BT-230

Brielle®

Professional

DIGITAL TENS

Transcutaneous
Electrical
Nerve
Stimulator

Operation Manual
Manual de Operación
Manuel d'utilisation
Bedienungsanleitung
操作手册
オペレーションマニュアル
사용 설명서

Operation Manual

Contents

1. INTRODUCTION

1.1 Product Introduction

Brielle Professional Digital Tens Monitoring BT-230 is a dual channel output: TENS, EMS and MASSAGE stimulator device. Before using, please read all the instructions in this user manual carefully and keep it safe for future use.

The COMBO stimulator belongs to the group of electrical stimulation systems. It has three basic functions- TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electronic Muscle Stimulation) and MASSAGE.

Functions of the COMBO stimulator: The device has 25 programs (10 TENS programs, 9 EMS programs and 6 MASSAGE programs) 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 simulating the body's natural pulses, the mechanism of electrical stimulation equipment is to create electric impulses that are transcutaneous transmitted to nerves or muscle fibers through the electrode. The intensity of the dual channel can be adjusted independently and applied individually to one body part. This dual channel device can be used with four pieces of electrode pads, which allow you to stimulate one 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 About pain

All of our body organs, incl. heart, brain, muscles and nerves, are not sensitive to the extremely feeble current. Bioelectricity has the necessary effects on our normal body operations. However, our bodies are sensitive to the external electrical simulations and will have various reactions. The bioelectricity abnormality is the body abnormality, which reflects as ache and sore. The treatment methods are electrotherapies, among which the low-frequency electrotherapy stands out. Frequently scheduled use of the COMBO stimulator Device on meridian points may have an effects to treat and alleviate

various physical pains, or use of the COMBO stimulator device for massage leads to body and mind relaxation during or after work.

1.3 TENS

(Transcutaneous Electrical Nerve Stimulation) is effective in relief of pain. It is daily used and clinically proven by physiotherapists, caregivers and top athletes around the world. High-frequency TENS currents activates the pain-inhibiting mechanisms of the nervous system. Electrical impulses from electrodes, placed on the skin over or near the pain area, 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.

1.4 EMS

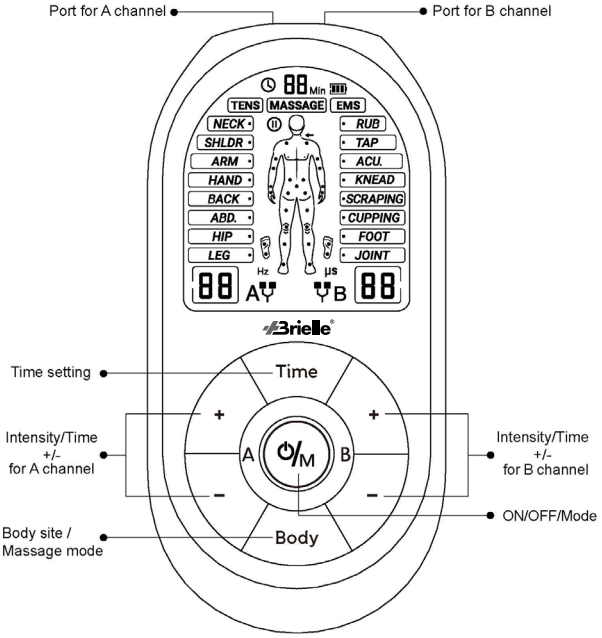
Electrical Muscle Stimulation is an internationally accepted and proven way of treating muscular injuries. It works by sending electronic pulses to the muscle needing treatment that causes the muscle to exercise passively. It is a product deriving from the square waveform, originally invented by John Faraday in 1831. Though the square wave pattern it is able to work directly on muscle motor neurons. The EMS System has low frequency and this in conjunction with the square wave pattern allowing direct work on muscle groupings.

1.5 MASSAGE

The massage function is non-medical function. The Massage stimulation program provides relaxing muscle vibration to loosen tight muscle.

2. ABOUT PRODUCT

2.1 Device illustration



Time Setting
• At standby mode, press “Time” button to set the treatment time.
+/- for A/B channel
• Press “+” buttom of A/B channel to increase the treatment time; long press to

rapidly increase the treatment time. The maximum treatment time is 60min.

