

itouch sure



INSTRUCTIONS FOR USE



READ CAREFULLY BEFORE USE

TensCare™

QUICKSTART GUIDE

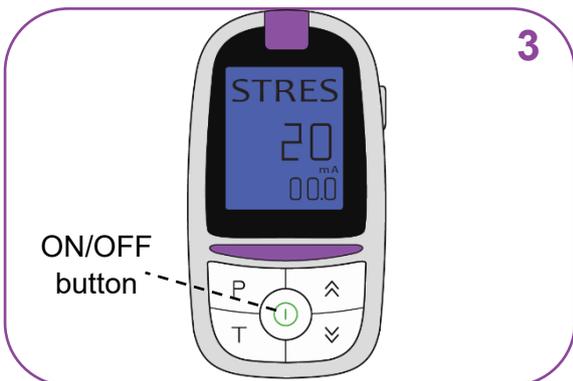
Read instructions for use and warnings carefully prior to use.



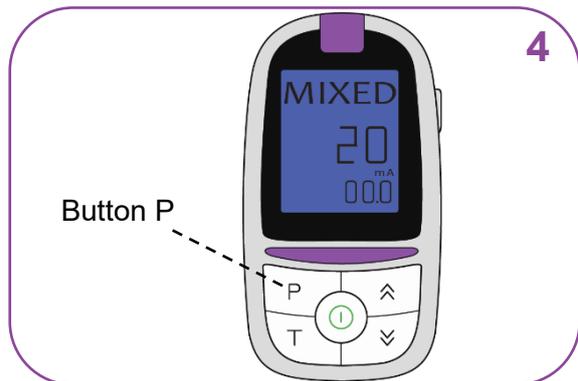
1
Clean the probe with an alcohol-free anti-bacterial wipe or with warm soapy water. Go to the toilet before use. Choose a comfortable position, such as a leaning back or lying down on your bed with your knees raised. Connect the unit with the vaginal probe.



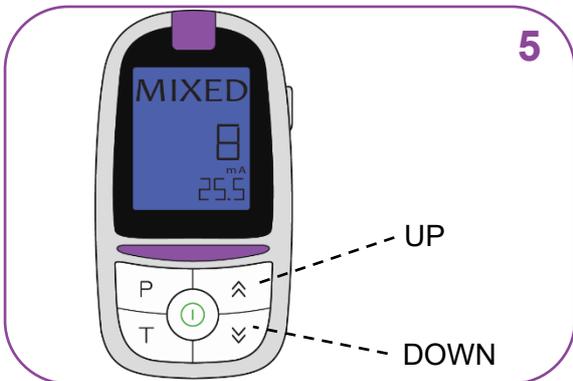
2
Firstly, test the unit with the probe in your hand—hold the probe tightly, covering as much of the metal plates on the probe with your skin. Then insert the vaginal probe (lubricate with a water-based lubricant or water)



3
Press and hold the ON/OFF button to switch the device on



4
Select the program by pressing the button P



5
Regulate the output intensity with the ▲ and ▼ buttons



6
Press and hold the ON/OFF button to switch the device off

Dear Customer,

Thank you for choosing the **itouch sure**. 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 keep this instruction manual in a safe place where it is readily available.

The illustrations in this manual may differ slightly from the product itself.

Best regards,

Your TensCare Team

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SYMBOLS USED

	TYPE BF APPLIED PART: 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.
	Humidity Limitation: indicates the humidity limits to which the medical device can be safely exposed.
	Atmospheric Pressure: indicates the atmospheric 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.
	Serial Number: indicates the manufacturer's serial number so that a specific medical device can be identified.
	Catalogue Number: indicates the manufacturer's catalogue number so that the device can be identified.
	Do not dispose in household waste.
	Manufacturer Symbol
	Date of Manufacture: indicates the date which the medical device was manufactured. This is included within the serial number found on the device (usually on the back of the device), either as "E/Year/Number" (YY/123456) or "E/Month/Year/Number" (MM/YY/123456).
	CE Mark
	Medical Device
	This medical device is indicated for home use.
IP22	This medical device is not water resistant and should be protected from liquids. The first number 2: Protected against access to hazardous parts with a finger, and the jointed test finger of 12 mm \varnothing , 80 mm length, shall have adequate clearance from hazardous parts, and protected against solid foreign objects of 12.5 mm \varnothing 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.

	Notes are used to provide clarification or recommendation.
	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.
	A Contraindication is used when a device should not be used because the risk of use clearly outweighs any foreseeable benefits and may result in serious injury or death.

1. INTRODUCTION

Device Description & Principles of Design

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

The **itouch sure** is a powered muscle stimulator used for strengthening the pelvic floor muscles.

