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INSTRUCTIONS FOR USE

READ CAREFULLY BEFORE STARTING USE
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INTRODUCTION

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

- 4 preset clinically tested programs
- The “Elise” programs treat STRESS, URGE and MIXED Incontinence using gentle electrical stimulation
- The “Elise” TONE program firms the pelvic floor and may improve sexual pleasure
- The “Elise” is easy to use with full instructions
- Elegant slim design
- One touch memory
- Rechargeable Li-ion Battery

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 and may also treat erectile dysfunction using gentle electrical stimulation (i.e. EMS – electrical muscle stimulation & TENS - transcutaneous electrical nerve stimulation). Do not use this device for any purpose other than this intended use.

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

1. “Elise” FEATURES

- Comfortable Stimulation
  The strength of the stimulation increases gradually, making the feeling very comfortable and in your control.

- Easy Start - One Touch Memory
  The “Elise” has intelligent memory that enables the unit to remember the last program and the strength setting used. At the press of only one button the strength level returns to 50% of the last level used.

- Safety Duration Override
  A safety duration override feature has been incorporated into the “Elise” to ensure that the pelvic floor muscle is not overworked. This is set at twenty minutes after which time the unit will switch off. It is possible to alter the time in order to customise the unit to your needs.

- Usage Memory
  The “Elise” has a usage memory which shows the length of time that the unit has been in use and the average level of strength utilised.

- Rechargeable Li-ion battery
  The “Elise” is powered by a slimline 3.7V Li-ion rechargeable battery. The rechargeable battery, charging cradle and power adaptor are included in the kit.
2. PELVIC FLOOR MUSCLE

The “FLOOR” of your pelvis is made up of layers of muscles that support the bowel, bladder, urethra and uterus. These muscles are like a hammock, or the bottom and sides of a bowl, in shape. They run from pubic bone in the front to the end of the spinal column (or tail bone) in the back.

The pelvic floor muscles:
• assist in supporting the abdominal and pelvic organs
• work with the abdominal and back muscles to stabilise and support the spine

- in women also
  - provide support for the baby during pregnancy and
  - assist in the birthing process

Pelvic floor muscles are also important for sexual function in both men and women:
• in men, it is important for erectile function and ejaculation.
• in women, voluntary contractions (squeezing) of the pelvic floor contribute to sexual sensation and arousal.

However pelvic floor muscles may become weak. If your pelvic floor muscles become stretched or weakened, your pelvic organs may no longer be fully supported and you may lose control of your bladder or bowel movements.

For some women, the pelvic floor muscles can also become too tight. This condition is less common, but it can lead to pelvic pain and make it difficult for you to empty your bladder or bowel completely.

**Common signs that can indicate a pelvic floor problem include:**
• accidentally leaking urine when you exercise, laugh, cough or sneeze
• needing to get to the toilet in a hurry or not making it there in time
• constantly needing to go to the toilet
• finding it difficult to empty the bladder or bowel
• accidentally losing control of the bladder or bowel
• accidentally passing wind
• pain in your pelvic area
• painful sex, or
• a prolapse
  - in women, this may be felt as a bulge in the vagina or a feeling of heaviness, discomfort, pulling, dragging or dropping. This occurs when one or more of the pelvic organs (bladder, bowel or uterus)
become displaced and sag down into the vagina. It is very common in Australia and New Zealand 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 bowels but not actually needing to go. Like other muscles in your body, the pelvic floor can be strengthened with regular exercise. Building pelvic floor strength enables the muscles to better support your pelvic organs, improves your bladder and bowel control and can stop accidental urine, faeces or wind leakage.

It can also reduce your risk of prolapse, improve your recovery from childbirth and gynaecological surgery, and increase your sexual pleasure. A continence therapist can help you learn how to exercise your pelvic floor.

Doing just a few pelvic floor exercises every day will help to treat bladder weakness or prolapse symptoms, and will help to prevent problems later on.

