

viva

Wireless pelvic floor exerciser



Instructions for Use



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viva

The ultimate wireless pelvic floor exerciser



1.1 Introduction:

The **viva** consists of:

The “Viva” Control Unit

The “Viva” Vaginal Trainer

The “Viva” Trainer Holder

The **viva** operates using Wi-Fi technology meaning that there is no physical connection between the control unit and the trainer, making the **viva** discreet and unique.

The control unit sends messages to the trainer so that it can gently stimulate and exercise your pelvic floor muscles. The trainer sends messages back to the control unit, confirming correct operation and battery condition.

The range of the Wi-Fi signal between the control unit and the trainer is about 1.0 metre. Beyond this distance communication between the control unit and trainer may be lost, but the trainer will continue to operate safely.

IMPORTANT

The Trainer must be stored correctly in the specially designed Trainer holder. The holder has a magnetic switch which automatically switches off the trainer. On removing the trainer it switches back on again and ready for use. The **viva** will not operate until the “**clock and date**” have been programmed into the control unit and the control unit “**paired**” with the trainer. Please see instructions, section 3 “First Use”. These two procedures are essential and will only take a couple of minutes.

If in doubt, contact your incontinence advisor or call our helpline on +44 (0)1372 72 34 34.

Please read the instructions carefully before use

Introduction

1.2 Indications for Use

The **viva**, in conjunction with the viva vaginal trainer, provides electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence. **viva** will also help tone your pelvic floor muscles to improve your sexual health.

The international identification code for this type of product is:
GMDNS [36784] Stimulator, electrical, neuromuscular, incontinence

1.3 Types of Incontinence

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

Stress :

Describes the involuntary leakage of urine when a person coughs, sneezes, strains or makes sudden movements. It is particularly common in women and occurs when the bladder neck and the other mechanisms that act to hold urine in the bladder are not working properly.

Urge :

Describes an overactive bladder. A person may experience a strong and sudden urge to go to the toilet but are not always able to hold on, or have to go so frequently that it becomes inconvenient.

Mixed :

Is a combination of both Stress and Urge Incontinence.

1.3.1 **Tone:**

A toned pelvic floor means strong pelvic floor muscles may improve your sexual health

Introduction

1.4 Pelvic Floor Exercises

Once your Viva has helped you to develop control of your Pelvic Floor muscles and built muscle strength, you should make Pelvic Floor (sometimes called Kegel) Exercises part of your daily life.

The pelvic floor muscles help to support and keep the bladder, uterus & bowel in place. So it's really important to exercise these muscles to keep them strong.

These exercises can be done at any time, whether you're lying, sitting down or standing up. What can be really helpful is to think about doing these exercises during your working day such as when you are at your computer or watching TV. Getting into the habit of doing these exercises at regular times each day is very beneficial.

It's important first of all to find your pelvic floor muscles and feel them working. Here are a couple of ways that may help:-

1. Try inserting a finger or maybe two into your vagina and then squeezing the surrounding muscles, lifting up and towards your tummy 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 your exercising the correct muscles.
****A point to note here is that this way is only to confirm that you are using the correct muscles. So it is important to have an empty bladder before starting the actual exercises.****
3. Your Viva can help you to learn which muscles you need to contract, and what this feels like. During a Viva session you can practice holding on after the Viva stimulation has finished.

Introduction

To do the exercises:

- Aim to hold each contraction for 3-5 seconds, then release and relax. You should feel a 'letting go' of the muscles.
- Repeat the exercise – remembering to squeeze and lift for that 3-5 seconds and then to relax for 5 second
- Repeat the exercise for 8-10 squeezes per session and aim for 3-4 sets a day. Over a period of time try to increase the muscle contractions up to 10 seconds each time, but remember to rest in between each contraction for longer periods.

It's important to aim for quality contractions, not quantity. Don't worry if you find holding for 3 seconds difficult at first. Aim to hold for as long as you feel is comfortable. The more the exercises are done the more the muscles gain in strength.

A final point to note - be careful when doing these exercises not to squeeze the muscles in your legs, abdomen or buttocks and remember to breathe.

2 Contraindications, Cautions and Warnings

2.1 Contraindications

Do **NOT** use the **viva** *pelvic floor exerciser* under the following circumstances:

- If you have a heart pacemaker or a heart rhythm problem. Stimulation in the direct vicinity of a pacemaker may affect some models.
- If you are, or may be pregnant It is not known whether electrical stimulation may affect foetal development
- If you have been diagnosed or treated for cervical cancer. In vitro experiments have shown that electricity can promote cell growth.

- If you have or have had epilepsy. TENS may affect seizure threshold
- Do not use within 12 weeks of any surgery in the area of the vagina or nearby. Scars should be fully healed before use.

2.2 Cautions

- Whilst driving, or during any activity in which involuntary muscle contractions may put you at undue risk of injury. Sudden changes in contact may cause brief involuntary muscle movements
- If you have a metal coil IUD fitted and experience any sharp discomfort during stimulation Strong electromagnetic fields (electrosurgery/microwave cookers/mobile phones) may affect the correct operation of this unit. If it appears to behave unusually, move it away from these devices.

