple push button control.

#### 2. INDICATIONS FOR USE

The **Kegel Toner** is intended to provide electrical stimulation and neuromuscular re-

education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress incontinence in women. The **Kegel Toner** is intended for adult women suffering from the involuntary loss of urine when coughing, laughing, sneezing or exercising (known as stress urinary incontinence).

If you leak urine when you cough, sneeze, laugh, strain or make sudden movements, this is called Stress Incontinence.

It is particularly common in women who have had a natural childbirth and occurs when the bladder neck and the other mechanisms that act to hold urine in the bladder are not working properly. The most common cause is a weak pelvic floor.

**Kegel Toner** is not recommended if you ONLY have symptoms of urinary frequency or urgency (using the restroom very frequently or having to rush to the restroom) and have NO symptoms of leakage when coughing, laughing, sneezing or exercising.



**Warning:** Not suitable for use in children without medical supervision.

# 3. KEGEL TONER FEATURES

#### Single Channel

Single channel unit to treat symptoms of urinary incontinence via a vaginal **Kegel Trainer**.

#### • Comfortable Stimulation

Gentle stimulation with fine tune adjustment settings for different levels of intensity, 1 mA per step.

#### • 2 Preset Programs

**TRAIN** for stress incontinence and **TONE** for aftercare.

#### Memory

Features 3 functions: program retention (automatically starts in the last program used), number of uses and time of usage.

#### Treatment Timer

Unit defaults to 20 minutes' treatment to ensure the pelvic floor muscles are not over-worked. The user can manually select a shorter session of 10 minutes if required.

#### • Open Circuit Detection

Automatically resets the strength to zero and flashes **LEADS** if the connection comes loose.

#### Keypad Lock

Manual keypad lock prevents any accidental changes in settings.

#### Large LCD Screen

Clearly shows the operation of the unit and the program and intensity being used.

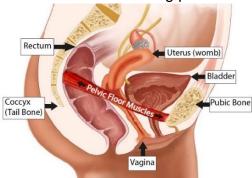
# 4. PELVIC FLOOR EXERCISES

# 4.1. PELVIC FLOOR MUSCLES

The "FLOOR" of your pelvis is made up of layers of muscles that support the bowel, bladder, urethra and uterus. These muscles are like a hammock, or the bottom and sides of a bowl, in shape. They run from the pubic bone in the front to the end of the spinal column (or tail bone) in the back.

The pelvic floor muscles:

- Assist in supporting the abdominal and pelvic organs.
- Work with the abdominal and back muscles to stabilize and support the spine.
- In women, also
  - provide support for the baby during pregnancy and
  - o assist in the birthing process



Pelvic floor muscles are also important for sexual function in both men and women:

- In men, it is important for erectile function and ejaculation.
- In women, voluntary contractions (squeezing) of the pelvic floor contribute to sexual sensation and arousal.

However pelvic floor muscles may become weak. If your pelvic floor muscles become stretched or weakened, your pelvic organs may no longer be fully supported and you may lose control of your bladder or bowel movements.

For some women, the pelvic floor muscles can also become too tight. This condition is less common, but it can lead to pelvic pain and make it difficult for you to empty your bladder or bowel completely.

Common signs that can indicate a pelvic floor problem include:

Accidentally leaking urine when you exercise, laugh, cough or sneeze

- Needing to get to the toilet in a hurry or not making it there in time
- Constantly needing to go to the toilet
- Finding it difficult to empty the bladder or bowel
- Accidentally losing control of the bladder or bowel
- · Accidentally passing wind
- Pain in your pelvic area
- Painful sex, or
- A prolapse

In women, this may be felt as a bulge in the vagina or a feeling of heaviness, discomfort, pulling, dragging dropping. This occurs when one or more of the pelvic organs (bladder, bowel or uterus) become displaced and sag down into the vagina. It is very common in the United Kingdom and occurs in about 40% of women. **Symptoms** tend to become exacerbated towards the end of each day and if left untreated, they will generally worsen over time.

In men, this may be felt as a bulge in the rectum or a feeling of needing to use the bowel but not actually needing to go.

Like other muscles in your body, the pelvic floor can be strengthened with regular exercise. Building pelvic floor strength enables the muscles to better support your pelvic organs, improves your bladder and bowel control and can stop accidental urine, feces or wind leakage.

It can also reduce your risk of prolapse, improve your recovery from childbirth and gynecological surgery, and increase your sexual pleasure. A continence therapist can help you learn how to exercise your pelvic floor.

Doing just a few pelvic floor exercises every day will help to treat bladder weakness or prolapse symptoms, and will help to prevent problems later on.

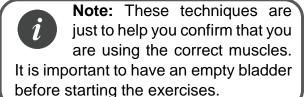
# 4.2. PERFORMING PELVIC FLOOR EXERCISES

It is recommended to make Pelvic Floor Exercises (sometimes called Kegel Exercises) part of your daily life.

