

ULTRATENS™ II

INSTRUCTION MANUAL

Portable Ultrasound and TENS Combo Device

Model # DU6012



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

*This manual is valid for the UltraTENS™ II
Portable Ultrasound and TENS Combo Device*

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United States Federal Law Restricts this device to sale by or on the order of a physician or licensed practitioner.

Declaration of Conformity:

Roscoe Medical, Inc. declares that the UltraTENS™ II complies with the following normative documents:

IEC60601-1, IEC60601-1-2, IEC60601-2-10, IEC60601-2-5, IEC61689,
ISO 7010, ISO14971, ISO10993-1, ISO10993-5, ISO10993-10,
IEC 60601-1-11

Complies with MDD 93/42/EEC and
Amended by directive 2007/47/EC requirements

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1. Foreword

1.1 General

This manual has been written for the users of UltraTENS™ II. It contains general information on the operation, precautionary practices, and maintenance information of the device. In order to maximize the use, efficiency, and life of the device, please read the manual thoroughly and become familiar with the controls, as well as the accessories before operating the device.

Pay attention to the following before using the UltraTENS™ II:

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

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

1.2 Therapy Possibilities

UltraTENS™ II is a therapy apparatus that offers both ultrasound therapy and electrotherapy in combination. Pain affects the quality and enjoyment of life, especially for those who suffer chronic pain. UltraTENS™ II is an ultrasound and electrotherapy therapy device for the treatment of chronic and acute muscular pain. The applicator has a radiant surface of 4.0cm² and an operating frequency of 1MHz. Combination therapy of ultrasound and electrotherapy is ideal to localized trigger points and or pain points.

1.3 Applicator

The ultrasound applicator for UltraTENS™ II has a single-frequency head. This applicator supplies 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 optimal treatment possible.

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 definitions of these symbols are as follows:

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

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

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

2.2 Cautions

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 informed of the contraindications.
3. DO NOT operate the device when connected to any other medical device.
4. DO NOT operate this device in an environment where other devices used, intentionally radiate electromagnetic energy in an unshielded manner.
5. Ultrasound should be routinely checked before each use to ensure that all controls function normally.
 - Check intensity control – make sure it properly adjusts the intensity of the ultrasonic power output in a stable manner.
 - Check treatment time control – make sure it terminates 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. Handle 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 to avoid the ingress of conductive fluid.
9. Inspect applicator cables and associated connectors before each use.
10. The ultrasound therapy control unit is not designed to prevent the ingress of water or liquids. Ingress of water or liquids may cause malfunction of internal components of the device and therefore create risk of injury to the patient.
11. Caution should be used:
 - With patients suspected or diagnosed with epilepsy.
 - With patients suspected or diagnosed with 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 a menstruating or pregnant uterus.
 - Over areas of the skin which lack normal sensation.

13. Some patients may experience 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 reach of 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 will possibly damage the device and startle the patient.
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 UltraTENS™ II should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk for injury.

2.3 Warnings



Warnings

1. Care must be taken when operating around other equipment.
2. Potential electromagnetic or other interference may occur to either this device or to the other equipment, or both. Minimize this interference by not using this device in conjunction with the other equipment.
3. This device may not be used in close proximity (i.e. less than 2 meters) to short-wave equipment.
4. Avoid exposure to direct sunlight, rain, excessive dust, moisture, mechanical vibrations, and shocks.
5. This device may not be used in so-called "wet rooms" (hydrotherapy rooms).

6. Only use this device for the recommended applications. This device should only be used under medical supervision.
7. Before administering any treatment, you should become acquainted with the operating procedures for each program of treatment, as well as the indications, contraindications, warnings, and precautions. Consult other resources for additional information regarding the application of electrotherapy and ultrasound.
8. Do not use solvents to clean this device.
9. Do not use this device if it is damaged in any way.
10. This device must only be serviced, repaired and opened by individuals at authorized service centers.
11. Dispose of this device in accordance with local regulations. Keep the operating instructions with the device.
12. Pregnant and nursing women should use caution when using the device.
13. Avoid use over or near bone growth centers until bone growth is complete.
14. Treatment time should not exceed 30 minutes a day.
15. Do not use a cell phone while operating the device.
16. Patients with sensitivity to the coupling gel should use caution when using the device.
17. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
18. Stimulation should not be applied over the neck or mouth. 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 trans-cerebrally (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.

