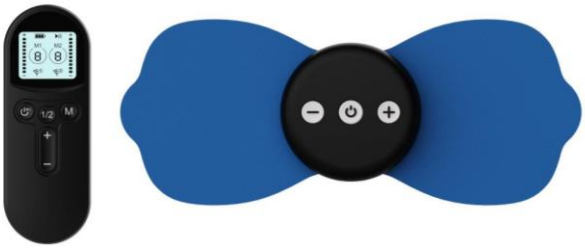
User Manual

SM9116 main unit

SM9116 remote control



Indications for Use

Over-The-Counter Use:

TENS (Transcutaneous Electric Nerve Stimulation):

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.

PMS (Powered Muscle Stimulation):

It is intended to be 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, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

Prescription Use:

TENS (Transcutaneous Electric Nerve Stimulation):

Symptomatic relief and management of chronic, intractable pain;

Adjunctive treatment for post-surgical and post-trauma acute pain.

PMS (Powered Muscle Stimulation):

Temporary relaxation of muscle spasm;

Prevention or retardation of disuse atrophy;

Muscle re-education;

Maintaining or increasing range of motion;

Increase of local blood flow in the treatment area;

Prevention of post-surgical venous thrombosis through immediate stimulation of calf muscles;

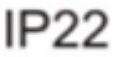
Before operation, please read this user's manual carefully, and be clear about the instructions!

2023-03-15 Version: 1.0

Contents

I. Foreword

It is important to read the entire contents of this instruction for user manual before using your Wireless TENS & EMS. The warnings, contraindications and subsequent chapters contained within this manual are intended to help ensure proper use and optimal results.

Symbol	Meaning
	Type BF applied part
	Manufacturer
	Follow the instructions for use
	Serial Number
	Denotes a product which must be disposed of safely
	Attention, see instructions for use
	Waterproof IP Rating
	Manufacturing date (Month/Year)

1.Five key points for operations

1) This device is intended for use on healthy skin.
2) The electrode pads are for single patient use.
3) Intensity is based upon your level of comfort.
4) Begin the first session with a low intensity and a short duration while learning how to operate.
5) If you feel pain, dizziness, or discomfort, call your physician.

2.Syncing the remote control and the Wireless TENS & EMS

If your remote control and main unit ever lose communication, please repeat these syncing instructions.

1） Make sure the main unit has enough power, charge it if not.
2） Make sure the remote control has enough power, charge it if not.
3） Firstly turn on the switch button of Wireless TENS & EMS, then click the ON/OFF button of remote control. The remote control and your main unit will connected automatically.

▲ Note:

* Your remote control and main unit can’t connected with other device during the communication.
* The LED of Wireless TENS & EMS flashes means it’s ready for use.

II. Description of the Device

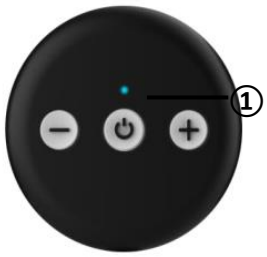
1. Introduction

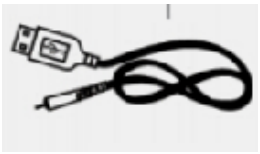
Congratulations on your purchase of the Wireless TENS & EMS (Model SM9116). It is a unique wireless remote controlled device that includes Wireless TENS & EMS technology. The flexible design perfectly contours the target areas for maximum surface contact.

This device is safe, drug-free, easy to use, discreet and comfortable to wear, and most importantly allows you to control your pain or exercise healthy muscle.

2. Contents

• 2 x Main unit
• 2 x Set of electrode pads [K183154]
• 1 x USB charging cable
• 1 x Remote control
• User Manual

<table>
<tr>
<td> 

Main unit (built-in lithium battery)</td>
<td> 
Electrode Pad - Butterfly [K183154]
Size: 193*79mm</td>
</tr>
<tr>
<td> 
USB cable (31”) 80cm</td>
<td> 

Remote control(built-in lithium battery)</td>
</tr>
</table>

Icon and function

Icon	***Explanation***
①	Switch of Wireless TENS & EMS
②	On/Off button: Press to turn on/off the remote control
+ / -	Press to increase or decrease stimulation intensity

M	Press to select treatment mode
►II	Pause or start

Introduction of the remote controls

* SM9116 - Black Remote control

The LCD screen of the black remote control shows the curing mode, curing time, strength and battery level of the remote control. There are six patterns for users to identify different patterns. Digital display mode on the display screen: M1-M6. Ten small black squares represent strength levels, with each square representing 2 levels of strength.The battery power mark on the remote control shows the remaining power of the remote control.The WiFi mark on the remote control indicates whether it is well connected to the main unit . If it is not connected, it is a gray space, and if it is connected, it is white.

Product operation function description

The Main unit can be used alone or in conjunction with the remote control

When the Main unit works alone:

1.Fully charge the Main unit.

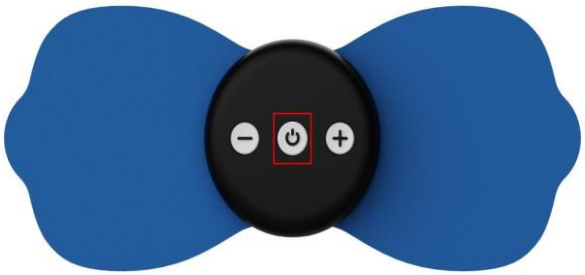
2.Long press the 3 seconds power key to boot the Main unit, after boot, short press the power key to switch the mode (mode 1-6 cycle switch); Press and hold the key for about 3 seconds to shut down the Main unit.