- Press “-” button of A/B channel to reduce the treatment time: long press to quickly reduce the treatment time. The minimum treatment time is 5min.
- At standby mode, press ”+” button of A/B channel to increase the intensity and start running the A channel.
- Press “-” button of A/B channel to reduce the intensity

ON/OFF/MODE

- At power saving mode, press “⏻” button for 2s to start up.
- At standby mode, press “⏻” button to select treatment mode.
- At standby mode, press “⏻” button for 2s to shutdown.
- At treating mode, press “⏻” button 2s to stop the treatment.

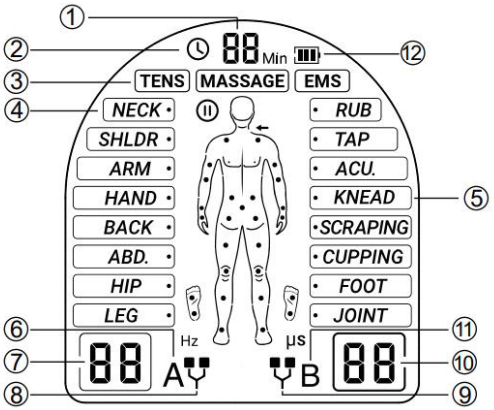
Port for A channel

Port for B channel

Body

- At standby mode, press “Body” button to select the treatment body part / massage type.

2.2 LCD display



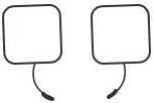
1	Treatment time	**7**	Intensity for Channel A
2	Timer icon	**8**	Icon of electrode pad in channel A
3	Treatment mode	**9**	Icon of electrode pad in channel B
4	Therapy part	**10**	Intensity for Channel B
5	Massage type	**11**	Icon of Channel B
6	Icon of Channel A	**12**	Battery indicator

2.3 Packing list

COMBO stimulator device	1
Electrode wire	2
Instruction manual	1
Electrode pad	4
AAA 1.5V dry battery	3
Storage bag	1

Accessory

Electrode pads



Note: Electrode wire is used to make connection between the host and the electrode pads and not for any other use.

2.4 Product features

1. 25 treatment modes switchable on the COMBO Electrotherapy Device.
2. Dual-channel treatment available for two people/two body parts at the same time.
3. Adjustable intensity of treatment at any time.
4. Fall-off alert for electrode pad, followed by automatic stop of treatment.
5. Automatic shutdown in case of no-operation within 2 minutes except working state, more energy efficiency.
6. Exquisite and compact appearance, lightweight and portable.
7. Pads holder, easy to store and carry electrode pads.
8. Dry battery supply the power, easy to replace.

2.5 Intended use

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.

This device is intended to be operated by an adult who can understand this instruction manual. User should be 18 years old and above.

2.5.1 TENS mode

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

2.5.2 EMS mode

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
6. Maintaining or increasing range of motion
7. For adjuvant treatment of pain and arthralgia such as back pain, neural paralysis and muscle pain.

3. Operations

3.1 Installing the battery

1. Slide the battery cover off along the marked direction and take it off.
2. Insert the three AAA (1.5V) dry batteries into the compartment according to the stated polarities.

⚠ Make sure that the batteries are installed correctly. Otherwise, the unit may be damaged.

⚠ If the low-battery symbol is displayed on the screen, please replace the batteries.

⚠ Batteries of the same type should be used. Dispose the used batteries in accordance with the local environmental policies.

3.1.1 Low battery specification

When the battery voltage is low, the battery symbol ▭ appears and flashes. If the battery runs out of power, the device will automatically shut down.

3.2 Install the therapy device and connect to the treatment sites

Insert the electrode wire connector into the electrode connector. Make sure they are properly connected. Ensure that the device is completely switched OFF. Hold the insulated portion of the electrode wire connector, and insert the plug into the receptacle on the top of the main device. Peel the protective cover of the electrode pads and attach them closely and firmly to the therapy site. After therapeutic procedures, place back the protective covers to the protective films for future uses.

Caution

1) The electrode pads may only be connected with the COMBO stimulator device. Make sure that the device is turned off when attaching or removing the electrode pads.
2) If you want to reposition the electrode pads during therapy, turn the device off first.

3) Using electrode pads may cause skin irritation. Stop using the pads if you experience redness, blistering, or itching. Do not use the Device on the same body part for a long time, as this may also lead to skin irritation.

