

Kegel 8[®] pel★fit

Kegel8 PF-200

(Pelvic Muscle Exerciser)



Owner Guidelines & Instructions

Working together for positive changes



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The Kegel8 PF-200 is a personal home use pelvic floor muscle exerciser that uses “Kegel” like stimulation pulses that strengthen the pelvic floor muscles to aid in the control of urinary incontinence in women.

For more information about incontinence in women please refer to the following organizations:

The Continence Foundation:
www.continence-foundation.org.uk

The National Association for Continence:
www.nafc.org

About your Kegel8 PF-200

Working together for positive changes

Making changes for the better is everyone’s goal – you have taken the first step to making a positive change by purchasing your Kegel8 PF-200. Whether you suffer from stress incontinence or urge incontinence – or a combination of both – the Kegel8 PF-200 pelvic muscle exerciser can improve pelvic floor muscle strength which has been proven in most cases to improve this difficult and often embarrassing condition. Your Kegel8 PF-200 pelvic muscle exerciser is specially designed with no cords or wires for ease of use and is so discrete that it can be used both at home and while travelling (a useful storage/travel bag is provided). Being able to use your exerciser while travelling is especially important so you don’t interrupt you daily schedule - allowing you to keep on track for optimum results.

For best results please follow these guidelines;

- Become familiar with your Kegel8 PF-200 – read all instructions in this user manual before use.
- Get to know the control buttons and what the displays mean – In order to know what sensation to expect, place the exerciser in the palm of your hand and while squeezing gently increase the stimulation level. Most women begin to feel the sensation between levels 12 – 20.
- Once you are comfortable with what to expect and how to use the control unit, insert the exerciser and start your pelvic muscle exercise session.
- Adjust level of stimulation to suit your body.
- Use your Kegel8 PF-200 twice a day for 15 minutes each session for 12 – 15 weeks.
- Once you begin to feel improvement you can adjust your schedule to meet your needs and maintain muscle tone.

As each of us is different, response times are also different. Some will see improvement within a couple of weeks, and some may take longer – this is why we recommend the initial time frame of 12 – 15 weeks for everybody.

Some important things to remember about the Kegel8 PF-200 pelvic exerciser: it should always...

- Have sufficient battery power for correct functioning
- Successfully complete a self test when turned on
- Set up stimulation level the same as previous session
- Set up frequency of stimulation
- Generate stimulation pulses for 15 minute sessions

SECTION 1: PRECAUTIONS — NOTES ON SAFETY

Kegel8 PF-200 is a single user product and should not be shared with others

Do not use the Kegel8 PF-200 if you:

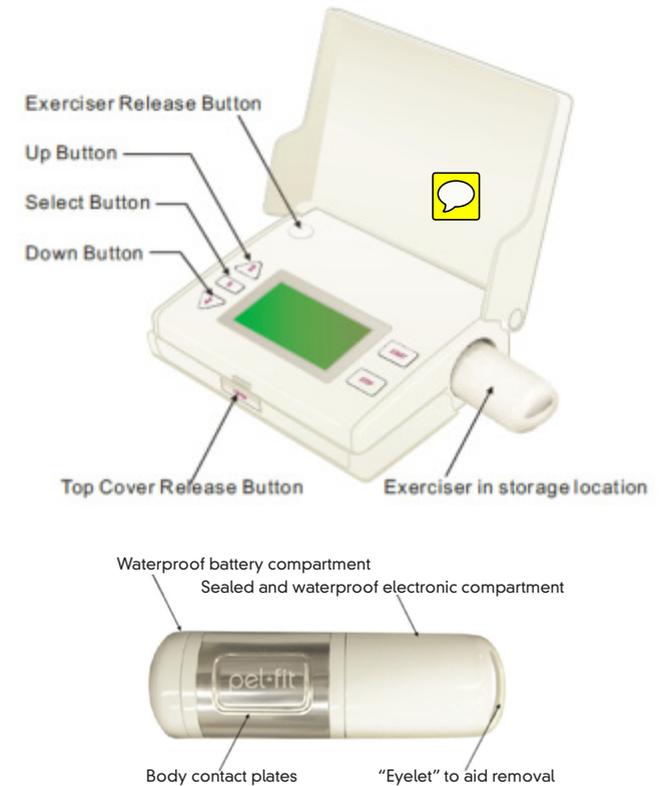
- Are immersed in water e.g. swimming or bathing
- Are menstruating
- Are pregnant
- Have a pacemaker
- Are sleeping
- Are engaged in sexual activity
- Have anything in your vagina e.g. a tampon or diaphragm

