kegel*fit*

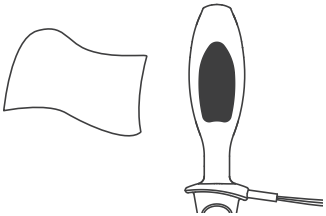
Pelvic floor strengthener

For stress urinary incontinence and pelvic floor toning

Instructions for Use
Please read carefully

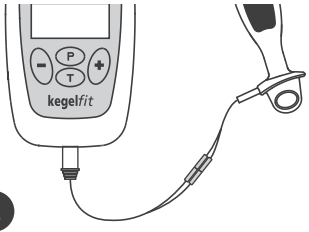
TensCare™

Quickstart Guide



1

Clean the probe with a wipe or with warm soapy water.



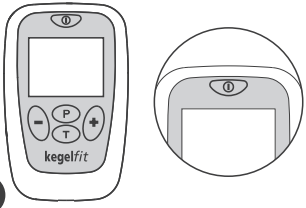
2

Connect the probe to the device.



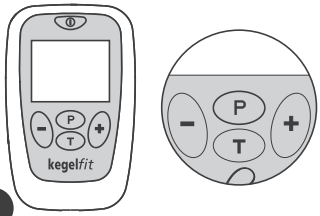
3

Insert the probe into the vagina with the metal plates facing outwards.



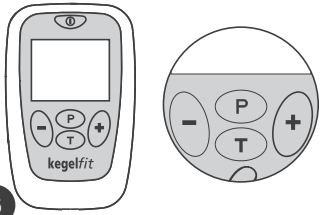
4

Press and hold the power button to turn the device on.



5

Select a programme by pressing the P button.



6

Start the session by increasing the intensity.

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1. Device Description

1.1. Introduction

The Kegelfit is a non-implanted muscle stimulator designed to treat female stress urinary incontinence. It uses gentle electrical signals delivered through a small vaginal probe to stimulate and contract the pelvic floor muscles. This promotes pelvic floor muscle strength, helping to reduce the frequency of stress incontinence episodes.

When used as intended, the Kegelfit can provide the following clinical benefits:

- Reduced frequency of stress incontinence episodes
- Improved pelvic floor muscle strength

1.2. Intended purpose

The Kegelfit is a medical device designed to be used in the home healthcare environment to treat symptoms of stress urinary incontinence. Kegelfit is suitable for use by adults (18 years+) who can control the device and understand the instructions.

Do not use the device for any other purpose.

1.3. Kit contents

1 x Kegelfit device

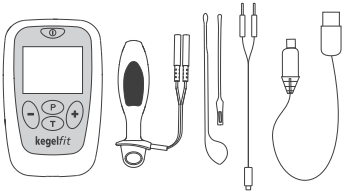
1 x Liberty Loop vaginal probe (X-VPL)

1 x Lead wire (L-ELGR)

1 x Charging cable (X-ELISE2-USB)

1 x Storage pouch

1 x Instructions for Use



1.4. Safety guidelines

CONTRAINDICATIONS

- Do not use if you are pregnant
- Do not use if you are attempting to become pregnant
- Do not use if you have a cardiac demand pacemaker or implanted defibrillator
- Do not use if you have symptoms of active urinary tract infection, vaginal infections, or localized lesions
- Do not use if you have a diagnosis of extra-urethral or overflow incontinence
- Do not use if you have severe urine retention
- Do not use if you have poor sensation in the pelvic region
- Do not use if you have cognitive disabilities, i.e.; Alzheimer's disease or dementia
- Do not use if you are unable to properly insert the Trainer
- Do not use if you have active pelvic cancer
- Do not use if you have an intestinal clamp
- You must be 6 weeks post pelvic surgery or vaginal childbirth to use this device

• Do not use this device for diagnostic purposes or critical patient monitoring

• This device is not (external) defibrillator-proof

WARNINGS, CAUTIONS AND NOTES

This manual uses Warnings, Cautions and Notes.

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

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

Notes are used to provide clarification or recommendation.

WARNINGS

Warning: The Kegelfit Trainer is intended for single patient use only. Do not share your Kegelfit Trainer with anyone else. Improper treatment or cross-infection may occur.