- Kegel exercises can be done at any time and are very discreet so you can do them almost anywhere; lying in bed, sitting at the computer or waiting for a bus. It is a good idea to try and develop a routine which you can repeat each day.
- 2) First, it is important to find your pelvic floor muscles and feel them working. So here are a couple of techniques which might help:

Try inserting one or two clean fingers into your vagina and then squeezing the surrounding muscles, lifting up and towards your belly button – a squeezing and lifting sensation.

Another way is to try and stop the flow of urine during urination. If you are successful, then you know you are exercising the correct muscles.



 Try to remember the lifting and squeezing sensation and when you are ready try to recreate it just using the muscles you identified earlier; don't tense the muscles in your legs, stomach or buttocks and remember to breathe normally.

- 4) Aim to hold each squeeze or 'contraction' for three to five seconds, then release and relax. You should feel a 'letting go' of the muscles. Rest for five seconds and then repeat.
- 5) Try and do about ten squeezes in this way.
- 6) Repeat the whole process three or four times a day.
- 7) Over a period of time try to increase the muscle contractions up to about ten seconds, but remember to rest in between each squeeze for longer periods.

Note: It is important to aim for quality contractions, not quantity, so a few good hard squeezes are better than a series of weak ones.

Do not worry if you find holding for 3 seconds difficult at first. Just squeeze for as long as you feel comfortable to do so. The more exercise you do, the stronger the muscles will become and the longer you will be able to squeeze.

8) Using your Kegel Toner pelvic floor stimulator in conjunction with Kegel exercises will give you a better understanding of how they work and how to get the greatest benefit from them.

## 5. HOW 'EMS' WORKS

E.M.S. stands for Electrical Muscle Stimulation and has successfully been used in medical rehabilitation and training in competitive sports. EMS produces intensive and effective muscular contraction.

In rehabilitation, EMS is a wellestablished method for treatment of a broad field of musculoskeletal diagnoses as well as pelvic floor weakness. Electrical stimulation of an intact peripheral nervous system may create motor responses in patients with impaired or lost ability for voluntary muscle activity.

EMS is a complement to other physical therapy and should always be combined with active training such as Kegel exercises (see section 4.2.).

#### **Advantages of EMS**

Use of EMS may lead to faster progress in the patient's treatment program. The method is simple and appropriate for treatment in the clinical setting as well as for self-treatment at home.

#### **How EMS Works**

Electrical Muscle Stimulators can play a vital role in educating women and men about their pelvic floor and the sensation they should feel when doing pelvic floor exercises. Electrical Pelvic Floor Exercisers (PFE) offer a noninvasive method of producing contraction of muscles via a gentle stimulation to the pelvic floor through a discreet trainer. This current then passes into the nerve fibres controlling that part of the muscle stimulating it to contract. So, electrical stimulation (EMS) artificially activates a muscle for you enabling you to develop your own muscle control. These contractions exercise the muscles and, as with any kind of exercise if performed regularly, build strength and tone.

In urge incontinence, pelvic floor exercisers work in a slightly different way. The electrical stimulation is designed to soothe your bladder muscles rather than exercise your pelvic floor. **Kegel Toner** uses a gentler, low frequency setting which promotes release of endorphins and reduces involuntary contractions of the bladder (detrusor) muscle.

Different frequencies have different effects; low frequencies (1-10 Hz) coupled with long impulse times, for example, have a purifying and relaxing effect through individual contractions, whereby the circulation in the treated muscle is simultaneously improved and removal of metabolic end products is supported (lymphatic drainage).

In contrast, by means of a rapid succession of contractions (fibrillation), medium frequencies (20-50 Hz) can put a high level of strain on the muscle, thus promoting the muscular structure.

Each preset program has a specific frequency and pulse width that will offer the best results for the type of incontinence treated.

# 6. CONTRAINDICATIONS, WARNINGS & PRECAUTIONS

#### In this manual:

A **Warning** is used when failure to follow the instructions may result in serious injury or death.

A **Caution** is used when failure to follow the instructions may result in a minor or moderate injury, or damage to the device or other property.



**Notes** are used to provide clarification or recommendation.

#### CONTRAINDICATIONS:

- **Do not use** if you are pregnant
- Do not use if you are attempting to become pregnant
- Do not use if you have a cardiac demand pacemaker or implanted defibrillator
- Do not use if you have symptoms of active urinary tract infection, vaginal infections, or localized lesions
- Do not use if you have a diagnosis of extra-urethral or overflow incontinence
- Do not use if you have severe urine retention
- Do not use if you have poor sensation in the pelvic region
- Do not use if you have cognitive disabilities, i.e.; Alzheimer's disease or dementia
- Do not use if you are unable to properly insert the Trainer
- Do not use if you have active pelvic cancer
- Do not use if you have an intestinal clamp
- You must be 6 weeks post pelvic surgery or vaginal childbirth to use this device
- Do not use this device for diagnostic purposes or critical patient monitoring
- This device is not (external) defibrillator-proof

#### **WARNINGS:**

Warning: The Kegel Trainer is intended for single patient use only. Do not share your Kegel Trainer with anyone else. Improper treatment or cross-infection may occur.

