

Wireless TENS&EMS&NMES Heating Stimulator Model: SM9125

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Limited.

User Manual

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Contents

Content

Foreword	3
1. SAFETY GUIDE	3
1.1 Warnings	3
1.2 Precautions	4
1.3 Contraindications	5
1.4 Adverse Reactions	6
1.5 Special Population	6
1.6 Intended Use / Indications for Use	6
2. DEVICE DESCRIPTION	7
2.1 General Description	7
2.2 Device Drawing	7
2.3 Specifications	12
3. INSTRUCTION OF USE	16
3.1 Preparation before use Step 1: Charging	16
3.2 Treatment site guidance	19
3.3 Electrode Pads Guideline	20
4. CLEANING AND MAINTENANCE	21
5. TRANSPORT AND STORAGE	21
6. TROUBLE SHOOTING	22
7. DISPOSAL	22
8. WARRANTY CARD	23
9. LABEL SYMBOLS	24
10. EMC DECLARATION	25

Foreword

Thank you very much for your purchase of Wireless TENS&EMS&NMES Heating Stimulator. Before using the device, please read the User's manual carefully and pay attention to the SAFETY GUIDE, so that you can operate it correctly for best results. The User's manual should be kept for your future reference.

1. SAFETY GUIDE

Please read the entire instructional manual before using the Wireless TENS&EMS&NMES Heating Stimulator. It will give you a better understanding of how the product works. If you are not sure which kind of medical condition, you should preclude yourself from using this device, consult your Chiropractor, Physiotherapist, Osteopath or Medical practitioner.

1.1 Warnings

- The patient should be the intended operator.
- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied transcerebrally.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- This device must not be used on persons with cardiac pacemakers, implanted defibrillator, other implanted metallic or electronic devices. Such use could cause electric shock, burns, electrical interference, or death.
- The device may cause lethal rhythm disturbances in certain susceptible individuals.
- MR Unsafe – keep away from magnetic resonance imaging (MRI) equipment.
- Implanted with a life-supporting medical electronic device such as an artificial heart or lung or respirator.
- In the presence of electronic monitoring equipment (e. g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- Over areas of damaged skin, scratched areas or blisters.
- Do not apply the pads to your head, face, the front and sides of the neck, the throat, or on both sides of the thorax at the same time.
- Do not share electrode pads with another person. This may cause a skin irritation or skin infection. Individuals should have their own set of pads for personal use.
- Do not leave pads attached to the skin after treatment.
- Do not use the unit in the presence of a flammable anesthetic gas mixture, compressed Oxygen or Nitrous Oxide.
- If the unit is not functioning properly or you feel uncomfortable during use, stop using the device.
- Do not use for any other purpose except for what it is intended for.
- Do not use the device while wearing other electronic devices as this may damage the device.
- Please keep the device from the reach of infants, children or pets, inhalation or swallowing of small parts is dangerous and can be potentially fatal.
- If you are allergic to plastic, please don't use this device.
- Long cables have the potential to strangulate, therefore, please be careful when using cables around the neck and shoulder areas.
- Do not bend or pull the end of the cord.
- Do not use the device in the presence of the following:
 - a. When there is a tendency to hemorrhage following acute trauma or fracture.
 - b. Following recommendation of doctor after surgery because stimulation may disrupt the healing process.
 - c. Do not use if you are pregnant.
 - d. Over areas of the skin that are damaged, cut, with rash or blistered.

- Do not throw the batteries into fire. The batteries may explode.
- The safety system for pregnancy to use electrical stimulation has not been established; Do not use the stimulator during the pregnancy.
- If you have diagnosed heart disease or have any heart problem, you should follow precautions recommended by your physician.
- If you have suspected or diagnosed epilepsy, you should follow precaution recommended by your physician.
- Do not directly Stimulate over the front of your neck or mouth. This could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Do not place pads directly over the heart. Electrical current into the heart may cause cardiac arrhythmias.
- TENS is not a substitute for pain medications and other pain management therapies.
- TENS devices have no curative value.
- TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
- Do not use over areas of skin that lack of normal sensation.
- Trans thoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Please use the rated voltage required by the product label. If the supply voltage is lower than or higher than the additional input voltage, the product will not work properly.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Wireless TENS&EMS&NMES Heating Stimulator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The replacement of lithium batteries by inadequately trained personnel could result in hazard.

DO NOT USE THIS DEVICE DURING THESE ACTIVITIES

- When in the bath or shower;
- The device should not be used while asleep or if intending on falling asleep while treatment is still occurring.
- You have open wounds, rashes, swollen, red, infected or inflamed areas or skin eruptions; (e. g., phlebitis, thrombophlebitis, varicose veins); On top of, or in proximity to, cancerous lesions.

1.2 Precautions

- No special training is required to use this device. However, users must have independent reading comprehension and read this manual before using this device
- Consult with your physician before using this device.
- Safety of the device for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following:
 - a. When there is a tendency to hemorrhage following acute trauma or fracture;
 - b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
 - c. Over the menstruating or pregnant uterus; and
 - d. Over areas of the skin which lack normal sensation.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using

- an alternate conductive medium, or alternate electrode placement.
- The device should be kept out of the reach of children.
- The device should be used only with the leads and electrodes recommended for use by the manufacturer.
- The device should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
- If you feel abnormal symptoms during the treatment, please stop using the unit and consult a doctor before resuming treatment.
- Against servicing and maintenance while the ME EQUIPMENT is in use
- During the treatment, if you wish to move the electrodes to another part of your body, switch OFF the unit first, and then move the electrodes before resuming treatment.
- If you have any problems on setting, maintaining or using this device, please contact manufacturer or customer service. Please report to manufacturer if the device malfunctions. Don't open or repair the device by yourself.
- If damage is found to the device casing, please do not use the device and contact the manufacturer.
- Cotton, wool and dust may affect the performance of the unit, please use a soft cloth to clean the device as needed.
- Do not place the device in direct sunlight to avoid affecting its performance.
- Please use the device according to the requirement of the Users' manual, otherwise the effectiveness of the device will be affected.
- Please use accessories that are specified/authorized by manufacturer only. The use of unauthorized accessories may cause damage to the unit or danger to the operator/patient.
- Use/storage environment, cotton wool, dust, lighting (including sunlight) and other effects on the equipment
- Do not bend or fold the pads frequently, this may cause the pads to not function properly. Store the pads on the plastic pad holder or on the protective clear plastic sheet when not in use.
- Do not use the unit in areas of high humidity, such as the bathroom or in the shower as this may cause damage to the unit.
- During treatment ensure that metallic items with conductive capabilities such as necklaces, belts, rings etc. are kept away from the electrodes.
- Make sure the wire is securely plugged into the device, the wires are well connected, and the pads are stuck tightly on the skin area where you wish to treat to ensure effective therapy. Loose pads on the skin can cause uncomfortable pins and needle sensations.
- Replace the cord when it was broken or damaged.
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrically conductive medium (gel).
- Electrode placement and simulation settings should be based on the practitioner.
- Should be used only with the leads and electrodes recommended for use by the manufacturer.
- Should not use while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
- Do not use to treat one region for extended periods of time (more than 40 minutes a session, up to 3 times/day) or muscles in that region may become exhausted and sore.
- Before operation, ensure that the electrode gel is in good contact with the skin. Improper attaching to the motor may cause excessive local current density.

