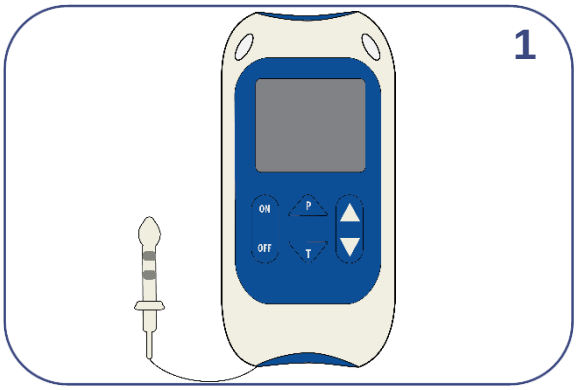
perfect PFE

INSTRUCTIONS FOR USE

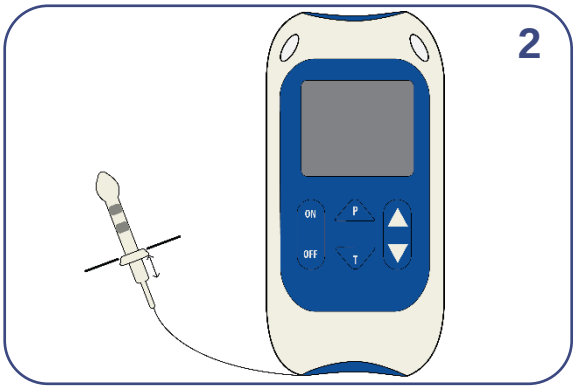
READ CAREFULLY BEFORE USE

TensCare™

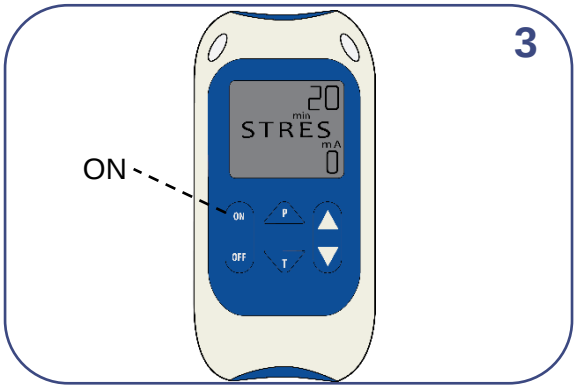
QUICKSTART GUIDE



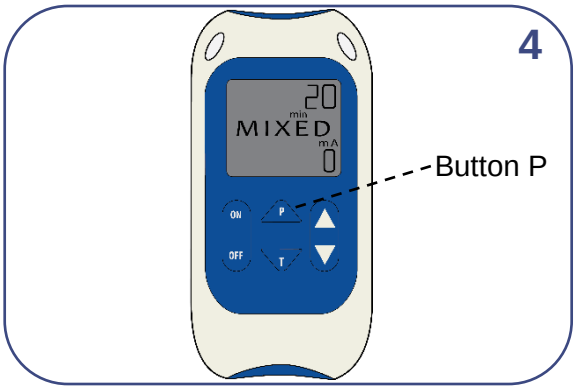
Connect the unit to the anal probe



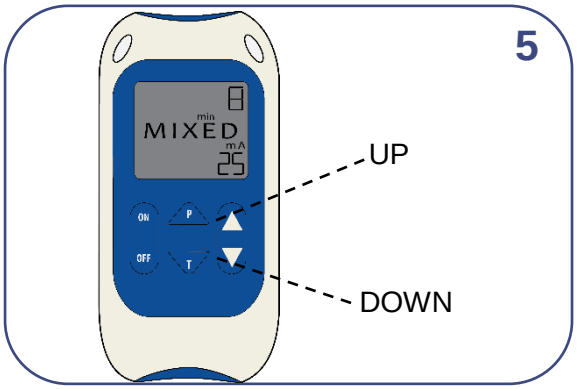
Insert the anal probe until the base of the flange touches the anus
You can adjust the position of the flange



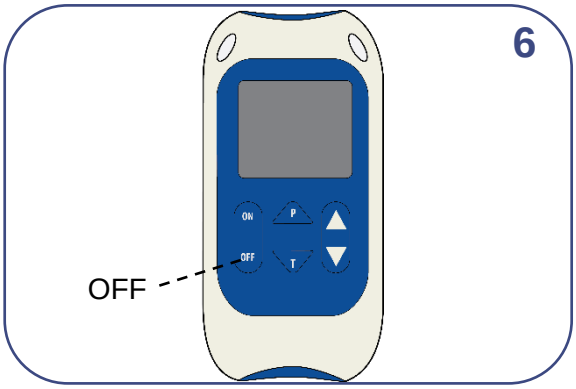
Press and hold the ON button to switch the device on



Select the programme 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 **perfect PFE**. 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

Contents

SYMBOLS USED

	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	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.
S/N	Serial Number: indicates the manufacturer's serial number so that a specific medical device can be identified.
	Do not dispose in household waste.
REF	Catalogue Number: indicates the manufacturer's catalogue number so that the device can be identified.
	This medical device is not water resistant and should be protected from liquids.
	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.
IP22	**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 recognised as the way of preventing and treating symptoms of incontinence and pelvic floor weakness.

