Federal Law restricts this device to sale by or on the order of a licensed practitioner

ULTRATENS™

Pain Relieving Combination of Ultrasound and TENS Technology

www.currentsolutionsnow.com

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1 FOREWORD

1.1 General

This manual has been written for the users of ULTRA TENS Pain Relief Device. It contains general information on the operation, precautionary practices, and maintenance information. In order to maximize its use, efficiency, and the life of the system, please read this manual thoroughly and become familiar with the controls, as well as the accessories before operating the system.

Pay attention to the following before using ULTRA TENS:

1. Keep yourself informed of the contra-indications (see chapter 3).
2. The apparatus may not be used in close proximity (i.e. less than 2 meters) to shortwave equipment.
3. The apparatus may not be used in so-called “wet rooms” (hydrotherapy rooms).

The manufacturer can not be held responsible for the results of using this apparatus for any purposes other than described in these operating instructions.

1.2 Therapy possibilities

This is an apparatus therapy unit that offers both ultrasound therapy and electrotherapy, which can be combined. Pain affects the quality and enjoyment of life, especially for those who suffer chronic pain. ULTRA TENS is ultrasound and electrotherapy therapy device for the treatment of chronic and acute muscular pain. The applicator has a radiant surface of 4.0cm^2 and an operating frequency of 1 MHz. Combination therapy of ultrasound and electrotherapy is, for instance, ideal to localize trigger points and or pain points.

1.3 Applicator

The ultrasound applicator is one-frequency head. This applicator can now supply 1 MHz ultrasound. The head has excellent beam characteristics, fully meeting the requirements of the existing standards. The excellent beam characteristics, ergonomic design and effective contact control of the single-frequency applicator make an optimal treatment possible.

1.4 Finally

You have made a wise choice in selecting the product. We are confident that your unit will continue to give satisfaction over many years of use. Nevertheless, if you have any queries or suggestions, please contact your authorized distributor.

CAUTION: This equipment is to be used only under the prescription and supervision of a licensed practitioner

2 SAFETY PRECAUTIONS

2.1 PRECAUTIONARY DEFINITIONS

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment. The definition of these symbols is as follows;

 **Caution:** Text with a “CAUTION” indicator will explain possible safety infractions that could have the potential to cause minor to moderate injury or damage to equipment.

 **Warning:** Text with a “WARNING” indicator will explain possible safety infractions that will potentially cause serious injury and equipment damage.

 **Danger:** Text with a “DANGER” indicator will explain possible safety infractions that are imminently hazardous situations that would result in death or serious injury.

2.2 Caution

 **Caution**

1) Read, understand, and practice the precautionary and operating instructions. Know the limitations and hazards associated with using any ultrasound device. Observe the precautionary and operational decals placed on the unit.
2) Keep yourself informed of the contraindications.
3) DO NOT operate the device when connected to any other medical devices.
4) DO NOT operate this unit in an environment where other devices are used that intentionally radiates electromagnetic energy in an unshielded manner.
5) Ultrasound should be routinely checked before each use to determine that all controls function normally, especially that the intensity control does properly adjust the intensity of the ultrasonic power output in stable manner. Also, determine that the treatment time control does actually terminate ultrasonic power output when the timer reaches zero.
6) DO NOT use sharp objects such as pencil point or ballpoint pen to operate the buttons on the control panel.

7) The Ultrasound Applicator with care. Inappropriate handling of the Ultrasound applicator may adversely affect its characteristics.
8) Before each use, inspect the Ultrasound Applicator for cracks, which may allow the ingress of conductive fluid.
9) Inspect Applicator cables and associated connectors before each use.
10) The ultrasound therapy controls unit is not designed to prevent the ingress of water or liquids. Ingress of water of liquids could cause malfunction of internal components of system and therefore create risk of injury to the patient.
11) Caution should be used:
    - For patients with suspected or diagnosed epilepsy.
    - For patients with suspected or diagnosed heart problems.
12) Caution should be used in the presence of the following:
    - When there is a tendency to hemorrhage following acute trauma or fracture.
    - Following recent surgical procedures when muscle contraction may disrupt the healing process.
    - Over the menstruating or pregnant uterus.
    - Over areas of the skin which lack normal sensation.
13) Some patients may cause skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium or alternate electrode placement.
14) Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
15) Never apply electrodes over irritated or broken skin.
16) The device should be kept out of the children.
17) The device should be used only with the leads and electrodes recommended for use by the manufacturer.
18) Do not use in the bath or shower. The device should not be submerged in water or other liquids as this may startle the patient and possibly damage the device.
19) The use of heat and cold producing devices, such as electric heating blankets, heating pads or ice packs, may impair the performance of the electrodes or alter the patient's circulation and increase the risk of injury to the patient.
20) The device should not be used on driving, operating machinery, or during any activity in which in voluntary muscle contractions may put the user at under risk of injury.

