



K-fit

**Kegel Toner
User Guide**

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What is the Pelvic Muscle Trainer?

K-fit is a dual channel exercise machine that combines several programs into one unit. It was designed to aid women in the toning of their pelvic floor muscles. If you have heard of the benefits of doing Kegels, but aren't sure if you are doing them correctly, the K-fit can help you achieve maximum results with minimum effort.

Customer Care

We value customer feedback and welcome the submission of your personal experience with K-fit. Should you encounter any difficulties with your device, our customer care team is available to provide quick trouble-shooting and instruction based on their invaluable personal experience using the K-fit themselves. Our goal is to help you achieve the maximum potential from your new K-fit Kegel Toner. Customer satisfaction is our number one priority. Please contact us using the link on our website www.KfitKegelToner.com or email us directly at customercare@kfitkegeltoner.com

1. SAFETY GUIDE

Please read the entire instruction manual before you use **K-fit Kegel Toner (Model: KM518)**. It will give you a better understanding of how the product works. If you are unsure whether a medical condition should preclude you from using the device, consult your physiotherapist, osteopath, or medical practitioner. During the heavy days of your period do not use the unit. This pelvic muscle trainer is intended to use on healthy muscles only.

1.1 Special population

The pelvic muscle trainer is designed for women, which is a safe and effective way of strengthening pelvic floor muscles.

This device should not be used:

- If you have been fitted with a demand style cardiac pacemaker, any electronic implanted device such as a defibrillator, neurostimulator, pacemaker, or ECG monitor
- If you have any body worn medical device such as an insulin pump.
- If you have any active cancer or suspicious or cancerous lesions.
- If you have a history of epilepsy or seizures.
- If you are pregnant.
- If you are recovering from a recent surgery.
- If you have undiagnosed pain in the vaginal area.
- On an area lacking normal sensation.
- With open wounds or rashes.

1.2 Contraindications & Precautions

- Only use the K-fit Kegel Toner as described in this user guide. Never use the K-fit Kegel Toner on other parts of your body as the electrical pulses could damage your health.
- To ensure your personal hygiene, do not allow other people to use your probes. Always clean your probes thoroughly after use.
- Only use K-fit Kegel Toner approved accessories. All official K-fit Kegel Toner probes have been approved for use with this toning unit.
- To power your K-fit Kegel Toner, use a 9v battery. Never connect your toning unit or its probes to a mains power supply as this could result in electrocution.
- Do not immerse your K-fit Kegel Toner unit in water, fluids or any other substance.

1.3 Warnings

- Type BF equipment, Continuous Operation.
- Do not insert lead wires into a mains power supply.
- Do not immerse unit into water or any other substance.
- The unit is not protected from the ingress of water droplets and should not be used in the shower.
- Do not use the unit in the presence of a flammable anesthetic gas mixture and air or with oxygen or Nitrous Oxide.
- Only use 9V alkaline batteries do not use rechargeable batteries.
- Patient probes are for single patients use only.
- Keep out of reach of children.
- Application of probes near the thorax may increase the risk of cardiac fibrillation.
- Operation in close proximity (e.g. 1m) to shortwave or microwave therapy equipment may produce instability in the stimulator output.
- Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the stimulator probes and possible damage to the stimulator.
- No modification of this equipment is allowed.

1.4 Adverse reactions

Stimulation has been used for many years to stimulate muscle and nerve fibers to treat a number of muscle and nerve related conditions. Over the last 30 years numerous clinical trials and papers have been written. Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

2. INTENDED USE / INDICATIONS FOR USE

K-fit Kegel Toner (model: KM518) is a non-implanted muscle stimulator designed to treat stress, urge and/or mixed urinary incontinence in women. It applies stimulation to the pelvic floor muscles and surrounding structures to improve strength and support.

3. DEVICE DESCRIPTION

3.1 General description of the device

This device is one of a new breed of modern Neuromuscular Stimulators (STIM) developed with the aim of achieving optimum pelvic health in women. Our principal aim was to design a product that gives users the opportunity to strengthen weak muscles and nerve fibers using a device that is compact, user friendly and affordably priced.

This device is a dual channel device combining several treatment programs 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. It offers precision control of Pulse Widths, Rates, Ramp up times, Work/Rest cycles as well as alternating or synchronous application.