3. HOW TO PERFORM PELVIC FLOOR EXERCISES

Once the "Elise" has helped you develop control of the pelvic floor muscles and built muscle strength, it is recommended to make Pelvic Floor Exercises (sometimes called Kegel Exercises) part of your daily life. Kegel exercises can be done at any time and are very discreet so you can do them almost anywhere; lying in bed, sitting at the computer or waiting for a bus. It is a good idea to try and develop a routine which you can repeat each day.

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

1) Try inserting one or two clean fingers into your vagina and then squeezing the surrounding muscles, lifting up and towards your belly button – a squeezing and lifting sensation.

2) Another way is to try and stop the flow of urine during urination. If you are successful then you know you are exercising the correct muscles.

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.

• 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.

• Aim to hold each squeeze or 'contraction' for between three and five seconds, then release and relax. You should feel a 'letting go' of the muscles. Rest for five seconds and then repeat. Try and do about ten squeezes in this way. Repeat the whole process three or four times a day.

• 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. The more exercise you do, the stronger the muscles will become and the longer you will be able to squeeze.
4. TYPES OF INCONTINENCE

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

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

- **Urge Incontinence**
  Describes an overactive bladder. A person may experience a strong and sudden urge to go to the toilet but are not always able to hold on, or have to go so frequently that it becomes inconvenient. It can be caused by diabetes or a urinary tract infection, or by a nerve-affecting disorder like stroke, Alzheimer's disease, or multiple sclerosis. In some cases, it can be an early sign of bladder cancer.

- **Mixed Incontinence**
  Is a combination of both Stress and Urge Incontinence

5. THE ADVANTAGES OF “Elise”

- It can reduce leakage - not simply contain it
- It is drug-free
- It is easy to use
- It is discreet
- It may help to avoid surgery
- It may improve sexual pleasure

6. HOW “Elise” WORKS

Electrical stimulation consists of temporarily placing electrodes in the vagina/anus. Small pulses of electricity generate muscle contractions and can help women identify how to do the contractions themselves.

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

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

The “Elise”, through a vaginal probe or pads, sends a gentle electrical stimulation to your pelvic floor muscles using clinically recognised programs. The “Elise” sends small pulses of electricity to generate muscle contractions and can help you identify how to do the contractions on your own. The “Elise” is the result of considerable research and consultation with continence advisors.

It is also possible to treat urinary and faecal incontinence in both males and females using an anal probe. See section 15 for more details.

Please note that we recommend the Liberty Vaginal Probe (as supplied with the unit) and accessories listed on page 39, as the unit has been tested with these.

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. See page 30 for more details.

If in doubt contact your healthcare professional before using the “Elise”.
In this manual:

A **Warning** is used when failure to follow the instructions may result in serious injury or death.

A **Caution** is used when failure to follow the instructions may result in a minor or moderate injury, or damage to the device or other property.

7. **CONTRAINDICATIONS, CAUTIONS AND WARNINGS**

**CONTRAINDICATIONS:**

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

**Do NOT use** if you have a pacemaker (or you have a heart rhythm problem) or with any electronic medical devices. *Using this unit with electronic medical devices may cause erroneous operation of the device. Stimulation in the direct vicinity of an implanted device may affect some models. Stimulation on the front of the neck can affect your heart rate. Very strong stimulation across the chest may cause an extra heartbeat.*

**WARNINGS:**

**Do NOT use** if you have symptoms of active urinary tract infection, vaginal infections, or localized lesions. *Introducing the probe may irritate sensitive tissue.*

**Do NOT use** if you have poor sensation in the pelvic region. *You may not be able to control the intensity of stimulation safely.*

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

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

The device should not be used while walking, driving, operating machinery, or any other activity in which involuntary muscle contraction may put you at risk of injury.

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

**CAUTIONS:**

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

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

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

**Caution:** It is important that the vaginal/anal probe is cleaned after each use. Ineffective cleaning may lead to irritation or infection.
Caution: If tissue irritation occurs, discontinue treatment immediately. Ask your healthcare professional for advice before continuing further treatment to prevent injury.