The **perfect PFE** 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 an anal probe with stainless steel electrodes or with optional electrode pads. These signals make your pelvic floor muscles contract. If you have forgotten how to contract them, are having trouble getting muscle response, or simply want to bring back the condition of your pelvic floor muscles, the **perfect PFE** can work them for you to build up their strength and help you to develop your own muscle control. It perfectly complements pelvic floor exercises. The **perfect PFE** is very easy to use, with four clearly labelled preset training programmes, a fifth programme for chronic pelvic pain and a simple push button control.

The **perfect PFE** provides relief from conditions such as:

- **Urinary and faecal incontinence:** including stress, urge and mixed types as well as post prostatectomy urinary incontinence in men. Additionally, it may help improve sexual intimacy by toning the pelvic floor muscles.
- **Chronic prostatitis/chronic pelvic pain syndrome:** unexplained chronic pelvic pain associated with irritative voiding symptoms and/or pain located in the groin, genitalia, or perineum in the absence of pyuria and bacteriuria.
- **Treatment of erectile dysfunction in men** and improvement of pelvic strength.

Also, can be used for non-medical purposes to:

- maintain a healthy bowel movement
- achieve a more satisfying erection
- improve rectal sensation for enhanced pleasure
- improve pelvic strength

2. INTENDED USE

Perfect PFE is a medical device designed to be used in the home healthcare environment to treat symptoms of urinary and/or faecal incontinence and to treat erectile dysfunction and is suitable for use by all who can control the device and understand the instructions.

Perfect PFE may help to relieve symptoms of chronic prostatitis/chronic pelvic pain.

Do not use the device for any purpose other than this intended use.

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

3. PERFECT PFE FEATURES

- **Single Channel**

Single channel unit to treat symptoms of urinary and faecal incontinence via an anal probe with adjustable depth.

- **Comfortable Stimulation**

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

- **5 Preset Programmes**

EMS programmes including **STRES**, **URGE**, **MIXED** and **TONE** aftercare; and additional TENS programme providing relief from prostatitis pain and pelvic pain.

- **Memory**

Features 3 functions: programme retention (automatically starts in the last programme 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 reset this (Continuous, 10, 20, 30, 45, 60 or 90 mins).

- **Open Circuit Detection**

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

- **Automatic Keypad Lock**

Automatic keypad lock prevents any accidental changes in settings.

- **Large LCD Screen**

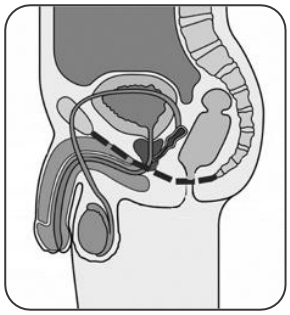
Clearly shows the operation of the unit and the programme and intensity being used.

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 stabilise and support the spine.

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

- In men, it is important for erectile function and ejaculation.

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.

Pelvic floor muscles can be made weaker by:

- Certain treatments for prostate cancer (surgery, radical prostatectomy or transurethral resection of the prostate TURP);
- Constipation;
- Being overweight;
- Heavy lifting;
- Coughing that goes on for a long time (such as smoker's cough, bronchitis or asthma); or
- Not being fit.

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 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, faeces or wind leakage.

Men with stress incontinence – that is, men having bladder leakage when they cough, sneeze or are active – will find pelvic floor muscles training can help in getting over this problem.

Pelvic floor muscles training may also be of use for men who have an urgent need to pass urine more often (called urge incontinence).

Men who have problems with bowel control might find that training their pelvic floor can help the muscle that closes the back passage. This muscle is one of the pelvic floor muscles.

It can also reduce your risk of prolapse, improve your recovery from urology 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.

1) 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 is a technique which might help:
   Try to stop the flow of urine during urination. If you are successful, then you know you are exercising the correct muscles.

Note: This technique is just to help you confirm that you are using the correct muscles. It is important to have an empty bladder before starting the exercises.

Pelvic floor exercises can be done anywhere and anytime. You can perform them standing, squatting or lying down but at first you may find it easier to do the exercises sitting down:

- Sit on a chair, toilet seat or toilet lid.
- Make sure that your feet are flat on the floor and your legs are slightly apart.
- Lean forwards, resting your elbows on your knees.

There are two types of exercises – slow twitch and fast twitch. It is important that you do the slow twitch first and then the fast twitch each time you exercise your pelvic floor muscles.

