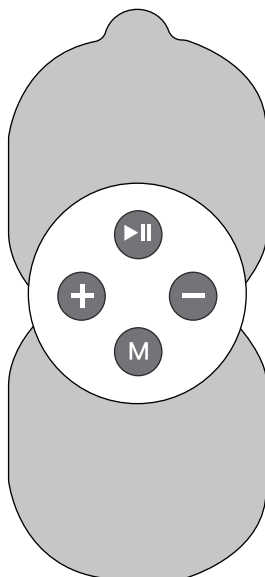


JUSTWILL

TENS AND EMS

User Manual



Model:JT8012C

Before using the TENS device, please read the user manual carefully.

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1.GENERAL DESCRIPTION

Model JT8012C is indicated for OTC TENS and OTC EMS.

OTC TENS (Transcutaneous Electric Nerve Stimulation):To be used for temporary relief of pain associated with sore and aching muscles in the shoulder,waist, back, neck,abdomen, bottom, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

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

2.CAUTIONS

2.1 CONTRAINDICATIONS

- (1)Patients with pace makers and cardiovascular problems should not use the device.
- (2)The device should not be administered over the abdomen or pelvis during pregnancy.
- (3)Patients with epilepsy should not apply the electrodes to the neck or head.
- (4)Patients with heart disease, cancer or any other health conditions should not use the device, unless recommended by a medical practitioner.
- (5)Patients who have suffered acute trauma or surgical procedures in the past six months.
- (6)Patients with undiagnosed pain syndromes should not use the device, unless recommended by a medical practitioner.

2.2 PRECAUTIONS

- (1) Do not apply the electrodes on inappropriate sites, such as over chest, the head, anterior neck, eyes, mouth and the front of throat.
- (2) Do not apply the electrodes on areas of broken or damaged skin, such as open wounds.
- (3) Do not apply the electrodes on the swollen, infected or inflamed areas or skin eruptions.
- (4) Do not apply the electrodes on the skin with diminished sensation because nerve damage is likely to diminish the effectiveness and the patient maybe unaware that high-intensity currents are causing skin irritation.
- (5) Patients should not use the device in water or when operating hazardous machinery such as driving.
- (6) Do not use the device near monitoring equipment.
- (7) Do not use the device close to transdermal drug delivery system.

3. WARNINGS

- (1) Patient with an implanted electronic device (such as a cardiac pacemaker) should not use the device unless specialist medical opinion has first been obtained.
- (2) Simultaneous connection of a patient to a high frequency surgical ME EQUIPMENT may results in burns at the site of the STIMULATOR electrodes and possible damage to the STIMULATOR.
- (3) Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy ME EQUIPMENT may produce instability in the STIMULATOR output.
- (4) Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- (5) Stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart.
- (6) Stimulation should not be applied over the carotid sinus nerves,

particularly in patients with a known sensitivity to the carotid sinus reflex.

(7) Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.

(8) Stimulation should not be applied transcranially.

(9) Never use the device while driving, operating machinery or during activities in which involuntary muscle contractions may endanger the user or others.

(10) Do not use the device in the bath or shower.

(11) Never use the device while sleeping.

(12) Never immerse the device in any liquid.

(13) No service and no maintenance shall be done while in use with a patient.

(14) Do not modify device without authorization of the manufacturer.

(15) Keep unit out of the reach of young children.

(16) Apply the whole surface of the electrodes firmly to the skin. Do not use electrodes that do not stick properly to the skin or only partially stick to the skin.

(17) The electrodes should be discarded when they are no longer adhering.

(18) Only use the electrodes provided by the manufacturer, do not use other kinds of electrodes. Otherwise, it will cause skin irritation if the current density is more than $2\text{mA}/\text{cm}^2$.

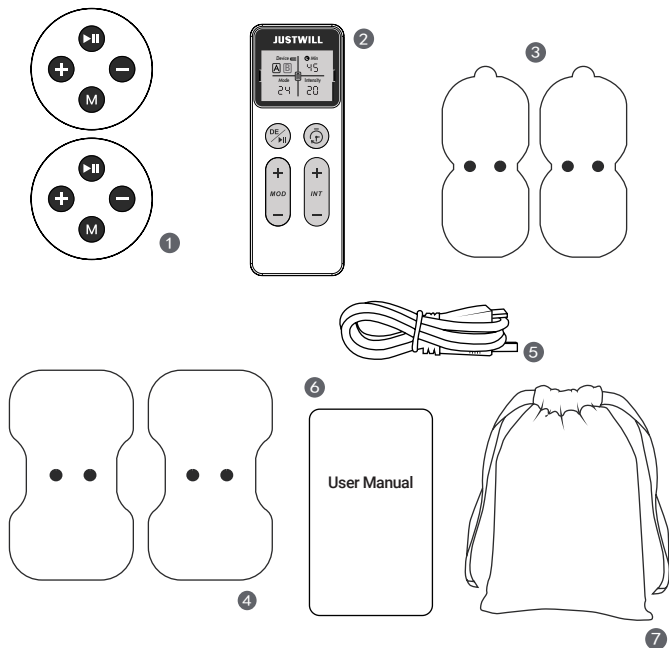
(19) Over long application may cause harm to the patient.