It sends a gentle stimulation (similar to your natural nerve impulses) direct to your pelvic floor muscles through a vaginal probe with stainless steel electrodes. These signals make your pelvic floor muscles contract. If you have forgotten how to contract them, are having trouble getting muscle response, or simply want to bring back the condition of your pelvic floor muscles, the **itouch sure** can work them for you to build up their strength and help you to develop your own muscle control. It perfectly complements pelvic floor exercises. The **itouch sure** is very easy to use, with four clearly labelled preset training programs and a simple push button control.

The **itouch sure** 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.

- Anal stimulation (requires an anal probe) may also help men who are otherwise unable to execute Kegel exercises to strengthen their pelvic floor. Pelvic floor muscle training is recommended for recovery from some causes of Erectile Dysfunction. However, it is not intended to treat any medical issues and your first step in deciding appropriate therapy should be to consult your professional medical advisor.

2. INTENDED USE



This device has been designed to be a medical device used in the home healthcare environment to treat urinary and/or faecal incontinence using gentle electrical stimulation (i.e. EMS – electrical muscle stimulation).

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



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

3. ITOUCH SURE FEATURES

- **Single Channel**

Single channel unit provides relief from symptoms of all types of incontinence via a tampon-shaped probe.

- **Comfortable Stimulation**

Gentle stimulation in small steps of intensity, 0.5 mA per step.

- **4 Preset Programs**

Clinically tested programs for all types of incontinence including stress, urge, mixed and a tone aftercare program.

- **Treatment Timer**

Unit defaults to 20 minutes' treatment to ensure the pelvic floor muscles are not overworked. The user can manually reset this (10, 20, 30, 45, 60 or 90 mins) or continuous.

- **Open Circuit Detection**

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

- **Keypad Lock**

Enables the user to manually lock the controls to prevent any accidental changes in settings.

- **Large Backlit Screen**

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

- **Memory**

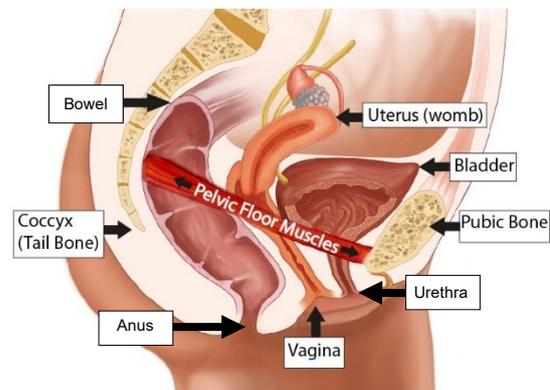
Features 3 functions: program retention (automatically starts in the last program used), duration of use and average strength used.

4. PELVIC FLOOR EXERCISES

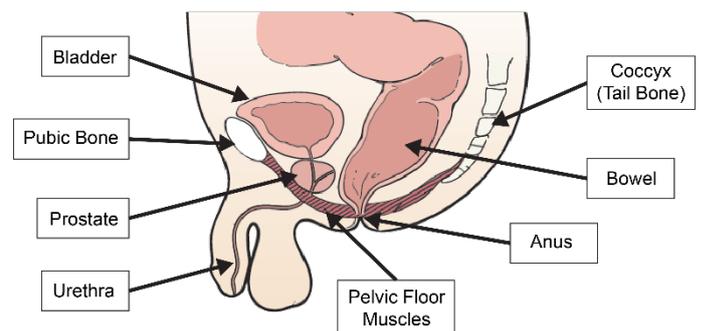
4.1. PELVIC FLOOR MUSCLES

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.

Women



Men



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 **itouch sure** 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.

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

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 program. The method is simple and appropriate for treatment in the clinical setting as well as for self-treatment at home.

How EMS Works

Electrical Muscle Stimulators can play a vital role in educating women and men about their pelvic floor and the sensation they should feel when doing pelvic floor exercises. Electrical Pelvic Floor Exercisers (PFE) offer a 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. **Itouch sure** uses a gentler, low frequency setting which promotes release of endorphins and reduces involuntary contractions of the bladder (detrusor) muscle.

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

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

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

7. CONTRAINDICATIONS, WARNINGS & CAUTIONS

If in doubt, contact your healthcare professional before using the **itouch sure**.