WARNINGS AND PRECAUTIONS REGARDING THE PADS

- Apply pads to normal, healthy, dry clean skin only. Do not apply pads onto wound or damaged skin because it will be painful and may disrupt the healing process.
- If you experience any skin irritation or redness after using this device, do not continue stimulating in that area until skin has returned to normal.
- Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

1.3 Contraindications

For the following patients, they should not use the device:

- Patients who have a cardiac pacemaker, implanted defibrillator, or other implanted

metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

- Patients whose pain syndromes are undiagnosed.
- During pregnancy.
- Infants or young children.
- Those who cannot express themselves.

1.4 Adverse Reactions

- You may experience skin irritation and burns beneath the stimulation electrodes applied to the skin.
- You should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

Note:

Adverse Event Report

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is NOT required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from the FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

1) Report Online at

www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

2) Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf

3) Call FDA at 1-800-FDA-1088 to report by telephone

a) Reporting Form FDA 3500 commonly used by health professionals. The form is available at www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf

1.5 Special Population

This device should not be used by patients with:

- Pacemakers, Defibrillators or extreme Cardiac Irregularities, Metals Implants or Electronic Auxiliary Devices
- Tendency toward internal Bleeding
- Epilepsy
- Pregnant Women

1.6 Intended Use / Indications for Use

The device (SM9125) is used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, leg and feet, due to strain from exercise or normal household and work activities and also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis, temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over the-counter pain medication for mode 3 of model SM9125.

EMS/NMES:

The device (SM9125) is used to stimulate healthy muscles in order to improve and facilitate

muscle performance.

To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, feet and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

2. DEVICE DESCRIPTION

2.1 General Description

Wireless TENS&EMS&NMES Heating Stimulator is pain management device with a combination of TENS and EMS/NMES therapy technology.

TENS: The electrodes placed on the skin send small-scale, low-voltage electrical pulses to specific nerves. The purpose is to change the way neurons send signals and prevent pain signals from reaching the brain to relieve pain.

EMS/NMES: A powered muscle stimulator for muscle conditioning is a device used for other than medical purposes to apply an electrical current to electrodes on a person's skin to temporarily affect the stimulated muscle's contractile properties, force output, and/or fatigue resistance. This device is not intended for use in patients with medical conditions and is intended only for muscle conditioning purposes.

Model SM9125 has eight modes, each with 19 output intensities that can be adjusted. Model SM9125 is equipped with output main unit, high-end remote control, lower-end remote control, electrode pads and charging cable. For details, please refer to the accessory list. The main unit has three buttons, for turning on/off the device, controlling the mode selection and output intensity. The low-end remote control and high-end remote control has four buttons, for turning on/off the device, controlling the mode selection and output intensity. One remote control can simultaneously control four main units.

2.2 Device Drawing

2.2.1 Components and Accessories List for all package is as below:

For model SM9125:

Item	Components	Function
Main Unit		The main unit have three buttons, for turning on/off the device, controlling the mode selection and output intensity. The main unit have indicator lights to show selected mode, intensity, charging status and pairing status. There is a pair of magnetic clasps on the back of the device, which are used to connect the electrode pads to output current. In addition, there is a charging contact point for charging.

Low-end remote control		There are four control buttons for turning on/off the device, controlling the mode selection and output intensity, treatment time.
High-end remote control		There are four control buttons for turning on/off the device, controlling the mode selection and output intensity. The selected mode and the remaining treatment time will be displayed above the remote control. In addition, there is a charging contact point for charging.



Patch electrode pad Size:		The big electrode pad is used to connect the main unit and stick it to the human body for stimulation output. The electrode pad should be directly connected to the main unit.
Waist electrode pad Size:		The waist electrode pad is used to connect the main unit and stick it to the human body for stimulation output. The electrode pad should be directly connected to the main unit.
Foot electrode pad Size:		The foot electrode pad is used to connect the main unit and stick it to the human body for stimulation output. The electrode pad should be directly connected to the main unit.
Charging cable		The USB cable is used to connect the remote control or main unit and the power grid to charge main unit and remote control.
Use Manual	/	/

2.2.2 Device Components



Fig. 2-1 Part Description of Main Unit

EXPLANATION	
Item	Function
①	Intensity indicator light: ● Indicate the selected intensity: The device has a total of 19 intensity levels, and each intensity level has a corresponding intensity indicator light. When a certain intensity level is selected, the corresponding intensity level indicator light will turn green. ● Indicate low battery level: When the battery power is $\leq 3.2+0.1V$, the intensity indicator light shows "1E", and the main unit is turned off approximately 10 seconds later.
②	Mode indicator light: ● Indicate the selected mode: The device has a total of 8 modes, and each mode has a corresponding mode indicator light. When a certain mode is selected, the corresponding mode indicator light will turn green. ● Indicate the charging status: When charging, eight indicator lights show a green light in the form of flowing water. After full charging, all indicator lights are constantly green.
③	+ button: ● Increase intensity: Each short press of the button increases the intensity by one level after the main unit is turned on (The maximum level of intensity is 19).
④	- button: ● Decrease intensity: Each short press of the button decreases the intensity by one level after the main unit is turned on. (The minimum level of intensity is 0). ● Enter the pairing state: Press this button for more than 6 seconds to enter the pairing status after the main unit is turned on. After entering the pairing state, if the connection is successful, it will automatically exit the pairing state (if it is not connected, turn off the main unit can exit the pairing).
⑤	M button: ● Turn on/off the main unit: Press the button for 2 seconds to turn on the main unit; Press the button for 2 seconds to turn off the main unit when the main unit is turned on. ● Select mode: Press the button briefly 1-8 times to cycle through available Mode 1-8.
⑥	Charging port: Plug in the cable to charge the device.
Please note: ● When the device is paired, all indicator lights will turn green and flash at intervals of 500ms to indicate a prompt. Once pairing is successful, they will flash rapidly at intervals of 100ms for 800ms to indicate a prompt.	

