StimOn

Pain Relief System

REF GM 2439

USER MANUAL

The Transcutaneous Electrical Nerve Stimulation Product

Contents

Version V2.1

SAFETY INFORMATION

Federal Communications Commission (FCC) Notice (U.S. Only)

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 instruction, may cause harmful interference to radio communication. 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.

1. Introduction

1.1 Background

Transcutaneous Electrical Nerve Stimulation (TENS) is a self-administered, non-invasive treatment that generates electrical stimulation transmitted through the skin using electrode pads attached to the surface of the skin. This involves nerve stimulation generated by applying electrical current to the distribution of nerve fibers via skin surface electrodes.

1.2 About the StimOn™ Pain Relief System (GM2439)

The StimOn™ Pain Relief System (GM2439) is a Transcutaneous Electrical Nerve Stimulation (TENS) product that generates Pulsed Radiofrequency (PRF) stimulation for the symptomatic relief of chronic intractable pain, and as an adjunct treatment in the management of postsurgical or post traumatic pain. The StimOn™ Pain Relief System with electrode pads is easy to attach to the treatment area, and is suitable for home and portable use. Begin treatment at the press of a button without the need to set stimulation parameters. Once stimulation begins, the electrical stimulation frequency is much higher than the nerve action potential. This product also provides a storage case to protect the product from staining.

This product is intended for use by one person, and should always be used in accordance with the **important safety information** and operating instructions included in this user manual. Do not use for any purpose other than indicated by the manufacturer.

1.3 Indications for use

StimOn™ Pain Relief System (GM2439) is used for the symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical or post-traumatic pain.

2. Important safety information

2.1 Contraindications

This TENS product should not be used on:

- *Patients with cardiac demand pacemakers.*
- *Patients with defibrillators and other metal implantation or electrical products (e.g., drug delivery system). Patients using this product under this condition may cause electric shock, burns, electrical interference, or even death.*
- *Patients with epilepsy.*
- *Patients who are pregnant.*
- *People with wounds in the treatment area.*
- *People with infectious skin diseases and other serious skin diseases.*
- *People who are allergic to hydrogel of electrode pad.*
- *People who do not understand the instructions for using this product.*

2.2 Warnings

- *Please read the entire user manual carefully before using the product.*
- *Do not modify the product or accessories without authorization, otherwise it will result in malfunction.*

- *Do not disassemble the product if it cannot be charged or for any other reason, because it is assembled via a plastic welding process. Any unauthorized disassembly may damage the battery and cause an explosion. Please contact the manufacturer or your local customer specialist for product replacement.*
- *Keep the product away from other magnetic objects during treatment.*
- *The product should not be used together with other equipment. If other equipment use is necessary, please consult with your physician or local customer specialist. For example, patients using medical monitoring or surgical equipment (such as cardiac monitors or a sphygmomanometer) should use with caution.*
- *Do not use this product when you are connected to high-frequency surgical medical equipment, as that may result in burns and possible damage to the product.*
- *Do not use the product if the cause of your pain has not been diagnosed. If you are not certain about the cause of your pain, consult your physician.*
- *It is recommended to use the product only once a day. If the pain relief is achieved, it is not recommended to use multiple times as there will be no major improvements.*
- *The long-term effects of chronic electrical stimulation are unknown.*
- *Please consult your physician if the treatment is not effective after 3 uses.*
- *Do not apply the stimulation over the carotid artery*

on either side of the neck.

- *Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.*
- *Do not apply stimulation to the head or either side of the head. Stimulation should not be applied transcerebrally.*
- *Do not apply stimulation to the chest area; doing so may increase the risk of heart fibrillation.*
- *Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.*
- *Do not place the electrode pad on a wound if you have had surgery recently.*
- *Do not place the electrode pad on or in any body cavities, such as the mouth or anus.*
- *Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.*
- *Stimulation should not be applied over swollen, infected, or inflamed areas of the skin or skin eruptions; e.g., phlebitis, thrombophlebitis, varicose veins, etc.*
- *Stimulation should not be applied over, or in proximity to, cancerous lesions.*
- *Do not operate the product close to shortwave or microwave equipment; doing so may produce instability in the stimulator output.*
- *Do not use this product in the presence of flammable gases or liquids.*

- *To maintain the effect of treatment, do not move the product during treatment. If the product is suddenly removed, it will turn off automatically. Please keep the treatment site in a steady and comfortable position during treatment.*
- *Do not use this product in the bath, shower, or swimming pool.*
- *Do not use this product if you have recently undergone surgery, are in the care of a physician, or have not consulted your physician.*
- *Do not operate dangerous machinery if you feel uncomfortable after the treatment.*
- *Do not use the product while it is charging.*
- *Do not use the product while the USB cable is still plugged into the product to prevent the product from being pulled off by the cable during treatment.*
- *Do not apply stimulation while the muscle is contracting; doing so worsens the symptoms of tendinitis.*
- *Do not use the product if you feel pain or a stabbing pain in the application area during use because the current density exceeds 2 mA/cm^2.*
- *Do not use the product near an MRI environment, it is not MRI-compatible.*
- *If pain increases, stop using the product and consult your physician.*

2.3 Cautions

- *In the USA, the user's education level must be higher than the 8th grade.*
- *Users of this product must be 22 years or older.*
- *Please charge the product at least once a month if*

you do not use it frequently.

- *Please use the product only with accessories provided by the manufacturer.*
- *This product must be stored and operated in a specific environment. Please refer to the "Specifications" section before use.*
- *The USB port should only be connected for power charging using the USB cable provided by the manufacturer.*
- *Do not use the product if there are obvious appearance defects on the product or accessories; please contact the manufacturer or your local customer specialist for product replacement.*
- *If the electrode pad is not firmly attached to the skin, it may increase the risk of burns and other adverse reactions.*
- *For problems with the product, please refer to the "Troubleshooting" section. Please contact a customer specialist if the problem persists.*
- *The electrode pad has a limited shelf life. Please check the packaging for the expiration date prior to use. Do not use an expired electrode pad.*
- *The electrode pad can be used several times depending on storage conditions; please do not use it if it loses its adhesiveness.*
- *Keep the hydrogel for the electrode pad away from heat and humidity to prevent it from drying out or losing adhesion.*
- *The connecting points on the electrode pad must be kept dry and should not come in contact with water. Please wipe dry if they are wet.*
- *Ensure that the skin is clean and dry both before and during treatment to prevent electrode pad*

detachment from the skin. Use a washcloth with mild soapy water to clean skin, rinse well, and pat dry thoroughly. Do not rub dry or apply moisturizer.

