

RICH-MAR

Theratouch 7.7-S



OPERATION HANDBOOK AND MANUAL

P/N: 400-120 Rev. 2

CAUTION

This device is not designed to be connected with any electrical equipment unless manufactured and approved by Rich-Mar.

NOTE: This includes whirlpools and accessories NOT manufactured by Rich-Mar. These include patient lead cords, self-adhesive electrodes, and carbon electrodes.

CAUTION: When using carbon electrodes with any Rich-Mar stimulator, a moistened interface (cloth or sponge) **MUST** be utilized between these electrodes and the patient to avoid skin irritation and/or electrical burns.

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Appendix A Ultrasound Technical Information

WARRANTY

Rich-Mar warrants that our units are free of defects in material and workmanship. This warranty shall remain in effect for (3) three years from the date of original customer purchase. If these Products fail to function during the three year warranty period due to a defect in material or workmanship, Rich-Mar or the selling dealer will repair or replace the respective Product without charge within a period of thirty (30) days from the date on which the Product is returned to Rich-Mar.

All repairs to the Product must be performed by Richmar or a Richmar Authorized Service Center. Any modifications or repairs performed by unauthorized centers or groups will void this warranty.

The warranty period for certain accessories is 90 days. Accessories consist of Lead Wires and Electrodes.

The warranty period for the Ultrasound Applicators is one year (12 months).

To participate in warranty coverage, the Product's warranty registration card (included with the Product) must be filled out and returned to Rich-Mar by the original owner within ten (10) business days from the date of purchase.

RICHMAR SHALL RESERVE THE RIGHT TO REQUEST PROOF OF PURCHASE FROM THE END-USER TO VALIDATE THE WARRANTY PERIOD.

This Warranty Does Not Cover:

- ~Replacement parts or labor furnished by anyone other than Rich-Mar, the selling dealer or a certified service technician.
- ~Defects or damage caused by labor furnished by someone other than Rich-Mar, the selling dealer or a certified service technician.
- ~Any malfunction in the Product caused by product misuse, including, but not limited to, the failure to provide reasonable and required maintenance or any use that is inconsistent with the Product's User's Manual.

RICH-MAR SHALL NOT BE LIABLE IN ANY EVENT FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES.

Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

To Obtain Service from Rich-Mar or the selling dealer under this warranty:

1. A written claim must be made within the warranty period to Rich-Mar or the selling dealer. Written claims made to Rich-Mar should be sent to:

Rich-Mar, Inc.
4120 South Creek Road
Chattanooga, TN 37406
Telephone (423)648-7730/(423) 648-7735

and

2. The Product must be returned to Rich-Mar or the selling dealer by the owner.

This warranty gives you specific legal rights and you may also have other rights which vary from location to location.

Rich-Mar does not authorize any person or representative to create for it any other obligation or liability in connection with the sale of the Product.

Any representative or agreement not contained in the warranty shall be void and of no effect.

THE FOREGOING WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Rich-Mar Muscle Stimulator Indications for Treatment (For Biphasic, Monophasic, and Russian Waveforms)

Rich-Mar stimulation devices are indicated for the following conditions:

- 1) Relaxation of muscle spasms.
- 2) Prevention or retardation of disuse atrophy.
- 3) Increasing local blood circulation.
- 4) Muscle re-education.
- 5) Maintaining or increasing range of motion.
- 6) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
- 7) *If the device has Quadpolar Interferential or Bipolar Interferential output capabilities they are also indicated for the following conditions:*
- 8) Symptomatic relief of chronic, intractable pain. 8) Management of pain associated with post-traumatic or post-operative conditions.

Rich-Mar Microamperage Pulsed Current Indications for Treatment (Microcurrent)

Rich-Mar stimulators that have microcurrent output are indicated for the following conditions:

- 1) Symptomatic relief of chronic, intractable pain.
- 2) Management of pain associated with post-traumatic or post-operative conditions.

Ultrasound Indications for Treatment (Therapeutic Ultrasound)

Rich-Mar Ultrasound devices are indicated to produce therapeutic deep heat for the following conditions:

- 1) Relief of pain.
- 2) Muscle spasms.
- 3) Joint contractures.

But not for the treatment of malignancies.

Rich-Mar Muscle Stimulator Contraindications and Warnings **(For Quadpolar, Bipolar, Biphasic, Monophasic & Russian Waveforms)**

WARNING - Federal law restricts this device to sale by or on the order of a physician or any other practitioner licensed by the law of the state in which said person practices.

Contraindications

This device should not be used in the following areas:

- 1) On persons wearing a cardiac pacemaker.
- 2) On persons who have known or suspected
- 3) malignant lesions. This includes cancer patients.
- 4) Over the carotid sinus area.
- 5) Transcerebrally.
- 6) Over the pregnant uterus.

Warnings

- 1) The long-term effects of chronic electrical stimulation are unknown.
- 2) Adequate precautions should be taken when stimulation is used on persons with suspected heart problems.
- 3) Adequate precautions should be taken when stimulation is used on persons with suspected or diagnosed epilepsy.
- 4) Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrodes are positioned over the neck or mouth. The contractions may be strong enough to close the airway or cause difficulty in breathing.
- 5) Electrical stimulation should not be used in electrically sensitive areas.
- 6) Electrical muscle stimulation (EMS) should not be used over swollen, infected, or inflamed areas of skin eruptions (e.g., phlebitis, thrombo phlebitis, varicose veins).
- 7) Caution should be used in the transthoracic application of electrical muscle stimulation (EMS) in that the introduction of electrical current into the heart may cause arrhythmias.
- 8) Electrical muscle stimulation (EMS) devices should be kept out of the reach of children.
- 9) Safety has not been established for use of electrical stimulation during pregnancy.
- 10) This device should be used only under the continued supervision of a physician.
- 11) Transcutaneous Electrical Nerve Stimulation (TENS) is a symptomatic treatment and as such suppresses the sensation of pain, which would otherwise serve as a protective mechanism.

Precautions

Precautions should be taken when using a RichMar muscle stimulator in the presence of one or more of the following conditions:

- 1) When there is a tendency to hemorrhage following acute trauma or fracture.
- 2) Following recent surgical procedures when muscle contractions may disrupt the healing process.
- 3) Over the menstruating uterus.
- 4) When sensory damage is present by a loss of normal skin sensation.
- 5) When using this device at current outputs above 40mA, extra caution should be observed to avoid
- 6) burns by using an adequate conductive medium and by frequently using an alternate electrode placement.
- 7) Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.