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 to 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 ultrasound head in constant motion.
24. Use ample conductive gel with the ultrasound head to ensure good coupling throughout the treatment. If needed, apply more when setting intensity.
25. United States 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



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 occurs.

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 or lotion. Anything used as a coupling agent must be highly conductive. Air is a very poor conductor of ultrasonic waves.

3. Intended Use

UltraTENS™ II is a Portable Ultrasound and TENS combo device that generates deep ultrasonic waves within body tissues and TENS, transcutaneous electrical nerve stimulation, for the treatment of selected medical conditions such as symptomatic relief of chronic intractable pain, post-traumatic pain and post-surgical pain, muscle spasms, and joint contractures. Not recommended for the treatment of malignancies. This is an FDA regulated product available by prescription only. Keep out of reach of children.

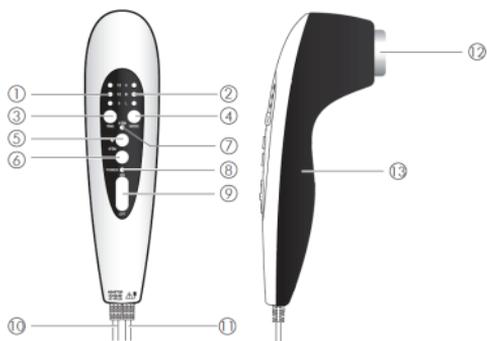
4. Contraindications

1. Do not use over or near bone growth centers (epiphyseal discs) until bone growth is complete.
2. Do not use over a healing fracture.
3. Do not use over the eyes.
4. Do not use over the heart.
5. Do not use over brain tissue.
6. Do not use on patients with demand type cardiac pacemakers.
7. Do not use on someone who is pregnant.
8. Do not use on testicles.
9. Do not use on patients post laminectomy.
10. Do not use on areas of the body that lack sensation.
11. Do not use on areas of post-traumatic sequelae.
12. Do not use if the patient has an endoprosthesis / metal implants.
13. Do not use on patients with implanted neurostimulation systems.
14. Do not use to treat malignancies nor in the region where tumors or malignant tumors are present.
15. Do not use on patients who have thrombophlebitis and/or varices.
16. Do not use on patients experiencing septic inflammation.
17. Do not use on patients who have diabetes mellitus.
18. Do not use on patients who have osteoporosis.
19. Do not use over ischemic tissues in patients with vascular disease where the blood supply would be unable to follow the increase in metabolic demand.
20. Do not use over the carotid sinus nerves or arteries, laryngeal or pharyngeal muscles.
21. Do not use on patients with hemorrhagic diatheses (excessive bleeding disorders).
22. Do not use over an area of the spinal cord following a laminectomy.
23. Do not use over areas that are under anesthesia.
24. Do not use on acute injuries.

25. Do not use on open wounds.
26. Do not use if patient is feverish (pyrexia).
27. Do not use on patient with tuberculosis.
28. Do not use on patients who have localized inflammation.

5. Presentation

1. **TIME LED:** Indicates treatment times of 5 minutes, 10 minutes and 15 minutes.
2. **TIME Button:** Adjusts treatment times to either 5 minutes, 10 minutes and 15 minutes.
3. **“+” Button:** Increases the intensity of stimulation.
4. **PWR LED:** Indicates power state.
5. **On/Off Switch:** Power on by shifting up or power off by shifting down.
6. **MODE LED:** Indicates intensity of the ultrasound Low (L), Medium (M) and High (H).
7. **MODE Button:** Adjusts the ultrasound intensity: Low, Medium and High.
8. **STIM LED:** Indicates the stimulation output state – when illuminate the stimulation is on.
9. **“-” Button:** Decreases the intensity of the stimulation.
10. **Adapter Connection Point**
11. **Lead Wire and Electrode Pad Connection Point**
12. **Ultrasound Head / Applicator**
13. **Main Body**



6. Installation

6.1 Before Use

Remove the equipment and all accessories from shipping carton and device storage case. Inspect the device for damages or missing parts and/or accessories. Report any damage or missing parts or accessories to your local dealer from which you purchased this unit. The case contains the following accessories:

Description	Quantity
UltraTENS™ II Combo Unit	1 PC
Operating Manual	1 PC
Electrode 50 x 100mm	1 PC
Lead wire	1 PC
Adapter 100-240V 50/60 Hz, 0.5A	1 PC
Ultrasound Transmission Gel (3 oz.)	1 PC

6.2 Connection

Prior to connecting this device to the power supply, verify that the voltage and frequency stated on the rating label match the available power supply.