Warning: The device should not be used while walking, driving, operating machinery, or any other activity in which involuntary muscle contraction may put you at risk of injury.

Warning: If you have active cancer, consult with your clinician before use due to concerns for stimulation potentially spreading cancerous cells.

Warning: Caution should be used if you have suspected or diagnosed heart problems because stimulation devices can affect heart rhythm in certain circumstances.

Warning: Caution should be used if you have suspected or diagnosed epilepsy as unexpected seizures may impair usage.

Warning: Caution should be used if you have a bleeding disorder as stimulation increases blood flow to the stimulated region.

#### **CAUTIONS:**

Caution: Read all instructions before use. Failure to follow these directions may result in personal injury or damage to the equipment.

Caution: Do not use a Kegel Toner device that appears to be damaged. Using a damaged device may result in personal injury.

Caution: If tissue irritation occurs, discontinue treatment immediately. Ask your care provider for advice before continuing further treatment to prevent injury.

Caution: Kegel Toner is intended for indoor use only

because it is an electronic device.

**Caution:** Only use recommended cleaning solutions that leave no residue to prevent irritation or infection. Do not soak as this could damage the device.

Caution: It is important that the Trainer is cleaned after each use. Ineffective cleaning may lead to irritation or infection.

Caution: Never insert or remove **Kegel Trainer** unless the control unit is powered OFF as insertion or removal when stimulation is active may cause discomfort or tissue irritation.

Caution: Do not use a silicone-based lubricant on the stimulation contacts as it may decrease the effectiveness of **Kegel Toner**'s muscle stimulation.

Caution: Caution should be used if you have total/partial prolapse of the uterus/vagina.

Caution: The long-term effects of chronic muscle stimulation are unknown.

**Caution:** Skin irritation and burns beneath stimulation contacts have been reported with the use of powered stimulators.

Caution: Do not use the device in water because it is an electronic device and use in water may cause patient injury.

Caution: Do not operate device within 10 feet of operating televisions, arc welders, radio thermal treatment equipment, X-ray machines, MRI machines, or any other equipment that produces magnetic fields, sparks, or radio

transmissions, RF communication equipment can affect this device.

Caution: The stainless steel in the Trainer electrodes contains some Nickel. This could cause a reaction if you have a Nickel allergy.

#### **KEGEL TRAINER CAUTIONS:**

- Caution: The Kegel Trainer is intended for single patient use only. Do not share your Kegel Trainer with anyone else. Improper treatment or cross-infection may occur.
- Caution: It is important that the Kegel Trainer is cleaned after each use. Ineffective cleaning may lead to irritation or infection.
- Caution: Never insert or remove Kegel Trainer unless the control unit is powered OFF as insertion or removal when stimulation is active may cause discomfort or tissue irritation.
- Caution: If tissue irritation occurs, discontinue treatment immediately. Ask your healthcare professional for advice before continuing further treatment to prevent injury.
- Caution: Do not use a siliconebased lubricant on the metal plates of the **Kegel Trainer** as it may decrease the effectiveness of **Kegel Toner**'s muscle stimulation.
- Caution: The stainless steel in the Kegel Trainer's metal plates contain some Nickel. This could cause a reaction if you have a Nickel allergy.
- Use with **caution** if you have a copper IUD. If discomfort occurs, discontinue treatment

immediately and ask your healthcare professional for advice. There is a small risk of stimulating the uterine wall if the IUD is not correctly positioned.

Caution: Do not use this device with Kegel Trainer other than those recommended by the manufacturer in section 13. Electrodes with smaller surface area may cause tissue irritation.

# TO KEEP YOUR DEVICE IN GOOD WORKING ORDER, OBSERVE THE FOLLOWING ADDITIONAL CAUTIONS:

- Do not use this device with a leadwire or Trainer other than those recommended by the manufacturer in section 13.
- Do not immerse your unit or Trainer in water or place it close to excessive heat as this may cause it to cease to operate correctly.
- **Do not** attempt to open up the unit. This may affect the correct operation of the unit and will invalidate the guarantee.
- Do not mix old, new or different types of batteries as this may lead to battery leakage or low battery indication.
- Caution: Temperature & Relative Humidity of storage: -20°C to +40°C, 8% to 70% R.H. Temperature & Relative Humidity of transportation: -20°C to +40°C, 8% to 70% R.H.