Adverse Reactions

Adverse reactions to electrical stimulation are usually limited to sensations of discomfort. Excessive stimulation can cause muscle spasms as well as soreness such as can be expected with excessive natural exercise. In all cases, treatment should not exceed the patient's comfortable tolerance to the stimulation level.

NOTE: Skin irritation and burns beneath the electrodes have been reported with the use of muscle stimulators.

Contraindications and Warnings

(For Microamperage Pulsed Current Waveform/ Microcurrent)

Contraindications

This device should not be used in the following areas:

- 1) On persons wearing a cardiac pacemaker.
- 2) On persons who have known or suspected malignant lesions. This includes cancer patients.
- 3) Over the carotid sinus area.
- 4) Transcerebrally.
- 5) Over the pregnant uterus.
- 6) Whenever pain syndromes are undiagnosed, until etiology has been established.

Warnings

- 1) This device is not effective for pain of the central origin (this includes headaches).
- 2) The long-term effects of chronic electrical stimulation are unknown.
- 3) Safety has not been established for the use of microcurrent during pregnancy.
- 4) Adequate precautions should be taken in the cases of persons with suspected or diagnosed seizures or heart problems.
- 5) This device is to be used as asymptomatic treatment for pain and has no curative value.
- 6) Patients should be cautioned and their activities regulated if pain is suppressed that would otherwise serve as a protective mechanism.
- 7) Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when the stimulation is on.
- 8) This device should be used only under the continued supervision of a physician.
- 9) The user **MUST** keep the device out of the reach of children.

Precautions

- 1) Isolated cases of skin rash may occur at the site of electrode placement, following long-term application. The irritation can usually be reduced by use of an alternate electrode placement and/or an alternative conductive medium.
- 2) Effectiveness of this treatment is dependent upon patient selection.

Adverse Reactions

Skin irritation and burns beneath the electrodes have been reported with the use of transcutaneous nerve stimulators.

Ultrasound Contraindications

Contraindications

Ultrasound should not be used in the following areas:

- 1) Near or over the heart.
- 2) Near or over the eyes.
- 3) On the head.
- 4) Near or over reproductive organs.
- 5) On the lower back during pregnancy or over the pregnant uterus.
- 6) Directly over the spinal column.
- 7) Over growing bone in children.
- 8) Where the skin suffers from any sensory impairment.
- 9) Over areas of malignancies.
- 10) In the area of visceral plexus and large autonomous ganglion.
- 11) Over the thoracic area if the patient is using a cardiac pacemaker.
- 12) Over a healing fracture.
- 13) Over ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result.

Precautions

Precautions should be taken when used:

- 1) Over anesthetized areas.
- 2) On patients with hemorrhagic diatheses.
- 3) Ultrasound treatment should not be performed over an area of the spinal cord following laminectomy (i.e.- when major covering tissues have been removed).

Caution

- 1) Excessive doses of ultrasound may cause damage to tissue. Periosteal pain is an indication of excess intensity and if it occurs, the power should be reduced; the transducer should be moved more rapidly over the area being treated; or a lower pulsed duty cycle should be used.
- 2) If the soundhead has been operated unloaded for an extended period of time, the transducer will get hot. If the soundhead is applied to the patient while the transducer is hot, a burn may result.

Warning

Do not operate the soundhead in an unloaded condition. It is possible that un-repairable damage may occur to the transducer in an unloaded state.

Introduction

- ✓ The Rich-Mar Theratouch 7.7-S is a powerful and easy-to-use stimulator and ultrasound, providing the most flexible selection of electrotherapy for treatment. This manual is meant to give a brief introduction to the Theratouch 7.7-S and its operation.
- ✓ The Theratouch 7.7-S offers six stimulation waveforms and two different sized ultrasound transducers with the ability to output both 1MHz and 3MHz.
- ✓ The Theratouch 7.7-S touch-screen and director dial are the main controls for operation.

User Interface

The Theratouch units are meant to use, not confuse. Paramount to their design was an interface that actually made treatment set up less daunting and more efficient. To facilitate this, the main input controls are the touch screen, the director dial, and the stop/clear button.

Touch-Screen/Status Screen

The Theratouch 7.7-S utilizes a touch-screen to navigate the software-driven operation of the Theratouch. The touch-screen is activated by a moderate amount of pressure to any of the buttons on the screen. After pressing each button, an audible beep will sound to signify that a choice has been accepted.

Director Dial

The director dial is a very useful and powerful input tool for the Theratouch 7.7-S. Its basic function is the “twist and click”. The dial allows precise control over parameters that it requires, such as intensity, balance, pulse rates, time, etc. Another feature of the director dial is the accept mechanism which activates by “clicking down” on the dial. Thus, when setting intensity, turn the dial to an acceptable level and click down to accept or select. The Theratouch 7.7-S will beep when the information has been accepted. The dial icon will appear on the Theratouch 7.7-S screen when the dial is active for an application (i.e.- to set a pulse rate or scroll through treatment choices).

Stop/Clear Button

The stop/clear button is a touch-sensitive button that will stop treatment and clear the screen back to the main menu when pressed. **This button functions as the immediate treatment override.**

Theratouch 7.7-S Operation

Logo Screen

First, turn the unit on by pressing the switch on the back of the device. Screen 1 will appear with the Rich-Mar logo, Theratouch name, and the software version of the unit. After five seconds, the main menu will automatically be painted.

Main Menu

The main menu for the Theratouch 7.7-S will appear next. From this menu, any combination of treatments, frequencies, and waveforms can be utilized, including alternating, surged, and pulsed rate chain options as well as one and three MHz. There are three basic Theratouch forms of treatment. Each will be explained along with instructions for set up and the parameters involved. The three forms include:

- 1) QuikSets
- 2) Presets
- 3) Wave(form) treatments.

QuikSets

The QuikSets are the first three buttons from the left of the channel indicator. They are labeled Quik1, Quik2, and Quik3. By selecting one of the QuikSets, treatment is completely set up for the user. Only the intensity will need to be set. The QuikSets are ideal for most common treatments.