4) The electrode pads provided with this device are for single patient use only. For hygienic reasons, electrode pads should not be shared between users.

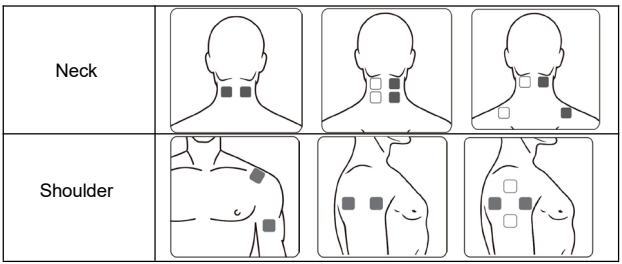
5) The electrode pads must be fully attached to the skin surface to prevent excessive localized currents that could cause skin burns.

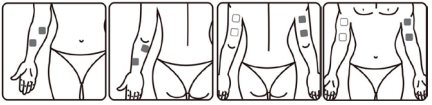
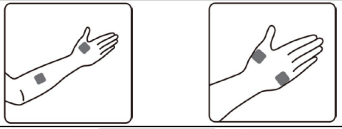
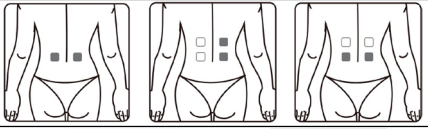
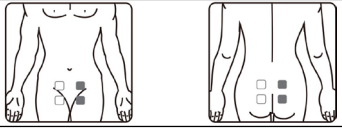
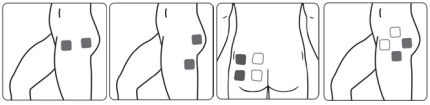
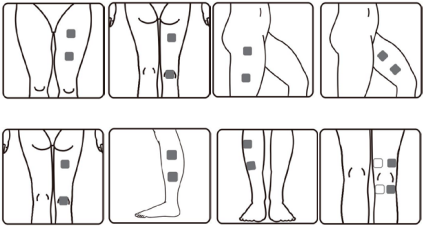
6) The adhesion of the electrode pads depends on the skin properties, storage, and the number of applications. If your electrode pads are no longer fully sticking to the skin surface, replace them with new electrode pads. Stick the electrode pads back on the protective film after use and store them in the storage bag to keep them from drying out. This maintains adhesion for a longer period.

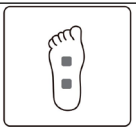
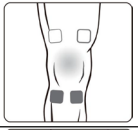
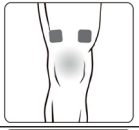
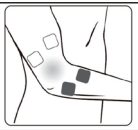
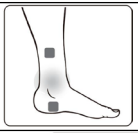
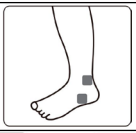
7) The electrode pads needs to be replaced after a certain period of usage (around 30 times). You can contact the retailer to obtain replacement electrodes. If you feel the electrode is loose, please replace it with a new one, because if the electrode is loose, it will reduce the contact area and can easily cause skin burns.

8) Each product in manufacturing has passed a systematic validation.The performance should be stable and no need to undertake the performance parameters of calibration and validation. If your product does not perform as expected or has changes in basic functions during normal use, please contact your retailer.

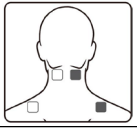
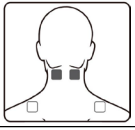
Position of electrode placement under TENS programs

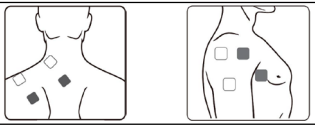
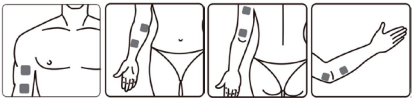
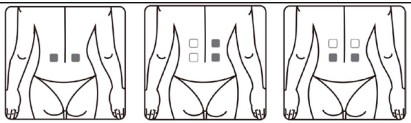
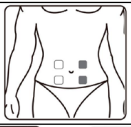
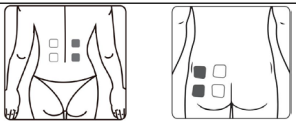
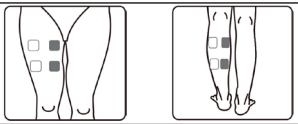