CONTRAINDICATIONS:

 **Do NOT use** if you are or may be pregnant; or in the first 6-8 weeks after childbirth or pelvic surgery. *It is not known whether EMS may affect foetal development. Stimulation may disrupt the healing process.*

 **Do NOT use** 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.*

 **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 walking, 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 and put you at risk of injury.*

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

 **Do NOT use** if you have, active or suspected vaginal, pelvic or prostate cancer or undiagnosed pain in the area being treated 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.*

 **Do NOT use** optional electrode pads near the thorax as this may increase the risk of cardiac fibrillation.

 **Do NOT use** optional electrode pads on the front of the neck. *Stimulation on the front of the neck can affect your heart rate or cause contraction of the throat.*

 **Do NOT use** optional electrode pads across the chest. *Very strong stimulation across the chest may cause an extra heartbeat and/or rhythm disturbances to your heart, which could be lethal.*

 **Do NOT use** optional electrode pads over the eyes. *May affect eyesight or cause headaches.*

 **Do NOT use** optional electrode pads across the front of the

head. *Effect on patients who have had strokes or seizures is not known. May affect your sense of balance. The effects of stimulation on the brain are unknown.*

 **Do NOT use** itouch Sure while simultaneously connected to high frequency surgical equipment as it may result in burns at the site of stimulator electrodes and possible damage to the stimulator.

 **Do NOT use** itouch Sure in close proximity (e.g. 1 m) to a shortwave or microwave as this may produce instability in the stimulator output.

CAUTIONS:

 **Caution** should be used if you have a bleeding disorder as *stimulation increases 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:** 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 **itouch sure** at high strength settings. *Prolonged use at high settings may cause muscle injury or tissue inflammation.*



Caution the operator should not touch the patient at the same time when touching the battery output.



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 **itouch sure** vaginal or anal probe is intended for single patient use only. Do not share your **itouch sure** probe with anyone else. *Improper treatment or cross-infection may occur.*



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



Caution: Never insert or remove vaginal or anal probe unless the control unit is powered OFF as insertion or removal

when stimulation is active may cause discomfort or tissue irritation.



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



Caution: Do not use a silicone based lubricant on the metal plates of the probe as it may decrease the effectiveness of **itouch sure's** muscle stimulation. Only use water-based.



Caution: The stainless steel in the probe's metal plates contain some Nickel. This could cause a reaction if you have a Nickel allergy.



Caution: Do not use this device with vaginal probe or anal probe other than those recommended by the manufacturer in section 17. Electrodes with smaller surface area may cause tissue irritation.



DO NOT PLACE OPTIONAL ELECTRODE PADS:

- On skin, which does not have normal sensation. *If the skin is numb too great a strength may be used, which could result in skin inflammation.*
- On broken skin. *The electrode pads could encourage infection.*
- The electrode pads are reusable but for single patient use. The adhesive is a peel- able hydrogel (water-based).

ELECTRODE PADS CAUTIONS:



Caution: Do not ignore any allergic reaction to the

electrode pads: *If a skin irritation develops, stop using, as this type of electrodes may not be suitable for you.*

 **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.*

 **Caution:** Do not use high intensity settings if electrodes are smaller than 50x50mm.

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 transport & storage: -10°C to +60°C, 8 to 93% R.H. Temperature & Relative Humidity of operation: 0°C to +40°C, 10 to 93% R.H.

 **Caution:** There are no user serviceable parts. Do not attempt to open or modify the device. *This may affect the safe operation of the unit and will invalidate the warranty.*

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

8. INFORMATION ABOUT THE PROGRAM SETTINGS

Each program 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

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

The **itouch sure** unit has pulse widths of 200 to 300 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.

9. PROGRAMS

9.1. PROGRAM SETTINGS

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

9.2. PRESET PROGRAMS

The **itouch sure** has 4 preset programs. One for each type of incontinence (stress, urge and mixed), and one aftercare program for toning the pelvic floor muscles (**TONE**).

STRESS INCONTINENCE:

Shown on the screen as: **STRES**

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

The stimulation causes the muscles to contract and work. This builds their strength. Like other fitness training, successful treatment requires stimulation once a day for one to three

months. Improvement starts becoming apparent after about four weeks.

The sensation is like a strong drawing in of the muscles 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.

URGE INCONTINENCE:

Shown on the screen as: **URGE**

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

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

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

MIXED INCONTINENCE:

Shown on the screen as: **MIXED**

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

The first 10 minutes uses the **URGE** program to reduce sensitivity, then in the second 10 minutes, the **STRES** program exercises the pelvic floor muscles. You may need to increase the

strength to feel the muscle contraction when the **STRES** program starts.

Note: The Mixed program can **ONLY** be set to a 20-minute time session

TONE:

Shown on the screen as: **TONE**

Once the pelvic floor muscles have been strengthened with **itouch sure**, continue to exercise them.