Simply enter the QuikSet's parameters once, or use the factory settings. Each QuikSet can also be named (up to five characters). Using different QuikSets on different channels will allow the user to perform a stimulation, ultrasound, or combination treatment. The "Defaults" section will further explain how to set parameters and name QuikSets.

Presets

The preset button will allow access to a menu of six preset treatments that work in the same manner as the QuikSets, with both stimulation and ultrasound options. Each of the presets can be programmed with specific names. By selecting the preset button, the user can scroll through the preset menu settings. Once a preset is selected and intensity is set, set up is complete. The "Defaults" section will further explain set up of Presets.

Wave

The wave button shows all the waveforms available in the Theratouch if selected on channels one through four and all ultrasound parameters if selected on the ultrasound channel. Once a waveform is selected, all parameters will appear for that choice, including mode, time, pulse rate, vector, phase duration, phase interval, etc., depending upon the waveform. The same flow is used with the ultrasound except the parameters are soundhead size, frequency, and duty cycle. The QuikSets and Presets allow a set treatment to be accessed very quickly, whereas the wave button allows the user to customize and adjust all parameters of a particular treatment. Operation of the wave button will be explained in greater detail in the "General Operation" section.

System

Select the system button at the bottom of the main menu. The ramps and low flow monitor buttons will appear.

Ramp up and Ramp Down

The ramp up button allows the user to adjust the amount of time it takes to achieve the set treatment intensity in a surged or alternating mode. For example, if the ramp up is set at four seconds, it will take four seconds of on time to reach the treatment intensity. The same applies to the ramp down. If set for three seconds, it will take three seconds of off time for the intensity to decrease to zero in a surge mode. Ramp up is adjustable from one to five seconds and ramp down is adjustable from zero to five seconds. These are adjusted by selecting the appropriate button, rotating the dial to select ramp time, and clicking down to enter.

3-D Buttons

Below the low flow monitor button is the 3-D buttons button. This control allows the user to toggle the appearance of the buttons on the Theratouch. When this button is on, the 3-D option will activate. If turned off, all buttons will revert to black and white.

Ultrasound Units This button will allow the user to choose how the ultrasound intensity is displayed (i.e., either watts or watts/cm²).

Screen Contrast

If this button is selected, use the dial to change the percentage of screen contrast. NOTE: The stop/ clear button will also allow a screen contrast change by pressing down and turning the dial to the desired contrast.

Defaults

In the main menu, select the defaults button next to the system button. The defaults set up menu allows the user to customize the Theratouch via QuikSets and Presets set up.

Setting QuikSets and Presets

Customizing QuikSets and Presets is very simple. To start, select the Quik3 button. All parameters will appear to customize the Quik3 treatment. If the waveform button is selected, the knob icon will appear in the upper-right corner of the screen. This indicates that the knob should be used to scroll through the waveform options. Click down on the knob to accept the desired option.

Stimulation

Once a waveform is chosen for a QuikSet or Preset, the Theratouch will display available treatment parameters. For example, if the Biphasic waveform is chosen the phase width (duration) and a fixed or scan pulse rate must be set. However, if the Bipolar waveform is chosen the phase width will not be an option, but options to have a fixed or scan pulse rate will appear as well as the option to vector the output. The Theratouch treats each waveform as a separate entity with its own specific features. Once the parameters for a QuikSet have been chosen, it can be named. Simply select TMT NAME. Then rotate the dial to the desired letter or number and click down to accept each until complete (Up to five characters). Once completed and named, select the exit button and the choices will be saved.

Ultrasound

Setting the ultrasound of the QuikSet is done in the same manner as the stimulation. The parameters can be set to use a specific combination with the Quik3 stimulation parameters or as an ultrasound only treatment. The head size, frequency, and duty cycle can each be selected. The treatment time for the ultrasound treatment will be the same as the stimulation setting.

General Operation

Stimulation QuikSets and Presets Operation

When a treatment is running with the QuikSets or Presets, the time and intensity can be adjusted or the user can independently end the treatment by using the buttons on the right hand side of the screen.

Wave Operation The Theratouch 7.7-S has six available stimulation waveforms. They are Quadpolar Classic Interferential, Premodulated Bipolar Interferential, Monophasic (High Volt), Biphasic (Low Volt), Russian, and Microcurrent. Each of these waveforms has different parameters to some degree, but generally follow the same path for set up in the wave and/or default menus.

Select Waveform

Once the wave button is pressed on any of the four stimulation channels, the desired waveform can be selected. Once selected, specific parameters available to that waveform can be chosen.

Treatment Mode

Modes available in the Theratouch 7.7-S, depending upon the waveform selected include continuous, surge, alternate, and chain. - Continuous will output continuously from one channel (two for Quadpolar) at a single pulse rate or scan.

- Surge will output intermittently on one channel at a single pulse rate scan with a stated on and off time.
- Alternate mode will output the same pulse rate or scan between two different channels alternating at a set time. It is capable of outputting different intensities for each channel.
- Chain mode will allow the user to treat with one pulse rate or scan for an entered time and then switch to a different pulse rate or scan for another entered time. It will continue to switch between the two pulse rates or scans as long as treatment time remains, if the sum of the two times is less than the treatment time.

Treatment Time

To select the treatment time, select one of the preset buttons or enter a different number with the dial.

Pulse Rate

Select any of the preset rates or scans, or select scan or fixed, which will allow the user to enter a different number with the dial. When entering a scan, use the dial to enter the low end, click down on the dial, enter the high end, and click the dial down to accept that scan. To select fixed, enter the fixed pulse rate with the dial and click down to accept.

Vector and Phase

Depending upon the chosen waveform, one of the following may need to be entered:

- If Quadpolar or Bipolar Interferential are selected, vector selection options will include depth and speed. Depth options include shallow, normal, deep and none. If none is selected, the vector is turned off. If depth is chosen, a speed of vector depth movement must be selected. Vector speed choices are slow, medium, and fast.
- If a phasic waveform was selected (Monophasic or Biphasic), the phase duration and phase interval must be selected (interval on Biphasic only). The screen will display the following: "PD 50/100/50". This means that the first phase duration is 50mS, the interphase interval is 100 mS, and the second phase duration is 50 mS. Phase duration is adjustable only in Biphasic. Interphase intervals are adjustable in both Biphasic and Monophasic.

