

Sure PRO



INSTRUCTIONS FOR USE

READ CAREFULLY BEFORE USE

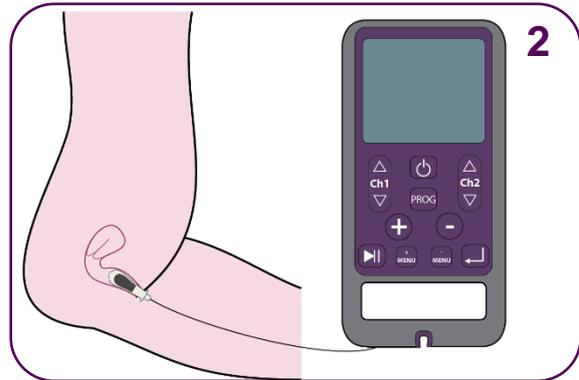


TensCare™

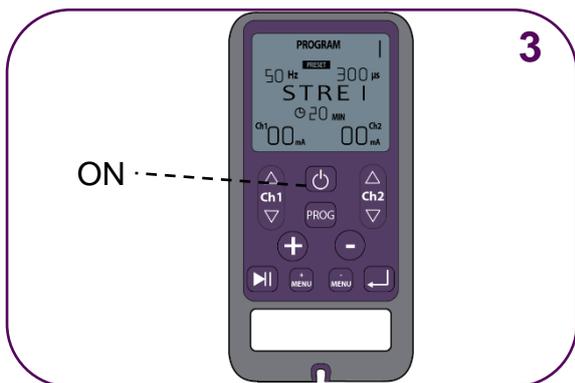
QUICKSTART GUIDE



Connect the unit with the vaginal probe



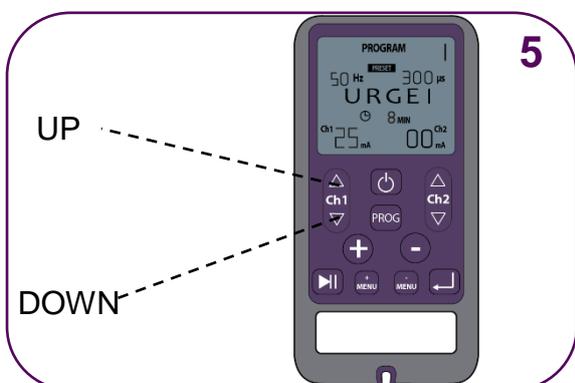
Insert the vaginal probe



Press 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 the OFF button to switch the device off

Dear Customer,

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

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

Best regards,

Your TensCare Team

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SYMBOLS USED

	Attention! Please follow the instructions in the user's instructions for use.
	TYPE BF EQUIPMENT: Equipment providing a degree of protection against electric shock, with isolated applied part. Indicates that this device has conductive contact with the end user.
	This symbol on the unit means "Refer to instructions for use".
	Temperature Limitation: indicates the temperature limits to which the medical device can be safely exposed.
	Lot Number: indicates the manufacturer's batch code so that the batch or lot can be identified.
	Humidity Limitation: indicates the humidity limits to which the medical device can be safely exposed.
	Serial Number: indicates the manufacturer's serial number so that a specific medical device can be identified.
	Do not dispose in household waste.
	Catalogue Number: indicates the manufacturer's catalogue number so that the device can be identified.
	Atmospheric Pressure: indicates the atmospheric limits to which the medical device can be safely exposed.
	Date of Manufacture: indicates the date which the medical device was manufactured. This is included within the serial number found on the device (usually in the battery compartment), either as "E/Year/Number" (YY/123456) or "E/Month/Year/Number" (MM/YY/123456).
	This medical device is indicated for home use.
	This medical device is not water resistant and should be protected from liquids.
	<p>The first number 2: Protected against access to hazardous parts with a finger, and the jointed test finger of 12 mm \varnothing, 80 mm length, shall have adequate clearance from hazardous parts, and protected against solid foreign objects of 12.5 mm \varnothing and greater.</p> <p>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.</p>

1. INTRODUCTION

Device Description & Principles of Design

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 incontinence and pain with four self-adhesive electrode pads.

The **Sure PRO** has 12 preset and 3 manual programmes. In addition to the standard settings, it has special programmes for transcutaneous stimulation of the tibial nerve for urge incontinence.

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

The **Sure PRO** 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 pelvic pain:** vulvodynia, symphysis pubis or interstitial cystitis.
- **Treatment of erectile dysfunction in men*** and improvement of pelvic strength (* requires an anal probe).

2. INTENDED USE



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

Sure PRO may help to relieve symptoms of 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. SURE PRO FEATURES

- **Dual channel**

Two independent channels to treat symptoms of all types of incontinence via a tampon-shaped probe and/or electrode pads.

- **Comfortable Stimulation**

Gentle stimulation with 99 small steps of intensity, 1mA per step.