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

Warning: If you have active cancer, consult with your clinician before use due to concerns for stimulation potentially spreading cancerous cells.

Warning: Caution should be used if you have suspected or diagnosed heart problems because stimulation devices can affect heart rhythm in certain circumstances. Do NOT use optional electrodes across the chest, head, eyes, mouth or front of your neck.

Warning: Caution should be used if you have suspected or diagnosed epilepsy as unexpected seizures may impair usage.

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

Warning: Do not apply stimulation over the front of your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

CAUTIONS

Caution: Read all instructions before use. Failure to follow these directions may result in personal injury or damage to the equipment.

Caution: Do not use a Kegelfit device that appears to be damaged. Using a damaged device may result in personal injury.

Caution: If tissue irritation occurs, discontinue treatment immediately. Ask your care provider for advice before continuing further treatment to prevent injury.

Caution: Kegelfit is intended for indoor use only because it is an electronic device.

Caution: Only use recommended cleaning solutions that leave no residue to prevent irritation or infection. Do not soak as this could damage the device.

Caution: It is important that the Trainer

is cleaned before and after each use. Ineffective cleaning may lead to irritation or infection.

Caution: Never insert or remove Kegelfit Trainer unless the control unit is powered OFF as insertion or removal when stimulation is active may cause discomfort or tissue irritation.

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

Caution: Caution should be used if you have total/partial prolapse of the uterus/vagina.

Caution: The long-term effects of chronic muscle stimulation are unknown.

Caution: Skin irritation and burns beneath stimulation contacts have been reported with the use of powered stimulators.

Caution: Do not use the device in water because it is an electronic device and use in water may cause patient injury.

Caution: Do not operate device within 10 feet of operating televisions, arc welders, radio thermal treatment equipment, X-ray machines, MRI machines, or any other equipment that produces magnetic fields, sparks, or radio transmissions, RF communication equipment can affect this device.

Caution: The stainless steel in the Trainer electrodes contains some Nickel. This could cause a reaction if you have a Nickel allergy.

Do not use this device with a leadwire or Trainer other than those recommended by the manufacturer in section 4.5 Replacement parts.

Do not immerse your unit or Trainer in water or place it close to excessive heat as this may cause it to cease to operate correctly.

Do not attempt to open up the unit. This may affect the correct operation of the unit and will invalidate the guarantee.

1.5. Treatment programmes

Kegelfit has two different Electrical Muscle Stimulation (EMS) treatment programmes that can be used for stress incontinence and toning the pelvic floor muscles.

Stress Incontinence

Stress incontinence is when urine leaks during activities like coughing, sneezing, laughing, or exercising. This happens because the muscles supporting the bladder and urethra weaken, often due to childbirth, aging, or surgery. As a result, the muscles can't control urine release, leading to accidental leakage.

Select from the following treatment programmes:

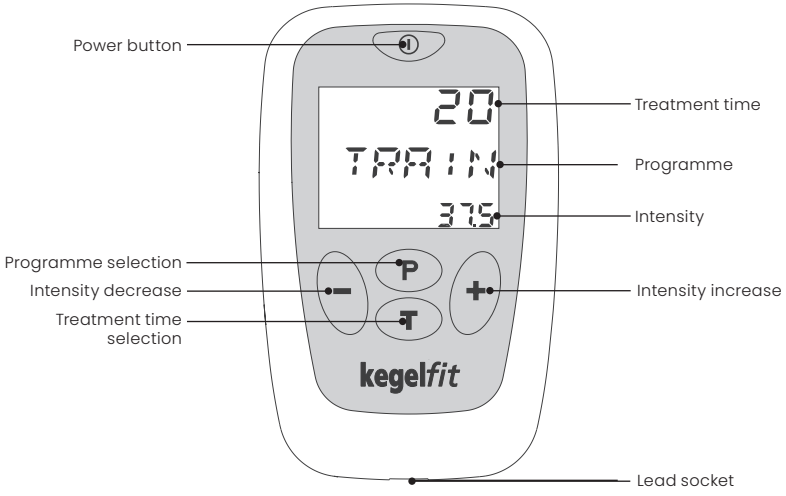
Load (Ω): 500Ω

Prog.	Frequency (Hz)	Pulse width (µS)
Train	50	300
Tone	35	250

Prog.	Description	Default treatment time	Usage guidance
Train	The stimulation triggers muscle contractions, which helps to strengthen them.	20 minutes	Use the device once daily, with noticeable improvements typically occurring within four weeks.
Tone	After-care programme for maintaining pelvic floor health once improvements have been made.	20 minutes	Use twice per week.