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

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

Caution: Strong magnetic or electromagnetic fields (electrosurgery/microwave cookers/mobile phones) may affect the correct operation of this unit - see section 20. If it appears to behave unusually, move it away from these devices.

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

Caution: Do not use this device with vaginal/anal probe or self-adhesive electrodes other than those recommended by the manufacturer in section 22. Electrodes with smaller surface area may cause tissue irritation.

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

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

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

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

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

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

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

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

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

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

The “Elise” has four preset programs. One for each type of incontinence and a fourth for toning of the pelvic floor muscles.

STRESS INCONTINENCE:
Shown on the screen as: “STRES”

The STRESS incontinence program 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 your muscles in and up, thereby exercising and strengthening them.

Note: For STRESS program the muscle MUST contract in order to give a benefit. Increase the strength as high as is comfortable and then take it down one step.

URGE INCONTINENCE:
Shown on the screen as: “URGE”

The URGE incontinence program reduces the involuntary contractions of the bladder (detrusor) muscle. This prevents the unwanted and unexpected emptying of the bladder.

This program is designed to soothe your bladder muscles rather than exercise your pelvic floor. It uses a gentler, low frequency setting which promotes release of endorphins.

Successful treatment will require stimulation once a day and improvements can be seen in as little as two weeks. Once the full strength of the muscles has returned it is recommended to continue using your pelvic floor exerciser once per month on an “as and when required basis”.

The sensation is of a longer and softer pulling in of the pelvic floor than in the Stress program.

Note: 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.
MIXED INCONTINENCE:
Shown on the screen as: “MIXED”
This program is recommended for those who suffer from both Stress and Urge incontinence or are not sure which form of incontinence is the problem. The stimulation frequency is midway between Stress and Urge.

The sensation, as you might expect, is a combination of both the Stress and Urge programs. The sensation is not as strong as the Stress program and has a slight throbbing sensation.

TONE:
Shown on the screen as: “TONE”
Regular use of this program, about twice a week, will ensure that your muscles remain toned.

The TONE program may also be used as an alternative treatment for STRESS.

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

Note: For TONE program the muscle MUST contract in order to give a benefit. Increase the strength as high as is comfortable and then take it down one step.

GENERAL POINTS
i) 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. As long as you can feel the contraction, it is working. You can build up slowly over a number of days. With the first two 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 “Elise” until the aching goes away, then start again using a lower strength and a shorter treatment time. As the pelvic floor begins to improve, it will be possible to maintain the stimulation for longer.

ii) All programs cycle between “work” and “rest” to allow your muscles to recover in between contractions. During the “rest” period, the strength display flashes 00.0 mA.

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

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

v) You may feel the stimulation through the probe more strongly on one side than the other.

vi) Once the pelvic floor has been strengthened using the “Elise”, continue to exercise the pelvic floor muscles. The pelvic floor needs to be worked and reacts well to such exercises.

Note: Strong pelvic floor muscles may increase sexual pleasure.
9. CONTROLS

**ON/ OFF Button**

To switch unit ON: Press and hold down for 3-5 seconds. When the unit is switched ON an audible “Beep” will be heard.

**One Touch Memory Start**

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

The strength returns to about 50% of the level that was being used when the unit was switched off.

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

To switch unit off: Press and hold down the button for 3-5 seconds and the unit will switch off.

When the unit switches OFF an audible double “Beep” will be heard.

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

**Strength UP Button**

To increase strength: Press and hold down until required strength is achieved. Press and release to increase in soft and gentle 0.5mA steps.

The unit will remain in the "Work" part of the cycle for 5 seconds while the strength is being adjusted.
Strength DOWN Button
To decrease strength: Hold down button and strength will decrease steadily in 0.5mA steps.

Program Button
The “Elise” has specifically selected programs. When you FIRST switch on the unit automatically goes to program STRESS.
Next time it is switched on it will default to the program last used.
Each time the “P” button is pressed and released the program changes. The screen will show the program selected.