2.3 Warning

Warning

1) Care must be taken when operating this equipment around other equipments. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with it.

2) The device may not be used in close proximity (i.e. less than 2 meters) to short-wave equipment.
3) Avoid exposure to direct sunlight, rain, excessive dust, moisture, mechanical vibrations and shocks.
4) The device may not be used in so-called “wet rooms”(hydrotherapy rooms)
5) Only use the device for the recommended applications. The device should be used under medical supervision.
6) Before administering any treatment, you should become acquainted with the operating procedures for each program of treatment available, as well as the indications, contraindications, warnings, and precautions. Consult other resources for additional information regarding the application of Electrotherapy and ultrasound.
7) Do not use solvents to clean the device.
8) A damaged device must no longer be used.
9) The device must only be serviced, repaired and opened by authorized sales centre.
10) Dispose of the device in accordance with local regulations. Keep the operating instructions with the device.
11) Pregnant and nursing women should use the device cautiously.
12) Avoid use over or near bone growth centers until bone growth is complete.
13) Treatment time should not exceed 30min a day.
14) Don’t use a cell phone while using the device.
15) Patients with sensitivity to the coupling gel should use the device cautiously.
16) Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
17) Stimulation should not be applied over the neck or mouth.
18) Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
19) Stimulation should not be applied transcerebrally (across the head), over the Carotid sinus (where the jaw meets the neck), over metal implants or in conjunction with sleep apnea or heart monitors.
20) Stimulation should not be applied transthoracically. Since the introduction of electrical current into the heart may cause cardiac arrhythmias.
21) Stimulation should not be applied swollen, infected or inflamed areas or skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
22) Stimulation should not be applied over, or in proximity to cancerous lesions.
23) Always keep the applicator in constant motion.
24) Use ample conductive gel to ensure good coupling throughout the treatment. If needed, apply when setting intensity.
25) U.S.A. Federal Law restricts these devices to sale by, or on the order of, a physician or licensed practitioner. This device should be used only under the continued supervision of a physician or licensed practitioner.

2.4 Danger

Danger

Patients with an implanted neurostimulation device must not be treated with or be in close proximity to any shortwave diathermy, microwave diathermy, therapeutic ultrasound diathermy, or laser diathermy anywhere on their body. Energy from diathermy (shortwave, microwave, ultrasound, and laser) can be transferred through the implanted neurostimulation system, can cause tissue damage, and can result in severe injury or death. Injury, damage, or death can occur during diathermy therapy even if the implanted neurostimulation system is turned "off."

Biohazardous materials

Handle, clean, and dispose of components and accessories that have come in contact with bodily fluids according to national, local, and facility rules, regulations, and procedures.

2.5 Adverse reaction

- Skin irritation, inflammation, and electrode burns beneath the electrodes are potential adverse reactions.
- Perform the following procedures to avoid the negative effects of ultrasound therapy.

- **Applicator Movement**

If movement of the applicator is too slow, the patient may feel periosteal pain characterized by a deep ache or pain. If motion is too fast, or if the applicator does not maintain good contact with the skin, the therapeutic effect of the sound waves will be reduced and the applicator may overheat.

- **Patient Susceptibility**

Some patients are more sensitive to ultrasound output and may experience a reaction similar to a heat rash. Be sure to inspect the treatment area during and following treatment, and discontinue if an adverse reaction does occur.