Arm	
Hand	
Back	
Abdomen	
Hip	
Leg	

Foot	
Joint (Knee)	 
Joint (Elbow)	 
Joint (Ankle)	  
Joint (wrist)	 

Position of electrode placement under EMS programs

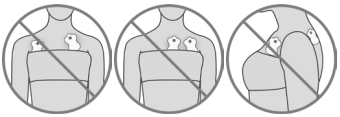
Neck	 

Shoulder	
Arm	
Hand	
Back	
Abdomen	
Hip	
Leg	

Foot	

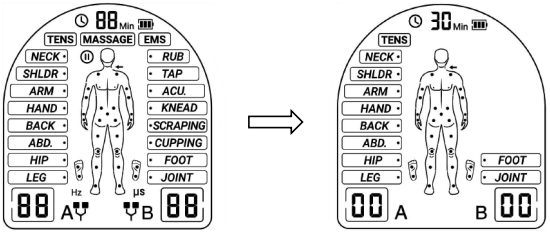
⚠ WARNING

- Do not apply the pads on both sides of the chest simultaneously (lateral or frontal and back), or across your chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.
- Do not apply the pads near the heart.



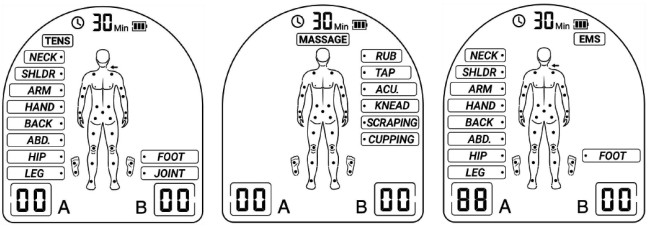
3.3 Turn on the device

Press the “ ⏻ ” button for 2s to turn on the device, the LCD will be lit. Then it will go into standby mode as below picture:



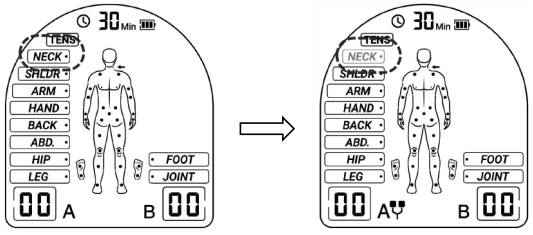
3.4 Select the therapy mode treatment

Press the “ ⏻ ” button to select treatment mode: TENS/MASSAGE/EMS
The treatment mode which you selected will show as below:



3.5 Select the treatment part

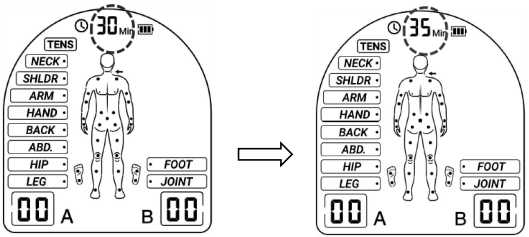
There are 10 treatment parts display on LCD.
(SHOULDER, NECK, BACK, HAND, HIP, LEG, FOOT, ARM, ABDOMEN, JOINT)
Press “Body” button to select treatment part, the therapy part will flash as below after you select it.



3.6 Select treatment time

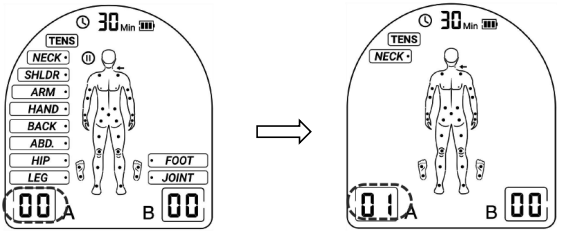
Press “ Time ” button to enter time settings, the time display will flash;
Press “ + ” / “ - ” button to adjust the treatment time based on your needs, you can increase or decrease five minutes at a time. The maximum treatment time is 60 min and the minimum treatment time is 5 min. Press “ Time ” or “ OK ” button to confirm if you have already set the time.

Tip: The treatment time is 30 minutes by default or the last set time.



3.7 Select treatment intensity and start treatment

Press "+" button to increase the output intensity of channel A or channel B and start the treatment.