Time Selector button
Each time you switch on the “Elise” the length of time of your program will automatically revert to 20 minutes.
During use the unit counts down the minutes which are shown on the screen. On reaching zero the unit will switch off.
By repeatedly pressing and releasing the Timer button you can manually override and select 10, 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 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.
11. USAGE MEMORY

The “Elise” has a usage memory which remembers the length of time and average strength that has been used.

To activate hold down the Time Selector and strength UP buttons together for 3 seconds. The screen will show the time in hours (to the nearest hour) and strength in mA.

Hold down Time Selector and strength DOWN button together for 3 seconds to reset the memory to zero.

12. LEADS ALARM

The “Elise” monitors the connection and the contact between you and probe, or pads.

If either of these goes outside of a standard range while the strength is above 20.0 mA, the unit will flash “LEADS”, beep three times, and return strength to zero.

Check the lead and if necessary, lubricate the probe.
13. CONTENTS

- Elise - Pelvic Floor Exerciser
- Liberty-Vaginal probe (single person use)
- Lead
- Rechargeable Li-ion BL-4B Battery
- Charger cradle
- Mains adaptor
- Instruction booklet
- Storage pouch

14. SETTING UP AND USING THE “Elise”

14.1 INSTALLATION OF BATTERIES

Setting up and using the “Elise” is very simple

**Step 1:** Insert battery into unit.

**Remove Battery Cover**
Press down the centre of the battery cover and slide downwards

**Insert battery**
Line up the 3 connectors on the battery with the contact in the unit. Slide in and press down. Replace Battery Cover.

**Step 2:** Plug the connecting lead wire into the “Elise”.

**Step 3:** Connect the other end of the connecting lead wire to the probe.

**Step 4:** To test that the battery has been fitted correctly and that the unit is working press and hold the “ON” button for at least three seconds. The display should appear and an audible “Beep” will be heard. Press and hold the “OFF” button to turn off the unit.
Step 5: To test the unit is working – hold the probe in your hand – hold the probe tightly, covering as much of the metal plates on the probe with your skin as possible. Increase the intensity by pressing the + button until you can feel the stimulation.

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

14.2 PREPARING FOR THE TRAINING SESSION

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

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

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

- Choose a comfortable position, such as leaning back or lying down on your bed with your knees raised.
- After wires are securely connected, insert the probe into the vagina, in the same way as a tampon, with the two silver plates side to side: one plate on left and the other on the right, until only the flange at the end is visible. The probe will naturally position itself with the widest part of the flange vertically. The metal parts conduct the electrical pulse and should be in contact with the main part of the muscle at all times.

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

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

14.3 TRAINING SESSION

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

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

2) You can select from the four pre-set programs. Details in section 8 will help you identify the best program to suit you.

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 machine will take itself to 00.0mA for a rest period and then take itself back up to the level of intensity you chose, to work the muscle. This cycle will continue for the 20 minute program.

Note: The strength required varies widely between users - some will use the “Elise” at full power - 99.5. The “Elise” strength will go up at 0.5 increments.
Initially the sensation through the probe may be limited but will improve during treatment. Take care not to use too much strength and thereby over stimulate the muscles until normal sensation is restored. The sensation may not be even as it may vary depending on the sensitivity of the nerves.

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

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

The “Elise” 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. This exercises and strengthens them.

For best results in the STRESS and TONE programs try to contract the pelvic floor muscles along with the “Elise”, 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.

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.

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

**Optional skin surface electrode placement for Urge**

An alternative method to a vaginal probe is to stimulate areas of the skin that are close to nerves that go to the bladder and urethra. These come from the parts of the spinal cord segment called S2-S3. The electrodes are placed on the skin between the anus and the genitals, or at the very bottom of the spine near your coccyx or “tail”. See electrode placement pictures.

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

**14.4 After Your Training Session**

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

1) Check that the control unit is OFF. If it is not, hold down the OFF button to switch off then remove the probe from your vagina by holding the positioning end rim and gently pulling outwards. Be careful not to pull the wire as this may damage it.

