

Kegel8[®] Go-Tone

User Guide

of the MD  Kegel8 Go-Tone



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Please read this user guide before use and use only as described. If in doubt, consult a healthcare professional. Carefully read the chapter Contraindications, Warnings and Precautions on page 33 before use. Keep unit out of reach of children.

Welcome to Your Kegel8® Go-Tone

Thank you for choosing the Kegel8® Go-Tone. You are now one step closer to having a stronger, healthier pelvic floor. By following the instructions in this user guide, you will quickly experience the extensive benefits of the Kegel8® Go-Tone.

This user guide is an integral part of the medical device; store it in a safe and protected place, ideally together with the device, to ensure availability and readability.

Created especially for you, the Kegel8® Go-Tone is an effective neuromuscular electrical stimulator (NMES). By harnessing the body's natural electrical signals, your Kegel8® Go-Tone stimulates the muscles and nerve fibres in your pelvic area in order to strengthen them. Kegel8® Go-Tone includes clinically proven programmes that are a safe and effective way of exercising your pelvic floor. Recommended by healthcare professionals.

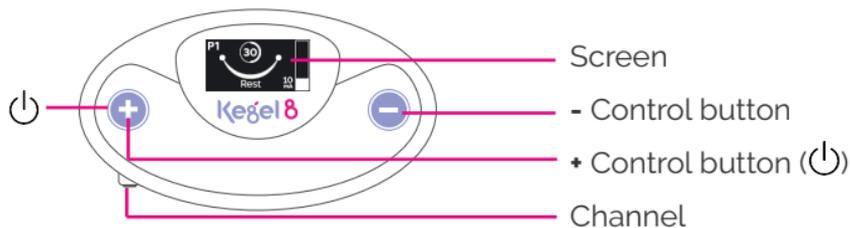
The Kegel8® Go-Tone can help prevent and treat the following conditions:

- Weak pelvic floor
- Pelvic pain
- Sexual dysfunction/lack of sensation
- Stress incontinence
- Urge and frequency incontinence, including mixed incontinence
- Overactive bladder/nocturia

In addition, the Kegel8® Go-Tone helps improve pelvic sensitivity, strength and endurance. Improving local blood circulation to maintain the optimum health and condition for these all-important muscles nerves.

Getting to Know Your Kegel8® Go-Tone

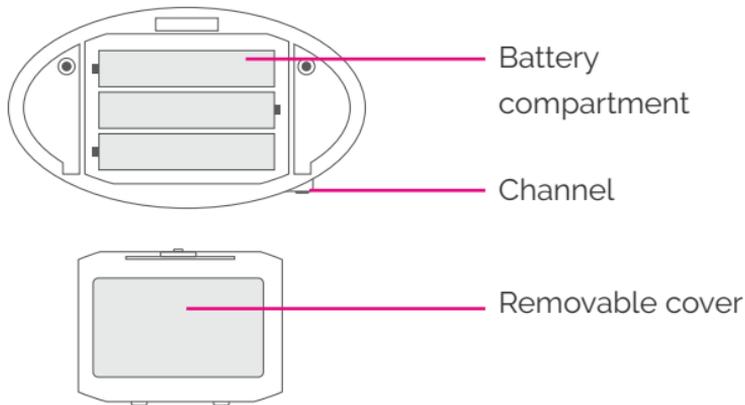
Front



Bottom



Back



Turn on the unit by pressing, and holding, the **+** Control button for at least 2 seconds. The screen will then turn on.

Turn off the unit by pressing, and holding, the **-** Control button for at least 2 seconds. The screen will then turn off.

What Comes with Your Kegel8® Go-Tone

When you open your Kegel8® Go-Tone box, you will find:

- 1 x Kegel8® Go-Tone Electronic Pelvic Toner (B13416)
- 1 x Kegel8® Glide Gold Vaginal Probe (11207)
- 1 x pack of 4 50x50mm Reusable Electrode Pads (81752)
- 1 x Kegel8® Lead Wire (13445)
- 3 x LR03 (AAA) Alkaline Batteries (8169)
- 1 x Kegel8® Carry Case (13450)
- 1 x Kegel8® Go-Tone User Guide (IFU13416)
- 1 x Kegel8® Go-Tone Quick Start Guide (QSG13416)
- 1 x Kegel8® Gel Exercise Lubricant sample 10 ml (11220)

In the unlikely event that any of the items above are missing, please contact Kegel8® Customer Services.

Customer Services.



We aim to provide our customers with outstanding products and customer service. Please get in touch.

Contact Us

Email: sales@kegel8.co.uk

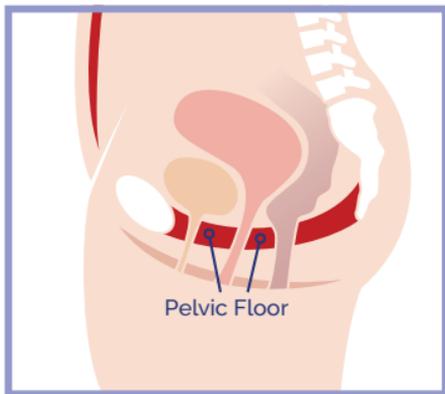
Web: www.kegel8.co.uk

Phone: 01482 496 932

How Your Kegel8® Go-Tone Works

The Kegel8® Go-Tone is one of a new breed of modern neuromuscular stimulators developed with the aim of achieving optimum pelvic floor health for women.