- **Coupling**

Coupling is described as contact between the applicator and the treatment site and may be accomplished through the use of a coupling agent, such as gel, lotion. Anything used as a coupling agent must be highly conductive. Air is a very poor conductor of ultrasonic waves

3 Indications and Contraindications

3.1 Indications

Therapeutic Ultrasound

1. Pain relief
2. Reduction of muscle spasm
3. Joint contractures

Transcutaneous Electrical Nerve Stimulation

1. Symptomatic relief of chronic intractable pain
2. Post-traumatic pain
3. Post-surgical pain

3.2 Absolute specific contraindications ultrasound

1) Eyes
2) Heart
3) Pregnancy
1) Epiphysial discs
5) Brain tissue
6) Testicles

3.3 Relative specific contraindications ultrasound

1) Status post laminectomy
2) Loss of sensation
3) Endoprostheses
4) Tumours
5) Post-traumatic sequelae
6) Thrombophlebitis and varices
7) Septic inflammation
8) Diabetes mellitus.
9) Osteoporosis
10) Malignant diseases
11) Acute injuries
12) Healing fracture
13) Cancerous lesions
14) Open wound
15) Pacemakers

3.4 Contra-indications Electrical stimulation therapy

1) Pyrexia
2) Tumours
3) Tuberculosis

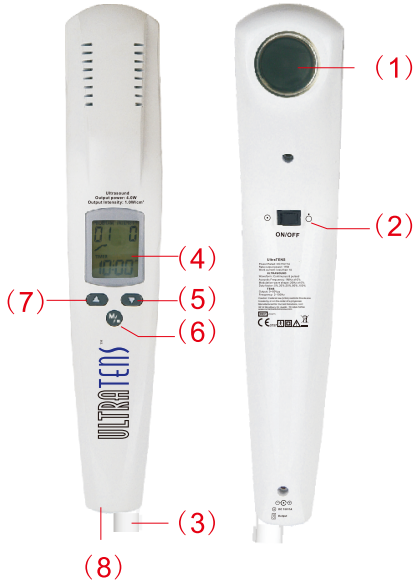
4) Localized inflammation
5) Thrombosis
6) Pregnancy
7) Pacemakers
8) Metal implants
9) Cancerous lesions
10) Eye area

3.5 Contra-indications combination therapy

Combination therapy contra-indications refer to ultrasound therapy and electrical stimulation therapy Contra-indications.

4 PRESENTATION

4.1 Presentation of the device



1) Applicator
2) On/Off Switch
3) AC/DC Adapter connector
4) Liquid Crystal Display
5) "▼" button
6) "M/■" button
7) "▲" button
8) Electrode connect end

4.2 Liquid crystal display

1) Program indicator

2) Ultrasound contact indicator
3) Timer
4) Time display or Duty cycle display
5) Output intensity
6) Electrode contact indicator
7) Duty cycle setting

4.3 Key Function

“⏻” On/Off Switch

- With this Switch ULTRA TENS is turned on or off.

“M/■” button

- Stop treatment working
- Program select

“▲” button

Setting state

- Combination therapy: Increase Duty cycle

Working state

- Electrotherapy : Increase stimulate intensity
- Ultrasound therapy: Increase Duty cycle
- Combination therapy: Increase stimulate intensity

“▼” button

Setting state

- Combination therapy: Decrease Duty cycle

Working state

- Electrotherapy : Decrease stimulate intensity
- Ultrasound therapy: Decrease duty cycle
- Combination therapy: Decrease stimulate intensity

5 INSTALLATION

5.1 Before Use

Remove the equipment and all accessories from shipping carton and giftbox. Visually check if there is any damage or missing parts or accessories.. If yes, please report to

local dealer or retailer where you purchase this unit. Your ultrasound equipment contains the following accessories.

Part	Quantity
ULTRA TENS	1
Operating instruction	1
Electrode 50*100mm	2
Lead for electrical	2
Adapter 100-240V 50 or 60 Hz	1
Lead for adapter	1
Ultrasound transmission gel	1

5.2 Connection

- Prior to connecting this apparatus to the power supply, check that the voltage and frequency stated on the rating label match with the available power supply.

- The power adapter is a part of the supply circuit on which the device's safety partly depends. The approvals for ULTRA TENS are only valid if used in combination with this type of adapter MM1510 SERIES.