- *To avoid affecting stimulation efficacy, do not apply cosmetics or chemical substances, such as sunscreen or skin care products, to the stimulation area.*
- *Keep the device away from sunlight, as long-term exposure to sunlight may affect the rubber causing it to become less elastic and crack and affect the plastic causing it to become crisp.*
- *Keep the device away from lint and dust, as long-term exposure to lint or dust may affect the stimulation pins inside the connection holes to develop bad contact.*
- *The unattended use of this device by children, incapacitated persons, or pets may be dangerous.*
- *Do not place the product in an environment that may cause the USB cable to uneasily unplug during charging mode; if there is the need to terminate the charging mode, please unplug the USB cable from the product or adaptor.*

2.4 Precautions

- *This product is not a substitute for pain medication or other pain management therapies.*
- *Electrical nerve stimulator devices have no curative value.*
- *Electrical nerve stimulators are a symptomatic treatment, which suppresses the sensation of pain.*
- *The safety of TENS for use during pregnancy has not been established.*

- *Caution should be used for patients with suspected or diagnosed heart problems.*
- *Caution should be used for patients with suspected or diagnosed epilepsy.*
- *Caution should be used in the presence of the following:*
  a. *When there is a tendency to hemorrhage following acute trauma or fracture*
  b. *Following recent surgical procedures when stimulation may disrupt the healing process*
  c. *Over the uterus when menstruating or pregnant*
  d. *Over areas of the skin which lack normal*
- *Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. If this occurs, stop using this product and consult your physician.*
- *Do not use stimulation on areas other than those stipulated in the "Indications for use" section. For example, the electrode pad should not be placed over the head or on either side of the head. The user might experience headaches and other painful sensations if stimulation is used near the eyes, head, or face.*
- *Always follow the instructions in the user manual for electrode pad placement and product operation.*
- *Any excess hair in the treatment area should be removed, but avoid shaving the skin just prior to use as this may increase the risk of skin irritation during and after treatment.*
- *The TENS product should be kept out of reach of children.*
- *The TENS product should be used only with the electrodes recommended for use by the manufacturer.*

- *[FOR PORTABLE DEVICES ONLY]: The portable TENS product should not be used while driving, operating machinery, or during any activity in which electrical stimulation can put the user at risk of injury.*

2.5 Adverse reactions

After using the product, if you experience any of the following symptoms, please stop use immediately and consult your physician:

- *Skin irritation or burns beneath the stimulation electrodes applied to the skin*
- *Redness, inflammation, and/or swelling of the skin*
- *Feeling of nausea, dizziness, or paresthesia for some time.*

3. Package contents

✓ Stimulator x 1
✓ Electrode pad pack* x 2
✓ USB charging cable x 1
✓ Storage case x 1
✓ User manual x 1
✓ Quick start guide x 1
✓ Warranty card x 1
*The applied part of the electrode pad is for skin adhesion.

The recommended power adaptor is one with a USB slot and a 5V/2.4A DC output adaptor or the recommend MEAN WELL GEM12I05-USB adaptor with the following interchangeable AC plug:
European model: AC plug-EU2
US model: AC plug-US2

4. System components

- Stimulator (see Fig. 1 and 2)

➪ On/off button

➪ Indicators and vibrating surface to indicate device status. Please refer to Table 1.

➪ USB cover to prevent water from coming into contact with the USB port. Open to plug in the USB cable.

➪ Stimulation pins inside the connection holes are connection points for the electrode pad.

▨ Slash marks indicate the magnetic areas inside the device; automatically connect stimulator and electrode pad (see Chapter 5.3. for connection method).

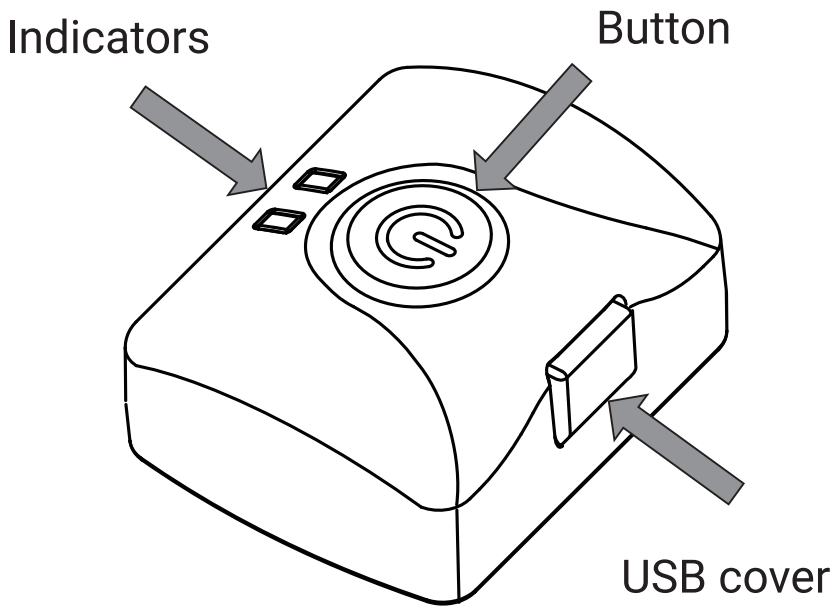
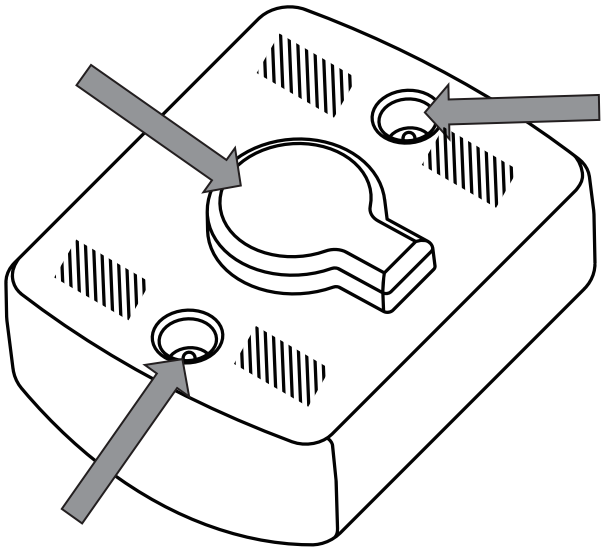


Figure 1. Top view of stimulator

Slash marks indicate magnetic areas inside the device.

Vibrating surface



Stimulation pin inside the connection hole

Stimulation pin inside the connection hole

Figure 2. Bottom view of stimulator

Table 1. Device status indications

Device status indication	Blue light	Orange light	Vibration
Press the button for treatment	Device turned on	Not displayed	Vibrates 3 times
During treatment	Device on	Not displayed	Vibrates one time per 5 sec
Automatic shut-down after treatment	Device turned off	Not displayed	Vibrates 3 times
Press the button again during treatment			
Low battery status during treatment	Not displayed	Flashes 3 times	Vibrates 3 times
Plug in the USB cable for charging	Not displayed	Light on	Not vibrating
Charging complete	Not displayed	Light turns off	Not vibrating
Connection problem during treatment	Flashes 3 times	Not displayed	Vibrates 3 times

- Electrode pad (see Fig. 3 and 4)

➡ The connecting points are contact points for the stimulation pins of stimulator.

➡ The hydrogel receives the stimulation signal from the contacting point.

▨ Slash marks indicate the magnetic areas inside the device (see section 5.3 for the connection method).

