

body clock

Classic *TENS*

ELECTROTHERAPY

Instructions for use



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Declaration of conformity:

Shenzhen Roundwhale Technology 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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1. Foreword

The Classic TENS is a dual channel output TENS stimulator. Before using, please read all the instructions in this user manual carefully and keep it safe for future use. The TENS stimulator belongs to the group of electrical stimulation systems. It has one basic function – TENS (Transcutaneous Electrical Nerve Stimulation).

Functions of the TENS stimulator:

The device has 3 programs (B (Burst), N (Normal) and M (Modulation)) and applies electric currents in the low-frequency range for therapy. Each program controls the generated electric impulses, their intensity, frequency and pulse width. Based on stimulating the body's natural pulses, the mechanism of electrical stimulation equipment creates electric impulses that are transcutaneous, transmitted to nerves or muscle fibers via the electrode pads.

The intensity of each channel can be adjusted independently and applied individually to one body part. This dual channel device can be used with four electrode pads, which allow you to stimulate muscle groups simultaneously with a wide selection of standard programs. The electrical pulse is firstly transmitted to the tissue, then it affects the transmission of stimulation in nerves as well as muscle tissues in the body parts.

1.2 MEDICAL BACKGROUND

1.2.1 About pain

Pain is an important signal in the human body warning system. It reminds us that something is wrong, without which, abnormal conditions may go undetected, causing damage or injury to vital parts of our bodies. Even though pain is a necessary warning signal of trauma or malfunction in the body, nature may have gone too far in its design. Aside from its function in diagnosis, long-lasting persistent pain serves no purpose.

Pain does not occur until an encoded message travels to the brain where it is decoded, analyzed, and reacted to. The message comes from the injured area, and travels along the small nerves leading to the spinal cord. There the message is transmitted to different nerves that travel up the spinal cord to the brain. Then the pain message is interpreted, referred to and pain is felt.

1.2.2 What is TENS?

TENS (Transcutaneous Electrical Nerve Stimulation) is an effective form of pain relief. It can be used daily and is clinically proven by physiotherapists and medical advisors. High-frequency TENS currents activate the pain-inhibiting mechanisms of the nervous system. Electrical impulses from electrodes, placed on the skin over or near the area of pain, stimulate the nerves to block the pain signals to the brain, causing the pain to go unperceived. Low-frequency TENS currents facilitate the release of endorphins, the body's natural painkillers.

2. Safety information

2.1 INTENDED USE

Intended Purpose

The device is designed to be used for temporary relief of pain, including the acute and chronic pain relief.

Target Population

The patient using this device must be an adult of 18 years or over.

Intended User

Medical staff or lay persons.

Indications

It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, joint, hip, hand, abdomen, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.



2.2 IMPORTANT SAFETY PRECAUTIONS & WARNINGS

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

2.2.1 Contraindications



- 1 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.
- 2) The device should not be used when cancerous lesions or other lesions are present in the treatment area.
- 3) 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.).
- 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 and 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 before 37 weeks of pregnancy.



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 the 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 devices 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 short wave 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 treatment and do not increase the intensity level if you feel discomfort during use.

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 patients.
- 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 hyper sensitivity 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) If pregnant, do not place the electrode pads over the abdomen.
- 12) For single patient use only.
- 13) This device should not be used by patients who are non compliant and emotionally disturbed including those who suffer with dementia or low IQ.
- 14) The instructions for use should be followed fully; 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 stimulator should be used only with the electrodes recommended for use by the manufacturer.
- 20) When the output of the device is more than 10mA or 10 V, the intensity light of the channel(s) will flicker.
- 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