3. Press the "+" and "-" keys to adjust the strength of the Main unit. Every time you press it, the strength will increase or decrease by one level until it is added to level 20 or reduced to level 0

Main unit and wireless remote control are used together

1. Fully charge the remote control and the Main unit.

2. Press the on/off button to open the remote control and the Main unit, as shown in the figure;



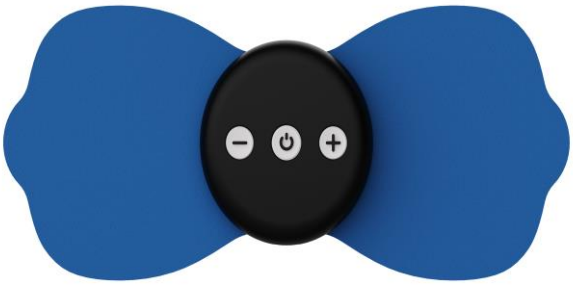
3. When the Main unit is turned on and the remote control is turned on, and it is within the connectable range, the Main unit and the remote control will be automatically paired and connected. After successful connection, the area will be displayed, and the icon on the left corresponds to Main unit 1 and the icon on the right corresponds to Main unit 2.

3. After the Main unit is connected to the remote control, the current working modes of the Main unit are displayed as 1-6 modes. Press the 1/2 key to select the Main unit,When No. 1 is selected as the adjustable Main unit, M1 flashes, and when No. 2 is selected as the adjustable Main unit, M2 flashes.

4. When the output is not turned on, the number of intensity grids is 0, a total of 20 levels of intensity, and a total of 10 grids of intensity display, two levels correspond to a grid of intensity display. When the singular level of intensity is increased, the corresponding number of display intensity grids is increased, and the Even number intensity increase does not increase the number of display grids; The icon on the left corresponds to Main unit number 1, and the icon on the right corresponds to Main unit number 2.

5.Short press the on/off key on the remote control to start the pause function,Short press the key,both two Main units pause output at the same time,short press the key again to restore the output.

6.Battery power display: the battery power mark on the remote control shows the remaining power of the remote control; When the power of the Main unit is lower than 3.3v, the red light flashes;



7. Long press the 3 seconds on/off button to turn off the remote control, and the connected Main unit will also turn off.

4. Mode Description

The Wireless TENS & EMS (Model SM9116) has six modes. All parameters are pre-programmed, except for the intensity.

Modes 2, 3, 6 are for TENS function, whose over-the-counter efficacy is used to 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.Its prescription efficacy is used for Symptomatic relief and management of chronic, intractable pain and adjunctive treatment for post-surgical and post-trauma acute pain.

Modes 1, 4, 5 are for PMS function, whose over-the-counter efficacy 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, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.Its prescription efficacy is used for Temporary relaxation of muscle spasm;Prevention or retardation of disuse atrophy;Muscle re-education;Maintaining or increasing range of motion;Increase of local blood flow in the treatment area;Prevention of post-surgical venous thrombosis through immediate stimulation of calf muscles.

We suggested that you experiment each of the 6 modes at first use. The mode that gives you the most desirable sensations and comfort is the most appropriate one to use for your current condition.

The treatment parameters of six modes are as follows:

Mode	*Frequency(Hz)*	*Pulse width(μs*	*Max. amplitude(V)*	*Time(min)*
Mode1	70	50	56.8	20
Mode2	1-55.5	100	52	20
Mode3	1.1	495	69.6	20
Mode4	111	100	51.2	20
Mode5	142	100	47.2	20
Mode6	1.1/20.8/30	100	72.8	20

5.Charging the Battery

1) The Lithium battery can be charged through both AC adaptor and computer USB input.

2) When stimulation intensity decreases or the main unit doesn't respond, it indicates that the device needs charging. Turn off the main unit.
3) Connect the main unit and the charger with USB extension cord. Plug the charger into any power outlet, and the LED indicator of the main unit is red, indicating that it is charging. The charging process will last about 3 hours. After charging is complete, the LED indicator of the main unit is blue.

▲**Note:** * Only charge the main unit when the battery is completely depleted for the first 2 times. Unplug the charger from the power outlet when charging is complete. Do not use the device while charging.

III. User Instruction

* Section 1 - For TENS purpose *

1.1 Indications for Use

Modes 2, 3, 6 are for TENS function, whose over-the-counter efficacy is used to 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.Its prescription efficacy is used for Symptomatic relief and management of chronic, intractable pain and adjunctive treatment for post-surgical and post-trauma acute pain.

1.2 Safety

⚠ CONTRAINDICATIONS

• Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, or are connected to high frequency surgical equipment. Such use could cause electric shock, burns, electrical interference, or death. It may also damage the stimulator.
• Do not use this device on patients whose pain syndromes are undiagnosed.

⚠ WARNINGS!

• Do not allow children to swallow or touch accessories or detachable parts (e.g., cable, button batteries).
• Do not use this device across or through your chest because the electrical currents introduced into the chest may cause rhythm disturbances to your heart, which may be lethal.
• Do not use this device if you are susceptible to rhythm disturbances to the heart unless under the direction of your physician.
• Do not use this device over your eyes, mouth, face, throat, front of neck (especially in the carotid sinus), head, or across your heart because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
• Consult with your physician before using this device if you are in the care of a physician.
• Consult with your physician before using this device if you have had medical or physical treatment for your pain.
• Stop using this device and consult your physician if your pain does not improve, becomes more than mild, or continues for more than five days.
• Do not use this device while sleeping, driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.
• Do not use this device over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).
• Do not use this device over, or in proximity to, cancerous lesions.
• Do not use this device on children because it has not been evaluated for pediatric use.
• Do not use this device 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.
• Do not immerse in water or use in a wet environment, such as the bath, shower or other sources

of moisture.
• Do not use this device on abnormal skin, or skin that is not intact, clean, or healthy.
• Do not operate in close proximity (e.g. 1 m) to shortwave or microwave therapy equipment as it may produce instability in the stimulator output.
• Do not use device near near-field communications (NFC) systems, wireless power transfer (WPT), electronic article surveillance (EAS) products such as wireless charger, NFC reader, etc.
• Do not heat up the device/battery or place near a direct flame. These actions can heat the battery and cause an explosion.
• Device may not work properly when applied over a sweaty part of the body during work and exercise.
• Other equipment could interfere with the medical device or device system, even if the other equipment complies with EMC requirements.
• The long-term effects of chronic electrical stimulation are unknown.
• Do not use in case of critical ischemia of the limbs.
• No modification of this equipment is allowed.