Set Intensity

The final step is to set intensity and press the dial down to accept.

Ultrasound QuikSet and Preset Operation

Ultrasound Only

If a QuikSet or Preset is selected on the bottom ultrasound channel, the user will be asked to choose whether to do a combination or ultrasound treatment. If ultrasound is selected, then the intensity of the treatment must be set.

Combination Treatment

If a QuikSet or Preset is selected on the bottom ultrasound channel and the combo button is selected, the stimulation intensity must be set first. Please note that any combination treatment will use channel four for stimulation, (three and four for quadpolar stimulation), using the white-ended lead on channel four for the electrode. Make sure that the pads are placed and note that the soundhead takes the place of the red pin for channel four output. Set stimulation intensity and press the dial to accept.

Remember to always keep the soundhead moving during any ultrasound treatment.

CAUTION: Do not operate the soundhead in an unloaded condition (without a coupling lotion and patient contact). This can cause the transducer to get very hot and may cause un-repairable damage to the transducer.

NOTE: When administering an ultrasound treatment, be sure that treatment area of the patient has an ample quantity of Rich-Mar lotion or gel as a coupling medium. The quantity and quality of the coupling medium used has a direct bearing on the amount of ultrasonic energy transmitted to the treatment area.

CAUTION: When operating the Theratouch 7.7-S in combination, note that both the metal faces of the Therapy Hammer will output stimulation.

Ultrasound - Wave Operation

- **Ultrasound Only** - If the wave button is selected on the ultrasound channel, the user will be asked to choose combo or ultrasound. If ultrasound is selected, the soundhead and frequency desired must be chosen. The user will also have the option of selecting a pulsed duty cycle or continuous output. The treatment time and intensity must then be set.
- **Combination** - If the wave button is selected on the bottom ultrasound channel and combo is selected, the stimulation can be set up on channel four (three & four for Quadpolar) in the same manner as described in the “Stimulation - Wave Operation” section. Again, be sure that the pads and soundhead are correctly positioned before increasing intensity. Once the stimulation is running, the soundhead size and ultrasound frequency should be selected. Then, select pulsed or continuous output.

CAUTION: When operating the Theratouch 7.7-S-S in combination, note that both the metal faces of the “Therapy Hammer” will output stimulation.

Lead Cord Tester

The Theratouch 7.7-S units come with a convenient and time-saving lead cord tester incorporated into the unit. To access it, go to the system screen and press “Lead Test”. The warning to disconnect the leads from the patient will appear. Once this has been completed, press start. Select one of the lead cords that are plugged in. Take the two ends of that lead cord and press them together. If the lead cord is still functioning correctly, a constant tone will sound and the graphics for that channel will come together. Repeat the same process for the other lead cords and channels. Press the stop button to stop the test. Press exit to return to the system menu.

Electrical Stimulation Site Preparation, Electrode Attachment, and Maintenance Guidelines

- 1) Know the stimulation characteristics, indications, and contraindications of the desired waveform. For most patients, the Micro amperage current will be sub-sensory. However, if stimulation sensation is perceived, be sure it is set at a level that is comfortable for the patient. On all other muscle stimulation and interferential current therapy, be sure that the intensity is set to a comfortable level. **DO NOT BRING UP THE INTENSITY UNTIL THE FOLLOWING PROCEDURES HAVE BEEN OBSERVED.**
- 2) Clean the area(s) of the skin to be treated with soap and water or an alcohol wipe.
- 3) Excessive hair may be trimmed, but shaving is not recommended immediately prior to electrode placement.
- 4) Choose the appropriate size electrode(s) for the body part being treated.
- 5) Be sure that the electrodes are securely attached to the lead wires. See the illustration on the following page for the appropriate patient lead wire connections.
- 6) Avoid placing an electrode over areas of broken skin, scars, moles, or unusual areas of skin discoloration. Also avoid skin folds/creases or areas of impaired sensation.
- 7) The single patient self-adhesive electrodes are well suited for most body areas in which electrical stimulation would be used. Remove the electrodes from the pouch and save it for subsequent storage of the product. Carefully peel the electrodes from the release backing and apply it to the chosen site. Press firmly to ensure uniform and secure contact with the skin and begin stimulation treatment.

Electrode Storage and Maintenance

IMPORTANT: The adhesive properties of these electrodes may be affected by ambient or patient skin conditions. While out of the package, extreme variations in humidity levels may affect the adhesive properties of these electrodes. To increase the adhesive properties of the electrodes, add a few drops of water to the electrodes conductive surface and spread evenly. Allow a couple of minutes for the increase in tack.

REMOVAL AND STORAGE OF ELECTRODES

Turn off the stimulation device and disconnect the cabling. Remove the electrodes from the skin and reapply to the plastic backing. Place in the pouch and reseal for storage to maintain proper adhesive quality when not in use. If possible, store the electrodes in a refrigerator to maintain adhesive.

CAUTION: In multiple, consecutive treatments of a patient, the electrodes should be discarded and replaced if damaged, or when proper adhesive tack or comfort can no longer be achieved. Electrodes should be replaced when they lose their adhesive quality, or when a change in stimulation intensity is noticed, or if the gel is separated. If in doubt about the integrity or proper function, replace the electrode before proceeding. In any instance, Rich-Mar recommends that the self-adhesive electrode NOT be used for more than 20 consecutive treatments.

Electrode Types and Sizes

The Rich-Mar Corporation recommends the use of our self-adhesive electrodes with this device. Either the MultiStim or SuperStim self-adhesive will provide the proper conductive properties.

Both the MultiStim and the SuperStim electrodes are available in 2' x 2'' square, 2" x 4" rectangular, 3'' x 5'' rectangular, and a 2" diameter round electrode.

Patient Lead Cord Maintenance

Rich-Mar Corporation recommends that your patient lead cords be replaced annually.

Please note that your patient lead cords bear a label with a space provided to write in the date that the lead cord was put into service (“Date in Service”). There is also a space to write in the replacement due date (“Replace By”), which will be one year from the date the lead cord was put into service.

Please take the time to write in these dates with a permanent marker. This will serve as a convenient reminder of the age of your lead cords.