2.3 Warnings

Before using the **viva** *pelvic floor exerciser* please note the following warnings:


- Incontinence may have many causes. You should try to identify your type of incontinence and the cause before use.
- If you have a urinary infection or any skin irritations within the vagina, it is recommended not to use the stimulator.
- Care must be taken if you are not experiencing normal sensation or feeling in your vagina.
- If you suspect or have any form of prolapse you **MUST** consult your medical advisor before using the **viva**. (Exercise may help mild prolapse, but causing contractions may be inadvisable for severe prolapse)
- The Stainless Steel of the **viva** vaginal trainer contains 8% Nickel and 18% Chromium. Do not use the trainer if you are allergic to either of these metals.

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

3 Preparing for Use


3.1 Inserting the batteries

In order to activate the **viva** it is necessary to insert two “AA” batteries into the back of the unit. See section 6.1.

To check that the batteries have been correctly inserted press the “**ON/OFF**” button marked  at the top right of the unit, and hold down. **Two beeps will sound.** Release the button after the second beep.

The screen will briefly display **viva** Rev, this shows the current software version. It will then change to the **Main Menu**.

The battery level of the **viva** is displayed as a bar at the top right of the screen. The battery level of the trainer is also displayed as a bar next to the **viva** battery level, when they are working together.

To switch the **viva** off press on “**ON/OFF**”  button until the unit beeps once.

3.2 Viva touch screen

The **viva** has a touch screen. The type of touch screen employed requires the screen to be pressed down over the relevant symbol, unlike other types of touch screens where only a touch is required. This represents a safety feature so that accidental operation of any symbol by simply touching does not occur.

When instructed to “press” a button, you should press firmly and release.




Preparing for Use

3.3 Set up of “Clock and Date”

****ESSENTIAL PROCEDURE BEFORE FIRST USE****

It is necessary to set the clock and the date into the **viva** before use.

Press the “” button and hold it until two beeps have sounded.

This will switch on the unit. The screen will light up and display the **Main Menu**.

Press the “**Setup**” button to open the **Setup Menu**.

Press the “**Time Date**” button to select the **Time Date Menu**

Use the ▲ and ▼ buttons to adjust the **YEAR**.

When this is correct, touch the “**Set Month**” button

Enter the correct month by using the ▲ and ▼ buttons.

Press the “**Set Day**” button to lock in the month.



Preparing for Use

Enter the correct day by using the ▲ and ▼ buttons.
Press the “**Set Hour**” button to lock in the day.

Enter the correct hour (12 hour clock) by using the ▲ and ▼ buttons.

Press the “**Set Minute**” button to lock in the hour
Enter the correct minute by using the ▲ and ▼ buttons.

Press the “**AM / PM**” button to lock in the minute.
Select AM or PM

Press the “**Finished**” button to return to the **Setup menu**



Preparing for Use

3.4 Pairing of Trainer

The trainer operates like your home Wi-Fi. It cannot accept instructions from the **viva** until “pairing” has occurred. The **viva** and trainer need to exchange security keys so that they can recognise each other. Each trainer has a unique identity number which enables the **viva** to recognise it. Pairing should only need to be undertaken at the time of “first use” or when starting to use another new trainer.

The **viva** can be paired with up to 60 trainers (but only one at a time). Care should be taken to ensure that only one trainer is activated (removed from holder) during pairing.

Procedure:

- a) Insert Trainer battery into trainer (See 6.1)
- b) Press the **“Setup”** button to open the **Setup Menu**.
- c) Press the **“Stim Trainer”** button to enter the Stimulation Trainer Setup Menu
- d) Press the **“Pairing”** button
- e) Place the trainer into the holder. Leave for a few seconds, and press **“Next”**



Preparing for Use

- f) Remove the trainer from the holder. This switches the Wi-Fi Transmitter on.
- g) Hold the trainer close to the **viva**.

Pairing should commence automatically. The green dots show pairing progress.

If nothing happens, press “**Cancel**” and try the following:
Return the trainer to the holder and try again.

- Ensure that the trainer is less than 1.5 metres from the control unit
- Move away from Wi-Fi devices and mobile phones
- Check the charge in all batteries.

g) When pairing is complete, the TRAINER PAIRING screen is shown, confirming the Serial Number of the probe which has been paired.

h) The trainer battery state will always be shown at the top right of the screen, next to the Wi-Fi signal quality.

i) You may check this information again by selecting the Setup Menu and pressing “**About**”

j) Press “**OK**” to return to the **Main Menu**.

The trainer is now paired with the **viva**.

If you try to use a trainer without pairing, you will see a warning message:-



Preparing for Use

IMPORTANT

The trainer must be stored in the specially designed trainer holder. This has a magnetic switch which turns off the trainer when it is not in use.

If it is not returned to the holder, the battery life may be seriously reduced.

The trainer remains active for 15 minutes after receiving the last command from the **viva**.

AFTER USE CLEAN THE TRAINER AND REPLACE IT
IN THE HOLDER TO PRESERVE BATTERY LIFE

3.5 Colour and Sound

The **viva** has three display colour schemes. You can select these from the **Setup Menu**

There is also a beeper to tell you when treatment has finished and remind you to return the trainer to its holder. (You may silence this beeper if you wish.)

3.6 Screen Cal

This is a service utility. If the touch screen is damaged, or stops working correctly, contact your supplier for further information.