2) Wash and thoroughly dry the probe as per section 16 and return it to the storage pouch.

**15. Anal Probe**

An anal probe (X-PR13) can be purchased as an accessory. This probe can be used for urinary and faecal incontinence in both males and females.
Conditions that may be treated
These anal probes may be used to treat Urinary and Faecal Incontinence in a similar way to the vaginal probe. Because the stimulation cannot be restricted to one muscle group, and the mucosal tissue has different electrical characteristics, anal stimulation is less comfortable than vaginal.
You should consult your healthcare professional before starting treatment.

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

You may benefit from the “Elise” if you either have no active anal sphincter contraction, or a weak or poorly sustained contraction. Use the STRESS 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 “Elise”.

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 STRESS, MIXED, or TONE programs to the highest tolerable.

15.1 HOW TO INSERT ANAL PROBE

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

• Before using “Elise” Pelvic Floor Exerciser you will need to visit the toilet.
• Connect the leadwires the same way as you would for Vaginal Probe.
• Lubricate the metal electrode surfaces and probe tip with a proprietary jelly, such as TensCare Go Gel or waterbased lubricant, or water.
• Choose a comfortable position, such as leaning back or lying down on your bed with your knees raised.
• After wires are securely connected, insert the probe into anus whilst ‘bearing down’ (as in the action of passing stool) to a comfortable limit until the base of the flange on the probe touches the anus. The metal parts conduct the electrical pulse and should be in contact with the main part of the muscle at all times. The tissues close to the entrance are more sensitive, so you should avoid stimulating them. It is recommended that the probe is inserted past the sphincter muscles of the anus, unless directed otherwise by a healthcare professional.

Note: Anal probes with long electrodes (the metal part) that run up and down the length of the attachment should always be inserted with the metal parts facing hip-to-hip. Anal probes with circular electrodes (the metal part) should be inserted simply to the desired depth. Sometimes the wearing of tight fitting undergarments or a tight pair of jeans will help to keep the probe in place and maintain correct contact during the program.

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

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

It is important that the probe is cleaned after each use. Clean with either an alcohol-free antibacterial wipe or by wiping with warm soapy water. Rinse and dry thoroughly and return the unit to the storage pouch. Do not immerse the probe in a liquid.

Clean the case of the unit and lead wires at least once a week using the same method.
- Do not immerse your “Elise” machine in water.
- Do not use any other cleaning solution

17. TROUBLESHOOTING

If the unit does not work:
- No display – charge the battery, please see section 18 for more details
- No sensation and LEADS alarm showing.
The “Elise” has a safety feature which will not allow the intensity to pass 20.0mA if the machine detects a connection error. If a connection error is detected the intensity will return to 00.0mA and the screen will flash ‘LEADS’. This safety feature will prevent the machine from giving any uncomfortable stimulation should the contact break between the machine and your skin. This will also prevent anyone from increasing the intensity to a high level without firm contact between the machine and the skin.

A connection error can occur if:

1. A break has developed within one of the two lead wires

If this happens, you can try the below solutions:
- 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 25.0mA.
  ii) If the ‘LEADS’ alarm shows and the unit will not allow you to pass 20.0mA. The lead wires need to be replaced. Note: The lead wires will need replacing every 3-4 months as they can wear with usage.

If you have tried the test above and DO have sensation when the probe is in your hand, then it may be that:

2. The skin is dry, meaning poor conductivity between the metal plates on the probe and your skin.

If this happens, you can try the below solutions:
- Using a water-based lubricant such as TensCare Go Gel, which will improve conduction.
- Crossing your legs and squeezing to increase pressure on the probe, which should improve the connection. If this enables you to use the unit, you should find that in a few weeks of stimulation the contact improves. If it does not, this unit may not be suitable for you. You may need to contact your healthcare professional to discuss other suitable options.
- The probe supplied with the unit has a 28mm diameter. An optional 32mm probe, part no. X-VPM, is available.