Note: Kegelfit EMS treatment is most effective when complemented by Kegel Exercises. These involve voluntary contractions and relaxing of the pelvic floor muscles. See section 2.9 for guidance on performing Kegel Exercises.

1.6. Controls and display

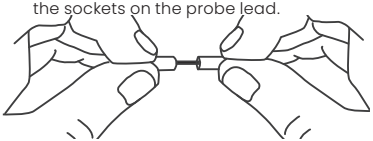


2. How to Use

2.1. Device setup

Connect the leads

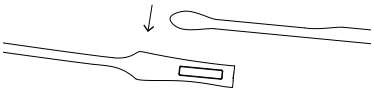
1. Insert the green, plastic end of the lead wire into the socket on the base of the device.
2. Push the metal pins of the lead wires into the sockets on the probe lead.



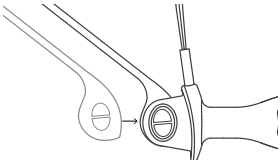
Connecting the pointer

The Liberty Loop probe features a detachable pointer, which serves as a visual indicator for monitoring the effectiveness of your pelvic floor muscle contractions.

1. Assemble the two halves of the pointer.



2. Insert the base of the pointer into the circular hole at the end of the probe, ensuring the pointer is positioned at the following angle:



2.2. Preparing for a session

1. Before inserting the probe, it is advised to empty your bladder.
2. Clean the probe before using for the first time and after each use. Clean with either an alcohol-free antibacterial wipe such as TensCare Wipes or by washing with warm soapy water.
3. Lubricate the metal plates of the probe with water or a water-based lubricant (such as TensCare's Go Gel).
4. Get into a comfortable position, such as sitting down or lying down with your knees bent and your feet flat.

2.3. Inserting the probe

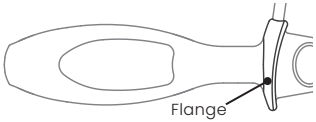
1. With the probe connected to the device and adequately lubricated, gently insert it into the vagina.

Warning: Ensure Kegelfit is switched off before inserting the probe.

2. Ensure the metal sides of the probe are facing toward your hips.



3. Avoid inserting the probe too deeply; the flange at the end should remain outside the vagina for proper positioning.

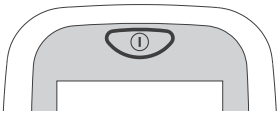


Note: Wearing tight-fitting underwear or jeans can help keep the probe in place and maintain proper contact during the session.

2.4. Starting a session

Turning on / off

1. Turn the device on/off by pressing and holding the power button for 3 to 5 seconds.



Note: The device will automatically turn off if the intensity setting is left at zero for more than 5 minutes.

Programme selection

1. Select the desired programme by pressing the P button. (See section 1.4 Treatment programmes).

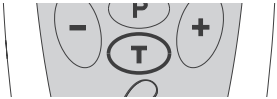


Each time you change the programme the intensity level will revert to zero.

When turning on, the device will remember the last programme used.

Treatment time selection

1. To select the treatment time, press the T button.



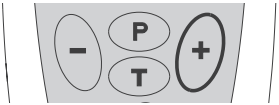
2. Press the T button to change the treatment time from either 10, 20, 30, 45, 60, 90 minutes or continuous (displayed as blank on the screen).

It is recommended to use the predetermined treatment times for each programme.

As with regular exercise, the longer the workout the greater the muscle fatigue and time for recovery.

Starting a session

With the probe inserted, start the treatment session by increasing the intensity with the + button.



The treatment countdown timer will begin.

2.5. During a session

Intensity selection

Select the stimulation intensity by using the + - buttons.

Kegelfit has a maximum intensity of 90mA. Each press of the + and - buttons will adjust the intensity by 0.5mA. The intensity can be

increased or decreased quickly by pressing and holding the + - buttons.

Prog.	Recommended intensity setting
Train	Increase the intensity until the muscles around the vagina contract.
Tone	Increase the intensity until the muscles around the vagina contract.