2.2.3 Low-end remote control

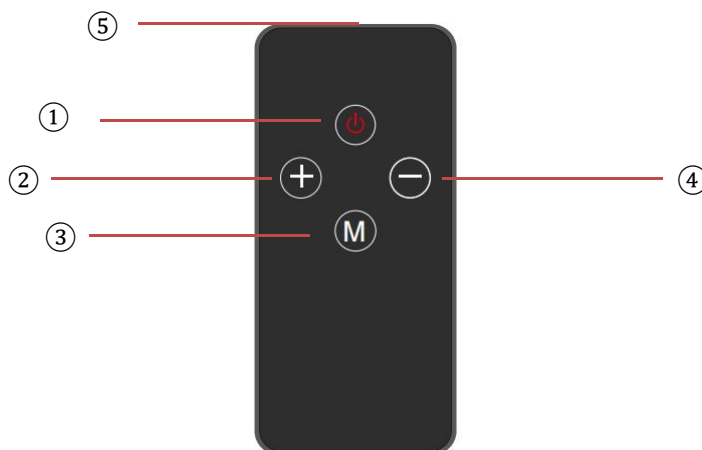


Fig. 2-2 Part Description of low-end remote control

EXPLANATION

Item	Function
①	Power button: Pressing this button can turn on or off the low-end remote control. Please note that when paired, when both the main unit and the remote control are on, pressing this button will turn off both the remote control and the main unit together.
②	Intensity increase button: Pressing this button can increase the output intensity. Each press increases the intensity by one level.
③	Mode selection button: Press the button 1-8 times to cycle through available Mode 1-8.
④	Intensity decrease button: - Pressing this button can decrease the output intensity. Each press decreases the intensity by one level. - Press and hold this button for more than 2 seconds. The low-end remote control will enter the pairing state. After entering the pairing state, if the connection is successful, it will automatically exit the pairing state (if it is not connected, turn off the low-end remote control or press again the button for 2 seconds can exit the pairing).
⑤	Indicator light: - Indicate pairing status: When the low-end remote control is in pairing status, the indicator light flashes red as a prompt. - Indicate buttons have been pressed: When the four buttons are pressed, the indicator light will flash red for a moment.

2.2.4 High-end remote control



Fig. 2-3 Part Description of Storage bin

EXPLANATION

Item	Function
①	Intensity decrease button: - Pressing this button can decrease the output intensity. Each press decreases the intensity by one level. - Press and hold this button for more than 6 seconds. The high-end remote control will enter the pairing state. After entering the pairing state, if the connection is successful, it will automatically exit the pairing state (if it is not connected, turn off the high-end remote control can exit the pairing).
②	Intensity increase button: Pressing this button can increase the output intensity. Each press increases the intensity by one level.
③	Power button: Pressing this button can turn on or off the high-end remote control. Please note that when both the main unit and the remote control are on, pressing this button will turn off both the remote control and the main unit together.
④	Heating level button: Because the model has no heating function, the device does not respond when pressing this button.

⑤	HOT indicator light: Press the heating level button, and this indicator light will turn green, indicating that the heating level is being adjusted. However, this model does not have a heating function.
⑥	LEVEL indicator light: Press the intensity decrease button or intensity increase button, and this indicator light will turn green, indicating that the output stimulus intensity level is being adjusted.
⑦	Intensity indicator light: The device has a total of 19 intensity levels, and each intensity level has a corresponding intensity indicator light. When a certain intensity level is selected, the corresponding intensity level indicator light will turn green.
⑧	Mode indicator light: - Each of the six modes has a corresponding indicator light. When a certain mode is selected, the indicator light next to the mode will turn green. - Indicate the charging status: When charging, mode indicator lights 1 to 6 show a green light in the form of flowing water. After full charging, all indicator lights are constantly green. - Indicate the pairing status: When pairing, all indicator lights will flash at intervals of 500ms to indicate a prompt. Once pairing is successful, they will flash rapidly at intervals of 100ms for 800ms to indicate a prompt.
⑨	Charging port: Plug in the cable to charge the high-end remote control.
Please note: When in the pairing state, the all indicator lights will turn on green and flash at intervals of 500ms. After a successful pairing, the all indicator lights will flash rapidly intermittently for 100ms and then flash for 800ms as a prompt before going out.	

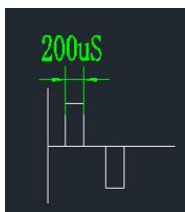
2.3 Specifications

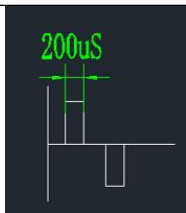
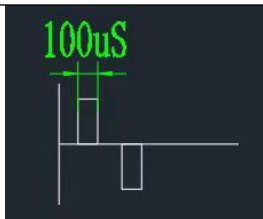
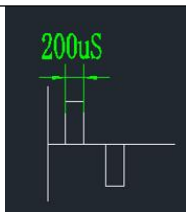
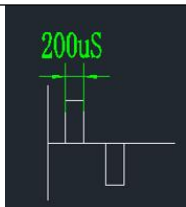
Specification		
Device Name		Wireless TENS&EMS&NMES Heating Stimulator
Model		SM9125
Power Source(s)		Main unit: 3.7V, 120mAh High-end remote control: 3.7V, 180mAh Low-end remote control: 3V
Number of Output Channels		1
Synchronous or alternating		Synchronous
Regulated Current or Regulated Voltage		Regulated Voltage
Software/Firmware/Microprocessor Control?		Software, V1.0
Automatic Overload Trip?		No
Automatic No-Load Trip?		Yes
Automatic shut Off?		Yes
Indication display	ON/Off status?	Yes
	Low Battery?	Yes
	Voltage /Current Level?	Yes
Number of Output Modes		For stimulation: 8 modes
Output Intensity Level		For stimulation: 19 levels
Timer Range		20minutes
Weight		Main unit: 17g±2g High-end remote control: 27.7g±2g Low-end remote control: 12g±2g