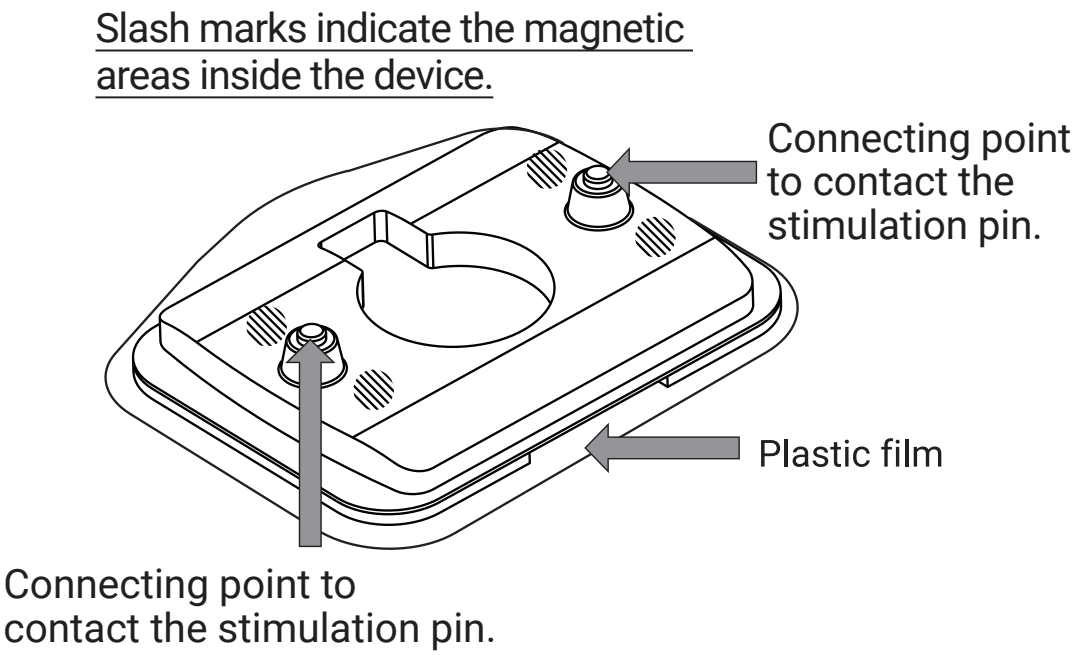


Figure 3. Top view of electrode pad with plastic film

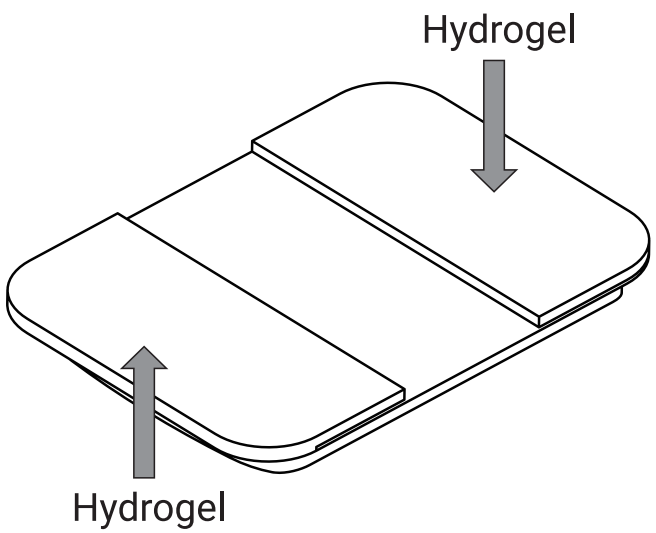


Figure 4. Bottom view of electrode pad without plastic film

- The USB charging cable (see Fig. 5.)

➡ Plug the Micro USB into the USB port of the stimulator.

⇨ Plug Type-A USB into a power supply source with voltage/current limited to 5V/2.4A DC current.

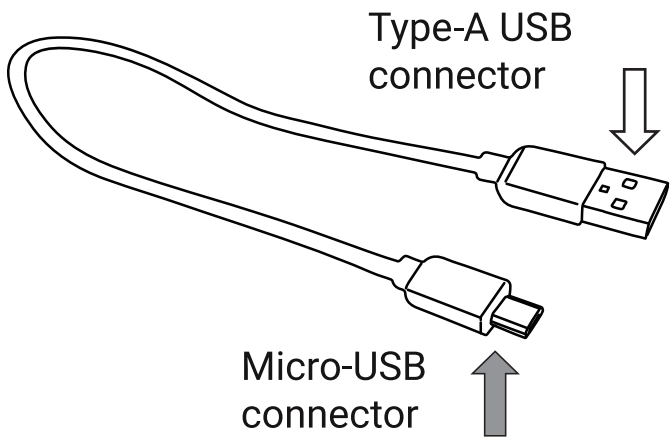


Figure 5. USB charging cable

- Electrode pad pack (see Fig. 6)

➡ The pack contains an electrode pad on a plastic film. The package cover can be opened from the edge.

Figure 6. The electrode pad pack

- Storage case (see Fig. 7)
  The storage case uses a magnetic pin closure. Its functions are indicated as follows:

➪ The grip area provides a fingertip grip to open the storage case easily.

➪ When storing the stimulator device in the case, place the electrode pad side on the film in the bottom of the case to avoid damage to the hydrogel.

➪ Magnets around storage case ensure a tight fit.

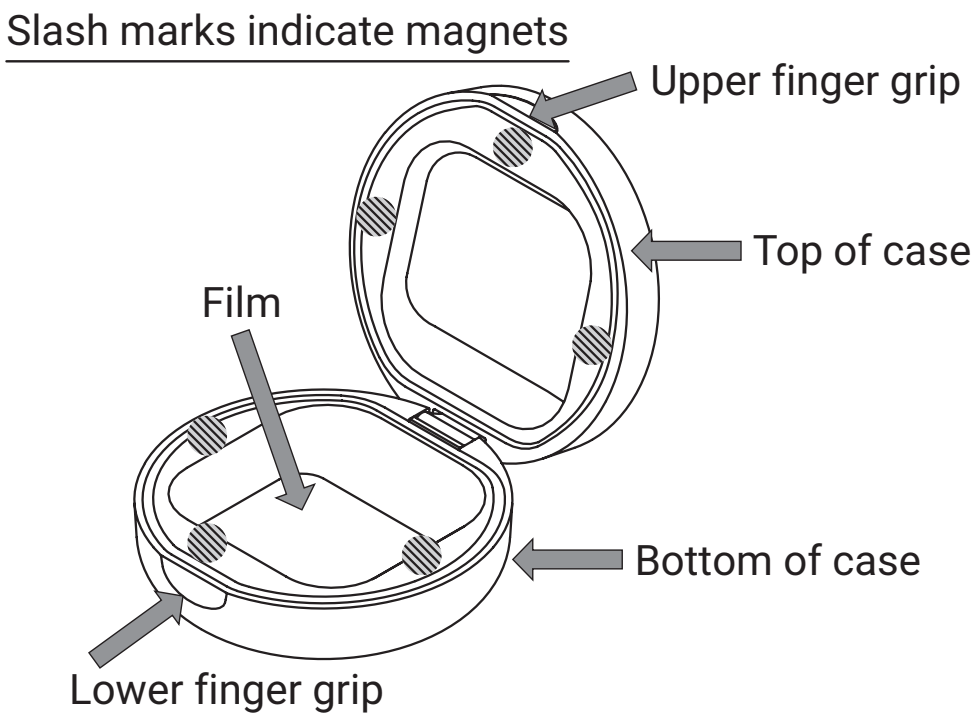


Figure7. Storage case

- User manual (see Fig. 8)
  Contains instructions for use

Figure 8. User manual

5. Preparation for use

5.1 The device must be charged before the first use. Follow the steps below.

1. Remove the stimulator from the packaging.
2. Remove USB cable from packaging and plug the Micro-USB into the USB port on the stimulator (see Fig. 9).
3. Plug the Type-A USB connector on the other end of the cable into the power supply source, **using the recommended adaptor (MEAN WELL GEM12I05-USB) or a power adaptor with DC output not exceeding 5V/2.4A.**
4. During charging, the indicator light will turn orange. The light will turn off when the device is fully charged; charging time is about 90 minutes.
5. Remove the USB cable from the stimulator and power supply source. Make sure the USB cover is closed after charging is complete.