(20) Stimulation should not be done in conjunction with OXYGEN RICH ENVIRONMENTS ADVERSE REACTIONS.

(21) ADVERSE REACTIONS: You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin. You should stop using the device and should consult with your healthcare advisor if you experience adverse reactions from the unit.

4. PACKAGE LIST

Please check the contents of the device carefully.



(1) TENS host x 2

(5) Dual port USB-C charging cable x 1

(2) Remoter X 1

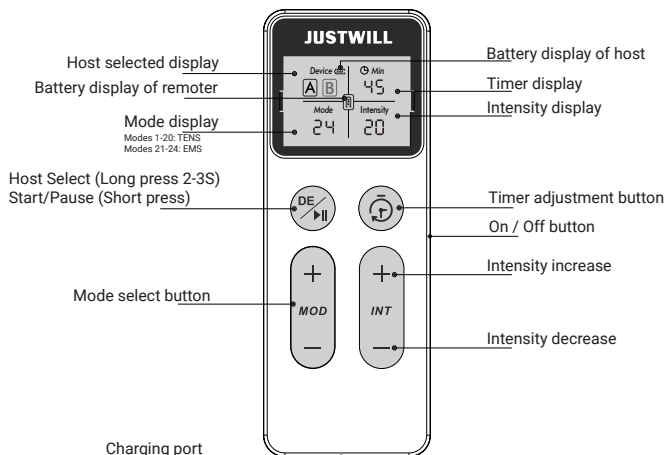
(6) User Manual x 1

(3) Butterfly electrodes x 2

(7) Storage bag

(4) Large electrodes x 2

5.REMOTE CONTROL OPERATION INSTRUCTIONS



Once you are familiar with features and general operating instructions, please follow the steps below:

How To Use:

- (1) Make sure the TENS host are connected into the snap-pin connectors of the electrode pads.
- (2) Peel off the plastic film from the opposite side of the butterfly or large electrodes supplied.
- (3) Place the TENS attached to the electrode pad onto the treatment areas. Press down firmly and ensure a full and firm contact is made with the skin.
- (4) Turn on the device by toggling the switch, and short press the  button on the host as indicated by the LED light being green.
- (5) Turn on the remoter you should hear 1 beep, this indicates the remoter and host are responding.

Long press the  button to choose the Host A/B. Press the MOD +/- button to select the modes. Once you have set Mode, increase the

intensity slowly by pressing the INT + button. Set a level that is a pleasant sensation and not too strong. Press the  button to adjust the treatment time as needed.

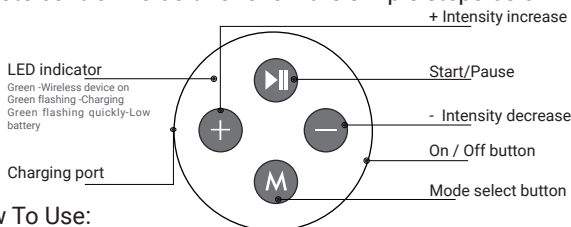
(6) When a treatment session is done, the device will be in a pause state. The green light on the host will stay on. This feature allows you to restart your treatment again if required. If you need to continue the treatment, just short press the  button to restart and then set the mode, intensity, and timer as you need.

(7) If you want to pause or restart, please short press the  button (Please set the mode, intensity, etc. as needed).

Note: If the host is not activated again within 30 minutes, the Bluetooth connection will automatically disconnect, please remember to turn off the host and remote control by toggling the switch to save power.

6. USING YOUR MODULE INDEPENDENTLY

You may use the device in a standalone mode without the use of the remote control. To do this follow the simple steps below.



How To Use:

(1) Place the TENS attached to the electrode pad onto the treatment areas. Press down firmly and ensure a full and firm contact is made with the skin.

(2) Turn on the device by toggling the switch, and short press the  button on the host as indicated by the LED light being green.

(3) Press the M button to change the modes, the device has 20 TENS modes (1-20) and 4 EMS modes (21-24).

(4) Press the +/- button to adjust the intensity level.

(5) The timer is always set at 45 minutes.