Preparing for Use

3.7 The “Start delay”

The “Start delay” is the time between when you press the “Press to run” and the trainer starts to operate. Every trainer is supplied with a “Start delay” of 30 seconds. The Start delay allows you to insert the trainer and get comfortable. To check or alter the “Start delay”, press “Setup” on the main menu, then “Stim Trainer” then press “Mode”.

The “Start delay” can be set to a time of up to 300 seconds.

The **viva** can be used in two ways:

- a) With the Start delay set to 30 seconds or above (known as the Hands Free Mode) once you have set the intensity, you can move away from the **viva** control unit and it will continue working but to alter the intensity or change programme you will have to return to about 50cms from the **viva** control unit.
- b) If you set the “Start delay” to less than 30 seconds, Hands Free Mode switches off. There is no delay before the Programme starts, but you will need to keep within Wi-Fi transmission range for the whole treatment.

Transmission range does vary between individuals.



Preparing for Use

3.8 Familiarising yourself with the sensation

We recommend that you get used to the sensation before using the **viva**.

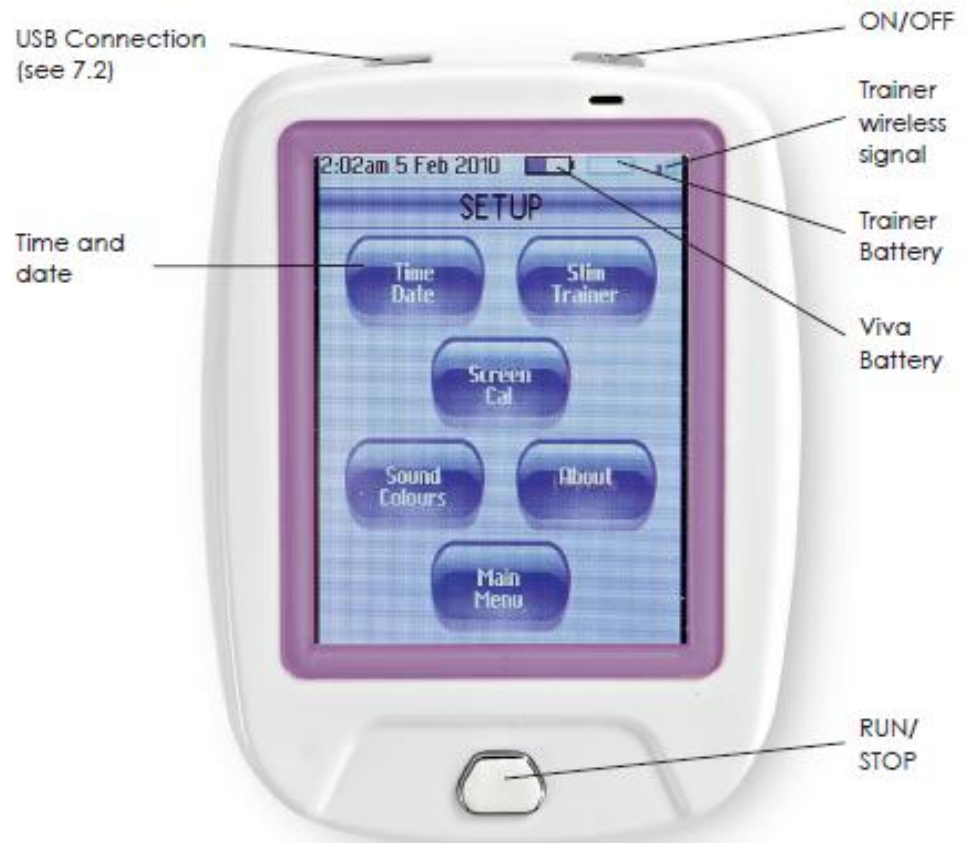
You can do this by trying it in the crook of your elbow (or under your arm):

- Dampen the inside of your elbow with water or a water-based lubricant
- Remove the trainer from the holder
- Turn the unit on and select the **STRESS** programme.
- Place the trainer in the crook of your arm (or under your arm) and squeeze
- Move it around until the water has spread to make good contact.
- Press **PRESS TO RUN** button and wait for the 30 second delay. Wait for the blue bar to cross 6 times, gradually increase the intensity until you start to feel a pulsing. Intensity can only be increased during the a “Work” cycle.
- If you get a “**Poor electrode contact**” error message, add more water or gel.
- Increase the intensity until you start to feel muscle contractions.
- Press the **STOP** button, or simply straighten your arm

Controls and Display

4. Controls and Display

The screen is touch activated. Simply press the icon you want to activate.



5 Using your **viva** cordless pelvic floor exerciser

5.1 Contenance Programmes

viva has four preset programmes plus two Custom Selectable Programmes

STRESS INCONTINENCE

The **STRESS** incontinence programme exercises the muscles of the pelvic floor using gentle stimulation.

The stimulation causes the muscles to contract and work thereby building their strength. 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 by a cough, sneeze or physical exertion. Importantly the stimulation helps you to understand what the correct muscle contraction should feel like. (See para 5.6.d)

The sensation of this programme is like a strong drawing in of the muscles of the vagina and pulling up of the pelvic floor. Your natural reaction will be to pull in and up with your muscles, thereby fully exercising and strengthening your muscles. Successful treatment requires 20 minutes stimulation once per day for one to three months. Improvement should start becoming apparent after about four weeks. Once the full strength of the muscles has returned it is recommended to continue using your **viva** once per month on an “as and when” required basis and to use the TONE programme, ideally on a twice a week basis.