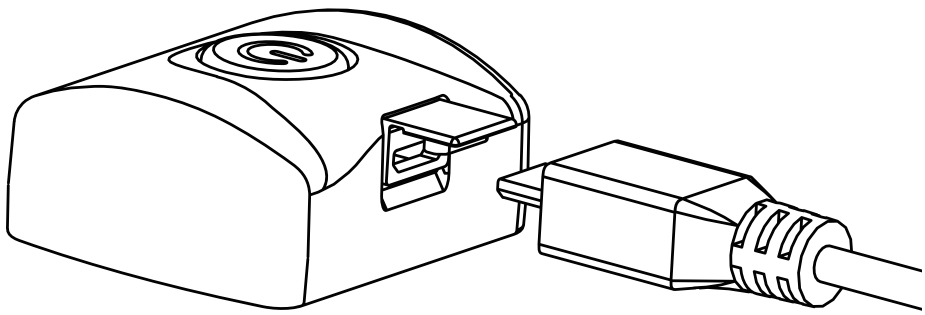
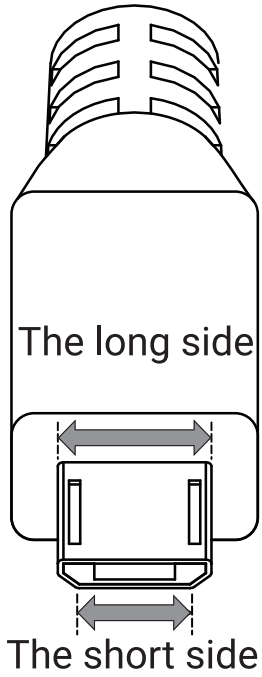


Figure 9. Connect the USB cable to the stimulator.

Figure 10. The longer side of the Micro-USB connector should face up.



Attention:

!! To start using the device, you must charge it first and wait until the device is fully charged.

!! The USB port on the stimulator and USB cable are only used for charging the device. Please only use the USB cable provided by the manufacturer and do not replace it without authorization.

!! If connecting the USB to the device according to Fig. 9, the long side of Micro-USB connector must be turned to the top (see Fig. 10).

!! Close the USB cover after charging is complete to prevent water or static electricity intrusion into the device.

5.2 Prepare the electrode pad as follows:

1. Take the electrode pad pack from the package and tear off the edge of the packaging. Then remove the electrode pad from the packaging.
2. Detach the plastic film on the bottom of the electrode pad (see Fig. 11).To remove the plastic

film, grasp the center section of the electrode pad (in the area with no hydrogel, shown by the solid arrow) with the fingers of one hand. Then grasp the plastic film (at the point indicated by the solid arrow) with the fingers of the other hand and gently separate the electrode pad from the plastic film. Be sure to avoid contacting with the hydrogel, or it may stick to the finger and deform after removal.

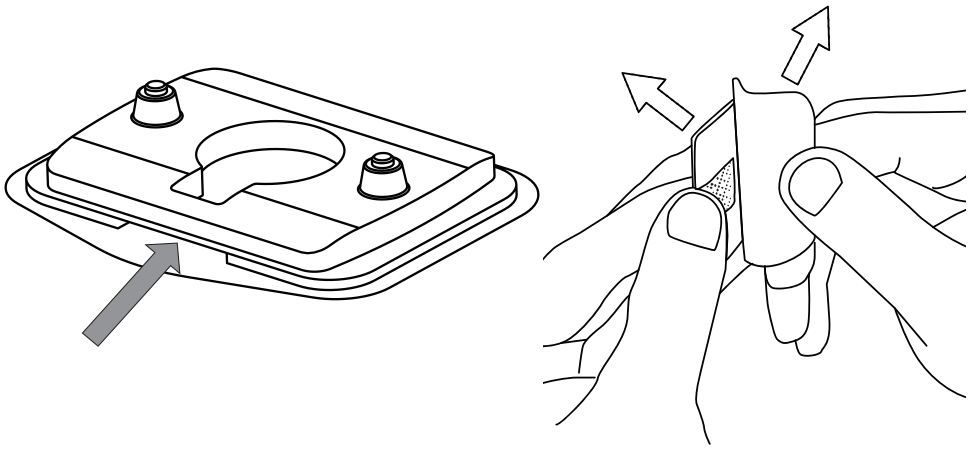


Figure 11. The electrode pad

Attention:

!! Check the expiration date before opening the package.

!! Detach the plastic film from the electrode pad gently to prevent residual hydrogel getting on the plastic film.

5.3 Connect the electrode pad

Connect the stimulator to the electrode pad (see Fig. 12). The two parts will automatically connect due to magnetic force.

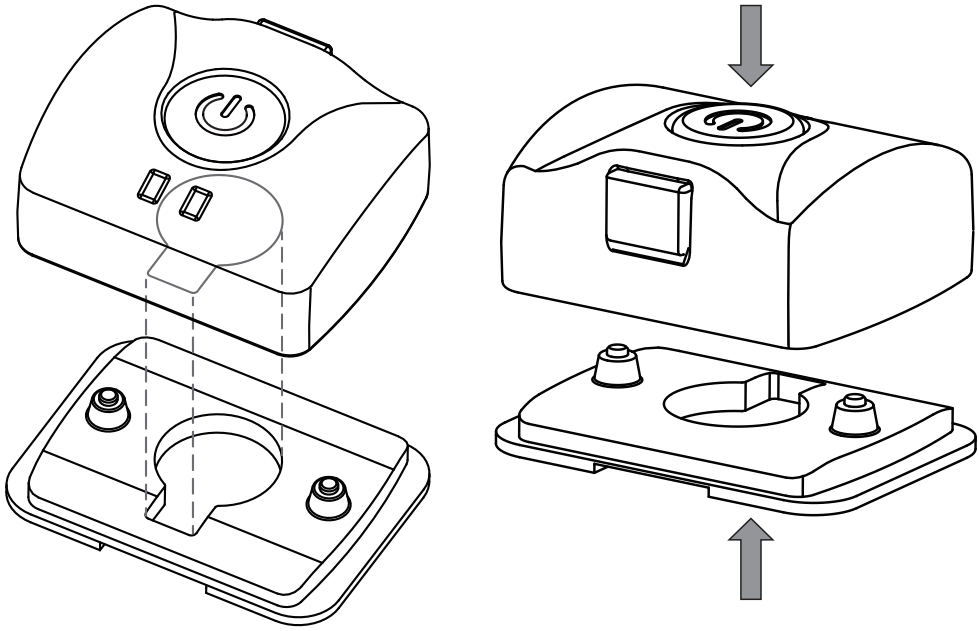


Figure 12. Connecting the stimulator to the electrode pad

Attention:

!! Make sure that the electrode pad and the stimulator are completely connected.

!! The pad and the stimulator are directionally constrained. If the pad direction is wrong, the stimulation effect will be influenced.

!! To avoid the hydrogel sticking to your hand, the electrode pad should be removed using the method described in 5.2.

!! If you are not ready to use the device, please place it in the storage case to prevent staining of the components.

5.4 Open the storage case

Grip both edges to open the storage case (see Fig.13).