#### 7. PROGRAMS

#### 7.1. PROGRAM SETTINGS

Prog	TRAIN	TONE
Freq. (Hz)	50	35
Pulse width (µs)	300	250
Ramp Up & Down (s)	1	2
Plateau (s)	5	3
Rest (s)	10	6
Default duration (min)	20	20

#### 7.2. PRESET PROGRAMS

The **Kegel Toner** has two preset programs. One to treat stress incontinence (**TRAIN**) and one aftercare program to tone the pelvic floor muscles (**TONE**).

#### STRESS INCONTINENCE:

Shown on the screen as: TRAIN

The **TRAIN** program strengthens the muscles of the pelvic floor using gentle stimulation. Once these muscles are stronger they are better able to resist urinary leakage caused by external pressure being applied to the bladder such as with a cough, sneeze or physical exertion.

The stimulation causes the muscles to contract and work. This builds their strength.

Like any exercise this takes time to show results. Successful treatment requires use once a day for one to three months. You may notice an improvement after about four weeks. It helps to keep a diary of leakage problems so that you can measure this improvement.

#### **AFTERCARE:**

Shown on the screen as: TONE

Having restored your pelvic floor muscles to an excellent condition you will want to keep them toned and strong. Regular use of this program, about twice a week, will ensure that your muscles remains fit and toned.

The **TONE** program may also be used as an alternative treatment for **TRAIN**.

#### 8. CONTENT

The pack contains:

- 1 x **Kegel Toner** continence stimulator unit
- 1 x Lead wire (L-CPT)
- 1 x Liberty **Kegel Trainer** (X-VPK)
- 2 x AA 1.5V alkaline batteries
- 1 x Storage pouch



### 9. UNIT INFORMATION

## 9.1. CONTROLS & DISPLAY



### 9.2. OPERATING **INSTRUCTIONS**

#### ON/OFF



To turn the unit on, press the ON button and hold for 3 to 5 seconds until the display shows.

To turn the unit off, press ▼ button to remove keypad lock and press the OFF button and hold for 3 to 5 seconds until the display stops.

At first use, or after changing batteries, the display shows that the unit is automatically set in program TRAIN at zero strength.

When switched on the unit will automatically start in the program which was being used when it was last switched off.

The strength returns to about 50% of the level that was being used when the unit was switched off. This simplifies start up dramatically.

During start up to stop the increase in strength at any time, press any key once.

The unit will turn off automatically:

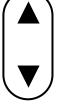
- When the Timer reaches zero,
- If it is left at zero strength for more than 5 minutes.



Note: Always check unit is OFF before applying or removing Kegel Trainer.

The backlight will turn off 10 seconds after the last button press.

#### STRENGTH CONTROLS



The buttons marked ▲ and ▼ are the strength controls.

To increase strength, press and hold down the button A until required strenath achieved.

To decrease the strength, press and release the button ▼.

To increase strength in steps of 1 mA, press and release the button .

The unit will remain in the WORK part of the cycle for 5 seconds while intensity is being adjusted.

The strength levels are shown on the LCD.

The strength control buttons will not operate until the unit is properly connected to you (Kegel Trainer inserted correctly). Kegel Toner disconnection detects а automatically returns the strength to zero.

The unit has 99 levels of strength. If you hold down the button ▲ for 3 to 5 seconds, the strength will start scrolling.

You may feel nothing over the first few presses. Continue pressing until the sensation is strong but comfortable. Further increases during use may be necessary if your body becomes used to the sensation.

The yellow LED on the output socket indicates that there is an active output. The display will remain on for 5 seconds after the plug is removed.

#### PROGRAM CONTROL



The button marked **P** is the program control. The Kegel **Toner** has two preset programs. At first use, the unit automatically goes to program **TRAIN**. Next time it is switched on, it will default to the program used last.

Each time you press and release the **P** button, the program changes and is shown on the LCD.

Each time you change the program, the strength level reverts back to zero. This is a safety feature to alleviate any sudden feeling of a surge, as each program gives a different sensation.

The LOCK BUTTON can be used to lock all controls except for the strength down ▼ and OFF buttons. To activate, press and hold down the P button for at least 5 seconds until the lock icon is displayed on the screen. To deactivate, press and hold down the P button for at least 5 seconds until the lock icon is no longer displayed on the screen and is replaced by the programme you are using.

#### TREATMENT TIMER

T Each time you switch on the **Kegel Toner** the length of time of your program will automatically revert to 20 minutes.

During use the unit counts down the minutes which are shown on the screen. On reaching zero the unit will switch off.

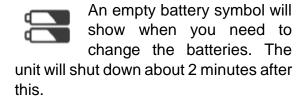
By pressing and releasing the **T** button you can manually override and select a shorter treatment time of 10 minutes. You may wish to use this during your early training sessions.

The length of time that you have selected will be shown on the screen. The minutes will start to count down once you start the program.

If you hold down this key for 5 seconds, you can PAUSE the timer, allowing you to interrupt the treatment session, and resume it later. Press and release the **T** button to resume the session.

Return to main screen by pressing any other key.

