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1. INTRODUCTION

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.

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.

Special Features

- Li-Ion mobile phone style battery
  Making it lightweight and compact, and is supplied complete with external charger.
- Unique locking lead connection and built-in cable tidy
- Backlit LCD screen
  Whenever a button is pressed the screen will light up making the screen easy to read and very clear.

2. INDICATIONS FOR USE

The Sure Pro is indicated for acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control:

- Improvement of urethral sphincter closure
- Strengthening of pelvic floor muscles
- Inhibition of the detruser (bladder) muscle through reflexive mechanisms

Sure Pro is also indicated for the specialised management of Faecal incontinence.

GMDNS Definition : Stimulator, electrical, neuromuscular, incontinence[36784]
A non-implantable neuromuscular electrical stimulator designed to treat urinary and/or faecal incontinence that consists of a pair of electrodes on a plug or pessary that are connected to a battery powered pulse source. The plug or pessary is inserted into the rectum or into the vagina and used to stimulate the muscles of the pelvic floor.

3. 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.
- 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.
- 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.

4. HOW CONTINENCE STIMULATION WORKS

ADVANTAGES

If successful, it can reduce leakage – not simply contain it

- It is Drug Free
- It is Easy to use

Stress Incontinence

The Sure Pro sends a strong, but comfortable, stimulation through a vaginal probe or pads to your pelvic floor muscles using clinically recognised programmes.

This stimulation works the pelvic floor muscles for you, building their strength, and helps you to recognize the sensation of the correct muscle movements and develop your own muscle control (Proprioception). It perfectly complements pelvic floor exercises.

Urge Incontinence

For urge incontinence, the aim is to soothe the oversensitive muscles in the bladder which are causing involuntary bladder contractions.

Sure Pro uses a gentler, low frequency setting, which promotes release of Endorphins – your body's own natural pain killer.

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.

Mixed Incontinence

When treating mixed incontinence, a stimulation appropriate for both urge incontinence and stress incontinence is used. The Sure Pro offers a choice of several programmes with combined stimulation.

Faecal Incontinence

For faecal incontinence, the aim is to improve bowel control by strengthening and toning pelvic floor and anal sphincter muscles.

Please note that we recommend the Liberty vaginal probe (as supplied with the unit) and accessories listed on page 27, as the unit has been tested with these. Other brands may be suitable, but caution should be exercised on first application.

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.

It is also possible to treat faecal incontinence in both males and females using an anal probe.

For more explanation of the programmes see Sections 8 and 9.

If in doubt contact your continence adviser before using the Sure Pro.

5. CAUTIONS AND WARNINGS

Do not use Sure Pro under the following circumstances:

- If you have been diagnosed or treated for cervical cancer. In vitro experiments have shown that electricity can promote cell growth.
- If you have epilepsy. TENS may affect seizure threshold.
- If you are pregnant. It is not known whether electrical stimulation may affect foetal development.
- When driving, operating machinery, or similar actions needing fine control. Loose pads, damaged leads, or sudden changes in contact may cause brief involuntary muscle movements.

BEFORE USE, PLEASE READ THE FOLLOWING WARNING:

- Incontinence can have many causes. You should try to identify the type of incontinence and the cause before using the Sure Pro.
- If you have a urinary infection or any skin irritations within the vagina, it is recommended not to use the Sure Pro.
- Care must be taken if you are not experiencing normal sensation or feeling in your vagina. Please see the section about inserting the probe.
- If you have prolapse, or any discomfort occurs when inserting the probe, consult your medical advisor before use.

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

Caution:

- Observe caution when using the Sure Pro at the same time as being connected to monitoring equipment with body worn electrode pads it may interfere with the signals being monitored.

- Simultaneous connection to high frequency surgical equipment may result in burns and damage to the stimulator.
- Strong electromagnetic fields (electrosurgery/microwave cookers/mobile phones) may affect the correct operation of this unit - See section 21. If it appears to behave unusually, move it away from these devices.
- Use caution following recent surgical procedures stimulation may disrupt the healing process.
- The stainless steel in the probes contains some nickel.
- If you have a copper coil that is incorrectly fitted, there is a remote chance of the copper coming into contact with the probe. If you experience discomfort, or pain, discontinue use immediately.
- Keep the device away from a fireplace or radiant heater, as the heat may affect the device.
- Keep the device away from nebuliser or steam kettle, as the moisture may affect the device.
- Keep the device away from sunlight, as long-term exposure to sunlight may affect the rubber become less elastic and cracked.
- Keep the device away from lint and dust, as long-term exposure to lint or dust may affect the sockets or battery connector become bad contact

Also do not:

- Immerse your unit or electrodes in water or place it close to excessive heat. It may cease to operate correctly.
- Attempt to open up or modify the unit. This will invalidate the guarantee and may affect safe use.
- Use this device with leads, electrodes, and accessories other than those recommended by the manufacturer in section 18. Performance may vary from specification. Electrodes with a surface area less than 4.8cm^2 may adversely affect safe use.
- After inserting plugs into both CH1 and CH2 sockets, please do not remove the plugs when the unit is working. Ensure that the unit is switched OFF before removing the plugs.
- The device must be kept out of reach of children.

