

User Guide

Tight for life

Kegel 8[®]
ULTRA *Vitality*

www.Kegel8.co.uk

Symbols on the unit and case

	Caution! (electrical output).
	Follow operating instructions! Failure to do so could place the patient or operator at risk. afgafadf
	Neuromuscular Stimulation (STIM) and EMG Triggered Stimulation (ETS) should not be used by Patients fitted with demand style cardiac pacemakers. Please seek advice from your health supervisor.
	Patient's shock protection type: BF (Body Floated) Equipment. This equipment is not earthed but contains a battery within an insulated unit.
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Manufacturer's LOT/Batch number. Present it together with SN number when you report a technical fault or claim a warranty return.
	Manufacturer's serial number of the unit. Present it together with LOT number when you report a technical fault or claim a warranty return.
	Name and address of Manufacturer.
	Date of manufacture.
	Conformity indication with the essential health and safety requirements set out in European Directives. 0120 - notified body identification (SGS).
	This product should be kept dry.
IP20 on the unit	This is an indication for protection against ingress of water and particulate matter. The mark IP20 on your unit means: your unit is protected against solid foreign objects of 12.5mm dia and greater. Not protected against water.
IP02 on the case	IP02 on the carrying case means: Protected from the ingress of water droplets from a shower of rain.
	Do not dispose in normal dustbin (see page 23 for the disposal instructions).



Warnings

- * Do not insert lead wires into a mains power supply.
- * Do not immerse unit into water or any other substance.
- * Type BF equipment, Continuous Operation.
- * Do not use the Kegel8® Ultra unit in the presence of a flammable anaesthetic gas mixture and air or with Oxygen or Nitrous Oxide.
- * The unit is not protected from the ingress of water droplets from a shower of rain if used outside the carrying case.
- * If using rechargeable 9 Volt PP3 Nickel Metal Hydride batteries, be sure to use a CE approved battery charger. Never connect the Kegel8® Ultra directly to a battery charger or to any other mains powered equipment.
We advise not to use Ni-Cad rechargeable batteries.
- * Patient Probes and/or Electrodes are for ***single patient use only.***
- * Keep out of reach of children.
- * Do not use this stimulator on your facial area unless you are under strict guidance from a qualified Clinician.
- * Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.
- * Simultaneous connection of a patient to a high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- * This unit must be used with the guidance of a Physiotherapist or Doctor.
- * No modification of this equipment is allowed!



Contents

Warnings	3
What is STIM?	5
Contra Indications & Precautions	6
Description & Functions of the Kegel8® ULTRA Pelvic Health Device	7
Lock Button	9
Quick Start Instructions	10
Pre-set Kegel8® ULTRA Pelvic Health Programmes	12
Which Programme to select?	18
Custom programme setting	20
Applications	21
Care & Maintenance of your Kegel8® ULTRA	22
Frequently Asked Questions	24
Specifications	28
Information regarding Electromagnetic compatibility and interference (EMC)	29
Warranty	32
Customer Service	33
Clinical References	34



What is STIM?

The Kegel8® ULTRA Pelvic Health Device is one of a new breed of modern Neuromuscular Stimulators (STIM) developed with the aim of achieving optimum pelvic health for women. Our principle aim was to design a product to give women the opportunity to tone and exercise their PC muscles, strengthen weak muscles and nerve fibres in a compact, easy to use device – we also wanted the device to be able to be versatile enough so that as a woman achieved greater muscle control, with high levels of functional use, are sensibly priced, compact and user friendly.

Neuromuscular Stimulation has been used for many years to stimulate muscle and nerve fibres to treat a number of muscle and nerve related conditions.

Over the last 30 years numerous clinical trials and papers have been written, you can view our Clinical References on page 34 of this users guide.

The Kegel8® ULTRA Pelvic Health Device is a dual channel device combining several treatment programmes into one unit. Neuromuscular Stimulation is increasingly understood by Therapists and Doctors. There is a better understanding of the mechanisms which exist between nerves and muscles that makes it possible to stimulate the neuromuscular system with precise electrical signals. The Kegel8® ULTRA Pelvic Health Device offers precision giving full control of Pulse Widths, Rates, Ramp up times, Work / Rest cycles as well as alternating or synchronous application if two channels are being applied.

Customer Care

We welcome constructive comments regarding our equipment particularly those that might help us to improve existing features, add new ones or develop new products for the future.

