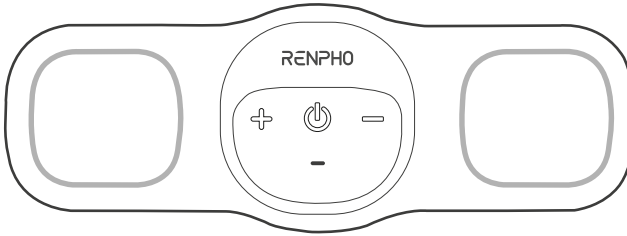
RENPHO

USER MANUAL



WIRELESS TENS & EMS

Model: SM9116

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.
EMS (Electrical Muscle Stimulation)/ NMES(NeuroMuscular Electrical Stimulation):
It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

Manual Version: V1.0
File No.: RP-SM9116-UM

Contents

FOREWORD

It is important to read the entire contents of this instruction for user manual before using the device. 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
	Manufacturer
	Follow the instructions for use
SN	Serial Number
	Denotes a product which must be disposed of safely
	Attention, see instructions for use
IP22	Waterproof IP Rating
	Manufacturing date (Month/Year)

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 ofcomfort.
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.

DESCRIPTION OF THE DEVICE

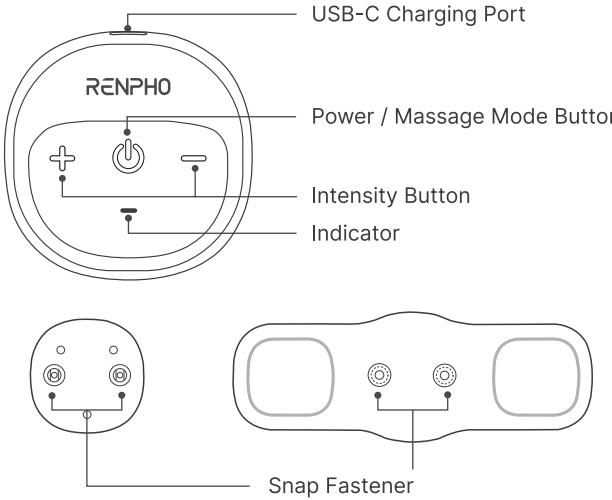
Congratulations on your purchase of the device (Model SM9116). It is a unique device that includes Wireless TENS & EMS technology. The flexible design perfectly contours the target areas for maximum surface contact. This device is safe, drug-free, easy to use, discreet and comfortable to wear, and most importantly allows you to control your pain or exercise healthy muscle. The device (Model SM9116) is a portable and DC 3.7V battery powered multifunction device with a wireless feature for over-the-counter use. The main unit has totally 6, and each mode has 20 intensity levels, applying electrical current to electrodes on a patient's skin to relieve pain or build up muscle. The device is equipped with accessories of electrode pads, and one USB-C cable. the USB-C cable is used to connect the AC adapter and the built-in lithium battery. All accessories, including USB-C cables, electrode pads, can only be changed or replaced by a qualified person. The electrode pad are 510(k) cleared under K183154.The electrode gels have passed the shelf life test, impedance test, adhesive test.

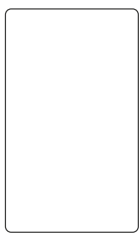
ABOUT THE DEVICE

1. What's in the Box
Emberace Pulse × 1
USB-C Charging Cable × 1
Release Liner × 2
Gel Electrode Pad × 4

2. Overview

Control Unit



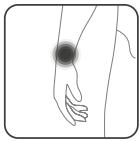


Release Liner

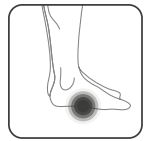
(Peel off the release liner's coating before use.)