To perform the slow twitch exercises:

1) Close and draw up the muscles around back passage, as if you are trying to stop passing wind. Make sure that you do not contract (tighten) your buttock muscles while you do this.

2) Now close and draw up the muscles around your urethra, as though you are trying to stop the flow of urine.

3) Try not to hold your breath, breathe normally. Pull upwards and count how long you can hold the squeeze. If you can hold for a count of 10, then relax for a count of 10.

4) Repeat this until you feel tired.

5) Over time you should be able to increase the length of time you can hold for.

To perform the fast twitch exercises:

1) Pull up the pelvic floor muscles as before.

2) Hold for one second and then relax.

3) Repeat until your muscles feel tired.

Pelvic floor muscles tire easily and you may notice that it takes a lot of concentration to begin with to do these exercises correctly. If you find that the muscles 'let go' too quickly and that you cannot hold for long, just hold them for as long as you can. If you can only hold the contraction for a count of three, then every time you do your exercises, contract the muscles for a count of three. Gradually try to work up to four, then five and so on. Once you feel confident in doing the exercises try doing them in other positions, such as standing or squatting.

Remember to tighten your pelvic floor muscles during and after any activity that makes you leak – like rising from a chair or coughing – so that tightening becomes an automatic reaction.

While performing the exercises, it is important not to:

- Squeeze your buttocks together
- Bring your knees together
- Hold your breath
- Lift your shoulders, eyebrows or toes upwards

Do not worry if you find holding for three 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.

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.

Using your **perfect PFE** 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. TYPES OF INCONTINENCE

There are three types of incontinence: Stress, Urge, and Mixed.

Stress 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 men after radical prostatectomy 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.

Urge Incontinence

Describes an overactive bladder. A person may experience a strong and sudden urge to go to the toilet but are not always able to hold on, or must go so frequently that it becomes inconvenient.

Mixed Incontinence

Is a combination of both Stress and Urge Incontinence.

Faecal Incontinence

Faecal incontinence can be the result of weakened or poorly functioning anal sphincter muscles or damage to the nerves controlling them. The purpose is to re-educate the anal sphincter and other muscles of the pelvic floor to contract. The treatments aim to progress towards graduated active exercises, in order to improve pelvic floor muscle strength and endurance and to regain function.

You may benefit from the **perfect PFE** if you either have no active anal sphincter contraction, or a weak or poorly sustained contraction. Use the **STRES** or **TONE** programmes. Intensity should be as strong as possible without being painful. When possible, try to contract the muscles at the same time as the **perfect PFE**.

Post Prostatectomy Urinary Incontinence

Electrical stimulation has been found to help urinary incontinence in men after radical prostatectomy in some trials. Choose the programme depending on the type of incontinence you are suffering from and increase the intensity to the highest tolerable.

Chronic prostatitis/chronic pelvic pain syndrome: unexplained chronic pelvic pain associated with irritative voiding symptoms and/or pain located in the groin, genitalia, or perineum in the absence of pyuria and bacteriuria.

Low frequency stimulation stimulates the release of Endorphins – your body's natural pain relief mechanism – to reduce pain without side effects.

6. 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 well-established 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 programme. 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 non-invasive method of producing contraction of muscles via a gentle stimulation to the pelvic floor through a discreet probe or electrode pads when they are placed close to the nerve that controls the pelvic floor muscles. 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. **Perfect PFE** 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). The oxygen supply to the muscle is improved.

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.

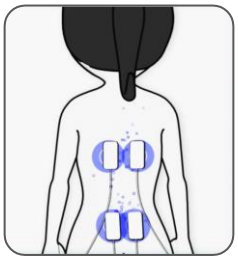
Each preset programme has a specific frequency and pulse width that will offer the best results for the type of incontinence treated.

7. HOW ‘TENS’ WORKS

T.E.N.S. stands for Transcutaneous Electrical Nerve Stimulation. T.E.N.S. stimulates your body’s own natural defences against pain, namely the release of endorphins. TENS is totally safe and has been used successfully by thousands of pain sufferers.

TENS sends a gentle stimulation through the skin which works in TWO ways:

Pain Gate

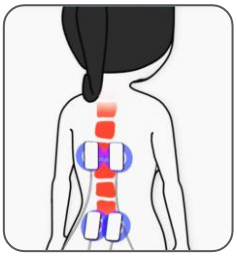


It stimulates the sensory nerves, which carry touch and temperature signals. These nerves go to the same connections in the spine as the nerves carrying pain. A strong sensory signal will block the pain signal travelling up the spine to the brain. This is known as closing the “Pain Gate” and takes effect quite quickly after the unit is switched on. When the gate is open, pain messages get through to the brain and we feel pain. When the gate is closed, these pain messages are blocked and we do not feel pain.

Evidence suggests that TENS produce pain relief in a similar way to ‘rubbing the pain better’. The pain gate can be closed by activation of mechanoreceptors through ‘rubbing the skin’.