#### **LOW BATTERY**



#### **LEADS ALARM**

The **Kegel Toner** monitors the connection and the contact between you and the **Kegel Trainer**, or the pads. This is to prevent sudden changes if a broken connection is re-made. If either of these goes outside of a standard range while the strength is above 20, the unit will flash **LEADS**, bleep three times, and return the strength to 0.

Check the lead and if necessary, lubricate the **Kegel Trainer** with a water-based lubricant. Please see section 15 for more troubleshooting tips.

#### **MEMORY**

The **Kegel Toner** has a Memory with three functions:

1) Program Retention. When you switch the unit on, it will automatically start in

the program which was being used when it was switched off.

2) Usage. Press **T** and **▼** together and hold down for 3 to 5 seconds. The display will show the number of times the unit has been used and the duration of use in hours.

Press the same buttons again to return to normal controls.

3) Memory Reset. To reset memory to zero, hold down the **T** and **OFF** buttons together for 3 to 5 seconds.



# 10. SETTING UP AND USING THE KEGEL TONER

# 10.1. INSTALLATION OF BATTERIES

1) Remove battery cover by pulling on tag.

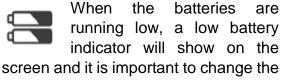


2) Insert batteries.

Ensure that the batteries are inserted the right way as shown in battery compartment and that the ribbon is behind them.



3) Replace battery cover.



batteries as soon as possible.

#### Rechargeable batteries

The unit will work with rechargeable batteries, but the display may appear dim.

#### Storage

Remove batteries from your **Kegel Toner** if the unit is unlikely to be used

for a long period. Some types of batteries may leak corrosive fluid.

#### **Battery Life**

Batteries should last about 18 hours at full power.

Unused batteries have a nominal shelf life of 3 years, but will usually last longer than this.

#### **Battery Warnings**

**Do NOT** pierce, open, disassemble, or use in a humid and/or corrosive environment.



**Do NOT** expose to temperatures over 60°C(140F).

Do NOT put, store or leave near sources of heat, in direct strong sunlight, in a high temperature location, in a pressurized container or in a microwave oven.



**Do NOT** immerse in water or sea water, or get wet.



Do NOT short-circuit.



**Do NOT** connect the device unless the battery cover is in place.

If battery leakage occurs and comes in contact with the skin or eyes, wash thoroughly with lots of water.

Keep batteries out of the reach of small children.

**Caution** NEVER attempt to recharge an alkaline battery. Risk of explosion.



Caution Do not mix old, new or different types of batteries as this may lead to battery leakage or low battery indication.

**Disposal:** Always dispose of batteries responsibly according to local government guidelines. Do not throw batteries onto a fire. Risk of explosion.

# 10.2. CONNECTING LEAD WIRE

Insert the lead wire plug into the base of the unit.

Connect the lead from the base of the unit to the lead in the Kegel Trainer.



Push the pin ends firmly into the pigtail ends of the **Kegel Trainer** lead.



The lead wires may be damaged by rough handling and should be treated with care.

#### Lead wire colour coding.

The ends of the lead wire are colored black or red. This coding is provided for some professional uses. For most purposes, the orientation makes no difference, and you can ignore this color coding.

## 10.3. PREPARING **SESSION**

**FOR** 

- 1) Before using **Kegel Toner** you will need to visit the toilet.
- 2) Lubricate the metal electrode surfaces and Kegel Trainer tip with a water-based lubricant, such as TensCare Go Gel or water.

Caution: Do not use a siliconebased **lubricant** on the stimulation contacts as it may decrease the effectiveness of the **Kegel Toner**'s muscle stimulation.

3) Choose a comfortable position, such as lying down on your bed on your side with your knees raised.



Warning: Ensure the Kegel **Toner** is switched OFF before inserting the **Kegel Trainer**.

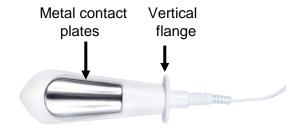
4) After wires are securely connected, insert the Kegel Trainer into the vagina, in the same way as a tampon, with the two silver plates side to side: one plate on left and the other on the right, until only the flange at the end is visible. The **Kegel Trainer** will naturally position itself with the widest part of the flange vertically.



5) The metal parts conduct the electrical pulse and should be in contact with the main part of the muscle at all times. The tissues close to the entrance are more sensitive. so you should avoid stimulating them.



**Note:** The flange should not be inserted into the vagina and should remain outside of the vagina at all times.



#### 10.4. TRAINING SESSION

- 1) Press and hold the **ON** button on the control unit for 3 to 5 seconds to switch the control unit on.
- 2) You can select from the two preset programs. Details in section 7 will help you identify the best program to suit you.
  - To change between the programs, press the program selector, which is labelled **P**, in the center of the control unit keypad.
- 3) With the required program selected, you can adjust the intensity of the muscle stimulation until you reach a comfortable level. Once you have reached a comfortable level, 5 seconds after you stop pressing the button, the intermittent work/rest phase will start. The machine will take itself to 0 mA for a rest period and then take itself back up to the level of intensity you chose, to work the muscle. This cycle will continue for the 20 minutes of the program.

Note: The strength required varies widely between users some will use the Kegel Toner at full power – 99 mA. The **Kegel Toner** strength will go up at 1 mA increments.

Initially the sensation through the **Kegel** Trainer may be limited but will improve during treatment. Take care not to use too much strength and thereby over stimulate the muscles until normal sensation is restored. The sensation may not be even as it may vary depending on the sensitivity of the nerves.

The LCD display shows the strength of intensity used. The aim is to increase this over a few days. But remember there is no hurry, so only increase the strength of the stimulation as and when you are comfortable and ready to progress.



**Note:** If the sensation becomes uncomfortable, reduce the intensity using the button ▼.

When switched on, in TRAIN and **TONE** programs the unit will go through an exercise program for 3-5 seconds. followed by a rest period of 6-10 seconds. The Kegel Toner causes a sensation which feels like a strong drawing in of the vagina and pulling up of the pelvic floor. The natural reaction will be to pull in and up with the muscles.

At lower strength settings, you may not feel any sensation at all, this depends very much on the individual and any pre-existing physical conditions, increase the intensity repeatedly pressing the **\( \Delta\)** button until you begin to feel the muscles around your vagina contract.

For best results in these programs try to contract the pelvic floor muscles along with the **Kegel Toner**, and to sustain the contraction into the rest interval. If possible, link the contraction to your breathing to get into a gentle rhythm.

Increase the strength as high as it is comfortable, and then take it back down one step.

The strength display on the control unit will reduce to 0 and flash during the rest period.

The length of each session is automatically set to 20 minutes. The length of each session for muscle strengthening will also depend on your ability to contract and your resistance to fatigue. Be careful not to overuse early on, as the resulting aches may not be felt until the next day.



lf Note: you experience cramping, switch the unit off until the symptoms go away then continue the session with the intensity set at a lower level.

### 10.5. AFTER YOUR TRAINING **SESSION**

When the timer reaches zero, your session is complete, and the unit turns off.

1) Check that the control unit is off. If it is not, hold down the OFF button to switch off then remove the Kegel Trainer from your vagina by holding the positioning end rim and gently pulling outwards.

If you are using the pointer, detach this first before removing the **Kegel Trainer**.

- Wash and thoroughly dry the Kegel Trainer and return it to the storage pouch.
- 3) The **Kegel Toner** will not only improve your pelvic floor muscles but also help you to recognise the correct sensation you need to feel when doing your Kegel exercises (explained in section 4.2.).



**Note:** When removing the **Kegel Trainer**, DO NOT PULL ON THE LEAD WIRE.

#### 11. CLEANING

It is important that the **Kegel Trainer** is cleaned after each use. Clean with either an alcohol-free antibacterial wipe or by wiping with warm soapy water. Rinse and dry thoroughly and return the unit to the storage pouch. Do not immerse the **Kegel Trainer** in a liquid.

Clean the case of the unit and lead wire at least once a week using the same method.

- Do not immerse your Kegel Toner unit in water.
- Do not use any other cleaning solution.

# 12. DISPOSAL OF WASTE ELECTRICAL AND ELECTRONIC PRODUCTS

At the end of its life, please dispose of your **Kegel Toner** responsibly.

Anything electrical or electronic should not be treated as domestic waste and simply thrown away. About half of the states currently have laws on disposal and recycling of electronics.

The Environmental Protection Agency makes recommendations for safe disposal of electronic waste on:

http://www.epa.gov/epawaste/conserve/materials/ecycling/index



#### 13. ACCESSORIES

#### **Expected Service Life**

- The machine will often last for more than 5 years but is warrantied for 2 years. Accessories (lead wire, Kegel Trainer, and batteries) are not covered by the warranty.
- Lead life depends greatly on use. Always handle the leads with care. We recommend to replace the lead wires regularly (about every 6 months).
- Replace the **Kegel Trainer** every 6 months to ensure hygiene.
- AA alkaline batteries should last about 18 hours of continuous use.

Replacement vaginal trainers, new batteries and lead wires are available from your supplier or distributor (see back cover for contact details), by mail order from TensCare, by telephone using a credit or debit card, or through the TensCare website.

The following replacement parts may be ordered from TensCare at www.tenscare.co.uk or +44(0) 1372 723434.

X-VPK Liberty **Kegel Trainer** (28

mm dia.)

L-CPT Replacement lead wire,

1.25 m length

B-AA 1.5V AA batteries

X- BL-PTT Replacement battery

cover

Note: You should only use the Kegel Trainer supplied with the unit or the replacements above as performance may vary with other electrodes.



**Warning:** Do NOT use silicone based or hybrid (mixed water and silicone) lubricants.

#### 14. WARRANTY

This warranty refers to the unit only. It does not cover to the vaginal trainer, battery, or the lead wires.