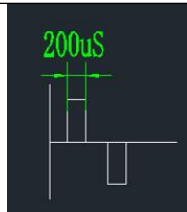
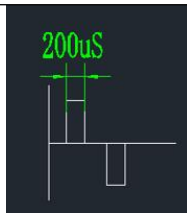
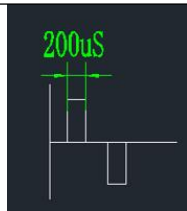
Dimension			Main unit: φ48.5*12.5
Electrode Surface Area			Patch electrode pad:107mm*59mm Waist electrode pad:27cm*20cm Foot electrode pad: 31.5cm*28.5cm
Housing Materials and Construction			Main unit: ABS Patch electrode pad: conductive hydrogel Waist electrode pad: conductive silicone rubber Foot electrode pad: conductive carbon paste
Durable period (Service Life)			Main unit: 2 years High-end Remote controller, Low-end remote control: 2 years Electrode pads: 30-50 times (The life of the electrodes varies depending on skin conditions, storage, amount of use, type of stimulation, and stimulation site.)
Shelf life			Electrode pads: 2 years
Waveform and Shape			Rectangular
Maximum Output Voltage	@500Ω	TENS :42V EMS: 42V NMES: 42V Dysmenorrhea: 37V	
	@2KΩ	TENS :60V EMS: 56V NMES: 56V Dysmenorrhea: 56V	
	@10KΩ	TENS :62V EMS: 61V NMES: 61V Dysmenorrhea: 62V	
Maximum Output Current	@500Ω	TENS :84mA EMS: 84mA NMES: 84mA Dysmenorrhea: 74mA	
	@2KΩ	TENS :30mA EMS: 28mA NMES: 28mA Dysmenorrhea: 28mA	
	@10KΩ	TENS :6.2mA EMS: 6.1mA NMES: 6.1mA Dysmenorrhea: 6.2mA	
Pulse Duration			TENS: 200μs EMS: 200μs NMES: 200μs Dysmenorrhea: 100μs
Pulse frequency			TENS: 8~45Hz EMS: 20~75.7Hz NMES: 8~66.6Hz Dysmenorrhea: 100Hz
Maximum Phase Charge (μC @ 500Ω)			TENS: 16.8μC@ 500Ω EMS: 16.8μC@ 500Ω

	NMES: 16.8 μ C@ 500 Ω Dysmenorrhea: 7.4 μ C@ 500 Ω
Maximum Current Density (mA/cm ² @ 500 Ω)	TENS: 1.819mA/cm ² @ 500 Ω EMS: 1.819mA/cm ² @ 500 Ω NMES: 1.819mA/cm ² @ 500 Ω Dysmenorrhea: 1.602mA/cm ² @ 500 Ω
Maximum Average Power Density (mW/ cm ² @ 500 Ω)	TENS: 0.0247mW/ cm ² @ 500 Ω EMS: 0.0700mW/ cm ² @ 500 Ω NMES: 0.0542mW/ cm ² @ 500 Ω Dysmenorrhea: 0.0237mW/ cm ² @ 500 Ω
Operation Environment	Temperature: 5 $^{\circ}$ C~40 $^{\circ}$ C Humidity: $\leq$ 80% RH Atmospheric pressure: 80 kPa~106 kPa
Storage Environment	Temperature: -20 $^{\circ}$ C~+55 $^{\circ}$ C Humidity: $\leq$ 93%RH Atmospheric pressure: 50 kPa~106 kPa
Specification of RF Wireless:	
Communication methods	user-defined protocol
Working Frequency	2.4GHz
Modulation	FSK
Transfer rate	1Mbps
Transmission power	-2.2dBm
Working voltage	3V
Operating distance	10m
Delay	$\leq$ 100ms

Treatment Modes Specification

Waveform 8 modes			
Mode 1 (TENS)			
Pulse duration:	200μs	Maximum Amplitude of output voltage:	42V @ 500Ω
Pulse Frequency:	45Hz		
Basic Waveform:			
Output of Mode 1	Outputting basic waveform for 28 seconds at a frequency that gradually increased from 8Hz to 19.1Hz and then decreased to 8Hz, pause the stimulation for 1.4 seconds. Output stimuli according to the above cycle until the scheduled treatment time is reached.		
Mode 2 (TENS)			
Pulse duration:	200μs	Maximum Amplitude of output voltage:	42V @ 500Ω
Pulse Frequency:	45Hz		

Basic Waveform:			
Output of Mode 2	Outputting basic waveform for 11.2 seconds, pause the stimulation for 3.3 seconds. Output stimuli according to the above cycle until the scheduled treatment time is reached.		
Mode 3 (Treat dysmenorrhea)			
Pulse duration:	100µs	Maximum Amplitude of output voltage:	37V @ 500Ω
Pulse Frequency:	100Hz		
Basic Waveform:			
Output of Mode 3	Continuously output the basic waveform without any pause time in between. Output stimuli according to the above cycle until the scheduled treatment time is reached.		
Mode 4 (EMS)			
Pulse duration:	200µs	Maximum Amplitude of output voltage:	42V @ 500Ω
Pulse Frequency:	37.3Hz		
Basic Waveform:			
Output of Mode 4	Outputting basic waveform for 1.6 seconds, pause the stimulation for 1.2 seconds. Output stimuli according to the above cycle until the scheduled treatment time is reached.		
Mode 5 (EMS)			
Pulse duration:	200µs	Maximum Amplitude of output voltage:	40V @ 500Ω
Pulse Frequency:	57.3Hz		
Basic Waveform:			
Output of Mode 5	Outputting basic waveform for 28 seconds, pause the stimulation for 1 second. Output stimuli according to the above cycle until the scheduled treatment time is reached.		
Mode 6 (EMS)			
Pulse duration:	200µs	Maximum Amplitude of output voltage:	42V @ 500Ω