Contra Indications & Precautions

**Please read this Kegel8® ULTRA users guide
before using this Stimulation device!**

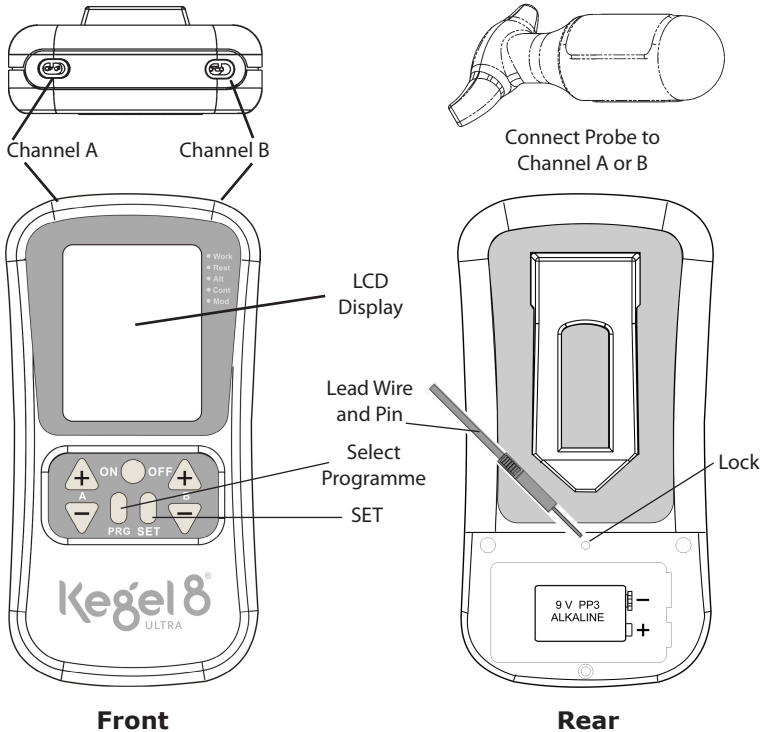
STIM should not be used:

- * By patients fitted with a demand style cardiac pacemakers unless so advised by their Doctor.
- * During pregnancy [unless medically advised].
- * By patients with undiagnosed pain conditions.
- * By patients with undiagnosed skin, vaginal or rectal conditions.
- * With patients who have diminished mental capacity or physical competence who cannot handle the device properly.
- * On anaesthetised or desensitised skin.
- * When driving a vehicle or operating potentially dangerous equipment.
- * Use the Kegel8® ULTRA only as directed.
- * Do not immerse the unit in water or any other liquid
- * Keep unit out of reach of children.
- * If in doubt about the use of the Kegel8® ULTRA unit call your distributor for advice, Doctor, or Healthcare professional.
- * Only use CE approved skin electrodes.
- * Only use CE approved vaginal or rectal probes.

Do not place electrodes:

- * Over carotid sinus nerves.
- * Over larynx or trachea.
- * Inside mouth.
- * Over the area of the heart unless so advised by your Doctor.

Description & Functions of the Kegel8® ULTRA Pelvic Health Device

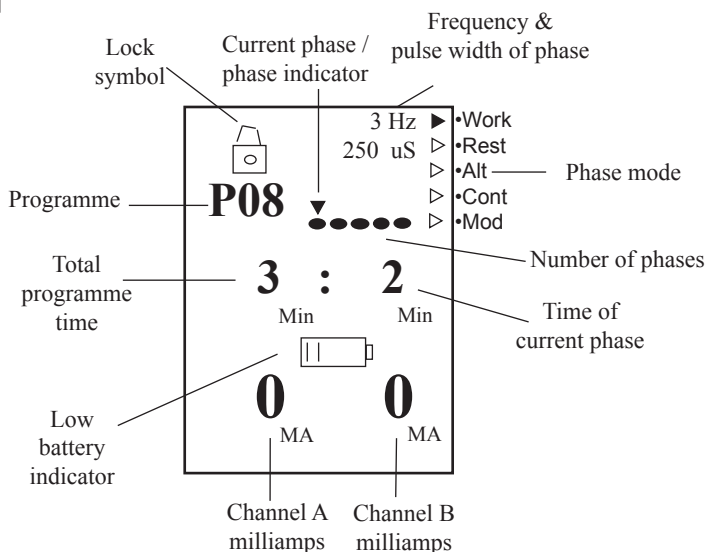


* PRG button

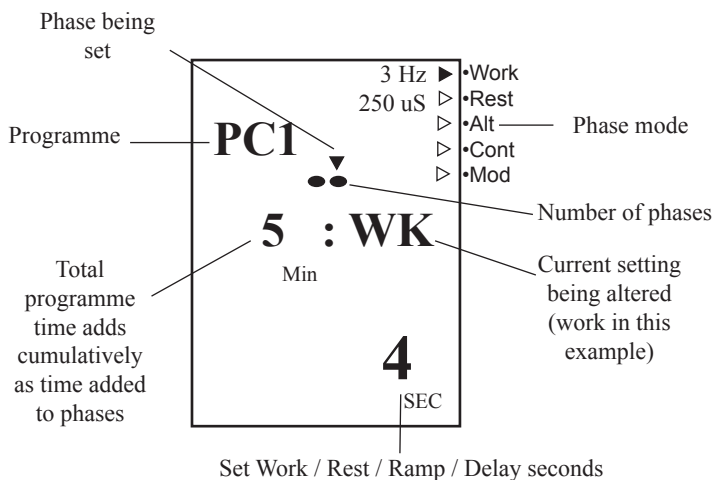
-Selects the desired set programme from P01 - P11 or customised programme PC1 - PC3.
 -Pauses (reducing the intensity (MA) to zero) and escapes from a running programme.