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

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

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

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

10. CONTENTS

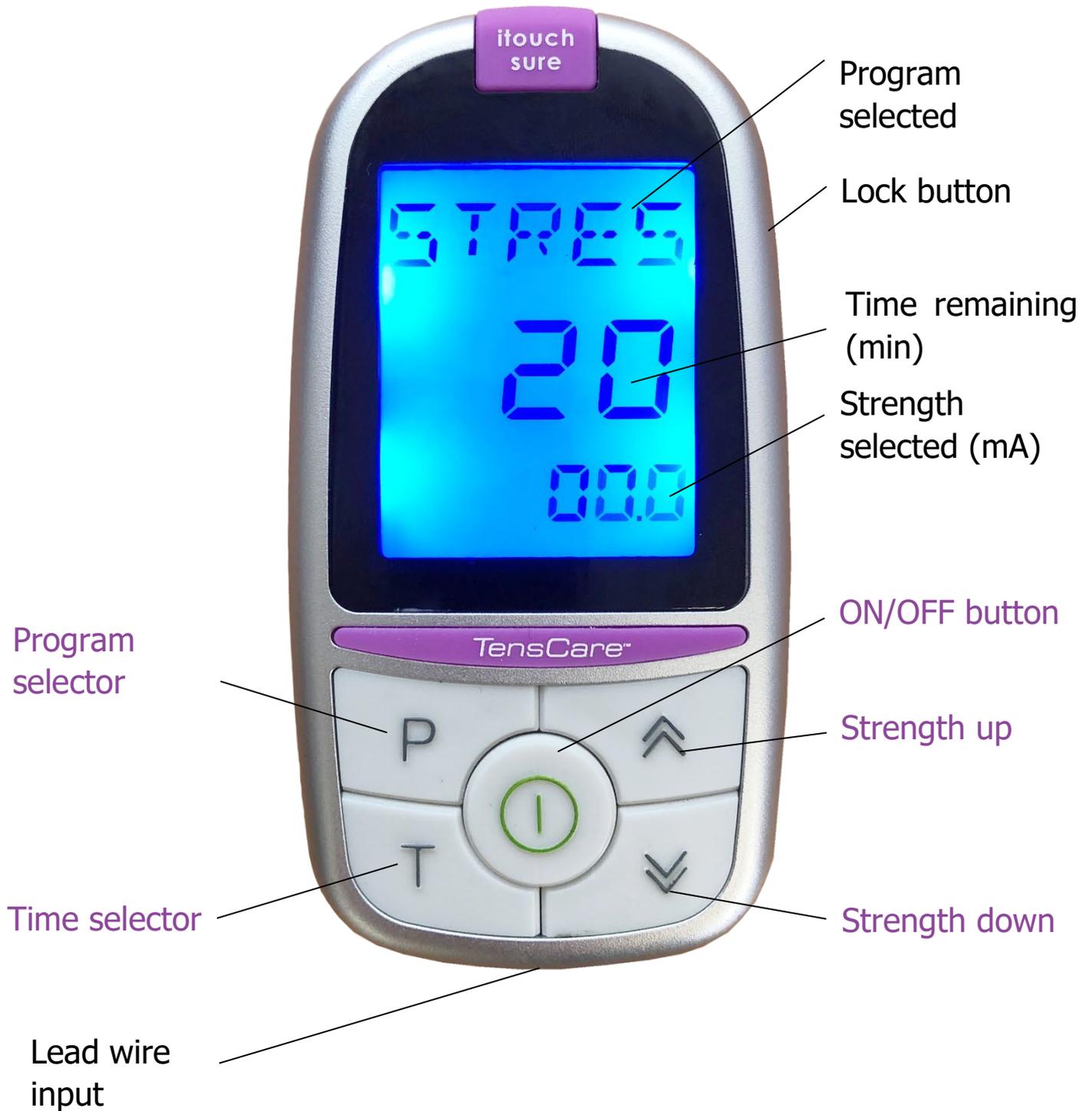
The pack contains:

- 1 x **itouch sure** pelvic floor exerciser
- 1 x Liberty vaginal probe (X-VP)
- 1 x Lead wire (L-IT1-NEW)
- 2 x AA 1.5V alkaline batteries
- 1 x Storage pouch
- 1 x Instructions for use booklet



UNIT INFORMATION

11.1. CONTROLS & DISPLAY



11.2. 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 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 program **STRES** at zero strength.

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

If you allow the program to continue to automatic switch off, next time you switch on the strength will return to 50% of the level that was being used.

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

The unit will turn off automatically:

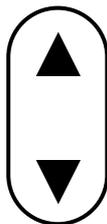
- When the timer reaches zero,
- If it is left at zero strength for more than 5 minutes.