Pulse Frequency:		20~75.7Hz	
Basic Waveform:			
Output of Mode 6		Outputting basic waveform for 11.3 seconds at a frequency that gradually increased from 20Hz to 75.7Hz, pause the stimulation for 1.2 seconds. Output stimuli according to the above cycle until the scheduled treatment time is reached.	
Mode 7 (NMES)			
Pulse duration:	200µs	Maximum Amplitude of output voltage:	42V @ 500Ω
Pulse Frequency:		8~50Hz	
Basic Waveform:			
Output of Mode 7		Outputting basic waveform for 15 seconds at a frequency that gradually increased from 8Hz to 50Hz, pause the stimulation for 1 second. Output stimuli according to the above cycle until the scheduled treatment time is reached.	
Mode 8 (NMES)			
Pulse duration:	200µs	Maximum Amplitude of output voltage:	42V @ 500Ω
Pulse Frequency:		25Hz, 66.6Hz	
Basic Waveform:			
Output of Mode 8		Outputting basic waveform for 3.12 seconds at a frequency of 25Hz without any pause time in between; Then outputting basic waveform for 3 seconds at a frequency of 66.6Hz, after pause the stimulation for 1.12 second. Output stimuli according to the above cycle until the scheduled treatment time is reached.	

3. INSTRUCTION OF USE

3.1 Preparation before use

Step 1: Charging

- For main unit
 - (1) Plug the cable into the main unit. Make sure the main unit is off before charging.
 - (2) Connect the charger to a power source. The eight mode indicator lights show a green light in the form of flowing water shows it is charging.
 - (3) Unplug it when the eight indicator lights are constantly green, it indicates a full charge.
- For high-end remote control
 - (1) Plug the cable into the main unit. Make sure the main unit is off before charging.

- (2) Connect the charger to a power source. The mode indicator lights 1 to 6 show a green light in the form of flowing water shows it is charging.
- (3) Unplug it when the mode indicator lights 1 to 6 are constantly green, it indicates a full charge.

Step 2: Connect electrode pad to the main unit

- 1) Take out the main unit and an electrode pad with magnetic suction ports, place the magnetic suction interface of the electrode pad corresponding to the magnetic suction interface of the main unit.
- 2) Ensure that the electrode pad is stably connected to the main unit.

Step 3: Electrode placement

Remove the protective film on the electrode and place electrode on clean, dry and healthy skin near the area with pain.

Please follow the "3.2 Treatment site guidance" to place the electrode pad.

Step 4: Operation

1. Connect the main unit and remote control
 - Connect the main unit and low-end remote control
- 1) After placing the electrode pad, please press the M button on the main unit to turn on the main unit, and press the - button for more than 6 seconds to enter the pairing state of the main unit. At this point, all the indicator lights on the main unit flash at intervals of 500ms as a prompt.
- 2) Press the power button of the low-end remote control to turn it on. Then, press the intensity decrease button for more than 2 seconds to put the low-end remote control into pairing state, and the indicator light on the low-end remote control will turn red and flash slowly.
- 3) After successful pairing, all the indicator lights on the main unit flash rapidly at intervals of 100ms for 800ms as a prompt, the indicator light of the low-end remote control flashes red quickly and then goes out. The low-end remote control and the main unit will automatically exit the pairing state. If the pairing is not successful, you can also exit the pairing state by turning off the low-end remote control and the main unit. For low-end remote controls, you can also exit the pairing state by pressing the intensity decrease button for 2 seconds. If you want to delete the paired remote control, please re-enter the paired state for pairing.
- Connect the main unit and high-end remote control
- 1) After placing the electrode pad, please press the M button on the main unit to turn on the main unit, and press the - button for more than 6 seconds to enter the pairing state of the main unit. At this point, all the indicator lights on the main unit flash at intervals of 500ms as a prompt.
- 2) Press the power button of the high-end remote control to turn it on. Then, press the intensity decrease button for more than 6 seconds to put the high-end remote control into pairing state. At this point, all the indicator lights on the main unit flash at intervals of 500ms as a prompt.
- 3) After successful pairing, all the indicator lights on the main unit flash rapidly at intervals of 100ms for 800ms as a prompt, all the indicator lights on the high-end remote control flash rapidly at intervals of 100ms for 800ms as a prompt before going out. The high-end remote control and the main unit will automatically exit the pairing state. If the pairing is not successful, you can also exit the pairing state by turning off the high-end remote control and the main unit. If you want to delete the paired remote control, please re-enter the paired state for pairing.

Please note:

- The main unit can operate normally without being connected to a remote control.
- One remote control can control four main units at most, but the mode and intensity of the four main units cannot be adjusted independently.

2. Select the treatment mode

The device has 8 output modes. Both the main unit and the remote control are equipped with

mode switch button for select treatment mode. The method of setting the mode is as follows.

Method 1:	Adjust the mode with the main unit: Press this M button on the main unit briefly, each press will switch the mode once. After the device is turned on, the initial mode is mode 1. Press this button multiple times, and the mode changes according to the rule of "mode 1-mode 2-mode 3-mode 4-mode 5-mode 6- mode 7-mode 8-mode 1.....". The device has a total of 8 modes, and each mode has a corresponding mode indicator light. When a certain mode is selected, the corresponding mode indicator light will turn green.
Method 2:	Adjust the mode with the low-end remote control: Press mode switch button on the low-end remote control. Each press switches to the output mode, and the mode changes according to the rule of " mode 1-mode 2-mode 3-mode 4-mode 5-mode 6- mode 7-mode 8-mode 1.....".
Method 3:	Adjust the mode with the high-end remote control: Press mode switch button briefly on the high-end remote control. Each press switches to the output mode, and the mode changes according to the rule of " mode 1-mode 2-mode 3-mode 4-mode 5-mode 6- mode 7-mode 8-mode 1.....". The indicator light is on the high-end remote control will indicate the selected mode. Each mode has a corresponding indicator light. If a certain mode is selected, the corresponding indicator light will turn green.

3. Select the intensity

The device has 19 output intensities. Both the main unit and the remote control are equipped with intensity decrease button and intensity increase button for increasing and decreasing the intensity. The method of setting the mode is as follows.