⚠ PRECAUTIONS

• Do not start stimulation of the device prior to application of the device to the back and shoulder.
• Keep this device out of the reach of children.
• The safety of nerve stimulation has not been established during pregnancy; therefore, do not use this device if you are pregnant, or suspect that you are pregnant, unless under the direction of your physician.
• This device is for use by adults over 21 years of age.
• This device should not be applied on or across your head or face since the effects of stimulation of the brain are unknown.
• This device is for symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
• If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
• If you have suspected or diagnosed epilepsy or experience convulsions, you should follow precautions recommended by your physician.
• Use this device with caution if you have a tendency to bleed internally, such as following an injury or fracture.
• Consult with your physician prior to using this device after a recent surgical procedure, because stimulation may disrupt the healing process.
• Do not use this device for pain of central origin, including headache.
• This device does not provide curative value.
• The long-term effects of nerve stimulation are unknown.
• You may experience skin irritation or hypersensitivity due to the electrical stimulation or adhesive medium (gel pads).
• Use this device with caution if stimulation is applied over the menstruating or pregnant uterus.
• Use this device with caution if stimulation is applied over areas of skin that lack normal sensation.
• Use this device only with the gel pads and accessories recommended by the manufacturer.
• Gel pads should be for single person use to avoid skin disease or any other transmissible disease.

• Do not remove this device from your skin with the stimulation mode of operation activated.
• Do not place your finger, or any object, between or near your skin and the adhesive gel pads during stimulation treatment.
• This device is not to be used in the presence of flammable or anesthesia gasses or liquids.
• Do not allow young children, pets, or pests contact with the device as alterations to the device may compromise product safety and/or performance.
• Handle the unit with care. Inappropriate handling of the unit may adversely affect its characteristics.
• Remove metallic objects around the treatment area, such as jewelry, piercings or belts.

⚠ ADVERSE REACTIONS

• Isolated cases of skin irritation or burns may occur due to electrical stimulation or adhesive medium (gel pads).
• Stop using the device and consult with your physician if you experience adverse reactions from use of this device.
• Prolonged use may cause discomfort or sore muscles.
• Burns may occur when the gel pads are not used properly, or if the gel pads are removed from the device or get damaged.

1.3 Preparation for use

Before using your Wireless TENS & EMS, you will need to connect the electrode pad to the main unit and prepare the device for a treatment.

1.3.1 Skin Preparation

1) Trim, not shave, excessive hair on the treatment area.
2) Wash the skin and dry completely.
3) Treatment area should be void of oils and/or lotions.

1.3.2 Conducting a Treatment

Note: Always read the safety warnings before conducting a treatment. Follow these steps to conduct a treatment.
1) Remove the transparent liners from the gel pads. Avoid contact of gel pad with other objects. Save the transparent liners for storage of the device.
2) Place the device on the treatment area. If you cannot place the device properly, ask another person for assistance.
Important! Do not apply the electrode pads directly over the spine or on the side or front of the neck. Do not activate the device when it is not properly placed.
3) Press the switch button on the Wireless TENS & EMS. Then press the ON/OFF button on the remote control. The default value is mode 1, intensity 0, time 20 min.
4) Press “M” button to select treatment mode and press “+/-” buttons to increase or decrease the intensity of the stimulation until it is at a comfortable level. Press the “►II” button to stop the treatment at any time.
5) Treatment will automatically stop after 20 minutes. The LED of the Wireless TENS & EMS flashes faster as the treatment intensity increases.
Note: Care should be taken not to inadvertently depress the switch button on the Wireless TENS & EMS and the ON/OFF button on the remote control during use. If the switch or ON/OFF button is depressed

during use, the treatment will stop.

1.4 Removing the device

Important! Do not remove the device until the treatment has stopped.

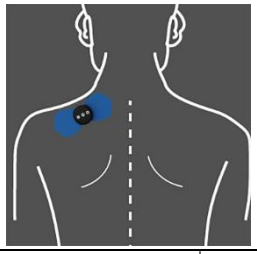
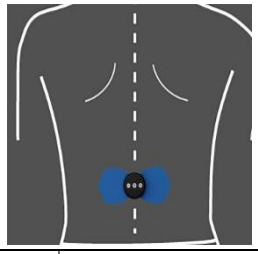
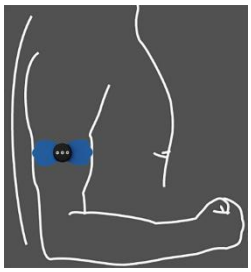
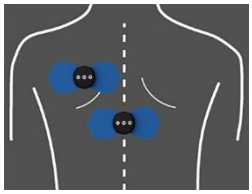
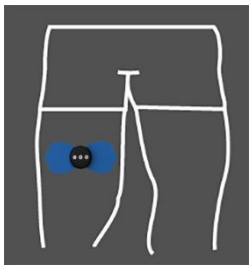
1) After treatment, or when you want to remove the device, grasp the edge of the device with gel pad to ensure the gel pad does not stay on the skin. Slowly peel the device away form the skin.

2) Align and cover the transparent liners on the gel pads. Ensure the pads are completely covered.

1.5 Regular TENS Application principle

1) Find the exact pain point or the area where it aches most.

Important! Do not place the electrode gel on the side or front of the neck.

<table>
<tr><td>Pain in shoulder</td><td colspan="2">Pain in waist</td></tr>
<tr><td>  </td><td colspan="2">  </td></tr>
<tr><td>Pain in arm</td><td>Pain in back</td><td>Pain in leg</td></tr>
<tr><td>  </td><td>  </td><td>  </td></tr>
</table>

2) Intensity: The intensity can be gradually increased up to the point when it becomes uncomfortable. Always stay below that point of discomfort.

If the stimulation sensation becomes weaker or disappears, you may increase the intensity by pressing the up key "+" to a point when the stimulation becomes uncomfortable, but if the sensation does become uncomfortable, press the down key "-" to decrease the intensity. **Always stay under the point of discomfort!**

3) Recommended application duration and Mode selection:

For first time user, choose Mode 1 at a low Intensity level to treat for 20 minutes per day, and then gradually up to 2 times a day. You may increase the intensity and time after you have become familiar with the device and the feel for the stimulation. Stay with Mode 1 for a few days before trying any of the other Modes and intensity settings. Remember, the modes to be used for pain relief are **Mode 2, 3, 6 .**It is difficult to recommend a particular mode for a specific type of pain and it is usually determined by the user's feel of relief. However, if you do not feel any relief of pain after having tried different modes and intensities for a period, it is recommended that you consult with your physician.