⚠ Caution: It is not permitted to connect ULTRA TENS to another type of adapter other than MM1510 SERIES.

⚠ Caution: Connection of accessories other than the ones specified by the manufacturer can adversely affect the safety of patients and proper functioning of the equipment; therefore, it is not permitted.

5.3 Connection of the power adapter

- Connect the power adapter to the connector.
- Connect the power adapter to a wall socket.

5.4 Switching on

- Switch on the apparatus, using On/Off switch

5.5 Select the therapy program

The device has 15 kinds of treatment program. Users can press " M/■ "

button to select preferred treatment program:

- 0 C program: Ultrasound + Electrical Stimulation combination therapy (C1～C7 program).
- 0 U program: Ultrasound therapy
- 0 E program: Electrotherapy (E1～E7 program)

5.6 Disconnect from power adapter

- Switch off the unit by switching. “  ” to “” position.
- Pull out the power adapter from the wall socket.

6 OPERATION

6.1 Measures with regards to treatments

6.1.1 Electrotherapy

Before treatment

- Ensure there are no contraindications to treatment
- Inspect the treatment area skin seriously for any abrasions, inflammation, surface veins etc.
- Clean the skin of the treatment area with soap or alcohol (70%).
- If the skin is hairy, shaving can get optimal treatment.
- Test the heat sensibility of the treatment area.

6.1.2 Ultrasound

Before treatment

- Ensure there are no contraindications to treatment
- Test the warm sensibility of the treatment area.
- Clean the skin of the treatment area with soap or alcohol (70%).
- If the skin is hairy, shaving can get optimal treatment.
- Apply some ultrasound transmission gel onto the treatment area. The gel is conducive and ensures effectiveness. (Please purchase the ultrasound gel with FDA approved)

During treatment

- Move the applicator in a circular motion. The area treated should be two times the diameter of the applicator.
- In case of poor transmission of ultrasound energy, it is advised to add more gel or reposition the ultrasound-head.

Caution

The applicator has to be moved in a normal speed - not too slow to avoid inducing heat; nor too fast to prevent a bad contact which would reduce the effectiveness of the treatment.

After treatment

- Clean the skin of the treated area as well as the ultrasound head by using a towel or a tissue.
- the ultrasound head should be cleaned up 70% alcohol.
- Check if there are any signs of improvement (e.g. pain, circulation or mobility).

6.1.3 Combination therapy

See both chapters 6.1.1. Electrotherapy and 6.1.2. Ultrasound.

6.2 Operating the apparatus

6.2.1 Introduction

6.2.1.1 Switch on the apparatus

Switch on the apparatus by switching. "  " to "  " position.

6.2.1.2 Select the therapy program

Select the therapy program by referring to chapter 5.5.

6.2.1.3 Adjusting intensity

Pressing ▲ and ▼ button to increase or decrease the output intensity.

6.2.1.4 Ultrasound duty cycle

- Ultrasound therapy: The ultrasound duty cycle is adjusted with ▲ and ▼ control button. The ultrasound intensity can be adjusted in 0～5, the corresponding duty factor is 0%, 5%, 20%, 50%, 80% and 100%.

- Combination therapy (Ultrasound with Electrotherapy) by pressing M/■ and ▼ button and hold for 3 seconds to enter the setting state. Press ▲ and ▼ button to select duty cycles. The ultrasound duty cycle will be displayed in 5%, 20%, 50%, 80%, or 100%.

6.2.1.5 Emergency stop

Pressing M/■ button will stop all active treatment.immediately.

6.2.2 Electrotherapy

- Connect the electrode pads to the unit as below picture.

⚠ Caution: The device must be turned off before connecting the lead wires to the device.

- Press the M/■ button to select the Electrotherapy program (therapy program E1～E7).

- Press ▲ or ▼ button to increase or decrease the output current strength. When reach the maximal value, the value won't be changed even if user continue to press it. The amplitude value can be adjusted in 1V for each step. The intensity range is from 0V to 80V(500Ω Load)

Caution

In standby mode, the LCD backlight is Cyan. When the strength is less than 50 levels, LCD backlight is Green. When the strength is equal or more than 50 levels, LCD backlight will turn to Purple.