Intensity may need to be increased mid-way through treatment as your body gets used to the sensation.

If the sensation becomes uncomfortable, reduce the intensity.

Note: At intensity levels about 20, if the Kegelfit detects a disconnection it will automatically return the intensity to zero, the display will flash "LEADS" and the device will beep three times.



To increase intensity, ensure the probe is properly inserted and the lead wires are securely connected to both the probe and the device.

Warning: When the yellow LEDs in the channel output sockets light, this indicates the stimulation intensity is high enough to be harmful if not used correctly. Please use with caution.

Note: If you experience muscle cramping, pause the treatment until the symptoms subside. Then, resume the session at a lower intensity.

Stimulation output

For the Train programme the stimulation is intermittent.

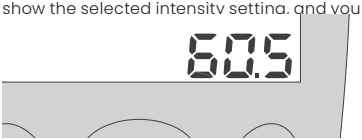
This programme has 'work' periods in which the stimulation is active and 'rest' periods with no stimulation.

This pattern ensures effective muscle engagement and adequate recovery time between contractions.

During the 'rest' periods, the intensity setting on the display will flash 00.0. The rest period will last between 5-10 seconds depending on the selected programme, before returning to the 'work period'.



During the 'work' period, the display will show the selected intensity setting, and you



For the best results, try to voluntarily contract the pelvic floor muscles during the work periods and sustain the contractions into the rest periods.

Using the pointer

The probe pointer will give an indication

of the strength and duration of each contraction, and whether or not the contraction is being performed correctly.

Correct muscle contractions will cause the pointer to move downwards.



Incorrect muscle contractions will cause the pointer to move upwards.



Little or no movements indicates weak muscle contractions.

2.6. After a treatment

Disconnecting the device

Once the treatment timer reaches zero, the treatment session will end, and the device turns off automatically.

1. Remove the probe by holding the flange and gently pulling outwards.

Warning: Make sure the device is off before removing the probe.

Note: Do not pull on the lead wire to remove the probe, as this can cause damage.

2. Disconnect the leads from the probe and the device.
3. Place the leads and the device in the storage pouch.

Cleaning the probe

It is important the probe is cleaned after every use.

1. Clean the probe with either an alcohol-free antibacterial wipe or by washing with warm soapy water.
2. Rinse in clean water and dry thoroughly.
3. Place the probe in the storage pouch between uses.

Frequency of use

Prog.	Frequency of use	Time to improvement
Train	Once per day	Improvements may be noticeable after 4 weeks
Tone	Twice per week	N/A – programme should be used to maintain pelvic health

Note: Time to improvements will vary from person to person.

Usage memory

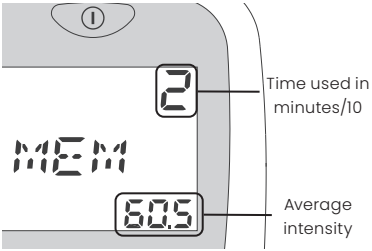
The Kegelfit has a memory function.

To view the usage memory, press T and + buttons for 3-5 seconds.

The display will show the total duration of use in 10-minute intervals (i.e. 1 = 10 minutes, 2 = 20 minutes) and the average intensity setting used.

Press the same buttons again to return to normal controls.

To reset memory to zero, hold down the T and - buttons together for 3 to 5 seconds.



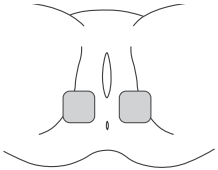
2.7. Treatment guidance summary

	Aim	Treatment time	Intensity	Frequency of use
Train	Treat stress incontinence	20 minutes	Increase until muscles contract	Once per day
Tone	After-care for maintaining pelvic floor health	20 minutes	Increase until muscles contract.	Twice per week

2.8. Alternative electrode treatment

Alternatively, stress incontinence can be treated using skin electrodes, though this method may be a less effective treatment than using a vaginal probe.

For stress incontinence, place the electrode on the skin between the anus and genitals.



Ensure the stimulation is strong enough to cause a slight contraction of the anus.

The stimulation should be strong yet comfortable.

Follow the treatment time guidance provided for vaginal probe treatment.