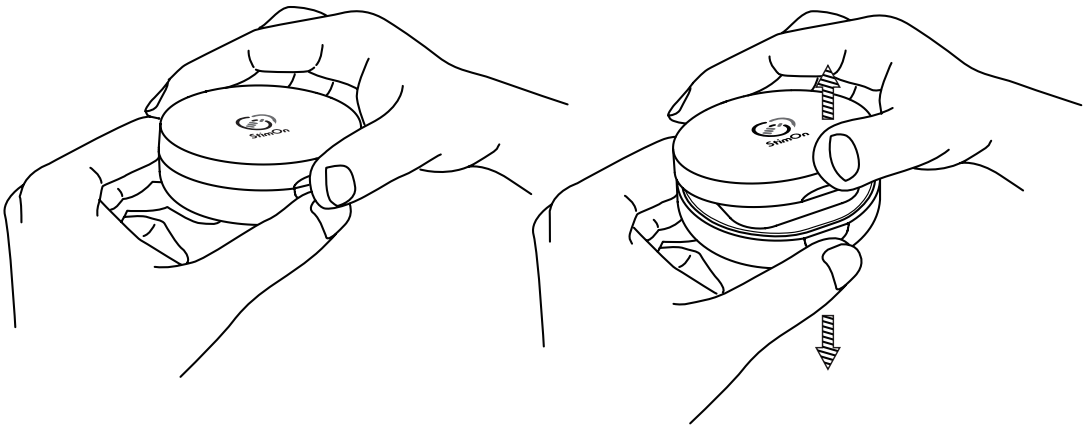


Figure 13. Opening the storage case

6. Operate the device using the following steps:

1. Ensure that the skin at the treatment site is dry before and during treatment to prevent the electrode pad from detaching from the skin. Use a washcloth with mild soapy water to clean skin, rinse well, and pat dry thoroughly. Do not rub dry or apply moisturizer.
2. Place the device on the treatment area and ensure the electrode pad is well attached to the treatment area. Recommended treatment areas are shown below (see Fig. 14-17). Place the device in the direction indicated in Fig. 14-17 below.
   - Ankle pain: Place the device under the process of the ankle or close to the heel.

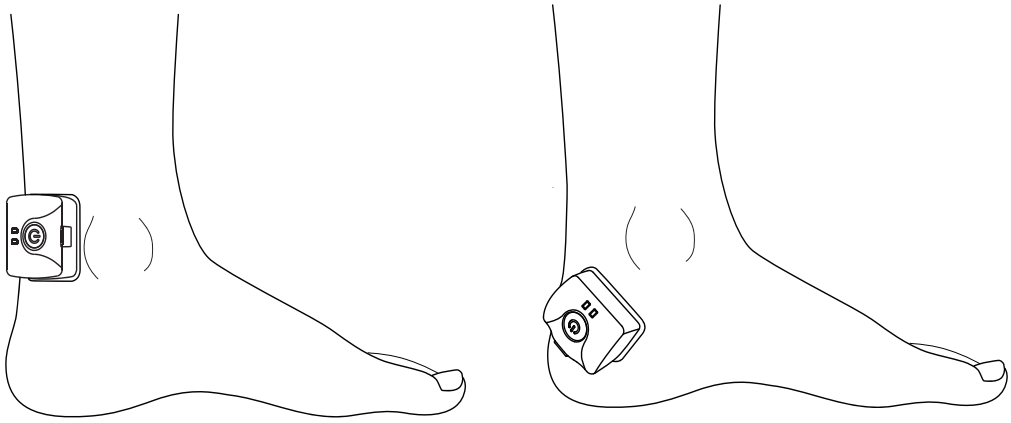


Figure 14. Recommended placement for ankle pain

- Pain of fingers and hands: Place the device at the base of the thumb.

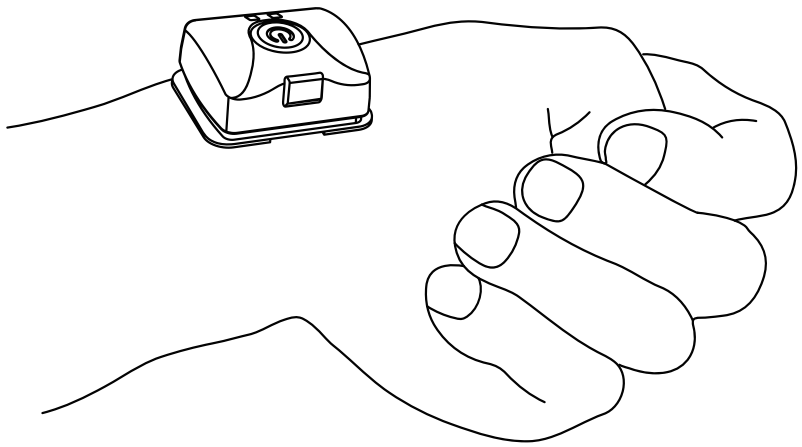


Figure 15. Recommended placement for pain in the fingers and hands

- Elbow joint pain: Place the device on the inside of the arm near the elbow joint.

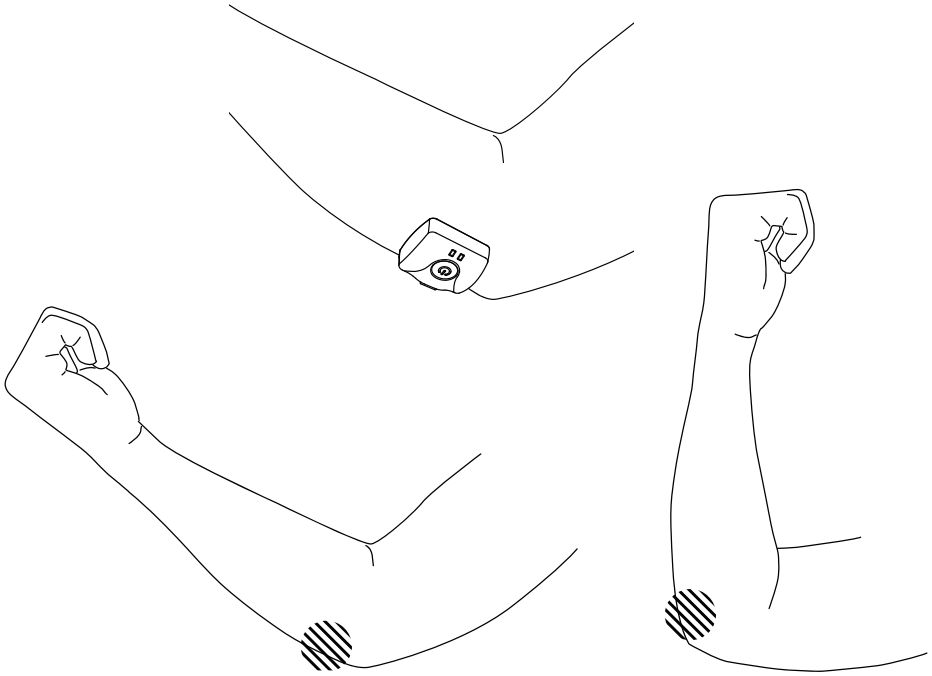


Figure 16. Recommended placement of the device for elbow joint pain. Slash marks show device placement from different viewing angles.

- Wrist joint pain: Place the device at the center of the inner wrist.