When the electrodes are not in good contact with patient, or the wires is not well connected to the electrodes or main unit, the LCD backlight will turn to Blue.

6.2.3 Ultrasound therapy

- Press M/■ button to select the Ultrasound therapy.

- Pressing ▲ or ▼ control button to select the duty cycle (please refer to 6.2.1.4). When you put the applicator onto your body and have a good contact (after applying the ultrasound gel onto the treatment area), the device will start emitting ultrasound energy.

- Apply some ultrasound gel onto the treatment area. The gel acts as a conducive substance and ensures effectiveness. (Please purchase the ultrasound gel with FDA approved label)

Caution

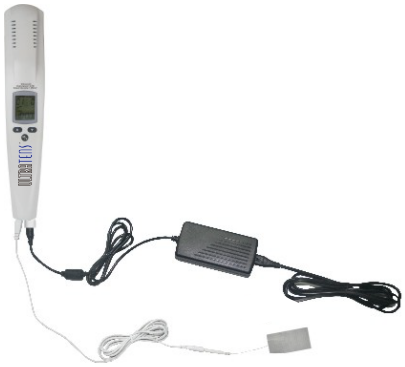
During standby mode, the LCD backlight is Cyan. During treatment mode, it will be changed to Green.. When the duty cycle is more than 5%, or the applicator is not in good contact with the body, the LCD color will turn to blue.

Caution

The device works without vibration. You must move the applicator in a normal speed with circular motion around the treatment point. After 10 minutes when the treatment is finished, the device will enter the waiting state. We do not recommend user to start the treatment again.

6.2.4 Combination therapy

- Connect the electrode pad to the unit as below picture. Please use single-electrode lead to connect electrodes with the unit. The applicator as negative electrode. The current flows between the positive electrode and the applicator.



Caution: The device must be turned off before connecting the lead wires to the device.

- Press M/■ button to select the combination therapy and program (therapy program C1～C7).

- Press hold M/■ and ▼ button for 3 seconds to enter the setting mode. Then press increase and decrease to select duty cycle (please refer to 6.2.1.4). When you put the applicator onto your body and have a good contact (using ultrasound gel), the device will start emitting ultrasound energy.

- Press ▲ or ▼ control button to increase or decrease output current strength. When reaching the maximal value, the value won't be changed even if user continues to press it. The amplitude value can be adjusted in 1V for each step. The intensity range is from 0V to 80V(500Ω Load)
- Apply some ultrasound transmission gel onto the treatment area. The gel acts as a conducive substance and ensures effectiveness. (Please purchase the ultrasound gel with FDA approved)

 **Caution**

In standby mode, LCD backlight is Cyan. When the strength is less than 50 levels, LCD backlight is Green. When the strength is equal or more than 50 levels, the LCD backlight will change to Purple. When the duty cycle is more than 5%, or the applicator is not in good contact with the body, or the electrode cable is not well connected to the electrode or main unit, the LCD color will turn to Blue.

 **Caution**

The device works without vibration. You must move the applicator in a normal speed with circular motion around the treatment point. After 10 minutes when the treatment is finished, the device will enter the waiting state. We do not recommend user to start the treatment again.

6.3 The applicator

Applicator is a precision instrument. Great care is taken in the development and production in order to obtain the best possible beam characteristics. Rough treatment (jarring or dropping) can adversely affect these characteristics, and must therefore be avoided.

6.4 The contact medium

- In the Ultrasound therapy or combination therapy, Coupling is described as contact between the applicator and the treatment site. In order to ensure efficient transfer of energy, a contact medium is required. Air causes virtually total reflection of the ultrasound energy. The best medium for the transfer of ultrasound energy is a gel. (Please purchase the ultrasound gel with FDA approved)
- Liberally apply transmission gel or equivalent to the treatment area.
- Move the applicator during therapy session in a circular motion. The area treated should be two times the diameter of the applicator.

 Caution: Never apply the gel to the applicator. The applicator will register this as contact and may emit ultrasound energy, which could damage the applicator.

7 MAINTENANCE

7.1 Cleaning of the apparatus

Switch off the apparatus and disconnect it from the power supply. The apparatus can be cleaned with a damp cloth. Use lukewarm water and a non-abrasive liquid household cleaner (no abrasive, no alcohol content solution). If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner.