Kegel8® Go-Tone works by producing electrical pulses that stimulate the perineal muscles and surrounding nerves, particularly the pubo-coccygeal and pubo-rectal muscles. This strengthens these muscles and improves blood circulation to give greater control.



The programmes on the Kegel8® Go-Tone are designed to treat specific pelvic floor conditions in 15-50 minute sessions – with a perfect balance of working and resting the muscles so you get the optimum results in the quickest time.

Your pelvic floor muscles do a lot for you; they support all of your pelvic organs, they help stabilise and support your spine, they help guide your baby during childbirth, they even contribute to your relationship by being responsible for intimate sensation for women and erectile function for men. Strengthen and maintain these all-important muscles by making the Kegel8® Go-Tone part of your routine.

What to Expect From Your Kegel8® Go-Tone

If you haven't used a neuromuscular stimulator before, the idea of applying electric pulses to your body may seem strange, but your body already uses electrical signals all the time. If you want to tense the bicep muscle in your arm, your brain sends an electrical signal to the muscle via your nervous system. When the signal reaches your bicep, it causes the muscle to contract, and when the signal is not present, your muscle relaxes again.

Kegel8® Go-Tone works in the same way – sending electric pulses to the weakened muscles in your pelvic area, causing them to contract and relax. Over time, this exercise strengthens them, giving you greater muscle control.

To deliver the stimulation to your pelvic floor you can use a Kegel8® vaginal probe (with programmes P1-P8) or skin electrodes (with programme P9). Both are designed to comfortably deliver the stimulation and, while you will be able to feel the effects of the electric pulses exercising your pelvic floor muscles, they should not cause any discomfort.

The Kegel8® probes are designed to suit your body. Their small dimensions, smooth outer casing and curved edges mean it is easy to insert and comfortable to use.

The Kegel8® Glide Gold Vaginal Probe is the most powerful vaginal probe on the market. It is ergonomically shaped for use for all women – even those with a low cervix or moderate pelvic organ prolapse. It can even be used comfortably when sitting down.



Programme P9 Overactive Bladder (OAB) works differently to the other programmes on your Kegel8® Go-Tone. Stimulating the posterior tibial nerve (PTNS); through two skin electrode pads placed on the skin on the inside of your ankle, above and below the ankle bone.



The tibial nerve runs down your leg from your pelvis, ending at your ankle. It's responsible for a lot of your body's motor functions, including those of your bladder, bowel and pelvic floor. This means that by using tibial nerve stimulation we can 'wake up' these areas, returning proper function and treating an overactive bladder.

The electrical stimulation is measured in mA (milliampere). At the start of every programme, your Kegel8® Go-Tone begins with no electrical current at 0 mA. You have full control over the level of stimulation by using the ⊕ and ⊖ control buttons. For all programmes (except P5 Urge Incontinence and P8 Pelvic Pain Relief) when the electrical current reaches a certain level, you will begin to feel a tapping, tingling or gentle pulling sensation in your pelvic muscles (depending on the programme and your sensitivity). When you get to this level, slowly increase the mA's to a level that is comfortable and you feel is working your muscles. Throughout each programme you will feel your muscles pull up, tighten, and then relax again as they are exercised in relation to work and rest periods incorporated into the programme.

The stronger the sensation you feel, the more work your pelvic muscles are doing. But don't push yourself too hard. If you feel discomfort, press the ⊖ control button to reduce the current. Some days you may need a lower mA to get the same workout.

Now, let's get started!

There have been numerous research papers and clinical studies confirming the safety and efficacy of neuromuscular electrical stimulation. If you are interested in finding out more, contact our Customer Service team (see page 6).

The Kegel8® Pelvic Floor Smile

The Kegel8® Pelvic Floor Smile has been designed to help you understand what the neuromuscular electrical stimulation (NMES) is doing to your pelvic floor muscles during certain programmes.

On programmes which use the Kegel8® Glide Gold Vaginal Probe, P1-P8, you will see the smile move up and down on your Kegel8® Go-Tone - raising to match the contraction of your muscles and lowering to reflect the relaxation you will be feeling.

The ends of the smile pulse, to show the stimulation is running through your muscles.

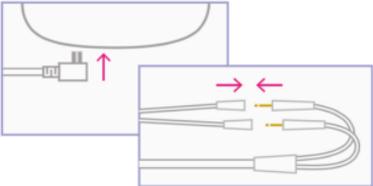


You may not feel any prominent contraction or relaxation during the following programmes, as they use continuous current:

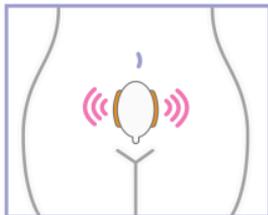
- P2 Rejuvenation
- P5 Urge Incontinence
- P8 Pelvic Pain Relief

Starting Your Kegel8® Go-Tone Exercises

Ready to start your pelvic floor exercises? Then let's get to it!

1. On the back of your Kegel8® Go-Tone, lift off the main battery cover and remove the battery compartment cover. Insert the three AAA batteries supplied, taking care to observe the polarities, and close the battery cover. Do not use the unit when the battery cover is removed.
2. *If using a probe (for programmes P1-P8):*
 - a) Make sure the probe is clean by rinsing it in lukewarm water or using the Kegel8® Cleaning Spray (see Taking Care of Your Kegel8® Go-Tone on page 25 for more advice).
 - b) Connect the double end of the lead wire to the wires of your Kegel8® Glide Gold Vaginal Probe. (If you are using a different Kegel8® probe, follow their instructions).
 - c) Connect the single end of the lead wires to the channel at the bottom of your Kegel8® Go-Tone.
 - d) To ease insertion and enhance the conductivity of the probe, apply a small tear-sized amount of good quality water-based lubricant (such as the Kegel8® KE GEL Kegel Exercise Lubricant) directly onto each of the gold electrodes.
 - e) Get into a comfortable position. Inserting a probe is similar to inserting a tampon, so you may already know which position suits you best.