3.2 Device components



Toning Unit



Vaginal Probe



Accessory Wires



User Guide



Quick-Start Guide

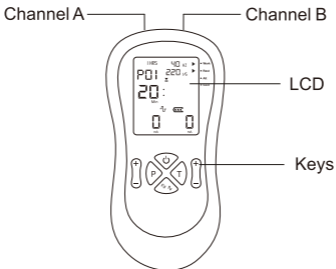


Cloth Storage Bag

K-fit Kegle Toner, Pelvic Muscle Trainer Checklist

- 1 x Toning Unit, Pelvic Muscle Trainer
- 1 x Vaginal Probe
- 2 x Accessory Wires
- 1 x User Guide
- 1 x Quick-Start Guide
- 1 x Cloth Storage Bag

Main Device



3.2.1 Key panel

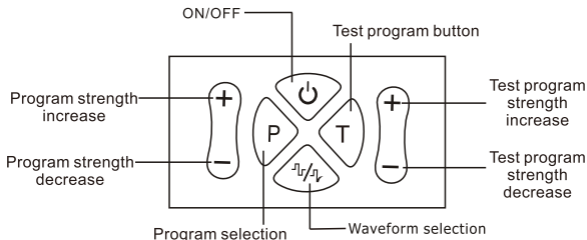


Figure 3.3.1-1 Key panel

P button:

- Selects programs from P01 –P08.

T button:

- Jump to Test program.

Waveform button:



Symmetrical, bipolar rectangular wave with zero DC current. It is stronger Waveform for beginning.



Asymmetrical, bipolar rectangular wave with zero DC current. It is soft Waveform for general patients.

Strength buttons:

The front of the pelvic muscle trainer also has two sets of "+" and "-" buttons. You can use these buttons to increase "+" or decrease "-" the strength of the electrical pulse being sent via Channel A and Channel B respectively.

Note: Channel A is comprised of 8 separate pre-set programs. Channel B is one short test program comprised of all pre-sets run 30 seconds at a time without stopping.

3.2.2 LCD display

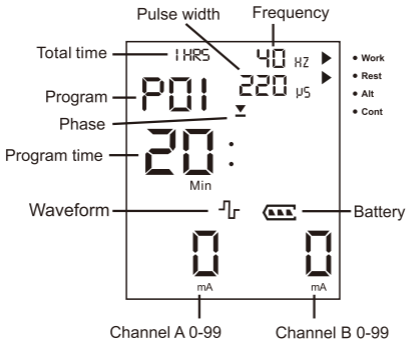


Figure 3.3.2-1 LCD display

Hz:

Hz is the number of electrical pulses per second. This value will vary, depending on the program you have selected.

μ S:

The μ S amount is the duration of a single electrical pulse. The higher the value, the larger the target area of application. The lower the number, the more focused the area of application. Again, this amount will vary depending on the program you have selected.

Total Time:

The top left of the LCD shows the total time that you have used your toning unit.

Program Number:

Below the Total Time run will be the number of the program that is currently selected if you are using Channel A, or currently cycling if you have selected the Channel B.

Program Time:

The middle of the LCD shows a countdown in minutes and seconds of each program selected. The time will begin running once you have started the program using the +/- keys.

Waveform and Battery:

Below the timer on the LCD screen is the waveform that is currently selected and the status of the battery. Waveform is adjusted by tapping on the waveform button at the bottom of the circle of four in the middle of your toning unit.

mA:

At the bottom of the screen on the left and right, depending on whether you have chosen a pre-set program or the test program, will be the strength of the program measured in mA's. This is the only setting controllable by the user. It is set using the +/- keys on the side of the toning using that you have chosen. The strength can go all the way to 99 mA's.

3.3 Treatment modes

For Channel A:

P01 – **Stress:** The strongest program that works at 40 Hz. Heavier lifting with a longer rest cycle suitable for Stress urinary incontinence.

P02 – **Stress:** A more gentle program for those just beginning a muscle toning routine, suitable for Stress urinary incontinence.

P03 – **Urge:** This program is 15 minutes long and is suitable for Urge urinary incontinence.

P04 – **Mixed:** This program applies current in a broader waveform, suitable for Mixed urinary incontinence.

P05 – **Other:** This program is designed to help relax the pelvic muscles, suitable for Pelvic floor muscle pain.

P06 – **Mixed:** This program is multiphase and will increase in strength over time, suitable for Mixed urinary incontinence.

P07 – **Mixed:** This program is multiphase and decreases in intensity over time, suitable for pelvic floor muscle rehabilitation 42 days after delivery.