- **12 Preset Programmes**

EMS programmes including stress, urge, mixed, endurance, pelvic floor workout and a tone aftercare. Additionally, dedicated TENS

programmes for Tibial Nerve Stimulation and a Pelvic Pain Relief programme.

- **3 Manual Programmes**

Choice of user defined programmes to experiment and save favourite settings.

- **Open Circuit Detection**

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

- **Large Backlit Screen**

Makes the screen easy to read under all conditions as well as it clearly shows the operation of the unit and the parameters being used.

- **Memory**

Features choice of sophisticated functions: exact history of daily usage by programme and by time and programme retention (automatically starts in the last programme used).

4. PELVIC FLOOR EXERCISES

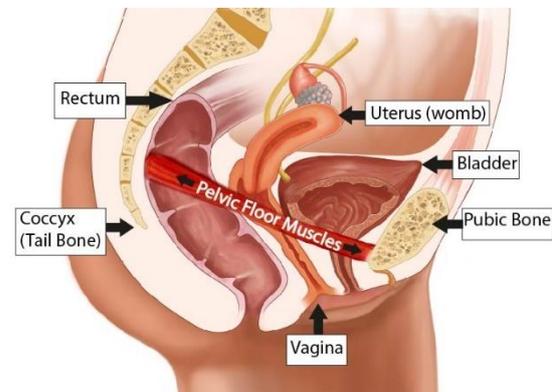
4.1. PELVIC FLOOR MUSCLES

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.
- 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 in the United Kingdom and occurs in about 40% of women. Symptoms tend to become exacerbated towards the end of each day and if left untreated, they will generally worsen over time.

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

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

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 are a couple of techniques which might help:
Try inserting one or two clean fingers into your vagina and then squeezing the surrounding muscles, lifting up and towards your belly button – a squeezing and lifting sensation.
Another way is to try and stop the flow of urine during urination. If you are successful, then you know you are exercising the correct muscles.

 **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.

- 3) Try to remember the lifting and squeezing sensation and when you are ready try to recreate it just using the muscles you identified earlier; don't tense the muscles in your legs, stomach or buttocks and remember to breathe normally.
- 4) Aim to hold each squeeze or 'contraction' for three to five seconds, then release and relax. You should feel a 'letting go' of the muscles. Rest for five seconds and then repeat.
- 5) Try and do about ten squeezes in this way.
- 6) Repeat the whole process three or four times a day.
- 7) Over a period of time try to increase the muscle contractions up to about ten seconds, but remember to rest in between each squeeze for longer periods.

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

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

- 8) Using your **Sure PRO** 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 women who have had a natural childbirth and occurs when the bladder neck and the other mechanisms that act to hold urine in the bladder are not working properly. The most common cause is a weak pelvic floor.

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 **Sure PRO** 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 **Sure PRO**.

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 Pelvic Pain

Pelvic pain can be due to several causes such as:

Vulvodynia, Symphysis Pubis, or Interstitial Cystitis.

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. **Sure PRO** uses a gentler, low frequency setting which promotes release of endorphins and reduces involuntary contractions of the bladder (detrusor) muscle.

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

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

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

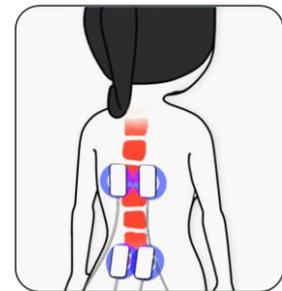
7. HOW 'TENS' WORKS

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



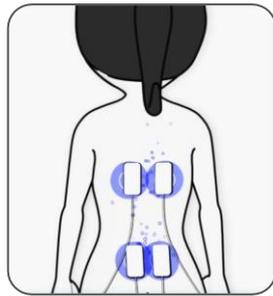
nerves carrying pain. A strong sensory signal will block the pain signal travelling up the spine to the brain. This is known as closing the "Pain Gate" and takes effect quite quickly after the unit is switched on. When the gate is open, pain messages get through to the brain and we feel pain. When the 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.
- TENS may also be used to treat many types of pain, such as migraine headaches, period pain and endometriosis (see **Ova+**), cystitis, sports injuries, fibromyalgia and neuralgia, plantar fasciitis, post-operative pain, TMJ disorder, diabetic neuropathy, osteo-arthritis

and sometimes non-painful conditions such as travel sickness.

- 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** if you are or may be pregnant. *It is not known whether TENS may affect foetal development.*
- **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 pelvic surgery or vaginal childbirth. *Stimulation may disrupt the healing process.*
- **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.*

WARNINGS:



Do NOT use if you are unable to properly insert the vaginal or anal 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 a bleeding disorder as stimulation may increase blood flow to the stimulated region.