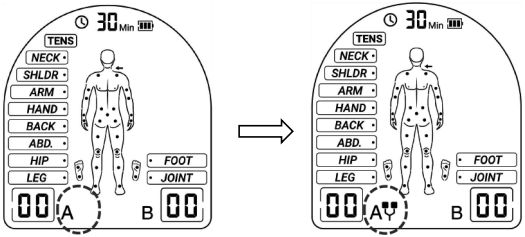
Base on your need, press "+" / '=' button to increase/decrease the output intensity of channel A or channel B. There are 40 different levels of intensity, from 0 to 40, the maximum intensity is 40. Please adjust the intensity to the condition that you feel comfortable. The level of output intensity will be shown on the LCD:

3.8 Stop treatment and turn off the device

At treating mode, press " olm " button for 2s to stop the treatment and return to standby mode. Long press the button again to turn off the stimulator, and the LCD will be blank. When the running time is displayed as 0, the device will automatically stop running.

3.9 Pad off alert

It will automatically detect the load if the intensity exceeds 3. If no load is detected or if the electrodes are not in well contact with the skin, the intensity will automatically reset to level 0 and return to standby mode with beep alert and electrode pad icon flashing, as figure below.



Notes:

1. If you aren't feeling well during treatment, stop using the device immediately.
2. During treatment, the adhesive surfaces of the electrode pads should have good contact with the skin so as to prevent sense of piercing pain due to untight contact.
3. During treatment, the slight paralysis sense may occur at treatment sites, which is the result of the coupling of the devices output current with human body, belonging to normal circumstances.
4. First-time users may feel uncomfortable due to too much pressure, so the intensity should not be too high at first, it is recommended that the intensity should gradually increase from 0 to 40, and it is appropriate to adjust the level acceptable to the user.
5. The intensity will be automatically reset when switching the treatment mode, and the intensity needs to be re-adjusted.
6. Always remove the electrode pads from the skin with a moderate pull in order to avoid injury in the event of highly sensitive skin.
7. Before applying the electrode pads, it is recommended to clean the skin, wash and towel dry.
8. Do not turn on the device if the electrode pads are not yet placed on the body.
9. To remove or move the electrode pads, turn off the device first in order to avoid unwanted irritation.
10. Never remove the electrode pads from the skin while the device is still working.

4. Specification

4.1 Technial information

Device name	Brielle Professional Digital Tens Monitoring
Model/type	BT-230
Output channel	Dual channel
Waveform	Bi-phase square-ware pulse
Output voltage	Max. 50V (at 500ohm load)
Output intensity	0 to 40 levels, adjustable
Treatment mode	TENS, EMS and MASSAGE mode
Operating condition	Ambient temperature: 5° C to 40° C Relative humidity: ≤80% Atmospheric pressure range: 70.0 kPa~106.0kPa
Storage condition	Ambient temperature: -20° C to 55° C; Relative humidity: 10%~93% Atmospheric pressure range: 70.0 kPa~106.0kPa
Dimension	130.2*63.8*22.9mm (LxWxH)
Main unit weight	93g (without battery)
Size of electrodes pad	50mm*50mm
Output precision	±20% error is allowed for all the output parameters
Power sources	3 x AAA batteries

TENS mode

Number of programs	10
P.W. (Pulse Width)	100-250μs
P.R. (Pulse Rate)	2-120Hz (Hz=vibration per second)
Treatment time	5-60 minutes (adjustable)

EMS mode

Number of programs	9
P.W. (Pulse Width)	150-200μs
P.R. (Pulse Rate)	4-60Hz (Hz=vibration per second)
Treatment time	5-60 minutes (adjustable)

MASSAGE mode

Number of programs	6 programs
P.W. (Pulse Width)	100-200μs
P.R. (Pulse Rate)	1-120Hz (Hz=vibration per second)
Treatment time	5-60 minutes (adjustable)

4.2 TENS mode

Part	Pulse rate (Hz)	Pulse width (μs)	Time (sec)	Part	Pulse rate (Hz)	Pulse width (μs)	Time (sec)
LEG	50	250	10	HAND	100	100	
	6	250	10	ARM	2	250	
HIP	100	150	0.25	SHLDR	80-100-80	100	12
ABD.	80-120-80	100	20	NECK	80-120-80	120	10
	50	200	10	FOOT	120	120-100	1
	45	200	10		80	120-100	1