Method 1:	Adjust the intensity with the main unit: Press + button on the main unit briefly after the main unit is turned on, each press increases the intensity by one level. When the intensity reaches 19 levels, pressing this button again will not cause any change. Press - button on the main unit briefly, each press decreases the intensity by one level. When the intensity reaches 0 level, pressing this button again will not cause any change. Press the + button or - button to adjust the intensity. The intensity indicator light in the middle of the main unit will turn green to indicate the selected intensity level.
Method 2:	Adjust the mode with the low-end remote control: Press intensity decrease button on the low-end remote control after the low-end remote control is turned on, each press increases the intensity by one level. When the intensity reaches 19 levels, pressing this button again will not cause any change. Press intensity decrease button on the low-end remote control, each press decreases the intensity by one level. When the intensity reaches 0 level, pressing this button again will not cause any change.
Method 3:	Adjust the mode with the high-end remote control: Press intensity decrease button on the high-end remote control after the high-end remote control is turned on, each press increases the intensity by one level. When the intensity reaches 19 levels, pressing this button again will not cause any change. Press intensity decrease button on the low-end remote control, each press decreases the intensity by one level. When the intensity reaches 0 level, pressing this button again will not cause any change. When adjusting the intensity, the LEVEL indicator light in the upper right corner of the remote control will turn green, and the selected intensity will be displayed above the remote control.

It should be noted that each time the mode is switched, the intensity will revert to 0 level.

4. Time setting

The device is set to a default timer of 20 minutes. The time is not adjustable.

Please note that when there is no load, the main unit will be shut down if there is no operation for 2 minutes.

5. Treatment

After setting the above parameters, you can start to enjoy the treatment.

6. Turn off

● Main unit

The main unit can be shut down automatically or manually.

Automatic shutdown:

1) The treatment time is over

After the treatment time is over, the main unit will automatically shut down.

2) No output

When there is no load, the main unit will be shut down if there is no operation for 2 minutes.

Manual shutdown

When the power of the main unit is on, pressing M button for 2 seconds can shut down the device.

- Low-end remote control

Manual shutdown

When the power of the low-end remote control is on, press the power button to turn off the remote control. If the main unit is on, it will also shut down along with the paired remote control.

- High-end remote control

Manual shutdown

When the power of the high-end remote control is on, press the power button to turn off the remote control. If the main unit is on, it will also shut down along with the paired remote control.

Step 5: Clean

Please refer to section 4.

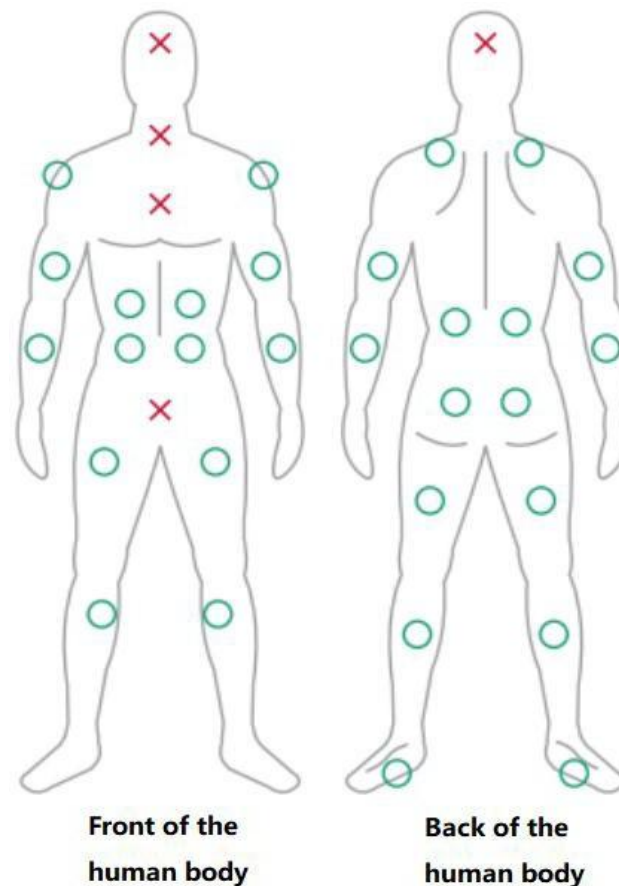
Step 6: Storage

Please refer to section 5.

NOTE:

1. Over-long-time treatment and strong stimulation may cause muscular fatigue and may generate adverse effects. In order to avoid excessive treatment, make sure that at the beginning select short time (10 minutes) and low intensity to treat for a period, and gradually increase time and intensity after you adapt to the stimulation, but never exceed your comfort level. However, each treatment should last less than 60 minutes with at least 2 hours of rest between each use.
2. Recommended usage is 1-2 times a day with at least 2 hours of rest between each use.
3. Select the intensity level that feels right for you. If you want to change the position of the electrode during treatment, turn off the device first before changing the pad position. After you place the electrode onto the new area, then you can turn on the device to start treatment. This procedure helps to avoid potential shock and discomfort.
4. If you want to stop the treatment at any time before the time is up, turn off the device first and then remove the electrode from your skin.
5. Never apply the pads to any other surface other than your skin. If the pads become soiled or dirty, the adhesive power may decrease. In this case, moisten the surface of the pads with water and wipe away the dirty portion. This will allow a temporary restoration of the adhesive power. However, too much water will result in loss of the adhesive power. Do not plunge the pads into water.

3.2 Treatment site guidance



The device is OTC and patients who are not under clinical supervision should have all the information and instructions for using the device. Electrodes placement on patient anatomy for pain application is different than for EMS application. Therefore:

Electrodes placement for TENS application:

TENS:

You can:

- place the electrodes directly on the spot of pain; or
- place the electrodes directly on opposite sides of the pain; or
- placing one electrode on the site of pain and the other 5 or 6 inches away from the site of pain to achieve pain relief.

Electrodes placement for EMS/NMES application:

EMS/NMES:

You can:

- place the electrodes on the middle of the muscle mass; or
 - place the electrodes on the largest part of the muscle you intend to stimulate; or
 - place the electrodes on opposite ends of the muscle
- for EMS/NMES application, such that you are able to stimulate as many muscle fibers as possible to achieve muscle simulation.