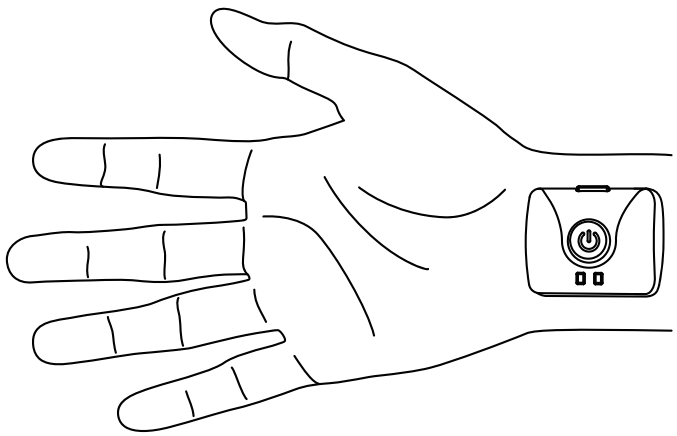


Figure 17. Recommended placement of the device for wrist joint pain

3. Press the button to start treatment. The stimulator indicator will light up in blue and vibrate 3 times.
4. The blue indicator light will remain on and the device will vibrate once every 5 seconds during treatment. The blue light will automatically turn off and the stimulator will vibrate again 3 times after the end of the 15- minute treatment.
5. Remove the device carefully to avoid damaging the skin. The stimulator can be removed first if the electrode pad is difficult to remove.

Attention:

!! The device will stop if the button is pressed during treatment. The blue light will turn off and the stimulator will vibrate 3 times.

!! The treatment will automatically stop if the stimulator is disrupted due to a device protection mechanism (e.g., if the stimulator is removed/ dropped or if the electrode pad detaches from the skin during treatment).

!! If the treatment time lasts less than 15 minutes, please refer to the "troubleshooting" section.

!! Do not bend the electrode pad while attaching it to the skin. Fit the electrode pad evenly to the skin after it is attached to the skin.

!! The device adheres best to clean, dry skin with gentle but firm pressure applied to the electrode pad. Do not apply with excessive force.

!! To remove the electrode pad, pinch it in the areas shown by the arrows in Fig. 11. Then, peel it back over itself, in the direction of hair growth. Peel slowly and progressively at an angle to the skin to avoid damaging the skin.

7. Cleaning and storage

7.1 Device storage

After treatment, place the device in a dry environment until the next use. The device should be stored with the electrode pad in the storage case to prevent it from getting dirty (see Fig. 18 for device storage in the storage case). Place the electrode pad on the film in the bottom side of the case to prevent damage to the hydrogel.

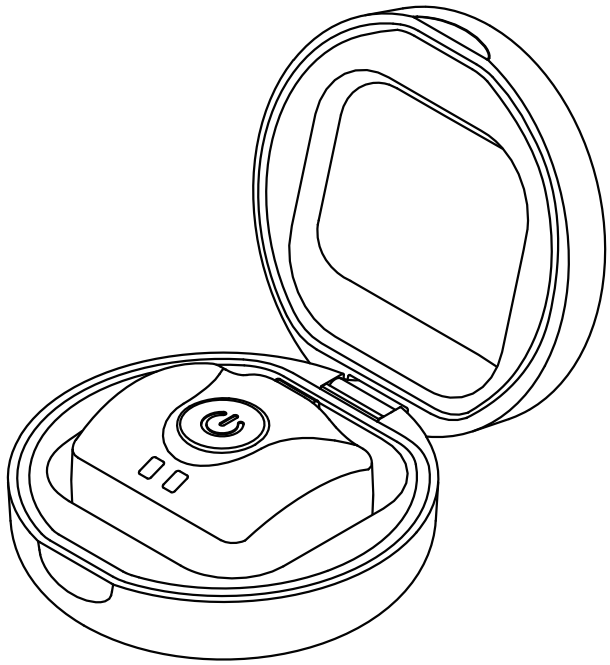


Figure 18. Device storage

7.2 Cleaning the stimulator

Use a clean, slightly damp washcloth to clean the stimulator. Do not apply heavy pressure when wiping the stimulator. Do not apply immerse the stimulator in water or spray water directly onto the stimulator, otherwise the water might seep into the stimulator through a gap or stimulation pin, damaging the device.

Attention:

!! Do not use any detergents or immerse the device in any liquid.

7.3 Replacing the electrode pad

The electrode pad has a lifetime of about 20 uses. The electrode pad may need replacement earlier if used frequently. The electrode pad's life will be considerably shortened if used on dirty or oily skin; it is best to clean the electrode pad application area with soap and water, then rinse and thoroughly dry before each session. If you're in doubt about the integrity of the electrode pads or if you want to order fresh electrode pads, please order online at www.gimermed.com

Attention:

!! Please replace the electrode pad if it:

– is past the expiration date labeled on the electrode pad pack.

– is defective or broken.

– will no longer adhere to the skin.

!! The electrode pad is designed for use by one person only. To prevent cross contamination, do not allow others to use it.

7.4 Rechargeable Battery

The battery has a finite lifetime of 12 months, with approximately 500 recharging cycles. To maximize battery life, please charge the stimulator every 3 months when not in use. A fully charged battery provides 2-3 hours of continuous use. If the battery cannot be charged effectively or if the fully

charged battery can only be used for a short time, contact your local customer specialist for a replacement.

8. Troubleshooting

The most common problems that might be encountered with the StimOn™ Pain Relief System are listed in the table below with their solutions. If the information provided below does not solve the problem, please contact the customer specialist in your country.

Problem	Possible cause	Solution
No response from the device when the button is pressed.	The device has no power	Charge the device. Have your local customer specialist replace the device if it is fully charged but does not turn on.
The indicator light turns from blue to orange, flashes 3 times, and the device suddenly vibrates 3 times during treatment.	The device is at low power.	Charge the device.
The device cannot be charged.	The USB cable you are using was not provided by the device manufacturer.	Use the correct USB cable.

The device cannot be charged.	The USB cable is inoperable.	Ask your local customer specialist to replace the cable.
	The USB cable is not plugged in the right direction or the power supply source is not adequate.	Charge the device properly (see Chapter 4.1).
The indicator light does not display when the button is pressed or after treatment, but the device still vibrates.	The indicator is inoperable.	Ask your local customer specialist to replace the device.
The device does not vibrate when the button is pressed or during treatment, but the indicator light is blue.	The vibrator is inoperable.	Ask your local customer specialist to replace the device.
Connection problems during treatment: The indicator light turns blue and flashes 3 times, and the device vibrates 3 times.	The connection between the stimulator and electrode pad is not in right direction.	Ensure the connection direction is correct according to the instructions.

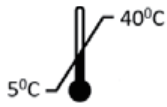
Connection problems during treatment: The indicator light turns blue and flashes 3 times, and the device vibrates 3 times.	The electrode pad is not attached to the skin firmly.	Reattach the electrode pad.
	The hydrogel area is damaged.	Ask your local customer specialist to replace the electrode pad.
	The electrode pad is past the expiration date.	Replace the electrode pad.
1. The indicator lights turn blue and orange at the same time. 2. The blue indicator light is on for over 15 minutes during treatment. 3. The orange indicator light stays on after the device finishes charging (about 120 minutes). 4. The vibrator does not vibrate 3 times to indicate device state, but vibrates continuously instead. 5. Other abnormal device status not indicated in the instructions.	Unknown; possibly due to user operating the device arbitrarily.	Press the button twice. If the above method does not work, press the button and hold for 20 seconds to restart the device or consult your local customer specialist.

9. Recycling

This product contains rechargeable lithium batteries which cannot be disposed of as general household trash. Please follow the regulations for waste electrical and electronic equipment in your country/region. Improper disposal of electrical and electronic goods may result in pollution or harm.