ADDITIONAL CAUTIONS AND WARNINGS FOR SELF-ADHESIVE PADS

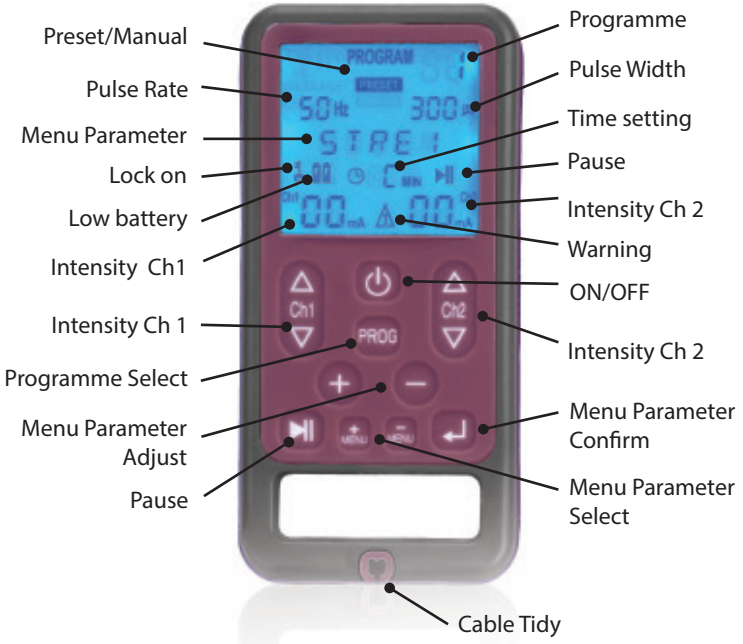
Do not place electrode pads :

- If you have a heart pacemaker or have a heart rhythm problem you MUST not place pads on the chest or front of the neck. Stimulation in the direct vicinity of a pacemaker 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.
- on broken skin, as this may encourage infection.
- to 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.
- on the carotid sinus nerves, on the front of the neck. This may affect heart rate or cause contraction of airways.
- over the eyes, or across the front of the head.
- near malignant tumours. In laboratory tests electical current has been shown to encourage cell division.
- Do not put the lead wire on or wrapped around the neck.

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.

6. CONTROLS AND DISPLAYS



6.1. Switch ON

Press ⏻ nd hold for 2 seconds.

Unit will display the last programme used.

Intensity defaults to zero.

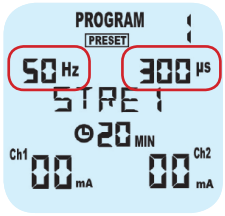
Backlight will turn off 5 seconds after the last button press.

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.

6.2. Select Programme



Press the P Program to cycle through the available programmes.

The Hz and uS settings for each programme are displayed
See section 20 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.

6.3. 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.

6.4. Manual Settings

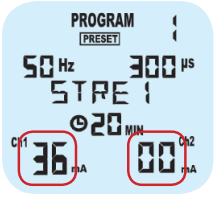
When a programme has manual settings available, MANUAL will be displayed.

Press Menu + Menu - buttons to cycle through parameters. Selected Parameter flashes.

Press +/- buttons to adjust setting.
Press return button ↵ accept change, Flashing stops.

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

6.5. Set Intensity



Use the s t buttons for each channel to adjust intensity.

Intensity in mA is displayed at the bottom of the screen.

6.6. 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.

6.7. Manual Programme Lock

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

The lock symbol the LCD flashes if you try to adjust manual settings.

To unlock the CSTM settings, simply press and hold ↵ button for 5 seconds again.

6.8. Pause ⏯

Pressing the ⏯ tton 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.

6.9. Low Battery

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

6.10. Warning ⚠

In Manual programmes a Warning triangle will be displayed if the Rest period is less than *Rest Time=Work Time*(WorkHz-16.66)/16.66 seconds.