* SET button

-Reduces the intensity (MA) to zero and pauses the programme (if a programme is running) and moves the phase one step forward.
 -Displays the menu for programmes PC1 - PC3 and allows the parameters for Time, Work, Rest, Ramp up time, CH.A / CH.B Synchronous or Alternating and delay to be set.

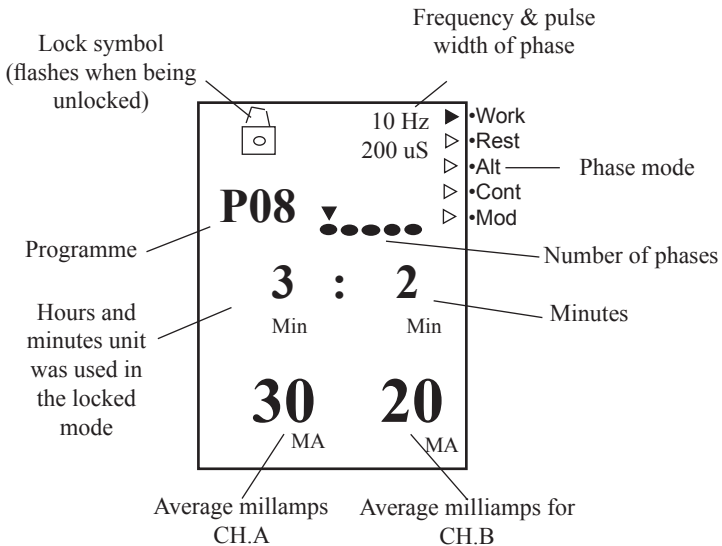


Example of preset programme



Example of custom programme

Lock Button



An optional "concealed" lock button is included in the Kegel8® ULTRA which allows to accurately record the time the device was used and the average intensity (MA). It also locks the customised programmes, stopping them from being altered.

To Lock the Unit

1. Select the pre-set or customised programme required. In the case of a customised programme, make sure that the pulse width, frequency, time etc. are set-up correctly (see page 20).
2. Remove the battery cover and, using a thin rod gently press on the lock button as shown in the diagram on page 7 until you hear a double beep. The unit is now "locked" and cannot be altered until "unlocked". Note: The lock symbol will appear on the LCD when the unit is "locked".

To Unlock the Unit

Remove the battery cover and press the concealed switch with a thin rod until a single beep is heard. Now the LCD will display the average mA used on each channel (A, B) and the total hours and minutes the unit has been in use (when locked) as shown in the above diagram. To return to normal "unlocked" operation, simply press SET.



Quick Start Instructions

Lets Get Started

1. Insert the battery into the Kegel8® ULTRA control panel, slide off the cover, slot in the battery aligning the + and - accordingly. The red material strip goes under the battery and should be pulled to remove the battery to avoid damage to your Kegel8 controller. Slide the battery cover back on.
2. Take one of the control leads, you have two of these and they have the black and red connectors at one end. Insert the white ended connector into the Kegel8 control unit, at the top left. This is called the A side. Push the lead tightly into the socket so it is fully connected.
3. Hold the probe at its base and insert it into the vagina, the base part remains outside the vagina. We recommend you use the lubricant supplied, this is not just to facilitate easy insertion, it also helps improve the level of conductivity of the stimulation to the muscle.
4. Plug the probe wire into the top left hand side of the controller, this is the A side used mainly for vaginal probes, and the B side can be used with an anal probe, please see online for more information or call our helpline.
5. Press the on button on the Kegel8 ULTRA control unit, the screen will illuminate. In the top left hand corner of the screen is displayed the programme setting. Click the PRG button (under the on/off button) to select your chosen programme.
6. To start the programme, press the + button on Channel A on the left hand side, you will see the mA change to 1, this will start your exercise programme. The timer [min:sec] will count down through the routine and switch the unit off when your exercise is complete.

7. Please remember the higher the mA's the better the programme will be - more mA's = more eventual pelvic power. The mA's can reach a maximum of 99, however you must choose a level of mA's that is comfortable not painful. Increase the mA's using the + button on the A side, or decreased by using the - button on the B side.

8. At the end of the programme, your Kegel8 will automatically switch off. Remove the probe by its base; do not pull on the wires. Rinse the probe under running water to clean, ensuring the connectors do not get wet. Dry and store.

WARNING! Do not immerse the probe in boiling water, the probe can be sterilized in a mild solution such as Milton Sterilizing fluid if required, but we find a simple rinse in warm water is adequate.