3. Electrode Pads

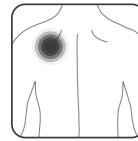
Small Pad



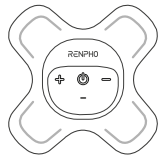
Wrists



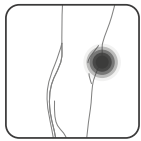
Feet



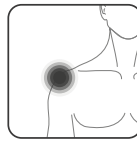
Shoulder Blades



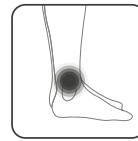
X-Shaped Pad



Knees

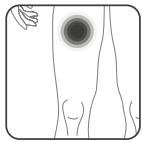


Shoulders

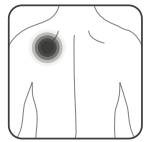


Ankles

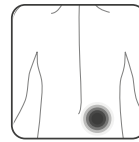
Large Pad



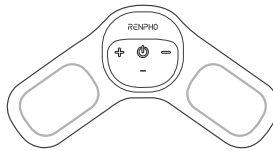
Thighs



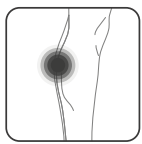
Shoulder Blades



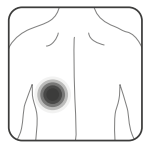
Waist



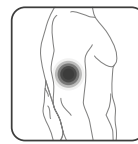
V-Shaped Pad



Calves



Back



Arms

USING THE DEVICE

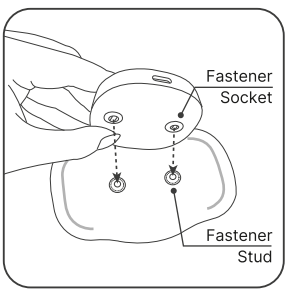
Before Use

* Ensure the contact points are clean and dry before connecting the control unit to the gel electrode pad.
* Replace the gel electrode pad if the contact points become damaged or corroded.
* Do not apply pads to the same area for more than 30 minutes at a time.

Operation

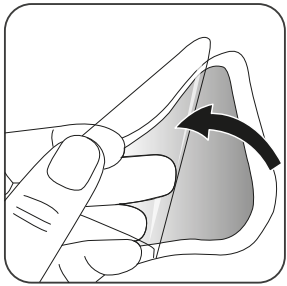
Step 1:

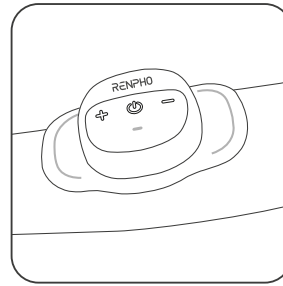
Select an electrode pad, then align the fastener sockets with the fastener stud, and press down to secure the connection.



Step 2:

Peel off the protective film from the pad and apply it to the skin. After use, turn the device off, remove the pad, and cover it with the original protective film or the release liner.





Note:
* Fully charge the device before the first use.
* When charging is completed, disconnect the power to prevent overcharging.
* Use the provided USB-C charging cable to charge the device. DO NOT use the device while charging.

Button Introduction

Button	Operation
⏻	Press and hold to turn On / Off the device. Press to switch the massage modes: Mode 1: Soothing (Default) Mode 2: Patting Mode 3: Pressure Point Mode 4: Vibration Mode 5: Ripple Mode 6: Rhythm
+	Press to increase the pulse intensity from 1 to 20.
−	Press to decrease the pulse intensity.

Indicator

Status	Indicator
Power On / Active	Flashing Blue
Charging	Solid Red
Fully Charged	Solid Blue
Low Battery	Flashing Red

Mode Description

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.
Modes 1, 4, 5 are for EMS/NMES function, whose over-the-counter efficacy is used to stimulate healthy muscles in order to improve and facilitate muscle performance. 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.