If the warning triangle appears at any other time, see “Troubleshooting”.

6.11. 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.

7. USAGE MEMORY

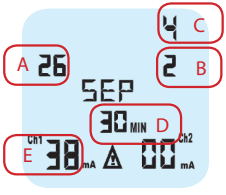
7.1. Date and Time Setting

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

7.2. 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.

8. THE PROGRAMMES

The Sure Pro has 11 preset and 3 custom programmes.

1	STRE 1	Stress 1 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 of the pelvic floor. Your natural reaction will be to pull in and up your muscles, thereby exercising and strengthening them.
2	STRE 2	Stress 2 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. The sensation is a mixture of a strong drawing in of the muscles and then releasing. The programme repeats this sensation. A strong and fit pelvic floor muscle may increase sexual health and enjoyment.
3	URGE	Shown on the screen as: "URGE" 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.

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	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 can be helped with the programme.
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. Start with A.
8	PFW B	Similar to PFW A. As your pelvic floor muscles strengthen you can progress to this programme, which has longer Work periods.
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	

9. USING THE Sure Pro

9.1. Pack Contents

- Sure Pro unit with belt clip
- 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
- Power adaptor
- Instruction booklet
- Storage pouch

9.2. Setup

Setting up and using the Sure Pro is very simple.
See section 9.5 for Guidance on using the programmes

Step 1: Charge the battery – see section 16

Step 2: Insert battery into unit. 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 bleep.

Press and release the OFF button once to turn off the unit.

Step 3: Attach the belt clip

The Sure Pro is supplied complete with a belt clip to allow you to wear it at the waist.

Removing the belt clip
To remove the belt clip pull the central spine marked "PULL" upwards, and slide the clip down.

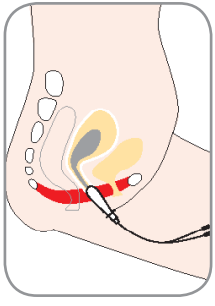
Replacing the belt clip
To attach the belt clip, firmly slide it into the slot. Test to ensure that the lock has engaged.

Step 4: 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). Insert a connecting lead wire into the Sure Pro as shown right.

Step 5: Connect the other end of the connecting lead wire to the probe. (For PAIN and TIBN, use optional pads

Step 6: Insert the probe.

Please note:



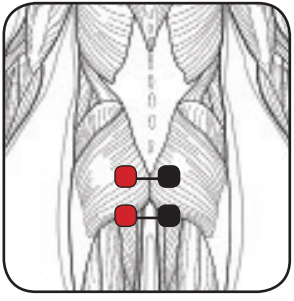
- Before inserting the probe go to the toilet
- Ensure the Sure Pro is switched OFF before insertion.
- Lubricate the probe with a proprietary jelly, such as Tenscare Go Gel, or water.
- Insert the probe into the vagina, in the same way as a tampon, until only the flange at the end is visible. The probe will naturally position itself with the widest part of the flange vertically.
- 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.

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 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.



9.3. Liberty Plus Probe

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.

9.4. Anal Probe

An anal probe (X-AP or X-PR13A) can be purchased as an accessory.

This probe can be used for stress or faecal incontinence in both males and females.

The X-AP is shorter and wider (may also be used as a small vaginal probe).

The X-PR13 is narrower and has adjustable length.

Conditions that may be treated with the anal probes

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 physician before starting treatment.

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 Stres, Mixed, or Tone programmes to the highest tolerable.

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 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.

9.5. Guidance on using the 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 - 99.5.

ii) It is advisable not to 'overdo' it early on. 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.

iii) For these exercise programmes, we suggest that you adopt a comfortable reclining position in bed or chair, so that you can concentrate on working the muscles and it is easier to keep the probe in the right place.

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

viii) Most of the programmes cycle between "work" and "rest" to allow your muscles to recover in between contractions. During the "rest" period, the strength display flashes "000".

ix) When you change the strength setting, this cycle stays on "work" until you stop pressing the buttons for more than 5 seconds.

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

9.6. 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.

9.7. 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 see 9.5.ii above. 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.

Voluntary muscular activity is more effective than stimulation, and it may improve progress if you combine voluntary contraction with stimulation.

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

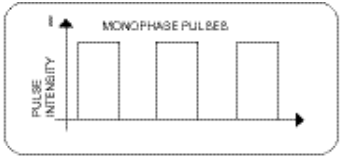
10. USING THE CUSTOM PROGRAMMES

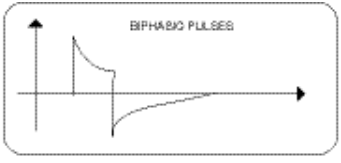
WARNING
Consult your healthcare professional before using these programmes. Correct settings depend on your muscle tone and exercise goals. Inappropriate settings could cause discomfort or muscle injury, or aggravate Urge incontinence.