Pre-set Kegel8 ULTRA Pelvic Health Programmes

Programme : P01	Pain Relief	Phase 1
Phase time	min	20
Mode		Cont
Frequency work	Hz	3
Pulse duration	μ S	150
Ramp up time	secs	1.0
Ramp down time	secs	0
Work time	secs	Cont
Rest time	secs	0
Alternating		
Synchronous		*
Overall time	20 min	

Programme: P02	Urge/Prolapse	Phase 1
Phase time	min	20
Mode		W/R
Frequency work	Hz	10
Pulse duration	μ S	250
Ramp up time	secs	1.0
Ramp down time	secs	0
Work time	secs	5
Rest time	secs	5
Alternating		
Synchronous		*
Overall time	20 min	

Programme: P03	Stress 1	Phase 1
Phase time	min	20
Mode		W/R
Frequency work	Hz	40
Pulse duration	µS	200
Ramp up time	secs	1.0
Ramp down time	secs	0
Work time	secs	6
Rest time	secs	15
Alternating		
Synchronous		*
Overall time	20 min	

Programme: P04	Stress 2	Phase 1
Phase time	min	20
Mode		W/R
Frequency work	Hz	30
Pulse duration	µS	200
Ramp up time	secs	0.8
Ramp down time	secs	0
Work time	secs	5
Rest time	secs	8
Alternating		
Synchronous		*
Overall time	20 min	

Programme: P05	Frequency / Urge 1 / New Mothers	Phase 1
Phase time	min	20
Mode		W/R
Frequency work	Hz	10
Pulse duration	µS	200
Ramp up time	secs	1.0
Ramp down time	secs	0
Work time	secs	5
Rest time	secs	5
Alternating		
Synchronous		*
Overall time	20 min	

Programme: P06	Frequency / Urge 2	Phase 1
Phase time	min	15
Mode		Cont
Frequency work	Hz	10
Pulse duration	µS	200
Ramp up time	secs	1.0
Ramp down time	secs	0
Work time	secs	Cont
Rest time	secs	0
Alternating		
Synchronous		*
Overall time	15 min	

Programme: P07	Frequency / Urge 3	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	20				
Mode		Cont				
Frequency work	Hz	10				
Pulse duration	µS	220				
Ramp up time	secs					
Ramp down time	secs					
Work time	secs					
Rest time	secs					
Alternating						
Synchronous		*				
Overall time	20 min					

This programme works continuously with no rest period. It is used in some countries where they have found continuous stimulation can work effectively.

Programme: P08	Lack of Sensitivity	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	3	10	5	4	3
Mode		W/R	W/R	W/R	W/R	W/R
Frequency work	Hz	3	10	20	30	40
Frequency rest	Hz					
Pulse duration	µS	250	250	250	200	200
Modulation time	secs					
Ramp up time	secs	0.8	0.8	0.8	0.7	0.7
Ramp down time	secs	0	0	0	0	0
Work time	secs	4	4	4	4	4
Rest time	secs	4	4	4	6	6
Alternating						
Synchronous		*	*	*	*	*
Overall time	25 min					

Programme: P09	Pelvic Floor Work Out	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	4	15	8	8	10
Mode		W/R	W/R	W/R	W/R	W/R
Frequency work	Hz	20	10	20	30	10
Pulse duration	µS	250	250	250	200	250
Ramp up time	secs	0.8	0.8	0.8	0.6	0.8
Ramp down time	secs	0	0	0	0	0
Work time	secs	5	5	5	5	5
Rest time	secs	5	5	5	6	7
Alternating						
Synchronous		*	*	*	*	*
Overall time	45 min					

Programme: P10	Endurance	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Phase time	min	20				
Mode		W/R				
Frequency work	Hz	20				
Pulse duration	µS	250				
Ramp up time	secs	0.8				
Ramp down time	secs	0				
Work time	secs	5				
Rest time	secs	5				
Alternating						
Synchronous		*				
Overall time	20 min					

Programme: P11	Relaxing the Pelvic Muscles	Phase 1
Phase time	min	20
Mode		W/R
Frequency work	Hz	2
Pulse duration	µS	220
Ramp up time	secs	1.2
Ramp down time	secs	1.2
Work time	secs	6
Rest time	secs	10
Alternating		
Synchronous		*
Overall time	20 min	

Programme:		Phase	Phase	Phase	Phase	Phase
PC2 Vitality		1	2	3	4	5
Phase time	min	5	5	5		
Mode		W/R	W/R	Cont		
Frequency work	Hz	35	80	80		
Pulse duration	µS	250	300	330		
Ramp up time	secs	0.6	0.6			
Ramp down time	secs	0	0			
Work time	secs	8	8			
Rest time	secs	4	4			
Alternating						
Synchronous	*	*	*	*	*	*
Overall time	15 min					

W/R = INTERMITTENT WORK/REST
 CONT = CONTINUOUS

Which Programme to select?

PO1 - Pain Relief

Vulvodynia is a chronic pain condition characterized by burning, stinging, irritation, and/or rawness in the female genital area this programme is designed to help. It also helps in cases where unknown pelvic pain has been diagnosed by a health care professional.