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 vaginal or 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 **Sure PRO** 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, vaginal tenderness, 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 **Sure PRO** vaginal probe is intended for single patient use only. Do not share your **Sure PRO** probe with anyone else. *Improper treatment or cross-infection may occur.*

 **Caution:** This probe is intended for single orifice use only (intra-vaginal or intra-anal use).

Improper treatment or cross-infection may occur.

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

 **Caution:** Never insert or remove vaginal 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 **Sure PRO'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).*

 Use with **caution** if you have a copper IUD. If discomfort occurs, discontinue treatment immediately and ask your healthcare professional for advice. *There is a small risk of stimulating the uterine wall if the IUD is not correctly positioned.*

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

DO NOT PLACE THE 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.*
- On the neck/throat. This could cause respiratory closures and discomfort in breathing. *This could also cause blood pressure to drop (vagal discomfort).*
- Over the eyes. *This can affect sight or cause headaches.*
- Across the forehead. *The effects on patients subject to stroke and epilepsy are not known.*

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: -25°C to + 70°C, up to 93% RH. Temperature & Relative Humidity of transportation: -25°C to + 70°C, up to 93% RH.

 **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 treating 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 μ s - millionths of a second)**

The **Sure PRO** unit has pulse widths of 50 to 500 μ s. 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

	Programme	Frequency (Hz)	Pulse Width (µs)	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	URGE 2	10	200	Constant			Continuous
6	SENS	3/10/20/30/40	250/200				25
7	PFW A	See the table below					
8	PFW B	See the table below					
9	ENDUR	20	250	2	5	10	20
10	PAIN	4	200	Constant			20
11	TIBN 1	10	200	Constant			20
12	TIBN 2	20	200	Constant			20
13	CSTM 1	4-90	50-400	1-10	1-20	0-30	5-60
14	CSTM 2	4-90	50-400	1-10	1-20	0-30	5-60
15	CSTM 3	4-90	50-400	1-10	1-20	0-30	5-60

PFW	Frequency (Hz)	Pulse Width (µs)	Work(sec)	Rest (sec)	Default duration (min)
A	20	250 µs fixed	4	6	2
	20	250 µs stepped	4	6	5
	3	250 µs fixed	4	4	5
	10	500 µs fixed	4	4	15
	20	250 µs stepped	4	6	10
	35	250 µs stepped	4	8	5
	45	250 µs stepped	4	8	5
	10	500 µs fixed	4	4	5
					Total
B	20	250 µs fixed	6	8	2
	20	250 µs stepped	6	8	5
	3	250 µs fixed	6	6	5
	10	500 µs fixed	6	6	15
	20	250 µs stepped	6	8	10
	35	250 µs stepped	6	12	5
	45	250 µs stepped	6	12	5
	10	500 µs fixed	6	6	5
					Total

In PFWA the Pulse Width increases from 175µs to 250 µs in 4 secs - 25 µs per sec. This stepping up occurs during Output ON time.

In PFWB the Pulse Width increases from 170 µs to 250 µs in 8 secs - 10 µs per sec.

10.2. PRESET PROGRAMMES

The **Sure PRO** has 12 preset programmes, with programmes for each type of incontinence (**STRESS**, **URGE** and **MIXED**), as well as other programmes for conditions including loss of sensation and pelvic pain .

1) STRE 1 - Stress Incontinence

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.

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

It is necessary that the pelvic floor muscles contract. Increase the intensity level as high as you can tolerate, then reduce by 1 mA.

2) STRE 2 - Stress Incontinence, aftercare

Having restored your pelvic floor muscles to an excellent condition with

STRE 1, 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**.

The sensation is a mixture of a strong drawing in of the muscles and then releasing. The programme repeats this sensation.

It is necessary that the pelvic floor muscles contract. Increase the intensity level as high as you can tolerate, then reduce by 1 mA.

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

3) URGE – Urge Incontinence

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.

The sensation is of a longer and softer pulling in of the pelvic floor than the **STRESS** programme.

It is important to feel this sensation throughout the programme, so you may need to increase the intensity during the treatment session. However, it is not necessary to contract the muscles

4) MIXED – Mixed Incontinence

This programme is ideal if you suffer both stress and urge incontinence. This programme is a combination of 15 minutes of the **URGE** programme,

followed by 15 minutes of the **STRE 1** programme.

During the first part, the sensation in the pelvic floor is soft, like a vibration. It is important to feel this sensation throughout the programme; you may need to increase the intensity during the treatment session. However, it is not necessary to contract the muscles.

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

It is necessary that the pelvic floor muscles contract. Increase the intensity level as high as you can tolerate, then reduce by 1 mA.

5) URGE2 – Urge Incontinence, aftercare

Similar to the programme 3, but the sensation is continuous (there is no work/rest period), which you may find more comfortable.

The sensation in the pelvic floor is soft, like a vibration. It is important to feel this sensation throughout the programme, so you may need to increase the intensity during the treatment session. However, it is not necessary to contract the muscles.

6) SENS - Lack of Sensation

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 may be helped with the programme.