- f) Hold the base of the probe (the plastic part at the end with the wires).
- g) Position the probe so that it is pointing towards your head with the wires pointing away. The gold electrodes should be on the left and right sides, facing towards each of your thighs. The scooped side should be against your back as you position it.
- h) Gently insert the probe about 2 inches (5 cm) into your vagina. This is less than you would insert a tampon - the base part of the probe should always be outside of your body.



If you have any issues inserting your Kegel8® probe or getting a strong connection with your pelvic floor it is likely to be due to lack of lubrication or incorrect positioning. Contact our Customer Service team for support, page 6.

3. *If using skin electrodes (for programme Pg):*

- a) Connect the double end of the lead wire to the wires of two of your skin electrodes.
- b) Connect the single end of the lead wires to the channel at the bottom of your Kegel8® Go-Tone.
- c) Clean and dry the area where you will attach the two skin electrode pads. Remove any oils or lotions as these could damage the pads.
- d) Remove the plastic backing on the skin electrodes and place them into position on the skin, sticky side down, a minimum of one pad length apart either side of your ankle bone.

For more advice on using skin electrodes visit
www.kegel8.co.uk

4. Turn on your Kegel8® Go-Tone by holding the ⊕ button for at least two seconds.
Sound is automatically enabled. To turn the sound off, select ⊖ whilst the Kegel8® Go-Tone logo appears, then push ⊖ to disable sound, or ⊕ to re-enable sound.
5. The last programme you were using will appear on screen, or P1 if this is the first time you are using your Kegel8® Go-Tone.
6. Press ⊖ to choose from one of the nine pre-set programmes.
See page 17 for advice on Choosing a Kegel8® Go-Tone Programme.
7. Select your chosen programme by pressing the ⊕ button.
8. If you are ready to go, press the ⊕ button to set up the stimulation level.
9. You can adjust the electrical stimulation level to suit you:
 - a) Press the ⊕ button to increase the intensity in 1 mA steps.
 - b) Press the ⊖ button to decrease the intensity in 1 mA steps.
 - c) Hold the ⊖ button for 2 seconds or more to switch-off the unit.
 - d) The programme will continue 3 seconds after any change in mA.

10. During each programme the level of electrical stimulation (mA's) will automatically adjust for the WORK and REST phases. The screen will show you which phase is active so you can recognise what a strong muscle contraction and full relaxation feels like. During some programmes, there is a very low frequency felt during the REST phase which improves the effectiveness of the treatment, without tiring the muscle. The electrical stimulation will not go above the electrical stimulation level (mA) you have set.

To change the stimulation level during a session, push the ⊕

or ⊖ button for the set intensity screen to appear:  15 min

- a) Press the ⊕ button to increase the intensity in 1 mA steps.
 - b) Press the ⊖ button to decrease the intensity in 1 mA steps.
 - c) The programme will automatically resume 3 seconds after any change in mA.
11. To pause the programme, simultaneously press the ⊕ and ⊖ buttons. To resume, push the ⊕ button. The stimulation will be progressively restored to the level it was at before, and the programme will continue.

See the  30 symbol to see the time remaining.

12. When the programme is complete press and hold the ⊖ button to turn off your Kegel8® Go-Tone. However, after a few minutes of inactivity, it will automatically switch off.

13. If using a Kegel8® probe (for programmes P1-P8) pull gently at its base to remove it. Do not pull on the wires as this could damage your probe.
14. If using skin electrodes (for programme P9) gently peel them away from your skin and replace the plastic backing.
15. Gently disconnect the lead wire from the Kegel8® Go-Tone and Kegel8® Glide Gold Vaginal Probe or skin electrodes.
16. Keep all parts in a clean, dry place. We recommend that you use the original packaging. See page 25 for more advice on taking care of your Kegel8® Go-Tone.

See Kegel8® Exercise Tips on page 16 to learn how to get the most out of your Kegel8® Go-Tone.

Kegel8® Exercise Tips

Use an Appropriate Amount of Power

The amount of electrical stimulation (mA level) needed to stimulate pelvic floor muscles varies from person to person. You should gradually increase it to a level where you can feel your muscles reacting comfortably. Only you can tell what is comfortable for you. As your pelvic floor muscles begin to strengthen, you may find that you can increase the power output.

Exercise Once a Day for 3 Weeks

We recommend that you use your Kegel8® Go-Tone once a day for a minimum of 3 weeks. but you can use as long as is needed. Alternate between your choice of programme and P1 Pelvic Floor Exercise (for more information on P1 see Choosing a Kegel8® Go-Tone Programme on page 17). For example: Monday P1, Tuesday P8, Wednesday P1, Thursday P8, Friday P1, and so on.

Aim to do just one Kegel8® programme a day, even if you do not feel the stimulation as strongly as you did before. If you decide to exercise twice a day, it is important that you do not do back-to-back sessions. This is because your pelvic floor muscles need time to recover between sessions. We suggest that you use your Kegel8® Go-Tone once in the morning and once at night. Leaving at least 8 hours between uses.

Be Patient - Kegel8® WILL Improve Your Pelvic Floor

If you use your Kegel8® Go-Tone regularly, you should notice improvements in your pelvic health in just a few weeks. However, some women take longer to respond.

Everybody is different. Some people respond to Kegel8® exercises very quickly, whereas with others, it can take a number of weeks to feel real improvements.

But rest assured, if you use your Kegel8® Go-Tone regularly and follow our instructions carefully, you will experience the benefits.

Choosing a Kegel8® Go-Tone Programme

Your Kegel8® Go-Tone includes nine exercise programmes. Each designed to treat a specific pelvic floor problem. If you are suffering with more than one pelvic floor problem, contact our expert Customer Service team (see page 6 for details). Or speak to a Women's Health Physiotherapist for advice.

Programmes P1-P8 have been designed to be used with a Kegel8® probe. P9 is designed to be used with skin electrodes.

- P1 Pelvic Floor Exercise – 16 minutes (see page 18)
- P2 Rejuvenation – 30 minutes (see page 19)
- P3 Intimate Sensation – 18 minutes (see page 19)
- P4 Stress Incontinence – 30 minutes (see page 20)
- P5 Urge Incontinence – 30 minutes (see page 20)
- P6 Mixed Incontinence – 28 minutes (see page 21)
- P7 Prolapse Management – 20 minutes (see page 22)
- P8 Pelvic Pain Relief – 50 minutes (see page 22)
- P9 Overactive Bladder (OAB) and Nocturia – 27 minutes (see page 22)

See page 24 for our glossary of keywords.

P1 Pelvic Floor Exercise

If your pelvic floor muscles are already strong and healthy, you'll want to keep them that way. Use P1 Pelvic Floor Exercise to maintain your muscle tone.

Alternate between your choice of programme and P1 to maintain a consistent strength whilst undergoing treatment.

Screen Will show: P1 (Session Time 16 mins)

Phase	Type of Exercise
1	Work 12 sec. (Ramp 10–50 Hz, 300µs) Rest 3 sec. (5 Hz, 200µs)

P2 Rejuvenation

Rejuvenate and nourish your vaginal walls with P2 Rejuvenation. Improving blood circulation with the added benefit of greater intimate sensation.

Screen Will Show: P2 (Session Time 30 mins)

Phase	Type of Exercise
1	Work 4 sec. (50 Hz, 300µs), Rest 1sec.
2	Continuous (18 Hz, 200 µs)
3	Work 6 sec. (40 Hz, 250 µs), Rest 1 sec. Continuous
4	(15 Hz, 200 µs)
5	Work 7 sec. (30 Hz, 250 µs), Rest 1 sec. Continuous
6	(15 Hz, 200 µs)

P3 Intimate Sensation

Improve your muscles on a fine scale with P3 Intimate Sensation. During this programme, both your motor and sensory nerve fibres are exercised. Your motor nerves tell your muscles to contract, and your sensory nerves gather information from the surrounding area and send it to your brain. A perfect programme to improve your intimate sensation.

Screen Will Show: P3 (Session Time 18 mins)

Phase	Type of Exercise
1	Work 10 sec. (Ramp 50--100 Hz, 300 μ s), Rest 20 sec. (5 Hz, 200 μ s)
2	Work 20 sec. (Ramp 15--30 Hz, 250 μ s), Rest 10 sec. (5 Hz, 200 μ s)
3	Work 59 sec. (Ramp 3--10 Hz, 200 μ s), Rest 10 sec.

P4 Stress Incontinence

The P4 Stress Incontinence programme has been designed to reduce urine losses by improving the ability of your muscles to react to sudden pressure. Protecting you from those little leaks when you sit down, run, cough, sneeze and much more.

Screen Will Show: P4(Session Time 30 mins)

Phase	Type of Exercise
1	Work 3 sec. (Ramp 30--50 Hz, 250 μ s), Rest 6 sec. (3 Hz, 200 μ s)

P5 Urge Incontinence

Urge incontinence is when you have the sudden urge to urinate and you may have little control in delaying it. P5 Urge Incontinence has been designed to inhibit the action of the muscles surrounding the bladder to prevent those sudden and unexpected leaks.

Screen Will Show: P5 (Session Time 30 mins)

Phase	Type of Exercise
1	Continuous (Ramp 5--15 Hz, 200 μ s)

P6 Mixed Incontinence

Many women suffer from both stress and urge incontinence. But don't worry, this doesn't mean that you'll have to do programme after programme – you can simply use P6 Mixed Incontinence and benefit from a programme designed to treat both. Combining the effects of P4 Stress Incontinence and P5 Urge Incontinence.

Screen Will Show: P6 (Session Time 28 mins)

Phase	Type of Exercise
1	Work 4 sec. (Ramp 30--40 Hz, 250 μ s), Rest 7 sec. (10 Hz, 200 μ s)

P7 Prolapse Management

Suffering with a prolapse can be quite devastating. Improve the strength of your pelvic floor muscles with P7 Prolapse Management to prevent the loss of muscle tone which can cause your pelvic organ prolapse to worsen. P7 Prolapse Management also improves the effectiveness of your pelvic floor muscles to react for better pelvic health. If you have suffered a prolapse, take care when inserting your Kegel8® probe. We recommend that you use a pillow to elevate your pelvis so that your bladder, bowel etc. can move back into position naturally. The Kegel8® Glide Gold Vaginal Probe has been specifically designed to be comfortable for women with a prolapse. Its curved shape sits comfortably against the pelvic floor muscles, away from your organs.

Screen Will Show: P7 (Session Time 20 mins)

Phase	Type of Exercise
1	Work 9 sec. (35 Hz, 250µs), Rest 12 sec. (3 Hz, 200 µs)
2	Work 6 sec. (55 Hz, 300 µs), Rest 15 sec. (3 Hz, 200 µs)

P8 Pelvic Pain Relief

For acute and chronic pain management use P8 Pelvic Pain Relief. This programme has been designed based on the "gate control" theory – limiting the sensation of pain. It also stimulates the production of endorphins, the bodies happy hormone that cause a natural analgesic effect

Screen Will Show: P8 (Session Time 50 mins)

Phase	Type of Exercise
1	Work 60 sec. (Ramp 70--100 Hz, 50 μ s),
2	work 60 sec. (Ramp 5--10 Hz, 100 μ s),

P9 Overactive Bladder (OAB) and Nocturia

Pg Overactive Bladder (OAB) stimulates the posterior tibial nerve (PTNS) through two electrode pads placed on the skin on the inside of your ankle, above and below the ankle bone. The tibial nerve runs down your leg from your pelvis, ending at your ankle. It's responsible for a lot of your body's motor functions, including those of your bladder, bowel and pelvic floor. This means that by using tibial nerve stimulation we can 'wake up' these areas, returning proper function and treating an overactive bladder.

Screen Will Show: Pg (Session Time 27 mins)

Phase	Type of Exercise
1	Work 8 sec. (Ramp 15--20 Hz, 300 μ s), Rest 1 sec.

On-Screen Symbols



Sound off



Sound on

Set Intensity

Set the intensity of the electrical stimulation in the unit mA (milliamp)



The pelvic floor is being exercised through a probe (appears during P1-P8)



The pelvic floor is resting (appears during P1-P8)



The pelvic floor is resting (appears during P9)



The pelvic floor is being exercised through skin electrodes (appears during P9)

P_n

P_n is the program in use, where 'n' is the program number (1–9).



Therapy timer countdown in minutes.

|| Pause

Programme paused



Battery low



No battery - the unit will now turn off

Connect or apply the probe

Connect or apply skin electrodes

No connection between the probe/skin electrodes, your body and the Kegel8® Go-Tone. The programme has paused. Check the lead wires are correctly pressed together and the probe/skin electrodes are correctly placed. Then select the + button to continue your programme.

Hz

Display in real-time frequency of the stimulation signal.

mA

Display output signal intensity in 'mA'.

Glossary

Term	Definition
Continuous	Active stimulation with no ramp.
Hz	Cycles per second, a measure of frequency. <ul style="list-style-type: none">• 3-5 Hz. are used specifically for treating muscle fatigue• less than 15 Hz. treats slow responding muscle fibres, chronic pain, and inhibit detrusor over-activity which can treat an overactive bladder and nocturia.• 35-45 Hz. are used to tone fast responding muscle fibres, treating urge incontinence• 45 Hz. and above promote general muscle strength.• 70-100 Hz. are used for acute pain treatment.
mA	Milliampere, a unit for measuring electrical current.
Ramp	The long and smooth variation of frequency as it changes.
Rest	The period where stimulation is inactive.
Work	The period where the stimulation is active. Can include times of rise and fall.
μ s	Microseconds, a measure of pulse width.

Taking Care of Your Kegel8® Go-Tone

Unit and Screen Care

To clean the Kegel8® Go-Tone and lead wires, use a soft, slightly damp (not wet) cloth or water-based cleaners.

Use three Alkaline LR03 batteries (AAA size) and replace when they are low on power. Remove the batteries from the unit when it is not used for prolonged periods. Check them regularly for signs of discharge and replace if they appear to be leaking as the release of battery acid could irreparably damage your Kegel8® Go-Tone. When required, replace always all the three battery.

Accessories

Only use CE approved accessories, such as our wide range of Kegel8® probes, with your Kegel8® Go-Tone.

Modifications

Do not modify your Kegel8® Go-Tone. Making unauthorised adjustments will invalidate your warranty and could result in injury.

Kegel8® Probe Care

Your Kegel8® Go-Tone comes with the Kegel8® Glide Gold Vaginal Probe,

- Never immerse your Kegel8® probe in boiling liquid.
- When inserting and removing a Kegel8® probe, hold its base, NOT the wires as this could damage them.
- Before use, always clean the probe with an approved antibacterial cleanser, such as the anti-bacterial Kegel8® Cleaning Spray or wash in warm soapy water – making sure to remove all soap residue before use.

- Never wipe the electrodes (metal parts) as this could damage their coating and reduce their effectiveness. Instead gently dab the electrodes dry.

Please refer to the individual manual that came with your Kegel8® probe for full cleaning and maintenance instructions. Or visit our website www.kegel8.co.uk.

Kegel8® Skin Electrode Pad Care

Your skin electrodes can be re-used and, if cared for, should last for around 10-15 exercise sessions. To take care of your electrode pads:

- After use, place the pads back onto the plastic sheet, sticky side down. If the surface is no longer sticky, you should buy replacement skin electrodes.
- Keep your skin electrodes in a clean, dry place. We recommend that you store them in their original packaging.

Please refer to the individual manual that came with your electrode pads for full cleaning and maintenance instructions. Or visit our website www.kegel8.co.uk.