• No sensation and no LEADS alarm
- Please make sure you are increasing the intensity high enough. Most people will start to feel the stimulation in their hand at around 25.0mA and with the probe inserted you will need to increase the intensity higher to around 40.0mA - 60.0mA, Max power is 99.5mA. Everyone is different so just keep increasing the intensity until you can feel. The intensity increases in very small steps of 0.5mA.
- You may have reduced sensitivity due to previously damaged or desensitised pudendal nerves (this can happen in childbirth or some surgical procedures). Please consult your healthcare professional.
18. CHARGING THE BATTERY

The "Elise" is powered by a type BL4B rechargeable Li-ion battery. A separate charging cradle and power adaptor are included in the kit. The battery should need charging about once a month. The battery should last at least 6 hours at 50mA 300uS 50Hz. To fully charge the battery it will take about 2 hours. When the battery is running low, the word “BATT” will show on the screen. Although the display fades as the batteries run down, the strength of the output does not change until the warning is shown.

To charge the battery:

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

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

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

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

**Caution:** Keep batteries out of reach of children.

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

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

**NB:** Remove the battery from your Elise if the unit is unlikely to be used for a long period.

**WARNING:**

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

- **Do NOT** pierce, open, disassemble it, or use it in a humid and/or corrosive environment.
- **Do NOT** expose to temperatures over 60°C (140°F)
- **Do NOT** put, store or leave it near sources of heat, in direct strong sunlight, in a high temperature location, in a pressurized container or in a microwave oven.
- **Do NOT** immerse the battery in water or sea water, or get it wet
- **Do NOT** short-circuit the battery.

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

Max Intensity 50V zero to peak. Setting 0-100 in steps of 0.5
OC cutout below 160 Ohm. Constant current 160-470 Ohm 470-
2000 Ohm constant voltage

Channels Single

Waveform Asymmetrical rectangular

Max Pulse energy * Total output limited to 25uC per pulse

Power BL-4B Li-ion battery 3.7V

Battery life At least 15 hours at 50mA 300uS 50Hz

Adjustable Timer 10, 20, 30 45, 60, 90 min Defaults to 20 min

Output plug Fully shielded: touch proof mini USB

Weight 90 gms without batteries

Dimensions 100 x 65 x 18 mm

Safety Classification Internal power source. Designed for continuous use.

Type BF Degree of protection against electrical shock.

Water resistance IP22 No special moisture protection.

Environmental Specifications

Operating:

Humidity: 20 to 93% RH

Temperature range: 10 to 35C

Atmospheric Pressure: 700hPa to 1060hPa

Storage:

Humidity: Up to 93% RH non condensing

Temperature range: -20 to 70C

Atmospheric Pressure: 700hPa to 1060hPa

Expected service life The machine will often last for more than 5 years, the warranty covers first 2 years. Accessories (leads, probes, pads, and batteries) are not covered by the warranty.

* 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.

* 3.7V Li-ion Rechargeable Battery should last about 6 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.

GMDN 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.

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.

PROGRAM SETTINGS

<table>
<thead>
<tr>
<th>Program</th>
<th>Hz</th>
<th>Pulse Width (µS)</th>
<th>Ramp Up &amp; Down (Sec)</th>
<th>Plateau (Sec)</th>
<th>Off (Sec)</th>
<th>Default Program Duration (Min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>STRES</td>
<td>50</td>
<td>300</td>
<td>1</td>
<td>5</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>URGE</td>
<td>10</td>
<td>200</td>
<td>1</td>
<td>5</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>MIXED</td>
<td>20</td>
<td>250</td>
<td>2</td>
<td>5</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>TONE</td>
<td>35</td>
<td>250</td>
<td>2</td>
<td>3</td>
<td>6</td>
<td>20</td>
</tr>
</tbody>
</table>
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.

**NB:** As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields $d = 3.3$ m at an IMMUNITY LEVEL of 3 V/m.

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

21. 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.

