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1. INTRODUCTION

Bladder leakage and incontinence are common problems for 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 "Sure Pro" is a versatile professional continence stimulator unit that offers the latest technology in a simple package that is equally suitable for home use.

It has two independent stimulation channels and can be used with vaginal or anal electrodes, or - for Urge and Pain - with four self adhesive electrode pads.

The "Sure Pro" has 11 preset and 3 custom programmes. In addition to the standard settings, it has a special programme for transcutaneous stimulation of the Tibial Nerve for Urge incontinence.

The custom programmes can be adjusted by healthcare professionals to the specific needs of the patient.

2. INTENDED USE



This device has been designed to be used in the home healthcare environment to treat symptoms of urinary and/or faecal incontinence and is suitable to be used by both men and women. It is also indicated for specialised management of Faecal incontinence. Anal probe sold separately. Do not use the device for any purpose other than this intended use.

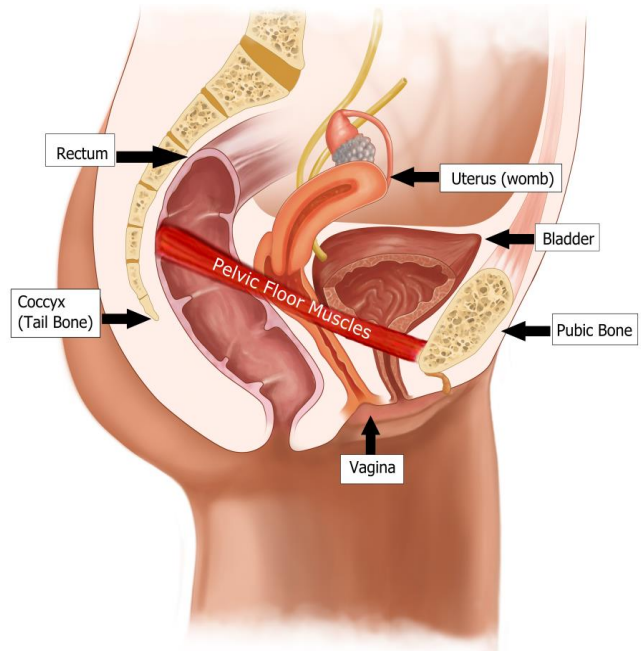
Warning: Not suitable for use in children without medical supervision.

3. "Sure Pro" FEATURES:

- **Comfortable Stimulation**
The strength of the stimulation increases gradually, making the feeling very comfortable and in your control.
- **Flexible**
"Sure Pro" is flexible enough to fulfil a wide range of professional requirements, yet has very simple operation for home use - giving unrivalled performance for a product of this size and price.
- **Usage Memory**
Sufficient memory for a 90 day daily treatment programme. The memory records usage time and average intensity used, giving an objective treatment record.
- **Automatic keypad lock and manual program lock**
To ensure your program doesn't change accidentally
- **Li-Ion mobile phone style battery**
Making it lightweight and compact, and is supplied complete with external charger.
- **Backlit LCD screen**
Whenever a button is pressed the screen will light up making the screen easy to read and very clear.
- **Choice of programmes**
11 preset and 3 manual programmes for optimal choice and a dedicated programme for the relief of Detrusor Instability. "Sure Pro" is also indicated for the specialised management of Faecal incontinence.
- **Unique locking lead connection and built-in cable tidy**
To ensure that leads remain in place and out of the way

4. THE 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 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
- in women also
 - provide support for the baby during pregnancy and
 - 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 or 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 and occurs in about 40-50% 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 bowels 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.

It can also reduce your risk of prolapse, improve your recovery from childbirth and gynaecological 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.

5. HOW TO PERFORM PELVIC FLOOR EXERCISES

Once the “Sure Pro” has helped you develop control of the pelvic floor muscle and built muscle strength, 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.

First of all, it is important to find your pelvic floor muscles and feel them working. So here are a couple of techniques which might help:

1) 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.

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

2) 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.

6. TYPES OF INCONTINENCE

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

- **Stress Incontinence**

Describes the involuntary leakage of urine when a person coughs, sneezes, strains or makes sudden movements. It is particularly common in women and occurs when the bladder neck and the other mechanisms that act to hold urine in the bladder are not working properly. This type of incontinence can be influenced by pregnancy, childbirth and menopause.

- **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 have to go so frequently that it becomes inconvenient. It can be caused by diabetes or a urinary tract infection, or by a nerve-affecting disorder like stroke, Alzheimer's disease, or multiple sclerosis. In some cases, it can be an early sign of bladder cancer

- **Mixed Incontinence**

Is a combination of both Stress and Urge Incontinence.

- **Faecal Incontinence**

Faecal incontinence, also called anal or bowel incontinence, is the impaired ability to control passage of gas or stool. There are many possible causes of faecal incontinence, the most common is injury to the anal sphincter (ring-like muscle), for instance during childbirth or surgery, or damage to the nerves that control the anal sphincters. The condition usually becomes worse as people age.

7. THE ADVANTAGES OF “Sure Pro”

- It is **Drug Free**
- It is **Easy** to use
- It is **Discreet**
- It may help to **avoid surgery**.
- It may **improve sexual pleasure**

8. HOW “Sure Pro” WORKS

Electrical stimulation consists of temporarily placing electrodes in the vagina. Small

pulses of electricity generate muscle contractions and can help women identify how to do the contractions themselves.

Research has shown that 30% of women who experience incontinence are unable to voluntarily contract the pelvic floor muscle and require additional assistance to aid their pelvic floor training.

The Pelvic Floor Exercisers can play a vital role in educating women about their pelvic floor and the sensation they should feel when doing pelvic floor exercises. For best results, it is recommended to use Pelvic Floor Exerciser in conjunction with Kegel Exercises.

The “Sure Pro”, through a vaginal probe or pads, sends a gentle electrical stimulation to your pelvic floor muscles using clinically recognised programmes. The “Sure Pro” sends small pulses of electricity to generate muscle contractions and can help you identify how to do the contractions on your own.

In some instances where a probe is not appropriate - particularly with Urge Incontinence - it is possible to treat incontinence by using electrode pads placed on the body, either across the base of the spine S2-S3, or on the ankle using the **Transcutaneous Tibial Nerve Stimulation** programme.

It is also possible to treat urinary and faecal incontinence in both males and females using an anal probe. See section 14 for more details.

Please note that we recommend the Liberty Vaginal Probe (as supplied with the unit) and accessories listed on page 37, as the unit has been tested with these.

If in doubt contact your healthcare professional before using the “Sure Pro”.

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.


9. CONTRAINDICATIONS, CAUTIONS AND WARNINGS


CONTRAINDICATIONS:

Do NOT use if you are or may be pregnant; or in the first 6-8 weeks after childbirth. *It is not known whether electrical stimulation may affect foetal development.*

Do NOT use if you have a pacemaker (or 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*

WARNINGS:

 **Do NOT use** if you have symptoms of active urinary tract infection, vaginal infections, 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.*



Do NOT use if you have active or suspected vaginal, pelvic or prostate cancer; or have undiagnosed pain in the area being treated with a history of cancer. *In vitro experiments have shown that electricity can promote cell growth.*



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



Do NOT use 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 a minor burn*



Do NOT use electrode pads on the carotid sinus nerves, front of the head, over the eyes, or on the front of the neck. *This may affect heart rate or cause contraction of airways.*



Do NOT ignore any allergic reaction to the electrode pads: If a skin irritation develops, stop use and allow the skin to heal. If the problem persists, try using a different make of electrode or change the electrode, try moving the electrode position each day by just the width of the electrode

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.

Incontinence can have many causes. You should try to identify the type of incontinence and the cause before starting to use this device.

CAUTIONS:

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

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

Caution: Use caution following recent surgical procedures. Stimulation may disrupt the healing process.

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

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

Caution: Never insert or remove the vaginal/anal probe or electrode pads unless the control unit is powered OFF as insertion or removal when stimulation is active may cause discomfort.

Caution: Do not use a silicone based lubricant on the stimulation contacts of the probe as it may decrease the effectiveness of the muscle stimulation.

Caution: Strong magnetic or electromagnetic fields (electrosurgery/ microwave cookers/ mobile phones) may affect the correct operation of this unit - see section 19. If it appears to behave unusually, move it away from these devices

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

Caution: The stainless steel in the probe electrodes contains some Nickel. This could cause a reaction if you have a Nickel allergy. The Liberty Gold Vaginal Probe (X-VPG) can be used as an alternative for those with particular reactions to base metals.

Caution: This device may interfere with patient monitoring equipment with body-worn electrode pads.

Caution: Do not use this device with vaginal/anal probe or self-adhesive electrodes other than those recommended by the manufacturer in section 19. Electrodes with smaller surface area may cause tissue irritation.

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

Caution: Not suitable for children under 5 years of age. Long cord - risk of strangulation in infants.

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

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

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

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 bad contact.

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

Note: You may safely use the stimulator during menstruation, although it may be a little less comfortable.

10. THE PROGRAMMES

The "Sure Pro" has 11 preset and 3 custom programmes.

1	STRE1	<p>Stress1</p> <p>The STRESS incontinence programme strengthens the muscles of the pelvic floor using gentle stimulation. Once muscular strength has been improved these muscles 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 thereby building their strength. Successful treatment requires stimulation once a day for one to three months. Improvement starts becoming apparent after about four weeks. It helps to keep a record of leakage problems so that you have an objective measure of your progress.</p> <p>The sensation is like a strong drawing in of the muscles of the vagina, pulling up of the pelvic floor. Your natural reaction will be to pull in and up your muscles, thereby exercising and strengthening them.</p>
2	STRE2	<p>Stress2</p> <p>Having restored your pelvic floor muscles to an excellent condition you will want to keep them toned and strong. Regular use of this programme, about twice a week, will ensure that your muscles remains fit and toned. May also be used as an alternative treatment for STRE 1.</p> <p>The sensation is a mixture of a strong drawing in of the muscles and then releasing. The programme repeats this sensation.</p> <p>A strong and fit pelvic floor muscle may increase sexual health and enjoyment.</p>
3	URGE	<p>Shown on the screen as: "URGE"</p> <p>The URGE incontinence programme reduces the involuntary contractions of the bladder (detrusor) muscle. This prevents the unwanted and unexpected emptying of the bladder. Successful treatment will require daily stimulation and improvements can be seen in as little as two weeks.</p> <p>The sensation is of a longer and softer pulling in of the pelvic floor than the Stress programme.</p>

4	MIXED	15 minutes of Programme 3 followed by 15 mins of Programme 1.
5	URGE2	A continuous version of programme 3. You may find this more comfortable.
6	SENS	<p>Lack of Sensation</p> <p>After surgery or childbirth, you may find that you have good muscle control, but experience a lack of sensitivity. This can be due to nerve damage and is a problem that can be helped with the programme.</p>
7	PFW A	<p>Pelvic Floor Workout.</p> <p>A multiphased programme for Mixed incontinence. The smaller steps in frequency are believed to be less likely to aggravate the Urge component. Start with A.</p>
8	PFW B	<p>Similar to PFW A.</p> <p>As your pelvic floor muscles strengthen you can progress to this programme, which has longer Work periods.</p>
9	ENDUR	Choose this programme if you find that you can tense your pelvic floor muscles quite easily, but can't keep them tense for very long. Endurance will help to build up muscle strength and improve muscle endurance.
10	PAIN	The Pain Relief programme helps treat pain in the pelvic area. It is particularly useful for treating vulvodynia, a condition that can cause burning, stinging, irritation and rawness in the female genital area.
11	TIBN	External stimulation of the ankle for Urge and Faecal incontinence
12	CSTM 1	The custom programmes allow you to choose your own settings. The number of variables mean that there are many choices. You are advised to take professional advice before using these programmes.
13	CSTM 2	
14	CSTM 3	

10.1. GUIDANCE ON USING THE PRESET PROGRAMMES

i) All the programmes except 3, 5, 10 and the first half of 4, exercise the pelvic floor muscles. The sensation is like a strong drawing in of the muscles of the vagina, pulling up of the pelvic floor.

The muscle MUST contract in order to give a benefit. Increase the strength as high as is comfortable, and then take it back down one step. The level required varies widely between users - some will use the "Sure Pro" at full power - 99.5mA.

ii) It is advisable not to 'overdo' it early on, as the resulting aches may not be felt until the next day. As long as you can feel the contraction, it is working. You can build up slowly over a number of days. With the first few sessions the muscles may ache the next day- the same reaction you would get with any unaccustomed exercise. With the pelvic floor, this gives a 'cramping' feeling. If this happens, stop using your "Sure Pro" until the aching goes away, then start again using a lower strength and a shorter treatment time. As the pelvic floor begins to improve, it will be possible to maintain the stimulation for longer.

ii) Most of the programmes cycle between "work" and "rest" to allow your muscles to recover in between contractions. When you change the strength setting, this cycle stays on "work" until you stop pressing the buttons for more than 5 seconds.

iv) The Urge programmes (3,5 and the first part of 4) and the Pain programme (10) work differently. There is no need to have a contraction. As long as you can feel the stimulation easily, it is working. You may need to increase the strength during the treatment session.

v) For best results in the exercise programmes try to contract the pelvic floor muscles along with the "Sure Pro", and to sustain the contraction into the rest interval. If possible, link the contraction to your breathing in order to get into a gentle rhythm.

vi) Once the pelvic floor has been strengthened using the "Sure Pro", continue to

exercise the pelvic floor muscles. The pelvic floor needs to be worked and reacts very well to such exercises.

vii) The usages mentioned for each programme are guidelines only, and may be altered depending on your personal needs.

Treatment Time And Treatment Interval

Current clinical evidence indicates that there should normally be no need to exceed the default Treatment Time settings in all but the Urge and Pain programmes. The Urge and Pain programmes may be used continuously if required.

Most clinical trials for Stress have used no more than one treatment per day. The evidence seems to show that there is no additional improvement to using stimulation more than 3 times a week. However, for home use, better long term compliance is achieved by establishing a routine of using "Sure Pro" daily.

Choosing The Right Strength

The object of STRESS and MIXED programmes is to produce powerful muscle contractions. The strength of the current should be increased to **about three times the level at which you can first feel the tingling**, or to as high as you can stand without causing pain. However it is advisable not to 'overdo' it early on, as the resulting aches may not be felt until the next day. You will probably feel that electrical contraction is being more powerful than a voluntary contraction, because the current also stimulates your sensory nerves. The signals have a pain-relieving effect.

You may find the sensation uncomfortable to start with, so that you may not get up to therapeutic strength at the start of treatment. The strength can be increased during the course of the treatment, as you become accustomed to the sensation.

The powerful muscle contractions caused by electrical stimulation sometimes give rise to training aches, which usually disappear within a week.

10.2. GUIDANCE ON USING THE CUSTOM PROGRAMMES

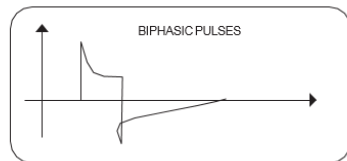
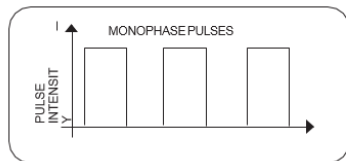


Warning. Consult your healthcare professional before using these programmes. Correct settings depend on your muscle tone and exercise goals. Inappropriate settings could cause discomfort or muscle injury, or aggravate Urge incontinence.

STIMULATION PARAMETERS:

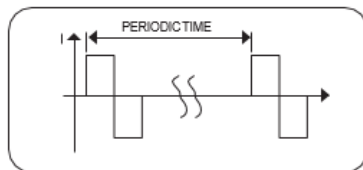
The effect of Electrical stimulation on the body depends on a number of current settings. In the custom programmes you can adjust the following:

Pulse Waveform



This describes the time function of the excitation current which may be either monophasic or biphasic. With monophasic pulse trains, the current flows in one direction. With biphasic pulses, the excitation current alternates its direction. The “Sure Pro” uses only biphasic pulse trains, as they reduce the strain on the muscle, leading to less muscle fatigue as well as safer application, and reduce the risk of skin irritation under the electrode.

Pulse Frequency



Frequency indicates the number of individual pulses per second, and is indicated in Hz (Hertz= pulses per second). It can be calculated by working out the inverse value of the periodic time.

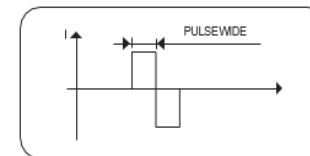
Different types of muscle fibres react preferentially to different frequencies:-

Slow-response fibres tend to react to lower pulse frequencies up to 15Hz, while fast-response fibres only respond to frequencies over approx. 35Hz.

With pulses of approx.45~70Hz, there is permanent tension in the muscle (tetany) combined with premature muscle fatigue. Higher pulse frequencies can therefore preferably be used for elasticity and maximum strength training.

For soothing and pain relief: A frequency of 90 Hz is good at blocking pain signals. A low frequency of 4 or 10 Hz allows for the release of endorphins, the body's natural morphine-like substances.

Pulse Width



Pulse width is used to indicate the duration of an individual pulse in microseconds. A larger muscle mass requires a greater pulse width. A higher Pulse Width is also more likely to activate pain nerves, so there is a fine balance between maximum muscle stimulation and tolerable sensation.

MUSCLE STIMULATION: 50-350 μ S.

PAIN RELIEF AND SOOTHING: 50 to 250 μ S.

Pulse Intensity

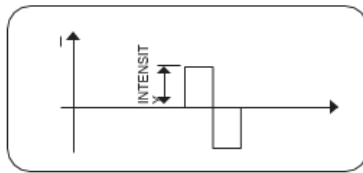
Setting the degree of intensity is dependent on the subjective feeling of each individual user and is determined by a number of parameters such as application site, skin circulation, skin thickness as well as quality of electrode contact. The actual

setting should be effective but should never produce any unpleasant sensation such as pain at the site of application.

In pain relief and soothing programmes, a slight tingling sensation indicates sufficient stimulation energy. As you become accustomed to the stimulation, you may need to increase the intensity.

In muscle stimulation programmes, the intensity needs to be as high as possible for maximum benefit – so set just below the pain threshold.

With prolonged application, you may need to increase intensity as nerves get used to the stimulation and become less sensitive (known as accommodation).

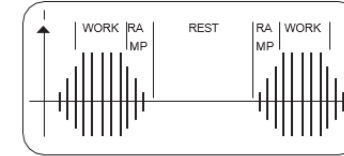


RAMP (RISE) is the time in seconds taken to move up and down between zero and the set stimulation strength. The “Sure Pro” can be adjusted from 1.0 to 10 seconds in steps of 0.5 sec.

WORK is the time in seconds that muscle is stimulated (not including Ramp time). The Sure Pro offers a range of work periods from 1-20 sec.

REST is the time in seconds at zero strength in between stimulation.

The Sure Pro offers a range of rest periods from 1-30 sec. The EMS programmes use an Active Rest - low frequency pulses help to clear metabolites in between Work periods.



Work/Rest Ratio

The Warning triangle \triangle is displayed if Rest period is less than $\text{Rest Time} = \text{Work time} * (\text{WorkHz} - 16.66) / 16.66 \text{ seconds}$

This is because muscle fibres can only activate a limited number of times a minute (about 1000) without becoming fatigued.

10.3. TRANSCUTANEOUS TIBIAL NERVE STIMULATION FOR URGE AND FAECAL INCONTINENCE

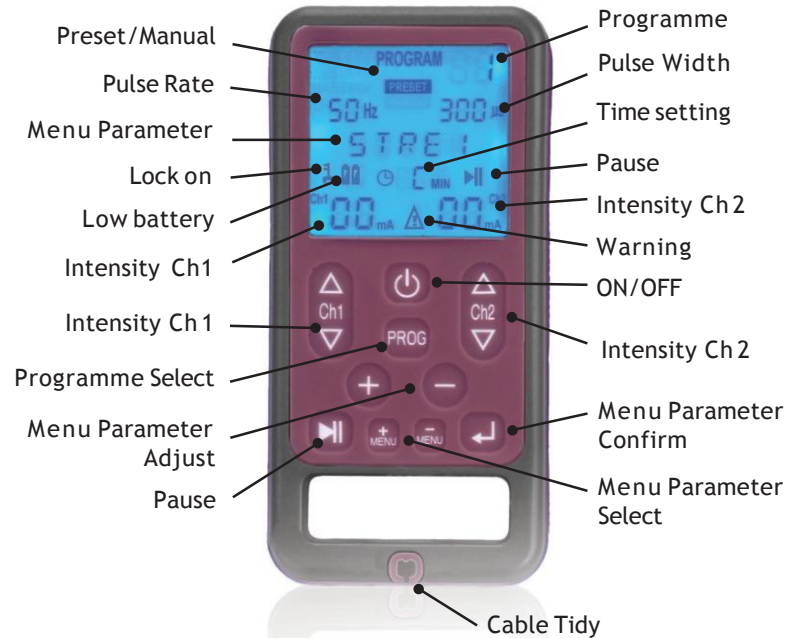
Clinical trials have shown that TNS using a self-adhesive surface stimulation electrode without an implanted needle electrode can be effective. (Ref:URODYNAMIC EFFECT OF ACUTE TRANSCUTANEOUS POSTERIOR TIBIAL NERVE STIMULATION IN OVERACTIVE BLADDER. G. AMARENCO et al THE JOURNAL OF UROLOGY. Vol. 169, 2210–2215, June 2003)

Place the self adhesive electrodes on the ankle skin with the negative (black) electrode behind the internal malleolus and the positive electrode 10 cm. above the negative electrode as shown

Adjust intensity level until you see your toes moving, then reduce two steps.

Use for 20 minutes once or twice daily.

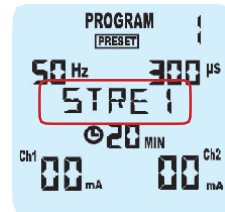
11. CONTROLS AND DISPLAYS



11.1. SWITCH ON

Press and hold for 2 seconds, the unit will display the last programme used. Intensity defaults to zero. Backlight will turn off 5 seconds after the last button press. Press again to switch off. If no button used for 10 seconds and intensity is set above zero there is an automatic keypad lock. Key symbol appears.

Press either Intensity Down button to unlock.



11.2. SELECT PROGRAMME

Press the button to cycle through the available programmes. The Hz and µs settings for each programme are displayed. See section 10 for the detailed programme settings.

1	STRE1
2	STRE 2
3	URGE
4	MIXED
5	URGE2
6	SENS
7	PFWA

8	PFWB
9	ENDUR
10	PAIN
11	TIBN
12	CSTM1
13	CSTM2
14	CSTM3



TIBN warning The TIBN programme is designed to be used with self-adhesive electrodes only. Using it with a vaginal probe could give uncomfortably high stimulation. When you select TIBN, intensity increase is stopped at 1, the warning triangle flashes, and the UP buttons are locked until you press key to confirm that you want to use this programme, or change Programme.

11.3. SET TREATMENT TIMER


The default setting for preset programmes is shown. To alter the Treatment Timer setting, press Menu+/- The Timer display will flash. Use +/- buttons to adjust the treatment time. Then press to accept change.

Choices are: Continuous, 5-60 mins in 5 min steps. Programmes 4, 6, 7 & 8 are preset programmes with fixed treatment times




11.4. MANUAL SETTINGS

When a programme has manual settings available, MANUAL will be displayed.

Press Menu + Menu - buttons to cycle through parameters. Selected Parameter flashes. Press +/- buttons to adjust setting. Press return button  to accept change, Flashing stops.


Parameters cycle through Hz, uS, Work, Rest, Ramp, Timer, "DATE", "TIME".

Set Intensity


There is an automatic keypad lock if no button used for 10 seconds and intensity is set above zero. Key symbol appears.  Press either Intensity Down button to unlock.



Use the s t buttons for each channel to adjust intensity. Intensity in mA is displayed at the bottom of the screen

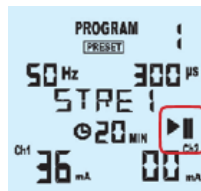
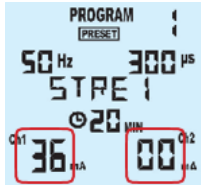
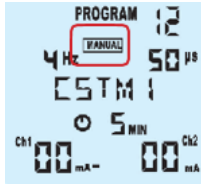
Automatic Keypad Lock

There is an automatic keypad lock if no button used for 10 seconds and intensity is set above zero. Key symbol appears.  Press either Intensity Down button to unlock.


Manual Programme Lock

When "Manual" is showing, you can protect the manual settings by pressing and holding  button for 5 seconds.

The lock symbol  in the LCD flashes if you try to adjust manual settings. To unlock the CSTM settings, simply press and hold button  for 5 seconds again.




Pause

Pressing the  button while a programme is in use stops the stimulation and the timer. Pause symbol is displayed. Press again to resume the programme. Stimulation will re-start at 75% of previous intensity setting. If left in PAUSE for more than 15 minutes, switches OFF.

Low Battery

When the battery voltage is low the Low Battery warning symbol will display. 


Warning


In Manual programmes a Warning triangle  will be displayed if the Rest period is less than $\text{Rest Time} = \text{Work Time} \times (\text{Work Hz} - 16.66) / 16.66$ seconds. If the warning triangle appears at any other time, see "Troubleshooting".

Usage Memory

Date and Time Setting

The Date (Day of month) and Time (Hour of day) can be set. This enables the memory to give an exact history of daily usage.

To set date and time, press M+ and cycle through parameters to DATE. Centre left shows Day of month and centre right shows Hour. Day is flashing. Adjust with +/- buttons and set with  button.

To set Hour, press Menu + and cycle through parameters to TIME. Adjust with +/- buttons and set with  button.

Memory Mode

A: Day of month


B: Recording number for day

C: Programme used for this recording D: Duration of recording

E: Average intensity for recording



If no programme has been used for more than 9 minutes, a NULL message is displayed and the unit returns to waiting mode.

To view the memory, press Menu+ or Menu- and cycle through parameters to the screen with MONTH showing in the middle and the warning triangle  at bottom centre.

Use the [+] and [-] buttons to select cycle through recordings. To clear the memory, press and hold the [M+] and [M-] buttons together for approx. 5 seconds while in memory mode.

Open Circuit Detector And Automatic Switch Off

If the electrodes become detached and the intensity is set to greater than 10, the “Sure Pro” will automatically reset intensity to zero, the zeroes in the display will flash, and the warning triangle symbol will flash.

To preserve battery life, the “Sure Pro” automatically switches off if left at zero intensity for more than 2 minutes or if it is left in PAUSE for more than 15 minutes. The backlight turns off 5 secs after the last press of the keypad.

12. PACK CONTENTS

- “Sure Pro” unit with beltclip
- X-VP Liberty vaginal probe
- CM5050 pack of 4 self adhesive electrodes
- 2 x L-ST2 Connecting lead wire
- B-BL6F Li-ion battery type BL-6F
- Charging cradle
- Multiplug (UK/EU) power adaptor
- Instruction booklet
- Storage pouch

13. SETTING UP AND USING THE “Sure Pro”

13.1. INSTALLATION OF BATTERIES

Setting up and using the “Sure Pro” is very simple.

Step 1: Insert battery into unit.

Remove Battery Cover

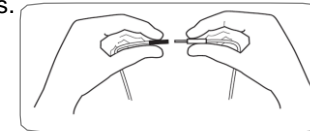
Remove the belt clip then press down the centre of the battery cover and slide downwards. (To remove the belt clip pull the central spine marked “PULL” upwards, and slide the clip down).

Insert battery

Line up the 3 connectors on the battery with the contact in the unit. Slide in and press down. Replace Battery Cover. Attach the belt clip.(To attach the belt clip, firmly slide it into the slot. Test to ensure that the lock has engaged.)

Step 2: Decide whether to use one channel or two. Unless you are told otherwise by your medical advisor you will only want to use one (Some treatment protocols use both vaginal and anal electrodes). Plug the connecting lead wire into the “Sure Pro”.

Step 3: Connect the other end of the connecting lead wire to the probe. For PAIN and TIBN, use electrode pads.



Step 4. To test that the battery has been fitted correctly and that the unit is working press and release the “ON” button once. The screen will light up and the sounder will beep.

Step 5: To test the unit is working – hold the probe in your hand – hold the probe tightly, covering as much of the metal plates on the probe with your skin as possible. Increase the intensity by pressing the + button until you can feel the stimulation. Press and release the OFF button once to turn off the unit

Note: Once you have passed 20.0mA, if you were to let go of the probe and break the contact between the probe and your skin, an alarm will sound and ‘leads’ will appear on the screen. This is a safety feature which doesn’t allow current to flow through the probe when there is poor contact between your skin and the probe.

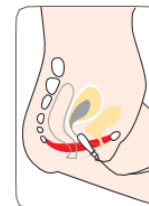
13.2. PREPARING FOR THE TRAINING SESSION

Caution: Ensure the “Sure Pro” is switched OFF before inserting the probe.

- Before using “Sure Pro” Pelvic Floor Exerciser you will need to visit the toilet.
- Lubricate the metal electrode surfaces and probe tip with a proprietary jelly, such as TensCare Go Gel or waterbased lubricant, or water.

Caution: Do not use a silicone based lubricant on the stimulation contacts as it may decrease the effectiveness of the “Sure Pro’s” muscle stimulation.

- Choose a comfortable position, such as leaning back or lying down on your bed with your knees raised.
- After wires are securely connected, insert the probe 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 probe will naturally position itself with the widest part of the flange vertically. The metal parts conduct the electrical pulse and should be in contact with the main part of the muscle at all times.



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

13.3. TRAINING SESSION

- 1) Press and hold the “ON” button on the control unit for at least 3 seconds to switch the control unit on.

When switched on for the first time, the “Sure Pro” will automatically select the ‘STRES’ programme. After that it will automatically select the programme you were using the last time it was switched off.

Caution: The Liberty vaginal probe that is supplied with the “Sure Pro” is intended strictly for single person use. Do not share your probe with anyone else as cross-infection may occur.

- 2) You can select from the four pre-set programmes. Details in section 8 will help you identify the best programme to suit you.
- 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 00.0mA 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 minute programme.

Note: The strength required varies widely between users - some will use the “Sure Pro” at full power - 99.5. The “Sure Pro” strength will go up at 0.5 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.

Note: If the sensation becomes uncomfortable, reduce the intensity.

The LCD display shows the strength of intensity used. The aim is to increase this over a number of 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.

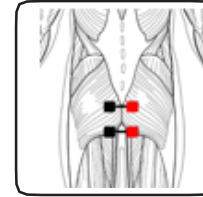
Note: If the Liberty Vaginal Probe does not make good contact, a medium sized probe, the Liberty Plus (X-VPM) is available as an optional accessory. The Liberty Plus is 32mm compared to the 28mm of the standard Liberty.

Optional skin surface electrode placement for Urge

An alternative method to a vaginal 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.

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



13.4. 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 vagina by holding the positioning end rim and gently pulling outwards. Be careful not to pull the wire as this may damage it.
- 2) Wash and thoroughly dry the probe as per section 16 and return it to the storage pouch.

14. ANAL PROBE

An anal probe (X-PR13) can be purchased as an accessory. This probe can be used for urinary and faecal incontinence in both males and females..



Conditions that may be treated

These anal probes may be used to treat Urinary and Faecal Incontinence in a similar way to the vaginal probe. Because the stimulation cannot be restricted to one muscle group, and the mucosal tissue has different electrical characteristics, anal stimulation is less comfortable than vaginal.

You should consult your healthcare professional before starting treatment.

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 “Sure Pro” if you either have no active anal sphincter contraction, or a weak or poorly sustained contraction. Use the STRESS 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 “Sure Pro”.

Post Prostatectomy Urinary Incontinence

Electrical stimulation has been found to help urinary incontinence in men after radical prostatectomy in some trials. Use the same programmes as for vaginal stimulation. Increase intensity in STRESS, MIXED, or TONE programmes to the highest tolerable.

[How To Insert Anal Probe](#)

Caution: Ensure the “Sure Pro” is switched OFF before inserting the probe.

- Before using “Sure Pro” Pelvic Floor Exerciser you will need to visit the toilet.
- Connect the leadwires the same way as you would for Vaginal Probe.
- Lubricate the metal electrode surfaces and probe tip with a proprietary jelly, such as TensCare Go Gel or waterbased lubricant, or water.
- Choose a comfortable position, such as lying down on your bed on your side with your knees raised.
- After wires are securely connected, insert the probe into 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. 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. 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. 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 ring 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.

15. TRANSCUTANEOUS TIBIAL NERVE STIMULATION FOR URGE AND FAECAL INCONTINENCE

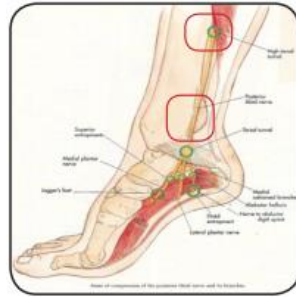
The exact mechanism of action is unclear but it is thought that Tibial Nerve contains mixed sensory motor nerve fibres that originate from the same spinal segments as the nerves to the bladder and pelvic floor.

Clinical trials have shown that TNS using a self-adhesive surface stimulation electrode without an implanted needle electrode can be effective.

(Ref: URODYNAMIC EFFECT OF ACUTE TRANSCUTANEOUS POSTERIOR TIBIAL NERVE STIMULATION IN OVERACTIVE BLADDER. G. AMARENCO et al THE JOURNAL OF UROLOGY. Vol. 169, 2210–2215, June 2003)

Place the self adhesive electrodes on the ankle skin with the negative (black) electrode behind the internal malleolus and the positive electrode 10 cm. above the negative electrode as shown above. Choose the programme 11 TINB. Adjust intensity level until you see your toes moving, then reduce two steps. Use for 20 minutes once or twice daily.

The “Sure Pro” will send an electrical impulse to the nerve. This nerve impulse is then transmitted to the sacral plexus which regulates the control of bladder and pelvic floor muscles.



16. CLEANING

It is important that the probe 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 probe in a liquid

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


- Do not immerse your “Elise” machine in water.
- Do not use any other cleaning solution


17. TROUBLESHOOTING

If the unit does not work:

- **No display** – charge the battery, please see section 18 for more details

• **Controls don't work:**

- If  is shown on display, press **t** button to unlock the keypad.

- No  showing. Ensure battery is charged.

• **Warning triangle flashing, cannot increase intensity**

You are in programme TIBN. If you have attached adhesive pads to your ankle, press **o** button to activate the programme, otherwise, select a different programme.

• **Intensity won't go above 10 mA and zeroes in display and warning triangle flashing**

A circuit is not being made

- Check if the lead wires properly connected at both ends
- Is the lead damaged? (Try using the other lead – if this works, then the original lead is faulty)

If using optional adhesive pads, check whether you properly applied both electrode pads (per lead wire) to ensure a complete circuit?

- Check lead and probeconnection:-
- Dampen your hand with water and a little table salt. Squeeze the probe firmly and carefully increase strength until you can feel something or intensity displayed drops to zero.
- If you can't feel anything, either lead or unit is faulty
- If you can feel something on your hand, and the intensity displayed does not drop to zero, then there is nothing wrong with the unit or lead.


The electrical conductivity of the vagina varies widely. The open circuit detection circuit in the product is there as a safety feature. It ensures that rapid changes in connection cannot cause very uncomfortable rapid changes in stimulation. Unfortunately this means that some users, who fall outside of the general range, may experience unwanted cut-outs.

If this happens to include you, you can try:-

- a) Using a water-based lubricant, such as GoGel, which will improve conductivity
- b) Crossing your legs and squeezing to increase pressure on the probe, which should improve the connection. If this enables you to use the unit, you should find that in a few weeks of stimulation the contact improves. If it does not, then we are sorry to say that the unit may not work for you.
- c) If b does not work, you can try the optional 32mm probe, part no X-VPM. (The probe supplied with the unit has a 28mm diameter.)

- **No sensation and displayed intensity does not drop to zero.**
 - If you have tried the test above and DO have sensation when the probe is in your hand, then you may have reduced sensitivity due to previously damaged or desensitised pudendal nerves (this can happen in childbirth or some surgical procedures).
- **No sensation on one side**
 - The current flows from one side of the probe to 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.
- **No sensation and no LEADS alarm**
 - Please make sure you are increasing the intensity high enough. Most people will start to feel the stimulation in their hand at around 25.0mA and with the probe inserted you will need to increase the intensity higher to around 40.0mA - 60.0mA, Max power is 99.5mA. Everyone is different so just keep increasing the intensity until you can feel. The intensity increases in very small steps of 0.5mA.
 - You may have reduced sensitivity due to previously damaged or desensitised pudendal nerves (this can happen in childbirth or some surgical procedures). Please consult your healthcare professional.

18. CHARGING THE BATTERY

The “Sure Pro” is powered by a type BL-6F rechargeable Li-ion battery. A separate charging cradle and power adaptor with interchangeable plug are included in the kit. The battery should need charging about once a month. The battery should last at least 6 hours at 50mA 300uS 50Hz. To fully charge the battery it will take about 2 hours. When the battery is running low, the symbol  will show on the screen. Although the display fades as the batteries run down, the strength of the output does not change until the warning is shown.

NB: Remove the battery from your “Sure Pro” if the unit is unlikely to be used for a long period.

Warning: Use only the power adaptor and charging cradle supplied. Use of other chargers could be hazardous and will negate the warranty.



To charge the battery:

Step 1. Insert the battery into the charging cradle, connect the charging cradle to the power adaptor and plug it into the mains socket.

Step 2. The red light will appear on the charging cradle – that means the battery is being charged.

Step 3. When the battery is charged, the indicator light on the cradle will change from red to green.

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

Caution: Keep batteries out of reach of children.

If necessary, it is recommended to obtain a replacement battery from your local distributor.

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

WARNING:

This product is equipped with a Lithium-ion battery. Failure to follow these instructions could cause the lithium-ion battery to leak acid, become hot, explode or ignite and cause injury and /or damage:

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

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

Do NOT put, store or leave it 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 the battery in water or sea water, or get it wet

Do NOT short-circuit the battery

Do NOT MIX 5V and 4.2V Power Supplies and Cradles. This could result in failure to charge or damage to the battery.

19. ACCESSORIES

Expected Service Life

- The machine will often last for more than 5 years, but is guaranteed for 2 years. Accessories (leads, pads, and batteries) are not covered by the guarantee.
- Lead life depends greatly on use. Always handle the leads with care
- Pads should last 12-20 applications, depending on skin condition and humidity.
- Li-Ion battery should last about 300 charge cycles.

PART NUMBER

REF	
X-VP	Liberty Vaginal Probe 28mm
X-VPM	Liberty Plus Vaginal Probe 32 mm
X-VPL	Liberty Loop VaginalProbe
X-VPG	Liberty Gold Vaginal Probe
X-PR13	Anal Probe ref PR13A
E-CM5050	Electrode pads 50x50mm for external use. Pack of 4*
L-ST2	Replacement lead 1.25m
B-BL6F	Li-Ion battery type BL-6F 3.7V 1100mAh
X-CR-SP	Charger Cradle
X-ELPA5V	Charger multiplug (UK/EU)
X-ELBATCH-US	Charger USA
X-ELBATCH-AU	Charger Australia
K-GO	Go Gel water-based personal lubricant

Further information on purchasing accessories can be obtained:

By contacting TensCare Ltd on +44 (0) 1372 723 434 or by going online to www.tenscare.co.uk. Please ensure that you order the correct part number.

20. 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 wheellie bin symbol as depicted below.



To comply with the Directive you can return your old electrotherapy 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 send your old device for components recovery and recycling to help to conserve the world's resources and minimise any adverse effects on the environment.


21. EMC PRECAUTIONS

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.

NB: 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

NB: For use in hospitals, full EMC tables are available on request

22. TECHNICAL SPECIFICATIONS

Max Intensity	99mA zero to peak. Setting 0-99 in steps of 1 OC cutout below 160 Ohm. Constant current 160-470 Ohm, Constant voltage 470-2000 Ohm
Channels	Single
Waveform	Asymmetrical rectangular
Max Pulse energy	Total output limited to 25uC per pulse
Power	BL-6F Li-Ion battery 3.7V 1100mAh Mains adaptor (Class II) with charging cradle. Input 110-240V, Output 4.2V DC600mA
Battery life	At least 10 hours at 50mA 300uS 50Hz
Adjustable Timer	10, 20, 30 45, 60, 90 min Defaults to 20 min
Output plug	Fully shielded: touch proof
Weight	90 gms without batteries
Dimensions	115x56x23mm
Environmental Specifications	
Operating:	Humidity: 20 to 93% RH, Temperature range: 0 to 35C Atmospheric Pressure: 700hPa to 1060hPa
Storage:	Humidity: 10 to 93% RH, Temperature range: 0 to 55C Atmospheric Pressure: 700hPa to 1060hPa
Contact Duration:	At least 10 minutes
TYPE BF EQUIPMENT	Equipment providing a degree of protection against electric shock, with isolated applied part. 



The unit is not water resistant, and should be protected from liquids.

IP22	The first number 2: Protected against access to hazardous parts with a finger, and the jointed test finger of 12mmø, 80mm length, shall have adequate clearance from hazardous parts, and protected against solid foreign objects of 12.5mmø 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.
Expected Service Life	<ul style="list-style-type: none"> The machine will often last for more than 5 years, but is guaranteed for 2 years. Accessories (leads, pads, and batteries) are not covered by the guarantee. Lead life depends greatly on use. Always handle the leads with care. Replace the probe every six 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 continuous use.
Storage life	<ul style="list-style-type: none"> Storage life of an unopened pack of electrodes is 2 years. This may be affected by very high temperatures or very low humidity. Storage life of batteries is 3 years. The unit and probe have no fixed shelf life.
Year of manufacture	The year your unit was manufactured is represented by the first two numbers of the serial number in the battery compartment of your unit. For example, a unit with serial number E11/0012345 was manufactured in 2011.
NB The electrical specifications are nominal and subject to variation from the listed values due to normal production tolerances	

PROGRAM SETTINGS











Prog	Display	Hz	Pulse width μ S	Ramp Sec	Work Sec	Rest Sec	Default Duration (Min)
1	STRE 1	50	300	1	5	10	20
2	STRE 2	35	250	2	3	6	20
3	URGE	10	200	1	5	10	20
4	MIXED	10/50	200/300				30
5	URGE2	10	200	Continuous			
6	SENS	3/10/20/ 30/40	250/200				25
7	PFWA	See below					
8	PFWB	See below					
9	ENDUR	20	250	2	5	10	20
10	PAIN	4	200	Continuous		20	
11	TIBN	10	200	Continuous		20	
12	CSTM 1	4-90	50-350	1-10	1-20	1-30	5-60
13	CSTM 2	4-90	50-350	1-10	1-20	1-30	5-60
14	CSTM 3	4-90	50-350	1-10	1-20	1-30	5-60

In Mode A the Pulse Width increases from 175us to 250 us in 4 secs - 25 us per sec. This stepping up occurs during Output On time.

In Mode B the Pulse Width increases from 170 us to 250 us in 8 secs - 10 us per sec.

PFW	Hz	Pulse width μ S	Work Sec	Rest Sec	Time (Min)	
A	20	250 us fixed	4	6	2	
	20	250 us stepped	4	6	5	
	3	250 us fixed	4	4	5	
	10	500 us fixed	4	4	15	
	20	250 us stepped	4	6	10	
	35	250 us stepped	4	8	5	
	45	250 us stepped	4	8	5	
	10	500 us fixed	4	4	5	
					Total	52 mins
	B	20	250 us fixed	6	8	2
20		250 us stepped	6	8	5	
3		250 us fixed	6	6	5	
10		500 us fixed	6	6	15	
20		250 us stepped	6	8	10	
35		250 us stepped	6	12	5	
45		250 us stepped	6	12	5	
10		500 us fixed	6	6	5	
					Total	52 mins

SYMBOLS USED

-  Attention! Please follow the instruction in the Instruction Manual.
-  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 Instruction Manual”
-  Temperature Limitation: Indicates the temperature limits to which the medical device can be safely exposed.
-  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.
-  This medical device is not water resistant and should be protected from liquids.
-  Do not dispose in household waste.
-  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), “E/Month/Year/Number” (MM/YY/123456).



This medical device is indicated for home use.



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

22. WARRANTY

This warranty refers to the unit only. It does not cover probe, pads (optional extra), battery, or the mono lead wire.

PRODUCT WARRANTY INFORMATION

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 and the failure does not amount to a major failure

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.

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.

Returning your unit for service

Should repair be needed within the warranty period, enclose the tear off section of this warranty card 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.

DO NOT SEND IN PROBE DUE TO BIO-HAZARD RISK. ONLY SEND IN UNIT AND THE LEADWIRE.

Please return the unit and warranty card at your cost to:

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 723434

**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 PROBES

RETAILERS NAME: _____

RETAILERS ADDRESS: _____

RETAILERS POSTCODE: _____

BRIEF DESCRIPTION OF PROBLEM YOU ARE EXPERIENCING: _____

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

Distributed by:



TensCare™

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Pub. Ref.: I-SP-UK Rev 2.0 10/16



INSTRUCTIONS FOR USE



READ CAREFULLY BEFORE STARTING USE