Discontinue use of the Kegel8 PF-200 if you notice the following:

- Pain
- Abnormal vaginal discharge
- Irritation to the tissues of the vagina
- Burning upon urination
- Development of lesions on the perineum

Kegel8 PF-200 is not a toy - KEEP OUT OF THE REACH OF CHILDREN

SECTION 2 – GETTING TO KNOW YOUR KEGEL8 PF-200



- Green display – everything is working correctly.
- Yellow displays indicate Caution - the stimulation output pulse level is changing or batteries are getting low.
- Red displays – some action is required before the KEGEL8 PF-200 is ready for use.
- The maximum stimulation level is 45; minimum level is 0.

The Display Symbols

<p>Battery</p>  <p>Available Power Indicators</p>	<p>Exerciser</p>  <p>Flash On/OFF When Stimulating</p>	<p>Time</p>  <p>Numbers Show Time Remaining</p>	<p>E</p> <p>Exerciser</p>
<p>Up Arrow</p>  <p>Change is Increasing</p>	<p>Down Arrow</p>  <p>Change is Decreasing</p>	<p>Mode Symbols</p> <p>S+U</p> <p>Stress, Urge Stress + Urge</p>	<p>C</p> <p>Controller</p>

SECTION 3 – THE CONTROLLER UNIT

Using the buttons and understanding what the displays mean – Please insert 2 x AA batteries into the controller. Open the controller top cover and a green display will appear.



The battery symbol shows the number of bars according to the amount of power left in the exerciser battery.

After a few seconds the display changes:



The 4 minute countdown (to allow for the positioning of the exerciser) has started – the 3:59 will count down in 1 second increments to 0. The display will turn yellow when the time remaining is 30 seconds.

Press **start** and the display will change:

The exerciser symbol shows that stimulation pulses are present.



The up arrow indicates that the stimulation level is increasing to 28 with the current level indicated as 1; it will count up to 28.

When stimulation level is reached the display changes:

The exerciser active symbol is flashing to indicate stimulation. The number 28 is the stimulation level and the number 15 is the amount of time left in the exercise session. The session time will count down in 1 minute increments until it reaches 0 when the session is ended and the Kegel8 PF-200 turns off automatically.

Adjusting Stimulation Level

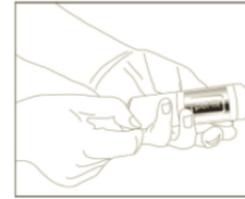


Press the up or down button until the new stimulation level 15 is reached - the display changes: There will be an up (↔) and a down (↔) arrow if the up button is pressed and a down (↔) arrow if the down button is pressed.

The new stimulation level is displayed in the right pane and will change as the up or down button is pressed.



The display changes: The number 10 indicates that the stimulation output level is at 10 and the number 15 that there are 15 minutes left in the exercise session.



Holding the exerciser in the hand and while gently squeezing, increase the pulsation level until a mild tingling sensation is felt. Please note that the pulsations are active for 2.5 seconds then off for 2.5 seconds to rest the muscles.

By increasing the stimulation levels by 2 or 3 you will become familiar with the sensation and how moving the exerciser into contact with the nerves causes muscle contraction.

Once comfortable with the sensation and position of the exerciser, increase/decrease the simulation level by 5 to experience the effects of adjusting the stimulation level.

When comfortable with controlling the stimulation level and sensation you are now ready to begin.