The treatment parameters of six modes are as follows:

Mode	Frequency (Hz)	Pulse Width (μs)	Time (min)
Mode 1	70	50	20
Mode 2	1~55.5	100	20
Mode 3	1.1	495	20
Mode 4	111	100	20

Mode 5	142	100	20
Mode 6	1.1/20.8/30	100	20

WARM TIPS FOR SKINCARE

To avoid skin irritation—especially if you have sensitive skin—follow these suggestions:

1. Clean the skin area where you will place the electrodes with mild soap and water. Rinse thoroughly and dry the skin completely with a clean towel.
2. Allow the skin to be dry before applying the electrodes as directed.
3. When removing electrodes, always pull them in the direction of hair growth to minimize irritation.
4. Moisturize the electrode placement area with skin lotion when not in use to maintain skin health.
5. Avoid applying electrodes over irritated, broken, or damaged skin.

MAINTENANCE & CARE & STORAGE

1. After use, turn off the device and remove the electrode pads.
2. Preserve the pads by covering them with protective film after each session. Lightly moistening them with a few drops of water before and after use can extend their lifespan.
3. Recharge the device at least every three months if not used regularly to maintain battery health.
4. Replace pads after 20–30 uses (varies based on usage, body type, and care).

To prevent damage or rust, always store the device in a cool, dry place away from damp areas.

TROUBLESHOOTING GUIDE

Problem	Possible Cause	Solution
The device stops working suddenly.	Battery is weak or depleted.	Charge the device and restart it.
	20-min auto-off timer is activated.	Restart the device if needed.
Failed to turn on the device.	Batteries are weak or depleted.	Charge the device and restart it.
	Power Button was pressed for only a short duration.	Press and hold the Power Button to turn on the device.
Slow charging / unable to charge.	Use other types of charging cables.	Use the provided charging cable only.
Weak intensity.	The gel electrode pad is not attached to the skin firmly.	Attach the pad firmly to the skin.
	Lower pulse intensity is selected.	Adjust to a higher pulse intensity.
	The battery is weak or depleted.	Charge the device and restart it.
No stimulation.	The gel electrode pad is not connect-ed to the control unit firmly.	According to “Operation” to assemble.

Skin turns red or the skin feels irritated.	The adhesive surface of the gel electrode pad is dirty or dry.	Wash the adhesive surface of pads gently with your fingertips for about 3 seconds under slow running water.
	Used for too long with the pulse intensity set too high.	Use the device less than 30 min a session and choose a lower pulse intensity.
	The gel electrode pad's surface is worn out.	Replace another gel electrode pad.

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.

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.
- 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 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.
- TENS is not a substitute for pain medications and other pain management therapies.
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.

⚠ 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.
- 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 not use the device.
- If you have suspected or diagnosed epilepsy or experience convulsions, you should not use the device.
- 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.

Skin Preparation

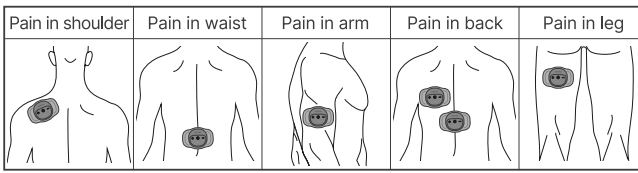
1) Trim, not shave, excessive hair on the treatment area.
2) Wash the skin and dry completely.
3) Treatment area should be void of oils and/or lotions.

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.

1.4 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.



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!**

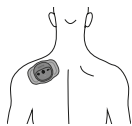
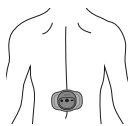
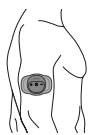
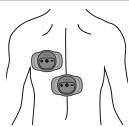
3) Recommended application duration and Mode selection: For first time user, choose Mode 1 at a low Intensity level to treat for 20 minutes per day, and then gradually up to 2 times a day. You may increase the intensity and time after you have become familiar with the device and the feel for the stimulation. 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.

1.5 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 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 arm		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 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 leg		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 EMS/NMES purpose ***

2.1 Indications for Use

Modes 1, 4, 5 are for EMS/NMES function, whose over-the-counter efficacy is used to stimulate healthy muscles in order to improve and facilitate muscle performance.

2.2 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 .