Caution: Do not submerse the apparatus in liquids. Should the unit accidentally become submersed, contact the dealer or Authorized Service center immediately. Do not attempt to use a system that has been wet inside until inspected and tested by a Service Technician Certified by Authorized Service center. Do not allow liquids to enter the ventilation holes.

7.2 Cleaning of the applicator

The applicator should be regularly inspected for damage, e.g. hairline cracks, which could allow penetration by liquids. Clean the contact surface immediately after each treatment. Make sure that no ultrasound gel remains on the applicator. We further recommend cleaning the head and cable daily, using lukewarm water. The applicator can be disinfected using a cloth moistened with 70% alcohol.

7.3 Cleaning the lead wires

Periodically wipe the lead wires clean with a cloth dampened in a mild soap solution, and then gently wipe them dry. Use of rubbing alcohol on the lead wires will damage the insulation and dramatically shorten their life.

7.4 Maintenance

- Maintenance and all repairs should only be carried out by an authorized agency. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.
- Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.
  Check the unit before each use for signs of wear and/or damage. Replace wear items as required.

Wear items are:

1. Electrodes
2. Lead wires

8 TROUBLESHOOTING PBOBLEMS

For optimal use:

1) Replace lead wires annually.
2) Please follow the directions on the electrode packaging for the care of electrodes. The life of the electrodes varies, depending on skin conditions, skin preparation, storage and climate. Replace electrodes that no longer stick.
3) Ensure the ultrasound gel is used between the applicator and the body.
4) NOTE: If the following measures fail to alleviate the problem, please call the authorized agency or your supplier.

Problem	Possible Cause	Solution
Displays fail to light up	Adapter contact failure	Ensure adapter is connect .Check the following contacts: • All contacts are in place. • All contacts are not broken.
Stimulation weak	Electrodes 1. Dried out or contaminated 2. Placement Lead wires 1.Old/worn/damaged Gel 1. insufficient gel	 1. Replace. 2. Electrodes must be a minimum of 2 inches apart. 1. Replace. 1. increase sufficient gel
Stimulation stops	Poor electrode contact Damaged or worn electrodes or lead wires Not contact medium	Reapply electrodes, secure firmly. Replace Use the ultrasound gel
Stimulation is uncomfortable.	Intensity is too high Electrodes are too close together Damaged or worn electrodes or lead wires Electrode active area size is too small.	Decrease intensity. Decrease duty cycle Reposition the electrodes. Electrodes must be a minimum of 2 inches apart. Replace. Replace electrodes with ones that have an active area no less than 5.58 in2 (36.0cm2).
Stimulation is ineffective.	Improper electrode and applicator placement Unknown	Reposition electrode and applicator Contact clinician.

9 SPECIFICATIONS AND TECHNICAL DATA

9.1 Technical date of Ultrasound

Acoustic frequency:	1MHz ± 10%
Generator output:	4.0W ± 20%
Modulation wave shape:	20Hz ± 10%
Duty factor:	5%,20%, 50%, 80%, 100%
Treatment time:	10min
Actual radiating area(AER):	4.0cm^2 ± 20%
Max intensity	1.0W/cm^2 ± 20%
RBN(MAX):	5.0
Program	U
Beam type:	Collimated
Material of applicator:	Aluminium

9.2 Technical data of Electronic Stimulator

Output characteristics:	constant voltage(CV)
Reading resolution:	1V
Treatment time	30min
Program:	E1～E7
Output wave	Monophasic square pulse
Frequency:	2~150Hz
Pulse duration:	60~250uS
Maximum output:	80Vpp (500 Ω Load)

9.3 Technical data of combination ultrasound and electrical Stimulator

Output characteristics:	Constant Voltage(CV)
Reading resolution:	1V
Treatment Time	10min
Program:	C1～C7
Output wave	Monophase pulse
Frequency:	2~150Hz
Pulse duration:	60~250uS
Maximum output:	80Vpp (500 Ω Load)