2.9. Kegel exercises

In addition to electrode therapy, performing Kegel exercises can help support your treatment. Kegel exercises involve repeatedly contracting and relaxing the pelvic floor muscles as part of a stress incontinence management routine. Regular practice of Kegel exercises is recommended for optimal results.

1. **Identify the right muscles:** To locate your pelvic floor muscles, try stopping urination midstream. The muscles you use for this are your pelvic floor muscles.
2. **Get comfortable:** You can do Kegel exercises in various positions—lying down, sitting, or standing. Choose a position that feels comfortable for you.
3. **Contract the muscles:** Tighten your pelvic floor muscles and hold the contraction for about 5 seconds.
4. **Relax:** Release the contraction and relax the muscles for 5 seconds. Make sure to breathe normally throughout the exercise.
5. **Repeat:** Aim for 10-15 repetitions per session. You can gradually increase the hold time and the number of repetitions as you get stronger.

Tips

- Avoid using your abdominal, leg, or buttock muscles while doing Kegels.
- Do not perform Kegels while urinating, as this can lead to incomplete emptying of the bladder over time.
- Be patient; it may take a few weeks to notice improvements.
- Perform Kegel exercises three times a day for the best results.

3. Troubleshooting

If you are experiencing issues with the device, refer to the troubleshooting guide below.

Problem	Possible causes	Solution
Display will not turn on	Flat batteries.	Charge device.
Controls will not operate	Device is faulty	Contact supplier.
Low battery display	Low batteries.	Charge device.

No stimulation sensation / LEADS showing on the display	There is a connection error. This should be noticeable by LEADS displaying on the screen. This may be due to a number of reasons:	
	Lead wire is not connected to the probe and device correctly.	Ensure the probe and device are connected correctly. To assess if the device is faulty, dampen your hand with water and a bit of salt. Firmly grip the probe, ensuring your skin covers the metal parts. Gradually increase the strength until you feel something, typically around 25.0 mA. If the LEADS alarm activates and the unit won't exceed 20.0 mA, the lead wires need replacing.
	There is a poor connection between your body and the vaginal probe.	Use a water-based lubricant such as TensCare Go Gel to improve conductivity. Cross your legs and squeeze. This can improve the probe's connection. If this helps, the contact should improve after a few weeks of use. If not, the unit may be unsuitable for you. Consult your healthcare professional for alternative options.
No stimulation sensation	Intensity level is not high enough.	Ensure you increase the intensity sufficiently. With the probe inserted, you may need to raise it to 40.0-60.0 mA. Max power is 90 mA. Adjust the intensity until you feel it.
	Reduced sensitivity in the area being treated.	You may have reduced sensitivity due to previously damaged or desensitised pudendal nerves (this can happen in childbirth or some surgical procedures). Please consult your healthcare professional.
No sensation of one side of the probe	The probe is not positioned correctly.	It's impossible for one side of the probe to malfunction while the other operates cor-rectly. Instead, you might experience a stronger sensation on one side. To address this, try adjusting the probe's position slightly, making sure the metal plates face outward toward the hips.
Sudden change in sensation	If you stop the stimulation and continue a few minutes later, the signal will feel quite a lot stronger.	Always return the intensity to zero after disconnecting the leads or electrode pads.

If you are unable to resolve the issue, please contact our customer service team:

Email: customer.service@tenscare.co.uk

Phone: 001 800 308 7390

Note: The Kegelfit has no essential performance characteristics. Device failure will not cause unacceptable clinical risk for the user.

4. Device Care

4.1. Cleaning

It is important that the probe is cleaned before using for the first time and after each use.

1. Clean with an alcohol-free antibacterial wipe such as TensCare wipes or by washing with warm soapy water.

Warning: Do not immerse the probe in a liquid.

2. Rinse in clean water and dry thoroughly.
3. Return the unit to the storage pouch.

Clean the device and lead wires at least once a week by wiping with a damp cloth & solution of mild soap and water. Wipe dry.

- Do not immerse the device in water.
- Do not use any other cleaning solution than soap and water.

4.2. Storage

Keep the device, probe and all accessories in the storage pouch between uses.

Storage life

- The device has no fixed shelf life.
- Unused batteries have a nominal shelf life of 1 year but will usually last longer than this.