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

The screen is illuminated whenever a button is pressed.

STRENGTH CONTROLS



The buttons marked ▲ and ▼ are the strength controls.

To increase strength, press and hold down the button ▲ until required strength is achieved.

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

To increase strength in steps of 0.5 mA, press and release the button ▲.

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

The strength levels are shown on the LCD.

The strength control buttons will not operate until the unit is properly connected to you (probe inserted correctly). The itouch sure detects a disconnection and automatically returns the strength to zero.

The unit has 198 levels of strength (0 to 99.5 mA). If you hold down the button ▲ for 3 to 5 seconds, the strength will start scrolling.

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

PROGRAM CONTROL



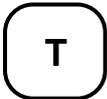
The button marked **P** is the program control. The **itouch sure** has four preset programs. At first use, the unit automatically goes to program **STRES**.

Next time it is switched on, it will default to the program used last.

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

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

TREATMENT TIMER

 The **TIMER** button can be used to set the session duration. When you switch the unit on, it is automatically set at 20 minutes for all the programs.

By repeatedly pressing and releasing the **TIMER** button you can manually override and select 10, 20, 30, 45, 60, 90 minutes or continuous time.

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

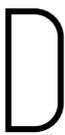
If you hold down this key for 3 to 5 seconds, you can **PAUSE** the timer, allowing you to interrupt the treatment session, and resume it later. Return to main screen by pressing any other key.

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

LOW BATTERY

A low battery indicator **BATT** will show when you need to change the batteries. The unit will shut down about 2 minutes after this.

LOCK BUTTON

 The **LOCK** button on the top right hand side of the unit can be used to lock all controls except for the **▼** and **OFF** buttons.

To activate, press and hold down the button for 3 to 5 seconds until **LOCK** is displayed on the screen. Repeat to deactivate.

LEADS ALARM

The **itouch sure** monitors the connection and the contact between you and the probe, or the pads. This is to prevent sudden changes if a broken connection is re-made. If either of these goes outside of a standard range while the strength is above 20.0 mA, the unit will flash **LEADS**, bleep three times, and return the strength to 00.0 mA.

Check the lead and if necessary, lubricate the probe with a water-based lubricant. Please see section 19 for more troubleshooting tips.

MEMORY

The **itouch sure** has a Memory with three functions:

- 1) Program Retention. When you switch the unit on, it will automatically start in the program which was being used when it was switched off.
- 2) Usage. Press the **TIMER** button and **▲** together and hold down for 3 to 5 seconds. The display will show the total duration of use in 10 minute intervals (where 1=10 minutes, 2=20 minutes etc.) and the average strength used.

Press the same buttons again to return to normal controls.

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



11. SETTING UP AND USING THE ITOUCH SURE

12.1. INSTALLATION OF BATTERIES

- 1) Remove the battery cover: Press down in the centre and slide backwards in direction of raised arrows.
- 2) Insert batteries: Ensure that the batteries are inserted the right way as shown in battery compartment and that the ribbon is behind them.
- 3) Replace the battery cover.

When the batteries are running low, a low battery indicator **BATT** will show on the screen and it is important to change the batteries as soon as possible.

Rechargeable batteries

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

Storage

Remove batteries from your **itouch sure** if the unit is unlikely to be used for a long period. *Some types of batteries may leak corrosive fluid.*

Battery Life

Batteries should last at least 15 hours at 50 mA, 300 µs, 50 Hz.

Unused batteries have a nominal shelf life of 1 year but will usually last longer than this.

Battery Warnings

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

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

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

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

 **Do NOT** short-circuit.

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

 Keep batteries out of the reach of children to prevent them from swallowing them by mistake. If swallowed by child, contact your healthcare professional immediately.

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

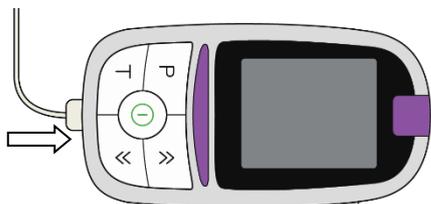
 **Do NOT** mix old, new or different types of batteries as this may lead to battery leakage or low battery indication

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

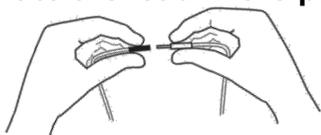
Disposal: Always dispose of batteries responsibly according to local government guidelines. Do not throw batteries onto a fire. Risk of explosion.

12.2. CONNECTING LEAD WIRE

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



Connect the lead from the base of the unit to the lead in the probe.



Push the pin ends firmly into the pigtail ends of the probe lead.

