Med-Fit

Pebble TENS Therapy Device

Model: JPD-ES200

CE 0598

med-fit

Med-Fit Pebble Dual Channel TENS
Patient Instructions & User Manual

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Contents

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01 PRODUCT OVERVIEW

1.2.2 What is TENS?

TENS (Transcutaneous Electrical Nerve Stimulation) is a proven and effective method for pain relief. Used daily by physiotherapists, and caregivers, TENS therapy harnesses electrical impulses to alleviate discomfort. High-frequency TENS stimulates the nervous system's pain-inhibiting mechanisms, blocking pain signals before they reach the brain. Meanwhile, low-frequency TENS promotes the release of endorphins, the body's natural painkillers, providing long-lasting relief. By placing electrodes on the skin near the affected area, TENS therapy offers a non-invasive, drug-free solution to managing pain.

02 SAFETY INFORMATION

2.1 Intended use

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.

Intended user and patient population

The TENS Therapy device is intended to be operated by adult who can understand this instruction manual. The patients should be 18 years or older adults.

Scope of application

For adjuvant treatment of pain and arthralgia such as back pain, neural paralysis and muscle pain.

Indications

1) It is used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household work activities.
2) Relaxation of muscle spasms.
3) Prevention or retardation of disuse atrophy.
4) Increasing local blood circulation.
5) Muscle re-education.
6) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
7) Maintaining or increasing range of motion.

2.2 Important Safety Precautions and Warnings

It is important that you read all the warnings and precautions included in this manual because they are intended to keep you safe, prevent risk of injury and avoid a situations that could result in damage to the device.

SAFETY SYMBOLS USED IN THIS MANUAL

⚠ 2.2.1 Contraindication

❶ 

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

❷ 

The device should not be used when cancerous lesions or other lesions are present in the treatment area.

❸ 

Stimulation should not be applied over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins, arteriosclerosis obliterans etc.).

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4.  Electrode placements must be avoided that apply current to the carotid sinus region (anterior neck) or transcerebrally (through the head).

5.  Apprehensive patients-usage of Electrical stimulation requires patient cooperation, hence the procedure shouldn't be attempted in patients with a communication handicap or a mental disability.

6.  Patients with cerebrovascular problems-patients with a history of aneurysm, stroke and transient ischaemia shouldn't be treated using electrical stimulation, as it stimulates peripheral blood flow which can be fatal in such cases.

7.  Epileptic patients-Electrical stimulation "pulses" have the potential to trigger a seizure.

8.  Acute pain cases/pain of unknown etiology-usage of TENS in undiagnosed cases may hinder in the diagnosis.

9.  Do not use in pregnancy, especially in the first trimester.

⚠ 2.2.2 WARNING

1) If you have had medical or physical treatment for your pain, consult with your physician before use.
2) If your pain is not subdued, Which becomes more than mild, or lasts for more than five days, stop using the device and consult with your physician.
3) Do not apply stimulation over your neck 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.

4 Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal.

5) Do not apply stimulation over, or in proximity to, cancerous lesions.
6) Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when electrical stimulation device is in use.
7) Do not apply stimulation when in bath or shower.
8) Do not apply stimulation while sleeping.
9) Do not apply stimulation while driving, operating machinery, or during any activity when electrical stimulation can put you at risk of injury.
10) Apply stimulation only to normal, intact, clean, healthy skin.
11) The long-term effects of electrical stimulation are unknown. Electrical stimulation device cannot replace drugs.
12) Stimulation should not take place while the user is connected to high-frequency surgical equipment, which may cause burn injuries on the skin under the electrodes, as well as problems with the stimulator.
13) Do not use the stimulator in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the stimulator.
14) Never use it near the cardiac area. Stimulation electrodes should never be placed anywhere on the front of the thorax (marked by ribs and breastbone), but above all not on the two large pectoral muscles. There it can increase the risk of ventricular fibrillation and lead to cardiac arrest.
15) Never use it on the eye, head and face area.
16) Never use it near the genitals.
17) Never use it on the areas of the skin which lack normal sensation.
18) Keep electrodes separate during treatment. It could result in improper stimulation or skin burns if electrodes are in contact with each other.
19) Keep the stimulator out of reach of children.
20) Consult your doctor if you are in any doubt whatsoever.
21) Discontinue it and do not increase the intensity level if you feel discomfort during use.