4.3. Charging the battery

The Kegelfit is powered by a pre-installed, rechargeable lithium-ion battery. Only remove the back battery cover if absolutely necessary, as a replacement cover will be needed if it is removed.

When the battery is low, the screen will display “BATT”. Follow these steps to charge the device:

1. Connect the charging cable to an adapter and to the device.
2. Plug the adapter into a main socket.
3. “BATT” will appear on the screen, indicating that the battery is charging.
4. Once the battery is fully charged, “BATT” will change to “FULL”.

Note: The device cannot be used while being charged.

Warning: Use only a power supply adapter that is certified according to IEC 60601-1 and IEC 60601-1-11 standards.

Battery life and maintenance:

- The battery should last at least 15 hours with a setting of 50 mA, 300 µs, 50 Hz.
- It takes approximately 2 hours to fully charge the battery.

- The battery will typically need to be charged once a month. To maintain battery health, charge it at least once every 3 months.

Note: When the battery is running low the display of the device may appear dim. This is to conserve power. The stimulation output does not change.

Note: Charging voltage: DC 5V, charging current: 60mA.

Battery Warnings

- Only use the charging cable provided. Use of other chargers could be hazardous and will negate the warranty.
- Do not pierce, open, disassemble, or use in a humid and/or corrosive environment.
- Do not expose to temperatures over 60°C(140F).
- Do not put, store or leave near sources of heat, in direct strong sunlight, in a high temperature location, in a pressurized container or in a microwave oven.
- Do not immerse in water or get wet.
- Do not short-circuit.
- Do not connect the device unless the battery cover is in place.
- If the battery pack creates an odour, generates heat, becomes discoloured or deformed, or in any way appear abnormal during use, recharging or storage, immediately remove it from the device or battery charge and stop using it.
- If battery leakage occurs and comes in contact with the skin or eyes, wash thoroughly with lots of water and immediately seek medical attention.
- Keep batteries out of the reach of children to prevent them from swallowing them by mistake. If swallowed by child, contact doctor immediately.
- Disposal: Always dispose of batteries and device responsibly according to local government guidelines. Do not throw batteries onto a fire. Risk of explosion.

4.4. Probe and lead wire care

- Replace the probe every 6 months to maintain proper hygiene.
- Do not pull on the lead wires of the probe. This may cause damage.
- The probe is intended for single patient use only. Do not share the probe with anyone else. Improper treatment or cross-infection may occur.
- It is important the probe is cleaned after each use. Ineffective cleaning may lead to irritation or infection.
- To ensure safety and effectiveness we recommend using TensCare probes and electrodes only.
- The life of the lead wires depends greatly on use. Always handle the leads with

care. We recommend replacing the lead wires regularly (about every 6 months).

4.5. Replacement parts/ accessories

The following replacement parts are compatible with the Kegelfit and may be ordered from TensCare at www.tenscare.co.uk or +44(0) 1372 723434.

X-VP	Liberty vaginal probe (28mm diameter)
X-VPL	Liberty loop vaginal probe (32mm diameter)
X-VPM	Liberty plus vaginal probe (32mm diameter)
X-AP	Liberty mini vaginal probe (24mm width)
X-VPLG	Gold liberty loop vaginal probe (32mm diameter)
K-GO100	Go Gel water-based lubricant (100ml)
E-CM5050	50x50mm electrodes (x4)
E-CR5050	50x50mm Cool Relief infused electrodes (x4)
E-TRBG	50x50mm Blue Gel hypoallergenic electrodes (pack of 4)
L-ELGR	Lead wire
X-ELISE2-USB	Charging cable
B-BL4B	Battery
X-EL2C	Battery cover

4.6. Servicing

There are no user-serviceable parts, and no calibration is required No modification of this equipment is allowed.

4.7. Warranty

Your Kegelfit is guaranteed for two years from the date of purchase. If a fault develops contact your dealer or Tenscare. (Contact details on last page)

The guarantee does not cover Trainer, batteries, or the lead wire. Please note that the Guarantee is invalidated if:

i) If the unit has been immersed in water, maltreated or tampered with.

4.8. Disposal of Electronic Waste

At the end of its life, please dispose of your Kegelfit responsibly.

Anything electrical or electronic should not be treated as domestic waste and simply thrown away. About half of the states currently have laws on disposal and recycling of electronics.