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.

It is necessary that the pelvic floor muscles contract. Increase the intensity level as high as you can tolerate, then reduce by 1 mA.

7) PFW A - Pelvic Floor Workout

A multiphased programme for Mixed incontinence. The smaller steps in frequency are believed to be less likely to aggravate the Urge component.

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.

It is necessary that the pelvic floor muscles contract. Increase the intensity level as high as you can tolerate, then reduce by 1 mA.

8) PFW B - Pelvic Floor Workout, aftercare

Having restored your pelvic floor muscles to an excellent condition with **PFW A**, you will want to keep them toned and strong with this programme which has a longer Work time (contraction time).

The sensation is the same as **PFW A**.

It is necessary that the pelvic floor muscles contract. Increase the intensity level as high as you can tolerate, then reduce by 1 mA.

9) ENDUR - Endurance

Choose this programme if you feel like you can contract your pelvic floor muscles quite easily, but can't keep them contracted for very long. **ENDUR** programme will help to build up muscle strength and improve muscle endurance.

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.

It is necessary that the pelvic floor muscles contract. Increase the intensity level as high as you can tolerate, then reduce by 1 mA.

10) PAIN – Pelvic pain

The **PAIN** 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.

The sensation in the pelvic floor is soft, like a vibration. It is important to feel this sensation throughout the programme; you may need to increase the intensity during the treatment session. However, it is not necessary to contract the muscles.

11) TIBN 1 – Transcutaneous tibial nerve stimulation

External stimulation of the ankle with self-adhesive electrode pads. It is particularly effective for urge and faecal incontinence. Uses 10Hz

See Section 10.3. for more information about this programme.

12) TIBN 2 - Transcutaneous tibial nerve stimulation

Same as 11, but at 20 Hz.

For the programmes that cause muscle contractions, 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.

Most of the programmes cycle between **Work** and **Rest** to allow your muscles to recover in between contractions.

For best results in the programmes that cause muscle contractions 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 to get into a gentle rhythm.

When you change the strength setting, this cycle stays on **Work** until you stop pressing the buttons **Ch1▲** or **Ch2▲** for more than 5 seconds

Once the pelvic floor has been strengthened using the **Sure PRO**, continue to exercise the pelvic floor muscles regularly.

The uses mentioned above for each programme are indicative only, it is possible to adapt the use according to your 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**, **URGE 2** and **PAIN** programmes. These may be used continuously if required.

Most clinical trials for stress incontinence (**STRE 1** and **STRE 2**) 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 goal of the programmes that cause muscle contractions is to produce powerful muscle contractions. The strength of the intensity 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. 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 the 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.

10.3. TRANSCUTANEOUS TIBIAL NERVE STIMULATION

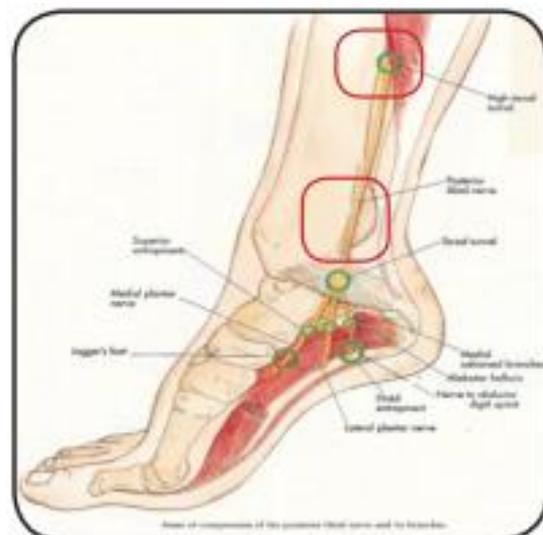
Transcutaneous stimulation of the posterior tibial nerve is effective for the treatment of urge and faecal incontinence.

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 (or internal electrode) can be effective.

(Ref: Joanne Booth et al. 2018. The effectiveness of transcutaneous tibial nerve stimulation (TTNS) for adults with overactive bladder syndrome: A systematic review. *Neurology and Urodynamics*. Volume37, Issue2. Feb 2018. 528-541)

Place the self-adhesive electrodes on the ankle skin with the negative (black lead wire connector) electrode behind the internal malleolus and the positive electrode (red lead wire connector)



about 10 cm, above the negative electrode as shown below.

Choose the programmes 11 or 12 (**TIBN 1** or **TIBN 2**). Adjust intensity level until you see your toes moving, then reduce 1 or 2 mA. 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.



Warning: The **TIBN 1** and **TIBN 2** programmes are designed to be used only with self-adhesive electrode pads. Using these programmes with a vaginal probe could produce a too strong and unpleasant stimulation.

When you select the **TIBN 1** or **TIBN 2** programmes, the intensity freezes to 1, the warning triangle flashes and the buttons **Ch1▲** and **Ch2▲** are locked. Press **←** to confirm the use of this programme or to change programmes.