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2.2.3 Precautions

1) TENS is not effective for pain of central origin including headache
2) TENS is not a substitute for pain medications and other pain management therapies.
3) TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
4) Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patient
5) Since the effects of stimulation of the brain are unknown, stimulation should not be applied across your head, and electrodes should not be placed on opposite sides of your head.
6) The safety of electrical stimulation during pregnancy has not been established.
7) You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (silica gel).
8) If you have suspected or diagnosed heart disease or epilepsy, you should follow precautions recommended by your physician.
9) Caution if you have a tendency to bleed internally, e.g. following an injury of fracture.
10) Consult with your physician prior to use the device after a recent surgical procedure, because stimulation may disrupt the healing process.
11) Caution if stimulation is intended to be applied over the menstruation or pregnant uterus.
12) For single patient use only.
13) This stimulator should not be used by patients who is noncompliant and emotionally disturbed including whom with dementia or low IQ.
14) The instruction of use is listed and should be obeyed; any improper use may be dangerous.
15) Rare cases of skin irritation may occur at the site of the electrode placement following long-term application.

16) Do not use this device in the presence of other equipment which sends electrical pulses to your body.
17) Do not use sharp objects such as a pencil or ballpoint tip to operate the buttons on the control panel.
18) Check the electrode connections before each use.
19) Electrical stimulators should be used only with the electrodes recommended for use by the manufacturer.
20) When output of device more than 10mA or 10 V, the intensity of Channel will filcker.
21) Users should consult a healthcare professional before using the device.
22) The user shall report any serious incident related to the device to the manufacturer and the competent authorities of the Member States establishing the user and / or the patient.

2.2.4 Adverse Reactions

1) Possible skin irritation or electrode burn under the electrodes may occur.
2) Possible allergic skin reaction to tape or gel may occur.
3) We recommend that you use the product while seated until you become accustomed to the sensation.
4) If symptoms of tachycardia and extrasystolia (rapid heartbeat or extra stimulation) appear during treatment, stop the treatment and seek medical attention immediately.
5) If the stimulation makes you uncomfortable, reduce the stimulation Intensity to a comfortable level and contact your physician if problems continue.

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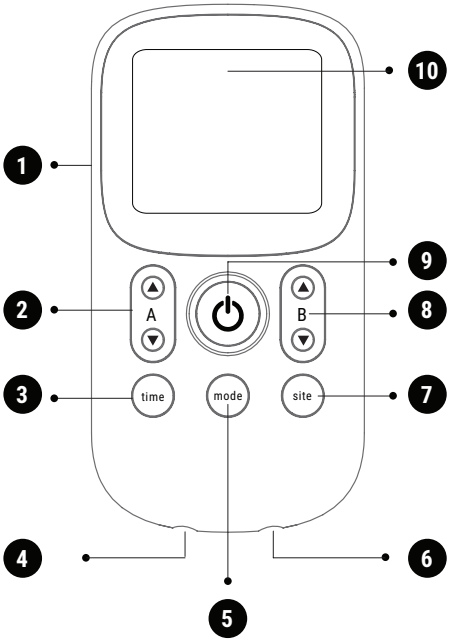
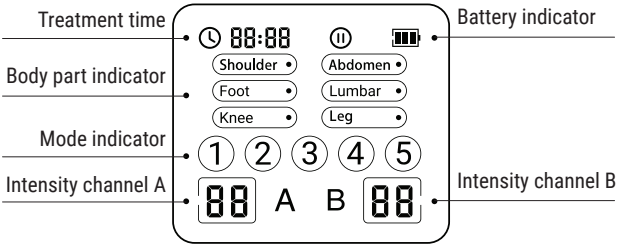
03 GETTING TO KNOW YOUR DEVICE

Product details



1. TENS Unit
2. Intensity +/- for A channel
3. Time setting
4. Port for channel A
5. Mode selection
6. Port for channel B
7. Site selection
8. Intensity +/- for B channel
9. Start / Pause / Off button
10. LCD screen

3.1 LCD display screen



3.2 Package includes

1 x TENS Unit.
4 x Electrode Pads
2 x Electrode Wires
4 x AAA 1.5V Batteries
1 x Instruction Manual
1 x Storage Bag

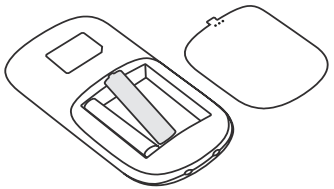
04 OPERATING YOUR DEVICE

4.1 Device instructions

Install the batteries

- Slide off the battery compartment cover.
- Insert four AAA batteries, ensuring correct polarity.
- Replace the cover securely.