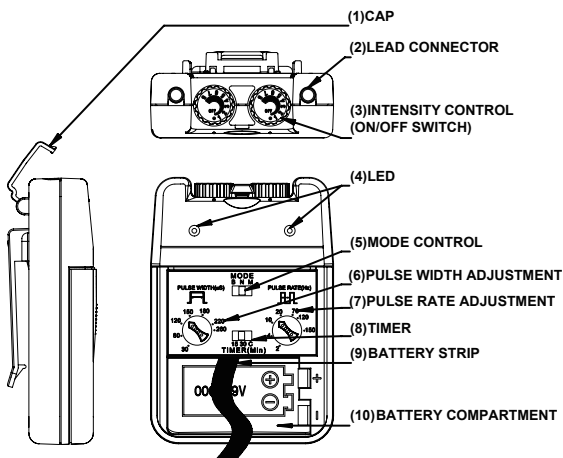
- 1) Possible skin irritation or electrode burn under the electrodes may occur.
- 2) Possible allergic skin reaction to tape or gel may occur.
- 3) If symptoms of tachycardia and extra systolia (rapid heartbeat or extra stimulation) appear during treatment, stop the treatment and seek medical attention immediately.
- 4) If the stimulation makes you uncomfortable, reduce the stimulation Intensity to a comfortable level and contact your physician if problems continue.

3. Getting to know your device

3.1 PACKAGE INCLUDES

- 1 x TENS Stimulator
- 4 x Electrode Pads (50 x 50mm)
- 2 x Electrode Leadwires
- 1 x 9V Battery
- 1 x User Manual and Pouch

3.2 DEVICE ILLUSTRATION



No	Description
1	Cap: Protects controls from being changed accidentally
2	LEAD CONNECTOR: Leadwire output sockets
3	INTENSITY CONTROL (ON/OFF SWITCH): Increase or decrease the output intensity of channel 1 and/or 2.
4	LED : These will light up green when a channel is"ON
5	Mode: B=Burst, N=Normal, M=Modulated.
6	Pulse Width: Duration each pulse lasts.
7	Pulse Rate: The amount of Hertz or pulses per second.
8	Timer: 15 min, 30 min, or continuous operation.
9	BATTERY STRIP: Place under 9-volt battery to assist in its removal
10	Battery Compartment: Insert battery, ensuring the positive(+) and negative (-) terminals are correctly positioned as marked

4. Specification

4.1 TECHNICAL INFORMATION

Device name	Classic TENS
Model/type	Dual Channel TENS
Power sources	One 9V battery
Output channel	Dual channel
Waveform	Bi-phase square-wave pulse
Output current	0-50V (Load:500 ohm)
Output intensity	Adjustable
Treatment mode:	TENS mode
Operating condition	5° C to 40° C with a relative humidity of 15%-93%, atmospheric pressure from 700 hPa to 1060 hPa
Storage condition	-10° C to 55° C with a relative humidity of 10%-95%, atmospheric pressure from 700 hPa to 1060 hPa
Dimension	9.5 cm (L) x 6.5 cm (W) x 2.35 cm (H)
Weight	122 grams with battery
Classification	BF type applied part, internal power equipment
Size of electrodes pad	50x50mm, square
Output precision	±20% error is allowed for all the output parameters

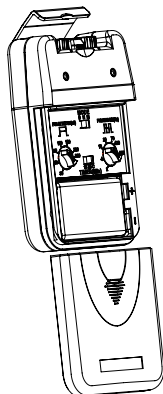
P.W. (Pulse Width)	Adjustable, from 30 to 260 μ s, 10 μ s/step
P.R. (Pulse Rate)	Adjustable, from 2 to 150 Hz, 1 Hz/step
Time	15, 30 minutes or continuous.
Device service life	5 years
Electrode pads shelf life	3 years
Modes	B (Burst), N (Normal) and M (Modulation)
Burst Mode	Bursts occur twice every second. Pulse width (adjustable), frequency = 100Hz.
Normal Mode	The pulse rate and pulse width are adjustable. They generate continuous stimulation based on setting value.
Modulation Mode	Pulse rate is automatically varied in a cyclic pattern over an interval of nominally 10 seconds (at max 150Hz). Pulse rate decreases lineally over a period of 4 seconds from the control setting to a value which is 40% less. The lower pulse rate will continue for 1 second and increases linearly over a 4 second period to its original value. The original pulse rate will continue for 1 second. The cycle is then repeated.

5. Operating Instructions

5.1 BATTERY

5.1.1 Check / replace batteries

To access the battery compartment, slide down the front cover down by gently pressing on the ribbed section with the thumb and move downwards. Insert battery, ensuring the positive(+) and negative (-) terminals are correctly positioned as marked in the battery compartment. Slide the front cover back up.



5.1.2 Disposal of battery

Spent batteries do not belong in household waste. Dispose of the battery following the current regulations. As a consumer, you have a legal obligation to dispose of spent batteries in a Recycling Bin.