Some Rich-Mar muscle stimulators are equipped with a feature that allows you to check lead cord continuity. If your device is equipped with this feature, it is recommended that the lead cords be checked at least monthly. Checking lead cords on a routine basis, and replacing them annually, will ensure your patient’s comfort, safety, and the effectiveness of the treatment.

Waveforms

The Theratouch 7.7-S represents the most sophisticated electrical waveform generation ever developed in electrotherapy. The waveforms are software generated by an extremely sophisticated computer that resides in each Theratouch 7.7-S.

Each waveform has particular characteristics that are particularly well suited to a physiological response. Classic, or Quadpolar Interferential, is the most conventionally thought to provide the smoothest “feeling” current available for sensory stimulation. Symmetric, Square-Wave Biphasic current is conventionally thought to provide the smoothest muscle contraction. Monophasic current provides a net charge effect, when needed, provides low current density stimulation, and historically has been used when an ultrasound combination is utilized. The Russian waveform is thought to be the best waveform for motor contraction. Within each waveform, a particular pulse rate or “beat” frequency can be chosen. Low pulse rates (0-10) are thought to be the best for indications involving chronic problems, while higher pulse rates (80-200) are thought to be best for indications involving acute problems. A pulse rate of 50 Hz is thought to provide the best motor stimulation (contraction) without rapid fatigue.

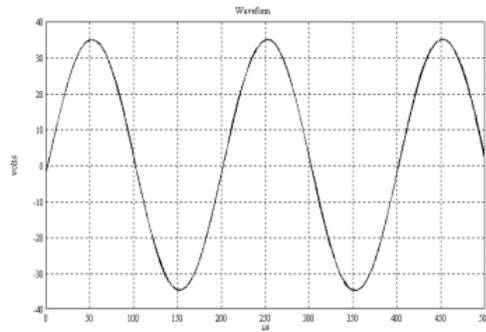
Broad base protocol conventions exist for all electrical stimulation as described above, but within each waveform, certain parameters are the key to eliciting a particular response.

The Theratouch 7.7-S has been programmed to have the most common treatment options as factory settings. However, the Theratouch 7.7-S is designed to provide the most sophisticated and customized treatments imaginable.

Helpful Hint: If you desire further information regarding waveform descriptions, recommended reading to supplement this section is ELECTROTHERAPEUTIC TERMINOLOGY in Physical Therapy, published by the American Physical Therapy Association. For more information, contact the APTA, 1111 North Fairfax Street, Alexandria, VA 22314-1488.

Quadpolar Interferential

(four pads)



Electrical stimulation at higher frequencies (5000Hz) penetrates the skin easily (due to capacitive effects of the skin) but has little therapeutic effect. Lower frequencies (0-200) are therapeutic, yet produce irritation or even pain if applied directly. Interferential current utilizes two high frequencies to pass through the skin barrier and then mixes the two frequencies to produce a low frequency within the tissues. Quadpolar mode is named such because two channels totaling four (quad) electrodes work in conjunction to provide treatment of one site. The Theratouch 7.7-S provides Quadpolar Interferential by producing two separate sine wave outputs. By crossing these electrodes, the two sine waves mix and produce a “beat” frequency within the tissue. This beat is the difference in the two sine wave outputs.

The Theratouch 7.7-S produces 5000Hz sine waves from channels one and three and produces between 5000 and 5200Hz sine waves and channels two and four. Channels one and two operate in concert to treat one site. The device scans between a low “beat” and a high “beat” setting.

Quadpolar Interferential Parameters:

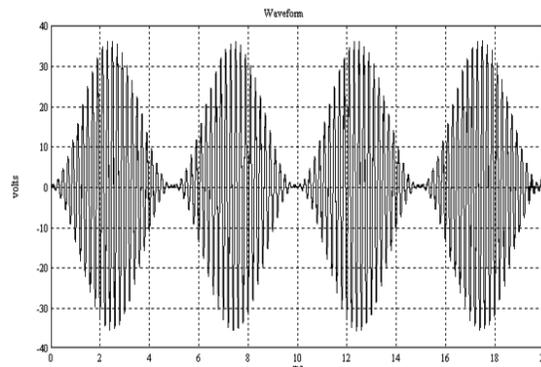
- Carrier Frequency: 5000Hz
- Beat Frequency Fixed: 0-200Hz
- Beat Frequency Scan Low: 0Hz to 200Hz
- Beat Frequency Scan High: 0Hz to 200Hz
- Pulse Rate Chain: 0-200Hz, either Fixed and/or Scan
- Vector Options: Shallow, Normal, Deep
- Vector Speeds: Slow, Medium, Fast
- Alternating Rate:* Not Available
- Surge Rates:* On: Not Available, Off: Not Available
- Ramp On: Variable 1-5 Seconds
- Ramp Off: Variable 0-5 Seconds

Quadpolar Interferential *cont.*

The Total Output Current = 50mA rms. The meter shown on the screen of the Theratouch is listed as RMS current. To convert RMS to peak current, multiply RMS by 1.414. Examples are given below.

Meter Reading (ms)	Peak Current Conversion (mA)
5	7.1
10	14.1
15	21.2
20	28.2
25	35.4
30	42.4
35	49.5
40	56.6
45	63.6
50	70.7

Bipolar Interferential



Bipolar Interferential operates with a carrier frequency but it is pre-modulated within the Theratouch 7.7-S. This enables a single channel (two electrode) system to be used. Bipolar Interferential can select a pulse rate or a “beat” frequency between 2 and 200Hz.

Bipolar Interferential Parameters:

- Carrier Frequency: 5000Hz
- Beat Frequency Fixed: 2-200Hz
- Beat Frequency Scan Low: 2Hz to 80Hz
- Beat Frequency Scan High: 80Hz to 150Hz
- Pulse Rate Chain: 5-200Hz, either Fixed and/or Scan
- Vector Options: Shallow, Normal, Deep
- Vector Speeds: Slow, Medium, Fast
- Alternating Rate: 2-99 Seconds
- Surge Rates: On: 2-99 seconds, Off: 2-180 seconds
- Ramp On: Variable 1-5 Seconds

- Ramp Off: Variable 0-5 Seconds

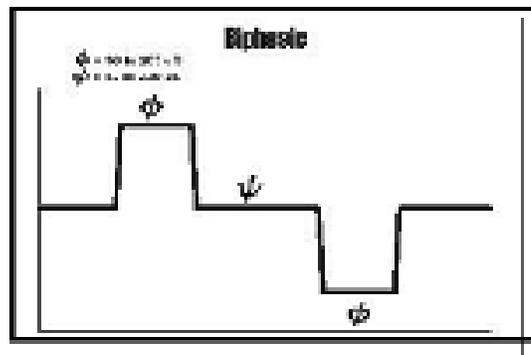
Bipolar Interferential cont.