Lead Wires and Connections

The lead wires and connections are vital to your Kegel8® Go-Tone, so its important that you treat them with care:

- Do not stretch or twist the wires as this could damage them. If your wires are damaged, your Kegel8® Go-Tone may be unable to send the electric pulses to your probe or skin electrodes.
- The connections on the Kegel8® Go-Tone and its probes are designed so that they connect to the wires with ease. Do not force the wires.
- Do not cut the wires or attempt to modify the connections.

Information for Disposal



This symbol indicates that the product (as an electric or electronic product) must be disposed of separately from normal waste at the end of its operational lifetime.

Dispose of this product by taking it to your local recycling centre or collection point for such equipment. This will help to protect the environment in which we all live. Alternatively, you can contact our Kegel8® Customer Service team (see page 6) and arrange for us to dispose of it correctly and recycle materials where possible.

Such obligation derives from directive 2002/96/CE, opportunely applied by the governments of every country member of the European community. The product contains parts that can be recovered or eliminated in differentiated way, contributing to the environmental improvement. The product contains substances which, if wasted in unsuitable way, can have harmful effects on the environment and human health. The Producer is available to withdraw the product, at the end of its cycle of life, for an appropriated recovery or elimination.

Frequently Asked Questions

Q: How soon after the birth of my baby can I start using my Kegel8® Go-Tone?

Please consult with your midwife or doctor before using a Kegel8® device. Generally, women start using Kegel8® after a successful six-week check-up.

Q: I have an IUD, Mirena coil and/or surgical mesh fitted. Can I use the Kegel8® Go-Tone?

Yes. Kegel8® devices do not affect these fittings.

Q: Can I use Kegel8® Go-Tone whilst I am pregnant?

No. Clinical guidelines advise against using any vaginal STIM devices during pregnancy.

Q: I have had pelvic surgery. How soon can I start using my Kegel8® Go-Tone?

Please consult with your doctor or consultant as every case is different. We recommend waiting a minimum of 12 weeks to allow your body to naturally recover. Using a Kegel8® device after pelvic surgery could help speed recovery by improving blood circulation.

Q: Can I use my Kegel8® Go-Tone when I have my period?

Yes. However, if you are at the peak of your period and the flow is heavy, you may prefer to wait or use skin electrodes instead of a probe.

Q: How far should I insert the probe?

Each Kegel8® vaginal probe needs to be inserted by just 2 inches (5 cm). This is the optimum level to stimulate the pelvic floor muscles.

Q: I find it painful inserting the probe. What should I do?

To ease insertion and enhance the conductivity of the probe, apply a small tear-sized amount of good quality water- based lubricant (such as the Kegel8® KE GEL Kegel Exercise Lubricant) directly onto each of the gold electrodes (metal parts).

If you are particularly dry you may be suffering from vaginal atrophy, a condition that causes dryness and thinning of your vaginal walls. Your doctor can prescribe an oestrogen cream to help. If you are using oestrogen cream, we recommend waiting a month before using your Kegel8® Go-Tone again to give your body time to replace lost moisture in the vaginal tissue. After this you will find using a probe more comfortable.

Please do not let vaginal atrophy stop you from experiencing the benefits of the Kegel8® Go-Tone. There are effective solutions available to overcome this painful condition.

Q: Why does the mA level change during the programmes?

In some programmes, there are multiple phases where the rate and length of electrical pulses vary. The unit is designed to prevent abrupt level increase, but different parameters may be felt differently. If you feel an overall decrease in stimulation, just use the ⊕ control button to increase the mA's back up to a comfortable level.

Q: Why can't I get the mA's to increase past 1 or 2? OR The screen says "Connect or apply skin electrodes"/"Connect or insert the probe".

If using the probe, this is usually caused by the probe not making effective contact with your muscles. We recommend that you try

using your Kegel8® Go-Tone whilst sitting with your legs elevated to help prevent the probe from falling out of position. You can also get better results by using a good quality water-based lubricant (such as the Kegel8® KE GEL Kegel Exercise Lubricant).

If your Kegel8® Go-Tone does not have a sufficient connection between the probe/skin electrodes, your body and the Kegel8® Go-Tone, the mA's cannot go higher and the current cuts off for your safety. The programme will pause, and a message will appear on the screen.

Check the lead wires are correctly pressed together and the probe/skin electrodes are correctly placed before continuing with the programme.

Q: Why can I only feel stimulation on one side?

This could be due to:

1. The position of the probe. To work correctly the gold electrodes on your probe need to be in direct contact with your muscles.

We recommend that you try using your Kegel8® Go-Tone whilst lying down or sitting with your legs elevated to help prevent the probe from falling out of position. You can also get better results by using a good quality water-based lubricant (such as the Kegel8® KE GEL Kegel Exercise Lubricant).

Q: How long will the battery last?

If you use your Kegel8® Go-Tone daily, the battery should last about 40 sessions (based on average programme settings). See Taking Care of your Kegel8® Go-Tone on page 25 for more information.

Q: How long will my Kegels® Glide Gold Vaginal Probe last?

Your Kegels® Glide Gold Vaginal Probe is itself a medical device. Please refer to its Instruction Manual.

For more information, see Taking Care of your Kegels® Go-Tone on page 25.

If you have any other questions visit our website www.kegels.co.uk or get in touch with our expert Kegels® Customer Service team (see page 6). We are here to help.