Scientifically, the pain gate works by release of chemical in the synapse at spinal level that inhibits transmission of pain signal.

Endorphin Release



At low frequency settings, and slightly stronger outputs, TENS drives the motor nerves to produce a small repetitive muscle contraction. This is seen by the brain as exercise, and this promotes the release of endorphins - your body’s own natural pain killer. The relief builds up and normally takes about 40 minutes to reach a maximum level which can last for hours after the machine is switched off.

By using TENS, you can expect to achieve a significant reduction in pain - if not complete relief from pain.

- TENS is effective for pain from a very wide range of causes.
- TENS machines can be used to help reduce pain from problems in muscles, joints and nerves.
- It can be also used for people with musculoskeletal pain such as long-term (chronic) back pain or knee joint arthritis. They are also often used for pain relief in the early stages of labour (see **perfect mamaTENS**), particularly whilst a pregnant woman remains at home.
- Other uses include migraine headaches, period pain and endometriosis (see **Ova+**), cystitis, sports injuries, Raynaud disease, fibromyalgia and neuralgia, plantar fasciitis, post-operative pain and sometimes non-painful conditions such as tiredness, insomnia, travel sickness, tinnitus or dementia.
- You can use low frequency (<10 Hz) programmes on acupuncture points,

to achieve similar effects to acupuncture.

- With neurogenic pain (caused by inflamed nerves) such as shingles and neuralgia, TENS may start by increasing the pain. We recommend that you only use TENS for these conditions under medical supervision.
- You can safely use TENS as long as it gives you pain relief. The effect may wear off after a few hours (this is called “accommodation”). If this happens, take a break of an hour or so before trying again. If you use settings that cause muscle movement for more than 40 minutes, you may experience aching muscles a few hours later.

8. CONTRAINDICATIONS, WARNINGS & CAUTIONS

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** with optional electrode pads if you have a pacemaker (or if you have a heart rhythm problem) or with any electronic medical devices. *Using this unit with electronic medical devices may cause erroneous operation of the device. Stimulation in the direct vicinity of an implanted device may affect some models. Stimulation on the front of the neck can affect your heart rate. Very strong stimulation across the chest may cause an extra heartbeat.*
- **Do NOT use** in the first 6 weeks following a surgery in the area being treated. *Stimulation may disrupt the healing process.*
- **Do NOT use** if you have symptoms of active urinary tract infection or localized lesions. *Introducing the probe may irritate sensitive tissue.*
- **Do NOT use** if you have poor sensation in the pelvic region. *You may not be able to control the intensity of stimulation safely.*

WARNINGS:

Do NOT use if you are unable to properly insert the probe. If you have a severe prolapse, or if any discomfort occurs when inserting the probe, consult your healthcare professional before use.

Do NOT use when driving, operating machinery, or similar actions needing muscular control. *Loose electrode pads, damaged leads, or sudden changes in contact may cause brief involuntary muscle movements.*

Do NOT use to mask or relieve undiagnosed pain. *This may delay diagnosis of a progressive condition.*

Do NOT use if you have, in the area being treated: active or suspected cancer or undiagnosed pain

with a history of cancer. *Stimulation directly through a confirmed or suspected malignancy should be avoided as it may stimulate growth and promote spread of cancer cells.*

CAUTIONS:

Caution should be used if you have suspected or diagnosed epilepsy as electrical stimulation may affect seizure threshold.

Caution should be observed when using the device at the same time as being connected to monitoring equipment with body worn electrode pads. *It may interfere with the signals being monitored.*

Caution: Simultaneous connection to high frequency surgical equipment may result in burns and damage to the stimulator.

Caution: Strong electromagnetic fields (electro-surgery/ microwave cookers/ mobile phones) may affect the correct operation of this unit. If it appears to behave unusually, move it away from these devices.

Caution Do not permit use by persons unable to understand the instructions or persons with cognitive disabilities, i.e.; Alzheimer's disease or dementia.

Caution: Insertion of the anal electrode makes it unsuitable for use in children without clinical supervision

Caution: Keep away from children under 5 years of age. *Long cord - risk of strangulation in infants*.

Caution should be observed when using the **perfect PFE** at high strength settings. Prolonged use at high settings may cause muscle injury or tissue inflammation.

Note: No serious or long term adverse effects have been reported. Mild adverse reactions are very rarely reported, but these have included muscular pain and cramps, irritation and bleeding, mild or short term urge or faecal incontinence, and tingling sensation in legs. If you experience any of these, stop use. When symptoms have gone, try resuming at a lower intensity setting.

PROBE CAUTIONS:

Caution: The **perfect PFE** anal probe is intended for single patient use only. Do not share your **perfect PFE** probe with anyone else. *Improper treatment or cross-infection may occur.*

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

Caution: Never insert or remove anal probe 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 silicone based lubricant on the metal

plates of the probe as it may decrease the effectiveness of **perfect PFE**'s muscle stimulation.