Note: If you stop using it, please remember to turn off the host by toggling the switch to save power.

7.ELECTRODE INSTRUCTIONS FOR USE

Turn Stimulator off before applying or removing electrodes.

7.1 Application of the self-adhesive pads & aftercare

The electrode pads have a maximum usage of 25-30 applications to keep your pads in good condition apply a small amount of water to the gel side of the pad every 4th application (do not over wet). Do not apply any gels or creams to the pads as this will destroy the hydro-gel on the electrode pad.

7.2 Application

(1) Skin site must be very clean and dry. Dirty, flaky or oily skin will prevent electrodes from adhering to the skin. If necessary, trim excess hair with scissors. If skin is oily, wipe down with an alcohol or electrode skin prep prior to application. Be sure to wash hands before handling electrodes.

(2) Remove electrodes from bag and reseal bag to protect remaining electrodes.

(3) Insert the stud electrodes on to the back of the device.

(4) Grasping a tiny edge of the electrode, peel and remove electrode from the protective plastic liner. Save liner for electrode storage.

(5) Place electrode onto skin treatment site (as recommended by your clinician) by firmly applying from the center of the electrode to the outer edges. Adhesion improves when electrodes reach skin temperature.

(6) If gel appears over-saturated with excessive moisture or perspiration, allow the electrode to air dry in a refrigerator with the gel side facing up until the gel regains its tack. If the gel appears dry, try adding a few drops of water to the gel and allow to rest in a dust-free environment until the gel regains its tack.

7.3 Removal and storage

(1) Lift a corner of the electrode and slowly peel the electrode off the skin, touching the adhesive gel as little as possible.

- (2) Place the electrodes pack onto the saved protective plastic liner.
- (3) Return the electrodes back into the storage bag and reseal tightly to prevent dry-out.
- (4) Store at room or cool temperature and keep out of direct sunlight.
- (5) The life of the electrode varies depending on skin conditions, amount of use, storage and climate. Electrode life may be extended by carefully following the application, removal, and storage instructions.

7.4 Caution

- (1) DO NOT place electrodes on broken skin. If skin irritation develops, discontinue use. Consult physician. Replace electrodes when they do not adhere or when treatment becomes uncomfortable.
- (2) DO NOT use unit while driving or operating machinery.
- (3) DO NOT wear electrodes when showering, bathing or swimming.
- (4) DO NOT apply electrodes across the head or across the heart or on the front neck.
- (5) Keep electrodes separated during treatment.
- (6) DO NOT exceed 0.1 watts/cm².
- (7) Using stimulation electrodes that are small or incorrectly applied could result in discomfort or skin burns.

8. TROUBLESHOOTING

When the device is turned on and the Start/Pause button is pressed, if the device emits 1 beep and the green light on, but you feel no sensation through the electrode pads, this may be due to the following conditions:

- (1) The Pads are not securely fastened to the skin.
- (2) The area being treated is too dry, please remove your pads and rub warm water into the treatment area and reapply the pads.
- (3) The electrode pads need replacing.

* Please note self-adhesive pads need replacing after 25-30 applications. To increase the life of your pads, smear a small amount of water onto the pad every 4th application.

If your device is not operating properly, please check for common

problems and suggested solutions. If there is no recommended action does not solve the problem, please contact the seller.

Stimulation is weak or non-existent:

- (1) Be sure skin is clean and gel electrode pads are firmly attached to the skin.
- (2) The battery is low and needs to be charged.
- (3) The gel electrode pad needs to be replaced.

9. MAINTENANCE TRANSPORTATION & STORAGE

- (1) Turn off the device before cleaning.
- (2) The electrode pad of the device can be cleaned with a soft and wet cloth.
- (3) Never use excessive water or cleaning agents to clean the device.
- (4) The gel electrode pad can remain on the control unit between uses, and are covered by the plastic film to avoid getting dirty and dry.
- (5) Avoid exposure to extreme moisture or temperature.

10. HELPFUL TIPS

It is important to place the TENS electrodes in a position which gives the most pain relief. This may take 3 or 4 attempts to find the most suitable position, for maximum pain relief.

If you are using two electrodes, place the electrodes directly onto the painful area at a position where you feel the pain starts and where it finishes. You may now position the electrodes around the painful area to locate the most suitable position for maximum pain relief.

11. EXECUTIVE STANDARDS

- (1) IEC 60601-1:2005+A1:2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance.

(2)IEC 60601-2-10:2013 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators.

(3)IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances -Requirements And Tests.

(4)IEC 60601-11:2015 Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment.