PO2 - Urge/Prolapse

Urge in this programme refers to a woman who does not have leakage problems, just the urge to pass urine. This programme is suitable for women suffering from bladder and vaginal prolapse. We can programme your K8 to help with anal prolapse, please telephone for more details.

PO3 - Stress 1

Stress incontinence is due to leakage of the bladder in particular when people jump up and down and when exercising or during lovemaking. This programme is set at a rate of 40Hz, the level favoured by UK physiotherapists.

PO4 - Stress 2

Stress incontinence is due to leakage of the bladder in particular when people jump up and down and when exercising or during lovemaking. This programme is set at a rate of 30Hz, the level favoured by Scandinavian physiotherapists.

PO5 - Frequency/Urge / New Mothers

When a woman has the urge and frequency to actually pass urine several times during the day and night.

This programme is recommended for new mothers who want to get back in shape after childbirth, start after your 6 week check up when your health care professional says it is OK to do so. After 12 weeks you can progress onto PO8 the thorough Pelvic Floor Workout, a couple of times a week.



PO6 and PO7 - Frequency/Urge

When a woman has the urge and frequency to actually pass urine several times during the day and night. This programme is used primarily in Scandinavian countries. It offers continuous stimulation. They prefer continuous stimulation, whereas here in the UK we prefer a work/rest programme to allow the muscle to rest and recuperate.

PO8 - Lack of Sensitivity

In some women following childbirth, although they have good muscle control, they have a lack of sensitivity. This could mean nerve damage and this programme helps to recondition the muscle and to facilitate nerve sprouting to regain sensitivity.

PO9 - Pelvic Floor Workout

An excellent overall pelvic floor workout. Good for women entering or out of the menopause (but not suffering vaginal atrophy – see our FAQ's)

P10 - Endurance

This programme is ideal if you feel your muscle tone is reasonable, and you can contract the muscle but you can't hold the contraction for long.

P11 - Relaxing the Pelvic Muscles

This programme is to help relax the pelvic muscle after the exercises, when the pelvic muscle has been working hard and some fatigue may have resulted. The very low 2 Hz frequency will help to relax the muscle.

PC2 - Vitality

We recommend this programme if you lack intimate sensation and want to tighten up your vaginal muscles. This programme can reinvigorate your pelvic floor to make it easier to reach orgasm and increase sensation for you and your partner during intimacy.

Custom Programme

Setting up the Customised Programmes PC1, PC2 or PC3

First, if a programme is running, press the PRG button twice to return to the home screen.

Refer to the example of custom programme diagram on page 7.

1. Press the PRG button until PC1, PC2 or PC3 is selected.
2. Press and hold the SET button for three seconds, the phase indicator arrow and Hz symbol will flash on and off.
3. Press CH.B +/- to set the frequency between 2 Hz and 100 Hz.
4. Press CH.A +, the μ S symbol will flash, press CH.B +/- to set the pulse duration between 50 μ S and 330 μ S.
5. Press CH.A +, the MIN symbol will flash, press CH.B +/- to set the length of the phase time between 1 and 99 minutes. Set the time to zero to end the programme on this phase.
6. Press CH.A +, the WORK / REST or the CONT symbols will flash, press the CH.B +/- to select WORK / REST or CONT (continuous).
Note: if continuous is selected, the menu will loop back to step 2.
7. Press CH.A +, WK will appear and flash, press CH.B +/- to set the work seconds between 2 and 99 seconds.
8. Press CH.A +, RT will appear and flash, press CH.B +/- to set the rest seconds between 2 and 99 seconds.
9. Press CH.A +, RP will appear and flash, press CH.B +/- to set the ramp seconds between 0.1 and 9.9 seconds.
10. Press CH.A +, AL or SY will appear and flash, press CH.B +/- to select alternating or synchronous current.
Note: if alternating is selected, the menu will loop back to step 2.
11. Press CH.A +, DY will appear and flash, press CH.B +/- to set the delay of channel B starting between 0 and 4 seconds after channel A.
12. The menu will now loop back to step 2 and the Hz symbol will flash.
13. To set the next phase, press the set button. The phase symbol will flash over the next phase, continue with step 2 to set this phase.

14. When finished setting the phases, press the PRG button to save the settings and return to the home screen.
The programme will be saved permanently.

Setting the phase time of phase 2,3,4 or 5 to zero will cause the programme to end at that phase.

Following procedures 1 to 12 can reprogramme a customised programme.

Applications

Why every woman should use the Kegel8® ULTRA Pelvic Health Device

- * The Kegel8® promotes continence.
- * The Kegel8® increases and improves muscle strength.
- * The Kegel8® maintains or improves range of movement.
- * The Kegel8® increases and improves the blood supply to the muscle.
- * The Kegel8® reduces pain.
- * The Kegel8® strengthens the pubococcygeus (PC) muscles in order to prevent or reduce pelvic floor problems and to increase sexual satisfaction.
- * The Kegel8® can be used to treat Vaginal and Uterine prolapses, depending on the severity of symptoms.
- * The Kegel8® can strengthen the levator muscles, weakened by damage or lost nerve input from childbirth, especially in the case of c-sections, operations for hernia and hysterectomy.