10.4. MANUAL PROGRAMMES

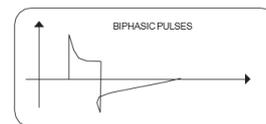
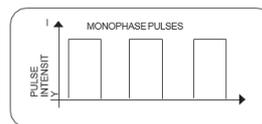


Warning: Consult your healthcare professional before using these programmes. Correct settings depend on your muscle tone and exercise goals. Inappropriate settings could cause discomfort or muscle injury or aggravate Urge incontinence.

The programmes 13, 14 and 15 (respectively **CSTM 1**, **CSTM 2**, **CSTM 3**) are the manual programmes.

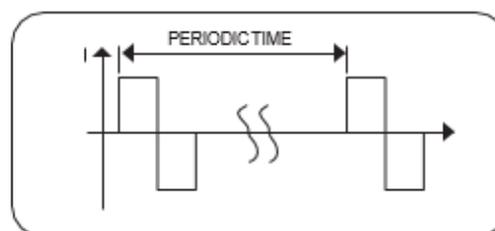
The effect of electrical stimulation on the body depends on a number of settings. In these programmes you can adjust the following:

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.

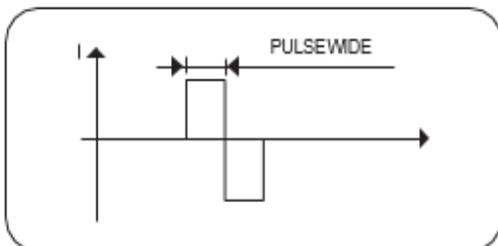
Different types of muscle fibres react preferentially to different frequencies:

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 45 to 70Hz, there is permanent tension in the muscle (tetany) combined with premature muscle fatigue. Higher pulse frequencies can therefore 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

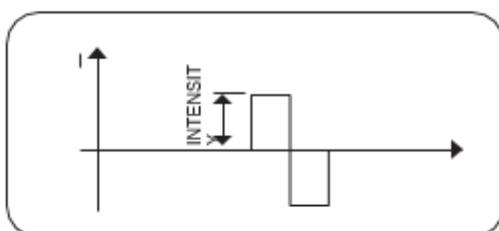


Pulse width is used to indicate the duration of an individual pulse in microseconds (μs). A larger muscle mass requires a greater pulse width. A higher Pulse Width is also more likely to activate pain nerves, so there is a fine balance between maximum muscle stimulation and tolerable sensation.

Muscle stimulation: 50-400 μs .

Pain relief and soothing: 50 to 250 μs .

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)

This 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 to 10 seconds in steps of 0.5 sec.

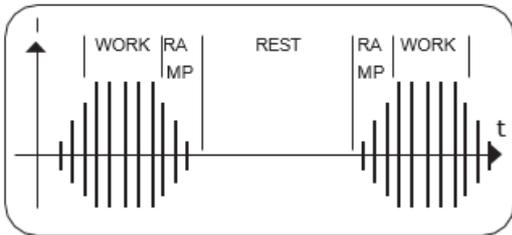
Work

This is the time in seconds that muscle is stimulated (not including Ramp time). The **Sure PRO** offers a range of work periods from 1 to 20 sec.

Rest

This is the time in seconds at zero strength in between stimulation. The **Sure PRO** offers a range of rest periods from 0 to 30 sec. The EMS programmes use an Active Rest - low frequency

pulses help to clear metabolites in between Work periods.



Note: If **Rest** is set to 0, **Ramp** is also zero and output is continuous.)

Work/Rest Ratio

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

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

If the warning triangle is displayed at any other time, see the troubleshooting in section 20.

11. CONTENT

The pack contains:

- 1 x **Sure PRO**, continence stimulator unit
- 2 x Lead wires (L-ST2)
- 1 x Liberty vaginal probe (X-VP)
- 4 x 50x50mm electrode pads (E-CM5050)
- 1 x Li-ion battery (BL-6F)
- 1 x Charging cradle
- 1 x Mains adaptor (EU/UK)
- 1 x Detachable belt clip
- 1 x Storage pouch
- 1 x Instructions for use



12. UNIT INFORMATION

12.1. CONTROLS & DISPLAY



12.2. OPERATING INSTRUCTIONS

ON/OFF

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

To turn the unit off, press **Ch1▼** or **Ch2▼** button to unlock the keypad and press the **ON/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 **STRE 1** 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.

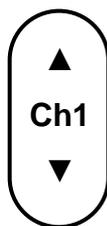


Note: Always check unit is OFF before applying or removing probe or pads.

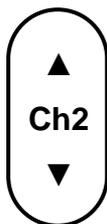
The backlight will turn off 10 seconds after the last button press.

STRENGTH CONTROLS

The buttons marked **Ch1▲**, **Ch1▼**, **Ch2▲** and **Ch2▼** are the strength controls.