The power adapter is a part of the supply circuit on which the device's safety depends on. The UltraTENS™ II is only approved to be used with the enclosed adapter (YLS0301A-T150120).



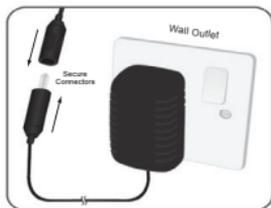
Caution: It is not permitted to connect UltraTENS™ II to any other type of adapter other than YLS0301A-T150120.



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

6.3 Connection of the Power Adapter

1. Connect the male connection point of the power adapter to the female connection point of the device's power cord.
2. Connect the power adapter to the wall outlet.



6.4 Therapy Modes

UltraTENS™ II offers two therapy modes:

1. Combination: Ultrasound + Electrical Stimulation Therapy
2. Ultrasound: Ultrasound Therapy

6.5 Disconnect from Power Adapter

1. Power off the unit by sliding the power on/off switch from "ON" to "OFF" position.
2. Remove the power adapter from the wall outlet.

7. Operation

7.1 Measures with Regards to Treatments

Before Treatment:

1. Ensure there are no contraindications to treatment.
2. Clean the skin of the treatment area with soap or rubbing alcohol (70%).
3. If the skin has excess hair, trim or shave hair for optimal treatment.
4. Apply a liberal amount of ultrasound transmission/conductive gel to the treatment area. Use only FDA approved ultrasound gel.

Ultrasonic Action Function Test:

Place the probe horizontally. Then apply several water drops on the middle surface of the probe. Turn the device on and press the time button to activate the ultrasound device. You will be able to observe the ultrasonic action as the water droplets will appear to be dancing on the sound head and you may notice a slight “steam” being released. The water droplets on the probe start to perform one million vibrations per second showing the atomization phenomenon.

During Treatment:

Move the ultrasound-head applicator in a circular motion. The area treated should be two times the diameter of the applicator.

NOTE: If experiencing poor transmission of ultrasound energy, it is advised to add more gel or reposition the ultrasound-head.

 **Caution:** The ultrasound-head applicator should be moved in a slow, flat, circular motion over the skin surface of the treatment area. Apply the sound head evenly (in time) over the treatment area - not too slow to avoid inducing heat; not too fast to prevent bad contact which would reduce the effectiveness of the treatment.

After Treatment:

1. Clean the contact surface immediately after each treatment. Make sure that no ultrasound gel remains on the treatment head.

NOTE: We recommend cleaning the treatment head, unit and cable daily using a soft cloth moistened with lukewarm water – do not immerse the device in water.

NOTE: The ultrasound treatment head can be disinfected using a soft cloth moistened with 70% rubbing alcohol. Do not use rubbing alcohol on the device itself.

2. Check if there are any signs of improvement (e.g. pain, circulation or mobility).

7.2 Operating the Device

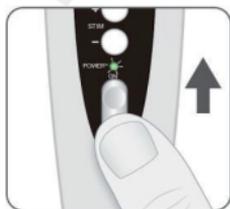
7.2.1 Ultrasound Therapy

1. **Apply Transmission Gel:** Apply a layer of ultrasound transmission gel on the treatment area. The gel acts as a coupling substance and ensures effectiveness. The area treated should be two times the diameter of the treatment head.

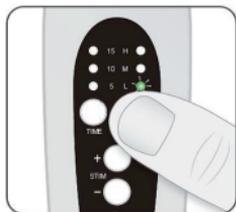


⚠ Caution: Never apply the gel to the applicator. The applicator will register this as contact and may emit ultrasound energy, which could damage the applicator.