If the low-battery symbol appears, replace the batteries immediately.

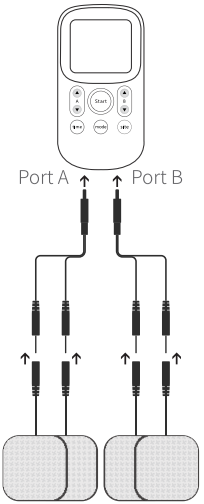


Notice of batteries:

1. Batteries may be fatal if swallowed. Therefore, keep the batteries and the product out of the reach of children. If a battery is swallowed, go to a hospital immediately.
2. If there's battery leakage, avoid contact with skin, eyes and mucus membranes. Rinse the affected spots with plenty of clear water immediately and contact a physician right away.
3. Batteries must not be charged, dismantled, thrown into fire or short-circuited.
4. Protect batteries from excess heat. Take the batteries out of the device if they are spent or in case that you will no longer use the them. This prevents damage caused by leaking batteries.

Connecting the pads to the TENS device

• Remove the TENS patient leads from the box and insert them into the base of the TENS device. One lead should be connected to port A, while the other lead connects to port B. Next, attach two pads to the 2 mm connectors. You can use either port A or port B and choose to use two or four pads.



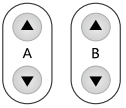
Place the pads on the treatment area

• Place the pads on the treatment area. You can now place the pads on the area to be treated. Refer to the electrode placement guide for assistance and tips on positioning the electrode pads.

Turing on the device

- To power on the device, press and hold the On/Off button for a few seconds until you hear a beep and the screen lights up.
- You can pause a treatment at any time by pressing the On/Off button once. A pause symbol will appear at the top of the screen to indicate that the treatment is on hold.

Choosing the treatment time time



- Press and hold the time button until the number flashes, and the clock symbol appears on the left of the displayed time.
- Use the left intensity arrow (up or down) to adjust the treatment time. The time can be changed in 5-minute intervals, ranging from 5 minutes to 90 minutes. If you see a "C," it indicates a constant treatment time.

Choosing your treatment site

- Press the "Site" button to select the area of the body you wish to treat. You can choose from any of the six body areas.

Choosing your treatment mode mode

- After selecting a body area, press the "Mode" button to choose a treatment mode. Each body part has five available modes, so press the mode button to select your desired mode, numbered 1 to 5.

Intensity settings

- You are now ready to begin the treatment. To start, press the up arrow on either the A or B port. The intensity levels for each port are independent, allowing you to adjust the intensity at any time.
  For your first treatment, we recommend setting a comfortable intensity and aiming for a treatment duration of at least 90 minutes.

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05 SPECIFICATION

5.1 Technical Information

Device name	Med-Fit Pebble
Model / type	JPD-ES200
Power sources	6V d.c., 4 x AAA batteries
Output channel	Dual channel
Waveform	Bi directional symmetric rectangular wave
Output current	48mA, error ±20%
Output intensity	Adjustable
Treatment mode	TENS mode
Operating condition	5’ C to 40’ C with a relative humidity of ≤80%, atmospheric pressure from 70.0 kPa~106.0 kPa
Storage condition	-20° C to 55’ C with a relative humidity of 10%-93%, atmospheric pressure from 70.0 kPa~106.0 kPa
Dimension	121.8 mm *63.6 mm *22.2 mm
Weight	86g (excluding battery)
Service life	5 years
Classification	BF type applied part, internal power equipment
Size of electrodes pad	50mm x 50mm
Output precision	±20% error is allowed for all the output parameters
P.W. (Pulse Width)	150μs/200μs,error ±20%
P.R. (Pulse Rate)	1-120Hz,error ±20%
Time	Adjustable, from 5 to 90 minutes or continuous.

06 TENS PROGRAMMES

Which programme should I use for my first treatment?

We always recommend starting with programme 4 as this is a conventional TENS programme used by numerous N.H.S. pain clinics and offers a good pain block for all types of acute and chronic pain.