- 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 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.
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.

⚠ 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.
- 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 not use the device.

- If you have suspected or diagnosed epilepsy or experience convulsions,you should not use the device.
- 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.

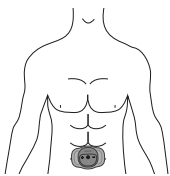
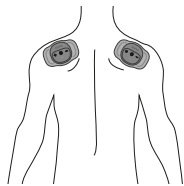
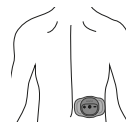
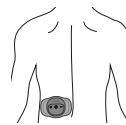
Important! Do not apply the electrode pads directly over the spine or on the side or front of the neck. Do not activate the device when it is not properly placed.

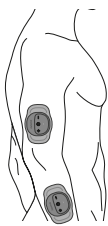
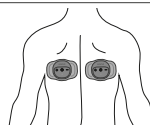
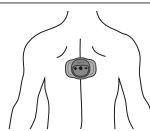
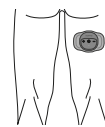
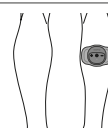
2.4 Regular EMS/NMES application principles

Note: Always read the safety warnings before conducting a treatment. Follow these steps to conduct a treatment.

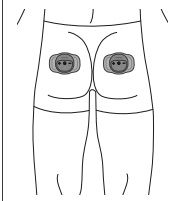
1) Find the targeted muscle which needs to be stimulated. Find the targeted muscle which needs to be stimulated. Place the Wireless TENS & EMS on the or nearby the muscle. If you cannot place the device properly, ask another person for assistance.

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:

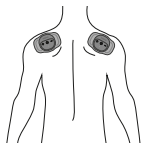
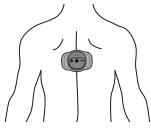
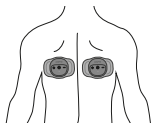
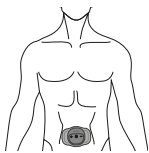
For first time user, choose Mode 1 at a low Intensity level to treat for 20 minutes per day, and then gradually up to 2-3 times a day. You may increase the intensity and time after you have become familiar with the device and the feel for the stimulation. Stay with Mode 1 for a few days before trying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

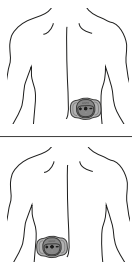
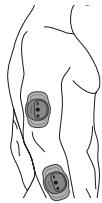
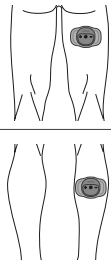
2.5 Regular EMS/NMES Application Methods

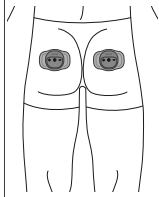
Please note that this device is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is not intended as therapy for any medical condition. Users can choose Mode 1,4,5 to stimulate the following points to quickly facilitate muscle performance. In order to better 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 & EMS 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.

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) 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.

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

B. For electrode pad:

- Normal working condition: 5°C~27°C (41-80°F), 30% -80%RH, 700hPa~1060hPa
- Store and transport condition: 10°C~40°C (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. Manufacturer information

Manufacturer: Hong Qiangxing(Shen Zhen) electronics Limited
Address: 2F,Yongcheng Blvd,Xicheng Industrial area, Xixiang Street,Bao'an District,Shenzhen City, Guangdong Province, China ,518126

5. 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 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

TECHNICAL SPECIFICATIONS

1. The Device

Product Name:	Wireless TENS & EMS
Model:	SM9116
Input:	5V ⎓ 0.2A
Battery Voltage:	DC 3.7V
Battery Capacity:	180mAh 0.666Wh
Charging Time:	About 3 h
Pulse Frequency:	1-142Hz
Pulse Width:	50-495μs