1. If a battery is swallowed accidentally, please seek medical assistance immediately!
2. In case of battery leakage, please avoid contact with the battery through skin, eyes and mucus membranes. Once it occurs, please wash the contacted part with plenty of clean water and contact your doctor immediately.
3. Batteries cannot be dismantled, thrown into fire or short circuited.
4. Protect the battery from excess heat; Take the battery out of the product if it is spent or you don't use it for a long time. This can prevent damage to the device due to the battery leakage.
5. Always use the same battery type for this device.

5.2 Connect electrode pads to electrode wires

Insert the electrode leadwire pins into the electrode connectors. Ensure they are properly connected to ensure a good performance. Please refer to the diagram below.



Caution



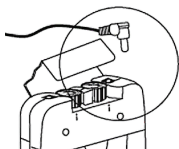
Always use the electrode pads which comply with the requirements of the IEC/EN60601-1, ISO10993-1/-5/-10 and IEC/ EN60601-1-2, as well as CE and FDA 510(K) regulations.

5.3 Connect electrode leadwires to the device

Before proceeding to this step, ensure that the device is completely switched OFF.

See the diagram above on page 15 and below to ensure you have connected the leadwires to both the unit and electrode pads correctly.

The device has two output dials controlling Channel 1 and Channel 2 at the top of the unit. You may choose to use one channel with one leadwire and two electrodes or both channels with two leadwires and four electrodes. Using both channels gives the user the advantage of stimulating two different areas at the same time.





Caution

Do not insert the plug of the leadwire into an AC power supply socket

5.4 ELECTRODE

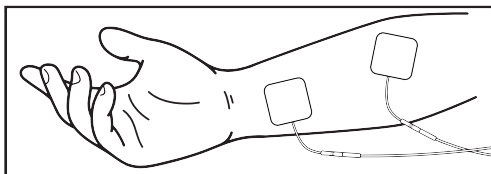
5.4.1 Electrode options

The electrodes should be routinely replaced when they start to lose their adhesiveness. If you are unsure of your electrode adhesive properties, please order new replacement electrodes from www.bodyclock.co.uk. Replacing electrodes should be reordered under the advice of your physician or the device manufacturer to ensure proper quality.

Follow application procedures outlined on the electrode packaging when using the new replacement electrodes to maintain optimal stimulation and to prevent skin irritation.

5.4.2 Place electrodes on skin

Place the electrode on the body part in need of treatment, according to the instruction of this user manual. Please make the skin clean before use and ensure the skin and electrode connect well.



Caution

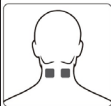
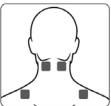
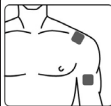
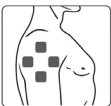
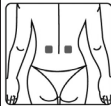
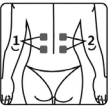
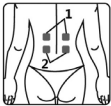
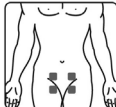
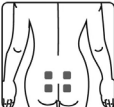


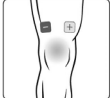
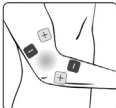
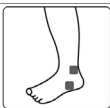
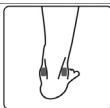
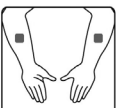
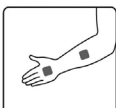
1. Always remove the electrodes from the skin by peeling them off gently in order to avoid injury in the event of highly sensitive skin.
2. Before applying the self-adhesive electrodes, it is recommended to wash and degrease the skin, and then dry it.
3. Do not turn on the device when the self-adhesive electrodes are not positioned on the body.
4. To remove or move the electrodes, switch off the device or the appropriate channel first in order to avoid unwanted irritation.
5. It is recommended that, at minimum, 1.5"x 1.5" self-adhesive square electrodes are used at the treatment area.
6. Never remove the self-adhesive electrodes from the skin while the device is still on.

5.4.3 Electrodes placement

The Classic TENS is suitable for home use which you should operate according to this user manual by placing the electrodes on the position where you feel pain. Conduct exercise, treatment and adjustment based on your own feeling.