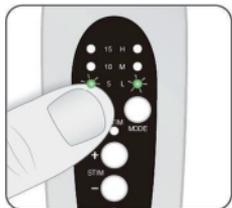
2. **Turn On the Device:** Connect the power adapter according to section 6.3. Switch on the device, using power on/off switch by switching from "OFF" to "ON" position. The LED power indicator will illuminate.



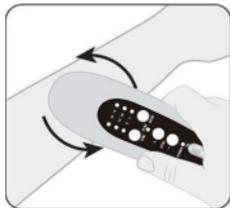
3. **Adjust Ultrasound Intensity:** Press the "MODE" button to select the ultrasound intensity. The intensity has three levels, Low (L), Medium (M) and High (H), each level corresponds to a light indicator.



4. **Set Treatment Time:** Press the "TIME" button to cycle through the treatment time (5, 10 and 15 minutes), as shown by the "TIME" indicators. When the time is chosen, the system will start working. During working time, the user can press the "TIME" button to adjust the treatment time.

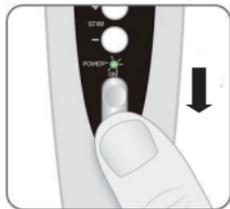


5. **Start Treatment:** Move the treatment head in a flat, slow, circular motion over the skin surface treatment area that is covered with a layer of ultrasound transmission gel. Apply the sound head evenly (in time) over the treatment area.



⚠ Caution:

- The device has a load detection system for safety. When the treatment head does not have good contact with the skin, the device will stop treatment automatically. During this time, the TIME LED will flash slowly (1Hz). The device will not restore treatment until the contact is good.
 - The device has a temperature protection function. When the temperature of the treatment head exceeds 107°F (42°C) the treatment will automatically stop and the TIME LED will flash quickly (2Hz). The device will not restore treatment until the temperature is below 104°F (40°C).
6. **Turn Off the Device:** After the time duration has been completed, the device will automatically revert back to standby state. Turn off the product by sliding the Power switch downwards from "ON" to the "OFF" position.

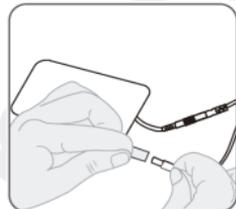
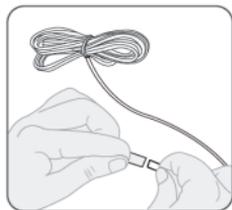


7.2.2 Combination Ultrasound and TENS Therapy

1. Connect the Lead Wire and Electrode Pad:

Connect the lead wire and electrode pad to the unit as shown by the pictures at the right.

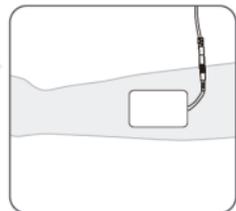
- Plug the lead wire into the connection point attached to the device.
- Connect the electrode pad to the lead wire.
- Make sure all connections are securely in place.



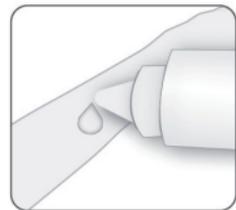
Caution: The device must be turned off before connecting the lead wires to the device.

2. **Electrode Pad Placement:** Place electrode firmly on the skin after cleaning and drying the treatment area.

- Place the electrode pad on the area of the body indicated by your physician or therapist.
- Make sure the electrode pad is placed firmly to the skin and has made good contact between the skin and the pad.

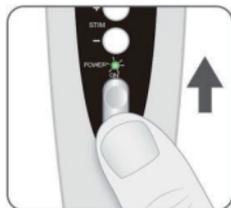


3. **Apply Transmission Gel:** Apply a layer of ultrasound transmission gel on the treatment area. The gel acts as a coupling substance and ensures treatment effectiveness. The area treated should be two times the diameter of the treatment head.



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

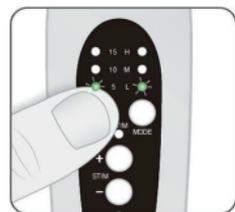
4. **Turn On the Device:** Connect the power adapter according to section 5.3. Switch on the device, using power on/off switch by switching from "OFF" to "ON" position. The LED power indicator will illuminate.