Note: it is very important to set the stimulation level to 5 as this will be the starting level for your first exercise session.



After setting the stimulation level press the Stop button; the display will change to indicate the number of minutes left in the session.

The number 12 indicates that there were 12 minutes remaining in the exercise session when the Stop button was pressed.

After a few seconds the Kegel8 PF-200 turns its self off and the display goes blank.

At this time you should understand that BOTH the position of the exerciser and the stimulation level are important to achieve muscle contractions. This is muscle stimulation.

Go back and repeat these exercises until you are completely comfortable with your Kegel8 PF-200.

Unusual Displays



The self test has passed and the Kegel8 PF-200 is ready for an exercise session but the exerciser battery has only enough power for a few more exercise sessions.



Replace the controller batteries as they do not have enough power for the correct functioning of the Kegel8 PF-200.



The Kegel8 PF-200 will automatically turn off after a few seconds showing this display.

Replace the exerciser battery as it does not have enough power for the correct functioning of the Kegel8 PF-200.

The Kegel8 PF-200 will automatically turn off after a few seconds showing this display.



The power on self test has failed.
The most likely reason is that the exerciser is not correctly stored in the controller storage location.

If the problem persists, call customer services.



SECTION 4 – USING YOUR KEGEL8 PF-200

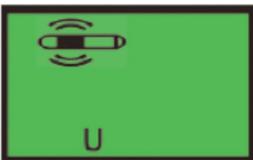
We recommend that you set aside plenty of time (especially for the first few sessions) so you can relax while following these instructions.



Before using the Kegel8 PF-200 wash your hands and the exerciser unit in warm soapy water. Open the Controller top cover and this green display will appear:

Stress Incontinence (Frequency selection S)

The leakage of urine when pressure is exerted on the bladder by laughing, coughing, exercising, sneezing etc.



Urge Incontinence (Frequency selection U)

The feeling of needing to urinate but being unable to make it to the bathroom in time.



Mixed Incontinence (Frequency selection S + U)

Having a combination of both kinds of incontinence.

When your final selection has been made press the select button (S) and the 4 minute countdown will start again.



When this display appears remove the exerciser from the controller storage location and insert it completely inside the vagina. If necessary, practice doing this before turning on the Kegel8 PF-200 so that you may take as much time as you need to become comfortable with positioning the exerciser.

The Kegel8 PF-200 is inserted into the vagina the same way that a tampon would be inserted.

You may find it easier to insert if you use water based, water soluble vaginal lubricant – recommended.

Press the start button and the stimulation pulses will start at 0 and slowly increase to 5 as shown on the display.

The stimulation level should be strong enough to feel the muscles contract without causing any pain.

Occasionally the exerciser will move once the muscle contractions have started and needs to be repositioned until it stays in place.

Some people experience the need for a higher stimulation level in different sessions – make adjustments as necessary for good strong exercise without pain. Morning and evening sessions may vary.

Relax and let the Kegel8 PF-200 do the rest until the 15 minute exercise session is over.

Remove and clean the exerciser and replace it in the controller storage location ready for your next session.

The Kegel8 PF-200 automatically remembers the frequency and stimulation level at the end of exercise sessions so that the settings will be automatically applied when the start button is pressed for the next session.

Exercise sessions have a maximum length of 15 minutes with a recommended schedule of twice daily at 12 hours intervals for 12 to 15 weeks. Thereafter once or twice a week is recommended to maintain the improvement in muscle strength.

Exercise sessions can be cancelled (stopped) at any time by pressing the stop button.



Stimulation History

To display your stimulation history, turn on the Kegel8 PF-200 and wait for this display.



Press and hold down the **up** button; Press and release the **down** button and then release the **up** button.

The following display will appear:



This display indicates that the last stimulation session type S (Stress) was at level 28.

Press and release the **up** button.



This display indicates that the last stimulation session type U (Urge) was at level 25.

Press and release the **up** button.



This display indicates that the last stimulation session type used was S + U (Stress + Urge).

Press and release the **up** button.