The left-hand buttons change strength in the left-hand lead, Ch1, and the right-hand buttons change the right-hand lead, Ch2.



To increase strength in steps of 1 mA, press and release the top part of the two channel buttons, marked **Ch1▲** and **Ch2▲**.

To decrease the strength, press and release the lower part of the buttons marked **Ch1▲** and **Ch2▲**.

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). Sure PRO detects a disconnection and automatically returns the strength to zero.

The unit has 99 levels of strength. If you hold down the button **Ch1▲** or **Ch2▲** 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 SELECT



The button marked **PROG** is the programme control. The **Sure PRO** has 12 preset programmes.

On first use the **STRE 1** programme is automatically selected. On the next use

it will start with the last programme used.

Each time you press and release the **PROG** button, the programme will change, and the screen will display the programme selected.

Each time you change the programme, the intensity will reset to zero. This safety feature prevents sudden unpleasant changes in stimulation, since each programme produces a different sensation.

The backlight turns off 5 seconds after the last button press.

TREATMENT TIMER

 The default setting for preset programmes is shown on the screen. 

To alter the Treatment Timer setting, press **+Menu** or **-Menu**. The display will flash. Use **+** and **-** buttons to adjust the treatment time. Then press **↵** to accept the change.

You can set session times of C (continuous) or 5 to 60 minutes in 5 minutes steps. Programmes 4, 6, 7 & 8 are preset programmes with fixed treatment times.

MANUAL SETTINGS

When a programme has manual settings available, **MANUAL** will be displayed on the screen.

Press **+Menu** or **-Menu** buttons to cycle through parameters. The selected parameter will flash. Press **+** or **-** to adjust the setting. Press **↵** to accept the change, and the flashing will stop.

Parameters cycle through Hz, μ s, WORK, REST, RAMP, TIMER, DATE, TIME.

MANUAL PROGRAMME LOCK

When **MANUAL** is showing, you can protect the manual settings (or default settings) by pressing and holding **↵** button for 3 to 5 seconds.



This symbol will appear on the screen and will flash if you try to adjust manual settings. To unlock simply press and hold button **↵** for 3 to 5 seconds again.

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 **+Menu** and cycle through parameters to **DATE**. Centre left shows Day of month and centre right shows Hour. Day is flashing. Adjust with **+** and **-** buttons and set with **↵** button.

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

Memory Mode:

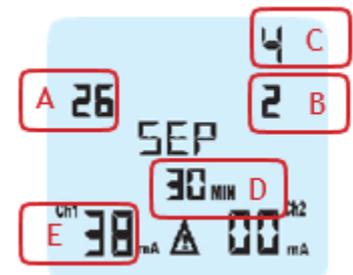
A: Day of month

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 cycle through recordings.

To clear the memory, press and hold the **+Menu** and **-Menu** buttons together for 3 to 5 seconds while in memory mode.

PAUSE

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

OPEN CIRCUIT DETECTOR

Sure PRO controls the connections and the contact between the probe or electrodes and your body.

This is to avoid sudden changes in stimulation if a broken connection is re-established.

If the lead or probe does not have good contact or become detached and the intensity is set to greater than 10mA, the warning triangle symbol  will flash, the zeroes in the display will flash, and the intensity will automatically reset to zero.

Check the lead and try using a water-based lubricating gel such as TensCare Go Gel (**K-GO**) with the probe.

If the problem persists, see section 20.

To preserve battery life, the **Sure PRO** automatically switches off if left at zero intensity for more than 2 minutes.

LOW BATTERY



A low battery warning symbol will display when you need to recharge the battery.

Automatic Keypad Lock



If no button used for 10 seconds and intensity is set above zero the keypad will lock automatically. This prevents accidental changes to settings.

Press **Ch1**  or **Ch2**  button to unlock.

13. SETTING UP AND USING THE SURE PRO

13.1. 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 10 hours at 50mA 300µs 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.



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:

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

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

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

Storage

Remove the battery from your **Sure PRO** if the unit is unlikely to be used for a long period. The stand-by current in the unit will gradually discharge the battery. Li-Ion batteries last longer if stored charged.

Battery Warnings

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.

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

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

Keep batteries out of reach of children.

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



13.2. INSTALLING THE BATTERY

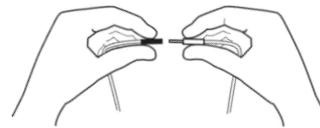
- 1) Remove the belt clip by pulling the central spine marked **PULL** upwards and sliding the clip down.



- 2) Press down the centre of the battery cover and slide downwards.
- 3) Line up the 3 connectors on the battery with the contact in the unit. Slide in and press down.
- 4) Replace Battery Cover and beltclip.

13.3. CONNECTING THE PROBE

- 1) 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).
- 2) Insert the lead wire plug into the base of the unit.
- 3) 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.