P08 – **Mixed:** This program 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.

Note: You should choose the program based on your issue and feeling: choose one mode that you feel challenged, but comfortable using which is best for your treatment.

For Channel B:

This program is a testing program with a treatment time of 3 minutes. Suitable for new users to adapt to this product.

3.4 Specifications

Basic Specification	
Power Source	9Vdc Battery
Method of Line Current Isolation	Type BF Applied Part
Patient leakage current	Comply with IEC 60601-1 and IEC 60601-2-10
- Normal Condition	< 100 μ A
- Single Fault Condition	< 500 μ A
Number of output modes	8 (12 sub modes)
Number of output channels	2 (only the selected one channel will work during operation)
Method of Channel Isolation	Individually isolated circuit
Turn Off Method	Automatic/Manual shut off
Output Intensity Level	100
Timer Range	15~20 minutes
Weight of Main Unit	300g
Weight of Accessories	200g
Dimension of Main Unit (L x W x H)	150mm x 73mm x 20mm
Dimension of Probe:	145mm x 25mm x 25mm
Electrode Surface Area:	7.85cm ² (x 2)
Housing Materials of Main Unit	ABS plastic
Materials of Accessories	Probe Material: ABS plastic, Stainless steel
Compliance Standards	IEC 60601-1 IEC 60601-2-10 IEC 60601-1-2 IEC 60601-1-11

Output Specification	
Waveform and Shape	Rectangular pulses, Biphasic
Maximum Output Voltage (+/- 10%)	37Vdc @500Ω
Maximum Output Current (+/- 10%)	<80mA @500Ω
Pulse Width	150us, 200us, 220us
Frequency	10-40Hz
Net Charge (per pulse)	0μC @ 500Ω
Maximum Phase Charge	19.80 μC @ 500Ω
Maximum Current Density	9.48 mA/cm ² @ 500Ω
Maximum Average Power Density	3.09 mW/cm ² @ 500Ω
Additional Features	
Environment for operation	Temperature:5-40°C
	Humidity:≤80%RH
	Atmospheric Pressure:86-106kPa
Environment for storage	Temperature: -10~50°C
	Humidity:≤90%RH
	Atmospheric Pressure:50-106kPa
Service life	3 years

4. OPERATION

4.1 Before treatment

Before you start to use your K-fit Kegel Toner, please read the Important Safety Information carefully.

4.2 Insert the battery

On the back of your toning unit, slide off the battery cover, remove plastic battery wrap and insert the battery.

4.3 Connect the probe to the system

Connect the lead wire to the probe and K-fit Kegel Toner unit. You can choose the left side, Channel A for pre-set workouts, or the right side, Channel B for testing the programs sensation before choosing your favorite program to begin on Channel A.


Please note that only the selected channel connected to a probe will work during operation. Do not connect two probes to the toning unit.

Warning:

- Make sure to clean your probe before use with warm water and hand soap. You may wipe the probe with rubbing alcohol after cleaning. Do not use industrial cleaners that are not meant for use on the body. Do not attempt to boil your probe. Urinate after use to prevent bladder infection.

4.4 Insert the probe

- Get into a comfortable position. You may choose to stand or lie down. Do not sit on your probe as this can damage the wire.
- Hold the base of the probe. The base is the plastic part at the 'tail' end (the end with the wires).
- Apply a water-based personal lubricant such as KY Jelly or its equivalent. Do not use an oil-based lubricant like Vaseline. Gently insert the 'head' end of the probe into your body. The tail-end of the probe should always be outside of the body. The metal electrode panels should always be inside the body. Do not allow the probe to slip out and expose the electrode panels as this will direct current to the vulva and will be uncomfortable. Insert as deeply as you are comfortable going as long as the tail-end of the probe remains outside the body.


- If you find that you are very sensitive to the stimulation, please choose the soft waveform. 
- If the lubricant doesn't help, you may be suffering from vaginal atrophy, a condition that causes dryness and thinning of your vaginal walls. Your doctor can prescribe an estrogen cream that can help. When you have completed the treatment, resume using the pelvic muscle trainer, you should find that you can insert the probe much more easily.
- Please do not let vaginal atrophy stop you from experiencing the benefits of pelvic muscle trainer. There are effective solutions available to overcome this painful condition.


4.5 Turn on the device

Press the power button on the pelvic muscle trainer control unit.