This display shows the cumulative number of stimulation sessions since the last history reset.

Press and release the **up** button.



This display shows the cumulative number of stimulation session cancelled (i.e. did not last for the full 15 minutes) since the last history reset.

Press and release the up button and the Kegel8 PF-200 will turn itself off.

Note that pressing the down button will cause the previous display to be shown i.e. press up to go forwards and down to go backwards.

At any time during any of the above displays the cumulative numbers can be reset by pressing and holding the **start** button; Pressing and releasing the **stop** button and then releasing the **start** button.

SECTION 5 – CARING FOR YOUR KEGEL8 PF-200

- Wash the Exerciser with a mild soap and water after each exercise session - the exerciser is waterproof.
- Dry and replace in the controller storage location.
- Wipe the controller with a damp cloth but do not immerse in water or get wet – the controller is not waterproof.
- Avoid dropping or treating in a rough manner – the Kegel8 PF-200 is a delicate electronic device with a glass display.
- Remove discharged batteries immediately – do not leave discharged batteries in your Kegel8 PF-200 as they will cause damage – we encourage you to dispose of the batteries responsibly – please recycle.
- Keep out of direct sunlight - store in travel bag provided.

SECTION 6 – BATTERY REPLACEMENT

Please follow these simple directions for inserting the battery prior to first use / replacing the battery in the controller unit.

Controller - bottom view



Using a small non sharp object, press the “latch” to open and remove the battery housing cover. Insert 2 x AA batteries. (In this view, - is to the left and + is to the right)

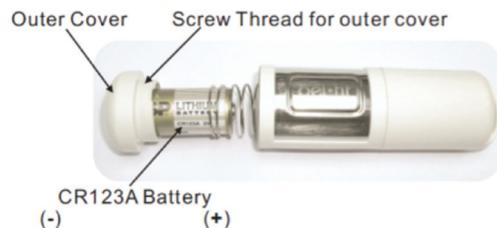
Please follow these simple directions for replacing batteries in the exerciser unit.

Unscrew the outer plastic cover to gain access to the battery. The battery positive end (+) points towards the contact plate. The negative (-) end connects to the outer cover.

Battery Compartment Twist cap anti clockwise to unlock



Insert battery positive end first
Replace cap and twist clockwise to lock
Use 1 x CR123A Battery



SECTION 7 COMMON QUESTIONS

- Q:** What is the best way to use the Kegel8 PF-200?
A: Always find a comfortable, quiet setting to use the Kegel8 PF-200. A reclining position is the most comfortable.
- Q:** How do I insert the Kegel8 PF-200?
A: The Kegel8 PF-200 is inserted into the vagina the same way that a tampon would be inserted. You may find it easier to insert if you use water based, water soluble vaginal lubricant.
- Q:** How do I start my exercise session once the Kegel8 PF-200 has been inserted?
A: You simply press the start button.
- Q:** How do I set the Kegel8 PF-200 to the right Level for my body?
A: The Kegel8 PF-200 can be adjusted up 1 level or down 1 level by pressing the up or down button once for each level change. The level should be strong enough to feel the muscle contractions without causing pain.
- Q:** How will the stimulation feel?
A: The Kegel8 PF-200 provides a gentle stimulation of the pelvic floor muscles causing them to contract. The stimulation will feel like flutters or mild contractions, much like the Kegel exercise which is done voluntarily.
- Q:** Can I stop an exercise session before the 15 minute session is over?
A: Yes, you may cancel a session by pressing the stop button and removing the exerciser.

SECTION 8 SPECIFICATIONS

Personal Exerciser (Kegel8 PF-200).....	Pelvic Muscle Exerciser
Agency Certification.....	Registered Medical CE Mark
Stimulation Pulse.....	200 Microseconds; adjustable from 0 to 36 V
Stimulation Frequency.....	50 Hz, 12.5 Hz or Mixed (50 & 12.5 Hz)
Electrodes.....	2 X 13.3 cm ²
Controller Battery.....	2 X 1.5V LR6 / AA
Exerciser Battery.....	1 X 3V CR123A
Battery Life	Approximately 1 Year
Display.....	LCD with Black Symbols
Backlight.....	Three Colour LED, Green, Yellow & Red
Accessories.....	Owner's Manual

For customer service, please contact Kegel8

Website: www.kegel8.co.uk

Email: info@kegel8.co.uk

EC REP

N. E. SERVICES LTD

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United Kingdom

Additional Warnings:

Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or oxygen or nitrous oxide.