## PRODUCT INFORMATION

WARRANTY

This product is warranted to be free from manufacturing defects for 2 years from date of purchase.

This warranty is void if the product is modified or altered, is subject to misuse or abuse; damaged in transit; lack of responsible care; is dropped; if incorrect battery has been fitted; if the unit has been immersed in water; if damage occurs by reason of failure to follow the written instruction booklet enclosed; or if product repairs are carried out without authority from TensCare Ltd.

We will repair, or at our option replace free of charge, any parts necessary to correct material or workmanship, or replace the entire unit and return to you during the period of the warranty. Otherwise, we will quote for any repair which will be carried out on acceptance of our quotation. The benefits conferred by this warranty are in addition to all other rights and remedies in respect of the product, which the consumer has under the Consumer Protection Act 1987.

Our goods come with guarantees that cannot be excluded under the UK consumer Law. You are entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality.

#### Before you send your unit for service

Before sending in your unit for service, please take a few minutes to do the following:

Read your manual and make sure you follow all the instructions.

#### Returning your unit for service

Should repair be needed within the warranty period, enclose the tear off section of the warranty card (see page 29) and your proof of purchase receipt. Please ensure all relevant details are completed before sending your unit in

for service. Please ensure your contact details are still current and include a brief description of the problem you are experiencing together with your purchase receipt.

For hygiene reasons, please do not include used probe (trainer). Send only the unit and the lead wire.

## Please return the unit and warranty card (see page 29):

#### **TensCare Ltd**

PainAway House, 9 Blenheim Road, Longmead Business Park, Epsom, Surrey KT19 9BE, UK

Should you require any further information please do not hesitate to contact us by calling our number:

+44 (0) 1372 723 434.

## 15. TROUBLESHOOTING

If your **Kegel Toner** is not working properly, please check the following:

Problem	Possible causes	Solution		
No display	Flat batteries.	Replace batteries.		
	Batteries inserted incorrectly.	Remove plastic wrap		
		Check + /		
	Damaged springs in battery compartment.	Contact supplier.		
Low battery display	Low batteries.	Replace batteries.		
Controls won't work	Keypad is locked.	If the lock icon is shown on display. Press and hold the <b>P</b> button for at least 5 seconds.		
		If no LOCK is showing, remove and replace the batteries.		
No sensation and LEADS alarm showing	The <b>Kegel Toner</b> has a safety feature which will not allow the intensity to pass 20 mA if the machine detects a connection error. If a connection error is detected the intensity will return to 0 mA and the screen will flash <b>LEADS</b> . This safety feature will prevent the machine from giving any uncomfortable stimulation should the contact break between the machine and your skin. This will also prevent anyone from increasing the intensity to a high level without firm contact between the machine and the skin.  A connection error can occur if:			
	1. A break has developed within one of the two lead wires.	If this happens, you can try to test the unit by holding the <b>Kegel Trainer</b> in your hand:  i) Dampen your hand with water and a little table salt. Squeeze the <b>Kegel Trainer</b> firmly and make sure your skin is covering the metal parts of the <b>Kegel Trainer</b> and carefully increase strength until you can feel something. Most people will start to feel the stimulation in their hand at around 25 mA.  ii) If the <b>LEADS</b> alarm shows and the unit will not allow you to pass 20 mA. The lead wires need to be replaced.		
	If you have tried the test above and DO have sensation when the <b>Kegel Trainer</b> is in your hand, then it may be that:  2. The skin is dry, meaning poor conductivity between	<ul> <li>If this happens, you can try the below solutions:</li> <li>i) Using a water-based lubricant), which will improve conduction.</li> <li>ii) Crossing your legs and squeezing to increase pressure on the <b>Kegel Trainer</b>, which should improve the connection. If this enables you to use the unit, you should find</li> </ul>		

	the metal plates on the <b>Kegel Trainer</b> and your skin.	that in a few weeks of stimulation the contact improves. If it does not, this unit may not be suitable for you. You may need to contact your healthcare professional to discuss other suitable options.  iii) The <b>Kegel Trainer</b> supplied with the unit has a 28 mm diameter. An optional 32 mm <b>Kegel Trainer</b> , part no. <b>X-VPM</b> , is available.
No sensation and no LEADS alarm showing	Intensity level is not high enough and/or reduced sensitivity in the area being treated.	<ul> <li>i) Please make sure you are increasing the intensity high enough. Most people will start to feel the stimulation in their hand at around 25 mA and with the <b>Kegel Trainer</b> inserted you will need to increase the intensity higher to around 40 mA – 60 mA. Max power is 99 mA. Everyone is different so just keep increasing the intensity until you can feel it. The intensity increases in very small steps of 1 mA.</li> <li>ii) You may have reduced sensitivity due to previously damaged or desensitized pudendal nerves (this can happen in childbirth or some surgical procedures). Please consult your healthcare professional.</li> </ul>
No sensation on one side of the Kegel Trainer (or electrode)	Position is not optimal – needs adjusting.	The current flows from one side of the <b>Kegel Trainer</b> to the other, so it is not possible to have one side "not working". However, the strength of the sensation depends on how close to the nerve the current flows, and also in which direction it flows relative to the nerve. You can try slightly adjusting the position on the <b>Kegel Trainer</b> , or exchanging the connection of the wires in the <b>Kegel Trainer</b> .
Sudden change in sensation	If you disconnect and reconnect a few minutes later, the signal will feel quite a lot stronger.	Always return strength to zero after disconnecting the lead or the <b>Kegel Trainer</b> .