Care & Maintenance of your Kegel8® ULTRA

WARNING! Only medically approved accessories should be used!

Control Unit:

- * Wipe the surface once a week with a damp cloth or antiseptic wipe.
- * Do not use cleaning sprays or alcohol based cleaning solutions.
- * Control unit disposal: please return to the distributor.

Battery:

- * To change the battery, open the battery door on the rear of the control unit by pressing down on the raised rib pattern just below the belt clip. Lift the battery out of the compartment. This is very easy and can be done by the user.
- * Check periodically for any discharge from the battery.
- * Remove battery completely from unit if not in use for any extended period of time (typically one week).
- * Low battery indicator of 6.9 volts shown on LCD display. When flashing change battery for a new one.
- * Preferably use a GP Alkaline Pro 9v battery, these can be ordered separately.
- * Battery disposal: please return to the distributor.

Lead Wires:

- * The lead wires should be handled carefully and never stretched, as this can cause the stimulation to function below normal standards or not at all.
- * Examine lead wires before each treatment for loose connections or damage.

- * Avoid stretching and twisting the lead wires.
- * Store the lead wires carefully after each use.
- * Lead wires Disposal: please return to the distributor.

Vaginal / Rectal Probes:

- * Check the connectors have not become separated from the probe.
- * Before use the probe can be washed in warm soapy water, the probe may also be cleaned with our antibacterial cleanser HiGenie.
- * Vaginal/Rectal Probe Disposal: please return it to the distributor.

Caution: Static electricity may damage this product.

NOTE: Only our appointed distributors /importers are approved to undertake servicing.

Responsible Recycling Initiative

In compliance with Waste Electrical and Electronic Equipment (WEEE) Regulations 2006, we aim to reduce the amount of electrical waste being sent to landfill sites.

Electronic devices contain toxic materials which seep into the ground when dumped irresponsibly causing serious health and environmental problems. To recycle responsibly, all you need to do is return your device to us. We will:

- Carefully and correctly dispose of your old Kegel8® product
- Ensure as much of it is recycled as possible

Address:
WEEE Recycling
Savantini Limited
14D iPark, Innovation Drive
Kingston upon Hull
HU5 1SG
Great Britain





Frequently Asked Questions

Q: I can't get the mA's past 6, 7 or 8

If you do not get an effective contact with the probe you will find that you cannot increase the mA's past level 6, 7 or 8. Initially we recommend you use the Kegel8 either lying down or sitting with your legs elevated. This will help you to get used to the kegel8 sensation but also to stop the probe being displaced. It is important that the probe maintains contact with the muscle to contract and exercise it properly. Conductivity is also improved by using the lubricant provided, it is water based, and body friendly and you'll get better results.

Q: How far do I put the probe in?

The vaginal probe needs to be inserted just 2 inches (5.5 cm) this is the optimum level to stimulate the pelvic floor muscle.

Q: I have an IUD or Mirena Coil - can I use the Kegel8?

Yes. The Mirena is plastic so not problems there. An IUD contains copper which is unaffected by the Kegel8 and STIM so no problems there either.

Q: Can I use my Kegel8 when I have my period?

There are no problems with this, however if you are at the peak of your period and flow is heavy you may prefer not to. Many users have reported it helps with menstrual cramps too. Here in the office we tend to use it on lighter flow days. Rinse the probe in warm water and towel dry, the probe can be sterilized using a mild sterilizing solution if necessary, do not immerse the connectors at the ends of the leads in water, do not boil (it will cause the plastic to crack).

Q: Can I use it whilst pregnant?

Clinical guidelines advise against using any STIM machines vaginally during pregnancy.

Q: I aim to have my mA's at 40, but on some programmes it drops to 30 - why is that?

While the programme goes through its preset routine the pulse width and pulse length varies, when the pulse rate and length increase the mA's drop so that the intensity does not take you by surprise, the mA's can again be increased. So if you feel a decrease in intensity increase the mA's back up to a comfortable level.

Q: How soon after the birth of my baby can I start with my Kegel8® ULTRA?

Consult with your Midwife or Doctor. Generally women feel happy to start after a successful six week check-up.

Q: I have had pelvic surgery - how soon can I start using my Kegel8® ULTRA?

Consult with your Doctor or Consultant, every case is different, but the Kegel8 could help to speed recovery. Stress Incontinence, and prolapse is usually a sign of a weak pelvic floor, so if you have had an operation to help with either of these conditions you will still need to strengthen it. The Kegel8 is ideal, but check with your Doctor or physiotherapist.

Q: I find it painful inserting the probe.

Use the lubricant, this isn't supplied just to help make insertion easier, it also helps with the conductivity.

The better conductivity, the more the muscle will be exercised and the more mA's you'll be able to achieve.