Duration: 20 minutes

URGE INCONTINENCE

The **URGE** incontinence programme reduces the involuntary contractions of the pelvic floor muscles. This prevents the unwanted and unexpected emptying of the bladder. Successful treatment will require stimulation once a day and improvements can become apparent in as little as two weeks. The sensation is of a longer and softer pulling in than in the Stress Programme. It is designed to soothe your bladder muscles rather than exercise your pelvic floor. Once the full strength of the muscles has returned it is recommended to continue using your **viva** once per month on an “as

Using your Viva Exerciser

Using your Viva Exerciser

and when” required basis and to use the TONE programme, ideally on a twice a week basis. Duration: 20 minutes

MIXED INCONTINENCE

The **MIXED** programme is suitable if you are suffering from both Stress and Urge Incontinence or are not sure which form of incontinence is the problem. The stimulation is a mix between the Stress and Urge programmes.

The overall effect is not such a strong feeling as the Stress programme but linked to a pleasurable throbbing sensation.

Duration: 20 minutes

An alternative is to use 10 minutes of Urge followed by 10 minutes of Stress

TONE

Having restored your pelvic floor muscles to an excellent condition use the **TONE** programme to keep them strong and toned. This can be achieved by using this programme, twice a week, on a regular basis.

The sensation when using the Tone programme is a mixture of a strong drawing in of the muscles and then releasing. The sensation is repeated during the programme.

Strong and fit pelvic floor muscles will increase and improve your sexual health, should make orgasms easier to achieve and generally increase sexual enjoyment.

Duration: 20 minutes

CUSTOM SELECTABLE

For some users, better results may be obtained by varying the settings- especially the Work and Rest periods, which can be shorter at the beginning of training, and increased as muscle tone improves. Muscle stimulation has many variables, and we recommend that you take professional advice before using these programmes.

See Paragraph 5.3 for default settings.

Using your Viva Exerciser

5.2 Selecting a programme

When the **viva** is switched on, the screen will display the “**Main Menu**”

To return to the last programme used press on, “**Last Programme**”

To select any other programme press on “**Choose Programme**”.

In the **Choose Programme** menu, press on the programme you want to use.

N.B: The **viva** has a memory for each programme. When changing programmes the set strength automatically goes to the last strength used in that programme (or 50% if not using “Hands Free” mode). The strength setting can be changed before pressing the **PRESS TO RUN** button. The intensity gradually increases to the set value over six “Work” periods.



Using your Viva Exerciser

5.3 Using a Custom programme

There are TWO Custom Selectable Programmes, shown on the screen as:

“Custom 1 and Custom 2”

In the custom programmes Frequency, Pulse Width, Work Time, and Rest time are adjustable.

Ramp up and down are fixed at 1second (unless Work is less than 2 seconds when they adjust to 0.25s).

Custom 1 defaults to:

PW 300 μ S, Frequency 2Hz, Work 5s, Rest 5s

This is a slow tapping sensation that soothes and relaxes

Custom 2 defaults to:

PW 300 μ s, Frequency 2.0Hz, Work 1s, Rest 0.5s

This a gentle, slow, squeezing/pulsing, sensation



Using your Viva Exerciser

To change settings, Press “**Change**”

Pulse Width and **Frequency** may now be adjusted.

Press ▲ and ▼ to choose the required setting.

Press “**Next**” to lock these settings and go to the next screen.

Work Time and **Rest Time** may now be adjusted.

Press ▲ and ▼ to choose the required setting.

If the ratio of Work to Rest is less than we would advise, the **WORK RATE HIGH** will be shown in red.

Insufficient Rest time can lead to early muscle fatigue and can cause aching muscles

Touch “**Next**” to start using the programme.

These programmes can be used for incontinence, pelvic floor training or toning.

Once set into the **viva** both of the selectable programmes are stored for future use.



Using your Viva Exerciser

5.4 Adjusting Programme Timer

When you select a programme, the duration (Time) will default to 20 minutes

Before you start to use the programme, you may adjust both the time and strength by touching the ▲ and ▼ buttons.

See section 5.6 before adjusting the Time setting

After the programme has started, the TIME display will count down to zero, then automatically end the programme.



Using your Viva Exerciser

5.5 Adjusting the Strength

You can set a strength level before starting the programme. If you do not change the setting, the **viva** will remember the setting you last used. When using the trainer for the first time the intensity will be at 0.5 and no “memory strength” will have been stored in the **viva**. Once stimulation has started, the strength will gradually increase over 6 “Work” periods to the set value.

The Wi-Fi System allows you to adjust the strength of the stimulation in the trainer remotely from the **viva** during use, provided that you are within Wi-Fi transmission range

To use your **viva** :-

- a) Remove the trainer from the holder
- b) Prepare to insert the trainer
(see section 5.8)
- c) Check the Set Strength
(This is the strength you ended on last time you used the programme)
- d) You can adjust the Set Strength before starting.
- e) To start the programme running, press the RUN/STOP button. The “Start delay” of 30 seconds will start
- f) Insert the trainer
- g) In the last 10 seconds, the control unit will beep each second.

When the counter reaches zero, the trainer will start automatically, and increase over six Work periods to the **Set Strength**.

The **Present Strength** display shows how close to the **Set Strength** you are.

To stop the stimulation press the Start/Stop button at any time. If the “sending stop message” display remains on the screen, move the control unit closer to the trainer.



Using your Viva Exerciser

viva cycles between active stimulation (or “Work”) and periods of rest to allow your muscles to recover between contractions. It is normal to feel the stimulation ramp down, stop briefly, and then ramp back up again during treatment.

The blue bar along the bottom of the screen shows the Work and Rest periods. During Rest periods the bar disappears, then at the beginning of a Work period, the blue bar grows as the strength ramps up.

In each Work period, the present strength is shown next to the bottom bar, so you can see how close you are to the final setting.

h) When the start delay reaches zero, stimulation will start.

For the first six Work periods, the strength increases gradually until it has reached the original Set Strength. Present Strength is shown in small numbers next to the moving bar.

i) Press the ▲ and ▼ buttons to increase or decrease the strength. You should see the “Set Strength” changing. If it does not, move the **viva** control unit closer to the inserted trainer.

Keep increasing the strength until the stimulation is strong but comfortable.

The **viva** is fitted with the “**Comfort Strength Control**” system which allows for very small increases in strength and makes using the trainer very comfortable. This means that, for the first use, you will need to press the ▲ button for a few seconds before you can feel any stimulation through the trainer. Keep pressing until a comfortable level of stimulation is reached. (**See section 5.6 about strength settings**)

You can reduce the strength at any time, but can only increase it during a Work period.

Using your Viva Exerciser

5.6 General Points on usage

a) The Stress, Mixed and Tone programmes exercise the pelvic floor muscles. The sensation is like a strong drawing in of the muscles of the vagina, a pulling up of the pelvic floor. The muscle **MUST** contract in order to achieve a benefit.

Increase the strength as high as is comfortable, and then take it back down one step. The level required varies widely depending on the person.

b) It is advisable not to 'overdo' it early on. As long as you can feel the contraction, it is working. You can build up slowly over a number of days. With the first few sessions the muscles may ache the next day– the same reaction you would get with any unaccustomed exercise. With the pelvic floor, this gives a 'cramping' feeling. If this happens, stop using your **viva** 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.

c) The Urge programme works differently. There is no need to have a contraction. As long as you can feel the stimulation easily, it is working. You may need to increase the strength during the treatment session.

d) For best results in the stress and mixed programmes try to contract the pelvic floor muscles along with the **viva** 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.

When you are strong enough, you should continue exercising daily without the **viva**.

e) Once the pelvic floor has been strengthened using the **viva**, continue to exercise the pelvic floor muscles. The pelvic floor needs to be worked and reacts very well to such exercises.

f) 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.

g) All programmes cycle between "work" and "rest" to allow your muscles to recover in between contractions.

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

Using your Viva Exerciser

5.7 When and where to use the viva

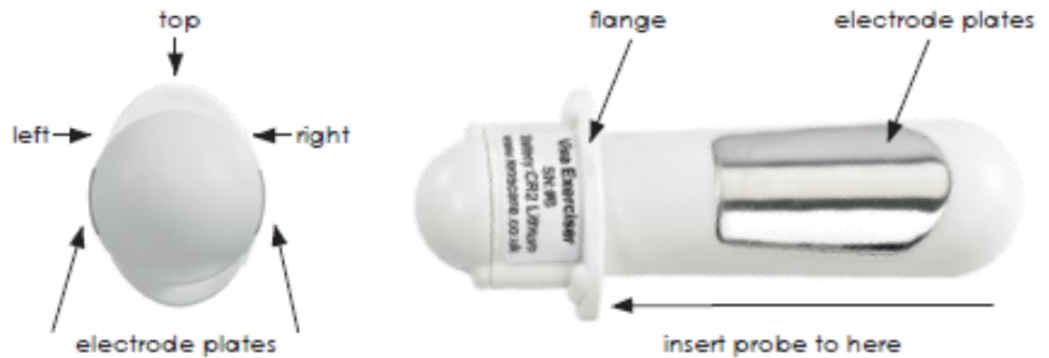
For **STRESS**: Until you have built up muscle strength, you will need to use your **viva** for 20 minutes every day. It is best to choose a similar time every day as it helps develop a routine.

To keep the trainer in place it is best to recline in bed or a comfortable chair.

For **URGE**: This programme is designed to be soothing. It does not have to produce muscle contractions. At lower strength settings, you can use it for longer periods of time.

5.8 Inserting the Trainer

- Go to the toilet before inserting the trainer.
- Switch on the **viva** before inserting the trainer.
- Remove the trainer from the holder
- You can tie a length of dental floss through the hole in the cap to create a loop about 6cm (2") long.
- Lubricate the trainer with lubricating jelly or water.
- Insert the trainer into the vagina, in the same way as a tampon, as far as the flange. Only the flange and positioning hub will remain visible. The trainer will naturally position itself with the widest part of the flange vertically.
- **It is important not to insert the trainer beyond the flange**



Using your Viva Exerciser

5.9 Pause facility

The Pause facility enables you to stop the stimulation for a while then return and complete the programme, without having to restart the programme from the beginning.