BACK	10	200	10		90	120-100	1
	50	200	10		100	120-100	1
	35	200	10		110	120-100	1
	60	200	10	**JOINT**	100	100-120 -100	0.25

4.3 EMS mode

Part	Pulse rate (Hz)	Pulse width (μs)	Time (sec)	Part	Pulse rate (Hz)	Pulse width (μs)	Time (sec)
NECK	30	200	12	**ABD.**	20	200	5
SHLDR	45	200	12	**HIP**	30	150	8
ARM	50	150	5	**LEG**	20	200	12
HAND	4	200		**FOOT**	4	200	
BACK	60	200	12				

4.4 MASSAGE mode

Mode	Pulse rate (Hz)	Pulse width (μs)	Time (sec)	Mode	Pulse rate (Hz)	Pulse width (μs)	Time (sec)
KNEAD	50	100	3.5	**TAP**	1	200	3
			2.5		2		3
			1.9		3		3
			1.5		4		3
			1.1		3		3
			0.9		2		3
			0.72		1		3
			0.56		2		3
			0.42	**SCRAP**	80	200	
RUB	30	150	3	**ACU.**	100-33 -10	150	8
	2	200	3	**CUPP**	120	150	1

5. Cleaning and maintenance

5.1 Cleaning and caring of this device:

Dip soft cloth in a small amount of neutral detergent to wipe the host and the connecting cable.

-Never allow the liquid to penetrate into the device.

-Do not use gasoline or volatile liquid for cleaning.

-Do not subject this device to moisture or dampness.

-Do not hold this device under running water, do not dip or put into a water or other liquids.

-This is sensitive to heat and should not be exposed to direct sunlight. Do no place this device on hot surfaces.

5.2 Cleaning and caring for the electrode pad:

-Rinse with clean water. Dry in the air, and it can be used repeatedly for 30 times.

-For hygienic purposes, each user should use his/her own set of electrodes.

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

5.3 Maintenance

1) The manufacturer didn't authorize any maintenance agencies. If your device has any problem, please contact the distributor. The manufacturer will not be responsible for the results of maintenance or repairs by unauthorized persons.
2) The user must not attempt any repairs to the device or any of its accessories. Please contact the retailer for repair.
3) Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim for warranty.

6. Troubleshooting

Problem	Probable cause	Solutions
Unable to boot	• Severe electricity shortage • The polarities of batteries are installed wrongly.	• Replace the battery • Install the batteries in correct polarities.
Sense of piercing pain during treatment	The electrode pad is not stuck tightly	• Re-stick electrode pads tightly • Replace the electrode pad
Fall-off of electrode pad	• Sweat on skin • Ineffective stickiness of electrode pads	• Wipe the sweat from the skin and re-attach the electrode pads • Replace the electrode pads
Inconsistent strength between two electrode pads	Disconnected main unit, electrode wires and electrode pads	• Make sure the connection among the main unit, the electrode wires and the electrode pads are okay.
Power failure during use	• Electricity shortage	• Replace the battery before using it
Sudden alert pause treatment during use	Fall-off of electrode pads	Re-attach the electrode pads on the treatment sites
⚠ **Note: If your problem cannot be solved by the above solutions, please contact customer service. Do not disassemble the device!**		

Technical statement

MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel designated by the manufacturer in parts repair.

7. Storage

1. For prolonged pause in treatment, store the device in a dry room and protect it against heat, sunshine and moisture.
2. Store the device in a cool, well-ventilated place.
3. Never place any heavy objects on the device.
4. Do not keep in places that can be easily reached by children.
5. When not in use for a long period, remove the battery before storage.

8. Disposal

Used fully discharged batteries must be disposed of in a specially labeled collection container, at toxic waste collection points or through an electrical retailer. You are under legal obligation to dispose of batteries correctly. Please dispose of the device in accordance with the directive 2002/96/EC WEEE (Waste Electrical and Electronic Equipment). Contact your local distributor for information regarding disposal of the unit and accessories.

9. Contraindications

Patients with skin diseases, malignant tumors, allergies from electrode pads, and implanted cardiac pacemaker are forbidden to use this device. Consult your doctor first if you have any other known ailments prior to using this device.