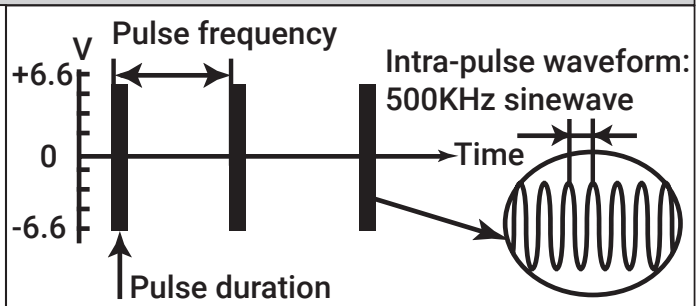
10. Symbol definitions

Symbol	Definition
	Read the instruction for use before using the product.
	Type BF Applied Part accd. to IEC 60601-1. This means that the product is applied to the user through conductive contact (electrode pad).
	Do not throw item in the trash (see Section 9, Recycling).
	Manufacturer name and address.
	Date (Year) of manufacture
	Caution of potential hazard. This means “Caution: TENS output”. You can see this symbol near the electrode.

	Lot number
	Model number
	Expiration date: Do not use if product is expired.
	Only operate device between 5 - 40 ºC.
	Only operate device between 15 - 90% humidity.
	Protected from touch by fingers or objects greater than 12 mm. Protected from water spray less than 15 degrees from vertical.
	Direct current (DC)

11. Specifications

Stimulator	
Product name	StimOn™ Pain Relief System
Model	GM2439
Dimension	31mm x 38 mm x 15mm
Weight	30g
Firmware version	V1.0.00
Ingress Protection Rating	IP22

Recharging time	About 90 minutes
Usage time after full charge	About 150 minutes.Usage time may decrease due to aging/power consumption because the battery may lose its charge over time.
Treatment session	15-minute single session
Power supply	Rechargeable 3.7V/125mAh lithium polymer battery.
Expected life of product:	Over 1 year, under normal usage.
Shelf life	1 year
Stimulation parameter	
Output waveform	
Pulse width	25 ms
Carrier frequency	500KHz Symmetric two-phase sine wave (Static voltage 0 DC)
Pulse frequency	2 Hz
Output peak current (Ip)	13.2mA @500 ohms under new electrode pad conditions
Output current (r.m.s)	9.3mA @500 ohms under new electrode pad conditions
Output peak voltage (Vp)	6.6V±20% @500 ohms under new electrode pad conditions
Output voltage (r.m.s)	4.7V @500 ohms under new electrode pad conditions

Operating Conditions	
Temperature	5 ºC to 40 ºC
Humidity	15 % to 90 % (non-condensing)
Atmospheric pressure	700 hPa to 1060 hPa
Transport /Storage Conditions	
Temperature	-25 ºC to 60 ºC The condition of -25 ºC or 70 ºC back to use should stand for at least 3 hours at room temperature.
Humidity	15 % to 90 % (non-condensing)
Atmospheric pressure	700 hPa to 1060 hPa
Accessories	
Electrode pad	Model: 3436 Dimensions: 29mm x 40mm x 7.6mm Contact area on the skin surface (pair of hydrogels): 772.3 mm^2 Shelf life: 18 months Reusability: About 20 times depending on usage and storage conditions Preferred storage conditions: temperature below 30 ºC, humidity 50%+/-5%
USB cable	Cable length: 60±2cm. (Not including the metal connector) ⎓ 5V/2.4A (DC).
Storage case dimensions	Diameter Ø64.0mm x 27.3mm

Compliance Standards	
IEC 60601-1:2005	IEC 60601-2-10: 2012
IEC/EN 60601-1-2:2014	IEC 60601-1-11: 2015

12.Warranty

※ This product provides a one-year warranty from the date of purchase. The warranty applies to the stimulator only. The warranty does not apply to damage resulting from failure to follow the user manual, accidents, or abuse, alteration or disassembly of the device by unauthorized personnel.

※ Please confirm if there are obvious appearance defects on the product or accessories; do not use a defective product. Product may be replaced within one month of the purchase date.

※ Please contact the manufacturer or local customer specialist for product replacement or other issues.

※ Please confirm the expiration date on the electrode pad pack before use.

13. Physician record

As noted in the section “Important Safety Information”, the following table can be utilized by your physician to record your issue history during your appointments with the physician.

Date	Consulting details	Remarks

14. Electromagnetic Compatibility Information

Safety and electromagnetic compatibility

When used in accordance with the manufacturer's instructions, the StimOn™ Pain Relief System complies with the general requirements for safety of medical electrical equipment IEC 60601-1 and the electromagnetic safety requirements of Medical electrical equipment IEC 60601-1-2.

- Power input voltages and frequencies during the Electromagnetic Compatibility tests

The【StimOn™ Pain Relief system】operation combination is as below: **OP 1:** Charger Mode – AC 110V (indicator light: Orange) **OP 2:** Charger Mode – AC 230V (indicator light: Orange) **OP 3:** Treatment Mode – DC 3.7 V (indicator light: Blue) Note: The device uses Adapter AC 100~240V by USB slot to charge.	
Test item	Power input Voltage and Line Frequency
RF conducted EMISSIONS CISPR 11	**OP 1:** Charger Mode – AC 110V (indicator light: Orange) **OP 2:** Charger Mode – AC 230V (indicator light: Orange)
RF radiated EMISSIONS CISPR 11	**OP 1:** Charger Mode – AC 110V (indicator light: Orange) **OP 2:** Charger Mode – AC 230V (indicator light: Orange) **OP 3:** Treatment Mode –DC 3.7V (indicator light: Blue)
Harmonic emissions IEC/EN 61000-3-2	**OP 1:** Charger Mode – AC 110V (indicator light: Orange) **OP 2:** Charger Mode – AC 230V (indicator light: Orange)

Voltage fluctuations/ Flicker emissions EN 61000-3-3	**OP 1:** Charger Mode – AC 110V (indicator light: Orange) **OP 2:** Charger Mode – AC 230V (indicator light: Orange)
Electrostatic Discharge IEC 61000-4-2	**OP 1:** Charger Mode – AC 110V (indicator light: Orange) **OP 2:** Charger Mode – AC 230V (indicator light: Orange) **OP 3:** Treatment Mode – DC 3.7 V (indicator light: Blue)
Radiated Susceptibility IEC 61000-4-3	**OP 1:** Charger Mode – AC 110V (indicator light: Orange) **OP 2:** Charger Mode – AC 230V (indicator light: Orange) **OP 3:**Treatment Mode – DC 3.7 V (indicator light: Blue)
Electrical fast transient/burst IEC 61000-4-4	**OP 1:**Charger Mode – AC 110V (indicator light: Orange) **OP 2:** Charger Mode – AC 230V (indicator light: Orange)
Surge IEC 61000-4-5	**OP 1:** Charger Mode – AC 110V (indicator light: Orange) **OP 2:** Charger Mode – AC 230V (indicator light: Orange)
conducted susceptibility IEC 61000-4-6	**OP 1:**Charger Mode – AC 110V (indicator light: Orange) **OP 2:** Charger Mode – AC 230V (indicator light: Orange)
Power frequency magnetic field IEC 61000-4-8	**OP 1:** Charger Mode – AC 110V (indicator light: Orange) **OP 2:** Charger Mode – AC 230V (indicator light: Orange) **OP 3:** Treatment Mode – DC 3.7 V (indicator light: Blue)
Voltage dips and interruption IEC 61000-4-11	**OP 1:**Charger Mode – AC 110V (indicator light: Orange) **OP 2:** Charger Mode – AC 230V (indicator light: Orange)