The Total Output Current = 30mA rms. The meter shown on the screen of the Theratouch is listed as RMS current. To convert RMS to peak current, multiply RMS by 2.34 (1.414/.707). Examples are given below:

Meter Reading (ms)	Peak Current Conversion (mA)
5	11.7
10	23.4
15	35.1
20	46.8
25	58.5
30	70.1

Biphasic

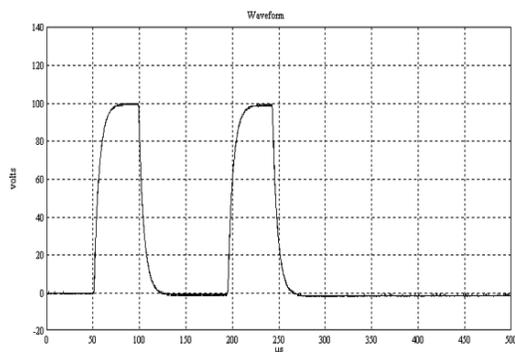
The Theratouch 7.7-S also has the capability to produce a Symmetric Square-Wave Biphasic stimulation having two phases per pulse - a positive phase, followed by a negative phase. This produces a net charge of zero.



Biphasic Parameters:

- Carrier Frequency: Not Applicable
- Beat Frequency Fixed: 2-200Hz
- Pulse Rate Chain: 2-200Hz, either Fixed and/or Scan
- Phase Duration: 50, 100, 150, 200mS
- Interphase Interval: 50, 100, 150, 200mS
- Alternating Rate: 2-99 Seconds
- Surge Rates: On: 2-99 seconds, Off: 2-180 seconds
- Ramp On: Variable 1-5 Seconds
- Ramp Off: Variable 0-5 Seconds

Monophasic



The Theratouch 7.7-S also has the capability to produce a Symmetric Square-Wave Monophasic stimulation having two equal positive phases per pulse. This results in a net charge effect. The polarity of monophasic can be either positive or negative (referring to the red pin for each channel). The Theratouch has the ability to change polarity “on-the-fly”. To change polarity of the waveform select the +/- button at any time while adjusting the intensity of the monophasic waveform. The polarity change utilizes a one-second “comfort ramp” down and back up in intensity to make the polarity change more gradual and comfortable.

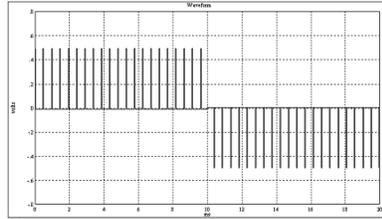
ADDITIONAL METERING

The Theratouch 7.7-S displays three meters for each Monophasic waveform. The peak reading is shown to the right of the bar. Below and left of the bar (while treating) is a meter that shows average charge per second. This will vary with the number of pulses-per-second. The third meter is to the right and below the bar (while treating) and is an accumulative net charge meter. It works much like an odometer, multiplying average charge meter time by the treatment time. Most experts say that this is an excellent way to determine the amount of total current a site has received.

Monophasic Parameters:

- Carrier Frequency: Not Applicable
- Pulse Rate: 2-200Hz
- Pulse Rate Chain: 2-200Hz, either Fixed and/or Scan
- Phase Duration: 50mS
- Interphase Interval: 50, 100, 150, 200mS
- Alternating Rate: 2-99 Seconds
- Surge Rates: On: 2-99 seconds, Off: 2-180 seconds
- Ramp On: Variable 1-5 Seconds
- Ramp Off: Variable 0-5 Seconds

Micro Current

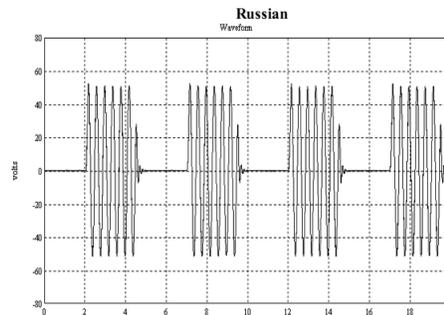


Micro current is a pulsed waveform that produces 50mS phases from .3-1000 pulses-per-second. The phases alternate from positive to negative every 2.7seconds. The amplitude is adjustable from zero to 1000mA.

Microcurrent Parameters:

- Carrier Frequency: Not Applicable
- Pulse Rate: Fixed .3-1000Hz
- Pulse Rate Chain: Fixed Low, Fixed
- High Phase Duration: 50mS
- Interphase Interval: Dependent upon pulse rate
- Positive/Negative Interval: 2.7 seconds
- Alternating Rate: Not Applicable
- Surge Rates: Not Applicable
- Ramp On: Not Applicable
- Ramp Off: Not Applicable

Russian



Russian is a 2500Hz time-modulated waveform having a sinusoidal frequency that is burst modulated at 50% duty. Russian is not available in a continuous mode, but it is available in surge, alternating, and continuous modes.

Russian Parameters:

- Carrier Frequency: 2500Hz
- Beat Frequency: Fixed 5-200Hz
- Scan: Low 5Hz to 200Hz, High 5Hz to 200Hz
- Pulse Rate : 5-200Hz, Fixed
- Alternating Rate: 2-99 seconds
- Vector Options: Not Available
- Surge Rates: On 2-99 seconds, Off 2-180 seconds
- Ramp On: Variable 1-5 seconds
- Ramp Off: Variable 0-5 seconds

Ultrasound Calibration and Tuning Procedure

Ultrasound Service Information

Rich-Mar Corporation recommends that all Rich-Mar ultrasonic therapy products be returned to the factory or to a servicing Rich-Mar distributor for service or calibration. It is recommended that the device be calibrated annually or when any major component is changed.