Warning ⚠

1) If you have any medical or physical treatment for your pain, consult with your physician before using this device.
2) If continued use for more than five days and pain does not improve, 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 in which electrical stimulation can put your at risk of injury.

10) Apply stimulation only to normal, intact, clean, healthy skin.

11) The long-term effects of electrical stimulation is unknown. Electrical stimulation device does not have any curative value.

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

13) 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 electrode pads, as well as problems with the stimulator.

14) Do not use the stimulator near shockwave or microwave therapy equipment as this may affect the stimulator output power.

15) Never use it near the heart. Stimulation electrode pads 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. Doing this can increase the risk of ventricular fibrillation and lead to cardiac arrest.

16) 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).

17) Never use near the genitals.
18) Never use on the areas of the skin which lack normal sensation.
19) Keep the electrod pads away from each other during use, electrode pads in contact each other may result to improper stimulation or skin burns.
20) Keep the stimulator out of reach of children, because the cord could cause strangulation.
21) Do not expose the device to pets.
22) Consult your doctor if you are in any doubt whatsoever.
23) Stop and do not increase the intensity level if you feel discomfort during use.
24) Advice that a patient with an implanted electronic device (for example a cardiac pacemaker) should not be subjected to stimulation unless specialist medical opinion is obtained first.
25) Advice that any electrodes that have current densities exceeding 2 mA/cm2 may require, the special attention of the operator.

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 devices have no curative value.
4) TENS is a symptomatic treatment, such as, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
5) Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
6) The long-term effects of electrical stimulation are unknown.
7) 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.

8) The safety of electrical stimulation during pregnancy has not been established.
9) You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (silica gel).
10) If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician
11) If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
12) Use caution if you have a tendency to bleed internally, such as following an injury or fracture.
13) Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt healing process.
14) Use caution if stimulation is applied over menstrual cycle or pregnancy.
15) Use caution if stimulation is applied over areas of skin that lack normal sensation.
16) For single patient use only (electrode pads).
17) Keep yourself informed of the contraindications.
18) This stimulator is never used by patients who are non-compliant based on the contraindications, emotionally disturbed, with dementia, or low IQ.
19) The instructions for use was listed; any improper use may bedangerous.
20) It should be used with caution in patients with suspected or confirmed heart problems.
21) Isolated cases of skin irritation may occur at the site of the electrode placement following long-term application.
22) Do not use this device at the same time as other equipment which sends electrical pulses to your body.

23) Do not use sharp objects such as pencil point or ballpoint pen to operate the buttons on the control panel.
24) Check the electrode connections before each use.
25) Electrical stimulators should be used only with the electrode pads recommended for use by the manufacturer. Otherwise, it may cause danger to the user.
26) The patient is an intended operator.
27) Do not use to treat one region more than 30 minutes per day.
28) Please wait for approximately half an hour for the device to warm up or cool down when the device is used in an environment within the temperature specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature.
29) Contact the manufacturer or manufacturer's representative to report unexpected operation or events when needed.
30) Service maintenance while using the device is strictly prohibited.
31) Please note the effects of degraded electrode pads that could degrade performance or cause other problems.

Adverse Reactions

1) Possible skin irritation or electrode bum under the electrode pads may occur.
2) If the stimulation levels are uncomfortable or became uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if problems persist.

10. Symbols

	Manufacturer
	Date of Manufacture

SN	Serial number
MD	Medical device
EC REP	Authorized European Representative
CE 0598	This product complies with the Regulation (EU) 2017/745 requirements
	Type BF applied part
IP22	Degree of protection against Ingress of water and particulate matter.
	Caution
	Refer to instruction manual/booklet
	Waste electrical materials should be sent to a dedicated collection point for recycling
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation

11. 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 other 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 equipment and may result in improper operation."

3* WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used not closer than 30 cm (12 inches) to any part of the ME equipment, including cables specified by the manufacturer. Otherwise, it may result to degradation of the device's performance.

Table 1

declaration - electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable

Table 2

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

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, ±1kV line(s) to lines ±0.5kV, ±1kV, ± 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
NOTE: UT is the a.c mains voltage prior to application of the test level.		

Table 3

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
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

Table 4

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	1.8W	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.

Brielle®

TENS BT-230

inmed.com.ph

INMED CORPORATION

Questions or comments? wecare@inmed.com.ph

IC-BM-TENSBT230-01