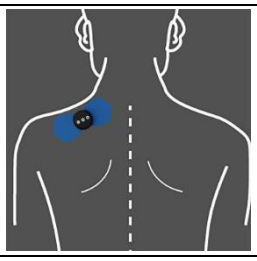
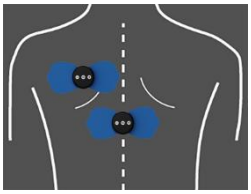
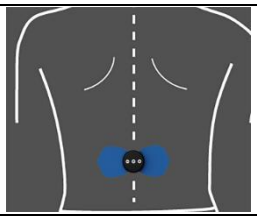
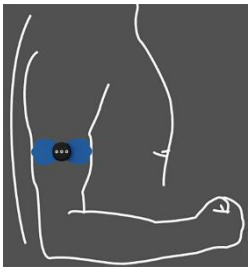
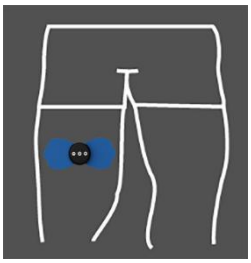
If you experience an adverse reaction (skin irritation/redness/burns /other painful sensation), or if you feel unusual discomfort, stop using the device immediately and consult with your physician.

1.6 Regular TENS Application Methods

Many people experience immediate relief from muscle pain, while others require several days of regular use to feel the benefits. The results vary and will depend upon your underlying conditions and how often you use the device. However, if you do not feel any relief of pain after having tried different modes and intensities for a period, it is recommended that you consult with your physician.

▲**Note:** 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 (20 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.

▲Note: The charts below are merely a suggestion for how to place the electrodes, what Mode to choose and how long to stimulate, but only after the user has gone through the starting procedure and is familiar with the device. Depending on your feeling or objective, you may select the appropriate mode combination for treatment.

Pain in shoulder		Mode 2 for 20 minutes, and Mode 3 or Mode 6 for 20 minutes; Recommended usage is 1-2 times a day with at least 2 hours of rest between each use. *Keep the area warm. Avoid sudden movements with the aching shoulders, gentle movements are advisable in the initial stage and full motions at a later stage.
Pain in back		Mode 2 for 20 minutes, and Mode 3 or Mode 6 for 20 minutes; Recommended usage is 1-2 times a day with at least 2 hours of rest between each use.
Pain in waist		Mode 2 for 20 minutes, and Mode 3 or Mode 6 for 20 minutes; Recommended usage is 1-2 times a day with at least 2 hours of rest between each use.
Pain in arms		Mode 2 for 20 minutes, and Mode 3 or Mode 6 for 20 minutes; Recommended usage is 1-2 times a day with at least 2 hours of rest between each use.
Pain in legs		Mode 2 for 20 minutes, and Mode 3 or Mode 6 for 20 minutes; Recommended usage is 1-2 times a day with at least 2 hours of rest between each use.

* Section 2 - For PMS purpose *

2.1 Indications for Use

Modes 1, 4, 5 are for PMS function, whose over-the-counter efficacy 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, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.Its prescription efficacy is used for Temporary relaxation of muscle spasm;Prevention or retardation of disuse atrophy;Muscle re-education;Maintaining or increasing range of motion;Increase of local blood flow in the treatment area;Prevention of post-surgical venous thrombosis through immediate stimulation of calf muscles.

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• Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, or are connected to high frequency surgical equipment. Such use could cause electric shock, burns, electrical interference, or death. It may also damage the stimulator.
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• Do not use this device across or through your chest because the electrical currents introduced into the chest may cause rhythm disturbances to your heart, which may be lethal.
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• Do not use this device over your eyes, mouth, face, throat, front of neck (especially in the carotid sinus), head, or across your heart because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
• Consult with your physician before using this device if you are in the care of a physician.
• Consult with your physician before using this device if you have had medical or physical treatment for your pain.
• Stop using this device and consult your physician if your pain does not improve, becomes more than mild, or continues for more than five days.
• Do not use this device while sleeping, driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.
• Do not use this device over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).
• Do not use this device over, or in proximity to, cancerous lesions.
• Do not use this device on children because it has not been evaluated for pediatric use.
• Do not use this device 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.

• Do not immerse in water or use in a wet environment, such as the bath, shower or other sources of moisture.
• Do not use this device on abnormal skin, or skin that is not intact, clean, or healthy.
• Do not operate in close proximity (e.g. 1 m) to shortwave or microwave therapy equipment as it may produce instability in the stimulator output.
• Do not use device near near-field communications (NFC) systems, wireless power transfer (WPT), electronic article surveillance (EAS) products such as wireless charger, NFC reader, etc.
• Do not heat up the device/battery or place near a direct flame. These actions can heat the battery and cause an explosion.
• Device may not work properly when applied over a sweaty part of the body during work and exercise.
• Other equipment could interfere with the medical device or device system, even if the other equipment complies with EMC emission requirements.
• The long-term effects of chronic electrical stimulation are unknown.
• Do not use in case of critical ischemia of the limbs.
• No modification of this equipment is allowed.

⚠ PRECAUTIONS

• Do not start stimulation of the device prior to application of the device to the back and shoulder.
• Keep this device out of the reach of children.
• The safety of nerve stimulation has not been established during pregnancy; therefore, do not use this device if you are pregnant, or suspect that you are pregnant, unless under the direction of your physician.
• This device is for use by adults over 21 years of age.
• This device should not be applied on or across your head or face since the effects of stimulation of the brain are unknown.
• This device is for symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
• If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
• If you have suspected or diagnosed epilepsy or experience convulsions, you should follow precautions recommended by your physician.
• Use this device with caution if you have a tendency to bleed internally, such as following an injury or fracture.
• Consult with your physician prior to using this device after a recent surgical procedure, because stimulation may disrupt the healing process.
• Do not use this device for pain of central origin, including headache.
• This device does not provide curative value.
• The long-term effects of nerve stimulation are unknown.
• You may experience skin irritation or hypersensitivity due to the electrical stimulation or adhesive medium (gel pads).
• Use this device with caution if stimulation is applied over the menstruating or pregnant uterus.
• Use this device with caution if stimulation is applied over areas of skin that lack normal sensation.
• Use this device only with the gel pads and accessories recommended by the manufacturer.