4.6 Select the waveform

Press the waveform button to select the output wave: symmetrical bipolar rectangular wave and asymmetrical bipolar rectangular wave.

 Symmetrical, bipolar rectangular wave with zero DC current. This is a stronger Waveform for general users.

 Asymmetrical, bipolar rectangular wave with zero DC current. This is a softer Waveform for more sensitive users.

4.7 Select the modes

Press "P" button to choose one mode, to start the program. Refer to "3.3 Treatment Modes" for modes selection.

Note: Please select the correct mode for your unique type of urinary incontinence. If you are not sure which type of urinary incontinence you have, please refer to the guidance below or consult your doctor.

Urge urinary incontinence: May present as a particularly strong need to suddenly want to urinate. You may have difficulty reaching the toilet without losing a small amount of water. Please note that this phenomenon may be caused by a urinary tract infection and it is best to seek a diagnosis from a doctor before proceeding.

Stress urinary incontinence: This is the loss of small amounts of urine associated with coughing, laughing, sneezing, standing up, exercising or other movements that increase intra-abdominal pressure and thus increase pressure on the bladder.

Mixed urinary incontinence: Urge urinary incontinence associated with the sudden need to urinate and stress urinary incontinence where there is loss of water with abdominal tightening exist together.

4.8 Adjust the power

Once your program has started, press the relevant “+” button to increase the amount of power (milliamps) in the electrical pulses. The mA can reach a maximum of 99, the higher the amount of mA, the more effective your program will be, but always choose a level that feels comfortable. If you are feeling discomfort or pain, reduce the amount of mA by pressing the (-) button for the channel you are using.

4.9 Turn off the device

When the program is complete, power off the device. Do not remove the probe before powering off. Remove the probe by pulling gently at its base.

Warning:

Do not pull the wires as this could damage your probe.

4.10 After the treatment

Step 1: Clean your probe with water and hand soap.

Step 2: Wipe the probe with alcohol.

Step 3: Wipe the toning unit with a damp cloth.

Step 4: Dry your probe and store it in a clean, dry place.

Step 5: Keep the device in a dry, clean package. (We recommend that you keep your pelvic muscle trainer its original packaging)

Warning:

- Do not place your probe in boiling water as this will damage your probe.
- You can wash your probes with water and alcohol. We also recommend that you wipe your toning unit clean with a damp cloth or antiseptic wipe. Do not use alcohol-based products on the LCD screen as this could damage the LCD.

5. EXERCISE TIPS

- Try to start with a Power Output of 30 mA or above
The amount of power needed to stimulate pelvic floor muscles varies from person to person.
By default, your toning unit has a 0 mA output and you need to increase the power manually, by pressing the + button. You should increase the power to a level where you can feel the effects of the electric pulse, but it is not causing any discomfort. Many women find that a setting of around 30 mA is a good starting point, but only you can tell what is comfortable for you.
As your pelvic floor muscles begin to strengthen, you should find that you can increase the power output.
- Exercise 1 - 2 times per day for 12 weeks and then as often as possible for maintenance
We recommend that you use your pelvic muscle trainer 1 or 2 times per day for 12 weeks. Alternate between your choice of programs. If you decide to exercise twice a day, it is important that you do not do back-to-back sessions. This is because your pelvic floor muscles need time to relax and recover between sessions. Muscle is built during rest. We suggest that you use your pelvic muscle trainer once in the morning and once at night.
- Be Patient
Everybody's different. Some people respond to pelvic muscle exercises very quickly, whereas with others it takes a number of weeks to feel real improvements. But rest assured, if you use your K-fit Kegel Toner regularly and follow our instructions carefully, your pelvic floor muscles and nerve fibers will get stronger.

6. TAKEING CARE

6.1 Accessories and Modifications

Only use K-fit Kegel Toner approved accessories.
Do not modify the device. Making unauthorized adjustments to the device will invalidate your warranty and could result in injury.

6.2 Screen (LCD) Care

If the screen panel is dirty, please wipe it with a dry soft cloth. If necessary, wipe the soft cloth with water (fully wring it dry) for cleaning.

6.3 Probe care

Each probe is designed for ease of use and should last 6-12 months with proper care.

- Never immerse your probe in boiling water or boiling liquids. This could damage your probe.
- When inserting a probe, hold its base. Do not hold it by the wires as this could damage the probe.
- Before use, always clean the probe in warm, but not boiling, soapy water.