Caution: The stainless steel in the probe's metal plates contain some Nickel. This could cause a reaction if you have a Nickel allergy. *Alternative gold probe specially made without Nickel is available (see **X-VPG**).*

Caution: Do not use this device with anal probe other than those recommended by the manufacturer in section 18. Electrodes with smaller surface area may cause tissue irritation.

DO NOT PLACE OPTIONAL ELECTRODE PADS:

- On skin, which does not have normal sensation. *If the skin is numb too great a strength may be used, which could result in skin inflammation.*
- On broken skin. *The electrode pads could encourage infection.*

ELECTRODE PADS CAUTION:

Caution: Do not ignore any allergic reaction to the electrode pads: *If a skin irritation develops, stop using TENS, as this type of electrodes may not be suitable for you. Alternative electrode pads specially made for sensitive skin are available (see **E-696-SS**).*

Caution: Do not use this device with leads or electrode pads other than those recommended by the manufacturer. *Performance may vary from specification. Electrodes with smaller surface area may cause tissue irritation.*

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

Caution: Do not immerse your device in water or place it close to excessive heat such as a fireplace or radiant heater or sources of high humidity such as a nebulizer or kettle as this may cause it to cease to operate correctly.

Caution: Keep the device away from sunlight, as long-term exposure to sunlight may affect the rubber causing it to become less elastic and crack.

Caution: Keep the device away from lint and dust, as long-term exposure to lint or dust may affect the sockets or cause the battery connector to develop a bad contact.

Caution: Temperature & Relative Humidity of storage:

-20°C–+40°C, 8%--70% R.H. Temperature & Relative Humidity of transportation: -20°C–+40°C, 8%--70% R.H.

Caution: Do not attempt to open or modify the TENS unit. *This may affect the safe operation of the unit and will invalidate the warranty.*

9. INFORMATION ABOUT THE PROGRAMME SETTINGS

Each programme has its own combination of Frequency and Pulse Width settings which allow for different sensations through the probe or optional electrode pads and help to treat the different types of incontinence.

- **Frequency (measured in Hz - pulses per second)**

Low frequencies (1-10 Hz) have a purifying and relaxing effect through individual contractions.

Medium frequencies (20-50 Hz) can put a high level of strain on the muscle, thus promoting the muscular structure

Endorphin release (programme **PAIN** only): A low frequency of 4 or 10 Hz allows for the release of endorphins, the body's natural morphine-like substances.

- **Pulse Width (measured in µs - millionths of a second)**

The **perfect PFE** unit has pulse widths of 200 to 300 µs. Generally speaking, the higher the pulse width, the more "aggressive" the stimulation feels, if the pulse width is set high enough, it will usually elicit a muscle contraction, which is required for an effective toning of the pelvic floor muscles.

10. PROGRAMMES

10.1. PROGRAMME SETTINGS

Prog	STRES	TONE	MIXED	URGE	PAIN
Freq. (Hz)	50	35	10 / 50	10	4
Pulse width (µs)	300	250	200 / 300	200	200
Ramp Up & Down (s)	1	2		Constant	Constant
Plateau (s)	5	3			
Rest (s)	10	6			
Default duration (min)	20	20	20	Conti-nuous	Conti-nuous

10.2. PRESET PROGRAMMES

The **perfect PFE** has five preset programmes. One for each type of incontinence (stress, urge and mixed), one for toning the pelvic floor muscles (**TONE**), and one to relieve chronic pelvic pain (**PAIN**).

STRESS INCONTINENCE:

Shown on the screen as: **STRES**

The **STRES** incontinence programme 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 other fitness training, successful treatment requires stimulation once a day for one to three months. Improvement starts becoming apparent after about four weeks.

The sensation is like a strong drawing in of the muscles, pulling up the pelvic floor. Your natural reaction will be to pull your muscles in and up, and this exercises and strengthens them

URGE INCONTINENCE:

Shown on the screen as: **URGE**

The **URGE** programme works in a different way to the **STRES** programme. The gentle continuous stimulation soothes the bladder (detrusor) muscle, reducing its involuntary contractions. This prevents the unwanted and unexpected emptying of the bladder.

Successful treatment requires stimulation once a day and improvements can sometimes be seen in as little as two weeks.

The sensation is a softer, vibrating, stimulation. Nevertheless, when the programme finishes, and your pelvic floor relaxes, it will become apparent how much your pelvic floor has been exercised.

MIXED INCONTINENCE:

Shown on the screen as: **MIXED**

This programme is perfect if you are suffering from both Stress and Urge incontinence. It is a combination of the **STRES** and **URGE** programmes.

The first 10 minutes uses the **URGE** programme to reduce sensitivity, then in the second 10 minutes, the **STRES** programme exercises the pelvic floor muscles. You may need to increase the strength to feel the muscle contraction when the **STRES** programme starts.