For the Pause facility to function the exerciser needs to be within range of the trainer.

Press the **PRESS TO STOP** button at any time to stop or pause a programme.

When you **PRESS TO RUN**, the programme will resume with the same time remaining.

In “Hands Free” mode, the initial delay and gradual increase in strength will start to give you time to adjust to the stimulation strength.

If you are not in “Hands Free” mode then the strength will automatically start at 50% of the strength level being used before the pause. You will then need to increase the stimulation until it is again at a comfortable level.

When the **viva** is in “Pause Mode” the trainer need not be removed from the vagina if the pause is only for a few minutes. If you do remove the trainer, do not return it to the holder as this will switch it off.

If the button is not pressed to restart the stimulation within 10 minutes the unit will automatically switch out of Pause mode and turn itself off. If you pause for more than 15 minutes, the trainer will switch off and will need to be returned to the holder and removed to start a new treatment.

Using your Viva Exerciser

5.10 End of Programme Display

At the end of each programme the screen will inform you that the programme has ended.

The screen will show :-

Press OK to return to Main Menu



Using your Viva Exerciser

5.11 Error Message : Poor Contact

If the strength is increased above 20.0 when there is no contact, a error message is displayed “**Poor electrode Contact- Refer to the user manual**” and strength resets to zero. Press OK to continue

If the trainer is unable to make good contact, it will display an Error Message and stop the treatment programme.

To improve contact try adding lubricant or changing your position to bring more pressure to bear on the plates on each side of the trainer.

The Pause facility enables you to stop the stimulation for a while then return and complete the programme, without having to restart the programme from the beginning.

For the Pause facility to function the exerciser needs to be within range of the trainer (Normally less than 1m).

5.12 Hygiene, Cleaning and Storage

- The trainer is intended strictly for **single patient use**.
- It is important that the trainer is cleaned after each use. It is recommended to use antibacterial wipes or similar anti-bacterial agents. Otherwise soap and water then rinse and dry thoroughly.
- It is important that the trainer is dry and clean before being placed into the holder.

****DO NOT IMMERSE THE TRAINER IN WATER****

- Always replace the trainer into the holder supplied. When the trainer is properly installed into the holder it will automatically switch off even if you have not switched off the exerciser, thereby safeguarding the trainer’s battery intensity.

6.0 Batteries

6.1 Battery Installation, Removal, and Disposal

viva Control Unit:

Removing battery cover - To remove battery cover lift the catch in the centre of the battery cover.

Removing batteries - To remove the batteries pull gently on the ribbon that goes round the back of the batteries.

Inserting Batteries - Ensure that the ribbon goes behind the batteries to aid removal. Ensure that the batteries are inserted in the correct way as shown in the diagram in the battery compartment. Always replace both batteries at the same time.

Battery Type for viva -Only use either **1.5v AA alkaline batteries or NiMH AA rechargeable batteries**. NEVER attempt to recharge an alkaline battery, there would be a risk of explosion. Do NOT mix batteries of different types.

Trainer:

Removing end cap battery cover - Unscrew the cap which forms the back end of the trainer.

Removing battery: To remove the battery simply unscrew the cap which forms the back end of the trainer, hold the trainer up and shake gently.

Inserting battery - Gently drop the trainer battery into the trainer with the positive end going in first. The trainer will only work if the battery is enclosed the correct way. Replace the cap and screw tight

Battery Type for trainer: Only use **CR2 3V** Lithium battery.



NB: Remove batteries from your viva and the trainer if they are unlikely to be used for a long period.

Batteries

6.2 Battery Disposal

Disposal of Batteries: - Always dispose of batteries according to government guidelines, see section 8.4

Never put batteries in a fire nor try to disassemble them.

Warning: - Keep batteries out of reach of small children

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

Do not attempt to revive alkaline batteries by heating, charging or other means.

6.3 Battery charge state

It is important that the batteries within the **viva** and trainer have adequate charge before use. The screen displays **viva** and trainer battery state at the top right.

If either of these symbols is framed in orange then the batteries need changing.

Replace the batteries as soon as possible. The trainer can only exchange signals with the **viva** when the batteries have sufficient charge.

The **viva** uses TWO “1.5v “AA” batteries (item code: B-AA)

The trainer uses a CR2 3V Lithium battery (item code: B-LICR2).

These batteries are available from Tenscare or from a high street retailer.

Memory

7. Memory

The **viva** has two memory functions:

1) **Data Capture.** It can remember which programmes have been used, for how long and at what intensity, and display this on the screen.

2) **Personal Diary.** You can use it as a continence diary, and download the stored information to your PC.

7.1 Data Capture

To view this information press the **“Diary & Memory”** button from **Main Menu**.

This will take you to the main **Memory** screen

Press **View Memory** to see the stored data. Treatment sessions which lasted less than 5 minutes, or used intensity less than 10 are not recorded.

Press **Reset All** to clear the memory.

The screen will show **DELETE MEMORY?**

Select Yes to Delete.

Press **Main Menu** to exit memory menu



Memory

7.2 Personal Progress Diary

The **viva** includes data input for a Personal Progress Diary. You can keep a daily record of your fluid intake and loss for the first three days of use to give an objective measure of your starting condition and thereby monitor your improvement.

Each time you go to the toilet, switch on the **viva**, and answer the questions.