Technical Specifications

- **Intended use:** Prevention and treatment of stress-incontinence, urge-incontinence, overactive bladder, mild prolapses and perineal pain management, for home use directly by the patient.
- **Supply voltage:** 4.5 V (3 x LR03 battery 1.5 V size AAA Alkaline).
- Minimum battery life: 20 hours / 40 sessions with standard alkaline batteries (variable according to the program and the output level set).
- **Output:** from 1 to 99 mA_{pp} in steps of 1 mA_{pp} on a resistive load of 1000 ohm (considering a pulse width of 200µs).
- **Frequency:** Pre-set according to the selected programme: 1 to 150 Hz (± 5%).
- **Frequency during rest:** Pre-set according to the selected programme: 3 to 10 Hz (± 5%).
- **Pulse width:** Pre-set according to the selected programme 25 to 400µs (± 5%).
- **Output wave-shape:** "bi-phasic symmetrical alternated" pulses. TRUE GALVANIC FREE!
- **RISE and FALL time:** Pre-set according to the selected programme 0 to 5 seconds (± 0.5 second).

- **PLATEAU time:** Pre-set according to the selected programme 1 to 60 seconds (± 0.5 second)
- **REST time:** Pre-set according to the selected programme 0 to 60 seconds (± 0.5 second).
- **Session time:** Range from 15-50 minutes (± 0.5 minutes).
- **Electrical safety:** Battery powered
- **Overall dimensions:** 90x50x30mm.
- **Weight:** Approximately 0.2kg (including batteries).
- **Environment using limits:** +5 / +40°C U.R.15% / 93% 700hPa / 1060hPa.
- **Transport and storage limits:** -25 / +70°C U.R. 93%.
- **Electromagnetic susceptibility:** Class B according to CISPR 11.
- **Expected service life:** Daily use for 5 years.
- **Applied parts:** Perineal probes or skin electrodes with conductive surface between 0.5 to 50 sq. cm.
- **Patient circuit output connection:** 1 channels with micro axial connector to which must be connected the supplied Lead Wire (13445) ending with a 2 mm protected plug.
- **Protection against the penetration of solids and liquids:** IP22

Contraindications, Warnings and Precautions

Description and Intended Use

The Kegel8® Go-Tone is intended for the electrical stimulation of the perineal muscles (especially the pubo-coccygeal and pubo-rectal muscles) for the prevention or treatment of stress and urge incontinence, for the treatment of overactive bladder, mild prolapse and pelvic pain, and is suitable for direct use by the patient.

Where Can You Use Your Kegel8® Go-Tone?

The Kegel8® Go-Tone is designed for personal use, regardless you are at home, in a medical centre or hospital.

Who Can Use the Kegel8® Go-Tone?

The Kegel8® Go-Tone is designed to be used by women who wish to strengthen and maintain strong pelvic floor muscles.

The Kegel8® Go-Tone can be used safely by women fitted with an IDU or Mirena coil. Kegel8® Go-Tone does not affect these devices.

Who Can Use the Kegel8® Go-Tone with Caution?

Consult your doctor before using the Kegel8® Go-Tone in any of these scenarios:

- If you have epilepsy.
- On children under 12.
- Patients who have diminished mental capacity or physical competence who cannot handle the device properly.

Who Cannot Use the Kegel8® Go-Tone?

- If you have been fitted with a demand style cardiac pacemaker.
- If you suffer from nephropathies or infections of the lower urinary tract organs
- If you suffer post-micturition residue greater than 100 ml
- If you are pregnant or have given birth in the last 6 weeks.
- If you are driving or operating potentially dangerous equipment.
- If you have serious hearth rhythm problems, unless so advised by your doctor.
- If you have undiagnosed pain, skin, vaginal or rectal conditions.
- On anaesthetised or desensitised skin
- If you have a tumor

IF IN DOUBT, CONSULT YOUR PHYSICIAN.

Warnings and Precautions

1. Carefully read this user guide before starting to use the unit.
2. Only use batteries LR03, 1.5 Volt Alkaline (AAA). The use of any other battery may damage the unit. Do not mix old and new batteries.
3. Remove the batteries when not used for prolonged periods (leaking battery acid may irreparably damage the unit).
4. The unit may not work if one or more batteries are wrongly inserted. Please note, the unit may not work with some rechargeable batteries.

5. CAUTION: There is a risk of explosion if the batteries are fitted incorrectly.
6. When no longer needed, do not dispose of batteries in fire and keep out of reach of children. Remove the batteries before the unit is scrapped and dispose of them safely.
7. The appliance must not be used to treat painful symptoms of unknown origin or which have been insufficiently diagnosed.
8. DO NOT use the device during sleep.
9. Keep the device and its accessories out of reach of children, the mentally impaired people or pets.
 - a. An improper use of lead wires (e.g. if twisted around the neck) may cause strangulation.
 - b. Small parts of the unit could be inhaled or swallowed.
10. In case of an evident or suspected defect in the unit, the user is suggested to contact our Kegel8® Customer Service team (see page 6).
11. DO NOT use the unit less than 3 metres from any high frequency therapy unit (short wave or microwave) or close to a microwave oven.
12. DO NOT use the unit at a distance less than those indicated in the table on page 31, with respect to a radio frequency communication device (RF transmitters, mobile phones, remote controls).
13. DO NOT use the unit on a patient in which it is used simultaneously an electrosurgical high frequency device. It may increase the risk of instability of the device and / or burns under the electrodes.
14. The equipment can deliver electrical pulses with a current density higher than $2 \text{ mA}_{\text{rms}} / \text{cm}^2$.