The Environmental Protection Agency makes recommendations for safe disposal of electronic waste on:

http://www.epa.gov/epawaste/conserve/materials/ecycling/index



5. Technical Specification

Waveform	Symmetrical Bi-Phasic
Voltage	45V zero to peak across 500Ω Constant voltage over 470-1500 Ohm Constant current over 160-470 Ohm
Amplitude (over 500 Ohm load)	90 mA zero to peak +ve in 199 steps +/- 10%
Frequency range	10-50Hz
Pulse width range	200-300us
Output plug	Fully shielded: touch proof
Channels	Single channel
Power supply	Rechargeable Li-ion battery Ratings: 600 mAh, 2.22Wh, 3.7V
Weight	90g
Dimensions	100 x 65 x 18 mm
Safety Classification	Internal power source. Designed for continuous use. No special moisture protection.
Service life	Device: >5 years, Probe: 6 months
Applied part	Vaginal probe, optional skin surface electrodes
Applied part classification	Type BF
IP rating	IP22

Environmental Specifications	
Operating conditions	Temperature range: 5 to 40°C Humidity: 15 to 90% RH non-condensing Atmospheric pressure: 700 hPa to 1060 hPa
Storage conditions	Temperature range: -25 to +60°C Humidity: 15 to 90% RH non-condensing Atmospheric pressure: 700 hPa to 1060 hPa

Symbols Table

	TYPE BF APPLIED PART: Equipment providing a degree of protection against electric shock, with isolated applied part. Indicates that this device has conductive contact with the end user.
	This symbol on the unit means “Refer to instructions for use”.
	Temperature Limitation: indicates the temperature limits to which the medical device can be safely exposed.
	Humidity Limitation: indicates the humidity limits to which the medical device can be safely exposed.
	Atmospheric Pressure: indicates the atmospheric limits to which the medical device can be safely exposed.
	Catalogue Number: indicates the manufacturer’s catalogue number so that the device can be identified.
	Do not dispose in household waste.
	Manufacturer Symbol

	Date of Manufacture: indicates the date which the medical device was manufactured. This is included within the serial number found on the device (usually on the back of the device), either as "E/Year/Number" (YY/123456) or "E/Month/Year/Number" (MM/YY/123456).
	This medical device is indicated for home use.
	Importer Symbol
IP22	This medical device is not water resistant and should be protected from liquids. The first number 2: Protected from touch by fingers and objects greater than 12 millimeters. The second number 2: Protected from water spray less than 15 degrees from vertical.
UDI	Unique Device Identified : Indicates a carrier that contains Unique Device Indentifie information
	Notes are used to provide clarification or recommendation.
	A Warning is used when failure to follow the instructions may result in serious injury or death.
	A Caution is used when failure to follow the instructions may result in a minor or moderate injury, or damage to the device or other property.
	A Contraindication is used when a device should not be used because the risk of use clearly outweighs any foreseeable benefits and may result in serious injury or death.

Guidance and manufacturer's declaration - electromagnetic emissions		
The kegel*fit* is intended for use in the electromagnetic environment specified below. The customer or the user of the kegel*fit* should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnatic environment - guidance
RF emissions CISPR 11	Group 1	The **kegel*fit*** 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 **kegel*fit*** is suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile
If floors are covered with synthetic material, the relative humidity should be at least 30 %.			
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for Input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T(>95% dip in U_T) for 0.5 cycle 40% U_T(60% dip in U_T) for 5 cycles 70% U_T(30% dip in U_T) for 25 cycles <5% U_T(>95% dip in U_T) For 5s	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable
NOTE U_T is the a.c. mains voltage prior to application of the test level			

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the **kegel*fit***, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter **Recommended separation distance 3V** d = 1.2√ P 80M Hz to 800MHz d = 2.3√ pt 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).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the symbol in this box 

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 the **kegel*fit*** is used exceeds the applicable RF compliance level above, the **kegel*fit*** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **kegel*fit***.
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 communications equipment and the kegel*fit*.

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

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

Thank you for using Kegelfit...

At TensCare, we strive to provide the best possible products and services. We value your feedback and continuously work to enhance our offerings. Understanding how our products benefit you is important to us. If you have any insights or suggestions, please get in touch.

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