3.3 Electrode Pads Guideline

1. Only use the electrode pads supplied by the manufacturer; Using other electrode pads may pose a risk of incompatibility. This may not be able to connect successfully.
2. Do share the electrode pads with others to avoid skin reaction or cross infection.
3. Always turn power off before removing or repositioning the electrodes.
4. Make sure the skin has been washed thoroughly and keep dry before applying the electrodes.
5. Apply the whole surface of the electrode pads firmly to the skin. Do not use electrode

pads that do not stick properly to the skin or only partially stick to the skin.

6. In case of skin redness under the electrode pads after stimulation, do not stimulate in the same place since the skin turn to normal condition
7. Please replace the electrode with a new electrode after it loses its viscosity, and you can purchase the electrode that has already been marketed.
8. The number of times can be used of our electrode is 30-50 times, and the life of the electrodes varies depending on skin conditions, storage, amount of use, type of stimulation, and stimulation site.

4. CLEANING AND MAINTENANCE

For main unit:

1. Wiped the main unit by a damp cloth. Do not use thinner or alcohol because they can cause damage to the main unit.
2. After cleaning, please allow the main unit to dry naturally.
3. Visually inspect the main unit for any dirt. If so, repeat steps 1-2. If not, store the device as required.

For low-end remote control and high-end remote control:

1. Wiped the remote control by a damp cloth. Do not use thinner or alcohol because they can cause damage to the remote control.
2. After cleaning, please allow the remote control to dry naturally.
3. Visually inspect the remote control for any dirt. If so, repeat steps 1-2. If not, store the remote control as required.

For electrode pad:

1. Clean the sticky surface of the electrode pads by spraying water lightly on the surface of the electrode.
2. After cleaning, please allow the main unit to dry naturally.
3. Visually inspect the electrode pad surface for any dirt. If so, repeat steps 1-2. If not, store the electrode pads as required.

Note:

- Each person should use their own set of electrode pads for best hygiene.
- It should be replaced after no stickiness at all.

Always place the clear plastic protective film over the Electrodes pads when not in use. Do not place them on any other surfaces as they will get dirty.

- Never stick two electrode pads to each other.
- Keep the electrode pads clean, and never put them under high temperature and direct sunshine.
- Do not clean the electrode pads with hot water or any chemical.
- Do not touch the sticky surface of the pad, otherwise it will cause the viscosity to decrease.
- Do not clean the electrode pads with any chemical.

5. TRANSPORT AND STORAGE

Please reapply the release paper to the dry electrode pad and place main unit and remote control in the storage bin or storage bag to protect it from contamination.

Store the machine in a dry place, out of reach of children. Do not disassemble the device for any purpose.

Storage Temperature: -20°C~+55°C

Humidity: ≤93%RH

Atmospheric pressure: 50 kPa~106 kPa

When the unit will not be used for a long duration, remove the battery.

6. TROUBLE SHOOTING

- 1) Please keep the device from the reach of infants, children or pets, inhalation or swallowing of small parts is dangerous or even fatal.

Problem	Possible Causes	Solution
One pad feels stronger than the other	This is normal. Different areas of your body will react differently.	Make sure the pads are sticky and are making good contact.
The intensity is not felt. Very weak intensity level.	Pads are not attached to the body firmly.	Attach both pads firmly to the skin.
	The transparent films are still stuck to the pads.	Peel off film on the adhesive surface of pads.
	The pads stacked together or overlap.	Do not stack pads together or overlap pads.
	The intensity setting is getting weak.	Increase the intensity level.
	The battery capacity is low.	Charge the battery.
The skin turns red or the skin feels irritated.	The adhesive surface of pads is dirty or dry	Wash adhesive surface of pads softly with your finger tips for about 3 seconds under slow running water.
	The therapy time is too long or the intensity is set too high.	Reduce the application time or reduce the intensity.
	The electrode pad surface is worn out	Replace electrode pad
No power source of the main unit	The battery of the main unit is depleted.	Charge the main unit.
No display on the remote control.	The battery of the remote control is depleted.	Charge the remote control.
The main unit or remote control can not to charge.	The main unit or remote control is not properly placed in the storage bin or storage bag.	Place the magnetic suction interface in the charging compartment corresponding to the main unit and remote control correctly.
It is difficult to attach the pad to the skin.	Have you removed the transparent film from the pad?	Peel off film on the adhesive surface of pads.
	Was the pad applied immediately after washing?	Dry the pad.
	Is the adhesive surface of the pad	Replace the pad.
Adhesive surface of pads not sticky.	Are you using pad when perspiring?	Use when not perspiring, in a cool room.
	Were the pads stored under high temperature, high humidity, or direct sunshine?	Replace the pad
Treatment interruption	The device was disturbed by other RF devices.	Wait a few minutes and the device may recover automatically; Turn off the device and wait for a minute to restart; Move to another location for treatment.

7. DISPOSAL

- The device and accessories out of shelf life or use life should not be thrown randomly and should be recycled by the manufacturer.
- To dispose of packing materials, take appropriate actions in accordance with the rules and regulations in force in your area to prevent adverse ecological effects.

8. WARRANTY CARD

We hereby guarantee this consumer purchased product, if it is used normally according to each instruction in manual in a non-commercial setting, in case of failure, please contact us, Plexus Yoga LLC Dba Chirp, first, we will sort the problem for you, please ship or mail to: Hong Qiangxing (Shenzhen) Electronics Limited.

Address: 2F, Yongcheng Blvd, Xicheng Industrial area, Xixiang Street, Bao'an District, Shenzhen City, Guangdong Province, 518126, China

For exchange, please mail the failed unit along with copy of receipt as proof of purchase to us or to the local dealer where did you purchase the product. Pack the product carefully to prevent damage in transit. Because of possible loss in transit, we recommend ensuring the product with tracking number and return receipt.