▪ Guidance and manufacturer's declaration – Electromagnetic Emission Table

Guidance and manufacturer's declaration – **Electromagnetic Emission**			
The 【StimOn™ Pain Relief system】 is intended for use in the electromagnetic environment specified below. The customer or the user of the 【StimOn™ Pain Relief system】 should ensure that the devices are used in such an environment.			
	Emissions test	**Compliance**	**Electromagnetic Environment**
1	RF emissions CISPR 11	■ Group 1 □ Group 2	The 【StimOn™ Pain Relief system】 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. (CISPR 11：2015 +A1：2016，Annex A)
2	RF Emissions CISPR 11	□ Class A ■ Class B	The 【StimOn™ Pain Relief system】 is suitable for use in all establishments, including domestic establishments and those directly connected to the public

3	Harmonic Current Emissions IEC 61000-3-2	■ Class A / ☐ Class B ☐ Class C / ☐ Class D ☐ Not Applicable	low-voltage power supply network that supplies buildings used for domestic purposes.
4	Voltage fluctuations/ flicker emissions IEC 61000-3-3	■ Complies ☐ Not Applicable	

▪ Guidance and manufacturer's declaration– Electromagnetic Immunity

Electromagnetic immunity - **recommended separation distance** between portable and mobile RF communications equipment and the StimOn™ Pain Relief System
The【StimOn™ Pain Relief system】is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 【StimOn™ Pain Relief system】 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Portable and mobile RF communications equipment, while in use, should not be closer to any part of the 【StimOn™ Pain Relief system】than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF IEC 61000 -4-6	3 Vrms outside the ISM Band, 6 Vrms in the ISM Band	Not applicable	d = 1.2√P 150 kHz to 80 MHz d=0.35√P 80 MHz to 800 MHz d=0.7√P 800 MHz to 2,7 GHz Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated RF IEC 61000 -4-3	3 V/m (Professional healthcare facility environment) 10 V/m (Home healthcare environment) (80 MHz to 2.7 GHz)	10 V/m 80 MHz to 2.7 GHz	
Recommended separation distances between portable and mobile radio-frequency (RF) communications equipment and the device			

Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)		
	150 kHz to 80 MHz(m) d=1.2√P	80 MHz to 800 MHz (m) d=0.35√P	800 MHz to 2.7 GHz (m) d=0.7√P
0.01	N/A	0.04	0.07
0.1	N/A	0.11	0.22
1	N/A	0.35	0.7
10	N/A	1.11	2.21
100	N/A	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (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 higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

▪ Guidance and manufacturer's declaration– Electromagnetic Immunity(continued)

The 【StimOn™ Pain Relief system】is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 【StimOn™ Pain Relief system】 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 【StimOn™ Pain Relief system】as recommended below Table, according to the maximum output power of the communications equipment.

Declaration – electromagnetic immunity			
The【StimOn™ Pain Relief system】 is intended for use in the electromagnetic environment specified below. The customer or the user of the 【StimOn™ Pain Relief system】 should ensure that the device is used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge IEC 61000-4-2	■ ±8 kV contact ■ ±2kV, ±4kV, ±8kV, ±15kV air	The Same	Home Healthcare Environment.
Radiated RF EM Fields IEC 61000-4-3 (RS)	■ 10V/m □ 3V/m	Complies	Home Healthcare Environment.
Proximity Fields From RF Wireless Communications Equipment IEC 61000-4-3	■ Table 9	The Same	Home Healthcare Environment.

Electrical fast transient/burst IEC 61000-4-4	■ ±2 kV For power supply lines ■ ±1 kV For input/output lines 100kHz	Complies	Home Healthcare Environment
Surge IEC 61000-4-5	■ ±1 kV Line(s) to line(s) ■ ±2 kV Line(s) to Ground	Complies	Home Healthcare Environment.
Conducted Disturbances induced by RF Fields IEC 61000-4-6(CS)	■ 3Vrms 0.15kHz~80MHz ■ 6Vrms, in ISM and amateur radio bands between 0.15 and 80MHz ■ 6Vrms, in ISM bands between 0.15 and 80MHz	Complies	Home Healthcare Environment.
Voltage dips IEC 61000-4-11	■ Dip to 0% U_T ；0.5 Cycle (0°~360°, Step 45°) ■ Dip to 0% U_T ；1 Cycle (0°) ■ Dip to 70% U_T ；25/30 Cycles (0°)	Complies	Home Healthcare Environment.

Declaration – electromagnetic immunity			
The【StimOn™ Pain Relief system】 is intended for use in the electromagnetic environment specified below. The customer or the user of the 【StimOn™ Pain Relief system】 should ensure that the device is used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage interruptions IEC 61000-4-11	■ Residual 0% U_T ；250/300 Cycles	Complies	Home Healthcare Environment.
Rated Power Frequency Magnetic Fields (MS) (50/60 Hz) IEC 61000-4-8	■ 30 A/m	Complies	Home Healthcare Environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

15. Electromagnetic Interference

- The StimOn™ Pain Relief System has been tested and complying with IEC 60601-1-2.
- As with all electrical devices, the StimOn™ Pain Relief System may be susceptible to electromagnetic interference (EMI) from a variety of radio wave sources. Electromagnetic waves emitted from sources such as - but not limited to - TV stations, two-way radios, cell phones, radio stations, and “HAM” radio transmitters may cause the StimOn™ Pain Relief System to affect operation function. These EMI sources may also permanently damage the StimOn™ Pain Relief System's control system.
- Electromagnetic interference from various sources varies in intensity as well as potential for effect on your StimOn™ Pain Relief System. Every electrical device can resist EMI sources up to a certain intensity. This means that each electrical device has a certain “immunity” to EMI interference. The intensity of the interfering source can be measured in volts per meter (V/m). Your StimOn™ Pain Relief System has been tested and passed an immunity level of 10 V/m.
- Electromagnetic energy rapidly gains intensity as you move close to the transmitting source. As such, certain devices are of particular concern if the StimOn™ Pain Relief System is used near or around these devices. EM interference from hand-held radio wave sources are usually of the highest intensity and thus, most prone to affect the functions of your electrical stimulation. These hand-held sources

include - but are not limited to - cell phones and CB radios. It is always a good idea to turn OFF your cell phone when you are using your StimOn™ Pain Relief System.

- If you notice that your StimOn™ Pain Relief System is intermittent stimulation or stops unintentionally (behaving abnormally or erratically), detach your device immediately and check for potential sources of EMI interference.
- Be aware of nearby transmitters, such as radio or TV stations and try to avoid coming close to them.
- If unintended stop or intermittent stimulation occurs, detach the StimOn™ stimulator device as soon as it is safe.
- Be aware that adding accessories or components, or modifying the StimOn™ Pain Relief System, may make it more susceptible to EMI; and NOTE: There is no easy way to evaluate their effect on the overall immunity of the StimOn™ Pain Relief System.
- Report all incidents of unintended stop or intermittent stimulation to the distributor and/or manufacturer listed on the back of this manual, and note whether there is a radio wave source of EMI nearby.

16. Submitting Adverse Event Reports to FDA

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 acknowledgment 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:
Report Online at www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

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 https://www.fda.gov/media/85598/download

Manufacturer

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