22. ACCESSORIES

<table>
<thead>
<tr>
<th>REF</th>
<th>PART NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-VP</td>
<td>Liberty Vaginal Probe</td>
</tr>
<tr>
<td>X-VPM</td>
<td>Liberty Plus Vaginal Probe 32mm</td>
</tr>
<tr>
<td>X-VPL</td>
<td>Liberty Loop Vaginal Probe</td>
</tr>
<tr>
<td>X-VPG</td>
<td>Liberty Gold Vaginal Probe</td>
</tr>
<tr>
<td>X-PR13</td>
<td>PR13 Anal Probe</td>
</tr>
<tr>
<td>E-CM5050</td>
<td>Electrode pads 50x50mm for external use. Pack of 4. Go Gel Personal Lubricant</td>
</tr>
<tr>
<td>K-GO</td>
<td>Replacement lead 1.25m</td>
</tr>
<tr>
<td>L-IT1-NEW</td>
<td>Li-ion battery</td>
</tr>
<tr>
<td>B-BL4B</td>
<td>Charger for Australia</td>
</tr>
<tr>
<td>X-ELBATCH-AU</td>
<td>Charger cradle</td>
</tr>
</tbody>
</table>

**Change of lead**
Please note that from serial number :14/004471 the “Elise” has an all-plastic connecting plug on the lead to comply with current safety regulations. For earlier models use L-IT1 leads.

Further information on purchasing accessories can be obtained:
In Australia – by contacting JA Davey Pty Ltd on 1800 010 891 or online at www.tenscare.com.au.

In New Zealand - by contacting JA Davey Ltd (C/-Healthcare Logistics) on 0800 523 583 or online at www.tenscare.co.nz.

**HELPLINE**
A helpline is available, Monday to Friday.
Australia - please call JA Davey Pty Ltd on 1800 010 891
New Zealand - please call JA Davey Ltd (C/- Healthcare Logistics) on 0800 523 583
SYMBOLS USED

Attention! Please follow the instruction in the Instruction Manual.

TYPE BF EQUIPMENT: Equipment providing a degree of protection against electric shock, with isolated applied part. Indicates that this device has conductive contact with the end user.

This symbol on the unit means “Refer to Instruction Manual”

Temperature Limitation: Indicates the temperature limits to which the medical device can be safely exposed.

Humidity Limitation: indicates the humidity limits to which the medical device can be safely exposed.

Serial Number: indicates the manufacturer’s serial number so that a specific medical device can be identified.

This medical device is not water resistant and should be protected from liquids.

Do not dispose in household waste.

Atmospheric Pressure: indicates the atmospheric limits to which the medical device can be safely exposed.

Date of Manufacture: indicates the date which the medical device was manufactured. This is included within the serial number found on the device (usually in the battery compartment), “E/Month/Year/Number” (MM/YY/123456).

This medical device is indicated for home use.

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

23. WARRANTY

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

PRODUCT WARRANTY INFORMATION

This product is warranted to be free from manufacturing defects for 2 years from date of purchase.

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

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

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

Contact TensCare customer service. Our staff are trained to assist you with most issues you may have experienced, without the need to send your product in for service.

Returning your unit for service

Should repair be needed within the warranty period, enclose the tear off section of this warranty card and your proof of purchase receipt. Please ensure all relevant details are completed and before sending your unit in for service. Please ensure your contact details are still current and include a brief description of the problem you are experiencing together with your purchase receipt.

DO NOT SEND IN PROBES OR LEADS DUE TO BIOHAZARD RISK. ONLY SEND IN UNIT, ADAPTOR & CHARGER CRADLE.

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

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

IN NEW ZEALAND
BV Medical – TensCare Repairs
Unit 7, 110 Mays Road
Onehunga
Auckland 1061

Should you require any further information please do not hesitate to contact us by calling our toll free number:

IN AUSTRALIA Free call: 1800 010 891
IN NEW ZEALAND Free call: 0800 523 583

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:


