Manual of Electronic Pulse Stimulator

PL-029K8B
Operation Manual
PL-029K8B Edition V1.0

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Introduction

Electronic Pulse Stimulator delivers electric pulses generated to the user's skin through the electrodes. The portable and compact device has multiple modes of different pulse frequencies, covering Transcutaneous Electrical Nerve Stimulation (TENS) and Powered Muscle Stimulation (PMS). It includes operating elements of ON/OFF button, intensity increase/mode selection button, and intensity decrease/timer selection button, and could be attached and detached to the electrode through the two snap-on connectors.

Indications for Use

TENS

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities.

It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

PMS

To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks.

It is also intended to temporarily increase local blood circulation in the lower extremity.

Safety Warning

Contraindications

Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
Do not use this device on patients whose pain syndromes are undiagnosed.

Warnings

Do not apply stimulation over the patient's neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
Do not apply stimulation across the patient's chest, because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal.
Do not apply stimulation over, or in proximity to, cancerous lesions.
Do not apply stimulation when the patient is in the bath or shower.
If you have one of the following conditions, please consult with your physician before purchasing or using this device.
Acute disease, malignant tumor, infective disease, pregnant, heart disease, high fever, abnormal blood pressure, lack of skin sensation or an abnormal skin condition, any condition requiring the active supervision of a physician.

Precautions

Do not use this device while driving.
Do not use this device while sleeping.
Do not use this device in high humidity areas such as a bathroom.
Keep the device away from wet, high temperature and direct-sunlight place.
Keep this device out of reach of children.
Stop using this device at once if you feel pain, discomfort, dizziness or nausea and consult your physician.
Do not attempt to move the electrode pads while the device is operating.
Do not use the device around the heart, on the head, mouth, pudendum or blemished skin areas.
Do not apply stimulation of this device in the following conditions:
(1) across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal;
(2) over painful areas. Please consult with your physician before using this device if you have painful areas;
(3) over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins). Apply stimulation only to normal, intact, clean, healthy skin;
(4) in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms). The electronic Stimulator may not operate properly when the electrical stimulation device is in use;
(5) while operating machinery, or during any activity in which electrical stimulation can put you at risk of injury;
(6) on children.
Be aware of the following.
(1) to consult with your physician before using this device. The simulation with the device may:
    i. cause lethal rhythm disturbances to the heart in susceptible individuals, and,

ii. disrupt the healing process after a recent surgical procedure;
(2) that the device is not effective for pain of central origin, including headache;
(3) that the device is not a substitute for pain medications and other pain management therapies;
(4) that the device has no curative value;
(5) that the device is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism;
(6) that the long-term effects of electrical stimulation are unknown;
(7) that the user may experience skin irritation, burns or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel);
(8) if the user has suspected or diagnosed epilepsy, the user should follow precautions recommended by his or her physician;
(9) to use caution if the user has a tendency to bleed internally, such as following an injury or fracture;
(10) use caution if stimulation is applied over the menstruating uterus;
(11) use caution if stimulation is applied over areas of skin that lack normal sensation;
(12) stop using the device if the device does not provide pain relief; and,
(13) use this device only with the leads, electrodes, and accessories that the manufacturer recommends.
(14) Do not share the use of the electrode pads with others.
(15) Do not use the device while it's charging.
(16) The device contains the lithium battery. If overheating of the device occurred during the charging, stop the charging or operation immediately and report to the distributor/seller.
(17) Dispose of the battery-containing device according to the local, state, or federal laws.

The long-term effects of electrical stimulation are unknown.
Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.
The safety of electrical stimulation during pregnancy has not been established.
Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians.
Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
Use caution if stimulation is applied over the menstruating or pregnant uterus.

Adverse Reactions
Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin;
Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.
Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

Environmental condition for transport and storage
- Normal working ambient temperature: 10~40°C
- Normal working ambient humidity: 30~80%
- Store and transport ambient temperature: -10 ~50°C
- Store and transport ambient humidity: 30~90%

Symbols interpretation

	Fragile, handle with care		Type BF applied part
	Keep the product in the dry place Away from water and rain.		CAUTION, Avoid injury. Read and understand owner's manual before operating this product.
	This way up		Manufacturer
	Product package should be recycled.	EC REP	Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"
	Unrecyclable	CE 0120	CE marking, Certificate issued by SGS.
	Date of manufacture	FDA APPROVED	FDA register
SN	Serial number	IP22	IP code of the device
LOT	Batch code		

The Electronic Pulse Stimulator is compliant with:

- Medical Devices Directive 93/42/EEC
- IEC 60601-1:2005+A1:2012/EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-10:2012/EN 60601-2-10:2000+A1:2001 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle simulators

Electromagnetic Compatibility and FCC Compliance Statement

(1) This product needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile radio frequency (RF) communications equipment.

(2) Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.

(3) Caution: This unit has been thoroughly tested and inspected to assure proper performance and

operation!
(4) Caution: This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used

Guidance and manufacturer's declaration – electromagnetic emission		
The device *is* intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The device 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 emission CISPR 11	Class B	The device 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 floor 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	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
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 5 sec	<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 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 V_{rms} 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

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

The subject device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

The product generates, uses, and can radiate radio frequency energy and, if not installed and used accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that the interference will not occur in a particular installation. If the product does cause harmful interference to radio or television reception, which can be determined by turning the product on or off, the user is encouraged to try to correct the interference by one or more of the following measures:

a) Reorient or relocate the receiving antenna;
b) Increase the separation between the product and the receiver;
c) Consult the dealer or an experienced radio / TV technician for help.
d) Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Changes or modifications to this product not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

RF warning statement:

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Product Specifications

Accessories included in the package.
(1).Accessories included in the package.
(2).Tens unit controller * 1pc
(3).Large, medium, small gel pads * 3pcs
(4).4*4 cm gel pads * 4pcs
(5).USB line *1pc
(6).Output wire * 1pc
(7).Storage bag * 1pc

Controller introduction

+ Intensity increase and mode change
⏻ On/Off
– Intenstiy decrease and timer change
● Light indicator

Technical Information

Device name	Electronica pulse stimulator	Dimensions	35*68*11.5mm
Model/type	PL-029K8B	Weight	19g
Power supply	Powered by internal3.7V li-ion battery	Automatic shutoff	30 minutes
Waveform and wave shape	Biphasic rectangular wave pulse	Degree of protection against electric shock	Type BF applied part
Pulse duration	50-500us (Microseconds)	Type of protection against electric shock	Internally powered equipment

Pulse frequency	1-500 Hz (Hz=vibration per second)	Grade of waterproof	IP22
Output Voltage	Max. 80Vpp ±20%(at 500ohm load)	Product life	1 year
Treatment time	10 min, 20 min, 30 min, 40 min, 50 min, 60 min,90 min, 120 min,540 min	Lifetime for electrode	Storage for 1 year（no use）, Times of reusable: 30 times
Output intensity	0 to 100 levels, adjustable	Mode of operation	Continuous operation
Modes	8 auto modes and 1 manual mode	Software version	A0
Note: Not intended to be sterilized. Not for use in an OXYGEN RICH ENVIRONMENT			

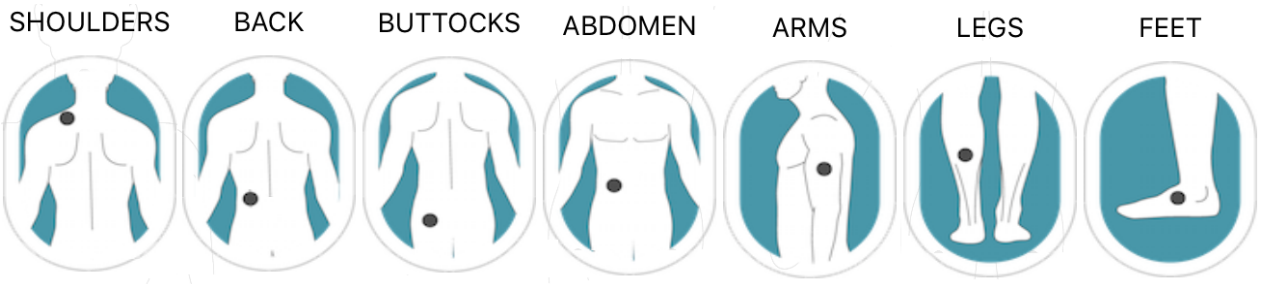
Product Programs

Program name	Time min.	Frequency (Hz)	Pulse Width (μs)
Mode 1	10,20,30,40,50,60,120,540	62.5，12.5-55.5，1.2，100，100，20,160	100
Mode 2	10,20,30,40,50,60,120,540	62.5	100
Mode 3	10,20,30,40,50,60,120,540	12.5-55.5	100
Mode 4	10,20,30,40,50,60,120,540	1.2	100
Mode 5	10,20,30,40,50,60,120,540	100	100
Mode 6	10,20,30,40,50,60,120,540	100	100
Mode 7	10,20,30,40,50,60,120,540	20	100
Mode 8	10,20,30,40,50,60,120,540	160	100

Setup

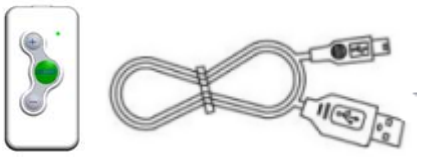
Unpack the box of the product, take the product and accessories out, and connect the electrode pad onto the device. There are large, medium, and small size gel pads suitable for different body position. For example, large size gel pad is suitable for back and waist, medium size gel pad for shoulder and neck, the small size gel pad for joints. If you'd like to use the gel pad on a small and specific body position, you can use the 4*4CM gel pads and you need to connect the gel pad with the controller by the output wire with four snappers.

Recommended Use Positions



Operating instruction

The following steps are used to guide the device operation, and the details about each step are listed in the following table.

1st Step – Check the battery power for the Electronic Pulse Stimulator	 Battery charging
The Electronic Pulse Stimulator comes with a built-in rechargeable battery, and could be used as received. If the control unit has a flashing LED light when turned on, it means the battery is running out of power. Turn off and charge the control unit with the enclosed USB cable. The LED light is flashing during charging, and becomes solid when the control unit is charged fully.	
2nd Step - Install the electrode pad onto the Electronic Pulse Stimulator	 Electrode pad installment
The electrode pad has two snap-on male connectors, and the Electronic Pulse Stimulator has two snap-on female connectors on its back side. Snap the enclosed electrode pad onto the Electronic Pulse Stimulator through the snap-on connectors. This should be done prior to applying the device onto the skin of treatment areas.	
3rd Step - Put the electrode pad-installed Stimulator on the stimulation-needed body area	 Place the device on the body area
Place the pad-installed device onto the treatment areas (such as shoulder and leg). Press down firmly and ensure a full and firm contact with skin. **Note:** Keep the skin clean before placing the pads	
4th Step - Press the "ON/OFF" to turn on the power	On/0ff
Press the On/Off button to turn on the unit.	
5th Step - Select one of the stimulation modes	 Intensity Increase and Mode Change
Change the output stimulation modes by pressing the + button for 3 seconds.	
6th Step - Choose the stimulation time	

Press the - button for 3 seconds to change the stimulation time.	Intensity Decrease and Timer Change
7th Step - Adjust the stimulation intensity Press and release the "+" button to increase the stimulation intensity, and press and release the "-" button to decrease the intensity. **Note:** With the increase of intensity, you may experience sensations like tingling, vibration, etc. Therefore, gradually increase the intensity, and stop increasing when a comfortable level is reached.	 Intensity selection
8th Step - Stay with the stimulation Enjoy the stimulation provided by the device, after the above mode, time, and intensity were set up.	 Stay with the stimulation
9th Step - Press the "ON/OFF" to turn off the power after done When the timer is up, the device will turn off automatically. The device could be also turned off by pressing the On/Off button. **Note:** When not in use, store the device and accessory in a cool place, out of direct sunlight.	 On/0ff

As shown in the above device operation, the biocompatible electrode, consisting of electrode gel, carbon film, backing material, and snap-on connectors, is used with the device as the accessory. Please see the following for the Use Directions, Removal, and Storage for the electrode.

Directions for Use

- Clean skin thoroughly prior to each application of electrodes, which will not stick well if any lotion, make-up, or dirt is left on the body skin.
- Turn the Electronic Pulse Stimulator off before applying the electrode to the body skin.
- Install the pad included onto the back side of the Electronic Pulse Stimulator.
- Apply the pad-installed device firmly to the skin.
- To choose suitable size gel pad for different body position.

Removal and Storage

- Turn the device off before removing the electrode from the body skin.

- Lift at the edge of the electrode and peel.
- When not in use, store the electrode in the re-sealable bag in a cool place, out of direct sunlight and dirty.

Recommended practice:

- Duration suggested for each skin area is 20 min and 2 times per day. Consult with your physician for longer and more frequent uses.
- Start from the lowest intensity and gradually adjust the intensity to a comfortable level at a scale from 1 to 100.
- Good skin care is important for a comfortable use of device. Be sure the treatment site is clean of dirt and body lotion.
- Keeping the electrode in the storage bag after use will extend its lifespan. The electrode is disposable and should be replaced when it loses the adhesiveness. To purchase additional electrodes, please contact the seller.

APP application

Download the APP.
(1). Make sure your smart phone is above Bluetooth 4.0 version. This APP can only be applied to the phone with Bluetooth version above 4.0.

(2).When you search **"TENS+EMS"** in the App Store and Google Play, you will find the APP icon as below, download it and install it to your phone.

If the optional accessory of the phone application interface was provided, the Quick Response (QR) code would be included in the packaging. The user could directly use the remote and/or just scan the code for automatic installation.

(3). After the App is installed, the icon will show  on the phone.

Introduction of the APP

Application interface

Icon on the Phone Application Interface	Indication
	Timer icon to change the countdown timer
	Icon to stop and exit the operation of the device
	Icon for useful information, such as warnings
	Intensity bar to increase and decrease the intensity
	Mode icon to select one of the modes displayed on the LCD
	Icon to pause and resume the operation of the device

Use the APP
(1).Manual has to be read before using the APP. Make sure you have understood all the warnings.