From the Diary & Memory screen, press Add to Diary

You will be asked the following questions:

How much urine?	S	M	L	(small, medium, large)	
Strong Urge?	Y	N		(yes, no)	
Leaks since last visit?	N	S	M	L	(none,small,medium,large)
Activity during leak	N	G	B	S	(none,gentle,brisk,severe)
Drinks since last visit	N	1	2	>2 cups	

At the end of this list you will be asked to **Confirm Entry**. Press **Save** or **Cancel**

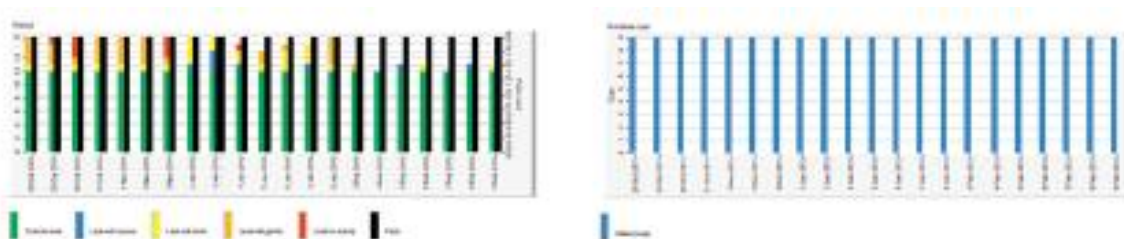
All your answers, including date and time will be saved to a database.

In 4-6 weeks time, you can repeat this process, and get an objective measure of your improvement

The Personal Progress Diary needs to be downloaded to a PC before the data can be reviewed. You can use a standard USB to MiniUSB cable (camera cable) to connect the **viva** to your PC.

You can log on to the **viva** page of www.continencesure.co.uk to download the Viva PC software together with more complete instructions on the use of the diary.

The **viva** PC software attaches the serial number of the trainer being used to the answers, and allows you to print out the data or email it anonymously to your medical advisor.



8. Maintenance

8.1 Troubleshooting

If the unit does not work:

No Display: Check that batteries have been correctly installed.
Also check that the batteries have sufficient charge

Trainer not found: 1) Place the trainer in its' case, then remove it and try again.
2) *Loss of communication may be due to poor signal intensity or strong interference.*
Replace the trainer battery.

Move 2 metres away from any Wi-Fi devices and mobile phones.

8.2 Consumables and Servicing

Part number:

X – VAVP : **viva** Vaginal Trainer
X - VAVPH : **viva** Vaginal Trainer holder
X - VAGEL : Lubricating gel 250mls
B – AA : 1.5v Alkaline batteries
B – LICR2 : 3v CR2 Lithium battery

These batteries can be purchased from TensCare or on the High Street

There are no user serviceable parts, and no maintenance or calibration is required.

TensCare will make available on request instructions for testing the device to verify performance and safety.

Service personnel require no special qualifications to carry out these instructions, but will need access to, and ability to operate, an oscilloscope with suitable bandwidth.

WARNING: No modification of this equipment is allowed.
This will invalidate the warranty and may affect performance and patient safety.

Maintenance

8.3 Guarantee

Your **viva** is guaranteed for two years from the date of purchase.

If a fault develops contact your dealer or TensCare Limited.

The guarantee does not cover the batteries.

Please note that the guarantee is invalidated if:

- incorrect batteries have been fitted
- if the exerciser has been immersed in water, maltreated or tampered with
- if the trainer has been tampered with

8.4 Disposal of Waste Electrical and Electronic Products (WEEE)


One of the provisions of the European Directive 2002/96/CE is that anything electrical or electronic should not be treated as domestic waste and simply thrown away. To remind you of this Directive all affected products are now being marked with a crossed-out wheelie bin symbol



To comply with the Directive you can return your old electrotherapy unit to us for disposal. Simply place the old unit in a post paid padded bag and send it to Tenscare Limited at 9 Blenheim Road, Longmead Business Park, Epsom, Surrey KT19 9BE. Upon receipt we shall send your old unit for component recovery and recycling to help to conserve the world's resources and minimise adverse effects on the environment.

9. Technical Specification

9.1 General Specifications

Model	Viva
Max Strength	50V zero to peak. Setting 0-100 in steps of 0.5 OC cutout above 10-20 k Ohm. Constant Charge 0-500 Ohm Constant voltage >500 Ohm
Channels	Single
Waveform	Asymmetrical rectangular
Max Pulse energy	Total output limited to 50uC per pulse
Power	Control unit: 2 x AA Trainer: CR2 Lithium battery 3V
Battery life	Around 15 hours at 50mA 300uS 50Hz
Adjustable Timer	1-60 min in steps of 1. Defaults to 20 min
Output plug	None
Dimensions	Control unit: 93 x 72 x 17 mm Trainer: 100mm x 27mm diameter
Safety Classification	Internal power source. Vaginal Trainer is a Type BF APPLIED PART. Designed for continuous use. Not intended for use in an oxygen rich environment
Moisture Protection	The Control Unit is not water resistant, and should be protected from liquids. Control Unit IP40 Vaginal Trainer IP43
	