All programmes have been carefully chosen to provide the best possible pain relief and we do recommend that over time try each programme to find which works best for you.

How high should I turn the intensity?

Everybody reacts differently to TENS Stimulation so you must increase the intensity (sensation feeling) to the correct level.

Increase the intensity to a sensation that is comfortable and always perceptible; never turn up to a level that is strong and uncomfortable.

You may use TENS if required for long periods to combat long-term chronic pain, however, please remember to place the electrodes in slightly different areas around the painful site, as this will help reduce skin irritation.

How long should a typical treatment

The most up-to-date research in TENS treatment times indicates that a minimum of 1 to 2 hours is required for effective pain relief. Your TENS may be used for much longer periods and you may find treatment times of 3 to 4 hours may work best for you.

Please remember that the intensity level is always kept at a pleasant sensation, never increase the intensity to uncomfortable levels as this can have a detrimental effect on your results.

TENS Treatment Programmes

The Med-Fit Pebble TENS unit is equipped with 30 pre-set treatment programmes, each tailored to different body regions. For each area, there are five specialised programmes, incorporating subtle variations in pulse rate and pulse width to optimise pain relief.

Each of these five programmes is based on four key TENS therapy modes:
Fixed Frequency TENS – Provides steady stimulation to reduce nerve accommodation.
Modulation TENS – Adjusts frequency to prevent the body from adapting to the stimulus.
Burst TENS – Sends pulses in bursts, mimicking natural pain suppression mechanisms.
Conventional TENS – A clinically validated setting widely used in pain management.

Programme 1 - Fixed Frequency TENS

- Delivers a constant pulse rate and fixed pulse width to ensure continuous pain relief.
- Ideal for long-term treatment and effective for both acute and chronic pain.
- Helps prevent the body from developing resistance to the therapy.

Programme 2 - Modulation TENS

- Dynamically varies the pulse frequency to prevent nerve adaptation.
- Suitable for extended use without diminishing effectiveness.
- Can be used for several hours or until pain subsides.

Programme 3 - Burst TENS

- Sends short bursts of high-frequency pulses at low intensity.
- Most effective for radiating nerve pain, such as sciatica and neuropathic pain.
- Particularly beneficial for pain that worsens later in the day.

- It is recommended to start at a low intensity and gradually increase to a comfortable level.

Programme 4 - Enhanced Conventional TENS

- A widely used setting recommended by NHS pain clinics for its clinical effectiveness.
- Provides rapid pain relief, suitable for both acute and chronic pain.
- Often used for postoperative pain, arthritis, and musculoskeletal conditions.

Programme 5 - Conventional TENS

- Similar to Programme 4 but operates at a lower pulse width for people who require a more comfortable pain inhibition.
- Recommended for patients requiring a weaker analgesic effects.

Guidelines for Effective Pain Relief

- Treatment Duration: For optimal results, TENS therapy should last at least 60 minutes per session.
- Extended Sessions: In many cases, longer treatment durations are necessary for sustained pain relief.
- Frequency of Use: TENS can be used multiple times per day, depending on individual pain levels.
- First-Time Users: It is advisable to start with shorter sessions to allow the body to adjust to the sensation and gradually increase session time as needed.
- By selecting the appropriate programme and adhering to these guidelines, users can effectively manage acute and chronic pain using the Med-Fit Pebble TENS unit.

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When using any of the TENS programmes for pain relief always start with the lowest intensity and gradually increase the level of intensity until you feel a “tingling” sensation. All programmes are different and therefore feel differently. You may try all programmes in the beginning and choose one that feels pleasant. Never increase the intensity to a level so that it hurts, always stay under the point of discomfort. Start with short sessions of 5 or 10 minutes until your body gets used to the stimulation.