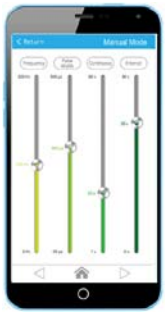
(2).Snap the gel pad on the controller and turn the TENS unit on before open the APP.

(3).Click the App icon to open the App, you will be reminded to open Bluetooth first.
Once the blue tooth is opened, the app will automatically connect to the TENS unit which has been turned on. The Tens unit controller will make buzz after successfully connected with the APP.

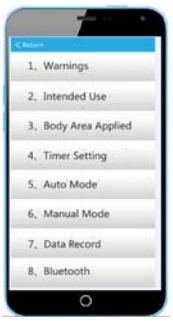
Note: If the App did not connected automatically, please click the upper right corner to access the BLUETOOTH section to scan the TENS unit for the connection. Click "Connect" as below.

(4). Slightly sliding the intensity bar on the phone application interface could increase the intensity of the Electronic Pulse Stimulator, and sliding the intensity bar in the other direction could decrease the intensity. The corresponding intensity will display on the App interface. And the user will feel the stimulation on the treatment body area. Remember always increase the intensity bar very slightly.

(5).The initial mode is auto mode 1, if you'd like to change to other modes, press  , there will be 8 modes for selection. Remember every time you change one mode to another mode,the intensity will start from level 0, you have to increase the intensity for the new selected mode. This design aims not to make people feel shocked when they change to a new mode.

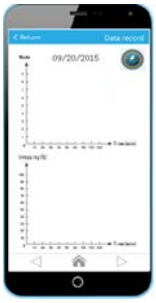


(6).If you are interested to try more modes, you can use the manual modes by setting different frequencies, pulse widths, continuous and intervals, there will be more modes to be created. You can find the one you like. Or you can consult your physician what is the best setting for you.



(7).Click the SETTINGS in the upper right corner of the main App interface to view the related information, such as Warnings, Intended Use, and Body Area Applied, and change the parameters, such as Timer, Auto Mode, and Manual Mode. By clicking the  icon on the phone application interface could pause the device; click it again to resume.

(8). The following information could be viewed when the user clicks Warnings, Intended Use, and Body Area Applied, respectively.



(9). The recorded pulse mode, Intensity, and Time could be viewed when the user click "Data Record".

(10). The Bluetooth page will display the TENS device connected to the App.

(11). When done, turn off the Electronic Pulse Stimulator and exit the phone application interface, and put them away for the next use.

Note: In addition to using the App to control the TENS device, the device could be operated independently and also control the App, as follows.

- Press and release the + button to increase the intensity
- Press and release the - button to decrease the intensity
- Hold the + button to change the mode
- Hold the - button to change the timer
- Hold both the + and - buttons to pause/resume the device.

Note: It is suggested to use the wireless control in an operating distance of 3 meters with the device. At any distance and time, you could switch to operate the device itself independently to deal with any risks and problems that may arise.

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Cleaning and maintenance

Please use the moisturized cloth of water or neutral detergent to clean the device first, and then use the dry cloth to wipe it again. The electrode pads coming with the device are disposable, and should be replaced when their adhesiveness becomes worse. Contact the seller for replacements. Do not let the sticky side of the pad touch anything, including the greasy finger tips.

Disposal

You will find these markings on batteries containing harmful substances: Pb= battery containing lead, Cd= battery containing cadmium, Hg = battery containing mercury. Please dispose of the device in accordance with the directive 2002 / 96 / EC–WEEE (Waste Electrical and Electronic Equipment). If you have any queries, please refer to the local authorities responsible for waste disposal.

NOTE: You will find these markings on batteries containing harmful substances: Pb=battery containing lead, Cd = battery. containing cadmium, Hg = battery containing mercury.

Disposal of battery
Spent batteries do not belong in the household waste. Dispose of the battery according to the current regulations. As a consumer, you are obligated by law to return spent battery to the Recycle Bin.

Please dispose of the device in accordance with the directive 2002/96/EC – WEEE (Waste Electrical and Electronic Equipment). If you have any queries, please refer to the local authorities responsible for waste disposal.

Trouble Shooting

If your device is not operating properly, please check below for common problems and suggested solutions. If the recommended action does not solve the problem, please contact the seller.

Stimulation is weak or non-existent

- Be sure skin is clean and pads are firmly attached to skin.
- The battery is low and needs to be charged.

Devise does not turn on

- Check if battery is low and needs to be charged.

Electrodes are not sticky

- The pads will lose adhesiveness over use. Please contact the distributor or dealer for replacements.

Skin turns red

- Stop to treat another area.
- If problem persists, contact your physician.

Wireless control not connected

- Restart the device and wireless controller to re-connect automatically.
- Switch to operate the device itself manually.

Manufacturer：

JKH Health Co., Ltd.
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