Position of electrode placement under TENS programs

Neck				
Shoulder				
Arm				
Hand				
Back				
Abdomen				

Hip	   
Leg	       
Foot	
Joint (knee)	  
Joint (elbow)	 
Joint (ankle)	  
Joint (wrist)	 

6. Instructions for use

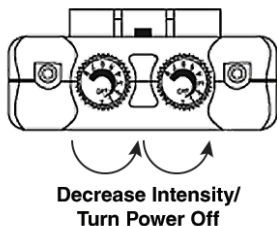
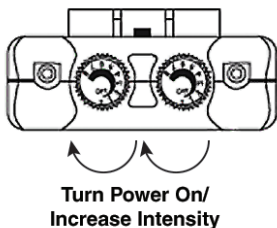
6.1 Power On/Off Switch and Intensity Controls:

Check that the device is switched off before placing the electrodes in the desired position on the treatment area. Only switch on the device once it is set up with the electrodes placed on the body.

By turning the controls clockwise, the appropriate channel is switched on and the impulses display LED will illuminate and begin to pulse according to the frequency set.

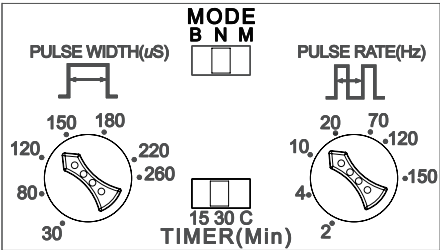
The current strength of the impulses transmitted to the electrodes increase further when the control is turned clockwise.

To reduce the current strength or switch the device off, turn the controls counter clockwise to the required setting or off-position.



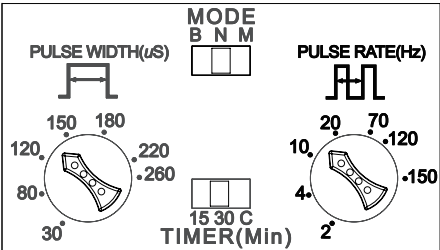
6.2 Mode Control

Expose the controls by sliding front cover down from the top of unit. The Mode control switch has 3 positions; B for Burst stimulation, N for Constant Stimulation, and M for modulation stimulation. Slide the Mode Selector until engaged in the desired position.



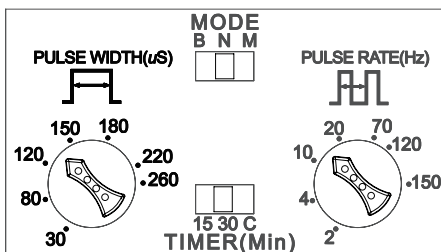
6.3 Pulse Rate Control

This dial determines how many electrical impulses are applied through the skin each second. By adjusting this dial, the number of current impulses per second (Hz) for both channels can be adjusted continually.



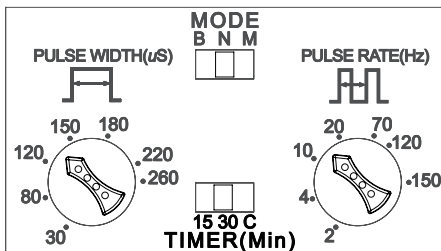
6.4 Pulse Width Control

This dial adjusts the length of time each electrical signal is applied through the skin, which controls the strength and sensation of the stimulation. If no instructions regarding the pulse width are given in therapy, set the control to the suggested 70-120 μ s.



6.5 Timer Control

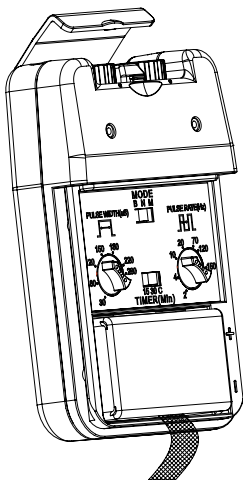
Control Treatment time of TENS can be preset with the Timer Control. This switch has 3 positions: 15, 30 and C (Continuous). Slide the Timer Control until engaged in the desired position.



6.6 Check/Replace the Battery:

Over time, in order to ensure the functional safety of TENS, changing the battery is necessary.

1. Make sure that both intensity controls are switched to the off position.
2. Slide the battery compartment cover down to reveal the battery.
3. Remove the old battery.
4. Insert the new battery into the compartment. Note the polarity indicated on the battery and in the compartment.
5. Replace the battery compartment cover and press to close.