Site	Mode	Pulse width	Pulse rate
Shoulder	1	150µs/200µs	30Hz/2Hz
	2	150µs	33Hz-100Hz/100Hz-33Hz
	3	200µs	1Hz/2Hz/3Hz/4Hz/3Hz/2Hz/1Hz
	4	200µs	80Hz
	5	150µs	120Hz
Abdomen	1	150µs/200µs	60Hz/2Hz
	2	150µs	33Hz-100Hz/100Hz-33Hz
	3	200µs	1Hz/2Hz/3Hz/4Hz/3Hz/2Hz/1Hz
	4	200µs	80Hz
	5	150µs	120Hz
Foot	1	150µs/200µs	40Hz/2Hz
	2	150µs	33Hz-100Hz/100Hz-33Hz
	3	200µs	1Hz/2Hz/3Hz/4Hz/3Hz/2Hz/1Hz
	4	200µs	80Hz
	5	150µs	120Hz

Site	Mode	Pulse width	Pulse rate
Lumbar	1	150μs/200μs	70Hz/2Hz
	2	150μs	33Hz-100Hz/100Hz-33Hz
	3	200μs	1Hz/2Hz/3Hz/4Hz/3Hz/2Hz/1Hz
	4	200μs	80Hz
	5	150μs	120Hz
Knee	1	150μs/200μs	50Hz/2Hz
	2	150μs	33Hz-100Hz/100Hz-33Hz
	3	200μs	4Hz/5Hz/6Hz/7Hz/8Hz/7Hz/6Hz/5Hz/4Hz
	4	200μs	100Hz
	5	150μs	120Hz
Leg	1	150μs/200μs	80Hz/2Hz
	2	150μs	33Hz-100Hz/100Hz-33Hz
	3	200μs	4Hz/5Hz/6Hz/7Hz/8Hz/7Hz/6Hz/5Hz/4Hz
	4	200μs	100Hz
	5	150μs	120Hz

07 CLEANING AND MAINTENANCE

Fully comply with the following necessary daily maintenance requirements to make sure the device is intact and guarantee its long-term performance and safety.

7.1 Cleaning and care for the device

7.1.1 Pull the electrodes out of the stimulator, clean the device with a soft, slightly damp cloth. In case of heavier dirt build-up, you may also apply a mild detergent.

7.1.2 Do not expose the Med-Fit Pebble TENS Device to moisture or dampness. And do not hold the Med-Fit Pebble TENS Device under running water, nor submerge it in water or other liquids.

7.1.3 The Med-Fit Pebble TENS Device is sensitive to heat and may not be exposed to direct sunlight. And do not place it on hot surfaces.

7.1.4 For reasons of hygiene, each user should use his/her own set of electrodes.

7.1.5 Do not use any chemical cleaners or abrasive agents for cleaning.

7.1.6 Ensure that no water penetrates into the machine. Should this happen, use the device again only when it is completely dry.

7.1.7 Do not clean the device during treatment. Be sure that the device is turned off before cleaning.

7.2 Maintenance

7.2.1 The manufacturer didn't authorise any maintenance agencies abroad. If your device has any problems, please contact the distributor. The manufacturer will not be responsible for the results of maintenance or repairs by unauthorised persons.

7.2.2 The user must not attempt any repairs to the device or any of its accessories. Please contact the retailer for repair.

7.2.3 Opening of the equipment by unauthorised agencies is not allowed and will terminate any claim to warranty.

Each product in manufacturing has been inspected through the systematic validation. The performance is stable and does not need to undertake calibration and validation. If your product can't reach the expected performance and the basic function has changed in normal use, please contact the retailer.

08 WARRANTY

For warranty claims, contact your dealer or service center.

Warranty Terms:

1. Coverage: The device is covered for one year from the purchase date.
2. Repairs: Warranty repairs do not extend the original warranty period.
3. Exclusions: The warranty does not cover:
   Damage from improper use or failure to follow instructions.
   Repairs or tampering by unauthorised parties.
   Damage during transport.
   Normal wear and tear of accessories.
   Damage from unauthorised disassembly.

The manufacturer is not liable for direct or indirect losses, even if a warranty claim is accepted.

09 USAGE OF ELECTRODE PADS

1. The electrode may only be connected with the TENS Device. Make sure that the device is turned off when attaching or removing the electrode pads.
2. The electrode can only be connected to the Med-Fit Pebble TENS Device. Ensure that the device is turned off when attaching or removing the electrode pads. If you need to reposition the electrode during application, please turn off the device first.
3. Be aware that electrodes might cause skin irritations. If you experience any irritation, such as redness, blistering, or itching, discontinue use immediately. Avoid using the Med-Fit Pebble TENS Device on the same body part permanently, as this can also lead to skin irritations.
4. Electrode pads are for single-person use only. The electrode must make complete contact with the skin to prevent hot spots, which can result in skin burns.