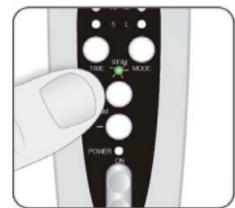
5. **Adjust Ultrasound Intensity:** Press the "MODE" button to select the ultrasound intensity. The intensity has three levels, Low (L), Medium (M) and High (H), each level corresponds to a light indicator.



6. **Set Treatment Time:** Press the "TIME" button to cycle through the treatment time (5, 10 and 15 minutes), as shown by the "TIME" indicators. When the time is chosen, the system will start working. During working time, the user can press the "TIME" button to adjust the treatment time.



7. **Adjust Stimulation Intensity:** Press the "+" button to increase the intensity of the stimulation. Press the "-" button to decrease the intensity of the stimulation. The STIM LED will flash every time the "+" or "-" button is pressed.



Remark: There are two colors of Stim LED lights to indicate the output intensity of stimulation.

Green light: Output intensity <10V;

Orange light: Output intensity $\geq 10V$.



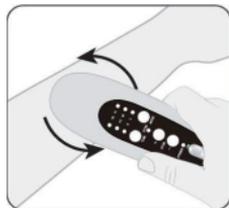
Caution:

- If the stimulation level is uncomfortable or becomes uncomfortable, reduce the stimulation intensity to a comfortable level and contact your medical practitioner if problems persist.

- If the electrode pad or the ultrasound treatment head do not have good contact with the skin, the STIM LED will flash after the output intensity of stimulation surpasses 5V. The intensity will automatically but slowly increase to setting level after the pad and treatment head have made good contact with the skin.
- Move the ultrasound treatment head while you are adjusting the stimulation intensity to prevent the local skin temperature from becoming too high or burning.
- Each step of increase output intensity is 1V when the output intensity is less than 5V; 0.5V/step when the output intensity is over 5V

8. Start Treatment:

Move the treatment head in a flat, slow, circular motion over the skin surface treatment area that is covered with a layer of ultrasound transmission gel. Apply the sound head evenly (in time) over the treatment area.



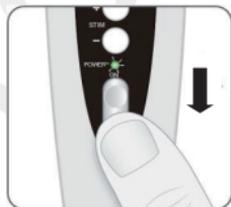
Caution:

- The device has a load detection system for safety. When the treatment head does not have good contact with the skin, the device will stop treatment automatically. During this time, the TIME LED will flash slowly (1Hz). The device will not restore treatment until the contact is good.
- The device has a temperature protection function. When the temperature of the treatment head exceeds 107°F (42°C) the treatment will automatically stop and the TIME LED will flash quickly (2Hz). The device will not restore treatment until the temperature is below 104°F (40°C).

- The device works without vibration. You must move the applicator with a slow, but deliberate speed, flat against the treatment area and in a circular motion around the treatment area. After finishing the treatment, the device will enter the waiting state. It is not recommended that the user restart treatment upon completion of therapy.

9. Turn Off the Device:

After the time duration has been completed, the device will automatically revert back to standby state. Turn off the device by sliding the power switch downwards from "ON" to the "OFF" position.



7.3 The Ultrasound Head / Applicator

The 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.

8. Maintenance

8.1. Measures with Regards to Treatments

Switch off the device and disconnect it from the power supply. The device 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 submerge the device in liquids. Should the unit accidentally become submerged, contact the Supplier or Authorized Service Center immediately. Do not attempt to use the device that

has been submersed in any liquid substrate until inspected and tested by a service technician certified by an Authorized Service Center. Do not allow liquids to enter the ventilation holes.

8.2 Cleaning of the Ultrasound Head/Applicator

The applicator should be regularly inspected for damage, e.g. hairline cracks, which could allow the penetration of 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. If a more sterile cleaning is needed, use a cloth moistened with 70% rubbing alcohol.

8.3 Cleaning the Lead Wire and Adapter

Periodically wipe the lead wire and adapter clean with a cloth dampened with a mild soap solution, and then gently wipe them dry.

NOTE: Use of rubbing alcohol on the lead wire will damage the insulation and dramatically shorten its life.