6.4 Lead wires and connections care

The lead wires and connections are vital to the device, so please treat them with care:

- Always handle the wires carefully. Do not wrap tightly around your device during storage.
- Do not stretch or twist the wires as this could damage them. If your wires are damaged, the device may be unable to send the electric pulses to your probe.
- Do not cut the wires or attempt to modify the connections.

6.5 Battery care

To take care of the battery:

- Replace the battery when it is low on power (a battery indicator is shown on the LCD screen when the power is low).
- If you are not going to use the device for a week or longer, please remove the battery.
- We recommend you use a 9V alkaline battery.

7. STORAGE

- Store it in a clean, dry place. We recommend that you keep your pelvic muscle trainer its original packaging.
- Store the machine in a place where it is out of reach of children.
- Do not disassemble the unit without authorization.
- When the unit will not be used for a long duration, remove the battery.
- Do not disassemble for repair without prior notification or you may void your warranty.

8. TROUBLESHOOTING GUIDE

8.1 Troubleshooting

Problem	Possible Cause	Solution
No stimulation	The wire is not connected.	Connect the wire correctly.
	The probe needs to be replaced.	Replace your probe.
	The device hasn't been turn on yet.	Press the power button.
	The intensity hasn't been set.	Set the intensity by pressing the (+) or (-) button.
Weak stimulation	The probe is in an area of low sensitivity.	Adjust the placement by sweeping back and forth and monitoring the depth that the probe is resting at.
	The battery is low.	Replace the battery.
	Intensity set too low.	Continue pressing the (+) key until adequate stimulation is achieved.
	The probe is expired.	Replace the probe every 6-12 months.

Bladder infection or other bacterial infection	The user is not urinating after each use.	Always urinate after any vaginal penetration to clear normal bacteria from the urethra.
	Cross contamination is occurring	Do not share your probe.
		Consult the doctor.
Treatment is cut off during therapy	The connecting wire is coming loose.	Turn off the power, connect the probe wires again.
	The program has completed.	The power will turn off after the program has completed.
	The probe is expired.	Replace the probe.
Electrical shock	The electrode panels have become exposed outside the body.	Power off and reinsert the probe. Monitor the position of the electrode at all times.
	The wires are broken and exposing the user to unregulated current.	Check the wires regularly to ensure they have not been broken at the base of the probe.
		Do not sit on your probe during use.
		Replace the probe.
Wrong Display	Software Faults	Contact customer service.

8.2 Frequently asked questions

Q: I can't get the mA's past 10.

The main cause for the 10 mA stop is that the wires are not connected properly. The accessory wire has waterproof sleeves at the ends and these connection points are VERY tight. The probe pegs must be pressed very firmly into these sleeves to ensure proper connection. If you attempt to activate the probe while it is held in the air, the toner will stop at 10 mA's for safety reasons. If the probe is expired or broken then the toner will stop at 10 mA's.

Q: I have an IUD or Mirena Coil - can I use the K-fit Kegel Toner?

Yes. The Mirena is plastic so no problem there. An IUD contains copper which is unaffected by the pelvic muscle trainer so no problem there either.

Q: Can I use my K-fit Kegel Toner 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 due to increased sensitivity. Many users have reported it helps with menstrual cramps. Here in the office, we tend to use it on lighter flow days. Wash the probe well after exposure to blood to prevent staining. 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 while pregnant?

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

Q: How far do I put the probe in?

Probes are designed to rest at optimum depths when inserted properly. Insert your probe until the electrode panels are no longer exposed and the base of the probe is still outside the body.

Q: How soon after the birth of my baby can I start with my K-fit Kegel Toner?

Please 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 K-fit Kegel Toner?

We advise that you consult your doctor. Stress incontinence, and prolapse are 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 pelvic muscle trainer is ideal, but check with your doctor or physiotherapist to find out when you have been cleared for this activity.

Q: I find it painful inserting the probe.

Always use personal lubricant to ensure you aren't putting undue stress or abrasion to these delicate tissues. 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 medicated cream to treat the condition. Use this for the recommended time, and then recommence using the pelvic muscle trainer. 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 for general use and is comprised of 8 pre-set programs, each with a treatment time of 15-20 minutes. Channel B (right hand side) is a testing program with a treatment time of 3 minutes. This is suitable for new users to adapt to this product.

Q: How do I clean my probe?

Simply wash the insertable part with hand soap and warm water, keeping the wire connections dry at all times. Do not boil the probe. It can be disinfected with rubbing alcohol if you choose to do so.