Environmental Specifications:	
Operating:	Temperature 0°C to 35°C and Humidity: 20%R.H. to 93%R.H. Atmospheric pressure: 700hPa to 1060hPa
Storage:	Temperature range: 0 to 55C Humidity: 10 to 93% RH, non condensing Atmospheric Pressure: 700hPa to 1060hPa

Technical Specification

Expected Service Life	<ul style="list-style-type: none"> • The machine will often last for more than 5 years, but is guaranteed for 2 years. Batteries are not covered by the guarantee. • AA Alkaline Batteries should last about 18 hours continuous use. • Lithium battery should last 42 20 minute treatments
Storage life	<ul style="list-style-type: none"> • Storage life of batteries is 3 years. • The unit and probe have no fixed shelf life .
Year of manufacture	The year your unit was manufactured is represented by the first two numbers of the serial number in the battery compartment of your unit. For example, a unit with serial number E12/0012345 was manufactured in 2012.

Standard Symbols



TYPE BF EQUIPMENT: Equipment providing a degree of protection against electric shock, with isolated applied part.



This symbol on the unit means "Refer to Instruction Manual"

NB: The electrical specifications are nominal and subject to variation from the listed values due to normal production tolerances



This symbol means "manufactured by".



Product is compliant with EU MDD. Notified Body code 0473 -Intertek



The manufacturer is registered with a WEEE scheme



This device contains a radio transmitter, ID: UYI24 FCC ID: UYI24 which complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

Technical Specification

IP?? The first number:
4: Protected against access to hazardous parts with a test finger 1 mm Φ , and protect against solid foreign objects of 1 mm Φ and greater.

The second number:

0: No protection against water ingress.

4: Protected against spraying water.

Water falling as a spray at any angle up to 60° from the vertical shall have no harmful effect.

Programme Settings

Prog	Hz	Pulse Width (uS)	Ramp Up & Down (Sec)	Plateau (Sec)	Off (Sec)	Default Program Duration (Min)
STRES	50	300	1	5	10	20
URGE	10	200	1	5	10	20
MIXED	20	250	1	5	10	20
TONE	35	250	1	3	6	20
CUST 1	2	300	1	5	5	
CUST 2	2	300	1	1	0.5	

CUSTOM PROGRAMME SETTING RANGE:

Hz : 1 - 110 in steps of 1

uS : 50 - 300 in steps of 10

Work : 0.5 - 30 in steps of 0.5

Rest : 0.5 - 60 in steps of 0.5

9.2 USB connection

The **viva** is fitted with a mini-USB connector.

This is provided to automatically set the date and time to the PC clock, to download diary data to the PC programme, and to allow for future product enhancements.

Technical Specification

9.3 R&TTE Directive

DECLARATION OF CONFORMITY

June 29, 2010

RF Digital declares that the transmitters used in the **viva** control unit and vaginal trainer comply with ETSI EN 300 440-2 power requirements as called out in the R&TTE V1.2.1 Directive



9.4 Radio Interference

INSTRUCTION TO THE USER

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and if used in accordance with the instructions, may cause interference to radio communications. There is no guarantee that interference will not occur in a particular installation. Checking to see if this equipment does cause interference to radio or television reception can be achieved by turning the equipment off and on, which will show if the interference is caused by the equipment. The user is encouraged to try to correct the interference by one or more of the following measures:

- * Increase the distance between the equipment and receiver.
- * Consult the dealer or an experienced radio/TV technician for help.

The user is cautioned that changes and modifications made to the equipment without the approval of the manufacturer could void the user's authority to operate this equipment.

Technical documents for the radio modules are held at
RF Digital Corporation, 13715 Alton Pkwy., Irvine, CA 92618

9.5 RoHS (Hazardous substances)

Declaration Of Conformity

TensCare declares that the **viva** control unit and vaginal trainer are manufactured with RoHS compliant materials.

Technical Specification

9.6 EMC Precautions

Use special precautions regarding EMC according to the information provided below.

- Other portable and mobile RF communications equipment can affect performance.
- Do not use when adjacent to or stacked with other electrical equipment.

Guidance and manufacturer's declaration - electromagnetic emissions		
The viva is intended for use in the electromagnetic environment specified below. The customer or the user of the viva should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model VIVA uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The model VIVA is suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

The viva is intended for use in the electromagnetic environment specified below. The customer or the user of the viva should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile
If floors are covered with synthetic material, the relative humidity should be at least 30 %.			
Electrical transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for Input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) For 5s	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Recommended separation distances between portable and mobile RF communications equipment and the viva

The model VIVA is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model VIVA can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model VIVA as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter M		
	150kHz to 80MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Your **viva** details:

viva reference number:

.....
.....
...


viva software revision: Base unit Rev

.....
.....

(Press **Setup** then **About** to find software version)

viva Vaginal Trainer reference

The viva is intended for use in the electromagnetic environment specified below. The customer or the user of the viva should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the model VIVA, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance 3V $d = 1.2\sqrt{P}$ 80M Hz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the symbol on the left of this box
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field intensity in the location in which the model VIVA is used exceeds the applicable RF compliance level above, the model VIVA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the model VIVA.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

number.....

viva Trainer software revision: Stimulation Trainer SV00.....

Date of Purchase/...../..... Place of Purchase

Notes

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Distributed by:



Manufactured by:
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Surrey KT19 9BE



www.continencesure.co.uk

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