For **PAIN** and **TIBN**, use the self-adhesive electrode pads.

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.

13.4. PREPARING FOR SESSION

- 1) Before using **Sure PRO** 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.



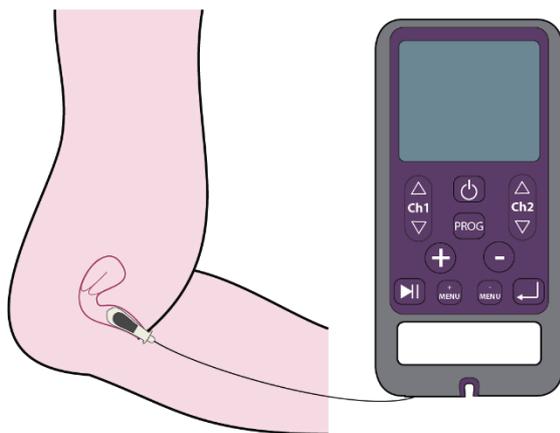
Caution: Do not use a silicone based lubricant on the stimulation contacts as it may decrease the effectiveness of the **Sure PRO**'s muscle stimulation.

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



Warning: Ensure the **Sure PRO** is switched OFF before inserting the probe.

- 4) After the wire is securely connected, insert the probe into your vagina, in the same way as you would a tampon, until only the plastic rim at the base of the probe is visible.



- 5) 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. The tissues close to the entrance are more sensitive, so you should avoid stimulating them.

Metal plates

Flange



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

13.5. TRAINING SESSION

- 1) Press and hold the ON/OFF button on the control unit for at least 3 seconds to switch the control unit on.
- 2) You can select from the pre-set programmes or a manual programme. Details in section 10 will help you identify the best programme to suit you.

To select a programme, press the **PROG** button.

- 3) With the required programme selected, you can adjust the intensity of the muscle stimulation with the ▼ and ▲ buttons 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 minute programme.



Note: The strength required varies widely between users - some will use the **Sure PRO** at full power – 99 mA. The **Sure PRO** 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 in the treatment area.

The 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 sensation becomes uncomfortable, reduce the intensity with the **Ch1** ▼ or **Ch2** ▼ button.



Note: If the Liberty probe does not make good contact with the walls of the vagina, you can try the Liberty Plus probe (**X-VPM**). This probe is 32mm diameter compared with the 28mm of the liberty probe.

The duration of most treatment sessions is automatically set to 20 minutes. The duration of muscle building sessions will depend greatly on your ability to contract and your fatigue resistance. Be careful not to overdrive the muscles, this could cause painful aches the next day.



Note: If you have aching or cramping muscles, stop treatment until the symptoms go away, then resume at a lower intensity

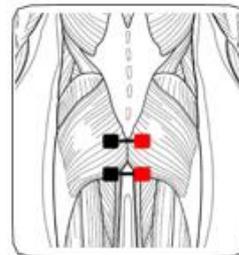
Optional skin surface electrode placement for URGE

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.

It is also possible to place the electrodes on the ankle using the **TIBN 1** or **TIBN 2** programmes (see section 10.3.).



13.6. 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 **ON/OFF** button to switch off then remove the probe from your vagina by holding the positioning end rim and gently pulling outwards.
- 2) Wash and thoroughly dry the probe and return it to the storage pouch.

- 3) **Sure PRO** 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. ANAL PROBE

14.1. CONDITIONS THAT MAY BE TREATED

An anal probe, such as TesnCare **X-PR13** or **X-AP** can be purchased as an accessory. These probes can be used for urinary and faecal incontinence in both males and females.

These anal probes may be used 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 muscles' 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 **STRE 1** or **STRE 2** 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 to the highest tolerable.

Erectile dysfunction

To help treating erectile dysfunction, use the programme **STRE 1**, **STRE 2**, **PFW A** or **PFW B**. This will help strengthening the pelvic floor muscles and achieve a more satisfying erection.

14.2. HOW TO INSERT THE ANAL PROBE

- 1) Before using **Sure PRO** 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 **Sure PRO**'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 **Sure PRO** is switched OFF before inserting the probe.

- 4) After wires are securely connected, insert the probe into the 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.
- 5) 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 and for Erectile Dysfunction, the aim is to stimulate the levator muscles and the probe should be inserted deeper.

15. 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 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 **Sure PRO** unit in water.
- Do not use any other cleaning solution.

16. 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 tables are available on request.

17. 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 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.



18. 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 battery) 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.
- Electrode pads should last 12-20 applications, depending on skin condition and humidity.
- The battery should last about 300 charge cycles.

Replacement electrode pads, new battery 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-VP	Liberty vaginal probe (28 mm dia.)
X-VPM	Liberty Plus vaginal probe (32 mm dia.)
X-VPL	Liberty Loop vaginal probe (32 mm dia.)
X-VPG	Gold vaginal probe (26 mm dia.)

X-PR13	Anal probe (19.6 mm dia.)
X-AP	Small probe (12 mm dia.)
E-CM5050	Pack of 4 electrode pads (50x50 mm)
L-ST2	Replacement lead wire, 1.25 m length
B-BL6F	Li-ion battery type BL-6F 3.7 V 1100mAh
X-CR-SP	Charging cradle
X-ELPA5V	Power Adaptor with interchangeable plug
X-ELBATCH-US	USA charger
X-ELBATCH-AU	Australian charger
K-GO	Go Gel Personal Water-based Lubricant
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.

19. 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 from date of purchase.

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

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

Our goods come with guarantees that cannot be excluded under the UK consumer Law. You are entitled to have

the goods repaired or replaced if the goods fail to be of acceptable quality.

Before you send your unit for service

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

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

Returning your unit for service

Should repair be needed within the warranty period, enclose the tear off section of the warranty card (see page 40) 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 40):

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.

20. TROUBLESHOOTING

If your **Sure PRO** is not working properly, please check the following:

Problem	Possible causes	Solution
No display	Flat battery	Charge battery. See section 13.1.
	Battery incorrectly positioned	Check the battery position. See section 13.2.
	Damaged charging cradle or battery	Contact supplier.
Low battery display	Low battery	Charge battery.
Controls don't work	Key pad is locked	If  is shown on display, press Ch1▼ or Ch2▼ button to unlock the keypad. If  is not showing, check that battery is charged.
Warning triangle flashing	Awaiting confirmation or wrong programme	If you are in programme TIBN 1 or TIBN 2 and you have attached the self-adhesive electrode pads to your ankle, press  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	The Sure PRO has a safety feature which will not allow the intensity to pass 10 mA if the machine detects a connection error. If a connection error is detected the intensity will return to 0 mA and the warning triangle will flash. 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.	<ul style="list-style-type: none"> i) If this happens, check that the lead wire is correctly connected. (If you are using the electrode pads, ensure that they are correctly attached to the skin). ii) If you are using the probe, you can try to test the unit by holding the probe in your hand: 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. iii) If the warning triangle flashes and the unit will not allow you to pass 10 mA, the lead wire may need to be replaced. Try again using the other lead.
	If you have tried the test above and DO have sensation when	If this happens, you can try these solutions:

	<p>the probe is in your hand but not when inserted vaginally, then it may be that:</p> <p>2. The skin is dry, meaning poor conductivity between the metal plates on the probe and your skin.</p>	<p>i) Using a water-based lubricant such as TensCare Go Gel (see K-GO), which will improve conduction.</p> <p>ii) 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, this unit may not be suitable for you. You may need to contact your healthcare professional to discuss other suitable options.</p> <p>iii) The probe supplied with the unit has a 28 mm diameter. An optional 32 mm probe, part no. X-VPM, is available.</p>
No sensation and no warning triangle showing	<p>Intensity level is not high enough and/or reduced sensitivity in the area being treated.</p>	<p>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 to 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.</p> <p>ii) 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.</p>
No sensation on one side of the probe (or electrode)	<p>Position is not optimal – needs adjusting.</p>	<p>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.</p>
Sudden change in sensation	<p>If you disconnect and re-connect a few minutes later, the signal will feel quite a lot stronger.</p>	<p>Always return strength to zero after disconnecting the lead or the probe.</p>

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.

21. GENERAL SPECIFICATION

Waveform	Asymmetrical rectangular
Max Intensity	99mA zero to peak. Setting 0-99 in steps of 1 OC cut-out below 160 Ohm Constant voltage 470 to 2000 Ohm Constant current 160 to 470 Ohm
Channels	Dual channel
Max Pulse energy	Total output limited to 25 μ C per pulse
Output plug	Fully shielded: touch proof
Power	BL-6F Li-Ion battery 3.7V 1100mAh Mains adaptor (Class II) with charging cradle. Input 110-240V, output 4.2V DC 600 mA
Battery life	At least 10 hours at 50 mA 300 μ s 50 Hz
Weight	90 g without batteries
Dimensions	115 x 56 x 23mm
Safety classification	Internal power source

Environmental Specifications

Operating:		Temperature range: 5 to 40°C
		Humidity: 15 to 93% RH
		Atmospheric Pressure: 700 to 1060 hPa
Storage:		Temperature range: -25 to 70°C
		Humidity: Up to 93% RH
		Atmospheric Pressure: 700 to 1060 hPa
Type BF equipment		Equipment providing a degree of protection against electric shock, with isolated applied part.
		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 and 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



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

RETAILERS NAME: _____

RETAILERS ADDRESS: _____

RETAILERS POSTCODE: _____

BRIEF DESCRIPTION OF PROBLEM YOU ARE EXPERIENCING: _____

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

NOTES

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

www.tenscare.co.uk

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EC Declaration of Conformity

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

Distributed by:



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www.tenscare.co.uk