Note: Do not use the same probe both vaginally and rectally, even after cleaning.

Q: How long will the battery last?

If you use the K-fit Kegel Toner daily, it should last about 1 month. Every brand is different. You can get replacements at your local supermarket. You will know when your battery is low because a battery icon will flash on your pelvic muscle trainer screen.

Q: How long will my probe last?

With normal use, your probe should last approximately 12 months. We recommend that you replace it regularly to receive the maximum benefit from your toning unit. You will know when it is time to replace your probe because your toner will stop going over 10 mA's or will go to 99 without delivering sensation. We recommend that you take care with the leads and wires of the probe. Don't bend them sharply by sitting on them during exercise, or wrap them tightly around the toning unit during storage. This could cause wire damage and stop the probe from 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 repeatedly over time, you can damage them.

9. CUSTOMER SUPPORT, SALES AND SERVICE**Customer Service Center**

Company name: K-fit Kegel Toner, LLC.

Address: 630 Hickory St NW

Suite 120-128

Albany, OR 97321

Tel.: 702-285-5944

E-mail: customercare@kfitkegeltoner.com

Website: KfitKegelToner.com

Manufacturer

Company name: Shenzhen Konmed Technology Co., Ltd.

Address: 601, Building B4, Shenchengtou Creative Factory Life Science Park, Julongshan A Road, Xiuxin Block, Kengzi Street, Pingshan District, Shenzhen, Guangdong, CHINA.

Post code: 518118

Tel.: +86 755 8670 4556








Fax: +86 755 8670 4556

Website: www.konmed.cn

E-mail: sales@konmed.cn

10. LABEL SYMBOLS

Label symbols are shown in the following table:

Labels on device		
No.	Symbols	Description
1		Refer to instruction manual/ booklet
2		Symbol for "ATTENTION, CONSULT ACCOMPANYING DOCUMENTS".
3		Symbol for "SERIAL NUMBER". This symbol shall be accompanied by the manufacturer's serial number.
4		DATE OF MANUFACTURE. This symbol shall be accompanied by a date to indicate the date of manufacture.
5		Symbol for "MANUFACTURER". This symbol shall be accompanied by the name and the address of the manufacturer.
6		"WEEE (Waste Electrical and Electronic Equipment)". The waste devices should be handled legally.
7		Type BF Applied Part.

11. SAFETY, EMC & BIOCOMPATIBILITY REQUIREMENT

11.1 Safety requirement

The stimulator is Class II equipment to type BF applied part. It complied with Medical Electrical Safety Standards (IEC 60601-1, IEC 60601-2-10).

11.2 EMC requirement

K-fit 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. For more information, please refer to the tables 201,202,204 and 206.

Table 201: Guidance and manufacturer's declaration electromagnetic emissions

The KM518 product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should ensure that it is used in such an environment.

Emissions	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The KM518 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	The KM518 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.
Harmonic emissions IEC 61000-3-2 IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IHC 61000-3-3	Not applicable	


Table 202: Guidance and manufacturers declaration electromagnetic immunity

The KM518 product is intended for use in the electromagnetic environment specified below. The customer or the user of the 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	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at characteristic levels of a typical location in a typical commercial or hospital environment.

Table 204: Guidance and manufacturer's declaration electromagnetic Immunity

The KM518 product is intended for use in the electromagnetic environment specified below. The customer or the user of the KM518 product should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF	3 Vrms	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
IEC 61000-4-6	150 kHz to 80MHz 3 V/m	150 kHz to 80MHz	
Radiated RF IEC 61000-4-3	80 MHz to 2.5GHz	3 V/m 80 MHz to 2.5GHz	<p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$ $d = 2.3\sqrt{P} \quad 800\text{MHz to } 2.5\text{GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation Distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^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:</p> 

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 model KM518 is used exceeds the applicable RF compliance level above, the model KM518 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the model KM518.

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

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

The KM518 product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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 (m)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
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 metres (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.

NOTE1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a. MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.
- b. Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

11.3 Biocompatibility Requirements

The Nature of body contact is surface, vaginal mucosal membrane contact. And the contact duration is less than 24 hours. According to Initial evaluation tests for consideration in ISO10993-5 and ISO10993-10, the applicable biological effect is:

1. Cytotoxicity
2. Sensitization
3. Irritation or intracutaneous reactivity