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

12.3. PREPARING FOR SESSION

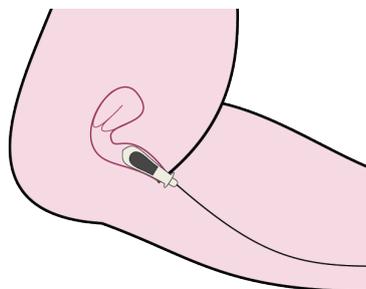
- 1) Before using **itouch sure** you will need to visit the toilet.
- 2) Lubricate the metal electrode surfaces and probe tip with a water-based lubricant.

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

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

 **Warning:** Ensure that the **itouch sure** 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.



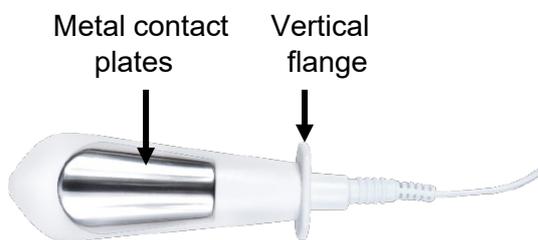
- 5) The metal parts conduct the electrical pulse and should be in contact with the main part of the

muscle at all times. The tissues close to the entrance are more sensitive,

so you should avoid stimulating them.

Ensure that the probe is aligned so that the contact plates are to the sides and the longer sides of the positioning end rim are vertical.

The probe will naturally position itself with the widest part of the flange vertically.



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

12.4. TRAINING SESSION

- 1) Press and hold the **ON** button on the control unit for 3 to 5 seconds to switch the control unit on.
- 2) You can select from the four preset programs. Details in section 9 will help you identify the best program to suit you.
To change between the programs, press the program selector, which is labelled **P**.
- 3) With the required program selected, you can adjust the intensity of the muscle stimulation until you reach a comfortable level. Once you have reached a comfortable level, 5 seconds after you stop pressing the button, the intermittent work/rest

phase will start. The device will take itself to 0 mA for a rest period and then take itself back up to the level of intensity you chose, to work the muscle. This cycle will continue for the 20 minutes of the program.

i **Note:** The strength required varies widely between users - some will use the **itouch sure** at full power – 99.5 mA. The **itouch sure** strength will go up at 0.5 mA increments.

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

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

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

When switched on, in **STRES** and **STONE** programs the unit will go through an exercise program for 4-5 seconds, followed by a rest period of 8-10 seconds. The **itouch sure** causes a sensation which feels like a strong drawing in of the vagina and pulling up of the pelvic floor. The natural reaction

will be to pull in and up with the muscles.

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

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

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

The strength display on the control unit will reduce to 00.0 mA and flash during the rest period.

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

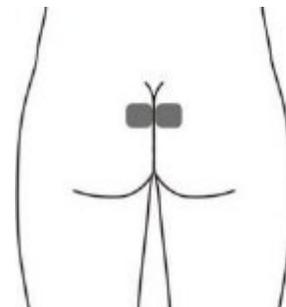
The length of each session is automatically set to 20 minutes. The length of each session for muscle strengthening will also depend on your ability to contract and your resistance to fatigue. Be careful not to overuse early on, as the resulting aches may not be felt until the next day.

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

Optional skin surface electrode placement for URGE (this may not be as effective as the stimulation with the vaginal probe)

An alternative method to a vaginal probe is to stimulate areas of the skin that are close to the nerves that go to the bladder and urethra. These come from the parts of the spinal cord segment called S2-S3. See electrode placement picture below.

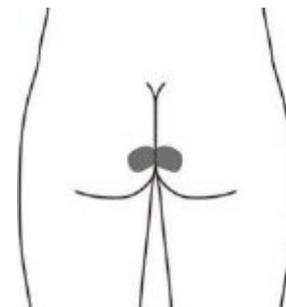
The strength should be comfortable, but always remain noticeable. You may need to increase it over the course of the treatment.



Optional skin surface electrode placement for STRESS (this may not be as effective as the stimulation with the vaginal probe)

The electrodes are placed on the skin between the anus and the genitals. See electrode placement picture below.

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



12.5. AFTER YOUR TRAINING SESSION

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

- 1) Check that the control unit is off. If it is not, hold down the **OFF** button to switch off then remove the probe from your 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) The **itouch sure** 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.

13. ANAL PROBE

13.1. CONDITIONS THAT MAY BE TREATED

An anal probe such as TensCare **X-PR13** can be purchased. This probe can be used for urinary and faecal incontinence in both males and females.

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

You should consult your healthcare professional before starting treatment.