TONE:

Shown on the screen as: **TONE**

Once the pelvic floor muscles have been strengthened with **perfect PFE**, continue to exercise them

Regular use of this programme, about twice a week, will ensure that your muscles remain fit and toned.

The **TONE** programme may also be used as an alternative treatment for stress incontinence.

The sensation when using the **TONE** programme is a mixture of a strong drawing in of the muscles and then releasing.

A strong and fit pelvic floor may increase sexual health and enjoyment.

PAIN:

Shown on the screen as: **PAIN**

The **PAIN** programme can be used to alleviate chronic pelvic pain from many causes. As with all TENS, it does not treat the underlying condition and you should obtain a professional diagnosis of the cause before starting use. It gives a constant soothing tingling sensation. Use with the anal probe or with optional electrode pads (see placement in section 13.4.) for at least 40 minutes two or three times a week. Set the strength as high as you can while remaining comfortable.

11. CONTENT

The pack contains:

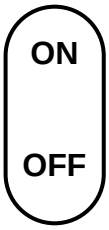
- 1 x **Perfect PFE for men** continence stimulator unit
- 1 x Lead wire (L-CPT)
- 1 x anal probe (X-PR13)
- 4 x 50x50 mm electrode pads (E-CM5050)
- 2 x AA 1.5V alkaline batteries
- 1 x Detachable belt clip
- 1 x Storage pouch
- 1 x Manual instruction

12. UNIT INFORMATION

12.1. CONTROLS & DISPLAY

12.2. 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 programme **STRES** at zero strength.

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

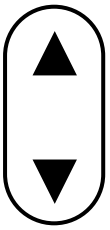
The unit will turn off automatically:

- 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 probe or pads.

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 ▲ until required strength is 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 (probe inserted correctly). Perfect PFE detects a disconnection and 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.

PROGRAMME CONTROL

The button marked **P** is the programme control. The **perfect PFE** has five preset programmes. At first use, the unit automatically goes to programme **STRES**. Next time it is switched on, it will default to the programme used last.

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

Each time you change the programme, the strength level reverts back to zero. This is a safety feature to alleviate any

sudden feeling of a surge, as each programme gives a different sensation.

TREATMENT TIMER

The button marked **T** can be used to set the session duration. When you switch the unit on, it is automatically set at 20 min or Continuous, (displayed as C) depending on the programme chosen.

To set a different time, set the strength to zero and press **T**. The **min** display will flash.

You can set session times of C (Continuous) or 10, 20, 30, 45, 60 or 90 minutes with the buttons ▲ and ▼.

Press **T** again to save your selection.

The LCD shows the session duration next to the clock symbol. The unit automatically counts down the minutes set and switches off when it reaches 0.

LOW BATTERY

An empty battery symbol will show when you need to change the batteries. The unit will shut down about 2 minutes after this.

KEYPAD LOCK

If you do not press any keys for 30 seconds, the keypad will lock. This is to avoid accidental changes in setting.

To unlock, press and hold the strength down control (button ▼).

LEADS ALARM

The **perfect PFE** monitors the connection and the contact between you and the probe, 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 probe with a water based lubricant such as TensCare Go Gel (see **K-GO**). Please see section 20 for more troubleshooting tips.

MEMORY

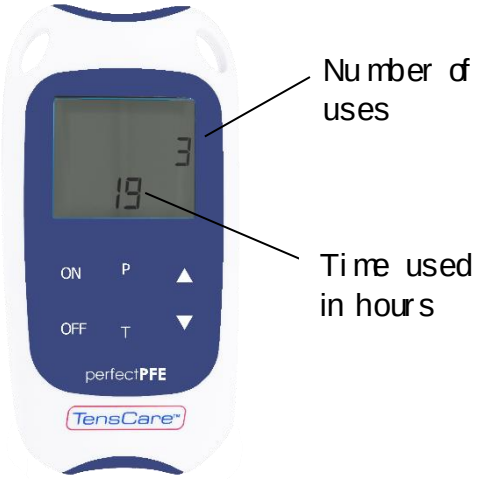
The **perfect PFE** has a Memory with three functions:

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



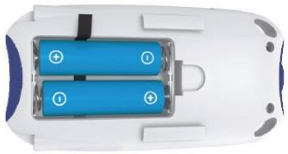
13. SETTING UP AND USING THE PERFECT PFE

13.1. INSTALLATION OF BATTERIES

1) Remove belt clip by sliding down.

2) Remove battery cover by pulling on tag.

3) Insert batteries.



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

4) Replace battery cover and belt clip.

When the batteries are running low, a low battery indicator will show on the screen and it is important to change the 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 **perfect PFE** 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 – There is a risk of explosion.