2. Gel Electrode Pads

Target Populations:	Single Patient use and multiple application
Shape:	Small/Large/X-Shape/V-Shape
Features & Materials:	- Top cover material - Conductive carbon film - Conductive hydrogel: - PET release liner (polyethylene terephthalate)
Sterility Status:	Non-sterile
Shelf life:	2 years
Shelf life:	ASTM F1980:2016,ISO 10993-5:2009 , ISO 10993-10:2021,and ISO 10993-23:2021

3. Technological characteristics of lithium battery

1.	Name of the battery manufacturer:		Dongguan Nuolei Electronics Co., Ltd
2.	Model number of the battery:		402030
3.	General Technological Characteristics	Nominal Capacity	180mAh
		Nominal Voltage	3.7V
		Charge Current	100mA

		Continuous Current:	
		Max. Discharge Current:	180mA
		Standard Charge Voltage:	4.2V
		Discharge Cut-off Voltage:	2.75V
		Charging temp. upper Limit:	45°C
		Charging temp. lower Limit:	-5°C
4.	Chemistry Used in the Battery:	Polymer Lithium Battery	
5.	Charging Time	3h	
6.	Complied standards EC62133:2012	IEC62133:2012	

4. 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.

Model	SM9116
Wireless technology	2.4GHz RF
Type	Undefined
RF Frequencies	2402.0 - 2481.0MHz
Modulation type	GFSK
Antenna Type	PCB antenna
Antenna Gain	0dBi
Number of Channel	66CH
Channel spacing	1MHz
Wireless rate	1-Mbps
Maximum Output Power	5.5dBm
Maximum Receiver Sensitivity	-88dBm
Range	10m
Operating supply voltage	1.9V~3.6V
Operating ambient temperature range	-40~85°C
Storage temperature range	-40~125°C
Bandwidth	1Mbps
FCC ID	2AMYMSM9116
Company standards	FCC 47CFR part 15 Subpart C FCC 47CFR part 15 Subpart B

APPENDIX - 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		
The Wireless TENS & EMS is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless TENS & EMS should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Wireless 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	
Harmonic emissions IEC 61000-3-2	Not applicable	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.
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

The Wireless TENS & EMS is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless 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 the home 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 the home environment.
Voltage dips, short interruptions and voltage variations on power	<5% UT (>95% dip in UT) for 0.5 cycle <40% UT (60% dip in	<5% UT (>95% dip in UT) for 0.5 cycle <40% UT (60% dip in	Mains power quality should be that of the home environment. If the user of the Wireless TENS & EMS requires continued operation during power

supply input lines IEC 61000-4-11	UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (>95% dip in UT) for 0.5 sec	UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (>95% dip in UT) for 0.5 sec	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 home 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			
The Wireless TENS & EMS is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless 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 the Wireless 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 the Wireless TENS & EMS is used exceeds the applicable RF compliance level above, The Wireless TENS & EMS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Wireless 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 the Wireless TENS & EMS

The Wireless 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 the Wireless 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 kHz to 800 MHz $d = 1.2\sqrt{p}$	80 kHz to 800 MHz $d = 1.2\sqrt{p}$
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.

WARRANTY POLICY

Your RENPHO product purchase is covered by a one-year limited manufacturer warranty from the date of delivery.

For warranty terms and conditions, please visit:
https://renpho.com/pages/warranty-terms-and-conditions

Note: Product registration is not required for the warranty. If you choose not to register your product, it will not diminish the product warranty.

CUSTOMER SERVICE

Please feel free to contact us if you have any questions or concerns. RENPHO Customer Service Team guarantees a quick response and hassle-free solutions to any issue you may have within business hours.

Tel: **+1(844) 417 0149 (US&CA)**
Monday-Friday 9:00AM-4:30PM
Email: **support@renpho.com (US&CA)**

*For defective products or the return of items, please contact us with your order number within the specified warranty period. DO NOT dispose of any product parts as they may be required for inspection/repair.

FCC Regulatory Compliance

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.

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

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.

ISED Regulatory Compliance

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1: This device may not cause interference.

2: This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage;
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

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