• Gel pads should be for single person use to avoid skin disease or any other transmissible disease.
• Do not remove this device from your skin with the stimulation mode of operation activated.
• Do not place your finger, or any object, between or near your skin and the adhesive gel pads during stimulation treatment.
• This device is not to be used in the presence of flammable or anesthesia gasses or liquids.
• Do not allow young children, pets, or pests contact with the device as alterations to the device may compromise product safety and/or performance.
• Handle the unit with care. Inappropriate handling of the unit may adversely affect its characteristics.
• Remove metallic objects around the treatment area, such as jewelry, piercings or belts.

⚠ ADVERSE REACTIONS

• Isolated cases of skin irritation or burns may occur due to electrical stimulation or adhesive medium (gel pads).
• Stop using the device and consult with your physician if you experience adverse reactions from use of this device.
• Prolonged use may cause discomfort or sore muscles.
• Burns may occur when the gel pads are not used properly, or if the gel pads are removed from the device or get damaged.

2.3 Preparation for use

Before using your Wireless TENS & EMS, you will need to connect the electrode pad to the main unit and prepare the device for a treatment.

2.3.1 Skin Preparation

1) Trim, not shave, excessive hair on the treatment area.
2) Wash the skin and dry completely.
3) Treatment area should be void of oils and/or lotions.

2.3.2 Conducting a Treatment

Note: Always read the safety warnings before conducting a treatment. Follow these steps to conduct a treatment.
1) Remove the transparent liners from the gel pads. Avoid contact of gel pad with other objects. Save the transparent liners for storage of the device.
2) Place the device on the treatment area. If you cannot place the device properly, ask another person for assistance.
Important! Do not apply the electrode pads directly over the spine or on the side or front of the neck. Do not activate the device when it is not properly placed.
3) Press the switch button on the Wireless TENS & EMS. Then press the ON/OFF button on the remote control. The default value is mode 1, intensity 0, time 20min.
4) Press “M” button to select treatment mode and press “+/-” buttons to increase or decrease the intensity of the stimulation until it is at a comfortable level. Press the “►II” button to stop the treatment at any time.
5) Treatment will automatically stop after 20 minutes. The LED of the Wireless TENS & EMS flashes faster as the treatment intensity increases.
Note: Care should be taken not to inadvertently depress the switch button on theWireless TENS & EMS

and the ON/OFF button on the remote control during use. If the switch or ON/OFF button is depressed during use, the treatment will stop.

2.4 Removing the device

Important! Do not remove the device until the treatment has stopped.

1) After treatment, or when you want to remove the device, grasp the edge of the device with gel pad to ensure the gel pad does not stay on the skin. Slowly peel the device away form the skin.

2) Align and cover the transparent liner on the gel pad. The same is true for the second gel pad. Ensure the pads are completely covered.

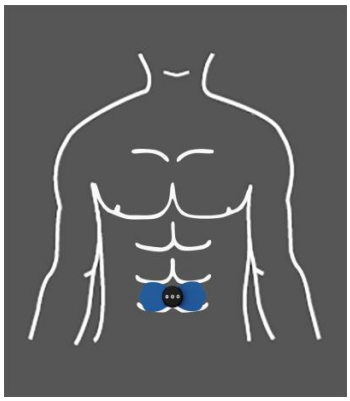
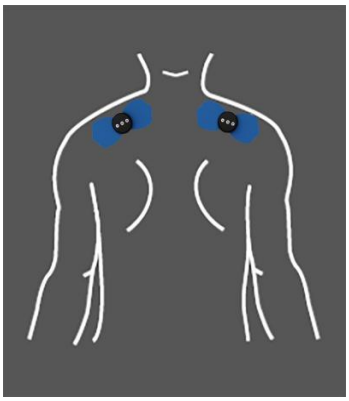
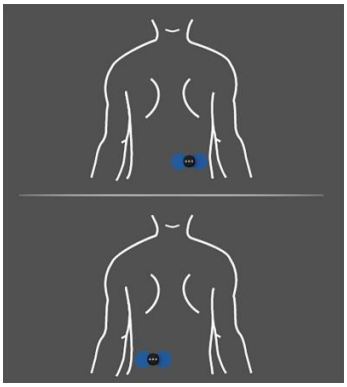
2.5 Regular PMS application principles

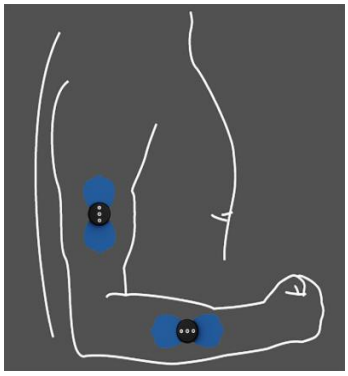
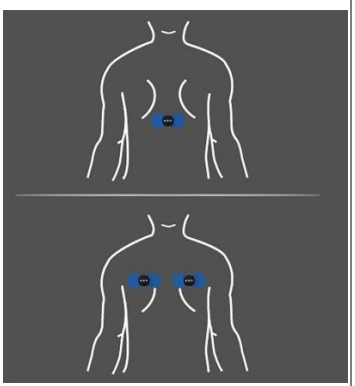
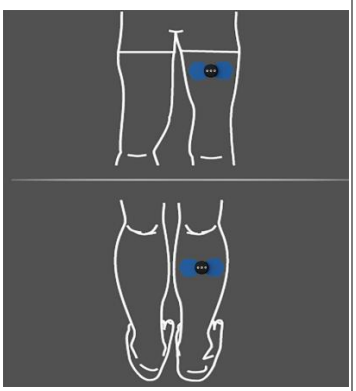
1) Find the targeted muscle which needs to be stimulated.