12. TECHNICAL SPECIFICATIONS

(1)Impulse frequency: 2-150Hz

(2)Pulse width: 50-450 μ s

(3)Waveform: biphasic. Shape: square

(4)The product output has no the DC component.

(5)Influence of output end open circuit and short circuit: it is able to support the influence of output end open and short circuit, and its performance will not be allowed to weaken.

(6)Safety classification: internal electric source class and type BF equipment

(7)Model: JT8012C

(8)Product Power Requirement:

Power source: Rechargeable lithium battery 3.7v/100mAh

Device safety classes: class II type BF

(9)Product Environmental Requirement:

a)Normal work environmental requirements:

Environment temperature: +5 $^{\circ}$ C ~+40 $^{\circ}$ C ;

Environment humidity: 0%-80%RH;

Atmospheric environment conditions: 860hPa-1060hPa.

b)Storage environment requirements:

Environment temperature: -25℃ ~+55℃ ;

Environment humidity: 0-93%RH;

Atmospheric environment conditions: 500hPa-1060hPa.

c)Transport environment requirements:

Environment temperature: -25℃ ~+55℃ ;

Environment humidity: 0-93%RH;

Atmospheric environment conditions: 500hPa-1060hPa.

13.GLOSSARY OF SYMBOLS

	Authorized Representative in the European Community		
	CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC		
	Class II equipment		
	Date of manufacture		Production Batch
	Manufacturer		Product catalogue reference code
	Specifies serial number		Caution
	Type BF applied part		
	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.		
	Follow instructions for use.		
	Medical device		
IP22	Level of protection against the insertion of solid bodies of size/diameter ≥ 12 mm and liquids in the presence of dripping water when tilted at 15° compared with product		

14.APPENDIX EMC DECLARATION

The equipment is intended for use in the electromagnetic environment specified below.

The customer or the user of the EQUIPMENT should assure that it is used in such an environment.

The Transcutaneous Electrical Nerve Stimulators is suitable for use in a professional health care environment, not including areas where there are sensitive equipment or sources of intense electromagnetic disturbances, such as the RF shielded room of an imaging system magnetic resonance imaging, in operating rooms near active AF surgical equipment, electrophysiology laboratories, armored rooms or areas where short wave therapy equipment is used.



- Do not use the system around strong electric field, electromagnetic field (e.g. MRI scan room) and mobile wireless communication devices. Using the device in an improper environment may cause malfunction or damage.
- The compliance with EMC and EMI regulation cannot be guaranteed by the use of modified cables or those which does not comply with the same standards under what the equipment was validated.
- The system must not be used adjacent or supported by other equipment. The recommendations of this manual must be followed.
- Do not use accessories, transducers, internal parts of components and other cables other than those previously specified by the manufacturer. This may result in increased emission or decreased electromagnetic immunity and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm to any part of the ultrasound system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- To maintain basic safety in relation to electromagnetic disturbances during the expected service life, always use the system in the specified electromagnetic environment and follow the maintenance recommendation described in this manual.

The following tables provide information on compliance of the equipment according to the standard EN 60601-1-2:2015.

Table 1 Compliance class

Emissions Test	Compliance	Electromagnetic Environment and Guidance
RF emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2- Compliance standards

Phenomenon	Basic Standard of	Immunity Test	Level of
Electrostatic discharge	IEC 61000-4-2	±8 KV contact ±2 KV, ±4 KV, ±8 KV, ±15KV air	±8 KV contact ±2 KV, ±4 KV, ±8 KV, ±15KV air
Radiated RF EM fields ¹	IEC 61000-4-3	3V/m 80 MHz-2.7 GHz 80% AM at 1 KHz	3V/m 80 MHz-2.7 GHz 80% AM at 1 KHz
Proximity fields from RF wireless communication equipment	IEC 61000-4-3	See table	See table
Electrical Fast/Transients bursts	IEC 61000-4-4	±1 KV 100 KHz repetition frequency	±1 KV 100 KHz repetition frequency
Conducted disturbances induced by RF fields.	IEC 61000-4-6	3V 0.15 MHz-80 MHz 6 Vm in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1KHz	3V 0.15 MHz-80 MHz 6 Vm in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1KHz
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz

Table 3- Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipments

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS460	FM ±5 KHz deviation 1KHz sine	2	0.3	28
710	704-787	LTE 13, 17 Band	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810						
870	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE 5 Band	Pulse modulation 18 Hz	2	0.3	28
930						
1720						
1845	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT/LTE 1, 3, 4, 25 Band, UMTS	Pulse modulation 217 Hz	2	0.3	28
1970						
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE 7 Band	Pulse modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						



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FCC Warning Statement: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. 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.

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

FCC Radiation Exposure Statement

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