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:

10.1 Pulse Waveform



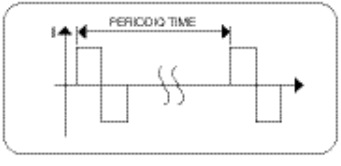


This describes the time function of the excitation current which may be either monophasic or biphasic. With monophasic pulse trains, the current flows in one direction. With biphasic pulses, the excitation current alternates its direction

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.

10.2 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.



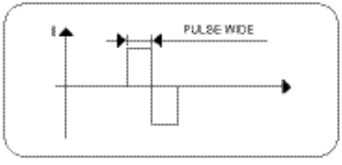
Different types of muscle fibres react preferentially to different frequencies:-

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 by 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.

10.3. 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.

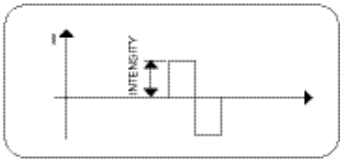
MUSCLE STIMULATION: 50-350 µS.
PAIN RELIEF AND SOOTHING: 50 to 250 µS.

10.4. 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.



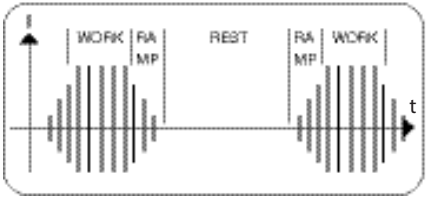
With prolonged application, you may need to increase intensity as nerves get used to the stimulation and become less sensitive (known as accommodation).

10.5. 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.

10.6. 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.

10.7. 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.



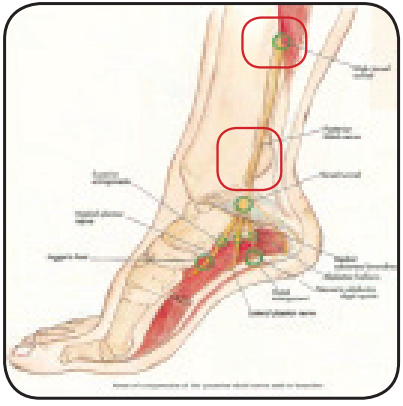
10.8. WORK/REST RATIO

The Warning triangle ⚠ splayed if Rest period is less than
Rest Time=Work Time*(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.

11. 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.

12. GENERAL PAD ADVICE

- The electrode pads supplied are reusable but are for single patient use.
- In order to obtain the best conductivity through the pads always ensure that they are in good condition and tacky.
- Before use make sure your skin is clean and dry.
- Peel the electrode pads from their protective plastic shield by holding and lifting one corner of the pad and pulling. Do not pull on the pigtail wire of the pad.

- After use always replace the pads on the plastic liner and replace in the re-sealable plastic bag.
- If the pads dry out then it is best to buy a replacement pack of electrodes. In an emergency it may be possible to restore some of the tackiness of the pad by adding a tiny drop of water on each pad and spreading around. If too much water is added the pads will become too soft then it is suggested in order to try to re-establish some adhesiveness to place them sticky side up in a refrigerator for a few hours.
- In very hot weather the gel on the pads may become soft. In such cases place the pads, still on their plastic liners and in their bag into a fridge until they return to their normal condition.

13. TROUBLESHOOTING

If your Sure Pro is not working properly please check the following:

Problem: No display/ Won't turn on:

BATTERY:
- Is it fitted?
- Is it charged?

Problem: Controls don't work
- If is shown on display, press t button to unlock the keypad.
- No showing. Ensure battery is charged.

Problem: Warning triangle flashing, cannot increase intensity

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

Problem: Intensity won't go above 10 mA and zeroes in display and warning triangle flashing

A circuit is not being made

- Are 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, have you applied both electrode pads (per lead wire) to ensure a complete circuit?
- Check lead and probe connection:-

- 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 conduction

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.)

Problem: 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).

Problem: 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.

If the above review has failed to resolve your problem, call JA Davey or your local dealer (address on back cover) for advice.

We are continuously trying to improve our products.
If you have any comments or suggestions, please do contact us at info@jadavey.com.au

14. CLEANING

The Liberty vaginal probe - that is supplied with the Sure Pro is intended strictly for single patient use. It is important that the probe is cleaned after each use. Clean with either an alcohol-free antibacterial wipe or by washing in warm soapy water, rinse and dry thoroughly.