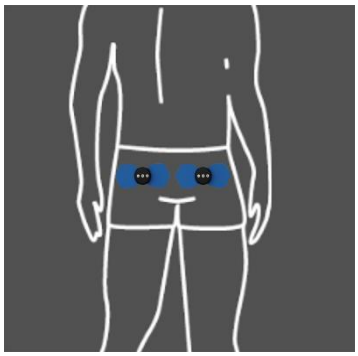
Find the targeted muscle which needs to be stimulated. Place the Wireless TENS & EMS on the or nearby the muscle. If you cannot place the device properly, ask another person for assistance.

Important! Do not apply the device directly over the spine.

Important! Do not place the electrode gel on the side or front of the neck.

Exercise abdomen	Exercise shoulder	Exercise waist
		

Exercise arms	Exercise back	Exercise legs
		
Exercise buttocks		



2) Intensity: The intensity can be gradually increased up to the point when it becomes uncomfortable. Always stay below that point of discomfort.

If the stimulation sensation becomes weaker or disappears, you may increase the intensity by pressing the up key (+) to a point when the stimulation becomes uncomfortable, but if the sensation does become uncomfortable, press the down key (-) to decrease the intensity. Always stay under the point of discomfort!

3) Recommended application duration and Mode selection:

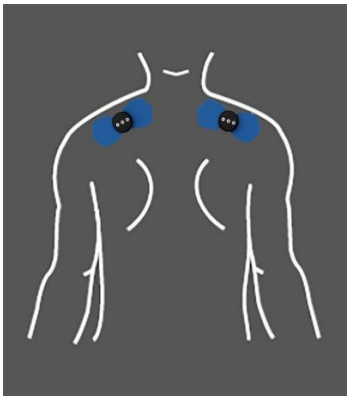
For first time user, choose Mode 1 at a low Intensity level to treat for 20 minutes per day, and then gradually up to 2-3 times a day. You may increase the intensity and time after you have become familiar with the device and the feel for the stimulation. Stay with Mode 1 for a few days before trying any of the other Modes and intensity settings.

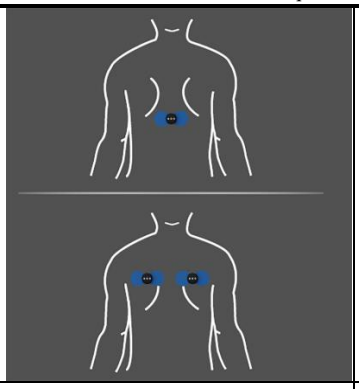
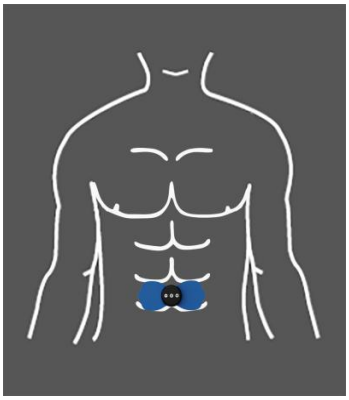
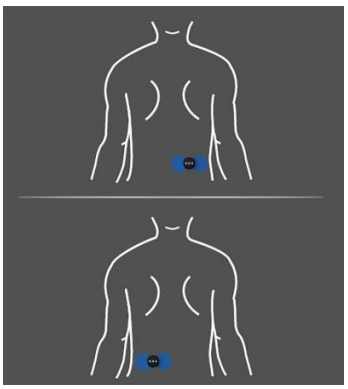
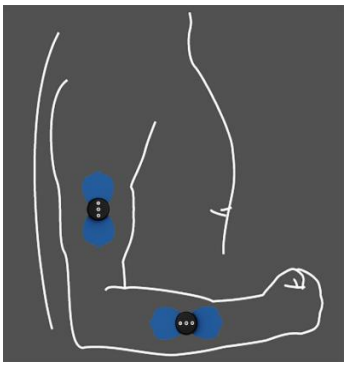
2.6 Regular PMS Application Methods

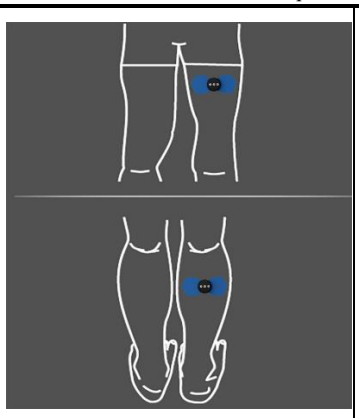
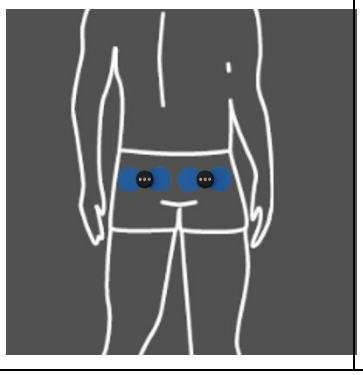
Please note that this device is intended to stimulate **healthy** muscles in order to improve or facilitate muscle performance. It is not intended as therapy for any medical condition.

Users can choose **Mode 1,4,5** to stimulate the following points to quickly facilitate muscle performance. In order to better improve the muscle performance, you may increase the intensity gradually to a level which is still comfortable and does not cause pain or discomfort. Furthermore, you should use TENS & PMS regularly to maintain the benefit you may have gained during exercise.

▲Note: The charts below are merely a suggestion for how to place the electrodes, what Mode to choose and how long to stimulate, but only after the user has gone through the starting procedure and is familiar with the device. Depending on your feeling or objective, you may select the appropriate mode combination for muscle exercise. However, each workout should last less than **60 minutes**, and the interval between two workouts should be longer than **12 hours**. Since the strength programs deliver a training load, recovery is important to ensure that the body's capacity to absorb another workout is large.

Exercise shoulder		Mode 1 for 20 minutes, and Mode 4 for 20 minutes, Mode 5 for 20 minutes Recommended usage is 1-2 times a day, each use less than 60 minutes, at least 12 hours of rest between each use.