6.7 Usage of electrode pads

1. Make sure that the device is turned off when attaching or removing the electrode pads.
2. If you want to reposition the electrodes during the application, turn the device off first.
3. The usage of electrodes may lead to skin irritations. If you experience such skin irritations, e.g. redness, blistering or itching, discontinue using them. Do not use the TENS stimulator permanently on the same body part, as this may also lead to skin irritations.
4. Electrode pads are intended for single patient use.
5. The electrodes must connect entirely to the skin surface to prevent hot spots, which may lead to skin burns.
6. Do not use the electrode pads for more than approximately 15 times, as connection between the electrodes and the skin deteriorates over time.
7. The adhesive force of the electrodes depends on the skin properties, storage condition, and the number of applications. If your electrode pads no longer fully stick to the skin's surface, replace them with new ones from www.bodyclock.co.uk. Place the electrode pads back onto the protective foil after use and store them in the storage bag between uses to prevent them from drying out. This retains the adhesive force for a longer period.
8. Do not use detergent to clean the electrode pads before and after use to avoid damaging the adhesion of the electrode pads.
9. The electrode pads must always be touched with clean hands, it is recommended to replace the electrode pads if they become soiled.

Caution



- 1) Before applying the electrodes, it is recommended for users to wash and degrease the skin, and then dry it.
- 2) Never remove the electrode from the skin while the device is still on.
- 3) Only use the electrode pads provided by the Body Clock Health Care Ltd. Usage of other companies' products could result in injuries to the user.

6.8 Where do I attach electrode pads?

1. Each person reacts differently to electric nerve stimulation. Therefore, the placement of the electrodes may deviate from the standard. If application is not successful, contact your physician to find out which placement techniques are best for you.
2. Only use electrodes supplied by Body Clock Health Care Ltd.
3. The size of the adhesive pads may not be changed, e.g. by clipping off parts of them.
4. Make sure that the region radiating the pain is surrounded by the electrodes. In case of painful muscle groups, attach the electrodes in such a way that the affected muscles are also surrounded by the electrodes.

Usage advice for TENS

If you do not feel any discomfort during treatment, we advise you to use the device until the session ends. Normally pain relief occurs after 5~10mins of treatment; If you feel discomfort during your treatment, you can either pause the session or decrease the intensity of the output. Normally, we recommend 1~2 treatments per day and one week, as a period of treatment; After a period of treatment, if the pain relief is not achieved or the pain gets even worse, please consult your doctor.

7. 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 Gently remove the leadwires from the device. 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 device to moisture or dampness. Do not hold the TENS stimulator under running water, nor submerge it in water or other liquids.
- 7.1.3 The TENS stimulator 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 has not authorized any maintenance agencies. If your device has any problems, please contact Body Clock Health Care Ltd. The manufacturer will not be responsible for the results of maintenance or repairs by unauthorized persons.
- 7.2.2 The user must not attempt any repairs to the device or any of its accessories. Please contact Body Clock Health Care Ltd. for repair.
- 7.2.3 Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.

Each product in manufacturing has been inspected through 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.

8. Troubleshooting

Should any malfunction occur whilst using the device, please check the following table for solutions.

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 oppositely. 3. There is foreign body in the battery interface. 4. The battery is not the right model or something goes wrong with the battery interface.	1. Check and clean the compartment. 2. Replace the new battery or install the battery correctly. 3. Check and clean the interface. 4. Replace the battery with the right model.
No sensation of stimulation	1. The electrode does not connect well to the skin. 2. If the connection between electrode connects well to the stimulator. 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.
Automatic halt in the treatment	1. The electrode loses connection with the skin. 2. If the battery is used up.	1. Check the electrode is placed properly on the skin. 2. Replace the battery.

Malfunction	Common Reasons	Countermeasure
Rash or tickle on the skin during treatment.	1. The treatment time lasts too long. 2. The electrode does not stick well to the skin. 3. The surface 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 down well. 3. Wipe the electrode with a wet cotton cloth before use. 4. Check your 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

Storage

9.1 STORING THE ELECTRODE PADS AND LEAD WIRES

1. Turn the device off and gently remove the lead wires from the unit.
2. Gently remove the electrodes from your body and disconnect the lead wires from the electrodes.
3. Place the electrodes onto the plastic backing sheet, and then store into the sealed outer package.
4. Wrap the leadwires and store into the sealed package.