Caution

Calibration and peaking adjustments must not be attempted unless the person performing these adjustments has the proper test equipment, which must include an acceptable ultrasonic wattmeter, such as the Ohmic UPM-30 or equivalent. Degassed water must be used to obtain accurate readings.

Warning

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.

Calibration and Tuning Procedure Screen Calibration

- 1) Hold down the selector knob and turn the unit on.
- 2) Release the knob when the combination safe icon appears on the display.
- 3) By adjusting the knob, dial in 07. Select the setting by pressing down on the knob. Now dial in 40 and select the setting. Dial in the final setting, 36, and select. The unit should chime and enter factory mode. If it does not, reenter the combination.
- 4) Select the button "CAL PANEL." A small "X" will appear in the lower left corner of the display. Use a dull, pointed object and press the center of the "X". The "X" will move to the next corner. Repeat the procedure until all four corners have been reset. Select the button "THERA SKETCH."
- 5) Use a dull, pointed object to depress any section of the touch screen. Pixels in the display should darken wherever the screen is touched. The screen can be erased by pressing down on the knob. Press Stop/Clear to return to the Factory Mode menu.

Annual Ultrasound Calibration Check

- 1) Place the transducer to be tested in an Ohmic UPM-30 wattmeter, or equivalent.
- 2) Set up an ultrasound treatment to activate the transducer at either 1MHz or 3Mhz and 100% duty cycle.
- 3) Increase the intensity to maximum.
- 4) If the 2 cm transducer is being tested, it should be emitting at least 3.2 and no more than 4.8 watts.
- 5) The 5cm transducer should emit at least 9 and no more than 11 watts.

NOTE: If this is not the case, perform the full calibration procedure listed in the following section.

Full Calibration Procedure

- 1) Hold down the selector knob and turn the unit on.
- 2) Release the knob when the combination safe icon appears on the display.
- 3) By adjusting the knob, dial in 07. Select the setting by pressing down on the knob. Dial in 40 and select the setting. Dial in the final setting, 36, and select. The unit should chime and enter factory mode. If it does not, reenter the combination.
- 4) Clamp the transducer being calibrated into the ultrasound wattmeter.
- 5) Select one of the transducer and frequency buttons located in the bottom half of the display.
- 6) Select the "RES FREQ" button.
While observing the wattmeter adjust the frequency setting until the maximum power reading is measured by the wattmeter.
- 7) Advance the frequency 5kHz for 2cm transducer or 10kHz for the 5cm transducer. (For example, if the frequency of maximum output is .938MHz then set the frequency to .988MHz.)
- 8) Record this setting on the "Calibration Parameters" chart below.
- 9) Select the "POWER CORR" button.
While observing the wattmeter, increase the volts setting until the appropriate watt reading is measured. **NOTE: 4 watts for the 2cm and 10 watts for the 5cm.**
- 10) Record this reading on the "Calibration Parameters" chart below.
- 11) Store the settings in the 7.7-S memory bank by pressing down on the knob.
- 12) Press Stop/Clear to get back to the factory mode menu.
- 13) Repeat the calibration procedure steps 5 - 12 for the remaining transducer and frequency combinations.
- 14) After each transducer and frequency combination has been calibrated and settings stored in the 7.7-S memory bank, press Stop/Clear to return the unit to treatment mode.

Theratouch 7.7-S Ultrasound Calibration Values

2cm @ 1MHz: _____ MHz _____ Volts

5cm @ 1MHz: _____ MHz _____ Volts

2cm @ 3MHz: _____ MHz _____ Volts

5cm @ 3MHz: _____ MHz _____ Volts

Disinfecting Recommendations

To disinfect the soundhead between therapy treatments, Rich-Mar recommends using a disinfectant cleaner for ultrasound. OSHA addresses the need for prudent infection control (OSHA Instruction CPL 2-2.44C) to include decontamination of equipment between patients.

Trouble-Shooting

We have an outstanding staff available for technical support to help with diagnosing and troubleshooting problems.

Rich-Mar Corporation Technical Support Hotline: 1-888-549-4945.

If the screen is not bright enough

Try adjusting the screen contrast by pressing “System” (at the bottom of the regular screen). The screen will change. Press “SCRN Contrast” and a dark outline will appear over the box. Turn the knob until the desired contrast is achieved and then press “SCRN Contrast” again until the dark outline is under the box.

Theratouch 7.7-S Specifications

Dimensions:	16.25”W x 15.5”D x 7”H
Weight:	19.65 lbs.
Power Input:	110 VAC, 60Hz 220 VAC, 50 Hz
Power Consumption:	110 Watts
Fuse:	1 Amp
Line Leakage:	Less than 50 μ A

Theratouch 7.7-S Accessories

Standard Accessory Package

The accessories that come standard with the Theratouch 7.7-S are listed below.

One (1) AC Power Cord

One (1) 16oz. Lotion

Four (4) sets of Patient Interface Stim Lead Cords

Patient Control Switch

Two (2) packages of one of the following SuperStim self-adhesive electrodes:

2” x 2” Foam (P/N: 400-898)

or

2” x 2” Cloth (P/N: 400-899)

APPENDEIX A

Ultrasound Technical Information

Applicator Type

The ultrasonic radiation fields produced by Rich-Mar therapeutic ultrasound transducers are of the plane wave type and are essentially cylindrical in shape. This type of applicator is referred to as a collimating applicator.

Applicator Label

Each Rich-Mar applicator is labeled to provide the user with information on its applicable parameters. The following abbreviations are used on the label.

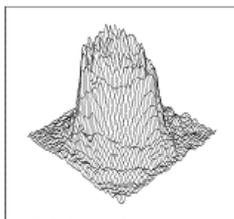
- Gen: The Rich-Mar ultrasonic generator for which the applicator is intended.
- f: The operating frequency in MHz for the applicator.
- Area: The effective radiating area of the applicator in square centimeters.
- BNR: The Beam Non-uniformity Ratio.
- Type: Coll-means collimating applicator.

Near Field/ Far Field

If measurements are made of the sound intensity along the central axis of the beam produced by the applicator, the intensity distribution shows maxima and minima near the applicator and then a gradual decline beyond the last maximum intensity.