The patient is an intended operator. There are no user-serviceable parts inside the unit, and no calibration is required.

If the above review has failed to resolve your problem, or to report unexpected operation or events, call TensCare or your local dealer (address on back cover) for advice.

Contact TensCare customer service on +44 (0) 1372 723 434. Our staff are trained to assist you with most issues you may have experienced, without the need to send your product in for service.

## 16. GENERAL SPECIFICATION

Waveform	Asymmetrical rectangular
Amplitude	99 mA
(over 500 Ohm load)	+/- 10%
Max intensity	50V zero to peak
	Constant voltage over 470-1500 Ohm
	Constant current over 160-470 Ohm
Output plug	Fully shielded
Channels	Single channel
Batteries	2 x AA alkaline (two AA batteries) or 2 x AA NiMH
Weight	75 g without batteries
Dimensions	120 x 60 x 20 mm
Safety Classification	Internal power source.
Environmental Specifications	:
Operating:	Temperature range: 5 to 40°C
<u>*</u> _	Humidity: 15 to 93% RH non-condensing
	Atmospheric pressure: 700hPa to 1060hPa
Storage:	Temperature range: -25-+70°C
	Humidity: Up to 93% RH non-condensing
<del>•••</del>	Atmospheric pressure: 700hPa to 1060hPa
TYPE BF	Equipment providing a degree of protection against
EQUIPMENT \(\Lambda\)	electric shock, with isolated applied part.
	Designed for continuous use.
	This symbol on the unit means "Refer to Instructions for
	Use"
IP22	The unit is not water resistant, and should be protected
	from liquids.
	Complies with EU WEEE regulations
Applied Part	Vaginal electrodes. See section 13.

Contact duration: At least 10 minutes.



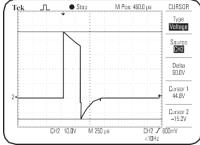
**Note:** The electrical specifications are nominal and subject to variation from the listed values due to normal production tolerances of at least 5%.

#### **Device output parameters**

The waveform below demonstrates a typical output waveform form the **Kegel Toner** device:

Max Pulse Energy: 23 C

Use special precautions regarding EMC according to the information provided below. Other portable and mobile RF communications equipment can affect performance. Do not use when adjacent or stacked with other electrical equipment.



#### 17. EMC

Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d = 3,3 m away from the equipment.

(Note. As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d = 3,3 m at an IMMUNITY LEVEL of 3 V/m).

Use special precautions regarding EMC according to the information provided below.

- Other portable and mobile RF communications equipment can affect performance.
- Do not use when adjacent to or stacked with other electrical equipment.
- Use of leads or probes other than those listed in section 13 may affect EMC performance.



Note: For hospital use, full EMC advice tables are available on request.

#### PLEASE RETAIN THIS WARRANTY CARD.

RETURN THIS PORTION ONLY WHEN YOU RETURN YOUR PRODUCT FOR REPAIR UNDER WARRANTY.

NAME:
ADDRESS:
POSTCODE:
DAYTIME TELEPHONE:
E-MAIL:
MODEL:
DATE OF PURCHASE:
ATTACH PROOF OF PURCHASE  DO NOT SEND IN KEGEL TRAINER
RETAILERS NAME:
RETAILERS ADDRESS:
RETAILERS POSTCODE:
BRIEF DESCRIPTION OF PROBLEM YOU ARE EXPERIENCING:

WARRANTY IS VOID UNLESS THE ABOVE INFORMATION IS COMPLETED AND CORRECT.



## **Notes**

TensCare aim to give you the best possible product and service. We listen to your suggestions and are constantly trying to improve our products. We also want to learn about the way our products are used, and the benefits they give. If you have anything you would like to share with us, please contact:

#### www.tenscare.co.uk

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#### **EC Declaration of Conformity**

TensCare Ltd hereby declare that an examination of the production quality assurance system has been carried out following the requirements of the UK national legislation according to Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0088 marking on this product.

## Distributed by:





Manufactured by:

TensCare Ltd, 9 Blenheim Road, Epsom, Surrey KT19 9BE, UK Tel: +44(0) 1372 723434 www.tenscare.co.uk