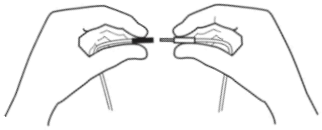
Caution Do not mix old, new or different types of batteries as this may lead to battery leakage or low battery indication.

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

13.2. 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 probe.



Push the pin ends firmly into the pigtail ends of the probe 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 coloured black or red. This coding is provided for some professional uses. For most purposes, the orientation makes no difference, and you can ignore this colour coding.

13.3. PREPARING FOR SESSION

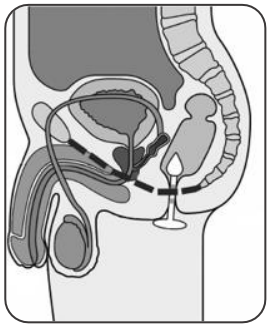
1) Before using **perfect PFE** you will need to visit the toilet.
2) Lubricate the metal electrode surfaces and probe tip with a water-based lubricant, such as TensCare Go Gel or water.

Caution: Do not use a silicone based lubricant on the stimulation contacts as it may decrease the effectiveness of the **perfect PFE**'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 **perfect PFE** is switched OFF before inserting the probe.

4) After the wire is securely connected, insert the probe into your anus, whilst 'bearing down' (as in the action of passing stool) to a comfortable limit until the base of the flange on the probe touches the anus.



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

6) It is recommended that the probe is inserted past the sphincter muscles of the anus, unless directed otherwise by a healthcare professional.

Note: Anal probes with long electrodes (the metal part) that run up and down the length of the attachment should always be inserted with the metal parts facing hip-to-hip. Anal probes with circular electrodes (the metal part) should be inserted simply to the desired depth.

Note: Sometimes the wearing of tight fitting undergarments or a tight pair of jeans will help to keep the probe in place and maintain correct contact during the programme.

For Faecal incontinence, the aim is to stimulate the external sphincter and/or pubo-rectal muscle, so circular electrodes should be placed so that the external ring is just inside the sphincter.

For Urinary Stress incontinence, the aim is to stimulate the levator muscles and the probe should be inserted deeper.

13.4. 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 five preset programmes. Details in section 10 will help you identify the best programme to suit you.
   To change between the programmes, press the programme selector, which is labelled **P**, in the centre of the control unit keypad.
3) With the required programme 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 programme.

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

Initially the sensation through the probe 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 **STRES** and **TONE** programmes the unit will go through an exercise programme for 4-5 seconds, followed by a rest period of 8-10 seconds. The **perfect PFE** causes a sensation which feels like a strong drawing in of the muscle 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, so slowly increase the intensity by repeatedly pressing the ▲ button until you begin to feel the muscles contract.

For best results in these programmes try to contract the pelvic floor muscles along with the **perfect PFE**, 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 0.00 mA and flash during the rest period.

The **URGE** and **PAIN** programmes work differently. There is no need to have a contraction. The strength should be comfortable, but always remain noticeable. You may need to increase it over the course of the treatment.

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.

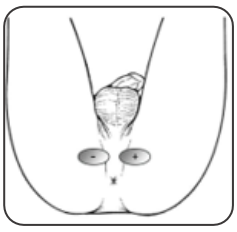
Note: If you experience cramping, switch the unit off until the symptoms go away then continue the session with the intensity set at a lower level.

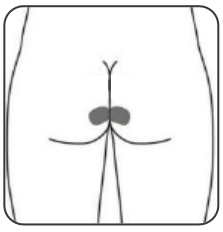
Optional skin surface electrode placement for URGE

An alternative method to an anal probe is to stimulate areas of the skin that are close to nerves that go to the bladder and urethra. These come from the parts of the spinal cord segment called S2-S3.

The electrodes are placed on the skin between the anus and the genitals, or at the very bottom of the spine near your coccyx or “tail”. See electrode placement pictures below.

The stimulation should be strong enough to make your anus contract slightly.





13.5. 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 probe from your anus by holding the positioning end rim and gently pulling outwards.
2) Wash (see cleaning instructions below) and thoroughly dry the probe and return it to the storage pouch.
3) The **perfect PFE** 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 probe, DO NOT PULL ON THE LEAD WIRE.

14. CLEANING

It is important that the probe is cleaned after each use. Clean with either an alcohol-free antibacterial wipe such as TensCare Wipes (see **X-WIPES**) or by wiping with warm soapy water. Rinse and dry thoroughly and return the unit and accessories to the storage pouch. Do not immerse the probe 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 **perfect PFE** unit in water.
- Do not use any other cleaning solution.

15. 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).

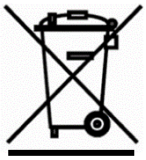
Note: For hospital use, full EMC advice table is available on request.

16. DISPOSAL OF WASTE ELECTRICAL AND ELECTRONIC PRODUCTS (WEEE)

One of the provisions of the European Directive 2002/96/CE is that anything electrical or electronic should not be treated as domestic waste and simply thrown away. To remind you of this Directive all affected products are now being marked with a crossed-out wheelie bin symbol, as depicted below.