9.4 Technical data of ULTRA TENS main part

Supply voltage:	15V
Current consumption:	10W
Working current:	< 1.0A
Safety class:	Class II, BF-type
Dimension:	358mm(L)x64mm(W)x97mm(H)
Protection degree:	IPX7 for transducer (5mm)

9.5 Technical data of power supply

Supply voltage:	100V~240V
Frequency:	50Hz~60Hz
Power	18W
Output voltage:	15V DC
Output current:	1.0A
Dimensions:	110mm(L)x54mm(W)x33mm(H)

9.6 Environmental conditions

Operating conditions	Environment temperature:5~40℃ with a relative humidity of 30%~75% Atmospheric pressure from 700~1060hPa
Storage conditions	Environment temperature:-10~50℃ with a relative humidity of 10%~90% Atmospheric pressure from 700~1060hPa

9.7 Program list table

Program	Frequency(Hz)	Pulse Width(uS)	Wave Character
C1	35	180	Burst
C2	70	60~200	PM
C3	80	200	Con.
C4	100	175	Burst
C5	2~100	250	MF
C6	2~110	175	MF
C7	150	60~200	PM
E1	35	180	Burst
E2	70	60~200	PM
E3	80	200	Con.
E4	100	175	Burst
E5	2~100	250	MF
E6	2~110	175	MF
E7	150	60~200	PM

10 STORAGE

For a prolonged pause in treatment, store the device with the adapter in a dry room and protect it against heat, sunshine and moisture. Store the machine in a cool, well-ventilated place. Never place any heavy objects on the machine.

11 DISPOSAL

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.

12 EMC TABLE

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The device is intended for use in the electromagnetic environment specified below. The customer or the user should assures that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 2</td><td>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.</td></tr>
<tr><td>RF emissions CISPR11</td><td>Class B</td><td rowspan="3">The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions lEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations / flicker emissions lEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Guidance and manufacturer's declaration — electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) lEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

<table>
<tr><th colspan="4">Guidance and- manufacturer’s declaration. Electromagnetic immunity</th></tr>
<tr><td colspan="4">The device is intended for use in. the electromagnetic environment specified below. The customer or the user of the should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60501 test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3 Vrms
150 kHz to 80 MHz
3 V/m
80 MHz to 2.5 GHz</td><td>3 Vrms

3 V/m</td><td>Portable and mobile RF communications equipment should be used no 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
$d = 1{,}2\sqrt{P}$
$d = 1{,}2\sqrt{P}$, 80MHz to 800MHz
$d = 2{,}3\sqrt{P}$, 800MHz to 2,5MHz
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 meters (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.[b]
Interference may occur In the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">NOTE I At 80 MHz ends 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.</td></tr>
<tr><td colspan="4">[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, 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.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the device

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

NOTE I At 80 MHz and 800 MHz. the separation distance for 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.

13 .WARRANTY

Please contact your dealer or the device centre in case of a claim under the warranty. If you have to send in the unit, enclose a copy of your receipt and state what the defect is.

The following warranty terms apply:

1) The warranty period is 18 months from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.

2) Defects in material or workmanship will be removed free of change within the warranty period.

3) Repairing under warranty do not extend the warranty period either for the unit or for the replacement parts.

4) The following is excluded from the warranty:
   - All damage which has arisen due to improper treatment, e.g. non-observance of the user instruction.
   - All damage which is due to repairing or tampering by customer or unauthorized third parties.
   - Damage which has arisen during transportation from the manufacturer to the consumer or to the service centre.

14 .NORMALZED SYMBOLS

ON/OFF Switch

Program Select/Stop

Intensity Increase

Intensity decrease

Protected against the effects of immersion

Power polarity

Power connect

Electrode connect

Mode or type designation, order number

Class II symbol

Symbol for protection against electric shock: Type BF

SN:XXXXXXX Serial number attached on the topside and sticker on the packaging

LOT: MED2011WHK10/01 LOT: Lot Number
MED: Medical instrument
2011: Number
WH: Color
K: Year
10: Month
01: Batch Number

Disposal in accordance with Directive 2002/96/EC (WEEE)

Complies with the European Medical Device Directive (93/42/EEC) and amended by directive 2007/47/EC requirements.
Notified body TÜV Rheinland (CE0197)

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