If you are menopausal you could be suffering from vaginal atrophy, this causes vaginal dryness, thinning of the vaginal membrane and great discomfort.



If the lubricant does not help, your Doctor can prescribe a course of oestrogen cream, use this for the recommended time, and then re commence using the Kegel8. Remember the pelvic floor needs to be exercised, do not be put off by vaginal atrophy, there are easy solutions for all women to overcome this painful condition.

Q: Why are there two channels?

Channel A (left hand side) is generally used for a vaginal probe, Channel B on the right hand side is generally used for an anal probe. If you have suffered from an anal prolapse please telephone us and we can help you with a customised programme for your condition, a selection of anal probes are also available online at StressNoMore.co.uk

Q: How do I clean my probe?

Simply rinse the insertable part under the tap, keeping the wires dry at all times. Do not boil the probe. It can be sterilized using a mild sterilizing solution.

If you want to use the same probe vaginally and anally this is fine, but always clean the probe thoroughly.

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

You do not have proper connectivity with the probe you need to adjust your position, ensuring the probe touches both sides of the vagina/muscle wall. If your vagina has been stretched through childbirth and you are not feeling the probe on both sides, you need to sit with your legs tightly together, squeezing your pelvic floor as much as you can against the probe. Don't forget the lubricant to add greater conductivity.

Q: How long will the battery last?

If you use the Kegel8 daily, it should last about 3 months. You can get replacements from us or at your local supermarket - please choose a quality 9v battery that will not leak. You will know when your battery is low because a battery icon will flash on your Kegel8 screen.

Q: How long will my probe last?

With normal use your probe should last between 12 - 18 months. We recommend you replace it after this time to keep getting the maximum results from your Kegel8. We recommend you take care with the leads and wires of the probe don't bend them in two, or tie them up, this could cause wire damage and stop the probe working effectively. When inserting and removing the probe always hold the base of the probe, not the wires, especially when removing the probe. If you pull the wires instead of the probe base, you can damage the wires. We always offer a range of different probes for all uses, please check online or telephone us for more information.

Q: I can't find the answer to my question?

Give us a call, we have personal experience of the Kegel8 and if we can't answer it, the medical manufactures will.

Specifications

STIM

1. Dual channel: individually isolated circuits.
2. Amplitude: 0 - 90 mA into 500 Ohm load; indication only. Actual mA will tend to be less than indicated due to electrode impedance: at 1000 Ohms load (Electrodes in poor condition) the maximum will be limited to 70 mA, at 1500 Ohms load the maximum will be limited to 65 mA.
3. Type: Constant Current, maximum output voltage 180 Volts +10 / -30 Volts
4. Waveform: Asymmetrical, rectangular bi-phasic with zero DC current.
5. Selectable pulse width: 50 μ S - 330 μ S [2% accuracy].
6. Pulse Rate selection: in the continuous mode 2 Hz - 100 Hz [2% accuracy].
7. Time duration of the treatment selectable: 1 minute to 90 minutes.
8. Low Battery Indicator: If the battery goes below 6.9 volts +/- 0.2 volts the battery symbol will flash on/off once every second.
9. Open Electrode Detect: If an open circuit is detected at the output of channel A or B the output current will be reset at zero.
10. Ramp up time 0.3 - 9.9 seconds.
11. If the battery voltage is below 6.6 (+/- 0.2) volts the unit will not turn on. Expected average battery set life [of standard 800 mAh, alkaline]: 19h.

Expected service life:

5 years. Careful use and maintenance extends the life of the unit over the service life limit.

Physical dimensions: 108 x 62 x 23 mm.

Weight: 70g without battery, 100g with battery.

Environmental Conditions for use: +5 to +40 degrees Centigrade. 15-93% Humidity.

Environmental conditions for storage & transport: -10 to +50 degrees Centigrade. 0-90% Humidity.

Information regarding Electromagnetic compatibility and interference (EMC)

Kegel8® products are designed to produce very low levels of radio frequency (RF) emissions (interference), to be immune from effects of interference produced by other equipment operating in their vicinity and damage due to electrostatic discharge all when operating in a typical domestic and or clinical environment. They are certified to meet the international EMC standard EN60601-1-2.

Table 201: Guidance and manufacturer's declaration - electromagnetic emissions

The Kegel8® product is intended for use in the electromagnetic environment specified below. The customer or the user of the Kegel8® product should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Kegel8® product 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	
Harmonic emissions IEC 61000-3-2 IEC 61000-3-2	Not applicable	The Kegel8® product 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.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 202: Guidance and manufacturer declaration - electromagnetic immunity

The Kegel8® product is intended for use in the electromagnetic environment specified below. The customer or the user of the Kegel8® product should ensure that it is used in such an environment, and that precautions regarding that environment are heeded.