8.4 Cleaning the Electrode Pad

1. Switch the power off and remove the pad from the skin and the lead wire.
2. Wash the pad when the adhesive surface becomes dirty and/or the pad is difficult to attach to the skin.
 - Wash the pad softly with your fingertips under slow running cold water for several seconds (do not use a sponge/cloth/sharp object like a nail on adhesive side. Do not use detergents, chemicals or soap).
3. Dry the pads and let the adhesive surface air-dry completely (do not wipe with tissue paper or cloth).
4. Replace the pad on the clear plastic film and store in plastic bag.

**Caution:**

- The life of the electrode pad may vary by the frequency of washing, skin condition, and storage state.
- If the electrode pad no longer sticks to your skin or the electrode pad is broken, you should replace with a new electrode pad.
- Before applying the electrode pad, it is recommended to wash and degrease the skin, and then completely dry the area.
- Do not turn on the device when the electrode pad is not positioned on the body.
- Never remove the electrode pad from the skin while the device is still powered on.
- If replacement electrode is necessary, use only electrode pads that are 2 inch x 4 inch (50 x100mm), the same as the electrode pad provided with the Ultra TENS™ II device.
- Use of electrode pads larger than provided may reduce the effect of the stimulation. Use of an electrode pad that is much smaller than the electrode pad provided with Ultra TENS™ II device may increase the chance of skin irritation or electrode burns occurring under the electrode pad.
- Always use electrode pads that have been cleared for use in the United State by the FDA.

9. Storage

9.1 Storing the Electrode Pad and Lead Wires

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

9.2 Storing the Unit

- Place the unit, electrode pad, lead wires and manual back into the device storage case. Store the case in a cool, dry place, 14°F~131°F (-10°C~55°C); 10% ~90% relative humidity; atmospheric pressure 700~1060 hPa.
- Do not keep at places that can be easily reached by children.

10. Disposal



Please dispose of the device in accordance with the legal obligation in your area.

11. Prescription Statement

⚠ Caution: United States Federal Law restricts these devices to sale by, or on the order of, a physician or licensed practitioner by the law of the State in which he/she practices, according to 21 CFR 801.109.

This device should be used only under the continued supervision of a physician or licensed practitioner.

12. Troubleshooting

If your device does not seem to be operating correctly, refer to the chart below to determine what may be wrong. Should none of these measures correct the problem, the device should be serviced.

Problem	Possible Cause	Solution
LED indicator lights fail to light up.	Adapter contact failure.	Ensure adapter is connected.
		Check the following contacts: ◇ All contacts are in place. ◇ All contacts are not broken.
Electrical Stimulation is weak or can not feel any stimulation.	Electrode pad is dried out or is contaminated.	Replace with new electrode pad.
	Electrode pad does not stick to skin well.	Reconnect the electrode pad or replace with new electrode pad.
	Lead wire is old/worn /damaged.	Replace new lead wire.
	Electrical stimulation intensity is low.	Increase the output intensity.

Problem	Possible Cause	Solution
Electrical stimulation is uncomfortable.	Intensity is too high.	Decrease intensity.
	Electrode active area size is too small.	Use only electrode pads that are 2 x 4 inch (50 x 100 mm).
	Damaged or worn electrode or lead wire.	Replace with new electrode pad or lead wire.
	May not be operating the device according to the manual.	Please check the manual before use.
Electrical stimulation stops.	Poor electrode contact.	Re-apply electrode, and secure firmly.
	Damaged or worn electrode or lead wire.	Replace with new electrode pad or lead wire.
	No contact medium.	Use with appropriate ultrasound gel.
Stimulation is ineffective.	Improper electrode and applicator placement.	Reposition electrode and applicator.
	Unknown.	Contact clinician.