9.2 STORING THE UNIT

1. Place the unit, electrodes, lead wires and manual back into the provided pouch. Store the box in a cool, dry place, $-10^{\circ}\text{C} \sim 55^{\circ}\text{C}$; 10% ~ 95% relative humidity.
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.



10. Disposal

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 normal household waste. 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 jeopardize human health.

11. Electromagnetic compatibility (EMC) tables

Guidance and manufacturer's declaration - electromagnetic emissions.

The device is intended for use in the electromagnetic environment specified below. The customer or the user has to ensure that it is used in such environment.

Emissions Test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR11.	Group 1.	The device 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 CISPR11.	Class B.	The device is suitable for use in all establishments including those directly connected to the public low-voltage power supply network that supplies to buildings power used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable.	
Voltage fluctuations Flicker emissions IEC 61000-3-3.	Not applicable.	

Guidance and manufacturers' declaration - electromagnetic immunity. The device is intended for use in the electromagnetic environment specified below. The customer of the device should assure that it is used in such environment

Immunity test	IEC 60601 Test level	Compliance Level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV direct & indirect contact; ±15kV air discharge	±8kV direct & indirect contact; ±15kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Not applicable	not applicable (for INTERNALLY POWERED ME EQUIPMENT)
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	Not applicable	not applicable (for INTERNALLY POWERED ME EQUIPMENT)
Voltage dips, short interruptions and volt-age variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT)for 5 sec	Not applicable	not applicable (for INTERNALLY POWERED ME EQUIPMENT)

Immunity test	IEC 60601 Test level	Compliance Level	Electromagnetic environment- guidance
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	10V/m	10V/m	Power frequency magnetic fields should be at levels characteristic of a typical location in typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such environment.

Immunity test	IEC 60601 Test level	Compliance Level	Electromagnetic environment-guidance
Radiated RF IEC 61000-4-3	10V/m & table 9	10V/m & table 9	Portable and mobile RF communications equipment should be used not closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.167\sqrt{P}$:0 MHz to 800 MHz $d = 2.333\sqrt{P}$:00 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 : At 80 MHz and 800 MHz, the higher frequency range applies.

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

a) Field Strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the

measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

- b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_i] V/m.

Test specifications for enclosure port immunity wireless communications equipment (Table 9)

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM800/ 900, TETRA 800, iDEN 820, CMDA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450 LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

NOTE If it is necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

- a) For some services, only the uplink frequencies are included.
- b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
- c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because it does not represents actual modulation. It would be worst case.

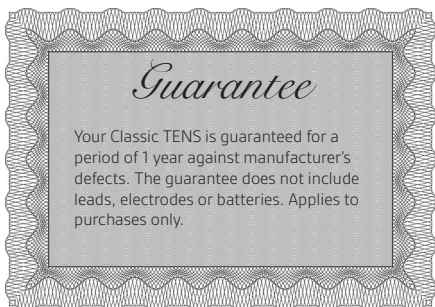
12. Normalized Symbols

	WEEE Symbol		Applied part of type BF
	Refer to instruction manual	IP22	IP classification
	Batch code		Authorized representative in the European Community
	Manufacturer		Date of manufacture
	Fragile, handle with care		Keep away from sunlight
	Keep dry		Temperature limit
	Use-by date		Serial number
	Humidity limitation		Atmospheric pressure limitation
	Caution		Recycling symbol
	Users of the artificial pacemaker are prohibited from using the device		CE mark
	Packaging material cycle mark		Unique device identifier
	Medical device		

13. Warranty

Please contact Body Clock Health Care Ltd. in case of a claim under the warranty. The warranty terms are as below:

1. The warranty period for this device is 1 year from the date of purchase which does not include leadwires, electrodes battery or other accessories. In the case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2. Repairs under warranty should be in the warranty period either for the device or for the replacement parts.
3. The following cases are excluded under the warranty
 - All damages that arise due to improper operation, e.g. non observance of the user instruction.
 - All damages due to repairs or tampering by the customer or unauthorized third parties
 - Accessories which are subject to normal wear and tear
 - Device damages due to privately disassembling devices.
4. Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.





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