Operation in close proximity (e.g. 1 m) to shortwave or microwave therapy equipment may produce instability in the stimulation output.

Application of electrodes near the thorax may increase the risk of cardiac fibrillation.

The simultaneous connection of a patient to a high frequency surgical unit may cause burns at the points of contact of the stimulator's electrodes and the stimulator may be damaged.

Not for use in life supporting or life sustaining applications.

Use special precautions regarding EMC according to the information provided in the ACCOMPANYING DOCUMENTS.

Other portable and mobile RF communications equipment can affect performance.

Do not use when adjacent to or stacked with other electrical equipment.

Do not use Kegel8 PF-200 on the heart area

Please remove these batteries (both controller and exerciser) if Kegel8 PF-200 is not likely to be used for some time.

IPX0 rating (no protection from dust and liquid ingress)

Please consult ACCOMPANYING DOCUMENTS

 Mode of operations: continuous

 NON-IONIZED RADIATION

 TYPE BF EQUIPMENT

Electrical Properties:

Output Current: 0-70mA

Pulse Width: 200uS at 1%

Frequency: 12.5Hz and 50Hz

Output Type: Constant voltage over range of 100 to 1000 Ohms

Output isolation: >100 meg Ohms

Radio Frequency Properties:

Frequency Band of Transmission: 433.28 MHz

Frequency Modulation: GFSK (Gaussian Frequency Shift Keying)

maximum Effective Radiated Power: 10 dBm

Rated Voltage: 1.9 Volts – 3.6 Volts

Transportation and Storage:

Ambient temperature range: -40 Degrees C to 70 degrees C.

(-40 degrees F to 158 degrees F)

Relative Humidity range: 10% to 100% including condensation

Atmospheric pressure range: 500hPa to 1060Pa. (7.25 PSI to 15.36 PSI)

Operation Condition:

Temperature:



Environmental:

This product is not repairable and must be disposed of in accordance with local regulatory standards and WEEE – Waste Electrical and Electronic Equipment Directive.



If at any time in the future you should need to dispose of this product please note that waste electrical products should not be disposed of with household waste.

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

Emissions	Test	Compliance
RF emissions CISPR 11	Group 1	The Personal Exerciser 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 Personal Exerciser is suitable for use in all establishments, including all domestic establishments.
Harmonic emissions IEC 61000-3-2	Not applicable	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	Not applicable

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environmental 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%
Surge IEC 61000-4-5	±1 kV line and neutral	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 6100-4-11	>5 % UT (>95% dip in UT) for 0,5 cycle 40% UT(60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles >5 % UT (>95 % dip in UT) for 5s	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environmental guidance
Conducted RF IEC 61000-4-6	3 Vms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the Personal Exerciser, including cables, than the recommended including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ 26MHz to 80MHz $d = 1,2\sqrt{P}$ 80MHz 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 the equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 26 MHz to 2,5 GHz	3 V/m	

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

a. Field strengths from fixed transmitters, such as base stations for radio (no 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 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 the Personal Exerciser is used exceeds the applicable RF compliance level above, the Personal Exerciser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocation the Ultrasound aerosol therapy device.
 b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communication equipment and the Personal Exerciser

The Personal Exerciser is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Personal Exerciser can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Personal Exerciser 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		
	26 MHz to 80MHz	26 MHz to 80MHz	26 MHz to 80MHz
0.01	0.12 $d = 1,2\sqrt{P}$	0.12 $d = 1,2\sqrt{P}$	0.23 $d = 2,3\sqrt{P}$
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 26 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.



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