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%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-2	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 204: Guidance and manufacturer's declaration - electromagnetic immunity

The Kegel8® product is intended for use in the electromagnetic environment specified below. The customer or the user of the Kegel8® product should ensure 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 Radiated RF IEC 61000-4-3	3 Vrms 150 KHz to 80 MHz 3V/m 80 MHz to 2, 5 GHz	3 Vrms 150 KHz to 80 MHz 3V/m 80 MHz to 2, 5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Kegel8® product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P} \text{ (150 KHz to 80 MHz);}$ $d=1.2\sqrt{P} \text{ (80 MHz to 800 MHz);}$ $d=2.3\sqrt{P} \text{ (800 MHz to 2.5 GHz);}$ where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range; (b) interference may occur in the vicinity of equipment marked with the following symbol: 

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 strength in the location in which Kegel8® product is used exceeds the applicable RF compliance level above, the Kegel8® product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Kegel8 product.

(b) Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3V/m.

Table 206: Recommended separation distances between portable and mobile RF communications equipment and Kegel8® product.

The Kegel8® product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Kegel8® product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Kegel8® product 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		
	150k Hz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d=1.2\sqrt{P}$	$d=1.2\sqrt{P}$	$d=2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	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 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 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.



Warranty

Savantini Limited (Medical Dep) 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 years from the date of purchase [invoice date].

If Savantini Limited is satisfied that the product/s is defective the purchaser may return this unit/s to Savantini Limited (Medical Dep) or the appointed distributor for repair or replacement with a new unit.

All returns must first be authorised by Savantini Limited (Medical Dep) in advance. The liability of Savantini Limited (Medical Dep) under this limited product warranty does not extend to any 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.

Manufactured by: Verity Medical Ltd. Unit 7 Upper Slackstead Farm, Farley Lane, Braishfield, Romsey, Hampshire, SO51 0QL

This product is manufactured in compliance with the European Union Medical Device Directive MDD93/42/EEC under the supervision of SGS, Notified Body number 0120.

CE 0120

Verity Medical Ltd., is certified by SGS to the following

Quality Standards: ISO 9001:2008, ISO13485:2003.

Customer Service

Any queries should be addressed to:

Helpline +44(0)1482 888 785

**Call us! We're here to help you
Monday-Friday, 8am - 5pm.**

Address:
Savantini LTD
14D iPark
Innovation Drive
Hull HU5 1SG
England

Email: Sales@Kegel8.co.uk

Web: www.Kegel8.co.uk

Clinical References

Neuromuscular Stimulation:

Knight S, Laycock J, Naylor D. [1998] Evaluation of neuromuscular electrical stimulation in the treatment of genuine stress incontinence; Physiotherapy 84, No. 2, 61 - 71.

Gibson J.N, Smith K, Rennie MJ. [1988] Prevention of disuse muscle atrophy by means of electrical stimulation. Maintenance of protein synthesis; The Lancet; 2(8614: 767-70).

Lindstrom S, Fall M, Carlson C A, Erlandson BE. [1983] The neurophysiological basis of bladder inhibition in response to intravaginal electrical stimulation.

Fall M, Ahlstrom K., Carlsson C, Ek A, Erlandson BE, Frankenberg AS, Mattiasson A. [1986] Contelle: Pelvic floor stimulator for female stress-urge incontinence. A multicentre study; Urology 27, 282-287.

Berghmans L C, Hendriks H J, Bo K, Hay Smith E J, deBie R A, van Waalwijk Van Doorn E S. [1998] Conservative treatment of stress urinary incontinence in women: a systematic review of randomised clinical trials. Br. J. Urol. 82(2), 181 - 191.

Eriksen B C, Bergmann S, Eik-Nes S H. [1989] Maximal Electrostimulation of the pelvic floor in female idiopathic detrusor instability and urge incontinence. Neurourol. Urodynam, 8, 219 - 230.

Miller K, Richardson D A, Siegel S W, Karram M M, Blackwood N B, Sand P K. [1998] Pelvic Floor electrical stimulation for genuine stress incontinence, who will benefit and when? Int. Urogynecol, J. Pelvic Floor Dysfunction, 9(5), 265 - 270.

Osterberg, Graf W, Eeg-Olofsson K, Hallden M, Pahlman L. [1999] Is electrostimulation of the pelvic floor an effective treatment for neurogenic faecal incontinence. Scan J Gastroenterology 34(3):319-24



Notes

Customer Service and Distribution:



Helpline **+44(0)1482 496 932**
Call us! We're here to help you
Monday-Friday, 8am - 5pm.

Address:
Savantini Ltd.
14D iPark
Innovation Drive
Hull HU5 1SG
England

Email: Sales@Kegel8.co.uk
Web: www.Kegel8.co.uk

Manufactured by: Verity Medical Ltd. Unit 7 Upper Slackstead Farm, Farley Lane,
Braishfield, Romsey, Hampshire, SO51 0QL

This product is manufactured by Verity Medical Ltd in compliance with the
European Union Medical Device Directive MDD93/42/EEC under supervision
of SGS, Notified Body number 0120.

CE0120

Verity Medical Ltd is certified by SGS to the following Quality Standards:
ISO 9001:2008, ISO 13485:2003