Near Field

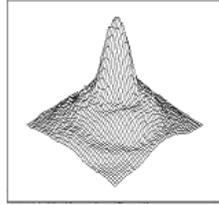
The “interference” or “near field” is the area in the ultrasound beam extending from the applicator surface to the location of the most distant intensity maximum. In this area, maxima and minima of intensity are located close to each other. This is the area in which most therapeutic application occurs. This is shown in the following figure measured 0.5cm from the transducer face.



Near Field Distribution

Far Field

Beyond this point, the beam has a more uniform intensity and is called the “far field”. Below is shown the far field distribution at 16cm from the transducer face.



Far Field Distribution

The preceding descriptions apply for radiation emitted into the equivalent of an infinite medium of distilled, degassed water at 30 C.

Transducer Parameters and Tolerances

The Rich-Mar ultrasound units operate at frequencies of either 1MHz or 3MHz +/- 10%. The effective radiating areas (ERA) of the transducers are ten, five, or two square centimeters, depending upon the size of the transducer being used. The tolerance for the ERA is +/-25% on the 2 and 5 square centimeter transducers. The tolerance for the 10 square centimeter transducers is +0. -25%. The BeamNonuniformity-Ratio (BNR) of any Rich-Mar transducer is 5.5:1 or less.

100% Mode

When operated in the 100% mode, the generator produces a non-interrupted sinusoidal waveform of one (1) or three (3) MHz. The peak power and average power are therefore the same. The error in indication of radiated power in intensity for the continuous mode does not exceed +/- 14% allowing for a 6% error in the wattmeter, which equals +/- 20%.

Pulsed Mode

When operated in the pulsed mode, the generator produces a square-wave burst of sinusoidal waveform of one (1) or three (3) MHz of 2.5 milliseconds in duration. Depending on the Rich-Mar model of therapeutic ultrasound in use, the duty cycle can be chosen between 5% and 95% duty. This then implies the repetition rate is selectable between 20 and 380 pulses per second. (This is computed by taking the inverse of the duty cycle $1/380 = .0026$, $1/20 = .05$). The tolerance for the pulsed mode is +/- 20%. See the following chart for second comparison on %Duty Cycle to pulses.

% Duty Cycle	Pulses/Second
(Indicated on front panel of device)	
5	20
10	40
15	60
20	80
25	100
30	120
35	140
40	160
45	180
50	200
55	220
60	240
65	260
70	280
75	300
80	320
85	340
90	360
95	380

The error in indication of radiated power in intensity for the pulsed mode does not exceed +/- 14% allowing for an allowable 6% error in the wattmeter, which equals +/- 20%.

Timer Accuracy

The Food and Drug Administration requires that the treatment timer accuracy is to within 0.5 minutes for the preset duration of emission for settings less than five minutes, to within 10% of the preset duration of emission for settings from five to ten minutes, and to within one minute of the preset duration of emission for settings greater than ten minutes.

Ratio of Temporal Peak to Temporal Average (Rtpa)

The ratios of temporal peak to temporal average intensities (Rtpa) will vary with the pulse rate of the device. Depending upon the Rich-Mar model of therapeutic ultrasound in use, the duty cycle can be chosen between 5% and 95% duty. The ratios of temporal peak to temporal average intensities (Rtpa) is calculated in the following manner:

$$Rtpa = (1/Duty):1$$

Example 5% duty = .05 (min. duty, max. Rtpa)

$$Rtpa = (1/.05):1$$

Rtpa = 20:1 Example 95% duty = .95 (max. pulsed duty, min. Rtpa)

$$Rtpa = (1/.95):1 \quad Rtpa = 1.05:1$$

See the following chart for %Duty Cycle to Rtpa comparison.

% Duty	(Indicated on front panel of device)	Cycle Rtpa
5		20:1
10		10:1
15		8.33:1
20		5:1
25		4:1
30		3.33:1
35		2.86:1
40		2.5:1
45		2.22:1
50		2:1
55		1.82:1
60		1.66:1
65		1.54:1
70		1.43:1
75		1.33:1
80		1.25:1
85		1.18:1
90		1.11:1
95		1.05:1

The Rtpa tolerance does not exceed +/- 20%. The temporal maximum intensity for each duty cycle as well as the 100% modulation is whatever is indicated on the meter.

The temporal average intensity for each duty cycle will be the meter indication multiplied by the percentage duty cycle.

$$\text{Temporal Average} = (\text{Duty}) \times (\text{Meter Indication})$$

Example, 5 Watts, 35% Duty Temporal Average = .35 x 5 Watts = 1.75 Watts

The Spatial Average Intensities for each of these setting will be divided by the transducer's Effective Radiating Area (ERA)

$$\text{Spatial Average} = (\text{Temporal Average}) / (\text{ERA})$$

Example, 5 Watts, 35% Duty, 5cm Transducer

$$\text{Spatial Average} = (1.75 \text{ Watts}) / (5\text{cm}^2) = 0.35 \text{ Watts/cm}^2$$

The pulse width (On time) of all Rich-Mar therapeutic ultrasound devices is 2.5 milliseconds (mS). The time between pulses (Off time) in milliseconds is calculated as follows:

$$\begin{aligned} \text{Pulse width (On time)} &= 2.5\text{mS} \\ \text{Off time} &= [2.5 - 2.5(\% \text{Duty cycle})] / (\% \text{Duty cycle}) \\ &\text{Where \%Duty cycle is represented as a decimal.} \end{aligned}$$

Please see the following example for computing the Off time for a 10% Duty cycle:

$$\text{Off time} = [2.5 - 2.5(0.10)] / (0.10) = 22.5 \text{ milliseconds.}$$

Additional Technical Notes

The peak power is the same in the pulsed modes as in the 100% modulated mode. Unless otherwise stated, all technical parameters are accurate within +/- 20%. When in the pulse modes the unit is still generating therapeutic heat, although it is an amount reduced by a factor directly related to the duty cycle. The pulse rates are used to allow the practitioner to treat areas of bony prominences without creating periosteal pain. The line leakage is tested in both the forward and reverse polarities to be less than 50 microamperes exceeding all standards for medical devices in this class.

The device is designed to meet or exceed UL Standards 2601-1 for medical devices and the Canadian Standards Association C22.2 No. 601.1.