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 Sure Pro machine in water.

Do not use any other cleaning solution

15. CHARGING THE BATTERY

The Sure Pro is powered by a type BL-6F rechargeable Li-ion battery.

A separate Charging Cradle and Power Adaptor are included in the kit.

The battery should need charging about once a week

When the battery is running low, a low battery indicator will show on the screen (battery symbol).

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

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

For a replacement battery, contact JA Davey Ltd or your local distributor.
Use only the power adaptor and charging cradle supplied. USE OF OTHER CHARGERS COULD BE HAZARDOUS AND WILL NEGATE THE GUARANTEE

Warning

There is a risk of smoke, fire, or rupture if the battery is not used according to the following guidelines:-

- Do not disassemble the battery
- Do not short-circuit the battery
- Do not incinerate or heat the battery
- Do not use or leave battery near a fire, stove or heated place (more than 80°C)
- Do not immerse the battery in water or sea water, or get it wet
- Do Not charge battery nearby the fire or in strong sunlight
- Only use the charger provided and observe charging instructions

Disposal

Always dispose of batteries responsibly according to local government guidelines.

16. GUARANTEE

Your device is guaranteed for two years from the date of purchase. If a fault develops return the unit to JA Davey Pty Ltd, together with a copy of your invoice and details of the problem. The guarantee does not cover the batteries, electrode pads or mono lead wire.

Please note that the Guarantee is invalidated if

- incorrect batteries have been fitted
- the unit has been immersed in water, maltreated or tampered with.

17. CONSUMABLES AND SERVICING

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	
X-VP	Liberty Vaginal Probe 28mm
X-VPM	Liberty Plus Vaginal Probe 32 mm
X-VPL	Liberty Loop Vaginal Probe
X-PR13	Anal Probe ref PR13A
X-AP	Anuform Anal Probe
E-CM5050	Electrode pads 50x50mm for external use. Pack of 4
L-ST2	Replacement lead 1.25m
E-CM5050	Electrode pads 50x50mm for external use. Pack of 4*
B-BL6F	Li-Ion battery type BL-6F 3.7V 1100mAh
X-ST2CR	Charger Cradle
X-ELBATCH	Charger UK
X-ELBATCH-EURO	Charger Euro 2 pin

X-ELBATCH-US	Charger USA
X-ELBATCH-AU	Charger Australia
K-GO	Go Gel water-based personal lubricant

These consumables can be purchased either by contacting JA Davey Ltd on the number below, or by going online to www.jadavey.com.au or www.jadavey.co.nz, or from your local supplier. Please ensure that you order the correct part number.

For servicing please call JA Davey Pty Ltd in Australia on 1800 807 464 or in New Zealand on 0800 523 583 to discuss any problem.

If your unit needs to be returned please send it to:
Service Department,
JA Davey Pty Ltd, 626 Lorimer Street, Port Melbourne, VIC 3207 Australia
or
BV Medical - Repairs, Unit 7, 110 Mays Road, Onehunga, Auckland, New Zealand 1061

Please ensure that you enclose your name, address and contact telephone number so that you can be contacted and informed about any problem and any costs involved.

18. DISPOSAL OF WASTE ELECTRICAL AND ELECTRONIC PRODUCTS

At the end of its life, please treat this device as electronic waste and dispose of responsibly according to current local regulations.

19. 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: Storage:	 Humidity: 20 to 93% RH, Temperature range: 0 to 35C Atmospheric Pressure: 700hPa to 1060hPa 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.
	This symbol on the unit means “Refer to Instructions for use”

	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	• 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	• 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.
Country of origin	Made in China
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 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	URGE2	10	200	Continuous			
6	SENS	3/10/20/ 30/40	250/200				25
7	PFW A	See below					
8	PFW B	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 µS	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

20. 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.

(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).

CE 0473

Distributed by:

In Australia:
JA Davey Pty Ltd
626 Lorimer Street
Port Melbourne, VIC 3207
Tel: 1800 807 464
Web: www.jadavey.com.au

In New Zealand:
JA Davey Ltd
58 Richard Pearse Drive
Mangere, Auckland 2022
Tel: 0800 523 583
Web: www.jadavey.co.nz

Manufactured by:

TensCare™

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

Pub Ref.: I-SP-AU Rev 1.1 4/15

*Sure*PRO

INSTRUCTIONS FOR USE

TensCare™