To comply with the Directive, you can return your old electro-therapy unit to us for disposal. Simply print a postage-paid PACKETPOST RETURNS label from our website www.tenscare.co.uk, attach this to an envelope or padded bag with the unit enclosed, and post it back to us. Upon receipt, we will process your old device for components recovery and recycling to help conserve

the world's resources and minimise adverse effects on the environment.



17. ACCESSORIES

Expected Service Life

- The machine will often last for more than 5 years, but is warrantied for 2 years. Accessories (lead wire, probe, 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 probe every 6 months to ensure hygiene.
- Optional electrode pads should last 12-20 applications, depending on skin condition and humidity.
- AA alkaline batteries should last about 18 hours of continuous use.

Replacement electrode pads, 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-VPL	Liberty Loop Vaginal Probe (32 mm dia.)
X-VP	Liberty Vaginal Probe (28 mm dia.)
X-VPM	Liberty Plus Vaginal Probe (32 mm dia.)
X-VPG	Gold Vaginal Probe (26 mm dia.)
L-CPT	Replacement lead wire, 1.25 m length
X-PR13	Anal probe (19.6 mm dia.)
E-CM5050	Pack of 4 electrode pads (50x50 mm)
K-GO	Go Gel Personal Water-based Lubricant
B-AA	1.5V AA batteries
X- BC-PT	Replacement belt clip
X- BL-PTT	Replacement battery cover
X-WIPES	Pack of 30 wipes

Note: You should only use the probe 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.

18. WARRANTY

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

PRODUCT WARRANTY INFORMATION

This product is warranted to be free from manufacturing defects for 2 years fromdate 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 24) 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 or electrode pads. Send only the unit and the lead wire.

Please return the unit and warranty card (see page 32):

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.

19. TROUBLESHOOTING

If your **perfect PFE** 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 LOCK is shown on display, press and hold the ▼ button. If no LOCK is showing, remove and replace the batteries.
No sensation and LEADS alarm showing	The **perfect PFE** 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 **LEADS**. 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 probe in your hand: i) Dampen your hand with water and a little table salt. Squeeze the probe firmly and make sure your skin is covering the metal parts of the probe 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 **LEADS** 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 probe is in your hand, then it may be that: 2. The skin is dry, meaning poor conductivity between	If this happens, you can try the below solutions: i) Using a water–based lubricant such as TensCare Go Gel (see **K-GO**), which will improve conduction. ii) Crossing your legs and squeezing to increase pressure on the probe, which should improve the connection. If this

	the metal plates on the probe and your skin.	enables you to use the unit, you should find 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) Sometimes the wearing of tight fitting undergarments or a tight pair of jeans will help to keep the probe in place and maintain correct contact during the programme.
No sensation and no LEADS alarm showing	Intensity level is not high enough and/or reduced sensitivity in the area being treated.	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 probe 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. ii) You may have reduced sensitivity due to previously damaged or desensitised pudendal nerves (this can happen in some surgical procedures). Please consult your healthcare professional.
No sensation on one side of the probe (or electrode)	Position is not optimal – needs adjusting.	The current flows from one side of the probe 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 probe, or exchanging the connection of the wires in the probe.
Sudden change in sensation	If you disconnect and re-connect a few minutes later, the signal will feel quite a lot stronger.	Always return strength to zero after disconnecting the lead or the probe.

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.

20. GENERAL SPECIFICATION

Waveform	Asymmetrical rectangular
Amplitude (over 500 Ohm load)	99.0 mA +/- 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 gms without batteries
Dimensions	120 x 60 x 20 mm
Safety Classification	Internal power source.
Environmental Specifications:	
Operating:  Storage: 	Temperature range: 5 to 40°C Humidity: 15 to 93% RH non-condensing Atmospheric pressure: 700hPa to 1060hPa Temperature range: -25-+70°C Humidity: Up to 93% RH non-condensing Atmospheric pressure: 700hPa to 1060hPa
TYPE BF EQUIPMENT 	Equipment providing a degree of protection against 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 and anal electrodes. Optional skin surface electrode pads. See section 18.

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%.

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 PROBE OR ELECTRODE PADS

RETAILER'S NAME: _____

RETAILER'S ADDRESS: _____

_____

RETAILER'S 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

Follow us:

https://www.facebook.com/pages/TensCare-Ltd

https://twitter.com/TensCareLtd

https://www.linkedin.com/company/tenscare-limited

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https://uk.pinterest.com/TensCareLtd/

https://tenscareltd.wordpress.com/

https://www.youtube.com/channel/UCzpik9dmLlJ3j0aHOpQ-0sg

CE
0088

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

Pub No.: I-PPFE-MEN-UK Version 1.2 03/17