15. Store the unit and accessories in the carry case for storage and transportation.
16. The package is intended for one patient use. If the unit should be used by different patients, it is imperative to adopt a personal probe and personal electrodes for each patient.
17. The operator should contact Kegel8®:
 1. for assistance and, if needed, for the maintenance.
 2. to report unexpected operations or events.
18. Do not insert lead wires into a mains power supply.
19. Do not use the Kegel8® Go-Tone unit in the presence of a flammable anaesthetic gas mixture and air or with Oxygen or Nitrous Oxide.
20. Only use CE approved vaginal probes with your Kegel8® device. All official Kegel8® probes are CE approved.
21. To power your Kegel8® device, use 3 x 1.5 Volt LR03 Alkaline (AAA) batteries. Never connect your Kegel8® device or its probes to a mains power supply as this could result in electrocution and death.
22. Do not use the unit when the battery cover is removed.
23. Do not immerse your Kegel8® device in water, fluids, or any other substance.
24. Please be aware that Kegel8® is Type BF equipment (provides some protection against electric shock).
25. Be careful when using on a patient with decreased sensitivity.

Do not place electrodes:

- Over the throat or larynx nor over the carotid sinus of the sides of the neck, (the area of heartbeat detection). This may increase the risk of abnormalities of blood pressure or heart rhythm.
- Over or inside the mouth. This may increase the risk of suffocation.
- On the eyelids or around the eyes. This could affect intra-ocular pressure.
- On your facial area unless under strict guidance from a qualified clinician.
- Over the area of the heart, unless so advised by your doctor.
- On the chest and upper back or crossing over the heart. The application of the electrodes close to the thorax may increase the risk of arrhythmias or cardiac fibrillation.
- Across or through the head, which could cause symptoms of dizziness, nausea, vomiting and headache.
- Over any area affected by acute phlebitis.

Electromagnetic Compatibility

Kegel8® Go-Tone is intended for use in the electromagnetic environments specified below. The user should assure that it is used in such an environment.

Table 1 - Guidance and Manufacturer's declaration – electromagnetic emission		
Emission test	Compliance	Electromagnetic environment - guidance
RF emission – CISPR 11	Group 1	The Kegel8 Go-Tone uses RF energy only for its internal function. Therefore its emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emission – CISPR 11	Class B	The Kegel8 Go-Tone is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes

**Table 2 - Guidance and Manufacturer's declaration –
electromagnetic immunity**

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 KV contact ±15 KV air	±8 KV contact ±15 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%
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

**Table 3 - Guidance and Manufacturer's declaration –
electromagnetic immunity**

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2,5 GHz	10 V/m	<p>Portable and mobile RF communication equipment should be used no closer to any part of the Kegels Go-Tone, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance.</p> <p>$d=1,167*\sqrt{(P)}$ 80 MHz to 800 MHz $d=2,333*\sqrt{(P)}$ 800 MHz to 2,5 GHz</p> <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div align="center" data-bbox="601 972 702 1053"> </div>

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.

Table 4 - Recommended separation distances between portable and mobile RF communication equipment and the Kegel8 Go-Tone

The equipment Kegel8 Go-Tone is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Kegel8 Go-Tone can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Kegel8 Go-Tone as recommended below, according to the maximum power of communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 KHz to 80 MHz $d=1,17*\sqrt{(P)}$ m	80 MHz to 800 MHz $d=1,17*\sqrt{(P)}$ m	800 MHz to 2,5 GHz $d=2,33*\sqrt{(P)}$ m
0,01	0,117	0,117	0,233
0,1	0,370	0,370	0,740
1	1,17	1,17	2,33
10	3,70	3,70	7,40
100	11,7	11,7	23,3

For transmitters rated at maximum output power not listed above, the recommended separation distance d 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 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.

Product Labelling and Symbols

	Read and follow this user manual before use.
	Follow instructions for use
	Medical device applied parts type BF - has conductive contact with the patient.
	Manufactured by.....(Name & address of Manufacturer)
	Manufactured on.....(date of manufacturing)
IP22	Protection against ingress of objects larger than 12 mm and dripping water, from angles up to 15 degrees off vertical.
 0051	CE Marking authorised by the Notified Body IMQ (0051)
	This symbol indicates that the product (as Electric or Electronic product) must be disposed of separately from normal waste, at the end of its operational lifetime.
	Keep dry
SN	Serial number.
	Use before date
	Supplied by batteries
	The device can delivery energy as electrical impulse

Warranty

Savantini Limited provides a warranty to the original purchaser that this product will be free from defects in the material, components and workmanship for a period of 2 year from the date of purchase.

If Savantini Limited is satisfied that the product/s is defective the purchaser may return the product/s to Savantini Limited. The liability of Savantini Limited under this limited product warranty does not extend to misuse or abuse such as dropping or immersing the unit in water or other liquid substance or tampering with the unit or normal wear and tear. Any evidence of tampering will nullify this warranty.

Distributor:

Savantini Ltd. Savantini House, Foster Street, Hull, HU8 8BT

Email: sales@kegel8.co.uk

Web: www.kegel8.co.uk

Customer Service: 01482 496 932

Manufacturer:

BEACMED s.r.l., Via Monte Bianco 12, 27040 Portalbera (PV), Italy

Email: info@beacmed.eu

Web: <http://www.beacmed.eu/en/>

IFU13416_1120

Kegel8[®]
Go-Tone



Contact Us

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