Faecal Incontinence

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

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

Post Prostatectomy Urinary Incontinence

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

Erectile dysfunction

Electrical stimulation may also help men who are otherwise unable to execute Kegel exercises to strengthen their pelvic floor. Pelvic floor muscle training is recommended for recovery from some causes of Erectile Dysfunction. Use the program **STRES**

or TONE. However, it is not intended to treat any medical issues and your first step in deciding appropriate therapy should be to consult your professional medical advisor.

13.2. HOW TO INSERT THE ANAL PROBE

- 1) Before using **itouch sure** you will need to visit the toilet.
- 2) Lubricate the metal electrode surfaces and probe tip with a water-based lubricant.

 **Caution:** Do not use a silicone based lubricant on the stimulation contacts as it may decrease the effectiveness of the **itouch sure**'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 **itouch sure** 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 program.

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

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

14. CLEANING

It is important that the probe is cleaned before using for the first time and after each use. Clean with either an alcohol-free antibacterial wipe or by washing with warm soapy water. Rinse in clean water 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 **itouch sure** unit in water.

- Do not use any other cleaning solution.

15. EMC

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

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



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

16. DISPOSAL

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



17. ACCESSORIES

Expected Service Life

- The device will often last for more than 5 years, however, is warranted for 2 years. Accessories (lead wire, probe, and batteries) are not covered by the warranty.
- Lead life depends greatly on use. Always handle the leads with care. We recommend replacing the lead wires regularly (about every 6 months).
- Replace the probe every 6 months to ensure hygiene.
- Optional electrode pads should last 12-20 applications, depending on skin condition and humidity.
- AA alkaline batteries should last at least 15 hours at 50 mA, 300 μ s, 50 Hz.

The following replacement parts may be ordered from JA Davey Pty Ltd.

X-AP	Liberty Mini Probe (21.5 mm dia.)
X-VP	Liberty Vaginal Probe (28.6 mm dia.)
X-VPM	Liberty Plus Vaginal Probe (32.5 mm dia.)
X-VPL	Liberty Loop Vaginal Probe (31.9 mm dia.)
X-PR13	Liberty Fit Anal probe (20.6 mm dia.)
E-CM5050	Pack of 4 electrode pads (50x50 mm)
L-IT1-NEW	Replacement lead wire, 1.25 m length
L-VPCE	Liberty X-VP & X-VPM Probe Replacement Lead



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.

CHANGE OF LEAD

Please note that from serial number E14/009931 (since 2014) the **itouch sure** has an all-plastic connecting plug on the lead to comply with current safety regulations. Please ensure that you purchase the replacement lead L-IT1-NEW, see picture below.



The connection to plug into the unit is made of plastic (not metal).

18. WARRANTY

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

PRODUCT WARRANTY INFORMATION

Please register your warranty information at www.tenscare.com.au

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 JA Davey Pty 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 trade practices act and other state or territory laws in Australia and New Zealand. Our goods come with guarantees that cannot be excluded under Australian and New Zealand Consumer Law. You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

Extended Warranty:

Register your warranty online to receive an extra 2 years warranty. By registering your device online it will have an extended 4 year total warranty period.

Before you send your unit for service

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

- In this instruction manual, read the troubleshooting section that describes common errors, their cause and remedies.
- Contact TensCare customer service. Our staff are trained to assist you with most issues you may have experienced, without the need to send your product in for service.

PLEASE CALL OUR TOLL-FREE NUMBER:

IN AUSTRALIA:

Free call: 1800 010 891

IN NEW ZEALAND:

Free call: 0800 523 583

Sending in your unit for service

1. Should repair be needed within the warranty period, enclose the tear off section of the warranty card and your proof of purchase receipt. Please ensure all relevant details are completed before sending your unit in for service. Please ensure your contact details are still current and include a brief description of the problem you are experiencing together with your purchase receipt.
2. Include the unit with all product components in your package. This is extremely important, so our repair technicians can make the correct diagnosis with any problems.
3. Please return the unit and warranty card (page 32) at your cost to:

IN AUSTRALIA

J.A. Davey Pty Ltd
TensCare Repairs
PO Box 84, Port Melbourne
Victoria, Australia 3207

IN NEW ZEALAND

BV Medical
TensCare Repairs
Unit 7, 110 Mays Road, Onehunga
Auckland, New Zealand 1061

**DO NOT SEND IN PROBE OR LEADS
DUE TO BIO HAZARD RISK. ONLY
SEND IN UNIT.**

19. TROUBLESHOOTING

If your **itouch sure** is not working properly, please check the following:

Problem	Possible causes	Solution
No display	Flat batteries.	Replace batteries.
	Batteries inserted incorrectly.	Remove plastic wrap Check + / - .
	Damaged springs in battery compartment.	Contact supplier.
Low battery display	Low batteries.	Replace batteries.
Controls won't work	Keypad is locked.	If LOCK is shown on display, press and hold the LOCK button for 3 to 5 seconds to unlock. If no LOCK is showing, remove and replace the batteries.
No sensation and LEADS alarm showing	The itouch sure has a safety feature which will not allow the intensity to pass 20.0 mA if the device detects a connection error. If a connection error is detected the intensity will return to 00.0 mA and the screen will flash LEADS . This safety feature will prevent the device from giving any uncomfortable stimulation should the contact break between the device and your skin. This will also prevent anyone from increasing the intensity to a high level without firm contact between the device and the skin. A connection error can occur if:	
	1. A break has developed within one of the two lead wires.	If this happens, you can try to test the unit by holding the probe in your hand: i) Dampen your hand with water and a little table salt. Squeeze the probe firmly and make sure your skin is covering the metal parts of the probe and carefully increase strength until you can feel something. Most people will start to feel the stimulation in their hand at around 25.0 mA. ii) If the LEADS alarm shows and the unit will not allow you to pass 20.0 mA. The lead wires need to be replaced.
	If you have tried the test above and DO have sensation when the probe is in your hand, then it may be that: 2. The skin is dry, meaning poor	If this happens, you can try the below solutions: i) Using a water-based lubricant, which will improve conduction. 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

	conductivity between the metal plates on the probe and your skin.	stimulation the contact improves. If it does not, this unit may not be suitable for you. You may need to contact your healthcare professional to discuss other suitable options. iii) The probe supplied with the unit has a 28 mm diameter. An optional 32 mm probe, part no. X-VPM , is available.
No sensation and no LEADS alarm showing	Intensity level is not high enough and/or reduced sensitivity in the area being treated.	i) Please make sure you are increasing the intensity high enough. Most people will start to feel the stimulation in their hand at around 25.0 mA and with the probe inserted you will need to increase the intensity higher to around 40.0 mA to 60.0 mA. Max power is 99.5 mA. Everyone is different so just keep increasing the intensity until you can feel it. The intensity increases in very small steps of 0.5 mA. 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.
No sensation on one side of the probe (or electrode)	Position is not optimal – needs adjusting.	The current flows from one side of the probe to the other, so it is not possible to have one side “not working”. However, the strength of the sensation depends on how close to the nerve the current flows, and also in which direction it flows relative to the nerve. You can try slightly adjusting the position on the probe or exchanging the connection of the wires in the probe.
Sudden change in sensation	If you disconnect and re-connect a few minutes later, the signal will feel quite a lot stronger.	Always return strength to zero after disconnecting the lead or the probe.

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

If the above review has failed to resolve your problem, or to report unexpected operation or events please contact us.

Contact TensCare customer service on (Australia) 1800 010 891 or (New Zealand) 0800 523 583. Our staff are trained to assist you with most issues you may have experienced, without the need to send your product in for service.

20. GENERAL SPECIFICATION

Waveform	Asymmetrical rectangular
Amplitude (over 500 Ohm load)	99.5 mA +/- 10%
Max intensity	50V zero to peak across 500 Ω Constant voltage over 470-1500 Ohm Constant current over 160-470 Ohm
Output plug	Fully shielded
Channels	Single channel
Max Pulse energy	Total output limited to 25 μ C per pulse
Batteries	2 x AA alkaline (two AA batteries) or 2 x AA NiMH
Weight	90 g without batteries
Dimensions	102 x 53 x 28 mm
Safety Classification	Internal power source.
Environmental Specifications:	
Operating:	Temperature range: 0 to +40°C Humidity: 10 to 93% RH non-condensing Atmospheric pressure: 700hPa to 1060hPa
Transport & Storage:	Temperature range: -10 to +60°C Humidity: 8 to 93% RH non-condensing Atmospheric pressure: 700hPa to 1060hPa
Applied Part	Vaginal and anal electrodes. Optional skin surface electrode pads. See section 17.
Contact duration:	At least 10 minutes



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



PLEASE RETAIN THIS WARRANTY CARD.

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

NAME: _____

ADDRESS: _____

POSTCODE: _____

DAYTIME TELEPHONE: _____

E-MAIL: _____

MODEL: _____

DATE OF PURCHASE: _____

ATTACH PROOF OF PURCHASE

DO NOT SEND IN PROBES OR LEADS

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 us.

www.tenscare.com.au

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TensCare Limited



@tenscare_anz



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 2797 marking on this product.

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