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10 TROUBLESHOOTING

Should any malfunction occur while using the device, check whether the parameters are set appropriately for therapy, and adjust the control correctly. Please see the following table:

Malfunction	Common reasons	Countermeasure
No display after replacing the battery.	1. There's foreign body in the battery compartment. 2. The battery has been used up or installed incorrectly. 3. There is foreign body in the battery interface. 4. The battery is not the correct type.	1. Check and clean the compartment. 2. Replace the new battery or install the battery correctly. 3. Check and clean the battery connections 4. Replace the battery with the correct type.
Automatic halt in the treatment	1. The electrode loses connection with the skin. 2. If the battery is used up.	1. Check and place the electrode properly on the skin. 2. Replace the battery.

Malfunction	Common reasons	Countermeasure
No sensation of stimulation	1. The electrode does not connect well to the skin. 2. Poor connection between the patient lead and the electrode 3. The battery is used up. 4. The skin is too dry.	1. Check and re-paste it on skin. 2. Check the connection. 3. Replace the battery. 4. Wipe the electrode and the skin with a wet cotton cloth.
Rash or tickle on the skin occurs in treatment	1. The treatment time lasts too long. 2. The electrode does not stick well to the skin. 3. The interface of the electrodes is dirty or dry. 4. The skin is sensitive to the electrode.	1. Do the treatment once a day and shorten the treatment time. 2. Check and stick the electrode well. 3. Wipe the electrode with a wet cotton cloth before use. 4. Check your a Allergic history. Please change the sticking place or shorten the treatment time. If your skin is over-sensitive, you should stop the treatment or go to see a doctor.

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11 NORMALISED SYMBOLS

	WEEE Symbol		Applied part of type BF
	Refer to instructions	IP22	IP classification
LOT	Batch code	EC REP	Authorised representative in the European Community
	Manufacturer	UK REP	Authorised representative in the United Kingdom
	Fragile, handle with care		Date of manufacture
	Keep dry		Keep away from sunlight
	Use by date		Temperature limit
	Humidity Limitation	SN	Serial number
	Caution		Atmospheric pressure limitation
	Users of the artificial pacemaker are prohibited from the device		Recycle symbol
	Packaging material cycle mark	CE 0598	CE mark
UDI	Unique device identifier	MD	Medical device

12 STORAGE

12.1 Storing The Electrode Pads and Lead Wires

1. Turn the device off and remove the lead wires from the unit.
2. Remove the electrodes from your body and disconnect the lead wires from the electrodes.
3. Place the electrodes onto the plastic film and then store into the sealed package.
4. Wrap the lead wires and store into the sealed package.

12.2 Storing the Unit

1. Place the unit, electrodes, lead wires and manual back into the carrying case. Store the box in a cool, dry place, -20°C ~ 55°C; Relative humidity: 10%~93%.
2. Do not keep in places that can be easily reached by children.
3. When not in use for a long period, remove the battery before storage.

13 DISPOSAL

Spent batteries do not belong to the household wastes. Disposal of the battery according to the current regulations. As a consumer, you have the obligation to dispose of batteries correctly.
Consult your municipal authority or your dealer for information about disposal.

At the end of the product life cycle, do not throw this product into the normal household garbage, but bring it to a collection point for the recycling of electronic equipment. Obsolete electrical and electronic equipment may have potentially harmful effects on the environment. Incorrect disposal can cause toxins to build up in the air, water and soil and jeopardise human health.

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14. ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

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

2* WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

3* WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

Emissions test	Compliance
RF emissions CISPR II	Group 1
RF emissions CISPR II	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations Flicker emissions IEC 61000--3-3	Not applicable

Declaration electromagnetic immunity		
Immunity test	IEC 60601 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air

Declaration electromagnetic immunity		
Immunity test	IEC 60601 Test level	Compliance level
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	Not applicable
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m
NOTE u_T is the a.c. mains voltage prior to application of the test level.		

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Declaration - IMMUNITY to proximity fields from RF wireless communications equipment

Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8 W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m

Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.

Declaration of conformity:

Shenzhen Jumper Medical Equipment Co., Ltd. Declares that the device complies with following normative documents: IEC60601-1, IEC60601-1-2, IEC60601-1-11, IEC60601-2-10, IEC62304, ISO10993-5, ISO10993-10, ISO10993-1,ISO10993-23, ISO14971.

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