13. Glossary of symbols

IPX7	Only for treatment head: Protected against the effects of temporary immersion in water.
IPX7	Only for main body: Protected against solid foreign objects of 12.5 mm \emptyset and greater. Protection against vertically falling water drops when enclosure tilted up to 15°.
	Class II symbol
	Type of protection against electric shock: Type BF Applied Part
	Please refer to instruction manual because of the higher levels of output.
	Electrical devices are recyclable material and should not be disposed of with household waste after their useful life! Help us to protect the environment and save resources and take this device to the appropriate collection points. Please contact the organization which is responsible for waste disposal in your area if you have any questions.
	Date of manufacture
SN	Serial number
LOT	Batch code

14. Specifications and Technical Data

13.1 Technical information of Ultrasound:

Acoustic frequency:	1MHz \pm 10%
Temporal maximum power:	9.6W \pm 20% (duty factor:100%)
Pulse repetition rate:	100Hz \pm 10%
Duty factor:	30%, 40%, 50%
Effective radiating area (ERA):	4.0cm ² \pm 20%
Temporal maximum effective intensity:	2.4W/cm ²
BNR (max):	5.0
Beam type:	Collimated
Waveform:	Pulsed
Treatment time:	5min, 10min, 15min
Material of treatment head:	Aluminum

13.2 Technical information of Electrical Stimulation:

Output characteristics:	Constant voltage (CV)
Treatment time:	5min, 10min, 15min
Output wave:	Bi-phasic square waveform
Carrier frequency (C.F.):	2.5kHz
Sweep low beat frequency (Beat L):	1Hz, 5Hz, 80Hz
Sweep low beat frequency (Beat H):	10Hz, 120Hz
Maximum output:	0-15V (at 500 Ω Load)

13.3 Technical information of UltraTENS™ II Main Device:

Current consumption:	18W
Working current:	< 1.1A
Safety class:	Class II, BF-type
Dimension (L x W x H):	202mm x 49mm x 70mm
Weight:	7.4 oz. (210g)

13.4 Technical information of Power Supply:

Supply voltage:	100V~240V
Frequency:	50Hz~60Hz
Power:	18W
Output voltage:	15V
DC output current:	1.2A
Dimension (L x W x H):	209mm x 53mm x 89mm
Weight:	7.1 oz. (201g)

13.5 Environmental Conditions:

Operating conditions: Temperature: 41 °F~104 °F (5 °C~40 °C)
Relative humidity: 30%~75%
Atmospheric pressure: 700~1060hPa

Storage conditions: Temperature: 14 °F~122 °F (-10 °C~50 °C)
Relative humidity: 10%~90%
Atmospheric pressure: 700~1060hPa

13.6 Program List

Program	Duty Factor	Output Power	Beat L.	Beat H.
L	30%	2.9W ±20%	1Hz	10Hz
M	40%	3.8W ±20%	5Hz	120Hz
H	50%	4.8W ±20%	80Hz	120Hz

15. Important information regarding electromagnetic compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.

Medical devices should also not interfere with other devices. In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Medical devices manufactured by Roscoe Medical, Inc. conform to this IEC60601-1-2:2007 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by Roscoe Medical may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- Refer to EMC table guidance regarding the EMC environment in which the device should be used.

Guidance and manufacturer's declaration - electromagnetic emissions

The DU6012 device is intended for use in the electromagnetic environment specified below. The customer or the user of the DU6012 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	This 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 CISPR 11	Class B	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.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacturer's declaration - electromagnetic immunity

The DU6012 device is intended for use in the electromagnetic environment specified below. The customer or the user of the DU6012 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	±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%.

Guidance and manufacturer's declaration - electromagnetic emissions

The DU6012 device is intended for use in the electromagnetic environment specified below. The customer or the user of the DU6012 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the DU6012 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
			<p>Recommended separation distance:</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}, 80\text{MHz to } 800\text{MHz}$ $d = 2.3\sqrt{P}, 800\text{MHz to } 2.5\text{GHz}$ <p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>

NOTE 1: 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.

^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 $[3]V/m$.

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 of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and 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) according to the transmitter manufacturer.

NOTE 1 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.

16. WARRANTY

Please contact your dealer or the device center 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 for UltraTENS™ is two years 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 charge within the warranty period.
3. Repairs under warranty do not extend the warranty period either for the device or for the replacement parts.
4. The following is excluded under the warranty:
 - ◇ All damage which has arisen due to improper treatment, e.g. nonobservance of the user instruction.
 - ◇ All damage which is due to repairs or tampering by the customer or unauthorized third parties.
 - ◇ Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service center.
 - ◇ Accessories which are subject to normal wear and tear.
5. 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.

Note:

- 1) Shelf life is most influenced by several factors: exposure to light and heat, transmission of gases (including humidity), and mechanical stresses.



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