Exercise back		Mode 1 for 20 minutes, and Mode 4 for 20 minutes, Mode 5 for 20 minutes Recommended usage is 1-2 times a day, each use less than 60 minutes, at least 12 hours of rest between each use.
Exercise abdomen		Mode 1 for 20 minutes, and Mode 4 for 20 minutes, Mode 5 for 20 minutes Recommended usage is 1-2 times a day, each use less than 60 minutes, at least 12 hours of rest between each use.
Exercise waist		Mode 1 for 20 minutes, and Mode 4 for 20 minutes, Mode 5 for 20 minutes Recommended usage is 1-2 times a day, each use less than 60 minutes, at least 12 hours of rest between each use.
Exercise arms		Mode 1 for 20 minutes, and Mode 4 for 20 minutes, Mode 5 for 20 minutes Recommended usage is 1-2 times a day, each use less than 60 minutes, at least 12 hours of rest between each use.

Exercise legs		Mode 1 for 20 minutes, and Mode 4 for 20 minutes, Mode 5 for 20 minutes Recommended usage is 1-2 times a day, each use less than 60 minutes, at least 12 hours of rest between each use.
Exercise buttocks		Mode 1 for 20 minutes, and Mode 4 for 20 minutes, Mode 5 for 20 minutes Recommended usage is 1-2 times a day, each use less than 60 minutes, at least 12 hours of rest between each use.

IV. Troubleshooting

Failure state	**Reason**	**Method**
The device did not respond after power on.	The device may be low battery.	Check and use after charging or replacing battery.
Stimulation becomes weaker.	The gel pad is not in contact with the skin.	Keep gel pad in good contact with skin.
	The surface of the gel pad is stained.	Clean or replace gel pad.
	There is grease in the body.	Clean the body.
	The device may be low battery.	Check and use after charging or replacing battery.
The skin turns red or the skin feels irritated	The adhesive surface of gel pads is dirty or dry.	Wash adhesive surface of gel pads softly with your fingertips 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.
Adhesive surface of gel pad is not sticky.	Are you using gel pad when perspiring?	Use when not perspiring, in a cool room.
	Were the gel pads stored under high temperature, high humidity, or direct sunshine?	Replace the gel pad.
Treatment interruption	The device may be low battery.	Check and use after charging or replacing battery.
The main unit can not connect with remote control	The ON/OFF button of remote control and main unit do not open.	Turn on the main unit and remote control.
	The distance between main unit and the remote control is more than 10m.	Control the operation range between main unit and the remote control less than 10m.
The buttons don’t response	The battery power is too low.	Check the battery of main unit and remote control.
The wireless communication delay or failure	The wireless communication is disrupted	Wait for minute and the device will reconnect automatically; Move device to another location.
If the above measures are not effective, contact Hong Qiangxing (Shen Zhen) Electronics Limited Tel: 0086-755-26423615; E-mail: info@sunmas.com		

V. Service and Maintenance

1. Cleaning and maintenance

A.For the main unit:

1) To keep the main unit clean, use a soft and dry cloth for dust or a soft damp cloth for any dirt and smudges. Do not use any cleaning solutions to clean the main unit and its pads.

2) Do not use or store the device where there are magnetic fields or electric waves (near TV set or speakers).

3) Do not place the devices in areas of high temperature, high humidity, or under direct sunlight.

4) Keep the device out of reach of children.

B.For electrode pad:

1) If the electrode gels become soiled or dirty, the adhesive power may decrease. In this case, moisten the surface of the gels 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.

2) Use alcohol to clean the release liner.

3) The electrode gel is for signal use. When the electrodes dry out and do not stick, buy new gels.

2.Storage

Caution: Do not store in a damp area. Dampness may affect the device and cause rust.

A.For the main unit:

- Normal working condition: 5 ℃~40 ℃ (40-104 ℉), ≤80%RH, 700hPa~1060hPa
- Store and transport condition: 10 ℃~40 ℃ (50 °-104 °F), 30-85%RH, 700hPa~1060hPa

B.For electrode pad:

- Normal working condition: 5 ℃~27 ℃ (41-80 ℉), 30% -80%RH, 700hPa~1060hPa
- Store and transport condition: 10 ℃~40 ℃ (50 °-104 °F), 30-85%RH, 700hPa~1060hPa

3.Disposal


To dispose of the electrode, device and packing materials, take appropriate actions in accordance with the rules and regulations in force in your area to prevent adverse ecological effects.

4.Warranty period

We give a warranty of 1 year from the date of purchase onWireless TENS & EMS. This warranty does not cover cables and electrodes.

5. Manufacturer information


Manufacturer: Hong Qiangxing (Shen Zhen) Electronics Limited
Address: 2F, Yongcheng Building, Xicheng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen City, Guangdong province, China

Web site: www.hqxdomas.com

Email: info@sunmas.com

VI. Technical specifications

A. Basic Unit:

Device Name	Wireless TENS & EMS/Wireless remote control
Model	SM9116 main unit/SM9116 remote control
Power Source(s)	Main unit: DC 3.7V lithium battery
Battery information	SM9116 main unit : Model：042030 3.7V 180mAh 0.666Wh SM9116 remote control: Model：501030 1ICP4/12/32 110mAh 3.7V 0.407Wh
Mode number	6 modes
Intensity	20 levels
Timer control	20 minutes
Weight (g)	SM9116 main unit :31 g SM9116 remote control:33g
Dimensions (in.)	SM9116 main unit :59mm(D)×13.2mm(H) SM9116 remote control:36.7×101.6×12.5 (mm)
Waveform	Biphasic pulse
Shape	Rectangular
Pulse width(μs)	50~495μs
Pulse Frequency (Hz)	1~142Hz
Control range	10m
IP rating	IP22

B. Electrode gel:

Target population:	Single patient use and multiple application
Shape:	Butterfly according toWireless TENS & EMS
Size:	193*79mm
Features & Materials:	- Top cover material - Conductive carbon film - Conductive hydrogel: - PET release liner (polyethylene terephthalate)
Sterility Status:	Non-sterile
Shelf life:	2 years

Complied standards	ASTM F1980:2016, ISO 10993-5:2009, ISO 10993-10:2010

C. Technological characteristics of lithium battery

1.	Name of the battery manufacturer:		Shenzhen Lanlin Technology CO. Ltd
2.	Model number of the battery:		042030
3.	General technological characteristics	- Nominal capacity	180mAh
		- Nominal voltage	3.7V
		- Charge current	100mA
		- Max. continuous charge current:	180mA
		- Max. discharge current:	180mA
		- Standard charge voltage:	4.2V
		- Discharge cut-off voltage:	2.75V
		- Charging temp. upper limit	45℃
		- Charging temp. lower limit	-5℃
4.	Chemistry used in the battery:		Polymer lithium battery
5.	Charging time		3h
6.	Complied standards		IEC62133:2012

D. Wireless technology

QoS: The value of pulse duration, amplitudes, and repetition frequencies do not deviate by more than ±10% when measured with a load resistance of 500ohm.