Warranty List

Device Name:	Model:
Purchase date:	User's address:
Name:	Telephone:
Dealer:	Address:
Telephone:	
description of the specific problem:	
Stamp:	

9. LABEL SYMBOLS

Label symbols are shown in the following table:

1.		Medical device. Indicates the item is a medical device
2.		DATE OF MANUFACTURE. This symbol shall be accompanied by a date to indicate the date of manufacture.
3.		Symbol for "MANUFACTURER". This symbol shall be accompanied by the name and the address of the manufacturer.
4.		Collect separately from other household waste
5.		Type BF Applied Part
6.	IP22	IP22: The first number 2: Protected against solid foreign objects of 12.5 mm Φ and greater. The second number 2: Protection against vertically falling water drops when ENCLOSURE tilted up to 15° on either side of the vertical.
8.		Refer to user manual
9.		MR unsafe
10.	FCC	The product has met FCC regulatory requirements and passed FCC certification testing.
11.		Caution
12.		Serial number
13.		Unique device identifier

10. EMC DECLARATION

Before installing or using the device or system, keep an appropriate distance from radio frequency (RF) sources whenever possible. The sources include but not limit to:

Radio and TV stations

Portable and mobile RF communication devices (cell phones, two-way radios, base station, etc.)

High-frequency surgical units, such as diathermy, electrocautery, argon beam coagulators, etc.

X-ray, CT, or MRI devices

These devices are also possible sources of interference as they may emit higher levels of electromagnetic radiation.

WARNING:

EQUIPMENT MALFUNCTION OR INTERFERENCE

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Wireless TENS&EMS&NMES Heating Stimulator or system, including cables specified by the manufacturer. Degradation of the performance of this equipment could result.

Use of accessories, transducers and cables other than those specified or provided by the Hong Qiangxing (Shenzhen) Electronics Limited. manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Magnetic and electric fields may interfere with the performance of the device or system. Make sure that all peripheral components operated in the vicinity of the device comply with the relevant EMC requirements. X-ray equipment, MRI devices, radio systems (cellular phones) and so forth, are possible sources of interference because they may emit higher levels of electromagnetic radiation. Verify the performance of the system before use.

ESSENTIAL PERFORMANCE

The essential performance of the system may be lost or degraded because of electromagnetic disturbances. For expected degradations and instructions of the basic safety and essential performance maintenance in the case of electromagnetic disturbances, see the table below:

Essential Performance	Degradation Caused by Electromagnetic Disturbances	Essential Performance Maintenance
Produce Protection	No degradation	Not Applicable
Produce Function	No degradation	Not Applicable
Note: Essential Performance: The device has two functions are TENS and EMS. For TENS: pulse frequency 6~40Hz, pulse width 105~200μs, and the maximum voltage is 52V@500Ω. For EMS: pulse frequency 30~180Hz, pulse width 82~240μs, and the maximum voltage is 50V@500Ω.		

The following tables provide information on compliance of the equipment according to the standard IEC 60601-1-2:2014 + A1:2020.

Guidance and manufacturer's declaration – electromagnetic emissions

This equipment is intended for use in the electromagnetic environments specified below, and the purchasers or users shall ensure that it is used in these electromagnetic environments.

Emissions	Compliance
RF emissions (Radiated) CISPR 11	Group 1 Class B
RF emissions (Conducted) CISPR 11	Group 1 Class B
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	Environments
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	HOME HEALTHCARE environment
Electrical fast transient/burst (EFT) IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	HOME HEALTHCARE environment
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	HOME HEALTHCARE environment
Voltage dips, short interruptions and Voltage variations on power supply input lines IEC 61000-4-11	0% UT, 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT, 1 cycle at 0° 70% UT, 25 / 30 cycle at 0° 0% UT, 250 / 300 cycle	0% UT, 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT, 1 cycle at 0° 70% UT, 25 / 30 cycle at 0° 0% UT, 250 / 300 cycle	HOME HEALTHCARE environment
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	HOME HEALTHCARE environment
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz to 80MHz 6 Vrms in ISM bands between 0.15 MHz and 80MHz 6 Vrms in amateur radio bands between 0.15 MHz and 80MHz	3 Vrms 0.15 MHz to 80MHz 6 Vrms in ISM bands between 0.15 MHz and 80MHz 6 Vrms in amateur radio bands between 0.15 MHz and 80MHz	HOME HEALTHCARE environment
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.7GHz 80% AM at 1KHz	3 Vrms 80 MHz to 2.7GHz 80% AM at 1KHz	HOME HEALTHCARE environment

Proximity magnetic fields IEC 61000-4-39	30 kHz / CW / 8A/m 134.2 kHz / Pulse modulation 2.1KHz / 65A/m 13.56MHz / Pulse modulation 50 kHz / 7.5A/m	30 kHz / CW / 8A/m 134.2 kHz / Pulse modulation 2.1KHz / 65A/m 13.56MHz / Pulse modulation 50 kHz / 7.5A/m	HOME HEALTHCARE environment
NOTE 1. UT is the a.c. mains voltage prior to application of the test level; 25 / 30 and 250 / 300 cycle means 25 / 250 for 50 Hz system and 30 / 300 for 60Hz system. 2. The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz. 3. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot, theoretically, be predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, consider conducting an electromagnetic site survey. If the measured field strength in the location the system is used exceeds the applicable RF compliance level listed in this table, observe the system to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system. 4. At 80 MHz and 800 MHz, the higher frequency range applies. 5. These guidelines may not apply in all situations. Electromagnetic propagation is affected by the reflection from structures, objects, and people. 6. 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. 7. This test is applicable only to ME EQUIPMENT and ME SYSTEM intended for use in the HOME HEALTHCARE ENVIRONMENT. 8. The carrier shall be modulated using a 50% duty cycle square wave signal. 9. r.m.s., before modulation is applied.			

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	27
450	430-470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	28
710	704-787	LTE Band 13,17	Pulse modulation b) 217Hz	9
745				
780				
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	28
870				
930				
1 720		GSM 1800; CDMA 1900;	Pulse	
1 845				

1 970	1 700-1 900	GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	modulation b) 217Hz	28
2 450	2 400-2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217Hz	28
5 240	5 100-5 800	WLAN 802.11a/n	Pulse modulation b) 217Hz	9
5 500				
5 785				

This device complies with part 15 of the FCC Rules. Operation is subject to the two conditions below:

- (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment 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. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the measures below:

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

WARNING: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

RF Exposure:

This device has been evaluated and shown compliant with the FCC portable RF Exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter used in other systems.

Hong Qiangxing (Shenzhen) Electronics Limited.
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