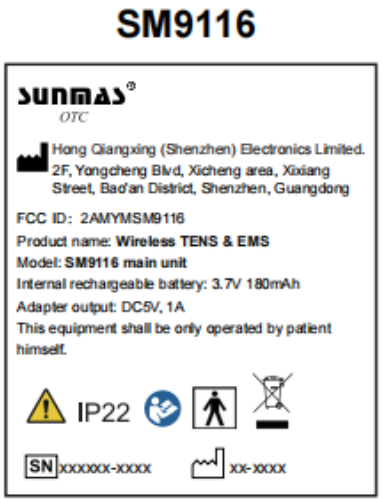
Wireless security manage: The SM9116 uses advanced encryption standard (AES) security coprocessor. The Aes-128 CCM encryption algorithm is used for data packet encryption and authentication. The transmitter emits a 16-byte command, and the receiver checks the command and completes the point-to-point pairing.

Model	SM9116 main unit/SM9116 remote control
Wireless technology	2.4GHz RF
Type	Undefined
RF Frequencies	2402~2481MHz
Modulation type	FSK
Antenna Type	PCB antenna
Antenna Gain	2dBi
Number of Channel	80
Channel spacing	1MHz

Wireless rate	1-Mbps
Maximum Receiver Sensitivity	-88dBm
Range	10m
Operating supply voltage	1.9V~3.6V
Operating ambient temperature range	-40~85℃
Storage temperature range	-40~125℃
Bandwidth	1Mbps
Company standards	FCC 47CFR part 15 Subpart C FCC 47CFR part 15 Subpart B

Appendix A - Labels on the device

Main unit:



Remote control:

Appendix B - Electromagnetic compatibility

With the increased number of electronic devices such as PC and mobile (cellular) telephones, radio transceivers, mobile radio transmitters, radio-controlled toys, and so on, Medical devices in use may be susceptible to electromagnetic interference from other device. Electromagnetic interference may result in incorrect operation of the medical devices and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC 60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices.

This unit has been thoroughly tested and inspected to assure proper performance and operation! This product needs special precautions regarding EMC and needs to put into service according to the EMC information provided, the following tables recommend minimum separation distances between portable and mobile RF communications equipment and the TENS unit.

Caution:

* The use of accessories and cables other than those specified by Hong Qiangxing, with the exception of cables sold by Hong Qiangxing as replacement parts for internal components, may result in increased emission or decreased immunity of the device.
* This device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.
* Refer to further guidance below regarding the EMC environment in which the device should be used.

There is no guarantee that interference will not occur in a particular installation. Radiated or conducted electromagnetic signals can cause:

1) As to devices:

• Deviation of the values of pulse duration, amplitudes, and repetition frequencies, may impair the unit's essential performance. The device has passed EMC test, and the parameters do not deviate the essential performance requirement.

2) As to patients:

• The sensitivity of stimulation may be weaker or stronger, but it does not produce safety issues.
• It cannot achieve expected effect.

If this equipment is found to cause or respond to interference, attempt to correct the problem by one or more of the following measures:

• If feeling too weak or too strong stimulation, adjust the strength level to an acceptable level.
• If the device is abnormal, power off and restart the device and check whether it shows properly.
• Re-orient or re-locate the affected device.
• Increase the separation between the unit and the affected device.
• Power the equipment from a source other than that of the affected device.
• Consult the service representative for further suggestions.

Guidance and manufacturer ´s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer's declaration - electromagnetic emission		
TheWireless TENS & EMS is intended for use in the electromagnetic environment specified below. The customer or the user of theWireless TENS & EMS should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	TheWireless TENS & EMS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Wireless TENS & EMS 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer ́s declaration – electromagnetic immunity			
TheWireless TENS & EMS is intended for use in the electromagnetic environment specified below. The customer or the user of theWireless TENS & EMS 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	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV 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)	±1 kV line(s) to line(s)	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% UT (>95% dip in UT) for 0.5 cycle <40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (>95% dip in UT) for 0.5 sec	<5% UT (>95% dip in UT) for 0.5 cycle <40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (>95% dip in UT) for 0.5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of theWireless TENS & EMS requires continued operation during power mains interruptions, it is recommended that the Wireless TENS & EMS be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer´s declaration – electromagnetic immunity –

for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer ´s declaration – electromagnetic immunity			
TheWireless TENS & EMS is intended for use in the electromagnetic environment specified below. The customer or the user of theWireless TENS & EMS 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 Radiated RF IEC 61000-4-3	3 V rms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz	3 V rms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.57 GHz	Portable and mobile RF communications equipment should be used no closer to any part of theWireless TENS & EMS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{p}$ 150kHz to 80MHz $d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 800 MHz to 2.7GHz 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: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic 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 theWireless TENS & EMS is used exceeds the applicable RF compliance level above, TheWireless TENS & EMS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating theWireless TENS & EMS. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and theWireless TENS & EMS			
TheWireless TENS & EMS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Wireless TENS & EMS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and theWireless TENS & EMS as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{p}$	80 MHz to 800 MHz $d = 1.2\sqrt{p}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres(m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer. Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2 These guidelines may not apply in all situation. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

FCC Caution:

Part 15.21

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

Part 15.19

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.
3. The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Part 15.105

Note: 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 following measures:

—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.